IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARD PERIPHERAL VASCULAR, INC. Plaintiff, v. ANGIODYNAMICS, INC. Defendant.	REDACTED PUBLIC VERSION C.A. No. 15-218-SLR **JURY TRIAL DEMANDED**

SUPPLEMENTAL COMPLAINT

Plaintiff Bard Peripheral Vascular, Inc. ("BPV" or "Plaintiff") complains and alleges as follows against Defendant AngioDynamics, Inc. ("Defendant"):

NATURE OF THE ACTION

1. The underlying Complaint in this action was filed on March 10, 2015, alleging infringement of three patents. Plaintiff BPV brings this Supplemental Complaint to reflect the change in ownership of the patents asserted in the underlying Complaint that occurred on July 12, 2017. On that date, C. R. Bard, Inc. assigned the patents to BPV, a wholly-owned subsidiary of C. R. Bard.

2. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*

3. Plaintiff has filed this lawsuit to stop Defendant's unlawful infringement of Plaintiff's patented inventions and to obtain damages, an injunction, and other relief.

THE PARTIES

4. BPV is a corporation organized and existing under the laws of the State of Arizona with its principal place of business located at 1625 West 3rd Street, Tempe AZ, 85281. Upon information and belief, Defendant is a corporation organized under the laws of the State of Delaware with its principal place of business at 14 Plaza, Latham, NY 12110. Defendant makes,

sells, offers for sale, and/or uses medical products, including implantable power-injectable port products throughout the United States, including within this District.

5. BPV is an innovator and market leader in vascular access devices.

6. BPV has manufactured and distributed implantable power-injectable port products, including PowerPort® products, since 2012. BPV's PowerPort® products were first introduced in 2006 by a sister company, Bard Access Systems, Inc. ("BAS"). In 2012, BAS transferred a number of businesses to BPV, including the port business. The groundbreaking innovations of the PowerPort® products are covered by the Asserted Patents.

7. BPV competes directly with Defendant in the market for implantable power-injectable port products in the United States.

JURISDICTION AND VENUE

8. This Court has exclusive subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c) and 1400(b).

10. This Court has personal jurisdiction over Defendant because, among other reasons, Defendant is incorporated in Delaware and Defendant has conducted and conducts business in this District. Additionally, upon information and belief, Defendant has committed and continues to commit acts of patent infringement in this District, and has harmed and continues to harm Plaintiff in this District by selling or offering for sale infringing products in this District and by inducing its customers' infringement in this District.

THE PATENTS-IN-SUIT

11. On July 2, 2013, the United States Patent and Trademark Office (the "PTO") duly and legally issued U.S. Patent No. 8,475,417 (the '417 patent"), entitled "Assemblies for Identifying a Power Injectable Access Port." A true and accurate copy of the '417 patent is attached hereto as Exhibit 1.

12. On October 1, 2013, the PTO duly and legally issued U.S. Patent No. 8,545,460 (the ’460 patent”), entitled “Infusion Apparatuses and Related Methods.” A true and accurate copy of the ’460 patent is attached hereto as Exhibit 2.

13. On August 12, 2014, the PTO duly and legally issued U.S. Patent No. 8,805,478 (the ’478 patent”), entitled “Methods of Performing a Power Injection Procedure Including Identifying Features of a Subcutaneously Implanted Access Port for Delivery of Contrast Media.” A true and accurate copy of the ’478 patent is attached hereto as Exhibit 3.

14. C. R. Bard, Inc. was the owner by assignment of the ’417 patent, the ’460 patent, and the ’478 patent (the “Asserted Patents”).

15. C. R. Bard, Inc. assigned all rights in the Asserted Patents to BPV on July 12, 2017, including all money damages awarded in connection with any patent infringement suit to BPV.

16. Since July 12, 2017, BPV is the owner by assignment of the Asserted Patents.

17. Pursuant to 35 U.S.C. § 287(a), Plaintiff has marked its PowerPort® products with respect to the ’417 and ’460 patents.

FIRST CAUSE OF ACTION

18. Plaintiff realleges and incorporates paragraphs 1 – 17 as through fully set forth herein.

19. Defendant has infringed, and continues to infringe, claims 1, 5, 6, 8, 12, and 13 of the ’417 patent by making, using, selling, offering for sale within the United States, and/or importing into the United States, implantable power-injectable port products, including its Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products, as set forth in Final Infringement Contentions served on Defendant on May 19, 2017.

20. Defendant has had constructive notice of the ’417 patent by virtue of Plaintiff’s marking of its products, and actual notice at least by the filing of this Complaint.

[redacted]

24. Upon information and belief, Defendant has committed and continues to commit all of the above acts of infringement despite its lack of a good-faith belief that the claims of the '417 patent are noninfringed, invalid, or unenforceable.

25. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

26. As a result of Defendant's infringement of the '417 patent, Plaintiff has suffered damages and will continue to suffer damages.

27. Defendant's infringement of the '417 patent has been and continues to be willful and deliberate. [redacted]

28. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using, selling, offering to sell, and/or importing Plaintiff's patented inventions. BPV has suffered harm to goodwill, lost customers, lost market share, tarnishment to brand, and price erosion due to Defendant's low-quality competing implantable power-injectable port products, including its Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products. Upon information and belief, Defendant will continue to infringe the '417 unless permanently enjoined by this Court.

SECOND CAUSE OF ACTION

29. Plaintiff realleges and incorporates paragraphs 1 – 28 as through fully set forth herein.

30. Defendant has infringed, and continues to infringe, claims 1, 2, and 4 of the '460 patent by making, using, selling, offering for sale within the United States, and/or importing into the United States, implantable power-injectable port products, including its Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products, as set forth in Final Infringement Contentions served on Defendant on May 19, 2017.

31. Upon information and belief, Defendant has committed and continues to commit all of the above acts of infringement despite its lack of a good-faith belief that the claims of the '460 patent are noninfringed, invalid, or unenforceable.

32. Defendant has had constructive notice of the '460 patent by virtue of Plaintiff's marking of its products, and actual notice at least by the filing of this Complaint.

[redacted]

36. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

37. As a result of Defendant's infringement of the '460 patent, Plaintiff has suffered damages and will continue to suffer damages.

38. Defendant's infringement of the '460 patent has been and continues to be willful and deliberate. [redacted]

[redacted]

39. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using, selling, offering to sell, and/or importing Plaintiff's patented inventions. BPV has suffered harm to goodwill, lost customers, lost market share, tarnishment to brand, and price erosion due to Defendant's low-quality competing implantable power-injectable port products, including its Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products. Upon information and belief, Defendant will continue to infringe the '460 patent unless permanently enjoined by this Court.

THIRD CAUSE OF ACTION

40. Plaintiff realleges and incorporates paragraphs 1 – 39 as through fully set forth herein.

41. Upon information and belief, Defendant has infringed, and continues to infringe, claims 1, 3, 5, 8, 9, and 11 of the '478 patent by making, using, selling, offering for sale within the United States, and/or importing into the United States, implantable power-injectable port products, including Smart Port® products Xcela Port products, Xcela Plus Port products, and BioFlo Port products, as set forth in Final Infringement Contentions served on Defendant on May 19, 2017.

[redacted]

44. Since becoming aware of the patent, Defendant has known that the use of its Smart Port® products infringes the '478 patent.

45. Upon information and belief, Defendant's customers, including radiologists, physicians, nurses, surgeons, medical technicians, and other medical professionals, are infringing claims 1, 3, 5, 8, 9, and 11 of the '478 through their use of Defendant's Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products.

46. Upon information and belief, Defendant has specifically intended to induce its customers to use the Smart Port® products so as to infringe the '478 patent, including through activities relating to marketing, advertising, promotion, support, and distribution of the Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products.

47. For example, Defendant provides information and materials on how to use the Smart Port products for power injection procedures on its website, at http://www.angiodynamics.com/products/smart-port-ct.

48. Defendant provides instructions to its customers titled "Guidelines for Health Care Providers" regarding its Smart Port® products. The "Guidelines for Health Care Providers" is available at http://www.angiodynamics.com/uploads/pdf/071310-083617_MLC%20240.pdf and is attached hereto as Exhibit 4. The "Guidelines for Health Care Providers" includes a 14-step "Procedure for Power Injection" that instructs Defendant's customers on how to use its Smart Port® products for power injection.

49. Defendant actively publicizes other promotional and instructional materials for Smart Port® products through numerous means, including through its website at http://www.angiodynamics.com/. Specific examples of these materials can be found on Defendant's website at http://www.angiodynamics.com/uploads/pdf/020515-100211_MLC%20220_SmartPort-brochure-RevJ-ipad.pdf (attached hereto as Exhibit 5); http://www.angiodynamics.com/uploads/pdf/052014-085404_107102_Rev_D.pdf (English version attached hereto as Exhibit 6).

50. Upon information and belief, Defendant has committed and continues to commit all of the above acts of infringement despite its lack of a good-faith belief that the claims of the '478 patent are noninfringed, invalid, or unenforceable.

51. Defendant has committed and continues to commit all of the above acts of infringement without license or authorization.

52. As a result of Defendant's infringement of the '478 patent, Plaintiff has suffered damages and will continue to suffer damages.

53. Defendant's infringement of the '478 patent has been and continues to be willful and deliberate. [redacted]

54. Under 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement. Defendant's wrongful conduct has caused and will continue to cause Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent right to exclude others from making, using, selling, offering to sell, and/or importing Plaintiff's patented inventions. BPV has suffered harm to goodwill, lost customers, lost market share, tarnishment to brand, and price erosion due to Defendant's low-quality competing implantable power-injectable port products, including Smart Port® products, Xcela Port products, Xcela Plus Port products, and BioFlo Port products. Upon information and belief, Defendant will continue to infringe the '478 patent unless permanently enjoined by this Court.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rule of Civil Procedure, Plaintiff hereby demands trial by jury on all issues raised by the Complaint.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment in favor of Plaintiff and prays that the Court grant the following relief to Plaintiff:

A. A judgment that Defendant has infringed claims 1, 5, 6, 8, 12, and 13 of the '417 patent;

B. A judgment that Defendant has infringed claims 1, 2, and 4 of the '460 patent;

C. A judgment that Defendant has induced infringement of claims 1, 3, 5, 8, 9, and 11 of the '478 patent;

D. An injunction barring Defendant and its officers, directors, agents, servants, employees, affiliates, attorneys, and all others acting in privity or in concert with it, and its parents, subsidiaries, divisions, successors, and assigns, from further acts of infringement of the Asserted Patents;

E. An award of damages adequate to compensate for Defendant's infringement of the Asserted Patents, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

F. An accounting for infringing sales not presented at trial and an award of additional damages for any such infringing sales;

G. An award of trebled damages under 35 U.S.C. § 284;

H. A declaration that this case is exceptional under 35 U.S.C. § 285;

I. An award of Plaintiff's costs and attorneys' fees under 35 U.S.C. § 285; and

J. Any other remedy to which Plaintiff may be entitled.

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Dated: [redacted]

EXHIBIT 1

US008475417B2

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

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

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

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

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

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

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

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

(65) **Prior Publication Data**

US 2009/0227951 A1 Sep. 10, 2009

Related U.S. Application Data

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

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

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

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

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

(56) **References Cited**

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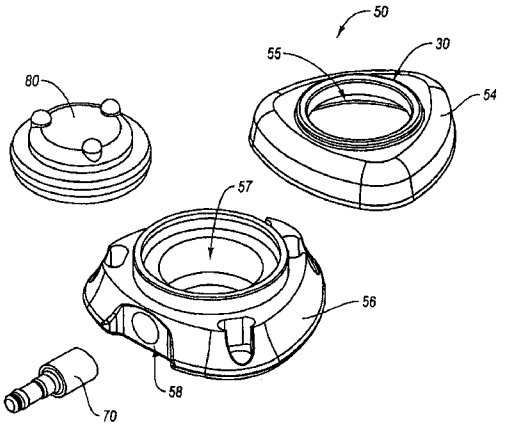
(Continued)

Primary Examiner — Kevin C Sirmons
Assistant Examiner — Imani Hayman
(74) *Attorney, Agent, or Firm* — Rutan & Tucker, LLP

(57) **ABSTRACT**

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

16 Claims, 32 Drawing Sheets



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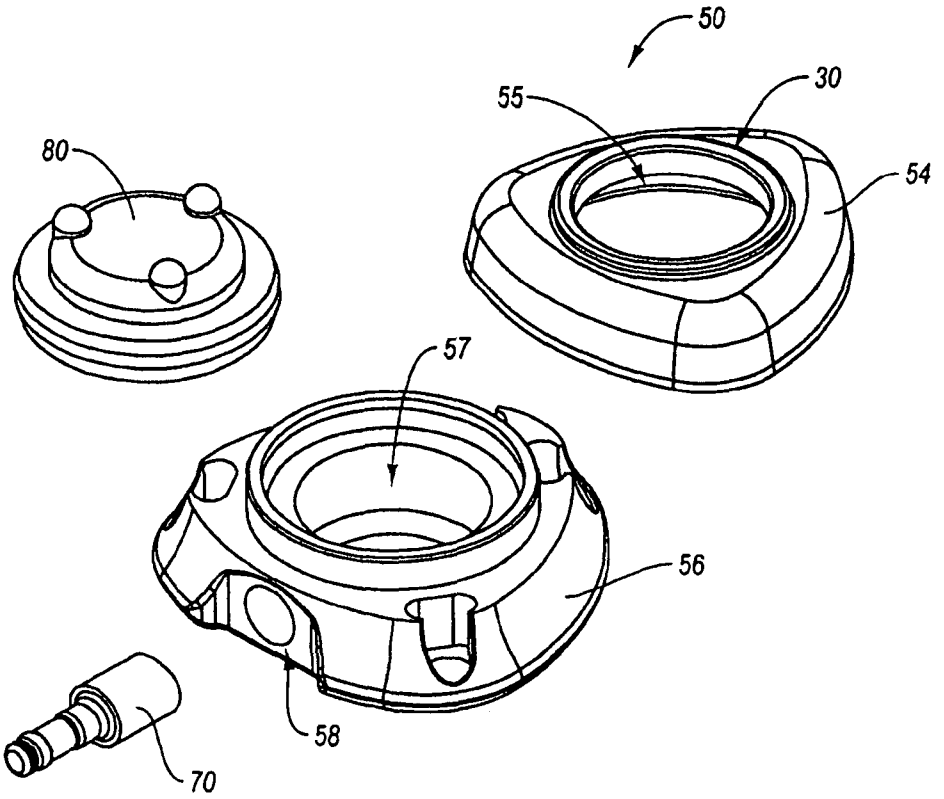


FIG. 1

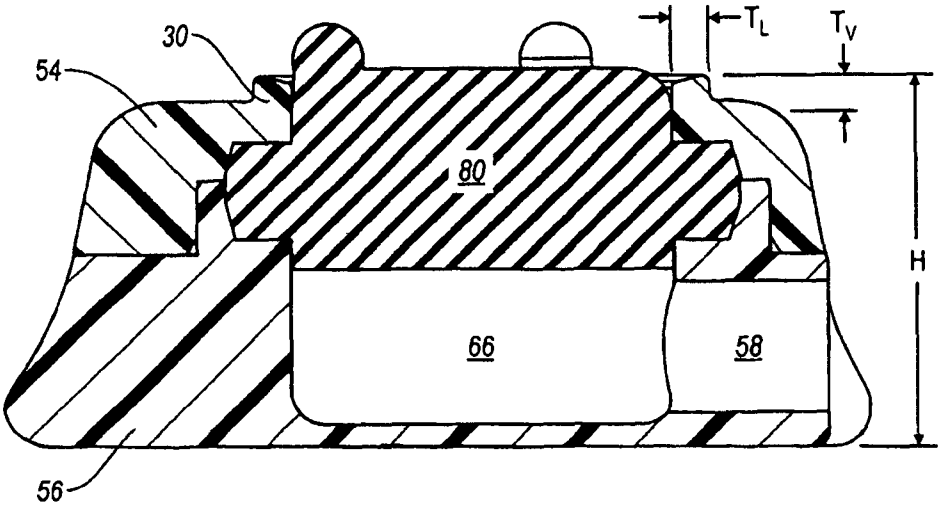


FIG. 2

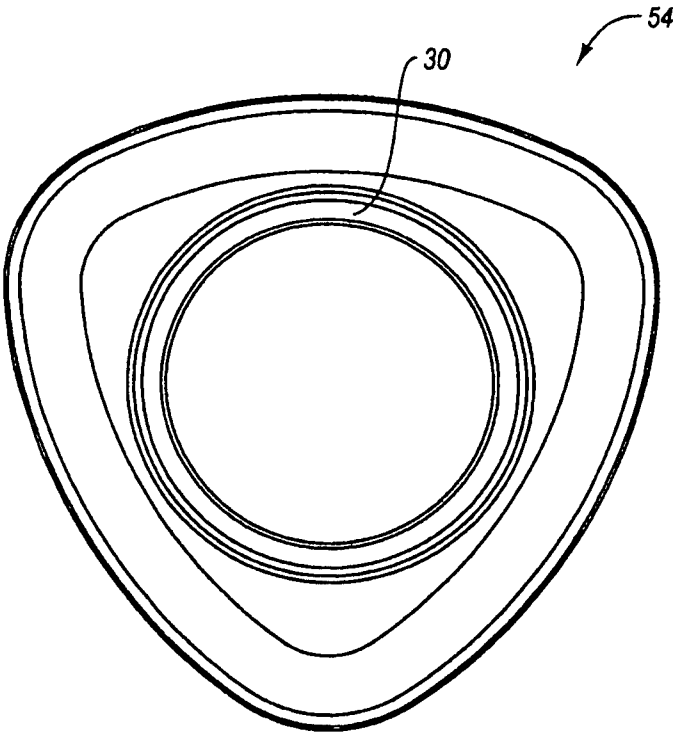


FIG. 3

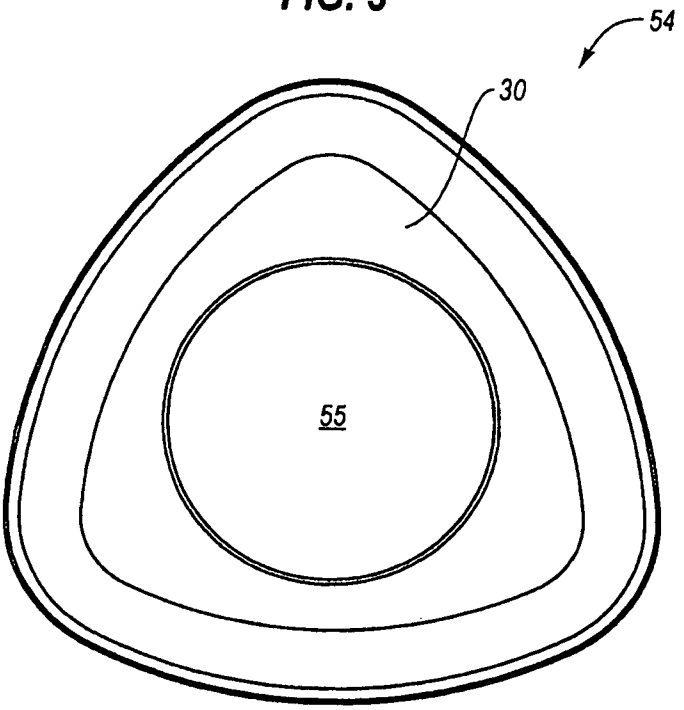


FIG. 4

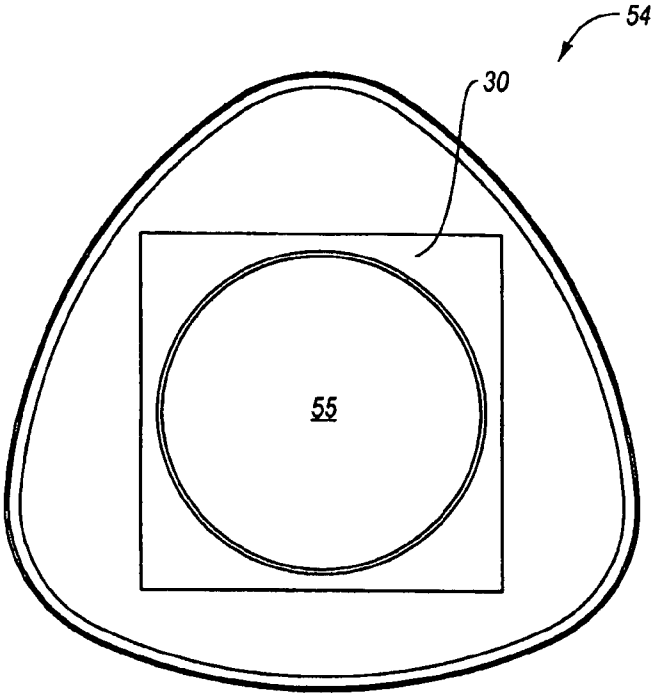


FIG. 5

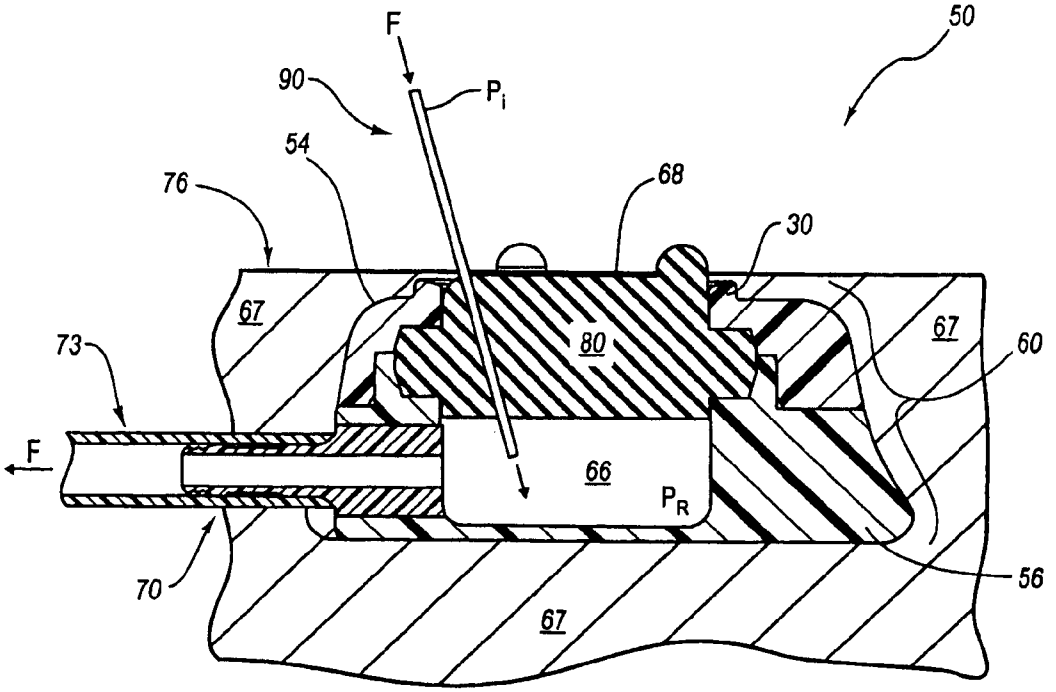


FIG. 6

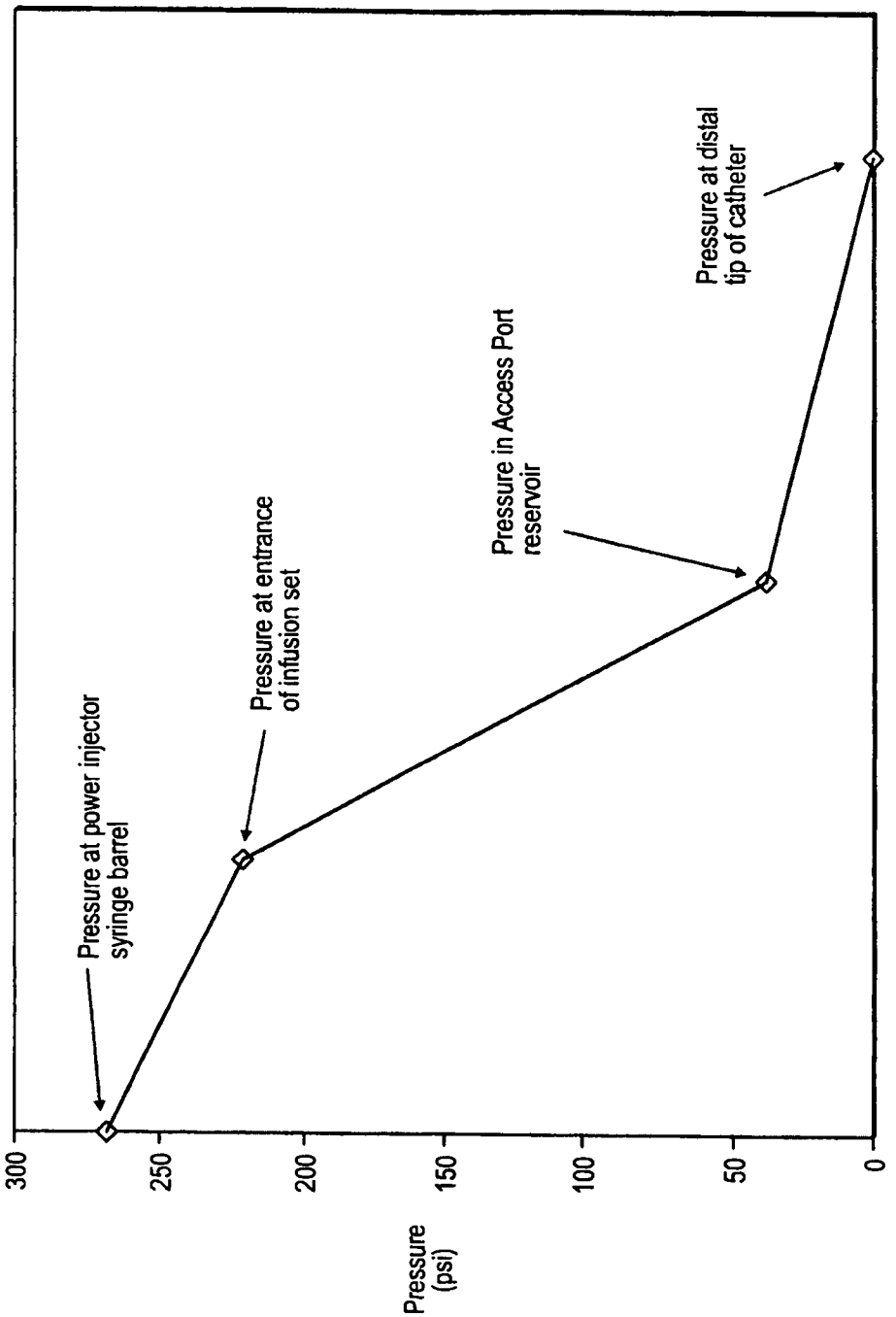

Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7

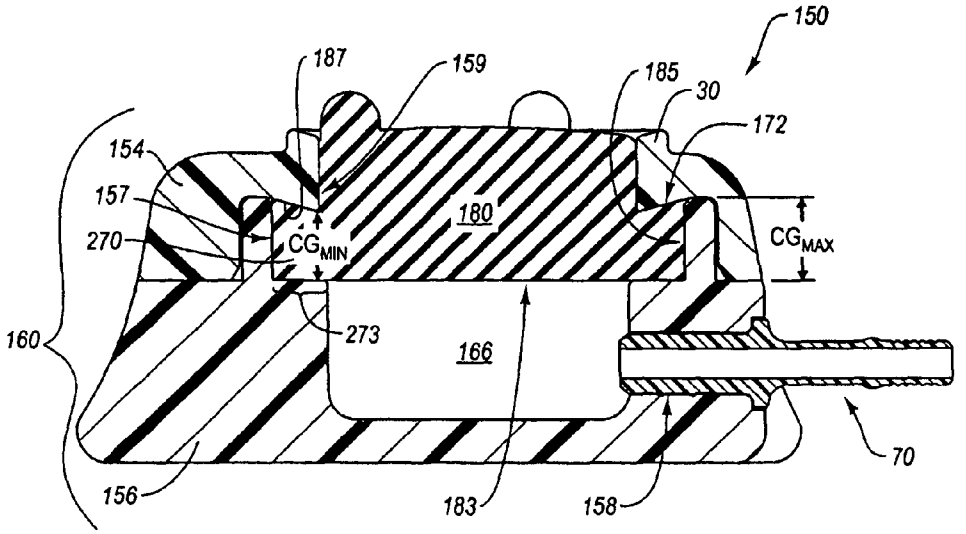

150
187
159
185
30
172
154
157
270
180
CG_{MIN}
CG_{MAX}
160
273
166
70
156
183
158

FIG. 8

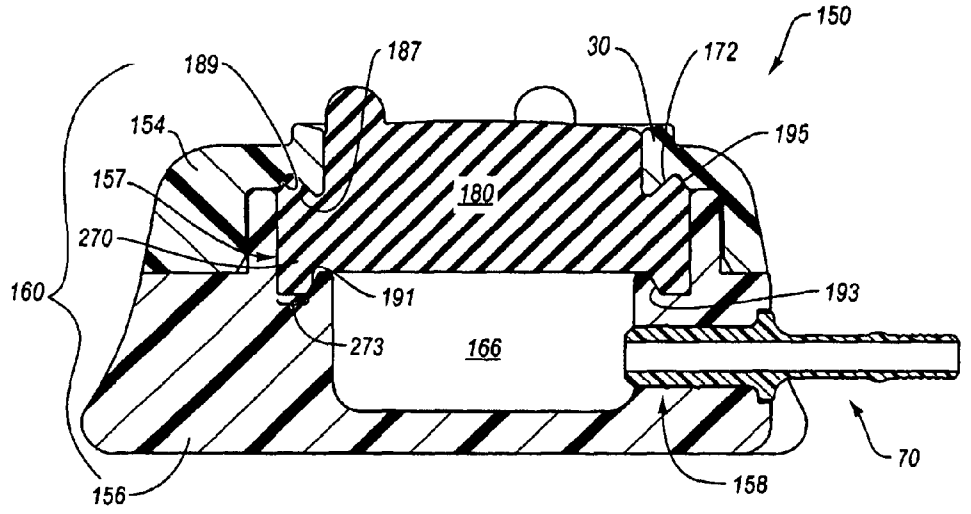
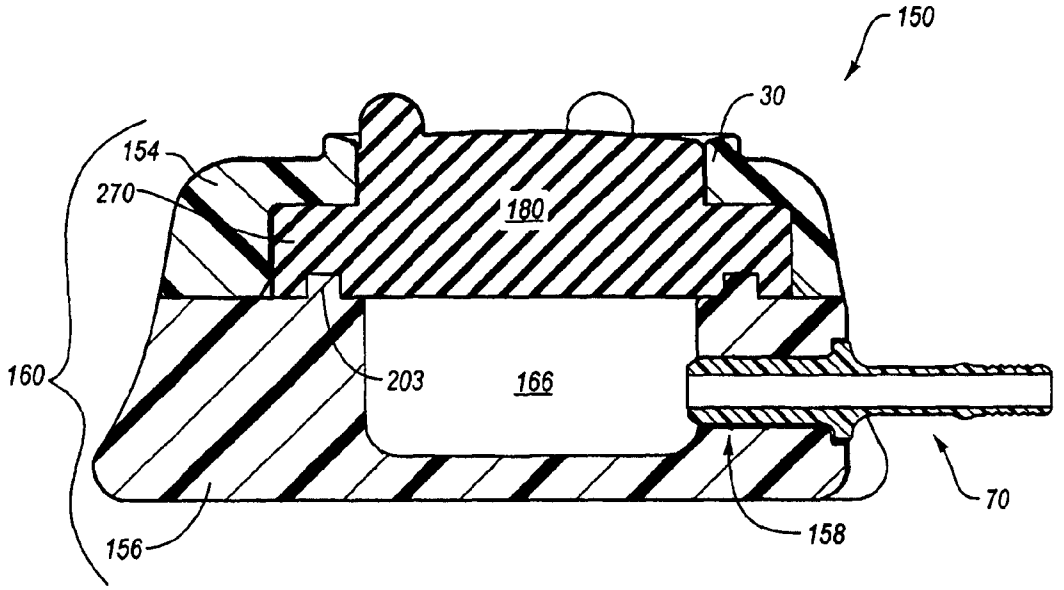

150
189
187
30
172
154
195
157
180
270
160
191
193
273
166
70
156
158

FIG. 9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30
154
270
180
160
203
166
70
156
158

FIG. 10

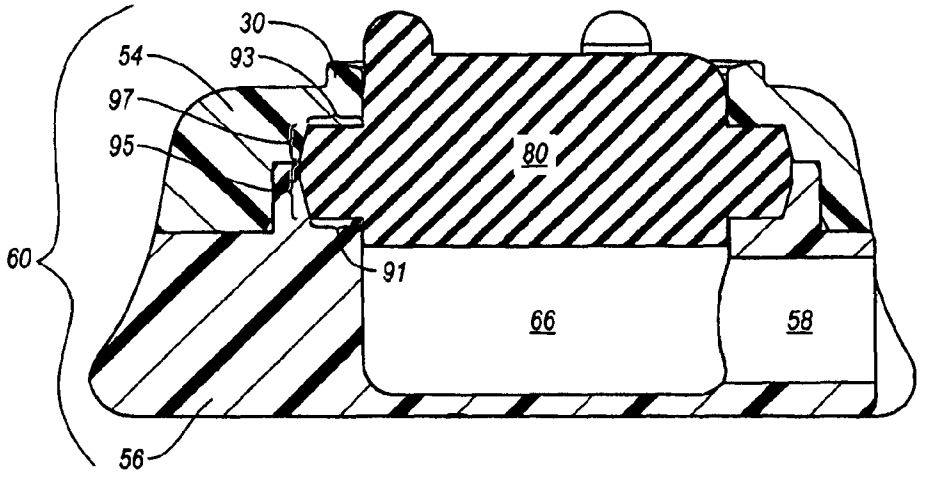

30
54
93
97
95
80
60
91
66
58
56

FIG. 11

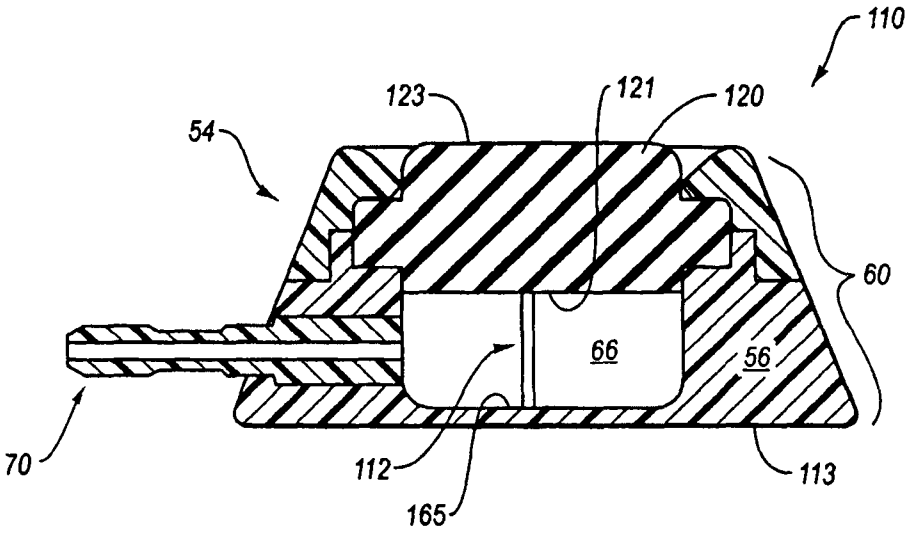

110
123
121
120
54
60
66
56
70
112
113
165

FIG. 12

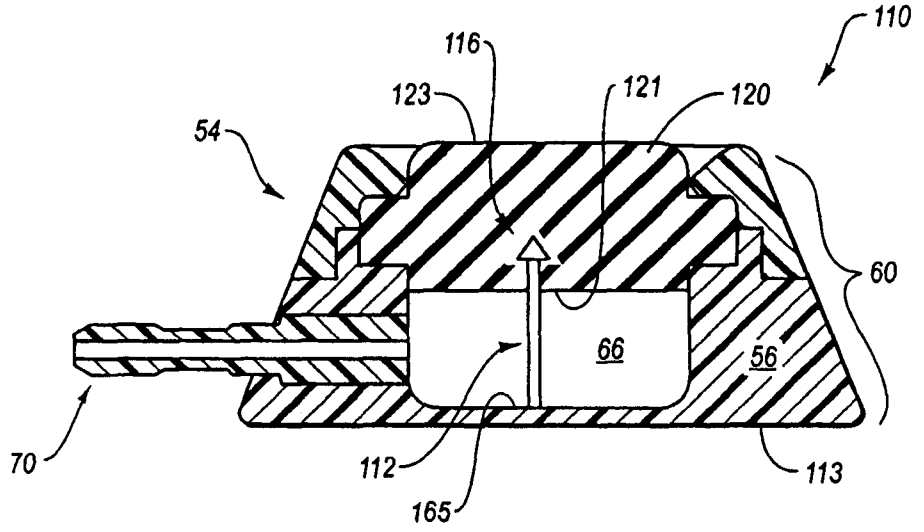
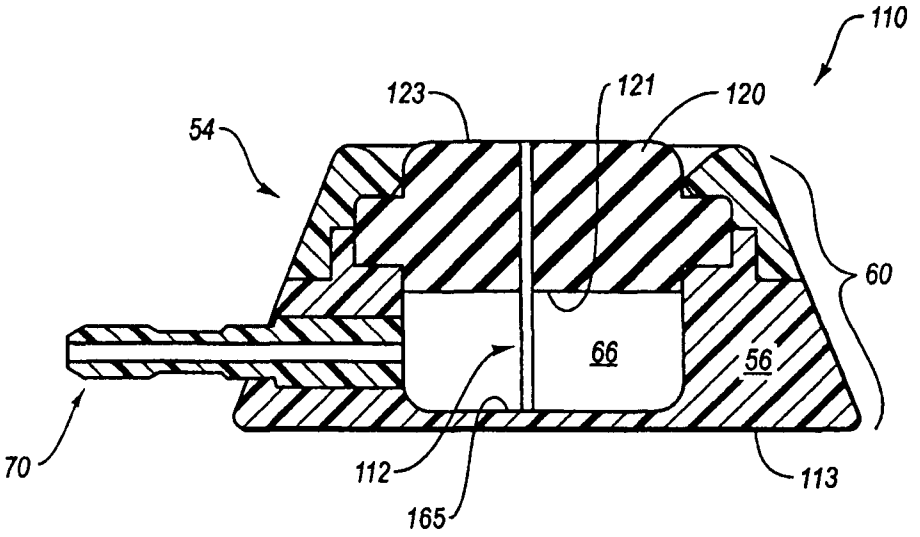

110
116
123
121
120
54
60
66
56
70
112
113
165

FIG. 13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120
54
60
66
56
70
112
113
165

FIG. 14

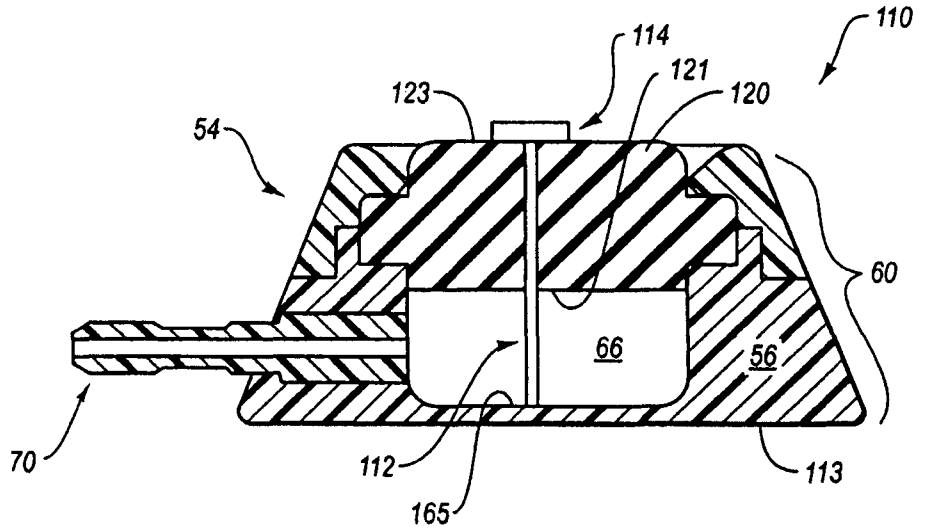
110
114
121
123
120
54
60
66
56
70
112
113
165

FIG. 15

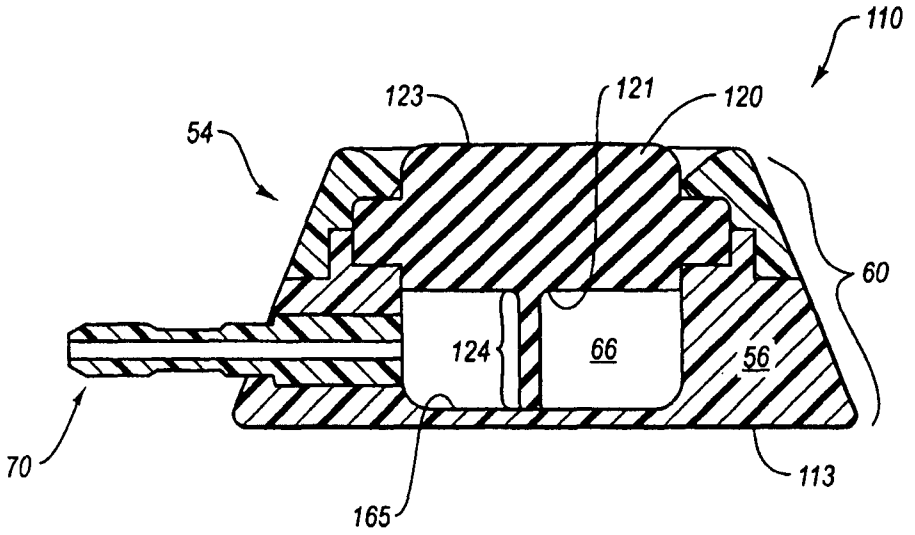
110
123
121
120
54
60
124
66
56
70
113
165

FIG. 16

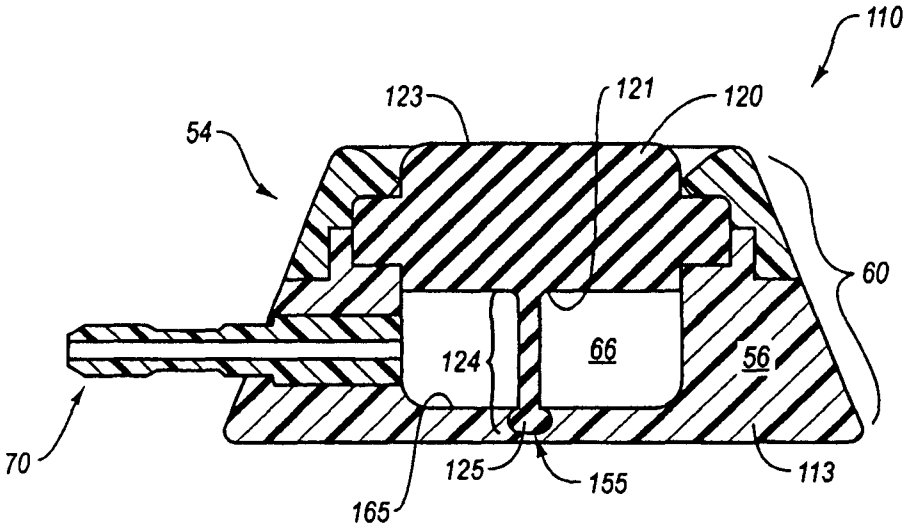
110
123
121
120
54
60
124
66
56
70
125
155
113
165

FIG. 17

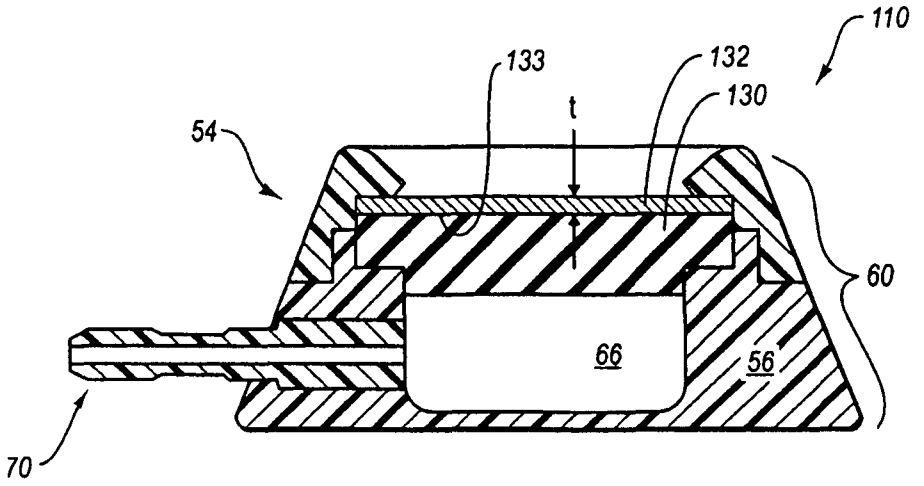
110
133
132
130
t
54
60
66
56
70

FIG. 18

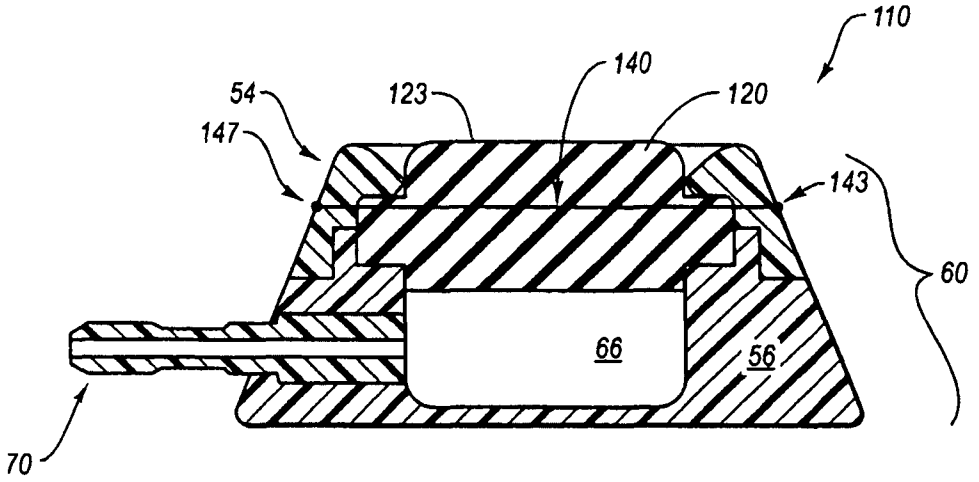
110
140
54
123
120
147
143
60
66
56
70

FIG. 19

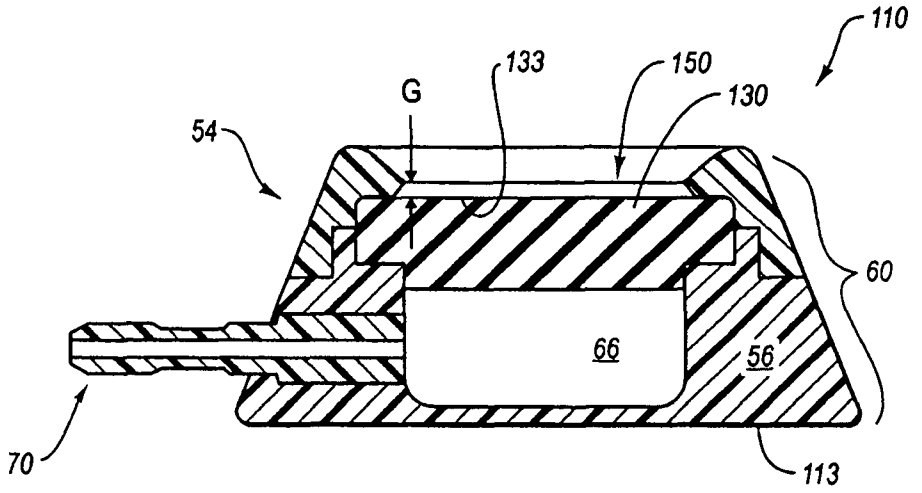

FIG. 20

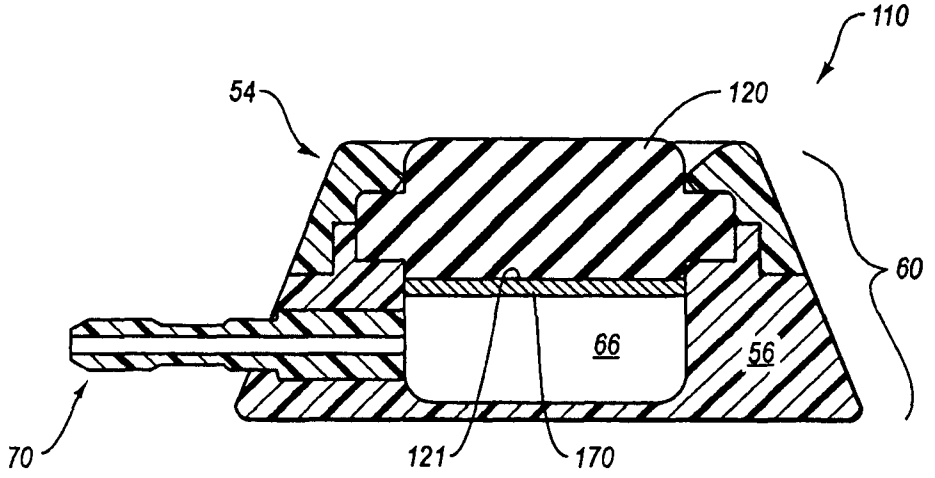

FIG. 21

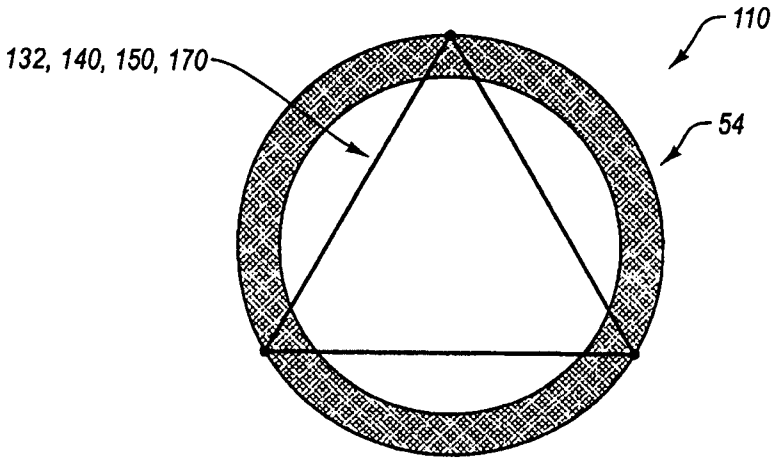

FIG. 22

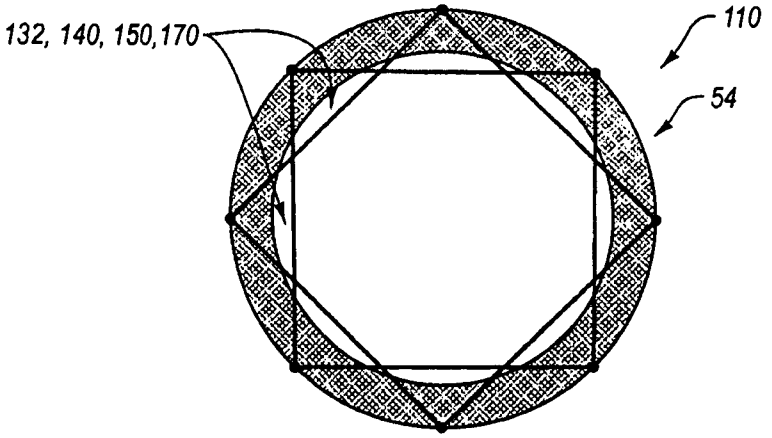

FIG. 23

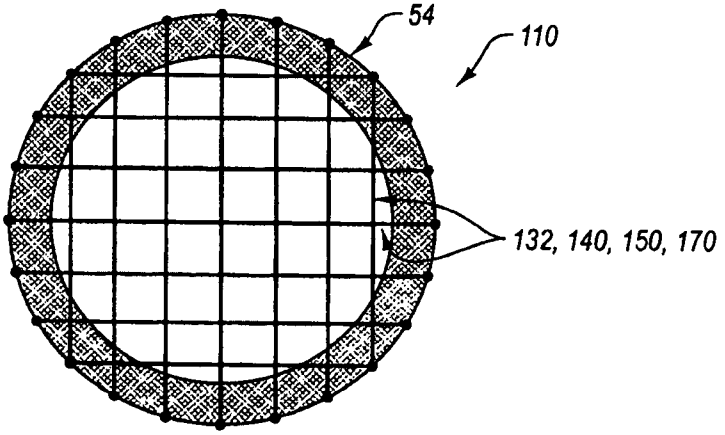

FIG. 24

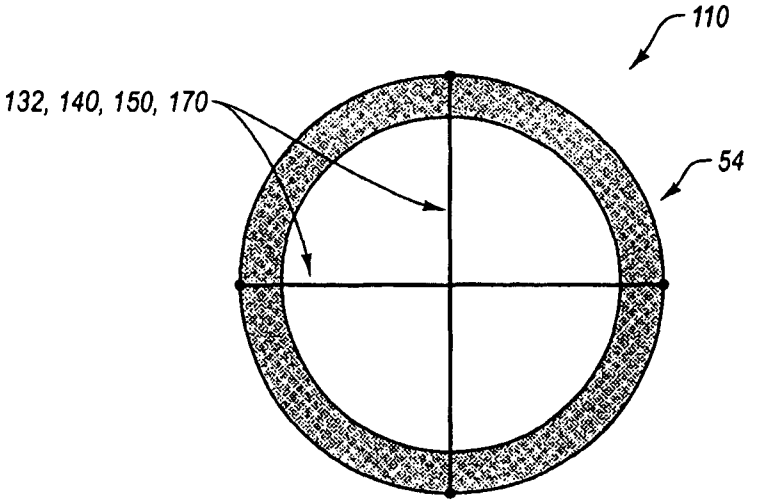

FIG. 25

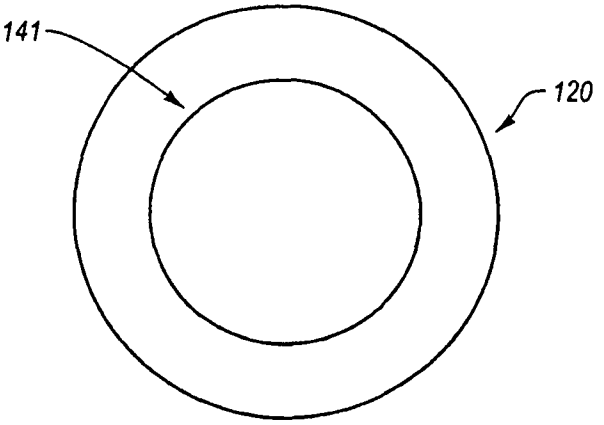

FIG. 26

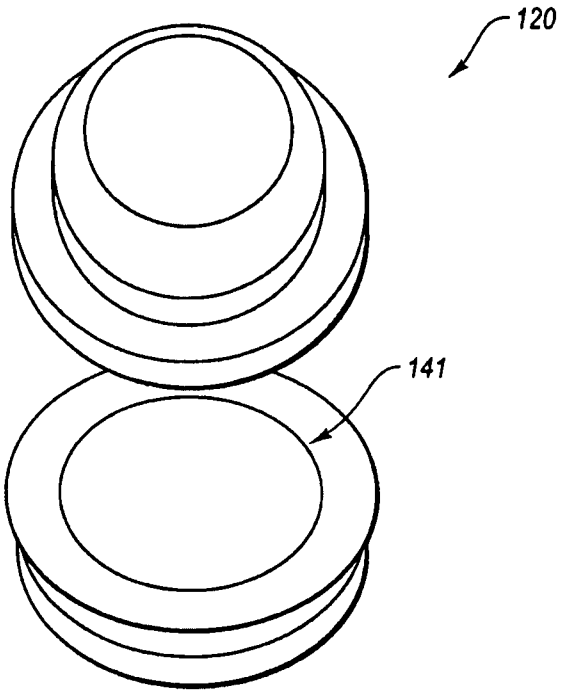

FIG. 27

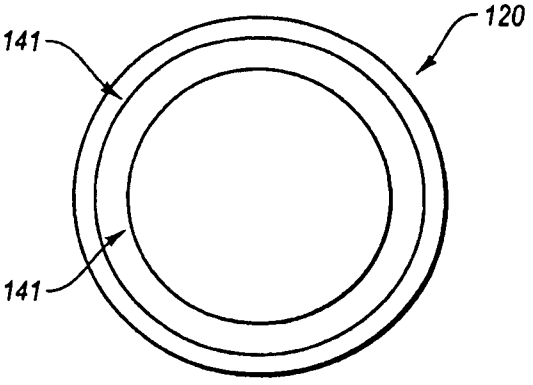

FIG. 28

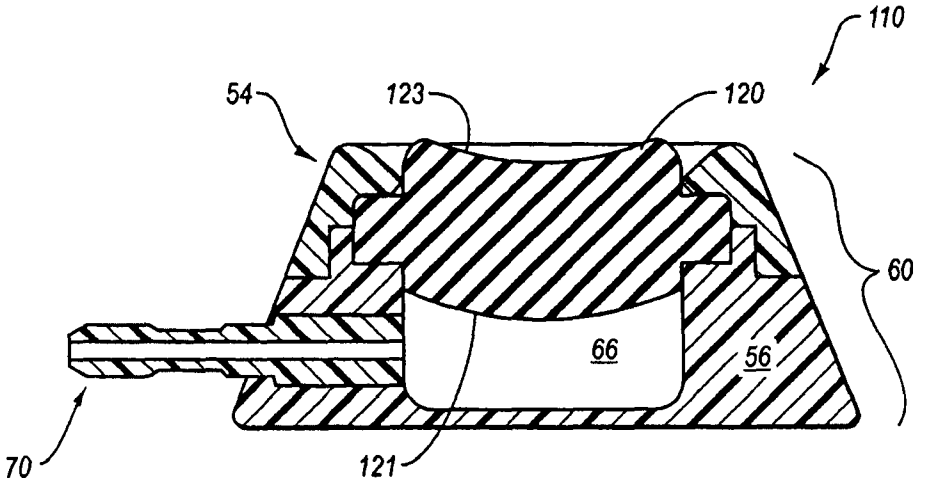

FIG. 29

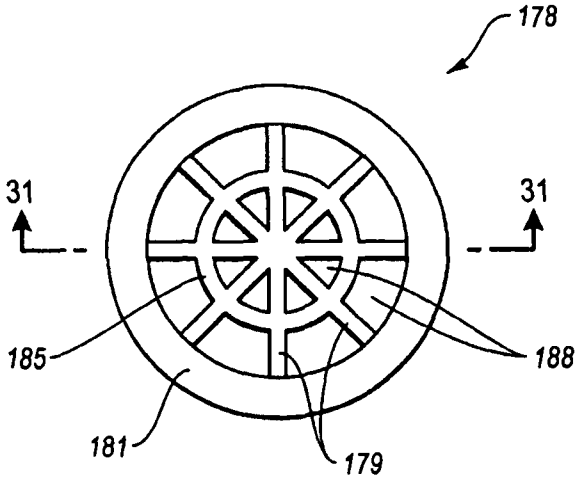

FIG. 30

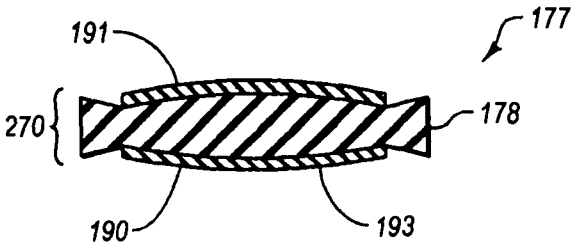

FIG. 31

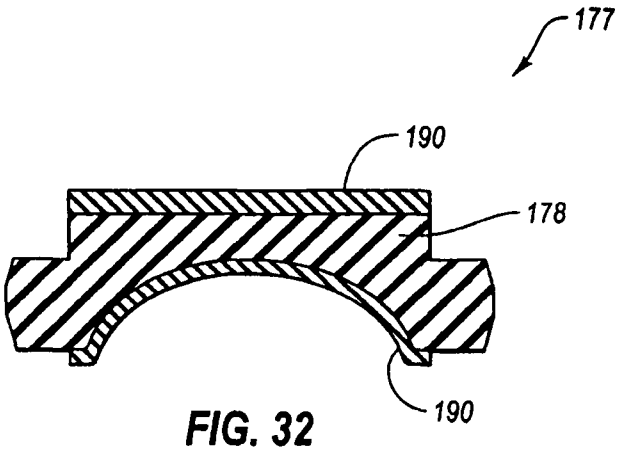

FIG. 32

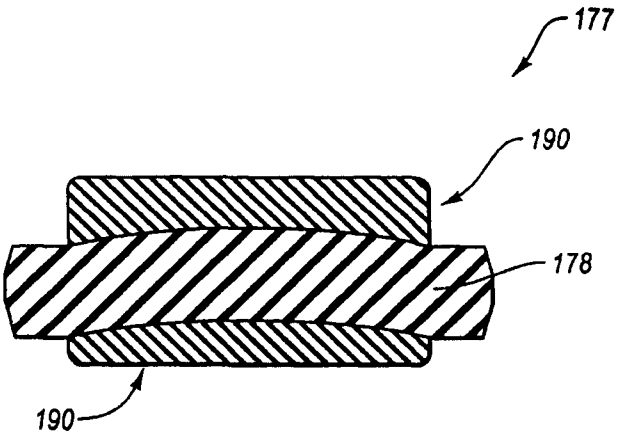

FIG. 33

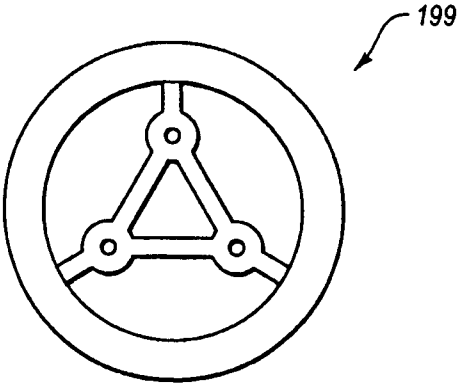

FIG. 34

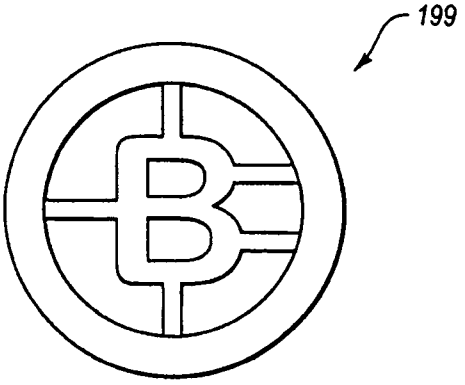

FIG. 35

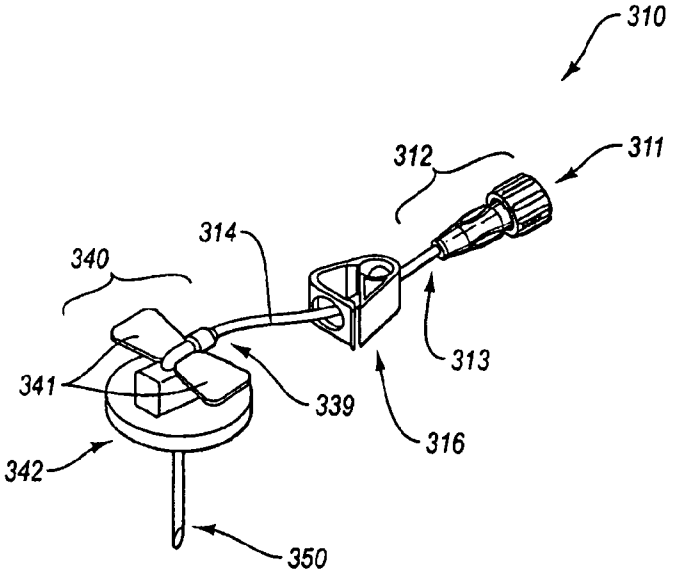
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FIG. 36

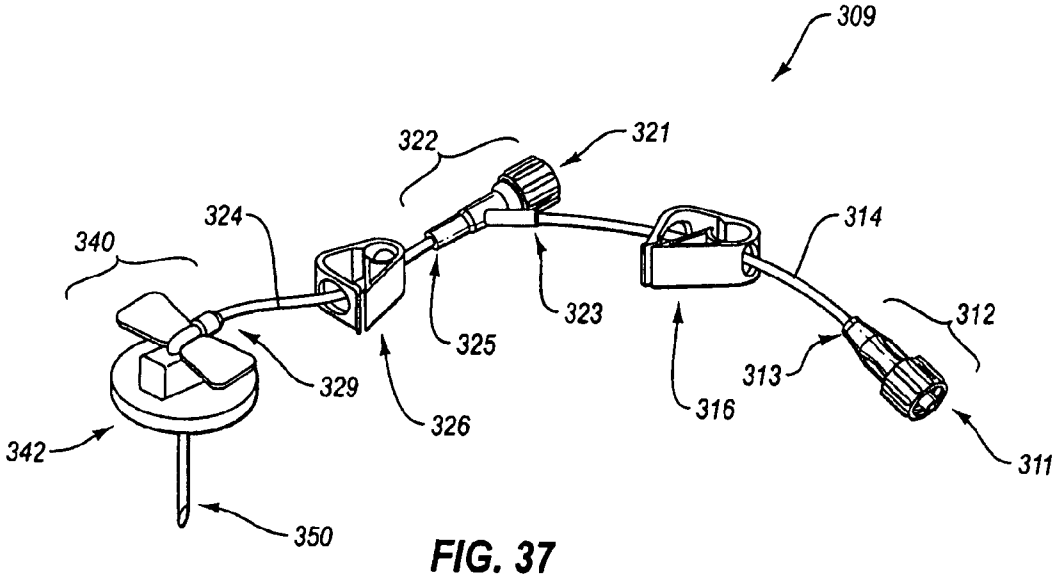
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FIG. 37

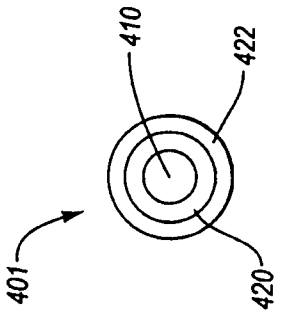

FIG. 39

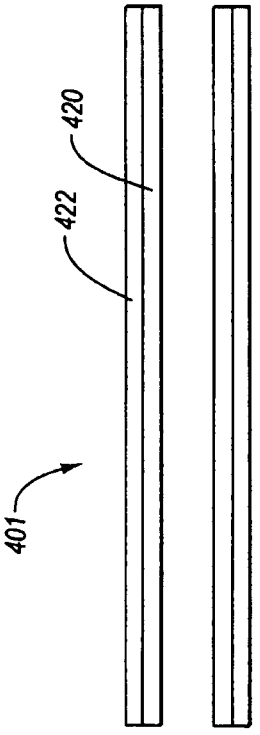

FIG. 38

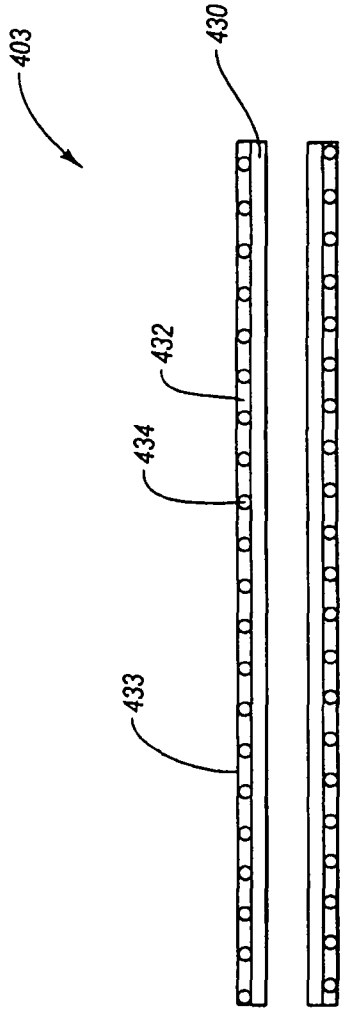

FIG. 40

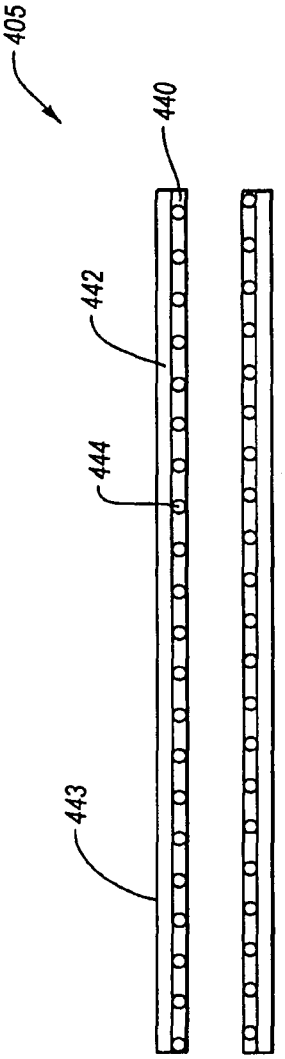

FIG. 41

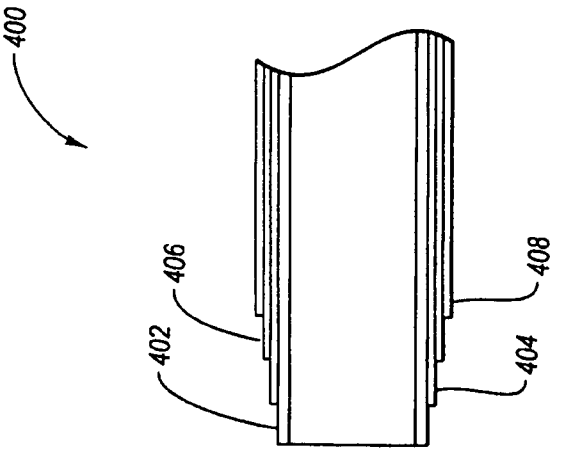

FIG. 43

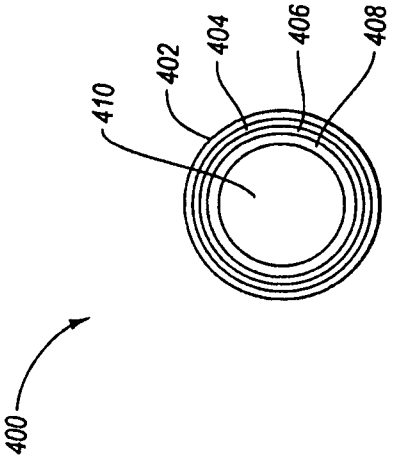

FIG. 42

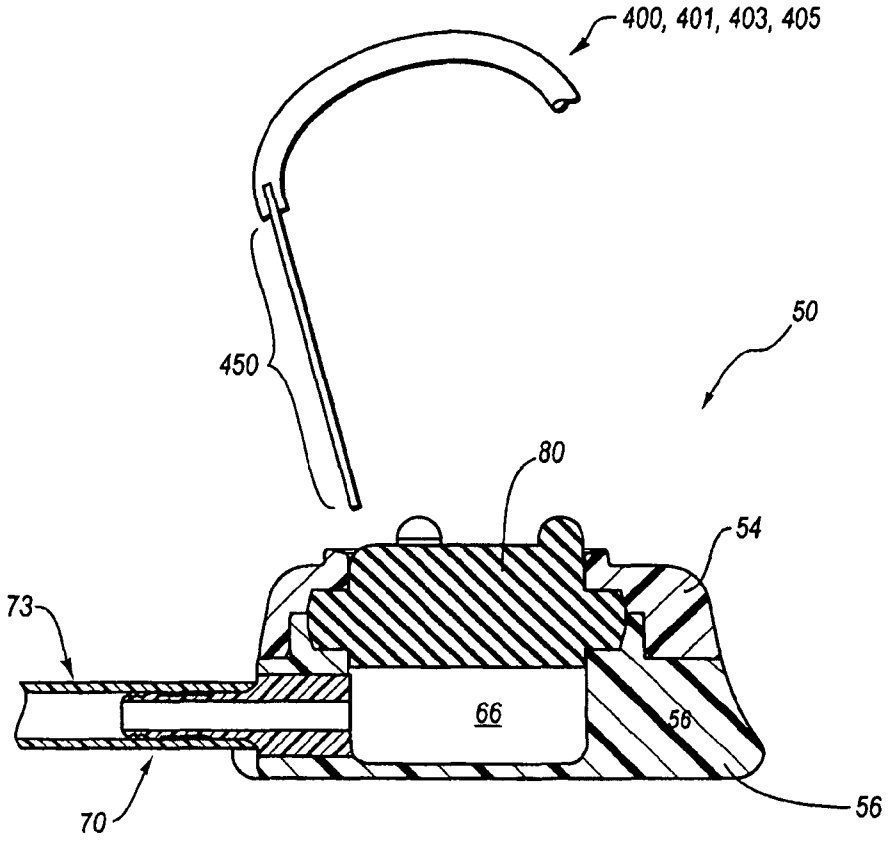
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FIG. 44

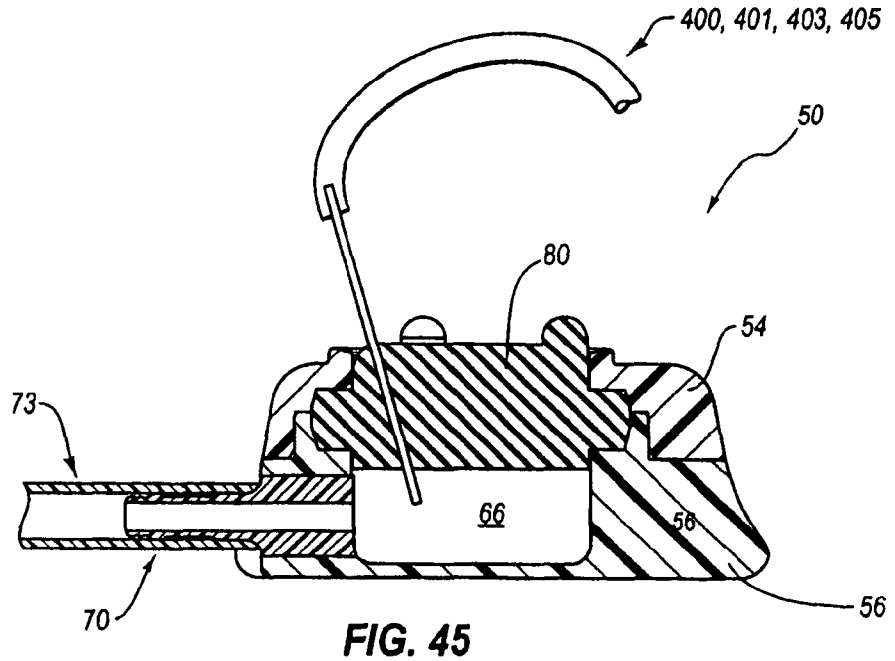
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FIG. 45

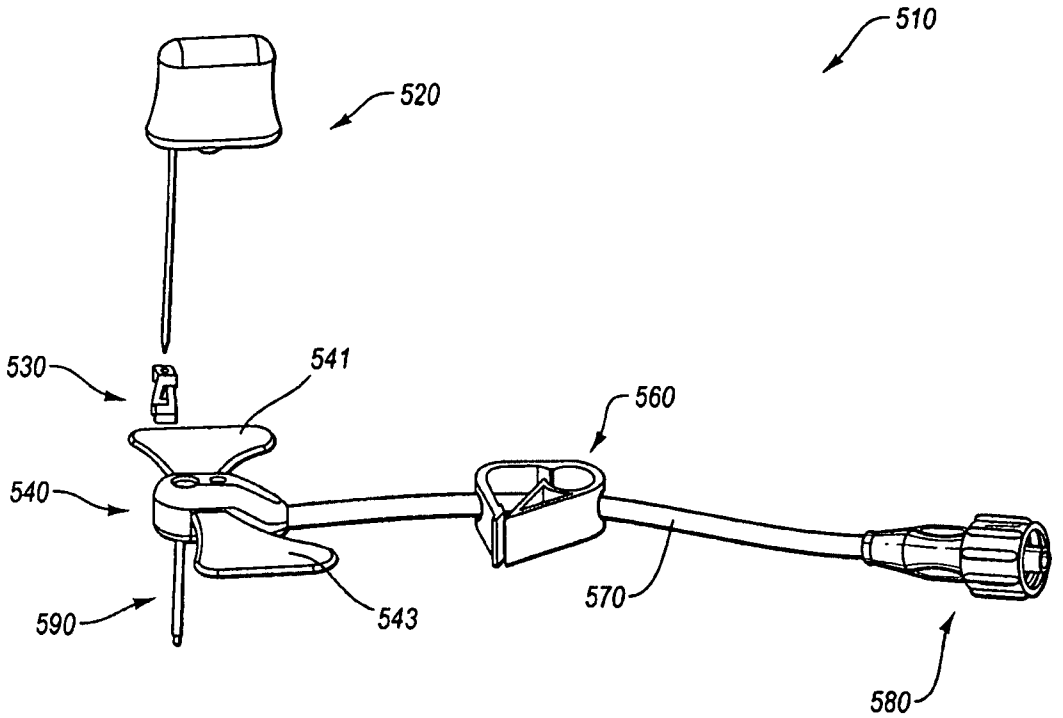

FIG. 46

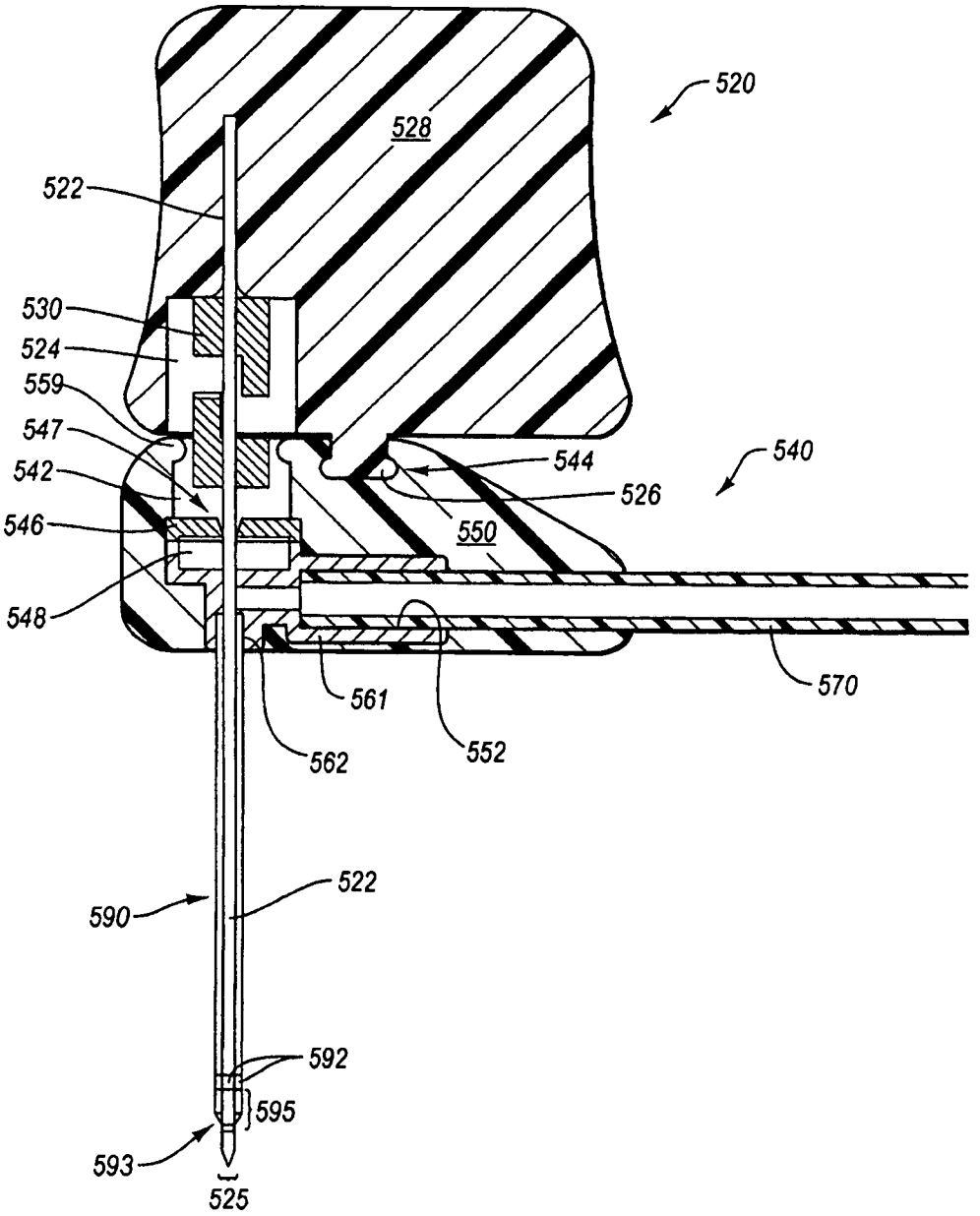
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FIG. 47

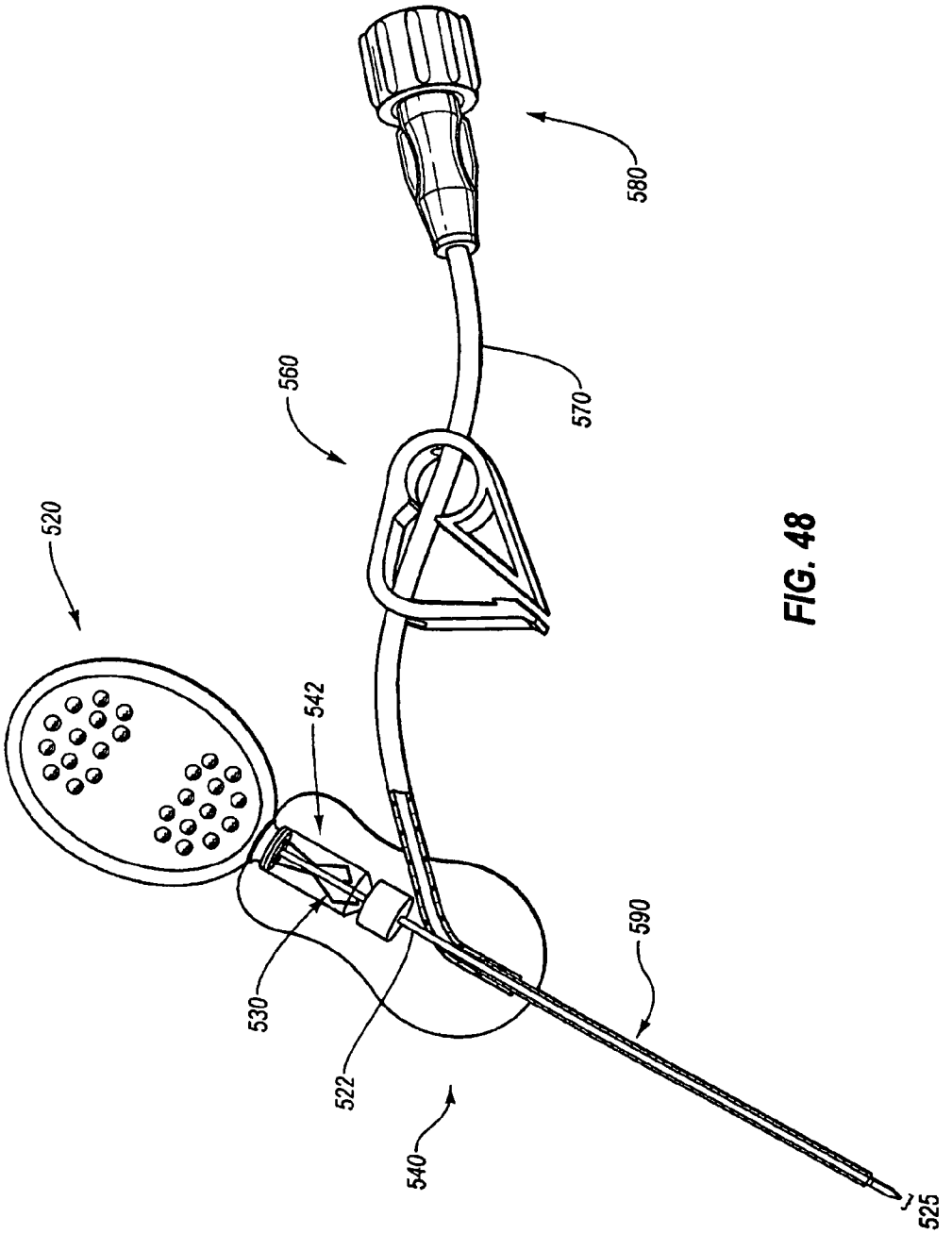

FIG. 48

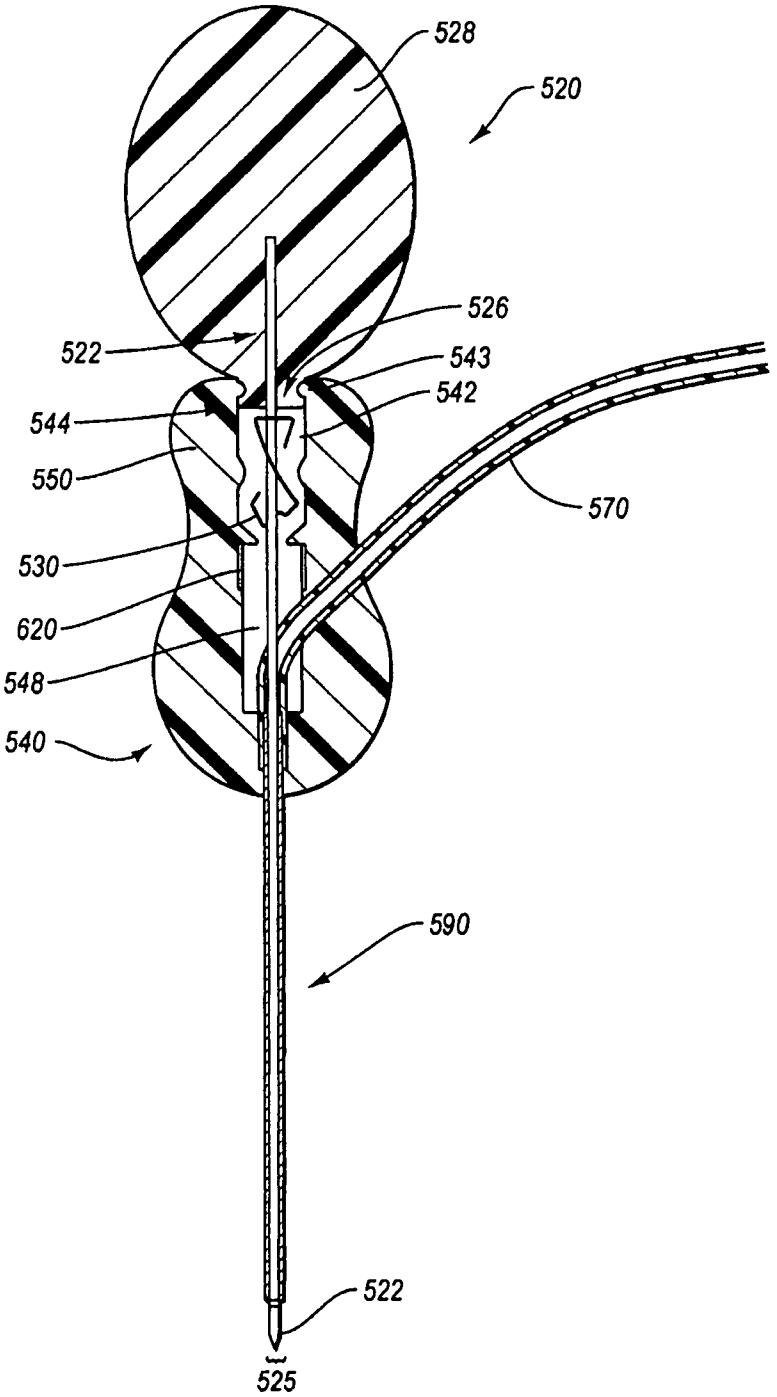

FIG. 49

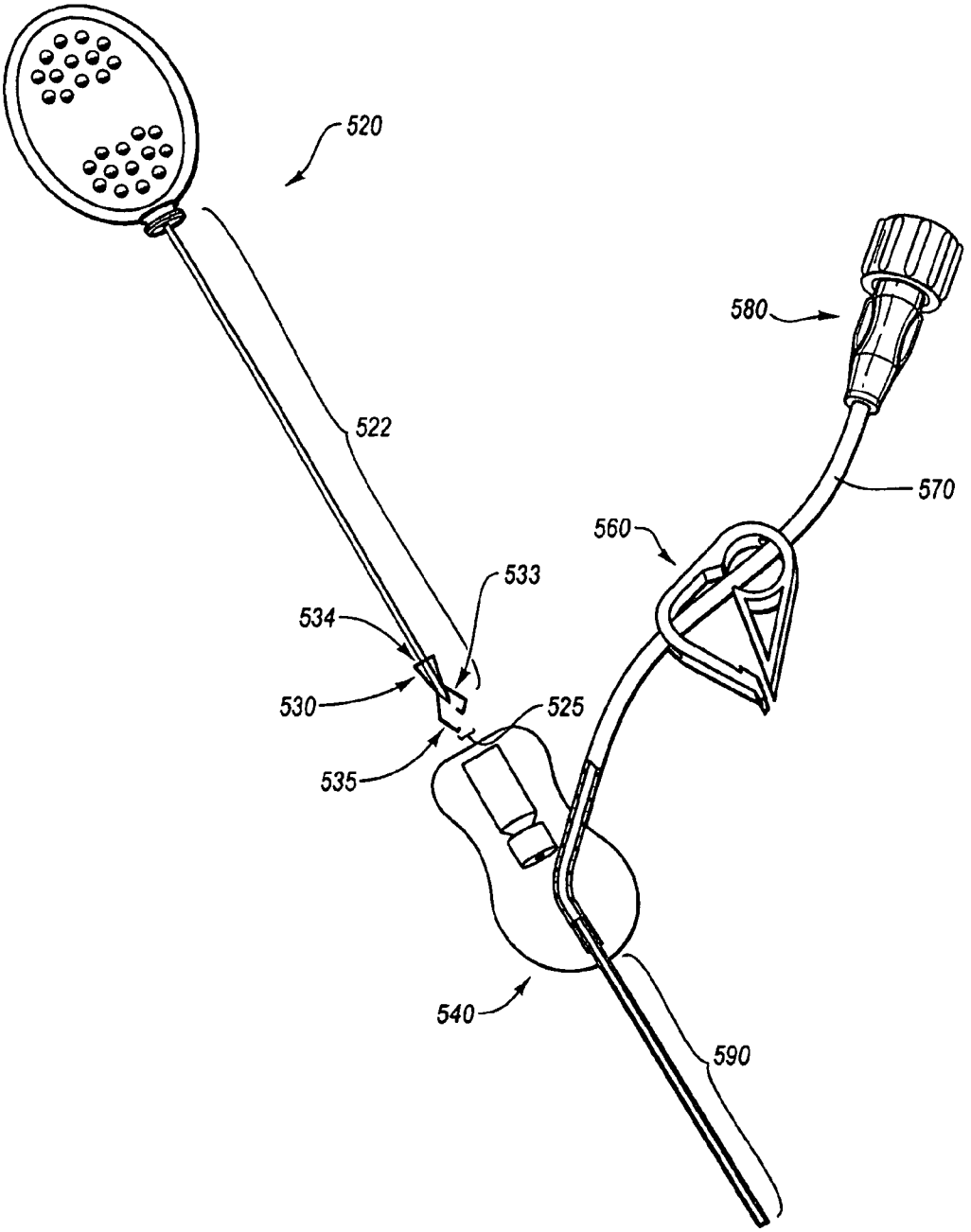

FIG. 50

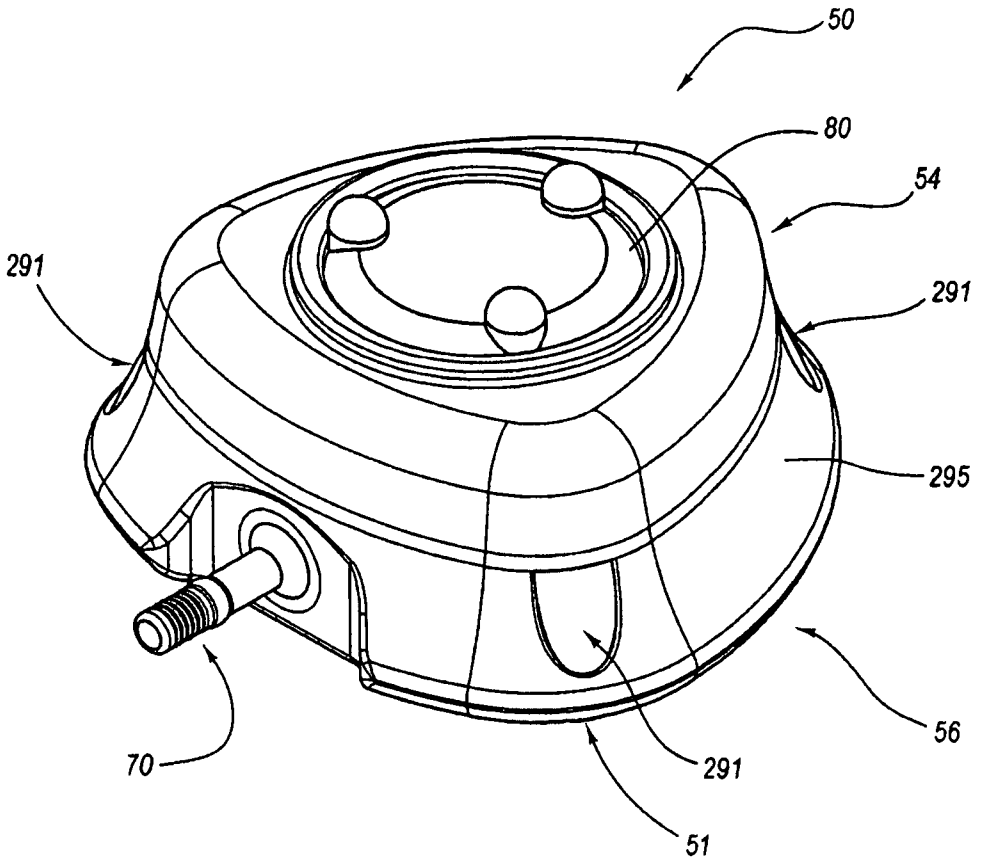

FIG. 51

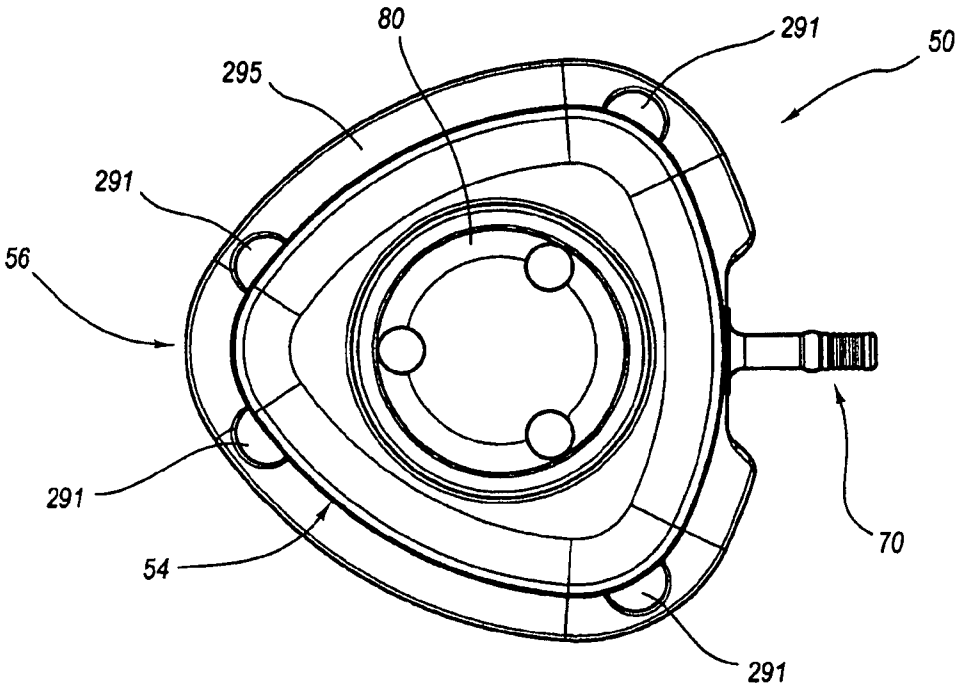

FIG. 52

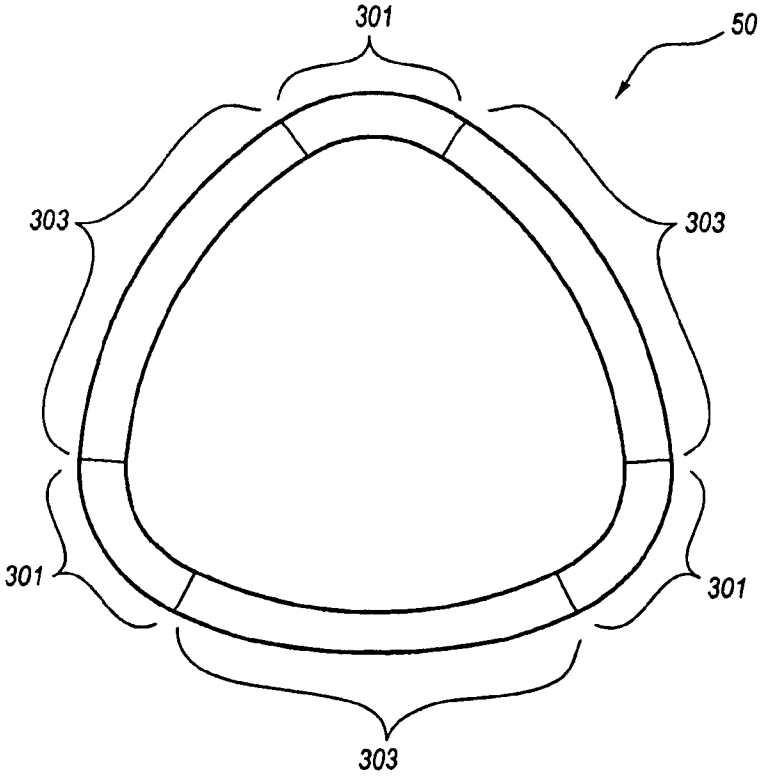

FIG. 53

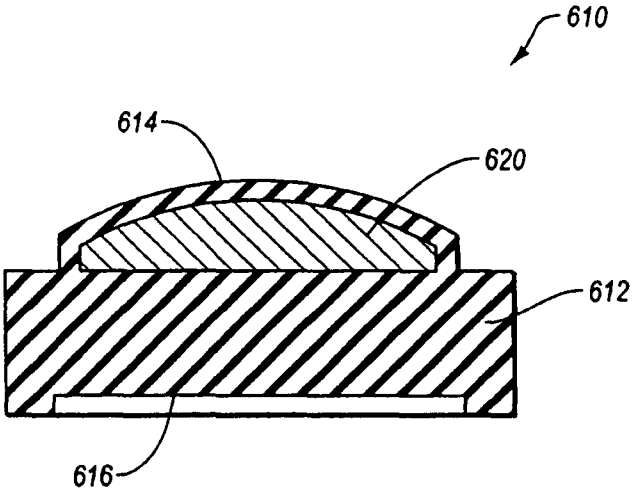

FIG. 54

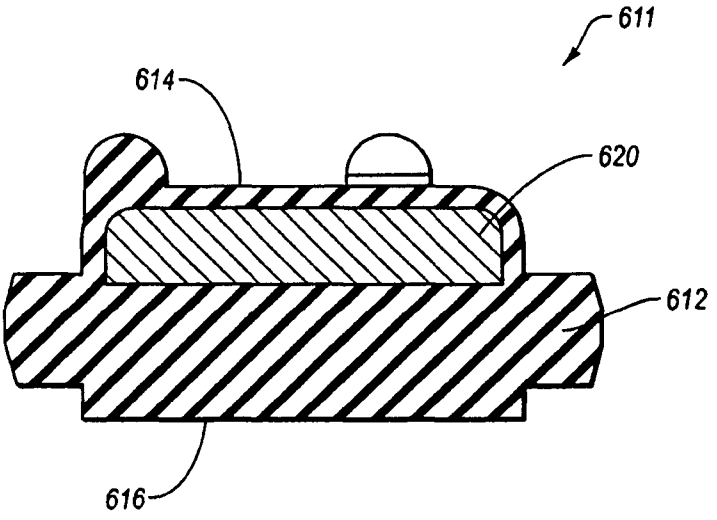

FIG. 55

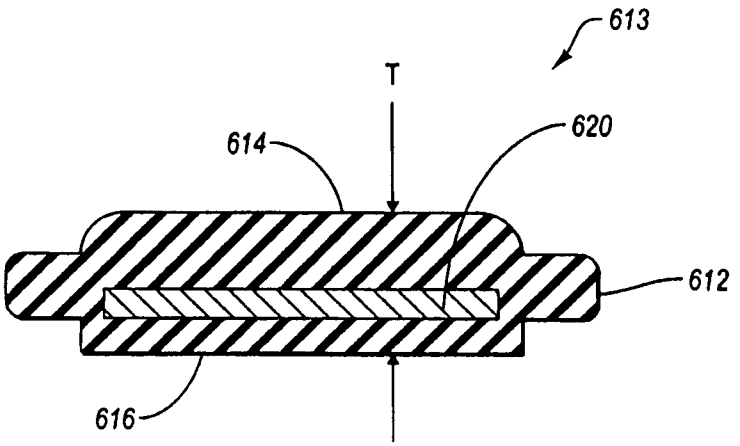

FIG. 56

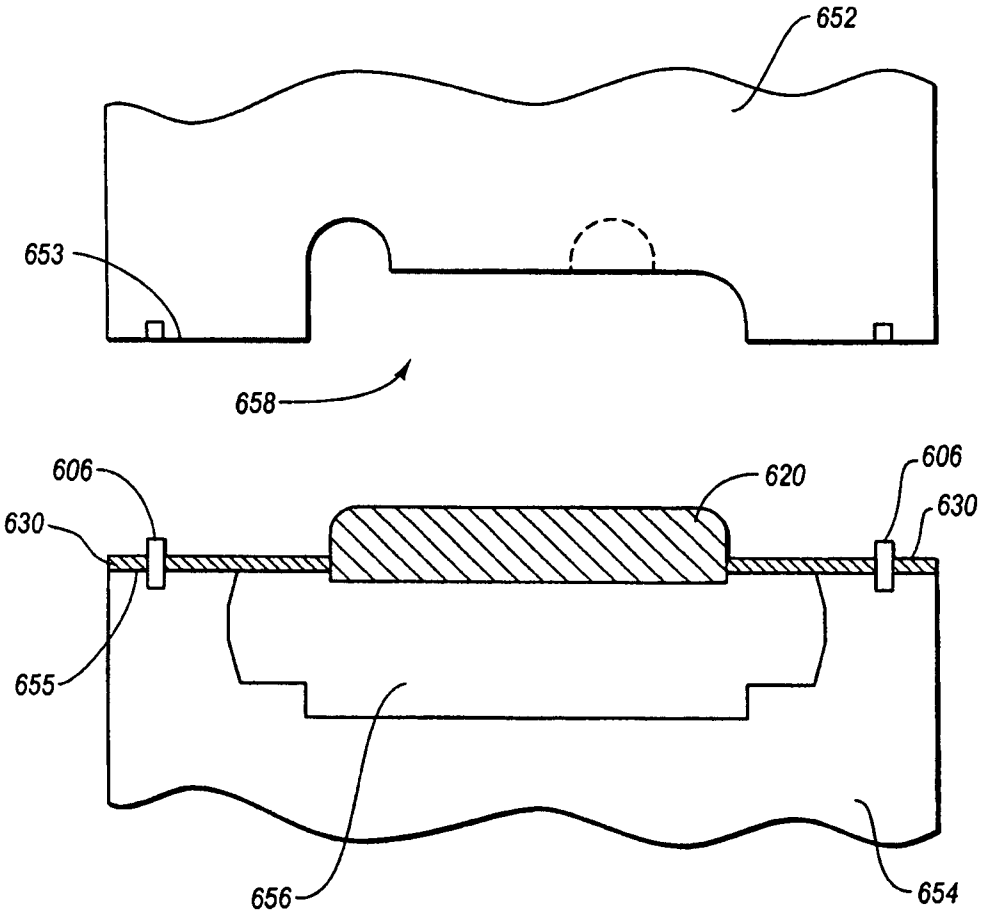

FIG. 57

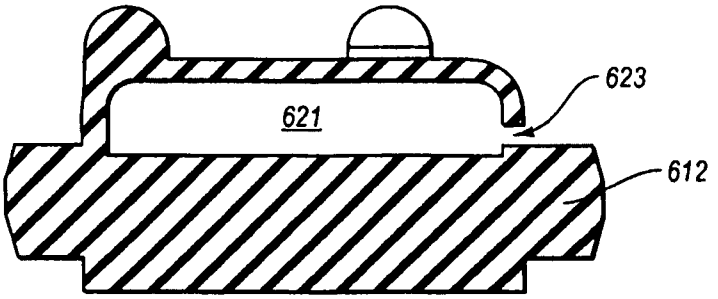

FIG. 58

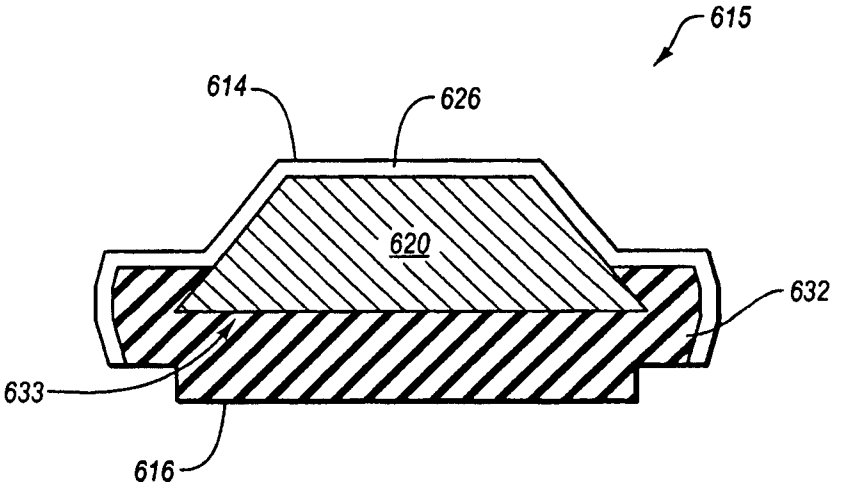

FIG. 59

ASSEMBLIES FOR IDENTIFYING A POWER INJECTABLE ACCESS PORT

CROSS-REFERENCE TO RELATED APPLICATIONS

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

BACKGROUND

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

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

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

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

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

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

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

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

SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

What is claimed is:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

* * * * *

EXHIBIT 2

US008545460B2

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

(10) **Patent No.: US 8,545,460 B2**
(45) **Date of Patent: Oct. 1, 2013**

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

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A61M 37/00 (2006.01)

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

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

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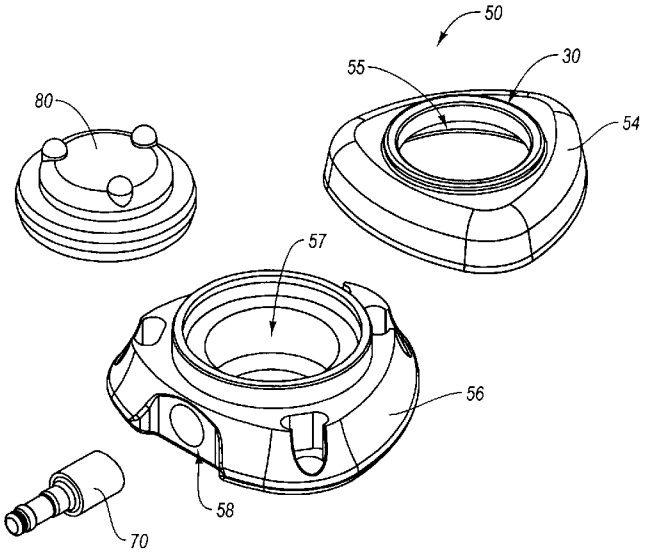
(57) **ABSTRACT**

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

4 Claims, 32 Drawing Sheets



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U.S. Appl. No. 95/002,090, filed Aug. 20, 2012 Office Action in and Order Granting/Denying Request for Inter Partes Reexamination dated Nov. 7, 2012.
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U.S. Appl. No. 12/420,007, filed Apr. 7, 2009 Final Office Action dated Mar. 22, 2013.
U.S. Appl. No. 12/917,323, filed Nov. 1, 2010 Advisory Action dated Apr. 10, 2013.
U.S. Appl. No. 13/438,586, filed Apr. 3, 2012 Final Office Action dated Mar. 7, 2013.
U.S. Appl. No. 13/571,088, filed Aug. 9, 2012 Non-Final Office Action dated Feb. 27, 2013.

* cited by examiner

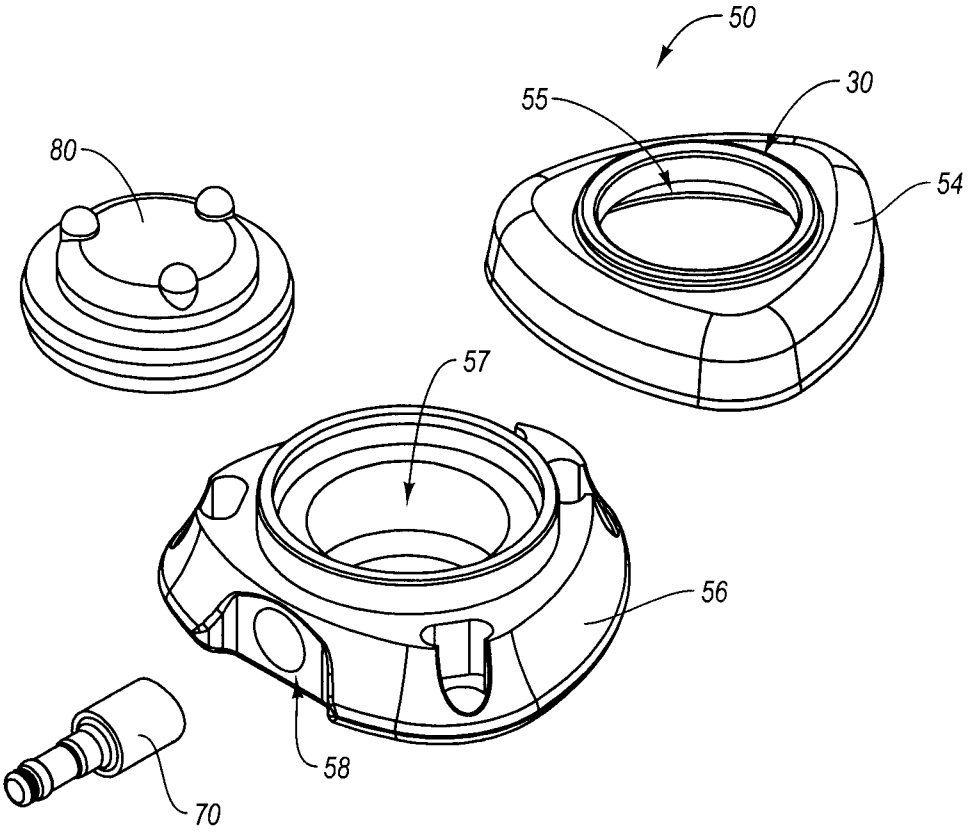


FIG. 1

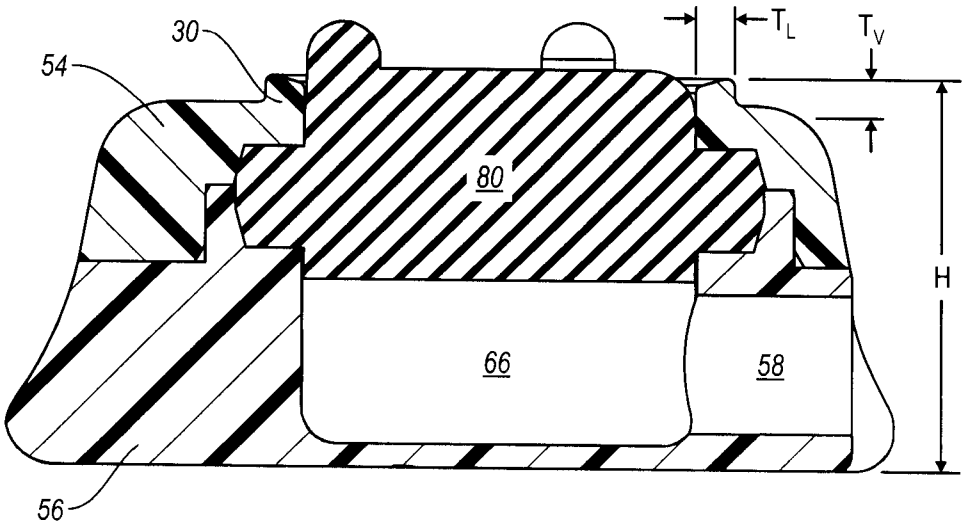


FIG. 2

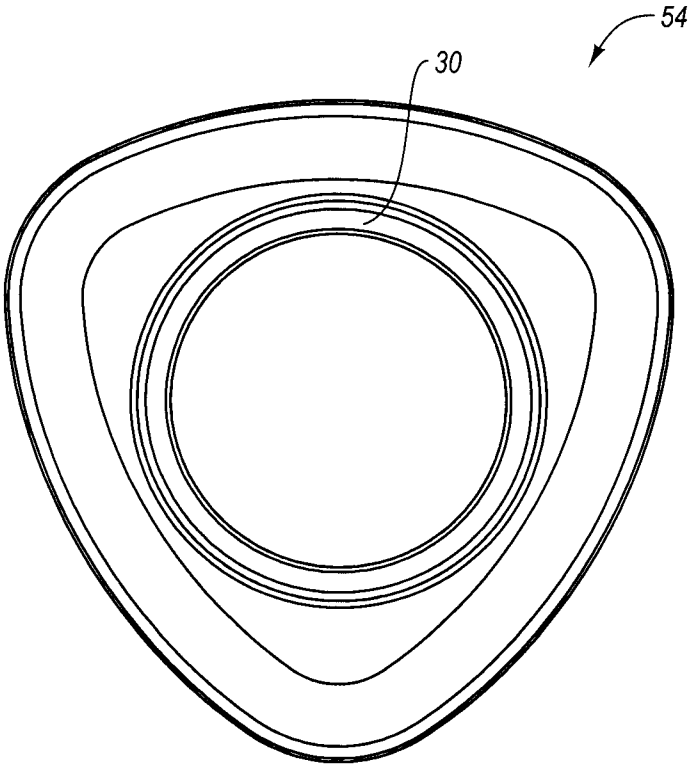


FIG. 3

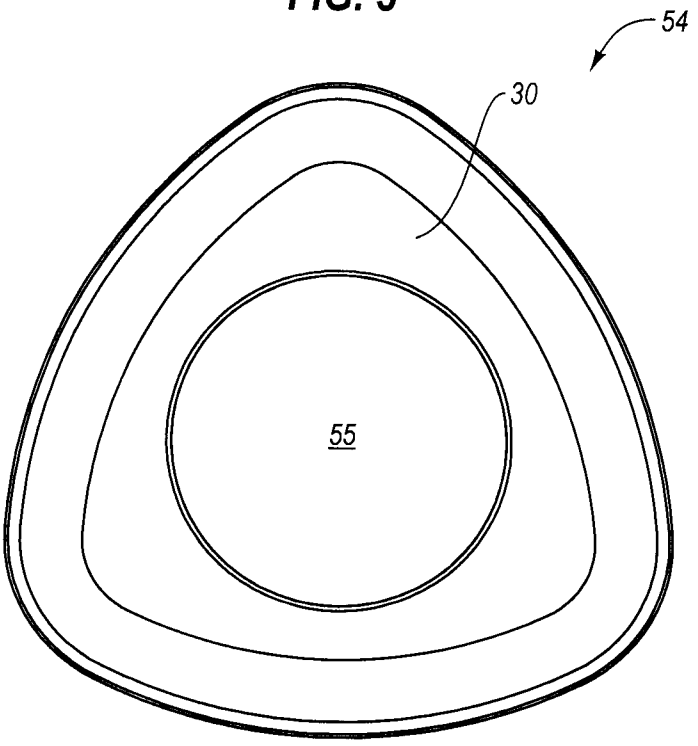


FIG. 4

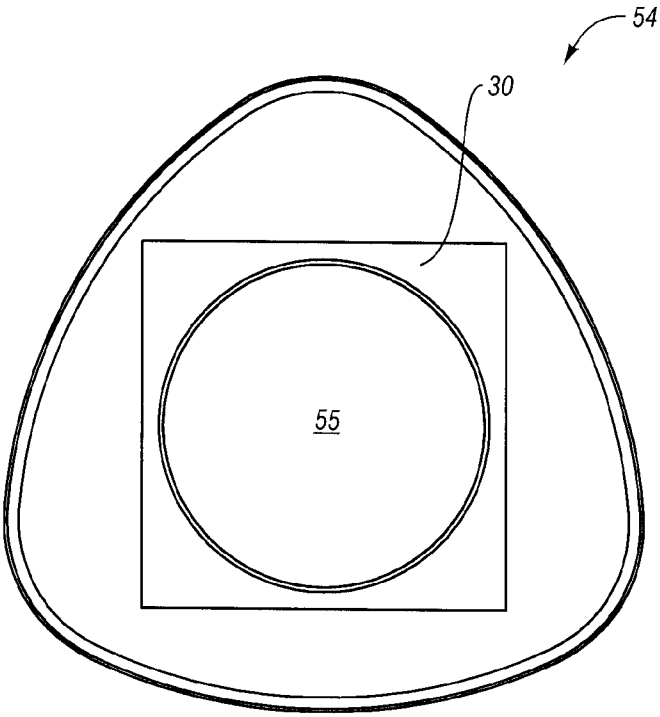


FIG. 5

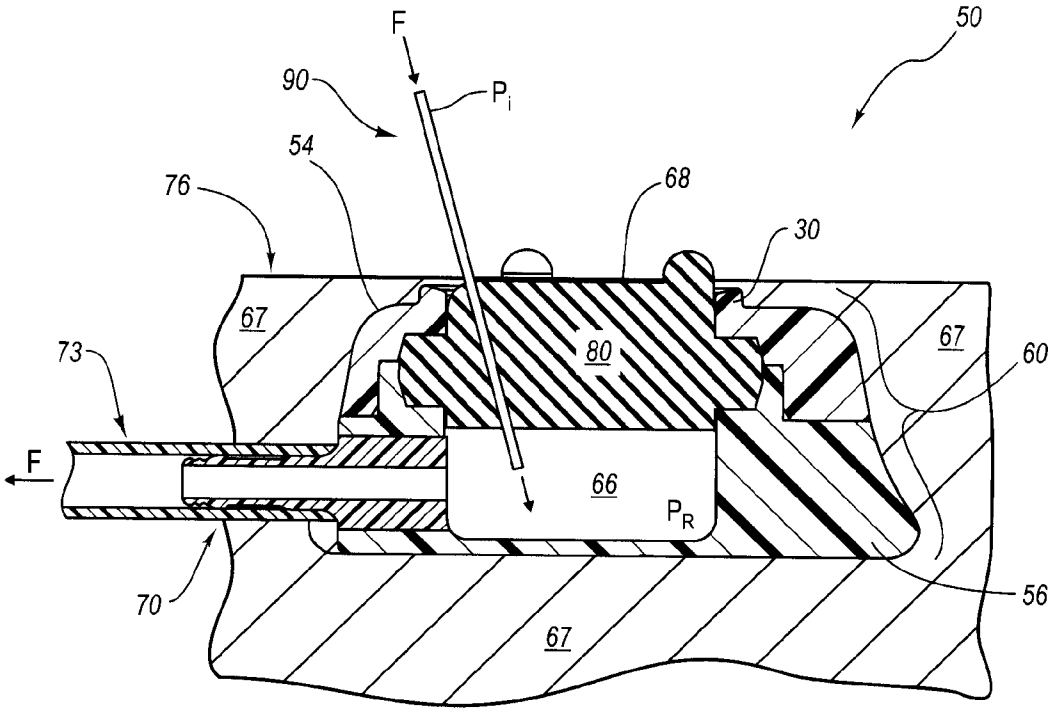


FIG. 6

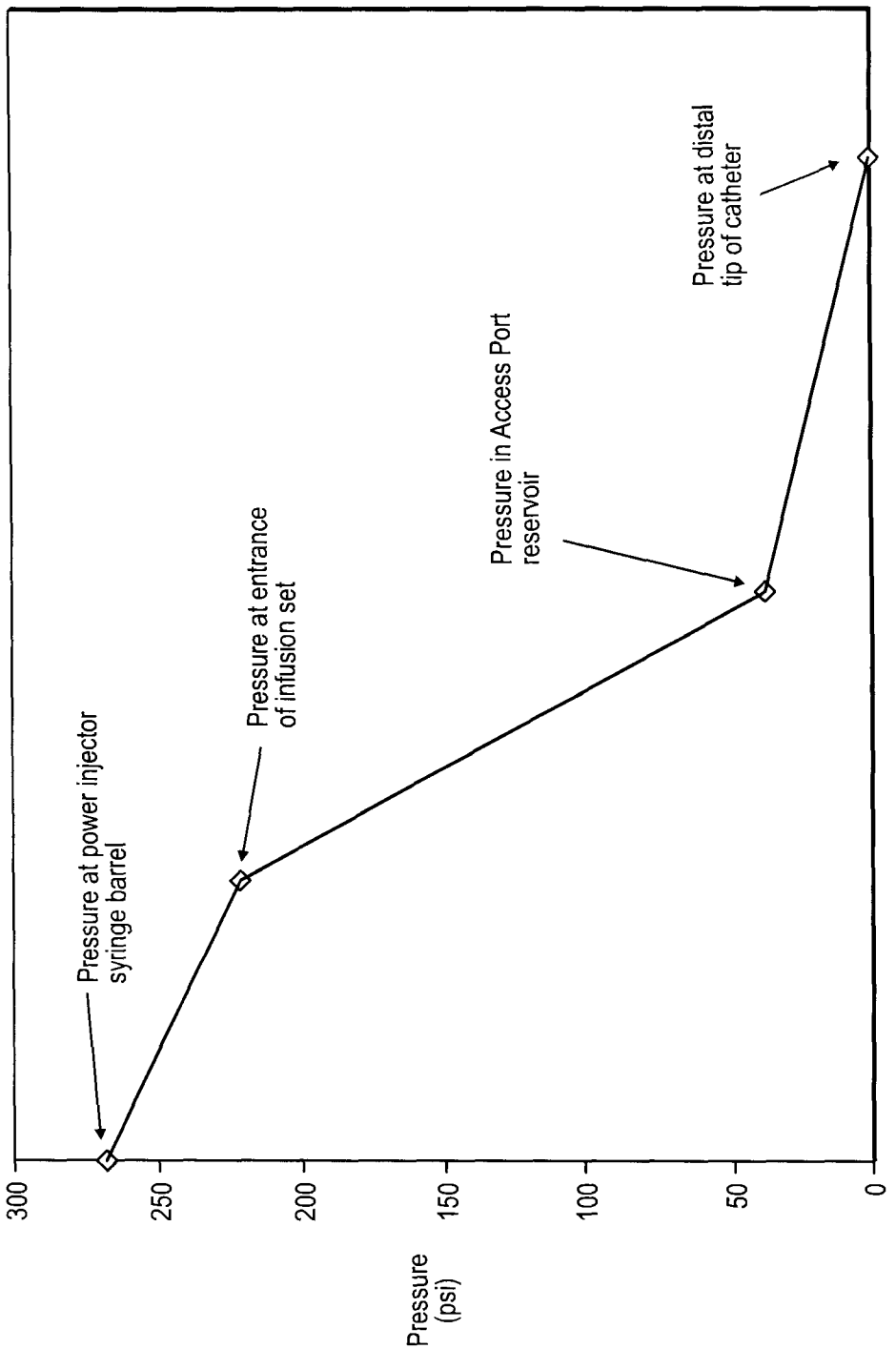

Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7

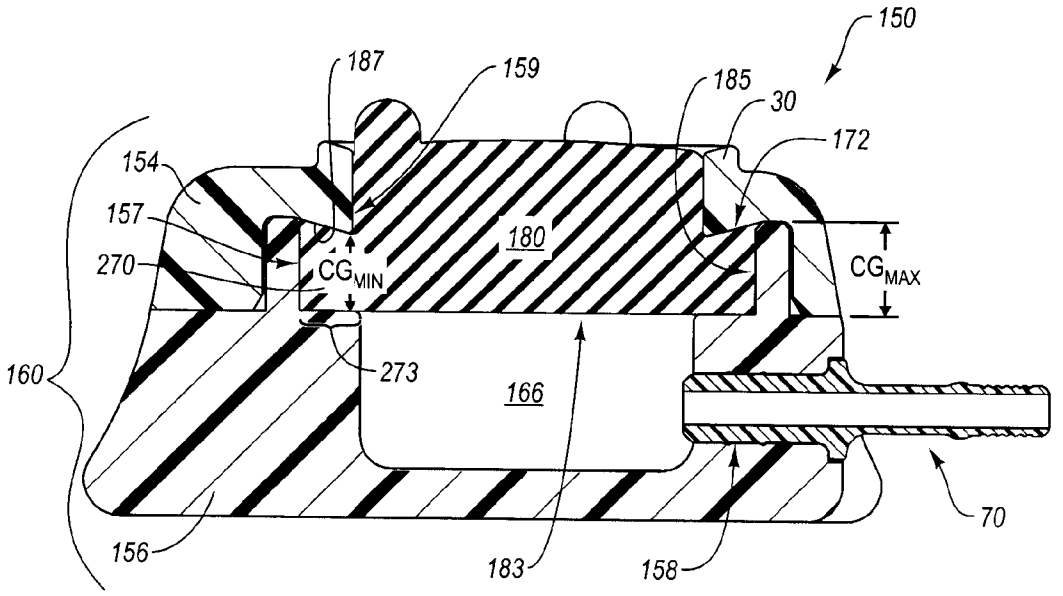

150
187
159
185
30
172
154
157
180
270
CG_{MIN}
CG_{MAX}
160
273
166
70
156
183
158

FIG. 8

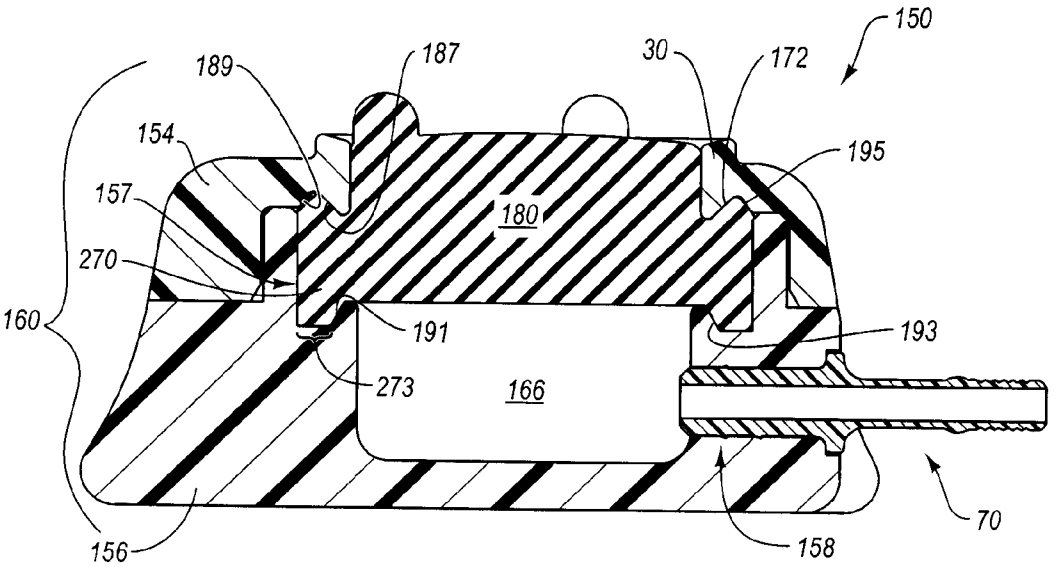

150
189
187
30
172
154
195
157
180
270
160
191
193
273
166
70
156
158

FIG. 9

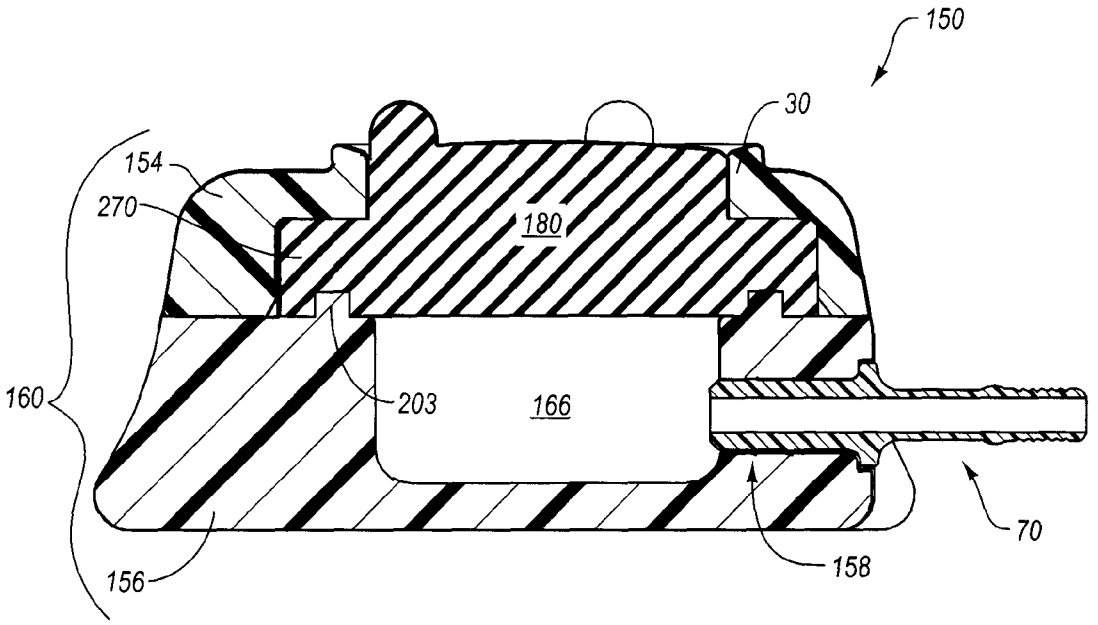
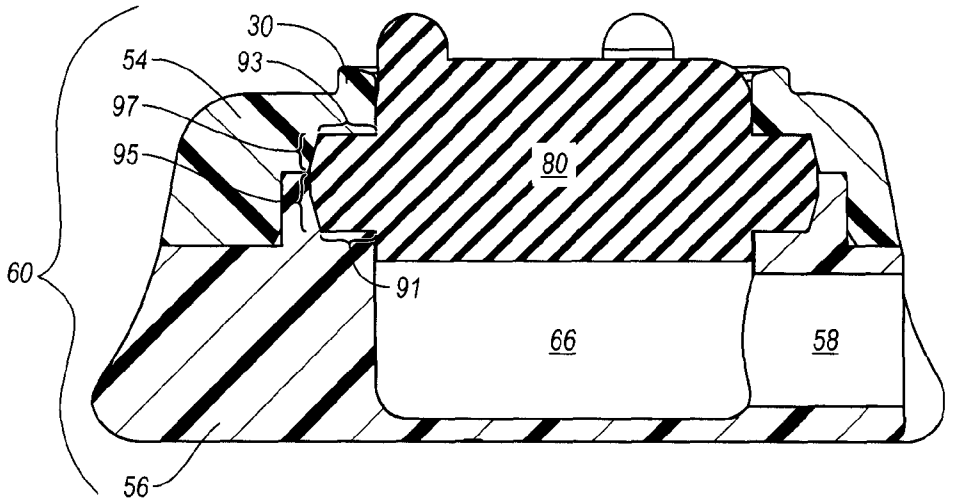

150
30
154
270
180
160
203
166
70
156
158

FIG. 10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54
93
97
95
80
60
91
66
58
56

FIG. 11

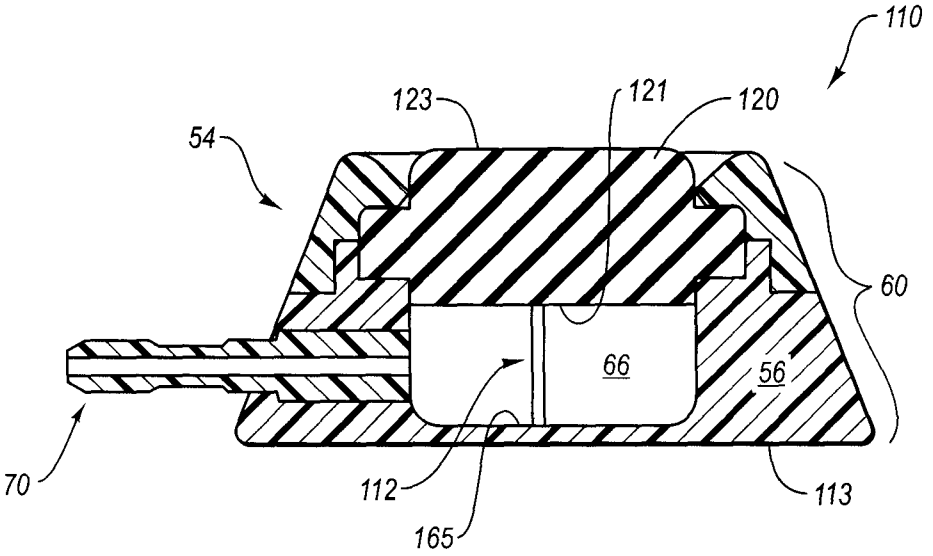
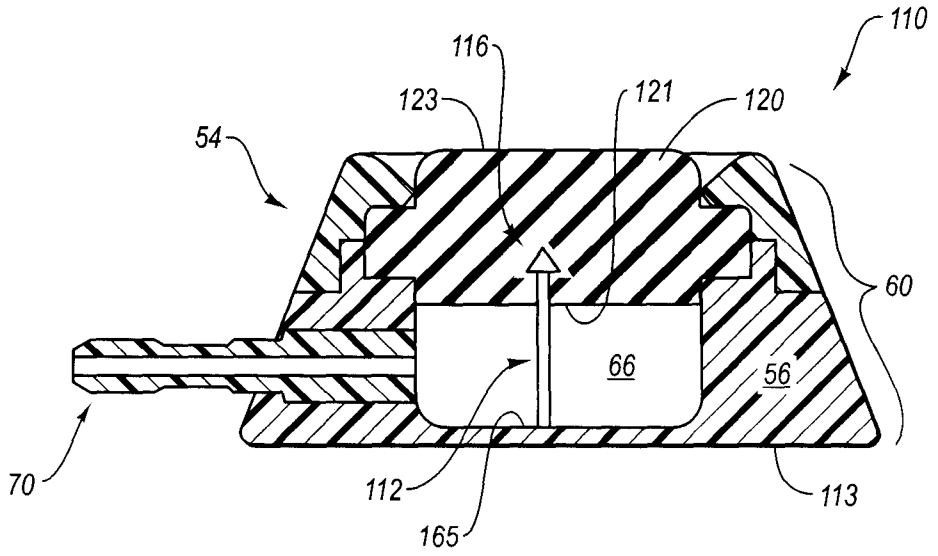

110
123
121
120
54
60
66
56
70
112
113
165

FIG. 12


110
116
123
121
120
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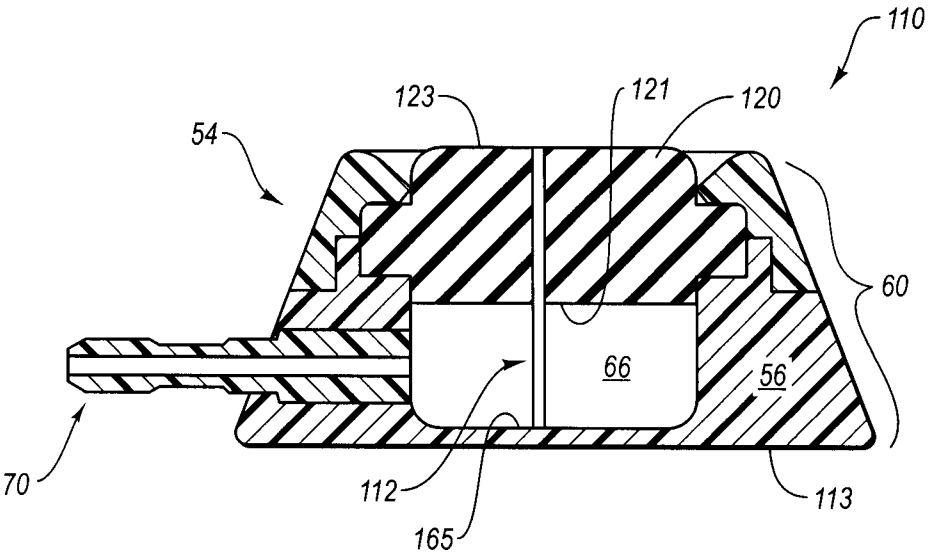
60
66
56
70
112
113
165

FIG. 13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123
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120
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66
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70
112
113
165

FIG. 14

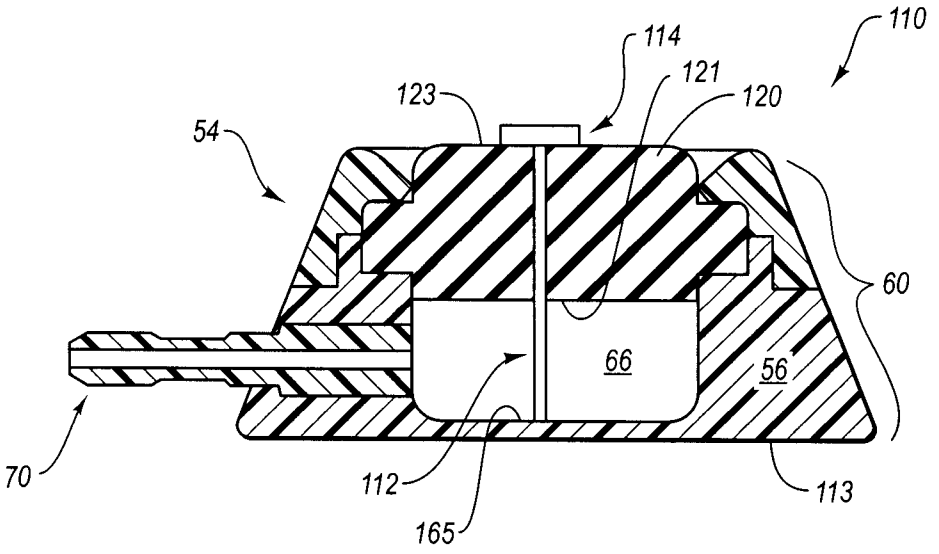
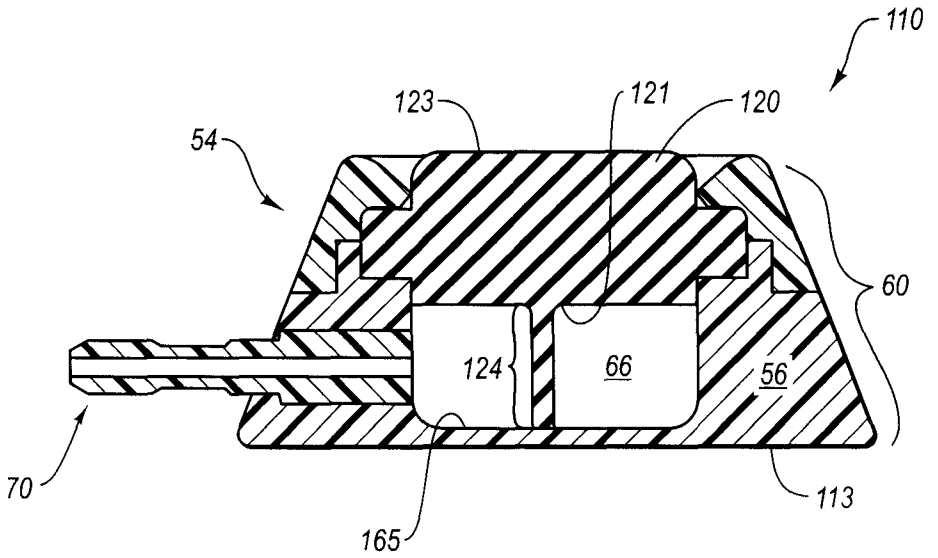

110
114
121
123
120
54
60
66
56
70
112
113
165

FIG. 15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123
121
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54
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124
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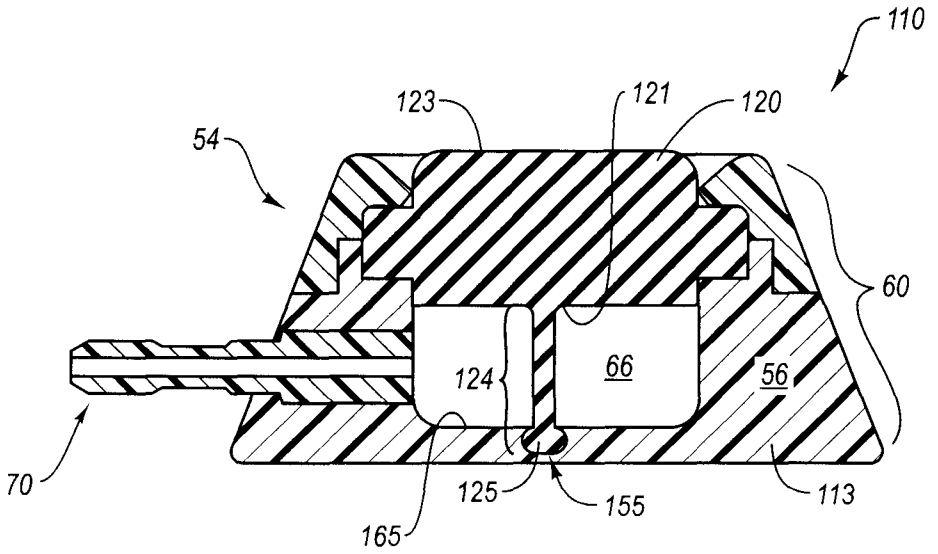
113
165

FIG. 16


110
123
121
120
54
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124
66
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70
125
155
113
165

FIG. 17

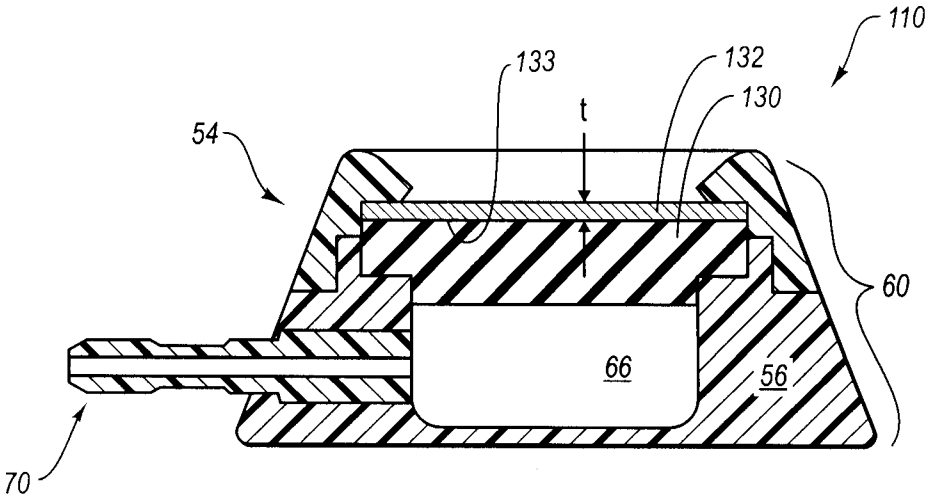
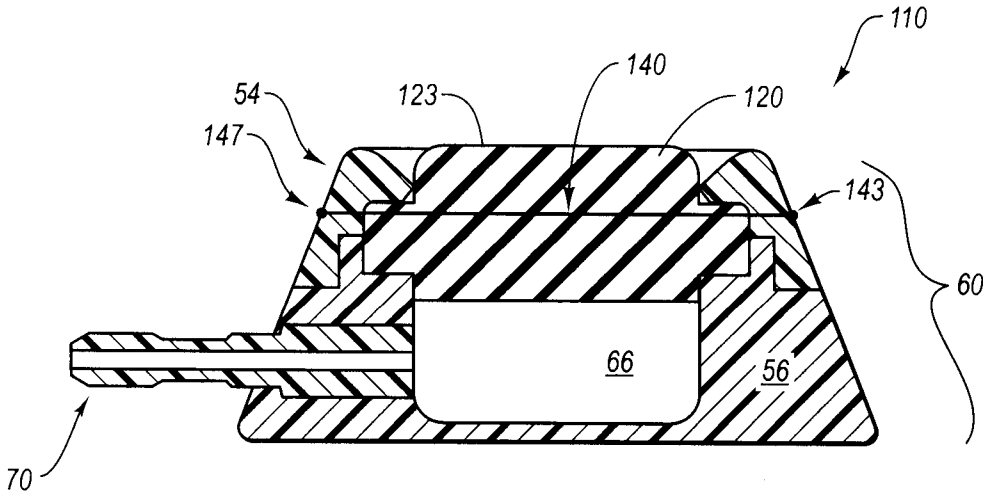

110
133
132
130
t
54
60
66
56
70

FIG. 18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140
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123
120
147
143
60
66
56
70

FIG. 19

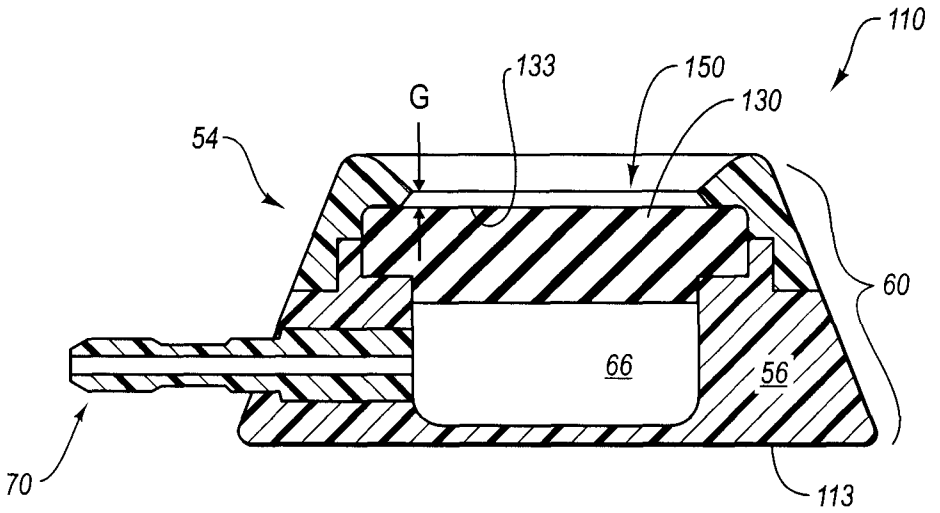


FIG. 20

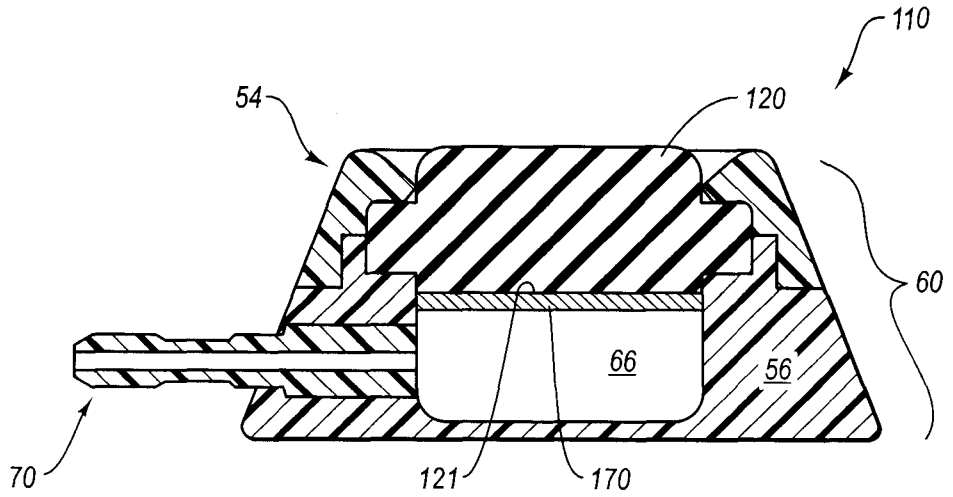


FIG. 21

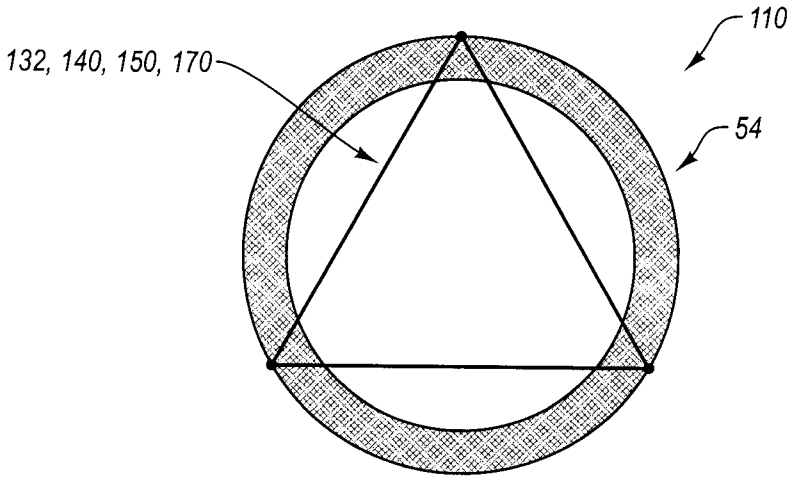


FIG. 22

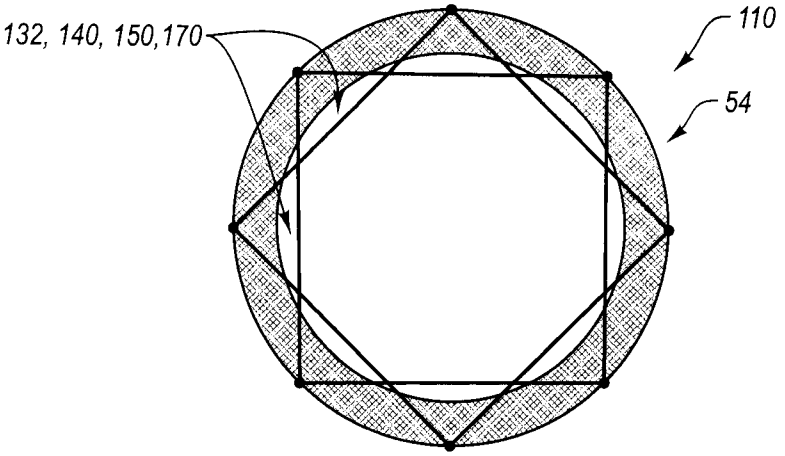


FIG. 23

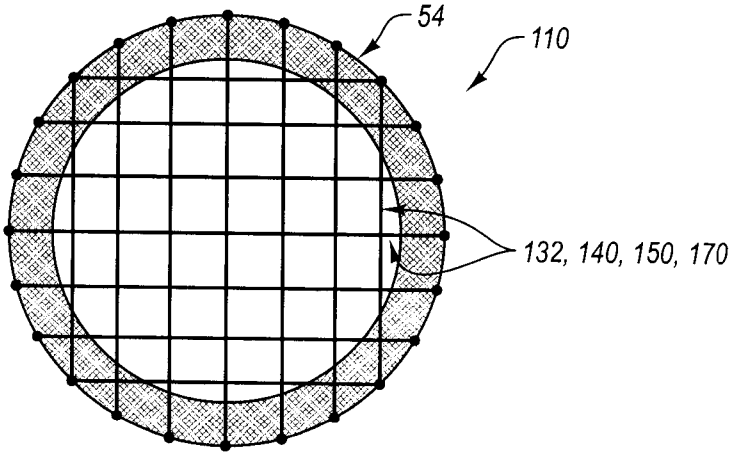


FIG. 24

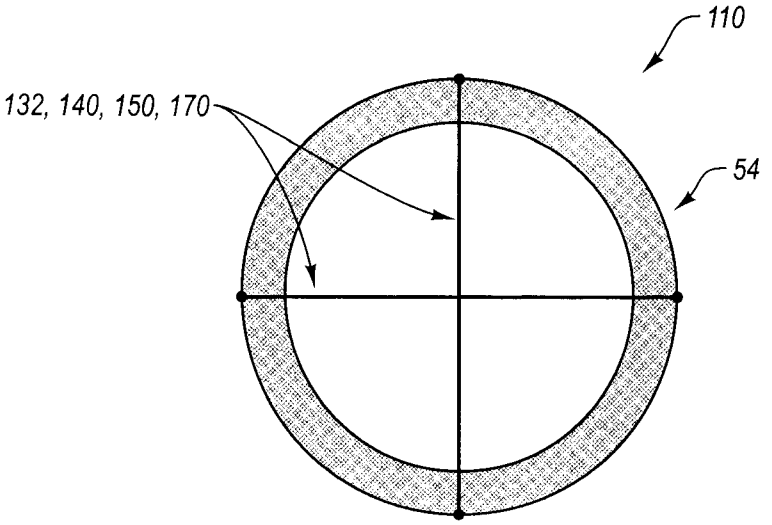


FIG. 25

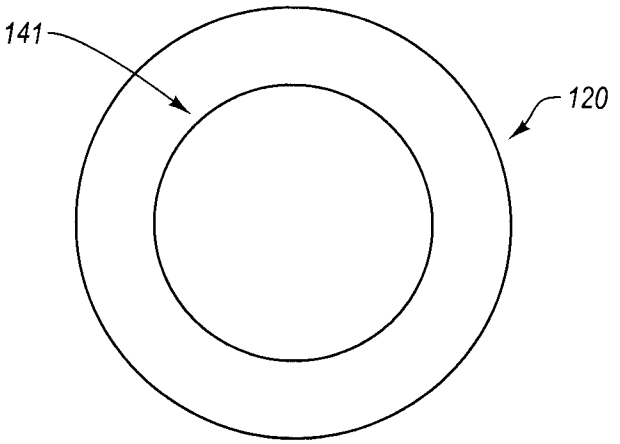


FIG. 26

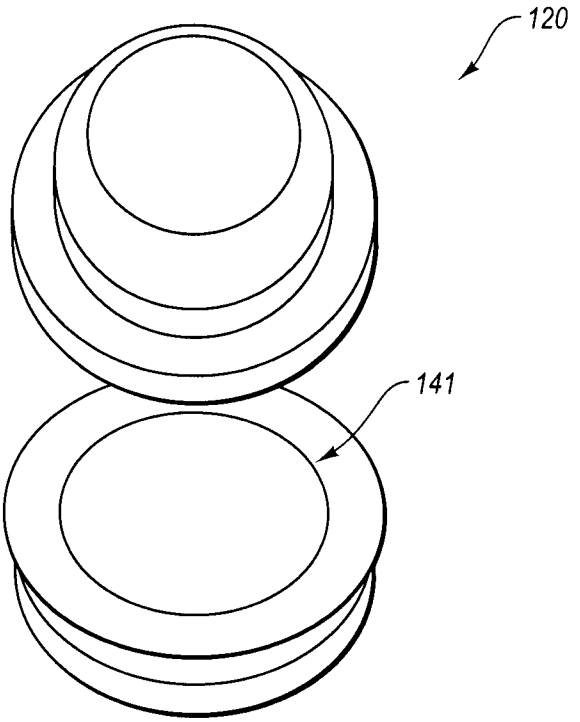


FIG. 27

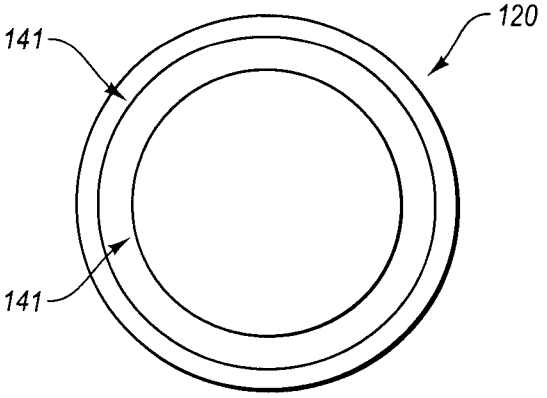


FIG. 28

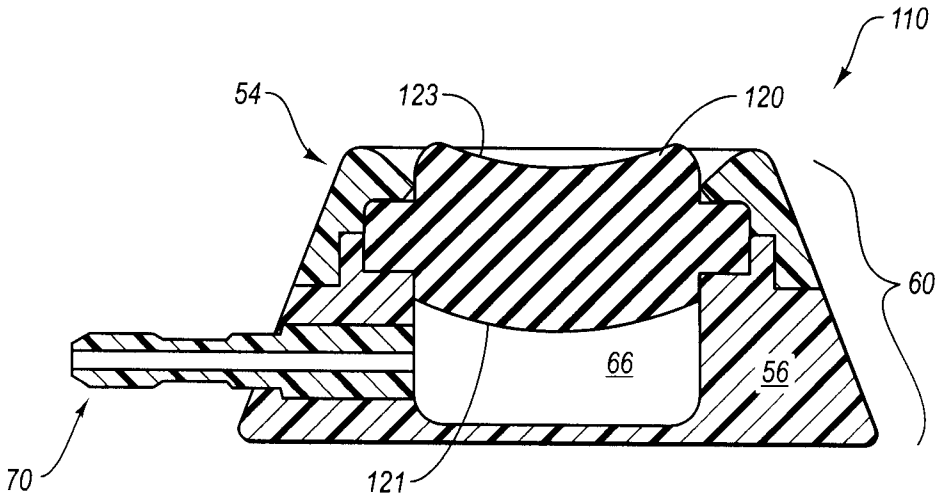


FIG. 29

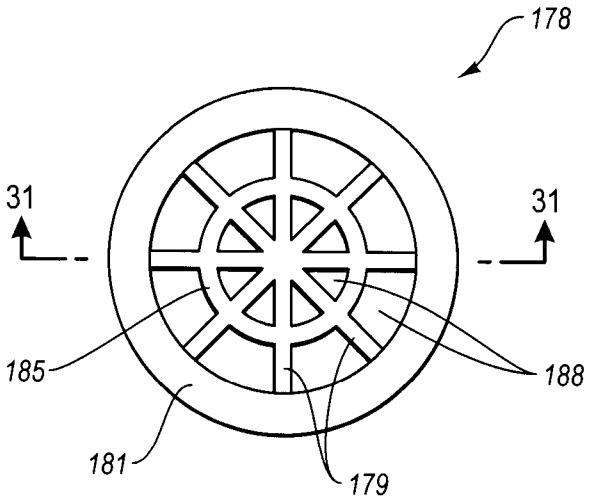


FIG. 30

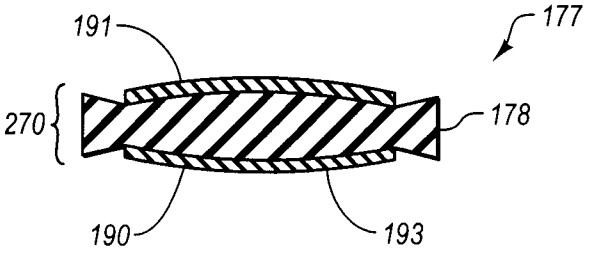


FIG. 31

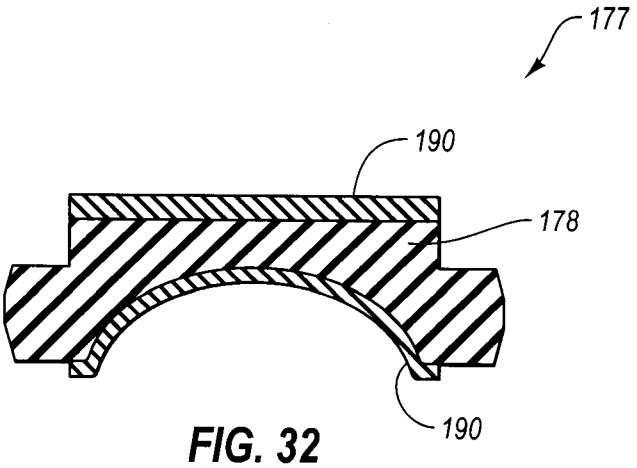


FIG. 32

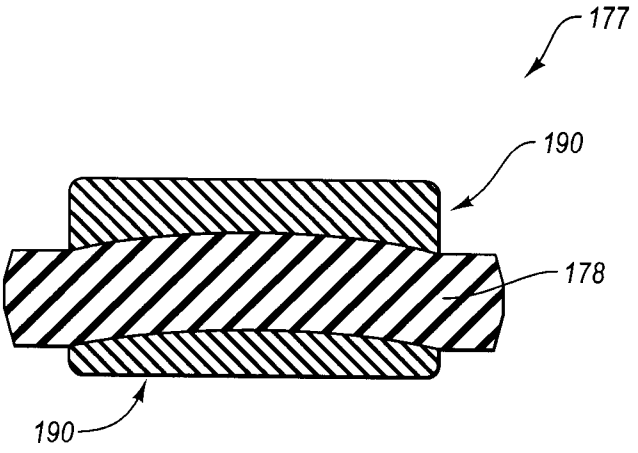


FIG. 33

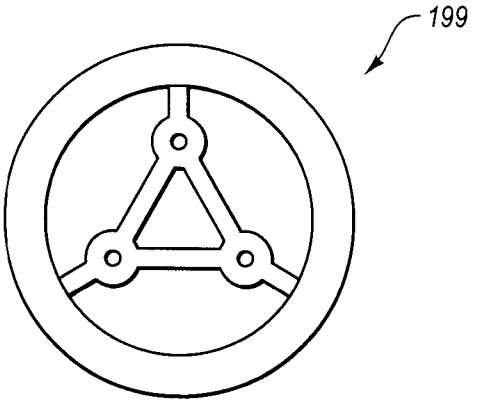


FIG. 34

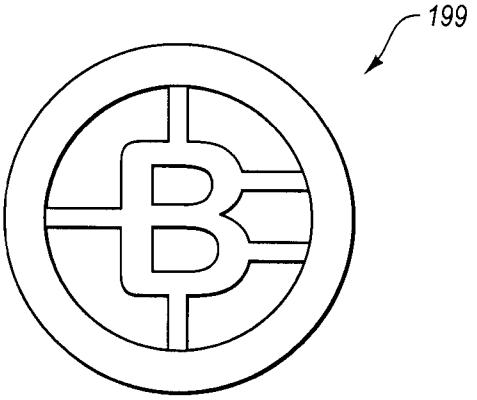
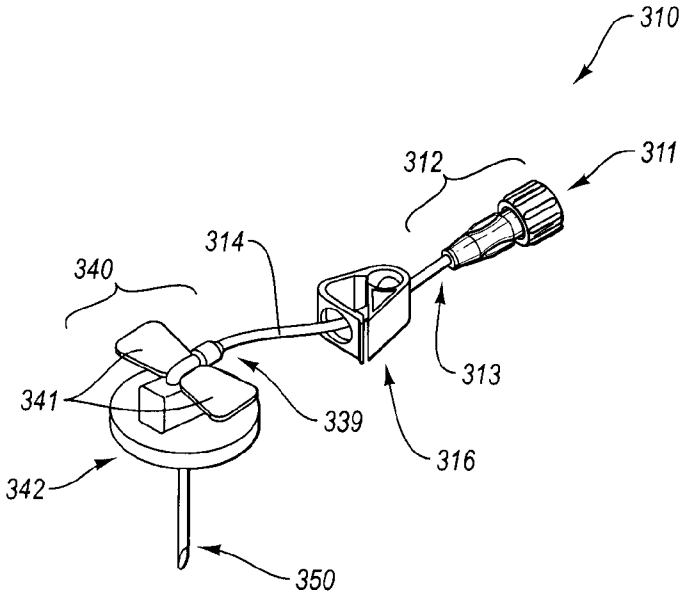


FIG. 35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312
311
314
340
313
341
339
316
342
350

FIG. 36

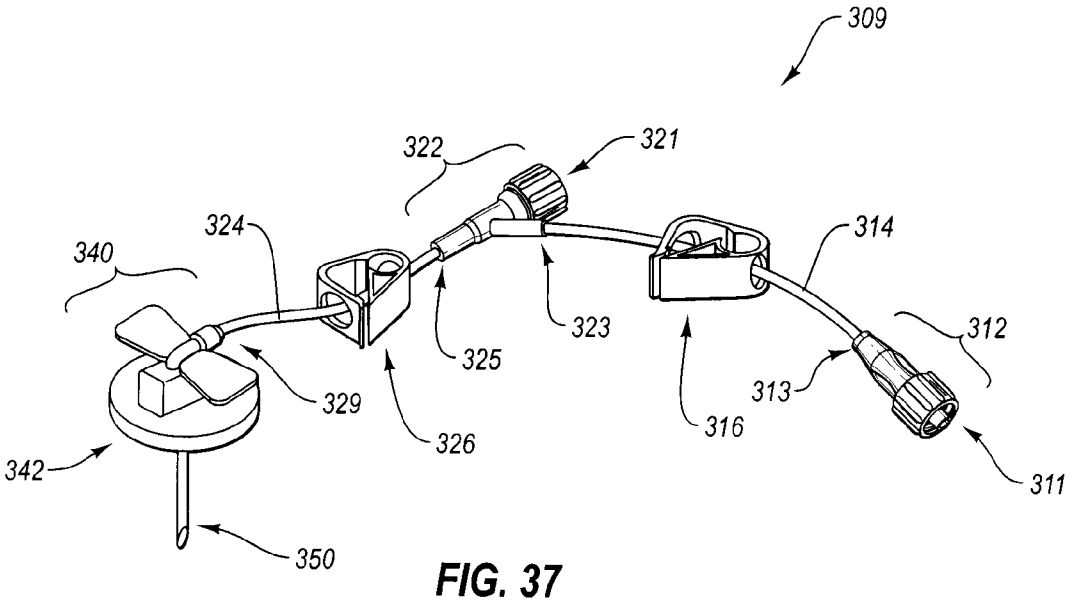
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FIG. 37

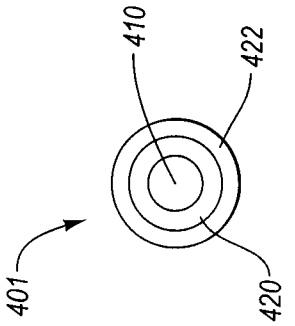


FIG. 39

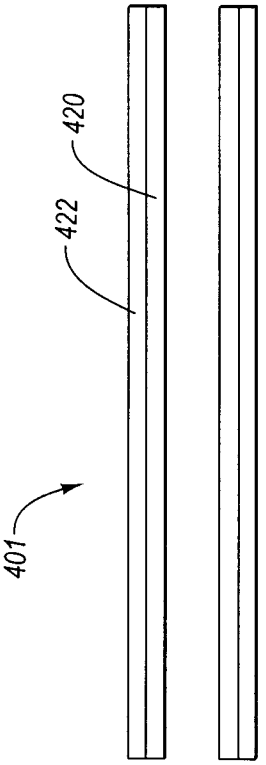


FIG. 38

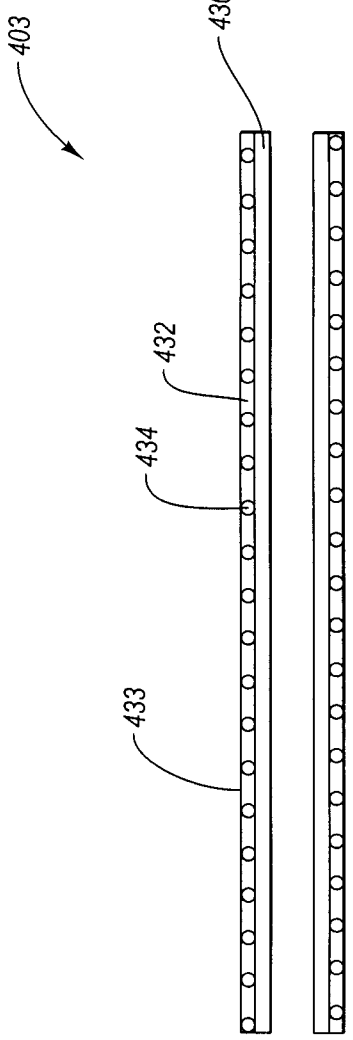


FIG. 40

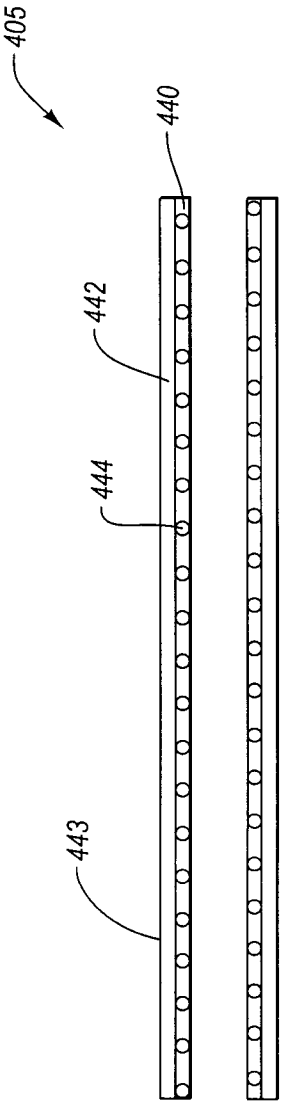


FIG. 41

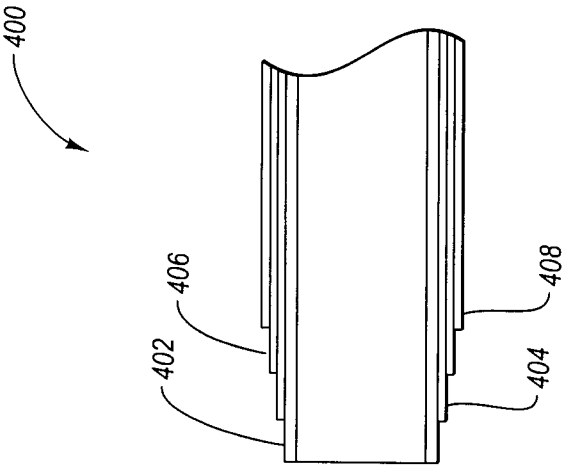


FIG. 43

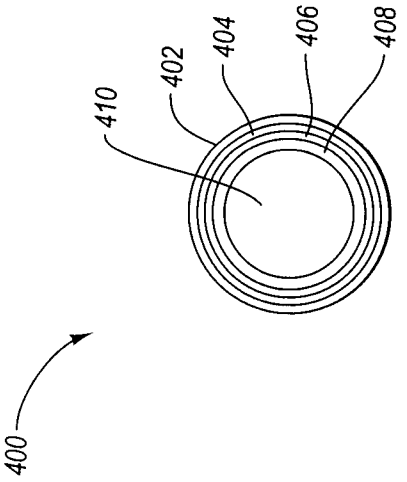
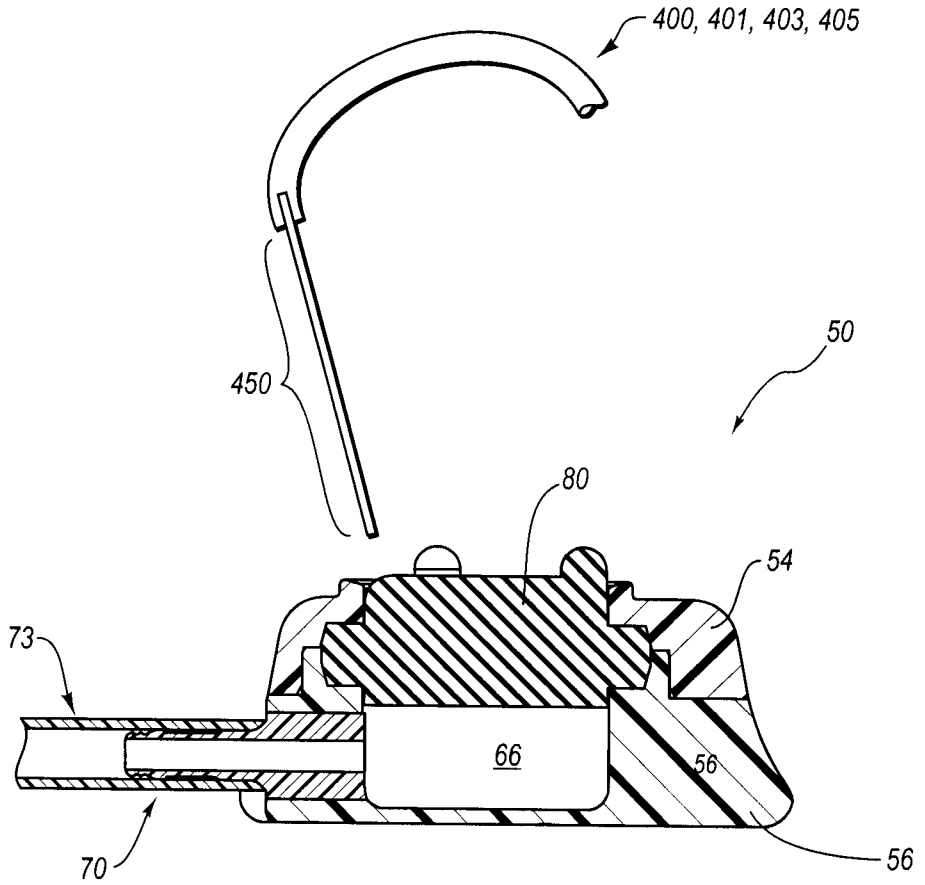


FIG. 42


400, 401, 403, 405
450
50
80
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73
66
56
70
56

FIG. 44

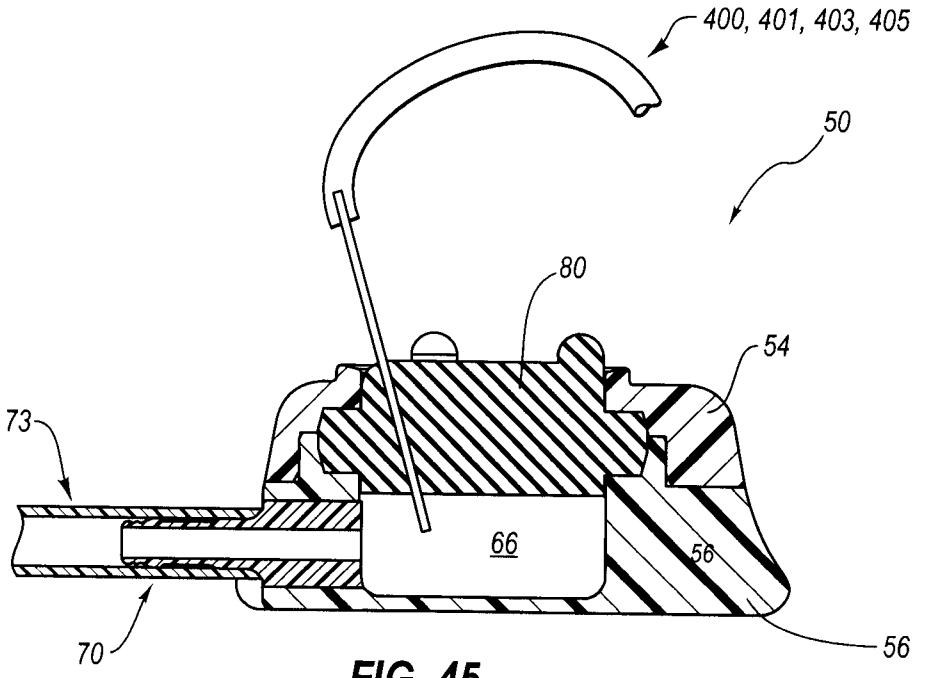
400, 401, 403, 405
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FIG. 45

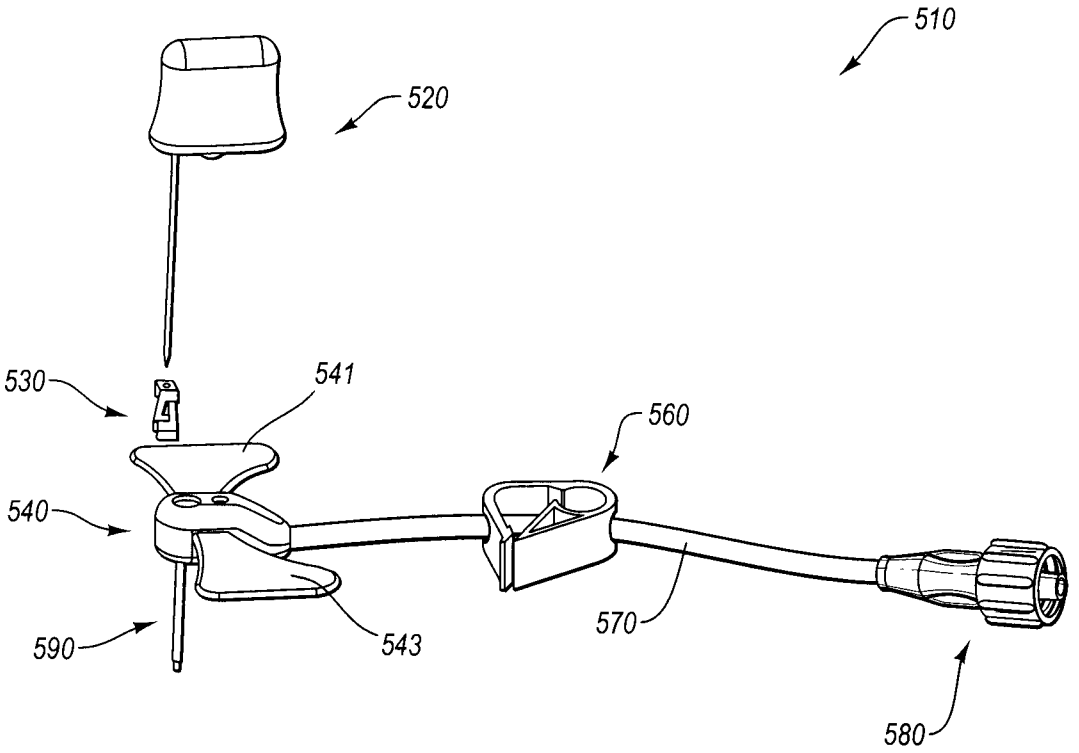

FIG. 46

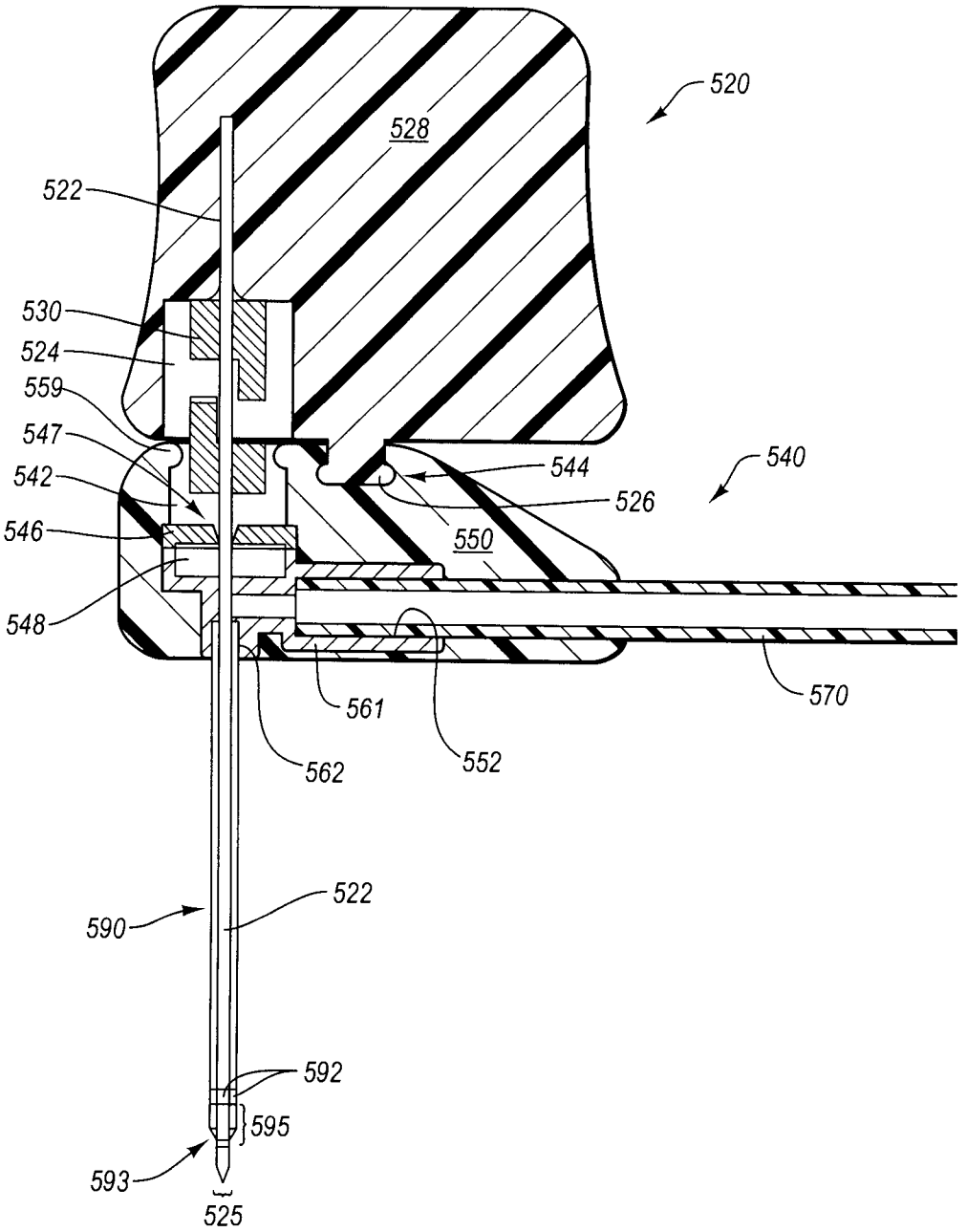
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FIG. 47

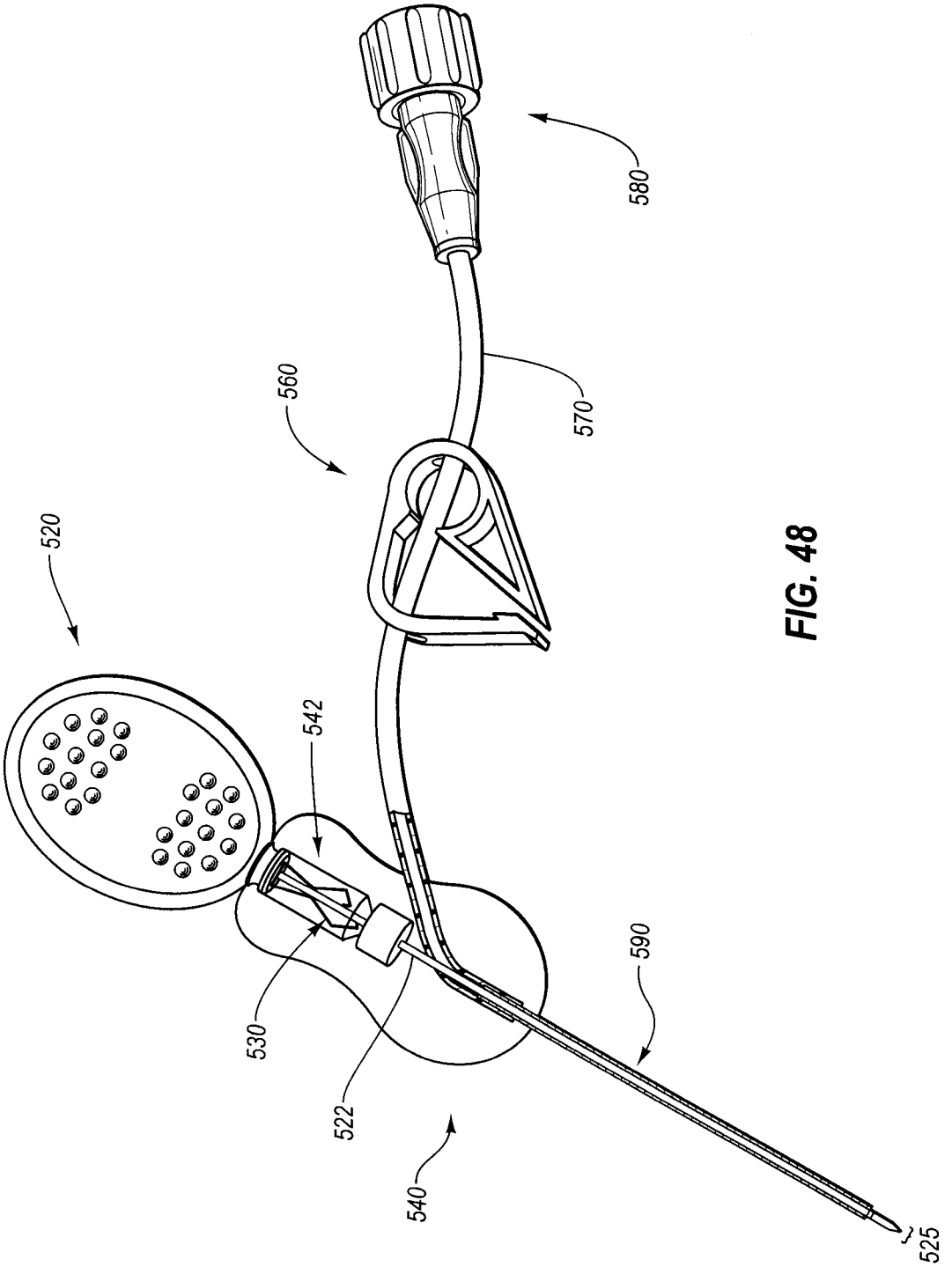

FIG. 48

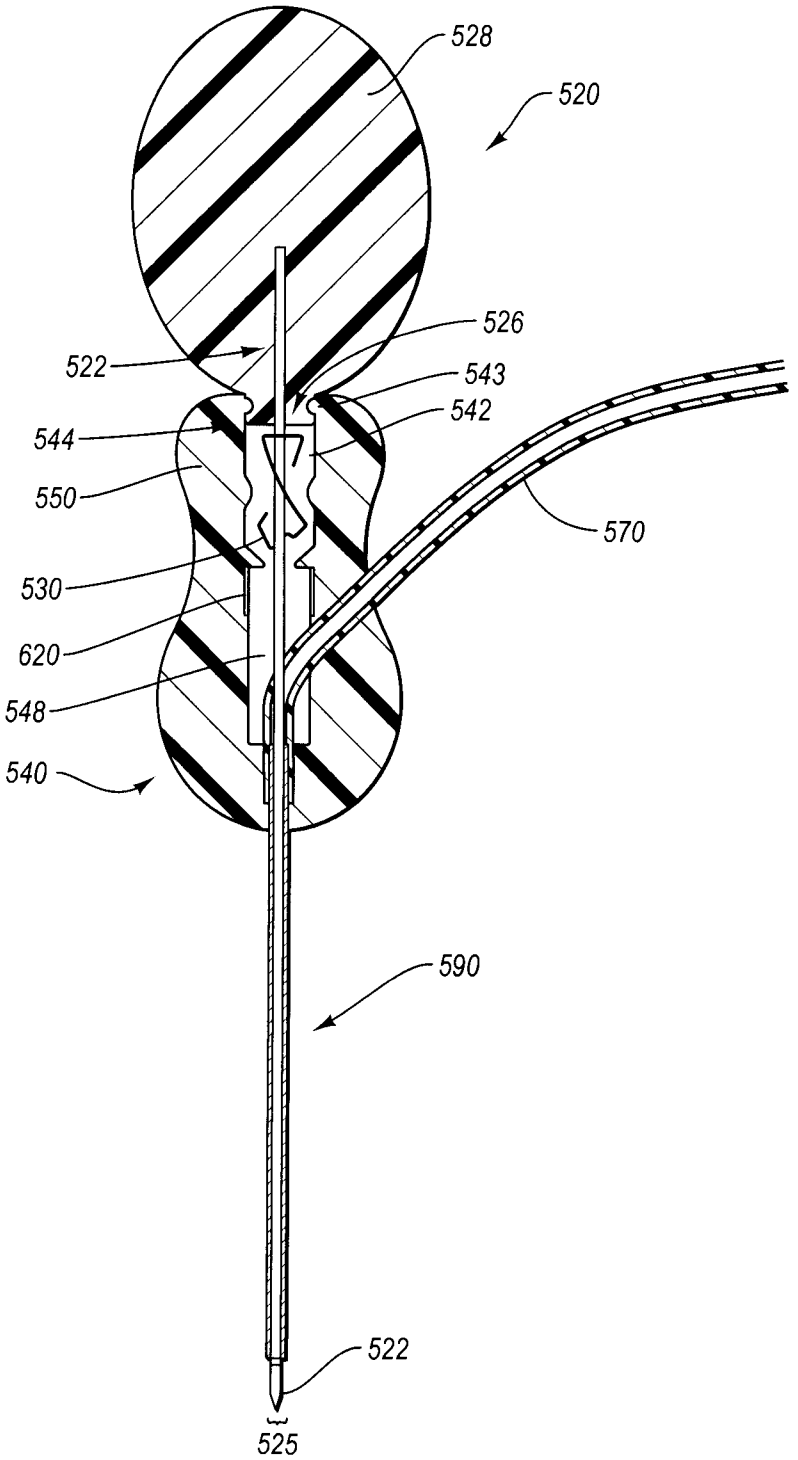

FIG. 49

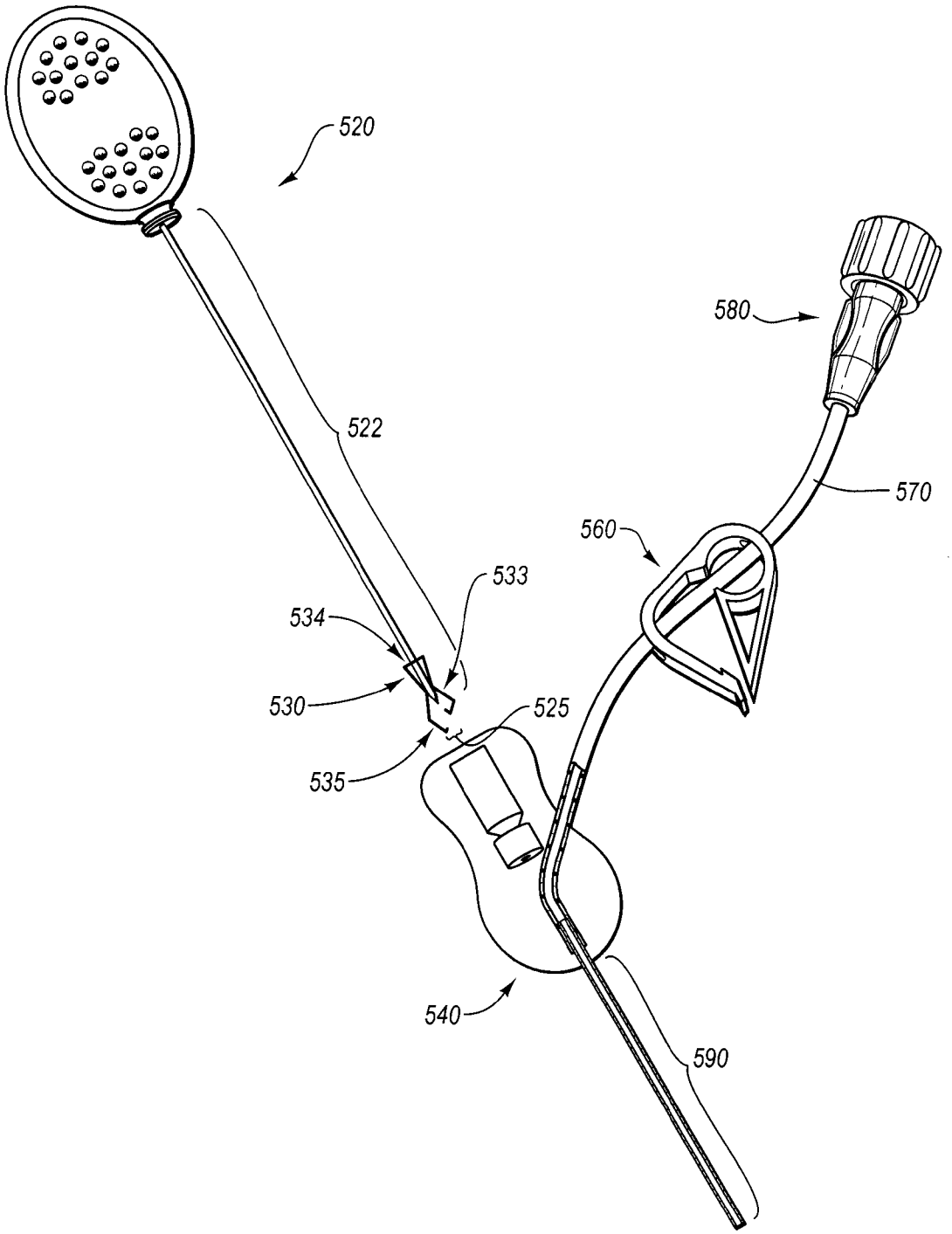

FIG. 50

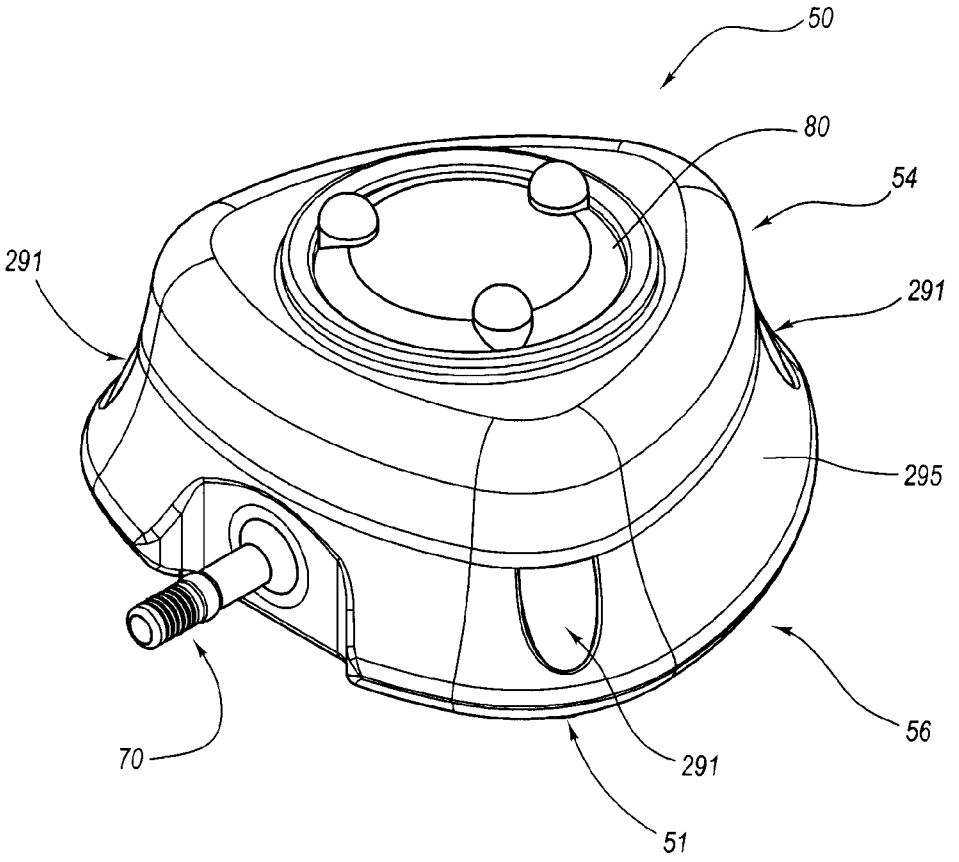

FIG. 51

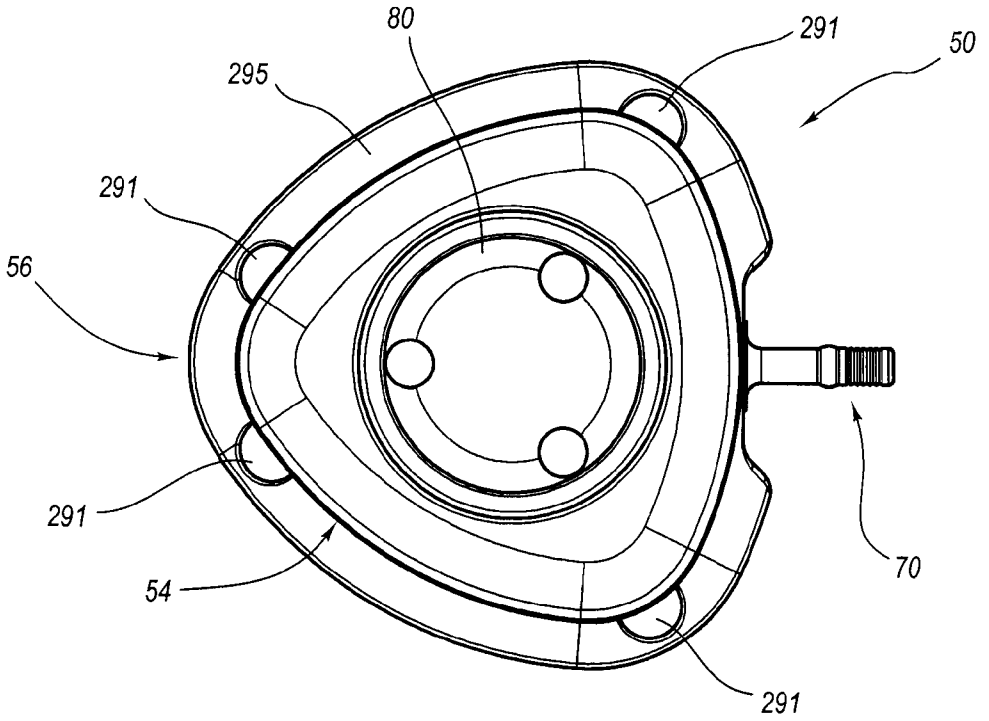

FIG. 52

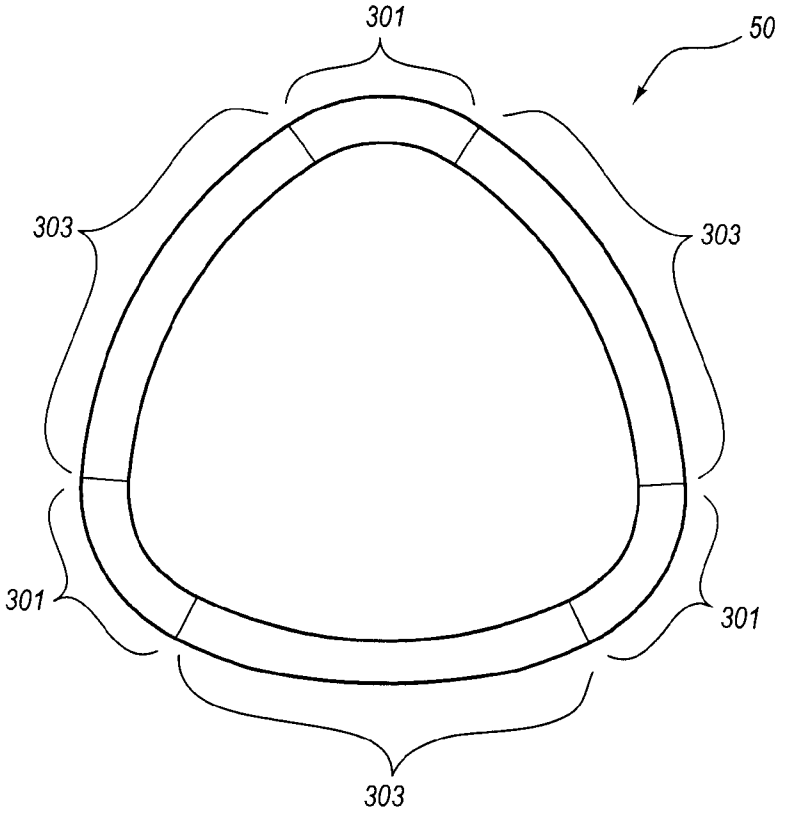

FIG. 53

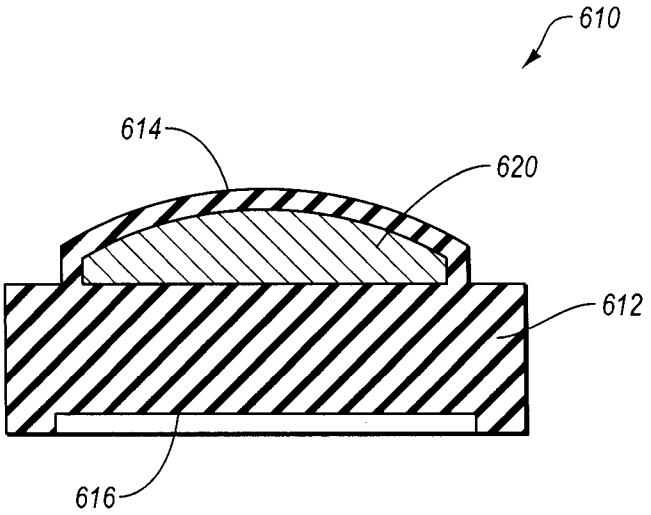

FIG. 54

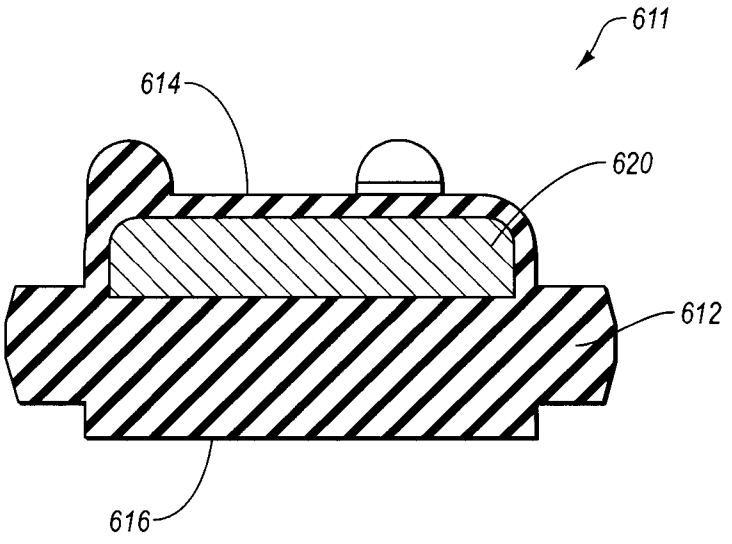

FIG. 55

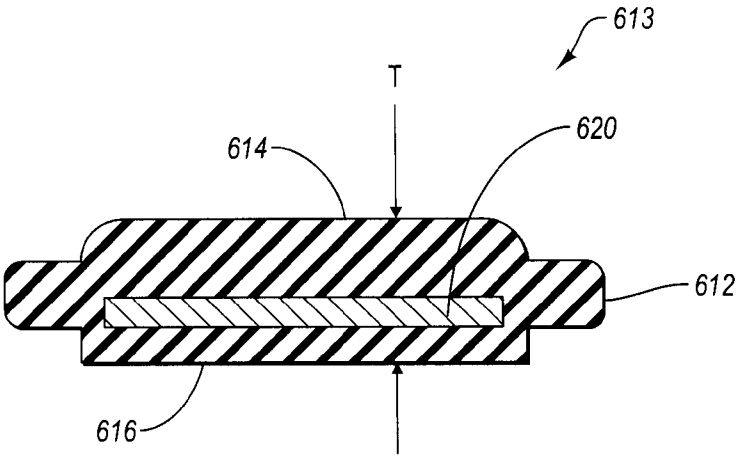

FIG. 56

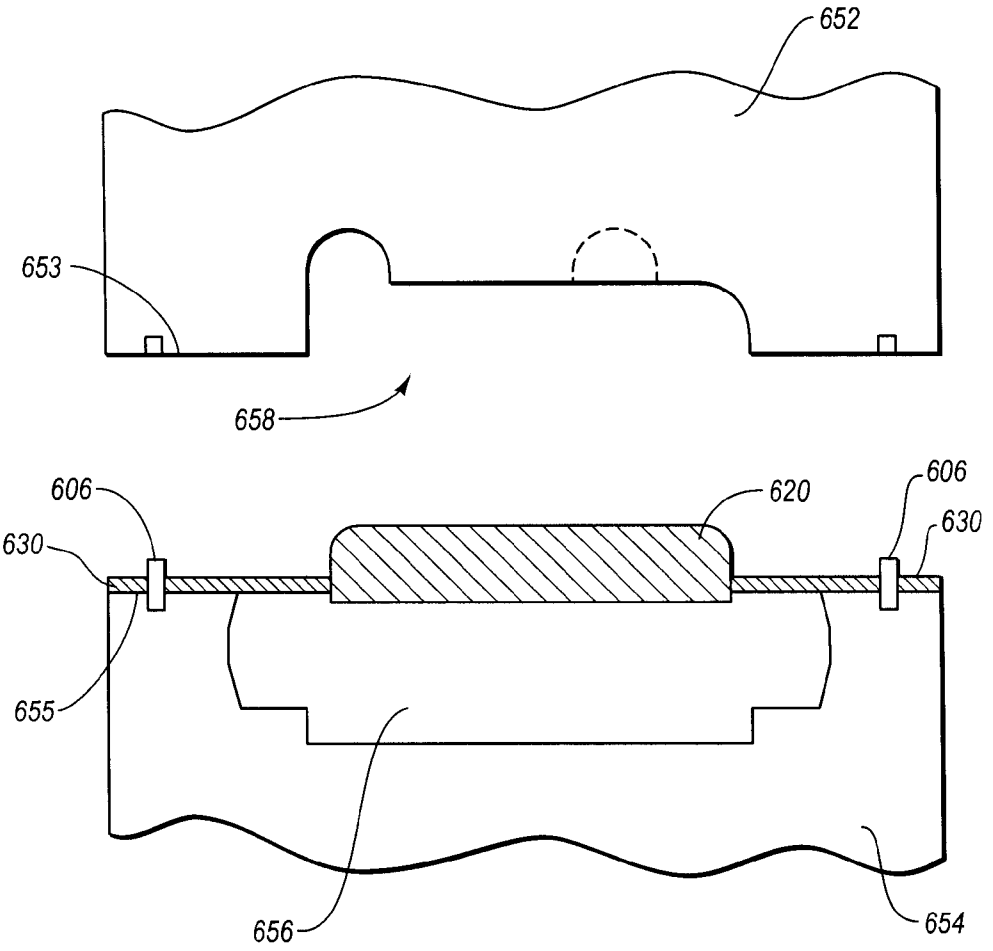

FIG. 57

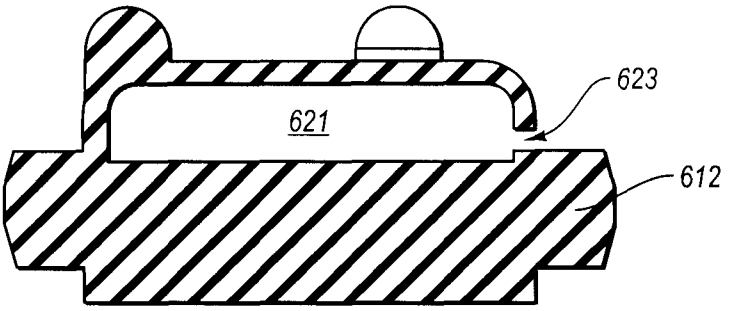

FIG. 58

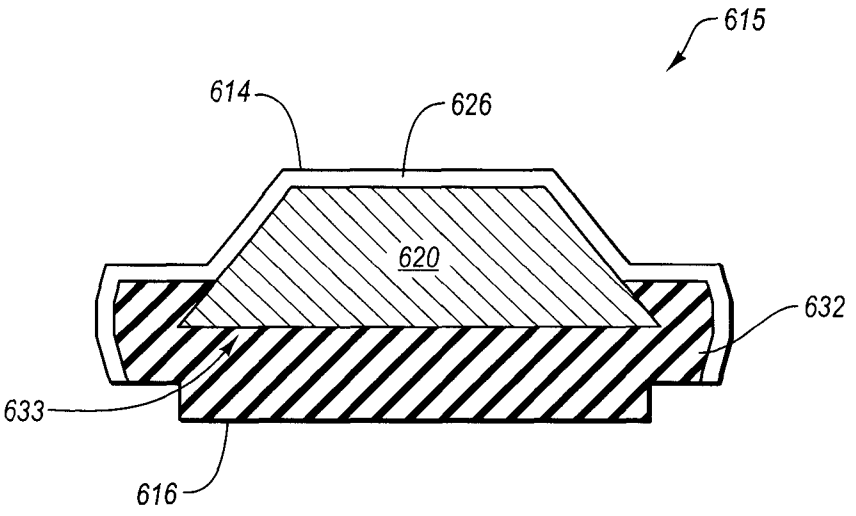

FIG. 59

INFUSION APPARATUSES AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

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

BACKGROUND

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

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

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

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

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

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

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

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

SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

What is claimed is:

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

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

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

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

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

3. The system according to claim 1, wherein the second identifiable feature is included on an infusion set couplable to the vascular access port.

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

* * * * *

EXHIBIT 3

US008805478B2

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

(10) **Patent No.: US 8,805,478 B2**
(45) **Date of Patent: *Aug. 12, 2014**

(54) **METHODS OF PERFORMING A POWER INJECTION PROCEDURE INCLUDING IDENTIFYING FEATURES OF A SUBCUTANEOUSLY IMPLANTED ACCESS PORT FOR DELIVERY OF CONTRAST MEDIA**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 198 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

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(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/427**; 604/288.01; 600/431

(58) **Field of Classification Search**
USPC 600/407, 425, 420, 423, 431, 426, 433, 600/434, 427, 435; 604/131, 890.1
See application file for complete search history.

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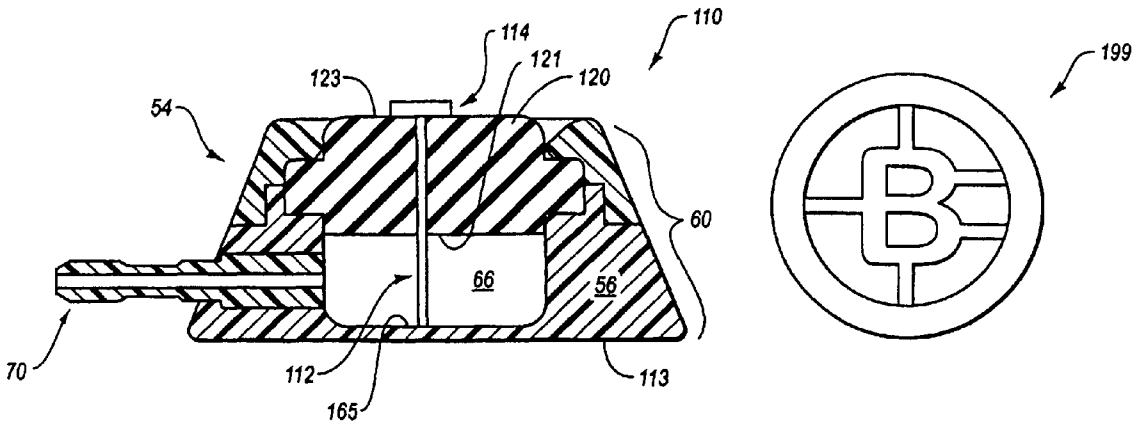
(57) **ABSTRACT**

Methods of performing a power injection procedure are described. One method includes taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least about 1 milliliter per second through the access port, identifying the indicating radiographic feature on the x-ray, and flowing a fluid through the access port at a rate of at least about 1 milliliter per second.

14 Claims, 32 Drawing Sheets



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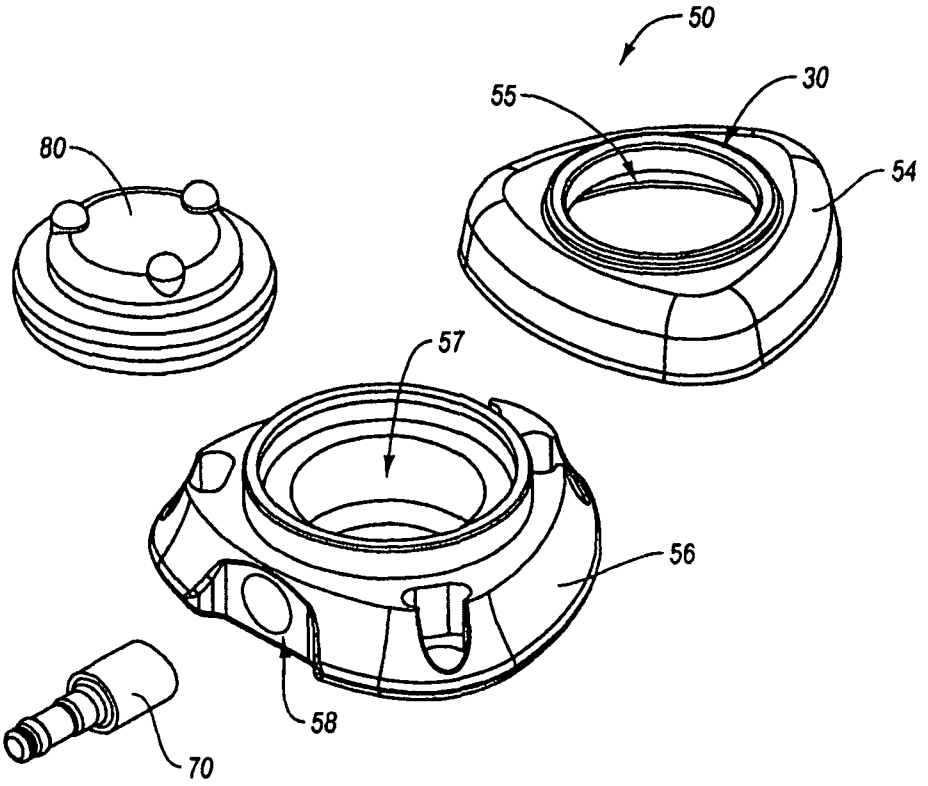


FIG. 1

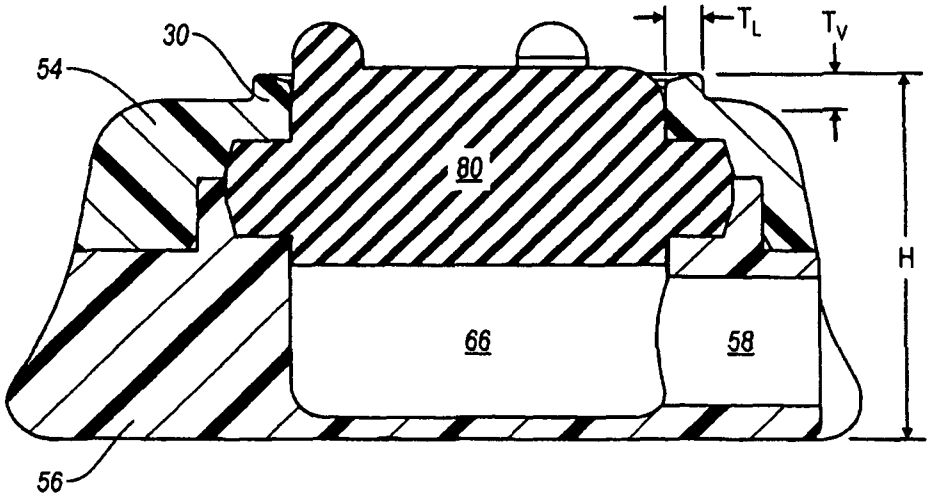


FIG. 2

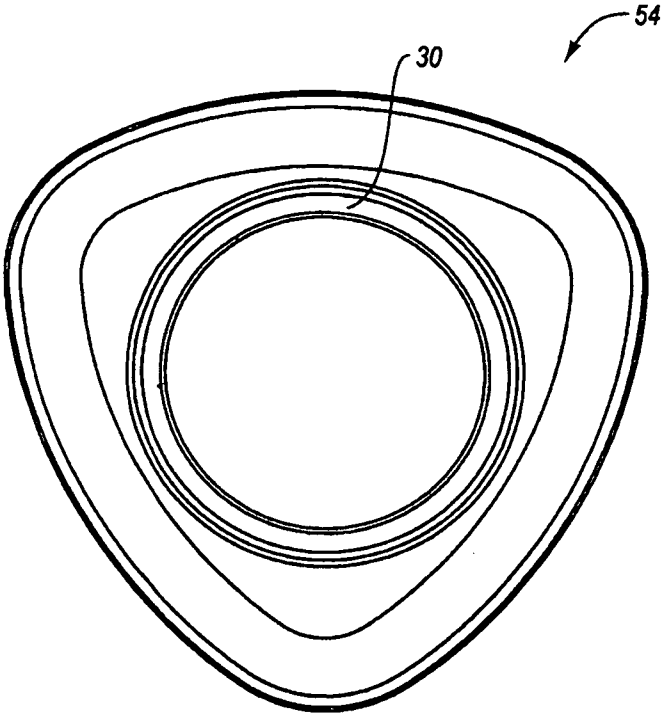


FIG. 3

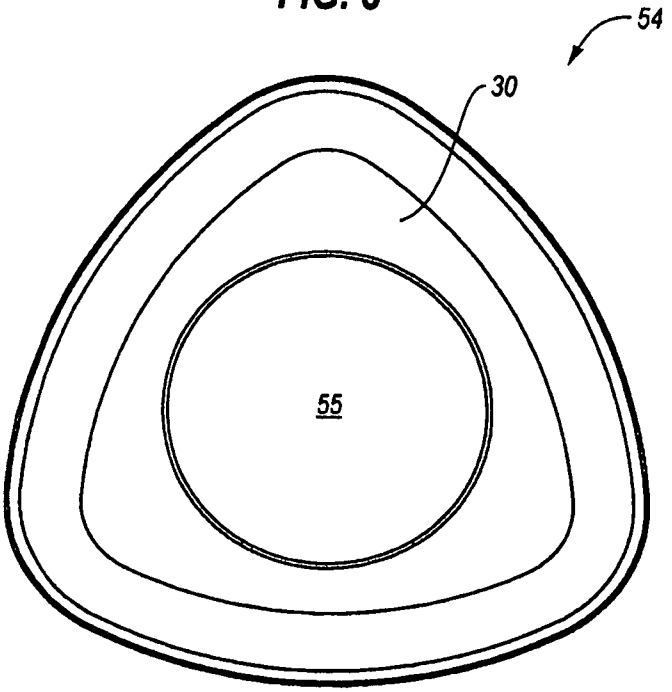


FIG. 4

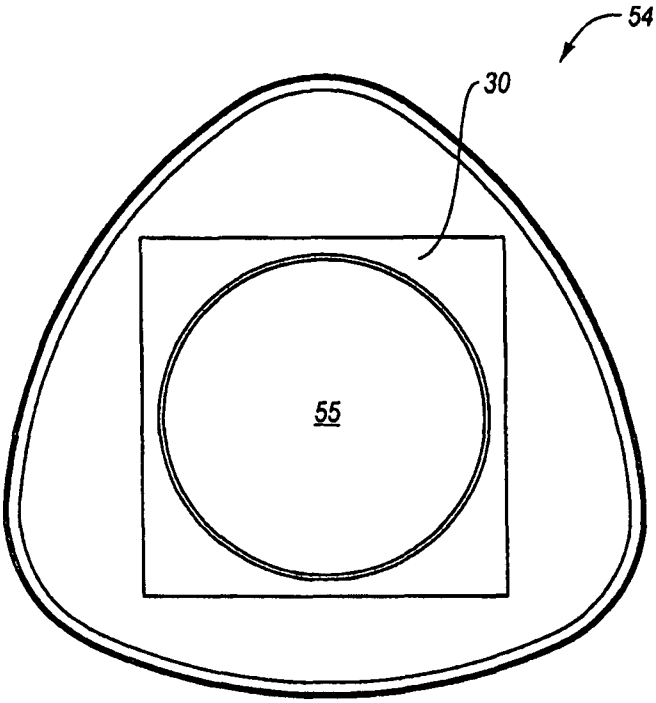


FIG. 5

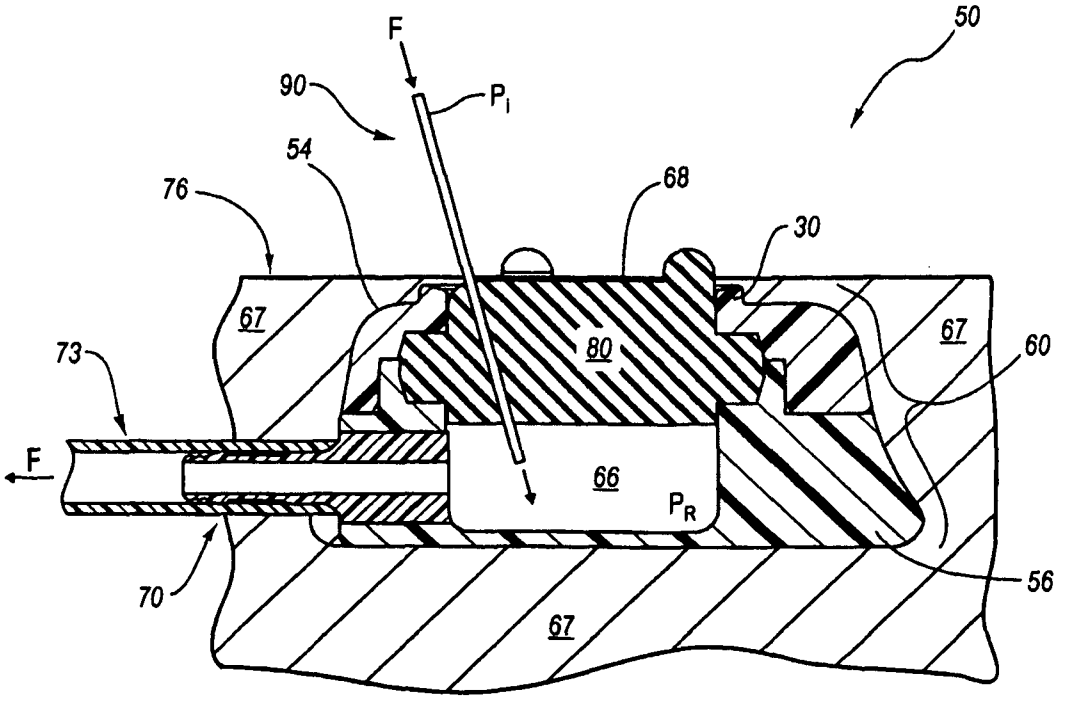


FIG. 6

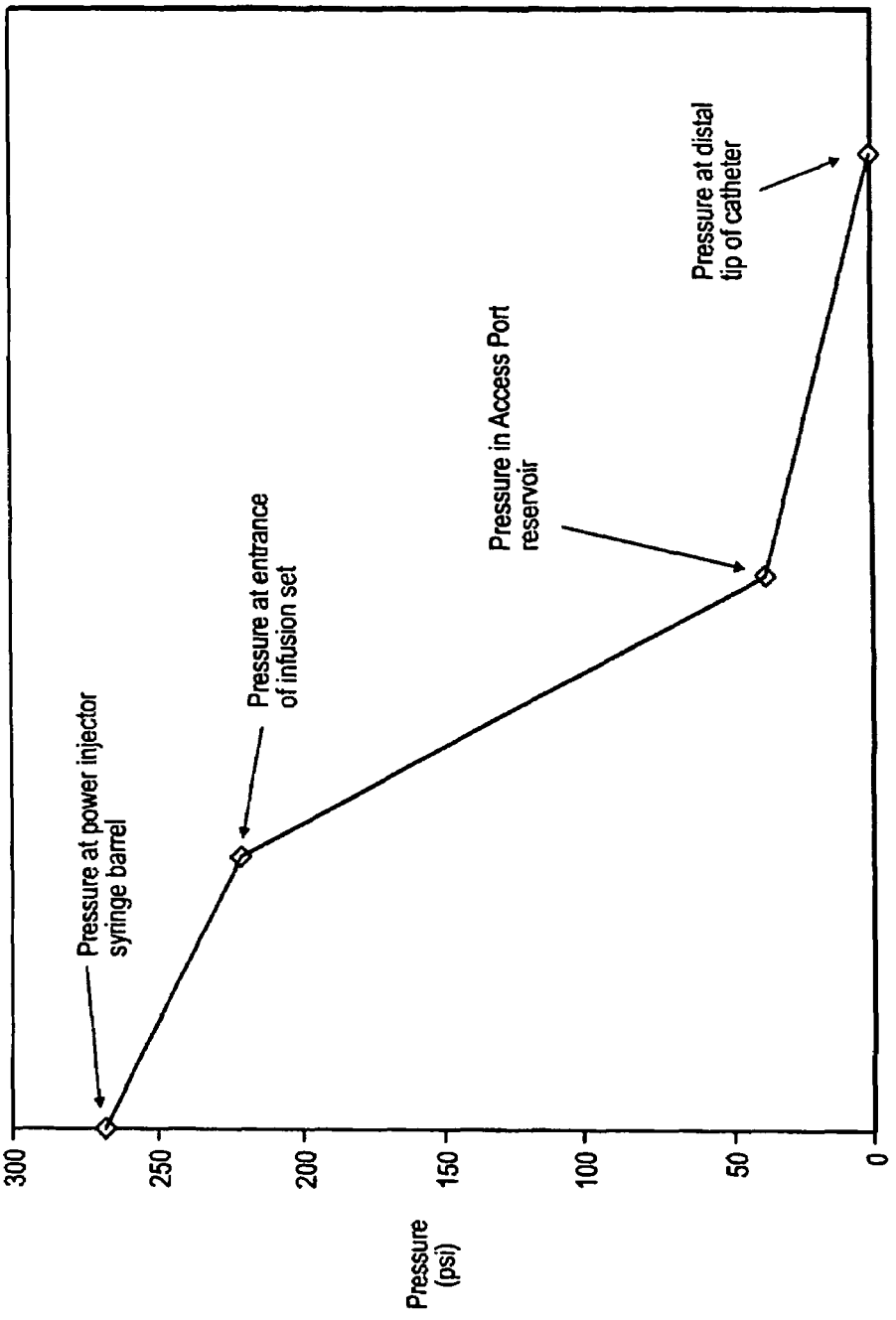
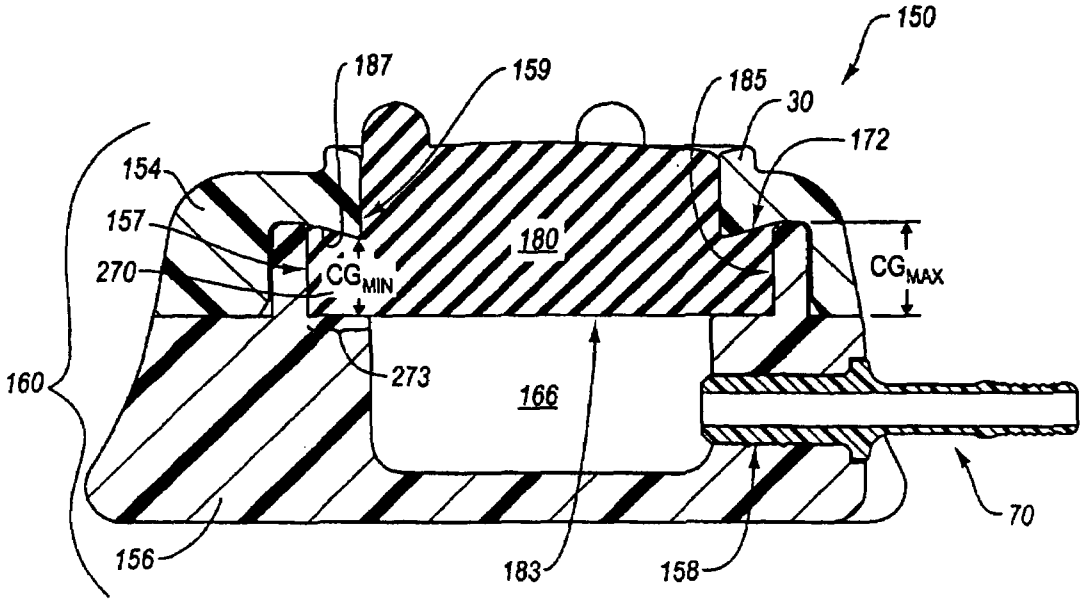

Pressure at power injector syringe barrel
Pressure at entrance of infusion set
Pressure in Access Port reservoir
Pressure at distal tip of catheter
300
250
200
150
100
50
0
Pressure (psi)

FIG. 7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187
159
185
30
172
154
157
180
270
CG_{MIN}
CG_{MAX}
160
273
166
70
156
183
158

FIG. 8

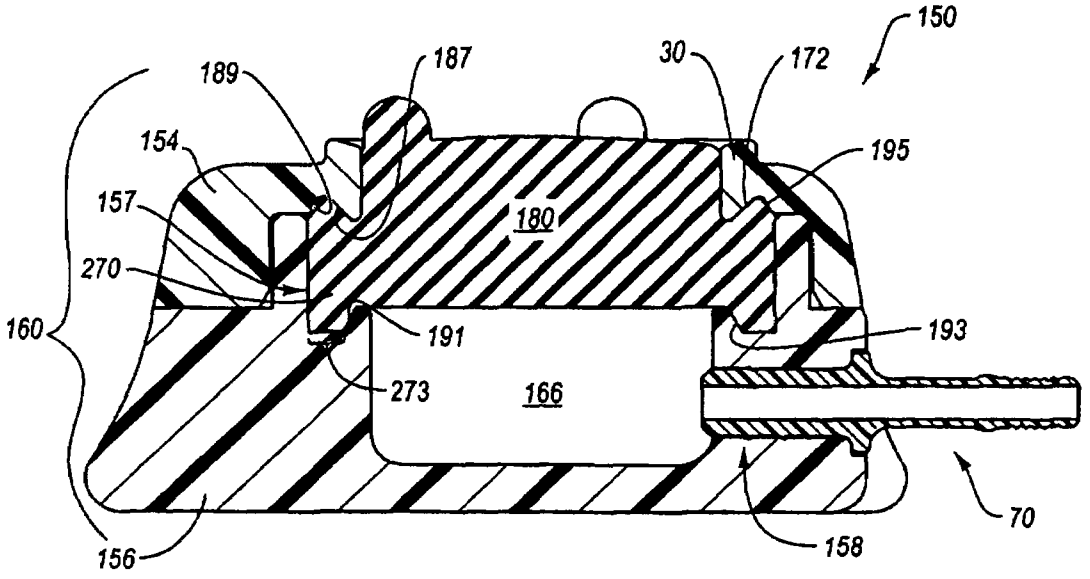
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FIG. 9

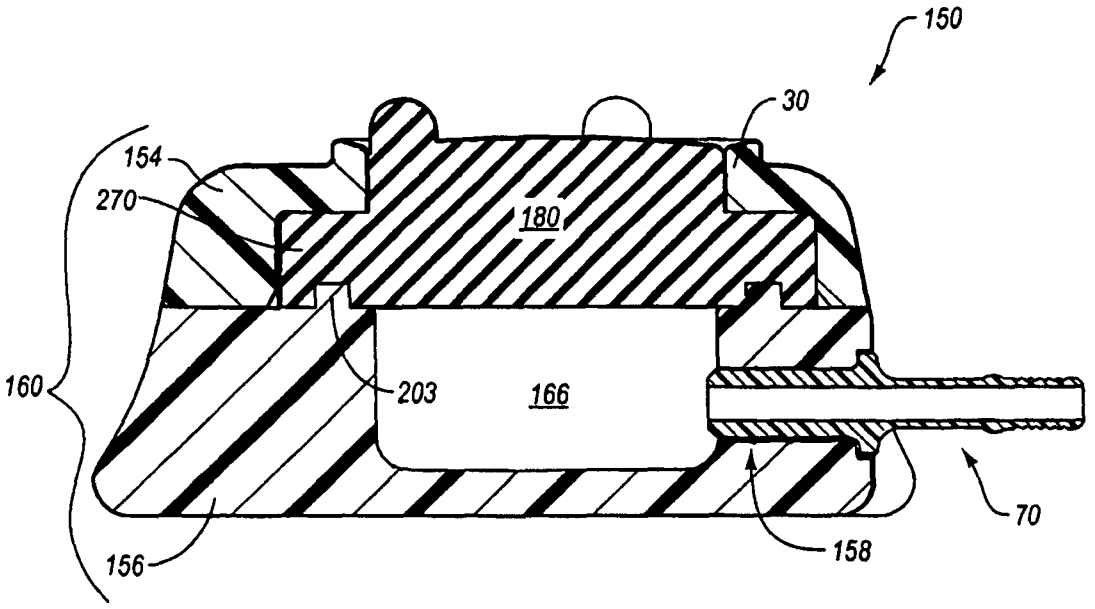
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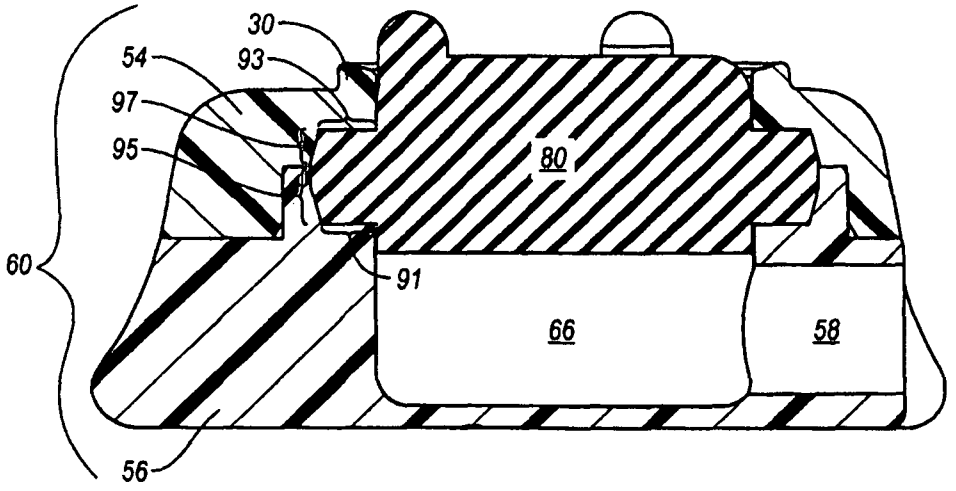
FIG. 10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93
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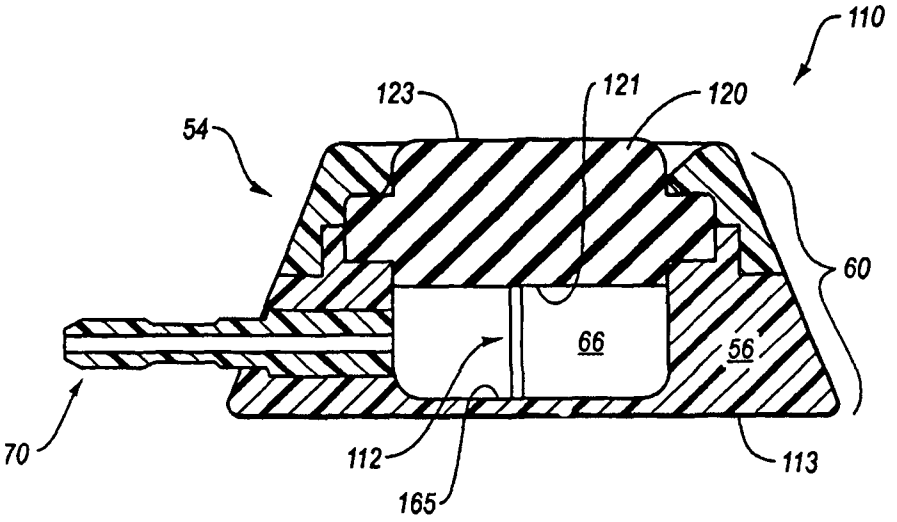
FIG. 11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123
121
120
54
60
66
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112
113
165

FIG. 12

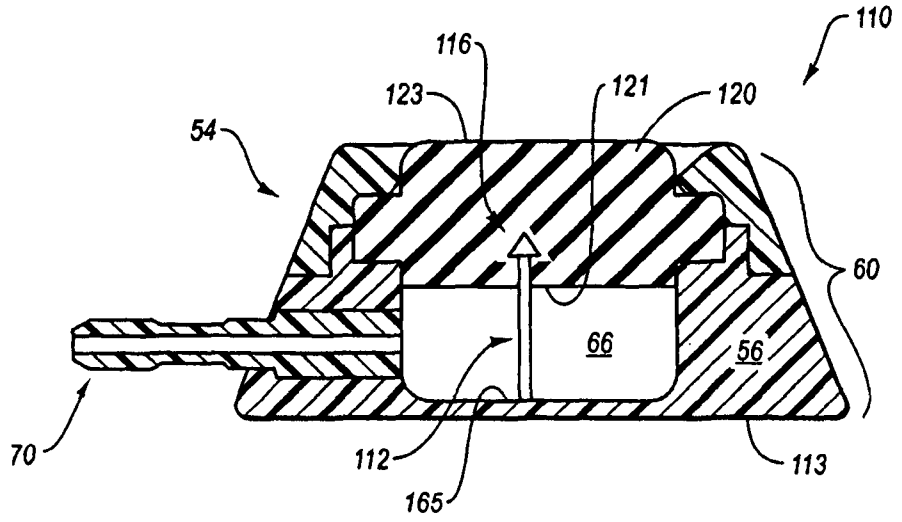
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FIG. 13

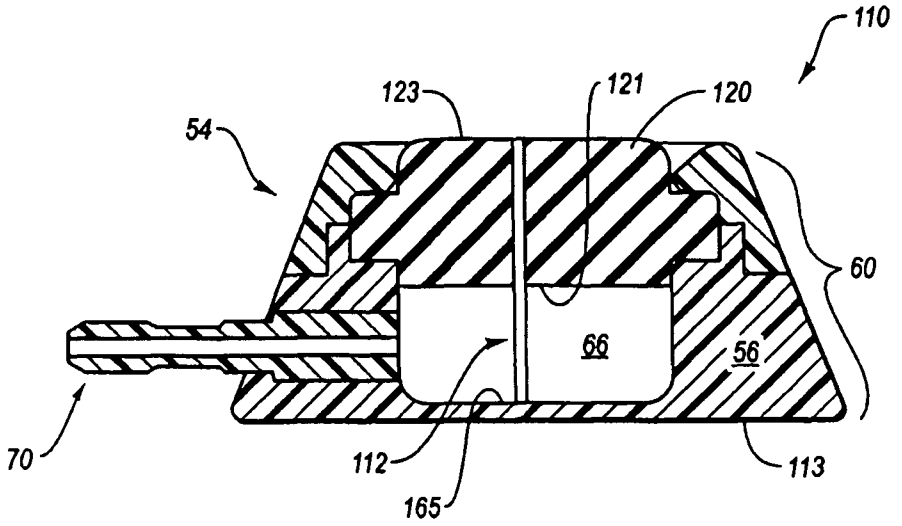
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FIG. 14

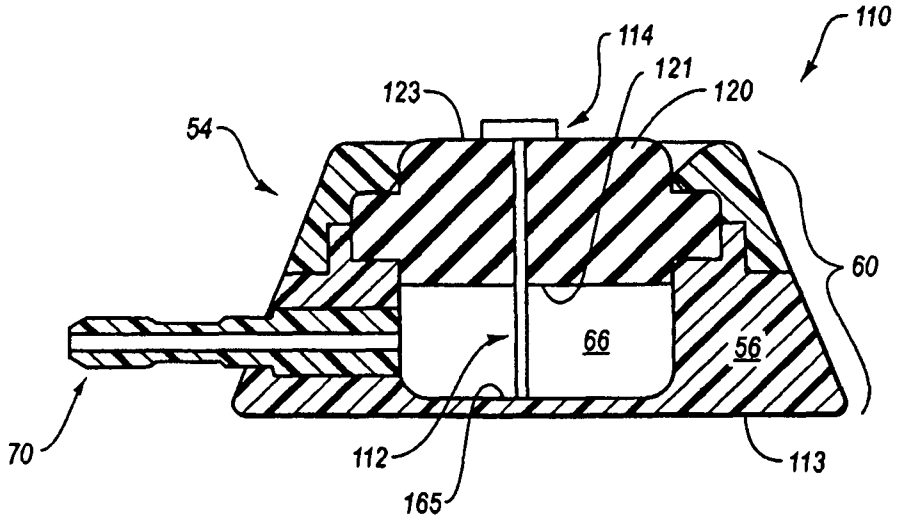
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FIG. 15

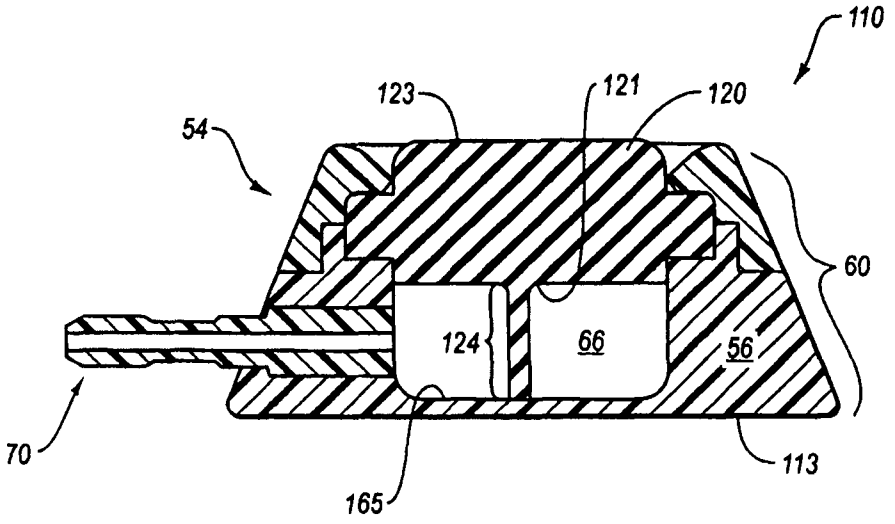
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FIG. 16

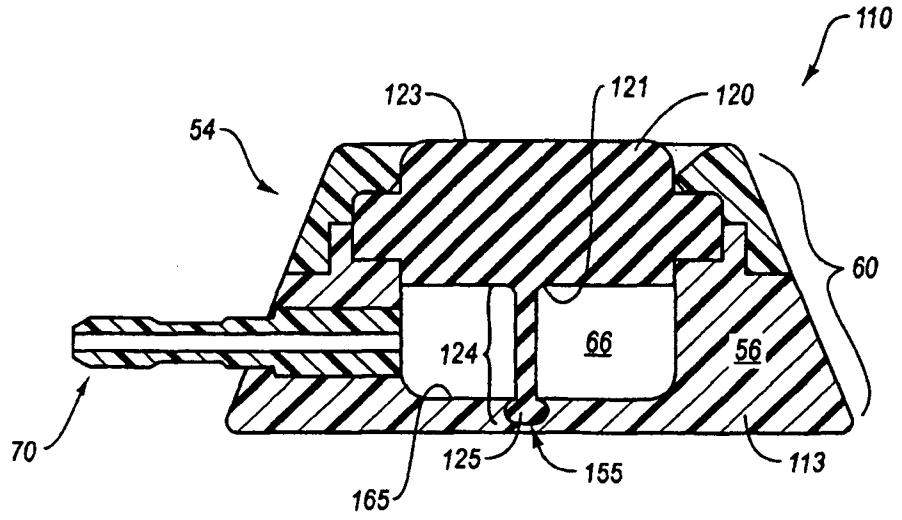
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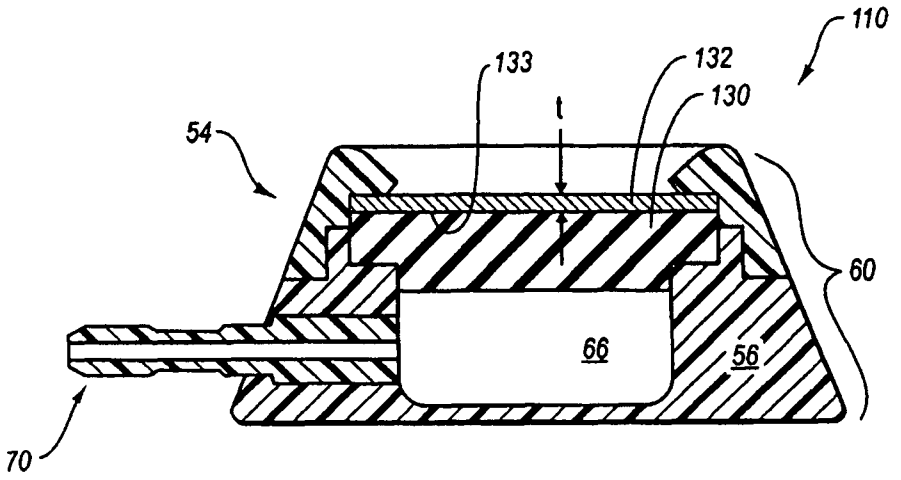
FIG. 17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t
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FIG. 18

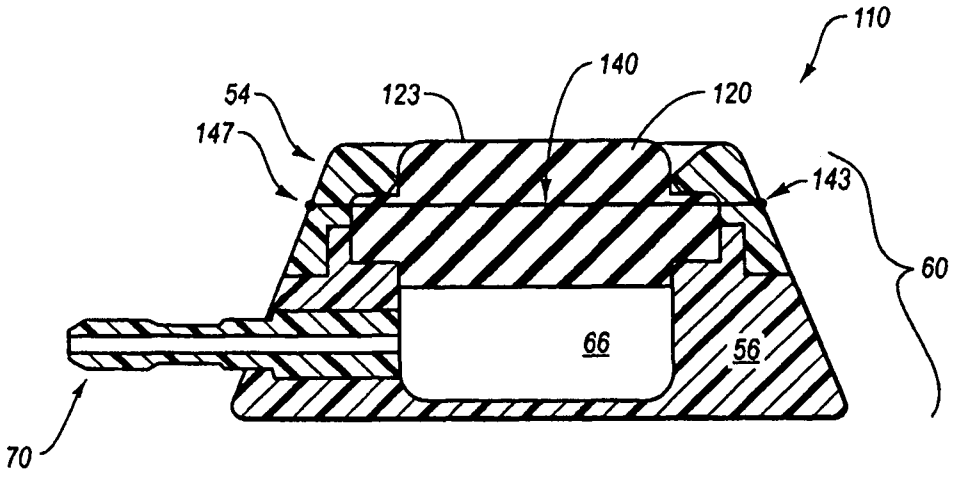
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FIG. 19

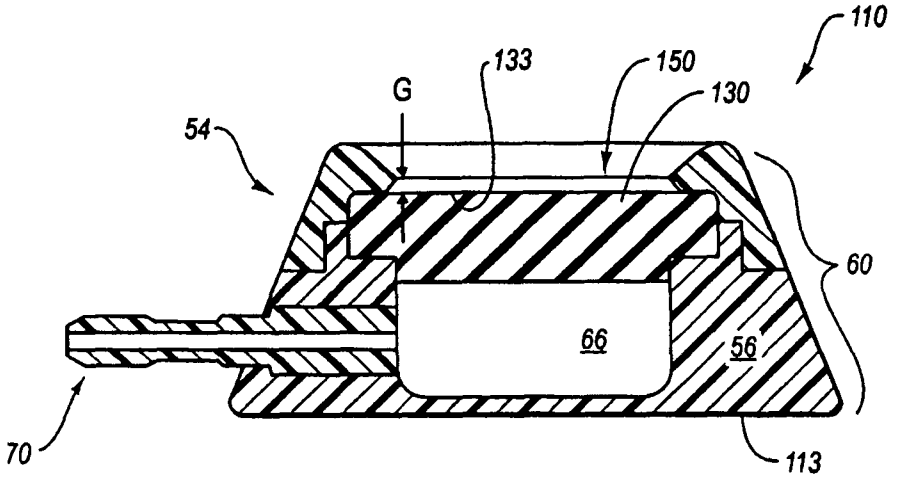


FIG. 20

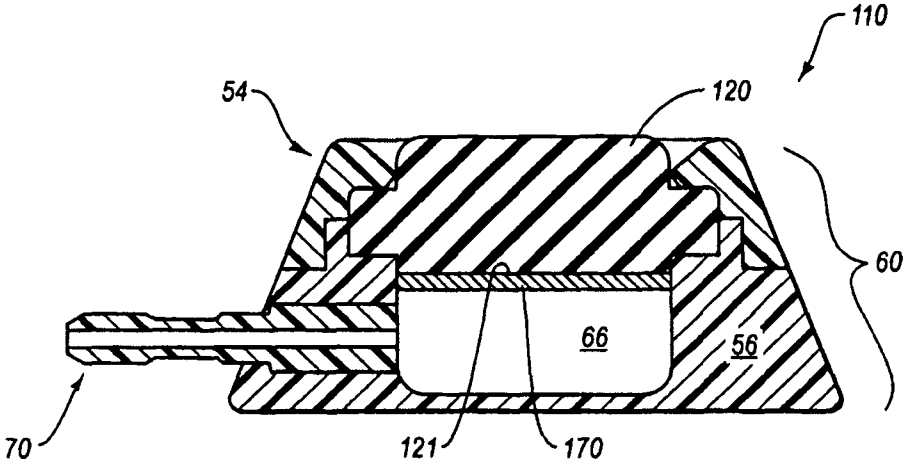


FIG. 21

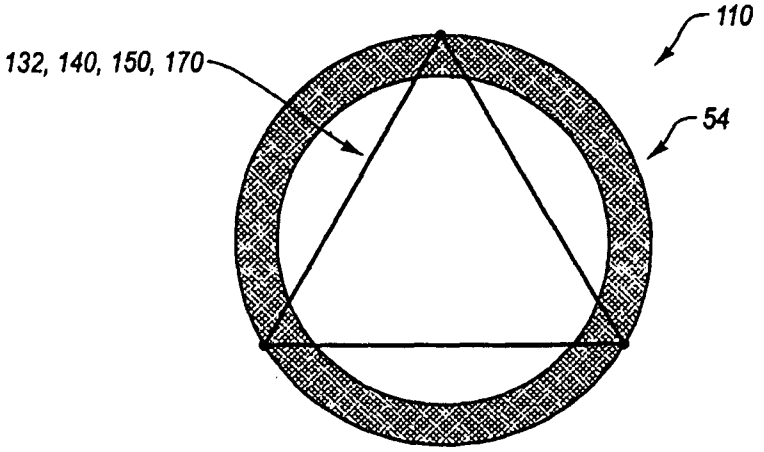


FIG. 22

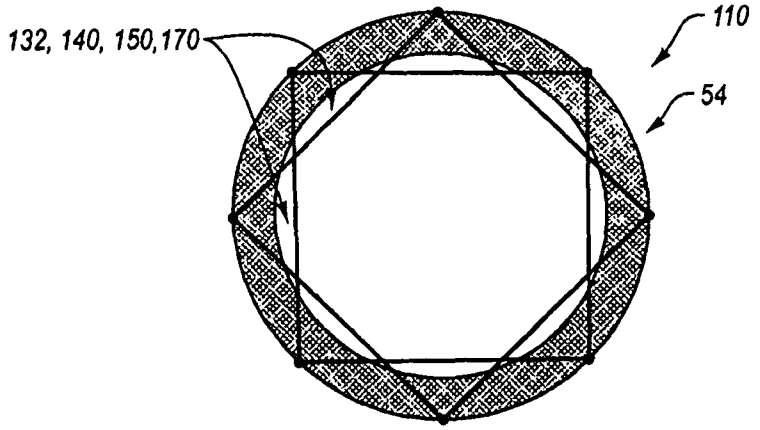


FIG. 23

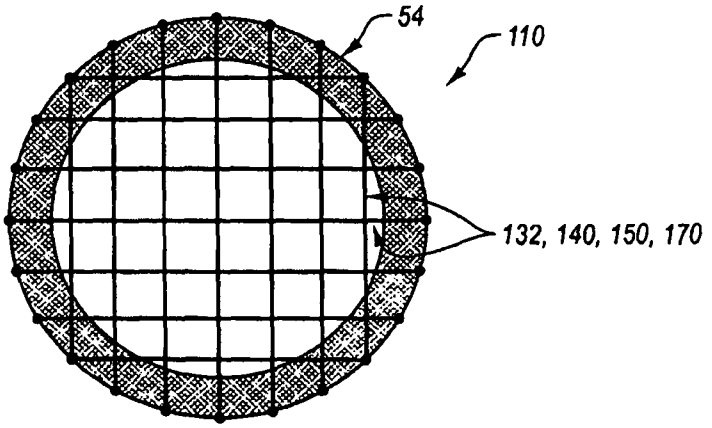


FIG. 24

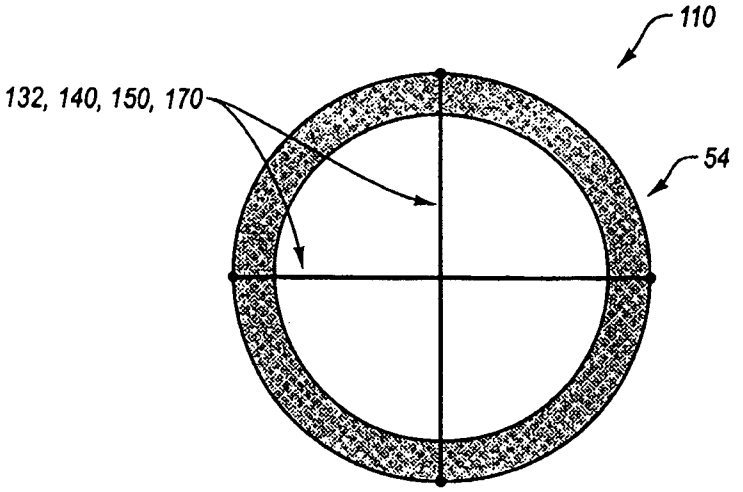


FIG. 25

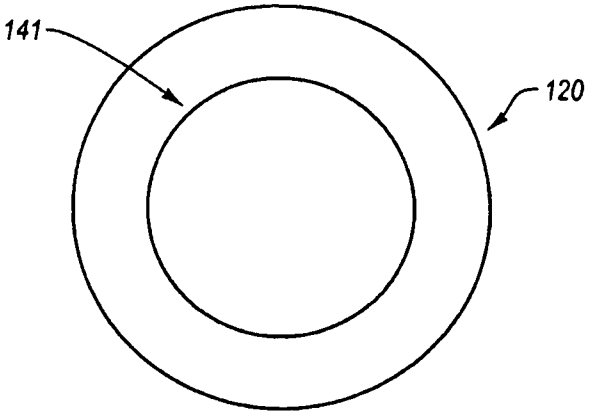


FIG. 26

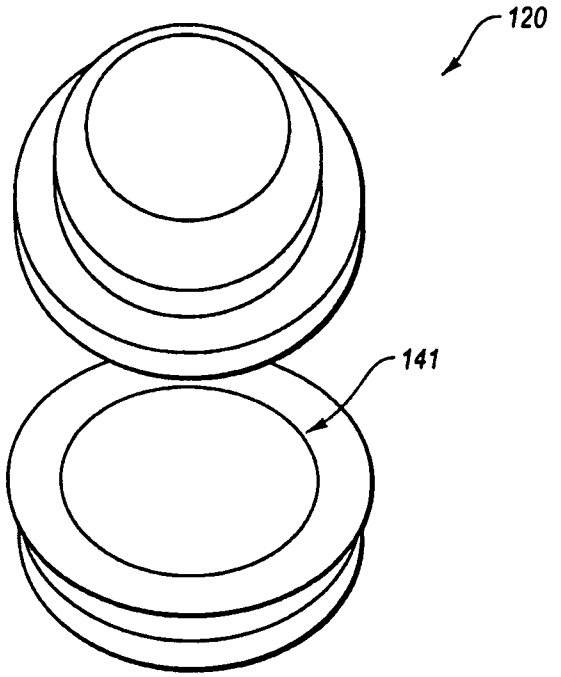


FIG. 27

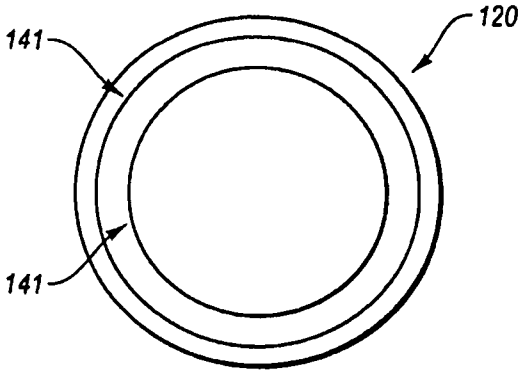


FIG. 28

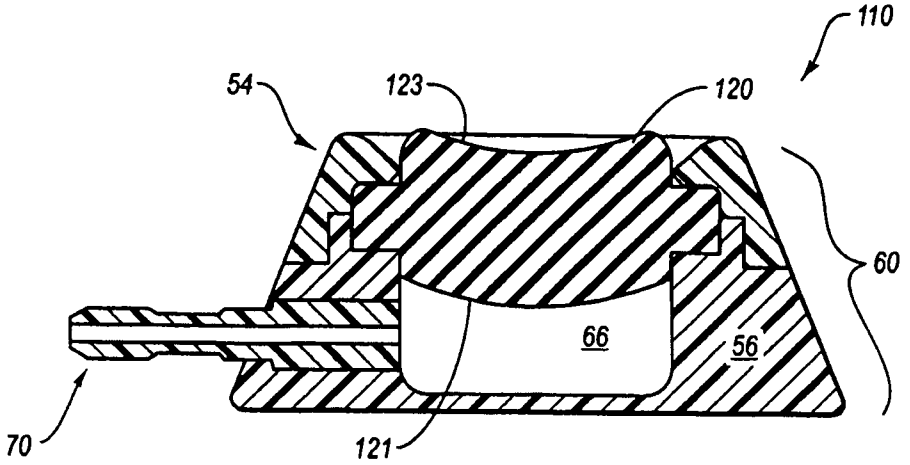


FIG. 29

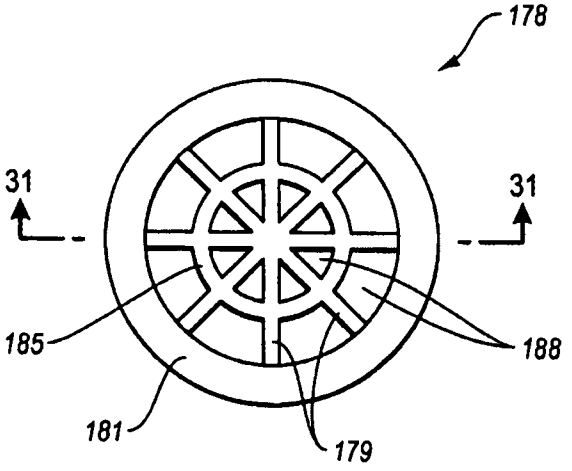


FIG. 30

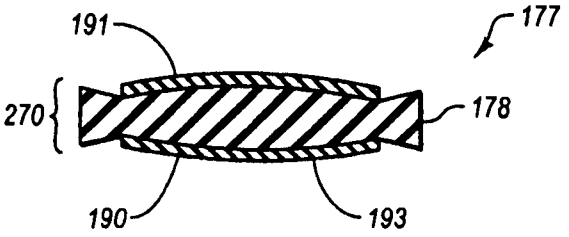


FIG. 31

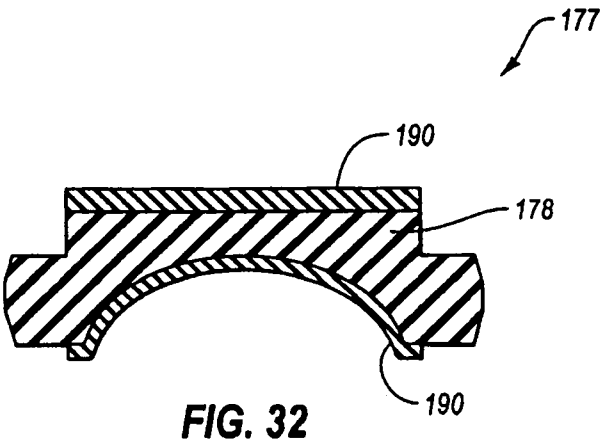


FIG. 32

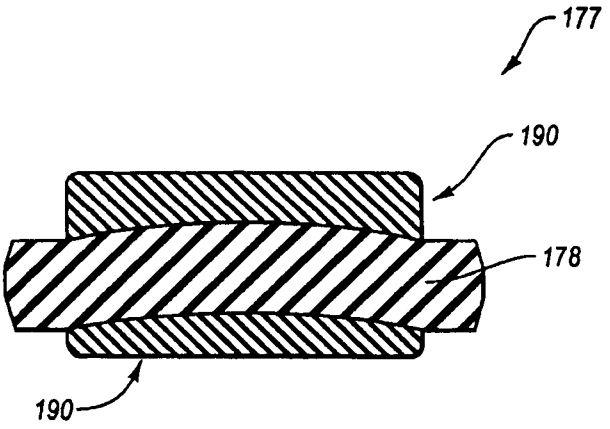


FIG. 33

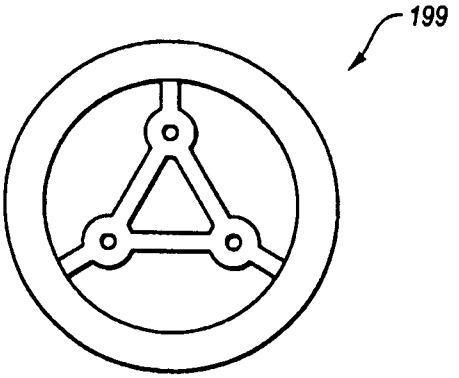


FIG. 34

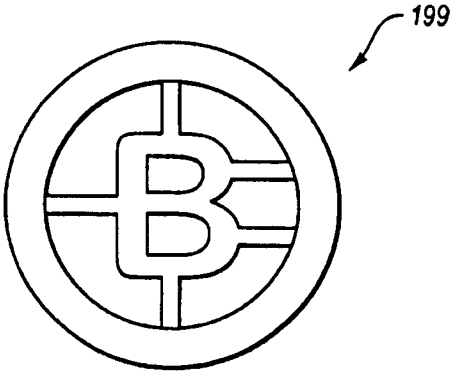
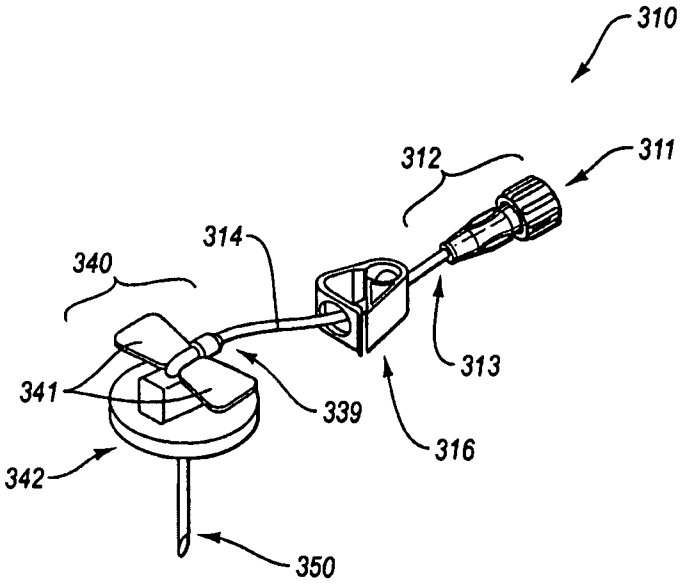


FIG. 35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350

FIG. 36

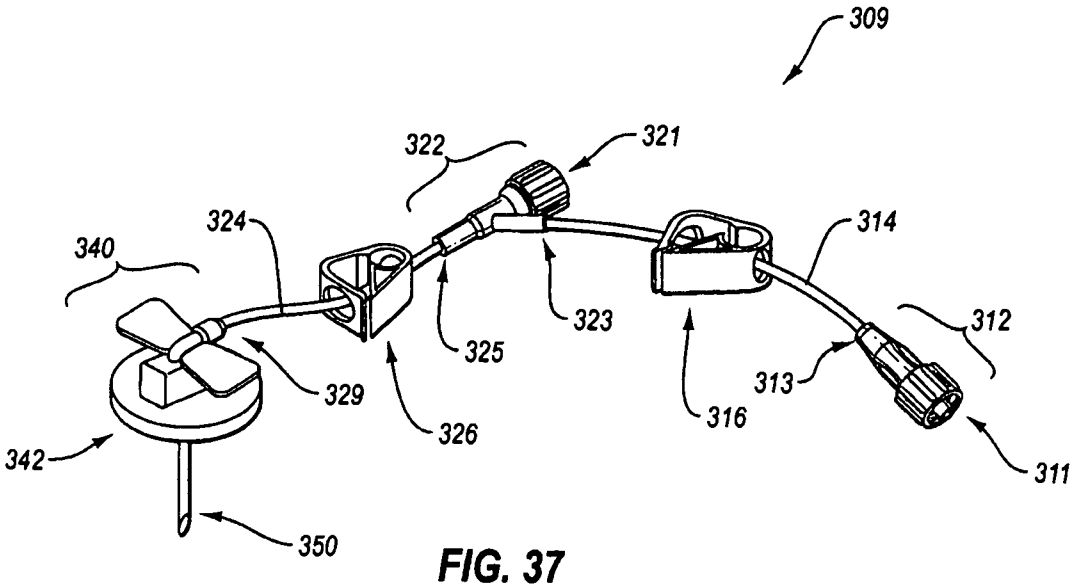
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FIG. 37

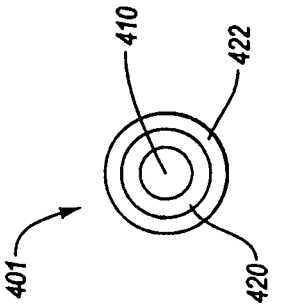

FIG. 39

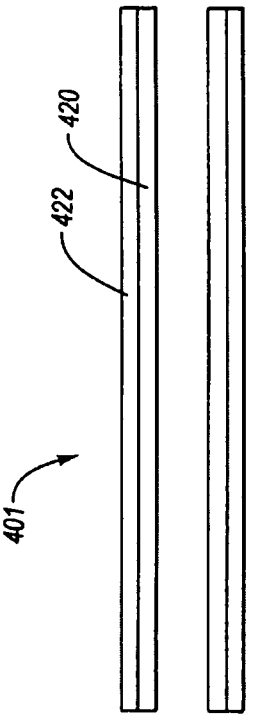

FIG. 38

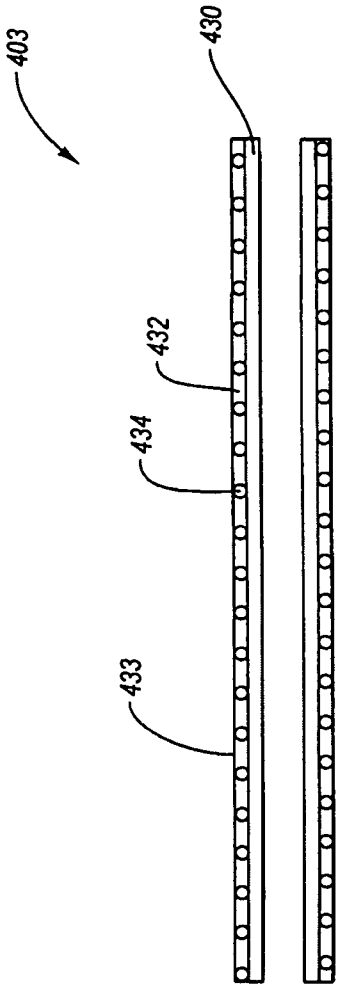

FIG. 40

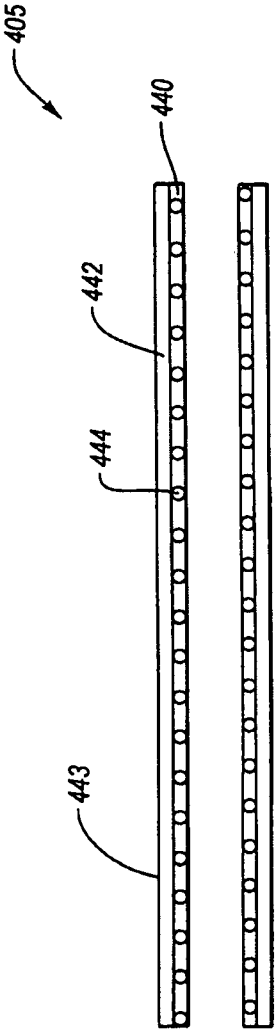

FIG. 41

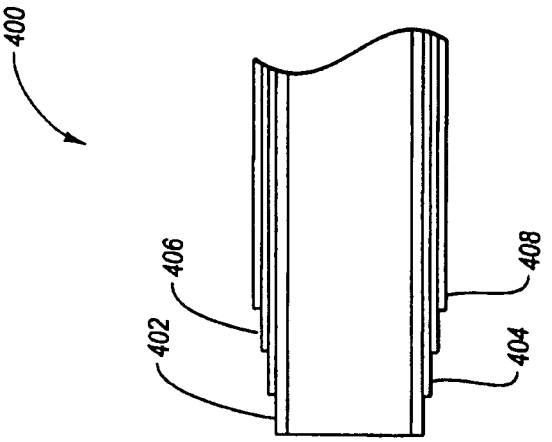

FIG. 43

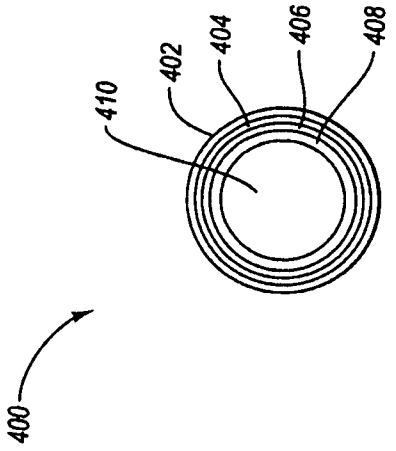

FIG. 42

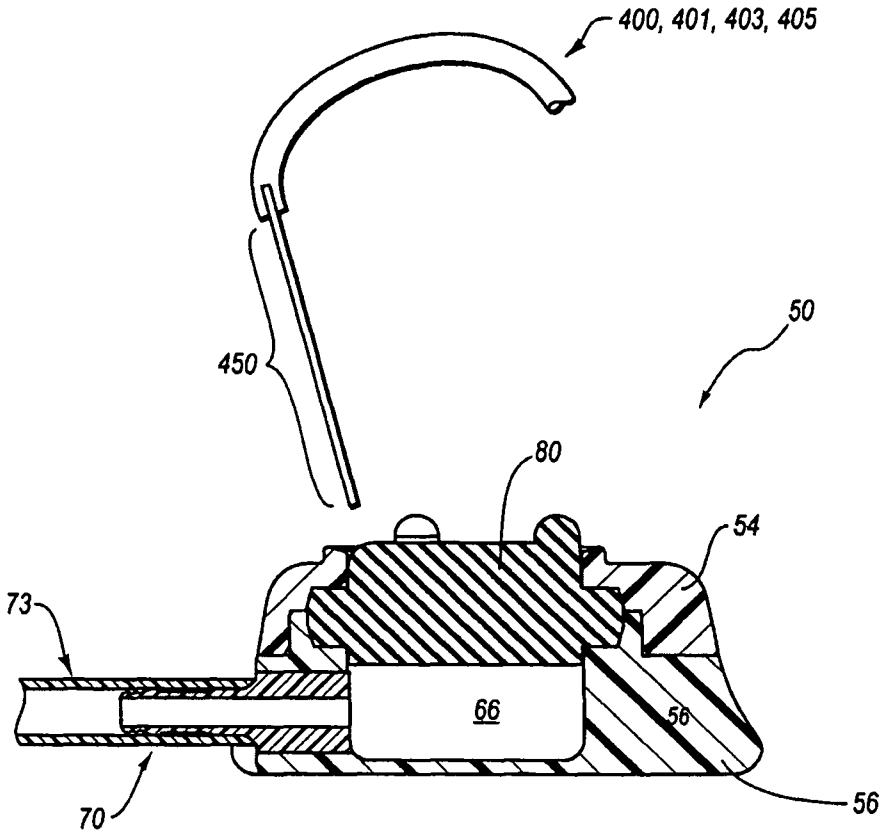
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FIG. 44

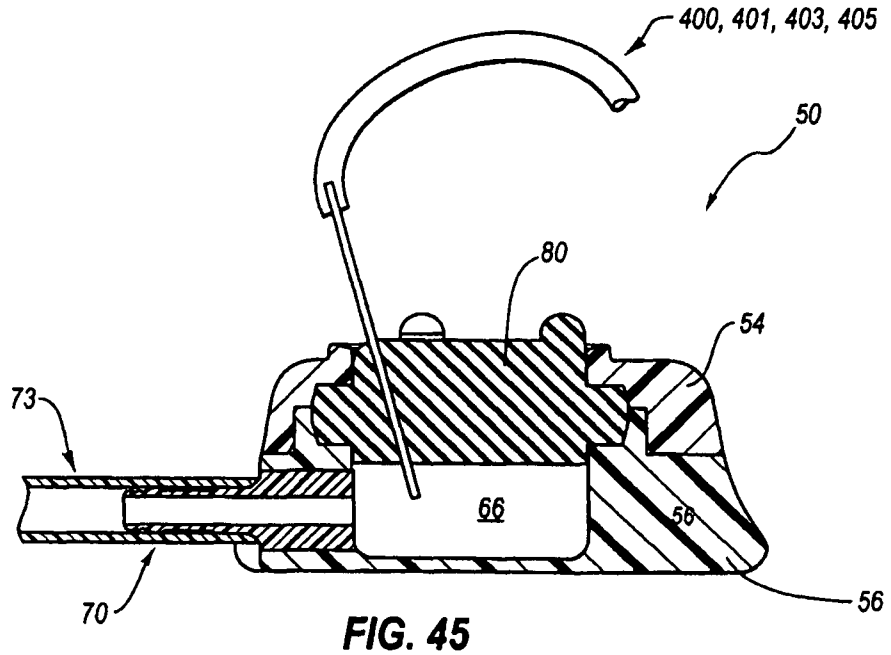
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FIG. 45

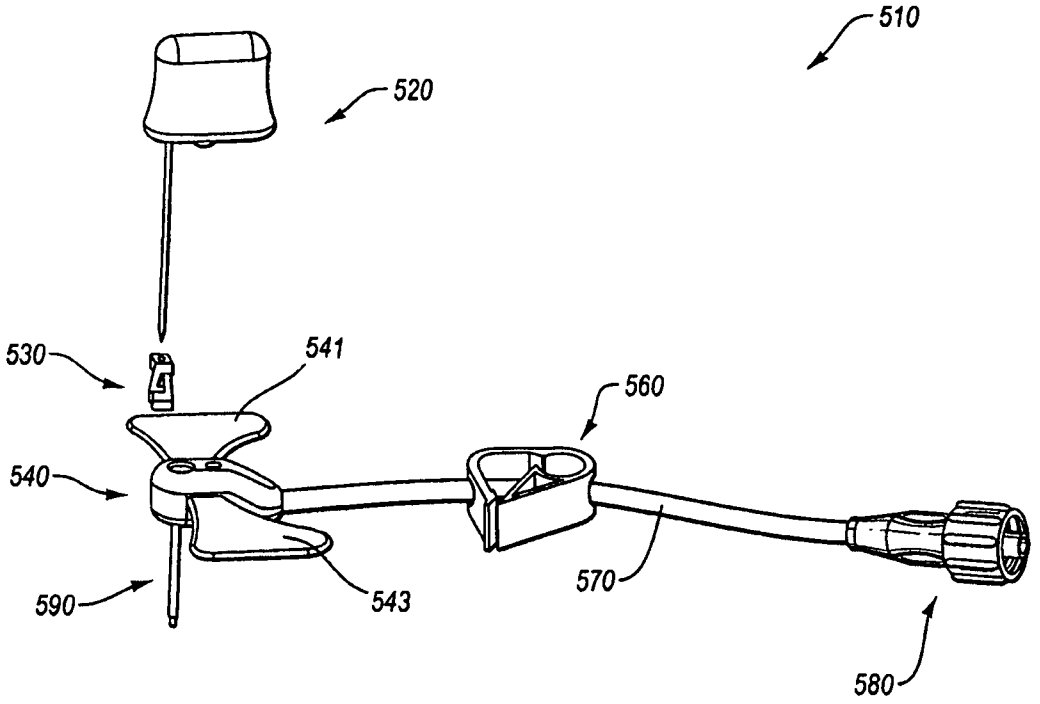

FIG. 46

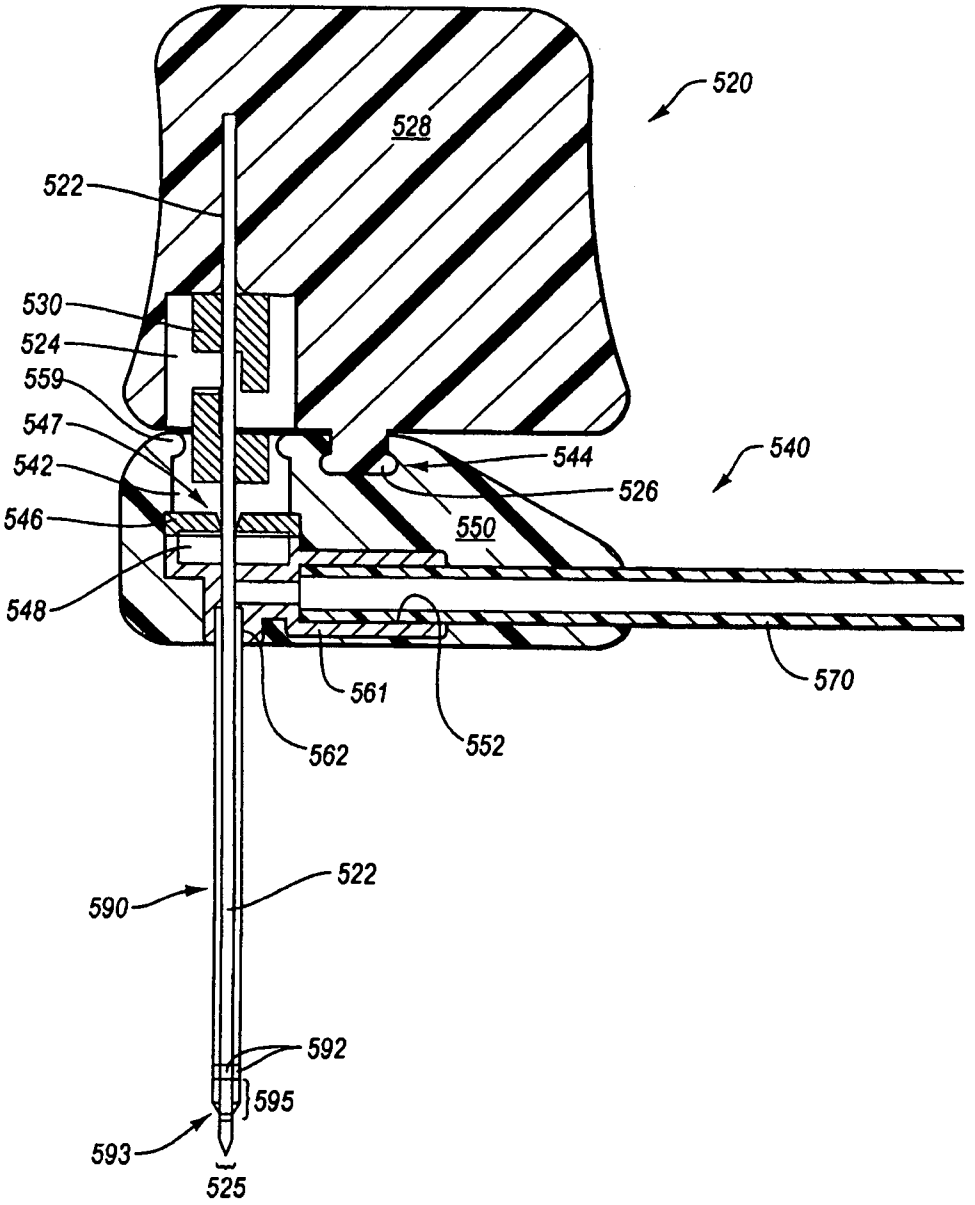
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FIG. 47

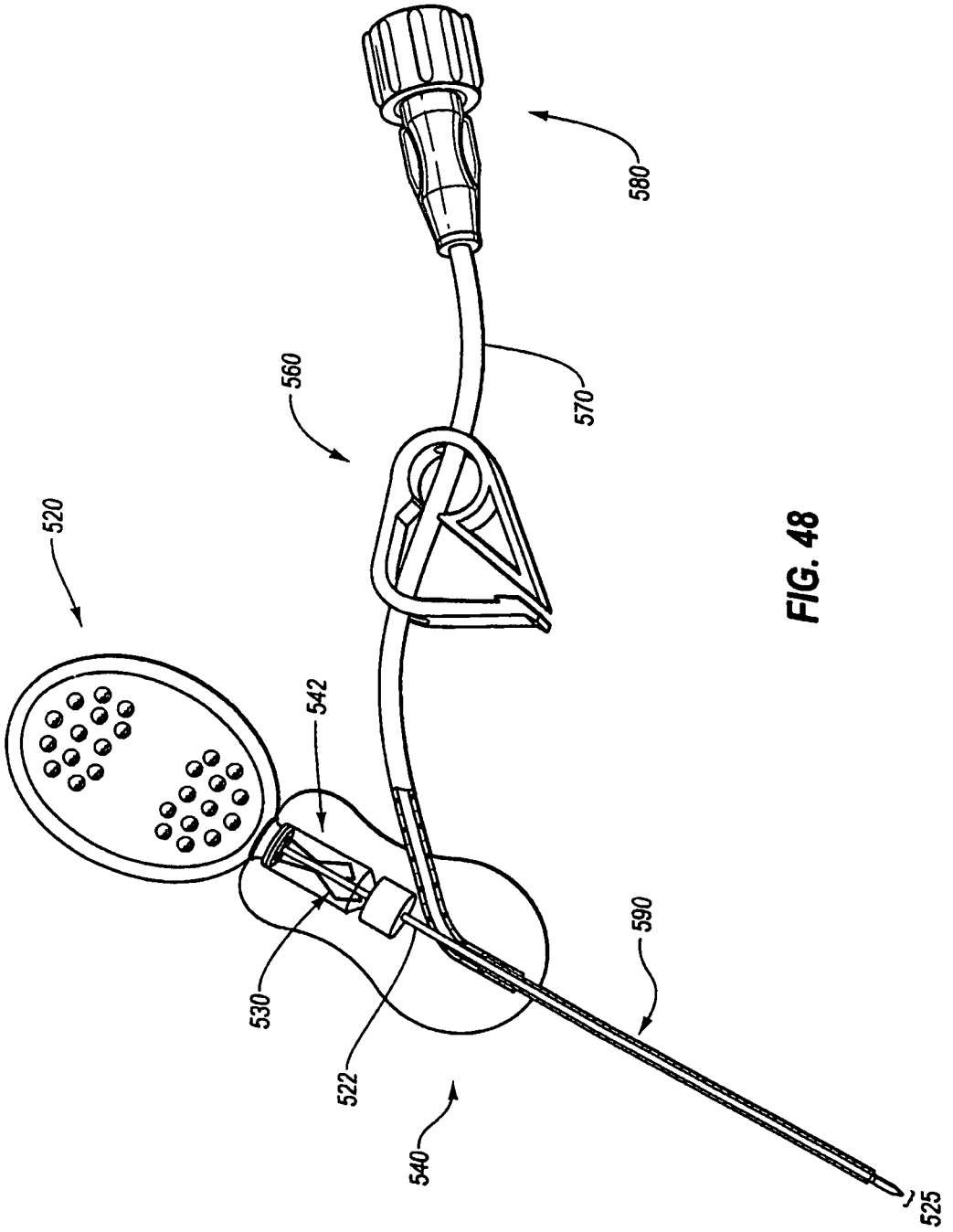


FIG. 48

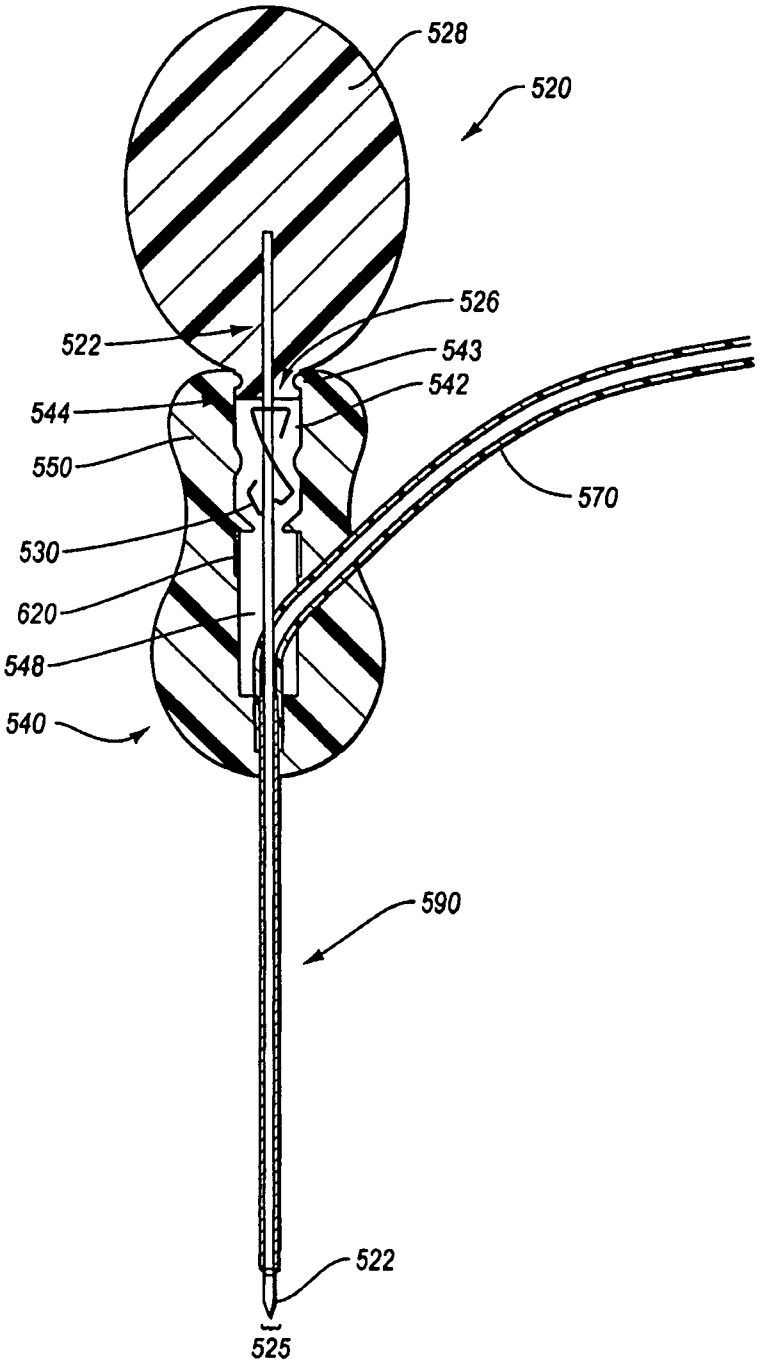


FIG. 49

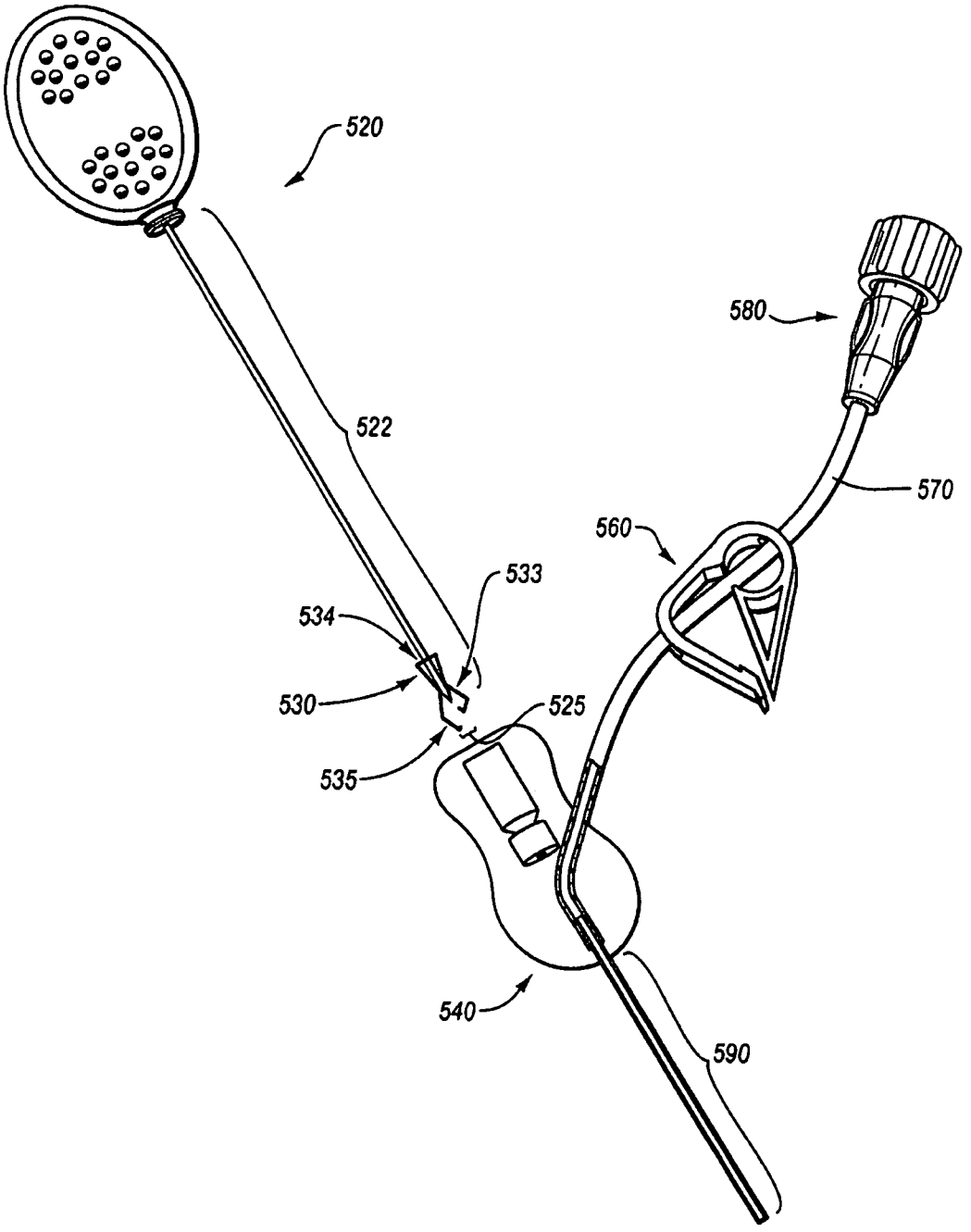


FIG. 50

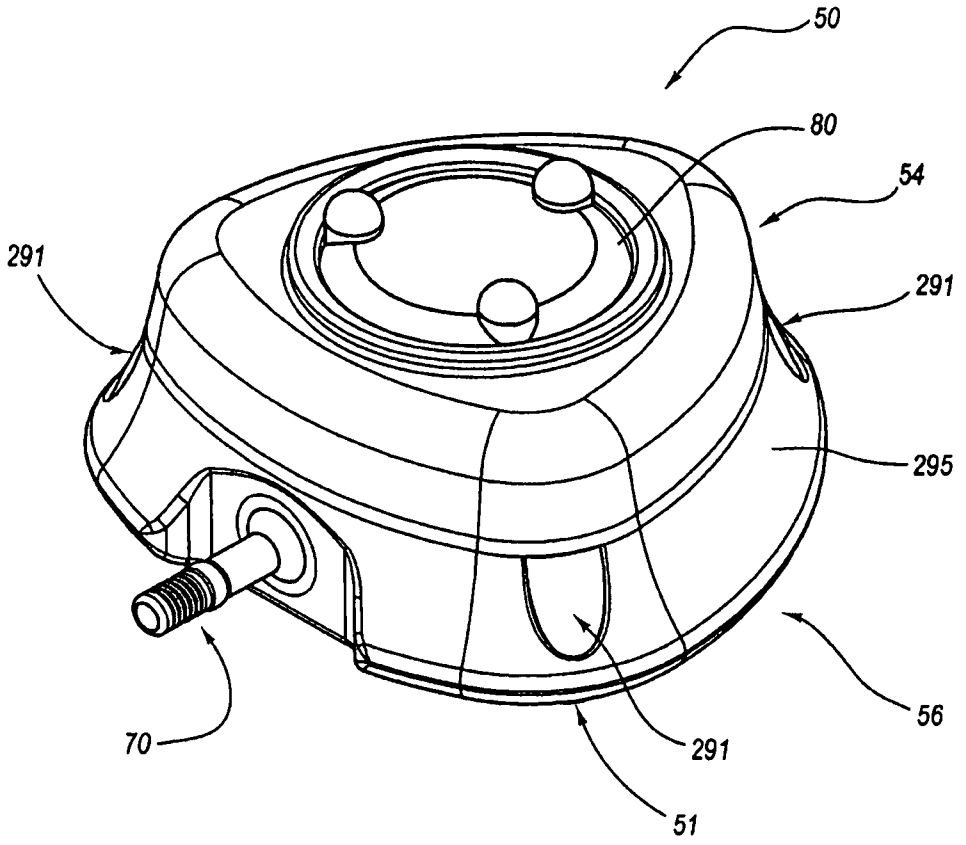


FIG. 51

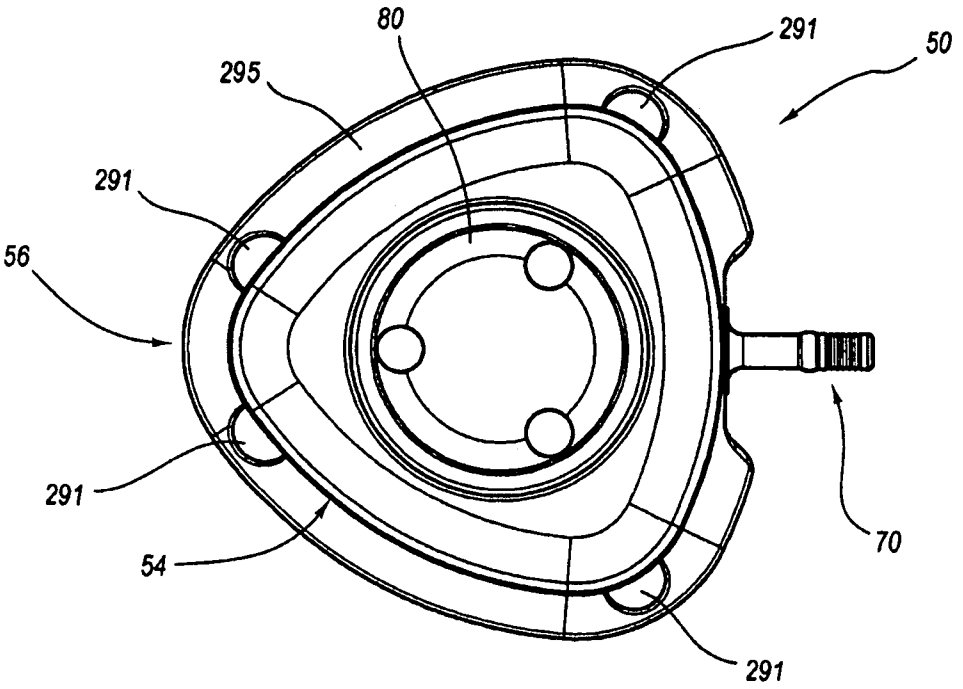


FIG. 52

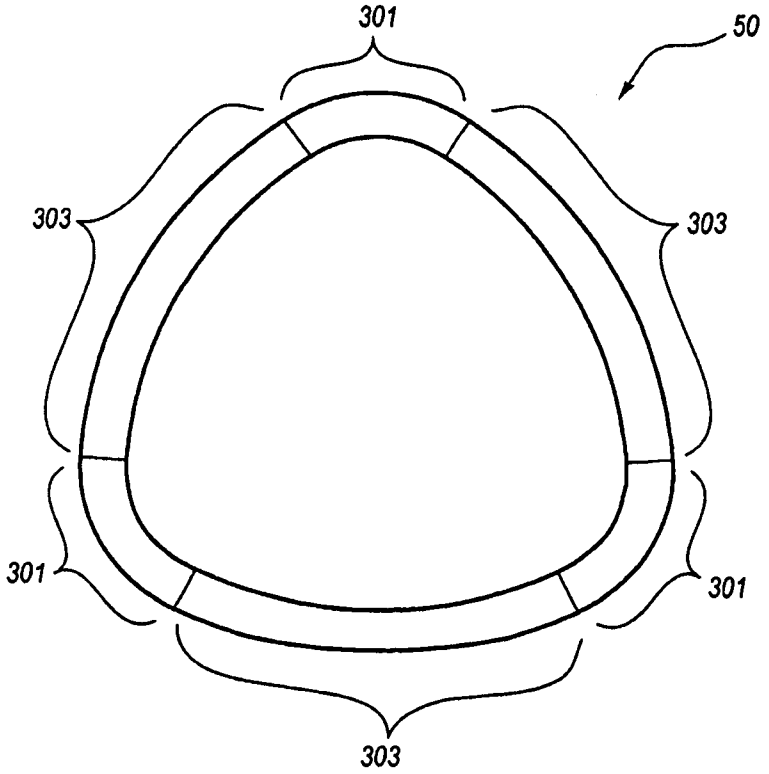


FIG. 53

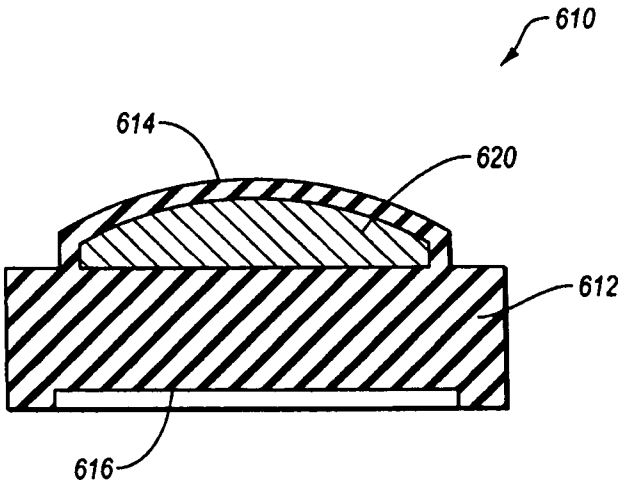


FIG. 54

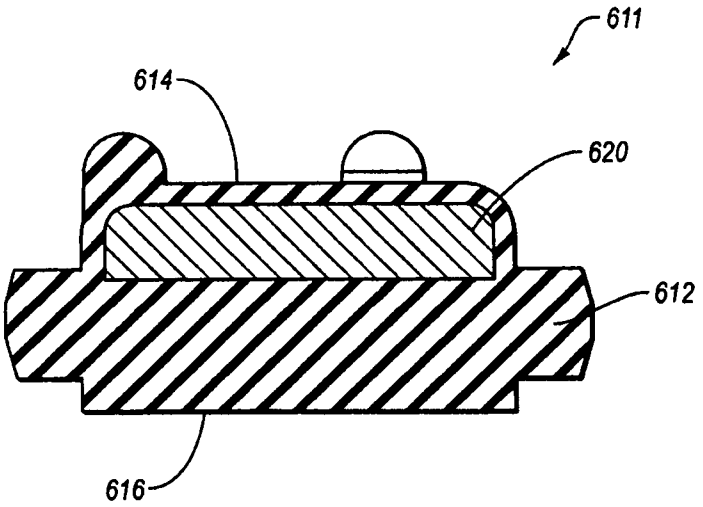


FIG. 55

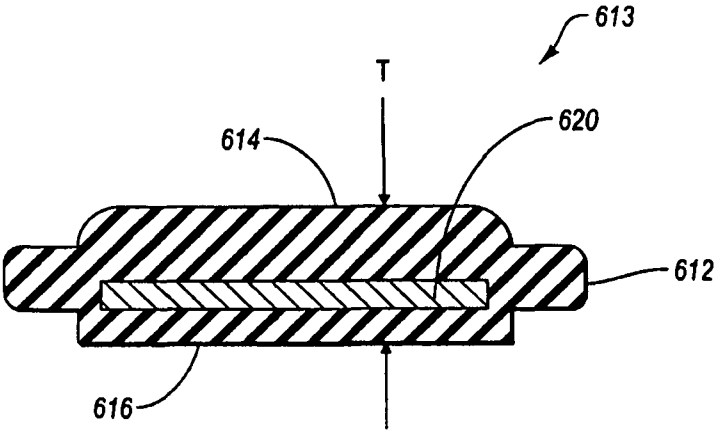


FIG. 56

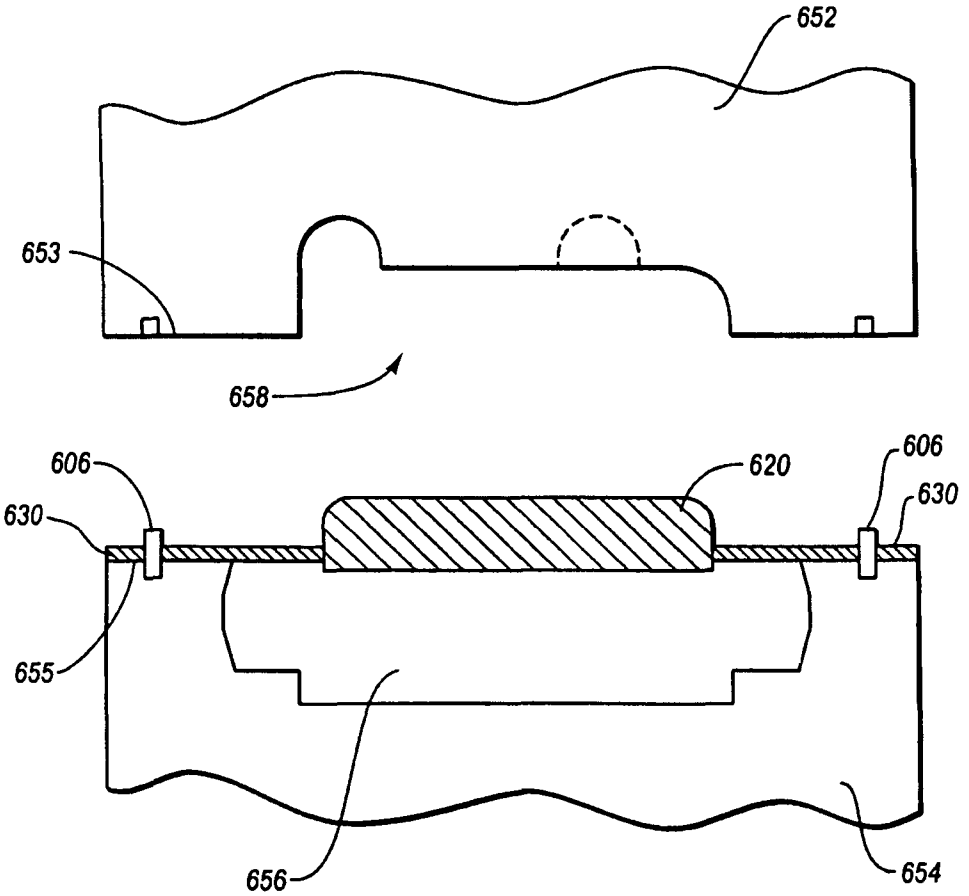


FIG. 57

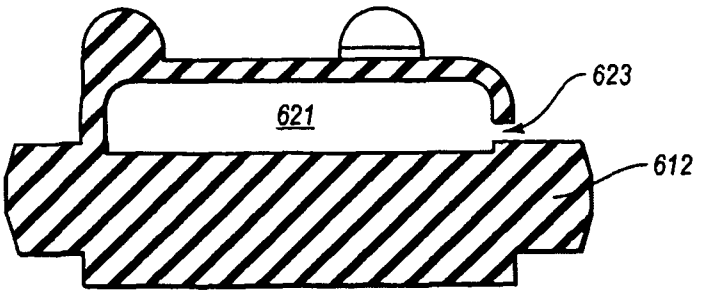


FIG. 58

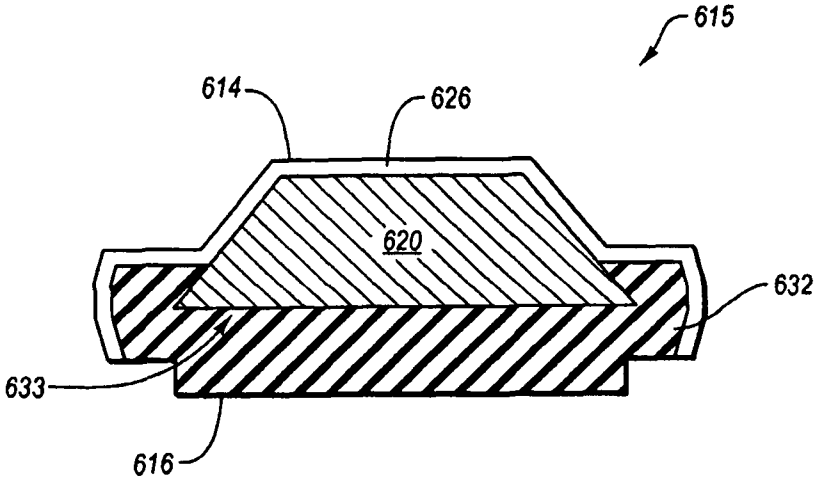


FIG. 59

METHODS OF PERFORMING A POWER INJECTION PROCEDURE INCLUDING IDENTIFYING FEATURES OF A SUBCUTANEOUSLY IMPLANTED ACCESS PORT FOR DELIVERY OF CONTRAST MEDIA

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of U.S. patent application Ser. No. 11/380,124, filed Apr. 25, 2006, now U.S. Pat. No. 8,545,460, which claims the benefit of priority to U.S. Provisional Patent Application No. 60/737,466, filed Nov. 15, 2005, and to U.S. Provisional Patent Application No. 60/675,309, filed Apr. 27, 2005, each of which applications is hereby incorporated by reference in its entirety into this application.

BACKGROUND

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

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

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

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

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

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

Particularly, the use of power injection systems in combination with conventional vascular access ports has achieved less than ideal results. Thus, it may be appreciated that vascular access ports for infusion systems and infusion-related apparatuses structured for performing power injection may be advantageous.

SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION

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

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

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

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

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

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

Explaining further, housing **60** of access port **50** may comprise a biocompatible material such as polysulfone, titanium, or any other suitably biocompatible material. Thus, cap **54** and base **56** may couple to one another generally along a mating line and may be secured or affixed to one another. More particularly, in one embodiment, both cap **54** and base **56** may comprise titanium and may be welded, brazed, soldered, or otherwise affixed to one another. Such a configuration may provide suitable mechanical strength for capturing

septum **80** between cap **54** and base **56**. Optionally, cap **54** and base **56** may be coupled to one another by at least one fastening element (e.g., at least one bolt, at least one screw, at least one rivet, etc.), at least one adhesive, or a combination of such coupling mechanisms. Similarly, in one embodiment, outlet stem **70** and base **56** may each comprise titanium and may be welded or otherwise bonded or coupled to one another.

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

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

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

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

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

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

secure, capture, or retain a portion of tenon region **270** of septum **180** within the mortise region of housing **160** even if a selected maximum pressure is developed within reservoir **166** of access port **150**.

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

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

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

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

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

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

Further, structural element **112** may be coupled to septum **120** by an adhesive, welding, snap-fitting, molding the septum **120** about a portion of the structural element **112**, otherwise imbedding a portion of structural element **112** within septum **120**, or as otherwise suitable. Similarly, structural element **112** may be coupled to base **56** by an adhesive, welding, or imbedding a portion of structural element **112** within base **56**. It may also be appreciated that, optionally, structural element **112** may exhibit a modulus of elasticity that exceeds a modulus of elasticity of septum **120**. Such a configuration may allow for structural element **112** to resist

deformation of septum **120** in response to a pressure developed within reservoir **66** (e.g., during a "power injection" process).

FIG. **13** shows a schematic cross-sectional view of an access port **110** according to the instant disclosure including another embodiment of structural element **112**. Particularly, as shown in FIG. **13**, structural element **112** may include a barbed end **116**, which is positioned at least partially within septum **120**. Such a configuration may couple structural element **112** to septum **120** and may resist against deformation of the septum **120** in response to pressure developed within reservoir **166**. Furthermore, as shown in FIG. **13**, the barbed end **116** of structural element **112** may, optionally, be pointed. Further, the point of barbed end **116** may be oriented toward upper surface **123** of septum **120**. Such a structure may deflect a cannula that is inserted through septum **120** and contacts barbed end **116** so that the cannula is directed away from structural element **112**. Optionally, in another embodiment, structural element **112** may extend through base **56** and may be affixed to lower surface **113** of base **56**.

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

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

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

Another aspect of the instant disclosure contemplates that at least a portion of an upper surface of a septum may be constrained or limited in its deformation. In one embodiment, at least one structural element may be positioned upon or adjacent to an upper surface of a septum to limit deformation of the septum in a direction toward the structural element. Put another way, at least one structural element may extend laterally upon or adjacent to at least a portion of an upper surface of a septum. For example, FIG. **18** shows a schematic, side cross-sectional view of an access port **110** including a septum **130** and a structural element **132** positioned adjacent to an upper surface **133** of septum **130**. Optionally, structural element **132** may be bonded or affixed to upper surface **133** of septum **130**. Structural element **132** may be structured to resist deformation of septum **130** in a direction generally away from reservoir **166**. In one embodiment, structural element **132** may substantially overlay or cover upper surface **133** of septum **130**. Optionally, structural element **132** may be at least partially embedded within septum **130**. In one embodiment, structural element **132** may be penetrable by a cannula (e.g., a needle). In another embodiment, structural element **132** may cover a selected portion (i.e., at least a portion) of upper surface **133** of septum **130**, which may allow for openings or apertures formed in structural element **132** through which a cannula may be inserted into upper surface **133** of septum **130**. It may be appreciated that, optionally, a modulus of elasticity of structural element **132** may exceed a modulus of elasticity of septum **130**, so that deformation of septum **130** may be inhibited to a selected degree by structural element **132**. Further, although a thickness (labeled "t") of structural element **132** is shown in FIG. **18** as being substantially uniform, the instant disclosure contemplates that a thickness "t" of structural element **132** may vary, with-

out limitation. For example, thickness "t" of structural element **132** may be maximum proximate to a centroid of the upper surface **133** of septum **130**. In addition, as shown in FIG. **18**, structural element **132** may be positioned between cap **54** and septum **130**. Structural element **132** may be affixed to one or both of cap **54** and septum **130**, if desired. For example, structural element **132** may be adhesively affixed, welded, mechanically fastened, or otherwise suitably coupled to one or both of cap **54** and septum **130**. Furthermore, structural element **132** may comprise a metal (e.g., titanium, steel, etc.), a polymer (e.g., DELRIN® polyurethane, nylon, etc.), or any other suitable material. In another embodiment, as discussed further below, structural element **132** may comprise a relatively tightly woven fabric that resists tissue ingrowth (if positioned in potential contact with an internal cavity of the body). In a further embodiment, a structural element **132** may comprise a substantially fluffy or compressible polyester that may promote tissue healing of punctures created by a cannula passing through septum **130** of access port **110** (if positioned in potential contact with an internal cavity of the body).

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

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

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

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

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

In another embodiment, the instant disclosure contemplates that a structural element may be at least partially embedded within a septum and may be in the form, configuration, or shape of a two-dimensional or plane (e.g., a circle, ellipse, triangle, rectangle, etc.) within the septum. For example, FIG. **26** shows a partial top elevation view of a septum **120** and a structural element **141** extending within the septum **120**. In further detail, FIG. **27** shows a perspective

view of a sectioned septum **120** including a structural element **141** embedded within the septum **120**. As shown in FIGS. **26** and **27**, in one embodiment, structural element **141** may be generally circular. More generally, one or more structural elements **141** may be at least partially embedded within a septum (e.g., a septum **120** or **130**, as discussed above), if desired. For example, a plurality of structural elements **141** may be embedded within a septum **120** and arranged substantially concentrically with respect to one another, as shown in FIG. **28** in a partial, top elevation view. Structural element **141** may be generally elongated (as shown in FIGS. **26-28**) or may, more generally, exhibit a shape and size configured to resist deformation of the septum **120**, without limitation. Thus, it should be appreciated that one or more structural elements **141** may embody, for example, a washer or a disk that is frustoconical, domed, or otherwise shaped. In another embodiment, at least one structural element **141** may form, generally, a toroid. Further, at least one structural element **141** may exhibit at least one selected characteristic (e.g., exhibiting a selected size, shape, elasticity, strength, etc.) to impart a desired level of resistance to deformation (i.e., flexibility) of septum **120**. Such a configuration may provide a selected level of resistance to deformation of septum **120** in response to a pressure developed within a reservoir of an access port.

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

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

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

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

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

55D or a polymer, such as TECOTHANE® 95A. For example, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.048 inches (+0.003 inches) (i.e., 19 GA), tubing section **314** may comprise a polymer, such as TECOTHANE® 55D. In other examples, if tubing section **314** has an inner diameter (i.e., a lumen) of about 0.041 inches or 0.034 inches (+0.003 inches) (i.e., 20 GA or 22 GA, respectively), tubing section **314** may comprise a polymer, such as TECOTHANE® 95A. Optionally, any polymer, such as TECOTHANE® type material may be at least substantially free of a plasticizer, such as, for instance, Di(2-Ethylhexyl) Phthalate ("DEHP"). In one embodiment, connector **312** may comprise polyvinylchloride ("PVC") and may be, optionally, at least substantially free of plasticizer. The materials disclosed above are merely examples; more generally, tubing section **314**, connector **312**, base member **340**, and cannula **350** may comprise any material (e.g., thermoplastic, polyurethane, metal, etc.) suitable for providing a robust and effective infusion set **310**.

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

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

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

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

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

In another embodiment, a reinforcing element may be incorporated within at least one of the plurality of layers comprising tubing. For example, FIG. **40** shows a schematic side cross-sectional view of tubing **403** including inner layer **430** and outer layer **432**, wherein at least one reinforcing element **434** is incorporated within outer layer **432**. Optionally, at least one reinforcing element **434** may be incorporated within any layer or layers of a plurality of layers comprising tubing, without limitation. As shown in FIG. **40**, reinforcing

element **434** may comprise a coil, in one embodiment. One of ordinary skill in the art will appreciate that many variations are possible, for example, at least one reinforcing element may comprise a mesh (e.g., a wire mesh, a fabric, a fiber mesh, etc.). In another embodiment, at least one reinforcing member may comprise one or more elongated members extending longitudinally within at least one layer comprising tubing (e.g., aligned with the direction of extension of the tubing). In another embodiment, at least one reinforcing member may comprise one or more rings. Such a configuration may provide radial stiffness, strength, or both to a tubing section.

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

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

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

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

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

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

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

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

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

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

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

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

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

In a further embodiment, an infusion system may be structured so that a slender pointed element passes through an extension tube, a flexible catheter, or both. Explaining further, appropriate placement and configuration of a septum may allow for a slender pointed element to pierce or pass into an extension tube, a flexible catheter, or both. FIGS. **48** and **49** show another embodiment of a hub **540** including recess **542**, sleeve **620**, and septum **548**. In addition, at least a portion of each of extension tube **570** and flexible catheter **590** may extend partially within hub body **550**. Further, flexible catheter **590** extends partially within extension tube **570**. Put another way, flexible catheter **590** may at least partially overlap with extension tube **570** and vice versa. In another embodiment, a single tubular element may extend through hub **540** and function as both the flexible catheter **590** and extension tube **570**, if desired. Further, optionally, septum **548** may at least partially surround a portion of extension tubing **570**. Such a configuration may facilitate sealing of septum **548** upon removal of slender pointed element **522** therefrom. Sleeve **620** may compress septum **548** so as to

facilitate sealing of septum **548** upon removal of slender pointed element **522** from the region of the septum **620** that the sleeve **620** surrounds. Septum **548** may be structured according to any septum embodiments disclosed herein (e.g., including at least one structured element, etc.) for performing power injection, without limitation.

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

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

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

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

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

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

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

It will be appreciated that other equipment and devices (e.g., infusion sets, tubing, injectors, etc.) may be identifiable in relation to a suitable maximum flow rate or maximum pressure. For example, particular infusion apparatuses may include one or more of the above-mentioned identification attributes or features. Such a configuration may allow for different components (e.g., tubing, needles, access ports, mechanical injectors, etc.) to be matched with one another. For example, substantially similar or matching identification attributes shared by a power injection apparatus, an infusion set, and an access port may indicate suitability for use with one another to perform a selected power injection process.

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

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

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

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

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

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

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

The instant disclosure contemplates a variety of different manufacturing methods may be employed for forming a septum comprising a gel. For example, generally, a body of a septum may be formed to substantially surround at least one

gel region or a recess or chamber may be formed by a septum body that is filled with a gel. In one embodiment, a gel region may be suspended within a mold for forming a body of a septum. More particularly, FIG. **57** shows a schematic, side cross-sectional view of a first mold **652** and a second mold **654**, wherein gel region **620** is positioned between (e.g., suspended) first mold **652** and second mold **654**. As shown in FIG. **57**, gel region **620** is positioned by a frame element **630**, which abuts parting surface **655** of second mold **654**. As shown in FIG. **57**, frame element **630** may be positioned by pins **606**. In other embodiments, frame element **630** may be suitably positioned, without limitation. In a particular embodiment, parting surface **653** of first mold **652** may be positioned proximate to parting surface **655** of second mold **654** (i.e., parting surfaces **653** and **655** may be separated by frame element **630**) to form a chamber defined by cavity **658** and cavity **656**. Further, a hardenable material (e.g., a curable material, such as a curable silicone, a thermoplastic, a resin, etc.) may be injected into the chamber and hardened. Thus, the hardenable material may surround or encapsulate gel region **620** and may exhibit a geometry that is complimentary to cavities **656** and **658**.

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

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

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

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

What is claimed is:

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

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

identifying the indicating radiographic feature on the x-ray; and

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

2. The method according to claim **1**, wherein the identifying step comprises identifying a radiographic pattern included in the cannula-penetrable septum of the access port.

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

4. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by palpating to feel a structural feature of the access port indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

5. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by visually perceiving information outside of the body of the patient included on an element selected from the group consisting of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof, the element indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

6. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting a radiofrequency identification (RFID) tag associated with the implanted access port, the RFID tag signaling that the access port is suitable for flowing fluid at a rate of at least about 1 milliliter per second through the access port.

7. The method according to claim **1**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an ultrasound-detectable feature associated with the implanted access port, the ultrasound-detectable feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

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

providing an access port including a cannula-impenetrable housing and a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port;

implanting the access port in a subcutaneous pocket formed under a patient's skin;

taking an image of the implanted access port via imaging technology;

identifying the access port as being suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port via the image of the radiographic feature of the access port; and

injecting contrast media fluid through the access port at a rate of at least 1 milliliter per second.

9. The method according to claim **8**, wherein the identifying step comprises identifying a radiographic letter.

10. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by palpating to feel a structural feature of the access port indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

11. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by visually perceiving information outside of the body of the patient included on an element selected from the group consisting of a key chain, a bracelet, a wrist band, a sticker provided on a patient's chart, a patient ID card, a label provided on packaging of the access port, and combinations thereof, the element indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

12. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an RFID tag associated with the implanted access port, the RFID tag signaling that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

13. The method according to claim **8**, further comprising the step of confirming that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second by detecting an ultrasound-detectable feature associated with the implanted access port, the ultrasound-detectable feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

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

implanting an access port including a fluid reservoir accessible through a septum and a radiographic feature, the radiographic feature indicating that the access port is capable of handling pressures associated with power injection;

taking an image of the implanted access port via imaging technology;

identifying the access port as capable of handling pressures associated with power injection via the image of the radiographic feature of the access port;

palpating the access port to identify the location of the septum;

inserting a needle through a septum, the needle connected to tubing and in fluid communication therewith, the needle and tubing structured to accommodate a fluid pressure of at least 400 psi; and

injecting contrast media fluid through the tubing and needle to induce a pressure within the access port in the range of 37 psi and 65 psi.

* * * * *

EXHIBIT 4

SMART PORT® Guidelines for Health Care Providers

The Smart Port® power-injectable port is intended to facilitate frequent blood sampling or the delivery of medications, nutritions, blood products and power injection of contrast media for imaging. Access is performed by percutaneous needle insertion using an anticoring (huber point) needle.

HOW TO IDENTIFY THE SMART PORT® POWER-INJECTABLE PORT

Each Smart Port® power-injectable port is packaged with a Smart Port® Patient Education Packet that includes a Smart Port® Patient Information Booklet, Smart Port® Patient Identification Card, a Key Ring Card and Patient ID Bracelet. The patient should receive these items at the time the port is implanted.

If the patient does not have at least one of the above items needed to identify their port as being capable of power injection of contrast media, the port can be identified by the Smart Angle® identifier technology on the CT and CT Low-Profile models or CT engraving on all models through Chest X-Ray or CT Scout Scan.

VORTEX TECHNOLOGY

Tangential outlet and clear-flow technology set up efficient flushing action to hyper-cleanse the entire chamber, resist sludge build up, and reduce occlusions and infections.

IMPORTANT INFORMATION

Read all instructions prior to utilization of device.
The LifeGuard™ Safety Infusion Set 19 or 20 gauge non Y-site needles must be utilized to access the Smart Port® implanted port for power injection of contrast media.

The LifeGuard™ Safety Infusion Set 19 or 20 gauge needles should be used in all procedures. These needles have been designed and tested to ensure that septum life is preserved.

Contrast dye should be warmed to body temperature prior to utilization for power injection. Failure to have contrast at body temperature may lead to device failure.

Do not exceed the maximum flow rate of 5 mL/sec. Failure can result in over pressurization of the port device. The power injection machine may not prevent over pressurization in the presence of occlusion or resistance.

Do not exceed 300 psi Exceeding pressures of 300 psi could lead to device rupture or catheter malposition.

Failure to assess the patency of the Smart Port® implanted port prior to power injection may lead to device rupture or failure.

Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to device usage. A blood return should be present prior to usage of device for any therapy or testing.

If the patient complains of pain, or if there is swelling when the device is flushed or when medication or contrast media is administered, evaluate the device for infiltration, proper needle placement, and potential complications such as occlusion, kinking, breakage, Pinch-Off Syndrome, thrombosis or malposition. Failure to assess these complaints or observations can lead to device failure.

Power injection machine pressure limiting (safety cut-off) settings may not prevent over pressurization of an occluded device.

10 mL syringes or larger are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.

The catheter tip should be evaluated for proper location prior to power injection.

Do not exceed 300 psi or 5 mL/sec when using the LifeGuard™ Safety Infusion Set.

Power injection using the Smart Port® implanted port should be performed by trained clinicians who are knowledgeable about the utilization of the Smart Port® implanted port.

100% Guaranteed Against Sludge Buildup

Ask your AngioDynamics sales representative for details.

PATIENT EDUCATION PACKET

Patient Info Guide Contents:
> The Smart Port® Power Injectable Port Advantage
> Description of the Smart Port® Power Injectable Port
> Placement of The Smart Port® Power Injectable Port
> Use of Smart Port® Power Injectable Port
> Potential Problems with the Smart Port® Power Injectable Port
> Care of the Smart Port® Power Injectable Port
> Questions Regarding Your Smart Port® Power Injectable Port


Patient Education Guide


Patient Care Checklist


Patient ID Card/Key Ring


Implant Record Stickers for Charts


Patient ID Bracelet

PROCEDURE FOR POWER INJECTION

1. The clinician should first review the patient chart to ensure that the patient has a Smart Port® implanted port that is indicated for power injection of contrast media. The patient should have a Smart Port® Patient Identification Card, Smart Port® Patient Information Guide or Smart Port® Key Ring Card.

Note: The completed patient identification card should be given to the patient, who should be instructed to carry it at all times.

2. The Smart Port® Implanted Port should be accessed with a 19 or 20 gauge non y-site LifeGuard™ Safety Infusion Set for injection of contrast media. The tubing on the safety needle should be clamped.

3. Remove the injection cap attached to the end of the LifeGuard™ Safety Infusion Set.

4. Attach a 10 mL or larger syringe to the luer hub end of the LifeGuard™ Safety Infusion Set, release the clamp and aspirate to confirm blood return.

Note: Absence of blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to catheter usage. A blood return should be present prior to usage of device. Note: Testing aspiration for simulated blood return is 0.5 mL/sec.

5. Flush the Smart Port® Implantable Port with 10–20 mL 0.9% normal saline. The device should flush without resistance. *Warning: Not assessing patency may result in device failure.*

6. Close the clamp of the LifeGuard™ Safety Infusion Set tubing.

7. Remove the syringe from the LifeGuard™ Safety Infusion Set.

8. Attach the power injection tubing per manufacturer's recommendations to the luer hub end of the LifeGuard™ Safety Infusion Set. Release the clamp.

9. Set the power injection machine per manufacturer's recommendations for a maximum pressure of 300 psi.

10. Perform the study. Do not exceed 5 mL/sec or 300 psi during injection of contrast dye.

11. Close the clamp. Disengage the power injection tubing from the luer hub end of the LifeGuard™ Safety Infusion Set.

12. Place a new injection cap on the LifeGuard™ Safety Infusion Set luer hub.

13. Flush the Smart Port® Implantable Port with 10–20 mL 0.9% normal saline.

14. Flush the Smart Port® Implantable Port with 3–5 mL of 10–100 units/mL heparinized saline. Actual amount and strength depends on facility policy.

Smart Port® CT

Description	Introducer Size (Fr.)	Part #	Material Port Body/Catheter	Catheter				Port
				ID/OD (mm)	O.D. (Fr.)	Length (cm)	Internal Volume (mL/cm)	Internal Volume (mL)
Detached silicone catheter	8	CT75STSD	Titanium/Silicone FluoroMax®	1.4/2.5	7.5	66	0.015	0.7
Detached polyurethane catheter	8	CT80STPD	Titanium/Polyurethane FluoroMax®	1.5/2.7	8	66	0.020	0.7
Detached silicone catheter	10	CT96STSD	Titanium/Silicone FluoroMax®	1.6/3.2	9.6	66	0.020	0.7
Detached silicone catheter non filled suture holes	8	CT75STSD-NF	Titanium/Silicone FluoroMax®	1.4/2.5	7.5	66	0.015	0.7
Detached polyurethane catheter non filled suture holes	8	CT80STPD-NF	Titanium/Polyurethane FluoroMax®	1.5/2.7	8	66	0.020	0.7
Detached silicone catheter non filled suture holes	10	CT96STSD-NF	Titanium/Silicone FluoroMax®	1.6/3.2	9.6	66	0.020	0.7
Attached silicone catheter	8	CT75STSA	Titanium/Silicone FluoroMax®	1.4/2.5	7.5	66	0.015	0.7
Attached polyurethane catheter	8	CT80STPA	Titanium/Polyurethane FluoroMax®	1.5/2.7	8	66	0.020	0.7
Attached silicone catheter	10	CT96STSA	Titanium/Silicone FluoroMax®	1.6/3.2	9.6	66	0.020	0.7

Smart Port® CT Mini

Description	Introducer Size (Fr.)	Part #	Material Port Body/Catheter	Catheter				Port
				ID/OD (mm)	O.D. (Fr.)	Length (cm)	Internal Volume (mL/cm)	Internal Volume (mL)
Detached polyurethane catheter	7	CT66PTPD	Titanium/Carbothane®	1.4/2.2	6.6	55	0.016	0.3

Smart Port® CT Low-Profile

Description	Introducer Size (Fr.)	Part #	Material Port Body/Catheter	Catheter				Port
				ID/OD (mm)	O.D. (Fr.)	Length (cm)	Int Vol (mL/cm)	Int Vol (mL)
Detached polyurethane catheter	7	CT66LTPD	Titanium/Carbothane®	1.4/2.2	6.6	55	0.016	0.4

SMART PORT® POWER-INJECTABLE PORT SYSTEM MAINTENANCE

After each delivery of medications or fluid: Flush with at least 20 mL of normal saline followed by 3-5 mL of heparinized saline solution.

After blood withdrawal: Flush with a minimum of 10 mL of saline followed by 3-5 mL of heparinized saline solution.

Port not in use: 3-5 mL of heparinized saline solution should be administered every four weeks.

After power injection of contrast media: Flush with 10-20 mL normal saline, followed by 3-5 mL of heparinized saline solution.

LIFEGUARD™ SAFETY INFUSION SETS

LifeGuard™ Non Y-site Models

Description	Part #
19 Ga X .75"	LG-19-75
19 Ga X 1"	LG-19-100
20 Ga X .50"	LG-20-50
20 Ga X .75"	LG-20-75
20 Ga X 1"	LG-20-100
20 Ga X 1.5"	LG-20-150

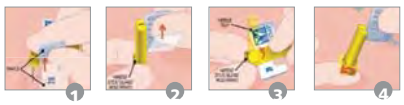
>> Quantity of 20 per box

>> Maximum Setting for Flow Rates for all models is 5 mL/sec

>> Maximum Pressure Setting is 300 psi

OPERATING LIFEGUARD™ SAFETY INFUSION SET

1. Access the Port >> Grasp the wings with thumb and middle finger, placing your index finger on top of the needle head. >>Insert needle perpendicular to the port. >> Advance needle through the skin and the septum until it makes contact with the bottom of the reservoir.



2. De-Access the Port >> Raise the needle trap to a 90° angle. >> Using your non-dominant hand, grasp the needle stick guard and hold down firmly.

3. De-Access Part 2 >> While holding the needlestick guard firmly, grasp the flexible wings and pull upward until the needle is completely encapsulated in the needle trap. >> Note: The needle trap allows for visual confirmation that the needle is fully encapsulated and safe. Additionally, you may feel or hear it lock into the safe position.

4. De-Access Part 3 >> Flip the needlestick guard toward the needle trap. >> Dispose in Sharps Container port.

ANGIODYNAMICS®

EXHIBIT 5

SMART PORT

POWER-INJECTABLE PORTS

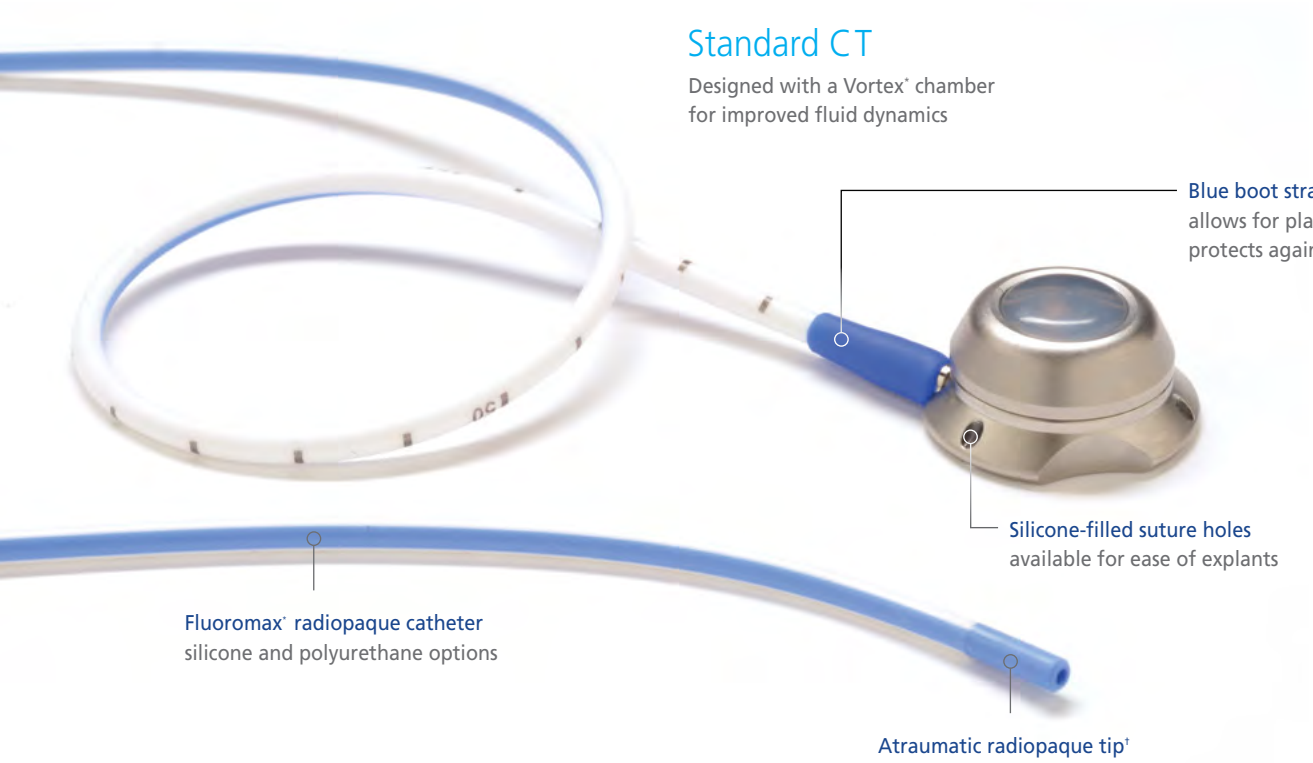
VORTEX TECHNOLOGY

angiodynamics

Engineered *for* Life

Smart Port* High-Performance Titanium Power-Injectable Ports

are indicated up to 5mL/sec and 300 psi and are MRI-conditional—3 Tesla.



Standard CT

Designed with a Vortex* chamber for improved fluid dynamics

Blue boot strain-relief mechanism
allows for placement flexibility and protects against catheter kinking

Silicone-filled suture holes
available for ease of explants

Fluoromax* radiopaque catheter
silicone and polyurethane options

Atraumatic radiopaque tip†

Low-Profile CT

6.6F catheter reduces the risk of thrombosis

Mini CT

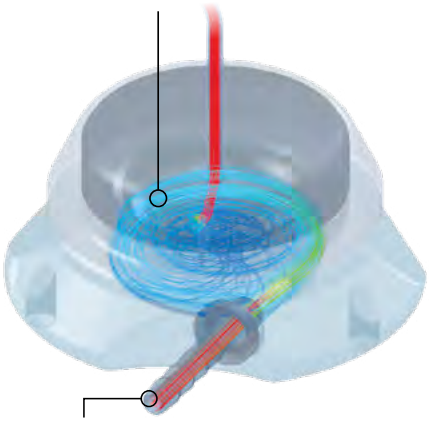
Smallest profile titanium CT-rated port indicated for chest or peripheral placement

Each Smart Port model features a light-weight design and a CT-engraved port body for better identification.

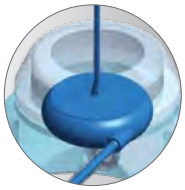
The Vortex Technology Difference

Reduce chamber occlusions.
Increase nursing efficiency.
Reduce overall interventions.

Superior Fluid Dynamics
compared to conventional ports.



Tangential Outlet
helps create a flushing action within the port to hyper cleanse the entire chamber leading to a reduced rate of occlusions.



Round Chamber
allows fluid to reach all surfaces in the chamber, helping eliminate dead spaces, resist sludge build-up, and reduce occlusions.

VORTEX TECHNOLOGY

A comparison of conventional vs. Vortex chambered ports shows a clear advantage.[1]

Vortex demonstrated

73%
fewer port occlusions[1]

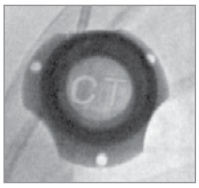
69%
fewer secondary interventions[1]

Use of Vortex port technology results in

$1,224
average savings per patient over conventional ports.[2]

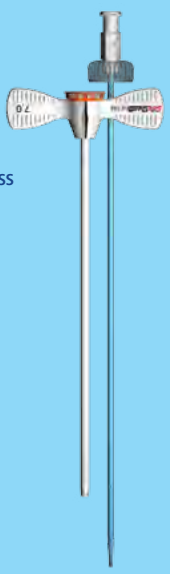
Identifying a Smart Port Power-Injectable Port

Smart Port power-injectable ports can be identified by the Smart Angle* technology on the CT and CT Low-Profile models. The CT engraving on all models can be identified through chest x-ray or CT Scout Scan. Each Smart Port patient receives an education packet—including an information booklet, ID card, key ring card and ID bracelet.



Safe Sheath* Ultra Lite
Valved, peel-away sheath

- Provides for effortless access for port insertion
- Decreased risk of blood loss and air embolism
- Ergonomically designed, easy-splitting break away hub and positive locking connector
- Available in select Smart Port kits



[1] Stevens B, Barton SE, Brechbill M, et. al. A Randomized, Prospective Trial of Conventional Vascular Ports vs. The Vortex "Clear-Flow" Reservoir Port in Adult Oncology Patients. JVAD 2000; (Summer).
[2] Third party verification by Pinnacle Healthcare Management.

Smart Port CT

Description	Introducer Size (Fr.)	UPN	UPN w/ Safe Sheath	Material Port Body/Catheter	Catheter ID/OD (mm)	Catheter O.D. (Fr.)	Catheter Length (cm)	Catheter Int Vol (mL/cm)	Port Int Vol (mL)
Detached silicone catheter	8	H787CT75STSD0	H787CT75STSDVI1	Titanium/Silicone FluoroMax	1.4/2.5	7.5	66	0.015	0.7
Detached polyurethane catheter	8	H787CT80STPD0	H787CT80STPDVI1††	Titanium/Polyurethane FluoroMax	1.5/2.7	8	66	0.020	0.7
Detached silicone catheter	10	H787CT96STSD0	H787CT96STSDVI1	Titanium/Silicone FluoroMax	1.6/3.2	9.6	66	0.020	0.7
Detached silicone catheter non filled suture holes	8	H787CT75STSDNF0	—	Titanium/Silicone FluoroMax	1.4/2.5	7.5	66	0.015	0.7
Detached polyurethane catheter non filled suture holes	8	H787CT80STPDNF0	—	Titanium/Polyurethane FluoroMax	1.5/2.7	8	66	0.020	0.7
Detached silicone catheter non filled suture holes	10	H787CT96STSDNF0	—	Titanium/Silicone FluoroMax	1.6/3.2	9.6	66	0.020	0.7
Attached silicone catheter	8	H787CT75STSA0	—	Titanium/Silicone FluoroMax	1.4/2.5	7.5	66	0.015	0.7
Attached polyurethane catheter	8	H787CT80STPA0	—	Titanium/Polyurethane FluoroMax	1.5/2.7	8	66	0.020	0.7
Attached silicone catheter	10	H787CT96STSA0	—	Titanium/Silicone FluoroMax	1.6/3.2	9.6	66	0.020	0.7

Smart Port CT Low-Profile

Description	Introducer Size (Fr.)	UPN	UPN w/ Safe Sheath	Material Port Body/Catheter	Catheter ID/OD (mm)	Catheter O.D. (Fr.)	Catheter Length (cm)	Catheter Int Vol (mL/cm)	Port Int Vol (mL)
Detached polyurethane catheter	7	H787CT66LTPD0	H787CT66LTPDVI1	Titanium/Carbothane	1.4/2.2	6.6	55	0.016	0.4

Smart Port CT mini

Description	Introducer Size (Fr.)	UPN	UPN w/ Safe Sheath	Material Port Body/Catheter	Catheter ID/OD (mm)	Catheter O.D. (Fr.)	Catheter Length (cm)	Catheter Int Vol (mL/cm)	Port Int Vol (mL)
Detached polyurethane catheter	7	H787CT66PTPD0	H787CT66PTPDVI1	Titanium/Carbothane	1.4/2.2	6.6	55	0.016	0.3

† Available on select models

†† Only available with 8.5F Introducer

IMPORTANT RISK INFORMATION

The following is a brief summary of important risk information for the Smart Port power-injectable port line. For detailed information on the categories referenced, please consult the instructions for use packaged with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

INDICATIONS FOR USE: The Smart Port CT power injectable port line is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, sampling of blood and power injection of contrast media for imaging.

Use of non Y site LifeGuard Safety Infusion Set (size = 20Ga or 19Ga) is indicated for power injection of contrast media. For power injection of contrast media, maximum recommended infusion rate is 5ml/sec.

INDICATIONS FOR USE: The Safe Sheath Ultralite is indicated for the introduction of various types of pacing leads and catheters. This device is intended for one time use only. Read instructions prior to use.

CONTRAINDICATIONS: Smart Port CT should not be implanted in the presence of known or suspected infections, bacteremia, septicemia and peritonitis, or in patients who have exhibited prior intolerance to the materials of construction, or patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.

WARNINGS AND PRECAUTIONS: Please see package insert for complete list of warnings and precautions.

POTENTIAL COMPLICATIONS: Consult package insert for a complete list of potential complications.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

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USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 > fax: 518-798-1360 > Canada tel: 800-268-0184
International > Haaksbergweg 75 (Margriettoren), 1101 BR, Amsterdam Z-O > The Netherlands
tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

www.angiodynamics.com

EXHIBIT 6

8.6 French Size
Calibre (F)
F-Größe (French)
Calibro F (French)
Tamanho Francês
Tamaño francés

Attachable
Amovible
Anschließbar
Collegabile
Anexável
Conectable

Attached
Intégré
Angeschlossen
Collegato
Anexado
Conectado

Ti Titanium
Titane
Titan
Titanio
Titânio
Titanio

MRI MRI Conditional 3 Tesla
Sans danger dans certaines conditions de RM 3T
Bedingte MRT-Sicherheit bei 3 Tesla
RM condizionata a 3 Tesla
Aprovado para RM de 3 Tesla
3 Tesla condicional a RM

Keep dry

Keep away from sunlight

CE 0086

Single use only. Do not reuse.
Do not resterilize.

STERILE EO Sterilized with Ethylene Oxide

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

ANGIODYNAMICS®

AngioDynamics®, Incorporated
One Horizon Way
Manchester, GA 31816 USA
518-798-1215 • 800-772-6446
www.AngioDynamics.com

P/N 107102 Rev. D

SMART PORT®

POWER INJECTABLE IMPLANTABLE PORT SYSTEMS

Instructions For Use

ANGIODYNAMICS®

TABLE OF CONTENTS

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INSTRUCTIONS FOR USE

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OVERVIEW

Introduction

AngioDynamics, Incorporated manufactures a complete line of implantable access ports. Ports are totally implantable devices designed to provide repeated access to the vascular system or a selected body site. These subcutaneous devices reduce the trauma associated with multiple punctures or the inconvenience of an externalized catheter.

The port is intended to facilitate frequent blood sampling or the delivery of medications, nutritions, blood products and power injection of contrast media for imaging. Access is performed by percutaneous needle insertion using an noncoring (Huber point) needle.

Important Information Regarding Smart Port® CT Power Injectable Ports

- Read all instructions prior to utilization of device.
- The LifeGuard™ Safety Infusion Set, 19 or 20 gauge non Y-site needles are recommended to access the Smart Port® CT implanted ports for power injection of contrast media.
- Contrast dye should be warmed to body temperature prior to utilization for power injection. Failure to have contrast at body temperature may lead to device failure.
- Maximum pressure limit settings for power injection have been established for each Smart Port® CT implantable port. Refer to the Procedure for Power Injection section in this booklet for additional information and instructions. Failure to follow these guidelines can result in over pressurization of the port device. The power injection machine may not prevent over pressurization in the presence of occlusion or resistance.
- Do not exceed 300 p.s.i. Exceeding pressures of 300 p.s.i. could lead to device rupture or catheter malposition.
- Failure to assess the patency of the Smart Port® CT implanted port prior to power injection may lead to device rupture or failure.
- Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to device usage. A blood return should be present prior to usage of device for any therapy or testing.
- If the patient complains of pain, or if there is swelling when the device is flushed or when medication or contrast media is administered, evaluate the device for infiltration, proper needle placement, and potential complications such as occlusion, kinking, breakage, Pinch-Off Syndrome, thrombosis or malposition. Failure to assess these complaints or observations can lead to device failure.
- Power injection machine pressure limiting (safety cut-off) settings may not prevent over pressurization of an occluded device.

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- 10 mL syringes or larger are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.
- The catheter tip should be evaluated for proper location prior to power injection.
- Do not exceed 300 p.s.i. when using the LifeGuard™ Safety Infusion Set.
- Power injection using the Smart Port® CT implanted ports should be performed by trained clinicians who are knowledgeable about the utilization of the Smart Port® CT implanted ports.

Procedure for Power Injection

1. Ensure that the patient has a Smart Port® CT implanted port. The patient should have a Patient Identification Card, Patient Information Guide, or Key Ring Card.

   The LifeGuard™ 19 or 20 gauge non Y-site Safety Infusion Sets should be utilized to perform power injection with Smart Port® CT power injectable ports

Model #	Maximum Setting for Flow Rates	Maximum Pressure Setting
CT96 codes	5 mL/sec	300 psi
CT80 codes	5mL/sec	300 psi
CT75 codes	5mL/sec	300 psi

Note: The completed patient identification card should be given to the patient, who should be instructed to carry it at all times

2. The Smart Port® CT Implanted Ports should be accessed with a 19 or 20 gauge non Y-site LifeGuard™ Safety Infusion Set for injection of contrast media. The tubing on the safety needle should be clamped prior to accessing the port.
3. Remove the injection cap attached to the end of the Power Injectable Safety Infusion Set.
4. Attach a 10 mL or larger syringe to the luer hub end of the Power Injectable Safety Infusion Set tubing, release the clamp and aspirate to confirm blood return.

Note: **Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to catheter usage. A blood return should be present prior to usage of device.**

Note: Testing aspiration for simulated blood return is 0.5 mL/sec.

5. Flush the Smart Port® CT Implantable Port with 10-20 mL 0.9% normal saline. The device should flush without resistance.

Warning: **Not assessing patency may result in device failure.**

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6. Close the clamp on the Power Injectable Safety Infusion Set tubing.
7. Remove the syringe from the Power Injectable Safety Infusion Set.
8. Attach the power injection tubing per manufacturer's recommendations to the luer hub end of the Power Injectable Safety Infusion Set. Release the clamp.
9. Set the power injection machine per manufacturer's recommendations for a maximum pressure of 300 p.s.i.
10. Perform the study. Do not exceed 300 p.s.i. during injection of contrast dye. Refer to the Procedure for Power Injection section in this booklet for additional information and instructions.
11. Close the clamp. Disengage the power injection tubing from the luer hub end of the Power Injectable Safety Infusion Set.
12. Place a new injection cap on the Power Injectable Safety Infusion Set luer hub.
13. Flush the Smart Port® CT Implantable Port with 10-20 mL 0.9% normal saline.
14. Flush the Smart Port® CT Implantable Port with 3-5 mL of 10-100 units/mL heparinized saline. Actual amount and strength depends on facility policy.

Indications for Use

The Smart Port® CT power injectable port line is indicated for any patient requiring repeated access of the vascular system, for delivery of medications, nutritional supplementation, fluids, blood, blood products, and sampling of blood and power injection of contrast media for imaging.

Contraindications

AngioDynamics port systems should not be implanted in the presence of known or suspected infections, bacteremia, septicemia and peritonitis in patients who have exhibited prior intolerance to the materials of construction, or patients whose body size or tissue is insufficient to accommodate the size of the port or catheter.

Warnings

- Do not use smaller than a 10 mL syringe. These syringes are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.
- Contrast dye should be warmed to body temperature prior to utilization for power injection. Failure to have contrast at body temperature may lead to device failure.
- Do not exceed the maximum pressure settings that have been established for the Smart Port® CT power injectable ports. Failure can result in over pressurization of the port device. Power injection machine may not prevent over pressurization in the presence of occlusion or resistance. Refer to the Procedure for Power Injection section in this booklet for additional information and instructions.
- Do not exceed 300 p.s.i. Exceeding pressures of 300 p.s.i. could lead to device rupture or catheter malposition.

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- Failure to assess the patency of the Smart Port® CT Implanted Port prior to power injection may lead to device rupture or failure.
- Absence of a blood return or a poor blood return can be a sign of a potential complication such as occlusion, kinking, breakage, Pinch-Off Syndrome, fibrin formation, thrombosis or malposition. This should be evaluated prior to device usage. A blood return should be present prior to usage of device for any therapy or testing.
- Do not attempt to measure the patient's blood pressure on the arm in which a peripheral system is located, since catheter occlusion or other damage to the catheter could occur.
- If the patient complains of pain, or there is swelling when the device is flushed or when medication or contrast media is administered, evaluate the device for infiltration, proper needle placement, and potential complications such as occlusion, kinking, breakage, Pinch-Off Syndrome, thrombosis or malposition. Failure to assess these complaints or observations can lead to device failure.
- Power injection machine pressure limiting (safety cut-off) settings may not prevent over pressurization of an occluded device.
- Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.
- Reprocessing may compromise the integrity of the device and/or lead to device failure.

How to Identify the Smart Port® CT Implantable Ports

1. Refer to the patient's chart for implant information (sticker).
2. Each Smart Port® CT power injectable port is packaged with a Patient Education Packet, which includes a Patient Information Booklet, a Patient Identification Card and a Key Ring Card.
3. Smart Port® CT implantable ports are identifiable under X-ray or scout scan through visualization of the CT markings located on the bottom of the port.
   - Identifying the power injection capability of a Smart Port® CT implantable port should be verified with xray or scout scan prior to the power injection procedure. If you need additional information, please contact the AngioDynamics Customer Service department at 800-772-6446.

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Potential Complications

Use of an AngioDynamics port system involves potential risks normally associated with the insertion or use of any implanted device or indwelling catheter including but not limited to:
These complications are well documented in literature and should be considered when a venous access device is utilized.

Air embolism
Bleeding
Cardiac arrhythmia
Cardiac puncture
Cardiac tamponade
Catheter disconnection or migration
Catheter embolization
Catheter fragmentation
Catheter malposition
Catheter Pinch-off
Chylothorax
Clot formation
Device rotation
Drug extravasation (leakage)
Endocarditis
Erosion of vessel and skin
Fibrin sheath
Hematoma
Hemorrhage
Hemothorax
Implant rejection
Inadequate anchoring
Infection
Inflammation
Laceration
Migration
Necrosis or scarring of skin over implant area
Occlusion
Peripheral nerve damage
Peritonitis
Pneumothorax
Puncture of Vessel
Right arterial puncture
Surgical complications
Thoracic duct injury
Thromboembolism
Thrombophlebitis
Thrombosis
Twiddler Syndrome
Vein puncture
Vessel trauma

MRI Conditional 3T

For all AngioDynamics Smart Port® CT family of ports, the term MRI conditional is applied. The devices are tested in accordance with the ASTM standard for MRI sensitivity. The exact meaning is as follows: Non-clinical testing has demonstrated the device is MR Conditional. It can be scanned safely under:

- static magnetic field of 3 Tesla or less
- spatial gradient field of 720 Gauss/cm or less
- maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the device produced a temperature rise of less than 0.7°C at a maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of MR scanning in a field (field strength 3 Tesla)(model EXCITE)(manufacturer GE)(software version G3.0-052B) MR scanner.

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Needles

Use of AngioDynamics' non-coring (19 or 20 gauge Huber point) needles are recommended for all procedures. These needles have been designed and tested to ensure that septum life is preserved. Use of AngioDynamics LifeGuard™ Safety Infusion Sets (19 or 20 gauge non Y-site) is recommended for injection of contrast media. Needles are for single use only.

***Note: Septum Puncture Life* — Under qualified testing procedures, the septum testing was conducted at 10 p.s.i. This pressure exceeds typical levels experienced in clinical practice.**

Needle Gauge	Puncture Life
19 Gauge	500 Punctures
20 Gauge	1000 Punctures

IMPLANTATION INSTRUCTIONS

General Guidelines

The following suggestions for surgical insertion are provided as an aid to facilitate safe and prolonged use of the AngioDynamics port systems. The Smart Port® CT family of ports may be placed in a number of areas of the body and the catheter may be placed in a variety of vessels or other selected sites. Use the surgical procedure and the sterile technique which best suits your application and is appropriate for the patient. AngioDynamics recommends that the patient, when appropriate, be placed in the Trendelenburg position.

Precautions

- Strict aseptic technique is of paramount importance when implanting any device.
- Before handling the port, ensure that fingers of surgical gloves are free of talc.
- When suturing around the catheter, avoid excessive suture tightness to prevent occlusion of the catheter. Sutures should not be placed directly on the catheter.
- For peripheral placement, irritation to the vein, resulting in postoperative thrombophlebitis, has been associated with guidewire and introducer insertion.

***Caution:* Do not flush or wipe polyurethane catheters with alcohol at any time prior to implantation or during use.**

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Port and Catheter Preparation

Prime the port system prior to placement using 10 mL of normal saline or heparinized saline (100 units/mL). Attach the non-coring (Huber point) needle to the syringe, penetrate the septum of the port, and flush the system.

Caution: **Use a 10 mL or larger syringe when administering fluid into system.**

Port Placement Considerations

- Placement needs to be supported by underlying bony structure.
- A minimum of three sutures should be used to secure port body.
- Port location should be convenient and comfortable to the patient.
- Avoid placing port system directly under port pocket incision.
- Avoid placing port too deep or too shallow (minimum 0.5 cm - maximum 2 cm under skin surface).
- Pre-operative mapping of location is recommended whenever possible.

Catheter Placement Considerations

Place catheter tip in area of high blood flow.

Warning: **Avoid medial catheter placement into subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the subclavian vein.**[1]

[1] Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters.
Am J Surgery 1994; 148:633-636.

The port catheter should be positioned at the selected site of therapy and secured by accepted surgical technique to prevent catheter dislodgement. Position should be confirmed by appropriate radiographic procedures.

Caution: **Sufficient slack should be left between the catheter insertion point and the port body to preclude strain on the catheter.**

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Implantation of Attachable Catheter (Venous/Vascular)

***Percutaneous Procedure* (attachable catheter)**

Prime the port system prior to placement.

a. Select appropriate French-size sheath introducer.

b. Puncture skin with introducer needle into the subclavian vein at selected venous site. Gently aspirate while inserting.

***Warning:* The use of alcohol, acetone, or solutions containing these agents may result in degradation of the plastic introducer needle hub.**

c. Remove syringe, leaving needle in place.

***Caution:* To prevent air embolism, place thumb over exposed orifice of needle.**

d. Slide the "J" guidewire straightener over the "J" tip of wire. Insert the straightened "J" tip through the percutaneous entry needle and advance the wire 5-10 cm into the vein. Verify guidewire position radiographically.

e. Withdraw the needle and guidewire straightener, leaving the guidewire in place. Clamp guidewire with hemostat to prevent further advancement into the vascular system.

f. Create a subcutaneous pocket for the port. An incision is made and pocket formed by either sharp or blunt dissection down to underlying fascia.

g. Unclamp guidewire and advance dilator/sheath over the exposed "J" wire. Withdraw vessel dilator and "J" wire, leaving sheath in place.

***Caution:* To prevent air embolism, place thumb over exposed orifice of sheath.**

h. Insert catheter into sheath. Position the distal end of the catheter at the desired location. Peel away sheath while withdrawing it from vessel. Care should be taken not to withdraw catheter as sheath is removed. Catheter position should be confirmed radiographically. Secure catheter in place.

i. Trim proximal end of catheter and advance through subcutaneous tunnel to the port pocket. Attach catheter to the port body

Blue Strain Relief Mechanism

Slide the blue strain relief mechanism over the end of the catheter. The tapered end of the blue strain relief mechanism should point away from the proximal end of the catheter. For optimal results, the proximal end of the catheter should be dry. Slide the trimmed end of the catheter tip onto the stem until the catheter is flush with the stem flanges. Slide the strain relief mechanism over the catheter and onto the stem until it contacts the port body.

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j. Secure port body to underlying fascia using non-absorbable sutures and a minimum of three suture sites. Care should be exercised so that incision does not cross septum of port after closure.

Caution: Avoid piercing catheter with suture needle.

k. Prior to wound closure, aspirate septum to confirm ability to withdraw blood. Flush port with 3-5 mL of 10-100 units/mL of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip. Stabilize port while withdrawing needle.

l. Close incision after wound irrigation by appropriate surgical technique. Dress wound per hospital protocol.

***Surgical Cutdown* (attachable catheter)**

Follow general port placement guidelines described under "Port Placement Considerations" and "Percutaneous Procedure".

a. A small incision is made in deltopectoral groove to expose cephalic vein or a small transverse incision in neck to expose external jugular vein. Isolate vessel.

b. Introduce catheter through venotomy and advance to desired location. Confirm catheter placement by appropriate radiographic technique. Catheter is passed to pocket site via subcutaneous tunnel.

c. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.

Caution: **Sufficient slack should be left between port and catheter insertion point to preclude strain on the catheter. When using external jugular vein, carefully position the catheter over clavicle to avoid kinking or occlusion.**

***Implantation of Preattached Catheter* (Venous/Vascular)**

Prime the port system prior to placement.

1. Select appropriate site for portal placement.
2. Measure appropriate catheter length. Provide slack from port site to allow for body movement, but not enough to allow kinking of catheter.
3. Trim excess catheter by cutting squarely across the distal end. Do not trim catheter at an angle since this could cause the catheter tip to seal off against the side of the vessel.

***Percutaneous Procedure* (preattached catheter)**

a. Select appropriate French-size sheath introducer.

b. Puncture skin with introducer needle into the subclavian vein at selected venous site. Gently aspirate while inserting.

Warning: **The use of alcohol, acetone, or solutions containing these agents may result in degradation of the plastic introducer needle hub.**

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c. Remove syringe, leaving needle in place.

Caution: To prevent air embolism, place thumb over exposed orifice of needle.

d. Slide the "J" guidewire straightener over the "J" tip of wire. Insert the straightened "J" tip through the percutaneous entry needle and advance the wire 5-10 cm into the vein. Verify guidewire position radiographically.

e. Withdraw the needle and guidewire straightener, leaving the guidewire in place. Clamp guidewire with hemostat to prevent further advancement into the vascular system.

f. Create a subcutaneous pocket for the port. An incision is made and pocket formed by either sharp or blunt dissection down to underlying fascia.

g. **Place port in pocket and pass catheter from port pocket to entry site via subcutaneous tunnel.**

h. Unclamp guidewire and advance dilator/sheath over the exposed "J" wire. Withdraw vessel dilator and "J" wire, leaving sheath in place.

Caution: **To prevent air embolism, place thumb over exposed orifice of sheath.**

i. Insert catheter into sheath. Position the distal end of the catheter at the desired location. Peel away sheath while withdrawing it from vessel. Care should be taken not to withdraw catheter as sheath is removed. Catheter position should be confirmed radiographically. Secure catheter in place.

j. Secure port body to underlying fascia using non-absorbable sutures and a minimum of three suture sites. Care should be exercised so that incision does not cross septum of port after closure.

Caution: **Avoid piercing catheter with suture needle.**

k. Prior to wound closure, aspirate septum to confirm ability to withdraw blood. Flush port with 3-5 ml of 10-100 units/ml of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip. Stabilize port while withdrawing needle.

l. Close incision after wound irrigation by appropriate surgical technique. Dress wound per hospital protocol.

Note: **A 90 degree non-coring needle with winged infusion set may be positioned in port septum intraoperatively for patient comfort during initial access.**

Surgical Cutdown *(preattached catheter)*

Follow general port placement guidelines described under "Port Placement Considerations" and "Percutaneous Procedure".

a. A small incision is made in deltopectoral groove to expose cephalic vein or a small transverse incision in neck to expose external jugular vein. Isolate vessel.

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b. Introduce catheter through venotomy and advance to desired location. Confirm catheter placement by appropriate radiographic technique.
c. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.

Caution: **Sufficient slack should be left between port and catheter insertion point to preclude strain on the catheter. When using external jugular vein, carefully position the catheter over clavicle to avoid kinking or occlusion.**

Note: **A 90 degree non-coring needle with winged infusion set may be positioned in the port septum intraoperatively for patient comfort during initial access.**

Cut-Down Procedure, Cephalic Vein

a. Perform vessel incision to expose chosen vein. Isolate vein and stabilize to prevent bleeding and air aspiration.
b. Insert the tapered end of the vein pick through the incision and advance into the vessel.
c. Position the vein. Slide the catheter tip into the grooved underside of pick and advance the catheter tip into the vessel.
d. Withdraw the vein pick.
e. Advance the catheter into the vessel to the desired infusion site.
f. Confirm catheter placement by radiographic technique.
g. Anchor catheter at venotomy site. Avoid excessive suture tightness to prevent catheter occlusion.
h. Make a skin incision at the puncture site, approximately 2.5 cm in length. Create a subcutaneous pocket for the port by either sharp or blunt dissection down to underlying fascia.
i. Suture port to underlying fascia using at least one 2-0 silk suture placed through each suture hole. Care should be exercised so that the incision does not cross the septum access area.
j. Before closing the incision, aspirate to confirm ability to draw blood. Flush port with 5-10 ml of normal saline followed by 10-100 units/ml of heparinized saline. Maintain positive pressure. Confirm the position of the catheter again using fluoroscopy or X-ray.
k. Close incision by appropriate surgical technique. Dress wound per hospital protocol.

After Implantation and During System Use

- Do not attempt to measure the patient's blood pressure on the arm in which a peripheral system is located, since catheter occlusion or other damage to the catheter could occur.

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Post-Operative Care

The incision site should be monitored for signs of infection, inflammation, hematoma, device rotation or erosion. Routine wound care should be given to these sites. The Smart Port® CT implantable port may be used immediately after verification of catheter placement. Instruct patient to avoid any heavy exertion or strenuous activity during the first few days after surgery.
Confirm correct positioning of the needle within the port reservoir by aspiration of blood before any infusion.
Contact physician if unable to obtain blood return. Following each infusion, the system should be flushed immediately with 5-10 ml of normal saline followed by 3-5 ml of 10-100 units/ml of heparinized saline. Determination of the appropriate heparin concentrations, volume and flushing frequency should be based on patient's medical condition and prior clinical experience.

PROCEDURES FOR USE

Accessing the Smart Port® CT Power Injectable Ports

General Guidelines

- Each access of an AngioDynamics Smart Port® CT implantable port should be performed using aseptic technique.
- Identify the port septum by palpating outer perimeter of the Smart Port® CT power injectable port.
- Attach syringe with 10-20 mL 0.9% normal saline to tubing and non-coring (Huber point) needle. Locate the port silicone septum and place the LifeGuard™ Safety Infusion Set perpendicular into the septum until the bevel of the needle stops against the bottom of port. Once positioned in the septum, the needle should not be rocked or tilted. Such movement may cause septum damage.
- Unclamp tubing and inject 3-5 mL of normal saline to flush port catheter. Close clamp of tubing.
- Attach at least a 10 mL syringe with 10 mL 0.9% normal saline flush and aspirate blood to confirm placement and aspiration.
- Flush port with 3-5 mL of 10-100 units/mL of heparinized saline. Maintain positive pressure on syringe plunger to avoid reflux of blood into catheter tip.

Note: **Determination of the appropriate amounts of sterile normal saline and heparinized saline concentration, volume, and flushing frequency should be based on patient's condition and facility protocol.**

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Bolus Injection/Continuous Infusion

1. Identify the Smart Port® CT power injectable port septum by palpating outer perimeter of the port.
2. Observing aseptic technique, prepare injection site.
3. Attach syringe with normal saline to tubing and non-coring (Huber point) needle.
4. Insert the non-coring (Huber point) needle through the skin perpendicular to the port and advance slowly until contact with the base is made.

Note: **Needle placement should be confirmed by aspiration.**

5. Unclamp tubing and inject 3-5 mL of normal saline to flush port catheter. Clamp tubing.
6. Remove syringe from tubing and attach drug syringe. Unclamp tubing and inject drug slowly.
7. For continuous infusion, connect infusion pump to extension tubing. Tighten all connections. Position and secure height adjustable wings of infusion set. Start infusion pump. Open tubing clamp.

Caution: **Examine injection site closely. If patient feels an abnormal sensation or pain at injection site, it may indicate the drug has extravasated. Discontinue infusion immediately and proceed with accepted extravasation protocol. Notify physician immediately.**

8. Clamp tubing and carefully disconnect syringe.
9. Reattach syringe filled with normal saline. Unclamp tubing and flush catheter.
10. If additional drug infusions are required, flush port with an adequate volume of saline between infusions and repeat steps 6 through 10.
11. Heparin Lock Procedure
    a. Attach syringe containing 3-5 mL of heparinized saline (100 units/mL) to tubing.
    b. Flush catheter.

Caution: **Maximum flow rate of 5 mL/min is recommended for heparin lock procedure. This flow will minimize blood reflux into catheter.**

    c. Maintenance of positive pressure on syringe plunger will prevent blood reflux.
12. Gently withdraw needle from port septum and apply adhesive bandage.

Caution: **It is extremely important to adequately flush the port after blood withdrawal. Occlusion of the catheter can occur if blood is left in the catheter for an extended period of time.**

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Blood Sampling

Blood sampling may be performed as an isolated procedure at the time of bolus injection, or during the continuous infusion process.

1. Insert the non-coring needle into the prepared site and flush with 5-10 mL of normal saline solution.
2. Withdraw "discard sample" consisting of 5 mL of blood. Discard this sample and syringe. Perform required blood sampling.
3. Immediately flush the catheter with a minimum of 10 mL of saline followed by 3-5 mL of 10-100 units/ml heparinized saline solution to establish the heparin lock.

System Maintenance

- INS guidelines suggest every 24-48 hour dressing changes with a gauze-tape type dressing. If utilizing transparent dressings, the dressing change frequency for the catheter should be every 3-7 days, or as needed.
- ALWAYS maintain Universal Precautions and utilize sterile technique throughout insertion and care and maintenance procedures.
- Change the dressing immediately if the dressing is wet or is not occlusive, using sterile technique. An occlusive dressing should be placed over insertion site at all times.

Troubleshooting the Smart Port® CT Implantable Ports Catheter Obstruction

- Power injection should not be performed if blood aspiration is not present or the port is difficult to flush. If the implanted port is utilized, it may result in device failure or patient injury.

One-Way Obstruction (able to infuse through the port system but unable to aspirate blood):

Causes

- Failure to adequately flush the implanted port.
- The catheter may be abutting the vessel wall. Aspiration may cause the vessel wall to be drawn into the catheter, thus blocking withdrawal. An infusion forces the catheter tip away from the wall and restores patency.
- Repositioning of the patient may restore the ability to aspirate blood from the port system. The following maneuvers may be helpful:
  - Have the patient turn head in the opposite direction from the port body.
  - Have patient perform Valsalva maneuver.
  - Have patient cough.
  - Have patient extend arm over head.
  - Have patient lie in the decubitus position.

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- Positional access problems with port may be found to be self correcting during a subsequent access of the port system.
- Improper needle placement.
- A fibrin tail, clot or sheath may be on or within the catheter.
- A Thrombolytic agent may be used on the order of a physician to restore patency. The procedure should be outlined by the drug manufacturer's labeling. Use facility protocol to determine which Thrombolytic agent to use.
- The use of Streptokinase has been known to cause allergic and anaphylactogenic reactions.
- A contrast study performed through the port may confirm fibrin sheath presence, kinking, malposition, or Pinch-Off Syndrome.
- Malposition of the catheter from the lower portion of superior vena cava (SVC).

Caution: **Do not use a syringe smaller than 10 mL.**

Two-Way Obstruction (unable to infuse through the port system and unable to aspirate blood):

Causes

- A fibrin tail, clot or sheath may be on or within the catheter.
- The non-coring (Huber point) needle may not be patent or properly positioned within the port septum.
- Confirm that the needle is of sufficient length and, when positioned in the septum, the needle opening is not occluded by the septum.
- The clamp on the non-coring (Huber point) needle should be open.
- A drug precipitate caused by incompatible drugs infused through the port may be obstructing the system. To prevent, use adequate amounts of sterile normal saline between incompatible solutions.
- A Thrombolytic agent may be used on the order of a physician to restore patency. The procedure should be outlined by the drug manufacturer's labeling. Use facility protocol to determine which Thrombolytic agent to use.
- The use of Streptokinase has been known to cause allergic and anaphylactogenic reactions.
- A contrast study performed through the port may confirm fibrin sheath presence, kinking, malposition, or Pinch-Off Syndrome.

Caution: **Do not force solutions through the port system to clear an obstruction. A high pressure situation may cause irreversible catheter damage, leading to port system explant.**

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Pinch-Off Syndrome

Pinch-Off Syndrome signs may include difficulty in aspirating blood, resistance to flushing or infusion of medications or fluids that improves with position changes, infraclavicular pain and/or swelling with catheter flushing or infusion palpitations, sudden onset chest pain, cardiac arrhythmias, extra heart sound, chest wall swelling at the port pocket, vein insertion site, pain in shoulder or port area not associated with swelling, cough, paresthesia of arm on side of catheter withdrawal occlusion or swishing sound with catheter flushing.

Warning: **Avoid medial catheter placement into Subclavian vein through percutaneous technique. This placement could lead to catheter occlusion, damage, rupture, shearing, or fragmentation due to compression of the catheter between the first rib and clavicle. Catheter shearing has been reported when the catheter is inserted via a more medial route in the Subclavian vein.[1]**

[1] Aiken DR, Minton JP. The "pinch-off" sign: a warning of impending problems with permanent subclavian catheters.
Am J Surgery 1994; 148:633-636.

Note: **If infusion or aspiration is successful upon lifting arm above the head and turning the head, consider Pinch-Off Syndrome as a possible cause. The line should be radiologically evaluated if Pinch-Off Syndrome is suspected.**

A chest x-ray can help diagnose the grade of pinch-off or catheter fracture radiologically at the costoclavicular area.
Below is a chart that will help define grade, catheter distortion, significance and recommendation:

Warning: **If Pinch-Off Syndrome is suspected, the port should be evaluated prior to power injection.**

Grade	Catheter Distortion	Significance	Recommended Intervention
0	No distortion	NONE	NONE
1	Some degree of distortion with luminal narrowing	Not certain	Close follow-up
2	Distortion with luminal narrowing	Fracture likely	Remove catheter
3	Fracture	Risk of catheter embolization	Remove catheter promptly

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Use of a Thrombolytic Agent for Catheter Clearance

There are no Thrombolytic agents that are contraindicated for use with ports manufactured by AngioDynamics, Inc. Thrombolytic agents have been successfully utilized to restore patency of both One-Way and Two-Way Obstructions. The type and amount of the Thrombolytic agent used for catheter clearance should be based on facility policy.

Note: **Thrombolytic agents will not successfully clear occlusions caused by administration of incompatible medications. Adequate amounts of 0.9% normal saline between incompatible medications should be utilized to help prevent occlusions.**

Explantation of a Smart Port® CT Power Injectable Port

Ports and catheters which are explanted due to suspected malfunction should be returned to AngioDynamics for analysis. The AngioDynamics customer service department must be contacted to obtain a return authorization number and instructions. AngioDynamics will provide an explant kit for use in storage and shipment of the explanted device. Hospitals must advise AngioDynamics of any infectious disease that the patient is known to have.

No returned product will be accepted without an RGA number and properly packaged in a AngioDynamics explant kit or equivalent.

Discontinuing System Use

AngioDynamics recommends that the clinician consider explantation of the system once it is determined that it is no longer required for therapy. If the clinician decides to leave the system in place, AngioDynamics recommends that periodic X-rays be taken with the patient in an upright, arms at side position. This procedure will verify catheter placement and detect problems with the system such as pinching of the catheter between the clavicle and first rib.

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SMART PORT® CT IMPLANTABLE PORT SYSTEM CARE GUIDELINES

Site Preparation: Always access the system using aseptic technique.

Syringes: 10 mL syringes or larger are recommended for all flushing or injection procedures. Use of smaller syringes may result in system damage.

Needles: The use of AngioDynamics non-coring (huber point) needles are recommended. Use of AngioDynamics LifeGuard™ Safety Infusion sets (19 or 20 gauge non y-site) are recommended for injection of contrast media.

Saline Flushes: Prior to drug administration, flush the system with saline solution to remove heparin. If more than one drug is administered, flush the system with saline solution between drugs. After patient treatment is completed, always flush the system to cleanse the catheter and port chamber.

Heparin Flush Schedule: To keep the Smart Port® CT implantable port system patent, the system must be flushed with heparinized saline at regular intervals.

Heparin Concentration: (10-100 units/mL) of heparinized saline. Typical volume of 3-5 mL.

Venous Systems: "Heparin lock" once every 4 weeks.

Note: **Follow institutional guidelines for infusion set use. Center for Disease Control (CDC) recommends that I.V. tubing be changed every 48 hours.**