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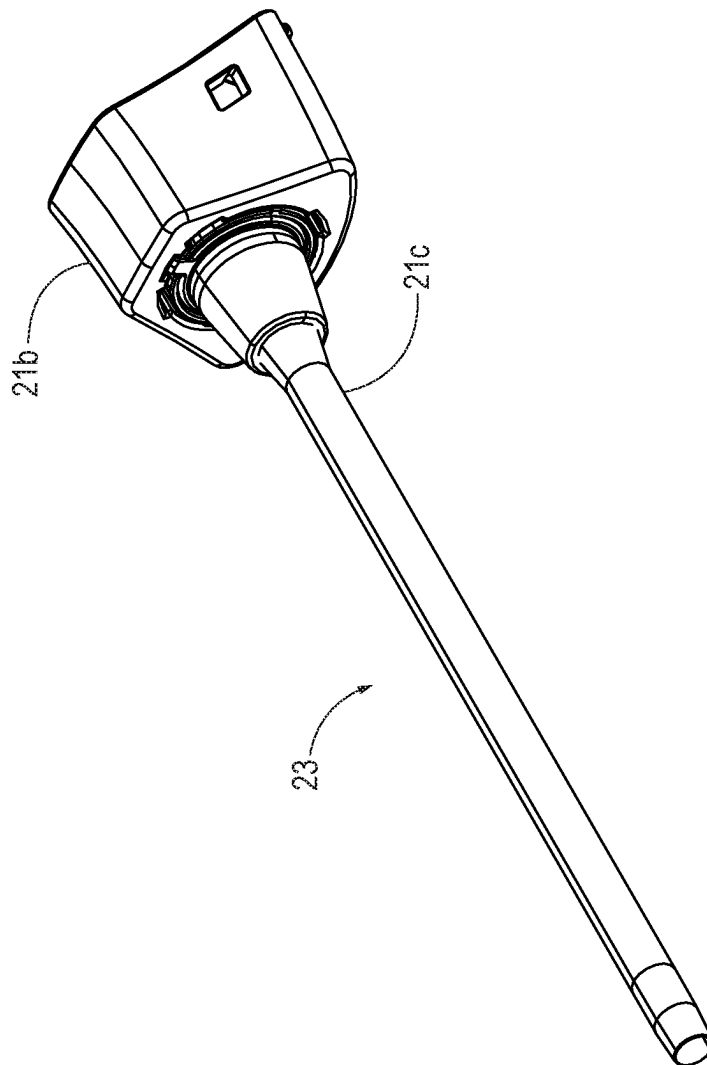
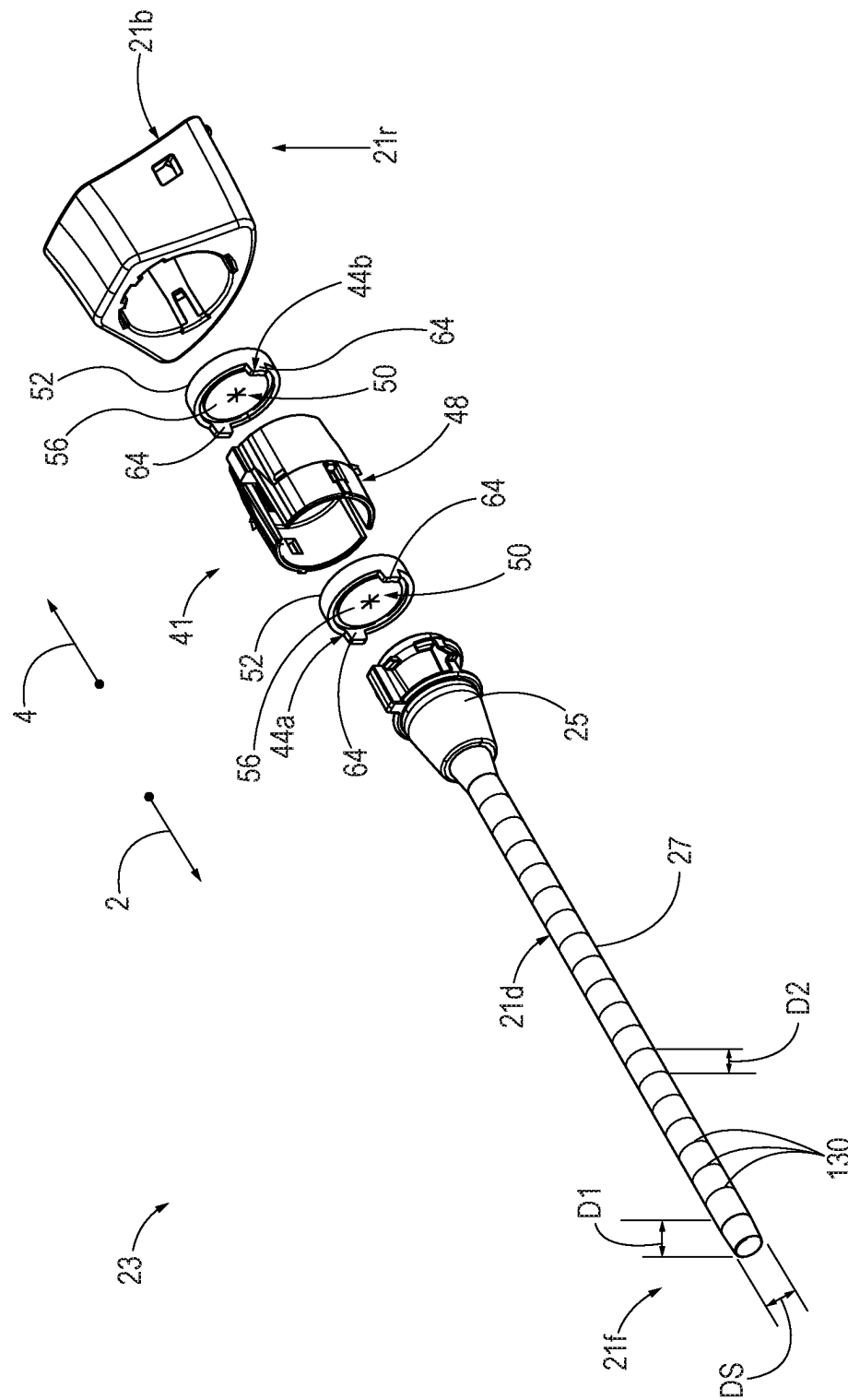
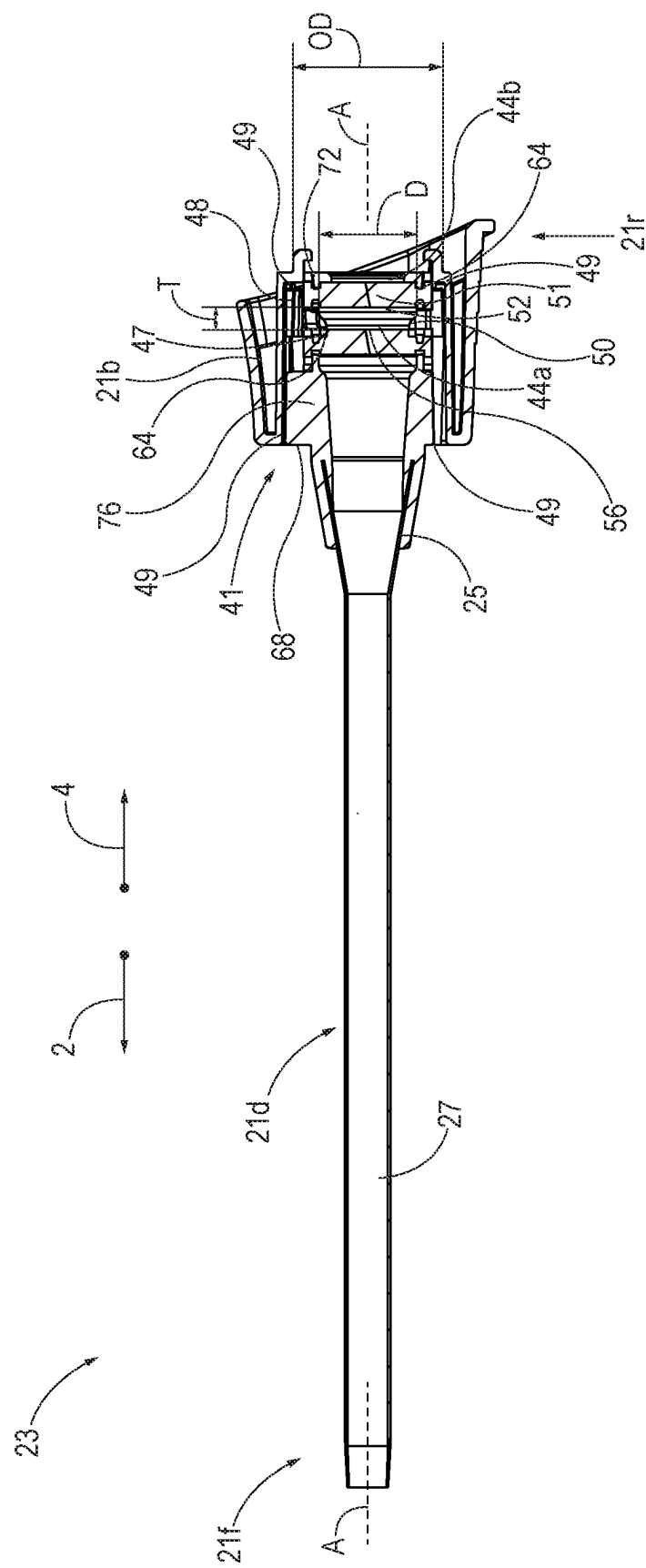
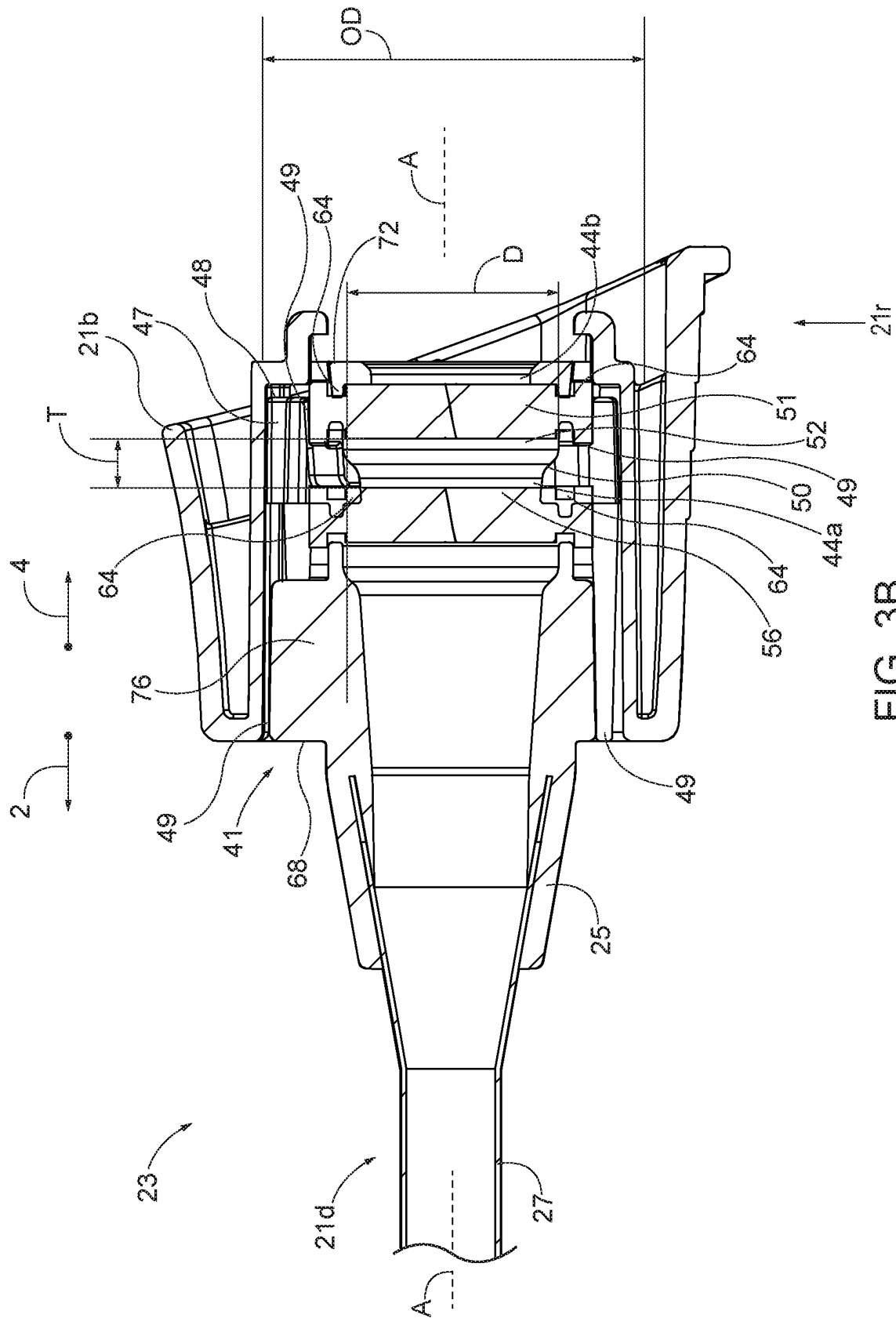


FIG. 1



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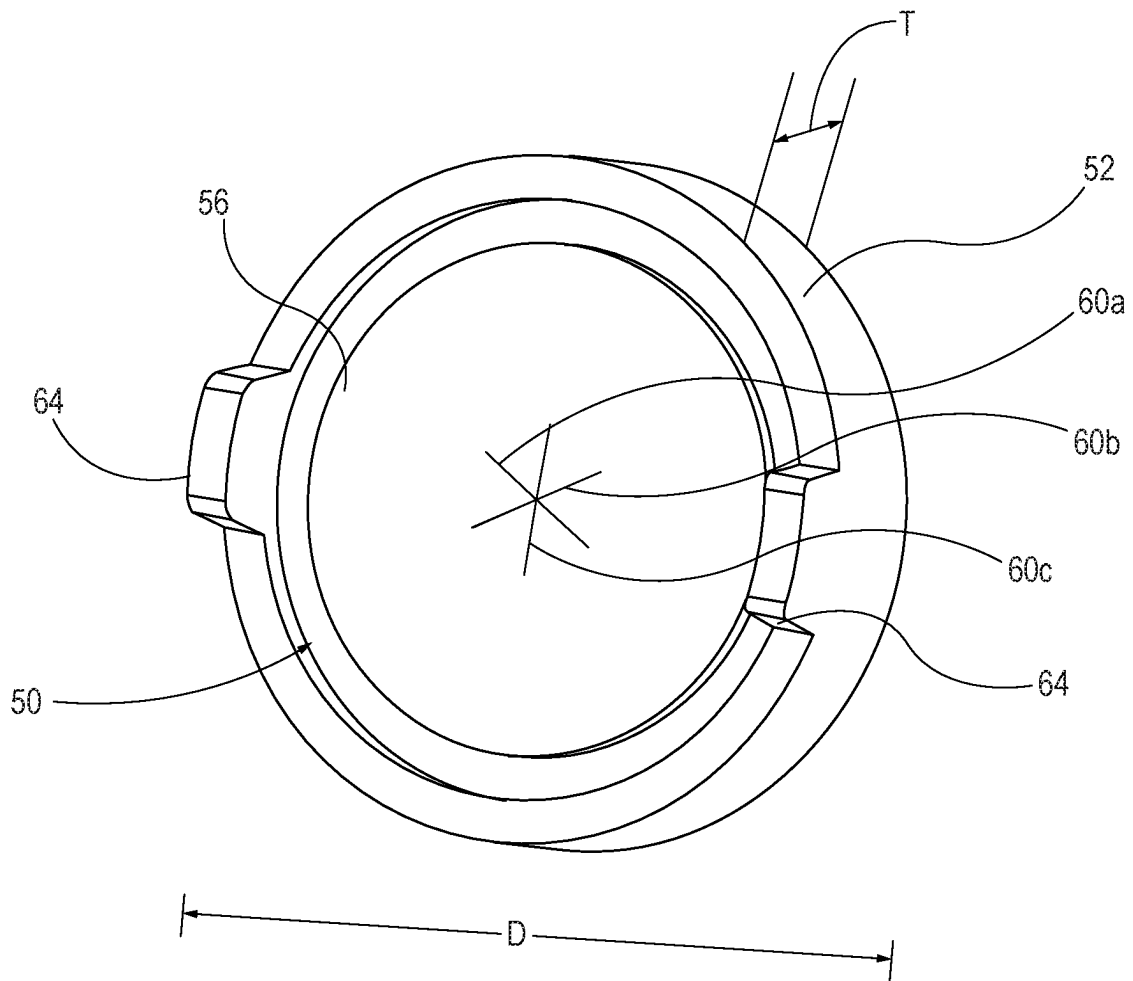


FIG. 4A

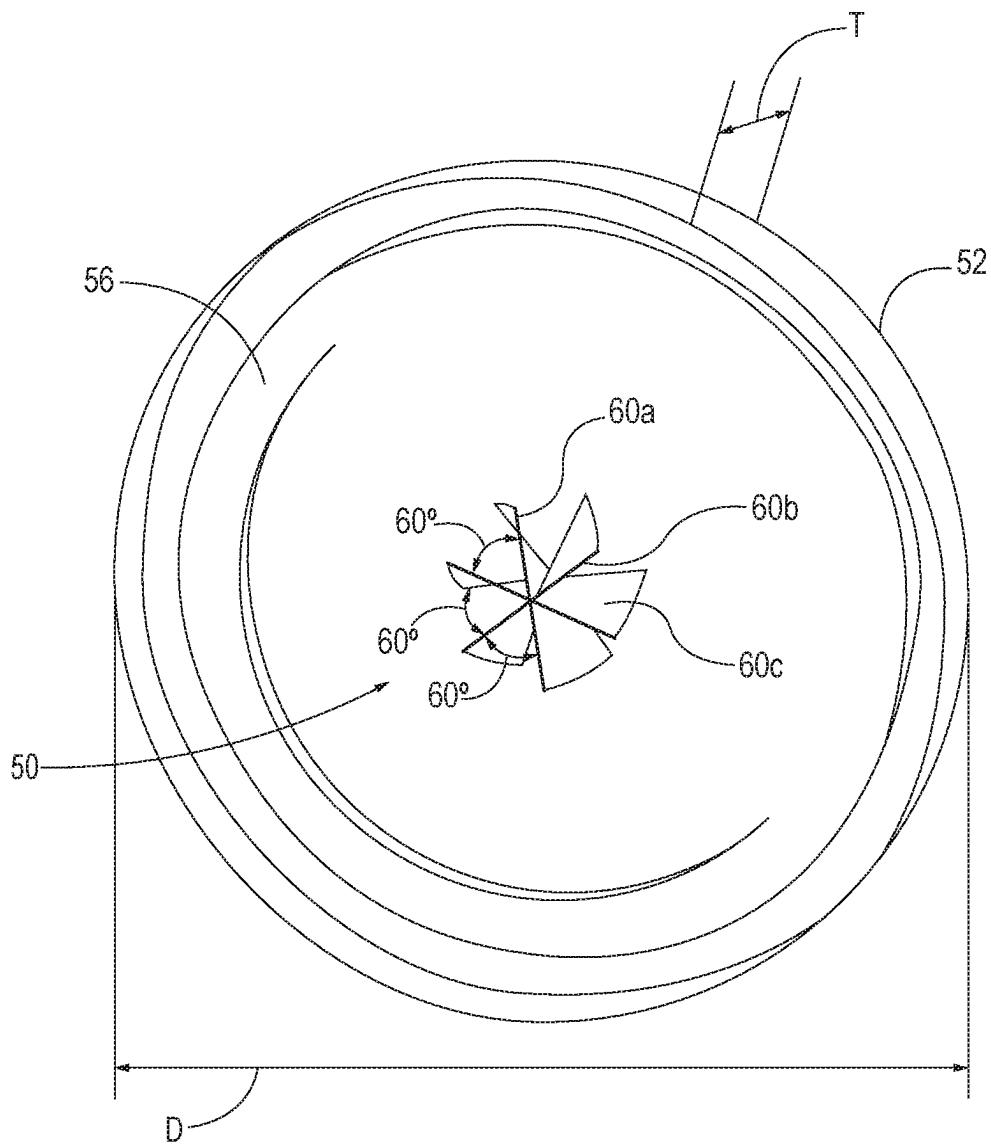


FIG. 4B

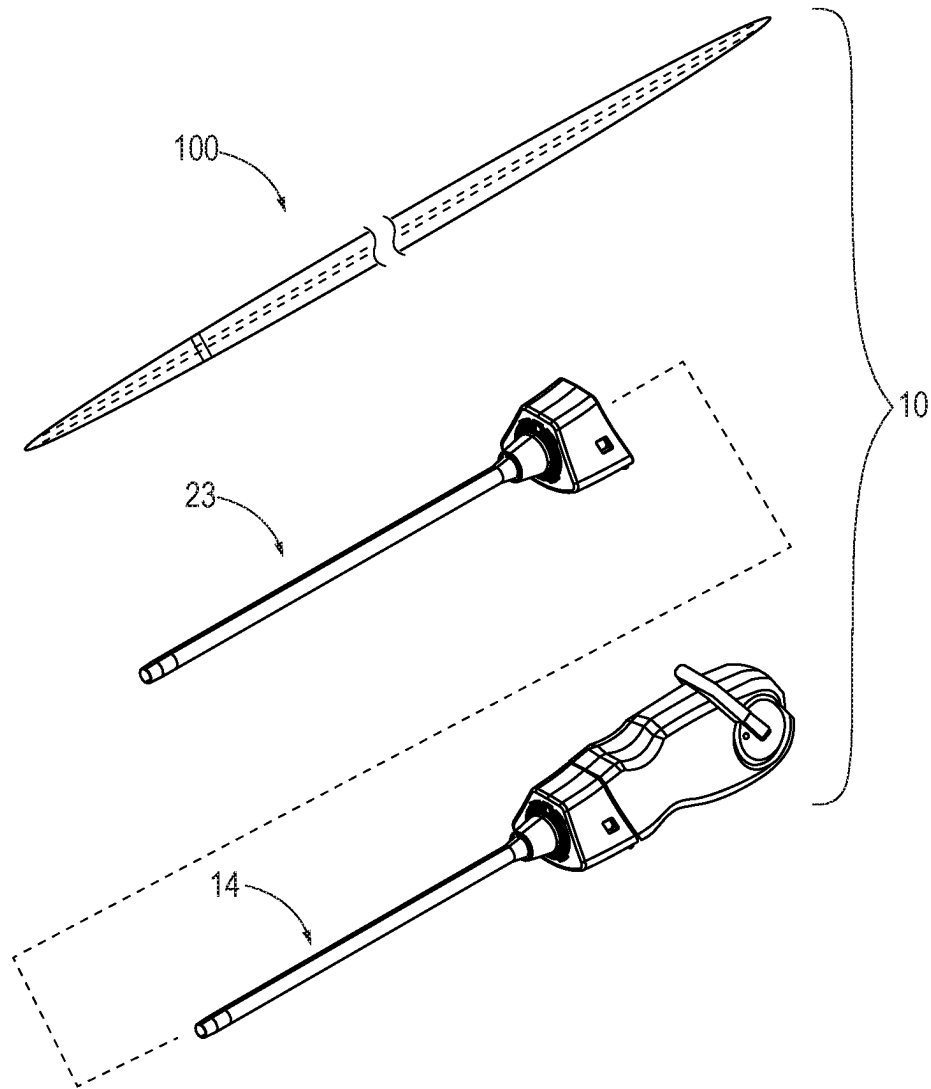


FIG. 5

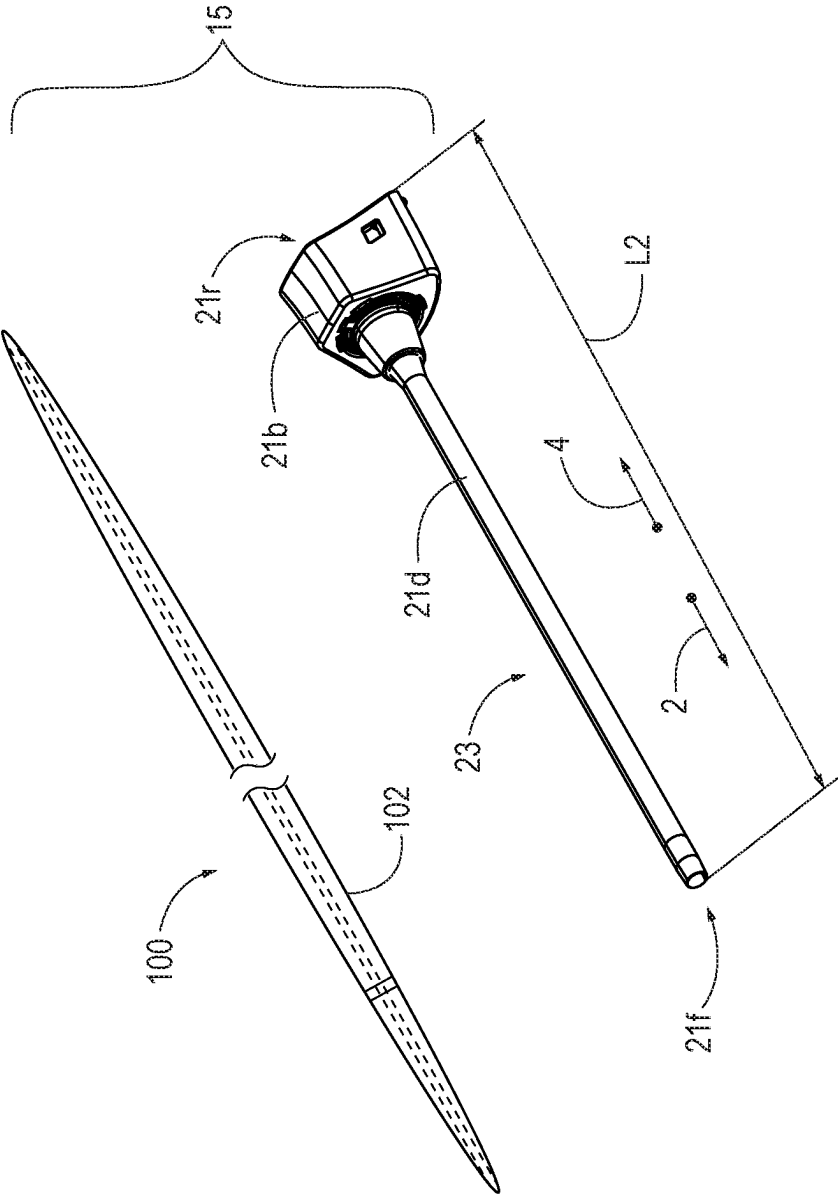


FIG. 6A

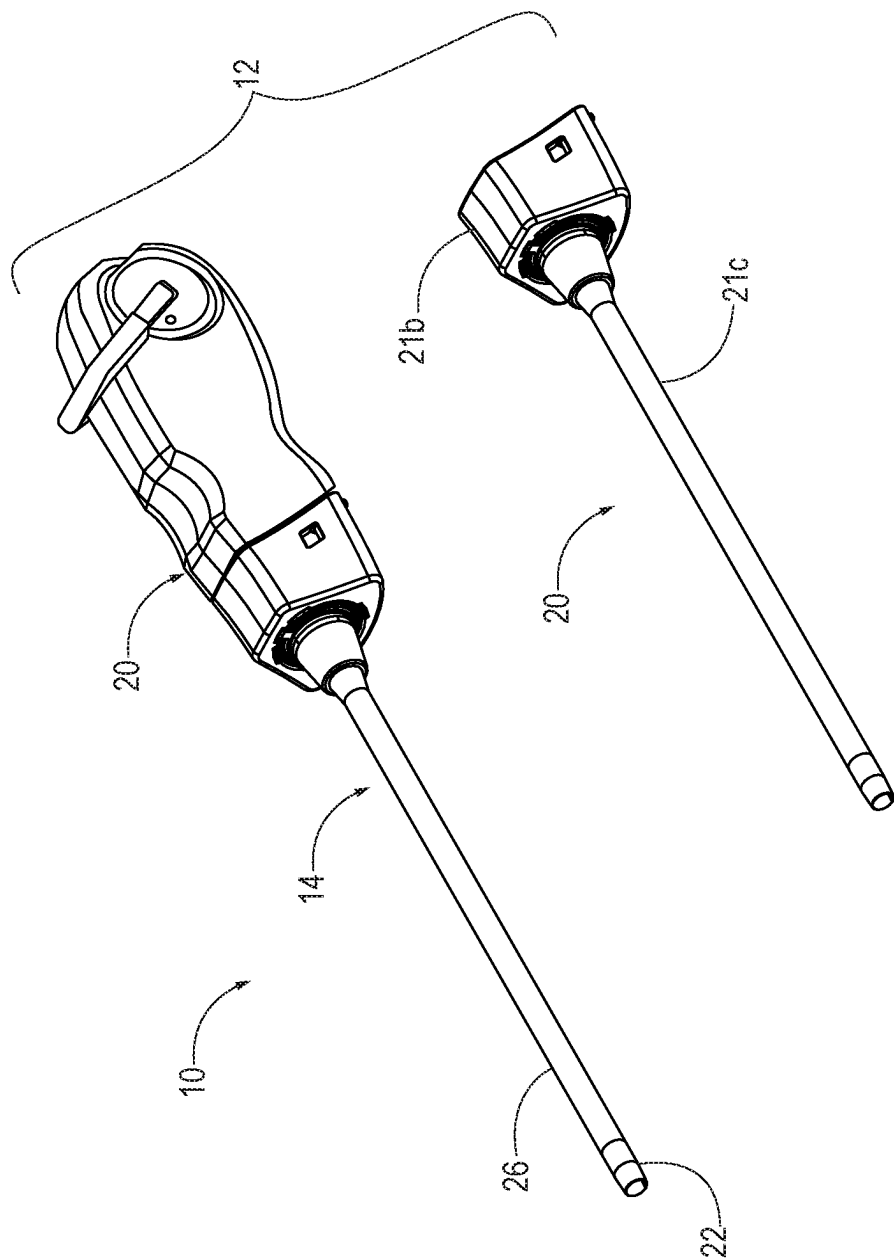


FIG. 6B

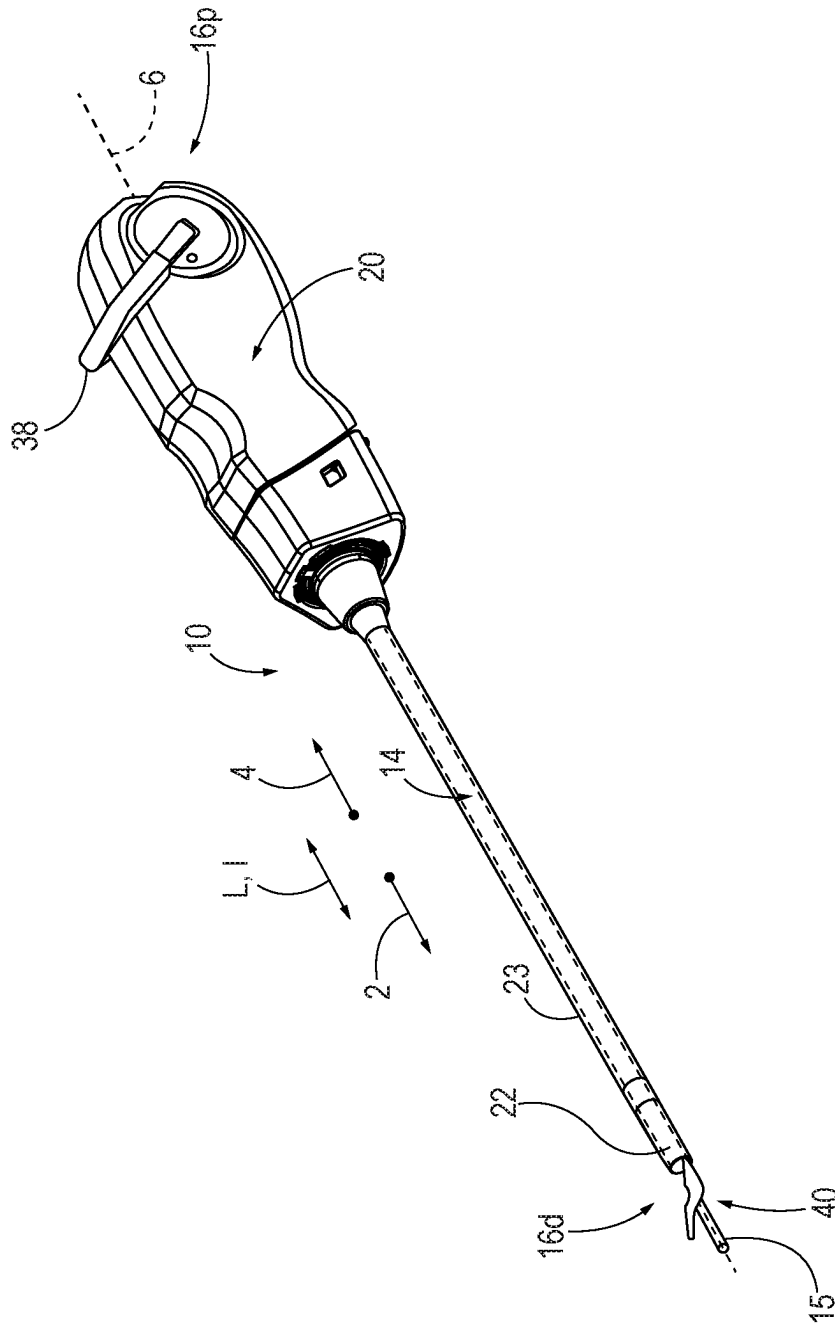


FIG. 7A

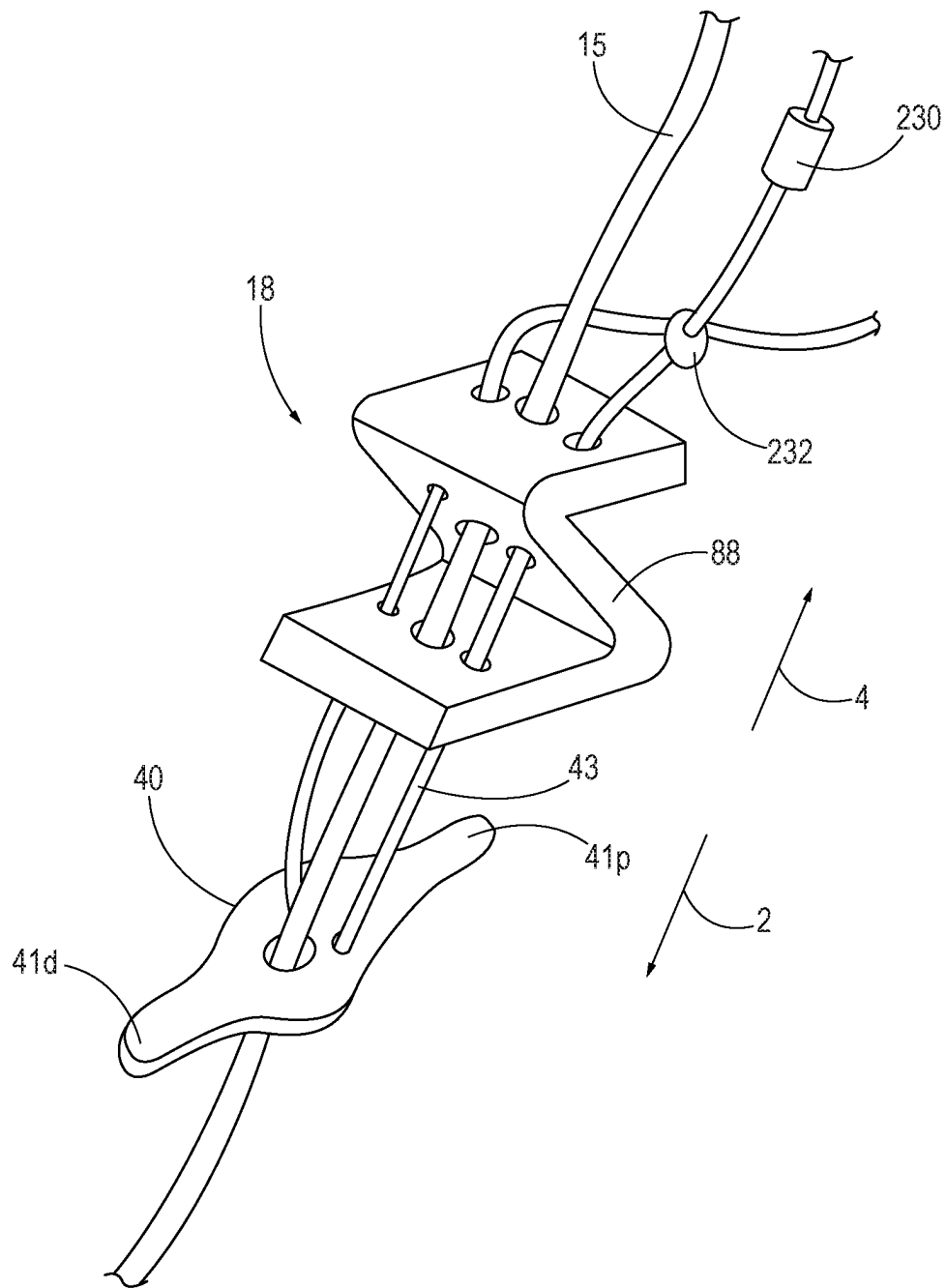


FIG. 7B

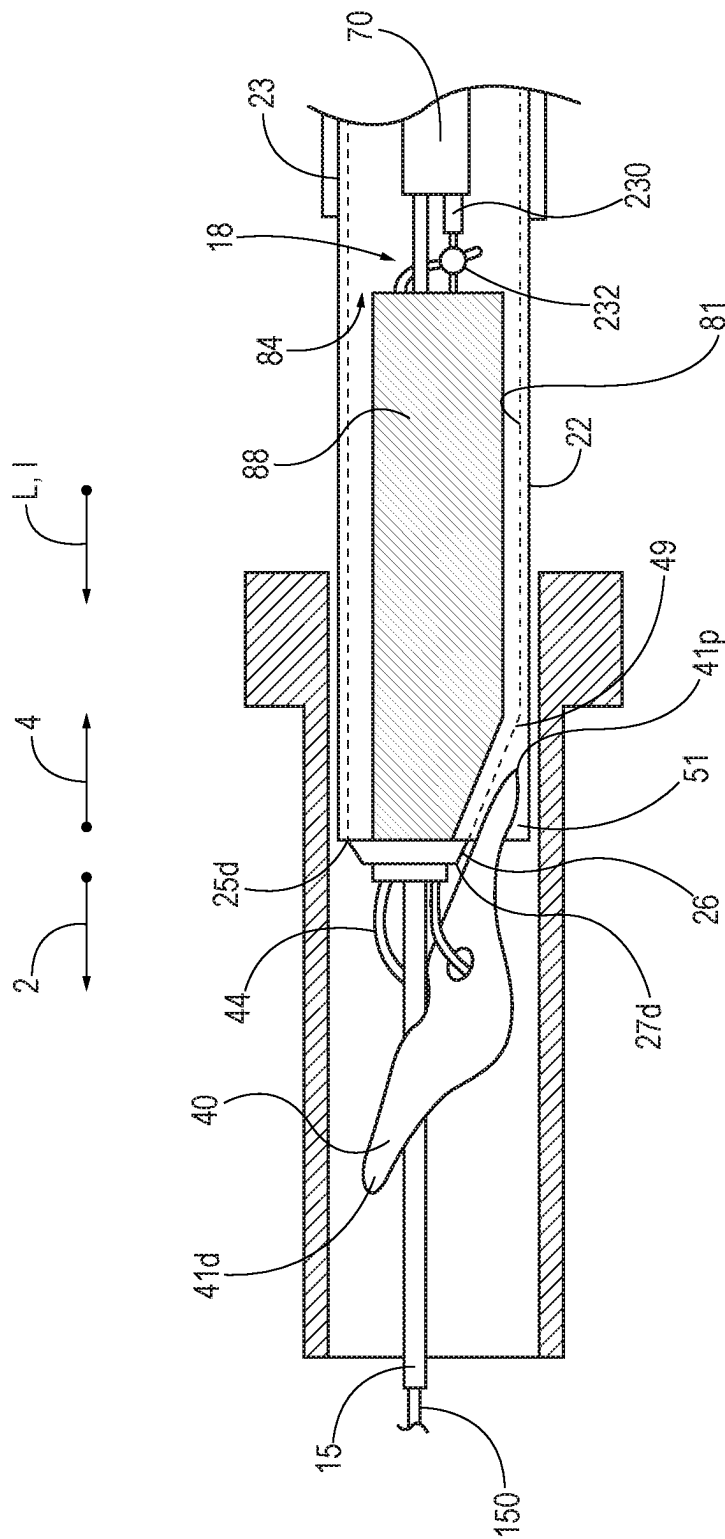


FIG. 7C

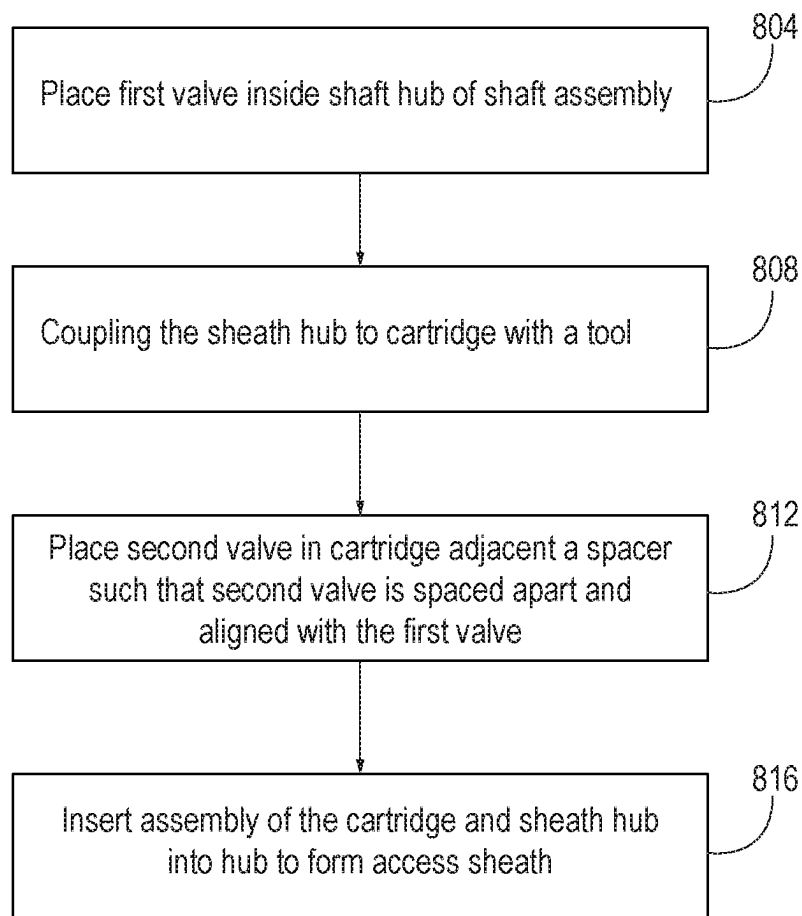


FIG. 8

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ACCESS SHEATH WITH VALVE ASSEMBLY**TECHNICAL FIELD**

The present disclosure relates to an access sheath for device introduction and exchange in a vessel.

BACKGROUND

Percutaneous procedures often involve accessing vasculature with elongated instruments, e.g., catheters, deployed in an ordered sequence. During an interventional cardiovascular procedure access to the cardiovascular system may be obtained via an artery or vein in situations where an artery is not a suitable approach path. In one example, a vascular closure system may include a sheath introducer and a delivery system having a sealing unit designed to seal a puncture in a vessel. Such systems and related devices may function to exchange a procedure access sheath used to guide a catheter (or other medical device) into the vessel, e.g. the femoral artery or the aorta, with an access sheath for use with a device. The access sheath may have a valve that is designed to minimize blood loss during device insertion into the access sheath. Current valves, however, present leakage issues as well as high device introduction forces. In order to accommodate larger diameters, the valves stretch beyond their tear limits. The tear reduces the likelihood of the valve being able to seal around a guidewire prior to introduction of the delivery system or during catheter exchange. Leakage may occur during the exchange between catheters, such as between the sheath introducer and the delivery system, resulting in blood loss. In addition, existing efforts to improve leakage can increase insertion forces, as the delivery system requires more force to pierce through the valve.

SUMMARY

An embodiment of the present disclosure is an access sheath configured to be disposed along a guidewire into a puncture of a vessel. The access sheath includes a hub having a proximal end and a distal end spaced from the proximal end. The access sheath further includes a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend through first valve and the second valve, respectively, along the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to hub disposed relative the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction.

Another embodiment of the present disclosure is an access sheath. The access sheath is configured to be disposed along a guidewire into a puncture of a vessel. The access sheath includes a hub having a proximal end and a distal end spaced from the proximal end. The access sheath further includes a cartridge carried by the hub. The cartridge has a first valve, a second valve spaced from the first valve along a central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend along, and twist about, the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to the hub and

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disposed relative to the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction.

A further embodiment of the present disclosure is a vascular closure system. The vascular closure system includes an access sheath configured to be inserted into the vessel. The access sheath has a proximal end and a distal end spaced from the proximal end along a central axis. The access sheath further includes a hub, a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along the central axis, and a spacer disposed between the first valve and the second valve. The first valve and the second valve each have at least two slits that extend along the central axis. The access sheath further includes a shaft assembly having a shaft hub coupled to hub and disposed relative to the cartridge in a distal direction along the central axis, and a shaft that extends from the shaft hub in the distal direction to define the distal end of the access sheath. The access sheath further includes an access channel that extends from the proximal end at the hub to the distal end along the central axis. The vascular closure system further includes a deployment assembly having a sealing element configured to seal the puncture in the vessel. The deployment assembly is insertable into the access channel and into engagement with the first valve and the second valve such that the first valve and second valve stretch around the deployment assembly.

Another embodiment of the present disclosure is a method. The method includes placing a first valve inside a sheath hub of a shaft assembly, the shaft assembly including an elongated shaft that extends from the sheath hub. The method further includes coupling the sheath hub to a cartridge with a tool. The method further includes placing a second valve in the cartridge adjacent a spacer such that second valve is spaced apart and aligned with the first valve, wherein the first valve and the second valve each have at least two slits. The method further includes inserting an assembly of the cartridge and sheath hub to a hub to form an access sheath.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary, as well as the following detailed description, will be better understood when read in conjunction with the appended drawings. The drawings show illustrative embodiments of the disclosure. It should be understood, however, that the application is not limited to the precise arrangements and instrumentalities shown.

FIG. 1 is a perspective view of an access sheath according to an embodiment of the present disclosure;

FIG. 2 is an exploded view of the access sheath shown in FIG. 1;

FIG. 3A is a side sectional view of the access sheath shown in FIGS. 1 and 2;

FIG. 3B is a side sectional view of the access sheath shown in FIG. 3A;

FIG. 4A is a perspective view of the valve shown in FIG. 2;

FIG. 4B is a perspective cross-sectional view of the valve shown in FIG. 4A;

FIG. 5 is a perspective view of a vascular closure system according to an embodiment of the present disclosure;

FIG. 6A is a perspective view of an introducer and an access sheath of the system shown in FIG. 1;

FIG. 6B is a perspective view of the vascular closure device and access sheath of the system shown in FIG. 1;

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FIG. 7A is a perspective view of a vascular closure device in accordance with an embodiment of the present disclosure;

FIG. 7B is a perspective view of a sealing device associated with the vascular closure device in FIG. 3A;

FIG. 7C is a side sectional view of a distal portion of the vascular closure device;

FIG. 8 is a process flow diagram illustrating a method for assembling the access sheath.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Certain terminology is used in the following description for convenience only and is not limiting. The words “right”, “left”, “lower” and “upper” designate directions in the drawings to which reference is made. The words “proximally” and “distally” refer to directions toward and away from, respectively, the individual operating the system. The terminology includes the above-listed words, derivatives thereof and words of similar import.

Referring to FIGS. 1 and 2, an access sheath 23 is configured to be inserted into a vessel of a patient for sheath introduction or exchange in a vessel. The access sheath 23 has a front end 21f, a rear end 21r opposite to the front end 21f, and a lumen (not numbered) that extends from the front end 21f to the rear end 21r. The access sheath 23 includes a hub 21b, a shaft assembly 21d that extends from the hub 21b in the distal direction 2, and a valve assembly 41. The rear end 21r of the access sheath includes the hub 21b that is configured to be coupled to the deployment assembly 14 during a closure procedure. The shaft assembly 21d includes a shaft hub 25 coupled to the valve assembly 41 and a shaft 27 that extends from the shaft hub 25 in the distal direction 2. When the access sheath 23 is coupled to the deployment assembly 14, the shaft assembly 21d extends along the release component 22 and delivery component 26 in the distal direction 2. The shaft 27 includes at least one marker 130. Thus, there may be a single marker 130 or a plurality of markers 130. In the illustrated embodiment, the markers 130 are evenly spaced along the shaft 27 and can be positioned to aid in identifying the location of the shaft assembly 21d in the vessel. The marker 130 is one of a laser etch, radio opaque band, a radio opaque ink, or a radio opaque paint. The shaft 27 includes an outer diameter DS. In one embodiment, the outer diameter DS of the shaft 27 may be 14 F. In another embodiment, the outer diameter of the shaft may be 18 F. Other sizes are contemplated. In one example, the shaft length may vary as needed.

Referring to FIGS. 3A and 3B, the valve assembly 41 carries the valves 44a, 44b. As shown, the valve assembly 41 is coupled to the shaft assembly 21d and the hub 21b. The valve assembly 41 includes a cartridge 48 that carries a first valve 44a and a second valve 44b. The first and second valves 44a, 44b may be hemostasis valves and are configured to minimize the loss of blood during insertion of the deployment assembly 14 into the access sheath 23.

The cartridge 48 includes a cartridge body 47 that is configured to house and hold the first and second valves 44a, 44b. As shown the cartridge body 47 has a first end 68 and a second end 72 opposite the first end along the central axis A. The cartridge body 47 has an outer diameter OD that extends through and intersects the central axis A. The cartridge body 47 further defines an internal surface 76, which in turn, defines a spacer 51 that extends inwardly toward the central axis A. The spacer 51 is configured to separate the first valve 44a and the second valve 44b. The cartridge body 47 further defines one or more grooves 49

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disposed on either end of the cartridge 48. In the illustrated embodiment, the cartridge 48 has an outer diameter of approximately 19 mm. The outer diameter OD can range between 15 mm and 30 mm as needed. The cartridge 48 may be formed from any polymeric material. It should be appreciated, however, that the cartridge 48 can be made of other materials and can have other configurations.

The first and second valves 44a, 44b include a body 50 having a proximal surface 52 and a distal surface 56 opposite the proximal surface 52 along the central axis A. The valve body 50 can further define a thickness T that extends from the proximal surface 52 to the distal surface 56 in a direction that is parallel to the central axis A. In the illustrated embodiment, the thickness of the first and second valves 44a, 44b is approximately 3 mm. However, the thickness T may range between 2 mm and 5 mm or higher as needed. Furthermore, each valve body has a circular cross-sectional shape to fit with the cartridge. As shown, each valve has a diameter D that intersects and is perpendicular to the central axis A. In one example, the diameter D of the first and second valves 44a, 44b is approximately 15 mm. The diameter D may range between 8 mm and 20 mm, as needed. This size permits the deployment assembly 14 to pass through the slits as explained further below. The first and second valves 44a, 44b may be made of silicone. It should be appreciated, however, that the first and second valves 44a, 44b can be made of other materials and can have other configurations.

The first and second valves 44a includes a set of tabs 64 disposed on the distal surface 56 of the body 50. The tabs 64 of the first valve 44a are configured to couple the first valve 44a to the shaft hub 25 of the shaft assembly 21d via the cartridge 48. The tabs 64 of the second valve 44b are configured to couple the second valve 44b to the hub 21b via the cartridge 48. The grooves 49 of the cartridge 48 with the tabs 64 of the first and second valves 44a, 44b, couple the first and second valves 44a, 44b to the shaft assembly 21d and hub 21b, respectively. This configuration further enhances sealing within the access sheath 23.

Referring to FIGS. 4A and 4B, the first and second valves 44a, 44b include at least two slits 60. As shown, the valves 44a, 44b include three slits 60a, 60b, 60c that extend along and spiral about the central axis A. In the illustrated embodiments, the valves 44a, 44b include a minimum of two slits. In alternative embodiments, the valves 44a, 44b may include more than three slits. The slits 60a, 60b, 60c extend diametrically across a portion of the body 47. The slits 60a, 60b, 60c bisect each other at the center axis A. In this manner, the three slits form six identically sized flap portions with a 60 degree rotation on the body 50. The slits 60a, 60b, 60c extend in a spiral form about the central axis A from the distal surface 56 to the proximal surface 52. The slits 60a, 60b, 60c allow for the guidewire and the deployment assembly 14 to pass through the valve assembly 41 and the shaft assembly 21d of the access sheath 23 while still providing a seal to inhibit leakage and blood flow and loss. In the illustrated embodiments, the slits 60a, 60b, 60c are equal in size. In alternative embodiments, the slits 60a, 60b, 60c may vary in size. The first and second valves 44a, 44b are configured to stretch to accept the insertion of introducers (as needed) and in particular for insertion of the deployment assembly 14. The first and second valves 44a, 44b are configured to stretch around the deployment assembly 14 to minimize leakage/flow around a and the deployment assembly 14 is advanced.

The first valve 44a is positioned within the access sheath 23 such that the distal surface 56 of the first valve 44a is

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firmly seated against the shaft hub 25 while the proximal surface 52 of the first valve 44a abuts the spacer 51 of the cartridge 48. Engagement between the shaft hub 25 and the distal surface 56 of the first valve 44a and between the proximal surface 52 and the cartridge 48 creates a fluid-tight seal therebetween to prevent leakage and blood loss. Similarly, the second valve 44b is positioned within the access sheath 23 such that the proximal surface 52 of the second valve 44b is firmly seated against the hub 21b while the distal surface 56 of the second valve 44b abuts the spacer 51 of the cartridge 48. Engagement between the hub 21b and the proximal surface 52 of the second valve 44b and between the distal surface 56 and the cartridge 48 creates a fluid-tight seal therebetween to further prevent leakage and blood loss.

Referring to FIGS. 5-7C, in the illustrated embodiment, the valve assembly described herein is used in connection with a vascular closure system 10 for sheath introduction and exchange during vascular closure procedures. In alternative embodiments, the valve assembly described herein may be used for any sheath introduction or exchange in a vessel. Continuing with FIGS. 5-6B, the vascular closure system 10 includes an introducer 100 and a closure device 12 that is configured to seal a puncture in a vessel wall. The introducer 100 is configured to facilitate placement of the closure device 12 into the desired position within a puncture site of a vessel wall following a surgical procedure. The closure device 12 includes a deployment assembly 14 and an access sheath 23. The access sheath 23 can be inserted into the vessel and the deployment assembly 14 can be inserted into the access sheath 23 to position a sealing unit 18 (FIG. 5C) into the vessel. The access sheath 23 and introducer 100 can be referred to as insertion assembly 15.

Referring to FIGS. 7A and 7B, a vascular closure device 12 includes a sealing unit 18 at least partially disposed within a deployment assembly 14. The vascular closure device 12 can be configured such that after a distal portion of deployment assembly 14 is inserted through a puncture site of the vessel, the sealing unit 18 is deployed to thereby seal or otherwise close the puncture site of the vessel. The deployment assembly 14 is configured to control orientation of a toggle 40 of the sealing unit 18 in an easier and more efficient manner during deployment of the sealing unit 18. Furthermore, the deployment assembly 14 is configured to reduce forces required to deploy the sealing unit 18 and seal the puncture.

In accordance with the illustrated embodiment, the deployment assembly 14 includes a release component 22 that restrains the toggle 40, a delivery component 26 (See FIG. 2B) that contains at least a portion of the toggle 40 and a suture 43 of the sealing unit 18, a guide member 35, and one or more actuators 38 coupled to the release component 22. The deployment assembly 14 may also include a tamper 70, in the form a tube, that extends along the suture 43 and is located in a proximal direction relative to the locking member 230 (See FIG. 3C). The guide member 35 extends through the sealing unit 18 and is configured to receive a guidewire as will be discussed below. In another example, the deployment assembly 14 can be configured so that the guidewire extends along the side of the toggle 40. The release component 22 is operatively associated with the suture 43 such that actuation of the actuator 38 causes the release component 22 to 1) release the toggle 40, and 2) apply tension to the suture 43, which urges the toggle 40 against the delivery component 26 and orients the toggle 40 in the sealing position. The guide member 35 is configured to be removed from at least the sealing unit 18 prior the sealing unit 18 sealing the puncture.

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Turning to FIG. 7C, the sealing unit 18 includes the toggle 40 connected to the suture 43, a plug 88 coupled to the suture 43 and spaced from the toggle 40 in a proximal direction 4, and a locking member 230 proximal to the plug 88. The toggle 40 includes a distal end 45d and a proximal end 41p opposite to the proximal end 41p, and a plurality of apertures (not numbered) extending therethrough. The suture 43 extends through the apertures as illustrated such that an end of the suture 43 is formed into a slidable knot 232. The knot 232 is slidable along the suture 43 between the plug 88 and the locking member 230. In an implanted state, the toggle 40 is adjacent to an inner surface of the vessel and the locking member 230 squeezes the toggle 40 and the plug 88 against the vessel to seal the puncture.

The sealing unit 18 is formed with materials suitable for surgical procedures such as any biocompatible material. It should be appreciated, however, that the toggle 40 can be made of other materials and can have other configurations so long as it can be seated inside the vessel against the vessel wall. The plug 88 can comprise a strip of compressible, resorbable, collagen foam and can be made of a fibrous collagen mix of insoluble and soluble collagen that is cross linked for strength. It should be appreciated, however, that the plug member 88 can have any configuration as desired and can be made from any material as desired. The suture 43 can be any elongate member, such as, for example a filament, thread, or braid.

Now referring to FIG. 8, a method 800 for assembling the access sheath 23 shown in FIGS. 1-6B will be described. It should be appreciated that the access sheath 23 can be assembled during manufacture or at the surgical site prior to its use as described above. In step 804, the first valve 44a is placed inside the shaft hub 25 of the shaft assembly 21d. In step 808, the shaft hub 25 is coupled to the cartridge 48. In step 812, the second valve 44b is placed in the cartridge 48 adjacent the spacer 51 such that second valve 44b is spaced apart and aligned with the first valve 44a. In step 816, the assembly of the cartridge 48 and the shaft hub 25 is inserted into the hub 21b, forming the access sheath 23. The second valve 44b may be inserted such that the tabs 64 of the second valve 44b are configured to mate with the grooves of the hub 21b.

The systems and devices as described herein may be used to seal punctures in a femoral artery. In particular, the valve assembly 41 may be utilized with a vascular closure system to seal so-called large bore punctures, such as 10 F French, 12 French, 14 French or larger sized bore. Such a system is typically used to seal a puncture in vessel within a patient's limb. In addition, the method may be used to seal a puncture in a so-called trans-caval procedure. In alternative embodiments, the valve assembly 41 may be utilized to allow sheath introduction and exchange in the vessel for any procedure.

While the foregoing description and drawings represent the preferred embodiment of the present invention, it will be understood that various additions, modifications, combinations and/or substitutions may be made therein without departing from the spirit and scope of the present disclosure as defined in the accompanying claims. In particular, it will be clear to those skilled in the art that the present disclosure may be embodied in other specific forms, structures, arrangements, proportions, and with other elements, materials, and components, without departing from the spirit or essential characteristics thereof. One skilled in the art will appreciate that the present disclosure may be used with many modifications of structure, arrangement, proportions, materials, and components, which are particularly adapted to specific environments and operative requirements without

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departing from the principles of the present disclosure. In addition, features described herein may be used singularly or in combination with other features. For example, features described in connection with one component may be used and/or interchanged with features described in another component. The presently disclosed embodiment is therefore to be considered in all respects as illustrative and not restrictive, the scope of the present disclosure being indicated by the appended claims, and not limited to the foregoing description. It will be appreciated by those skilled in the art that various modifications and alterations of the present disclosure can be made without departing from the broad scope of the appended claims. Some of these have been discussed above and others will be apparent to those skilled in the art.

What is claimed:

1. An access sheath configured to be disposed along a guidewire into a puncture of a vessel, the access sheath comprising:
 - a hub having a proximal end and a distal end spaced from the proximal end;
 - a cartridge carried by the hub, the cartridge including:
 - a first valve,
 - a second valve spaced from the first valve along a central axis, and
 - a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the spacer disposed between the first valve and the second valve,
 - wherein:
 - the first valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis,
 - the second valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis,
 - the first slit of the valve body of the first valve and the first slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body,
 - the second slit of the valve body of the first valve and the second slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body, and
 - the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge body proximal to the spacer; and
 - a shaft assembly having a shaft hub coupled to the hub, and a shaft that extends from the shaft hub in a distal direction;
 - wherein the first valve and the second valve include at least one set of tabs disposed on a distal surface of each valve body and configured to couple the first valve to the shaft hub and the second valve to the hub, respectively.
2. The access sheath of claim 1, wherein the first valve and the second valve are hemostasis valves.
3. The access sheath of claim 1, wherein the valve body of each of the first and second valves includes a third slit, such that the three slits of each valve body spiral about the central axis.

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4. The access sheath of claim 1, wherein:
 - the valve body of the first valve has a proximal surface spaced from the respective distal surface along the central axis, wherein the first and second slits of the valve body of the first valve extend from the proximal surface to the distal surface of the valve body of the first valve, and
 - the valve body of the second valve has a proximal surface spaced from the respective distal surface of the valve body of the second valve along the central axis, wherein the first and second slits of the valve body of the second valve extend from the proximal surface to the distal surface of the valve body of the second valve.
5. The access sheath of claim 4, wherein the first valve is seated against the shaft hub while the proximal surface of the valve body of the first valve abuts the spacer.
6. The access sheath of claim 4, wherein the second valve is firmly seated against the hub while the distal surface of the valve body of the second valve abuts the spacer.
7. The access sheath of claim 4, wherein the valve body of each of the first and second valves includes a third slit, wherein the three slits of each valve body bisect each other at the central axis.
8. The access sheath of claim 7, wherein the three slits of the valve body of the first valve extend in a spiral about the central axis from the proximal surface of the valve body of the first valve to the distal surface of the valve body of the first valve.
9. The access sheath of claim 7, wherein the three slits of the valve body of the second valve extend in a spiral about the central axis from the proximal surface of the valve body of the second valve to the distal surface of the valve body of the second valve.
10. An access sheath configured to be disposed along a guidewire into a puncture of a vessel, the access sheath comprising:
 - a hub having a proximal end and a distal end spaced from the proximal end;
 - a cartridge carried by the hub, the cartridge including:
 - a first valve that includes a distal surface and at least one tab extending distally from the distal surface,
 - a second valve that includes a distal surface, and
 - a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the spacer positioned between the first valve and the second valve so that the first valve and the second valve are spaced apart with respect to each other along a central axis,
 - wherein:
 - each of the first valve and the second valve has a valve body and at least two slits that extend partially across the respective valve and twist about the central axis as they extend through the valve body such that the at least two slits of the first valve and the at least two slits of the second valve are oriented in substantially the same directions diametrically across a portion of the respective valve body, and
 - the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge body proximal to the spacer; and
 - a shaft assembly having a shaft hub coupled to the hub and the at least one tab of the first valve, and a shaft that extends from the shaft hub in a distal direction.

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11. The access sheath of claim 10, wherein the first valve and the second valve are hemostasis valves.

12. The access sheath of claim 10, wherein the at least two slits of each of the first and second valves are three slits that twist about the central axis.

13. The access sheath of claim 10, wherein the valve bodies of the first valve and the second valve each have a proximal surface spaced from the respective distal surface along the central axis, and wherein the at least two slits extend from the respective proximal surface to the respective distal surface.

14. The access sheath of claim 13, wherein the distal surface of the valve body of the first valve is seated against the shaft hub while the proximal surface of the valve body of the first valve abuts the spacer.

15. The access sheath of claim 13, wherein the second valve is firmly seated against the hub while the distal surface of the valve body of the second valve abuts the spacer.

16. The access sheath of claim 13, wherein the at least two slits of each of the first and second valves are three slits, and wherein the three slits of each of the first and second valves bisect each other at the central axis.

17. The access sheath of claim 16, wherein the three slits of the first valve extend in a spiral about the central axis from the proximal surface of the valve body of the first valve to the distal surface of the valve body of the first valve.

18. The access sheath of claim 16, wherein the three slits of the second valve extend in a spiral about the central axis from the proximal surface of the valve body of the second valve to the distal surface of the valve body of the second valve.

19. A vascular closure system configured to seal a puncture in a vessel, the vascular closure system comprising:

an access sheath configured to be inserted into the vessel, the access sheath having a proximal end and a distal end spaced from the proximal end along a central axis, the access sheath further including

a hub;

a cartridge carried by the hub, the cartridge having a first valve, a second valve spaced from the first valve along the central axis, and

a spacer defined by and extending from an internal surface of the cartridge between the first valve and the second valve, wherein:

the first valve and the second valve each having at least two slits that extend partially across the first valve and the second valve, respectively, and spiral about the central axis such that the at least two slits of the first valve and the at least two slits of the second valve are oriented in substantially the same directions diametrically across a portion of the respective valve,

the first valve and the second valve each further comprises a proximal surface and a distal surface, the respective distal surfaces each including one or more distally extending tabs, and

the cartridge is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge distal to the spacer, and the second valve is inserted into a second longitudinal end of the cartridge proximal to the spacer;

a shaft assembly having a shaft hub coupled to the hub, and a shaft that extends from the shaft hub in a distal direction to define the distal end of the access sheath; and

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an access channel that extends from the proximal end at the hub to the distal end along the central axis; and a deployment assembly having a sealing element configured to seal the puncture in the vessel, wherein the deployment assembly is insertable into the access channel and into engagement with the first valve and the second valve such that the first valve and the second valve stretch around the deployment assembly.

20. The vascular closure system of claim 19, wherein the first valve and the second valve are hemostasis valves.

21. The vascular closure system of claim 19, wherein the at least two slits of each of the first and second valves are three slits that spiral about the central axis.

22. The vascular closure system of claim 19, wherein the at least two slits extend from the respective proximal surface to the respective distal surface of each of the first valve and the second valve.

23. The vascular closure system of claim 22, wherein the first valve is seated against the shaft hub while the proximal surface of the first valve abuts the spacer.

24. The vascular closure system of claim 22, wherein the second valve is firmly seated against the hub while the distal surface of the second valve abuts the spacer.

25. The vascular closure system of claim 22, wherein the at least two slits of each of the first and second valves are three slits, wherein the three slits of each of the first and second valves bisect each other at the central axis.

26. The vascular closure system of claim 25, wherein the three slits of the first valve extend in a spiral about the central axis from the proximal surface of the first valve to the distal surface of the first valve.

27. The vascular closure system of claim 25, wherein the three slits of the second valve extend in a spiral about the central axis from the proximal surface of the second valve to the distal surface of the second valve.

28. The vascular closure system of claim 19, wherein the first valve and the second valve are configured to inhibit blood flow along an outer surface of the deployment assembly when 1) the deployment assembly is engaged with the first valve and the second valve and 2) a distal end of the deployment assembly is placed inside the vessel.

29. The vascular closure system of claim 19, wherein the first valve and the second valve are configured to transition from an unstretched state into a stretched state when the deployment assembly is inserted therein.

30. A method, comprising: providing a first valve and a shaft assembly having a shaft hub and an elongated shaft that extends from the shaft hub in a distal direction;

coupling the shaft hub to a cartridge with a tool, the cartridge including:

a cartridge body defining an internal surface and defining a spacer extending inwardly from the internal surface, the cartridge body is open at longitudinal ends so that the first valve is inserted into a first longitudinal end of the cartridge body distal to the spacer;

placing a second valve in the cartridge by inserting into a second longitudinal end of the cartridge body proximal to and adjacent the spacer such that the second valve is spaced apart from and aligned with the first valve along a central axis and the spacer is disposed between the first valve and the second valve, wherein:

the first valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis,

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the second valve includes a valve body having a first slit and a second slit that intersect each other and twist about the central axis,

the first slit of the valve body of the first valve and the first slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body;

the second slit of the valve body of the first valve and the second slit of the valve body of the second valve are oriented in substantially the same direction diametrically across the respective valve body, and

the first valve and the second valve include at least one set of tabs disposed on a distal surface of each valve body and configured to couple the first valve to the shaft hub and the second valve to a hub; and
inserting an assembly of the cartridge and the shaft hub to the hub to a hub to form an access sheath.

31. The method of claim **30**, wherein the twist of the first slit and the second slit of the first valve, and the first slit and second slit of the second valve, each are spirals about the central axis.

32. The method of claim **31**, wherein;
the first valve includes a third slit,
the second valve includes a third slit,

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the first slit, the second slit, and the third slit of the first valve bisect each other at the central axis, and

the first slit, the second slit, and the third slit of the second valve bisect each other at the central axis.

33. The method of claim **32**, wherein;

the first valve and the second valve have a proximal surface, and the distal surface is spaced from the proximal surface along the central axis,

the first slit and the second slit of the first valve extend from the proximal surface to the distal surface, and

the first slit and second slit of the second valve extend from the proximal surface to the distal surface.

34. The method of claim **33**, wherein the first slit, the second slit, and the third slit of the first valve extend in a spiral about the central axis from the proximal surface of the first valve to the distal surface of the first valve.

35. The method of claim **33**, wherein the first slit, the second slit, and the third slit of the of the second valve extend in a spiral about the central axis from the proximal surface of the second valve to the distal surface of the second valve.

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