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(54) **HEMOSTATIC VALVE FOR MEDICAL DEVICE INTRODUCER**

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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 525 days.

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(51) **Int. Cl.**

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- A61M 25/06** (2006.01)

(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.

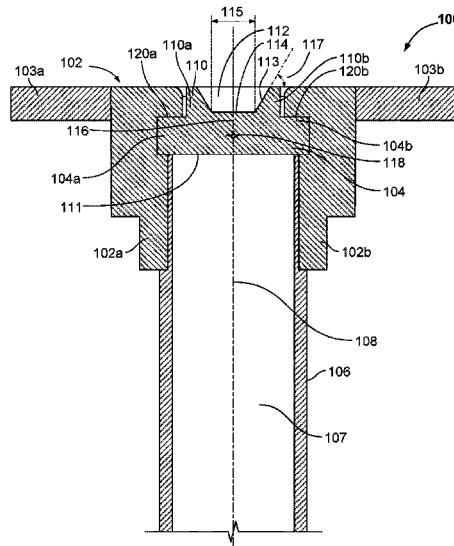
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See application file for complete search history.

16 Claims, 8 Drawing Sheets



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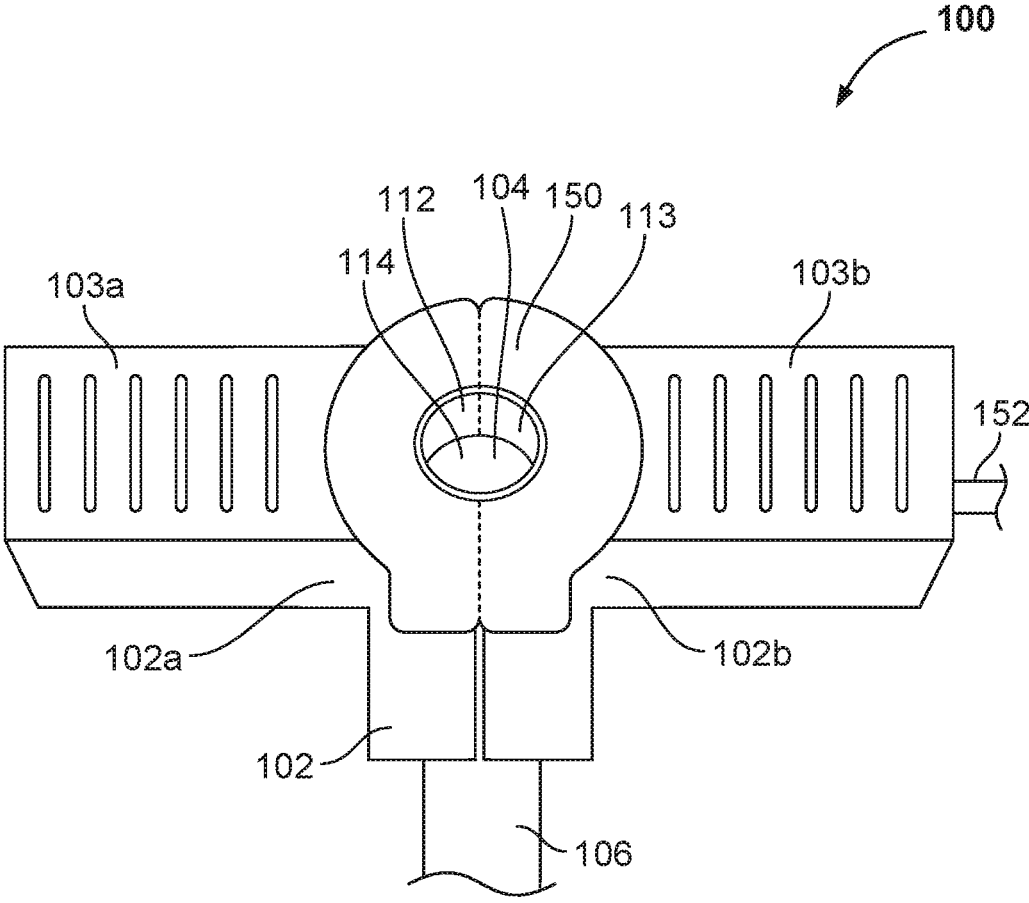


FIG. 3

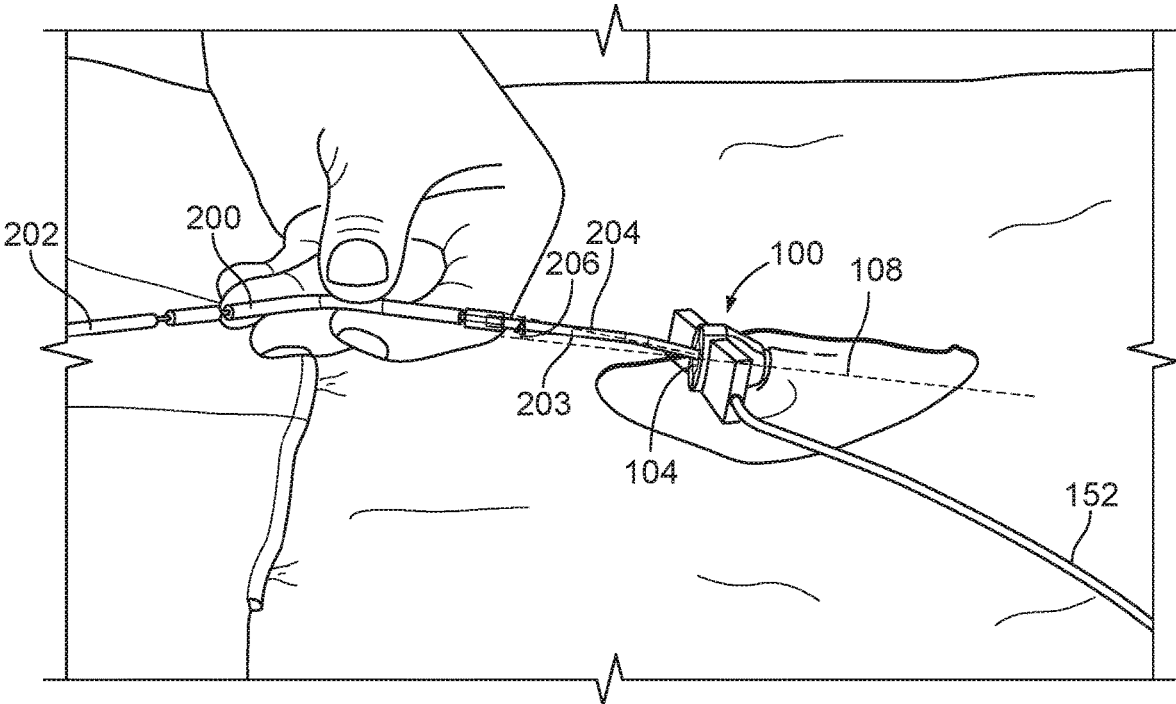


FIG. 4

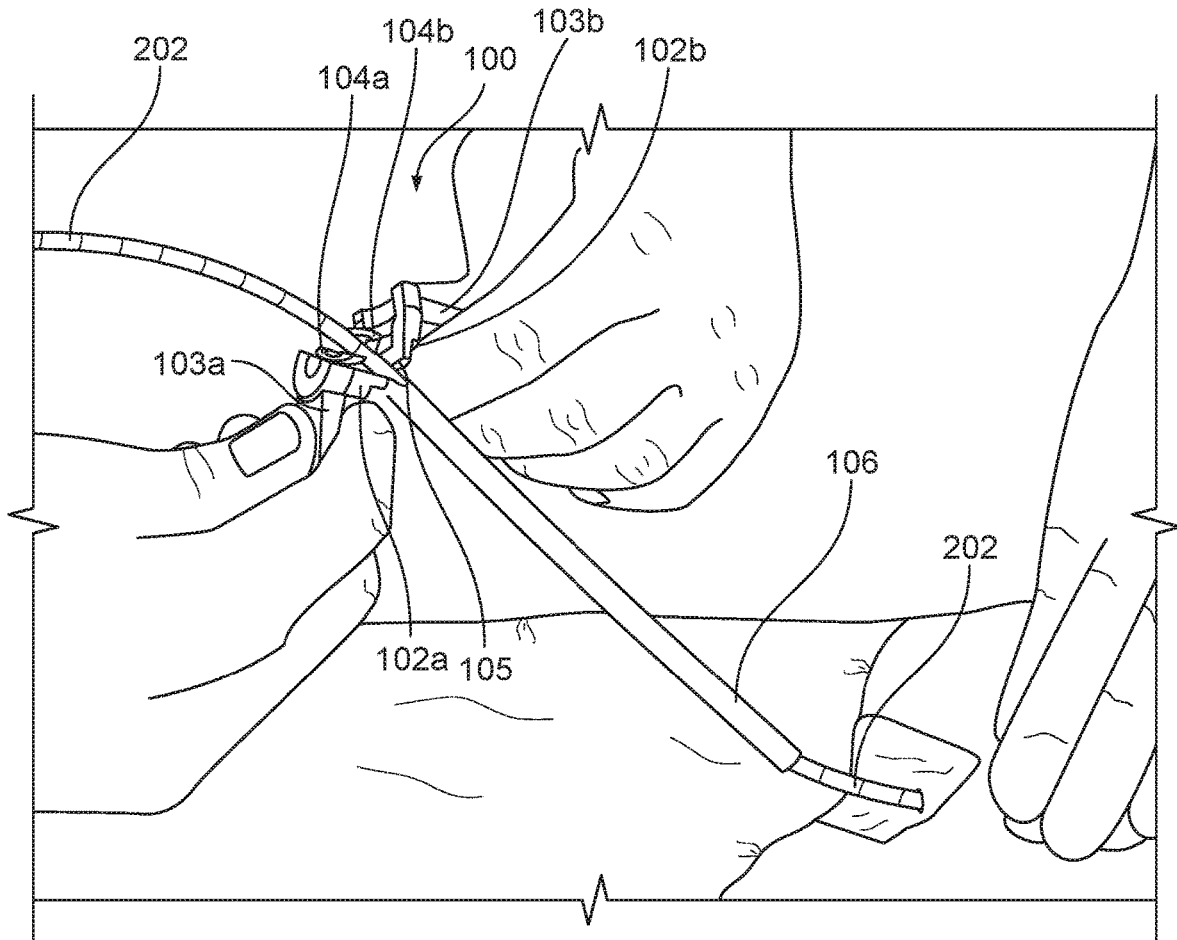


FIG. 5

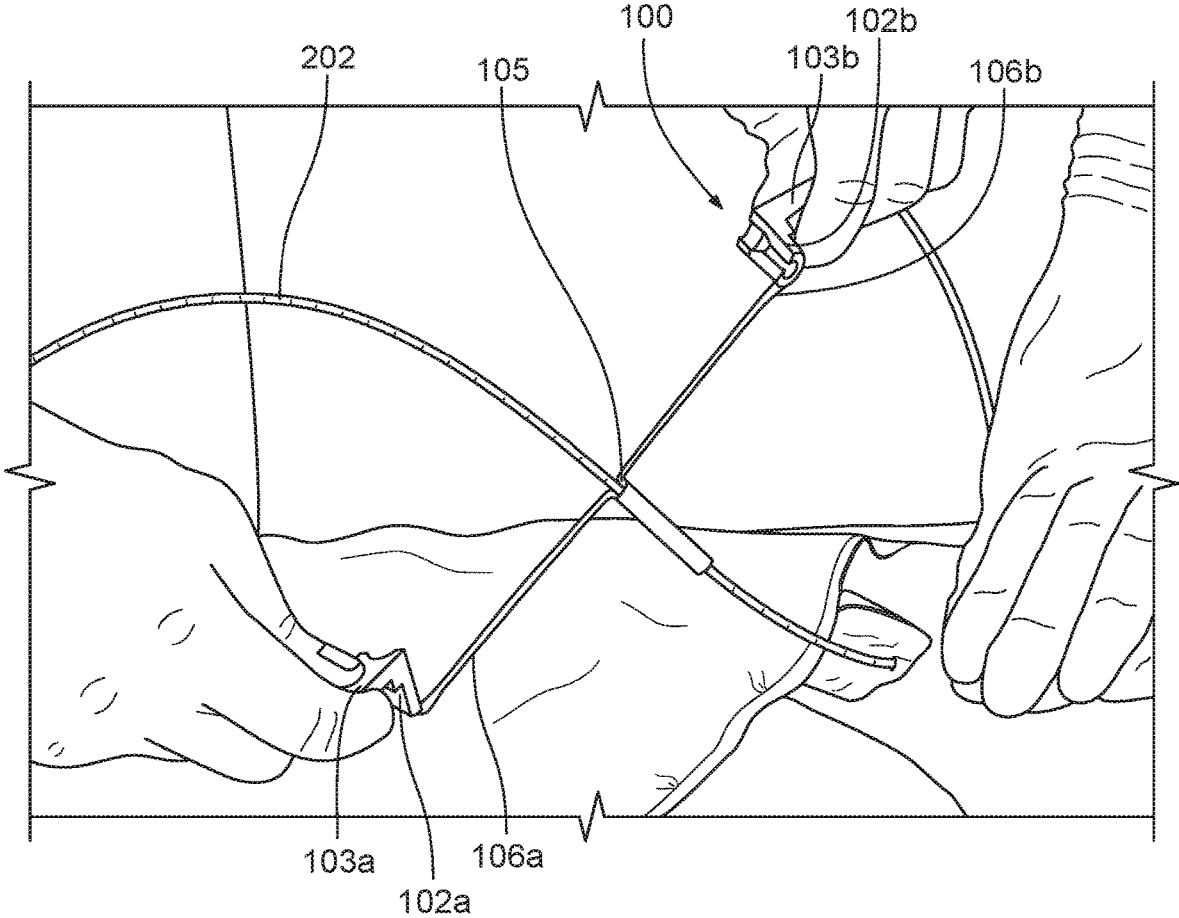


FIG. 6

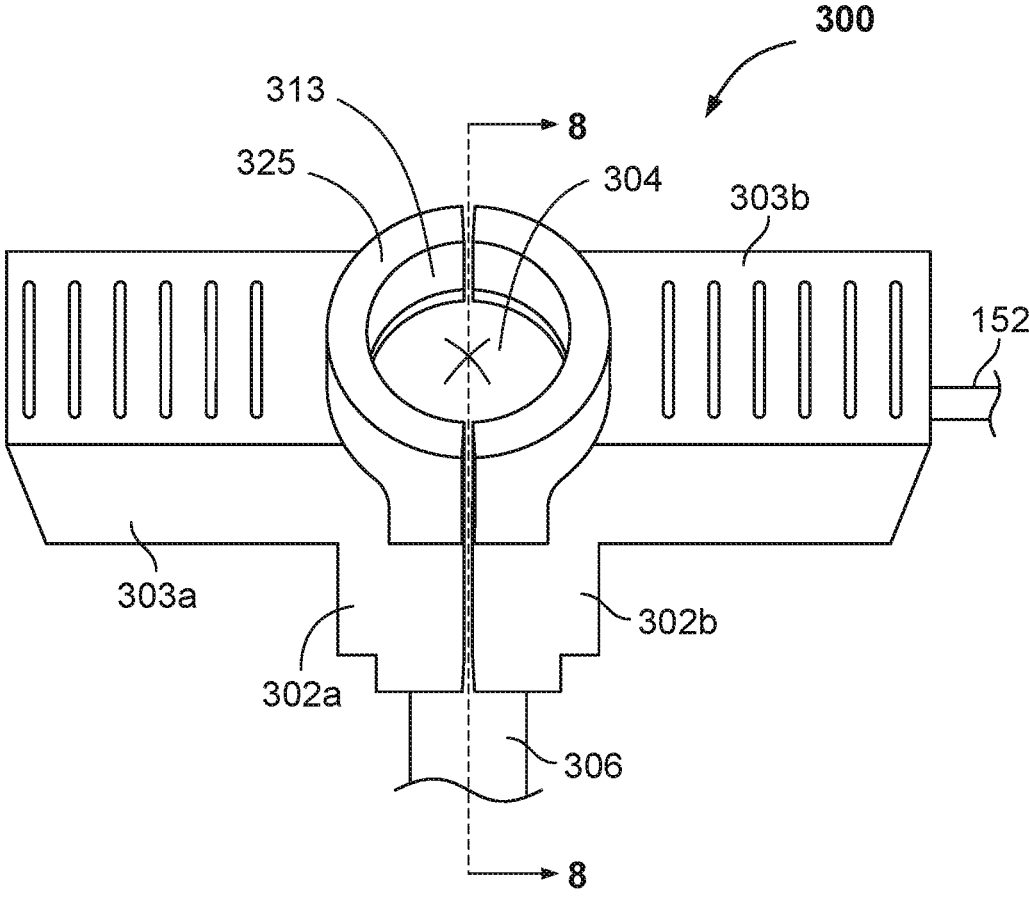


FIG. 7

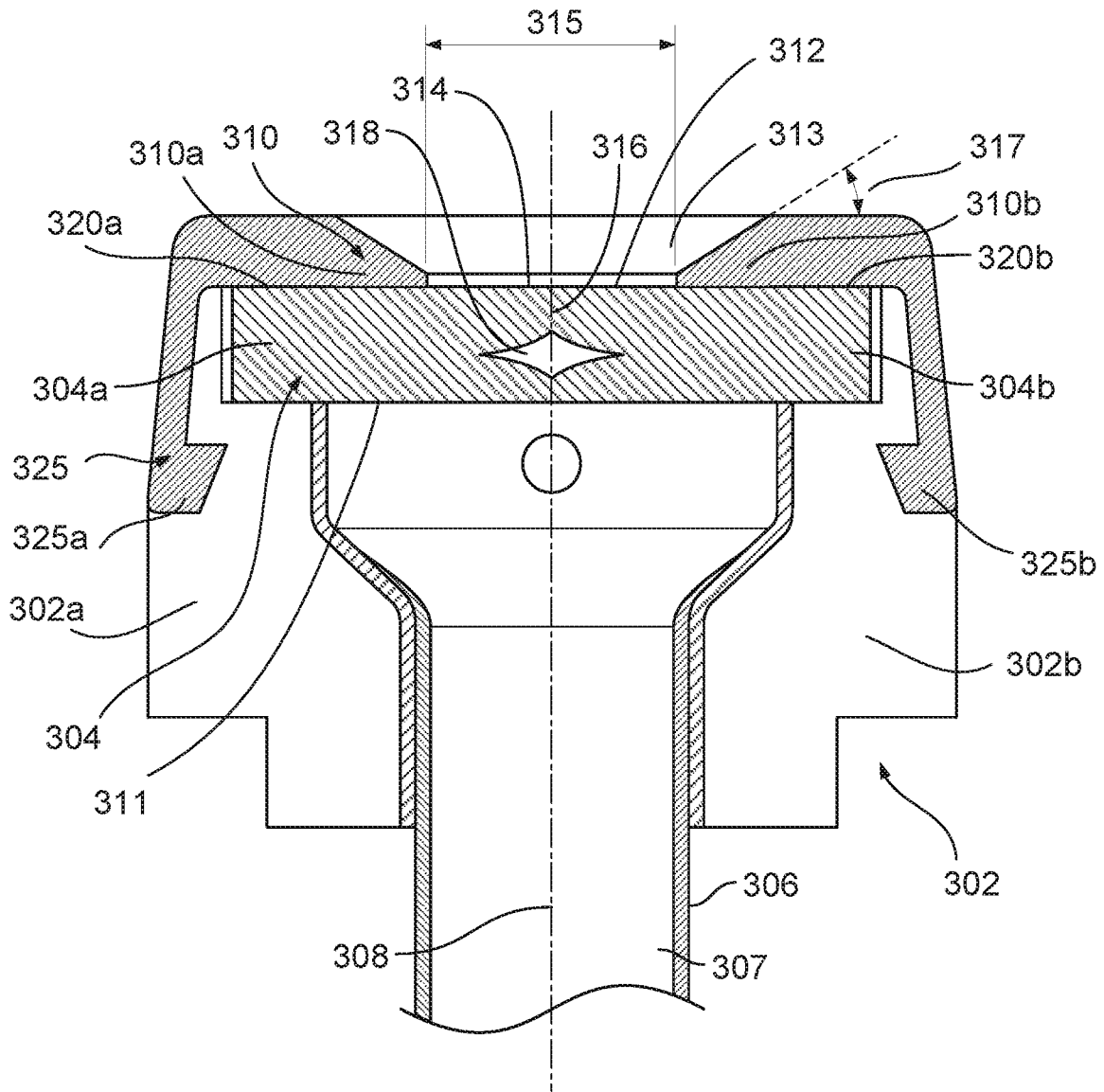


FIG. 8

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HEMOSTATIC VALVE FOR MEDICAL DEVICE INTRODUCER

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 15/245,982, filed Aug. 24, 2016 (now U.S. Pat. No. 10,576,258), which claims the benefit of U.S. Provisional Patent Application No. 62/209,288, filed on Aug. 24, 2015, which are hereby incorporated herein by reference in its entirety.

BACKGROUND

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.

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

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.

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.

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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 3 mm 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

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:

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

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

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

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

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

DETAILED DESCRIPTION

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.

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 (heart pumps), guidewires, dilators, or other objects. This can reduce or prevent blood leakage through the hemostatic valve.

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.

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.

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.

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 (4.67 mm), 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 (6.67 mm), 21 French (7 mm), or any other suitable diameter.

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 region 113 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.

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 4°, 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.

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.

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**.

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**.

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 hemo-

static 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**.

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.

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**.

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.

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

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.

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 sub-combinations), 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.

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 hub and the hemostatic valve are configured to part together,
 wherein the hemostatic valve includes a proximal surface and a distal surface and a sloped region that is disposed in the proximal surface and is angled relative to a plane perpendicular to the longitudinal axis of the introducer body, wherein the sloped surface is configured to direct an object toward a central region of the hemostatic valve,
 wherein the hemostatic valve includes a central void disposed between the distal surface and the proximal surface that reduces a stiffness of the central region of the hemostatic valve,
 wherein the central void is enclosed by material of the hemostatic valve.

2. The introducer of claim **1**, wherein the central region is flat and substantially perpendicular to the longitudinal axis of the introducer body and the proximal surface comprises the flat central region.

3. The introducer of claim **2**, wherein the flat central region has a diameter of about 3 mm or less.

4. The introducer of claim **1**, wherein the sloped region is angled about 30° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

5. The introducer of claim **1**, wherein the sloped region is angled about 60° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

6. The introducer of claim **1**, wherein the sloped region is a funnel.

7. The introducer of claim **1**, wherein the introducer is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body.

8. The introducer of claim **1**, wherein the hemostatic valve is configured to part along a parting surface substantially parallel to the longitudinal axis of the introducer body.

9. The introducer of claim **8**, wherein the parting surface defines the central void.

10. The introducer of claim **1**, wherein the hemostatic valve is configured with a base portion having a first outer diameter, and an upper portion having a second outer diameter, wherein the first outer diameter is greater than an inner diameter of the hub, and the second outer diameter is smaller than the first outer diameter.

11. The introducer of claim **1**, wherein the central void is configured such that the hemostatic valve forms a double seal against the object when inserted through the hemostatic valve.

12. 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 introducer and the hemostatic valve are configured to part together,

wherein the hub includes a sloped region configured to direct an object towards a central region of the hemostatic valve during insertion of the object through the hemostatic valve, wherein the sloped region is a funnel, wherein the hemostatic valve includes a proximal surface and a distal surface and a central void disposed between the distal surface and the proximal surface that reduces a stiffness of the central region of the hemostatic valve, wherein the central void is enclosed by material of the hemostatic valve.

13. The introducer of claim **12**, wherein the sloped region is a funnel.

14. The introducer of claim **13**, wherein the sloped region extends circumferentially around the hemostatic valve.

15. The introducer of claim **13**, wherein the sloped region is angled about 30° or greater relative to the plane perpendicular to the longitudinal axis of the introducer body.

16. The introducer of claim **12**, wherein the central void is configured such that the hemostatic valve forms a double seal against the object when inserted through the hemostatic valve.