No. 23-2056

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

C.R. BARD, INC., BARD PERIPHERAL VASCULAR, INC.,

Plaintiffs-Appellants,

v.

ANGIODYNAMICS, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware, No. 1:15-cv-00218-JFB-SRF, Judge Joseph F. Bataillon

OPENING BRIEF OF C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.

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OCTOBER 5, 2023

'417 Patent Claims 1, 5, 8, 12

1. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

5. The assembly according to claim 1, wherein the radiographic marker is one or more radiographic letters.

8. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port separate from the first identifiable feature, the second feature perceivable following subcutaneous implantation of the access port to identify the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

12. The assembly according to claim **8**, wherein the radiographic marker is one or more radiographic letters.

'460 Patent Claims 1, 4

1. A system for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature comprising a radiographic marker identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port; and

a second identifiable feature separated from the subcutaneously implanted access port, the second feature visually observable following subcutaneous implantation to confirm that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

4. The system according to claim 1, wherein the radiographic marker is selected from the group consisting essentially of an observable pattern, a symbol, a typographical character, an indicium, and combinations thereof.

'478 Patent Claims 1, 3

1. A method of performing a power injection procedure, comprising:

taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port, the access port defining one or more fluid reservoirs, each fluid reservoir accessible through a cannula-penetrable septum; identifying the indicating radiographic feature on the x-ray; and flowing a fluid through the access port at a rate of at least 1 milliliter per second.

3. The method according to claim 1, wherein the identifying step comprises identifying a radiographic letter.

CERTIFICATE OF INTEREST

Counsel for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case.

C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Bard Peripheral Vascular, Inc. is a wholly-owned subsidiary of C. R. Bard, Inc. C. R. Bard, Inc. is a wholly-owned subsidiary of Becton, Dickinson and Company. No publicly held company owns 10% or more of Becton, Dickinson and Company's stock.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

MORRISON & FOERSTER LLP: Vincent J. Belusko, Nicole M. Smith, Jonathan McNeal Smith, Ashleigh K. Landis, John Raleigh O'Donnell (all no longer with firm); and Rose S. Lee.

RAIFE LAW, PLLC: Dylan J. Raife

ASHBY & GEDDES: John G. Day, Andrew Colin Mayo, and Tiffany Geyer Lydon.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP: Brian P. Egan and Jack B. Blumenfeld.

QUINN EMANUEL URQUHART & SULLIVAN, LLP: Lauren N. Martin, Anne-Raphalle Aubry, Jared W. Newton, Jodie Cheng, and Bianca Fox.

5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes, see separately filed notice.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

Dated: October 5, 2023

/s/ Deanne E. Maynard
Deanne E. Maynard

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STATEMENT OF RELATED CASES

This is a patent infringement action between Bard Peripheral Vascular, Inc. and AngioDynamics, Inc. related to U.S. Patent Nos. 8,475,417, 8,545,460, and 8,805,478. This Court previously decided an appeal from the same action in a precedential decision authored by Judge Reyna and joined by Judges Schall and Stoll. *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372 (Fed. Cir. 2020). Counsel for Bard know of no other cases pending in this Court or any other court that will directly affect or be affected by this Court's decision in this appeal.[1]

JURISDICTIONAL STATEMENT

Bard appeals from a final judgment. The district court resolved timely post-judgment motions on June 1, 2023. Appx12-48. Bard filed a timely notice of appeal on June 16, 2023. Appx6362-6364. The district court had subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1338. This Court has jurisdiction under 28 U.S.C. § 1295(a)(1).

[1] C. R. Bard, Inc. is no longer a plaintiff. C. R. Bard transferred the asserted patents to Bard Peripheral Vascular, Inc., which then filed an amended complaint naming only itself as plaintiff. Appx316-318. C. R. Bard remains only as a cross-claim/counterclaim defendant. Unless noted, this brief uses "Bard" to refer to either or both.

INTRODUCTION

This is the second time this case about Bard's patented vascular access ports has been before this Court. Last time, this Court held that the district court had procedurally erred when it used Rule 50 to *sua sponte* raise and then decide invalidity issues never presented to the jury. On the merits, this Court reversed outright the district court's judgment on patent eligibility, holding that Bard's claims to ports and methods of using them "are patent eligible under 35 U.S.C. § 101." *Bard*, 979 F.3d at 1375. It rejected the district court's grant of judgment as a matter of law on willfulness, holding "there was substantial evidence in the record to support a jury finding of infringement and willfulness." *Id.* And it vacated the district court's grant of summary judgment on anticipation because "conflicting evidence created a genuine dispute of material fact as to the novelty of the asserted claims." *Id.* at 1385.

On remand, the district court disregarded this Court's decision. After a jury returned a verdict for Bard on all issues, the district court granted judgment under Rule 50 for AngioDynamics and largely reinstated its prior judgment. Although the district court had properly limited the remand trial to infringement, willful infringement, and invalidity for anticipation and obviousness, it then (like last time) *sua sponte* raised patent ineligibility at the end of trial: "I believe the Federal Circuit only ruled on half of the 101 defense not the second half." Appx6068. In its post-

judgment order, it invalidated Bard's claims for purportedly being directed to the abstract ideas of safety and identification. The district court also *sua sponte* raised and decided indefiniteness—an issue never tried nor even mentioned in the Rule 50 hearings or any post-trial briefing. And it set aside the jury's verdict on both anticipation and willfulness despite this Court's previous holdings that the same or materially similar evidence sufficed to support a verdict for Bard on each issue.

This Court should reverse for multiple independent reasons. The district court's failure to follow this Court's previous decision requires rejecting the bulk of its judgment. So does its continued defiance of basic procedural requirements, like resolving Rule 50 motions based only on the issues actually presented at trial and raised in post-trial motions. And on the merits, the district court wrongly based its Rule 50 decision on a one-sided view of the evidence, selectively picking evidence from AngioDynamics's witnesses or substituting its own inferences to support AngioDynamics's positions while overlooking the wealth of evidence supporting the jury's verdict for Bard.

STATEMENT OF THE ISSUES

1. Whether the district court erred in *sua sponte* raising and then granting judgment as a matter of law on patent ineligibility, an issue that was not tried because this Court's mandate already resolved it.

2. Whether the district court erred in *sua sponte* granting judgment as a matter of law on indefiniteness, an issue never tried nor raised in any post-judgment motion because the experts agreed the claims' scope depends on objective boundaries.

3. Whether the district court erred in granting judgment as a matter of law on anticipation for multiple independent reasons, including because this Court already held materially identical evidence sufficient for a jury to find in Bard's favor; the jury reasonably so found; and no prior art discloses radiographic letters, which are required by all but one asserted claim.

4. Whether the jury's verdict finding willful infringement should be reinstated because this Court already held materially identical evidence sufficient for a jury to find in Bard's favor and, in any event, the jury reasonably so found.

5. Whether the district court erred in alternatively granting a new trial *sua sponte* based on purportedly erroneous jury instructions, because the instructions properly reflected the court's correct claim constructions and Bard and its witnesses faithfully applied those constructions.

6. Whether the district court's repeated errors in defiance of this Court's mandate warrant reassignment on remand.

STATEMENT OF THE CASE

A. Power-Injectable Ports Are Critical For Many Patients, And So Is Ensuring They Can Be Correctly Identified After Implantation

1. At the time of Bard's inventions, there was a significant need for an identifiable, power-injectable vascular access port

Bard's patents cover vascular access ports and methods for using them. Appx51; Appx109; Appx167. Vascular access ports are life-changing medical devices for patients who require repeated injections, such as for chemotherapy. Appx4410-4411. The ports are "implanted underneath a patient's skin" to "allow medical providers to inject fluid into the patient's veins on a regular basis without needing to start an intravenous line each time." *Bard*, 979 F.3d at 1375.

These figures show an exemplary port:

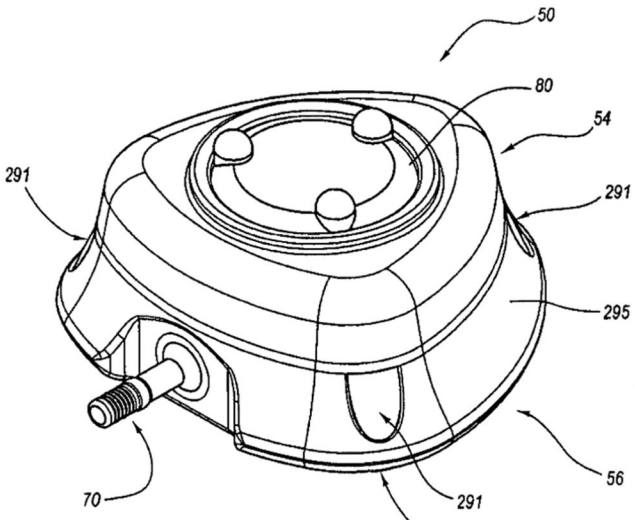


FIG. 51

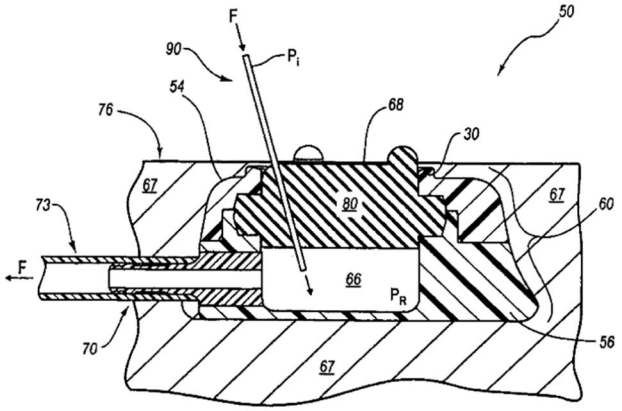


FIG. 6

Appx63; Appx88. The port has a housing **60** that includes a septum **80** and a reservoir **66**. Appx96 (col.7:51-col.8:48); Appx4410-4411. The reservoir **66**

connects to an outlet stem **70** and then to a catheter **73** to transfer fluid from the reservoir **66** to the body. Appx96 (col.7:51-col.8:48). Figure 6 shows an implanted port. Although the septum's top appears largely flush with the surface of the patient's skin **76**, the top actually sits below the skin and is not visible. Appx97 (col.9:4-61); Appx4410. A medical professional punctures the skin **76** and septum **80** with a needle **90** to inject fluid into the reservoir **66**. Appx97 (col.9:4-61); Appx4468-4469.

"Vascular access ports were traditionally used to administer injections at a low pressure and flow rate." *Bard*, 979 F.3d at 1375. But some medical procedures, such as computed tomography (CT), require injecting a viscous fluid under high pressure at high flow rates. Appx93 (col.1:29-60) Appx4474. These high-pressure, high-flow-rate injections are called "power injections." *Bard*, 979 F.3d at 1376.

At the time of Bard's invention, some clinicians had tried power injecting ordinary vascular access ports using flow rates and pressures beyond what the port's manufacturer recommended. This was dangerous because power-injecting such ports "might work at times," but "[a]t other times, it could result in a catastrophic complication." Appx4885. Existing vascular access ports had not been designed, tested, and approved for such use. Appx4582-4587. And there were "no means for being able to reliably and accurately identify a port as structured for power injection" after implantation. Appx4884; *see C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748

F. App'x 1009, 1011 (Fed. Cir. 2018) (addressing related Bard patents). Some medical professionals would nonetheless risk power injecting existing access ports because patients who need repeated CT scans often suffer "depleted vascular access," making it difficult or impossible to access the vein by other methods. Appx4473. Physicians "were so desperate to get back access to get some contrast into [these patients] that they would try anything." Appx4473.

"[I]n some cases, the pressure of the injection ruptured the port, seriously injuring the patient." *Bard*, 979 F.3d at 1375. These incidents led the FDA in 2004 and 2005 to issue repeated warnings to medical providers against power injecting into ports not structured for power injection because of the risk of serious injury. *Id.*

2. Bard's patents claim identifiable power-injectable ports and methods for using them

Researchers at Bard recognized a multi-faceted problem: patients needed a port that was both structured for power injection at high flow rates and pressure *and* "absolutely reliably" distinguishable—after implantation—from existing conventional ports that could potentially break apart in a patient under the same flow and pressure. Appx4887. As this Court explained when rejecting another decision invalidating related Bard patents, there were many existing ports with "'substantially similar geometries.'" *AngioDynamics*, 748 F. App'x at 1011. Bard recognized that these similarities would "prevent[] doctors from distinguishing so-called 'power injectable ports' from ordinary ones." *Id.*

a. The apparatus claims—'417 claims 5 and 12 and '460 claim 4

Bard's patents embody its solutions to these problems. The asserted apparatus claims recite a system or assembly including "a power injectable vascular access port." Appx107-108 (col.30:51-col.32:6); Appx165-166 (col.30:51-col.31:14). Each claim requires combining that power-injectable "vascular access port" with both intrinsic and extrinsic "identifiable feature[s]" that indicate the port's power-injection capabilities, such as that the port is "suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second" and "for accommodating a pressure within the [port] cavity of at least 35 psi." Appx107-108 (col.30:51-col.32:6); Appx165-166 (col.30:51-col.31:14). The intrinsic features are "identifiable feature[s] incorporated into the access port perceivable following subcutaneous implantation." Appx107-108 (col.30:51-col.32:6); Appx165-166 (col.30:51-col.31:14). At least one of those features "is a radiographic marker perceivable via x-ray." Appx107-108 (col.30:51-col.32:6); Appx165-166 (col.30:51-col.31:14). '417 claims 5 and 12 limit the marker to "one or more radiographic letters." Appx108 (col.31:16-17, 59-60).

Bard's new port structure addressed the twin safety challenges Bard had recognized. Through years of research, Bard understood a key insight—before CT procedures, technicians would perform a "scout" scan, a "preliminary" x-ray scan of the body at low resolution. Appx4530. Bard recognized it could leverage those

routine scout scans to create a "foolproof" port, one that both had the structure needed to withstand high pressure and flow rates and had x-ray visible identifiers to give medical providers certainty about that power-injectability. Appx4491, Appx4530. For example, Bard developed "a radiographic marker in the form of the letters 'CT' etched in titanium foil on the device." *Bard*, 979 F.3d at 1375; Appx107-108 (col.30:51-col.32:6). Bard also researched and developed other intrinsic identifiable features including "a triangular shape and small bumps," both of which were "palpable through the skin." *Bard*, 979 F.3d at 1375.

b. Method claim 3 of the '478 patent

Bard's asserted method claim recites uses of its new port technology. Like the apparatus claims, it requires a vascular access port structured for power injection at 1 mL/s and a cavity pressure of 35 psi. Appx223-224; Appx311. The claim requires taking an image of an implanted port with "a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port." Appx223-224 (col.30:58-col.31:9). It requires using the image to identify the port's radiographic feature, including by identifying "a radiographic letter." Appx223-224 (col.30:58-col.31:9). And it requires "flowing fluid" through the port at a rate of "at least 1 milliliter per second." Appx223-224 (col.30:58-col.31:9).

B. AngioDynamics Copied Bard's Inventions To Keep Up In The Market

In 2006, Bard launched the first port in its novel PowerPort-branded line. *Bard*, 979 F.3d at 1375; Appx4717-4718. This "remarkably successful" line of power-injectable ports went on to sell more than 4,250,000 units. Appx5950-5951.

AngioDynamics itself attributed that success to Bard's innovative technology. It recognized Bard's PowerPort as "the first power injectable port." Appx25583. In internal documents, AngioDynamics conceded the PowerPort "helped establish a new segment in the implantable port market." Appx25583; Appx25208; Appx25442. AngioDynamics also recognized that "[m]uch of the company's [Bard's] success in this market can be attributed to its innovation, as evidenced by its first-to-market advantage for a number of device features." Appx24251.

AngioDynamics tried and failed to compete without fully copying Bard's patented technology. It introduced a round power-injectable port—the SmartPort CT—that lacked intrinsic identifiers. Appx24817; Appx25604. That product failed to gain traction, with "the number 1 obstacle" to sales being the need to "make [the port] identifiable as CT injectable" after implantation. Appx24817; Appx25604. The feedback AngioDynamics got was clear: "many customer's [*sic*] saw the first version of the Smart[Port] and said no way" until the port was "more identifiable." Appx25469; Appx25635 (customers "resistant to adopt the Smart Port because of the identifiable features of the Bard Power port"); Appx25692 (similar).

AngioDynamics began copying Bard, first by changing the port geometry to use scalloped edges. Appx24817. But AngioDynamics discovered using port shape to identify the port was harder than expected because the scalloped edges "could not be seen in all patients." Appx24817; Appx25654 (customers asking for multiple identifiers). Bowing to market pressure and the "need to accommodate our customers with" reliable indicators similar to "Bard's PowerPort," AngioDynamics added an additional intrinsic identifier to its ports, "a CT indication on the bottom of our port to help identify the Smart[P]ort as power-injectable." Appx24817; Appx24884; *Bard*, 979 F.3d at 1377 (recognizing AngioDynamics's adoption of multiple identifiers). Only after copying Bard's technology was AngioDynamics able to compete in the new power-injectable port market: "Now that the CT identifier is available on SmartPort, the IR docs have agreed to trial." Appx25485.

C. This Court Reversed In Part, Vacated In Part, And Remanded After The District Court Granted Judgment For AngioDynamics Halfway Through The First Trial

Bard sued AngioDynamics for infringing claims of the '417, '460, and '478 patents. *Bard*, 979 F.3d at 1375-77. AngioDynamics moved to dismiss under 35 U.S.C. § 101. Appx282-307. The district court, then Judge Robinson, denied the motion, explaining that AngioDynamics's motion "conflate[d] the § 101 analysis with anticipation and obviousness," issues "more properly reserved to analysis on a full record." Appx305-306.

The case was reassigned to Judge Bataillon of the District of Nebraska, who denied cross-motions for summary judgment and presided over the first trial. *Bard*, 949 F.3d at 1377. After Bard rested its case in chief on "infringement, willfulness, and damages," the district court "sua sponte" raised patent ineligibility and "terminated the trial, indicating that it would grant JMOL on willfulness and ineligibility." *Bard*, 979 F.3d at 1377-78. In a later written opinion, the district court granted judgment on those grounds and non-infringement, as well as multiple invalidity grounds never presented at trial. *Id.*

Bard appealed, and this Court reversed in part and vacated in part. *Id.* at 1378. The Court held that Bard presented sufficient evidence to create "a question for the jury" on infringement and willfulness, including because Bard showed that "AngioDynamics's Director of Intellectual Property was aware of the applications that issued as the patents-in-suit" and that "AngioDynamics intentionally copied Bard's" technology. *Id.* at 1378-80.

This Court rejected the judgment of invalidity as both procedurally improper and substantively incorrect. The district court "granted both summary judgment and JMOL that the patents were invalid and patent ineligible, without specifying the statutory grounds for invalidity." *Id.* at 1380. But at the time the district court ruled, "AngioDynamics had not yet presented its invalidity case at trial and Bard had not had the opportunity to defend the validity of its asserted claims." *Id.* "The district

court's JMOL of invalidity was thus procedurally improper because Rule 50 provides that JMOL against a party is only appropriate once the party 'has been fully heard on an issue.'" *Id.* (quoting Fed. R. Civ. P. 50).

On the merits, this Court first addressed the printed matter doctrine, which may affect patents reciting "information claimed for its communicative content." *Id.* at 1380-82. Applying the doctrine to Bard's claims, the Court held "that the content of the information conveyed by the claimed markers—i.e. that the claimed access ports are suitable for injection at the claimed pressure and flow rate—is printed matter not entitled to patentable weight." *Id.* at 1382.

Turning to eligibility, this Court "h[eld] that the asserted claims are not patent ineligible under § 101." *Id.* at 1384. First, "[w]hen each claim is read as a whole, the focus of the claimed advance is not solely on the content of the information conveyed, but also on the means by which that information is conveyed." *Id.* at 1384 (citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014)). Second, "even if we were to conclude that the sole focus of the claimed advance was the printed matter, AngioDynamics's evidence is not sufficient to establish as a matter of law, at *Alice* step two, that the use of a radiographic marker, in the 'ordered combination' of elements claimed, was not an inventive concept." *Id.* (citation omitted) (evidence did "not establish that radiographic marking was routine and conventional").

The Court also rejected the district court's "conclusion that the method claims contained no more than a recitation of the standards of medical care." *Id.* Although "the FDA directed medical providers to verify a port's suitability for power injection before using a port for that purpose, it did not require doing so via imaging of a radiographic marker." *Id.* Nor was there "evidence in the record that such a step was routinely conducted in the prior art." *Id.*

On anticipation, this Court held that the issue was for a jury, including because "there remained a factual dispute" about whether "certain features of two prior art ports, the ATP [Adult Titanium Port] and Port-a-Cath" were "radiographically discernible and could" be "used to distinguish or identify the device or its functionality." *Id.* at 1384-85.

Given these holdings, the Court "reverse[d]-in-part the district court's judgment of invalidity as it pertains to ineligibility under § 101," "vacate[d]-in-part the court's judgment of invalidity as to all other grounds," "vacate[d] the judgment of non-infringement and no willful infringement," and "remand[ed] the case for further proceedings consistent with this opinion." *Id.*

AngioDynamics unsuccessfully sought rehearing. It argued "the panel held the claims eligible at *Alice* step one" thus "precluding AngioDynamics from raising its ineligibility defense at trial," including that "the claims are directed to the abstract mental process of identification." *Bard*, No. 19-1756, Reh'g Pet., ECF 76 at 4, 10,

13. The Court denied AngioDynamics's petition without requesting a response or noting any dissent. *Id.*, Reh'g Denial, ECF 77 at 2.

D. After A Jury Ruled For Bard On Remand, The District Court Again Granted JMOL For AngioDynamics, Reinstating Parts Of Its Prior Judgment

1. The district court initially followed this Court's mandate on Section 101, ordering that trial be limited to infringement, willfulness, anticipation, and obviousness

On remand, AngioDynamics changed its tune about the meaning of this Court's decision, arguing the decision "cannot 'foreclose'" the district court from deciding eligibility "based upon the entire record." Appx2038-2039 (citation and alteration omitted). And AngioDynamics asked the district court to stay this case pending resolution by this Court of *C.R. Bard, Inc. v. Medical Components* (No. 22-1136), an appeal involving related Bard patent claims that had been invalidated under Section 101 by a Utah district court. Appx2035. AngioDynamics argued that *Medical Components* would decide "whether claims directed to the same subject matter and abstract idea are ineligible," and the ruling there "must apply here." Appx2039-2040.

The district court denied the stay: "[t]he Federal Circuit did not remand the issue of § 101 eligibility of the '478, '460, and '417 patents for further consideration by this court of additional ineligibility arguments raised by Defendant. Instead, the Federal Circuit reversed the holding of the district court and concluded that the

asserted claims of the '478, '460, and '417 patents are eligible under § 101." Appx2308-2309. The district court concluded it was "not free to disregard the Federal Circuit's explicit holding." Appx2309. It thus ordered: "The subjects of the trial on remand are infringement, willful infringement, and whether the asserted claims of the patent are invalid as anticipated or obvious." Appx2309.

2. At the close of trial, the district court again **sua sponte** *raised ineligibility*

The parties proceeded to trial. Before opening statements, the district court rejected AngioDynamics's request to construe the "radiographic letter" claim limitations as printed matter not entitled to patentable weight, recognizing this Court "ha[s]n't done it in this case." Appx4089. But the district court reversed course after the close of evidence, adopting AngioDynamics's construction. Appx6025-6037. AngioDynamics then moved for judgment as a matter of law that "all three asserted patents are invalid as anticipated under Section 102 and invalid as obvious under Section 103," the only invalidity issues pressed at trial. Appx6063. After AngioDynamics's counsel finished presenting its invalidity arguments, the district court asked "Are you guys giving up on the 101 defense?" Appx6068. Counsel for AngioDynamics answered: "I believe the Federal Circuit has made it so we have to." Appx6068. Contradicting its earlier ruling, the district court responded, "I believe the Federal Circuit only ruled on half of the 101 defense not the second half of the 101 defense. Are you reasserting a motion to dismiss on the second half of

the 101 defense?" Appx6068. The court directed AngioDynamics's counsel to "[a]rticulate that for us." Appx6068. AngioDynamics's counsel then added: "we also move for a judgment as a matter of law that these patents are ineligible under 101." Appx6069.

3. The district court overrode the jury verdict for Bard based on issues this Court already resolved and issues never tried or raised

Jury verdict. The jury returned a verdict for Bard on all tried issues. It found AngioDynamics had willfully infringed, directly or indirectly, all asserted claims. Appx2-4, Appx9. It rejected AngioDynamics's anticipation and obviousness defenses, as well as its prior-use defense under 35 U.S.C. § 273. Appx5-8, Appx10-11. Because the district court concluded partway through trial that damages should be bifurcated for a subsequent trial, the jury was not asked to decide that issue. Appx1-11.

Patent ineligibility. After the jury's verdict but before the district court resolved post-trial motions, this Court issued its decision in *Medical Components*. The Court held it was "bound by our precedent" set in this case. *Medical Components*, No. 22-1136, 2023 WL 2064163, at *2 (Fed. Cir. Feb. 17, 2023) (citing *Bard*, 979 F.3d 1384). Based on that binding precedent holding "substantially similar" claims "eligible under § 101," this Court "conclude[d] that the asserted

claims in Bard's three patents are directed to eligible subject matter under § 101." *Id.*

Despite this reiteration of this Court's prior decision, the district court invalidated Bard's claims as patent ineligible. Appx26-31. Based on trial testimony discussing other issues like the prior art, the district court characterized Bard as having presented "new trial constructions of 'suitable' and 'identifiable'" that "imbued" the claims "with the medical standard of care or safety to the FDA's satisfaction." Appx20, Appx22-26. It readopted its previously rejected view that Bard allegedly "claim[ed] merely the medical standard of care—recognition of a port such that doctors would be comfortable power injecting." Appx27; Appx30 (same for method claim). It also thought requiring a port "'suitable' for power injection" meant the claims focused on "merely the degree of safety and reliability necessary to secure FDA approval." Appx27.

At *Alice* step two, the district court dismissed the radiographic indicia this Court held had not been shown to be routine and conventional. *Bard*, 979 F.3d at 1384. In the district court's view, it was enough that those indicia were "known in the prior art." Appx29.

Indefiniteness. The district court also based its grant of judgment as a matter of law on indefiniteness, an untried issue never raised in any post-trial motion or hearing. Appx31-34. Focusing on the experts' competing views on anticipation, the

district court believed the claims' scope "varies according to the subjective judgment of each professional based upon their individual training, experience, risk tolerance, and circumstance." Appx32.

Anticipation. This Court remanded on anticipation because the evidence created a dispute of fact for a jury about whether prior-art ports included "radiographically discernible" features that could "be used to distinguish or identify the device or its functionality." *Bard*, 979 F.3d at 1384-85. The district court overrode the jury on that issue anyway. Appx34-46. Focusing on the same prior art features previously before this Court—like a square or round port shape and suture holes—and relying almost entirely on disputed evidence from AngioDynamics's expert, the district court concluded that "port shape and basic features" visible via x-ray disclosed the claimed radiographically identifiable features. Appx41-44. Again taking a one-sided view of the evidence, it also concluded the jury could not have reasonably found the prior-art ports—Port-A-Cath, Vortex, and Bard's own Adult Titanium Port—not structured for power injection at the required flow rate (1 mL/s) and cavity pressure (35 psi). Appx34-41; *see* Appx44-46 (similar for method claim).

Willfulness. Although this Court held that Bard's evidence at the first trial sufficed to support a jury verdict on willfulness, the district court held the opposite,

overriding the jury's willfulness finding despite Bard's presentation of materially identical evidence. Appx47.

New trial. The district court also alternatively granted AngioDynamics a new trial because of a supposed "failure of the jury instructions to adequately account" for Bard's purported new claim constructions. Appx20.

SUMMARY OF ARGUMENT

I.A. The district court erred when it again invalidated Bard's claims based on subject matter ineligibility. This Court already resolved eligibility when it held the same claims directed to eligible matter and reversed the district court's first contrary judgment. The mandate left no room for the district court to reconsider that issue.

B. Nor did ordinary procedure. The district court again *sua sponte* raised ineligibility, and it decided ineligibility on a ground AngioDynamics never pressed. Rule 50 prohibits district courts from taking such matters into their own hands.

C. The district court's ineligibility decision is also wrong. The district court wrongly focused on the result Bard's inventions achieved—ports that could be safely and reliably identified and power injected. But Bard did not *claim* safety and reliability. It claimed concrete means for achieving both, a port structured for power injection that incorporates x-ray identifiable features. Such concrete means are patentable subject matter.

II.A. The district court's disregard of proper procedure also led it to commit reversible error in granting JMOL on indefiniteness. Because indefiniteness was neither tried nor raised in any Rule 50 motion, the district court had no authority to grant JMOL on the issue.

B. AngioDynamics did not raise indefiniteness for good reason: Bard's claims identify the precise structures claimed, as AngioDynamics's witness confirmed by admitting he could objectively assess what was within the claims' scope. The district court was wrong that claims are indefinite merely because experts disagree about whether prior-art ports anticipated the claims.

III.A. The district court also wrongly departed from this Court's prior decision on anticipation. This Court already concluded that a reasonable jury could find common port features—like a square or round port shape or suture holes—insufficient to satisfy the claim requirement of a radiographic feature that identifies a port or its functionality. That foreclosed the district court from holding the opposite: that the jury was unreasonable in making that finding.

B. Regardless, the jury's verdict on anticipation should be reinstated. The district court merely catalogued evidence, or inferences from that evidence, it thought favorable to AngioDynamics. That is not its role. The rules and the constitutional guarantee of a jury trial required the district court to consider the evidence favorable to Bard, draw all reasonable inferences from that evidence in

Bard's favor, and disregard evidence favorable to AngioDynamics that the jury was not required to believe. And the district court was required to do all that through the lens of the heavy clear-and-convincing burden AngioDynamics bore on anticipation. Under that required approach, the jury's verdict is amply supported, including because AngioDynamics's own pre-litigation documents show it thought prior-art ports lacked radiographic identifiable features and thought Bard's non-prior-art PowerPort was the first power-injectable port.

C. The district court's close-of-trial claim construction also requires reversal or a new trial on the "radiographic letter" claims. The district court was wrong to sidestep the absence of such letters in the prior art by construing "radiographic letter" as printed matter entitled to no patentable weight. This Court already held printed matter is the content of information, not the means for conveying it. Radiographic letters are such means because they are just one kind of radiographic marker, as the claim language itself confirms.

IV. This Court's mandate also controls on willfulness. In the prior appeal, this Court reversed the grant of JMOL on willfulness because the evidence Bard presented at the first trial of AngioDynamics's deliberate copying and knowledge of these patents would have sufficed to support a jury verdict. That conclusion compelled the district court to accept the second jury's verdict finding willful infringement based on the same or materially similar evidence.

In any event, the district court misread precedent in holding the verdict flawed without a start date. That precedent merely held that a party generally cannot willfully infringe until *after* it has knowledge of the patents. Bard's evidence cleared that hurdle because it showed AngioDynamics knew of Bard's patents at least by their issuance date, supporting the jury's finding of willfulness for *all* infringement here.

V. The district court likewise committed reversible error in alternatively granting a new trial because of a supposed error in jury instructions on certain claim constructions. AngioDynamics never asked for a new trial because of supposed jury instructional error. Under Third Circuit law, that forecloses a new-trial grant. Regardless, the jury was properly instructed on those claim constructions, and Bard's trial presentation was consistent with them.

VI. Because a remand will require significant further proceedings on at least Bard's untried damages claims, any remand should be accompanied with an order that the case be reassigned to a different district court judge. To preserve the appearance of impartiality, this and other circuit courts have ordered reassignment in similar circumstances—where a district court repeats the same error after a first appeal.

STANDARD OF REVIEW

This Court "review[s] the district court's interpretation of [the Court's] mandate de novo under Federal Circuit law." *Omega Patents, LLC v. CalAmp Corp.*, 13 F.4th 1361, 1374 (Fed. Cir. 2021). It reviews rulings on motions for judgment as a matter of law or a new trial under the law of the regional circuit. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1330 (Fed. Cir. 2010). The Third Circuit reviews rulings on motions for judgment as a matter of law de novo, applying the same standard as the district court. *Rotondo v. Keene Corp.*, 956 F.2d 436, 438 (3d Cir. 1992). It reviews rulings on new trial motions for abuse of discretion unless the ruling "is based on the application of a legal precept, in which case the standard of review is plenary." *Id.*

ARGUMENT

I. JMOL On Eligibility Should Be Reversed Because The Mandate, Precedent, And The Record Foreclose The District Court's Invalidation Of Bard's Claims Under Section 101

A. This Court's Mandate Holding Bard's Claims "Patent Eligible" Requires Reversal

This Court already held "the asserted claims are not patent ineligible under § 101." *Bard*, 979 F.3d at 1381, 1384. The district court's invalidation of Bard's claims again on that already decided ground violates that mandate.

The mandate rule dictates that an "inferior court has no power or authority to deviate from the mandate issued by an appellate court." *Briggs. v. Pa. R.R. Co.*, 334

U.S. 304, 306 (1948). "[A]ll issues within the scope of the appealed judgment are deemed incorporated within the mandate and thus are precluded from further adjudication" unless the Court expressly orders otherwise. *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1382-83 (Fed. Cir. 1999). All issues means all, both issues "implicitly" and "explicitly" decided on appeal. *Id.* ("both the letter and the spirit of the mandate" bind a district court).

The mandate rule barred the district court from reinstating its ineligibility ruling on remand. Unlike issues that were vacated and remanded "for further proceedings," this Court explicitly reversed "the district court's judgment of invalidity as it pertains to ineligibility under § 101." *Bard*, 979 F.3d at 1381, 1384-85. The Court ended any Section 101 inquiry in holding at *Alice* step one that the asserted claims are directed to "patent eligible" matter, including an implantable vascular access "port" with a "radiographic marker" that could "be readily and reliably identified via x-ray" after implantation. *Id.* at 1381, 1384-85; *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1372 (Fed. Cir. 2020) ("step one presents a legal question that can be answered based on the intrinsic evidence"). The mandate left no room for the district court to reconsider that issue on remand.

Medical Components confirms Section 101 was off the table. 2023 WL 2064163, at *2. Addressing "substantially similar" Bard patent claims, this Court recognized it was "bound by our precedent in *C R Bard*" to hold "eligible under

§ 101" claims "directed to radiopaque markers that could be used to identify venous access ports as power injectable." *Id.* The district court here was all the more bound, both as a subordinate court and because the claims were not just "substantially similar" but the very ones addressed by this Court's prior decision.

Both the district court and AngioDynamics previously agreed. In requesting rehearing of this Court's prior decision, AngioDynamics acknowledged the decision "foreclosed" any Section 101 defense on remand. *Bard*, Petition for Rehearing, ECF 76 at 2, 16-18. And even after changing its tune, AngioDynamics conceded this Court's decision in *Medical Components* would resolve its ineligibility defense. Appx2035; *see* Appx6295. The district court initially agreed as well: "This Court is not free to disregard the Federal Circuit's explicit holding that the claims are not patent ineligible under § 101." Appx2308-2309.

Nothing justifies the district court's subsequent about-face. Although the district court suggested "Bard's reframing of the asserted claims invalidates them" (Appx26), Bard never "refram[ed]" its claims and there was no revised claim construction. Rather, as the district court recognized in at least one place, the focus of the claims remained the same as in the first appeal and in *Medical Components*: "Bard's application of a radiographic indicia" to a power-injectable port "to convey to medical professionals" information about the port. Appx30-31. The district court merely disagreed with this Court's legal conclusion that such a focus suffices under

Section 101. Appx30-31. But the mandate rule prohibits such disagreement. *Engel*, 166 F.3d at 1382-83.

The district court also suggested, at the Rule 50 hearing, that the issue remained open on remand because "I believe the Federal Circuit only ruled on half of the 101 defense not the second half of the 101 defense." Appx6068-6070. That is legally and factually wrong. Even had this Court addressed only *Alice* step one, a claim directed to eligible matter at step one is patent eligible, full stop. *E.g.*, *Core Wireless Lic. S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1363 (Fed. Cir. 2018) (holding claims "not directed to an abstract idea" are "patent eligible" and Court need "not proceed to the second step of the inquiry"). Regardless, this Court also addressed *Alice* step two, holding that "[e]ven if" the claims failed step one, AngioDynamics failed to prove "radiographic marking was routine and conventional." *Bard*, 979 F.3d at 1384.

Simply, this Court's decision left no eligibility issue open for remand. *Id.* The district court's violation of the mandate rule alone requires reversal (again) of its ineligibility judgment.

B. JMOL On Eligibility Should Independently Be Reversed Because The Issue Was Never Tried

Another error independently warrants reversal of JMOL on Section 101. The district court believed Bard's claims are directed to the "abstract solution" of "safety and reliability"—to making a port "safe and reliable for power injection and safely

and reliably 'identifiable' as such to doctors." Appx27-28. But "Rule 50 provides that JMOL against a party is only appropriate once the party 'has been fully heard on an issue.'" *Bard*, 979 F.3d at 1380 (quoting Fed. R. Civ. P. 50). A ground "not advanced" in a party's pre- or post-verdict Rule 50 motions may "not be relied upon, post-trial, as a ground for granting Rule 50 relief." *Kutner Buick, Inc. v. Am. Motors Corp.*, 868 F.2d 614, 617 (3d Cir. 1989); *see infra* Part.II.A (further discussing same).

The procedural history establishes the reversible error here. When AngioDynamics asked the district court to stay this case pending the outcome of *Medical Components*, the district court denied the request and expressly (and correctly) ordered that "[t]he subjects of the trial on remand are infringement, willful infringement, and whether the asserted claims of the patent are invalid as anticipated or obvious." Appx2309. Given that order, neither party identified ineligibility as a disputed factual or legal issue in the joint pre-trial order. Appx2681-2826.[2] Nor did either party ask for, or the district court give, a jury instruction on ineligibility. Appx3189-3323; Appx3895-3948 (instructing jury only on anticipation and obviousness). And when AngioDynamics moved orally under Rule 50(a), its

[2] Although the table of contents of AngioDynamics's statement of factual issues for trial lists a section I.M on "Patent Ineligibility" and a section III.D on "Ineligibility" (Appx2705), the actual body omits both sections and mentions ineligibility just once when addressing willfulness. Appx2704-2750.

counsel identified the invalidity grounds only as "invalid as anticipated under Section 102 and invalid as obvious under Section 103." Appx6063.

Although AngioDynamics eventually added a Section 101 challenge at the district court's urging, it raised a different ground from the one the district court ultimately decided. AngioDynamics argued the claims "are directed to the abstract idea of communicating information." Appx6068-6070; Appx3849-3853. And AngioDynamics stopped pressing even that issue following this Court's rejection of the identical argument in *Medical Components*. Appx6353-6354; Appx6368-6390. The district court declined to address AngioDynamics's ground, recognizing it was foreclosed. Appx26 n.7. Instead, the district court's Rule 50 order raised and decided a new ground of the district court's own creation based on purported "safety and reliability." Appx27-28.

The constitutional guarantees of due process and a jury trial, as well as the Federal Rules of Civil Procedure, prohibited the district court from granting judgment on such a ground. *Kutner*, 868 F.2d at 617. As in the prior appeal, "[t]he district court's JMOL of invalidity was thus procedurally improper." *Bard*, 979 F.3d at 1380. But unlike in the prior appeal, the district court's *sua sponte* grant of judgment cannot be treated as one for summary judgment because AngioDynamics never moved for summary judgment on the ground that Bard's claims were directed to ineligible "safety and reliability" matter. *See id.* (considering invalidity judgment

"only as to the grounds on which AngioDynamics moved for summary judgment"). Because that issue had never been raised at any point, the ineligibility judgment should be reversed for this reason as well. *Kutner*, 868 F.2d at 617.

C. In Any Event, Bard's Claims Are Directed To Eligible Matter

Reversal is independently required for yet a third reason: this Court was right that Bard's claims are patent eligible.

At *Alice* step one, the apparatus claims focus on improved access ports that are both power injectable and identifiable as such after implantation. Appx93-94 (col.1:7-col.3:4). And the method claim focuses on using those machines, and the added radiographic features, to distinguish the ports and treat patients with them. Appx223-224.

Even so, the claims recite inventive concepts at step two, including the ordered combination of a power-injectable vascular access port with distinguishing radiographic features. Appx107-108; Appx165-166; Appx223-224. AngioDynamics itself called this technology an "innovation." Appx24251; Appx25583. It described Bard's PowerPort as "the first power injectable port," which "helped establish a new segment in the implantable port market." Appx25583; Appx24208; Appx25442. And it lauded Bard's "success in this market," which "can be attributed to its [Bard's] innovation, as evidenced by its first-

to-market advantage for a number of device features." Appx24251. Such evidence shows Bard's inventions were a far cry from routine and conventional.

The district court's contrary ineligibility conclusion is riddled with errors. *First*, instead of evaluating the claims in light of the specification, as required, the district court purported to derive "[t]he focus of the claims, *distilled from the prior art*." Appx27-28 (emphasis added). As a result, the district court did just what this Court and the Supreme Court have repeatedly cautioned against: "'overgeneralizing claims' in the § 101 analysis" by characterizing them "'untethered from the language of the claims.'" *TecSec, Inc. v. Adobe Inc.*, 978 F.3d 1278, 1292-93 (Fed. Cir. 2020) (citation omitted).

Here, no claim text suggests Bard claimed the idea of "safety and reliability" for port power-injection. *Contra* Appx27. Rather, the claims focus on a technological solution to achieve safety and reliability—a power-injectable port with integrated radiographic features—not on any abstract idea. Appx107-108; Appx165-166; Appx223-224; *see TecSec*, 978 F.3d at 1293 (claims "identifying a 'specific' improvement" "rather than only claiming a desirable result" are eligible).

Second, the district court was wrong that what "Bard didn't patent," such as "power injection" alone, is somehow "telling." Appx27-28. Bard's choice to claim a combination of inventive features, rather than any one feature alone, hardly shows

a lack of inventiveness. *Bard*, 979 F.3d at 1384 ("ordered combination" can also be "inventive").

Third, the district court erroneously turned the step-two inquiry into a question of obviousness. Appx28-31. For example, it thought it relevant whether "any skilled artisan would have known how to" combine radiographic markers with power-injectable access ports. Appx28-29. But this Court already explained—and reversed the district court for overlooking—that "[e]ven if" AngioDynamics "demonstrated that it would have been obvious to combine radiographic marking with the other claim elements, that evidence does not establish that radiographic marking was routine and conventional under *Alice* step two." *Bard*, 979 F.3d at 1384. Rightly so, because patent ineligibility cannot be based on "an obviousness analysis under 35 U.S.C. § 103." *Bascom Glob. Internet Servs. v. AT&T Mobility*, 827 F.3d 1341, 1350 (Fed. Cir. 2016).

In short, even were this Court to reassess these claims under Section 101, it should reach the same conclusion.

* * * * *

For all these reasons, the judgment on patent ineligibility should once again be reversed.

II. JMOL On Indefiniteness Should Be Reversed Because The District Court Procedurally And Substantively Erred In *Sua Sponte* Granting It

A. The District Court Committed Reversible Error In Granting JMOL On An Issue No Party Raised In A Rule 50 Motion

The district court's failure to follow procedural rules also led it to err in granting judgment on indefiniteness, an issue neither tried nor raised in any parties' Rule 50 motions. The district court's procedural error warrants reversal, as confirmed by this Court's decision in *Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314 (Fed. Cir. 2003).

In *Hewlett-Packard*, "the [district] court granted JMOL of infringement under the doctrine of equivalents" even though "the jury had not addressed the issue" and "Hewlett's motion had not requested judgment as a matter of law (JMOL) on this issue." *Id.* at 1318. This Court reversed because "no timely motion for JMOL of infringement under the doctrine of equivalents had been made." *Id.* at 1322 (citing *Johnson v. N.Y., New Haven & Hartford R.R. Co.*, 344 U.S. 48, 50 (1952)). The Third Circuit applies the same rule, barring district courts from granting judgment under Rule 50 on a ground "not advanced" in a party's pre- or post-verdict Rule 50 motions. *Kutner*, 868 F.2d at 617; *see Mountain Dudes v. Split Rock Holdings, Inc.*, 946 F.3d 1122, 1130 (10th Cir. 2019) (citing *Hewlett-Packard* and holding "district courts are limited by Rule 50 to granting judgment as a matter of law only on grounds

raised by the parties"); *Murphy v. City of Long Beach*, 914 F.2d 183, 186 (9th Cir. 1990) (similar).

The district court violated that basic rule here. It purported to grant "AngioDynamic[s]'s motion for judgment as a matter of law" under Rule 50 that "the asserted patents are invalid for indefiniteness." Appx31-34, Appx48 (capitalization altered). But AngioDynamics never moved for judgment as a matter of law on indefiniteness; it never even identified that as a disputed legal or factual issue for trial. Appx2639; Appx3842-3865; Appx3972-4018. The issue thus "could not be relied upon, post-trial, as a ground for granting Rule 50 relief." *Kutner*, 868 F.2d at 617; *Hewlett-Packard*, 340 F.3d at 1322.[3]

The district court thought the issue one of Bard's own making because of Bard's supposed new constructions of the claims during the trial. Appx31-34. But none of the testimony the district court cited as purportedly advancing new constructions addressed claim construction. Appx22-26. That testimony addressed different issues, like the problem the Bard inventors were trying to solve or the scope and content of the prior art. Appx22-26. Even had Bard offered new constructions,

[3] Although AngioDynamics had raised a different indefiniteness issue during claim construction in 2017, that issue had long been resolved and was no longer before the court. Appx311-313.

the district court still would not have free reign to raise and decide indefiniteness *sua sponte*. *Hewlett-Packard*, 340 F.3d at 1322; *Kutner*, 868 F.2d at 617.

That is especially so because the indefiniteness issue the district court decided is factual in nature, as the district court's own discussion shows. The district court based its ruling on trial testimony it believed the jury could not "reasonably have disregarded" and its own view of what "the trial record shows." Appx31-34. Such a factual issue on invalidity would have been for the jury. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (indefiniteness is "amenable to resolution by the jury where the issues are factual in nature"); *Bombardier Recreational Prods. Inc. v Arctic Cat Inc.*, 785 F. App'x 858, 867 (Fed. Cir. 2019) (same). Because those factual issues were not grounds on which the district court could grant a Rule 50 judgment here, that error alone requires reversal of the indefiniteness judgment. *Hewlett-Packard* 340 F.3d at 1322; *Kutner*, 868 F.2d at 617 (reversing similar error and noting that where jury "reached a verdict" remedy is "entry of judgment on that verdict").

B. In Any Event, No Evidence Supports Holding Bard's Claims Indefinite

The district court's indefiniteness ruling independently fails on the merits. Claim text need only inform persons of ordinary skill in the relevant art with "reasonable certainty" about an invention's scope. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 134 S. Ct. 2120, 2124 (2014). Claims clear that hurdle when an

ordinary artisan reading the claims "in light of the rest of the patent and the knowledge" in the art would have a "reasonably certain understanding of what" they mean. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365-66 (Fed. Cir. 2017). A defendant challenging definiteness bears the burden of proving otherwise by clear and convincing evidence. *Id.*

Bard's claims are precise about the structural elements and properties a power injectable vascular access port must possess. For example, claim 1 of the '417 patent recites, among other things, a port with "a body defining a cavity," "a septum," "an outlet in communication with the cavity," and "a radiographic marker perceivable via x-ray." Appx107-108 (col.30:51-col.31:6). It further specifies that the port must be "suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second" and "suitable for accommodating a pressure within the cavity of at least 35 psi"; the radiographic marker must identify at least one of those properties. Appx107-108 (col.30:51-col.31:6). The district court's claim construction decision equated "suitable for" with "structured for," which no party has challenged. Appx309-315; *see Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (explaining that common claim phrase "suitable for" can also mean "adapted to"). Given that interpretation, claim 1's meaning is plain—the claimed port must have a cavity, septum, outlet, and radiographic marker, must be structured for power injection with a fluid flow rate of at least 1 milliliter per second and a pressure within

the cavity of at least 35 psi, and the radiographic marker must identify at least one of those properties on an x-ray. Appx107-108 (col.30:51-col.31:6); Appx309-315. Other claims are similarly precise. Appx107-108; Appx165-166; Appx223-224.

Despite the claims' precision, the district court thought their scope depended on a standard that "varies according to the subjective judgment of each professional based upon their individual training, experience, risk tolerance, and circumstance." Appx32-33. In its view, "the trial record reveals" this defect because "equally qualified and respected doctors, in the exercise of their medical judgment, reach[ed] different conclusions" about whether the allegedly anticipatory prior-art ports were structured and "safe for power injection" and were "identifiable" under x-ray. Appx32-33.

That reasoning fails to identify any lack of reasonable certainty about the claims' scope. Rather, the testimony the district court cited addresses factual disputes over the scope and content of the prior art, such as what "hospital protocols" show about prior-art ports and how to interpret "independent and published test data" for those ports. Appx22-26, Appx32-33. Those disputes go to the second step of the well-known "two-step procedure" for deciding prior-art invalidity (and infringement): "'The first step involves the proper interpretation of the claims. The second step involves determining whether the limitations of the claims as properly interpreted are met by the prior art.'" *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d

1313, 1335 (Fed. Cir. 2002) (also discussing similar two steps for infringement, *id.* at 1323). The district court overlooked this distinction when it complained that "[w]hether or not an *identical* medical device infringes (or anticipates) a patent cannot depend on which doctor, according to their own unchallenged medical judgment, uses it." Appx32-33 (emphasis by district court). Factual disputes like that are the bread and butter of virtually every patent case, not a basis for indefiniteness.

The district court would have erred even were those disputes about the claims' meaning. The test for indefiniteness "is not merely whether a claim is susceptible to differing interpretations." *Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 41 (Fed. Cir. 2020). After all, "[s]uch a test would render nearly every claim term indefinite." *Id.* Thus in *Nevro*, this Court reversed a district court's ruling that the term "configured to" rendered claims indefinite because the term "could be 'reasonably construed to mean'" different things. *Id.* at 40-41 (alteration omitted). The district court's reasoning here fails for the same reason.

The district court also thought the claims indefinite because Bard's patents "recite no port-lifespan." Appx33-34. The district court believed that a "port becomes less 'suitable for power-injection with *every use*" and so the claims must specify "whether they capture a port suitable merely for twenty-one injections," "for twenty-two injections," or more. Appx33-34 (emphasis by district court). This

Court has consistently rejected similar reasoning—"'an inventor need not explain every detail because a patent is read by those of skill in the art.'" *BASF*, 875 F.3d at 1366 (citation omitted). Also, "[t]he mere observation of information not 'recited' does not answer the question whether a person of ordinary skill in the art would *need* to be given" the uncited information to understand the claims' scope with reasonable certainty. *Id.* (emphasis by Court). Here, the district court never found persons of ordinary skill would lack reasonable certainty about whether a port is structured for power-injection without an express statement in the claims about a "port-lifespan." Appx33-34. Nor is there evidence to support such a finding. Appx33-34; *BASF*, 875 F.3d at 1366 (reversing indefiniteness because of absence of similar evidence).

To the contrary, AngioDynamics's own expert opined about whether ports were structured for power injection without any express mention of port-lifespan in the claims. Appx5783 (expert opining prior-art ports "were each structured for power injection as claimed"). And by his own admission, he did so "[o]bjectively, by evidence." Appx5783; *see BASF*, 875 F.3d at 1368 (defendant's expert's ability to apply claims objectively contradicts indefiniteness). As explained, that Bard's experts offered competing testimony and evidence for a different conclusion does not render the claims indefinite.

* * * * *

The district court's procedural and substantive errors, alone or combined, require reversing the indefiniteness judgment.

III. Judgment Of No Anticipation Should Be Entered Because Both This Court's Prior Decision And The Record Foreclose Invalidation Of Bard's Claims On That Basis

A. This Court's Holding Of A Triable Dispute Of Fact On Anticipation Requires Reinstatement Of The Jury's Verdict

This Court's prior decision alone requires reversal of the district court's JMOL on anticipation. Before the first appeal, the district court had granted summary judgment to AngioDynamics on anticipation, concluding there was no factual dispute about whether the claim requirement of a radiographic marker or identifiable feature was met by prior art ports with features like a generic "round shape," or an equally generic "square shape," or "suture or orientation holes" used for securing the implanted port. *Bard*, Opening Br. 60-61, ECF 37. Addressing the prior-art Port-A-Cath and Adult Titanium Port, this Court disagreed: "Bard presented contrary evidence that these features were not radiographically discernible and could not be used to distinguish or identify the device or its functionality." *Bard*, 979 F.3d at 1384-85. That evidence included: expert opinion that round and square shapes were too common to distinguish a port or its functionality; evidence that the features on which AngioDynamics relied were difficult to see on an x-ray under appropriate clinical settings; and internal AngioDynamics documents stating that its own round port with suture holes lacked x-ray identifiable features. *Bard*, Opening

Br. 58-61, ECF 37; Reply 33-36, ECF 46. This Court held that Bard's evidence "created a genuine dispute of material fact" sufficient to send the case to the jury." *Bard*, 979 F.3d at 1384-85.

On remand, and as detailed further in Part III.B.2, *infra*, Bard presented the same or materially similar evidence to the jury. Once again, Bard showed that the prior-art features on which AngioDynamics relied—like a square or round shape and suture holes—were either not radiographically discernible, were insufficient to distinguish a port or its functionality, or both. *Infra*, Part III.B.2. As in this Court, Bard presented the jury with images of ports before and after implantation (images from Bard's first appeal briefs on top; images admitted into evidence at second trial on bottom):

Bard, Opening Br. 58-61; Reply 33-36; Appx29288; Appx29545. The jury agreed with Bard, finding AngioDynamics failed to prove anticipation by clear and convincing evidence. Appx1-11. Yet the district court again held no reasonable jury could find for Bard. Appx41-46 (citation omitted).

This Court's decision in the first appeal foreclosed that result on the facts here. Rule 56's genuine-dispute inquiry "is the same" as Rule 50's reasonable-jury inquiry. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-52 (1986). Thus, this Court's holding that Bard's evidence sufficed to create a genuine dispute of fact for trial on AngioDynamics's anticipation defense meant a reasonable jury could find against AngioDynamics. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1308 (Fed. Cir. 2011) (holding that prior decision reversing summary judgment was "law of the case" precluding JMOL on same issue). This conclusion follows for all

asserted claims and allegedly anticipatory prior art. This Court already ruled on Port-A-Cath and the Adult Titanium Port. *Bard*, 979 F.3d 1384-85. And while it did not expressly consider the Vortex port, Bard presented materially the same evidence on that port as the evidence this Court previously considered, including the same AngioDynamics internal documents describing a Vortex lookalike as lacking identifiable features. *Bard*, Opening Br. 58-61; Reply 33-36. The rationale essential to this Court's reversal of summary judgment thus applied equally to the dispute over the Vortex port's features. *Humphrey's Executor v. United States*, 295 U.S. 602, 627-28 (1935) (courts must follow "necessary reach" of a decision); *Valspar Sourcing, Inc. v. PPG Indus., Inc.*, 780 F. App'x 917, 922 (Fed. Cir. 2019) (lower tribunal must follow reasoning and "context provided by this court's opinion").

B. In Any Event, The Record Supports The Jury's Verdict

Even without this Court's prior decision, reversal of JMOL is required because substantial evidence supports the jury's verdict.

1. The jury's rejection of a defendant's failure to prove an affirmative defense by clear-and-convincing evidence can rarely be set aside

The Third Circuit only "'sparingly'" invokes judgment as a matter of law on factual issues. *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (citation omitted). Courts must "'view[] the evidence in the light most favorable to the nonmovant and giv[e] it the advantage of every fair and reasonable inference.'"

Id. (citation omitted). They also "'must disregard all evidence favorable to the moving party that the jury is not required to believe.'" *Springer v. Henry*, 435 F.3d 268, 281 (3d Cir. 2006) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 151 (2000)). And courts "must refrain from weighing the evidence, determining the credibility of witnesses, or substituting [their] own version of the facts for that of the jury." *Marra*, 497 F.3d at 300. Unless this narrow inquiry shows "the record 'is critically deficient of that minimum quantum of evidence from which a jury might reasonably" have reached its verdict, judgment as a matter of law should be denied. *Dawson v. Chrysler Corp.*, 650 F.2d 950, 959 (3d Cir. 1980).

That already high bar to disturbing the jury's verdict is even higher here. Courts deciding a Rule 50 motion "must view the evidence presented through the prism of the substantive evidentiary burden." *Anderson*, 477 U.S. at 253-55 (addressing motions under both Rules 50 and 56). Here, AngioDynamics bore "a heavy burden of persuasion" on its affirmative defenses of invalidity, under the "heightened" clear-and-convincing standard. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 102 (2011); 35 U.S.C. § 282. And because all three allegedly anticipatory prior-art ports were considered by the Patent Office during prosecution (Appx5895-5896), AngioDynamics had "the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job." *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1560 (Fed. Cir. 1986).

2. The jury reasonably found that no prior-art port both incorporated an "identifiable feature" and was structured for power injection

Viewed through this prism, the jury had ample evidence to reject AngioDynamics's anticipation defense. For both the apparatus and method claims, the parties and their experts hotly contested whether the prior-art ports—Vortex, Port-A-Cath, and Bard's own Adult Titanium Port—met two claim requirements: whether they (1) had an "identifiable feature incorporated into the access port"; and (2) were structured for power injection at the claimed flow rate and pressure.

As for the first, all asserted claims require at least one "identifiable" or "radiographic feature." Appx107-108 (col.30:51-col.32:60); Appx165-166 (col.30:51-col.31:34); Appx223-225 (col.30:58-col.32:54). The district court construed that requirement as an attribute "perceivable via x-ray" that "identifies an access port as being structured for power injection." Appx313-314. While this Court held that the requirement to identify the port "as being structured for power injection" is "printed matter not entitled to patentable weight," it also explained that, to anticipate, the prior art must include an attribute that can "distinguish or identify the device or its functionality." *Bard*, 979 F.3d at 1382, 1385.

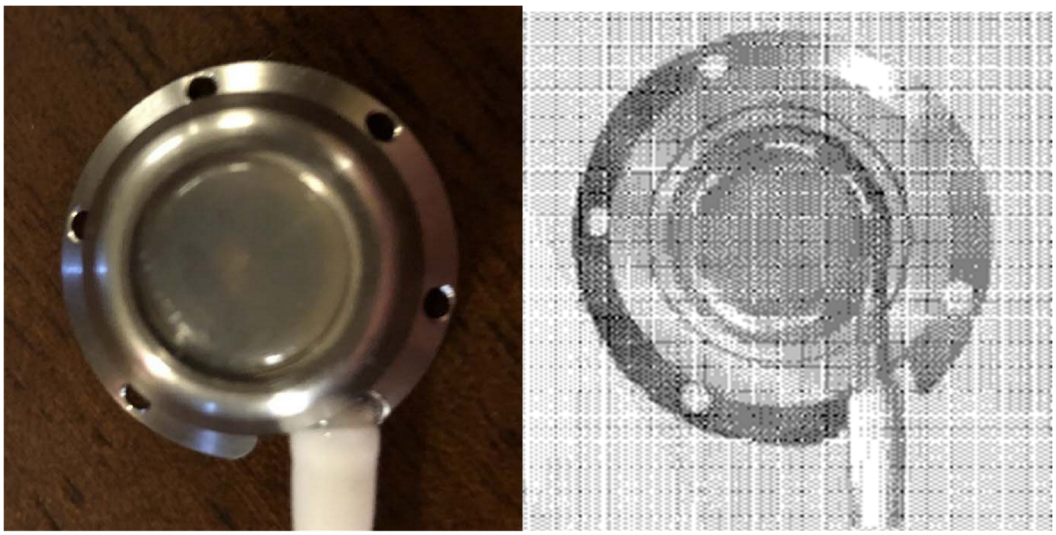
As for the second limitation, the district court relied on the plain text of the asserted claims in construing them to require a port structured for power injection, which means a port structured to be "'suitable for flowing fluid at a fluid flow rate

of at least 1 milliliter per second through the access port' and 'suitable as well for accommodating a pressure within the cavity of at least 35 psi.'" Appx311 (quoting Appx107-108 (col.30:51-col.31:6)).

The absence of either limitation in a prior-art port defeats AngioDynamics's defense based on that port. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("each limitation of a claim" must be in "a single reference"). And the Court "presume[s] that the jury resolved the underlying factual disputes in favor of the verdict winner," meaning here, it presumes the jury found both disputed limitations missing from each prior-art port. *Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991). As explained below, the evidence supports the jury's verdict on each port.

a. The record supports the jury's findings on Vortex

i. Not identifiable. Bard's expert testimony alone supports the jury's verdict that the Vortex port lacked any x-ray identifiable feature. Combined with other documentary evidence and admissions from AngioDynamics's witnesses, the supporting evidence is overwhelming. Bard's expert explained that the Vortex port looks identical to AngioDynamics's original power-injectable SmartPort, with the same round shape, suture holes, and tangential outlet stem (Vortex on left; SmartPort on right):



Appx31094; Appx25423 (both cropped); Appx5520-5521, Appx5789, Appx5931-5932. Bard's expert explained how AngioDynamics's internal documents showed that neither port has x-ray features that could distinguish the port or its functionality—"they couldn't identify it." Appx5931-5932; Appx24942-24943. The jury heard similar testimony from AngioDynamics's own witness: after launching the Vortex-lookalike SmartPort, "the number one obstacle" to sales was, "How do we make it identifiable as CT?" Appx5838-5839; Appx25604-25606; *see* Appx24817 (original SmartPort "released with no indicators that could identify it as CT compatible" via x-ray). Only after AngioDynamics "[c]hanged the shape of the port" and added radiographic lettering did the port "contain any identifiable feature that's visible under X-ray." Appx5931-5933; Appx24942-24943 (AngioDynamics document explaining changes needed to create "uniquely shaped" port). From this non-litigation-inspired evidence generated years before this lawsuit, Bard's expert

concluded that the Vortex port failed to "anticipate any of the asserted claims" because it lacked an identifiable feature. Appx5933.

ii. Not power-injectable. The jury heard similarly clear evidence that the Vortex port was not structured for power injection. Bard's expert explained that "in 2010" AngioDynamics itself had "said that the Vortex family of ports is non-power-injectable." Appx5931. He agreed, testifying that the Vortex port failed to meet "the claim limitations that require a port structured for power injection." Appx5931. AngioDynamics's own documents reflect the same conclusion, stating that the Vortex port "is not power injectable." Appx24210.

The jury also had documentary evidence and admissions from an AngioDynamics witness to the same effect. Appx5498-5500; Appx29231-29264. The FDA had informed AngioDynamics that the "performance data you provided does not demonstrate" Vortex to be "safe and effective" to be marketed as power injectable. Appx5498-5500; Appx29231-29264. And AngioDynamics's witness admitted that the FDA required "extensive" material changes to Vortex before it could be marketed as power injectable, ultimately leading AngioDynamics to rename and rebrand the redesigned port as the SmartPort. Appx5518-5520.

b. The record supports the jury's findings on Port-A-Cath

i. Not identifiable. The evidence on Port-A-Cath was much the same. As the jury saw, the Port-A-Cath had a generic square shape and standard suture holes,

none of which distinguished it radiographically or identified anything about its functionality:

Appx29288; Appx29545 (both cropped). Bard's expert explained that the "etching on the back" was invisible "on an X-ray," and that none of the other attributes was "an identifiable feature perceived via X-ray." Appx5936-5937. The jury also heard that Bard had considered and rejected using a square-shaped port for its PowerPort—Bard "tested it with actual users in simulated conditions" and decided against a square shape "because the goal here was to make it distinguishable from everything that was out there." Appx4539; Appx27422.

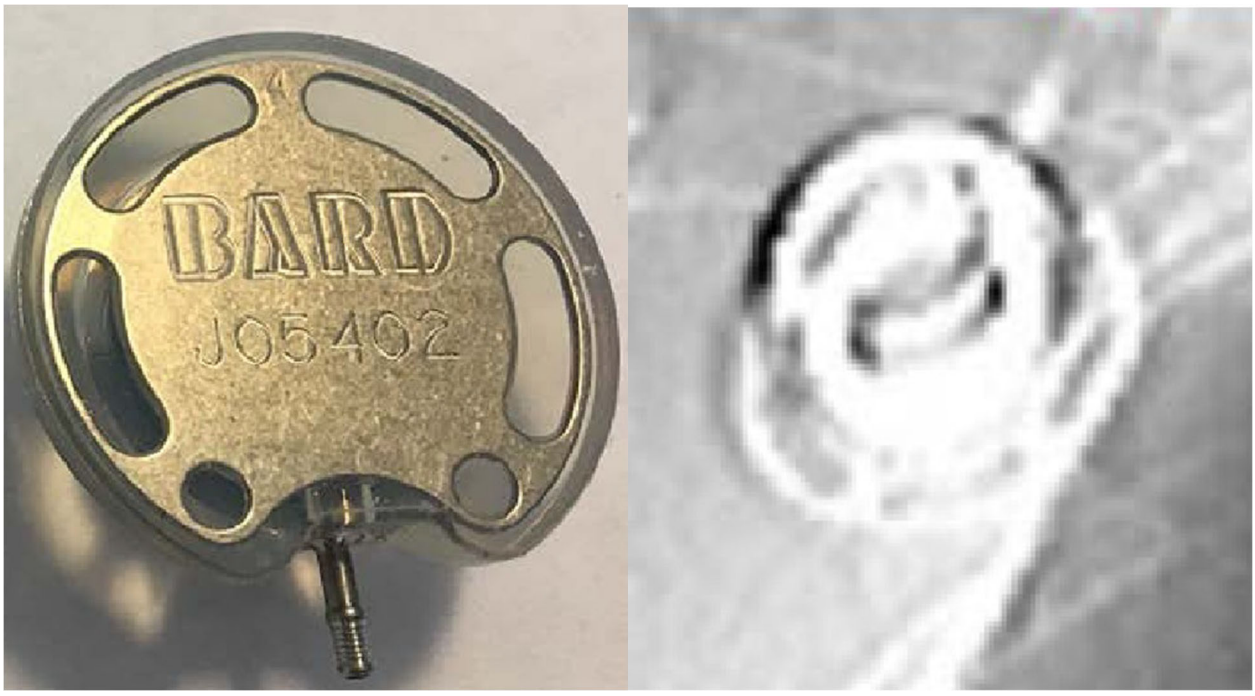
ii. Not power-injectable. Bard also gave the jury clear evidence that Port-A-Cath was not structured for power injection, including at a cavity pressure of at least 35 psi, as required by the claims. In discussing the prior-art Gebauer article,

AngioDynamics's expert admitted that "the manufacturer's max pressure" for Port-A-Cath "is 15 psi." Appx5846; Appx5914. The jury heard the same expert admit that two other prior-art references—the Wayne Memorial Protocol and Carlson—disclosed "nothing about the pressure inside the cavity" for Port-A-Cath. Appx5845.

Bard's expert testified similarly, again supporting the jury's verdict. He explained that Carlson, for example, measured pressure at a different point; based on that measurement, the pressure in the cavity would have been "very far below the mandated 35 psi." Appx5903-5904. He explained that the flow rates reported in the Wayne Memorial Protocol were too low to generate a cavity pressure of at least 35 psi. Appx5974-5975, Appx5923. And he testified that the only successful power injection reported in Gebauer was at 2 mL/s but with cavity pressure "under 35 psi." Appx5917-5918. Although Gebauer also attempted to inject fluid at higher flow rates and pressures, he explained that none of those attempts succeeded because the power-injection machine was "pressure limited" and unable to inject fluid into the port as intended. Appx5858-5860 ("definitively a failure of power injection"). Indeed, the Gebauer authors' conclusion was that they "do not recommend routine use of port systems for contrast injection of CT." Appx5918.

c. The record supports the jury's findings on the Adult Titanium Port

i. Not identifiable. The evidence before the jury was similar for Bard's Adult Titanium Port:



Appx25785, Appx25788-25789 (cropped images of Adult Titanium Port). Bard's expert explained that "as a practicing radiologist" he would not "be able to conclude anything about the port" from an x-ray. Appx5925. As with Port-A-Cath, he could not "see any of the etching" nor did any feature distinguish the port or its functionality on an x-ray. Appx5920-5925.

The jury also heard that, when modifying the Adult Titanium Port to create the eventual claim-embodying PowerPort, Bard recognized a "[p]rimary design challenge": "How will this port be identified as power injectable post-placement?" Appx27196-27197. Bard understood that for a port attribute, such as its shape, to convey anything about the port, the attribute needed to make the port "uniquely discernable from other ports." Appx4609-4614; Appx25524 (needs "a unique port shape"). Because the Adult Titanium Port lacked such features, Bard changed to a

new triangular shape for the PowerPort "to make it distinguishable" from other devices. Appx4539-4540 (inventor testimony).

ii. Not power-injectable. The jury also reasonably found the Adult Titanium Port not structured for power injection. The jury heard from a named inventor that in testing the Adult Titanium Port, Bard learned that "the variation in all of these component parts"—such as where the septum fits within the port body to enclose the cavity—"when you added them all up into this assembly, was too much" to allow the port to withstand the pressure and fluid flow rates required for power injection. Appx4511-4512. To create the PowerPort, Bard started with the same nominal dimensions as the Adult Titanium Port but had to "add a lot of precision," "control these dimensions," and make them "tighter, more precise"; "[i]n some cases, we had to change the processes." Appx4511-4512; Appx5928 (Bard expert explaining same). This "precision of the individual parts that would add up to a final device" capable of withstanding the demands of power injection. Appx4758-4759.

The jury also heard evidence that, before this litigation began, AngioDynamics itself described Bard's PowerPort (and not the earlier Adult Titanium Port) as "the first power injectable port." Appx25583. The jury similarly heard that, despite being aware of Bard's earlier Adult Titanium Port, the FDA described the PowerPort as a "first of its kind" device. Appx4582-4587 (explaining that "first of its kind" referred to "first port used for power injection"); Appx27399.

The jury could reasonably credit this non-litigation-based evidence as showing the Adult Titanium Port was not power-injectable as required by the claims.

d. For all three ports, the district court wrongly substituted its views of the evidence for the jury's

The district court cast aside the jury's well-supported findings by wrongly drawing inferences *against* Bard. Appx36-44. And it expressly declared it could "disregard evidence, even favorable to Bard, that the jury is not required to believe." Appx18 (citing *Reeves v. Sanderson Plumbing Prod., Inc.*, 530 U.S. 133, 150-51 (2000)). *Reeves* says no such thing. *Reeves* requires courts to "give credence to the evidence favoring the *nonmovant*," Bard, and "disregard all evidence favorable to the *moving party*," AngioDynamics. *Reeves*, 530 U.S. at 150-51 (emphasis added). The district court's flawed treatment of the evidence on both the identifiable-feature and power-injectability requirements violates Rule 50 and the Seventh Amendment. *Marra*, 497 F.3d at 300.

i. Not identifiable. The district court skipped past all the testimony and evidence that the prior-art ports lacked identifiable features, discussing none of it. Appx41-44. Instead, the district court quoted testimony from AngioDynamics's expert that at most created a factual dispute for the jury. In that testimony, AngioDynamics's expert identified the same features already discussed—such as round or square port shapes, suture holes, and outlet stems—and claimed they made the ports "readily identifiable" based on "pattern recognition" (which he called

"Aunt Minnie"). Appx42-43 (citing Appx5760-5762, Appx5785-5789). But the jury was entitled to reject this evidence, and credit Bard's instead—and it did. The district court legally erred in "substituting [its] own version of the facts for that of the jury." *Marra*, 497 F.3d at 300.

Plus, the district court ignored evidence identifying flaws in that expert's methodology. Bard's expert explained that AngioDynamics's expert had relied on an x-ray taken using non-clinical settings that would have exposed a patient to "far too much radiation," "40 times more" than a standard x-ray. Appx5921-5922. AngioDynamics's expert used so much radiation that "[i]t looks like the metal has been thinned because the radiation is going so hard through it." Appx5921-5922. The x-ray was also taken without a body phantom (which simulates a human body), making the x-ray "inadequate" to assess the claims, which require identifiable features perceivable following implantation. Appx5923. The jury reasonably declined to credit such flawed testimony.

In short, ample evidence supports the jury's findings that none of the three prior-art ports met the "identifiable" limitation. Lack of this limitation alone requires reinstatement of the no-anticipation verdict. *Atofina*, 441 F.3d at 999.

ii. Not power-injectable. The district court repeated the same errors in overriding the jury's findings that AngioDynamics failed to prove, by clear and convincing evidence, that any prior art port was structured for power injection at the

claimed flow rates and pressure. Appx36-41. For Port-A-Cath and Vortex, the district court all but ignored the trial testimony, instead adopting its own interpretations of technical testing data and scientific articles despite the well-supported contrary opinion of Bard's expert. Appx38-40.

The district followed a similarly flawed approach with the Adult Titanium Port. For example, the district court classified as an "undisputed fact" a statement submitted by AngioDynamics that the Adult Titanium Port "was structurally suitable for power injection." Appx38 (quoting Appx2666 (¶8)). But as shown, Bard did dispute that statement with evidence that the jury reasonably credited. *Supra* pp. 49-52. The district court also pointed to Bard's agreement that "[a]t least some of Bard's current and former vascular access port models that have not been marketed as being power injectable are structurally capable of withstanding the pressures and flow rates of power injection procedures." Appx38 (quoting Appx2663 (¶37)). But that statement never specifies whether any of the "current and former" ports pre-date Bard's inventions here, let alone that the Adult Titanium Port was one of those "current and former" ports. Appx2663 (¶37).

Because the district court again erred in substituting its views for the jury's, this independent reason also requires reinstating the jury verdict.

3. The verdict on the method claim is further supported

The jury's verdict of no-anticipation on the method claim should be reinstated for an additional, independent reason. To anticipate that claim, AngioDynamics needed to show by clear and convincing evidence either that a single reference discloses every claimed step or that someone actually practiced every step. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 738 (Fed. Cir. 2002) (discussing prior public use). That meant showing, among other things, disclosure or practice of taking an x-ray of an implanted port, identifying the port's radiographic identifiable feature, and then flowing fluid though the port at a rate of at least 1 mL/sec. Appx223-224 (col.30:58-col.31:4), Appx224 (col.31:41-56).

The evidence amply supports the jury's finding that none of AngioDynamics's evidence disclosed or proved performance of all those steps. For Port-A-Cath and Vortex, AngioDynamics relied on instructions that never mention identifying a radiographic feature or power-injecting fluid at a rate of at least 1 mL/sec. Appx28957-29067; Appx29267-29281. At most, the instructions state to use fluoroscopy during catheter insertion to determine the catheter tip location. Appx28957-29067; Appx29267-29281. Other references that AngioDynamics relied on for those ports were similar, such as the Gebauer article or the AngioDynamics engineer's lab notebook—those references did not even describe performing steps on an implanted port, as the method claim requires, let alone x-

raying that port before any injection to identify a radiographic feature. Appx28337-28356; Appx29217-29230.

The evidence on any method performed using the Adult Titanium Port was similarly insufficient and reasonably supports the jury's verdict of no-anticipation. AngioDynamics's expert attempted to rely on inherency, pointing to the Herts reference, which describes merely performing CT scans using an implanted port without specifying whether the port is an Adult Titanium Port. Appx5790-5791. His testimony was that "I know, as anyone of ordinary skill in the art would realize, that a CT scan involves X-rays, involves imaging of the port, and therefore, in that process, it would [be] identified." Appx5790-5791. But inherency is a high bar, requiring AngioDynamics "to establish that the limitation was necessarily present" by clear and convincing evidence. *Crown Operations Int'l v. Solutia Inc.*, 289 F.3d 1367, 1377 (Fed. Cir. 2002). AngioDynamics's expert testimony fails to clear that bar, let alone compel the jury to find in its favor. The method claim requires more than "imaging of the port" or even identifying it generally. They require taking an x-ray "to determine whether the access port includes a radiographic feature indicating" information about the port and "identifying the indicating radiographic feature on the x-ray." Appx107-108 (col.30:51-col.31:6). AngioDynamics failed to present any evidence, express or inherent, that anyone identified a radiographic feature on an implanted Adult Titanium Port. Appx5790-5791.

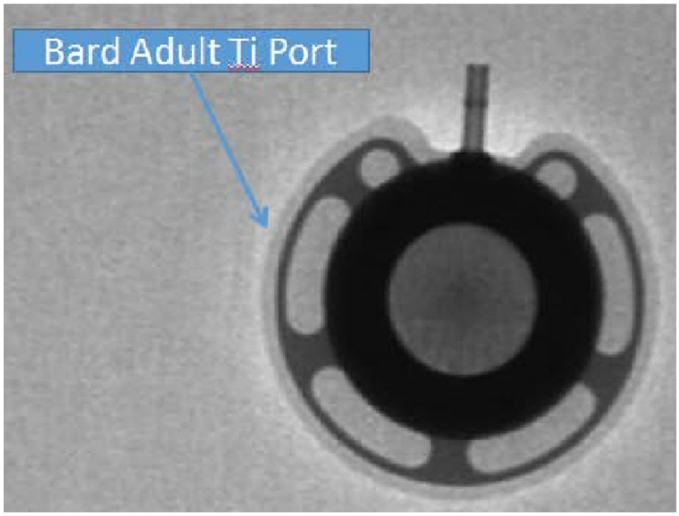
The district court based its contrary conclusion on testimony from Bard's infringement expert about the steps taken as part of routine practice *after* Bard introduced its highly successful PowerPort. Appx44-46 (citing Appx4333-4334). The district court found "irony" in Bard's reliance on "testimony of standard medical practice" to prove infringement while contesting that evidence for invalidity, thinking "[s]auce for the goose" was sauce for the gander. Appx46. But anticipation requires evidence showing the claimed method steps were disclosed or performed *before* Bard's invention, not after it. 35 U.S.C. § 102 ("before the invention thereof"). Bard's infringement evidence was evidence of a standard of care that resulted from Bard's invention. Appx4333-4334. Contrary to the district court's conclusion, that evidence cannot be a basis to overturn the jury's verdict of no-anticipation.

C. The Court Should Also Reverse Because No Allegedly Anticipatory Port Includes A Radiographic Letter

The Court should reverse on anticipation for another independent reason: no prior-art port has the claimed "radiographic letter," a requirement entitled to patentable weight under a proper claim construction.

Claims 5 and 12 of the '417 patent explicitly recite a "radiographic marker" that is "one or more radiographic letters," and claim 3 of the '478 patent requires "identifying a radiographic letter" on an x-ray. Appx108 (col.31:16-17, col.31:27-49); Appx224 (col.31:8-9). After the parties disputed whether these claims recite

printed matter, trial proceeded under the district court's initial (correct) claim construction giving them patentable weight. Appx4089. At trial, AngioDynamics conceded neither Vortex nor Port-A-Cath includes a radiographic letter. Appx3990 (Port-A-Cath: "engravings were not visible on an x-ray"), Appx3993 (Vortex: letters "not visible under x-ray"). As for the Adult Titanium Port, Bard's expert explained that no letters were visible even on the x-ray of an unimplanted port taken with more radiation than would be used on a patient:



Appx25810; Appx5922-5923. Then, after the trial conclusively showed all three prior-art ports lack radiographic letters, the district court reversed itself and construed "radiographic letter(s)" as printed matter carrying no patentable weight. Appx6025-6027; Appx41.

That belated construction is wrong. The district court thought a "radiographic letter" was printed matter that could be ignored because it "intrinsically conveys its typographical meaning." Appx41. Not so. Printed matter is only "the content of

the information conveyed." *Bard*, 979 F.3d at 1381-82. This Court distinguished that content from "the means by which the information is conveyed," such as "radiographic markers," and held that the means are not printed matter and thus are entitled to patentable weight. *Id.* at 1384-85. And it recognized that radiographic markers may "be in the form of radiographic letters or other symbols, patterns, or characters." *Id.* at 1376. That is exactly what the claims here recite—they limit the independent claims to a form of "radiographic marker." Appx108 (col.31:16-17, col.31:27-49); Appx224 (col.31:8-9). Indeed, the information conveyed by the marker is recited in a separate portion of the claims. Appx108 (col.31:16-17, col.31:27-49); Appx224 (col.31:8-9). Thus, contrary to the district court's last-minute construction, radiographic letters are not the content of information; they are information-conveying means entitled to patentable weight.

Once this claim-construction error is corrected and these limitations are properly given patentable weight, reversal is required on '417 claims 5 and 12 and '478 claim 3 for two independent reasons. First, given AngioDynamics's concessions on Port-A-Cath and Vortex, and the unrebuttable evidence and image of Adult Titanium Port, "no reasonable jury could have found" that the prior art contains radiographic letters "under the proper claim construction." *SimpleAir, Inc. v. Sony Ericsson Mobile Commc'ns AB*, 820 F.3d 419, 425 (Fed. Cir. 2016). That alone suffices to reverse outright.

Second, and in any event, the jury's verdict already includes a presumed finding of no radiographic letters, which this Court should reinstate because substantial evidence supports it. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1330 (Fed. Cir. 2021) (applying Third Circuit law, reversing JMOL and reinstating jury verdict because record supported "presumed jury findings" under correct legal standard). The upshot of the district court's erroneous claim construction is that, to find no anticipation, the jury had to find that the prior art lacked *any* radiographic identifiable features. The jury's verdict of no anticipation thus necessarily included a finding that no prior-art port had radiographic letters, a subset of radiographic identifiable features. *Id.* at 1328 (presuming all findings in verdict's favor). Because, as shown, substantial evidence supports that finding, the jury's verdict on '417 claims 5 and 12 and '478 claim 3 should be reinstated for that reason as well.[4] At the least, the claim-construction error requires a new trial on anticipation. *SimpleAir*, 820 F.3d at 425.

* * * * *

For all these reasons, the judgment on anticipation should once again be reversed.

[4] To be sure, the district court set aside the jury's no-anticipation verdict, but it never suggested a finding of no radiographic letters was unsupported (Appx41-44)—nor could it have, given the concessions and evidence.

IV. The Jury's Verdict Finding Willful Infringement Should Be Reinstated Because This Court Already Held The Same Or Materially Similar Evidence Would Suffice To Support A Verdict And Because The Jury Reasonably So Found

In the prior appeal, this Court held that Bard introduced "sufficient evidence to support a jury verdict of willfulness" by showing AngioDynamics "was aware of the applications that issued as the patents-in-suit prior to their issuance" and still "intentionally copied Bard's" technology. *Bard*, 979 F.3d at 1380. But after Bard introduced the same or materially similar evidence on remand and the jury found for Bard, the district court reinstated judgment for AngioDynamics on willfulness. That was reversible error. This Court had already held Bard's evidence sufficed to support a jury verdict in Bard's favor. *Id.* The mandate thus foreclosed the district court from reaching a different conclusion. *Engel*, 166 F.3d at 1383. That alone requires reinstatement of the jury's verdict of willful infringement.

In addition, and in any event, the district court erred in setting aside the verdict for supposed lack of a "start date" for willfulness. Appx47. The district court cited *SRI International, Inc. v. Cisco Systems, Inc*., but that decision has no application here. There, this Court rejected a verdict of willfulness going back to the date the defendant had first developed the allegedly infringing product for the unremarkable reason that the defendant had been unaware of the plaintiff's patent until later. *SRI*, 930 F.3d 1295, 1309 (Fed. Cir. 2019).

But here, Bard's evidence showed AngioDynamics was aware of Bard's patents even before they issued. As this Court previously recognized, AngioDynamics's former director of intellectual property admitted to AngioDynamics's pre-issuance knowledge. Appx5109; *see Bard*, 979 F.3d at 1380. Indeed, AngioDynamics received opinion letters about each patent on its issuance date. Appx20413-20884; Appx20885-23143; Appx23144-23727. The evidence thus supports the jury's verdict that AngioDynamics willfully infringed for the life of each patent. And as *SRI* confirms, the jury must be presumed to have resolved all "underlying factual disputes in favor of the verdict winner." 930 F.3d at 1309-10.

For these independent reasons, the jury's willfulness verdict should be reinstated.

V. The Alternative Grant Of A New Trial Should Be Reversed Because The District Court Procedurally And Substantively Erred

In alternatively granting a new trial because the jury was purportedly not "properly instructed" relative to the constructions of "suitable" and "identifiable" (Appx20), the district court abused its discretion, including by committing legal error.

First, AngioDynamics failed to preserve any jury-instruction challenge or request a new trial on that basis, so the district court could not grant one. *Harkins v. Ford Motor Co.*, 437 F.2d 276, 278 (3d Cir. 1970). In *Harkins*, a district court had granted the plaintiff a new trial for lack of an "adequate jury instruction on strict

liability." *Id.* But the plaintiff's motion for a new trial never "clearly stated" that basis, nor had plaintiff's counsel "object[ed] to any portion of the instruction on strict liability." *Id.* at 276, 278. The Third Circuit held the rules were "emphatically clear" that no new trial was "warrant[ed]" in those circumstances. *Id.* at 278-79. The district court erred here for the same reason.

Second, and regardless, the district court erred in concluding that the jury was not "properly instructed" and that Bard presented new claim constructions. Appx20. The jury was correctly instructed on the district court's constructions about "suitable" and "identifiable." Appx3894-3895. Indeed, the instructions went further, telling the jury that "[t]he asserted claims do not require FDA 'indication' for power injection." Appx3952-3953.

Also, as already discussed, the Bard testimony and argument to which the district court pointed addressed different issues, not new claim constructions or anything improper. *Supra* pp. 25-26, 36-37; Appx18-26. The testimony and argument merely described the safety and reliability problems Bard set out to solve with its invention, and contested whether the prior art anticipated Bard's invention. Appx18-26. Far from improper, such statements went to the heart of the issues being tried.

VI. This Case Should Be Reassigned On Remand

A decision reversing or vacating the judgment will require a remand and further proceedings, including on the bifurcated damages issues. Under the unusual circumstances here, such a remand should be accompanied by an order to reassign the matter to a different district court judge.

An appellate court should order reassignment to ensure the "appearance of impartiality." *United States v. Bergrin*, 682 F.3d 261, 282 (3d Cir. 2012) (citing 28 U.S.C. § 2106). The inquiry is "objective"; it "is not concerned with the question whether a judge actually harbors bias against a party." *United States v. Kennedy*, 682 F.3d 244, 258 (3d Cir. 2012). Although "an extraordinary remedy," reassignment is appropriate for "repeated" failures to follow the law. *Bergrin*, 682 F.3d at 282-84. For instance, this Court has concluded "a different judge is necessary to preserve the appearance of justice" where "[t]he district court has now been reversed twice after entering summary judgment against [the plaintiff]." *TriMed, Inc. v. Stryker Corp.*,608 F.3d 1333, 1344 (Fed. Cir. 2010).

The district court here repeated the same critical legal errors on remand that warranted correction in the first appeal. As explained above, it again *sua sponte* raised ineligibility in a procedurally improper way; failed to follow this Court's decisions rejecting, as a matter of law, eligibility challenges to these or nearly identical claims; raised and decided an indefiniteness issue of its own creation;

reinstated its prior no-anticipation and no-willfulness judgments, despite this Court's decision holding the evidence sufficient to support a jury verdict; and it again improperly took upon itself the jury's role of resolving factual disputes, which required remand after the prior appeal. Reassignment is warranted.

CONCLUSION

The grant of judgment as a matter of law should be reversed or vacated, the jury's verdict reinstated, and the case remanded for further proceedings before a different district court judge.

Dated: October 5, 2023

Respectfully submitted,

/s/ Deanne E. Maynard

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ADDENDUM

C.R. BARD, INC.

v.

ANGIODYNAMICS, INC.

No. 23-2056 (Fed. Cir.)

ADDENDUM TABLE OF CONTENTS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARD PERIPHERAL VASCULAR, INC., Plaintiff and Counterclaim-Defendant, v. ANGIODYNAMICS, INC., Defendant, Counterclaim-Plaintiff, v. C.R. BARD, INC., Counterclaim/Third-Party Complaint Defendant.	C.A. No. 15-218-JFB-SRF VERDICT FORM

Ladies and gentlemen of the jury, it is now your duty to answer the questions presented in this Verdict Form, according to your unanimous decision after due deliberation. Please answer the questions in the order in which they appear.

During your deliberations, you may refer to the instructions that I have read to you in the courtroom at the start and conclusion of the trial.

Once you have completed this Verdict Form, please advise the Clerk and have your Foreperson sign and date this form.

I. INFRINGEMENT

A. DIRECT INFRINGEMENT OF THE '417 PATENT

1. Has Bard proven by a preponderance of the evidence that AngioDynamics's Smart Port CT and Smart Port LP products have directly infringed either or both of claims 5 and 12, including each and every limitation of their underlying independent claims, of the '417 patent? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES DID INFRINGE	NO DID NOT INFRINGE
Smart Port CT		
Claim 5	✓	
Claim 12	✓	
Smart Port LP		
Claim 5	✓	
Claim 12	✓	

B. DIRECT INFRINGEMENT OF THE '460 PATENT

2. Has Bard proven by a preponderance of the evidence that AngioDynamics's Smart Port, Xcela, Xcela Plus, and BioFlo Port products have directly infringed claim 4, including each and every limitation of the underlying independent claim, of the '460 patent? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES DID INFRINGE	NO DID NOT INFRINGE
Smart Port CT		
Claim 4	✓	
Smart Port LP		
Claim 4	✓	
Smart Port MP		
Claim 4	✓	
Xcela Ports		
Claim 4	✓	
Xcela Plus Ports		
Claim 4	✓	
BioFlo Ports		
Claim 4	✓	

C. INDUCED INFRINGEMENT OF THE '478 PATENT

3. Has Bard proven by a preponderance of the evidence that a single entity has directly infringed claim 3 of the '478 patent, including each and every limitation of the underlying independent claim, and that AngioDynamics has induced that entity's infringement? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES DID INFRINGE	NO DID NOT INFRINGE
Claim 3	✓	

II. PATENT VALIDITY

A. ANTICIPATION

4. Has AngioDynamics proven by clear and convincing evidence that either or both of claims 5 and 12 of the '417 patent are invalid because they are anticipated by a single prior art reference? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	NO NOT INVALID
Claim 5	_____	✓
Claim 12	_____	✓

5. Has AngioDynamics proven by clear and convincing evidence that claim 4 of the '460 patent is invalid because it is anticipated by a single prior art reference? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	NO NOT INVALID
Claim 4	_____	✓

6. Has AngioDynamics proven by clear and convincing evidence that claim 3 of the '478 patent is invalid because it is anticipated by a single prior art reference? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	**NO** NOT INVALID
Claim 3	_____	✓

B. OBVIOUSNESS

7. Has AngioDynamics proven by clear and convincing evidence that either or both of claims 5 and 12 of the '417 patent are invalid because they would have been obvious to one of skill in the art at the time of the invention? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	**NO** NOT INVALID
Claim 5	_____	✓
Claim 12	_____	✓

8. Has AngioDynamics proven by clear and convincing evidence that claim 4 of the '460 patent is invalid because it would have been obvious to one of skill in the art at the time of the invention? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	**NO** NOT INVALID
Claim 4	_____	✓

9. Has AngioDynamics proven by clear and convincing evidence that claim 3 of the '478 patent is invalid because it would have been obvious to one of skill in the art at the time of the invention? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES INVALID	**NO** NOT INVALID
Claim 3	_____	✓

If you found that AngioDynamics infringed a valid claim, that is, you answered "yes" to any of questions 1 through 3 and answered "no" for each of the corresponding of questions 4 through 9, you must answer the remaining questions 10 through 15. If you did not find that AngioDynamics infringed any valid claim, you should skip the remaining questions and return this verdict form to the Court.

III. WILLFUL INFRINGEMENT

10. Has Bard proven by a preponderance of the evidence that AngioDynamics's infringement of the '417 patent was willful? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES WILLFUL	NO NOT WILLFUL
Claim 5	✓	
Claim 12	✓	

11. Has Bard proven by a preponderance of the evidence that AngioDynamics's infringement of the '460 patent was willful? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES WILLFUL	NO NOT WILLFUL
Claim 4	✓	

12. Has Bard proven by a preponderance of the evidence that AngioDynamics's infringement of the '478 patent was willful? [*A "yes" answer to this question is a finding for Bard. A "no" answer is a finding for AngioDynamics.*]

	YES WILLFUL	NO NOT WILLFUL
Claim 5	✓	

IV. PRIOR USE

13. Has AngioDynamics proven by clear and convincing evidence that AngioDynamics, or a company it acquired, commercially used the '417 Patent in good faith and in the United States before April 25, 2005? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.]*

	YES PRIOR USE	NO NO PRIOR USE
Claim 5	_____	✓
Claim 12	_____	✓

14. Has AngioDynamics proven by clear and convincing evidence that AngioDynamics, or a company it acquired, commercially used the '460 Patent in good faith and in the United States before April 25, 2005? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES PRIOR USE	NO NO PRIOR USE
Claim 4	_____	✓

15. Has AngioDynamics proven by clear and convincing evidence that AngioDynamics, or a company it acquired, commercially used the '478 Patent in good faith and in the United States before April 25, 2005? [*A "yes" answer to this question is a finding for AngioDynamics. A "no" answer is a finding for Bard.*]

	YES PRIOR USE	**NO** NO PRIOR USE
Claim 3	_____	✓

You have now completed this Verdict Form and should so advise the Clerk. The Foreperson should sign and date the Form below:

DATED: 11/22/2022 FOREPERSO[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CR BARD INC. and BARD PERIPHERAL VASCULAR, INC., Plaintiffs/Counterclaim Defendants. vs. ANGIODYNAMICS, INC., Defendant/Counterclaim Plaintiff.	**CIV. NO. 15-218-JFB-SRF** **MEMORANDUM AND ORDER**

Following eight years of litigation, one-and-a-half jury trials, a trip to the Court of Appeals, and finally a blanket verdict of willful infringement and rejection of invalidity and infringement defenses in favor of Plaintiffs and patent owners CR Bard Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), this matter is before the Court on defendant AngioDynamics, Inc.'s motion for judgment as a matter of law. D.I. 572. Bard's claim reconstructions at trial would render the claims invalid either for recitation of ineligible subject matter or indefiniteness, whereas adherence to the original claim construction renders the claims anticipated. To the extent below, the motion is granted.

BACKGROUND

This case concerns the vascular access port, a small receptacle attached to a catheter implanted under a patient's skin to ease regular medical injection. More specifically, this case concerns Bard's purported patentable improvement of the vascular access port.

Doctors have used vascular access ports for decades to inject pharmaceutical drugs, such as chemotherapy. For most of this time, they injected these drugs a little at

a time—at low pressures and fluid flow rates, in the parlance of this case. Along the way, the development of the computed tomography, or "CT," scan expanded the value of the ports but added complications. Contrast fluid, a substance injected into patients to improve the visibility (and therefore efficacy) of a CT scan, proved too thick, or "viscous," for easy injection. And to get a good picture, the contrast fluid would need to be injected quickly into the patient. That just couldn't be done with traditional, usually manual, methods. So called "power-injection" machines entered the market, capable of pumping contrast media at pressures above 300 pounds per square inch (psi) and fluid flow rates beyond 1 milliliter (one thousandth of a liter) per second (mL/s)—well beyond what could previously have been done by hand. Solving one problem, though, power injection exposed another.

Previous ports hadn't been designed to accommodate such high pressures and fluid flow rates. Like overfilled balloons, some ports began bursting under power injection. Not always. And not even the first or first several times. But it happened enough that in 2004 the Food & Drug Administration warned doctors nationwide "of the potential for serious patient injury when vascular access devices not designed to tolerate high pressures are used for power injection of CT or MRI contrast media." The FDA reported over 250 different rupture events and stressed that doctors should "[c]heck the labeling of each vascular access device for its maximum pressure and flow rate" and not exceed those parameters. PX-508 (Reminders from FDA Regarding Ruptured Vascular Devices from Power Injection, July 2004).

Sensing the opportunity to market a port FDA-indicated, that is approved, for power injection, Bard got to work and eventually became the first to obtain approval to market a

power-injectable vascular access port. Bard's PowerPort entered the market in July 2006, followed by the PowerPort MRI (a plastic, as opposed to titanium, version) in March 2007. Others also sought FDA approval to market power-injectable ports, including AngioDynamics.

In the meantime, Bard had moved to protect its development, filing several applications with the United States Patent & Trademark Office. Ultimately, several patents issued, including the three at issue here, Patent No. 8,475,417, Patent No. 8,545,460, and Patent No. 8,805,478.[1] But rather than patenting the apparently new capability of the vascular access ports to withstand the heightened pressures and flow rates of power injection, the asserted patents instead focused on the labeling of such ports for that purpose. Claim 1 of the '460 patent fairly represents the lot:

> 1. A system for identifying a power injectable vascular access port, comprising:
>
> [a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;
>
> [b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature comprising a radiographic marker identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port; and
>
> [c] a second identifiable feature separated from the subcutaneously implanted access port, the second feature visually observable following subcutaneous implantation to confirm that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

Asserted claim 4 of the '460 patent adds the requirement that the "radiographic marker [be] selected from the group consisting essentially of an observable pattern, a symbol, a

[1] The three share a specification and trace either directly, by continuation, or division to application no. 11/380,124.

typographical character, an indicium, and combinations thereof." Asserted (dependent) claims 5[2] and 12[3] of the '417 patent recite the same substance in the form of "[a]n assembly for identifying a power injectable vascular access port," additionally requiring the "radiographic marker [to be] one or more radiographic letters." And asserted (dependent) claim 3[4] of the '478 patent recites the method of using such labeled vascular

[2] Claim 1 of the '417 patent reads:

An assembly for identifying a power injectable vascular access port, comprising:

[a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

[b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

[c] a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

[d] a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

[3] Independent claim 8 of the '417 patent reads:

An assembly for identifying a power injectable vascular access port, comprising:

[a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

[b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

[c] a second identifiable feature incorporated into the access port separate from the first identifiable feature, the second feature perceivable following subcutaneous implantation of the access port to identify the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

[d] a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

[4] Claim 1 of the '478 patent reads:

A method of performing a power injection procedure, comprising:

[a] taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port, the access port defining one or more fluid reservoirs, each fluid reservoir accessible through a cannula-penetrable septum;

[b] identifying the indicating radiographic feature on the x-ray; and

[c] flowing a fluid through the access port at a rate of at least 1 milliliter per second.

access port in a power-injection procedure, again also requiring the radiographic marker to be "a radiographic letter."

In 2015, Bard sued Angio for patent infringement. Following discovery and claim construction, D.I. 156, the parties proceeded to trial in March 2019. At the close of Bard's infringement case-in-chief, the Court granted judgment as a matter of law to Angio on noninfringement, but chiefly, on invalidity, finding the asserted claims invalid for recitation of patent ineligible print matter with no redeeming inventive concept. The asserted claims, the Court found, did not capture the technical developments in crafting a power injectable port but instead merely recited the labeling and instructions—print matter—of a port for such use. *C R Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332 (D. Del. 2019); *see also*, *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

The Court of Appeals for the Federal Circuit agreed that the claims recited generally ineligible print matter but disagreed with this Court's ultimate conclusions. Specifically, an inventive concept could be discerned:

> When each claim is read as a whole, the focus of the claimed advance is not solely on the content of the information conveyed, but also on the means by which that information is conveyed. In particular, the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the radiographic marker in the claimed invention that makes the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified via x-ray, as used during CT imaging.

Thus, the panel ruled, "the asserted claims are not patent ineligible under [35 U.S.C.] § 101 because the claims in their entireties are not solely directed to printed matter." The panel also cautioned this Court against granting judgment as a matter of law before Bard's rebuttal case on invalidity. *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1380,

1384 (Fed. Cir. 2020). With this guidance, the Court and the parties reconvened in November 2022.

An eventful retrial followed. Bard's first witness, named-inventor Kelley Powers, admitted on direct examination that the novelty of the PowerPort lay neither in creating a power-injectable port nor in making one radiographically visible, but instead in crafting a reliable radiographic label and in tightening the manufacturing tolerances of an existing port design such that it would endure repeated power injection, each to a satisfactory degree of safety.

Then, in a surprise twist, Bard's damages expert, Dr. Cox, admitted that in his reasonable royalty calculations he had not apportioned the value imparted by each discrete aspect of the allegedly infringing products, but simply picked a royalty rate based upon the entire revenue of the products that seemed "fair" to his mind. Under long-standing guidance from the Federal Circuit, *see, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 977 (Fed. Cir. 2018), this Court had no choice but to strike Dr. Cox's testimony in full. Aiming to salvage at least an untainted infringement and validity verdict, though, the Court bifurcated the trial, giving Bard a chance to redeem its damages case at a later date.

As will be detailed below, throughout the trial, Bard's witnesses, both percipient and expert, flouted the Court's claim construction order, construing newly-material terms for the first time. Remedial attempts evidently failed. After five hours of deliberation, the Tuesday before Thanksgiving, the jury returned a blanket verdict for Bard: direct infringement, induced infringement, willful infringement, novelty, nonobviousness, and

rejecting AngioDynamics' prior use defense. D.I. 565. Angio now moves for judgment as a matter of law of invalidity, noninfringement, and nonwillfullness. D.I. 576.

LEGAL STANDARD

Judgment as a matter of law may disturb a jury verdict if, and only if, a party has been fully heard on an issue *and* "the record is critically deficient of the minimum quantum of evidence upon which a jury could reasonably base its verdict." *C R Bard Inc.*, 979 F.3d at 1378; *Pitts v. Delaware*, 646 F.3d 151, 155 (3d Cir. 2011) (cleaned up). In invoking this "sparingly" used remedy, the Court must view the record in the light most favorable to Bard, giving it the advantage of every fair and reasonable inference, and refrain from substituting its own view of the facts. *Marra v. Philadelphia Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge"—though a court should disregard evidence, even favorable to Bard, that the jury is not required to believe. *Reeves v. Sanderson Plumbing Prod., Inc.*, 530 U.S. 133, 150–51 (2000).

Judgment as a matter of law may be appropriate, however, when based on a legal determination not itself premised on a rejection of the jury's findings. *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009). After all, claim construction, along with its "evidentiary underpinnings," remains "exclusively" the Court's realm. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015).

DISCUSSION

This case highlights the danger in construing claim terms during discovery, without the context of infringement and invalidity cases. At claim construction, D.I. 156, the Court

understood the claimed port descriptors "suitable" for power injection and "identifiable" as such as characteristics present or not—as though flipping a light switch—in a port. Five-and-a-half years on, trial testimony reveals otherwise.

As Mr. Powers detailed, Bard's task lay not in crafting a power-injectable port from a blank slate, but in modifying the manufacturing tolerances of then-existing ports to make them "suitable" for power injection. Previous ports, such as Bard's Adult Titanium which had been on the market since 2003, *had* successfully endured power-injection procedures, and those that had failed had not necessarily done so in the first instance. This makes sense—vascular access ports facilitate not just one but *repeated* injections, such as multiple CT scans over time to track a course of treatment. '460 pat. at 2:35–8. The repeated cycles of power-pressurization and depressurization, like a balloon blown up and deflated or a paper clip folded back and forth, over and over, wear the port until it fails. A power-injectable vascular access port may be designed for five cycles, ten, twenty, or thirty, before the device must be replaced. D.I. 580 at 163 (Tr. 2-380:24–83:6, Tr. 2-389:13–90:18) (Powers); D.I. 581 at 206 (Tr. 3-747:8–14), D.I. 582 at 49 (Tr. 4-872:3–10) (Dr. Clark); D.I. 584 at 178 (Tr. 6-1652:23–53:16) (Dr. Johnson); PX-69 at 143–44, 174 (letter dated July 14, 2006 from Chiu Lin, PhD., FDA, to Susan Scott, Bard Access Systems, Inc., re Section 510(k) Premarket Notification No. K060812); PX-488. The question was not then whether a vascular access port was suitable for power injection, but *how* suitable.

So too, as Mr. Powers explained, the distinct shape, patient records, and radiographic markers served the reliability of port identification. Removal of the features would not render a port invisible once implanted. It could still be seen and felt under a

patient's skin and viewed under X-ray. The radiographic "CT" granted doctors certainty. D.I. 580 at 166 (Tr. 2-383:4–6, Tr. 2-395:20–96:7, Tr. 2-404:17–05:7) (Powers). Again, the question was not whether a vascular-access port was identifiable as power injectable, but *how* identifiable.

It should go without saying that Bard's new trial constructions of "suitable" and "identifiable" and the failure of the jury instructions to adequately account entitles AngioDynamics to a new trial—defendants being entitled to a properly instructed jury.[5] *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1352–53 (3d Cir. 1991); *E.E.O.C. v. State of Del. Dep't of Health & Soc. Servs.*, 865 F.2d 1408, 1413 (3d Cir. 1989); Fed. R. Civ. P. 59(a). Yet a simpler path than retrial appears. Under Bard's new constructions, imbued variously with the medical standard of care or safety to the FDA's satisfaction, the claims recite patent-ineligible subject matter. Stripped of such of considerations of safety and reliability—under the constructions Bard litigated for years—Bard's own Adult Titanium port, among others, anticipates the asserted claims. And construing the terms anywhere in between these bounds renders the claims indefinite.

Before diving in, however, it's worth noting some running themes. First, noted yet largely inchoate through trial and post-trial briefing, this case spans the ken of two federal agencies. While the PTO governs the patents, *the FDA governs* the marketing of the ports themselves. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); 21 C.F.R. § 807.87(e). The FDA asks whether a device is safe and effective for its intended purpose. The patentability inquiry asks what a device teaches. Unsurprisingly, the ultimate-structural capacities, potential

[5] This order does not address the remainder of Bard's alleged claim reconstructions.

uses, and teachings of a medical device fall, often enough, beyond what the FDA would consider safe and effective use. So, as will be seen throughout, Bard's continual reliance on labels or FDA "indication" does not actually answer Angio's reliance on test data to prove the prior-art ports' capabilities.

Second, "the rule of law embodies evenhandedness . . . sauce for the goose is normally sauce for the gander." *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. ___, 138 S. Ct. 2361, 2385 (2018) (Breyer, J., dissenting). In patent, this timeless tenet of the common law takes a simple form: a patent owner's infringement and invalidity cases *must* conform. *CommScope Techs. LLC v. Dali Wireless Inc.*, 10 F.4th 1289, 1299 (Fed. Cir. 2021); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1449 (Fed. Cir. 1984). Time and again, then, the testimony of Bard's validity expert, Dr. Johnson, must be discarded because Bard's infringement expert, Dr. Clark, testified otherwise.

Third, with the patent owner's privilege to act as lexicographer, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005), comes the price that it will be held to that use of the term. As corollary to the previous, obviously, terms must take the same construction for infringement and validity. Most dispositive, as will be seen, will be Bard's definition of "power injection." Use of the phrase by others need not convey the specific claimed flow rate and pressure parameters. But, having defined "power injection" in the patents and in this case to mean those specific parameters, Bard's own use, or incorporation without clarification, of the phrase necessarily conveys that meaning. Introductory matter complete, this order turns to the merits.

1. According to Bard, "Suitable" and "Identifiable" Mean Safely So

Undisputedly (as will be detailed later), Bard's precursor to the PowerPort, the Adult Titanium could endure power injection—albeit only those batches built closer to design specification. D.I. 580 at 197 (Tr. 2-414:23–17:17, Tr. 2-495:10–19, Tr. 2-503:15–06:7); D.I. 581 at 26 (Tr. 3-567:9–68:12, Tr. 3-620:21–21:6) (Powers); D.I. 583 at 252 (Tr. 5-1405:5–7) (Kevin Sheetz); PX-69 at 142, 174 (FDA 510(k) Premarket Notification Letter); DX-41 (Bard Document P57279, Rev. 000, *PowerPort Equivalency to the Titanium Adult Port Protocol* (Oct. 2005)). The problem for Bard's engineers to solve was safety. Mr. Powers testified:

> Q. Okay. Now when you said before that the current ports weren't structured for power injection, would it have been dangerous from your perspective to hook up the power injector to your existing ports in 2002?
>
> A. Absolutely. It would be Russian roulette to do that.
>
> Q. By Russian roulette, what do you mean?
>
> A. Well, what I mean is [that] it might work one time. It might work ten times. You might damage the device, and it could fail another time, or it could fail outright or not fail. So unless you knew for sure, *it wasn't safe*. The consequences of failing are too serious.

D.I. 580 at 165 (Tr. 2-382:17–83:6). Mr. Powers continued:

> [Prior ports] weren't structured [for power injection] because it is important that if a device is used for something like that and there—every condition, under every—for the first stick or the hundredth stick, after two days or after two years, *that it performs safely* for that entire period.
>
> * * *
>
> [T]hey *have to be safe* under all conditions. . . you can't tolerate one in a million.
>
> * * *
>
> [I]t had to be a port structurally capable of handling all the extremes of this application.
>
> * * *

> The definition of "power injectable" means that *it is safe* under—safely used under all the use conditions.
>
> * * *
>
> [P]ower injectable to me means that *it has to be safe with high certainty* under all the conditions. Not just some of the time, all of the time.

D.I. 580 at 164 (Tr. 2-381:3–8, Tr. 2-390:9–18, Tr. 2-432:9–13); D.I. 581 at 54 (Tr. 3-595:4–6, Tr. 3-618:25–19:3).[6]

Bard's infringement expert, Dr. Clark, agreed:

> [I]t was known at the time to those of us in the field that if you power injected a port, you were placing the patient at risk. It might work at times. At other times, it could result in a catastrophic complication. Most of us didn't do it because there was no product available to be able to do that.

D.I. 581 at 206 (Tr. 3-747:8–14, Tr. 3-756:10–14).

And so did Bard's validity expert, Dr. Johnson. "[T]he problem at the time, was people who had these patients, like me, didn't know *whether it was safe* to [power inject]." D.I. 584 at 171 (Tr. 6-1645:22–24, Tr. 6-1651:2–8).

Testing, however, revealed the solution. Mr. Powers again:

> Q. You said you tested [the] Adult Titanium Port, and sometimes it would pass and sometimes it would fail?
>
> A. Yes.
>
> * * *
>
> The nominal dimension is sort of the target, but everything you manufacture has certain natural variation as part of the process.
>
> * * *
>
> So what we found was the variation in all of these component parts, when you added them all up into this assembly, was too much. And on the boundaries, it would fail. In the center, it wouldn't. That was really important information . . . [W]e needed to control these dimensions.

D.I. 580 at 196 (Tr. 2-413:23–17:17). In other words, the problem wasn't designing the first port capable of power injection—it was modifying the design of the Adult Titanium

[6] Emphasis added throughout unless noted.

port to ensure safety and reliability in power injection. And the solution, Bard engineers determined, was to tighten the Adult Titanium's manufacturing tolerances. On this demonstration of safe and reliable use for power injection, the FDA approved Bard's Power Port. PX-69 (FDA 510(k) Premarket Notification Letter).

Beside touting its own achievement as one of safety, Bard imbued its asserted claim with this notion of safety to avoid the admittedly-power-injectable prior art. Sometimes it stated that outright. For example, Dr. Clark overtly invoked safety to distinguish power injection with a Vortex port: "Q. . . . Dr. Clark. Prior to 2006, did you consider any Vortex ports to be power injectable? A. I did not. Q. Why not? A. It's not safe to do so. It could result in catastrophic failure and hurt the patient." D.I. 581 at 253 (Tr. 3-794:22–95:17); D.I. 580 at 163 (Tr. 2-380:2–83:6), D.I. 581 at 66 (Tr. 3-607:12–24) (Powers); D.I. 584 at 194 (Tr. 6-1668:4–69:25) (Dr. Johnson). Often Bard relied on product labeling or FDA indication to imply it. For example, Mr. Powers described Bard's endeavor to obtain FDA approval for the PowerPort:

> A. . . . [W]e [we]re creating a new—a new port family with the ability to—it [was] structured for these kinds of things and also indicated for these procedures.
>
> Q. Okay. When you say "indicated," does that mean the FDA?
>
> A. It means, yeah, the FDA agreed. We supported it with data.
>
> * * *
>
> [T]hey expect us to understand the use environment and simulate the use environment for all of our engineering so it's not just a matter of engineering in a vacuum. It has to be safe and effective for its intended use, and as I said, even for sometimes unintended use, so they expect us to confirm that and ask us to support it.

D.I. 580 at 234 (Tr. 2-451:5–52:4); *see also*, D.I. 584 at 196 (Tr. 6-1670:14–71:11) (Dr. Johnson quoting port label). Thus, under Bard's own telling at trial, a port "suitable" for power injection is one safe for it.

Bard likewise construed "identifiable." Mr. Powers: "[A] big challenge for this product would be if we structured the product to handle all of the strains of power injection, how could you tell in a patient with *extreme certainty and never misidentify it*? How could you do that?" D.I. 580 at 178 (Tr. 2-395:20–25, Tr. 2-396:1–5).

He continued:

> [I]t has to be foolproof . . . [I]t was critical not—to not just have a port that was structured for power injection but also have one that you could, with great certainty, discern—a clinician can discern in patients and not make a mistake.
>
> * * *
>
> [W]e needed a way that would be recognizable to everybody who might potentially try to identify it.
>
> * * *
>
> [I]it had to be identified with great certainty by a number of different people.
>
> * * *
>
> And so our goal here is to have a really foolproof identification that—because it's a—because it will affect patient safety.
>
> * * *
>
> [I]t had to be reliably discernable from everything else that was in the market at the time so that clinicians could recognize it with great certainty, make a decision about it to—make a decision to use it for power injection.
>
> * * *
>
> [I]f they [mistook] a port that wasn't structured for power injection and they power injected it at these levels that were routine, they could have a failure.

D.I. 580 at 187 (Tr. 2-404:20–05:7, Tr. 2-431:12–16, Tr. 2-432:9–13, Tr. 2-434:19–35:9); D.I. 581 at 77 (Tr. 3-618:1–12).

> Again, Dr. Clark agreed:
> You had no means for being able to reliably and accurately identify a port as structured for power injection.
>
> * * *
>
> That's fundamental to the inventiveness of the technology. So again, it's to ensure that the ports structure[d] for power injection can be absolutely reliably identified with a hundred percent certainty every time.

* * *

> [The] [r]adiographic marker is something that you can visualize after the port has already been implanted into the patient and that it can be seen with X-ray, either scout scan or chest X-ray or some other form of X-ray, with a highly characteristic shape that's not going to confuse it with another structure that isn't a power injector.
>
> * * *
>
> [Bard's instructions] provide further assurance that the ports can be safely identified as being structured for power injection and then used for that purpose.

D.I. 581 at 205 (Tr. 3-746:21–23, Tr. 3-749:21–25, Tr. 3-750:7–14, Tr. 3-766:14–20).

And again, Bard distinguished prior art on the grounds that it wasn't reliably identifiable enough. D.I. 584 at 191 (Tr. 6-1665:14–17, Tr. 6-1670:5–10, Tr. 6-1671:24–73:24, Tr. 6-1689:10–15) (Dr. Johnson). In sum, again under Bard's telling at trial, a port "identifiable" as power-injectable is one safely and reliably identified as such.

2. The Asserted Claims Recite Ineligible Subject Matter

But Bard's reframing of the asserted claims invalidates them. Patents don't cover natural phenomena or abstract ideas, absent some transformative addition. *Alice Corp. Pty.*, 573 U.S. at 216; *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012).[7]

"[A] claimed invention must embody a concrete solution to a problem having the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it." *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1343 (Fed. Cir. 2018) (quotation omitted). "An improved result, without more stated in the claim" does not "confer eligibility to an otherwise abstract idea . . . To be patent-eligible, the claims

[7] Angio renews its argument that recitation of print matter accompanied by a trial record revealing no transformative concept renders the asserted claims invalid. Bound by the Federal Circuit's prior ruling, the argument is preserved for appeal.

must recite a specific means or method that solves a problem in an existing technological process." That bears repeating—the claim itself must "sufficiently capture the inventors' asserted technical contribution to the prior art by reciting how the solution specifically improves the function of prior art . . .." *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143, 1150–51 (Fed. Cir. 2019) (emphasis added); *see also Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019); *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1121, 1134 (Fed. Cir. 2018); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016).

With due care to neither oversimplify the invention, *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1347 (Fed. Cir. 2017), nor fall draftsman's prey, *Mayo*, 566 U.S. at 72, *by Bard's own word* the "focus" of the asserted claims and their "character as a whole" lies in the concept of safety, *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). By "suitable" for power injection, Bard claims merely the degree of safety and reliability necessary to secure FDA approval. And by "identifiable" as such, Bard claims merely the medical standard of care—recognition of a port such that doctors would be comfortable power injecting. Both standards comprise human judgments of risk tolerance, and thus, Bard claims an abstract solution to human, not technical, problems.

The technical solutions Bard didn't patent prove telling. Bard patented neither power injection, nor the design parameters of a power-injection capable port, nor the process to manufacture a power-injectable port. The claims omit any reference to the tightened tolerances. Bard claimed neither discovery of nor improvement to x-ray, radio-opacity, or radiographic letters. It does not purport to have invented the identification of subcutaneous medical devices via x-ray, with or without radiographic marking. Bard did

not patent improved radiographic marking, or an improved process for radiographic marking, such as better etching or film inlays. Nor did Bard claim an improved arrangement of radiographic makers to make a port recognizable. The focus of the claims, distilled from the prior art, according to Bard, is that it designed a port the FDA deemed safe and reliable for power injection and safely and reliably "identifiable" as such to doctors. Safety and reliability, however, are unquestionably abstract ideas. *See Mayo*, 566 U.S. at 77–79.

Nor do the claims recite a redeeming inventive concept, transforming the claims into a patent-eligible application of the underlying abstract concept. *Alice*, 573 U.S. at 221. "[A]n inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces." *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). Though "the components must involve more than performance of well-understood, routine, conventional activit[ies] previously known to the industry." *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016) (quotes omitted). Generally, "[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact" which may involve extrinsic evidence or testimony. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). The present matter, however, lacking dispute of material fact, is appropriate for the Court's disposition.

A transformative concept regarding the claimed "suitability" for power injection can be easily dismissed. No one, let alone the asserted claims which wholly ignore the topic, even pretends that the effort to refine the existing structure of the Adult Titanium port into the PowerPort contained an inventive spark. Nor could they—structural testing and the

narrowing of manufacturing tolerances being the bread and butter of mechanical engineering.

This lapse alone condemns the asserted claims to invalidity. But, given the effort expended on the patentability of the radiographic indicia throughout this case, it is worth evaluating their transformativeness. Following trial, it is indisputable that medical devices with radiographic markers and lettering were known in the prior art, as the witnesses agreed across party lines. D.I. 582 at 243 (Tr. 4-1066:24–67:4 (stipulated facts), Tr. 4-1110:14–11:7) (Kenneth Eliasen); D.I. 583 at 122 (Tr. 5-1275:20–76:3) (former-Angio engineer Anthony David Smith); D.I. 584 at 69 (Tr. 6-1537:6–43:20 (Dr. Vogelzang), Tr. 6-1696:6–97:20 (Dr. Johnson)); *e.g.*, DX-539 (U.S. Pat. 6,287,239 to Jones, *et al.*); DX-540 (U.S. Pat. 4,863,470 to Carter). Indeed, as former-Bard-engineer Mr. Eliasen told the PTO in a different proceeding, any skilled artisan would have known how to do it:

> Because (i) the housing base provides the largest outside surface to place the radiopaque indicia, (ii) locating the indicia on the housing base has the least impact on the functionality of the port, and (iii) placing the radiopaque markings on the outside surface of the housing base (i.e., the bottom of the port) requires relatively simple manufacturing processes, the outside surface of the housing base location would have been obvious to try, as evidenced by the fact that nearly every port has a lot number and/or company logo printed, embossed, engraved, etc. on the bottom of the housing base, i.e., one of ordinary skill in the art in the 2006 timeframe would have immediately thought to put the radiopaque markings on the housing base.

DX-977 at ¶ 38 (Eliasen Declaration). And, it should go without saying, there's nothing inventive about using the abbreviation "CT" to convey suitability for use in conjunction with a, wait for it, CT scan. Simply put, no *technical* hurdle prevented application of radiographic indicia indicating suitability for power injection to a port.

Instead, Bard simply discovered that doctors and medical professionals liked the radiographic marker and felt confident enough to perform power injections after seeing

the markers via x-ray. D.I. 580 at 227 (Tr. 2-444:13–25), D.I. 581 at 44 (Tr. 3-585:15–86:8, Tr. 3-599:2–22, Tr. 3-617:6–18:12; 3-626:9–15) (Powers). In fact, having initially launched the titanium PowerPort *without* the "CT" label, Bard *added* it after seeing how popular it was on the plastic PowerPort MRI. As Mr. Powers explained: "[W]e launched this as the plastic PowerPort, and the CT marker radiopaque feature was so preferred and popular that we decided to do it with the titanium also." D.I. 580 at 282 (Tr. 2-449:3–12); *see also*, D.I. 581 at 61 (Tr. 3-602:7–24). Indeed, as Bard proclaimed, medical professionals' preference for the specific label (and thus its incorporation into medical standard of care) drove Angio to incorporate it—and at this point would prevent them from removing it. D.I. 580 at 273 (Tr. 2-490:11–20) (Powers); D.I. 581 at 222 (Tr. 3-763:11–12), D.I. 582 at 35 (Tr. 4-859:2–3) (Dr. Clark), *see also, e.g.*, PX-123 at 1 (Erin Young, AngioDynamics, mem. re Infusion Nurses Society Annual Meeting (Aug. 14, 2007)); PX-271 (Danny Garrison, Market Summary Report (August 2007)).

And as Dr. Clark admitted, the remaining method limitations, directing an x-ray to identify the port and performing the power injection, describe merely the ordinary use of the port under the medical standard of care. D.I. 581 at 236 (Tr. 3-777:6–83:8); *see also* D.I. 584 at 57 (Tr. 6-1531:4–34:15) (Dr. Vogelzang concurring). Obviously enough, recitation of a natural phenomenon with the bare command, "apply it," does not transform an abstract idea into a patentable application. *Mayo*, 566 U.S. at 77–78.

At bottom, vascular access ports were already power injectable, so that step wasn't patentable. Radiographic indica were known; that addition wasn't patentable. And medical preference for radiographic indicia is just the standard of care; so, it's also not patentable. Which leads us, yet again, to the crux of the case. The supposed invention

here is Bard's application of a radiographic indicia to a port to convey to medical professionals that the port is power injectable. The hurdle Bard had to overcome to achieve that development was the FDA. That is, manufacturers may only apply to a port a radiographic label indicating suitability for power injection *because the FDA lets them*. It hardly needs be said; obtaining FDA approval to market is routine in the medical device industry.

Under Bard's own telling at trial, then, the asserted claims recite patent-ineligible subject matter.

3. The Asserted Patents Are Invalid for Indefiniteness.

Even assuming the recitation of safety does not render the asserted claims ineligibly abstract, they would remain invalid, for a claim must delineate its bounds with "with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

If not to the FDA's satisfaction, just what rates a port as safe for power injection? Beyond the obvious avoidance of port rupture, the patents do not say. The only statements on point,

> Further, an access port may be identified by a maximum rate at which fluid may safely be infused.
>
> * * *
>
> In one embodiment, at least one physical attribute (e.g., size, shape, etc.) of an access port may identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port.

fail to define the terms, leaving the meaning to those skilled in the art, that is, the medical standard of care. '460 pat. 25:54–55, 63–67.

To be sure, no one would call the medical standard of care "purely subjective." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). Patient wellbeing and some degree of communal consensus would seem to provide an "objective baseline." *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1378 (Fed. Cir. 2017). Yet the standard varies according to the subjective judgment of each professional based upon their individual training, experience, risk tolerance, and circumstance. And while perhaps this variation alone would not render the claims indefinite, *Interval*, 766 F.3d at 1370, the trial record reveals a marked disjoint.

Some doctors considered prior ports safe for power injection. Dr. Vogelzang, considering Bard's test data, Bard-witness testimony, and independent-published test data, considered the Adult Titanium suitable for injection at the claimed parameters. D.I. 584 at 39 (Tr. 6-1513:1–15:18). Considering hospital protocols and two sets of independent and published test data, Dr. Vogelzang concluded the Port-A-Cath suitable for power injection. D.I. 584 at 43 (Tr. 6-1517:8–19:14). And considering Angio test data and submissions to the FDA, Dr. Vogelzang considered the Vortex port suitable for power injection. D.I. 584 at 46 (Tr. 6-1520:11–22:7). Other doctors, including Dr. Scott Trerotola at the University of Pennsylvania, agreed. D.I. 584 at 48 (Tr. 6-1522:13–23:1). Dr. Johnson disagreed. D.I. 584 at 195 (Tr. 6-1669:2–6, 6-1671:7–11, 6-1675:13–19).

Some doctors recognized, or trusted their recognition of, the shape and characteristics of the various ports under x-ray. Dr. Vogelzang thought the Adult Titanium, Port-A-Cath, and Vortex ports readily identifiable in his own experience and according to his training. D.I. 584 at 26 (Tr. 6-1500:23–02:9, 6-1525:2–18) (Adult Titanium), (Tr. 6-1516:1–2, 24–25, 6-1527:14–21, 6-1528:15–18) (Port-A-Cath), (Tr. 6-

1529:1–11) (Vortex). Notably, *Bard's* Dr. Clark agreed that similar features identified ports under x-ray. D.I. 581 at 226 (Tr. 3-767:15–23, 3-770:24–71:3, 3-774:12–16, 3-778:19–23 (Bard's Power Port), 4-837:4–13 (Angio's SmartPort). Dr. Johnson disagreed. D.I. 584 at 187 (Tr. 6-1661:2–4, 6-1663:13–15, 6-1665:10–17, 6-1670:6–9, 6-1672:5–73:20, 6-1676:5–22).

The issue here is not an evidentiary discrepancy between experts—that would be a question for the jury. It is instead that equally qualified and respected doctors, in the exercise of their medical judgment, reach different conclusions. The Court discerns, and Bard cites no, evidence upon which the jury could reasonably have disregarded Dr. Vogelzang's testimony that *he* could recognize each of the prior art ports and deemed them safe for power injection, or that Dr. Trerotola found the Vortex port safe for power injection, or that Dr. Clark found various ports identifiable based on shape. Dr. Johnson's testimony that, in *his* judgment, the ports were not sufficiently identifiable is to not the contrary. Nor is his and Dr. Clark's testimony that, in *their* judgment, the ports would not have been safe for power injection. Whether or not an *identical* medical device infringes (or anticipates) a patent cannot depend on which doctor, according to their own unchallenged medical judgment, uses it. *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 635 (Fed. Cir. 2015).

This aside, the asserted claims are also indefinite because, as the trial record shows, vascular access ports are not designed for endless use but are designed with a specific life span—in the Bard PowerPort's case, twenty-one power injections. PX-69 at 173–44 (FDA 510(k) Premarket Notification Letter). The limiting factor is material fatigue, the cyclic wear of the device after repeated pressurization and depressurization; a port

becomes less "suitable" for power-injection with *every use*. And so, without indication a port that *looks* suitable, becomes unsuitable. PX-488 (FDA - Caution on Power Injection of MRI and CT Contrast Media (October 2005)); D.I. 580 at 165 (Tr. 2-382:25–83:3, 2-389:13–23) (Powers); D.I. 581 at 206 (Tr. 3-747:8–14) (Dr. Johnson). Naturally, the claims do not purport to cover a port suitable for unlimited power injection—Bard has not invented that. *E.g.* *O'Reilly v. Morse*, 56 U.S. 62, 113–14 (1853). Yet, as Dr. Clark confirmed, the asserted claims recite no port-lifespan. D.I. 582 at 49 (Tr. 4-872:3–10). Read in light of the specification (which fails to mention the matter), the claims fail to denote whether they capture a port suitable merely for twenty-one injections—as Bard developed—or for twenty-two injections, let alone thirty, forty, or as Mr. Powers referenced at trial, one hundred. D.I. 580 at 164 (Tr. 2-381:3–8). That is, only the vagaries of Bard's whim tell the skilled competing artisan whether the asserted claims cover a longer-lasting port. *Dow*, 803 F.3d at 635.

4. Bard's Own Existing Port Anticipates the Asserted Claims

Assuming the Court were to reject Bard's reinterpretation of the claims and return to the construction under which Bard has litigated for years, D.I. 156, the trial record leaves no room for a reasonable jury to conclude but that several prior art references each anticipate the asserted claims, reciting each and every limitation. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019).

A step not to be taken lightly—especially as *Angio*, not Bard, bears the burden of proof on this front—judgment as a matter of law probes not just the sufficiency of the evidence, but its overwhelming effect. And while it can hardly be said that a *properly* instructed jury has decided the case, given the claim construction debacle, nevertheless,

to find the asserted claims anticipated, "[t]he Court must be able to say not only that there is sufficient evidence to support the finding, even though other evidence could support as well as contrary finding, but additionally that there is insufficient evidence for permitting any different finding." *Bayer Healthcare LLC v. Baxalta Inc.*, 407 F. Supp. 3d 462, 469 (D. Del. 2019) (citing *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976)) (cleaned up).

Angio offers three anticipatory prior-art ports: Bard's own Adult Titanium marketed since 2003; the Port-A-Cath, manufactured in various corporate iterations by Pharmacia Deltec, Smiths Medical, and now ICU Medical, marketed since at least 1992; and the Vortex Access port, manufactured by Horizon Medical Products (then RITA Medical Systems, now Angio) since at least 2002. DX-77 (Bard Access Systems, Inc. Product Brochure (2003)); DX-81 (Carlson, *et al.*, *Safety Considerations in the Power Injection of Contrast Media Via Central Venous Catheters During Computed Tomography Examinations*, 27 INVEST. RADIOL. 337 (1992)); DX-509 (Horizon Medical Products, *2002 Product Catalog*). Given the patents' critical date of April 25, 2005, no one disputes that these ports constitute prior art under 35 U.S.C. § 102.[8] Review of the trial record, guided by the governing law and proper claim construction, reveals that the jury had *no sufficient basis* to reject that Bard's Adult Titanium, the Port-A-Cath, and the Vortex ports each anticipate the asserted claims.

Taken together, as Bard told the jury, the asserted claims of the '460 and '417 patents recite: (1) a vascular access port suitable for power injection; (2) a palpable feature; (3) a radiographic feature comprising an observable pattern or symbol or the like;

[8] For what it's worth, the pre-America Invents Act version of the statute governs here.

and (4) an external feature, including an ID card, key ring, bracelet, or similar identifier carried by the patient. No one contests that prior art ports included both palpable features—as Dr. Clark admitted, port shape is palpable through the skin—and external features—every vascular access port includes instructions. D.I. 581 at 232 (Tr. 3-773:22–74:14 (Dr. Clark)); D.I. 584 at 49 (Tr. 6-1523:25–24:16 (Dr. Vogelzang)). The remaining, indisputably on this record, may each be found in the three ports.

The jury lacked sufficient basis to reject the power-injectability of the three prior-art ports

As construed by the Court, the asserted claims recite a port's capacity to withstand 35 psi in the chamber and suitable for a flow rate of at least 1 mL/s. Again, highlighting the dangers of claim construction divorced from a patent owner's infringement case, a few points require resolution. First, the vagaries of safety and efficacy would invalidate the claims under Section 101 or 112 and play no part in the analysis here.

Second, while various witnesses testified to the effects of needle and catheter dimensions on port pressures, and the (in)propriety of inferring port pressure based upon pressure measurements elsewhere in the power-injection system, throughout its *infringement case* Bard interpreted the pressure requirement as being satisfied by a showing of 300 psi or more at the power-injector machine. As Dr. Clark repeatedly testified:

> Q. What does that mean in terms of the internal pressure inside the port cavity when it's operating at the flow rate and 300 psi pressure setting on the power injection machine?
>
> A. That corresponds to a pressure inside the cavity of at least 35 psi.
>
> * * *
>
> [Bard's PowerPorts] are structured to accommodate power injector pressure of 300 psi, which we know corresponds to pressure of at least 35 psi in the cavity.

* * *

Q. Dr. Clark what type of procedures are the AngioDynamics SmartPorts structured to be used in?

A. They're structured to be used for injection of contrast [media] up to 5 milliliters per second and up to 300 psi on the injector, which corresponds to a pressure inside the cavity of over 35 psi.

* * *

Q. What type of procedures are the Xcela ports designed or marketed for, Dr. Clark?

A. These are for doing power-injected CT scans, so power injection with rates of contrast injection up to 5 milliliters per second and pressure ratings on the injector up to 300 psi, which corresponds to a pressure inside the port of 35 psi.

* * *

Q. Dr. Clark, are the Xcela Plus Power-Injectable Ports indicated for power injection procedures involving 5 milliliters per second flow rate and 300 psi on the power injection machine?

A. Yes.

Q. What does that tell you about how the internal cavity port is structured during these procedures?

A. As with the other ports, capable of going up to 300 psi on the power injector machine. That tells us that the pressure inside the cavity itself is in excess of 35 psi.

D.I. 581 at 220 (Tr. 3-761:17–22, 3-775:1–4, 3-789:8–14, 3-804:5–12, 3-809:3–15). Bard doesn't get to choose one claim interpretation for infringement because (placing the cart before the horse) "Angio designed the ports to infringe" and pick another for validity because "those products weren't designed to infringe." The same construction applies to both cases. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1449 (Fed. Cir. 1984).

Third, and the running theme of this case, while the PTO governs the patents, *the FDA governs* the marketing of the underlying medical devices. Labels and instructions do not counter actual test data of a port's capacity.

Turning to those capacities, no great inquiry is required for Bard's Adult Titanium port; Bard itself admitted that at least some of these ports were structurally capable of the claimed flow conditions:

> [A]t least some of Bard's current and former vascular access port models that have not been marketed as being power injectable are structurally capable of withstanding the pressures and flow rate of power injection procedures.
>
> * * *
>
> At least as early as 2005, Bard's commercially marketed vascular port product, the Adult Titanium port, was structurally suitable for power injection, although it had not yet been approved for such use.
>
> * * *
>
> Q. What Bard ports were capable of withstanding the pressures of power injection?
>
> A. The Adult Titanium Port, for sure.

D.I. 530-1, Ex. 1 ¶ 37, Ex. 1a ¶ 8 (statements of undisputed facts); D.I. 583 at 252 (Tr. 5-1405:5–7 (Kevin Sheetz)). After all, Bard used hand-picked Adult Titanium ports to prove up the power-injectability of its patent-practicing PowerPort. D.I. 580 at 278 (Tr. 2-495:10–19; 2-503:15–06:7); D.I. 581 at 26 (Tr. 3-567:9–68:12 (Powers)).

Setting aside the admitted facts, and the data submitted to the FDA, one might quibble that some of Bard's witnesses only ever admitted its Adult Titanium suitable for "power injection," and never specified the pressure and flow rate parameters. But recall that, as lexicographer, Bard has defined the meaning of "power injection" here as the claimed pressure and flow rates, has actively wielded that definition to distinguish prior art, and may not selectively recant.

That only a subset of Adult Titanium ports proved structurally capable of power injection is of no consequence. Imperfect practice is enough. *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003). And the repeatedly invoked

various (unclaimed) changes between the Adult Titanium and the PowerPort served safety and reliability, not satisfaction of the basic claim requirement.

The Adult Titanium alone would be enough, yet evidence confirmed that the Port-A-Cath too could sustain a flow rate of 1 mL/s and injection-machine pressure of 300 psi. Regardless of the port labeling, in 2005, Gebauer *et al.* successfully achieved flow rates in a Port-A-Cath of 2.3, 4.2, 6.2, and 8.2 mL/s, at machine pressures of 191, 333, 352, and 371 psi, respectively, without rupture or disconnection. DX-529 (translated copy of Gebauer, *et al.*, *Contrast Media Power Injection Using Central Venous Port Catheters—Results of an In Vitro Study*, 177 RöFo 1417 (Oct. 2005)).

Dr. Johnson quibbles with the *duration* of those pressures because, as the study notes, the higher pressures triggered the power-injector machine pressure limit of 325 psi, prompting the machine to either back off to safe pressures or shut down entirely (the study describes both scenarios but does not specify which happened in each test). D.I. 584 at 183 (Tr. 6-1657:4–8). But this misconstrues the claim language as requiring a fluid flow rate of 1 mL/s *at* a chamber pressure of 35 psi throughout. Not so. The claims and specification confirm these to be separate requirements:

> In addition, the housing and septum may be structured for accommodating a flow rate through the reservoir of at least about 1 milliliter per second. In another embodiment, an access port may include a housing and septum, as described above, wherein the housing and the septum are structured for accommodating a pressure developed within the reservoir of at least about 35 psi.

'460 pat. at 3:32–39. Certainly, the flow rate element implies a duration necessary to complete a power-injection, "the access port [i]s suitable for *flowing fluid at a fluid flow rate of at least 1 milliliter per second* through the access port." But the pressure element includes no such language, requiring only that the port be capable of "accommodating a

pressure within the cavity of at least 35 psi." '417 pat. claim 1[c]–[d]. And so, nothing requires these elements be proven in the same go around.

This all makes intuitive sense. The claimed flow rate describes function; the pressure requirement ensures safety. A port might simply be designed, as the Port-A-Cath unquestionably is—to achieve the required flow rate at a lower pressure. In effect, Dr. Clark criticizes Gebauer *et al.* for, having proven the flow-rate capabilities, searching for the pressure failure point and, finding none, triggering instead the *power-injector machine* safety feature. Regardless, as claimed, the Port-A-Cath supports power-injection at 1 mL/s or greater and can accommodate injector-machine pressures well above 300 psi, which Bard confirms indicates a chamber pressure above 35 psi.

Test data also confirms the Vortex's power-injectability. On April 27, 2005—according to his *unchallenged* lab notebook—Angio (then-RITA) engineer Anthony David Smith successfully achieved a flow rate of 5 mL/s at a machine pressure of 305 psi with a stock, already marketed, Vortex port, model No. P5355K. DX-687 at 6 (Smith Laboratory Notebook); DX-509 at 17 (HMP 2002 Catalog); D.I. 583 at 43 (Tr. 5-1196:10–1200:4). Whether or not the FDA thought this data sufficient does not matter here. Bard's best bet might be to note that Mr. Smith's testing came two days *after* the patent critical date of April 25, 2007. But, as Mr. Smith's uncontroverted testimony and the documents make clear, the tested ports had been on the market since 2002.

Bard can neither retract admissions that its own prior port was power-injectable nor challenge the test data, instead continually muddying the waters with irrelevant labels and safety considerations. In sum, the jury had no substantial evidence upon which to reject the objective capabilities of the prior-art ports.

Nor had the jury any sufficient basis to reject the radiographic identifiability of the prior-art ports

As construed, the recited radiographic identifier need be no more than an "attribute . . . perceivable via x-ray." D.I. 156 at 5. And as far as one could "[r]ecogniz[e] that the radiographic attribute on the x-ray identifies an access port as being structured for power injection," *id.* at 6, the patent explains that "identification . . . means the ability to correlate selected information of interest with a perceivable feature," '460 pat. at 25:37–41. Again, considerations of safety and reliability in identifying a port would invalidate the asserted claims and play no part in this analysis.

Now unquestionably, no prior-art port bore a label or instruction for power injection. Nor, without FDA signoff, could they. Of course, as the Federal Circuit held previously in this case, the actual identification of a port as suitable for power injection is printed matter not entitled to patentable weight. 979 F.3d at 1382. The matter must be considered—"we do not strike out the printed matter and analyze a 'new' claim"—but it will not distinguish the claim from the prior art. *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015); *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). And, as the Court determined at trial, the recitation that the radiographic markers be a letter ('417 pat. claims 5 and 12, '478 pat. claim 3) also rates as print matter. A letter, after all, intrinsically conveys its typographical meaning, and Bard has pointed to no technical hurdle traversed by the asserted claims in making the radiographic marker a letter as opposed to any other indicia. Here then, the analysis asks whether the prior-art ports possessed radiographic attributes by which one skilled in the art could identify the port and, with reference to the label or instructions, determine its parameters of use and, by extension, its suitability for power injection. They did, and the jury had no sufficient basis to reject that fact.

As above, Dr. Vogelzang found each prior-art port readily identifiable in his own experience and according to his training.

> Q. Now let's move to the ports . . . [w]hat do we see here?
>
> A. . . . These are radiographs of the ports to illustrate a basic principle that I was espousing, which is pattern recognition. These are radiographs, and each one has a distinctive, characteristic look that's readily identifiable. The Adult Titanium Port obviously has a certain shape. It has some suture holes and orientation holes. The Port-A-Cath is square. Vortex Access has a distinctive shape as well as the outlet stem. So they are distinctive in and of themselves under a radiograph.
>
> Q. [And] there's a reference up there to the ports being "Aunt Minnie." What does that refer to?
>
> A. Now, "Aunt Minnie" is an interesting term that we used for years in radiology and was taught to radiology residents . . . this concept which has
>
> been widely known and is taught to radiology residents in the first year. It's essentially pattern recognition, and the description is how do I know my Aunt Minnie when I see her across the street? Because I know what she looks like. And the same thing is true in pattern recognition for certain diseases and other anatomy. *That's what these ports are, they are Aunt Minnie in the sense that once I'm told what they are, I know what they are*.

D.I. 584 at 26 (Tr. 6-1500:15–02:9). Regarding Bard's Adult Titanium:

> The radiograph is provided by Bard's expert, Dr. Johnson, and I used this to show the radiographic features which would be present and available and visible on a radiograph, which is the characteristic shape, the so-called "Aunt Minnie" shape, as well as the suture holes, distinctive, as well as the circular holes which they describe as orientation holes, all visible under X-ray.

D.I. 584 at 51 (Tr. 6-1525:2–18). Port-A-Cath:

> Q. What are the radiographic incorporated features of the Port-A-Cath that you've identified here?
>
> A. I've done the same thing, this time, the physical specimen on the left, the radiograph on the right. It's obvious it's different, and we can see it. It has a different, unique square shape and Aunt Minnie, square shape with suture holes at the corners. Obviously, very distinctive, as well as etching, which is present on the physical specimen.

D.I. 584 at 53 (Tr. 6-1527:14–21). And Vortex:

> Q. Let's move to Vortex Access . . . [w]hat are the identifiable incorporated radiographic features you found here?
>
> A. Again, we've arranged them—I arranged them in the physical on the left and the radiograph on the right. The typical Aunt Minnie shape is unique. It has suture holes in a specific outline around the periphery and in this case the tangential outlet stem, which is part of the Vortex technology. It also has that notch at the bottom near the outlet stem which would be very visible.

D.I. 584 at 54 (Tr. 6-1528:23–29:11). And—it cannot be overstated—Bard's infringement expert, Dr. Clark, agreed that port shape and basic features would be among the usual identifiable attributes via x-ray:

> Q. And can you walk us through some of the key steps in the instructions in the CT guidelines?
>
> A. Yes. So[,] it begins with identification to verify that the port is, in fact, a PowerPort.
>
> Q. Okay. And that identification step, that might include looking at the CT marker; is that correct?
>
> A. Yes.
>
> Q. How would that identification be made when looking at the CT marker?
>
> A. Well, the CT marker is visible on scout scan, so the CT technologist or radiologist or combination of the two will look at the image and verify that the triangular shape, that . . . is one radiographic marker and the CT letter is present as the second radiographic marker.

D.I. 581 at 225 (Tr. 3-766:21–67:14). Perhaps grasping the admission in real time, Bard's counsel appeared to attempt a retraction, yet the doctor doubled down:

> Q. I think you misspoke. The triangular shape was a radiographic marker. Were you saying the CT is the radiographic marker?
>
> A. Well, the radiographic lettering is the CT, but the triangular shape is radiographically visible. It's a characteristic.
>
> Q. So you can make out the shape of the triangle—
>
> A. Yes.

Q. —under X-ray, and that's a radiographically made identification?

A. Yes.

D.I. 581 at 226 (Tr. 3-767:12–23); *see also*, D.I. 581 at 229 (Tr. 3-770:24–71:3, 3-774:12–16, 3-778:19–23, 3-779:5–8). The patent specifications naturally agree, '460 pat. at 26:10–45, though Dr. Clark's testimony alone leaves Dr. Johnson without a leg to disagree on. *Kimberly-Clark*, 745 F.2d at 1449.

Yet again, the trial record left the jury with no basis to reject the radiographic identifiability of the prior-art ports.

And the jury lacked sufficient basis to reject anticipation of the method steps

The asserted method claim recites the taking of an x-ray, identification of the port (and by extension its capabilities), and flow of fluid. Again, no radiographic indication of power injectability need be found, nor need medical professionals have searched for such indication. As above, it suffices as a matter of law, that medical professionals looked for radiographic identifying attributes, identified the port, and determined the corresponding pressure and flow-rate parameters. It is also worth noting that while claim 1 (and by extension asserted claim 3) of the '478 patent requires a port capable of specific fluid-flow and chamber-pressure parameters, the third recited step requires its *use* only at the specified flow rate—"flowing a fluid through the access port at a rate of at least 1 milliliter per second"—not at the recited pressure.

But for this fluid-flow-rate requirement, Dr. Johnson admitted that each step would be performed in standard medical practice with an access port, usually by a CT technologist: "[A]n X-ray technologist with further training in performing CT scans and in current era, that includes the identification of ports structured for power injection, accessing those ports, and then flowing contrast [fluid] through those power-injectable

ports to perform contrast and CT scans." D.I. 581 at 239 (Tr. 3-780:23–81:4). First and second, an x-ray to identify the port:

> [T]he patient arrives to the CT scanner. They are positioned on the table of the CT scanner. The CT technologist does this preliminary, quick scan, scout scan, and that image is reviewed to look for the CT lettering and/or the shape of the port.
>
> * * *
>
> A. [A] scout scan is performed 100 percent of the time.
>
> Q. Okay. How do you know that?
>
> A. That is known to everyone who's a practicing radiologist.
>
> Q. As a radiologist, would you find it safe or okay to not do a scout scan prior to a power injection?
>
> A. I would not.

D.I. 581 at 238 (Tr. 3-779:3–8, 3-781:15–23). And third, injection and fluid flow:

> Through accessing the port with a cannula or needle that goes through the skin and into the central reservoir and flowing the X-ray contrast or contrast media at the prescribed settings that you've set on the CT power injector up to 300 psi up to 5 milliliters per second and performing the study.

D.I. 581 at 238 (Tr. 3-779:17–23). Dr. Vogelzang agreed. D.I. 584 at 57 (Tr. 6-1531:10–16, 6-1532:19–24, 6-1534:8–15).

Dr. Clark contested that the prior-art ports would have necessarily been used at the claimed flow rate. D.I. 582 at 64 (Tr. 4-887:20–889:9). But objective, documentary evidence confirmed doctors already had. D.I. 584 at 57 (Tr. 6-1531:4–34:23). Herts, *et al.*, flowed contrast media through dozens of patients' Adult Titanium ports at 1.5 mL/s before February 2001. PX-95 (Herts, *et al.*, *Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, & Efficacy*, 176 AM. J. ROENTGENOLOGY 447 (Feb. 2001)). Carlson, *et al.*, flowed 1.0 mL/s through five patients' Port-A-Caths in early 1991. DX-81 (Carlson, 27 INVEST. RADIOL. 337). Additionally, Bard survey data from Wayne Memorial Hospital in Goldsboro, North Carolina reports injections of up to 1.2

mL/s with the Port-A-Cath. DX-11 (Wayne Memorial Hospital, *Protocol for Using Port-A-Caths For CT Scans* (1999)). So too, Dr. Treretola reported his power injection of a Vortex port. PX-246 at 39 n. 17 (C.R. Bard Inc., Doc. 56636, Rev. 0, *PowerPort Product Opportunity Appraisal* (July 2005)). And by Dr. Clark's own explication of standard medical practice, these doctors scout scanned and identified the ports "100 percent of the time." None of Bard's objections compel.

Bard notes that Dr. Trerotola does not specify the fluid flow rate. But Bard obviously believed the report enough to describe it as "power injection." Again, that use, without clarification, binds Bard to the definition it gave to the phrase. And so, as a matter of law, Dr. Trerotola injected at a sufficient flow rate.

Similar to the discussion above regarding indefiniteness, the question here isn't one of balancing evidence. The question is whether the jury had any evidence to disbelieve that these professionals did what they said they did. Bard introduced no such evidence, so the jury did not.

More seriously, Bard faults Angio for failing to introduce direct testimony from a CT technologist who performed the method steps and instead relying on testimony of standard medical practice. But one cannot miss the irony in Bard rejecting such reliance on general medical practice for validity where it relies on precisely the same to prove the necessary-direct infringement by Angio's customers, underlying the charge of induced infringement. D.I. 582 at 19 (Tr. 4-842:4–43:15); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920–21 (2014). Sauce for the goose, after all . . .

* * *

In sum, Bard left the jury with no evidentiary basis to reject the anticipation of its asserted claims. Bard's own admissions, along with uncontroverted test data, identify *three different* prior-art ports capable of withstanding at least a flow rate of 1 mL/s and chamber pressure of 35 psi. Dr. Clark admitted the identifiability of the radiographic features present on each prior-art port, and that the method steps would naturally be performed in standard medical use of any port. This overwhelming evidence leaves but one supportable conclusion: Bard's own Adult Titanium port, Port-A-Cath, and Vortex all anticipate the asserted claims.

5. The Willfulness Verdict Lacks Substantial Evidence

Leaving aside all the foregoing and skipping to the end, a final failure plagues Bard's verdict. A jury determination of willful infringement requires "no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1327 (Fed. Cir. 2021). Yet willfulness at one point does not poison the entirety of a defendant's course of conduct; culpability is "measured against the actor's knowledge at the time of the challenged conduct." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 (2016). So, a finding of willfulness should have a start date. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019).

The time-unbounded willfulness verdict here lacks substantial evidence. Bard blurs together a range of Angio's conduct across a span of years—both before and after patent issuance. This judges Angio's culpability based on what it knew *at some other point*. Having both declined either to ask the jury to specify a start date or to provide one in post-trial briefing, Bard has also waived the matter.

CONCLUSION

More than enough forgoing to adjudge the asserted claims invalid at a matter of law, the Court reserves the matters of obviousness and noninfringement by dint of prior use, on the latter specifically declining to embark on an unnecessary course of statutory interpretation.

THEREFORE, IT IS ORDERED THAT AngioDynamic's motion for judgment as a matter of law, D.I. 572, is granted in part as specified above. Judgment to follow.

Dated this 1st day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CR BARD INC. and BARD PERIPHERAL VASCULAR, INC., Plaintiffs/Counterclaim Defendants. vs. ANGIODYNAMICS, INC., Defendant/Counterclaim Plaintiff.	**CIV. NO. 15-218-JFB-SRF** **JUDGMENT**

Pursuant to the order granting defendant's motion for judgment as a matter of law, entered on this date, judgment is ordered in favor of AngioDynamics, Inc. and against CR Bard Inc. and Bard Peripheral Vascular, Inc. This action is dismissed.

Dated this 1st day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CR BARD INC. and BARD PERIPHERAL VASCULAR, INC., Plaintiffs/Counterclaim Defendants. vs. ANGIODYNAMICS, INC., Defendant/Counterclaim Plaintiff.	**CIV. NO. 15-218-JFB-SRF** **ORDER**

The Court is in receipt of a letter dated June 13, 2023, D.I. 590, from Defendant AngioDynamics, Inc. seeking to clarify the finality of the recent judgment, D.I. 588, and querying the Court's willingness to adjudge various equitable counter and crossclaims. The Court considers the judgment final. The asserted claims have been found invalid on several grounds, D.I. 587; no further ruling could render them more so. Assuming, however, that equitable defenses to invalid claims remain viable, the Court would find no just reason to delay appeal of the multiple dispositive rulings and would direct entry of final judgment on behalf of defendant for invalidity of the asserted claims. All other defenses are moot.

Dated this 14th day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge

US008475417B2

(12) **United States Patent**
Powers et al.

(10) **Patent No.: US 8,475,417 B2**
(45) **Date of Patent: Jul. 2, 2013**

(54) **ASSEMBLIES FOR IDENTIFYING A POWER INJECTABLE ACCESS PORT**

(75) Inventors: **Kelly B. Powers**, North Salt Lake, UT (US); **Jim C. Beasley**, Phoenix, AZ (US); **Kevin W. Sheetz**, Sandy, UT (US); **Matthew M. Lowe**, South Jordan, UT (US); **Eddie K. Burnside**, Bountiful, UT (US); **Jay Gerondale**, Newbury Park, CA (US)

(73) Assignee: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 655 days.

(21) Appl. No.: **12/420,007**

(22) Filed: **Apr. 7, 2009**

(65) **Prior Publication Data**

US 2009/0227951 A1 Sep. 10, 2009

Related U.S. Application Data

(63) Continuation of application No. 11/380,124, filed on Apr. 25, 2006.

(60) Provisional application No. 60/737,466, filed on Nov. 15, 2005, provisional application No. 60/675,309, filed on Apr. 27, 2005.

(51) **Int. Cl.**
A61M 37/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/288.02**; 604/288.01; 604/116

(58) **Field of Classification Search**
USPC 604/246–256, 288.01–288.04, 116
See application file for complete search history.

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(Continued)

Primary Examiner — Kevin C Sirmons
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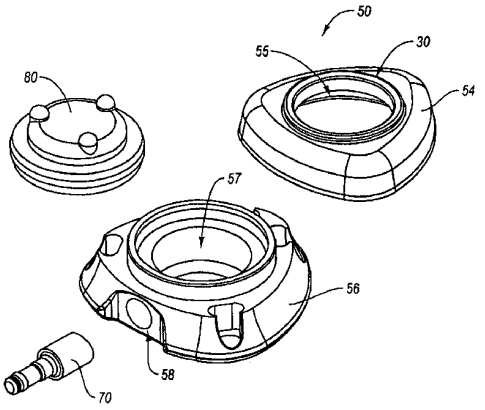
(57) **ABSTRACT**

Assemblies for identifying a power injectable vascular access port are described. One assembly includes a vascular access port, a first identifiable feature, a second identifiable feature, and a third identifiable feature. The first identifiable feature is incorporated into the access port and identifies the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port. The second identifiable feature is incorporated into the access port and identifies the access port as suitable for accommodating a pressure within the cavity of at least 35 psi. The third identifiable feature is separated from the access port and confirms that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

16 Claims, 32 Drawing Sheets



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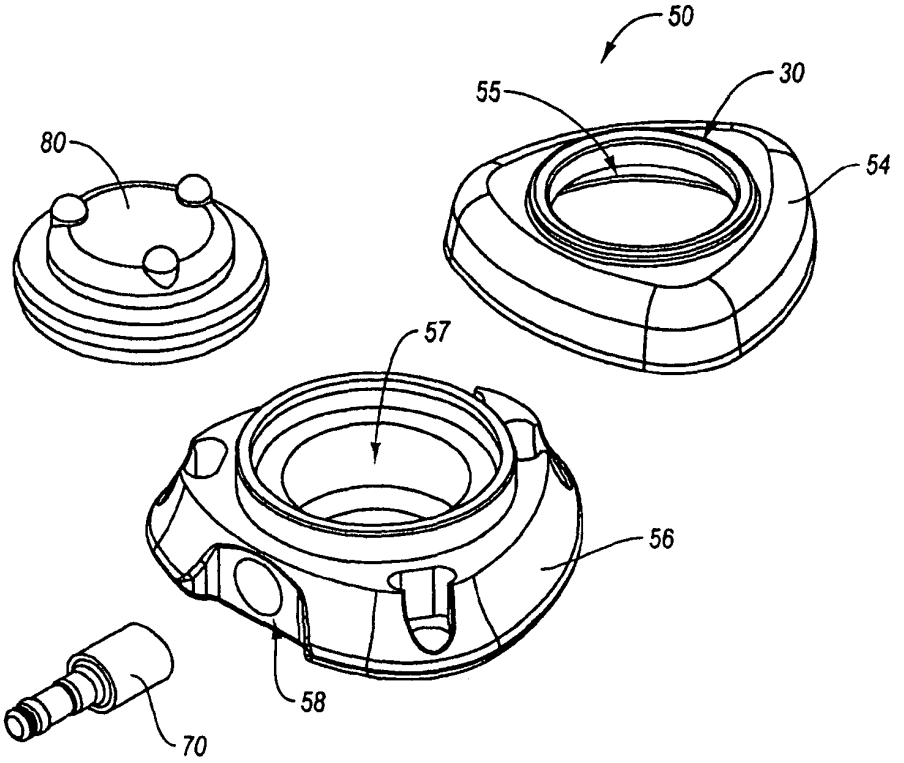
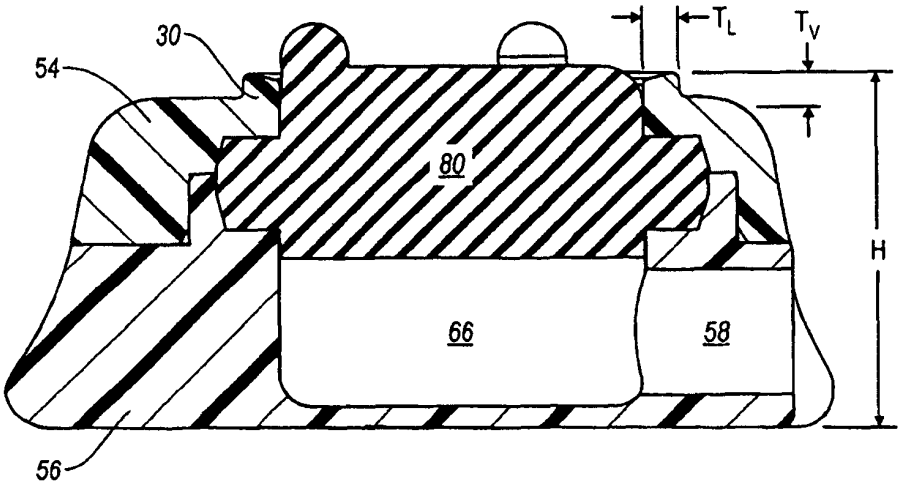


FIG. 1



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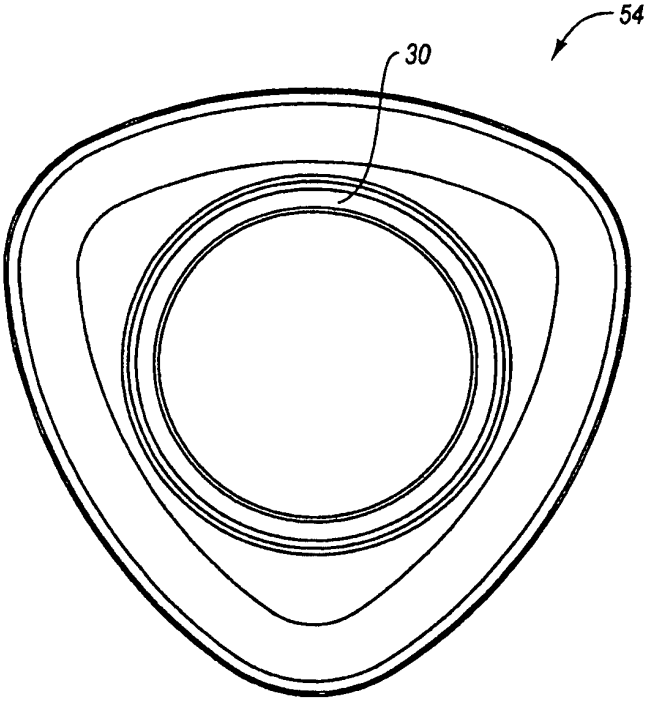

FIG. 3

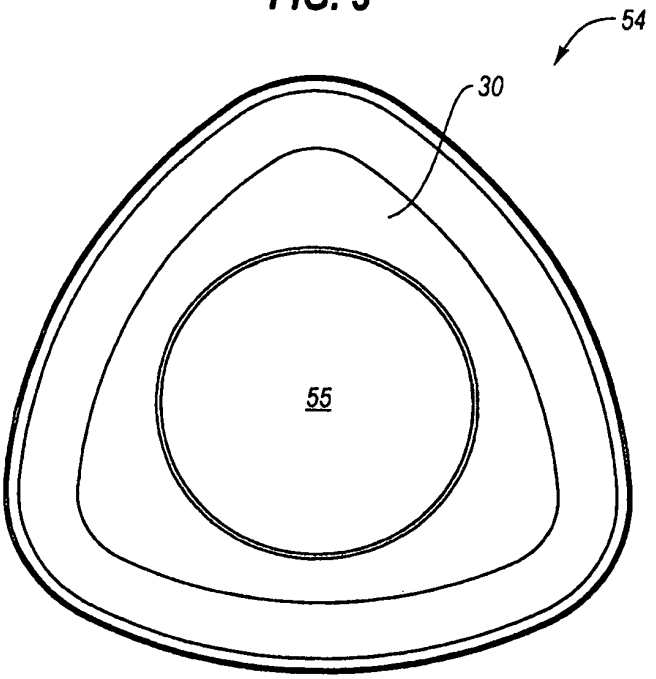

FIG. 4

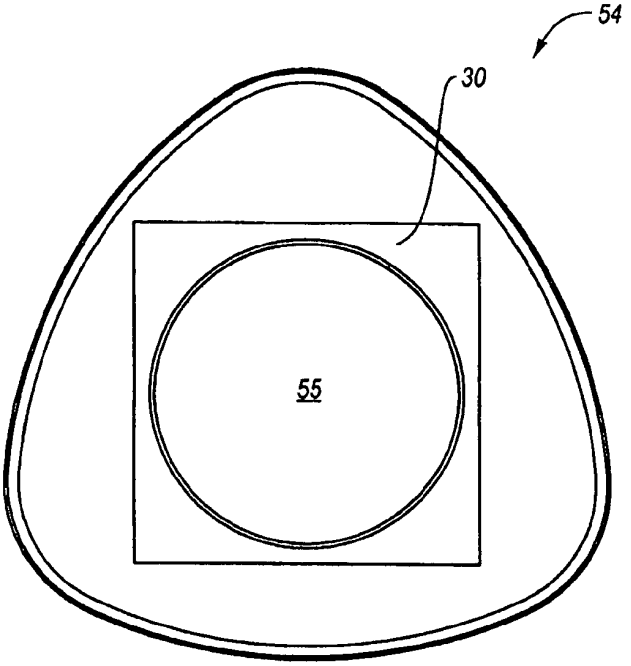

FIG. 5

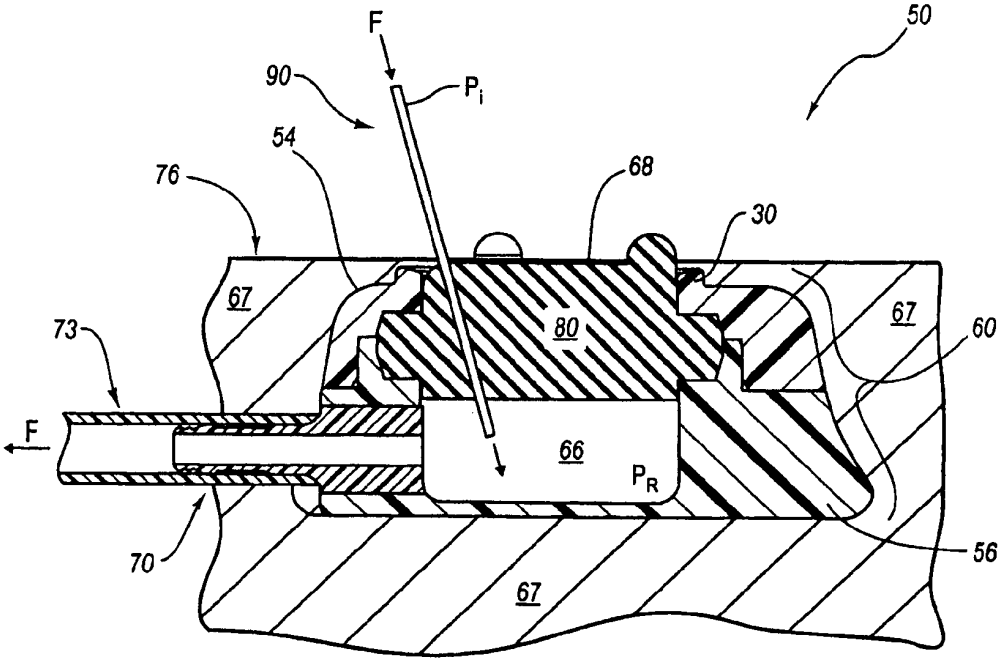

FIG. 6

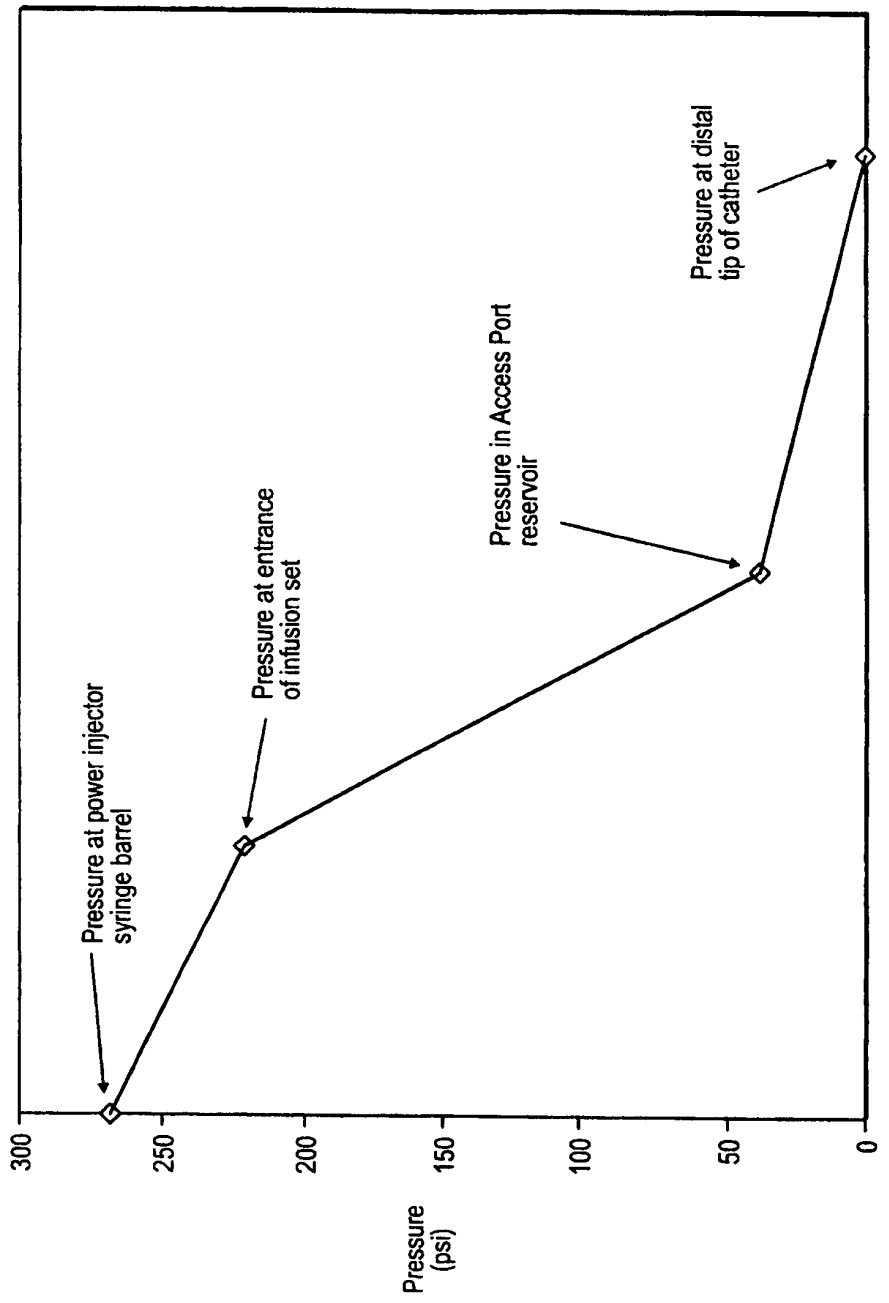
Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7

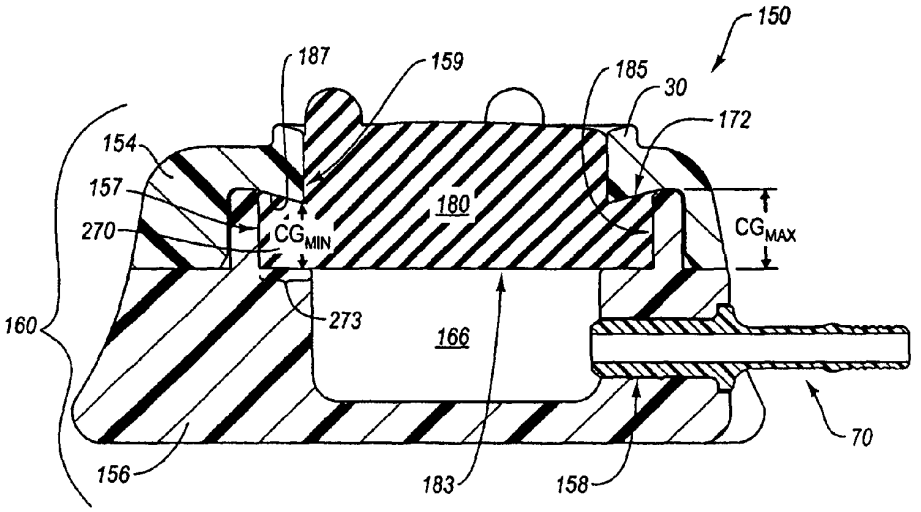
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FIG. 8

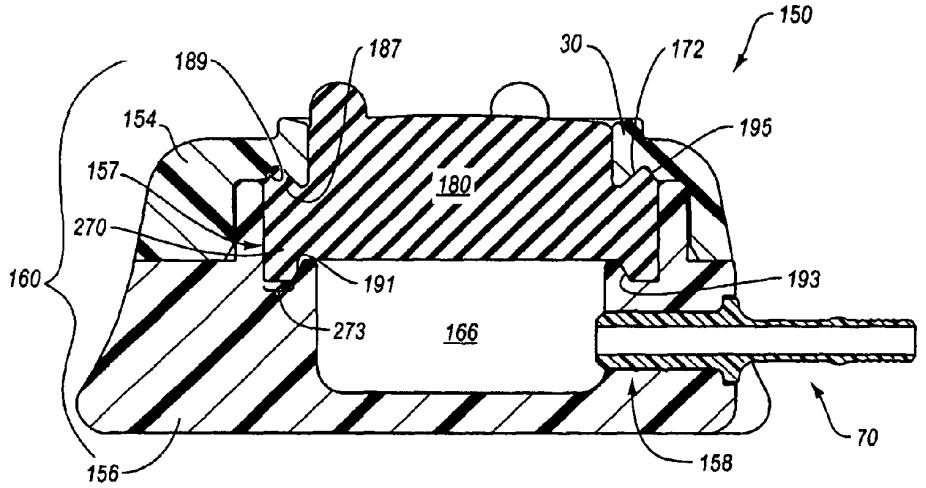
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FIG. 9

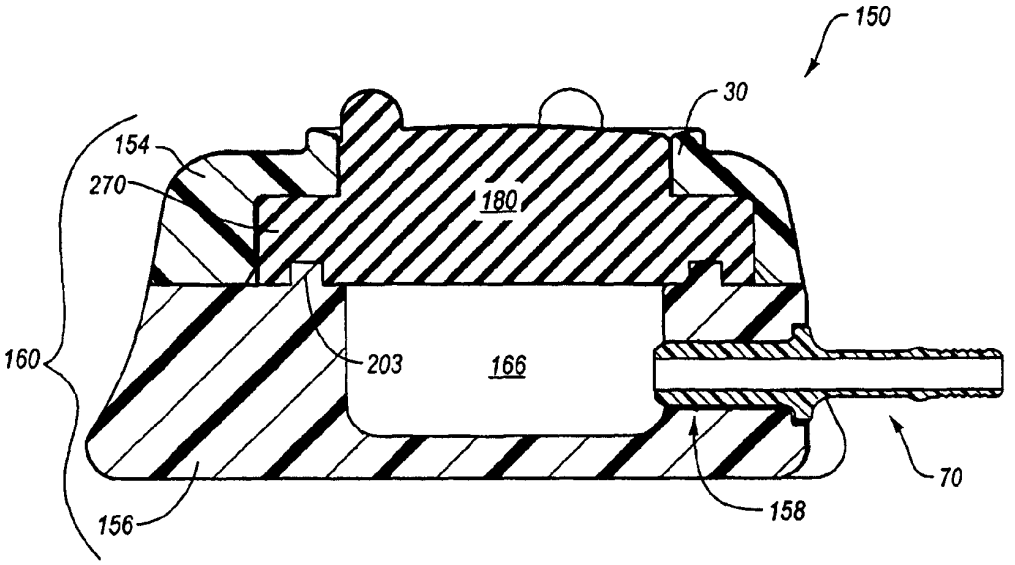
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FIG. 10

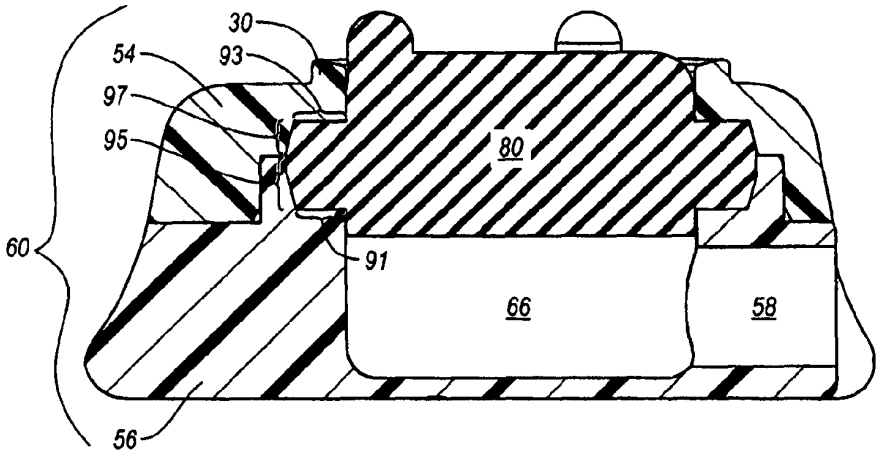
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FIG. 11

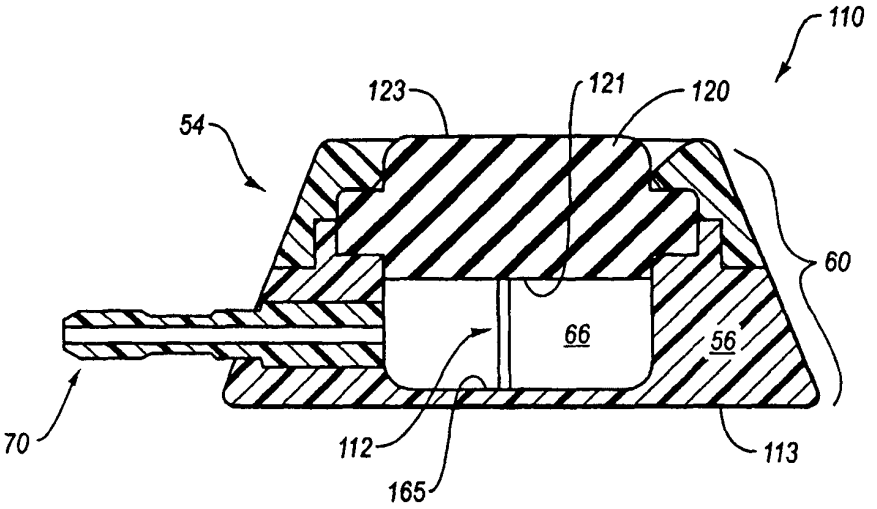
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FIG. 12

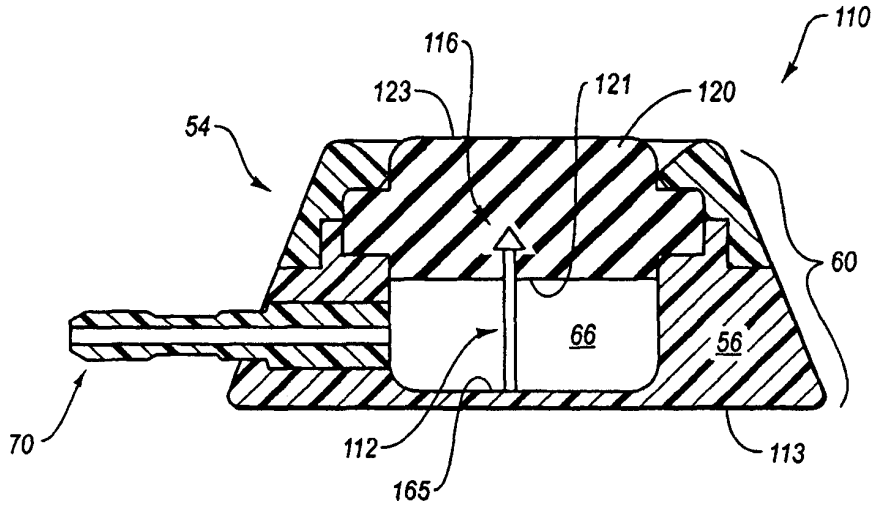
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FIG. 13

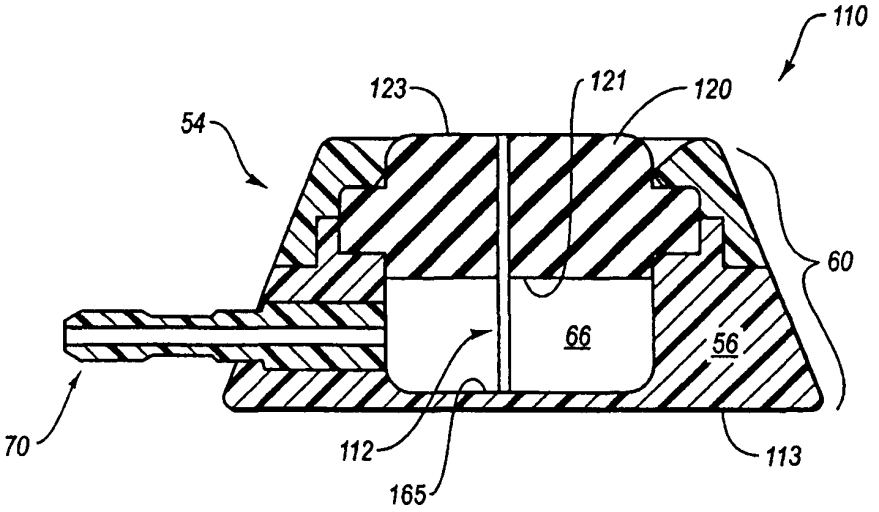
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FIG. 14

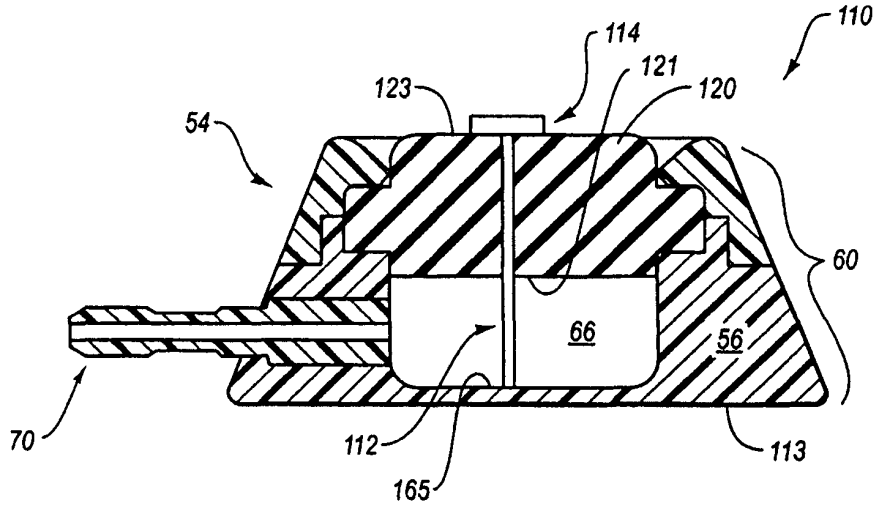
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FIG. 15

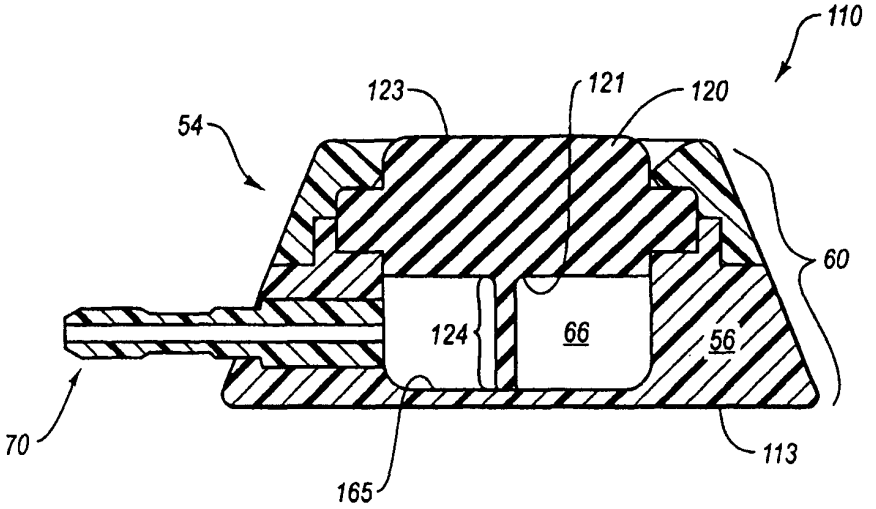
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FIG. 16

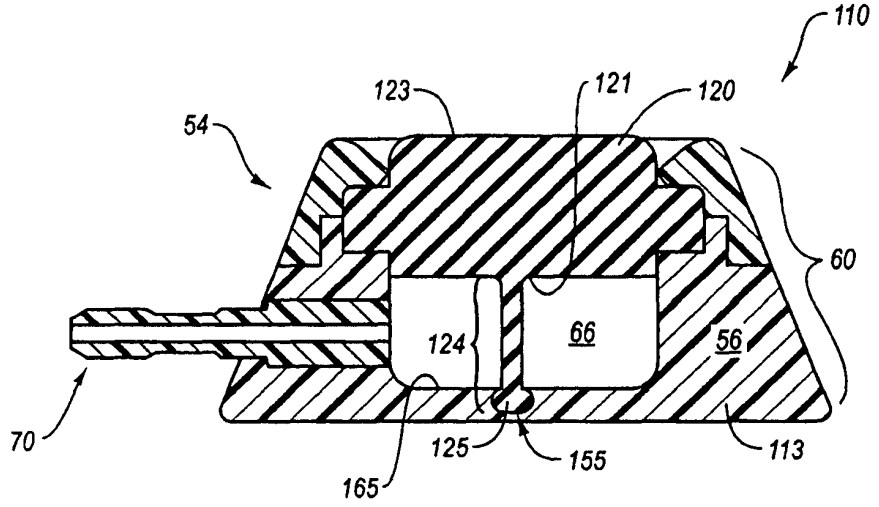
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FIG. 17

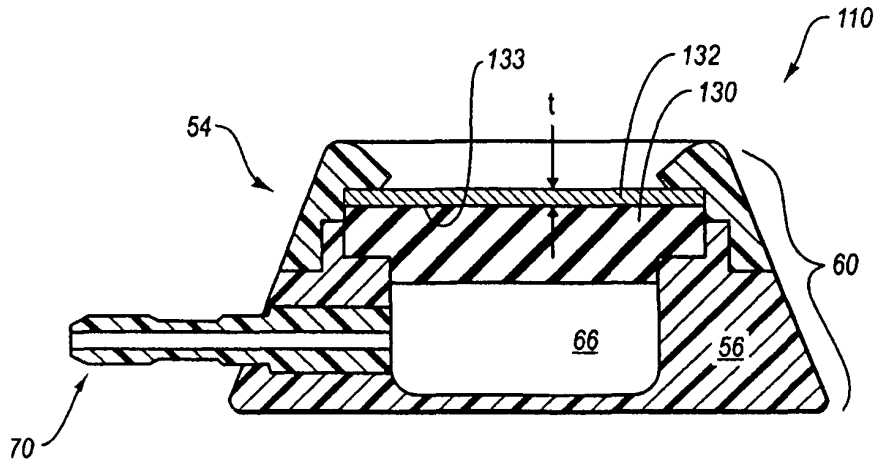
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FIG. 18

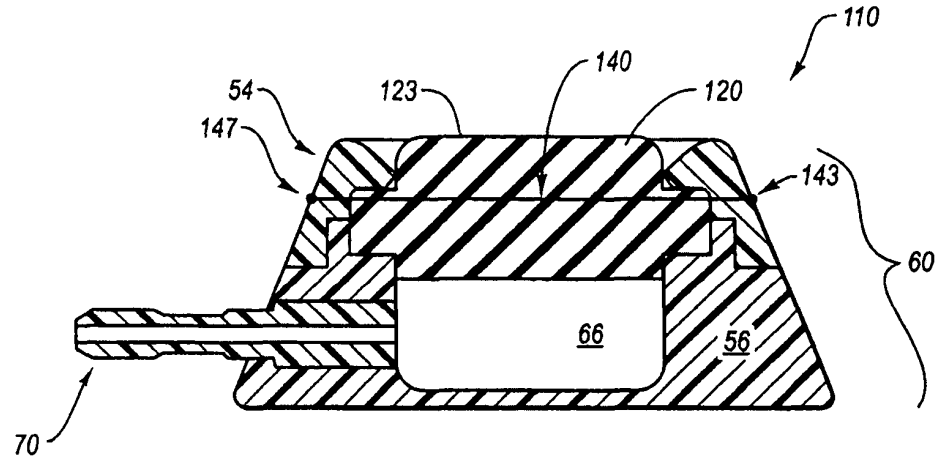
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FIG. 19

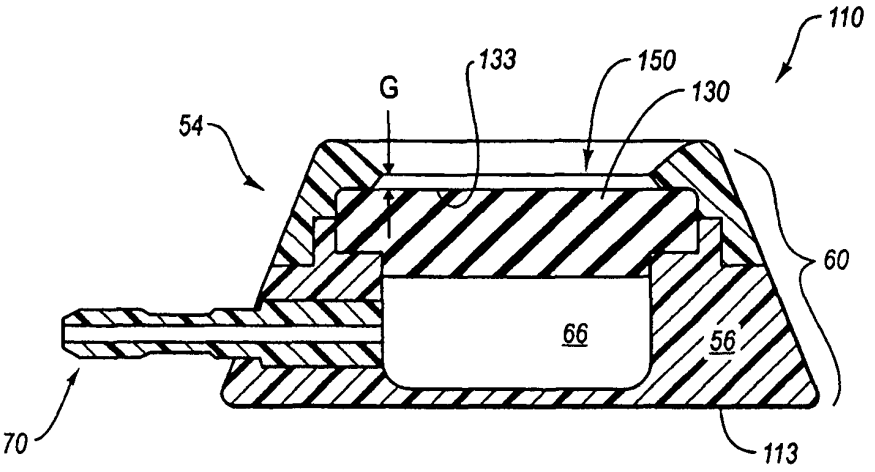

FIG. 20

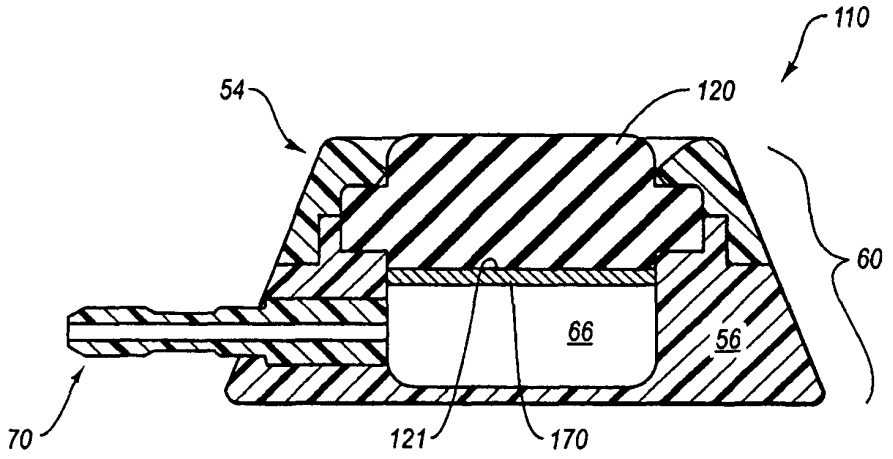

FIG. 21

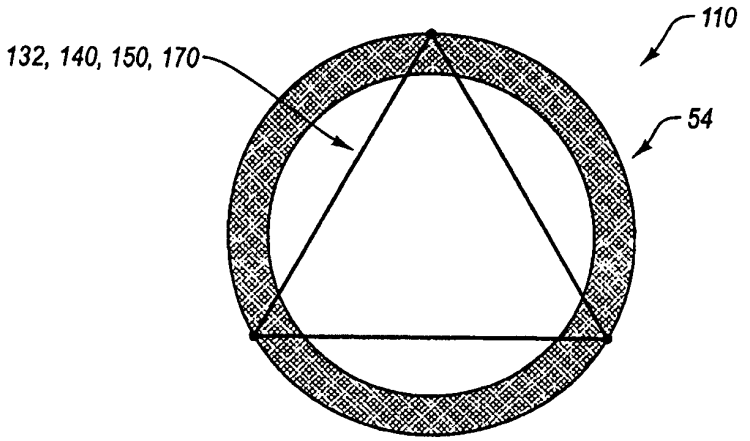

FIG. 22

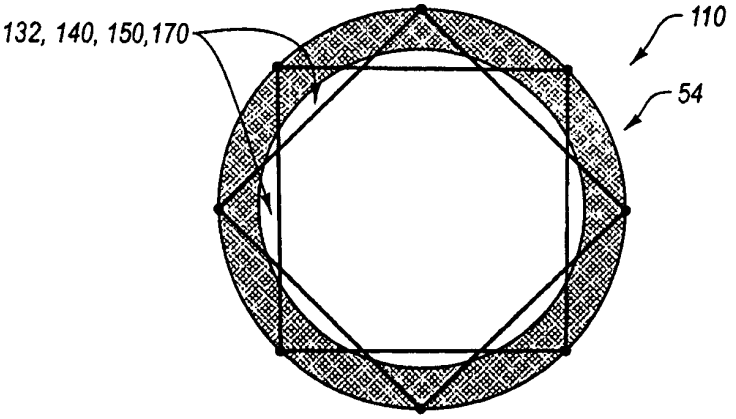

FIG. 23

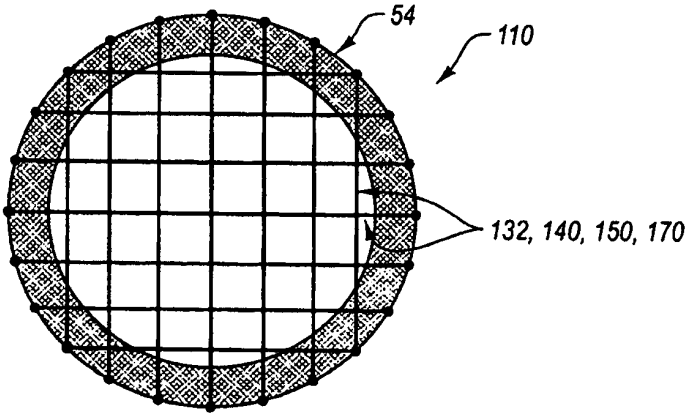

FIG. 24

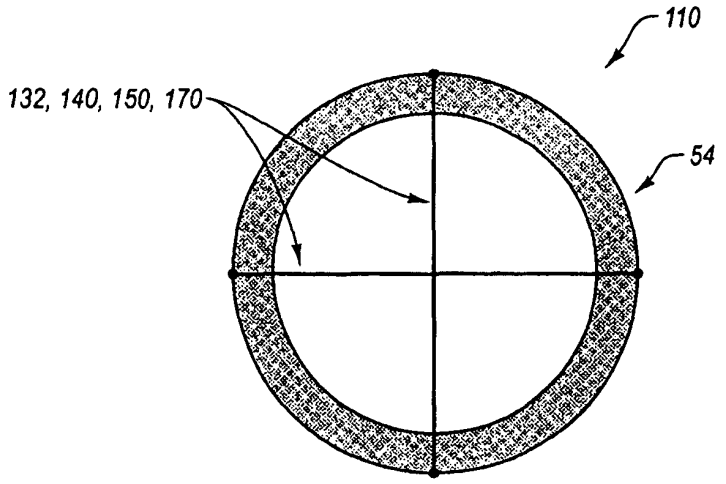

FIG. 25

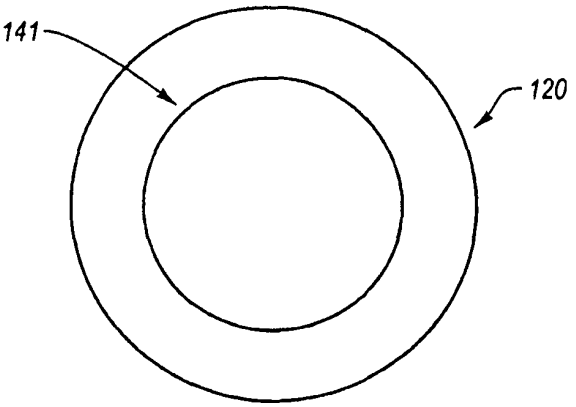

FIG. 26

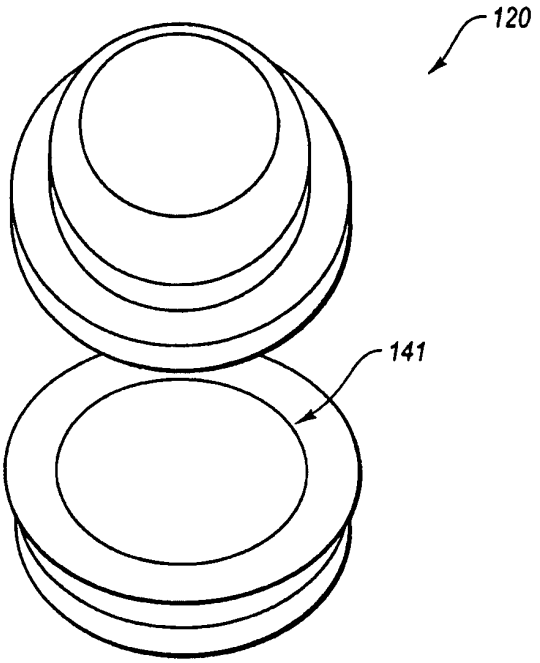

FIG. 27

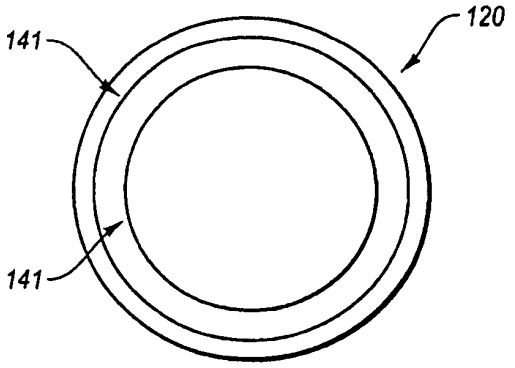

FIG. 28

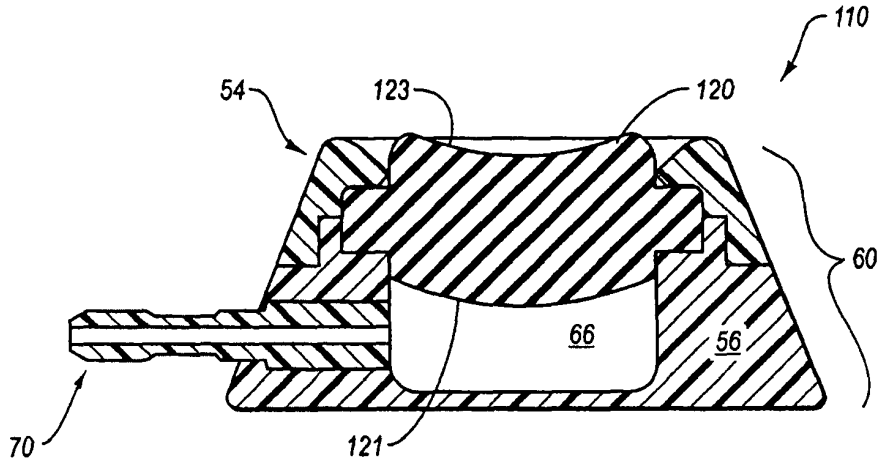

FIG. 29

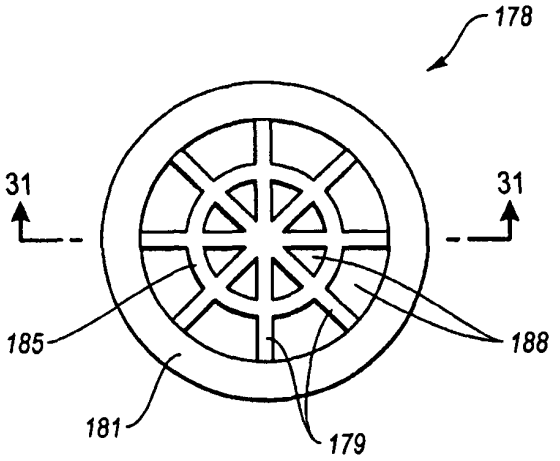

FIG. 30

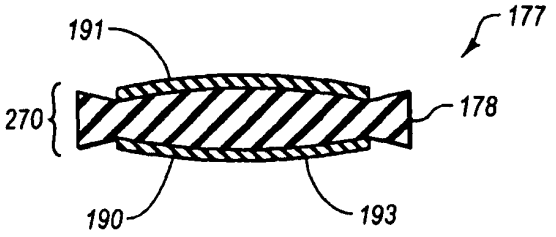

FIG. 31

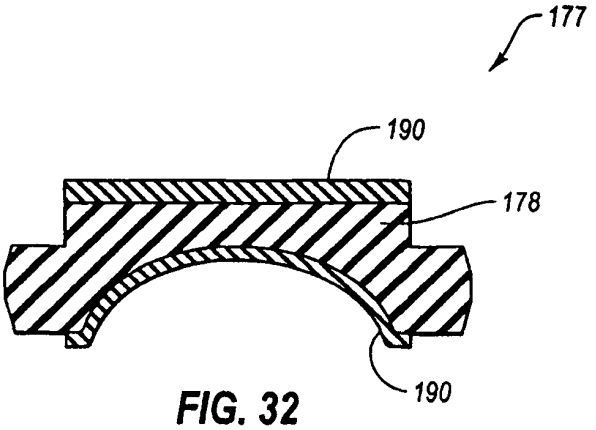

FIG. 32

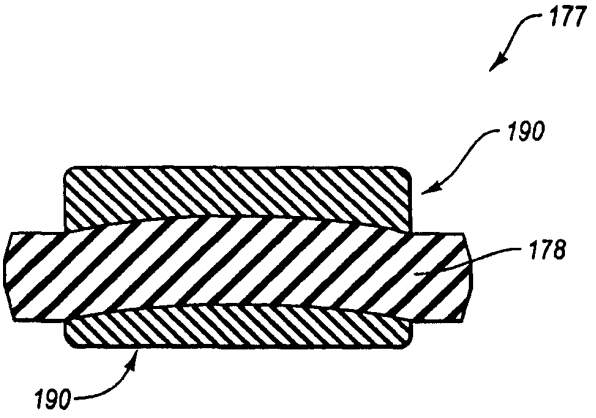

FIG. 33

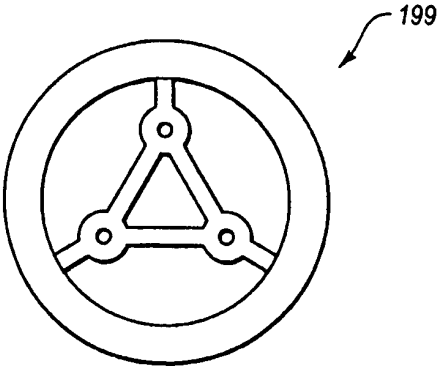

FIG. 34

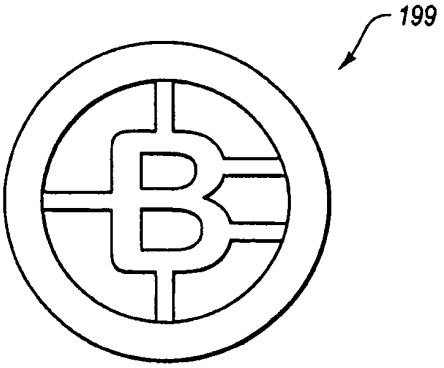

FIG. 35

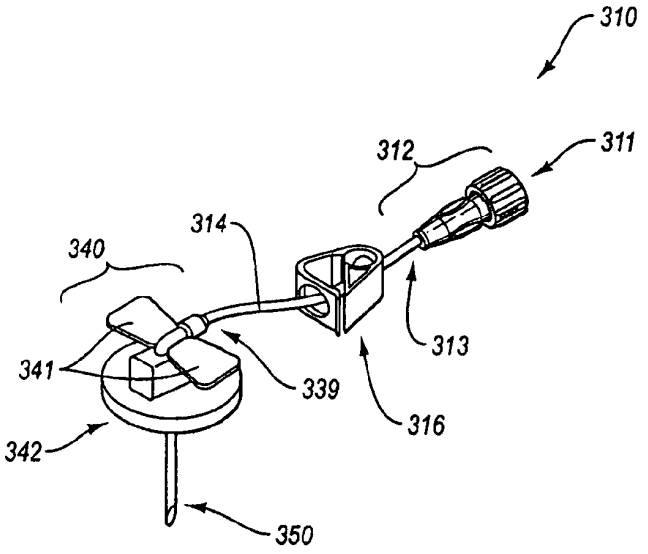
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FIG. 36

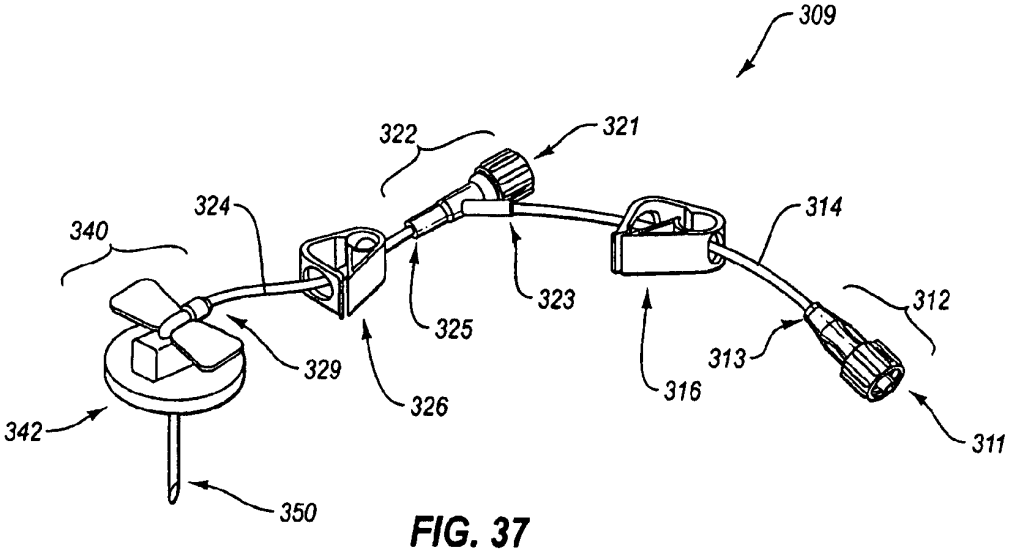
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FIG. 37

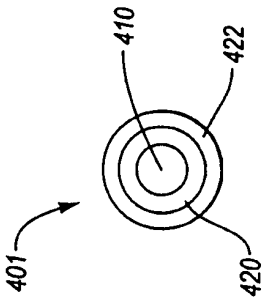

FIG. 39

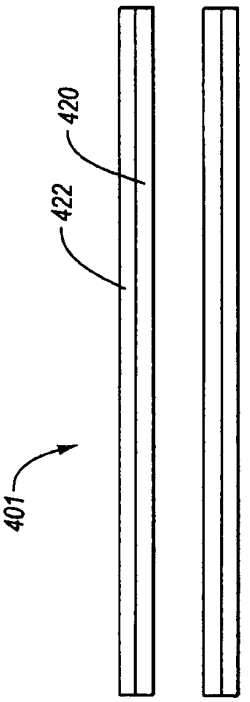

FIG. 38

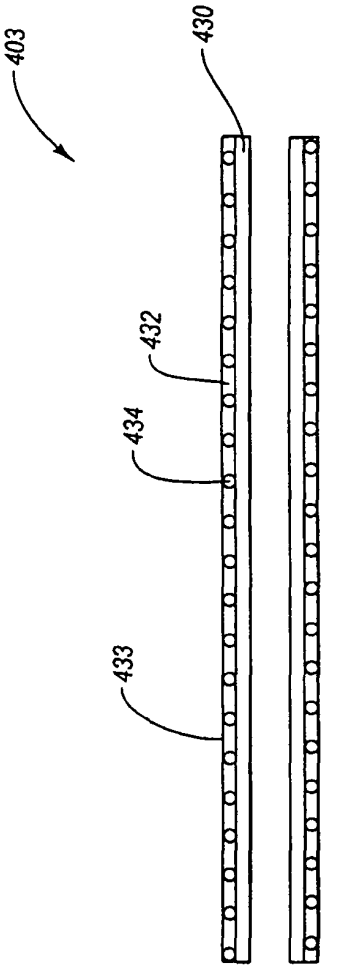

FIG. 40

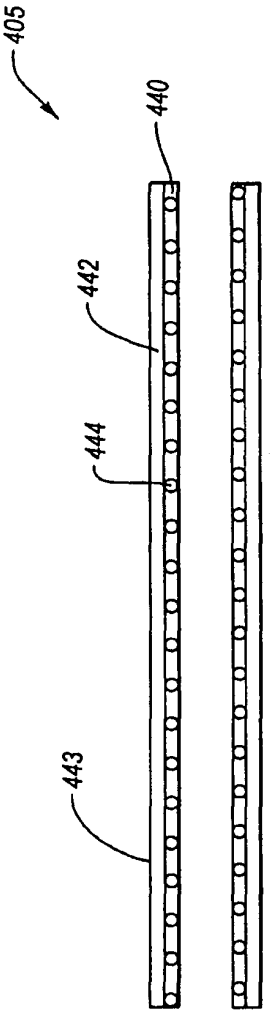

FIG. 41

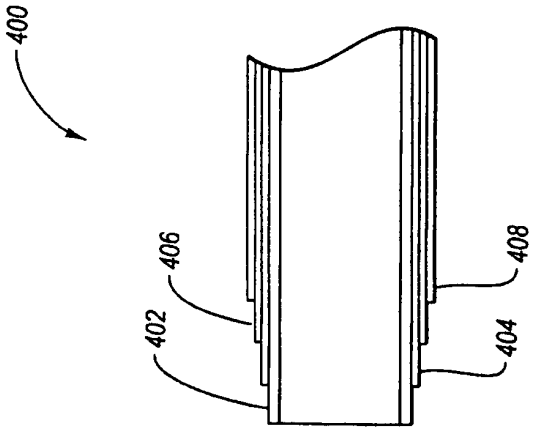

FIG. 43

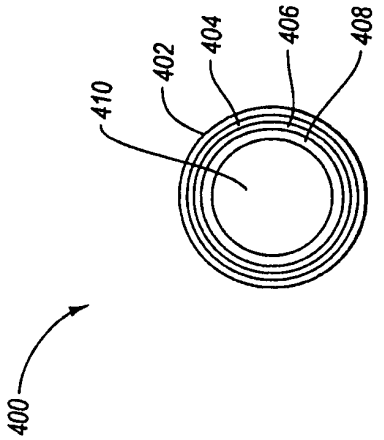

FIG. 42

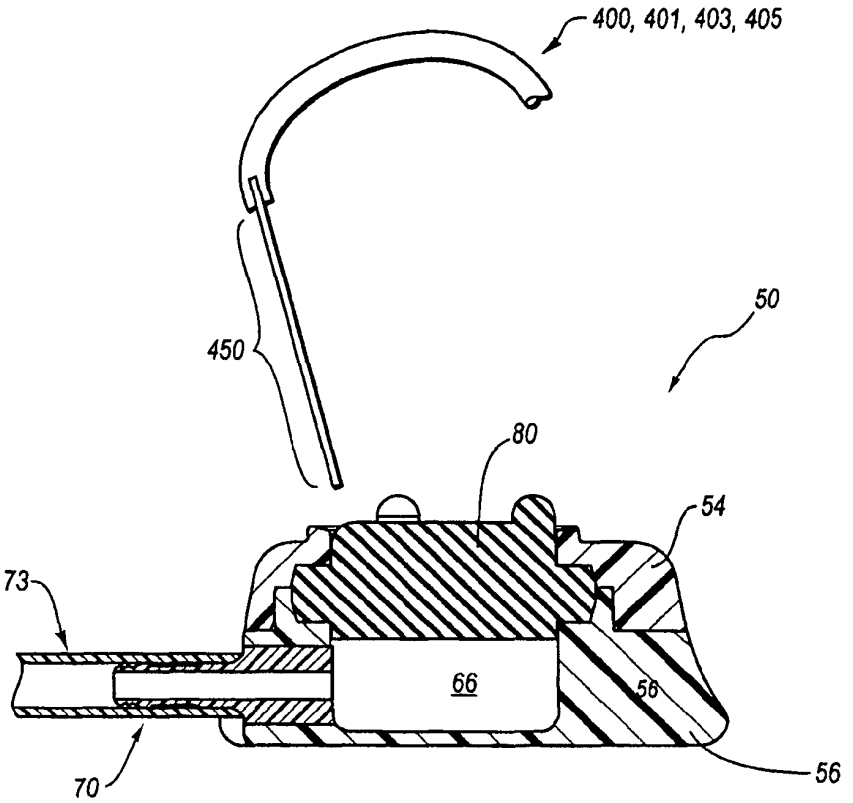
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FIG. 44

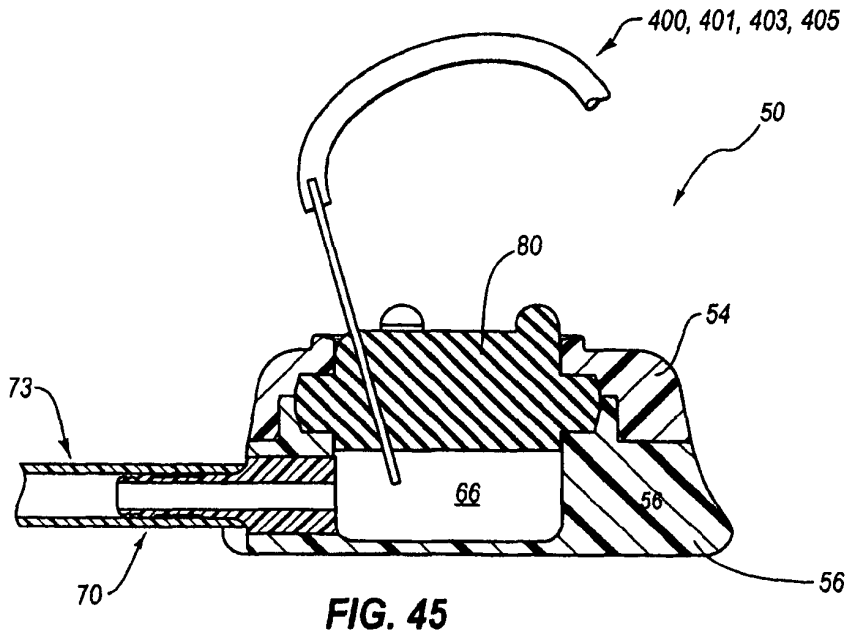
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FIG. 45

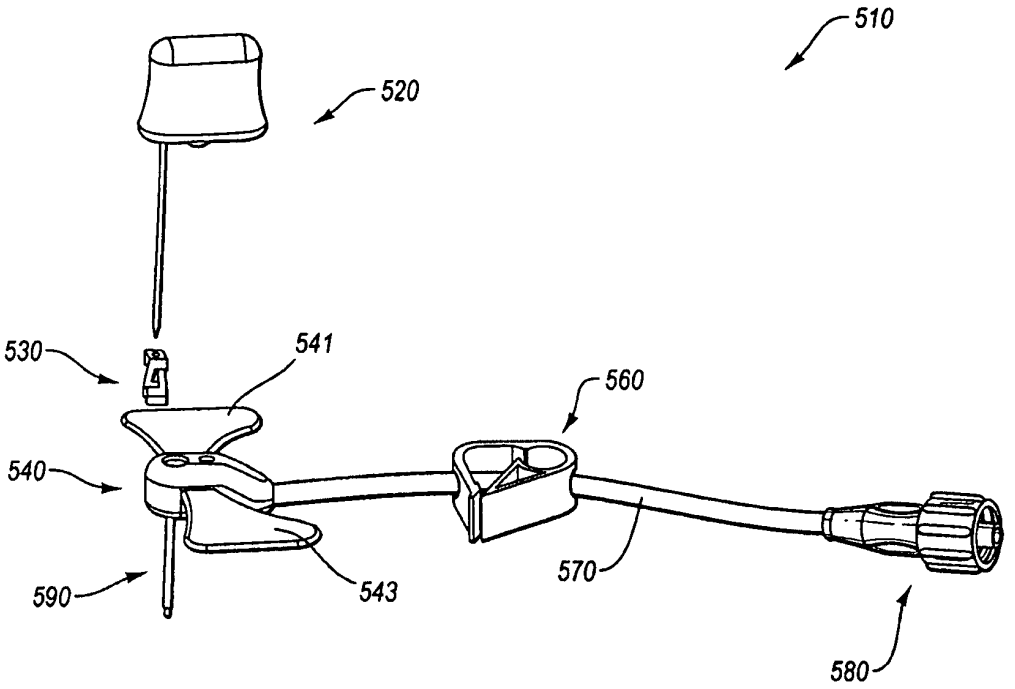

FIG. 46

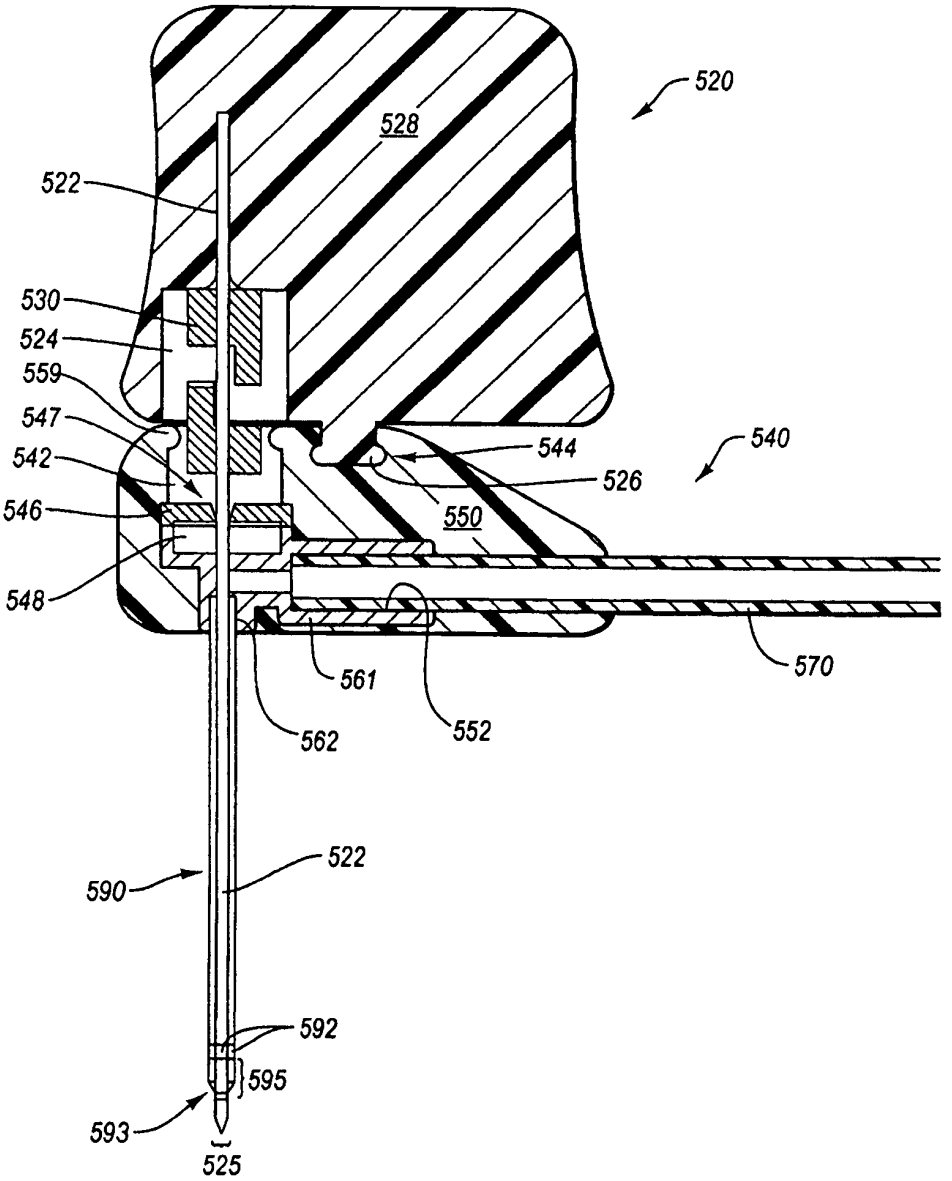
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FIG. 47

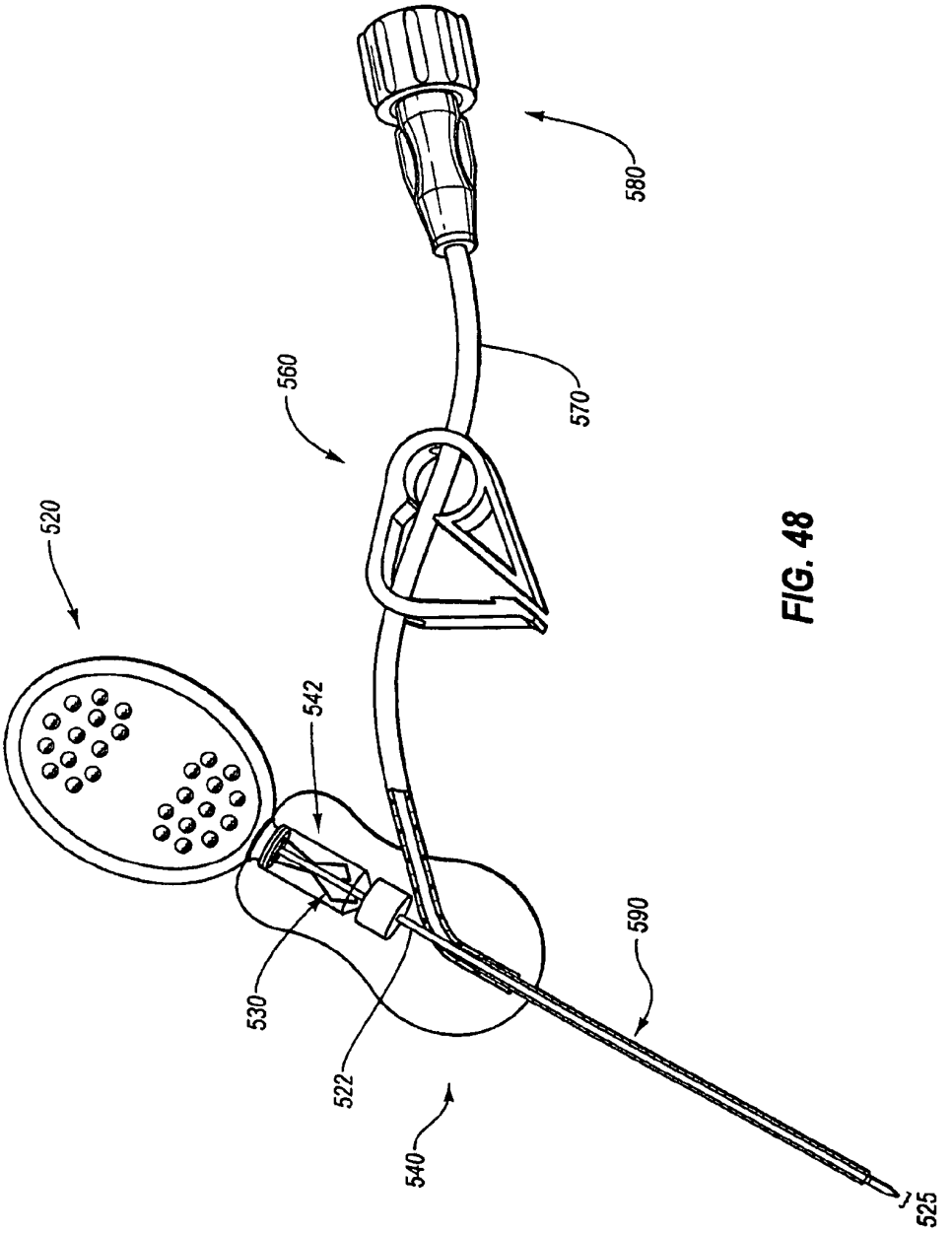

FIG. 48

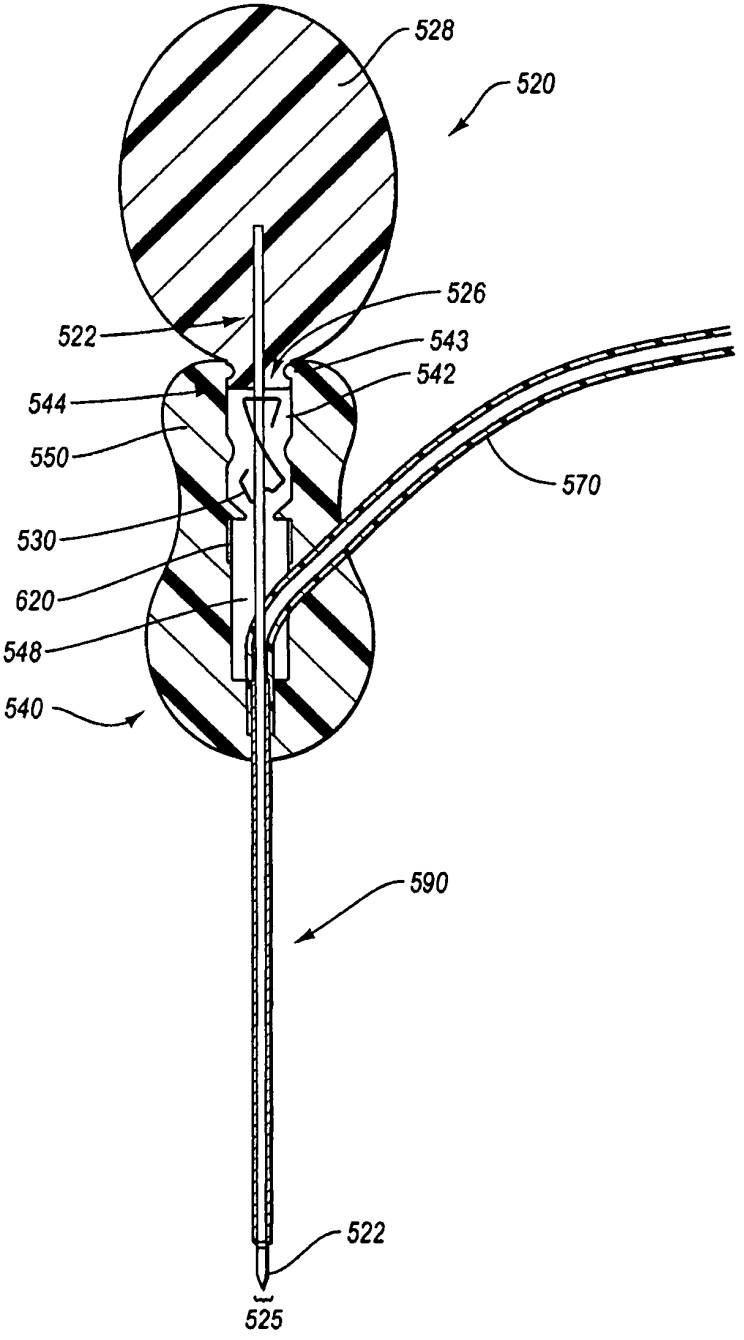

FIG. 49

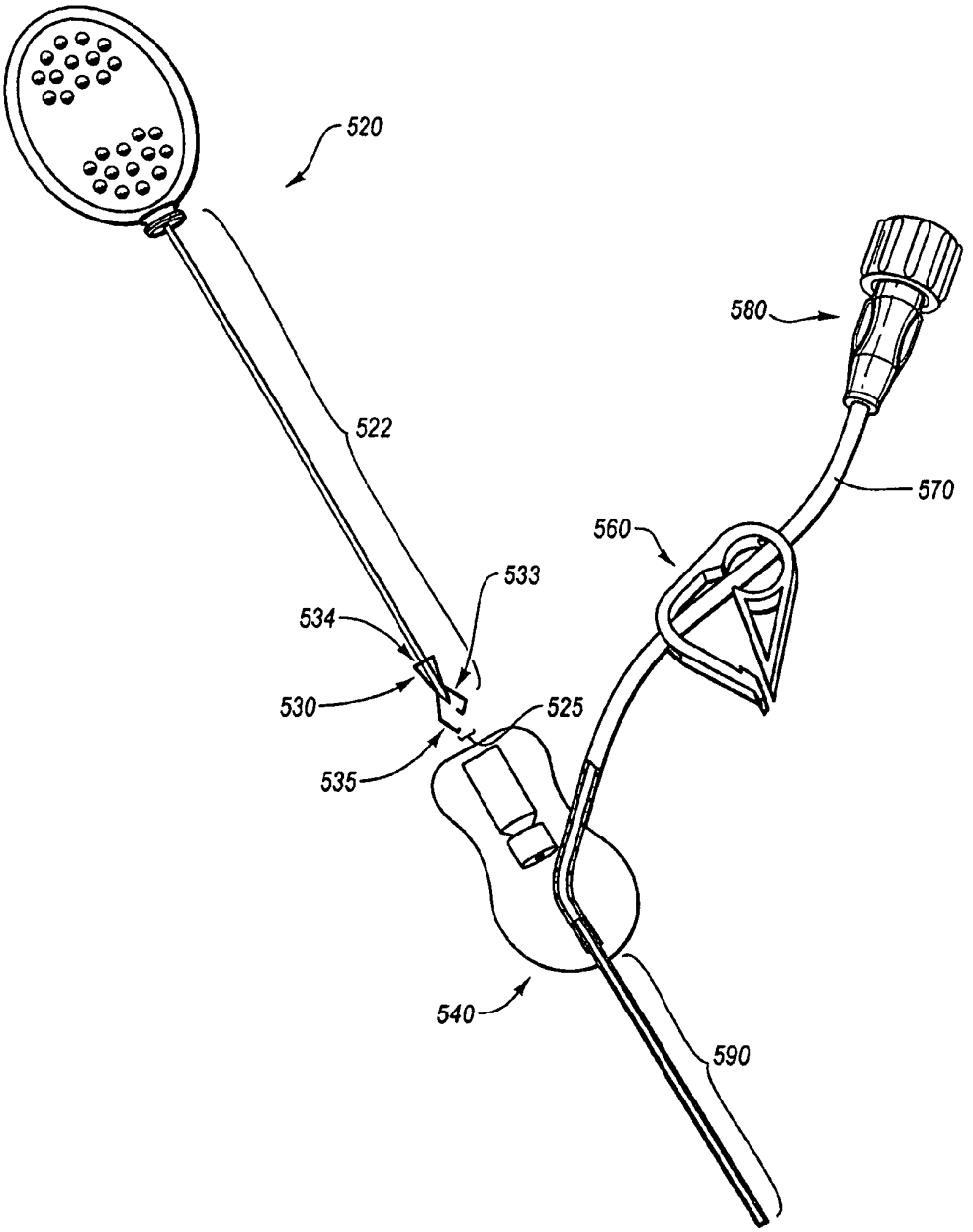

FIG. 50

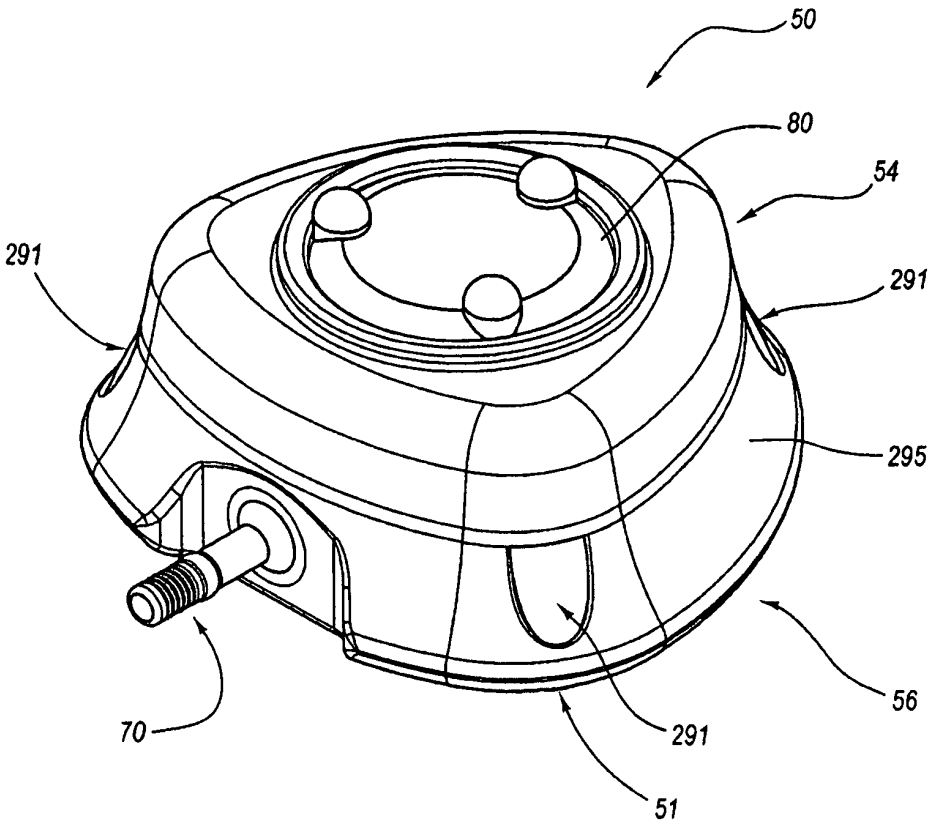

FIG. 51

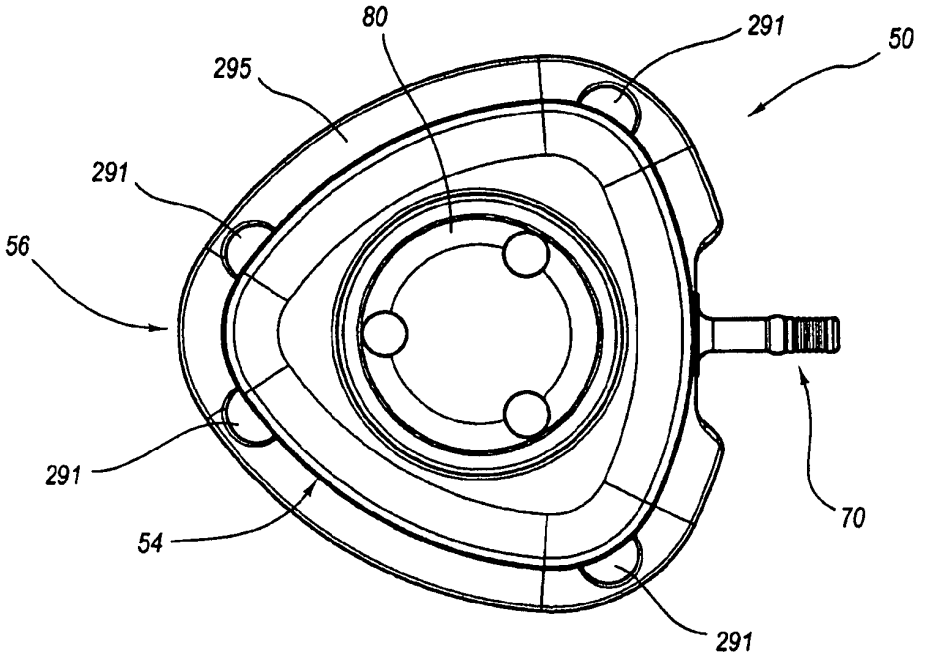

FIG. 52

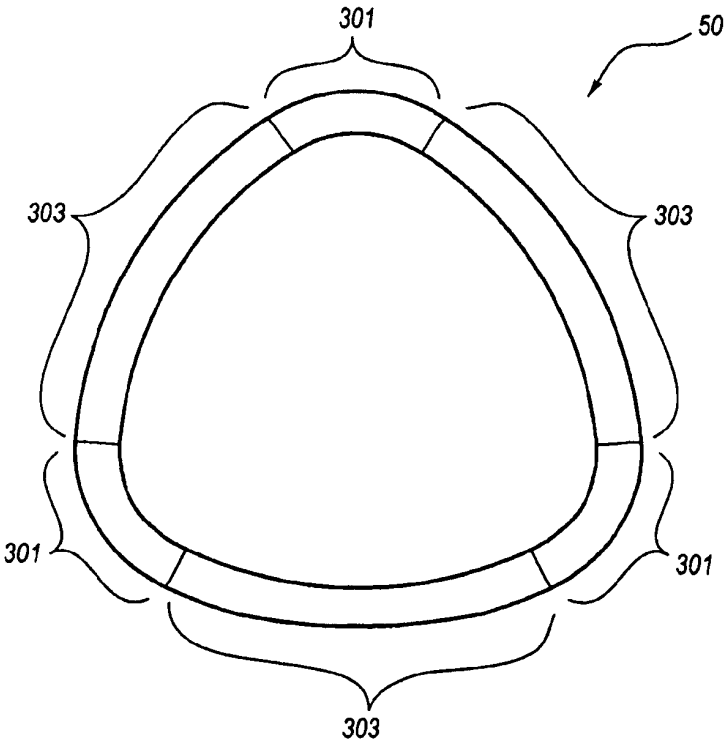

FIG. 53

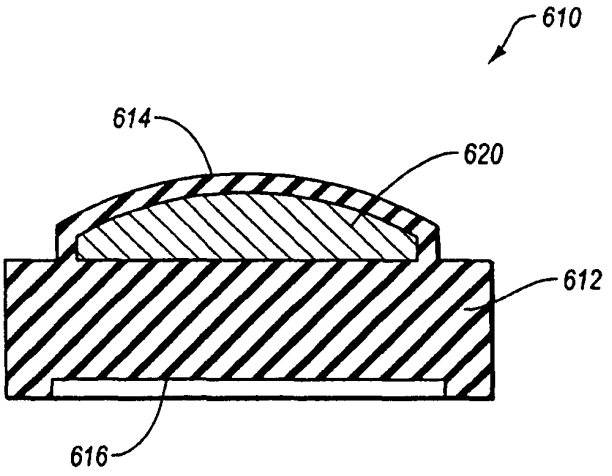

FIG. 54

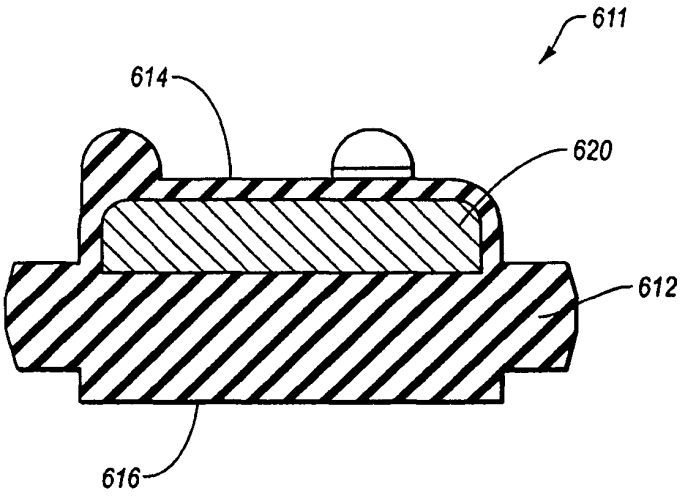

FIG. 55

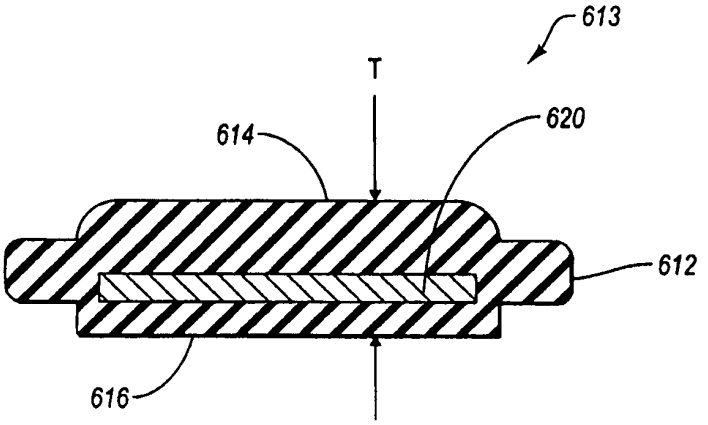

FIG. 56

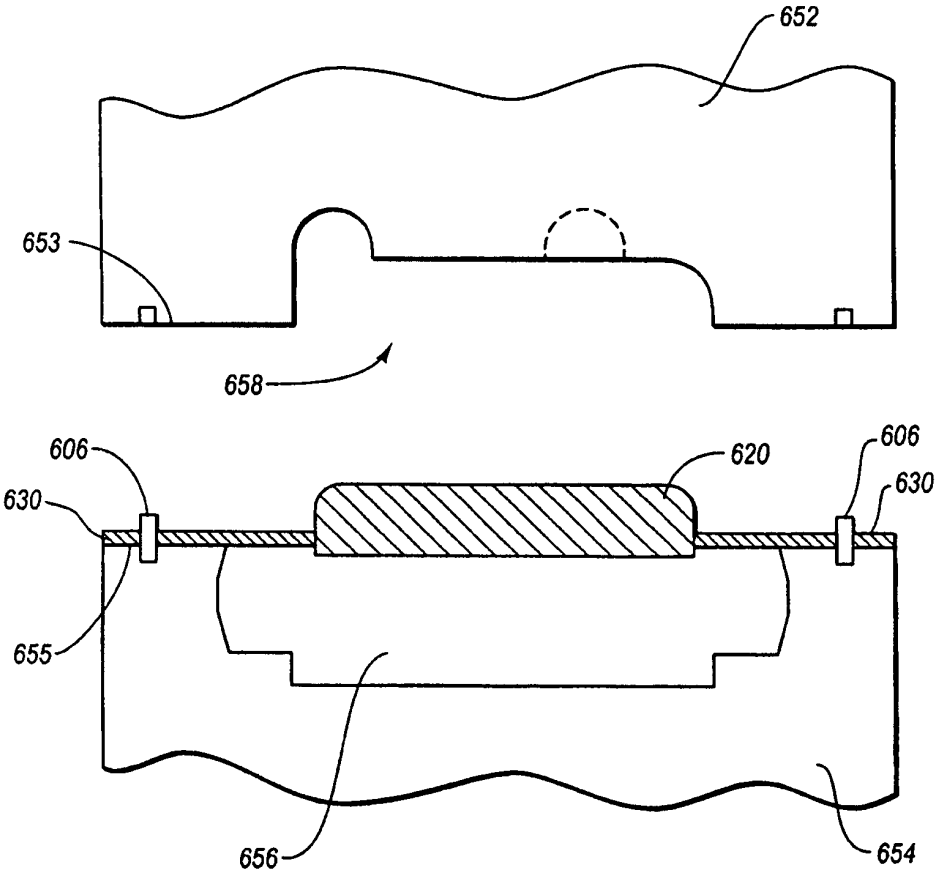

FIG. 57

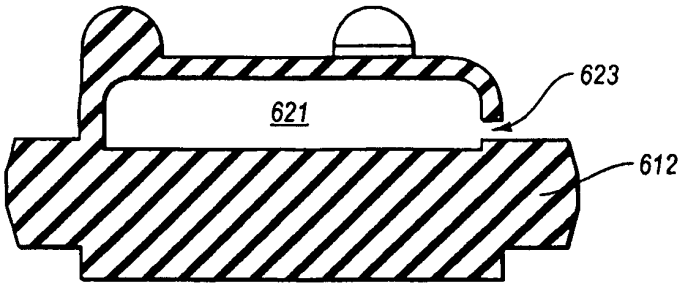

FIG. 58

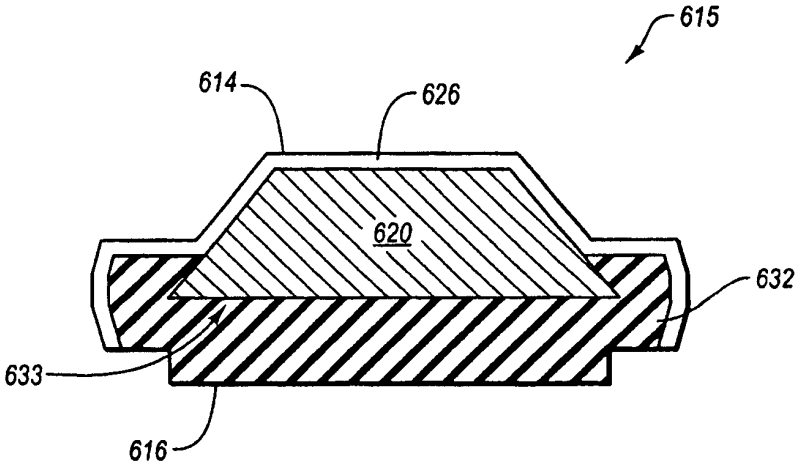

FIG. 59

ASSEMBLIES FOR IDENTIFYING A POWER INJECTABLE ACCESS PORT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 11/380,124, filed Apr. 25, 2006, which claims the benefit of priority to U.S. Provisional Patent Application No. 60/737,466, filed Nov. 15, 2005, and to U.S. Provisional Patent Application No. 60/675,309, filed Apr. 27, 2005, each of which applications is hereby incorporated by reference in its entirety into this application.

BACKGROUND

A wide variety of medical procedures require infusion of a fluid into a patient. For example, vascular imaging technologies may require use of a contrast media that is injected into the patient. More specifically, computed tomography (CT) is an imaging technology that utilizes a contrast media and may be employed for the noninvasive evaluation and assessment of a vascular system (i.e., CT angiography or CTA). Multidetector computed tomography (MDCT) is one specific type of CT that may be utilized for CTA. For proper imaging of a vascular system via CT, intravenous contrast media injection protocols are coordinated and selected for the anatomic area of interest.

More particularly, conventionally, a so-called "power injector" system may be employed for injecting contrast media at a high pressure into a peripherally inserted intravenous (IV) line. For example, such power injectors or injection systems may be commercially available from Medrad, Inc., a subsidiary of Schering AG, Germany and may be marketed as STELLANT® injection systems. Because CT procedures are often defined in terms of a desired flow rate of contrast media, such power injection systems are, in general, controllable by selecting a desired flow rate. Accordingly, such power injection systems may develop pressure (within the maximum pressure capability of the power injection system) as is necessary to maintain the selected flow rate. Accordingly, as may be appreciated, obstructions in the IV lines or use of IV lines that are not structured to withstand the pressures of a desired injection rate may cause the power injector to generate a pressure that exceeds a suitable pressure limit for the IV line. After intravenous injection, a bolus of contrast material, may flow within the vascular system of the patient to the right side of the heart, through the lungs, into the left side of the heart, and through the remaining circulatory system. After the bolus of contrast media is injected into the patient, portions of the contrast media may remain in the right side of the heart. Thus, the overall effectiveness of contrast enhancement may depend on a multitude of factors. For example, a patient's characteristics (e.g., body size; circulation, including cardiac output and circulating volume, and renal function), the contrast characteristics (e.g., volume, injection rate, iodine concentration, etc.), and the CT technique (e.g., access and route of administration, scan delay, scan speed, and injection pattern) may each influence the overall degree of contrast enhancement.

By way of background, conventionally, relatively long scan times have been accompanied by relatively long contrast media delivery times. However, because scan times continue to decrease, relatively fast delivery of contrast media may be desired. Explaining further, in coronary CTA, a large enough volume of contrast material must be administered at a sufficiently high rate to reach and maintain a suitable concentration throughout a selected scan time (e.g., a 15 second scan time), and within a selected region of the anatomy (e.g., an axial scan distance of 20 cm, which may include the left ventricle and outflow tract). It also may be desirable that contrast density values are sufficient to facilitate the segmentation techniques used in multidimensional post-processing. A typical contrast media used in coronary CTA may have an iodine density of about 300 milligrams per milliliter to about 350 milligrams per milliliter. Also, since contrast media may be radioactive, reducing the overall quantity of contrast media required to perform an imaging process may be advantageous.

The pressure required for contrast injection depends on many factors, including flow rate, contrast viscosity, configuration of infusion tubing, such as tube diameter and length, and any obstruction or restriction to flow (e.g., kinks, curves, fittings, compression). As mentioned above, to maintain the flow rate required for a CT or MRI study, a power injector may generate high pressures. Ruptures can occur when the injection pressure exceeds the tolerance of the vascular access device(s). Other problems may occur due to timing errors between the scan and the contrast. In order to maximize the rapid scanning capacity of the newer vascular imaging devices, the starting of the scanning process can be delayed a predetermined amount of time after injection of the contrast media has begun. If the scan starts too early, just as the contrast is arriving at the heart, arteries can appear smaller than they really are when the image is post-processed. On the other hand, if scanning is delayed too long, image artifacts can arise from diluted contrast in the cardiac veins. The window of opportunity for optimal scans may be very small, because contrast media circulates quickly through cardiac arteries and into cardiac veins.

Some diagnostic or medical procedures may advantageously employ a subcutaneous vascular access port for introducing a fluid into the vasculature of a patient. Access portals, or ports, provide a convenient method to repeatedly deliver medicants to remote areas of the body without utilizing surgical procedures. The port is implantable within the body, and permits the infusion of medications, parenteral solutions, blood products, contrast media, or other fluids. Additionally, the port may be used to aspirate blood from the patient. Such access ports typically include a cannula-impenetrable housing which encloses one or more fluid cavities or reservoirs and defines for each such fluid cavity an access aperture communicating through the housing. A cannula-penetrable septum is positioned adjacent to and seals each access aperture. An outlet stem communicates with one or more of the fluid cavities for dispensing medication therefrom to a predetermined location in the body of the patient through an implanted catheter attached to the access port. Once the access port and the catheter have been implanted beneath the skin of a patient, quantities of fluid, such as medication, blood, etc., may be dispensed through one such fluid cavity by, for example, a cannula (e.g., a needle), passed through the skin of the patient and penetrating the septum into one of the respective fluid cavities. This medication is directed through the distal end of the catheter to an entry point into the venous system of the body of the patient. Further, blood may be aspirated through the subcutaneous access port. Thus, use of an access port may allow for vascular access without needle sticks into the vasculature of a patient.

However, conventional access ports and attendant infusion systems have not been suitable for performing power injection.

Particularly, the use of power injection systems in combination with conventional vascular access ports has achieved

less than ideal results. Thus, it may be appreciated that vascular access ports for infusion systems and infusion-related apparatuses structured for performing power injection may be advantageous.

SUMMARY

One aspect of the instant disclosure relates to a method of flowing fluid through an access port. More particularly, a vascular access port may be provided and a fluid may be caused to flow through the access port at a rate of at least about 1 milliliter per second.

A further aspect of the instant disclosure relates to a method of flowing fluid through an infusion set. For example, an infusion set may be provided and a fluid may be flowed through the infusion set at a rate of at least about 1 milliliter per second.

Another aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Specifically, an access port may comprise a housing defining an aperture for capturing a septum, wherein the housing and septum define a reservoir. In addition, the septum may include a tenon region wherein the housing of the access port defines a complimentary mortise region structured for accepting at least a portion of the tenon region of the septum. Optionally, the housing may include a ring structure proximate to at least a portion of a side periphery of the septum.

An additional aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. In one embodiment, an access port may comprise a housing defining an aperture for capturing a septum, the housing and septum defining a reservoir. In addition, the housing and septum may be structured for accommodating a flow rate through the reservoir of at least about 1 milliliter per second. In another embodiment, an access port may include a housing and septum, as described above, wherein the housing and the septum are structured for accommodating a pressure developed within the reservoir of at least about 35 psi.

Yet another aspect of the instant disclosure relates to an infusion set for use in subcutaneously accessing a patient. For example, in one embodiment, an infusion set may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section. Also, the cannula may be configured for insertion through a septum of an access port, and the tubing section and the cannula may be structured for allowing a fluid to flow at a rate of at least about 1 milliliter per second. Optionally the cannula may be configured for puncturing a septum of an access port and the tubing section and the cannula may be structured for accommodating a pressure of at least about 400 psi. For example, the tubing section and the cannula may be structured for accommodating a pressure of about 600 psi.

A further aspect of the instant disclosure relates to infusion tubing for use in accessing a vascular system of a patient. In one embodiment, infusion tubing may comprise a plurality of layers, wherein the tubing is structured for accommodating a fluid flow rate of at least about 1 milliliter per second. In another embodiment, infusion tubing may comprise a plurality of layers, wherein at least one layer of the plurality of layers extends beyond at least another of the plurality of layers and is structured for forming a cannula for puncturing a septum of an access port. In yet an additional embodiment, an infusion set for use in subcutaneously accessing a patient may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section, wherein the cannula is configured for insertion through a septum of an access port. Additionally, the tubing section and cannula may be structured for accommodating a pressure of at least about 400 psi.

Another aspect of the instant disclosure relates to a method of identifying an access port as being suitable for power injection. More specifically, an access port including a septum may be provided. Further, the access port may be identified as being suitable for power injection.

Yet a further aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Particularly, an access port may comprise a housing configured for capturing a septum, the septum configured for inserting a cannula therethrough and into a reservoir defined within the housing and at least one structural element configured for resisting deformation of the septum in response to a pressure developed within the reservoir.

In an additional aspect of the instant disclosure, a method of operation of an access port may comprise providing a housing configured for capturing a septum, the septum configured for inserting a cannula (which can include a needle, a Huber needle, a trocar with an associated cannula, or any combination thereof) therethrough and into a reservoir defined within the housing, and developing a pressure within the reservoir of the housing. Further, such a method may comprise limiting deformation of the septum in response to the pressure developed within the reservoir.

In addition, one aspect of the instant disclosure relates to a septum comprising a gel or a viscous liquid. For example, in one embodiment, a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body including an upper surface and a lower surface and at least one gel region positioned generally between the upper surface and the lower surface. Another embodiment may comprise a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body, a layer formed over at least a portion of the body, and a gel region positioned at least partially between the layer and the body.

The above-described infusion apparatuses and related methods may be beneficially employed for effecting or facilitating power injection processes. For instance, such methods and apparatuses may be employed for infusing a fluid (e.g., a contrast media) at a rate of between about 1 milliliter per second and about 5 milliliters per second.

Features from any of the above mentioned embodiments may be used in combination with one another in accordance with the instant disclosure. In addition, other features and advantages of the instant disclosure will become apparent to those of ordinary skill in the art through consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the instant disclosure will become apparent upon review of the following detailed description and drawings, which illustrate representations (not necessarily drawn to scale) of various aspects of the instant disclosure, wherein:

FIG. **1** shows an exploded, perspective view of an access port according to the instant disclosure;

FIG. **2** shows a schematic, side cross-sectional view of the access port shown in FIG. **1**;

FIG. **3** shows a schematic, top elevation view of a cap including a ring feature as shown in FIGS. **1** and **2**;

FIG. **4** shows a schematic, top elevation view of another embodiment of a cap including a ring feature;

FIG. **5** shows a schematic, top elevation view of a further embodiment of a cap including a ring feature;

FIG. **6** shows a schematic, side cross-sectional view of an implanted access port with a cannula extending through the septum of the access port;

FIG. **7** shows a graph depicting pressures at selected regions within an infusion system for a given flow rate;

FIG. **8** shows a schematic, side cross-sectional view of an access port including a septum with a tenon region and a housing with a mortise region;

FIG. **9** shows a schematic, side cross-sectional view of another embodiment of an access port including a septum with a tenon region and a housing defining a mortise region;

FIG. **10** shows a schematic, side cross-sectional view of a further embodiment of an access port including a tenon region and a housing defining a mortise region;

FIG. **11** shows a schematic, side cross-sectional view of an access port, wherein at least a portion of a side periphery of the septum is affixed to the housing;

FIG. **12** shows a schematic, side cross-sectional view of an access port including a structural element extending between the septum and the housing;

FIG. **13** shows a schematic, side cross-sectional view of an access port including a structural element with a barbed end positioned within the septum;

FIG. **14** shows a schematic, side cross-sectional view of an access port including a structural element extending between an upper surface of the septum and the housing;

FIG. **15** shows a schematic, side cross-sectional view of an access port as shown in FIG. **14** and also including a support element positioned adjacent to an upper surface of the septum;

FIG. **16** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg that extends to the housing;

FIG. **17** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg comprising an enlarged end that couples to a recessed form in the housing;

FIG. **18** shows a schematic, side cross-sectional view of an access port including a septum in a structural element positioned adjacent to an upper surface of the septum;

FIG. **19** shows a schematic, side cross-sectional view of an access port including a septum and a structural element extending laterally through the septum;

FIG. **20** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to an upper surface of the septum;

FIG. **21** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to a lower surface of the septum;

FIG. **22** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a generally triangular pattern;

FIG. **23** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in two generally rectangular patterns;

FIG. **24** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a first plurality of substantially parallel lines and a second plurality of substantially parallel lines;

FIG. **25** shows a partial, top elevation view of an access port as shown in FIGS. **18-21**, wherein structural elements are arranged as two intersecting substantially straight members;

FIG. **26** shows a partial, top elevation view of a septum including a structural element positioned within the septum;

FIG. **27** shows a perspective view of a sectioned septum, as shown in FIG. **26**;

FIG. **28** shows a partial, top elevation view of a septum including a plurality of structural elements;

FIG. **29** shows a schematic, side cross-sectional view of an access port including a septum exhibiting curvature;

FIG. **30** shows a top elevation view of one embodiment of a septum frame;

FIG. **31** shows a schematic, side cross-sectional view of one embodiment of a septum including the frame shown in FIG. **30** and another material at least partially surrounding the frame;

FIG. **32** shows a schematic, side cross-sectional view of another embodiment of a septum including a frame that is at least partially surrounded by another material;

FIG. **33** shows a schematic, side cross-sectional view of yet an additional embodiment of a septum including a frame that is at least partially surrounded by another material;

FIGS. **34** and **35** show a respective schematic view of different patterns that may be generated by radiopaque material comprising a septum;

FIG. **36** shows a perspective view of one embodiment of an infusion set according to the instant disclosure;

FIG. **37** shows a perspective view of another embodiment of an infusion set according to the instant disclosure;

FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of one embodiment of tubing including an inner layer and an outer layer;

FIG. **40** shows a schematic, side cross-sectional view of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIG. **41** shows a schematic, side cross-sectional view of another embodiment of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIGS. **42** and **43** show an end cross-sectional view and a schematic, side cross-sectional view, respectively, of tubing including four layers;

FIGS. **44** and **45** show schematic, side cross-sectional views of a tubing section including a plurality of layers, wherein at least one layer of the plurality of layers extends from a distal end of the tubing to form a slender hollow region for insertion through a septum of an access port;

FIG. **46** shows a perspective view of one embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **47** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **46**;

FIG. **48** shows a perspective view of another embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **49** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **48**;

FIG. **50** shows a perspective view of the infusion system shown in FIG. **48**, wherein the insertion assembly is removed from the hub;

FIG. **51** shows a perspective view of one embodiment of an access port according to the instant disclosure;

FIG. **52** shows a top elevation view of the access port shown in FIG. **51**;

FIG. **53** shows a simplified representation of a transverse cross-section of the access port shown in FIGS. **51** and **52**;

FIG. **54** shows a schematic, side cross-sectional view of one embodiment of a septum including at least one gel region;

FIG. **55** shows a schematic, side cross-sectional view of another embodiment of a septum including at least one gel region;

FIG. **56** shows a schematic, side cross-sectional view of a further embodiment of a septum including at least one gel region;

FIG. **57** shows a side cross-sectional view of a first mold and a second mold, wherein a gel region is positioned between the first mold and the second mold;

FIG. **58** shows a schematic, side cross-sectional view of an embodiment of a septum including at least one chamber to capture a gel; and

FIG. **59** shows a schematic, side cross-sectional view of an additional embodiment of a septum including at least one gel region.

DETAILED DESCRIPTION

One aspect of the instant disclosure relates to vascular access ports. More particularly, in one embodiment, the instant disclosure contemplates that a vascular access port may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second. Further, the instant disclosure contemplates that a vascular access port may be structured to withstand at least about 180 pounds per square inch (psi) of pressure developed within the reservoir defined by the septum and the access port housing. In one embodiment, an access port may be structured for operating within a range of pressures of about 80 psi to about 180 psi. Such an access port may be advantageous for use in infusing a fluid into a patient (e.g., infusing contrast media into a patient for CT or MR imaging).

Generally, an access port may comprise a housing that captures a septum that may be repeatedly pierced or punctured with a hollow slender element (e.g., a cannula, or needle), which can include a Huber needle, a trocar with a circumferentially disposed cannula, or any other suitable access mechanism, without limitation. The words "cannula" or "needle," as used herein, encompass any slender element (e.g., a cannula, a needle, a trocar, with a circumferentially disposed cannula, etc.) as known in the art or described herein, without limitation. Such a septum may comprise a material (e.g., silicone) that seals, under suitable compression, passages formed by puncturing the septum with such an access mechanism. Thus, the septum may be at least partially compressed to facilitate closure of passages formed by puncturing the septum with the access mechanism. The instant disclosure contemplates that the housing and septum may be structured so that a flow rate from the reservoir of the access port may be at least about 1 milliliter per second without damaging the housing or septum or compromising the structural integrity of the reservoir (e.g., causing the septum to become separated from the housing).

In one embodiment, an access port may comprise a cap and base which define, in combination, a housing in which a septum may be positioned to form a reservoir. For example, FIGS. **1** and **2** show, respectively, an exploded perspective view and a side cross-sectional view of an access port **50** including a base **56**, a cap **54**, a septum **80**, and an outlet stem **70**. As shown in FIGS. **1** and **2**, cap **54** and base **56**, may be configured for capturing a septum **80** between cap **54** and **56**. Generally, cap **54** and base **56** may collectively form a housing **60** for capturing septum **80** and at least partially defining reservoir **66**. Explaining further, cap **54** may include an aperture **55** through which a portion of septum **80** may extend and base **56** may include a recess **57** configured to accept at least a portion of septum **80**. Thus, a portion of septum **80** may be placed within recess **57** of base **56** and aperture **55** of cap **54** may be positioned about septum **80** to collectively define a reservoir **66** within access port **50**, the reservoir **66** being in fluid communication with a lumen of outlet stem **70**. In other embodiments, a plurality of reservoirs may be collectively defined by a housing and at least one septum, without limitation. For example, any access port known in the art including a plurality of reservoirs (or one reservoir) may include any aspects) of the instant disclosure, without limitation. As shown in FIG. **1**, a portion of outlet stem **70** may be positioned within and coupled to an aperture **58** formed within base **56**.

Although FIG. **1** shows that access port **50** may include an outlet stem **70**, other embodiments of access port **50** may not include an outlet stem **70**. Therefore, FIG. **2** shows access port **50** without an outlet stem **70**. Put another way, the instant disclosure contemplates that access port **50** may, optionally, include an outlet stem **70** or may be otherwise configured. For instance, in one embodiment, outlet stem **70** may be formed as a part of with base **56**, if desired. In another embodiment, a catheter may be operably coupled to the access port **50** (e.g., to aperture **58**) without outlet stem **70**. In yet a further embodiment, access port **50** may simply include at least one outlet passage (e.g., aperture **58**) in fluid communication with the reservoir **66** and extending through the housing **60** and structured for allowing fluid flow through, if desired. As shown in FIG. **2**, a portion of septum **80** may be positioned between cap **54** and base **56** and may be configured to withstand, without damage or deforming to an extent that compromises the reservoir **66** (i.e., blowing out), a selected magnitude of pressure developed within reservoir **66**.

For example, as shown in FIGS. **1** and **2**, cap **54** may optionally include a circumferential ring structure **30** that is formed adjacent to a side periphery of septum **80**. Ring structure **30** may be structured to inhibit deformation of the cap **56** in response to a pressure developed within reservoir **66** of access port **50**. As shown in FIG. **3**, in a top elevation view of cap **54**, ring structure **30** may be generally circular. Further, ring structure **30** may be substantially congruent to a side peripheral shape of septum **80** or may exhibit a different shape than the side periphery of septum **80**. In addition, the size of ring structure **30** may be selected to provide a selected rigidity to a region of cap **54** adjacent to of aperture **55** of cap **54**. Such a configuration may inhibit deformation of the cap **54** in response to pressure developed within reservoir **66**. For example, as shown in FIG. **2**, a lateral thickness T_L, vertical thickness T_V, or both may be selected for providing a selected rigidity to a region of cap **54** adjacent to a periphery of septum **80** (i.e., adjacent to aperture **55**). In one embodiment, the overall height H (FIG. **2**) of access port **50** may be less than about 0.600 inches.

In other embodiments, ring structure **30** may be generally rectangular, generally triangular, generally oval, generally polygonal, or of another geometrical shape, without limitation. For example, FIG. **4** shows a top elevation view of a ring structure **30** that is generally triangular. Further, FIG. **5** shows a generally rectangular ring structure **30**.

Explaining further, housing **60** of access port **50** may comprise a biocompatible material such as polysulfone, titanium, or any other suitably biocompatible material. Thus, cap **54** and base **56** may couple to one another generally along a mating line and may be secured or affixed to one another. More particularly, in one embodiment, both cap **54** and base **56** may comprise titanium and may be welded, brazed, soldered, or otherwise affixed to one another. Such a configuration may provide suitable mechanical strength for capturing septum **80** between cap **54** and base **56**. Optionally, cap **54** and base **56** may be coupled to one another by at least one fastening element (e.g., at least one bolt, at least one screw, at least one rivet, etc.), at least one adhesive, or a combination of such coupling mechanisms. Similarly, in one embodiment,

outlet stem **70** and base **56** may each comprise titanium and may be welded or otherwise bonded or coupled to one another.

In further detail, FIG. **6** shows an access port **50** implanted within a patient **67**. In one embodiment, sutures may be used to affix the access port **50** within the patient **67**, if desired. After the housing **60** is implanted in a patient **67**, the upper surface of the septum **80** may be generally flush or aligned with the surface of the skin surface **76** of the patient **67** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the reservoir **66**. The outlet stem **70** may create a fluid-communicative passageway extending from the reservoir **66** and through the outlet stem **70**, catheter **73**, and into the interior of the patient **67**. Generally, catheter **73** may be coupled to the outlet stem **70** for fluid communication with the reservoir **66** and for conducting fluid to a desired remote location from the reservoir **66** and within patient **67**. In one embodiment, catheter **73** may extend from the access port **50** to at least partially within a vena cava of the patient. Such a configuration may allow for infusion of a contrast media proximate to the heart of a patient. Because such a contrast media may be harmful (e.g., radioactive or otherwise injurious) infusion directly into a vena cava of a patient may reduce an overall quantity of contrast media required to perform a selected imaging procedure.

As shown in FIG. **6**, a cannula **90** may be inserted through the septum **80** and fluid may be injected into the reservoir **66**. For example, fluid may be injected into reservoir **66** at a rate that causes pressure (i.e., a positive pressure) to be developed within reservoir **66**. For example, a positive pressure, labeled "P_R" in FIG. **6**, may develop within reservoir **66** and may act upon the portion of septum **80** defining, in part, reservoir **66**. Such a pressure P_R acting on a portion of septum **80** may develop force upon the septum **80**. Likewise, force may be developed on surfaces of the base **56** that are acted upon by pressure Pr. In one embodiment, cap **54** may be coupled to base **56** and structured to suitably position septum **80** and couple septum **80** to housing **60** against force applied to the septum **80**. Therefore, the septum **80**, cap **54**, and base **56** may be structured for accommodating attendant forces developed by pressure P_R. In one embodiment, access port **50** may be structured for accommodating (without damage) a pressure P_R of at least about 185 psi with reservoir **66**. In another embodiment, access port **50** may be structured for accommodating (i.e., without damage) a range of pressures of about 37 psi to about 65 psi with reservoir **66**.

In further detail, during power injection, a fluid flow F may be caused to flow through cannula **90**. A fluid flow rate (depicted in FIG. **6** by arrows labeled "F") may be at least about 1 milliliter per second. In another embodiment, a fluid flow rate F may be between about 1 milliliter per second to about 5 milliliters per second. During power injection, a pressure P_i may be developed within cannula **90** may be at least about 30 psi. Accordingly, cannula **90** may be structured to withstand the forces associated with the above-discussed pressure, flow rate, or both. As discussed in further detail below, the cannula may comprise a portion of an infusion set (e.g., a safety winged infusion set (SWIS)) or another infusion system configured for use with an access port and a power injection system, without limitation.

More particularly, FIG. **7** shows a graph depicting pressure measurements at different locations within an infusion system including an infusion set (as discussed in greater detail below) in fluid communication with an access port during infusion of a fluid at a rate of 5 milliliters per second. As shown in FIG. **7**, a pressure generally within a syringe barrel of a power injector may be about 265 psi. Further, a pressure generally at the entrance of an infusion set may be about 225 psi and a pressure generally within a reservoir of an access port may be about 40 psi. Thus, the pressure drop through an infusion set may be about 185 psi. As shown in FIG. **7**, a pressure generally at the distal end of a catheter extending from the access port may be about 0 psi. Many factors may influence a pressure (and a pressure drop) developed within an infusion system (e.g., infusion set, access port, etc.) during flow of a fluid through the infusion system, such as, for example, fluid viscosity, tubing inner diameter (i.e., lumen cross-sectional size), length of the flow path, and flow rate. Accordingly, as will be appreciated by the above discussion of the access port **50** shown in FIGS. **1-3**, such access port **50** may be structured to accommodate a selected flow rate and associated pressure P_R developed within reservoir **66** of access port **50**.

In another embodiment, the septum, housing, or both may be structured to mechanically secure or constrain at least a portion of the septum. For example, in one embodiment, the septum may include at least one coupling feature configured to mate or couple with a complementary coupling feature included by the housing. For example, male and female features (e.g., without limitation, ribs, flanges, interlocking features, tenon and mortise type features, tongue-in-groove features, T-slot features, dovetail features, snap-fit features, tabs and slots or other coupling features as known in the art) may comprise the at least one coupling feature included by the septum and the at least one complementary feature included by the housing, without limitation. "Tenon," as used herein, means a projecting member for at least partial insertion into a mortise to make a joint. "Mortise," as used herein, means a recess, hole, groove, or slot formed within a material for receiving at least a portion of a tenon to make a joint.

Generally, in one embodiment, the septum may include at least one tenon region (i.e., at least one coupling feature) for coupling to a complementary mortise region formed by the housing. Thus, the housing may include a recess (i.e., at least one complementary feature) for accepting at least a portion of the tenon region of the septum. For example, FIG. **8** shows a side cross-sectional view of one embodiment of a septum **180** including a tenon region **270**. Particularly, tenon region **270** includes tapered surface **187** of septum **180**, which may increase in height (i.e., from lower surface **183** of septum **180**) along an increasing radial direction (i.e., relative to a radial distance from a central axis of septum **180**; that is, in a direction from rim **159** of cap **154** toward side surface **157** of base **156**). Thus, as shown in FIG. **8**, a height CG_{MIN} of septum **180** (measured at a radially innermost extent of tenon region **270**) is less than a height CG_{MAX} of septum **180** (at a radially outermost extent of tenon region **270**). Further, tenon region **270** may be a continuous peripheral feature (i.e., an annular feature) of septum **180** or may comprise one or more circumferentially separate regions, without limitation. Further, as shown in FIG. **8**, housing **160** (including cap **154** and base **156**) may generally define a complementary mortise region (e.g., a circumferentially extending recess) for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined by side surface **157** of base **156**, lower flange surface **273** of base **156**, and tapered surface **172** of cap **154**. Such a configuration may secure, capture, or retain a portion of tenon region **270** of septum **180** within the mortise region of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In another embodiment, an access port may comprise a septum including a tenon region including a plurality of

tapered surfaces. For example, FIG. **9** shows a schematic side cross-sectional view of a septum **180** including a tenon region **270** comprising tapered surface **187**, tapered surface **189**, and tapered surface **191**. Further, as shown in FIG. **9**, housing **160** may generally define a complementary mortise region tapered recess for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined within housing **160** by side surface **157** of base **156**, lower flange surface **273** of base **156**, tapered surface **172** of cap **154**, tapered surface **193** of base **156**, and tapered surface **195** of cap **154**. Such a configuration may secure, capture, or retain at least some of tenon portion **270** of septum **180** within a tapered recess of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In summary, it should be understood that a portion of a septum may comprise, generally, at least one tenon region for coupling with a complementary mortise region formed in a housing. In another embodiment, generally, at least a portion of a housing may comprise a tenon for coupling with a complementary mortise formed in a septum. As described above, a tenon region and a complimentary mortise region may comprise one or more tapered surfaces. In another embodiment, a tenon region and complementary mortise region may comprise a T-slot or other nontapered geometry, without limitation. For example, FIG. **10** shows a schematic, side cross-sectional view of one embodiment of an access port **150** comprising a septum **180** including a tenon region **270**. Further, a complementary mortise region may be defined within housing **160** for accepting at least a portion of tenon region **270**. As shown in FIG. **10**, a mortise region may be at least partially defined by an annular extension or protrusion **203** of base **156**. Such a configuration may secure, capture, or retain at least a portion of tenon region **270** of septum **180** within housing **160** and suitably seal reservoir **166** even if an anticipated maximum pressure is developed within reservoir **166**. It should be further understood that any of the tenon region and mortise region embodiments shown in FIGS. **8-10** may be described in terms of extensions, ridges, protrusions, recesses, grooves, slots, etc., without limitation.

A further aspect contemplated by the instant disclosure relates to coupling or affixing at least a portion of a peripheral region of a septum to a housing. Such a configuration may maintain the integrity of the access port during use of the access port for infusing a fluid at a flow rate of at least about 1 milliliter per second. For example, in one embodiment, at least a portion of a side periphery of a septum may be affixed to at least a portion of a housing. FIG. **11** shows a side cross-sectional view of an access port **50** wherein at least a portion of a periphery of septum **80** adjacent to housing **60** is affixed to one or both of cap **54** and base **56** adjacent to septum **80**. More particularly, as shown in FIG. **11**, a periphery of septum **80** (adjacent to cap **54** and base **56**) may include upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95**. Thus, in one embodiment, an adhesive, (e.g., glue, epoxy, cement, tape, or any other adhesive as known in the art) may affix at least a portion of one or more of upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95** to the cap **54** or base **56**, respectively. Such a configuration may secure septum **80** to housing **60** and may provide a relatively robust access port **50** suitable for power injection. It should further be appreciated that affixing at least a portion of a peripheral region of a septum may encompass affixing at least a portion of a tenon region (of either a septum or housing) to a mortise region (of either a housing or septum), without limitation.

As described above, septum deformation is a design consideration with respect to performing power injection via an access port. Further, one aspect of the instant disclosure relates to a septum that is structurally reinforced or otherwise limited against deformation exceeding a selected magnitude. More specifically, the instant disclosure contemplates that at least one structural element may be configured to inhibit or limit deformation of a septum of an access port in response to pressure developed within a chamber or reservoir of the access port. Some embodiments of an access port including at least one structural element for limiting deformation of a septum are disclosed in U.S. Patent Application No. 60/737,466, filed 15 Nov. 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the access ports encompassed by U.S. Patent Application No. 60/737,466 may be structured for power injection.

In one embodiment, the instant disclosure contemplates that a septum may be structurally coupled to a housing nonperipherally. Put another way, one aspect of the instant disclosure relates to coupling a nonperipheral portion of a septum to a housing of an access port. For example, FIG. **12** shows one embodiment of an access port **110** according to the instant disclosure including a cap **54** and a base **56** that capture a septum **120** to form a reservoir **66**. Optionally, cap **54** may include a ring feature proximate to a periphery of the septum, as described above. In addition, outlet stem **70** may allow for fluid communication with reservoir **66** to perform infusion or fluid sampling processes. As shown in FIG. **12**, a structural element **112** may extend between septum **120** and housing **60**. More particularly, structural element **112** extends generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Thus, if pressure (positive/negative) is developed within reservoir **66**, structural element **112** may inhibit deflection or deformation of lower surface **121** of septum **120** toward or away from upper surface **165** of base **56**. Generally, a structural element may inhibit deformation of a septum in relation to one or more selected directions (i.e., either toward or away from upper surface **165** of base **56**).

Generally, a structural element (e.g., structural element **112**) may comprise any of the following: at least one wire, at least one pin or columnar element, or at least one filament, without limitation. Such a structural element may comprise titanium, steel (e.g., stainless steel), polymers (e.g., DELRIN®, nylon, polyester, KEVLAR®, polytetrafluoroethylene (PTFE) (expanded or nonexpanded), polyurethane, etc.), or other materials as known in the art. In other embodiments, a structural element may comprise a composite, such as a fiber-reinforced matrix. In one embodiment, a structural element may comprise fibers (glass, carbon, etc.) dispersed or aligned within a silicone matrix.

Further, structural element **112** may be coupled to septum **120** by an adhesive, welding, snap-fitting, molding the septum **120** about a portion of the structural element **112**, otherwise imbedding a portion of structural element **112** within septum **120**, or as otherwise suitable. Similarly, structural element **112** may be coupled to base **56** by an adhesive, welding, or imbedding a portion of structural element **112** within base **56**. It may also be appreciated that, optionally, structural element **112** may exhibit a modulus of elasticity that exceeds a modulus of elasticity of septum **120**. Such a configuration may allow for structural element **112** to resist deformation of septum **120** in response to a pressure developed within reservoir **66** (e.g., during a "power injection" process).

FIG. **13** shows a schematic cross-sectional view of an access port **110** according to the instant disclosure including another embodiment of structural element **112**. Particularly,

as shown in FIG. **13**, structural element **112** may include a barbed end **116**, which is positioned at least partially within septum **120**. Such a configuration may couple structural element **112** to septum **120** and may resist against deformation of the septum **120** in response to pressure developed within reservoir **166**. Furthermore, as shown in FIG. **13**, the barbed end **116** of structural element **112** may, optionally, be pointed. Further, the point of barbed end **116** may be oriented toward upper surface **123** of septum **120**. Such a structure may deflect a cannula that is inserted through septum **120** and contacts barbed end **116** so that the cannula is directed away from structural element **112**. Optionally, in another embodiment, structural element **112** may extend through base **56** and may be affixed to lower surface **113** of base **56**.

In another embodiment of an access port, a structural element may extend through a septum. For example, FIG. **14** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from lower surface **121** of septum **120** to upper surface **123** of septum **120**. As shown in FIG. **14**, structural element **112** may also extend to upper surface **165** of base **56**, to mechanically couple septum **120** to housing **60**. Optionally, structural element **112** may include at least one barb, which may be positioned within septum **120** and configured for coupling septum **120** to housing **60**. In addition, structural element **112** may be affixed, if desired, to at least one of upper surface **123** and lower surface **121** of septum **120**. As may be appreciated, it may be advantageous for upper surface **123** of septum **120** to be mechanically coupled to housing **60** to resist deformation of septum **120** in response to a pressure developed within reservoir **66**.

The instant disclosure further contemplates that a structural element may be employed in combination with a support element extending over a selected area of the upper surface of the septum. Such a support element may be positioned adjacent to an upper surface of a septum and may be configured to contact the upper surface of the septum with a selected surface area (e.g., when the septum deforms). For example, FIG. **15** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from housing **60** to an upper surface **123** of septum **120**. Furthermore, structural element **112** is coupled to a support element **114**, which is positioned adjacent to upper surface **123** of septum **120**. Such a configuration may provide a selected amount of contact area between support element **114** and upper surface **123** of septum **120**. Such a selected contact area between support element **114** and septum **120** may reduce otherwise undesirably high stresses within septum **120** when a pressure develops within reservoir **66** by distributing such stresses over a selected area or region of septum **120**. In addition, support element **114** may be observable (e.g., visually or by palpation) and, therefore, may be avoided when inserting a cannula through septum **120**. Additionally, the support element **114** can be used to identify the port **110** as being power injectable.

In another embodiment of an access port, a structural element may comprise a portion of a septum affixed to a housing of an access port to resist deformation of the septum. For example, FIG. **16** shows a schematic, side cross-sectional view of an access port **110** including a septum **120**, which comprises an extension leg **124** (i.e., a structural element) that is coupled to housing **60**. More particularly, as shown in FIG. **16**, extension leg **124** may extend generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Extension leg **124** may abut and may be affixed to upper surface **165** of base **56**. Such a configuration may resist against deformation of septum **120** in response to pressure developed within reservoir **166**. In one embodiment, extension leg **124** may be substantially centered (i.e., positioned generally at a centroid of lower surface **121**) with respect to lower surface **121** of septum **120**. Substantially centering extension leg **124** with respect to lower surface **121** of septum **120** may limit deformation of lower surface **121** of septum **120** to a greater extent than other positions of extension leg **124** may limit deformation of lower surface **121** of septum **120**. Additionally, it should be appreciated that while FIG. **16** shows one extension leg **124**, the instant disclosure contemplates that at least one extension leg (i.e., one or more extension legs) may extend from or be coupled to septum **120**, without limitation. In another embodiment, at least one extension leg may be coupled to a housing of an access port by an interference fit or a so-called "snap-fit." More particularly, as shown in FIG. **17**, extension leg **124** includes a bulbous or rounded end **125** that is configured to fit within a recess **155** formed in base **56**. Recess **155** may comprise an opening formed in upper surface **165** of base **56** that is smaller than a maximum lateral dimension of rounded end **125**, so that rounded end **125** may be forced through such an opening and "snap" into a portion of recess **155**. Optionally, extension leg **124** may be affixed (e.g., adhesively affixed, welded, pinned, or affixed by other suitable methods to recess **155** formed in base **56**. Such a configuration may couple septum **120** to base **60** of access port **110** and may resist or limit deformation of septum **120** in response to pressure developed within reservoir **66**.

Another aspect of the instant disclosure contemplates that at least a portion of an upper surface of a septum may be constrained or limited in its deformation. In one embodiment, at least one structural element may be positioned upon or adjacent to an upper surface of a septum to limit deformation of the septum in a direction toward the structural element. Put another way, at least one structural element may extend laterally upon or adjacent to at least a portion of an upper surface of a septum. For example, FIG. **18** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** and a structural element **132** positioned adjacent to an upper surface **133** of septum **130**. Optionally, structural element **132** may be bonded or affixed to upper surface **133** of septum **130**. Structural element **132** may be structured to resist deformation of septum **130** in a direction generally away from reservoir **166**. In one embodiment, structural element **132** may substantially overlay or cover upper surface **133** of septum **130**. Optionally, structural element **132** may be at least partially embedded within septum **130**. In one embodiment, structural element **132** may be penetrable by a cannula (e.g., a needle). In another embodiment, structural element **132** may cover a selected portion (i.e., at least a portion) of upper surface **133** of septum **130**, which may allow for openings or apertures formed in structural element **132** through which a cannula may be inserted into upper surface **133** of septum **130**. It may be appreciated that, optionally, a modulus of elasticity of structural element **132** may exceed a modulus of elasticity of septum **130**, so that deformation of septum **130** may be inhibited to a selected degree by structural element **132**. Further, although a thickness (labeled "t") of structural element **132** is shown in FIG. **18** as being substantially uniform, the instant disclosure contemplates that a thickness "t" of structural element **132** may vary, without limitation. For example, thickness "t" of structural element **132** may be maximum proximate to a centroid of the upper surface **133** of septum **130**. In addition, as shown in FIG. **18**, structural element **132** may be positioned between cap **54** and septum **130**. Structural element **132** may be affixed to one or both of cap **54** and septum **130**, if desired. For

example, structural element **132** may be adhesively affixed, welded, mechanically fastened, or otherwise suitably coupled to one or both of cap **54** and septum **130**. Furthermore, structural element **132** may comprise a metal (e.g., titanium, steel, etc.), a polymer (e.g., DELRIN® polyurethane, nylon, etc.), or any other suitable material. In another embodiment, as discussed further below, structural element **132** may comprise a relatively tightly woven fabric that resists tissue ingrowth (if positioned in potential contact with an internal cavity of the body). In a further embodiment, a structural element **132** may comprise a substantially fluffy or compressible polyester that may promote tissue healing of punctures created by a cannula passing through septum **130** of access port **110** (if positioned in potential contact with an internal cavity of the body).

In a further embodiment, the instant disclosure contemplates that at least one structural element may be at least partially embedded within a septum and may extend laterally through at least a portion of the septum. For example, FIG. **19** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** and a structural element **140** extending laterally (i.e., across an opening in the housing **60** closed by the septum **120**) through the septum **120**. As shown in FIG. **19**, structural element **140** may be affixed to housing **60** (e.g., cap **54** or base **56**). More particularly, as shown in FIG. **19**, structural element **140** may be affixed to cap **154** at connection regions **147** and **143**. In addition, a selected level of tension may be developed within structural element **140**, if desired, to provide for a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected degree of resistance to deformation of septum **120** in a direction generally perpendicular to a direction of extension of structural element **140**.

In another embodiment, a structural element may be positioned proximate to an upper surface of a septum to limit deformation of the septum. For example, FIG. **20** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** positioned within a housing **60** and a structural element **150** positioned proximate to an upper surface **133** of septum **130**. As shown in FIG. **20**, structural element **150** extends laterally over at least a portion of upper surface **133** of septum **130**. Thus, structural element **150** may allow septum **130** to deform a selected distance (e.g., a gap labeled "G") prior to contact with structural element **150**. Further, structural element **150** may be affixed to cap **54** and may be selectively tensioned to exhibit a selected degree of flexibility in response to contact between septum **130** and structural element **150**. In one embodiment, structural element **150** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **130** in response to a pressure developed within reservoir **66**.

In another embodiment, a structural element may be positioned proximate to or abutting a lower surface of a septum to limit deformation of the septum. For example, FIG. **21** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** positioned within a housing **60** and a structural element **170** positioned proximate to a lower surface **121** of septum **120**. As shown in FIG. **21**, structural element **170** may extend laterally over at least a portion of lower surface **121** of septum **120**. Further, structural element **170** may be affixed to lower surface **121** or septum **120** or otherwise coupled to lower surface **121** of septum **120**. Thus, structural element **170** may inhibit deformation of septum **120**. Further, structural element **170** may be affixed to base **56** (or otherwise coupled to housing **60**) to provide adequate resistance to deformation of septum **120**. Optionally, structural element **170** may be selectively tensioned to exhibit a selected flexibility in response to forces applied to the structural element **170**. Optionally, structural element **170** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **120**.

Referring to FIGS. **18-21**, it will be appreciated that structural elements **132**, **140**, **150**, or **170** may comprise, in some embodiments, elongated elements, such as, for instance, wire, ribbon, thread, fibers, columnar elements, or the like. Accordingly, such at least one elongated element may be arranged in a selected pattern adjacent or proximate to an upper surface of a septum. Further, in one embodiment, a structural element positioned proximate to or abutting a lower surface of a septum, proximate to or abutting an upper surface of a septum, or within a septum, may comprise a mesh (e.g., a metal or plastic mesh, a fabric, a fiber mesh, etc.). For instance, in one embodiment, a structural element may comprise a fabric comprising fibers or threads that seal against one another (e.g., fibers or threads coated with silicone). Such a configuration may allow for a cannula to pass through the fabric and for the fabric to seal about the cannula, but may also allow for the fibers or threads to seal against one another when the cannula is removed. In addition, it will be understood that, based upon the instant disclosure, structural elements **132**, **140**, **150**, or **170** as shown in FIGS. **18-21** may be arranged in a variety of configurations.

For example, FIG. **22** shows a partial top elevation view of one embodiment of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged to form a generally triangular shape or pattern. In a further example, FIG. **23** shows a partial top elevation view of an access port **110** as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged in two partially intersecting generally rectangular shapes or pattern. In yet a further embodiment, FIG. **24** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising a first plurality of substantially parallel lines and a second plurality of substantially parallel lines, wherein the first plurality of substantially parallel lines is substantially perpendicular to and intersects with the second plurality of substantially parallel lines. In an additional embodiment, FIG. **25** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising two substantially straight (i.e., linear) members that intersect with one another. As shown in FIG. **25**, structural elements **132**, **140**, **150**, **170** may be substantially perpendicular to one another. As shown in FIGS. **22-25**, structural elements **132**, **140**, **150**, **170** may be affixed to cap **54** at selected connection regions. Such configurations may allow for varying degrees of limitation of deformation of a septum, while allowing ample access to a surface of a septum for perforation by a cannula (e.g., a needle).

In another embodiment, the instant disclosure contemplates that a structural element may be at least partially embedded within a septum and may be in the form, configuration, or shape of a two-dimensional or plane (e.g., a circle, ellipse, triangle, rectangle, etc.) within the septum. For example, FIG. **26** shows a partial top elevation view of a septum **120** and a structural element **141** extending within the septum **120**. In further detail, FIG. **27** shows a perspective view of a sectioned septum **120** including a structural element **141** embedded within the septum **120**. As shown in FIGS. **26** and **27**, in one embodiment, structural element **141** may be generally circular. More generally, one or more structural elements **141** may be at least partially embedded within a septum (e.g., a septum **120** or **130**, as discussed above), if

desired. For example, a plurality of structural elements **141** may be embedded within a septum **120** and arranged substantially concentrically with respect to one another, as shown in FIG. **28** in a partial, top elevation view. Structural element **141** may be generally elongated (as shown in FIGS. **26-28**) or may, more generally, exhibit a shape and size configured to resist deformation of the septum **120**, without limitation. Thus, it should be appreciated that one or more structural elements **141** may embody, for example, a washer or a disk that is frustoconical, domed, or otherwise shaped. In another embodiment, at least one structural element **141** may form, generally, a toroid. Further, at least one structural element **141** may exhibit at least one selected characteristic (e.g., exhibiting a selected size, shape, elasticity, strength, etc.) to impart a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected level of resistance to deformation of septum **120** in response to a pressure developed within a reservoir of an access port.

In another aspect of the instant disclosure, a septum may exhibit a curvature that resists deformation in response to a pressure developed within a reservoir of an access port. For example, FIG. **29** shows a septum **120** including a generally concave upper surface **123** and a generally convex lower surface **121**. Explaining further, generally concave upper surface **123** and a generally convex lower surface **121** may be exhibited by septum **120** in the absence of external forces (i.e., in an unstressed, equilibrium state). Such a configuration may provide resistance of the septum **120** to deformation due to a pressure developed within reservoir **66** of access port **110**, because the upper surface **123** of septum **120** would be forced to flatten (i.e., via deformation of septum **120**) before extending beyond the upper surface of housing **60**. In other embodiments, a septum may be compressed (e.g., by way of a tenon and mortise coupling or another peripheral coupling configuration between a septum and a housing) so that a curvature of the septum may be reduced or eliminated when the septum is assembled within the housing. However, such a configuration may increase the bulk flexibility or spring constant of the septum. Optionally, a structural element (as described above) may be included within the septum or upon a surface of the septum and may also be fabricated to exhibit concavity or convexity in the absence of external forces. Such a configuration may facilitate a favorable compressive stress field within the septum when coupled to a housing and may enhance resistance of the septum to deformation.

In a further configuration, a septum may include a structural frame or skeleton and a more pliant material configured to seal punctures created by a cannula. More specifically, a frame may comprise a material with a shore A hardness of at least about 80. Optionally, a frame may include a plurality of whiskers, fibers, or particles to stiffen or strengthen the frame. In one embodiment, nylon fibers, barium sulfate, or the like may be dispersed within a frame. Further, such a frame may be at least partially surrounded by a more pliant material exhibiting a Shore A hardness of about 50 or less (e.g., a Shore A hardness of about 40 to about 50). FIG. **30** shows top elevation view of a frame **178** including a plurality of spokes **179** extending from a generally common origin or region as well as rings **181** and **185**. As shown in FIG. **30**, spokes **179** in combination with one or both of rings **181** and **185** form apertures **188**. According to the instant disclosure, a relatively pliant material configured to seal punctures formed by a cannula passing through the material may at least partially surround such a frame **178**. For instance, FIG. **31** shows a schematic side cross-sectional view of septum **177** comprising a frame **178** and another material **190** molded partially about frame **178**. Thus, material **190** may substantially surround spokes **179** and may extend within apertures **188**. Further, as shown in FIG. **31**, ring **181** may form a tenon region **270** for coupling with a housing (as described above) as well as an upper septum surface **191** and a lower septum surface **193**. As may be appreciated with reference to shown in FIG. **31**, during use, a cannula may pass through a continuous upper layer of material **190** and a continuous lower layer of material **190**. Such a configuration may provide suitable sealing capability for septum **177**. It will be appreciated that many variations are contemplated by the instant disclosure. For example, FIGS. **32** and **33** show side cross-sectional views of different embodiments of a septum **177** including a frame **178** and another material **190** at least partially surrounding the frame **178**. Thus, a frame and a material at least partially surrounding the frame may exhibit arcuate or substantially planar surfaces and may be formed of selected thickness and comprising selected materials (e.g., silicone, etc.).

In a further aspect of a septum according to the instant disclosure, a septum may include a radiopaque material and may be configured to form a selected pattern when an x-ray is taken through the septum. For example, FIGS. **34** and **35** show schematic views of patterns **199** that may be generated by correspondingly positioned radiopaque material within a septum. Such a configuration may be useful for identifying the access port as being capable of accommodating particular power injection processes or for locating the septum of an access port.

The instant disclosure further contemplates that any infusion apparatus or device that is used in combination with an access port for infusing fluid at a rate of at least about 1 milliliter per second may be configured accordingly. For example, an infusion set for accessing a vascular access port may include a needle or cannula for puncturing a septum of the access port, a distal end for coupling to an injection apparatus, and tubing (e.g., at least one tubing section) extending between the cannula and the distal end. Generally, any components comprising an infusion set may be configured to withstand a selected flow rate and associated pressure developed by such a selected flow rate.

FIG. **36** shows one embodiment of an infusion set **310** including a base member **340**, a cannula **350**, a tubing section **314**, and connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and base **342** generally at joints **313** and **339**, respectively. Also, as shown in FIG. **36**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Further, each of the base member **340**, cannula **350**, tubing section **314**, and end connector **312** may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second through the infusion set **310**. In further detail, tubing section **314** may exhibit sufficient strength for withstanding at least about 200 psi without damage. Optionally, tubing section **314** may withstand at least about 300 psi without damage. Further a pressure at which a portion of the infusion set bursts (i.e., a burst pressure of the infusion set **310**) may be at least about 400 psi; optionally, such a burst pressure may be at least 600 psi. In one embodiment, tubing section **314** may be substantially optically clear or may be at least partially transparent. In one embodiment, generally, tubing section **314** may comprise a polymer, such as TECOTHANE®. More specifically, tubing section may comprise a polymer, such as TECOTHANE® 55D or a polymer, such as TECOTHANE® 95A. For example, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.048 inches (±0.003 inches) (i.e., 19 GA), tubing section **314** may comprise a polymer, such as TECOTHANE® 55D. In other examples, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.041 inches or

0.034 inches (±0.003 inches) (i.e., 20 GA or 22 GA, respectively), tubing section **314** may comprise a polymer, such as TECOTHANE® 95A. Optionally, any polymer, such as TECOTHANE® type material may be at least substantially free of a plasticizer, such as, for instance, Di(2-Ethylhexyl) Phthalate ("DEHP"). In one embodiment, connector **312** may comprise polyvinylchloride ("PVC") and may be, optionally, at least substantially free of plasticizer. The materials disclosed above are merely examples; more generally, tubing section **314**, connector **312**, base member **340**, and cannula **350** may comprise any material (e.g., thermoplastic, polyurethane, metal, etc.) suitable for providing a robust and effective infusion set **310**.

During use of the infusion set **310**, a mechanical injector may be operably coupled to connector **312** via fastening structure **311**. For example, fastening structure may comprise a luer-type connection or any other fluid connection structure. Thus, a fluid may be flowed through the infusion set at a flow rate of at least about 1 milliliter per second via an injection apparatus. As discussed above, a pressure drop through the infusion set **310** may be at least about 100 psi; optionally, a pressure drop through infusion set **310** may be at least about 185 psi.

In another embodiment, an infusion set may include two connectors. In one configuration, one connector may be structured for performing power injection and another connector may be structured for allowing syringe access. For example, FIG. **37** shows an infusion set **309** including a base member **340**, a cannula **350**, a tubing section **324**, an intermediate connector **322**, a tubing section **314**, and an end connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and connector **322** generally at joints **313** and **323**, respectively. Similarly, tubing **324** may be affixed or otherwise coupled to connector **322** and base member **340** generally at joints **325** and **329**, respectively. Infusion set **309** may be structured for fluid flow rates and pressures as discussed above in relation to infusion set **310**. Accordingly, tubing sections **314** and **324** may comprise materials (e.g., a polymer, such as TECOTHANE® and sizes as discussed above in relation to infusion set **310**, without limitation. Similarly, connectors **312** and **322** may comprise any materials (e.g., PVC) discussed above in relation to infusion set **310**, without limitation. As shown in FIG. **37**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Likewise, clamp device **326** may be suitably configured for allowing or preventing fluid flow through tubing **324**. In addition, connector **312** may include a fastening structure **311** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **312** to an injection apparatus. Also, connector **322** may include a fastening structure **321** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **322** to an injection apparatus.

Generally, the instant disclosure contemplates that, in one embodiment, connector **312** may be used for power injection, while connector **322** is capped. In another embodiment, a valve mechanism may selectively allow flow through tubing sections **314** and **324** via fluid flow through connector **312**, while preventing leakage from connector **322**. In addition, if infusion set **309** is not being used for power injection, a cap including a septum may be coupled to connector **322**, connector **312**, or both. Such a configuration may allow for a syringe to puncture the septum and infuse medication or remove a blood sample. Such a configuration may provide a convenient infusion set with separate connectors for power injection and syringe access, respectively.

In a further aspect contemplated by the instant disclosure, tubing that is used in connection with power injection may be structured for withstanding a selected pressure during use (e.g., power injection) and, optionally, may be configured to resist kinking. Generally, the instant disclosure contemplates that tubing may comprise a plurality of layers. In one embodiment, tubing may comprise a relatively high strength layer and at least one relatively flexible layer. Thus, any layers of tubing may comprise PTFE, polypropylene, polyetheretherketone ("PEEK"), polyimide silicone, fluorinatedethylenepropylene (FEP), perfluoroalkoxy (PFA), ethylenetetrafluoroethylene (ETFE), polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing. In one embodiment, the layers may be bonded to one or more adjacent layers. In another embodiment, each of the layers may be movable or slidable relative to one or more adjacent layers.

For example, FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of tubing **401** including an inner layer **420** and an outer layer **422**. Generally, at least one of inner layer **420** and outer layer **422** may exhibit relatively high strength and the other of inner layer **420** and outer layer **422** may be relatively flexible or vice versa. In one embodiment, inner layer **420** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like. Further, outer layer **422** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone or the like. Conversely, outer layer **422** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like, while inner layer **420** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone, or the like. Further, optionally, tubing may comprise a first layer exhibiting a modulus of elasticity and at least another layer exhibiting a modulus of elasticity that is less than the modulus of elasticity of the first layer. For example, a relatively high strength material may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, a relatively flexible material may exhibit a modulus of elasticity below about 390,000 psi. In another embodiment, at least one of layers **420** and **422** may comprise a composite material (e.g., a composite including particulate or fiber reinforcement). For example, in one embodiment, tubing may comprise polyurethane or PTFE including glass or carbon reinforcing fibers or particles. In one embodiment, each of the layers **420** and **422** may be movable or slidable relative to one or more adjacent layers. Such a configuration may withstand a selected internal pressure without damage to the tubing and may also resist kinking.

In another embodiment, a reinforcing element may be incorporated within at least one of the plurality of layers comprising tubing. For example, FIG. **40** shows a schematic side cross-sectional view of tubing **403** including inner layer **430** and outer layer **432**, wherein at least one reinforcing element **434** is incorporated within outer layer **432**. Optionally, at least one reinforcing element **434** may be incorporated within any layer or layers of a plurality of layers comprising tubing, without limitation. As shown in FIG. **40**, reinforcing element **434** may comprise a coil, in one embodiment. One of ordinary skill in the art will appreciate that many variations are possible, for example, at least one reinforcing element may comprise a mesh (e.g., a wire mesh, a fabric, a fiber mesh, etc.). In another embodiment, at least one reinforcing member

may comprise one or more elongated members extending longitudinally within at least one layer comprising tubing (e.g., aligned with the direction of extension of the tubing). In another embodiment, at least one reinforcing member may comprise one or more rings. Such a configuration may provide radial stiffness, strength, or both to a tubing section.

Referring to FIG. **40**, in one embodiment, inner layer **430** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, outer layer **432** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, silicone, or polyurethane. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.001 inches. As mentioned above, layers **430** and **432** may be bonded to one another or may be movable (slidable, twistable, etc.) with respect to one another. Optionally, a coating **433** may be applied to at least a portion of exterior surface of layer **432**. Such a coating **433**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In a further embodiment, FIG. **41** shows a schematic side cross-sectional view of tubing **405**, including inner layer **440** and outer layer **442**, wherein at least one reinforcing element **444** is incorporated within inner layer **440**. As shown in FIG. **41**, reinforcing element **444** may comprise a coil, in one embodiment. In other embodiments, reinforcing element may comprise any structure discussed above in relation to reinforcing element **434**, without limitation. In addition, in one embodiment, inner layer **440** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, or polyurethane. Further, outer layer **442** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.010 inches. Optionally, a coating **443** may be applied to at least a portion of exterior surface of layer **442**. Such a coating **443**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In an additional embodiment, tubing may include four layers. For example, FIGS. **42** and **43** show a cross-sectional end view and a side cross-sectional view of another embodiment of tubing **400**. More particularly, as shown in FIGS. **42** and **43**, tubing **400** includes layers **402**, **404**, **406**, and **408**. As shown in FIG. **42**, layer **402** defines a lumen **410**. In one embodiment, lumen **410** may have a substantially circular cross-sectional shape and may exhibit a diameter of about 0.024 inches. In another embodiment, each of the layers **402**, **404**, **406**, and **408** may be movable or slidable relative to one or more adjacent layers. In addition, layer **402** may comprise a material exhibiting a relatively high tensile strength. Such a configuration may withstand relatively high pressures within lumen **410**. For example, layer **402** may comprise PEEK, polyimide, etc. Typically, such relatively high strength materials may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, each of layers **404**, **406**, and **408** may comprise a material that is relatively flexible. Such layers **404**, **406**, and **408** may each exhibit a tensile strength that is less than the tensile strength of layer **402**. For example, each of layers **404**, **406**, and **408** may comprise a fluoropolymer, PEBAX®, polyethylene terephthalate ("PET"), silicone, etc. Typically, such relatively flexible materials may exhibit a modulus of elasticity below about 390,000 psi. However, any layers may comprise PTFE, polypropylene, silicone, FEP, PFA, ETFE, polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing, without limitation.

In a further aspect of the instant disclosure, at least one layer comprising a tubing section may extend distally from a slender hollow structure for accessing a reservoir of an access port through a septum. Put another way, at least one layer may extend from a tubing section and may be structured for puncturing a septum of an access port. For instance, FIGS. **44** and **45** show a schematic side cross-sectional view of tubing **400**, **401**, **403**, **405**, and an access port **50**. Tubing **400**, **401**, **403**, **405** (as described above) includes a slender hollow region **450**. Further, slender hollow region **450** may be relatively stiff and suited for penetrating a septum **80** of an access port **50**, as shown in FIG. **45**. Thus, a slender hollow region **450** extending from a distal end of tubing **400**, **401**, **403**, **405** (which comprises a plurality of layers) may form a needle or cannula for fluid communication between a lumen of tubing **400**, **401**, **403**, **405**, and a reservoir **66** of access port **50**. More particularly, a slender hollow region **450** may comprise one or more layers exhibiting a relatively high strength of relatively high-strength layers (e.g., PEEK) forming tubing **400**, **401**, **403**, **405**. In one embodiment, an innermost layer of tubing **400**, **401**, **403**, **405** may form slender hollow region **450**. Such a configuration may be advantageous and may, for example, reduce the complexity of manufacturing an infusion set.

Many different embodiments of vascular access apparatuses or infusion systems may incorporate one or more aspects of the instant disclosure. Some embodiments of a vascular access apparatuses or infusion systems are disclosed in U.S. Patent Application No. 60/675,309, filed Apr. 27, 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the infusion systems, apparatuses, or methods, taken alone or in combination, described in U.S. Patent Application No. 60/675,309, may be structured or otherwise suited for performing power injection (e.g., accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation).

For example, the instant disclosure contemplates that an infusion system configured for establishing fluid communication between a flexible tube and a reservoir of an access port may be structured for power injection. Such an infusion system may include a slender pointed element that facilitates placement of the flexible tube through a septum of the access port and is removable from the infusion system once the flexible tube is appropriately positioned.

Particularly, FIG. **46** shows in one embodiment an infusion system **510** in an exploded assembly view, including an insertion assembly **520**, a safety clip **530**, a hub **540** flexible tubing **590**, extension tube **570**, clamp device **560**, and tube connector **580**. In further detail, FIG. **47** shows a partial side cross-sectional view of infusion system **510**. As shown in FIG. **47**, insertion assembly **520** comprises a base **528** and a slender pointed element **522** (e.g., a needle, a trocar, or a cannula) secured thereto. As shown in FIG. **47**, slender pointed element **522** includes a pointed end **525**. In a particular embodiment, the instant disclosure may utilize a slender pointed element having a "non-coring" pointed end (i.e., pointed end **525** is not "open" or hollow) to avoid damaging a septum of a port into which the slender pointed element is inserted. The slender pointed element **522** may comprise any conventional needle, trocar, or cannula material, such as a stainless steel (e.g., AISI 304 stainless steel), or may, in another embodiment, comprise a relatively hard plastic. In one embodiment, base **528** may be injection molded or otherwise formed about slender pointed element **522** to capture a portion of the slender pointed element within the base **528**, as best seen in FIG.

47. Further, base **528** may optionally include a recess **524** structured for accommodating other mechanisms (e.g., safety clip **530**), if such a recess is desirable. Base **528** may also, optionally, include a coupling feature **526** (e.g., a protrusion) structured for coupling to a coupling feature **544** (e.g., a recess) formed in hub **540**. Hub **540**, as shown in FIG. **47**, may generally include hub body **550**, manifold element **561**, septum **548** and cap **546**. In one embodiment, hub body **550** may comprise TECOFLEX® (e.g., such as TECOFLEX® 85A-B20). Further, hub body **550** may define wing structures **541** and **543** (FIG. **46**), which may be configured for affixing the hub to skin of a patient (e.g., by taping wing structures **541** and **543** to a patient, adhesively affixing wing structures **541** and **543** to a patient, or otherwise affixing wing structures **541** and **543** to a patient). Wing structures **541** and **543** may be employed for manipulation of the hub, such as, for example, when inserting the slender pointed element **522** and flexible catheter **590** into an implanted port or when removing the slender pointed element **522** from an implanted port. Hub body **550** may optionally include a recess **542**, if such a recess is desirable. As shown in FIG. **47**, recess **542** may have a retaining lip **559** for retaining safety clip **530** therein, while long slender element **522** is positioned through the safety clip, as discussed in further detail hereinbelow.

Hub **540** may be structured for allowing the slender pointed element **522** of insertion assembly **520** to pass through the hub **540** and through septum **548**, which is positioned within the hub **540**. Put another way, manifold element **561** may define a plurality of passageways and at least one septum **548** through which fluid communication with the plurality of passageways may be accomplished. Explaining further, a manifold element **561** may be configured for housing septum **548** to provide a seal a port or opening of a plenum defined by manifold element **561**. Optionally, a cap element **546** may be positioned to capture septum **548** between cap element **546** and manifold element **561**. Cap **546** may include an aperture **547** for allowing a slender pointed element to pass therethrough and through septum **548**. Thus, slender pointed element **522** (e.g., an appropriately sized trocar, non-coring needle, or non-coring cannula) may be inserted through and removed from septum **548** without compromising the ability of septum **548** to seal. Further, the presence of cap **546** may allow for so-called "power injection" to occur via manifold element **561**, wherein pressures within manifold element **561**, tubing **570**, and flexible catheter **590** may reach at least about 200 psi or higher. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, for performing power injection, etc.), without limitation.

As shown in FIG. **47**, flexible catheter **590** may be affixed to manifold element **561** and extension tube **570** may be affixed to manifold element **561**. In one example, extension tube **570** and flexible catheter **590** may be chemically bonded to manifold element **561**. In another example, an adhesive may affix extension tube **570** to surface **552** a part of manifold element **561**. Similarly, an adhesive may affix flexible catheter **590** to inner surface **562** another port of manifold element **561**. Further, the hub body **550** may be formed (e.g., injection molded, cured, or otherwise over-molded) over the manifold element **561** (and, optionally the septum **548**, the cap **546**, or both) and at least a portion of the extension tube **570** as shown in FIG. **47**. In another embodiment, the hub body **550** may be formed over at least a portion of the flexible catheter **590**, if desired.

Generally, as mentioned above, any tubing disclosed in the instant disclosure may comprise a portion of infusion system **510**. Further, tubing clamps and connection devices as known in the art, may be employed for extension tubing **570**, clamp device **560**, and tube connector **580**.

Flexible catheter **590** may comprise any material that is suitable for power injection. For example, in one embodiment, flexible catheter **590** may comprise a polymer, such as TECOTHANE® (e.g., TECOTHANE® TT1055 D). As shown in FIG. **47**, flexible catheter **590** may include an elongated lumen therein. Further, flexible catheter **590** may have, proximate to opening **593** thereof, a transition region **595** wherein a cross-sectional size (transverse to the lumen **594**) of the flexible catheter **590** increases as a function of increasing distance from opening **593**. Optionally, transition region **595** may include two distinct tapers, although the instant disclosure contemplates more generally that at least one taper, at least one arcuate surface, or combinations thereof may define transition region **595**. Generally, at least one aperture (e.g., one or more than one) may be provided proximate opening **593** that extends through the tubular body of flexible catheter **590** and communicates with lumen **594**. As shown in FIG. **47**, flexible catheter **590** may include two apertures **592** in fluid communication with lumen **594**.

As shown in FIG. **47**, slender pointed element **522** may extend through safety clip **530**, through aperture **547** of cap **546**, and into flexible catheter **590**. Slender pointed element **522** may be structured for allowing fluid communication within flexible catheter **590**. More particularly, slender pointed element **522** may be sized so as to allow for clearance between the exterior of the slender pointed element **522** and the interior (i.e., the lumen) of the flexible catheter **590**. In one embodiment, slender pointed element **522** may include at least one longitudinally extending indentation (with respect to a nominal cross-sectional shape of the slender pointed element **522**). For example, slender pointed element **522** may have a pointed end **525** and may include longitudinally extending indentations extending along (i.e., along a longitudinal axis of) slender pointed element **522**. In another embodiment, slender pointed element **522** may be generally circular, and longitudinally extending indentations may form a substantially triangular cross section of the slender pointed element **522** over the portion of the slender pointed element that they are formed.

In a further embodiment, an infusion system may be structured so that a slender pointed element passes through an extension tube, a flexible catheter, or both. Explaining further, appropriate placement and configuration of a septum may allow for a slender pointed element to pierce or pass into an extension tube, a flexible catheter, or both. FIGS. **48** and **49** show another embodiment of a hub **540** including recess **542**, sleeve **620**, and septum **548**. In addition, at least a portion of each of extension tube **570** and flexible catheter **590** may extend partially within hub body **550**. Further, flexible catheter **590** extends partially within extension tube **570**. Put another way, flexible catheter **590** may at least partially overlap with extension tube **570** and vice versa. In another embodiment, a single tubular element may extend through hub **540** and function as both the flexible catheter **590** and extension tube **570**, if desired. Further, optionally, septum **548** may at least partially surround a portion of extension tubing **570**. Such a configuration may facilitate sealing of septum **548** upon removal of slender pointed element **522** therefrom. Sleeve **620** may compress septum **548** so as to facilitate sealing of septum **548** upon removal of slender pointed element **522** from the region of the septum **620** that the sleeve **620** surrounds. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, etc.) for performing power injection, without limitation.

Further, FIG. **50** shows a perspective view of safety clip **530** positioned generally about pointed end **525** of slender pointed element **522**. Safety clip **530** includes legs **533** and **535** each having a curved end region, respectively, and a hole **534** sized for passing there through slender pointed element **522**. In further detail, initially slender pointed element **522** may be passed through hole **534** and between legs **533** and **535** may be positioned and configured so as to allow the slender pointed element **522** to extend there past. Further, when the slender pointed **522** element is positioned therein and safety clip **530** is positioned within recess **542**, safety clip **530** may be sized so that it will fit within the retaining lip **543** (FIG. **49**) of recess **542** (FIG. **49**). However, legs **533** and **535** may be biased so that if the pointed end **525** of the slender pointed element **522** is moved toward hole **534** and does not extend past the curved end regions of the legs **533** and **535**, legs **533** and **535** will move toward one another to effectively capture the pointed end **525** of the slender pointed element **522**. Safety clip **530** may comprise any self-actuating device for capturing a pointed end **525** of a slender pointed element **522**. Such a safety clip **530** may reduce the chance of inadvertent insertion of the slender pointed element **522** into another person, particularly the medical practitioner that is installing and removing the slender pointed element **522**.

The instant disclosure further recognizes that because the consequences of improperly pressurizing an access port (and a catheter affixed to the access port, if any) or an infusion set may be problematic, it may be advantageous to provide at least one identification attribute to components of an infusion system so that all of such components may be suitable for withstanding an anticipated maximum flow rate and pressure associated with a selected infusion process. Put another way, an access port that is configured for accommodating a flow rate of at least about 1 milliliter per second may include at least one identification attribute. Such an at least one identification attribute may be observed (e.g., visually, by palpation, ultrasonically, radiographically, etc.) or otherwise detected. The term, "identification," as used herein and in connection with any infusion devices (an access port, infusion set, etc.), means the ability to correlate selected information of interest with a perceivable feature.

The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. Patent Application No. 60/658,518, filed 4 Mar. 2005, may identify an access port as being structured for power injection. Also, embodiments of an access port including at least one identification attribute are disclosed in U.S. patent application Ser. No. 11/320,223, filed 28 Dec. 2005, the disclosure of which is incorporated, in its entirety, by this reference. The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. patent application Ser. No. 11/320,223 may identify an access port as being structured for power injection. Further, an access port may be identified by a maximum rate at which fluid may safely be infused. For example, at least one identification attribute may indicate that an access port is configured for accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation.

Referring to an access port encompassed by the instant disclosure, at least one attribute of a housing of an access port may provide at least one identification attribute for identifying the access port as being structured for power injection at a rate of at least about 1 milliliter per second. In one embodiment, at least one physical attribute (e.g., size, shape, etc.) of an access port may identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port.

Thus, one aspect of the instant disclosure relates to a method of identifying an access port (e.g., subcutaneously implanted or otherwise situated, without limitation) as being suited for power injection. More particularly, an access port including a septum may be provided. Further, at least one attribute of the access port may be perceived. In addition, the subcutaneously implanted access port may be identified as being suitable for power injection in response to perceiving the at least one attribute of the access port.

In one embodiment, at least one attribute for identification may comprise at least one feature of an access port housing. In further detail, FIG. **51** shows a perspective view of an assembled access port **50**. As shown in FIG. **51**, a side periphery **295** (e.g., one or more side walls and, optionally, exposed surfaces of suture plugs **291**) of access port **50** may be generally triangular. Thus, cap **54** and base **56** may collectively form a generally triangular housing **60** of access port **50**. Also, the instant disclosure contemplates that side periphery **295** may taper or arcuately extend between an upper surface **61** of cap **54** and lower surface **51** of base **56**. As shown in FIG. **51**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **51**, if planar, of base **56**) of access port **50** may be larger proximate to lower surface **51** of base **56** and may be relatively smaller proximate to an upper surface of cap **54**. FIG. **52** shows a top elevation view of the access port **50** shown in FIG. **52** and illustrates a generally triangular shape defined by side periphery **295**. Additionally, FIG. **53** shows a simplified representation of a transverse cross section of access port **50**. As shown in FIG. **53**, side periphery **295** of access port **50** may define three side regions **303** that extend between associated vertex regions **301**. In addition, in one embodiment and as shown in FIG. **53**, side periphery **295** may define a substantially equilateral generally triangular shape. As may be appreciated, side regions **303** may arcuately extend between associated vertex regions **301**; thus, side regions **303** may form "sides" of a generally triangular shape. Further, although vertex regions **301** are rounded, it will be appreciated that such vertex regions **301** form an intersection between adjacent side regions **303**. Accordingly, it will be appreciated that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect at or within vertex regions, without limitation. For example, "generally triangular" encompasses three-sided polygons, circular triangles, equilateral triangles, etc., without limitation.

Furthermore, in a further embodiment, at least one attribute for identification may comprise a radiographic marker. More particularly, an access port may exhibit an observable pattern, symbol, marker, or other indicium that indicates that the access port is structured for accommodating a particular flow rate, pressure, or both. In another embodiment, at least one attribute for identification may comprise a perceptible aspect, such as a visually perceivable feature. For example, at least one color, at least one symbol, at least one typographical character (e.g., a letter, a number, etc.), a pattern, or any other indicium that may be visually perceivable or otherwise perceptible may be used. In a yet additional embodiment, an ultrasound detectable feature may be incorporated within an access port. In a further additional embodiment, an access port may comprise an RFID tag.

It will be appreciated that other equipment and devices (e.g., infusion sets, tubing, injectors, etc.) may be identifiable in relation to a suitable maximum flow rate or maximum pressure. For example, particular infusion apparatuses may include one or more of the above-mentioned identification attributes or features. Such a configuration may allow for different components (e.g., tubing, needles, access ports,

mechanical injectors, etc.) to be matched with one another. For example, substantially similar or matching identification attributes shared by a power injection apparatus, an infusion set, and an access port may indicate suitability for use with one another to perform a selected power injection process.

Another aspect of identification of an access port may relate to identification of a patient within which an access port is implanted. More specifically, a patient may be provided with an identification card that carries perceptible (e.g., visually, via magnetic strip, bar code, manually, or by other suitable mechanisms) information regarding an implanted port. Thus, such an identification card may be presented to a health care worker, the information carried by the identification card may be perceived, and the access port may be identified. Upon identifying the access port, characteristics of the access port may be ascertained, such as, for instance, a maximum flow rate, a maximum pressure, suitability for a particular procedure or procedures, etc. In another embodiment, a wristband or bracelet may be provided to a patient within whom an access port is implanted. In a further embodiment, a key chain including an information carrying device, such as, for example, a magnetic strip, a bar code, a computer readable media or device (e.g., a compact disk, "flash" memory, a disk drive, etc.), or any other suitable information carrying device. In another embodiment, a sticker containing the port information can be applied to the chart of the patient. In further embodiments, labeling on the infusion set can be used to identify the set as power injection compatible.

A further aspect of the instant disclosure relates to a septum comprising a gel or viscous liquid. The term "gel," as used herein, means a colloid with at least one solid component suspended within at least one liquid component, wherein the solid particles (e.g., polymer particles) are attracted or otherwise linked to one another (e.g., entangled or cross-linked) by covalent, ionic, or dispersion (physical) forces. Thus, in one embodiment, a gel may be a colloid in which the solid disperse phase forms a network in combination with the fluid continuous phase to produce a viscous or semi-rigid sol. A gel may exhibit stress-strain behavior that is elastic, viscoelastic, or plastic, without limitation. The term "viscous liquid," as used herein, means a liquid exhibiting a viscosity of about 20,000 centipoises or higher.

One or more passageways formed through a septum positioned within a housing to form an access port may allow for leaking of fluid through the one or more passageways if the reservoir of the access port is pressurized. The instant disclosure contemplates that a gel region may be generally positioned between an upper surface of a septum and a lower surface of a septum, to facilitate a cannula extending through the septum from the upper surface to the lower surface to also pass through at least a portion of the gel region.

For example, in one embodiment, a septum may include a gel that is at least substantially surrounded by a body material. For instance, FIG. **54** shows a schematic, side cross-sectional view of a septum **610** including a body **612** and a gel region **620** positioned within body **612**. Gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. In one embodiment, gel region **620** may comprise a silicone gel. In another embodiment, a gel region may comprise an initially an uncured liquid (i.e., has a relatively low viscosity) that may be cured to cause the liquid to form a gel. In a further embodiment, gel region **620** may comprise a viscous liquid, or a viscoelastic material.

In one example, gel region **620** may comprise an elastomer, such as, DOW CORNING® 7-9600 Soft Filling Elastomer, Parts A & B, which is commercially available from DOW CORNING Corporation of Midland, Mich. In another embodiment, gel region **620** may comprise Silicone Gel MED-6340, which is commercially available from NuSil Technology of Carpinteria, Calif. In yet a further embodiment, gel region **620** may comprise an elastomer exhibiting a Shore A hardness of about 20 to about 30, such as, for instance, DOW CORNING® C6-515 Liquid Silicone Rubber, Parts A & B or DOW CORNING® C6-530 Liquid Silicone Rubber Parts A & B, either of which is available from DOW CORNING Corporation of Midland, Mich. Further, optionally, body **612** of septum **610** may comprise a silicone material with a Shore A hardness of about 50 to about 60. In another embodiment, body **612** and/or upper surface **614** of septum **610** may comprise a silicone material with a Shore A hardness of about 60 to about 80. Optionally, body **612** and/or upper surface **614** of septum **610** may comprise a fluoropolymer (e.g., PTFE, etc.) or polyurethane.

One of ordinary skill in the art will understand that, upon removal of a cannula extending through at least a portion of gel region **620**, a passageway or channel formed through gel region **620** may rebound, recover, seal, or heal. Further, gel region **620** may seal passageways formed through body **612** and upper surface **614**. For example, gel region **620** may inhibit or prevent fluid leakage from a reservoir of an access port through the septum **610** when a pressure within the reservoir exceeds an ambient pressure external to the access port (e.g., during a power injection process, any process for flowing a fluid through an access port as described above, or any process for flowing a fluid through an access port as known in the art, without limitation). In addition, gel region **620** may be formulated and/or body **612** may be structured so that a cannula passing through septum **610** will resist transferring or removing any of the material comprising gel region **620** outside of a selected boundary or envelope. In one embodiment, body **612** may be structured to remove a material comprising gel region **620** from a cannula passing through the body **612**.

Any of the septum embodiments discussed herein may include at least one gel region. For example, FIG. **55** shows a schematic, side cross-sectional view of a septum **611** including a body **612** and a gel region **620**. As discussed above, gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. Such a configuration may provide a robust septum that resists leaking even if a multitude of passages are formed through the septum with a cannula. Furthermore, providing a septum comprising a gel may improve a sealing ability or quality of the septum. Accordingly, a septum including a gel material may exhibit a reduced thickness (i.e., from an upper surface to a lower surface) in comparison to a conventional septum. For example, FIG. **56** shows a septum **613** including a body **612** and a gel region **620**, wherein a thickness T is less than a conventional thickness of a conventional septum. In one embodiment, a thickness T of septum **613** may be about 0.500 inches or less.

The instant disclosure contemplates a variety of different manufacturing methods may be employed for forming a septum comprising a gel. For example, generally, a body of a septum may be formed to substantially surround at least one gel region or a recess or chamber may be formed by a septum body that is filled with a gel. In one embodiment, a gel region may be suspended within a mold for forming a body of a septum. More particularly, FIG. **57** shows a schematic, side cross-sectional view of a first mold **652** and a second mold **654**, wherein gel region **620** is positioned between (e.g., suspended) first mold **652** and second mold **654**. As shown in

FIG. **57**, gel region **620** is positioned by a frame element **630**, which abuts parting surface **655** of second mold **654**. As shown in FIG. **57**, frame element **630** may be positioned by pins **606**. In other embodiments, frame element **630** may be suitably positioned, without limitation. In a particular embodiment, parting surface **653** of first mold **652** may be positioned proximate to parting surface **655** of second mold **654** (i.e., parting surfaces **653** and **655** may be separated by frame element **630**) to form a chamber defined by cavity **658** and cavity **656**. Further, a hardenable material (e.g., a curable material, such as a curable silicone, a thermoplastic, a resin, etc.) may be injected into the chamber and hardened. Thus, the hardenable material may surround or encapsulate gel region **620** and may exhibit a geometry that is complimentary to cavities **656** and **658**.

Generally, frame element **630** may be coupled to or affixed to gel region **620**. In one embodiment, frame element **630** may couple or engage at least a portion of a periphery of gel region **620**. In another embodiment, frame element **630** may be substantially planar and gel region **620** may rest upon or may be formed upon frame element **630**. Further, in one embodiment, frame element **630** may extend at least partially through gel region **620**. Optionally, frame element **630** may cover or extend across mold cavity **656** of second mold **654**. In one example, frame element **630** may comprise a mesh (e.g., a metal or polymer mesh, a fabric, a fiber mesh, etc.). In another example, frame element **630** may comprise a sheet or layer of silicone and may be, optionally, perforated. If frame element **630** comprises a mesh or is perforated, fluid communication (of a hardenable material) between cavity **658** and cavity **656** may occur, which may be desirable for avoiding shifting of gel region **620** and/or frame element **630** during encapsulation. Once gel region **620** is encapsulated, selected portions of frame element **630** may be trimmed or cut, if desired.

In another method of forming a septum including at least one gel region, a septum body may be formed to include at least one chamber, which may be filled with a gel. For example, FIG. **58** shows a septum body **612** defining chamber **621**. Optionally, opening **623** may be defined by body **612**. Accordingly, a gel may be introduced within chamber **621** via the opening **623** and the opening, optionally, may be closed. For example, an uncured gel may be introduced within chamber **621**. Further, the uncured gel may be cured by heating or by other suitable methods. Such a configuration may form a gel region as described above in relation to FIG. **55**. In one embodiment, chamber **621** may be formed by an air injection molding process, a blow molding process or any other process known in the art for creating a chamber **621** within body **612**. In another embodiment, body **612** may be formed about a removable plug or filler (e.g., a silicone plug, steel, or aluminum insert). Such a plug or filler may be coated with a nonstick coating (e.g., TEFLON®, silicone, or any nonstick coating known in the art). Thus, chamber **621** may be formed upon removal of the plug or filler. In other embodiments, portions of a septum may be formed, filled with a gel (or a liquid precursor to a gel), and bonded to one another to form a septum. In a further embodiment, body **612** may be initially formed and may enclose chamber **621** within body **612**. In addition, body **612** may be cut to form an opening to allow chamber **621** to be filled with a gel. Such an opening of body **612** may be closed or sealed to capture or form a gel region. In yet a further embodiment, a solid body may be formed and a chamber may be formed by slicing the solid body. In such a configuration, filling the chamber may cause the solid body to deform to form a domed or raised region, if desired. It will be appreciated that many different approaches may be employed for forming a chamber **621** within body **612** and subsequently filling the chamber with a gel.

In an additional embodiment, a septum may include a gel region positioned between a body and a layer of material bonded to or formed over at least a portion of the gel region and at least a portion of the body. For example, FIG. **59** shows a schematic, side cross-sectional view of a septum **615** including a body **632**, a gel region **620**, and a layer **626**. As shown in FIG. **59**, gel region **620** may be positioned within a recess **633** formed in the body **632** and layer **626** may extend over a portion of gel region **620** and a portion of body **632**. One of ordinary skill in the art will understand that gel region **620** may be positioned or formed within recess **633** of body **632** and then layer **626** may be formed or positioned over gel region **620** and body **632**. Further, layer **626** may be bonded (e.g., adhesively bonded, bonded via curing, bonded via welding, or as otherwise known in the art) or otherwise affixed to body **632** to capture gel region **620**. In one embodiment, septum **615** may be formed by a multiple head (e.g., a two head) injection molding apparatus. More particularly, such a molding apparatus may be capable of forming the body **632**, forming the gel region **620** within the body **632**, and forming (e.g., over molding) the layer **626** over the gel region **620** and body **632** by suitable mold configurations and material injections. Layer **626**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 60 and about 80. Body **632**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 40 and about 50. Accordingly, during use of septum **615** (installed within a housing to form an access port) a cannula may pass through layer **626**, at least a portion of gel region **620**, and body **632**. Such a configuration may facilitate positioning of a cannula extending through layer **626**, at least a portion of gel region **620**, and body **632**.

While certain representative embodiments and details have been shown for purposes of illustrating aspects of the instant disclosure, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing form the scope of the instant disclosure, which is defined in the appended claims. For example, other access port sizes and shapes may be employed; and various other embodiments structures may be employed for forming at least one identifiable feature of an access port of the instant disclosure. The words "including" and "having," (including their variants) as used herein including the claims, shall have the same meaning as the word "comprising."

What is claimed is:

1. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

2. The assembly according to claim **1**, wherein the other of the first and second features is a structural feature of the body or septum of the access port perceivable via palpation.

3. The assembly according to claim **2**, wherein the structural feature comprises a body having a particular geometric shape.

4. The assembly according to claim **1**, wherein the radiographic marker is a radiographic pattern included in the septum of the access port.

5. The assembly according to claim **1**, wherein the radiographic marker is one or more radiographic letters.

6. The assembly according to claim **1**, wherein the third feature comprises visually perceptible information provided on an element selected from the group consisting essentially of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patientID card, a label provided on packaging of the access port, and combinations thereof.

7. The assembly according to claim **1**, wherein the third feature is incorporated in an infusion set packaged with the vascular access port.

8. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port separate from the first identifiable feature, the second feature perceivable following subcutaneous implantation of the access port to identify the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

9. The assembly according to claim **8**, wherein the other of the first and second features is a structural feature of the body or septum of the access port perceivable via palpation.

10. The assembly according to claim **9**, wherein the structural feature comprises a body having a particular geometric shape.

11. The assembly according to claim **8**, wherein the radiographic marker is a radiographic pattern included in the septum of the access port.

12. The assembly according to claim **8**, wherein the radiographic marker is one or more radiographic letters.

13. The assembly according to claim **8**, wherein the third feature comprises visually perceptible information provided on an element selected from the group consisting essentially of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof.

14. The assembly according to claim **8**, wherein the third feature is incorporated in an infusion set packaged with the vascular access port.

15. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is an RFID tag; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

16. An assembly for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is an ultrasound-detectable feature; and

a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

* * * * *

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Beasley et al.

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(54) **INFUSION APPARATUSES AND RELATED METHODS**

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(58) **Field of Classification Search**
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See application file for complete search history.

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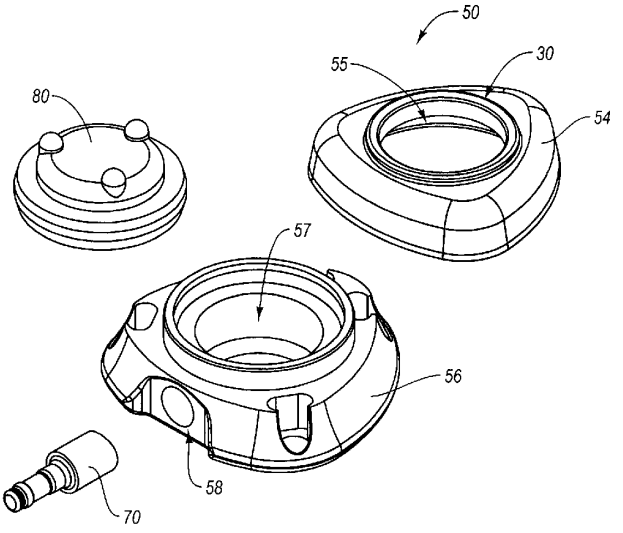
(57) **ABSTRACT**

Assemblies for identifying a power injectable vascular access port are described. One assembly includes a vascular access port, a first identifiable feature, a second identifiable feature, and a third identifiable feature. The first identifiable feature is incorporated into the access port and identifies the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port. The second identifiable feature is incorporated into the access port and identifies the access port as suitable for accommodating a pressure within the cavity of at least 35 psi. The third identifiable feature is separated from the access port and confirms that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

4 Claims, 32 Drawing Sheets



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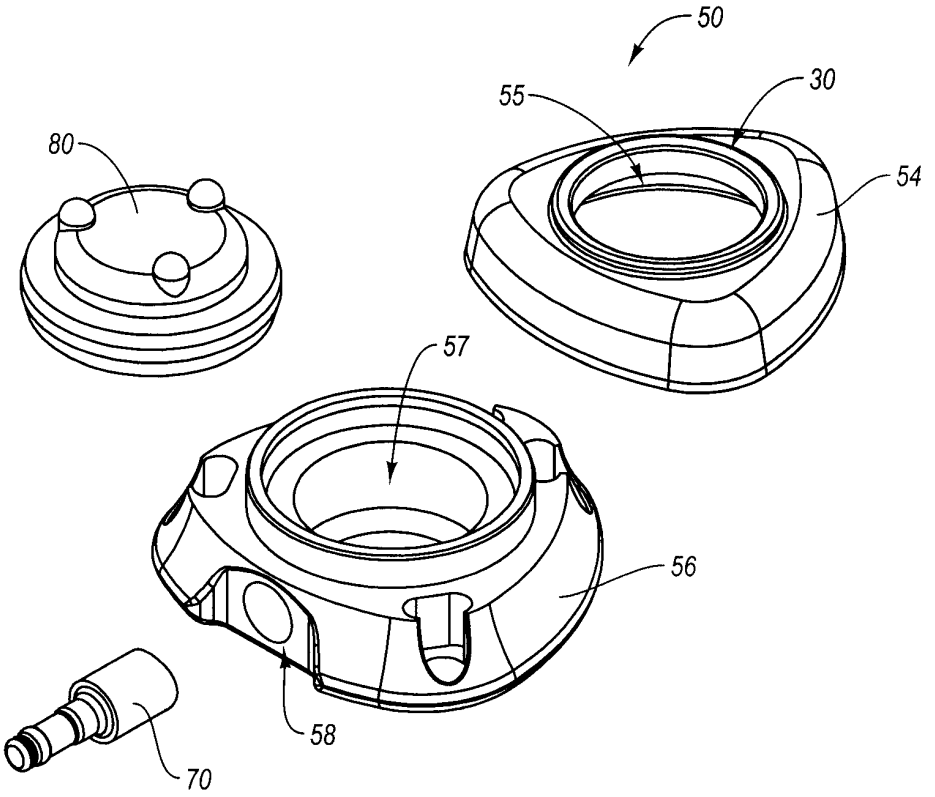


FIG. 1

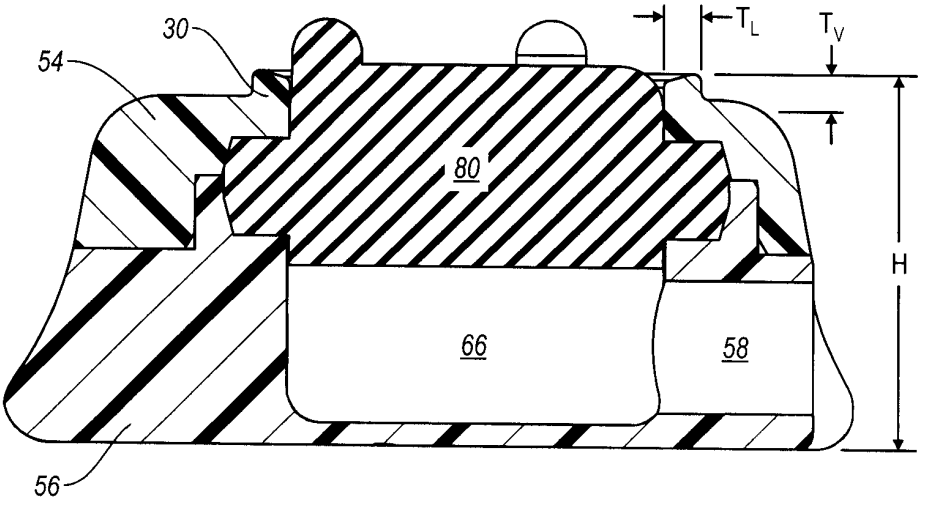


FIG. 2

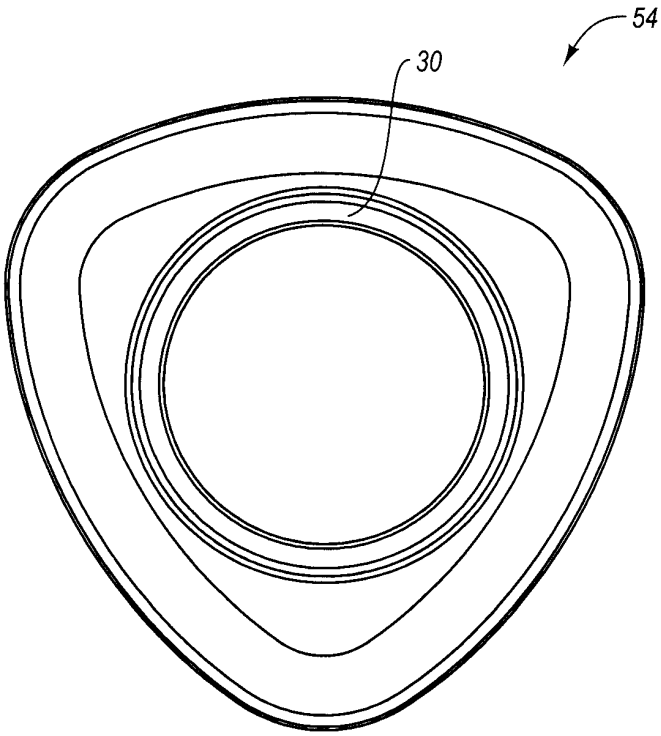


FIG. 3

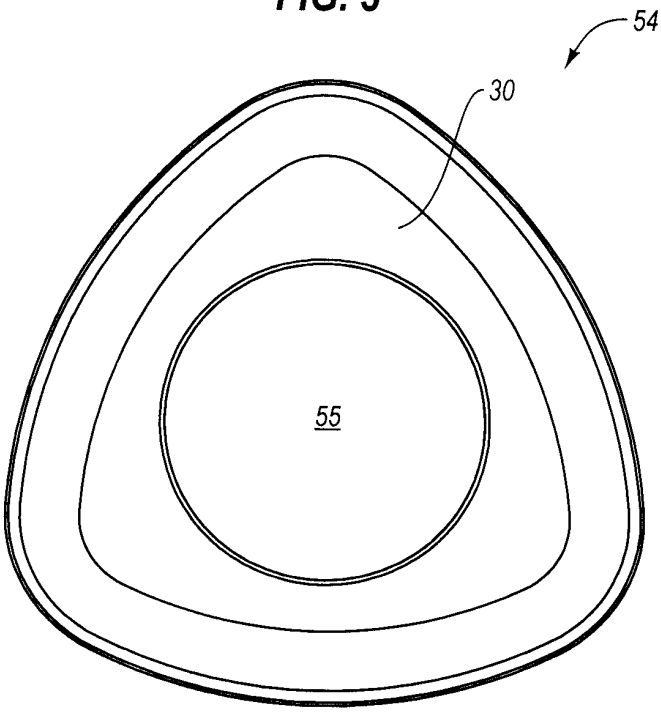


FIG. 4

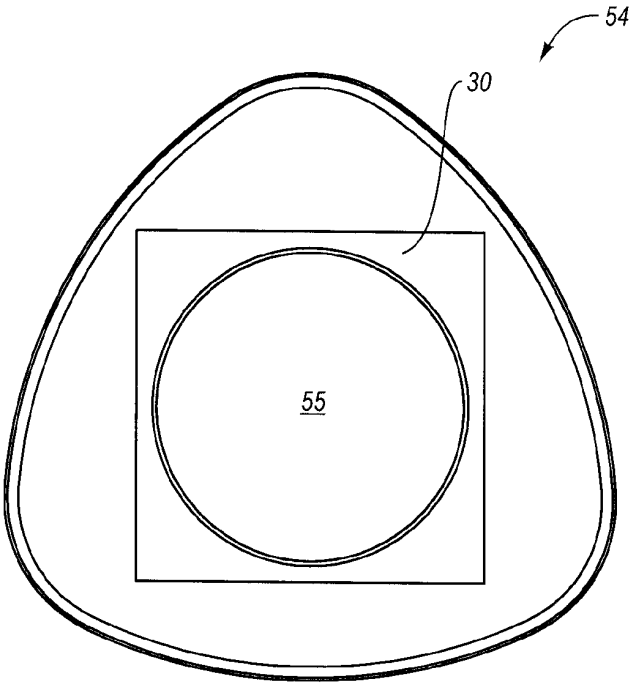


FIG. 5

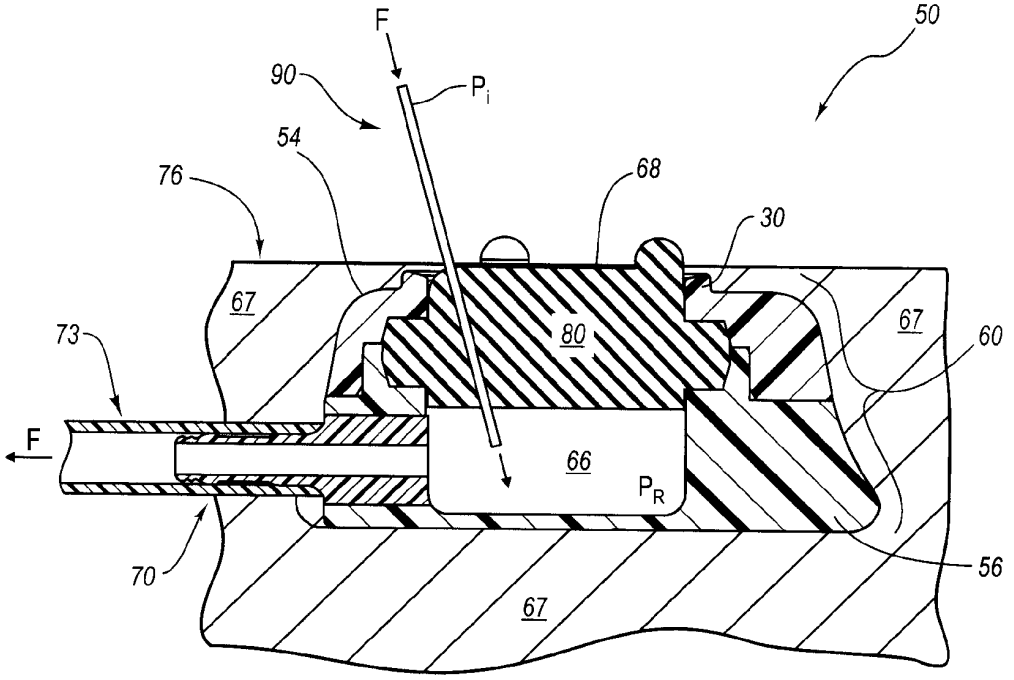


FIG. 6

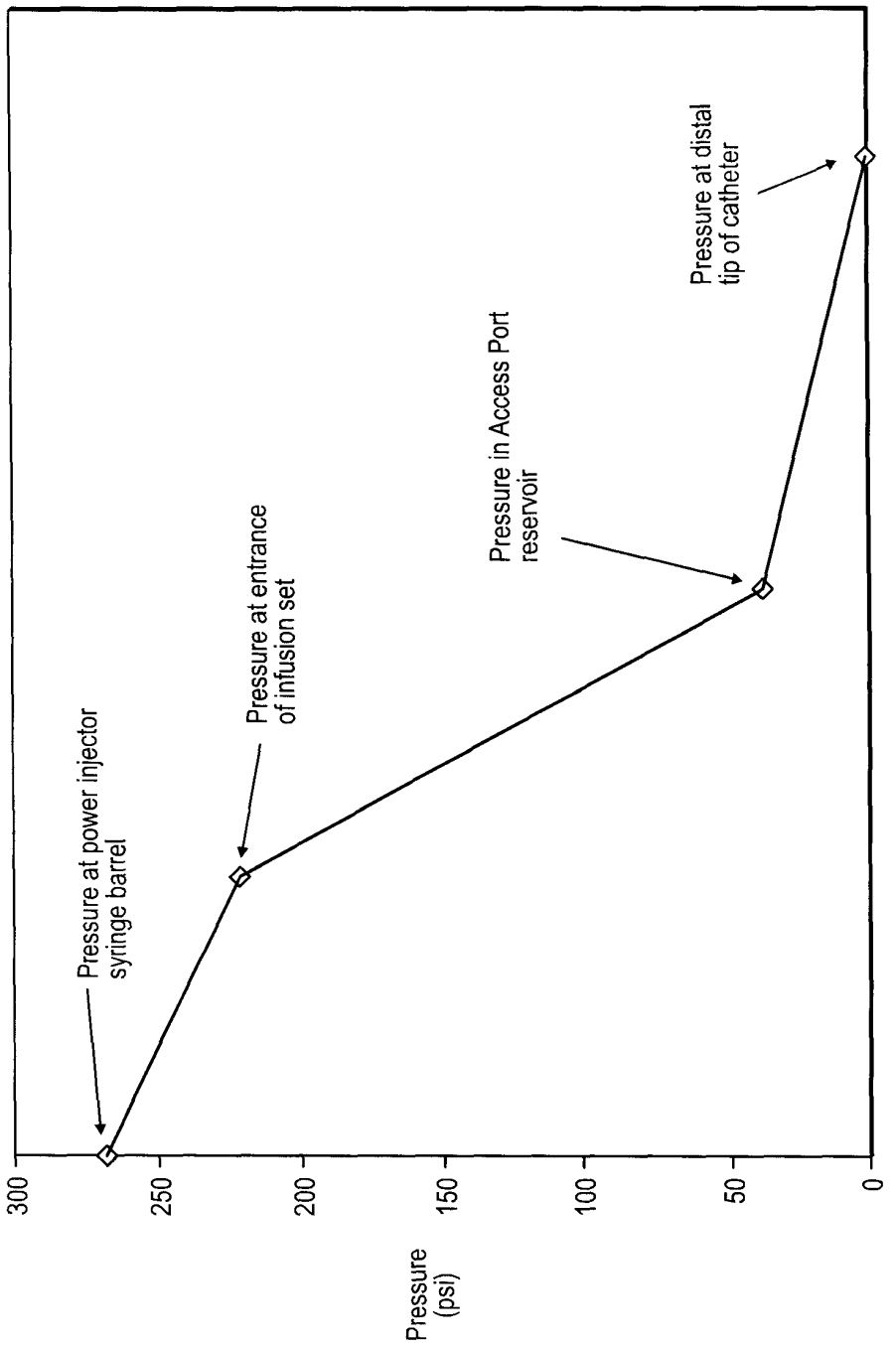
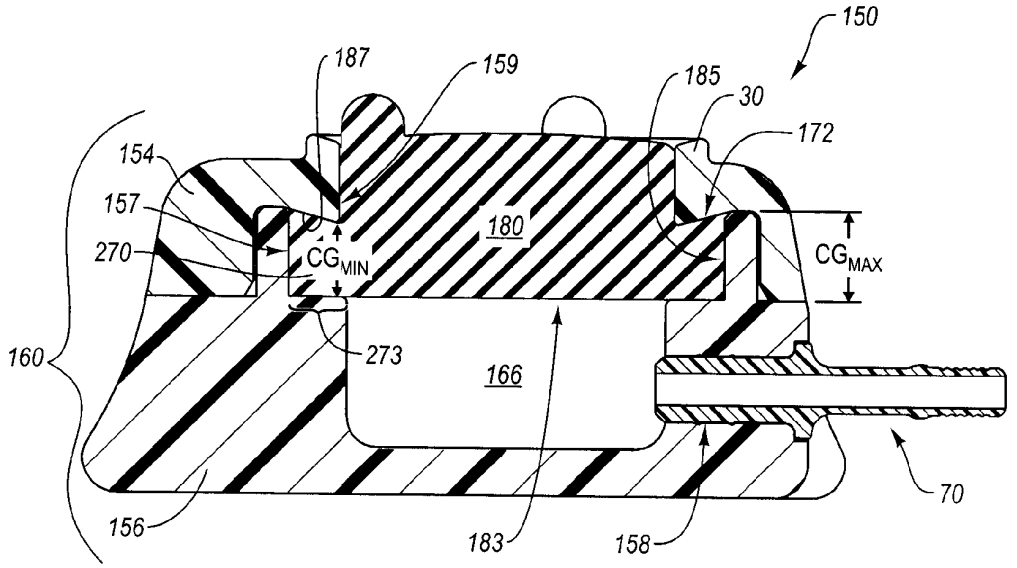

Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7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CG_{MAX}
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156
183
158

FIG. 8

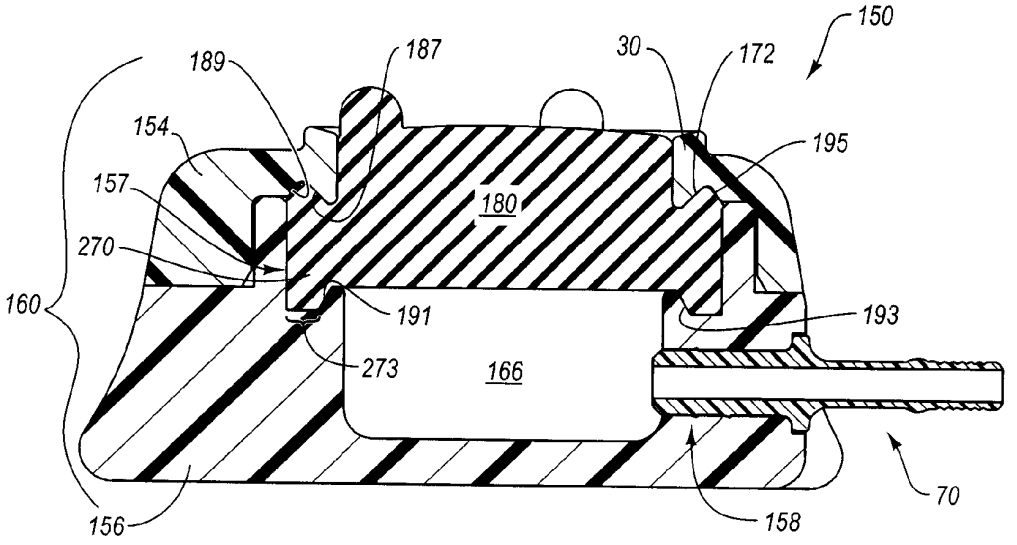
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FIG. 9

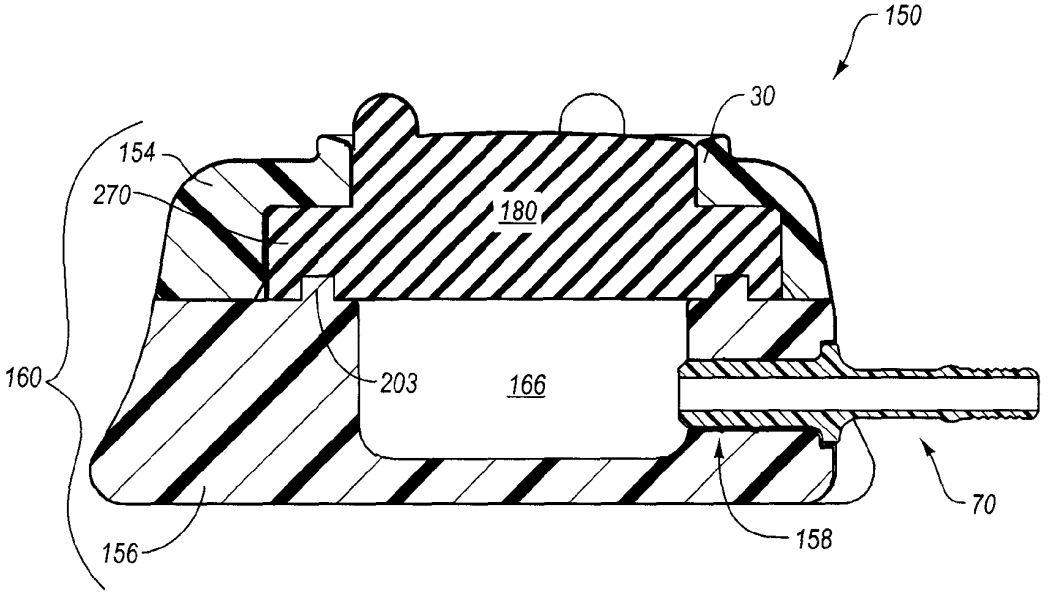
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FIG. 10

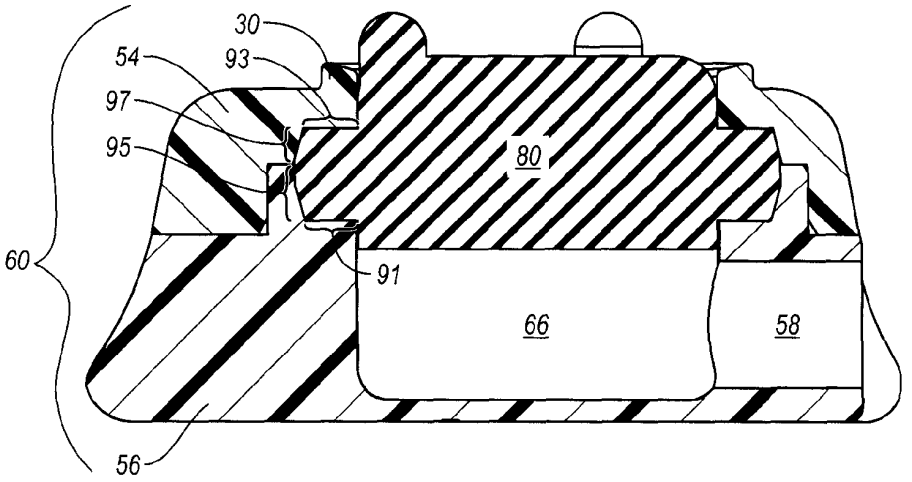
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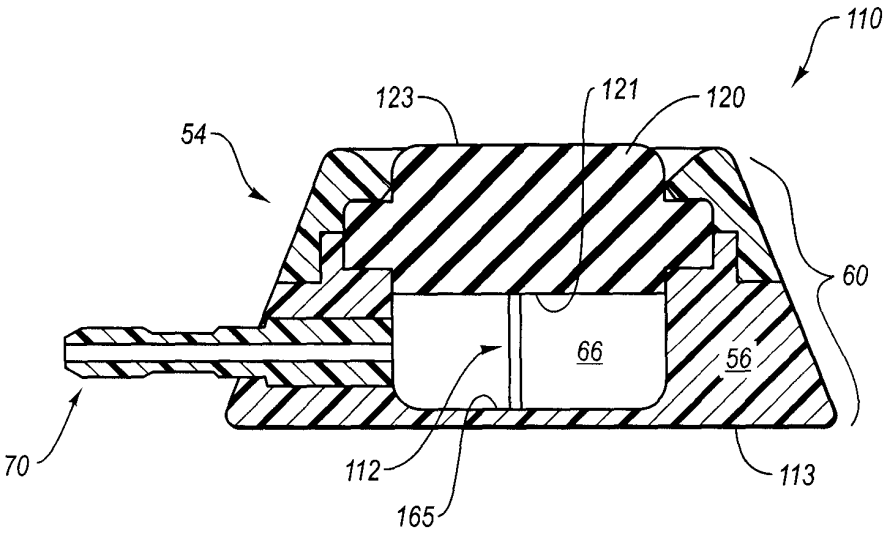
FIG. 11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165
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FIG. 12

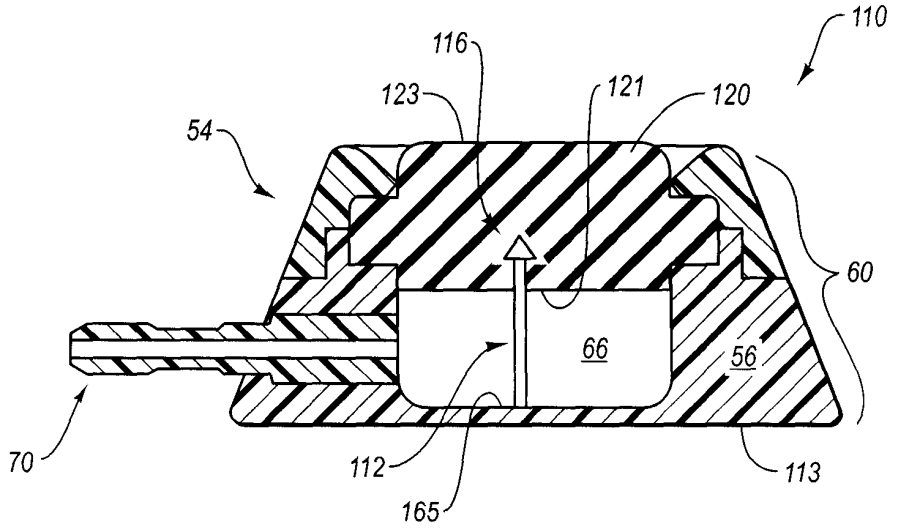
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FIG. 13

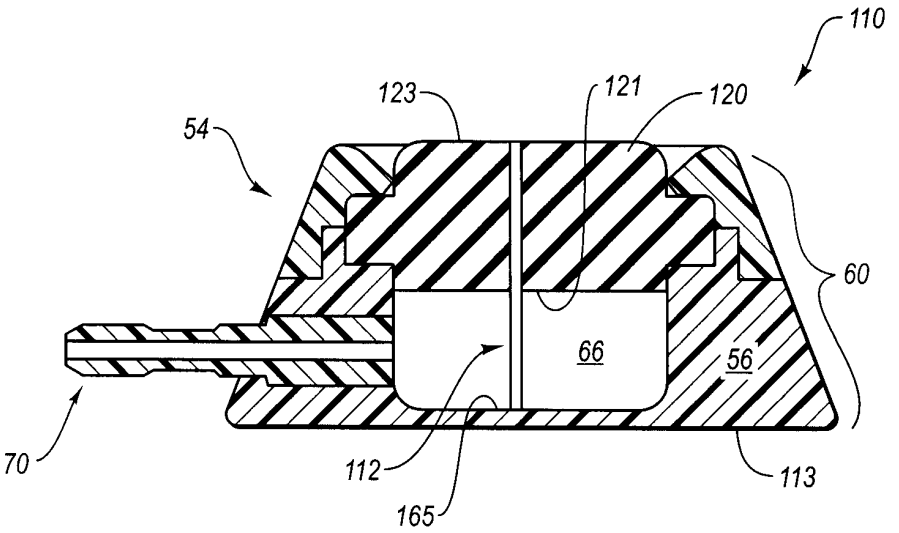
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FIG. 14

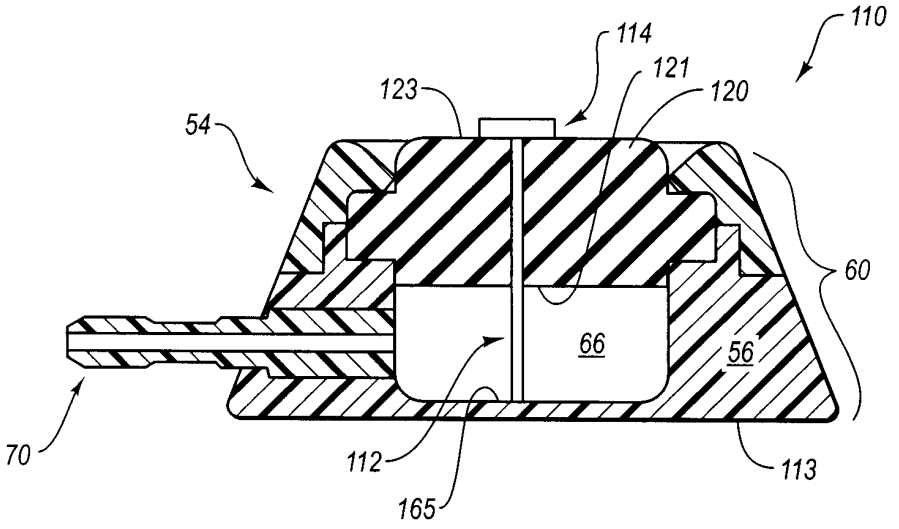
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FIG. 15

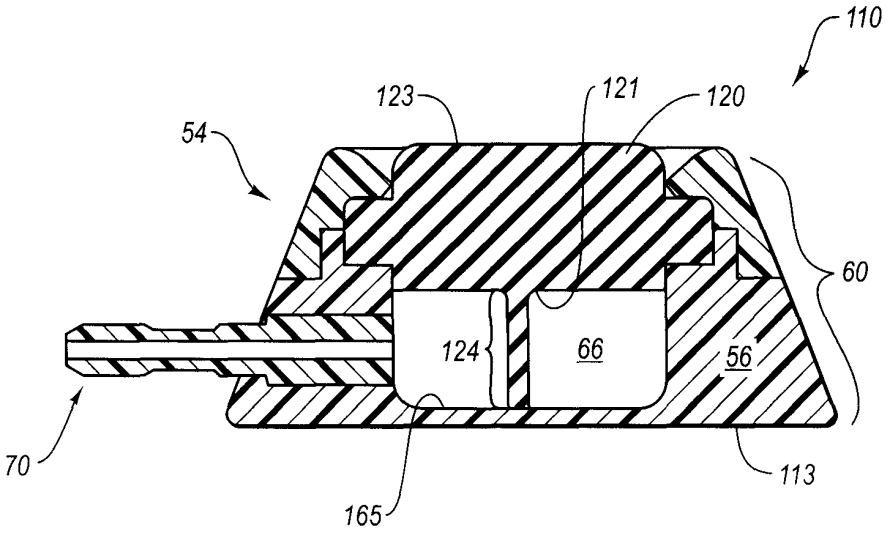
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FIG. 16

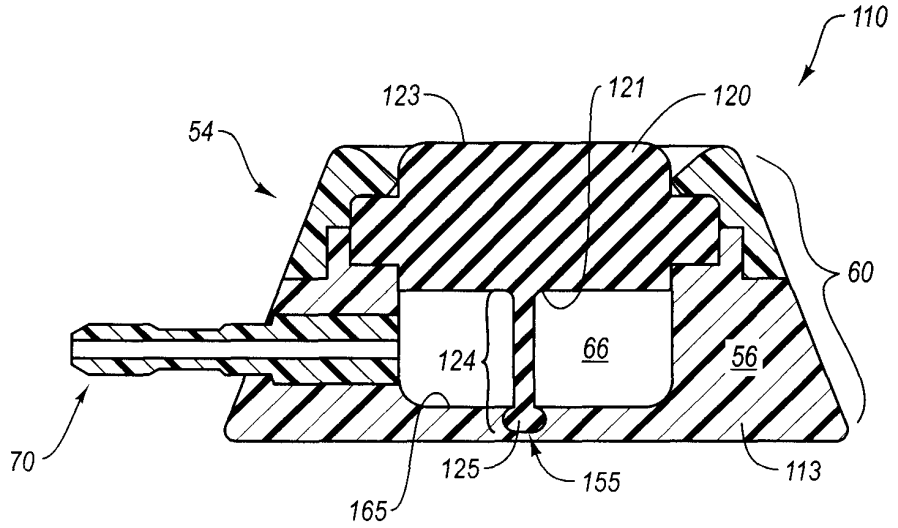
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FIG. 17

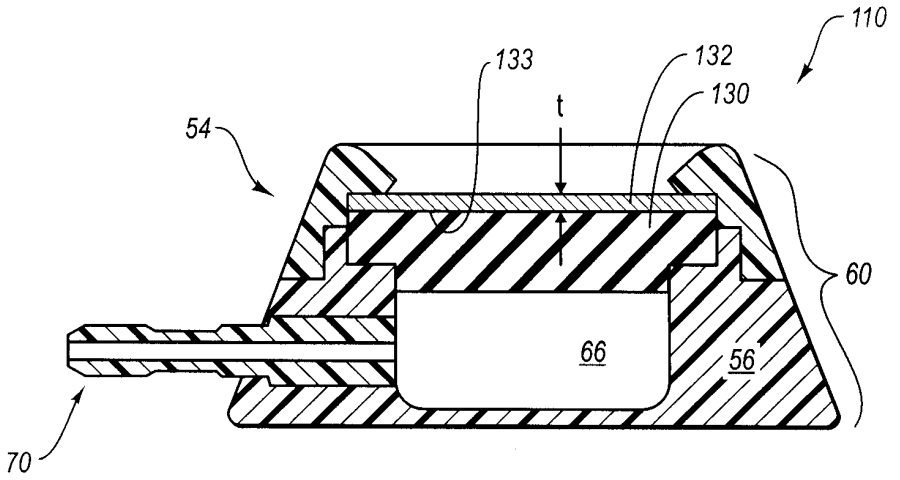
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FIG. 18

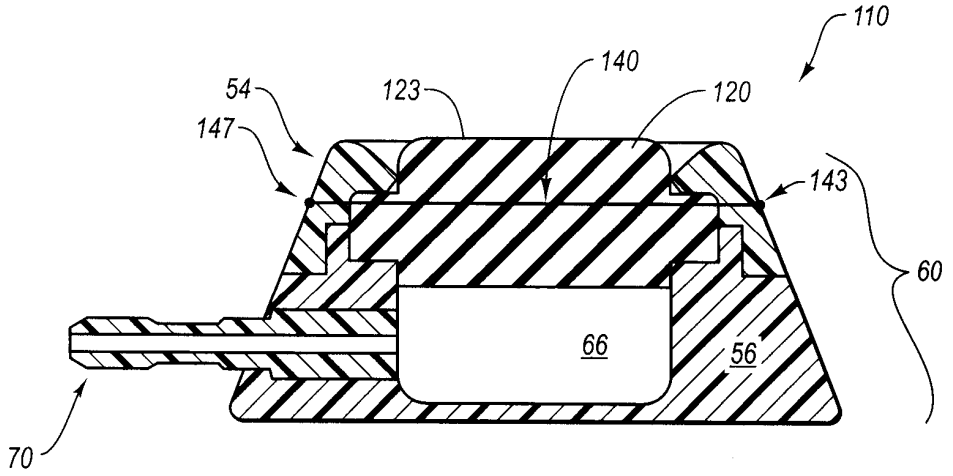
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FIG. 19

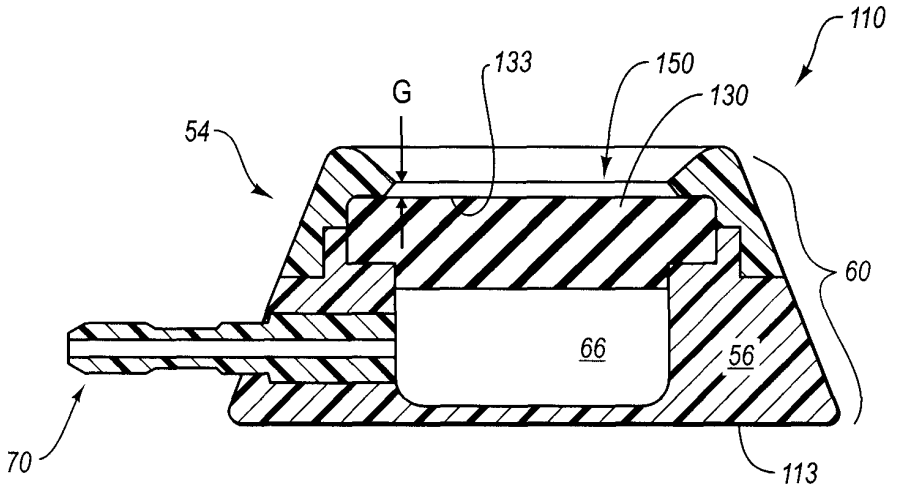

FIG. 20

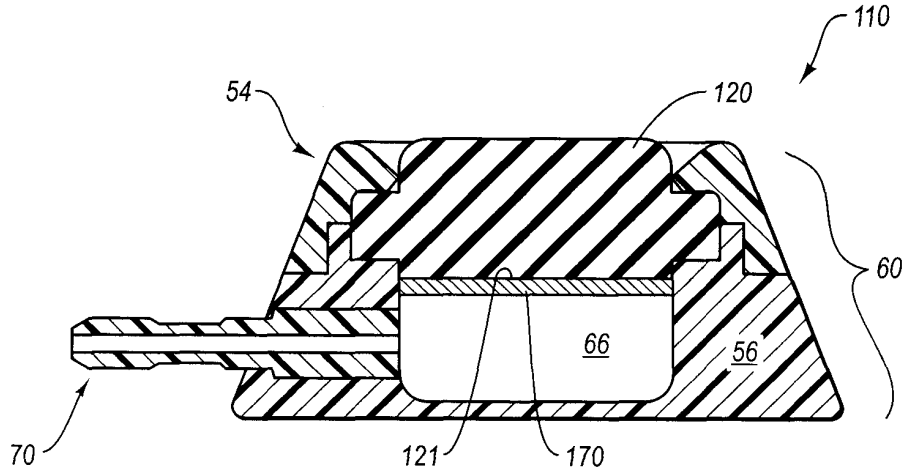

FIG. 21

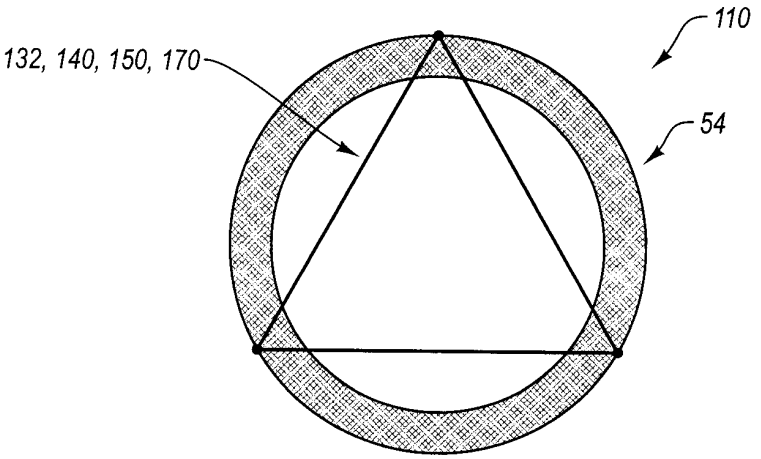

FIG. 22

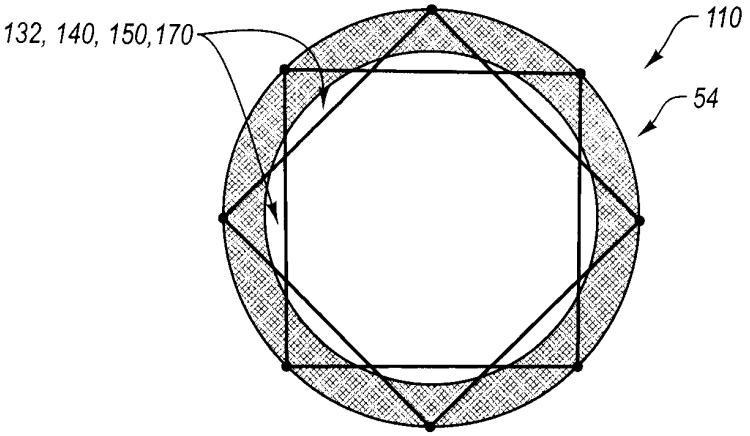

FIG. 23

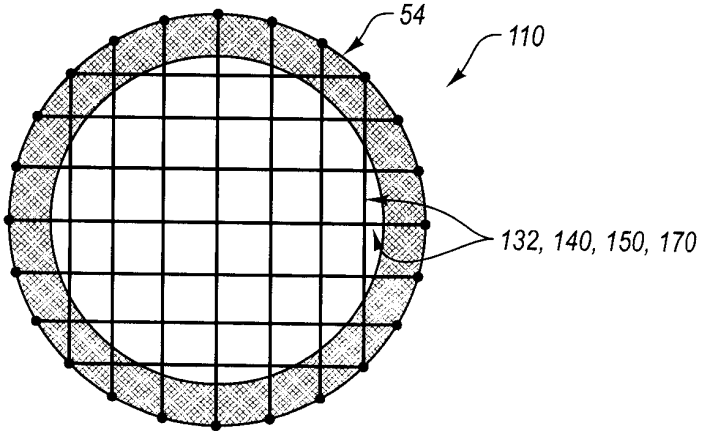

FIG. 24

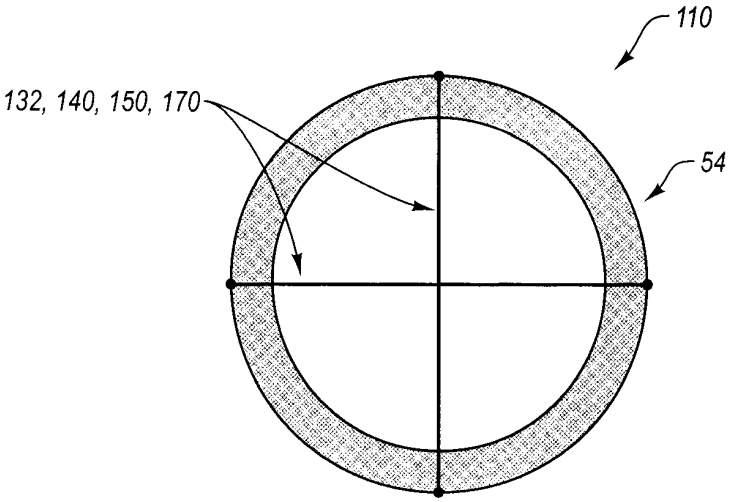

FIG. 25

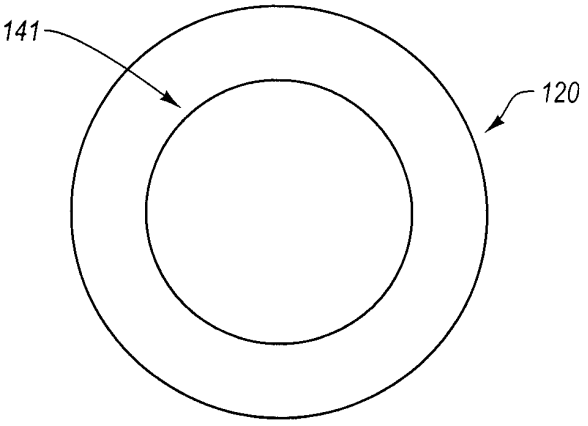

FIG. 26

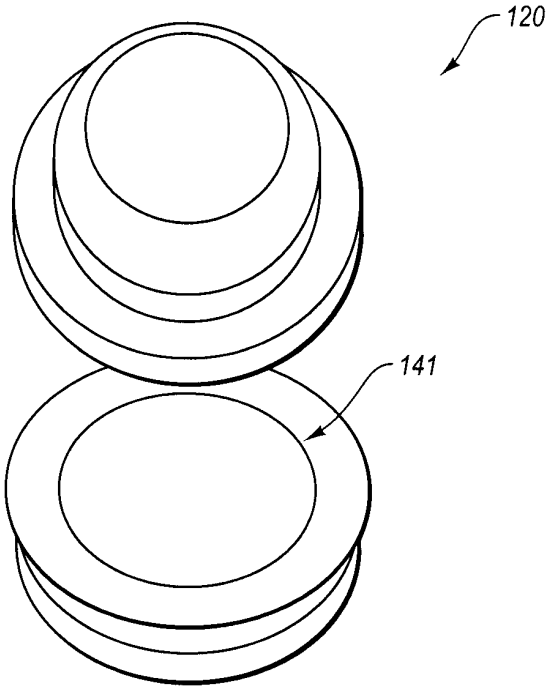

FIG. 27

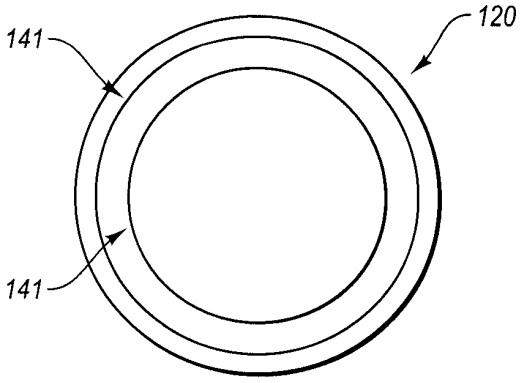

FIG. 28

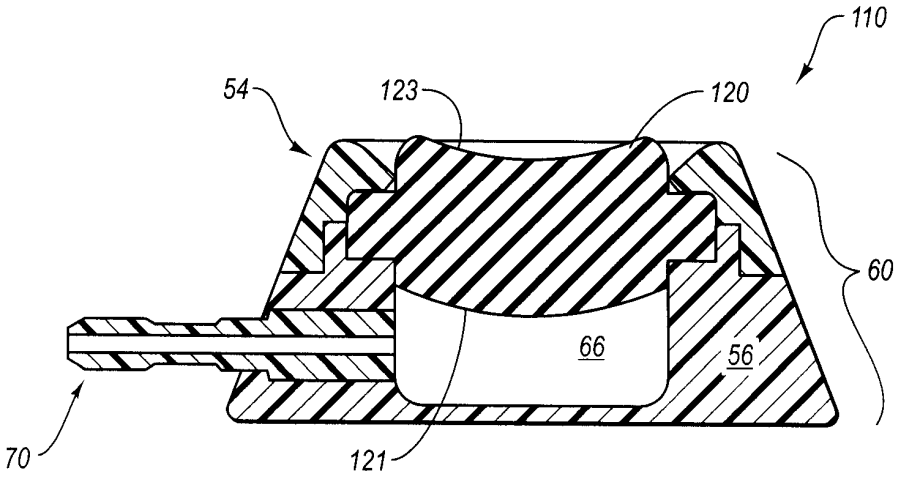

FIG. 29

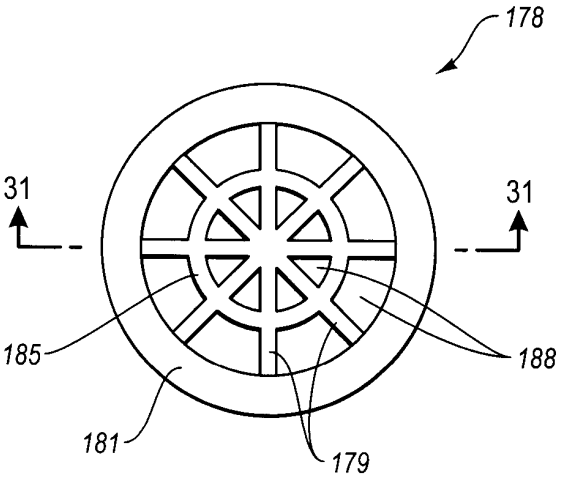

FIG. 30

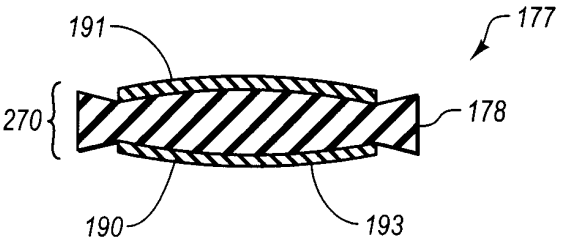

FIG. 31

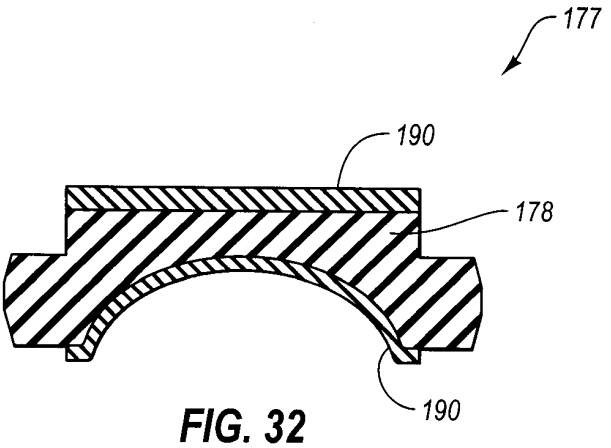

FIG. 32

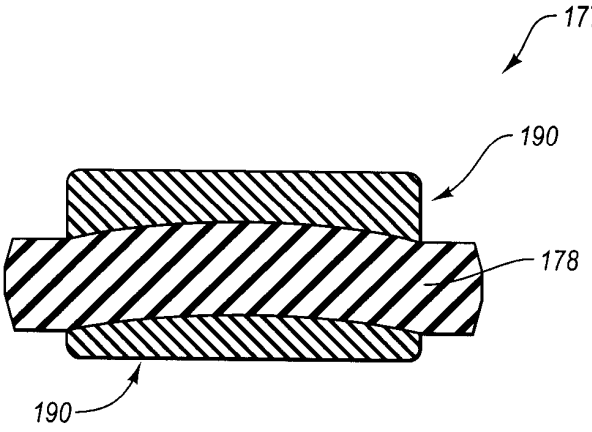

FIG. 33

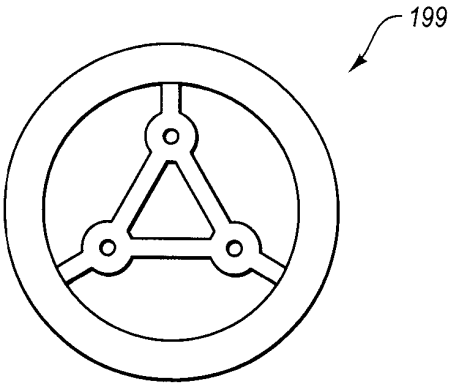

FIG. 34

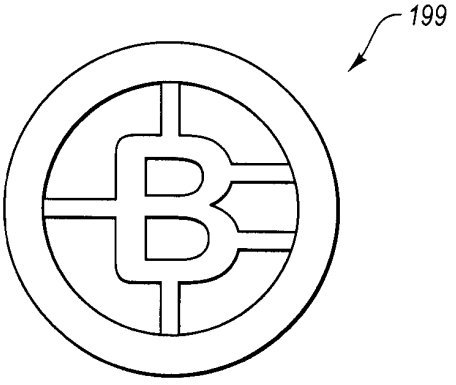

FIG. 35

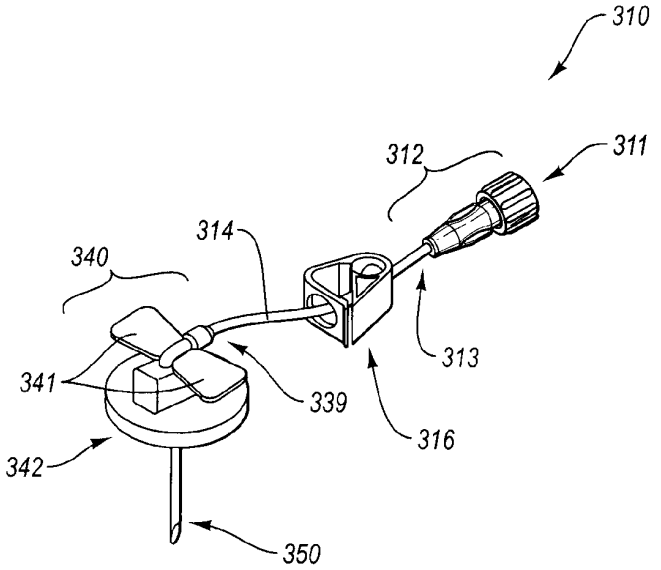
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FIG. 36

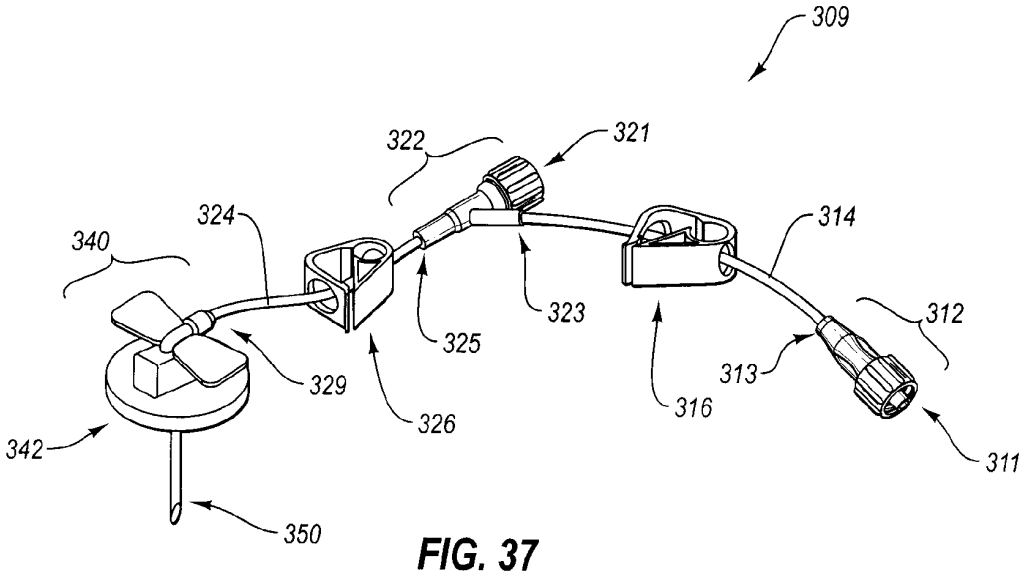
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FIG. 37

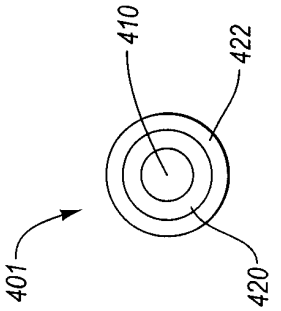

FIG. 39

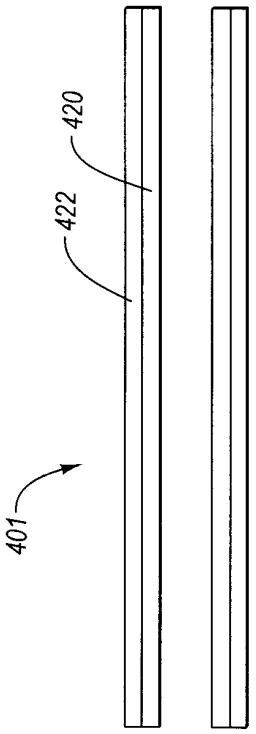

FIG. 38

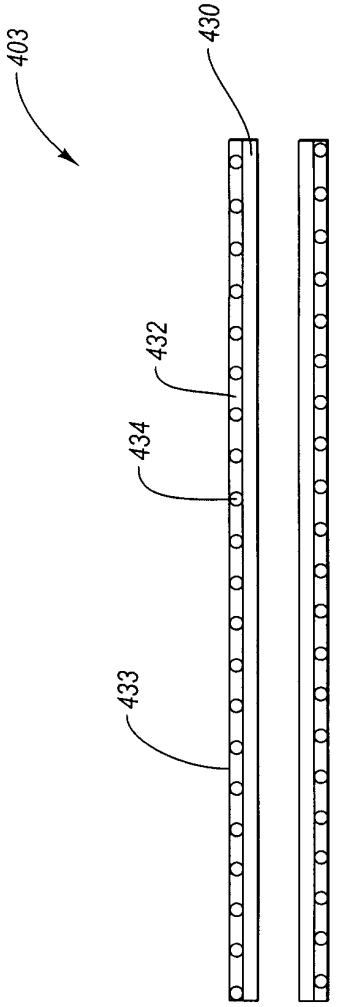

FIG. 40

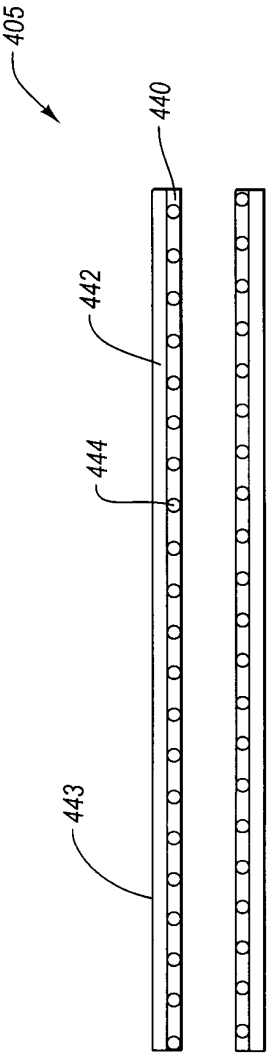

FIG. 41

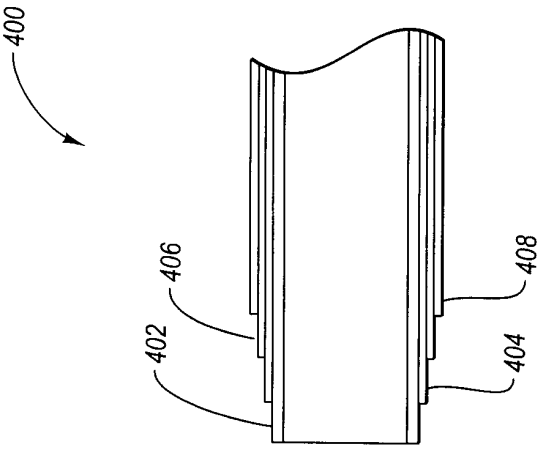

FIG. 43

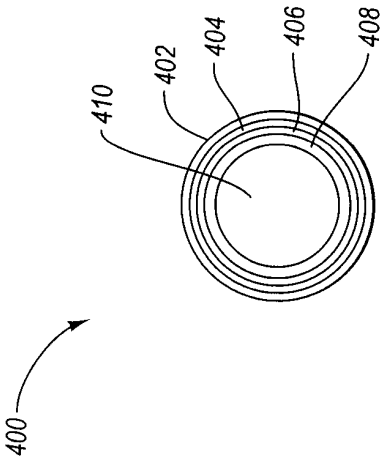

FIG. 42

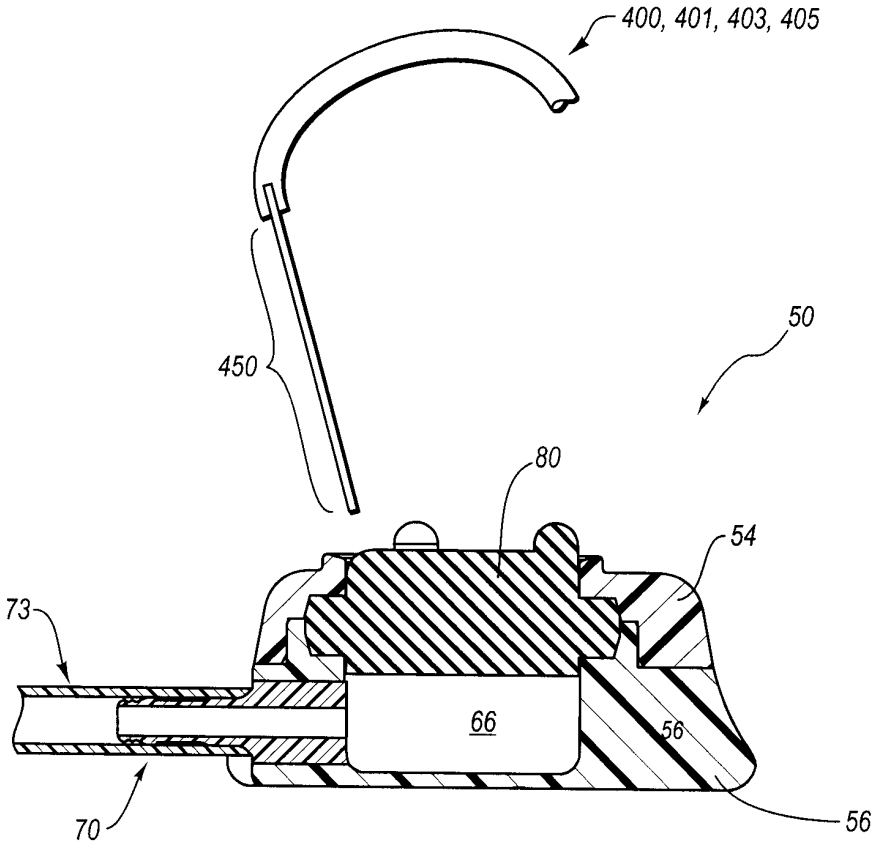
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FIG. 44

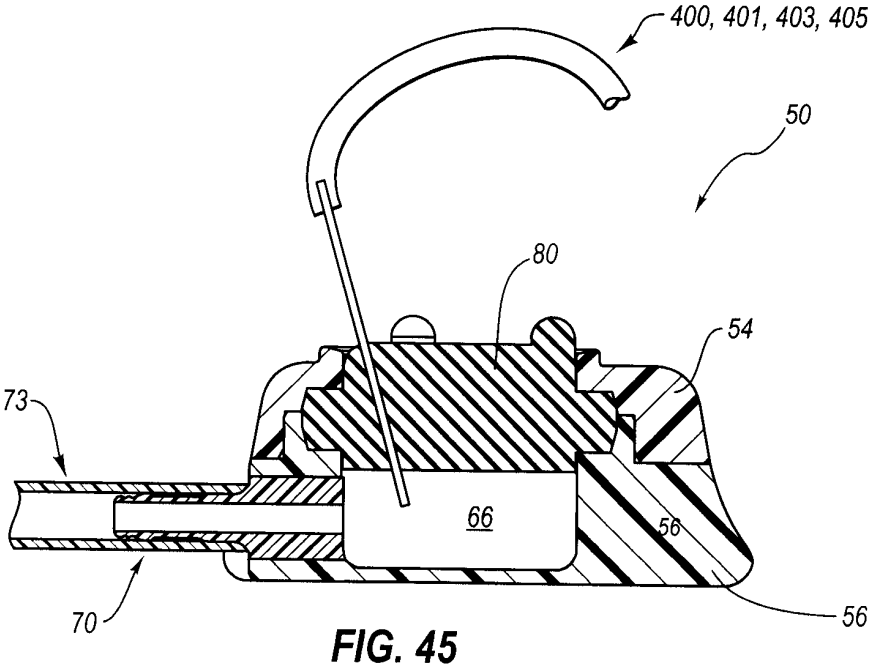
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FIG. 45

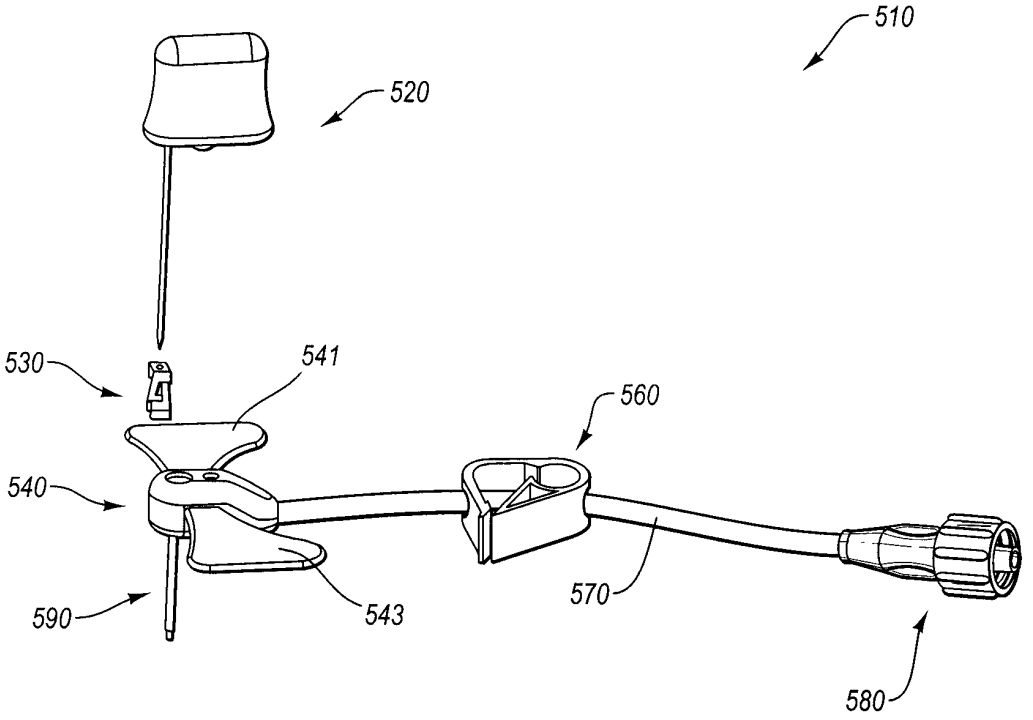

FIG. 46

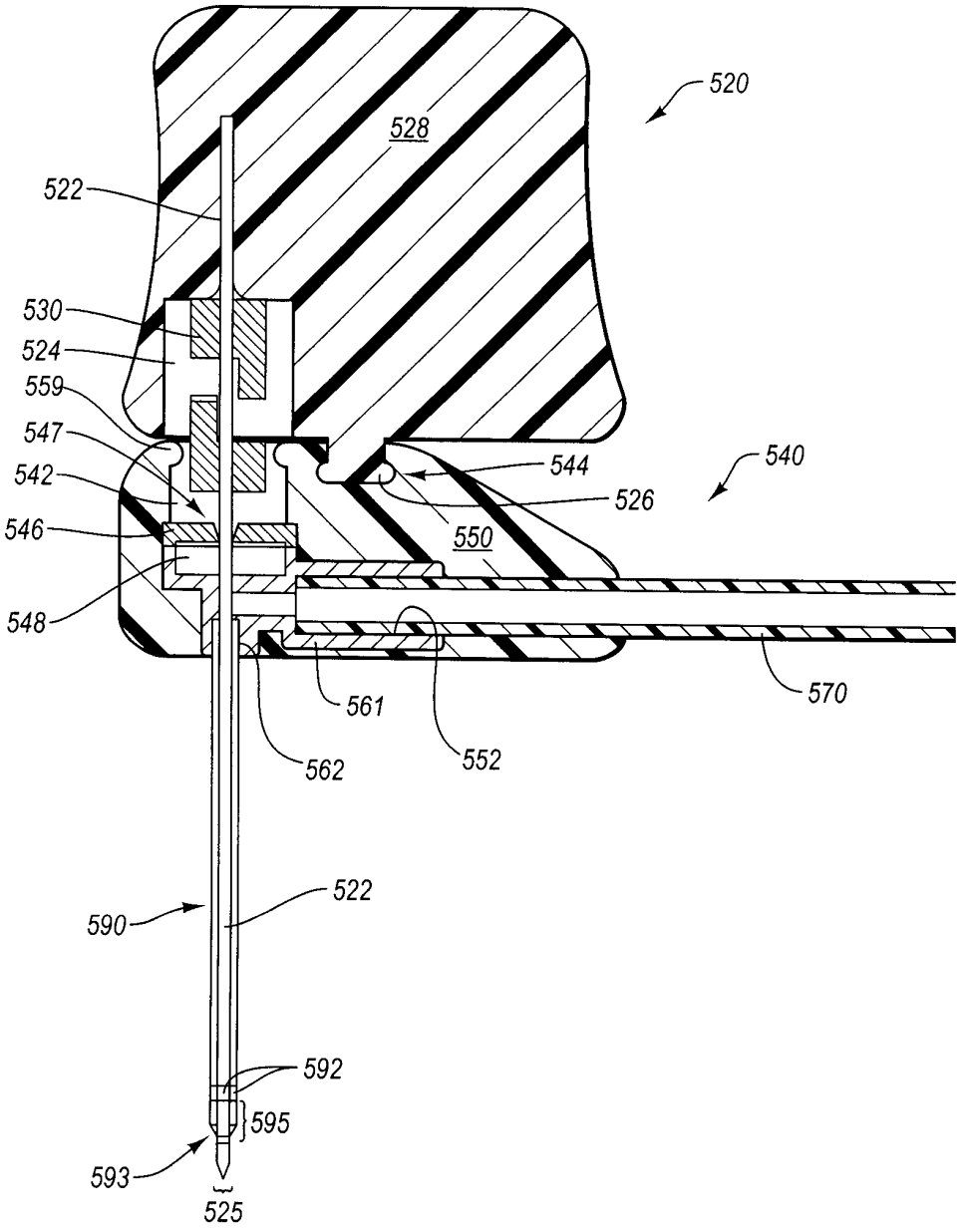
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FIG. 47

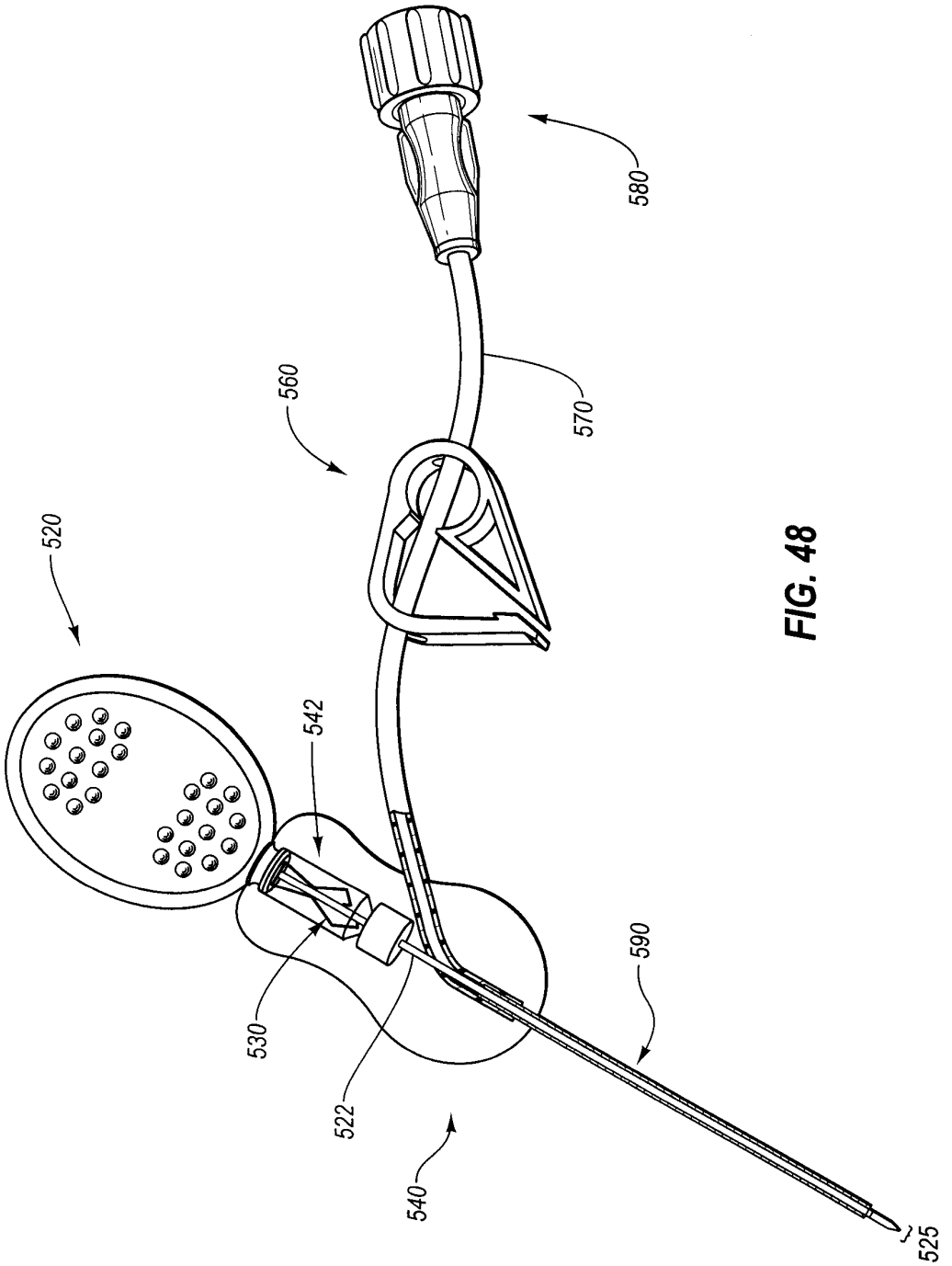

FIG. 48

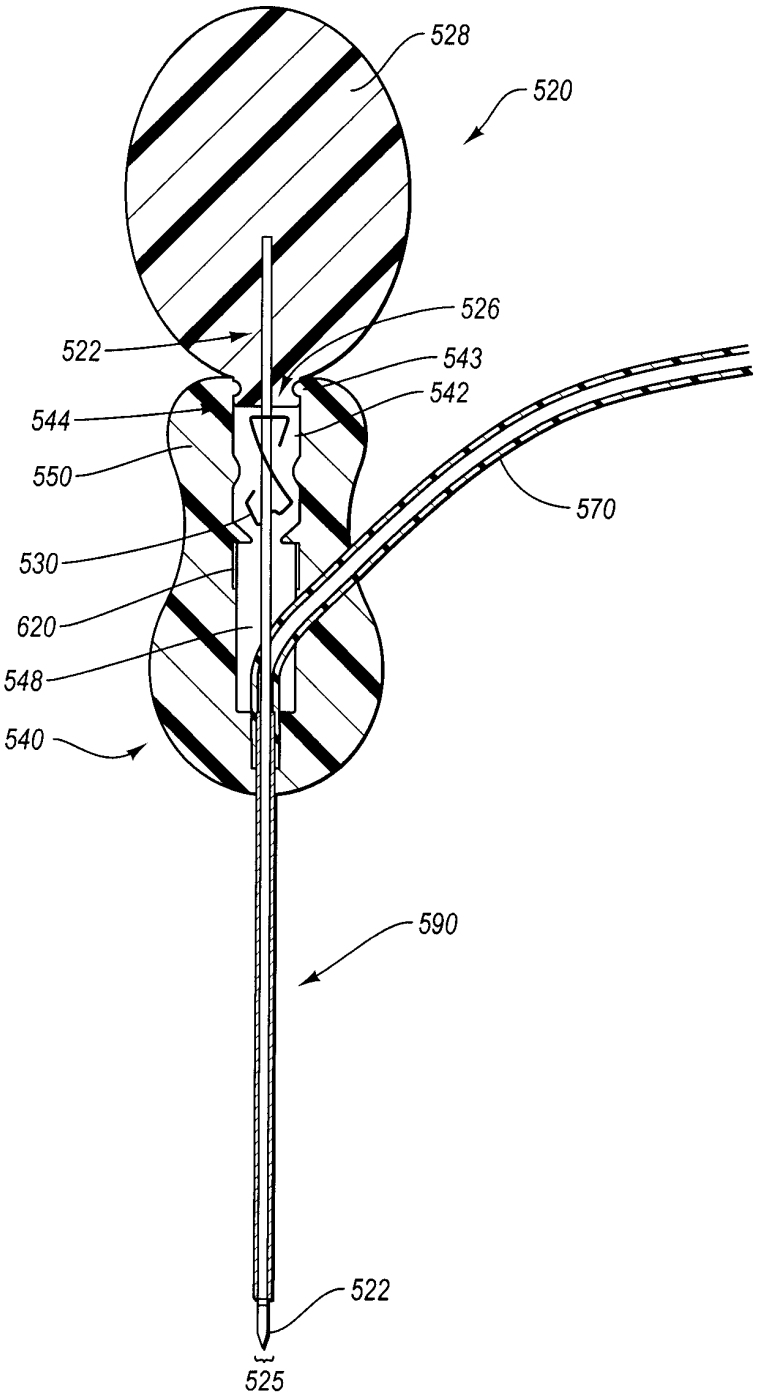

FIG. 49

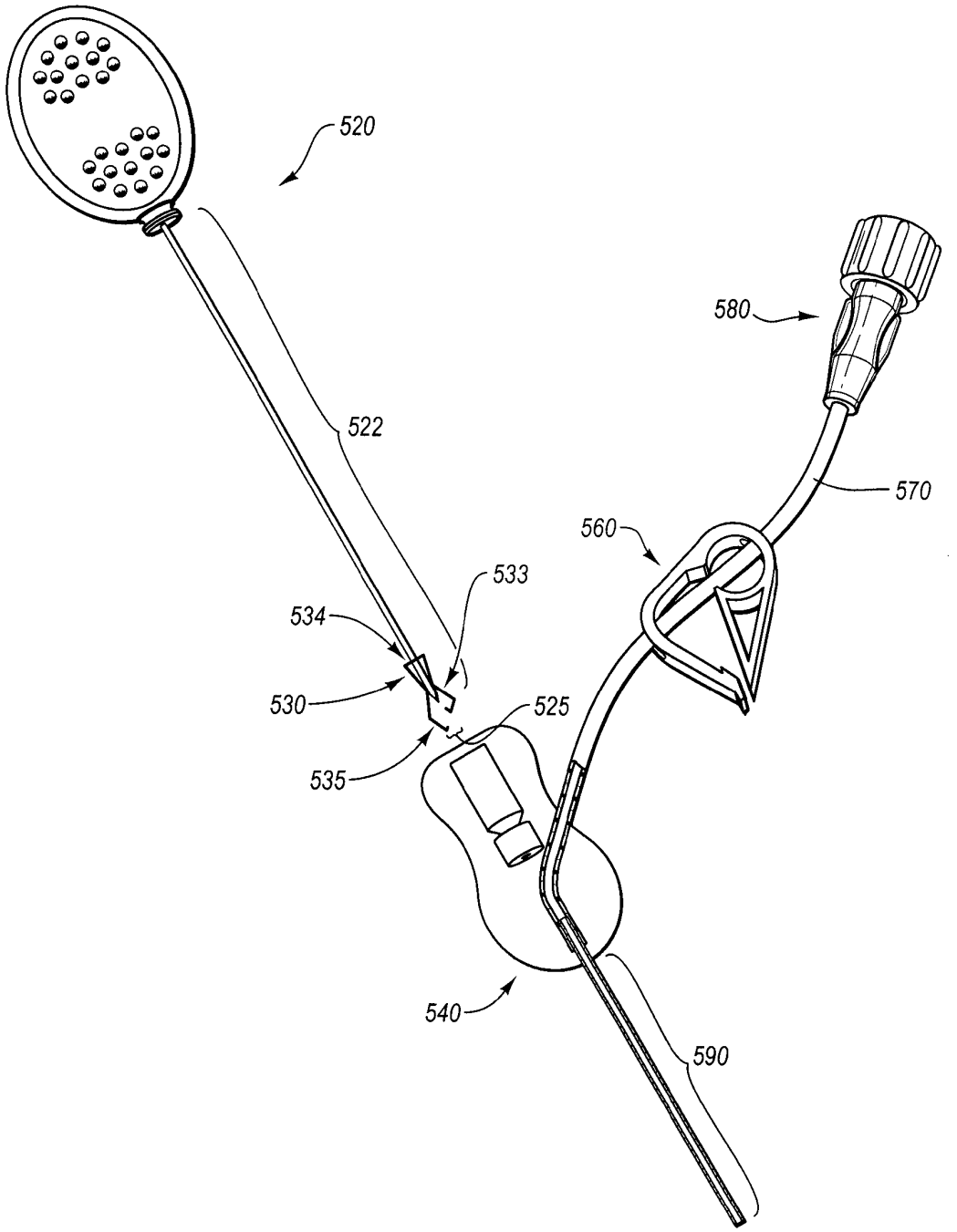

FIG. 50

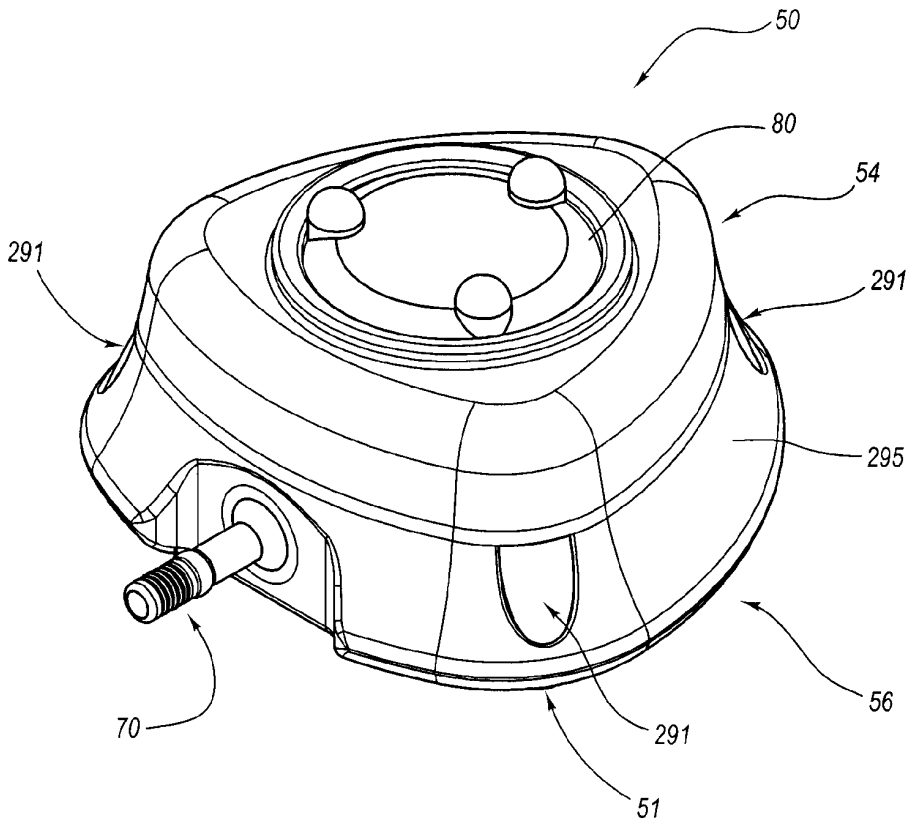

FIG. 51

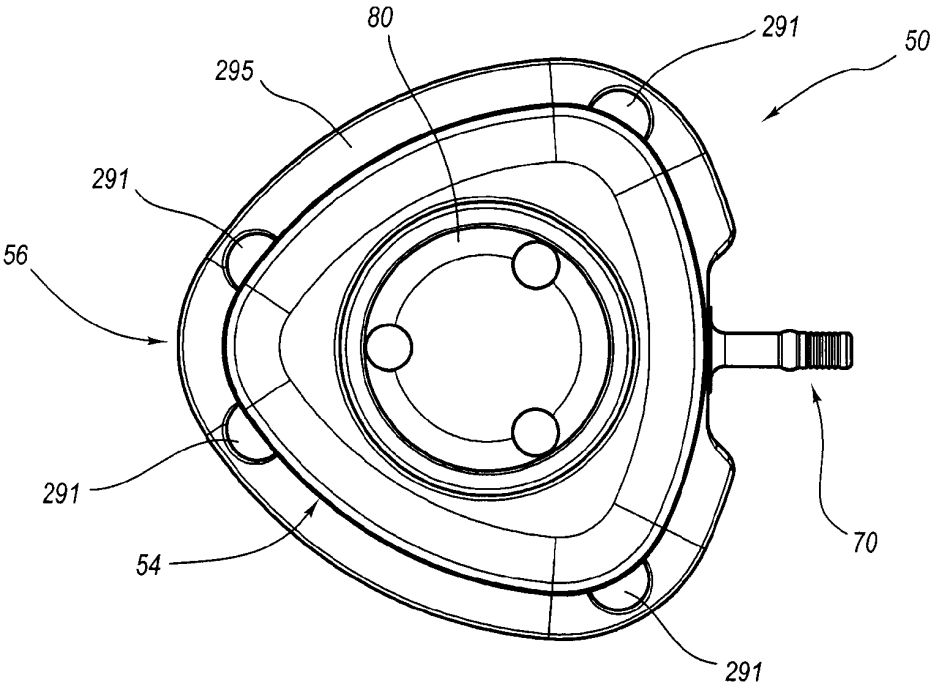

FIG. 52

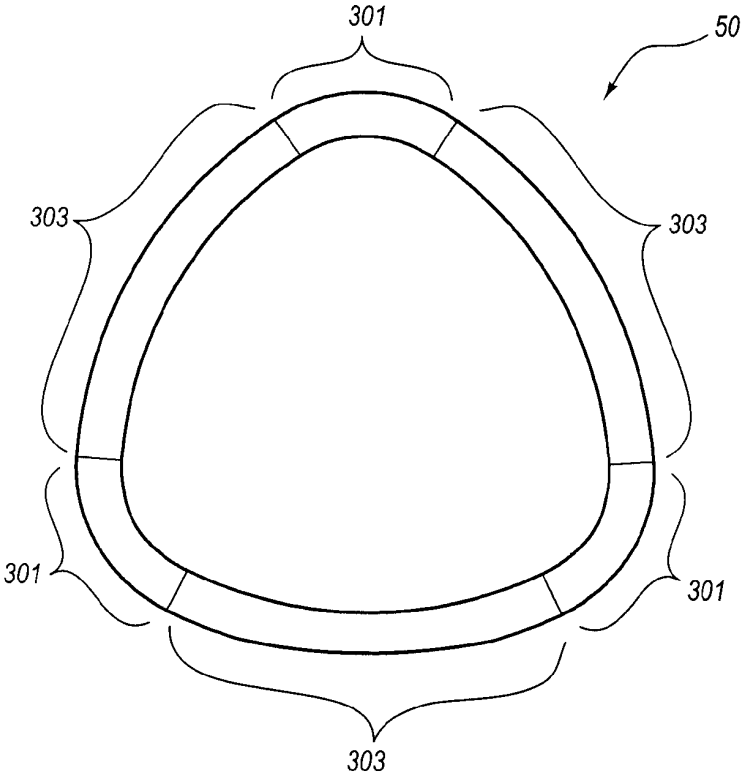

FIG. 53

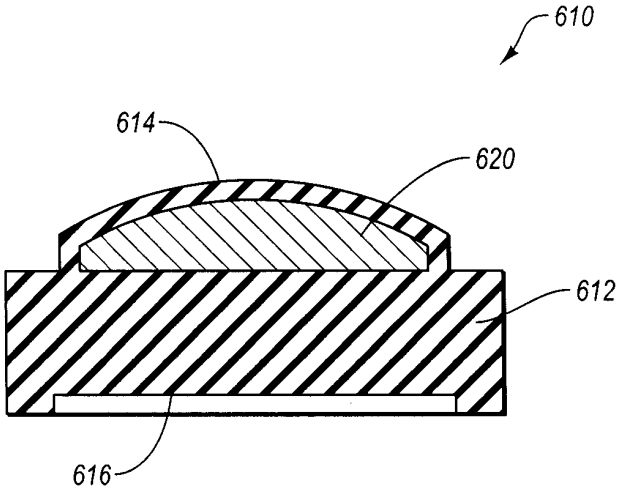

FIG. 54

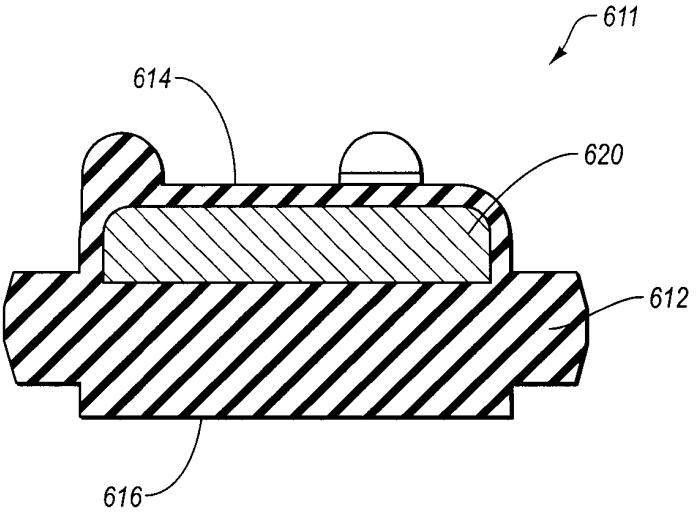

FIG. 55

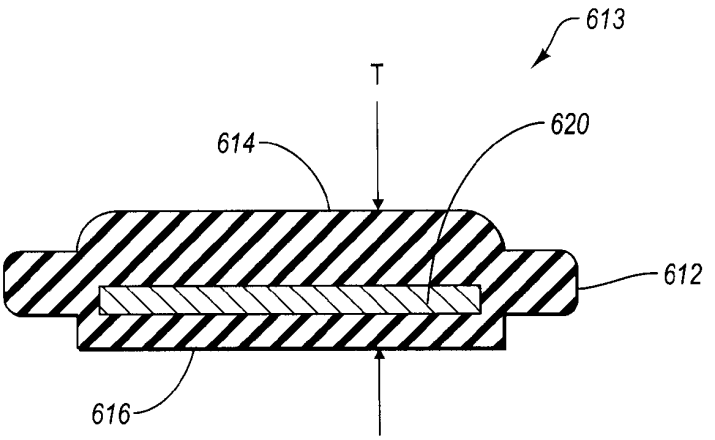

FIG. 56

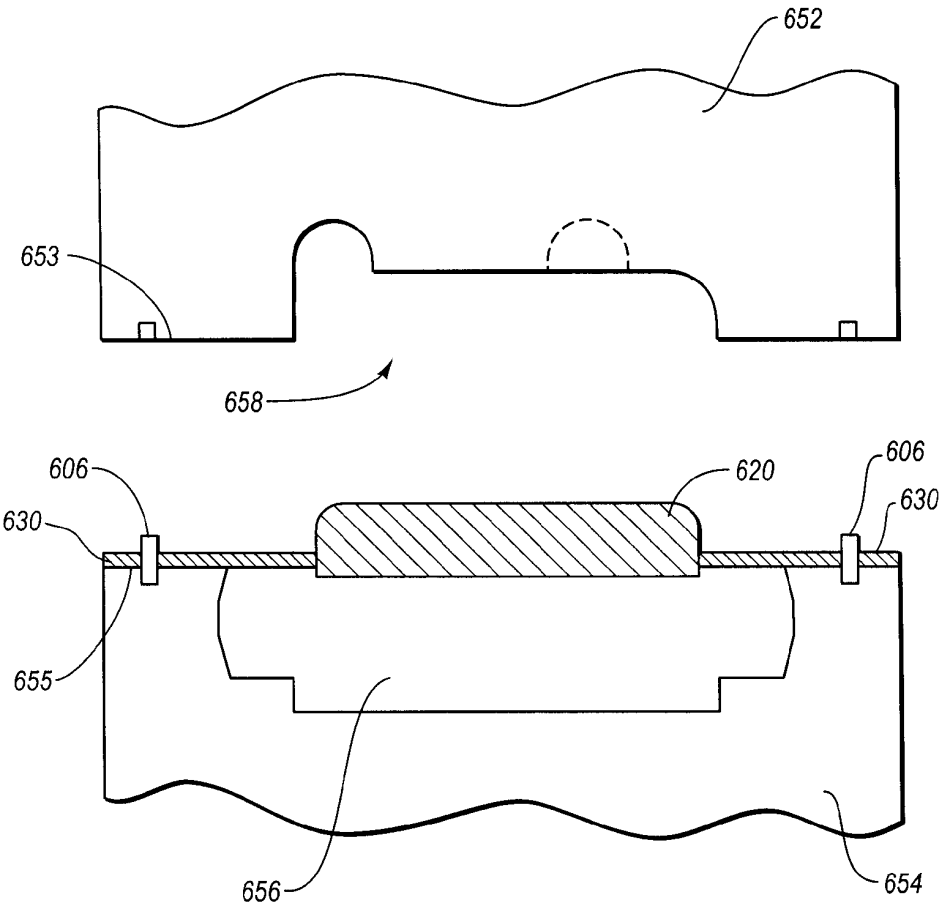

FIG. 57

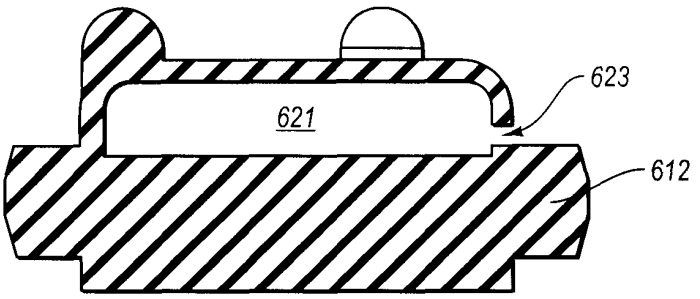

FIG. 58

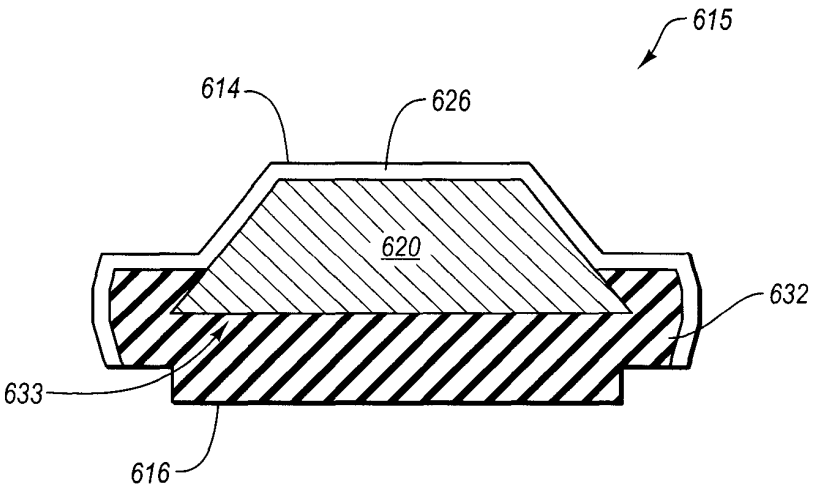

FIG. 59

INFUSION APPARATUSES AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Patent Application No. 60/737,466, filed 15 Nov. 2005, the disclosure of which is incorporated, in its entirety, by this reference. This application further claims the benefit of U.S. Patent Application No. 60/675,309, filed 27 Apr. 2005, the disclosure of which is incorporated, in its entirety, by this reference.

BACKGROUND

A wide variety of medical procedures require infusion of a fluid into a patient. For example, vascular imaging technologies may require use of a contrast media that is injected into the patient. More specifically, computed tomography (CT) is an imaging technology that utilizes a contrast media and may be employed for the noninvasive evaluation and assessment of a vascular system (i.e., CT angiography or CTA). Multidetector computed tomography (MDCT) is one specific type of CT that may be utilized for CTA. For proper imaging of a vascular system via CT, intravenous contrast media injection protocols are coordinated and selected for the anatomic area of interest.

More particularly, conventionally, a so-called "power injector" system may be employed for injecting contrast media at a high pressure into a peripherally inserted intravenous (IV) line. For example, such power injectors or injection systems may be commercially available from Medrad, Inc., a subsidiary of Schering AG, Germany and may be marketed as STELLANT® injection systems. Because CT procedures are often defined in terms of a desired flow rate of contrast media, such power injection systems are, in general, controllable by selecting a desired flow rate. Accordingly, such power injection systems may develop pressure (within the maximum pressure capability of the power injection system) as is necessary to maintain the selected flow rate. Accordingly, as may be appreciated, obstructions in the IV lines or use of IV lines that are not structured to withstand the pressures of a desired injection rate may cause the power injector to generate a pressure that exceeds a suitable pressure limit for the IV line. After intravenous injection, a bolus of contrast material, may flow within the vascular system of the patient to the right side of the heart, through the lungs, into the left side of the heart, and through the remaining circulatory system. After the bolus of contrast media is injected into the patient, portions of the contrast media may remain in the right side of the heart. Thus, the overall effectiveness of contrast enhancement may depend on a multitude of factors. For example, a patient's characteristics (e.g., body size; circulation, including cardiac output and circulating volume, and renal function), the contrast characteristics (e.g., volume, injection rate, iodine concentration, etc.), and the CT technique (e.g., access and route of administration, scan delay, scan speed, and injection pattern) may each influence the overall degree of contrast enhancement.

By way of background, conventionally, relatively long scan times have been accompanied by relatively long contrast media delivery times. However, because scan times continue to decrease, relatively fast delivery of contrast media may be desired. Explaining further, in coronary CTA, a large enough volume of contrast material must be administered at a sufficiently high rate to reach and maintain a suitable concentration throughout a selected scan time (e.g., a 15 second scan time), and within a selected region of the anatomy (e.g., an axial scan distance of 20 cm, which may include the left ventricle and outflow tract). It also may be desirable that contrast density values are sufficient to facilitate the segmentation techniques used in multidimensional post-processing. A typical contrast media used in coronary CTA may have an iodine density of about 300 milligrams per milliliter to about 350 milligrams per milliliter. Also, since contrast media may be radioactive, reducing the overall quantity of contrast media required to perform an imaging process may be advantageous.

The pressure required for contrast injection depends on many factors, including flow rate, contrast viscosity, configuration of infusion tubing, such as tube diameter and length, and any obstruction or restriction to flow (e.g., kinks, curves, fittings, compression). As mentioned above, to maintain the flow rate required for a CT or MRI study, a power injector may generate high pressures. Ruptures can occur when the injection pressure exceeds the tolerance of the vascular access device(s). Other problems may occur due to timing errors between the scan and the contrast. In order to maximize the rapid scanning capacity of the newer vascular imaging devices, the starting of the scanning process can be delayed a predetermined amount of time after injection of the contrast media has begun. If the scan starts too early, just as the contrast is arriving at the heart, arteries can appear smaller than they really are when the image is post-processed. On the other hand, if scanning is delayed too long, image artifacts can arise from diluted contrast in the cardiac veins. The window of opportunity for optimal scans may be very small, because contrast media circulates quickly through cardiac arteries and into cardiac veins.

Some diagnostic or medical procedures may advantageously employ a subcutaneous vascular access port for introducing a fluid into the vasculature of a patient. Access portals, or ports, provide a convenient method to repeatedly deliver medicants to remote areas of the body without utilizing surgical procedures. The port is implantable within the body, and permits the infusion of medications, parenteral solutions, blood products, contrast media, or other fluids. Additionally, the port may be used to aspirate blood from the patient. Such access ports typically include a cannula-impenetrable housing which encloses one or more fluid cavities or reservoirs and defines for each such fluid cavity an access aperture communicating through the housing. A cannula-penetrable septum is positioned adjacent to and seals each access aperture. An outlet stem communicates with one or more of the fluid cavities for dispensing medication therefrom to a predetermined location in the body of the patient through an implanted catheter attached to the access port. Once the access port and the catheter have been implanted beneath the skin of a patient, quantities of fluid, such as medication, blood, etc., may be dispensed through one such fluid cavity by, for example, a cannula (e.g., a needle), passed through the skin of the patient and penetrating the septum into one of the respective fluid cavities. This medication is directed through the distal end of the catheter to an entry point into the venous system of the body of the patient. Further, blood may be aspirated through the subcutaneous access port. Thus, use of an access port may allow for vascular access without needle sticks into the vasculature of a patient.

However, conventional access ports and attendant infusion systems have not been suitable for performing power injection.

Particularly, the use of power injection systems in combination with conventional vascular access ports has achieved less than ideal results. Thus, it may be appreciated that vas-

cular access ports for infusion systems and infusion-related apparatuses structured for performing power injection may be advantageous.

SUMMARY

One aspect of the instant disclosure relates to a method of flowing fluid through an access port. More particularly, a vascular access port may be provided and a fluid may be caused to flow through the access port at a rate of at least about 1 milliliter per second.

A further aspect of the instant disclosure relates to a method of flowing fluid through an infusion set. For example, an infusion set may be provided and a fluid may be flowed through the infusion set at a rate of at least about 1 milliliter per second.

Another aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Specifically, an access port may comprise a housing defining an aperture for capturing a septum, wherein the housing and septum define a reservoir. In addition, the septum may include a tenon region wherein the housing of the access port defines a complimentary mortise region structured for accepting at least a portion of the tenon region of the septum. Optionally, the housing may include a ring structure proximate to at least a portion of a side periphery of the septum.

An additional aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. In one embodiment, an access port may comprise a housing defining an aperture for capturing a septum, the housing and septum defining a reservoir. In addition, the housing and septum may be structured for accommodating a flow rate through the reservoir of at least about 1 milliliter per second. In another embodiment, an access port may include a housing and septum, as described above, wherein the housing and the septum are structured for accommodating a pressure developed within the reservoir of at least about 35 psi.

Yet another aspect of the instant disclosure relates to an infusion set for use in subcutaneously accessing a patient. For example, in one embodiment, an infusion set may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section. Also, the cannula may be configured for insertion through a septum of an access port, and the tubing section and the cannula may be structured for allowing a fluid to flow at a rate of at least about 1 milliliter per second. Optionally the cannula may be configured for puncturing a septum of an access port and the tubing section and the cannula may be structured for accommodating a pressure of at least about 400 psi. For example, the tubing section and the cannula may be structured for accommodating a pressure of about 600 psi.

A further aspect of the instant disclosure relates to infusion tubing for use in accessing a vascular system of a patient. In one embodiment, infusion tubing may comprise a plurality of layers, wherein the tubing is structured for accommodating a fluid flow rate of at least about 1 milliliter per second. In another embodiment, infusion tubing may comprise a plurality of layers, wherein at least one layer of the plurality of layers extends beyond at least another of the plurality of layers and is structured for forming a cannula for puncturing a septum of an access port. In yet an additional embodiment, an infusion set for use in subcutaneously accessing a patient may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section, wherein the cannula is configured for insertion through a septum of an access port. Additionally, the tubing section and cannula may be structured for accommodating a pressure of at least about 400 psi.

Another aspect of the instant disclosure relates to a method of identifying an access port as being suitable for power injection. More specifically, an access port including a septum may be provided. Further, the access port may be identified as being suitable for power injection.

Yet a further aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Particularly, an access port may comprise a housing configured for capturing a septum, the septum configured for inserting a cannula therethrough and into a reservoir defined within the housing and at least one structural element configured for resisting deformation of the septum in response to a pressure developed within the reservoir.

In an additional aspect of the instant disclosure, a method of operation of an access port may comprise providing a housing configured for capturing a septum, the septum configured for inserting a cannula (which can include a needle, a Huber needle, a trocar with an associated cannula, or any combination thereof) therethrough and into a reservoir defined within the housing, and developing a pressure within the reservoir of the housing. Further, such a method may comprise limiting deformation of the septum in response to the pressure developed within the reservoir.

In addition, one aspect of the instant disclosure relates to a septum comprising a gel or a viscous liquid. For example, in one embodiment, a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body including an upper surface and a lower surface and at least one gel region positioned generally between the upper surface and the lower surface. Another embodiment may comprise a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body, a layer formed over at least a portion of the body, and a gel region positioned at least partially between the layer and the body.

The above-described infusion apparatuses and related methods may be beneficially employed for effecting or facilitating power injection processes. For instance, such methods and apparatuses may be employed for infusing a fluid (e.g., a contrast media) at a rate of between about 1 milliliter per second and about 5 milliliters per second.

Features from any of the above mentioned embodiments may be used in combination with one another in accordance with the instant disclosure. In addition, other features and advantages of the instant disclosure will become apparent to those of ordinary skill in the art through consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the instant disclosure will become apparent upon review of the following detailed description and drawings, which illustrate representations (not necessarily drawn to scale) of various aspects of the instant disclosure, wherein:

FIG. **1** shows an exploded, perspective view of an access port according to the instant disclosure;

FIG. **2** shows a schematic, side cross-sectional view of the access port shown in FIG. **1**;

FIG. **3** shows a schematic, top elevation view of a cap including a ring feature as shown in FIGS. **1** and **2**;

FIG. **4** shows a schematic, top elevation view of another embodiment of a cap including a ring feature;

FIG. **5** shows a schematic, top elevation view of a further embodiment of a cap including a ring feature;

FIG. **6** shows a schematic, side cross-sectional view of an implanted access port with a cannula extending through the septum of the access port;

FIG. **7** shows a graph depicting pressures at selected regions within an infusion system for a given flow rate;

FIG. **8** shows a schematic, side cross-sectional view of an access port including a septum with a tenon region and a housing with a mortise region;

FIG. **9** shows a schematic, side cross-sectional view of another embodiment of an access port including a septum with a tenon region and a housing defining a mortise region;

FIG. **10** shows a schematic, side cross-sectional view of a further embodiment of an access port including a tenon region and a housing defining a mortise region;

FIG. **11** shows a schematic, side cross-sectional view of an access port, wherein at least a portion of a side periphery of the septum is affixed to the housing;

FIG. **12** shows a schematic, side cross-sectional view of an access port including a structural element extending between the septum and the housing;

FIG. **13** shows a schematic, side cross-sectional view of an access port including a structural element with a barbed end positioned within the septum;

FIG. **14** shows a schematic, side cross-sectional view of an access port including a structural element extending between an upper surface of the septum and the housing;

FIG. **15** shows a schematic, side cross-sectional view of an access port as shown in FIG. **14** and also including a support element positioned adjacent to an upper surface of the septum;

FIG. **16** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg that extends to the housing;

FIG. **17** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg comprising an enlarged end that couples to a recessed form in the housing;

FIG. **18** shows a schematic, side cross-sectional view of an access port including a septum in a structural element positioned adjacent to an upper surface of the septum;

FIG. **19** shows a schematic, side cross-sectional view of an access port including a septum and a structural element extending laterally through the septum;

FIG. **20** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to an upper surface of the septum;

FIG. **21** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to a lower surface of the septum;

FIG. **22** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a generally triangular pattern;

FIG. **23** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in two generally rectangular patterns;

FIG. **24** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a first plurality of substantially parallel lines and a second plurality of substantially parallel lines;

FIG. **25** shows a partial, top elevation view of an access port as shown in FIGS. **18-21**, wherein structural elements are arranged as two intersecting substantially straight members;

FIG. **26** shows a partial, top elevation view of a septum including a structural element positioned within the septum;

FIG. **27** shows a perspective view of a sectioned septum, as shown in FIG. **26**;

FIG. **28** shows a partial, top elevation view of a septum including a plurality of structural elements;

FIG. **29** shows a schematic, side cross-sectional view of an access port including a septum exhibiting curvature;

FIG. **30** shows a top elevation view of one embodiment of a septum frame;

FIG. **31** shows a schematic, side cross-sectional view of one embodiment of a septum including the frame shown in FIG. **30** and another material at least partially surrounding the frame;

FIG. **32** shows a schematic, side cross-sectional view of another embodiment of a septum including a frame that is at least partially surrounded by another material;

FIG. **33** shows a schematic, side cross-sectional view of yet an additional embodiment of a septum including a frame that is at least partially surrounded by another material;

FIGS. **34** and **35** show a respective schematic view of different patterns that may be generated by radiopaque material comprising a septum;

FIG. **36** shows a perspective view of one embodiment of an infusion set according to the instant disclosure;

FIG. **37** shows a perspective view of another embodiment of an infusion set according to the instant disclosure;

FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of one embodiment of tubing including an inner layer and an outer layer;

FIG. **40** shows a schematic, side cross-sectional view of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIG. **41** shows a schematic, side cross-sectional view of another embodiment of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIGS. **42** and **43** show an end cross-sectional view and a schematic, side cross-sectional view, respectively, of tubing including four layers;

FIGS. **44** and **45** show schematic, side cross-sectional views of a tubing section including a plurality of layers, wherein at least one layer of the plurality of layers extends from a distal end of the tubing to form a slender hollow region for insertion through a septum of an access port;

FIG. **46** shows a perspective view of one embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **47** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **46**;

FIG. **48** shows a perspective view of another embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **49** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **48**;

FIG. **50** shows a perspective view of the infusion system shown in FIG. **48**, wherein the insertion assembly is removed from the hub;

FIG. **51** shows a perspective view of one embodiment of an access port according to the instant disclosure;

FIG. **52** shows a top elevation view of the access port shown in FIG. **51**;

FIG. **53** shows a simplified representation of a transverse cross section of the access port shown in FIGS. **51** and **52**;

FIG. **54** shows a schematic, side cross-sectional view of one embodiment of a septum including at least one gel region;

FIG. **55** shows a schematic, side cross-sectional view of another embodiment of a septum including at least one gel region;

FIG. **56** shows a schematic, side cross-sectional view of a further embodiment of a septum including at least one gel region;

FIG. **57** shows a side cross-sectional view of a first mold and a second mold, wherein a gel region is positioned between the first mold and the second mold;

FIG. **58** shows a schematic, side cross-sectional view of an embodiment of a septum including at least one chamber to capture a gel; and

FIG. **59** shows a schematic, side cross-sectional view of an additional embodiment of a septum including at least one gel region.

DETAILED DESCRIPTION

One aspect of the instant disclosure relates to vascular access ports. More particularly, in one embodiment, the instant disclosure contemplates that a vascular access port may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second. Further, the instant disclosure contemplates that a vascular access port may be structured to withstand at least about 180 pounds per square inch (psi) of pressure developed within the reservoir defined by the septum and the access port housing. In one embodiment, an access port may be structured for operating within a range of pressures of about 80 psi to about 180 psi. Such an access port may be advantageous for use in infusing a fluid into a patient (e.g., infusing contrast media into a patient for CT or MR imaging).

Generally, an access port may comprise a housing that captures a septum that may be repeatedly pierced or punctured with a hollow slender element (e.g., a cannula, or needle), which can include a Huber needle, a trocar with a circumferentially disposed cannula, or any other suitable access mechanism, without limitation. The words "cannula" or "needle," as used herein, encompass any slender element (e.g., a cannula, a needle, a trocar, with a circumferentially disposed cannula, etc.) as known in the art or described herein, without limitation. Such a septum may comprise a material (e.g., silicone) that seals, under suitable compression, passages formed by puncturing the septum with such an access mechanism. Thus, the septum may be at least partially compressed to facilitate closure of passages formed by puncturing the septum with the access mechanism. The instant disclosure contemplates that the housing and septum may be structured so that a flow rate from the reservoir of the access port may be at least about 1 milliliter per second without damaging the housing or septum or compromising the structural integrity of the reservoir (e.g., causing the septum to become separated from the housing).

In one embodiment, an access port may comprise a cap and base which define, in combination, a housing in which a septum may be positioned to form a reservoir. For example, FIGS. **1** and **2** show, respectively, an exploded perspective view and a side cross-sectional view of an access port **50** including a base **56**, a cap **54**, a septum **80**, and an outlet stem **70**. As shown in FIGS. **1** and **2**, cap **54** and base **56**, may be configured for capturing a septum **80** between cap **54** and **56**. Generally, cap **54** and base **56** may collectively form a housing **60** for capturing septum **80** and at least partially defining reservoir **66**. Explaining further, cap **54** may include an aperture **55** through which a portion of septum **80** may extend and base **56** may include a recess **57** configured to accept at least a portion of septum **80**. Thus, a portion of septum **80** may be placed within recess **57** of base **56** and aperture **55** of cap **54** may be positioned about septum **80** to collectively define a reservoir **66** within access port **50**, the reservoir **66** being in fluid communication with a lumen of outlet stem **70**. In other embodiments, a plurality of reservoirs may be collectively defined by a housing and at least one septum, without limitation. For example, any access port known in the art including a plurality of reservoirs (or one reservoir) may include any aspects) of the instant disclosure, without limitation. As shown in FIG. **1**, a portion of outlet stem **70** may be positioned within and coupled to an aperture **58** formed within base **56**.

Although FIG. **1** shows that access port **50** may include an outlet stem **70**, other embodiments of access port **50** may not include an outlet stem **70**. Therefore, FIG. **2** shows access port **50** without an outlet stem **70**. Put another way, the instant disclosure contemplates that access port **50** may, optionally, include an outlet stem **70** or may be otherwise configured. For instance, in one embodiment, outlet stem **70** may be formed as a part of with base **56**, if desired. In another embodiment, a catheter may be operably coupled to the access port **50** (e.g., to aperture **58**) without outlet stem **70**. In yet a further embodiment, access port **50** may simply include at least one outlet passage (e.g., aperture **58**) in fluid communication with the reservoir **66** and extending through the housing **60** and structured for allowing fluid flow through, if desired. As shown in FIG. **2**, a portion of septum **80** may be positioned between cap **54** and base **56** and may be configured to withstand, without damage or deforming to an extent that compromises the reservoir **66** (i.e., blowing out), a selected magnitude of pressure developed within reservoir **66**.

For example, as shown in FIGS. **1** and **2**, cap **54** may optionally include a circumferential ring structure **30** that is formed adjacent to a side periphery of septum **80**. Ring structure **30** may be structured to inhibit deformation of the cap **56** in response to a pressure developed within reservoir **66** of access port **50**. As shown in FIG. **3**, in a top elevation view of cap **54**, ring structure **30** may be generally circular. Further, ring structure **30** may be substantially congruent to a side peripheral shape of septum **80** or may exhibit a different shape than the side periphery of septum **80**. In addition, the size of ring structure **30** may be selected to provide a selected rigidity to a region of cap **54** adjacent to of aperture **55** of cap **54**. Such a configuration may inhibit deformation of the cap **54** in response to pressure developed within reservoir **66**. For example, as shown in FIG. **2**, a lateral thickness T_L, vertical thickness T_V, or both may be selected for providing a selected rigidity to a region of cap **54** adjacent to a periphery of septum **80** (i.e., adjacent to aperture **55**). In one embodiment, the overall height H (FIG. **2**) of access port **50** may be less than about 0.600 inches.

In other embodiments, ring structure **30** may be generally rectangular, generally triangular, generally oval, generally polygonal, or of another geometrical shape, without limitation. For example, FIG. **4** shows a top elevation view of a ring structure **30** that is generally triangular. Further, FIG. **5** shows a generally rectangular ring structure **30**.

Explaining further, housing **60** of access port **50** may comprise a biocompatible material such as polysulfone, titanium, or any other suitably biocompatible material. Thus, cap **54** and base **56** may couple to one another generally along a mating line and may be secured or affixed to one another. More particularly, in one embodiment, both cap **54** and base **56** may comprise titanium and may be welded, brazed, soldered, or otherwise affixed to one another. Such a configuration may provide suitable mechanical strength for capturing septum **80** between cap **54** and base **56**. Optionally, cap **54** and base **56** may be coupled to one another by at least one fastening element (e.g., at least one bolt, at least one screw, at least one rivet, etc.), at least one adhesive, or a combination of such coupling mechanisms. Similarly, in one embodiment,

outlet stem **70** and base **56** may each comprise titanium and may be welded or otherwise bonded or coupled to one another.

In further detail, FIG. **6** shows an access port **50** implanted within a patient **67**. In one embodiment, sutures may be used to affix the access port **50** within the patient **67**, if desired. After the housing **60** is implanted in a patient **67**, the upper surface of the septum **80** may be generally flush or aligned with the surface of the skin surface **76** of the patient **67** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the reservoir **66**. The outlet stem **70** may create a fluid-communicative passageway extending from the reservoir **66** and through the outlet stem **70**, catheter **73**, and into the interior of the patient **67**. Generally, catheter **73** may be coupled to the outlet stem **70** for fluid communication with the reservoir **66** and for conducting fluid to a desired remote location from the reservoir **66** and within patient **67**. In one embodiment, catheter **73** may extend from the access port **50** to at least partially within a vena cava of the patient. Such a configuration may allow for infusion of a contrast media proximate to the heart of a patient. Because such a contrast media may be harmful (e.g., radioactive or otherwise injurious) infusion directly into a vena cava of a patient may reduce an overall quantity of contrast media required to perform a selected imaging procedure.

As shown in FIG. **6**, a cannula **90** may be inserted through the septum **80** and fluid may be injected into the reservoir **66**. For example, fluid may be injected into reservoir **66** at a rate that causes pressure (i.e., a positive pressure) to be developed within reservoir **66**. For example, a positive pressure, labeled "P_R" in FIG. **6**, may develop within reservoir **66** and may act upon the portion of septum **80** defining, in part, reservoir **66**. Such a pressure P_R acting on a portion of septum **80** may develop force upon the septum **80**. Likewise, force may be developed on surfaces of the base **56** that are acted upon by pressure Pr. In one embodiment, cap **54** may be coupled to base **56** and structured to suitably position septum **80** and couple septum **80** to housing **60** against force applied to the septum **80**. Therefore, the septum **80**, cap **54**, and base **56** may be structured for accommodating attendant forces developed by pressure P_R. In one embodiment, access port **50** may be structured for accommodating (without damage) a pressure P_R of at least about 185 psi with reservoir **66**. In another embodiment, access port **50** may be structured for accommodating (i.e., without damage) a range of pressures of about 37 psi to about 65 psi with reservoir **66**.

In further detail, during power injection, a fluid flow F may be caused to flow through cannula **90**. A fluid flow rate (depicted in FIG. **6** by arrows labeled "F") may be at least about 1 milliliter per second. In another embodiment, a fluid flow rate F may be between about 1 milliliter per second to about 5 milliliters per second. During power injection, a pressure P_i may be developed within cannula **90** may be at least about 30 psi. Accordingly, cannula **90** may be structured to withstand the forces associated with the above-discussed pressure, flow rate, or both. As discussed in further detail below, the cannula may comprise a portion of an infusion set (e.g., a safety winged infusion set (SWIS)) or another infusion system configured for use with an access port and a power injection system, without limitation.

More particularly, FIG. **7** shows a graph depicting pressure measurements at different locations within an infusion system including an infusion set (as discussed in greater detail below) in fluid communication with an access port during infusion of a fluid at a rate of 5 milliliters per second. As shown in FIG. **7**, a pressure generally within a syringe barrel of a power injector may be about 265 psi. Further, a pressure generally at the entrance of an infusion set may be about 225 psi and a pressure generally within a reservoir of an access port may be about 40 psi. Thus, the pressure drop through an infusion set may be about 185 psi. As shown in FIG. **7**, a pressure generally at the distal end of a catheter extending from the access port may be about 0 psi. Many factors may influence a pressure (and a pressure drop) developed within an infusion system (e.g., infusion set, access port, etc.) during flow of a fluid through the infusion system, such as, for example, fluid viscosity, tubing inner diameter (i.e., lumen cross-sectional size), length of the flow path, and flow rate. Accordingly, as will be appreciated by the above discussion of the access port **50** shown in FIGS. **1-3**, such access port **50** may be structured to accommodate a selected flow rate and associated pressure P_R developed within reservoir **66** of access port **50**.

In another embodiment, the septum, housing, or both may be structured to mechanically secure or constrain at least a portion of the septum. For example, in one embodiment, the septum may include at least one coupling feature configured to mate or couple with a complementary coupling feature included by the housing. For example, male and female features (e.g., without limitation, ribs, flanges, interlocking features, tenon and mortise type features, tongue-in-groove features, T-slot features, dovetail features, snap-fit features, tabs and slots or other coupling features as known in the art) may comprise the at least one coupling feature included by the septum and the at least one complementary feature included by the housing, without limitation. "Tenon," as used herein, means a projecting member for at least partial insertion into a mortise to make a joint. "Mortise," as used herein, means a recess, hole, groove, or slot formed within a material for receiving at least a portion of a tenon to make a joint.

Generally, in one embodiment, the septum may include at least one tenon region (i.e., at least one coupling feature) for coupling to a complementary mortise region formed by the housing. Thus, the housing may include a recess (i.e., at least one complementary feature) for accepting at least a portion of the tenon region of the septum. For example, FIG. **8** shows a side cross-sectional view of one embodiment of a septum **180** including a tenon region **270**. Particularly, tenon region **270** includes tapered surface **187** of septum **180**, which may increase in height (i.e., from lower surface **183** of septum **180**) along an increasing radial direction (i.e., relative to a radial distance from a central axis of septum **180**; that is, in a direction from rim **159** of cap **154** toward side surface **157** of base **156**). Thus, as shown in FIG. **8**, a height CG_{MIN} of septum **180** (measured at a radially innermost extent of tenon region **270**) is less than a height CG_{MAX} of septum **180** (at a radially outermost extent of tenon region **270**). Further, tenon region **270** may be a continuous peripheral feature (i.e., an annular feature) of septum **180** or may comprise one or more circumferentially separate regions, without limitation. Further, as shown in FIG. **8**, housing **160** (including cap **154** and base **156**) may generally define a complementary mortise region (e.g., a circumferentially extending recess) for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined by side surface **157** of base **156**, lower flange surface **273** of base **156**, and tapered surface **172** of cap **154**. Such a configuration may secure, capture, or retain a portion of tenon region **270** of septum **180** within the mortise region of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In another embodiment, an access port may comprise a septum including a tenon region including a plurality of

tapered surfaces. For example, FIG. **9** shows a schematic side cross-sectional view of a septum **180** including a tenon region **270** comprising tapered surface **187**, tapered surface **189**, and tapered surface **191**. Further, as shown in FIG. **9**, housing **160** may generally define a complementary mortise region tapered recess for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined within housing **160** by side surface **157** of base **156**, lower flange surface **273** of base **156**, tapered surface **172** of cap **154**, tapered surface **193** of base **156**, and tapered surface **195** of cap **154**. Such a configuration may secure, capture, or retain at least some of tenon portion **270** of septum **180** within a tapered recess of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In summary, it should be understood that a portion of a septum may comprise, generally, at least one tenon region for coupling with a complementary mortise region formed in a housing. In another embodiment, generally, at least a portion of a housing may comprise a tenon for coupling with a complementary mortise formed in a septum. As described above, a tenon region and a complimentary mortise region may comprise one or more tapered surfaces. In another embodiment, a tenon region and complementary mortise region may comprise a T-slot or other nontapered geometry, without limitation. For example, FIG. **10** shows a schematic, side cross-sectional view of one embodiment of an access port **150** comprising a septum **180** including a tenon region **270**. Further, a complementary mortise region may be defined within housing **160** for accepting at least a portion of tenon region **270**. As shown in FIG. **10**, a mortise region may be at least partially defined by an annular extension or protrusion **203** of base **156**. Such a configuration may secure, capture, or retain at least a portion of tenon region **270** of septum **180** within housing **160** and suitably seal reservoir **166** even if an anticipated maximum pressure is developed within reservoir **166**. It should be further understood that any of the tenon region and mortise region embodiments shown in FIGS. **8-10** may be described in terms of extensions, ridges, protrusions, recesses, grooves, slots, etc., without limitation.

A further aspect contemplated by the instant disclosure relates to coupling or affixing at least a portion of a peripheral region of a septum to a housing. Such a configuration may maintain the integrity of the access port during use of the access port for infusing a fluid at a flow rate of at least about 1 milliliter per second. For example, in one embodiment, at least a portion of a side periphery of a septum may be affixed to at least a portion of a housing. FIG. **11** shows a side cross-sectional view of an access port **50** wherein at least a portion of a periphery of septum **80** adjacent to housing **60** is affixed to one or both of cap **54** and base **56** adjacent to septum **80**. More particularly, as shown in FIG. **11**, a periphery of septum **80** (adjacent to cap **54** and base **56**) may include upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95**. Thus, in one embodiment, an adhesive, (e.g., glue, epoxy, cement, tape, or any other adhesive as known in the art) may affix at least a portion of one or more of upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95** to the cap **54** or base **56**, respectively. Such a configuration may secure septum **80** to housing **60** and may provide a relatively robust access port **50** suitable for power injection. It should further be appreciated that affixing at least a portion of a peripheral region of a septum may encompass affixing at least a portion of a tenon region (of either a septum or housing) to a mortise region (of either a housing or septum), without limitation.

As described above, septum deformation is a design consideration with respect to performing power injection via an access port. Further, one aspect of the instant disclosure relates to a septum that is structurally reinforced or otherwise limited against deformation exceeding a selected magnitude. More specifically, the instant disclosure contemplates that at least one structural element may be configured to inhibit or limit deformation of a septum of an access port in response to pressure developed within a chamber or reservoir of the access port. Some embodiments of an access port including at least one structural element for limiting deformation of a septum are disclosed in U.S. Patent Application No. 60/737,466, filed 15 Nov. 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the access ports encompassed by U.S. Patent Application No. 60/737,466 may be structured for power injection.

In one embodiment, the instant disclosure contemplates that a septum may be structurally coupled to a housing nonperipherally. Put another way, one aspect of the instant disclosure relates to coupling a nonperipheral portion of a septum to a housing of an access port. For example, FIG. **12** shows one embodiment of an access port **110** according to the instant disclosure including a cap **54** and a base **56** that capture a septum **120** to form a reservoir **66**. Optionally, cap **54** may include a ring feature proximate to a periphery of the septum, as described above. In addition, outlet stem **70** may allow for fluid communication with reservoir **66** to perform infusion or fluid sampling processes. As shown in FIG. **12**, a structural element **112** may extend between septum **120** and housing **60**. More particularly, structural element **112** extends generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Thus, if pressure (positive/negative) is developed within reservoir **66**, structural element **112** may inhibit deflection or deformation of lower surface **121** of septum **120** toward or away from upper surface **165** of base **56**. Generally, a structural element may inhibit deformation of a septum in relation to one or more selected directions (i.e., either toward or away from upper surface **165** of base **56**).

Generally, a structural element (e.g., structural element **112**) may comprise any of the following: at least one wire, at least one pin or columnar element, or at least one filament, without limitation. Such a structural element may comprise titanium, steel (e.g., stainless steel), polymers (e.g., DELRIN®, nylon, polyester, KEVLAR®, polytetrafluoroethylene (PTFE) (expanded or nonexpanded), polyurethane, etc.), or other materials as known in the art. In other embodiments, a structural element may comprise a composite, such as a fiber-reinforced matrix. In one embodiment, a structural element may comprise fibers (glass, carbon, etc.) dispersed or aligned within a silicone matrix.

Further, structural element **112** may be coupled to septum **120** by an adhesive, welding, snap-fitting, molding the septum **120** about a portion of the structural element **112**, otherwise imbedding a portion of structural element **112** within septum **120**, or as otherwise suitable. Similarly, structural element **112** may be coupled to base **56** by an adhesive, welding, or imbedding a portion of structural element **112** within base **56**. It may also be appreciated that, optionally, structural element **112** may exhibit a modulus of elasticity that exceeds a modulus of elasticity of septum **120**. Such a configuration may allow for structural element **112** to resist deformation of septum **120** in response to a pressure developed within reservoir **66** (e.g., during a "power injection" process).

FIG. **13** shows a schematic cross-sectional view of an access port **110** according to the instant disclosure including another embodiment of structural element **112**. Particularly,

as shown in FIG. **13**, structural element **112** may include a barbed end **116**, which is positioned at least partially within septum **120**. Such a configuration may couple structural element **112** to septum **120** and may resist against deformation of the septum **120** in response to pressure developed within reservoir **166**. Furthermore, as shown in FIG. **13**, the barbed end **116** of structural element **112** may, optionally, be pointed. Further, the point of barbed end **116** may be oriented toward upper surface **123** of septum **120**. Such a structure may deflect a cannula that is inserted through septum **120** and contacts barbed end **116** so that the cannula is directed away from structural element **112**. Optionally, in another embodiment, structural element **112** may extend through base **56** and may be affixed to lower surface **113** of base **56**.

In another embodiment of an access port, a structural element may extend through a septum. For example, FIG. **14** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from lower surface **121** of septum **120** to upper surface **123** of septum **120**. As shown in FIG. **14**, structural element **112** may also extend to upper surface **165** of base **56**, to mechanically couple septum **120** to housing **60**. Optionally, structural element **112** may include at least one barb, which may be positioned within septum **120** and configured for coupling septum **120** to housing **60**. In addition, structural element **112** may be affixed, if desired, to at least one of upper surface **123** and lower surface **121** of septum **120**. As may be appreciated, it may be advantageous for upper surface **123** of septum **120** to be mechanically coupled to housing **60** to resist deformation of septum **120** in response to a pressure developed within reservoir **66**.

The instant disclosure further contemplates that a structural element may be employed in combination with a support element extending over a selected area of the upper surface of the septum. Such a support element may be positioned adjacent to an upper surface of a septum and may be configured to contact the upper surface of the septum with a selected surface area (e.g., when the septum deforms). For example, FIG. **15** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from housing **60** to an upper surface **123** of septum **120**. Furthermore, structural element **112** is coupled to a support element **114**, which is positioned adjacent to upper surface **123** of septum **120**. Such a configuration may provide a selected amount of contact area between support element **114** and upper surface **123** of septum **120**. Such a selected contact area between support element **114** and septum **120** may reduce otherwise undesirably high stresses within septum **120** when a pressure develops within reservoir **66** by distributing such stresses over a selected area or region of septum **120**. In addition, support element **114** may be observable (e.g., visually or by palpation) and, therefore, may be avoided when inserting a cannula through septum **120**. Additionally, the support element **114** can be used to identify the port **110** as being power injectable.

In another embodiment of an access port, a structural element may comprise a portion of a septum affixed to a housing of an access port to resist deformation of the septum. For example, FIG. **16** shows a schematic, side cross-sectional view of an access port **110** including a septum **120**, which comprises an extension leg **124** (i.e., a structural element) that is coupled to housing **60**. More particularly, as shown in FIG. **16**, extension leg **124** may extend generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Extension leg **124** may abut and may be affixed to upper surface **165** of base **56**. Such a configuration may resist against deformation of septum **120** in response to pressure developed within reservoir **166**. In one embodiment, extension leg **124** may be substantially centered (i.e., positioned generally at a centroid of lower surface **121**) with respect to lower surface **121** of septum **120**. Substantially centering extension leg **124** with respect to lower surface **121** of septum **120** may limit deformation of lower surface **121** of septum **120** to a greater extent than other positions of extension leg **124** may limit deformation of lower surface **121** of septum **120**. Additionally, it should be appreciated that while FIG. **16** shows one extension leg **124**, the instant disclosure contemplates that at least one extension leg (i.e., one or more extension legs) may extend from or be coupled to septum **120**, without limitation. In another embodiment, at least one extension leg may be coupled to a housing of an access port by an interference fit or a so-called "snap-fit." More particularly, as shown in FIG. **17**, extension leg **124** includes a bulbous or rounded end **125** that is configured to fit within a recess **155** formed in base **56**. Recess **155** may comprise an opening formed in upper surface **165** of base **56** that is smaller than a maximum lateral dimension of rounded end **125**, so that rounded end **125** may be forced through such an opening and "snap" into a portion of recess **155**. Optionally, extension leg **124** may be affixed (e.g., adhesively affixed, welded, pinned, or affixed by other suitable methods to recess **155** formed in base **56**. Such a configuration may couple septum **120** to base **60** of access port **110** and may resist or limit deformation of septum **120** in response to pressure developed within reservoir **66**.

Another aspect of the instant disclosure contemplates that at least a portion of an upper surface of a septum may be constrained or limited in its deformation. In one embodiment, at least one structural element may be positioned upon or adjacent to an upper surface of a septum to limit deformation of the septum in a direction toward the structural element. Put another way, at least one structural element may extend laterally upon or adjacent to at least a portion of an upper surface of a septum. For example, FIG. **18** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** and a structural element **132** positioned adjacent to an upper surface **133** of septum **130**. Optionally, structural element **132** may be bonded or affixed to upper surface **133** of septum **130**. Structural element **132** may be structured to resist deformation of septum **130** in a direction generally away from reservoir **166**. In one embodiment, structural element **132** may substantially overlay or cover upper surface **133** of septum **130**. Optionally, structural element **132** may be at least partially embedded within septum **130**. In one embodiment, structural element **132** may be penetrable by a cannula (e.g., a needle). In another embodiment, structural element **132** may cover a selected portion (i.e., at least a portion) of upper surface **133** of septum **130**, which may allow for openings or apertures formed in structural element **132** through which a cannula may be inserted into upper surface **133** of septum **130**. It may be appreciated that, optionally, a modulus of elasticity of structural element **132** may exceed a modulus of elasticity of septum **130**, so that deformation of septum **130** may be inhibited to a selected degree by structural element **132**. Further, although a thickness (labeled "t") of structural element **132** is shown in FIG. **18** as being substantially uniform, the instant disclosure contemplates that a thickness "t" of structural element **132** may vary, without limitation. For example, thickness "t" of structural element **132** may be maximum proximate to a centroid of the upper surface **133** of septum **130**. In addition, as shown in FIG. **18**, structural element **132** may be positioned between cap **54** and septum **130**. Structural element **132** may be affixed to one or both of cap **54** and septum **130**, if desired. For

example, structural element **132** may be adhesively affixed, welded, mechanically fastened, or otherwise suitably coupled to one or both of cap **54** and septum **130**. Furthermore, structural element **132** may comprise a metal (e.g., titanium, steel, etc.), a polymer (e.g., DELRIN® polyurethane, nylon, etc.), or any other suitable material. In another embodiment, as discussed further below, structural element **132** may comprise a relatively tightly woven fabric that resists tissue ingrowth (if positioned in potential contact with an internal cavity of the body). In a further embodiment, a structural element **132** may comprise a substantially fluffy or compressible polyester that may promote tissue healing of punctures created by a cannula passing through septum **130** of access port **110** (if positioned in potential contact with an internal cavity of the body).

In a further embodiment, the instant disclosure contemplates that at least one structural element may be at least partially embedded within a septum and may extend laterally through at least a portion of the septum. For example, FIG. **19** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** and a structural element **140** extending laterally (i.e., across an opening in the housing **60** closed by the septum **120**) through the septum **120**. As shown in FIG. **19**, structural element **140** may be affixed to housing **60** (e.g., cap **54** or base **56**). More particularly, as shown in FIG. **19**, structural element **140** may be affixed to cap **154** at connection regions **147** and **143**. In addition, a selected level of tension may be developed within structural element **140**, if desired, to provide for a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected degree of resistance to deformation of septum **120** in a direction generally perpendicular to a direction of extension of structural element **140**.

In another embodiment, a structural element may be positioned proximate to an upper surface of a septum to limit deformation of the septum. For example, FIG. **20** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** positioned within a housing **60** and a structural element **150** positioned proximate to an upper surface **133** of septum **130**. As shown in FIG. **20**, structural element **150** extends laterally over at least a portion of upper surface **133** of septum **130**. Thus, structural element **150** may allow septum **130** to deform a selected distance (e.g., a gap labeled "G") prior to contact with structural element **150**. Further, structural element **150** may be affixed to cap **54** and may be selectively tensioned to exhibit a selected degree of flexibility in response to contact between septum **130** and structural element **150**. In one embodiment, structural element **150** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **130** in response to a pressure developed within reservoir **66**.

In another embodiment, a structural element may be positioned proximate to or abutting a lower surface of a septum to limit deformation of the septum. For example, FIG. **21** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** positioned within a housing **60** and a structural element **170** positioned proximate to a lower surface **121** of septum **120**. As shown in FIG. **21**, structural element **170** may extend laterally over at least a portion of lower surface **121** of septum **120**. Further, structural element **170** may be affixed to lower surface **121** or septum **120** or otherwise coupled to lower surface **121** of septum **120**. Thus, structural element **170** may inhibit deformation of septum **120**. Further, structural element **170** may be affixed to base **56** (or otherwise coupled to housing **60**) to provide adequate resistance to deformation of septum **120**. Optionally, structural element **170** may be selectively tensioned to exhibit a selected flexibility in response to forces applied to the structural element **170**. Optionally, structural element **170** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **120**.

Referring to FIGS. **18-21**, it will be appreciated that structural elements **132**, **140**, **150**, or **170** may comprise, in some embodiments, elongated elements, such as, for instance, wire, ribbon, thread, fibers, columnar elements, or the like. Accordingly, such at least one elongated element may be arranged in a selected pattern adjacent or proximate to an upper surface of a septum. Further, in one embodiment, a structural element positioned proximate to or abutting a lower surface of a septum, proximate to or abutting an upper surface of a septum, or within a septum, may comprise a mesh (e.g., a metal or plastic mesh, a fabric, a fiber mesh, etc.). For instance, in one embodiment, a structural element may comprise a fabric comprising fibers or threads that seal against one another (e.g., fibers or threads coated with silicone). Such a configuration may allow for a cannula to pass through the fabric and for the fabric to seal about the cannula, but may also allow for the fibers or threads to seal against one another when the cannula is removed. In addition, it will be understood that, based upon the instant disclosure, structural elements **132**, **140**, **150**, or **170** as shown in FIGS. **18-21** may be arranged in a variety of configurations.

For example, FIG. **22** shows a partial top elevation view of one embodiment of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged to form a generally triangular shape or pattern. In a further example, FIG. **23** shows a partial top elevation view of an access port **110** as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged in two partially intersecting generally rectangular shapes or pattern. In yet a further embodiment, FIG. **24** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising a first plurality of substantially parallel lines and a second plurality of substantially parallel lines, wherein the first plurality of substantially parallel lines is substantially perpendicular to and intersects with the second plurality of substantially parallel lines. In an additional embodiment, FIG. **25** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising two substantially straight (i.e., linear) members that intersect with one another. As shown in FIG. **25**, structural elements **132**, **140**, **150**, **170** may be substantially perpendicular to one another. As shown in FIGS. **22-25**, structural elements **132**, **140**, **150**, **170** may be affixed to cap **54** at selected connection regions. Such configurations may allow for varying degrees of limitation of deformation of a septum, while allowing ample access to a surface of a septum for perforation by a cannula (e.g., a needle).

In another embodiment, the instant disclosure contemplates that a structural element may be at least partially embedded within a septum and may be in the form, configuration, or shape of a two-dimensional or plane (e.g., a circle, ellipse, triangle, rectangle, etc.) within the septum. For example, FIG. **26** shows a partial top elevation view of a septum **120** and a structural element **141** extending within the septum **120**. In further detail, FIG. **27** shows a perspective view of a sectioned septum **120** including a structural element **141** embedded within the septum **120**. As shown in FIGS. **26** and **27**, in one embodiment, structural element **141** may be generally circular. More generally, one or more structural elements **141** may be at least partially embedded within a septum (e.g., a septum **120** or **130**, as discussed above), if

desired. For example, a plurality of structural elements **141** may be embedded within a septum **120** and arranged substantially concentrically with respect to one another, as shown in FIG. **28** in a partial, top elevation view. Structural element **141** may be generally elongated (as shown in FIGS. **26-28**) or may, more generally, exhibit a shape and size configured to resist deformation of the septum **120**, without limitation. Thus, it should be appreciated that one or more structural elements **141** may embody, for example, a washer or a disk that is frustoconical, domed, or otherwise shaped. In another embodiment, at least one structural element **141** may form, generally, a toroid. Further, at least one structural element **141** may exhibit at least one selected characteristic (e.g., exhibiting a selected size, shape, elasticity, strength, etc.) to impart a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected level of resistance to deformation of septum **120** in response to a pressure developed within a reservoir of an access port.

In another aspect of the instant disclosure, a septum may exhibit a curvature that resists deformation in response to a pressure developed within a reservoir of an access port. For example, FIG. **29** shows a septum **120** including a generally concave upper surface **123** and a generally convex lower surface **121**. Explaining further, generally concave upper surface **123** and a generally convex lower surface **121** may be exhibited by septum **120** in the absence of external forces (i.e., in an unstressed, equilibrium state). Such a configuration may provide resistance of the septum **120** to deformation due to a pressure developed within reservoir **66** of access port **110**, because the upper surface **123** of septum **120** would be forced to flatten (i.e., via deformation of septum **120**) before extending beyond the upper surface of housing **60**. In other embodiments, a septum may be compressed (e.g., by way of a tenon and mortise coupling or another peripheral coupling configuration between a septum and a housing) so that a curvature of the septum may be reduced or eliminated when the septum is assembled within the housing. However, such a configuration may increase the bulk flexibility or spring constant of the septum. Optionally, a structural element (as described above) may be included within the septum or upon a surface of the septum and may also be fabricated to exhibit concavity or convexity in the absence of external forces. Such a configuration may facilitate a favorable compressive stress field within the septum when coupled to a housing and may enhance resistance of the septum to deformation.

In a further configuration, a septum may include a structural frame or skeleton and a more pliant material configured to seal punctures created by a cannula. More specifically, a frame may comprise a material with a shore A hardness of at least about 80. Optionally, a frame may include a plurality of whiskers, fibers, or particles to stiffen or strengthen the frame. In one embodiment, nylon fibers, barium sulfate, or the like may be dispersed within a frame. Further, such a frame may be at least partially surrounded by a more pliant material exhibiting a Shore A hardness of about 50 or less (e.g., a Shore A hardness of about 40 to about 50). FIG. **30** shows top elevation view of a frame **178** including a plurality of spokes **179** extending from a generally common origin or region as well as rings **181** and **185**. As shown in FIG. **30**, spokes **179** in combination with one or both of rings **181** and **185** form apertures **188**. According to the instant disclosure, a relatively pliant material configured to seal punctures formed by a cannula passing through the material may at least partially surround such a frame **178**. For instance, FIG. **31** shows a schematic side cross-sectional view of septum **177** comprising a frame **178** and another material **190** molded partially about frame **178**. Thus, material **190** may substantially surround spokes **179** and may extend within apertures **188**. Further, as shown in FIG. **31**, ring **181** may form a tenon region **270** for coupling with a housing (as described above) as well as an upper septum surface **191** and a lower septum surface **193**. As may be appreciated with reference to shown in FIG. **31**, during use, a cannula may pass through a continuous upper layer of material **190** and a continuous lower layer of material **190**. Such a configuration may provide suitable sealing capability for septum **177**. It will be appreciated that many variations are contemplated by the instant disclosure. For example, FIGS. **32** and **33** show side cross-sectional views of different embodiments of a septum **177** including a frame **178** and another material **190** at least partially surrounding the frame **178**. Thus, a frame and a material at least partially surrounding the frame may exhibit arcuate or substantially planar surfaces and may be formed of selected thickness and comprising selected materials (e.g., silicone, etc.).

In a further aspect of a septum according to the instant disclosure, a septum may include a radiopaque material and may be configured to form a selected pattern when an x-ray is taken through the septum. For example, FIGS. **34** and **35** show schematic views of patterns **199** that may be generated by correspondingly positioned radiopaque material within a septum. Such a configuration may be useful for identifying the access port as being capable of accommodating particular power injection processes or for locating the septum of an access port.

The instant disclosure further contemplates that any infusion apparatus or device that is used in combination with an access port for infusing fluid at a rate of at least about 1 milliliter per second may be configured accordingly. For example, an infusion set for accessing a vascular access port may include a needle or cannula for puncturing a septum of the access port, a distal end for coupling to an injection apparatus, and tubing (e.g., at least one tubing section) extending between the cannula and the distal end. Generally, any components comprising an infusion set may be configured to withstand a selected flow rate and associated pressure developed by such a selected flow rate.

FIG. **36** shows one embodiment of an infusion set **310** including a base member **340**, a cannula **350**, a tubing section **314**, and connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and base **342** generally at joints **313** and **339**, respectively. Also, as shown in FIG. **36**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Further, each of the base member **340**, cannula **350**, tubing section **314**, and end connector **312** may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second through the infusion set **310**. In further detail, tubing section **314** may exhibit sufficient strength for withstanding at least about 200 psi without damage. Optionally, tubing section **314** may withstand at least about 300 psi without damage. Further a pressure at which a portion of the infusion set bursts (i.e., a burst pressure of the infusion set **310**) may be at least about 400 psi; optionally, such a burst pressure may be at least 600 psi. In one embodiment, tubing section **314** may be substantially optically clear or may be at least partially transparent. In one embodiment, generally, tubing section **314** may comprise a polymer, such as TECOTHANE®. More specifically, tubing section may comprise a polymer, such as TECOTHANE® 55D or a polymer, such as TECOTHANE® 95A. For example, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.048 inches (±0.003 inches) (i.e., 19 GA), tubing section **314** may comprise a polymer, such as TECOTHANE® 55D. In other examples, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.041 inches or

0.034 inches (±0.003 inches) (i.e., 20 GA or 22 GA, respectively), tubing section **314** may comprise a polymer, such as TECOTHANE® 95A. Optionally, any polymer, such as TECOTHANE® type material may be at least substantially free of a plasticizer, such as, for instance, Di(2-Ethylhexyl) Phthalate ("DEHP"). In one embodiment, connector **312** may comprise polyvinylchloride ("PVC") and may be, optionally, at least substantially free of plasticizer. The materials disclosed above are merely examples; more generally, tubing section **314**, connector **312**, base member **340**, and cannula **350** may comprise any material (e.g., thermoplastic, polyurethane, metal, etc.) suitable for providing a robust and effective infusion set **310**.

During use of the infusion set **310**, a mechanical injector may be operably coupled to connector **312** via fastening structure **311**. For example, fastening structure may comprise a luer-type connection or any other fluid connection structure. Thus, a fluid may be flowed through the infusion set at a flow rate of at least about 1 milliliter per second via an injection apparatus. As discussed above, a pressure drop through the infusion set **310** may be at least about 100 psi; optionally, a pressure drop through infusion set **310** may be at least about 185 psi.

In another embodiment, an infusion set may include two connectors. In one configuration, one connector may be structured for performing power injection and another connector may be structured for allowing syringe access. For example, FIG. **37** shows an infusion set **309** including a base member **340**, a cannula **350**, a tubing section **324**, an intermediate connector **322**, a tubing section **314**, and an end connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and connector **322** generally at joints **313** and **323**, respectively. Similarly, tubing **324** may be affixed or otherwise coupled to connector **322** and base member **340** generally at joints **325** and **329**, respectively. Infusion set **309** may be structured for fluid flow rates and pressures as discussed above in relation to infusion set **310**. Accordingly, tubing sections **314** and **324** may comprise materials (e.g., a polymer, such as TECOTHANE® and sizes as discussed above in relation to infusion set **310**, without limitation. Similarly, connectors **312** and **322** may comprise any materials (e.g., PVC) discussed above in relation to infusion set **310**, without limitation. As shown in FIG. **37**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Likewise, clamp device **326** may be suitably configured for allowing or preventing fluid flow through tubing **324**. In addition, connector **312** may include a fastening structure **311** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **312** to an injection apparatus. Also, connector **322** may include a fastening structure **321** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **322** to an injection apparatus.

Generally, the instant disclosure contemplates that, in one embodiment, connector **312** may be used for power injection, while connector **322** is capped. In another embodiment, a valve mechanism may selectively allow flow through tubing sections **314** and **324** via fluid flow through connector **312**, while preventing leakage from connector **322**. In addition, if infusion set **309** is not being used for power injection, a cap including a septum may be coupled to connector **322**, connector **312**, or both. Such a configuration may allow for a syringe to puncture the septum and infuse medication or remove a blood sample. Such a configuration may provide a convenient infusion set with separate connectors for power injection and syringe access, respectively.

In a further aspect contemplated by the instant disclosure, tubing that is used in connection with power injection may be structured for withstanding a selected pressure during use (e.g., power injection) and, optionally, may be configured to resist kinking. Generally, the instant disclosure contemplates that tubing may comprise a plurality of layers. In one embodiment, tubing may comprise a relatively high strength layer and at least one relatively flexible layer. Thus, any layers of tubing may comprise PTFE, polypropylene, polyetheretherketone ("PEEK"), polyimide silicone, fluorinatedethylenepropylene (FEP), perfluoroalkoxy (PFA), ethylenetetrafluoroethylene (ETFE), polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing. In one embodiment, the layers may be bonded to one or more adjacent layers. In another embodiment, each of the layers may be movable or slidable relative to one or more adjacent layers.

For example, FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of tubing **401** including an inner layer **420** and an outer layer **422**. Generally, at least one of inner layer **420** and outer layer **422** may exhibit relatively high strength and the other of inner layer **420** and outer layer **422** may be relatively flexible or vice versa. In one embodiment, inner layer **420** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like. Further, outer layer **422** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone or the like. Conversely, outer layer **422** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like, while inner layer **420** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone, or the like. Further, optionally, tubing may comprise a first layer exhibiting a modulus of elasticity and at least another layer exhibiting a modulus of elasticity that is less than the modulus of elasticity of the first layer. For example, a relatively high strength material may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, a relatively flexible material may exhibit a modulus of elasticity below about 390,000 psi. In another embodiment, at least one of layers **420** and **422** may comprise a composite material (e.g., a composite including particulate or fiber reinforcement). For example, in one embodiment, tubing may comprise polyurethane or PTFE including glass or carbon reinforcing fibers or particles. In one embodiment, each of the layers **420** and **422** may be movable or slidable relative to one or more adjacent layers. Such a configuration may withstand a selected internal pressure without damage to the tubing and may also resist kinking.

In another embodiment, a reinforcing element may be incorporated within at least one of the plurality of layers comprising tubing. For example, FIG. **40** shows a schematic side cross-sectional view of tubing **403** including inner layer **430** and outer layer **432**, wherein at least one reinforcing element **434** is incorporated within outer layer **432**. Optionally, at least one reinforcing element **434** may be incorporated within any layer or layers of a plurality of layers comprising tubing, without limitation. As shown in FIG. **40**, reinforcing element **434** may comprise a coil, in one embodiment. One of ordinary skill in the art will appreciate that many variations are possible, for example, at least one reinforcing element may comprise a mesh (e.g., a wire mesh, a fabric, a fiber mesh, etc.). In another embodiment, at least one reinforcing member

may comprise one or more elongated members extending longitudinally within at least one layer comprising tubing (e.g., aligned with the direction of extension of the tubing). In another embodiment, at least one reinforcing member may comprise one or more rings. Such a configuration may provide radial stiffness, strength, or both to a tubing section.

Referring to FIG. **40**, in one embodiment, inner layer **430** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, outer layer **432** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, silicone, or polyurethane. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.001 inches. As mentioned above, layers **430** and **432** may be bonded to one another or may be movable (slidable, twistable, etc.) with respect to one another. Optionally, a coating **433** may be applied to at least a portion of exterior surface of layer **432**. Such a coating **433**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In a further embodiment, FIG. **41** shows a schematic side cross-sectional view of tubing **405**, including inner layer **440** and outer layer **442**, wherein at least one reinforcing element **444** is incorporated within inner layer **440**. As shown in FIG. **41**, reinforcing element **444** may comprise a coil, in one embodiment. In other embodiments, reinforcing element may comprise any structure discussed above in relation to reinforcing element **434**, without limitation. In addition, in one embodiment, inner layer **440** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, or polyurethane. Further, outer layer **442** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.010 inches. Optionally, a coating **443** may be applied to at least a portion of exterior surface of layer **442**. Such a coating **443**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In an additional embodiment, tubing may include four layers. For example, FIGS. **42** and **43** show a cross-sectional end view and a side cross-sectional view of another embodiment of tubing **400**. More particularly, as shown in FIGS. **42** and **43**, tubing **400** includes layers **402**, **404**, **406**, and **408**. As shown in FIG. **42**, layer **402** defines a lumen **410**. In one embodiment, lumen **410** may have a substantially circular cross-sectional shape and may exhibit a diameter of about 0.024 inches. In another embodiment, each of the layers **402**, **404**, **406**, and **408** may be movable or slidable relative to one or more adjacent layers. In addition, layer **402** may comprise a material exhibiting a relatively high tensile strength. Such a configuration may withstand relatively high pressures within lumen **410**. For example, layer **402** may comprise PEEK, polyimide, etc. Typically, such relatively high strength materials may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, each of layers **404**, **406**, and **408** may comprise a material that is relatively flexible. Such layers **404**, **406**, and **408** may each exhibit a tensile strength that is less than the tensile strength of layer **402**. For example, each of layers **404**, **406**, and **408** may comprise a fluoropolymer, PEBAX®, polyethylene terephthalate ("PET"), silicone, etc. Typically, such relatively flexible materials may exhibit a modulus of elasticity below about 390,000 psi. However, any layers may comprise PTFE, polypropylene, silicone, FEP, PFA, ETFE, polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing, without limitation.

In a further aspect of the instant disclosure, at least one layer comprising a tubing section may extend distally from a slender hollow structure for accessing a reservoir of an access port through a septum. Put another way, at least one layer may extend from a tubing section and may be structured for puncturing a septum of an access port. For instance, FIGS. **44** and **45** show a schematic side cross-sectional view of tubing **400**, **401**, **403**, **405**, and an access port **50**. Tubing **400**, **401**, **403**, **405** (as described above) includes a slender hollow region **450**. Further, slender hollow region **450** may be relatively stiff and suited for penetrating a septum **80** of an access port **50**, as shown in FIG. **45**. Thus, a slender hollow region **450** extending from a distal end of tubing **400**, **401**, **403**, **405** (which comprises a plurality of layers) may form a needle or cannula for fluid communication between a lumen of tubing **400**, **401**, **403**, **405**, and a reservoir **66** of access port **50**. More particularly, a slender hollow region **450** may comprise one or more layers exhibiting a relatively high strength of relatively high-strength layers (e.g., PEEK) forming tubing **400**, **401**, **403**, **405**. In one embodiment, an innermost layer of tubing **400**, **401**, **403**, **405** may form slender hollow region **450**. Such a configuration may be advantageous and may, for example, reduce the complexity of manufacturing an infusion set.

Many different embodiments of vascular access apparatuses or infusion systems may incorporate one or more aspects of the instant disclosure. Some embodiments of a vascular access apparatuses or infusion systems are disclosed in U.S. Patent Application No. 60/675,309, filed Apr. 27, 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the infusion systems, apparatuses, or methods, taken alone or in combination, described in U.S. Patent Application No. 60/675,309, may be structured or otherwise suited for performing power injection (e.g., accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation).

For example, the instant disclosure contemplates that an infusion system configured for establishing fluid communication between a flexible tube and a reservoir of an access port may be structured for power injection. Such an infusion system may include a slender pointed element that facilitates placement of the flexible tube through a septum of the access port and is removable from the infusion system once the flexible tube is appropriately positioned.

Particularly, FIG. **46** shows in one embodiment an infusion system **510** in an exploded assembly view, including an insertion assembly **520**, a safety clip **530**, a hub **540** flexible tubing **590**, extension tube **570**, clamp device **560**, and tube connector **580**. In further detail, FIG. **47** shows a partial side cross-sectional view of infusion system **510**. As shown in FIG. **47**, insertion assembly **520** comprises a base **528** and a slender pointed element **522** (e.g., a needle, a trocar, or a cannula) secured thereto. As shown in FIG. **47**, slender pointed element **522** includes a pointed end **525**. In a particular embodiment, the instant disclosure may utilize a slender pointed element having a "non-coring" pointed end (i.e., pointed end **525** is not "open" or hollow) to avoid damaging a septum of a port into which the slender pointed element is inserted. The slender pointed element **522** may comprise any conventional needle, trocar, or cannula material, such as a stainless steel (e.g., AISI 304 stainless steel), or may, in another embodiment, comprise a relatively hard plastic. In one embodiment, base **528** may be injection molded or otherwise formed about slender pointed element **522** to capture a portion of the slender pointed element within the base **528**, as best seen in FIG.

47. Further, base **528** may optionally include a recess **524** structured for accommodating other mechanisms (e.g., safety clip **530**), if such a recess is desirable. Base **528** may also, optionally, include a coupling feature **526** (e.g., a protrusion) structured for coupling to a coupling feature **544** (e.g., a recess) formed in hub **540**. Hub **540**, as shown in FIG. **47**, may generally include hub body **550**, manifold element **561**, septum **548** and cap **546**. In one embodiment, hub body **550** may comprise TECOFLEX® (e.g., such as TECOFLEX® 85A-B20). Further, hub body **550** may define wing structures **541** and **543** (FIG. **46**), which may be configured for affixing the hub to skin of a patient (e.g., by taping wing structures **541** and **543** to a patient, adhesively affixing wing structures **541** and **543** to a patient, or otherwise affixing wing structures **541** and **543** to a patient). Wing structures **541** and **543** may be employed for manipulation of the hub, such as, for example, when inserting the slender pointed element **522** and flexible catheter **590** into an implanted port or when removing the slender pointed element **522** from an implanted port. Hub body **550** may optionally include a recess **542**, if such a recess is desirable. As shown in FIG. **47**, recess **542** may have a retaining lip **559** for retaining safety clip **530** therein, while long slender element **522** is positioned through the safety clip, as discussed in further detail hereinbelow.

Hub **540** may be structured for allowing the slender pointed element **522** of insertion assembly **520** to pass through the hub **540** and through septum **548**, which is positioned within the hub **540**. Put another way, manifold element **561** may define a plurality of passageways and at least one septum **548** through which fluid communication with the plurality of passageways may be accomplished. Explaining further, a manifold element **561** may be configured for housing septum **548** to provide a seal a port or opening of a plenum defined by manifold element **561**. Optionally, a cap element **546** may be positioned to capture septum **548** between cap element **546** and manifold element **561**. Cap **546** may include an aperture **547** for allowing a slender pointed element to pass therethrough and through septum **548**. Thus, slender pointed element **522** (e.g., an appropriately sized trocar, non-coring needle, or non-coring cannula) may be inserted through and removed from septum **548** without compromising the ability of septum **548** to seal. Further, the presence of cap **546** may allow for so-called "power injection" to occur via manifold element **561**, wherein pressures within manifold element **561**, tubing **570**, and flexible catheter **590** may reach at least about 200 psi or higher. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, for performing power injection, etc.), without limitation.

As shown in FIG. **47**, flexible catheter **590** may be affixed to manifold element **561** and extension tube **570** may be affixed to manifold element **561**. In one example, extension tube **570** and flexible catheter **590** may be chemically bonded to manifold element **561**. In another example, an adhesive may affix extension tube **570** to surface **552** a part of manifold element **561**. Similarly, an adhesive may affix flexible catheter **590** to inner surface **562** another port of manifold element **561**. Further, the hub body **550** may be formed (e.g., injection molded, cured, or otherwise over-molded) over the manifold element **561** (and, optionally the septum **548**, the cap **546**, or both) and at least a portion of the extension tube **570** as shown in FIG. **47**. In another embodiment, the hub body **550** may be formed over at least a portion of the flexible catheter **590**, if desired.

Generally, as mentioned above, any tubing disclosed in the instant disclosure may comprise a portion of infusion system **510**. Further, tubing clamps and connection devices as known in the art, may be employed for extension tubing **570**, clamp device **560**, and tube connector **580**.

Flexible catheter **590** may comprise any material that is suitable for power injection. For example, in one embodiment, flexible catheter **590** may comprise a polymer, such as TECOTHANE® (e.g., TECOTHANE® TT1055 D). As shown in FIG. **47**, flexible catheter **590** may include an elongated lumen therein. Further, flexible catheter **590** may have, proximate to opening **593** thereof, a transition region **595** wherein a cross-sectional size (transverse to the lumen **594**) of the flexible catheter **590** increases as a function of increasing distance from opening **593**. Optionally, transition region **595** may include two distinct tapers, although the instant disclosure contemplates more generally that at least one taper, at least one arcuate surface, or combinations thereof may define transition region **595**. Generally, at least one aperture (e.g., one or more than one) may be provided proximate opening **593** that extends through the tubular body of flexible catheter **590** and communicates with lumen **594**. As shown in FIG. **47**, flexible catheter **590** may include two apertures **592** in fluid communication with lumen **594**.

As shown in FIG. **47**, slender pointed element **522** may extend through safety clip **530**, through aperture **547** of cap **546**, and into flexible catheter **590**. Slender pointed element **522** may be structured for allowing fluid communication within flexible catheter **590**. More particularly, slender pointed element **522** may be sized so as to allow for clearance between the exterior of the slender pointed element **522** and the interior (i.e., the lumen) of the flexible catheter **590**. In one embodiment, slender pointed element **522** may include at least one longitudinally extending indentation (with respect to a nominal cross-sectional shape of the slender pointed element **522**). For example, slender pointed element **522** may have a pointed end **525** and may include longitudinally extending indentations extending along (i.e., along a longitudinal axis of) slender pointed element **522**. In another embodiment, slender pointed element **522** may be generally circular, and longitudinally extending indentations may form a substantially triangular cross section of the slender pointed element **522** over the portion of the slender pointed element that they are formed.

In a further embodiment, an infusion system may be structured so that a slender pointed element passes through an extension tube, a flexible catheter, or both. Explaining further, appropriate placement and configuration of a septum may allow for a slender pointed element to pierce or pass into an extension tube, a flexible catheter, or both. FIGS. **48** and **49** show another embodiment of a hub **540** including recess **542**, sleeve **620**, and septum **548**. In addition, at least a portion of each of extension tube **570** and flexible catheter **590** may extend partially within hub body **550**. Further, flexible catheter **590** extends partially within extension tube **570**. Put another way, flexible catheter **590** may at least partially overlap with extension tube **570** and vice versa. In another embodiment, a single tubular element may extend through hub **540** and function as both the flexible catheter **590** and extension tube **570**, if desired. Further, optionally, septum **548** may at least partially surround a portion of extension tubing **570**. Such a configuration may facilitate sealing of septum **548** upon removal of slender pointed element **522** therefrom. Sleeve **620** may compress septum **548** so as to facilitate sealing of septum **548** upon removal of slender pointed element **522** from the region of the septum **620** that the sleeve **620** surrounds. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, etc.) for performing power injection, without limitation.

Further, FIG. **50** shows a perspective view of safety clip **530** positioned generally about pointed end **525** of slender pointed element **522**. Safety clip **530** includes legs **533** and **535** each having a curved end region, respectively, and a hole **534** sized for passing there through slender pointed element **522**. In further detail, initially slender pointed element **522** may be passed through hole **534** and between legs **533** and **535** may be positioned and configured so as to allow the slender pointed element **522** to extend there past. Further, when the slender pointed **522** element is positioned therein and safety clip **530** is positioned within recess **542**, safety clip **530** may be sized so that it will fit within the retaining lip **543** (FIG. **49**) of recess **542** (FIG. **49**). However, legs **533** and **535** may be biased so that if the pointed end **525** of the slender pointed element **522** is moved toward hole **534** and does not extend past the curved end regions of the legs **533** and **535**, legs **533** and **535** will move toward one another to effectively capture the pointed end **525** of the slender pointed element **522**. Safety clip **530** may comprise any self-actuating device for capturing a pointed end **525** of a slender pointed element **522**. Such a safety clip **530** may reduce the chance of inadvertent insertion of the slender pointed element **522** into another person, particularly the medical practitioner that is installing and removing the slender pointed element **522**.

The instant disclosure further recognizes that because the consequences of improperly pressurizing an access port (and a catheter affixed to the access port, if any) or an infusion set may be problematic, it may be advantageous to provide at least one identification attribute to components of an infusion system so that all of such components may be suitable for withstanding an anticipated maximum flow rate and pressure associated with a selected infusion process. Put another way, an access port that is configured for accommodating a flow rate of at least about 1 milliliter per second may include at least one identification attribute. Such an at least one identification attribute may be observed (e.g., visually, by palpation, ultrasonically, radiographically, etc.) or otherwise detected. The term, "identification," as used herein and in connection with any infusion devices (an access port, infusion set, etc.), means the ability to correlate selected information of interest with a perceivable feature.

The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. Patent Application No. 60/658,518, filed 4 Mar. 2005, may identify an access port as being structured for power injection. Also, embodiments of an access port including at least one identification attribute are disclosed in U.S. patent application Ser. No. 11/320,223, filed 28 Dec. 2005, the disclosure of which is incorporated, in its entirety, by this reference. The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. patent application Ser. No. 11/320,223 may identify an access port as being structured for power injection. Further, an access port may be identified by a maximum rate at which fluid may safely be infused. For example, at least one identification attribute may indicate that an access port is configured for accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation.

Referring to an access port encompassed by the instant disclosure, at least one attribute of a housing of an access port may provide at least one identification attribute for identifying the access port as being structured for power injection at a rate of at least about 1 milliliter per second. In one embodiment, at least one physical attribute (e.g., size, shape, etc.) of an access port may identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port.

Thus, one aspect of the instant disclosure relates to a method of identifying an access port (e.g., subcutaneously implanted or otherwise situated, without limitation) as being suited for power injection. More particularly, an access port including a septum may be provided. Further, at least one attribute of the access port may be perceived. In addition, the subcutaneously implanted access port may be identified as being suitable for power injection in response to perceiving the at least one attribute of the access port.

In one embodiment, at least one attribute for identification may comprise at least one feature of an access port housing. In further detail, FIG. **51** shows a perspective view of an assembled access port **50**. As shown in FIG. **51**, a side periphery **295** (e.g., one or more side walls and, optionally, exposed surfaces of suture plugs **291**) of access port **50** may be generally triangular. Thus, cap **54** and base **56** may collectively form a generally triangular housing **60** of access port **50**. Also, the instant disclosure contemplates that side periphery **295** may taper or arcuately extend between an upper surface **61** of cap **54** and lower surface **51** of base **56**. As shown in FIG. **51**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **51**, if planar, of base **56**) of access port **50** may be larger proximate to lower surface **51** of base **56** and may be relatively smaller proximate to an upper surface of cap **54**. FIG. **52** shows a top elevation view of the access port **50** shown in FIG. **52** and illustrates a generally triangular shape defined by side periphery **295**. Additionally, FIG. **53** shows a simplified representation of a transverse cross section of access port **50**. As shown in FIG. **53**, side periphery **295** of access port **50** may define three side regions **303** that extend between associated vertex regions **301**. In addition, in one embodiment and as shown in FIG. **53**, side periphery **295** may define a substantially equilateral generally triangular shape. As may be appreciated, side regions **303** may arcuately extend between associated vertex regions **301**; thus, side regions **303** may form "sides" of a generally triangular shape. Further, although vertex regions **301** are rounded, it will be appreciated that such vertex regions **301** form an intersection between adjacent side regions **303**. Accordingly, it will be appreciated that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect at or within vertex regions, without limitation. For example, "generally triangular" encompasses three-sided polygons, circular triangles, equilateral triangles, etc., without limitation.

Furthermore, in a further embodiment, at least one attribute for identification may comprise a radiographic marker. More particularly, an access port may exhibit an observable pattern, symbol, marker, or other indicium that indicates that the access port is structured for accommodating a particular flow rate, pressure, or both. In another embodiment, at least one attribute for identification may comprise a perceptible aspect, such as a visually perceivable feature. For example, at least one color, at least one symbol, at least one typographical character (e.g., a letter, a number, etc.), a pattern, or any other indicium that may be visually perceivable or otherwise perceptible may be used. In a yet additional embodiment, an ultrasound detectable feature may be incorporated within an access port. In a further additional embodiment, an access port may comprise an RFID tag.

It will be appreciated that other equipment and devices (e.g., infusion sets, tubing, injectors, etc.) may be identifiable in relation to a suitable maximum flow rate or maximum pressure. For example, particular infusion apparatuses may include one or more of the above-mentioned identification attributes or features. Such a configuration may allow for different components (e.g., tubing, needles, access ports,

mechanical injectors, etc.) to be matched with one another. For example, substantially similar or matching identification attributes shared by a power injection apparatus, an infusion set, and an access port may indicate suitability for use with one another to perform a selected power injection process.

Another aspect of identification of an access port may relate to identification of a patient within which an access port is implanted. More specifically, a patient may be provided with an identification card that carries perceptible (e.g., visually, via magnetic strip, bar code, manually, or by other suitable mechanisms) information regarding an implanted port. Thus, such an identification card may be presented to a health care worker, the information carried by the identification card may be perceived, and the access port may be identified. Upon identifying the access port, characteristics of the access port may be ascertained, such as, for instance, a maximum flow rate, a maximum pressure, suitability for a particular procedure or procedures, etc. In another embodiment, a wristband or bracelet may be provided to a patient within whom an access port is implanted. In a further embodiment, a key chain including an information carrying device, such as, for example, a magnetic strip, a bar code, a computer readable media or device (e.g., a compact disk, "flash" memory, a disk drive, etc.), or any other suitable information carrying device. In another embodiment, a sticker containing the port information can be applied to the chart of the patient. In further embodiments, labeling on the infusion set can be used to identify the set as power injection compatible.

A further aspect of the instant disclosure relates to a septum comprising a gel or viscous liquid. The term "gel," as used herein, means a colloid with at least one solid component suspended within at least one liquid component, wherein the solid particles (e.g., polymer particles) are attracted or otherwise linked to one another (e.g., entangled or cross-linked) by covalent, ionic, or dispersion (physical) forces. Thus, in one embodiment, a gel may be a colloid in which the solid disperse phase forms a network in combination with the fluid continuous phase to produce a viscous or semi-rigid sol. A gel may exhibit stress-strain behavior that is elastic, viscoelastic, or plastic, without limitation. The term "viscous liquid," as used herein, means a liquid exhibiting a viscosity of about 20,000 centipoises or higher.

One or more passageways formed through a septum positioned within a housing to form an access port may allow for leaking of fluid through the one or more passageways if the reservoir of the access port is pressurized. The instant disclosure contemplates that a gel region may be generally positioned between an upper surface of a septum and a lower surface of a septum, to facilitate a cannula extending through the septum from the upper surface to the lower surface to also pass through at least a portion of the gel region.

For example, in one embodiment, a septum may include a gel that is at least substantially surrounded by a body material. For instance, FIG. **54** shows a schematic, side cross-sectional view of a septum **610** including a body **612** and a gel region **620** positioned within body **612**. Gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. In one embodiment, gel region **620** may comprise a silicone gel. In another embodiment, a gel region may comprise an initially an uncured liquid (i.e., has a relatively low viscosity) that may be cured to cause the liquid to form a gel. In a further embodiment, gel region **620** may comprise a viscous liquid, or a viscoelastic material.

In one example, gel region **620** may comprise an elastomer, such as, DOW CORNING® 7-9600 Soft Filling Elastomer, Parts A & B, which is commercially available from DOW CORNING Corporation of Midland, Mich. In another embodiment, gel region **620** may comprise Silicone Gel MED-6340, which is commercially available from NuSil Technology of Carpinteria, Calif. In yet a further embodiment, gel region **620** may comprise an elastomer exhibiting a Shore A hardness of about 20 to about 30, such as, for instance, DOW CORNING® C6-515 Liquid Silicone Rubber, Parts A & B or DOW CORNING® C6-530 Liquid Silicone Rubber Parts A & B, either of which is available from DOW CORNING Corporation of Midland, Mich. Further, optionally, body **612** of septum **610** may comprise a silicone material with a Shore A hardness of about 50 to about 60. In another embodiment, body **612** and/or upper surface **614** of septum **610** may comprise a silicone material with a Shore A hardness of about 60 to about 80. Optionally, body **612** and/or upper surface **614** of septum **610** may comprise a fluoropolymer (e.g., PTFE, etc.) or polyurethane.

One of ordinary skill in the art will understand that, upon removal of a cannula extending through at least a portion of gel region **620**, a passageway or channel formed through gel region **620** may rebound, recover, seal, or heal. Further, gel region **620** may seal passageways formed through body **612** and upper surface **614**. For example, gel region **620** may inhibit or prevent fluid leakage from a reservoir of an access port through the septum **610** when a pressure within the reservoir exceeds an ambient pressure external to the access port (e.g., during a power injection process, any process for flowing a fluid through an access port as described above, or any process for flowing a fluid through an access port as known in the art, without limitation). In addition, gel region **620** may be formulated and/or body **612** may be structured so that a cannula passing through septum **610** will resist transferring or removing any of the material comprising gel region **620** outside of a selected boundary or envelope. In one embodiment, body **612** may be structured to remove a material comprising gel region **620** from a cannula passing through the body **612**.

Any of the septum embodiments discussed herein may include at least one gel region. For example, FIG. **55** shows a schematic, side cross-sectional view of a septum **611** including a body **612** and a gel region **620**. As discussed above, gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. Such a configuration may provide a robust septum that resists leaking even if a multitude of passages are formed through the septum with a cannula. Furthermore, providing a septum comprising a gel may improve a sealing ability or quality of the septum. Accordingly, a septum including a gel material may exhibit a reduced thickness (i.e., from an upper surface to a lower surface) in comparison to a conventional septum. For example, FIG. **56** shows a septum **613** including a body **612** and a gel region **620**, wherein a thickness T is less than a conventional thickness of a conventional septum. In one embodiment, a thickness T of septum **613** may be about 0.500 inches or less.

The instant disclosure contemplates a variety of different manufacturing methods may be employed for forming a septum comprising a gel. For example, generally, a body of a septum may be formed to substantially surround at least one gel region or a recess or chamber may be formed by a septum body that is filled with a gel. In one embodiment, a gel region may be suspended within a mold for forming a body of a septum. More particularly, FIG. **57** shows a schematic, side cross-sectional view of a first mold **652** and a second mold **654**, wherein gel region **620** is positioned between (e.g., suspended) first mold **652** and second mold **654**. As shown in

FIG. **57**, gel region **620** is positioned by a frame element **630**, which abuts parting surface **655** of second mold **654**. As shown in FIG. **57**, frame element **630** may be positioned by pins **606**. In other embodiments, frame element **630** may be suitably positioned, without limitation. In a particular embodiment, parting surface **653** of first mold **652** may be positioned proximate to parting surface **655** of second mold **654** (i.e., parting surfaces **653** and **655** may be separated by frame element **630**) to form a chamber defined by cavity **658** and cavity **656**. Further, a hardenable material (e.g., a curable material, such as a curable silicone, a thermoplastic, a resin, etc.) may be injected into the chamber and hardened. Thus, the hardenable material may surround or encapsulate gel region **620** and may exhibit a geometry that is complimentary to cavities **656** and **658**.

Generally, frame element **630** may be coupled to or affixed to gel region **620**. In one embodiment, frame element **630** may couple or engage at least a portion of a periphery of gel region **620**. In another embodiment, frame element **630** may be substantially planar and gel region **620** may rest upon or may be formed upon frame element **630**. Further, in one embodiment, frame element **630** may extend at least partially through gel region **620**. Optionally, frame element **630** may cover or extend across mold cavity **656** of second mold **654**. In one example, frame element **630** may comprise a mesh (e.g., a metal or polymer mesh, a fabric, a fiber mesh, etc.). In another example, frame element **630** may comprise a sheet or layer of silicone and may be, optionally, perforated. If frame element **630** comprises a mesh or is perforated, fluid communication (of a hardenable material) between cavity **658** and cavity **656** may occur, which may be desirable for avoiding shifting of gel region **620** and/or frame element **630** during encapsulation. Once gel region **620** is encapsulated, selected portions of frame element **630** may be trimmed or cut, if desired.

In another method of forming a septum including at least one gel region, a septum body may be formed to include at least one chamber, which may be filled with a gel. For example, FIG. **58** shows a septum body **612** defining chamber **621**. Optionally, opening **623** may be defined by body **612**. Accordingly, a gel may be introduced within chamber **621** via the opening **623** and the opening, optionally, may be closed. For example, an uncured gel may be introduced within chamber **621**. Further, the uncured gel may be cured by heating or by other suitable methods. Such a configuration may form a gel region as described above in relation to FIG. **55**. In one embodiment, chamber **621** may be formed by an air injection molding process, a blow molding process or any other process known in the art for creating a chamber **621** within body **612**. In another embodiment, body **612** may be formed about a removable plug or filler (e.g., a silicone plug, steel, or aluminum insert). Such a plug or filler may be coated with a nonstick coating (e.g., TEFLON®, silicone, or any nonstick coating known in the art). Thus, chamber **621** may be formed upon removal of the plug or filler. In other embodiments, portions of a septum may be formed, filled with a gel (or a liquid precursor to a gel), and bonded to one another to form a septum. In a further embodiment, body **612** may be initially formed and may enclose chamber **621** within body **612**. In addition, body **612** may be cut to form an opening to allow chamber **621** to be filled with a gel. Such an opening of body **612** may be closed or sealed to capture or form a gel region. In yet a further embodiment, a solid body may be formed and a chamber may be formed by slicing the solid body. In such a configuration, filling the chamber may cause the solid body to deform to form a domed or raised region, if desired. It will be appreciated that many different approaches may be employed for forming a chamber **621** within body **612** and subsequently filling the chamber with a gel.

In an additional embodiment, a septum may include a gel region positioned between a body and a layer of material bonded to or formed over at least a portion of the gel region and at least a portion of the body. For example, FIG. **59** shows a schematic, side cross-sectional view of a septum **615** including a body **632**, a gel region **620**, and a layer **626**. As shown in FIG. **59**, gel region **620** may be positioned within a recess **633** formed in the body **632** and layer **626** may extend over a portion of gel region **620** and a portion of body **632**. One of ordinary skill in the art will understand that gel region **620** may be positioned or formed within recess **633** of body **632** and then layer **626** may be formed or positioned over gel region **620** and body **632**. Further, layer **626** may be bonded (e.g., adhesively bonded, bonded via curing, bonded via welding, or as otherwise known in the art) or otherwise affixed to body **632** to capture gel region **620**. In one embodiment, septum **615** may be formed by a multiple head (e.g., a two head) injection molding apparatus. More particularly, such a molding apparatus may be capable of forming the body **632**, forming the gel region **620** within the body **632**, and forming (e.g., over molding) the layer **626** over the gel region **620** and body **632** by suitable mold configurations and material injections. Layer **626**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 60 and about 80. Body **632**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 40 and about 50. Accordingly, during use of septum **615** (installed within a housing to form an access port) a cannula may pass through layer **626**, at least a portion of gel region **620**, and body **632**. Such a configuration may facilitate positioning of a cannula extending through layer **626**, at least a portion of gel region **620**, and body **632**.

While certain representative embodiments and details have been shown for purposes of illustrating aspects of the instant disclosure, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing form the scope of the instant disclosure, which is defined in the appended claims. For example, other access port sizes and shapes may be employed; and various other embodiments and structures may be employed for forming at least one identifiable feature of an access port of the instant disclosure. The words "including" and "having," (including their variants) as used herein including the claims, shall have the same meaning as the word "comprising."

What is claimed is:

1. A system for identifying a power injectable vascular access port, comprising:

a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature comprising a radiographic marker identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port; and

a second identifiable feature separated from the subcutaneously implanted access port, the second feature visually observable following subcutaneous implantation to confirm that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

2. The system according to claim 1, wherein the second identifiable feature comprises visually perceptible information provided on an element selected from the group consisting essentially of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof.

3. The system according to claim 1, wherein the second identifiable feature is included on an infusion set couplable to the vascular access port.

4. The system according to claim 1, wherein the radiographic marker is selected from the group consisting essentially of an observable pattern, a symbol, a typographical character, an indicium, and combinations thereof.

* * * * *

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(12) **United States Patent**
Powers et al.

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(54) **METHODS OF PERFORMING A POWER INJECTION PROCEDURE INCLUDING IDENTIFYING FEATURES OF A SUBCUTANEOUSLY IMPLANTED ACCESS PORT FOR DELIVERY OF CONTRAST MEDIA**

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USPC **600/427**; 604/288.01; 600/431

(58) **Field of Classification Search**
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See application file for complete search history.

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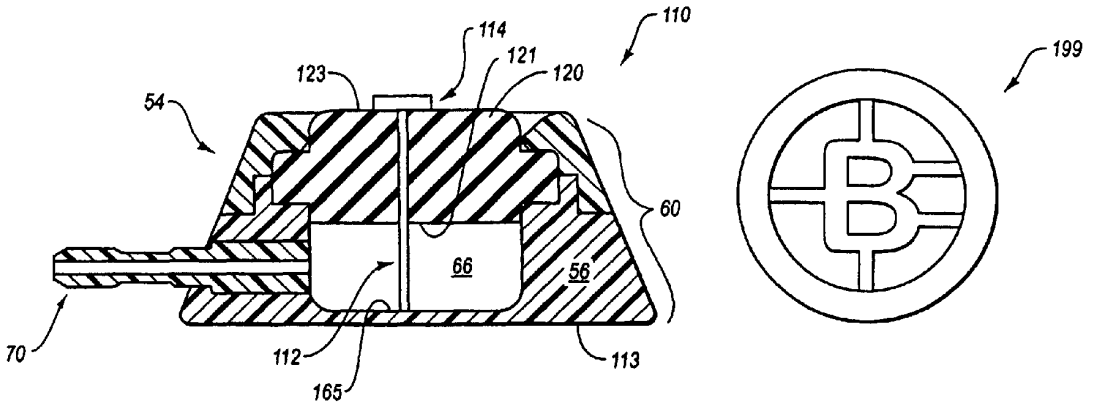
(57) **ABSTRACT**

Methods of performing a power injection procedure are described. One method includes taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least about 1 milliliter per second through the access port, identifying the indicating radiographic feature on the x-ray, and flowing a fluid through the access port at a rate of at least about 1 milliliter per second.

14 Claims, 32 Drawing Sheets



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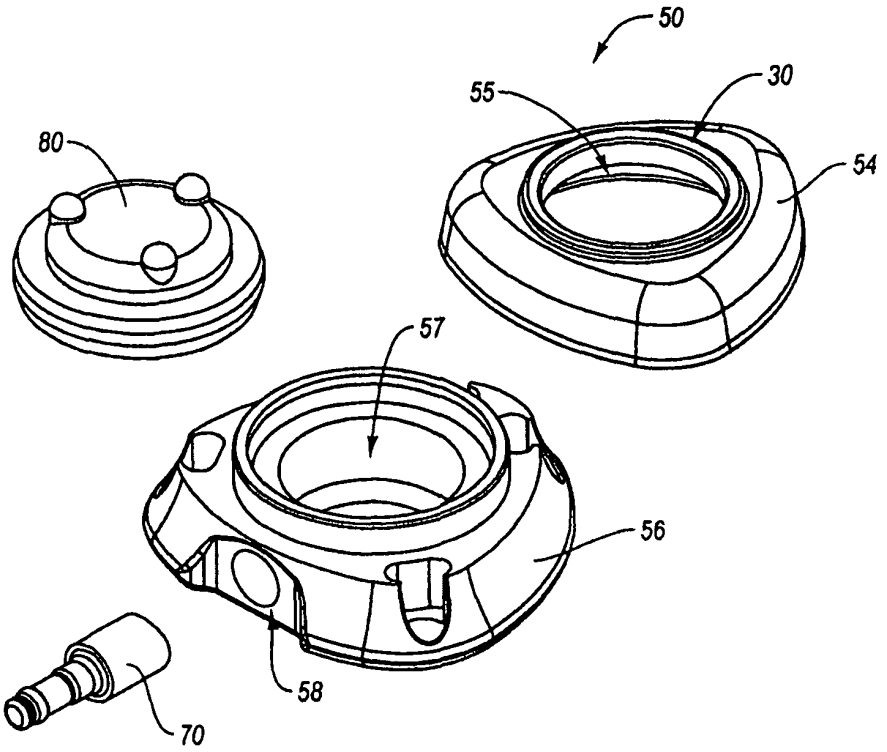


FIG. 1

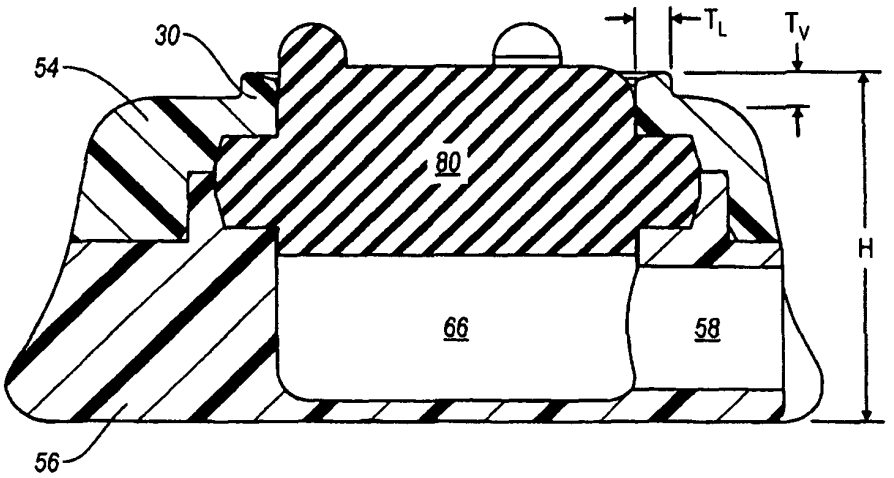


FIG. 2

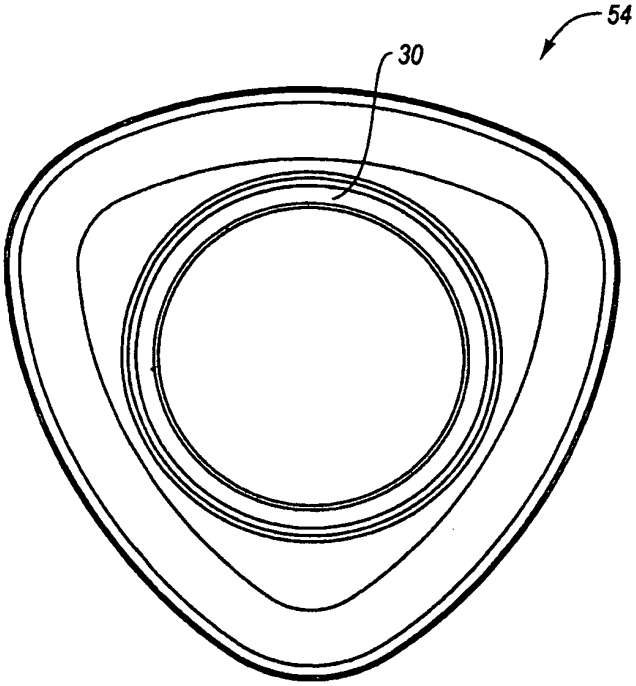


FIG. 3

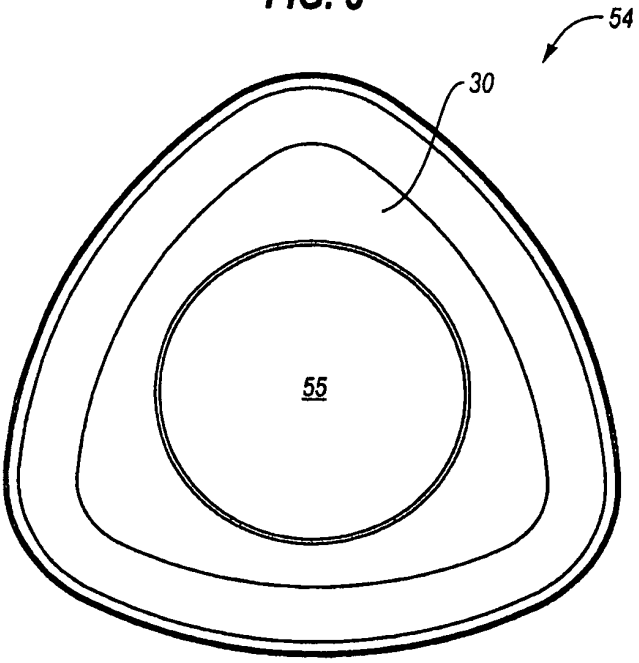


FIG. 4

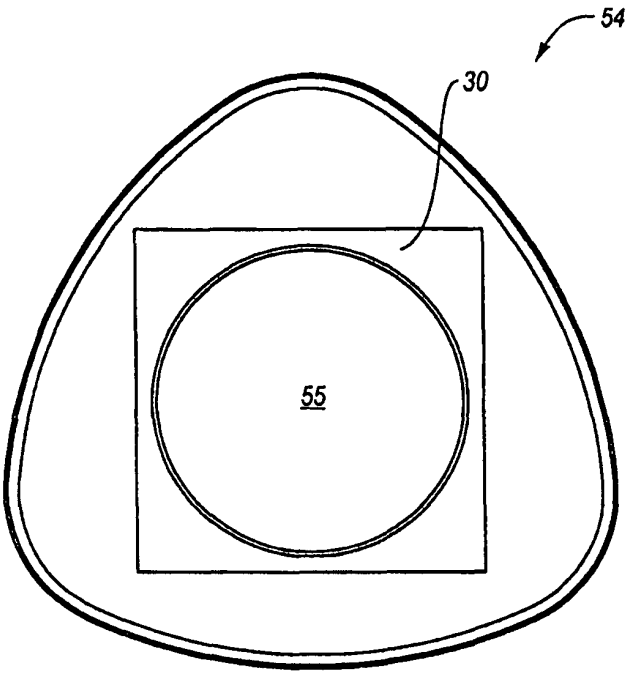


FIG. 5

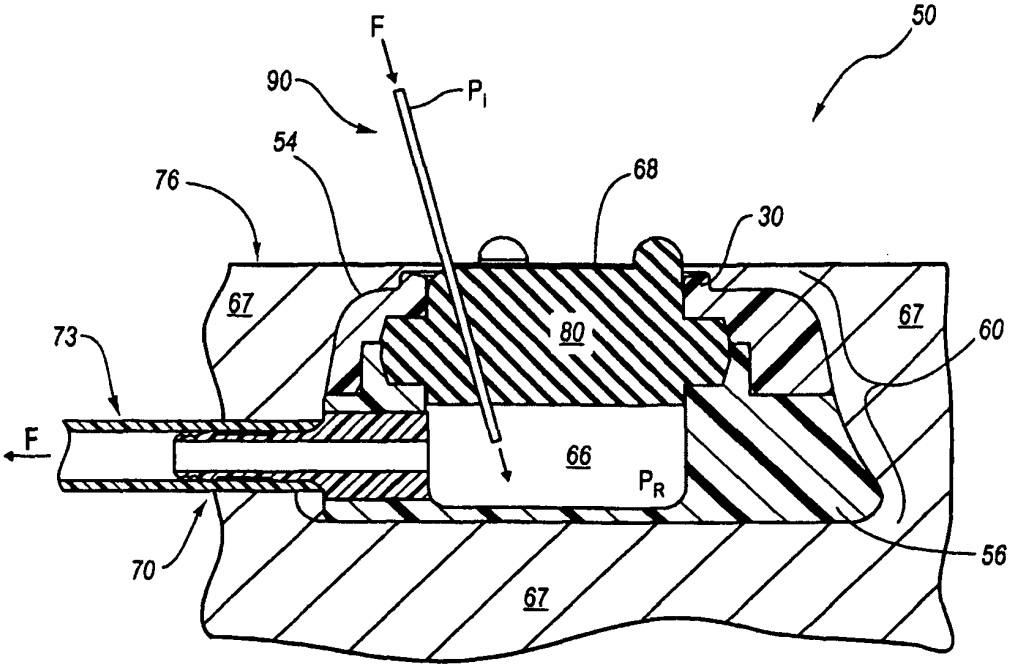


FIG. 6

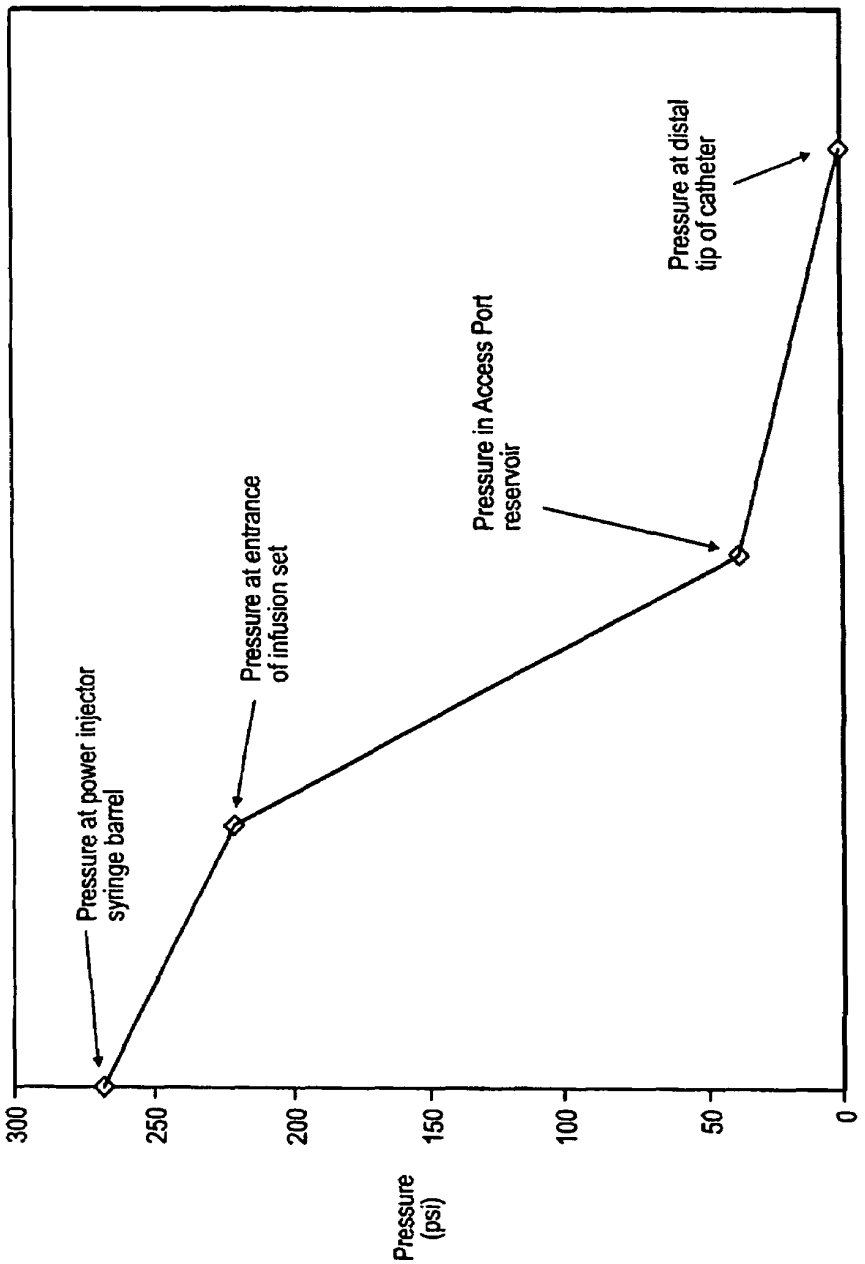
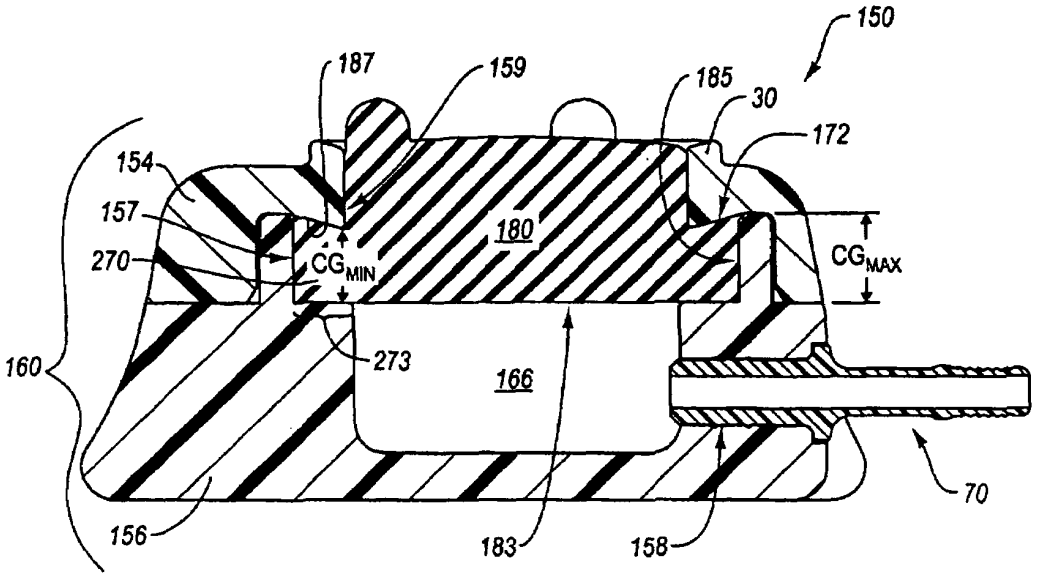

Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7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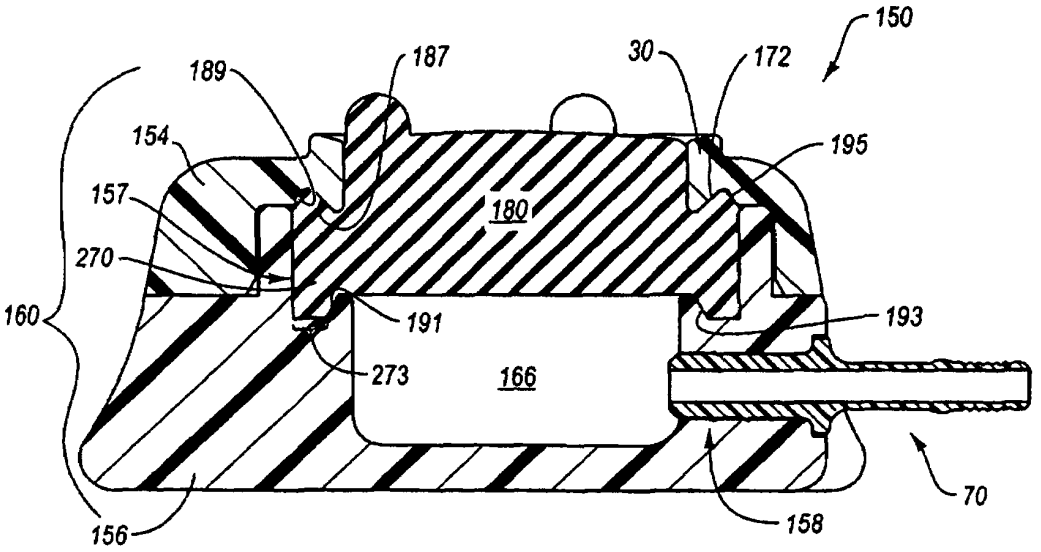
CG_{MIN}
CG_{MAX}
160
273
166
70
156
183
158

FIG. 8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189
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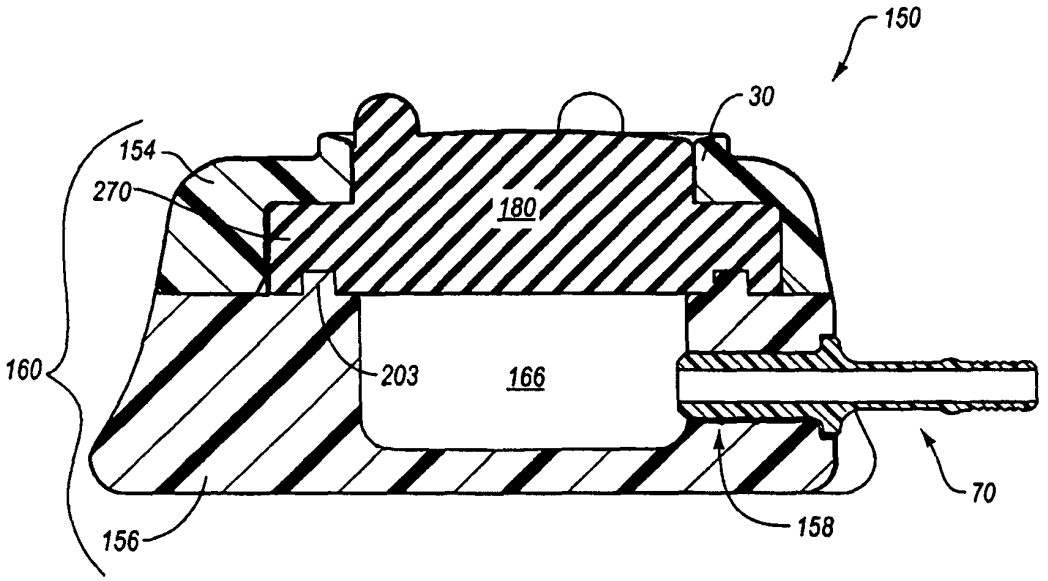
30
172
154
195
157
180
270
160
191
193
273
166
70
156
158

FIG. 9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270
180
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166
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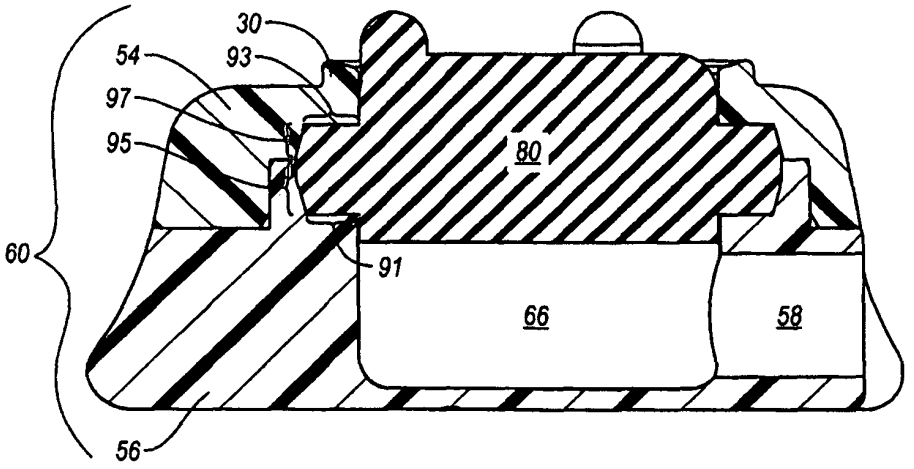
156
158

FIG. 10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93
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58
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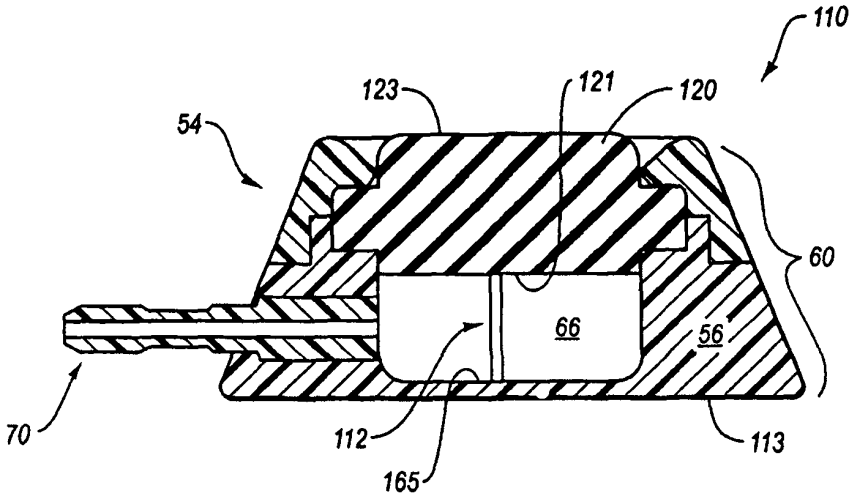
FIG. 11


110
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113
165

FIG. 12

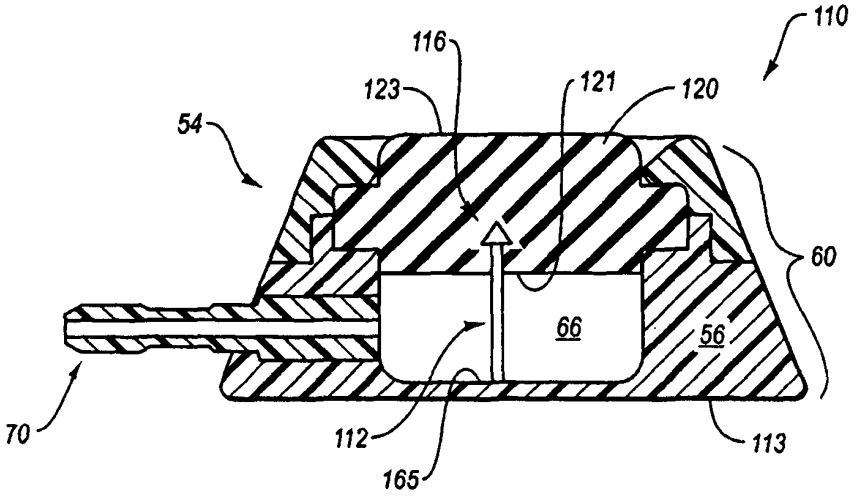
110
116
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FIG. 13

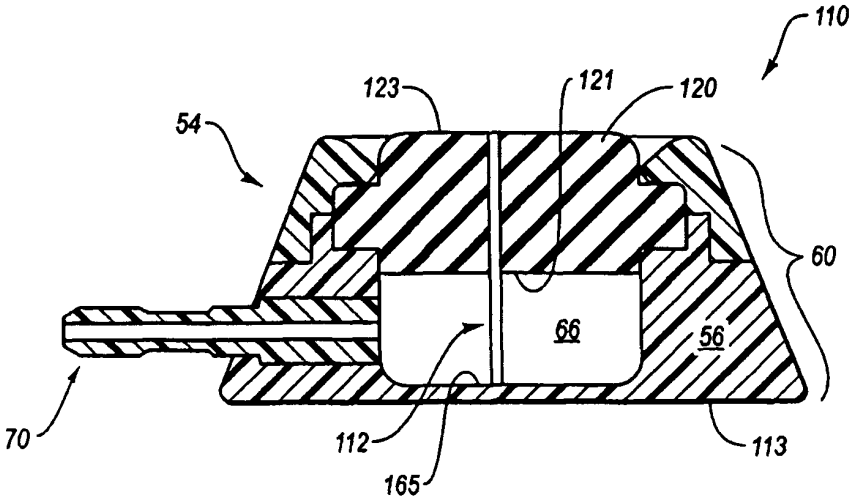
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FIG. 14

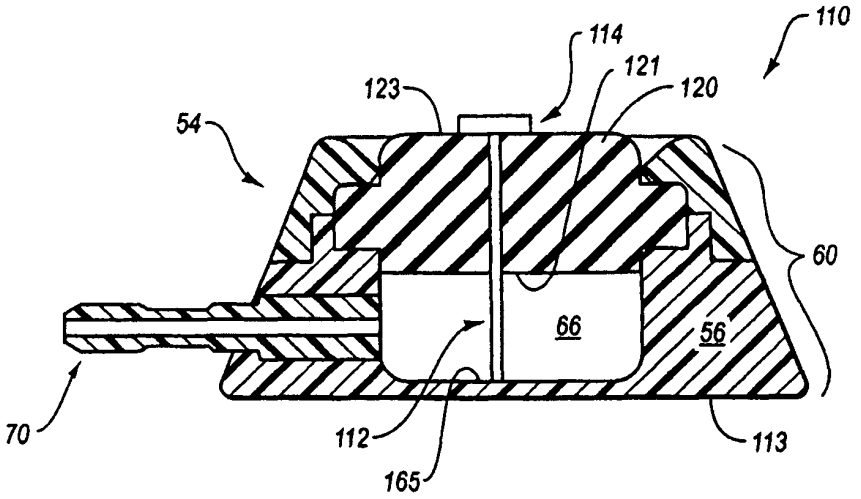
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FIG. 15

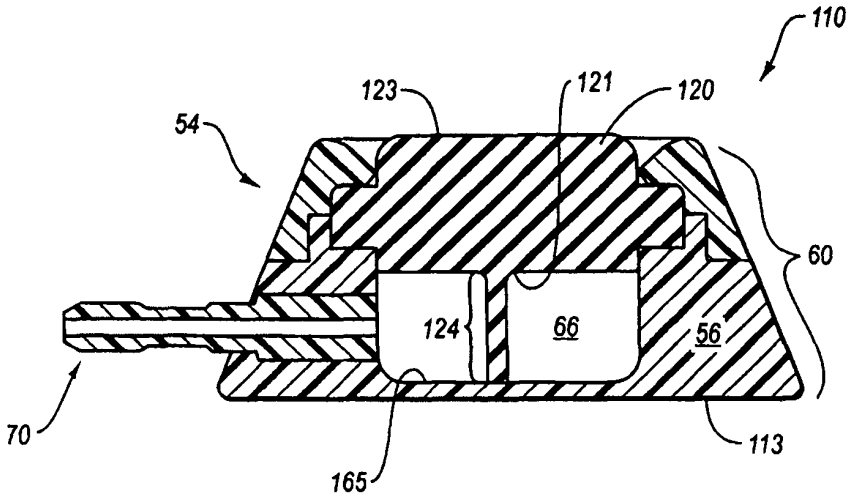
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FIG. 16

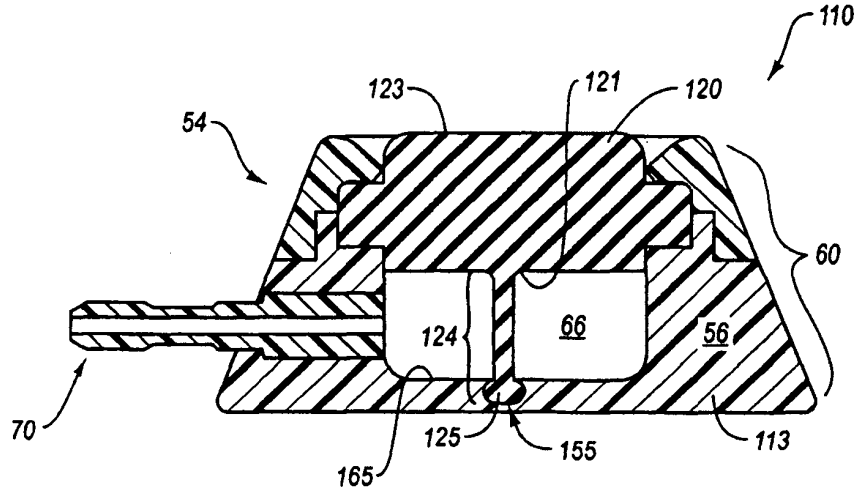
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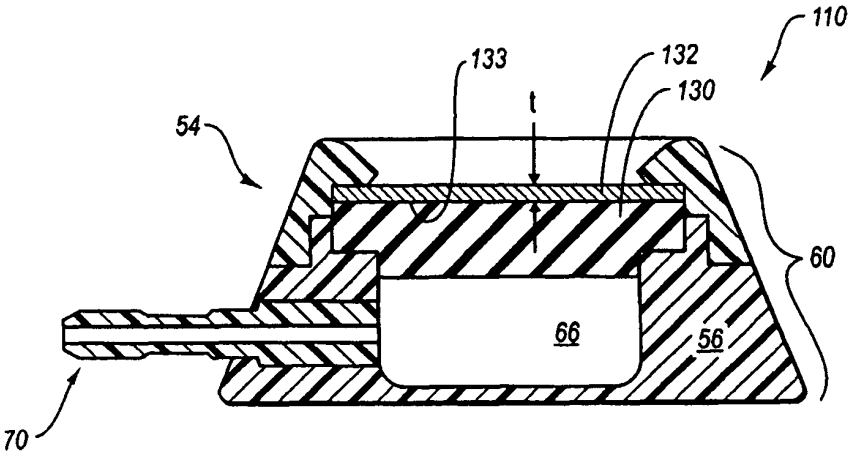
FIG. 17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t
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FIG. 18

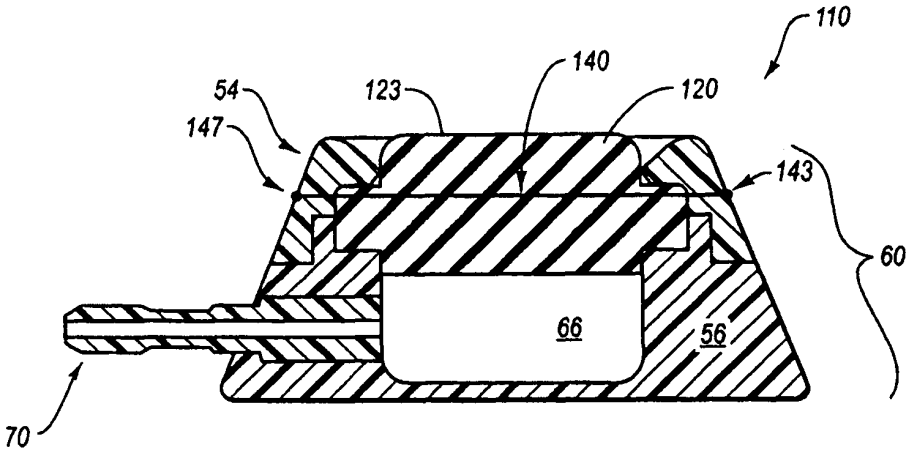
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FIG. 19

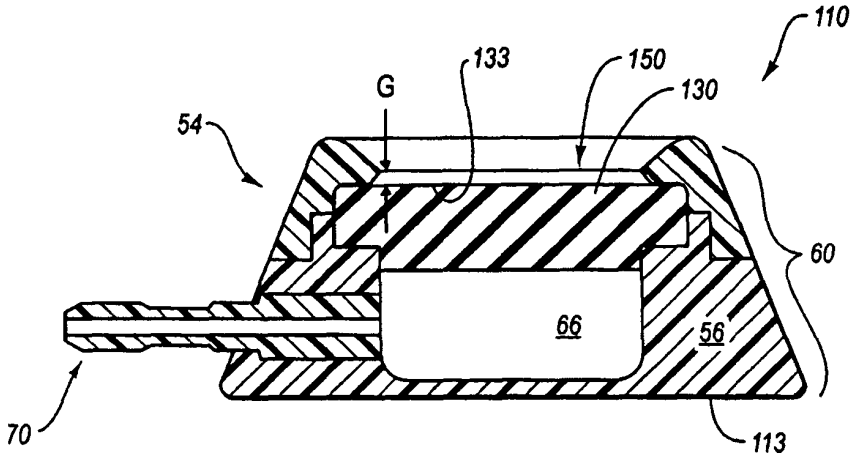

FIG. 20

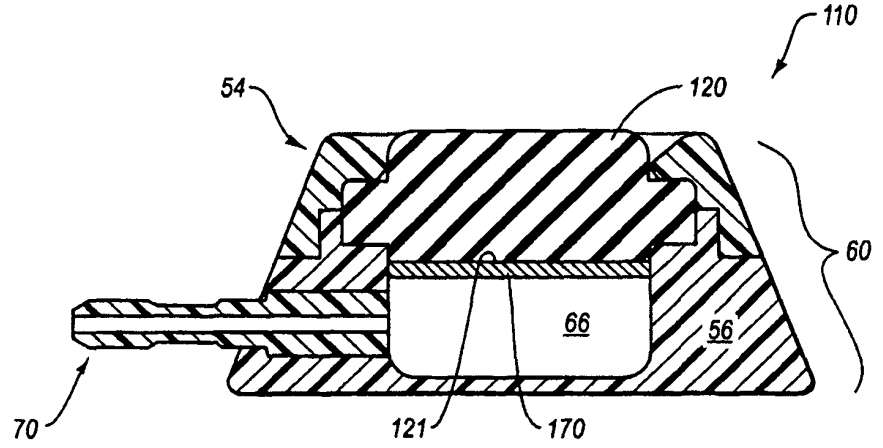

FIG. 21

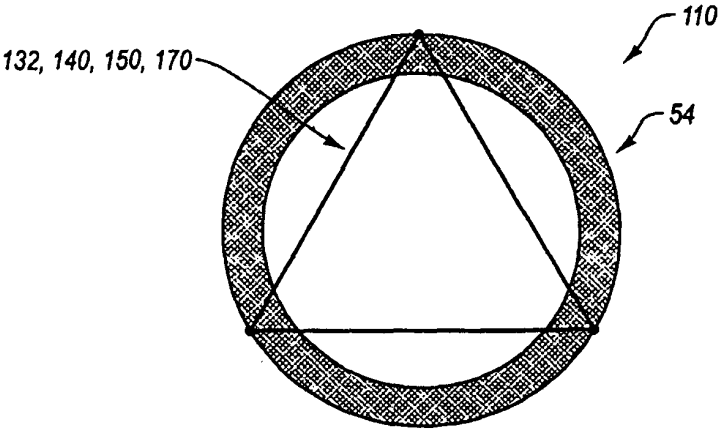

FIG. 22

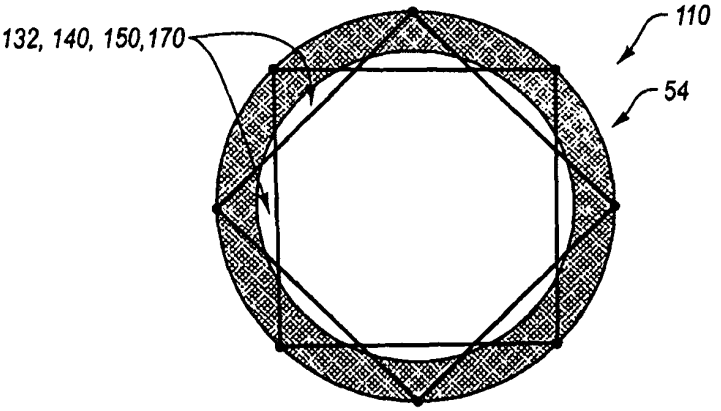

FIG. 23

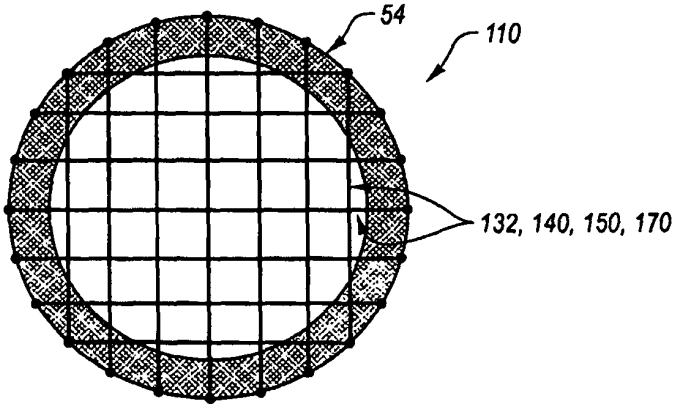

FIG. 24

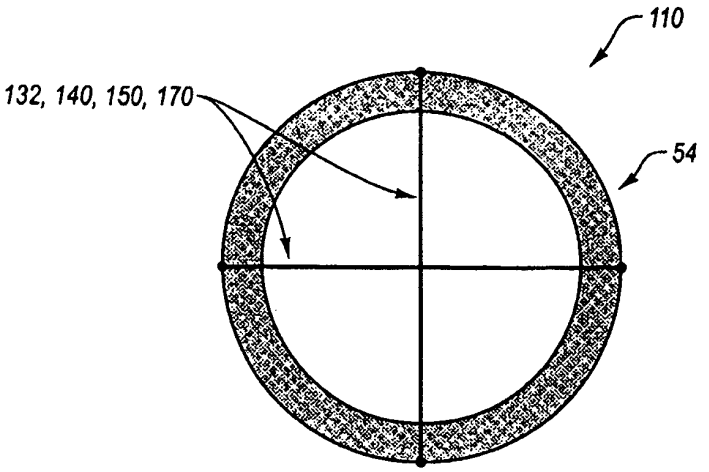

FIG. 25

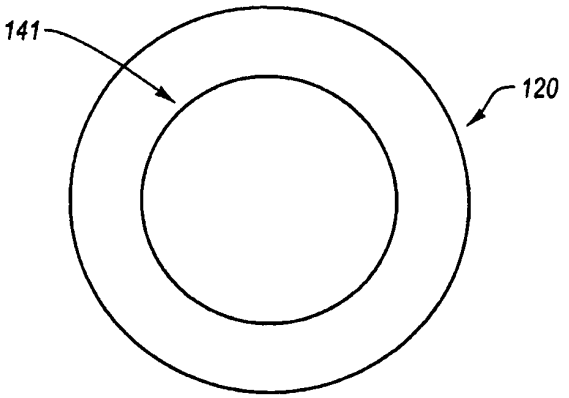

FIG. 26

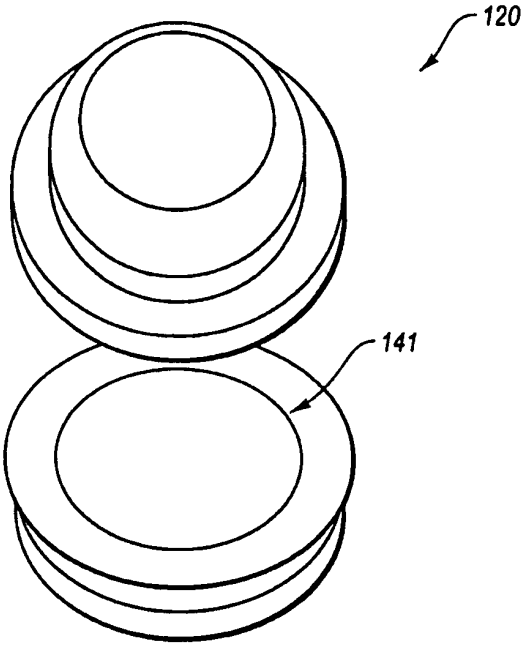

FIG. 27

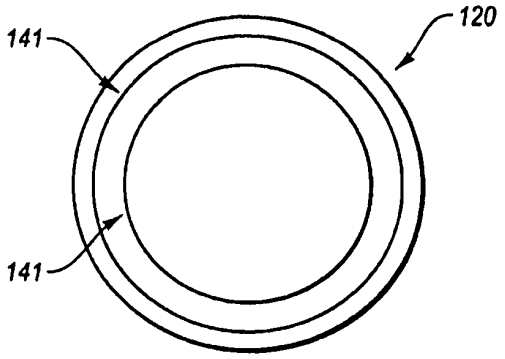

FIG. 28

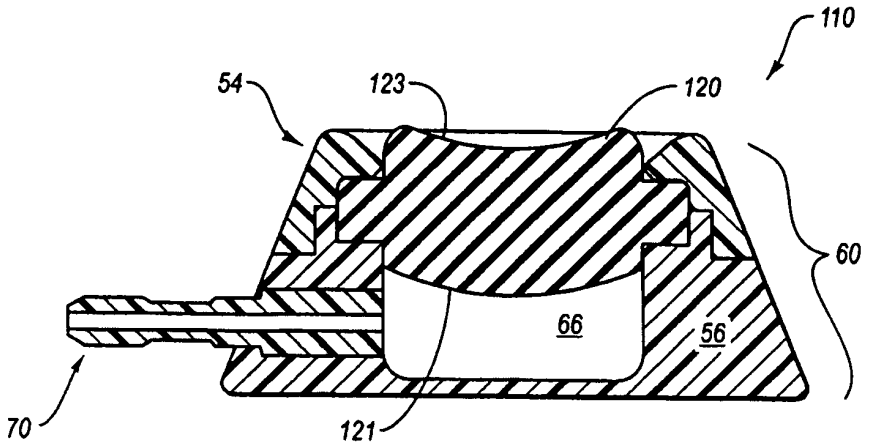

FIG. 29

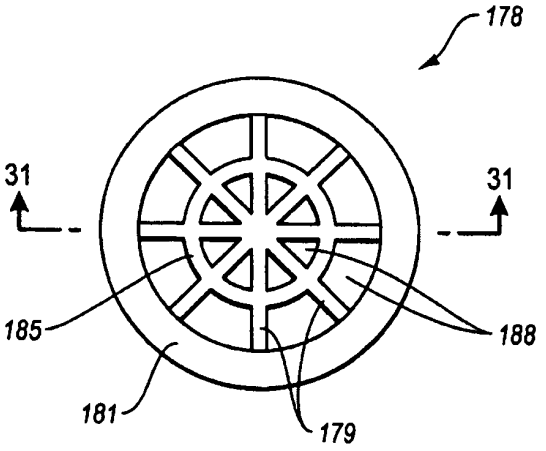

FIG. 30

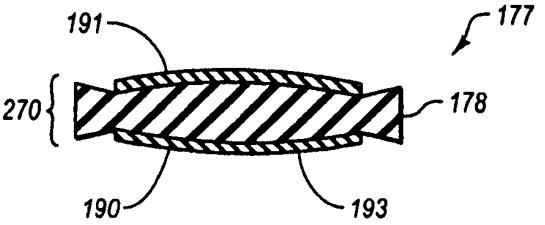

FIG. 31

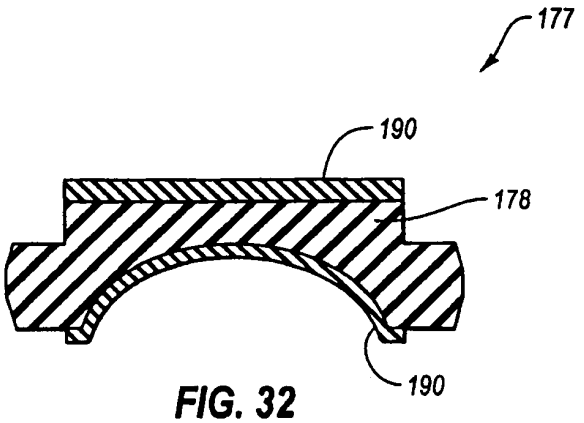

FIG. 32

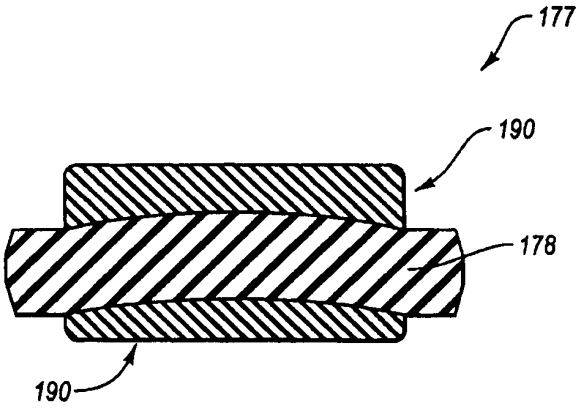

FIG. 33

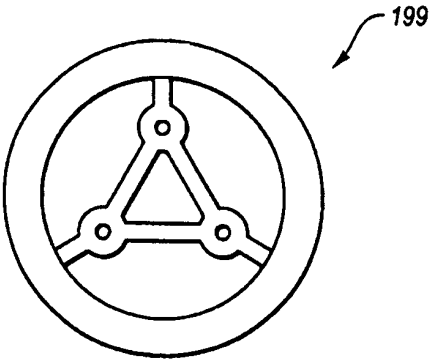

FIG. 34

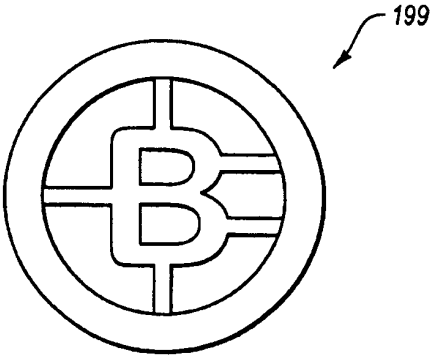

FIG. 35

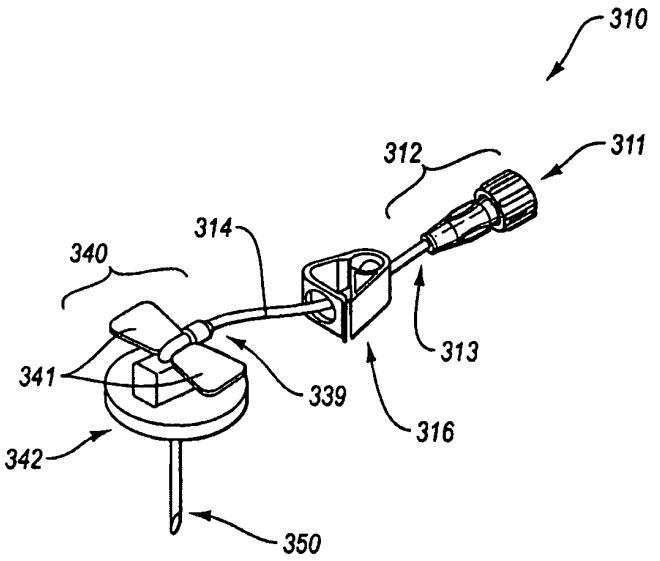
310
312
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FIG. 36

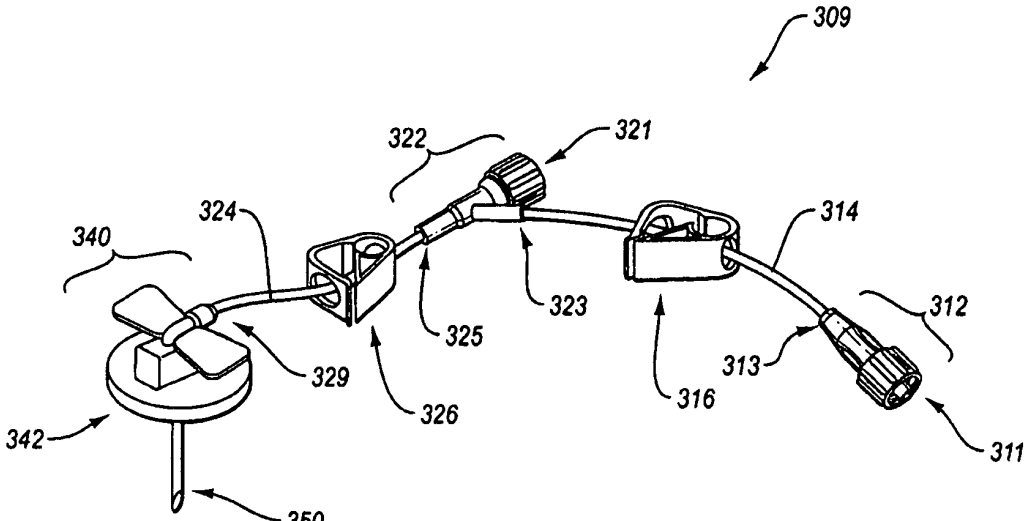
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FIG. 37

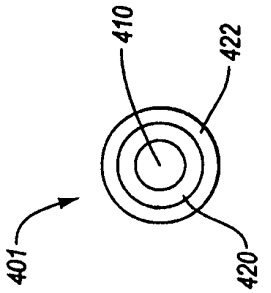

FIG. 39

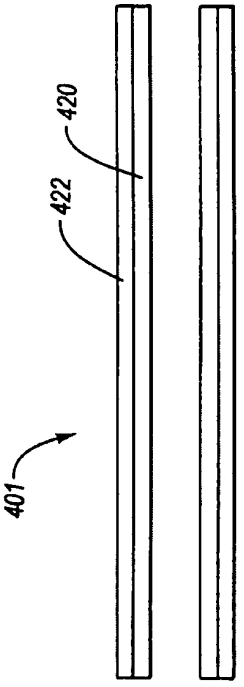

FIG. 38

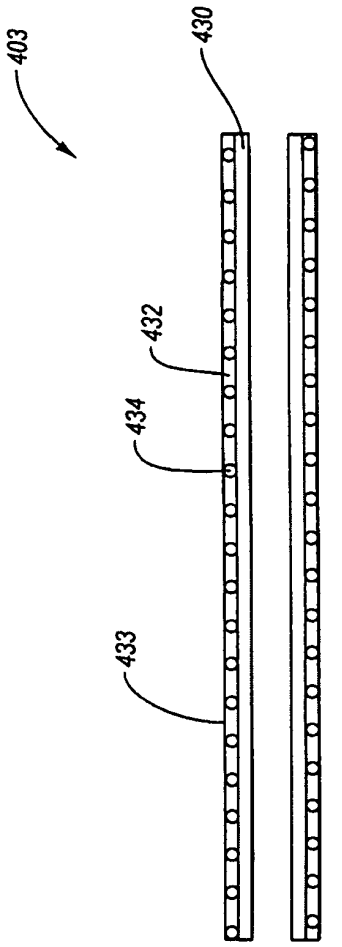

FIG. 40

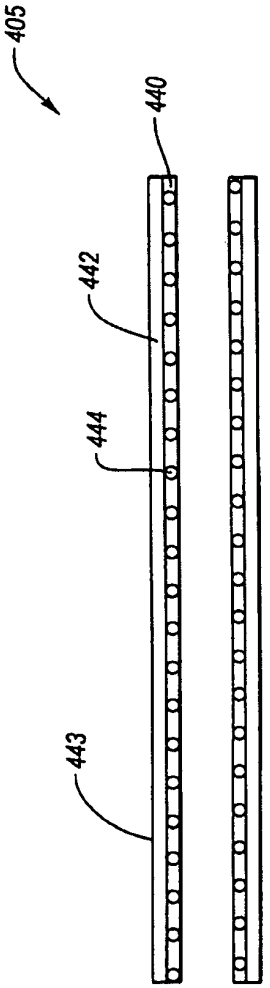

FIG. 41

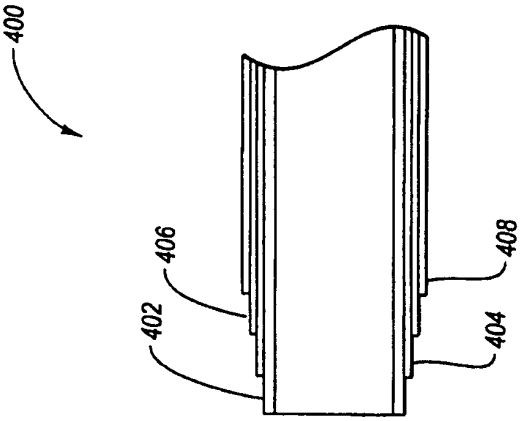

FIG. 43

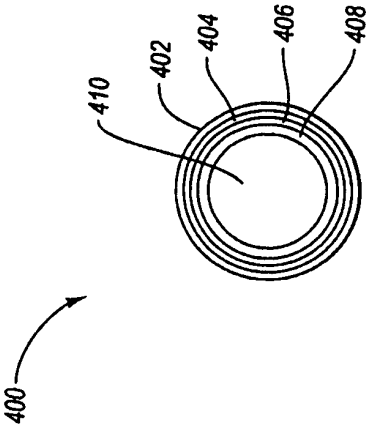

FIG. 42

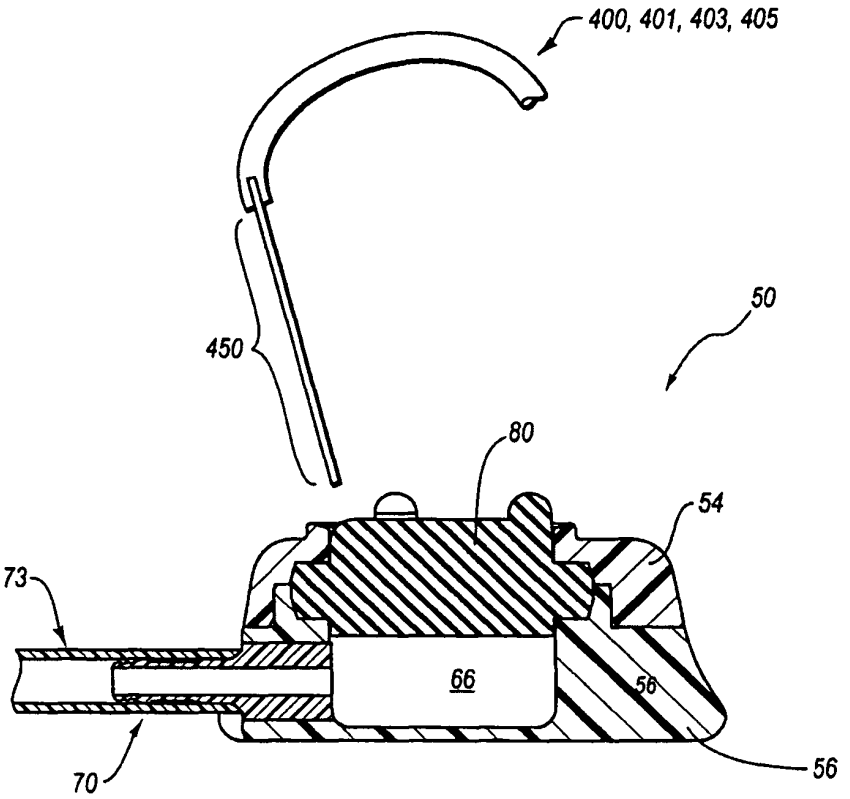
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FIG. 44

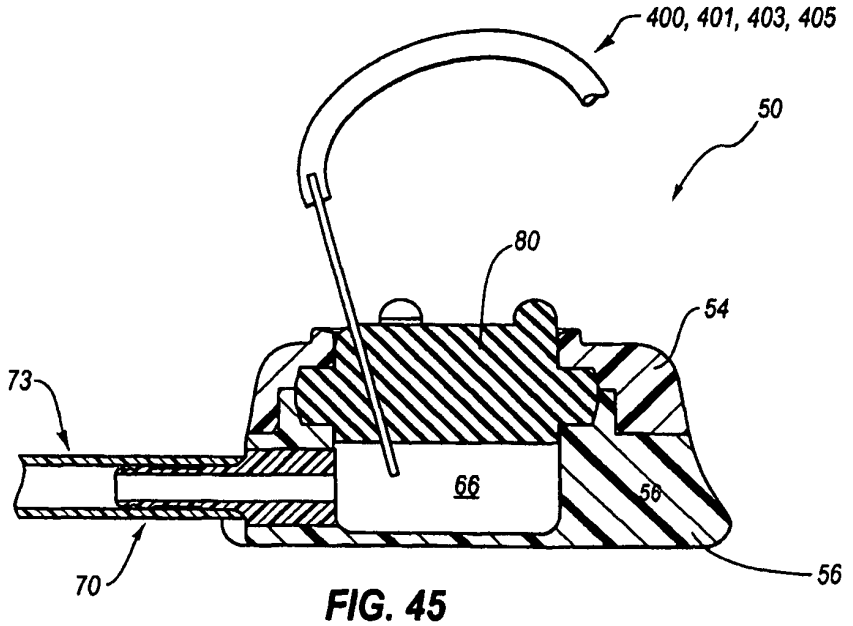
400, 401, 403, 405
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FIG. 45

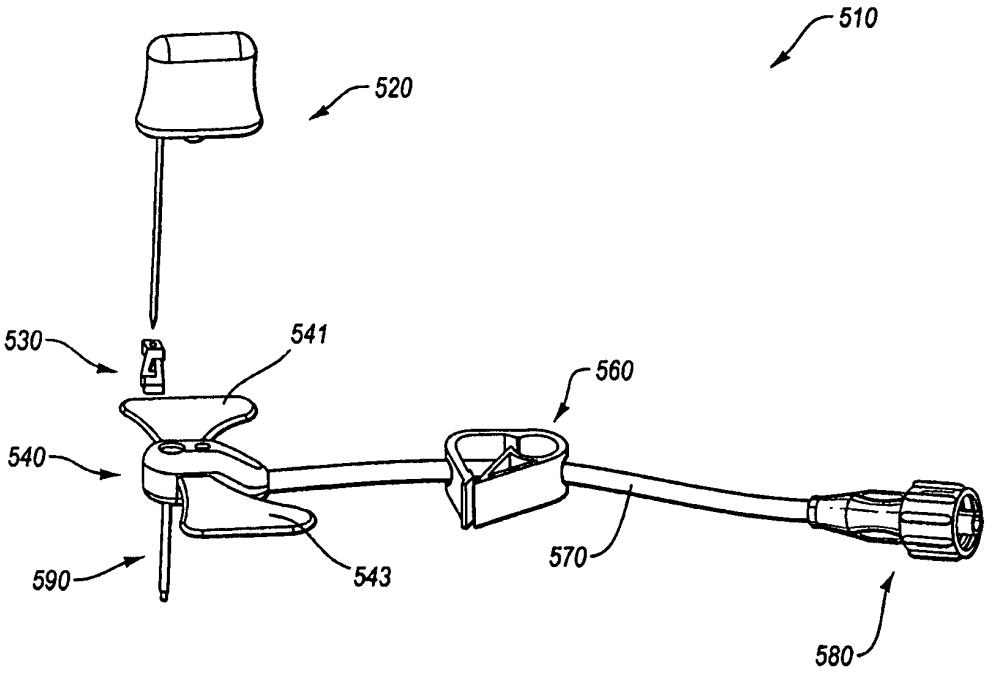

FIG. 46

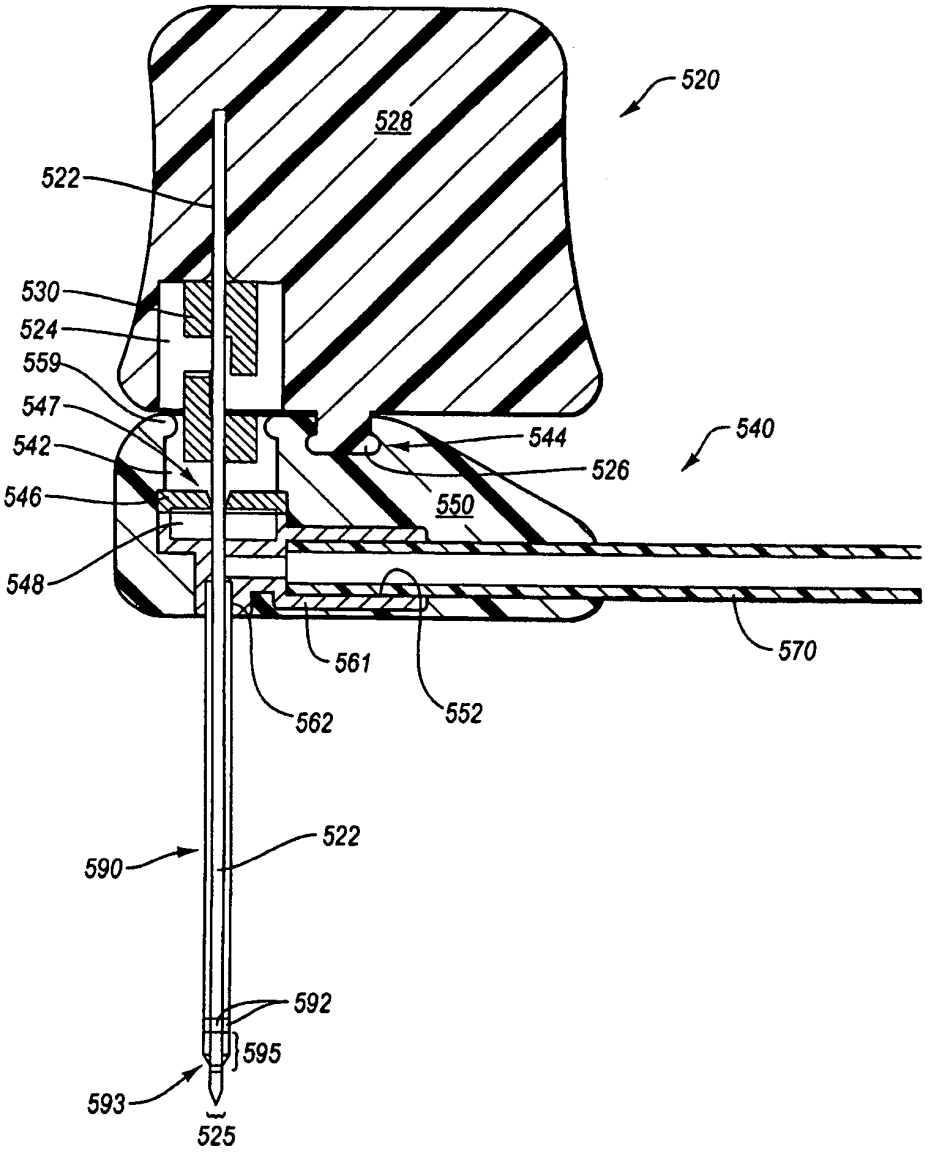
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FIG. 47

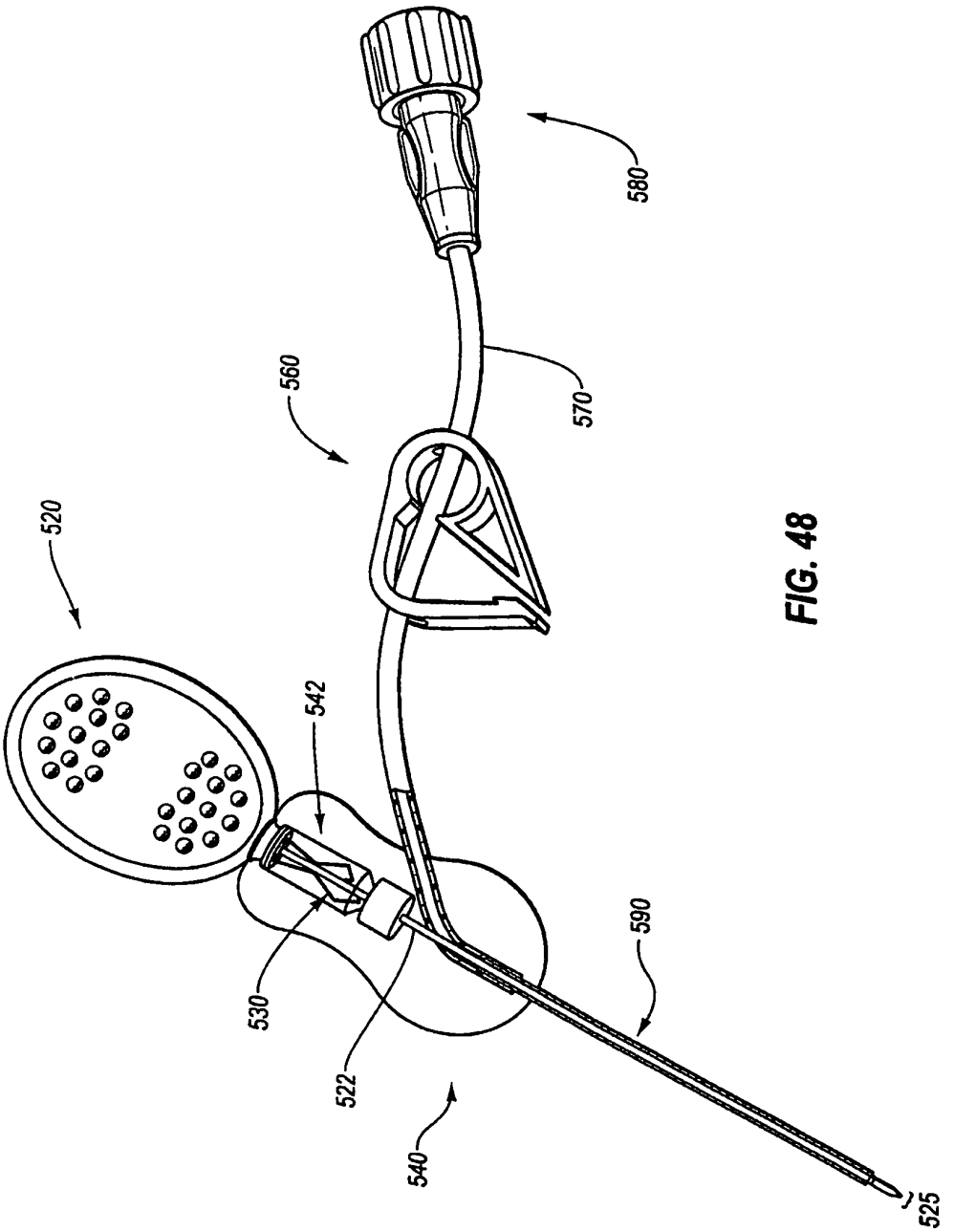

FIG. 48

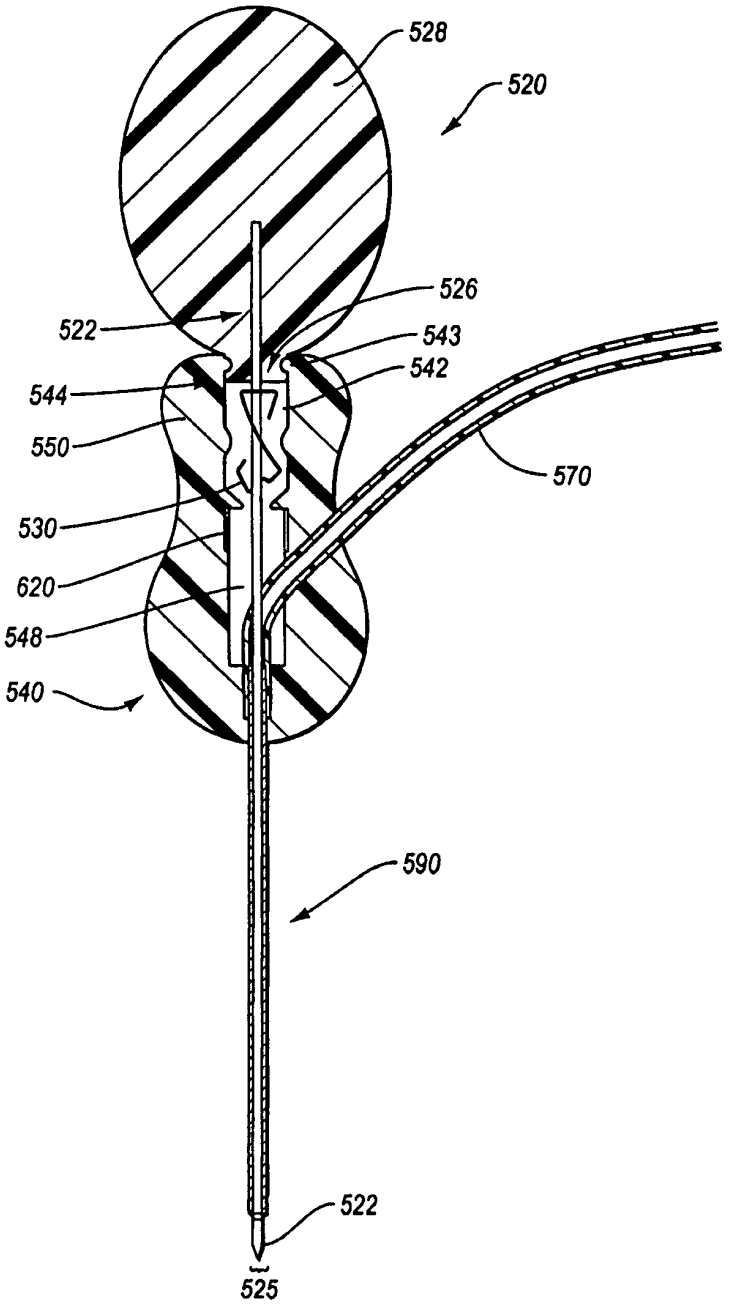

FIG. 49

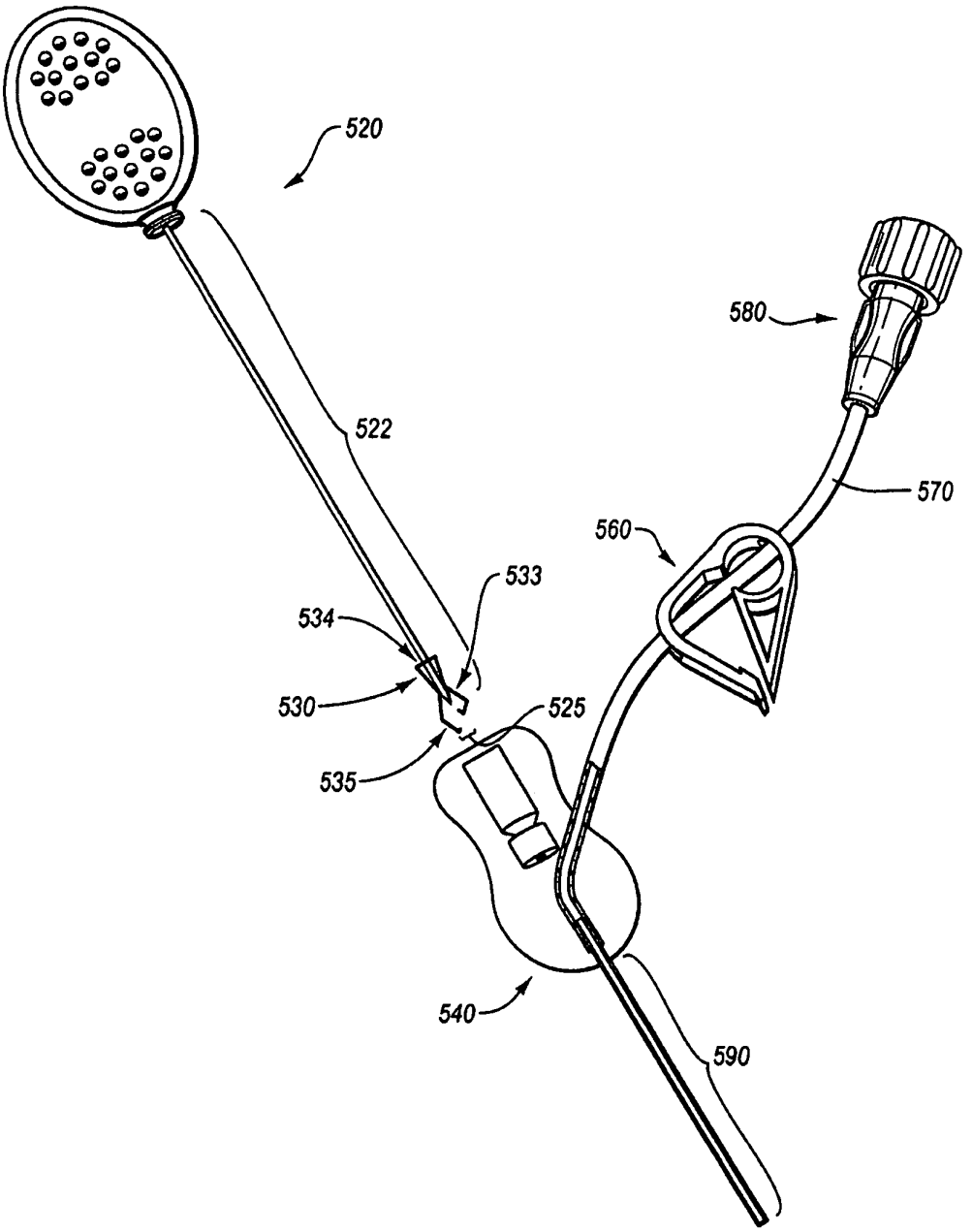

FIG. 50

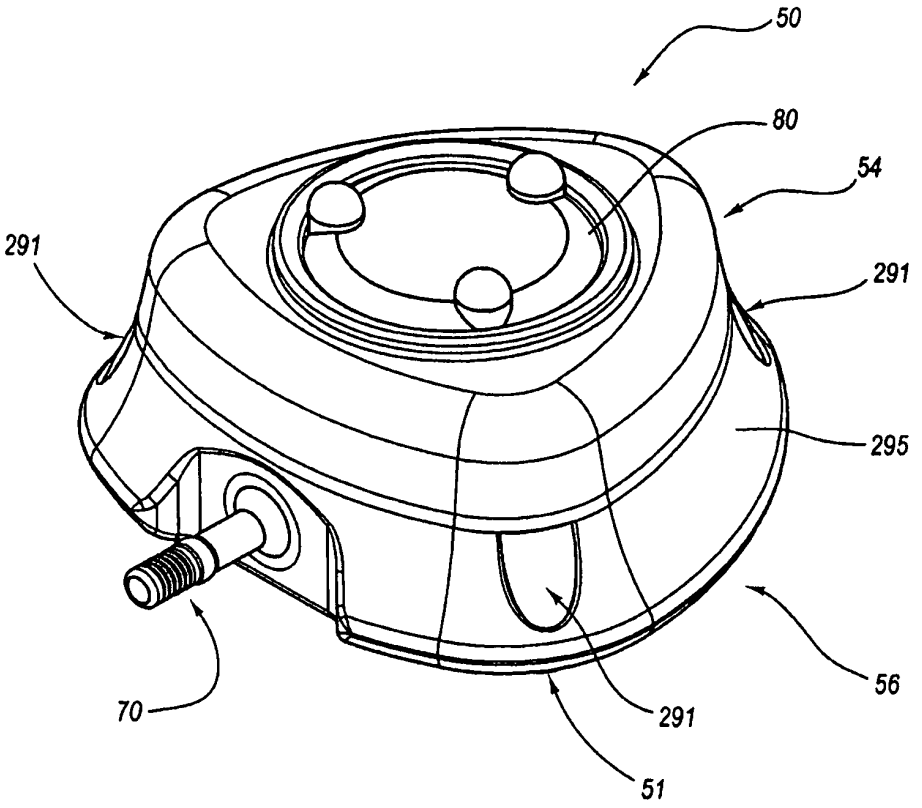

FIG. 51

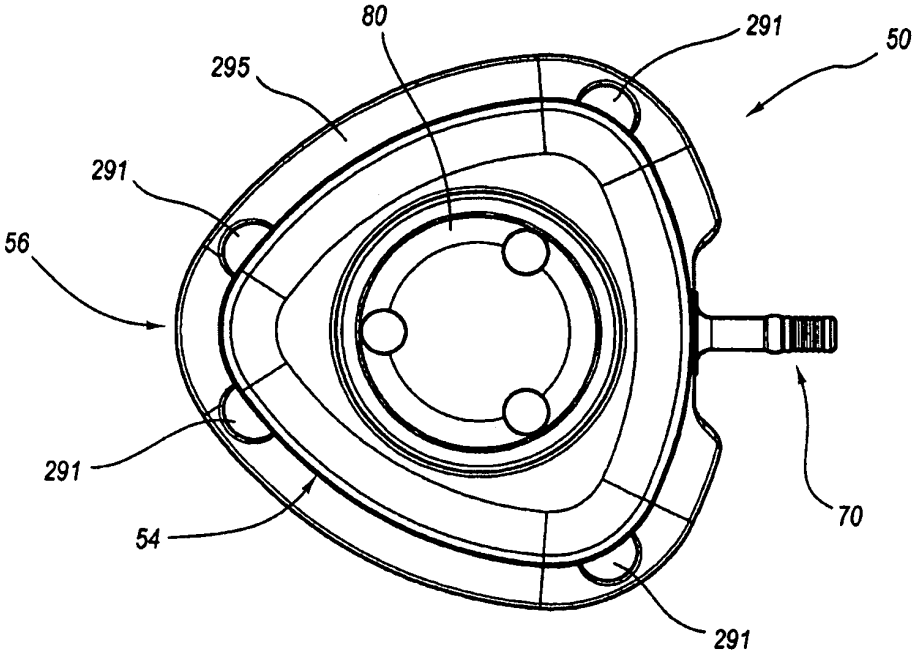

FIG. 52

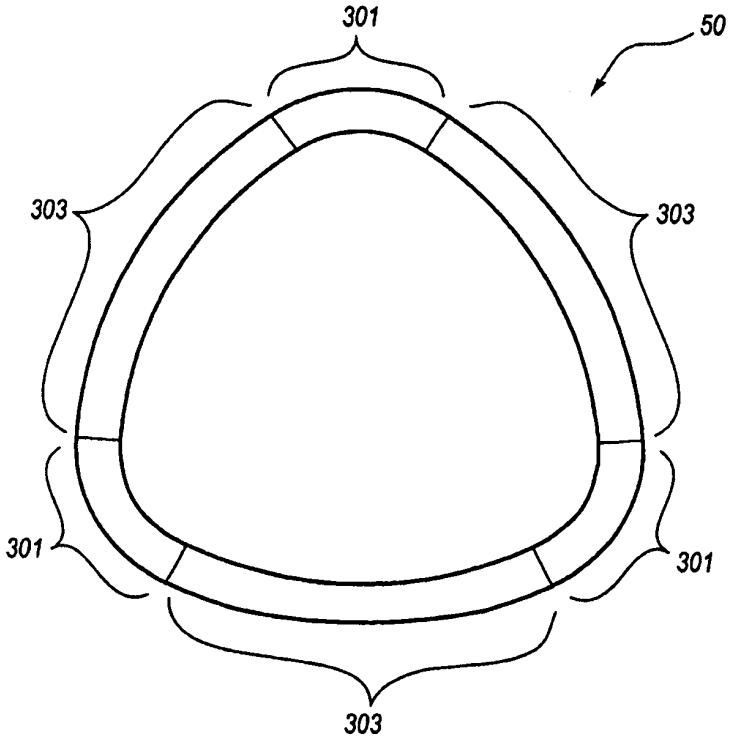

FIG. 53

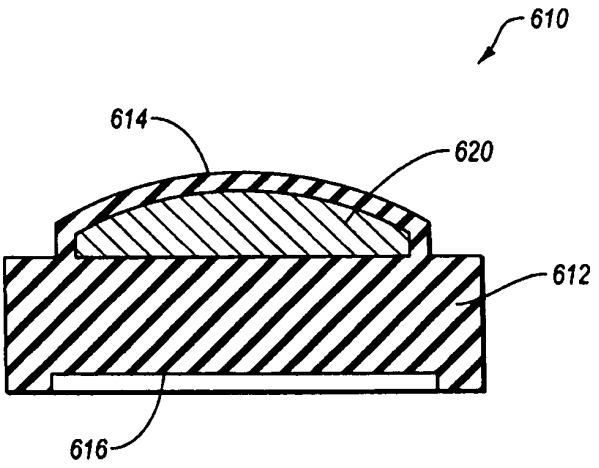

FIG. 54

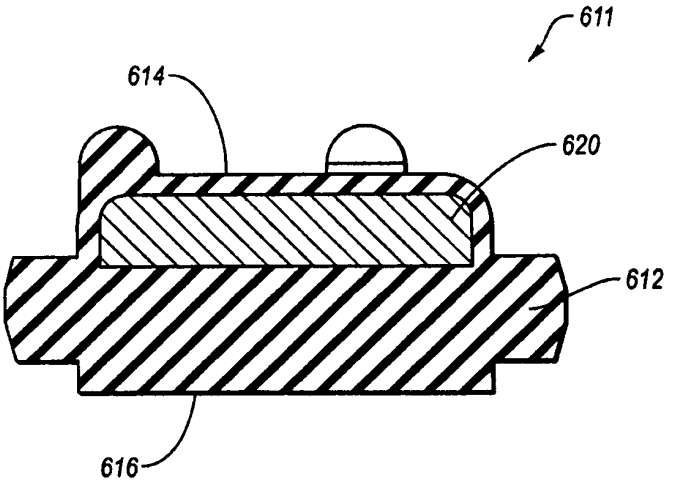

FIG. 55

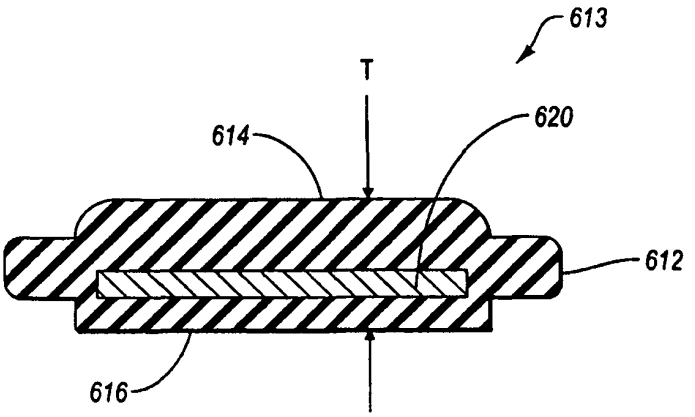

FIG. 56

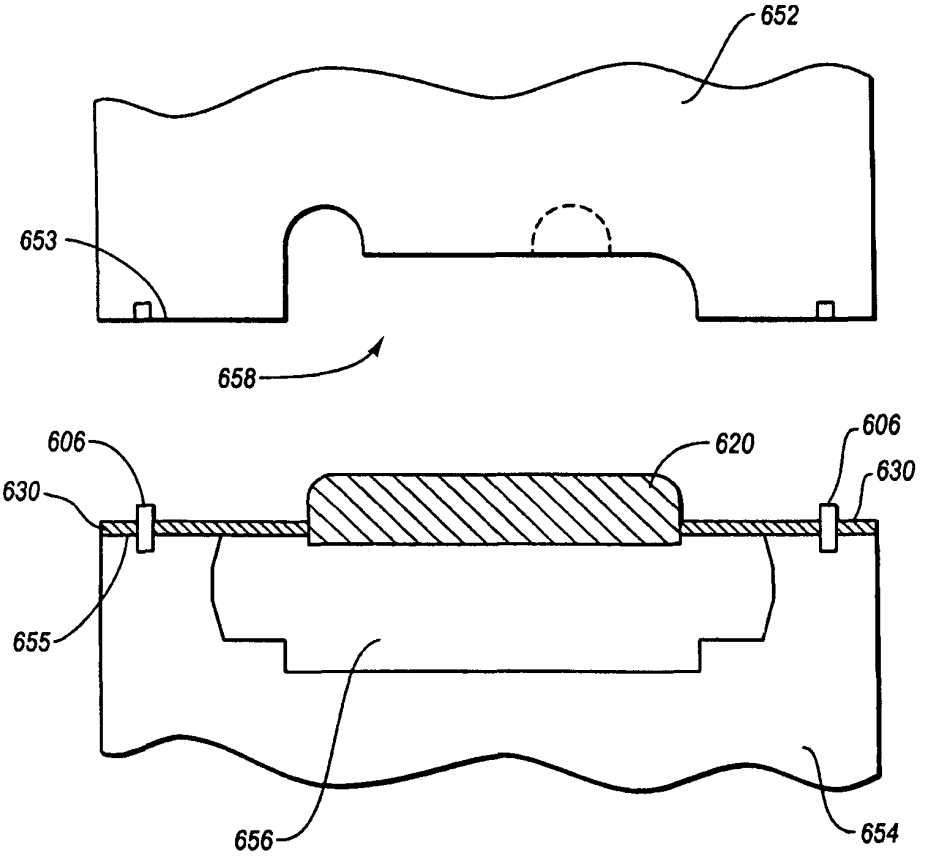

FIG. 57

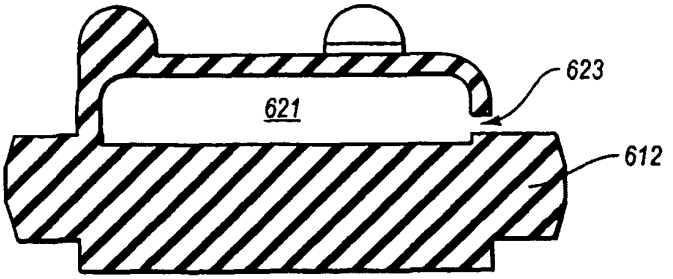

FIG. 58

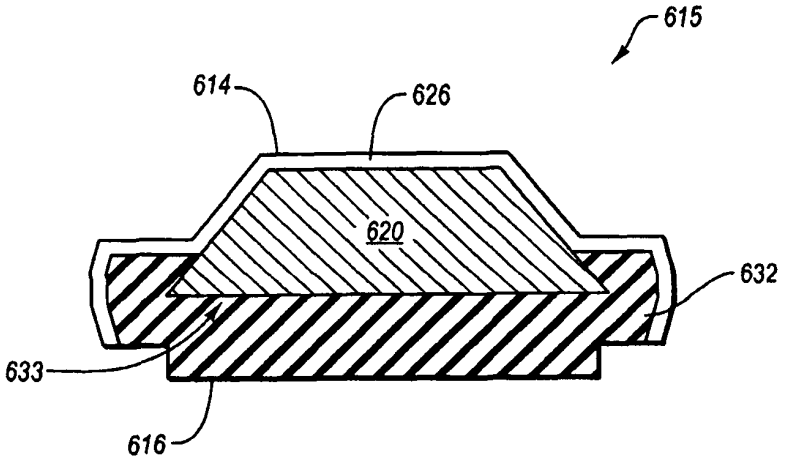

FIG. 59

METHODS OF PERFORMING A POWER INJECTION PROCEDURE INCLUDING IDENTIFYING FEATURES OF A SUBCUTANEOUSLY IMPLANTED ACCESS PORT FOR DELIVERY OF CONTRAST MEDIA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 11/380,124, filed Apr. 25, 2006, now U.S. Pat. No. 8,545,460, which claims the benefit of priority to U.S. Provisional Patent Application No. 60/737,466, filed Nov. 15, 2005, and to U.S. Provisional Patent Application No. 60/675,309, filed Apr. 27, 2005, each of which applications is hereby incorporated by reference in its entirety into this application.

BACKGROUND

A wide variety of medical procedures require infusion of a fluid into a patient. For example, vascular imaging technologies may require use of a contrast media that is injected into the patient. More specifically, computed tomography (CT) is an imaging technology that utilizes a contrast media and may be employed for the noninvasive evaluation and assessment of a vascular system (i.e., CT angiography or CTA). Multidetector computed tomography (MDCT) is one specific type of CT that may be utilized for CTA. For proper imaging of a vascular system via CT, intravenous contrast media injection protocols are coordinated and selected for the anatomic area of interest.

More particularly, conventionally, a so-called "power injector" system may be employed for injecting contrast media at a high pressure into a peripherally inserted intravenous (IV) line. For example, such power injectors or injection systems may be commercially available from Medrad, Inc., a subsidiary of Schering AG, Germany and may be marketed as STELLANT® injection systems. Because CT procedures are often defined in terms of a desired flow rate of contrast media, such power injection systems are, in general, controllable by selecting a desired flow rate. Accordingly, such power injection systems may develop pressure (within the maximum pressure capability of the power injection system) as is necessary to maintain the selected flow rate. Accordingly, as may be appreciated, obstructions in the IV lines or use of IV lines that are not structured to withstand the pressures of a desired injection rate may cause the power injector to generate a pressure that exceeds a suitable pressure limit for the IV line. After intravenous injection, a bolus of contrast material, may flow within the vascular system of the patient to the right side of the heart, through the lungs, into the left side of the heart, and through the remaining circulatory system. After the bolus of contrast media is injected into the patient, portions of the contrast media may remain in the right side of the heart. Thus, the overall effectiveness of contrast enhancement may depend on a multitude of factors. For example, a patient's characteristics (e.g., body size; circulation, including cardiac output and circulating volume, and renal function), the contrast characteristics (e.g., volume, injection rate, iodine concentration, etc.), and the CT technique (e.g., access and route of administration, scan delay, scan speed, and injection pattern) may each influence the overall degree of contrast enhancement.

By way of background, conventionally, relatively long scan times have been accompanied by relatively long contrast media delivery times. However, because scan times continue

to decrease, relatively fast delivery of contrast media may be desired. Explaining further, in coronary CTA, a large enough volume of contrast material must be administered at a sufficiently high rate to reach and maintain a suitable concentration throughout a selected scan time (e.g., a 15 second scan time), and within a selected region of the anatomy (e.g., an axial scan distance of 20 cm, which may include the left ventricle and outflow tract). It also may be desirable that contrast density values are sufficient to facilitate the segmentation techniques used in multidimensional post-processing. A typical contrast media used in coronary CTA may have an iodine density of about 300 milligrams per milliliter to about 350 milligrams per milliliter. Also, since contrast media may be radioactive, reducing the overall quantity of contrast media required to perform an imaging process may be advantageous.

The pressure required for contrast injection depends on many factors, including flow rate, contrast viscosity, configuration of infusion tubing, such as tube diameter and length, and any obstruction or restriction to flow (e.g., kinks, curves, fittings, compression). As mentioned above, to maintain the flow rate required for a CT or MRI study, a power injector may generate high pressures. Ruptures can occur when the injection pressure exceeds the tolerance of the vascular access device(s). Other problems may occur due to timing errors between the scan and the contrast. In order to maximize the rapid scanning capacity of the newer vascular imaging devices, the starting of the scanning process can be delayed a predetermined amount of time after injection of the contrast media has begun. If the scan starts too early, just as the contrast is arriving at the heart, arteries can appear smaller than they really are when the image is post-processed. On the other hand, if scanning is delayed too long, image artifacts can arise from diluted contrast in the cardiac veins. The window of opportunity for optimal scans may be very small, because contrast media circulates quickly through cardiac arteries and into cardiac veins.

Some diagnostic or medical procedures may advantageously employ a subcutaneous vascular access port for introducing a fluid into the vasculature of a patient. Access portals, or ports, provide a convenient method to repeatedly deliver medicants to remote areas of the body without utilizing surgical procedures. The port is implantable within the body, and permits the infusion of medications, parenteral solutions, blood products, contrast media, or other fluids. Additionally, the port may be used to aspirate blood from the patient. Such access ports typically include a cannula-impenetrable housing which encloses one or more fluid cavities or reservoirs and defines for each such fluid cavity an access aperture communicating through the housing. A cannula-penetrable septum is positioned adjacent to and seals each access aperture. An outlet stem communicates with one or more of the fluid cavities for dispensing medication therefrom to a predetermined location in the body of the patient through an implanted catheter attached to the access port. Once the access port and the catheter have been implanted beneath the skin of a patient, quantities of fluid, such as medication, blood, etc., may be dispensed through one such fluid cavity by, for example, a cannula (e.g., a needle), passed through the skin of the patient and penetrating the septum into one of the respective fluid cavities. This medication is directed through the distal end of the catheter to an entry point into the venous system of the body of the patient. Further, blood may be aspirated through the subcutaneous access port. Thus, use of an access port may allow for vascular access without needle sticks into the vasculature of a patient.

However, conventional access ports and attendant infusion systems have not been suitable for performing power injection.

Particularly, the use of power injection systems in combination with conventional vascular access ports has achieved less than ideal results. Thus, it may be appreciated that vascular access ports for infusion systems and infusion-related apparatuses structured for performing power injection may be advantageous.

SUMMARY

One aspect of the instant disclosure relates to a method of flowing fluid through an access port. More particularly, a vascular access port may be provided and a fluid may be caused to flow through the access port at a rate of at least about 1 milliliter per second.

A further aspect of the instant disclosure relates to a method of flowing fluid through an infusion set. For example, an infusion set may be provided and a fluid may be flowed through the infusion set at a rate of at least about 1 milliliter per second.

Another aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Specifically, an access port may comprise a housing defining an aperture for capturing a septum, wherein the housing and septum define a reservoir. In addition, the septum may include a tenon region wherein the housing of the access port defines a complimentary mortise region structured for accepting at least a portion of the tenon region of the septum. Optionally, the housing may include a ring structure proximate to at least a portion of a side periphery of the septum.

An additional aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. In one embodiment, an access port may comprise a housing defining an aperture for capturing a septum, the housing and septum defining a reservoir. In addition, the housing and septum may be structured for accommodating a flow rate through the reservoir of at least about 1 milliliter per second. In another embodiment, an access port may include a housing and septum, as described above, wherein the housing and the septum are structured for accommodating a pressure developed within the reservoir of at least about 35 psi.

Yet another aspect of the instant disclosure relates to an infusion set for use in subcutaneously accessing a patient. For example, in one embodiment, an infusion set may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section. Also, the cannula may be configured for insertion through a septum of an access port, and the tubing section and the cannula may be structured for allowing a fluid to flow at a rate of at least about 1 milliliter per second. Optionally the cannula may be configured for puncturing a septum of an access port and the tubing section and the cannula may be structured for accommodating a pressure of at least about 400 psi. For example, the tubing section and the cannula may be structured for accommodating a pressure of about 600 psi.

A further aspect of the instant disclosure relates to infusion tubing for use in accessing a vascular system of a patient. In one embodiment, infusion tubing may comprise a plurality of layers, wherein the tubing is structured for accommodating a fluid flow rate of at least about 1 milliliter per second. In another embodiment, infusion tubing may comprise a plurality of layers, wherein at least one layer of the plurality of layers extends beyond at least another of the plurality of layers and is structured for forming a cannula for puncturing a septum of an access port. In yet an additional embodiment, an infusion set for use in subcutaneously accessing a patient may comprise a tubing section defining a lumen and a cannula in fluid communication with the lumen of the tubing section, wherein the cannula is configured for insertion through a septum of an access port. Additionally, the tubing section and cannula may be structured for accommodating a pressure of at least about 400 psi.

Another aspect of the instant disclosure relates to a method of identifying an access port as being suitable for power injection. More specifically, an access port including a septum may be provided. Further, the access port may be identified as being suitable for power injection.

Yet a further aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Particularly, an access port may comprise a housing configured for capturing a septum, the septum configured for inserting a cannula therethrough and into a reservoir defined within the housing and at least one structural element configured for resisting deformation of the septum in response to a pressure developed within the reservoir.

In an additional aspect of the instant disclosure, a method of operation of an access port may comprise providing a housing configured for capturing a septum, the septum configured for inserting a cannula (which can include a needle, a Huber needle, a trocar with an associated cannula, or any combination thereof) therethrough and into a reservoir defined within the housing, and developing a pressure within the reservoir of the housing. Further, such a method may comprise limiting deformation of the septum in response to the pressure developed within the reservoir.

In addition, one aspect of the instant disclosure relates to a septum comprising a gel or a viscous liquid. For example, in one embodiment, a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body including an upper surface and a lower surface and at least one gel region positioned generally between the upper surface and the lower surface. Another embodiment may comprise a septum for assembly with a housing to form an access port for providing subcutaneous access to a patient may comprise a body, a layer formed over at least a portion of the body, and a gel region positioned at least partially between the layer and the body.

The above-described infusion apparatuses and related methods may be beneficially employed for effecting or facilitating power injection processes. For instance, such methods and apparatuses may be employed for infusing a fluid (e.g., a contrast media) at a rate of between about 1 milliliter per second and about 5 milliliters per second.

Features from any of the above mentioned embodiments may be used in combination with one another in accordance with the instant disclosure. In addition, other features and advantages of the instant disclosure will become apparent to those of ordinary skill in the art through consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the instant disclosure will become apparent upon review of the following detailed description and drawings, which illustrate representations (not necessarily drawn to scale) of various aspects of the instant disclosure, wherein:

FIG. **1** shows an exploded, perspective view of an access port according to the instant disclosure;

FIG. **2** shows a schematic, side cross-sectional view of the access port shown in FIG. **1**;

FIG. **3** shows a schematic, top elevation view of a cap including a ring feature as shown in FIGS. **1** and **2**;

FIG. **4** shows a schematic, top elevation view of another embodiment of a cap including a ring feature;

FIG. **5** shows a schematic, top elevation view of a further embodiment of a cap including a ring feature;

FIG. **6** shows a schematic, side cross-sectional view of an implanted access port with a cannula extending through the septum of the access port;

FIG. **7** shows a graph depicting pressures at selected regions within an infusion system for a given flow rate;

FIG. **8** shows a schematic, side cross-sectional view of an access port including a septum with a tenon region and a housing with a mortise region;

FIG. **9** shows a schematic, side cross-sectional view of another embodiment of an access port including a septum with a tenon region and a housing defining a mortise region;

FIG. **10** shows a schematic, side cross-sectional view of a further embodiment of an access port including a tenon region and a housing defining a mortise region;

FIG. **11** shows a schematic, side cross-sectional view of an access port, wherein at least a portion of a side periphery of the septum is affixed to the housing;

FIG. **12** shows a schematic, side cross-sectional view of an access port including a structural element extending between the septum and the housing;

FIG. **13** shows a schematic, side cross-sectional view of an access port including a structural element with a barbed end positioned within the septum;

FIG. **14** shows a schematic, side cross-sectional view of an access port including a structural element extending between an upper surface of the septum and the housing;

FIG. **15** shows a schematic, side cross-sectional view of an access port as shown in FIG. **14** and also including a support element positioned adjacent to an upper surface of the septum;

FIG. **16** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg that extends to the housing;

FIG. **17** shows a schematic, side cross-sectional view of an access port including a septum with an extension leg comprising an enlarged end that couples to a recessed form in the housing;

FIG. **18** shows a schematic, side cross-sectional view of an access port including a septum in a structural element positioned adjacent to an upper surface of the septum;

FIG. **19** shows a schematic, side cross-sectional view of an access port including a septum and a structural element extending laterally through the septum;

FIG. **20** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to an upper surface of the septum;

FIG. **21** shows a schematic, side cross-sectional view of an access port including a septum and a structural element positioned proximate to a lower surface of the septum;

FIG. **22** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a generally triangular pattern;

FIG. **23** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in two generally rectangular patterns;

FIG. **24** shows a partial, top elevation view of an access port, as shown in FIGS. **18-21**, wherein structural elements are arranged in a first plurality of substantially parallel lines and a second plurality of substantially parallel lines;

FIG. **25** shows a partial, top elevation view of an access port as shown in FIGS. **18-21**, wherein structural elements are arranged as two intersecting substantially straight members;

FIG. **26** shows a partial, top elevation view of a septum including a structural element positioned within the septum;

FIG. **27** shows a perspective view of a sectioned septum, as shown in FIG. **26**;

FIG. **28** shows a partial, top elevation view of a septum including a plurality of structural elements;

FIG. **29** shows a schematic, side cross-sectional view of an access port including a septum exhibiting curvature;

FIG. **30** shows a top elevation view of one embodiment of a septum frame;

FIG. **31** shows a schematic, side cross-sectional view of one embodiment of a septum including the frame shown in FIG. **30** and another material at least partially surrounding the frame;

FIG. **32** shows a schematic, side cross-sectional view of another embodiment of a septum including a frame that is at least partially surrounded by another material;

FIG. **33** shows a schematic, side cross-sectional view of yet an additional embodiment of a septum including a frame that is at least partially surrounded by another material;

FIGS. **34** and **35** show a respective schematic view of different patterns that may be generated by radiopaque material comprising a septum;

FIG. **36** shows a perspective view of one embodiment of an infusion set according to the instant disclosure;

FIG. **37** shows a perspective view of another embodiment of an infusion set according to the instant disclosure;

FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of one embodiment of tubing including an inner layer and an outer layer;

FIG. **40** shows a schematic, side cross-sectional view of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIG. **41** shows a schematic, side cross-sectional view of another embodiment of tubing including an inner layer, an outer layer, and at least one reinforcing element;

FIGS. **42** and **43** show an end cross-sectional view and a schematic, side cross-sectional view, respectively, of tubing including four layers;

FIGS. **44** and **45** show schematic, side cross-sectional views of a tubing section including a plurality of layers, wherein at least one layer of the plurality of layers extends from a distal end of the tubing to form a slender hollow region for insertion through a septum of an access port;

FIG. **46** shows a perspective view of one embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **47** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **46**;

FIG. **48** shows a perspective view of another embodiment of an infusion system configured for inserting a flexible catheter through a septum of an access port;

FIG. **49** shows a schematic, partial, side cross-sectional view of the infusion system shown in FIG. **48**;

FIG. **50** shows a perspective view of the infusion system shown in FIG. **48**, wherein the insertion assembly is removed from the hub;

FIG. **51** shows a perspective view of one embodiment of an access port according to the instant disclosure;

FIG. **52** shows a top elevation view of the access port shown in FIG. **51**;

FIG. **53** shows a simplified representation of a transverse cross-section of the access port shown in FIGS. **51** and **52**;

FIG. **54** shows a schematic, side cross-sectional view of one embodiment of a septum including at least one gel region;

FIG. **55** shows a schematic, side cross-sectional view of another embodiment of a septum including at least one gel region;

FIG. **56** shows a schematic, side cross-sectional view of a further embodiment of a septum including at least one gel region;

FIG. **57** shows a side cross-sectional view of a first mold and a second mold, wherein a gel region is positioned between the first mold and the second mold;

FIG. **58** shows a schematic, side cross-sectional view of an embodiment of a septum including at least one chamber to capture a gel; and

FIG. **59** shows a schematic, side cross-sectional view of an additional embodiment of a septum including at least one gel region.

DETAILED DESCRIPTION

One aspect of the instant disclosure relates to vascular access ports. More particularly, in one embodiment, the instant disclosure contemplates that a vascular access port may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second. Further, the instant disclosure contemplates that a vascular access port may be structured to withstand at least about 180 pounds per square inch (psi) of pressure developed within the reservoir defined by the septum and the access port housing. In one embodiment, an access port may be structured for operating within a range of pressures of about 80 psi to about 180 psi. Such an access port may be advantageous for use in infusing a fluid into a patient (e.g., infusing contrast media into a patient for CT or MR imaging).

Generally, an access port may comprise a housing that captures a septum that may be repeatedly pierced or punctured with a hollow slender element (e.g., a cannula, or needle), which can include a Huber needle, a trocar with a circumferentially disposed cannula, or any other suitable access mechanism, without limitation. The words "cannula" or "needle," as used herein, encompass any slender element (e.g., a cannula, a needle, a trocar, with a circumferentially disposed cannula, etc.) as known in the art or described herein, without limitation. Such a septum may comprise a material (e.g., silicone) that seals, under suitable compression, passages formed by puncturing the septum with such an access mechanism. Thus, the septum may be at least partially compressed to facilitate closure of passages formed by puncturing the septum with the access mechanism. The instant disclosure contemplates that the housing and septum may be structured so that a flow rate from the reservoir of the access port may be at least about 1 milliliter per second without damaging the housing or septum or compromising the structural integrity of the reservoir (e.g., causing the septum to become separated from the housing).

In one embodiment, an access port may comprise a cap and base which define, in combination, a housing in which a septum may be positioned to form a reservoir. For example, FIGS. **1** and **2** show, respectively, an exploded perspective view and a side cross-sectional view of an access port **50** including a base **56**, a cap **54**, a septum **80**, and an outlet stem **70**. As shown in FIGS. **1** and **2**, cap **54** and base **56**, may be configured for capturing a septum **80** between cap **54** and **56**. Generally, cap **54** and base **56** may collectively form a housing **60** for capturing septum **80** and at least partially defining reservoir **66**. Explaining further, cap **54** may include an aperture **55** through which a portion of septum **80** may extend and base **56** may include a recess **57** configured to accept at least a portion of septum **80**. Thus, a portion of septum **80** may be placed within recess **57** of base **56** and aperture **55** of cap **54** may be positioned about septum **80** to collectively define a reservoir **66** within access port **50**, the reservoir **66** being in fluid communication with a lumen of outlet stem **70**. In other embodiments, a plurality of reservoirs may be collectively defined by a housing and at least one septum, without limitation. For example, any access port known in the art including a plurality of reservoirs (or one reservoir) may include any aspects) of the instant disclosure, without limitation. As shown in FIG. **1**, a portion of outlet stem **70** may be positioned within and coupled to an aperture **58** formed within base **56**.

Although FIG. **1** shows that access port **50** may include an outlet stem **70**, other embodiments of access port **50** may not include an outlet stem **70**. Therefore, FIG. **2** shows access port **50** without an outlet stem **70**. Put another way, the instant disclosure contemplates that access port **50** may, optionally, include an outlet stem **70** or may be otherwise configured. For instance, in one embodiment, outlet stem **70** may be formed as a part of with base **56**, if desired. In another embodiment, a catheter may be operably coupled to the access port **50** (e.g., to aperture **58**) without outlet stem **70**. In yet a further embodiment, access port **50** may simply include at least one outlet passage (e.g., aperture **58**) in fluid communication with the reservoir **66** and extending through the housing **60** and structured for allowing fluid flow through, if desired. As shown in FIG. **2**, a portion of septum **80** may be positioned between cap **54** and base **56** and may be configured to withstand, without damage or deforming to an extent that compromises the reservoir **66** (i.e., blowing out), a selected magnitude of pressure developed within reservoir **66**.

For example, as shown in FIGS. **1** and **2**, cap **54** may optionally include a circumferential ring structure **30** that is formed adjacent to a side periphery of septum **80**. Ring structure **30** may be structured to inhibit deformation of the cap **56** in response to a pressure developed within reservoir **66** of access port **50**. As shown in FIG. **3**, in a top elevation view of cap **54**, ring structure **30** may be generally circular. Further, ring structure **30** may be substantially congruent to a side peripheral shape of septum **80** or may exhibit a different shape than the side periphery of septum **80**. In addition, the size of ring structure **30** may be selected to provide a selected rigidity to a region of cap **54** adjacent to of aperture **55** of cap **54**. Such a configuration may inhibit deformation of the cap **54** in response to pressure developed within reservoir **66**. For example, as shown in FIG. **2**, a lateral thickness T_L, vertical thickness T_V, or both may be selected for providing a selected rigidity to a region of cap **54** adjacent to a periphery of septum **80** (i.e., adjacent to aperture **55**). In one embodiment, the overall height H (FIG. **2**) of access port **50** may be less than about 0.600 inches.

In other embodiments, ring structure **30** may be generally rectangular, generally triangular, generally oval, generally polygonal, or of another geometrical shape, without limitation. For example, FIG. **4** shows a top elevation view of a ring structure **30** that is generally triangular. Further, FIG. **5** shows a generally rectangular ring structure **30**.

Explaining further, housing **60** of access port **50** may comprise a biocompatible material such as polysulfone, titanium, or any other suitably biocompatible material. Thus, cap **54** and base **56** may couple to one another generally along a mating line and may be secured or affixed to one another. More particularly, in one embodiment, both cap **54** and base **56** may comprise titanium and may be welded, brazed, soldered, or otherwise affixed to one another. Such a configuration may provide suitable mechanical strength for capturing

septum **80** between cap **54** and base **56**. Optionally, cap **54** and base **56** may be coupled to one another by at least one fastening element (e.g., at least one bolt, at least one screw, at least one rivet, etc.), at least one adhesive, or a combination of such coupling mechanisms. Similarly, in one embodiment, outlet stem **70** and base **56** may each comprise titanium and may be welded or otherwise bonded or coupled to one another.

In further detail, FIG. **6** shows an access port **50** implanted within a patient **67**. In one embodiment, sutures may be used to affix the access port **50** within the patient **67**, if desired. After the housing **60** is implanted in a patient **67**, the upper surface of the septum **80** may be generally flush or aligned with the surface of the skin surface **76** of the patient **67** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the reservoir **66**. The outlet stem **70** may create a fluid-communicative passageway extending from the reservoir **66** and through the outlet stem **70**, catheter **73**, and into the interior of the patient **67**. Generally, catheter **73** may be coupled to the outlet stem **70** for fluid communication with the reservoir **66** and for conducting fluid to a desired remote location from the reservoir **66** and within patient **67**. In one embodiment, catheter **73** may extend from the access port **50** to at least partially within a vena cava of the patient. Such a configuration may allow for infusion of a contrast media proximate to the heart of a patient. Because such a contrast media may be harmful (e.g., radioactive or otherwise injurious) infusion directly into a vena cava of a patient may reduce an overall quantity of contrast media required to perform a selected imaging procedure.

As shown in FIG. **6**, a cannula **90** may be inserted through the septum **80** and fluid may be injected into the reservoir **66**. For example, fluid may be injected into reservoir **66** at a rate that causes pressure (i.e., a positive pressure) to be developed within reservoir **66**. For example, a positive pressure, labeled "P_R" in FIG. **6**, may develop within reservoir **66** and may act upon the portion of septum **80** defining, in part, reservoir **66**. Such a pressure P_R acting on a portion of septum **80** may develop force upon the septum **80**. Likewise, force may be developed on surfaces of the base **56** that are acted upon by pressure Pr. In one embodiment, cap **54** may be coupled to base **56** and structured to suitably position septum **80** and couple septum **80** to housing **60** against force applied to the septum **80**. Therefore, the septum **80**, cap **54**, and base **56** may be structured for accommodating attendant forces developed by pressure P_R. In one embodiment, access port **50** may be structured for accommodating (without damage) a pressure P_R of at least about 185 psi with reservoir **66**. In another embodiment, access port **50** may be structured for accommodating (i.e., without damage) a range of pressures of about 37 psi to about 65 psi with reservoir **66**.

In further detail, during power injection, a fluid flow F may be caused to flow through cannula **90**. A fluid flow rate (depicted in FIG. **6** by arrows labeled "F") may be at least about 1 milliliter per second. In another embodiment, a fluid flow rate F may be between about 1 milliliter per second to about 5 milliliters per second. During power injection, a pressure P_i may be developed within cannula **90** may be at least about 30 psi. Accordingly, cannula **90** may be structured to withstand the forces associated with the above-discussed pressure, flow rate, or both. As discussed in further detail below, the cannula may comprise a portion of an infusion set (e.g., a safety winged infusion set (SWIS)) or another infusion system configured for use with an access port and a power injection system, without limitation.

More particularly, FIG. **7** shows a graph depicting pressure measurements at different locations within an infusion system including an infusion set (as discussed in greater detail below) in fluid communication with an access port during infusion of a fluid at a rate of 5 milliliters per second. As shown in FIG. **7**, a pressure generally within a syringe barrel of a power injector may be about 265 psi. Further, a pressure generally at the entrance of an infusion set may be about 225 psi and a pressure generally within a reservoir of an access port may be about 40 psi. Thus, the pressure drop through an infusion set may be about 185 psi. As shown in FIG. **7**, a pressure generally at the distal end of a catheter extending from the access port may be about 0 psi. Many factors may influence a pressure (and a pressure drop) developed within an infusion system (e.g., infusion set, access port, etc.) during flow of a fluid through the infusion system, such as, for example, fluid viscosity, tubing inner diameter (i.e., lumen cross-sectional size), length of the flow path, and flow rate. Accordingly, as will be appreciated by the above discussion of the access port **50** shown in FIGS. **1-3**, such access port **50** may be structured to accommodate a selected flow rate and associated pressure P_R developed within reservoir **66** of access port **50**.

In another embodiment, the septum, housing, or both may be structured to mechanically secure or constrain at least a portion of the septum. For example, in one embodiment, the septum may include at least one coupling feature configured to mate or couple with a complementary coupling feature included by the housing. For example, male and female features (e.g., without limitation, ribs, flanges, interlocking features, tenon and mortise type features, tongue-in-groove features, T-slot features, dovetail features, snap-fit features, tabs and slots or other coupling features as known in the art) may comprise the at least one coupling feature included by the septum and the at least one complementary feature included by the housing, without limitation. "Tenon," as used herein, means a projecting member for at least partial insertion into a mortise to make a joint. "Mortise," as used herein, means a recess, hole, groove, or slot formed within a material for receiving at least a portion of a tenon to make a joint.

Generally, in one embodiment, the septum may include at least one tenon region (i.e., at least one coupling feature) for coupling to a complementary mortise region formed by the housing. Thus, the housing may include a recess (i.e., at least one complementary feature) for accepting at least a portion of the tenon region of the septum. For example, FIG. **8** shows a side cross-sectional view of one embodiment of a septum **180** including a tenon region **270**. Particularly, tenon region **270** includes tapered surface **187** of septum **180**, which may increase in height (i.e., from lower surface **183** of septum **180**) along an increasing radial direction (i.e., relative to a radial distance from a central axis of septum **180**; that is, in a direction from rim **159** of cap **154** toward side surface **157** of base **156**). Thus, as shown in FIG. **8**, a height CG_{MIN} of septum **180** (measured at a radially innermost extent of tenon region **270**) is less than a height CG_{MAX} of septum **180** (at a radially outermost extent of tenon region **270**). Further, tenon region **270** may be a continuous peripheral feature (i.e., an annular feature) of septum **180** or may comprise one or more circumferentially separate regions, without limitation. Further, as shown in FIG. **8**, housing **160** (including cap **154** and base **156**) may generally define a complementary mortise region (e.g., a circumferentially extending recess) for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined by side surface **157** of base **156**, lower flange surface **273** of base **156**, and tapered surface **172** of cap **154**. Such a configuration may

secure, capture, or retain a portion of tenon region **270** of septum **180** within the mortise region of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In another embodiment, an access port may comprise a septum including a tenon region including a plurality of tapered surfaces. For example, FIG. **9** shows a schematic side cross-sectional view of a septum **180** including a tenon region **270** comprising tapered surface **187**, tapered surface **189**, and tapered surface **191**. Further, as shown in FIG. **9**, housing **160** may generally define a complementary mortise region tapered recess for accepting at least a portion of tenon region **270**. More particularly, a complementary mortise region may be defined within housing **160** by side surface **157** of base **156**, lower flange surface **273** of base **156**, tapered surface **172** of cap **154**, tapered surface **193** of base **156**, and tapered surface **195** of cap **154**. Such a configuration may secure, capture, or retain at least some of tenon portion **270** of septum **180** within a tapered recess of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

In summary, it should be understood that a portion of a septum may comprise, generally, at least one tenon region for coupling with a complementary mortise region formed in a housing. In another embodiment, generally, at least a portion of a housing may comprise a tenon for coupling with a complementary mortise formed in a septum. As described above, a tenon region and a complimentary mortise region may comprise one or more tapered surfaces. In another embodiment, a tenon region and complementary mortise region may comprise a T-slot or other nontapered geometry, without limitation. For example, FIG. **10** shows a schematic, side cross-sectional view of one embodiment of an access port **150** comprising a septum **180** including a tenon region **270**. Further, a complementary mortise region may be defined within housing **160** for accepting at least a portion of tenon region **270**. As shown in FIG. **10**, a mortise region may be at least partially defined by an annular extension or protrusion **203** of base **156**. Such a configuration may secure, capture, or retain at least a portion of tenon region **270** of septum **180** within housing **160** and suitably seal reservoir **166** even if an anticipated maximum pressure is developed within reservoir **166**. It should be further understood that any of the tenon region and mortise region embodiments shown in FIGS. **8-10** may be described in terms of extensions, ridges, protrusions, recesses, grooves, slots, etc., without limitation.

A further aspect contemplated by the instant disclosure relates to coupling or affixing at least a portion of a peripheral region of a septum to a housing. Such a configuration may maintain the integrity of the access port during use of the access port for infusing a fluid at a flow rate of at least about 1 milliliter per second. For example, in one embodiment, at least a portion of a side periphery of a septum may be affixed to at least a portion of a housing. FIG. **11** shows a side cross-sectional view of an access port **50** wherein at least a portion of a periphery of septum **80** adjacent to housing **60** is affixed to one or both of cap **54** and base **56** adjacent to septum **80**. More particularly, as shown in FIG. **11**, a periphery of septum **80** (adjacent to cap **54** and base **56**) may include upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95**. Thus, in one embodiment, an adhesive, (e.g., glue, epoxy, cement, tape, or any other adhesive as known in the art) may affix at least a portion of one or more of upper side region **97**, upper annular region **93**, lower annular region **91**, and lower side region **95** to the cap **54** or base **56**, respectively. Such a configuration may secure septum **80** to housing **60** and may provide a relatively robust access port **50** suitable for power injection. It should further be appreciated that affixing at least a portion of a peripheral region of a septum may encompass affixing at least a portion of a tenon region (of either a septum or housing) to a mortise region (of either a housing or septum), without limitation.

As described above, septum deformation is a design consideration with respect to performing power injection via an access port. Further, one aspect of the instant disclosure relates to a septum that is structurally reinforced or otherwise limited against deformation exceeding a selected magnitude. More specifically, the instant disclosure contemplates that at least one structural element may be configured to inhibit or limit deformation of a septum of an access port in response to pressure developed within a chamber or reservoir of the access port. Some embodiments of an access port including at least one structural element for limiting deformation of a septum are disclosed in U.S. Patent Application No. 60/737,466, filed 15 Nov. 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the access ports encompassed by U.S. Patent Application No. 60/737,466 may be structured for power injection.

In one embodiment, the instant disclosure contemplates that a septum may be structurally coupled to a housing nonperipherally. Put another way, one aspect of the instant disclosure relates to coupling a nonperipheral portion of a septum to a housing of an access port. For example, FIG. **12** shows one embodiment of an access port **110** according to the instant disclosure including a cap **54** and a base **56** that capture a septum **120** to form a reservoir **66**. Optionally, cap **54** may include a ring feature proximate to a periphery of the septum, as described above. In addition, outlet stem **70** may allow for fluid communication with reservoir **66** to perform infusion or fluid sampling processes. As shown in FIG. **12**, a structural element **112** may extend between septum **120** and housing **60**. More particularly, structural element **112** extends generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Thus, if pressure (positive/negative) is developed within reservoir **66**, structural element **112** may inhibit deflection or deformation of lower surface **121** of septum **120** toward or away from upper surface **165** of base **56**. Generally, a structural element may inhibit deformation of a septum in relation to one or more selected directions (i.e., either toward or away from upper surface **165** of base **56**).

Generally, a structural element (e.g., structural element **112**) may comprise any of the following: at least one wire, at least one pin or columnar element, or at least one filament, without limitation. Such a structural element may comprise titanium, steel (e.g., stainless steel), polymers (e.g., DELRIN®, nylon, polyester, KEVLAR®, polytetrafluoroethylene (PTFE) (expanded or nonexpanded), polyurethane, etc.), or other materials as known in the art. In other embodiments, a structural element may comprise a composite, such as a fiber-reinforced matrix. In one embodiment, a structural element may comprise fibers (glass, carbon, etc.) dispersed or aligned within a silicone matrix.

Further, structural element **112** may be coupled to septum **120** by an adhesive, welding, snap-fitting, molding the septum **120** about a portion of the structural element **112**, otherwise imbedding a portion of structural element **112** within septum **120**, or as otherwise suitable. Similarly, structural element **112** may be coupled to base **56** by an adhesive, welding, or imbedding a portion of structural element **112** within base **56**. It may also be appreciated that, optionally, structural element **112** may exhibit a modulus of elasticity that exceeds a modulus of elasticity of septum **120**. Such a configuration may allow for structural element **112** to resist

deformation of septum **120** in response to a pressure developed within reservoir **66** (e.g., during a "power injection" process).

FIG. **13** shows a schematic cross-sectional view of an access port **110** according to the instant disclosure including another embodiment of structural element **112**. Particularly, as shown in FIG. **13**, structural element **112** may include a barbed end **116**, which is positioned at least partially within septum **120**. Such a configuration may couple structural element **112** to septum **120** and may resist against deformation of the septum **120** in response to pressure developed within reservoir **166**. Furthermore, as shown in FIG. **13**, the barbed end **116** of structural element **112** may, optionally, be pointed. Further, the point of barbed end **116** may be oriented toward upper surface **123** of septum **120**. Such a structure may deflect a cannula that is inserted through septum **120** and contacts barbed end **116** so that the cannula is directed away from structural element **112**. Optionally, in another embodiment, structural element **112** may extend through base **56** and may be affixed to lower surface **113** of base **56**.

In another embodiment of an access port, a structural element may extend through a septum. For example, FIG. **14** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from lower surface **121** of septum **120** to upper surface **123** of septum **120**. As shown in FIG. **14**, structural element **112** may also extend to upper surface **165** of base **56**, to mechanically couple septum **120** to housing **60**. Optionally, structural element **112** may include at least one barb, which may be positioned within septum **120** and configured for coupling septum **120** to housing **60**. In addition, structural element **112** may be affixed, if desired, to at least one of upper surface **123** and lower surface **121** of septum **120**. As may be appreciated, it may be advantageous for upper surface **123** of septum **120** to be mechanically coupled to housing **60** to resist deformation of septum **120** in response to a pressure developed within reservoir **66**.

The instant disclosure further contemplates that a structural element may be employed in combination with a support element extending over a selected area of the upper surface of the septum. Such a support element may be positioned adjacent to an upper surface of a septum and may be configured to contact the upper surface of the septum with a selected surface area (e.g., when the septum deforms). For example, FIG. **15** shows a schematic, side cross-sectional view of an access port **110** including a structural element **112** that extends from housing **60** to an upper surface **123** of septum **120**. Furthermore, structural element **112** is coupled to a support element **114**, which is positioned adjacent to upper surface **123** of septum **120**. Such a configuration may provide a selected amount of contact area between support element **114** and upper surface **123** of septum **120**. Such a selected contact area between support element **114** and septum **120** may reduce otherwise undesirably high stresses within septum **120** when a pressure develops within reservoir **66** by distributing such stresses over a selected area or region of septum **120**. In addition, support element **114** may be observable (e.g., visually or by palpation) and, therefore, may be avoided when inserting a cannula through septum **120**. Additionally, the support element **114** can be used to identify the port **110** as being power injectable.

In another embodiment of an access port, a structural element may comprise a portion of a septum affixed to a housing of an access port to resist deformation of the septum. For example, FIG. **16** shows a schematic, side cross-sectional view of an access port **110** including a septum **120**, which comprises an extension leg **124** (i.e., a structural element) that is coupled to housing **60**. More particularly, as shown in FIG. **16**, extension leg **124** may extend generally from lower surface **121** of septum **120** to upper surface **165** of base **56**. Extension leg **124** may abut and may be affixed to upper surface **165** of base **56**. Such a configuration may resist against deformation of septum **120** in response to pressure developed within reservoir **166**. In one embodiment, extension leg **124** may be substantially centered (i.e., positioned generally at a centroid of lower surface **121**) with respect to lower surface **121** of septum **120**. Substantially centering extension leg **124** with respect to lower surface **121** of septum **120** may limit deformation of lower surface **121** of septum **120** to a greater extent than other positions of extension leg **124** may limit deformation of lower surface **121** of septum **120**. Additionally, it should be appreciated that while FIG. **16** shows one extension leg **124**, the instant disclosure contemplates that at least one extension leg (i.e., one or more extension legs) may extend from or be coupled to septum **120**, without limitation. In another embodiment, at least one extension leg may be coupled to a housing of an access port by an interference fit or a so-called "snap-fit." More particularly, as shown in FIG. **17**, extension leg **124** includes a bulbous or rounded end **125** that is configured to fit within a recess **155** formed in base **56**. Recess **155** may comprise an opening formed in upper surface **165** of base **56** that is smaller than a maximum lateral dimension of rounded end **125**, so that rounded end **125** may be forced through such an opening and "snap" into a portion of recess **155**. Optionally, extension leg **124** may be affixed (e.g., adhesively affixed, welded, pinned, or affixed by other suitable methods to recess **155** formed in base **56**. Such a configuration may couple septum **120** to base **60** of access port **110** and may resist or limit deformation of septum **120** in response to pressure developed within reservoir **66**.

Another aspect of the instant disclosure contemplates that at least a portion of an upper surface of a septum may be constrained or limited in its deformation. In one embodiment, at least one structural element may be positioned upon or adjacent to an upper surface of a septum to limit deformation of the septum in a direction toward the structural element. Put another way, at least one structural element may extend laterally upon or adjacent to at least a portion of an upper surface of a septum. For example, FIG. **18** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** and a structural element **132** positioned adjacent to an upper surface **133** of septum **130**. Optionally, structural element **132** may be bonded or affixed to upper surface **133** of septum **130**. Structural element **132** may be structured to resist deformation of septum **130** in a direction generally away from reservoir **166**. In one embodiment, structural element **132** may substantially overlay or cover upper surface **133** of septum **130**. Optionally, structural element **132** may be at least partially embedded within septum **130**. In one embodiment, structural element **132** may be penetrable by a cannula (e.g., a needle). In another embodiment, structural element **132** may cover a selected portion (i.e., at least a portion) of upper surface **133** of septum **130**, which may allow for openings or apertures formed in structural element **132** through which a cannula may be inserted into upper surface **133** of septum **130**. It may be appreciated that, optionally, a modulus of elasticity of structural element **132** may exceed a modulus of elasticity of septum **130**, so that deformation of septum **130** may be inhibited to a selected degree by structural element **132**. Further, although a thickness (labeled "t") of structural element **132** is shown in FIG. **18** as being substantially uniform, the instant disclosure contemplates that a thickness "t" of structural element **132** may vary, with-

out limitation. For example, thickness "t" of structural element **132** may be maximum proximate to a centroid of the upper surface **133** of septum **130**. In addition, as shown in FIG. **18**, structural element **132** may be positioned between cap **54** and septum **130**. Structural element **132** may be affixed to one or both of cap **54** and septum **130**, if desired. For example, structural element **132** may be adhesively affixed, welded, mechanically fastened, or otherwise suitably coupled to one or both of cap **54** and septum **130**. Furthermore, structural element **132** may comprise a metal (e.g., titanium, steel, etc.), a polymer (e.g., DELRIN® polyurethane, nylon, etc.), or any other suitable material. In another embodiment, as discussed further below, structural element **132** may comprise a relatively tightly woven fabric that resists tissue ingrowth (if positioned in potential contact with an internal cavity of the body). In a further embodiment, a structural element **132** may comprise a substantially fluffy or compressible polyester that may promote tissue healing of punctures created by a cannula passing through septum **130** of access port **110** (if positioned in potential contact with an internal cavity of the body).

In a further embodiment, the instant disclosure contemplates that at least one structural element may be at least partially embedded within a septum and may extend laterally through at least a portion of the septum. For example, FIG. **19** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** and a structural element **140** extending laterally (i.e., across an opening in the housing **60** closed by the septum **120**) through the septum **120**. As shown in FIG. **19**, structural element **140** may be affixed to housing **60** (e.g., cap **54** or base **56**). More particularly, as shown in FIG. **19**, structural element **140** may be affixed to cap **154** at connection regions **147** and **143**. In addition, a selected level of tension may be developed within structural element **140**, if desired, to provide for a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected degree of resistance to deformation of septum **120** in a direction generally perpendicular to a direction of extension of structural element **140**.

In another embodiment, a structural element may be positioned proximate to an upper surface of a septum to limit deformation of the septum. For example, FIG. **20** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** positioned within a housing **60** and a structural element **150** positioned proximate to an upper surface **133** of septum **130**. As shown in FIG. **20**, structural element **150** extends laterally over at least a portion of upper surface **133** of septum **130**. Thus, structural element **150** may allow septum **130** to deform a selected distance (e.g., a gap labeled "G") prior to contact with structural element **150**. Further, structural element **150** may be affixed to cap **54** and may be selectively tensioned to exhibit a selected degree of flexibility in response to contact between septum **130** and structural element **150**. In one embodiment, structural element **150** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **130** in response to a pressure developed within reservoir **66**.

In another embodiment, a structural element may be positioned proximate to or abutting a lower surface of a septum to limit deformation of the septum. For example, FIG. **21** shows a schematic, side cross-sectional view of an access port **110** including a septum **120** positioned within a housing **60** and a structural element **170** positioned proximate to a lower surface **121** of septum **120**. As shown in FIG. **21**, structural element **170** may extend laterally over at least a portion of lower surface **121** of septum **120**. Further, structural element **170** may be affixed to lower surface **121** or septum **120** or otherwise coupled to lower surface **121** of septum **120**. Thus, structural element **170** may inhibit deformation of septum **120**. Further, structural element **170** may be affixed to base **56** (or otherwise coupled to housing **60**) to provide adequate resistance to deformation of septum **120**. Optionally, structural element **170** may be selectively tensioned to exhibit a selected flexibility in response to forces applied to the structural element **170**. Optionally, structural element **170** may exhibit a flexibility or spring constant that exceeds a bulk flexibility or spring constant of septum **120**.

Referring to FIGS. **18-21**, it will be appreciated that structural elements **132**, **140**, **150**, or **170** may comprise, in some embodiments, elongated elements, such as, for instance, wire, ribbon, thread, fibers, columnar elements, or the like. Accordingly, such at least one elongated element may be arranged in a selected pattern adjacent or proximate to an upper surface of a septum. Further, in one embodiment, a structural element positioned proximate to or abutting a lower surface of a septum, proximate to or abutting an upper surface of a septum, or within a septum, may comprise a mesh (e.g., a metal or plastic mesh, a fabric, a fiber mesh, etc.). For instance, in one embodiment, a structural element may comprise a fabric comprising fibers or threads that seal against one another (e.g., fibers or threads coated with silicone). Such a configuration may allow for a cannula to pass through the fabric and for the fabric to seal about the cannula, but may also allow for the fibers or threads to seal against one another when the cannula is removed. In addition, it will be understood that, based upon the instant disclosure, structural elements **132**, **140**, **150**, or **170** as shown in FIGS. **18-21** may be arranged in a variety of configurations.

For example, FIG. **22** shows a partial top elevation view of one embodiment of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged to form a generally triangular shape or pattern. In a further example, FIG. **23** shows a partial top elevation view of an access port **110** as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged in two partially intersecting generally rectangular shapes or pattern. In yet a further embodiment, FIG. **24** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising a first plurality of substantially parallel lines and a second plurality of substantially parallel lines, wherein the first plurality of substantially parallel lines is substantially perpendicular to and intersects with the second plurality of substantially parallel lines. In an additional embodiment, FIG. **25** shows a partial top elevation view of an access port **110**, as shown in FIGS. **18-21**, wherein structural elements **132**, **140**, **150**, **170** are arranged as a pattern comprising two substantially straight (i.e., linear) members that intersect with one another. As shown in FIG. **25**, structural elements **132**, **140**, **150**, **170** may be substantially perpendicular to one another. As shown in FIGS. **22-25**, structural elements **132**, **140**, **150**, **170** may be affixed to cap **54** at selected connection regions. Such configurations may allow for varying degrees of limitation of deformation of a septum, while allowing ample access to a surface of a septum for perforation by a cannula (e.g., a needle).

In another embodiment, the instant disclosure contemplates that a structural element may be at least partially embedded within a septum and may be in the form, configuration, or shape of a two-dimensional or plane (e.g., a circle, ellipse, triangle, rectangle, etc.) within the septum. For example, FIG. **26** shows a partial top elevation view of a septum **120** and a structural element **141** extending within the septum **120**. In further detail, FIG. **27** shows a perspective

view of a sectioned septum **120** including a structural element **141** embedded within the septum **120**. As shown in FIGS. **26** and **27**, in one embodiment, structural element **141** may be generally circular. More generally, one or more structural elements **141** may be at least partially embedded within a septum (e.g., a septum **120** or **130**, as discussed above), if desired. For example, a plurality of structural elements **141** may be embedded within a septum **120** and arranged substantially concentrically with respect to one another, as shown in FIG. **28** in a partial, top elevation view. Structural element **141** may be generally elongated (as shown in FIGS. **26-28**) or may, more generally, exhibit a shape and size configured to resist deformation of the septum **120**, without limitation. Thus, it should be appreciated that one or more structural elements **141** may embody, for example, a washer or a disk that is frustoconical, domed, or otherwise shaped. In another embodiment, at least one structural element **141** may form, generally, a toroid. Further, at least one structural element **141** may exhibit at least one selected characteristic (e.g., exhibiting a selected size, shape, elasticity, strength, etc.) to impart a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected level of resistance to deformation of septum **120** in response to a pressure developed within a reservoir of an access port.

In another aspect of the instant disclosure, a septum may exhibit a curvature that resists deformation in response to a pressure developed within a reservoir of an access port. For example, FIG. **29** shows a septum **120** including a generally concave upper surface **123** and a generally convex lower surface **121**. Explaining further, generally concave upper surface **123** and a generally convex lower surface **121** may be exhibited by septum **120** in the absence of external forces (i.e., in an unstressed, equilibrium state). Such a configuration may provide resistance of the septum **120** to deformation due to a pressure developed within reservoir **66** of access port **110**, because the upper surface **123** of septum **120** would be forced to flatten (i.e., via deformation of septum **120**) before extending beyond the upper surface of housing **60**. In other embodiments, a septum may be compressed (e.g., by way of a tenon and mortise coupling or another peripheral coupling configuration between a septum and a housing) so that a curvature of the septum may be reduced or eliminated when the septum is assembled within the housing. However, such a configuration may increase the bulk flexibility or spring constant of the septum. Optionally, a structural element (as described above) may be included within the septum or upon a surface of the septum and may also be fabricated to exhibit concavity or convexity in the absence of external forces. Such a configuration may facilitate a favorable compressive stress field within the septum when coupled to a housing and may enhance resistance of the septum to deformation.

In a further configuration, a septum may include a structural frame or skeleton and a more pliant material configured to seal punctures created by a cannula. More specifically, a frame may comprise a material with a shore A hardness of at least about 80. Optionally, a frame may include a plurality of whiskers, fibers, or particles to stiffen or strengthen the frame. In one embodiment, nylon fibers, barium sulfate, or the like may be dispersed within a frame. Further, such a frame may be at least partially surrounded by a more pliant material exhibiting a Shore A hardness of about 50 or less (e.g., a Shore A hardness of about 40 to about 50). FIG. **30** shows top elevation view of a frame **178** including a plurality of spokes **179** extending from a generally common origin or region as well as rings **181** and **185**. As shown in FIG. **30**, spokes **179** in combination with one or both of rings **181** and **185** form apertures **188**. According to the instant disclosure, a relatively pliant material configured to seal punctures formed by a cannula passing through the material may at least partially surround such a frame **178**. For instance, FIG. **31** shows a schematic side cross-sectional view of septum **177** comprising a frame **178** and another material **190** molded partially about frame **178**. Thus, material **190** may substantially surround spokes **179** and may extend within apertures **188**. Further, as shown in FIG. **31**, ring **181** may form a tenon region **270** for coupling with a housing (as described above) as well as an upper septum surface **191** and a lower septum surface **193**. As may be appreciated with reference to shown in FIG. **31**, during use, a cannula may pass through a continuous upper layer of material **190** and a continuous lower layer of material **190**. Such a configuration may provide suitable sealing capability for septum **177**. It will be appreciated that many variations are contemplated by the instant disclosure. For example, FIGS. **32** and **33** show side cross-sectional views of different embodiments of a septum **177** including a frame **178** and another material **190** at least partially surrounding the frame **178**. Thus, a frame and a material at least partially surrounding the frame may exhibit arcuate or substantially planar surfaces and may be formed of selected thickness and comprising selected materials (e.g., silicone, etc.).

In a further aspect of a septum according to the instant disclosure, a septum may include a radiopaque material and may be configured to form a selected pattern when an x-ray is taken through the septum. For example, FIGS. **34** and **35** show schematic views of patterns **199** that may be generated by correspondingly positioned radiopaque material within a septum. Such a configuration may be useful for identifying the access port as being capable of accommodating particular power injection processes or for locating the septum of an access port.

The instant disclosure further contemplates that any infusion apparatus or device that is used in combination with an access port for infusing fluid at a rate of at least about 1 milliliter per second may be configured accordingly. For example, an infusion set for accessing a vascular access port may include a needle or cannula for puncturing a septum of the access port, a distal end for coupling to an injection apparatus, and tubing (e.g., at least one tubing section) extending between the cannula and the distal end. Generally, any components comprising an infusion set may be configured to withstand a selected flow rate and associated pressure developed by such a selected flow rate.

FIG. **36** shows one embodiment of an infusion set **310** including a base member **340**, a cannula **350**, a tubing section **314**, and connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and base **342** generally at joints **313** and **339**, respectively. Also, as shown in FIG. **36**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Further, each of the base member **340**, cannula **350**, tubing section **314**, and end connector **312** may be structured for accommodating a fluid flow rate of at least about 1 milliliter per second through the infusion set **310**. In further detail, tubing section **314** may exhibit sufficient strength for withstanding at least about 200 psi without damage. Optionally, tubing section **314** may withstand at least about 300 psi without damage. Further a pressure at which a portion of the infusion set bursts (i.e., a burst pressure of the infusion set **310**) may be at least about 400 psi; optionally, such a burst pressure may be at least 600 psi. In one embodiment, tubing section **314** may be substantially optically clear or may be at least partially transparent. In one embodiment, generally, tubing section **314** may comprise a polymer, such as TECOTHANE®. More specifically, tubing section may comprise a polymer, such as TECOTHANE®

55D or a polymer, such as TECOTHANE® 95A. For example, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.048 inches (+0.003 inches) (i.e., 19 GA), tubing section **314** may comprise a polymer, such as TECOTHANE® 55D. In other examples, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.041 inches or 0.034 inches (+0.003 inches) (i.e., 20 GA or 22 GA, respectively), tubing section **314** may comprise a polymer, such as TECOTHANE® 95A. Optionally, any polymer, such as TECOTHANE® type material may be at least substantially free of a plasticizer, such as, for instance, Di(2-Ethylhexyl) Phthalate ("DEHP"). In one embodiment, connector **312** may comprise polyvinylchloride ("PVC") and may be, optionally, at least substantially free of plasticizer. The materials disclosed above are merely examples; more generally, tubing section **314**, connector **312**, base member **340**, and cannula **350** may comprise any material (e.g., thermoplastic, polyurethane, metal, etc.) suitable for providing a robust and effective infusion set **310**.

During use of the infusion set **310**, a mechanical injector may be operably coupled to connector **312** via fastening structure **311**. For example, fastening structure may comprise a luer-type connection or any other fluid connection structure. Thus, a fluid may be flowed through the infusion set at a flow rate of at least about 1 milliliter per second via an injection apparatus. As discussed above, a pressure drop through the infusion set **310** may be at least about 100 psi; optionally, a pressure drop through infusion set **310** may be at least about 185 psi.

In another embodiment, an infusion set may include two connectors. In one configuration, one connector may be structured for performing power injection and another connector may be structured for allowing syringe access. For example, FIG. **37** shows an infusion set **309** including a base member **340**, a cannula **350**, a tubing section **324**, an intermediate connector **322**, a tubing section **314**, and an end connector **312**. Tubing **314** may be affixed or otherwise coupled to connector **312** and connector **322** generally at joints **313** and **323**, respectively. Similarly, tubing **324** may be affixed or otherwise coupled to connector **322** and base member **340** generally at joints **325** and **329**, respectively. Infusion set **309** may be structured for fluid flow rates and pressures as discussed above in relation to infusion set **310**. Accordingly, tubing sections **314** and **324** may comprise materials (e.g., a polymer, such as TECOTHANE® and sizes as discussed above in relation to infusion set **310**, without limitation. Similarly, connectors **312** and **322** may comprise any materials (e.g., PVC) discussed above in relation to infusion set **310**, without limitation. As shown in FIG. **37**, a clamp device **316** may be suitably configured for allowing or preventing fluid flow through tubing **314**. Likewise, clamp device **326** may be suitably configured for allowing or preventing fluid flow through tubing **324**. In addition, connector **312** may include a fastening structure **311** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **312** to an injection apparatus. Also, connector **322** may include a fastening structure **321** (e.g., a luer connection, another threaded connection, or any other fastening structure as known in the art) for releasably affixing or coupling the connector **322** to an injection apparatus.

Generally, the instant disclosure contemplates that, in one embodiment, connector **312** may be used for power injection, while connector **322** is capped. In another embodiment, a valve mechanism may selectively allow flow through tubing sections **314** and **324** via fluid flow through connector **312**, while preventing leakage from connector **322**. In addition, if infusion set **309** is not being used for power injection, a cap including a septum may be coupled to connector **322**, connector **312**, or both. Such a configuration may allow for a syringe to puncture the septum and infuse medication or remove a blood sample. Such a configuration may provide a convenient infusion set with separate connectors for power injection and syringe access, respectively.

In a further aspect contemplated by the instant disclosure, tubing that is used in connection with power injection may be structured for withstanding a selected pressure during use (e.g., power injection) and, optionally, may be configured to resist kinking. Generally, the instant disclosure contemplates that tubing may comprise a plurality of layers. In one embodiment, tubing may comprise a relatively high strength layer and at least one relatively flexible layer. Thus, any layers of tubing may comprise PTFE, polypropylene, polyetheretherketone ("PEEK"), polyimide silicone, fluorinatedethylenepropylene (FEP), perfluoroalkoxy (PFA), ethylenetetrafluoroethylene (ETFE), polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing. In one embodiment, the layers may be bonded to one or more adjacent layers. In another embodiment, each of the layers may be movable or slidable relative to one or more adjacent layers.

For example, FIGS. **38** and **39** show a side cross-sectional view and an end cross-sectional view of tubing **401** including an inner layer **420** and an outer layer **422**. Generally, at least one of inner layer **420** and outer layer **422** may exhibit relatively high strength and the other of inner layer **420** and outer layer **422** may be relatively flexible or vice versa. In one embodiment, inner layer **420** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like. Further, outer layer **422** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone or the like. Conversely, outer layer **422** may exhibit relatively high strength and may comprise, for example, PEEK, ULTEM®, polyimide, or the like, while inner layer **420** may be relatively flexible and may comprise, for example, FEP, PTFE, PEBAX®, ETFE, silicone, or the like. Further, optionally, tubing may comprise a first layer exhibiting a modulus of elasticity and at least another layer exhibiting a modulus of elasticity that is less than the modulus of elasticity of the first layer. For example, a relatively high strength material may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, a relatively flexible material may exhibit a modulus of elasticity below about 390,000 psi. In another embodiment, at least one of layers **420** and **422** may comprise a composite material (e.g., a composite including particulate or fiber reinforcement). For example, in one embodiment, tubing may comprise polyurethane or PTFE including glass or carbon reinforcing fibers or particles. In one embodiment, each of the layers **420** and **422** may be movable or slidable relative to one or more adjacent layers. Such a configuration may withstand a selected internal pressure without damage to the tubing and may also resist kinking.

In another embodiment, a reinforcing element may be incorporated within at least one of the plurality of layers comprising tubing. For example, FIG. **40** shows a schematic side cross-sectional view of tubing **403** including inner layer **430** and outer layer **432**, wherein at least one reinforcing element **434** is incorporated within outer layer **432**. Optionally, at least one reinforcing element **434** may be incorporated within any layer or layers of a plurality of layers comprising tubing, without limitation. As shown in FIG. **40**, reinforcing

element **434** may comprise a coil, in one embodiment. One of ordinary skill in the art will appreciate that many variations are possible, for example, at least one reinforcing element may comprise a mesh (e.g., a wire mesh, a fabric, a fiber mesh, etc.). In another embodiment, at least one reinforcing member may comprise one or more elongated members extending longitudinally within at least one layer comprising tubing (e.g., aligned with the direction of extension of the tubing). In another embodiment, at least one reinforcing member may comprise one or more rings. Such a configuration may provide radial stiffness, strength, or both to a tubing section.

Referring to FIG. **40**, in one embodiment, inner layer **430** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, outer layer **432** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, silicone, or polyurethane. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.001 inches. As mentioned above, layers **430** and **432** may be bonded to one another or may be movable (slidable, twistable, etc.) with respect to one another. Optionally, a coating **433** may be applied to at least a portion of exterior surface of layer **432**. Such a coating **433**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In a further embodiment, FIG. **41** shows a schematic side cross-sectional view of tubing **405**, including inner layer **440** and outer layer **442**, wherein at least one reinforcing element **444** is incorporated within inner layer **440**. As shown in FIG. **41**, reinforcing element **444** may comprise a coil, in one embodiment. In other embodiments, reinforcing element may comprise any structure discussed above in relation to reinforcing element **434**, without limitation. In addition, in one embodiment, inner layer **440** may be relatively flexible and may comprise, for example, FEP, PTFE, ETFE, or polyurethane. Further, outer layer **442** may exhibit relatively high strength and may comprise, for example, PEEK or polyimide. Further, layers **430** and **432** may have a thickness (e.g., a radial thickness) of between about 0.005 inches and about 0.010 inches. Optionally, a coating **443** may be applied to at least a portion of exterior surface of layer **442**. Such a coating **443**, in one embodiment, may comprise a polymer, such as TEFLON® and may have a thickness of between about 0.001 inches and about 0.002 inches.

In an additional embodiment, tubing may include four layers. For example, FIGS. **42** and **43** show a cross-sectional end view and a side cross-sectional view of another embodiment of tubing **400**. More particularly, as shown in FIGS. **42** and **43**, tubing **400** includes layers **402**, **404**, **406**, and **408**. As shown in FIG. **42**, layer **402** defines a lumen **410**. In one embodiment, lumen **410** may have a substantially circular cross-sectional shape and may exhibit a diameter of about 0.024 inches. In another embodiment, each of the layers **402**, **404**, **406**, and **408** may be movable or slidable relative to one or more adjacent layers. In addition, layer **402** may comprise a material exhibiting a relatively high tensile strength. Such a configuration may withstand relatively high pressures within lumen **410**. For example, layer **402** may comprise PEEK, polyimide, etc. Typically, such relatively high strength materials may exhibit a modulus of elasticity of at least about 400,000 psi. Furthermore, each of layers **404**, **406**, and **408** may comprise a material that is relatively flexible. Such layers **404**, **406**, and **408** may each exhibit a tensile strength that is less than the tensile strength of layer **402**. For example, each of layers **404**, **406**, and **408** may comprise a fluoropolymer, PEBAX®, polyethylene terephthalate ("PET"), silicone, etc. Typically, such relatively flexible materials may exhibit a modulus of elasticity below about 390,000 psi. However, any layers may comprise PTFE, polypropylene, silicone, FEP, PFA, ETFE, polyurethane (e.g., thermoplastic polyurethanes, including ISOPLAST®, TECOFLEX®, TECOTHANE®, CARBOTHANE®, TECOPLAST®, or TECOPHILIC® type polyurethanes), or combinations of the foregoing, without limitation.

In a further aspect of the instant disclosure, at least one layer comprising a tubing section may extend distally from a slender hollow structure for accessing a reservoir of an access port through a septum. Put another way, at least one layer may extend from a tubing section and may be structured for puncturing a septum of an access port. For instance, FIGS. **44** and **45** show a schematic side cross-sectional view of tubing **400**, **401**, **403**, **405**, and an access port **50**. Tubing **400**, **401**, **403**, **405** (as described above) includes a slender hollow region **450**. Further, slender hollow region **450** may be relatively stiff and suited for penetrating a septum **80** of an access port **50**, as shown in FIG. **45**. Thus, a slender hollow region **450** extending from a distal end of tubing **400**, **401**, **403**, **405** (which comprises a plurality of layers) may form a needle or cannula for fluid communication between a lumen of tubing **400**, **401**, **403**, **405**, and a reservoir **66** of access port **50**. More particularly, a slender hollow region **450** may comprise one or more layers exhibiting a relatively high strength of relatively high-strength layers (e.g., PEEK) forming tubing **400**, **401**, **403**, **405**. In one embodiment, an innermost layer of tubing **400**, **401**, **403**, **405** may form slender hollow region **450**. Such a configuration may be advantageous and may, for example, reduce the complexity of manufacturing an infusion set.

Many different embodiments of vascular access apparatuses or infusion systems may incorporate one or more aspects of the instant disclosure. Some embodiments of a vascular access apparatuses or infusion systems are disclosed in U.S. Patent Application No. 60/675,309, filed Apr. 27, 2005, the disclosure of which is incorporated, in its entirety, by this reference. Any of the infusion systems, apparatuses, or methods, taken alone or in combination, described in U.S. Patent Application No. 60/675,309, may be structured or otherwise suited for performing power injection (e.g., accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation).

For example, the instant disclosure contemplates that an infusion system configured for establishing fluid communication between a flexible tube and a reservoir of an access port may be structured for power injection. Such an infusion system may include a slender pointed element that facilitates placement of the flexible tube through a septum of the access port and is removable from the infusion system once the flexible tube is appropriately positioned.

Particularly, FIG. **46** shows in one embodiment an infusion system **510** in an exploded assembly view, including an insertion assembly **520**, a safety clip **530**, a hub **540** flexible tubing **590**, extension tube **570**, clamp device **560**, and tube connector **580**. In further detail, FIG. **47** shows a partial side cross-sectional view of infusion system **510**. As shown in FIG. **47**, insertion assembly **520** comprises a base **528** and a slender pointed element **522** (e.g., a needle, a trocar, or a cannula) secured thereto. As shown in FIG. **47**, slender pointed element **522** includes a pointed end **525**. In a particular embodiment, the instant disclosure may utilize a slender pointed element having a "non-coring" pointed end (i.e., pointed end **525** is not "open" or hollow) to avoid damaging a septum of a port into which the slender pointed element is inserted. The slender pointed element **522** may comprise any conventional needle, trocar, or cannula material, such as a stainless steel (e.g., AISI 304 stainless steel), or may, in another embodi-

ment, comprise a relatively hard plastic. In one embodiment, base **528** may be injection molded or otherwise formed about slender pointed element **522** to capture a portion of the slender pointed element within the base **528**, as best seen in FIG. **47**. Further, base **528** may optionally include a recess **524** structured for accommodating other mechanisms (e.g., safety clip **530**), if such a recess is desirable. Base **528** may also, optionally, include a coupling feature **526** (e.g., a protrusion) structured for coupling to a coupling feature **544** (e.g., a recess) formed in hub **540**. Hub **540**, as shown in FIG. **47**, may generally include hub body **550**, manifold element **561**, septum **548** and cap **546**. In one embodiment, hub body **550** may comprise TECOFLEX® (e.g., such as TECOFLEX® 85A-B20). Further, hub body **550** may define wing structures **541** and **543** (FIG. **46**), which may be configured for affixing the hub to skin of a patient (e.g., by taping wing structures **541** and **543** to a patient, adhesively affixing wing structures **541** and **543** to a patient, or otherwise affixing wing structures **541** and **543** to a patient). Wing structures **541** and **543** may be employed for manipulation of the hub, such as, for example, when inserting the slender pointed element **522** and flexible catheter **590** into an implanted port or when removing the slender pointed element **522** from an implanted port. Hub body **550** may optionally include a recess **542**, if such a recess is desirable. As shown in FIG. **47**, recess **542** may have a retaining lip **559** for retaining safety clip **530** therein, while long slender element **522** is positioned through the safety clip, as discussed in further detail hereinbelow.

Hub **540** may be structured for allowing the slender pointed element **522** of insertion assembly **520** to pass through the hub **540** and through septum **548**, which is positioned within the hub **540**. Put another way, manifold element **561** may define a plurality of passageways and at least one septum **548** through which fluid communication with the plurality of passageways may be accomplished. Explaining further, a manifold element **561** may be configured for housing septum **548** to provide a seal a port or opening of a plenum defined by manifold element **561**. Optionally, a cap element **546** may be positioned to capture septum **548** between cap element **546** and manifold element **561**. Cap **546** may include an aperture **547** for allowing a slender pointed element to pass therethrough and through septum **548**. Thus, slender pointed element **522** (e.g., an appropriately sized trocar, non-coring needle, or non-coring cannula) may be inserted through and removed from septum **548** without compromising the ability of septum **548** to seal. Further, the presence of cap **546** may allow for so-called "power injection" to occur via manifold element **561**, wherein pressures within manifold element **561**, tubing **570**, and flexible catheter **590** may reach at least about 200 psi or higher. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, for performing power injection, etc.), without limitation.

As shown in FIG. **47**, flexible catheter **590** may be affixed to manifold element **561** and extension tube **570** may be affixed to manifold element **561**. In one example, extension tube **570** and flexible catheter **590** may be chemically bonded to manifold element **561**. In another example, an adhesive may affix extension tube **570** to surface **552** a part of manifold element **561**. Similarly, an adhesive may affix flexible catheter **590** to inner surface **562** another port of manifold element **561**. Further, the hub body **550** may be formed (e.g., injection molded, cured, or otherwise over-molded) over the manifold element **561** (and, optionally the septum **548**, the cap **546**, or both) and at least a portion of the extension tube **570** as shown in FIG. **47**. In another embodiment, the hub body **550** may be formed over at least a portion of the flexible catheter **590**, if desired.

Generally, as mentioned above, any tubing disclosed in the instant disclosure may comprise a portion of infusion system **510**. Further, tubing clamps and connection devices as known in the art, may be employed for extension tubing **570**, clamp device **560**, and tube connector **580**.

Flexible catheter **590** may comprise any material that is suitable for power injection. For example, in one embodiment, flexible catheter **590** may comprise a polymer, such as TECOTHANE® (e.g., TECOTHANE® TT1055 D). As shown in FIG. **47**, flexible catheter **590** may include an elongated lumen therein. Further, flexible catheter **590** may have, proximate to opening **593** thereof, a transition region **595** wherein a cross-sectional size (transverse to the lumen **594**) of the flexible catheter **590** increases as a function of increasing distance from opening **593**. Optionally, transition region **595** may include two distinct tapers, although the instant disclosure contemplates more generally that at least one taper, at least one arcuate surface, or combinations thereof may define transition region **595**. Generally, at least one aperture (e.g., one or more than one) may be provided proximate opening **593** that extends through the tubular body of flexible catheter **590** and communicates with lumen **594**. As shown in FIG. **47**, flexible catheter **590** may include two apertures **592** in fluid communication with lumen **594**.

As shown in FIG. **47**, slender pointed element **522** may extend through safety clip **530**, through aperture **547** of cap **546**, and into flexible catheter **590**. Slender pointed element **522** may be structured for allowing fluid communication within flexible catheter **590**. More particularly, slender pointed element **522** may be sized so as to allow for clearance between the exterior of the slender pointed element **522** and the interior (i.e., the lumen) of the flexible catheter **590**. In one embodiment, slender pointed element **522** may include at least one longitudinally extending indentation (with respect to a nominal cross-sectional shape of the slender pointed element **522**). For example, slender pointed element **522** may have a pointed end **525** and may include longitudinally extending indentations extending along (i.e., along a longitudinal axis of) slender pointed element **522**. In another embodiment, slender pointed element **522** may be generally circular, and longitudinally extending indentations may form a substantially triangular cross section of the slender pointed element **522** over the portion of the slender pointed element that they are formed.

In a further embodiment, an infusion system may be structured so that a slender pointed element passes through an extension tube, a flexible catheter, or both. Explaining further, appropriate placement and configuration of a septum may allow for a slender pointed element to pierce or pass into an extension tube, a flexible catheter, or both. FIGS. **48** and **49** show another embodiment of a hub **540** including recess **542**, sleeve **620**, and septum **548**. In addition, at least a portion of each of extension tube **570** and flexible catheter **590** may extend partially within hub body **550**. Further, flexible catheter **590** extends partially within extension tube **570**. Put another way, flexible catheter **590** may at least partially overlap with extension tube **570** and vice versa. In another embodiment, a single tubular element may extend through hub **540** and function as both the flexible catheter **590** and extension tube **570**, if desired. Further, optionally, septum **548** may at least partially surround a portion of extension tubing **570**. Such a configuration may facilitate sealing of septum **548** upon removal of slender pointed element **522** therefrom. Sleeve **620** may compress septum **548** so as to

facilitate sealing of septum **548** upon removal of slender pointed element **522** from the region of the septum **620** that the sleeve **620** surrounds. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, etc.) for performing power injection, without limitation.

Further, FIG. **50** shows a perspective view of safety clip **530** positioned generally about pointed end **525** of slender pointed element **522**. Safety clip **530** includes legs **533** and **535** each having a curved end region, respectively, and a hole **534** sized for passing there through slender pointed element **522**. In further detail, initially slender pointed element **522** may be passed through hole **534** and between legs **533** and **535** may be positioned and configured so as to allow the slender pointed element **522** to extend there past. Further, when the slender pointed **522** element is positioned therein and safety clip **530** is positioned within recess **542**, safety clip **530** may be sized so that it will fit within the retaining lip **543** (FIG. **49**) of recess **542** (FIG. **49**). However, legs **533** and **535** may be biased so that if the pointed end **525** of the slender pointed element **522** is moved toward hole **534** and does not extend past the curved end regions of the legs **533** and **535**, legs **533** and **535** will move toward one another to effectively capture the pointed end **525** of the slender pointed element **522**. Safety clip **530** may comprise any self-actuating device for capturing a pointed end **525** of a slender pointed element **522**. Such a safety clip **530** may reduce the chance of inadvertent insertion of the slender pointed element **522** into another person, particularly the medical practitioner that is installing and removing the slender pointed element **522**.

The instant disclosure further recognizes that because the consequences of improperly pressurizing an access port (and a catheter affixed to the access port, if any) or an infusion set may be problematic, it may be advantageous to provide at least one identification attribute to components of an infusion system so that all of such components may be suitable for withstanding an anticipated maximum flow rate and pressure associated with a selected infusion process. Put another way, an access port that is configured for accommodating a flow rate of at least about 1 milliliter per second may include at least one identification attribute. Such an at least one identification attribute may be observed (e.g., visually, by palpation, ultrasonically, radiographically, etc.) or otherwise detected. The term, "identification," as used herein and in connection with any infusion devices (an access port, infusion set, etc.), means the ability to correlate selected information of interest with a perceivable feature.

The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. Patent Application No. 60/658,518, filed 4 Mar. 2005, may identify an access port as being structured for power injection. Also, embodiments of an access port including at least one identification attribute are disclosed in U.S. patent application Ser. No. 11/320,223, filed 28 Dec. 2005, the disclosure of which is incorporated, in its entirety, by this reference. The instant disclosure contemplates that any of the identification features or attributes, taken alone or in combination, described in U.S. patent application Ser. No. 11/320,223 may identify an access port as being structured for power injection. Further, an access port may be identified by a maximum rate at which fluid may safely be infused. For example, at least one identification attribute may indicate that an access port is configured for accommodating a fluid flow rate of at least about 1 milliliter per second, without limitation.

Referring to an access port encompassed by the instant disclosure, at least one attribute of a housing of an access port may provide at least one identification attribute for identifying the access port as being structured for power injection at a rate of at least about 1 milliliter per second. In one embodiment, at least one physical attribute (e.g., size, shape, etc.) of an access port may identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port.

Thus, one aspect of the instant disclosure relates to a method of identifying an access port (e.g., subcutaneously implanted or otherwise situated, without limitation) as being suited for power injection. More particularly, an access port including a septum may be provided. Further, at least one attribute of the access port may be perceived. In addition, the subcutaneously implanted access port may be identified as being suitable for power injection in response to perceiving the at least one attribute of the access port.

In one embodiment, at least one attribute for identification may comprise at least one feature of an access port housing. In further detail, FIG. **51** shows a perspective view of an assembled access port **50**. As shown in FIG. **51**, a side periphery **295** (e.g., one or more side walls and, optionally, exposed surfaces of suture plugs **291**) of access port **50** may be generally triangular. Thus, cap **54** and base **56** may collectively form a generally triangular housing **60** of access port **50**. Also, the instant disclosure contemplates that side periphery **295** may taper or arcuately extend between an upper surface **61** of cap **54** and lower surface **51** of base **56**. As shown in FIG. **51**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **51**, if planar, of base **56**) of access port **50** may be larger proximate to lower surface **51** of base **56** and may be relatively smaller proximate to an upper surface of cap **54**. FIG. **52** shows a top elevation view of the access port **50** shown in FIG. **52** and illustrates a generally triangular shape defined by side periphery **295**. Additionally, FIG. **53** shows a simplified representation of a transverse cross section of access port **50**. As shown in FIG. **53**, side periphery **295** of access port **50** may define three side regions **303** that extend between associated vertex regions **301**. In addition, in one embodiment and as shown in FIG. **53**, side periphery **295** may define a substantially equilateral generally triangular shape. As may be appreciated, side regions **303** may arcuately extend between associated vertex regions **301**; thus, side regions **303** may form "sides" of a generally triangular shape. Further, although vertex regions **301** are rounded, it will be appreciated that such vertex regions **301** form an intersection between adjacent side regions **303**. Accordingly, it will be appreciated that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect at or within vertex regions, without limitation. For example, "generally triangular" encompasses three-sided polygons, circular triangles, equilateral triangles, etc., without limitation.

Furthermore, in a further embodiment, at least one attribute for identification may comprise a radiographic marker. More particularly, an access port may exhibit an observable pattern, symbol, marker, or other indicium that indicates that the access port is structured for accommodating a particular flow rate, pressure, or both. In another embodiment, at least one attribute for identification may comprise a perceptible aspect, such as a visually perceivable feature. For example, at least one color, at least one symbol, at least one typographical character (e.g., a letter, a number, etc.), a pattern, or any other indicium that may be visually perceivable or otherwise perceptible may be used. In a yet additional embodiment, an ultrasound detectable feature may be incorporated within an access port. In a further additional embodiment, an access port may comprise an RFID tag.

It will be appreciated that other equipment and devices (e.g., infusion sets, tubing, injectors, etc.) may be identifiable in relation to a suitable maximum flow rate or maximum pressure. For example, particular infusion apparatuses may include one or more of the above-mentioned identification attributes or features. Such a configuration may allow for different components (e.g., tubing, needles, access ports, mechanical injectors, etc.) to be matched with one another. For example, substantially similar or matching identification attributes shared by a power injection apparatus, an infusion set, and an access port may indicate suitability for use with one another to perform a selected power injection process.

Another aspect of identification of an access port may relate to identification of a patient within which an access port is implanted. More specifically, a patient may be provided with an identification card that carries perceptible (e.g., visually, via magnetic strip, bar code, manually, or by other suitable mechanisms) information regarding an implanted port. Thus, such an identification card may be presented to a health care worker, the information carried by the identification card may be perceived, and the access port may be identified. Upon identifying the access port, characteristics of the access port may be ascertained, such as, for instance, a maximum flow rate, a maximum pressure, suitability for a particular procedure or procedures, etc. In another embodiment, a wristband or bracelet may be provided to a patient within whom an access port is implanted. In a further embodiment, a key chain including an information carrying device, such as, for example, a magnetic strip, a bar code, a computer readable media or device (e.g., a compact disk, "flash" memory, a disk drive, etc.), or any other suitable information carrying device. In another embodiment, a sticker containing the port information can be applied to the chart of the patient. In further embodiments, labeling on the infusion set can be used to identify the set as power injection compatible.

A further aspect of the instant disclosure relates to a septum comprising a gel or viscous liquid. The term "gel," as used herein, means a colloid with at least one solid component suspended within at least one liquid component, wherein the solid particles (e.g., polymer particles) are attracted or otherwise linked to one another (e.g., entangled or cross-linked) by covalent, ionic, or dispersion (physical) forces. Thus, in one embodiment, a gel may be a colloid in which the solid disperse phase forms a network in combination with the fluid continuous phase to produce a viscous or semi-rigid sol. A gel may exhibit stress-strain behavior that is elastic, viscoelastic, or plastic, without limitation. The term "viscous liquid," as used herein, means a liquid exhibiting a viscosity of about 20,000 centipoises or higher.

One or more passageways formed through a septum positioned within a housing to form an access port may allow for leaking of fluid through the one or more passageways if the reservoir of the access port is pressurized. The instant disclosure contemplates that a gel region may be generally positioned between an upper surface of a septum and a lower surface of a septum, to facilitate a cannula extending through the septum from the upper surface to the lower surface to also pass through at least a portion of the gel region.

For example, in one embodiment, a septum may include a gel that is at least substantially surrounded by a body material. For instance, FIG. **54** shows a schematic, side cross-sectional view of a septum **610** including a body **612** and a gel region **620** positioned within body **612**. Gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. In one embodiment, gel region **620** may comprise a silicone gel. In another embodiment, a gel region may comprise an initially an uncured liquid (i.e., has a relatively low viscosity) that may be cured to cause the liquid to form a gel. In a further embodiment, gel region **620** may comprise a viscous liquid, or a viscoelastic material.

In one example, gel region **620** may comprise an elastomer, such as, DOW CORNING® 7-9600 Soft Filling Elastomer, Parts A & B, which is commercially available from DOW CORNING Corporation of Midland, Mich. In another embodiment, gel region **620** may comprise Silicone Gel MED-6340, which is commercially available from NuSil Technology of Carpinteria, Calif. In yet a further embodiment, gel region **620** may comprise an elastomer exhibiting a Shore A hardness of about 20 to about 30, such as, for instance, DOW CORNING® C6-515. Liquid Silicone Rubber, Parts A & B or DOW CORNING® C6-530 Liquid Silicone Rubber Parts A & B, either of which is available from DOW CORNING Corporation of Midland, Mich. Further, optionally, body **612** of septum **610** may comprise a silicone material with a Shore A hardness of about 50 to about 60. In another embodiment, body **612** and/or upper surface **614** of septum **610** may comprise a silicone material with a Shore A hardness of about 60 to about 80. Optionally, body **612** and/or upper surface **614** of septum **610** may comprise a fluoropolymer (e.g., PTFE, etc.) or polyurethane.

One of ordinary skill in the art will understand that, upon removal of a cannula extending through at least a portion of gel region **620**, a passageway or channel formed through gel region **620** may rebound, recover, seal, or heal. Further, gel region **620** may seal passageways formed through body **612** and upper surface **614**. For example, gel region **620** may inhibit or prevent fluid leakage from a reservoir of an access port through the septum **610** when a pressure within the reservoir exceeds an ambient pressure external to the access port (e.g., during a power injection process, any process for flowing a fluid through an access port as described above, or any process for flowing a fluid through an access port as known in the art, without limitation). In addition, gel region **620** may be formulated and/or body **612** may be structured so that a cannula passing through septum **610** will resist transferring or removing any of the material comprising gel region **620** outside of a selected boundary or envelope. In one embodiment, body **612** may be structured to remove a material comprising gel region **620** from a cannula passing through the body **612**.

Any of the septum embodiments discussed herein may include at least one gel region. For example, FIG. **55** shows a schematic, side cross-sectional view of a septum **611** including a body **612** and a gel region **620**. As discussed above, gel region **620** may be structured so that a cannula inserted through upper surface **614** and extending through lower surface **616** will pass through a portion of gel region **620**. Such a configuration may provide a robust septum that resists leaking even if a multitude of passages are formed through the septum with a cannula. Furthermore, providing a septum comprising a gel may improve a sealing ability or quality of the septum. Accordingly, a septum including a gel material may exhibit a reduced thickness (i.e., from an upper surface to a lower surface) in comparison to a conventional septum. For example, FIG. **56** shows a septum **613** including a body **612** and a gel region **620**, wherein a thickness T is less than a conventional thickness of a conventional septum. In one embodiment, a thickness T of septum **613** may be about 0.500 inches or less.

The instant disclosure contemplates a variety of different manufacturing methods may be employed for forming a septum comprising a gel. For example, generally, a body of a septum may be formed to substantially surround at least one

gel region or a recess or chamber may be formed by a septum body that is filled with a gel. In one embodiment, a gel region may be suspended within a mold for forming a body of a septum. More particularly, FIG. **57** shows a schematic, side cross-sectional view of a first mold **652** and a second mold **654**, wherein gel region **620** is positioned between (e.g., suspended) first mold **652** and second mold **654**. As shown in FIG. **57**, gel region **620** is positioned by a frame element **630**, which abuts parting surface **655** of second mold **654**. As shown in FIG. **57**, frame element **630** may be positioned by pins **606**. In other embodiments, frame element **630** may be suitably positioned, without limitation. In a particular embodiment, parting surface **653** of first mold **652** may be positioned proximate to parting surface **655** of second mold **654** (i.e., parting surfaces **653** and **655** may be separated by frame element **630**) to form a chamber defined by cavity **658** and cavity **656**. Further, a hardenable material (e.g., a curable material, such as a curable silicone, a thermoplastic, a resin, etc.) may be injected into the chamber and hardened. Thus, the hardenable material may surround or encapsulate gel region **620** and may exhibit a geometry that is complimentary to cavities **656** and **658**.

Generally, frame element **630** may be coupled to or affixed to gel region **620**. In one embodiment, frame element **630** may couple or engage at least a portion of a periphery of gel region **620**. In another embodiment, frame element **630** may be substantially planar and gel region **620** may rest upon or may be formed upon frame element **630**. Further, in one embodiment, frame element **630** may extend at least partially through gel region **620**. Optionally, frame element **630** may cover or extend across mold cavity **656** of second mold **654**. In one example, frame element **630** may comprise a mesh (e.g., a metal or polymer mesh, a fabric, a fiber mesh, etc.). In another example, frame element **630** may comprise a sheet or layer of silicone and may be, optionally, perforated. If frame element **630** comprises a mesh or is perforated, fluid communication (of a hardenable material) between cavity **658** and cavity **656** may occur, which may be desirable for avoiding shifting of gel region **620** and/or frame element **630** during encapsulation. Once gel region **620** is encapsulated, selected portions of frame element **630** may be trimmed or cut, if desired.

In another method of forming a septum including at least one gel region, a septum body may be formed to include at least one chamber, which may be filled with a gel. For example, FIG. **58** shows a septum body **612** defining chamber **621**. Optionally, opening **623** may be defined by body **612**. Accordingly, a gel may be introduced within chamber **621** via the opening **623** and the opening, optionally, may be closed. For example, an uncured gel may be introduced within chamber **621**. Further, the uncured gel may be cured by heating or by other suitable methods. Such a configuration may form a gel region as described above in relation to FIG. **55**. In one embodiment, chamber **621** may be formed by an air injection molding process, a blow molding process or any other process known in the art for creating a chamber **621** within body **612**. In another embodiment, body **612** may be formed about a removable plug or filler (e.g., a silicone plug, steel, or aluminum insert). Such a plug or filler may be coated with a nonstick coating (e.g., TEFLON®, silicone, or any nonstick coating known in the art). Thus, chamber **621** may be formed upon removal of the plug or filler. In other embodiments, portions of a septum may be formed, filled with a gel (or a liquid precursor to a gel), and bonded to one another to form a septum. In a further embodiment, body **612** may be initially formed and may enclose chamber **621** within body **612**. In addition, body **612** may be cut to form an opening to allow chamber **621** to be filled with a gel. Such an opening of body **612** may be closed or sealed to capture or form a gel region. In yet a further embodiment, a solid body may be formed and a chamber may be formed by slicing the solid body. In such a configuration, filling the chamber may cause the solid body to deform to form a domed or raised region, if desired. It will be appreciated that many different approaches may be employed for forming a chamber **621** within body **612** and subsequently filling the chamber with a gel.

In an additional embodiment, a septum may include a gel region positioned between a body and a layer of material bonded to or formed over at least a portion of the gel region and at least a portion of the body. For example, FIG. **59** shows a schematic, side cross-sectional view of a septum **615** including a body **632**, a gel region **620**, and a layer **626**. As shown in FIG. **59**, gel region **620** may be positioned within a recess **633** formed in the body **632** and layer **626** may extend over a portion of gel region **620** and a portion of body **632**. One of ordinary skill in the art will understand that gel region **620** may be positioned or formed within recess **633** of body **632** and then layer **626** may be formed or positioned over gel region **620** and body **632**. Further, layer **626** may be bonded (e.g., adhesively bonded, bonded via curing, bonded via welding, or as otherwise known in the art) or otherwise affixed to body **632** to capture gel region **620**. In one embodiment, septum **615** may be formed by a multiple head (e.g., a two head) injection molding apparatus. More particularly, such a molding apparatus may be capable of forming the body **632**, forming the gel region **620** within the body **632**, and forming (e.g., over molding) the layer **626** over the gel region **620** and body **632** by suitable mold configurations and material injections. Layer **626**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 60 and about 80. Body **632**, in one embodiment, may comprise a silicone-based material exhibiting a Shore A hardness of between about 40 and about 50. Accordingly, during use of septum **615** (installed within a housing to form an access port) a cannula may pass through layer **626**, at least a portion of gel region **620**, and body **632**. Such a configuration may facilitate positioning of a cannula extending through layer **626**, at least a portion of gel region **620**, and body **632**.

While certain representative embodiments and details have been shown for purposes of illustrating aspects of the instant disclosure, it will be apparent to those skilled in the art that various changes in the methods and apparatus disclosed herein may be made without departing form the scope of the instant disclosure, which is defined in the appended claims. For example, other access port sizes and shapes may be employed; and various other embodiments structures may be employed for forming at least one identifiable feature of an access port of the instant disclosure. The words "including" and "having," (including their variants) as used herein including the claims, shall have the same meaning as the word "comprising."

What is claimed is:

1. A method of performing a power injection procedure, comprising:

taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port, the access port defining one or more fluid reservoirs, each fluid reservoir accessible through a cannula-penetrable septum;

identifying the indicating radiographic feature on the x-ray; and

flowing a fluid through the access port at a rate of at least 1 milliliter per second.

2. The method according to claim **1**, wherein the identifying step comprises identifying a radiographic pattern included in the cannula-penetrable septum of the access port.

3. The method according to claim **1**, wherein the identifying step comprises identifying a radiographic letter.

4. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by palpating to feel a structural feature of the access port indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

5. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by visually perceiving information outside of the body of the patient included on an element selected from the group consisting of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof, the element indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

6. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting a radiofrequency identification (RFID) tag associated with the implanted access port, the RFID tag signaling that the access port is suitable for flowing fluid at a rate of at least about 1 milliliter per second through the access port.

7. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an ultrasound-detectable feature associated with the implanted access port, the ultrasound-detectable feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

8. A method of performing a power injection procedure, comprising:

providing an access port including a cannula-impenetrable housing and a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port;

implanting the access port in a subcutaneous pocket formed under a patient's skin;

taking an image of the implanted access port via imaging technology;

identifying the access port as being suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port via the image of the radiographic feature of the access port; and

injecting contrast media fluid through the access port at a rate of at least 1 milliliter per second.

9. The method according to claim **8**, wherein the identifying step comprises identifying a radiographic letter.

10. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by palpating to feel a structural feature of the access port indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

11. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by visually perceiving information outside of the body of the patient included on an element selected from the group consisting of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof, the element indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

12. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an RFID tag associated with the implanted access port, the RFID tag signaling that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

13. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an ultrasound-detectable feature associated with the implanted access port, the ultrasound-detectable feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

14. A method of performing a power injection procedure, comprising:

implanting an access port including a fluid reservoir accessible through a septum and a radiographic feature, the radiographic feature indicating that the access port is capable of handling pressures associated with power injection;

taking an image of the implanted access port via imaging technology;

identifying the access port as capable of handling pressures associated with power injection via the image of the radiographic feature of the access port;

palpating the access port to identify the location of the septum;

inserting a needle through a septum, the needle connected to tubing and in fluid communication therewith, the needle and tubing structured to accommodate a fluid pressure of at least 400 psi; and

injecting contrast media fluid through the tubing and needle to induce a pressure within the access port in the range of 37 psi and 65 psi.

* * * * *

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 32(b) because it contains 13,929 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b)(2), as determined by the word-counting feature of Microsoft Word.

This brief complies with the typeface requirement of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface, including serifs, using Microsoft Word in Times New Roman 14-point font.

Dated: October 5, 2023 /s/ Deanne E. Maynard

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