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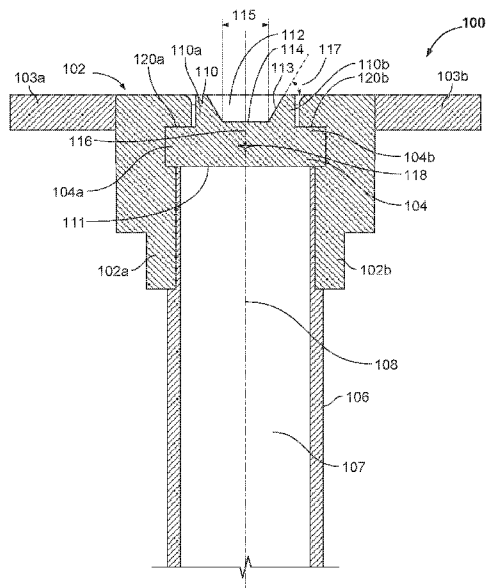

FIG. 1

(57) Abstract: An introducer for insertion of a medical device into a patient's vasculature includes an elongate introducer body, a hub, and a hemostatic valve. The elongate introducer body includes a longitudinal axis, a proximal region, a distal region, and an inner lumen. The hub is coupled to the proximal region of the introducer body. The hemostatic valve is disposed within the hub and forms a liquid-tight seal across the inner lumen. The introducer includes a guide configured to guide an object towards the center of the valve during insertion of the object.

HEMOSTATIC VALVE FOR MEDICAL DEVICE INTRODUCER

Cross Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/209,288, filed on August 24, 2015, which is hereby incorporated herein by reference in its entirety.

Background

[0002] Patients with cardiac ailments are sometimes treated with heart pumps adapted to be inserted into the heart through adjoining blood vessels and configured to assist the natural cardiac pump function or to replace natural cardiac pump function by a continuous pumping operation.

[0003] In one common approach, an introducer sheath is used to gain vascular access prior to insertion of a medical device such as a heart pump. The introducer sheath includes a hemostatic valve that prevents blood leakage from the proximal end of the introducer sheath upon insertion of the introducer sheath into a blood vessel. The hemostatic valve should prevent excessive blood leakage when no objects are present in the valve or when guidewires, catheters, blood pumps, or other objects are inserted through the valve. One of the primary causes of excess leakage in an introducer sheath is damage to or perforation of the hemostatic valve.

Summary

[0004] Disclosed herein is an introducer sheath for percutaneous insertion of a heart pump. The introducer sheath includes a guide and a hemostatic valve. The introducer sheath guides an object towards the center of the hemostatic valve to reduce the risk of inadvertently puncturing the hemostatic valve during insertion of the object (e.g., a heart pump). Such inadvertent punctures could result when the object is inserted into the hemostatic valve at a position that is away/laterally offset from the center of the hemostatic valve or angularly offset from a central longitudinal axis of the hemostatic valve, thereby increasing the risk of damage to the hemostatic valve. The guide may be formed from the hemostatic valve or as a

separate element. The systems, methods, and devices described herein reduce or eliminate the risk of valve perforation during insertion of medical devices (e.g., heart pumps), guidewires, dilators, or other objects by guiding inserted objects toward the center of the hemostatic valve. This can reduce or prevent blood leakage through the hemostatic valve.

[0005] The hemostatic valve will additionally simplify user interaction with the introducer sheath. Current systems, methods, and devices may require a pre-requisite level of experience or attention from a user during a preparation phase, or during insertion of medical devices (e.g., heart pumps), guidewires, dilators, or other objects. However the proposed introducer sheath would improve ease of use with the system without requiring such pre-requisite levels of experience or attention from a user. Additionally, performance of the introducer sheath would be independent of the location on the hemostatic valve at which medical devices (e.g., heart pumps) are inserted. This minimizes human factor considerations and accommodates a wider range of use conditions.

[0006] In one aspect, an introducer for insertion of a medical device into a patient's vasculature includes an elongate introducer body, a hub, and a hemostatic valve. The elongate introducer body includes a longitudinal axis, a proximal region, a distal region, and an inner lumen. The hub is coupled to the proximal region of the introducer body. The hemostatic valve is disposed within the hub and forms a liquid-tight seal across the inner lumen. The hemostatic valve includes a guide configured to guide an object towards the center of the valve during insertion of the object. The guide may be a funnel. In some implementations, the hemostatic valve has a proximal surface and a distal surface, and the funnel is defined by sloped regions of the proximal surface of the hemostatic valve. The funnel may be separate from the hemostatic valve. The sloped regions may be angled about 30°, about 45°, about 60°, or greater relative to the plane perpendicular to the longitudinal axis of the introducer body. In certain implementations, the proximal surface includes a flat central region that is substantially perpendicular to the longitudinal axis of the elongate introducer body. The flat central region may have a diameter of about 3mm or less. In some implementations, the introducer is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body. In certain implementations, the hemostatic valve is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body. The hemostatic valve may include a central void that reduces the stiffness of the center of the hemostatic valve.

Brief Description of the Drawings

[0007] The foregoing and other objects and advantages will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

[0008] FIGS. 1 and 2 show cross-section views of an introducer assembly including a funnel valve according to certain embodiments;

[0009] FIG. 3 shows a perspective view of the introducer assembly of FIGS. 1 and 2;

[0010] FIG. 4 shows percutaneous insertion of a heart pump using the introducer assembly of FIGS. 1 and 2;

[0011] FIGS. 5 and 6 show parting of the introducer assembly of FIGS. 1 and 2; and

[0012] FIGS. 7 and 8 show cross-section views of an alternate introducer assembly including a funnel valve according to certain embodiments.

Detailed Description

[0013] To provide an overall understanding of the systems, method, and devices described herein, certain illustrative embodiments will be described. Although the embodiments and features described herein are specifically described for use in connection with introducer sheaths and hemostatic valves for percutaneous insertion of heart pumps, it will be understood that all the components and other features outlined below may be combined with one another in any suitable manner and may be adapted and applied to other types of introducer sheaths and hemostatic valves or other types of cardiac assist devices, including balloon pumps.

[0014] The apparatus described herein provides an introducer sheath and a hemostatic valve for percutaneous insertion of a heart pump. The introducer sheath includes a guide and a hemostatic valve. The introducer sheath guides an object towards the center of the hemostatic valve to reduce the risk of inadvertently puncturing the hemostatic valve during insertion of the object (e.g., a heart pump). The guide may be formed from the hemostatic valve or as a separate element. The systems, methods, and devices described herein thus reduce or eliminate the risk of valve perforation during insertion of medical devices (e.g., heart pumps), guidewires, dilators, or other objects. This can reduce or prevent blood leakage through the hemostatic valve.

[0015] FIGS. 1 and 2 show cross-section views of an introducer assembly 100 including a funnel valve according to certain embodiments. The introducer assembly 100 includes an

elongate introducer body 106, a hub 102, and a hemostatic valve 104. The elongate introducer body 106 has an inner lumen 107 and a longitudinal axis 108. The hub 102 includes a first hub portion 102a, a second hub portion 102b, a first wing 103a, and a second wing 103b. The hemostatic valve 104 includes a first hemostatic valve portion 104a, a second hemostatic valve portion 104b, a guide 110, a distal surface 111, a proximal surface 112, a sloped region 113, a flat region 114, an outer region 120, a parting surface 116, and a central void 118.

[0016] The hemostatic valve 104 creates a liquid tight seal across the inner lumen 107 of the elongate introducer body 106. The guide 110 of the hemostatic valve 104 guides objects inserted into the hemostatic valve 104 such that the objects are guided to the central flat region 114. This reduces the risk of inadvertently puncturing the hemostatic valve 104 during insertion of an object (e.g., a heart pump). The guide 110 includes a first guide portion 110a and a second guide portion 110b. The guide 110 is formed by the proximal surface 112 of the hemostatic valve 104. The proximal surface 112 includes the sloped region 113, which defines the funneled shape of the guide 110, and the central flat region 114. The sloped region 113 is angled relative to the central flat region 114 by a funnel angle 117. The funnel angle 117 is about 30°. In some implementations, the funnel angle is about 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60°, 65°, 70°, 75°, 80°, 85°, or any other suitable angle. The funnel angle 117 is suitably steep to guide inserted objects towards the central flat region 114. The funnel angle 117 is shown as substantially constant in FIG. 1, but the person of ordinary skill will appreciate that the funnel angle can flare or vary over the length of the sloped region 113. The central flat region 114 of the hemostatic valve has a diameter 115. The diameter 115 may be 1 cm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, less than 1 mm, or any other suitable dimension. The guide 110 may have different surface properties, durometer, material, or other properties compared to the remainder of hemostatic valve 104. For example, the guide 110 may be more rigid, tougher, or harder, relative to the remainder of hemostatic valve 104. Although the guide 110 is shown in FIG. 1 as being formed in the hemostatic valve 104, in some embodiments the guide 110 is separate from the hemostatic valve 104. For example, the guide 110 may be formed in the hub 102.

[0017] The hemostatic valve 104 is formed of the first hemostatic valve portion 104a and the second hemostatic valve portion 104b. The first hemostatic valve portion 104a and the second hemostatic valve portion 104b are held together by the hub 102 and interface at the parting surface 116. The parting surface 116 separating the first hemostatic valve portion 104a and the second hemostatic valve portion 104b allow the hemostatic valve 104 to be

completely separated after insertion of an object. The first hemostatic valve portion 104a is connected to the first hub portion 102a at the outer region 120a, and the second hemostatic valve portion 104b is connected to the second hub portion 102b at the outer region 120b. The connection between the hub 102 and the hemostatic valve 104 may be an interference fit, an adhesive bond, a connection by a mechanical fastener, or any other suitable connection. The parting surface 116 also defines a central void 118. The central void 118 reduces the stiffness of the hemostatic valve 104 in the central flat region 114. This may allow the valve to easily give or to deform in the central flat region 114 when an object is inserted. This may also allow the hemostatic valve 104 to form a double seal against an object inserted through the hemostatic valve 104. A double seal may provide redundancy, thereby decreasing the risk of valve leakage or failure.

[0018] The hemostatic valve 104 is coupled to the elongate introducer body 106 by the hub 102. Similar to the hemostatic valve 104, the hub 102 is split along the parting surface 116 into the first hub portion 102a and the second hub portion 102b. The first and second wings 103a-b provide a lever arm that allows the hub 102 to be manually split into the first hub portion 102a and the second hub portion 102b. This splitting may facilitate the replacement of the introducer assembly 100 with another assembly or sheath during the use of a heart pump. Splitting of the hub 102 also initiates splitting of the elongate introducer body 106 into two parts so that the entire introducer assembly 100 can be removed as will be discussed further in relation to FIGS. 5 and 6. The elongate introducer body 106 has an outer diameter sized for percutaneous insertion. In some implementations, the outer diameter of the elongate introducer body 106 is 10 French (3.33 mm), 11 French (3.67 mm), 12 French (4 mm), 13 French (4.33 mm), 14 French (4.67mm), 15 French (5 mm), 16 French (5.33 mm), 17 French (5.67 mm), 18 French (6 mm), 19 French (6.33 mm), 20 French (6.67mm), 21 French (7 mm), or any other suitable diameter.

[0019] FIG. 3 shows a perspective view of the introducer assembly of FIGS. 1 and 2. The introducer assembly 100 includes the elongate introducer body 106, the hub 102, the hemostatic valve 104, a reinforcing ring 150, and a fluid line 152. The hub 102 includes the first hub portion 102a, the second hub portion 102b, the first wing 103a, and the second wing 103b. The hemostatic valve 104 includes the proximal surface 112 having the sloped region113 and the central flat region 114. The fluid line 152 allows the inner lumen 107 (not shown) to be flushed with saline or any other biocompatible fluid to prevent stagnation of blood or blood clot formation in the introducer assembly 100. The reinforcing ring 150 connects the first hub portion 102a and the second hub portion 102b. The reinforcing ring

150 may prevent inadvertent or premature separation of the first and second portions 102a-b of the hub 102. For example, the reinforcing ring 150 may be tougher or stronger than the hub 102 to prevent separation. In some implementations, the reinforcing ring 150 and the tubular sheath body 106 are the only elements of the introducer assembly 100 that are not parted before use. In such an implementation, after the reinforcing ring 150 is separated, no other element holds the first hub portion 102a and the second hub portion 102b together. Separation of the introducer assembly 100 may be more predictable if separation depends on fewer elements.

[0020] FIG. 4 shows percutaneous insertion of a heart pump assembly 200 using the introducer assembly of FIGS. 1 and 2. The heart pump assembly 200 includes a distal end portion 203 and a supply catheter 202. The sheath assembly 100 includes the hemostatic valve 104 and the fluid supply line 152. The fluid supply line 152 may be used to flush the introducer assembly 100 before during or after insertion of the heart pump assembly 200. In some implementations, the supply catheter 202 of the heart pump assembly 200 includes a flexible drive shaft. The distal end portion 203 of the heart pump assembly 200 is inserted into the introducer assembly 100 along an insertion path 204. The insertion path 204 forms an angle of insertion 206 relative to the longitudinal axis 108 of the introducer assembly 100. The guide (not shown) of the introducer assembly 100 limits the angle of insertion 206 to prevent puncture of the hemostatic valve 104 during insertion of the heart pump assembly 200. The guide may limit the angle of insertion 206 to less than 90°, less than 80°, less than 70°, less than 60°, less than 50°, less than 45°, less than 40°, less than 35°, less than 30°, less than 25°, less than 20°, less than 15°, less than 10°, less than 5°, or to any other suitable angle.

[0021] FIGS. 5 and 6 show parting of the introducer assembly of FIGS. 1 and 2. After the heart pump assembly 200 (not shown in FIGS. 5 and 6) has been inserted into the patient, the introducer assembly 100 is separated along a parting surface while remaining on the supply catheter 202. A healthcare professional applies force to the first and second wings 103a-b to part (e.g., "peel-away") the introducer assembly 100. This separates the hub 102 into a first hub portion 102a and a second hub portion 102b. This also separates the hemostatic valve 104 into a first hemostatic valve portion 104a and a second hemostatic valve portion 104b. This also initiates a crack 105 in the proximal region of the elongate introducer body 106. The crack 105 is advanced by pulling the first hub portion 102a and the second hub portion 102b farther apart as shown in FIG. 6. This process may continue until the introducer

assembly 100 is completely split and separated from the supply catheter 202. This allows another sheath (not shown) to be advanced over the supply catheter 202 into the patient.

[0022] FIGS. 7 and 8 show an alternate introducer assembly 300. The introducer assembly 300 includes an elongate introducer body 306, a hub 302, and a hemostatic valve 304. The elongate introducer body 306 has an inner lumen 307 and a longitudinal axis 308. The hub 302 includes a first hub portion 302a, a second hub portion 302b, a first wing 303a, and a second wing 303b. The hemostatic valve 304 includes a first hemostatic valve portion 304a, a second hemostatic valve portion 304b, a distal surface 311, a proximal surface 312, a parting surface 316, and a central void 318.

[0023] In introducer assembly 300, the distal surface 311 and the proximal surface 312 of the hemostatic valve 304 are both substantially flat. A hemostatic valve 304 having a substantially flat profile would less material and complexity to manufacture and implement. The hub 302 also includes a bracket 325 comprising a first bracket portion 325a and a second bracket portion 325b. A guide 310 is integrally formed with the bracket 325 and comprises a first guide portion 310a and second guide portion 310b that define a central opening 314. The bracket 325 substantially encompasses the hemostatic valve 304 such that a portion 320a and 320b of the proximal surface 312 of the hemostatic valve 304 is in contact with the guide portions 310a and 310b of the bracket 325. In this configuration, the guide 310 exposes a portion of the substantially flat proximal surface 312 of the hemostatic valve 304 in the vicinity of the central opening 314.

[0024] The guide 310 includes a sloped region 313, which defines the funneled shape of the guide 310 and the central opening 314, which, in turn, exposes the substantially flat proximal surface 312 of the hemostatic valve 304. The guide 310 is therefore able to guide objects towards the central opening 314 and hence the proximal surface 312 of hemostatic valve 304. The sloped region 313 is angled relative to the exposed flat proximal surface 312 of the hemostatic valve 304 by a funnel angle 317. The funnel angle 317 is about 30°. In some implementations, the funnel angle 317 is about 10°, 15°, 20°, 25°, 30°, 35°, 40°, 45°, 50°, 55°, 60°, 65°, 70°, 75°, 80°, 85°, or any other suitable angle. The funnel angle 317 is suitably steep to guide inserted objects towards the central opening 314 and the flat proximal surface 312 of the hemostatic valve 304. The funnel angle 317 is shown as substantially constant in FIG. 8, but the person of ordinary skill will appreciate that the funnel angle 317 can flare or vary over the length of the sloped region 313. It will also be understood that while the guide 310 in FIG. 8 is shown to have a substantially linear profile, any other suitable profile may be implemented (e.g. a concave downward profile). The central opening 314 of the hemostatic

valve has a diameter 315. The diameter 315 may be 1 cm, 5 mm, 4 mm, 3 mm, 2 mm, 1 mm, less than 1 mm, or any other suitable dimension. The bracket 325 may have different surface properties, durometer, material, or other properties compared to the hub 302 or the hemostatic valve 304. For example, the bracket 325 may be more rigid, tougher, or harder, relative to the hub 302 or the hemostatic valve 304.

[0025] The hemostatic valve 304 is formed of the first hemostatic valve portion 304a and the second hemostatic valve portion 304b. The first hemostatic valve portion 304a and the second hemostatic valve portion 304b are held together by the bracket 325 in the hub 302 and interface at the parting surface 316. The parting surface 316 separating the first hemostatic valve portion 304a and the second hemostatic valve portion 304b allow the hemostatic valve 304 to be completely separated after insertion of an object. The first hemostatic valve portion 304a is connected to the first bracket portion 325a at the portion 320a of the proximal surface 312 of the hemostatic valve 304, while the second hemostatic valve portion 304b is connected to the second bracket portion 325b at the portion 320b of the proximal surface 312. The connection between the bracket 325 and the hemostatic valve 304 may be an interference fit, an adhesive bond, a connection by a mechanical fastener, or any other suitable connection. The parting surface 316 also defines a central void 318. The central void 318 reduces the stiffness of the hemostatic valve 304 in the vicinity of the central opening 314. This may allow the valve to easily give or to deform in the vicinity of the central opening 314 when an object is inserted. This may also allow the hemostatic valve 304 to form a double seal against an object inserted through the hemostatic valve 304. A double seal may provide redundancy, thereby decreasing the risk of valve leakage or failure.

[0026] Similar to the hemostatic valve 304, the hub 302 and bracket 325 are split along the parting surface 316 into the first hub portion 302a and first bracket portion 325a, and the second hub portion 302b and second bracket portion 325b. The first and second wings 303a-b provide a lever arm that allows the hub 302 and guide 310 to be manually split into the first hub portion 302a the first bracket portion 325a, and the second hub portion 302b and the second bracket portion 325b. This splitting may facilitate the replacement of the introducer assembly 300 with another assembly or sheath during the use of a heart pump. Splitting of the hub 302 also initiates splitting of the elongate introducer body 306 into two parts so that the entire introducer assembly 300 can be removed as previously discussed in relation to FIGS. 5 and 6.

[0027] The reinforcing ring 150 discussed in relation to FIGS 1 to 3 can also be used with the introducer assembly 300 to connect the hub portions 302a-b and the bracket portions

325a-b. The reinforcing ring 150 may prevent inadvertent or premature separation of the first and second portions 302a-b of the hub 302 and the first and second portions 325a-b of the bracket 325. For example, the reinforcing ring 150 may be tougher or stronger than the hub 302 to prevent separation. In some implementations, the reinforcing ring 150 and the tubular sheath body 306 are the only elements of the introducer assembly 300 that are not parted before use. In such an implementation, after the reinforcing ring 150 is separated, no other element holds the first and second hub portions 302a-b and the first and second bracket portions 325a-b together.

[0028] In a further alternate implementation, the guide portion 310 may be located in the reinforcing ring 150.

[0029] The foregoing is merely illustrative of the principles of the disclosure, and the apparatuses can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation. It is to be understood that the apparatuses disclosed herein, while shown for use in percutaneous insertion of heart pumps, may be applied to apparatuses in other applications requiring hemostasis.

[0030] Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombination (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

[0031] Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein. All references cited herein are incorporated by reference in their entirety and made part of this application.

We Claim:

1. An introducer for insertion of a medical device into a patient's vasculature, the introducer comprising:

an elongate introducer body having a longitudinal axis, a proximal region, a distal region, and an inner lumen;

a hub coupled to the proximal region of the introducer body;

a hemostatic valve disposed within the hub and forming a liquid-tight seal across the inner lumen;

wherein the hemostatic valve includes a guide configured to guide an object towards a center of the hemostatic valve during insertion of the object.

2. The introducer of claim 1, wherein the guide is a funnel.

3. The introducer of claim 2, wherein the hemostatic valve has a proximal surface and a distal surface, and wherein the funnel is defined by sloped regions of the proximal surface.

4. The introducer of claim 3, wherein the sloped regions are angled about 30° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

5. The introducer of claim 3, wherein the sloped regions are angled about 45° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

6. The introducer of claim 3, wherein the sloped regions are angled about 60° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

7. The introducer of claim 3, wherein the proximal surface includes a flat central region that is substantially perpendicular to the longitudinal axis of the elongate introducer body.

8. The introducer of claim 7, wherein the flat central region has a diameter of about 3mm or less.

9. The introducer of claim 2, wherein the funnel is separate from the hemostatic valve.

10. The introducer of any of claims 1-9, wherein the introducer is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body.

11. The introducer of any of claims 1-10, wherein the hemostatic valve is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body.

12. The introducer of any of claims 1-10, wherein the hemostatic valve includes a central void that reduces the stiffness of the center of the hemostatic valve.

13. An introducer for insertion of a medical device into a patient's vasculature, the introducer comprising:

an elongate introducer body having a longitudinal axis, a proximal region, a distal region, and an inner lumen;

a hub coupled to the proximal region of the introducer body;

a hemostatic valve disposed within the hub and forming a liquid-tight seal across the inner lumen; and

a guide configured to direct an object towards a center of the hemostatic valve during insertion of the object through the hemostatic valve.

14. The introducer of claim 13, wherein the guide is formed on the hub.

15. The introducer of claim 14, wherein the guide includes a sloped surface which defines a funnel configured to guide the object towards the center of the hemostatic valve.

16. The introducer of claim 15, wherein the sloped surface extends circumferentially around the hemostatic valve.

17. The introducer of claim 15, wherein the sloped regions are angled about 30° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

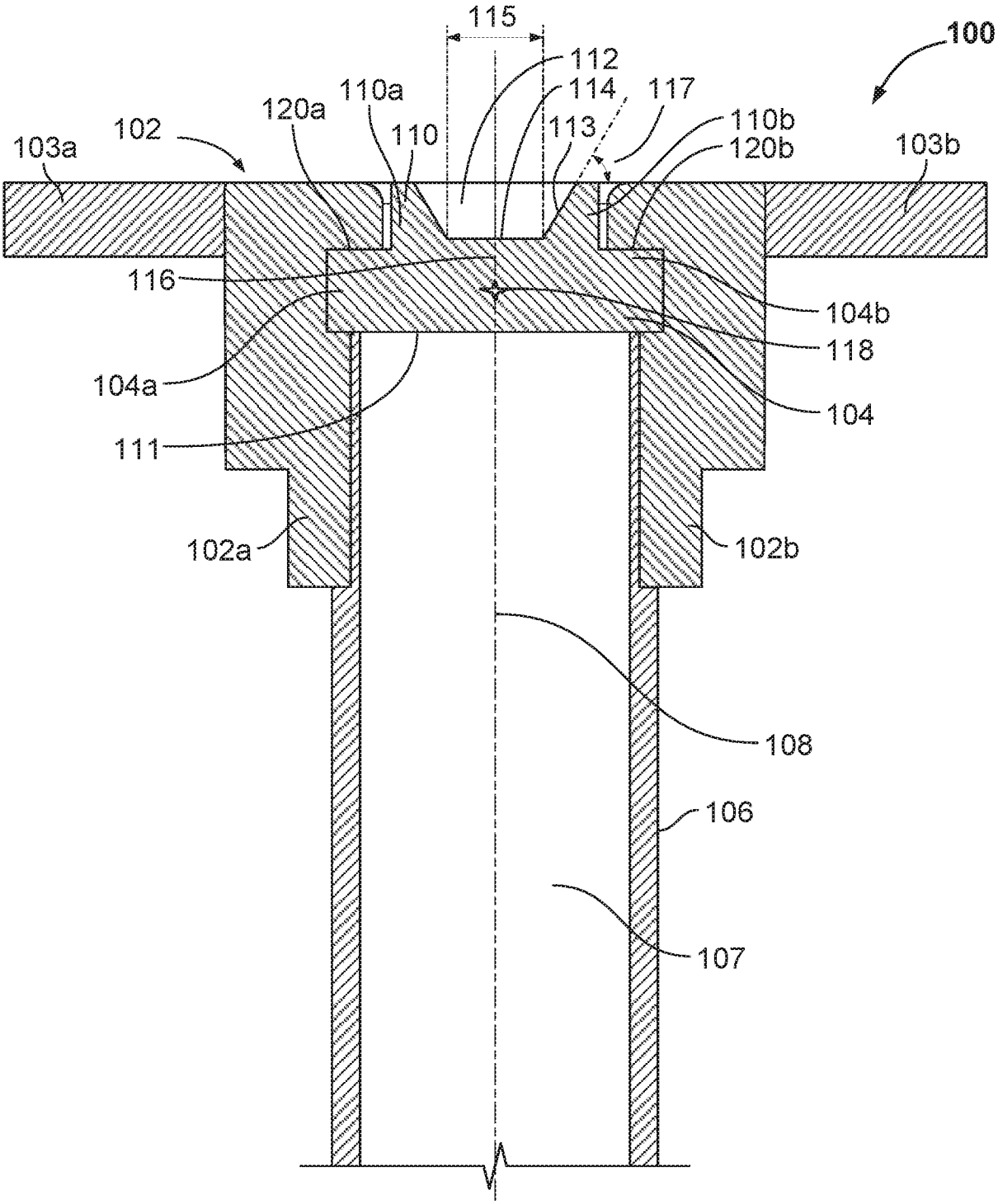
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FIG. 1

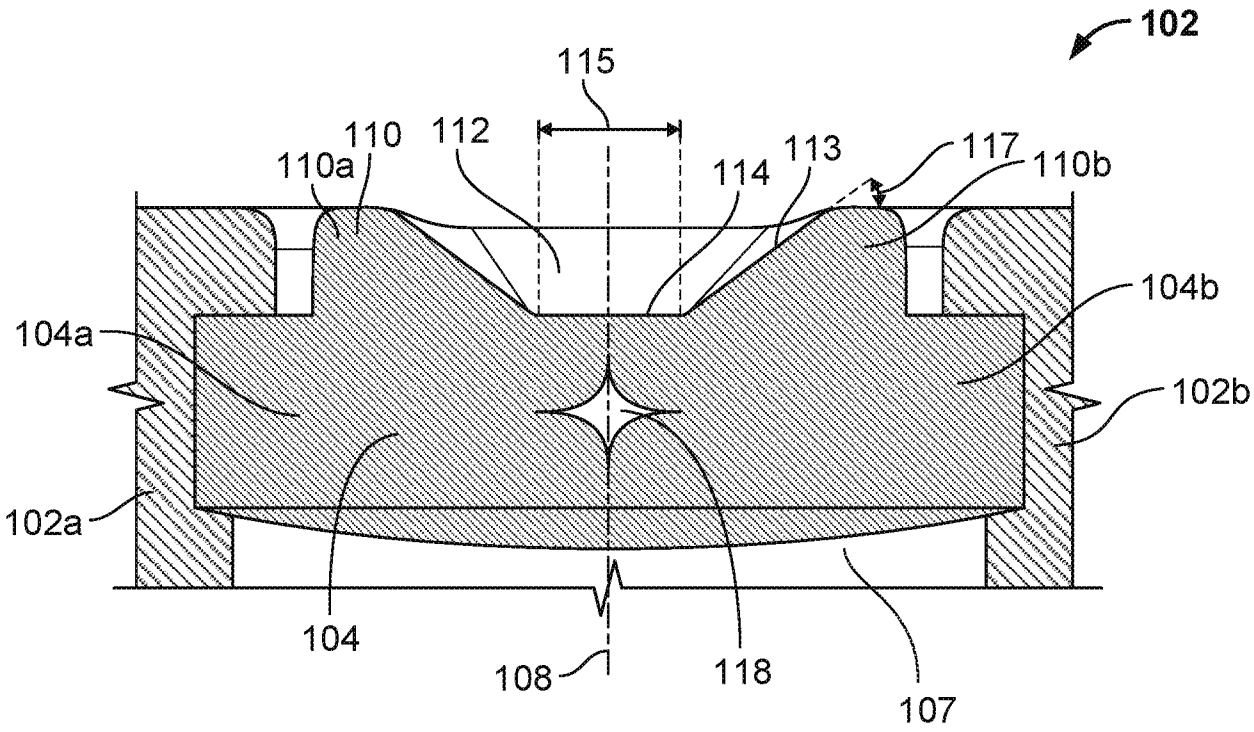
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FIG. 2

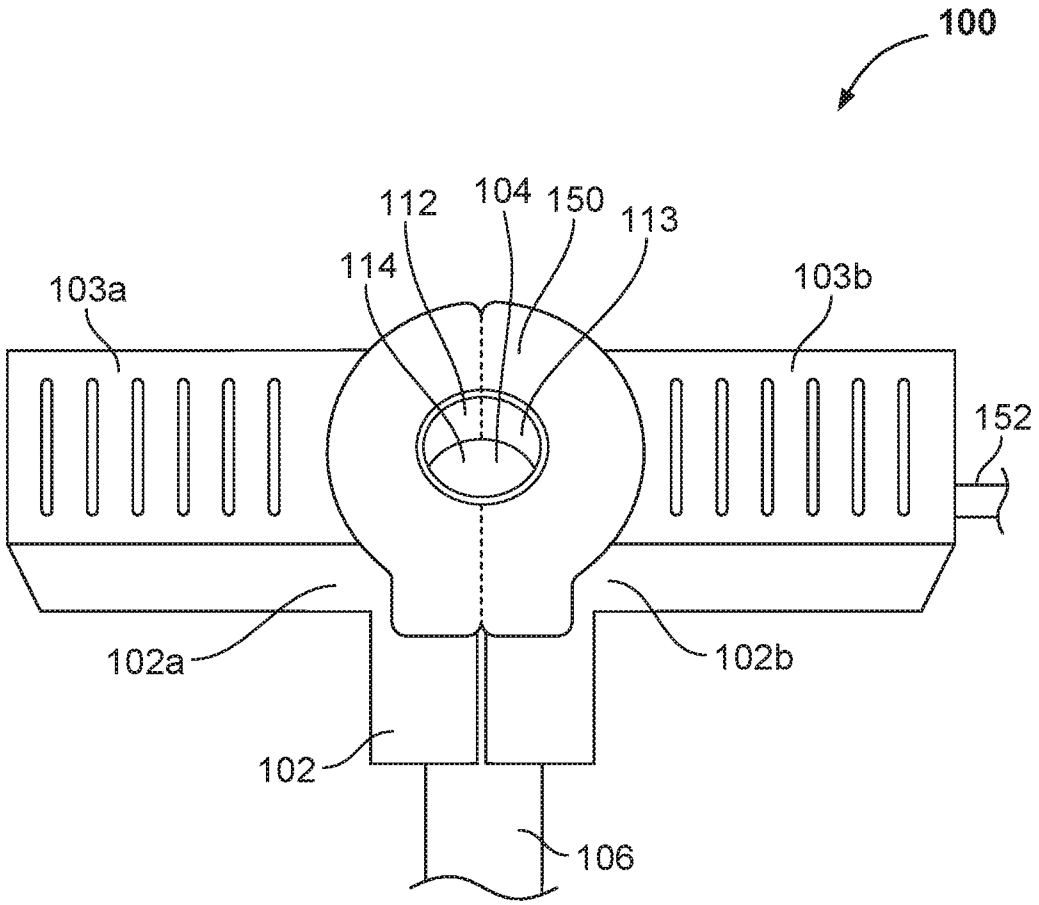


FIG. 3

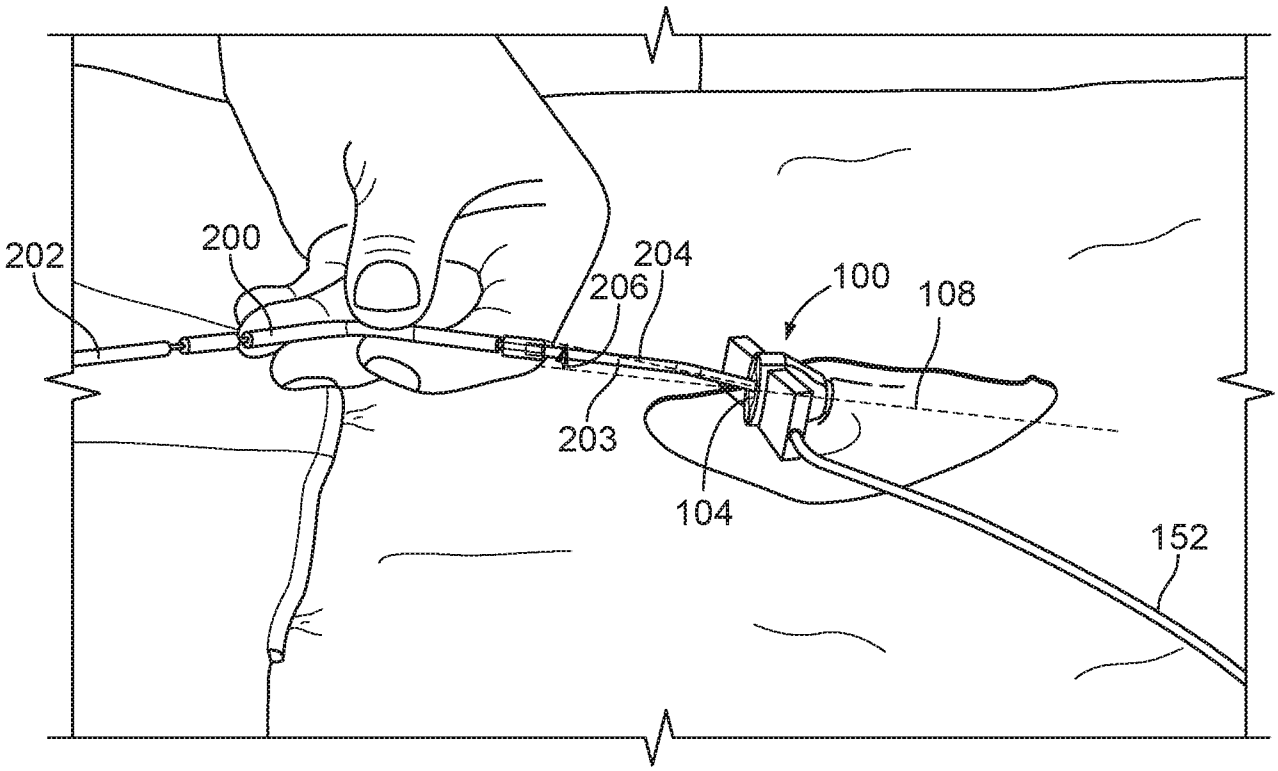


FIG. 4

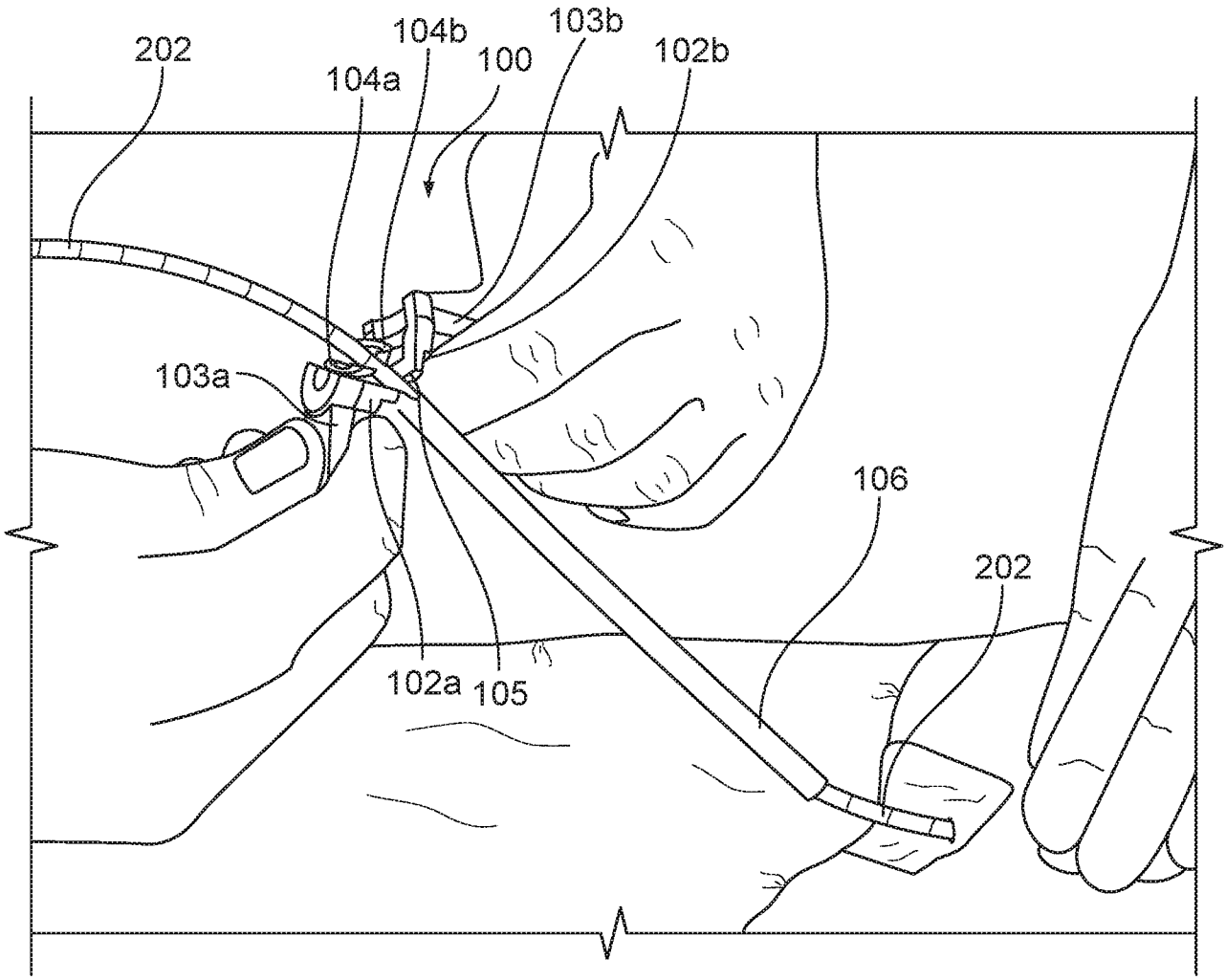


FIG. 5

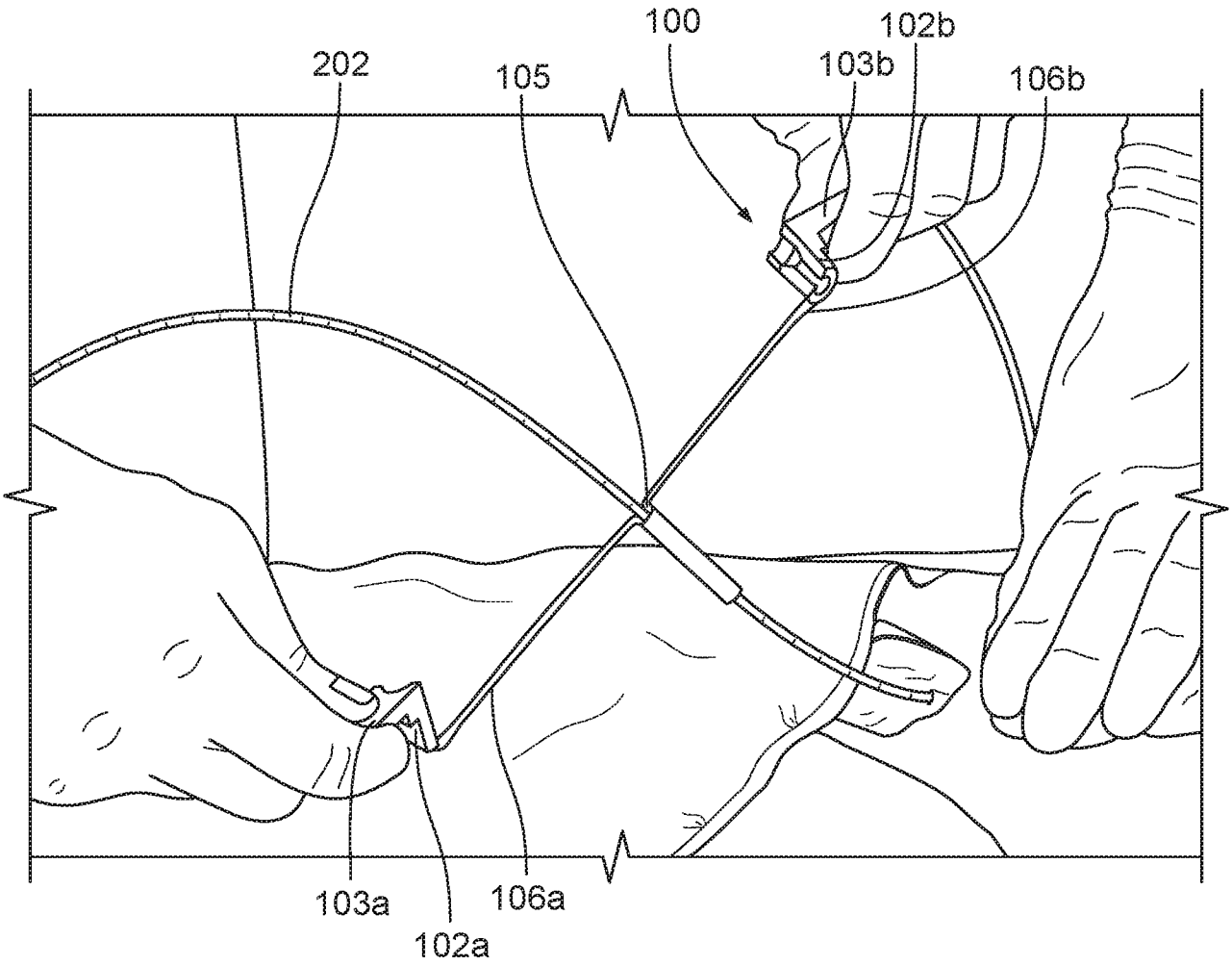


FIG. 6

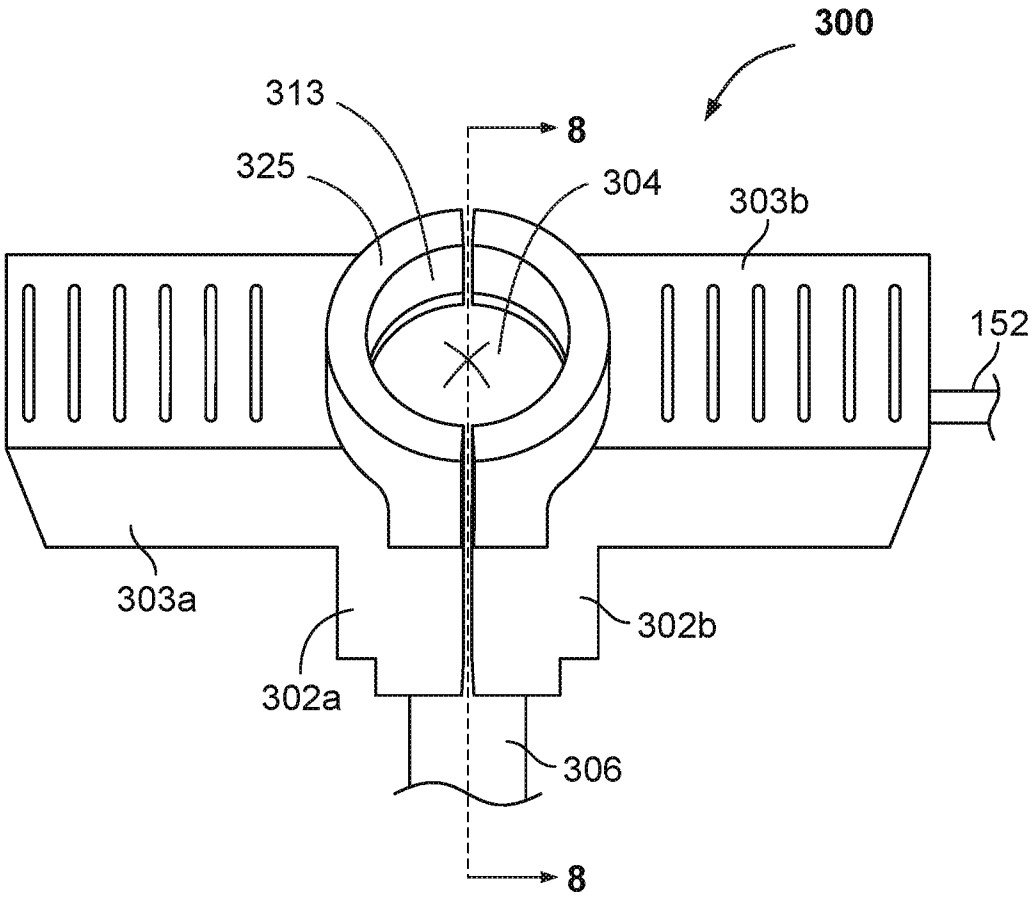
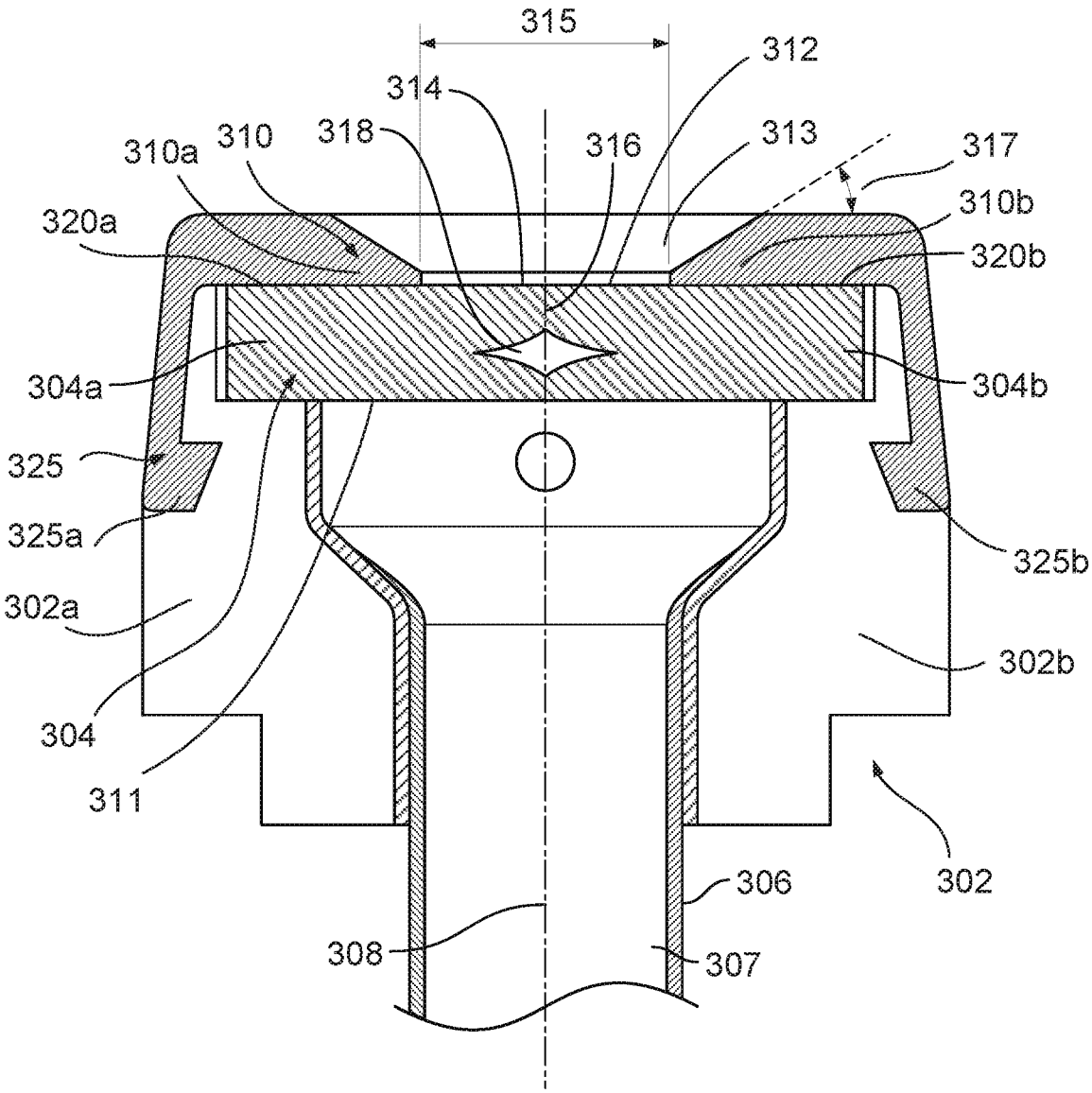


FIG. 7


315
312
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310a
310
318
316
313
317
310b
320a
320b
304a
304b
325
325a
325b
302a
302b
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307

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/048459

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 39/06; A61B 17/34; A61M 5/178; A61M 25/06 (2016.01)
CPC - A61M 39/0606; A61B 17/34; A61M 25/0668; A61M 39/02; A61M 39/045; A61M 2017/3466 (2016.08)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61M 39/06; A61B 17/34; A61M 5/178; A61B 25/06 (2016.01)
CPC - A61B 17/34; A61M 25/0668; A61M 39/02; A61M 39/045; A61M 39/0606; A61M 2017/3466; A61M 2039/062; A61M 2039/0633; A61M 2039/064; A61M 2039/066

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/160; 604/161; 604/164; 604/167.050; 604/167.060 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Orbit, Google Patents, Google Scholar, Google
Search terms used: Hemostatic valve; Introducer; Introducer sheath; heart pump; Splittable hemostatic valve; Splitabble introducer sheath; Splittable medical valve; Breakaway hemostasis hub

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0234290 A1 (FISHER et al) 17 September 2009 (17.09.2009) entire document	1-8, 10, 13-17
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Y		9
Y	US 8,147,456 B2 (FISHER et al) 03 April 2012 (03.04.2012) entire document	9
A	US 5,312,355 A (LEE) 17 May 1994 (17.05.1994) entire document	1-10, 13-17
A	US 6,712,791 B2 (LUI et al) 30 March 2004 (30.03.2004) entire document	1-10, 13-17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2016	10 NOV 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/048459

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 11, 12
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.