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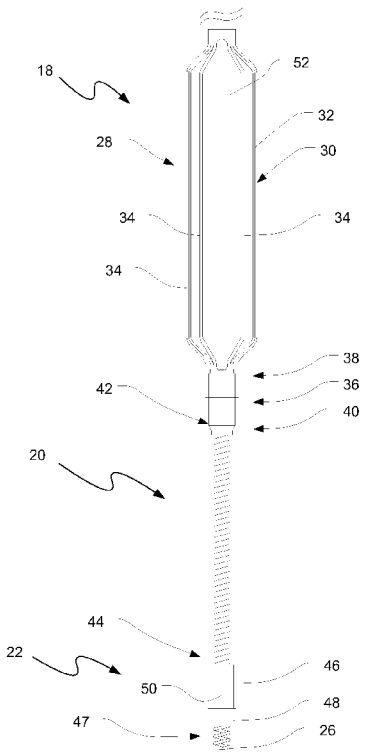
(54) Title: IMPLANT DELIVERY AND DEPLOYMENT SYSTEM AND METHOD

FIG. 2



(57) Abstract: An implant delivery system comprising a catheter including at least one lumen, an implant configured to be received in the lumen, and a latching mechanism configured to be received in the implant. The latching mechanism may be configured to releasably couple the implant to a delivery wire and to transmit a torque through the delivery wire to cause at least a portion of the implant to rotate. The an implant may comprise a shaft, a spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through the heart valve in a closed position, a garage configured to couple the spacer to a first end region of the shaft, and at least one anchor mechanism. The garage may define a cavity configured to receive the latching mechanism and to increase rotational and translational stability of the latching mechanism.

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IMPLANT DELIVERY AND DEPLOYMENT SYSTEM AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

The subject application is a continuation-in-part of co-pending U.S. Patent Application Serial No. 11/258,828, entitled "Heart Valve Implant" filed on October 26, 2005, U.S. Patent Application Serial No.: 11/940,694, filed November 15, 2007, entitled IMPLANT DELIVERY SYSTEM AND METHOD, and U.S. Patent Application Serial No. 12/209,686, filed September 12, 2008 and entitled SYSTEM AND METHOD FOR IMPLANTING A HEART IMPLANT, the entire disclosures of which are incorporated herein by reference

FIELD

The present disclosure relates to the repair and/or correction of dysfunctional heart valves, and more particularly pertains to heart valve implants and systems and methods for delivery and implementation of the same.

BACKGROUND

A human heart has four chambers, the left and right atrium and the left and right ventricles. The chambers of the heart alternately expand and contract to pump blood through the vessels of the body. The cycle of the heart includes the simultaneous contraction of the left and right atria, passing blood from the atria to the left and right ventricles. The left and right ventricles then simultaneously contract forcing blood from the heart and through the vessels of the body. In addition to the four chambers, the heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves may become damaged, or otherwise fail to function properly, resulting in their inability to properly close when the

downstream chamber contracts. Failure of the valves to properly close may allow blood to flow backward through the valve resulting in decreased blood flow and lower blood pressure.

Mitral regurgitation is a common variety of heart valve dysfunction or insufficiency. Mitral regurgitation occurs when the mitral valve separating the left coronary atrium and the left ventricle fails to properly close. As a result, upon contraction of the left ventricle blood may leak or flow from the left ventricle back into the left atrium, rather than being forced through the aorta. Any disorder that weakens or damages the mitral valve can prevent it from closing properly, thereby causing leakage or regurgitation. Mitral regurgitation is considered to be chronic when the condition persists rather than occurring for only a short period of time.

Regardless of the cause, mitral regurgitation may result in a decrease in blood flow through the body (cardiac output). Correction of mitral regurgitation typically requires surgical intervention. Surgical valve repair or replacement is carried out as an open heart procedure. The repair or replacement surgery may last in the range of about three to five hours, and is carried out with the patient under general anesthesia. The nature of the surgical procedure requires the patient to be placed on a heart-lung machine. Because of the severity/complexity/danger associated with open heart surgical procedures, corrective surgery for mitral regurgitation is typically not recommended until the patient's ejection fraction drops below 60% and/or the left ventricle is larger than 45 mm at rest.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantage of the claimed subject matter will be apparent from the following description of embodiments consistent therewith, which description should be considered in conjunction with the accompanying drawings, wherein:

FIG. 1 is a perspective view of one embodiment of a mitral valve implant delivery system consistent with the present disclosure;

FIG. 2 depicts a plan view of one embodiment of an implant consistent with the present disclosure;

FIG. 3 depicts a cross-sectional view of one embodiment of an implant illustrated in **FIG. 2** consistent with the present disclosure;

FIG. 4 depicts an explode, cross-sectional view of the implant illustrated in **FIG. 3** consistent with the present disclosure;

FIG. 5 depicts one embodiment of a latching mechanism comprising a first and second latching pin in a decoupled position consistent with the present disclosure;

FIG. 6 depicts one embodiment of a latching mechanism comprising a first and second latching pin in a coupled position consistent with the present disclosure;

FIG. 7 depicts a partial view of one embodiment of an implant and latching mechanism with the anchoring mechanism in a retracted position consistent with the present disclosure;

FIG. 8 depicts a partial view of one embodiment of an implant and latching mechanism with the anchoring mechanism in an extended position consistent with the present disclosure;

FIG. 9 depicts one embodiment of a loading sheath consistent with the present disclosure;

FIG. 10 depicts a cross-sectional view of one embodiment of an implant, a pusher and loading sheath consistent with the present disclosure;

FIGS. 11-14 illustrate one embodiment of loading an implant into a delivery catheter consistent with the present disclosure;

FIG. 15 depicts a schematic diagram illustrating one embodiment of the implant de-airing procedure consistent with the present disclosure;

FIG. 16 depicts a schematic diagram illustrating one embodiment of the de-airing driver handle system consistent with the present disclosure; and

FIGS. 17-22 illustrate one embodiment for delivering an implant consistent with the present disclosure.

DESCRIPTION

Referring to **FIG. 1**, a perspective view of one embodiment of a percutaneous delivery system 1 for delivering and/or recapturing a mitral valve implant 10 within the heart is shown. The delivery system 1 may include a mitral valve implant 10, a delivery catheter 12, a guidewire 14 and a deployment/clamping mechanism 16 configured to releasably couple the implant 10 to a delivery wire (not shown). The implant 10 may comprise a spacer 18, a shaft or stop tube 20 and an anchoring mechanism 22. In general, the mitral valve implant 10 may be delivered within the heart 1 and anchored to the native coronary tissue 6 as generally illustrated in **FIG. 1** such that at least a portion of the spacer 18 is disposed proximate a mitral valve 3 and the mitral valve implant 10 may interact and/or cooperate with at least a portion of the native mitral valve 3 to reduce and/or eliminate excessive regurgitation, for example, as discussed in U.S. Patent Application Serial No. 12/209,686, filed on September 12, 2008 and entitled SYSTEM AND METHOD FOR IMPLANTING A HEART IMPLANT, the entire disclosure of which is incorporated herein by reference. For example, at least a portion of one or more cusps 4 of the heart 1 valve may interact with, engage, and/or seal against at least a portion of the heart valve implant 10 (for example, but not limited to, the spacer 18) when the heart valve 3 is in a closed condition. The interaction, engagement and/or sealing between at least a portion of at least one cusp 4 and at least a portion of the heart valve implant 10 may reduce and/or eliminate regurgitation in a heart valve 3, for example, providing insufficient sealing, including only a single cusp 4, e.g.,

following removal of a diseased and/or damaged cusp 4, and/or having a ruptured cordae. A heart valve implant 10 consistent with the present disclosure may be used in connection with various additional and/or alternative defects and/or deficiencies.

As shown, the delivery system 1 may include a delivery catheter 12 (for example, but not limited to, a steerable delivery catheter) configured to be percutaneously introduced or inserted into one or more vessels of the body (e.g., one or more veins and/or arteries) and conveyed to the heart 1 for delivery and/or recapture of the mitral valve implant 10. Conveyance of the catheter 12 and/or of the mitral valve implant 10 to the heart 1 may be directed and/or assisted by monitoring the travel of the catheter 12, e.g., via radiographic and/or other imaging techniques and/or by passing the catheter 12 through another, larger catheter already in place (not shown). The catheter 12 may have a length and outer diameter configured to extend from the incision site in the patient's body through one or more veins and/or arteries to the desired location within the heart 1 (e.g., the left ventricle 5).

The catheter 12 may define at least one lumen 24 having an internal diameter configured to receive and convey the guidewire 14, the deployment mechanism 16 and the implant 10 from a proximal end of the catheter 12 to a distal end of the catheter 12. The catheter 12 may include a flexible material having sufficient rigidity, strength and inner lubricity to be guided through the blood vessels to the heart and to convey the implant 10. For example, the catheter 12 may include a combination or combinations of polymeric and/or metallic materials having an inner diameter of between 5 French size and 50 French size, an outer diameter of between .004 inches .250 inches larger than the corresponding inner diameter, and a length of between 10 centimeters and 200 centimeters.

The guidewire 14 may be configured to be disposed within the lumen 24 of the catheter 12 and may have a length greater than the length of the catheter 12. The guidewire 14 may include a flexible wire having sufficient strength and/or rigidity to convey and/or

urge the implant 10 through the lumen 24 of the catheter 12. For example, the guidewire 14 may include a combination or combinations of polymeric and/or metallic materials having a diameter of between .004 inches and .060 inches and a length of between 100 centimeters and 500 centimeters. Consistent with at least one embodiment herein, the guidewire 14 may have a diameter of 1/32".

Turning now to **FIG. 2**, an implant 10 consistent with at least one embodiment of herein is illustrated. The implant 10 may comprise a spacer or valve body portion 18 (for example, a resiliently deformable spacer configured to be received in the lumen 24 of the catheter 12) which may be coupled to a shaft 20. The shaft 20 may be coupled to at least one anchor portion/mechanism 22 configured to couple, attach, and/or otherwise secure the mitral valve implant 10 to native coronary tissue 6. According to one embodiment, at least a portion of the anchor mechanism 22 may include a generally helical screw or the like 26 configured to be at least partially screwed into the native coronary tissue 6.

The spacer 18 may comprise a spacer cage 28 having at least a portion of the outer surface 30 covered with a balloon 32. The spacer cage 28 and/or the balloon 32 may comprise a resiliently flexible structure configured to at least partially collapse from an expanded position as illustrated to a retracted or collapsed position. When in the collapsed position, the spacer cage 28 and balloon 32 may be configured to be received in and advanced along the lumen 24 of the delivery catheter 12. When in the expanded position, the spacer cage 28 and balloon 32 may be configured to interact and/or cooperate with at least a portion of the native mitral valve 3 (e.g., at least one cusp 4) to reduce and/or eliminate excessive regurgitation as generally illustrated in **FIG. 1**.

The spacer cage 28 may comprise a frame or ribbed structure, for example, a frame of resilient flexible material such as, but not limited to, shape memory materials (for example, but not limited to, nickel titanium compositions (e.g., Nitinol) or the like). The spacer cage

28 may comprise a plurality of support structures or ribs 34 extending generally along the longitudinal axis of the implant 10. The support structures 34 may be configured to resiliently bend radially inwardly and/or outwardly, for example, to facilitate loading of the implant 10 within the delivery catheter 12 and/or to facilitate sealing with the mitral valve 3. The number and location of the support structures 34 may depend upon the particulars of the patient's condition as well as the desired flexibility and desired shape of the spacer 18. For example, the implant 10 may comprise between 5 to 12 support structures 34.

The balloon 32 may be configured to be at least partially disposed about the outer surface 30 of the spacer cage 28. The balloon 32 may comprise a resilient flexible, biologically acceptable material. For example, the balloon 32 may comprise Elasteon™ material or the like configured to generally encapsulate the outer surface 30 of the spacer cage. The balloon 32 may be coupled or otherwise secured to at least a portion of one or more of the support structures 34 (for example, but not limited to, overmolding, adhesives, and/or laminating) and/or may be only secured about the ends of the spacer cage 28.

The spacer 18 may therefore be configured to interact and/or cooperate with at least a portion of the native mitral valve 3 to reduce and/or eliminate excessive regurgitation. As such, the configuration and/or geometries of the spacer 18 may depend upon the particulars of the condition of the patient's mitral valve 3 and the damage thereto. The implant 10 may have sufficient overall flexibility to facilitate advancement of the implant 10 within the delivery catheter 12 to minimize the potential of the implant 10 becoming wedged or stuck within the delivery catheter 12. In addition, the implant 10 may also have sufficient overall rigidity to maintain the spacer 18 within the mitral valve 3 such that the implant 10 performs as intended.

The spacer 18 may optionally include a garage 36 configured to couple the spacer 18 to the shaft or stop tube 20. Consistent with at least one embodiment herein, the support

structures 34 of the spacer cage 28 may be coupled to the garage 36, for example, about a first end region 38 of the garage 36. A proximal end region 40 of the stop tube 20 may be coupled to a second end region 42 of the garage 36 generally opposite the first end region 38. The distal end region 44 of the stop tube 20 may be coupled to a can 46 configured to receive at least a portion of an anchoring device 47, for example, the helical screw 26. A portion of the can 46 (for example, but not limited to, the distal end region) may include a sheath or pledget 48 configured to stimulate ingrowth of the native coronary tissue 6 over time and to further anchor or secure the implant 10 to the tissue. The garage 36 may also define a cavity 50 configured to engage with the deployment mechanism 16 as described herein.

Turning now to **FIGS. 3** and **4**, a cross-sectional view of an implant 10 is generally illustrated including a deployment mechanism 16. As will be explained in greater detail herein, the deployment mechanism 16 is configured to be releasably coupled to the implant 10 such that the implant 10 may be advanced through the delivery catheter 12 and secured to the native coronary tissue 6 of the patient's heart 1 (for example, the wall of the left ventricle 5 proximate the apex). According to at least one embodiment, the deployment mechanism 16 may be configured to advance the implant 10 through the delivery catheter 12 to the implant site, rotate the implant 10 to secure the anchoring mechanism 22 to the tissue, and release the implant 10.

The deployment mechanism 16 may comprise a sleeve 52 configured to releasably engage a latching mechanism 54. The sleeve 52 may comprise a generally flexible tubing such as, but not limited to, a poly(tetrafluoroethylene) (PTFE) tube defining an lumen or passageway 56. The sleeve 52 may be configured to be disposed within the lumen 24 of the delivery catheter 12 and extend from within the implant 10 (for example, but not limited to, from the spacer 18 and/or the garage 36) and out beyond the proximal end of the delivery catheter 12. The sleeve 52 may also have an outer surface having a size and/or shape

configured to be received within the chamber or cavity 58 of the garage 36. For example, the sleeve 52 may have an outer configuration configured to engage the garage cavity 58 and to provide rotational and/or lateral stability of the sleeve 52 and/or the latching mechanism 54 as is discussed further herein. According to at least one embodiment consistent herein, the sleeve 52 and the cavity 58 of the garage 36 may have a generally cylindrical configuration; however, the sleeve 52 and/or the cavity 58 may have other shapes configured to provide rotational and/or lateral stability of the sleeve 52 and/or the latching mechanism 54. For example, the sleeve 52 and/or the cavity 58 may have a non-circular cross-section such as, but not limited to, a rectangular, triangular or hexagonal shape or the like.

The latching mechanism 54 may comprise a first latch pin 60 configured to cooperate with a second latch pin 62 to form a releasable connection. The first latch pin 60 may be coupled to a delivery wire 64 configured to be received within the lumen 56 of the sleeve 52 and to extend beyond the distal end of the sleeve 52.

The second latch pin 62 may be coupled to a portion of the implant 10 such as, but not limited to, the spacer 18, stop tube 20, and/or the anchoring mechanism 22. For example, the second latch pin 62 may be coupled to a first end region of an anchoring wire 66. The anchoring wire 66 may extend through a lumen or passageway 68 of the stop tube 20 and a second end region may be coupled to the anchoring mechanism 22, for example, the helical screw 26. Optionally, one or more centering inserts 70 may be provided along the length of the anchoring wire 66. For example, one or more inserts 70 may be provided within the can 46 and/or the stop tube 20. The inserts 70 may include an opening/passageway configured to receive the anchor wire 66 to keep the anchor wire 66 centered with respect to the implant 10 and minimize buckling and/or kinking of the anchor wire 66 during the deployment of the implant 10. The inserts 70 may be integrally formed with or a separate element from the can 46 or stop tube 20.

Turning now to **FIGS. 5** and **6**, one embodiment of the first and second latch pins 60, 62 is illustrated in an uncoupled and coupled position, respectively. The first and second latch pins 60, 62 may each have a generally "C" shaped engagement potion 72a, 72b. At least one of the engagement portions 72a, 72b may define a cavity or recess 74 configured to receive a tab or protrusion 76 of the other engagement portion 72a, 72b as generally illustrated in **FIG. 6**. The engagement portions 72a, 72b may also have a variety of other configurations configured to form a connection.

The first and second latch pins 60, 62 of the latching mechanism 54 may be held in place in the coupled position by the sleeve 52 as generally illustrated in **FIGS. 3, 4** and **7**. For example, the sleeve 52 and the first and second latch pins 60, 62 may have a size and/or shape configured to substantially prevent the first and second latch pins 60, 62 from moving relative to one another and to provide rotational and/or lateral stability when the latching mechanism is received within the sleeve. To decouple the latching mechanism 54, the sleeve 52 may be pulled back (i.e., pulled proximally away from the heart) to expose one or more of the first and second latch pins 60, 62. Once at least one of the first and second latch pins 60, 62 is exposed, the delivery wire 64 may be moved (for example, twisted/rotated or the like) to decouple the first and second latch pins 60, 62.

As discussed above, the anchoring mechanism 22 of the implant 10 may also include a helical screw 26 coupled to the anchoring wire 66 and a stop mechanism 78. The helical screw 26 may be configured to be advanced from a retracted position in which the helical screw 26 is substantially disposed entirely within the can 46 as generally illustrated in **FIG. 7** to an extended position in which the helical screw 26 is configured to engage the heart tissue as generally illustrated in **FIG. 8**. The implant 10 may be advanced through the delivery catheter 12 while in the retracted position. Retracting the helical screw 26 within the can 46 while advancing the implant 10 through the delivery catheter 12 may facilitate loading and/or

advancing the implant 10 through the delivery catheter 12 by minimizing the likelihood that the anchoring mechanism 22 may become jammed within the lumen 24 of the delivery catheter 12. Alternatively, a portion of the helical screw 26 (for example, the distal most end region) may be disposed beyond the can 46.

The stop mechanism 78 may be configured to control the maximum depth that the helical screw 26 may be extended from the can 46 thereby controlling the maximum depth that the helical screw 26 may be inserted into the native coronary tissue 6 when securing the implant 10. Consistent with at least one embodiment herein, the stop mechanism 78 may comprise a threaded region 80 disposed within the can 46 of the anchoring mechanism 22. The threaded region may 80 may have a thread pitch and size substantially corresponding to a first portion 82 of the helical screw 26. As such, the first portion 82 of the helical screw 26 may be rotated and threaded through the threaded region 82 of the stop mechanism 78 to advance the helical screw 26 out of the can 46 from the retracted position (as generally illustrated in **FIG. 7**) to the extended position (as generally illustrated in **FIG. 8**).

The helical screw 26 may also include a second portion 84 having a pitch (for example, but not limited to, a zero pitch) which cannot pass through the threaded region 80. As the anchoring wire 66 is rotated (e.g., from a rotational torque applied to the delivery wire 64 and transmitted through the latching mechanism 54), the first region 82 of the helical screw 26 may be threaded through the stop mechanism 78 until the second region 84 engages (e.g., binds against) the threaded region 80 of the stop mechanism 78. As such, the stop mechanism 78 may be configured to control the maximum depth that the helical screw 26 may be extended from the can 46 thereby controlling the maximum depth that the helical screw 26 may be inserted into the native coronary tissue 6 when securing the implant 10 in the heart 2.

To deliver the implant 10, the first and second latch pins 60, 62 of the latching mechanism 54 may be coupled together as generally illustrated in **FIG. 6** and loaded into the distal end region of the sleeve 52 as generally illustrated in **FIG. 7**. The sleeve 52 may be configured to keep the first and second latch pins 60, 62 of the latching mechanism 54 secured together by generally preventing movement of the first and second latch pins 60, 62 relative to each other. The distal end region of the sleeve 52 (including the first and second latch pins 60, 62) may then be received into the implant 10, for example, into the cavity formed by the garage 36 as generally illustrated in **FIGS. 3** and **4**. The arrangement/configuration of the garage 36 and the sleeve 52 may provide rotational stability to the first and second latch pins 60, 62 of the latching mechanism 54 when a force or torque is applied to the delivery wire 64.

With distal end of the sleeve 52 and the first and second latch pins 60, 62 of the latching mechanism 54 disposed within the can 36 as generally illustrated in **FIGS. 3** and **4**, the implant 10 may be loaded into and advanced through the delivery catheter 12 by using a pusher (for example, but not limited to, a low density polyethylene tube or the like). The pusher may be received into the delivery catheter 12 after the implant 10 and may urge the implant 10 through the delivery catheter 12.

The implant 10 may be advanced through the delivery catheter 12 until the anchoring mechanism 22 of the implant 10 is disposed proximate the distal end region of the delivery catheter 12 as generally illustrated **FIG. 7**. As the implant 10 is advanced through the delivery catheter12, the sleeve 52 may be maintained around the latching mechanism 54 to ensure that the latching mechanism 54 remains coupled. Additionally, the dimensional tolerances between the garage cavity 58 and the sleeve 52 as well as the latching mechanism 54 and the sleeve 52 may increase the rotational and/or lateral stability of the latching mechanism 54. Once the anchoring mechanism 22 is disposed proximate the distal end

region of the delivery catheter 12 and the delivery catheter 12 is in the appropriate location within the heart 1 (for example, but not limited to, proximate the apex of the left ventricle 5), a translational force may be applied to the pusher to urge the anchoring mechanism 22 of the implant 10 (e.g., but not limited to, the can 46) against the native coronary tissue 6 in the heart 1.

A torque may also be applied to the delivery wire 64 and transmitted through the latching mechanism 54 and the anchoring wire 66 causing the helical screw 26 to rotate within the stop mechanism 78 as generally illustrated **FIG. 7**. The delivery wire 64 may have sufficient flexibility to pass through the delivery catheter 12 while also having sufficient rigidity to resist buckling or kinking under load. According to one embodiment, the delivery wire 64 may include a 1/32" wire. The translational force applied to the pusher may urge the can 46 against the native coronary tissue 6. As a result, the torque applied to the delivery wire 64 and anchor wire 66 may cause the helical screw 26 of the anchoring mechanism 22 to rotate with respect to the can 46 while keeping the can 46 (and the remainder of the implant 10) substantially stationary.

As the anchoring mechanism 22 is rotated, the helical screw 26 may be advanced from the retracted position to the extended position in which at least a portion of the helical screw 26 is exposed beyond the distal end of the can 46 as generally illustrated in **FIG. 8**. The dimensional tolerances between the garage cavity 58 and the sleeve 52 as well as the latching mechanism 54 and the sleeve lumen 56 may increase the rotational and/or lateral stability of the latching mechanism 54. Additionally, the centering inserts 70 may increase the rotational and/or lateral stability of the anchoring wire 66 within the implant 10 during rotation of the helical screw 26. The helical screw 26 may be threaded into the tissue of the heart until the second region 84 of the helical screw 26 engages against (e.g., binds) the stop mechanism 78. The stop mechanism 78 may therefore control the maximum depth that the

helical screw 26 may be threaded into the native coronary tissue 6 and may reduce the potential of the helical screw 26 puncturing through the opposite side of the heart 1. Additional long-term fixation of the implant 10 may be provided by the pledget 48 disposed about the distal end region of the anchoring mechanism 22.

Once the helical screw 26 of the implant 10 is secured to the native coronary tissue 6, the distal end region of the sleeve 52 may be pulled back (i.e., towards the proximal end of the delivery catheter 12) to expose one or more of the latching pins 60, 62. Once exposed, the delivery wire 64 may be rotated to decouple the latching pins 60, 62 and therefore decouple the delivery wire 64 from the implant 10. The delivery wire 64 (along with the first latching pin 60) may then be pulled back and removed from the implant 10.

Turning now to **FIGS. 9-14**, one embodiment of a loading system 90 for loading an implant 10 into the delivery catheter 12 is generally illustrated. As discussed herein, the implant 10 may include a spacer 18 having a diameter which, when expanded, is greater than the diameter of the delivery catheter lumen 24. The loading system 90 may include a loading sheath 92, as generally illustrated in **FIG. 9**, configured to load the implant 10 into the delivery catheter 12. The loading sheath 92 may include a distal end 93, a proximal end 94 and a hollow shaft or lumen 96. The at least a portion of the implant spacer 18 may be received into the hollow shaft/lumen 96 of the loading sheath 92 as generally illustrated in **FIG 10**. The internal dimensions of the lumen loading sheath 96 may be configured to at least partially compress and/or collapse the spacer 18, thereby reducing the cross-section of the implant 10.

Optionally, the lumen 96 of the loading sheath 92 may be configured to receive the entire implant 10 as illustrated. For example, the anchor portion 22 of the implant 10 may be located proximate the distal end 93 of the loading sheath 92. The proximal end 94 of the loading sheath 92 may also be configured receive a portion of a pusher 98, for example, the

proximal end region 99 of the pusher 98. As discussed herein, the pusher 98 may be configured to advance the implant 10 through the delivery catheter to the implant 10 site and may include a low density polyethylene tube or the like. The delivery wire 64 may also be disposed within the loading sheath 92 and through the lumen of the pusher 98.

Turning now to **FIG. 11**, with the implant 10 and pusher 98 received in the lumen 96 of the loading sheath 92, the distal end 93 of the loading sheath 92 may be first advanced through the hemostasis valve 100 of the delivery catheter 12 and optionally into the control handle 101 of the delivery catheter 12 (which is configured to control the position of the distal end of the delivery catheter 12) as generally illustrated in **FIG. 12**. The loading sheath 92 may be further advanced into the delivery catheter 12 until the entire spacer 18 is received in the delivery catheter 12. Optionally, the loading sheath 92 may be advanced until the proximal end region 94 of the loading sheath 92 is received in the delivery catheter 12. As such, the distal end region of the pusher 98 may also be loaded into the delivery catheter 12 as well the implant 10.

With the implant 10 received within the delivery catheter 12, the loading sheath 92 may be removed from the delivery catheter 12 as well as the implant 10 and the pusher 98. According to one embodiment, the pusher 98 may be held in place and the loading sheath 92 may be pulled distally out of the hemostatsis valve 100 and away from the delivery catheter 12. The loading sheath 92 may then be advanced over the remaining length of the exposed pusher 98. As may be appreciated, however, the pusher 98 may relatively long and other objects of the percutaneous delivery system 1 may prevent the loading sheath 92 from simply sliding off.

To facilitate the removal of the loading sheath 92, the loading sheath 92 may optionally include a peel-away sheath as generally illustrated in **FIGS. 9, 10** and **13**. According to this embodiment, the loading sheath 92 may include a longitudinal split,

perforation, or the like 102 and optionally one or more (for example, two) tabs 103a, 103b and/or knobs 104a and 104b. Once the implant 10 and/or the pusher 98 are received inside the lumen of the delivery catheter 12, the loading sheath 92 may be removed by holding the pusher 98 substantially stationary and pulling on the two knobs 104a, 104b attached to the tabs 103a, 103b of the loading sheath 92 causing the loading sheath 92 to split in half along its longitudinal axis. With the loading sheath 92 split, it may be easily removed from the pusher 98. As a result, the implant 10 and the pusher 98 may be loaded into the delivery catheter 12 as generally illustrated in **FIG. 14**.

Turning now to **FIG. 15**, one embodiment of a de-airing system 106 is generally illustrated. The de-airing system 106 is configured to allow the user (e.g., physician) to remove any air associated with the implant 10 prior to inserting the implant 10 into the delivery catheter 12. If entrapped air from the percutaneous delivery system is allowed to be introduced into the patient's cardiovascular system, the air may be travel to the patient's brain or other parts of the patient's body where it may cause serious bodily harm and/or death (for example, due to blood clotting or the like).

According to at least one embodiment herein, the de-airing system 106 may include a fluid (such as, but not limited to, a saline solution or the like) which may be injected around the implant 10 to flush away and/or remove any entrapped air before the implant 10 is inserted into the delivery catheter 12. The de-airing system 106 may include a first reservoir 108 of fluid which may be configured to be fluidly coupled to the lumen 56 of the sleeve 52, for example, about the proximal end 109 of the sleeve 52. The sleeve 52 may be disposed within a lumen 110 of the pusher 98 which may be substantially abutting against a distal end of the implant 10. The fluid may be injected into the lumen 56 of the sleeve 52 where it may flow through the sleeve 52 and around delivery wire 64 and the latching mechanism 54. A portion of the fluid may also flow pass the latching mechanism 54, through the garage 36 and

stop tube 20, around anchor wire 66, into the can 46 and through the threaded region 80 and helical screw 26, and out the distal end of the implant 10.

The sleeve 52 may also include one or more openings, slots, apertures 112 or the like configured allow some of the fluid to pass out of the sleeve 52 and fill spacer 18. The fluid may then flow from the spacer 18 into the lumen 110 of the pusher 98 back to a second reservoir 114 fluidly coupled to the pusher 98. As may be appreciated, the fluid flowing through the de-airing system 106 may remove any air entrapped around the implant 10. As a result, the implant 10 may be loaded into the delivery catheter 12 without introducing any unwanted air into the patient's cardiovascular system.

Turning now to **FIG. 16**, one embodiment of a de-airing driver handle system 116 is illustrated in an exploded or unassembled view. The de-airing driver handle system 116 may include a de-airing system and/or a driver handle. The de-airing system may be configured to remove air from the implant 10 prior to inserting the implant 10 into the delivery catheter 12 as discussed herein while the driver handle may be configured to manage the position of the sleeve 52 and decoupling of the latching mechanism 54 as well as to enable rotation of the helical screw 26 into the native coronary tissue 6 upon deployment of the implant 10.

The de-airing driver handle system 116 may include a pusher fitting 120 configured to terminate the proximal end of the pusher 98. The pusher fitting 120 may be configured to allow the sleeve 52 to be disposed within the lumen 110 of the pusher 98 and to extend beyond the proximal end of the pusher 98. For example, the pusher fitting 120 may a compression fitting or the like. A fluid receiving reservoir 122 may be fluidly coupled to the pusher fitting 120 and may be configured to receive fluid flowing from the implant 10 and the pusher lumen 110. According to at least one embodiment, the fluid receiving reservoir 122 may include a fitting including a needle-less injector port 123 or the like.

A sleeve fitting 124 may also be coupled to the fluid receiving reservoir 122 for terminating the proximal end of the sleeve 52. The sleeve fitting 124 may be configured to allow the delivery wire 64 to be disposed within the lumen 56 of the sleeve 52 and to extend beyond the proximal end of the sleeve 52. For example, the sleeve fitting 124 may include a compression fitting or the like. A fluid injection reservoir 126 may be fluidly coupled to the sleeve fitting 124 and may be configured to inject fluid into lumen 54 of the sleeve 52 where it ultimately flows around the implant 10 and into the pusher 98 as discussed herein. According to at least one embodiment, the fluid injection reservoir 126 may include a fitting configured to be fluidly coupled to a syringe 128 or the like and the sleeve 52. The fitting may be configured to allow the delivery wire 64 to sealingly pass through. Optionally, a valve 130 (such as, but not limited to, a stopcock or the like) may be provided to further regulate the flow of fluid form the fluid injection reservoir 126. A drive knob 132 or the like may be coupled to the delivery wire 64 to rotate the delivery wire 64 and, ultimately, the helical screw 26 of the anchor mechanism 22. The drive knob 132 may include a set-screw, clamp or the like 134 configured to allow the drive knob 132 to be releasably coupled to the delivery wire 64.

It may be appreciated that one embodiment of the functional components of the de-airing driver handle system 116 have been illustrated and described. The various components may be combined and/or split into one or more systems. For example, the various fittings may be combined into a single driver handle device to facilitate their use.

Turning now to **FIGS. 17-22**, one embodiment illustrating the procedure for anchoring the implant 10 into the native coronary tissue 6 is generally illustrated. The implant 10 may be advanced through the delivery catheter 12 by applying a translational force to the pusher 98 and against the implant 10. As the implant 10 along with the entire pusher 98 assembly (de-airing driver handle system 116) is advanced forward through the

delivery catheter 12, the can 46 of the implant 10 may emerge from the distal end of the delivery catheter 12 and may be urged/biased against the native coronary tissue 6 (for example, against the wall of the left ventricle 5 proximate the apex) as generally illustrated in **FIGS. 1** and **17**. As can be seen, the distal end region of the sleeve 52 may be disposed substantially around the latching mechanism 54 including the first and second latching pins 60, 62. In addition, the anchoring mechanism 22 may be disposed in the retracted position in which the helical screw 26 may be disposed within the can 46.

Turning now to **FIG. 18**, the set-screw 134 on the driver knob 132 may optionally be loosened and the drive knob 132 may be moved back from the proximal end of the de-airing handle system 116 along the delivery wire 64 and retightened to allow the helical screw 26 to be advanced during the subsequent steps. For example, the drive knob 132 may be moved back approximately 1 cm.

With the can 46 against the native coronary tissue 6 and the driver knob 132 moved back from the de-airing handle system 116, the driver knob 132 may be rotated and urged forward to cause the delivery wire 64 to be rotated as generally illustrated in **FIG. 19**. The torque may be transmitted through the latching mechanism 54 causing the anchoring wire 66 and ultimate the helical screw 26 to rotate. Additionally, a translational force may be applied to the pusher 98 to urge the can 46 of the implant 10 against the native coronary tissue 6 and generally prevent rotation of the can 46. The sleeve 52 may be disposed about the first and second latching pins 60, 62 and, along with the garage 36, may be configured to provide lateral and rotational stability to the latching mechanism 54 as described herein. Additionally, one or more centering inserts 70 may also provide additional lateral and rotational stability.

The first portion 82 of the helical screw 26 may rotate within the threaded region 80 to advance the helical screw 26 beyond the distal end of the can 46 and into the native

coronary tissue 6. The helical screw 26 may be advanced beyond the distal end of the can 46 until the second portion engages 84 against or binds with the threaded region 80. As a result, the maximum depth that the helical screw 26 may be advanced into the native coronary tissue 6 may be controlled and puncturing of the heart wall 1 may be avoided.

Turning now to **FIG. 20**, the set-screw 134 on the driver knob 132 may optionally be loosened and the drive knob 132 may be moved back from the proximal end of the de-airing handle system 116 along the delivery wire 64 and retightened to allow the latching mechanism 54 to be decoupled. For example, the drive knob 132 may be moved back approximately 2 inches.

To decouple the latching mechanism 54, the sleeve 52 fitting of the de-airing handle system 116 may be disconnected and the sleeve 52 may be retracted (i.e., moved proximally away from the implant 10) as generally illustrated in **FIG. 21**. As the sleeve 52 is retracted, one or more of the latching pins 60, 62 may be exposed from the distal end region of the sleeve 52. The latching pins 60, 62 may still be loosely coupled at this point.

Turning now to **FIG. 22**, the delivery wire 64 may also be retracted. Retracting the delivery wire 64 may fully disengage/decouple the first and second latching pins 60, 62. The disengagement of the latching mechanism 54 may be seen on fluoroscopy or the like and may also be felt by the physician (the delivery wire 64 will feel loose when disengaged/decoupled). The sleeve 52 and the delivery wire 64 may be retracted out of the implant 10 (not shown). The pusher 98 may be held against the implant 10 and the delivery catheter 12 may be retracted to further deploy the implant 10.

As mentioned above, the present disclosure is not intended to be limited to a system or method which must satisfy one or more of any stated or implied object or feature of the present disclosure and should not be limited to the preferred, exemplary, or primary embodiment(s) described herein. The foregoing description of a preferred embodiment of the

present disclosure has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the present disclosure to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment was chosen and described to provide the best illustration of the principles of the present disclosure and its practical application to thereby enable one of ordinary skill in the art to utilize the present disclosure in various embodiments and with various modifications as is suited to the particular use contemplated. All such modifications and variations are within the scope of the present disclosure as determined by the claims when interpreted in accordance with breadth to which they are fairly, legally and equitably entitled.

What is claimed is:

1. An implant delivery system comprising:

a catheter including at least one lumen;

an implant configured to be received in said lumen; and

a latching mechanism configured to be received in said implant, said latching mechanism further configured to releasably couple said implant to a delivery wire and to transmit a torque through said delivery wire to cause at least a portion of said implant to rotate.

2. The implant delivery system of claim 1, wherein said implant comprises a shaft, a spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, at least one anchor mechanism coupled to a first end region of said shaft.

3. The implant delivery system of claim 2, wherein said latching mechanism comprises a first and at least a second latch pin configured to engage with each other to form a connection, wherein said first latching pin is coupled to said delivery wire and said second latching pin is configured to be coupled to said implant.

4. The implant delivery system of claim 3, further comprising a sleeve defining lumen having a distal end region configured to receive at least a portion of said delivery wire and said first and said second latching pins.

5. The implant delivery system of claim 4, wherein said lumen of said sleeve is further to substantially prevent movement of said first latching pin relative to said second

latching pin when said first and said second latching pins are received in said distal end region.

6. The implant delivery system of claim 5, wherein said implant further comprises garage configured to couple said spacer to said shaft, said garage defining a cavity configured to receive said distal end region of said sleeve to increase rotational and translational stability of said sleeve.

7. The implant delivery system of claim 6, wherein sleeve is configured to be retracted to expose at least one of said latching pins from said distal end region and to decouple said first latching pin from said second latching pin.

8. The implant delivery system of claim 5, wherein said distal end region of said sleeve further comprises at least one opening configured to provide a passageway between said lumen of said sleeve and said spacer of said implant.

9. The implant delivery system of claim 5, further comprising an anchoring having a first end coupled to said second latching pin and a second end coupled to said anchoring mechanism.

10. The implant delivery system of claim 9, wherein said anchoring mechanism comprises a cavity configured to at least partially receive a helical screw.

11. The implant delivery system of claim 10, wherein said anchoring mechanism further comprises a threaded region secured within said cavity, said threaded region having a

thread pitch and size substantially corresponding to a first threaded region of said helical screw.

12. The implant delivery system of claim 11, wherein said helical screw further comprises a second threaded region disposed proximate said anchoring wire, said second threaded region configured to not pass through said threaded insert.

13. An implant comprising:

a shaft;

a spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through said heart valve in a closed position;

a garage configured to couple said spacer to a first end region of said shaft, said garage defining a cavity configured to receive a latching mechanism and to increase rotational and translational stability of said latching mechanism; and

at least one anchor mechanism coupled to a second end region of said shaft.

14. The implant of claim 13, wherein said anchor mechanism comprises a cavity configured to at least partially receive a helical screw, said helical screw coupled to a first end of an anchoring wire, wherein a second end of said helical screw is coupled to a latching pin configured to be received in said cavity of said garage.

15. The implant of claim 14, wherein said anchoring mechanism further comprises a threaded region secured within said cavity, said threaded region having a thread pitch and size substantially corresponding to a first threaded region of said helical screw.

16. The implant of claim 15, wherein said helical screw further comprises a second threaded region disposed proximate said anchoring wire, said second threaded region configured to not pass through said threaded insert.

17. The implant of claim 13, wherein said anchoring mechanism further comprises a pledget configured to stimulate ingrowth of tissue.

18. A method of delivering an implant within a heart, said implant including a shaft, a spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, and at least one anchor mechanism coupled to a first end region of said shaft, said method comprising.

providing a delivery wire having a first latch pin;

coupling said first latch pin to a second latch pin disposed within said implant;

advancing a distal end of a sleeve over said first and said second latch pins to prevent movement of said first and said second latch pins;

percutaneously delivering a catheter proximate said heart;

loading said implant and said distal end of said sleeve into said catheter; and

advancing said implant and said distal end of said sleeve through said catheter.

19. The method of claim 18, further comprising rotating said delivery wire and transmitting torque through said first and said second pins to cause said anchoring mechanism to engage tissue within said heart.

20. The method of claim 19, further comprising:

retracting said distal end of said sleeve to expose at least one of said first and second pins; and

decoupling said first and said second latching pins.

FIG. 1

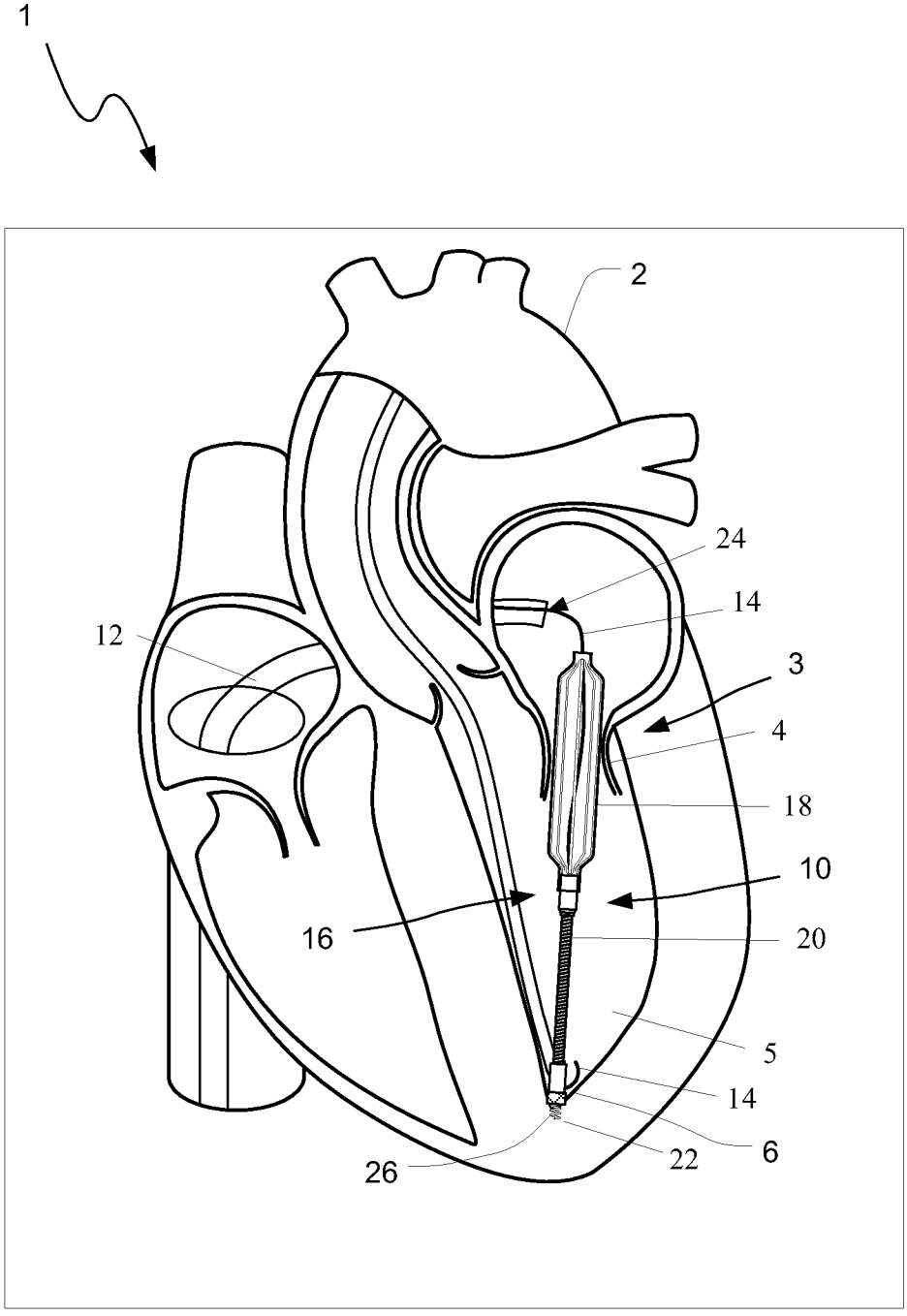

FIG. 2

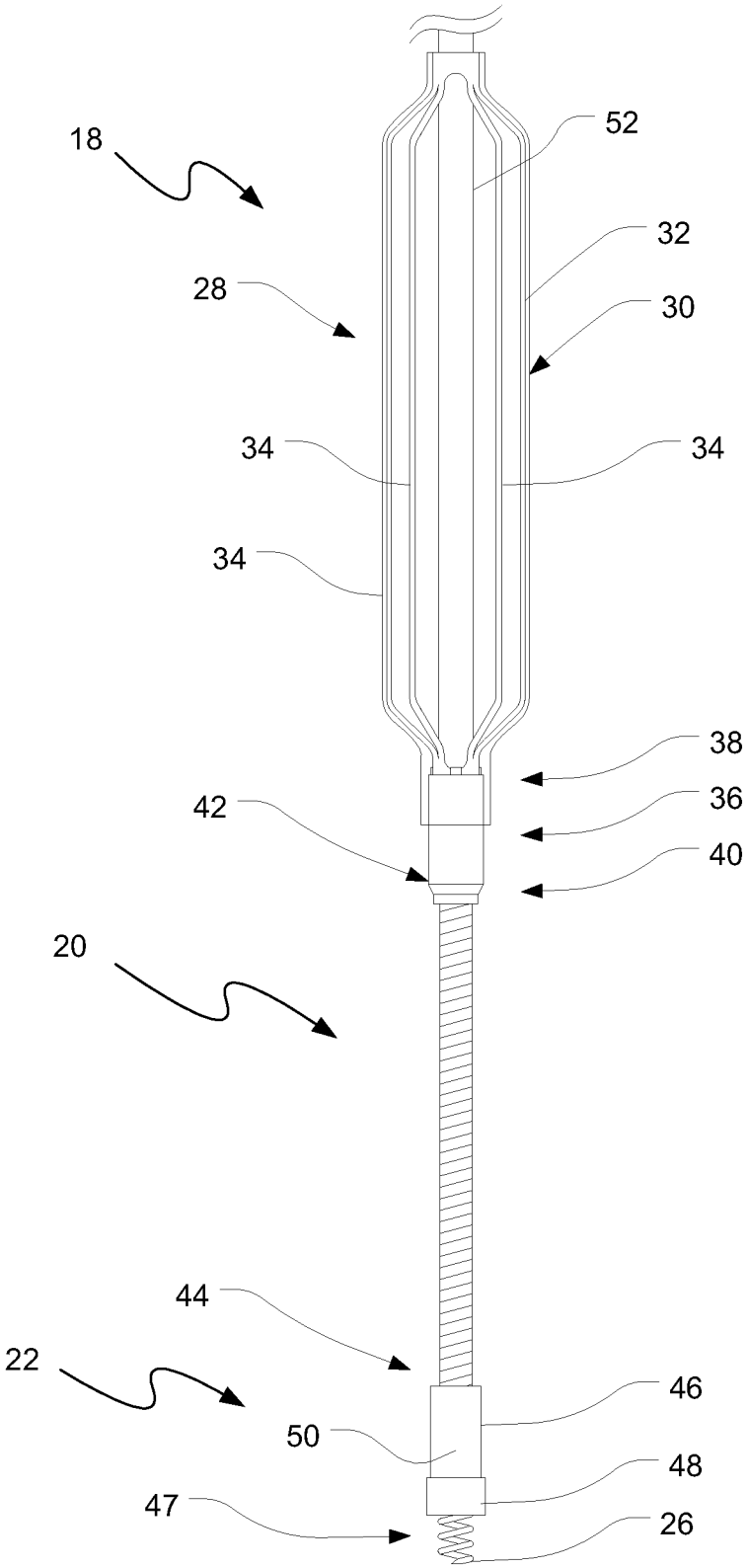

FIG. 3

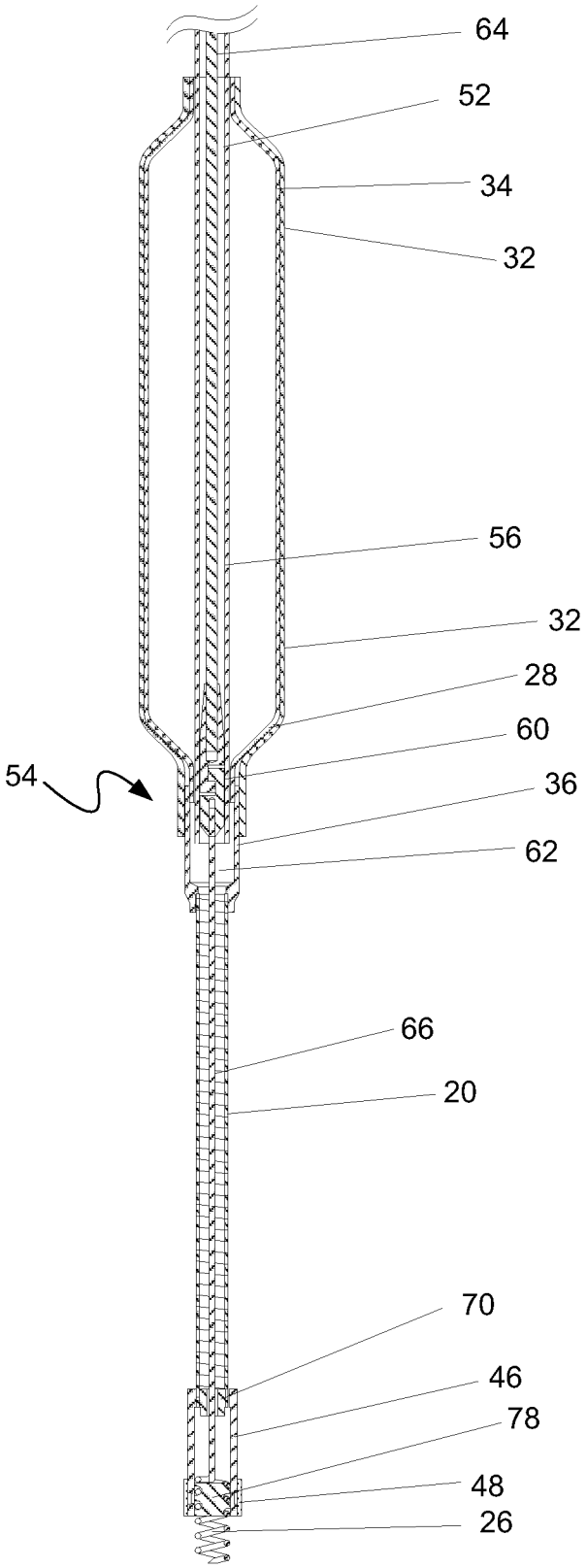
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FIG. 4

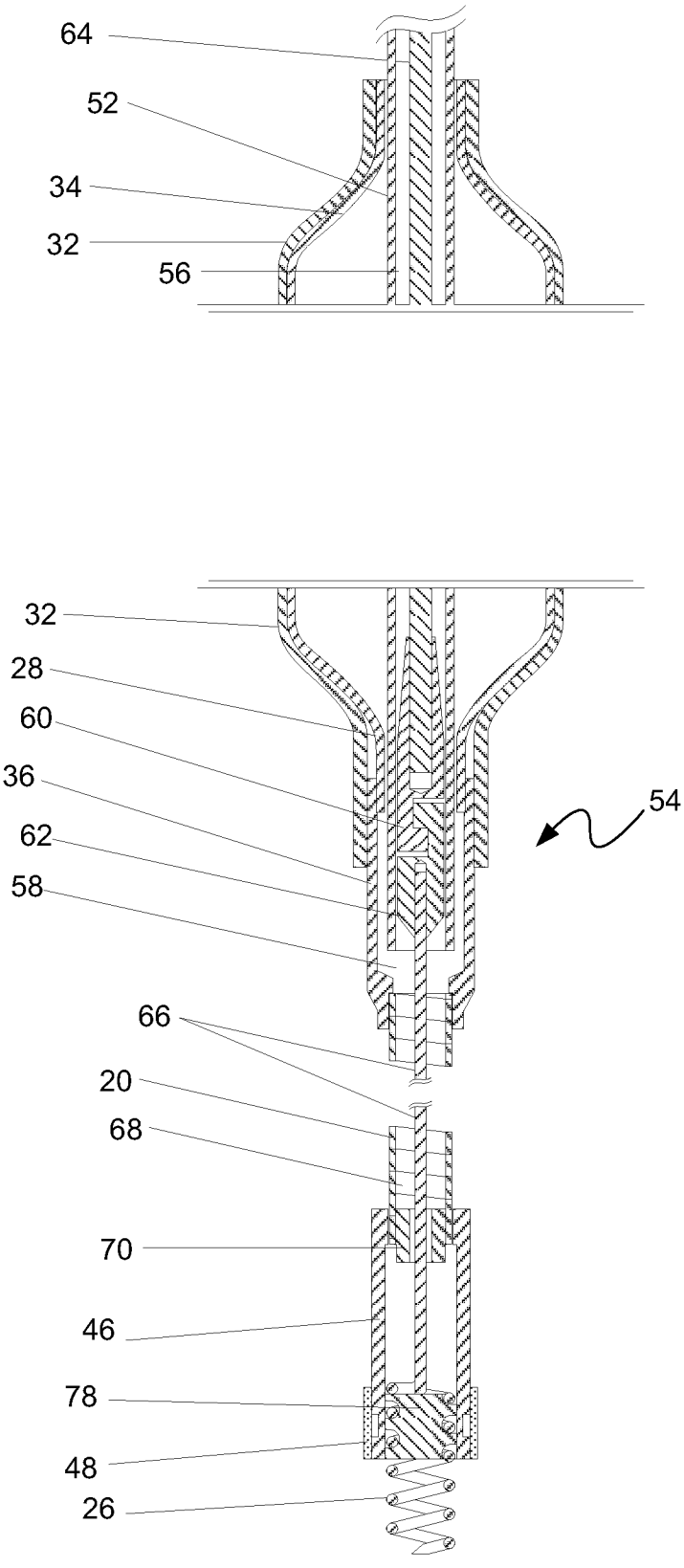
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FIG. 5

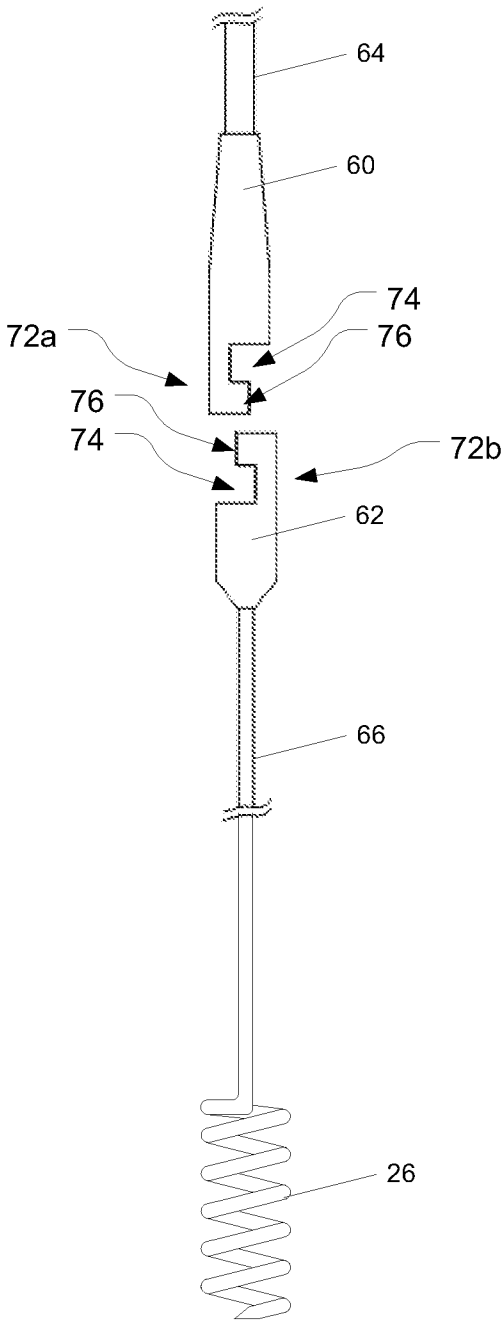

FIG. 6

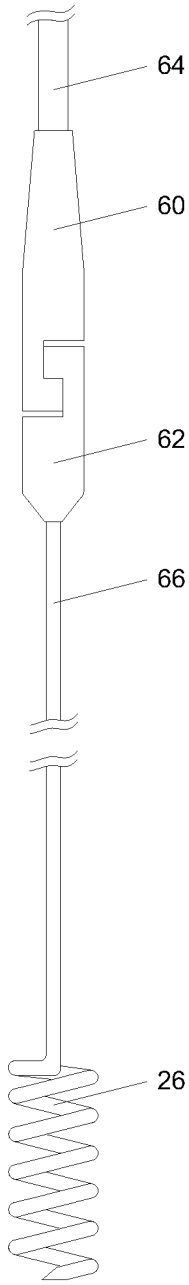

FIG. 7

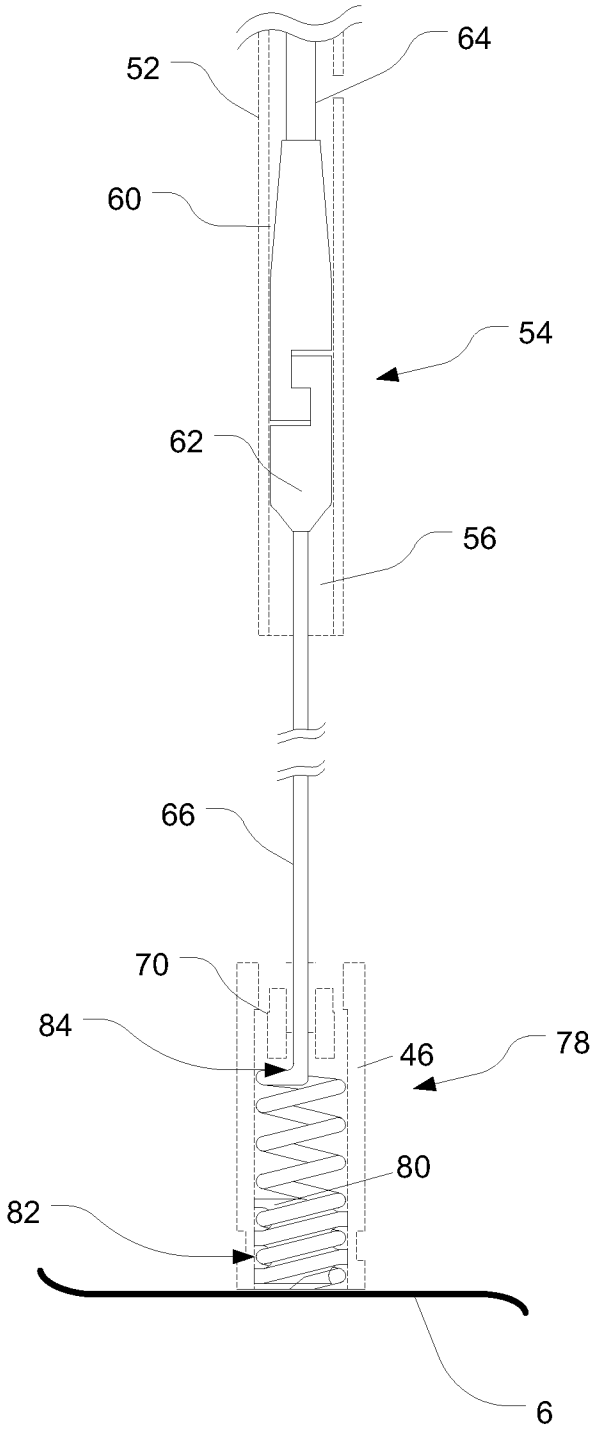
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FIG. 8

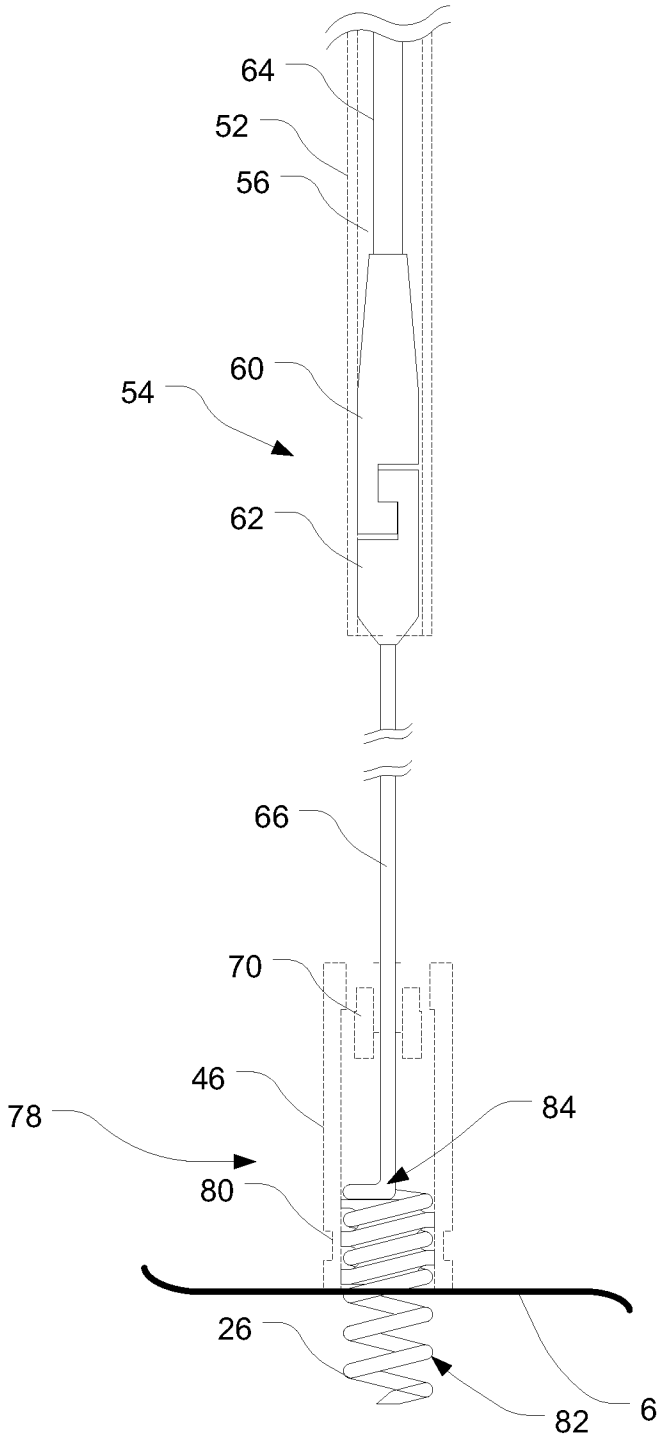
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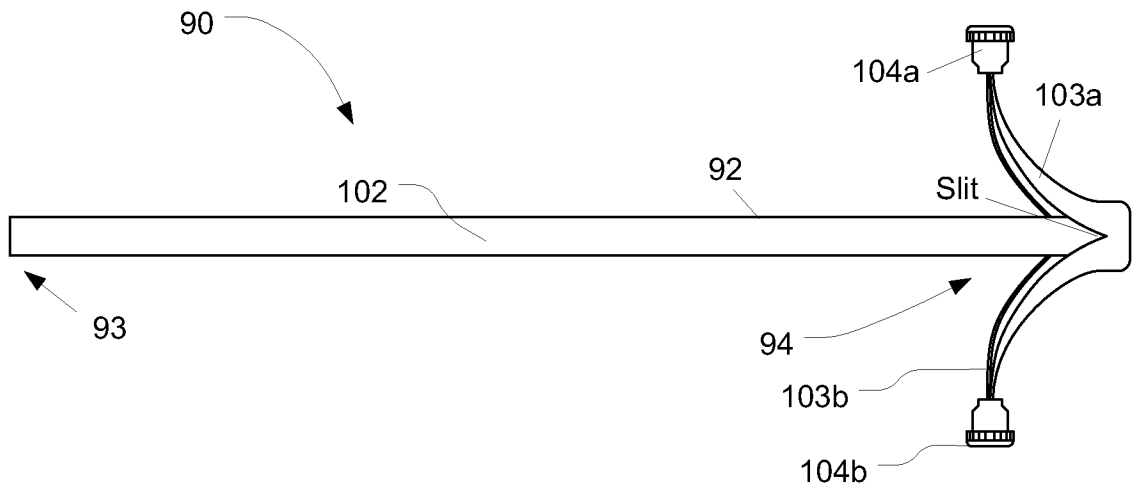
FIG. 9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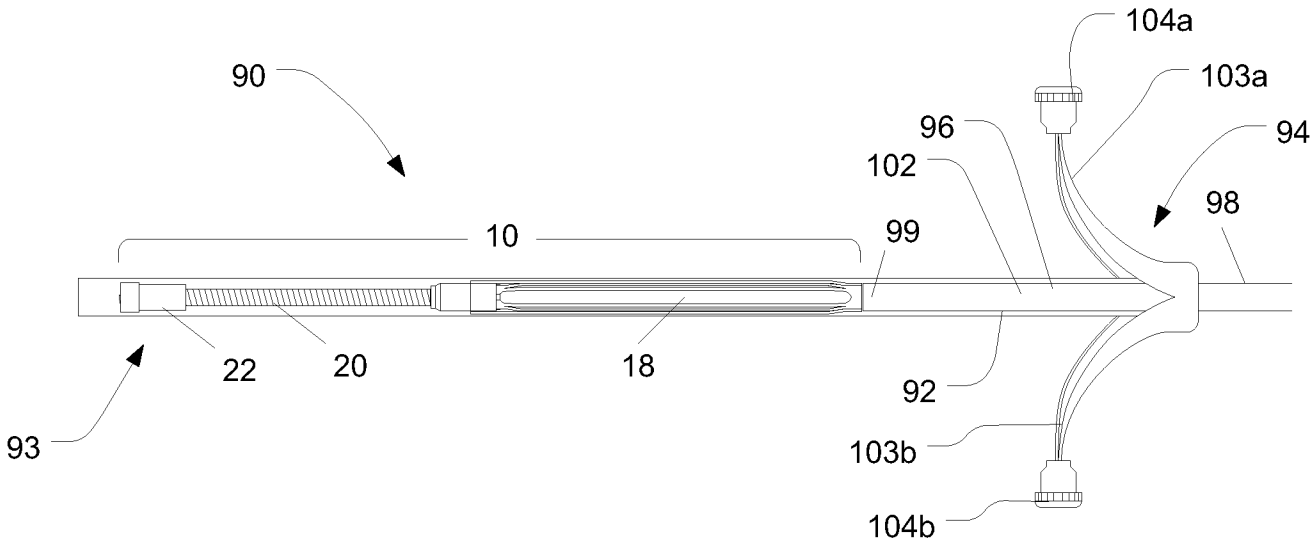
103a
92
102
Slit
93
94
103b
104b

FIG. 10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93
103b
104b

FIG. 11

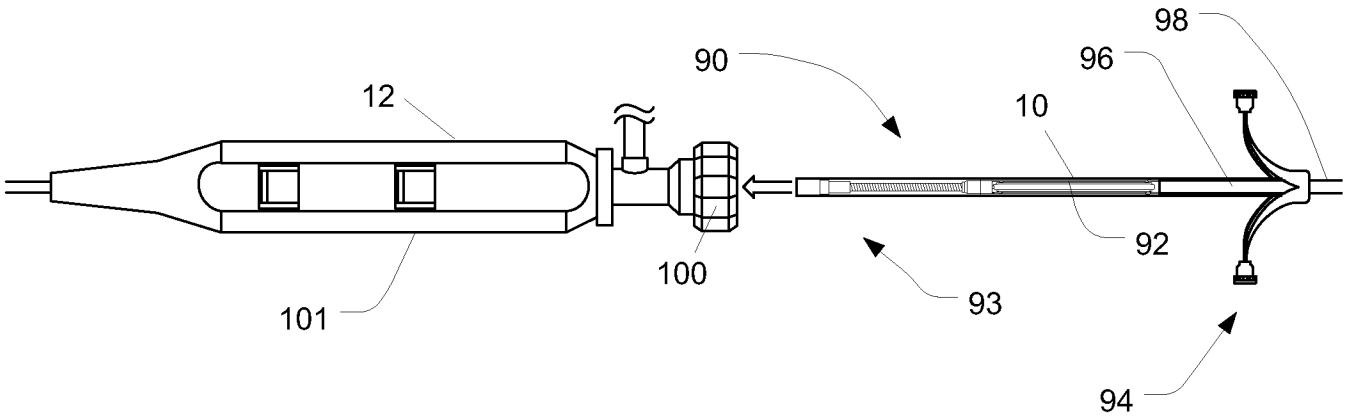

FIG. 12

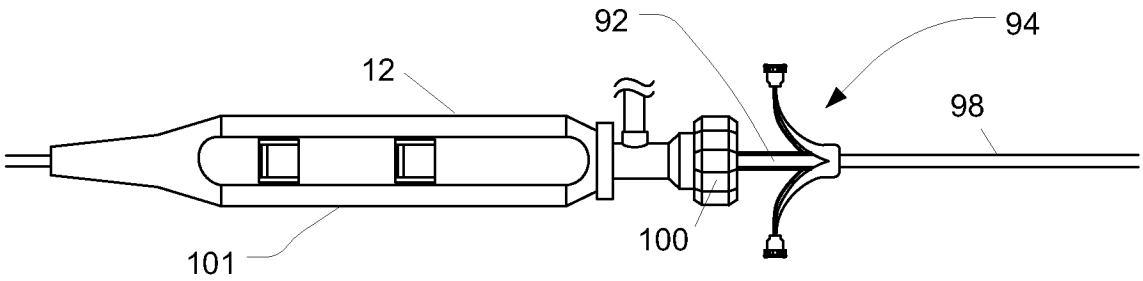

FIG. 13

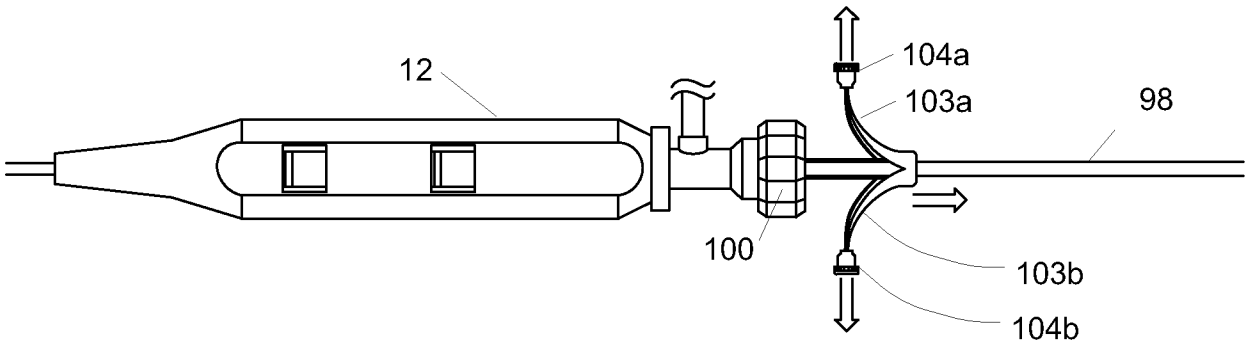

FIG. 14

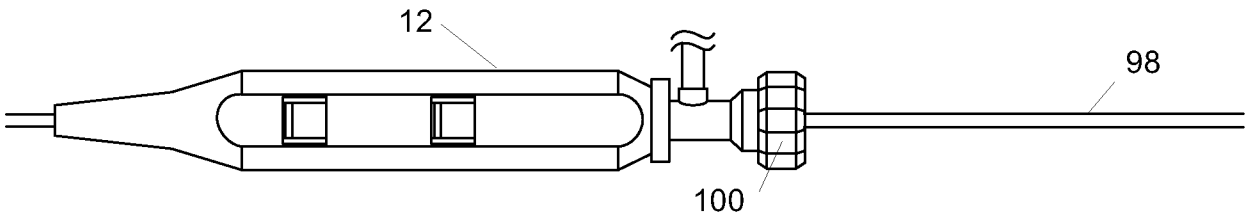

FIG. 15

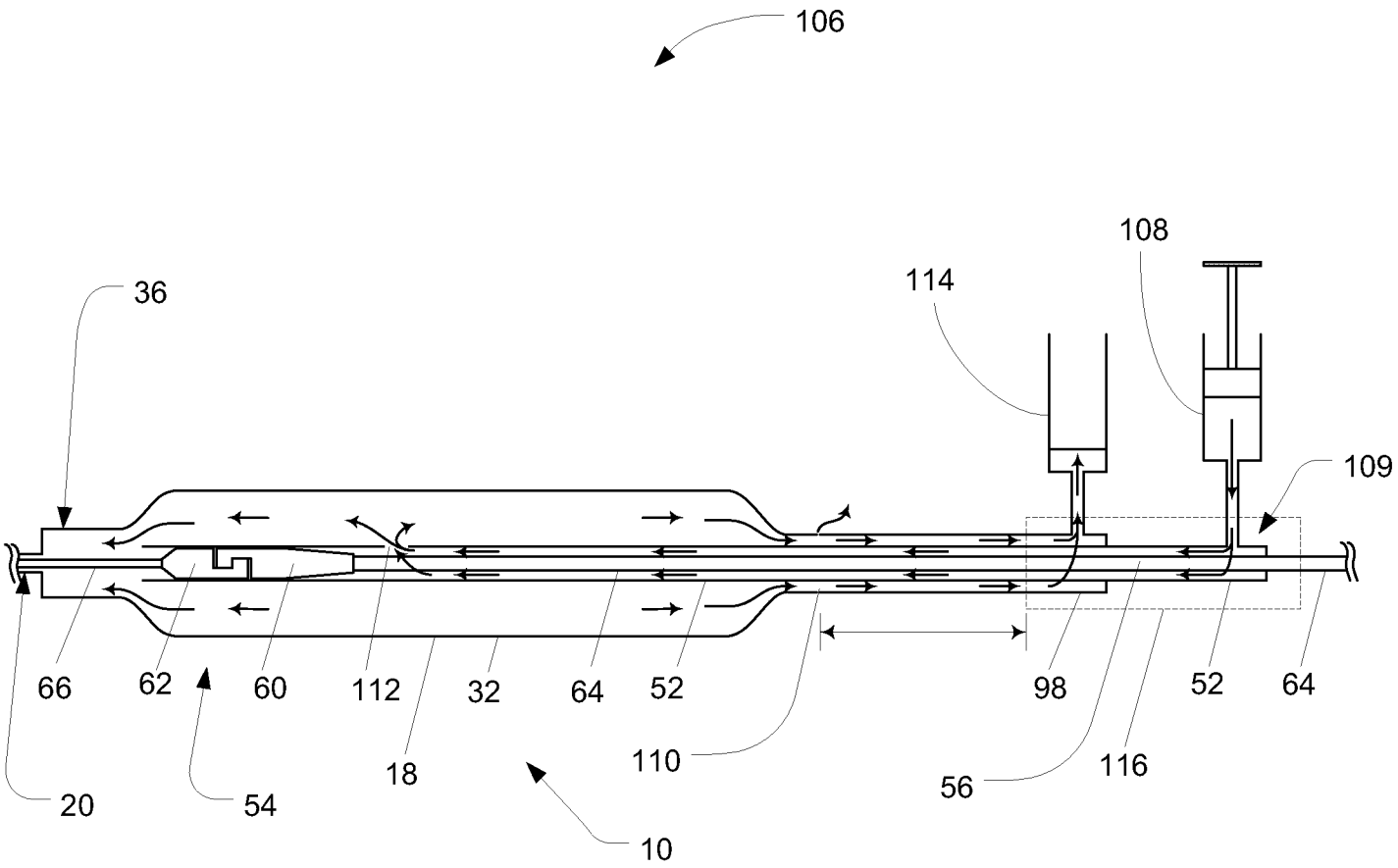
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FIG. 16

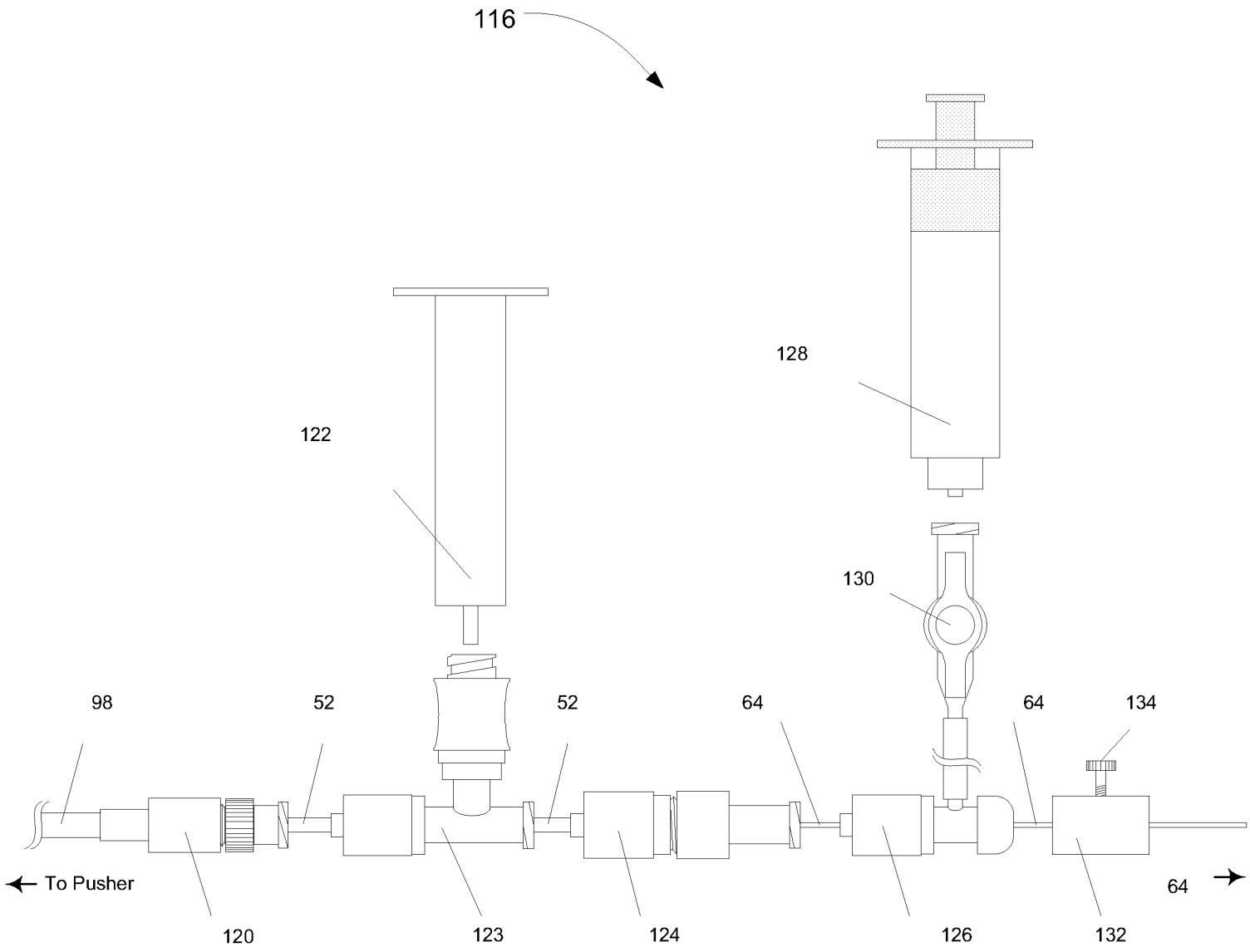
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FIG. 17

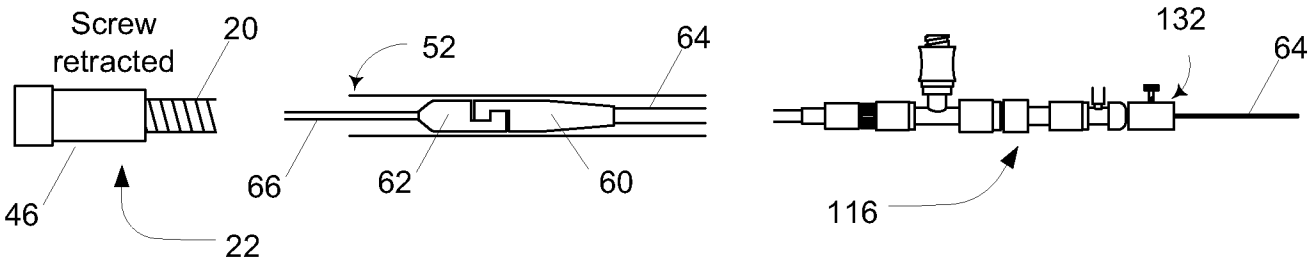


FIG. 18

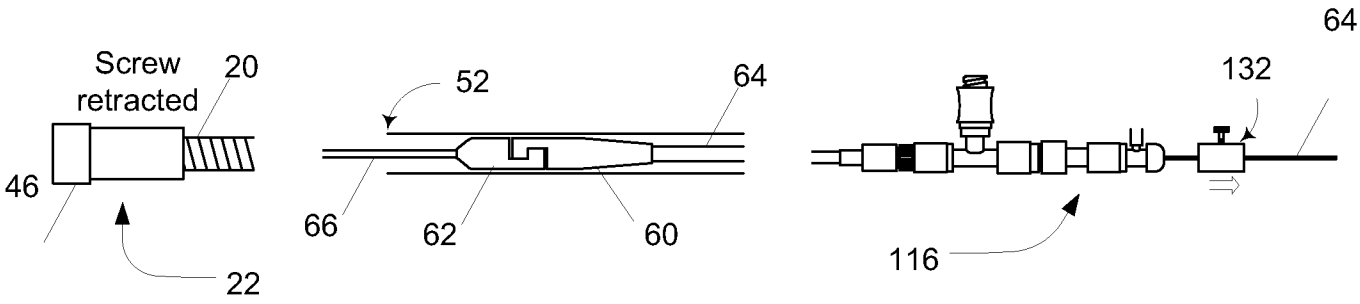


FIG. 19

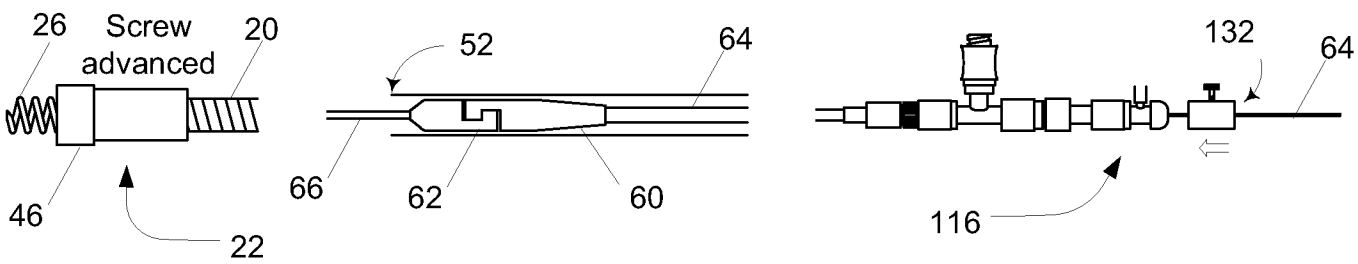


FIG. 20

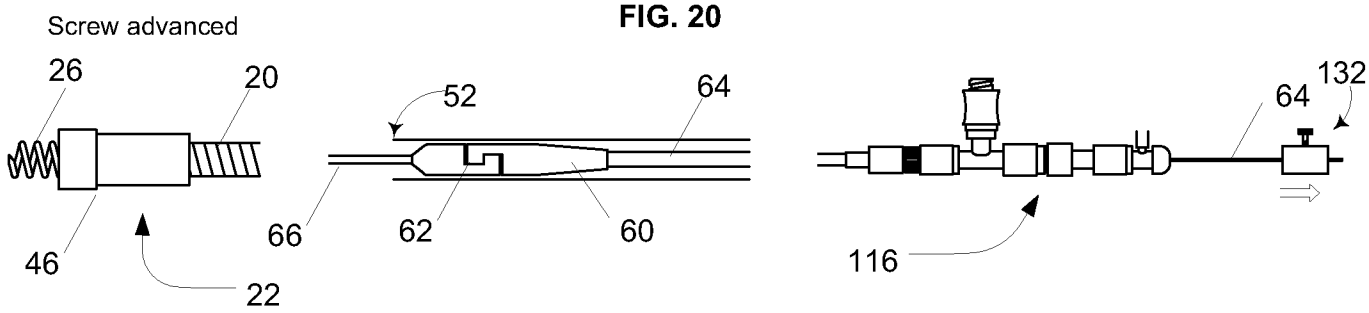


FIG. 21

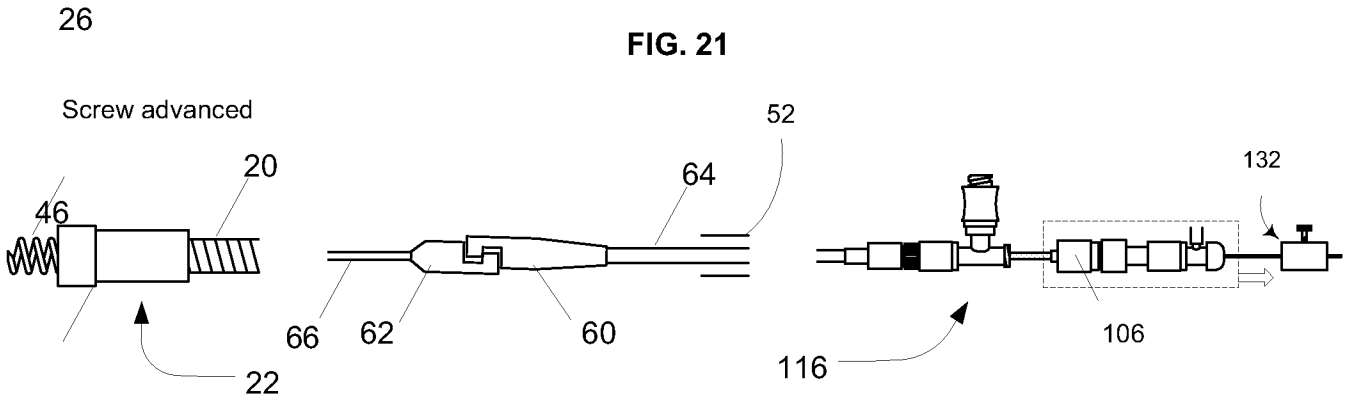
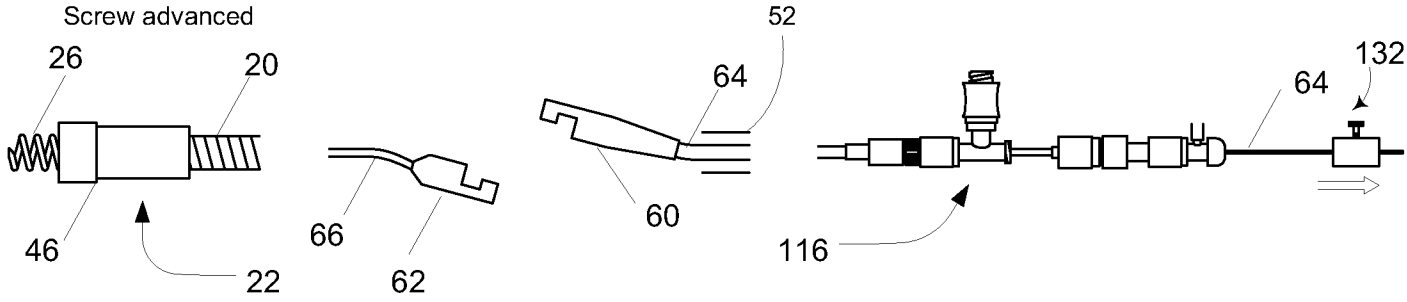


FIG. 22



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/032764

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/24 (2010.01)
USPC - 623/2.11
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(8) - A61F 2/24; A61M 25/00 (2010.01)
USPC - 623/2.11, 2.36; 604/264

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 2009/0048668 A1 (WILSON et al) 19 February 2009 (19.02.2009) entire document	1-5, 8, 9, 18 --- 6, 7, 10-17, 19, 20
Y	US 6,971,998 B2 (ROSENMAN et al) 06 December 2005 (06.12.2006) entire document	6, 7, 13-17, 19, 20
Y	US 2002/0081553 A1 (TRAMONTE) 27 June 2002 (27.06.2002) entire document	10-12, 14-16
Y	US 2007/0118151 A1 (DAVIDSON) 24 May 2007 (24.05.2007) entire document	17

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"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
21 June 2010	06 JUL 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774