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(71) Applicant: **MEDTRONIC INC.** [US/US]; 710 Medtronic Parkway, Minneapolis, Minnesota 55432 (US).

(72) Inventors: **MURPHY, Christopher**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US). **DUFFY, Niall**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US). **ANDERSON, Marc**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US). **CORISH, Kate**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, CA 95403 (US). **RYAN, Timothy**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US). **KEOGH, James**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US). **GLOSS, Michael**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US).

(74) Agent: **HAYNES, William L.**; c/o IP Legal Department, Medtronic Vascular Inc., 3576 Unocal Place, Santa Rosa, California 95403 (US).

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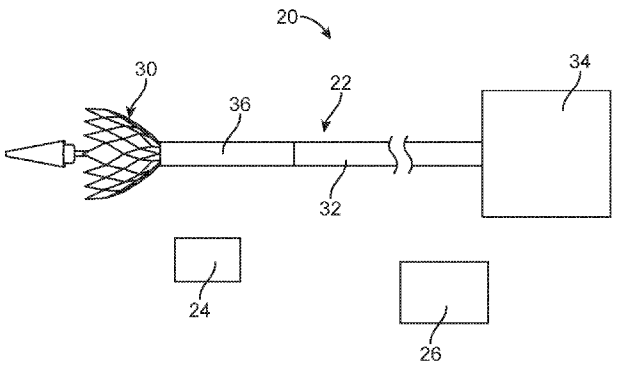

FIG. 1

(57) Abstract: A delivery system (20) for implanting a prosthetic heart valve (30) at a target site. The delivery system includes a delivery device and at least one feedback sensor (24). The delivery device includes a delivery sheath (32) and an inner shaft. The inner shaft is coaxially received within the delivery sheath and includes a valve retainer configured for temporary connection to the prosthetic valve in a loaded state. The delivery sheath contains the prosthetic valve in the loaded state. The feedback sensor is adapted to sense a parameter implicating a delivery procedure characteristic, such as implicate a spatial relationship of the prosthetic valve relative to the delivery sheath or the target site, or of an interface between the sheath and the prosthetic valve. In some embodiments, the system further includes a user interface for conveying the feedback information to a clinician such as a touch screen.

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TRANSCATHETER PROSTHETIC HEART VALVE DELIVERY SYSTEM WITH CLINICIAN FEEDBACK

Cross Reference to Related Applications

[01] This Non-Provisional Patent Application claims the benefit of the filing date of U.S. Provisional Patent Application Serial Number 62/093,553, filed December 18, 2014, entitled "Transcatheter Prosthetic Heart Valve Delivery System with Clinician Feedback," which is herein incorporated by reference.

Background

[02] The present disclosure relates to catheter-based systems for delivering a prosthetic heart valve. More particularly, it relates to transcatheter heart valve delivery systems providing clinician feedback during the prosthesis delivery procedure.

[03] A human heart includes four heart valves that determine the pathway of blood flow through the heart: the mitral valve, the tricuspid valve, the aortic valve, and the pulmonary valve. The mitral and tricuspid valves are atrio-ventricular valves, which are between the atria and the ventricles, while the aortic and pulmonary valves are semilunar valves, which are in the arteries leaving the heart. Ideally, native leaflets of a heart valve move apart from each other when the valve is in an open position, and meet or "coapt" when the valve is in a closed position. Problems that may develop with valves include stenosis in which a valve does not open properly, and/or insufficiency or regurgitation in which a valve does not close properly. Stenosis and insufficiency may occur concomitantly in the same valve. The effects of valvular dysfunction vary, with regurgitation or backflow typically having relatively severe physiological consequences to the patient.

[04] Diseased or otherwise deficient heart valves can be repaired or replaced using a variety of different types of heart valve surgeries. One conventional technique involves an open-heart surgical approach that is conducted under general anesthesia, during which the heart is stopped and blood flow is controlled by a heart-lung bypass machine.

[05] More recently, minimally invasive approaches have been developed to facilitate catheter-based implantation of the valve prosthesis on the beating heart, intending to obviate the need for the use of classical sternotomy and cardiopulmonary bypass. In general terms, an expandable prosthetic valve is compressed about or within a catheter,

inserted inside a body lumen of the patient, such as the femoral artery, and delivered to a desired location in the heart.

[06] The heart valve prosthesis employed with catheter-based, or transcatheter, procedures generally includes an expandable multi-level frame or stent that supports a valve structure having a plurality of leaflets. The frame can be contracted during percutaneous transluminal delivery, and expanded upon deployment at or within the native valve. One type of valve stent can be initially provided in an expanded or uncrimped condition, then crimped or compressed about a balloon portion of a catheter. The balloon is subsequently inflated to expand and deploy the prosthetic heart valve. With other stented prosthetic heart valve designs, the stent frame is formed to be self-expanding. With these systems, the valved stent is crimped down to a desired size and held in that compressed state within a sheath for transluminal delivery. Retracting the sheath from this valved stent allows the stent to self-expand to a larger diameter, fixating at the native valve site. In more general terms, then, once the prosthetic valve is positioned at the treatment site, for instance within an incompetent native valve, the stent frame structure may be expanded to hold the prosthetic valve firmly in place. One example of a stented prosthetic valve is disclosed in U.S. Pat. No. 5,957,949 to Leonhardt *et al.*, which is incorporated by reference herein in its entirety.

[07] The actual shape and configuration of any particular transcatheter prosthetic heart valve is dependent, at least to some extent, upon the valve being replaced or repaired (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). The stent frame must oftentimes provide and maintain (e.g., elevated hoop strength and resistance to radially compressive forces) a relatively complex shape in order to achieve desired fixation with the corresponding native anatomy. Taken in combination, these design features can give rise to delivery obstacles. For example, when compressed and constrained within the delivery device's outer sheath capsule, a self-expanding stent frame will exert significant radial forces on the capsule. Thus, the capsule must have a robust construction, capable of statically resisting the applied force. However, the capsule, as well as other portions of the outer sheath, must also be sufficiently flexible to traverse the tortuous path leading to the native valve annulus site. As a point of reference, the preferred delivery approach oftentimes includes one or more significant bends or turns. In many instances, the native anatomy creates the "tight" or small radius of curvature bends; as the capsule (or other components of the delivery device) comes into atraumatic contact with the native

anatomy, the native anatomy naturally assists in "forcing" the outer sheath (including the capsule) to the necessary shape. A retrograde approach to the aortic valve is but one example, where contact with the native anatomy assists in directing the delivery device about the significant curvature of the aortic arch.

[08] It is imperative that the stented prosthetic heart valve be accurately positioned relative to the native valve immediately prior to deployment from the catheter as successful implantation requires the transcatheter prosthetic heart valve intimately lodge and seal against the native tissue. If the prosthesis is incorrectly positioned relative to the native tissue, serious complications can result as the deployed device can leak (such as paravalvular leakage) and may even dislodge from the implantation site. In an effort to enhance the accuracy of the prosthetic heart valve placement, imaging technology has been utilized to assist a clinician in better evaluating the position of the transcatheter prosthetic heart valve immediately prior to deployment and implantation.

[09] In current surgical and diagnostic medical procedures, multiple types of imaging modalities are utilized to conduct the procedure. For example, a procedure may utilize both a fluoroscopic imaging device (obtaining images using x-ray radiation) and an ultrasound imaging device (obtaining images using sound waves). In each modality, different components can be more or less transparent depending upon the imaging modality. For example, internal tissue can be transparent to a fluoroscopic imaging device, yet visible with an ultrasound imaging device. In other instances, components can create artifacts that disrupt images that are obtained. For example, medical devices such as catheters can be readily observed with a fluoroscopic imaging device. However, such devices can create artifacts when imaged by an ultrasound imaging device

[10] Although there have been multiple advances in transcatheter prosthetic heart valves and related delivery systems and techniques, there is a continuing need to provide different delivery systems capable of providing accurate, real-time feedback information to the clinician.

Summary

[11] Some aspects of the present disclosure are directed toward a delivery system for implanting a stented prosthetic heart valve at a target site. The delivery system includes a delivery device and at least one feedback sensor. The delivery device includes a delivery sheath assembly and an inner shaft assembly. The inner shaft assembly is coaxially

received within the delivery sheath assembly and includes a valve retainer configured for temporary connection to the stented prosthetic heart valve in a loaded state of the delivery device. The delivery sheath assembly contains the stented prosthetic heart valve in the loaded state. The feedback sensor is associated with the delivery device and is adapted to sense a parameter implicating one or more delivery procedure-related attributes. For example, the feedback information can implicate a spatial relationship of the capsule relative to the stented prosthetic heart valve, a spatial relationship of the stented prosthetic heart valve relative to the target site, or an interface between the capsule and the stented prosthetic heart valve as the delivery sheath assembly is transitioned from the loaded state. In some embodiments, the system further includes a user interface for conveying the feedback information to a clinician. The user interface can include a touch screen, a motor carried by a handle assembly of the delivery device, etc.

Brief Description of the Drawings

[12] FIG. 1 is a schematic diagram of a delivery system in accordance with principles of the present disclosure;

[13] FIGS. 2A and 2B illustrate portions of an exemplary transcatheter valve delivery procedure;

[14] FIG. 3A is a side view of a stented prosthetic heart valve useful with systems, devices and methods of the present disclosure and in a normal, expanded condition;

[15] FIG. 3B is a side view of the prosthetic heart valve of FIG. 3A in a compressed condition;

[16] FIG. 4 is a side view of another exemplary prosthetic heart valve stent useful with systems, devices and methods of the present disclosure and in a normal, expanded condition;

[17] FIG. 5A is an exploded perspective view of an exemplary delivery device useful with systems of the present disclosure;

[18] FIG. 5B is a side view of the delivery device of FIG. 5A upon final assembly;

[19] FIG. 6A is a simplified perspective view of a delivery system in accordance with principles of the present disclosure;

[20] FIG. 6B is a partial, cross-sectional view of a handle assembly of the delivery system of FIG. 6A;

[21] FIG. 6C is a partial, cross-sectional view of the handle assembly of FIGS. 6A and 6B;

[22] FIG. 7A is a perspective view of portions of another delivery system in accordance with principles of the present disclosure;

[23] FIG. 7B is a side view of portions of the delivery system of FIG. 7A;

[24] FIGS. 8A and 8B are simplified side views of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[25] FIGS. 9A and 9B are simplified side views of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[26] FIG. 9C is an enlarged view of a portion of the system of FIGS. 9A and 9B;

[27] FIG. 10A is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure, along with a stented prosthetic heart valve;

[28] FIG. 10B is a simplified side view of the delivery system of FIG. 10A as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[29] FIG. 10C is a simplified side view of another portion of the delivery system of FIG. 10A;

[30] FIG. 11 is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[31] FIG. 12A is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[32] FIG. 12B schematically illustrates feedback sensors of the delivery system of FIG. 12A;

[33] FIG. 13 is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site;

[34] FIG. 14A is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure along with a stented prosthetic heart valve;

[35] FIG. 14B is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure along with a stented prosthetic heart valve; and

[36] FIG. 15 is a simplified side view of portions of another delivery system in accordance with principles of the present disclosure as part of a procedure in delivering a stented prosthetic heart valve to a target site.

Detailed Description

[37] Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms "distal" and "proximal" are used in the following description with respect to a position or direction relative to the treating clinician. "Distal" or "distally" are a position distant from or in a direction away from the clinician. "Proximal" and "proximally" are a position near or in a direction toward the clinician. As used herein with reference to an implanted valve prosthesis, the terms "distal", "outlet", and "outflow" are understood to mean downstream to the direction of blood flow, and the terms "proximal", "inlet", or "inflow" are understood to mean upstream to the direction of blood flow. In addition, as used herein, the terms "outward" or "outwardly" refer to a position radially away from a longitudinal axis of a frame of the valve prosthesis and the terms "inward" or "inwardly" refer to a position radially toward a longitudinal axis of the frame of the valve prosthesis. As well the terms "backward" or "backwardly" refer to the relative transition from a downstream position to an upstream position and the terms "forward" or "forwardly" refer to the relative transition from an upstream position to a downstream position.

[38] Aspects of the present disclosure are directed toward systems and methods providing feedback and/or other information to a clinician (or other user) during a stented transcatheter prosthetic heart valve delivery procedure. The information and its delivery to the clinician can take various forms, and can relate to one or more procedural aspects of interest. FIG. 1 is a schematic diagram of a system 20 in accordance with principles of the present disclosure and including a delivery device 22, one or more feedback sensors 24, and an optional user interface 26. The delivery device 22 can assume various forms as described below, and is generally configured for delivering a stented prosthetic heart valve 30 to a target site. In this regard, the delivery device 22 includes an outer sheath or

catheter 32 operably connected to a handle assembly 34. The outer sheath 32 forms or is connected to a capsule 36 otherwise adapted for selectively encompassing the stented prosthetic heart valve 30. The outer sheath 32 is slidable relative to the stented prosthetic heart valve 30 via various mechanisms provided with or at the handle assembly 34, permitting user-prompted release of the stented prosthetic heart valve 30 from the confines of the capsule 36. As a point of reference, FIG. 1 reflects a partial deployment state in which the capsule 36 has been partially retracted from over the stented prosthetic heart valve 30, with the so-exposed segment of the prosthetic heart valve self-expanding (in accordance with some non-limiting embodiments of the present disclosure).

[39] With this background in mind, the one or more feedback sensors 24 provide information relating to at least one of a spatial location of the stented prosthetic heart valve 30 and/or the capsule 36 relative to anatomical features of an intended target site, a spatial relationship of the capsule 36 relative to the stented prosthetic heart valve 30 and/or other components of the delivery device 22, etc. By way of further context, FIGS. 2A and 2B generally reflect one non-limiting example of steps associated with conventional prosthetic heart valve deliveries procedures. At the stage of FIG. 2A, the delivery device 22 has been routed to a target site 50 (e.g., mitral valve in the exemplary procedure of FIGS. 2A and 2B, it being understood that the systems and methods of the present disclosure are equally applicable to any valve of the human heart), with the stented prosthetic heart valve 30 (hidden in FIG. 2A) loaded within the capsule 36. A spatial location and/or orientation of the capsule 36 and/or the contained stented prosthetic heart valve 30 relative to the target site 50 can be of interest to the clinician (or others monitoring the procedure), and information indicative of one or more of these parameters can be sensed by the one or more feedback sensors 24 (FIG. 1) in some embodiments. The capsule 36 is then retracted to partially expose the stented prosthetic heart valve 30 as in FIG. 2B. The extent of retraction of the capsule 36 relative to the stented heart valve 30 and/or other components of the delivery device 22, a spatial location and/orientation of the capsule 26 and/or the stented prosthetic heart valve 30 relative to the target site 50, etc. can be of interest to the clinician (or others monitoring the procedure), and information indicative of one or more of these parameters can be sensed by the one or more feedback sensors 24 in some embodiments. Returning to FIG. 1, the one or more feedback sensors 24 can assume various forms, and can be provided with (e.g., assembled to) the delivery device 22 or can be apart from the delivery device 22. Information from the one or more

feedback sensors 24 can be conveyed to the user in various fashions as described below. For example, the information can be utilized to provide tactile (or other) feedback at the handle 34, displayed in various formats at the optional user interface 26, etc.

[40] As referred to herein, stented transcatheter prosthetic heart valves useful with and/or as part of the various systems, devices and methods of the present disclosure may assume a wide variety of different configurations, such as a bioprosthetic heart valve having tissue leaflets or a synthetic heart valve having polymeric, metallic or tissue-engineered leaflets, and can be specifically configured for replacing any of the four valves of the human heart. Thus, the stented prosthetic heart valve useful with the systems, devices, and methods of the present disclosure can be generally used for replacement of a native aortic, mitral, pulmonic or tricuspid valve, or to replace a failed bioprosthesis, such as in the area of an aortic valve or mitral valve, for example. The stented prosthetic heart valves of the present disclosure may be self-expandable, balloon expandable and/or mechanically expandable or combinations thereof.

[41] In general terms, the stented prosthetic heart valves of the present disclosure include a stent or stent frame having an internal lumen maintaining a valve structure (tissue or synthetic), with the stent frame having a normal, expanded condition or arrangement and collapsible to a compressed condition or arrangement for loading within a delivery device. For example, the stents or stent frames are support structures that comprise a number of struts or wire segments arranged relative to each other to provide a desired compressibility and strength to the prosthetic heart valve. The struts or wire segments are arranged such that they are capable of self-transitioning from, or being forced from, a compressed or collapsed condition to a normal, radially expanded condition. The struts or wire segments can be formed from a shape memory material, such as a nickel titanium alloy (e.g., Nitinol™). The stent frame can be laser-cut from a single piece of material, or can be assembled from a number of discrete components.

[42] With the above understanding in mind, one simplified, non-limiting example of a stented prosthetic heart valve 100 useful with systems, devices and methods of the present disclosure is illustrated in FIG. 3A. As a point of reference, the prosthetic heart valve 100 is shown in a normal or expanded condition in the view of FIG. 3A; FIG. 3B illustrates the prosthetic heart valve in a compressed condition (e.g., when compressively retained within an outer catheter or sheath as described below). The prosthetic heart valve 100 includes a stent or stent frame 102 and a valve structure 104.

[43] The stent frame 102 can assume any of the forms mentioned above, and is generally constructed so as to be self-expandable from the compressed condition (FIG. 3B) to the normal, expanded condition (FIG. 3A) in some embodiments. In other embodiments, the stent frame 102 is expandable to the expanded condition.

[44] The valve structure 104 can assume a variety of forms, and can be formed, for example, from one or more biocompatible synthetic materials, synthetic polymers, autograft tissue, homograft tissue, xenograft tissue, or one or more other suitable materials. In some embodiments, the valve structure 104 can be formed, for example, from bovine, porcine, equine, ovine and/or other suitable animal tissues. In some embodiments, the valve structure 104 can be formed, for example, from heart valve tissue, pericardium, and/or other suitable tissue. In some embodiments, the valve structure 104 can include or form one or more leaflets 106. For example, the valve structure 104 can be in the form of a tri-leaflet bovine pericardium valve, a bi-leaflet valve, or another suitable valve. In some constructions, the valve structure 104 can comprise two or three leaflets that are fastened together at enlarged lateral end regions to form commissural joints, with the unattached edges forming coaptation edges of the valve structure 104. The leaflets 106 can be fastened to a skirt that in turn is attached to the stent frame 102. The upper ends of the commissure points can define an outflow portion 108 corresponding to a first or outflow end 110 (forcing out fluid) of the prosthesis 100. The opposite end of the valve 104 can define an inflow portion 112 corresponding to a second or inflow end 114 (receiving fluid) of the prosthesis 100. As shown, the stent frame 102 can have a lattice or cell-like structure, and optionally forms or provides crowns 116 and/or eyelets 118 (or other shapes) at the outflow and inflow ends 110, 114.

[45] With the one exemplary construction of FIGS. 3A and 3B, the prosthetic heart valve 100 can be configured (e.g., sized and shaped) for replacing or repairing an aortic valve. Alternatively, other shapes are also envisioned, adapted to mimic the specific anatomy of the valve to be repaired (e.g., stented prosthetic heart valves useful with the present disclosure can alternatively be shaped and/or sized for replacing a native mitral, pulmonic or tricuspid valve). For example, FIG. 4 illustrates another non-limiting example of a stent frame 150 portion of another prosthetic heart valve with which the systems, devices and methods of the present disclosure are useful. In the normal or expanded condition of FIG. 4, the stent frame 150 can be sized and shaped for mitral valve implantation. Though not shown, the valve structure attached to the stent frame 150

defines an outflow portion 152 arranged at a first or outflow end 154, and an inflow portion 156 arranged at a second or inflow end 158. As compared to the stent frame 102 of FIG. 3A, the inflow portion 156 can exhibit a more pronounced change in shape relative to the corresponding outflow portion 152. Regardless, the stent frame 150 can be forced and constrained to a compressed condition (not shown, but akin to the shape of FIG. 3A) during delivery, and will self-expand to (or can be forced to) the natural condition of FIG. 4 upon removal of the constraining force(s). As reflected in FIG. 4, crowns 160 and/or eyelets 162 (or other shapes) optionally can be formed at one or both of the outflow and inflow ends 154, 158. Further, the stent frame 150 can optionally include or carry additional structural components, such as support arm(s) 164.

[46] With the above understanding of the stented prosthetic heart valves in mind, one non-limiting example of the delivery device 22 for percutaneously delivering a self-expandable prosthesis is shown in simplified form in FIGS. 5A and 5B. The delivery device 22 includes an outer or delivery sheath assembly (or outer catheter) 200, an inner shaft assembly 202, and a handle assembly 204. Details on the various components are provided below. In general terms, however, the delivery device 22 provides a loaded or delivery state in which a stented prosthetic heart valve (not shown) is loaded over the inner shaft assembly 202 and is compressively retained within a capsule 210 of the delivery sheath assembly 200. For example, the inner shaft assembly 202 can include or provide a valve retainer 212 configured to selectively receive a corresponding feature (e.g., posts or eyelets) provided with the prosthetic heart valve stent frame. The delivery sheath assembly 200 can be manipulated to withdraw the capsule 210 proximally from over the prosthetic heart valve via operation of the handle assembly 204, permitting the prosthesis to self-expand and partially release from the inner shaft assembly 202. When the capsule 210 is retracted proximally beyond the valve retainer 212, the stented prosthetic heart valve can completely release or deploy from the delivery device 22. The delivery device 22 can optionally include other components that assist or facilitate or control complete deployment, such as an outer stability tube (not shown).

[47] FIG. 5A further schematically reflects the one or more feedback sensors 24 and the optional user interface 26. In some embodiments, the sensor(s) 24 is assembled to a component of the delivery device 22, and thus can be considered "part" of the delivery device 22. In other embodiments, one or more of feedback sensors 24 is separate or apart from the delivery device 22. Similarly, in some embodiments, the user interface 26 (or

portions thereof) is assembled to or provided with the handle assembly 204 and thus can be considered "part" of the delivery device 22. In other embodiments, the user interface 26 (or portions thereof) is separate or apart from the delivery device 22.

[48] Various features of the components 200-204 reflected in FIGS. 5A and 5B and as described below can be modified or replaced with differing structures and/or mechanisms. Thus, the present disclosure is in no way limited to the delivery sheath assembly 200, the inner shaft assembly 202, or the handle assembly 204 as shown and described below. Any construction that generally facilitates delivery of a stented prosthetic heart valve (e.g., a self-expandable, a balloon-expandable, or a mechanically-expandable stented prosthetic heart valve) is acceptable. Further, the delivery device 22 can optionally include additional components or features, such as a flush port assembly 220, a recapture sheath (not shown), a stability tube (not shown), etc. In some embodiments, the delivery sheath assembly 200 defines proximal and distal ends 230, 232, and includes the capsule 210 and an outer shaft 234. The delivery sheath assembly 200 can be akin to a catheter, defining a lumen 236 (referenced generally) that extends from the distal end 232 through the capsule 210 and at least a portion of the outer shaft 234. The lumen 236 can be open at the proximal end 230 (e.g., the outer shaft 234 can be a tube). The capsule 210 extends distally from the outer shaft 234, and in some embodiments has a more stiffened construction (as compared to a stiffness of the outer shaft 234) that exhibits sufficient radial or circumferential rigidity to overtly resist the expected expansive forces of the stented prosthetic heart valve (not shown) when compressed within the capsule 210. For example, the outer shaft 234 can be a polymer tube embedded with a metal braiding, whereas the capsule 210 includes a laser-cut metal tube that is optionally embedded within a polymer covering. Alternatively, the capsule 210 and the out shaft 234 can have a more uniform or even homogenous construction (e.g., a continuous polymer tube). Regardless, the capsule 210 is constructed to compressively retain the stented prosthetic heart valve at a predetermined diameter when loaded within the capsule 210, and the outer shaft 234 serves to connect the capsule 210 with the handle assembly 204. The outer shaft 234 (as well as the capsule 210) is constructed to be sufficiently flexible for passage through a patient's vasculature, yet exhibits sufficient longitudinal rigidity to effectuate desired axial movement of the capsule 210. In other words, proximal retraction of the outer shaft 234 is directly transferred to the capsule 210 and causes a corresponding proximal retraction of

the capsule 210. In other embodiments, the outer shaft 234 is further configured to transmit a rotational force or movement onto the capsule 210.

[49] The inner shaft assembly 202 can have various constructions appropriate for supporting a stented prosthetic heart valve (not shown) within the capsule 210. In some embodiments, the inner shaft assembly 202 includes the valve retainer 212, a proximal shaft or tube 240 and an intermediate shaft or tube 242. In general terms, the valve retainer 212 can be provided with or assembled to a distal retention member 244, and incorporates features for retaining the stented prosthetic heart valve within the capsule 210. The intermediate tube 242 connects the distal retention member 244 to the proximal tube 240, with the proximal tube 240, in turn, coupling the inner shaft assembly 202 with the handle assembly 204. The components 240-244 can combine to define a continuous lumen sized to slidably receive an auxiliary component such as a guide wire (not shown).

[50] The intermediate tube 242 is optionally formed of a flexible polymer material (e.g., PEEK), and is sized to be slidably received within the delivery sheath assembly 200 and in particular the shaft 234. The proximal tube 240 can include a leading portion 250 and a trailing portion 252. The leading portion 250 serves as a transition between the proximal and intermediate tubes 240, 242, and thus can be a flexible tubing (e.g., PEEK) having a diameter slightly less than that of the intermediate tube 242. The trailing portion 252 can have a more rigid construction, configured for robust assembly with the handle assembly 204. For example, the trailing portion 252 can be a metal hypotube, although other constructions are also acceptable. In other embodiments, the proximal and intermediate tubes 240, 242 are integrally formed as a single, homogenous tube or shaft.

[51] The distal retention member 244 can include a tip 260, a support tube 262, and the valve retainer 212. The tip 260 forms or defines a nose cone having a distally tapering outer surface adapted to promote atraumatic contact with bodily tissue. The tip 260 can be fixed or slidable relative to the support tube 262. The support tube 262 extends proximally from the tip 260 and is configured to internally support a compressed, stented prosthetic heart valve (not shown) generally disposed thereover. The valve retainer 212 is mounted to the support tube 262, and can generally have a hub-like construction. The valve retainer 212 forms or carries features (e.g., slots, grooves, posts, etc.) configured to selectively receive corresponding feature(s) provided with the stented prosthetic heart valve.

[52] The handle assembly 204 generally includes a housing 270 and one or more actuator mechanisms 272 (referenced generally). The housing 270 maintains the actuator mechanism(s) 272, with the handle assembly 204 configured to facilitate sliding movement of the delivery sheath assembly 200 relative to other components (e.g., the inner shaft assembly 202). In some optional embodiments, the actuator mechanism 272 is mechanically linked to the delivery sheath assembly 200 by a motor (not shown) that provides motorized control over movement of the delivery sheath assembly 200. The housing 270 can have any shape or size appropriate for convenient handling by a user.

[53] With the above general explanations of exemplary embodiments of the delivery devices of the present disclosure in mind, one embodiment of a delivery system 300 in accordance with principles of the present disclosure is shown in FIGS. 6A-6C. The system 300 includes a delivery device 302, at least one feedback sensor 304a (referenced generally), 304b, 304c, and a user interface 306 (referenced generally). The delivery device 302 can be akin to any of the descriptions herein, and generally includes a catheter 322 connected to a delivery sheath assembly 310 forming a capsule 312, a tip 314, and a handle assembly 316. In various embodiments, the catheter 322 is arranged and configured to be disposable so that the handle assembly 316 can be reused with a new catheter. The handle assembly 316 can have a variety of different shapes and constructions, and includes an actuator mechanism 318 (e.g., a user control slider or a trigger) formatted to effectuate movement of the outer sheath assembly 310 in response to a user-applied force.

In some embodiments, feedback sensor(s) 304a is located at or along the capsule 312 and is configured to detect stresses in the capsule 312. For example, the feedback sensor(s) 304a can be akin to a force transducer, such as a metal strip electrically connected to an energy source (e.g., electrical current). In other embodiments, feedback sensors 304b, 304c are incorporated within the handle assembly 316 to provide an indication of a deployment percentage of the stented prosthetic heart valve with respect to the capsule 312, as will be discussed in further detail below. Regardless of an exact form of the feedback sensor(s) 304a-c, the user interface 306 is electronically connected (wired or wirelessly) to each feedback sensor(s) 304a-c, and is provided with or assembled to the handle assembly 316. The user interface 306 includes a battery 324 or alternative power source for powering a motor 320 and programmed logic 326 (e.g., a printed circuit board) adapted or programmed to receive and act upon a signal from the feedback sensor(s) 304a-

c. The motor 320 can take various forms, and in some embodiments is a servo-motor (e.g., DC or AC powered). The user interface 306 can include circuitry components adapted to amplify the respective feedback sensor(s) 304a-c signal(s) to the motor 320. With this construction, the user interface 306 is configured to provide qualitative and/or quantitative feedback to the clinician while the clinician is attempting to retract the capsule 312 from over a stented prosthetic heart valve 30.

[54] For example, the motor 320 can be linked via a gearbox 328 to a linear actuator or ballscrew 330 that in turn is linked to the actuator mechanism 318. In response to the signal received from the feedback sensor(s) 304a at the capsule 312, the motor 320 transmits a torque to the linear actuator 330, with the linear actuator 330 generating a corresponding "push back" on the actuator mechanism 318 to give a sense of feel to the clinician. The resistance strength of the actuator mechanism 318 can be increased or decreased as a function of the forces sensed or experienced at the capsule 312 (as otherwise sensed by the feedback sensor(s) 304a).

[55] Alternatively or in addition, the motor 320 can be configured to vibrate in response to signals from the feedback sensor(s) 304a at levels that can be felt at the handle assembly 316. A clinician can thus be provided with tactile feedback that forces are being experienced at the capsule 312 by feedback sensor 304a.

[56] Alternatively or in addition, the level of force implicated by the feedback sensor(s) 304a-c can be transmitted to a display screen (not shown but see display screen 362 of FIGS. 7A-7B, for example), such as a touch screen, for display to a user. The display screen can be considered the user interface, or as a sub-component of the user interface, and can be carried by the handle assembly 316 or provided apart from the handle assembly 316. The feedback sensor(s) 304a-c can be wired or wirelessly connected to the display screen.

[57] Alternatively or in addition, the level of force implicated by the feedback sensor(s) 304a can be transmitted to one or more devices apart from the delivery device 302. For example, to a dedicated monitor and/or fluro screen conventionally employed with transcatheter stented heart valve delivery procedures, an off-site location (e.g., cloud network), etc. The level of force (or the raw data of the feedback sensor(s) 304a-c signal) can be delivered wirelessly via appropriate circuitry of the circuit board 326 carried by the handle assembly 316 (e.g., transreceiver components and a controller programmed to

effectuate conventional Bluetooth transmission protocols). Data sent to off-site locales can be stored and/or viewed by others.

[58] By utilizing feedback sensor(s) 304a, stresses felt when retracting (or "opening") the capsule 312 are sensed and given to the clinician as feedback. Other feedback information available with systems of the present disclosure (e.g., systems akin to the system 300 of FIG. 6A-6C) includes forces felt or experienced at the tip 314. Additionally or alternatively, a deployment percentage of the delivery device 300 can be provided as feedback information. The deployment percentage relates to an extent to which the stented prosthetic heart valve (not shown) has been "exposed" by retraction of the capsule 312, and can be estimated by the position of the linear actuator 330 or stresses experienced or sensed at the feedback sensor(s) 304b, 304c located within the handle assembly 316. For example, feedback sensors 304a can be provided in the capsule 312 and/or feedback sensors 304b, 304c are provided at either end of the linear actuator 330, within the handle assembly 316. In the illustrated embodiment, the feedback sensors 304b, 304c are optical sensors. When the delivery system 300 is powered on with the battery 324, the motor 320 advances the linear actuator 330 distally until the linear actuator 330 triggers the feedback sensor 304a. When feedback sensor 304a is triggered, it indicates that the capsule 312 is fully closed and the circuit board 326 records this as the starting point of the delivery process when the capsule 312 fully encapsulates the stented prosthetic heart valve 30. The feedback sensor 304b at the proximal end of the linear actuator 330 detects, or is triggered, when the linear actuator 330 is at its most proximal position, thus indicating that the capsule 312 is in the fully retracted position.

[59] Additionally or alternatively, a distance the capsule 312 has moved or traveled relative to the tip 314 and/or the inner shaft assembly (hidden) can be provided to the clinician (e.g., the feedback sensor(s) 304a can be or include a magnetic sensor). Additionally or alternatively, pressure experienced by the capsule 312 can be provided to the user (e.g., the feedback sensor(s) 304a can be or include a pressure sensor). In yet other embodiments, feedback can include information relating to forces felt in the handle assembly 316, ultrasound imaging, etc.

[60] As implied above, some embodiments systems of the present disclosure can include a display screen. With this in mind, FIGS. 7A-7B illustrate portions of another embodiment delivery system 350 in accordance with principles of the present disclosure. The system 350 includes a delivery device 352 and a user interface 354. Though not

shown, the system 350 can further include one or more feedback sensors as described above (e.g., a feedback sensor configured and located to provide information relating to forces experienced by and/or movement of a capsule (not shown) provided with delivery device 352). The delivery device 352 can assume any of the forms described above, and generally includes a delivery sheath assembly 356 and a handle assembly 358. The user interface 354 includes a display screen module 360 that includes a display screen 362 and an appropriate programmed controller. The display screen module 360 can be assembled to or carried by the handle assembly 358, and in some embodiments is or includes a touch screen. The display screen module 360 can include a platform 366 and corresponding devices configured to receive and connect to the housing 364. In other embodiments, the display screen module 360 canbe integrally formed into a housing 364 of the handle assembly 358. In related embodiments, the controller provided with the display screen module 360 is programmed (e.g., software) to receive and act upon inputted information and/or interact with a motor (not shown) provided with the handle assembly 358.

[61] With the above construction, the display screen 362 can display feedback information to the clinician. The displayed information can include one or more of level of forces being experienced at the capsule (not shown), patient information, information specific to the delivery device 352 and/or the stented prosthetic heart valve (not shown) being delivered, fluro images, ultrasound images, etc. The display screen module 360 can further optionally be configured to interact with a motor provided with the handle assembly 358 (that otherwise operates to control and/or monitor movement of the outer sheath assembly 356). A clinician could input speeds and patient information into the display screen module 360 to allow it to adapt to specific patients and/or clinician preferences.

[62] The system 350 further includes a wireless connection module 370 (referenced generally). The wireless connection module 370 can assume a variety of forms known in the art, configured or programmed to establish a wireless electronic connection with one or more other devices (e.g., Bluetooth or Wi-Fi connectivity). This would allow, for example, the system 350 to send real time information to other monitors (such as the monitors in a cath lab). The delivered information could be similar to information displayed on the display screen 362; additional information, such as fluro, video from the procedure, etc. could also be included. The so-provided information could be beneficial in the training of new physicians in remote locations. Further, the off-site location could

effectuate remote control of the handle assembly 358 (and thus of portions of the delivery procedure) based upon the received information. Sensors and/or force transducers (not shown) would allow a device controller to "know" at which stage of the delivery procedure the clinician is at. This would allow feedback and tips to be given. It could also provide a record of what happened during the procedure for purposes of review following the procedure.

[63] Portions of another embodiment delivery system 400 in accordance with principles of the present disclosure are shown in FIGS. 8A and 8B in various stages of performing a delivery procedure relative to a target site 402. The delivery system 400 includes a delivery device 404 and one or more feedback sensors 406 (referenced generally). Though not shown, the system 400 further includes a user interface akin to any of the user interfaces in other embodiments of the present disclosure. The delivery device 404 includes a delivery sheath assembly 408 forming or providing an outer shaft 410 and a capsule 412 commensurate with the descriptions above.

[64] The feedback sensor(s) 406 is or includes a force or touch sensor or pad coated or printed on to the delivery sheath assembly 408. The feedback sensor(s) 406 can be formed in accordance with known thin coating (e.g., metal oxide) touch sensor technology. An entirety of the delivery sheath assembly 408 can be coated with the touch-sensitive material, or the material can be coated to select locations along one or both of the outer shaft 410 and the capsule 412. Regardless, the applied feedback sensor(s) 406 operates to "sense" contact with tissue, providing a clinician with physical contact feedback during the delivery procedure. As a point of reference, FIGS. 8A and 8B identify two contact regions of interest in connection with a transcatheter procedure performed on the aortic valve (it being understood that the present disclosure is not limited to repair of the aortic valve). As highlighted at 420 in FIG. 8A, knowledge of contact between the capsule 412 and leaflets of the native valve can be useful in evaluating whether the capsule 412 is correctly located relative to the target site 402 prior to deploying the stented prosthetic heart valve (hidden). Similarly, FIG. 8B highlights at 422 that contact between the outer shaft 410 and the aortic arch can be useful in evaluating an obtained position of the capsule 412.

[65] Signaled information (e.g., capacitance) from the feedback sensor(s) 406 can be delivered to the user interface (not shown) and acted upon in manners akin to descriptions provided elsewhere in the present disclosure, providing the clinician with physical contact

information. For example, the sensed contact information can be displayed to the clinician, e.g., as an overlay on other displayed information such as ultrasound information, a CT scan of the target site, etc. The displayed sensed contact information can be continuously updated, providing a clinician with a real time indication or depiction of spatial locations of the delivery sheath assembly 408 as the delivery device 404 is guided toward the target site 402. In addition or alternatively, the sensed information can be used to generate tactile feedback to the clinician, such as at a handle assembly of the delivery device 404. Other feedback sensors (not shown) can further be provided with the system 400 to further enhance the real time tracking or representation of the delivery device 404 relative to the native anatomy (e.g., an accelerometer carried by the delivery device 404). Regardless, the system 400 can be useful in minimizing the need for fluoroscopic guidance (and corresponding contrast medium).

[66] Portions of a related embodiment delivery system 450 are shown in FIGS. 9A-9C in various stages of performing a delivery procedure relative to a target site 452. The delivery system 450 includes a delivery device 454 and one or more feedback sensors 456 (referenced generally). Though not shown, the system 450 further includes a user interface akin to any of the user interfaces in other embodiments of the present disclosure. The delivery device 454 includes a delivery sheath assembly 458 and a tip 460 commensurate with the descriptions above.

[67] The feedback sensor(s) 456 can be a pressure sensor formed or applied to the tip 460 at a known location relative to a distal end 462 of the delivery sheath assembly 458. The pressure sensor(s) 456 is generally configured to be "activated" or otherwise sense pressure applied by coapting leaflets 464 of the target site 452. Information generated at or by the feedback pressure sensor(s) 456 can be signaled to, and acted upon by, the user interface (not shown) in accordance with any of the embodiments of the present disclosure. For example, the feedback pressure sensor 456 information can be delivered to a user interface device carried by a handle assembly (not shown) of the delivery device 454, displayed on a display screen, etc. Regardless, during use as the delivery device 454 is manipulated to bring the tip 460 into close proximity to the target site 452, the coapting leaflets 464 will touch or contact the feedback pressure sensor(s) 456. The feedback pressure sensor(s) 456, in turn, signal information indicative of this event, thus indicating that the tip 460 is at the target site 452. Other feedback sensors (not shown) can further be provided with the system 450 to further enhance the real time tracking or representation of

the delivery device 454 relative to the native anatomy (e.g., an accelerometer carried by the delivery device 454). The system 450 can be useful in minimizing the need for fluoroscopic guidance (and corresponding contrast medium).

[68] Portions of another related embodiment delivery system 500 are shown in FIGS. 10A-10C, including the system 500 delivering a stented prosthetic heart valve 502 (illustrated in simplified form) to a target site 504 in FIG. 10B. The delivery system 500 includes a delivery device 506, one or more feedback sensors 508 (referenced generally), and a user interface 510. The delivery device 506 includes a delivery sheath assembly 512, an inner shaft assembly 514, and a handle assembly 516 commensurate with the descriptions above. The inner shaft assembly 514 includes or carries a valve retainer 518 for maintaining the stented prosthetic heart valve 502. As a point of reference, with the non-limiting embodiment of FIGS. 10A-10C, the stent of the prosthetic heart valve 502 includes support arms 520 intended to engage native leaflets 522 of the target site 504 during the deployment procedure, and the delivery device 506 is adapted to facilitate staged deployment of the prosthetic heart valve 502. For example, the delivery device 506 is operable to permit deployment of the support arms 520 while the prosthetic heart valve 502 remains connected to the valve retainer 518 as reflected in FIGS. 10A and 10B. Once the support arms 520 are deployed, the prosthetic heart valve 502 is maneuvered to locate the leaflets 522 within respective ones of the support arms 520 by manipulating the delivery device 506. In the desired arrangement of FIGS. 10B, then, the support arms 520 are seated in the corresponding coronary cusps of the native valve target site 504. As part of this seating step, forces experienced at the support arms 520 are directly linked, indirectly linked or transferred to the feedback sensor 508 of the valve retainer 518 or to one or more other feedback sensors (not shown) electronically connected to the user interface 510.

[69] With the above general descriptions of the delivery procedure in mind, the feedback sensor 508 is a force or pressure sensor attached to or carried by the valve retainer 518. The feedback sensor 508 is electronically connected to the user interface 510 that is otherwise assembled to or carried by the handle assembly 516. The user interface 510 can assume various forms appropriate for conveying information generated by the feedback sensor 508 to a clinician. For example, the user interface 510 includes one or more lights 524a, 524b adapted to convey certain feedback or status information when illuminated. The lights 524a, 524b can be of differing colors (e.g., the first light 524a is

red and the second light 524b is green). A number of other user interface constructions are equally acceptable as described below.

[70] In some embodiments, the feedback sensor 508 at the valve retainer 518 provides information indicative of desired seating of the deployed support arms 520 relative to the target site 504. More particularly, as the delivery device 500 is manipulated to bring the support arms 520 into a fully seated relationship with the coronary cusps (e.g., contact with the coronary cusps impedes or resists further movement of the support arms 520 and thus of the stented prosthetic heart valve 502), a force is transferred on to the valve retainer 518 and in turn is sensed by the feedback sensor 508. The user interface 510 is configured to convey information relating to the sensed force to the clinician. For example, at sensed forces below a certain, pre-determined level, the first light 524a is illuminated and the second light 524b is powered off. Thus, where the force characteristics sensed by the feedback sensor 508 otherwise implicate that the support arms 520 have not sufficiently seated at the coronary cusps, a red (or other color) is displayed, informing the clinician that desired seating has not yet been achieved. Once the sensed force reaches the pre-determined level, the second light 524b is powered on, and the first light 524a is powered off. Thus, where the sensed force characteristics otherwise implicate that the support arms 520 have become sufficiently seated, a green (or other color) is displayed, informing the clinician that the support arms 520 are positioned correctly. The clinician can then proceed to perform subsequent steps of the delivery procedure. The force information can alternatively be presented or conveyed to a clinician in a wide variety of other manners (e.g., a differently configured user interface) that may or may not include lights along the handle assembly 516. Other feedback sensors (not shown) can further be provided with the system 500 (e.g., an accelerometer carried by the delivery device 506). The system 500 can be useful in minimizing the need for fluoroscopic guidance (and corresponding contrast medium).

[71] Portions of another embodiment delivery system 550 are shown in FIG. 11 in delivering a stented prosthetic heart valve 552 to a target site 554. The system 550 includes a delivery device 560 and one or more feedback sensors 562a, 562b. Though not shown, the system 550 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 560 can assume any of the forms described above, and may include a delivery sheath assembly 570 configured to selectively retain the stented prosthetic heart valve 552. As a point of reference, FIG. 11

illustrates the delivery device 560 in a partial deployment state in which the delivery sheath assembly 570 has been partially retracted from over the stented prosthetic heart valve 552.

[72] The feedback sensors 562a, 562b can assume various forms and may be provided apart from the delivery device 560 or as part of the delivery device 560. In some embodiments, the feedback sensors 562a, 562b include or are akin to proximity sensors. For example, each of the feedback sensors 562a, 562b can be provided as part of a pigtail catheter or wire, and are electronically connected to a user interface (or other device programmed to received and act upon data signaled by the corresponding feedback sensor 562a, 562b). With this construction, the feedback sensors 562a, 562b can be deployed to the target site 554 apart from the delivery device 560 and provide information indicative of a spatial location and/or orientation of the stented prosthetic heart valve 552 relative to the target site 554 as described below.

[73] The feedback sensors 562a, 562b can be configured to be located or seated at a native cusp 580 of the target site 554 (or are carried by a device such as a pigtail catheter appropriate for delivering the corresponding feedback sensor 562a, 562b to the native cusps). At this location, then, the feedback sensors 562a, 562b signal information relating to a spatial position of an annulus 582 of the target site 554. In some embodiments, the feedback sensors 562a, 562b are delivered to the target site 554 in advance of the delivery device 560. Regardless, the spatial information or data provided by the feedback sensors 562a, 562b can be utilized in evaluating a location of the partially deployed stented prosthetic heart valve 552.

[74] For example, a spatial location of portions of a distal end 586 of the stented prosthetic heart valve 552 relative to the annulus 582 can be evaluated, for example as a function of one more distances d_1, d_2. The distances d_1, d_2 can be estimated based on information from the feedback sensors 562a, 562b in various manners. For example, in some embodiments, one or more indicators 590a, 590b can be provided with the stented prosthetic heart valve 552 at or adjacent the distal end 586. In other embodiments, three or more of the indicators 590a, 590b can be provided. The indicators 590a, 590b can be conventional markers. In other embodiments, the indicators 590a, 590b are or include pressure or proximity sensors that are electronically connected (wired or wirelessly) to the user interface (or a controller interfacing with the user interface). The distances d_1, d_2 can be determined by comparing spatial information associated with the feedback sensors

562a, 562b with that of the indicators 590a, 590b, providing feedback on a location of the stented prosthetic heart valve 552 relative to the native annulus 582. Further, feedback indicative of an orientation of the stented prosthetic heart valve 552 relative to the target site 554 can be generated by comparing the distances d_1, d_2 using fluoroscopy, echo, etc. Alternatively or in addition, a clocking or rotational orientation of the stented prosthetic heart valve 552 relative to the target site 554 can be detected, evaluated or provided to the clinician as feedback information. Further, where the indicators 590a, 590b are pressure sensors, feedback information can be generated indicative of surface pressure or stress being experience by the stented prosthetic heart valve 552 at the distal end 586. This feedback information, in turn, can assist a clinician in evaluating possible undesired placement of the stented prosthetic heart valve 552 at an anatomical location that might cause trauma to the native conduction system. With reference to the feedback information, the clinician can reposition the stented prosthetic heart valve 552 based on threshold data that can help reduce or minimize contact pressure or stress on the conduction system anatomy. In yet other embodiments, the pressure sensor format of the indicators 590a, 590b can provide feedback information indicative of a pressure gradient across the annulus 582 and/or across the prosthetic heart valve 552.

[75] Portions of another embodiment delivery system 600 are shown in FIG. 12A in delivering a stented prosthetic heart valve (hidden in the view, but referenced generally at 602) to a target site 604. The system 600 includes a delivery device 610, a first feedback sensor 612, a second feedback sensor 614, and a third feedback sensor 616. Though not shown, the system 600 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 610 can assume any of the forms described above, and may include a delivery sheath assembly 620 configured to selectively retain the stented prosthetic heart valve 602. As a point of reference, FIG. 12A illustrates the delivery device 610 in a loaded state in which an entirety of the stented prosthetic heart valve 602 is within the delivery sheath assembly 620.

[76] The first feedback sensor 612 is provided apart from the delivery device 610 and can assume various forms. In some embodiments, the first feedback sensor 612 includes or is akin to a position sensor or proximity sensor. For example, the first feedback sensor 612 can be provided as part of a pigtail catheter or wire, and is electronically connected to a user interface (or other device programmed to receive and act upon data signaled by the first feedback sensor 612). With this construction, the first feedback sensor 612 can be

deployed to the target site 604 apart from the delivery device 610 and provides information indicative of a spatial location and/or orientation of an anatomical feature of the target site 604. For example, the first feedback sensor 612 can be configured to be located or seated against a native cusp 630 (or other anatomical structure) of the target site 604 (or is carried by a device such as a pigtail catheter appropriate for delivering the first feedback sensor 612 to the native cusps 630). At this location, then, the first feedback sensor 612 signals information relating to a spatial position of an annulus 632 of the target site 604.

[77] Each of the second and third feedback sensors 614, 616 is or includes a position sensor or proximity sensor, and is attached to or carried by the delivery device 610 at a known location (e.g., longitudinal location) relative to one another and relative to the stented prosthetic heart valve 602 in the loaded state. For example, the second and third feedback sensors 614, 616 can be attached to the delivery sheath assembly 620 (either exteriorly or interiorly), the inner shaft assembly (not shown) or other component of the delivery device 610. The second and third feedback sensors 614, 616 are longitudinally spaced from one another (along a longitudinal axis of the delivery sheath assembly 620). The second feedback sensor 614 is optionally located at or adjacent a distal end 640 of the delivery sheath assembly 620. The third feedback sensor 616 is placed at a location that is aligned with the stented prosthetic heart valve 602 in the loaded state (e.g., proximal end, distal end, mid-point, etc., of the stented prosthetic heart valve 602). The second and third feedback sensors 614, 616 are each electronically connected to the user interface (not shown) or other device programmed to receive an act upon data signaled by the second and third feedback sensors 614, 616.

[78] In some embodiments, the first feedback sensor 612 is delivered to the target site 604 in advance of the delivery device 610. As shown in FIG. 12A, the first feedback sensor 612 has been manipulated to contact one of the native cusps 630, and thus signals information indicative of a spatial location of the annulus 632. The delivery device 610 is then maneuvered, in the loaded state, to bring the stented prosthetic heart valve 602 into an estimated region of the target site 604. The clinician can be provided with feedback information indicative of a location or depth of the stented prosthetic heart valve 602 relative to the target site 604, and in particular relative to the annulus 632, via information from the first-third feedback sensors 612-616, prior to retracting the delivery sheath assembly 620/deploying the stented prosthetic heart valve 602. In particular, a depth of

the loaded stented prosthetic heart valve 602 relative to the annulus 632 is determined or evaluated by estimating a linear distance between the first feedback sensor 612 and the second feedback sensor 614 along a line or vector of the second and third feedback sensors 614, 616. As a point of reference, FIG. 12B reflects the first-third feedback sensors 612-616 in isolation. As shown by the arrow "V", a directional vector can be identified from the second feedback sensor 614 to the third feedback sensor 616. With additional reference to FIG. 12A, a distance between the first feedback sensor 612 and the second feedback sensor 614 in a direction of the vector V is representative of a depth of the stented prosthetic heart valve 602 relative to the annulus 632. Based upon this feedback information (that again can be presented to the clinician via a user interface in various formats), the clinician can re-position the delivery device 610 until a desired depth is obtained prior to releasing or deploying the stented prosthetic heart valve 602.

[79] Portions of another embodiment delivery system 650 are shown in FIG. 13 in delivering a stented prosthetic heart valve 652 to a target site 654. The system 600 includes a delivery device 660 and a plurality of feedback sensors 662. Though not shown, the system 650 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 660 can assume any of the forms described above, and may include a delivery sheath assembly 670 configured to selectively retain the stented prosthetic heart valve 652. As a point of reference, FIG. 13 illustrates the delivery device 660 in a partial deployment state in which the delivery sheath assembly 670 has been partially retracted from over the stented prosthetic heart valve 652.

[80] The plurality of feedback sensors 662 are individually located at pre-determined, longitudinally spaced locations along a length of the stented prosthetic heart valve 652, and can assume various forms. In some embodiments, each of the feedback sensors 662 includes or is akin to a proximity sensor or a position sensor. The feedback sensors 662 can be secured to the stented prosthetic heart valve 652 in various fashions that will not interfere with intended functioning of the prosthesis 652 following implant (e.g., attached to the stent), and are electronically connected (wirelessly or wired) to a user interface (or other device programmed to receive and act upon data signaled by the feedback sensors 652). With this construction, the feedback sensors 652 can provide information indicative of a spatial location and/or orientation of the partially deployed stented prosthetic heart valve 652 relative to the target site 654 as described below.

[81] In some embodiments, the plurality of feedback sensors 662 can include sets or groupings of two or more feedback sensors that are longitudinally aligned with one another (relative to a longitudinal length of the stented prosthetic heart valve 652), and that are circumferentially spaced from other sets of feedback sensors 662. For example, with the non-limiting embodiment of FIG. 13, the plurality of feedback sensors 662 are arranged to provide a first set A of longitudinally aligned feedback sensors 662A-1, 662A-2, 662A-3 and a second set B of longitudinally aligned feedback sensors 662B-1, 662B-2, 662B-3. Selective ones of the feedback sensors 662 within each of the set A, B are circumferentially aligned relative to a circumference of the stented prosthetic heart valve 652 (e.g., the first feedback sensors 662A-1, 662B-1 are circumferentially aligned, the second feedback sensors 662A-2, 662B-2 are circumferentially aligned, and the third feedback sensors 662A-3, 662B-3 are circumferentially aligned). By comparing information signaled (or absence of a signal) from the feedback sensors 662 with one another, a depth and angle of the partially deployed stented prosthetic heart valve 652 can be estimated. For example, in the arrangement of FIG. 13, the partially deployed stented prosthetic heart valve 652 has been spatially located at an angle relative to the target site 654 such that a first "side" 680 is at a greater depth than a second side 682 relative to a plane P of the target site 654. Information from the feedback sensors 662 implicates this arrangement. For example, with respect to the first side 680 (otherwise corresponding with the first set A), information from one or more of the feedback sensors 662A-1, 662A-2, 662A-3 indicates that the second feedback sensor 662A-2 is at or in close proximity to the plane P and/or that the first sensor 662A-1 has progressed through and beyond the plane P. With respect to the second side 682 (otherwise corresponding with the second set B), information from one or more of the feedback sensors 662B-1, 662B-2, 662B-3 indicates that the first feedback sensor 662B-1 is at or in close proximity the plane P. From this information, then, feedback information is provided to the clinician indicative of an angled orientation of the stented prosthetic heart valve 652 relative to the plane P (i.e., the sensors 662A-2, 662B-1 otherwise determined to be at or in close proximity to the plane P are not circumferentially aligned (relative to a circumference of the stented prosthetic heart valve 652)) and of a depth of the stented prosthetic heart valve 652 relative to the plane P. Based upon this feedback information, the clinician may decide to re-position the stented prosthetic heart valve 652 prior to effectuating full release or deployment from the delivery device 660.

[82] Portions of another embodiment delivery system 700 in accordance with principles of the present disclosure are shown in simplified form in FIG. 14A, along with a stented prosthetic heart valve 702. The system 700 includes a delivery device 710 (referenced generally) and a feedback sensor 712. Though not shown, the system 700 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 710 can assume any of the forms described above, and generally includes a delivery sheath assembly 720 and an inner shaft assembly 722. Commensurate with the above descriptions, the delivery device 710 is configured such that in a loaded state, the stented prosthetic heart valve 702 is collapsed over, and temporarily connected to, the inner shaft assembly 722 and contained within the delivery sheath assembly 720. In the view of FIG. 14A, the delivery sheath assembly 720 has been retracted from over the stented prosthetic heart valve 702 and is in a fully expanded condition.

[83] The feedback sensor 712 is attached to or carried by a distal end 730 of the delivery sheath assembly 720, and is configured to electronically interface with other features provided with the inner shaft assembly 722 as described below. The feedback sensor 712 is electronically connected to the user interface (not shown) or other device programmed to receive and act upon data signaled by the feedback sensor 712.

[84] In particular, the feedback sensor 712 is configured to sense or measure electrical resistance (or other electrical property) of marker bodies 740 (referenced generally) provided along the inner shaft assembly 722. The marker bodies 740 are longitudinally spaced from one another at pre-determined locations each having a known spatial relationship or location relative to the stented prosthetic heart valve 702 in the loaded state. For example, it will be recalled that the inner shaft assembly 722 includes or carries a valve retainer (not shown) that connects to or receives a component of the stented prosthetic heart valve 702 (e.g., one or more of the crowns 742 identified in FIG. 14A) in the loaded state. The valve retainer thus provides a known location of the stented prosthetic heart valve 702 relative to a length of the inner shaft assembly 722 in the loaded state. The marker bodies 740 can be located at pre-determined, spaced increments from this known location. During a deployment procedure, as the delivery sheath assembly 720 is retracted relative to the stented prosthetic heart valve 702, and thus relative to the inner shaft assembly 722, the feedback sensor 712 will electrically interface with sequential ones of the marker bodies 740 (e.g., sense or measure a resistance at each of the marker bodies 740, for example the marker body 740 closest to the feedback sensor 712). This

information, in turn, can be provided to a clinician as feedback information indicative of the extent to which the distal end 730 of the delivery sheath assembly 720 has been retracted relative to the stented prosthetic heart valve 702 and/or as an estimated percent deployment of the stented prosthetic heart valve 702. For example, a longitudinal location of each of the marker bodies 740 can be correlated to an estimated percent deployment of the stented prosthetic heart valve 702.

[85] Portions of another related embodiment delivery system 750 in accordance with principles of the present disclosure are shown in simplified form in FIG. 14B, along with a stented prosthetic heart valve 752. The system 750 includes a delivery device 760 (referenced generally) and a plurality of feedback sensors 762. Though not shown, the system 750 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 760 can assume any of the forms described above, and generally includes a delivery sheath assembly 770 and an inner shaft assembly 772 (referenced generally). Commensurate with the above descriptions, the delivery device 760 is configured such that in a loaded state, the stented prosthetic heart valve 752 is collapsed over, and temporarily connected to, the inner shaft assembly 772 and contained within the delivery sheath assembly 770. In the view of FIG. 14B, the delivery sheath assembly 770 has been partially retracted from over the stented prosthetic heart valve 752.

[86] The feedback sensors 762 are attached to or carried by the delivery sheath assembly 770, and are configured to electronically interface with other features provided with the inner shaft assembly 772 and/or the stented prosthetic heart valve 752 as described below. The feedback sensors 762 are electronically connected to the user interface (not shown) or other device programmed to receive and act upon data signaled by the feedback sensors 762. The feedback sensors 762 are longitudinally spaced from one another at pre-determined locations each having a known spatial relationship or location relative to a distal end 780 of the delivery sheath assembly 770.

[87] In particular, the feedback sensors 762 are configured to sense or measure electrical resistance (or other electrical property) of a marker body 790 (referenced generally) provided along the inner shaft assembly 772 and/or along the stented prosthetic heart valve 752. For example, it will be recalled that the inner shaft assembly 772 is connected to the stented prosthetic heart valve 752 at a known longitudinal location in the loaded state. The marker body 790 can be at or in close proximity to this known location of the stented prosthetic heart valve 752. During a deployment procedure, as the delivery

sheath assembly 770 is retracted relative to the stented prosthetic heart valve 752, and thus relative to the inner shaft assembly 772, sequential ones of the feedback sensors 762 will electrically interface with the marker body 790 (e.g., sense or measure a resistance as the corresponding feedback sensor 762 passes over the marker body 790). This information, in turn, can be provided to a clinician as feedback information indicative of the extent to which the distal end 780 of the delivery sheath assembly 770 has been retracted relative to the stented prosthetic heart valve 752 and/or as an estimated percent deployment of the stented prosthetic heart valve 752. For example, a longitudinal location of each of the feedback sensors 762 can be correlated to an estimated percent deployment of the stented prosthetic heart valve 752.

[88] Feedback information relating to percent deployment and/or extent of outer sheath assembly retraction can be generated and provided to the clinician in various other manners in accordance with principles of the present disclosure. Marks on the outer sheath assembly, stops, bumps, or other tactile feedback or audible features can communicate to the clinician that the outer delivery sheath assembly has been retracted to a sufficient degree such that the partially deployed stented prosthetic heart valve is functioning with sufficient flow so that the patient is not at risk from a hemodynamic perspective. Alternatively or in addition, the delivery systems of the present disclosure can provide the clinician with feedback information indicative of the delivery sheath assembly having been retracted to a point where the stented prosthetic heart valve cannot be recaptured or re-sheathed (e.g., marks on the outer sheath assembly, stops, bumps or other tactile or audible features).

[89] Portions of another embodiment delivery system 800 in accordance with principles of the present disclosure are shown in FIG. 15 in delivering a stented prosthetic heart valve 802 to a target site 804. In general terms, the delivery system 800 may be configured to provide feedback information to a clinician indicative of possible leakage (e.g., paravalvular leakage) about the deployed or partially deployed stented prosthetic heart valve 802. The system 800 includes a delivery device 810 and at least one feedback sensor 812. Though not shown, the system 800 can further include a user interface akin to any of the user interfaces of the present disclosure. The delivery device 810 can assume any of the forms described above, and may include a delivery sheath assembly 820 and an inner shaft assembly 822. As a point of reference, FIG. 15 illustrates the delivery device

800 in a partial deployment state in which the delivery sheath assembly 820 has been partially retracted from over the stented prosthetic heart valve 802.

[90] In one embodiment, the feedback sensor 812 is carried by the inner shaft assembly 822 at a location distal the stented prosthetic heart valve 802. The feedback sensor 812 is electronically connected to the user interface (not shown) or other device programmed to receive and act upon data signaled by the feedback sensor 812. In some embodiments, the feedback sensor 812 is configured to detect or sense a marker released into the bloodstream, such as a dye or other biocompatible chemical. More particularly, the delivery system 800 is configured to selectively release the dye or other chemical marker 830 at a location proximal the prosthetic heart valve 802, for example via a port 832 formed in or by the inner shaft assembly 822. During a deployment procedure and following initial, partial deployment of the stented prosthetic heart valve 802 (e.g., the arrangement of FIG. 15) and/or following complete deployment, the dye or other chemical 830 is released. Release may be timed with opening and closing of the stented prosthetic heart valve 802 (e.g., via use of pressure sensors (blood pressure sensors) or flow sensors). The delivery system 800 can be designed so that he stented prosthetic heart valve 802 does not need to be fully deployed to test the fit of the prosthetic heart valve 802 within the target site 804. For example, paravalvular leakage, or the seal between the circumference of the prosthetic heart valve 802 and tissue of the target site 804 can be assessed with the prosthetic heart valve 802 in a partially deployed configuration and/or a fully deployed configuration. Under circumstances where the feedback chemical sensor 812 does not sense or otherwise indicate presence of the chemical marker 830, the clinician is provided with feedback information indicating that leakage is not occurring across the prosthetic heart valve 802. Conversely, where the feedback chemical sensor 812 detects or otherwise indicates presence of the chemical marker (e.g., as illustrated at 840 in FIG. 15), the clinician is provided with feedback information indicating that leakage across the prosthetic heart valve 802 (e.g., paravalvular leakage) is occurring and thus that the stented prosthetic heart valve 802 is not positioned correctly relative to the target site 804. Depending upon the type of delivery or approach of the prosthetic heart valve 802 (e.g., antegrade or retrograde delivery), the feedback sensor 812 may be located along the delivery system 800 either proximal or distal to the prosthetic heart valve 802. In addition, the feedback sensor 812 may be located upstream or downstream of the prosthetic heart valve 802 depending upon the delivery system 800 and the desired test or tests to be

performed. In most embodiments, the feedback sensor 812 will be positioned on the opposite side of the prosthetic heart valve 802 from where the chemical marker 830 is released.

[91] In addition or alternatively, the feedback sensor 812 and additional feedback sensors (not shown) can be blood pressure or flow sensors located on the delivery system 800 proximal and distal to the prosthetic heart valve 802 to test for proper functioning, position and sealing of the stented prosthetic heart valve 802 before complete deployment and release of the stented prosthetic heart valve 802 from the delivery system 800 is effectuated. In some embodiments, the feedback sensor 812 may be located on a separate sensing catheter while the chemical marker 830 is released from the prosthetic valve delivery system 800. In some embodiments, the chemical marker 830 can be released from a separate catheter or delivery system while the feedback sensor 812 is located on the prosthetic valve delivery system 800. In some embodiments, the chemical marker 830 may be released from a catheter or device separate from the prosthetic heart valve delivery system 800 while the feedback sensor 812 is also located on a catheter or device also separate from the prosthetic heart valve delivery system 800. In some embodiments, the chemical marker 830 may be released from the same device as the feedback sensor 812 is located.

[92] The delivery systems, devices and methods of the present disclosure provide a marked improvement over previous designs. By providing the clinician with feedback information relating to a location and/or spatial orientation of the loaded prosthetic heart valve relative to the target site and/or retraction of the outer sheath assembly relative to the loaded prosthetic heart valve, significant improvement in procedure time and efficacy are achieved.

[93] Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure. For example, while the devices and systems of the present disclosure have been described as being useful for delivering a stented prosthetic heart valve, a number of other implantable devices can be employed.

What is claimed is:

1. A delivery device for implanting a stented prosthetic heart valve at a target site, the delivery device comprising:

an inner shaft assembly including a valve retainer configured for temporary connection with a stented prosthetic heart valve in a loaded state;

a delivery sheath assembly co-axially received over the inner shaft assembly and including a capsule configured to contain the stented prosthetic heart valve in the loaded state; and

a feedback sensor associated with the delivery device and adapted to sense a parameter implicating a relationship of the stented prosthetic heart valve relative to the delivery sheath assembly.

2. The delivery device of claim 1, wherein the feedback sensor is selected from the group consisting of a force transducer, a pressure sensor, a magnetic sensor, an electrical resistance sensor, a flow sensor and an optical sensor.

3. The delivery device of claim 1, wherein the feedback sensor is carried by the capsule.

4 The delivery device of claim 3, wherein the feedback sensor is carried by the handle assembly.

5. The delivery device of claim 1, further comprising a user interface electronically connected to the feedback sensor and configured to convey information relating to the sensed parameter to a clinician.

6. The delivery device of claim 1, wherein the handle assembly includes an actuator mechanism, a motor and a linear actuator.

7. The delivery device of claim 6, wherein the motor can transmit a torque to the linear actuator to generate resistance forces on the actuator mechanism in response to signals from the feedback indicator.

8. The delivery device of claim 6, wherein the motor is configured to vibrate in response to signals from the feedback indicator.

9. The delivery device of claim 6, wherein two feedback sensors are positioned on respective ends of the linear actuator; wherein the feedback sensors indicate when the capsule is fully retracted from the prosthetic heart valve and when the capsule is fully covering the prosthetic heart valve.

10. The delivery device of claim 1, wherein the delivery sheath includes a tip proximate the capsule; wherein the parameter includes a distance the capsule has traveled relative to the tip.

11. The delivery device of claim 1, wherein the parameter is an extent to which the stented prosthetic heart valve has been exposed by retraction of the capsule.

12. A delivery device for implanting a stented prosthetic heart valve at a target site, the delivery device comprising:

a handle assembly;

an inner shaft assembly connected to the handle assembly, the inner shaft assembly including a valve retainer configured for temporary connection with a stented prosthetic heart valve in a loaded state;

a delivery sheath assembly connected to the handle assembly; the delivery sheath assembly co-axially received over the inner shaft assembly and including a capsule configured to contain the stented prosthetic heart valve in the loaded state; and

a first feedback sensor; wherein the first feedback sensor indicates a percentage in which capsule has been retracted with respect to the stented prosthetic heart valve.

13. The delivery device of claim 12, wherein the feedback sensor is selected from the group consisting of a force transducer, a pressure sensor, a magnetic sensor, an electrical resistance sensor, a flow sensor and an optical sensor.

14. The delivery device of claim 12, wherein the handle assembly includes a linear actuator that controls the position of the capsule; wherein the linear actuator defines two ends.

15. The delivery device of claim 14, wherein the first feedback sensor is in the handle assembly; the handle assembly including a second feedback sensor, one of the first and second feedback sensors at each end of the linear actuator.

16. The delivery device of claim 14, the delivery device further comprising an actuator mechanism that effectuates movement of the outer sheath assembly and a motor that transits a torque to the linear actuator, with the linear actuation configured to generate a resistive force on the actuator mechanism.

17. The delivery device of claim 12, further comprising a user interface electronically connected to the first feedback sensor and configured to convey information relating to the position of the capsule.

18. The delivery device of claim 1, wherein the first feedback sensor located on the capsule.

19. The delivery device of claim 1, the delivery device further including a motor, wherein the motor is configured to vibrate in response to signals from the first feedback sensor.

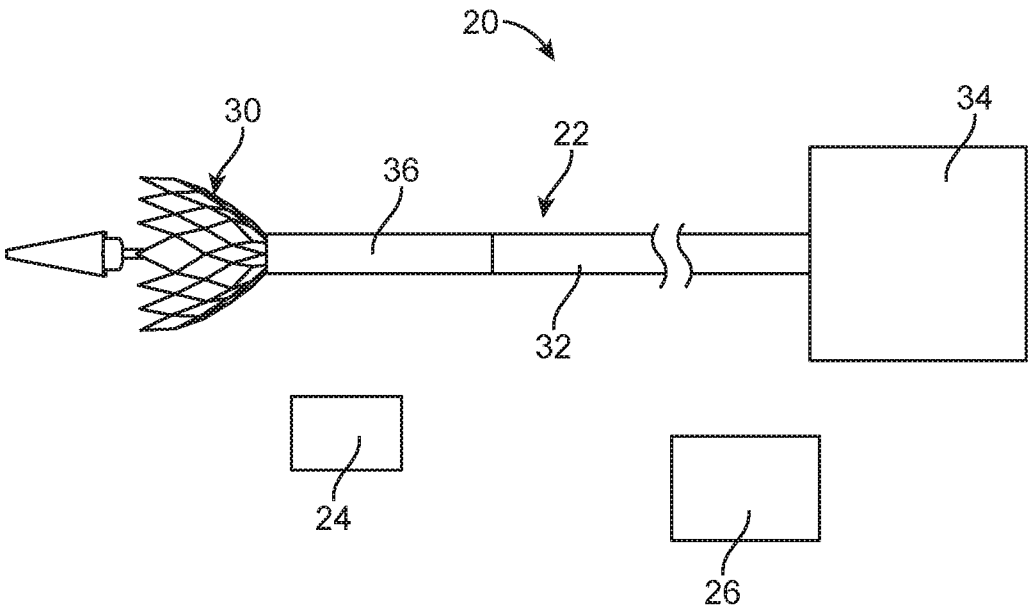

FIG. 1

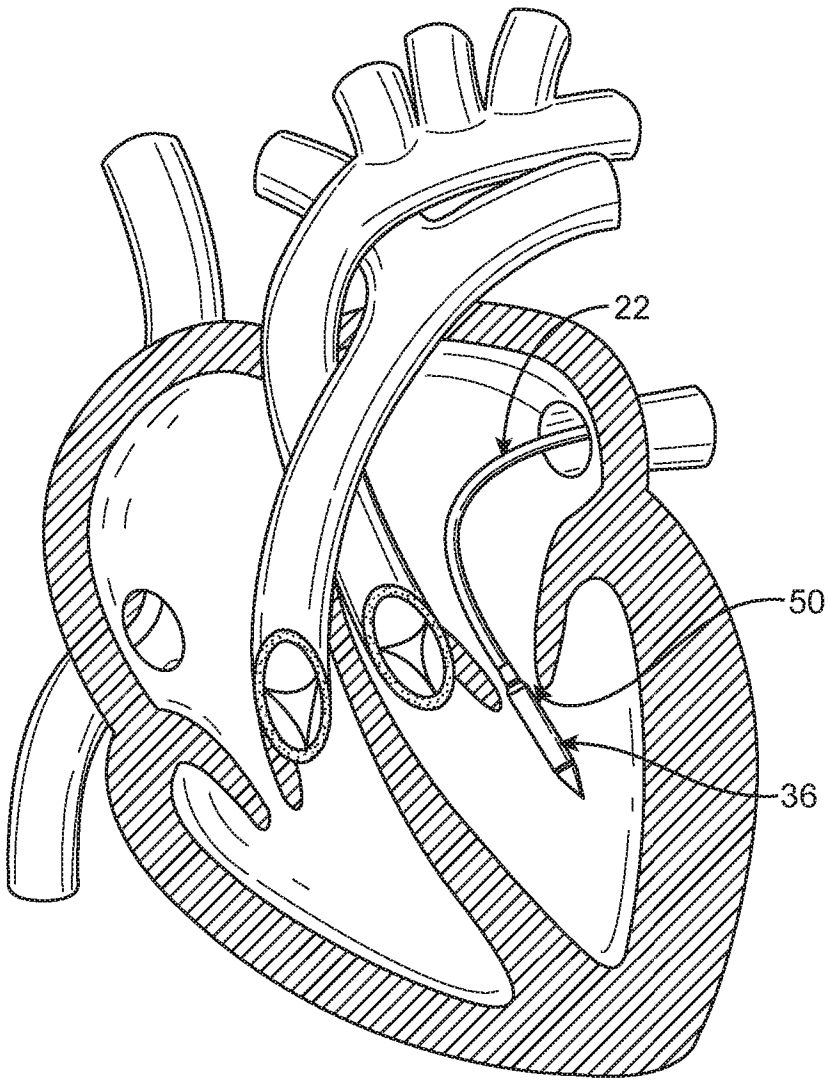

FIG. 2A

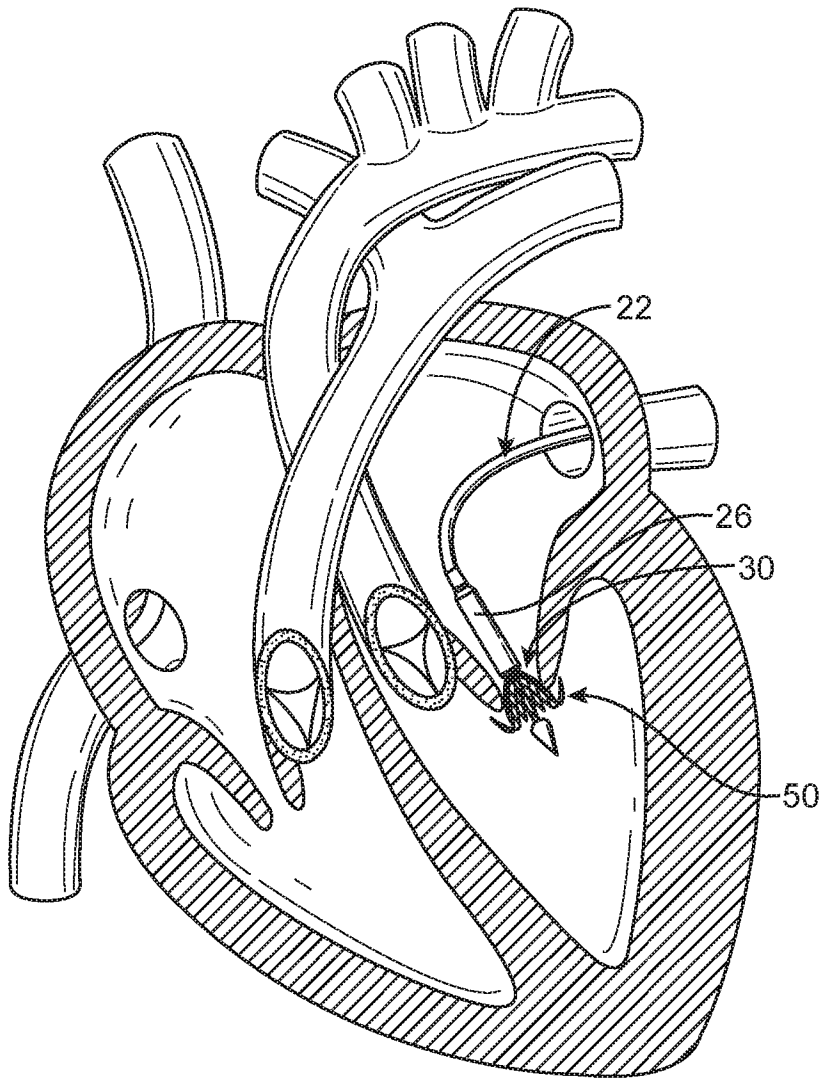

FIG. 2B

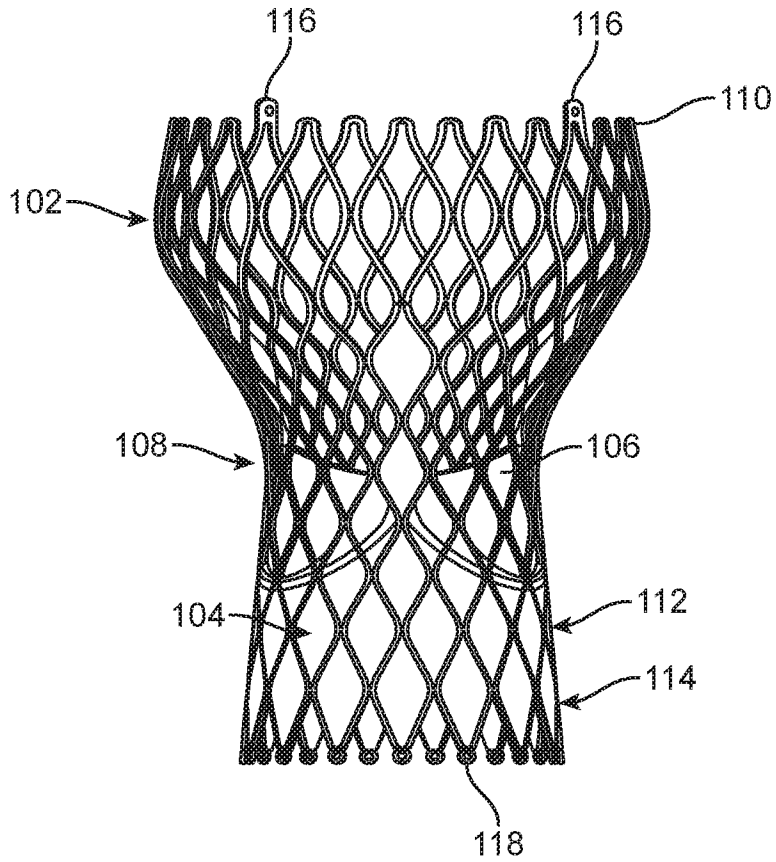
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FIG. 3A

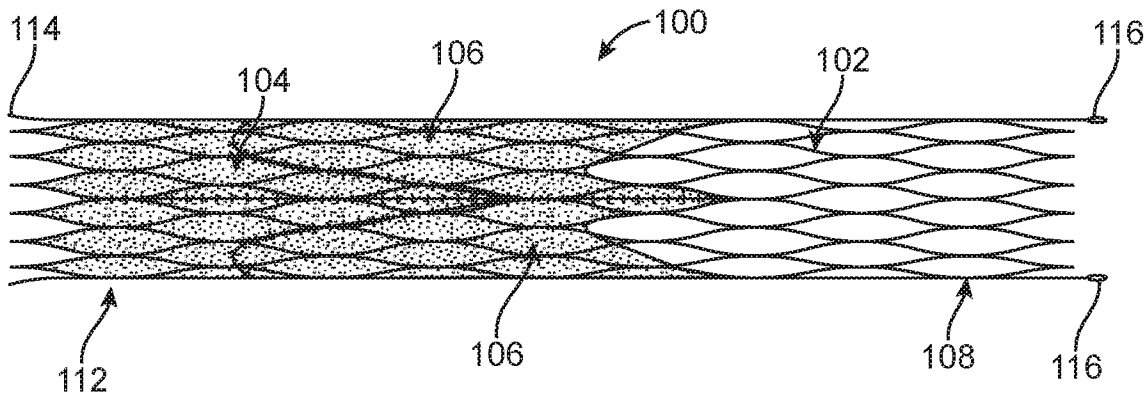
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FIG. 3B

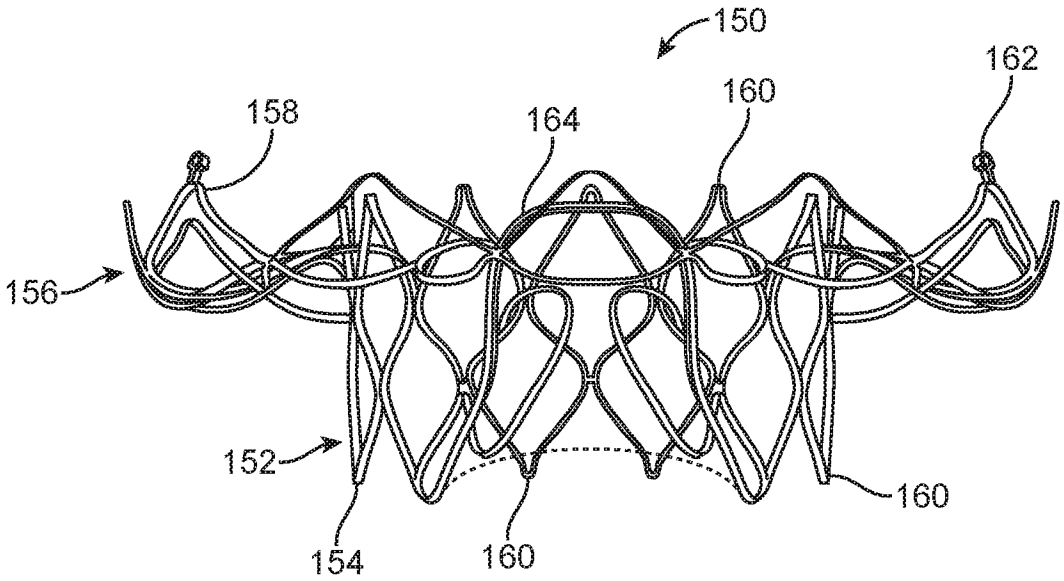

FIG. 4

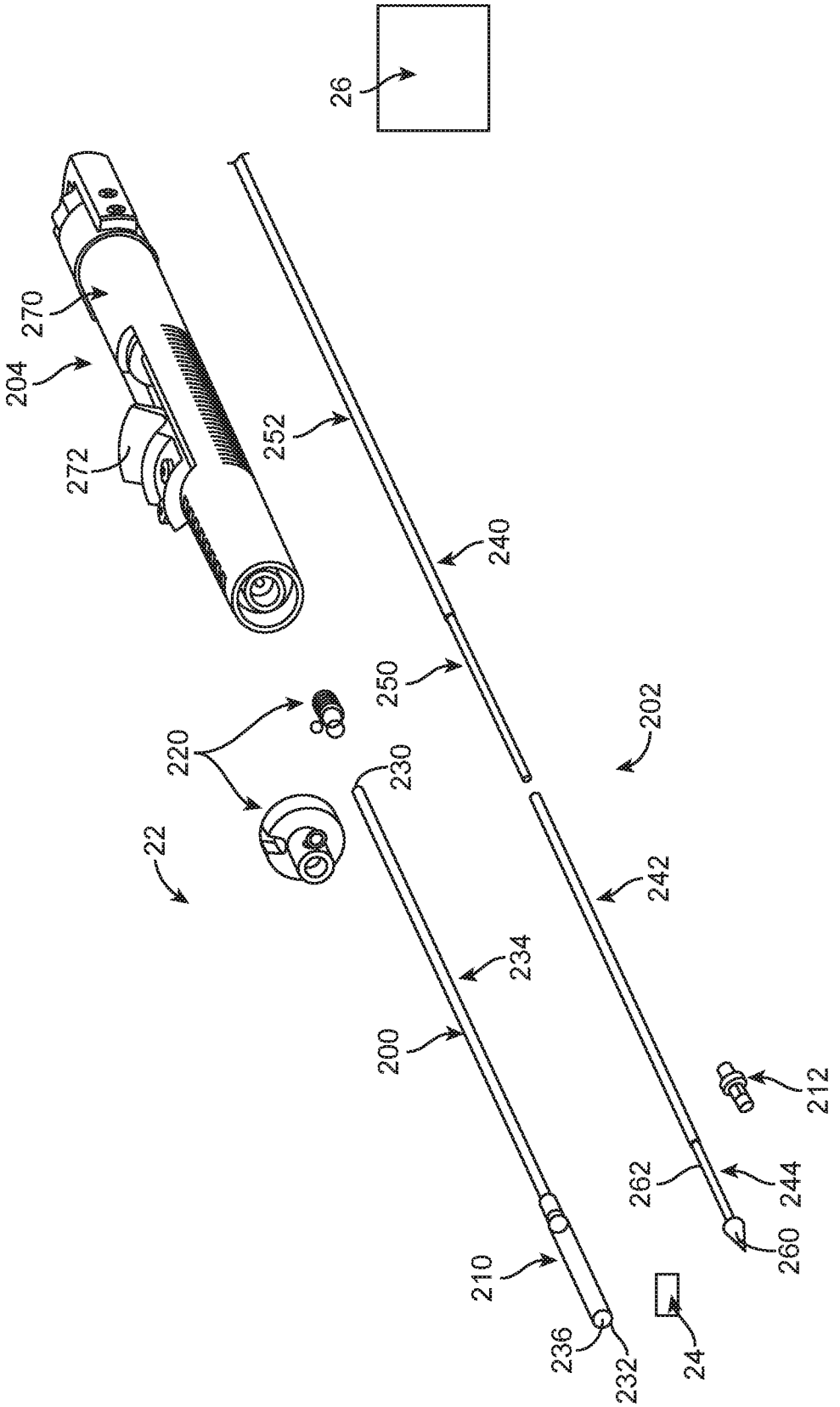
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FIG. 5A

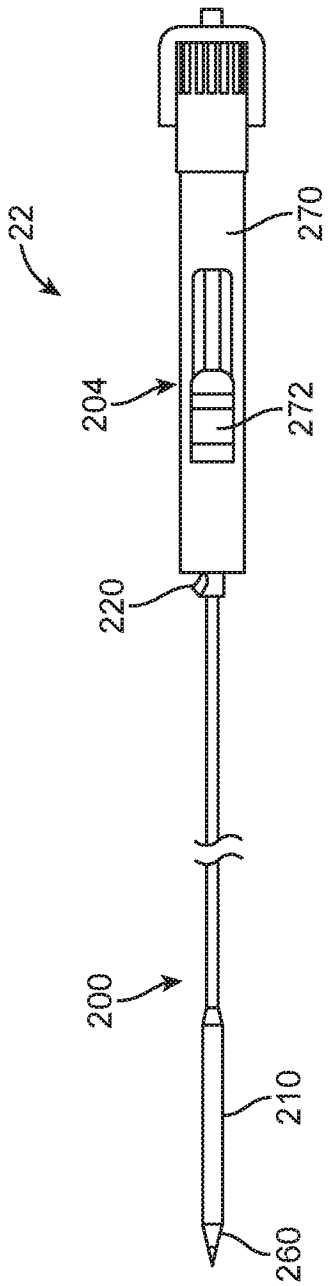

FIG. 5B

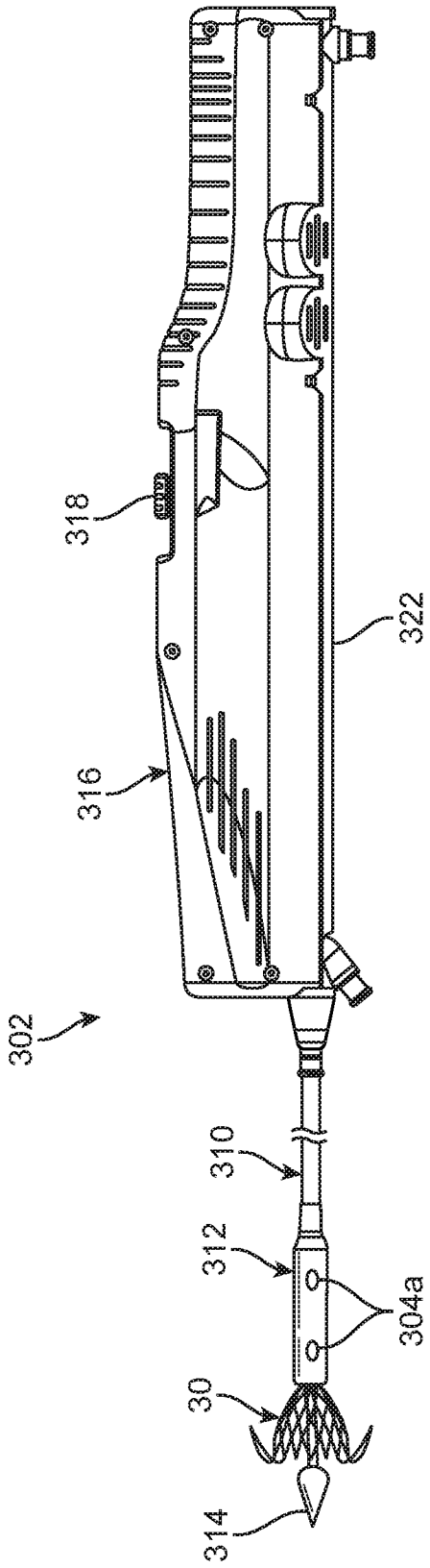

FIG. 6A

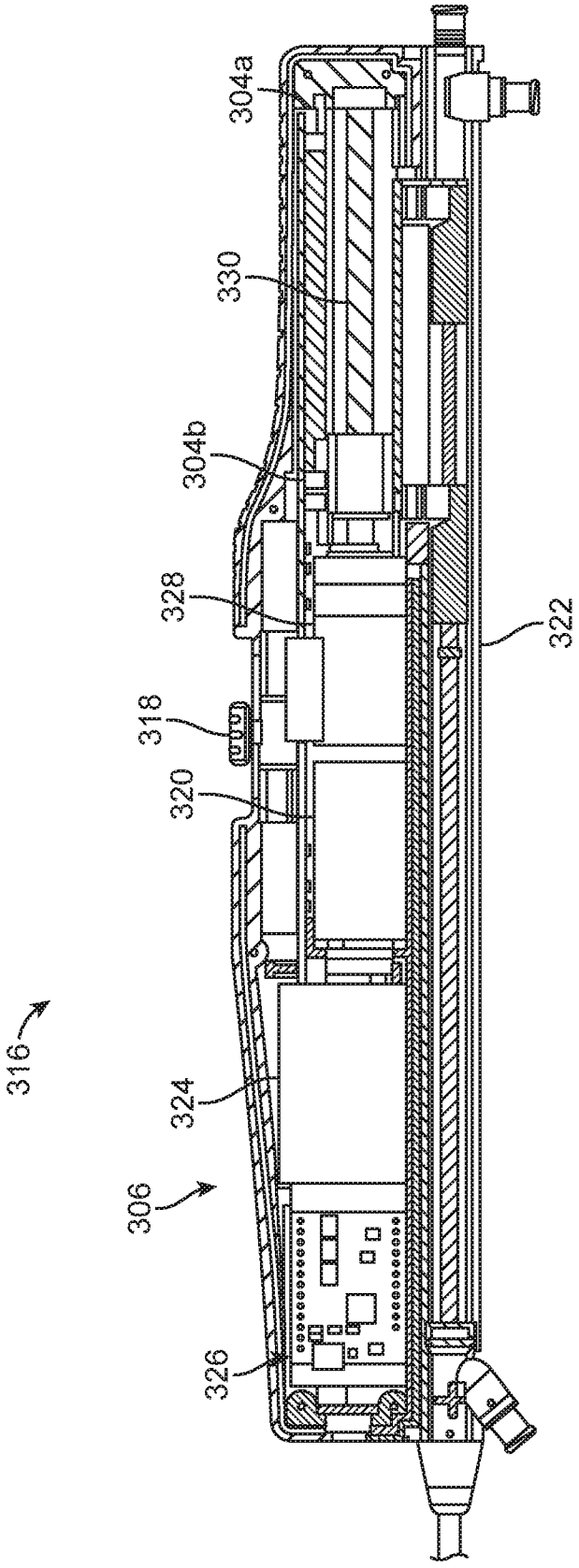

FIG. 6B

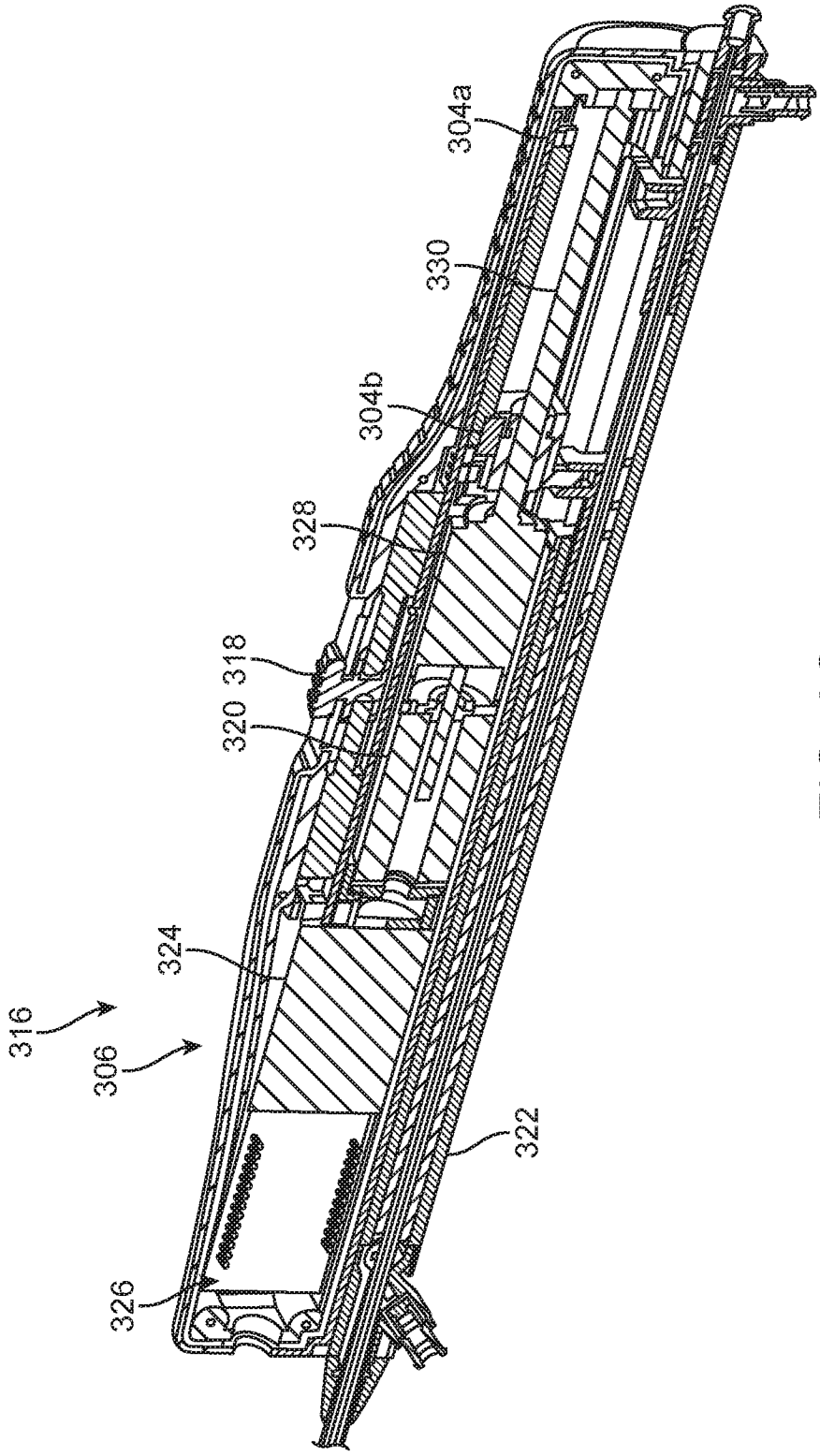

FIG. 6C

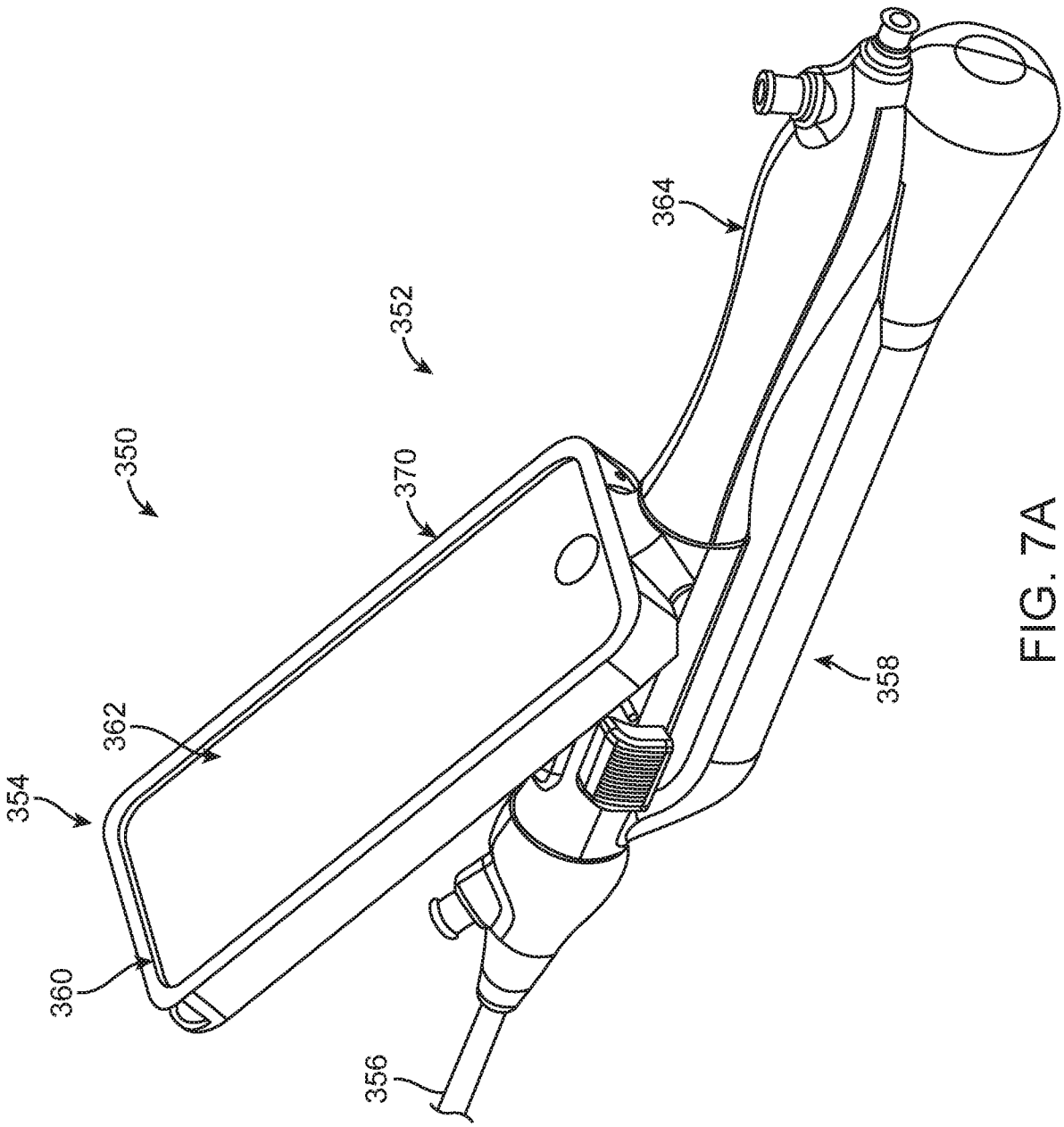

FIG. 7A

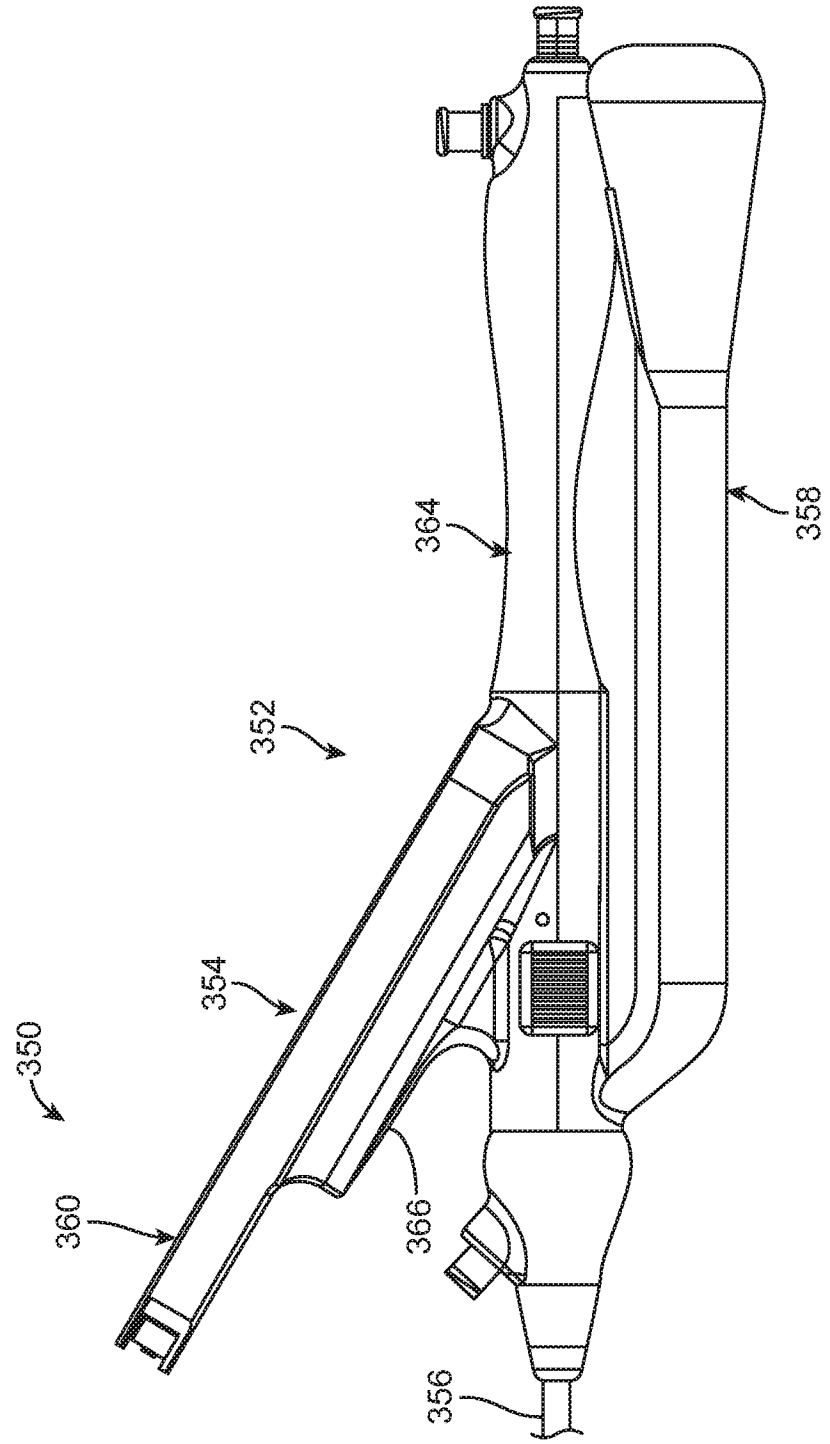

FIG. 7B

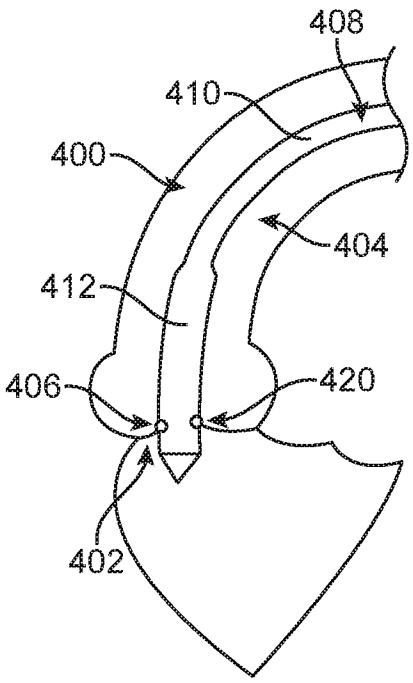
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FIG. 8A

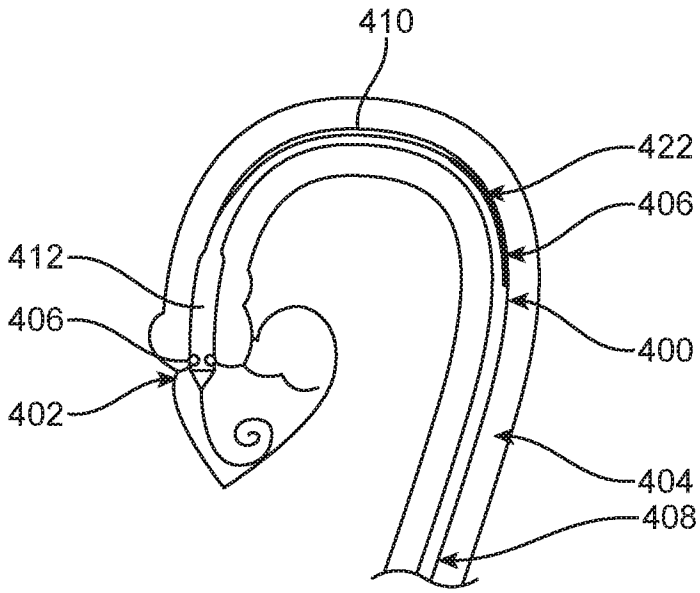
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FIG. 8B

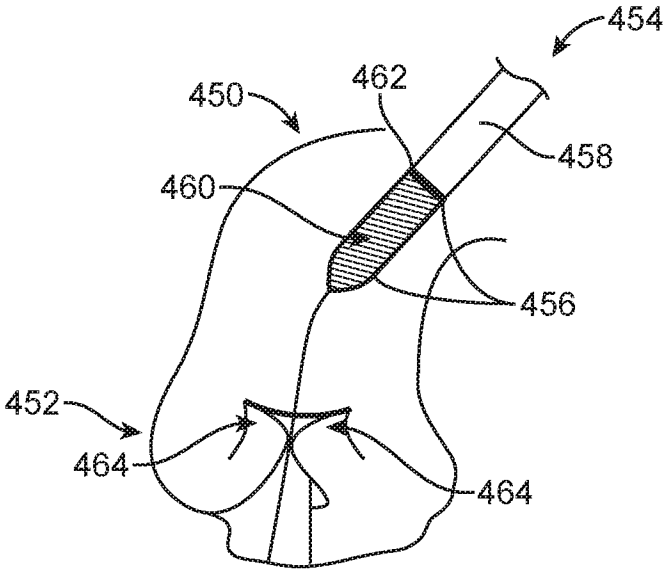

FIG. 9A

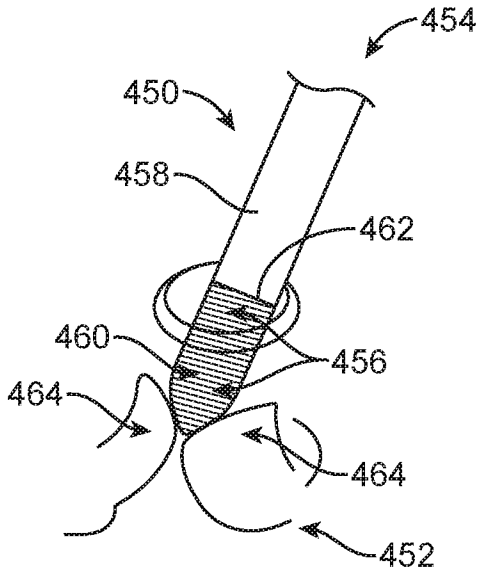

FIG. 9B

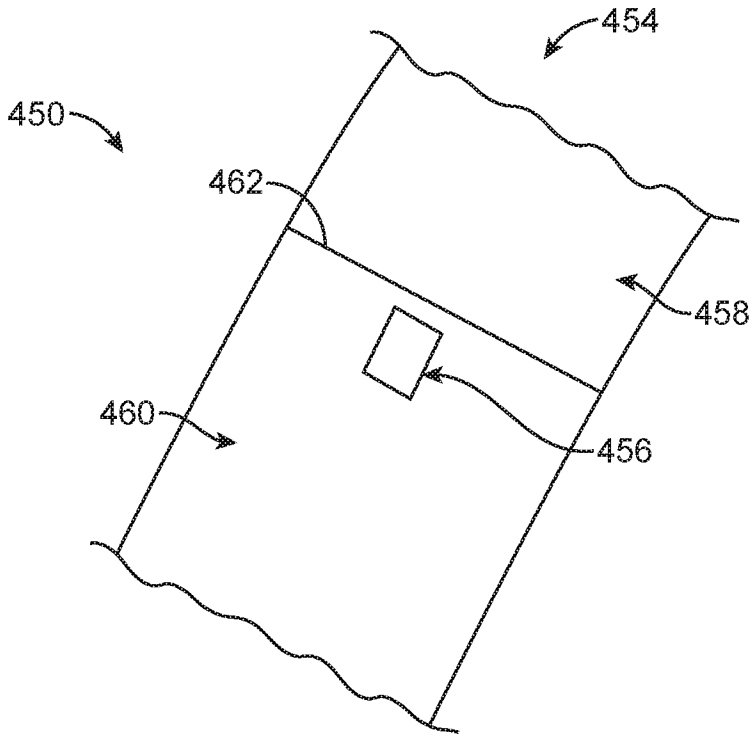

FIG. 9C

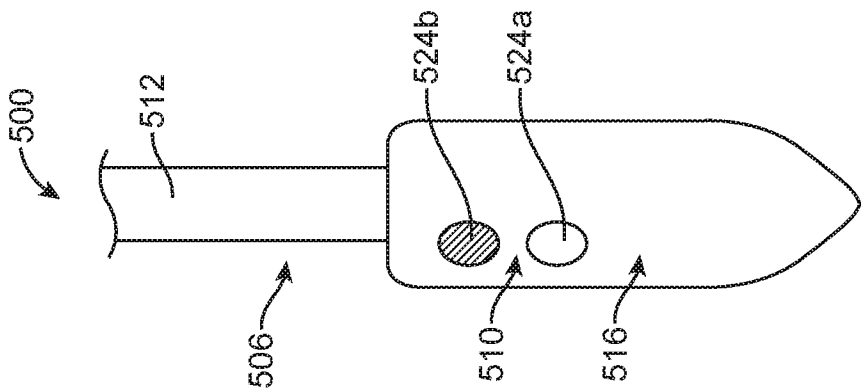

FIG. 10C

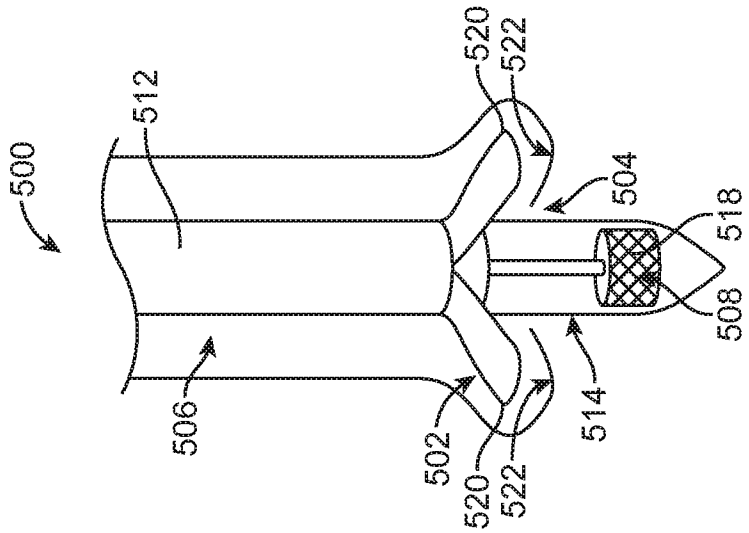

FIG. 10B

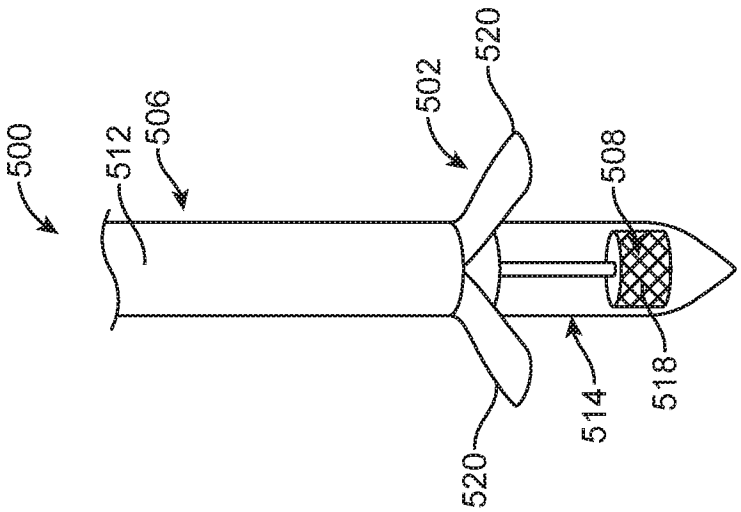

FIG. 10A

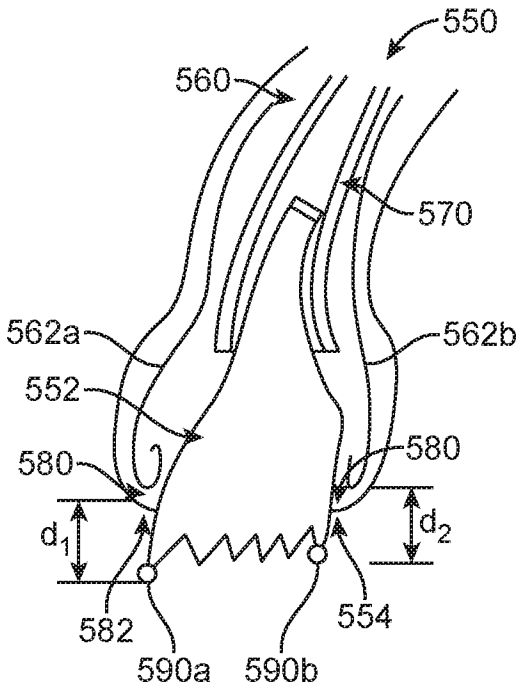

FIG. 11

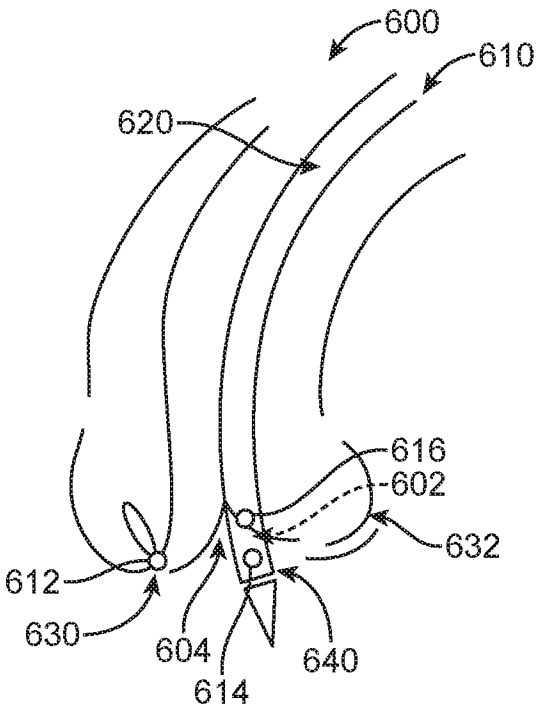

FIG. 12A

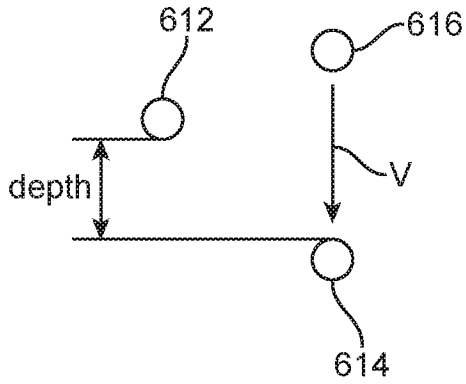

FIG. 12B

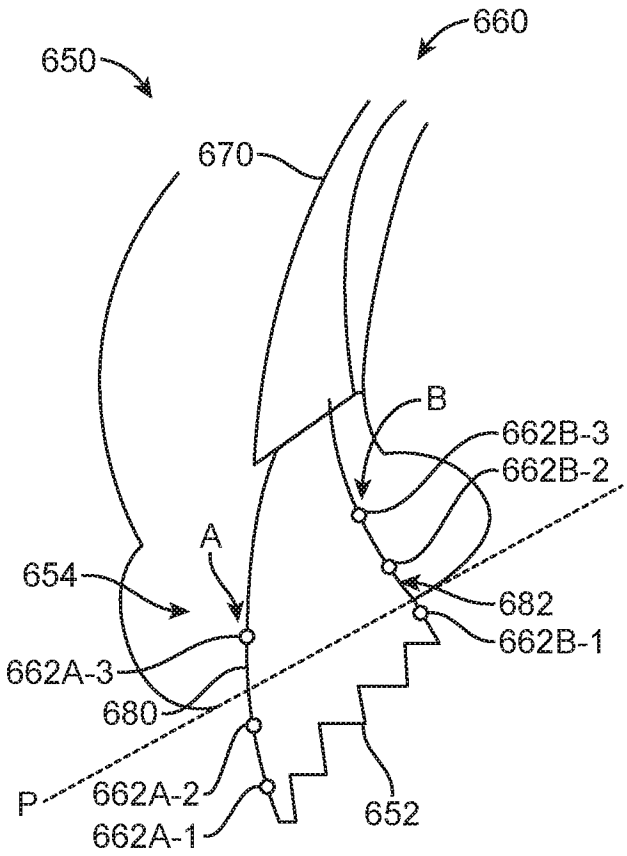
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FIG. 13

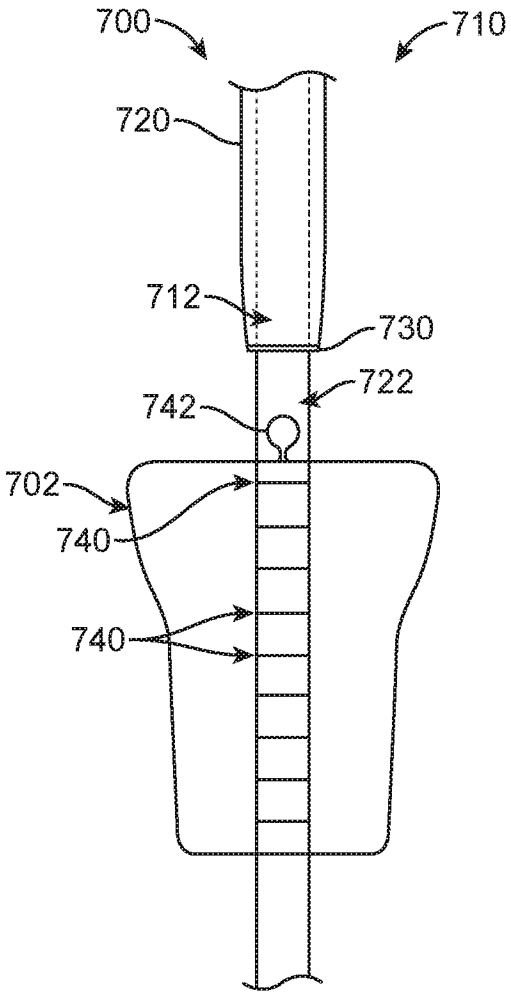

FIG. 14A

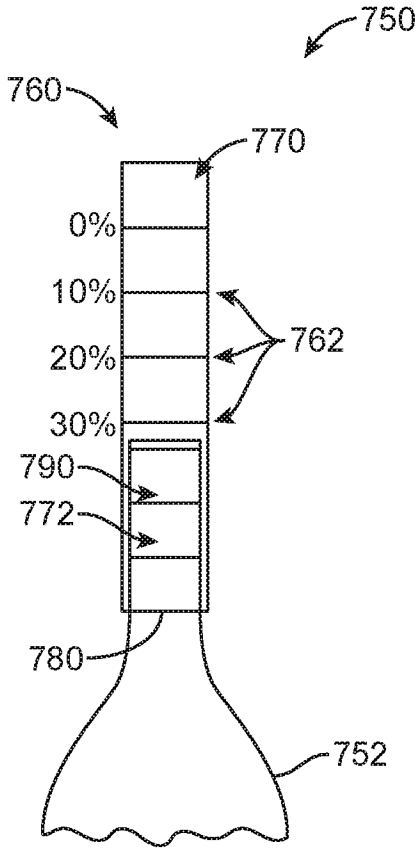

FIG. 14B

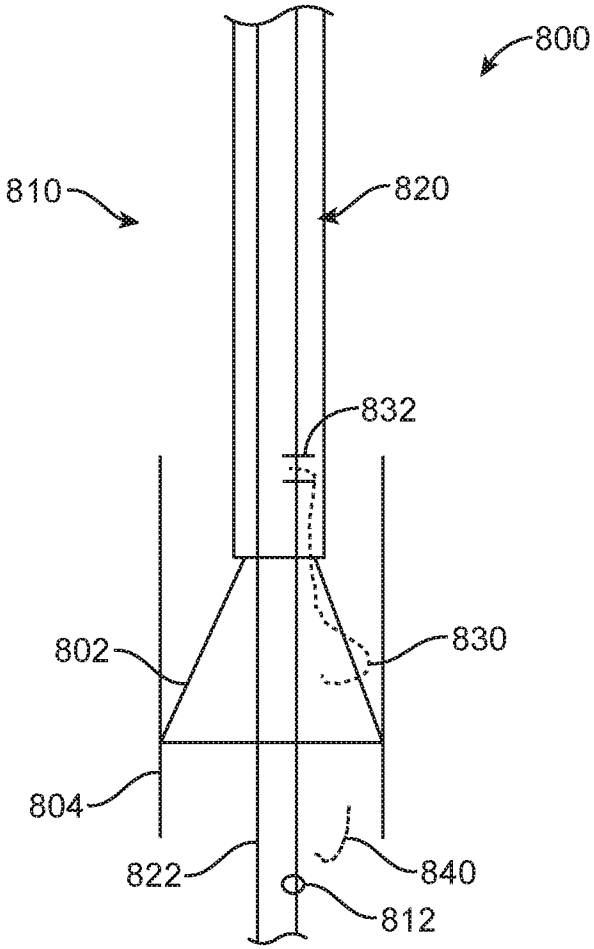

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/066636

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24
ADD.

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)
A61F

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/198346 A1 (KEOGH JAMES R [US] ET AL) 5 August 2010 (2010-08-05) paragraphs [0011] - [0020], [0046], [0047], [0057] - [0067], [0121] - [0172]; figures 1-9	1-3,5,6, 8,10-13, 17-19
X	US 2013/046373 A1 (CARTLEDGE RICHARD [US] ET AL) 21 February 2013 (2013-02-21) paragraphs [0244] - [0256]	1,2,4-7, 9-18
X	US 2014/257457 A1 (GLAZIER VALERIE J [US] ET AL) 11 September 2014 (2014-09-11)	1,5
A	paragraphs [0002] - [0006], [0032] - [0041]	12
A	US 6 091 980 A (SQUIRE JAMES C [US] ET AL) 18 July 2000 (2000-07-18) the whole document	1,12

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 2016	01/04/2016

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010198346 A1	05-08-2010	US 2010198346 A1	05-08-2010
		US 2013072786 A1	21-03-2013
		US 2014221823 A1	07-08-2014
		WO 2011041123 A2	07-04-2011
US 2013046373 A1	21-02-2013	AU 2012325756 A1	15-05-2014
		CA 2852958 A1	25-04-2013
		CN 104114126 A	22-10-2014
		EP 2768429 A1	27-08-2014
		JP 2014530724 A	20-11-2014
		KR 20140084243 A	04-07-2014
		US 2013046373 A1	21-02-2013
		WO 2013059776 A1	25-04-2013
US 2014257457 A1	11-09-2014	NONE	
US 6091980 A	18-07-2000	NONE	