Appeal Nos. 22-1136, -1186

United States Court of Appeals

for the

Federal Circuit

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

Plaintiffs-Appellants,

v.

MEDICAL COMPONENTS, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court for the District of Utah,
Case No. 2:12-cv-00032-RJS-DAO, Judge Richard J. Shelby

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

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PATENTS CLAIMS AT ISSUE

This appeal concerns claims 1, 3-8 and 10 of U.S. Patent No. 7,785,302, claims 1, 3, 5, 8-10, 12 and 14 of U.S. Patent No. 7,947,022, and claim 8 of U.S. Patent No. 7,959,615. Claim 5 of the '302 patent and claim 8 of the '615 patent are exemplary:

'302 patent, Claim 5: A venous access port assembly for implantation into a patient, comprising:

> a housing having an outlet, and a needle-penetrable septum, the needle-penetrable septum and the housing together defining a reservoir, wherein:
>
> > the assembly includes a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly, and
> >
> > the alphanumeric message indicating that the assembly is power injectable.

'615 patent, Claim 8: An access port for providing subcutaneous access to a patient, comprising:

> a body defining a cavity accessible by inserting a needle through a septum,
>
> > the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum,
> >
> > the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and
>
> at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation,
>
> > the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

CERTIFICATE OF INTEREST

Counsel for C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. certifies the following:

1. The full name of every party or amicus represented by me is: C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.

2. The name of the Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is: None.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party or amicus curiae represented by me are: 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, a publicly held company.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

QUINN EMANUEL URQUHART & SULLIVAN, LLP: Lauren N. Martin; Anne-Raphaëlle Aubry; Brian P. Biddinger; Christopher P. Hill*; Jared W. Newton; Nicola R. Felice

DORSEY & WHITNEY LLP: Bryon J. Benevento; Kimberly Neville

KIRKLAND & ELLIS LLP: Amanda Hollis*; Amy R. Lemyre*; Elizabeth A. Cutri*; Jordan Malz*; Leslie M. Schmidt*

* No longer with firm and/or has withdrawn as counsel

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: *C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc.*, C.A. No. 20-1543-CFC (D. Del.); *C.R. Bard, Inc. et al. v. AngioDynamics*, *Inc.*, C.A. No. 20-1544-CFC (D. Del.).

6. 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: December 8, 2021

Respectfully submitted,

s/ *Steven C. Cherny*
Attorney for Appellants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.

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STATEMENT OF RELATED CASES

No other appeal in or from the same civil action in the lower court was previously before this or any other appellate court. The following cases are known to counsel to be pending in other courts that will be directly affected by this Court's decision in the pending appeal:

C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc., C.A. No. 20-1543-CFC (D. Del.);

C.R. Bard, Inc. et al. v. AngioDynamics, *Inc.*, C.A. No. 20-1544-CFC (D. Del.).

PRELIMINARY STATEMENT

This is an appeal from a partial final judgment of the U.S. District Court for the District of Utah (Shelby, J.) holding certain claims of Bard's U.S. Patent Nos. 7,785,302, 7,947,022, 7,959,615 (the "'302, '022, and '615 patents," respectively) invalid under 35 U.S.C. § 101. The '302 and '022 patents claim the use of radiopaque (also known as radiographic) markers to identify a vascular access port as being power injectable after it has been implanted into a patient, while the '615 patent claims structural features on a port that similarly can be used to identify the port as being power injectable after implantation.

In an earlier decision involving the same patents, this Court explained the importance of being able to confirm that a port is power injectable: "Power injecting a non-power injectable port can cause the port to fracture while in the patient's body, leading to serious bodily injury or even death." *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 748 F. App'x 1009, 1012 (Fed. Cir. 2018) ("*Port I*"). But identifying the type of port after implantation is difficult; identification is also imperative given that patients often see multiple medical professionals at different times. The technology described in the patents-in-suit solves the problem of identifying a port as being power injectable after implantation, thereby providing a critically important safety

feature that helped Bard launch the first FDA-approved power injectable port.

Purporting to apply the printed matter doctrine, the district court ruled that the asserted claims ('302 claims 1, 3-8 and 10; '022 claims 1, 3, 5, 8-10, 12 and 14; and '615 claim 8)—several of which MedComp did not even seek summary judgment on—are directed solely to non-functional printed matter and therefore are patent ineligible under § 101. That ruling departs from this Court's controlling decision in *C.R. Bard Inc. v. AngioDynamics*, 979 F.3d 1372 (Fed. Cir. 2020) ("*AngioDynamics*")—a case with strikingly similar legal issues and facts.

In *AngioDynamics*, this Court held that the claims of other Bard patents directed to the use of radiographic features to identify a port as being power injectable were patent eligible because they were not "solely directed" to printed matter. *Id.* at 1381, 1384. This Court explained that "the focus of the claimed advance [was] not solely on the ***content*** of the information conveyed but also on the ***means*** by which that information is conveyed ['a radiographic marker']." *Id.* at 1384 (emphasis added). There is no material distinction, at *Alice* step one, between the claims at issue in *AngioDynamics* and the claims at issue here. Both are directed not just to

the content of information ***but also to the same technological means of conveying information in conjunction with a physical port***.

Another district judge in the District of Utah correctly applied *AngioDynamics* and ruled that patents from the same family as the patents-in-suit here were directed to patent-eligible subject matter at *Alice* step one. *C.R. Bard Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754. Dkt. No. 754-01 (D. Utah March 11, 2021) (Nielson, J.) (Appx03726-3738). Again, there is no material distinction between the claims found patent eligible in that case and the claims found ineligible below.

The district court purported to distinguish *AngioDynamics* based on supposed differences in the factual record. However, *AngioDynamics* held Bard's claims were directed to patent-eligible subject matter at *Alice* step one—a question of law turning on claim scope, not the record. And the records, in any event, are almost identical. The district court further departed from *AngioDynamics* by creating a new four-step § 101 framework for assessing patent eligibility in the context of the printed matter doctrine and then invalidating Bard's claims based on its incorrect view that the printed matter doctrine encompasses not only the ***content*** of information conveyed, but the ***means*** of conveying that information, regardless of the technology employed. The court also overlooked that Bard's claims are

directed to physical port assemblies—subject matter that falls squarely within the statutorily-permissible category of a "machine." 35 U.S.C. § 101.

The district court deviated from *AngioDynamics* at *Alice* step two as well and, based on a substantially similar record as this Court considered, determined that the radiopaque indicia claimed by the '302 and '022 patents to identify a port's power injection's capability were routine and conventional. In so ruling, the court impermissibly broadened the inventive-concept standard such that it mirrored the test for obviousness and improperly relied on the same obviousness evidence that *AngioDynamics* had explicitly cautioned against. That flawed reasoning likewise undergirded the district court's conclusion that the identifying structural features claimed by the '615 patent lacked an inventive concept as a matter of law.

For all these reasons and as further explained below, the judgment of invalidity should be reversed or at the very least vacated.

JURISDICTIONAL STATEMENT

The district court had jurisdiction over this patent case under 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction under 28 U.S.C. § 1295(a)(1). On November 5, 2021, the district court entered partial final

judgment pursuant to Fed. R. Civ. P. 54(b). Appx00070-71. Bard timely filed its notice of appeal the same day. Appx04226-4227.

STATEMENT OF THE ISSUES

1. Whether, at *Alice* step one, Bard's claims directed to vascular access ports containing, *inter alia*, structures such as a port body, a septum and an outlet stem and either a radiopaque marker or a structural feature having a concave side surface that identify the port as power injectable are directed to patent-eligible subject matter.

2. Whether, at *Alice* step two, Bard's use of radiopaque markers and identifying structural features on a power injectable port constitutes an inventive concept.

STATEMENT OF THE CASE

A. The Importance Of Correctly Identifying Power-Injectable Access Ports

Bard's patents are directed to "medical devices, called access ports, implanted beneath a patient's skin to enable direct access to a central vein for delivery of medicine or other fluids." *Port I*, 748 F. App'x at 1011. Figure 1B of the patents-in-suit depicts an exemplary port, having a housing made up of body 16 and cap 14, septum 18, and reservoir 36:

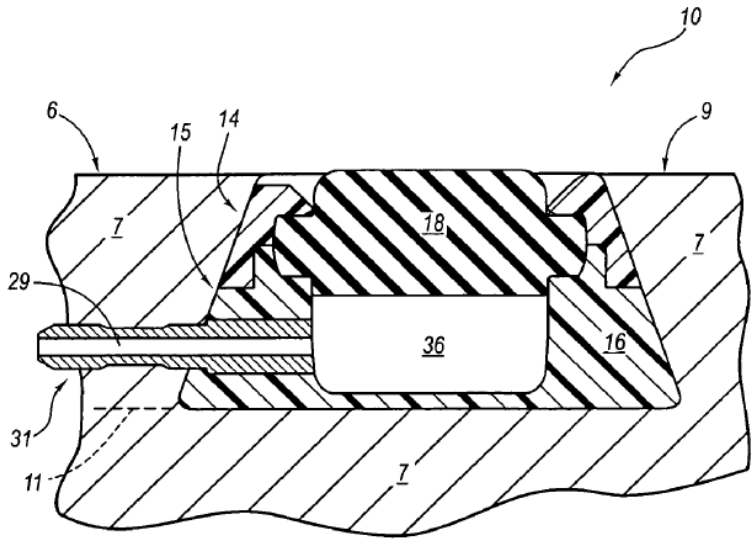

FIG. 1B

Appx00079. The reservoir 36 connects to an outlet stem 31, which in turn connects to a catheter (not shown) sutured to a major blood vessel. Ports are implanted subcutaneously just beneath a patient's skin and can be accessed by inserting a needle through the patient's skin and through the septum to deliver fluid into the reservoir. *Port I*, 748 F. App'x at 1011. The fluid then flows from the reservoir through the catheter and into the patient's circulatory system. "For patients requiring frequent and long-term intravenous therapy, these devices allow medical professionals to easily and repeatedly access a major vein without having to go through tissue or muscle each time." *Id.*

The patents-in-suit are specifically directed to power injectable ports, which "may be employed in … computed tomography ("CT") scanning

processes." Appx00110 (3:48-50). Because CT scans require that contrast media be delivered at a pre-defined flow rate, a power injector system is typically used to achieve the desired flow rate. Appx00110 (3:30-59). Accordingly, "[p]ower injectable ports are designed to be 'injected and pressurized by mechanical assistance' at high flow rates." *Port I*, 748 F. App'x at 1011.

In contrast, traditional ports are not designed to withstand the high pressures and flow rates associated with power injection procedures. Thus, "[p]ower injecting a non-power injectable port can cause the port to fracture while in the patient's body, leading to serious bodily injury or even death." *Id.* at 1012. Prior to the filing of the patents-in-suit, the U.S. Food and Drug Administration ("FDA") had warned medical providers "that they should not use vascular access ports for power injection unless the ports were specifically and identifiably labeled for such use" given the potential for serious patient injury when ports that are not designed to withstand high pressures are used for power injection. *AngioDynamics*, 979 F.3d at 1375. The "FDA directed medical providers to verify a port's suitability for power injection before using a port for that purpose," e.g., by confirming a port was labeled for power injection. *Id.* at 1384, 1375. The need to make power-injectable ports unambiguously identifiable presented a significant obstacle

because, after implantation, ports can no longer be inspected visually. Appx00109 (1:46-54).

B. Bard's Patents Claim Novel Self-Identifying Access Ports And Methods For Using Them

Bard's patents solve the port-identification problem by including "at least one identifiable characteristic that may be sensed or otherwise determined subsequent to subcutaneous implantation." Appx00109 (1:55-58). "In some embodiments, the 'identifiable characteristic' is a message that 'may be perceived via x-ray or ultrasound imaging.'" *Port I*, 748 F. App'x at 1012 (citing Appx00110 (4:15-24)). "In other embodiments, medical professionals can use the port's geometry to identify whether the port is power injectable by touch, even after it is implanted." *Id.*

The '302 and '022 patents claim ports where the identifying feature is a radiopaque marker. As shown in Figure 52, the radiopaque marker can be a plate or disc with an alphanumeric message etched in it:

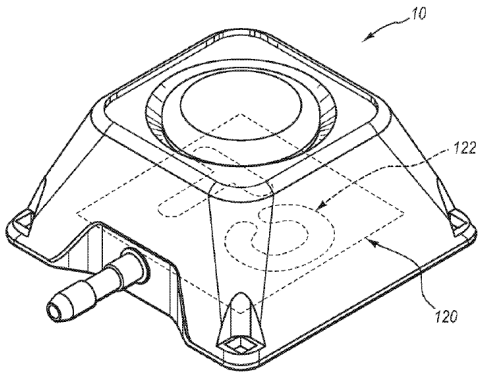

FIG. 52A

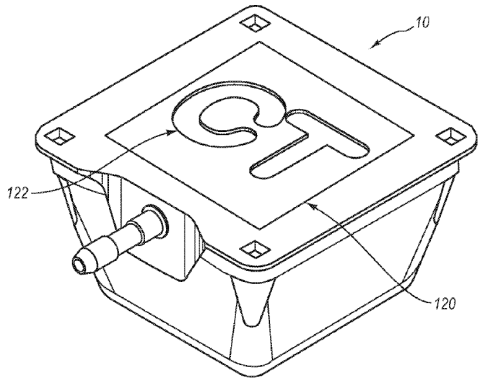

FIG. 52B

Appx00108; *see* Appx00114 (11:41-12:8). Claim 5 of the '302 patent exemplifies the claims directed to the radiopaque identifier embodiment:

> 5. A venous access port assembly for implantation into a patient, comprising:
>
> > a housing having an outlet, and a needle-penetrable septum, the needle-penetrable septum and the housing together defining a reservoir,
> >
> > wherein:
> >
> > > the assembly includes a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly, and
> > >
> > > the alphanumeric message indicating that the assembly is power injectable.

Appx00115 (13:8-19).

The '615 patent claims ports where the identifier is a structural feature, specifically a concave side surface that curves inward toward the center of the port. "Like the alphanumeric message in the radiopaque claims, a concave side allows a doctor to identify the access port, albeit by palpation, after implantation." *Port I*, 748 F. App'x at 1012. Figure 15 depicts an embodiment having concave sides, as claimed by the '615 patent:

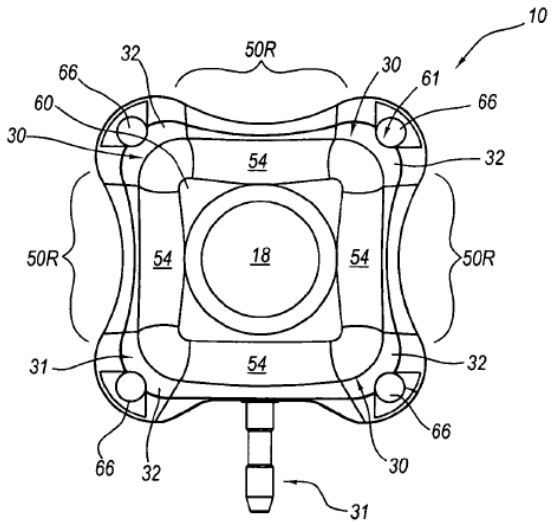

FIG. 15B

Appx00193; *see* Appx00218-219 (8:62-9:9). Claim 8 of the '615 patent exemplifies the claims directed to the identifying structural feature embodiment:

> 8. An access port for providing subcutaneous access to a patient, comprising:
>
> a body defining a cavity accessible by inserting a needle through a septum,
>
> the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum,
>
> the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and
>
> at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation,
>
> the at least one structural feature comprising at least one concave side surface in a second side surface different

> from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

Appx00221 (13:23-14:7).

C. The Proceedings Below

In January 2012, Bard filed a complaint against Defendant-Cross-Appellant Medical Components, Inc. ("MedComp"), alleging infringement of the '302, '022, and '615 patents. Appx00251; *see* Appx00310-324. MedComp counterclaimed, alleging that Bard infringed its U.S. Patent No. 8,021,324 (the "'324 patent"), titled "Venous Access Port Assembly with X-Ray Discernable Indicia." Appx00251; *see* Appx00325-377.

In December 2012, the action was stayed and administratively closed while Bard's patents-in-suit underwent inter partes reexamination before the U.S. Patent and Trademark Office. There, the Patent Trial and Appeal Board initially found twenty-eight of the thirty-four challenged claims invalid as anticipated and/or obvious. On appeal, this Court reversed the Board's anticipation rulings and vacated its obviousness rulings. *See Port I*, 748 F. App'x at 1013-19, 1021. On remand, the Board held only two of the thirty-four challenged claims were invalid.[1] Upon resolution of the

[1] *See AngioDynamics, Inc. v. C.R. Bard, Inc.*, Appeal 2015-001533, 2019 WL 411125; Appeal 2015-004506, 2019 WL 411126; Appeal 2015-004554, 2019 WL 411127 (P.T.A.B. Jan. 28, 2019).

reexamination proceedings, in October 2019, the district court lifted the stay. Appx00259.

MedComp thereafter moved for summary judgment, arguing that "the asserted Bard patent claims fail, as a matter of law, to meet the eligibility requirements of 35 U.S.C. § 101." Appx02483; Appx02471-2483. The district court granted the motion in relevant part and invalidated Bard's patents. Appx00001-40.[2] The district court, contrary to this Court's holding in *AngioDynamics* (and the decision of another judge in the District of Utah), ruled that Bard's claims were solely directed to patent-ineligible subject matter at *Alice* step one and that the claims lacked an inventive concept at *Alice* step two.

Deviating from the *Alice* two-step analysis that this Court applied to printed matter in *AngioDynamics*, the district court crafted a new four-step § 101 inquiry for supposed printed matter. The first two steps, which the court termed the "*AngioDynamics* framework," are nearly identical to the *Alice* two-step analysis: "'a claim may be found patent ineligible under

[2] The district court did not limit its order to the claims MedComp raised on summary judgment; instead, it *sua sponte* included "all the remaining asserted independent and dependent claims in the '302 and '022 Patents." Appx00021. The district court did not give notice to Bard that it was considering invalidating asserted claims not raised in MedComp's motion. *See* Fed. R. Civ. P. 56(f).

§ 101 on the grounds that it is [1] directed solely to non-functional printed matter and [2] the claim contains no additional inventive concept.'" Appx00025 (quoting *AngioDynamics*, 979 F.3d at 1383).

At the first step of its "*AngioDynamics* framework," the district court ruled that the claims were directed solely to non-functional printed matter based on its expansion of the printed matter doctrine to include not only the ***content*** of the information communicated, but the ***means*** of communication as well (Appx00017)—in plain conflict with *AngioDynamics* itself (*see* 979 F.3d at 1384). Consequently, the court concluded that both the content captured by Bard's claims—the communication to a medical practitioner that a port is capable of power injection—and the means of conveying that information—the technological innovation of employing radiopaque indicia or identifying structural features—constituted printed matter. Appx00026-28.

Based on its expansion of the printed matter doctrine, the district court concluded that the "addition of merely novel yet nonfunctional printed matter identifiers does not change the fact that the focus of the claimed advance is solely on the content of the information conveyed." Appx00027. Having excluded Bard's physical and technological improvements to port technology as printed matter, the court concluded, at the second step of its

"*AngioDynamics* framework," that "there are no other elements that could be considered 'inventive.'" Appx00027-28.

The district court next turned to *Alice* step one, where it ruled that, "[b]ecause each asserted claim at issue here requires the use of an identifier to communicate information about the power injectability of the underlying port and provides no functional improvement to the port itself or the X-ray technology used to view the radiopaque identifiers, the court finds the claims are directed to an abstract idea." Appx00032. That ruling reflected the court's expansion of the printed matter doctrine to include the means of communication, not just the content communicated.

And, at *Alice* step two, with respect to the '022 and '302 patents, the court determined the "that the application of radiopaque identifiers to subcutaneous medical devices was well-understood, routine, and conventional." Appx00036. With respect to the '615 patent, the court determined that the identifying structural feature failed to "describe how a person may utilize [it] to determine any identifying information about the port," declining to read the claim in light of the specification's teaching that it "may be perceived by a person through touch." Appx00039. It also ruled that, while the art did "not address the innovation of using palpation in conjunction with the shape of the medical devices, it is clear that utilizing a

device's shape to convey information is not a new concept." Appx00039-40.

The district court acknowledged that its "holding may appear in tension with the Federal Circuit's holding in *AngioDynamics* concerning whether similar claims are directed solely to printed matter." Appx00028. It justified this clear "tension" based on supposed differences in the record. Appx00017, Appx00028. The court similarly noted that it had "parted ways with one of [its] colleagues" (Appx03795-3796), Judge Nielson, who ruled that a related set of Bard's patents directed to radiopaque indicia and identifying structural features for port identification were directed to patent eligible subject matter (Appx03729-3738).

Given the similarities between Bard's invalidated claims and MedComp's asserted claims in the '324 patent, the district court invited Bard to move for summary judgment, under the law-of-the-case doctrine, that MedComp's asserted claims are invalid under § 101. Appx03796-3797. Bard, despite strongly disagreeing with the court's analysis and application of § 101, complied and so moved while explicitly reserving its right to challenge the district court's earlier ruling on appeal. Appx03923; Appx00048 (acknowledging that "Bard maintains it disagrees with the court's [initial] Order and reserves the right to challenge it once it becomes

final."). MedComp did not oppose that motion, and instead committed to "accept the consequences of the Court's application of the same correct and well-reasoned analysis with respect to MedComp's asserted '324 Patent claims." Appx04213. The district court applied the same legal framework and invalidated the asserted claims of the '324 patent. Appx00041-55.

The district court thereafter entered a Rule 54(b) partial final judgment. Appx00056-71.[3] This appeal followed.

D. Related Proceedings

In addition to this action, Bard is asserting patents related to port identification in three other actions. *First*, Bard is asserting the '302, '022 and '615 patents against AngioDynamics and the '302 and '022 patents against Smiths Medical in separate actions in the District of Delaware. *See supra*, Statement of Related Cases. Both AngioDynamics and Smiths have sought judgment on the pleadings based on the district court's entry of partial final judgment in this action; however, both Delaware actions involve asserted claims beyond those found invalid in this action. *See C.R. Bard v. Smiths*, C.A. No. 20-01543-CFC, Dkt. No. 275 at 1, Dkt. No. 276 at 10-21;

[3] MedComp's inequitable conduct counterclaim remains pending below, but the district court determined that "there is no just reason for delay" in entering final judgment as to the parties' fully resolved infringement claims. Appx00064-68.

C.R. Bard v. AngioDynamics, C.A. No. 20-1544-CFC, Dkt. No. 241 at 1, Dkt. No. 242 at 6-14.

Second, Bard is asserting four patents from the same family as the one at issue here against MedComp in another action in the District of Utah. *See C.R. Bard Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754 (D. Utah). In that action, MedComp also moved for summary judgment of invalidity under § 101, making arguments that closely parallel the ones MedComp made here. However, Judge Nielson squarely rejected MedComp's arguments and applied *AngioDynamics* to rule as a matter of law that Bard's claims were directed to patent-eligible subject matter at *Alice* step one:

> In the context of claims that implicate the printed matter doctrine, the Federal Circuit's holding in *AngioDynamics* thus makes clear that the *Alice* step one inquiry focuses on whether the claim as a whole is directed solely to printed matter; i.e., the content of the information conveyed. Only if the claim is solely so directed is it necessary to move to *Alice* step two and search for an additional inventive concept.
>
> In this case, the court again concludes, as it previously held in its claim construction opinion, that the asserted Port ID patent claims are "materially indistinguishable" from the claims analyzed in *AngioDynamics*….
>
> It follows that when read as a whole, none of the Port ID claims asserted here is directed "solely" to "the content of the information conveyed" and thus to "non-functional" and patent-ineligible "printed

> matter." And I'm quoting much of that language from *AngioDynamics*, at pages 1383 to 1384.

Appx03734. Then, in the alternative, Judge Nielson rejected MedComp's arguments at *Alice* step two, that, as a matter of law, the use of radiopaque indicia or identifying structural features as a means to identify a port's power injection capabilities, was well-known, routine, and conventional. Appx03736-3738.

SUMMARY OF THE ARGUMENT

The judgment of invalidity should be reversed or, alternatively, vacated.

I. The district court erred in ruling that Bard's claims are directed to patent-ineligible printed matter under § 101. That ruling conflicts with this Court's controlling decision in *AngioDynamics*. In *AngioDynamics*, this Court addressed the interplay between the printed matter doctrine and § 101 and held that a patent claim is ineligible under § 101 when "it is directed ***solely*** to non-functional printed matter and the claim contains no additional inventive concept." 979 F.3d at 1383 (emphasis added). Applying that standard to claims directed to the same class of invention as Bard's claims here, this Court determined at *Alice* step one that the claims were not directed to patent-ineligible subject matter. *Id.* at 1383-84. The district court acknowledged that its decision is in "tension" with *AngioDynamics*,

but maintained that different records permitted different results. Appx00028. Yet even if there were material differences in records (there are not), that would not matter at *Alice* step one, which presents a pure question of law regarding the scope of the claims.

The district court also failed to adhere to the analytical framework set out in *AngioDynamics*. Instead, it created a redundant four-step test to evaluate patent eligibility in the printed-matter context. In applying that modified § 101 framework, the district court disregarded the claim limitations directed to the components of physical port assemblies, and erroneously expanded the doctrine to include both the ***content*** of the information conveyed and the ***means*** of conveying that information. Due to those errors, the court wrongly failed to attribute patentable weight to the claimed radiopaque indicia and identifying structural features as a means of conveying information, and wrongly determined that Bard's claims to mechanical devices are directed solely to non-functional printed matter.

Even if *AngioDynamics* alone does not compel reversal, Bard's asserted claims here still satisfy *Alice* step one, for two independent reasons, each of which requires reversal. *First*, each Bard claim recites structural elements of the port, such as a "body," "septum" and "cap," that are not printed matter and demonstrate that the claims are not directed solely to

printed matter. Rather, they are directed to a "machine" (a vascular access port), which is one of the patent-eligible categories explicitly recited in § 101.

Second, the claimed identifier, whether the claimed radiopaque indicia in the '302 and '022 patents or the claimed structural feature in the '615 patent, is not printed matter. As this Court explained in *AngioDynamics*, "the focus of [such clams] is not solely on the content of the information conveyed, but also on ***the means by which that information is conveyed***." 979 F.3d at 1384 (emphasis added). The means claimed here make "the claimed port particularly useful … because the marker allows the implanted device to be readily and reliably identified" as power injectable either by x-ray or by touch. *Id.* The claims are directed to port assemblies having physical, technological means of conveying information about said ports. Such claims are not directed ***solely*** to unpatentable subject matter for that reason too.

II. Even if Bard's claims are directed solely to printed matter (the claimed mechanical devices plainly are not), the district court still erred in granting summary judgment to MedComp because the record is insufficient as a matter of law to establish that the patents lack an inventive concept at *Alice* step two.

The use of radiopaque indicia on ports to enable a medical practitioner to identify power injectability is an inventive concept. The record here is no more amenable to summary judgment of invalidity than in *AngioDynamics*, which this Court held insufficient to find patent ineligibility as a matter of law. The district court wrongly determined that the use of radiopaque indicia on ports was well-understood, routine, and conventional at the time of invention.

The district court likewise erred in concluding that the use of identifying structural features on ports to enable a medical practitioner to determine whether the port is power injectable was well-understood, routine, and conventional at the time of invention. The district court ignored the explicit requirement in the claims the structural identifying feature enable identification post-implantation and further erred by disregarding the specification's teaching that the claimed port-identifying feature enables the port to be identifiable was identifiable via palpation. Moreover, MedComp's evidence purportedly establishing the use of structural features to identify ***other*** medical devices is insufficient to preclude the existence of an inventive concept as a matter of law, even if application to ports would have been obvious.

ARGUMENT

This Court reviews orders granting summary judgement under regional circuit law, while applying its own law to issues unique to patent law. *See, e.g.*, *Centrak v. Sonitor Techs.*, 915 F.3d 1360, 1365 (Fed. Cir. 2019). The Tenth Circuit (the regional circuit here) reviews orders granting summary judgments *de novo*. *See, e.g.*, *Birch v. Polaris Indus., Inc.*, 812 F.3d 1238, 1251 (10th Cir. 2015). This Court "review[s] an ultimate conclusion on patent eligibility de novo." *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1159 (Fed. Cir. 2018). "Patent eligibility under 35 U.S.C. § 101 is a question of law that may contain underlying issues of fact." *Id.*

The two-step framework set forth in *Alice Corp. Pty. Ltd. v. CLS Bank International*, 573 U.S. 208 (2014), governs whether claimed subject matter is patent eligible. At step one, the Court must "determine whether the claims at issue are directed to a patent-ineligible concept," such as an abstract idea. *Id.* at 218. "To determine if the claim's character as a whole is directed to excluded subject matter, [the Court] 'look[s] at the focus of the claimed advance over the prior art.'" *AngioDynamics*, 979 F.3d at 1382 (quoting *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 935 F.3d 1341, 1346 (Fed. Cir. 2019)). If the Court concludes that "the claim is directed to a patent-

ineligible subject matter, then at step two, [it] examine[s] the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed ineligible subject matter into a patent-eligible application." *Id.* (internal quotation marks omitted).

This Court has applied the *Alice* framework in the printed matter context, holding that "a claim may be found patent ineligible under §101 on the grounds that it is directed ***solely*** to non-functional printed matter and the claim contains no additional inventive concept." *AngioDynamics*, 979 F.3d at 1383 (emphasis added).

On *de novo* review, this Court should reverse the district court's contrary judgment and, as in *AngioDynamics*, hold Bard's claims patent eligible.

I. THE DISTRICT COURT'S INVALIDITY JUDGMENT SHOULD BE REVERSED AT *ALICE* STEP ONE

A. This Court's *AngioDynamics* Decision Is Controlling And Indistinguishable

This Court need look no farther than its recent decision in *AngioDynamics*, 979 F.3d 1372, to hold that the district court erred in invalidating Bard's claims under § 101. *AngioDynamics* reversed a judgment that claims directed to the same class of invention as Bard's claims-in-suit were patent ineligible, first holding at *Alice* step one that the

claims were not directed solely to non-functional printed matter. The similarities between the claims at issue in *AngioDynamics* and here demonstrate that the district court's ruling is irreconcilable with *AngioDynamics*. For example, both sets of claims recite various structural features of the port, a radiographic marker that enables identification after implantation where the radiographic marker indicates that the port in power injectable. Given these similarities, the reasoning and decision in *AngioDynamics* controls the outcome here.

In *AngioDynamics*, this Court held that although "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," 979 F.3d at 1382, that determination did not render the claims as a whole invalid under § 101 at *Alice* step one. Rather, the claims were held patent eligible because, when "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 (emphasis added). This Court explained that, "[i]n 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." *Id.* Thus, "each claim as a whole is patent eligible because none are solely directed to the printed matter." *Id.* at 1381.[4]

That holding governs here. The '302 and '022 patents, just as those at issue in *AngioDynamics*, claim various structural features of a port and radiopaque indicia that enable medical practitioners to identify the port as being power injectable after implantation:

Exemplary *AngioDynamics* Claim (Claim 8 of '478 Patent)	**Exemplary Claim-in-Suit** (Claim 5 of '302 Patent; Appx00115 (13:8-19)))
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	5. A **venous access port assembly** for implantation into a patient, comprising: **a housing having an outlet**, and a needle-penetrable septum, the needle-penetrable septum and the housing together defining a reservoir, wherein: the assembly includes **a radiopaque alphanumeric message observable through**

[4] The Court's holding in *AngioDynamics* aligns with its earlier conclusion in *Port I* that "[d]istinguishing between the two types of ports is the crux of what the patents claim." 748 F. App'x at 1016.

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.	**interaction with X-rays subsequent** to subcutaneous implantation of the assembly, and **the alphanumeric message indicating that the assembly is power injectable**.

And although the '615 patent uses different structural means of port identification than the claims at issue in *AngioDynamics*, the analysis under *Alice* step one remains the same. The identifying structural features, like the radiopaque indicia, are "particularly useful … allow[ing] the implanted device to be readily and reliably identified." 979 F.3d at 1384; *see Port I*, 748 F. App'x at 1016 ("Claim 8 of the '615 patent likewise explains that the recited structural feature 'identif[ies] the access port as being power injectable.'") (citation omitted).

Indeed, in the parallel Utah proceeding, Judge Nielson correctly applied *AngioDynamics* to another set of similar claims from related patents directed to radiopaque indicia and identifying structural features.

Exemplary Claim before J. Nielson (Claim 1 of '052 Patent)[5]	**Exemplary Claim-in-Suit** (Claim 5 of '302 Patent; Appx00115 (13:8-19))
1. **A power injectable access port** for providing subcutaneous access to a patient, comprising: **a body defining a cavity accessible by inserting a needle through a septum**, the body including: a first side surface from which an outlet stem extends; a second side surface different from the first side surface, the second side surface having a concave portion; and a bottom surface bounded by a bottom perimeter including a concave portion contiguous with the second side surface concave portion, the bottom surface including **an identifier observable via imaging technology subsequent to implantation of the access port**, **the identifier identifying the access port as a power injectable port.**	5. **A venous access port assembly** for implantation into a patient, comprising: **a housing** having an outlet, and a needle-penetrable septum, **the needle-penetrable septum and the housing together defining a reservoir**, wherein: the assembly includes **a radiopaque alphanumeric message observable through interaction with X-rays subsequent** to subcutaneous implantation of the assembly, and **the alphanumeric message indicating that the assembly is power injectable**.

Judge Nielson recognized that the claims are "'materially indistinguishable' from the claims analyzed in *AngioDynamics*," and he correctly concluded

[5] *C.R. Bard, Inc. v. Med. Components, Inc.*, No. 2:17-cv-00754, Dkt. No. 2-4 at 12:52-65.

that, as in *AngioDynamics*, "when read as a whole, none of the Port ID claims asserted here is directed 'solely' to 'the content of the information conveyed' and thus to 'non-functional' and patent-ineligible 'printed matter.'" Appx03734. Judge Nielsen reached the same conclusion both as to the claims directed to radiopaque indicia and the claims directed to identifying structural features, explaining that *AngioDynamics* required the conclusion that the latter claims were not "directed 'solely' to 'the content of the information conveyed.'" Appx03734-3738.

Despite acknowledging the "obvious similarities between *AngioDynamics* and the instant case," the district court here, unlike Judge Nielson, declined to follow it because "the facts and procedural posture are different." Appx00017; *see* Appx00028 (noting "tension" with *AngioDynamics* but stating "the evidence and arguments before this court differ substantially from the evidence and arguments presented in AngioDynamics"). But in *AngioDynamics*, this Court held that Bard's patents were valid at *Alice* step one. *See* 979 F.3d at 1381, 1384.[6] Because

[6] To the extent the district court read *AngioDynamics* to have proceeded directly to *Alice* step two (*see* Appx00016-17), it simply misapprehended this Court's decision. Judge Nielson, on the other hand, correctly understood this Court's decision. *See* Appx03733 ("To be sure, in *AngioDynamics*, the Federal Circuit went on to address *Alice* step two, but it clearly did so as an alternative holding.").

"*Alice* step one presents a legal question that can be answered based on the intrinsic evidence," *CardioNet, LLC v. InfoBionic, Inc.*, 955 F.3d 1358, 1372 (Fed. Cir. 2020), *cert. denied sub nom.*, 141 S. Ct. 1266 (2021), any supposed differences in the record are irrelevant and thus provide no basis to depart from this Court's holding that claims directed to features on ports for the purposes of post-implantation identification traverse *Alice* step one.

Nor was the district court empowered to create a new *four-step* framework for § 101 challenges based on printed matter, rather than adhering to the familiar two-step *Alice* inquiry that this Court applied to alleged printed matter in *AngioDynamics*. 979 F.3d at 1382-84. The district court's novel framework uses two sets of largely redundant inquiries, first asking whether a claim is [1] "directed solely to non-functional printed matter" and [2] "contains [an] additional inventive concept," before then asking again whether a claim is [3] "directed to a patent-ineligible subject matter" and [4] "contains an inventive concept." Appx00024-25. Though the redundancy renders this error largely harmless, it reinforces the serious deficiencies in the district court's § 101 analysis and its repeated failure to adhere to this Court's governing precedent. The district court's judgment should be reversed for these reasons alone.

B. In All Events, Bard's Claims Are Directed To Patent-Eligible Subject Matter, Not Printed Matter

Even if *AngioDynamics* does not by itself compel reversal here, the judgment should still be reversed because none of Bard's claims is directly solely to patent-ineligible printed matter. At *Alice* step one, the directed-to inquiry "is a meaningful one"; courts "cannot simply ask whether the claims *involve* a patent-ineligible concept." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (emphasis by Court). Instead, courts evaluate the "claims, considered in light of the specification" to determine "whether 'their character as a whole is directed to excluded subject matter.'" *Id.* (citation omitted).

The printed matter doctrine ensures that informational content is not attributed patentable weight where that information is functionally unrelated from its substrate. *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) ("Claim limitations directed to printed matter are not entitled to patentable weight unless the printed matter is functionally related to the substrate on which the printed matter is applied."). That doctrine, however, does not extend to either physical products or the physical means of conveying information. *Burr v. Duryee*, 68 U.S. 531, 570 (1863); *AngioDynamics*, 979 F.3d at 1384. Nor does it apply to the content of information if that content is functionally related to

use of the substrate to which it is applied. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010). The district court erred in ruling otherwise.

1. Bard's Claims Are Directed To Physical Port Assemblies

Section 101 identifies several categories of inventions as patent-eligible, including a "machine." 35 U.S.C. § 101. "The Supreme Court has defined the term 'machine' as 'a concrete thing, consisting of parts, or of certain devices and combination of devices.' This 'includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result.'" *In re Nuijten*, 500 F.3d 1346, 1355 (Fed. Cir. 2007) (quoting *Burr,* 68 U.S. at 570, and *Corning v. Burden,* 56 U.S. 252, 267 (1853)). Bard's claims fit squarely within this definition because they are directed to a mechanical device, *i.e.*, a physical port assembly.

The claims recite a "venous port assembly" capable of power injection, comprising, *e.g.*, "housing having a discharge port, a needle-penetrable septum, [] a cap securable to the housing," and radiopaque indicia or identifying structural features. Appx00114-115; Appx00177; Appx00221. The alleged printed matter is but one aspect of this claimed structure. A claimed combination incorporating printed matter is not

directed to ineligible matter merely because "printed matter by itself is not patentable subject matter." *In re Miller*, 418 F.2d 1392, 1395-96 (C.C.P.A. 1969); *see AngioDynamics*, 979 F.3d at 1383 ("a claim may be found patent ineligible under § 101 on the grounds that it is directed ***solely*** to non-functional printed matter and the claim contains no additional inventive concept") (emphasis added). Indeed, if the asserted claims did not have ***additional limitations*** regarding the radiopaque identifier or recited structural feature, one would be hard pressed to credibly argue any § 101 issue at all. Adding elements relating to the content of information cannot convert a mechanical device into printed matter.

The district court concluded at *Alice* step one that "all the asserted claims are directed to using a specific identifier—either a radiopaque identifier or a structural element including at least one concave side—to communicate information to a medical practitioner that the access port in question is power injectable subsequent to implantation." Appx00030. In so ruling, the court discounted all of the claimed structural elements because "[t]he claims are not directed to an improvement in port technology—the port will function in exactly the same manner whether the identifier is present or not." Appx00031; *see also* Appx00026 ("When each claim is read as a whole, the focus of the claimed advance is using the abovenamed

identifying features, in conjunction with an already known and typically constructed access port, to convey the information that the access port is power injectable."). The court erred in discounting the claimed structural features of the "venous port assembly" based on their alleged lack of novelty.

Indeed, the district court's approach is directly contrary to *Diamond v. Diehr*, 450 U.S. 175 (1981), where the Supreme Court held that "[t]he question … of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" *Id.* at 189 (quoting *In re Bergy,* 596 F.2d 952, 961 (CCPA 1979)). The Supreme Court specifically cautioned against "dissecting a claim into old and new elements" when conducting a patent-eligibility analysis because such an approach "would, if carried to its extreme, make all inventions unpatentable, because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Id.* at 189 n.12; *see Enfish*, 822 F.3d at 1337 ("[D]escribing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule.").

The district court justified its refusal to consider the allegedly conventional structural features recited in the claims based on this Court's

decision in *Ultramercial, Inc. v. Hulu*, *LLC*, 772 F.3d 709 (Fed. Cir. 2014). Appx00027. *Ultramercial* does not support the district court's importation of a novelty analysis into the *Alice* step one inquiry. In *Ultramercial*, this Court considered all eleven steps recited in the claimed method and determined ***that the claims as a whole*** were directed to "the abstract idea of showing an advertisement before delivering free content" and that the claimed method recited "an idea, having no particular concrete or tangible form." 772 F.3d at 715. After concluding, based on all of the claimed limitations, that the claim was directed to an abstract idea, this Court rejected the patentee's argument that "the addition of merely novel or non-routine components to the claimed idea necessarily turns an abstraction into something concrete" and stated that "any novelty in implementation of the idea is a factor to be considered only in the second step of the *Alice* analysis." *Id*. This holding simply restates the proper two-step *Alice* framework—having found at step one that the claim in *Ultramercial* as whole was directed to an abstract idea, this Court proceeded at step two to consider whether the implementation of that abstract idea was sufficiently novel to transform it into patent-eligible subject matter. *See Alice*, 573 U.S. at 218. Thus, contrary to the district court's conclusion, *Ultramercial* does

not permit claim limitations directed to allegedly known features of a vascular access port to be discounted entirely at *Alice* step one.

For these reasons, even if the means of conveying information is non-functional printed matter entitled to no patentable weight (they are not, *see infra* Part I.B.2), the district court erred in concluding the claims in their entirety recite printed matter.

2. The Means Bard's Claims Use To Convey Information Are Patent-Eligible Subject Matter

Bard's claims are not solely directed to patent-ineligible printed matter for the additional reason that they are directed to technological and tangible ***means*** of conveying information, namely, the claimed radiopaque indicia and claimed identifying structural feature.

This Court repeatedly has distinguished between the non-functional ***content*** of information, which is subject to the printed matter doctrine, and the tangible or technological ***means*** of conveying that information, which is not subject to that doctrine. *See, e.g.*, *AngioDynamics*, 979 F.3d at 1384 (claims not directed to patent-ineligible printed matter where "the focus of the claimed advance is ***not solely on the content*** of the information conveyed, but also on the ***means*** by which the information is conveyed") (emphasis added); *Praxair*, 890 F.3d at 1032 ("Claim limitations directed to the ***content of information*** and lacking a requisite functional relationship are

not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101.") (emphasis added); *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015) ("Our past cases establish a necessary condition for falling into the category of printed matter: a limitation is printed matter ***only if it claims the content of information***.") (emphasis added).

Applying the printed matter doctrine in the manner prescribed by this Court, Bard's patents are not directed solely to printed matter; rather the claims are directed to ports with radiopaque indicia and structural features—two novel ***means*** of conveying information about ports that enable use of the full scope of their functionality by making them identifiable after implantation. Those radiopaque indicia and structural features are not directed to the content of any information; they are directed to technological ***means*** for conveying information and thus are entitled to patentable weight. *See Miller*, 418 F.2d at 1396 ("[P]rinted matter, in an article of manufacture claim, can be given 'patentable weight.'"). Indeed, the claims themselves explicitly distinguish between the ***means*** of identifying the port after implantation ("a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly" (Appx00115 (13:14-16)) and the ***content*** of the information

conveyed by the means ("the alphanumeric message indicating that the assembly is power injectable" (Appx00115 (13:17-18)).[7]

The district court erred by expanding the printed matter doctrine beyond the content of the information conveyed to include the physical means of conveying information: "the court holds that printed matter includes not only the information being conveyed ***but the matter used to convey the information***." Appx00017 (emphasis added); *see id.* (the court "disagrees with Bard's assertion that … the content of the information conveyed can be divorced from the ***medium used*** to convey the information") (emphasis added). That expansion prevented the tangible and concrete innovation of Bard's patents—technological means of post-implantation identification—from consideration at *Alice* step one merely due

[7] Beyond its § 101 analysis, *AngioDynamics*'s holding with respect to anticipation further confirms that radiopaque indicia and structural features are entitled to patentable weight. This Court also vacated a grant of summary judgment of anticipation because there was a "factual dispute over whether any of the prior art access ports contained a 'radiographic marker' or 'radiographic feature' as required by the asserted claims." *Id.* at 1384-85. "If the radiopaque markers themselves, as opposed to the content of the information conveyed, were printed matter, then they could not be considered as part of the validity analysis." Appx02350; *see AngioDynamics*, 979 F.3d at 1384 (explaining "the ***information*** that the claimed access ports are suitable for injection" is "assign[ed] no patentable weight") (emphasis added); *see also Distefano*, 808 F.3d at 848 ("In performing this analysis we do not strike out the printed matter and analyze a 'new' claim, but simply do not give the printed matter any patentable weight: it may not be a basis for distinguishing prior art.").

to the presence of informational content. *See* Appx00027 ("The addition of merely novel yet nonfunctional printed matter identifiers does not change the fact that the focus of the claimed advance is solely on the content of the information conveyed."). There is simply nothing in this Court's precedents that suggests the printed matter doctrine encompasses novel technological means of communicating information. And for good reason: such an interpretation of the printed matter doctrine would lead to absurd results, e.g., an improvement to a mechanical clock would merely recite a novel, but unpatentable, means of communicating information about time.

The district court's expansion of the printed matter doctrine was, in part, predicated upon unfounded monopolization fears. Appx00027-28 ("If the court were to find otherwise [that Bard's claims were not directed solely to printed matter], it would undermine the rationale underlying the printed matter doctrine, which 'guard[s] against attempts to monopolize the conveyance of information using any medium.'") (quoting *AngioDynamics*, 979 F.3d at 1381); *cf. In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) ("If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."). There is no monopolization concern here. Bard's claims do not encompass "the conveyance of information using ***any medium***." *AngioDynamics*, 979

F.3d at 1381 (emphasis added). Rather, Bard's claims are limited to the use of particular means and media—radiopaque indicia and structural features on power injectable ports—with respect to a constrained set of information, sufficient for identification of power injection properties. *See, e.g., Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) (holding claims patent eligible as directed to an inventive concept; "the claims [do not] preempt all ways of filtering content on the Internet; rather, they recite a specific, discrete implementation of the abstract idea of filtering content").

Instead of following this Court's directly-applicable decision in *AngioDynamics*, which addressed the ***same class of invention and the same Section 101 issues*** as here, the district court erroneously opted to analogize Bard's claims to the postal-marking claims at issue in *Secured Mail Solutions LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed. Cir. 2017), which this Court held were directed to ineligible subject matter. The district court understood that case to involve "methods asserted in the claim language [that] were directed solely 'to the abstract process of communicating information about a mail object using a personalized marking," and concluded, "[t]he same is true here." Appx00030-31 (quoting *Secured Mail*, 873 F.3d at 911). The court's analogy is imprecise, and more

importantly, inaccurate. In *Secured Mail*, this Court determined that claims reciting a "method of verifying mail identification data" where "various identifiers are affixed to a mail object, stored in a database, scanned from the mail object, and retrieved from the database" were invalid under § 101. 873 F.3d at 908, 910. There were "[n]o special rules or details of the computers, databases, printers, or scanners [] recited." *Id.* at 910. Here, to the contrary, Bard's claims describe and recite the particular and physical components of power-injectable ports. Bard's claims are not directed to the abstract process of communicating information, but rather to power-injectable ports outfitted with a specific tangible means of identifying the ports after implantation—either a radiopaque identifier or a structural feature including a concave side surface.

Finally, the district court committed additional error by discounting the claimed radiopaque indicia and claimed identifying structural feature because "[t]he claims are also void of any discussion of the X-ray technology used to view the radiopaque identifiers after implantation of the port, meaning the claims are not directed to determining if certain radiopaque identifiers or their placement on the port improves their visibility when subject to X-ray." Appx00031. But as discussed (*supra* Part I.B.1), the Section 101 inquiry does not include a limitation-by-limitation

assessment of novelty. Here, the claimed identifiers are affixed to a power injectable port to enable them to be identified after implantation. Whether the claims optimize the visibility or location of the claimed identifiers does not affect whether they are directed to patent-eligible subject matter.

The district court thus erred in ruling that Bard's claims were directed to patent-ineligible subject matter—a conclusion only possible due to its failure to attribute patentable weight to the means by which the claimed ports convey information.[8]

II. THE DISTRICT COURT'S INVALIDITY JUDGMENT SHOULD BE REVERSED AT *ALICE* STEP TWO

If this Court concludes that Bard's claims are not directed solely to printed matter under *Alice* step one, then it need not consider *Alice* step two. But if this Court proceeds to *Alice* step two, then it should reverse or at the

[8] Although not necessary for this appeal, the district court also erroneously concluded that the content of the information conveyed in Bard's claims—"the alphanumeric message indicating that the assembly is power injectable" (Appx00020-21)—is not functionally related to the substrate on which it is applied. *See Praxair*, 890 F.3d at 1032. In *Port I*, this Court, relying on the claim language reciting the contents of the information conveyed by the radiopaque marker, concluded that the claims were structurally limited to power injectable ports and therefore a "mislabeled" port was not within the scope of the claims. 748 F. App'x at 1015-17. Indeed, the only reference to power injectability is found in the portion of the claim relating to the contents of the message. Accordingly, there is a direct functional relationship between the substrate (a power injectable port) and the message (that the port is power injectable).

very least vacate the invalidity judgment because MedComp's evidence is insufficient to establish as a matter of law the lack of an inventive concept.

"Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018). "Something is not well-understood, routine, and conventional merely because it is disclosed in a prior art reference. There are many obscure references that nonetheless qualify as prior art … [but] would not suffice to establish that something is 'well-understood, routine, and conventional activity previously engaged in by scientists who work in the field.'" *Exergen Corp. v. Kaz USA, Inc.*, 725 F. App'x 959, 966 (Fed. Cir. 2018) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79 (2012)). Even if the relevant field indicates that a claimed advance may be obvious, that too is insufficient to establish the lack of an inventive concept. *AngioDynamics*, 979 F.3d at 1384.

MedComp did not establish that use of radiopaque indicia or identifying structural features to identify a particular type of port was well-known, routine, or conventional at the time of patenting. MedComp's reliance on obscure references and inferences of obviousness did not suffice

to establish as a matter of law that Bard's claims do not satisfy *Alice* step two. The district court erred in ruling otherwise.

A. Use Of Radiopaque Markers On Medical Ports Is An Inventive Concept

Contrary to the district court's ruling, MedComp failed to show that the use of radiopaque markers was well-understood, routine, and conventional at the time of invention. Just as in *AngioDynamics* and in the parallel proceeding before Judge Nielson, the record was insufficient to establish that the ordered combination of the elements claimed was not an inventive concept. Instead, the record merely evidences the ***generic*** use of radiopaque markers on ***different*** medical devices with ***different*** purposes—well less than necessary to invalidate Bard's claims at *Alice* step two.

In *AngioDynamics*, this Court concluded that the record there—including, "Bard's admission that the use of radiographically identifiable markings on implantable medical devices was known in the prior art, and … evidence of such use in the prior art, including one vascular port with an x-ray tag that identified the port's flow rate"—was "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." 979 F.3d at 1384. This Court made clear that obviousness does not negate an inventive concept. *Id.* ("Even if the prior art asserted by

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.").[9]

The record presented by MedComp in the parallel proceeding before Judge Nielson was similarly found legally insufficient to permit summary judgment of invalidity. Relying on this Court's reasoning in *AngioDynamics*, Judge Nielson stated that "none of the evidence provided by MedComp here supports a different conclusion." Appx03736. That record included "various prior art patents that show that radiographic markings were used in connection with other medical devices or procedures, [but] none of these patents show[ed] a radiographic marker being used to identify a port as suitable for power injection." *Id.*

[9] *See also Diehr*, 450 U.S. at 191 ("A rejection ['under § 102 or nonobviousness under § 103'] does not affect the determination that respondents' claims recited subject matter which was eligible for patent protection under § 101."); *In re Morsa*, 809 F. App'x 913, 917 (Fed. Cir. 2020) ("abstractness, novelty, and non-obviousness are separate legal and factual concepts"); *Intell. Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1315 (Fed. Cir. 2016) ("the jury's general finding that Symantec did not prove by clear and convincing evidence that three particular prior art references do not disclose all the limitations of or render obvious the asserted claims ***does not resolve the question of whether the claims embody an inventive concept*** at the second step of *Mayo*/*Alice*.") (emphasis added).

The evidence that MedComp offered below fares no better. The record here is limited to a vague reference to patent prior art,[10] obviousness-like analogies, and the generic use of radiopaque markers in different contexts for different purposes. Appx00034-35; Appx02476-2479. MedComp's bare reference to patent prior art should carry no weight, as it failed to identify any patents specifically and made no effort to connect those references to the claimed radiopaque indicia. Appx02476. And MedComp did not demonstrate, or even suggest, that the products described by those unidentified patents were ever commercialized, let alone that they were routine and conventional, making them nothing more than "obscure references" that are insufficient at *Alice* step two. Appx02476-2479; *see Exergen*, 725 F. App'x at 965-66 ("Something is not well-understood, routine, and conventional merely because it is disclosed in a prior art reference."); *Berkheimer*, 881 F.3d at 1367-68.

MedComp's remaining evidence includes statements by Bard as well as "several articles from medical journals and industry publications discussing the use of radiographic marking on implantable medical devices years before Bard's asserted patents were issued." Appx00035. Beyond

[10] Appx02476 ("Even putting aside the library of patent prior art, evidence is legion that those skilled in the art have long recognized the conventionality of radiographic marking.").

Bard's statements allegedly relating to "how obvious it is to use radiographic markers on implanted ports," MedComp relied on examples of the generic use of radiopaque markers employed in markedly different circumstances: (1) the use of biliary stents where the radiopaque marker allows for better stent visualization, pre- and post-placement; (2) radiopaque ink for easy tracking; (3) implantable defibrillators where the specific components of the device enabled identification of the device; and (4) surgical swabs and sponges where the radiopaque marker enabled identification of inadvertently retained (or forgotten) swabs and sponges post-surgery. Appx02477-2479; Appx02523-2559.

This record does not demonstrate the routine or conventional use of radiopaque markers on ports in any manner. Assertions of obviousness do not negate an inventive concept. *AngioDynamics*, 979 F.3d at 1384. And, the use of radiopaque markers on surgical tools and implantable medical devices broadly, employed for a variety of different purposes, does not equate to routine or conventional use of such indicia on ports for the purpose of identifying of port properties. Just as in *AngioDynamics* and the parallel proceeding before Judge Nielson, MedComp failed to show as a matter of law that Bard's patents lack an inventive concept.

The district court erred in concluding otherwise. The court cast the *Alice* step-two question too broadly, asking whether radiopaque markers had been used in any medical device, for any purpose. Appx00036-37 (framing *Alice* step two as whether "application of radiopaque identifiers to ***subcutaneous medical devices*** was well-understood, routine, and conventional") (emphasis added). The relevant question, however, is whether radiopaque markers ***used for identification of port properties*** was well-known or routine. *See, e.g., BASCOM Glob.*, 827 F.3d at 1350-52 (holding an inventive concept existed where the claims "transform the abstract idea of filtering content into a ***particular, practical application*** of that abstract idea" and "recite a ***specific, discrete implementation*** of the abstract idea of filtering content" via "a prior art filter solution"; stating that the "inventive concept inquiry requires more than recognizing that each claim element, by itself, was known in the art") (emphasis added); *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1302 (Fed. Cir. 2016) ("Claim 1 is also like the claims in *BASCOM* because even though the system in the '065 patent relies upon some arguably generic limitations, when all limitations are considered individually and as an ordered combination, they provide an inventive concept through the use of distributed architecture."). Thus, MedComp's record—evidencing the use of

radiopaque markers in ***different*** products for ***different*** purposes—does not establish that radiographic marking on ports for the purposes of identification of power-injectability was routine and conventional at *Alice* step two.[11]

Pursuant to an appropriately tailored *Alice* step-two analysis, the use of radiopaque indicia to enable a medical practitioner to determine whether an implanted port is power injectable via x-ray is an inventive concept. The district court's judgment of invalidity as to the claimed radiopaque indicia, if not reversed at *Alice* step one, should be reversed or at the very least vacated at *Alice* step two.

B. Use Of Identifying Structural Features On Medical Ports Is An Inventive Concept

The district court also wrongly ruled that the use of identifying structural features was well-understood, routine, and conventional at the

[11] The district court acknowledged that, in *AngioDynamics*, this Court had "reviewed and rejected, based on the record there provided, the trial court's factual finding that use of radiographic markings was routine and conventional in the art at the relevant time." Appx00036. The court, however, asserted that the record before it differed from *AngioDynamics*, and its record was "sufficient to show that the use of radiopaque identifiers was well-understood, routine, and conventional at the time of the asserted Bard patents." *Id.* As explained in text, that anomalous conclusion is unfounded.

time of invention.[12] MedComp's evidence of supposed routine and conventional use of structural features was limited to an undifferentiated reference to "patent prior art" and a series of medical articles and charts "describing the use of shape to differentiate between the brand and type of implanted pacemaker."[13] Appx00039-40; Appx02480-2483. As with the radiopaque indicia, these ambiguous references to patent prior art failed to identify any patents specifically or establish any connection between those references and the claimed structural features. And, again, MedComp did not demonstrate, or even suggest, that those references were connected to the claimed features or that the products described therein were ever commercialized, let alone that they were routine and conventional. Such "obscure references" are insufficient at *Alice* step two. *See Exergen*, 725 F. App'x at 965-66; *Berkheimer*, 881 F.3d at 1367-68.

The district court's contrary ruling rests on two errors.

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[12] The district court incorrectly stated that "Bard advance[d] in relation to the '615 Patent only an argument concerning *Alice* step one." Appx0038. Bard argued that "none of MedComp's evidence describes any 'port shape,' let alone the use of port shape for identification" (Appx02647-2648) and relied on *AngioDynamics* to argue that "MedComp's purported evidence … that 'using shape is also routine and conventional' is insufficient to establish lack of inventive concept at *Alice* step two." Appx02680-2681.

[13] The district court did not address MedComp's unspecified reference to patent prior art, basing its decision only on the medical articles and charts submitted by MedComp. Appx00037-40.

First, the district court's ruling contravenes this Court's precedent holding that claims must be understood and interpreted in light of the specification. *See ChargePoint, Inc. v. SemaConnect, Inc.*, 920 F.3d 759, 775 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 983 (2020) (relying on the "claims and the specification" at *Alice* step two); *Universal Secure Registry LLC v. Apple Inc.*, 10 F.4th 1342, 1353 (Fed. Cir. Aug. 26, 2021) (finding patent-ineligibility at *Alice* step two, because "[t]here is nothing in the specification suggesting[] … that the claimed combination of these conventional authentication techniques" is an inventive concept). The district court erroneously declined to read the claims of the '615 patent in light of the teaching of the specification: "Although the specification of the '615 Patent describes an embodiment of an access port wherein an identifiable feature may be perceived by a person through touch, the asserted claim does not recite this alleged innovation." Appx00039; *see id.* ("'The main problem that [Bard] cannot overcome is that the claim—as opposed to something purportedly described in the specification—is missing an inventive concept.'") (quoting *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017)). The court therefore did not weigh 'identification of the port by touch' in its *Alice* step-two analysis.

But the claims make clear that the claimed "structural feature" "identif[ies] the access port as being power injectable ***subsequent to subcutaneous implantation***." Appx00220 (12:61-62) (emphasis added). And the specification teaches that this claim limitation of identification after implantation can be achieved via palpation, *i.e.*, by touch. *See, e.g.,* Appx00216 (4:17-22); Appx00218 (7:21-26). By requiring that the "structural feature" enable identification "subsequent to subcutaneous implantation," the claims make clear that the specification's disclosure of palpating the port to feel a particular port shape is within the scope of the claims. *See, e.g.,* Appx00216 (4:17-22); Appx00218 (7:21-26); Appx00220 (12:61-62).

The decision upon which the district court relied (Appx00039), *Two-Way Media*, 874 F.3d 1329, is not applicable here. That case addressed a circumstance where the patentee attempted to read a limitation into a claim. There, while the specification discussed the purported inventive concept (a "particular scalable network architecture"), the claims "recite[d] only conventional computer components" and did not describe the scalable network architecture. *Id.* at 1338-39. *Two-Way* thus merely stands for the established principle that "the specification cannot be used to import details from the specification if those details are not claimed." *ChargePoint*, 920

F.3d at 769. Conversely, here, the identifiable structural feature is specifically claimed as permitting identification after implantation, and the specification merely teaches how that claimed structural feature can be identified once the port is implanted.[14] Bard is not seeking to import unclaimed physical components into the § 101 inquiry; such features are plainly claimed here.

Second, in concluding that MedComp's evidence demonstrated, as a matter of law, that the use of an identifying structural feature on ports was well-understood, routine, and conventional, the court again failed to sufficiently tailor its analysis in *Alice* step two. It cast the question too broadly, asking whether identifying structural features had been used in ***any*** medical device, for ***any*** purpose. Appx00037; Appx00039. The appropriate inquiry is whether structural features used for the ***identification after subcutaneous implantation of port properties*** was well-understood, routine, and conventional. *See AngioDynamics,* 979 F.3d at 1384; *Berkheimer*, 881 F.3d at 1369; *Bascom Glob.*, 827 F.3d at 1350.

[14] *See* Appx00221 (13:23-14:7) (claim 8; "at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation"); Appx00216 (4:19-22) ("Accordingly, a person of interest may touch or feel the access port through the skin to perceive at least one identifying characteristic thereof.").

The district court thus wrongly relied on structural features on pacemakers to support the absence of an inventive concept here. Such ***generic*** use of identifying structural devices on a ***different*** medical device is insufficient as a matter of law. And in any event the pacemaker evidence did not disclose the use of particular structures designed to enable identification of particular ***properties*** after implantation. Rather, it related to the use of x-ray imaging to determine the general shape and circuit board configuration of a pacemaker to enable identification of the ***brand*** of pacemaker and ***model***. Appx02480-2483.

The district court recognized that "the articles [cited by MedComp] do not address the innovation of using palpation in conjunction with the shape of the medical devices," but stated "that utilizing a device's shape to convey information is not a new concept." Appx00039-40. That conclusion both acknowledges that the claimed mechanism of identification—touch—was novel, and wrongly transforms *Alice* step two into a question of obviousness. That standard ensnares inventive concepts that were not present in the art. As explained with respect to radiopaque indicia, even assuming that use of identifying structural features on ports was obvious in light of prior use on other types of medical devices, such evidence is insufficient as a matter of

law to preclude finding an inventive concept at *Alice* step two. *See AngioDynamics*, 979 F.3d at 1384.

The record presented by MedComp in the parallel proceeding before Judge Nielson is analogous to the record here—relying on the same evidence of pacemaker identification based on shape and circuit board configuration.[15] *See C.R. Bard Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754, Dkt. No. 607 at 12-15 (D. Utah). Judge Nielson rightly found that record legally insufficient, concluding that "MedComp again fails to provide any specific evidence that the use of port shape to identify a port as power injectable was routine and conventional for purposes of Alice step two." Appx03738 ("MedComp's argument regarding these claims thus fails at Alice step two

[15] Before Judge Nielson, unlike here, MedComp also identified three alleged patent prior art references, including: "Sheetz WO 2006/096686, Reuter European Patent No. 1238682, and Sanfilippo U.S. Patent No. 5,919,160." *C.R. Bard Inc. v. Medical Components, Inc.*, No. 2:17-cv-00754, Dkt. No. 607 at 9. Sheetz is the published foreign counterpart to the patents-in-suit. Its disclosure is substantively identical to the patents-in-suit and claims priority to the same provisional application as the patents-in-suit. *Id.* at Dkt. No. 607-1 at 149. Thus, Sheetz is not prior art under 35 U.S.C. § 102(e) because it was not filed before the patents-in-suit and because it reflects the inventor's own work. *See In re Costello*, 717 F.2d 1346, 1351 (Fed. Cir. 1983) ("[I]n order to overcome a prior art reference under section 102(e)," a party can "establish that the relevant disclosure describes their own invention."). "Reuter discloses an access port with a base plate having concave cutouts that can be used to securely handle the port during implantation." *Port I*, 748 F. App'x at 1017. "Sanfilippo discloses a dual-reservoir port having curved indentations on the sides thereof that allow a doctor to determine, via palpation, the reservoirs' relative orientation." *Id.*

for essentially the same reason as its argument regarding the radiographic markers."). The district court below should have reached the same conclusion.

For all these reasons, the district court's judgment of invalidity as to the claimed identifying structural feature, if not reversed at *Alice* step one, should be reversed or vacated at *Alice* step two.

CONCLUSION

The judgment should be reversed or, alternatively, vacated, and the case remanded for further proceedings on Bard's infringement claims.

Respectfully submitted,

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Addendum

Memorandum Decision and Order Granting in Part Defendant's Motion for Partial Summary Judgment, dated July 22, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**MEMORANDUM DECISION AND ORDER GRANTING IN PART DEFENDANT'S PARTIAL MOTION FOR SUMMARY JUDGMENT** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

In this patent infringement action, Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, Bard) assert three patents against Defendant Medical Components, Inc. (MedComp). All three patents are directed to systems and methods for identifying a vascular access port as suitable for power injection following implantation of the device in the human body. Now before the court is MedComp's Motion for Partial Summary Judgment on the grounds of non-infringement and invalidity as to Bard's patents-in-suit.[1] For the reasons explained below, MedComp's Motion is GRANTED IN PART. The court defers consideration of MedComp's request for summary judgment on Bard's alleged infringement of MedComp's asserted patent.

BACKGROUND

Bard and MedComp are medical device manufacturers who develop, produce, and market various vascular access devices, including subcutaneous access ports. Access ports are devices

[1] Dkt. 463. In its Motion for Partial Summary Judgment, MedComp, as Counterclaimant, asserts its own U.S. Patent No. 8,021,324, seeking summary judgment against Bard for infringement. The court will not address MedComp's counterclaims in this Order.

that are implanted within the body of a patient, providing a convenient method of repeatedly delivering infusions of medicine, blood products, or other fluids into a patient's veins without requiring invasive surgical procedures or the need to start a new intravenous line on each occasion.[2] Power injection machines employing high pressure are sometimes used to deliver highly viscous fluids through access ports at specific desired rates of flow.[3] Unlike regular access ports that can fracture and cause significant bodily injury or death if subjected to power injection, special power injectable ports are designed to withstand high pressures.[4]

Generally, access ports offered by different manufacturers and different models exhibit substantially similar geometries, making it difficult to differentiate between power injectable ports and regular access ports once they have been implanted in the body.[5] Due to reported cases of injury, "the FDA cautioned medical providers in 2004 and 2005 that they should not use vascular access ports for power injection unless the ports were specifically and identifiably labeled for such use."[6] Access port manufacturers thus seek methods of adding identifiers to their ports that enable identification of power-injectability following implantation.[7] The various iterations of port identification methods comprise the heart of the patent disputes between Bard and MedComp.

Bard asserts three patents in this case: U.S. Patent Nos. 7,785,302 (the '302 Patent), 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent).[8] The '302 Patent is the "parent"

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[2] *See* Dkt. 585-2 (Bard's Redacted Tutorial Exhibit) at 4.

[3] *See id.* at 15–18.

[4] *See id.* at 20, 23–24.

[5] *See id.* at 26–27.

[6] *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1375 (Fed. Cir. 2020).

[7] *See* Dkt. 585-2 at 29–33; *see also* Dkt. 579 (Disk with MedComp's Technology Tutorial) at 26–30 (on file with Clerk's Office).

[8] Dkt. 463 at 1, ¶ 1.

patent, while the '615 Patent is a continuation and the '022 Patent is a continuation in part of the '302 Patent.[9] All three of the asserted patents are directed to systems and methods for venous access port identification.[10] The background and summary sections of the specifications in the '302 and '615 Patents are substantially similar,[11] and the detailed description sections of the specifications in the '302 and '022 Patents are also substantially similar.[12] Each of the independent and dependent claims in the '302 and '022 Patents require the presence of a type of radiopaque marker identifying the claimed port as power injectable.[13] And the claim at issue in the '615 Patent requires the presence of a structural feature identifying the claimed port as power injectable.[14]

The '302 and '022 Patents claim access ports wherein at least one radiopaque identifier is included in the port assembly, identifying the port as suitable for power injection. Regarding the '302 Patent, Bard asserts independent claims 1, 5, 8, and 10, and dependent claims 3, 4, 6, and 7, each dependent from either claim 1 or claim 5.[15] From the '022 Patent, Bard asserts independent claims 1 and 10, and dependent claims 3, 5, 8, 9, 12, and 14, each dependent from either claim 1 or claim 10.[16] Claim 1 of the '302 Patent is illustrative of these claims:

> 1. A venous access port assembly for implantation into a patient comprising:
>
> a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a

[9] Dkt. 534 (Bard's Opposition to Partial Motion for Summary Judgment) at 7, ¶ 2. MedComp disputes that the '615 Patent is properly characterized as a continuation of the '302 Patent. *See* Dkt. 604 (MedComp's Reply). The court need not address this issue here as it is immaterial to the analysis at hand.

[10] *See* Dkt. 457-1 (Joint Appendix), JA-38 at 1:1-2; JA-101 at 1:1-2; and JA 148 at 1:1-2.

[11] *See id.* JA-38 at 1:13–2:24; JA-148 at 1:17–2:28.

[12] *See id.* JA-39 at 3:23–4:24; JA-101 at 2:63–3:62.

[13] *See id.* JA-43 at 12:56–14:21; JA-108 at 15:11–16:44.

[14] *See id.* JA-154 at 13:23–14:9.

[15] Dkt. 534 at 7, ¶ 3.

[16] *Id.*

housing base defining a bottom wall of at least one reservoir, and outwardly facing bottom surface,

the housing base including radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an X-ray of the patient is taken after implantation.[17]

The '615 Patent claims access ports wherein at least one structural feature is included in the port assembly, identifying the port as suitable for power injection. Bard asserts independent claim 8 of the '615 Patent:

8. An access port for providing subcutaneous access to a patient, comprising:

a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and

at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.[18]

PROCEDURAL HISTORY

On January 11, 2012, Bard filed the above-captioned action against MedComp, alleging infringement of the '302, '022, and '615 Patents.[19] At the same time, Bard also filed two similar infringement cases against AngioDynamics and Smiths Medical in this court.[20] These are known as the *Port I* cases. On December 17, 2012, the *Port I* actions were stayed and administratively closed while the patents-in-suit underwent *inter partes* reexamination before the United States

[17] Dkt. 457-1, JA-43 at 12:57–67.

[18] *Id.* JA-154 at 13:23–14:7.

[19] Dkt. 115 at 2–3.

[20] Dkt. 458 (Bard's Opening Claim Construction Brief) at 1. The case against AngioDynamics involves the same three Bard patents at issue in this case, and the case against Smiths involves two of the three patents. *See id.* at n.3.

Patent and Trademark Office (USPTO).[21] The stay remained in place for approximately seven years until it was lifted on October 4, 2019.[22] In November 2020, the AngioDynamics and Smiths Medical cases were transferred to the District of Delaware, but the instant MedComp action remained in Utah.[23]

In 2015, while the *Port I* actions were stayed, Bard filed a separate suit against AngioDynamics in the District of Delaware (*Port II*), alleging infringement of Bard's patents from a separate port patent family.[24] The patents at issue in *Port II* also claim strategies for identifying a power injectable port, specifically through the presence of radiographic markers.[25] On July 7, 2017, Bard filed a second infringement action against MedComp in the District of Utah (*Port III*).[26] That case, now pending before Judge Howard Nielson, involves Bard's patents from both the *Port I* and *Port II* patent families.[27]

Following the lifting of the stay in the *Port I* actions, this case has recommenced and progressed as follows: fact discovery commenced on March 30, 2020 and closed on February 8, 2021; the parties completed claim construction briefing on April 2, 2021; summary judgment briefing was completed on April 16, 2021; and the parties conducted a technology tutorial for the court on April 28, 2021.[28] After reviewing the claim construction briefs and cross-motions for

[21] *Id.* at 3–4.

[22] *See* Dkt. 161.

[23] *See* Dkt. 458 at 1 n.3.

[24] *Id.*

[25] *See AngioDynamics*, 979 F.3d at 1375.

[26] *See* Dkt. 458 at 1 n.3.

[27] *Id.*

[28] *See* Dkt. 539 (Bard's Opposition to MedComp's Motion to Consolidate Cases) at 2–3.

summary judgment, the court finds issues concerning the invalidity of Bard's patents-in-suit ripe for review.

LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[29] A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[30] A fact is material if, under the governing substantive law, it could "affect the outcome of the suit."[31] When applying this standard, the court "view[s] the evidence and make[s] all reasonable inferences in the light most favorable to the nonmoving party."[32]

ANALYSIS

In its opening claim construction brief, MedComp argues that several of the claim terms in Bard's asserted patents are directed to printed matter and are, therefore, not entitled to patentable weight under the printed matter doctrine.[33] MedComp further argues that if the court adopts MedComp's proposed construction of the disputed terms and agrees the printed matter doctrine applies, the asserted Bard patent claims fail to meet the subject matter eligibility requirements of 35 U.S.C. § 101, rendering them invalid.[34] Based on these arguments, the Court will begin by analyzing whether the printed matter doctrine applies before turning to the discussion of subject matter eligibility and invalidity.

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[29] Fed. R. Civ. P. 56(a).

[30] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

[31] *Id.*; *see also United States v. Simons*, 129 F.3d 1386, 1388 (10th Cir. 1997) ("The substantive law of the case determines which facts are material.").

[32] *N. Natural Gas Co. v. Nash Oil & Gas, Inc.*, 526 F.3d 626, 629 (10th Cir. 2008).

[33] *See* Dkt. 459 (MedComp's Opening Claim Construction Brief) at 11–17.

[34] *See* Dkt. 463 at 10–22.

I. The Printed Matter Doctrine

The Federal Circuit has long held that certain "printed matter" falls outside the scope of patentable subject matter as set forth in 35 U.S.C. § 101.[35] Although early cases employing this doctrine applied it to claims that literally encompassed "printed" materials, "the doctrine has evolved over time to guard against attempts to monopolize the conveyance of information using any medium."[36] Currently, the printed matter doctrine encompasses "any information claimed for its communicative content."[37] Thus, any "claim limitations directed to the content of information are not entitled to patentable weight because such information is not patent eligible subject matter" under § 101.[38]

Although printed matter is generally patent ineligible, there is a recognized exception to the rule: if a limitation claims printed matter that is "functionally related" to its "associated physical substrate," the printed matter is given patentable weight and may serve to distinguish the new invention from the prior art.[39] "The first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[40] In other words, does the limitation in question claim the content of information? If so, "the next

[35] *See, e.g.*, *AngioDynamics*, 979 F.3d at 1381 (explaining that the Federal Circuit has "long recognized that certain 'printed matter' falls outside the scope of patentable subject matter under U.S. patent law"); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010) ("This court has generally found printed matter to fall outside the scope of § 101")).

[36] *AngioDynamics*, 979 F.3d at 1381 (citing *Praxair Distribution, Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) (extending the printed matter doctrine to claim limitations reciting certain mental steps or processes physicians take when prescribing a drug and finding the limitations were not entitled to patentable weight); *In re Distefano*, 808 F.3d 845, 849–50 (Fed. Cir. 2015) (citing cases developing the printed matter doctrine and providing examples of what qualifies as printed matter)).

[37] *Id.* (citing *Praxair*, 890 F.3d at 1032; *Distefano*, 808 F.3d at 848–49).

[38] *Praxair*, 890 F.3d at 1032.

[39] *Id.*; *see also AstraZeneca*, 633 F.3d at 1064.

[40] *Distefano*, 808 F.3d at 848.

step is to ascertain whether the printed matter is functionally related to its 'substrate.'"[41] For example, the Federal Circuit held in *In re Gulack* that although a sequence of printed digits on a wristband was printed matter, the sequence was still entitled to patentable weight[42] because "the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for educational and recreational mathematical purposes."[43] In contrast, the Federal Circuit found that the printed matter in *AstraZeneca*, which merely added an FDA-required instruction sheet to a known drug product, was not sufficient to create a functional relationship and could not be given patentable weight.[44]

Here, MedComp identifies three claim limitations that it argues are printed matter: (1) "markings" ('302 Patent, claim 10), (2) "identification feature" ('022 Patent, claims 1, 3, 5, 8, 9, and 10), and (3) "structural feature of the access port identifying the access port as being power injectable" ('615 Patent, claim 8).[45] With respect to the "identification feature" and "markings," MedComp asserts that these terms fall squarely within the printed matter doctrine because they are "information conveyors" whose only purpose is to identify the port in question as capable of power injection.[46] Similarly, MedComp contends the "structural feature" described in the '615 Patent, which comprises at least one concave side surface of the port in question, serves the identical purpose of solely conveying information identifying the port as power injectable.[47]

[41] *Praxair*, 890 F.3d at 1032.

[42] *See In re Gulack*, 703 F.2d 1381, 1386–87 (Fed. Cir. 1983).

[43] *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (distinguishing *Gulack* from the printed matter under consideration in *Ngai*).

[44] *AstraZeneca*, 633 F.3d at 1065.

[45] *See* Dkt. 557 (Joint Claim Construction Chart) at 3–4.

[46] *See* Dkt. 459 at 13–14.

[47] *See id.* at 16.

In response, Bard contends that because the claims at issue in the '022 Patent require a "radiopaque identification feature" and the claims at issue in the '302 Patent require "radiopaque markings," the proposed claim limitations should be extended to include the terms "radiopaque markings" ('302 Patent) and "radiopaque identification feature" ('022 Patent).[48] Bard further argues that MedComp's proposed limitations "read the term 'radiopaque' completely out of the claims and therefore cannot be right."[49] If the term "radiopaque" is included, Bard maintains the claim limitations cannot be considered printed matter because the radiopacity of the marker/identification feature is merely a structural element, which makes the marker observable when viewed on X-ray, and does not specify the content of information.[50] Rather, the radiographic marker element "merely claims a technological way to convey information subcutaneously."[51]

Similarly, Bard argues the claim limitation concerning the '615 Patent—the structural feature identifying the port as being power injectable—is also not subject to the printed matter doctrine because the claimed structural feature is not directed to the content of information.[52] It is merely the means of conveying the information, and "[t]he fact that it eventually is used for identification does not make it any less of a structural feature."[53]

Both parties' arguments rely heavily on the Federal Circuit's recent decision in the *Port II* action, *C R Bard v. AngioDynamics*.[54] In that case, the Federal Circuit considered three

[48] *See* Dkt. 458 at 15, 17.

[49] *See* Dkt. 531 (Bard's Responsive Construction Brief) at 10.

[50] *Id.* at 11.

[51] *Id.* at 13.

[52] *Id.* at 19.

[53] *Id.*

[54] 979 F.3d 1372 (Fed. Cir. 2020).

similar Bard patents claiming strategies for identifying a power injectable port.[55] Each of the asserted claims at issue "require[d] the presence of a radiographic marker identifying the claimed port as power injectable."[56] The district court had considered the claim limitations "radiographic letters" and "visually perceptible information,"[57] holding "that the asserted claims were invalid because they were directed to printed matter as ineligible subject matter and were not inventive."[58] On appeal, the Federal Circuit agreed that the printed matter doctrine applied.[59] Because the asserted claims contained printed matter that was not functionally related to the remaining elements of the claims, the Federal Circuit found that the printed matter was not entitled to patentable weight.[60] However, upon continuing its analysis concerning the subject matter eligibility of the claims under § 101, the Federal Circuit found that the asserted claims retained patent eligibility because, when viewed as a whole, none of the claims were solely directed to the printed matter.[61]

Here, the parties disagree about the scope and meaning of the Federal Circuit's printed matter analysis in the *AngioDynamics* decision. Bard asserts "the Federal Circuit gave patentable weight to the radiopaque markers while separately holding that the content of the

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[55] *Id.* at 1375.

[56] *Id.*

[57] Prior to trial, the district court requested a report and recommendation from Magistrate Judge Fallon as to whether the terms "radiographic letters" and "visually perceptible information" were entitled to patentable weight under the printed matter doctrine. Judge Fallon found that the limitations were directed to the content of information and were not "functionally or structurally related" to the claimed ports, meaning the terms could not be entitled to patentable weight as they were printed matter. *See Bard Peripheral Vascular, Inc. v. AngioDynamics, Inc.*, No. CV 15-218-JFB-SRF, 2019 WL 1996022, at *3–6 (D. Del. Feb. 11, 2019). The district court adopted this recommendation. *AngioDynamics*, 979 F.3d at 1376.

[58] *AngioDynamics*, 979 F.3d at 1378 (citing *C R Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332, 337–41 (D. Del. 2019)).

[59] *Id.* at 1381–82.

[60] *Id.*

[61] *Id.* at 1381, 1383–84.

information the markers conveyed was printed matter."[62] Bard supports this argument by pointing to the Federal Circuit's language from the case stating, "we hold 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."[63]

MedComp disputes Bard's characterization of the *AngioDynamics* decision, arguing that even though the Federal Circuit afforded no patentable weight to an element of the claim, it went on to examine the claims "as a whole" in order to determine whether the claimed subject matter was patent eligible under § 101.[64] Specifically, MedComp contends that the "proper analysis [under the printed matter doctrine] is that the element that imparts information is not entitled to patentable weight when the claim is viewed as a whole."[65] Based on this reading of *AngioDynamics*, MedComp here contends that it is not "the abstract information imparted by the element (*i.e.*, that the ports are power injectable) that is denied patentable weight." Rather, it is "the element itself" (the radiopaque identifiers or the structural feature of the port) that should be given no patentable weight.[66] The claim should then be "evaluated as a whole to determine whether there exists any new and unobvious functional relationship between the shape or markings and the port."[67]

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[62] Dkt. 531 at 11.

[63] Dkt. 458 at 5 (quoting *AngioDynamics*, 979 F.3d at 1382). Bard also identifies a later statement from the Federal Circuit's Anticipation analysis, where the court stated, "[W]hen evaluating the novelty and non-obviousness of claims, we must assign no patentable weight to the non-functional printed matter in the claims, which in this case is the information that the claimed access ports are suitable for injection at the claimed pressure and flow rate." *See id.* (quoting *AngioDynamics*, 979 F.3d at 1384).

[64] Dkt. 527 at 5 (quoting *AngioDynamics*, 979 F.3d at 1381).

[65] *Id.* (emphasis omitted).

[66] *Id.* at 6 (emphasis omitted).

[67] *Id.*

Before engaging the two-step printed matter analysis, the court must first address two preliminary questions presented by the parties' disputes. First, should the word "radiopaque" be included in the claim language at issue in the '302 and '022 Patents when considering the printed matter doctrine? And second, is printed matter restricted solely to the content of the information conveyed, or does it also encompass the medium used to convey the information? The court will answer the questions in turn.

A. The Term "Radiopaque" Must be Included in the Claim Limitation Language at Issue

As an initial matter, the court reiterates the current procedural posture of this case. The parties completed claim construction briefing on April 2, 2021. If construction of some of the proposed terms could be dispositive of the invalidity and/or infringement issues, Local Patent Rule 6.2 also requires the parties to submit "any motion for partial summary judgment on that issue . . . at the same time the moving party files its Cross-Motion for Claim Construction." Because MedComp asserts that certain of its proposed claim constructions, if adopted by the Court, will render some of Bard's asserted patent claims invalid, MedComp concurrently filed the instant Motion for Partial Summary Judgment.

"Although the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter, claim construction is not an inviolable prerequisite to a validity determination under § 101."[68] When the "basic character of the claimed subject matter in dispute . . . is clearly evident to the Court . . . no further construction of the claims is required."[69] Here, it is clearly evident to the court that all of the '302, '022, and '615 Patent

[68] *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (citations omitted).

[69] *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat. Ass'n*, No. 12-2501 MAS TJB, 2013 WL 3964909, at *5 (D.N.J. July 31, 2013), *aff'd*, 776 F.3d 1343 (Fed. Cir. 2014).

claims at issue encapsulate the use of a feature—either a radiopaque marking/identifier or a structural feature including at least one concave side surface—which serves the purpose of conveying to a medical practitioner, subsequent to implantation, that the claimed access port is suitable for power injection. As such, the relevant claim terms at issue here, according to MedComp, are those that relate to the specific identification feature used in the claimed port: "markings" ('302 Patent), (2) "identification feature" ('022 Patent), and (3) "structural feature of the access port identifying the access port as being power injectable" ('615 Patent).

The court agrees with MedComp that these are the relevant terms to be considered. However, the court also agrees with Bard that "it cannot be right" to read the term "radiopaque" out of the proposed claim terms in the '302 and '022 Patents.[70] All of the asserted claims at issue in these two patents require a type of marking or identifier indicating that the claimed port is power injectable—but not just any type of marking or identifier. It must be "radiopaque," meaning that the marker/identifier is observable when viewed on X-ray after the port has been implanted in a patient's body. No other type of identifier is mentioned in the claims, and it would be erroneous for the court to omit the term "radiopaque" when construing these terms. Therefore, the court holds that the claim terms at issue for the '302 and '022 Patents are "radiopaque markings" and "radiopaque identification feature."

Because the court has not engaged in formal claim construction, "the Court must adopt a construction of the claims 'most favorable to the patentee[.]'"[71] Here, the court adopts Bard's

[70] Dkt. 531 at 10.

[71] *Content Extraction*, 2013 WL 3964909, at *5 (citing *Utramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1339–40 (Fed. Cir. 2013), *cert. granted, judgment vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 573 U.S. 942 (2014) (vacated on other grounds) ("At summary judgment, the district court may choose to construe the claims in accordance with this court's precedent, or if not it may choose to give a construction most favorable to the patentee, and to apply the usual rules pertaining to summary judgment from there, and still require clear and convincing evidence of ineligible subject matter.")).

proposed constructions as provided in Bard's Opening Claim Construction Brief: (1) "radiopaque identification feature" is "[a] feature that is opaque when viewed on an x-ray";[72] (2) "radiopaque markings" are "[m]arkings that are opaque when viewed on an x-ray";[73] and (3) "structural feature of the access port identifying the access port as being power injectable" is a "[s]tructural feature of the access port identifying that the claimed access port is power injectable."[74] However, the court makes clear that it is not adopting, at this time, Bard's contention that the printed matter doctrine does not apply to these terms. Such a determination requires further analysis.

As explained below, further claim construction is not required to resolve the portion of MedComp's Motion for Partial Summary Judgment directed to invalidity.

B. Printed Matter Encompasses the Medium Used to Convey Information

The roots of the printed matter doctrine date back to 1869 in *Ex Parte Abraham*, where the court found that coupons with various kinds of stamps and figures were not patentable subject matter.[75] The doctrine continued to evolve until the modern rule became fully developed in the 1931 case, *In re Russell*.[76] There, the court considered the claimed invention, which related to "improvements in indexes particularly to the indexing of names in directories," and held that "[t]he mere arrangement of printed matter on a sheet or sheets of paper . . . does not constitute any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ." [77]

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[72] Dkt. 531 at 10.

[73] *Id.*

[74] *Id.* at 17.

[75] *See Distefano*, 808 F.3d at 849 (citing *Ex Parte Abraham*, 1869 C.D. 59 (Comm.Pat.1869)).

[76] *Id.* (citing *In re Russell*, 18 C.C.P.A. 1184, 48 F.2d 668, 669) (1931)).

[77] *Id.* (quoting *Russell*, 48 F.2d at 669).

Since 1931, both the Federal Circuit and its predecessor court "have consistently limited the printed matter rule to *matter* claimed for its communicative content."[78] After *Russell*, the following matter has been found to be printed matter: *markings* on meat "arranged in a certain manner for the purpose of identifying the meat,"[79] an FDA *label* providing the dosage instructions for using a medical product,[80] a *label* instructing a patient to take a drug with food,[81] *instructions* on how to perform a DNA test,[82] *numbers* printed on a wristband,[83] *markings* on dice communicating whether a player has won or lost a wager,[84] and the *mental step* requiring a medical provider to weigh the benefit of treating neonatal patients with inhaled nitric oxide.[85] Although this is not an exhaustive list, it is clear that "[t]he common thread amongst all of these cases is that printed matter must be *matter* claimed for what it communicates."[86]

Here, Bard argues the Federal Circuit in *AngioDynamics* "made clear that the radiopaque markers themselves, as opposed to the identification information conveyed by the markers, are

[78] *Id.* (emphasis added).

[79] *In re McKee*, 20 C.C.P.A. 1018, 64 F.2d 379, 379–80 (1933).

[80] *See AstraZeneca*, 633 F.3d at 1064–65.

[81] *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) ("Although these 'printed matter' cases involved the addition of printed matter, such as written instructions, to a known product, we see no principled reason for limiting their reasoning to that specific factual context. Rather, we believe that the rationale underlying these cases extends to the situation presented in this case, wherein an instructional limitation is added to a method, as opposed to a product, known in the art.").

[82] *See In re Ngai*, 367 F.3d 1336, 1338–39 (Fed. Cir. 2004).

[83] *See In re Gulack*, 703 F.2d 1381, at 1384–85 (Fed. Cir. 1983) (holding that even though the claim included printed matter, the printed matter was still entitled to patentable weight because there was a functional relationship between the printed matter and its underlying substrate).

[84] *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018) ("The markings on Appellant's dice, however, constitute printed matter, as pointed out by the Board, and this court has generally found printed matter to fall outside the scope of § 101.").

[85] *Praxair*, 890 F.3d at 1033–34 ("Because claim limitations directed to mental steps may attempt to capture informational content, they may be considered printed matter lacking patentable weight . . . .").

[86] *Distefano*, 808 F.3d at 850 (emphasis added).

not printed matter."[87] Based on the Federal Circuit's own printed matter doctrine precedent, the court disagrees with this reading of the *AngioDynamics* decision.

As previously explained, "[t]he first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[88] The court must examine whether the limitation claims the content of information. However, because the parties in *AngioDynamics* agreed that the asserted claims included printed matter, the Federal Circuit's analysis at the first step was limited.[89] The Federal Circuit explained that "[e]ach claim requires one or more markers 'identifying' or 'confirming' that the implanted access port is 'suitable' either 'for flowing fluid at a rate of at least 1 milliliter per second through the access port' or 'for accommodating a pressure with the cavity of at least 35 psi,' or both."[90] The court then went on to confirm that "[t]hese elements are directed to the content of the information conveyed."[91] It is unclear from this statement exactly which elements the Federal Circuit was referring to, nor is it clear which specific claim limitation was being analyzed because the parties already conceded that the claims included printed matter.

As this court sees it, the real disagreement over printed matter in *AngioDynamics* occurred at the second step of the printed matter analysis. Bard argued that the printed matter in the claims was functionally related to the power injectable port because the information conveyed by the markers provided new functionality by making the port "self-identifying."[92] The Federal Circuit disagreed with Bard's argument, citing past precedent and explaining that

[87] Dkt. 458 at 5.

[88] *Distefano*, 808 F.3d at 848.

[89] *See AngioDynamics*, 979 F.3d at 1381.

[90] *Id.* at 1382.

[91] *Id.*

[92] *Id.*

"as early as the 1930s, our predecessor court recognized that the mere marking of products, such as meat and wooden boards, with information concerning the product, does not create a functional relationship between the *printed information* and the substrate."[93] Based on this explanation and the Federal Circuit's reliance on previous decisions regarding the printed matter doctrine, this court disagrees with Bard's assertion that the *AngioDynamics* decision stands for the proposition that, when applying the printed matter doctrine, the content of the information conveyed can be divorced from the medium used to convey the information.

Indeed, the first step of the printed matter analysis explicitly requires a court to determine whether the claim limitation in question *is directed to* the content of information. The claim limitation is the "*matter* claimed for its communicative content" and is therefore linked to the content of the information because it is the medium through which the information is conveyed.[94] And as the Federal Circuit in *AngioDynamics* further explained, the matter claimed for its communicative content is not strictly limited to "printed" material, but instead encompasses "the conveyance of information using *any medium*."[95] Based on this reasoning, the court holds that printed matter includes not only the information being conveyed but the matter used to convey the information.

Although there are obvious similarities between *AngioDynamics* and the instant case, the facts and procedural posture are different. Unlike in *AngioDynamics*, where Bard agreed the claims included printed matter, here Bard insists that the asserted claim limitations are not

[93] *Id.* (citations omitted) (emphasis added). The *AngioDynamics* court also explained that "[a] conclusion that mere identification of a device's own functionality for purposes of the printed matter doctrine would eviscerate our established case law that 'simply adding new instructions to a known product' does not create a functional relationship." *Id.* (citing *AstraZeneca*, 633 F.3d at 1065 (citing *Ngai*, 367 F.3d at 1339)).

[94] *Distefano*, 808 F.3d at 850 (emphasis added).

[95] *AngioDynamics*, 979 F.3d at 1381.

printed matter at all because the structures at issue, which convey information, are distinct from the information conveyed.[96] Having found that this argument is not supported by Federal Circuit precedent, the court will now analyze whether the printed matter doctrine applies to this case.

C. The Asserted Claim Limitations Are Printed Matter

As previously explained, the court employs a two-step process to determine whether a claim limitation in question is printed matter. "The first step in the printed matter analysis is determining whether the limitation in question is in fact directed toward printed matter."[97] Federal Circuit cases "establish a necessary condition for falling into the category of printed matter: a limitation is printed matter only if it claims the content of information."[98] If this condition is met, "the next step is to ascertain whether the printed matter is functionally related to its 'substrate.'"[99]

Here, the claim limitations in question are "radiopaque markings" ('302 Patent), "radiopaque identification feature" ('022 Patent), and "structural feature of the access port identifying the access port as being power injectable" ('615 Patent). Both the radiopaque markings and radiopaque identification feature, which are observable on X-ray following subcutaneous implantation, convey to a medical practitioner that the access port is power injectable.[100] The '615 Patent uses a "structural feature," which includes at least one concave side surface, allowing a medical practitioner to identify a power-injectable port after implantation.

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[96] Dkt. 458 at 17. ("MedComp again improperly conflates the structure conveying information with the information conveyed to advance its printed matter argument.").

[97] *Distefano*, 808 F.3d at 848.

[98] *Id.*

[99] *Praxair*, 890 F.3d at 1032.

[100] *See, e.g.*, Dkt. 457-1, JA-44 at 14:17–21; JA-108 at 15:16–21.

Bard argues the radiopaque marking and identification feature elements are structural elements that do not specify the content of information.[101] They are simply "marker[s] that [are] observable when viewed on X-ray and can be used to convey information about an implanted access port."[102] But this statement from Bard's Responsive Claim Construction Brief about the ability of the markers to convey information generally is at odds with Bard's argument in its Opposition to MedComp's summary judgment motion. There, Bard clarified that "Bard's patents claim power injectable access ports that are identifiable as such after implantation."[103] Specifically, "the '302 and '022 Patent claims require power injectable access ports with a 'radiopaque alphanumeric message' that is opaque to radiation, so it is visible on an x-ray and indicates that the assembly is power injectable."[104]

Bard makes a similar argument regarding the structural feature claimed in the '615 Patent. Bard contends the structural feature is not directed to the content of information because it is merely the means used to convey information, and it is improper for the court to read a function into the structural element.[105] Yet, in its Opposition to summary judgment, Bard itself gives a function to the structural element, explaining that "[t]he '615 Patent claims a power injectable port with a structural feature—at least one concave side surface—that *identifies the port as power injectable*."[106]

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[101] *See* Dkt. 531 at 11.

[102] *Id.*

[103] Dkt. 534 at 2.

[104] *Id.* at 35 (citing *C.R. Bard v. AngioDynamics, Inc.*, 748 Fed. App'x. 1009, 1012) (Fed Cir. 2018) (internal quotation marks omitted)).

[105] Dkt. 531 at 19.

[106] Dkt. 534 at 36 (emphasis added).

Examining the claim language and reviewing Bard's own statements, it is evident that the claim limitations in question are directed to and claim the content of the information that a subcutaneously implanted port is suitable for power injection. The fact that the identification features at issue are a "technological way to convey information subcutaneously"[107] does not change this conclusion. Whether or not the limitations are technological structural features of the access ports, their sole function is to convey the information that the port is power injectable. Accordingly, the court finds that the claim limitations in question are printed matter.

Having so found, the court must proceed to the second step in the printed matter analysis and determine whether the printed matter should nevertheless be given patentable weight. In doing so, the court must "read the claim as a whole, considering each and every claim limitation."[108] Printed matter is only given patentable weight "if the matter is functionally or structurally related to the associated physical substrate[.]"[109]

Bard makes no argument that the radiopaque markers/identifiers and structural feature are functionally related to the underlying power injection port. And MedComp's argument against a functional relationship relies on the Federal Circuit's holding in *AngioDynamics* that "mere identification of a device's own functionality" is not "sufficient to constitute new functionality for purposes of the printed matter doctrine."[110]

Here, the court finds there is no functional relationship between the printed matter and the underlying power-injectable access port upon which it is printed. The printed matter does not change how the port works once it is implanted, it does not affect whether the port is capable of

[107] Dkt. 531 at 13.

[108] *Distefano*, 808 F.3d at 848.

[109] *Id.* at 851.

[110] Dkt. 459 at 15 (citing *AngioDynamics*, 979 F.3d at 1382).

power injection, and it does not interrelate with the port to produce a new and useful product. In other words, "the printed matter in no way depends on the [port], and the [port] does not depend on the printed matter. All that the printed matter does is [add a subcutaneous identifier to] an existing product."[111] For this reason, the court finds that the claim limitations in question are printed matter not entitled to patentable weight.

This means the court must address MedComp's argument that because the claim limitations in question are printed matter, MedComp is entitled to summary judgment of invalidity for all the asserted claims in which the limitations appear. The term "radiopaque identification feature" appears in asserted independent claims 1 and 10, and asserted dependent claims 3, 5, 8, and 9 of the '022 Patent; the term "radiopaque markings" appears in asserted independent claim 10 of the '302 Patent; and the term "structural feature . . ." appears in asserted independent claim 8 of the '615 Patent. However, rather than limit the validity analysis to only these claims, the court will expand its analysis to include all the remaining asserted independent and dependent claims in the '302 and '022 Patents. These include asserted independent claims 1, 5, and 8, and asserted dependent claims 3, 4, 6, and 7 of the '302 Patent, and asserted dependent claims 12 and 14 of the '022 Patent.

The reasons for the court's inclusion of the remaining claims are manifold. In conducting the printed matter analysis, the court naturally reviewed the specifications and all claim language from the asserted patents. In doing so, it became clear to the court that all the asserted claims contained limitations similar to the claim limitations the court has already found to be printed matter. For example, within the '302 Patent, independent claim 1 requires "radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is

[111] *Ngai*, 367 F.3d at 1339.

power injectable when an X-ray of the patient is taken after implantation";[112] independent claim 5 requires "a radiopaque alphanumeric message observable through interaction with X-rays . . . and the alphanumeric message indicating that the assembly is power injectable;[113] and independent claim 8 requires "a radiopaque alphanumeric message . . . identifying the venous access port assembly as suitable for power injection."[114] The various dependent claims in both patents incorporate the port assembly described in the independent claims, including any radiopaque markings/messages and merely specify where or how such markings/messages are displayed.[115]

It is clear from the cited claim language that the radiopaque alphanumeric characters/messages serve the same purpose as the radiopaque markings/identification features: to convey to a medical practitioner, through a feature that is opaque to X-rays subsequent to implantation, that the port in question is power injectable. Having already resolved the question whether the printed matter doctrine applied to similar claim limitations, it would be illogical and tremendously inefficient for the court to ignore the obvious presence of printed matter in the other asserted claims. The radiopaque alphanumeric characters/messages in the remaining asserted claims are similarly directed to the content of information with no functional relationship to the underlying access port and constitute printed matter.

Moreover, the court is cognizant that, due to Local Patent Rules 4.1(b) and 6.2, the parties were artificially constrained as to what they could argue at the summary judgment stage.

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[112] Dkt. 457-1, JA-44 at 12:64–67.

[113] *Id.* at 13:14–18.

[114] *Id.* at 14:5–10.

[115] *See id.* at 13:3–7, 13:19–22; JA-108 at 16:13–14, 16:18–20. Although dependent claim 14 of the '022 Patent does not specify how or where the radiopaque identification feature is displayed, it incorporates the port assembly of independent claim 10, which includes a radiopaque identification feature on the bottom surface of the port.

Local Rule 4.1(b) restricts parties to no more than ten terms or phrases that may be presented to the court for claim construction. If the parties cannot agree on ten terms, as here, then five terms are allocated to the plaintiff and five to the defendant.[116] The parties must then decide how to allocate their five terms to address the most significant arguments and issues from their prospective. And under LPR 6.2, "[w]henever construction of a term may be dispositive of an issue, any motion for partial summary judgment must be filed at the same time the moving party files its Cross-Motion for Claim Construction." On its face, LPR 6.2 contemplates summary judgment based on the limited number of construed terms offered by the parties. Yet because the parties do not have the benefit of the court's construction of the proposed terms at this stage, they are required to file their motions for summary judgment without knowing how to precisely tailor their arguments. Here, the Local Patent Rules effectively prevented the parties from making more complete printed matter doctrine arguments.

Although the parties have not briefed the question of printed matter in all the asserted claims, the court finds that it is not necessary for them to do so as the arguments at issue will be identical to those already briefed by the parties. To conserve time and judicial resources,[117] the court holds that the printed matter doctrine applies to all the asserted claims in the '302, '022, and '615 Patents and will include them all in the following invalidity analysis.

II. Subject Matter Eligibility

The Patent Act, under 35 U.S.C. § 101, defines patent-eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful

[116] *See* LPR 4.1(b).

[117] *See I/P Engine, Inc. v. AOL Inc.*, 576 F. App'x 982, 996 (Fed. Cir. 2014) (Mayer, J., concurring) ("From a practical perspective, there are clear advantages to addressing section 101's requirements at the outset of litigation. Patent eligibility issues can often be resolved without lengthy claim construction, and an early determination that the subject matter of asserted claims is patent ineligible can spare both litigants and courts years of needless litigation.").

improvement thereof." However, the Supreme Court has "long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable."[118] The Federal Circuit has confirmed that "where printed matter, irrespective of the material upon which it is printed, is the sole feature of alleged novelty, it does not come within the purview of [§ 101], as it is merely an abstract idea, and, as such, not patentable."[119]

Courts must "tread carefully" when considering whether a § 101 exception to patentability applies because "[a]t some level, 'all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'"[120] Therefore, "an invention is not rendered ineligible for patent simply because it involves an abstract concept."[121] Such concepts remain eligible for patent protection if their application is directed "to a new and useful end."[122] To distinguish patents that claim abstract ideas from those that claim patent-eligible applications of those ideas, the Supreme Court has set forth a two-step framework for determining subject matter eligibility under § 101. This is known as the *Alice* inquiry.[123] At *Alice* step one, a court must decide whether the claims at issue, in their entirety, are directed to ineligible subject matter, such as an abstract idea.[124] "If not, the inquiry ends."[125] But if the claims are directed to an abstract idea, the court must then analyze the claims—both individually

[118] *Alice Corp. Pry. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

[119] *See AngioDynamics*, 979 F.3d at 1383 (citing *In re McKee*, 75 F.2d 991, 992 (C.C.P.A 1935)).

[120] *Alice*, 573 U.S. at 217 (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012)).

[121] *Id.*

[122] *Id.* (internal quotation marks and citation omitted).

[123] The framework was first established in *Mayo*, but it was in *Alice* where the Supreme Court distilled *Mayo's* analysis into a distinct two-step process. *See Alice*, 573 U.S. at 217 (discussing *Mayo*, 566 U.S. at 77–82).

[124] *See Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 909 (Fed. Cir. 2017) (citing *Alice*, 573 U.S. at 217).

[125] *Id.* (citations omitted).

and as an "ordered combination"—under *Alice* step two to determine whether they contain an "inventive concept" sufficient to "transform the nature of the claim into a patent-eligible application."[126]

Although the printed matter doctrine's "underlying rationale is in subject matter eligibility" under § 101, courts have typically applied the doctrine "in analyzing other patentability requirements, including novelty under 35 U.S.C. § 102 and nonobviousness under 35 U.S.C. § 103."[127] However, in *AngioDynamics*, the Federal Circuit confirmed that "a patent claim as a whole can be deemed patent ineligible" when a court analyzes a claim containing printed matter under the *Alice* inquiry.[128] But before a court may proceed to the *Alice* framework, the Federal Circuit added a preliminary inquiry for claims involving printed matter: "a claim may be found patent ineligible under § 101 on the grounds that it is [1] directed solely to non-functional printed matter and [2] the claim contains no additional inventive concept."[129] Following this directive, the court will now analyze the claims at issue here under what the court will refer to as the *AngioDynamics* framework.

A. The Claims at Issue are Directed Solely to Non-Functional Printed Matter and Contain No Additional Inventive Concept

The nearly identical specification language in the background section of the '302 and '615 Patents describes the purpose of conventional access ports—that they "provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures"[130]—and their typical construction—a housing assembly, a septum, a reservoir, and

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[126] *See Alice*, 573 U.S. at 217–18.

[127] *Praxair*, 890 F.3d at 1032 (citations omitted); *see also AngioDynamics*, 979 F.3d at 1383.

[128] *AngioDynamics*, 979 F.3d at 1383.

[129] *Id.*

[130] Dkt 457-1, JA-38 at 1:13–15; JA-148 at 1:17–19.

an outlet of the housing that communicates with a catheter which access a vein.[131] The specifications go on to explain that "once an access port is implanted, it may be difficult to determine the model, style, or design of the access port."[132] Therefore, "it would be advantageous to provide an access port which provides at least one identifiable characteristic that may be sensed or otherwise determined subsequent to subcutaneous implantation of the access port."[133] Likewise, the specification language of the '022 Patent also "relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient."[134] It is clear from this language that the sole motivation of the patents at issue is providing some type of identifiable feature that communicates information about the underlying access port.

Following this general language, the claim language in each of the asserted patents then goes on to recite with specificity the exact type of identifiable feature and the exact information being communicated about the port in question. All the claims at issue in the '302 and '022 Patents require a type of radiopaque identifier conveying to a medical practitioner that the implanted port is power injectable. And the claim at issue in the '615 Patent requires a structural feature with at least one concave side, which also conveys that the implanted port is suitable for power injection.

When each claim is read as a whole, the focus of the claimed advance is using the above-named identifying features, in conjunction with an already known and typically constructed access port, to convey the information that the access port is power injectable. Bard disputes that

[131] *See id.* JA-38 at 1:20–24; JA-148 at 1:24–28.

[132] *Id.* JA-38 at 1:48–50; JA-148 at 1:52–54.

[133] *Id.* JA-38 at 1:54–57; JA-148 at 1:58–61.

[134] *Id.* JA-102 at 3:31–34.

the ports described in the asserted claims are typical or use conventional features, contending that each of the claims require a power injectable port, which was not a conventional feature as of the priority date of Bard's patents.[135] This argument is unpersuasive.

The various asserted claim language merely describes venous access port assemblies, including a housing or body with an outlet, a needle-penetrable septum, and a reservoir or cavity. There is nothing in the language of any of the asserted claims to specify what about these conventional features makes them capable of power injection. Bard's argument attempts to shift the focus away from the stated purpose of the asserted claims—identifying power-injectable ports subsequent to implantation—to the purported novelty of power-injectable ports. The court will not countenance this argument.

At the core of each of the asserted claims at issue here is the basic idea of using a specific type of identifier to convey information that a port is capable of power injection. The addition of merely novel yet nonfunctional printed matter identifiers does not change the fact that the focus of the claimed advance is solely on the content of the information conveyed. Any novelty in the implementation of this idea, through radiopaque features or concave surfaces, "is a factor to be considered only in the second step of the *Alice* analysis."[136] If the court were to find otherwise, it would undermine the rationale underlying the printed matter doctrine, which "guard[s] against

[135] *See* Dkt. 534 at 6.

[136] *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715 (Fed. Cir. 2014).

attempts to monopolize the conveyance of information using any medium."[137] Accordingly, the court holds that the claims at issue are directed solely to non-functional printed matter. [138]

At the second step of the *AngioDynamics* framework, the court finds that the claims at issue contain no additional inventive concept beyond the claimed printed matter. As explained above, all the asserted claims recite only the assembly of a typical venous access port, including the conventional and known features described in the specification, coupled with a printed matter identifier conveying that the port is power injectable. Beyond the printed matter, there are no other elements that could be considered "inventive."

Having found that the claims at issue are directed solely to non-functional printed matter and contain no additional inventive concept, the court will proceed to the two-step *Alice* inquiry. Before doing so, however, the court must address Bard's argument that if the court were to find the identifiers at issue are printed matter, then the court cannot consider them in its validity analysis.[139] The court disagrees. When a court finds that a claim contains printed matter, it simply means that the printed matter is not given any patentable weight and may not be a basis for distinguishing prior art.[140] This is a concern when conducting § 102 novelty or § 103

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[137] *AngioDynamics*, 979 F.3d at 1381; *see also King*, 616 F.3d at 1279 ("The rationale behind this line of [printed matter doctrine] cases is preventing the indefinite patenting of known products by the simple inclusion of novel, yet functionally unrelated limitations."); *Ngai*, 367 F.3d 1336, 1339 (explaining that the court will not allow a party to continue patenting a product indefinitely simply because the party added a new instruction sheet to the already known product).

[138] The court recognizes that Federal Circuit decisions in the realm of patent law are binding authority, and the *AngioDynamics* decision is no exception to this rule. The court is also cognizant that this holding may appear in tension with the Federal Circuit's holding in *AngioDynamics* concerning whether similar claims are directed solely to printed matter. Crucially, the evidence and arguments before this court differ substantially from the evidence and arguments presented in *AngioDynamics*. Moreover, the Federal Circuit's decision in *AngioDynamics* provides this court and these parties the benefit of a clear framework for evaluating these issues that was not available to the trial court or the parties in *AngioDynamics* prior to the Federal Circuit's decision. At least in this court's view, the significant differences between the records compel a different result.

[139] *See* Dkt. 531 at 12. Bard argues that the Federal Circuit found the radiopaque markers in *AngioDynamics* were not printed matter because, otherwise, "they would not be entitled to patentable weight, and the Federal Circuit would not have considered them in its validity analysis."

[140] *See Distefano*, 808 F.3d at 848.

nonobviousness analyses. But determining whether a claim is directed to patent eligible subject matter under § 101 is a different matter. A validity analysis concerning whether a claim is directed to statutory subject matter is a "threshold test"[141] that "must precede the determination of whether that discovery is, in fact, new or obvious."[142] As such, "[t]he novelty and nonobviousness of the claims under §§ 102 and 103 does [sic] not bear on whether the claims are directed to patent-eligible subject matter under § 101."[143] The court must therefore look to the claim language in its entirety, including the printed matter, when conducting a validity analysis.[144]

B. The *Alice* Inquiry

"The validity of asserted claims under § 101 is a 'threshold inquiry' for the court to decide as a matter of law."[145] As previously explained, when determining subject matter eligibility under § 101, courts must follow the two-step framework established by the Supreme Court in *Alice*. "[A] claim falls outside § 101 where (1) it is directed to a patent-ineligible concept, *i.e.*, a law of nature, natural phenomena, or abstract idea, and (2), if so, the particular elements of the claim, considered both individually and as an ordered combination, do not add enough to transform the nature of the claim into a patent eligible application."[146] The first step of the inquiry examines "the focus of the claims, their character as a whole," and the second step

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[141] *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) ("The § 101 patent-eligibility inquiry is only a threshold test.").

[142] *Parker v. Flook*, 437 U.S. 584, 593 (1978).

[143] *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC,* No. CV 14-1006-RGA, 2016 WL 4373698, at *4 (D. Del. Aug. 15, 2016), *aff'd*, 874 F.3d 1329 (Fed. Cir. 2017).

[144] *See Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1337 (Fed. Cir. 2017) ("Under *Alice* step one, the claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter.") (internal quotation marks and citation omitted)).

[145] *Two-Way Media*, 2016 WL 4373698, at *3.

[146] *Elec. Power Grp., LLC v. Alston S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (citing *Alice*, 573 U.S. at 217–18) (internal quotation marks omitted).

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looks "more precisely at what the claim elements add—specifically, whether . . . they identify an inventive concept in the application of the ineligible matter to which (by assumption at stage two) the claim is directed."[147]

1. *Alice* Step One

Under *Alice* step one, the court must "consider the claims in their entirety to ascertain whether they are directed to patent eligible subject matter."[148] Here, all the asserted claims are directed to using a specific identifier—either a radiopaque identifier or a structural element including at least one concave side—to communicate information to a medical practitioner that the access port in question is power injectable subsequent to implantation.

This case is similar to the Federal Circuit's recent decision in *Secured Mail*. There, the Court analyzed multiple patents involving "methods whereby a sender affixes an identifier, [an Intelligent Mail Barcode, a QR code, or a Personalized URL], on the outer surface of a mail object . . . before the mail object is sent."[149] Once the object is mailed, "[c]omputers and networks are used to communicate the information about the mail object's contents and its sender after the mail object is delivered."[150] The Court observed the claims were "not directed to an improvement in computer functionality," nor were they "directed to a new barcode format [or] an improved method of generating or scanning barcodes."[151] There was also "no description of how the unique identifier was generated."[152] The Federal Circuit ultimately concluded the

[147] *Id.* (internal quotation marks and citations omitted).

[148] *Secured Mail*, 873 F.3d at 909.

[149] *Id.* at 907.

[150] *Id.*

[151] *Id.* at 910.

[152] *Id.*

methods asserted in the claim language were directed solely "to the abstract process of communicating information about a mail object using a personalized marking."[153]

The same is true here. All the asserted claim language from the three patents at issue requires an identification feature that is incorporated into the underlying access port, which then communicates information about the port's capability to withstand power injection. The claims are not directed to an improvement in port technology—the port will function in exactly the same manner whether the identifier is present or not—and there is no description in the claim language describing how the radiopaque identifiers or concave side surfaces are generated. The claims are also void of any discussion of the X-ray technology used to view the radiopaque identifiers after implantation of the port, meaning the claims are not directed to determining if certain radiopaque identifiers or their placement on the port improves their visibility when subject to X-ray.

The specification language in the '302 and '615 Patents alludes to the difficulty of determining the model of the access port once it has been implanted and states that "such uncertainty may be undesirable, at least for replacement timing purposes, among other reasons."[154] The specification then goes on to explain that "it would be advantageous to provide an access port" with "at least one identifiable characteristic" that may be sensed or determined following implantation of the port.[155] But this is not enough to render the subject matter of the asserted claims patent eligible. Not only is this problem-solving language not included in any of

[153] *Id.* at 911.

[154] *See* Dkt. 457-1, JA-38 at 1:48–51; JA-148 at 1:52–55.

[155] *Id.* JA-38 at 1:54–57; JA-148 at 1:58–61.

the asserted claims, but the Federal Circuit has also clarified that "[t]he fact that an identifier can make a process more efficient . . . does not necessarily render an abstract idea less abstract."[156]

The Federal Circuit explicitly held in *Secured Mail* that the process of communicating information using a marking or identifier that does not functionally improve any aspect of the underlying object or identification process is an abstract idea not directed to patent eligible subject matter.[157] Because each asserted claim at issue here requires the use of an identifier to communicate information about the power injectability of the underlying port and provides no functional improvement to the port itself or the X-ray technology used to view the radiopaque identifiers, the court finds the claims are directed to an abstract idea.

2. *Alice* Step Two

At *Alice* step two, a court must "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent eligible application."[158] The second step of the *Alice* inquiry "is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known in the industry."[159] "[W]hether a claim recites patent eligible subject matter is a question of law which may contain underlying facts."[160] Determining whether a claim element "is well-understood, routine, and conventional to a skilled

[156] *Secured Mail*, 873 F.3d at 910.

[157] *Id.* at 910–11.

[158] *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 78–79); *see also Electric Power*, 830 F.3d at 1354 (explaining that under *Alice* step two, a court must scrutinize the claim elements "microscopically" to determine whether there is anything in the claims to render their subject matter patent eligible).

[159] *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (internal quotation marks, internal alteration, and citations omitted).

[160] *Id.* at 1368.

artisan in the relevant field is a question of fact."[161] "Any fact . . . that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence."[162]

The court will begin the *Alice* step two analysis by scrutinizing the asserted claims in the '302 and '022 Patents before turning to the single asserted claim in the '615 Patent.

a. The Asserted Claims in the '302 and '022 Patents Do Not Contain an Inventive Concept

The specification for the '302 Patent explains that "the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient."[163] One example of the "information of interest" communicated by the identifiable feature is that the "access port may be correlative with the access port being power injectable."[164] The specification then describes one embodiment of an access port, in which "at least one identifiable feature may be perceived via x-ray or ultrasound imaging."[165] Likewise, the specification for the '022 Patent contains nearly identical language[166] and also teaches an embodiment where "at least one identifiable feature may be perceived via x-ray or ultrasound imaging."[167]

"The improvements in the specification, to the extent they are captured in the claims, create a factual dispute regarding whether the invention describes well-understood, routine, and

[161] *Id.*

[162] *Id.*

[163] Dkt. 457-1, JA-39 at 3:60–64.

[164] *Id.* at 4:5–10.

[165] *Id.* at 4:20–21.

[166] *See* Dkt. 457-1, JA-102 at 3:31–34, 42–44.

[167] *Id.* at 3:58–59.

conventional activities."[168] The court must therefore analyze the asserted claims "more microscopically"[169] to determine whether they capture the stated improvements.[170]

Here, the parties do not dispute that the alleged improvements to port identification are captured in the asserted claims. Indeed, it is clear from the claim language that each independent and dependent claim at issue requires the inclusion of some type of radiopaque identifier, perceivable via x-ray, conveying to a medical practitioner the information that the access port is power injectable. What the parties dispute is whether use of radiopaque identifiers "on implantable medical devices" was "well-understood, routine and conventional at the relevant time[.]"[171]

MedComp provides numerous pieces of evidence supporting its argument that radiopaque identifiers were well-understood, routine, and conventional to those skilled in the art of implantable medical devices. To begin, MedComp contends the "conventionality of radiopaque marking" can be found in Bard's own representations.[172] In an affidavit filed with the USPTO during the prosecution of the '302 Patent, a former Bard project engineer in the vascular access product area represented "that placement of a radiopaque marking on the surface of a port housing base was 'obvious to a person of ordinary skill in the art' and 'would have only involved ordinary creativity on behalf of the designer.'"[173]

Additionally, MedComp points to a 2001 news bulletin in Medical Industry Week, where Bard promoted the availability of its self-expanding nitinol biliary stent, which included

[168] *Berkheimer*, 881 F.3d at 1369.

[169] *Electric Power*, 830 F.3d at 1354.

[170] *Berkheimer*, 881 F.3d at 1369.

[171] *See* Dkt. 463 at 15.

[172] *Id.*

[173] *Id.* at 15–16 (citing APP-08081 at ¶ 27).

radiopaque marker technology to allow for better visualization following placement of the stent within a patient.[174] MedComp argues that Bard's representations before the USPTO, along with Bard's statements to the press, support a finding that use of radiopaque identifiers is not an inventive concept unique to Bard's access port technology.[175]

Beyond Bard's own representations, MedComp also cites several articles from medical journals and industry publications discussing the use of radiographic marking on implantable medical devices years before Bard's asserted patents were issued. Specifically, the articles discuss the use of radiopaque identifiers to permit identification of implantable defibrillators, provide easy tracking and precise positioning of implantable stents, and allow for the detection of stray surgical swabs and sponges in post-operative patients.[176] According to MedComp, this evidence is incontrovertible proof "that the use of radiographic marking on implantable medical devices was routine and conventional at the time of the asserted Bard patents."[177]

In response, Bard points to the Federal Circuit's *AngioDynamics* decision in *Port II* to argue that MedComp's purported evidence "is insufficient to establish lack of inventive concept at *Alice* step two."[178] In *AngioDynamics*, the Federal Circuit found that the claims at issue in *Port II* were not solely directed to non-functional printed matter, and thus were not directed to patent ineligible subject matter under *Alice* step one.[179] However, the Federal Circuit explained that even if it "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

[174] *Id.* at 16 (citing APP-037).

[175] *Id.*

[176] *See id.* at 17–18.

[177] *Id.* at 18.

[178] Dkt. 534 at 38.

[179] *AngioDynamics*, 979 F.3d at 1384.

two, that the use of a radiographic marker, in the 'ordered combination' of elements claimed, was not an inventive concept."[180]

As previously explained, determining if a claim element "is well-understood, routine, and conventional to a skilled artisan in the relevant field is a question of fact."[181] As this court reads it, the Federal Circuit in *AngioDynamics* essentially reviewed and rejected, based on the record there provided, the trial court's factual finding that use of radiographic markings was routine and conventional in the art at the relevant time. Both the trial court's ruling and the Federal Circuit's evaluation were undoubtedly constrained by the evidence and arguments presented by the parties. But this court does not have before it the same record AngioDynamics's generated in *Port II*. The evidence and arguments submitted here by MedComp are considerably different. This court can only consider in the context of the arguments presented by the parties whether MedComp's evidence is sufficient to show that the use of radiopaque identifiers was well-understood, routine, and conventional at the time of the asserted Bard patents. The court concludes the evidence establishes exactly that.

In reviewing MedComp's evidence, it is clear that the application of radiopaque identifiers to subcutaneous medical devices was well-understood, routine, and conventional within the implantable medical device industry long before Bard decided to add the identifiers to its power-injectable ports. Indeed, Bard was already utilizing the technology on its own implantable stent products.[182] And by its own admission in the *Port III* case pending before

[180] *Id.*

[181] *Id.*

[182] *See* Dkt. 463 at 16.

Judge Nielson in this court, "Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging."[183]

When analyzing the asserted claims individually, the use of a radiopaque identifier to convey information is not an inventive concept. Based on the evidence provided by MedComp, radiopaque identifiers were routinely used as information conveyors throughout the implantable medical device industry at the time of Bard's asserted patents. And when scrutinizing the asserted claims as an "ordered combination," the court still cannot find an inventive concept that transforms the claims into a patent-eligible application. Each of the claims begins with a typical access port made up of conventional features and then incorporates a radiopaque identifier into the port for the purpose of conveying its suitability for power injection. The addition of a non-functional radiopaque identifier to a known product is not an inventive concept. If the court were to hold otherwise, any medical device manufacturer would be able to add a radiopaque identifier to any commonly produced implantable medical product and—so long as they are the first to the patent office—claim a monopoly over an established product. Accordingly, the court finds that none of the asserted claims in the '302 and '022 Patents contain an inventive concept under *Alice* step two.

b. The Asserted Claim in the '615 Patent Does Not Contain an Inventive Concept

Identically to the specification for the '302 Patent, the specification for the '615 Patent explains that "the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable

[183] *See* Dkt. 593 (Memorandum Decision and Order Construing Disputed Claim Terms and Phrases) at 44, *C.R. Bard, Inc. et al. v. Medical Components, Inc.*, Case No. 2:17-cv-00754-HCN-DAO.

after the access port is implanted within a patient."[184] The '615 specification also teaches the "information of interest" communicated by the identifiable feature is that the "access port may be correlative with the access port being power injectable."[185] The specification then describes one embodiment of an access port, in which "at least one identifiable feature may be perceived by palpation (i.e., to examine by touch), by way of other physical interaction, or by visual observation."[186] This embodiment allows a "person of interest" to "touch or feel the access port through the skin to perceive at least one identifying characteristic thereof."[187]

Similar to its argument regarding the radiopaque identifiers in the '302 and '022 Patents, MedComp maintains here that the use of shape (referring to the required structural feature of one concave side surface in the asserted claim) is routine and conventional in the medical device field.[188] Bard does not respond to this argument. Rather, Bard advances in relation to the '615 Patent only an argument concerning *Alice* step one. Bard insists the focus of the claimed advance in the '615 Patent—a concave side that can be perceived by palpation after implantation—is not directed solely to content of the information conveyed but also to the means by which the information conveyed.[189] Having already rejected this argument in its preliminary inquiry to the *Alice* test, the court will not repeat here why that argument fails.

"When there is no genuine issue of material fact regarding whether the claim element or claimed combination is well-understood, routine, conventional to a skilled artisan in the relevant

[184] Dkt. 457-1, JA-149 at 3:62–65.

[185] *Id.* at 4:6–12.

[186] *Id.* at 4:17–19.

[187] *Id.* at 4:19–22.

[188] Dkt. 463 at 19.

[189] Dkt. 534 at 36.

field, this issue can be decided on summary judgment as a matter of law."[190] For the following two reasons, the court finds that the asserted claim in the '615 Patent does not contain an inventive concept.

First, the Federal Circuit has explained that to save a patent at *Alice* step two, "an inventive concept must be evident in the claims."[191] Here, Bard asserts only independent claim 8 of the '615 Patent. The claim language begins by describing the conventional features comprising the access port assembly, and then continues by requiring:

> at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

Although the specification of the '615 Patent describes an embodiment of an access port wherein an identifiable feature may be perceived by a person through touch, the asserted claim does not recite this alleged innovation. Indeed, the claim language completely fails to describe how a person may utilize the "one structural feature" to determine any identifying information about the port. "The main problem that [Bard] cannot overcome is that the *claim*—as opposed to something purportedly described in the specification—is missing an inventive concept."[192]

Second, the evidence presented by MedComp establishing the use of shape identifiers in the medical device field is persuasive. MedComp provides articles and charts from medical journals dating between 1969 to 2019, describing the use of shape to differentiate between the brand and type of implanted pacemakers.[193] While the articles do not address the innovation of

[190] *Berkheimer*, 881 F.3d at 1368.

[191] *Two-Way Media*, 874 F.3d at 1338.

[192] *Id.* (emphasis in original).

[193] *See* Dkt. 463 at 19–22.

using palpation in conjunction with the shape of the medical devices, it is clear that utilizing a device's shape to convey information is not a new concept. Consequently, in analyzing the asserted claim language under *Alice* step two, the court finds that claim 8 of the '615 Patent does not contain an inventive concept.

Because the claims at issue are directed to the ineligible abstract idea of communicating information and lack an inventive concept, the court holds that asserted claims 1, 3, 4, 5, 6, 7, 8 and 10 of the '302 Patent, asserted claims 1, 3, 5, 8, 9, 10, 12, and 14 of the '022 Patent, and asserted claim 8 of the'615 Patent are invalid under § 101.

CONCLUSION

For the foregoing reasons, Defendant's Motion for Partial Summary Judgment is GRANTED IN PART on the grounds of invalidity.[194]

SO ORDERED this 22nd day of July 2021.

BY THE COURT:

ROBERT J. SHELBY
Chief United States District Judge

[194] Dkt. 463.

Memorandum Decision And Order Certifying Claims Under Rule 54(b), dated November 4, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**MEMORANDUM DECISION AND ORDER CERTIFYING CLAIMS UNDER RULE 54(b)** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

Before the court are the parties' respective case management briefs concerning the most efficient way to proceed in this aged case.[1] Plaintiffs C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, Bard) contend the most efficient route is to certify for immediate appeal under Federal Rule of Civil Procedure 54(b) the court's recent Summary Judgment Orders,[2] which found all asserted patents in this case invalid.[3] Defendant Medical Components, Inc. (MedComp) argues conducting a bench trial on the issue of Bard's alleged inequitable conduct prior to appeal would be more efficient because the bench trial will resolve a potentially dispositive issue, and resolving the inequitable conduct issue first would allow all issues in the case to be appealed to the Federal Circuit together.[4] For the reasons explained below, the court

[1] Dkt. 743 (Bard's Opening Case Management Brief); Dkt. 744 (MedComp's Opening Case Management Brief).

[2] *See* Bard's Case Management Brief at 3.

[3] Dkt. 715-1 (Memorandum Decision and Order Partially Granting MedComp's Motion for Summary Judgment) (hereinafter Summary Judgment Order I); Dkt. 765 (Memorandum Decision and Order Granting Motion for Summary Judgment) (hereinafter Summary Judgment Order II).

[4] *See* MedComp's Case Management Brief at 1–2.

finds Bard's proposed course preferable, and certifies its Summary Judgment Orders for immediate appeal under Rule 54(b).

BACKGROUND AND PROCEDURAL HISTORY

The court will not recite at length the facts underlying this longstanding patent litigation. Briefly, Bard asserts three patents: U.S. Patent Nos. 7,785,302 (the '302 Patent); 7,947,022 (the '022 Patent), and 7,959,615 (the '615 Patent).[5] MedComp's counterclaim asserts U.S. Patent No. 8,021,324 (the '324 Patent).[6] The patents all relate to the radiopaque identification of subcutaneous access ports.[7]

On January 11, 2012, Bard filed the instant action against MedComp, alleging infringement of the '022, '302, and '615 Patents.[8] MedComp counterclaimed, alleging Bard infringed its '324 Patent.[9] On December 17, 2012, the case was stayed and administratively closed while the patents-in-suit underwent *inter partes* reexamination before the United States Patent and Trademark Office.[10] On October 4, 2019, the stay was lifted.[11] Since that time, the case has progressed as follows: (1) fact discovery commenced on March 30, 2020 and closed on February 8, 2021; (2) the parties completed claim construction briefing on April 2, 2021; and (3) the parties conducted a technology tutorial for the court on April 28, 2021.[12]

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[5] Dkt. 69 (Amended Complaint) ¶¶ 7–10.

[6] Dkt. 640 (Second Amended Answer and Amended Counterclaims) at 27–28.

[7] *See* Dkt. 2-1 (U.S. Patent No. 7,785,302); 2-2 (U.S. Patent No. 7,947,022); Dkt. 2-3 (U.S. Patent No. 7, 959,615); Dkt. 19-1 (U.S. Patent No. 8,021,324).

[8] Dkt. 2 (Complaint) ¶¶ 11–20.

[9] Dkt. 19 (Answer and Counterclaim) ¶¶ 33–35.

[10] *See* Dkt. 93 (Memorandum Decision and Order Administratively Closing Case).

[11] *See* Dkt. 161 (Order Reopening Case).

[12] *See* Dkt. 539 (Bard's Memorandum in Opposition to MedComp's Motion to Consolidate Cases) at 2–3 (summarizing procedural history).

On March 5, 2021, the parties filed Cross-Motions for Summary Judgment.[13] Bard argued in its Motion the '324 Patent must be invalidated because its PowerPort MRI was prior art.[14] MedComp argued in its Motion, *inter alia*, that it was entitled to summary judgment on the invalidity of Bard's asserted patents under the printed matter doctrine.[15]

On July 22, 2021, this court issued a Memorandum Decision and Order (Summary Judgment Order I) partially granting MedComp's Motion for Summary Judgment, specifically finding Bard's three asserted patents were invalid under the printed matter doctrine.[16] The court declined to consider MedComp's request for summary judgment on the grounds Bard had infringed MedComp's patent.[17]

On July 25, 2021, Bard moved to certify Summary Judgment Order I under Rule 54(b), arguing that immediate appeal of the patents' invalidity would be efficient given that Bard is asserting the same patents in concurrent litigation pending in other districts.[18] The court denied the 54(b) Motion without prejudice[19] in light of the discussion at a July 27, 2021 hearing, in which Bard was invited to move for summary judgment against MedComp's '324 Patent under the law of the case adopted in Summary Judgment Order I.[20] Bard took up that invitation, filing a second Motion for Summary Judgment on August 27, 2021.[21] The court granted that motion

[13] Dkt. 460 (Bard's First Motion for Summary Judgment); Dkt. 463 (MedComp's Motion for Summary Judgment).

[14] *See* Bard's First Motion for Summary Judgment at 17–29.

[15] See MedComp's Motion for Summary Judgment at 10–22.

[16] *See* Summary Judgment Order I.

[17] *See id.* at 1 n.1.

[18] Dkt. 718 (Bard's Motion to Certify Under Rule 54(b)) at 5–8.

[19] Dkt. 721 (Docket Text Order).

[20] *See* Dkt. 727 (Hearing Transcript) at 3:18–5:14.

[21] Dkt. 750 (Bard's Second Motion for Summary Judgment).

on November 3, 2021, finding the '324 Patent invalid in its Memorandum Decision and Order Granting Bard's Motion for Summary Judgment (Summary Judgment Order II).[22]

In the July 27 hearing, the parties were directed to submit case management briefs proposing the most efficient way to proceed.[23] Those briefs have now been filed. Bard contends that the court's Orders finding all of the asserted patents in this case invalid should be certified under Rule 54(b) for immediate appeal.[24] MedComp argues that the court should first hold a bench trial on its inequitable conduct claim, enabling appeal of all the issues in the case together after that trial is completed.[25]

Having considered these arguments, for the reasons explained below, the court concludes that the most efficient course will be to immediately certify for appeal under Rule 54(b) its Summary Judgment Orders finding invalidity, and to stay the case while the appeal is pending.

LEGAL STANDARD

Under 28 U.S.C. § 1295, the United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over "an appeal from a final decision of a district court of the United States . . . in any civil action arising under . . . any act of Congress relating to patents."[26] Because 28 U.S.C. § 1291 also limits the jurisdiction of the courts of appeals (other than the United States Court of Appeals for the Federal Circuit) to "final decisions of the district courts,"[27] the Federal Circuit applies principles of finality promulgated under § 1291 to determine whether a judgment

[22] Dkt. 765 (Summary Judgment Order II).

[23] See Dkt. 721 (Docket Text Order).

[24] Bard's Case Management Brief at 2–3.

[25] MedComp's Case Management Brief at 1.

[26] 28 U.S.C. § 1295(a)(1).

[27] 28 U.S.C. § 1291.

is final under § 1295.[28] A "final" decision is one that "ends litigation on the merits and leaves nothing for the court to do but execute the judgment."[29]

"[F]or a district court judgment to be appealable to [the Federal Circuit] under 28 U.S.C. § 1295(a)(1), the judgement must resolve all claims and counterclaims or make an express determination under Rule 54(b) . . . that there is no just reason for delay."[30] Rule 54(b) provides, in relevant part, that "[w]hen an action presents more than one claim for relief—whether as a claim, counterclaim, cross-claim, or third-party claim—or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines there is no just reason for delay."[31]

"Rule 54(b) was implemented to specifically 'avoid the possible injustice of delay[ing] judgment on a distinctly separate claim [pending] adjudication of the entire case.'"[32] In deciding whether to certify a claim under Rule 54(b), the district court "act[s] as a dispatcher," weighing the "historic" policy of preventing piecemeal appeals against the "equities involved."[33] "It is left to the sound discretion of the district court to determine the appropriate time when each final

[28] *See, e.g.*, *Alfred E. Mann Foundation for Scientific Research v. Cochlear Corp.*, 841 F.3d 1334, 1347 (Fed. Cir. 2016); *W.L. Gore & Assocs., Inc. v. Int'l Med. Prosthetics Research Assocs., Inc.*, 975 F.2d 858, 862 n.3 (Fed. Cir. 1992).

[29] *Gelboim v. Bank of America Corp.*, 574 U.S. 405, 409 (2015) (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945)); *see also W.L. Gore*, 975 F.2d at 863–64 (Fed. Cir. 1992) (holding district court's order finding patent invalid was final, appealable decision under § 1295).

[30] *Synchronoss Technologies, Inc. v. Dropbox, Inc.*, 987 F.3d 1358, 1365 (Fed. Cir. 2021).

[31] Fed. R. Civ. P. 54(b); *see also, e.g.*, *Int'l Elec. Tech. Corp. v. Hughes Aircraft Co.*, 476 F.3d 1329, 1331 (Fed. Cir. 2007) (cautioning that parties may only appeal to the Federal Circuit when a judgment is final or with a Rule 54(b) certification).

[32] *Alfred E. Mann Foundation*, 841 F.3d at 1347 (citing *Gelboim*, 574 U.S. at 409); *see also W.L. Gore*, 975 F.2d at 861 ("Rule 54(b) acknowledges the policy that in multiple claim actions 'some final decisions, on less than all of the claims, should be appealable without waiting for a final decision on all of the claims.'") (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 432 (1956)).

[33] *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980) (citing *Sears*, 351 U.S. at 435, 438).

decision in a multiple claims action is ready for appeal."[34] Rule 54(b) certifications should not "be granted routinely."[35] Accordingly, "[t]here are three prerequisites for invoking Rule 54(b): (1) multiple claims for relief or multiple parties must be involved; (2) at least one claim or the rights and liabilities of at least one party must be finally decided; and (3) the district court must find that there is no just reason for delaying an appeal."[36] The court will consider each prerequisite in turn.

ANALYSIS

I. The Summary Judgment Orders are Certified Under Rule 54(b)

Having found MedComp's '324 Patent invalid,[37] and having previously found Bard's '302, '022, and '615 Patents invalid,[38] the court has disposed of all claims relating to the validity of the asserted patents, leaving only MedComp's inequitable conduct claim. Rule 54(b) certification of the invalidity rulings is warranted because: (1) this case involves multiple claims and parties, (2) the summary judgment orders finding invalidity represent final decisions, and (3) there is no just reason for delaying appeal.[39]

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[34] *Id.*

[35] *Id.* at 10.

[36] *Alfred E. Mann Foundation*, 841 F.3d at 1347 (citing 10 Charles Alan Wright et al., Federal Practice and Procedure § 2656 (3d ed. 2016)).

[37] Summary Judgment Order II.

[38] Summary Judgment Order I.

[39] While the court will discuss all three necessary prerequisites for Rule 54(b) certification, it bears noting that the parties' case management briefing does not dispute the first and second prerequisites. Bard writes in its Opening Case Management Brief that "[t]here is no dispute that the Court's invalidity Summary Judgment Order disposed of/mooted all of Bard's claims against MedComp, leaving nothing left to do but to enter judgment on those claims." Dkt. 743 at 1. MedComp does not contest this. *See* Dkt. 744; Dkt. 758 (MedComp's Responsive Case Management Brief). The parties' Rule 54(b) arguments and counterarguments largely focus on the third prerequisite—that is, whether there is "no just reason for delaying appeal." The court assumes therefore the parties agree that the first and second prerequisites for Rule 54(b) certification are met in this case and will focus its analysis on the third prerequisite.

a. This Lawsuit Involves Multiple Claims

For Rule 54(b) certification to be appropriate, a case must involve multiple claims for relief or multiple parties.[40] A claim or counterclaim may be viewed as "a separable unit" suitable for certification under the rule.[41] The instant lawsuit involves multiple claims and counterclaims, each concerning the various patents at issue, and the parties seek relief under different theories involving distinct facts.[42] Specifically, Bard brings claims for infringement of the '302, '022, and '615 Patents.[43] MedComp brings counterclaims alleging the invalidity of the Bard Patents, infringement of the '324 Patent, and inequitable conduct.[44] The parties each seek damages based on the alleged patent infringement and attorneys' fees and costs.[45] Therefore, the first element for Rule 54(b) certification is satisfied.

b. The Summary Judgment Orders Represent a Final Decision

For Rule 54(b) certification to be appropriate, the decision resolving the claim or claims at issue must be final.[46] Additionally, "[c]ourts analyzing whether Rule 54(b) applies must focus on both the finality of the judgment and the separateness of the claims for relief."[47]

[40] *Alfred E. Mann Foundation*, 841 F.3d at 1347.

[41] 10 Charles Alan Wright et al., Federal Practice and Procedure § 2657 (4th ed.).

[42] *See Sears*, 351 U.S. at 436, 437, n.9 (discussing different theories of relief in multiple claims in the context of affirming a district court's Rule 54(b) certification).

[43] Dkt. 69 (Amended Complaint).

[44] Dkt. 640 (Second Amended Answer to Amended Complaint).

[45] *See* Amended Complaint at 12–13; Second Amended Answer at 50–51.

[46] *Alfred E. Mann Foundation*, 841 F.3d at 1347.

[47] *W. L. Gore*, 975 F.2d at 861–62 (citing *Sears*, 351 U.S. at 436).

Finality is a "statutory mandate and not a matter of discretion."[48] A district court may only certify judgments that are final under § 1291.[49] For purposes of Rule 54(b), an order is final if it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action."[50] Here, the Summary Judgment Orders finding the Bard Patents and the '324 Patent invalid under 35 U.S.C. § 101 represented final judgments on Bard's claims for infringement and MedComp's counterclaim for infringement because a finding that a patent is invalid represents a final decision in a patent enforcement action under § 1295.[51] Accordingly, the claims to be certified under Rule 54(b) are final.

In addition, a claim certified under Rule 54(b) must be separate from others in the same action.[52] Determining whether a claim is sufficiently separate falls within the district court's discretion and turns on factors such as: (1) "whether the claims under review were separable from the others remaining to be adjudicated" and (2) "whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals."[53]

Here, the claims are sufficiently separable from the remaining claims in the case. The Summary Judgment Orders left intact MedComp's claim alleging Bard engaged in inequitable conduct.[54] This claim is sufficiently separate and distinct from the Summary Judgment Orders,

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[48] *W.L. Gore*, 975 F.2d at 862 (citing *Sears*, 351 U.S. at 437) (applying § 1291 finality analysis to Federal Circuit jurisdiction under § 1295).

[49] *Id.*

[50] *Curtiss-Wright Corp.*, 446 U.S. at 7 (citing *Sears*, 351 U.S. at 436).

[51] *W.L. Gore*, 975 F.2d at 864 ("Because the infringement claim and several dipositive defenses were ruled upon [by the decision that the patent-in-suit was invalid] the district court's judgment was final.").

[52] *Id.* at 861–62.

[53] *W.L. Gore*, 975 F.2d at 862 (citing *Curtiss-Wright Corp.*, 446 U.S. at 8).

[54] *See* Dkt. 727 (July 27, 2021 Hearing Transcript) at 9:2–11:19 (discussing the outstanding inequitable conduct claim).

as it concerns Bard's conduct before the PTO and relies on a distinct set of facts and legal arguments.[55] Were there separate appeals of the Summary Judgment Orders and the inequitable conduct claim, the Federal Circuit would not need to decide the same issues more than once, as the appeal based on the '324 and Bard Patents' invalidity takes up the patents' relationship to the printed matter doctrine, unlike a hypothetical future appeal of the inequitable conduct claim, which concerns Bard's conduct before the PTO. These inquiries turn on different factual questions, legal questions, and would provide for separate recovery.

The Summary Judgment Orders finding invalidity of the patents represent final decisions that are sufficiently separable from the remaining claim in the case, meeting the second prerequisite for Rule 54(b) certification.

c. There is No Just Reason for Delaying Appeal

A district court must make a finding there is "no just reason for delay" and "explain why judicial economy supports its . . . determination" in certifying a claim for immediate appeal under Rule 54(b).[56] In this evaluation, "a district court must take into account judicial administrative interests as well as the equities involved."[57] Both interests—intertwined in this case—are served by permitting immediate appeal of the Summary Judgment Orders finding the patents are invalid.

Bard argues there is no just reason to delay appeal because immediate appeal of the patents' invalidity would allow resolution of the "tension" between the Summary Judgment Orders and Federal Circuit case law, and conserve judicial resources by obtaining the Federal

[55] *See* Second Amended Answer at 30–50 (detailing factual allegations concerning Bard's alleged inequitable conduct that are distinct from the facts surrounding the specifications of the patents-in-suit for purposes of the infringement claims and counterclaims).

[56] *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332, 1336 (Fed. Cir. 2017).

[57] *Curtiss-Wright*, 446 U.S. at 8.

Circuit's guidance on the validity of the Bard Patents in this and other cases.[58] MedComp responds that Rule 54(b) certification prior to a bench trial on inequitable conduct is inefficient and will lead to piecemeal appeals.[59] The court agrees with Bard.

As an initial matter, the validity of the asserted patents is at the heart of this case. Having found that none of the asserted patents in this case are valid, there is nothing left to decide on the merits of Bard's infringement claims, MedComp's infringement counterclaim, nor any of MedComp's defenses to infringement. Waiting for conclusion of a bench trial on the inequitable conduct issue would cause significant delay in resolving an issue central to most of the claims in this case. That delay will also have ripple effects considering pending litigation in other districts and the need to clarify an important doctrinal question.

And Rule 54(b) certification will also give the Federal Circuit an opportunity to further address the application of its patent eligibility case law as it relates to 35 U.S.C. § 101 and the printed matter doctrine.[60] As the court acknowledged in a hearing following Summary Judgment Order I, the finding that the Bard Patents are invalid is in "some tension" with how Judge Howard Nielsen interpreted the Federal Circuit's recent holding in another case Bard is litigating in this district.[61] As this doctrine affects a number of patents, and the law in this area has continued to evolve,[62] immediate appeal would enable litigants and courts to more quickly receive guidance from controlling authority that will assist with resolving disputes.

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[58] Bard's Opening Case Management Brief at 3–4.

[59] MedComp's Opening Case Management Brief at 1–2.

[60] Bard's Opening Case Management Brief at 3–4 ("There is much uncertainty here that requires appellate resolution.").

[61] Dkt. 727 (July 27, 2021 Hearing Transcript) at 15:13; *see C.R. Bard, Inc. v. Medical Components, Inc.*, No. 2:17-CV-00754, 2020 WL 6902367, at *20–21 (D. Utah Nov. 24, 2020) (finding Bard's asserted patents valid under the printed matter doctrine).

[62] *See, e.g.*, *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 217–18, 221 (2014) (refining two-step test for patent eligibility when a patent concerns abstract ideas); *C R Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372,

Further, Rule 54(b) certification will avoid duplicative and potentially conflicting judgments in pending litigation in other districts.[63] Bard has asserted the same patents against two other companies.[64] Typically, this court's invalidity ruling would be issue preclusive in these cases,[65] but issue preclusion will not apply until the Summary Judgment Order becomes final.[66] Absent Rule 54(b) certification, the parties to the pending cases may have to relitigate the issue of the Bard Patents' validity, creating the possibility of conflicting judgments and additional appeals.

MedComp's primary argument against Rule 54(b) certification is that holding a bench trial on the issue of inequitable conduct before any appeal would allow all issues in this case to be appealed "in a single package," thereby preventing piecemeal appeals.[67] MedComp also asserts that "[a]n inequitable conduct bench trial is short and efficient and will not result in unreasonable delay."[68] MedComp further argues that if the '302 Patent is held unenforceable on the basis of inequitable conduct, "the continuations and continuations-in-part of the '302 Patent here and in the 2017 Litigation, will be rendered unenforceable in accordance with the doctrine of infectious unenforceability."[69] For that reason, MedComp asserts, "both invalidity and

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1381–82 (Fed. Cir. 2015) (using two-step inquiry to determine whether a claimed invention is directed toward printed matter).

[63] Bard's Opening Case Management Brief at 4.

[64] *See C.R. Bard, Inc. v. Smiths Medical ASD, Inc.*, No. 1:20-cv-01543-CFC (D. Del.); *C.R. Bard, Inc. v. AngioDynamics, Inc.*, No. 1:20-CV-01544-CFC (D. Del.).

[65] *See, e.g., Blonder-Tongue Labs, Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 334 (1971).

[66] *See, e.g., Vardon Golf Co. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1334 (Fed. Cir. 2002) (a "partial summary judgment was not an appealable final judgment" when it was not certified as "final under Rule 54(b)").

[67] MedComp's Responsive Case Management Brief (Dkt. 758) at 5.

[68] MedComp's Case Management Brief at 1.

[69] *Id.* at 3. The doctrine of infectious unenforceability applies when a patent rendered unenforceable by inequitable conduct causes other related patents in the same technology family to also be rendered unenforceable. *See id.* at 4 (citing *Therasense v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288–89 (Fed. Cir. 2011)).

inequitable conduct are potentially dispositive issues . . . [which] would benefit from a unified appeal."[70] Bard counters that holding a bench trial first would require claim construction, causing delay and violating Bard's Seventh Amendment right to have factual questions decided first by a jury.[71] Bard additionally disputes that finding the '302 Patent unenforceable would lead to others in its line being affected by the doctrine of infectious unenforceability.[72]

MedComp is correct that the inequitable conduct claim could provide an independent reason the Federal Circuit affirms the Bard Patents' invalidity. However, the Federal Circuit will have to consider the invalidity issues decided in Summary Judgment Order I and II in any of the following scenarios: (1) the Federal Circuit does not affirm a hypothetical finding of inequitable conduct following a bench trial, (2) a bench trial finds no inequitable conduct, or (3) either this court or the Federal Circuit finds that the doctrine of infectious unenforceability does not apply to the '022 and '615 Patents. Regardless of the outcome of the inequitable conduct bench trial, these possible scenarios suggest the Federal Circuit will likely take up the invalidity issue and, as previously discussed, the Federal Circuit's guidance on the invalidity issue is strongly desirable not just in this case but in other pending litigation.[73] Therefore, both the equities and judicial efficiencies counsel finding "no just reason for delay."

[70] MedComp's Responsive Case Management Brief at 5.

[71] Bard's Opening Case Management Brief at 6–13.

[72] Bard's Responsive Case Management Brief at 11–13.

[73] Similarly, MedComp is also correct that a holding the '302 Patent is unenforceable would have ripple effects across other litigation in which Bard asserts the '302 Patent (though again, the parties dispute whether a finding the ''302 Patent is unenforceable would cause other related Bard patents to be found unenforceable through the doctrine of infectious unenforceability). Regardless of the extent of this hypothetical unenforceability, this court's Orders finding all the asserted patents unenforceable under § 101 will certainly have ripple effects across any litigation asserting similar patents, and therefore, receiving the Federal Circuit's guidance on the validity of the patents-in-suit is critical.

More practically, even assuming *arguendo* that the court need not construe patent claims prior to a bench trial on inequitable conduct, and that the trial could be completed in only two to three days, the issue likely could not be resolved before next summer. Both the court's calendar and the ongoing pandemic would adversely impact the time to resolution. The court has confirmed first-place jury trial settings for cases in November, December, and January. The latter two are multiweek trials. This is in addition to the court's other work, including numerous fully briefed motions already set for hearing or awaiting a hearing date. Given its current docket, it is likely the court would need at least a couple months to provide its findings and conclusions even after a not-yet-scheduled bench trial could be completed.[74] And the concerning state of the pandemic in the District of Utah continues to present significant health risks (especially with evidentiary hearings) and impair the court's efficiency in many ways. Under these circumstances, withholding a Rule 54(b) certification likely would result in a ten-to-twelve-month delay in resolving patent validity issues important in several pending cases in multiple district courts. In light of these judicial administrative interests, certifying the Summary Judgment Orders for immediate appeal is the more efficient course.[75]

Thus, having considered the equities involved as well as the judicial administrative interests, the court finds there is "no just reason for delay" and that Rule 54(b) certification of the Summary Judgment Orders is appropriate.[76]

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[74] As Bard notes, expert discovery and pre- and post-trial motion practice could also take significant time, further delaying appeal. *See* Bard's Opening Case Management Brief at 9.

[75] *See* Dkt. 743-1 (Exhibit A to Bard's Opening Case Management Brief) (demonstrating that the median time from docketing date to decision in Federal Circuit cases decided on the merits is about thirteen months).

[76] Having certified the patent invalidity issue under Rule 54(b), the court does not reach the issue of whether holding the inequitable conduct bench trial prior to a jury trial on the infringement claims violates Bard's Seventh Amendment rights, nor does it decide whether claim construction would be necessary prior to an inequitable conduct trial.

II. The Case is Stayed Pending Appeal

Having certified the Summary Judgment Orders for immediate appeal under Rule 54(b), the proceedings in this action are stayed, and the case is administratively closed while the appeal is pending.[77] The parties are directed to submit status reports to the court every six (6) months concerning the progress of the appeal.

Finally, all currently-pending motions in the case are DENIED without prejudice. Should the case be remanded following consideration by the Federal Circuit, the parties may refile any motions remaining relevant to the litigation.

CONCLUSION

For the foregoing reasons, the court's prior summary judgment orders[78] in this case are certified for appeal under Rule 54(b), the case is STAYED and ADMINISTRATIVELY CLOSED pending appeal, and all pending motions are DENIED without prejudice.

SO ORDERED this 4th day of November, 2021.

BY THE COURT:

ROBERT J. SHELBY
United States Chief District Judge

[77] *See Landis v. N. Am.* Co., 299 U.S. 248, 254 (1936) (the district court has the power to stay proceedings pending before it as part of its inherent power to control its docket); *accord Cherokee Nation of Oklahoma v. United States*, 124 F.3d 1413, 1416 (Fed. Cir. 1997). The court recognizes MedComp's argument that a stay would be inefficient, *see* MedComp's Responsive Case Management Brief at 5, but notes the argument is the same as MedComp's opposition to Rule 54(b), namely, that waiting to try all issues in this case in one appeal would be most efficient. Having decided to certify the Summary Judgment Orders for immediate appeal, the court has determined staying the case will be most efficient to avoid the possibility of redoing work following a ruling from the Federal Circuit.

[78] Dkt. 715-1; Dkt. 765.

Rule 54(b) Judgment On Claims For Patent Infringement, dated November 5, 2021

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

C.R. BARD, INC., a New Jersey corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Plaintiffs, v. MEDICAL COMPONENTS, INC., a Pennsylvania corporation, Defendant.	**RULE 54(b) JUDGMENT ON CLAIMS FOR PATENT INFRINGEMENT** 2:12-cv-00032-RJS-DAO Chief District Judge Robert J. Shelby Magistrate Judge Daphne A. Oberg

On July 22, 2021, the court granted in part Defendant Medical Components, Inc.'s (MedComp) Motion for Summary Judgment,[1] finding all asserted claims of Plaintiff C.R. Bard, Inc. and Plaintiff Bard Peripheral Vascular, Inc.'s (collectively, Bard) three asserted patents invalid.[2] On November 3, 2021, the court granted Bard's Motion for Summary Judgment,[3] finding all asserted claims of MedComp's asserted patent invalid.[4]

The court subsequently issued a Memorandum Decision and Order expressly determining under Rule 54(b) of the Federal Rules of Civil Procedure that there is "no just reason for delay" and certifying the patent infringement claims and counterclaim for immediate appeal.[5]

[1] Dkt. 463.

[2] Dkt. 715-1 (Memorandum Decision and Order Granting in Part Motion for Summary Judgment) (finding claims 1, 3, 4, 5, 6, 7, 8, and 10 of the '302 Patent, 1, 3, 5, 8, 9, 10, 12, and 14 of the '022 Patent, and claim 8 of the '615 Patent invalid under 35 U.S.C. § 101).

[3] Dkt. 750.

[4] Dkt. 765 (Memorandum Decision and Order Granting Motion for Summary Judgment) (finding claims 1, 19, 20, 26, 39, 40, 41, and 42 of the '324 Patent invalid under 35 U.S.C. § 101).

[5] Dkt. 766 (Memorandum Decision and Order Certifying Claims Under Rule 54(b)).

Accordingly, the court hereby enters Judgment pursuant to Rule 54(b) as to Bard's claims for patent infringement[6] and MedComp's counterclaim for patent infringement.[7]

SO ORDERED this 5th day of November, 2021.

BY THE COURT:

ROBERT J. SHELBY
United States Chief District Judge

[6] Dkt. 69 (Amended Complaint) ¶¶ 11–51 (Bard's First, Second, and Third Causes of Action).

[7] Dkt. 640 (Second Amended Answer, Affirmative Defenses, and Amended Counterclaims) ¶¶ 63–74 (MedComp's Seventh Counterclaim).

U.S. Pat. No. 7,785,302

US007785302B2

(12) **United States Patent**
Powers

(10) **Patent No.: US 7,785,302 B2**
(45) **Date of Patent: Aug. 31, 2010**

(54) **ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS**

(75) Inventor: **Kelly B. Powers**, North Salt Lake, UT (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 1086 days.

(21) Appl. No.: **11/368,954**

(22) Filed: **Mar. 6, 2006**

(65) **Prior Publication Data**

US 2006/0247584 A1 Nov. 2, 2006

Related U.S. Application Data

(60) Provisional application No. 60/658,518, filed on Mar. 4, 2005.

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

(52) **U.S. Cl.** **604/288.02**

(58) **Field of Classification Search** 604/288.01, 604/288.02

See application file for complete search history.

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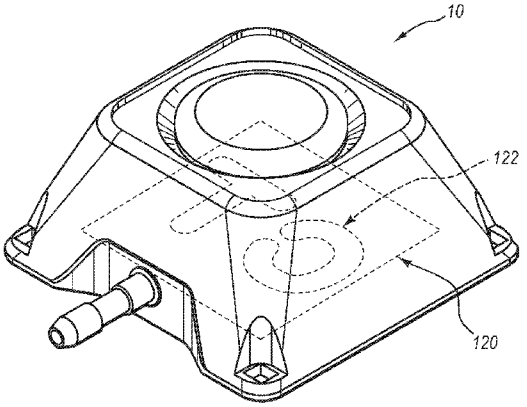
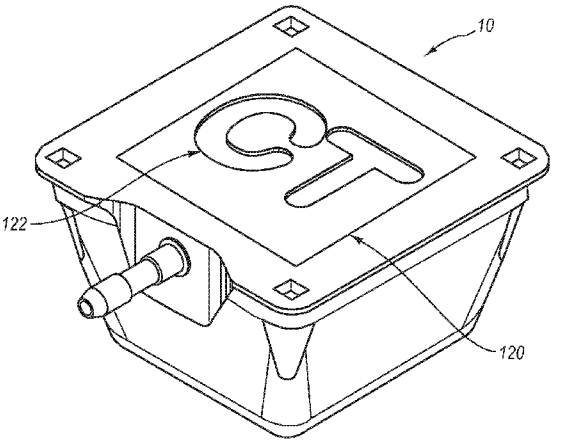
(57) **ABSTRACT**

An access port for subcutaneous implantation is disclosed. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, the access port may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation. Methods of identifying a subcutaneously implanted access port are also disclosed. For example, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted access port may be identified in response to perceiving the at least one feature.

10 Claims, 30 Drawing Sheets





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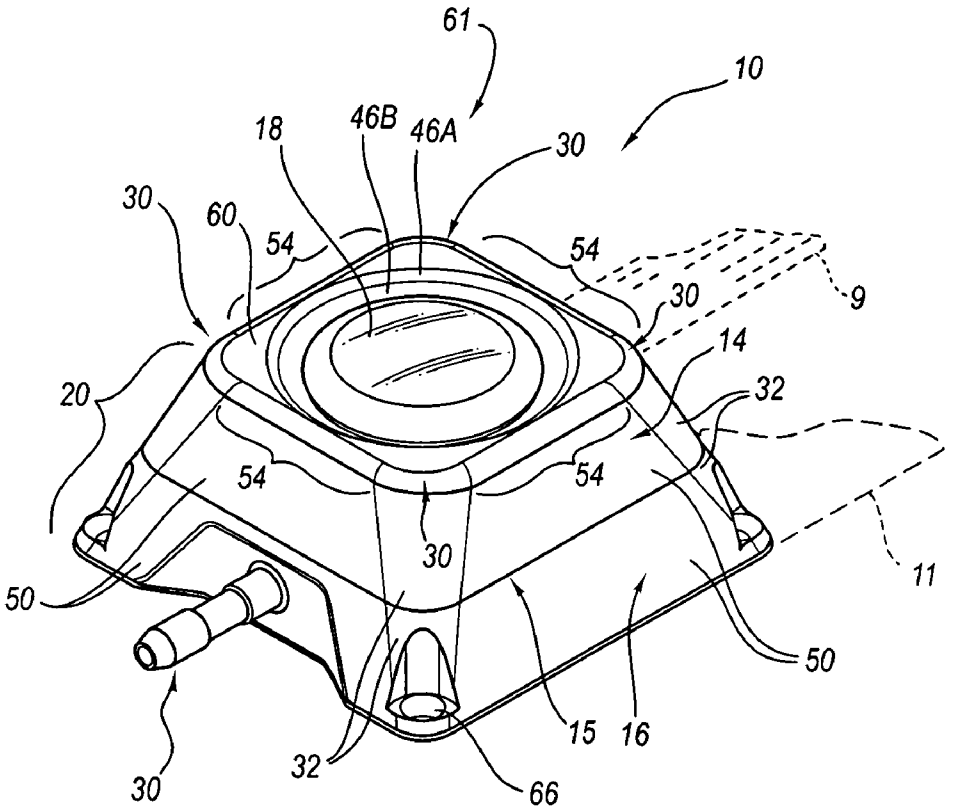
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FIG. 1A

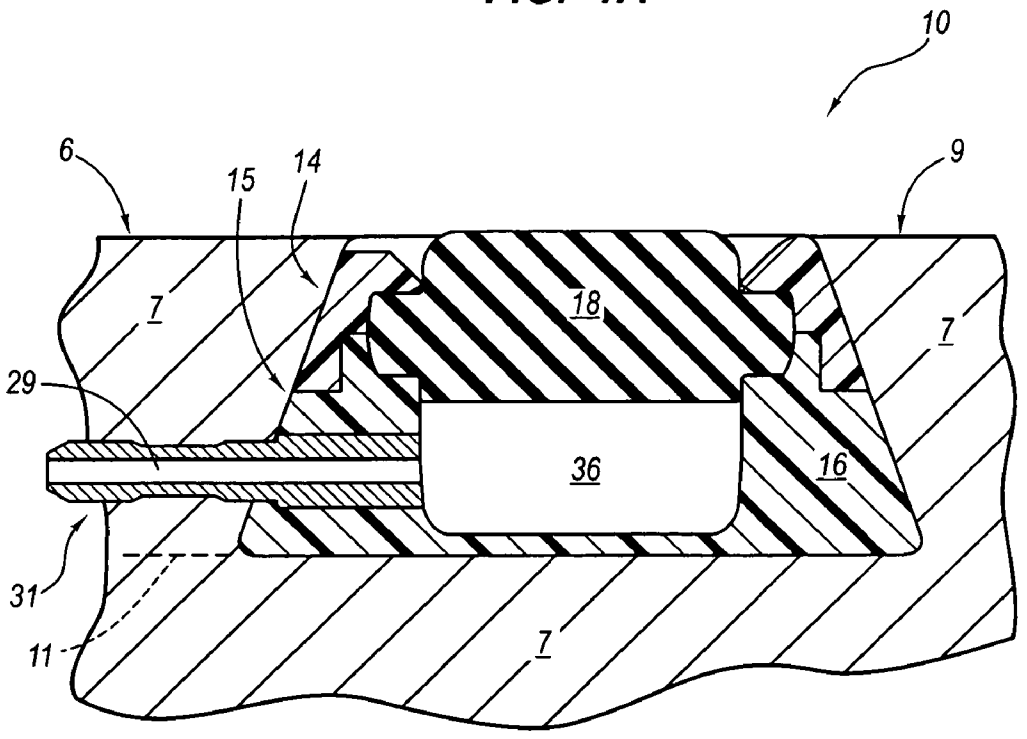
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FIG. 1B

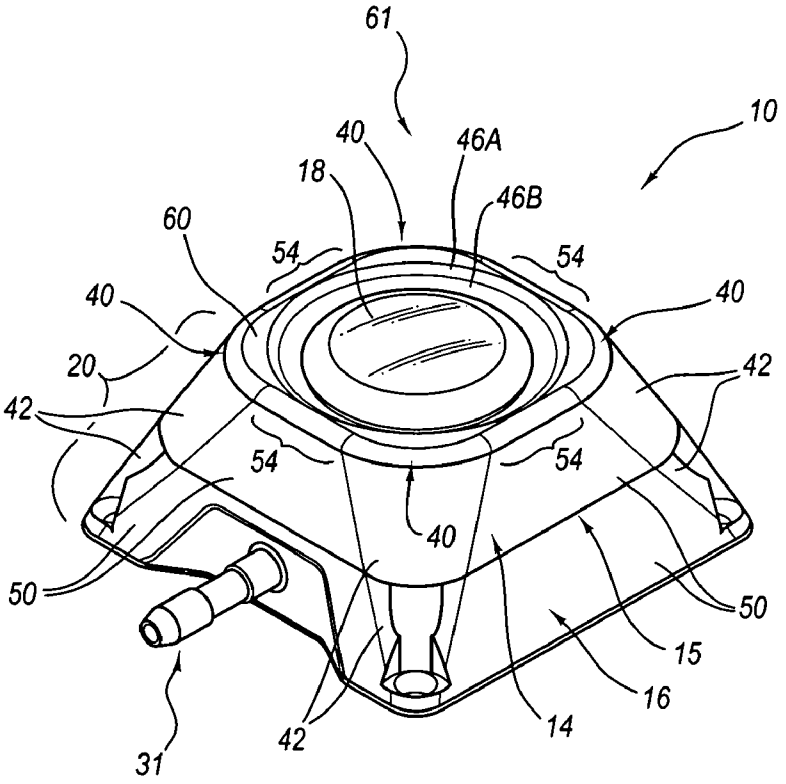
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FIG. 2

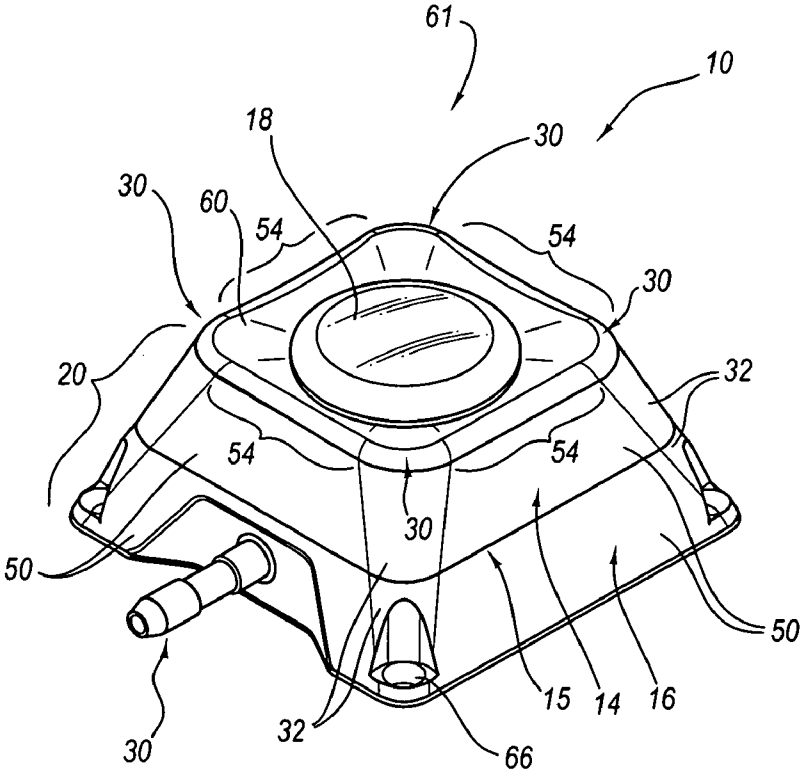
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FIG. 3

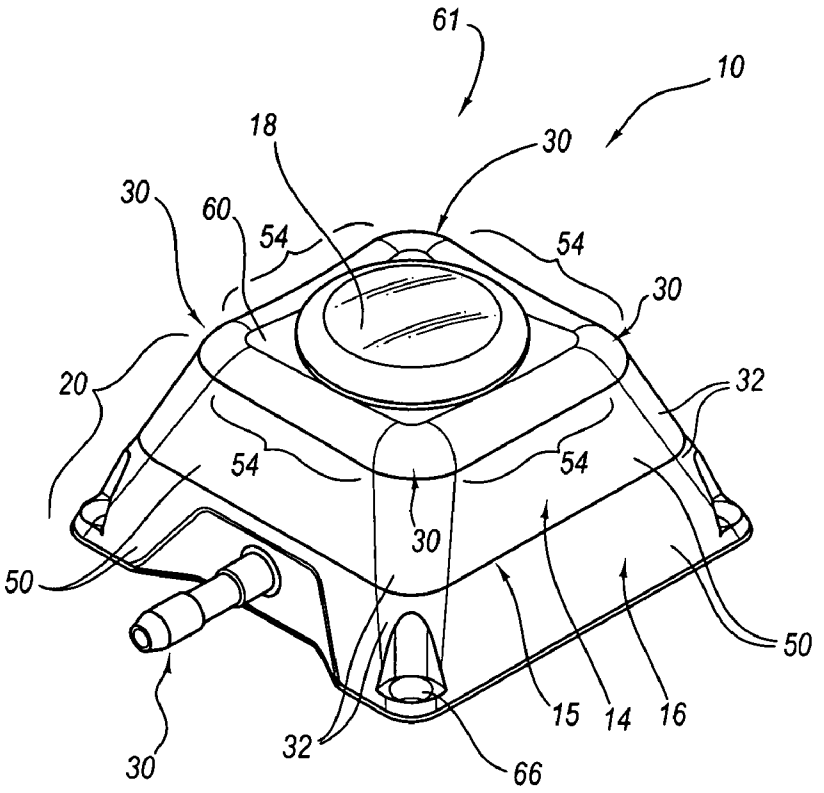
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FIG. 4

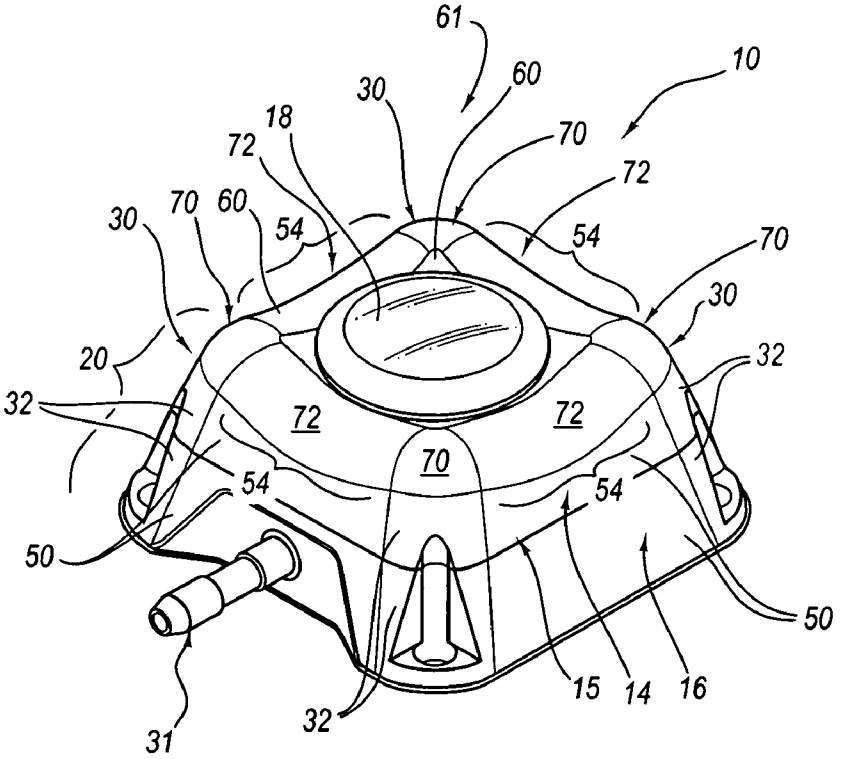
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FIG. 5

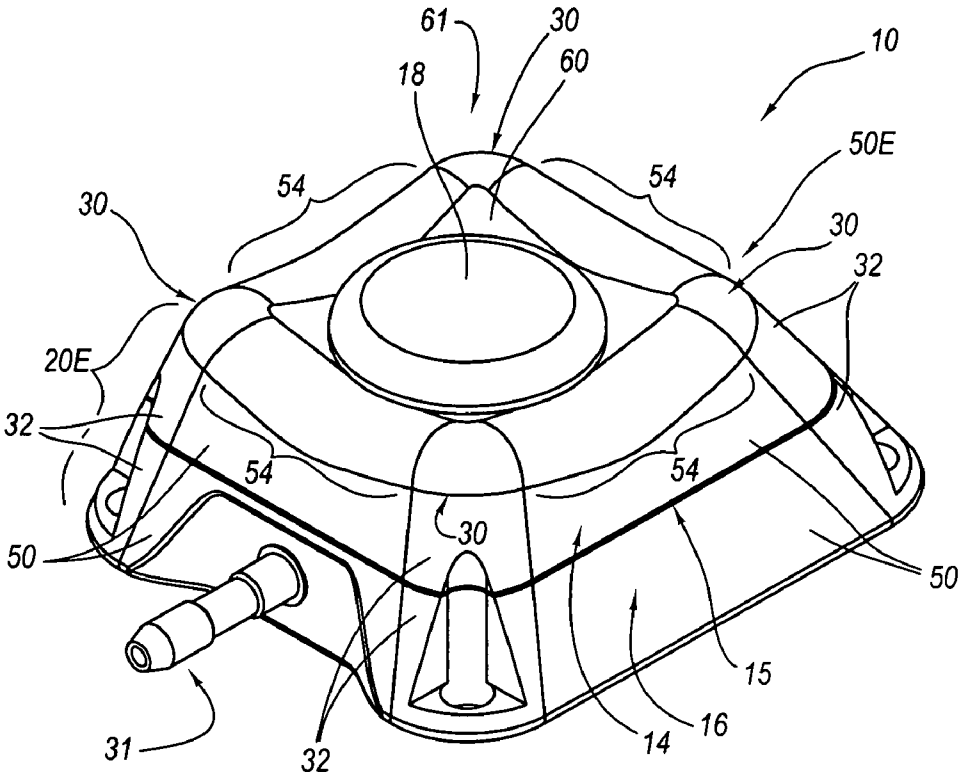
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FIG. 6A

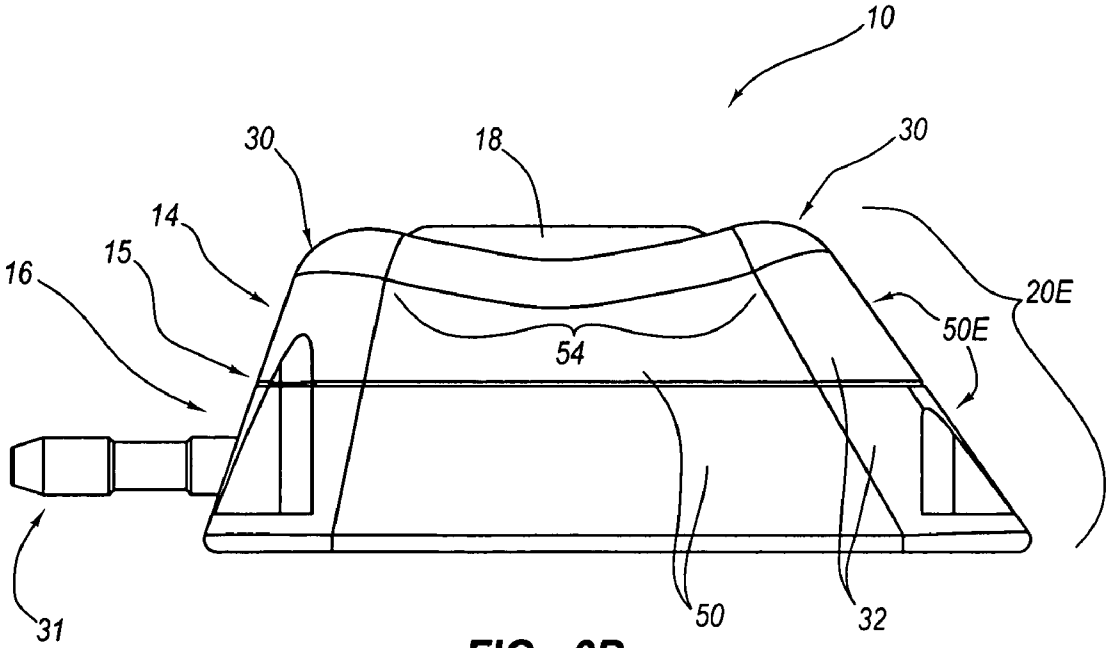
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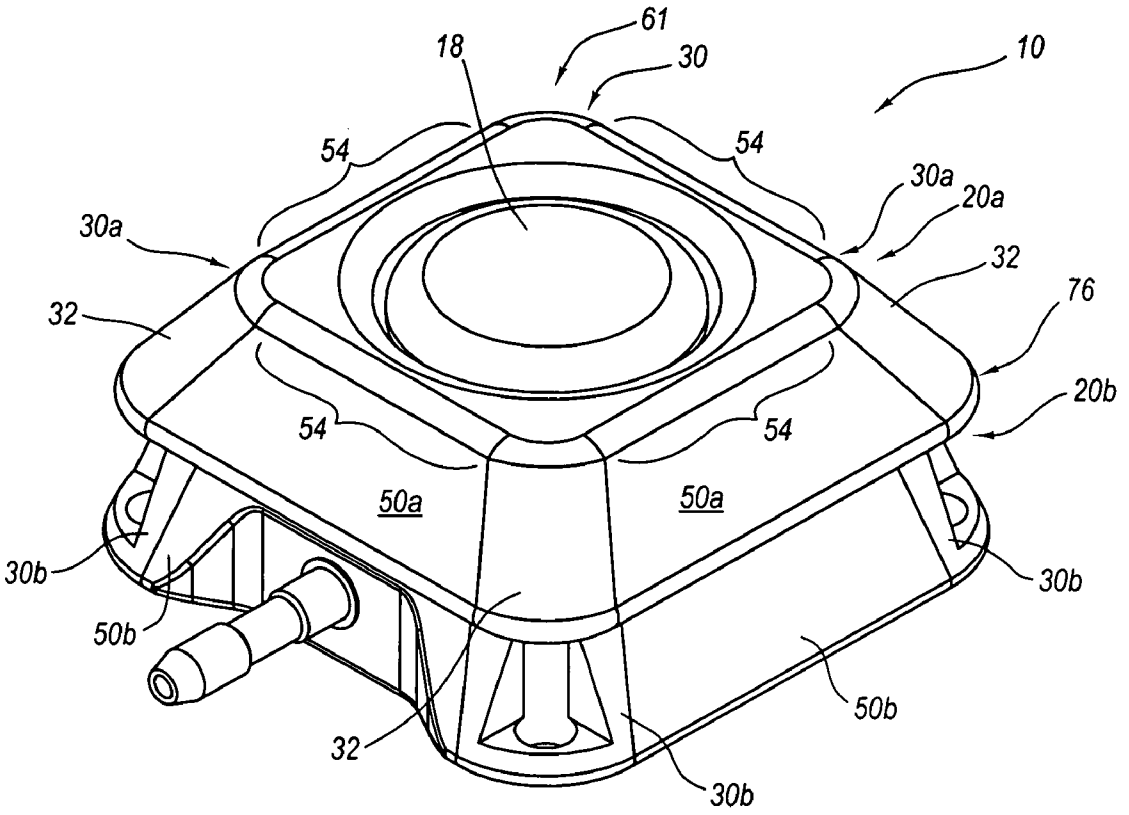
FIG. 6B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30b
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50b
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30b

FIG. 7

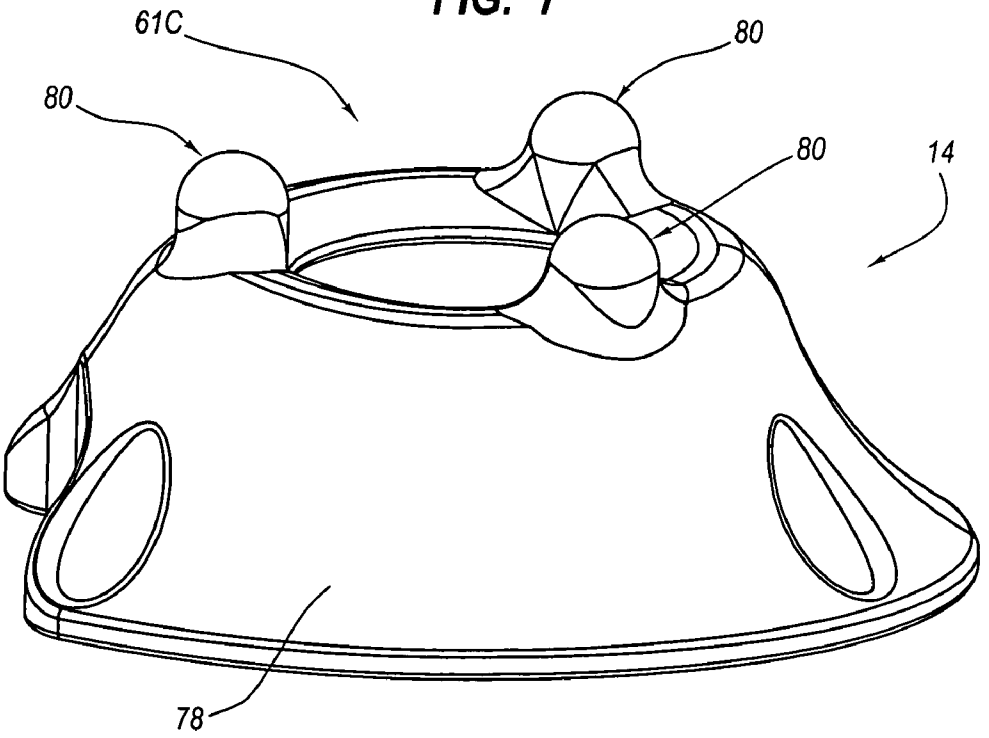
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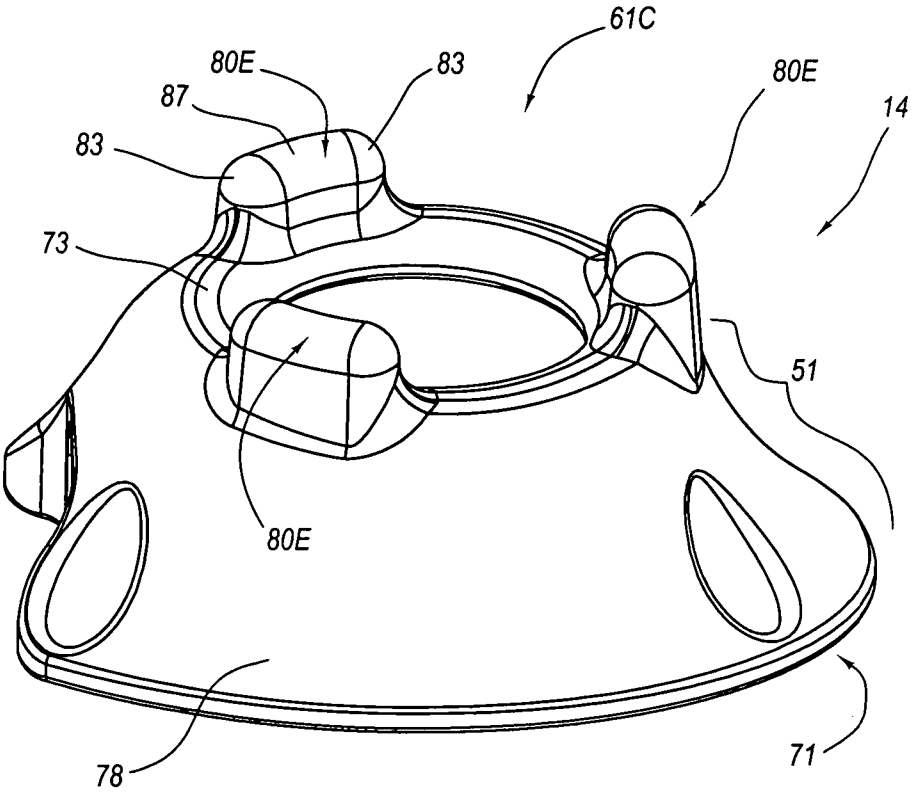
FIG. 8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80E
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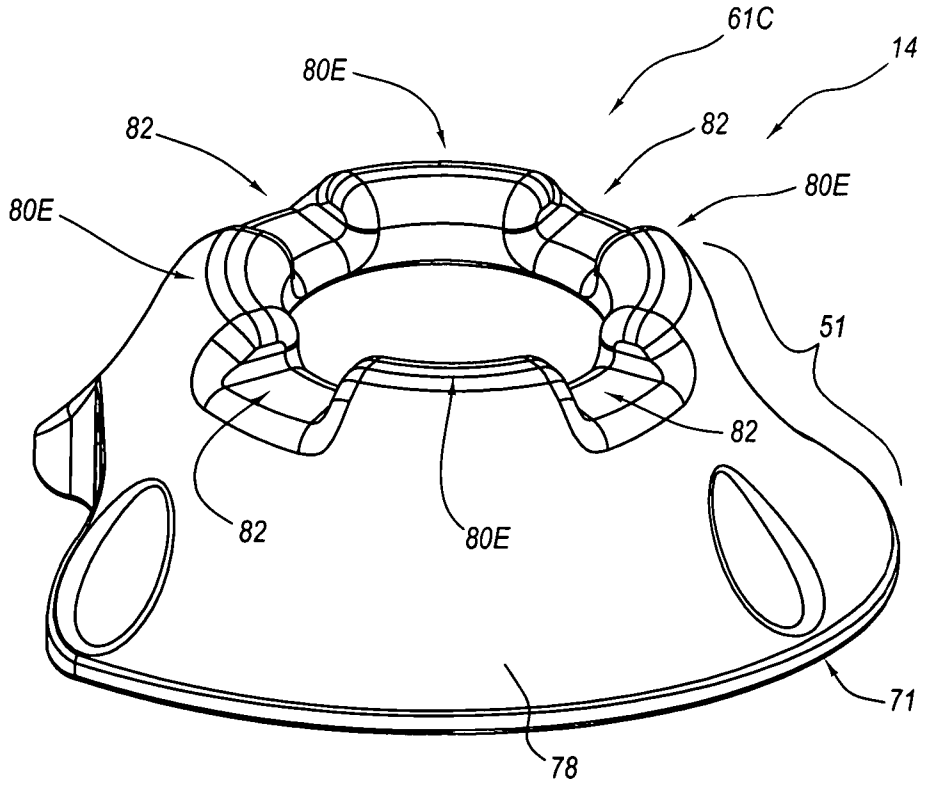
73
51
80E
78
71

FIG. 9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51
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80E
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78

FIG. 10

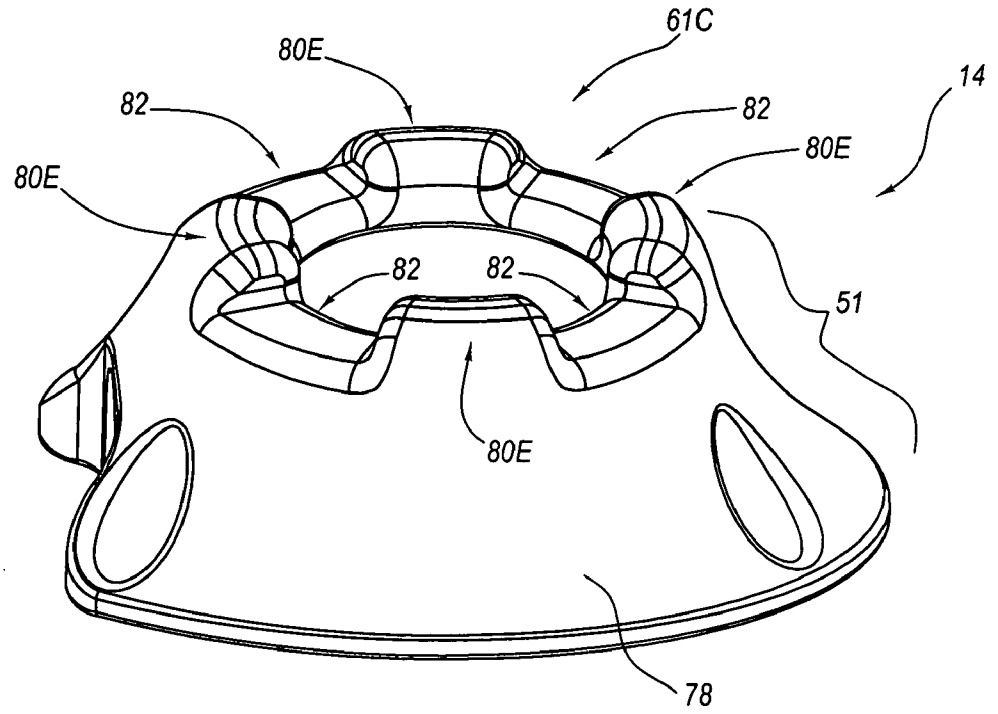

FIG. 11

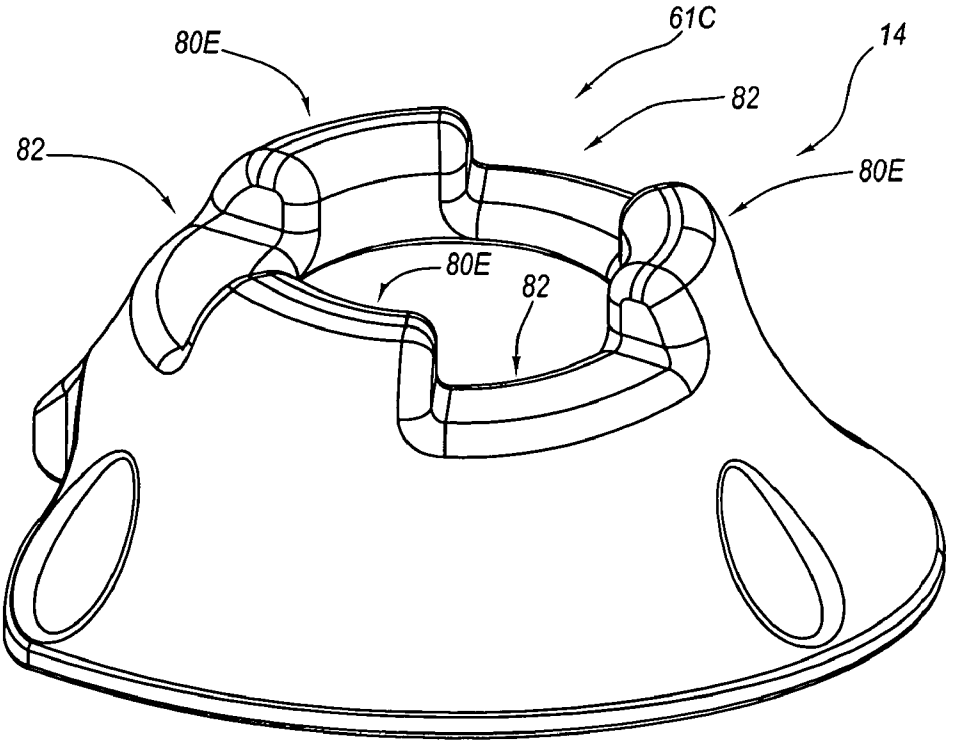

FIG. 12

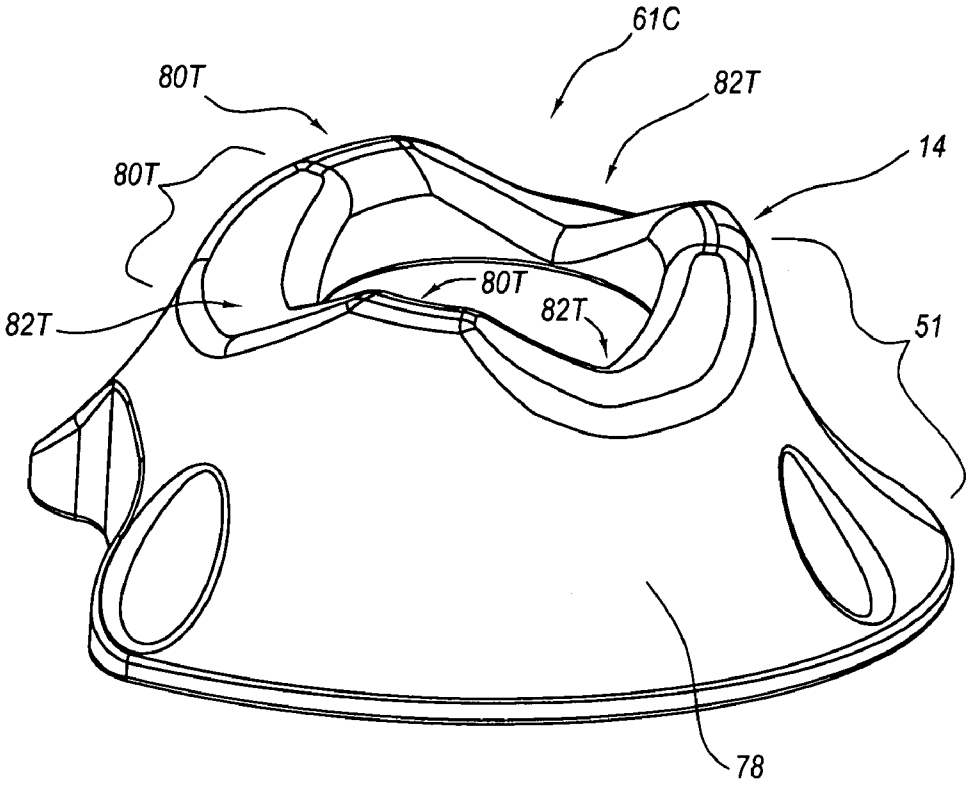

FIG. 13

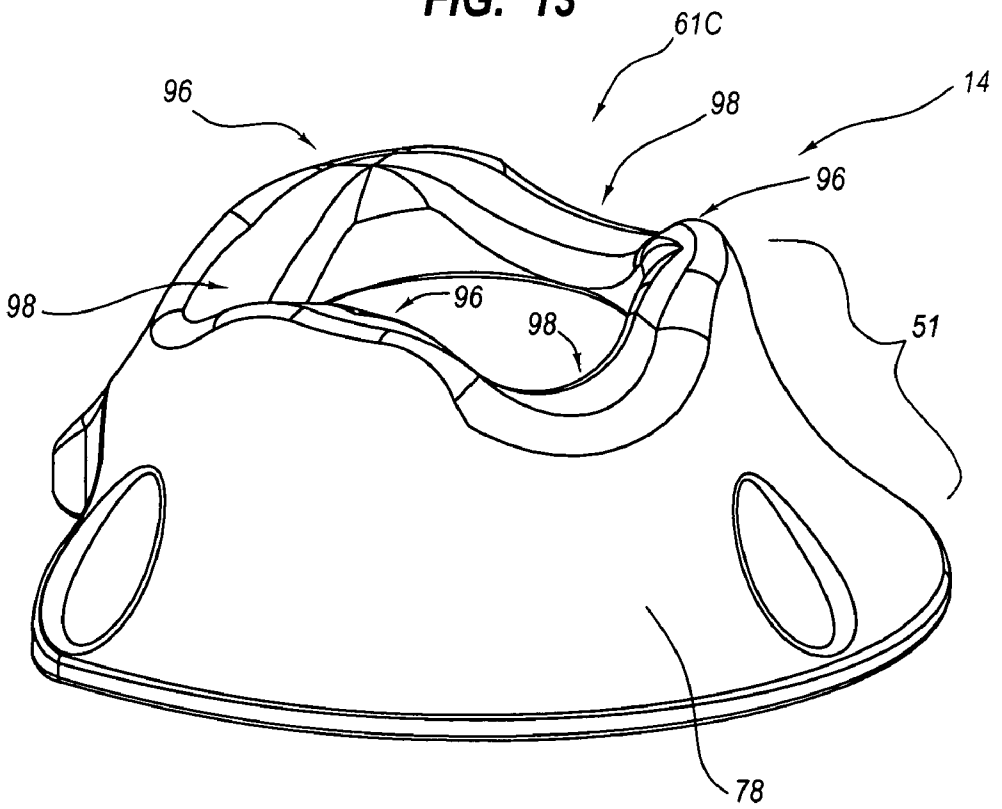

FIG. 14

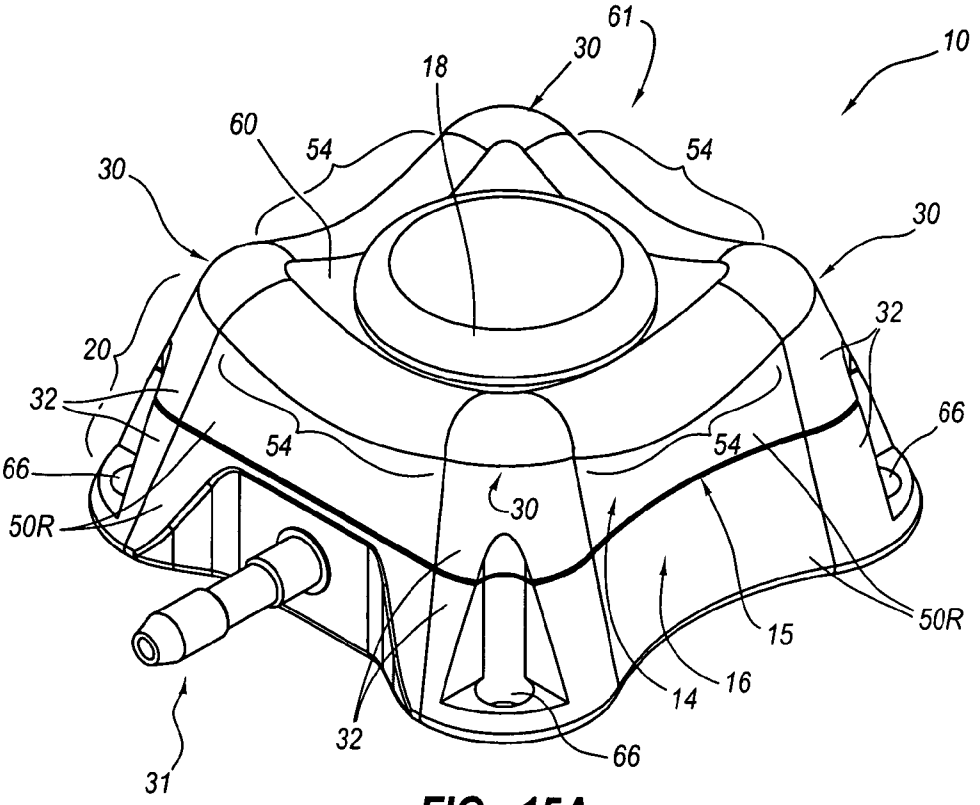

FIG. 15A

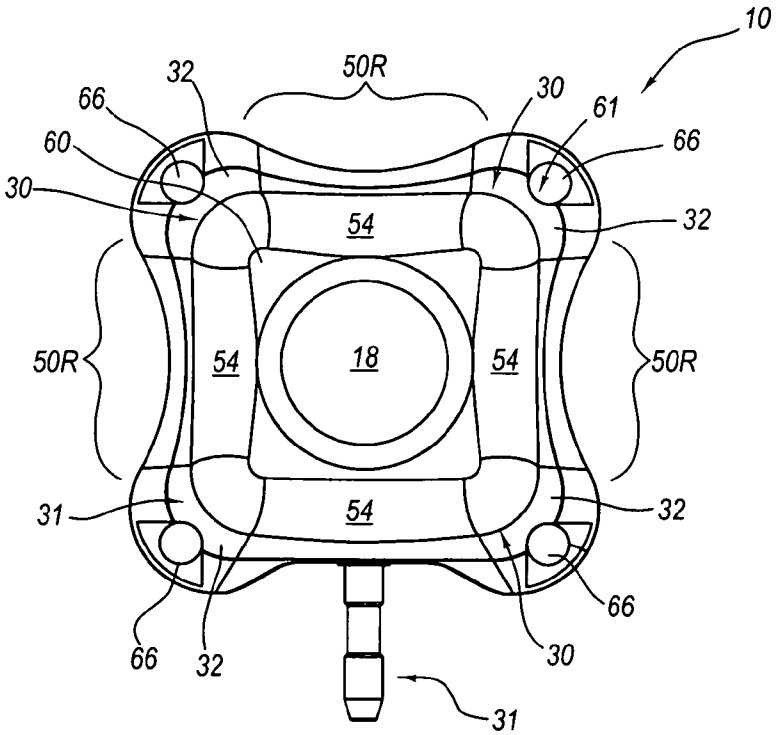

FIG. 15B

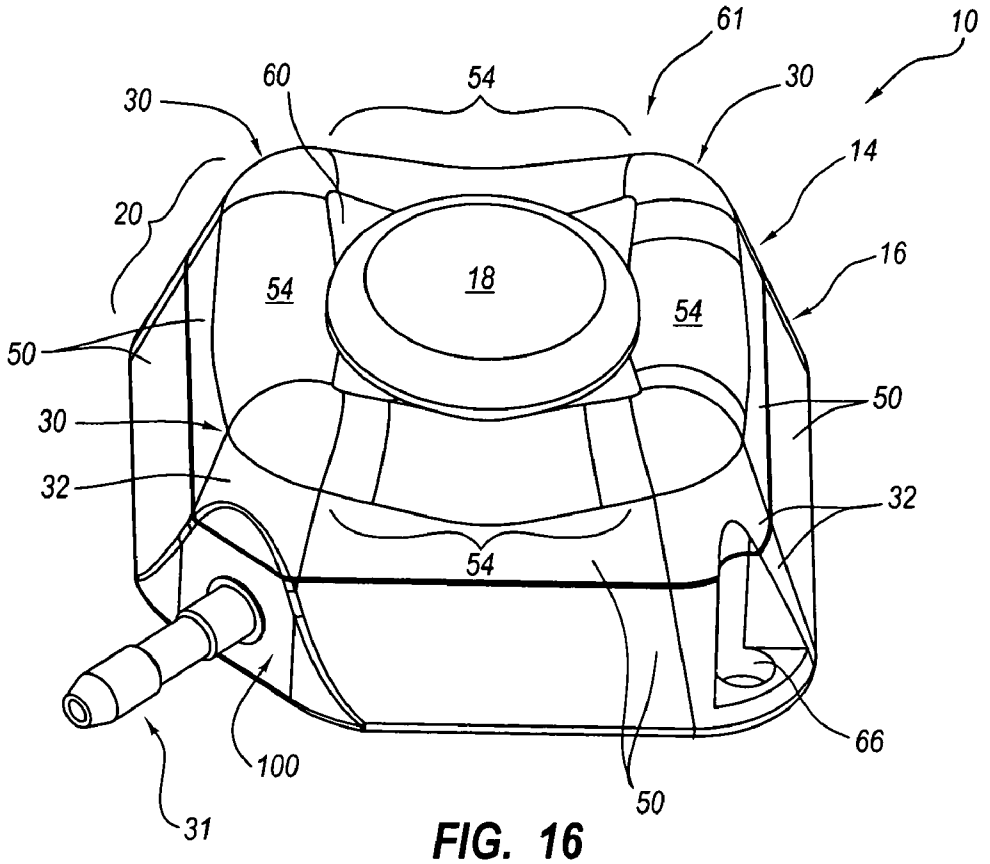
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FIG. 16

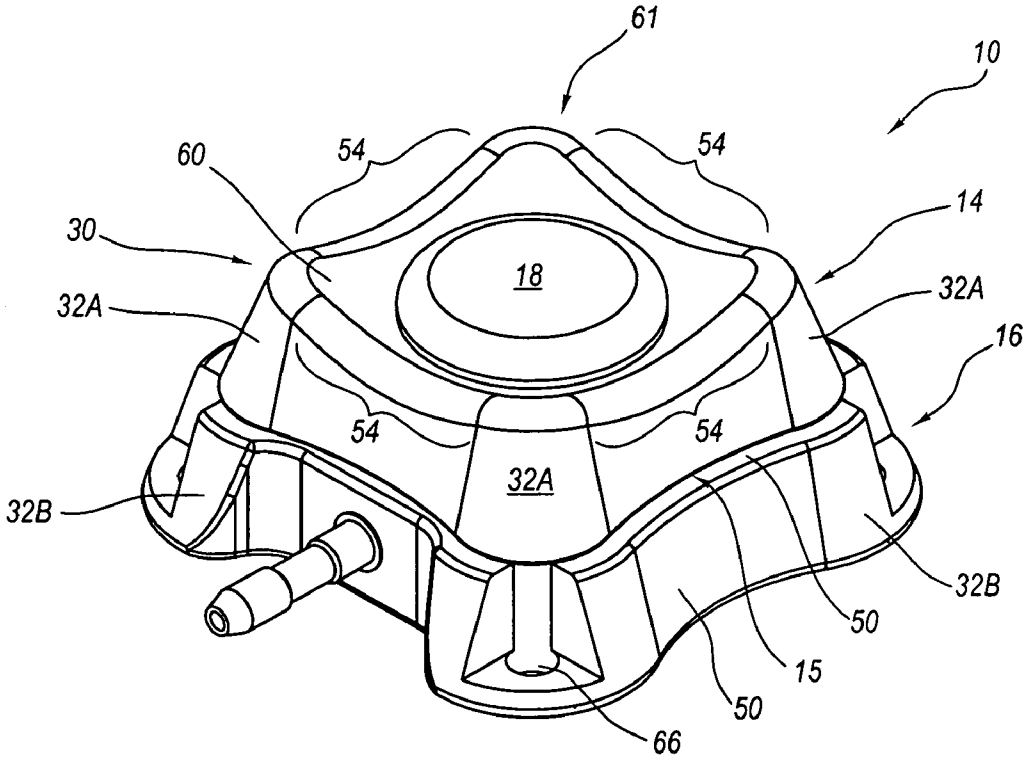
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FIG. 17

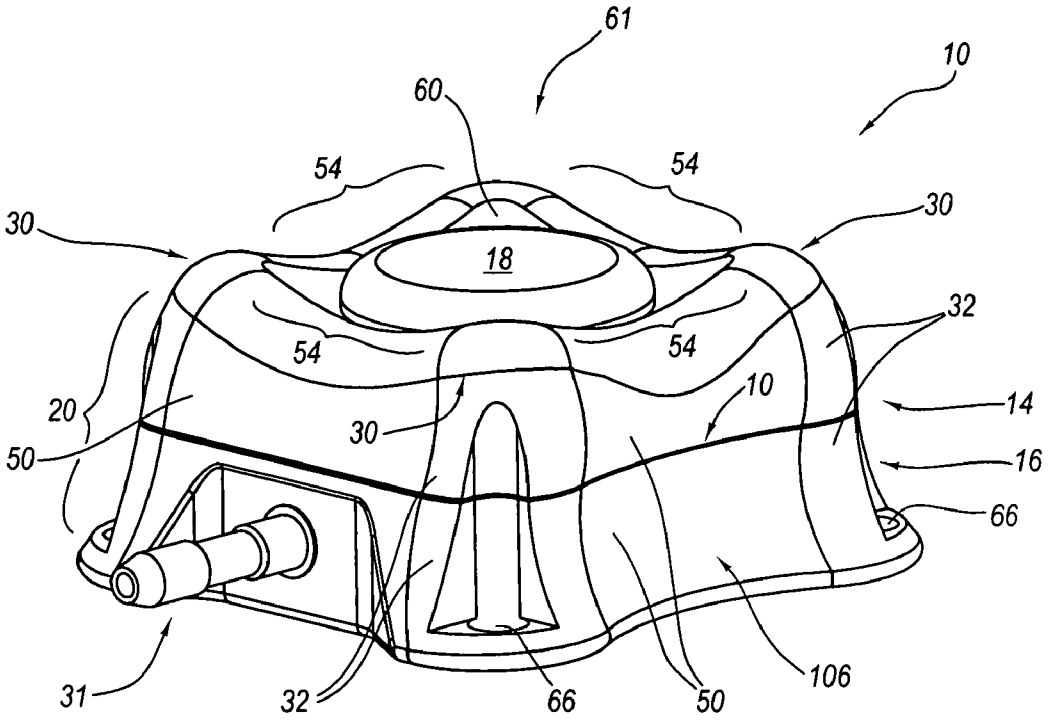
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FIG. 18

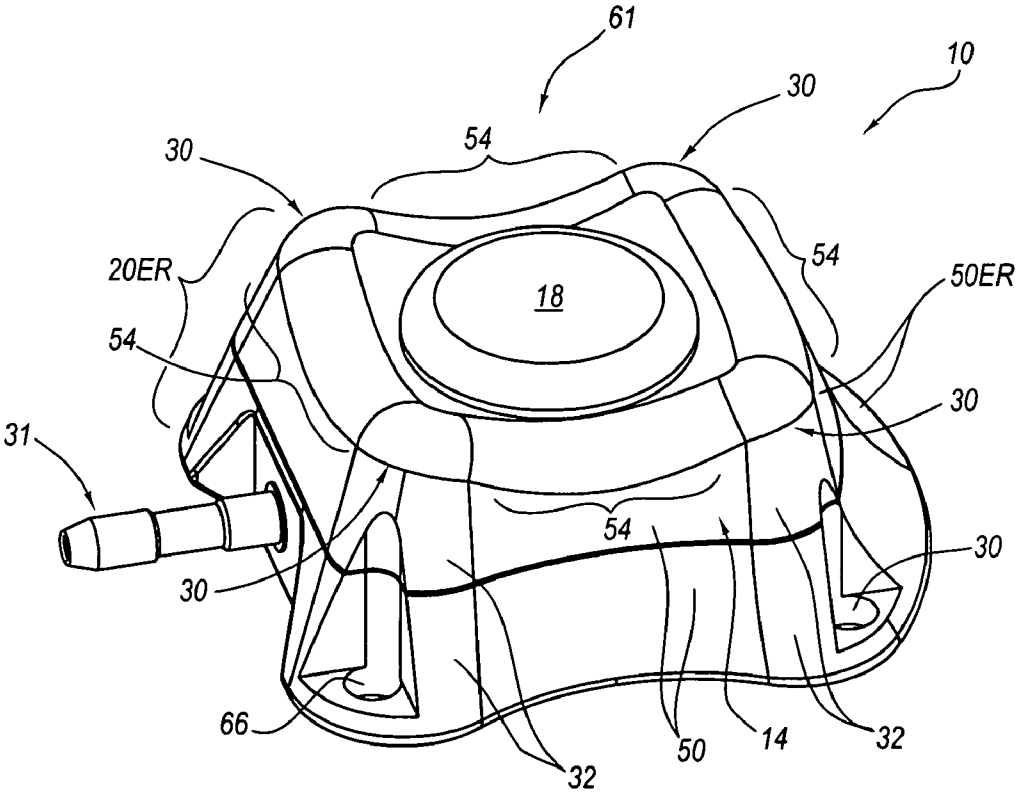
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FIG. 19

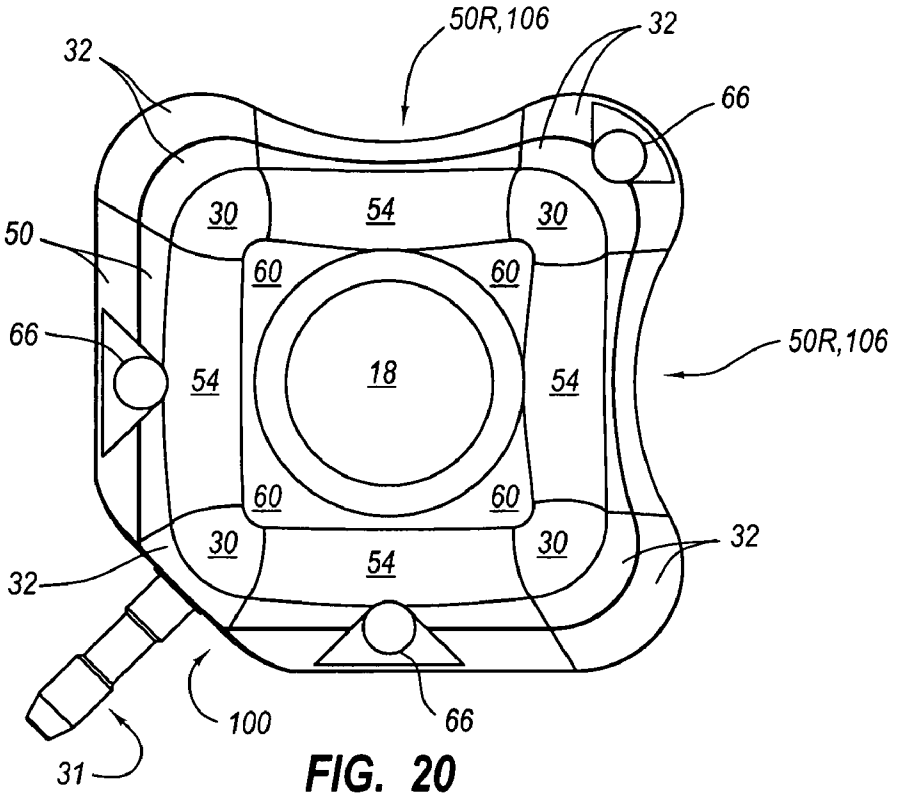
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FIG. 20

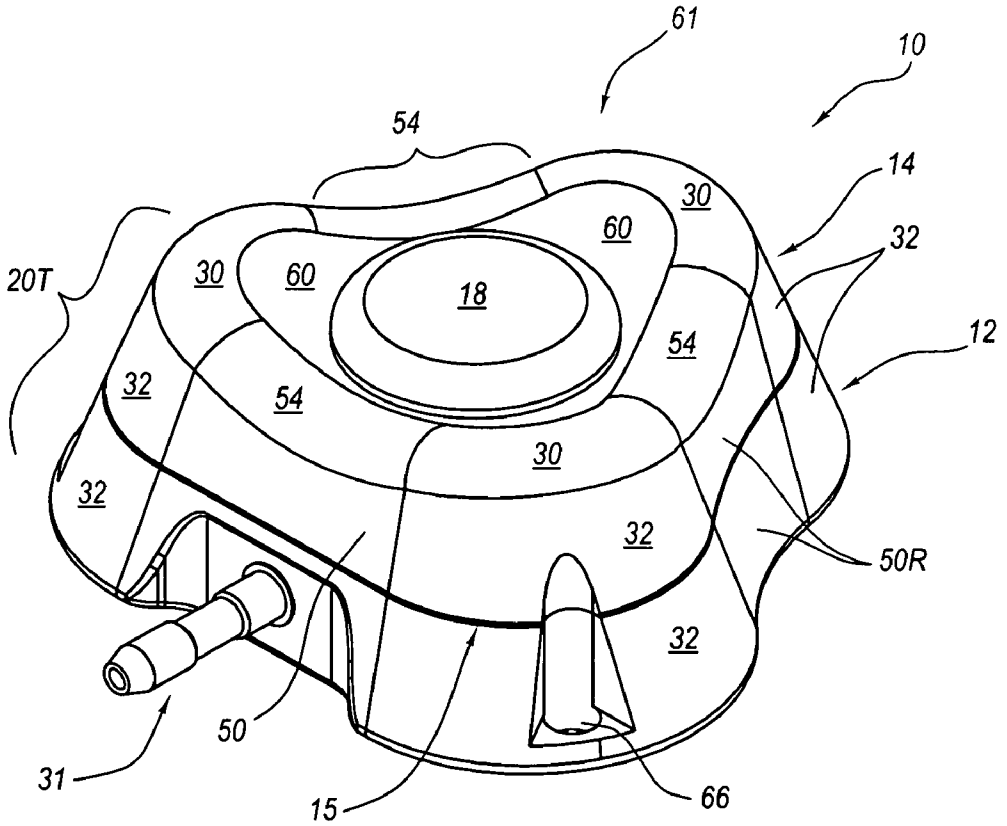
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FIG. 21

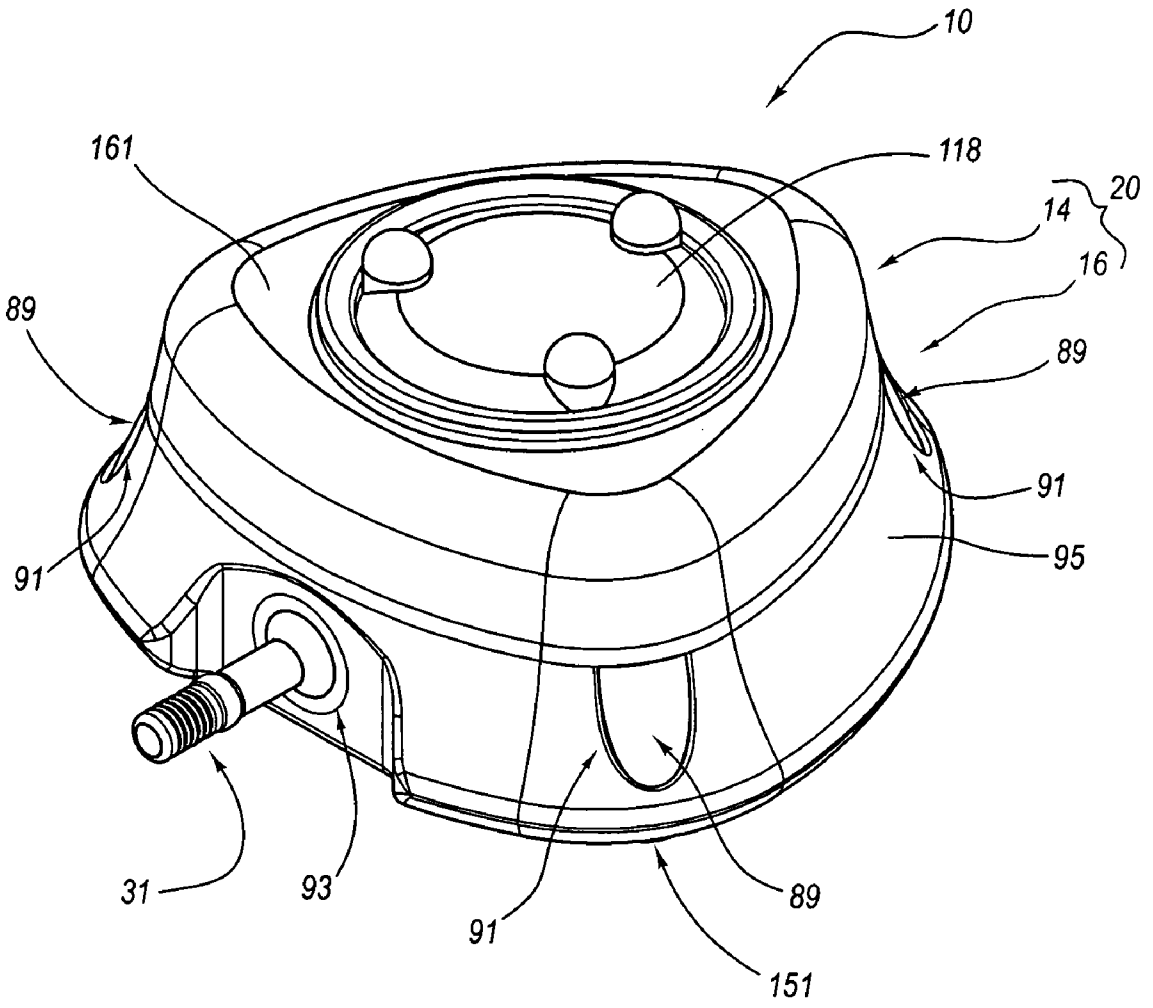


FIG. 22

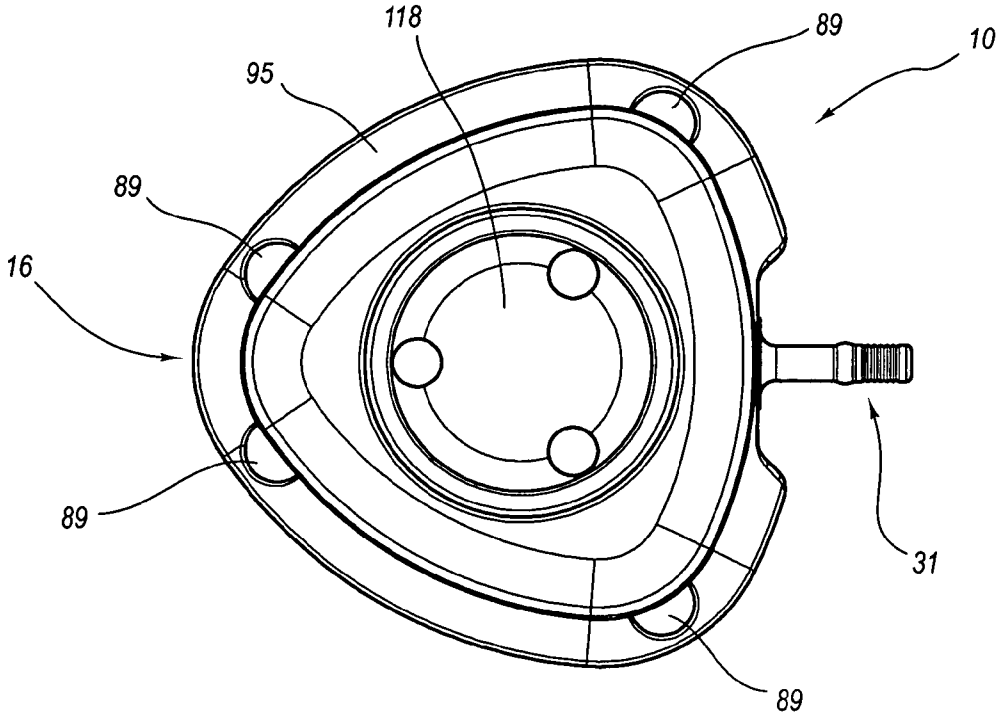


FIG. 23

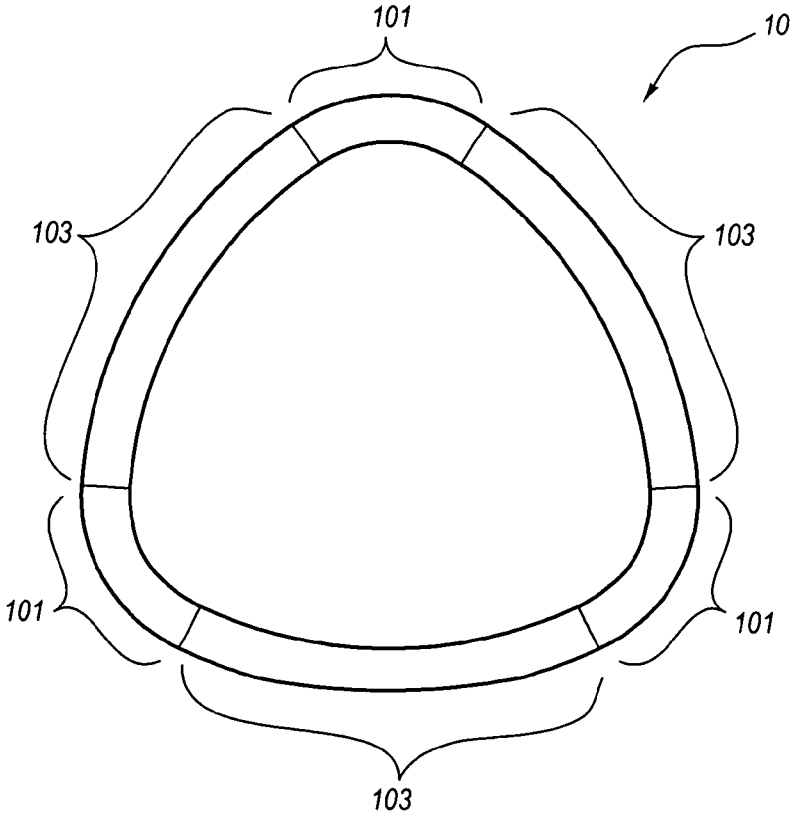


FIG. 24

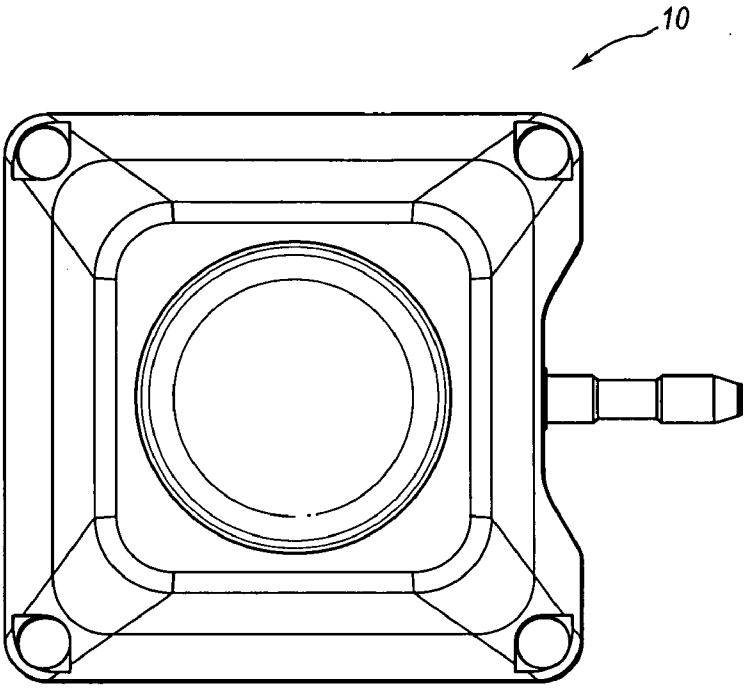


FIG. 25

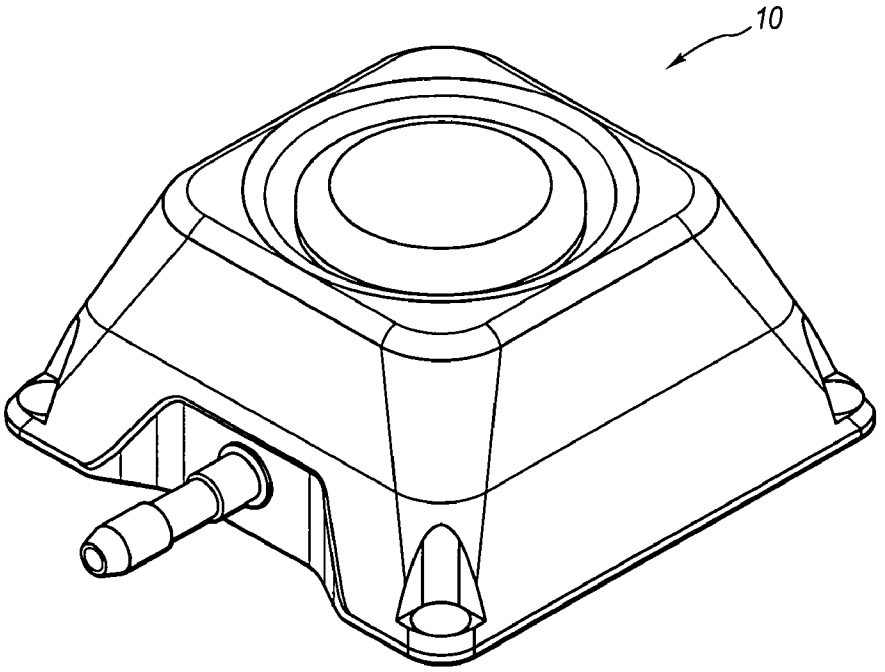


FIG. 26

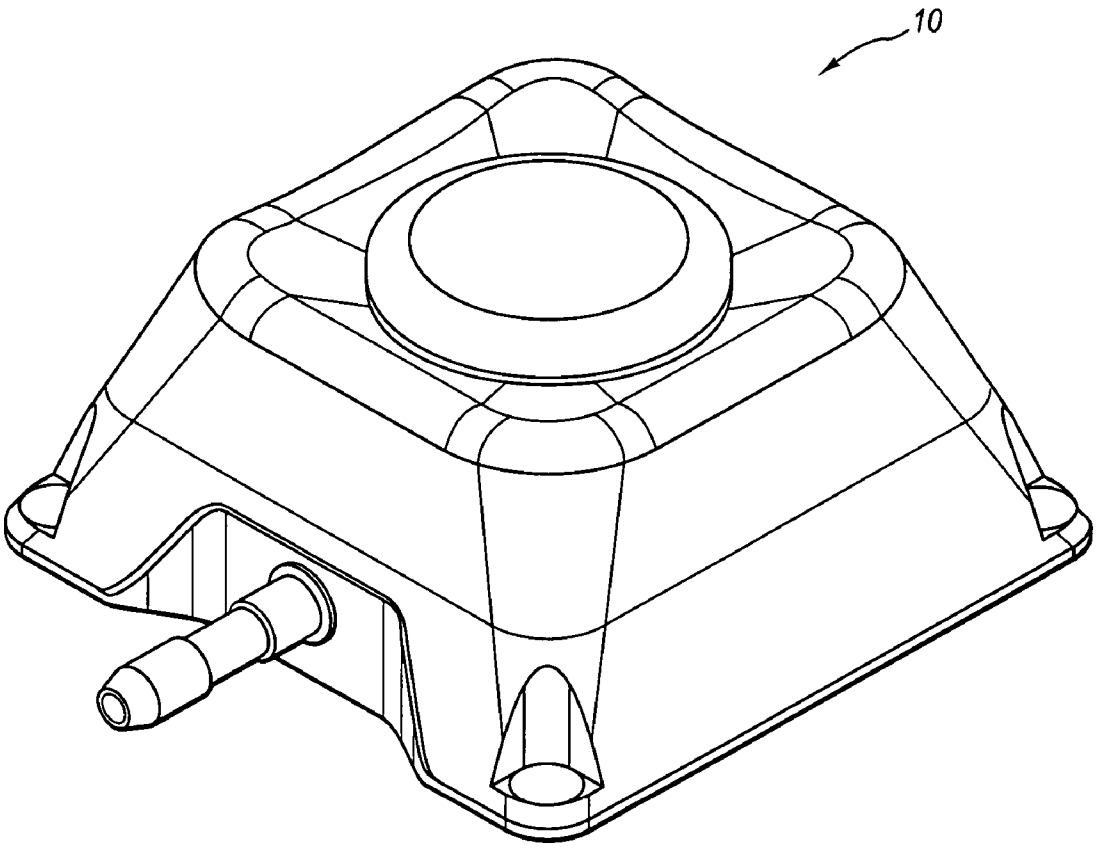


FIG. 27

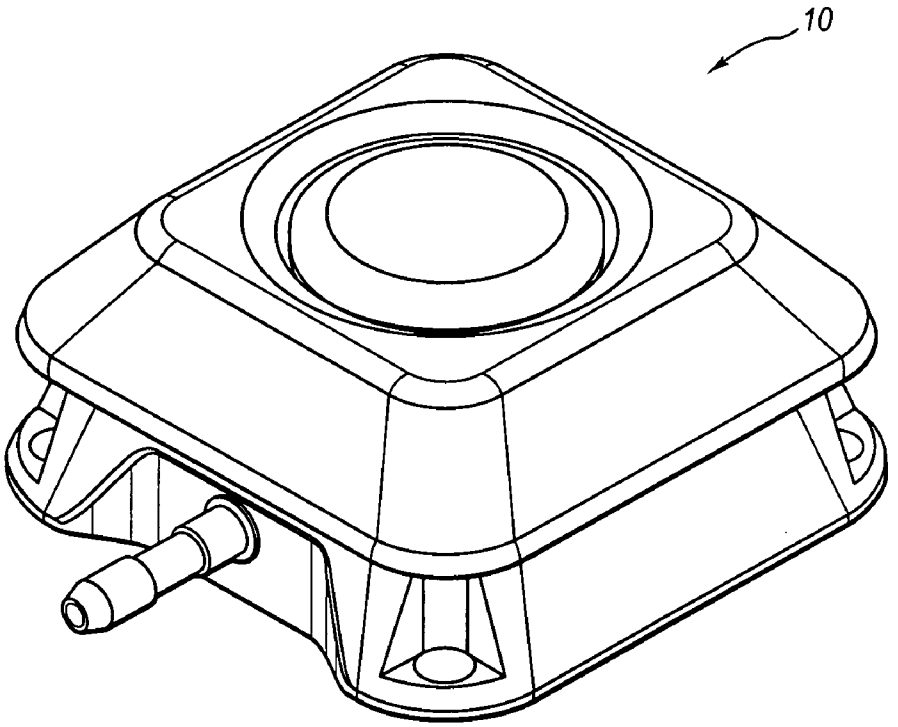


FIG. 28

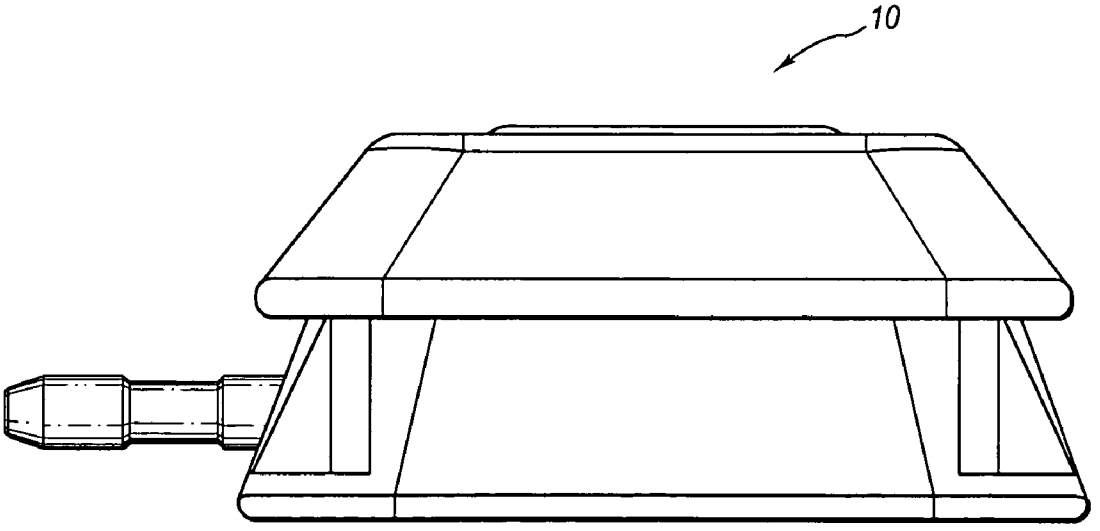


FIG. 29

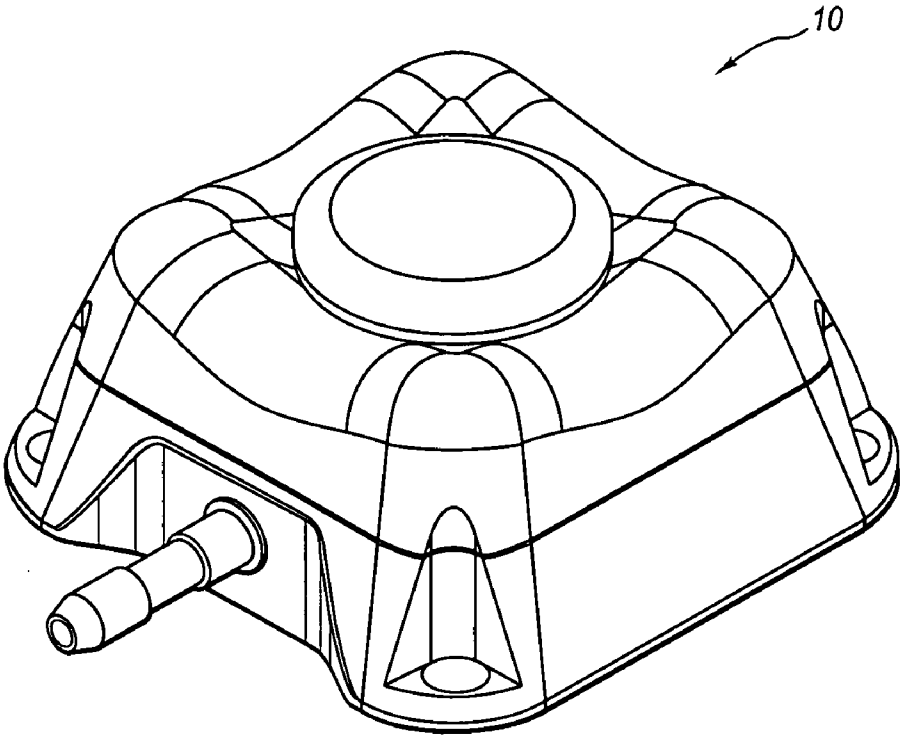


FIG. 30

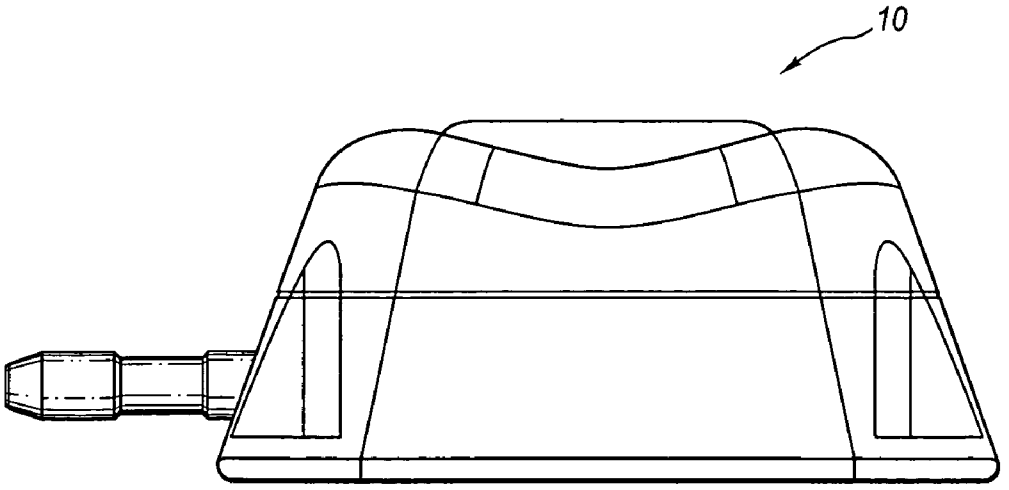


FIG. 31

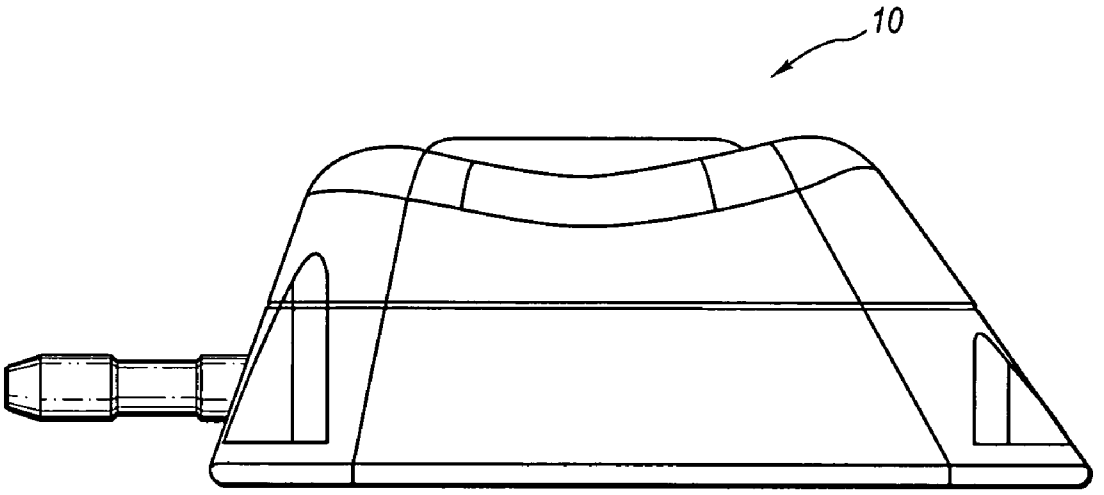


FIG. 32

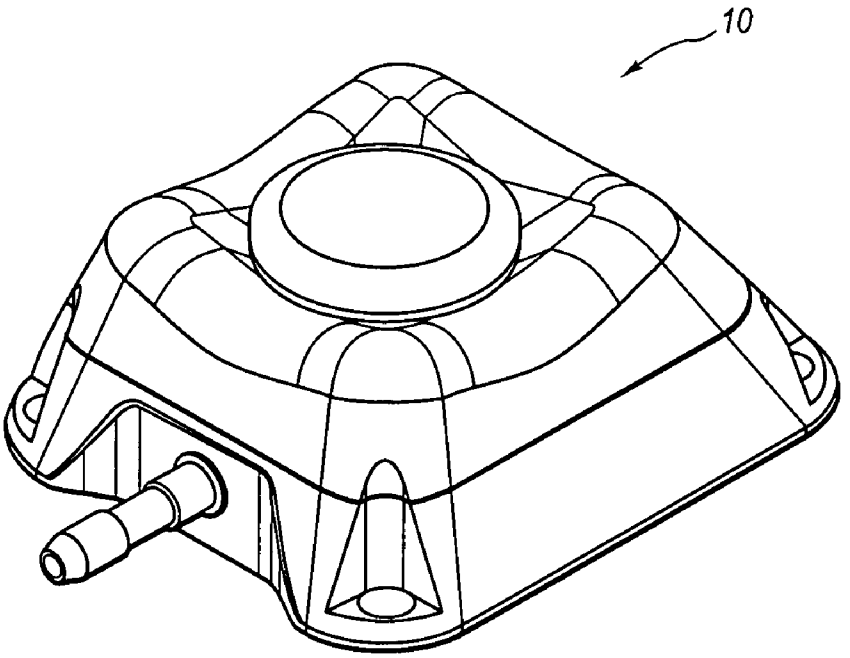


FIG. 33

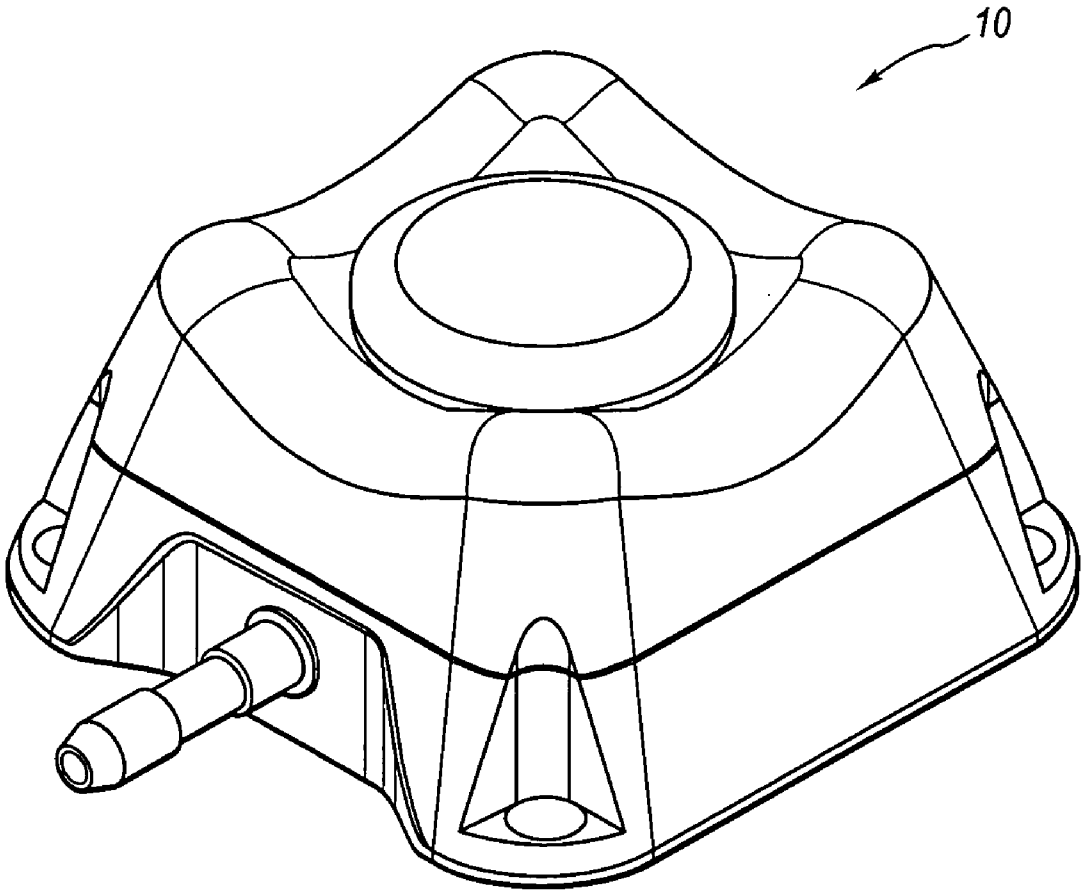


FIG. 34

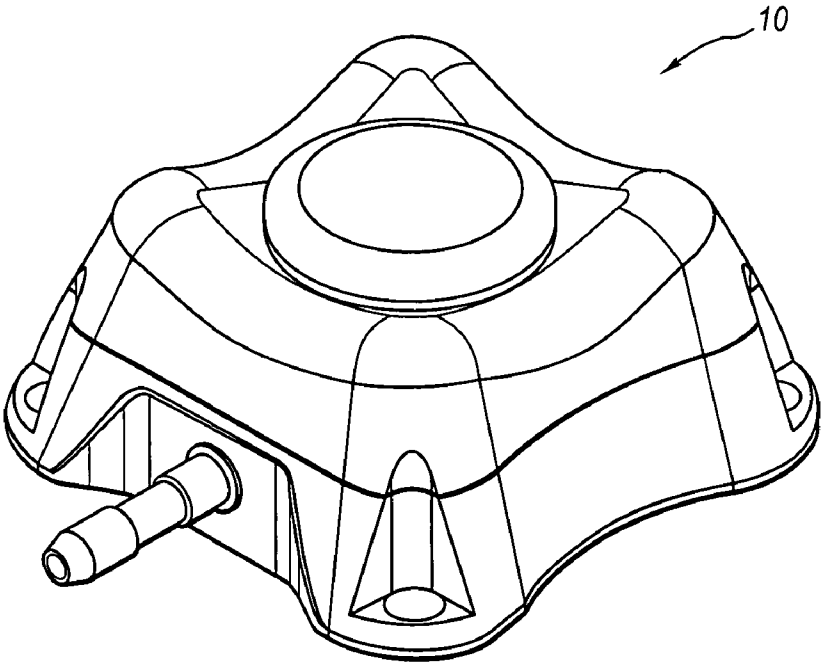


FIG. 35

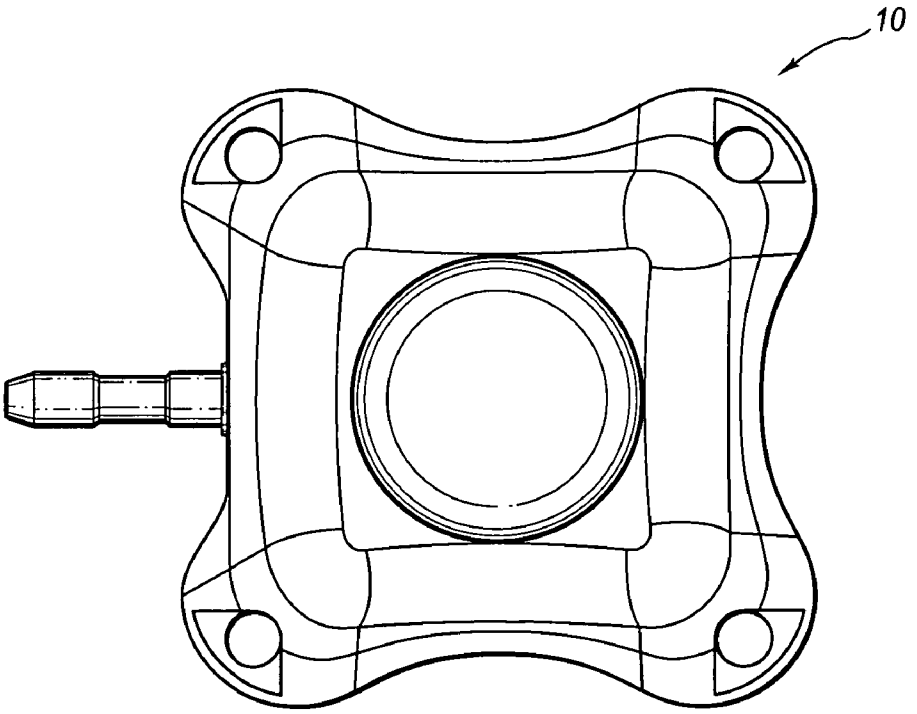


FIG. 36

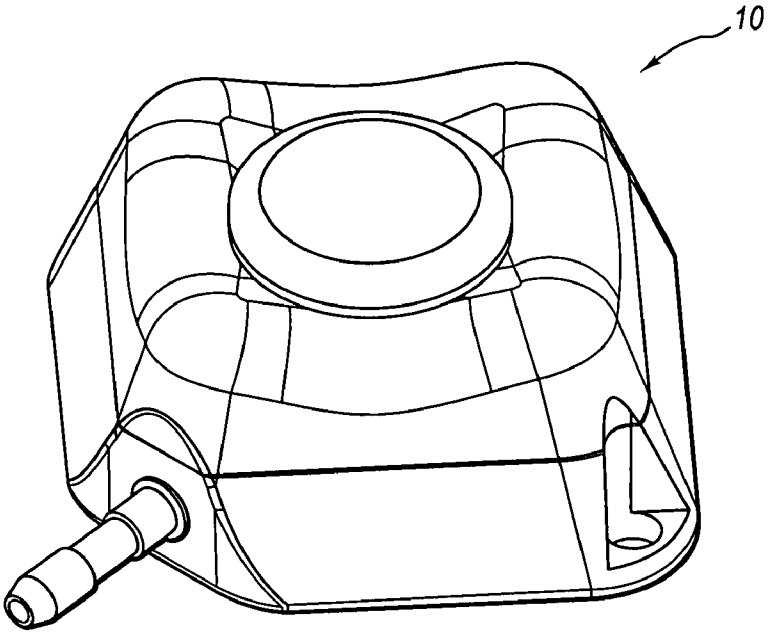


FIG. 37

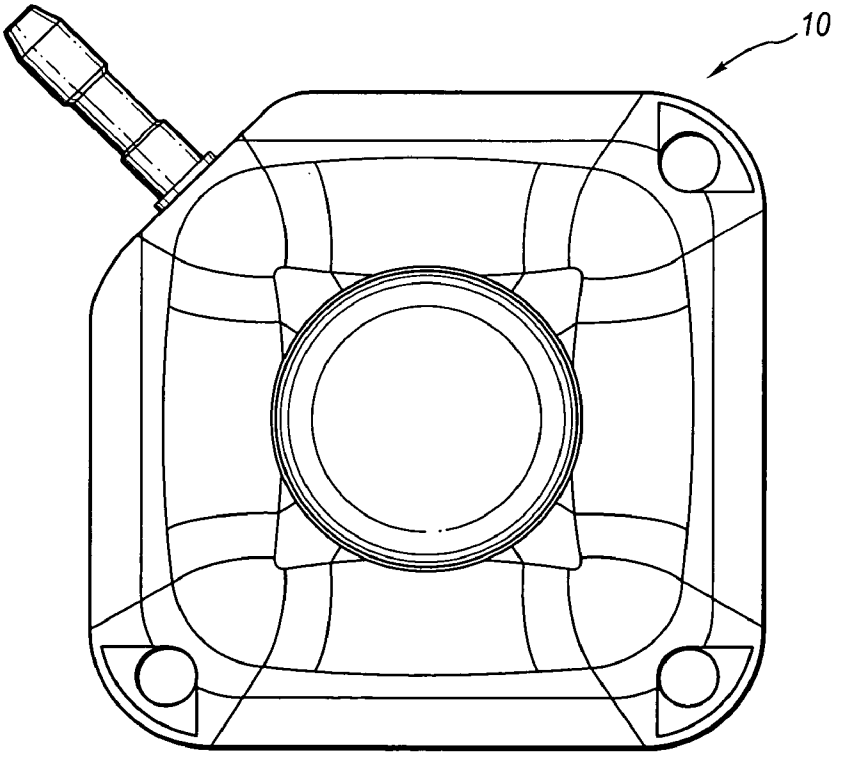


FIG. 38

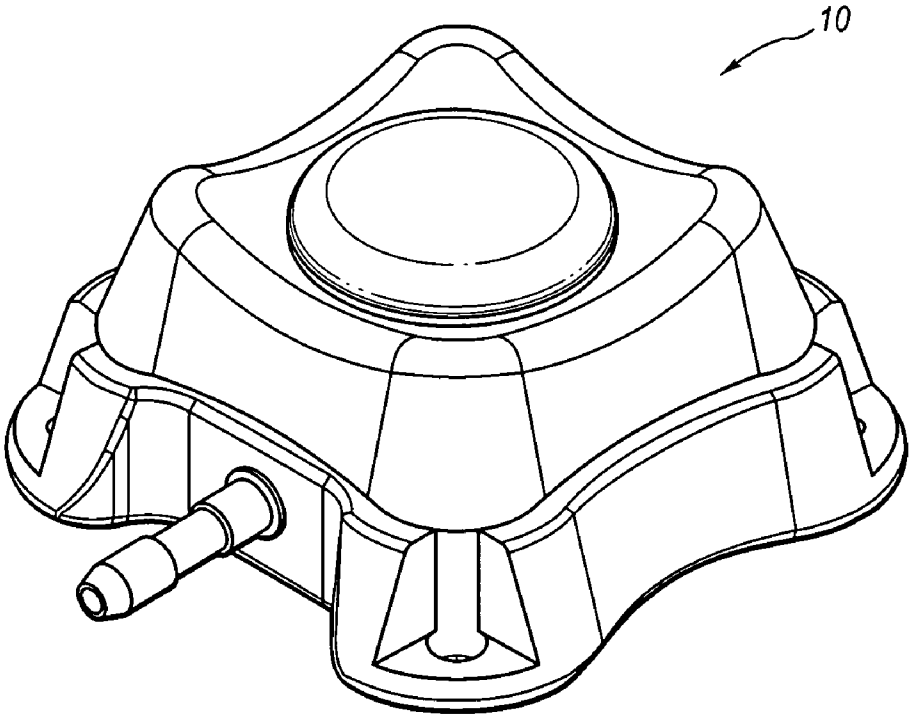


FIG. 39

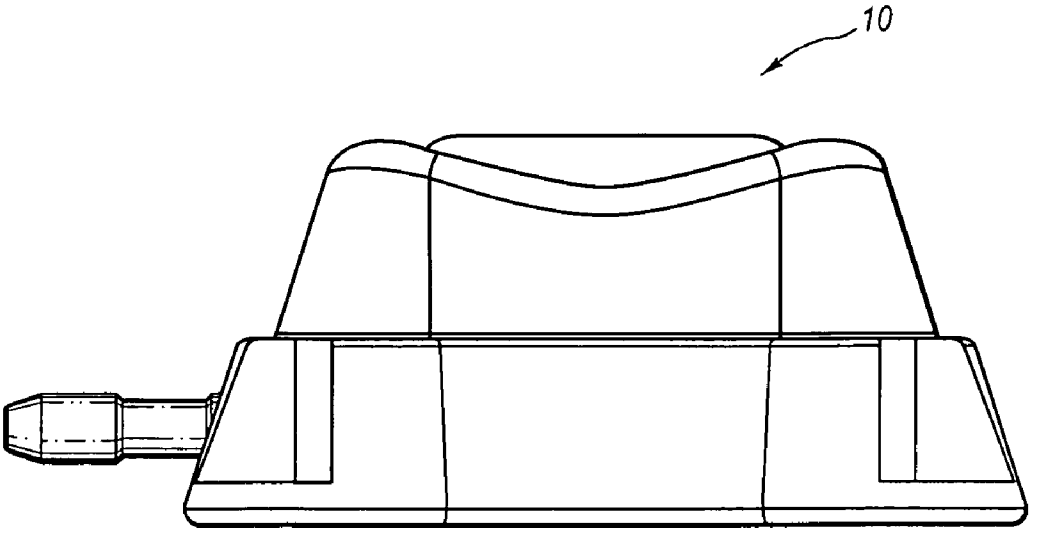


FIG. 40

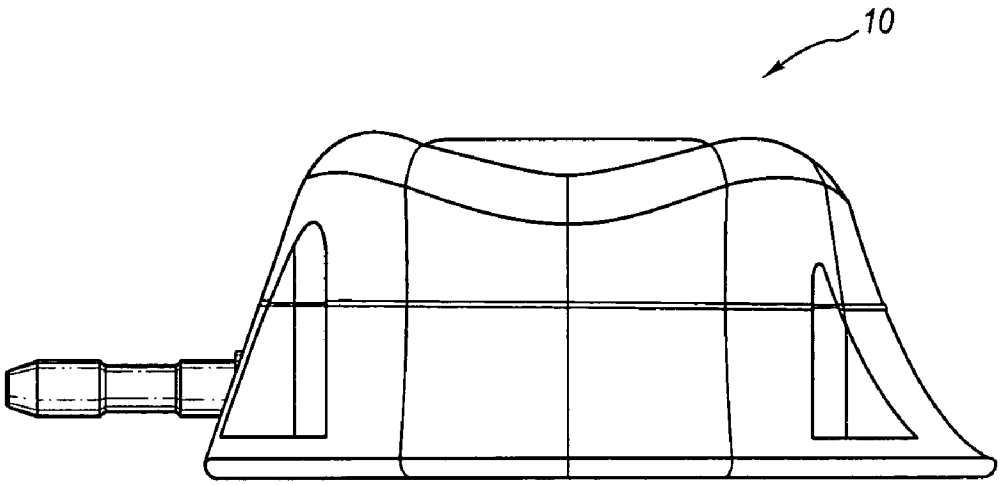


FIG. 41

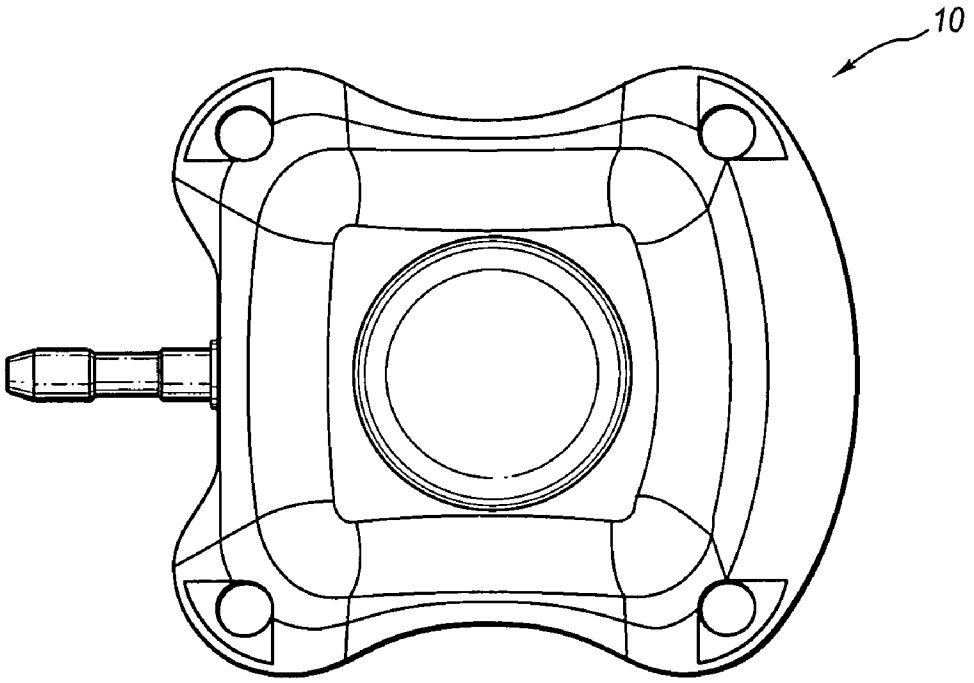


FIG. 42

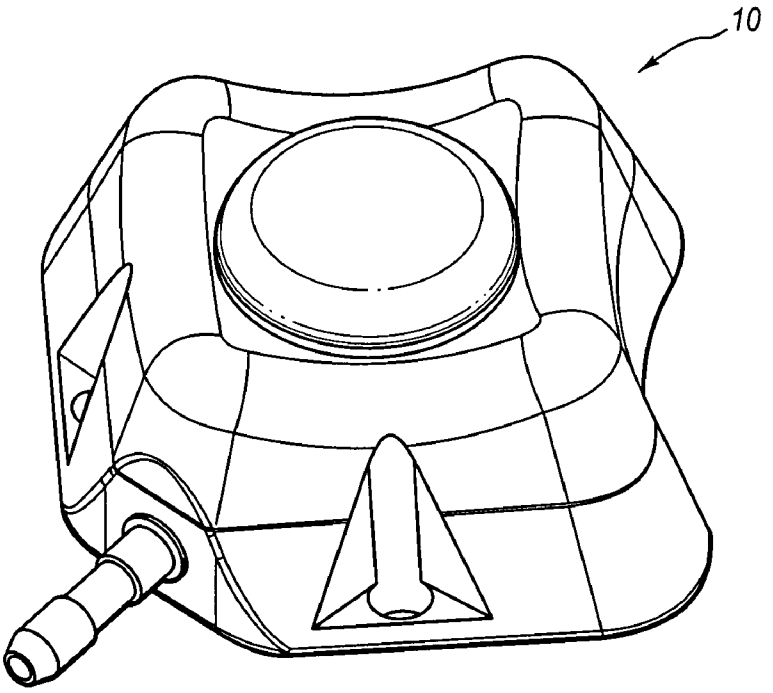


FIG. 43

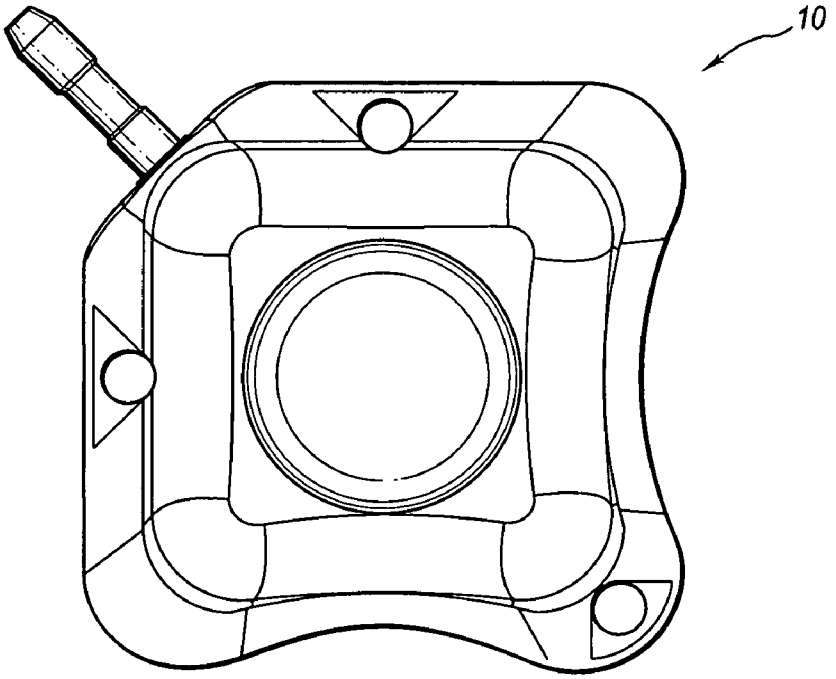


FIG. 44

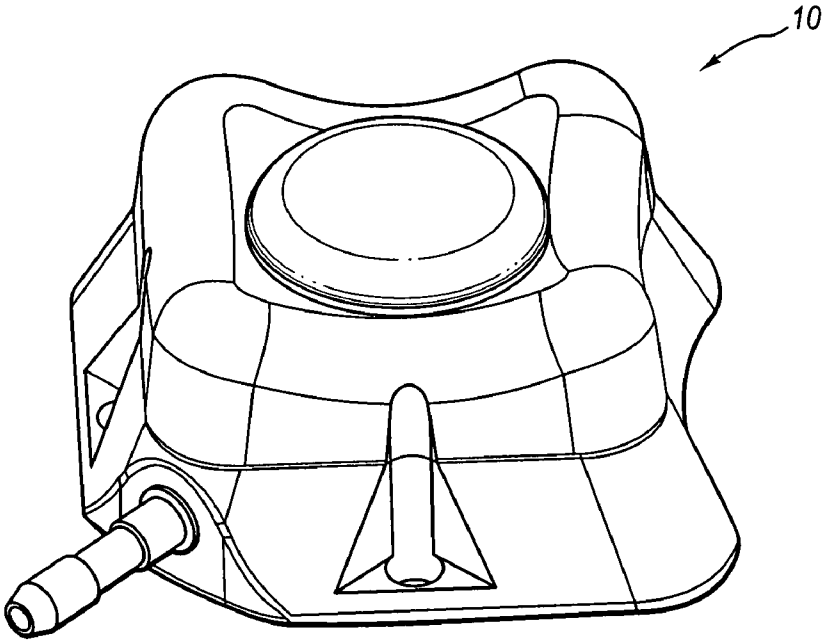


FIG. 45

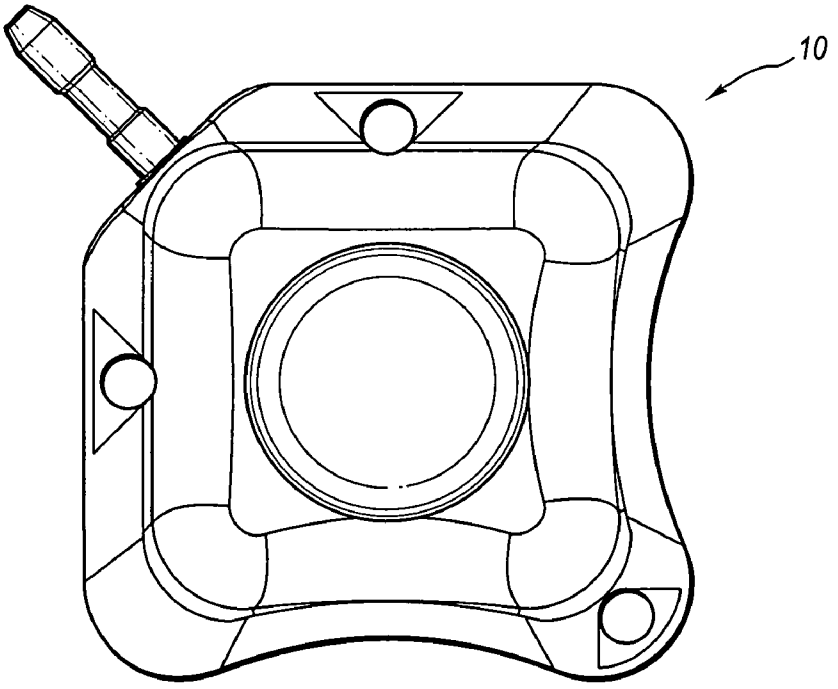


FIG. 46

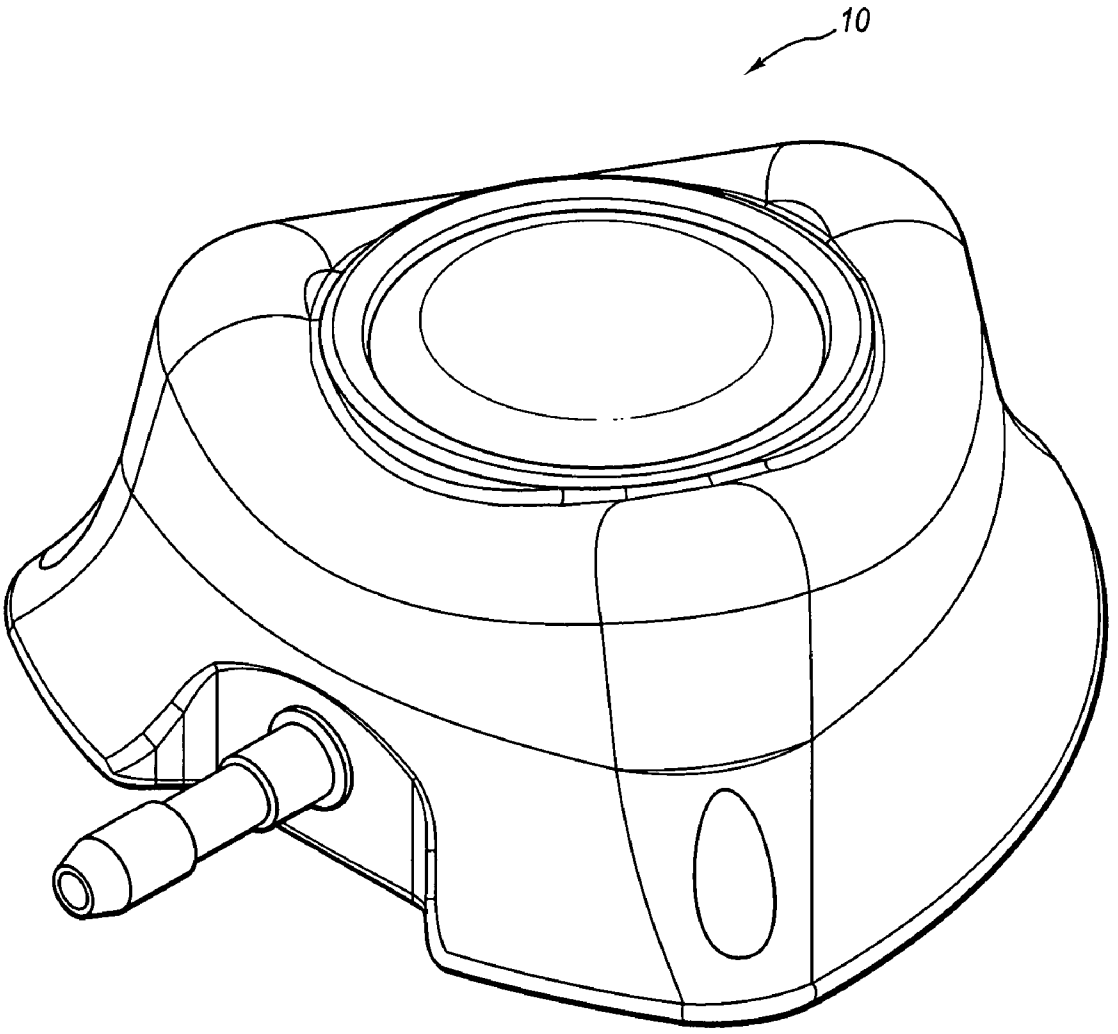


FIG. 47

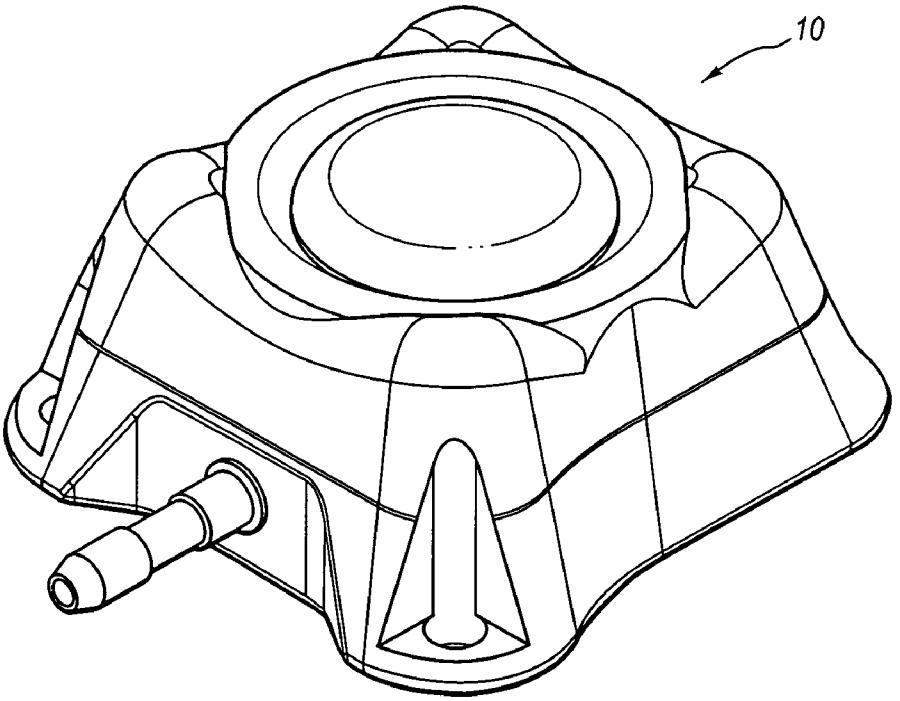


FIG. 48

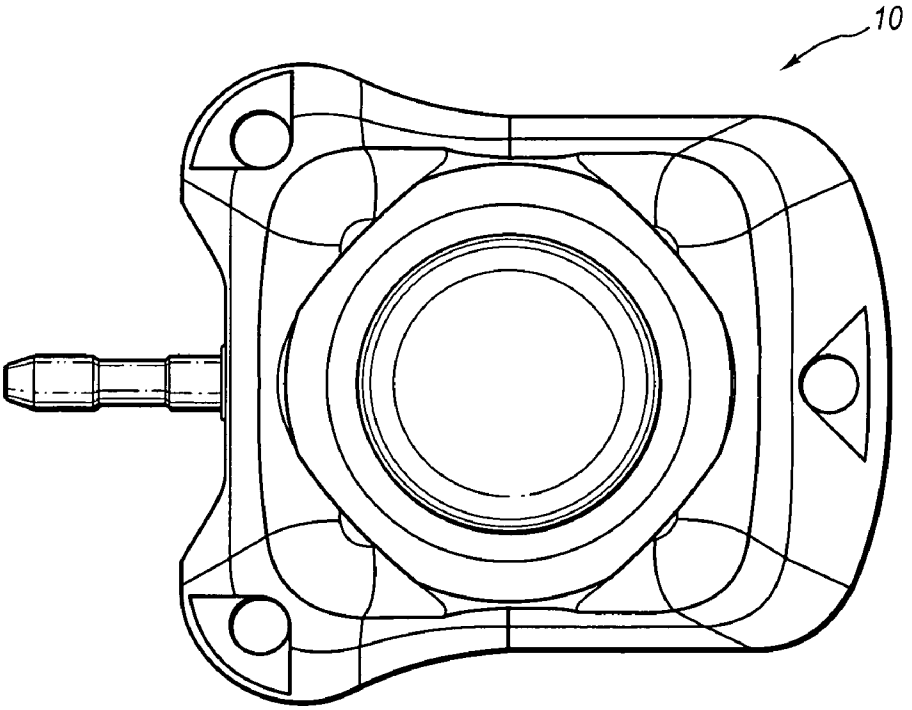


FIG. 49

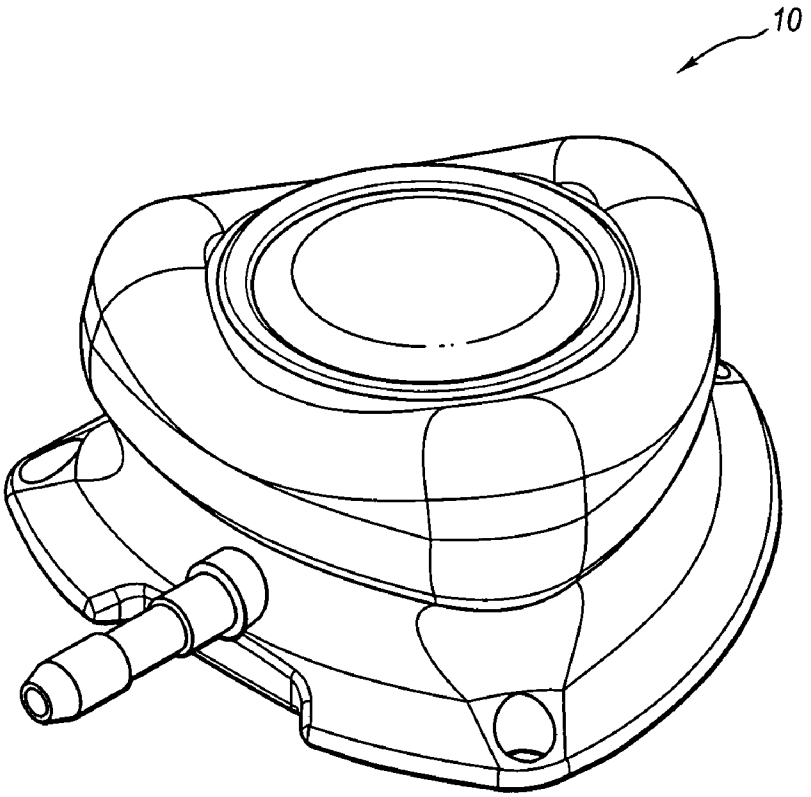


FIG. 50

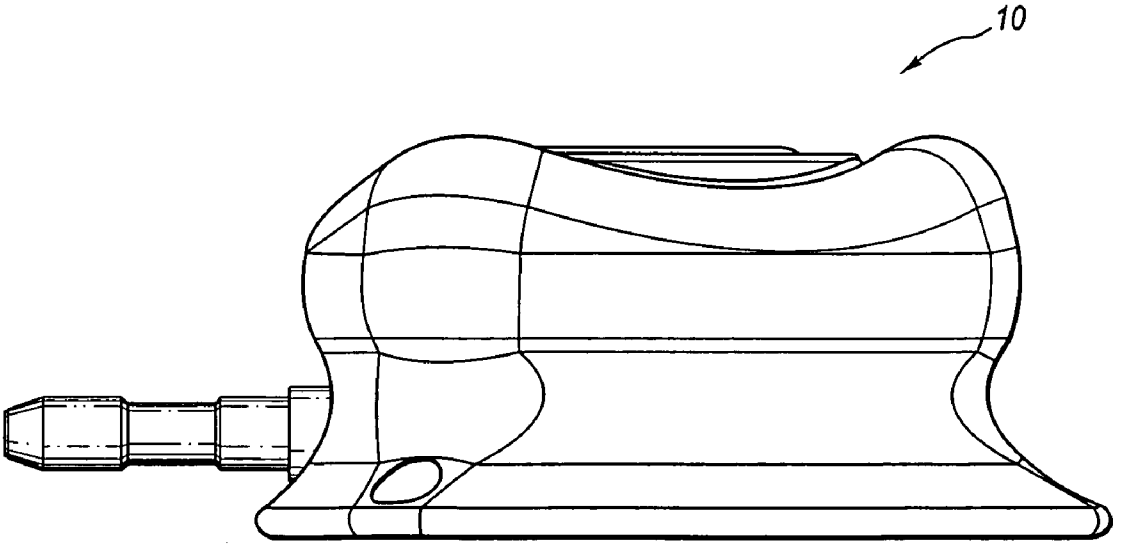


FIG. 51

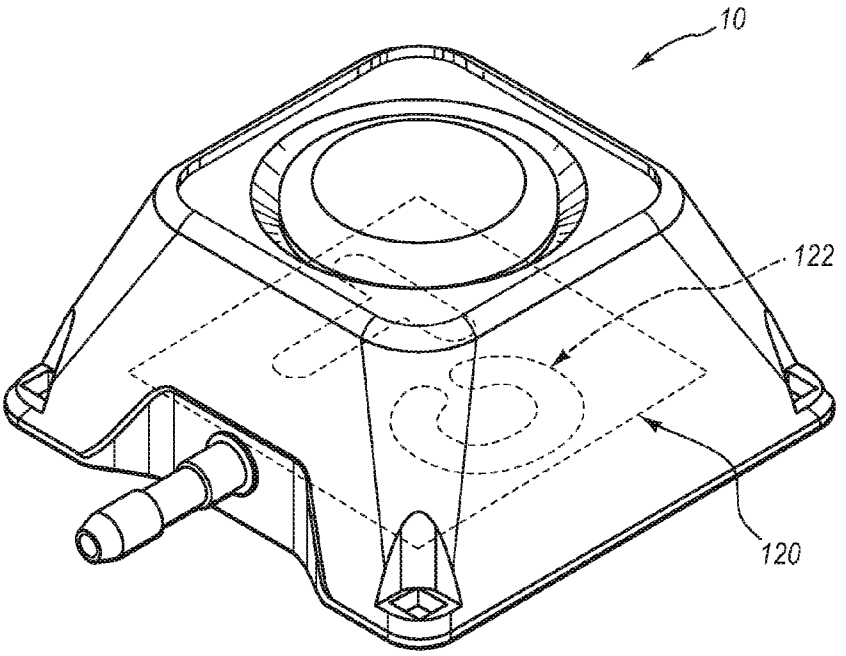


FIG. 52A

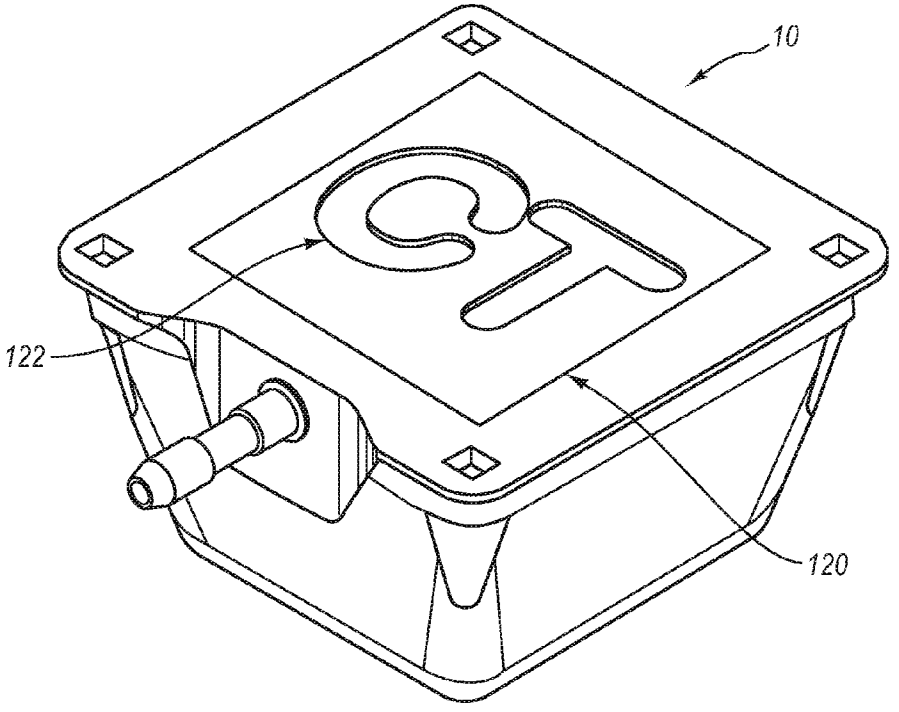


FIG. 52B

ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

This claims the benefit of U.S. patent application Ser. No. 60/658,518, filed 4 Mar. 2005, the disclosure of which is incorporated, in its entirety, by this reference.

BACKGROUND

Access ports provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures. Ports are totally implantable within the body (i.e. subcutaneously) and may permit the infusion of medicine, parenteral solutions, blood products, or other fluids. Additionally, ports may also be used for blood sampling.

A typical port typically includes a housing assembly, a septum, and an outlet. The housing assembly and septum define a reservoir which is accessible through the septum. The outlet of the housing may communicate with a catheter which accesses a vein. Thus, the catheter may be employed for delivering a fluid from the port to a remote location in the body, for example, the superior vena cava.

In common practice, a port is implanted within the body and the catheter is routed to a remote area where a fluid is desired to be delivered. To deliver the fluid, a caregiver locates the septum of the port by palpation of a patient's skin. Port access is accomplished by percutaneously inserting a needle, typically a non-coring needle, through the septum of the port and into the reservoir. A fluid, such as a drug or other beneficial substance, may then be administered by bolus injection or continuous infusion into the reservoir. Thus, the fluid may flow through the reservoir into the catheter and finally to the site were the fluid is desired.

Ports generally come in two different types, surgical and cosmetic. Surgical ports may typically be used for delivering medicinal substances, including chemotherapy drugs which may be harmful to surrounding tissue, or for sampling blood. Cosmetic ports, on the other hand, are utilized to deliver saline or some other non-reactive substance to a prosthesis which supplements a body feature.

Generally, conventional access ports of different manufacturers or models may typically exhibit substantially similar geometries that may not be differentiable with respect to one another. Accordingly, once an access port is implanted, it may be difficult to determine the model, style, or design of the access port. Such uncertainty may be undesirable, at least for replacement timing purposes, among other reasons, especially if identification of the implanted access port is difficult to otherwise determine.

Thus, it would be advantageous to provide an access port which provides at least one identifiable characteristic that may be sensed or otherwise determined subsequent to subcutaneous implantation of the access port.

SUMMARY

One aspect contemplated by the instant disclosure relates to an access port for providing subcutaneous access to a patient. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, an access port according to the instant disclosure may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation.

Another aspect contemplated by the instant disclosure relates to a method of identifying a subcutaneously implanted access port. More particularly, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted access port may be identified in response to perceiving the at least one feature.

A further aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Particularly, such an access port may comprise a body configured for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, the access port may comprise at least one feature structured to identify the access port as being power injectable subsequent to subcutaneous implantation.

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 contemplated by 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

FIG. **1**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **1**B shows a schematic side cross-sectional view the access port shown in FIG. **1**A;

FIG. **2** shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **3** shows a perspective view of an access port according to the instant disclosure;

FIG. **4** shows a perspective view of an access port according to the instant disclosure;

FIG. **5** shows a perspective view of an access port according to the instant disclosure;

FIG. **6**A shows a perspective view of an access port according to the instant disclosure;

FIG. **6**B shows a side view of the access port shown in FIG. **6**A;

FIG. **7** shows a perspective view of an access port according to the instant disclosure;

FIG. **8** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **9** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **10** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **11** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **12** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **13** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **14** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **15**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **15**B shows a top elevation view of the access port shown in FIG. **15**A;

FIG. **16** shows a perspective view of an access port according to the instant disclosure;

FIG. **17** shows a perspective view of an access port according to the instant disclosure;

FIG. **18** shows a perspective view of an access port according to the instant disclosure;

FIG. **19** shows a perspective view of an access port according to the instant disclosure;

FIG. **20** shows a perspective view of an access port according to the instant disclosure;

FIG. **21** shows a perspective view of an access port according to the instant disclosure;

FIG. **22** shows a perspective view of another embodiment of an access port according to the instant disclosure;

FIG. **23** shows a top elevation view of the assembled access port shown in FIG. **22**;

FIG. **24** shows a simplified representation of a transverse cross section of the access port shown in FIGS. **22** and **23**;

FIGS. **25-51** show perspective views of additional embodiments of an access port.

FIG. **52**A shows a top perspective view of an embodiment of an access port with an alphanumeric message in the bottom of the port.

FIG. **52**B shows a bottom perspective view of the embodiment in FIG. **52**A.

DETAILED DESCRIPTION

The instant disclosure relates generally to percutaneous access and, more specifically, to methods and devices associated with percutaneous access. Generally, the instant disclosure relates to an access port for subcutaneous implantation. In one embodiment, an access port may allow a physician or other medical personnel to obtain long term percutaneous access to the interior of a patient's body. Employing an access port for percutaneous access may reduce the opportunity for infection by inhibiting fluid connections (that extend into the interior of a patient's body) from the patient's skin and from the external environment. The access device allows access to the interior of the patient without requiring a needle to pierce the skin. Further, internal components, such as a catheter or a valve, may be replaced without a surgical procedure. Features or aspects of the instant disclosure may apply to any such access ports for subcutaneous access to a patient, without limitation. The access port may be injected by hand (e.g., via a syringe including a needle) for example, or may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port).

Power injectable ports may be employed in, among other processes, for example, computed tomography ("CT") scanning processes. More particularly, a so-called "power injector" system may be employed for injecting contrast media 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 under the trademark STELLANT®. Because fluid infusion 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.

More specifically, the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient. For example, at least one or perhaps multiple identifiable feature(s) of an access port contemplated by the instant disclosure may be correlative to information (e.g., a manufacturer's model or design) pertaining to the access port. Thus,

an identifiable feature from an access port of a particular model may be unique in relation to most if not all other identifiable features of another access port of a different models or design. Of course, the at least one identifiable feature of an access port contemplated by the instant disclosure may be further correlative with any information of interest, such as type of port, catheter type, date of manufacture, material lots, part numbers, etc. In one example, at least one identifiable feature of an access port may be correlative with the access port being power injectable. In this way, once at least one identifiable feature of an access port is observed or otherwise determined, correlation of such at least one feature of an access port may be accomplished, and information pertaining to the access port may be obtained.

In one embodiment, at least one feature may be perceived by palpation (i.e., to examine by touch), by way of other physical interaction, or by visual observation. Accordingly, a person of interest may touch or feel the access port through the skin to perceive at least one identifying characteristic thereof. In another embodiment, at least one identifiable feature may be perceived via x-ray or ultrasound imaging. In yet a further embodiment, at least one identifiable feature may be perceived through magnetic, light, or radio energy interaction or communication with the access port.

Turning to the embodiment wherein at least one feature may be perceived through palpation, other physical interaction, or visual observation, a topography or exterior surface feature of an access port contemplated by the instant disclosure may be configured for perception. For example, referring to FIGS. **1**A and **1**B, an exemplary access port **10** contemplated by the instant disclosure is shown. FIGS. **1**A and **1**B show a perspective view and a schematic side cross-sectional view, respectively, of an access port **10** for allowing percutaneous or otherwise internal access to a patient's body. Access port **10** includes a housing or body **20** defined by a cap **14** and a base **16**. Cap **14** and base **16**, as known in the art, may be configured for capturing therebetween a septum **18**. As shown in FIG. **1**A, cap **14** and base **16** may matingly engage one another along a mating line **15**. Cap **14** and base **16** may be secured or affixed to one another via mechanical fasteners such as screws or other fastening devices, may be adhesively affixed to one another, or may be affixed to one another as known in the art. Further, cap **14**, base **16**, and septum **18** may collectively define a cavity **36** in fluid communication with a lumen **29** of outlet stem **31**.

The body **20** may be implanted in a patient **7**, as shown in FIG. **1**B, to dispose the cavity **36** subcutaneously within the patient **7**. Also, suture apertures **66** (FIG. **1**A) may be used to affix the access port **10** within the patient **7**, if desired. After the body **20** is implanted in a patient **7**, the upper surface of the septum **18** may be substantially flush with the surface of the skin **6** of the patient **7** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the cavity **36**. The outlet stem **31** may create a fluid-communicative passageway from the cavity **36** through the outlet stem **31** and into the interior of the patient **7**. A catheter may be coupled to the outlet stem **31** for fluid communication with the cavity **36** and for transferring fluid from the cavity **36** to a desired remote location from the cavity **36** and within a patient **7**.

Body **20** of access port **10** may comprise a bio-compatible material such as polysulfone, titanium, or any other suitably bio-compatible material as known in the art. Accordingly, the body **20** may be formed from a bio-compatible plastic material. If desired, the body **20** may comprise a penetrable material for penetration by sutures or needles. In another embodiment, and as discussed further hereinbelow, body **20** may

comprise an impenetrable material such as, for instance, a metal if desired. Body **20** may include a concave bottom or, in another embodiment, may include a flat bottom, without limitation.

According to the instant disclosure, access port **10** may comprise a body **20** exhibiting at least one identifiable feature. More particularly, as shown in FIG. **1**A, body **20** may exhibit a partial generally pyramidal shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex otherwise known as a frustum). Generally, a body **20** of an access port **10** may exhibit a partial pyramidal shape extending between a generally quadrilateral shaped base positioned at reference plane **11** and a generally quadrilateral shaped upper base positioned at reference plane **9**. Reference planes **9** and **11** will not be shown in FIGS. **2**-**21**, for clarity; however, reference to planes **9** or **11** with respect to FIGS. **2**-**21**, as used herein, will refer to corresponding reference planes analogous to reference planes **9** and **11** as shown in FIGS. **1**A and **1**B.

As shown in FIG. **1**A, the exterior of access port **10** is substantially defined by four substantially planar side surfaces **50** connected to one another by radiuses **32**. In addition, the upper topography **61** of access port **10** is defined by upper surface **60** in combination with chamfers **46**A and **46**B and may be further defined by the upper surface of septum **18**. Explaining further, the outer periphery of upper topography **61** may be described as a generally quadrilateral exterior formed by side regions **54** and having rounded corner regions **30** adjacent side regions **54**. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

It may be appreciated that there are many variations to the geometry of access port **10** as shown in FIG. **1**A. For instance, while the body **20** of access port **10** may be described as a partially pyramidal shape or frustum, the instant disclosure is not so limited. Rather, one or more of side surfaces **50** may be oriented at as may be desired, without reference to any other side surfaces **50**. Accordingly, for example, one of surfaces **50** may be substantially vertical while the remaining surfaces **50** may be oriented at respective, selected angles. Furthermore, it should be understood that FIG. **1**A is merely exemplary and that the dimensions and shape as shown in FIG. **1**A may vary substantially while still being encompassed by the instant disclosure.

FIG. **2** shows a perspective view of another embodiment of access port **10** according to the instant disclosure. As shown in FIG. **2**, the exterior of access port **10** is substantially defined by a generally parallelogram-shaped base (positioned at reference plane **11** as shown in FIGS. **1**A and **1**B) extending generally pyramidally to a generally parallelogram-shaped upper surface (positioned at reference plane **9** as shown in FIGS. **1**A and **1**B). As shown in FIG. **2**, radiuses **42** may be larger than radiuses **32** as shown in FIG. **1**A. Furthermore, the upper topography **61** of access port **10** as shown in FIG. **2** may include rounded corner regions **40** which are larger than rounded corner regions **30** as shown in FIG. **1**A. Thus, FIG. **2** shows an exemplary embodiment of an access port **10** that may be perceivably distinguishable from access port **10** as shown in FIGS. **1**A and **1**B. For example, a difference between one exterior of an access port contemplated by the instant disclosure and another exterior of a different access port contemplated by the instant disclosure may be determined by way of palpation.

In another embodiment, in another aspect contemplated by the instant disclosure, a template may be employed for perceiving at least one feature of an access port. For instance, a complementarily-shaped template may be positioned over and abutted against an access port contemplated by the instant disclosure so as to determine if the access port matches or substantially corresponds to the shape of the template. Such a process may reliably indicate or perceive at least one feature of an access port contemplated by the instant disclosure. Of course, a plurality of templates corresponding to different models of access ports may be serially engaged with an unknown access port so as to perceive at least one feature thereof. Such a process may allow for identification (e.g., of a model or manufacturer) of an access port contemplated by the instant disclosure.

In another aspect contemplated by the instant disclosure, an upper topography of an access port may include at least one feature for identifying the access port. For example, as shown in FIG. **3**, upper surface **60** of access port **10** may be nonplanar. More specifically, upper surface **60** may be tapered or may arcuately extend downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B) as it extends radially inwardly toward septum **18**. Otherwise, access port **10**, as shown in FIG. **3**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Thus, upper surface **60** is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In yet a further embodiment of an access port contemplated by the instant disclosure, side regions **54** extending between rounded corner regions **30** may exhibit at least one perceivable feature. For example, as shown in FIG. **4**, access port **10** may include one or more side regions **54** that extend arcuately between adjacent rounded corner regions **30**. Otherwise, access port **10**, as shown in FIG. **4**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Side regions **54** may be congruent or symmetric with respect to one another or, in another embodiment, may be configured differently with respect to one another, without limitation.

FIG. **5** shows a further exemplary embodiment of an access port contemplated by the instant disclosure. More specifically, access port **10**, as shown in FIG. **5**, includes side regions **54** that form recessed regions **72** between adjacent rounded corner regions **30**. Put another way, the upper topography **61** may include alternating recessed regions **72** and protruding regions **70** positioned generally about a periphery of septum **18**. Otherwise, access port **10**, as shown in FIG. **5**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Such a configuration may provide an access port having at least one identifiable feature.

In a further embodiment of an access port contemplated by the instant disclosure, FIGS. **6**A and **6**B show a perspective view and a side view, respectively, of an access port **10** generally configured as is described with reference to FIG. **5** but having an elongated body **20**E. More specifically, elongated body **20**E of access port **10**, as shown in FIGS. **6**A and **6**B, includes a side surface **50**E that extends generally from upper topography **61** downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B) and having a slope (e.g., an angle with respect to a vertical axis normal to an upper surface of septum **18**) which is different from the other side surfaces **50**. Otherwise, access port **10**, as shown in FIG. **6**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Such a configuration may provide an elongated body **20**E of an access port **10** having an elongated side portion.

Of course, one or more side surfaces of an access port according to the instant disclosure may be configured for forming a body exhibiting a selected shape as may be desired. An elongated body portion of an access port contemplated by

the instant disclosure may form, in combination with other features as described hereinabove or, in another embodiment, taken alone, at least one perceivable feature for identification of an access port according to the instant disclosure.

FIG. **7** shows a further embodiment of an access port encompassed by the instant disclosure. Particularly, as shown in FIG. **7**, access port **10** may include an upper body portion **20***a* and a lower body portion **20***b*. Furthermore, each of upper body portion **20***a* and lower body portion **20***b* may exhibit a partial pyramidal shape (i.e., a frustum), wherein the body portions **20***a* and **20***b* are stacked vertically with respect to one another. Accordingly, upper body portion **20***a* may form an overhanging rim feature **76** extending along a periphery of access port **10**. Explaining further, lower body portion **20***b* may have an exterior substantially defined by side surfaces **50***b* and rounded corner regions **30***b*, while upper body portion **20***a* may have an exterior substantially defined by side surfaces **50***a*, rounded corner regions **30***a*, and upper topography **61**. It may be appreciated that overhanging rim feature **76** may be sized and configured for perception via palpation. Such a configuration may provide a suitable access port for delivery of a beneficial or medicinal substance, the access port being identifiable (e.g., by model number, manufacturer, etc.) after implantation.

It should be understood that the instant disclosure contemplates access ports having an exterior geometry that is not quadrilateral in nature. Rather, the instant disclosure contemplates that an access port may have an exterior which is generally cylindrical, generally conical, generally elliptical, generally oval, or an exterior that is otherwise arcuate in nature. Specifically, the instant disclosure contemplates that an access port having a substantially rounded or arcuate exterior may include at least one feature configured for identification of the access port after implantation. For example, as shown in FIG. **8**, shows a cap **14** that exhibits an exterior surface **78** that is substantially conical. Cap **14** may be assembled to a suitable base (not shown) for capturing a septum (not shown) as described hereinabove to form an access port **10** as generally described with reference to FIGS. **1-7**.

The instant disclosure further contemplates that at least one protrusion, protruding region, recess, recessed region, undulation, or adjacent features of different elevation may comprise a feature for identifying an access port contemplated by the instant disclosure. More specifically, upper topography **61**C, as shown in FIG. **8**, may include a plurality of protrusions **80**. Protrusions **80** may exhibit partially spherical upper surfaces that transition into a lower portion of cap **14**. In further detail, protrusions **80** may be circumferentially spaced about the periphery of septum (not shown) as may be desired. In one embodiment, a plurality of protrusions **80** may be symmetrically circumferentially spaced about the periphery of septum (not shown). More generally, at least one protrusion **80** may be sized, configured, and positioned for forming at least one identifiable feature of an access port. Of course, at least one protrusion **80** may be structured for facilitating comfort of a patient within which the access port is implanted. As may be appreciated, at least one protrusion **80** or more than one protrusion **80** may be included in an upper topography **61**C of an access port (not shown) contemplated by the instant disclosure.

FIG. **9** shows another embodiment of a cap **14** including at least one protrusion **80**E for forming and identifying an access port contemplated by the instant disclosure after implantation thereof within a patient. Protrusions **80**E may extend circumferentially about a center of revolution. Thus, protrusions **80**E may exhibit a body **87** portion circumferentially extending between rounded ends **83**. Further, cap **14** may have an exterior surface **78** that is substantially symmetric about an axis of revolution. More generally, body **20** may extend from a generally circular, generally elliptical, or generally oval base positioned at a lower extent **71** of the cap **14** to an upper generally circular, generally elliptical, or generally oval cross section that is smaller than a cross section of the base and is positioned at an upper extent **73** (without considering protrusions **80**E) of the cap **14**. In addition, side surface **51**, as shown in FIG. **9**, extends arcuately between the base and the upper topography **61** of cap **14**. Side surface **51** may extend in a generally tapered or conical fashion, may exhibit a radius or other arcuate shape, or may otherwise transition between a cross section of the base of the access port to a cross section proximate the upper topography **61**C thereof.

Further, FIG. **10** shows an embodiment of a cap **14** for forming an access port contemplated by the instant disclosure having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E are circumferentially larger than the circumferentially extending recesses **80**E. In another embodiment of an access port contemplated by the instant disclosure, FIG. **11** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) sized or extension. In yet a further embodiment of a cap **14** for forming an access port contemplated by the instant disclosure, FIG. **12** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising three circumferentially extending protrusions **80**E and three circumferentially extending recesses **82**, arranged so as to alternate circumferentially, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) size.

FIG. **13** shows a perspective view of an additional embodiment of an cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T, wherein transition regions **81** are provided between circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T. Such transition regions **81**, as shown in FIG. **13**, may taper or generally smoothly transition between a circumferentially extending protrusion **80**T and a circumferentially extending recess **82**T. Also, FIG. **14** shows a perspective view of an additional embodiment of a cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including protrusion regions **96** and recessed regions **98** that transition between one another and alternate circumferentially so as to form an undulating topography comprising upper topography **61**C. Such an undulating topography, as shown in FIG. **14**, generally smoothly transitions between circumferentially adjacent protrusion regions **96** and recessed regions **98**.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **15**A and **15**B show a perspective view and a top elevation view, respectively, of an access port **10** generally configured as is described with reference to FIG. **5** but may include at least one nonplanar side surface. In another embodiment, access port **10** as shown in FIG. **15** may be configured as shown in FIGS. **1-4** or FIGS. **6-7**, or any embodiments described hereinbelow, without limitation.

More specifically, elongated body **20** of access port **10**, as shown in FIGS. **15**A and **15**B, includes three side surfaces **50**R that extend arcuately (as shown in FIG. **15**B). Such a configuration may provide an access port **10** that is identifiable subsequent to implantation. In yet another embodiment of an access port contemplated by the instant disclosure, FIG. **16** shows a perspective view of an access port **10** including a side wall **100** that truncates a portion of a radius **32** formed between side surfaces **50** of access port **10**. It may also be noted that such an access port **10** may include three suture apertures **66**, which may, taken alone or in combination with at least one other feature, comprise at least one identifiable feature of an access port contemplated by the instant disclosure. In addition, as shown in FIG. **16**, outlet stem **31** may extend from side wall **100**.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **17** shows a perspective view of an access port **10** wherein cap **14** and base **16**, when assembled to one another along mating line **15**, form a flange feature or lip feature **102** that extends about at least a portion of the periphery of the access port **10**. As shown in FIG. **17**, lip feature **102** extends substantially about the periphery of the access port **10**, proximate to the mating line **15** between cap **14** and base **16**. Such a feature may comprise at least one identifiable feature of an access port contemplated by the instant disclosure. Thus, it may be appreciated that a peripheral discontinuity between the cap **14** and base **16** may be formed generally along the mating line **15** therebetween. In the embodiment of an access port as shown in FIG. **7**, an overhanging rim feature **76** may comprise a peripheral discontinuity or, in the embodiment of an access port as shown in FIG. **17**, a lip feature **102** may comprise a peripheral discontinuity.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, concave region **106** of side surface **50** is concave. Concavity (i.e., a concave region **106**) may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, region **106** of side surface **50** is concave. Concavity may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **19** shows a perspective view of an access port **10** generally configured as is described with reference to FIG. **6**A and **6**B. More specifically, elongated body **20**ER, as shown in FIG. **19** includes a side surface **50**ER that extends arcuately from upper topography **61** of access port **10** downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B). Such a configuration may provide an elongated body **20**E of an access port **10** having an elongated side portion.

It should be understood from the above-described various embodiments of an access port contemplated by the instant disclosure that many variations, additions, or different features may be encompassed by the instant disclosure. Thus, the instant disclosure is not limited to the several above-described exemplary embodiments.

For example, as shown in FIG. **20**, which shows a top elevation view of an access port **10** contemplated by the instant disclosure, an access port **10** may include a side wall **100** that at least partially truncates a radius **32** between side surfaces **50**, outlet stem **31** extending from side wall **100**, and at least one of a concave region **106** and an arcuate surface **50**R. Further, as shown in FIG. **20**, suture apertures **66** may be positioned so as to identify the access port **10** after subcutaneous implantation.

Additionally, the instant disclosure contemplates access ports having an exterior geometry that is polygonal in nature. Specifically, the instant disclosure contemplates that an access port contemplated by the instant disclosure may exhibit a generally triangular exterior. Thus, as shown in FIG. **21**, body **20** may exhibit a generally pyramidal or tapered shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex). Generally, a body **20**T of an access port **10** may extend between a generally triangularly-shaped base and a relatively smaller, generally triangularly-shaped upper base. Accordingly, the exterior of access port **10** may be substantially defined by three side surfaces (e.g., **50**, **50**R, **102**, **50**E) having radiuses **32** extending therebetween. In addition, the upper topography **61** of access port **10** may be defined by upper surface **60** in combination with side regions **54** and rounded corner regions **30**. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

FIGS. **22** and **23** show a perspective view and a top elevation view of another embodiment of an access port including a generally triangular exterior geometry. More particularly, as shown in FIGS. **22** and **23**, a cap **14** and base **16** (collectively forming a housing) may capture a septum **118** to form an access port **10**. Further, outlet stem **31** may include a stem base that may be positioned within and sealed to an outlet recess **93** formed within base **16**. The outlet stem **31** may be in fluid communication with a cavity formed within the access port **10**. Optionally, suture plugs **89** may be positioned within suture cavities **91** formed in base **16**. Suture plugs **89** may comprise a pliant material (e.g., silicone, rubber, etc.) that may provide some resilience between sutures coupling the access port **10** (i.e., the base **16**) to a patient. In further detail, a side periphery **95** (e.g., one or more side walls) of access port **10** may be generally triangular. Thus, cap **14** and base **16** may collectively form a generally triangular housing or body of access port **10**. Also, the instant disclosure contemplates that side periphery **95** may increase or decrease in cross-sectional size (e.g., by tapering or arcuately transforming) between upper surface **161** of cap **14** and lower surface **151** of base **16**. As shown in FIGS. **22** and **23**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **151** of base **16**) of access port **10** may be larger proximate to lower surface **151** of base **16** and may be relatively smaller proximate upper surface **161** of cap **14**.

Additionally, FIG. **24** shows a simplified representation of a transverse cross section of access port **10**. As shown in FIG. **24**, side periphery **95** of access port **10** may define three side regions **103** that extend between associated vertex regions **101**. In addition, in one embodiment and as shown in FIG. **24**,

side periphery **95** may define a substantially equilateral generally triangular shape. As one of ordinary skill in the art will appreciate, side regions **103** may arcuately extend between associated vertex regions **101**; thus, side regions **103** may form "sides" of a generally triangular shape. Further, although vertex regions **101** are rounded, it may be appreciated that such vertex regions **101** form an intersection between adjacent side regions **103**. Accordingly, one of ordinary skill in the art will appreciate that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect, without limitation. For example, the phrase "generally triangular" encompasses three sided polygons, circular triangles, equilateral triangles, etc., without limitation.

The instant disclosure also contemplates that at least one feature of an access port contemplated by the instant disclosure may not be observable visually or by palpation but, rather, may be otherwise observable. For example, the instant disclosure contemplates that at least one feature of an access port may be observable through interaction with an imaging technology such as x-ray or ultrasound. For example, in one embodiment, a metal feature (e.g., a plate or other metal geometry) may be included by an access port contemplated by the instant disclosure. As may be appreciated, such a metal feature may be represented on an x-ray generated by exposure of the access port to x-ray energy while simultaneously exposing x-ray sensitive film to x-ray energy passing through the access port. Further, the instant disclosure contemplates that a size, shape, or both size and shape of a metal feature of an access port may be configured for enhancing identification of an access port. For example, assuming that a metal feature comprises a metal plate, a size, shape, or both may be selectively tailored for identification of an access port. Similarly, a feature of an access port contemplated by the instant disclosure may be tailored for detection via ultrasound interaction. Such a feature may comprise an exterior topographical feature. In another embodiment, such a feature may comprise a composite structure including two or more materials that form an interface surface that may be identified by ultrasound imaging.

The instant disclosure also contemplates that at least one feature of an access port contemplated by the instant disclosure may not be observable visually or by palpation but, rather, may be otherwise observable. For example, the instant disclosure contemplates that at least one feature of an access port may be observable through interaction with an imaging technology such as x-ray or ultrasound. The access port may be constructed of both metal and plastic. For example, in one embodiment, a metal feature (e.g., a plate or other metal geometry) may be included by an access port contemplated by the instant disclosure. As may be appreciated, such a metal feature may be represented on an x-ray generated by exposure of the access port to x-ray energy while simultaneously exposing x-ray sensitive film to x-ray energy passing through the access port. In another embodiment, the access port may incorporate a metal disk in the bottom of the plastic port. The disk may include an alphanumeric message etched in the port disk that would be visible on radiograph (x-ray). FIGS. **52**A-B illustrate one embodiment of an alphanumeric message **122** etched in a disk or plate **120** in the bottom of a port **10**. Further, the instant disclosure contemplates that a size, shape, or both size and shape of a metal feature of an access port may be configured for enhancing identification of an access port. For example, assuming that a metal feature comprises a metal plate, a size, shape, or both may be selectively tailored for identification of an access port. Additionally, by way of example, a metal port may be configured to leave a square imprint on an x-ray that could identify the port as a power-injectable port. Similarly, a feature of an access port contemplated by the instant disclosure may be tailored for detection via ultrasound interaction. Such a feature may comprise an exterior topographical feature. In another embodiment, such a feature may comprise a composite structure including two or more materials that form an interface surface that may be identified by ultrasound imaging.

In one exemplary example, it is contemplated that radio frequency identification technology may be employed for identification of an access port contemplated by the instant disclosure. Particularly, so-called active RFID tags are powered by an internal battery and are typically read/write devices. Currently, a suitable cell coupled to suitable low power circuitry can ensure functionality for as long as ten or more years, depending upon the operating temperatures and read/write cycles and usage. So-called passive RFID tags operate without a separate external power source and obtain operating power generated from the reader. Passive RFID tags are typically programmed with a unique set of data (usually 32 to 128 bits) that cannot be modified. Read-only tags may operate as an identifier comparable to linear barcodes which may contain selected product-specific information. Thus, passive RFID tags may be much lighter than active RFID tags, less expensive, and may offer a virtually unlimited operational lifetime. The tradeoff is that they have shorter read ranges than active tags and require a higher-powered reader.

One advantage of RFID approach is the noncontact, non-line-of-sight nature of the technology. Tags can be read through a variety of substances such as snow, fog, ice, paint, crusted grime, and other visually and environmentally challenging conditions, where other optically read technologies may be less effective. RFID tags can also be read in challenging circumstances at rapid speeds, in most cases responding in less than about 100 milliseconds.

While certain representative embodiments and details have been shown for purposes of illustrating aspects contemplated by 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 contemplated by 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 contemplated by the instant disclosure. In particular, FIGS. **25-51** illustrate a number of additional exemplary embodiments of access port **10**. As is apparent from these figures, access port **10** may be formed in any number of shapes and sizes, such that any number of modifications and changes are possible to any of the embodiments described and illustrated herein without departing from the spirit and scope of the instant disclosure.

What is claimed is:

1. A venous access port assembly for implantation into a patient, comprising:

a housing having a discharge port, a needle-penetrable septum, and a cap securable to the housing and retaining the septum securely in the assembly, the housing having a housing base defining a bottom wall of at least one reservoir, and an outwardly facing bottom surface,

the housing base including radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an X-ray of the patient is taken after implantation.

2. The assembly of claim 1, wherein the radiopaque alphanumeric message is applied to a surface of the housing base.

3. The assembly of claim 1 wherein the radiopaque alphanumeric message is applied to the outwardly facing bottom surface of the housing base.

4. The assembly of claim 1, wherein the radiopaque alphanumeric characters include the letters "C" and "T".

5. A venous access port assembly for implantation into a patient, comprising:

a housing having an outlet, and

a needle-penetrable septum, the needle-penetrable septum and the housing together defining a reservoir,

wherein:

the assembly includes a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly, and

the alphanumeric message indicating that the assembly is power injectable.

6. The assembly of claim 5, wherein the alphanumeric message includes an abbreviation for computed tomography.

7. The assembly of claim 5, wherein the alphanumeric message is applied to the exterior of the assembly.

8. A venous access port assembly for implantation into a patient, comprising:

a housing and a needle-penetrable septum together defining a reservoir; and

the housing including an outlet and a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly into the patient, the radiopaque alphanumeric message identifying the venous access port assembly as suitable for power injection.

9. The assembly of claim 8, wherein the radiopaque alphanumeric message includes "C" and "T".

10. A venous access port assembly for implantation into a patient, comprising:

a housing and a needle-penetrable septum together defining a reservoir; and

the housing including radiopaque markings including the alphanumeric message "CT" that conveys to a practitioner when an X-ray of the patient is taken after implantation that the venous access port assembly is suitable for power injection.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

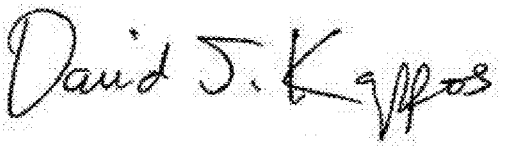
CERTIFICATE OF CORRECTION

PATENT NO.	: 7,785,302 B2
APPLICATION NO.	: 11/368954
DATED	: August 31, 2010
INVENTOR(S)	: Kelly B. Powers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the issued patent, Column 11, delete paragraph consisting of line numbers 15-40.

Signed and Sealed this
Nineteenth Day of July, 2011



David J. Kappos
Director of the United States Patent and Trademark Office

U.S. Pat. No. 7,947,022

US007947022B2

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

(10) **Patent No.: US 7,947,022 B2**
(45) **Date of Patent: *May 24, 2011**

(54) **ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 212 days.

This patent is subject to a terminal disclaimer.

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

(52) **U.S. Cl.** **604/288.02**

(58) **Field of Classification Search** 604/288.01, 604/288.02

See application file for complete search history.

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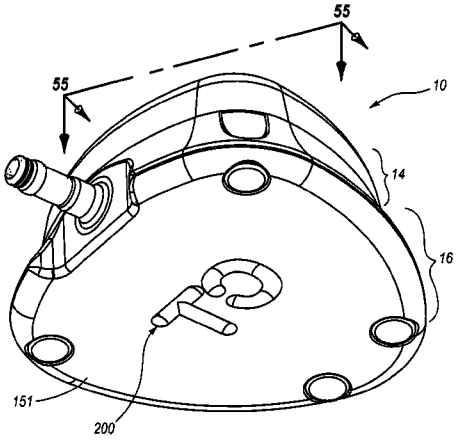
(57) **ABSTRACT**

An access port for subcutaneous implantation is disclosed. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle into a cavity defined within the body. Further, the access port may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation. Methods of identifying a subcutaneously implanted access port are also disclosed. For example, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted access port may be identified in response to perceiving the at least one feature. In one embodiment, an identification feature is engraved or otherwise defined by the access port, so as to be visible after implantation via x-ray imaging technology.

20 Claims, 46 Drawing Sheets



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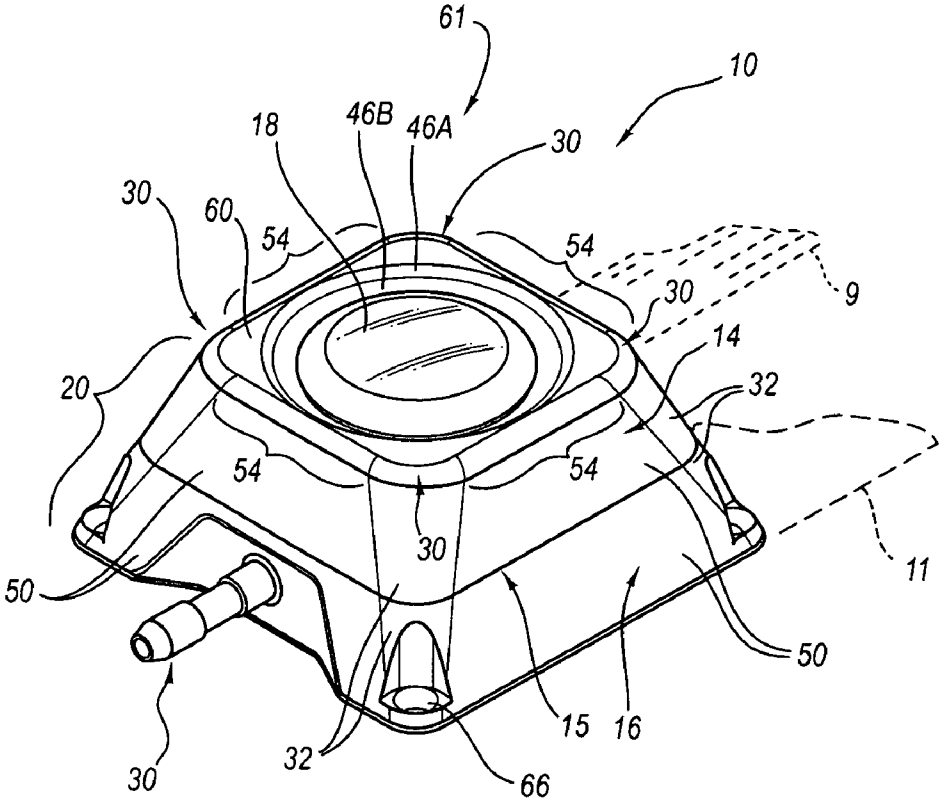
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FIG. 1A

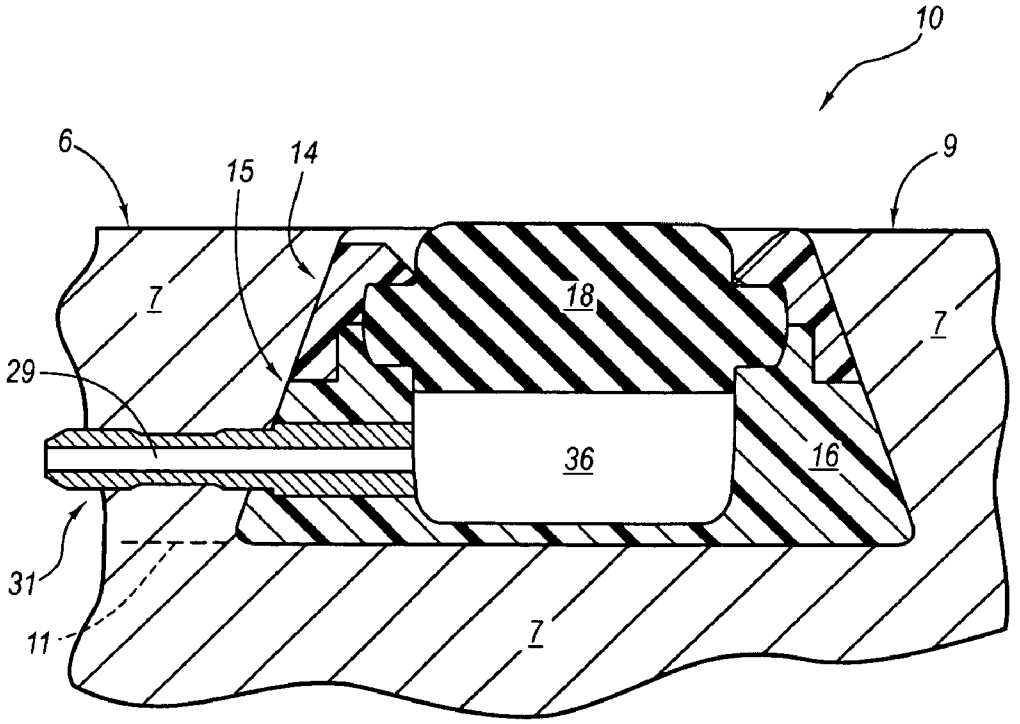
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FIG. 1B

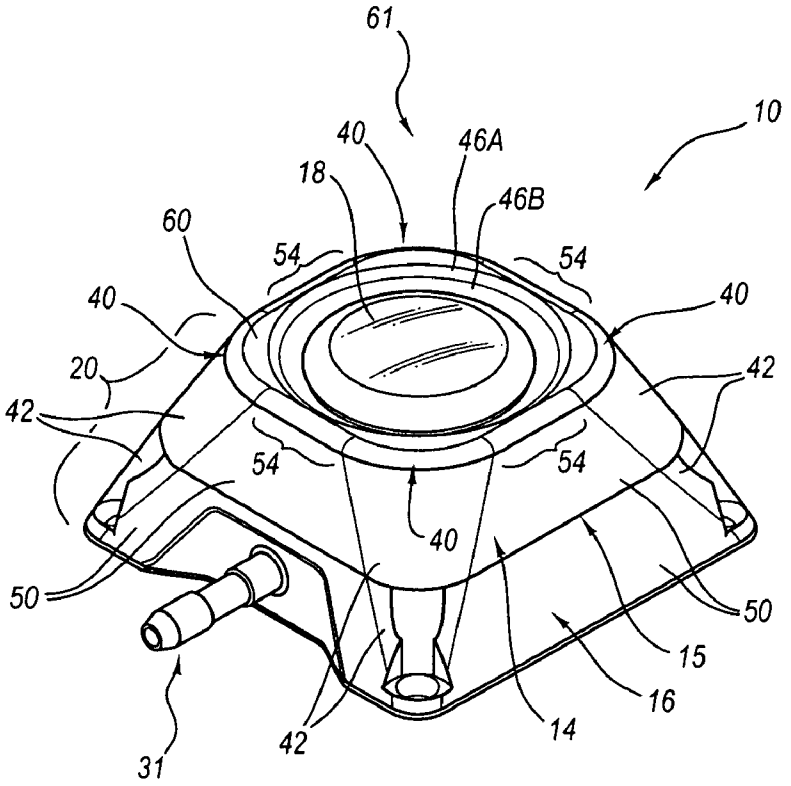
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FIG. 2

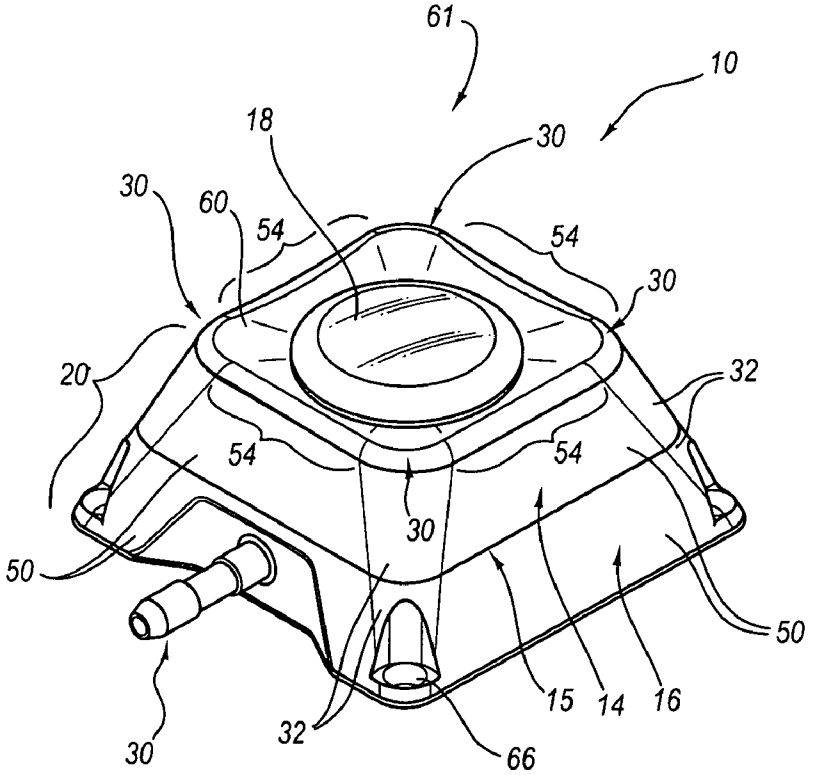
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FIG. 3

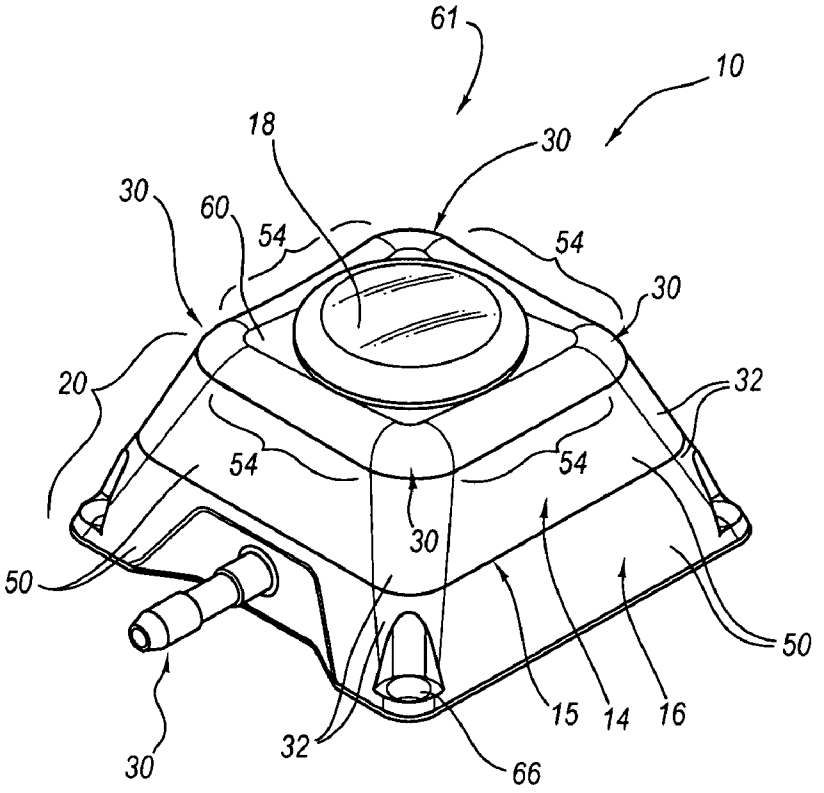
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FIG. 4

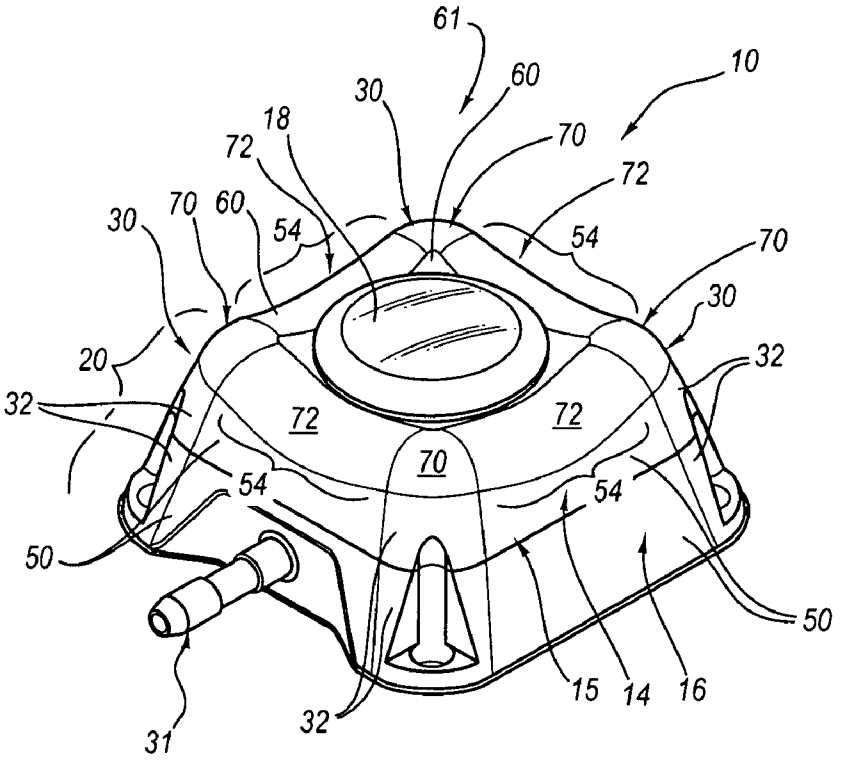
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FIG. 5

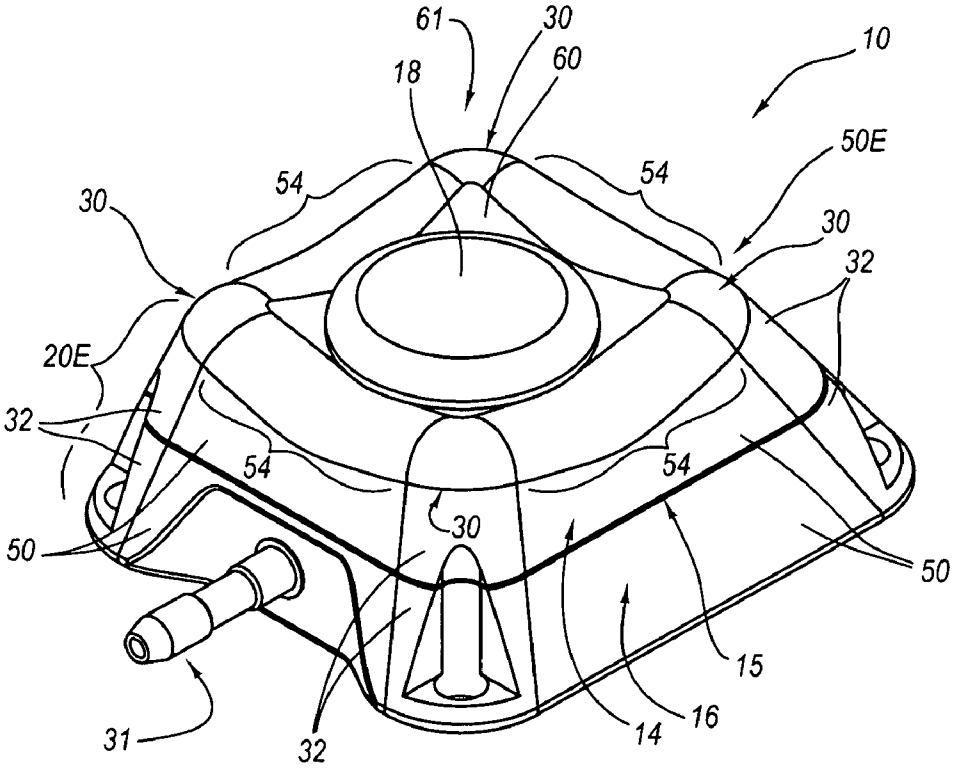
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FIG. 6A

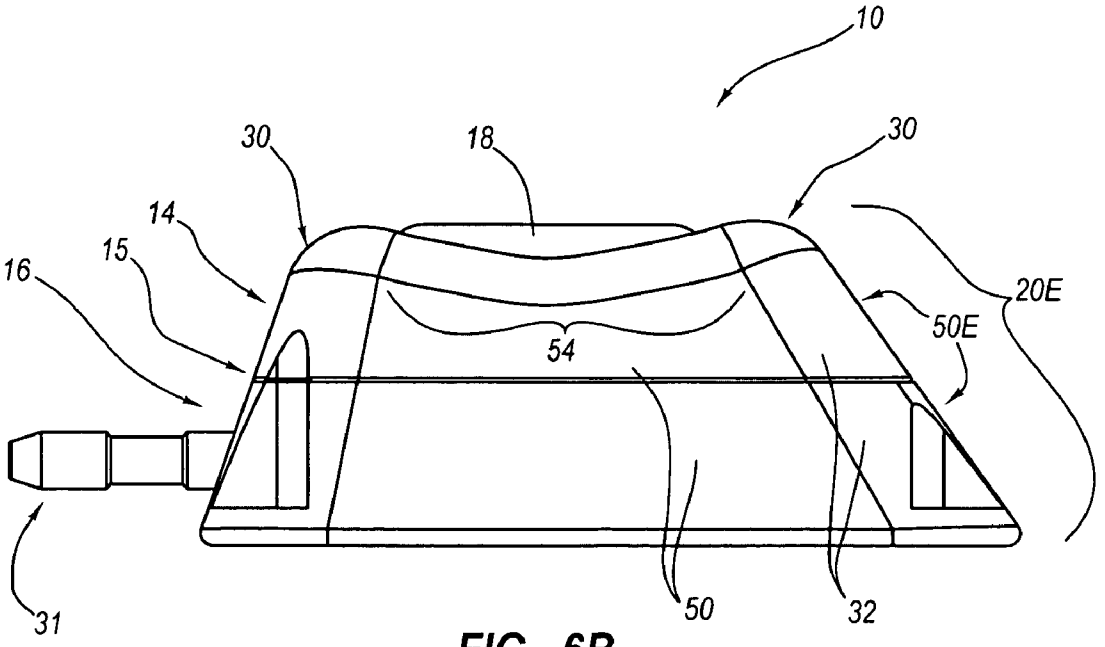
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FIG. 6B

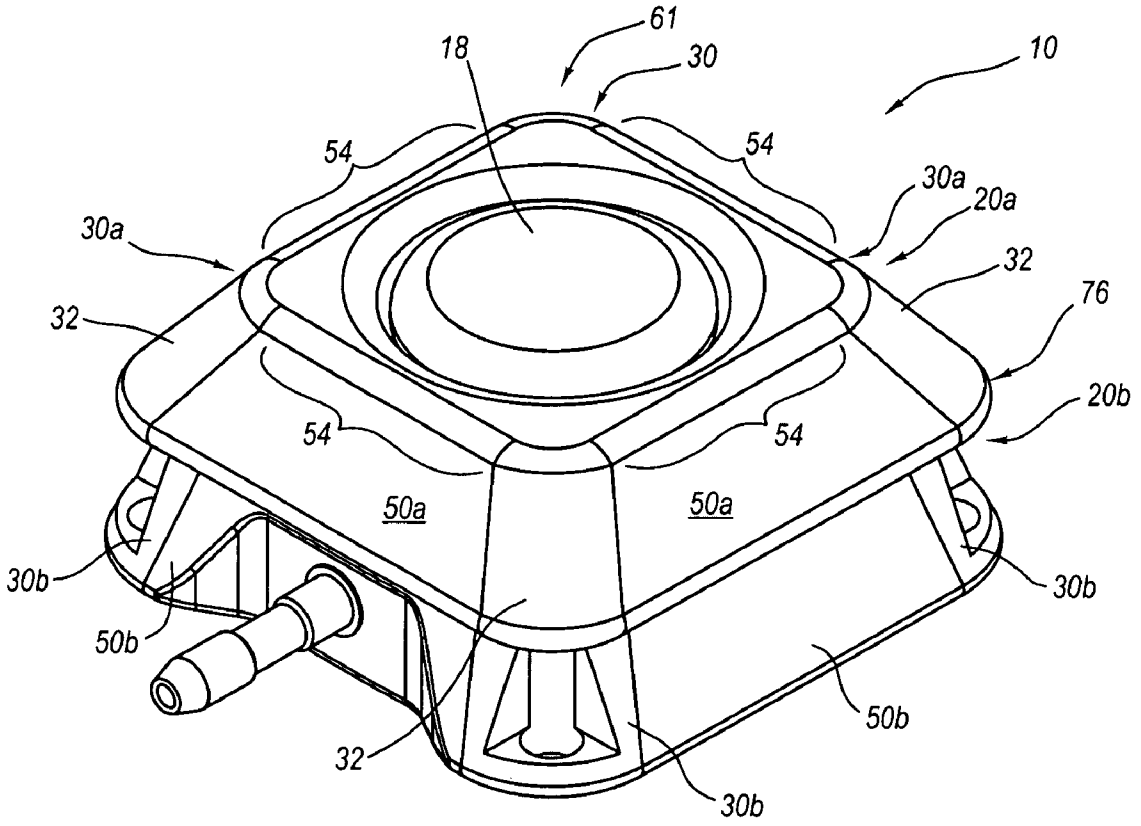
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FIG. 7

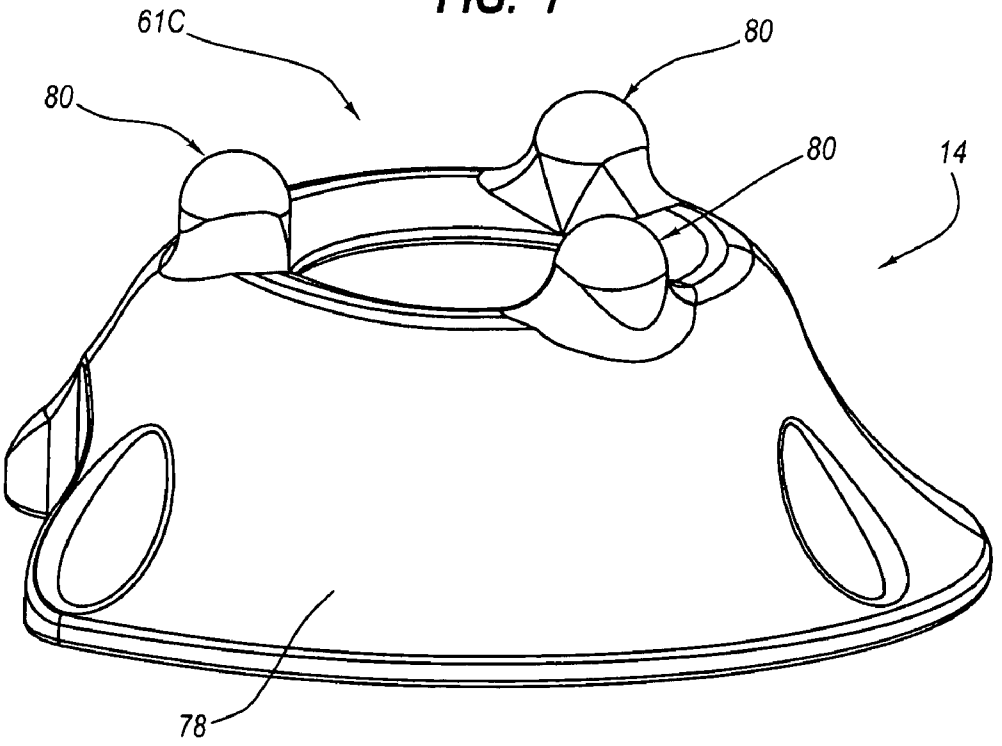
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FIG. 8

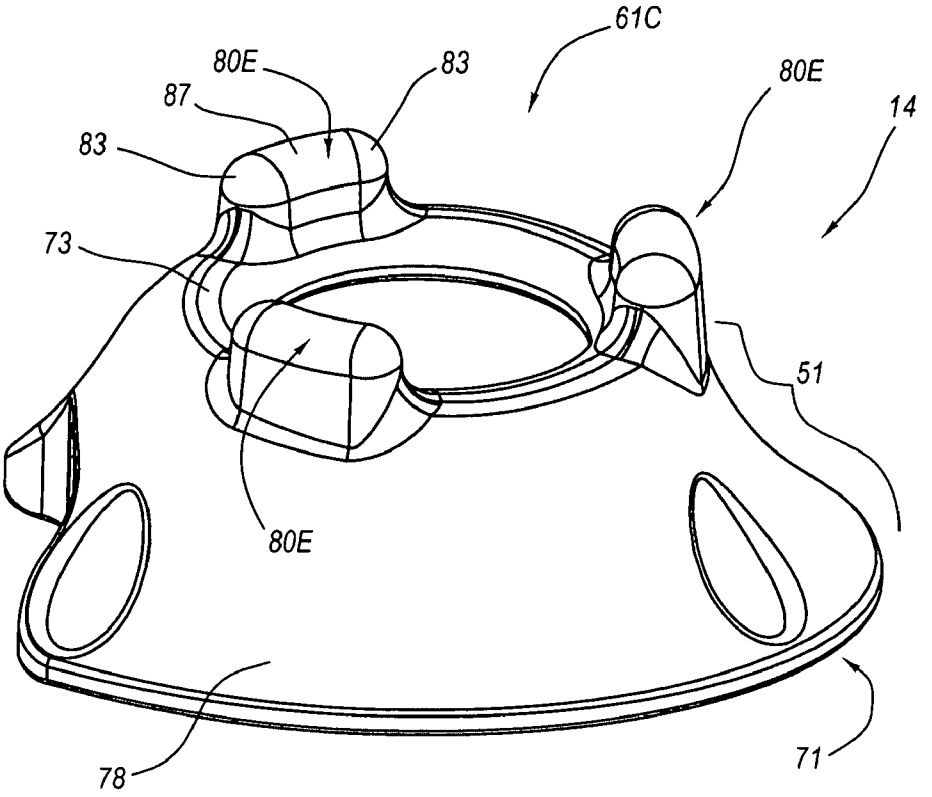
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FIG. 9

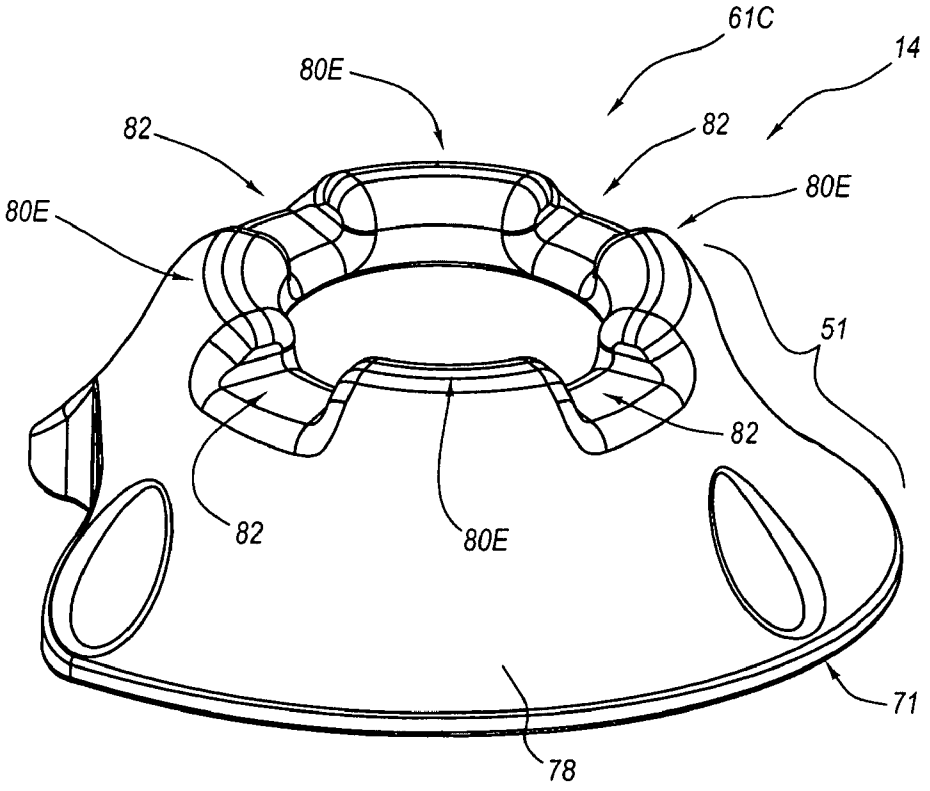
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FIG. 10

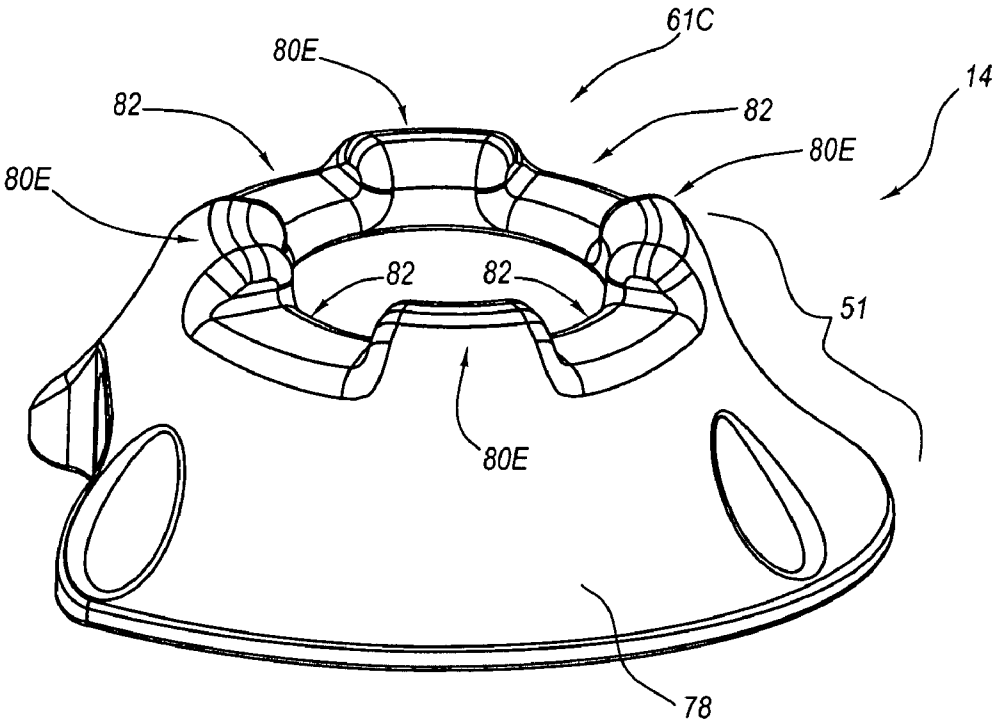

FIG. 11

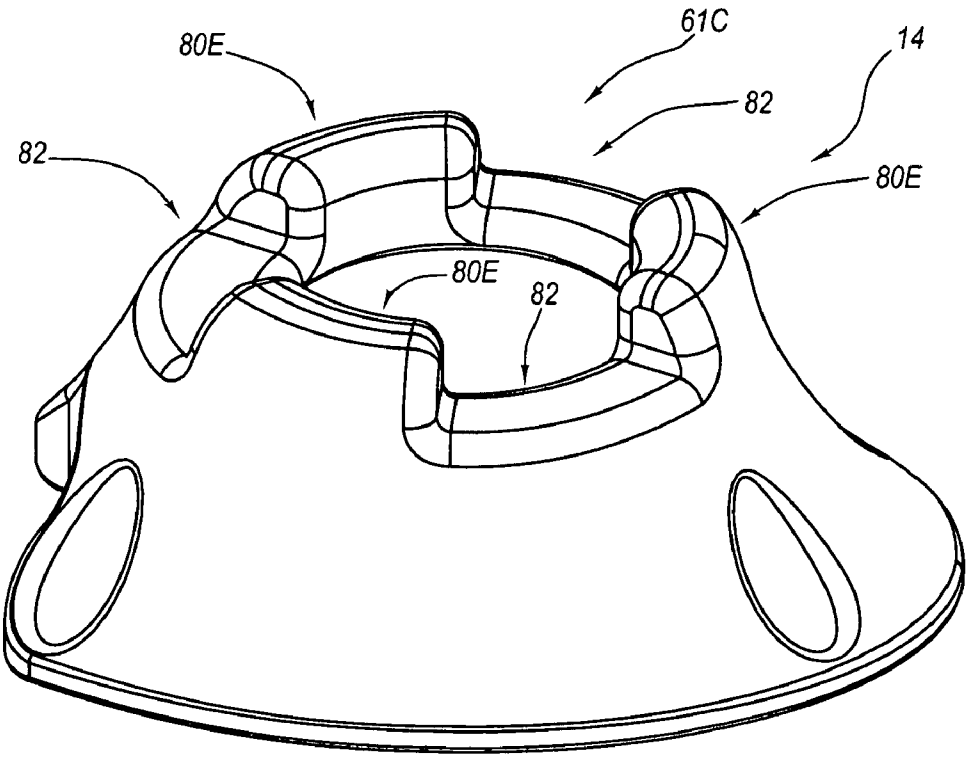

FIG. 12

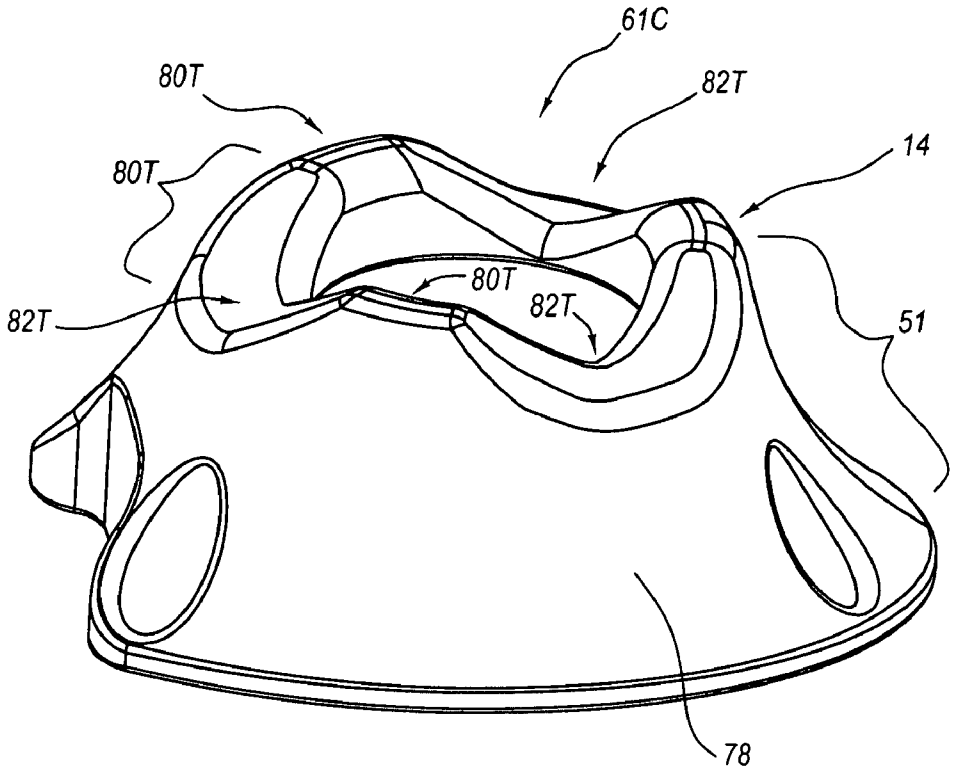

FIG. 13

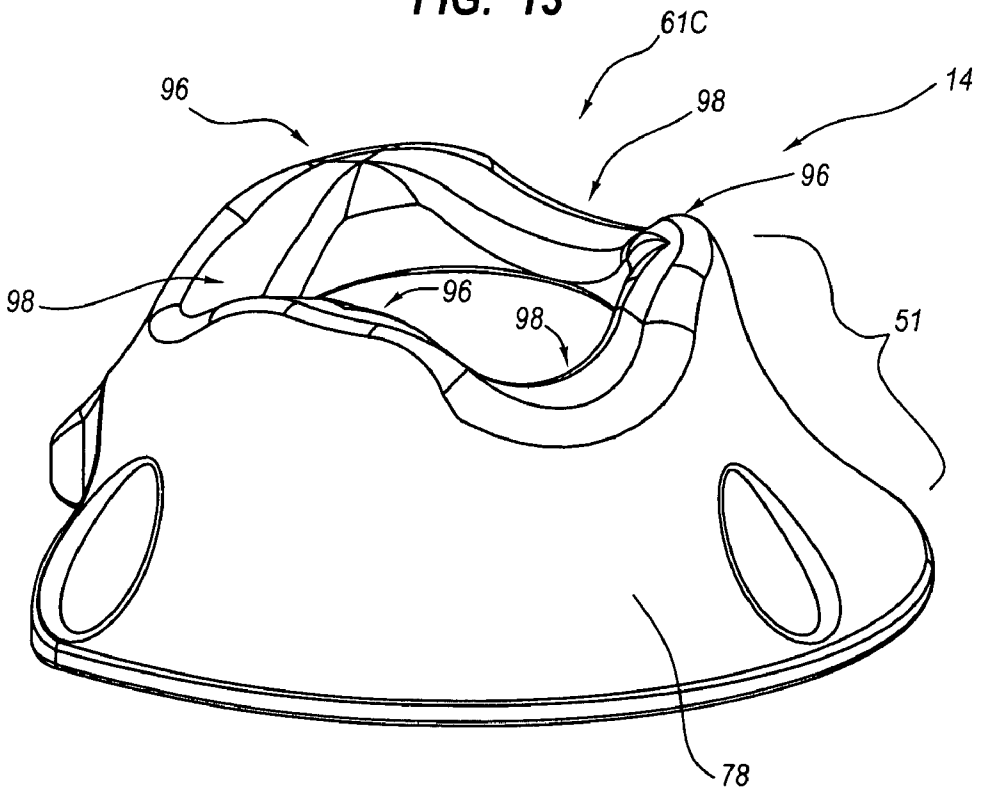

FIG. 14

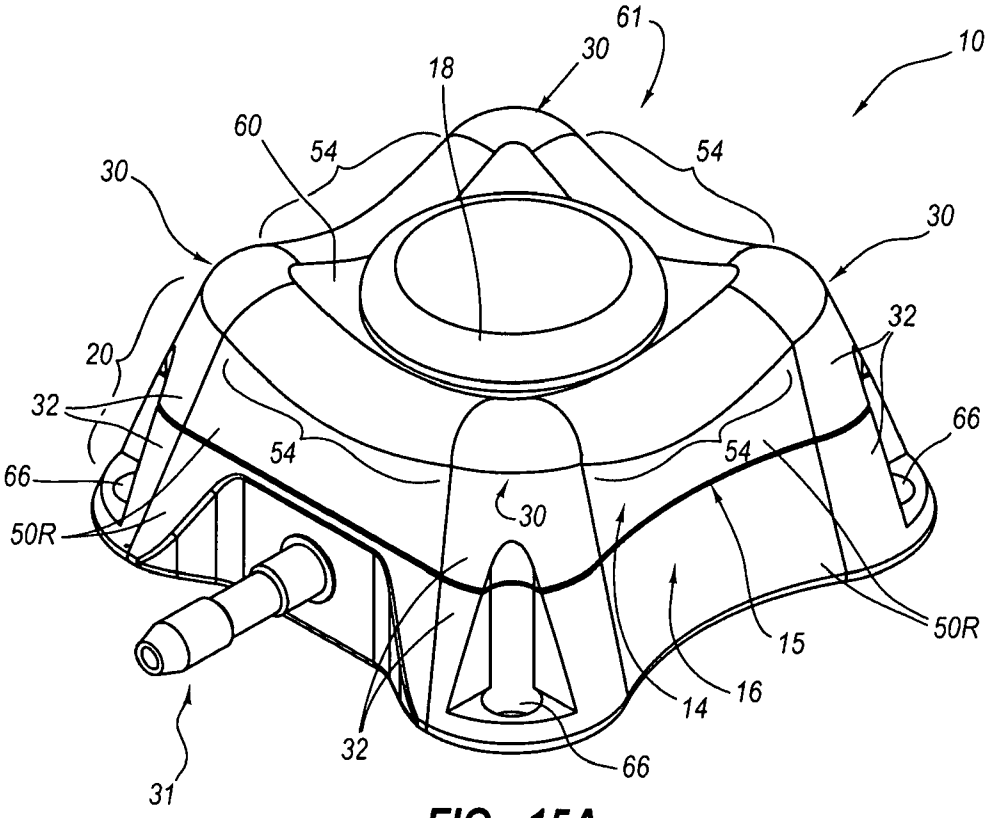

FIG. 15A

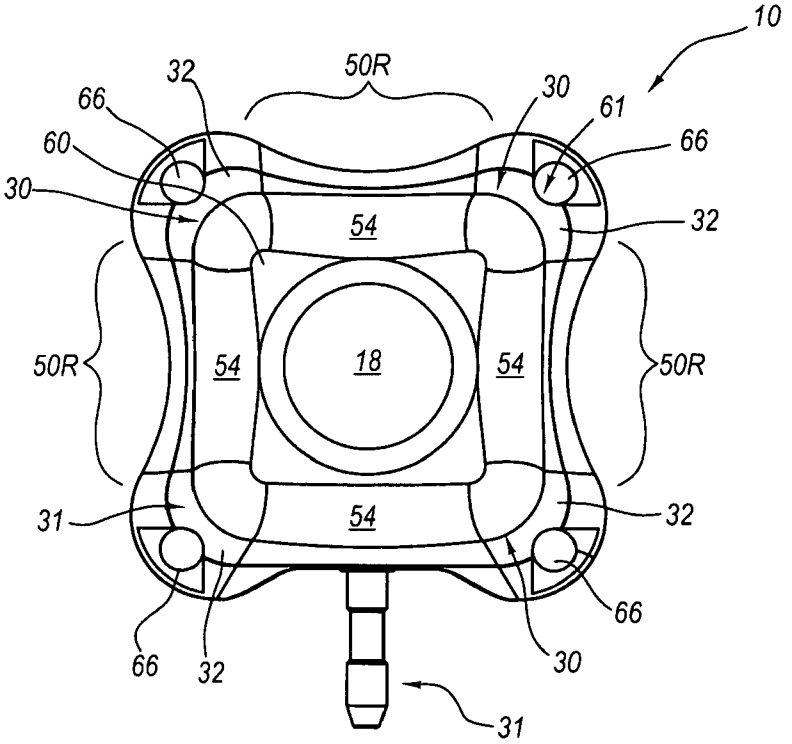

FIG. 15B

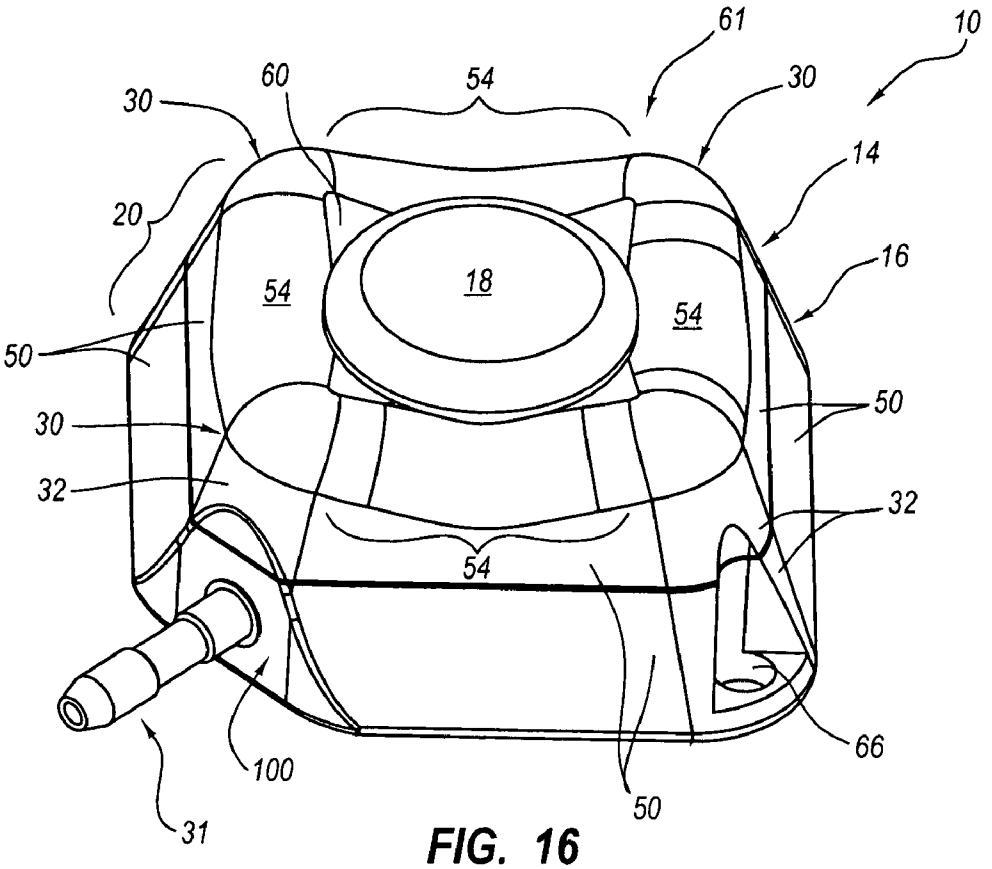
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FIG. 16

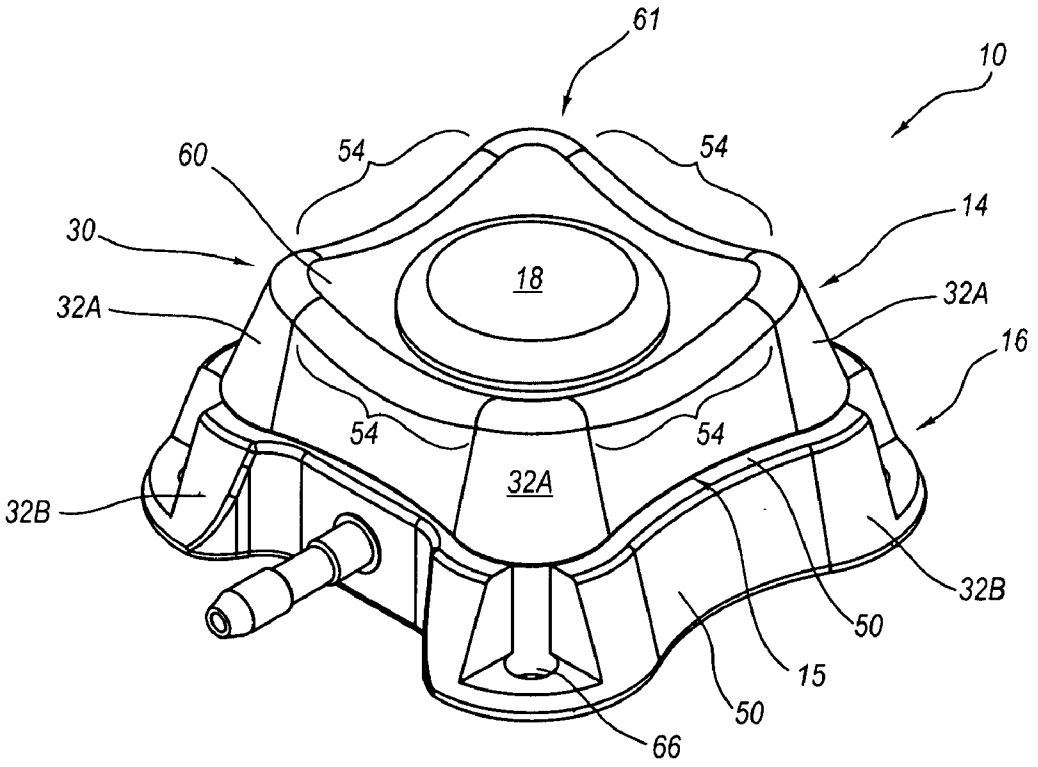
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FIG. 17

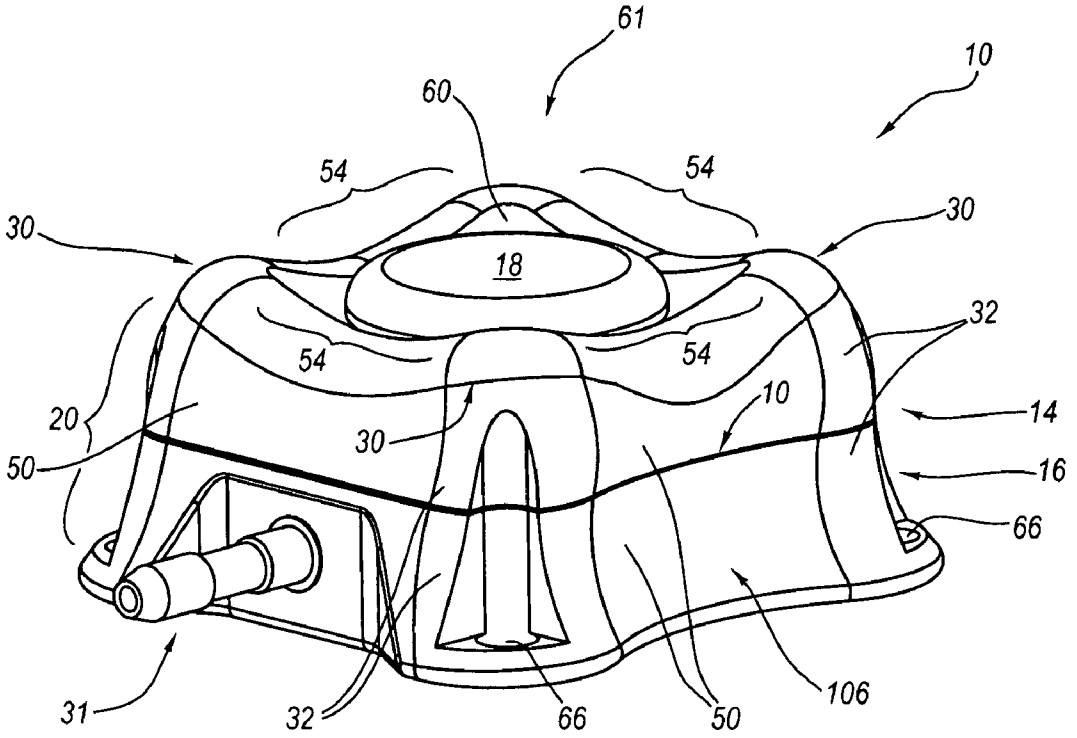
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FIG. 18

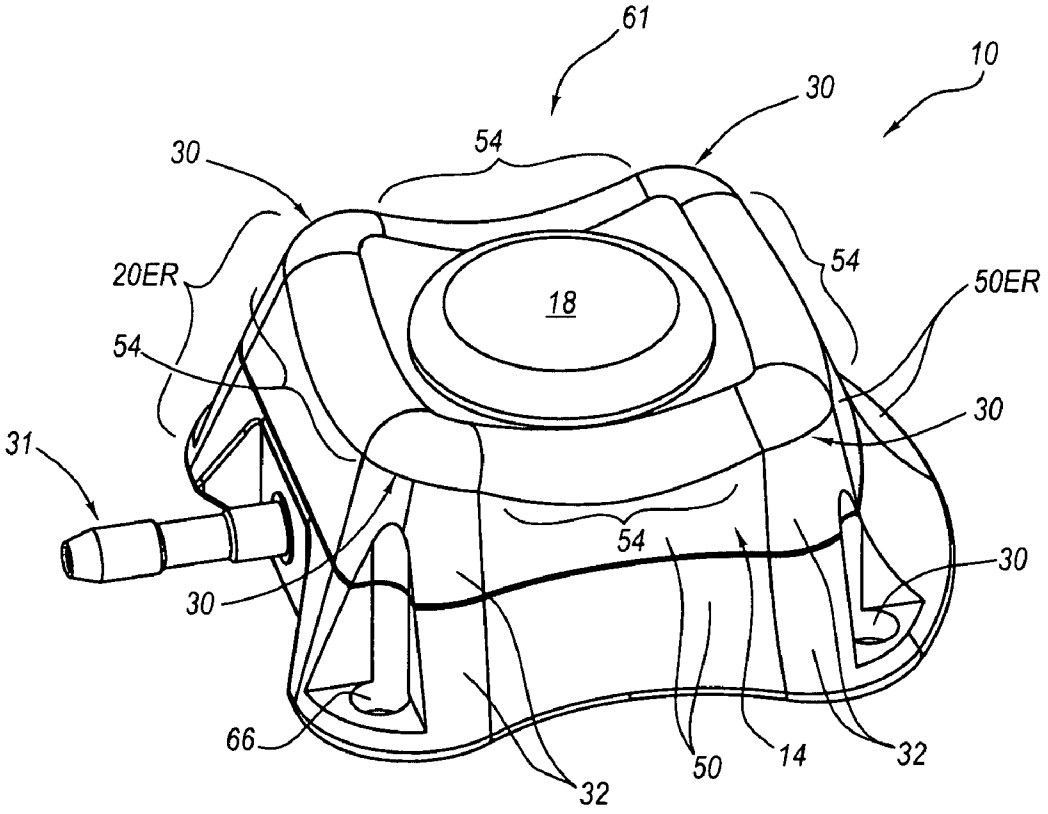
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FIG. 19

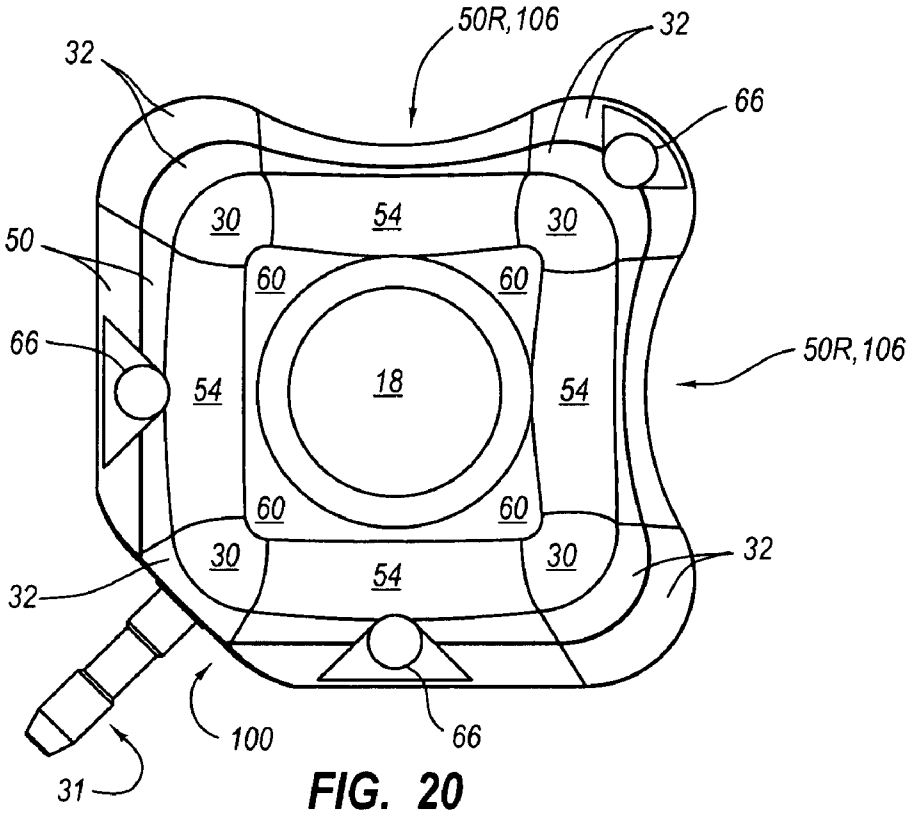
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FIG. 20

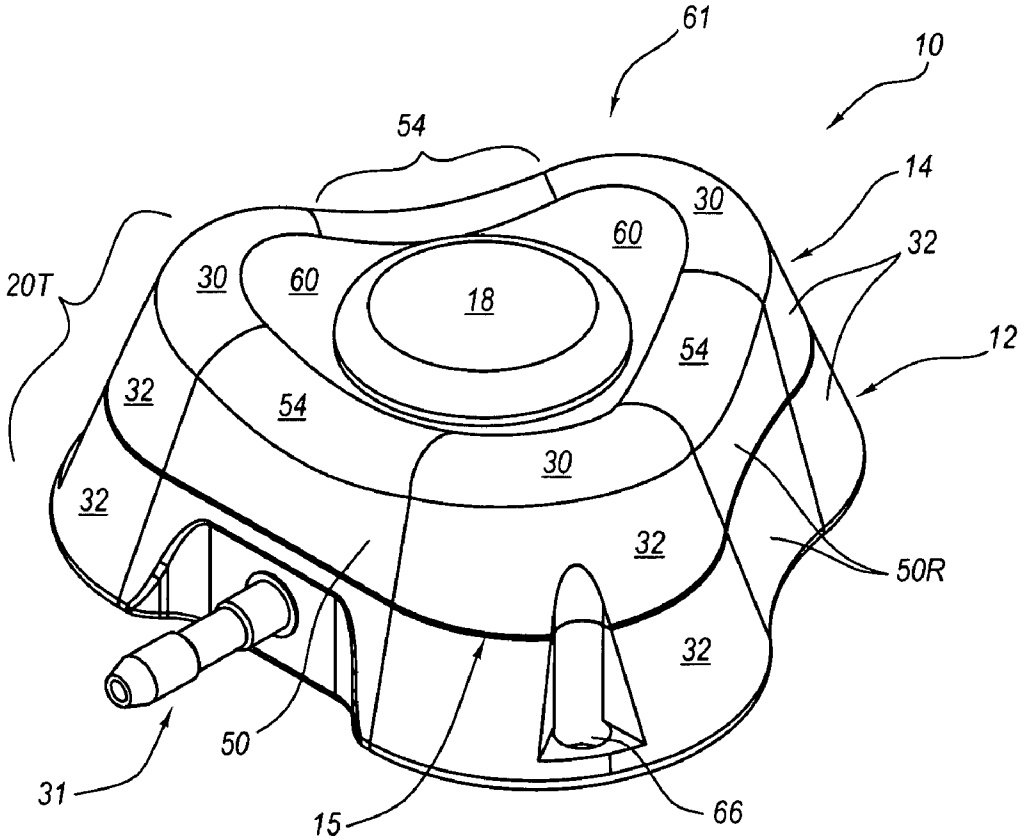
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FIG. 21

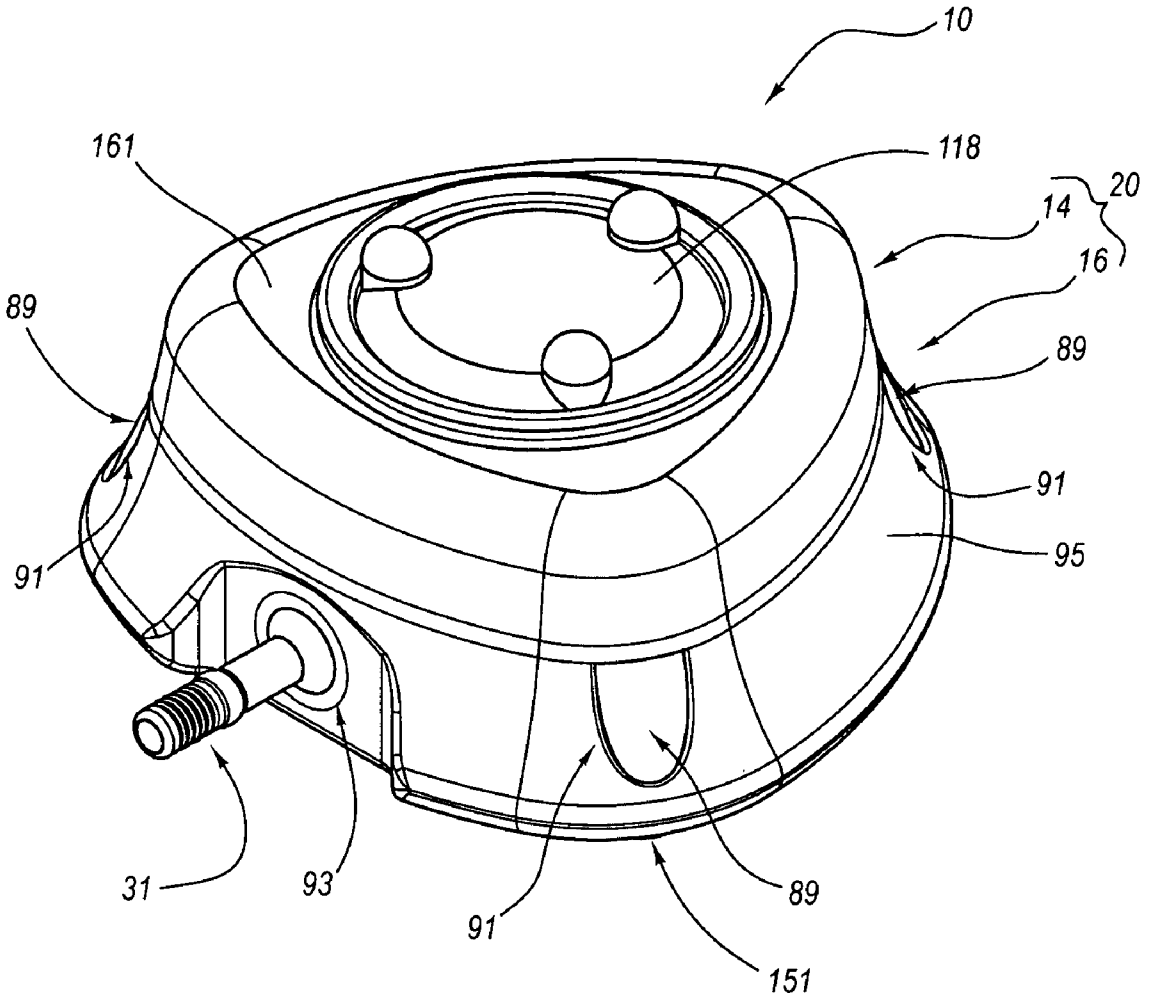
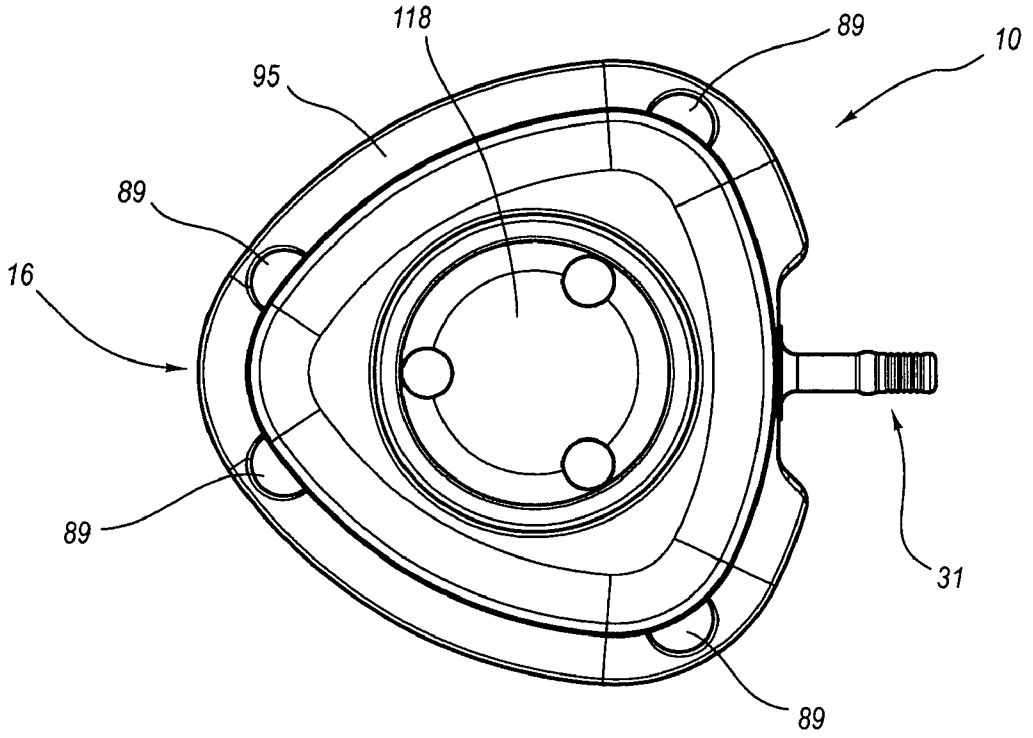


FIG. 22



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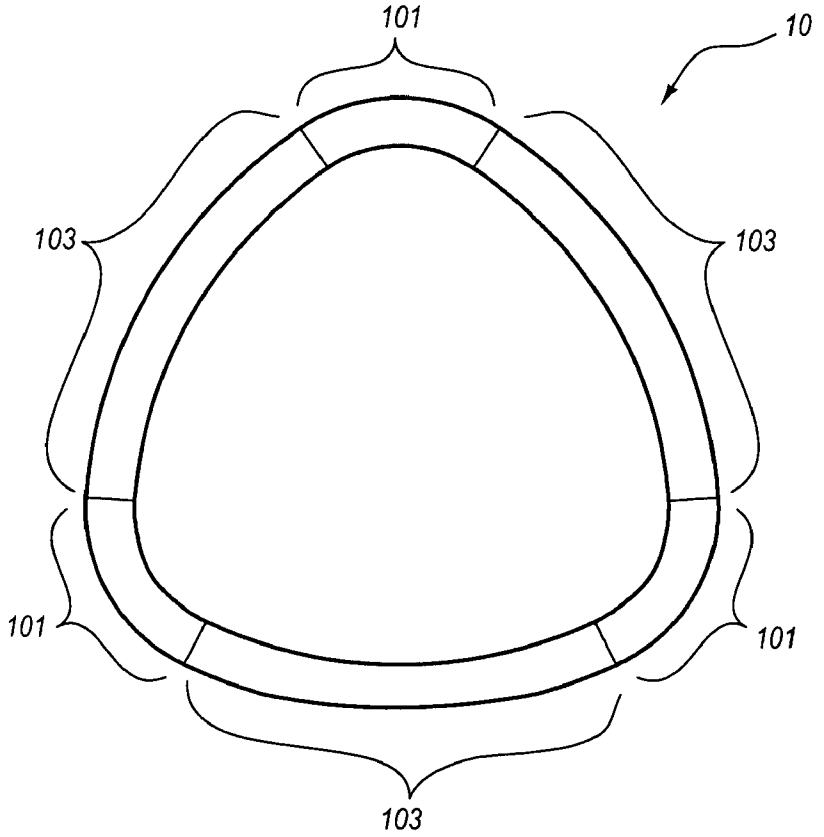

FIG. 24

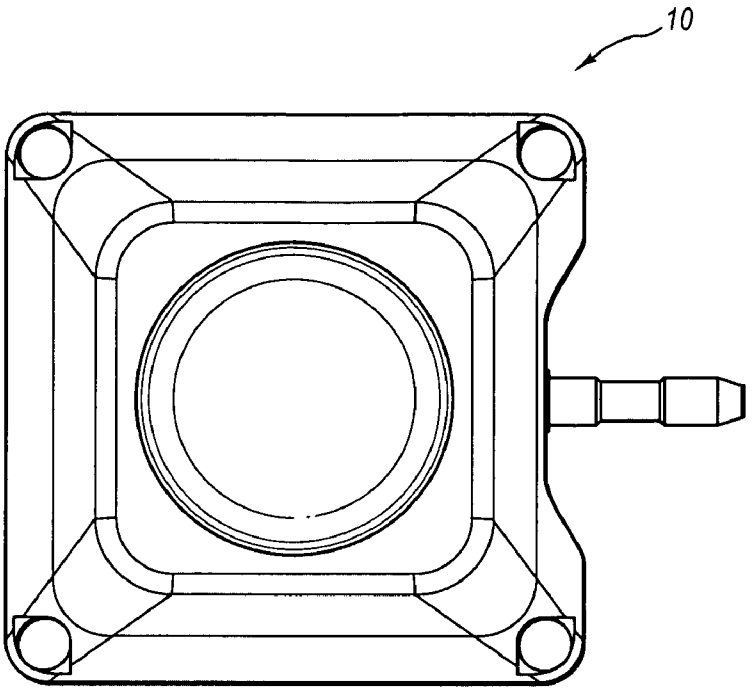

FIG. 25

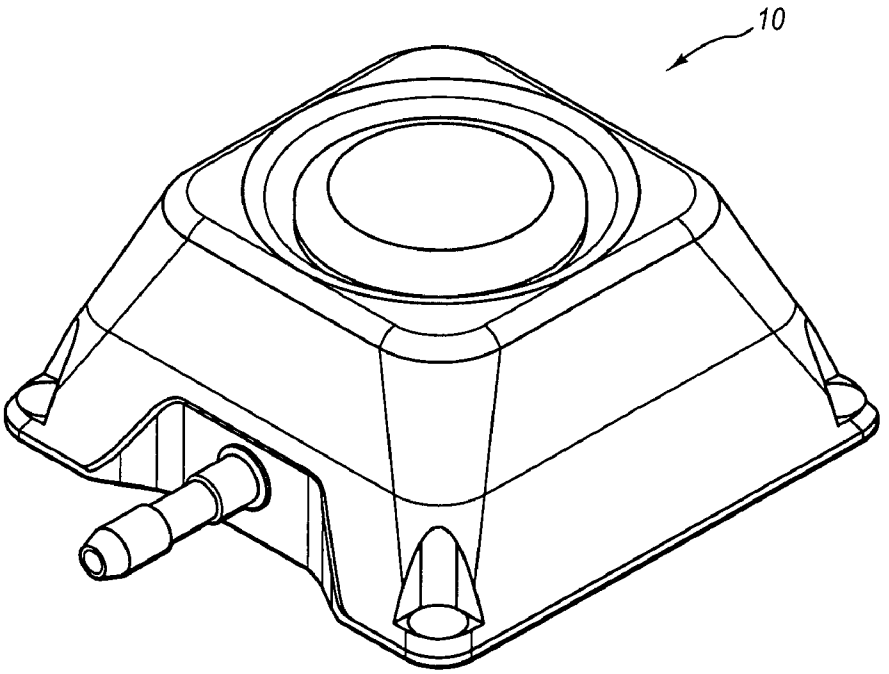

FIG. 26

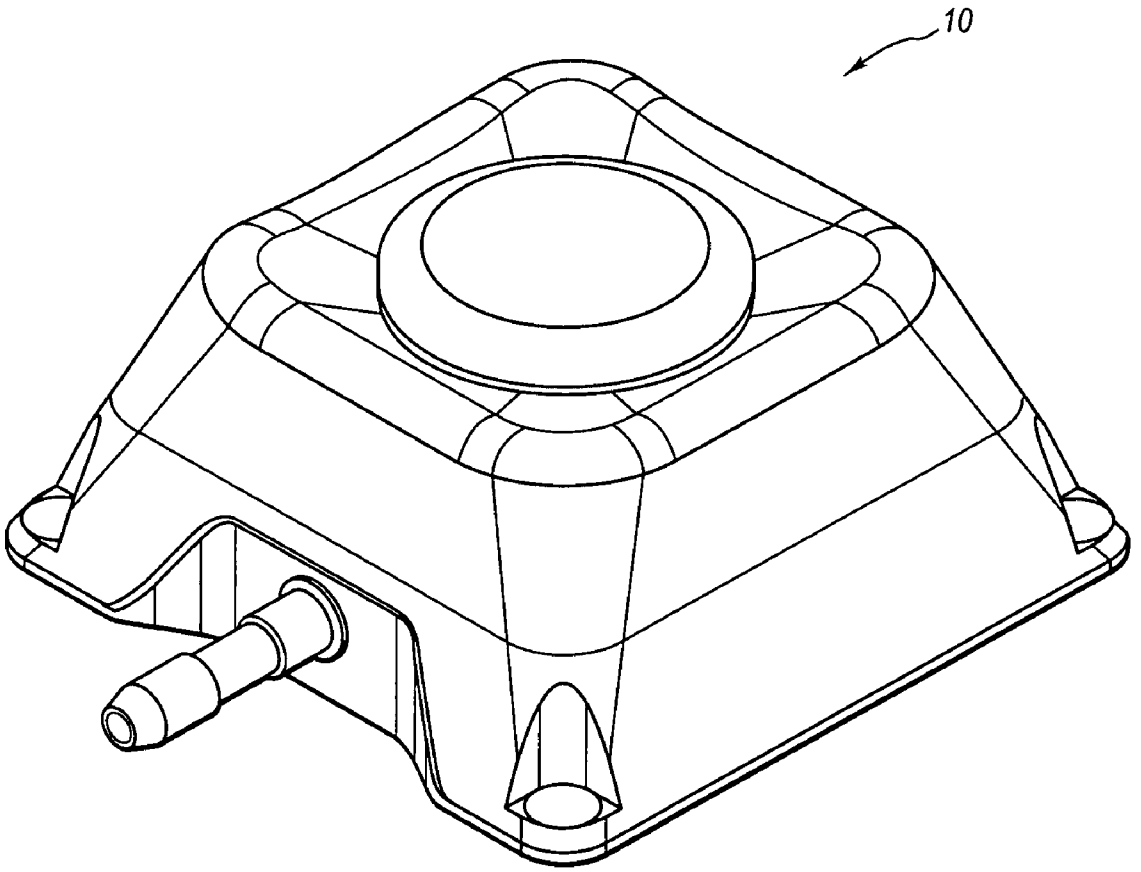

FIG. 27

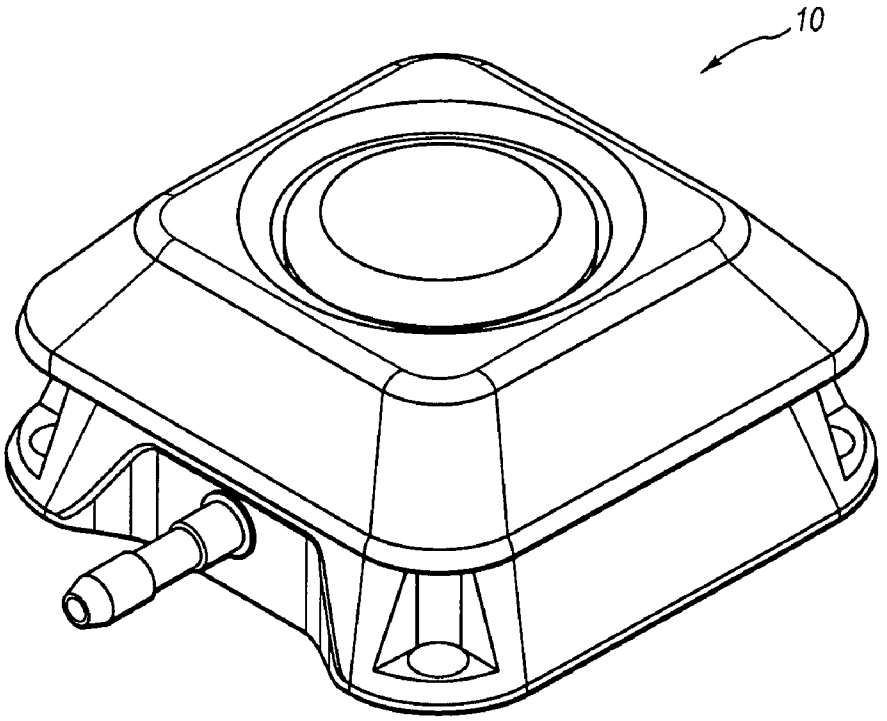

FIG. 28

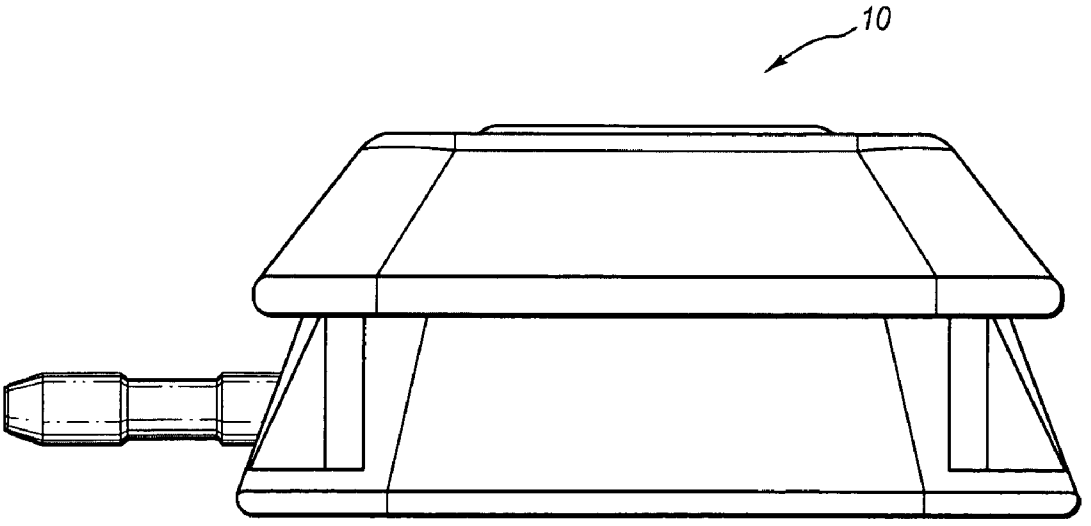

FIG. 29

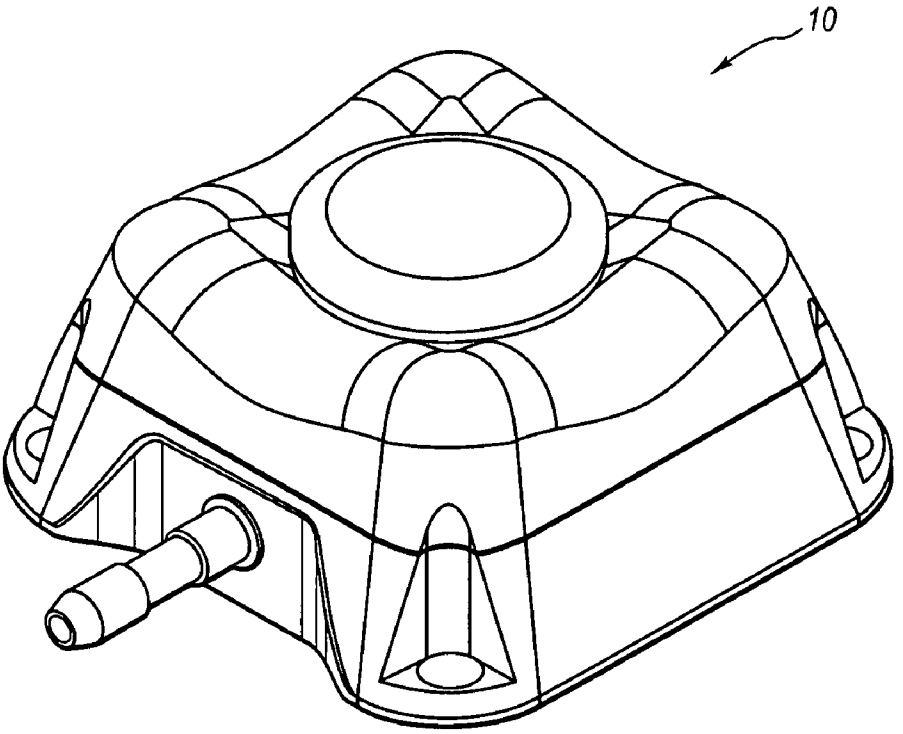

FIG. 30

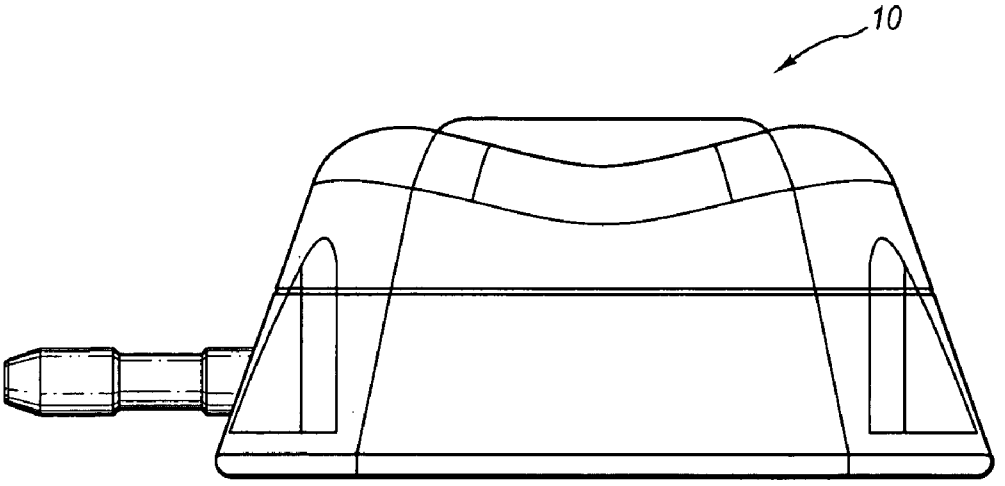

FIG. 31

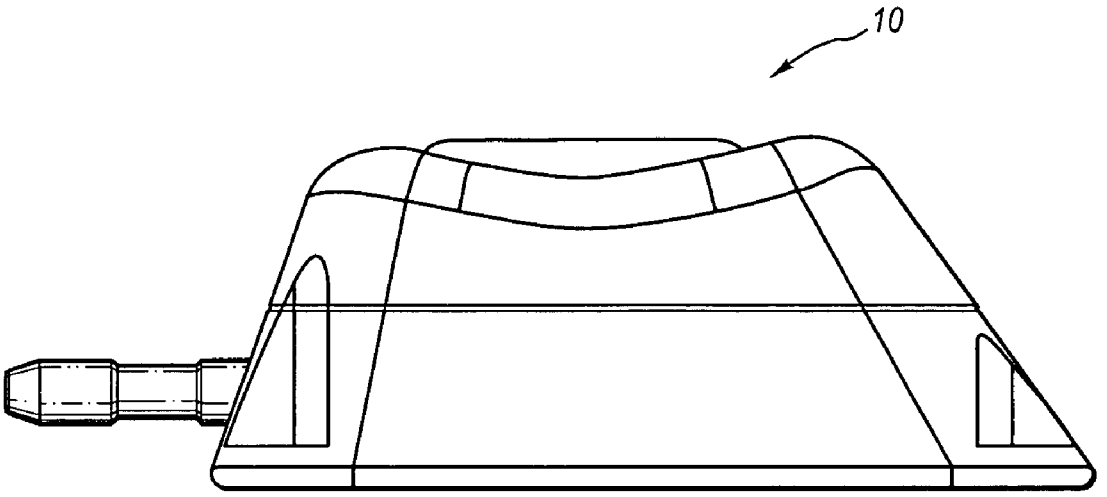

FIG. 32

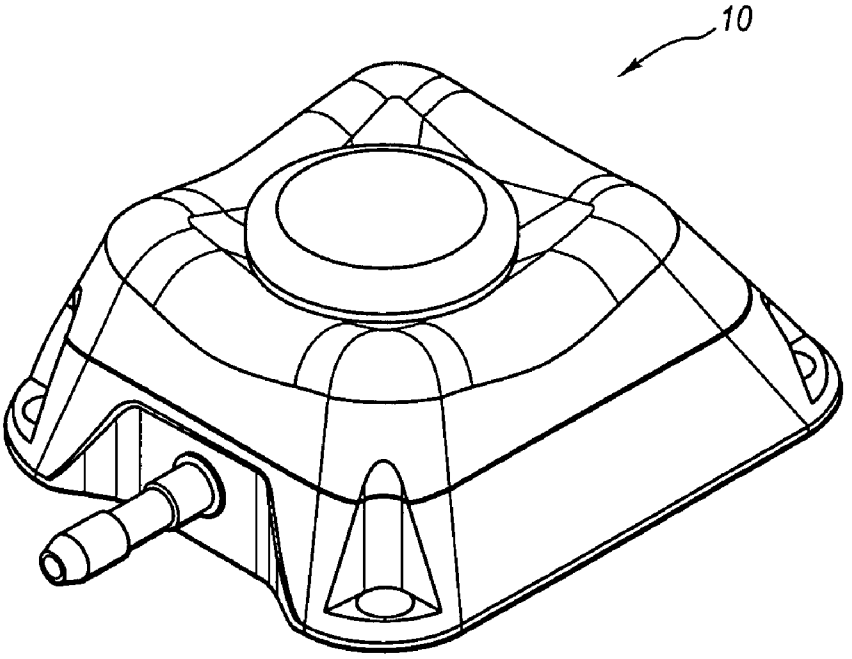

FIG. 33

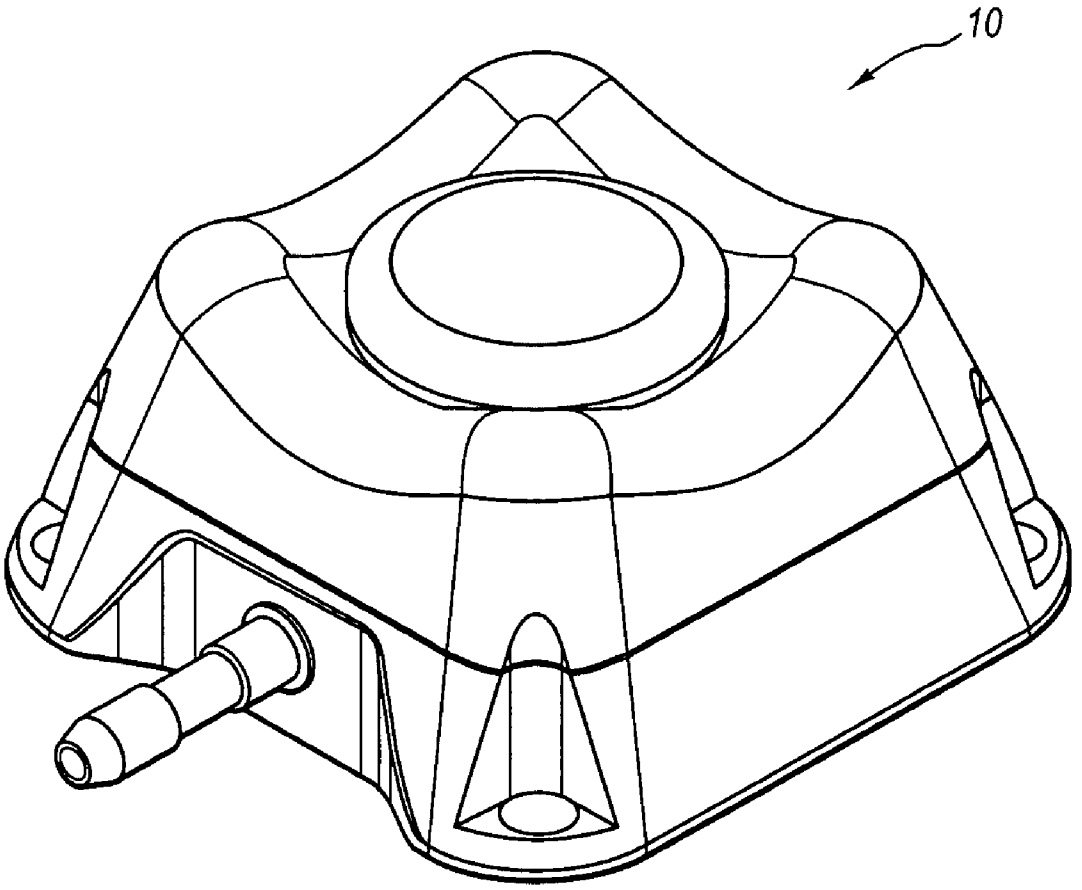

FIG. 34

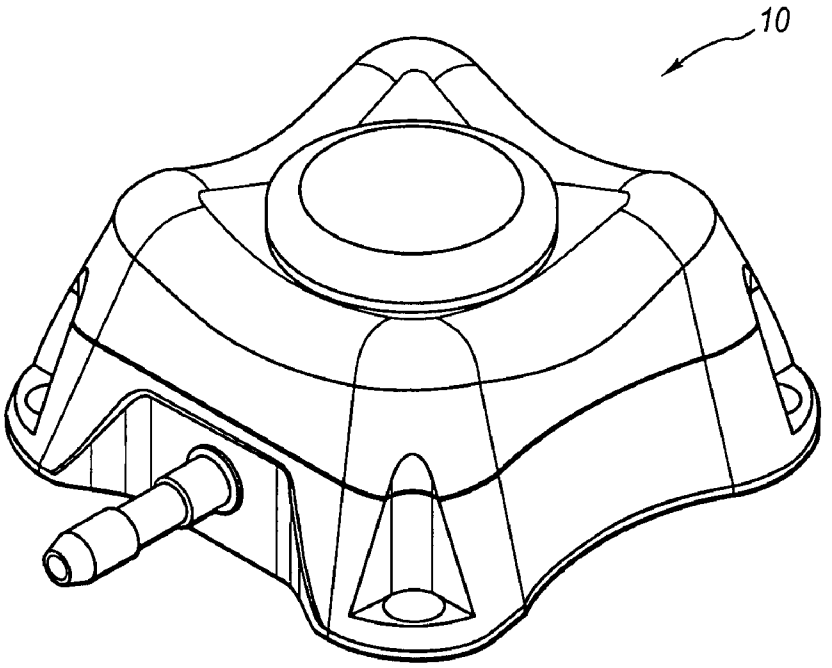

FIG. 35

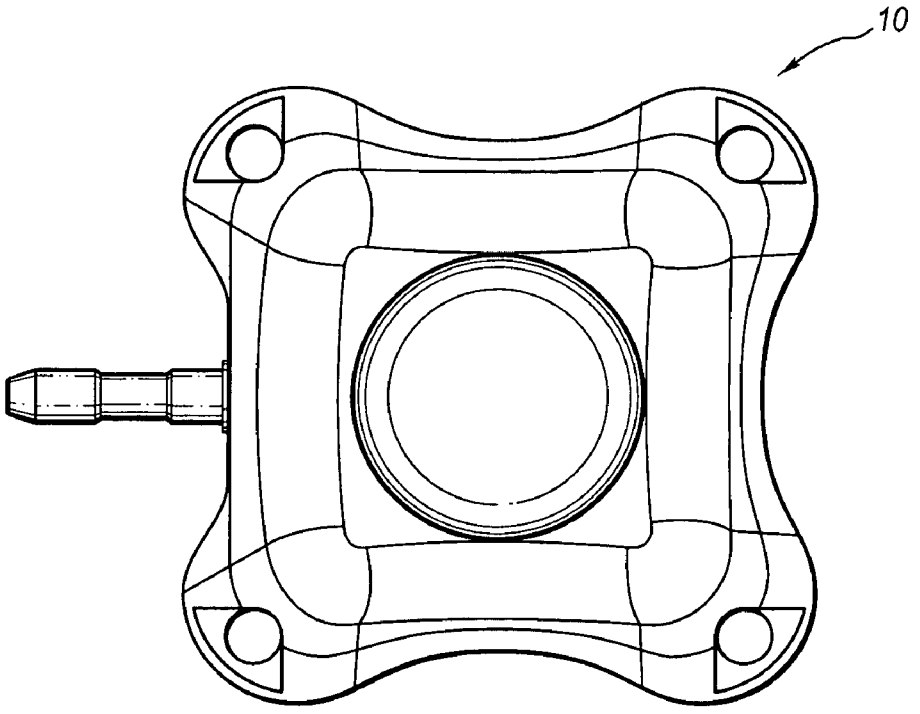

FIG. 36

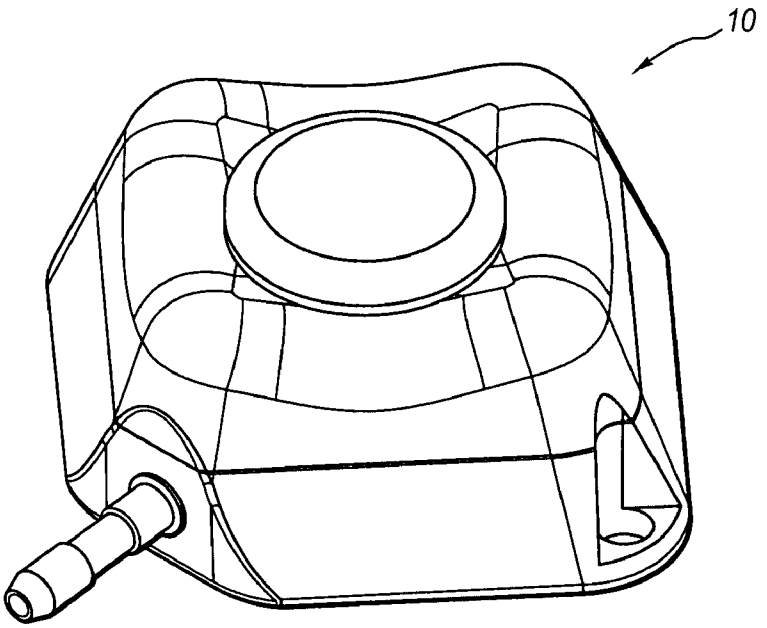

FIG. 37

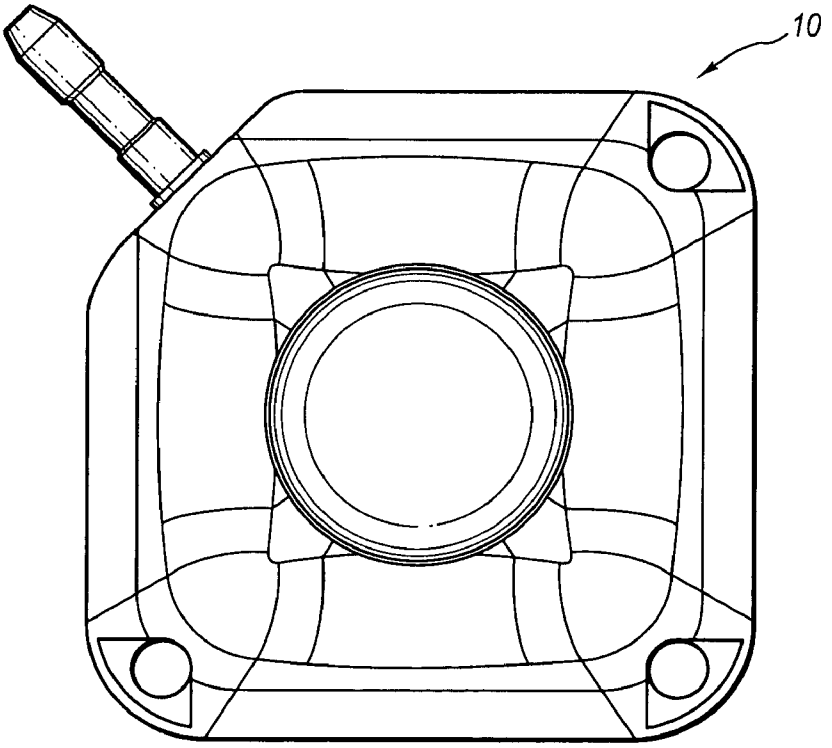

FIG. 38

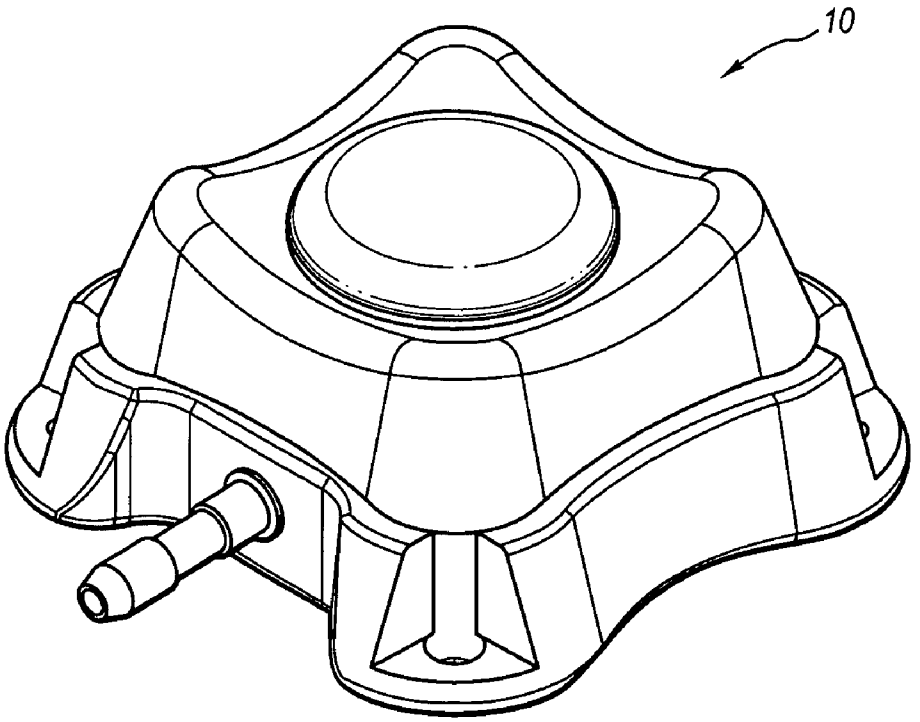

FIG. 39

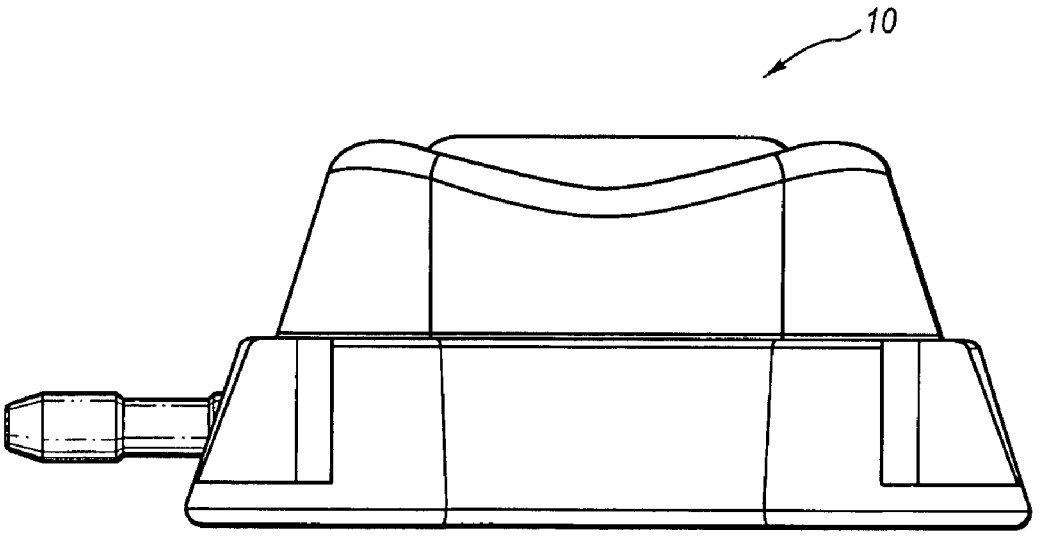

FIG. 40

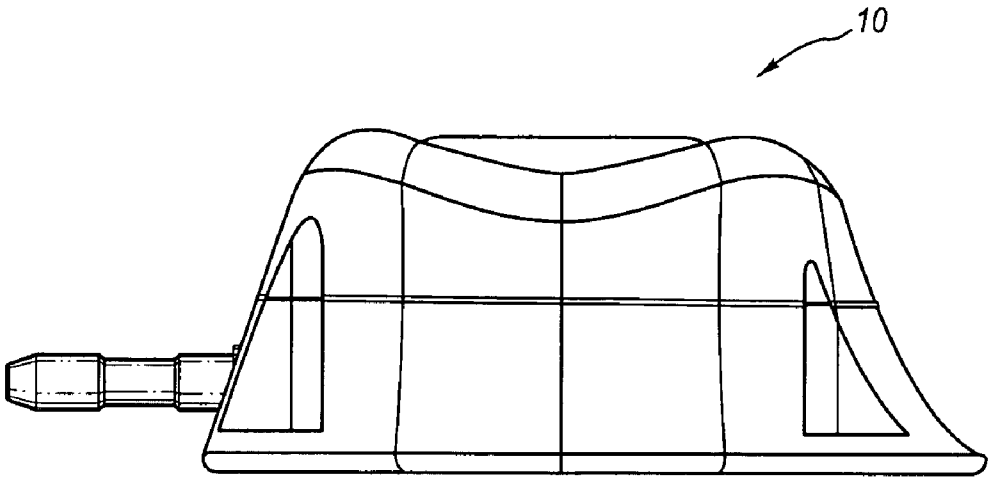

FIG. 41

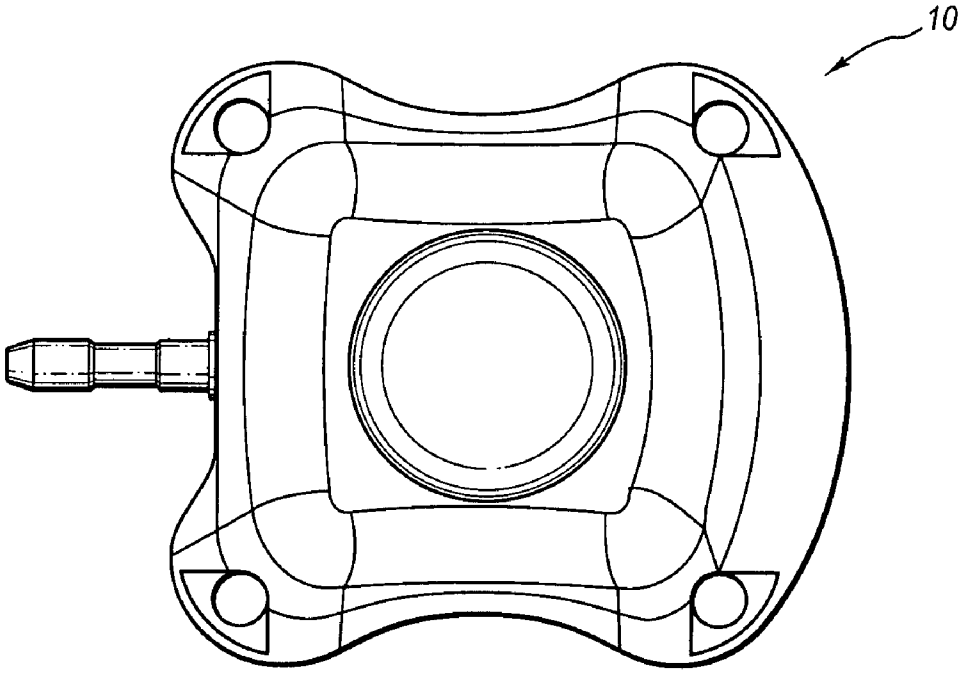

FIG. 42

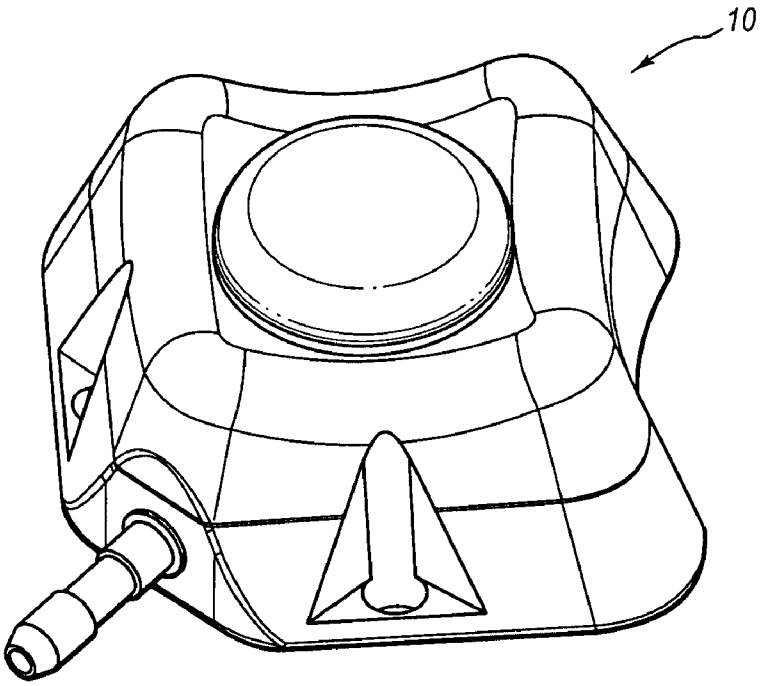

FIG. 43

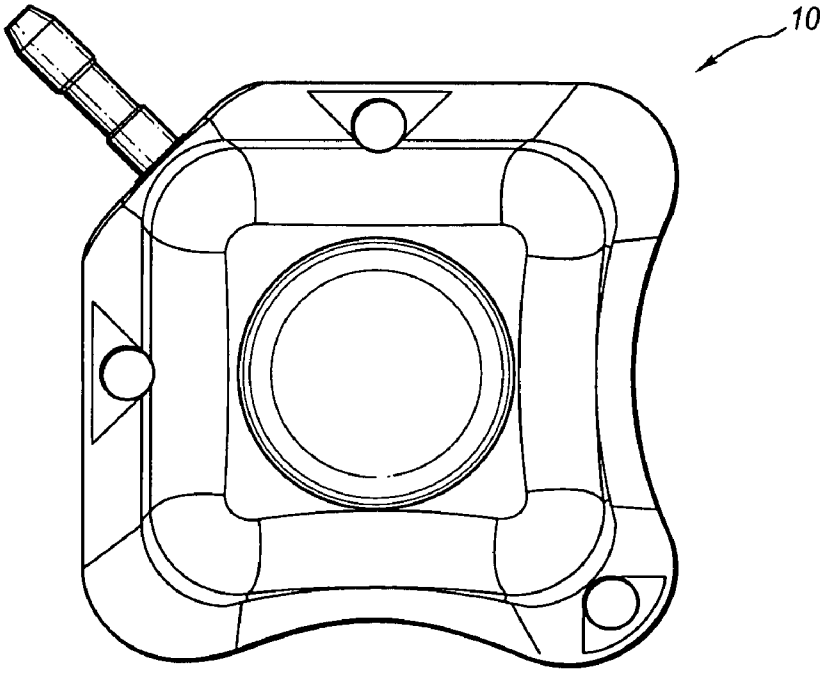

FIG. 44

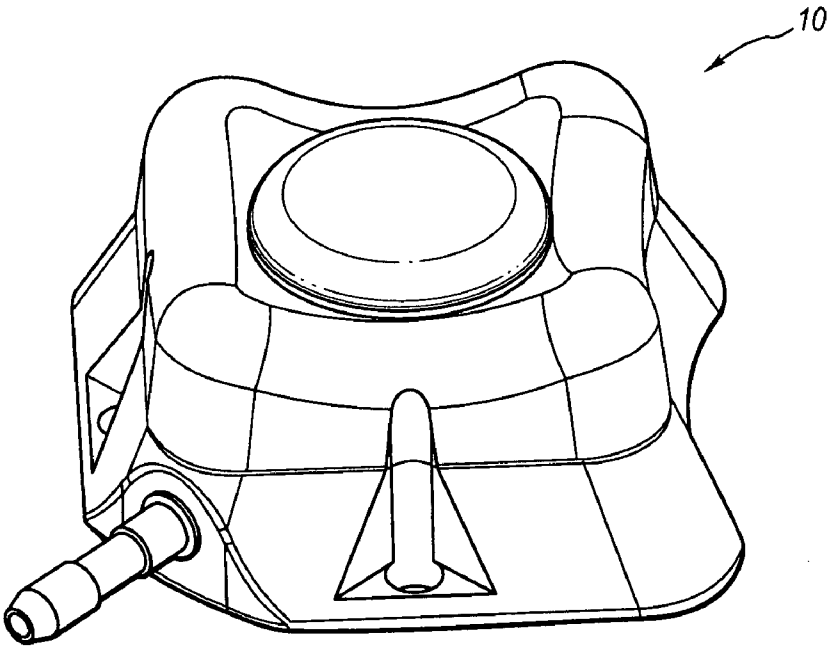

FIG. 45

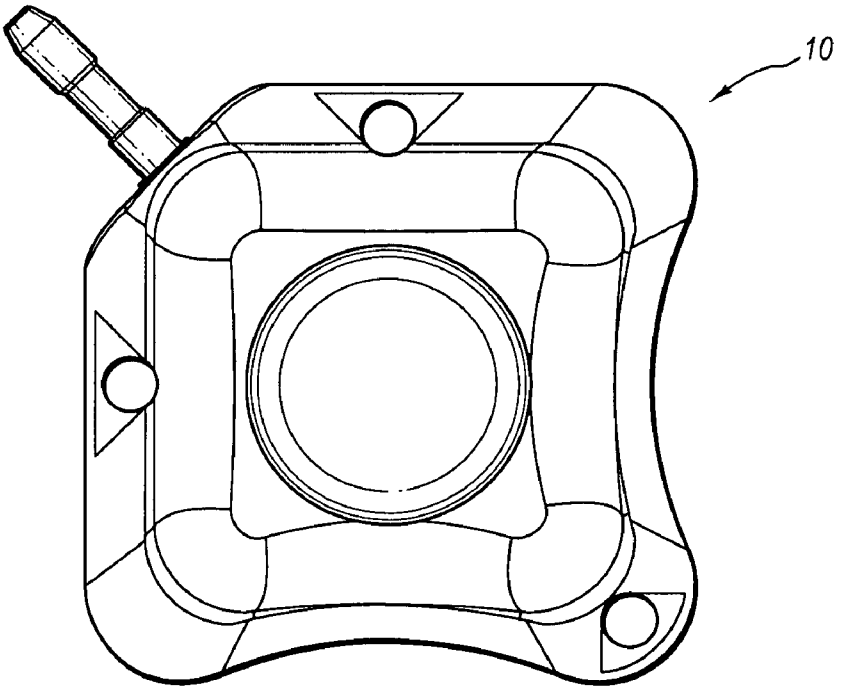

FIG. 46

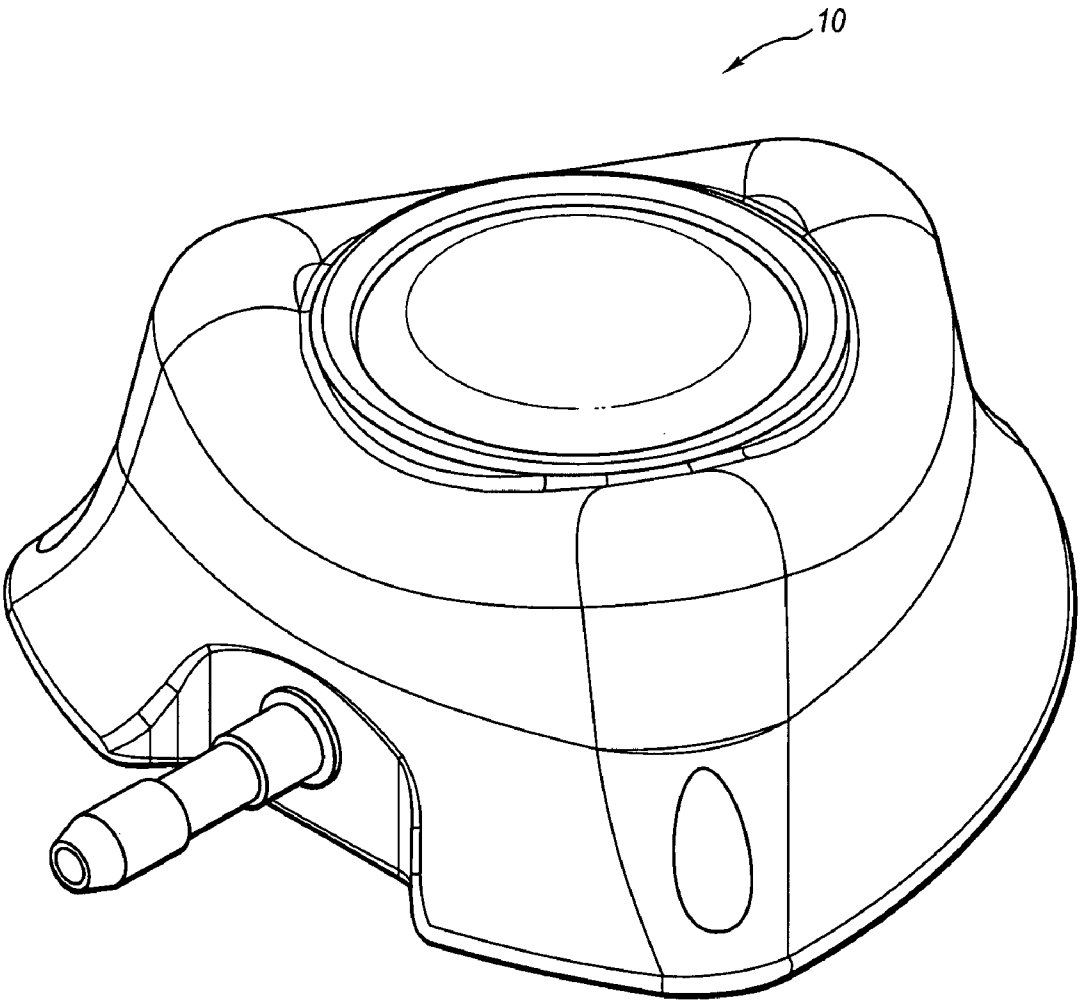

FIG. 47

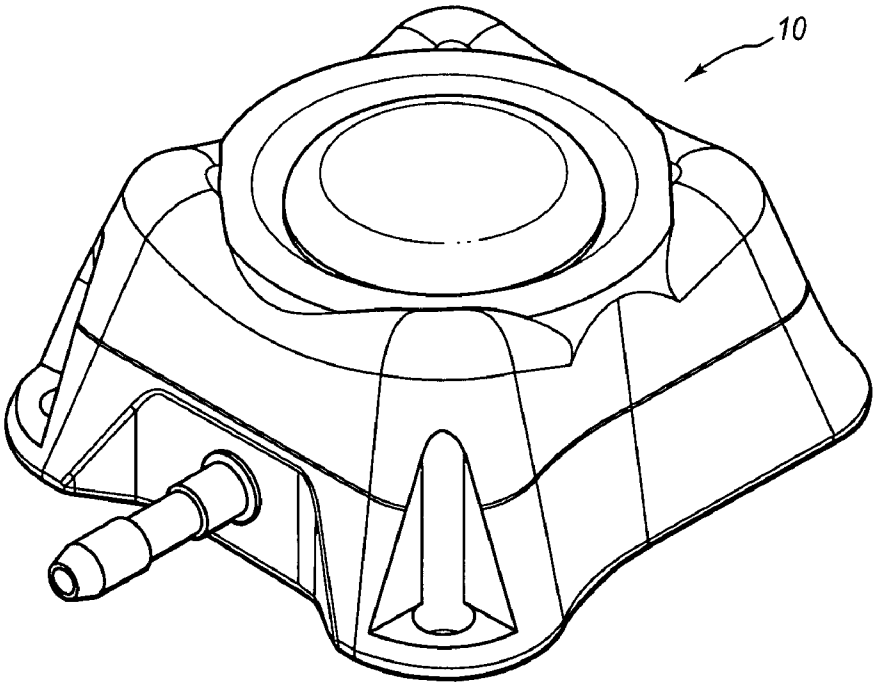

FIG. 48

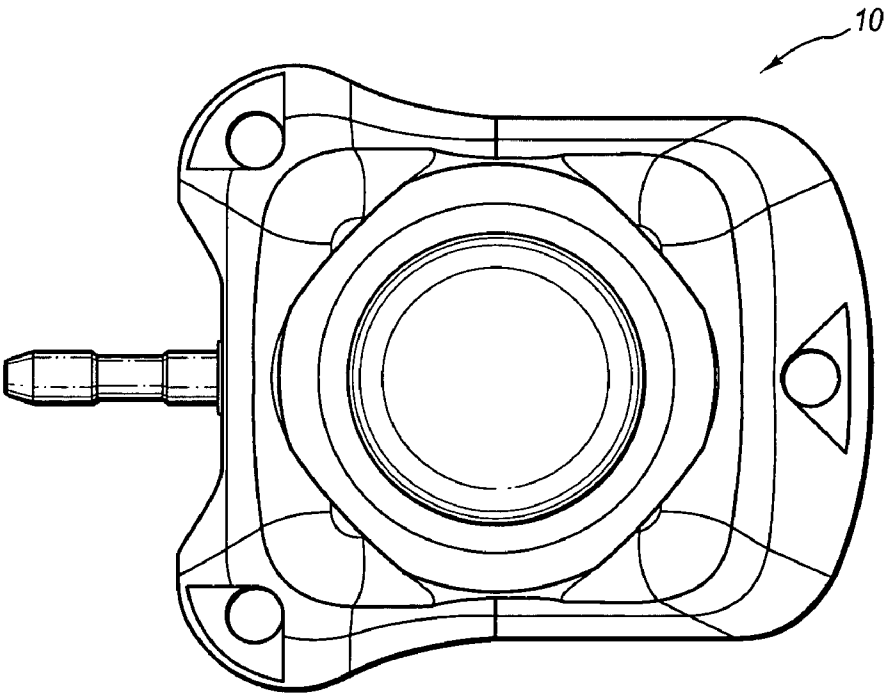

FIG. 49

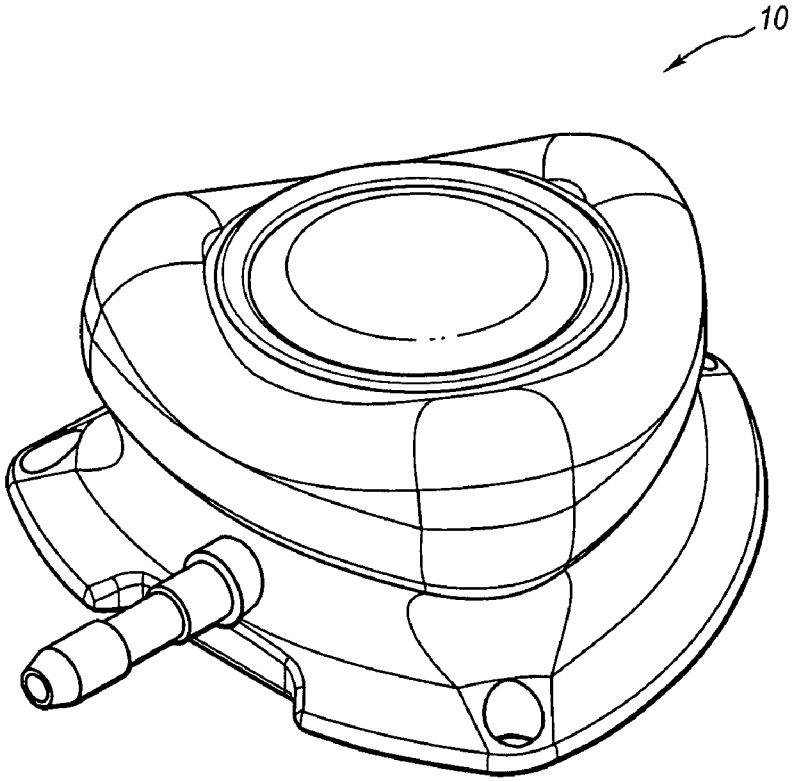

FIG. 50

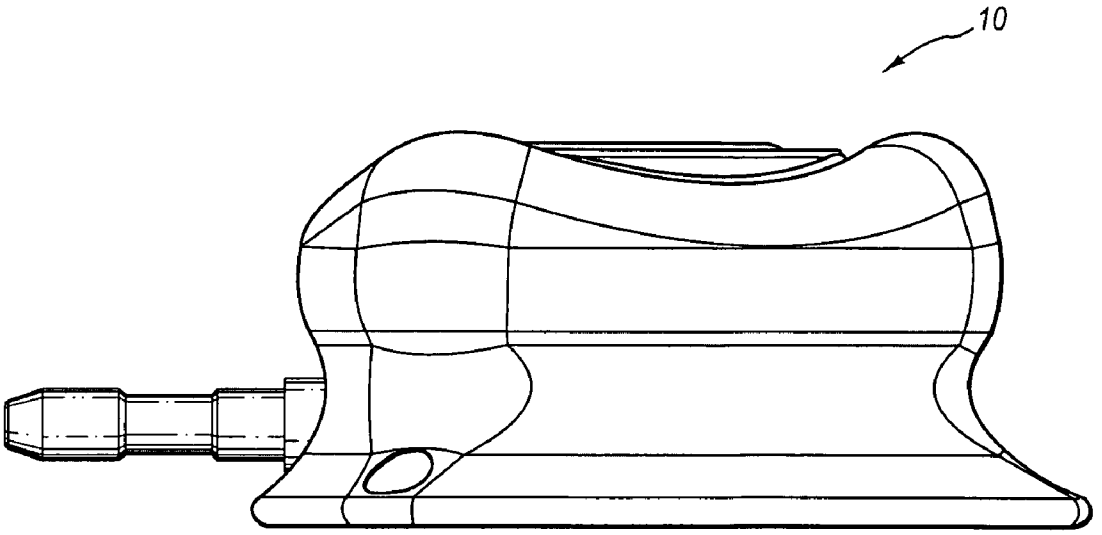

FIG. 51

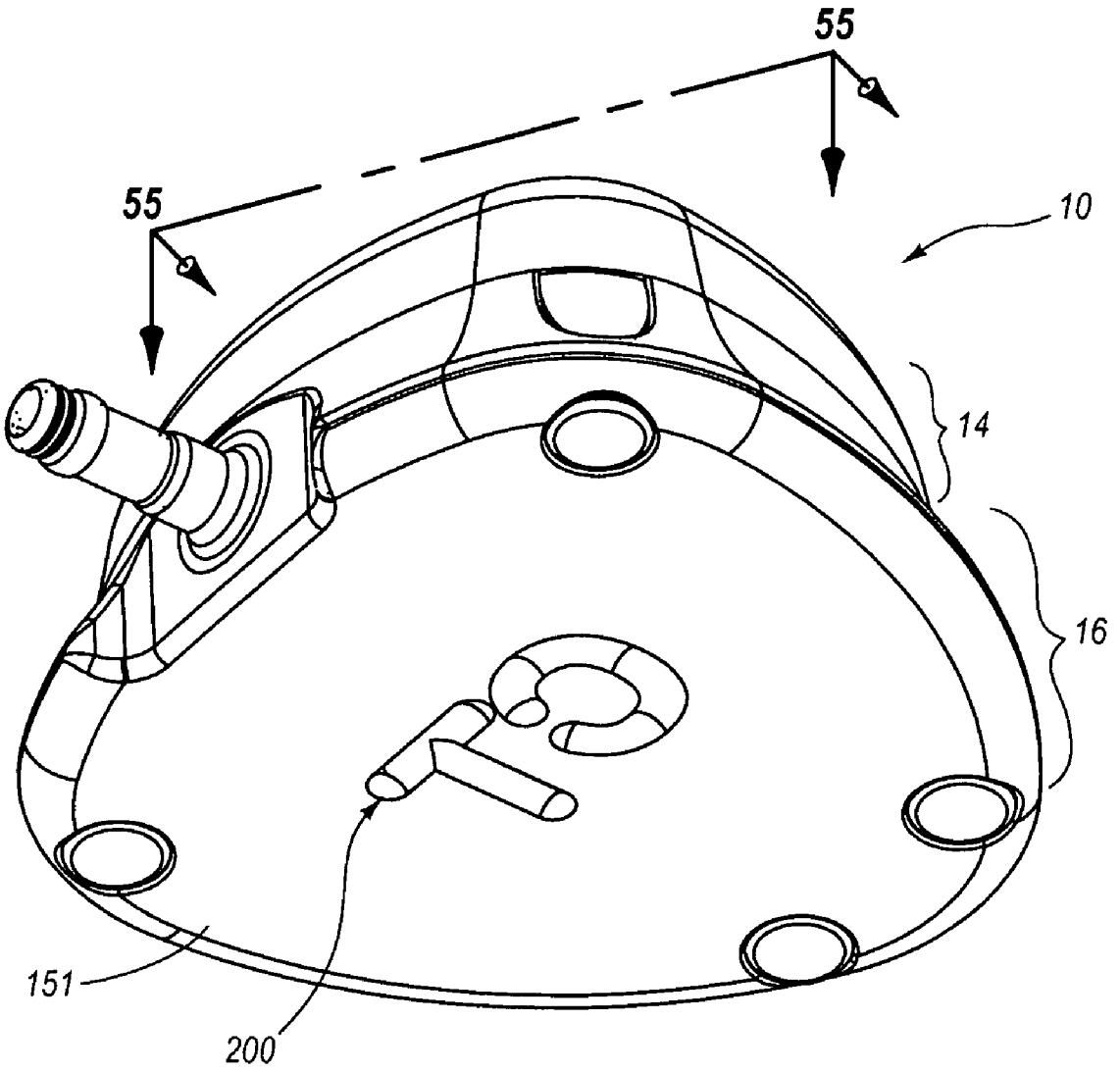

FIG. 52

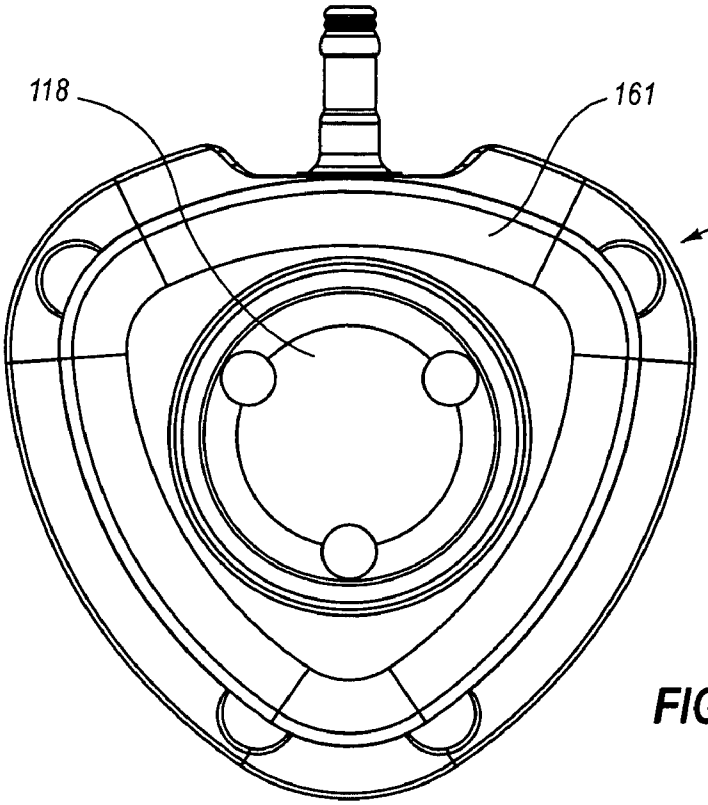

FIG. 53A

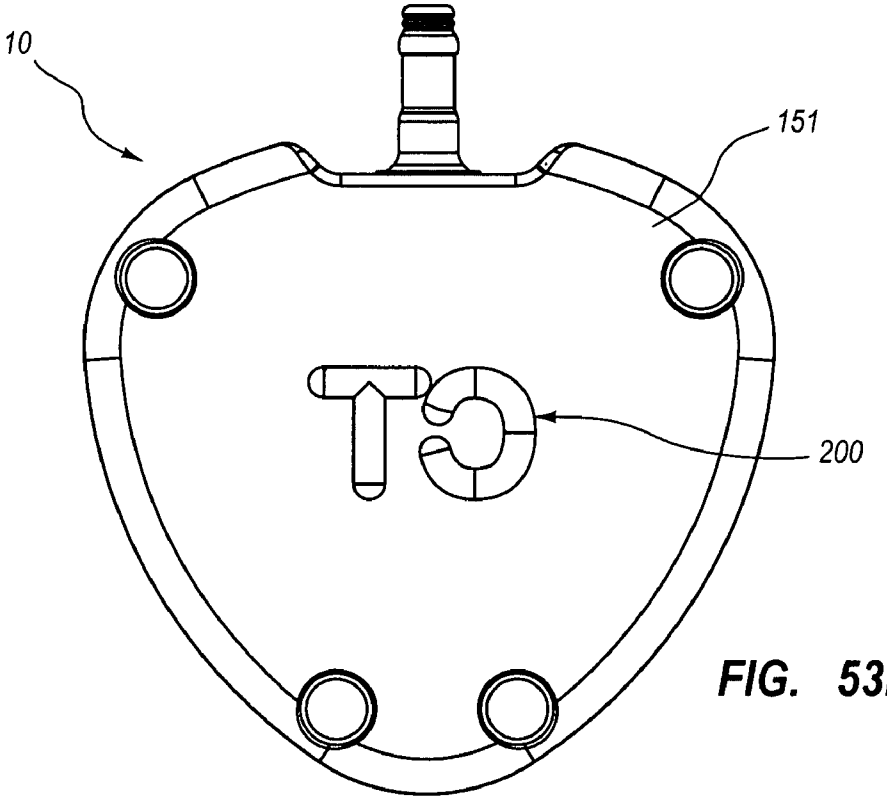

FIG. 53B

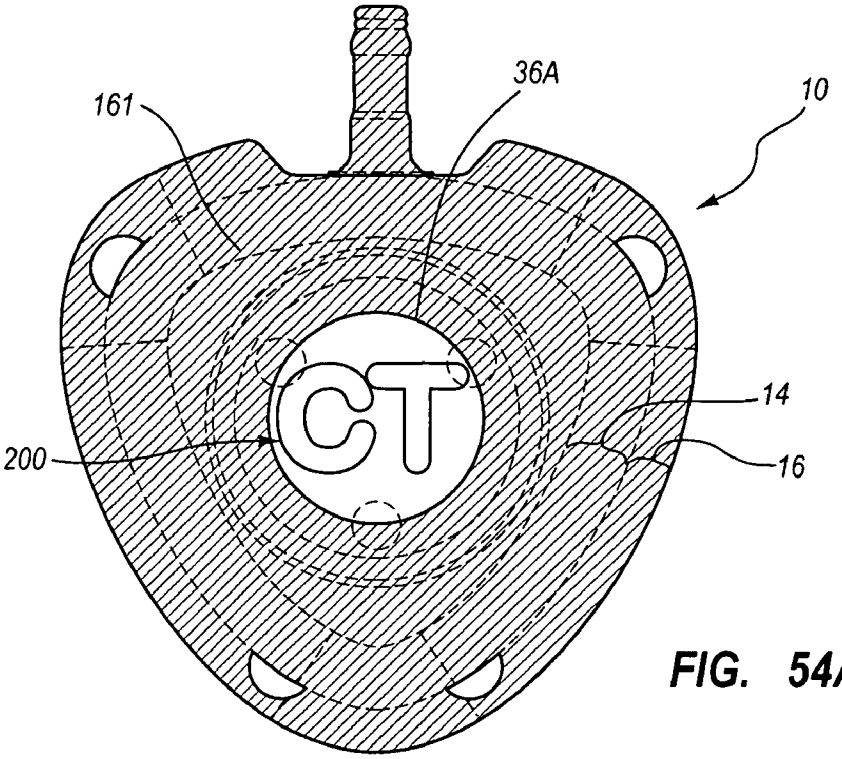

FIG. 54A

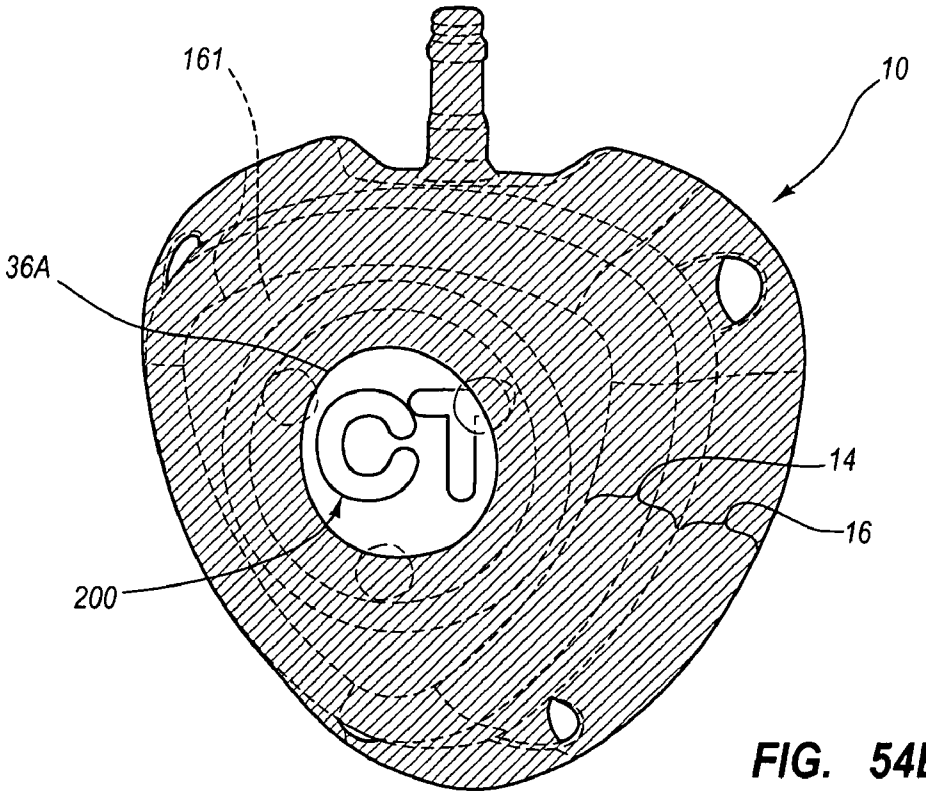

FIG. 54B

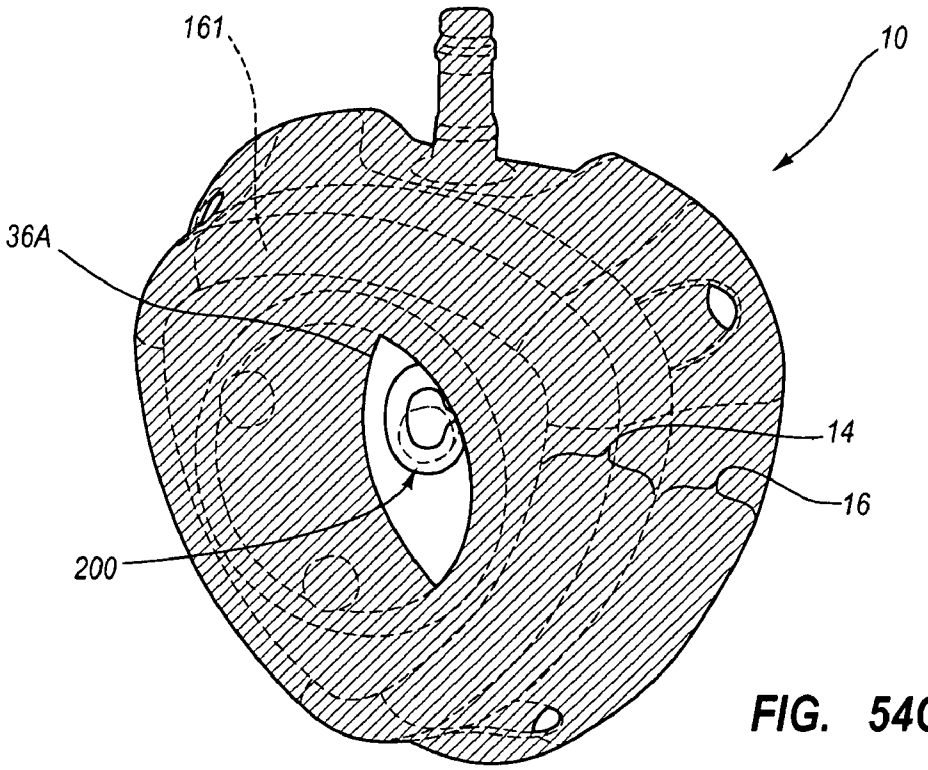

FIG. 54C

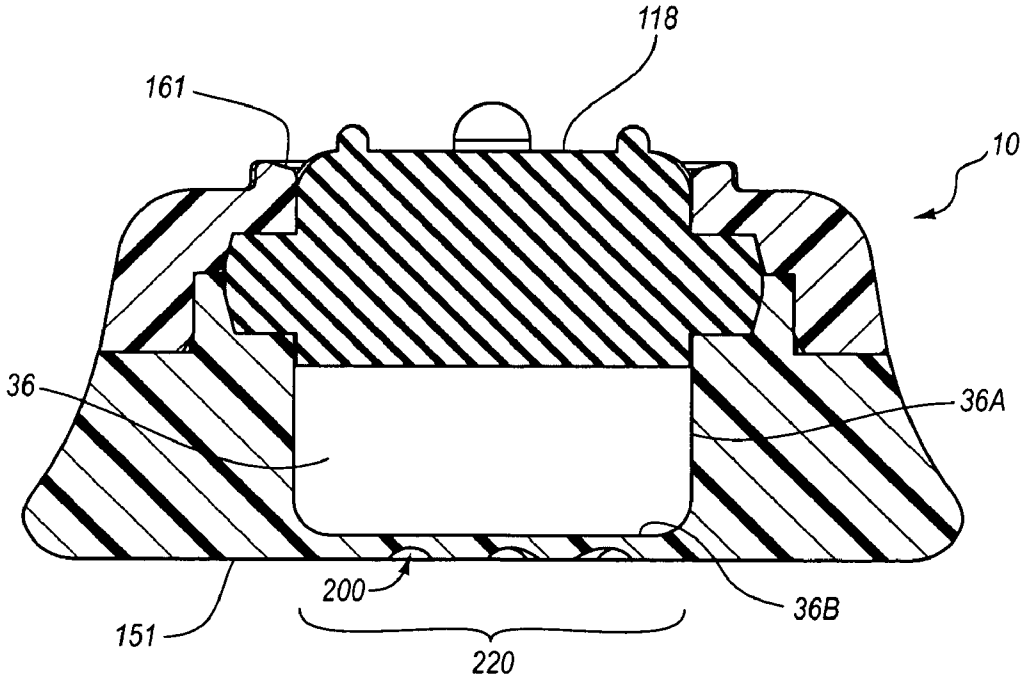

FIG. 55

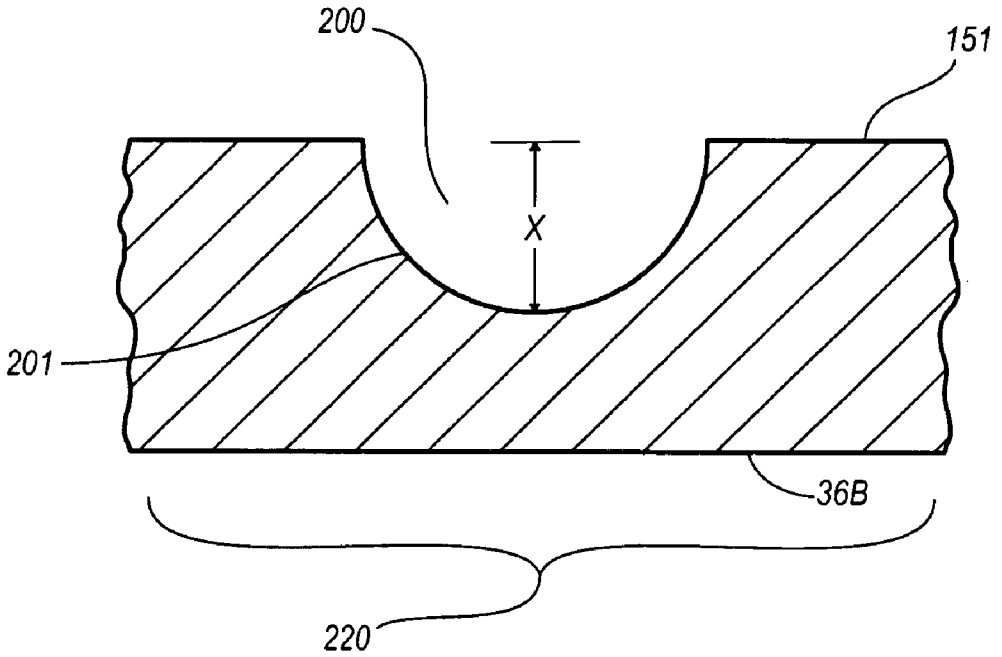

FIG. 56A

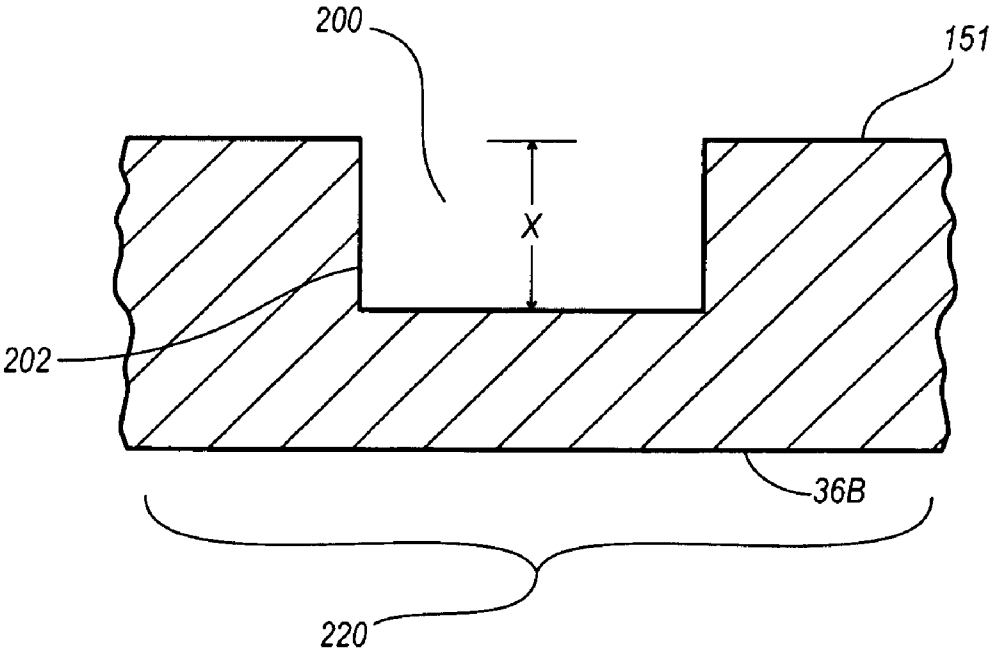

FIG. 56B

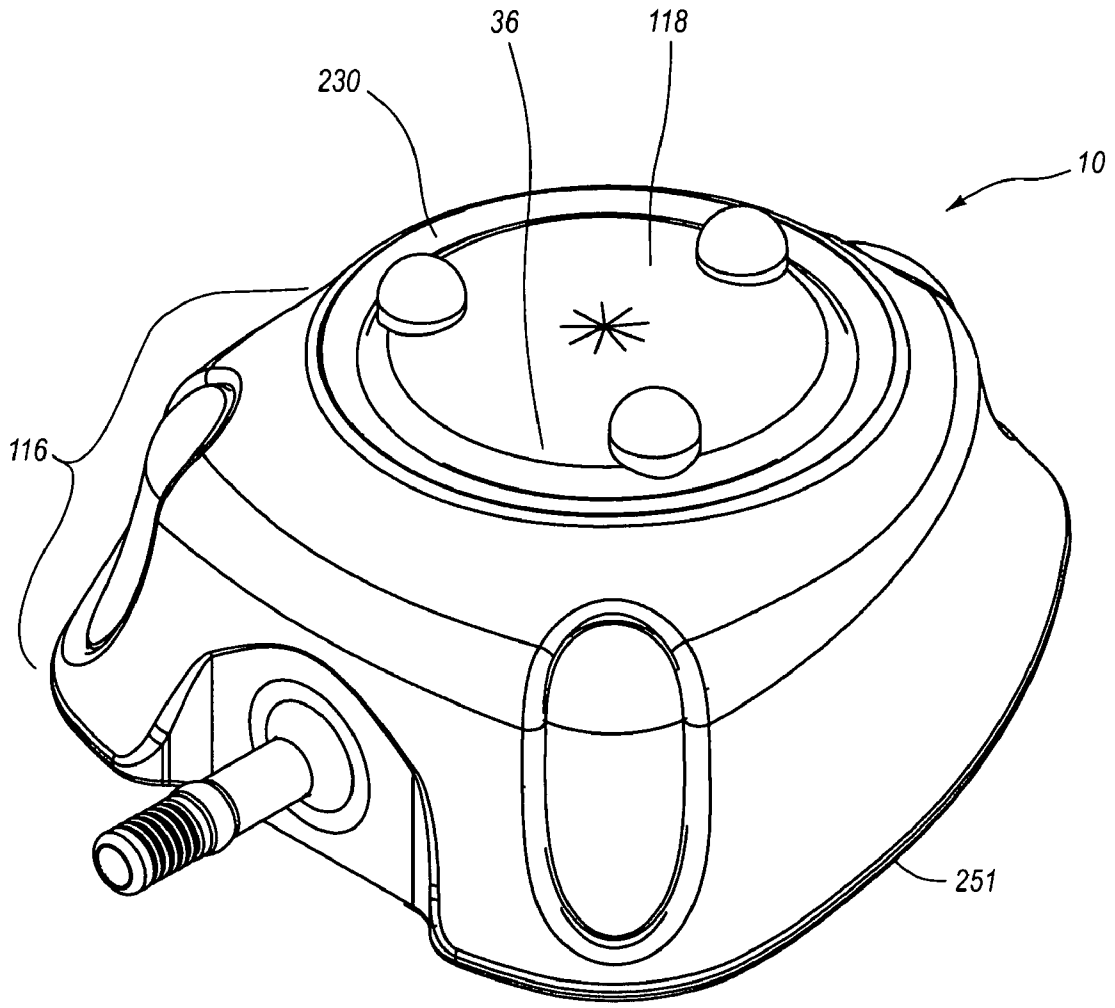

FIG. 57A

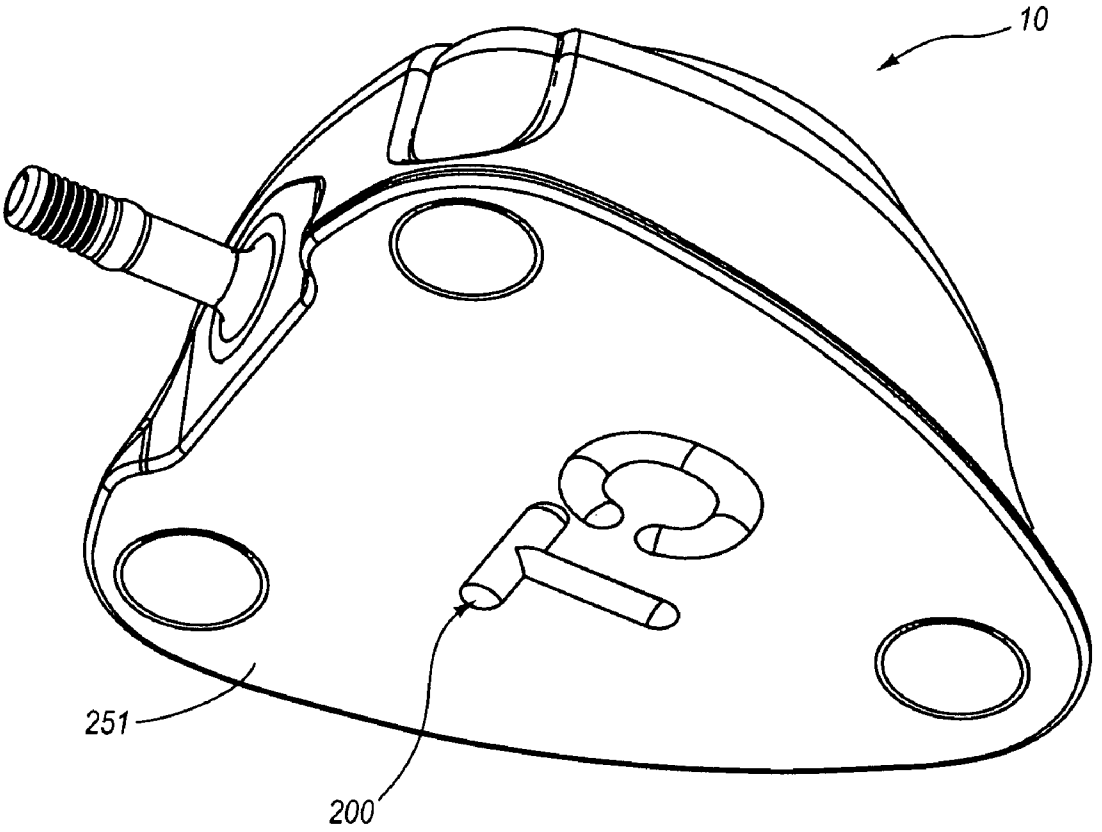

FIG. 57B

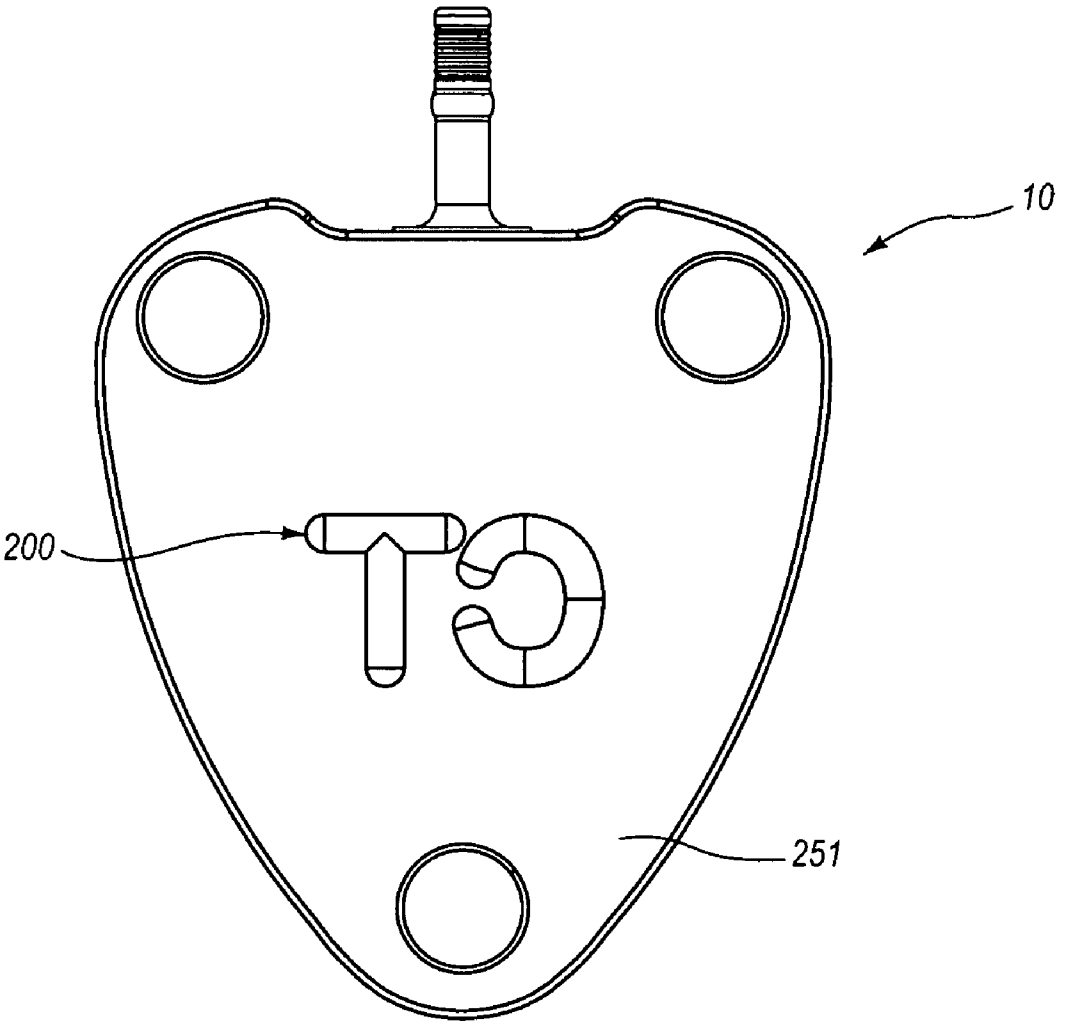

FIG. 57C

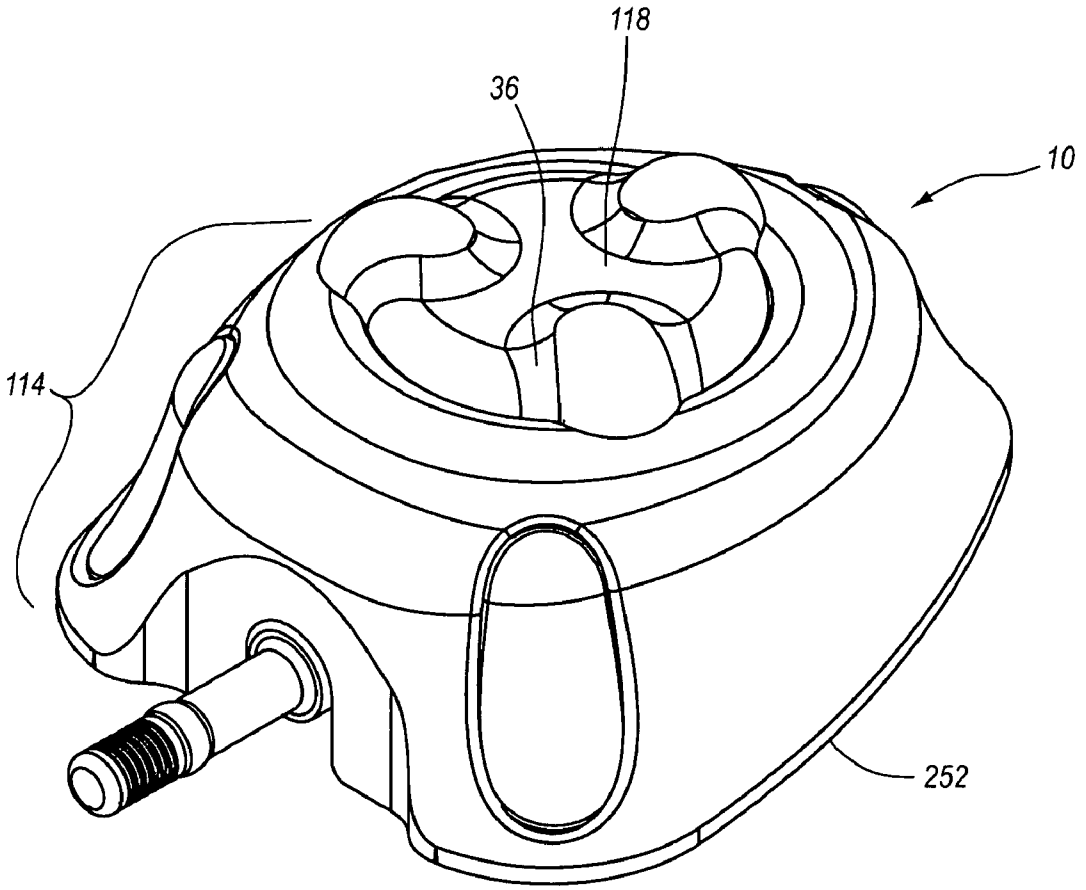

FIG. 58A

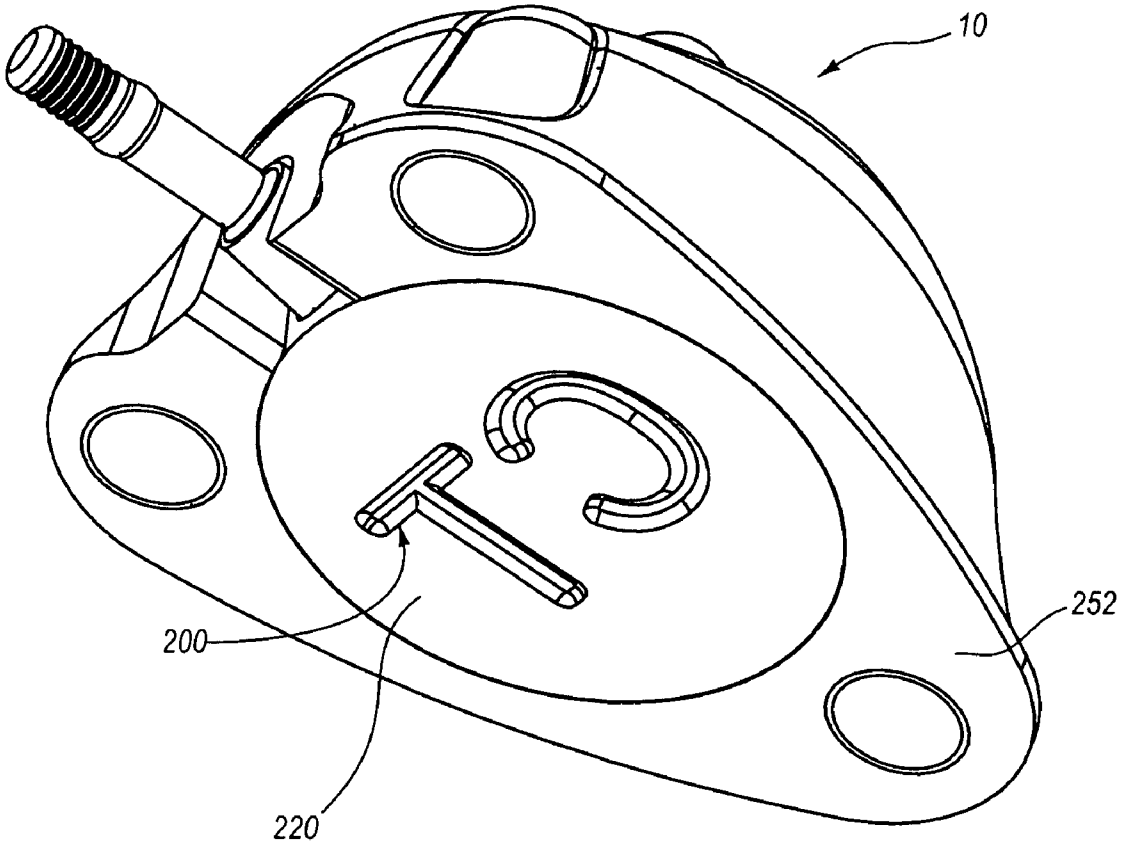

FIG. 58B

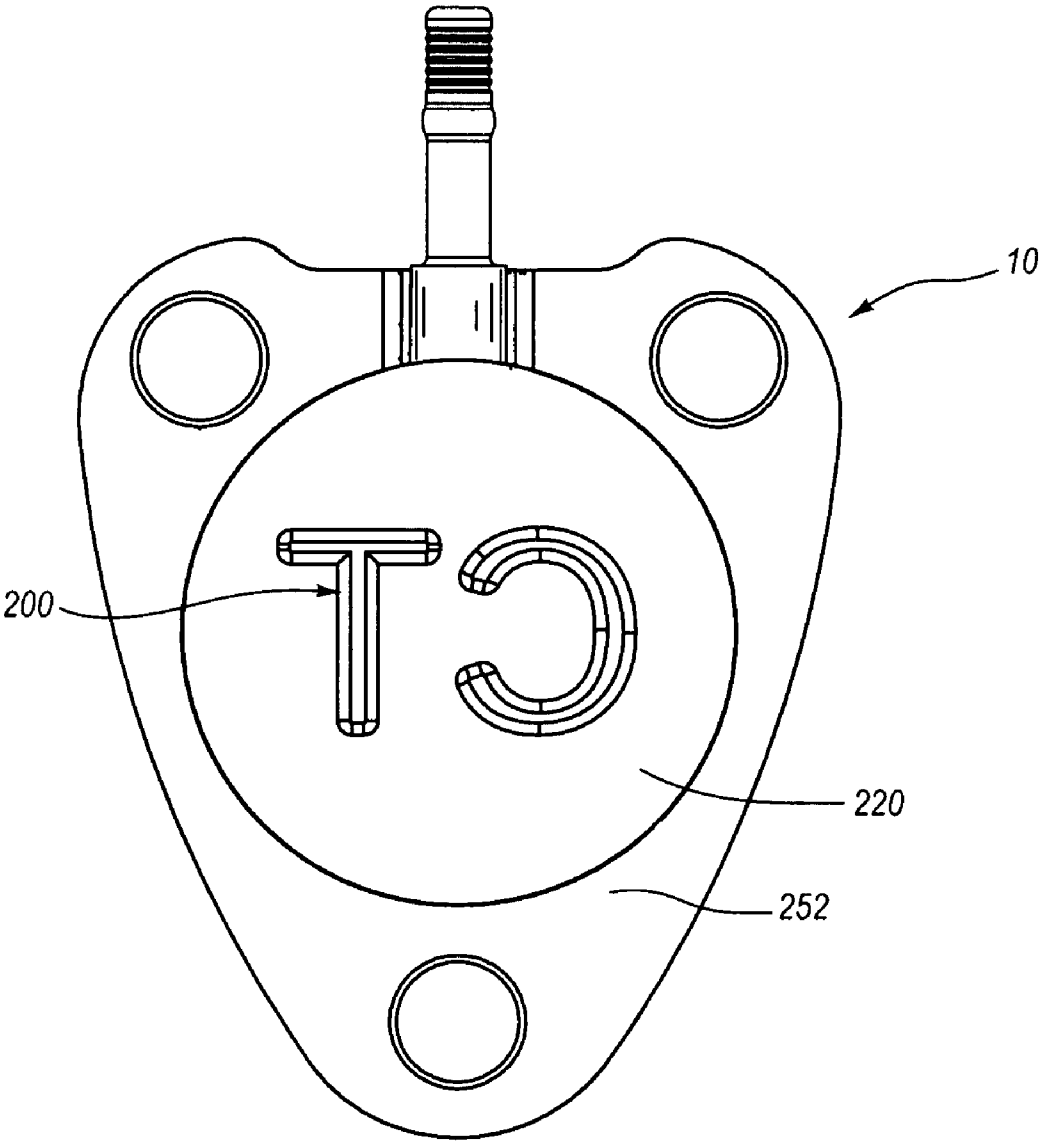

FIG. 58C

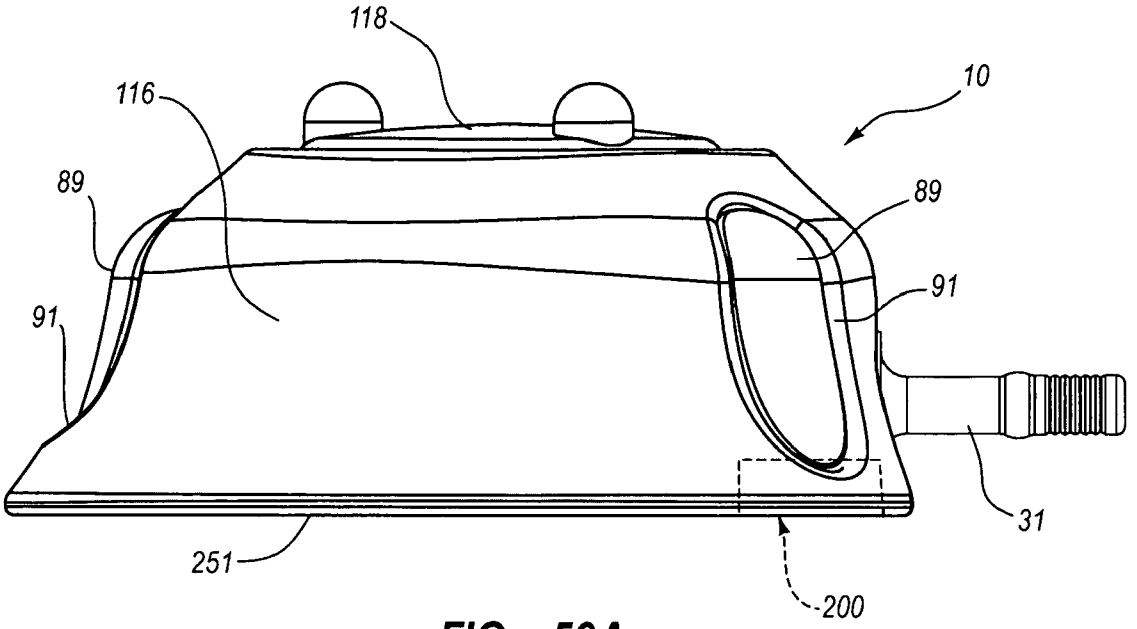

FIG. 59A

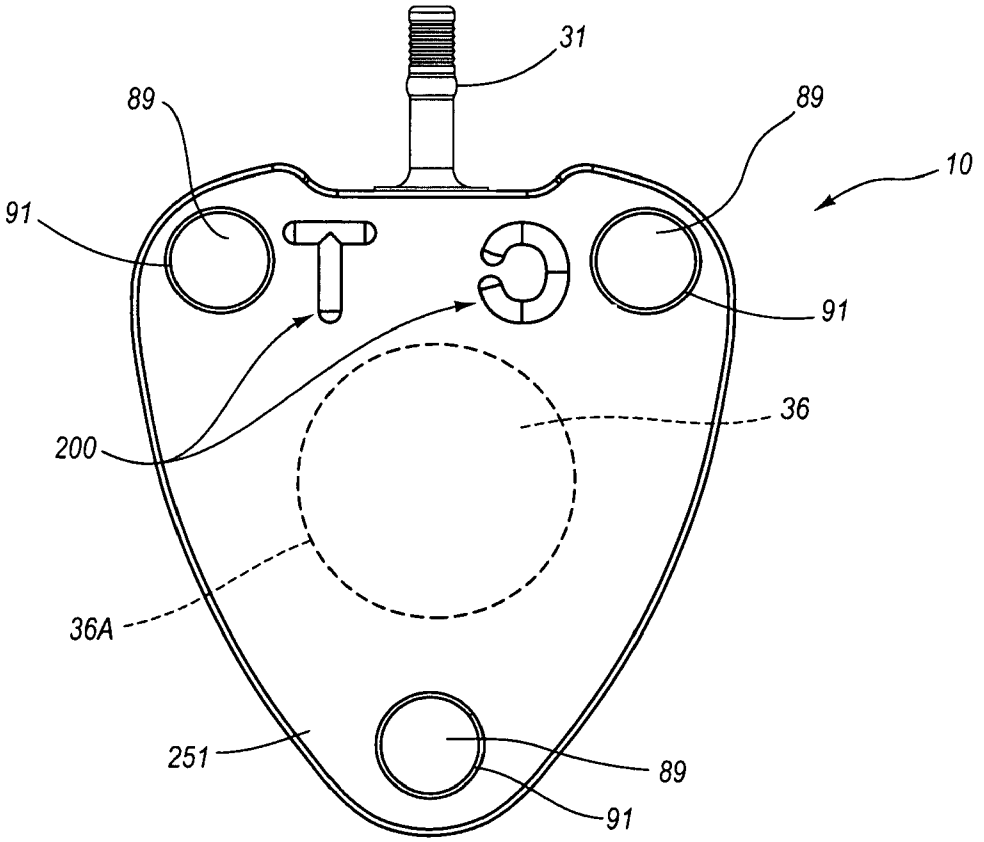

FIG. 59B

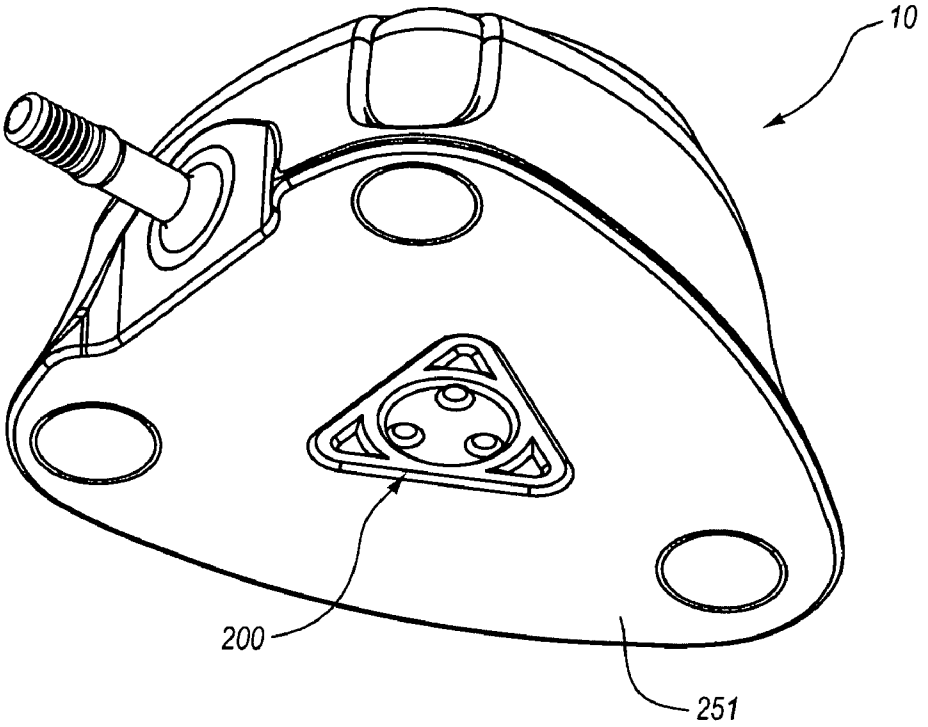

FIG. 60A

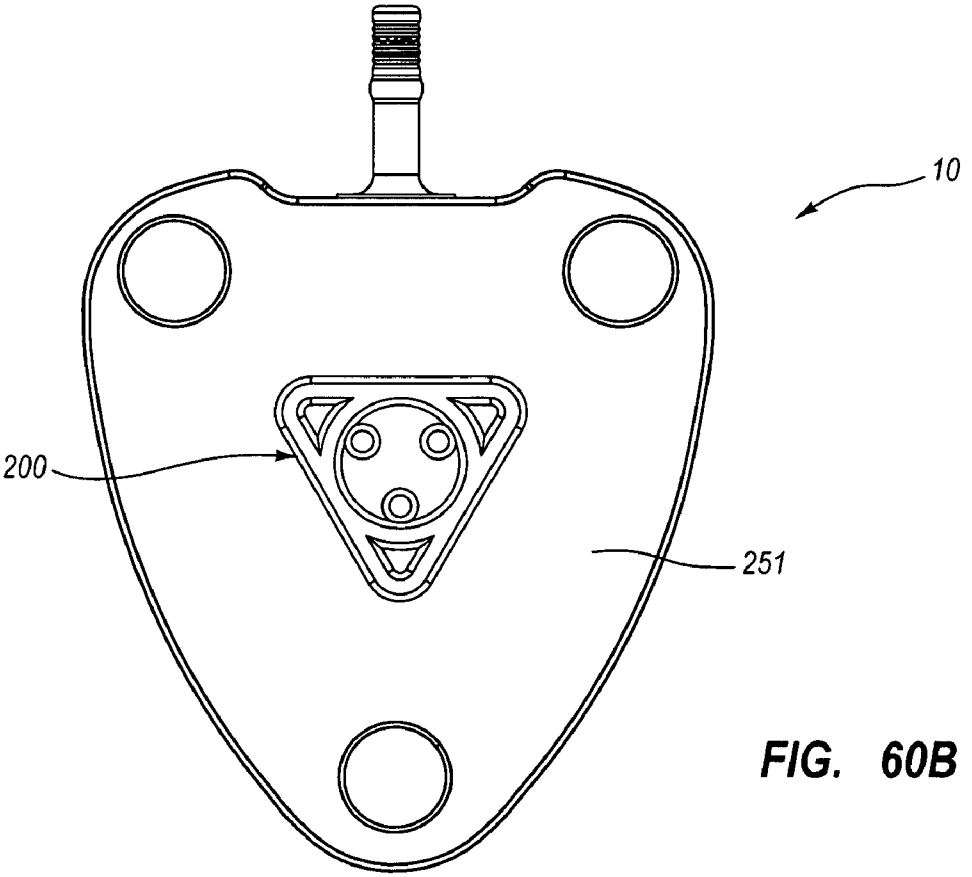

FIG. 60B

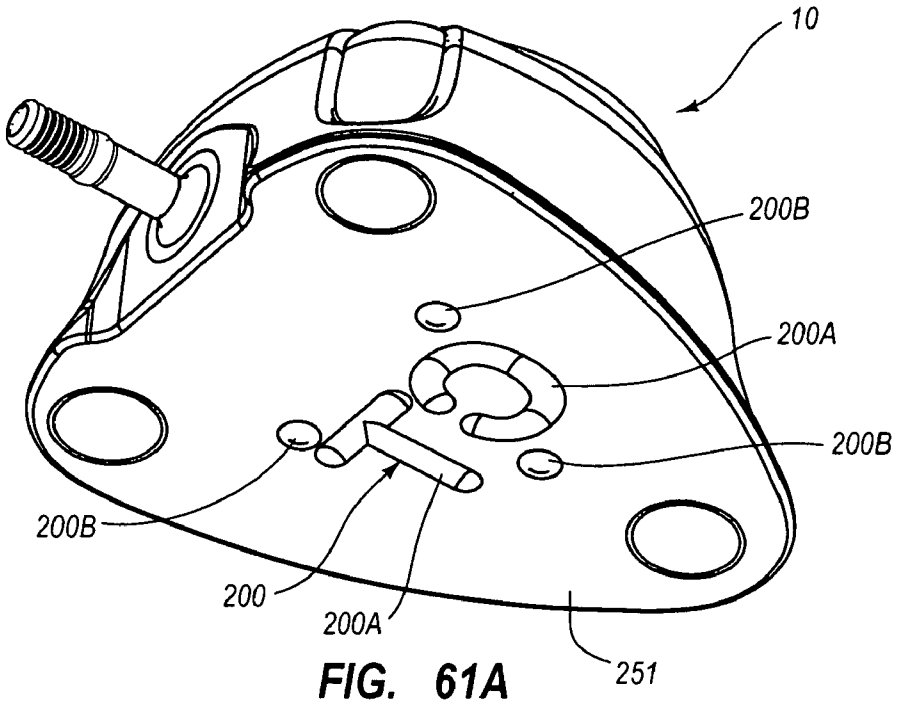

FIG. 61A

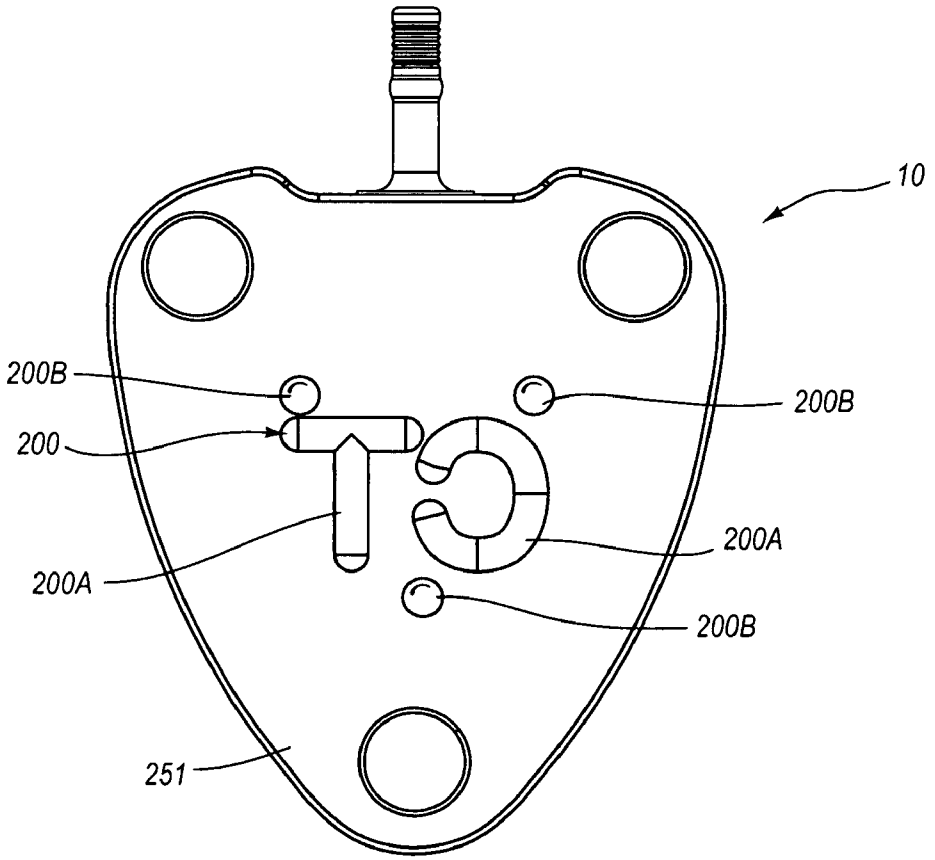

FIG. 61B

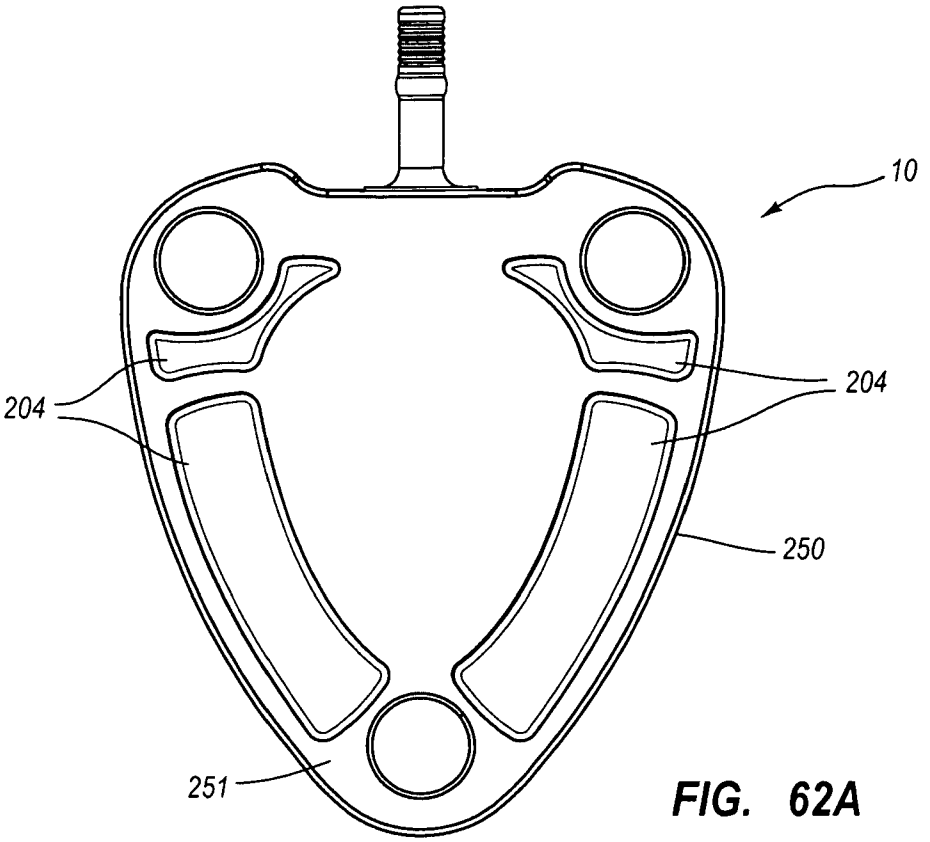

FIG. 62A

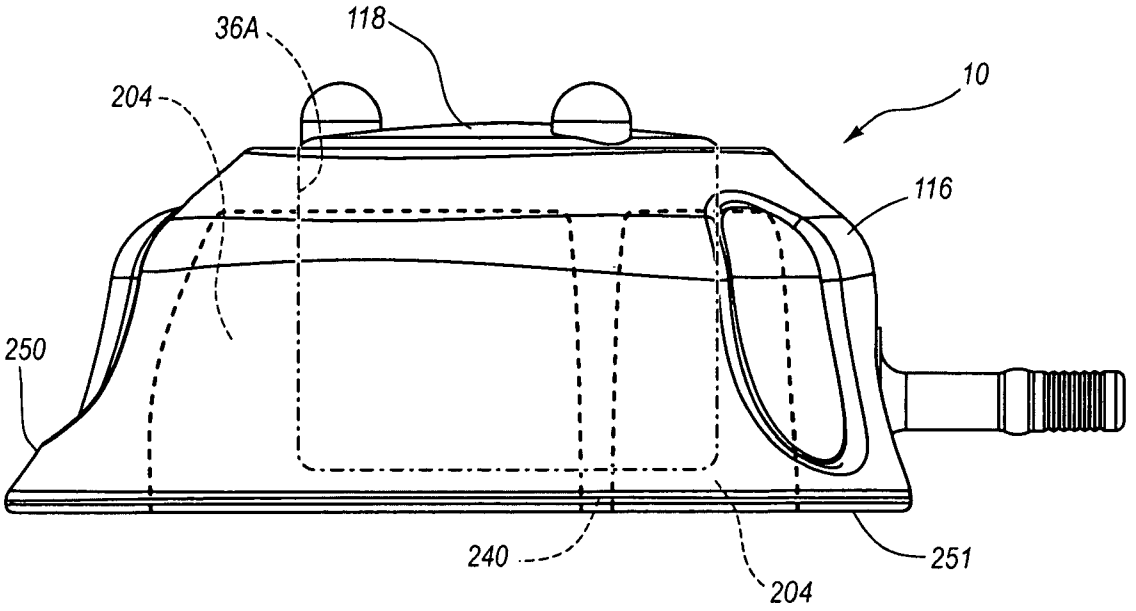

FIG. 62B

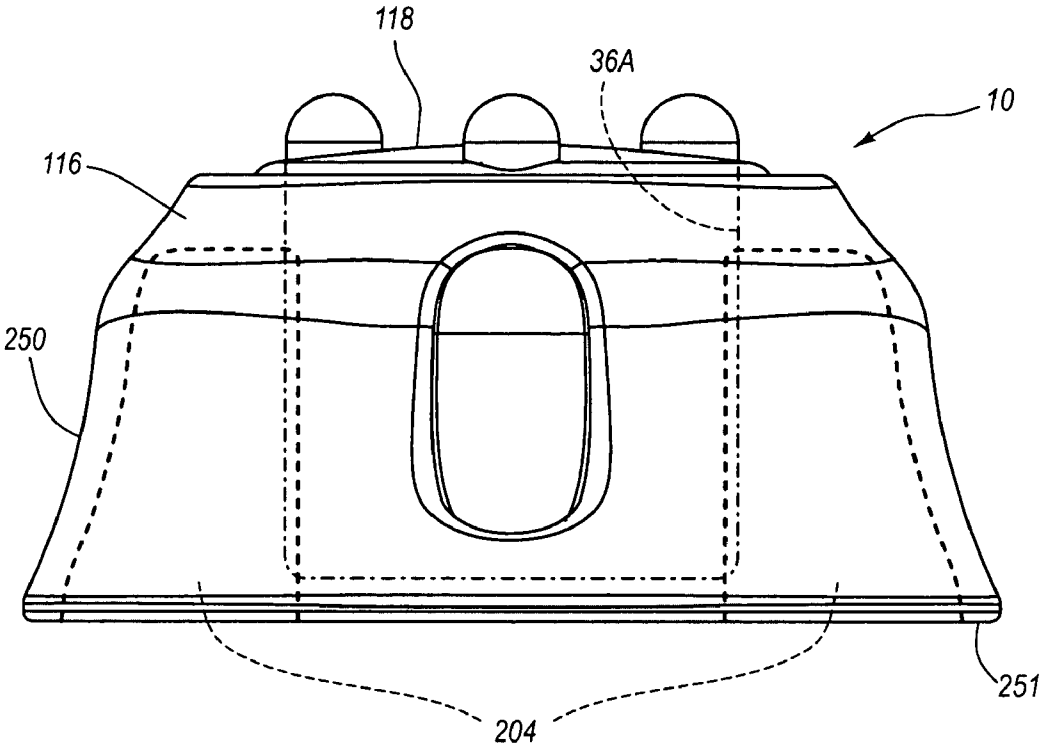

FIG. 62C

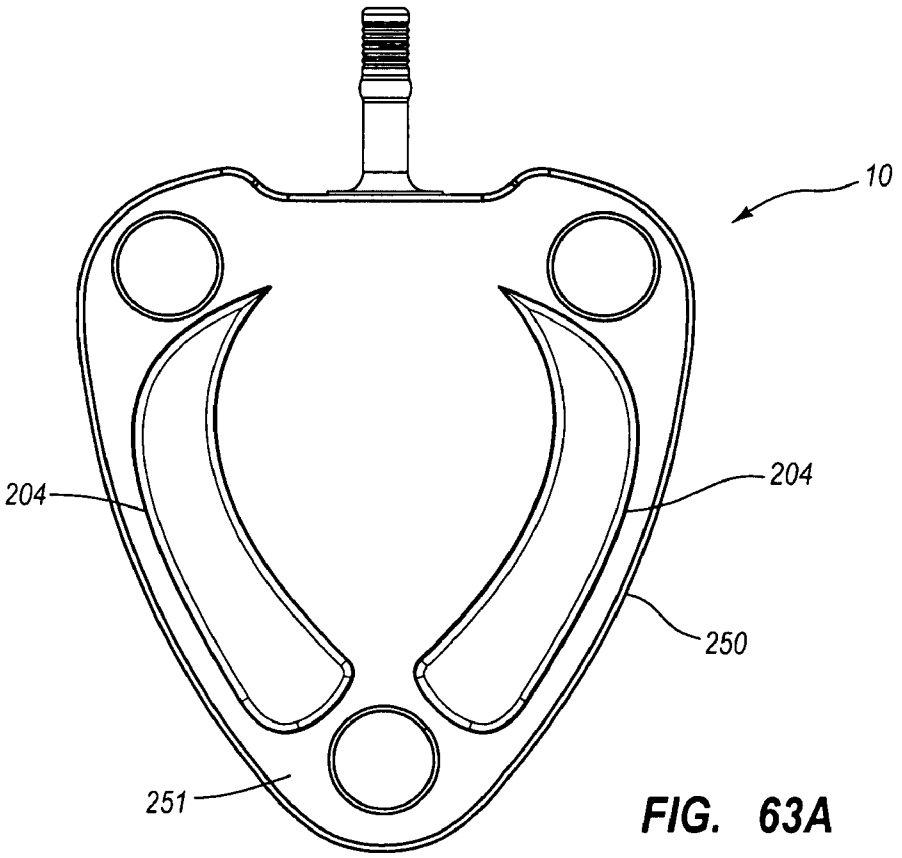

FIG. 63A

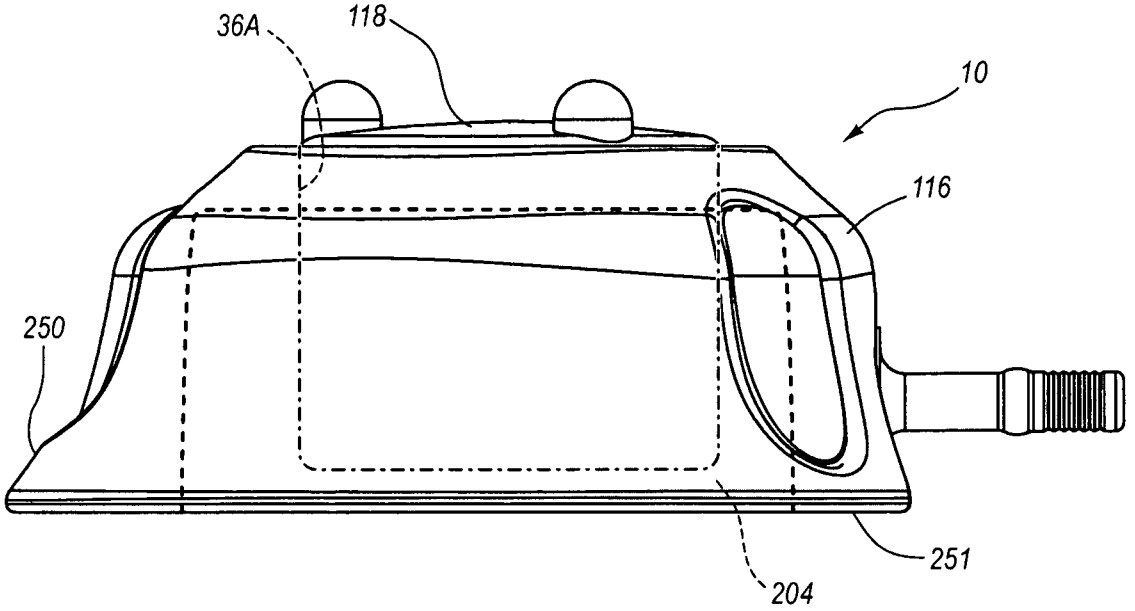

FIG. 63B

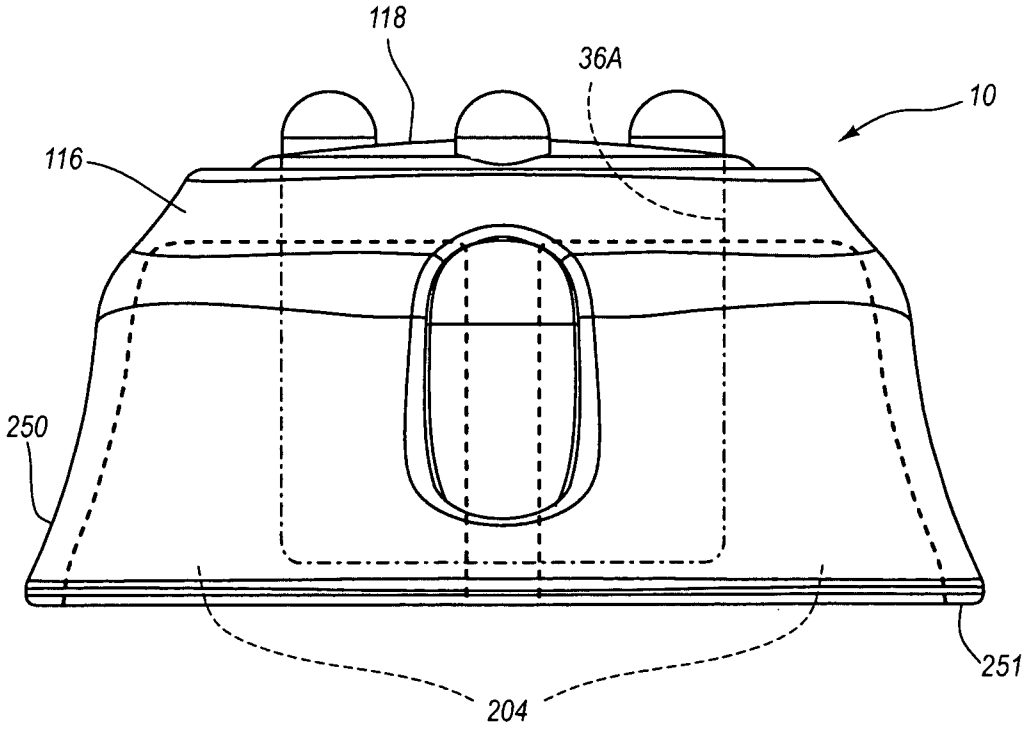

FIG. 63C

ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. application Ser. No. 11/368,954, filed Mar. 6, 2006, and entitled "Access Port Identification Systems and Methods," now U.S. Pat. No. 7,785,302, which claims the benefit of U.S. Provisional U.S. Patent Application No. 60/658,518, filed Mar. 4, 2005, and entitled "Access Port Identification System." Each of the afore-referenced applications is incorporated, in its entirety, by this reference.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **1**B shows a schematic side cross-sectional view the access port shown in FIG. **1**A;

FIG. **2** shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **3** shows a perspective view of an access port according to the instant disclosure;

FIG. **4** shows a perspective view of an access port according to the instant disclosure;

FIG. **5** shows a perspective view of an access port according to the instant disclosure;

FIG. **6**A shows a perspective view of an access port according to the instant disclosure;

FIG. **6**B shows a side view of the access port shown in FIG. **6**A;

FIG. **7** shows a perspective view of an access port according to the instant disclosure;

FIG. **8** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **9** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **10** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **11** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **12** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **13** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **14** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **15**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **15**B shows a top elevation view of the access port shown in FIG. **15**A;

FIG. **16** shows a perspective view of an access port according to the instant disclosure;

FIG. **17** shows a perspective view of an access port according to the instant disclosure;

FIG. **18** shows a perspective view of an access port according to the instant disclosure;

FIG. **19** shows a perspective view of an access port according to the instant disclosure;

FIG. **20** shows a perspective view of an access port according to the instant disclosure;

FIG. **21** shows a perspective view of an access port according to the instant disclosure;

FIG. **22** shows a perspective view of another embodiment of an access port according to the instant disclosure;

FIG. **23** shows a top elevation view of the assembled access port shown in FIG. **22**;

FIG. **24** shows a simplified representation of a transverse cross section of the access port shown in FIGS. **22** and **23**;

FIGS. **25-51** show perspective views of additional embodiments of an access port.

FIG. **52** shows a bottom perspective view of an access port according to one embodiment;

FIG. **53**A shows a top view of the access port shown in FIG. **52**;

FIG. **53**B shows a bottom view of the access port shown in FIG. **52**;

FIG. **54**A represents a radiographic image of the access port shown in FIG. **52** when viewed from above the access port;

FIG. **54**B represents a radiographic image of the access port shown in FIG. **52** when viewed at an angle of approximately 20 degrees;

FIG. **54**C represents a radiographic image of the access port shown in FIG. **52** when viewed at an angle of approximately 50 degrees;

FIG. **55** shows a cross-sectional view of the access port shown in FIG. **52**;

FIGS. **56**A and **56**B show cross-sectional views of example embodiments of engraved features on an access port surface;

FIG. **57**A shows a top perspective view of an access port according to one embodiment;

FIG. **57**B shows a bottom perspective view of the access port shown in FIG. **57**A;

FIG. **57**C shows a bottom view of the access port shown in FIG. **57**A;

FIG. **58**A shows a top perspective view of another embodiment of an access port;

FIG. **58**B shows a bottom perspective view of the access port shown in FIG. **58**A;

FIG. **58**C shows a bottom view of the access port shown in FIG. **58**A;

FIG. **59**A shows a side view of an embodiment of an access port;

FIG. **59**B shows a bottom view of the access port shown in FIG. **59**A;

FIG. **60**A shows a bottom perspective view of an additional embodiment of an access port;

FIG. **60**B shows a bottom view of the access port shown in FIG. **60**A;

FIG. **61**A shows a bottom perspective view of an additional embodiment of an access port;

FIG. **61**B shows a bottom view of the access port shown in FIG. **61**A;

FIG. **62**A shows a bottom view of an additional embodiment of an access port;

FIG. **62**B shows a side view of the access port shown in FIG. **62**A;

FIG. **62**C shows an end view of the access port shown in FIG. **62**A;

FIG. **63**A shows a bottom view of another embodiment of an access port;

FIG. **63**B shows a side view of the access port shown in FIG. **63**A; and

FIG. **63**C shows an end view of the access port shown in FIG. **63**A.

DETAILED DESCRIPTION

The instant disclosure relates generally to percutaneous access and, more specifically, to methods and devices associated with percutaneous access. Generally, the instant dis-

closure relates to an access port for subcutaneous implantation. In one embodiment, an access port may allow a physician or other medical personnel to obtain long term percutaneous access to the interior of a patient's body. Employing an access port for percutaneous access may reduce the opportunity for infection by inhibiting fluid connections (that extend into the interior of a patient's body) from the patient's skin and from the external environment. The access device allows access to the interior of the patient without requiring a needle to pierce the skin. Further, internal components, such as a catheter or a valve, may be replaced without a surgical procedure. Features or aspects of the instant disclosure may apply to any such access ports for subcutaneous access to a patient, without limitation. The access port may be injected by hand (e.g., via a syringe including a needle) for example, or may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port).

Power injectable ports may be employed in, among other processes, for example, computed tomography ("CT") scanning processes. More particularly, a so-called "power injector" system may be employed for injecting contrast media 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 under the trademark STELLANT®. Because fluid infusion 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.

More specifically, the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient. For example, at least one or perhaps multiple identifiable feature(s) of an access port contemplated by the instant disclosure may be correlative to information (e.g., a manufacturer's model or design) pertaining to the access port. Thus, an identifiable feature from an access port of a particular model may be unique in relation to most if not all other identifiable features of another access port of a different models or design. Of course, the at least one identifiable feature of an access port contemplated by the instant disclosure may be further correlative with any information of interest, such as type of port, catheter type, date of manufacture, material lots, part numbers, etc. In one example, at least one identifiable feature of an access port may be correlative with the access port being power injectable. In this way, once at least one identifiable feature of an access port is observed or otherwise determined, correlation of such at least one feature of an access port may be accomplished, and information pertaining to the access port may be obtained.

In one embodiment, at least one feature may be perceived by palpation (i.e., to examine by touch), by way of other physical interaction, or by visual observation. Accordingly, a person of interest may touch or feel the access port through the skin to perceive at least one identifying characteristic thereof. In another embodiment, at least one identifiable feature may be perceived via x-ray or ultrasound imaging. In yet a further embodiment, at least one identifiable feature may be perceived through magnetic, light, or radio energy interaction or communication with the access port.

Turning to the embodiment wherein at least one feature may be perceived through palpation, other physical interaction, or visual observation, a topography or exterior surface feature of an access port contemplated by the instant disclosure may be configured for perception. For example, referring to FIGS. **1**A and **1**B, an exemplary access port **10** contemplated by the instant disclosure is shown. FIGS. **1**A and **1**B show a perspective view and a schematic side cross-sectional view, respectively, of an access port **10** for allowing percutaneous or otherwise internal access to a patient's body. Access port **10** includes a housing or body **20** defined by a cap **14** and a base **16**. Cap **14** and base **16**, as known in the art, may be configured for capturing therebetween a septum **18**. As shown in FIG. **1**A, cap **14** and base **16** may matingly engage one another along a mating line **15**. Cap **14** and base **16** may be secured or affixed to one another via mechanical fasteners such as screws or other fastening devices, may be adhesively affixed to one another, or may be affixed to one another as known in the art. Further, cap **14**, base **16**, and septum **18** may collectively define a cavity **36** in fluid communication with a lumen **29** of outlet stem **31**.

The body **20** may be implanted in a patient **7**, as shown in FIG. **1**B, to dispose the cavity **36** subcutaneously within the patient **7**. Also, suture apertures **66** (FIG. **1**A) may be used to affix the access port **10** within the patient **7**, if desired. After the body **20** is implanted in a patient **7**, the upper surface of the septum **18** may be substantially flush with the surface of the skin **6** of the patient **7** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the cavity **36**. The outlet stem **31** may create a fluid-communicative passageway from the cavity **36** through the outlet stem **31** and into the interior of the patient **7**. A catheter may be coupled to the outlet stem **31** for fluid communication with the cavity **36** and for transferring fluid from the cavity **36** to a desired remote location from the cavity **36** and within a patient **7**.

Body **20** of access port **10** may comprise a bio-compatible material such as polysulfone, titanium, or any other suitably bio-compatible material as known in the art. Accordingly, the body **20** may be formed from a bio-compatible plastic material. If desired, the body **20** may comprise a penetrable material for penetration by sutures or needles. In another embodiment, and as discussed further hereinbelow, body **20** may comprise an impenetrable material such as, for instance, a metal if desired. Body **20** may include a concave bottom or, in another embodiment, may include a flat bottom, without limitation.

According to the instant disclosure, access port **10** may comprise a body **20** exhibiting at least one identifiable feature. More particularly, as shown in FIG. **1**A, body **20** may exhibit a partial generally pyramidal shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex otherwise known as a frustum). Generally, a body **20** of an access port **10** may exhibit a partial pyramidal shape extending between a generally quadrilateral shaped base positioned at reference plane **11** and a generally quadrilateral shaped upper base positioned at reference plane **9**. Reference planes **9** and **11** will not be shown in FIGS. **2**-**21**, for clarity; however, reference to planes **9** or **11** with respect to FIGS. **2**-**21**, as used herein, will refer to corresponding reference planes analogous to reference planes **9** and **11** as shown in FIGS. **1**A and **1**B.

As shown in FIG. **1**A, the exterior of access port **10** is substantially defined by four substantially planar side surfaces **50** connected to one another by radiuses **32**. In addition, the upper topography **61** of access port **10** is defined by upper surface **60** in combination with chamfers **46**A and **46**B and may be further defined by the upper surface of septum **18**. Explaining further, the outer periphery of upper topography **61** may be described as a generally quadrilateral exterior formed by side regions **54** and having rounded corner regions

30 adjacent side regions 54. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

It may be appreciated that there are many variations to the geometry of access port 10 as shown in FIG. 1A. For instance, while the body 20 of access port 10 may be described as a partially pyramidal shape or frustum, the instant disclosure is not so limited. Rather, one or more of side surfaces 50 may be oriented at as may be desired, without reference to any other side surfaces 50. Accordingly, for example, one of surfaces 50 may be substantially vertical while the remaining surfaces 50 may be oriented at respective, selected angles. Furthermore, it should be understood that FIG. 1A is merely exemplary and that the dimensions and shape as shown in FIG. 1A may vary substantially while still being encompassed by the instant disclosure.

FIG. 2 shows a perspective view of another embodiment of access port 10 according to the instant disclosure. As shown in FIG. 2, the exterior of access port 10 is substantially defined by a generally parallelogram-shaped base (positioned at reference plane 11 as shown in FIGS. 1A and 1B) extending generally pyramidally to a generally parallelogram-shaped upper surface (positioned at reference plane 9 as shown in FIGS. 1A and 1B). As shown in FIG. 2, radiuses 42 may be larger than radiuses 32 as shown in FIG. 1A. Furthermore, the upper topography 61 of access port 10 as shown in FIG. 2 may include rounded corner regions 40 which are larger than rounded corner regions 30 as shown in FIG. 1A. Thus, FIG. 2 shows an exemplary embodiment of an access port 10 that may be perceivably distinguishable from access port 10 as shown in FIGS. 1A and 1B. For example, a difference between one exterior of an access port contemplated by the instant disclosure and another exterior of a different access port contemplated by the instant disclosure may be determined by way of palpation.

In another embodiment, in another aspect contemplated by the instant disclosure, a template may be employed for perceiving at least one feature of an access port. For instance, a complementarily-shaped template may be positioned over and abutted against an access port contemplated by the instant disclosure so as to determine if the access port matches or substantially corresponds to the shape of the template. Such a process may reliably indicate or perceive at least one feature of an access port contemplated by the instant disclosure. Of course, a plurality of templates corresponding to different models of access ports may be serially engaged with an unknown access port so as to perceive at least one feature thereof. Such a process may allow for identification (e.g., of a model or manufacturer) of an access port contemplated by the instant disclosure.

In another aspect contemplated by the instant disclosure, an upper topography of an access port may include at least one feature for identifying the access port. For example, as shown in FIG. 3, upper surface 60 of access port 10 may be nonplanar. More specifically, upper surface 60 may be tapered or may arcuately extend downwardly (i.e., toward reference plane 11 as shown in FIGS. 1A and 1B) as it extends radially inwardly toward septum 18. Otherwise, access port 10, as shown in FIG. 3, may be configured substantially as described hereinabove with reference to FIGS. 1A and 1B. Thus, upper surface 60 is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In yet a further embodiment of an access port contemplated by the instant disclosure, side regions 54 extending between rounded corner regions 30 may exhibit at least one perceivable feature. For example, as shown in FIG. 4, access port 10 may include one or more side regions 54 that extend arcuately between adjacent rounded corner regions 30. Otherwise, access port 10, as shown in FIG. 4, may be configured substantially as described hereinabove with reference to FIGS. 1A and 1B. Side regions 54 may be congruent or symmetric with respect to one another or, in another embodiment, may be configured differently with respect to one another, without limitation.

FIG. 5 shows a further exemplary embodiment of an access port contemplated by the instant disclosure. More specifically, access port 10, as shown in FIG. 5, includes side regions 54 that form recessed regions 72 between adjacent rounded corner regions 30. Put another way, the upper topography 61 may include alternating recessed regions 72 and protruding regions 70 positioned generally about a periphery of septum 18. Otherwise, access port 10, as shown in FIG. 5, may be configured substantially as described hereinabove with reference to FIGS. 1A and 1B. Such a configuration may provide an access port having at least one identifiable feature.

In a further embodiment of an access port contemplated by the instant disclosure, FIGS. 6A and 6B show a perspective view and a side view, respectively, of an access port 10 generally configured as is described with reference to FIG. 5 but having an elongated body 20E. More specifically, elongated body 20E of access port 10, as shown in FIGS. 6A and 6B, includes a side surface 50E that extends generally from upper topography 61 downwardly (i.e., toward reference plane 11 as shown in FIGS. 1A and 1B) and having a slope (e.g., an angle with respect to a vertical axis normal to an upper surface of septum 18) which is different from the other side surfaces 50. Otherwise, access port 10, as shown in FIG. 6, may be configured substantially as described hereinabove with reference to FIGS. 1A and 1B. Such a configuration may provide an elongated body 20E of an access port 10 having an elongated side portion.

Of course, one or more side surfaces of an access port according to the instant disclosure may be configured for forming a body exhibiting a selected shape as may be desired. An elongated body portion of an access port contemplated by the instant disclosure may form, in combination with other features as described hereinabove or, in another embodiment, taken alone, at least one perceivable feature for identification of an access port according to the instant disclosure.

FIG. 7 shows a further embodiment of an access port encompassed by the instant disclosure. Particularly, as shown in FIG. 7, access port 10 may include an upper body portion 20*a* and a lower body portion 20*b*. Furthermore, each of upper body portion 20*a* and lower body portion 20*b* may exhibit a partial pyramidal shape (i.e., a frustum), wherein the body portions 20*a* and 20*b* are stacked vertically with respect to one another. Accordingly, upper body portion 20*a* may form an overhanging rim feature 76 extending along a periphery of access port 10. Explaining further, lower body portion 20*b* may have an exterior substantially defined by side surfaces 50*b* and rounded corner regions 30*b*, while upper body portion 20*a* may have an exterior substantially defined by side surfaces 50*a*, rounded corner regions 30*a*, and upper topography 61. It may be appreciated that overhanging rim feature 76 may be sized and configured for perception via palpation. Such a configuration may provide a suitable access port for delivery of a beneficial or medicinal substance, the access port being identifiable (e.g., by model number, manufacturer, etc.) after implantation.

It should be understood that the instant disclosure contemplates access ports having an exterior geometry that is not quadrilateral in nature. Rather, the instant disclosure contemplates that an access port may have an exterior which is

generally cylindrical, generally conical, generally elliptical, generally oval, or an exterior that is otherwise arcuate in nature. Specifically, the instant disclosure contemplates that an access port having a substantially rounded or arcuate exterior may include at least one feature configured for identification of the access port after implantation. For example, as shown in FIG. **8**, shows a cap **14** that exhibits an exterior surface **78** that is substantially conical. Cap **14** may be assembled to a suitable base (not shown) for capturing a septum (not shown) as described hereinabove to form an access port **10** as generally described with reference to FIGS. **1-7**.

The instant disclosure further contemplates that at least one protrusion, protruding region, recess, recessed region, undulation, or adjacent features of different elevation may comprise a feature for identifying an access port contemplated by the instant disclosure. More specifically, upper topography **61**C, as shown in FIG. **8**, may include a plurality of protrusions **80**. Protrusions **80** may exhibit partially spherical upper surfaces that transition into a lower portion of cap **14**. In further detail, protrusions **80** may be circumferentially spaced about the periphery of septum (not shown) as may be desired. In one embodiment, a plurality of protrusions **80** may be symmetrically circumferentially spaced about the periphery of septum (not shown). More generally, at least one protrusion **80** may be sized, configured, and positioned for forming at least one identifiable feature of an access port. Of course, at least one protrusion **80** may be structured for facilitating comfort of a patient within which the access port is implanted. As may be appreciated, at least one protrusion **80** or more than one protrusion **80** may be included in an upper topography **61**C of an access port (not shown) contemplated by the instant disclosure.

FIG. **9** shows another embodiment of a cap **14** including at least one protrusion **80**E for forming and identifying an access port contemplated by the instant disclosure after implantation thereof within a patient. Protrusions **80**E may extend circumferentially about a center of revolution. Thus, protrusions **80**E may exhibit a body **87** portion circumferentially extending between rounded ends **83**. Further, cap **14** may have an exterior surface **78** that is substantially symmetric about an axis of revolution. More generally, body **20** may extend from a generally circular, generally elliptical, or generally oval base positioned at a lower extent **71** of the cap **14** to an upper generally circular, generally elliptical, or generally oval cross section that is smaller than a cross section of the base and is positioned at an upper extent **73** (without considering protrusions **80**E) of the cap **14**. In addition, side surface **51**, as shown in FIG. **9**, extends arcuately between the base and the upper topography **61** of cap **14**. Side surface **51** may extend in a generally tapered or conical fashion, may exhibit a radius or other arcuate shape, or may otherwise transition between a cross section of the base of the access port to a cross section proximate the upper topography **61**C thereof.

Further, FIG. **10** shows an embodiment of a cap **14** for forming an access port contemplated by the instant disclosure having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E are circumferentially larger than the circumferentially extending recesses **80**E. In another embodiment of an access port contemplated by the instant disclosure, FIG. **11** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) sized or extension. In yet a further embodiment of a cap **14** for forming an access port contemplated by the instant disclosure, FIG. **12** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising three circumferentially extending protrusions **80**E and three circumferentially extending recesses **82**, arranged so as to alternate circumferentially, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) size.

FIG. **13** shows a perspective view of an additional embodiment of an cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T, wherein transition regions **81** are provided between circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T. Such transition regions **81**, as shown in FIG. **13**, may taper or generally smoothly transition between a circumferentially extending protrusion **80**T and a circumferentially extending recess **82**T. Also, FIG. **14** shows a perspective view of an additional embodiment of a cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including protrusion regions **96** and recessed regions **98** that transition between one another and alternate circumferentially so as to form an undulating topography comprising upper topography **61**C. Such an undulating topography, as shown in FIG. **14**, generally smoothly transitions between circumferentially adjacent protrusion regions **96** and recessed regions **98**.

In a further embodiment of an access port contemplated by the instant disclosure, FIGS. **15**A and **15**B show a perspective view and a top elevation view, respectively, of an access port **10** generally configured as is described with reference to FIG. **5** but may include at least one nonplanar side surface. In another embodiment, access port **10** as shown in FIG. **15** may be configured as shown in FIGS. **1-4** or FIGS. **6-7**, or any embodiments described hereinbelow, without limitation. More specifically, elongated body **20** of access port **10**, as shown in FIGS. **15**A and **15**B, includes three side surfaces **50**R that extend arcuately (as shown in FIG. **15**B). Such a configuration may provide an access port **10** that is identifiable subsequent to implantation. In yet another embodiment of an access port contemplated by the instant disclosure, FIG. **16** shows a perspective view of an access port **10** including a side wall **100** that truncates a portion of a radius **32** formed between side surfaces **50** of access port **10**. It may also be noted that such an access port **10** may include three suture apertures **66**, which may, taken alone or in combination with at least one other feature, comprise at least one identifiable feature of an access port contemplated by the instant disclosure. In addition, as shown in FIG. **16**, outlet stem **31** may extend from side wall **100**.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **17** shows a perspective view of an access port **10** wherein cap **14** and base **16**, when assembled to one another along mating line **15**, form a flange feature or lip feature **102** that extends about at least a portion of the periphery of the access port **10**. As shown in FIG. **17**, lip feature **102** extends substantially about the periphery of the access port **10**, proximate to the mating line **15** between cap **14** and base **16**. Such a feature may comprise at least one identifiable feature of an access port contemplated by the instant disclosure. Thus, it may be appreciated that a peripheral discontinuity between the cap **14** and base **16** may be formed generally along the mating line **15** therebetween. In

the embodiment of an access port as shown in FIG. **7**, an overhanging rim feature **76** may comprise a peripheral discontinuity or, in the embodiment of an access port as shown in FIG. **17**, a lip feature **102** may comprise a peripheral discontinuity.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, concave region **106** of side surface **50** is concave. Concavity (i.e., a concave region **106**) may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, region **106** of side surface **50** is concave. Concavity may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **19** shows a perspective view of an access port **10** generally configured as is described with reference to FIGS. **6**A and **6**B. More specifically, elongated body **20**ER, as shown in FIG. **19** includes a side surface **50**ER that extends arcuately from upper topography **61** of access port **10** downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B). Such a configuration may provide an elongated body **20**E of an access port **10** having an elongated side portion.

It should be understood from the above-described various embodiments of an access port contemplated by the instant disclosure that many variations, additions, or different features may be encompassed by the instant disclosure. Thus, the instant disclosure is not limited to the several above-described exemplary embodiments.

For example, as shown in FIG. **20**, which shows a top elevation view of an access port **10** contemplated by the instant disclosure, an access port **10** may include a side wall **100** that at least partially truncates a radius **32** between side surfaces **50**, outlet stem **31** extending from side wall **100**, and at least one of a concave region **106** and an arcuate surface **50**R. Further, as shown in FIG. **20**, suture apertures **66** may be positioned so as to identify the access port **10** after subcutaneous implantation.

Additionally, the instant disclosure contemplates access ports having an exterior geometry that is polygonal in nature. Specifically, the instant disclosure contemplates that an access port contemplated by the instant disclosure may exhibit a generally triangular exterior. Thus, as shown in FIG. **21**, body **20** may exhibit a generally pyramidal or tapered shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex). Generally, a body **20**T of an access port **10** may extend between a generally triangularly-shaped base and a relatively smaller, generally triangularly-shaped upper base. Accordingly, the exterior of access port **10** may be substantially defined by three side surfaces (e.g., **50**, **50**R, **102**, **50**E) having radiuses **32** extending therebetween. In addition, the upper topography **61** of access port **10** may be defined by upper surface **60** in combination with side regions **54** and rounded corner regions **30**. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

FIGS. **22** and **23** show a perspective view and a top elevation view of another embodiment of an access port including a generally triangular exterior geometry. More particularly, as shown in FIGS. **22** and **23**, a cap **14** and base **16** (collectively forming a housing) may capture a septum **118** to form an access port **10**. Further, outlet stem **31** may include a stem base that may be positioned within and sealed to an outlet recess **93** formed within base **16**. The outlet stem **31** may be in fluid communication with a cavity formed within the access port **10**. Optionally, suture plugs **89** may be positioned within suture cavities **91** formed in base **16**. Suture plugs **89** may comprise a pliant material (e.g., silicone, rubber, etc.) that may provide some resilience between sutures coupling the access port **10** (i.e., the base **16**) to a patient. In further detail, a side periphery **95** (e.g., one or more side walls) of access port **10** may be generally triangular. Thus, cap **14** and base **16** may collectively form a generally triangular housing or body of access port **10**. Also, the instant disclosure contemplates that side periphery **95** may increase or decrease in cross-sectional size (e.g., by tapering or arcuately transforming) between upper surface **161** of cap **14** and lower surface **151** of base **16**. As shown in FIGS. **22** and **23**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **151** of base **16**) of access port **10** may be larger proximate to lower surface **151** of base **16** and may be relatively smaller proximate upper surface **161** of cap **14**.

Additionally, FIG. **24** shows a simplified representation of a transverse cross section of access port **10**. As shown in FIG. **24**, side periphery **95** of access port **10** may define three side regions **103** that extend between associated vertex regions **101**. In addition, in one embodiment and as shown in FIG. **24**, side periphery **95** may define a substantially equilateral generally triangular shape. As one of ordinary skill in the art will appreciate, side regions **103** may arcuately extend between associated vertex regions **101**; thus, side regions **103** may form "sides" of a generally triangular shape. Further, although vertex regions **101** are rounded, it may be appreciated that such vertex regions **101** form an intersection between adjacent side regions **103**. Accordingly, one of ordinary skill in the art will appreciate that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect, without limitation. For example, the phrase "generally triangular" encompasses three sided polygons, circular triangles, equilateral triangles, etc., without limitation.

The instant disclosure also contemplates that at least one feature of an access port contemplated by the instant disclosure may not be observable visually or by palpation but, rather, may be otherwise observable. For example, the instant disclosure contemplates that at least one feature of an access port may be observable through interaction with an imaging technology such as x-ray or ultrasound. For example, in one embodiment, a metal feature (e.g., a plate or other metal geometry) may be included by an access port contemplated by the instant disclosure. As may be appreciated, such a metal feature may be represented on an x-ray generated by exposure of the access port to x-ray energy while simultaneously exposing x-ray sensitive film to x-ray energy passing through the access port. Further, the instant disclosure contemplates that a size, shape, or both size and shape of a metal feature of an access port may be configured for enhancing identification

of an access port. For example, assuming that a metal feature comprises a metal plate, a size, shape, or both may be selectively tailored for identification of an access port. Similarly, a feature of an access port contemplated by the instant disclosure may be tailored for detection via ultrasound interaction. Such a feature may comprise an exterior topographical feature. In another embodiment, such a feature may comprise a composite structure including two or more materials that form an interface surface that may be identified by ultrasound imaging.

One example embodiment of a feature observable through interaction with imaging technology contemplated by the instant disclosure is shown in FIGS. **52**, **53**A, and **53**B. FIG. **52** depicts a bottom perspective view of an access port **10**. FIG. **53**A shows a top view of the access port **10**, while FIG. **53**B shows a bottom view of the access port. The access port **10** of FIGS. **52**, **53**A, and **53**B is similar in some respects to the access port **10** as seen in FIGS. **22** and **23**, including a cap **14** and a base **16** that cooperate to define a body. In the present example embodiment, however, the lower surface **151** of the base **16** includes an identification feature **200**, as seen in FIGS. **52** and **53**B. It is contemplated that the identification feature **200** can be one or more alphanumeric characters, such as the "CT" depicted. Additionally, the instant disclosure contemplates the use of other markings, such as one or more symbols, patterns, characters, designs, a combination thereof, etc. The identification feature **200** can be of any size, shape, or both in order to tailor the identification feature for the specific identification of one or more of a variety of characteristics of the access port. Specifically, in one embodiment the identification feature **200** can convey information to a practitioner regarding the power-injectability of the implanted access port. Note that in the present embodiment, the identification feature **200** is defined as a recessed feature, whereas in other embodiments the identification feature may be defined in other ways, as discussed hereafter.

As mentioned above, FIG. **53**A depicts a top view of the access port **10**. Note that the identification feature **200** is not observable through the upper surface **161** of the cap **14** or through the septum **118** without the interaction of imaging technology. As seen in FIG. **53**B, the alphanumeric characters of the identification feature **200**, "CT," are engraved mirror-reversed on the lower surface **151** of the base **16**. The "CT" is engraved mirror-reversed so that when imaging technology, such as x-ray imaging, is used to identify a subcutaneously implanted access port, the "CT" will be visible in the proper orientation. By engraving a desired identification feature mirror-reversed on the bottom surface of an access port, a practitioner will be able to determine if there is a problem with the port after implantation, such as if the access port has flipped or otherwise become mis-oriented while in the body of the patient. Thus, if the identification feature is seen mirror-reversed or askew in an x-ray image, the practitioner can correct the problem before attempts are made to use the access port.

Although also useful in access ports where only a portion of a port includes a metallic material, e.g., a metal plate, the engraving technique is well-suited in one embodiment for access ports that are composed of solid metal, such as titanium, stainless steel, or other materials that are typically radiopaque, i.e., non-transmissive to x-rays in sufficient thickness. FIGS. **54**A-**54**C are representative images of the access port **10** of FIG. **52**, which includes titanium or other metallic material, as seen via x-ray imaging after implantation into the patient. The access port **10** includes the identification feature **200** as seen in FIGS. **52** and **53**B. Due to the relative thickness of the access port **10**, the material of the base **16** and cap **14** surrounding a cavity periphery **36**A of the cavity **36**, which is a fluid cavity, is substantially non-transmissive to x-rays and therefore appears relatively dark in the x-ray image of FIG. **54**A. However, the material of the access port **10** within the cavity periphery **36**A is relatively thinner through a cavity base **220** (as seen in FIG. **55**) than through the material of the cap **14** and base **16**. Thus, additional thinning of the material when creating the identification feature **200** enables the identification feature to appear relatively more radiographically transmissive than the surrounding material of the cavity base under x-ray imaging. Note that the identification feature **200** in FIG. **54**A is visible in the proper orientation, indicating that the access port is not flipped.

FIGS. **54**B and **54**C are additional representative x-ray images of the identification feature **200** of the access port **10**, wherein the access port is tilted at angles of approximately 20 and 50 degrees, respectively. Thus, the identification feature **200** is also useful for determining relative orientation of the access port **10** after implantation.

FIG. **55** shows a cross-sectional view taken at line **55**-**55** of the access port **10** in FIG. **52**. In this example embodiment, the identification feature **200** is disposed beneath the septum **118** and the cavity **36**. FIGS. **56**A and **56**B further depict enlarged cross-sectional views of potential cut profiles of the recessed identification feature **200**. FIG. **56**A shows a rounded engraving profile **201**, engraved on the lower surface **151** of the base **16** and used for purposes of aesthetics and ease of manufacturing. For a relatively more defined contrast under imaging technology, however, a sharp-edged engraving profile **202** may be used, as seen in FIG. **56**B. Note that a variety of cross-sectional recessed profiles may be employed. This disclosure further contemplates that although engraving is discussed here, other methods of marking the identification feature may be used, such as milling, machining, chemical or laser etching, molding, stamping, etc.

Regardless of the cut profile used, better contrast is achieved generally with greater engraving depth X. The optimal engraving depth X will depend, however, on the thickness of the overall cavity base **220**, which is the portion of the base directly below the cavity **36**, as shown in FIG. **55**. For example, in an embodiment of an access port including titanium, if the overall thickness of the cavity base **220** is approximately 0.020" then sufficient contrast for x-ray imaging purposes can be obtained in one embodiment by engraving the identification feature **200** to a depth X (FIGS. **56**A, **56**B) of between about 0.009" and about 0.011". In another example embodiment of an access port including titanium, where the overall thickness of the cavity base **220** is approximately 0.030", sufficient contrast can be obtained by engraving the identification feature **200** to a depth X of between about 0.015" and about 0.021". One of ordinary skill in the art will appreciate that the depth of an engraved identification feature can be varied substantially in order to comply with a product's safety requirements and still remain within the scope contemplated by this disclosure. In addition, the depth X of the identification feature can vary according to the position of the feature on the access port, the thickness of material to be penetrated by the imaging technology, the type of material included in the access port, etc.

It is also contemplated by this disclosure that the use of an identification feature in a metallic or other radiopaque access port can be applied to access ports having a variety of possible configurations, such as is seen in FIGS. **57**A-**58**C, for example. FIGS. **57**A-**57**C depict one embodiment, wherein the access port **10** includes an identification feature **200** on a lower surface **251** of a base or body **116**. The access port **10** in FIGS. **57**A-**57**C includes a retaining ring **230**, which seals the septum **118** to the base or body **116**, over the cavity **36**. In one

embodiment, the retaining ring **230** is press fit into the base or body **116** to hold the septum **118** in place. FIGS. **58**A-**58**C show yet another embodiment, wherein the access port **10** includes an identification feature **200** on the cavity base **220** and wherein the cavity base is mated to and flush with a lower surface **252** of a cap **114** to define a body. In a particular embodiment, the cavity base **220** is press fit into the cap **114**, though other mating configurations can also be employed.

In another embodiment contemplated by the instant disclosure, FIGS. **59**A and **59**B show that the location of the identification feature **200** can vary as well. Rather than placing the identification feature **200** under the cavity **36**, it is possible to place the identification feature under another portion of the access port **10**, such as under the outlet stem **31** and between the septum plugs **89**, i.e., proximate the outer periphery of the access port bottom surface. Though the overall thickness of the access port structure above the identification feature **200** is greater in this location than if engraved under the cavity **36**, the change in location allows for a relatively deeper engraving, which will increase contrast without risk of excessive thinning of the cavity base **220**. Additionally, in one embodiment, it is possible to define the identification feature compositely by engraving into both the bottom and top surfaces, such that the engravings are vertically aligned. This enables the remaining material thickness to be substantially reduced in order to provide relatively greater radiographic transmission through the identification feature.

Additionally, the instant disclosure contemplates access ports having any variety or combination of desired identification features for indicating power-injectability or other aspect or characteristic of an access port. Specifically, FIGS. **60**A-**61**B depict different types of identification features **200**, according to example embodiments. FIGS. **60**A-**60**B depict a symbolic identification feature **200**. FIGS. **61**A-**61**B depict an exemplary embodiment of an access port **10** including a combination of identification features **200**, namely an alphanumeric identification feature **200**A and a patterned identification feature **200**B. A patterned or symbolic identification feature can also be used to help indicate the orientation of the port or for any other desired reason. It is understood by the instant disclosure that other symbols, patterns, marks, and alphanumeric characters can be used both alone and in any combination with each other on a variety of access port configurations.

In additional embodiments, the identification feature can be defined on an inside bottom surface **36**B of the cavity **36** of an access port **10**, or in addition to the identification feature **200** provided on the bottom surface **251**. In another embodiment, the material surrounding the defining edges of the desired radiopaque alphanumeric character, symbol, pattern, etc., can be removed instead of removing the desired feature shape itself so as to define a "positive" relief image of the identification feature. Such a positive relief identification feature can be defined on a lower surface of an access port body or on the inside bottom surface of the cavity, for example.

In addition to the various types of symbols, patterns, marks, and alphanumeric characters that are contemplated by the instant disclosure, FIGS. **62**A-**63**C disclose additional example embodiments of identifying features on access ports that are observable via x-ray or other suitable imaging technology. Specifically, the instant disclosure contemplates the use of shelled-out cavities **204**, wherein portions of the access port **10** are hollowed out. This results in shelled-out cavities **204** extending inward from the lower surface **251** of the base or body **116** or corresponding port lower surfaces of the other embodiments described herein, including the lower surface **151** of the base **16**, as in FIG. **151**, and the lower surface **252** of a cap **114**, as in FIGS. **58**A-**58**C. This is done by removing the material surrounding the cavity **36** without disrupting the cavity periphery **36**A or the outer side surfaces **250** of the access port **10**. As seen in FIG. **62**B, ribs **240** may be left to support the remaining "shelled" frame of the access port **10**. The definition of such cavities **204** provides a relative difference in radiopacity of the access port **10** that can be identified via x-ray imaging. As such, the cavities **204** can be arranged to define a pattern or to form an indicia for identification of an aspect or characteristic of the access port **10**. Note that in other embodiments, the cavities can be defined so as to extend from other surfaces of the access port, including the top and sides thereof.

In a further aspect contemplated by the instant disclosure, it is contemplated that a communicative technology may be utilized wherein information is encompassed by an access port contemplated by the instant disclosure. Generally, a communication device (e.g., a radio beacon, a light-emitting element, an ultrasound emitting transducer, etc.), may be imbedded or otherwise affixed to an access port contemplated by the instant disclosure. Such a communication device may be configured for transmitting information in response to a given impetus. More specifically, the instant disclosure contemplates that an access port contemplated by the instant disclosure may be exposed to a request signal (e.g., a sound, an impact or an acceleration, light, radio waves, etc.). Such a request signal may cause the communication device to transmit information therefrom via sound, light, radio waves, or as otherwise known in the art. Such information may be employed for identifying an access port contemplated by the instant disclosure.

In one exemplary example, it is contemplated that radio frequency identification technology may be employed for identification of an access port contemplated by the instant disclosure. Particularly, so-called active RFID tags are powered by an internal battery and are typically read/write devices. Currently, a suitable cell coupled to suitable low power circuitry can ensure functionality for as long as ten or more years, depending upon the operating temperatures and read/write cycles and usage. So-called passive RFID tags operate without a separate external power source and obtain operating power generated from the reader. Passive RFID tags are typically programmed with a unique set of data (usually 32 to 128 bits) that cannot be modified. Read-only tags may operate as an identifier comparable to linear barcodes which may contain selected product-specific information. Thus, passive RFID tags may be much lighter than active RFID tags, less expensive, and may offer a virtually unlimited operational lifetime. The tradeoff is that they have shorter read ranges than active tags and require a higher-powered reader.

One advantage of RFID approach is the noncontact, non-line-of-sight nature of the technology. Tags can be read through a variety of substances such as snow, fog, ice, paint, crusted grime, and other visually and environmentally challenging conditions, where other optically read technologies may be less effective. RFID tags can also be read in challenging circumstances at rapid speeds, in most cases responding in less than about 100 milliseconds.

While certain representative embodiments and details have been shown for purposes of illustrating aspects contemplated by 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 contemplated by 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 contemplated by the instant disclosure. In particular, FIGS. **25-51** illustrate a number of additional exemplary embodiments of access port **10**. As is apparent from these figures, access port **10** may be formed in any number of shapes and sizes, such that any number of modifications and changes are possible to any of the embodiments described and illustrated herein without departing from the spirit and scope of the instant disclosure.

What is claimed is:

1. An access port for providing subcutaneous access to a patient, comprising:

a body defining a fluid cavity accessible by inserting a needle through a septum; and

at least one radiopaque identification feature of the access port observable via imaging technology subsequent to subcutaneous implantation of the access port, the at least one radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power-injectable port.

2. The access port according to claim **1**, wherein the imaging technology includes x-ray imaging technology.

3. The access port according to claim **1**, wherein the radiopaque identification feature is defined on a bottom surface of the access port.

4. The access port according to claim **1**, wherein the radiopaque identification feature is defined as a recessed feature in the body of the access port.

5. The access port according to claim **1**, wherein the access port includes a metallic portion and the radiopaque identification feature is disposed on the metallic portion.

6. The access port according to claim **1**, wherein the at least radiopaque identification feature includes at least one of the following: a symbol, a pattern, a mark, or any combination thereof.

7. The access port according to claim **1**, wherein the at least one radiopaque identification feature includes at least one cavity extending inward from a bottom surface of the body.

8. The access port according to claim **1**, wherein the at least one radiopaque identification feature indicates an orientation of the access port when the access port is imaged by x-ray imaging technology.

9. The access port according to claim **1**, wherein the one or more alphanumeric characters includes the letters "C" and "T."

10. An access port for providing subcutaneous access to a patient, comprising:

a metallic body defining a fluid cavity; and

an radiopaque identification feature included on a bottom surface of the access port, the feature being an alphanumeric message observable via imaging technology subsequent to subcutaneous implantation of the access port, the alphanumeric message identifying the access port as a power-injectable port.

11. The access port according to claim **10**, wherein the alphanumeric message is recessed in the bottom surface of the access port.

12. The access port according to claim **10**, wherein the alphanumeric message is disposed below the port fluid cavity.

13. The access port according to claim **10**, wherein the alphanumeric message is proximate a periphery of the bottom surface of the access port.

14. The access port according to claim **10**, wherein the body includes titanium and includes a base, the base defining at least a portion of the bottom surface of the access port.

15. The access port according to claim **10**, wherein the alphanumeric message is disposed on an inside bottom surface of the fluid cavity.

16. An access port for providing subcutaneous access to a patient, comprising:

a body including a metallic material and defining a fluid cavity, the fluid cavity covered by a septum; and

at least one recessed identification feature defined by the body, observable via x-ray imaging technology subsequent to subcutaneous implantation of the access port, the at least one identification feature identifying the access port as a power-injectable access port.

17. The access port according to claim **16**, wherein the at least one recessed identification feature is included on an inside surface of the fluid cavity.

18. The access port according to claim **16**, wherein the at least one recessed identification feature includes an engraved feature and is relatively more x-ray transmissive with respect to other portions of the access port body.

19. The access port according to claim **16**, wherein the at least one recessed identification feature includes one or more alphanumeric characters.

20. The access port according to claim **19**, wherein the one or more alphanumeric characters includes the letters "C" and "T."

* * * * *

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(54) **ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS**

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A61M 37/00 (2006.01)

(52) **U.S. Cl.** **604/288.02**

(58) **Field of Classification Search** 604/288.01, 604/288.02

See application file for complete search history.

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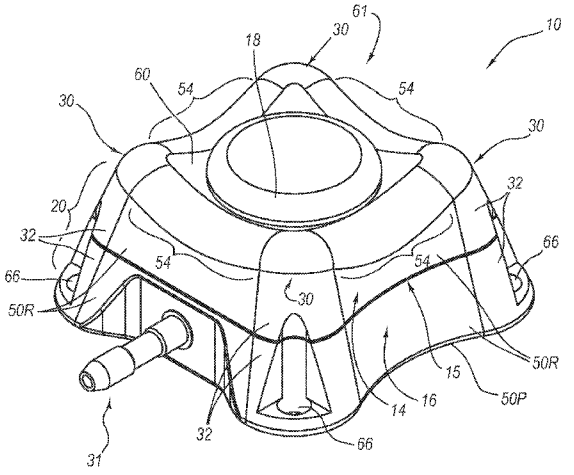
(57) **ABSTRACT**

An access port for subcutaneous implantation is disclosed. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, the access port may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation. Methods of identifying a subcutaneously implanted access port are also disclosed. For example, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted access port may be identified in response to perceiving the at least one feature.

11 Claims, 30 Drawing Sheets



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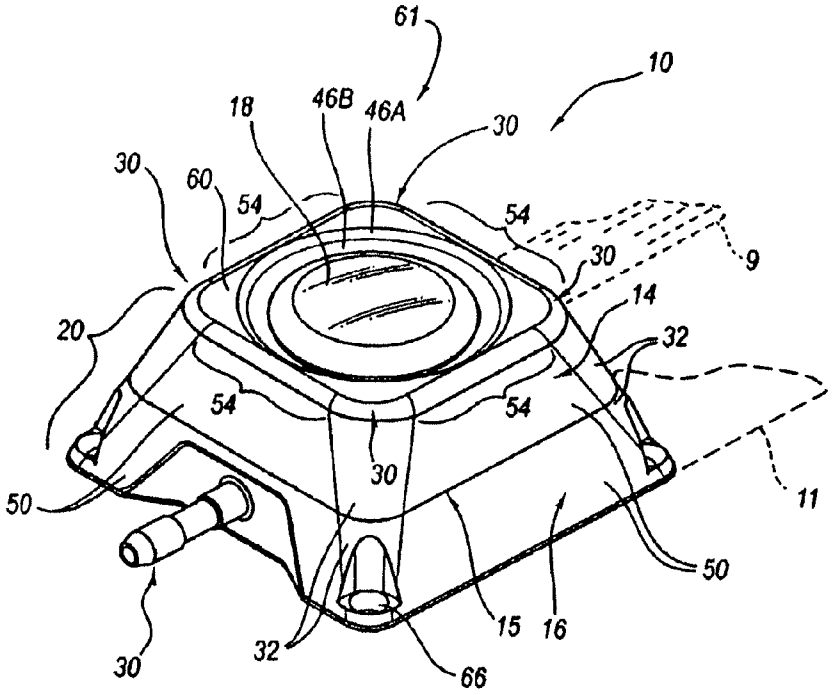
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FIG. 1A

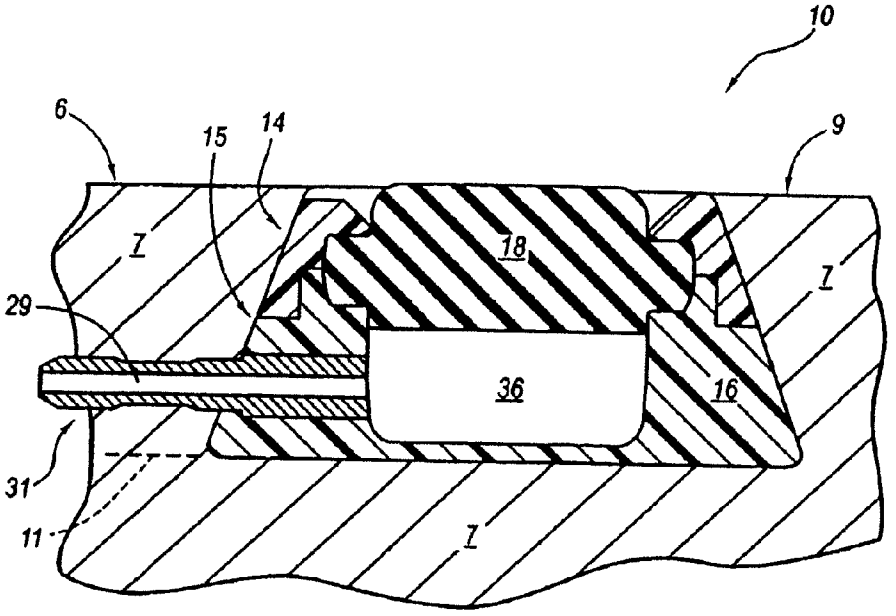
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FIG. 1B

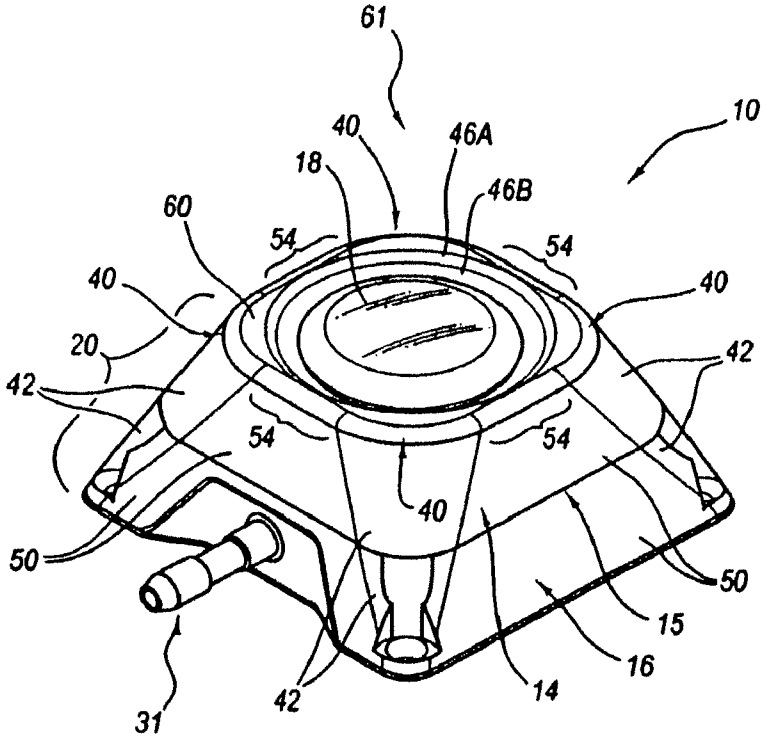
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FIG. 2

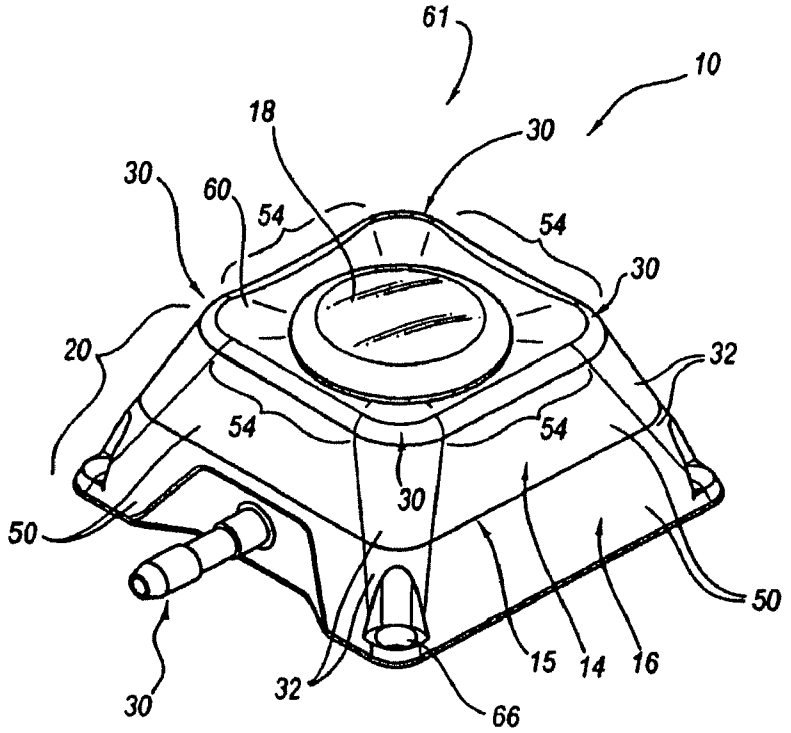
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FIG. 3

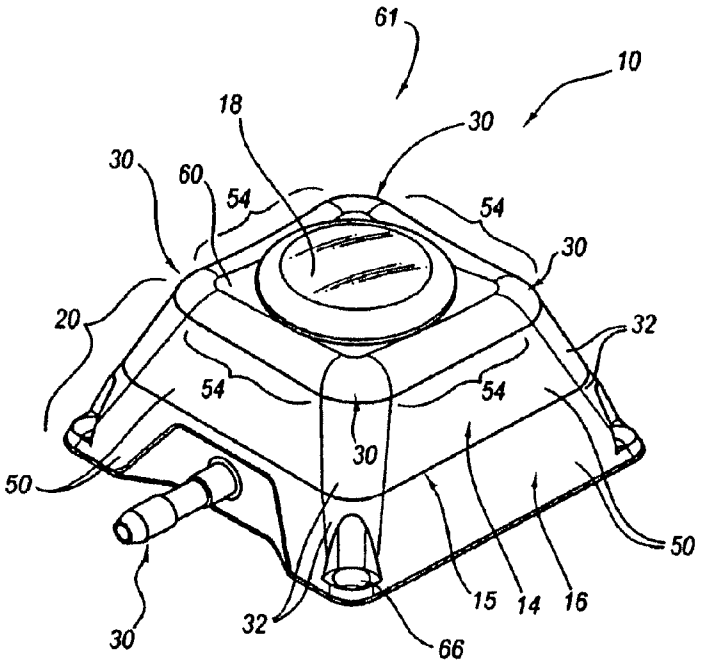
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FIG. 4

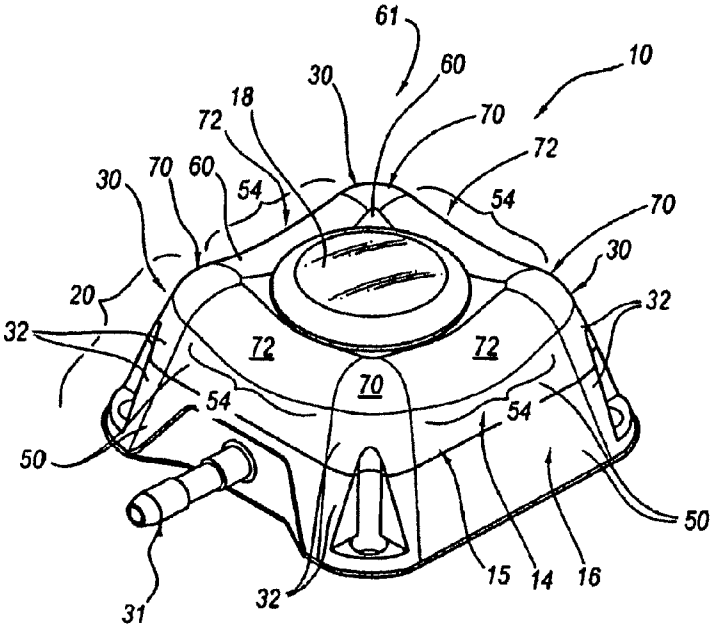
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FIG. 5

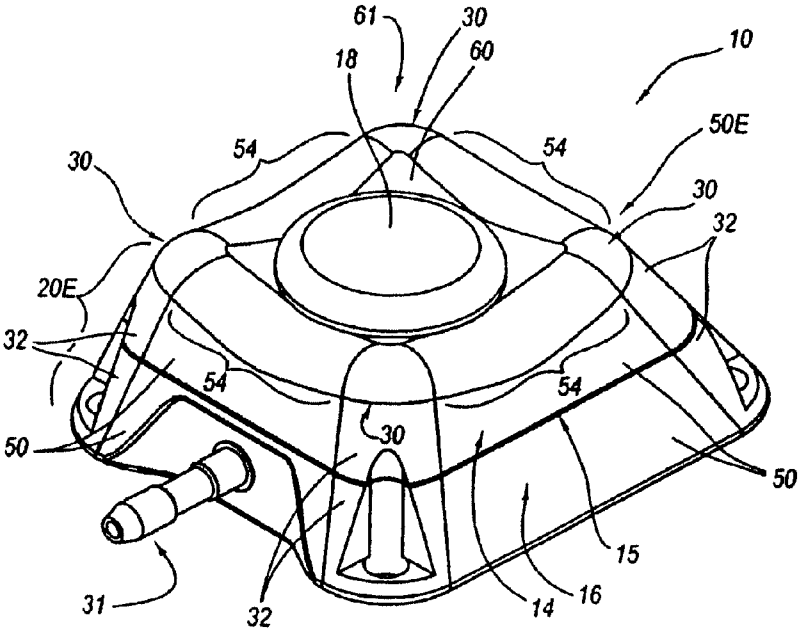
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FIG. 6A

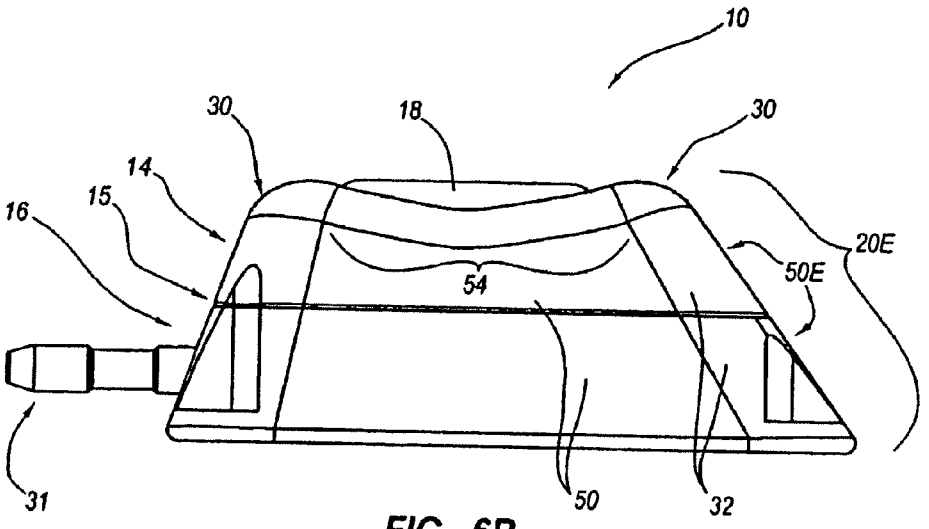
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FIG. 6B

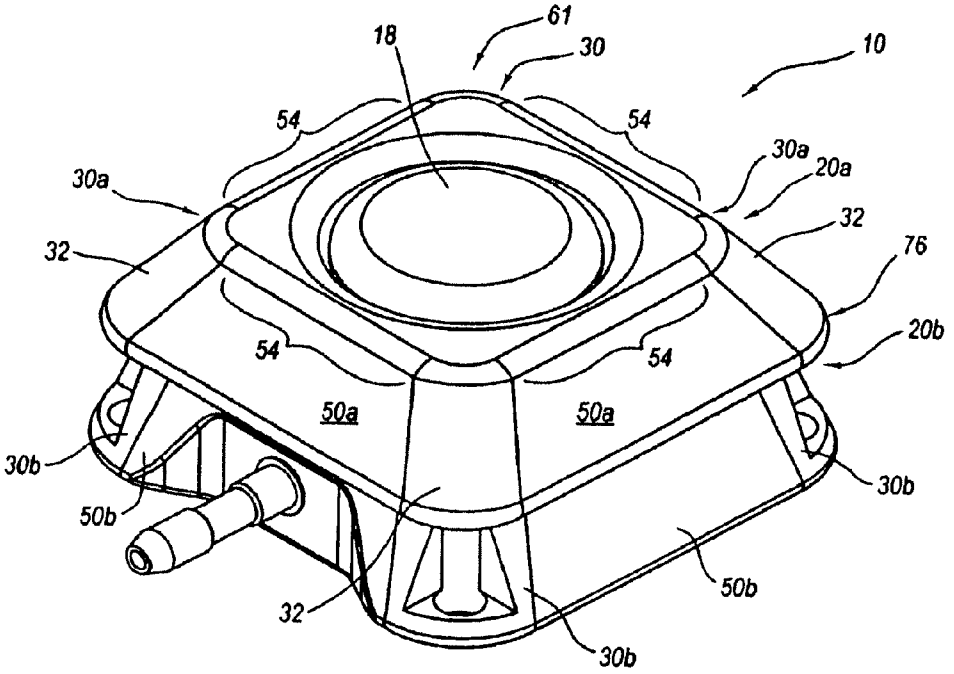
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FIG. 7

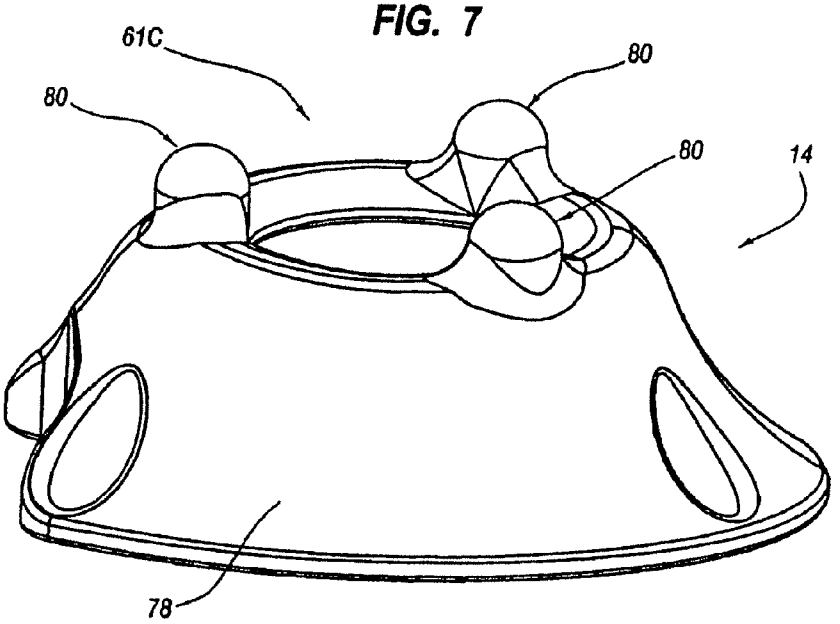
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FIG. 8

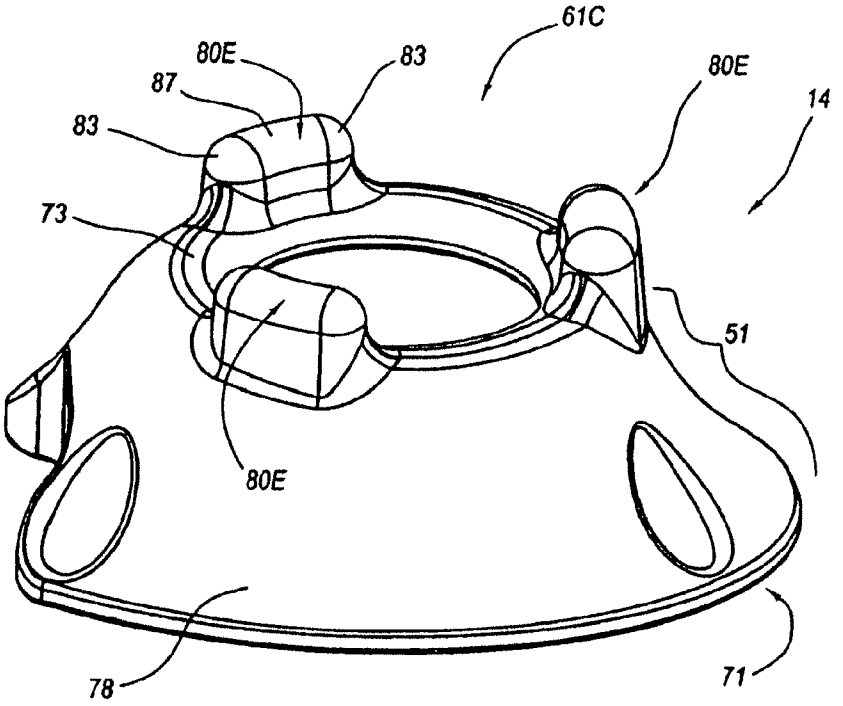
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FIG. 9

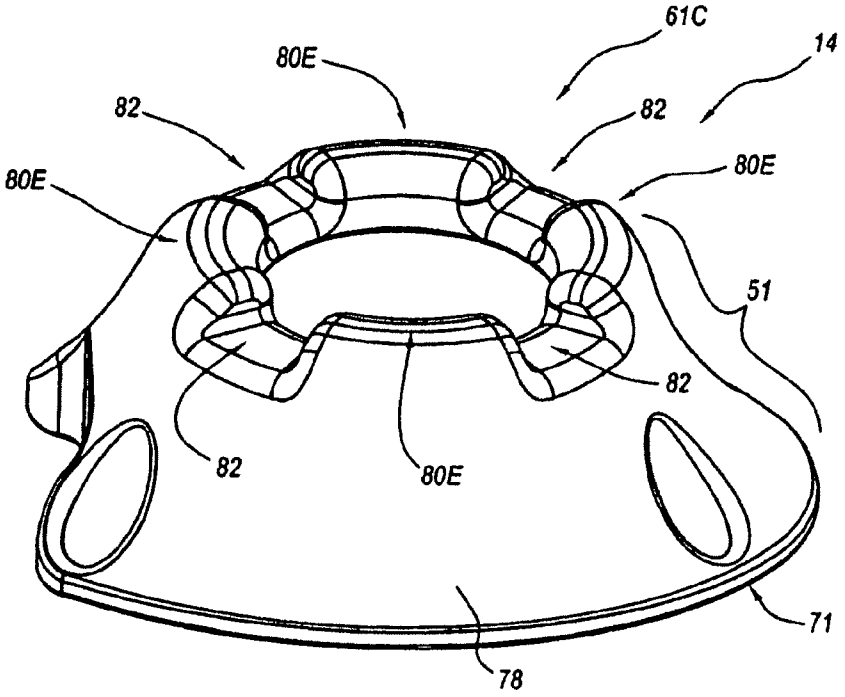
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FIG. 10

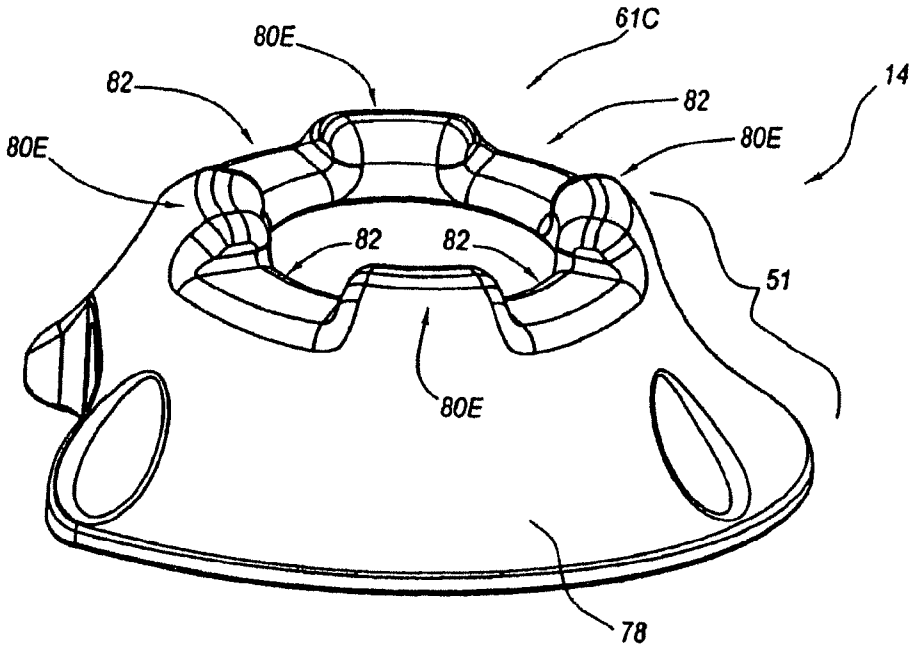

FIG. 11

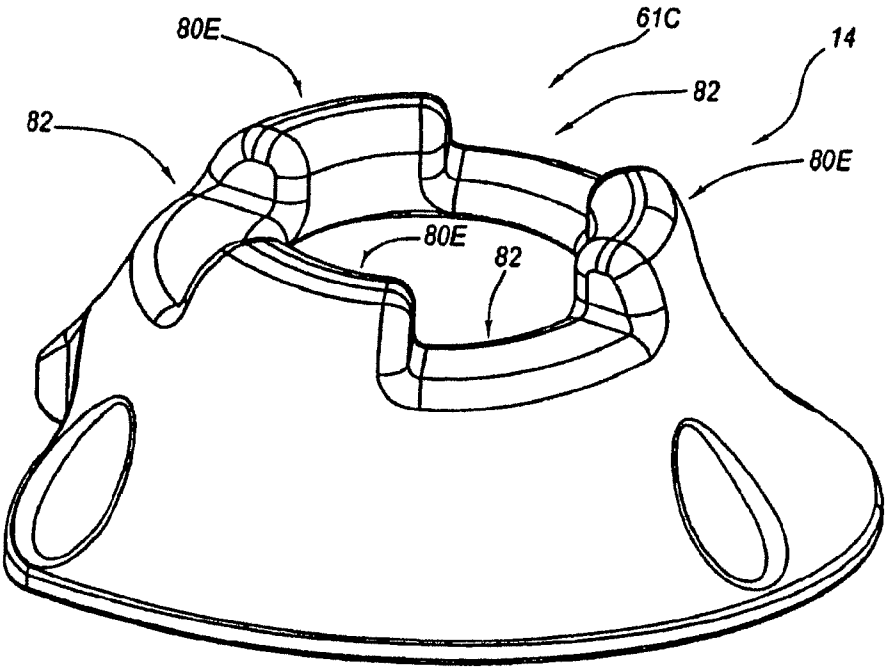

FIG. 12

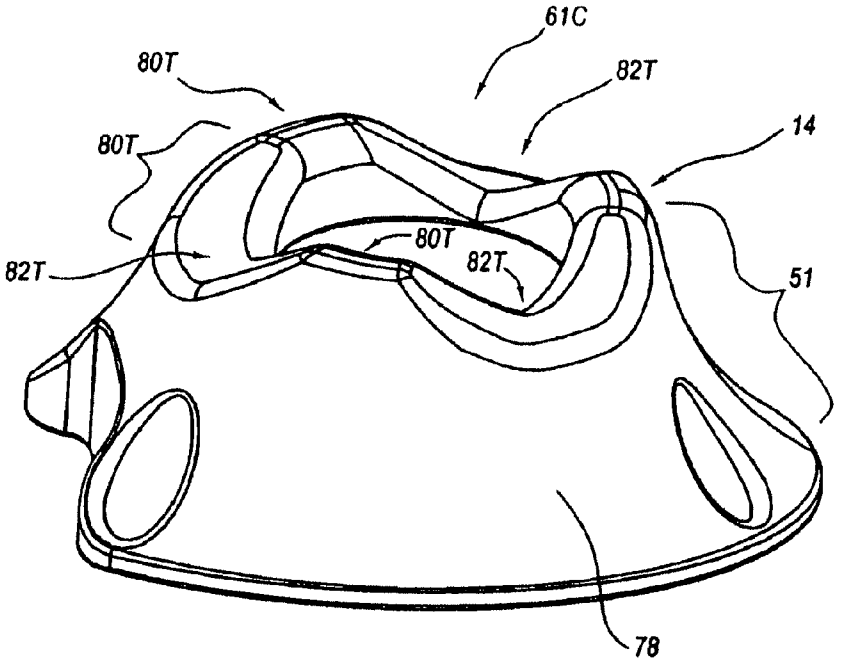

FIG. 13

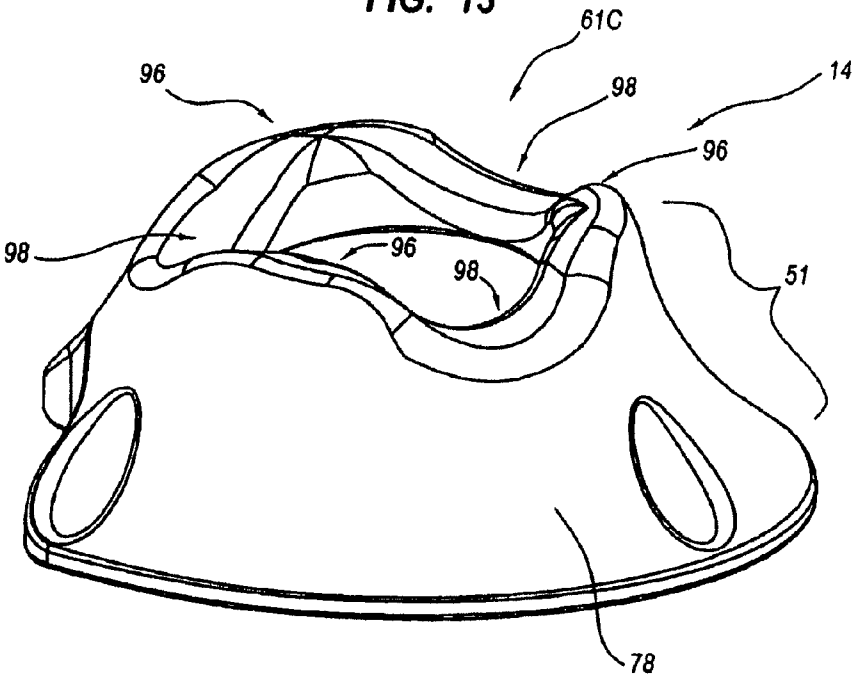

FIG. 14

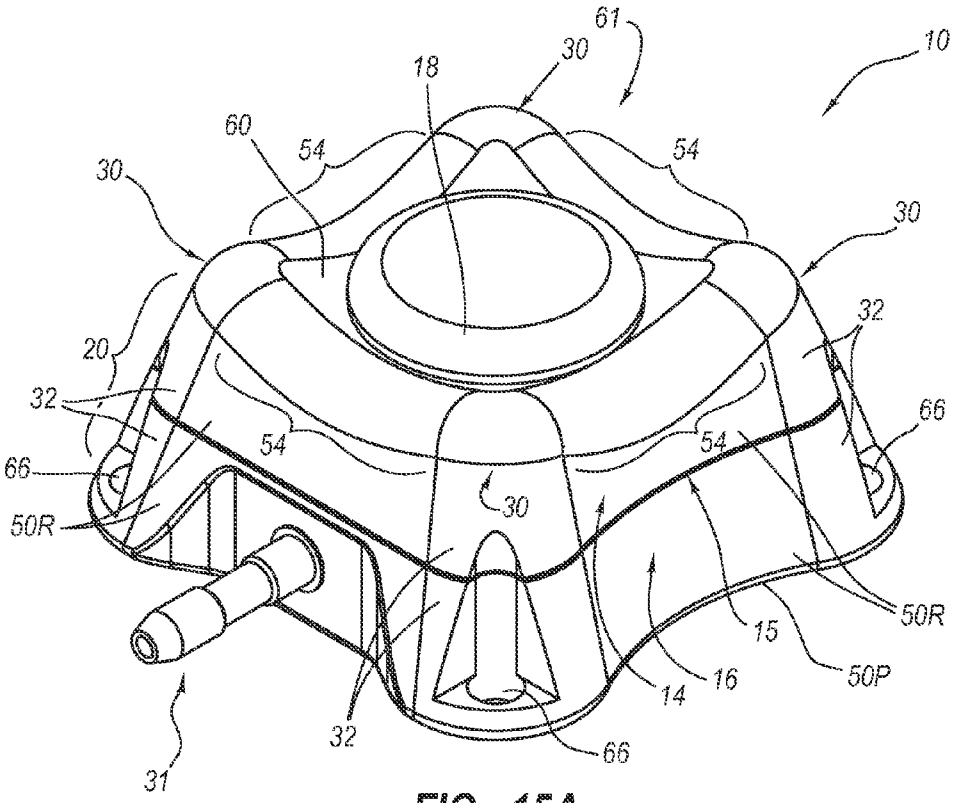

FIG. 15A

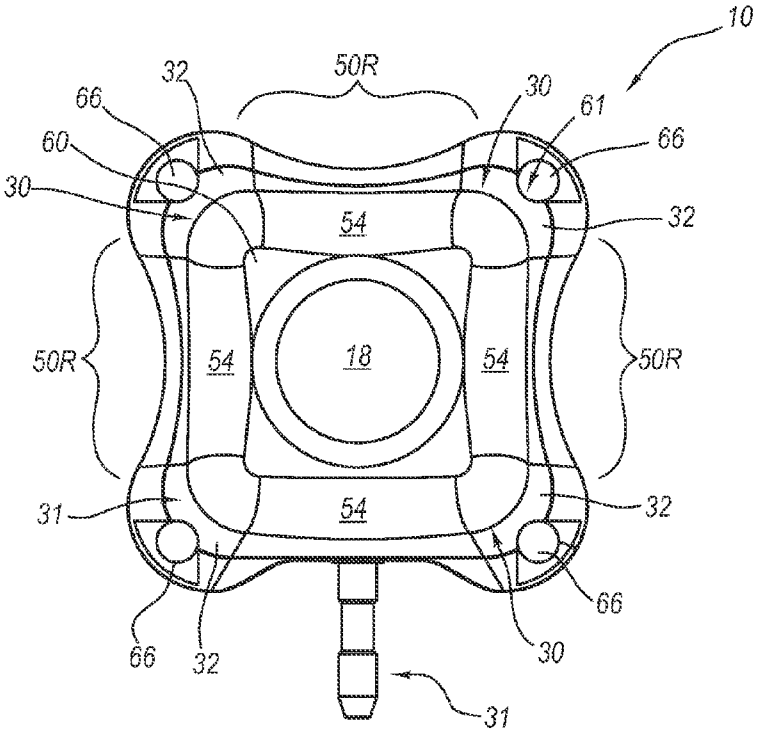

FIG. 15B

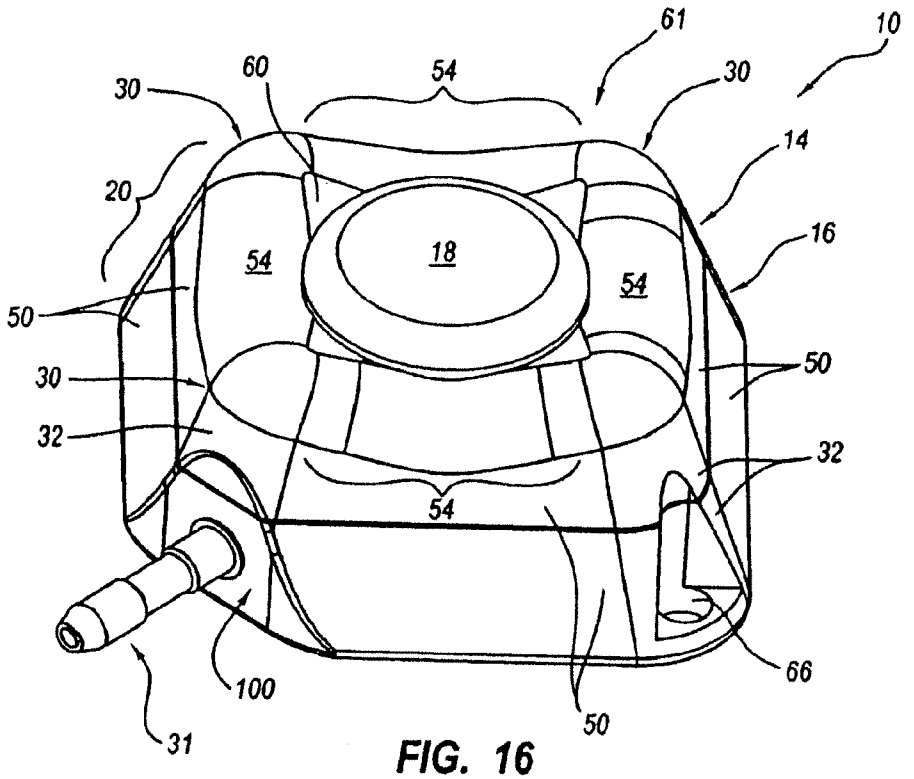
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FIG. 16

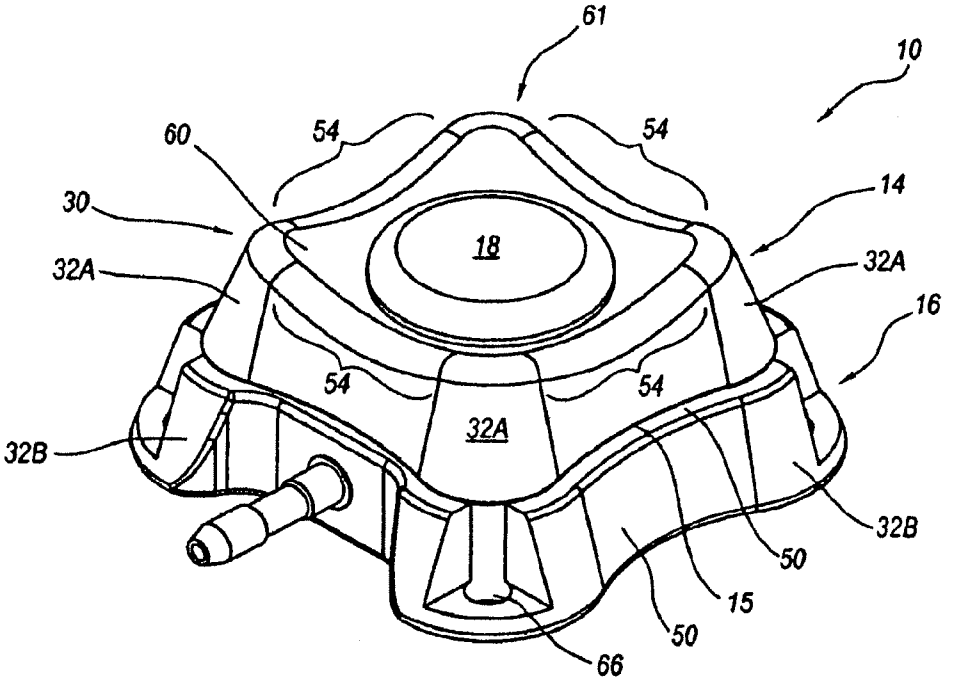
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FIG. 17

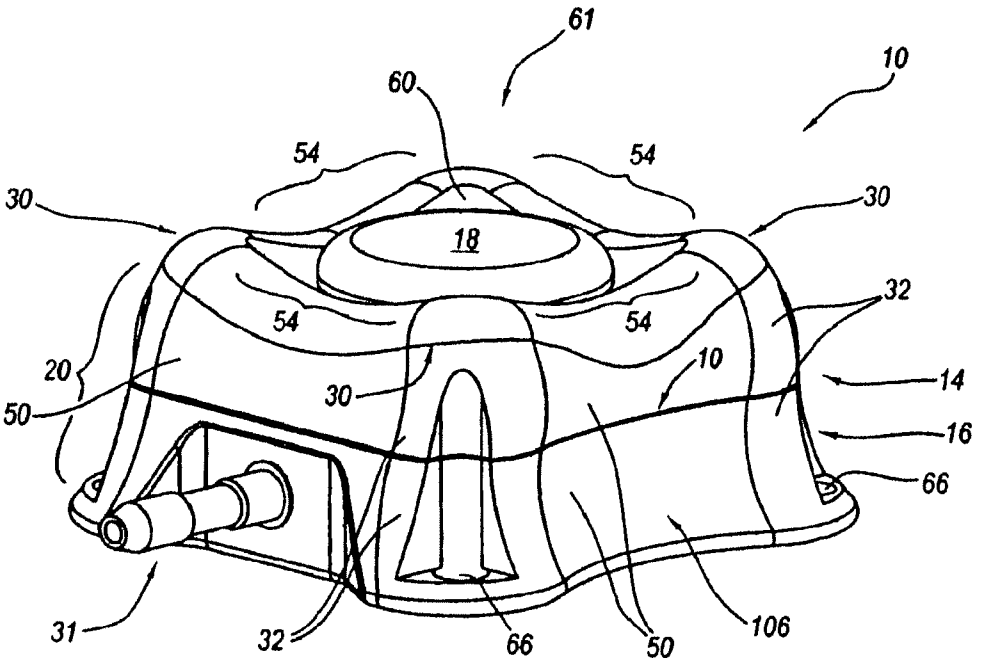
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FIG. 18

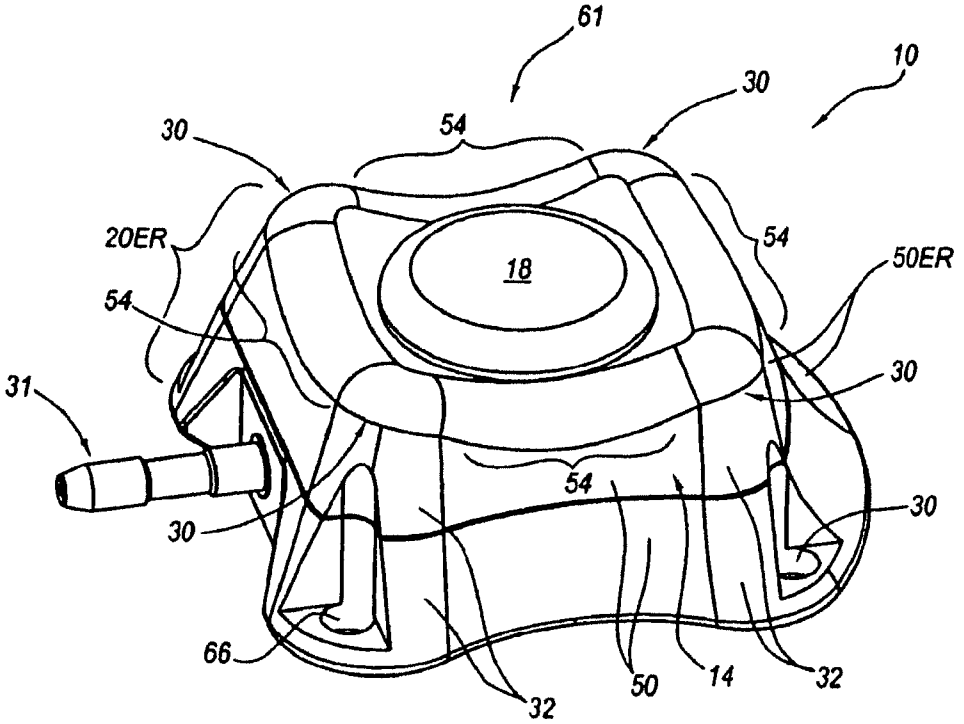
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FIG. 19

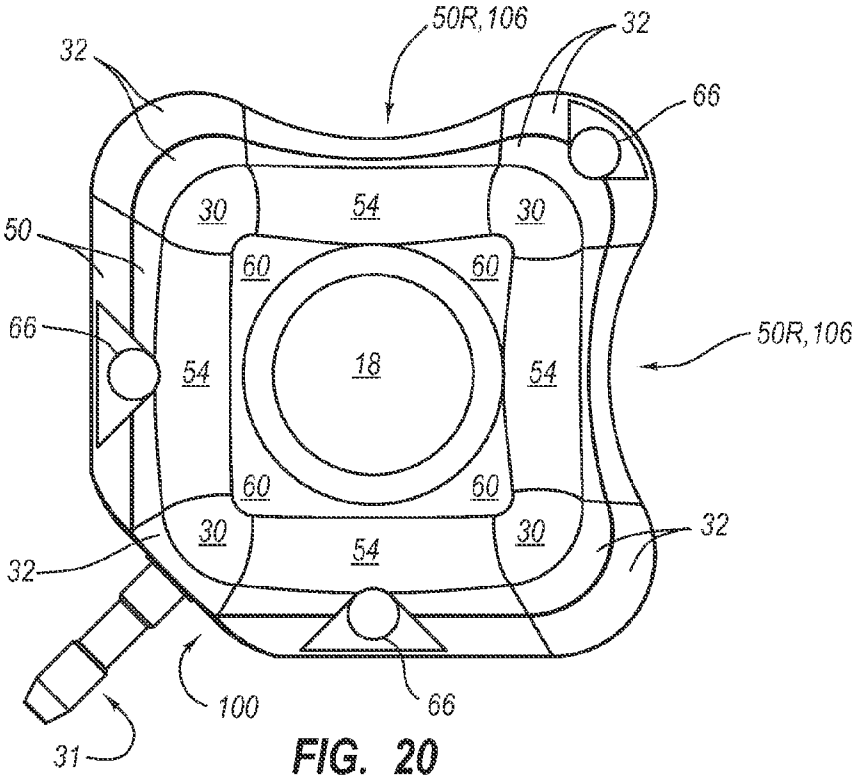
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FIG. 20

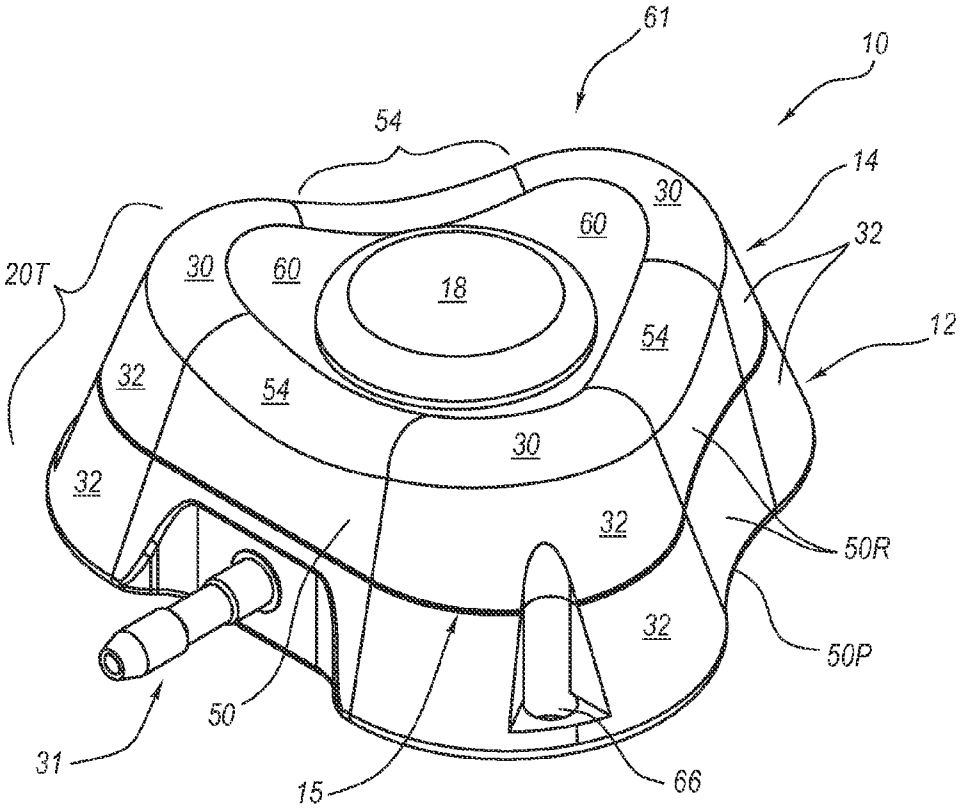
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FIG. 21

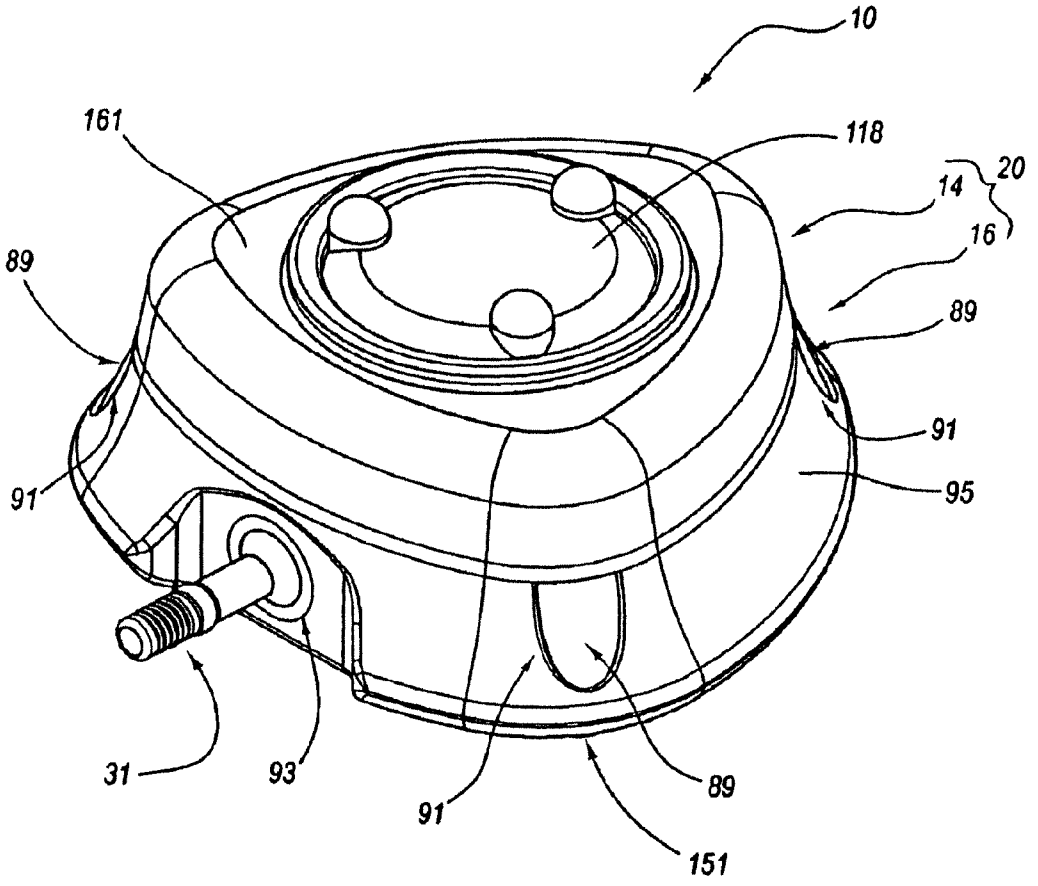
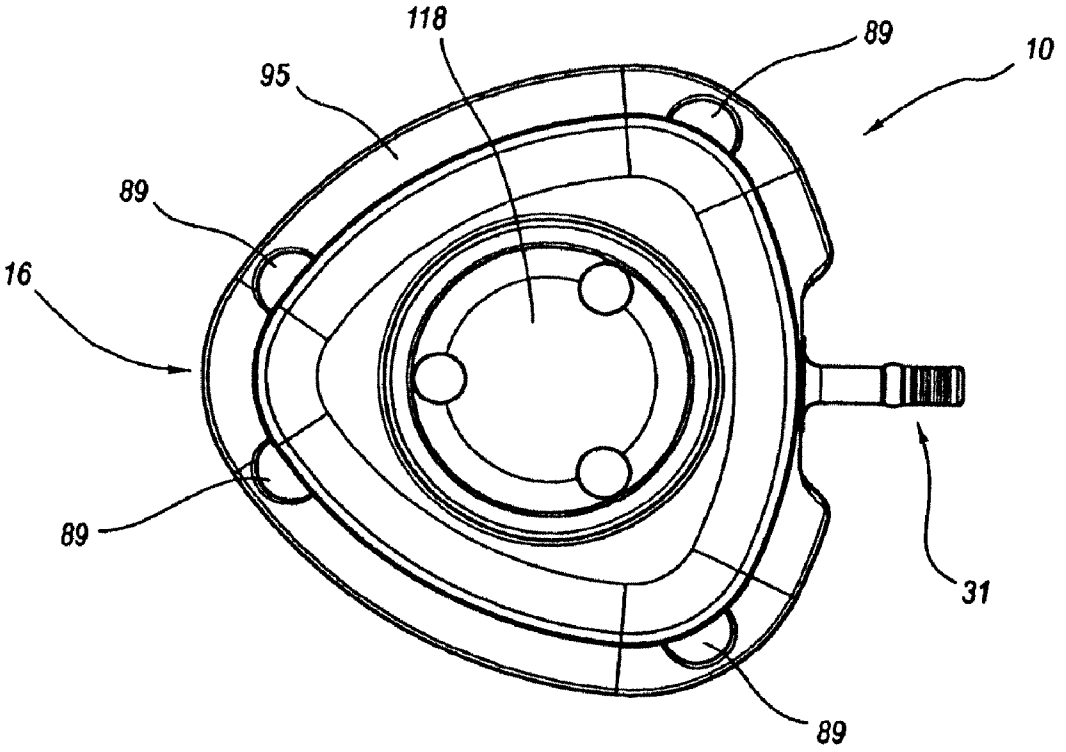


FIG. 22



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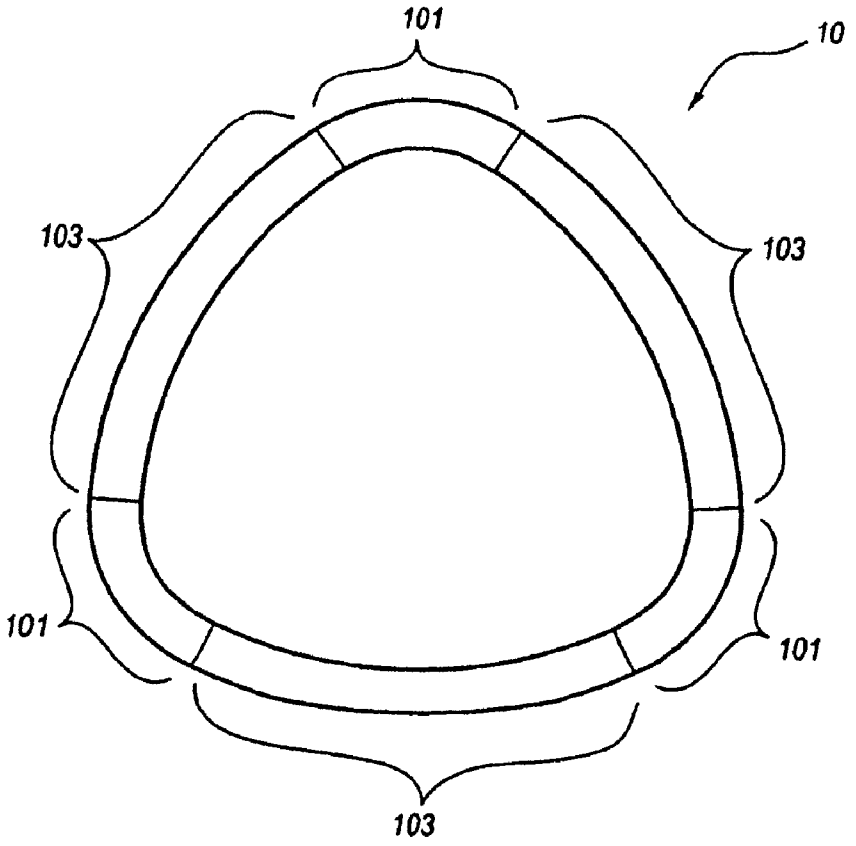

FIG. 24

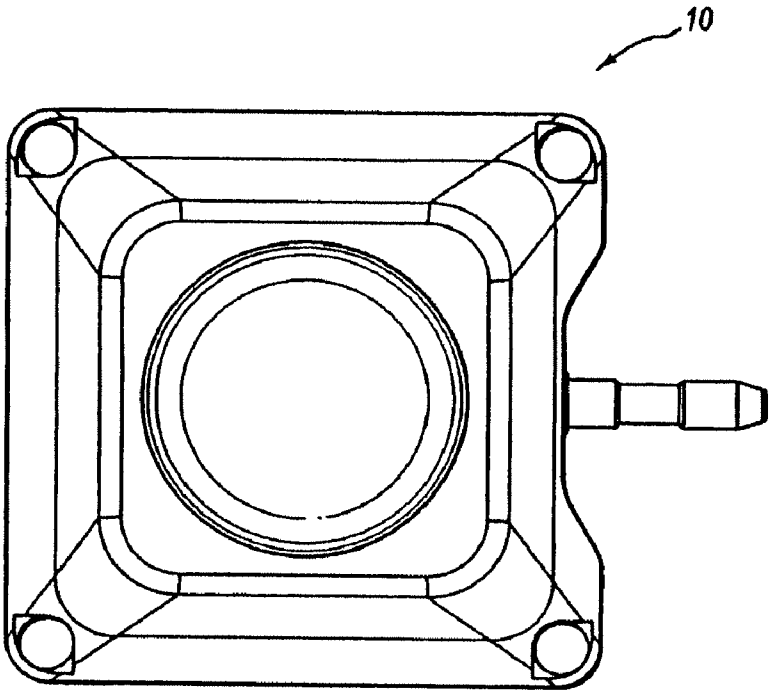

FIG. 25

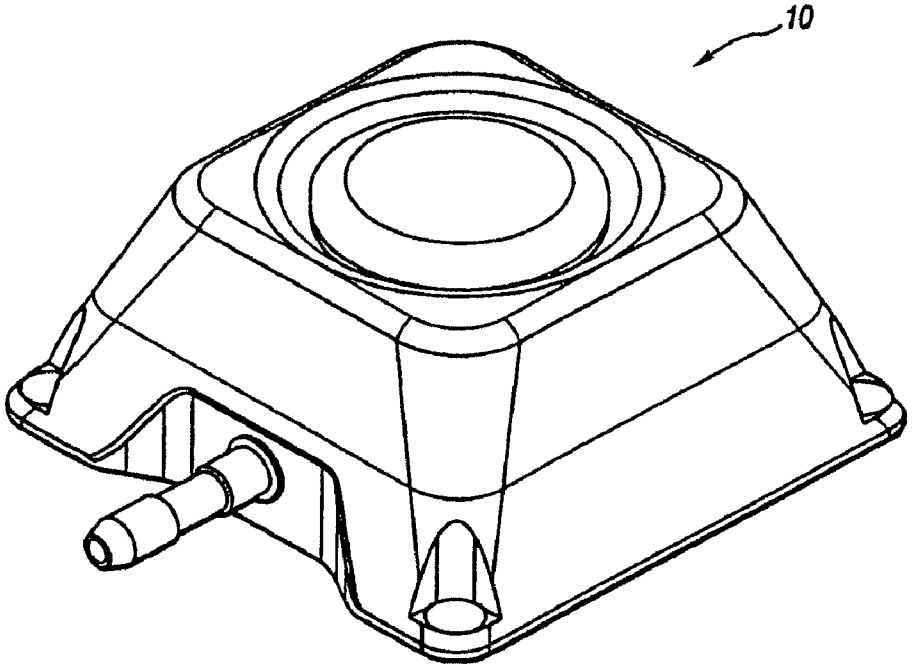

FIG. 26

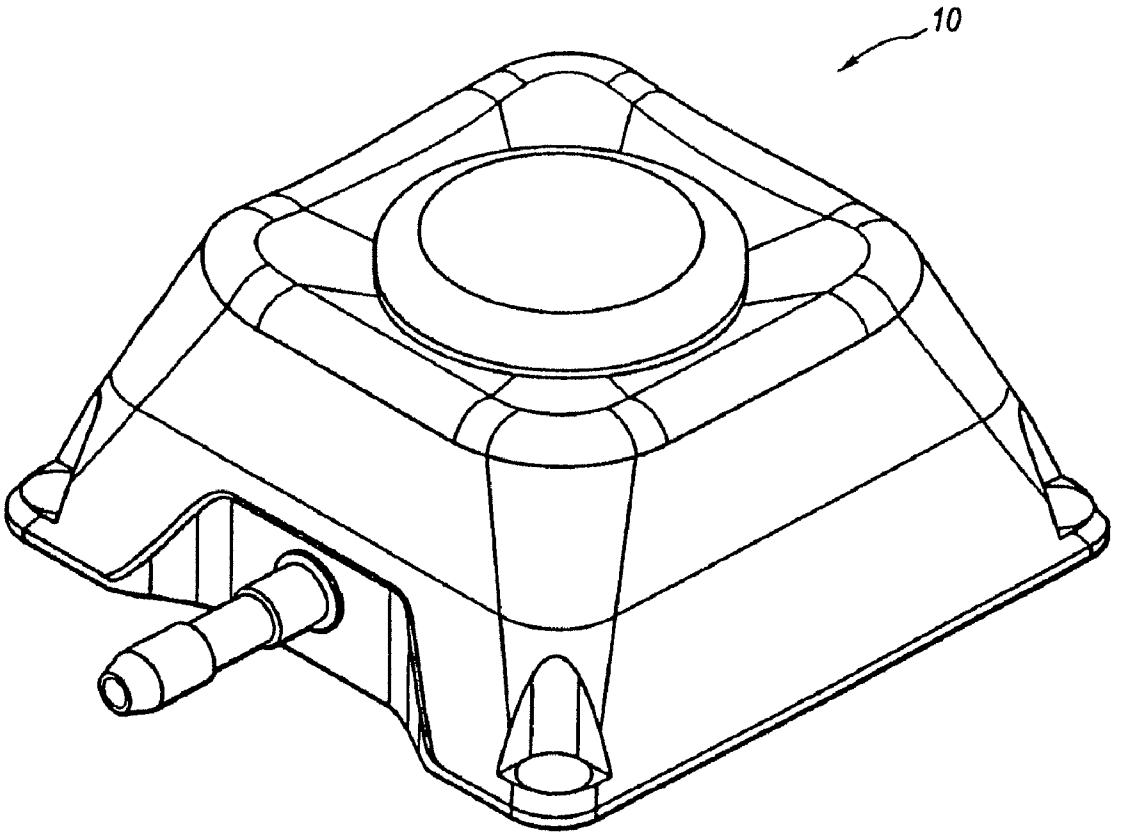

FIG. 27

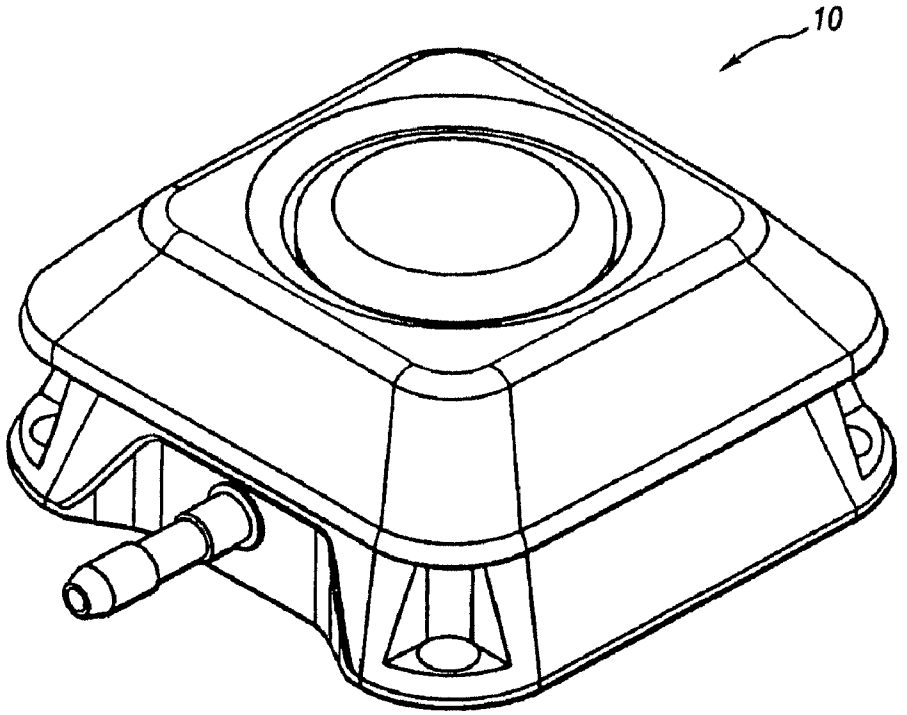

FIG. 28

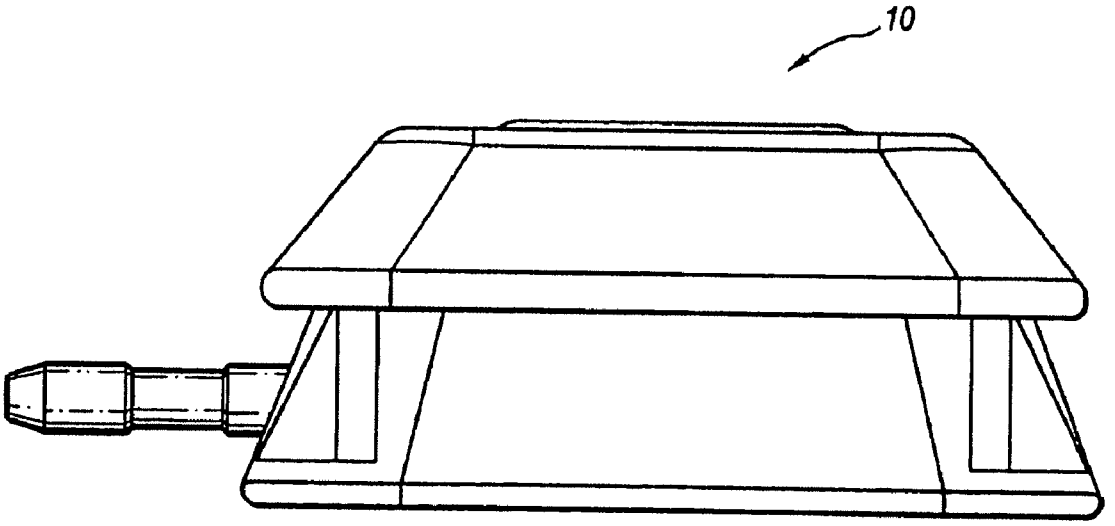

FIG. 29

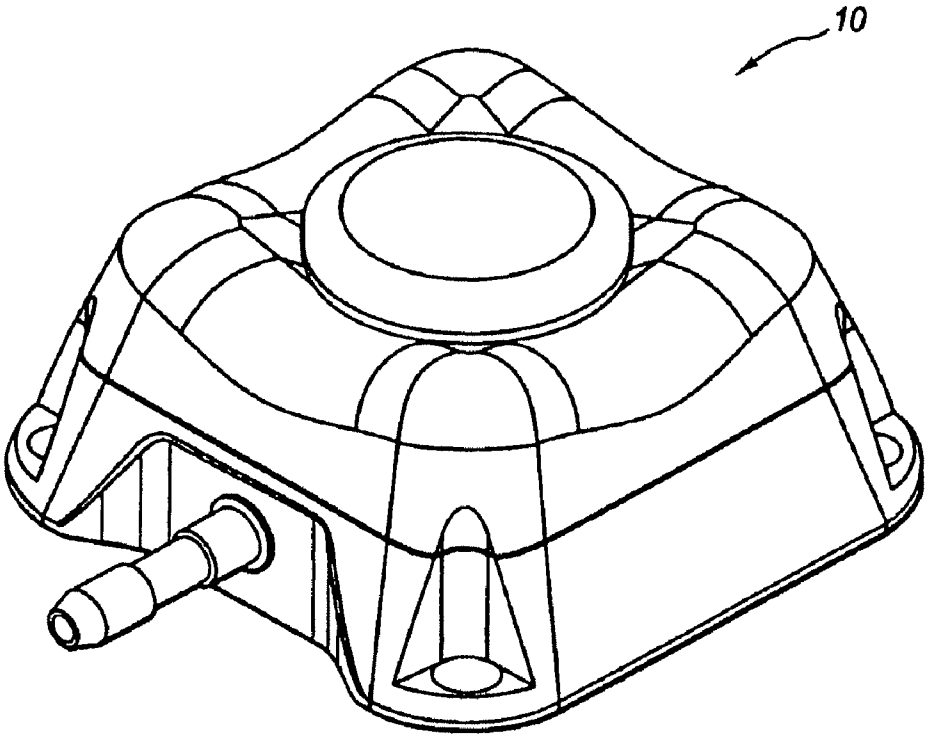

FIG. 30

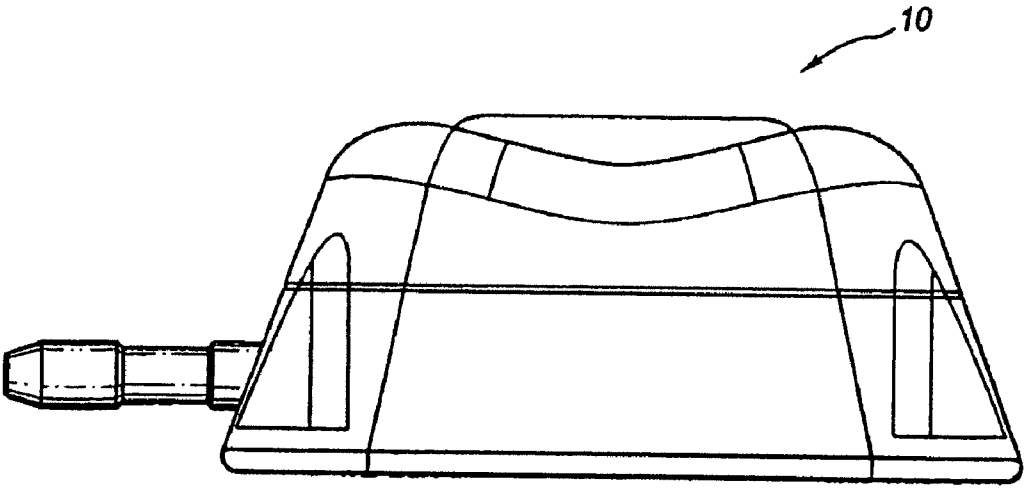

FIG. 31

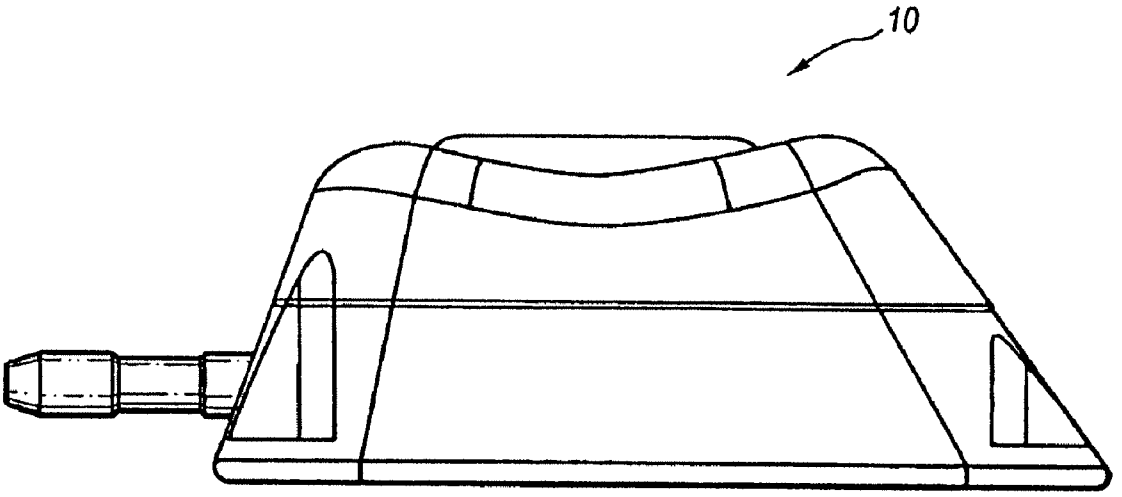

FIG. 32

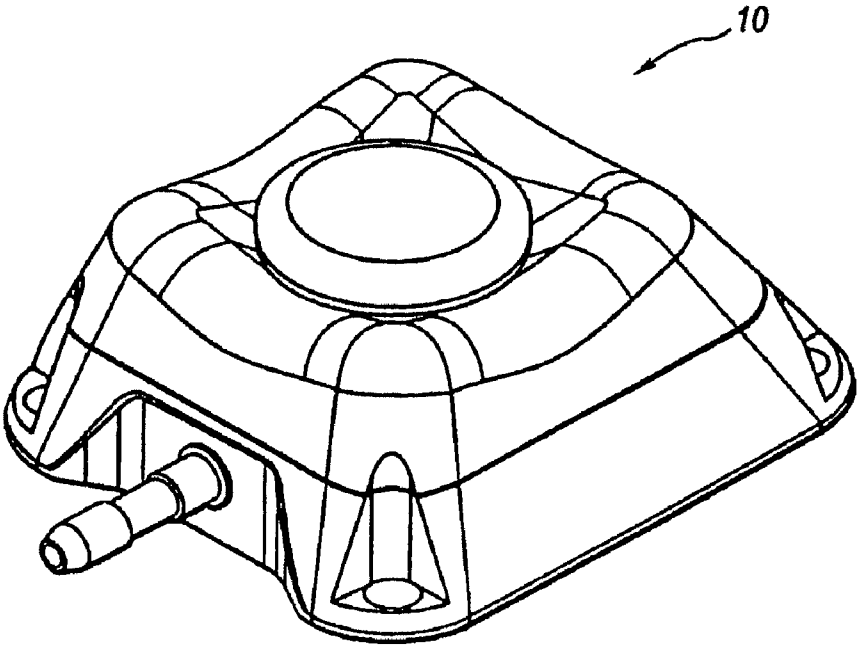

FIG. 33

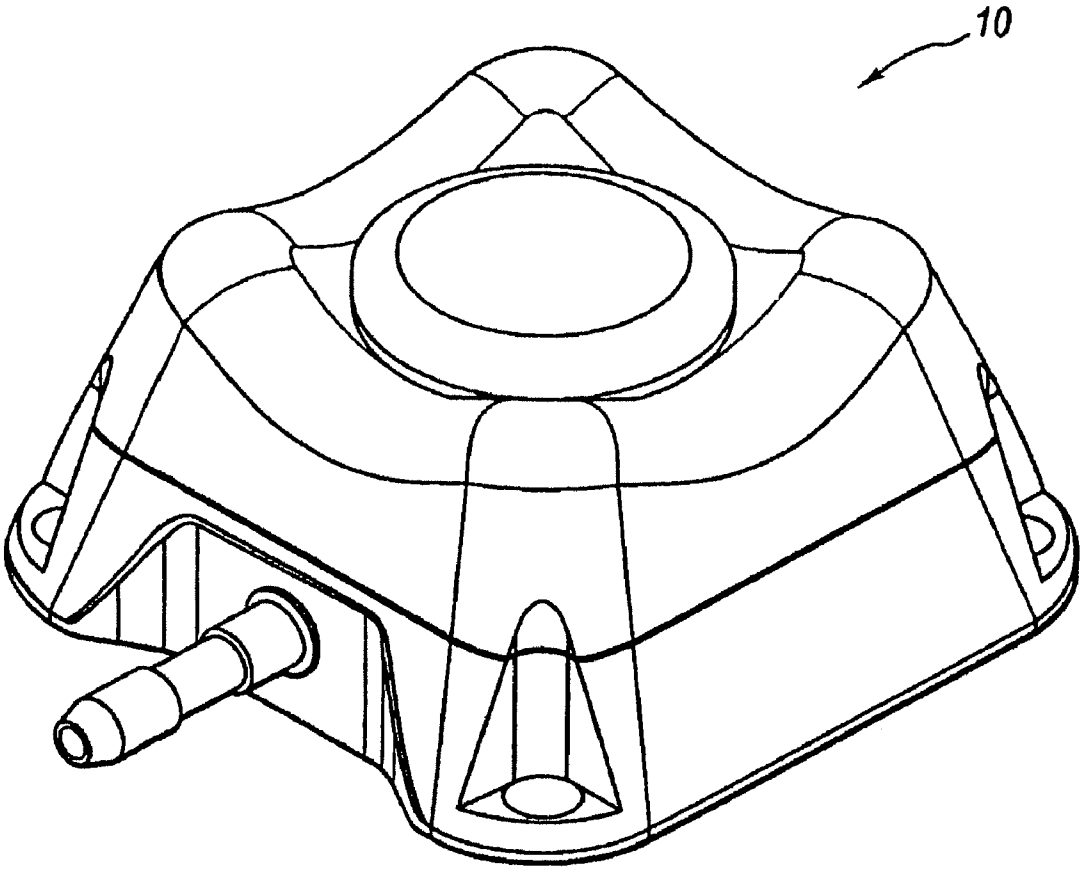

FIG. 34

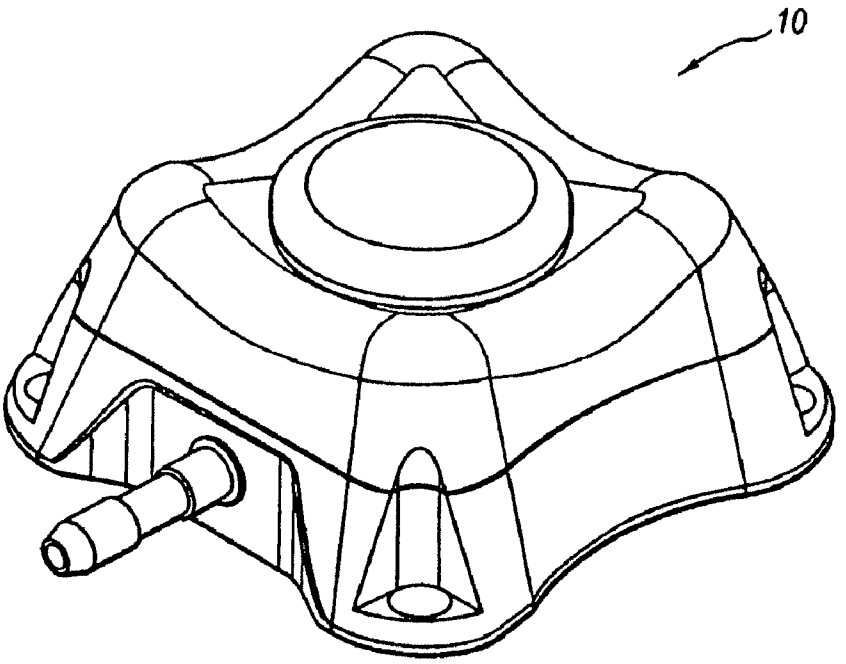

FIG. 35

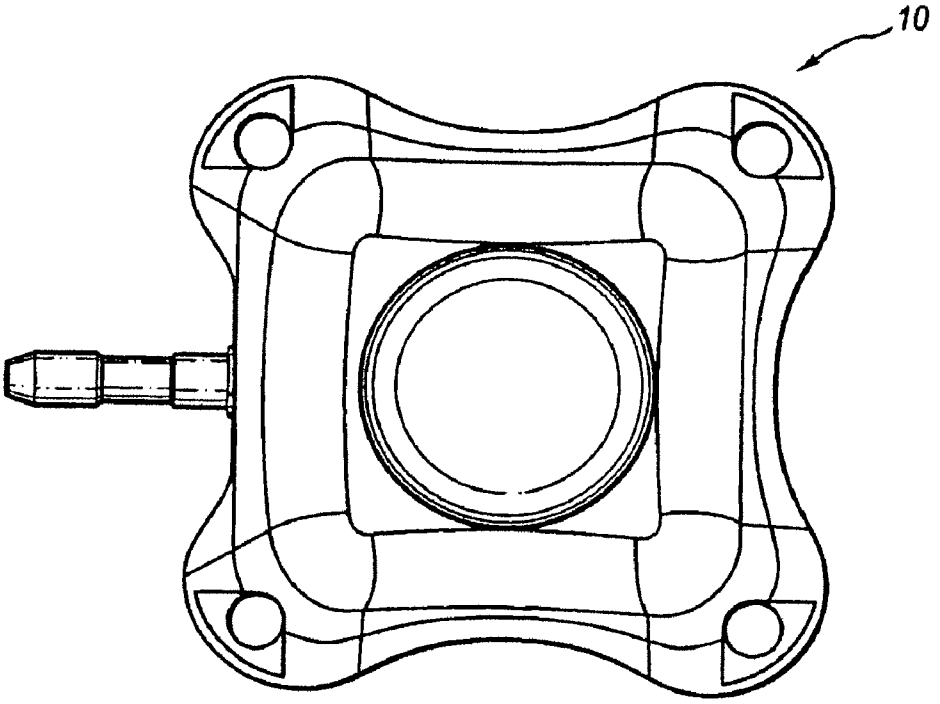

FIG. 36

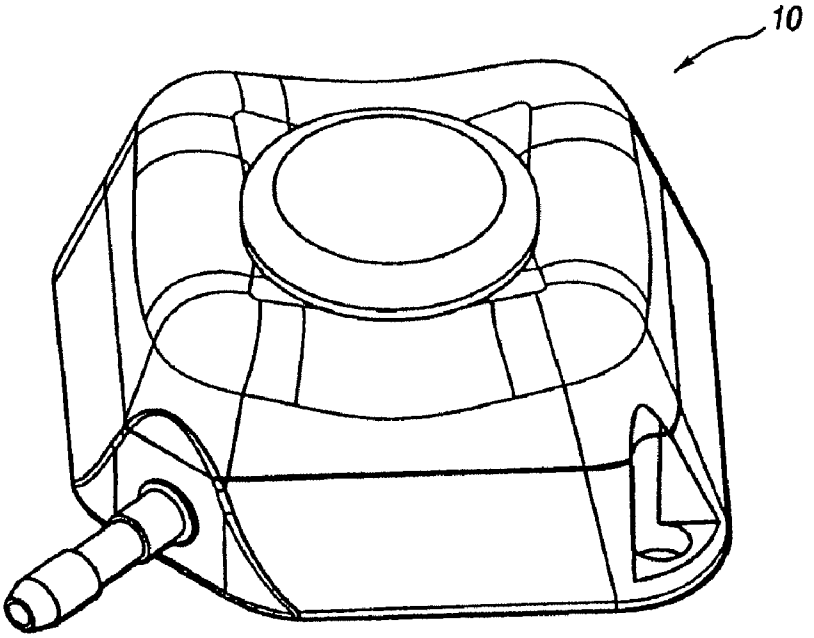

FIG. 37

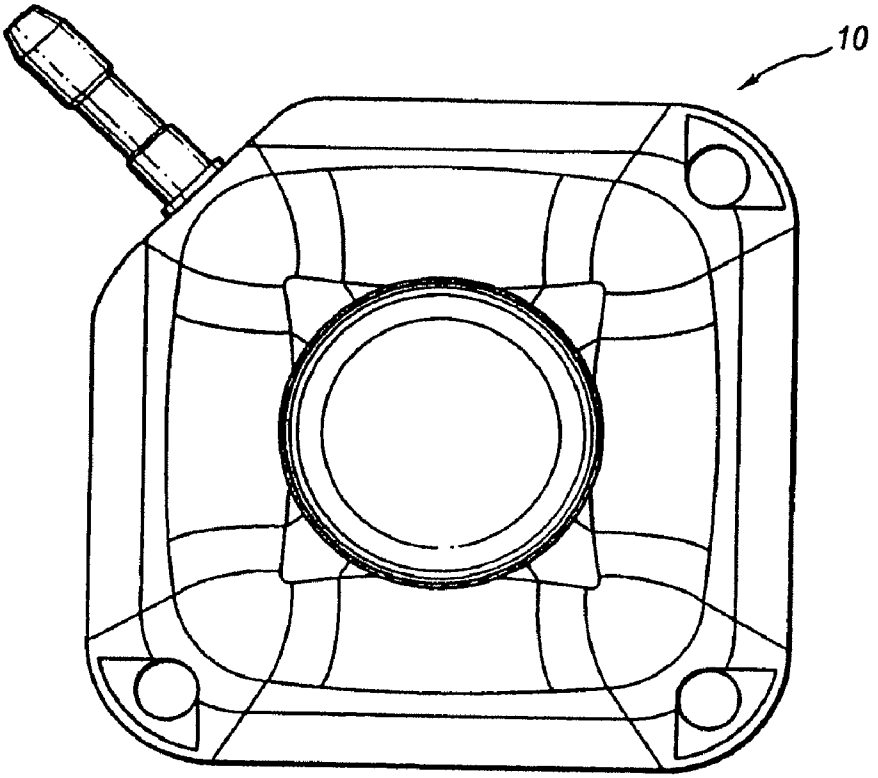

FIG. 38

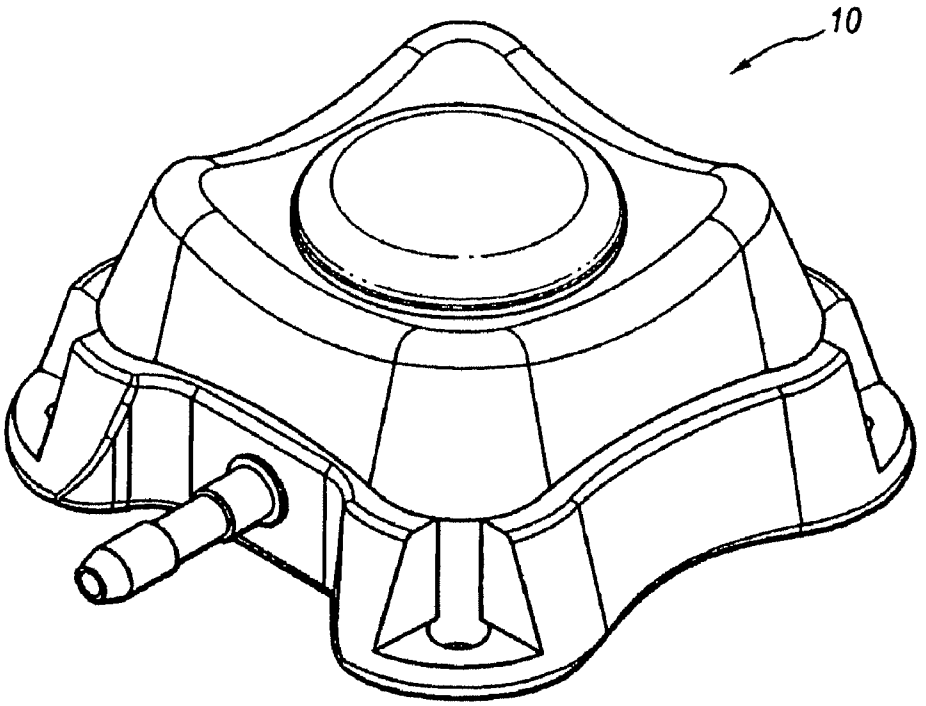

FIG. 39

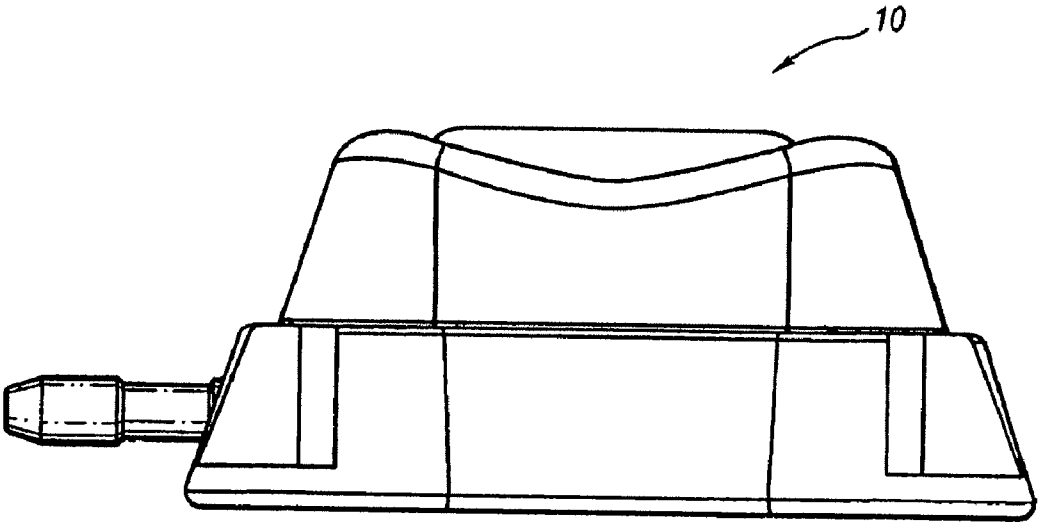

FIG. 40

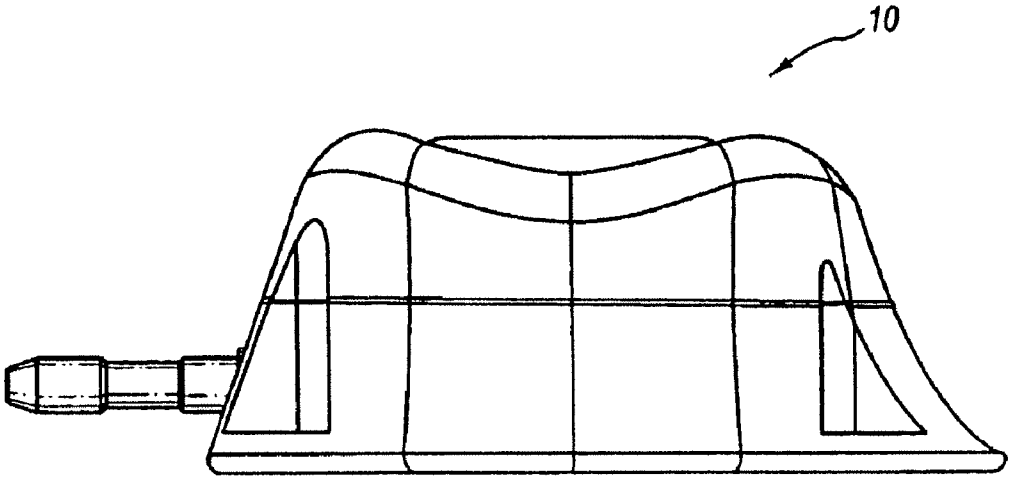

FIG. 41

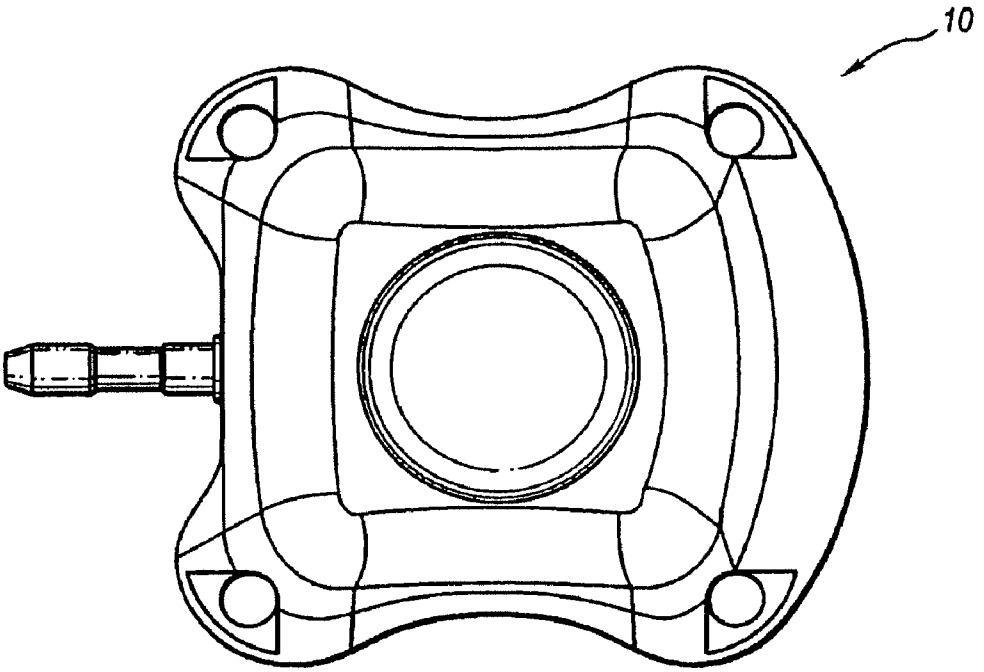

FIG. 42

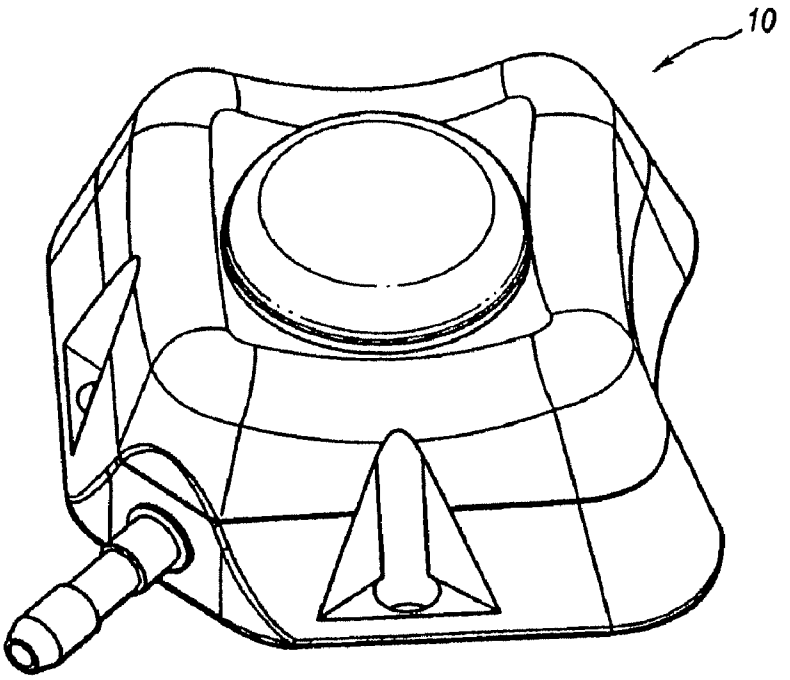

FIG. 43

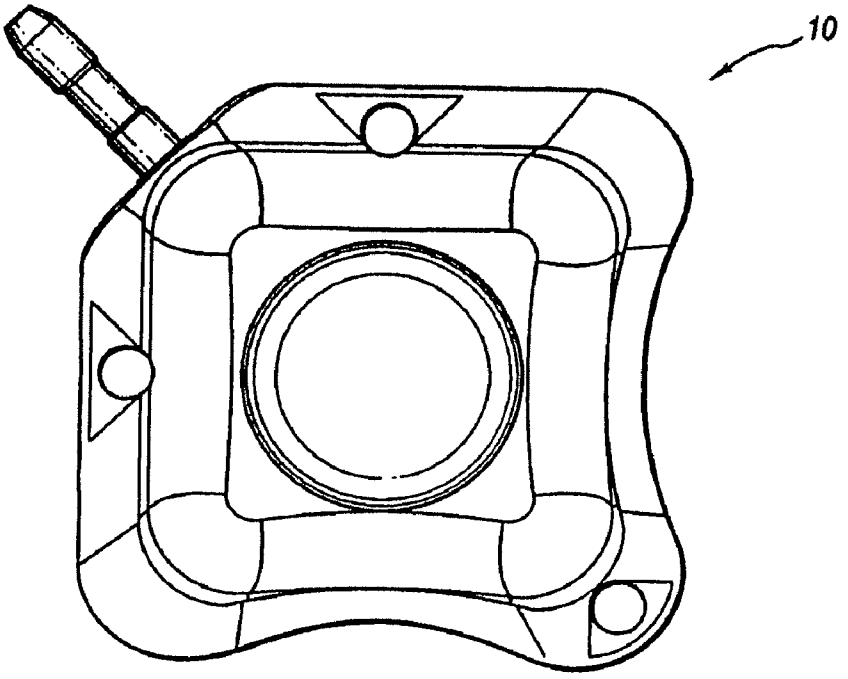

FIG. 44

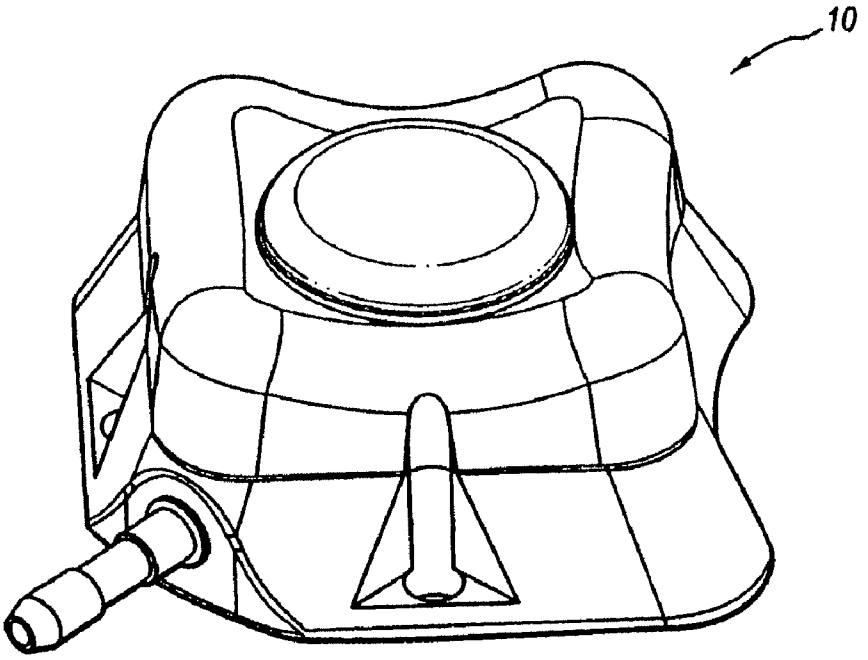

FIG. 45

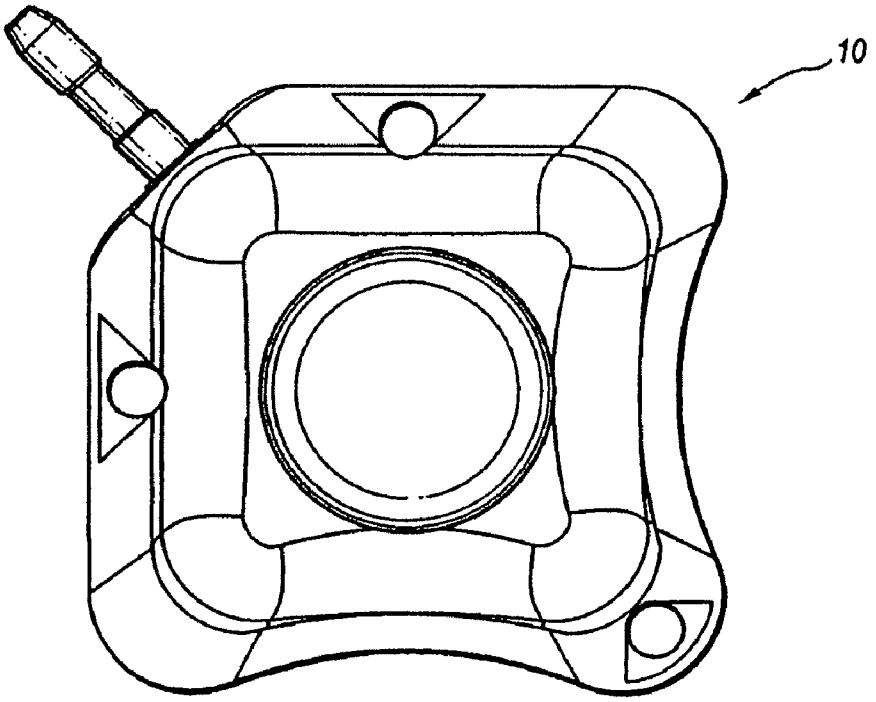

FIG. 46

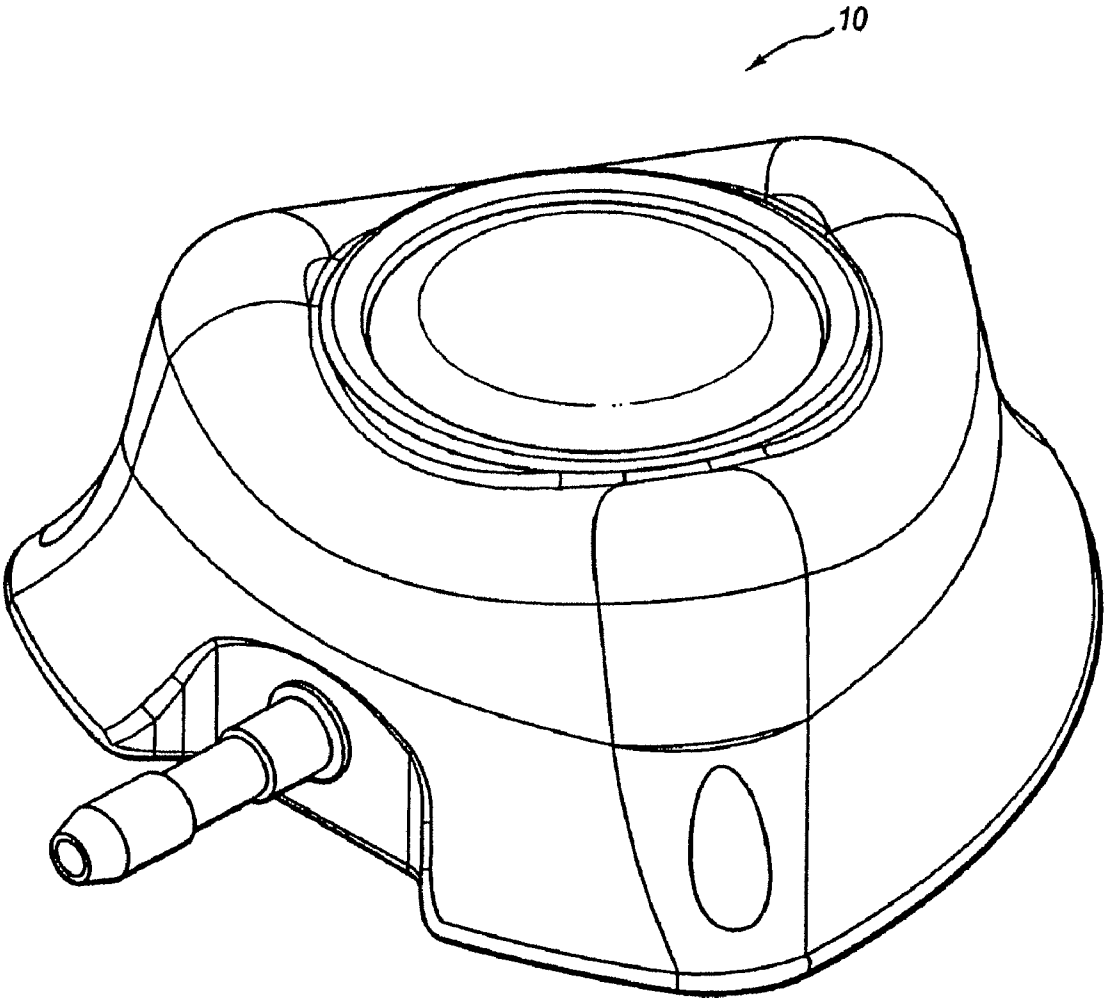

FIG. 47

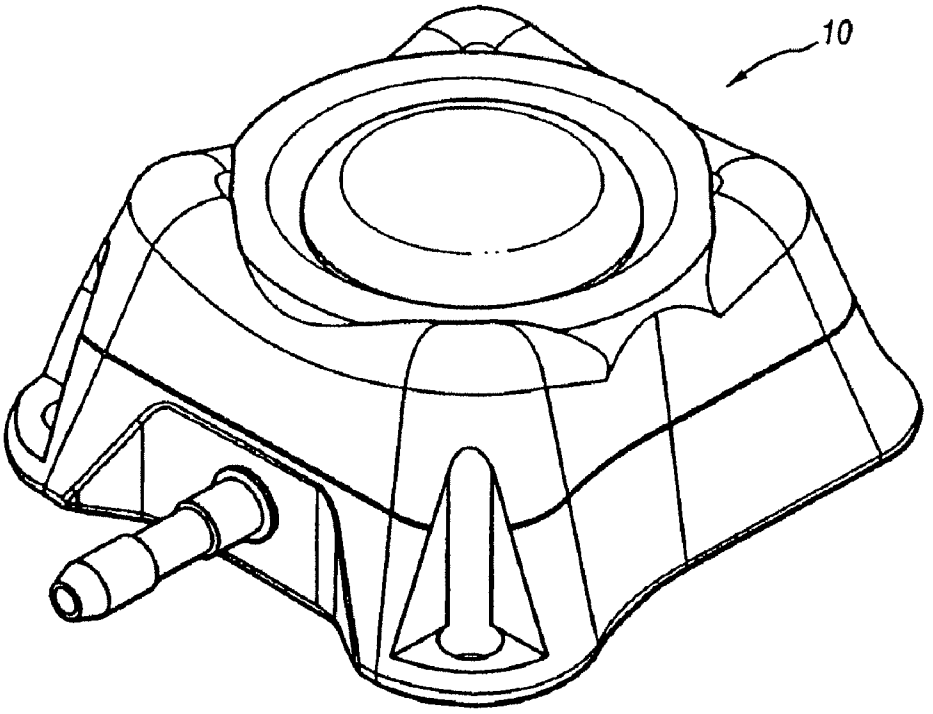

FIG. 48

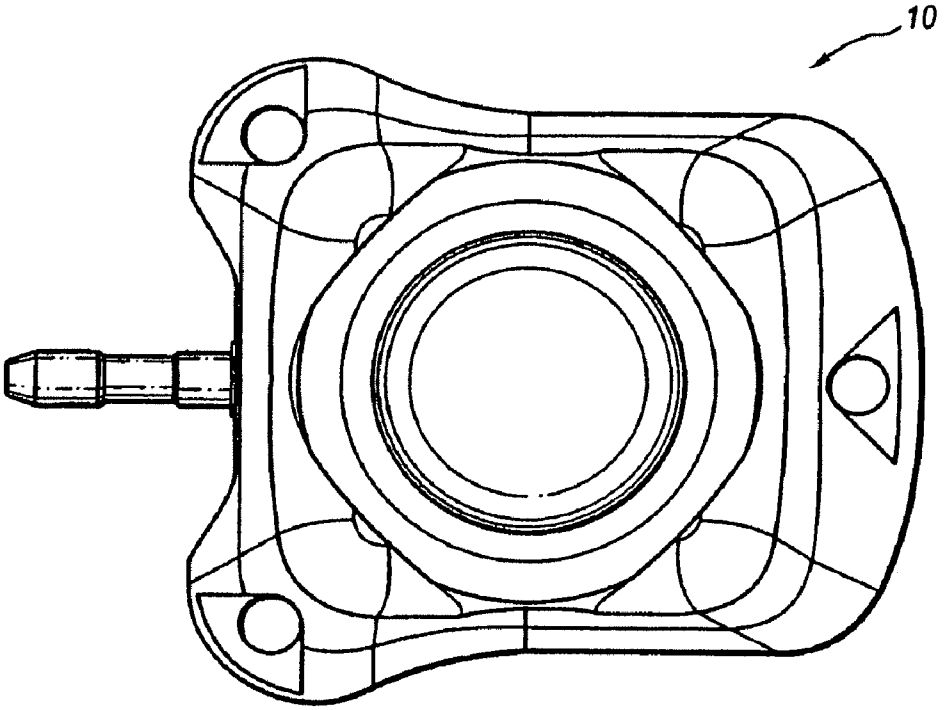

FIG. 49

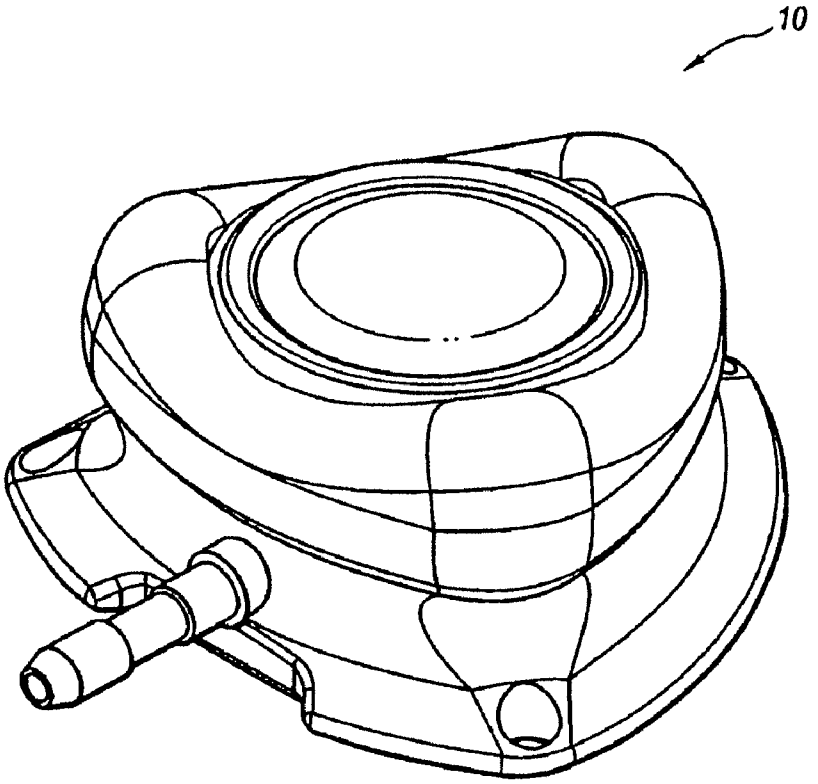

FIG. 50

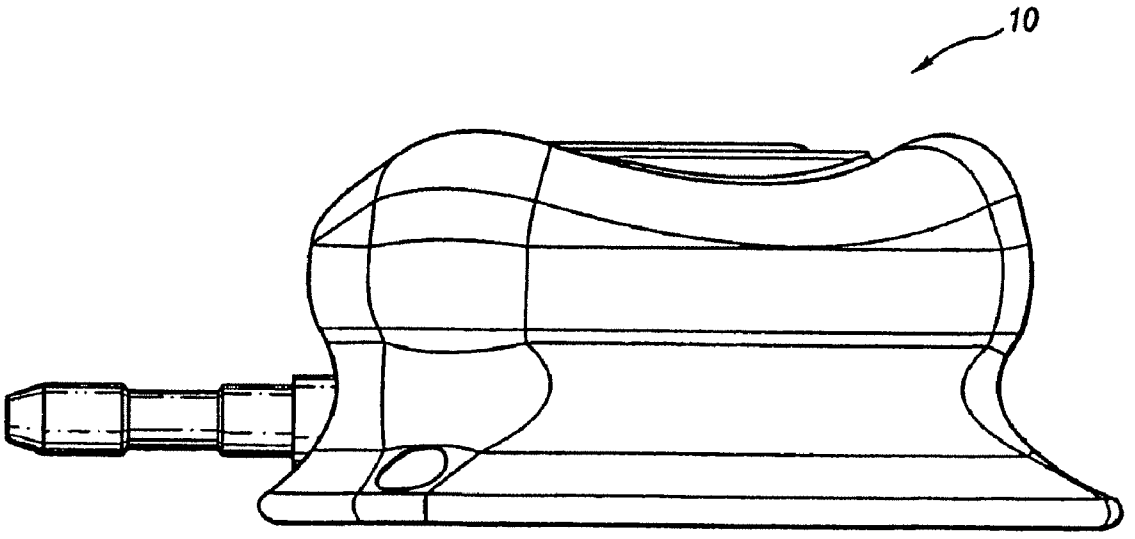

FIG. 51

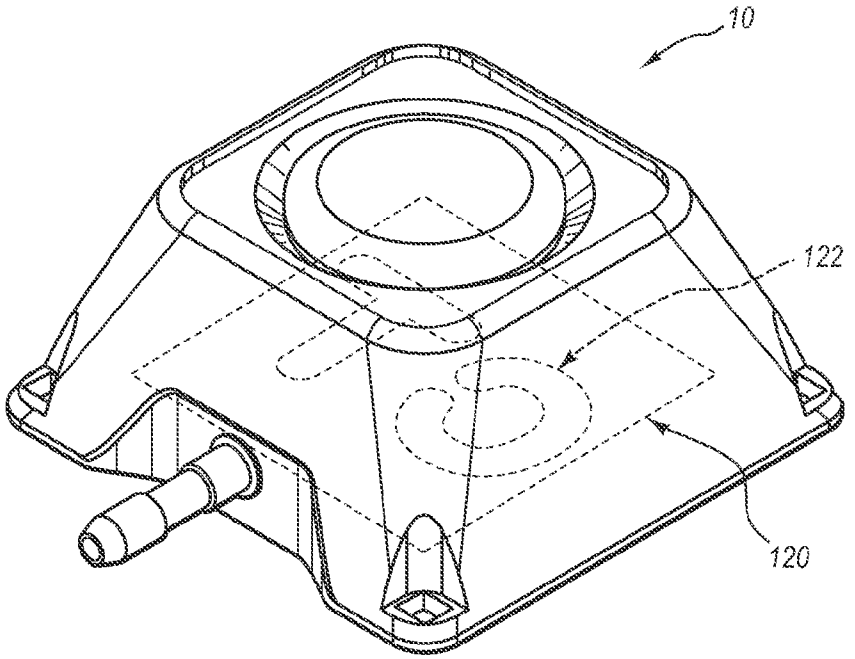

FIG. 52A

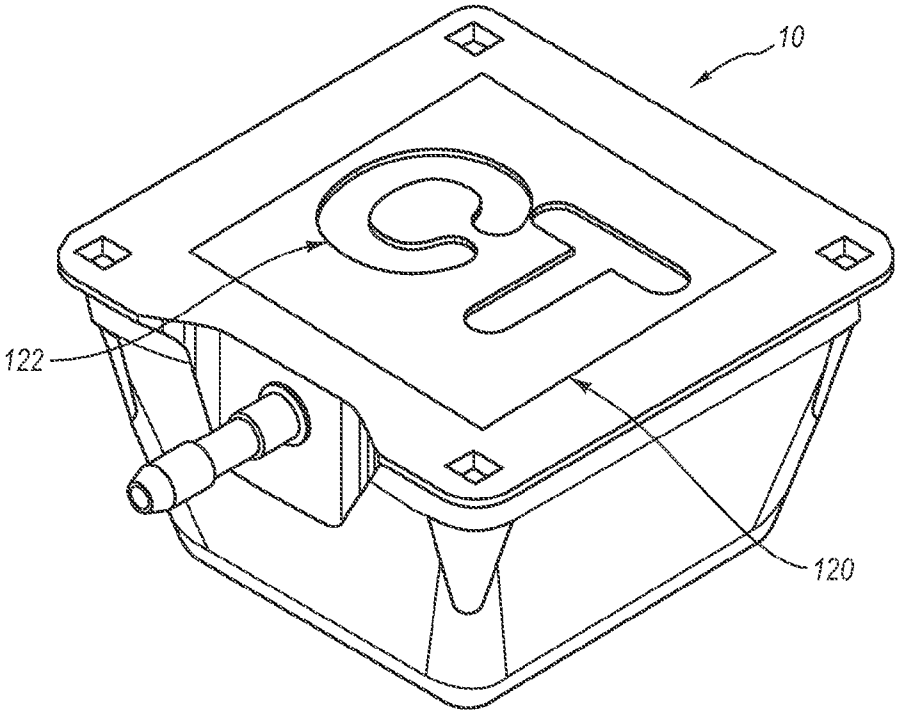

FIG. 52B

ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 11/368,954, entitled "ACCESS PORT IDENTIFICATION SYSTEMS AND METHODS," filed Mar. 6, 2006, now U.S. Pat. No. 7,785,302, which claims the benefit of U.S. Provisional Application No. 60/658,518, entitled "ACCESS PORT IDENTIFICATION SYSTEM," filed Mar. 4, 2005, all of which are hereby incorporated by reference in their entireties.

BACKGROUND

Access ports provide a convenient method to repeatedly deliver a substance to remote areas of the body without utilizing surgical procedures. Ports are totally implantable within the body (i.e. subcutaneously) and may permit the infusion of medicine, parenteral solutions, blood products, or other fluids. Additionally, ports may also be used for blood sampling.

A typical port typically includes a housing assembly, a septum, and an outlet. The housing assembly and septum define a reservoir which is accessible through the septum. The outlet of the housing may communicate with a catheter which accesses a vein. Thus, the catheter may be employed for delivering a fluid from the port to a remote location in the body, for example, the superior vena cava.

In common practice, a port is implanted within the body and the catheter is routed to a remote area where a fluid is desired to be delivered. To deliver the fluid, a caregiver locates the septum of the port by palpation of a patient's skin. Port access is accomplished by percutaneously inserting a needle, typically a non-coring needle, through the septum of the port and into the reservoir. A fluid, such as a drug or other beneficial substance, may then be administered by bolus injection or continuous infusion into the reservoir. Thus, the fluid may flow through the reservoir into the catheter and finally to the site were the fluid is desired.

Ports generally come in two different types, surgical and cosmetic. Surgical ports may typically be used for delivering medicinal substances, including chemotherapy drugs which may be harmful to surrounding tissue, or for sampling blood. Cosmetic ports, on the other hand, are utilized to deliver saline or some other non-reactive substance to a prosthesis which supplements a body feature.

Generally, conventional access ports of different manufacturers or models may typically exhibit substantially similar geometries that may not be differentiable with respect to one another. Accordingly, once an access port is implanted, it may be difficult to determine the model, style, or design of the access port. Such uncertainty may be undesirable, at least for replacement timing purposes, among other reasons, especially if identification of the implanted access port is difficult to otherwise determine.

Thus, it would be advantageous to provide an access port which provides at least one identifiable characteristic that may be sensed or otherwise determined subsequent to subcutaneous implantation of the access port.

SUMMARY

One aspect contemplated by the instant disclosure relates to an access port for providing subcutaneous access to a patient. Such an access port may comprise a body for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, an access port according to the instant disclosure may include at least one feature structured and configured for identification of the access port subsequent to subcutaneous implantation.

Another aspect contemplated by the instant disclosure relates to a method of identifying a subcutaneously implanted access port. More particularly, a subcutaneously implanted access port may be provided and at least one feature of the subcutaneously implanted access port may be perceived. Further, the subcutaneously implanted access port may be identified in response to perceiving the at least one feature.

A further aspect of the instant disclosure relates to an access port for providing subcutaneous access to a patient. Particularly, such an access port may comprise a body configured for capturing a septum for repeatedly inserting a needle therethrough into a cavity defined within the body. Further, the access port may comprise at least one feature structured to identify the access port as being power injectable subsequent to subcutaneous implantation.

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 contemplated by 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

FIG. **1**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **1**B shows a schematic side cross-sectional view the access port shown in FIG. **1**A;

FIG. **2** shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **3** shows a perspective view of an access port according to the instant disclosure;

FIG. **4** shows a perspective view of an access port according to the instant disclosure;

FIG. **5** shows a perspective view of an access port according to the instant disclosure;

FIG. **6**A shows a perspective view of an access port according to the instant disclosure;

FIG. **6**B shows a side view of the access port shown in FIG. **6**A;

FIG. **7** shows a perspective view of an access port according to the instant disclosure;

FIG. **8** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **9** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **10** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **11** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **12** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **13** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **14** shows a simplified perspective view of a cap for forming an access port according to the instant disclosure;

FIG. **15**A shows a perspective view of an embodiment of an access port according to the instant disclosure;

FIG. **15**B shows a top elevation view of the access port shown in FIG. **15**A;

FIG. **16** shows a perspective view of an access port according to the instant disclosure;

FIG. **17** shows a perspective view of an access port according to the instant disclosure;

FIG. **18** shows a perspective view of an access port according to the instant disclosure;

FIG. **19** shows a perspective view of an access port according to the instant disclosure;

FIG. **20** shows a perspective view of an access port according to the instant disclosure;

FIG. **21** shows a perspective view of an access port according to the instant disclosure;

FIG. **22** shows a perspective view of another embodiment of an access port according to the instant disclosure;

FIG. **23** shows a top elevation view of the assembled access port shown in FIG. **22**;

FIG. **24** shows a simplified representation of a transverse cross section of the access port shown in FIGS. **22** and **23**;

FIGS. **25-51** show perspective views of additional embodiments of an access port.

FIG. **52**A shows a top perspective view of an embodiment of an access port with an alphanumeric message in the bottom of the port.

FIG. **52**B shows a bottom perspective view of the embodiment in FIG. **52**A.

DETAILED DESCRIPTION

The instant disclosure relates generally to percutaneous access and, more specifically, to methods and devices associated with percutaneous access. Generally, the instant disclosure relates to an access port for subcutaneous implantation. In one embodiment, an access port may allow a physician or other medical personnel to obtain long term percutaneous access to the interior of a patient's body. Employing an access port for percutaneous access may reduce the opportunity for infection by inhibiting fluid connections (that extend into the interior of a patient's body) from the patient's skin and from the external environment. The access device allows access to the interior of the patient without requiring a needle to pierce the skin. Further, internal components, such as a catheter or a valve, may be replaced without a surgical procedure. Features or aspects of the instant disclosure may apply to any such access ports for subcutaneous access to a patient, without limitation. The access port may be injected by hand (e.g., via a syringe including a needle) for example, or may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port).

Power injectable ports may be employed in, among other processes, for example, computed tomography ("CT") scanning processes. More particularly, a so-called "power injector" system may be employed for injecting contrast media 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 under the trademark STELLANT®. Because fluid infusion 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.

More specifically, the instant disclosure relates to an access port having at least one perceivable or identifiable feature for identifying the access port, wherein the identifiable feature is perceivable after the access port is implanted within a patient. For example, at least one or perhaps multiple identifiable feature(s) of an access port contemplated by the instant disclosure may be correlative to information (e.g., a manufacturer's model or design) pertaining to the access port. Thus, an identifiable feature from an access port of a particular model may be unique in relation to most if not all other identifiable features of another access port of a different models or design. Of course, the at least one identifiable feature of an access port contemplated by the instant disclosure may be further correlative with any information of interest, such as type of port, catheter type, date of manufacture, material lots, part numbers, etc. In one example, at least one identifiable feature of an access port may be correlative with the access port being power injectable. In this way, once at least one identifiable feature of an access port is observed or otherwise determined, correlation of such at least one feature of an access port may be accomplished, and information pertaining to the access port may be obtained.

In one embodiment, at least one feature may be perceived by palpation (i.e., to examine by touch), by way of other physical interaction, or by visual observation. Accordingly, a person of interest may touch or feel the access port through the skin to perceive at least one identifying characteristic thereof. In another embodiment, at least one identifiable feature may be perceived via x-ray or ultrasound imaging. In yet a further embodiment, at least one identifiable feature may be perceived through magnetic, light, or radio energy interaction or communication with the access port.

Turning to the embodiment wherein at least one feature may be perceived through palpation, other physical interaction, or visual observation, a topography or exterior surface feature of an access port contemplated by the instant disclosure may be configured for perception. For example, referring to FIGS. **1**A and **1**B, an exemplary access port **10** contemplated by the instant disclosure is shown. FIGS. **1**A and **1**B show a perspective view and a schematic side cross-sectional view, respectively, of an access port **10** for allowing percutaneous or otherwise internal access to a patient's body. Access port **10** includes a housing or body **20** defined by a cap **14** and a base **16**. Cap **14** and base **16**, as known in the art, may be configured for capturing therebetween a septum **18**. As shown in FIG. **1**A, cap **14** and base **16** may matingly engage one another along a mating line **15**. Cap **14** and base **16** may be secured or affixed to one another via mechanical fasteners such as screws or other fastening devices, may be adhesively affixed to one another, or may be affixed to one another as known in the art. Further, cap **14**, base **16**, and septum **18** may collectively define a cavity **36** in fluid communication with a lumen **29** of outlet stem **31**.

The body **20** may be implanted in a patient **7**, as shown in FIG. **1**B, to dispose the cavity **36** subcutaneously within the patient **7**. Also, suture apertures **66** (FIG. **1**A) may be used to affix the access port **10** within the patient **7**, if desired. After the body **20** is implanted in a patient **7**, the upper surface of the septum **18** may be substantially flush with the surface of the skin **6** of the patient **7** and may be repeatedly punctured for creating a percutaneous passageway from the exterior of the skin of the patient into the cavity **36**. The outlet stem **31** may create a fluid-communicative passageway from the cavity **36** through the outlet stem **31** and into the interior of the patient **7**. A catheter may be coupled to the outlet stem **31** for fluid communication with the cavity **36** and for transferring fluid from the cavity **36** to a desired remote location from the cavity **36** and within a patient **7**.

Body **20** of access port **10** may comprise a bio-compatible material such as polysulfone, titanium, or any other suitably bio-compatible material as known in the art. Accordingly, the body **20** may be formed from a bio-compatible plastic material. If desired, the body **20** may comprise a penetrable mate-

rial for penetration by sutures or needles. In another embodiment, and as discussed further hereinbelow, body **20** may comprise an impenetrable material such as, for instance, a metal if desired. Body **20** may include a concave bottom or, in another embodiment, may include a flat bottom, without limitation.

According to the instant disclosure, access port **10** may comprise a body **20** exhibiting at least one identifiable feature. More particularly, as shown in FIG. **1**A, body **20** may exhibit a partial generally pyramidal shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex otherwise known as a frustum). Generally, a body **20** of an access port **10** may exhibit a partial pyramidal shape extending between a generally quadrilateral shaped base positioned at reference plane **11** and a generally quadrilateral shaped upper base positioned at reference plane **9**. Reference planes **9** and **11** will not be shown in FIGS. **2**-**21**, for clarity; however, reference to planes **9** or **11** with respect to FIGS. **2**-**21**, as used herein, will refer to corresponding reference planes analogous to reference planes **9** and **11** as shown in FIGS. **1**A and **1**B.

As shown in FIG. **1**A, the exterior of access port **10** is substantially defined by four substantially planar side surfaces **50** connected to one another by radiuses **32**. In addition, the upper topography **61** of access port **10** is defined by upper surface **60** in combination with chamfers **46**A and **46**B and may be further defined by the upper surface of septum **18**. Explaining further, the outer periphery of upper topography **61** may be described as a generally quadrilateral exterior formed by side regions **54** and having rounded corner regions **30** adjacent side regions **54**. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

It may be appreciated that there are many variations to the geometry of access port **10** as shown in FIG. **1**A. For instance, while the body **20** of access port **10** may be described as a partially pyramidal shape or frustum, the instant disclosure is not so limited. Rather, one or more of side surfaces **50** may be oriented at as may be desired, without reference to any other side surfaces **50**. Accordingly, for example, one of surfaces **50** may be substantially vertical while the remaining surfaces **50** may be oriented at respective, selected angles. Furthermore, it should be understood that FIG. **1**A is merely exemplary and that the dimensions and shape as shown in FIG. **1**A may vary substantially while still being encompassed by the instant disclosure.

FIG. **2** shows a perspective view of another embodiment of access port **10** according to the instant disclosure. As shown in FIG. **2**, the exterior of access port **10** is substantially defined by a generally parallelogram-shaped base (positioned at reference plane **11** as shown in FIGS. **1**A and **1**B) extending generally pyramidally to a generally parallelogram-shaped upper surface (positioned at reference plane **9** as shown in FIGS. **1**A and **1**B). As shown in FIG. **2**, radiuses **42** may be larger than radiuses **32** as shown in FIG. **1**A. Furthermore, the upper topography **61** of access port **10** as shown in FIG. **2** may include rounded corner regions **40** which are larger than rounded corner regions **30** as shown in FIG. **1**A. Thus, FIG. **2** shows an exemplary embodiment of an access port **10** that may be perceivably distinguishable from access port **10** as shown in FIGS. **1**A and **1**B. For example, a difference between one exterior of an access port contemplated by the instant disclosure and another exterior of a different access port contemplated by the instant disclosure may be determined by way of palpation.

In another embodiment, in another aspect contemplated by the instant disclosure, a template may be employed for perceiving at least one feature of an access port. For instance, a complementarily-shaped template may be positioned over and abutted against an access port contemplated by the instant disclosure so as to determine if the access port matches or substantially corresponds to the shape of the template. Such a process may reliably indicate or perceive at least one feature of an access port contemplated by the instant disclosure. Of course, a plurality of templates corresponding to different models of access ports may be serially engaged with an unknown access port so as to perceive at least one feature thereof. Such a process may allow for identification (e.g., of a model or manufacturer) of an access port contemplated by the instant disclosure.

In another aspect contemplated by the instant disclosure, an upper topography of an access port may include at least one feature for identifying the access port. For example, as shown in FIG. **3**, upper surface **60** of access port **10** may be nonplanar. More specifically, upper surface **60** may be tapered or may arcuately extend downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B) as it extends radially inwardly toward septum **18**. Otherwise, access port **10**, as shown in FIG. **3**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Thus, upper surface **60** is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In yet a further embodiment of an access port contemplated by the instant disclosure, side regions **54** extending between rounded corner regions **30** may exhibit at least one perceivable feature. For example, as shown in FIG. **4**, access port **10** may include one or more side regions **54** that extend arcuately between adjacent rounded corner regions **30**. Otherwise, access port **10**, as shown in FIG. **4**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Side regions **54** may be congruent or symmetric with respect to one another or, in another embodiment, may be configured differently with respect to one another, without limitation.

FIG. **5** shows a further exemplary embodiment of an access port contemplated by the instant disclosure. More specifically, access port **10**, as shown in FIG. **5**, includes side regions **54** that form recessed regions **72** between adjacent rounded corner regions **30**. Put another way, the upper topography **61** may include alternating recessed regions **72** and protruding regions **70** positioned generally about a periphery of septum **18**. Otherwise, access port **10**, as shown in FIG. **5**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Such a configuration may provide an access port having at least one identifiable feature.

In a further embodiment of an access port contemplated by the instant disclosure, FIGS. **6**A and **6**B show a perspective view and a side view, respectively, of an access port **10** generally configured as is described with reference to FIG. **5** but having an elongated body **20**E. More specifically, elongated body **20**E of access port **10**, as shown in FIGS. **6**A and **6**B, includes a side surface **50**E that extends generally from upper topography **61** downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B) and having a slope (e.g., an angle with respect to a vertical axis normal to an upper surface of septum **18**) which is different from the other side surfaces **50**. Otherwise, access port **10**, as shown in FIG. **6**, may be configured substantially as described hereinabove with reference to FIGS. **1**A and **1**B. Such a configuration may provide an elongated body **20**E of an access port **10** having an elongated side portion.

Of course, one or more side surfaces of an access port according to the instant disclosure may be configured for

forming a body exhibiting a selected shape as may be desired. An elongated body portion of an access port contemplated by the instant disclosure may form, in combination with other features as described hereinabove or, in another embodiment, taken alone, at least one perceivable feature for identification of an access port according to the instant disclosure.

FIG. **7** shows a further embodiment of an access port encompassed by the instant disclosure. Particularly, as shown in FIG. **7**, access port **10** may include an upper body portion **20***a* and a lower body portion **20***b*. Furthermore, each of upper body portion **20***a* and lower body portion **20***b* may exhibit a partial pyramidal shape (i.e., a frustum), wherein the body portions **20***a* and **20***b* are stacked vertically with respect to one another. Accordingly, upper body portion **20***a* may form an overhanging rim feature **76** extending along a periphery of access port **10**. Explaining further, lower body portion **20***b* may have an exterior substantially defined by side surfaces **50***b* and rounded corner regions **30***b*, while upper body portion **20***a* may have an exterior substantially defined by side surfaces **50***a*, rounded corner regions **30***a*, and upper topography **61**. It may be appreciated that overhanging rim feature **76** may be sized and configured for perception via palpation. Such a configuration may provide a suitable access port for delivery of a beneficial or medicinal substance, the access port being identifiable (e.g., by model number, manufacturer, etc.) after implantation.

It should be understood that the instant disclosure contemplates access ports having an exterior geometry that is not quadrilateral in nature. Rather, the instant disclosure contemplates that an access port may have an exterior which is generally cylindrical, generally conical, generally elliptical, generally oval, or an exterior that is otherwise arcuate in nature. Specifically, the instant disclosure contemplates that an access port having a substantially rounded or arcuate exterior may include at least one feature configured for identification of the access port after implantation. For example, as shown in FIG. **8**, shows a cap **14** that exhibits an exterior surface **78** that is substantially conical. Cap **14** may be assembled to a suitable base (not shown) for capturing a septum (not shown) as described hereinabove to form an access port **10** as generally described with reference to FIGS. **1-7**.

The instant disclosure further contemplates that at least one protrusion, protruding region, recess, recessed region, undulation, or adjacent features of different elevation may comprise a feature for identifying an access port contemplated by the instant disclosure. More specifically, upper topography **61**C, as shown in FIG. **8**, may include a plurality of protrusions **80**. Protrusions **80** may exhibit partially spherical upper surfaces that transition into a lower portion of cap **14**. In further detail, protrusions **80** may be circumferentially spaced about the periphery of septum (not shown) as may be desired. In one embodiment, a plurality of protrusions **80** may be symmetrically circumferentially spaced about the periphery of septum (not shown). More generally, at least one protrusion **80** may be sized, configured, and positioned for forming at least one identifiable feature of an access port. Of course, at least one protrusion **80** may be structured for facilitating comfort of a patient within which the access port is implanted. As may be appreciated, at least one protrusion **80** or more than one protrusion **80** may be included in an upper topography **61**C of an access port (not shown) contemplated by the instant disclosure.

FIG. **9** shows another embodiment of a cap **14** including at least one protrusion **80**E for forming and identifying an access port contemplated by the instant disclosure after implantation thereof within a patient. Protrusions **80**E may extend circumferentially about a center of revolution. Thus, protrusions **80**E may exhibit a body **87** portion circumferentially extending between rounded ends **83**. Further, cap **14** may have an exterior surface **78** that is substantially symmetric about an axis of revolution. More generally, body **20** may extend from a generally circular, generally elliptical, or generally oval base positioned at a lower extent **71** of the cap **14** to an upper generally circular, generally elliptical, or generally oval cross section that is smaller than a cross section of the base and is positioned at an upper extent **73** (without considering protrusions **80**E) of the cap **14**. In addition, side surface **51**, as shown in FIG. **9**, extends arcuately between the base and the upper topography **61** of cap **14**. Side surface **51** may extend in a generally tapered or conical fashion, may exhibit a radius or other arcuate shape, or may otherwise transition between a cross section of the base of the access port to a cross section proximate the upper topography **61**C thereof.

Further, FIG. **10** shows an embodiment of a cap **14** for forming an access port contemplated by the instant disclosure having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E are circumferentially larger than the circumferentially extending recesses **80**E. In another embodiment of an access port contemplated by the instant disclosure, FIG. **11** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising alternating circumferentially extending protrusions **80**E and circumferentially extending recesses **82**, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) sized or extension. In yet a further embodiment of a cap **14** for forming an access port contemplated by the instant disclosure, FIG. **12** shows a perspective view of a cap **14** having an upper topography **61**C thereof comprising three circumferentially extending protrusions **80**E and three circumferentially extending recesses **82**, arranged so as to alternate circumferentially, wherein the circumferentially extending protrusions **80**E and the circumferentially extending recesses **82** are substantially equal in (circumferential) size.

FIG. **13** shows a perspective view of an additional embodiment of an cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T, wherein transition regions **81** are provided between circumferentially extending protrusions **80**T and circumferentially extending recesses **82**T. Such transition regions **81**, as shown in FIG. **13**, may taper or generally smoothly transition between a circumferentially extending protrusion **80**T and a circumferentially extending recess **82**T. Also, FIG. **14** shows a perspective view of an additional embodiment of a cap **14** for forming an access port contemplated by the instant disclosure including an upper topography **61**C including protrusion regions **96** and recessed regions **98** that transition between one another and alternate circumferentially so as to form an undulating topography comprising upper topography **61**C. Such an undulating topography, as shown in FIG. **14**, generally smoothly transitions between circumferentially adjacent protrusion regions **96** and recessed regions **98**.

In a further embodiment of an access port contemplated by the instant disclosure, FIGS. **15**A and **15**B show a perspective view and a top elevation view, respectively, of an access port **10** generally configured as is described with reference to FIG. **5** but may include at least one nonplanar side surface. In another embodiment, access port **10** as shown in FIG. **15** may

be configured as shown in FIGS. **1-4** or FIGS. **6-7**, or any embodiments described hereinbelow, without limitation. More specifically, elongated body **20** of access port **10**, as shown in FIGS. **15**A and **15**B, includes three side surfaces **50**R that extend arcuately (as shown in FIG. **15**B) to a concave portion **50**P of a bottom perimeter that bounds or shapes a bottom surface of the access port. Such a configuration may provide an access port **10** that is identifiable subsequent to implantation. In yet another embodiment of an access port contemplated by the instant disclosure, FIG. **16** shows a perspective view of an access port **10** including a side wall **100** that truncates a portion of a radius **32** formed between side surfaces **50** of access port **10**. It may also be noted that such an access port **10** may include three suture apertures **66**, which may, taken alone or in combination with at least one other feature, comprise at least one identifiable feature of an access port contemplated by the instant disclosure. In addition, as shown in FIG. **16**, outlet stem **31** may extend from side wall **100**.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **17** shows a perspective view of an access port **10** wherein cap **14** and base **16**, when assembled to one another along mating line **15**, form a flange feature or lip feature **102** that extends about at least a portion of the periphery of the access port **10**. As shown in FIG. **17**, lip feature **102** extends substantially about the periphery of the access port **10**, proximate to the mating line **15** between cap **14** and base **16**. Such a feature may comprise at least one identifiable feature of an access port contemplated by the instant disclosure. Thus, it may be appreciated that a peripheral discontinuity between the cap **14** and base **16** may be formed generally along the mating line **15** therebetween. In the embodiment of an access port as shown in FIG. **7**, an overhanging rim feature **76** may comprise a peripheral discontinuity or, in the embodiment of an access port as shown in FIG. **17**, a lip feature **102** may comprise a peripheral discontinuity.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, concave region **106** of side surface **50** is concave. Concavity (i.e., a concave region **106**) may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **18** shows a perspective view of an access port **10** wherein at least a portion of at least one side surface **50** is concave. As shown in FIG. **18**, region **106** of side surface **50** is concave. Concavity may be exhibited over at least a portion of a side surface of an access port of any of the embodiments as shown herein, without limitation. Thus, at least one side surface **50** of an access port contemplated by the instant disclosure having at least at least a portion thereof that is concave is one exemplary example of at least one perceivable feature for identification of an access port contemplated by the instant disclosure.

In a further embodiment of an access port contemplated by the instant disclosure, FIG. **19** shows a perspective view of an access port **10** generally configured as is described with reference to FIGS. **6**A and **6**B. More specifically, elongated body **20**ER, as shown in FIG. **19** includes a side surface **50**ER that extends arcuately from upper topography **61** of access port **10** downwardly (i.e., toward reference plane **11** as shown in FIGS. **1**A and **1**B). Such a configuration may provide an elongated body **20**E of an access port **10** having an elongated side portion.

It should be understood from the above-described various embodiments of an access port contemplated by the instant disclosure that many variations, additions, or different features may be encompassed by the instant disclosure. Thus, the instant disclosure is not limited to the several above-described exemplary embodiments.

For example, as shown in FIG. **20**, which shows a top elevation view of an access port **10** contemplated by the instant disclosure, an access port **10** may include a side wall **100** that at least partially truncates a radius **32** between side surfaces **50**, outlet stem **31** extending from side wall **100**, and at least one of a concave region **106** and an arcuate surface **50**R. Further, as shown in FIG. **20**, suture apertures **66** may be positioned so as to identify the access port **10** after subcutaneous implantation.

Additionally, the instant disclosure contemplates access ports having an exterior geometry that is polygonal in nature. Specifically, the instant disclosure contemplates that an access port contemplated by the instant disclosure may exhibit a generally triangular exterior. Thus, as shown in FIG. **21**, body **20** may exhibit a generally pyramidal or tapered shape (i.e., a polygonal base having surfaces for each side of the polygon extending toward a common vertex). Generally, a body **20**T of an access port **10** may extend between a generally triangularly-shaped base and a relatively smaller, generally triangularly-shaped upper base. Accordingly, the exterior of access port **10** may be substantially defined by three side surfaces (e.g., **50**, **50**R, **102**, **50**E) having radiuses **32** extending therebetween. The arcuate or concave side surfaces **50**R may extend to the bottom perimeter concave portion **50**P. In addition, the upper topography **61** of access port **10** may be defined by upper surface **60** in combination with side regions **54** and rounded corner regions **30**. Such a configuration may provide an access port having at least one feature that may be perceived by palpation.

FIGS. **22** and **23** show a perspective view and a top elevation view of another embodiment of an access port including a generally triangular exterior geometry. More particularly, as shown in FIGS. **22** and **23**, a cap **14** and base **16** (collectively forming a housing) may capture a septum **118** to form an access port **10**. Further, outlet stem **31** may include a stem base that may be positioned within and sealed to an outlet recess **93** formed within base **16**. The outlet stem **31** may be in fluid communication with a cavity formed within the access port **10**. Optionally, suture plugs **89** may be positioned within suture cavities **91** formed in base **16**. Suture plugs **89** may comprise a pliant material (e.g., silicone, rubber, etc.) that may provide some resilience between sutures coupling the access port **10** (i.e., the base **16**) to a patient. In further detail, a side periphery **95** (e.g., one or more side walls) of access port **10** may be generally triangular. Thus, cap **14** and base **16** may collectively form a generally triangular housing or body of access port **10**. Also, the instant disclosure contemplates that side periphery **95** may increase or decrease in cross-sectional size (e.g., by tapering or arcuately transforming) between upper surface **161** of cap **14** and lower surface **151** of base **16**. As shown in FIGS. **22** and **23**, a transverse cross section (taken in a selected plane substantially parallel to lower surface **151** of base **16**) of access port **10** may be larger proximate to lower surface **151** of base **16** and may be relatively smaller proximate upper surface **161** of cap **14**.

Additionally, FIG. **24** shows a simplified representation of a transverse cross section of access port **10**. As shown in FIG. **24**, side periphery **95** of access port **10** may define three side regions **103** that extend between associated vertex regions **101**. In addition, in one embodiment and as shown in FIG. **24**, side periphery **95** may define a substantially equilateral generally triangular shape. As one of ordinary skill in the art will appreciate, side regions **103** may arcuately extend between associated vertex regions **101**; thus, side regions **103** may form "sides" of a generally triangular shape. Further, although vertex regions **101** are rounded, it may be appreciated that such vertex regions **101** form an intersection between adjacent side regions **103**. Accordingly, one of ordinary skill in the art will appreciate that the phrase "generally triangular," as used herein, encompasses any generally three-sided geometry wherein adjacent sides intersect, without limitation. For example, the phrase "generally triangular" encompasses three sided polygons, circular triangles, equilateral triangles, etc., without limitation.

The instant disclosure also contemplates that at least one feature of an access port contemplated by the instant disclosure may not be observable visually or by palpation but, rather, may be otherwise observable. For example, the instant disclosure contemplates that at least one feature of an access port may be observable through interaction with an imaging technology such as x-ray or ultrasound. The access port may be constructed of both metal and plastic. For example, in one embodiment, a metal feature (e.g., a plate or other metal geometry) may be included by an access port contemplated by the instant disclosure. As may be appreciated, such a metal feature may be represented on an x-ray generated by exposure of the access port to x-ray energy while simultaneously exposing x-ray sensitive film to x-ray energy passing through the access port. In another embodiment, the access port may incorporate a metal disk in the bottom of the plastic port. The disk may include an alphanumeric message etched in the port disk that would be visible on radiograph (x-ray). FIGS. **52**A-B illustrate one embodiment of an alphanumeric message **122** etched in a disk or plate **120** in the bottom of a port **10**. Further, the instant disclosure contemplates that a size, shape, or both size and shape of a metal feature of an access port may be configured for enhancing identification of an access port. For example, assuming that a metal feature comprises a metal plate, a size, shape, or both may be selectively tailored for identification of an access port. Additionally, by way of example, a metal port may be configured to leave a square imprint on an x-ray that could identify the port as a power-injectable port. Similarly, a feature of an access port contemplated by the instant disclosure may be tailored for detection via ultrasound interaction. Such a feature may comprise an exterior topographical feature. In another embodiment, such a feature may comprise a composite structure including two or more materials that form an interface surface that may be identified by ultrasound imaging.

In a further aspect contemplated by the instant disclosure, it is contemplated that a communicative technology may be utilized wherein information is encompassed by an access port contemplated by the instant disclosure. Generally, a communication device (e.g., a radio beacon, a light-emitting element, an ultrasound emitting transducer, etc.), may be imbedded or otherwise affixed to an access port contemplated by the instant disclosure. Such a communication device may be configured for transmitting information in response to a given impetus. More specifically, the instant disclosure contemplates that an access port contemplated by the instant disclosure may be exposed to a request signal (e.g., a sound, an impact or an acceleration, light, radio waves, etc.). Such a request signal may cause the communication device to transmit information therefrom via sound, light, radio waves, or as otherwise known in the art. Such information may be employed for identifying an access port contemplated by the instant disclosure.

In one exemplary example, it is contemplated that radio frequency identification technology may be employed for identification of an access port contemplated by the instant disclosure. Particularly, so-called active RFID tags are powered by an internal battery and are typically read/write devices. Currently, a suitable cell coupled to suitable low power circuitry can ensure functionality for as long as ten or more years, depending upon the operating temperatures and read/write cycles and usage. So-called passive RFID tags operate without a separate external power source and obtain operating power generated from the reader. Passive RFID tags are typically programmed with a unique set of data (usually 32 to 128 bits) that cannot be modified. Read-only tags may operate as an identifier comparable to linear barcodes which may contain selected product-specific information. Thus, passive RFID tags may be much lighter than active RFID tags, less expensive, and may offer a virtually unlimited operational lifetime. The tradeoff is that they have shorter read ranges than active tags and require a higher-powered reader.

One advantage of RFID approach is the noncontact, non-line-of-sight nature of the technology. Tags can be read through a variety of substances such as snow, fog, ice, paint, crusted grime, and other visually and environmentally challenging conditions, where other optically read technologies may be less effective. RFID tags can also be read in challenging circumstances at rapid speeds, in most cases responding in less than about 100 milliseconds.

While certain representative embodiments and details have been shown for purposes of illustrating aspects contemplated by 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 contemplated by 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 contemplated by the instant disclosure. In particular, FIGS. **25-51** illustrate a number of additional exemplary embodiments of access port **10**. As is apparent from these figures, access port **10** may be formed in any number of shapes and sizes, such that any number of modifications and changes are possible to any of the embodiments described and illustrated herein without departing from the spirit and scope of the instant disclosure.

What is claimed is:

1. An access port for providing subcutaneous access to a patient, comprising:

a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and

at least one structural feature of the access port identifying the access port subsequent to subcutaneous implantation as a particular type of access port, the at least one structural feature comprising a concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

2. The access port of claim 1, wherein the body has a generally quadrilateral exterior.

3. The access port of claim 1, wherein the first side surface is connected to the second side surface by a first radius.

4. The access port of claim 1, wherein the at least one structural feature further comprises a concave side surface in a third side surface different from the first and second side surfaces.

5. The access port of claim 4, wherein the first side surface is connected to the second side surface by a first radius, and the second side surface is connected to the third side surface by a second radius.

6. The access port of claim 4, wherein the at least one structural feature further comprises a concave side surface in a fourth side surface different from the first, second, and third side surfaces.

7. The access port of claim 6, wherein the first side surface is connected to the second side surface by a first radius, the second side surface is connected to the third side surface by a second radius, the third side surface is connected to the fourth side surface by a third radius, and the fourth side surface is connected to the first side surface by a fourth radius.

8. An access port for providing subcutaneous access to a patient, comprising:

a body defining a cavity accessible by inserting a needle through a septum, the body including a plurality of side surfaces and a bottom surface bounded by a bottom perimeter, the bottom surface on a side of the port opposite the septum, the bottom perimeter including a concave portion, the side surfaces including a first side surface through which an outlet stem extends; and

at least one structural feature of the access port identifying the access port as being power injectable subsequent to subcutaneous implantation, the at least one structural feature comprising at least one concave side surface in a second side surface different from the first side surface, the concave side surface extending to the bottom perimeter concave portion.

9. The access port of claim 8, wherein the body has a generally triangular exterior.

10. A method of identifying a subcutaneously implanted access port, comprising:

palpating a subcutaneously implanted access port,

wherein the port comprises a body including a plurality of side surfaces, wherein one of the plurality of side surfaces includes an outlet stem extending therefrom;

feeling at least one structural feature of the subcutaneously implanted access port, the at least one structural feature comprising one or more concave side surfaces in side surfaces different from the side surface through which the outlet stem extends, each of said one or more concave side surfaces extending to a concave portion in a bottom perimeter of a bottom surface; and

identifying the type of subcutaneously implanted access port through the feeling of the at least one structural feature.

11. The method of claim 10, wherein the step of identifying the type of subcutaneously implanted access port comprises identifying the subcutaneously implanted access port as being a power injectable access port.

* * * * *

CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2021, I electronically filed the Opening Brief of Appellants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7) AND FEDERAL CIRCUIT RULE 32

Counsel for Appellants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. certifies that the brief contained herein has a proportionally spaced 14-point typeface, and contains 11,507 words, based on the "Word Count" feature of Word for Microsoft 365 MSO, including footnotes and endnotes, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7) and Fed. Cir. R. 32(b).

Dated: December 8, 2021

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