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(54) **Titre : APPAREIL DE POSE ET PROCEDES D'IMPLANTATION DE PROTHESES**
(54) **Title: DELIVERY APPARATUS AND METHODS FOR IMPLANTING PROSTHETIC DEVICES**

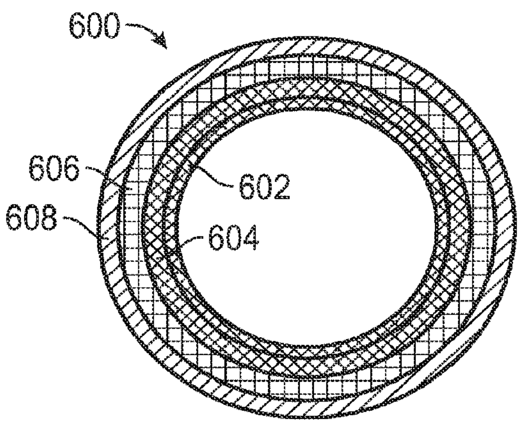

FIG. 22

(57) **Abrégé/Abstract:**
A delivery apparatus (300) for delivering a prosthetic implant (200) includes a handle body (304), an outer shaft (309), and an inner shaft (305, 600). The handle body includes a proximal end (308), a distal end (312), and a longitudinal axis (315) extending between the proximal end and the distal end. The outer shaft includes a proximal end movably coupled to the handle body. The inner shaft extends through a lumen (313) of the outer shaft and is fixed relative to the handle body. The inner shaft includes a first reinforcement layer (604) and a second reinforcement layer(606). The first reinforcement layer extends from a proximal end portion of the inner shaft to a first distal location of the inner shaft. The second reinforcement layer extends from the proximal end portion of the inner shaft to a second distal location of the inner shaft, and the second distal location is proximal to the first distal location.

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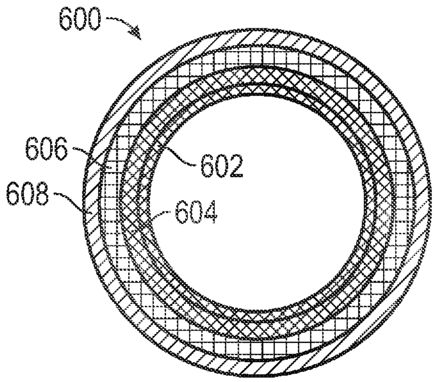

FIG. 22

(57) **Abstract:** A delivery apparatus (300) for delivering a prosthetic implant (200) includes a handle body (304), an outer shaft (309), and an inner shaft (305, 600). The handle body includes a proximal end (308), a distal end (312), and a longitudinal axis (315) extending between the proximal end and the distal end. The outer shaft includes a proximal end movably coupled to the handle body. The inner shaft extends through a lumen (313) of the outer shaft and is fixed relative to the handle body. The inner shaft includes a first reinforcement layer (604) and a second reinforcement layer(606). The first reinforcement layer extends from a proximal end portion of the inner shaft to a first distal location of the inner shaft. The second reinforcement layer extends from the proximal end portion of the inner shaft to a second distal location of the inner shaft, and the second distal location is proximal to the first distal location.

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DELIVERY APPARATUS AND METHODS FOR IMPLANTING PROSTHETIC DEVICES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/237,755, filed on August 27, 2021, which is incorporated by reference herein.

FIELD

[0002] The present disclosure relates generally to delivery apparatus and methods for implanting prosthetic devices and more particularly to delivery apparatus and method for implanting support structures and/or prosthetic heart valves.

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.

[0004] In one specific example, a prosthetic 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 valve reaches the implantation location in the heart. The prosthetic 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 valve, or by deploying the prosthetic valve from a sheath of the delivery apparatus so that the prosthetic valve can self-expand to its functional size.

[0005] In some cases, it may not be possible to secure the prosthetic valve to the native valve annulus, for example, if the native valve annulus is too large or if the geometry of the native valve is too complex to allow secure implantation of the valve. One approach in these cases is to first deploy a docking station at the implantation location and then install the prosthetic valve in the docking station. The docking station can be selected to provide the necessary interface to anchor the prosthetic valve within the native valve annulus. Desirably, the docking station can be delivered to the implantation location with a minimally invasive procedure, which would allow the docking station to be deployed within the same procedure used to deliver the prosthetic valve.

SUMMARY

[0006] Disclosed herein are examples of a delivery apparatus that can be used to deliver a prosthetic implant, such as a docking station, to an implantation location within a patient's body.

[0007] A docking station can include a frame (which can also be called a "stent" or a "prestent") comprising a plurality of struts. The struts can be interconnected in a manner that allows the struts to move between a radially-compressed state and a radially-expanded state.

[0008] The delivery apparatus includes a handle and (optionally) a shaft assembly coupled to the handle. In some examples, the shaft assembly includes one or more shafts. In some examples, the shaft assembly includes an outer shaft and an inner shaft extending through a lumen of the outer shaft.

[0009] In some examples, one or more shafts of a delivery apparatus can include one or more reinforcement layers. The reinforcement layers can be configured to strengthen the shaft, while also allowing the shaft to be sufficiently flexible. As such, the disclosed shafts can withstand the forces applied to the shafts (e.g., during an implantation procedure) and can be navigated through a patient's anatomy (e.g., vasculature).

[0010] In some examples, a delivery apparatus includes a handle body, an outer shaft, and an inner shaft. The handle body comprises a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end. The outer shaft comprises a proximal end movably coupled to the handle body. The inner shaft extends through a lumen of the outer shaft and fixed relative to the handle body. The inner shaft comprises a first reinforcement layer and a second reinforcement layer. The first reinforcement layer extends from a proximal end portion of the inner shaft to a first distal location of the inner shaft. The second reinforcement layer extends from the proximal end portion of the inner shaft to a second distal location of the inner shaft. The second distal location is proximal to the first distal location.

[0011] In some examples, a delivery apparatus includes a handle body, an outer shaft, and an inner shaft. The handle body includes a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end. The outer shaft includes a proximal end movably coupled to the handle body. The inner shaft extends through a lumen of the outer shaft and is fixed relative to the handle body. The inner shaft includes a first braided material comprising a first braid density and a second braided material comprising a second braid density. The second braid density is less than the first braid density.

[0012] In some examples, a shaft for a delivery apparatus includes a proximal end, a distal end, a first reinforcement layer, and a second reinforcement layer. The first reinforcement layer extends from a first proximal location of the shaft to a first distal location of the shaft. The second reinforcement layer extends from a second proximal location of the shaft to a second distal location of the shaft, and the second distal location is proximal to the first distal location.

[0013] In some examples, a shaft for a delivery apparatus includes a proximal end, a distal end, a first braided material, and a second braided material. The first braided material includes a first braid density. The second braided material includes a second braid density, which is less than the first braid density.

[0014] In some examples, a shaft for a delivery apparatus includes a proximal end, a distal end, and a reinforcement layer. The reinforcement layer extends from a first proximal location of the shaft to a distal location of the shaft and comprises a triaxial braided material.

[0015] The above devices can be used as part of an implantation procedure performed on a living animal or on a simulation, such as on a cadaver, cadaver heart, anthropomorphic ghost, simulator (e.g., with body parts, heart, tissue, etc. being simulated).

[0016] 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

[0017] FIG. 1 is an elevation view of a portion of a frame of a docking station in a radially-expanded state.

[0018] FIG. 2 is a perspective view of the frame of FIG. 1 in a radially-compressed state.

[0019] FIG. 3 is a perspective view of a docking station including the frame of FIG. 1.

[0020] FIG. 4 is a cut-away view of the docking station of FIG. 3 deployed at an implantation location within a patient's anatomy, which is depicted schematically in cross-section, and with a prosthetic heart valve deployed therein.

[0021] FIG. 5A is a perspective view of a delivery apparatus for deploying a docking station.

[0022] FIG. 5B illustrates the docking station of FIG. 3 disposed around a distal portion of the delivery apparatus of FIG. 5A.

[0023] FIG. 6A is an elevation view of a distal portion of the delivery apparatus of FIG. 5A with an outer shaft of the delivery apparatus in a retracted position.

[0024] FIG. 6B is an elevation view of a distal portion of the delivery apparatus of FIG. 5A with an outer shaft of the delivery apparatus in an extended position and cut away to show an encapsulated docking station.

[0025] FIGS. 6C-6F illustrate stages in deployment of the docking station of FIG. 3 from the delivery apparatus of FIG. 5A.

[0026] FIG. 7A is a perspective view of a handle portion of the delivery apparatus illustrated in FIG. 5A.

[0027] FIGS. 7B and 7C are perspective views of the handle portion of FIG. 7A with a portion of the handle cut away to show various internal components.

[0028] FIGS. 8A and 8B are perspective views of a carriage member of the handle portion of FIG. 7A.

[0029] FIG. 8C is a cross-sectional view of the carriage member of FIGS. 8A and 8B.

[0030] FIG. 9 is a cross-sectional view of a head portion of the carriage member of FIGS. 8A and 8B.

[0031] FIG. 10 is a cross-sectional view of the carriage member of FIGS. 8A and 8B with a proximal portion of a shaft assembly extending through the carriage member.

[0032] FIG. 11A is a cross-sectional view of the handle portion of FIG. 7A, taken along a plane intersecting line 11A-11A as depicted in FIG. 7A.

[0033] FIG. 11B is a cross-sectional view of the handle portion of FIG. 7A, taken along line 11B-11B as depicted in FIG. 11A.

[0034] FIG. 12A is a cross-sectional view of a proximal portion of the shaft assembly coupled to the handle portion of FIG. 7A with a portion of the shaft assembly cut away to show fluid ports in an inner shaft of the shaft assembly.

[0035] FIG. 12B is a cross-sectional view of a portion of the inner shaft of the shaft assembly illustrated in FIG. 12A.

[0036] FIG. 12C is an enlarged view of the region 12C as depicted in FIG. 12A.

[0037] FIGS. 13A and 13B are elevation views of a frame connector.

[0038] FIGS. 14 is a perspective view of the frame connector of FIGS. 13A and 13B with a cut-away plane taken along line 14-14 as depicted in FIG. 13A.

[0039] FIG. 15 illustrates the frame connector of FIGS. 13A and 13B with a connector tab of a docking station retained in a recess of the frame connector.

[0040] FIG. 16A is a perspective view of the frame connector of FIGS. 13A and 13B with a cut-away plane taken along line 16A-16A as depicted in FIG. 13A.

[0041] FIG. 16B is a cross-sectional view of the frame connector of FIGS. 13A and 13B at the cut-away plane shown in FIG. 16A.

[0042] FIG. 17A is a perspective view of the frame connector of FIGS. 13A and 13B with a cut-away plane taken along line 17A-17A as depicted in FIG. 13A.

[0043] FIG. 17B is a cross-sectional view of the frame connector of FIGS. 13A and 13B at the cut-away plane shown in FIG. 17A.

[0044] FIG. 18 is a cross-sectional view of a distal portion of a delivery apparatus illustrating the frame connector of FIGS. 13A and 13B connected to an inner shaft of the shaft assembly of FIGS. 5A and 5B.

[0045] FIG. 19 is an elevation view of a distal portion of the delivery apparatus of FIG. 5A with an outer shaft of the delivery apparatus in an extended position and cut away to show a docking station restrained by the outer shaft and the frame connector of FIGS. 13A and 13B.

[0046] FIG. 20 is a rotated view of the distal portion of the delivery apparatus depicted in FIG. 19 with the frame connector cut away to show engagement with connector tabs of a docking station.

[0047] FIG. 21 illustrates radial deflection of the connector tabs of the docking station of FIGS. 19 and 20 in response to axial tension applied to the connector tabs.

[0048] FIG. 22 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to one example.

[0049] FIG. 23 is a partial side view of the shaft of FIG. 22, depicting a portion of the shaft comprising a cover tube and a plurality of fluid ports.

[0050] FIG. 24 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0051] FIG. 25 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0052] FIG. 26 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0053] FIG. 27 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0054] FIG. 28 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0055] FIG. 29 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

[0056] FIG. 30 is a schematic cross-sectional view of a shaft for a delivery apparatus, according to another example.

DETAILED DESCRIPTION

[0057] General Considerations

[0058] 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.

[0059] 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.

[0060] In the interest of conciseness, and for the sake of continuity in the description, same or similar reference characters may be used for same or similar elements in different figures, and description of an element in one figure will be deemed to carry over when the element appears in other figures with the same or similar reference character. In some cases, the term "corresponding to" may be used to describe correspondence between elements of different figures. In an example usage, when an element in a first figure is described as corresponding to another element in a second figure, the element in the first figure is deemed to have the characteristics of the other element in the second figure, and vice versa, unless stated otherwise.

[0061] 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. The word "comprise" and derivatives thereof, such as "comprises" and "comprising," are to be construed in an open, inclusive sense, that is, as "including, but not limited to." 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.

[0062] 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.

[0063] As used herein, the term "simulation" means a performing an act on a cadaver, cadaver heart, anthropomorphic ghost, and/or a computer simulator (e.g., with the body parts, tissue, etc. being simulated).

[0064] Introduction to the Disclosed Technology

[0065] This disclosure describes a plurality of delivery apparatus that can be used to deliver prosthetic implants such as docking stations and/or prosthetic heart valves to an implantation location within a patient's anatomy. The delivery apparatus includes a shaft assembly coupled to a handle, which controls operations of the delivery apparatus. A prosthetic implant can be encapsulated within a distal end portion of one of the shafts of the shaft assembly for delivery to the implantation location.

[0066] The shaft assembly includes an outer shaft that is movable between an extended position to encapsulate a prosthetic implant loaded onto the delivery apparatus and a retracted position to expose the prosthetic implant for deployment at the implantation location. A carriage member is included in the handle to move the outer shaft between the retracted and extended positions. The shaft assembly includes an inner shaft that extends through the lumen of the outer shaft.

[0067] In certain examples, the carriage member and the outer shaft form a gland or annular groove to hold a seal member. In certain examples, the inner shaft includes one or more fluid ports that together with the seal member disposed within the carriage member allow the inner shaft and the outer shaft to be flushed with fluid from a single injection port.

[0068] In certain examples, the inner shaft can carry a frame connector having one or more recesses to receive one or more connector tabs of the prosthetic implant and thereby axially restrain the prosthetic implant. In certain examples, the recesses have undercut walls that translate tensile force applied to the connector tabs to radial force acting on the connector tabs, which can help maintain engagement of the connector tabs with the recesses during recompression and/or retrieval of the prosthetic implant.

[0069] Also disclosed herein are examples of shafts for a delivery apparatus. The disclosed shafts can include one or more reinforcement layers. The reinforcement layers can be configured to strengthen the shaft, while also allowing the shaft to be sufficiently flexible. As such, the disclosed shafts can withstand the forces applied to the shafts (e.g., during an implantation procedure) and can be navigated through a patient's anatomy (e.g., vasculature).

[0070] In some examples, a plurality of reinforcement layers can be provided. In some instances, each reinforcement layer can extend along a different portion of the shaft. In particular instances, the reinforcement layers can axially overlap for at least a portion of the length and/or can be non-overlapping for at least a portion of the length.

[0071] In some examples, one or more of the reinforcement layers can include a braided material, such as a metal braid. In examples with a plurality of reinforcement layers, each reinforcement material can be the same or can be different. In certain examples, a first braided material having a first braid density and/or a first wire count can be used as a first reinforcement layer and a second braided material having a second braid density and/or a second wire count can be used as a second reinforcement layer.

[0072] <u>Examples of the Disclosed Technology</u>

[0073] Turning now to the drawings, FIG. 1 illustrates an exemplary implementation of a frame 100 (or stent) that can form a body of a docking station. The frame 100 has a first end 104 and a second end 108. In some examples, the first end 104 can be an inflow end, and the second end 108 can be an outflow end. In some examples, the first end 104 can be an outflow end, and the second end 108 can be an inflow end. The terms "inflow" and "outflow" are related to the normal direction of blood flow (e.g., antegrade blood flow) through the frame. In the unconstrained, expanded state of the frame 100 shown in FIG. 1, a relatively narrower portion (or waist) 112 of the frame 100 between the first end 104 and the second end 108 forms a valve seat 116. The frame 100 can be compressed (as illustrated in FIG. 2) for delivery to an implantation location by a delivery apparatus.

[0074] Although the docking stations, delivery apparatus, prosthetic heart valves, and/or methods are described herein with respect to a particular implantation location (e.g., a pulmonary valve) and/or a particular delivery approach (e.g., transfemoral), the device and methods disclosed herein can be adapted to various other implantation locations (e.g., an aortic valve, a mitral valve, and a tricuspid valve) and/or delivery approaches (e.g., transapical, transseptal, etc.).

[0075] In the example illustrated by FIG. 1, the frame 100 includes a plurality of struts 120 arranged to form cells 124. The ends of the struts 120 form apices 128 at the ends of the frame 100. One or more of the apices 128 can include a connector tab 132. The portions of the struts 120 between the apices 128 and the valve seat 116 (or the waist 112) form a sealing portion 130 of the frame 100. In the unconstrained, expanded state of the frame 100 illustrated in FIG. 1, the apices 128 extend generally radially outward and are radially outward of the valve seat 116.

[0076] The frame 100 can be made of a highly resilient or compliant material to accommodate large variations in the anatomy. For example, the frame 100 can be made of a flexible metal, metal alloy, polymer, or an open cell foam. An example of a highly resilient metal is Nitinol, which is a metal alloy of nickel and titanium, but other metals and high resilient or compliant non-metal materials can be used. The frame 100 can be self expanding, manually expandable (e.g., expandable via a balloon), or mechanically expandable. A self-expanding frame can be made of a shape memory material, such as, for example, Nitinol. In this manner, the frame can be radially compressed as depicted in FIG. 2 (e.g., via a crimping device) and can radially expand to the configuration depicted in FIG. 1.

[0077] FIG. 3 illustrates an exemplary docking station 136 including the frame 100 and an impermeable material 140 disposed within the frame. The impermeable material 140 is attached to the frame 100 (e.g., by sutures 144). In the example illustrated by FIG. 3, the impermeable material 140 covers at least the cells 124 in the sealing portion 130 of the frame 100. The seal formed by the impermeable material 140 at the sealing portion 130 can help funnel blood flowing into the docking station 136 from the proximal inflow end 104 to the valve seat 116 (and the valve once installed in the valve seat). One or more rows of cells 124 proximate to the distal outflow end 108 can be open.

[0078] The impermeable material 140 can be a fabric that is impermeable to blood. A variety of biocompatible materials can be used as the impermeable material 140, such as, for example, foam or a fabric that is treated with a coating that is impermeable to blood, a polyester material, or a processed biological material, such as pericardium. In one particular example, the impermeable material 140 can be polyethylene terephthalate (PET).

[0079] The docking station 136 may include a band 146 that extends around the waist 112 (or that is integral to the waist) of the frame 100. The band 146 can constrain expansion of the valve seat 116 to a specific diameter in the deployed state to enable the valve seat 116 to support a specific valve size. The band 146 can take on a wide variety of different forms and can be made of a wide variety of different materials. For example, the band 146 can be made of PET, one or more sutures, fabric, metal, polymer, a biocompatible tape, or other relatively nonexpanding materials known in the art and that can maintain the shape of the valve seat 116.

[0080] FIG. 4 illustrates the docking station 136 in a deployed state within a native valve annulus 148. As can be seen, the frame 100 of the docking station 136 is in an expanded condition, with the end portions of the frame pressed against the inner surface 152 of the native valve annulus. The band 146 (shown in FIG. 3) can maintain the valve seat 116 at a constant or substantially constant diameter in the expanded condition of the frame 100. FIG. 4 also shows a prosthetic valve 200 deployed within the docking station 136 and engaged with the valve seat 116 of the docking station 136. The prosthetic valve 200 can be implanted by first deploying the docking station 136 at the implantation location and then installing the prosthetic valve within the docking station.

[0081] The prosthetic valve 200 can be configured to replace a native heart valve (e.g., aortic, mitral, pulmonary, and/or tricuspid valves). In one example, the prosthetic valve 200 can include a frame 204 and a valvular structure 208 disposed within and attached to the frame 204. The valvular structure 208 can include one or more leaflets 212 that cycle between open and closed states during the diastolic and systolic phases of the heart. The frame 204 can be made of the frame materials described for the frame 100 of the docking station 136. The leaflets 212 can be made in whole or in part from pericardial tissue (e.g., bovine pericardial tissue), biocompatible synthetic materials, or various other suitable natural or synthetic materials known in the art.

[0082] The docking station 136 is not limited to use with the particular example of the prosthetic valve 200 illustrated in FIG. 4. For example, mechanically expandable prosthetic valves such as described in U.S. Patent Publication Nos. 2018/0153689 and 2019/0060057; U.S. Patent Application No. 62/869,948; and International Application No. PCT/US2019/056865, the relevant disclosures of which are incorporated by reference herein, may be installed in the docking station 136.

[0083] FIG. 5A illustrates an exemplary delivery apparatus 300 that can be used to deliver the docking station to an implantation location. The delivery apparatus 300 generally includes a handle 302 and a shaft assembly 303 coupled to the handle 302 and extending distally from the handle 302. The shaft assembly 303 includes an inner shaft 305 and an outer shaft 309. The inner shaft 305 extends through a lumen of the outer shaft 309.

[0084] In the example illustrated by FIG. 5A, a frame connector 400 is coupled to the inner shaft 305. The docking station 136 can be disposed around a portion of the inner shaft 305 extending distally from the frame connector 400, as shown in FIG. 5B. In one example, the frame connector 400 includes one or more recesses that can receive one or more connector tabs 132 at the proximal end of the docking station 136 and thereby axially restrain the docking station 136.

[0085] A nosecone 317 can be attached to a distal end of the inner shaft 305. The nosecone 317 includes a central opening 319 for receiving a guidewire. As such, a proximal end of the guidewire can be inserted into the central opening 319 and through the inner shaft 305, and a distal end portion of the delivery apparatus 300 can be advanced over the guidewire through a patient’s vasculature and to an implantation location. The guidewire can pass through the nosecone 317 into the inner shaft 305 during advancing of the delivery apparatus through a patient’s vasculature.

[0086] The handle 302 can be operated to move the outer shaft 309 relative to the inner shaft 305, generally between an extended position and a retracted position. The handle 302 can be extended to slide the outer shaft 309 over the frame connector 400 and over any docking station coupled to the frame connector 400 to encapsulate the docking station within the outer shaft 309. As the outer shaft 309 slides over the docking station 136, the outer shaft 309 can compress the docking station 136 such that the docking station is encapsulated within the outer shaft 309 in the compressed state. In the fully extended position, a distal end of the outer shaft 309 can abut a proximal end of the nosecone 317 such that there are no gaps in the delivery assembly. Additionally or alternatively, a crimping device can be used to radially compress the docking station such that it can be inserted into the outer shaft of the delivery apparatus.

[0087] FIGS. 6A-7D illustrate a method of deploying a docking station at an implantation location within an anatomy. For purposes of illustration, the patient's anatomy is omitted. In FIG. 6A, the method includes retracting the outer shaft 309 by the handle of the delivery apparatus to allow loading of the docking station 136 onto the inner shaft 305. In FIG. 6B, the method includes disposing the docking station 136 around the inner shaft 305 and engaging each of the connector tabs 132 of the docking station 136 with the frame connector 400. The method also includes positioning the outer shaft 309 over the docking station such that the docking station is encapsulated therein. This can be accomplished by manipulating the handle of the delivery apparatus. As shown in FIG. 6B, the distal end of the outer shaft 309 abuts the proximal end of the nosecone 317. The method includes inserting the delivery apparatus, from the nosecone 317 end, into a patient's vasculature and advancing the delivery apparatus through the patient's vasculature to the implantation location.

[0088] At the implantation location, the method includes retracting the outer shaft 309 by the handle of the delivery apparatus to expose the docking station 136. FIGS. 6C-6F show different stages of retracting the outer shaft 309. As can be seen, in cases where the docking station 136 is self-expanding, the docking station 136 gradually emerges from the outer shaft 309 and gradually expands from the compressed state as the outer shaft 309 is retracted. When the outer shaft 309 is sufficiently retracted, the connector tabs 132 disengage from the frame connector 400. Once the docking station 136 is disengaged from the frame connector 400, the docking station 136 can radially expand to engage the anatomy.

[0089] FIGS. 7A-7C illustrate an exemplary implementation of the handle 302 of the delivery apparatus. The handle 302 includes a handle body 304 and a deployment mechanism 306 coupled to and partially disposed within the handle body. The handle body

304 includes a proximal end 308, a distal end 312, and a cavity 316 extending from the proximal end 308 to the distal end 312. The handle 302 includes a longitudinal axis 315 extending from the proximal end 308 to the distal end 312. The longitudinal axis 315 defines the axial direction of the handle.

[0090] The handle body 304 can be a single piece body with the cavity 316. Alternatively, the handle body 304 can have two body pieces 304a, 304b that can be assembled together to form the cavity 316. For example, the first body piece 304b may have snap hooks 307 that snap into complementary recesses in the second body piece 304a.

[0091] The deployment mechanism 306 of the handle 302 includes a carriage member 500 and a drive member 320. The carriage member 500 is disposed within the cavity 316 and movable relative to the handle body 304 in the axial direction. The drive member 320 engages with the carriage member 500 and is movable (e.g., rotatable) relative to the handle body 304 to adjust the axial position of the carriage member 500 relative to the handle body 304.

[0092] Proximal portions of the shafts 305, 309 are inserted into the cavity of the handle body 304. A proximal end portion of the outer shaft 309 of the shaft assembly 303 can be coupled to the carriage member 500 (e.g., by fasteners, adhesive, and/or other means for coupling) such that movement of the carriage member 500 relative to the handle body 304 causes movement of the outer shaft 309 between the extended and retracted positions.

[0093] A proximal portion of the inner shaft 305 extends through a lumen 313 of the outer shaft 309 into a proximal portion of the cavity 316 and is coupled to the handle body 304. The inner shaft 305 can be fixed relative to the handle body 304 such that the inner shaft 305 is stationary while the outer shaft 309 moves relative to the handle body 304.

[0094] In the example illustrated by FIGS. 7A-7C, an injection port 324 is mounted at an opening at the proximal end 308 of the handle body 304. The injection port 324 can be, for example, a Luer fitting. A proximal end of the inner shaft 305 can be inserted into the injector port 324 (shown in FIG. 11A) and secured to the injection port 324 (e.g., by bonding). In some cases, the attachment of the inner shaft 305 to the injection port 324 can serve the purpose of fixing the inner shaft 305 relative to the handle body 304.

[0095] The injection port 324 can be used to inject flushing fluid, such as saline, into the lumen of the inner shaft 305. In some cases, the inner shaft 305 can include one or more fluid ports 311 through which the injected fluid exits the inner shaft 305 and enters the lumen 313 of the outer shaft 309, thereby allowing flushing of the lumens of the inner shaft 305 and outer shaft 309 from a single injection port.

[0096] FIGS. 8A-8C illustrate an exemplary implementation of the carriage member 500. The carriage member 500 includes a carriage body 504 having a distal end 506 and a proximal end 510. The carriage body 504 has a head portion 508 and a stem portion 512 between the distal end 506 and the proximal end 510. The carriage body 504 can be formed (e.g., molded) as a single, unitary component. Preferably, the carriage body 504 has enough rigidity to support a portion of the shaft assembly received within the handle body 304 (shown in FIGS. 7B and 7C).

[0097] The head portion 508 of the carriage body 504 has an external surface 516. External threads 518 are formed on the portion of the external surface 516 at opposite sides of the head portion 508. The external threads 518 can engage a complementary internal thread in the drive member 320 (shown in FIGS. 7B and 7C) of the handle. The head portion 508 has an internal surface 520 that defines an internal bore 524 configured to receive a portion of the shaft assembly.

[0098] The stem portion 512 includes a central opening 532, which is longitudinally aligned with and connected to the internal bore 524 of the head portion 508, forming a passage extending along the entire length of the carriage body 504. Longitudinal slots 536a, 536b (or guide members) are formed on opposite sides of the stem portion 512. The longitudinal slot 536a may be connected to the central opening 532 (or to the passage formed by the bore 524 and central opening 532) as illustrated in FIG. 8C. The longitudinal slots 536a, 536b can receive complementary guide members 348a, 348b (shown in FIGS. 11A and 11B) within the elongated cavity of the handle body.

[0099] Referring to FIG. 9, a locating shoulder 540 is formed on the internal surface 520 of the head portion 508. The locating shoulder 540 defines a first stepdown transition in the internal bore 524. For example, the locating shoulder 540 steps down the diameter of the internal bore 524 from diameter d1 to diameter d2, where the diameter d1 is greater than the diameter d2. The locating shoulder 540 is offset from the distal end 506 of the carriage body 504 by a distance L1. The locating shoulder 540 has an annular face that is oriented towards the distal end 506 and may be referred to as “a distally facing annular shoulder” in some cases.

[0100] A gland shoulder 544 is formed on the internal surface 520 of the head portion 508. The gland shoulder 544 defines a second stepdown transition in the internal bore 524. For example, the gland shoulder 544 steps down the diameter of the internal bore 524 from diameter d2 to diameter d3, where the diameter d2 is greater than the diameter d3. The gland shoulder 544 is offset from the distal end 506 of the carriage body 504 by a distance L2 that is greater than the distance L1, which means that the gland shoulder 544 is located proximally to the locating shoulder 540. The gland shoulder 544 has an annular face that is oriented towards the distal end 506 and may be referred to as “a distally facing annular shoulder” in some cases.

[0101] FIG. 10 shows the shaft assembly 303 extending through the passage formed by the internal bore 524 and the central opening 532 such that the proximal end (or proximal face) of the outer shaft 309 is positioned within the internal bore 524. The proximal end of the outer shaft 309 forms a shoulder 546 that is in opposing relation to and distal relative to the gland shoulder 544. The outer shaft 309 can be secured to the head portion 508 of the carriage member 500 in this position (e.g., via fasteners, adhesive, and/or other means for coupling). An annular groove 548 (or gland) is defined within the internal bore 524 by the opposed shoulders 544, 546 and the portion of the internal surface 520 between the opposed shoulders 544, 546. The annular groove 548 can receive a seal member 552.

[0102] In some examples, the locating shoulder 540 can act as a stop surface for the proximal end of the outer shaft 309. In this case, the diameter d2 (shown in FIG. 9), which corresponds to the inner diameter of the locating shoulder 540, can be selected to be larger than an inner diameter of the outer shaft 309 at the proximal end of the outer shaft 309 such that when the proximal end of the outer shaft 309 abuts the locating shoulder 540, a portion of the proximal end of the outer shaft 309 forms the shoulder 546 at the first stepdown transition. As shown for example in FIG. 10, the shoulder 546 formed by the proximal end of the outer shaft 309 can be radially inward of the locating shoulder 540 at the first stepdown transition.

[0103] In some examples, the carriage body 504 can be formed without the locating shoulder 540, and the outer shaft 309 can be inserted into the internal bore 524 to a point at which the proximal face of the outer shaft 309 abuts the distal face of the seal member 522, which would at the same time form the distal end of the annular groove 548.

[0104] As illustrated by FIG. 10, the inner shaft 305 extending through the lumen of the outer shaft 309 passes through the portion of the internal bore 524 between the opposed gland shoulders 544, 546, which means that the annular groove 548 is disposed around a circumference of the inner shaft 305. Thus, the seal member 552 disposed in the annular groove 548 can form a seal between the inner shaft 305 and the internal surface 520 and at the proximal end of the outer shaft 309. The seal member 552 can cycle between dynamic sealing and static sealing. Dynamic sealing occurs when the seal member 552 slides along the inner shaft 305 as the carriage member 500 moves relative to the handle body 304 (shown in FIGS. 7B and 7C). In this manner, the seal member 552 can also be referred to as “a wiper seal.” The seal member 552 can be any suitable seal (e.g., an O-ring).

[0105] The gland shoulder 544 forms the proximal end of the annular groove 548 (or the proximal gland shoulder), and the proximal end (or proximal face) of the outer shaft 309 forms the distal end of the annular groove 548 (or the distal gland shoulder). In some cases, the locating shoulder 540 can form a stop for the outer shaft 309. Forming the shoulders of the carriage body as stepped shoulders can, among other things, allow the carriage body 504 (or carriage member 500) to be molded as a single piece. The molding process can include forming a mold cavity for the carriage body and a core pin to form the internal bore including the locating and gland shoulders 540, 544. The core pin is secured within the mold cavity, and molten thermoplastic material is injected into the mold cavity to form the molded body. The stepped shoulders can, for example, allow the core pin to be easily removed from the distal end of the molded part. As such, the disclosed configuration simplifies both manufacture and assembly of the handle as one exemplary advantage.

[0106] Returning to FIG. 7C, the carriage member 500 is axially movable within the cavity 316 and relative to the handle body 304 by rotation of the drive member 320. In the example illustrated by FIG. 11A, the drive member 320 has a barrel portion 320a extending into the cavity 316 from the distal end 312 of the handle body 304 and a knob portion 320b projecting from the distal end 312 of the handle body 304. The barrel portion 320a has a ring member 332 that extends into a recess 336 in the handle body 304. A distal face of the ring member 332 can abut a proximal face of the recess 336 to limit movement of the drive member 320 in the distal direction.

[0107] The drive member 320 includes an internal surface 328 that defines an internal bore 340. The internal surface 328 includes an internal thread 344, which is complementary to the external threads 518 (shown in FIGS. 8A and 8B) on the head portion of the carriage member 500. As shown, the carriage member 500 extends into the internal bore 340 such that the external threads 518 on the head portion of the carriage member 500 are engaged with the internal thread 344 in the drive member 320.

[0108] Rotation of the knob portion 320b causes rotation of the drive member 320 relative to the handle body 304, which causes the carriage member 500 to move along the internal bore 340 of the drive member 320. The threads 344, 518 translate the rotary motion of the drive member 320 to a linear motion of the carriage member 500. However, other mechanisms besides a lead screw mechanism can be used to translate the carriage member 500 axially relative to the handle body 304.

[0109] Referring to FIGS. 11A and 11B, the handle body 304 can include flattened projections 348a, 348b (or guide members) extending into the cavity 316. The flattened projections 348a are received in the longitudinal slot 536a of the carriage member 500. The flattened projection 348b is received in the longitudinal slot 536b. The longitudinal slots 536a, 536b move along respective flattened projections 348a, 348b as the carriage member 500 moves axially within the cavity 316 and relative to the handle body 304. The flattened projections 348a, 348b are longitudinally aligned with the handle body 304 and cooperate with the longitudinal slots 536a, 536b to prevent rotation of the carriage member 500 when the drive member 320 is rotated.

[0110] FIG. 12A shows a proximal portion of the shaft assembly 303 (i.e., the portion of the shaft assembly 303 immediately coupled to the handle). The proximal portion of the shaft assembly 303 includes a proximal portion of the outer shaft 309 and a proximal portion of the inner shaft 305 extending through the lumen 313 of the outer shaft 309. As previously described with respect to FIG. 11A, the proximal end of the outer shaft 309 is received within the carriage member 500, and the inner shaft 305 extends through the outer shaft 309 and through the carriage member. As shown in FIG. 12A, the proximal end portion of the inner shaft 305 includes the proximal end 305a that can be fluidly connected to the injection port 324 (shown in FIGS. 7A-7C and 11A) and the fluid ports 311 that allow fluid injected into the inner shaft 305 at the injection port to exit the inner shaft 305 and enter the lumen 313 of the outer shaft 309.

[0111] In one implementation, the inner shaft 305 includes a reinforced tube 321. In the example illustrated by FIG. 12B, the reinforced tube 321 can include an inner layer 325, a reinforcement layer 329 disposed over the inner layer 325, and an outer layer 333 disposed over the reinforcement layer 329. The inner layer 325, the reinforcement layer 329, and the outer layer 333 can be in the form of tubes extending substantially along the length of the inner shaft 305.

[0112] The reinforcement layer 329 can extend along various portions of the inner shaft 305. In some examples, the reinforcement layer 329 can extend from the proximal end 305 (e.g., adjacent the injection port 324) to the distal end of the inner shaft 305 (e.g., adjacent or at least partially axially overlapping with the nosecone 317). In some examples, the reinforcement layer 329 can extend along a lesser portion of the inner shaft (e.g., from the proximal end 305a to the portion of the inner shaft to which the frame connector 400 is mounted).

[0113] The reinforcement layer 329 can be, for example, a braided tube, which can be made from metal wire (such as stainless-steel wire or Nitinol wire) or from synthetic fibers (e.g., Kevlar). The wires can comprise various cross-sectional profiles taken in a plane perpendicular to the longitudinal axis of the wires. For example, the cross-sectional profile can be round, rectangular, etc.

[0114] In braided configurations, the reinforcement layer can be formed of a braid comprising 4-32 wires (or 8-24 wires in certain examples). In particular examples, the reinforcement layer can comprise 10-20 wires. In certain examples, the reinforcement layer can comprise a 16-wire braid. The braid densities can also vary. For example, the braid density of the reinforcement layer can be within a range of 40-60 picks per inch (PPI). In certain examples, the braid density can be 45 PPI.

[0115] The reinforcement layer can comprise one or more axially-extending elements (e.g., wires, fibers, etc.) in lieu of or in addition to the braided material. For example, a plurality of wires can extend axially along all or a portion of the length of the inner shaft. These wires differ from the braided wires because they do not intersect with each other (though they may intersect with the braid—which in some instances can be called a "triaxial braid"). In other words, these wires are spaced circumferentially relative to each other around the inner shaft.

[0116] The reinforced tube 321 can be configured as a flexible tube to facilitate movement of the tube through the vasculature of a patient. The inner layer 325 and the outer layer 333 can be tubes made of a polymer material. Examples of suitable polymer materials include, but are not limited to, PEBAX® elastomers, nylons, and polyurethane.

The inner layer 325 and outer layer 333 can be made of the same material or of different materials. In some cases, the reinforced tube 321 can be made by extrusion.

[0117] The inner shaft 305 can include one or more fluid ports. The fluid ports are formed in the wall of the reinforced tube and can allow a flushing fluid to flow from the inner lumen of the inner shaft and into the lumen of the outer shaft 309. In this manner, the fluid ports 311 enable flushing of the inner shaft 305 and the outer shaft 309 from a single injection port rather than requiring the shafts to be separately flushed. Referring to FIGS. 12B and 12C, each fluid port 311 includes a first opening 325a in the inner layer 325, a second opening 333a in the outer layer 333 that is radially aligned with the first opening, and the pores (or openings) in the portion 329a of the reinforcement layer 329 between the two openings 325a, 333a. The openings 325a, 333a can have any suitable shape (e.g., oval as shown in FIGS. 12A and 12C, circular, square, or rectangular shape).

[0118] Any number of fluid ports 311 can be formed in the reinforced tube 321. For example, the illustrated reinforced tube 321 comprises four ports 311 (shown in FIG. 12B). When there are multiple fluid ports 311, various arrangements of the fluid ports 311 on the reinforced tube 321 are possible. For example, FIGS. 12A-12C show two of the fluid ports 311 spaced apart axially and aligned circumferentially along the reinforced tube 321. As depicted in FIG. 12B, the reinforced tube 321 also comprises two additional fluid ports 311 that are axially aligned and circumferentially spaced apart (e.g., by 180 degrees) from the fluid ports depicted in FIG. 12C. In some examples, the fluid ports 311 can be spaced apart and/or staggered around the reinforced tube 321. For example, the fluid ports 311 can be spaced apart and staggered around the reinforced tube 321 to form a spiral pattern. In some examples, the fluid ports can form an alternating-type pattern such that a first side of the tube comprises a plurality of ports (e.g., a first proximal port and a first distal port), and a second side of the tube (e.g., located 180 degrees from the first side) comprises a plurality of ports (e.g., a second proximal port and a second distal port), and the ports are arranged axially in the following manner moving proximal to distal: first proximal port, second proximal port, first distal port, second distal port.

[0119] The inner shaft 305 can, in some instances, include a cover tube 337 extending over a proximal portion of the reinforced tube 321. The cover tube 337 includes one or more windows 341 positioned to expose the fluid ports 311. The cover tube 337 is the part of the inner shaft 305 that contacts the seal member 552 (shown in FIG. 11A) when the inner shaft 305 extends through the carriage member 500 (shown in FIG. 11A). The cover tube 337 is preferably a rigid member that can support sliding of the seal member. The cover tube 337 preferably has a surface finish to provide a proper sealing surface to the seal member 552. The cover tube 337 can be made of metal or plastic. For example, the cover tube 337 can be made from stainless steel. The cover tube 337 can be secured to the reinforced tube 321 by any suitable method, such as by crimping, adhesive, etc.

[0120] Referring to FIGS. 11A and 12A, fluid (e.g., saline) can be injected into the inner shaft 305 through the injection port 324 for the purpose of flushing the inner shaft. The fluid will move through the lumen of the inner shaft 305. A portion of the fluid moving through the lumen of the inner shaft 305 will exit through the fluid ports 311 and enter the lumen 313 of the outer shaft 309, allowing flushing of the outer shaft. Thus, both the inner shaft 305 and the outer shaft 309 can be flushed using a single injection port. The seal member 552 forms a seal at the proximal end of the outer shaft 309 and prevents leakage of the fluid from the proximal end of the outer shaft. Later, during use of the delivery apparatus, the seal member 552 will also prevent leakage of blood from the proximal end of the outer shaft, thereby maintaining hemostasis.

[0121] Returning to FIGS. 6A-6F, the docking station 136 can be configured as a self-expanding docking station where the docking station 136 and the connector tabs 132 are naturally biased toward an expanded configuration. While the docking station 136 is attached to the delivery system, the docking station 136 is compressed to a smaller configuration (shown in FIG. 6B) for insertion and tracking through the vasculature. The compressed configuration of the docking station is held in place axially by the frame connector 400 (which is fixed relative to the inner shaft 305) and held in place radially by the outer shaft 309. The docking station 136 is therefore prevented from premature deployment by the frame connector 400 and the outer shaft 309. Once the docking station 136 is at the implantation location within the anatomy, the outer shaft 309 can be retracted to expose and deploy the docking station 136.

[0122] As the outer shaft 309 is retracted to expose the docking station 136, the distal portion of the docking station 136 expands (as shown, for example, in FIGS. 6C and 6D). In some cases, prior to completing retraction of the outer shaft 309, it may be desirable to reposition and/or retrieve the docking station 136. In this case, the outer shaft 309 may be extended again to recapture and recompress the docking station 136 in order to allow the docking station 136 to be repositioned and/or retrieved. However, the bias toward an expanded configuration can create an axial tension between the docking station and the frame connector. The axial tension can concentrate at the flanges of the connector tabs of the docking station as the outer shaft is extended distally over the docking station for recapture. Due to the relatively high forces during recapture and/or retrieval, the connector tabs of the docking station tend to move radially outwardly attempting to disengage from the frame connector 400. This can increase the force required to recapture the docking station. In extreme instances, the connector tabs can disengage from the connector, which can inhibit recompression and/or retrieval of the docking station.

[0123] FIGS. 13A-17B illustrate an exemplary implementation of the frame connector 400 that can help retain the connector tabs in the radially-compressed configuration during recompression/retrieval of the docking station. Referring to FIGS. 13A and 13B, the frame connector 400 includes a connector body 404, a flange 408 attached to one end of the connector body 404, and a flange 412 attached to another end of the connector body 404. The flange 408 provides a proximal end 410 of the connector, and the flange 412 provides a distal end 414 of the connector. The frame connector 400 has a longitudinal axis 415 (or central axis) extending from the proximal end 410 to the distal end 414. The longitudinal axis 415 defines the axial direction of the connector.

[0124] As shown in FIG. 14, the frame connector 400 has an internal bore 413 extending through the flanges 408, 412 and connector body 404 and along the longitudinal axis (415 in FIG. 13B). The internal bore 413 can receive a proximal portion of the inner shaft of the shaft assembly of the delivery apparatus. The flange 408 can include radial holes 406 that connect to the internal bore 413. As will be described later, the radial holes 406 can play a role when the frame connector 400 is fixed to the inner shaft of the shaft assembly (e.g., by an over-molding process).

[0125] Returning to FIGS. 13A and 13B, the connector body 404 includes an exterior with an exterior surface 416 and one or more recesses 420. Each of the recesses 420 can receive one of the connector tabs of the docking station. In the implementation illustrated by FIGS. 13A-17B, two recesses 420 are formed in diametrically opposed positions on the exterior of the connector body 404. In general, when a plurality of recesses 420 are formed on the exterior of the connector body 404, the recesses 420 can be formed in angularly (which may also be referred to as “circumferentially”) spaced apart locations along the exterior of the connector body 404 (i.e., distributed along a circumference of the connector body 404).

[0126] Referring still to FIGS. 13A and 13B, each recess 420 can be a recessed slot having a first slot portion 420a and a second slot portion 420b arranged to form a "T" shape. As shown, the first slot portion 420a is generally aligned with the longitudinal axis 415 of the connector and is generally perpendicular to the second slot portion 420b. The first slot portion 420a has a first width W1, and the second slot portion 420b has a second width W2. The second width W2 is greater than the first width W1, which means that the recess 420 transitions from a larger width slot portion 420b to a smaller width slot portion 420a. As shown in FIG. 15, the recess 420 is open at the exterior surface 416 so that a connector tab 132 having a flared portion 132a can be positioned in the recess from the exterior surface 416.

[0127] Referring to FIGS. 13A and 16A, each recess 420 has a recess floor 424, opposite side walls 428, 429, and an end wall 430. The side walls 428, 429 project from opposite sides of the recess floor 424. The side wall 428 is connected to a portion 417 of the exterior surface 416. The side wall 429 is connected to a portion 418 of the exterior surface 416. The end wall 430 projects from an end of the recess floor 424 and is connected to a portion 419 of the exterior surface 416. The recess floor 424 is on a different plane compared to the surface portions 417, 418, 419. In particular, the recess floor 424 is recessed (or radially inward) relative to the surface portions 417, 418, 419, as shown more clearly in FIG. 16A.

[0128] In one example, the surface portions 417, 418 are on the same plane but on a different plane compared to the surface portion 419. For example, as shown in FIG. 13B, each of the surface portions 417, 418 can be radially outward of the surface portion 419 by an offset distance d. Stated differently, the height h1 of the side walls 428, 429 relative to the recess floor 424 can be greater than the height h2 of the end wall 430 relative to the recess floor 424. Since the connector tab that is received in the recess 420 will contact the side walls 428, 429, the height of the side walls 428, 429 can be selected to provide sufficient engagement surfaces for the connector tab.

[0129] A first portion 428a of the side wall 428 and a first portion 429a of the side wall 429 form opposite sides of the first slot portion 420a (in FIG. 13A) of the recess 420. The end wall 430 is longitudinally displaced from the first and second walls 428, 429 by a distance that determines the height of the second slot portion 420b (in FIG. 13A) of the recess 420. A second portion 428b of the side wall 428 and a second portion 429b of the side wall 429 are in opposing relation to the end wall 430. The end wall 430 and the second portions 428b, 429b of the side walls 428, 429 form opposite ends of the second slot portion 420b of the recess 420.

[0130] FIG. 15 shows a connector tab 132 of a docking station positioned within a recess 420 of the frame connector 400 prior to deployment of the docking station at an implantation location. The connector tab 132 can be formed at an apex of a strut 120 of the frame of the docking station as previously described. In the example illustrated by FIG. 15, the connector tab 132 has a flared portion 132a that sits in the second slot portion 420b and engages the side walls 428, 429. The flared portion 132a engages the side walls 428, 429 because the flared portion 132a is wider than the first slot portion 420a. When the flared portion 132a engages the side walls 428, 429 as shown, the connector tab 132 is prevented from being pulled axially through the first slot portion 420a.

[0131] To help retain the connector tab 132 in the radially-compressed configuration and thus its connection with the frame connector 400 when axial tension is created between the docking station and the frame connector, the second portions 428b, 429b of the side walls 428, 429 are formed as undercut walls, which means that there is a space or recess underneath each of the second portions 428b, 429b (or a space or recess between each of the second portions 428b, 429b and the recess floor 424). As illustrated in FIGS. 17A and 17B, the second portions 428b, 429b, which are formed as undercut walls, are inclined relative to the recess floor 424 (i.e., the second portions 428b, 429b are not perpendicular to the recess floor 424). The angle α between the second portion 428b and the recess floor 424 is less than 90 degrees, and the angle θ between the second portion 429b and the recess floor 424 is less than 90 degrees. In some examples, each of the angles α and θ can be in a range of 45-89.9 degrees. In some examples, each of the angles α and θ can be in a range of 75-89.9 degrees. In one preferred example, each of the angles α and θ can be in a range of 81-86 degrees. The angles α and θ can be the same or can be different.

[0132] When the frame connector 400 as illustrated by FIGS. 17A and 17B is used to axially restrain the docking station 136, the tensile force created by the bias of the docking station to the expanded configuration pulls the flared portion (132a in FIG. 15) of the connector tab axially against the second portions 428b, 429b. The undercut in the second portions 428b, 429b translates a portion of the tensile force into a radial force that pushes the connector tab radially inwardly toward the central axis of the frame connector 400, thereby improving retention characteristics of the docking station prior to deployment of the docking station. It has been found that each of the angles α, θ between the second portions 428b, 429b and the recess floor 424 in a range of 81-86 degrees (in certain instances) improves securement of the docking station to the delivery system when the outer shaft is extended during recapture of the docking station.

[0133] Returning to FIGS. 13A and 16A, the first portions 428a, 429a can be formed as undercut walls, which means that there is a space or recess underneath each of the first portions 428a, 429a (or a space or recess between each of the first portions 428a, 429a and the recess floor 424). As illustrated in FIG. 16B, the first portions 428a, 428b as undercut walls are inclined relative to the recess floor 424 (i.e., the first portions 428a, 429b are not perpendicular to the recess floor 424). The angle β between the first portion 428a and the recess floor 424 is less than 90 degrees, and the angle φ between the first portion 429a and the recess floor 424 is less than 90 degrees. In some examples, each of the angles β and φ can be in a range of 45-89.9 degrees. In some examples, each of the angles β and φ can be in a range of 75-89.9 degrees. In one example, each of the angles β and φ can be in a range of 81-86 degrees. The angles β and φ can be the same or can be different. In some examples, the angles β and/or φ can be the same as the angles α and/or θ. In some examples, the angles β and/or φ can be different than the angles α and/or θ.

[0134] Returning to FIG. 13A, each of the side walls 428, 429 includes a corner where the first slot portion 420a is connected to the second slot portion 420b. These corners can be rounded and can have undercuts such that an undercut extends underneath the entire length of each of the side walls 428, 429. The edges where the side walls 428, 429 meet the exterior surface portions 417, 418 can be similarly rounded.

[0135] Referring to FIG. 18, one preferred method of coupling the frame connector 400 to a distal portion of the inner shaft 305 (shown in FIG. 5A) is by an over-molding process. During the over-molding process, the radial holes 406 in the flange 408 can receive flow of injected material. The material in the radial holes 406, when solidified, can anchor the frame connector 400 to the inner shaft 305. FIG. 18 shows the inner shaft 305 extending through the lumen of the outer shaft 309. The frame connector 400 is sized relative to the outer shaft 309 such that the outer shaft 309 can be extended over the frame connector 400 and over a docking station disposed around a portion of the inner shaft 305 distal to the frame connector 400.

[0136] FIGS. 19 and 20 illustrate a portion of the delivery apparatus 300 including the docking station 136 in a compressed configuration. The outer shaft 309 is extended to encapsulate the docking station 136. Each of the connector tabs 132 of the docking station 136 is disposed in a respective recess 420 of the frame connector 400 and engaged with the side walls of the recess 420. The docking station 136 is held in place axially by the frame connector 400 and radially by the outer shaft 309. It should be understood that only a portion of the delivery apparatus is shown in FIGS. 19 and 20. The remaining portions of the delivery apparatus (e.g., the portion that extends to the nosecone, the portion that is coupled to the handle, the nosecone, and the handle) are visible in FIGS. 5A.

[0137] A delivery assembly that is configured as shown in FIGS. 19 and 20 can be inserted into a patient's body and advanced through the patient's vasculature to an implantation location. At the implantation location, the outer shaft 309 can be retracted to expose the docking station 136 and deploy the docking station (as illustrated in FIGS. 6C-6F). During recapture of the docking station 136, the inner shaft 305 can be under high tensile loads while the outer shaft 309 is extended to cover docking station 136. The undercut in the side walls of the recess 420 can translate the tensile force acting on the respective connector tab 132 to a radial force that pushes the connector tab 132 inwardly toward the central axis of the frame connector 400, as illustrated in FIG. 21, thereby retaining the connection between the delivery apparatus and the docking station.

[0138] FIGS. 22-30 depict various shafts for a delivery apparatus. These shafts can, in some instances, be used with the delivery apparatus 300 in lieu of the inner shaft 305. As such, these shafts can, in some instances, be referred to as "inner shafts." The disclosed shafts can additionally or alternatively be used with other delivery apparatus, such a delivery apparatus configured for implanting a prosthetic heart valve. The shafts depicted in FIGS. 22-30 are generally similar to the shaft 305, except the shaft of FIGS. 22-30 include one or more additional reinforcement elements (e.g., additional layers and/or members).

[0139] FIGS. 22-23 depict an example of a shaft 600. The shaft 600 comprises a first layer 602, a second layer 604, a third layer 606, and a fourth layer 608. The first layer 602 and the fourth layer 608 can be liner/cover layers. The second layer 604 and the third layer 606 can be reinforcing layers configured to strengthen the shaft 600, including when the shaft 600 is in tension (e.g., during recapture of a docking station).

[0140] The layers of the shaft 600 can be formed of various materials. For example, the first layer 602 and the fourth layer 608 of the shaft 600 can be made of a polymeric material. Examples of suitable polymeric materials include: PEBAX®, nylons, and/or polyurethane. The first layer 602 and the fourth layer 608 can be made of the same material or of different materials. In some examples, the first layer 602 and/or the fourth layer 608 can be made by extrusion.

[0141] The second layer 604 and the third layer 606 can be made of various materials. For example, in some instances, the second layer 604 and the third layer 606 can be formed of a braided material, one or more non-braided materials, woven material, and/or other material. In some examples, the second layer 604 and/or the third layer 606 can comprise one or more materials configured to carry the loads (e.g., tensile loads) applied to the shaft 600.

[0142] In instances comprising a braided material, a metal and/or non-metal braid can be used. Examples of metal braids include stainless steel, nitinol, and titanium, to name a few. Examples of non-metal braids include Kevlar, sutures, etc.

[0143] In some examples, the layers of the shaft 600 can be discrete layers (i.e., without radial overlap). In other words, each layer is "stacked on" a previous layer or "sandwiched" between two layers. In some examples, the layers of the shaft 600 radially overlap. This can be accomplished by reflowing the polymeric layers on the reinforcing layers. As such, the polymeric material can flow radially around and/or into the non-polymeric layers (e.g., into the openings of the braid, weave, etc.). In this manner, the reinforcing layers can, in some instances, be encapsulated in or surrounded by the polymeric material.

[0144] The second layer 604 and the third layer 606 can be made of the same or of different materials. As one example, the second layer 604 can comprise a first braided material having a first braid density, and the third layer 606 can comprise a second braided material having a second braid density, which is different (e.g., less) than the first braid density. In particular examples, the first braided material and the second braided material can be stainless steel braids. The braids can comprise various numbers of wires such as 4-32 wires. In certain examples, one or more of the braids can be 16-wire braids. The braid densities can also vary. For example, in some implementations, the first braid density can be within a range of 40-60 picks per inch (PPI), and the second braid density can be within a range of 5-20 PPI. In some examples, the first braid density can be 38-55 PPI (or 38-52 PPI) and/or the second braid density can be 1-10 PPI (or 2-8 PPI). In some examples, the first braid density can be 45 PPI and/or the second braid density can be 10 PPI. In some examples, the first braid density can be 45 PPI and/or the second braid density can be 5 PPI. The various braid densities described above apply to any of the braids disclosed here, unless explicitly stated otherwise.

[0145] The second layer 604 and the third layer 606 can extend along the same or different lengths of the shaft 600. As one example, the second layer 604 and/or the third layer 606 can extend from the proximal end of the shaft 600 to the distal end of shaft. In some examples, the second layer 604 and/or the third layer 606 can extend less than the entire length of the shaft 600.

[0146] In certain configurations, the second layer 604 can extend from the proximal end of the shaft 600 to a location adjacent or at the portion of the shaft 600 configured to have a nosecone coupled thereto. The third layer 606 can extend from the proximal end of the shaft 600 to a location proximal to the distal end of the second layer 604 (e.g., to a location of the shaft 600 configured to have a frame connector coupled thereto). In some examples, the third layer 606 can axially overlap with at least a portion of the frame connector. In some examples, the third layer 606 can extend to a location proximal to the proximal end of the frame connector. The relative locations of the reinforcement layers described with respect to the shaft 600 apply to the other shafts disclosed herein, unless explicitly stated otherwise.

[0147] The configuration of the shaft 600 (e.g., depicted in FIGS. 22-23) comprising a first, more densely braided material and a second, less densely braided material and/or having the first braided material run the entire length (or at least substantially the entire length) of the shaft and having the second braided material run a lesser portion of the length of the shaft can provide one or more advantages. For example, this configuration allows the shaft to be sufficiently flexible such that it can be navigated through a patient's winding vasculature, while also providing sufficient tensile strength to withstand the forces applied to the shaft, including when recapturing a prosthetic implant, which applies relatively high forces (e.g., tensile forces) to the shaft.

[0148] As depicted in FIG. 23, the shaft 600 can, in some instances, include one or more fluid ports 610. The fluid ports 610 extend radially through the shaft 600 and can allow a flushing fluid to flow from the inner lumen of the shaft 600 and into the lumen of the outer shaft of a delivery apparatus. In this manner, the fluid ports 610 enable flushing of the shaft 600 and the outer shaft from a single injection port (e.g., at the proximal end of the shaft 600) rather than requiring the shafts to be separately flushed. The shaft 600 can also have the cover tube 612 coupled thereto, which comprises the window 614. In some examples, the fluid ports 610 can be formed by removing the polymeric material of the shaft 600 (e.g., by ablation) and leaving the reinforcing layers 604, 606 in place. Additional information regarding the forming of the ports 610 can be found in International Application No. PCT/US2022/018093, which is incorporated by reference herein.

[0149] FIG. 24 depicts a shaft 700. The shaft 700 comprises a first layer 702, a second layer 704, a third layer 706, and a fourth layer 708. The first layer 702 and the fourth layer 708 can be liner/cover layers. The second layer 704 and the third layer 706 can be reinforcing layers configured to strengthen the shaft 700, including when the shaft 700 is in tension (e.g., during recapture of a docking station). In this manner, the shaft 700 is configured generally similar to shaft 600.

[0150] One difference between the shaft 700 and the shaft 600 is that the second layer 704 of the shaft 700 comprises a less densely braided material and the third layer 706 of the shaft 700 comprises a more densely braided material. The reinforcement layers of the shaft 700 are thus inverted relative to the shaft 600 in which the second layer 604 comprises a more densely braided material and the third layer 606 comprises a less densely braided material.

[0151] FIG. 25 depicts a shaft 800. The shaft 800 comprises a first layer 802, a second layer 804, a third layer 806, and a fourth layer 808. The first layer 802 and the fourth layer 808 can be liner/cover layers. The second layer 804 and the third layer 806 can be reinforcing layers configured to strengthen the shaft 800, including when the shaft 800 is in tension (e.g., during recapture of a docking station). In this manner, the shaft 800 is configured generally similar to shaft 600.

[0152] One difference between the shaft 800 and the shaft 600 (and the shaft 700) is that the third layer 806 of the shaft 800 comprises a plurality of axially-extending reinforcing members 810 extending therethrough rather than comprising a braided material like the third layer 606 of the shaft 600.

[0153] The number, size (e.g., diameter, length, etc.), material, and location of the reinforcing members 810 can vary. The depicted example includes eight reinforcing members 810. In some examples, the shaft can comprise less (e.g., 1-7) or more (e.g., 9-25) than eight reinforcing members. In some instances, the reinforcing members 810 can be spaced apart circumferentially such that there is a gap between at least some of the adjacent reinforcing members. The spacing between each of the reinforcing members can be uniform (e.g., as depicted) or non-uniform. In some instances, one or more adjacent reinforcing members can contact each other such that there is no gap.

[0154] FIG. 26 depicts a shaft 900. The shaft 900 is configured similar to the shaft 800, except that the second layer 904 comprises the reinforcing members 910 and the third layer 906 comprises the braided material, which is inverted relative to the configuration of the reinforcement layers of the shaft 800.

[0155] FIG. 27 depicts a shaft 1000. The shaft 1000 is configured similar to the shafts 600 and 800, except that the third layer 1006 comprises a triaxial braided material. A triaxial braided material may be viewed as a combination of a "regular" braided material, where the braided members are diagonal to the longitudinal axis of the shaft, and axially-extending members, which extend parallel to the longitudinal axis of the shaft.

[0156] FIG. 28 depicts a shaft 1100. The shaft 1100 is similar to the shaft 1000, except the second layer 1104 comprises the triaxial braid and the third layer comprises the "regular" braid, which is inverted relative to the shaft 1000.

[0157] FIG. 29 depicts a shaft 1200. The first layer 1202 and the fourth layer 1208 comprises polymeric material. The second layer 1204 and the third layer 1206 each comprise a triaxial braid. In the depicted configuration, the triaxial braid of the second layer 1204 has a higher braid density than the triaxial braid of the third layer 1206. In some examples, the triaxial braid of the second layer can have a lower braid density than the triaxial braid of the third layer.

[0158] FIG. 30 depicts a shaft 1300. This shaft comprises three layers. The first layer 1302 and the third layer 1306 comprises polymeric material. The second layer 1304 comprises a triaxial braid.

[0159] It should be noted that a shaft can comprise more or less layers than depicted in the illustrated examples. For example, a shaft can comprise a lubricious layer disposed radially inwardly of the first layer. As one example, a shaft can comprise a third reinforcing layer disposed adjacent to one or more other reinforcing layers.

[0160] It should be noted that the dimensions (e.g., diameters and/or relative thicknesses) of the shafts disclosed herein are schematic are intended to illustrate the various layers. The dimensions can be altered based on the desired implementation.

[0161] The various shaft configurations described herein can be sufficiently flexible, thereby allowing the shaft (and a delivery apparatus of which the shaft is a component) to be navigated through a patient's vasculature. The disclosed shafts can also provide sufficient strength to withstand the various loads that are applied to the shafts (e.g., during an implantation procedure). Although the shafts have similarities, each shaft configuration can provide unique advantages.

[0162] Any of the various systems, devices, apparatuses, etc. in this disclosure can be sterilized (e.g., with heat, radiation, ethylene oxide, hydrogen peroxide, etc.) to ensure they are safe for use with patients, and the methods herein can comprise sterilization of the associated system, device, apparatus, etc. (e.g., with heat, radiation, ethylene oxide, hydrogen peroxide, etc.).

[0163] 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.

[0164] Additional Examples of the Disclosed Technology

[0165] In view of the above-described implementations of the disclosed subject matter, 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.

[0166] Example 1. A delivery apparatus comprising a handle body, an outer shaft, and an inner shaft. The handle body comprises a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end. The outer shaft comprises a proximal end movably coupled to the handle body. The inner shaft extends through a lumen of the outer shaft and fixed relative to the handle body. The inner shaft comprises a first reinforcement layer and a second reinforcement layer. The first reinforcement layer extends from a proximal end portion of the inner shaft to a first distal location of the inner shaft. The second reinforcement layer extends from the proximal end portion of the inner shaft to a second distal location of the inner shaft. The second distal location is proximal to the first distal location.

[0167] Example 2. The delivery apparatus of any example herein, and particularly example 1, wherein the first distal location axially overlaps with a nosecone coupled to the inner shaft.

[0168] Example 3. The delivery apparatus of any example herein, and particularly either example 1 or example 2, wherein the second distal location axially overlaps with a frame connector couped to the inner shaft.

[0169] Example 4. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a distal end of a frame connector couped to the inner shaft.

[0170] Example 5. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a distal end of a frame connector couped to the inner shaft and distal to a proximal end of the frame connector.

[0171] Example 6. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a proximal end of a frame connector couped to the inner shaft.

[0172] Example 7. The delivery apparatus of any example herein, and particularly any one of examples 1-6, wherein the first reinforcement layer and the second reinforcement layer extend proximally to a proximal end of the inner shaft.

[0173] Example 8. The delivery apparatus of any example herein, and particularly any one of examples 1-7, wherein the proximal end portion of the inner shaft is configured to be disposed outside of a patient's body during an implantation procedure.

[0174] Example 9. The delivery apparatus of any example herein, and particularly any one of examples 1-8, wherein the first reinforcement layer comprises a first braided material.

[0175] Example 10. The delivery apparatus of any example herein, and particularly example 9, wherein the first braided material comprises metal wires.

[0176] Example 11. The delivery apparatus of any example herein, and particularly either example 9 or example 10, wherein the first braided material comprises a first braid density that is within a range of 5-60 PPI.

[0177] Example 12. The delivery apparatus of any example herein, and particularly example 11, wherein the first braided material comprises a first braid density that is within a range of 40-60 PPI.

[0178] Example 13. The delivery apparatus of any example herein, and particularly example 12, wherein the first braid density is 45 PPI.

[0179] Example 14. The delivery apparatus of any example herein, and particularly example 11, wherein the first braid density is within a range of 5-20 PPI.

[0180] Example 15. The delivery apparatus of any example herein, and particularly example 14, wherein the first braid density is 10 PPI.

[0181] Example 16. The delivery apparatus of any example herein, and particularly any one of examples 1-11, wherein the second reinforcement layer comprises a second braided material.

[0182] Example 17. The delivery apparatus of any example herein, and particularly example 16, wherein the second braided material comprises metal wires.

[0183] Example 18. The delivery apparatus of any example herein, and particularly either example 16 or example 17, wherein the second braided material comprises a second braid density that is within a range of 5-60 PPI.

[0184] Example 19. The delivery apparatus of any example herein, and particularly example 18, wherein the second braid density is within a range of 40-60 PPI.

[0185] Example 20. The delivery apparatus of any example herein, and particularly example 18, wherein the second braid density is 45 PPI.

[0186] Example 21. The delivery apparatus of any example herein, and particularly example 18, wherein the second braid density is within a range of 5-20 PPI.

[0187] Example 22. The delivery apparatus of any example herein, and particularly example 21, wherein the second braid density is 10 PPI.

[0188] Example 23. The delivery apparatus of any example herein, and particularly any one of examples 1-22, wherein the first reinforcement layer is disposed radially inwardly relative to the second reinforcement layer.

[0189] Example 24. The delivery apparatus of any example herein, and particularly any one of examples 1-22, wherein the first reinforcement layer is disposed radially outwardly relative to the second reinforcement layer.

[0190] Example 25. The delivery apparatus of any example herein, and particularly any one of examples 1-24, wherein the first reinforcement layer is a triaxial braided material.

[0191] Example 26. The delivery apparatus of any example herein, and particularly any one of examples 1-25, wherein the second reinforcement layer is a triaxial braided material.

[0192] Example 27. The delivery apparatus of any example herein, and particularly any one of examples 1-26, wherein the inner shaft further comprises one or more polymeric layers disposed radially inwardly relative to the first reinforcement layer or the second reinforcement layer.

[0193] Example 28. The delivery apparatus of any example herein, and particularly any one of examples 1-27, wherein the inner shaft further comprises one or more polymeric layers disposed radially outwardly relative to the first reinforcement layer or the second reinforcement layer.

[0194] Example 29. A delivery apparatus comprising a handle body, an outer shaft, and an inner shaft. The handle body includes a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end. The outer shaft includes a proximal end movably coupled to the handle body. The inner shaft extends through a lumen of the outer shaft and is fixed relative to the handle body. The inner shaft includes a first braided material comprising a first braid density and a second braided material comprising a second braid density. The second braid density is less than the first braid density.

[0195] Example 30. The delivery apparatus of any example herein, and particularly example 29, wherein the first braided material is disposed radially inwardly relative to the second braided material.

[0196] Example 31. The delivery apparatus of any example herein, and particularly example 29, wherein the first braided material is disposed radially outwardly relative to the second braided material.

[0197] Example 32. A shaft for a delivery apparatus comprising a proximal end, a distal end, a first reinforcement layer, and a second reinforcement layer. The first reinforcement layer extends from a first proximal location of the shaft to a first distal location of the shaft. The second reinforcement layer extends from a second proximal location of the shaft to a second distal location of the shaft, and the second distal location is proximal to the first distal location.

[0198] Example 33. A shaft for a delivery apparatus comprising a proximal end, a distal end, a first braided material, and a second braided material. The first braided material includes a first braid density. The second braided material includes a second braid density, which is less than the first braid density.

[0199] Example 34. A shaft for a delivery apparatus comprising a proximal end, a distal end, and a reinforcement layer. The reinforcement layer extends from a first proximal location of the shaft to a distal location of the shaft and comprises a triaxial braided material.

[0200] Example 35. A method comprising sterilizing any one of the docking stations or frames of any example herein, and particularly any one of examples 1-34.

[0201] Example 36. A method of implanting a prosthetic device comprising any one of the devices disclosed herein, and particularly any one of the devices of examples 1-34.

[0202] Example 37. A method of simulating an implantation procedure for a prosthetic device comprising any one of the devices disclosed herein, and particularly any one of the devices of examples 1-34.

[0203] 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.

[0204] 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 delivery apparatus comprising:

a handle body comprising a proximal end, a distal end, and a longitudinal axis extending between the proximal end and the distal end;

an outer shaft comprising a proximal end movably coupled to the handle body; and

an inner shaft extending through a lumen of the outer shaft and fixed relative to the handle body, wherein the inner shaft comprises a first reinforcement layer and a second reinforcement layer, wherein the first reinforcement layer extends from a proximal end portion of the inner shaft to a first distal location of the inner shaft, wherein the second reinforcement layer extends from the proximal end portion of the inner shaft to a second distal location of the inner shaft, and wherein the second distal location is proximal to the first distal location.

2. The delivery apparatus of claim 1, wherein the first distal location axially overlaps with a nosecone coupled to the inner shaft.

3. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location axially overlaps with a frame connector couped to the inner shaft.

4. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a distal end of a frame connector couped to the inner shaft.

5. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a distal end of a frame connector couped to the inner shaft and distal to a proximal end of the frame connector.

6. The delivery apparatus of either claim 1 or claim 2, wherein the second distal location is proximal to a proximal end of a frame connector couped to the inner shaft.

7. The delivery apparatus of any one of claims 1-3, wherein the first reinforcement layer and the second reinforcement layer extend proximally to a proximal end of the inner shaft.

8. The delivery apparatus of any one of claims 1-7, wherein the proximal end portion of the inner shaft is configured to be disposed outside of a patient's body during an implantation procedure.

9. The delivery apparatus of any one of claims 1-8, wherein the first reinforcement layer comprises a first braided material.

10. The delivery apparatus of claim 9, wherein the first braided material comprises metal wires.

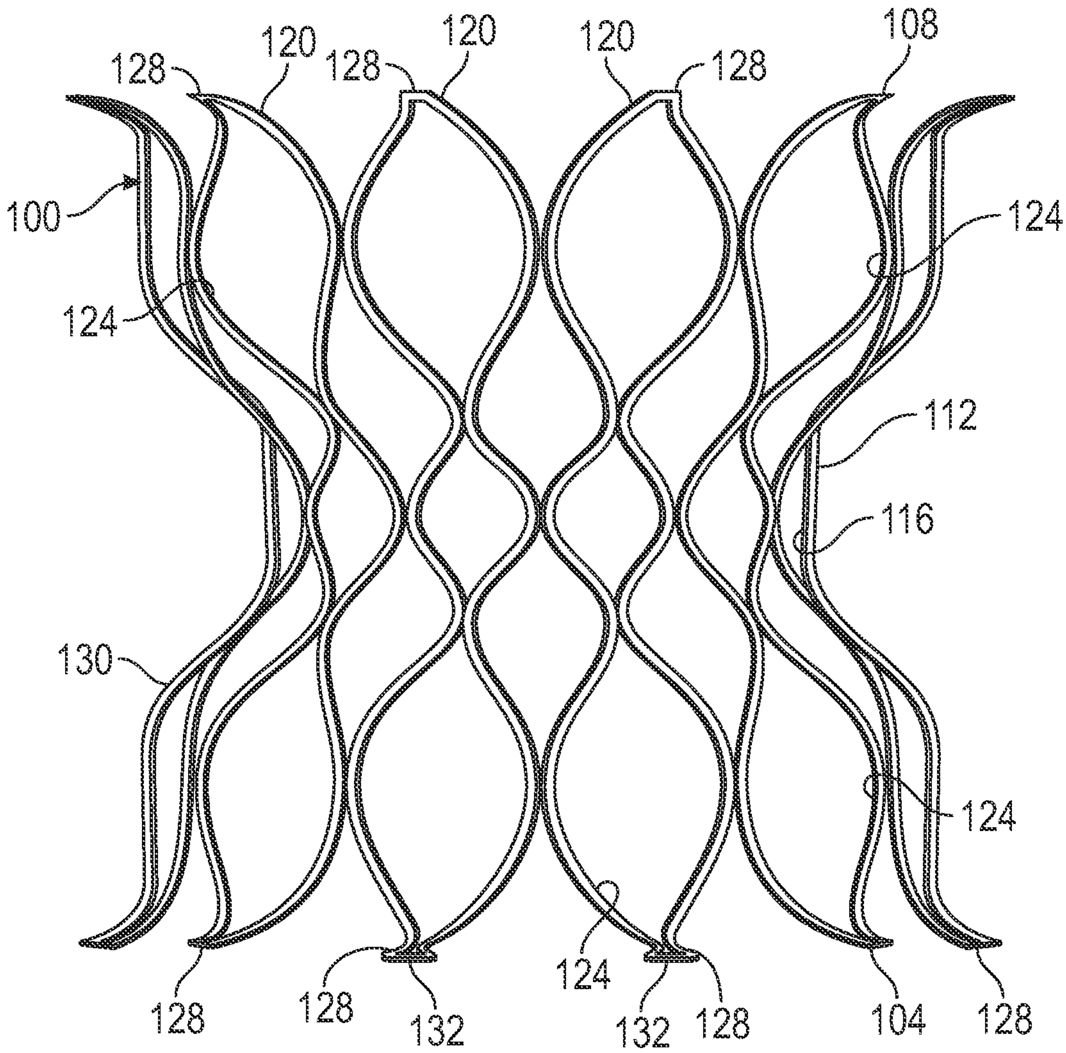
11. The delivery apparatus of either claim 9 or claim 10, wherein the first braided material comprises a first braid density that is within a range of 5-60 PPI.

12. The delivery apparatus of claim 11, wherein the first braided material comprises a first braid density that is within a range of 40-60 PPI.

13. The delivery apparatus of claim 12, wherein the first braid density is 45 PPI.

14. The delivery apparatus of claim 11, wherein the first braid density is within a range of 5-20 PPI.

15. The delivery apparatus of claim 14, wherein the first braid density is 10 PPI.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128

FIG. 1

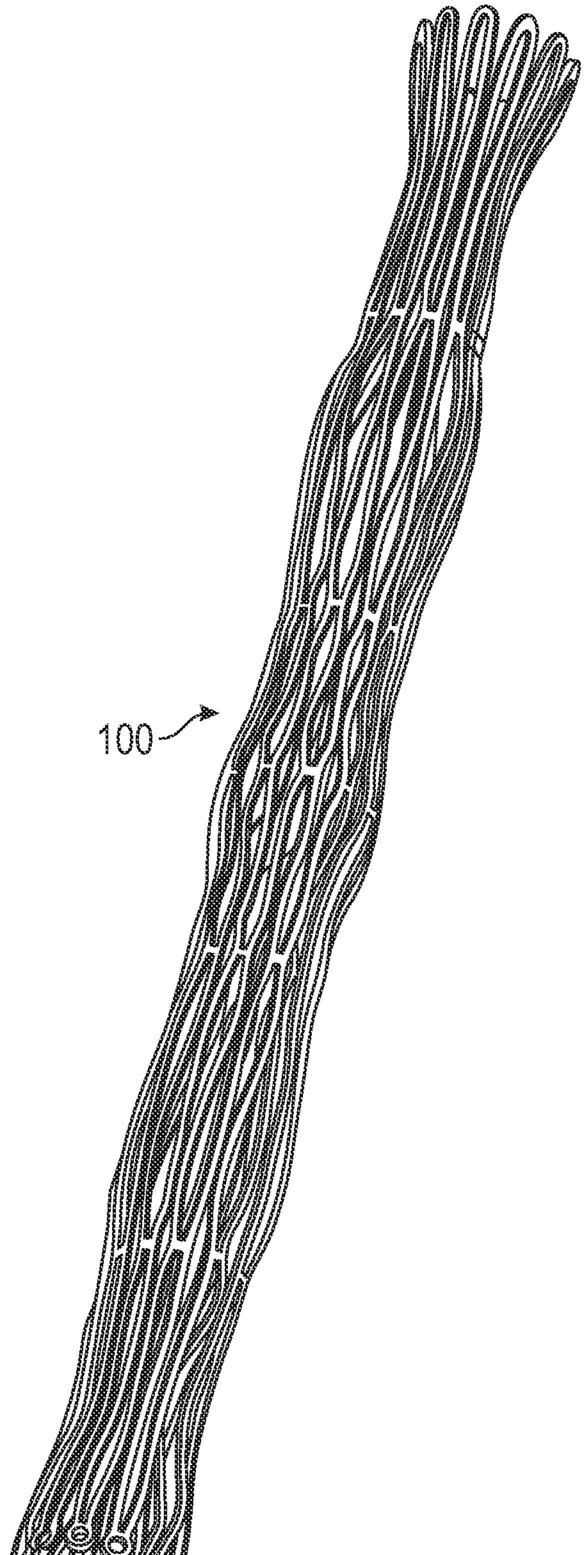


FIG. 2

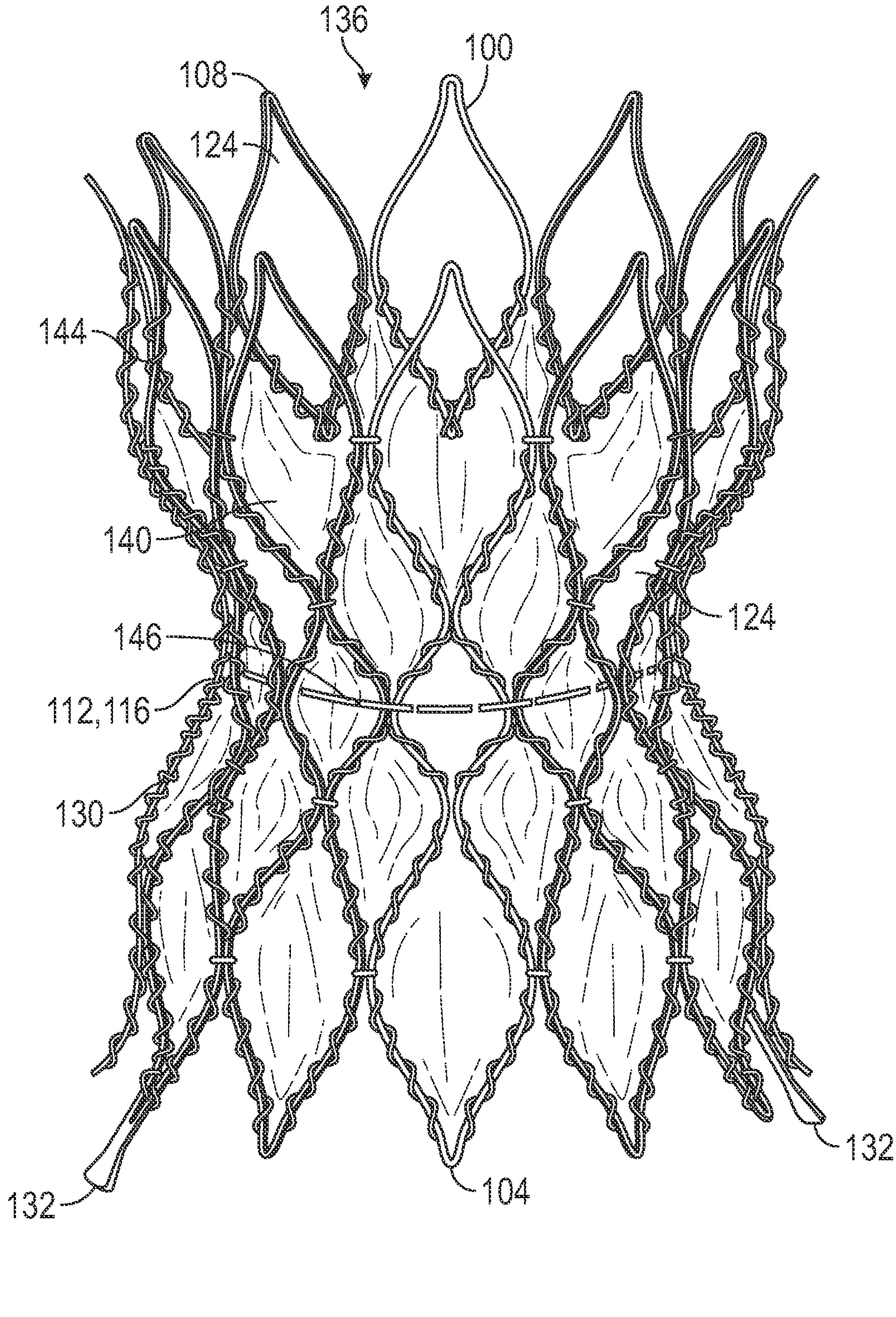


FIG. 3

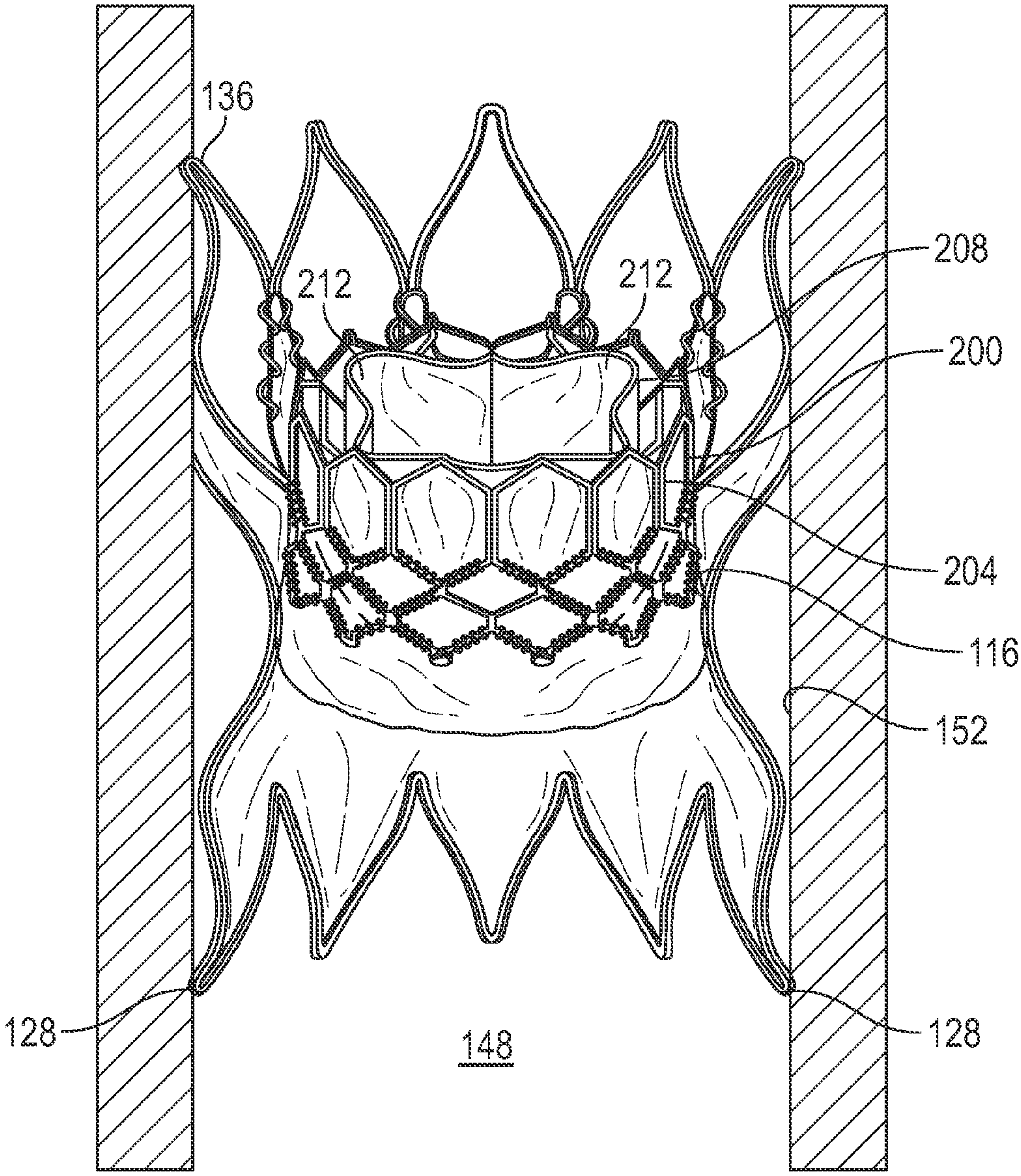
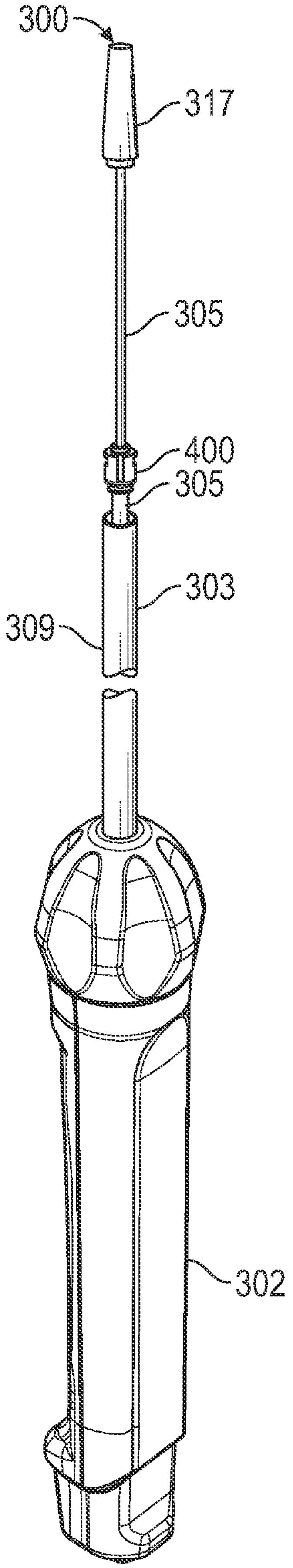


FIG. 4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302

FIG. 5A

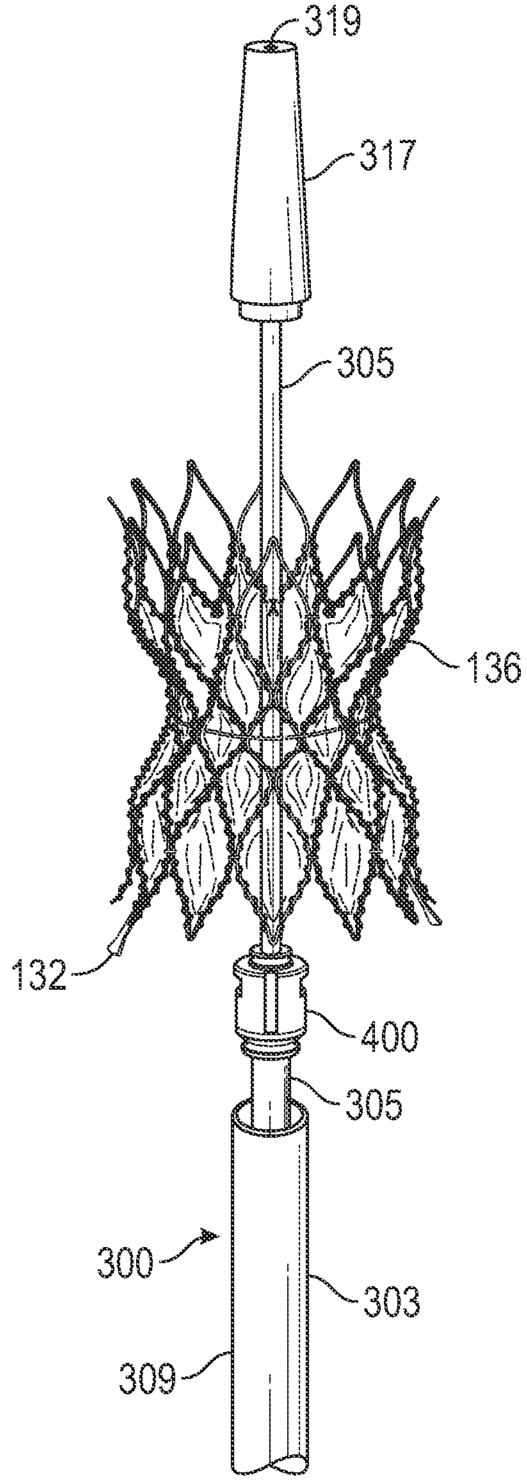
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FIG. 5B

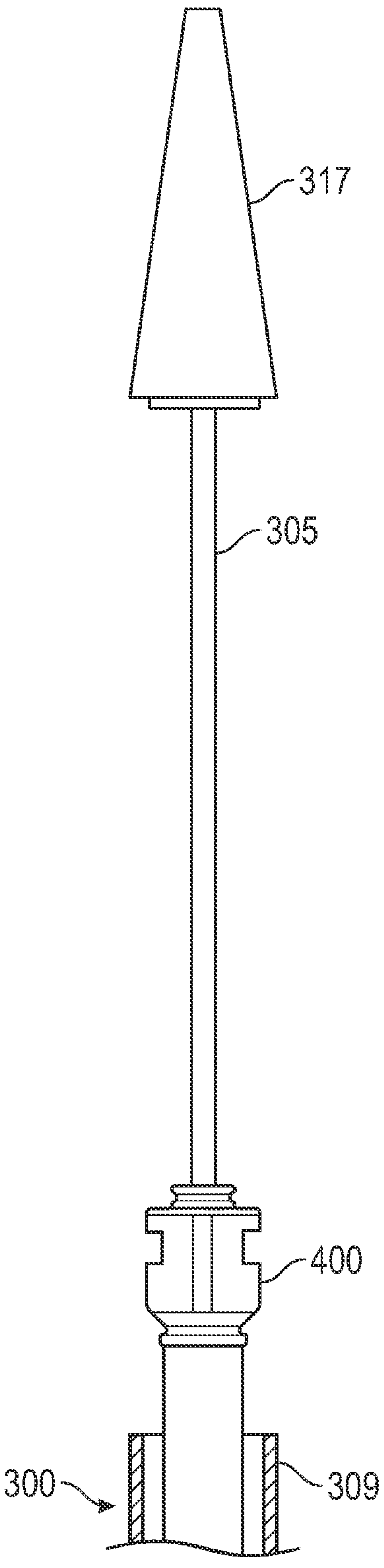


FIG. 6A

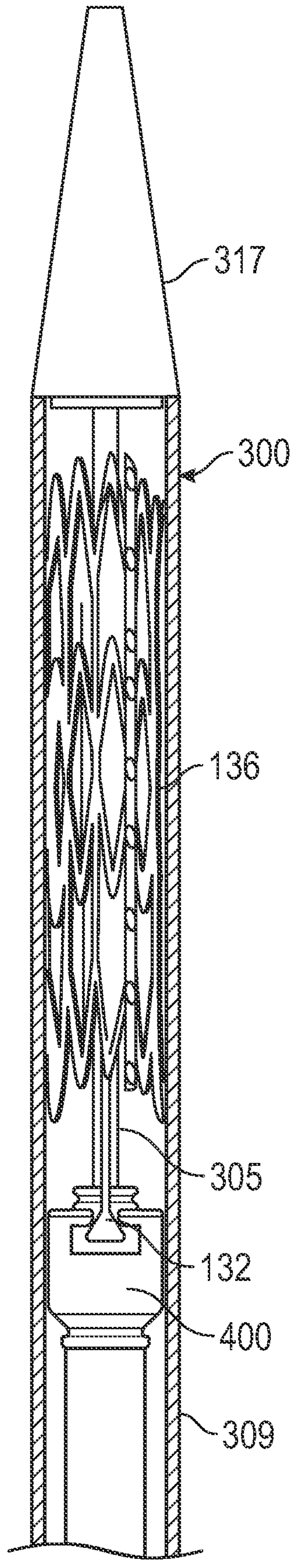


FIG. 6B

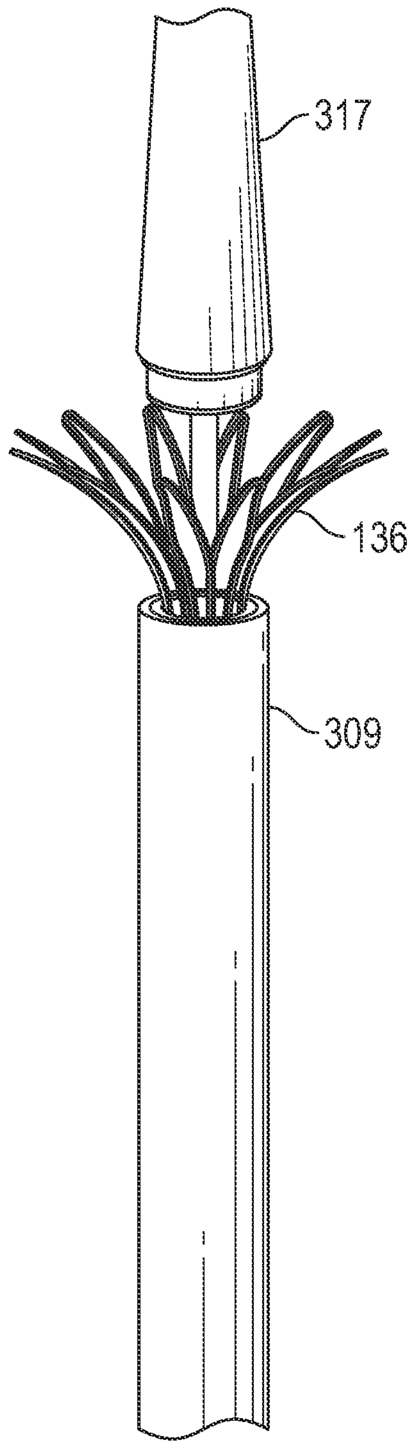


FIG. 6C

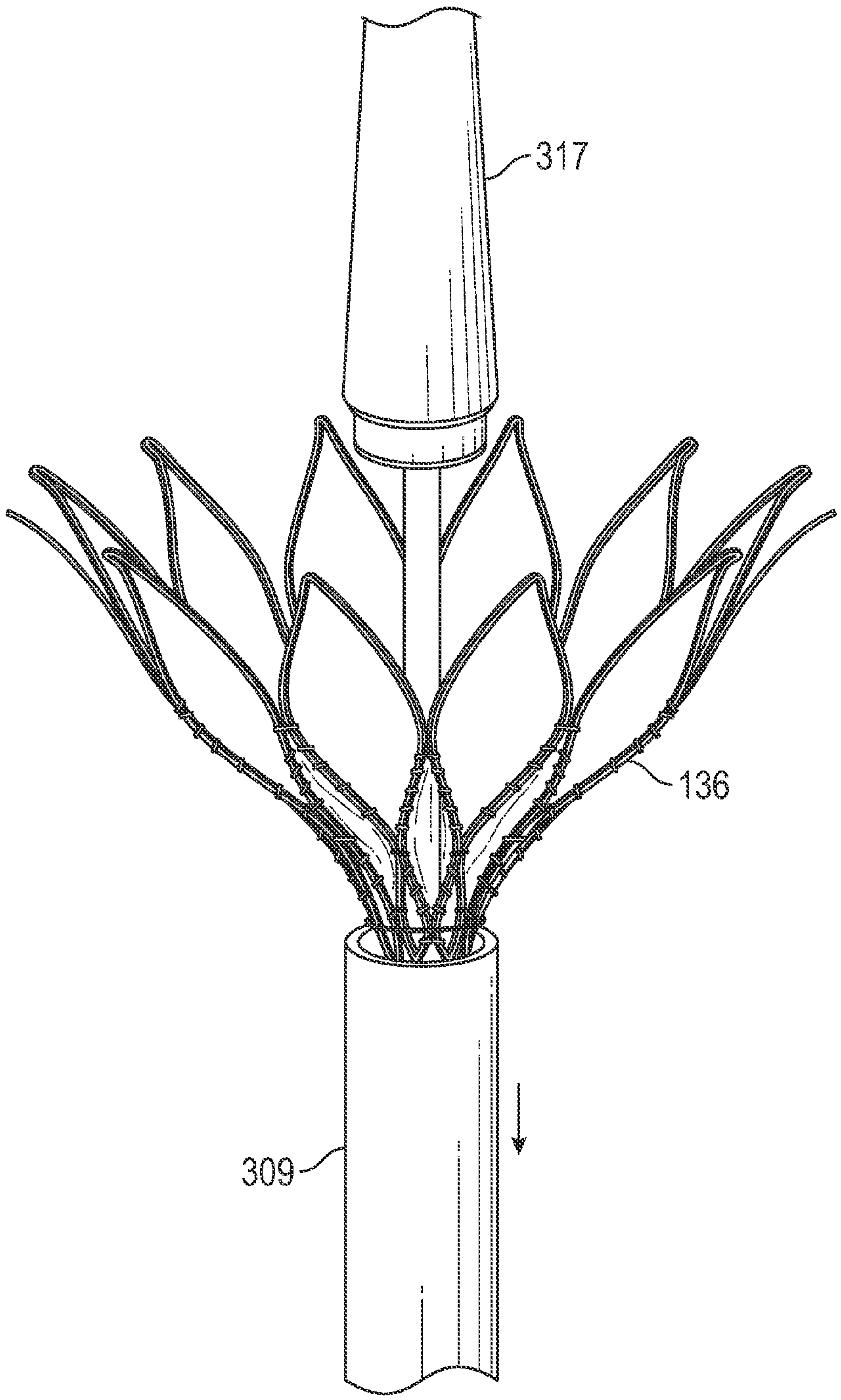


FIG. 6D

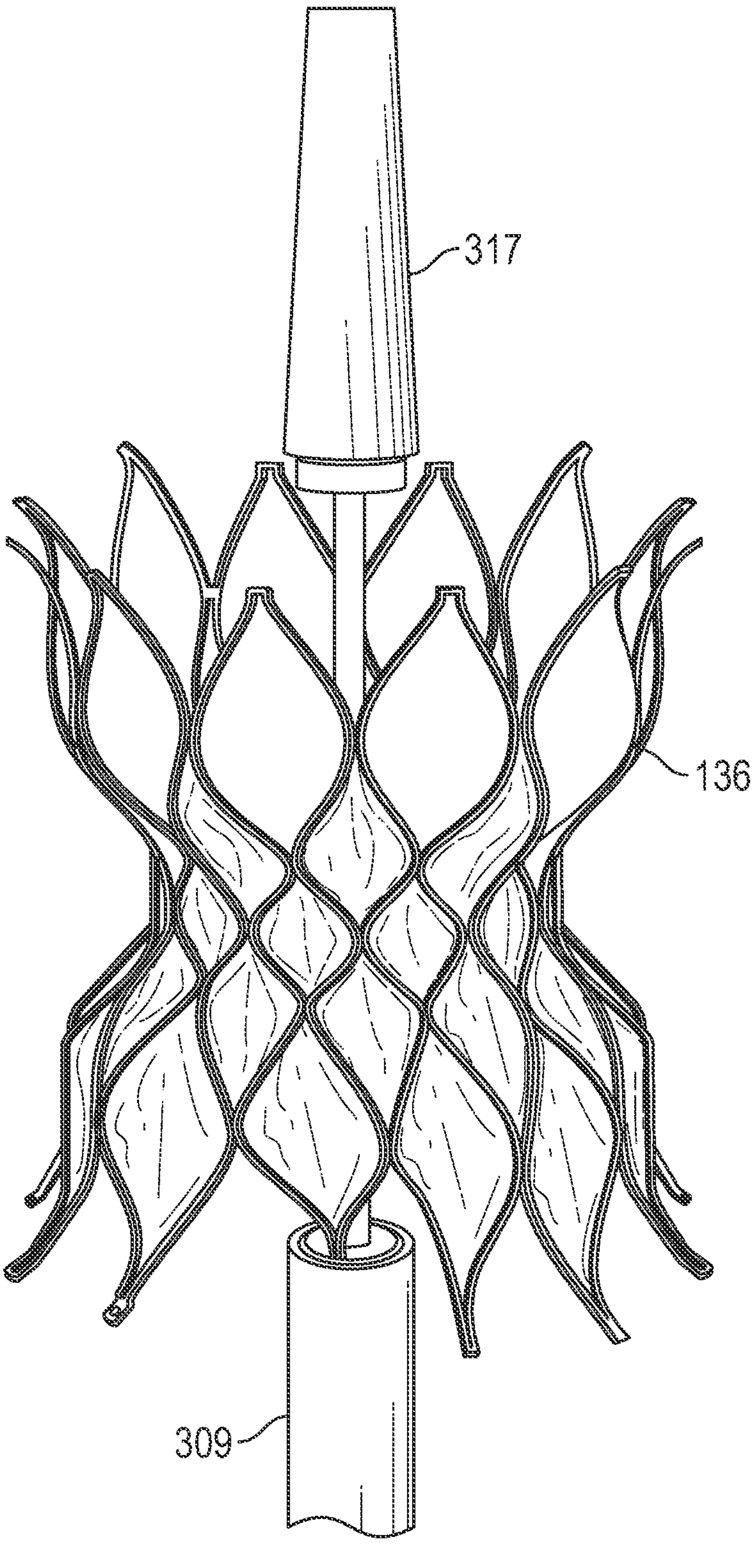


FIG. 6E

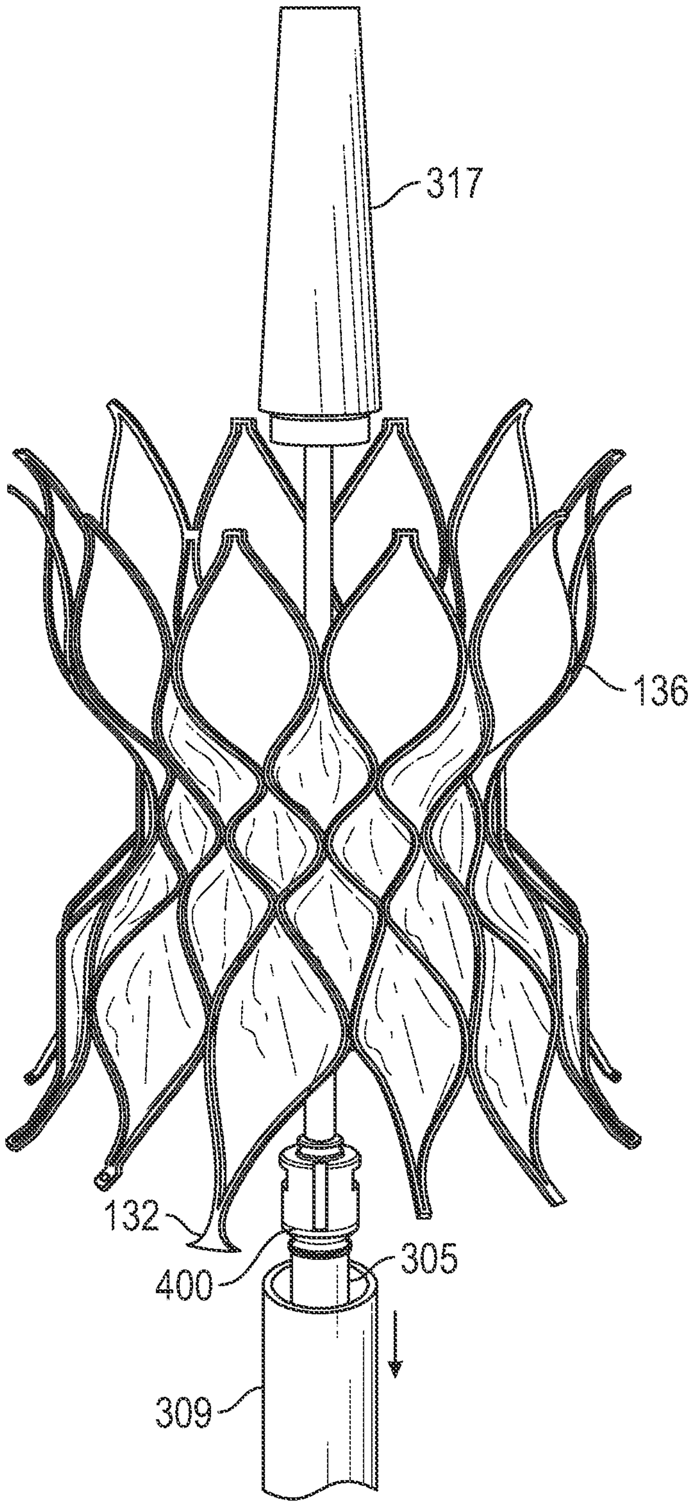


FIG. 6F

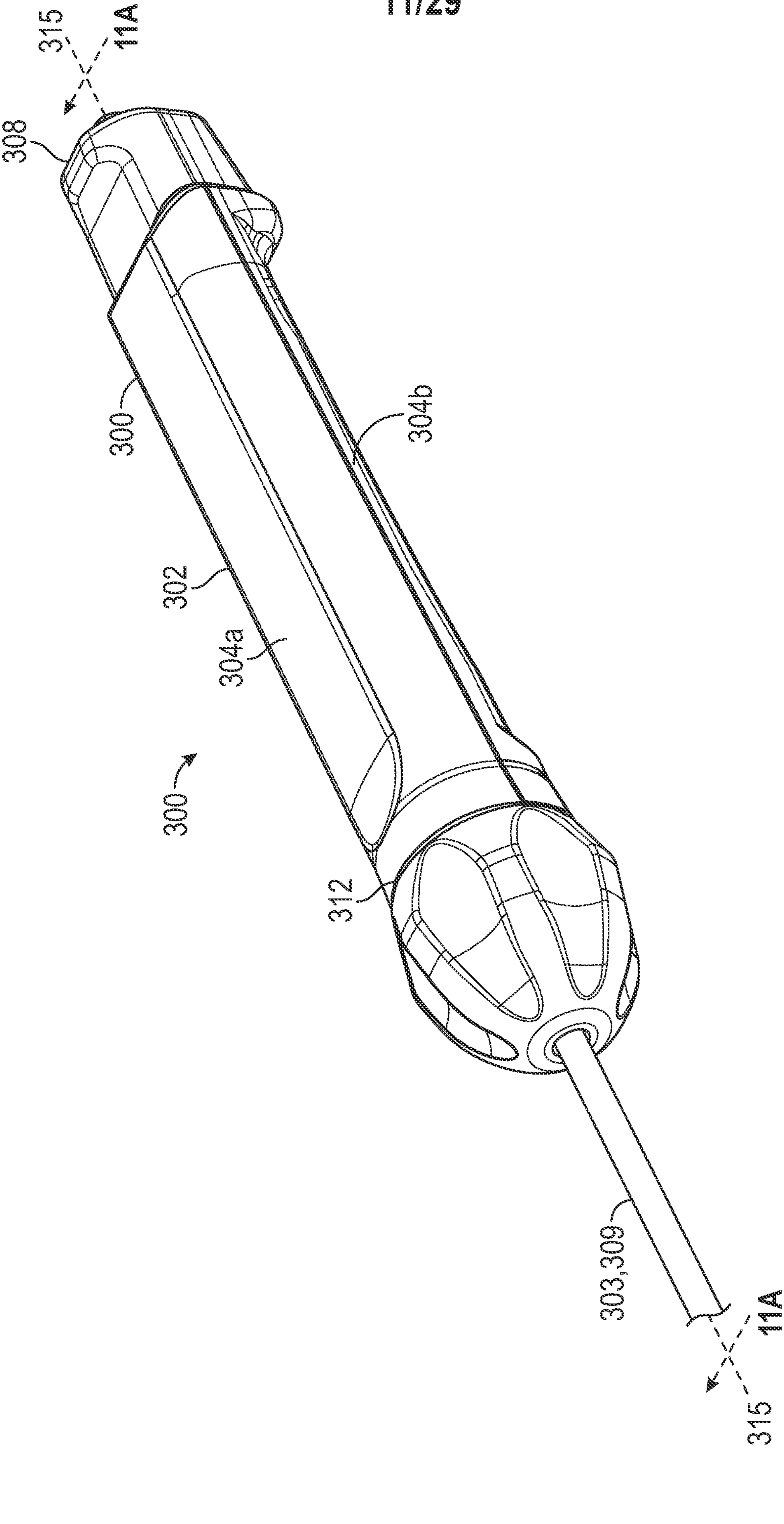
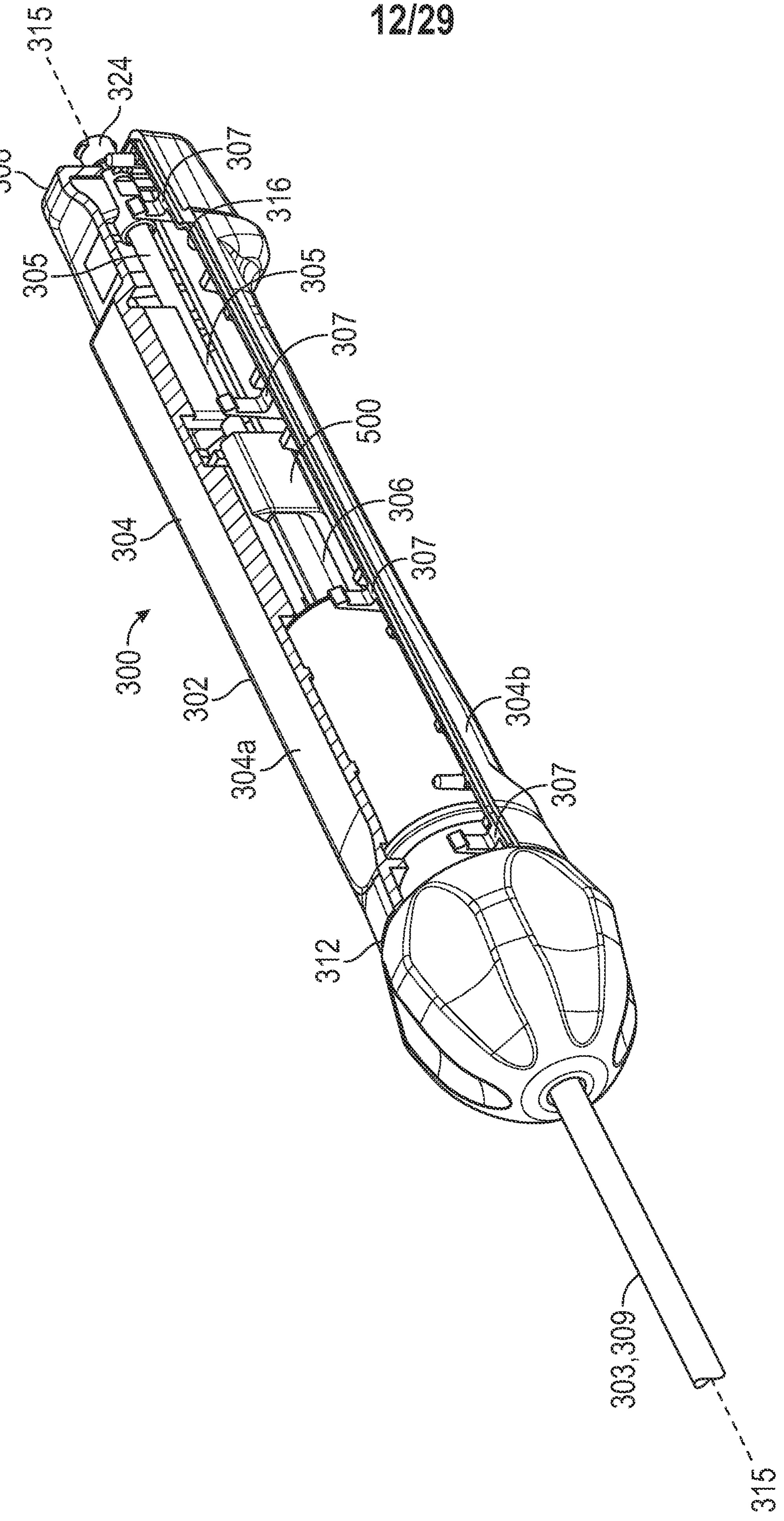


FIG. 7A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300
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304a
304b
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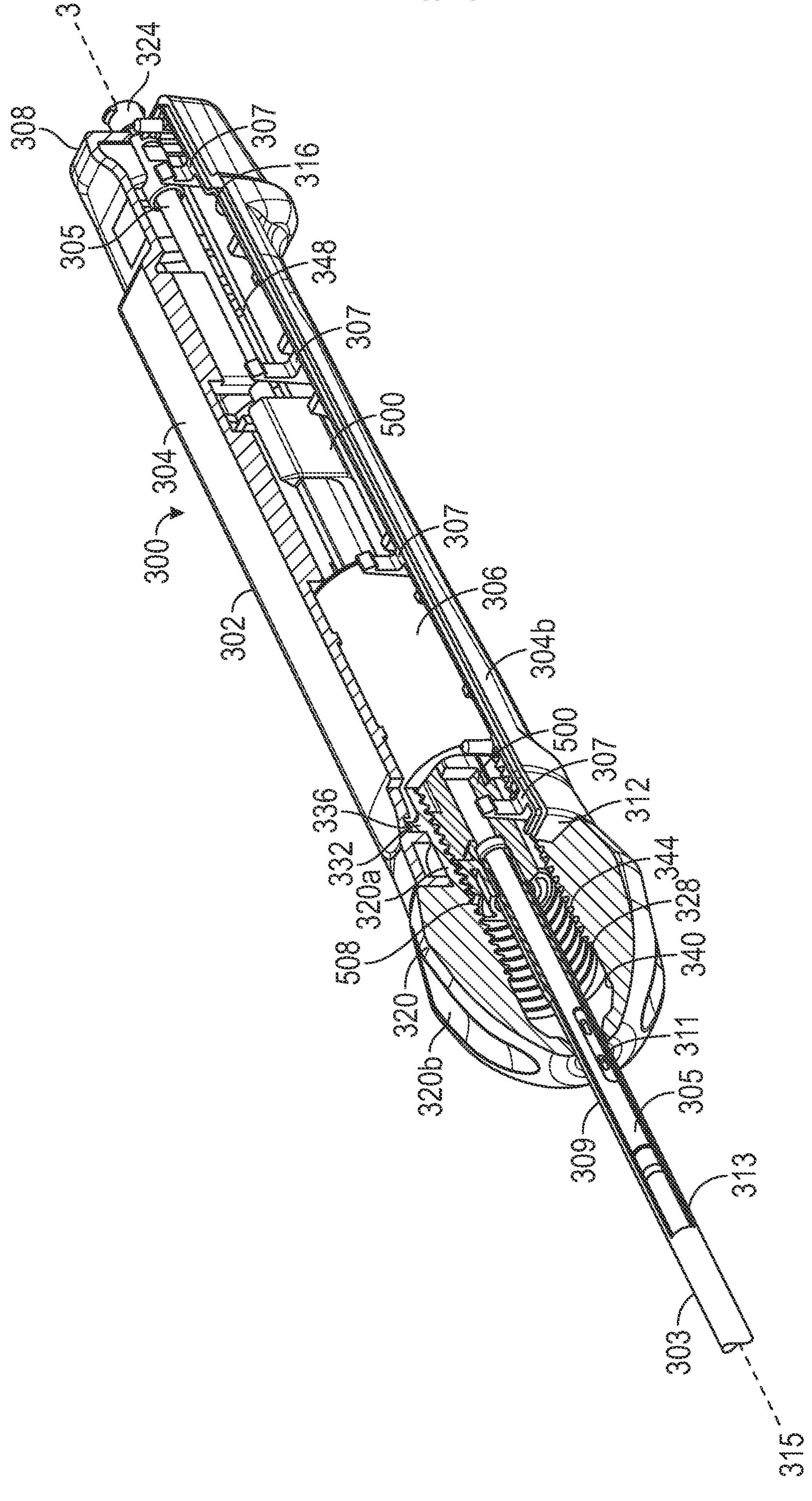
312
303,309
315

FIG. 7B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307
500
304
300
307
306
302
304b
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320b
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309
313
303
315

FIG. 7C

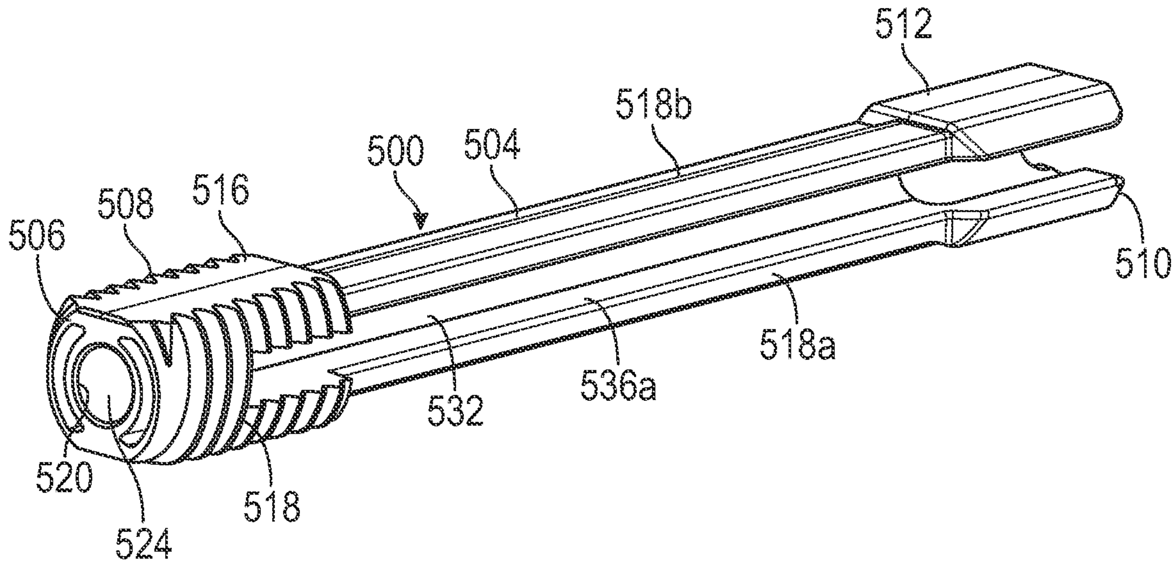


FIG. 8A

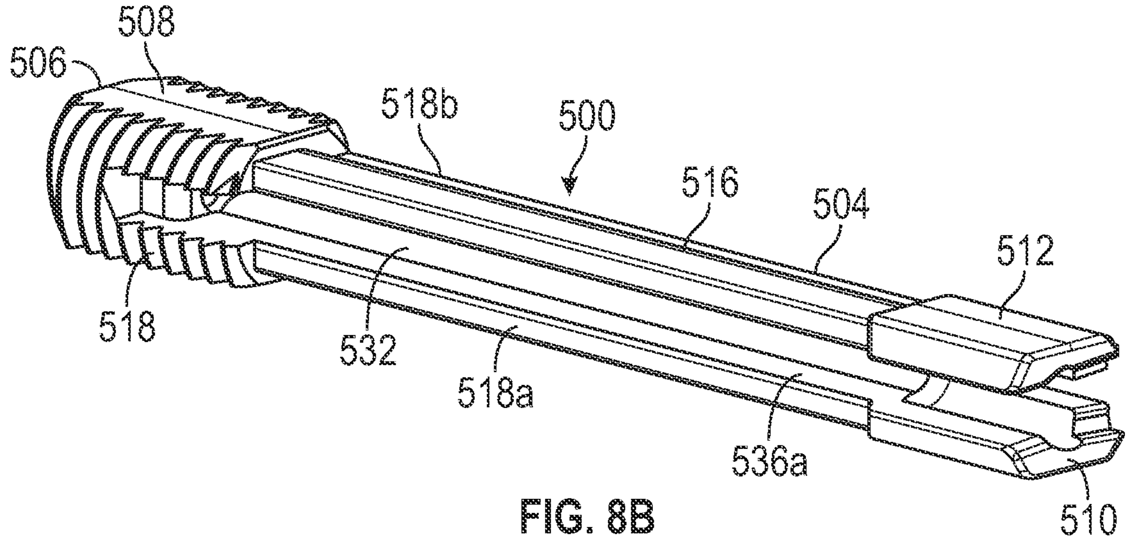


FIG. 8B

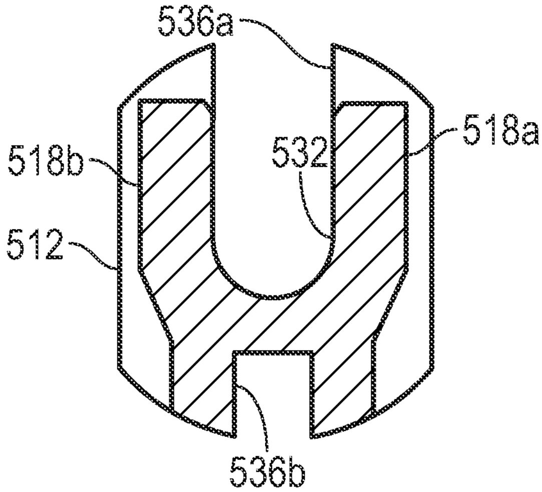


FIG. 8C

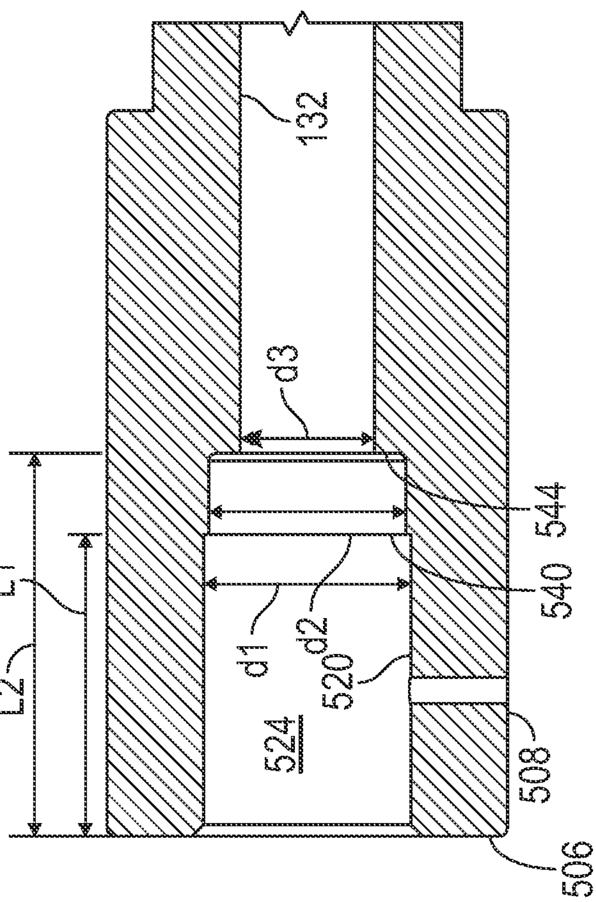
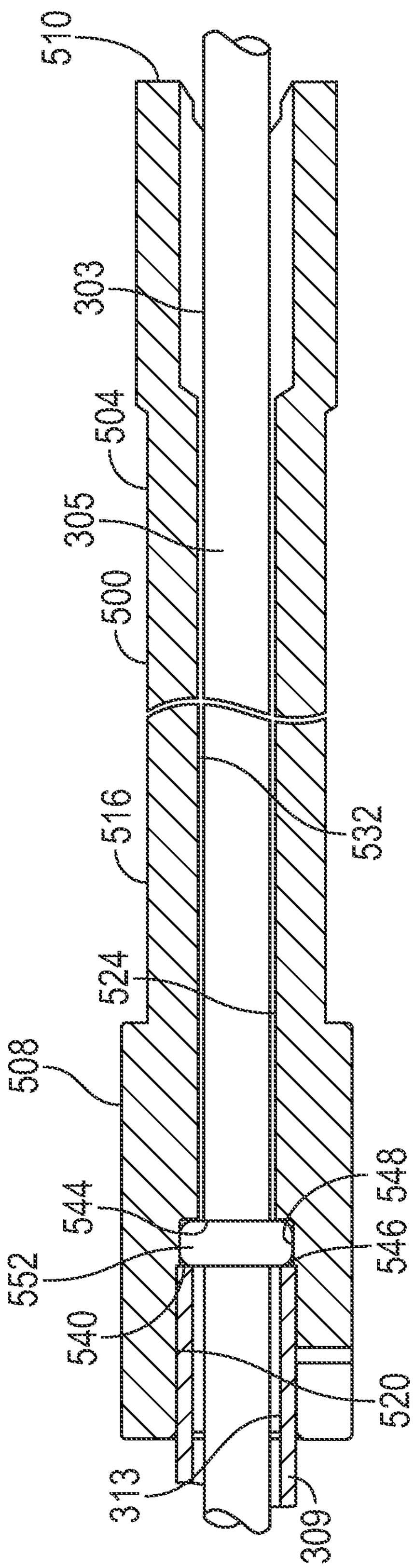

132
d3
544
540
L1
L2
d1
d2
520
524
508
506

FIG. 9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552
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313
309

FIG. 10

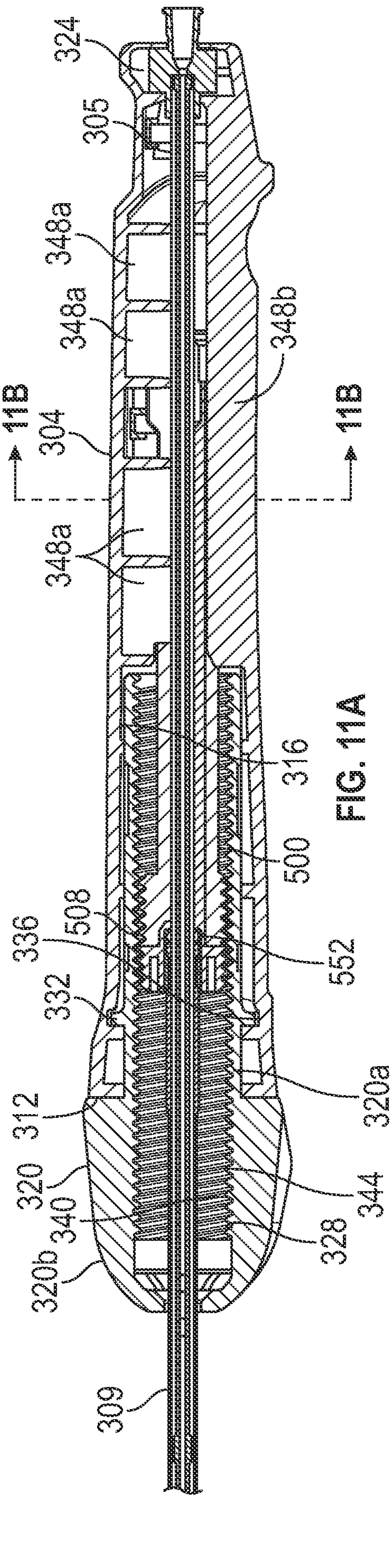


FIG. 11A

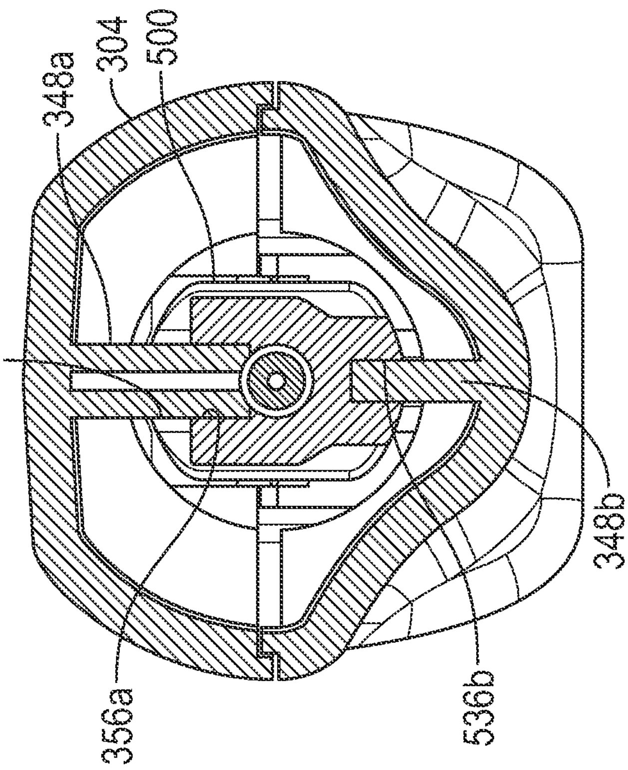


FIG. 11B

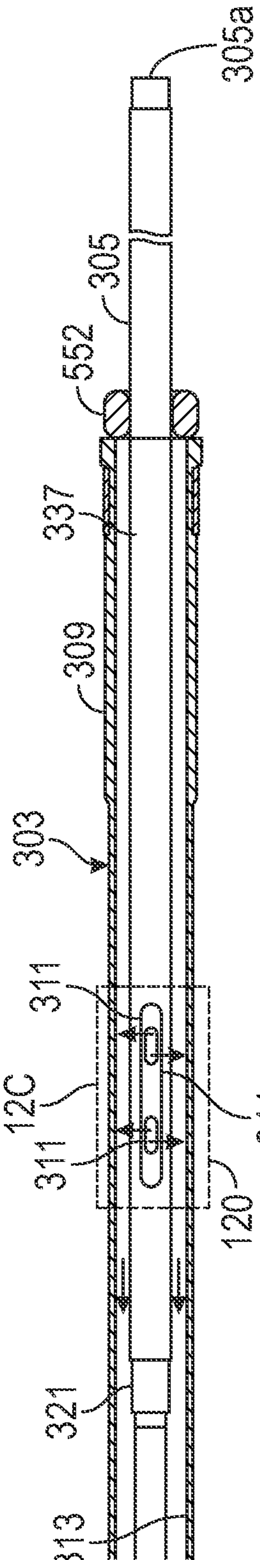


FIG. 12A

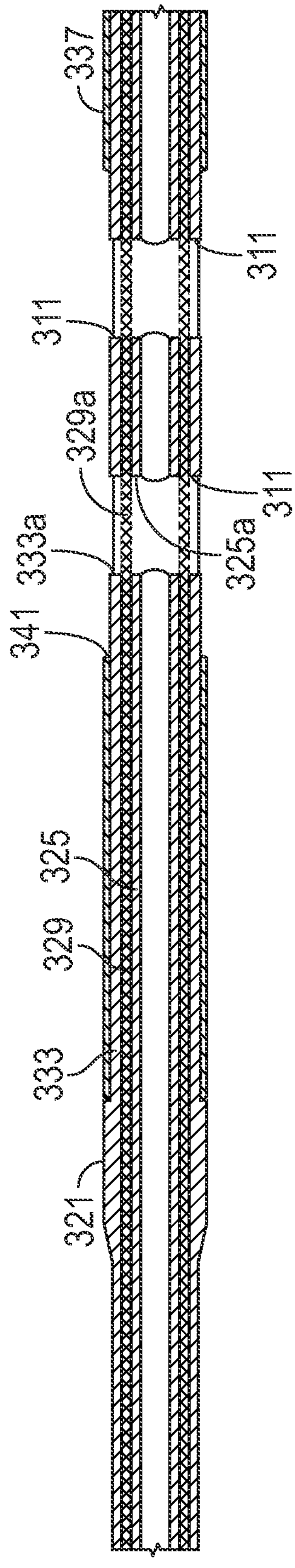


FIG. 12B

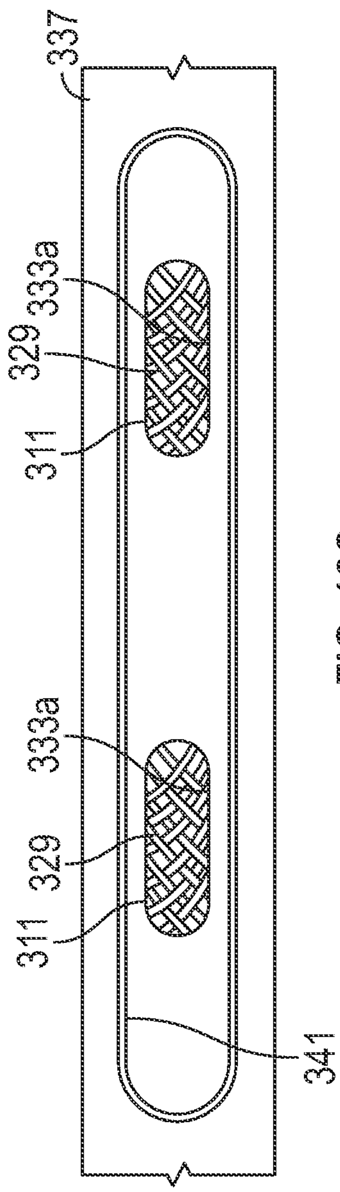


FIG. 12C

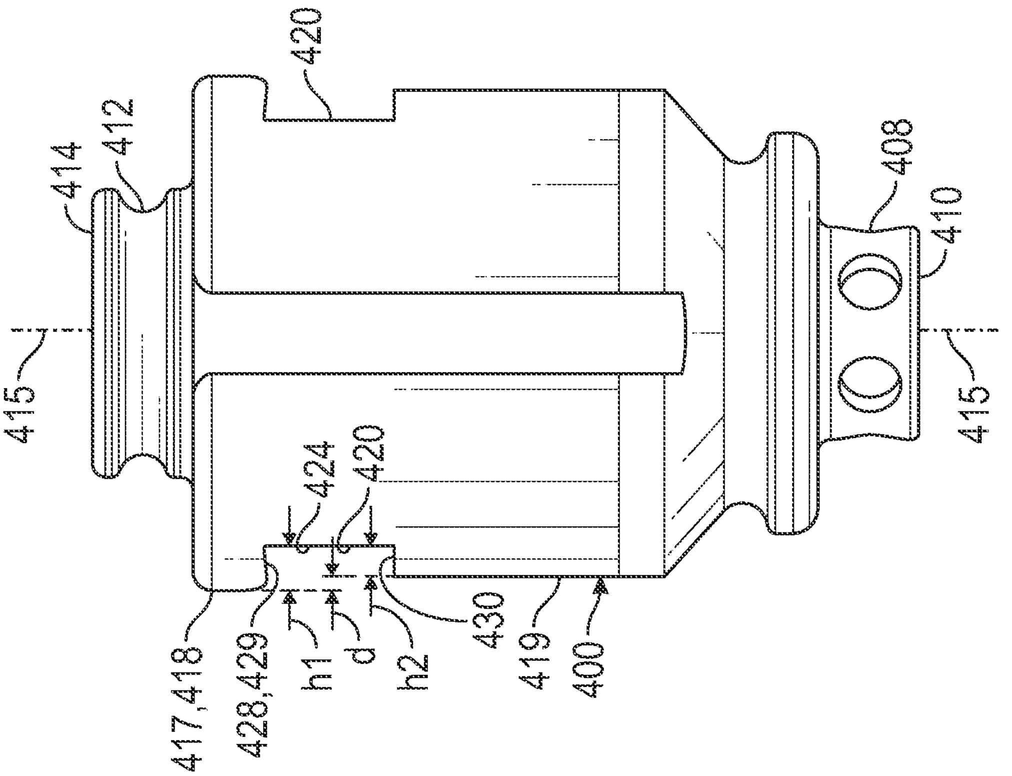


FIG. 13B

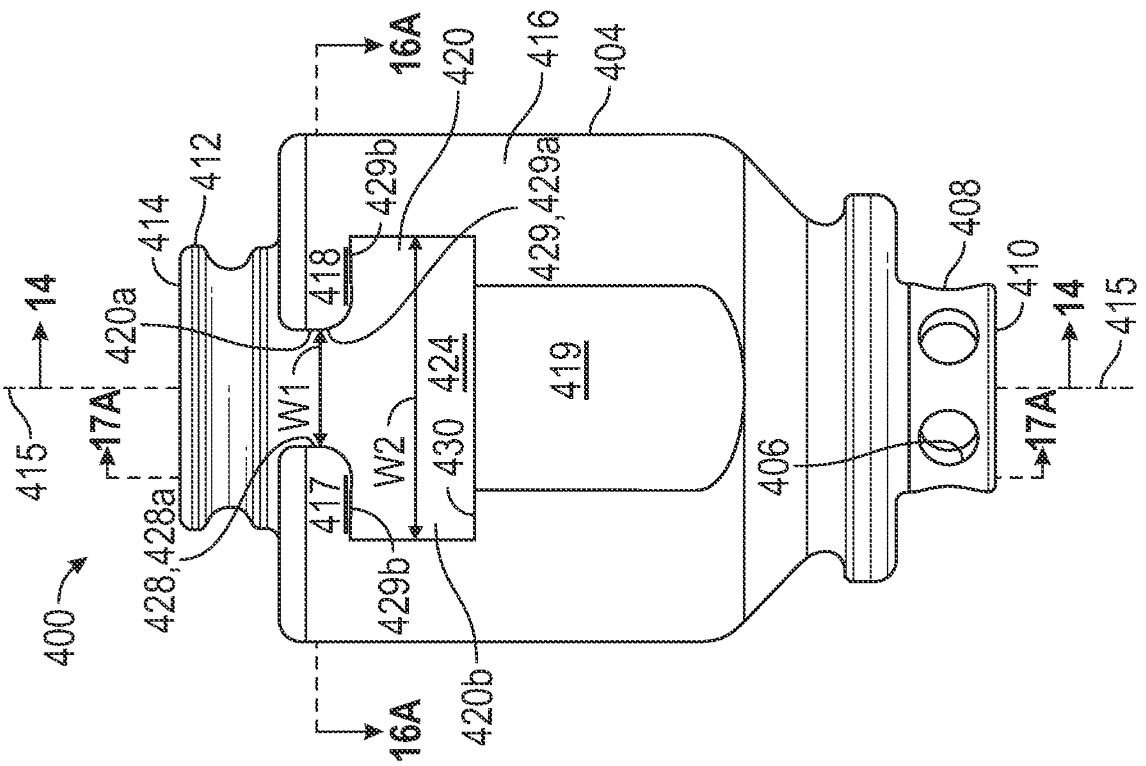
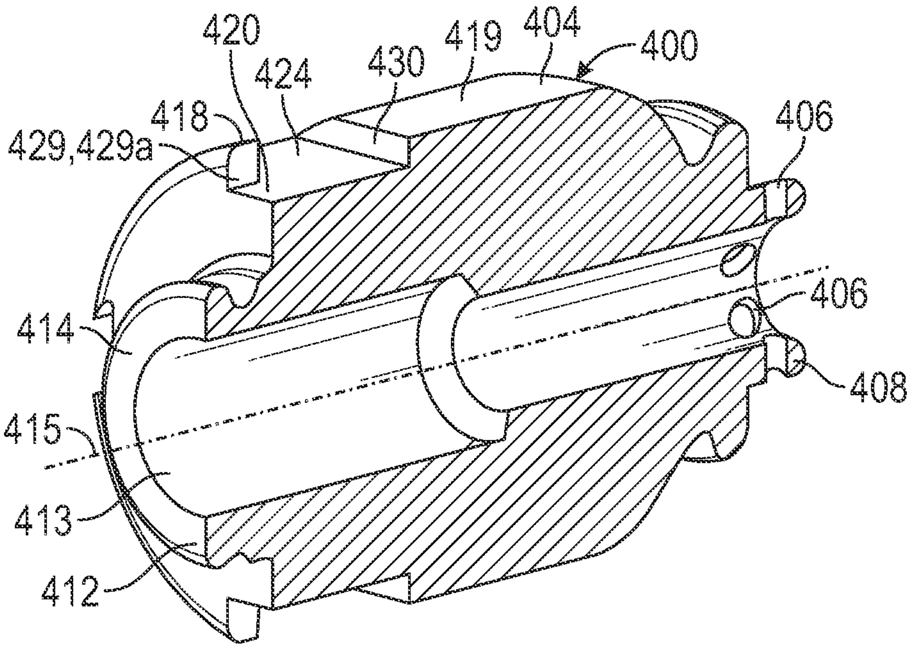


FIG. 13A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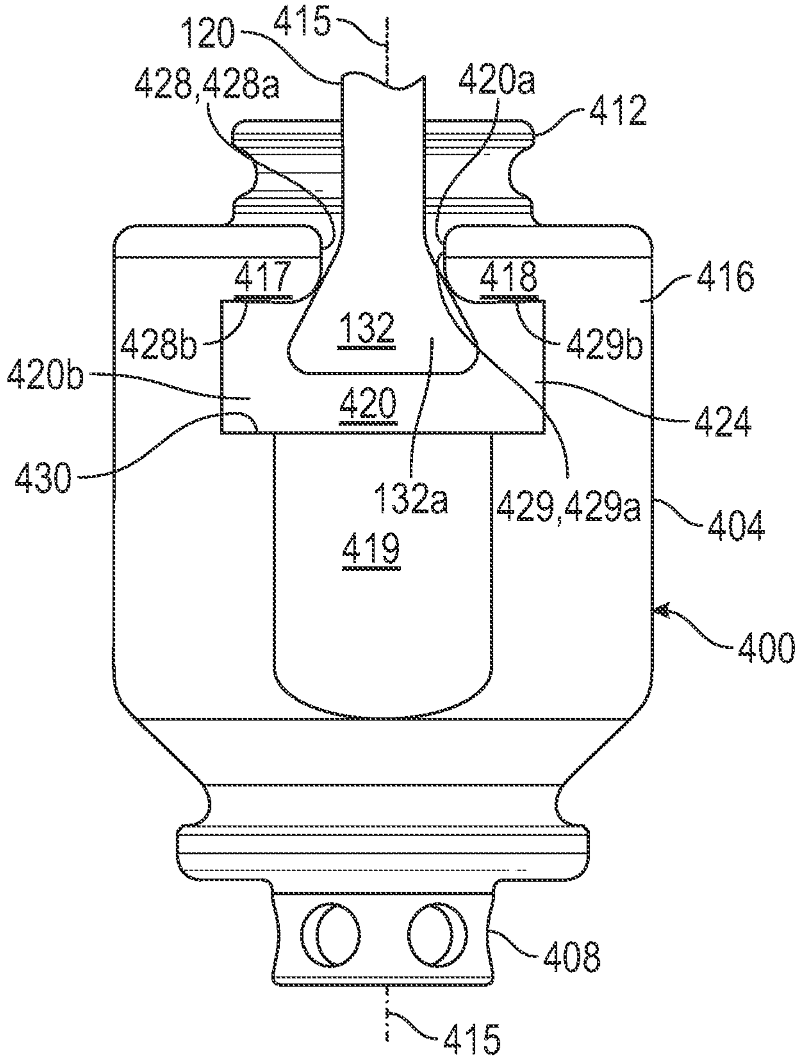
418
429,429a
406
406
414
408
415
413
412

FIG. 14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132a
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400
408
415

FIG. 15

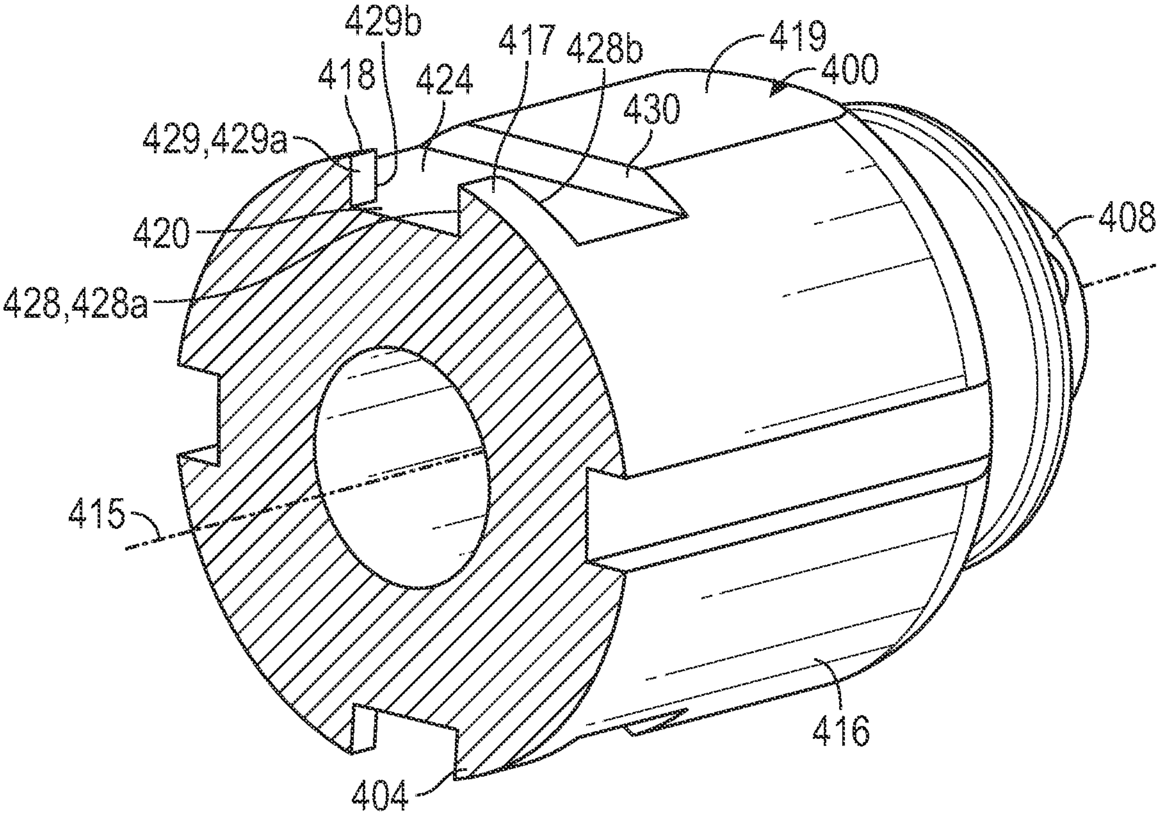

FIG. 16A

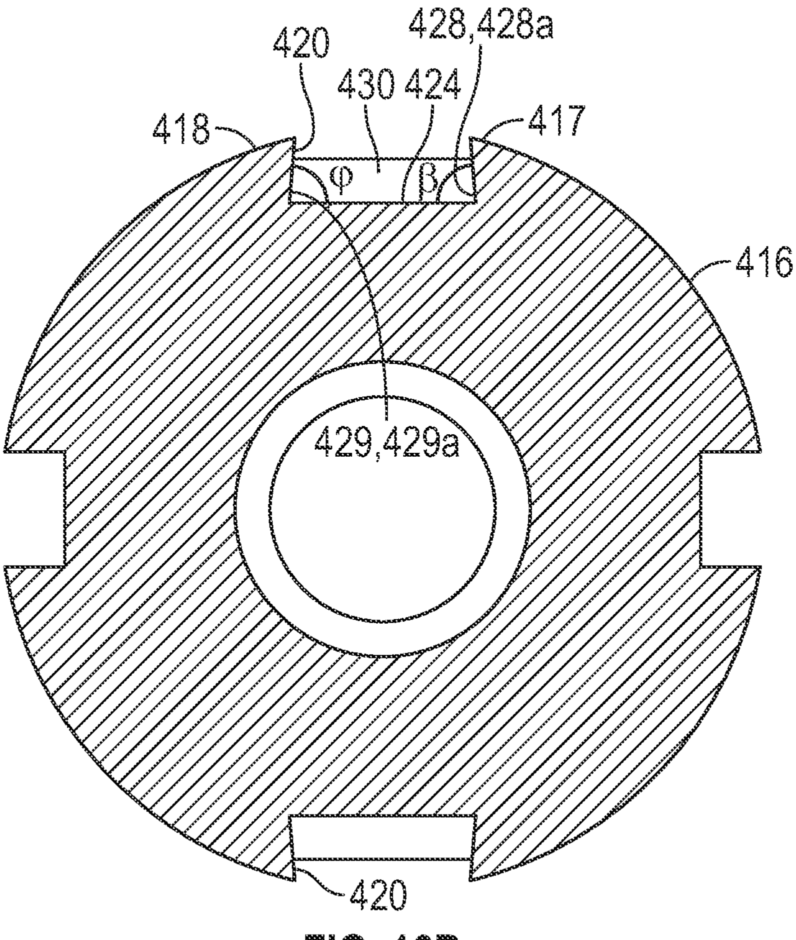

FIG. 16B

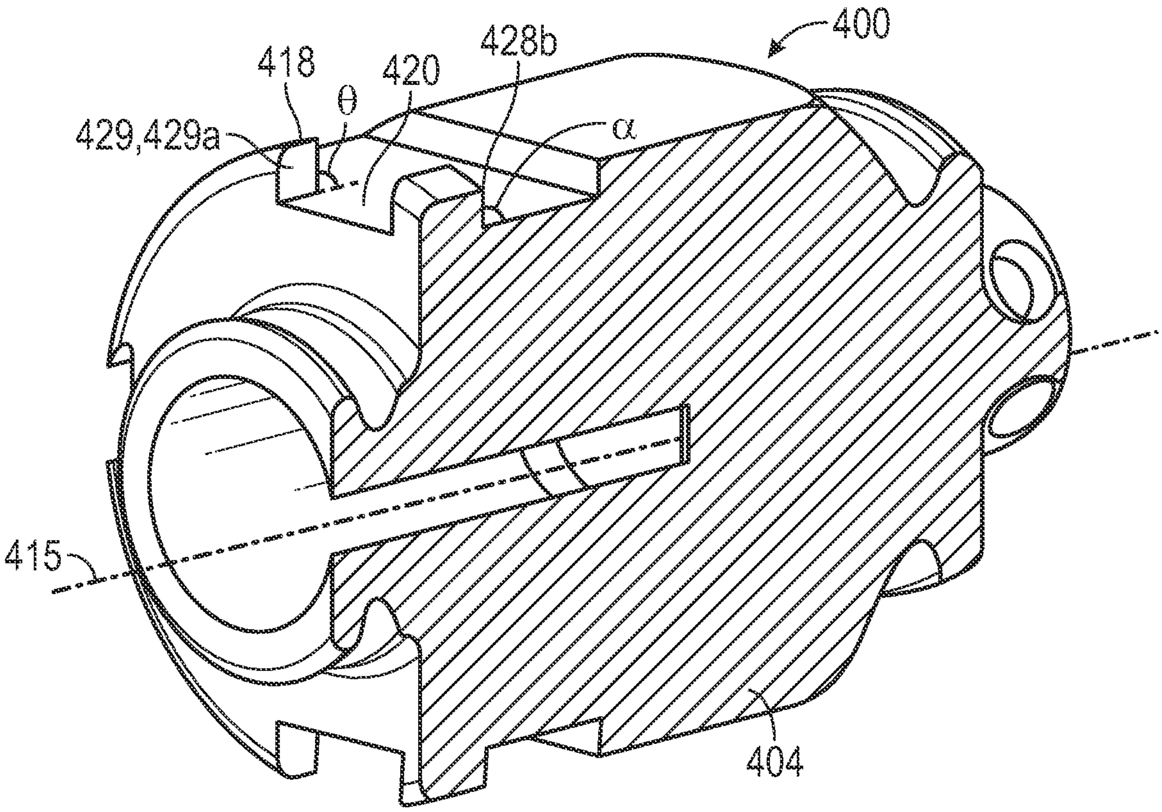

FIG. 17A

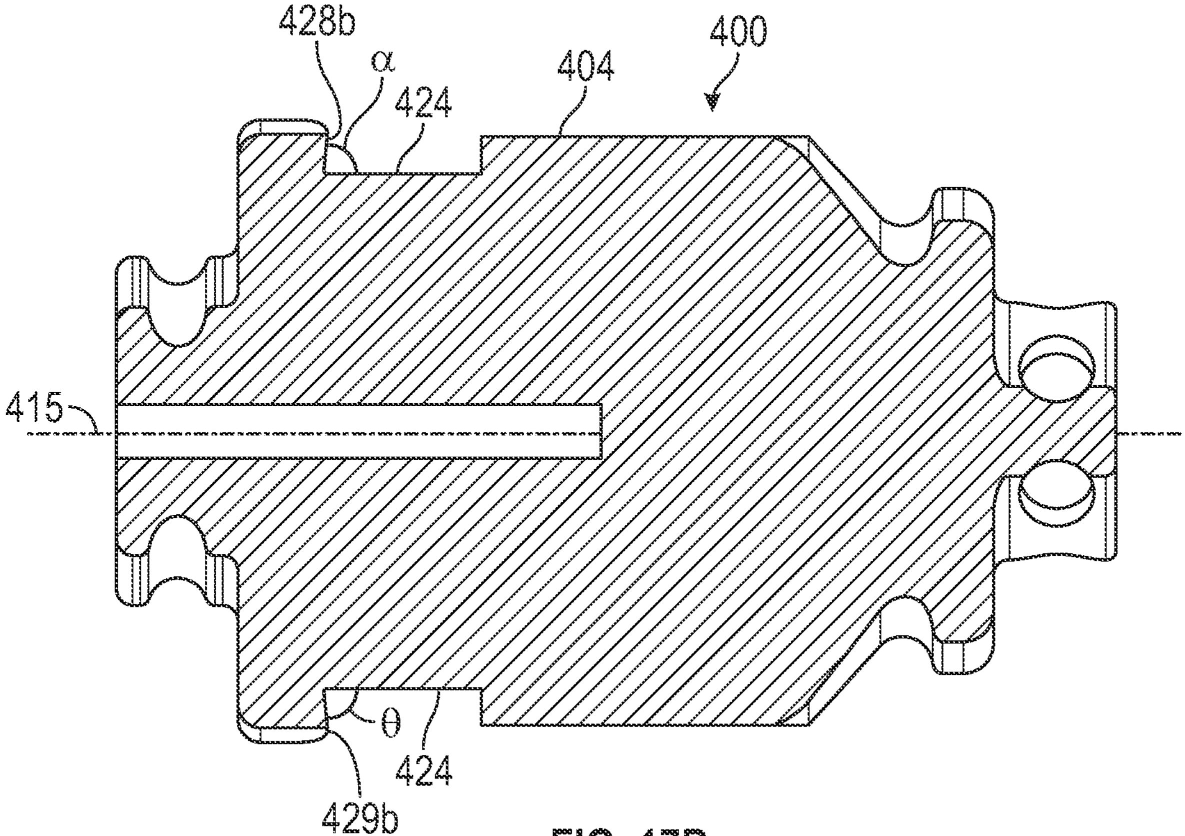

FIG. 17B

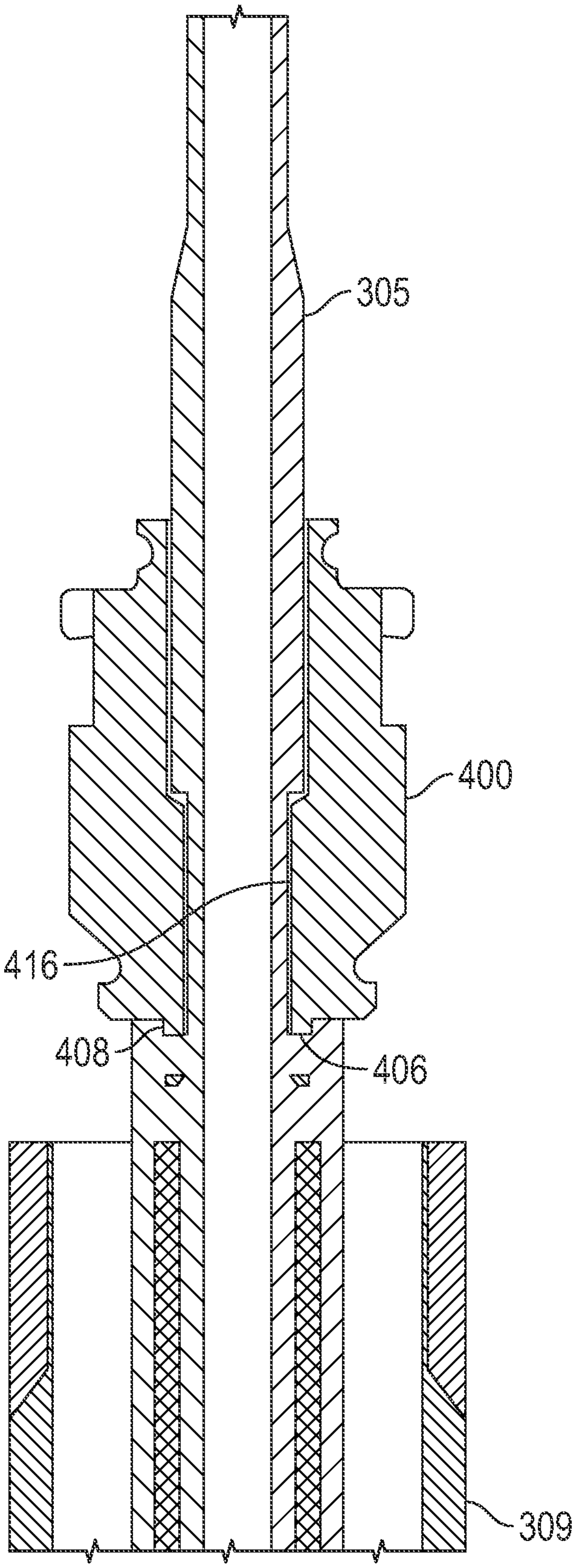

FIG. 18

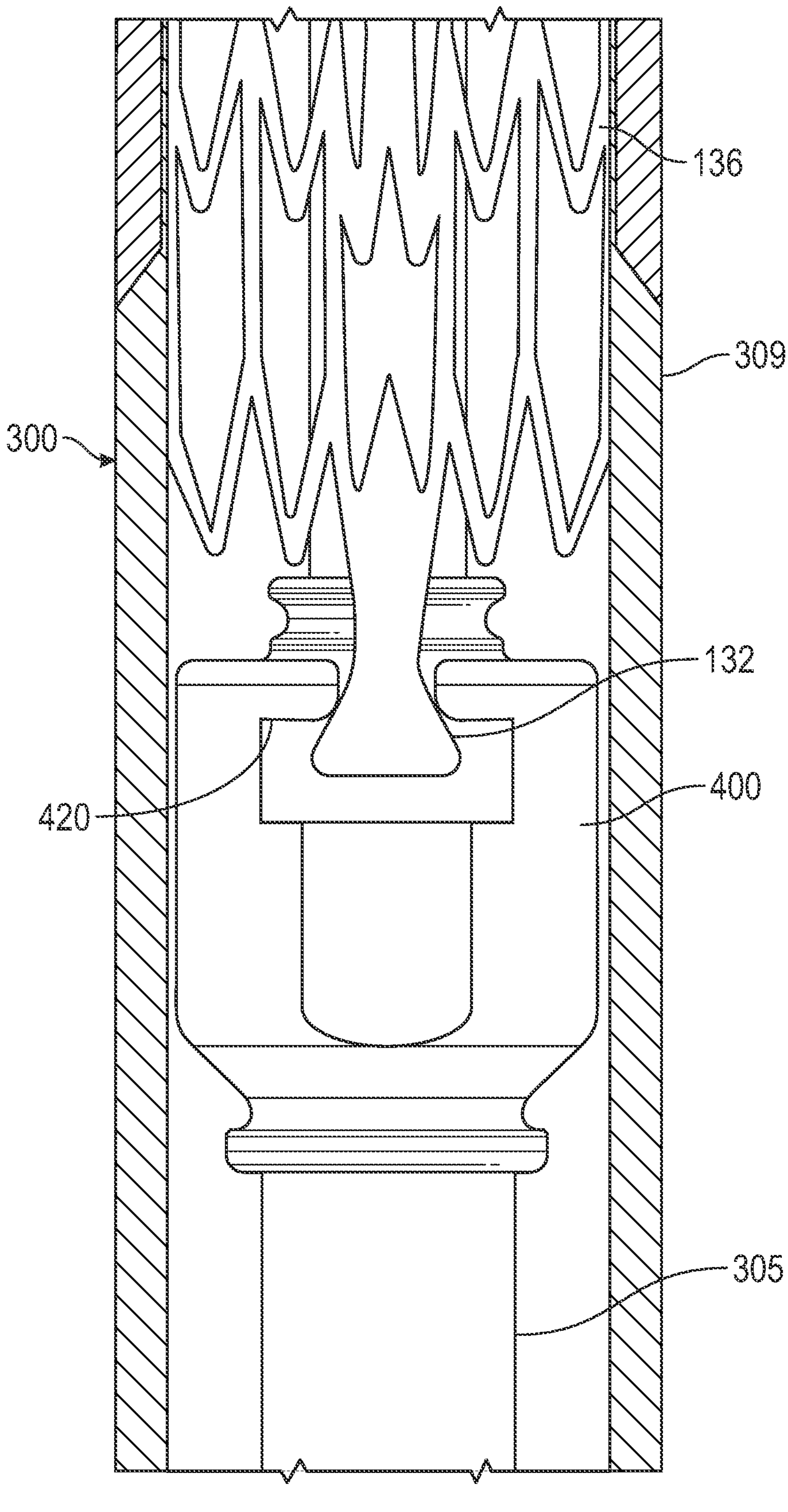

FIG. 19

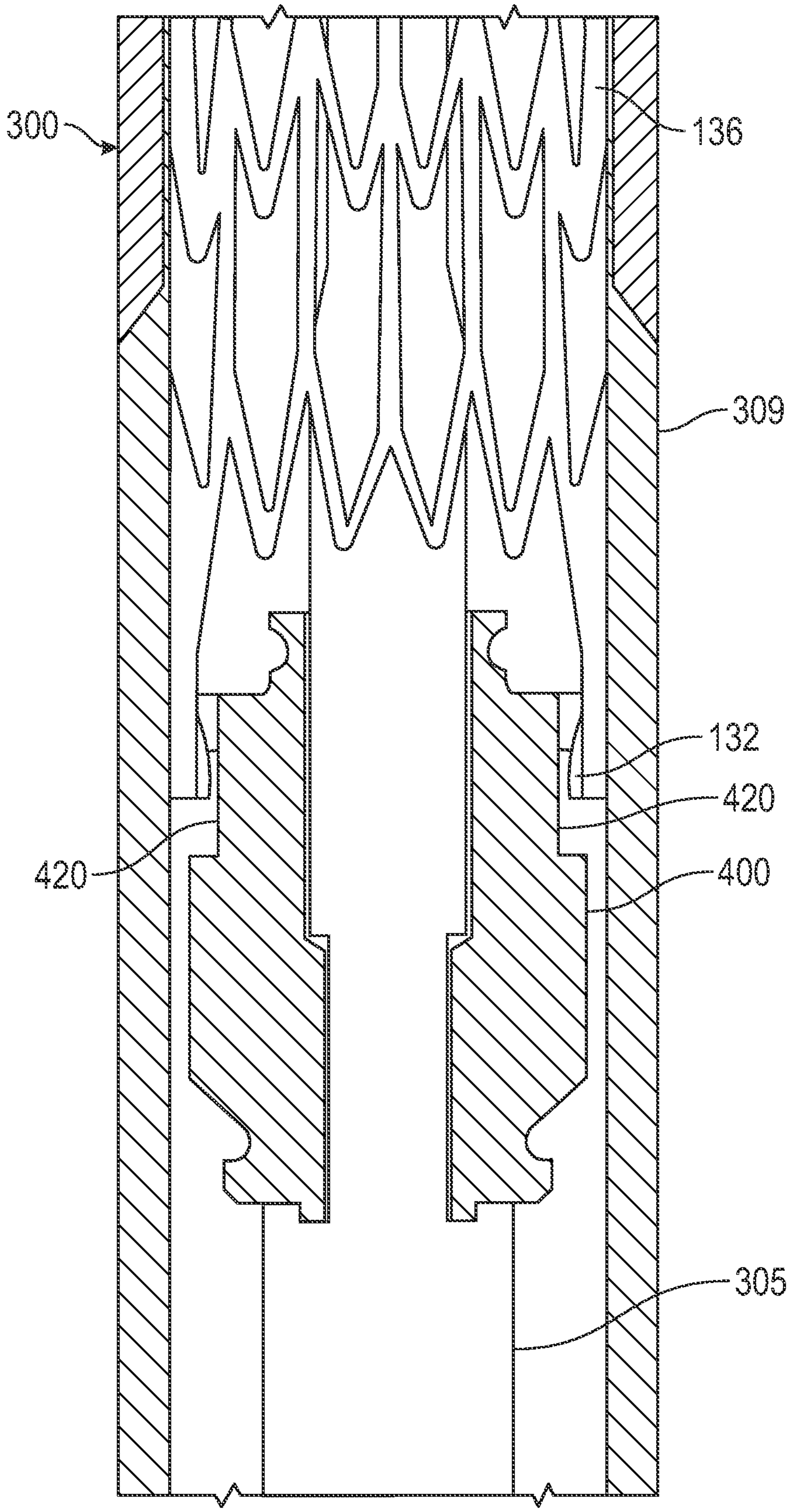

FIG. 20

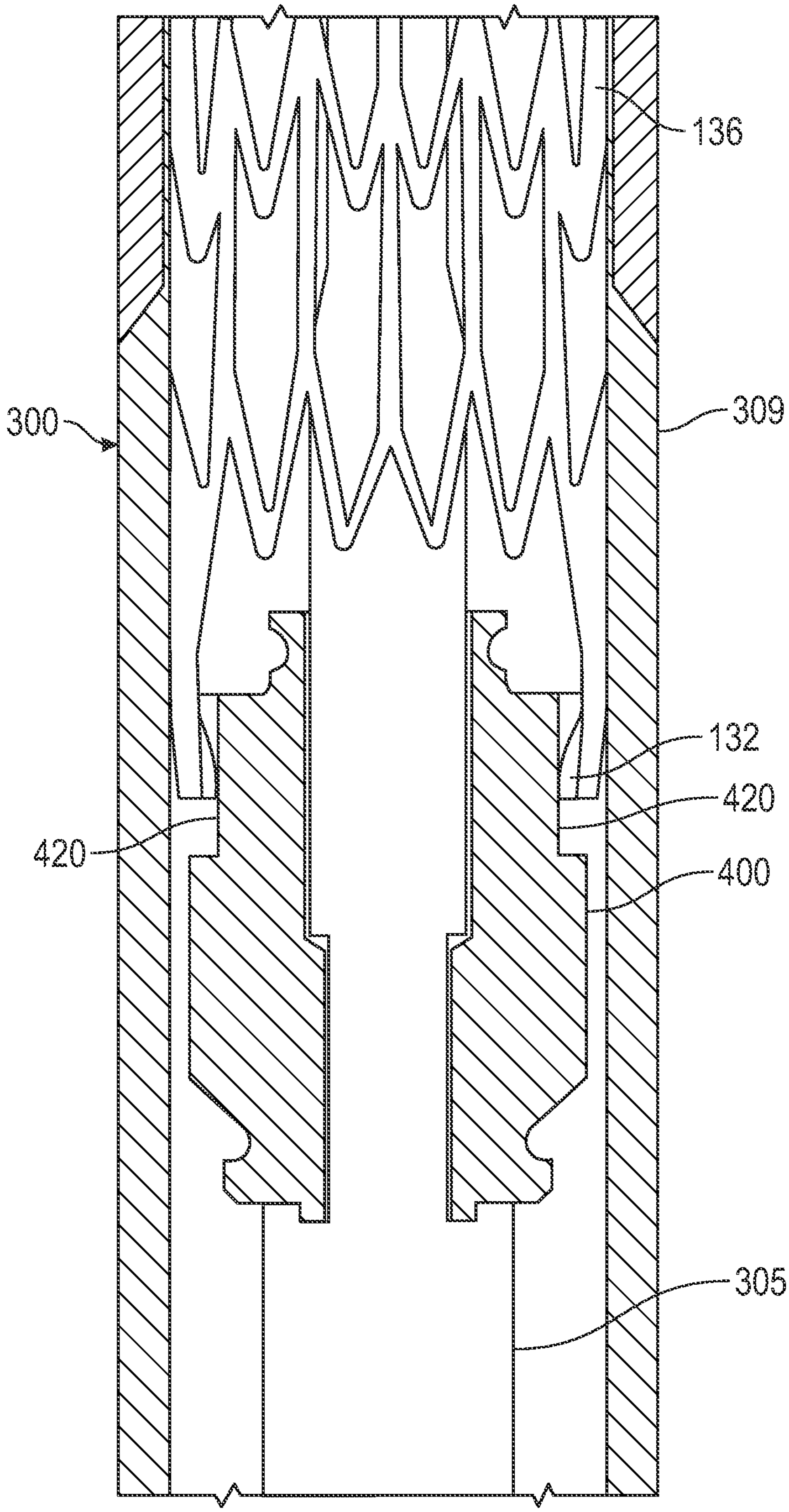

FIG. 21

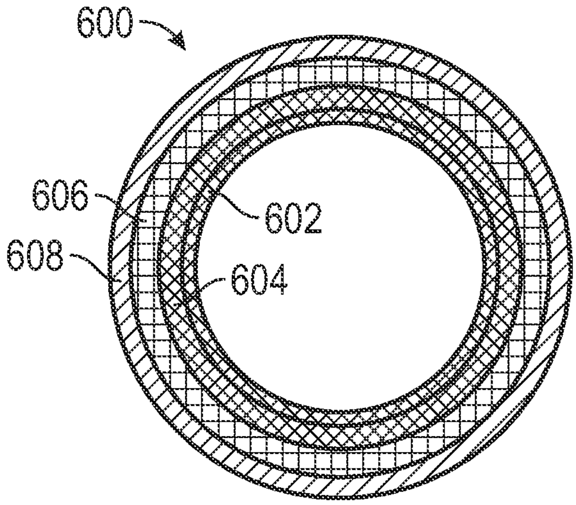

FIG. 22

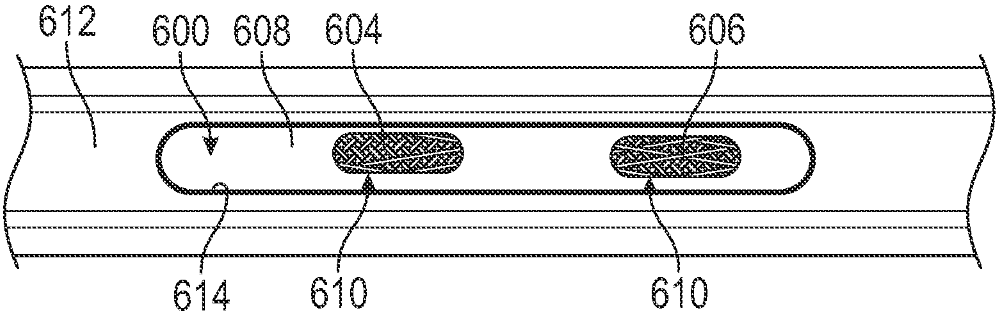

FIG. 23

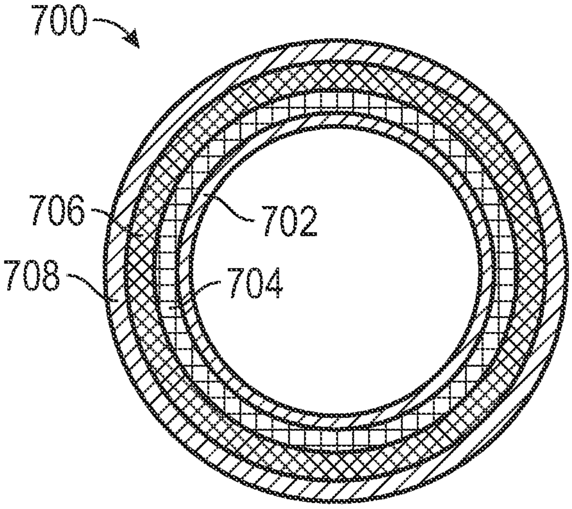

FIG. 24

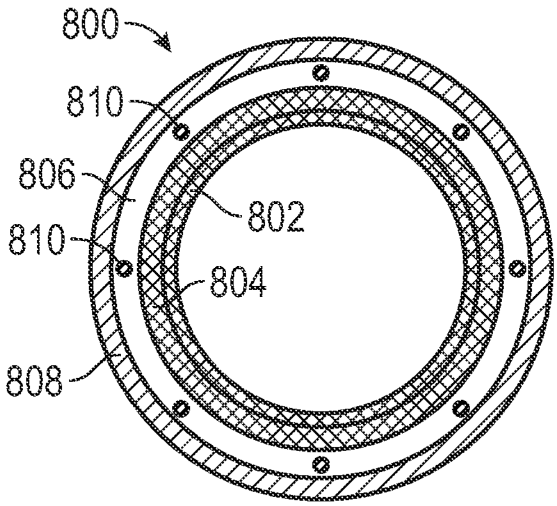

FIG. 25

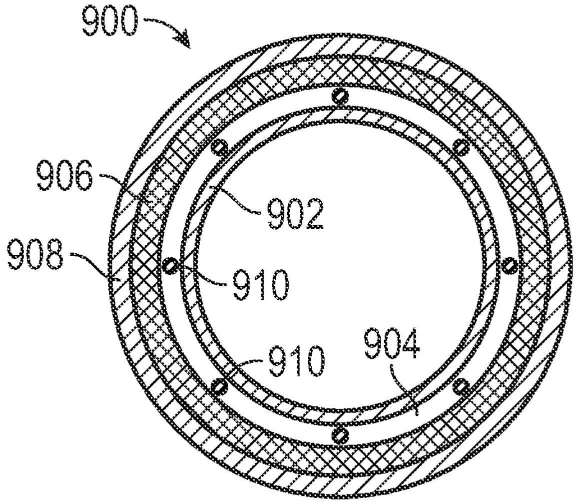

FIG. 26

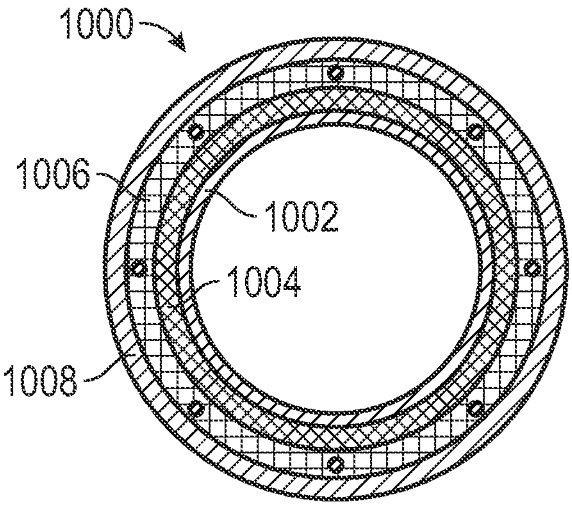

FIG. 27

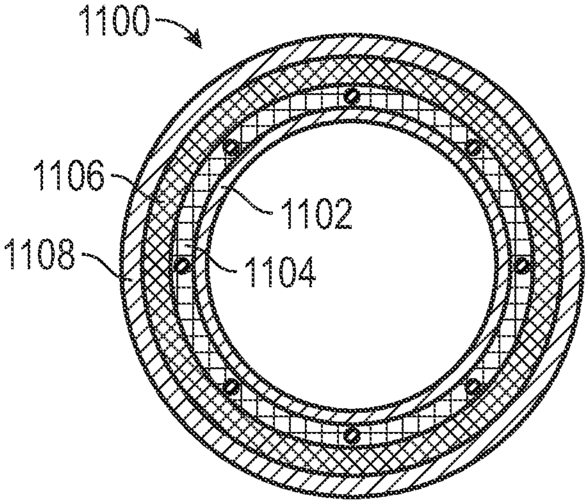

FIG. 28

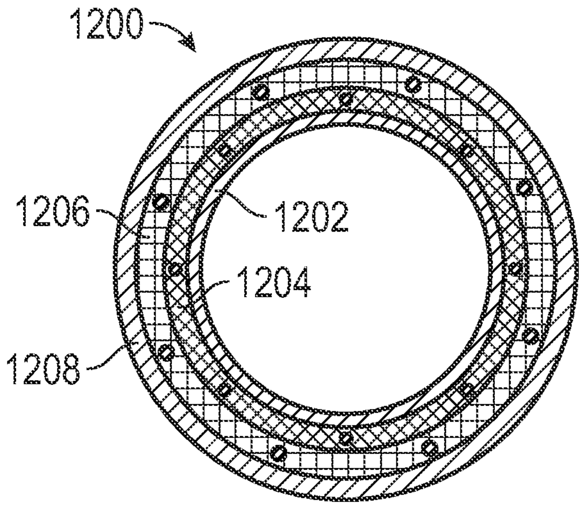

FIG. 29

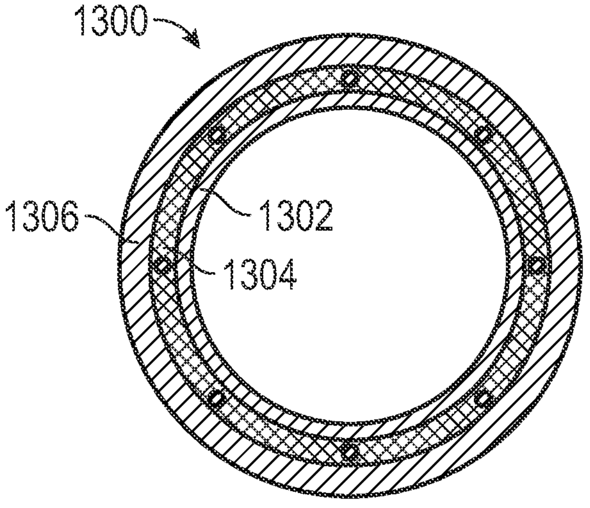

FIG. 30

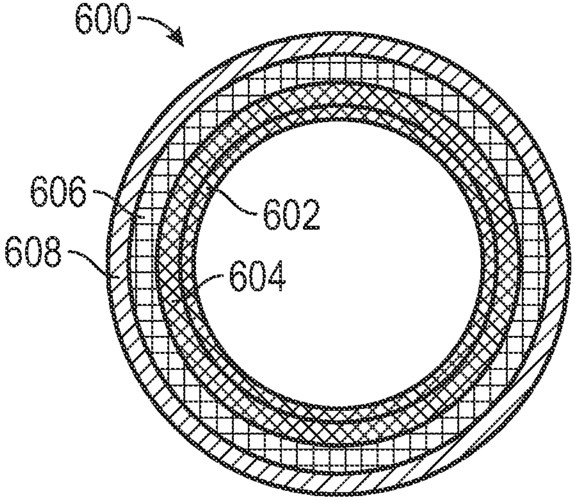

FIG. 22