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(71) Applicant: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92614 (US).

(72) Inventor: **REED, Kurt Kelly**; Edwards Lifesciences, One Edwards Way, Legal Department, Irvine, CA 92614 (US).

(74) Agent: **NASSIF, Linda Allyson**; Edwards Lifesciences, One Edwards Way, Irvine, CA 92614 (US).

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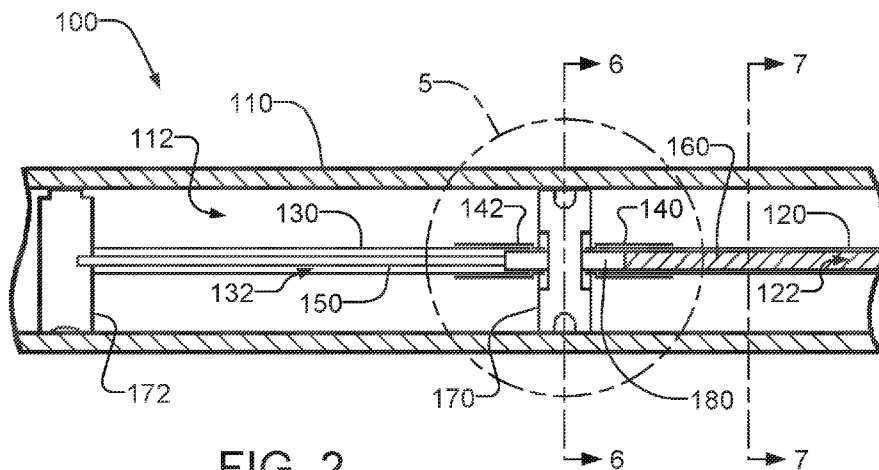


FIG. 2

(57) Abstract: Steerable delivery apparatuses with lumen liner seals and associated methods. In an example, a steerable delivery apparatus includes a flexible tube, a control wire lumen liner at least partially defining a control wire lumen, a control wire disposed within the control wire lumen, a coil sleeve disposed around the control wire, a coil stopper abutting the coil sleeve, and a lumen liner seal that forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper. In another example, a method includes positioning a control wire lumen liner proximate to a coil stopper, positioning a lumen liner seal over a portion of each of the control wire lumen liner and the coil stopper, and transitioning the lumen liner seal to a contracted configuration to form an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.



LUMEN LINER SEALS AND ASSOCIATED METHODS FOR PROSTHETIC IMPLANT DELIVERY APPARATUSES

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/507,710, filed June 12, 2023, which is incorporated by reference herein in its entirety.

FIELD

[0002] The present disclosure relates to delivery apparatuses for implantable prosthetic devices.

BACKGROUND

[0003] The human heart can suffer from various valvular diseases. These valvular diseases can result in significant malfunctioning of the heart and ultimately require repair of the native valve or replacement of the native valve with an artificial valve. There are a number of known repair devices (e.g., stents) and artificial valves, as well as a number of known methods of implanting these devices and valves in humans. Percutaneous and minimally-invasive surgical approaches are used in various procedures to deliver prosthetic medical devices to locations inside the body that are not readily accessible by surgery or where access without surgery is desirable. In one specific example, a prosthetic heart valve can be mounted in a crimped state on the distal end of a delivery apparatus and advanced through the patient's vasculature (e.g., through a femoral artery and the aorta) until the prosthetic heart valve reaches the implantation site in the heart. The prosthetic heart valve is then expanded to its functional size, for example, by inflating a balloon on which the prosthetic valve is mounted, actuating a mechanical actuator that applies an expansion force to the prosthetic heart valve, or by deploying the prosthetic heart valve from a sheath of the delivery apparatus so that the prosthetic heart valve can self-expand to its functional size.

[0004] In some examples, the prosthetic heart valve and/or a prosthetic docking device for supporting the prosthetic heart valve delivered to the implantation site via a steerable delivery apparatus. The steerable delivery apparatus can include a flexible tube and one or more control wires disposed in respective control wire lumens supported by the flexible tube. It is

desirable to manufacture such steerable catheters such that no unwanted material enters the control wire lumens. Accordingly, there is a need for steerable catheters with lumen liner seals and associated methods.

SUMMARY

[0005] Described herein delivery apparatuses for prosthetic implants (e.g., prosthetic heart valves) and methods for manufacturing the delivery apparatuses. The disclosed delivery apparatuses and methods can, for example, provide protection against unwanted material entering one or more lumens of the delivery apparatus during manufacture thereof. As such, the devices and methods disclosed herein can, among other things, overcome one or more of the deficiencies of typical prosthetic heart valves and their delivery apparatus.

[0006] A delivery apparatus for a prosthetic implant can comprise a handle and one or more shafts coupled to the handle.

[0007] A shaft for a delivery apparatus can comprise a lumen through which one or more other components of the delivery apparatus (e.g., a control wire) and/or a prosthetic implant can be disposed.

[0008] In some examples, a lumen liner seal can be used to form an at least substantially fluid-tight seal between a lumen liner and one or more other components of the shaft of the delivery apparatus.

[0009] In some examples, a delivery apparatus can comprise a lumen liner seal that forms an at least substantially fluid-tight seal between a control wire lumen liner and a coil stopper.

[0010] In some examples, the lumen liner seal is at least substantially tubular.

[0011] In some examples, the lumen liner seal is configured to transition from an expanded configuration to a contracted configuration.

[0012] In some examples, the lumen liner seal is formed of a heat-shrink material.

[0013] In a representative example, a steerable delivery apparatus for delivering a device to a native valve of a patient's heart comprises a flexible tube at least partially defining a main lumen, a control wire lumen liner at least partially defining a control wire lumen, a control wire disposed within the control wire lumen, a coil sleeve disposed around the control wire, a coil stopper abutting the coil sleeve, and a lumen liner seal surrounding an end of the control

wire lumen liner and a portion of the coil stopper such that the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0014] In some examples, a delivery apparatus comprises one or more of the components recited in Examples 1-20 below.

[0015] A method of manufacturing a steerable delivery apparatus can comprise positioning a lumen liner seal over a portion of a component that at least partially defines a lumen.

[0016] In some examples, a method of manufacturing a steerable delivery apparatus can comprise positioning a lumen liner seal over a portion of each of a control wire lumen liner and a coil stopper and transitioning the lumen liner seal to a contracted configuration in which the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0017] In some examples, the positioning the control wire lumen liner comprises positioning such that the control wire lumen liner extends over a portion of the coil stopper.

[0018] In some examples, the method comprises positioning a coil sleeve around a control wire within the control wire lumen liner, and the positioning the lumen liner seal comprises positioning such that the lumen liner seal extends partially over the coil sleeve.

[0019] In some examples, the positioning the lumen liner seal is performed with the lumen liner seal in an expanded configuration, in which the lumen liner seal is sized to be slid over the control wire lumen liner, and the transitioning the lumen liner seal to the contracted configuration comprises radially shrinking the lumen liner seal such that the lumen liner seal is restricted from translating relative to the control wire lumen liner.

[0020] In some examples, the method comprises reflowing a thermoplastic elastomer to form a flexible tube around at least a portion of the control wire lumen liner

[0021] In a representative example, a method of manufacturing a steerable delivery apparatus comprises positioning a control wire lumen liner proximate to a coil stopper, positioning a lumen liner seal over a portion of each of the control wire lumen liner and the coil stopper, and transitioning the lumen liner seal to a contracted configuration in which the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0022] In some examples, a method of manufacturing a steerable delivery apparatus comprises one or more of the elements recited in Examples 21-38 below.

[0023] The various innovations of this disclosure can be used in combination or separately. This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. The foregoing and other objects, features, and advantages of the disclosure will become more apparent from the following detailed description, claims, and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] FIG. 1 is a partial perspective view of a delivery device for implanting a prosthetic anchoring device at a native valve of a heart using a transseptal technique according to an example.

[0025] FIG. 2 is a schematic partial cross-sectional side view of a steerable delivery apparatus including a control wire, two lumen liner seals, and a proximal coil sleeve according to an example.

[0026] FIG. 3 is a schematic side view of a portion of a steerable delivery apparatus prior to formation of a flexible tube according to an example.

[0027] FIG. 4 is a schematic side view of the portion of the steerable delivery apparatus of FIG. 3 with a proximal lumen liner seal and a distal lumen liner seal loosely positioned relative to a coil stopper according to an example.

[0028] FIG. 5 is a schematic partial cross-sectional side view of the steerable delivery apparatus of FIG. 2 detailing the region labeled 5 in FIG. 2.

[0029] FIG. 6 is a schematic cross-sectional end view of the steerable delivery apparatus of FIG. 2 as viewed along the line 6-6 in FIG. 2.

[0030] FIG. 7 is a schematic cross-sectional end view of the steerable delivery apparatus of FIG. 2 as viewed along the line 7-7 in FIG. 2.

[0031] FIG. 8 is a schematic partial cross-sectional side view of a steerable delivery apparatus including a control wire, two lumen liner seals, and two coil sleeves according to an example.

[0032] FIG. 9 is a schematic side view of a steerable delivery apparatus including two control wires according to an example.

[0033] FIG. 10 is a schematic side view of a portion of the steerable delivery apparatus of FIG. 9.

[0034] FIG. 11 is a schematic cross-sectional end view of the steerable delivery apparatus of FIG. 9 as viewed along the line 11-11 in FIG. 9.

[0035] FIG. 12 is a schematic cross-sectional end view of the steerable delivery apparatus of FIG. 9 as viewed along the line 12-12 in FIG. 9.

[0036] FIG. 13 is a schematic cross-sectional end view of the steerable delivery apparatus of FIG. 9 as viewed along the line 13-13 in FIG. 9.

DETAILED DESCRIPTION

General Considerations

[0037] For purposes of this description, certain aspects, advantages, and novel features of examples of this disclosure are described herein. The disclosed methods, apparatus, and systems should not be construed as being limiting in any way. Instead, the present disclosure is directed toward all novel and nonobvious features and aspects of the various disclosed examples, alone and in various combinations and sub-combinations with one another. The methods, apparatus, and systems are not limited to any specific aspect or feature or combination thereof, nor do the disclosed examples require that any one or more specific advantages be present or problems be solved.

[0038] Although the operations of some of the disclosed examples are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth below. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be

used in conjunction with other methods. Additionally, the description sometimes uses terms like “provide” or “achieve” to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art.

[0039] As used in this application and in the claims, the singular forms “a,” “an,” and “the” include the plural forms unless the context clearly dictates otherwise. Additionally, the term “includes” means “comprises.” Further, the term “coupled” generally means physically, mechanically, chemically, magnetically, and/or electrically coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

[0040] As used herein, the term “proximal” refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation site. As used herein, the term “distal” refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation site. Thus, for example, proximal motion of a device is motion of the device away from the implantation site and toward the user (e.g., out of the patient’s body), while distal motion of the device is motion of the device away from the user and toward the implantation site (e.g., into the patient’s body). The terms “longitudinal” and “axial” refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

[0041] As used herein, the term “approximately” and “about” means the listed value and any value that is within 10% of the listed value. For example, “about 1 mm” means any value between about 0.9 mm and about 1.1 mm, inclusive.

[0042] Directions and other relative references (e.g., inner, outer, upper, lower, etc.) may be used to facilitate discussion of the drawings and principles herein, but are not intended to be limiting. For example, certain terms may be used such as “inside,” “outside,” “top,” “down,” “interior,” “exterior,” and the like. Such terms are used, where applicable, to provide some clarity of description when dealing with relative relationships, particularly with respect to the illustrated examples. Such terms are not, however, intended to imply absolute relationships, positions, and/or orientations. For example, with respect to an object, an “upper” part can

become a “lower” part simply by turning the object over. Nevertheless, it is still the same part and the object remains the same. As used herein, “and/or” means “and” or “or,” as well as “and” and “or.”

[0043] As used herein, “e.g.” means “for example,” and “i.e.” means “that is.”

Introduction to the Disclosed Technology

[0044] Described herein are examples of a steerable delivery apparatus (sometimes referred to as a steerable catheter) that can be used to navigate a subject’s vasculature to deliver an implantable, expandable medical device (e.g., a prosthetic heart valve), tools, agents, or other therapy to a location within the body of a subject. Examples of procedures in which the steerable catheters are useful include neurological, urological, gynecological, fertility (e.g., in vitro fertilization, artificial insemination), laparoscopic, arthroscopic, transesophageal, transvaginal, transvesical, transrectal, and procedures including access in any body duct or cavity. Particular examples include placing implants, including stents, grafts, embolic coils, and the like; positioning imaging devices and/or components thereof, including ultrasound transducers; and positioning energy sources, for example, for performing lithotripsy, RF sources, ultrasound emitters, electromagnetic sources, laser sources, thermal sources, and the like.

[0045] The steerable catheter can include a flexible tube and one or more control wires disposed in respective control wire lumens supported by the flexible tube. It is desirable to manufacture such steerable catheters such that no unwanted material enters the control wire lumens.

[0046] FIG. 1 shows an exemplary delivery device 10 including a steerable delivery apparatus 30 partially enclosed within a guide sheath 20. In the example of FIG. 1, the steerable delivery apparatus 30 is positioned for installing an anchoring device 40 at a native mitral valve annulus 50 using a transseptal technique. The same or similar delivery device also can be used to implant a prosthetic heart valve and/or docking device within the pulmonary artery for replacing the function of a diseased pulmonary valve, such as disclosed in U.S. Patent Application Publication No. 2017/0231756, which is incorporated by reference herein. In another example, the same or similar delivery device also can be used to implant a prosthetic heart valve and/or docking device within the superior or inferior vena cava for

replacing the function of a diseased tricuspid valve, such as disclosed in U.S. Patent Application Publication No. 2019/0000615, which is incorporated by reference herein.

Delivery Techniques

[0047] For implanting a prosthetic valve within the native aortic valve via a transfemoral delivery approach, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral artery and are advanced into and through the descending aorta, around the aortic arch, and through the ascending aorta. The prosthetic valve is positioned within the native aortic valve and radially expanded (e.g., by inflating a balloon, actuating one or more actuators of the delivery apparatus, or deploying the prosthetic valve from a sheath to allow the prosthetic valve to self-expand). Alternatively, a prosthetic valve can be implanted within the native aortic valve in a transapical procedure, whereby the prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the left ventricle through a surgical opening in the chest and the apex of the heart and the prosthetic valve is positioned within the native aortic valve. Alternatively, in a transaortic procedure, a prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the aorta through a surgical incision in the ascending aorta, such as through a partial J-sternotomy or right parasternal mini-thoracotomy, and then advanced through the ascending aorta toward the native aortic valve.

[0048] For implanting a prosthetic valve within the native mitral valve via a transseptal delivery approach, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral vein and are advanced into and through the inferior vena cava, into the right atrium, across the atrial septum (through a puncture made in the atrial septum), into the left atrium, and toward the native mitral valve. Alternatively, a prosthetic valve can be implanted within the native mitral valve in a transapical procedure, whereby the prosthetic valve (on the distal end portion of the delivery apparatus) is introduced into the left ventricle through a surgical opening in the chest and the apex of the heart and the prosthetic valve is positioned within the native mitral valve.

[0049] For implanting a prosthetic valve within the native tricuspid valve, the prosthetic valve is mounted in a radially compressed state along the distal end portion of a delivery apparatus. The prosthetic valve and the distal end portion of the delivery apparatus are inserted into a femoral vein and are advanced into and through the inferior vena cava, and into the right atrium, and the prosthetic valve is positioned within the native tricuspid valve. A similar approach can be used for implanting the prosthetic valve within the native pulmonary valve or the pulmonary artery, except that the prosthetic valve is advanced through the native tricuspid valve into the right ventricle and toward the pulmonary valve/pulmonary artery.

[0050] Another delivery approach is a transatrial approach whereby a prosthetic valve (on the distal end portion of the delivery apparatus) is inserted through an incision in the chest and an incision made through an atrial wall (of the right or left atrium) for accessing any of the native heart valves. Atrial delivery can also be made intravascularly, such as from a pulmonary vein. Still another delivery approach is a transventricular approach whereby a prosthetic valve (on the distal end portion of the delivery apparatus) is inserted through an incision in the chest and an incision made through the wall of the right ventricle (typically at or near the base of the heart) for implanting the prosthetic valve within the native tricuspid valve, the native pulmonary valve, or the pulmonary artery.

[0051] In all delivery approaches, the delivery apparatus can be advanced over a guidewire previously inserted into a patient's vasculature. Moreover, the disclosed delivery approaches are not intended to be limited. Any of the prosthetic valves disclosed herein can be implanted using any of various delivery procedures and delivery devices known in the art.

[0052] Any of the systems, devices, apparatuses, etc. herein can be sterilized (for example, with heat/thermal, pressure, steam, radiation, and/or chemicals, etc.) to ensure they are safe for use with patients, and any of the methods herein can include sterilization of the associated system, device, apparatus, etc. as one of the steps of the method. Examples of heat/thermal sterilization include steam sterilization and autoclaving. Examples of radiation for use in sterilization include, without limitation, gamma radiation, ultra-violet radiation, and electron beam. Examples of chemicals for use in sterilization include, without limitation, ethylene oxide, hydrogen peroxide, peracetic acid, formaldehyde, and glutaraldehyde. Sterilization with hydrogen peroxide may be accomplished using hydrogen peroxide plasma, for example.

Examples of the Disclosed Technology

[0053] FIG. 2 depicts a distal region of an example of a steerable delivery apparatus 100. As shown in FIG. 2, the steerable delivery apparatus 100 includes a flexible tube 110 that at least partially defines a main lumen 112. The main lumen 112 can be sized and/or otherwise configured to accommodate a prosthetic implant (e.g., the anchoring device 40 of FIG. 1 and/or a prosthetic heart valve) for delivery to a target implantation site. The steerable delivery apparatus 100 additionally includes a distal anchor ring 172 and a control wire 150 terminating at and fixedly coupled to the distal anchor ring 172 such that applying tension to the control wire 150 causes the flexible tube 110 to bend in a controlled manner. The steerable delivery apparatus 100 includes a proximal control wire lumen liner 120 at least partially defining a proximal control wire lumen 122 as well as a distal control wire lumen liner 130 at least partially defining a distal control wire lumen 132. The control wire 150 extends through each of the proximal control wire lumen 122 and the distal control wire lumen 132.

[0054] The steerable delivery apparatus 100 additionally includes a proximal coil sleeve 160 disposed within the proximal control wire lumen 122 and around the control wire 150. The proximal coil sleeve 160 can serve to protect the control wire 150 and to prevent the proximal control wire lumen liner 120 and/or the flexible tube 110 from compressing, foreshortening, or buckling when the control wire 150 is pulled. In this manner, the proximal coil sleeve 160 can provide for an anti-whipping or anti-bending effect through the steerable delivery apparatus 100 when the control wire 150 is operated, thereby allowing for full, controlled torqueability of the steerable delivery apparatus 100.

[0055] The steerable delivery apparatus 100 additionally includes a proximal anchor ring 170 disposed in the flexible tube 110 and a coil stopper 180 extending through the proximal anchor ring 170. The coil stopper 180 abuts the proximal coil sleeve 160 and is fixedly coupled to the proximal anchor ring 170. In this manner, the proximal anchor ring 170 and the coil stopper 180 operate to restrict the proximal coil sleeve 160 from translating in a distal direction beyond the coil stopper 180.

[0056] As shown in FIG. 2, the proximal anchor ring 170 is positioned on a distal side of the proximal control wire lumen liner 120 and on a proximal side of the distal control wire lumen

liner 130. In the example of FIG. 2, each of the proximal control wire lumen liner 120 and the distal control wire lumen liner 130 extends partially over the coil stopper 180.

[0057] In some examples, the outer diameter of the coil stopper 180 can be smaller than the inner diameter of each of the proximal control wire lumen liner 120 and the distal control wire lumen liner 130, thus permitting the ingress of undesired material within the proximal control wire lumen 122 and/or the distal control wire lumen 132. For example, a traditional method of manufacturing the steerable delivery apparatus 100 can include positioning the proximal control wire lumen liner 120 and the distal control wire lumen liner 130 relative to the coil stopper 180 and subsequently reflowing a thermoplastic elastomer (e.g., PEBAX®) over a coiled or braided tube to form the flexible tube 110.

[0058] FIG. 3 illustrates a portion of the steerable delivery apparatus 100 centered on the proximal anchor ring 170 in a configuration prior to formation of the flexible tube 110. FIG. 3 is annotated with arrows 124 that represent the manner in which the thermoplastic elastomer of the flexible tube 110 can enter the proximal control wire lumen 122 and the distal control wire lumen 132 during reflow of the thermoplastic elastomer. Introducing such material into the proximal control wire lumen and/or the distal control wire lumen 132 may, in some instances, introduce a source of friction to affect the function of the control wire 150 and/or of the proximal coil sleeve 160. Additionally or alternatively, such material may, in some instances, produce a bump that protrudes into the main lumen 112, which may potentially impeding the ability of a prosthetic implant (or other component, e.g., a guide wire) to slide freely through the steerable delivery apparatus 100.

[0059] Accordingly, and as shown in FIG. 2, the steerable delivery apparatus 100 additionally includes a proximal lumen liner seal 140 and a distal lumen liner seal 142 to seal the proximal control wire lumen liner 120 and the distal control wire lumen liner 130 against the coil stopper 180. In particular, the proximal lumen liner seal 140 surrounds a distal end of the proximal control wire lumen liner 120 and a portion of the coil stopper 180 distal to the distal end of the proximal control wire lumen liner 120 and is sealed against each of the proximal control wire lumen liner 120 and the coil stopper 180. Similarly, the distal lumen liner seal 142 surrounds a proximal end of the distal control wire lumen liner 130 and a portion of the coil stopper 180 proximal to the proximal end of the distal control wire lumen liner 130 and is sealed against each of the distal control wire lumen liner 130 and the coil

stopper 180. In this manner, the proximal lumen liner seal 140 forms an at least substantially fluid-tight seal between the proximal control wire lumen liner 120 and the coil stopper 180, while the distal lumen liner seal 142 forms an at least substantially fluid-tight seal between the distal control wire lumen liner 130 and the coil stopper 180.

[0060] While the present disclosure generally is directed to examples in which the disclosed lumen liner seals (e.g., the proximal lumen liner seal 140 and/or the distal lumen liner seal 142) are sealed against lumen liners (e.g., the proximal control wire lumen liner 120 and/or the distal control wire lumen liner 130) that at least partially define respective lumens, this is not required of all examples. For example, it additionally is within the scope of the present disclosure that the disclosed lumen liner seams can be sealed against structures that do not themselves directly define and/or line respective lumens, such as a tube, conduit, liner, etc. that is layered over a lumen liner as disclosed herein.

[0061] While FIG. 2 and the associate discussion herein pertains to an example in which the steerable delivery apparatus 100 includes each of the proximal lumen liner seal 140 and the distal lumen liner seal, this is not required of all examples. For example, it additionally is within the scope of the present disclosure that the steerable delivery apparatus 100 can include only the proximal lumen liner seal 140 or the distal lumen liner seal 142 (e.g., sealed against a selected coil stopper 180 thereof).

[0062] Each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can have any suitable form and/or configuration for forming seals as discussed herein. For example, each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can be substantially tubular, and/or can be formed of a heat-shrink material such as a thermoplastic polymer. As a more specific example, each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can be formed of polyethylene terephthalate (PET). In this manner, each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can be loosely positioned over the coil stopper 180 and subsequently shrunk, such as by applying heat, to conform to the coil stopper 180, the proximal control wire lumen liner 120, and the distal control wire lumen liner 130. It is desirable, however, that each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 be formed of a material that does not melt or otherwise introduce a fluid path therethrough when subject to the heat of the flexible tube reflow process.

[0063] Each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can have any suitable thickness, such as a thickness that is sufficiently small to avoid restricting motion of any devices within the main lumen 112. As examples, each of the proximal lumen liner seal 140 and/or the distal lumen liner seal 142 can have a thickness that is approximately 0.002-0.007 inches. Additionally, each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can have any suitable length, such as a length that facilitates positioning each lumen linear seal proximate the proximal anchor ring 170 while ensuring sufficient overlap with the corresponding control wire lumen liner. As an example, each of the proximal lumen liner seal 140 and/or the distal lumen liner seal 142 can have a length that is approximately 2-15 millimeters (mm).

[0064] FIGS. 4-5 illustrate a sequence by which the proximal lumen liner seal 140 and the distal lumen liner seal 142 can be attached to the proximal control wire lumen liner 120, the distal control wire lumen liner 130, and the coil stopper 180. For example, FIG. 4 shows the proximal lumen liner seal 140 loosely positioned over the proximal control wire lumen liner 120 and a proximal portion of the coil stopper 180 and shows the distal lumen liner seal 142 loosely positioned over the distal control wire lumen liner 130 and a distal portion of the coil stopper 180. In this manner, FIG. 4 may be described as illustrating each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 in an expanded configuration, in which the proximal lumen liner seal 140 may be slid over the proximal control wire lumen liner 120 and the coil stopper 180 and the distal lumen liner seal 142 may be slid over the distal control wire lumen liner 130 and the coil stopper 180.

[0065] FIG. 5 shows the proximal lumen liner seal 140 shrunk (i.e., contracted) onto the proximal control wire lumen liner 120 and the proximal portion of the coil stopper 180 and shows the distal lumen liner seal 142 shrunk (i.e., contracted) onto the distal control wire lumen liner 130 and the distal portion of the coil stopper 180. FIG. 5 additionally shows the flexible tube 110 in cross-section surrounding the proximal anchor ring 170, and thus represents a detail view of the region labeled 5 in FIG. 2.

[0066] In this manner, FIG. 5 may be described as illustrating each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 in a contracted configuration, in which the proximal lumen liner seal 140 forms the substantially fluid-tight seal between the proximal control wire lumen liner 120 and the coil stopper 180 and the distal lumen liner seal 142 form

the at least substantially fluid-tight seal between the distal control wire lumen liner 130 and the coil stopper 180. As described herein, the proximal lumen liner seal 140 can be transitioned from the expanded configuration to the contracted configuration by radially shrinking the proximal lumen liner seal 140 such that the proximal lumen liner seal 140 is restricted from translating relative to the proximal control wire lumen liner 120.

[0067] In some examples, a transition from the configuration of FIG. 4 to the configuration of FIG. 5 can be performed by first transitioning the proximal lumen liner seal 140 and/or the distal lumen liner seal 142 to the contracted configuration (such as by application of heat) and subsequently reflowing the thermoplastic elastomer material to form the flexible tube 110. In other examples, reflowing the thermoplastic elastomer material and transitioning each lumen liner seal to the contracted configuration can be performed at least partially concurrently. For example, the reflowing of the thermoplastic elastomer material to form the flexible tube 110 can cause the proximal lumen liner seal 140 and/or the distal lumen liner seal 142 to transition to the contracted configuration.

[0068] Each of the proximal lumen liner seal 140 and the distal lumen liner seal 142 can be positioned in any suitable configuration to seal each respective control wire lumen liner to the coil stopper 180. For example, and as shown in FIG. 5, each of the proximal lumen liner seal 140 and/or the distal lumen liner seal 142 can extend axially beyond the ends of the coil stopper 180. In particular, in such an example, the proximal lumen liner seal 140 can also at least partially axially overlap the proximal coil sleeve 160. Such a configuration is not required, however, and it additionally is within the scope of the present disclosure that an entirety (e.g., a full length) of the proximal lumen liner seal 140 and/or of the distal lumen liner seal 142 can axially overlap with the coil stopper 180.

[0069] FIG. 6 is a cross-sectional view of the steerable delivery apparatus 100 as viewed along the line 6-6 in FIG. 2 and illustrates the configuration of the control wire 150 and the coil stopper 180 relative to the proximal anchor ring 170 and the flexible tube 110. Similarly, FIG. 7 is a cross-sectional view of the steerable delivery apparatus 100 as viewed along the line 7-7 in FIG. 2 and illustrates the control wire 150 and the proximal coil sleeve 160 received within the proximal lumen liner seal 140.

[0070] With reference to FIG. 7, it may be appreciated that introducing extraneous material between the proximal coil sleeve 160 and the proximal lumen liner seal 140 could produce a bump or protrusion that extends into the main lumen 112, thus potentially impeding the motion of a prosthetic device therethrough.

[0071] While FIG. 7 illustrates the proximal control wire lumen liner 120 as extending partially into the main lumen 112, it also is within the scope of the present disclosure that the proximal control wire lumen liner 120 can be fully contained within the thickness of the flexible tube 110 such that the main lumen 112 is at least substantially cylindrical.

[0072] FIG. 8 illustrates a portion of a steerable delivery apparatus 200, which is at least substantially similar to the steerable delivery apparatus 100 of FIG. 5. In particular, components illustrated in FIG. 8 and labeled with a reference numeral beginning with a first digit of 2 can share any suitable features, attributes, etc. with corresponding components beginning with a first digit of 1 in FIG. 5 (i.e., components with reference numerals whose second and third digits are the same), even when such reference numerals are not specifically referenced here. As an example, the anchor ring 270 of FIG. 8 can be similar to and/or analogous to the proximal anchor ring 170 of FIG. 5.

[0073] In contrast with the steerable delivery apparatus 100 of FIG. 5, the steerable delivery apparatus 200 of FIG. 8 additionally includes a distal coil sleeve 262 disposed within the distal control wire lumen 230 around the control wire 250. In the example of FIG. 8, the distal lumen liner seal 242 extends over a distal end region of the coil stopper 280 and partially over the distal coil sleeve 262. This is not required, however, and it also is within the scope of the present disclosure that an entirety (e.g., a full length) of the proximal lumen liner seal 240 and/or of the distal lumen liner seal 242 can be positioned over the coil stopper 280.

[0074] FIGS. 9-13 illustrate aspects of another example of a steerable delivery apparatus 300 that can include lumen liner seals as disclosed herein. In particular, whereas FIGS. 2-8 illustrate aspects and/or regions of the steerable delivery apparatus 100 and the steerable delivery apparatus 200 including a single control wire 150/250, the steerable delivery apparatus 300 includes a first control wire 350 and a second control wire 352.

[0075] Any components illustrated in FIGS. 9-13 and labeled with a reference numeral beginning with a first digit of 3 can share any suitable features, attributes, etc. with

corresponding components beginning with a first digit of 1 in any of FIGS. 2-7 and/or with corresponding components beginning with a first digit of 2 in FIG. 8 (i.e., components with reference numerals whose second and third digits are the same), even when such reference numerals are not specifically referenced here. As an example, the flexible tube 310 can be similar to and/or analogous to the flexible tube 110 and/or the flexible tube 210.

[0076] As shown in FIG. 9, the steerable delivery apparatus 300 includes a flexible tube 310, a distal region of which encloses the first control wire 350 and the second control wire 352. The first control wire 350 and the second control wire 352 can be configured to be independently tensioned to independently flex respective portions of the distal region of the flexible tube 310. The steerable delivery apparatus 300 additionally includes a first anchor ring 370, a second anchor ring 372, and a third anchor ring 374.

[0077] FIG. 10 shows the steerable delivery apparatus 300 of FIG. 9 with the flexible tube 310 removed. As shown in FIG. 10, the first control wire 350 extends through each of the first anchor ring 370 and the second anchor ring 372 and terminates at the third anchor ring 374, to which it is fixedly coupled. The second control wire 352 extends through the first anchor ring 370 and terminates at the second anchor ring 372, to which it is fixedly coupled. A first coil stopper 380 extends through the first anchor ring 370 and a second coil stopper 382 extends through the second anchor ring 372. The second coil stopper 382 abuts a first coil sleeve 360 extending around the first control wire 350, while the first coil stopper 380 abuts a second coil sleeve 364 extending around the second control wire 352.

[0078] The first control wire 350 and the second control wire 352 extend into a distal region of the flexible tube 310 to bend respective portions of the flexible tube 310 to steer the steerable delivery apparatus 300. In particular, because the first control wire 350 is fixedly coupled to the third anchor ring 374 and because the first coil sleeve 360 is fixed in position relative to the second anchor ring 372, tensioning the first control wire 350 operates to bend a region of the flexible tube 310 between the second anchor ring 372 and the third anchor ring 374. Similarly, because the second control wire 352 is fixedly coupled to the second anchor ring 372 and because the second coil sleeve 364 is fixed in position relative to the first anchor ring 370, tensioning the second control wire 352 operates to bend a region of the flexible tube 310 between the first anchor ring 370 and the second anchor ring 372.

[0079] As shown in FIG. 10, the first coil sleeve 360 is contained within a first proximal control wire lumen liner 320, while the second coil sleeve 364 is contained within a second proximal control wire lumen liner 324. While not specifically illustrated in FIG. 10, it is to be understood that an interface between the first proximal control wire lumen liner 320 and the second coil stopper 382 and/or an interface between the second proximal control wire lumen liner 324 and the first coil stopper 380 can be sealed with corresponding lumen liner seals in a similar manner as the proximal lumen liner seals 140/240 or the distal lumen liner seal 242 disclosed herein. Similarly, any interface between the first coil stopper 380 and/or the second coil stopper 382 and a control wire lumen liner that does not enclose a coil sleeve can be sealed with a lumen liner seal in a similar manner as the distal lumen liner seal 142 disclosed herein.

[0080] The relative angular configuration of the first control wire 350 and the second control wire 352 is shown in FIGS. 11-13. Specifically, FIG. 11 is a cross-sectional view as viewed along the line 11-11 in FIG. 9, FIG. 12 is a cross-sectional view as viewed along the line 12-12 in FIG. 9, and FIG. 13 is a cross-sectional view as viewed along the line 13-13 in FIG. 9. As shown in FIGS. 12-13, the first control wire 350 and the second control wire 352 are separated by an angle of approximately 90 degrees, and thus serve to bend respective portions of the flexible tube 310 through planes that are perpendicular to one another.

[0081] Additional examples of steerable delivery apparatuses that can use lumen liner seals as disclosed herein are disclosed in U.S. Patent Application Publication No. 2021/0251757 and in U.S. Patent No. 11,382,744, the complete disclosures of which are incorporated by reference herein.

[0082] The treatment techniques, methods, steps, etc. described or suggested herein or in references incorporated herein can be performed on a living animal or on a non-living simulation, such as on a cadaver, cadaver heart, anthropomorphic ghost, simulator (e.g., with the body parts, tissue, etc. being simulated), etc.

Additional Examples of the Disclosed Technology

[0083] In view of the above-described implementations of the disclosed technology, this application discloses the additional examples enumerated below. It should be noted that one feature of an example in isolation or more than one feature of the example taken in

combination and, optionally, in combination with one or more features of one or more further examples are further examples also falling within the disclosure of this application.

[0084] Example 1. A steerable delivery apparatus for delivering a device to a native valve of a patient's heart, comprising: a flexible tube at least partially defining a main lumen; a control wire lumen liner at least partially defining a control wire lumen; a control wire disposed within the control wire lumen; a coil sleeve disposed around the control wire; a coil stopper abutting the coil sleeve; and a lumen liner seal surrounding an end of the control wire lumen liner and a portion of the coil stopper such that the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0085] Example 2. The steerable delivery apparatus of any example herein, particularly example 1, wherein the control wire lumen liner extends partially over the coil stopper.

[0086] Example 3. The steerable delivery apparatus of any example herein, particularly any one of examples 1-2, wherein the lumen liner seal is at least substantially tubular.

[0087] Example 4. The steerable delivery apparatus of any example herein, particularly any one of examples 1-3, wherein the lumen liner seal is configured to transition from an expanded configuration to a contracted configuration, wherein, when in the expanded configuration, the lumen liner seal may be slid over the control wire lumen liner and the coil stopper, and wherein, when in the contracted configuration, the lumen liner seal forms the substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0088] Example 5. The steerable delivery apparatus of any example herein, particularly any one of examples 1-4, wherein the lumen liner seal is formed of a heat-shrink material.

[0089] Example 6. The steerable delivery apparatus of any example herein, particularly any one of examples 1-5, wherein the lumen liner seal comprises a thermoplastic polymer.

[0090] Example 7. The steerable delivery apparatus of any example herein, particularly any one of examples 1-6, wherein the lumen liner seal comprises polyethylene terephthalate (PET).

[0091] Example 8. The steerable delivery apparatus of any example herein, particularly any one of examples 1-7, wherein the lumen liner seal extends partially over the coil sleeve.

[0092] Example 9. The steerable delivery apparatus of any example herein, particularly any one of examples 1-8, wherein an entirety of the lumen liner seal is positioned around the coil stopper.

[0093] Example 10. The steerable delivery apparatus of any example herein, particularly any one of examples 1-9, further comprising an anchor ring disposed within the flexible tube, and wherein the coil stopper extends through and is fixedly coupled to the anchor ring.

[0094] Example 11. The steerable delivery apparatus of any example herein, particularly example 10, wherein the anchor ring is a proximal anchor ring, wherein the steerable delivery apparatus further comprises a distal anchor ring, and wherein the control wire is fixedly coupled to the distal anchor ring.

[0095] Example 12. The steerable delivery apparatus of any example herein, particularly example 11, wherein the control wire terminates at the distal anchor ring.

[0096] Example 13. The steerable delivery apparatus of any example herein, particularly any one of examples 1-12, wherein the control wire lumen liner is a proximal control wire lumen liner, wherein the control wire lumen is a proximal control wire lumen, and wherein the lumen liner seal is a proximal lumen liner seal surrounding a distal end of the proximal control wire lumen liner and a portion of the coil stopper distal to the distal end of the proximal control wire lumen liner.

[0097] Example 14. The steerable delivery apparatus of any example herein, particularly example 13, wherein the coil sleeve is a proximal coil sleeve disposed within the proximal control wire lumen.

[0098] Example 15. The steerable delivery apparatus of any example herein, particularly example 14, wherein the proximal lumen liner seal extends partially over the proximal coil sleeve.

[0099] Example 16. The steerable delivery apparatus of any example herein, particularly any one of examples 1-12, wherein the control wire lumen liner is a distal control wire lumen liner, wherein the control wire lumen is a distal control wire lumen, and wherein the lumen liner seal is a distal lumen liner seal surrounding a proximal end of the distal control wire lumen liner and a portion of the coil stopper proximal to the proximal end of the distal control wire lumen liner.

[0100] Example 17. The steerable delivery apparatus of any example herein, particularly example 16, wherein the coil sleeve is a distal coil sleeve disposed within the distal control wire lumen.

[0101] Example 18. The steerable delivery apparatus of any example herein, particularly example 17, wherein the distal lumen liner seal extends partially over the distal coil sleeve.

[0102] Example 19. The steerable delivery apparatus of any example herein, particularly any one of examples 16-18, wherein the steerable delivery apparatus further comprises: a proximal control wire lumen liner at least partially defining a proximal control wire lumen; and a proximal lumen liner seal surrounding a distal end of the proximal control wire lumen liner and a portion of the coil stopper distal to the distal end of the proximal control wire lumen liner such that the proximal lumen liner seal forms an at least substantially fluid-tight seal between the proximal control wire lumen liner and the coil stopper.

[0103] Example 20. The steerable delivery apparatus of any example herein, particularly any one of examples 1-19, wherein the steerable delivery apparatus is sterilized.

[0104] Example 21. A method of manufacturing a steerable delivery apparatus, comprising: positioning a control wire lumen liner proximate to a coil stopper; positioning a lumen liner seal over a portion of each of the control wire lumen liner and the coil stopper; and transitioning the lumen liner seal to a contracted configuration in which the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

[0105] Example 22. The method of any example herein, particularly example 21, wherein the positioning the control wire lumen liner comprises positioning such that the control wire lumen liner extends over a portion of the coil stopper.

[0106] Example 23. The method of any example herein, particularly any one of examples 21-22, further comprising positioning a control wire within the control wire lumen liner.

[0107] Example 24. The method of any example herein, particularly example 23, wherein the positioning the control wire comprises positioning such that the control wire extends through the coil stopper.

[0108] Example 25. The method of any example herein, particularly any one of examples 23-24, further comprising positioning a coil sleeve around the control wire within the control wire lumen liner.

[0109] Example 26. The method of any example herein, particularly example 25, wherein the positioning the coil sleeve comprises positioning such that the coil sleeve abuts the coil stopper.

[0110] Example 27. The method of any example herein, particularly any one of examples 25-26, wherein the positioning the lumen liner seal comprises positioning such that the lumen liner seal extends partially over the coil sleeve.

[0111] Example 28. The method of any example herein, particularly any one of examples 25-26, wherein the positioning the lumen liner seal comprises positioning such that an entirety of the lumen liner seal is positioned around the coil stopper.

[0112] Example 29. The method of any example herein, particularly any one of examples 21-28, further comprising positioning the coil stopper within an anchor ring.

[0113] Example 30. The method of any example herein, particularly example 29, wherein the positioning the coil stopper within the anchor ring comprises fixedly coupling the coil stopper to the anchor ring.

[0114] Example 31. The method of any example herein, particularly any one of examples 29-30, wherein the positioning the lumen liner seal comprises positioning such that an edge of the lumen liner seal is proximate to the anchor ring.

[0115] Example 32. The method of any example herein, particularly any one of examples 21-31, wherein the positioning the lumen liner seal comprises positioning such that a first portion of the lumen liner seal directly overlies the control wire lumen liner and such that a second portion of the lumen liner seal directly overlies the coil stopper.

[0116] Example 33. The method of any example herein, particularly any one of examples 21-32, wherein the positioning the lumen liner seal is performed with the lumen liner seal in an expanded configuration, in which the lumen liner seal is sized to be slid over the control wire lumen liner, and wherein the transitioning the lumen liner seal to the contracted

configuration comprises radially shrinking the lumen liner seal such that the lumen liner seal is restricted from translating relative to the control wire lumen liner.

[0117] Example 34. The method of any example herein, particularly any one of examples 21-33, wherein the control wire lumen liner is a first control wire lumen liner positioned on a first side of the coil stopper, wherein the lumen liner seal is a first lumen liner seal, and wherein the method further comprises: positioning a second control wire lumen liner proximate to the coil stopper on a second side of the coil stopper; positioning a second lumen liner seal over a portion of each of the second control wire lumen liner and the coil stopper; and transitioning the second lumen liner seal to a contracted configuration in which the second lumen liner seal forms an at least substantially fluid-tight seal between the second control wire lumen liner and the coil stopper.

[0118] Example 35. The method of any example herein, particularly any one of examples 21-34, wherein the transitioning the lumen liner seal to the contracted configuration comprises applying heat to the lumen liner seal.

[0119] Example 36. The method of any example herein, particularly any one of examples 21-35, further comprising reflowing a thermoplastic elastomer to form a flexible tube around at least a portion of the control wire lumen liner.

[0120] Example 37. The method of any example herein, particularly example 36, wherein the transitioning the lumen liner seal to the contracted configuration is performed prior to the reflowing the thermoplastic elastomer.

[0121] Example 38. The method of any example herein, particularly example 36, wherein the transitioning the lumen liner seal to the contracted configuration and the reflowing the thermoplastic elastomer are performed at least partially concurrently.

[0122] Example 39. A method comprising sterilizing the apparatus of any example herein, particularly any one of examples 1-20.

[0123] The features described herein with regard to any example can be combined with other features described in any one or more of the other examples, unless otherwise stated. For example, any one or more of the features of one steerable delivery apparatus can be combined with any one or more features of another steerable delivery apparatus.

[0124] In view of the many possible ways in which the principles of the disclosure may be applied, it should be recognized that the illustrated configurations depict examples of the disclosed technology and should not be taken as limiting the scope of the disclosure nor the claims. Rather, the scope of the claimed subject matter is defined by the following claims and their equivalents.

Claims

1. A steerable delivery apparatus for delivering a device to a native valve of a patient's heart, comprising:
 - a flexible tube at least partially defining a main lumen;
 - a control wire lumen liner at least partially defining a control wire lumen;
 - a control wire disposed within the control wire lumen;
 - a coil sleeve disposed around the control wire;
 - a coil stopper abutting the coil sleeve; and
 - a lumen liner seal surrounding an end of the control wire lumen liner and a portion of the coil stopper such that the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.
2. The steerable delivery apparatus of claim 1, wherein the control wire lumen liner extends partially over the coil stopper.
3. The steerable delivery apparatus of any one of claims 1-2, wherein the lumen liner seal is at least substantially tubular.
4. The steerable delivery apparatus of any one of claims 1-3, wherein the lumen liner seal is configured to transition from an expanded configuration to a contracted configuration, wherein, when in the expanded configuration, the lumen liner seal may be slid over the control wire lumen liner and the coil stopper, and wherein, when in the contracted configuration, the lumen liner seal forms the substantially fluid-tight seal between the control wire lumen liner and the coil stopper.
5. The steerable delivery apparatus of any one of claims 1-4, wherein the lumen liner seal is formed of a heat-shrink material.
6. The steerable delivery apparatus of any one of claims 1-5, wherein the lumen liner seal extends partially over the coil sleeve.

7. The steerable delivery apparatus of any one of claims 1-6, wherein an entirety of the lumen liner seal is positioned around the coil stopper.

8. The steerable delivery apparatus of any one of claims 1-7, further comprising an anchor ring disposed within the flexible tube, and wherein the coil stopper extends through and is fixedly coupled to the anchor ring.

9. A method of manufacturing a steerable delivery apparatus, comprising:
positioning a control wire lumen liner proximate to a coil stopper;
positioning a lumen liner seal over a portion of each of the control wire lumen liner and the coil stopper; and
transitioning the lumen liner seal to a contracted configuration in which the lumen liner seal forms an at least substantially fluid-tight seal between the control wire lumen liner and the coil stopper.

10. The method of claim 9, wherein the positioning the control wire lumen liner comprises positioning such that the control wire lumen liner extends over a portion of the coil stopper.

11. The method of any one of claims 9-10, further comprising positioning a control wire within the control wire lumen liner.

12. The method of claim 11, further comprising positioning a coil sleeve around the control wire within the control wire lumen liner.

13. The method of claim 12, wherein the positioning the coil sleeve comprises positioning such that the coil sleeve abuts the coil stopper.

14. The method of any one of claims 12-13, wherein the positioning the lumen liner seal comprises positioning such that the lumen liner seal extends partially over the coil sleeve.

15. The method of any one of claims 12-14, wherein the positioning the lumen liner seal comprises positioning such that an entirety of the lumen liner seal is positioned around the coil stopper.

16. The method of any one of claims 9-15, wherein the positioning the lumen liner seal comprises positioning such that a first portion of the lumen liner seal directly overlies the control wire lumen liner and such that a second portion of the lumen liner seal directly overlies the coil stopper.

17. The method of any one of claims 9-16, wherein the positioning the lumen liner seal is performed with the lumen liner seal in an expanded configuration, in which the lumen liner seal is sized to be slid over the control wire lumen liner, and wherein the transitioning the lumen liner seal to the contracted configuration comprises radially shrinking the lumen liner seal such that the lumen liner seal is restricted from translating relative to the control wire lumen liner.

18. The method of any one of claims 9-17, further comprising reflowing a thermoplastic elastomer to form a flexible tube around at least a portion of the control wire lumen liner.

19. The method of claim 18, wherein the transitioning the lumen liner seal to the contracted configuration is performed prior to the reflowing the thermoplastic elastomer.

20. The method of claim 19, wherein the transitioning the lumen liner seal to the contracted configuration and the reflowing the thermoplastic elastomer are performed at least partially concurrently.

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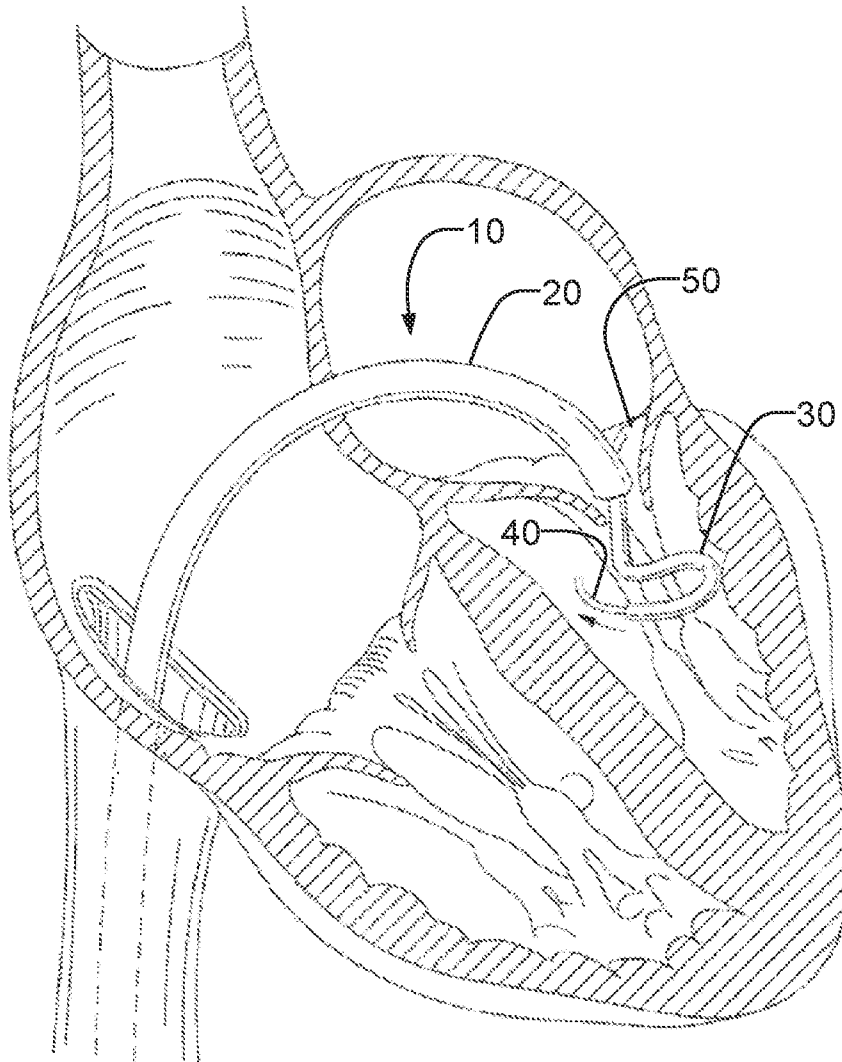
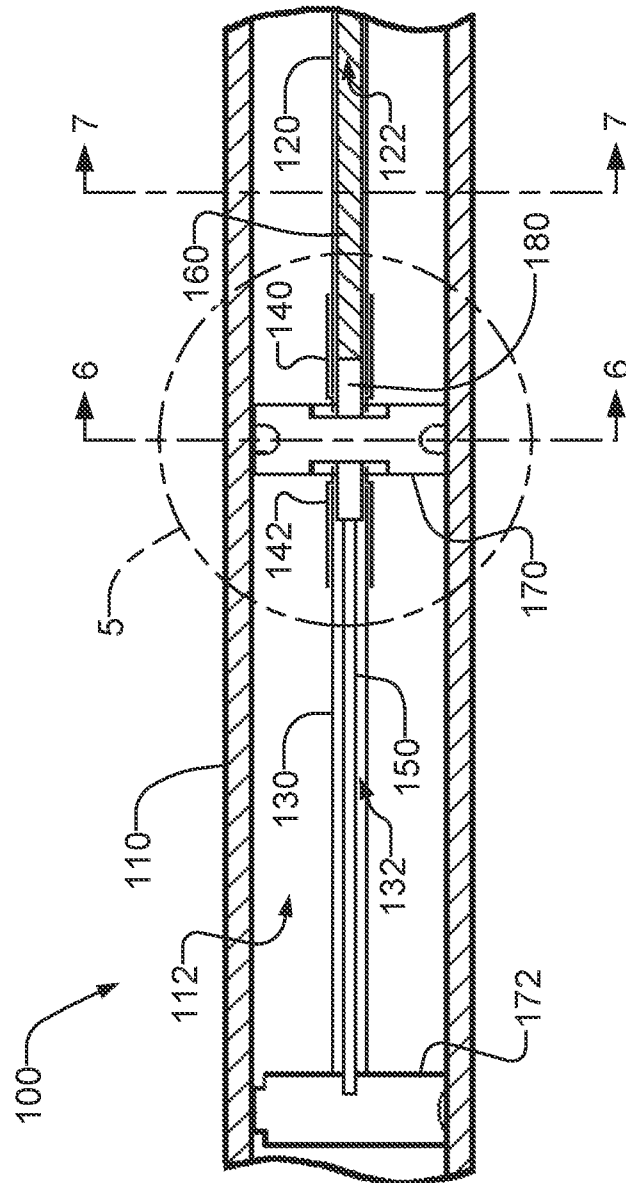


FIG. 1



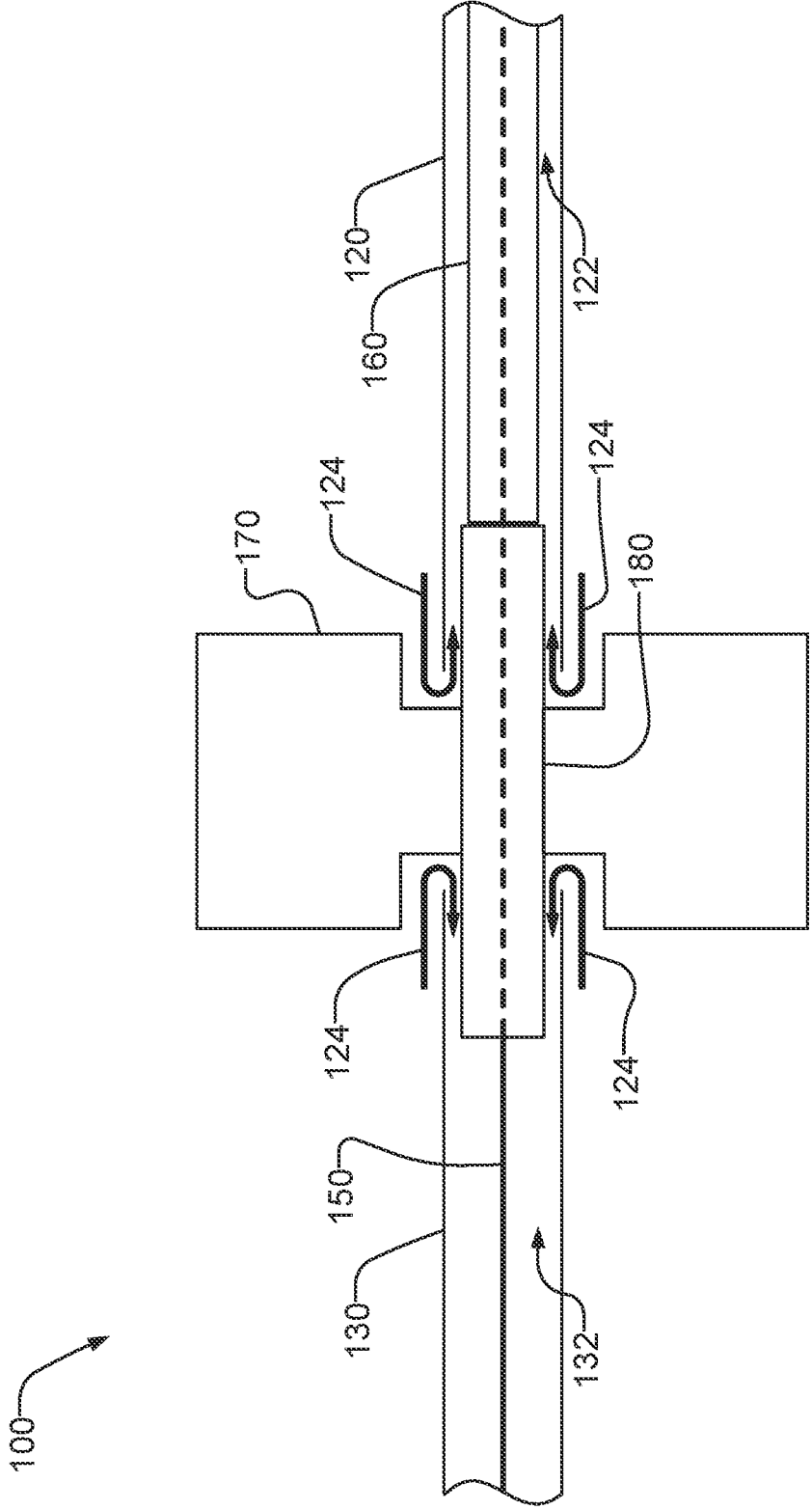


FIG. 3

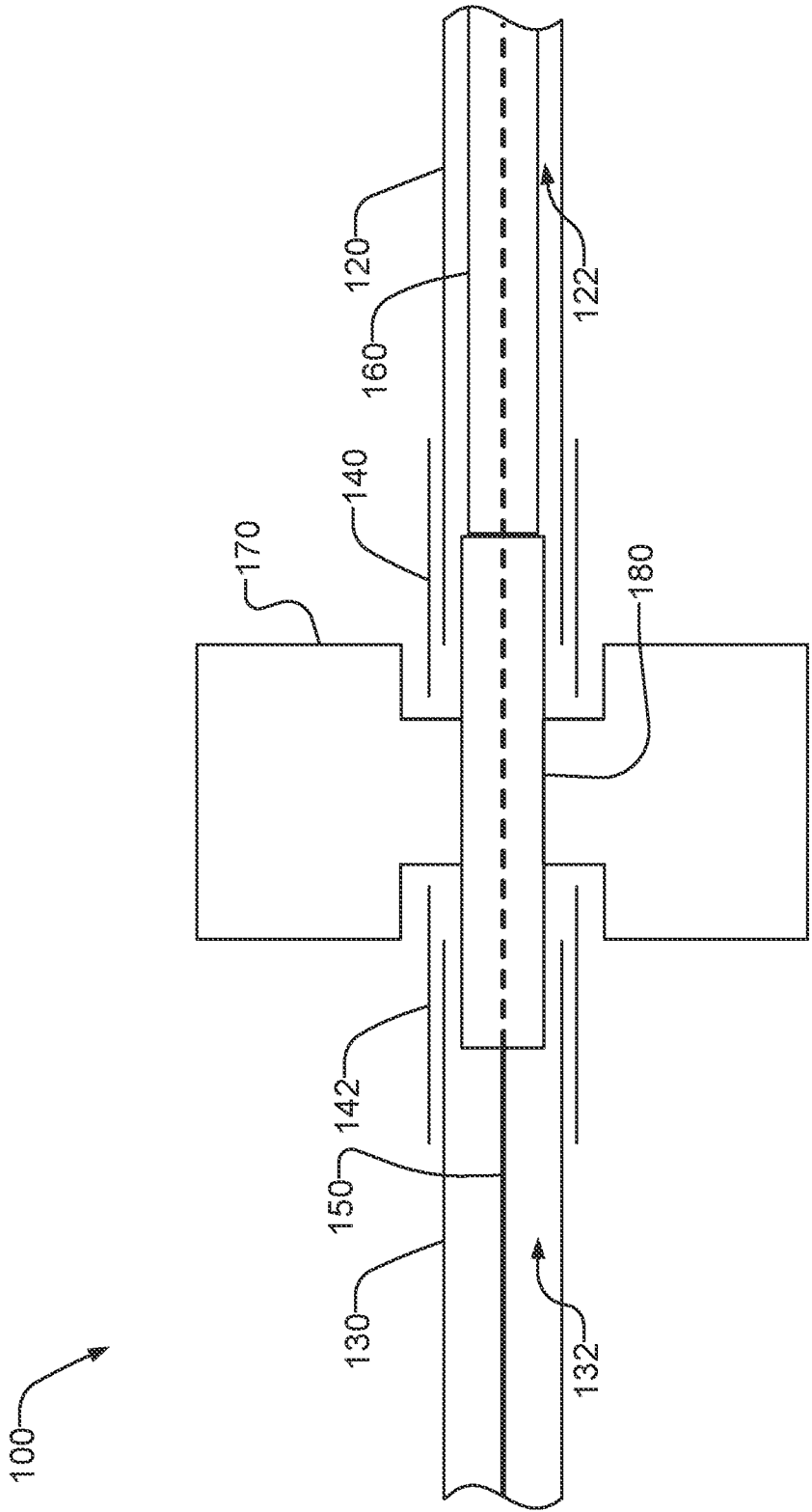


FIG. 4

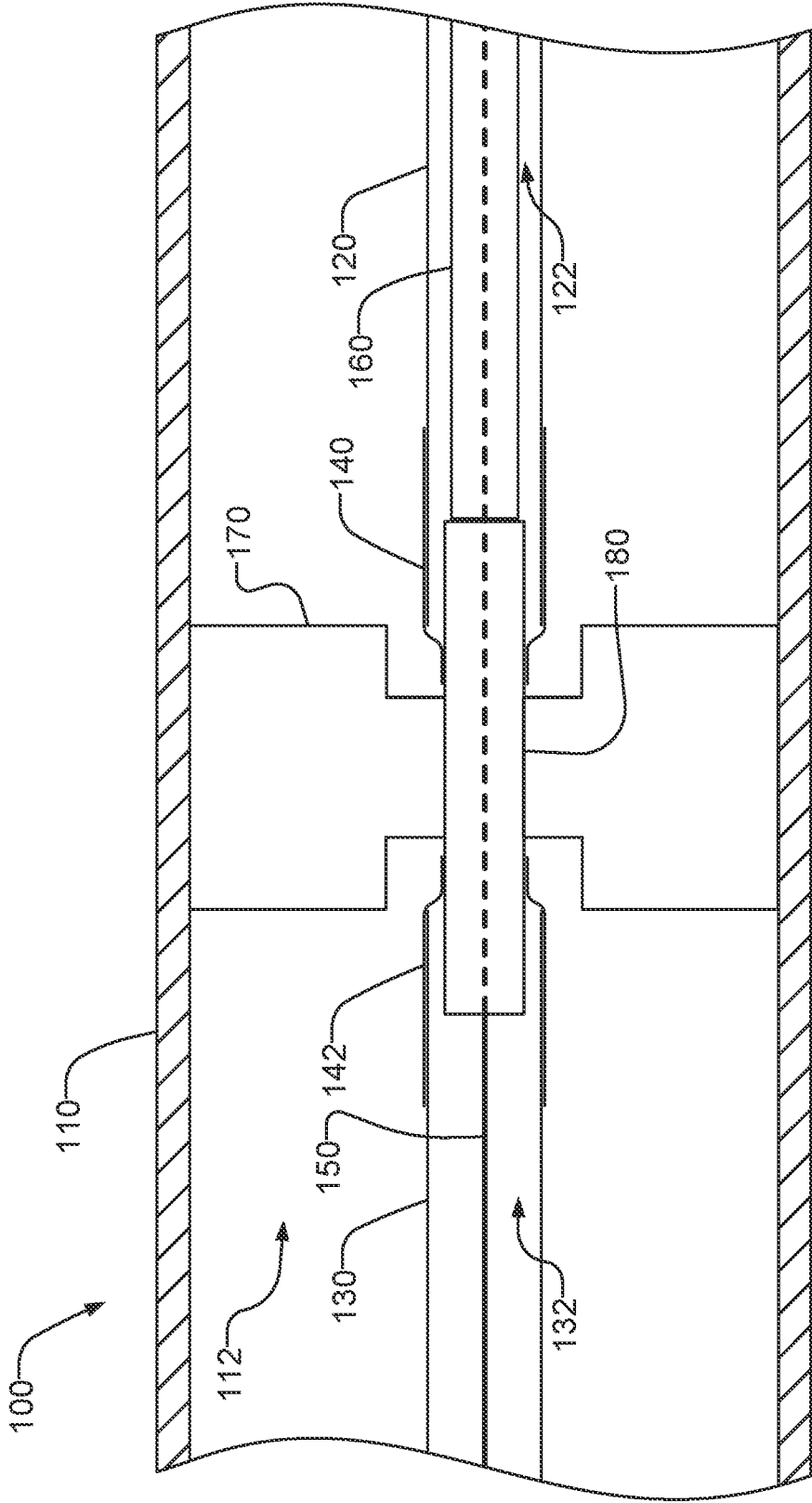


FIG. 5

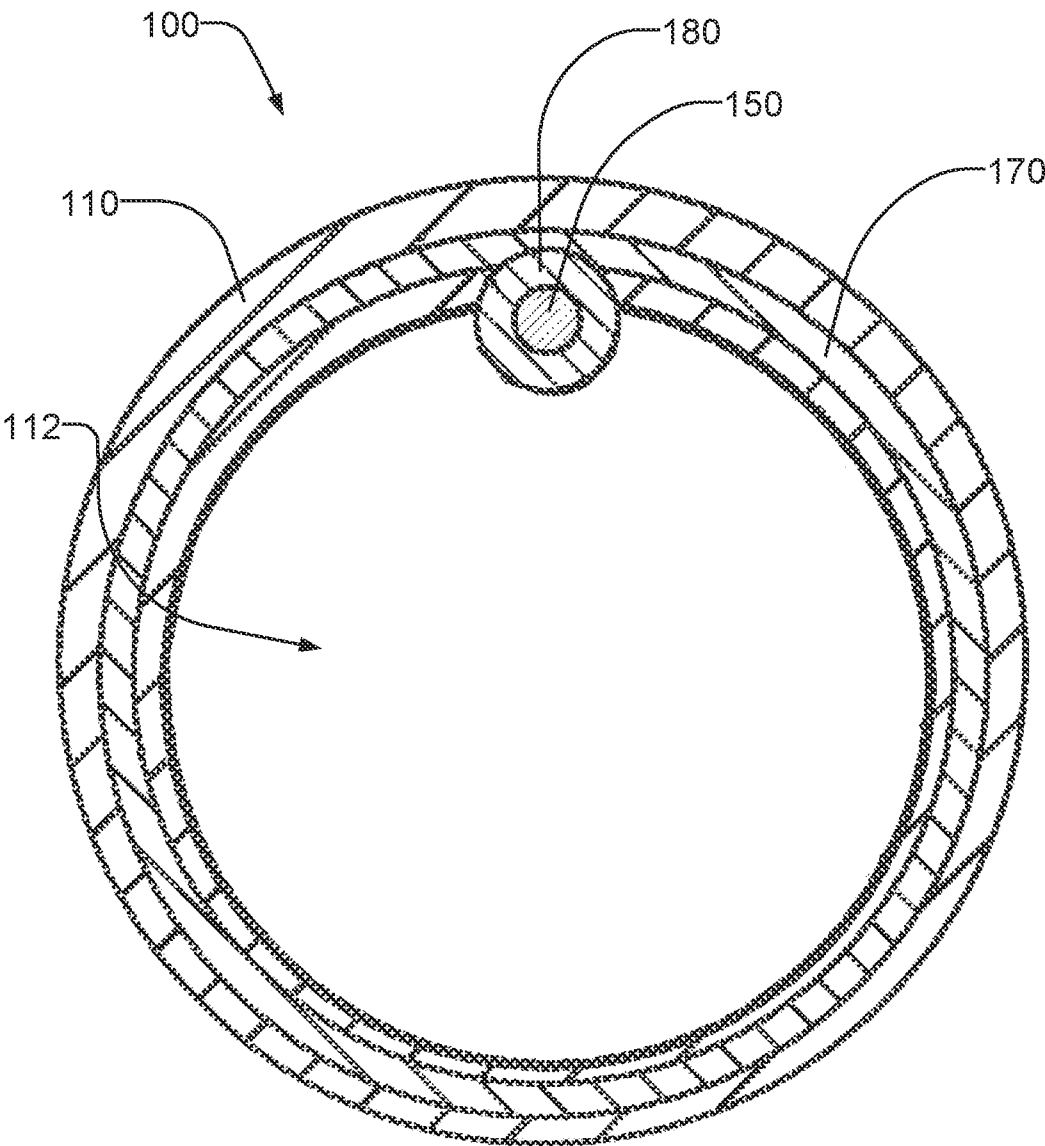


FIG. 6

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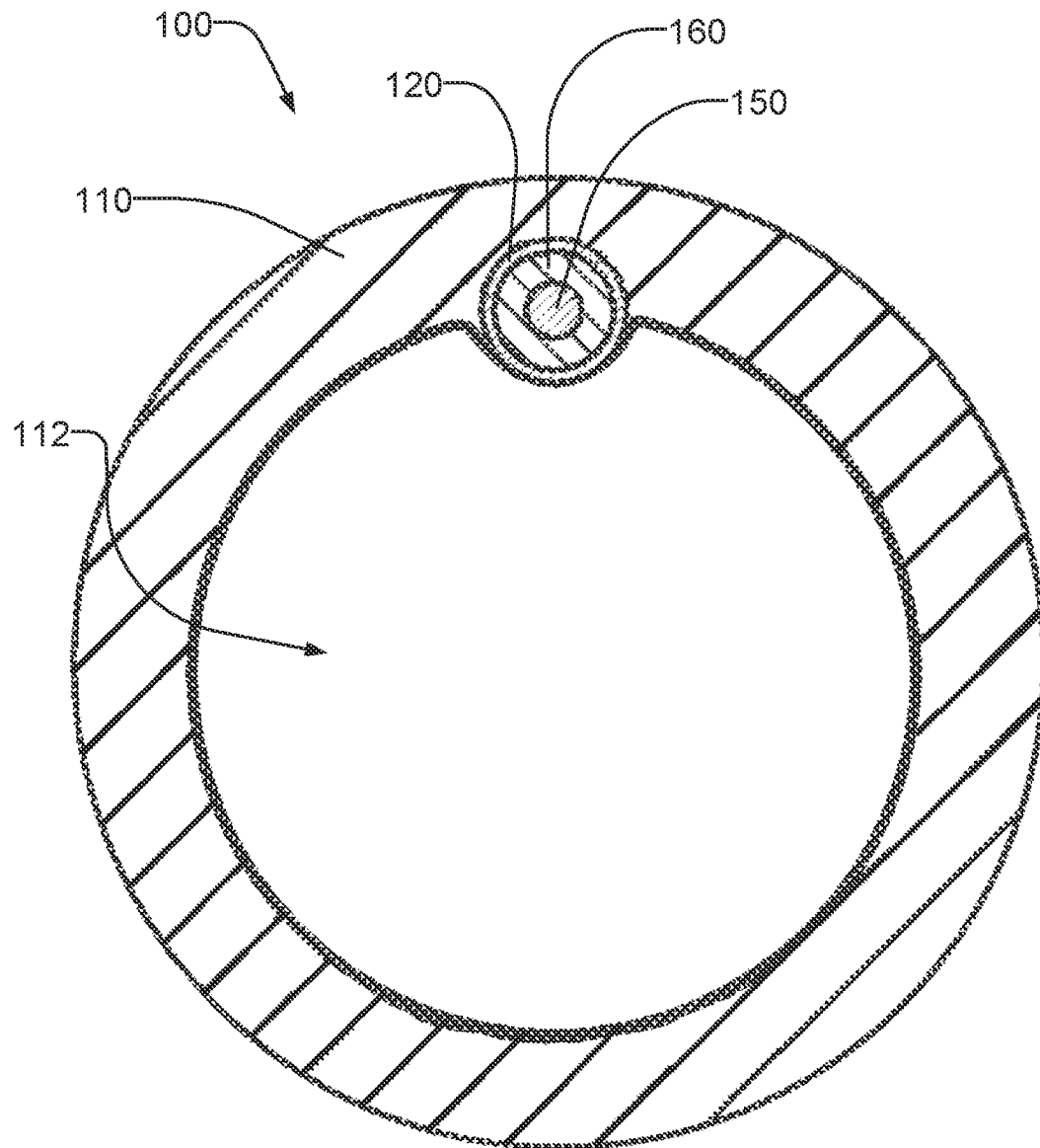
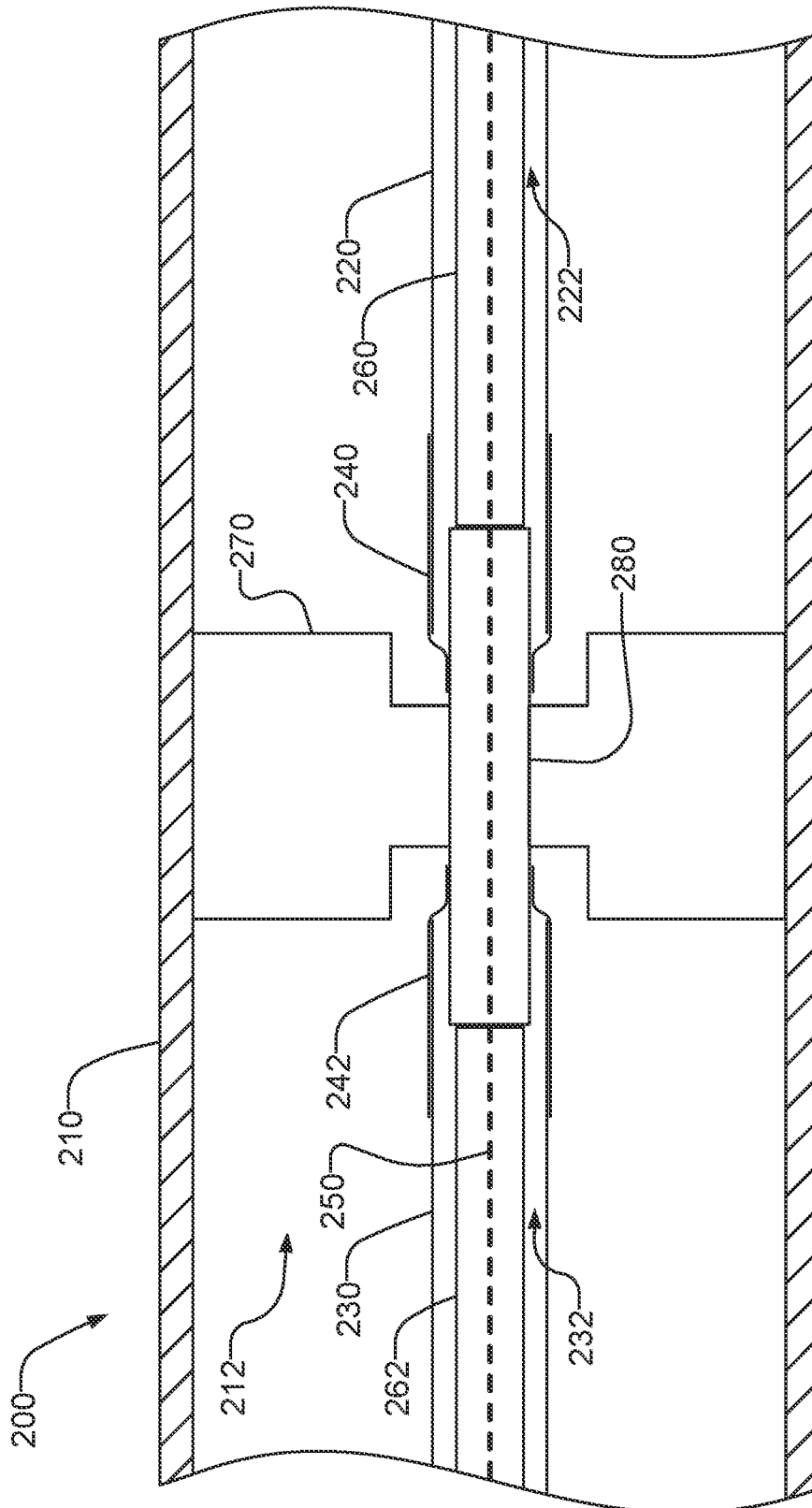


FIG. 7



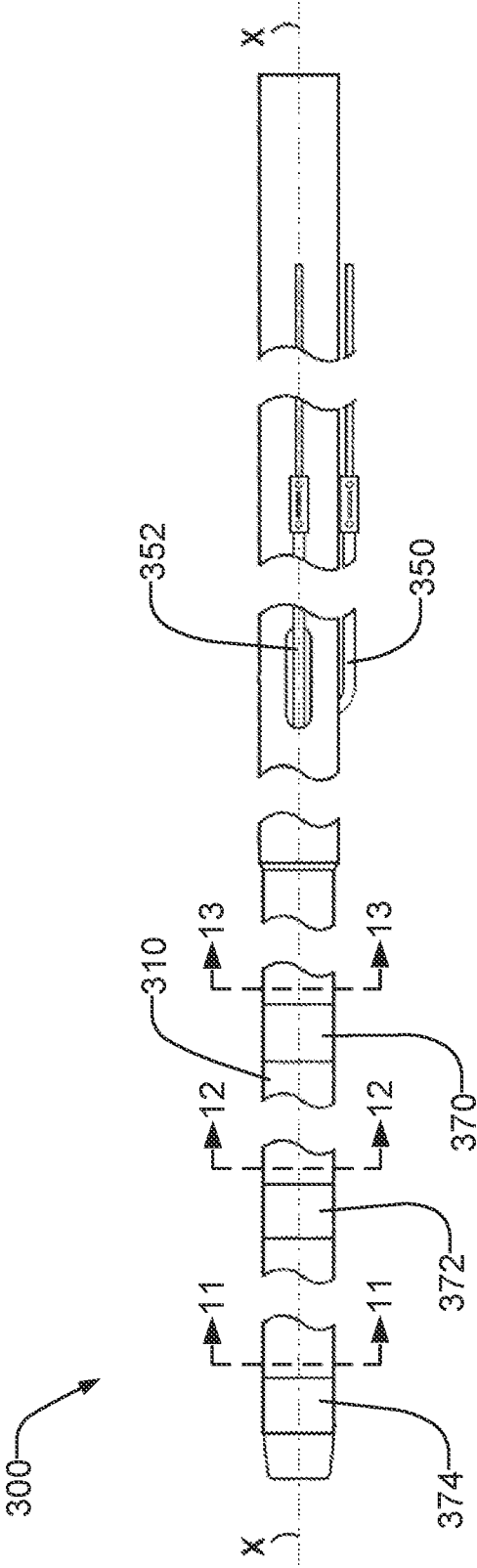


FIG. 9

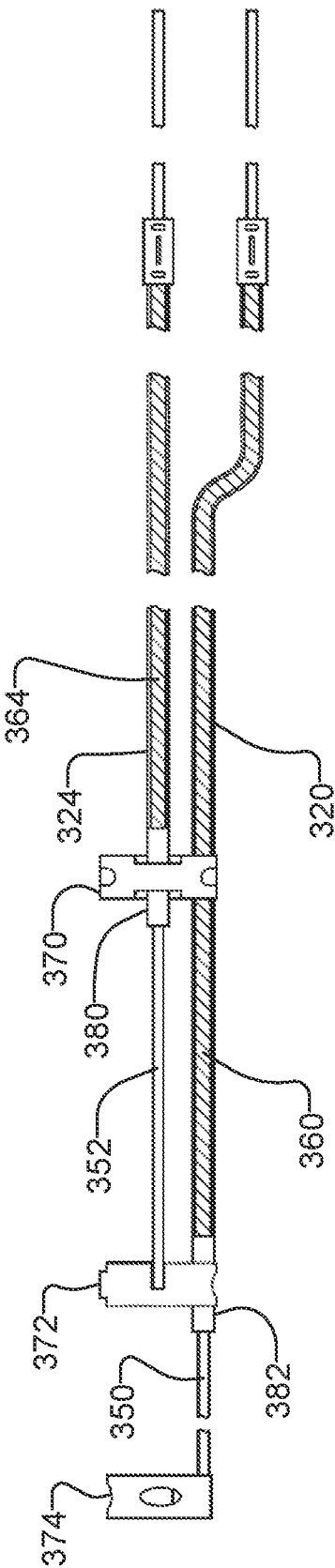


FIG. 10

11/13

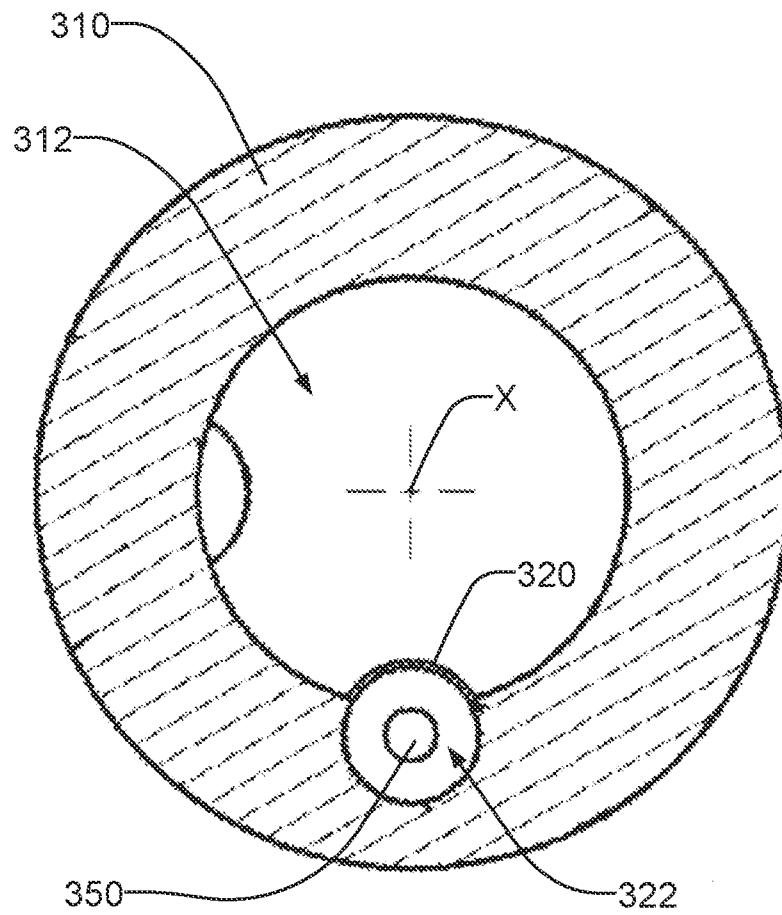


FIG. 11

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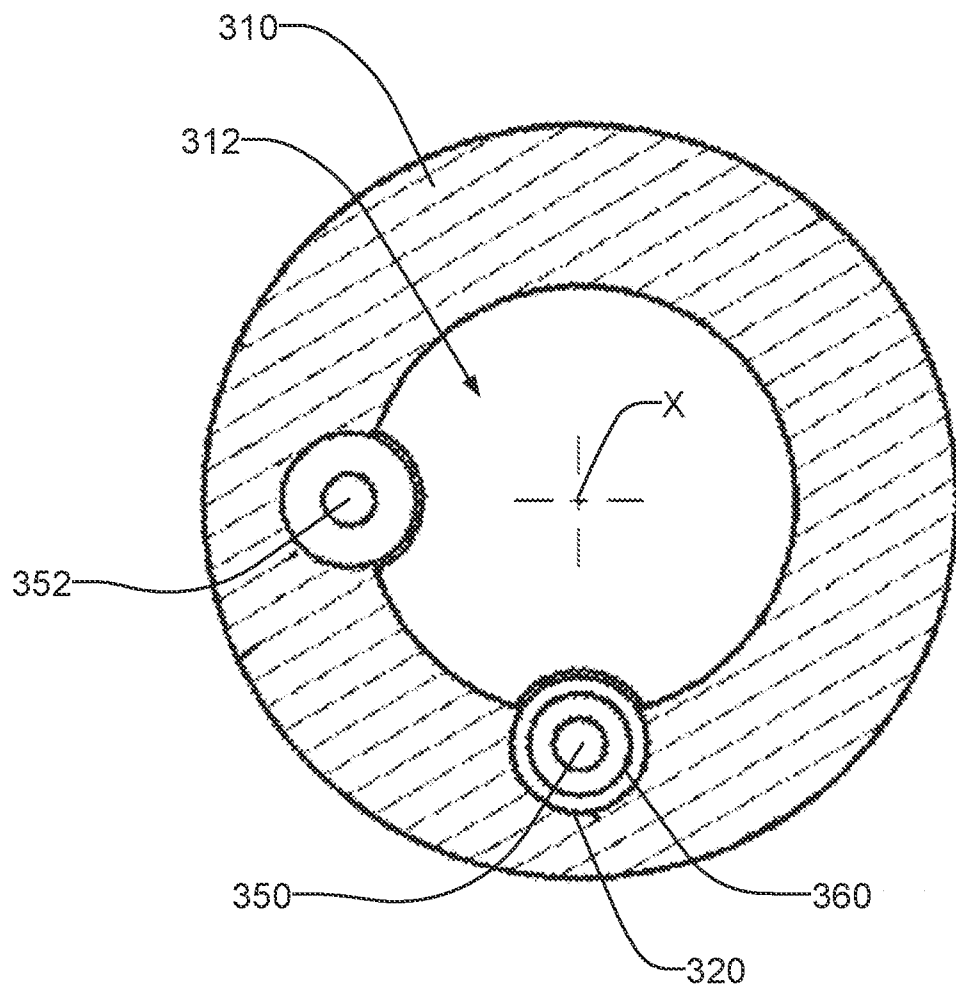


FIG. 12

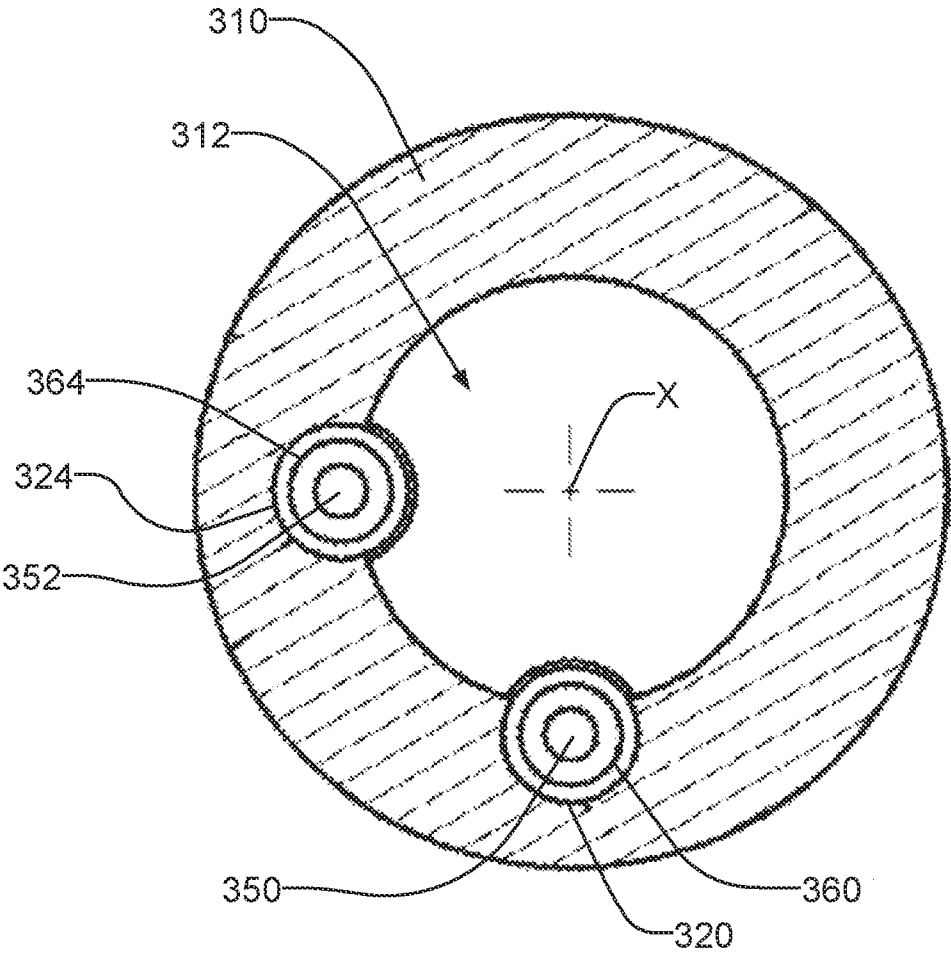


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/033390

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/24 A61M25/01 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 A61M 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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 3 226 956 B1 (EDWARDS LIFESCIENCES CORP [US]) 31 March 2021 (2021-03-31) fig. 1-1a, 3-5, par. 017-025 -----	1 - 20
A	US 2012/123327 A1 (MILLER AARON J [US]) 17 May 2012 (2012-05-17) fig. 1-4 and par. 028-054 -----	1 - 20
☐ 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 4 October 2024		Date of mailing of the international search report 16/10/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Porta, Marcello

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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