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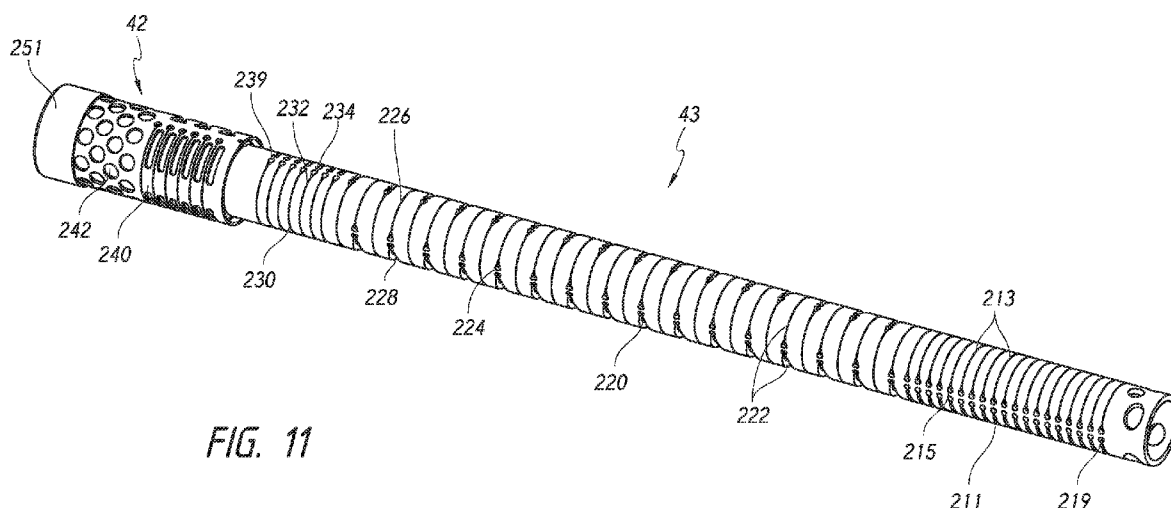


FIG. 11

(57) Abstract: Embodiments of the present disclosure are directed to delivery systems, devices and/or methods of use to deliver and/or controllably deploy an implant in the form of a prosthesis, such as but not limited to a replacement heart valve, to a desired location within the body. In some embodiments, a replacement heart valve and methods for delivering a replacement heart valve to a native heart valve, such as a mitral valve, are provided. Features of delivery systems are disclosed, as well as echogenic markers for delivery systems.

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DELIVERY SYSTEM FOR MEDICAL IMPLANT

BACKGROUND

Field

[0001] Certain embodiments disclosed herein relate generally to delivery systems for implants. In particular, delivery systems and implants relate in some embodiments to replacement heart valves, such as replacement mitral heart valves or other heart valves.

Background

[0002] Human heart valves, which include the aortic, pulmonary, mitral and tricuspid valves, function essentially as one-way valves operating in synchronization with the pumping heart. The valves allow blood to flow downstream, but block blood from flowing upstream. Diseased heart valves exhibit impairments such as narrowing of the valve or regurgitation, which inhibit the valves' ability to control blood flow. Such impairments reduce the heart's blood-pumping efficiency and can be a debilitating and life-threatening condition. For example, valve insufficiency can lead to conditions such as heart hypertrophy and dilation of the ventricle. Thus, extensive efforts have been made to develop methods and apparatuses to repair or replace impaired heart valves.

[0003] Prosthetic implants exist to correct problems associated with impaired heart valves. For example, mechanical and tissue-based heart valve prostheses can be used to replace impaired native heart valves. More recently, substantial effort has been dedicated to developing replacement heart valves, particularly tissue-based replacement heart valves that can be delivered with less trauma to the patient than through open heart surgery. Replacement valves are being designed to be delivered through minimally invasive procedures and even percutaneous procedures. Such replacement valves often include a tissue-based valve body that is connected to an expandable frame that is then delivered to the native valve's annulus.

[0004] Development of prosthetic implants including but not limited to replacement heart valves that can be compacted for delivery and then controllably expanded for controlled placement has proven to be particularly challenging. An additional challenge relates to the ability of such prostheses to be secured relative to intraluminal tissue, e.g., tissue within any body lumen or cavity, in an atraumatic manner.

[0005] Delivering an implant to a desired location in the human body, for example delivering a replacement heart valve to the mitral valve, can also be challenging. Obtaining

access to perform procedures in the heart or in other anatomical locations may require delivery of devices percutaneously through tortuous vasculature or through open or semi-open surgical procedures. The ability to control the deployment of the prosthesis at the desired location can also be challenging.

[0006] It may also be difficult to properly visualize or locate a delivery system for the implant, including utilizing ultrasound imaging.

SUMMARY

[0007] Embodiments of the present disclosure are directed to delivery systems, devices and/or methods of use to deliver and/or controllably deploy an implant in the form of a prosthesis, such as but not limited to a replacement heart valve, to a desired location within the body. In some embodiments, a replacement heart valve and methods for delivering a replacement heart valve to a native heart valve, such as a mitral valve, are provided.

[0008] In some embodiments, a delivery system and method are provided for delivering a replacement heart valve to a native mitral valve location. The delivery system and method may utilize a transseptal approach. In some embodiments, components of the delivery system facilitate bending of the delivery system to steer a prosthesis from the septum to a location within the native mitral valve. In some embodiments, a capsule is provided for containing the prosthesis for delivery to the native mitral valve location. In other embodiments, the delivery system and method may be adapted for delivery of implants to locations other than the native mitral valve.

[0009] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a capsule configured to surround the implant retention area and including a hypotube having one or more cuts forming a plurality of rings.

[0010] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a capsule configured to surround the implant retention area and including a hypotube having one or more cuts that bias a flexibility of the hypotube in a direction.

[0011] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a

proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a capsule configured to surround the implant retention area and including a hypotube having one or more cuts forming a spiral.

[0012] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule surrounding an implant retention area retaining an implant for implantation within the patient's body, the capsule including a hypotube having one or more cuts forming a plurality of rings; moving the capsule proximally to expose a portion of the implant within the patient's body; and moving the capsule distally to recapture a portion of the implant within the patient's body.

[0013] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, a capsule configured to surround the implant retention area, a shaft portion positioned proximal of the capsule, and a coupler configured to couple the capsule to the shaft portion and configured to allow the capsule to rotate relative to the shaft portion.

[0014] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule and a shaft portion positioned proximal of the capsule and a coupler coupling the capsule to the shaft portion and configured to allow the capsule to rotate relative to the shaft portion, the capsule surrounding an implant retention area retaining an implant for implantation within the patient's body; and moving the capsule proximally to expose a portion of the implant within the patient's body while the capsule rotates relative to the shaft portion.

[0015] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, a sheath having an interior lumen, an interior shaft positioned within the interior lumen, and an inflatable body positioned between the interior shaft and the sheath and configured to inflate to support the sheath.

[0016] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a sheath and an interior shaft positioned within an interior lumen of the sheath and an implant retention area retaining an implant for implantation within the patient's body; moving the sheath proximally to expose a

portion of the implant within the patient's body; inflating an inflatable body between the sheath and the interior shaft; and moving the sheath distally to recapture a portion of the implant within the patient's body while the inflatable body is inflated between the sheath and the interior shaft to support the sheath.

[0017] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a wall of the elongate shaft including: an outer jacket layer, an interior liner layer, a braid layer positioned between the outer jacket layer and the interior liner layer, and a metal layer positioned between the braid layer and the interior liner layer.

[0018] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, a sheath configured to bend in at least one plane, and a cable having a first end portion, a second end portion, and an intermediate portion extending between the first end portion and the second end portion, the first end portion coupled to a first side of the sheath and the second end portion coupled to a second side of the sheath opposite the first side. The delivery system includes a cable router configured to engage the intermediate portion of the cable and allow the cable to move along the cable router when the sheath is bent in the at least one plane; and a control mechanism for retracting the cable router and the sheath relative to the implant retention area.

[0019] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a sheath and a cable having a first end portion, a second end portion, and an intermediate portion extending between the first end portion and the second end portion, the first end portion coupled to a first side of the sheath and the second end portion coupled to a second side of the sheath opposite the first side, the intermediate portion engaged with a cable router; bending the sheath in a plane such that a length of the cable between the cable router and the first end portion increases and a length of the cable between the cable router and the second end portion decreases; and retracting the cable router and the sheath relative to the implant retention area.

[0020] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, a sheath having an interior lumen and a capsule configured to surround the implant retention area, an interior shaft positioned within the interior lumen, and a stop positioned on the interior shaft and configured to impede proximal movement of the capsule relative to the interior shaft.

[0021] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a sheath having an interior lumen and a capsule retaining an implant for implantation within the patient's body, the sheath including an interior shaft and a stop positioned on the interior shaft; moving the capsule proximally to expose a first portion of the implant within the patient's body until the sheath contacts the stop; and overcoming the stop and moving the capsule proximally to expose a second portion of the implant within the patient's body that is positioned proximal of the first portion of the implant.

[0022] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and an implant retention area, and an assembly configured to retain at least a portion of the implant within the implant retention area; and a handle coupled to the proximal end of the elongate shaft and including a control knob configured to be rotated to move the assembly to release at least the portion of the implant from the implant retention area, the control knob including an outer grip surface that is exposed for gripping around an entire outer circumference of the control knob.

[0023] An embodiment herein includes a method comprising: deploying a delivery apparatus to a location within a patient's body, the delivery apparatus including an elongate shaft and a handle coupled to a proximal end of the elongate shaft, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and an assembly configured to retain at least a portion of the implant within the implant retention area, the handle including a control knob configured to be rotated to move the assembly to release at least the portion of the implant from the implant retention area and including an outer grip surface that is exposed for gripping around an entire outer circumference of the control knob; gripping the grip surface of the control knob; and rotating the control knob to move the assembly to release at least the portion of the implant from the implant retention area.

[0024] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a marker configured to enhance an echogenicity of the elongate shaft to define a location of a portion of the elongate shaft when viewed with ultrasound imaging.

[0025] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a marker that enhances an echogenicity of the elongate shaft to define a location of a portion of the elongate shaft when viewed with ultrasound imaging.

[0026] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a capsule configured to surround the implant retention area and including a distal end configured to expand radially outward.

[0027] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule surrounding an implant retention area retaining an implant for implantation within the patient's body; moving the capsule proximally to expose a portion of the implant within the patient's body; and moving the capsule distally to recapture a portion of the implant within the patient's body and to pass a distal end of the capsule that is expanded radially outward over the portion of the implant that is recaptured.

[0028] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, and a pull tether coupled to a portion of the elongate shaft at or distal the implant retention area and configured to deflect the distal end of the elongate shaft.

[0029] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including: an implant retention area configured to retain the implant, a nose cone positioned at the distal end of the elongate shaft, and a pull tether coupled to the nose cone and configured to deflect the nose cone.

[0030] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including a proximal end and a distal end and an implant retention area retaining an implant for implantation within the patient's body; and deflecting the distal end of the elongate shaft utilizing a pull tether coupled to a portion of the elongate shaft at or distal the implant retention area.

[0031] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: a first elongate shaft having a proximal end and a distal end and extending along a first axis and being steerable; a second elongate shaft having a proximal end and a distal end and extending along a second axis and including an implant retention area configured to retain the implant; and a coupler configured to couple the second elongate shaft to the first elongate shaft such that the second elongate shaft may slide relative to the first elongate shaft with the second axis offset from the first axis.

[0032] An embodiment herein includes a method comprising: deploying a first elongate shaft to a location within a patient's body, the first elongate shaft extending along a first axis and being steerable; and sliding a second elongate shaft along the first elongate shaft to a location within the patient's body, the second elongate shaft being coupled to the first elongate shaft and extending along a second axis that is offset from the first axis and including an implant retention area retaining an implant therein.

[0033] An embodiment herein includes a delivery system for delivering an implant to a location within a patient's body, the delivery system comprising: an elongate shaft having a proximal end and a distal end, and including an implant retention area configured to retain the implant, and a covering layer on the elongate shaft including reinforcing fibers or beads.

[0034] An embodiment herein includes a method comprising: deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a covering layer including reinforcing fibers or beads.

[0035] An embodiment herein includes a method comprising: preparing a mixture of polytetrafluoroethylene (PTFE) with reinforcing fibers or beads; and providing an elongate shaft for a delivery system for delivering an implant to a location within a patient's body, the elongate shaft including the mixture of the polytetrafluoroethylene (PTFE) with the reinforcing fibers or beads as a covering layer of the elongate shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0036] FIG. 1 shows an embodiment of a delivery system.
- [0037] FIG. 2A shows a partial cross-sectional view of the distal end of the delivery system of FIG. 1 loaded with the valve prosthesis of FIG. 3A.
- [0038] FIG. 2B shows a partial cross-sectional view of the distal end of the delivery system of FIG. 1 without the valve prosthesis of FIG. 3A.
- [0039] FIG. 2C shows a partial cross-sectional view of the distal end of the delivery system of FIG. 1 without with certain shaft assemblies translated along the rail assembly.
- [0040] FIG. 3A shows a side view of an embodiment of a valve prosthesis that may be delivered using the delivery systems described herein.
- [0041] FIG. 3B shows a side view of an embodiment of an aortic valve prosthesis that may be delivered using the delivery systems described herein.
- [0042] FIG. 4 shows a perspective view of the distal end of the delivery system of FIG. 1.
- [0043] FIG. 5 shows components of the delivery system of FIG. 4 with the outer sheath assembly moved proximally and out of view.
- [0044] FIG. 6A shows components of the delivery system of FIG. 5 with the mid shaft assembly moved proximally and out of view.
- [0045] FIG. 6B illustrates a cross-section view of the rail assembly.
- [0046] FIG. 7 shows components of the delivery system of FIG. 6A with the rail assembly moved proximally and out of view.
- [0047] FIG. 8 shows components of the delivery system of FIG. 7 with the inner assembly moved proximally and out of view.
- [0048] FIGS. 9A and 9B illustrate embodiments of a guide wire shield.
- [0049] FIG. 10 illustrates an embodiment of an outer hypotube.
- [0050] FIG. 11 illustrates an embodiment of a mid shaft hypotube.
- [0051] FIG. 12A illustrates an embodiment of the mid shaft hypotube of FIG. 11 as a flat pattern.
- [0052] FIG. 12B illustrates an embodiment of an outer retention ring.
- [0053] FIG. 13 illustrates an embodiment of a rail assembly.

- [0054] FIG. 14 illustrates an embodiment of an inner assembly.
- [0055] FIG. 15 illustrates a cross-section of a capsule.
- [0056] FIG. 16 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0057] FIG. 17 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0058] FIG. 18 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0059] FIG. 19 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0060] FIG. 20 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0061] FIG. 21 illustrates an embodiment of a hypotube of an outer sheath assembly as a flat pattern.
- [0062] FIG. 22 illustrates a cross sectional view of a distal portion of an elongate shaft of a delivery system including a coupler coupling a capsule to a shaft.
- [0063] FIG. 23 illustrates a perspective view of a distal portion of an elongate shaft of a delivery system including a coupler coupling a capsule to a shaft.
- [0064] FIG. 24 illustrates a cross sectional view of a distal portion of an elongate shaft of a delivery system including a coupler coupling a capsule to a shaft.
- [0065] FIG. 25 illustrates a perspective view of a distal portion of an elongate shaft of a delivery system including a coupler coupling a capsule to a shaft.
- [0066] FIG. 26 illustrates a cross sectional view of a distal portion of an elongate shaft of a delivery system including an inflatable body positioned between an outer sheath and an interior shaft.
- [0067] FIG. 27 illustrates a cross sectional view of the distal portion of the elongate shaft shown in FIG. 26 with the distal portion bent and the inflatable body inflated.
- [0068] FIG. 28 illustrates a side view of an embodiment of a braid layer.

[0069] FIG. 29 illustrates a cross sectional schematic of a construction of a wall of an elongate shaft.

[0070] FIG. 30 illustrates a cross sectional schematic of components of an elongate shaft including a sheath, a cable, and a cable router.

[0071] FIG. 31 illustrates a cross sectional schematic of the sheath shown in FIG. 30 bent.

[0072] FIGS. 32A, 32B, and 32C each illustrate a cross sectional representation of a stop for a capsule.

[0073] FIGS. 33A, 33B, and 33C each illustrate a cross sectional representation of a stop for a capsule.

[0074] FIGS. 34A, 34B, and 34C each illustrate a perspective representation view of a stop for a capsule.

[0075] FIG. 35 illustrates an embodiment of a delivery system handle.

[0076] FIG. 36 illustrates a cross-section of the delivery system handle of FIG. 35.

[0077] FIG. 37 illustrates a perspective view of an embodiment of a delivery system handle.

[0078] FIG. 38 illustrates a side bottom view of the delivery system handle of FIG. 37.

[0079] FIG. 39 illustrates a center cross sectional view of the delivery system handle of FIG. 37 from the side bottom view of FIG. 38.

[0080] FIG. 40 illustrates a front perspective view of the delivery system handle of FIG. 37.

[0081] FIG. 41 illustrates a perspective cross sectional view of the delivery system handle of FIG. 37 along line A-A in FIG. 39.

[0082] FIG. 42 illustrates a perspective cross sectional view of the delivery system handle of FIG. 37 along line B-B in FIG. 39.

[0083] FIG. 43 illustrates a perspective cross sectional view of the delivery system handle of FIG. 37 along line C-C in FIG. 39.

[0084] FIG. 44 illustrates a perspective cross sectional view of the delivery system handle of FIG. 37 along line D-D in FIG. 39.

[0085] FIG. 45 illustrates a perspective cross sectional view of the delivery system handle of FIG. 37 along line E-E in FIG. 39.

[0086] FIG. 46 illustrates a side view of an embodiment of a nose cone.

[0087] FIG. 47 illustrates a cross sectional view of the nose cone of FIG. 46 along line A-A in FIG. 46.

[0088] FIG. 48 illustrates a side view of an embodiment of a nose cone including a marker.

[0089] FIG. 49 illustrates views of echocardiogram images.

[0090] FIG. 50 illustrates a side view of an embodiment of a nose cone including a marker.

[0091] FIG. 51 illustrates a perspective view of an embodiment of a nose cone including a marker.

[0092] FIG. 52 illustrates a perspective view of an embodiment of a nose cone including a marker.

[0093] FIG. 53 illustrates a perspective view of an embodiment of a nose cone including a marker.

[0094] FIG. 54 illustrates a side cross sectional view of an embodiment of a nose cone including a marker.

[0095] FIG. 55 illustrates a perspective view of an embodiment of a nose cone with portions shown in transparent view and including a marker.

[0096] FIG. 56 illustrates a perspective view of the nose cone of FIG. 55.

[0097] FIG. 57 illustrates a perspective view of an embodiment of a nose cone including a marker.

[0098] FIG. 58 illustrates a cross sectional view of an embodiment of an outer sheath including a marker.

[0099] FIG. 59 illustrates a cross sectional view of the marker of FIG. 58.

[0100] FIG. 60 illustrates views of echocardiogram images.

[0101] FIG. 61 illustrates a schematic representation of a transseptal delivery approach.

[0102] FIG. 62 illustrates a schematic representation of a valve prosthesis positioned within a native mitral valve.

- [0103] FIG. 63 shows a valve prosthesis frame located within a heart.
- [0104] FIGS. 64-66 show steps of a method for delivery of the valve prosthesis to an anatomical location.
- [0105] FIGS. 67A-B illustrate the methodology of the rail delivery system.
- [0106] FIG. 68 shows a side view of an embodiment of an implant in the form of a valve prosthesis that may be delivered using the delivery systems described herein.
- [0107] FIG. 69 show a view of an embodiment of an implant in the form of a valve prosthesis that may be delivered using the delivery systems described herein.
- [0108] FIG. 70 shows a cross sectional view of arms of an implant extending from a capsule.
- [0109] FIG. 71 shows a side cross sectional view of a distal end of a capsule expanding radially outward.
- [0110] FIG. 72 shows a side cross sectional view of a capsule having a distal end configured to expand radially outward.
- [0111] FIG. 73 shows a side cross sectional view of the capsule shown in FIG. 72.
- [0112] FIG. 74A shows a side view of a capsule having a pull tether coupled to a nose cone.
- [0113] FIG. 74B shows a side view of the capsule shown in FIG. 74A with the capsule flexed from the position shown in FIG. 74A.
- [0114] FIG. 75A shows a side view of a capsule and nose cone of a delivery system.
- [0115] FIG. 75B shows a side view of the capsule and nose cone of the delivery system shown in FIG. 75A.
- [0116] FIG. 76A shows a perspective view of a capsule of a delivery system.
- [0117] FIG. 76B shows a perspective view of the capsule of the delivery system shown in FIG. 76A.
- [0118] FIG. 77A shows a perspective view of a capsule of a delivery system.
- [0119] FIG. 77B shows a perspective view of the capsule of the delivery system shown in FIG. 77A.
- [0120] FIG. 78A shows a perspective view of a capsule of a delivery system.

[0121] FIG. 78B shows a perspective view of the capsule of the delivery system shown in FIG. 78A.

[0122] FIG. 79 shows a side view of a steerable elongate shaft.

[0123] FIG. 80 shows a side view of an elongate shaft including an implant sliding along the steerable elongate shaft shown in FIG. 79.

[0124] FIG. 81 shows a side view of an elongate shaft including an implant sliding along the steerable elongate shaft shown in FIG. 79.

DETAILED DESCRIPTION

[0125] The present specification and drawings provide aspects and features of the disclosure in the context of several embodiments of delivery systems and methods. The delivery systems and methods may be configured for use in the vasculature of a patient, such as for replacement of natural heart valves in a patient. These embodiments may be discussed in connection with replacing specific valves such as the patient's aortic, tricuspid, or mitral valve. However, it is to be understood that the features and concepts discussed herein can be applied to products other than heart valve implants. For example, the delivery systems and methods can be applied to medical implants, for example other types of expandable prostheses, for use elsewhere in the body, such as within an artery, a vein, or other body cavities or locations. In addition, particular features of a valve, delivery system, etc. should not be taken as limiting, and features of any one embodiment discussed herein can be combined with features of other embodiments as desired and when appropriate. While certain of the embodiments described herein are described in connection with a transfemoral delivery approach, it should be understood that these embodiments can be used for other delivery approaches such as, for example, transapical or transjugular approaches. Moreover, it should be understood that certain of the features described in connection with some embodiments can be incorporated with other embodiments, including those which are described in connection with different delivery approaches.

[0126] FIG. 1 illustrates an embodiment of a delivery system **10** according to an embodiment of the present disclosure. The delivery system **10** may be used to deploy an implant, such as a prosthetic replacement heart valve, within the body. In some embodiments, the delivery system **10** may use a dual plane deflection approach to properly deliver the implant. Replacement heart valves may be delivered to a patient's heart mitral valve annulus or other heart valve location in various manners, such as by open surgery, minimally-invasive surgery,

and percutaneous or transcatheter delivery through the patient's vasculature. While the delivery system **10** may be described in certain embodiments in connection with a percutaneous delivery approach, and more specifically a transfemoral delivery approach, it should be understood that features of delivery system **10** can be applied to other delivery systems, including delivery systems for a transapical delivery approach.

[0127] The delivery system **10** may be used to deploy an implant, such as a replacement heart valve as described elsewhere in this specification, within the body. The delivery system **10** may receive and/or cover portions of the implant such as a first end **301** and second end **303** of the implant **70**, or prosthesis, illustrated in FIG. 3A. For example, the delivery system **10** may be used to deliver an expandable implant **70**, where the implant **70** includes the first end **301** and the second end **303**, and wherein the second end **303** is configured to be deployed or expanded before the first end **301**.

[0128] FIG. 2A further shows an example of the implant **70** that can be inserted into a portion of the delivery system **10**, specifically into an implant retention area **16**. For ease of understanding, in FIG. 2A, the implant is shown with only the bare metal frame illustrated. The implant **70**, or prosthesis, can take any number of different forms. A particular example of frame for an implant is shown in FIG. 3A, although other designs may be utilized in other embodiments. The implant **70** may include one or more sets of anchors, such as distal (or ventricular) anchors **80** (marked in FIG. 3A) extending proximally when the implant frame is in an expanded configuration and proximal (or atrial) anchors **82** extending distally when the implant frame is in an expanded configuration. The implant may further include struts **72** which may end in mushroom-shaped tabs **74** at the first end **301** (marked in FIG. 3A).

[0129] In some embodiments, the delivery system **10** may be used in conjunction with a replacement aortic valve, such as shown in FIG. 3B. In some embodiments the delivery system **10** can be modified to support and deliver the replacement aortic valve. However, the procedures and structures discussed below can similarly be used for a replacement mitral and replacement aortic valve, as well as other replacement heart valves and other implants.

[0130] Referring to FIG. 1, the delivery system **10** may include an elongate shaft **12** that may comprise a shaft assembly. The elongate shaft **12** may include a proximal end **11** and a distal end **13**, wherein a housing in the form of a handle **14** is coupled to the proximal end of the elongate shaft **12**. The elongate shaft **12** may be used to hold the implant for advancement of the same through the vasculature to a treatment location. The elongate shaft **12** may further

comprise a relatively rigid live-on (or integrated) sheath **51** surrounding an interior portion of the shaft **12** that may reduce unwanted motion of the interior portion of the shaft **12**. The live-on sheath **51** can be attached at a proximal end of the shaft **12** proximal to the handle **14**, for example at a sheath hub.

[0131] The elongate shaft **12** and housing in the form of a handle **14** may form a delivery apparatus that is configured to deliver the implant **70** to a body location.

[0132] Referring to FIGS. 2A and 2B, the elongate shaft **12** may include an implant retention area **16** (shown in FIGS. 2A–B with FIG. 2A showing the implant **70** and FIG. 2B with the implant **70** removed) at its distal end. In some embodiments, the elongate shaft **12** can hold an expandable implant in a compressed state at implant retention area **16** for advancement of the implant **70** within the body. The shaft **12** may then be used to allow controlled expansion of the implant **70** at the treatment location. In some embodiments, the shaft **12** may be used to allow for sequential controlled expansion of the implant **70** as discussed in detail below. The implant retention area **16** is shown in FIGS. 2A–2B at the distal end of the delivery system **10**, but may also be at other locations. In some embodiments, the implant **70** may be rotated in the implant retention area **16**, such as through the rotation of the inner shaft assembly **18** discussed herein.

[0133] As shown in the cross-sectional view of FIGS. 2A–2B, the distal end of the delivery system **10** can include one or more assemblies such as an outer sheath assembly **22**, a mid shaft assembly **21**, a rail assembly **20**, an inner shaft assembly **18**, and a nose cone assembly **31** as will be described in more detail below. In some embodiments, the delivery system **10** may not have all of the assemblies disclosed herein. For example, in some embodiments a full mid shaft assembly may not be incorporated into the delivery system **10**. In some embodiments, the assemblies may be in a different radial order than is discussed.

[0134] Embodiments of the disclosed delivery system **10** may utilize a steerable rail in the rail assembly **20** for steering the distal end of the elongate shaft **12**, allowing the implant to be properly located in a patient's body. As discussed in detail below, the steerable rail can be, for example, a rail shaft that extends through the elongate shaft **12** from the handle **14** generally to the distal end of the elongate shaft **12**. In some embodiments, the steerable rail has a distal end that ends proximal to the implant retention area **16**. A user can manipulate the bending of the distal end of the rail, thereby bending the rail in a particular direction. In preferred embodiments, the rail has more than one bend along its length, thereby providing multiple

directions of bending. The rail may deflect the elongate shaft **12** in at least two planes. As the rail is bent, it presses against the other assemblies to bend them as well, and thus the other assemblies of the elongate shaft **12** can be configured to steer along with the rail as a cooperating single unit, thus providing for full steerability of the distal end of the elongate shaft **12**.

[0135] Once the rail is steered into a particular location in a patient's body, the implant **70** can be advanced along or relative to the rail through the movement of the other sheaths/shafts relative to the rail and released into the body. For example, the rail can be bent into a desired position within the body, such as to direct the implant **70** towards the native mitral valve. The other assemblies (e.g., the outer sheath assembly **22**, the mid shaft assembly **21**, the inner assembly **18**, and the nose cone assembly **31**) can passively follow the bends of the rail. Further, the other assemblies (e.g., the outer sheath assembly **22**, the mid shaft assembly **21**, the inner assembly **18**, and the nose cone assembly **31**) can be advanced together (e.g., relatively together, sequentially, simultaneously, almost simultaneously, at the same time, closely at the same time) relative to the rail while maintaining the implant **70** in the compressed position without releasing or expanding the implant **70** (e.g., within the implant retention area **16**). The other assemblies (e.g., the outer sheath assembly **22**, the mid shaft assembly **21**, the inner assembly **18**, and the nose cone assembly **31**) can be advanced distally or proximally together relative to the rail. In some embodiments, only the outer sheath assembly **22**, mid shaft assembly **21**, and inner assembly **18** are advanced together over the rail. Thus, the nose cone assembly **31** may remain in the same position. The assemblies can be individually, sequentially, or simultaneously, translated relative to the inner assembly **18** in order to release the implant **70** from the implant retention area **16**.

[0136] FIG. 2C illustrates the sheath assemblies, specifically the outer sheath assembly **22**, the mid shaft assembly **21**, the inner shaft assembly **18**, and the nose cone assembly **31** having translated distally together along the rail assembly **20**. In some embodiments, the outer sheath assembly **22**, the mid shaft assembly **21**, the inner shaft assembly **18**, and the nose cone assembly **31** translate together (e.g., relatively together, sequentially with one actuator, simultaneously, almost simultaneously, at the same time, closely at the same time). This distal translation can occur while the implant **70** remains in a compressed configuration within the implant retention area **16**.

[0137] As shown in FIGS. 2A–2C and as further shown in FIGS. 4–8, starting with the outermost assembly, the delivery system may include an outer sheath assembly **22** forming a

radially outer covering, or sheath, to surround an implant retention area **16** and prevent the implant from radially expanding. Specifically, the outer sheath assembly **22** may prevent radial expansion of the distal end of the implant from radially expanding. Moving radially inward and referring to FIG. 5, the mid shaft assembly **21** may be composed of a mid shaft hypotube **43** with its distal end attached to an outer retention member **42** or outer retention ring for radially retaining a portion of the implant in a compacted configuration, such as a proximal end of the implant **70**. The mid shaft assembly **21** may be located within an interior lumen of the outer sheath assembly **22**. Moving further inwards, and referring to FIG. 6A, the rail assembly **20** may be configured for steerability, as mentioned above and further described below. The rail assembly **20** may be located within an interior lumen of the mid shaft assembly **21**. Moving further inwards and referring to FIG. 7, the inner shaft assembly **18** may be composed of an inner shaft with its distal end attached to inner retention member or inner retention ring **40** (such as a PEEK ring) for axially retaining the implant, for example the proximal end of the implant. The inner shaft assembly **18** may be located within an interior lumen of the rail assembly **20**. Further, and referring to FIG. 8, the most radially-inward assembly may be the nose cone assembly **31** which includes the nose cone shaft **27** having its distal end connected to the nose cone **28**. The nose cone **28** can have a tapered tip and forms the tip of the elongate shaft **12**. The nose cone assembly **31** is preferably located within an interior lumen of the inner shaft assembly **18**. The nose cone assembly **31** may include an interior lumen for a guide wire to pass therethrough.

[0138] The elongate shaft **12** and its assemblies, more specifically the nose cone assembly **31**, inner assembly **18**, rail assembly **20**, mid shaft assembly **21**, and outer sheath assembly **22**, can be collectively configured to deliver an implant **70** positioned within the implant retention area **16** (shown in FIG. 2A) to a treatment location. One or more of the assemblies may then be moved to allow the implant **70** to be released at the treatment location. For example, one or more of the assemblies may be movable with respect to one or more of the other assemblies. The implant **70** may be controllably loaded onto the delivery system **10** and then later deployed within the body. Further, the handle **14** can provide steering to the rail assembly **20**, providing for bending/flexing/steering of the distal end of the elongate shaft **12**.

[0139] Referring to FIGS. 2A–2C, the inner retention member **40**, the outer retention member **42**, and the outer sheath assembly **22** can cooperate to hold the implant **70** in a compacted configuration. In FIG. 2A, the inner retention member **40** is shown engaging struts **72** (marked in FIG. 3A) at the proximal end **301** of the implant **70**. For example, slots located

between radially extending teeth on the inner retention member **40** can receive and engage the struts **72** which may end in mushroom-shaped tabs **74** on the proximal end of the implant **70** (marked in FIG. 3A). The mid shaft assembly **21** can be positioned over the inner retention member **40** so that the first end **301** of the implant **70** (marked in FIG. 3A) is trapped between the inner retention member **40** and the outer retention member **42**, thereby securely attaching it to the delivery system **10** between the mid shaft assembly **21** and the inner retention member **40**. The outer sheath assembly **22** can be positioned to cover the second end **303** of the implant **70** (marked in FIG. 3A).

[0140] The outer retention member **42** may be attached to a distal end of the mid shaft hypotube **43** which can in turn be attached to a proximal tube **44** at a proximal end (marked in FIG. 5), which in turn can be attached at a proximal end to the handle **14**. The outer retention member **42** can provide further stability to the implant **70** when in the compressed position. The outer retention member **42** can be positioned over the inner retention member **40** so that the proximal end of the implant **70** is trapped therebetween, securely attaching it to the delivery system **10**. The outer retention member **42** can encircle a portion of the implant **70**, in particular the first end **301**, thus preventing the implant **70** from expanding. Further, the mid shaft assembly **21** can be translated proximally with respect to the inner assembly **18** into the outer sheath assembly **22**, thus exposing a first end **301** of the implant **70** held within the outer retention member **42**. In this way the outer retention member **42** can be used to help secure an implant **70** to or release it from the delivery system **10**. The outer retention member **42** may have a cylindrical or elongate tubular shape, and may be referred to as an outer retention ring, though the particular shape is not limiting.

[0141] The mid shaft hypotube **43** itself (marked in FIG. 5) can be made of, for example, high density polyethylene (HDPE), as well as other appropriate materials as described herein. The mid shaft hypotube **43** can be formed of a longitudinally pre-compressed HDPE tube, which can provide certain benefits. For example, the pre-compressed HDPE tube can apply a force distally onto the outer retention member **42**, thus preventing accidental, inadvertent, and/or premature release of the implant **70**. Specifically, the distal force by the mid shaft hypotube **43** keeps the distal end of the outer retention member **42** distal to the inner retention member **40**, thus preventing the outer retention member **42** from moving proximal to the inner retention member **40** before it is desired by a user to release the implant **70**. This can remain true even when the elongate shaft **12** is deflected at a sharp angle.

[0142] As shown in FIG. 2A, the distal anchors **80** (marked in FIG. 3A) can be located in a delivered configuration where the distal anchors **80** point generally distally (as illustrated, axially away from the main body of the implant frame and away from the handle of the delivery system). The distal anchors **80** can be restrained in this delivered configuration by the outer sheath assembly **22**. Accordingly, when the outer sheath **22** is withdrawn proximally, the distal anchors **80** can flip positions (e.g., bend approximately 180 degrees) to a deployed configuration (e.g., pointing generally proximally). FIG. 2A also shows the proximal anchors **82** extending distally in their delivered configuration within the outer sheath assembly **22**. In other embodiments, the distal anchors **80** can be held to point generally proximally in the delivered configuration and compressed against the body of the implant frame.

[0143] The delivery system **10** may be provided to users with an implant **70** preinstalled. In other embodiments, the implant **70** can be loaded onto the delivery system **10** shortly before use, such as by a physician or nurse.

[0144] FIGS. 4-8 illustrate further views of delivery system **10** with different assemblies translated proximally and described in detail.

[0145] Starting with the outermost assembly shown in FIG. 4, the outer sheath assembly **22** can include an outer proximal shaft **102** directly attached to the handle **14** at its proximal end and an outer hypotube **104** attached at its distal end. A capsule **106** can then be attached generally at the distal end of the outer hypotube **104**. In some embodiments, the capsule **106** can be 28 French or less in size. These components of the outer sheath assembly **22** can form a lumen for the other subassemblies to pass through.

[0146] The outer proximal shaft **102** may be a tube and is preferably formed of a plastic, but could also be a metal hypotube or other material. The outer hypotube **104** can be a metal hypotube which in some embodiments may be cut or have slots, as discussed in detail below. The outer hypotube **104** can be covered or encapsulated with a layer of ePTFE, PTFE, or other polymer/material so that the outer surface of the outer hypotube **104** is generally smooth.

[0147] A capsule **106** can be located at a distal end of the outer hypotube **104**. The capsule **106** can be a tube formed of a plastic or metal material. In some embodiments, the capsule **106** is formed of ePTFE or PTFE. In some embodiments, this capsule **106** is relatively thick to prevent tearing and to help maintain a self-expanding implant in a compacted configuration. In some embodiments the material of the capsule **106** is the same material as the coating on the outer hypotube **104**. As shown, the capsule **106** can have a diameter larger than the outer

hypotube **104**, though in some embodiments the capsule **106** may have a similar diameter as the hypotube **104**. In some embodiments, the capsule **106** may include a larger diameter distal portion and a smaller diameter proximal portion. In some embodiments, there may be a step or a taper between the two portions. The capsule **106** can be configured to retain the implant **70** in the compressed position within the capsule **106**. Further construction details of the capsule **106** according to various embodiments are discussed below.

[0148] The outer sheath assembly **22** is configured to be individually slidable with respect to the other assemblies. Further, the outer sheath assembly **22** can slide distally and proximally relative to the rail assembly **20** together with the mid shaft assembly **21**, inner assembly **18**, and nose cone assembly **31**.

[0149] In embodiments, a hydrophilic layer may be applied to the elongate shaft of the delivery system **10**, and particularly to the outer sheath assembly **22**. The outer surface of the outer sheath assembly **22** may include a hydrophilic layer that may reduce the friction of the outer sheath assembly **22** as the elongate shaft is passed through the patient's vasculature. The hydrophilic layer may cover the entirety of the outer surface of the outer sheath assembly **22**, or may only cover the outer surface of the capsule **106**, or may cover other components of the delivery system **10** in embodiments.

[0150] In embodiments, the hydrophilic layer may be applied to a surface of the outer sheath assembly **22** comprising expanded polytetrafluoroethylene (ePTFE). The ePTFE surface may form an outer surface of the outer sheath assembly **22** that is then covered by the hydrophilic layer such that the hydrophilic layer then comprises the outer surface of the outer sheath assembly **22**. A process may be utilized in which a plasma layer serves as an intermediate layer or tie layer between the ePTFE surface and the hydrophilic layer, to bond the hydrophilic layer to the ePTFE surface. As such, in embodiments, the ePTFE outer surface may be provided, and then the plasma layer may be applied to the ePTFE outer surface. The hydrophilic layer may then be applied to the plasma layer (with the plasma layer serving as an intermediate layer).

[0151] In embodiments, other intermediate layers or tie layers may be utilized. For example, in embodiments, chemical etching or methods may be utilized as an intermediate layer or tie layer.

[0152] In embodiments, the hydrophilic layer may be comprised of reagents from PhotoLink® reagent families of Photo-Polyvinylpyrrolidone (PV), Photo-Polyacrylamide

(PA), and Photo-Crosslinker (PR), and the Kollidon® non-photo polymer povidone. In other embodiments, other formulations for hydrophilic layers may be utilized. In embodiments, a plasma layer may comprise a plasma hydroxyl treatment coating that may be comprised of carbon, hydrogen, and oxygen matter. In other embodiments, other forms of plasma layers may be utilized. The hydrophilic layer and/or intermediate or tie layer disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0153] Moving radially inwardly, the next assembly is the mid shaft assembly **21**. FIG. 5 shows a similar view as FIG. 4, but with the outer sheath assembly **22** removed, thereby exposing the mid shaft assembly **21**.

[0154] The mid shaft assembly **21** can include a mid shaft hypotube **43** generally attached at its proximal end to a mid shaft proximal tube **44**, which in turn can be attached at its proximal end to the handle **14**, and an outer retention ring **42** located at the distal end of the mid shaft hypotube **43**. Thus, the outer retention ring **42** can be attached generally at the distal end of the mid shaft hypotube **43**. These components of the mid shaft assembly **21** can form a lumen for other subassemblies to pass through.

[0155] Similar to the other assemblies, the mid shaft hypotube **43** and/or mid shaft proximal tube **44** can comprise a tube, such as a hypodermic tube or hypotube (not shown). The tubes can be made from one of any number of different materials including Nitinol, stainless steel, and medical grade plastics. The tubes can be a single piece tube or multiple pieces connected together. Using a tube made of multiple pieces can allow the tube to provide different characteristics along different sections of the tube, such as rigidity and flexibility. The mid shaft hypotube **43** can be a metal hypotube which in some embodiments may be cut or have slots as discussed in detail below. The mid shaft hypotube **43** can be covered or encapsulated with a layer of ePTFE, PTFE, or other material so that the outer surface of the mid shaft hypotube **43** is generally smooth.

[0156] The outer retention ring **42** can be configured as a prosthesis retention mechanism that can be used to engage with the implant **70**, as discussed with respect to FIG. 2A. For example, the outer retention ring **42** may be a ring or covering that is configured to radially cover the struts **72** on the implant **70**. The outer retention ring **42** can also be considered to be part of the implant retention area **16**, and may be at the proximal end of the implant retention area **16**. With struts or other parts of an implant **70** engaged with the inner retention member

40, discussed below the outer retention ring **42** can cover both the implant **70** and the inner retention member **40** to secure the implant **70** on the delivery system **10**. Thus, the implant **70** can be sandwiched between the inner retention member **40** of the inner shaft assembly **18** and the outer retention ring **42** of the mid shaft assembly **21**.

[0157] The mid shaft assembly **21** is disposed so as to be individually slidable with respect to the other assemblies. Further, mid shaft assembly **21** can slide distally and proximally relative to the rail assembly **20** together with the outer sheath assembly **22**, inner shaft assembly **18**, and nose cone assembly **31**.

[0158] Next, radially inwardly of the mid shaft assembly **21** is the rail assembly **20**. FIG. 6A shows approximately the same view as FIG. 5, but with the mid shaft assembly **21** removed, thereby exposing the rail assembly **20**. FIG. 6B further shows a cross-section of the rail assembly **20** to view the pull wires. The rail assembly **20** can include a rail shaft **132** (or rail) generally attached at its proximal end to the handle **14**. The rail shaft **132** can be made up of a rail proximal shaft **134** directly attached to the handle at a proximal end and a rail hypotube **136** attached to the distal end of the rail proximal shaft **134**. The rail hypotube **136** can further include an atraumatic rail tip at its distal end. Further, the distal end of the rail hypotube **136** can abut a proximal end of the inner retention member **40**, as shown in FIG. 6. In some embodiments, the distal end of the rail hypotube **136** can be spaced away from the inner retention member **40**. These components of the rail shaft assembly **20** can form a lumen for the other subassemblies to pass through.

[0159] As shown in FIG. 6B, attached to an inner surface of the rail hypotube **136** are one or more pull wires which can be used apply forces to the rail hypotube **136** and steer the rail assembly **20**. The pull wires can extend distally from the knobs in the handle **14**, discussed below, to the rail hypotube **136**. In some embodiments, pull wires can be attached at different longitudinal locations on the rail hypotube **136**, thus providing for multiple bending locations in the rail hypotube **136**, allowing for multidimensional steering.

[0160] In some embodiments, a distal pull wire **138** can extend to a distal section of the rail hypotube **136** and two proximal pull wires **140** can extend to a proximal section of the rail hypotube **136**, however, other numbers of pull wires can be used, and the particular amount of pull wires is not limiting. For example, a two pull wires can extend to a distal location and a single pull wire can extend to a proximal location. In some embodiments, ring-like structures attached inside the rail hypotube **136**, known as pull wire connectors, can be used as attachment

locations for the pull wires, such as proximal ring **137** and distal ring **135**. In some embodiments, the rail assembly **20** can include a distal ring **135** may comprise a distal pull wire connector and the proximal ring **137** may comprise a proximal pull wire connector. In some embodiments, the pull wires can directly connect to an inner surface of the rail hypotube **136**.

[0161] The distal pull wire **138** can be connected (either on its own or through a connector **135**) generally at the distal end of the rail hypotube **136**. The proximal pull wires **140** can connect (either on its own or through a connector **137**) at a location approximately one quarter, one third, or one half of the length up the rail hypotube **136** from the proximal end. In some embodiments, the distal pull wire **138** can pass through a small diameter pull wire lumen **139** (e.g., tube, hypotube, cylinder) attached on the inside of the rail hypotube **136**. This can prevent the wires **138** from pulling on the rail hypotube **136** at a location proximal to the distal connection. Further, the lumen **139** can act as compression coils to strengthen the proximal portion of the rail hypotube **136** and prevent unwanted bending. Thus, in some embodiments the lumen **139** is only located on the proximal half of the rail hypotube **136**. In some embodiments, multiple lumens **139**, such as spaced longitudinally apart or adjacent, can be used per distal wire **138**. In some embodiments, a single lumen **139** is used per distal wire **138**. In some embodiments, the lumen **139** can extend into the distal half of the rail hypotube **136**. In some embodiments, the lumen **139** is attached on an outer surface of the rail hypotube **136**. In some embodiments, the lumen **139** is not used.

[0162] For the pair of proximal pull wires **140**, the wires can be spaced approximately 180° from one another to allow for steering in both directions. Similarly, if a pair of distal pull wires **138** is used, the wires can be spaced approximately 180° from one another to allow for steering in both directions. In some embodiments, the pair of distal pull wires **138** and the pair of proximal pull wires **140** can be spaced approximately 90° from each other. In some embodiments, the pair of distal pull wires **138** and the pair of proximal pull wires **140** can be spaced approximately 0° from each other. However, other locations for the pull wires can be used as well, and the particular location of the pull wires is not limiting. In some embodiments, the distal pull wire **138** can pass through a lumen **139** attached within the lumen of the rail hypotube **136**. This can prevent an axial force on the distal pull wire **138** from creating a bend in a proximal section of the rail hypotube **136**.

[0163] The rail assembly **20** is disposed so as to be slidable over the inner shaft assembly **18** and the nose cone assembly **31**. In some embodiments, the outer sheath assembly **22**, the mid shaft assembly **21**, the inner shaft assembly **18**, and the nose cone assembly **31** can be

configured to slide together along or relative to the rail assembly **20**, such as proximally and distally with or without any bending of the rail assembly **20**. In some embodiments, the outer sheath assembly **22**, the mid shaft assembly **21**, the inner shaft assembly **18**, and the nose cone assembly **31** can be configured to retain the implant **70** in a compressed position when they are simultaneously slid along or relative to the rail assembly **20**.

[0164] Moving radially inwards, the next assembly is the inner shaft assembly **18**. FIG. 7 shows approximately the same view as FIG. 6A, but with the rail assembly **20** removed, thereby exposing the inner shaft assembly **18**.

[0165] The inner shaft assembly **18** can include an inner shaft **122** generally attached at its proximal end to the handle **14**, and an inner retention ring **40** located at the distal end of the inner shaft **122**. The inner shaft **122** itself can be made up of an inner proximal shaft **124** directly attached to the handle **14** at a proximal end and a distal section **126** attached to the distal end of the inner proximal shaft **124**. Thus, the inner retention ring **40** can be attached generally at the distal end of the distal section **126**. These components of the inner shaft assembly **18** can form a lumen for the other subassemblies to pass through.

[0166] Similar to the other assemblies, the inner proximal shaft **124** can comprise a tube, such as a hypodermic tube or hypotube (not shown). The tube can be made from one of any number of different materials including Nitinol, cobalt chromium, stainless steel, and medical grade plastics. The tube can be a single piece tube or multiple pieces connected together. A tube comprising multiple pieces can provide different characteristics along different sections of the tube, such as rigidity and flexibility. The distal section **126** can be a metal hypotube which in some embodiments may be cut or have slots as discussed in detail below. The distal section **126** can be covered or encapsulated with a layer of ePTFE, PTFE, or other material so that the outer surface of the distal section **126** is generally smooth.

[0167] The inner retention member **40** can be configured as an implant retention mechanism that can be used to engage with the implant **70**, as discussed with respect to FIG. 2A. For example, the inner retention member **40** may be a ring and can include a plurality of slots configured to engage with struts **72** on the implant **70**. The inner retention member **40** can also be considered to be part of the implant retention area **16**, and may be at the proximal end of the implant retention area **16**. With struts or other parts of an implant **70** engaged with the inner retention member **40**, the outer retention ring **42** can cover both the prosthesis and the inner retention member **40** to secure the prosthesis on the delivery system **10**. Thus, the implant

70 can be sandwiched between the inner retention member **40** of the inner shaft assembly **18** and the outer retention ring **42** of the mid shaft assembly **21**.

[0168] The inner shaft assembly **18** is disposed so as to be individually slidable with respect to the other assemblies. Further, the inner assembly **18** can slide distally and proximally relative to the rail assembly **20** together with the outer sheath assembly **22**, mid shaft assembly **21**, and nose cone assembly **31**.

[0169] Moving further inwardly from the inner shaft assembly **18** is the nose cone assembly **31** also seen in FIG. 8. This may be a nose cone shaft **27**, and in some embodiments, may have a nose cone **28** on its distal end. The nose cone **28** can be made of polyurethane for atraumatic entry and to minimize injury to venous vasculature. The nose cone **28** can also be radiopaque to provide for visibility under fluoroscopy.

[0170] The nose cone shaft **27** may include an interior lumen sized and configured to slidably accommodate a guide wire so that the delivery system **10** can be advanced over the guide wire through the vasculature. However, embodiments of the system **10** discussed herein may not use a guide wire and thus the nose cone shaft **27** can be solid. The nose cone shaft **27** may be connected from the nose cone **28** to the handle, or may be formed of different segments such as the other assemblies. Further, the nose cone shaft **27** can be formed of different materials, such as plastic or metal, similar to those described in detail above.

[0171] In some embodiments, the nose cone shaft **27** includes a guide wire shield **1200** located on a portion of the nose cone shaft **27**. Examples of such a guide wire shield can be found in FIGS. 9A–B. In some embodiments, the guide wire shield **1200** can be proximal to the nose cone **28**. In some embodiments, the guide wire shield **1200** can be translatable along the nose cone shaft **27**. In some embodiments, the guide wire shield **1200** can be locked in place along the nose cone shaft **27**. In some embodiments, the guide wire shield **1200** can be at least partially located within the nose cone **28**.

[0172] Advantageously, the guide wire shield **1200** can allow for smooth tracking of the guide wire with the implant **70** loaded, and can provide a large axial diameter landing zone for a distal end of the implant so that the distal end of the implant **70** may spread out properly and be arranged in a uniform radial arrangement. This uniformity allows for proper expansion. Furthermore, the guide wire shield **1200** can prevent kinking or damaging of the nose cone shaft **27** during compression/crimping of the implant **70**, which can exert a large compressive force on the nose cone shaft **27**. As the implant **70** can be crimped onto the guide wire shield

1200 instead of directly on the nose cone shaft **27**, the guide wire shield **1200** can provide a protective surface.

[0173] As shown in FIG. 9A, the guide wire shield **1200** can include a lumen **1202** configured to surround the nose cone shaft **27**. The guide wire shield **1200** can include a larger diameter distal end **1204** and a smaller diameter proximal end **1206**. In some embodiments, the dimension change between the two ends can be tapered, or can be a step **1208** such as shown in FIG. 9A. The distal end **1204** can include a number of indents **1210** for easier gripping by a user, but may not be included in all embodiments. The proximal end **1206** and the distal end **1204** can both be generally cylindrical, but the particular shape of the guide wire shield **1200** is not limiting.

[0174] The distal end of the implant **70** can be crimped so that it is radially in contact with the proximal end **1206** of the guide wire shield **1200**. This can allow the implant **70** to be properly spread out around an outer circumference of the proximal end **1206** of the guide wire shield **1200**. In some embodiments, the distal end of the implant **70** can longitudinally abut against the proximal end of the distal end **1204** (e.g., at the step **1208**), thus providing a longitudinal stop.

[0175] FIG. 9B shows an alternate embodiment of a guide wire shield **1200'** having a more tapered configuration. As shown, the proximal end **1206'** of the guide wire shield **1200'** can be a single radially outward taper **1208'** to the distal end **1204'** of the guide wire shield **1200'**, which can be generally cylindrical. The guide wire shield **1200'** can also include a lumen **1202'** for receiving the nose cone shaft **27**.

[0176] The nose cone assembly **31** is disposed so as to be individually slidable with respect to the other assemblies. Further, the nose cone assembly **31** can slide distally and proximally relative to the rail assembly **20** together with the outer sheath assembly **22**, mid shaft assembly **21**, and inner assembly **18**.

[0177] In embodiments, the nose cone shaft **27** may be made of a Nitinol material. Such a material may allow for flexibility of the nose cone shaft **27**, while allowing the nose cone shaft **27** to be resilient and return back to an unflexed state without kinking or damage to the shaft **27**. Further, such a material may be relatively strong, allowing the nose cone shaft **27** to resist forces applied by the delivery system **10** to the shaft **27** during flexing of the delivery system **10** and deployment, or potentially recapture, of an implant from the delivery system **10**. In

embodiments, the nose cone shaft **27** may comprise a hypotube including cut patterns that may enhance the flexibility of the shaft **27** and reduce the possibility of deformation of the shaft **27**.

[0178] In embodiments, a nose cone shaft **27** made of a Nitinol material may allow the guide wire shield **1200**, **1200'** to be excluded from use. The Nitinol nose cone shaft **27**, for example, may resist the force of compression/crimping of the implant **70** upon the shaft **27**, and thus the guide wire shield **1200**, **1200'** may not be necessary. In embodiments, however, a guide wire shield **1200**, **1200'** may yet be utilized with a nose cone shaft **27** made of a Nitinol material. A Nitinol nose cone shaft disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0179] In some embodiments, one or more spacer sleeves (not shown) can be used between different assemblies of the delivery system **10**. For example, a spacer sleeve can be located concentrically between the mid shaft assembly and the rail assembly **20**, generally between the mid shaft hypotube **43** and rail hypotube **136**. In some embodiments, the spacer sleeve can be generally embedded in the hypotube **43** of the mid shaft assembly **21**, such as on an inner surface of the mid shaft assembly **21**. In some embodiments, a spacer sleeve can be located concentrically between the rail assembly **20** and the inner assembly **18**, generally within the rail hypotube **136**. In some embodiments, a spacer sleeve can be used between the outer sheath assembly **22** and the mid shaft assembly **21**. In some embodiments, a spacer sleeve can be used between the inner assembly **18** and the nose cone assembly **31**. In some embodiments, 4, 3, 2, or 1 of the above-mentioned spacer sleeves can be used. The spacer sleeves can be used in any of the above positions.

[0180] The spacer sleeve can be made of a polymer material such as braided Pebax® and can be lined, for example with PTFE, on the inner diameter, though the particular material is not limiting. The spacer sleeve can advantageously reduce friction between the steerable rail assembly **20** and its surrounding assemblies. Thus, the spacer sleeves can act as a buffer between the rail assembly **20** and the inner/nose cone assembly **18/31**. Further, the spacer sleeve can take up any gap in radius between the assemblies, preventing compressing or snaking of the assemblies during steering. In some embodiments, the spacer sleeve may include cuts or slots to facilitate bending of the spacer sleeve. In some embodiments, the spacer sleeve may not include any slots, and may be a smooth cylindrical feature.

[0181] The spacer sleeve can be mechanically contained by the other lumens and components, and is thus not physically attached to any of the other components, allowing the

spacer sleeve to be “floating” in that area. The floating aspect of the spacer sleeve allows it to move where needed during deflection and provide a support and/or lubricious bear surface/surfaces. Accordingly, the floating aspect allows the delivery system **10** to maintain flex forces. However, in some embodiments, the spacer sleeve can be connected to other components.

[0182] Each of the outer sheath assembly **22**, the mid shaft assembly **21**, the inner assembly **18**, and the nose cone assembly **31** comprise shafts. Each of the outer sheath assembly **22**, the mid shaft assembly **21**, and the inner assembly **18** include sheaths having interior lumens. The nose cone assembly **31** comprises a sheath having an interior lumen in an embodiment in which the nose cone assembly **31** includes an interior lumen for a guide wire to extend along.

[0183] As discussed above, the outer sheath assembly **22**, the mid shaft assembly **21**, the inner assembly **18**, and the rail assembly **20** can contain an outer hypotube **104**, a mid shaft hypotube **43**, a distal section **126**, and a rail hypotube **136**, respectively. Each of these hypotubes/sections/shafts can be laser cut to include a number of slots, thereby creating a bending pathway for the delivery system to follow. While different slot assemblies are discussed below, it will be understood that any of the hypotubes can have any of the slot configurations discussed below. FIGS. 10–14 show the different hypotubes in isolated format.

[0184] The outer hypotube **104**, shown in FIG. 10, can be generally formed of a metal coil or a plurality of metal coils. In some embodiments, the outer hypotube **104** can be formed of a proximal metal coil **107** and a distal metal coil **108**. The proximal metal coil **107** and the distal metal coil **108** can be longitudinally separated by a tube portion **110**, such as shown in FIG. 10. However, in some embodiments the proximal metal coil **107** and the distal metal coil **108** connect. The proximal metal coil **107** and the distal metal coil **108** can be connected to an outer surface of the tube portion **110**, for example at the distal end of the proximal metal coil **107** and a proximal end of the distal metal coil **108**, in order to form the full outer hypotube **104**. In some embodiments, the proximal metal coil **107** and the distal metal coil **108** are generally the same. In some embodiments, the proximal metal coil **107** and the distal metal coil **108** are different, for example in spacing between coils, curvature, diameter, etc. In some embodiments, the distal metal coil **108** has a larger diameter than the proximal metal coil **107**, such as when the distal metal coil **108** forms the large diameter of the capsule **106**. In some embodiments, they have the same diameter. In some embodiments, one or both of the metal coils **108/107** can form the capsule **106**. The coils can be coated by polymer layers, such as

described in detail below regarding the capsule construction. The coil construction can allow the outer hypotube **104** to follow the rail in any desired direction.

[0185] Moving radially inwardly, FIGS. 11-12B shows that the mid shaft hypotube **43** can be a metal laser cut hypotube, such as a lasercut Nitinol hypotube. FIG. 12A illustrates a flat pattern of FIG. 11. As shown in the figures, the hypotube **43** can have a number of cuts forming slots/apertures in the hypotube. In some embodiments, the cut pattern can be the same throughout. In some embodiments, the mid shaft hypotube **43** can have different sections having different cut patterns.

[0186] For example, the proximal end of the mid shaft hypotube **43** can be a first section **211** having a plurality of circumferentially extending cut pairs **213** spaced longitudinally along the first section **211**. Generally, two slots are cut around each circumferential location forming almost half of the circumference. Accordingly, two backbones or spines **215** are formed between the cuts **213** extending up the length of the first section **211**. The cut pairs **213** can be composed of a first thin cut **217**. A second cut **221** of each of the cut pairs **213** can be thicker than the first cut **217**, such as 1, 2, 3, 4, or 5 times thicker. In some embodiments, the second cut **217** can be generally the same longitudinal thickness throughout the cut. Each of the cuts of the cut pair **213** can end in a teardrop shape **219** in some embodiments to facilitate bending.

[0187] Moving distally, the mid shaft hypotube **43** can include a second section **220** having a number of cut pairs **222**. Similar to the first section **211**, the second section **220** can have a plurality of circumferentially extending cuts spaced longitudinally along the second section **220**. Generally, two cuts (e.g., one cut pair **222**) are cut around each circumferential location, forming almost half of a circumference. Accordingly, “backbones” **224** can be formed between the cuts extending up the length of the second section **220**. Each cut pair **222** can include a first cut **226** that is generally thin and has no particular shape (e.g., it can look the same as the cuts **213** in the first section **211**), and a second cut **228** that is significantly longitudinally thicker than the first cut **226**. The second cut **228** can be narrower at its ends and longitudinally thicker in its middle portion, thereby forming a curved cut. Moving longitudinally along the second section **220**, each cut pair **222** can be offset approximately 45 or 90 degrees as compared to longitudinally adjacent cut pairs **222**. In some embodiments, a second cut pair **222** is offset 90 degrees from an adjacent first cut pair **222**, and a third cut pair **222** adjacent the second cut pair **222** can have the same configuration of the first cut pair **222**. This repeating pattern can extend along a length of the second section **220**, thereby providing a particular bending direction induced by the second cut **228** of the cut pairs **222**. Accordingly, the “backbone” or spine **224**

shifts circumferential position due to the offsetting of adjacent shifting slot pairs **222**. Each of the cuts of the cut pair **222** can end in a teardrop shape **229** in some embodiments to facilitate bending.

[0188] Moving distally, the mid shaft hypotube **43** can have a third section **230** having a number of cuts. The outer retention ring **240** can be attached to a distal end of the third section **230**. The third section **230** can have circumferentially extending cut pairs **232**, each cut on the cut pair extending about half way along the circumference to form the two backbones or spines **234**. The cut pairs **232** can be composed of a first thin cut **236**, similar to the cuts **213** discussed in the first section **211**. A second cut **238** of each of the cut pairs **232** can be thicker than the first cut **236**, such as 1, 2, 3, 4, or 5 times thicker. In some embodiments, the second cut **238** can be generally the same longitudinal thickness throughout the cut, unlike the second cut **228** of the second section **220**. The first cuts **236** and the second cuts **238** can be circumferentially aligned along a length of the third section **230** so that all of the first cuts **236** are in the same circumferential position and all of the second cuts **238** are in the same circumferential position. The second cuts **238** can be aligned with one of the circumferential positions of the second cuts **228** of the second section **220**. Each of the cuts of the cut pair **232** can end in a teardrop shape **239** in some embodiments to facilitate bending.

[0189] In some embodiments, an outer retention ring strengthener **240** which can partially or fully circumferentially surround the inner retention member **40** can have a number of cuts/slots/holes/apertures as well, such as shown in FIGS. 11–12. This can allow it to bend over curves, especially tight curves. In some embodiments, the distal end of the strengthener **240** includes a number of generally circular/elliptical holes **242**. This can last for approximately half of the length of the strengthener **240**. On the proximal half, one circumferential half of the strengthener **240** can include repeating thin cuts **244** spaced by elongate ovoid holes **246**. For example, two circumferentially spaced apart elongate ovoid holes **246** can be between each thin cut **244**. Each of the cuts **244** can end in a teardrop shape **249** in some embodiments to facilitate bending. On the other circumferential half of the proximal section, the strengthener **240** can include a number of large cuts **248**, for example 1, 2, 3, 4, or 5 large cuts **248** spaced longitudinally apart. The large cuts **248** can be larger in the middle and narrow towards each circumferential end. The large cuts **248** may include ending expansions **247** to facilitate flexibility.

[0190] Additionally, the outer retention strengthener **240** can provide strength to lower deployment forces, protect the implant **70** from any metal layers, and can add strength. In some

embodiments, the strengthener **240** be a polymer, such as PTFE, though the type of polymer or material is not limiting. In some embodiments, the strengthener **240** can be a metal. In some embodiments, the strengthener **240** can further include an outer polymer layer/jacket, such as a Pebax ® jacket. This prevents the strengthener **240** from catching on the outer sheath assembly **22**.

[0191] In certain embodiments, the outer retention ring **42** can further include an inner liner for smoothly transitioning over the implant **70**. The inner liner can be PTFE or etched PTFE, though the particular material is not limiting and other reduced friction polymers can be used. As shown in FIG. 12B, to prevent delamination during loading of the implant **70**, the liner **251** may not be flush at the distal end of the outer retention ring **42**. Instead, the liner **251** can be extended and inverted at the distal end in order to cover the distal end of the outer retention ring **42**. In some embodiments, the liner **251** can cover an outer surface of the strengthener **240** as well. This can create a seamless rolled reinforced tip of the liner **251**. The liner **251** can fully or partially cover an outer surface of the outer retention ring **42**, for example 1/4, 1/3, 1/2, 2/3, 3/4 (or greater than 1/4, 1/3, 1/2, 3/4), or all of the outer retention ring **42**. This solution is advantageous over previously known methods, such as disclosed in U.S. Pat. No. 6,622,367, incorporated by reference in its entirety, as PTFE lined applications do not adhere particularly well to reinforcements or the outer jacket. By inverting the liner **251** and fusing it to the outer retention ring **42** and/or the strengthener **240** and/or an outer polymer jacket on the strengthener **240**/outer retention ring **42**, this creates a seamless reinforced tip that can mitigate delamination. Delamination is a serious concern because the delaminated liner can tear and embolize during deployment, and the delaminated layer can cause extremely high loading and deployment forces. Delaminated layers can also cause lumen translation problems by locking up shafts thereby adding translational force requirements.

[0192] Next, again moving radially inward, FIG. 13 shows an embodiment of the rail hypotube **136** (distal end towards the right). The rail hypotube **136** can also contain a number of circumferential cuts in the form of slots. The rail hypotube **136** can generally be broken into a number of different sections. At the most proximal end is an uncut (or unslotted) hypotube section **231**. Moving distally, the next section is the proximal slotted hypotube section **233**. This section includes a number of circumferential slots cut into the rail hypotube **136**. Generally, two slots are cut around each circumferential location forming almost half of the circumference. Accordingly, two backbones or spines are formed between the cuts extending up the length of the hypotube **136**. This is the section that can be guided by the proximal pull

wires **140**. Moving further distally is the location **237** where the proximal pull wires **140** connect, and thus cuts can be avoided. This section is just distal of the proximally slotted section.

[0193] Distally following the proximal pull wire connection area is the distal slotted hypotube section **235**. This section is similar to the proximal slotted hypotube section **233**, but has significantly more slots cut out in an equivalent length. Thus, the distally slotted hypotube section **235** provides easier bending than the proximally slotted hypotube section **233**. In some embodiments, the proximal slotted section **233** can be configured to experience a bend of approximately 90 degrees with a half inch radius whereas the distal slotted section **235** can bend at approximately 180 degrees within a half inch. Further, as shown in FIG. 13, the spines of the distally slotted hypotube section **235** are offset from the spines of the proximally slotted hypotube section **233**. Accordingly, the two sections will achieve different bend patterns, allowing for three-dimensional steering of the rail assembly **20**. In some embodiments, the spines can be offset 30, 45, or 90 degrees, though the particular offset is not limiting. In some embodiments, the proximally slotted hypotube section **233** can include compression coils. This allows for the proximally slotted hypotube section **233** to retain rigidity for specific bending of the distally slotted hypotube section **235**.

[0194] At the distalmost end of the distal slotted hypotube section **235** is the distal pull wire connection area **241** which is again a non-slotted section of the rail hypotube **136**.

[0195] Moving radially inwardly in FIG. 14, the inner assembly **18** is composed generally of two sections. The proximal section is a hypotube **129**, either slotted or non-slotted. The distal section **126**, which at least partially overlaps an outer surface of the proximal hypotube **129**, can be designed to be particularly flexible. For example, the distal section **126** can be more flexible than any of the other shafts discussed herein. In some embodiments, the distal section **126** can be more flexible than any shaft discussed herein other than the nose cone shaft **27**. In some embodiments, the distal section **126** can be a flexible tube or hypotube. In some embodiments, the distal section **126** can be a cable, such as a flexible cable. For example, the cable can comprise several strands of wire, such as metal, plastic, polymer, ceramic, etc., wound together to form a rope or cable. Because the cable is so flexible, it can more easily bend with the rail assembly **20**. Further, the cable can be smooth, which allows the rail assembly **20** to track over a smooth surface, eliminating the need for any inner liner on the rail assembly **20**.

[0196] Referring to FIG. 15, the capsule **106** can be formed from one or more materials, such as PTFE, ePTFE, polyether block amide (Pebax®), polyetherimide (Ultem®), PEEK, urethane, Nitinol, stainless steel, and/or any other biocompatible material. The capsule is preferably compliant and flexible while still maintaining a sufficient degree of radial strength to maintain a replacement valve within the capsule **106** without substantial radial deformation, which could increase friction between the capsule **106** and a replacement valve or implant **70** contained therein. The capsule **106** also preferably has sufficient column strength to resist buckling of the capsule, and sufficient tear resistance to reduce or eliminate the possibility of replacement valve tearing and/or damaging the capsule **106**. Flexibility of the capsule **106** can be advantageous, particularly for a transseptal approach. For example, while being retracted along a curved member, for example while tracking over a rail assembly as described herein, the capsule **106** can flex to follow the curved member without applying significant forces upon the curved member, which may cause the curved member to decrease in radius. More specifically, the capsule **106** can bend and/or kink as it is being retracted along such a curved member such that the radius of the curved member is substantially unaffected.

[0197] FIG. 15 shows embodiments of a capsule **106** that can be used with embodiments of the delivery system **10**. The capsule **106** may include any of the materials and properties discussed above. With many implant capsules, compression resistance and flexibility are typically balanced together, as improved flexibility can lead to worse compression resistance. Thus, there tends to be a choice made between compression resistance and flexibility. However, disclosed are embodiments of a capsule **106** that can achieve both high compression resistance as well as high flexibility. Specifically, the capsule **106** can bend in multiple directions.

[0198] In particular, a metal hypotube can provide radial strength and compression resistance, while specific cuts such as slots in the hypotube can enable the flexibility of the capsule **106**. In some embodiments, a thin liner and a jacket can surround the capsule **106**, such as a polymer layer, to prevent any negative interactions between the implant **70** and the capsule **106**.

[0199] In some embodiments, the capsule **106** can have a particular construction to allow for it to achieve advantageous properties, as shown in FIG. 15. The capsule **106** can be made of several different layers to provide such properties.

[0200] In some embodiments, the capsule **106** can be formed of a metal layer **404**, which gives the capsule **106** its structure. This metal layer can include the coils discussed with respect to FIG. 10, or could be one or more hypotubes. The capsule **106** is then covered on an outer surface by a polymer layer and on an inner surface by a liner. All of these features are discussed in detail below.

[0201] As mentioned, the metal layer **404** can be, for example, a metal hypotube or laser cut hypotube. In some embodiments, the metal layer **404** can be a metal coil or helix, as discussed in detail above with respect to FIG. 10. Though not limiting, the metal layer **404** can have a thickness of 0.007 inches (or about 0.007 inches).

[0202] If a metal coil, such as shown in FIG. 10, is used, the coil dimensions can stay the same throughout a length of the metal layer **404**. However, in some embodiments the coil dimensions can vary along a length of the metal layer **404**. For example, the coils can vary between coils having a 0.014-inch gap with a 0.021-inch pitch (e.g., small coils), coils having a 0.020 inch-gap with a 0.02-inch pitch (e.g., large coils), and coils having a 0.020-inch gap with a 0.027-inch pitch (e.g., spaced large coils). However, these particular dimensions are merely examples, and other designs can be used as well.

[0203] The distalmost end of the metal layer **404** can be formed out of the small coils. Moving proximally, the metal layer **404** may then transition to a section of large coils, followed again by a section of small coils, and then finally the proximalmost section can be the spaced large coils. As an example set of lengths, though not limiting, the distalmost small coil section may have a length of 10 mm (or about 10 mm). Moving proximally, the adjacent large coil section may extend 40 mm (or about 40 mm) to 60 mm (or about 60 mm) in length. These two sections would be found in the distal metal coil **108** shown in FIG. 10. Moving to the proximal metal coil **107** shown in FIG. 10, the small coil section can have a length of 10 mm (or about 10 mm). The remaining portion of the proximal metal coil **107** can be the spaced large coil section. The spaced large coil section can have a length of 40 mm (or about 40 mm) to 60 mm (or about 60 mm) or greater.

[0204] As mentioned, the metal layer **404** (either coil or hypotube) can be covered by an outer polymer layer or jacket **402**. In some embodiments, the outer polymer **402** layer is an elastomer, though the particular material is not limiting. In some embodiments, the outer polymer layer **402** can comprise polytetrafluoroethylene (PTFE) or expanded polytetrafluoroethylene (ePTFE). The ePTFE can have very different mechanical properties

that PTFE. For example, ePTFE can be much more flexible while still maintaining good tensile/elongation properties. In some embodiments, the outer polymer layer **402** can comprise a thermoplastic elastomer, such as PEBAX®. In some embodiments, the outer polymer layer **402** can be pre-axially stressed before applying to the capsule. The outer polymer layer **402** can be approximately 0.006 to 0.008 inches in thickness, but the particular thickness is not limiting.

[0205] The outer polymer layer **402** can be applied to the metal layer **404** to form an outer jacket, such as by reflowing the polymer. In some embodiments, the outer polymer layer **402** can be directly applied to the metal layer **404**. In some embodiments, an adhesive layer **406** can be disposed between the metal layer **404** and the outer polymer layer **402** to promote attachment of the outer polymer layer to the metal layer. For example, a fluoropolymer, or other soft durometer fluoroelastomer, can be applied between the metal layer **404** and the outer layer **402** in order to attach the two layers together and prevent delamination. In some embodiments, the adhesive layer **406** is not used.

[0206] In some implementations, other materials can be included between the metal layer **404** and the outer polymer layer **402** in order to improve properties. For example, fluorinated ethylene propylene (FEP) sections **408** can improve radial strength, in particular when the implant is under compression. While an FEP layer **408** is discussed as a particular material, other high strength polymers, metals, or ceramics can be used as well, and the particular material is not limiting. The FEP layer **408** can also act as an adhesive in some instances.

[0207] FEP sections **408** can be included at the distal and proximal ends of the capsule **106**. The FEP sections **408** can either overlap the adhesive layer **406**. Thus, FEP sections **408** can be located between the adhesive layer **406** and the metal layer **404** or between the adhesive layer **406** and the outer polymer layer **402**. In some embodiments, the FEP sections **408** may be located in sections of the capsule **106** that do not include an adhesive layer **406**.

[0208] The FEP section **408** located at the distal end of the capsule **106** can have a length of 10 mm (or about 10 mm), though the particular length is not limiting. In some embodiments, the FEP section **408** is approximately 0.003 inches in thickness, but the thickness may vary and is not limited by this disclosure. In some embodiments, different FEP sections **408** (e.g., a proximal section and a distal section) can have different thicknesses. In some embodiments, all FEP **408** layers have the same thickness. Example thicknesses can be 0.006 inches or 0.003 inches.

[0209] Moving to the inside of the metal layer **404**, a liner **410** can be included on its radially inner surface. The liner **410** can be formed of a low friction and/or high lubricity material that allows for the capsule **106** to be translated over the implant **70** without catching or damaging portions of the implant **70**. In some embodiments, the liner **410** can be PTFE, which can resist radial expansion and decrease friction with the implant **70**.

[0210] In some embodiments, the liner **410** is made from ePTFE. However, it can be difficult to reflow a standard ePTFE liner **410** on the inner layer of the capsule **106**. Accordingly, the ePTFE liner layer **410** can be pre-compressed before applying onto the inner layer of the capsule **106**. In some embodiments, portions of the outer polymer layer **402** and the liner **410** can be in contact with one another. Thus, prior to bonding the two layers together, the ePTFE liner **410** and/or outer polymer layer **402** can be axially compressed. Then, the layers can be bonded together with reflow techniques during manufacturing. For example, the ePTFE liner **410** can be axially compressed, such as over a mandrel, while the outer polymer layer **402** can be placed over it. These two layers can then be reflowed (e.g., melting under pressure) to connect. The combined layers can be slid into and/or around the metal layer **404** discussed herein, and can be melted under pressure again to form the final capsule **106**. This technique can allow for the capsule **106** to maintain flexibility and prevent breakage/tearing.

[0211] As mentioned above, the inner liner **410** can be ePTFE in some embodiments. The surface friction of ePTFE can be about 15% less than standard PTFE, and can be about 40% less than standard extruded thermoplastics that are used in the art.

[0212] In certain embodiments, the liner layer **410** can extend only along an inner surface of the capsule **106** and terminate at a distal end. However, to prevent delamination during loading of the implant **70**, the liner **410** may not be flush at the distal end of the capsule **106**. Instead, the liner **410** can be extended and inverted at the distal end in order to cover the distal end of the capsule **106** as well as an outer diameter of a portion of the outer polymer layer **402**. This can create a seamless rolled reinforced tip of the liner **410**. This solution is advantageous over previously known methods, such as disclosed in U.S. Pat. No. 6,622,367, incorporated by reference in its entirety, as PTFE lined applications do not adhere particularly well to reinforcements or the outer jacket. By inverting the liner **410** and fusing it with the outer polymer layer **402**, this creates a seamless reinforced capsule tip that can mitigate delamination. Delamination is a serious concern because the delaminated liner can tear and embolize during deployment, and the delaminated layer can cause extremely high loading and deployment

forces. Delaminated layers can also cause lumen translation problems by locking up shafts thereby adding translational force requirements.

[0213] In some embodiments, another FEP section **412** can be included between the liner **410** and the metal layer **404**. The FEP section **412** can be located on distal metal coil **108**, as well as the tube **110** transitioning between the distal metal coil **108** and the proximal metal coil **107**. In some embodiments, the FEP section **412** may continue partially or fully into the proximal metal coil **107**.

[0214] In some embodiments, an FEP section **412** can be included in the proximalmost portion of the proximal metal coil **107**. This FEP section **412** be approximately 0.5 inches in length. In some embodiments, there is a longitudinal gap between the proximalmost FEP section **412** and the FEP section **412** that extends over the distal metal coil **108**. In some embodiments, the previously mentioned FEP sections **412** are continuous.

[0215] As shown in FIG. 15, the metal layer **404** may stop proximal to the edges of the outer polymer layer **402**, liner **410**, and FEP section **412**. If so, a thicker portion of an adhesive layer **409** can be applied at the distal end of the metal layer **404** to match the distal end of the other layers. However, this section can be removed during manufacture, so the distal end of the metal layer **404** is the distal end of the capsule **106**, which can then be covered by the liner **410**. In some embodiments, the extended sections distal to the metal layer **404** are not used.

[0216] In embodiments, a covering layer may be applied to the capsule **106** that may include reinforcing fibers or beads. A delivery system accordingly may include an elongate shaft, having a proximal end and a distal end, and including an implant retention area configured to retain the implant. A covering layer may be on the elongate shaft and may include reinforcing fibers or beads. The covering layer may form an interior liner of the elongate shaft. The covering layer may comprise the interior liner **410** of the capsule **106**, or a liner of another capsule as disclosed herein, or may be a liner of another portion of the delivery system **10**. For example, the covering layer may comprise a liner extending along the interior of the outer sheath assembly **22** from the capsule **106** back to the handle of the delivery system **10**, and thus may form an interior liner of the outer sheath. In embodiments, the covering layer may be applied to other components of the delivery system **10**, including the mid shaft assembly, or the interior shaft assembly, among other components. In embodiments, the covering layer may be applied to as an outer layer of one or more of the components.

[0217] The covering layer may include the reinforcing fibers or beads to provide strength for the covering layer. For example, the covering layer may include a material such as polytetrafluoroethylene (PTFE) that is mixed with the reinforcing fibers or beads. The PTFE may provide a lubricious surface that is then reinforced with the reinforcing fibers or beads for strength. The tensile strength of the covering layer, for example, may be improved with the use of the reinforcing fibers or beads. Further, in embodiments as shown in FIGS. 16–21, in which a hypotube including cut patterns is utilized in a capsule, the reinforcing fibers or beads may serve to protect an implant from the cut patterns of the hypotube. The reinforcing fibers or beads may comprise glass, and in embodiments may comprise silicate fibers or beads or carbon (e.g., graphite) fibers or beads.

[0218] The covering layer may further provide toughness and durability to protect any of the hypotube cut patterns (e.g., a laser cut member) from binding during relative translation. For example, as a cut hypotube of the capsule is retracted or advanced relative to a cut hypotube of the mid-assembly, then there may be a reduced possibility of such hypotubes binding during relative translation.

[0219] The covering layer may be formed by a mixture of the base material (e.g., PTFE) with the reinforcing fibers or beads. For example, PTFE pellets may be mixed with the reinforcing fibers or beads in a desired proportion. The mixture may be heated and then extruded to form the covering layer. The remainder of the delivery system **10**, for example, the capsule **106** and other portion of the outer sheath assembly **22** may be formed with the covering layer. For example, the covering layer may be applied as an interior liner for the capsule **106**.

[0220] The proportion of the base material (e.g., PTFE) to the reinforcing fibers or beads may be set as desired. In embodiments, the proportion may be a mixture of the base material (e.g., PTFE) and the reinforcing fibers and beads in which between 1% to 10%, inclusive, comprises the reinforcing fibers or beads. In embodiments, the proportion may be a mixture of the base material (e.g., PTFE) and the reinforcing fibers and beads in which 0.5% to 25%, inclusive, comprises the reinforcing fibers or beads. In embodiments, the proportion may be a mixture of the base material (e.g., PTFE) and the reinforcing fibers and beads in which 0.1% to 30%, inclusive, comprises the reinforcing fibers or beads. In embodiments, the proportion may be a mixture of the base material (e.g., PTFE) and the reinforcing fibers and beads in which up to 25% or 30%, inclusive comprises the reinforcing fibers or beads.

[0221] A method may include deploying the elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a covering layer including reinforcing fibers or beads. The method may include retracting a capsule surrounding the implant retention area, with the covering layer forming an interior liner of the capsule. The method may include sliding the interior liner along the implant, which may reduce friction with the implant and provide a tough and durable interior liner.

[0222] A method may include providing the elongate shaft and preparing the covering layer including reinforcing fibers or beads. The method may include preparing a mixture of PTFE with the reinforcing fibers or beads, or another base material. The mixture may be extruded with the PTFE including the reinforcing fibers or beads. The extrusion may be provided with the remainder of the elongate shaft, and may comprise a liner of the elongate shaft such as an interior liner of a capsule or another portion of the outer sheath. The covering layer disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0223] FIG. 16 illustrates an embodiment of a hypotube **500** shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **500** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **500** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **500** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes, or other portions of the assemblies. The hypotube **500** may be positioned between an outer jacket and a liner layer disclosed herein, among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 16, the hypotube **500** has outer sides **512**, **514** that when connected form a cylindrical shape for the hypotube **500** in a similar manner as the hypotube shown in FIG. 11.

[0224] The hypotube **500** may have one or more cuts **502a-h** that form a plurality of rings **504a-d** of the hypotube **500**. The cuts **502a-h** may be in shape of slots as shown in FIG. 16 or may have other shapes as desired. The plurality of rings **504a-d** may be spaced longitudinally from each other and extend circumferentially around the hypotube **500**.

[0225] The hypotube **500** may include a first section **506** that may be a distal portion of the hypotube **500**. The distal portion of the hypotube **500** may form a distal portion of the capsule **106**, or a distal portion of the assembly that the hypotube **500** is utilized with. The first section **506** may include cut pairs (**502a** and **502b** form a pair, with **502c** and **502d** forming another pair). The cuts **502a** and **502c** may be aligned longitudinally, at the same circumferential position, and the cuts **502b** and **502d** may be aligned longitudinally, at the same circumferential position, such that spines **508**, **510** may be positioned between circumferentially spaced cuts **502a**, **b**. The spines **508**, **510** may extend longitudinally along the hypotube **500**.

[0226] The hypotube **500** is shown in FIG. 16 in a flattened configuration, and as such, when the outer sides **512**, **514** of the hypotube **500** are connected such that the hypotube **500** forms a cylinder, the first section **506** will include a set of circumferentially extending cuts **502a**, **502c** on one side of the hypotube **500** and a set of circumferentially extending cuts **502b**, **502d** on the opposing side of the hypotube **500**. Each of the cuts disclosed in this application may end in a teardrop shape to facilitate bending.

[0227] Each cut in the pair **502a**, **b** may extend circumferentially around almost half of the circumference of the hypotube **500**, and similarly each cut in the pair **502c**, **d** may extend circumferentially around almost half of the circumference of the hypotube **500**. One cut **502a**, **c** in a pair may be circumferentially spaced from the other cut and have a greater longitudinal size or thickness than the other cut **502b**, **d** in the pair. The thickness of the cut **502a**, **c** may be 1, 2, 3, 4, or 5 times thicker than the thickness of the other cut in the pair **502b**, **d**, among other thicknesses. The cuts **502a**, **502c** having a greater longitudinal size or width than the other cuts **502b**, **502d** will cause the section **506** to have a bias to flex in a direction towards the cuts **502a**, **502c** and away from the cuts **502b**, **502d**. The spines **508**, **510** accordingly may extend along the neutral axis of bend when the first section **506** is bent.

[0228] The first section **506** accordingly may comprise a section of the hypotube **500** biased to flex in a single direction.

[0229] The hypotube **500** may include a second section **516**. The second section **516** may be positioned proximal of the first section **506** and may comprise a proximal portion of the capsule **106** or other proximal portion of an assembly that the hypotube **500** is utilized with.

[0230] The second section **516** may include longitudinally spaced rows of cuts **502e-h** that form rings **504c-d** of the hypotube **500** that are spaced longitudinally from each other and extend circumferentially around the hypotube **500**.

[0231] The cuts **502e–h** may comprise pairs of cuts **502e, f** and **502g, h**. Each cut in the pair **502e, f** may extend circumferentially around almost half of the circumference of the hypotube **500**, and similarly each cut in the pair **502g, h** may extend circumferentially around almost half of the circumference of the hypotube **500**.

[0232] One cut **502e, h** in the pair may have a greater longitudinal size or thickness than the other cut **502f, g** in the pair. The thickness of the cut **502e, h** may be 1, 2, 3, 4, or 5 times longitudinally thicker than the thickness of the other circumferentially spaced cut **502f, g** in the pair. The pairs of cuts **502e, f** and **502g, h** may be offset from each other circumferentially, and may be offset from each other by about 90 degrees as shown in FIG. 16, or by a different offset as desired. As such, the pairs of cuts **502e, f** and **502g, h** may form two pairs of spines **518, 520** and **522, 524**, with the spines **518, 520** longitudinally aligned with spines **508, 510** of the first section **506**. The pair of spines **518, 520** may be offset from the pair of spines **522, 524** by about 90 degrees as shown in FIG. 16, or by a different offset as desired. The spines within each pair may be positioned 180 degrees from each other. Such a configuration may be formed by a repeating pattern of staggered cuts comprising the pairs of cuts **502e, f** and **502g, h** being offset from each other along the length of the hypotube **500**. The position of the spines **518, 520** and **522, 524**, and the increased longitudinal size or width of the cuts **502e, h** will cause the section **516** to have a bias to flex in two directions (a first direction and a second direction), one towards the cuts **502e** and one towards the cuts **502h**. The spines **518, 520** and **522, 524** may each accordingly extend along the neutral axis of bend when the second section **516** is bent. A greater number of directions of bend may be provided if desired (e.g., at least two directions of bend).

[0233] The hypotube **500** may provide support for an assembly of the delivery system **10** and may provide support for the capsule **106**. The plurality of cuts shown in FIG. 16 may allow for flexibility of the capsule **106**, particularly in the directions of bias formed by the cut patterns.

[0234] The plurality of rings **504a–d** of the hypotube **500** may provide for support of the capsule **106**. In addition, the plurality of rings **504a–d** may allow for a force to be applied by the capsule **106** in a distal direction. Such a force may be applied in an embodiment in which the capsule **106** is utilized for recapture of an implant that may have been partially deployed from the implant retention area **16** (as shown in FIG. 2C). For example, if the capsule **106** has been retracted to deploy the implant from the implant retention area **16**, it may be desired to retrieve the partially deployed implant. The capsule **106** may then be forced distally to

recapture the partially deployed implant and possibly return the implant to the implant retention area **16**. The structural strength provided by the hypotube **500** may allow this distal force to be applied to the partially deployed implant for recapture. The plurality of rings **504a–d** of the hypotube **500** may compress against each other to allow the distal force to be applied.

[0235] Further, the biased flexibility provided by the plurality of cuts may allow the hypotube **500**, and accordingly the capsule **106**, to flex to accommodate bend of the capsule **106** which may include bending caused by translation along a bent rail assembly. The first section **506** may be biased to bend in a single direction to accommodate that direction of bend of the rail assembly. The second section **516** may be biased to bend in two directions (or at least two directions) to accommodate two directions of bend (or at least two directions of bend) of the rail assembly.

[0236] The configuration of the hypotube **500**, including use of the plurality of rings **504a–d**, may allow for an improved distal force to be applied by the capsule **106** or another portion of the assembly utilizing the hypotube **500**. The plurality of rings **504a–d** may contact and press against each other to allow the distal force to be applied. Notably, however, the directions of bend of the first section **506** and the second section **516** should be aligned with the directions of bend of the rail assembly or other bend of the elongate shaft **12** to allow for desired bend of the hypotube **500**. As such, it may be beneficial to produce a hypotube configuration that lacks a flex bias in a direction.

[0237] FIG. 17 illustrates an embodiment of a hypotube **600** shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **600** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **600** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **600** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes, or other portions of the assemblies. The hypotube **600** may be positioned between an outer jacket and a liner layer disclosed herein, among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 17, the hypotube **600** has outer sides **608**, **610** that when connected form a cylindrical shape for the hypotube **600** in a similar manner as the hypotube shown in FIG. 11.

[0238] The hypotube **600** has one or more cuts **602a–c** that form a plurality of rings **604a–b** of the hypotube **600**. The plurality of rings **604a–b** may be longitudinally spaced from each other and form a pattern of rings extending circumferentially for the length of the hypotube **600**. The one or more cuts represented as **602a–c** shown in FIG. 17 are cut into a spiral that extends circumferentially around the hypotube **600** for the length of the hypotube **600**. The cuts may be separated by spines **606a**, **606b**, **606c** that extend longitudinally along the hypotube **600** and connect the plurality of rings **604a–b**. The spines may be offset circumferentially from each other. The spines **606a**, **606b**, **606c** may be positioned such that a single cut of the cut pattern extends more than 360 degrees around the hypotube **600**.

[0239] The spiral configuration of the hypotube **600** may allow the hypotube **600** to lack a bias in a direction of bend. The hypotube **600** accordingly may be configured to bend in multiple directions without a particular bias towards a direction and may have equal flexibility in all radial directions. Such a feature may allow the hypotube **600** to have a greater variety of orientations about the directions of bend of the rail assembly, as the hypotube **600** lacks a particular bias towards one direction of bend of the rail assembly. The spiral configuration may allow the hypotube **600** to remain flexible, to flex in various directions of bend as desired.

[0240] Further, the spiral configuration of the hypotube **600** may allow the plurality of rings **604a–b** to more strongly contact and compress against each other to transmit a distal force for implant recapture or the like. The gaps formed by the cuts **602a–c** may be reduced in size when the hypotube **600** is distally compressed, such that a rigid rod structure is formed for recapture of the implant. The lack of bias of the hypotube **600** may also reduce the possibility of the hypotube **600** deflecting in a direction due to a flex bias of the hypotube **600**.

[0241] FIG. 18 illustrates an embodiment of a hypotube **700** shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **700** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **700** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **700** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes or other portions of the assemblies. The hypotube **700** may be positioned between an outer jacket and a liner layer disclosed herein, among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 18, the hypotube

700 has outer sides **712**, **714** that when connected form a cylindrical shape for the hypotube **700** in a similar manner as the hypotube shown in FIG. 11.

[0242] The hypotube **700** has one or more cuts **702a–d** that form a plurality of rings **704a–b** of the hypotube **700**. The plurality of rings **704a–b** may be longitudinally spaced from each other and form a pattern of rings extending circumferentially for the length of the hypotube **700**.

[0243] The one or more cuts **702a–d** shown in FIG. 18 are cut into pairs (cuts **702a** and **702b** form a pair, and cuts **702c** and **702d** form a pair) that are offset from each other. The cuts **702a–d** may have equal longitudinal widths, and may have equal circumferential lengths. The one or more cuts **702a–d** may form a repeating pattern of staggered cuts that have an equal size. The cuts may be separated by pairs of spines (**706** and **708** form a pair, and **710** and **712** form a pair) that are offset from each other and each extend longitudinally along the hypotube **700**. Each spine in the pair may be offset 180 degrees from the other spine in the pair. The amount of offset of the pairs of spines may be 90 degrees as shown in FIG. 18, or another amount as desired.

[0244] The offset configuration of the cuts **702a–d** of the hypotube **700** may allow the hypotube **700** to lack a bias in a direction of bend. The hypotube **700** accordingly may be configured to bend in a multitude of directions without a particular bias towards a direction and may have equal flexibility in all radial directions. Such a feature may allow the hypotube **700** to have a greater variety of orientations about the directions of bend of the rail assembly, as the hypotube **700** lacks a particular bias towards one direction of bend of the rail assembly. Further, the circumferential length and longitudinal width of the cuts **702a–d** is equal in FIG. 18, with equal offset of cuts in repeating rows of cuts.

[0245] Further, the small width of the cuts **702a–d** of the hypotube **700** may allow the plurality of rings **704a–b** to contact and compress against each other to transmit a distal force for implant recapture or the like. The gaps formed by the cuts **702a–d** may be reduced in size when the hypotube **700** is distally compressed, such that a rigid rod structure is formed for recapture of the implant. The lack of bias of the hypotube **700** may also reduce the possibility of the hypotube **700** deflecting in a direction due to a flex bias of the hypotube **700**.

[0246] FIG. 19 illustrates an embodiment of a hypotube **800** shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **800** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed

herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **800** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **800** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes or other portions of the assemblies. The hypotube **800** may be positioned between an outer jacket and a liner layer, among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 19, the hypotube **800** has outer sides **804**, **806** that when connected form a cylindrical shape for the hypotube **800** as shown in FIG. 19.

[0247] The hypotube **800** is configured similarly as the hypotube **700** shown in FIG. 18, however, the size of the one or more cuts **802a-d** that form a plurality of rings **806a-b** of the hypotube has increased. The length and width of the cuts **802a-d** remains equal, however. The increased size of the cuts **802a-d** may allow for greater flexibility of the hypotube **800**. The size of the cuts **802a-d** may be reduced when the hypotube **800** is distally compressed, such that a rigid rod structure is formed for recapture of the implant. The lack of bias of the hypotube **800** may also reduce the possibility of the hypotube **800** deflecting in a direction due to a flex bias of the hypotube **800**.

[0248] In certain embodiments, a hypotube may be utilized that includes a combination of a cut pattern having a bias to flex in a direction, and a cut pattern lacking a bias to flex in a direction. FIG. 20 illustrates such a pattern, in which a hypotube **900** includes a first section **902** that has a cut pattern **908** that is configured as the cut pattern of the hypotube **800** shown in FIG. 19. The hypotube **900** includes a second section **904** with a cut pattern **906** that is configured as the cut pattern of the section **506** of the hypotube **500** shown in FIG. 16. The first section **902** may be positioned proximally and the second section **904** may be positioned distally.

[0249] The hypotube **900** is shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **900** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **900** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **900** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes or other portions of the assemblies. The hypotube **900** may be positioned between an outer jacket and a liner layer,

among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 20, the hypotube **900** has outer sides **910**, **912** that when connected form a cylindrical shape for the hypotube **900** as shown in FIG. 20.

[0250] The hypotubes **600**, **700**, and **800** and the cut pattern **908** shown in FIG. 20 may beneficially lack a bias of towards a direction of bend, yet may provide flexibility in multiple directions of bend. The hypotubes **600**, **700**, and **800** and the cut pattern **908** may also provide a compressive force that allows the hypotubes **600**, **700**, and **800** and the cut pattern **908** to be utilized for implant recapture if desired.

[0251] FIG. 21 illustrates an embodiment of a hypotube **1000** shown in a flattened configuration that may be utilized with assemblies of the present disclosure. The hypotube **1000** may be utilized as a metal layer, or metal portion of one or more of the assemblies disclosed herein, and particularly may comprise a portion of a capsule **106** as shown in FIG. 4. The hypotube **1000** may be utilized with a capsule **106** that is configured to surround an implant retention area **16** of the elongate shaft **12**. The hypotube **1000** may be utilized as a metal layer **404** for a capsule as shown in FIG. 15, and may be utilized in other portions of the assemblies that utilize hypotubes or other portions of the assemblies. The hypotube **1000** may be positioned between an outer jacket and a liner layer, among other components disclosed in embodiments herein. Although shown in a flattened configuration in FIG. 21, the hypotube **1000** has outer sides **1010**, **1012** that when connected form a cylindrical shape for the hypotube **1000** as shown in FIG. 21.

[0252] Pairs of cuts (one pair includes cuts **1002a**, **b** and another pair includes cuts **1002c**, **d**) may be offset circumferentially from each other such that the spines **1006**, **1008** form an angle relative to the longitudinal direction. The cuts **1002a**, **b** and **1002c**, **d** accordingly may form an angled pattern or sweep pattern in which the hypotube **1000** has a bias to flex in a direction with the spines **1006**, **1008** extending along the neutral axis of bend. The direction of bend bias accordingly may vary along the length of the hypotube **1000**. The gaps formed by the cuts **1002a**, **b** and **1002c**, **d** may be reduced in size when the hypotube **1000** is distally compressed, such that a rigid rod structure is formed for recapture of the implant.

[0253] Notably, the directions of bias of the bend of the hypotube **1000** should be aligned with the directions of bend of the rail assembly. It may thus be beneficial to allow a portion of the delivery system including a hypotube having a biased direction of flex, to rotate to align the bias direction with the direction of bend of a rail assembly, or another structure forming a

bend of the delivery system. The embodiments of hypotubes disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0254] FIG. 22–25 illustrate embodiments in which the delivery system **10** may be configured to allow the capsule **106** to rotate. The rotation of the capsule **106** may allow a hypotube included with the capsule **106** to rotate such that a direction of bias of a cut pattern of the hypotube aligns with a direction of bend of the rail assembly. The capsule **106** may be configured to surround the implant retention area **16**. Thus, for the embodiments of hypotubes **500**, **900**, **1000** that include a direction of flex bias, the capsule **106** may be able to rotate to align the direction of the flex bias with a direction of bend of the rail assembly. Such a feature may be useful to reduce the possibility of hypotubes that include a direction of flex bias from becoming misaligned with the direction of bend of the rail assembly and having reduced operability.

[0255] FIG. 22 illustrates a distal portion of a delivery system that includes a coupler **1900** configured to couple the capsule **106** to a shaft portion **1902** of the elongate shaft **12** that is positioned proximal of the capsule **106**. The shaft portion **1902** may comprise a portion of the outer shaft assembly, which may include the outer hypotube **104**, or the shaft **102**, or another portion of the outer shaft assembly as desired.

[0256] The coupler **1900** may allow the capsule **106** to rotate about the axis of the elongate shaft **12**. The coupler **1900** may take a variety of forms and may include a protrusion **1904** that is positioned within a channel **1906**. The protrusion **1904** may be configured to rotate relative to the channel **1906** to allow the capsule **106** to rotate. As shown in FIG. 22, the protrusion **1904** may comprise a material that is deflected into the channel **1906**. For example, the protrusion **1904** may be swaged into the channel **1906** and thus able to rotate relative to the channel **1906**. The protrusion **1904** may be coupled to the capsule **106**, such as a proximal portion of the capsule **106**, and the channel **1906** may be coupled to a distal portion of the shaft portion **1902**. In other embodiments, the protrusion **1904** may be coupled to the shaft portion **1902** and the channel **1906** may be coupled to the capsule **106**. The protrusion **1904** and the channel **1906** may be positioned in other locations on either the capsule **106** or the shaft portion **1902** as desired.

[0257] FIG. 23 illustrates a side perspective view of an exterior of the elongate shaft **12** including the coupler **1900**. The capsule **106** may be configured to rotate about the axis of the

elongate shaft **12** relative to the shaft portion **1902**, as indicated with the arrows shown in FIG. 23.

[0258] FIG. 24 illustrates an embodiment of the coupler **2000** in which the coupler comprises a protrusion **2002** that may be configured to rotate relative to the channel **2004** to allow the capsule **106** to rotate. As shown in FIG. 24, the protrusion **2002** may comprise a pin. The channel **2004** may comprise a window. The pin may be configured to slide along the window to allow the capsule **106** to rotate. The window may be coupled to the capsule **106**, such as a proximal portion of the capsule **106**, and the pin may be coupled to a distal portion of the shaft portion **1902**. In other embodiments, the window may be coupled to the shaft portion **1902** and the pin may be coupled to the capsule **106**. The protrusion **2002** and the channel **2004** may be positioned in other locations on either the capsule **106** or the shaft portion **1902** as desired.

[0259] FIG. 25 illustrates a side perspective view of an exterior of the elongate shaft **12** including the coupler **2000**. The capsule **106** may be configured to rotate about the axis of the elongate shaft **12** relative to the shaft portion **1902**, as indicated with the arrows shown in FIG. 25.

[0260] The couplers **1900**, **2000** shown in FIGS. 22–25 may take a variety of other forms as desired, and may be varied from the protrusion and channel configurations shown in FIGS. 22–25. The perspective views shown in FIGS. 23 and 25 show the couplers positioned on an outer surface of the elongate shaft **12**, however, in other embodiments the couplers may be covered by an outer jacket or another structure as desired.

[0261] The couplers **1900**, **2000** may beneficially allow the capsule **106** to rotate. The rotation of the capsule **106** may allow a hypotube included with the capsule **106** to rotate such that a direction of bias of a cut pattern of the hypotube aligns with a direction of bend of the rail assembly. Thus, for the embodiments of hypotubes **500**, **900**, **1000** that include a direction of flex bias, the capsule **106** may be able to rotate to align the direction of the flex bias with a direction of bend of the rail assembly.

[0262] The hypotubes **500**, **900**, **1000** may be configured to passively rotate to align the direction of the flex bias with a direction of bend of the rail assembly. As such, as the hypotubes **500**, **900**, **1000** pass over the bend of the rail assembly, the reduced resistance to bending caused by aligning the direction of the flex bias with a direction of bend of the rail assembly, may allow the hypotubes **500**, **900**, **1000** to passively rotate.

[0263] Although the couplers **1900**, **2000** are shown in relation to the capsule **106**, in other embodiments other portions of the elongate shaft **12** may be configured to rotate through use of the couplers **1900**, **2000**. Such portions may comprise a mid shaft assembly, which may include an outer retention ring **42** that may be configured to rotate in a similar manner as the capsule **106**. The mid shaft assembly may include a hypotube, of which a coupler may allow the outer retention ring **42** to rotate with such that a direction of bias of a cut pattern of the hypotube aligns with a direction of bend of the rail assembly. Other portions of the elongate shaft **12** may utilize couplers for rotation as desired.

[0264] The rotation of the portion of the elongate shaft **12**, which may include the capsule **106**, may allow for rotation during a proximal retraction or a distal advancement of the portion of the elongate shaft **12**. For example, the capsule **106** may rotate via one of the couplers **1900**, **2000** when the capsule is being retracted proximally, or may rotate via one of the couplers **1900**, **2000** when the capsule is being advanced distally. Notably, during advancement of the capsule **106** distally, a compressive force may be applied to the capsule **106** both in a proximal direction due to compression of the expandable implant, and in a distal direction due to the force applied to the capsule **106** by the handle of the delivery system. It is noted that as a result of such forces, structural damage may be produced, such as crushing of the capsule **106** if such forces are sufficiently strong. The embodiments of couplers and capsules disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0265] FIG. 26 illustrates a distal portion of a delivery system that includes an inflatable body **2100**. The inflatable body **2100** may be configured to inflate to support a sheath. The inflation of the inflatable body **2100** may serve to reduce the possibility of structural damage to the sheath and may strengthen the sheath during distal movement such as implant recapture.

[0266] As shown in FIG. 26, the sheath may comprise an outer sheath, which may include the capsule **106** and other portions such as an outer hypotube **104** and a shaft **102** (as shown in FIG. 4). The inflatable body **2100** may be configured to inflate to support the outer shaft when the outer shaft is being extended distally. For example, when the capsule **106** is being extended distally for recapture of an expandable implant, the inflatable body **2100** may be inflated to provide support for the capsule **106** and other portions of the sheath. The support may reduce the possibility of structural damage to the capsule **106**, as structural strength is provided to the capsule **106**.

[0267] As shown in FIG. 26, the inflatable body **2100** may be positioned within an interior lumen of the sheath. The inflatable body **2100** may be positioned on an interior shaft that may be positioned within the lumen of the sheath. The inflatable body **2100** may be positioned between the interior shaft and the sheath and configured to inflate to support the sheath. The interior shaft may comprise a middle shaft (mid shaft) of the elongate shaft **12** as shown, or in other embodiments may comprise another shaft within the elongate shaft **12**. The inflatable body **2100** may be positioned on a shaft that is adjacent to the sheath, such that inflation of the inflatable body **2100** causes contact of an interior surface of the sheath.

[0268] A conduit **2102** may couple to the inflatable body **2100** and be configured to provide fluid to inflate the inflatable body **2100**. The conduit **2102** may extend along the length of the elongate shaft **12** and may be positioned within the outer lumen of the outer shaft. A proximal end of the conduit **2102** may couple to an inflation port or the like for inflating the inflatable body **2100**. The conduit **2102** may extend between the outer sheath and the mid sheath as shown in FIG. 26. In other embodiments, the conduit **2102** may be positioned in other locations as desired.

[0269] The inflatable body **2100** may include one or more balloons, which may be pleated or may have another form. The inflatable body **2100** may have other forms in other embodiments. The inflatable body **2100** may be configured to exert sufficient force against the interior surface of the sheath such that the sheath is supported upon the inflatable body **2100** inflating and contacting the interior surface of the sheath. Such support may occur as the sheath is being advanced distally, and may occur as the sheath is bent around the rail assembly **20**.

[0270] FIG. 27 illustrates the inflatable body **2100** inflated and supporting the sheath (shown as the capsule **106** of the outer sheath) at a bend of the outer shaft. The capsule **106** is being advanced distally, which may be for recapture of an expandable implant (although the implant is not visible in FIG. 27). A resistive force in the direction **2104** marked with a dashed arrow in FIG. 27 may be applied to the capsule **106**. Without the presence of the inflatable body **2100**, the resistive force in the direction **2104** may damage the capsule **106**. The inflatable body **2100**, however, may inflate to contact the interior surface of the capsule **106**, and fill the space between the capsule **106** and the mid shaft. The inflatable body **2100** may then be deflated at a desired time.

[0271] Although the outer sheath is shown as the capsule **106** in FIG. 27, an inflatable body may be utilized in any embodiment of sheath. For example, the mid shaft may comprise a

sheath that extends around the inner shaft, with the inner shaft positioned within the outer sheath of the mid shaft. An inflatable body may be positioned between the inner shaft and the sheath of the mid shaft and may support the mid shaft as the mid shaft is advanced proximally for recapture of an implant or the like. The inflatable body may be utilized in other locations as desired. The embodiments of inflatable bodies and shafts disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0272] In certain embodiments, the elongate shaft **12** of the delivery system may include a wall having a tensile layer that provides strength to the elongate shaft **12** upon being withdrawn proximally. FIG. 28, for example, illustrates an embodiment of a tensile layer in the form of a braid layer **2200** that may be utilized to provide strength to the elongate shaft **12** upon being withdrawn proximally.

[0273] The braid layer **2200** may comprise a weave, as shown in FIG. 28, of overlapping metal wires or other forms of fibers, that form a sheath. In other embodiments, other materials may be utilized to form the braid layer **2200** as desired.

[0274] FIG. 29 illustrates a cross sectional view of a wall of a sheath of the elongate shaft including the braid layer of FIG. 28. A wall **2203** extends circumferentially around an interior lumen **2201** to form the body of the sheath. The construction of the wall **2203** of the sheath is visible, including the braid layer **2200** surrounding a metal layer **2202**. An interior liner layer **2204** is visible surrounded by the metal layer **2202**. An outer jacket layer **2206** is visible extending around the braid layer **2200**. An interior lumen **2201** is surrounded by the sheath.

[0275] The metal layer **2202** may be configured similarly as the metal layers disclosed within this application, including embodiments of a coil or a hypotube disclosed herein, including the hypotubes shown in FIGS. 16–21. The braid layer **2200** may surround the metal layer **2202** such that as an axial force **2210** providing tension is applied to the braid layer **2200**, the braid layer **2200** compresses onto the metal layer **2202**. The compression is represented by arrows **2212**. The metal layer **2202** may resist the compression of the braid layer **2200** upon the metal layer **2202**, thus causing the braid layer **2200** to exhibit a high tensile strength. The braid layer **2200** may thus be utilized to strengthen the sheath of the elongate shaft, allowing a greater retraction force to be applied by the sheath of the elongate shaft.

[0276] A buffer layer **2214** may be positioned between the outer jacket layer **2206** and the braid layer **2200**. The buffer layer **2214** may prevent the outer jacket layer **2206** from flowing

between the weave of the braid layer **2200** and thus diminishing the effectiveness of the braid layer **2200** by filling the interstices of the braid layer **2200** with material. The buffer layer **2214** may be made of a polymer and may comprise expanded polytetrafluoroethylene (ePTFE) or in other embodiments may comprise other materials. The outer jacket layer **2206** may comprise PEBAX or another form of polymer.

[0277] The construction of the wall of the sheath of the elongate shaft as shown in FIG. 29, including the use of the braid layer **2200** may be utilized with various assemblies of the delivery system. For example, the capsule **106** of the outer sheath may be configured to include the construction shown in FIG. 29. In other embodiments, other assemblies, including any portion of the outer sheath, a middle sheath, or the inner assembly may utilize the construction of the elongate shaft as shown in FIG. 29. The construction of the wall of the sheath disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0278] Other devices, solely or in combination with a braid layer, may improve the retraction force of a portion of the elongate sheath. FIG. 30 illustrates an embodiment of a delivery system that utilizes a cable router **2300**. The delivery system may utilize a cable **2302** having two end portions **2304**, **2306**. The end portions **2304**, **2306** may couple to a sheath, which may comprise the capsule **106** as shown in FIG. 30, but in other embodiments may comprise other sheaths or portions of the delivery system, including the elongate shaft. The cable **2302** may include an intermediate portion **2308** that may extend between the end portions **2304**, **2306**. The end portions **2304**, **2306** may be coupled to respective opposite sides of the sheath. For example, the end portion **2304** may couple to an interior surface of the sheath and the end portion **2306** may couple to an interior surface of the sheath on an opposite side of the sheath. The end portions **2304**, **2306** may be separated by the interior lumen of the sheath. The end portions **2304**, **2306** may couple to portions of the sheath that are positioned on opposite sides of a neutral axis of the sheath within the same plane of bend. For example, the end portion **2304** may couple to a portion of the sheath that forms an interior curvature of the sheath when the sheath is bent, and the end portion **2306** may couple to a portion of the sheath that forms an outer curvature of the sheath when the sheath is bent. If the sheath is bent in the opposite direction, then the end portion **2304** may couple to a portion of a sheath that forms an outer curvature of the sheath, and the end portion **2306** may couple to a portion of the sheath that forms an inner curvature of the sheath when the sheath is bent in the opposite direction.

[0279] The cable **2302** may be configured to slide along the length of the sheath, and may extend within the interior lumen of the sheath. The cable **2302** may extend along the length of the sheath to engage the cable router **2300**.

[0280] The cable router **2300** may take a variety of forms and may comprise a pulley wheel as shown in FIG. 30. The cable router **2300** may comprise a channel to allow the cable **2302** to bend around the cable router **2300**. The channel for example may comprise a bent tube that redirects the direction of the cable **2302**. Other forms of cable router **2300** may be utilized as desired.

[0281] The cable router **2300** may be configured to engage the intermediate portion **2308** of the cable **2302** such that the cable may move along the cable router **2300** when the cable **2302** is slid due to a bending of the sheath such as the capsule **106** shown in FIG. 30. For example, in an embodiment in which the cable router **2300** is a pulley wheel, the pulley wheel may rotate to allow the cable **2302** to move along the cable router **2300**. In an embodiment in which the cable router **2300** is a channel, the channel may allow the cable **2302** to slide along the channel.

[0282] The delivery system may include a control mechanism **2310**. The control mechanism **2310** may comprise a body configured to move the cable router **2300** by applying tension to the cable router **2300** to retract the cable router **2300** in a proximal direction. The control mechanism **2310** may be configured to retract the sheath as well in a similar manner. The control mechanism **2310** may include threading or the like to allow the control mechanism **2310** to be operated by a mechanism of the handle or other portion of the delivery system. The cable router **2300** and control mechanism **2310** may be positioned in a handle of a delivery system or in another location as desired.

[0283] In operation, the cable **2302** may be configured to passively have its length vary between the end portion **2304** and the cable router **2300**, and between the end portion **2306** and the cable router **2300**, due to a deflection of the sheath. FIG. 31, for example, illustrates an operation of the cable **2302** and cable router **2300**. The sheath, shown as capsule **106**, may be deflected due to a variety of reasons, which may include a deflection of the rail assembly. The deflection of the sheath causes the end portion **2304** of the cable **2302** to be moved proximally, and the end portion **2306** of the cable **2302** to be moved distally. The amount of proximal movement of the end portion **2304** of the cable **2302** (the change in length) may be equal to the amount of distal movement of the end portion **2306** of the cable **2302** (the change in length)

and the variation in length may simultaneously occur. The cable router **2300** may serve to allow the intermediate portion **2308** of the cable **2302** to move along the cable router **2300** to transfer the length of the cable **2302** from the end portion **2304** to the end portion **2306**. Alternatively, the sheath may be deflected in an opposite direction, with the end portion **2304** extending distally and the end portion **2306** extending proximally.

[0284] The length of the cable **2302** may be routed between the end portions **2304**, **2306** to allow the cable **2302** to remain taut between the end portions **2304**, **2306** during flex of the sheath. The control mechanism **2310** may retract the cable router **2300** to allow the cable **2302** to pull on the sheath to enhance a pull strength of the sheath if the sheath is retracted. Such a feature may be utilized with a capsule **106** that may be retracted to allow an expandable implant to be deployed. Such a feature may be utilized with any other portion of the elongate sheath that is retracted, such as a middle sheath that is retracted to retract an outer retention ring **42**. A sheath coupled to a nose cone of the elongate shaft may be retracted as well, among other locations of use. The cable router disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0285] FIGS. 32–34 illustrate distal portions of delivery systems including stops that are positioned on an interior shaft of the delivery system and configured to impede proximal movement of the capsule **106**. FIG. 32A illustrates a side cross sectional view of a distal portion of the delivery system. The capsule **106** is shown to extend over the inner sheath assembly in FIG. 32A, although in other embodiments the capsule **106** may extend over other interior shafts such as the mid shaft assembly.

[0286] The interior shaft, shown as the distal section **126** of the inner shaft assembly, may include a stop **2400** positioned thereon. The stop **2400** may comprise a protrusion that extends radially outward from the interior shaft. The stop **2400** may be configured such that the stop **2400** applies a force to a proximal body **2402** of the capsule **106** that impedes proximal movement of the capsule **106**. FIG. 32B, for example, illustrates the capsule **106** having been withdrawn, with the proximal body **2402** contacting the stop **2400**. The position of the capsule **106** may thus be held until additional force is applied to the capsule **106** to overcome the protrusion of the stop **2400** and allow the capsule **106** to further move proximally to allow the expandable implant to deploy from the implant retention area **16**. FIG. 32C, for example, illustrates the capsule **106** having been withdrawn proximally past the stop **2400**.

[0287] The stop may have a variety of other forms as desired. For example, in FIGS. 33A–C, the stop **2404** may have the form of threading on the interior shaft. The capsule may include a threaded portion **2406** that may allow the capsule **106** to be rotated relative to the threading on the interior shaft to allow the capsule **106** to move proximally past the stop **2404**. FIG. 33C, for example, illustrates the capsule **106** having been withdrawn proximally past the stop **2404**.

[0288] In FIGS. 34A–C, the stop **2408** may have the form of a keyed shape on the interior shaft. The capsule **106** may include complementary keyed shape on a proximal body **2410** that is matched by the stop **2408** to allow the capsule **106** to move proximally past the stop. The capsule **106** may be rotated relative to the threading on the interior shaft to allow the capsule **106** to move proximally past the stop **2408**. FIG. 34C, for example, illustrates the capsule **106** having been withdrawn proximally past the stop **2408**.

[0289] The stops shown in FIGS. 32–34 may be configured to provide for two stage deployment of the implant retained within the implant retention area **16**. The stops may be positioned on the interior shaft to allow the capsule **106** to retract for a defined distance, to allow a defined amount of partial release, or partial exposure, or partial expansion of the implant upon the stop being contacted. For example, as shown in FIG. 33B, the capsule **106** may be retracted for a defined distance until the stop **2400** is contacted. The defined distance may be a stopping point for the user of the delivery system, to assure at this point that the implant is partially deployed in the desired location. The stop **2400** may prevent the user from retracting the capsule **106** entirely, without first stopping to confirm that the expandable implant is partially deployed in the desired location. Upon the user performing such a confirmation, the capsule **106** may continue to be retracted past the stop **2400** to allow the expansion and deployment of the expandable implant to continue. The stop **2400** thus may serve as a tactile feedback for the user of a desired stop location for the user to assure at this point that the expandable implant is partially deployed in the desired location. The stops **2404**, **2408** may serve a similar function as stop **2400**. The stops may be positioned proximate the capsule **106**, to allow for tactile feedback that is positioned proximate the capsule **106**, which may better allow the user to operate the delivery system. After the stops are overcome, full release or exposure or expansion of the implant may occur.

[0290] The stops may have varied configurations and positions than shown in FIGS. 32–34, as desired. The stops may be positioned on an interior shaft such as a middle shaft (mid shaft) or an inner shaft as desired, among other locations. The stops disclosed herein may be

utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0291] Referring to FIG. 35, a handle **14** is located at the proximal end of the delivery system **10**. A cross-section of the handle **14** is shown in FIG. 36. The handle **14** can include a number of actuators, such as rotatable knobs, that can manipulate different components of the delivery system **10**. The operation of the handle **14** is described with reference to delivery of a replacement mitral valve implant **70**, though the handle **14** and delivery system **10** can be used to deliver other devices as well.

[0292] The handle **14** is generally composed of two housings, a rail housing **202** and a delivery housing **204**, the rail housing **202** being circumferentially disposed around the delivery housing **204**. The inner surface of the rail housing **202** can include a screwable section configured to mate with an outer surface of the delivery housing **204**. Thus, the delivery housing **204** is configured to slide (e.g., screw) within the rail housing **202**, as detailed below. The rail housing **202** generally surrounds about one half the length of the delivery housing **204**, and thus the delivery housing **204** extends both proximally and distally outside of the rail housing **202**.

[0293] The rail housing **202** can contain two rotatable knobs, a distal pull wire knob **206** and a proximal pull wire knob **208**. However, the number of rotatable knobs on the rail housing **202** can vary depending on the number of pull wires used. Rotation of the distal pull wire knob **206** can provide a proximal force, thereby providing axial tension on the distal pull wires **138** and causing the distal slotted section **235** of the rail hypotube **136** to bend. The distal pull wire knob **206** can be rotated in either direction, allowing for bending in either direction, which can control anterior-posterior angles. Rotation of the proximal pull wire knob **208** can provide a proximal force, and thus axial tension, on the proximal pull wires **140**, thereby causing the proximal slotted section **233** of the rail hypotube **136** to bend, which can control the medial-lateral angle. The proximal pull wire knob **208** can be rotated in either direction, allowing for bending in either direction. Thus, when both knobs are actuated, there can be two bends in the rail hypotube **136**, thereby allowing for three-dimensional steering of the rail shaft **132**, and thus the distal end of the delivery system **10**. Further, the proximal end of the rail shaft **132** is connected on an internal surface of the rail housing **202**.

[0294] The bending of the rail shaft **132** can be used to position the system, in particular the distal end, at the desired patient location, such as at the native mitral valve. In some

embodiments, rotation of the pull wire knobs **206/208** can help steer the distal end of the delivery system **10** through the septum and left atrium and into the left ventricle so that the implant **70** is located at the native mitral valve.

[0295] Moving to the delivery housing **204**, the proximal ends of the inner shaft assembly **18**, outer sheath assembly **22**, mid shaft assembly **21**, and nose cone shaft assembly **31** can be connected to an inner surface of the delivery housing **204** of the handle **14**. Thus, they can move axially relative to the rail assembly **20** and rail housing **202**.

[0296] A rotatable outer sheath knob **210** can be located on the distal end of the delivery housing **204**, being distal to the rail housing **202**. Rotation of the outer sheath knob **210** will pull the outer sheath assembly **22** in an axial direction proximally, thus pulling the capsule **106** away from the implant **70** and releasing the distal end **303** of implant **70**. Thus the outer sheath assembly **22** is individually translated with respect to the other shafts in the delivery system **10**. The distal end **303** of the implant **70** can be released first, while the proximal end **301** of the implant **70** can remain radially compressed between the inner retention member **40** and the outer retention member **42**.

[0297] A rotatable mid shaft knob **214** can be located on the delivery housing **204**, in some embodiments proximal to the rotatable outer sheath knob **210**, being distal to the rail housing **202**. Rotation of the mid shaft knob **214** will pull the mid shaft assembly **21** in an axial direction proximally, thus pulling the outer retention ring **42** away from the implant **70** and uncovering the inner retention member **40** and the proximal end **301** of the implant **70**, thereby releasing the implant **70**. Thus, the mid shaft assembly **21** is individually translated with respect to the other shafts in the delivery system **10**.

[0298] Located on the proximal end of the delivery housing **204**, and thus proximal to the rail housing **202**, can be a rotatable depth knob **212**. As the depth knob **212** is rotated, the entirety of the delivery housing **204** moves distally or proximally with respect to the rail housing **202** which will remain in the same location. Thus, at the distal end of the delivery system **10**, the inner shaft assembly **18**, outer sheath assembly **22**, mid shaft assembly **21**, and nose cone shaft assembly **31** together (e.g., simultaneously) move proximally or distally with respect to the rail assembly **20** while the implant **70** remains in the compressed configuration. In some embodiments, actuation of the depth knob **212** can sequentially move the inner shaft assembly **18**, outer sheath assembly **22**, mid shaft assembly **21**, and nose cone shaft assembly **31** relative to the rail assembly **20**. In some embodiments, actuation of the depth knob **212** can

together move the inner shaft assembly **18**, outer sheath assembly **22**, and mid shaft assembly **21** relative to the rail assembly **20**. Accordingly, the rail shaft **132** can be aligned at a particular direction, and the other assemblies can move distally or proximally with respect to the rail shaft **132** for final positioning while not releasing the implant **70**. The components can be advanced approximately 1, 2, 3, 5, 6, 7, 8, 9, or 10 cm along the rail shaft **132**. The components can be advanced more than approximately 1, 2, 3, 5, 6, 7, 8, 9, or 10 cm along the rail shaft **132**. An example of this is shown in FIG. 2C. The capsule **106** and outer retention ring **42** can then be individually withdrawn with respect to the inner assembly **18** as discussed above, in some embodiments sequentially, releasing the implant **70**. The assemblies other than the rail assembly **20** can then be withdrawn back over the rail shaft **132** by rotating the depth knob **212** in the opposite direction.

[0299] The handle **14** can further include a mechanism (knob, button, handle) **216** for moving the nose cone shaft **27**, and thus the nose cone **28**. For example, a knob **216** can be a portion of the nose cone assembly **31** that extends from a proximal end of the handle **14**. Thus, a user can pull or push on the knob **216** to translate the nose cone shaft **27** distally or proximally individually with respect to the other shafts. This can be advantageous for proximally translating the nose cone **28** into the outer sheath assembly **22** /capsule **106**, thus facilitating withdraw of the delivery system **10** from the patient.

[0300] In some embodiments, the handle **14** can provide a lock **218**, such as a spring lock, for preventing translation of the nose cone shaft **27** by the knob **216** discussed above. In some embodiments, the lock **218** can be always active, and thus the nose cone shaft **27** will not move without a user disengaging the lock **218**. The lock can be, for example, a spring lock that is always engaged until a button **218** on the handle **14** is pressed, thereby releasing the spring lock and allowing the nose cone shaft **27** to translate proximally/distally. In some embodiments, the spring lock **218** allows one-way motion, either proximal or distal motion, of the nose cone shaft **27** but prevents motion in the opposite direction.

[0301] The handle **14** can further include a communicative flush port for flushing out different lumens of the delivery system **10**. In some embodiments, a single flush port on the handle **14** can provide fluid connection to multiple assemblies. In some embodiments, the flush port can provide fluid connection to the outer sheath assembly **22**. In some embodiments, the flush port can provide fluid connection to the outer sheath assembly **22** and the mid shaft assembly **21**. In some embodiments, the flush port can provide fluid connection to the outer sheath assembly **22**, the mid shaft assembly **21**, and the rail assembly **20**. In some

embodiments, the flush port can provide fluid connection to the outer sheath assembly **22**, the mid shaft assembly **21**, the rail assembly **20**, and the inner assembly **18**. Thus, in some embodiments, the rail shaft **132**, the outer retention ring **42**, and the capsule **106** can all be flushed by a single flush port.

[0302] FIGS. 37–45 illustrate an embodiment of a handle **14'** including control knobs **210'**, **214'**, **2500** that each have an outer grip surface that is exposed for gripping around an entire outer circumference of the respective control knob **210'**, **214'**, **2500**. This is in contrast with the control knobs **210**, **214** shown in FIG. 35 for example, in which a portion of the outer grip surface of the control knobs **210**, **214** is covered by a bridge portion of the handle **14** that extends over the control knobs **210**, **214**.

[0303] The handle **14'** shown in FIG. 37 does not include bridges over the respective control knobs **210'**, **214'**, **2500**, and accordingly each control knob **210'**, **214'**, **2500** has an outer grip surface that is exposed for gripping around an entire outer circumference of the respective control knob **210'**, **214'**, **2500**. Such a feature may advantageously allow for greater grip force to be applied to the respective control knobs **210'**, **214'**, **2500**, to better allow a user to rotate the knobs and move a respective portion of the delivery system to which the respective control knobs **210'**, **214'**, **2500** is coupled. The lack of presence of bridge portions of the handle **14** over the control knobs **210'**, **214'**, **2500** improves the ergonomics of the handle **14'** and allows for greater grip and forces to be applied by the user to the control knobs **210'**, **214'**, **2500**.

[0304] The handle **14'** may include a rail housing **202** that is configured similarly as the rail housing **202** shown in FIG. 35 and coupled to the delivery housing **204'** in a similar manner as the rail housing **202** couples to the delivery housing **204**. The pull wire knobs **206**, **208** are not shown in FIGS. 37–45 for clarity, and the depth knob **212** is not shown for clarity as well, although the pull wire knobs **206**, **208** and depth knob **212** would operate with the handle **14'** in the same manner as with the handle **14**.

[0305] FIG. 37 illustrates a side perspective view of the handle **14'**, and FIG. 38 illustrates a bottom view of the handle **14'**. FIG. 39 illustrates a center cross sectional view of the handle **14'** from the bottom view of FIG. 38. The interior construction of the handle **14'** is shown in FIG. 39. The distalmost control knob **210'** is positioned at a distal end of the handle **14'** and is configured to control operation of the outer sheath assembly. A distal surface **2502** (visible in FIG. 40) forms the distal face of the handle **14'** and connects opposite sides of the grip surface

of the control knob **210'**. A middle control knob **214'** is positioned on the delivery housing **204'** and is configured to control operation of the mid shaft assembly. A proximal control knob **2500** is positioned at a proximal end of the handle **14'** and is configured to control operation of the nose cone assembly. The distalmost control knob **210'** and middle control knob **214'** may each be configured to be rotated to move their respective assemblies to release a portion of an implant from an implant retention area **16**.

[0306] The delivery housing **204'** may include interior cavities that house respective sliders **2504, 2506, 2508** that are each coupled to the outer sheath assembly, the mid shaft assembly, and the nose cone assembly respectively. The sliders may be configured to slide along respective cavities that house the sliders **2504, 2506, 2508** to allow the sliders **2504, 2506, 2508** to translate the respective assemblies.

[0307] The control knobs **210', 214', 2500** may couple to bodies **2501, 2503, 2505** having threading that engages the threading of the sliders **2504, 2506, 2508**, to allow the rotational motion of the control knob **210', 214', 2500** to produce axial or linear sliding of the respective slider **2504, 2506, 2508**. One or more beams **2510, 2512** may be provided that may serve to prevent rotation of the sliders **2504, 2506, 2508** when the respective control knob **210', 214', 2500** rotates. Each beam **2510, 2512** may include a channel having a shape that is keyed to a shape of the respective slider **2504, 2506, 2508** to prevent rotation of the slider **2504, 2506, 2508** upon rotation of the control knob **210', 214', 2500**. Only a portion of the threading of the bodies (e.g., half) may engage a slider to cause movement of the slider, as a portion of the threading of the bodies is covered by a respective beam. The respective slider **2504, 2506, 2508** is positioned within the channel of the beam and slides along the channel to cause movement of the assembly that the slider **2504, 2506, 2508** is coupled to.

[0308] The beams **2510, 2512** may include walls that are positioned on both sides of an indentation to form the respective channel of the beams **2510, 2512**. As such, the beams **2510, 2512** may have a “u” shape, as shown in FIGS. 41–45. Such a shape provides enhanced structural support for the handle **14'** and resists torque applied to the beams **2510, 2512** upon rotation of the control knobs **210', 214', 2500**.

[0309] The beams **2510, 2512** may each extend within the cavities that house the sliders **2504, 2506, 2508**, and may be suspended within the cavities such that the threading of the control knobs **210', 214', 2500** does not engage or rotate the beams **2510, 2512**. The beams **2510, 2512** may be supported by the delivery housing **204'** at supports **2514, 2516, 2518, 2520**,

2522. The delivery housing **204'** may also include walls **2524**, **2526**, **2528** that separate the cavities of the delivery housing **204'** and serve to retain the beams **2510**, **2512** such that the beams **2510**, **2512** do not rotate with the respective cavities of the delivery housing **204'**.

[0310] FIG. 40 illustrates a front perspective view of the handle **14'** with the elongate shaft not visible. The distal surface **2502** includes a central opening that allows the elongate shaft to pass through.

[0311] FIG. 41 illustrates a cross sectional view along line A-A in FIG. 39. The “u” shape of the beam **2510** is visible, as well as the keyed shape of the slider **2504**.

[0312] FIG. 42 illustrates a cross sectional view along line B-B in FIG. 39. The support **2516** is shown as a protrusion entering a portion of the beam **2510**. A support wall **2524** is adjacent to the beam **2510** to prevent rotation of the beam **2510** within the handle **14'**.

[0313] FIG. 43 illustrates a cross sectional view along line C-C in FIG. 39. A support wall **2526** is adjacent to the beam **2510** to prevent rotation of the beam **2510** within the handle **14'**.

[0314] FIG. 44 illustrates a cross sectional view along line D-D in FIG. 39. The support **2520** is shown as a protrusion entering a portion of the beam **2512**. A support wall **2528** is adjacent to the beam **2512** to prevent rotation of the beam **2512** within the handle **14'**.

[0315] FIG. 45 illustrates a cross sectional view along line E-E in FIG. 39. The control knob **2500** is shown to include an unthreaded portion **2530** that serves as a stop to prevent the slider **2508** from being passed out of the proximal end of the handle **14'**.

[0316] The handle **14'** may be configured to control a length of a path of travel of the respective sliders **2504**, **2506**, **2508** in a variety of manners. For example, a threading of the control knobs may be discontinued at a certain point to prevent travel of the respective sliders **2504**, **2506**, **2508**. A size of the cavity that the slider **2504**, **2506**, **2508** travels in may be reduced as desired. In certain embodiments, stops in the form of protrusions may be placed along the beams **2510**, **2512** or otherwise in the path of travel to control a length of a path of travel of the respective sliders **2504**, **2506**, **2508**. In FIG. 39, the control knob **210'** serves as a distal stop to prevent distal axial movement of the slider **2504**. The handle **14'** may be utilized with any embodiment of delivery system disclosed herein. The handle **14'** disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0317] Embodiments of the delivery systems disclosed herein may include markers that are configured to enhance an echogenicity of the elongate shaft of the delivery systems, to define a location of a portion of the elongate shaft when viewed under ultrasound imaging. Such markers may be positioned in a variety of locations of the elongate shaft, and may be positioned on a portion of the elongate shaft that is beneficially identified under ultrasound imaging to improve the delivery of the expandable implant. The ultrasound imaging may include echocardiography among other forms of ultrasound imaging.

[0318] FIG. 46 illustrates a side view of a nose cone **28** of the delivery system. The nose cone **28** has a smooth tapered outer surface, which does not readily appear in ultrasound imaging. Further, FIG. 47 shows a cross sectional view of the nose cone **28** shown in FIG. 46. The nose cone **28** is shown to include a homogenous construction out of a single type of material, which is preferably soft and pliable such as a flexible polymer.

[0319] FIG. 48 illustrates a side view of a portion of the nose cone shown in FIG. 46 as nose cone **28'**, and including a marker that is configured to enhance an echogenicity of the elongate shaft (particularly the nose cone **28'**), to define a location of the portion (nose cone **28'**) of the elongate shaft when viewed under ultrasound imaging. The marker as shown in FIG. 48 has the form of a contoured portion of the nose cone **28'** that forms an edge **2600** of the nose cone **28'**. The edge **2600** extends around the circumference of the nose cone **28'** and forms a planar surface **2602** that extends around the circumference of the nose cone **28'**. The planar surface **2602** faces distally. The edge **2600** forms an abrupt transition of acoustic impedance for the nose cone **28'**, which enhances the echogenicity of the nose cone **28'**. Further, the edge **2600** shape extending around the circumference of the nose cone **28'** enhances the acoustic reflectance for a variety of directions of incident ultrasound waves, thus also enhancing the echogenicity of the nose cone **28'**.

[0320] FIG. 49 illustrates two echocardiogram images of the nose cone **28'** including the edge **2600** shown in FIG. 48. The edge **2600** is more brightly shown in the two echocardiogram images, as indicated by locations **2700** and **2702**, which may allow the user to more easily locate the position of the nose cone **28'** in the images.

[0321] FIG. 50 illustrates an embodiment of a nose cone **2800** including a marker including a plurality of edges **2802**, **2804**, **2806** that enhance an echogenicity of the elongate shaft (particularly the nose cone **2800**), to define a location of the portion (nose cone **2800**) of the elongate shaft when viewed under ultrasound imaging. The plurality of edges **2802**, **2804**,

2806 may operate similarly as the edge **2600** shown in FIG. 48, and may each extend around the circumference of the nose cone **2800** and form respective distal facing planar surfaces that extend around the circumference of the nose cone **2800**. A plurality of ledges may be formed by the plurality of edges **2802**, **2804**, **2806**.

[0322] FIG. 51 illustrates an embodiment of a nose cone **2900** including a marker including an edge **2902** that enhance an echogenicity of the elongate shaft (particularly the nose cone **2900**), to define a location of the portion (nose cone **2900**) of the elongate shaft when viewed under ultrasound imaging. The edge **2902** may operate similarly as the edge **2600** shown in FIG. 48, and may each extend around the circumference of the nose cone **2900** and form a distal facing planar surface that extends around the circumference of the nose cone **2900**. The edge **2902** may spiral around the nose cone **2900** to form a pattern in the shape of a spiral around the nose cone **2900**.

[0323] FIG. 52 illustrates an embodiment of a nose cone **3000** including a marker including a plurality of edges **3002** that enhance an echogenicity of the elongate shaft (particularly the nose cone **3000**), to define a location of the portion (nose cone **3000**) of the elongate shaft when viewed under ultrasound imaging. The edges **3002** may operate similarly as the edge **2600** shown in FIG. 48, and may form a pattern facing distally on the nose cone **3000**. The pattern may include a plurality of indentations in the form of dimples on the nose cone **3000**.

[0324] FIG. 53 illustrates an embodiment of a nose cone **3100** including a marker including a plurality of edges **3102** that enhance an echogenicity of the elongate shaft (particularly the nose cone **3100**), to define a location of the portion (nose cone **3100**) of the elongate shaft when viewed under ultrasound imaging. The edges **3102** may operate similarly as the edge **2600** shown in FIG. 48, and may form a pattern facing distally on the nose cone **3100**. The pattern may include a plurality of indentations in the form of slots on the nose cone **3100**.

[0325] The surfaces shown in FIG. 48, and FIGS. 50–53 may comprise the outer surfaces of the respective nose cones, or in other embodiments the markers may be encapsulated in material. The encapsulating material may comprise a material having different acoustic impedance than the markers, which may greater enhance the echogenicity of the markers. The encapsulating material may allow the nose cones to retain a smooth tapered surface.

[0326] FIG. 54 illustrates a side cross sectional view of a nose cone **3200** including two materials having different acoustic impedances than each other. One material forms the marker **3202** shown in FIG. 54 and the other material forms adjacent encapsulating material having a

different acoustic impedance than the material of the marker **3202** and that forms the outer surface of the nose cone **3200**. The marker **3202** may be encapsulated such that the nose cone **3200** retains a smooth tapered surface.

[0327] FIG. 55 illustrates a perspective view of the nose cone **3200** including the marker **3202**. The marker may include a plurality of edges, and may include multiple planar surfaces oriented along axial planes of the nose cone **3200** and planar surfaces oriented along the radial planes. The edges may form an abrupt transition of acoustic impedance for the nose cone **3200**, which enhances the echogenicity of the nose cone **3200**. Further, the edges and orientation of planar surfaces enhance the acoustic reflectance for a variety of directions of incident ultrasound waves, thus also enhancing the echogenicity of the nose cone **3200**. The marker **3202** includes a plurality of fins extending radially outward.

[0328] FIG. 56 illustrates a perspective view of the nose cone **3200** including the marker **3202** at a greater angle than shown in FIG. 55. The orientation of the plurality of fins is visible.

[0329] FIG. 57 illustrates a perspective view of a nose cone **3300** including a marker **3302** configured similarly as the marker **3202**, but with a greater number of fins than shown in FIG. 56.

[0330] The markers disclosed herein may be made of a material having a relatively high acoustic impedance, which may comprise metals or the like. The acoustic impedance may be greater than the impedance of an adjacent material to allow for enhanced echogenicity resulting from use of the marker.

[0331] The markers disclosed herein may be utilized in a variety of locations of the elongate shaft and not only on the nose cone comprising the tip of the elongate shaft. For example, the capsule, the outer retention ring of the mid shaft, and other locations on the outer sheath assembly, the mid shaft assembly, and the inner shaft assembly may include the markers as desired.

[0332] FIG. 58 illustrates a side cross sectional view of a capsule **106** including a marker **3400** at a distal end of the capsule **106**. The marker **3400** may include a plurality of edges that enhance an echogenicity of the elongate shaft (particularly the distal end of the capsule **106**), to define a location of the portion (the distal end of the capsule **106**) of the elongate shaft when viewed under ultrasound imaging.

[0333] FIG. 59 illustrates a close up perspective view of the marker **3400**. The marker may include the plurality of edges **3402** that bound apertures **3404** of the marker **3400**. The plurality

of apertures **3404** may be spaced circumferentially about the marker **3400**. The apertures **3404** may allow for a transition of acoustic impedance between the body of the marker **3400** and the apertures **3404**, which may be filled with a material having a different acoustic impedance than the body of the marker **3400**. The apertures **3404** may each have an oblong shape in which adjacent apertures **3404** overlap each other, such that a vertical scan slice taken of the marker along a vertical dimension, as represented by line **3406**, will pass through the apertures **3404** and allow for the transition in acoustic impedance caused by the apertures **3404**. Further, the angled profile of the apertures **3404** may enhance the acoustic reflectance for a variety of directions of incident ultrasound waves. The marker **3400** in the form of a ring extends about a longitudinal axis of the elongate shaft, and the plurality of apertures are positioned circumferentially about the longitudinal axis.

[0334] The position of the apertures **3404** vertically upon the body of the marker **3400** will also enhance the possibility of an acoustic slice passing through the apertures **3404** when extending in a transverse dimension, as represented by plane **3408** in FIG. 59.

[0335] The marker **3400** may comprise a band of material having a different acoustic impedance than adjacent material, and may be positioned as desired. The marker **3400** for example, may be positioned on the outer retention ring of the mid shaft, and on the nose cone or tip. Other locations on the outer sheath assembly, the mid shaft assembly, and the inner shaft assembly may include the markers as desired.

[0336] FIG. 60 illustrates two echocardiogram images of the capsule including the marker **3400**. The marker **3400** is more brightly shown in the two echocardiogram images, as indicated by locations **3500** and **3502**, which may allow the user to more easily locate the position of the capsule in the images. The markers may be coupled to a tip of the elongate shaft, or in any other location, and may appear more brightly viewed with ultrasound imaging such as echocardiography than remaining portions of the tip or remaining portions of the elongate shaft.

[0337] The markers may be configured to be activated in embodiments herein. The markers may be configured to have a greater echogenicity upon being activated. An activation mechanism, or another system, may be utilized to activate the markers as disclosed herein. FIG. 75A, for example, illustrates an embodiment of a marker **3800** that is configured to be activated. A distal end of a delivery system is shown in FIG. 75A, including a nose cone **3802** and a capsule **3804**. The outer surface of the nose cone **3802** and the outer surface of the capsule **3804** may comprise a smooth surface forming a smooth outer profile in the

configuration shown in FIG. 75A. In such a configuration, for example, a delivery system may be passed through the patient's body, with the smooth outer profile reducing the possibility of damaging a surface of the patient's body.

[0338] The capsule **3804** may be configured to be retracted to activate the marker **3800** and allow the marker **3800** to enhance the echogenicity of the elongate shaft of the delivery system. An activation mechanism accordingly may comprise the capsule **3804** and an indicator **3806** that may be positioned on a proximal portion of the elongate shaft. The indicator **3806** may be configured as a stop as shown in FIG. 75A, or may be configured as a tactile indicator, audible indicator, or other form of indicator in embodiments.

[0339] Upon the user desiring to activate the marker **3800**, a first portion of the elongate shaft may be moved relative to a second portion of the elongate shaft to activate the marker **3800**. For example, the capsule **3804** may be retracted a length **3810** (marked in FIG. 75A and 75B) to form a gap **3812** (marked in FIG. 75B) between two portions of the delivery system (e.g., the capsule **3804** and the nose cone **3802**). FIG. 75B, for example, illustrates the capsule **3804** retracted by the length **3810**. The capsule **3804** moves axially relative to the nose cone **3802**.

[0340] Referring to FIG. 75B, the gap **3812** formed by the movement of the capsule **3804** may expose the respective edges **3814**, **3816** of the capsule **3804** and the nose cone **3802** thus activating the marker **3800**. In such a configuration, a user may be able to identify the marker **3800** with ultrasound imaging. The marker **3800** includes a contoured portion forming edges **3814**, **3816** of the elongate shaft. A planar surface formed by edge **3814** may face distally, and a planar surface formed by edge **3816** may face proximally.

[0341] In embodiments, the indicator **3806** may indicate to the user to only retract the capsule **3804** a relatively short distance, to maintain a proximity between the edges **3814**, **3816**. The proximity of the edges **3814**, **3816** may enhance the echogenicity of the marker **3800**. Upon the user desiring to further retract the capsule **3804** (e.g. to deploy the implant), the indicator **3806** may be overcome, for example, by overcoming a stop or otherwise continuing movement past the indicator **3806**. For example, the indicator **3806** may be moved (such as being pressed or slid) such that the capsule **3804** may continue to be retracted.

[0342] In such a configuration, the portion of the delivery system including the marker **3800** may have a smooth outer profile, with the edges **3814**, **3816** exposed only at a desired time by the user operating the activation mechanism. Thus, the possibility of damage to the

patient's body caused by an uneven outer profile may be reduced until a desired time of activation of the marker **3800**.

[0343] Other configurations of activatable markers may be utilized in embodiments. FIG. 76A, for example, illustrates an embodiment in which a first portion of the elongate shaft (e.g., strip of material **3818**) forms an outer surface of the delivery system (e.g., an outer surface of a capsule **3820**). The portion as shown may comprise a capsule of the elongate shaft or another portion as desired. The strip of material **3818** may be moved relative to a second portion of the elongate shaft (e.g., an adjacent portion of the elongate shaft) to form a gap **3822** between the portions. A user may operate an activation mechanism as disclosed herein for example. The gap **3822** may expose edges **3824** of the marker **3826** (as marked in FIG. 76B). The material **3818** may be slid axially.

[0344] FIG. 77A, illustrates an embodiment in which a first portion of the elongate shaft (e.g., strip of material **3828**) forms an outer surface of the delivery system (e.g., an outer surface of a capsule **3830**). The strip of material **3828** may be moved to form a gap **3832** and expose edges **3834** of the marker **3836** (as marked in FIG. 77B). The material **3828** may be rotated relative to the second portion of the elongate shaft (e.g., an adjacent portion of the elongate shaft) to activate the marker **3836**. A user may operate an activation mechanism as disclosed herein for example to rotate the strip of material **3828**.

[0345] In embodiments, a plurality of markers may be positioned on the delivery system. The markers may be spaced from each other at a distance such that a user viewing the markers on ultrasound imaging is able to identify a relative location on the delivery system. FIG. 78A, for example, illustrates an embodiment in which the plurality of markers **3840** have graduated spacing on the delivery system. The markers **3840** may form a pattern in a spiral. As such, upon activation of the markers **3840** (as shown in FIG. 78B), a plurality of locations on the delivery system are indicated. A user may operate an activation mechanism as disclosed herein for example. Strips of material forming an outer surface of the delivery system may each be moved to form gaps and expose the edges of the markers **3840**. A user may be able to match the location of the marker **3840** with a respective location on the delivery system. Further, a user may be able to determine a relative scaling on the imaging system based on distance imaged between the markers **3840**. For example, if the user is aware that each marker is 3 millimeters apart from each other, then that scaling may be utilized to determine distance viewed on the imaging system.

[0346] The use of markers disclosed herein may more easily allow a user to locate a portion of the elongate shaft under ultrasound imaging, which may include echocardiography. The user may more easily be able to determine a deployment location for the expandable implant, which may include a depth of the expandable implant and a relation of the expandable implant relative to structures of the patient's heart, including papillary muscles and any valve flaps, including mitral valve flaps. The user beneficially may visualize the location of portions of the elongate shaft without relying solely on fluoroscopy for visualization. A marker as disclosed herein may be utilized on any part of a catheter, intravenous, or gastrointestinal system or implant or any other device for insertion into a human body where a specific location needs to be identified with ultrasound imaging or with echocardiography. The markers disclosed herein may be utilized solely, or may be utilized with any of the other apparatuses, systems, or methods disclosed herein.

[0347] Methods of using the delivery system **10** in connection with a replacement mitral valve will now be described. In particular, the delivery system **10** can be used in a method for percutaneous delivery of a replacement mitral valve to treat patients with moderate to severe mitral regurgitation. The below methods are merely examples of the how the delivery system may be used. It will be understood that the delivery systems described herein can be used as part of other methods as well. The embodiments shown in FIGS. 16–60 may be incorporated and utilized as desired.

[0348] As shown in FIG. 61, in one embodiment the delivery system **10** can be placed in the ipsilateral femoral vein **1074** and advanced toward the right atrium **1076**. A transseptal puncture using known techniques can then be performed to obtain access to the left atrium **1078**. The delivery system **10** can then be advanced in to the left atrium **1078** and then to the left ventricle **1080**. FIG. 61 shows the delivery system **10** extending from the ipsilateral femoral vein **1074** to the left atrium **1078**. In embodiments of the disclosure, a guide wire is not necessary to position the delivery system **10** in the proper position, although in other embodiments, one or more guide wires may be used.

[0349] Accordingly, it can be advantageous for a user to be able to steer the delivery system **10** through the complex areas of the heart in order to position a replacement mitral valve in line with the native mitral valve. This task can be performed with or without the use of a guide wire with the above disclosed system. The distal end of the delivery system can be advanced into the left atrium **1078**. A user can then manipulate the rail assembly **20** to target the distal end of the delivery system **10** to the appropriate area. A user can then continue to pass the bent

delivery system **10** through the transseptal puncture and into the left atrium **1078**. A user can then further manipulate the delivery system **10** to create an even greater bend in the rail assembly **20**. Further, a user can torque the entire delivery system **10** to further manipulate and control the position of the delivery system **10**. In the fully bent configuration, a user can then place the replacement mitral valve in the proper location. This can advantageously allow delivery of a replacement valve to an in-situ implantation site, such as a native mitral valve, via a wider variety of approaches, such as a transseptal approach.

[0350] The rail assembly **20** can be particularly advantageous for entering into the native mitral valve. As discussed above, the rail assembly **20** can form two bends, both of which can be located in the left atrium **1078**. The bends in the rail assembly **20** can position the implant **70**, located in the implant retention area **16**, so that it is coaxial with the native mitral valve. Once the implant **70** is coaxial, the outer sheath assembly **22**, mid shaft assembly **21**, inner assembly **18**, and nose cone assembly **31** can together be advanced (e.g., using the depth knob **212** of the handle **14**) distally relative to the rail assembly **20**. These assemblies advance straight off of the rail assembly **20**, thus advancing them coaxial with the native mitral valve until the implant **70** is to be released while maintain the implant **70** in the compressed configuration, as discussed below. Thus, the rail assembly **20** provides the ability for a user to lock the angular position in place, so that the user then has to just longitudinally advance the other assemblies over the rail assembly **20** while not needed to make any angular changes, greatly simplifying the procedure. The rail assembly **20** acts as an independent steering assembly, where all the assembly does is provide steerability and no further prosthesis release functionality. Further, the construction of the rail assembly **20** as described above is sufficiently rigid so that when the rail assembly is actuated to its bent shape, movement of the other components, e.g., the outer sheath assembly **22**, mid shaft assembly **21**, inner assembly **18**, and/or nose cone assembly **31**, the rail assembly **20** maintains its shape. Thus, the rail assembly **20** can remain in the desired bent position during the sliding of the other assemblies relative to the rail assembly **20**, and the rail assembly **20** can help direct the other assemblies to the final position. The proximal/distal translation of the other assemblies over the rail assembly **20** allows for ventricular-atrial motion. In addition, once the distal anchors **80** of the implant **70** have been released in the left ventricle **1080**, but prior to full release, the other assemblies can be proximally retracted over the rail assembly **20** to capture any leaflets or chordae.

[0351] Reference is now made to FIG. 62 which illustrates a schematic representation of a portion of an embodiment of a replacement heart valve (implant **70**) positioned within a native mitral valve of a heart **83**. Further details regarding how the implant **70** may be positioned at the native mitral valve are described in U.S. Publication No. 2015/0328000A1, the entirety of which is hereby incorporated by reference, including but not limited to FIGS. 13A-15 and paragraphs [0036]-[0045]. A portion of the native mitral valve is shown schematically and represents typical anatomy, including a left atrium **1078** positioned above an annulus **1106** and a left ventricle **1080** positioned below the annulus **1106**. The left atrium **1078** and left ventricle **1080** communicate with one another through a mitral annulus **1106**. Also shown schematically in FIG. 62 is a native mitral leaflet **1108** having chordae tendineae **1110** that connect a downstream end of the mitral leaflet **1108** to the papillary muscle of the left ventricle **1080**. The portion of the implant **70** disposed upstream of the annulus **1106** (toward the left atrium **1078**) can be referred to as being positioned supra-annularly. The portion generally within the annulus **1106** is referred to as positioned intra-annularly. The portion downstream of the annulus **1106** is referred to as being positioned sub-annularly (toward the left ventricle **1080**).

[0352] As shown in FIG. 62, the replacement heart valve (e.g., implant **70**) can be positioned so that the mitral annulus **1106** is located between the distal anchors **80** and the proximal anchors **82**. In some situations, the implant **70** can be positioned such that ends or tips of the distal anchors **80** contact the annulus **1106** as shown, for example, in FIG. 62. In some situations, the implant **70** can be positioned such that ends or tips of the distal anchors **80** do not contact the annulus **1106**. In some situations, the implant **70** can be positioned such that the distal anchors **80** do not extend around the leaflet **1108**.

[0353] As illustrated in FIG. 62, the implant **70** in the form of a prosthesis, specifically a replacement heart valve, can be positioned so that the ends or tips of the distal anchors **80** are on a ventricular side of the mitral annulus **1106** and the ends or tips of the proximal anchors **82** are on an atrial side of the mitral annulus **1106**. The distal anchors **80** can be positioned such that the ends or tips of the distal anchors **80** are on a ventricular side of the native leaflets beyond a location where chordae tendineae **1110** connect to free ends of the native leaflets. The distal anchors **80** may extend between at least some of the chordae tendineae **1110** and, in some situations such as those shown in FIG. 62, can contact or engage a ventricular side of the annulus **1106**. It is also contemplated that in some situations, the distal anchors **80** may not contact the annulus **1106**, though the distal anchors **80** may still contact the native leaflet **1108**.

In some situations, the distal anchors **80** can contact tissue of the left ventricle **1080** beyond the annulus **1106** and/or a ventricular side of the leaflets.

[0354] During delivery, the distal anchors **80** (along with the frame) can be moved toward the ventricular side of the annulus **1106**, such as by translating the other assemblies (e.g., outer sheath assembly **22**, mid shaft assembly **21**, inner assembly **18**, and nose cone assembly **31**) proximally with respect to the rail assembly **20**, with the distal anchors **80** extending between at least some of the chordae tendineae **1110** to provide tension on the chordae tendineae **1110**. The degree of tension provided on the chordae tendineae **1110** can differ. For example, little to no tension may be present in the chordae tendineae **1110** where the leaflet **1108** is shorter than or similar in size to the distal anchors **80**. A greater degree of tension may be present in the chordae tendineae **1110** where the leaflet **1108** is longer than the distal anchors **80** and, as such, takes on a compacted form and is pulled proximally. An even greater degree of tension may be present in the chordae tendineae **1110** where the leaflets **1108** are even longer relative to the distal anchors **80**. The leaflet **1108** can be sufficiently long such that the distal anchors **80** do not contact the annulus **1106**.

[0355] The proximal anchors **82**, if present, can be positioned such that the ends or tips of the proximal anchors **82** are adjacent the atrial side of the annulus **1106** and/or tissue of the left atrium **1078** beyond the annulus **1106**. In some situations, some or all of the proximal anchors **82** may only occasionally contact or engage atrial side of the annulus **1106** and/or tissue of the left atrium **1078** beyond the annulus **1106**. For example, as illustrated in FIG. 62, the proximal anchors **82** may be spaced from the atrial side of the annulus **1106** and/or tissue of the left atrium **1078** beyond the annulus **1106**. The proximal anchors **82** could provide axial stability for the implant **70**. It is also contemplated that some or all of the proximal anchors **82** may contact the atrial side of the annulus **1106** and/or tissue of the left atrium **1078** beyond the annulus **1106**. FIG. 63 illustrates the implant **70** implanted in the heart. Although the illustrated replacement heart valve includes both proximal and distal anchors, it will be appreciated that proximal and distal anchors are not required in all cases. For example, a replacement heart valve with only distal anchors may be capable of securely maintaining the replacement heart valve in the annulus. This is because the largest forces on the replacement heart valve are directed toward the left atrium during systole. As such, the distal anchors are most important for anchoring the replacement heart valve in the annulus and preventing migration.

[0356] FIGS. 64–66 illustrate the release mechanism of the delivery system **10**. During the initial insertion of the implant **70** and the delivery system **10** into the body, the implant **70** can be located within the system **10**, similar to as shown in FIG. 2A. The distal end **303** of the implant **70**, and specifically the distal anchors **80**, are restrained within the capsule **106** of the outer sheath assembly **22**, thus preventing expansion of the implant **70**. Similar to what is shown in FIG. 2A, the distal anchors **80** can extend distally when positioned in the capsule. The proximal end **301** of the implant **70** is restrained within the capsule **106** and within a portion of the inner retention member **40** and thus is generally constrained between the capsule **106** and the inner retention member **40**.

[0357] The system **10** can first be positioned to a particular location in a patient's body, such as at the native mitral valve, through the use of the steering mechanisms discussed herein or other techniques.

[0358] Once the implant **70** is loaded into the delivery system **10**, a user can thread a guide wire into a patient to the desired location. The guide wire passes through the lumen of the nose cone assembly **31**, and thus the delivery system **10** can be generally advanced through the patient's body following the guide wire. The delivery system **10** can be advanced by the user manually moving the handle **14** in an axial direction. In some embodiments, the delivery system **10** can be placed into a stand while operating the handle **14** controls.

[0359] Once generally in heart, the user can begin the steering operation of the rail assembly **20** using the distal pull wire knob **206** and/or the proximal pull wire knob **208**. By turning either of the knobs, the user can provide flexing/bending of the rail assembly **20** (either on the distal end or the proximal end), thus bending the distal end of the delivery system **10** in one, two, or more locations into the desired configuration. As discussed above, the user can provide multiple bends in the rail assembly **20** to direct the delivery system **10** towards the mitral valve. In particular, the bends of the rail assembly **20** can direct a distal end of the delivery system **10**, and thus the capsule **106**, along the center axis passing through the native mitral valve. Thus, when the outer sheath assembly **22**, mid shaft assembly **21**, inner assembly **18**, and nose cone assembly **31** are together advanced over the rail assembly **20** with the compressed implant **70**, the capsule **106** proceed directly in line with the axis for proper release of the implant **70**.

[0360] The user can also rotate and/or move the handle **14** itself in a stand for further fine tuning of the distal end of the delivery system **10**. The user can continually turn the proximal

and/or distal pull wire knobs **208/206**, as well as moving the handle **14** itself, to orient the delivery system **10** for release of the implant **70** in the body. The user can also further move the other assemblies relative to the rail assembly **20**, such as proximally or distally.

[0361] In a next step, the user can rotate the depth knob **212**. As discussed, rotation of this knob **212** together advances the inner shaft assembly **18**, mid shaft assembly **21**, outer sheath assembly **22**, and nose cone assembly **31** over/through the rail assembly **20** while the implant **70** remains in the compressed configuration within the implant retention area **16**. Due to the rigidity of, for example, either the inner shaft assembly **18**, the mid shaft assembly **21**, and/or the outer sheath assembly **22**, these assemblies proceed straight forward in the direction aligned by the rail assembly **20**.

[0362] Once in the release position, the user can rotate the outer sheath knob **210**, which individually translates the outer sheath assembly **22** (and thus the capsule **106**) with respect to the other assemblies, in particular the inner assembly **18**, in a proximal direction towards the handle **14** as shown in FIG. 64. By doing so, the distal end **303** of implant **70** is uncovered in the body, allowing for the beginning of expansion. At this point, the distal anchors **80** can flip proximally and the distal end **303** begins to expand radially outwardly. For example, if the system **10** has been delivered to a native mitral valve location through a transseptal approach, the nose cone is positioned in the left ventricle, preferably aligning the implant **70** such that it is generally perpendicular to the plane of the mitral annulus. The distal anchors **80** expand radially outwardly within the left ventricle. The distal anchors **80** can be located above the papillary heads, but below the mitral annulus and mitral leaflets. In some embodiments, the distal anchors **80** may contact and/or extend between the chordae in the left ventricle, as well as contact the leaflets, as they expand radially. In some embodiments, the distal anchors **80** may not contact and/or extend between the chordae or contact the leaflets. Depending on the position of the implant **70**, the distal ends of the distal anchors **80** may be at or below where the chordae connect to the free edge of the native leaflets.

[0363] As shown in the illustrated embodiment, the distal end **303** of the implant **70** is expanded outwardly. It should be noted that the proximal end **301** of the implant **70** can remain covered by the outer retention ring during this step such that the proximal end **301** remains in a radially compacted state. At this time, the system **10** may be withdrawn proximally so that the distal anchors **80** capture and engage the leaflets of the mitral valve, or may be moved proximally to reposition the implant **70**. For example, the assemblies may be proximally moved relative to the rail assembly **20**. Further, the system **10** may be torqued, which may

cause the distal anchors **80** to put tension on the chordae through which at least some of the distal anchors may extend between. However, in some embodiments the distal anchors **80** may not put tension on the chordae. In some embodiments, the distal anchors **80** may capture the native leaflet and be between the chordae without any further movement of the system **10** after withdrawing the outer sheath assembly **22**.

[0364] During this step, the system **10** may be moved proximally or distally to cause the distal or ventricular anchors **80** to properly capture the native mitral valve leaflets. This can be done by moving the outer sheath assembly **22**, mid shaft assembly **21**, inner assembly **18**, and nose cone assembly **31** with respect to the rail assembly **20**. In particular, the tips of the ventricular anchors **80** may be moved proximally to engage a ventricular side of the native annulus, so that the native leaflets are positioned between the anchors **80** and the body of the implant **70**. When the implant **70** is in its final position, there may or may not be tension on the chordae, though the distal anchors **80** can be located between at least some of the chordae.

[0365] The proximal end **301** of the implant **70** will remain in the outer retention ring **42** after retraction of the capsule **106**. As shown in FIG. 65, once the distal end **303** of the implant **70** is fully expanded (or as fully expanded as possible at this point), the outer retention ring **42** can be individually withdrawn proximally with respect to the other assemblies, in particular relative to the inner assembly **18**, to expose the inner retention member **40**, thus beginning the expansion of the proximal end **301** of the implant **70**. For example, in a mitral valve replacement procedure, after the distal or ventricular anchors **80** are positioned between at least some of the chordae tendineae and/or engage the native mitral valve annulus, the proximal end **301** of the implant **70** may be expanded within the left atrium.

[0366] The outer retention ring **42** can be moved proximally such that the proximal end **310** of the implant **70** can radially expand to its fully expanded configuration as shown in FIG. 66. After expansion and release of the implant **70**, the inner assembly **18**, nose cone assembly **31**, mid shaft assembly **21**, and outer sheath assembly **22** can be simultaneously withdrawn proximally along or relative to the rail assembly **20** back to their original position. In some embodiments, they are not withdrawn relative to the rail assembly **20** and remain in the extended position. Further, the nose cone **28** can be withdrawn through the center of the expanded implant **70** and into the outer sheath assembly **22**, such as by proximally translating the knob **216**. The system **10** can then be removed from the patient.

[0367] FIGS. 67A-B illustrate the advancement of the different assemblies over the rail assembly **20**. FIG. 67A illustrates the assemblies in their proximalmost position over the rail assembly **20**. FIG. 67B illustrates the assemblies in their distalmost position as compared to the rail assembly **20**, such as shown in FIG. 2C. Thus, the assemblies snake along the rail assembly **20** and extend distally away.

[0368] In some embodiments, the implant **70** can be delivered under fluoroscopy so that a user can view certain reference points for proper positioning of the implant **70**. Further, echocardiography can be used for proper positioning of the implant **70**.

[0369] Following is a discussion of an alternative implantation method for delivering a replacement mitral valve to a mitral valve location. Elements of the below can be incorporated into the above discussion and vice versa. Prior to insertion of the delivery system **10**, the access site into the patient can be dilated. Further, a dilator can be flushed with, for example, heparinized saline prior to use. The delivery system **10** can then be inserted over a guide wire. In some embodiments, any flush ports on the delivery system **10** can be pointed vertically. Further, if an introducer tube is used, integrated or otherwise, this can be stabilized. The delivery system **10** can be advanced through the septum until a distal end of the delivery system **10** is positioned across the septum into the left atrium **1078**. Thus, the distal end of the delivery system **10** can be located in the left atrium **1078**. In some embodiments, the delivery system **10** can be rotated, such as under fluoroscopy, into a desired position. The rail can be flex so that direct a distal end of the delivery system **10** towards the septum and mitral valve. The position of the delivery system **10**, and the implant **70** inside, can be verified using echocardiography and fluoroscopic guidance.

[0370] In some embodiments, the implant **70** can be located, prior to release, above the mitral annulus **1106**, in line with the mitral annulus **1106**, or below the mitral annulus **1106**. In some embodiments, the implant **70** can be located, prior to expansion, fully above the mitral annulus **1106**, in line with the mitral annulus **1106**, just below the mitral annulus **1106**, or fully below the mitral annulus **1106**. In some embodiments, the implant **70** can be located, prior to expansion, partially above the mitral annulus **1106**, in line with the mitral annulus **1106**, or partially below the mitral annulus **1106**. In some embodiments, a pigtail catheter can be introduced into the heart to perform a ventriculogram for proper viewing.

[0371] In some embodiments, the position of the mitral plane and the height of any papillary muscles on the fluoroscopy monitor can be marked to indicate an example target

landing zone. If needed, the delivery system **10** can be unflexed, reduced in rotation, and retracted to reduce tension on the delivery system **10** as well as reduce contact with the left ventricular wall, the left atrial wall, and/or the mitral annulus **1106**.

[0372] Further, the delivery system **10** can be positioned to be coaxial to the mitral annulus **1106**, or at least as much as possible, while still reducing contact with the left ventricular wall, the left atrial wall, and/or the mitral annulus **1106** and reducing delivery system tension. An echo probe can be positioned to view the anterior mitral leaflet (AML), the posterior mitral leaflet (PML) (leaflets **1108**), mitral annulus **1106**, and outflow tract. Using fluoroscopy and echo imaging, the implant **70** can be confirmed to be positioned at a particular depth and coaxiality with the mitral annulus **1106**.

[0373] Afterwards, the outer sheath assembly **22** can be retracted to expose the ventricular anchors **80**, thereby releasing them. In some embodiments, once exposed, the outer sheath assembly **22** can be reversed in direction to relieve tension on the outer sheath assembly **22**. In some embodiments, reversing the direction could also serve to partially or fully capture the implant **70**.

[0374] The distal anchors **80** can be released in the left atrium **1078**. Further, the proximal anchors **82**, if included in the implant **70**, are not yet exposed. Moreover, the body of the implant **70** has not undergone any expansion at this point. However, in some embodiments, one or more of the distal anchors **80** can be released in either the left atrium **1078** (e.g., super-annular release) or generally aligned with the mitral valve annulus **1106** (e.g., intra-annular release), or just below the mitral valve annulus **1106** (e.g., sub-annular release). In some embodiments, all of the distal anchors **80** can be released together. In other embodiments, a subset of the distal anchors **80** can be released while at a first position and another subset of the distal anchors **80** can be released while at a second position. For example, some of the distal anchors **80** can be released in the left atrium **1078** and some of the distal anchors **80** can be released while generally aligned with the mitral valve annulus **1106** or just below the mitral valve annulus **1106**.

[0375] If the distal anchors **80** are released “just below” the mitral valve annulus **1106**, the may be released at 1 inch, 3/4 inch, 1/2 inch, 1/4 inch, 1/8 inch, 1/10 inch or 1/20 inch below the mitral valve annulus **1106**. In some embodiments, the distal anchors **80** the may be released at less than 1 inch, 3/4 inch, 1/2 inch, 1/4 inch, 1/8 inch, 1/10 inch or 1/20 inch below the mitral valve annulus **1106**. This may allow the distal anchors **80** to snake through the chordae upon

release. This can advantageously allow the implant **70** to slightly contract when making the sharp turn down toward the mitral valve. In some embodiments, this may eliminate the need for a guide wire assisting to cross the mitral valve. In some embodiments, the guide wire may be withdrawn into the delivery system **10** before or following release of the distal anchors **80**.

[0376] In some embodiments, the distal anchors **80** can be released immediately after crossing the septum, and then the final trajectory of the delivery system **10** can be determined. Thus, the delivery system **10** can cross the septum, release the ventricular anchors **80**, establish a trajectory, and move into the left ventricle to capture the leaflets.

[0377] As discussed in detail above, upon release from the delivery system **10**, the distal anchors **80** can flip from extending distally to extending proximally. This flip can be approximately 180°. Accordingly, in some embodiments, the distal anchors **80** can be flipped in either the left atrium **1078** (e.g., super-annular flip), generally aligned with the mitral valve annulus **1106** (e.g., intra-annular flip), or just below the mitral valve annulus **1106** (e.g., sub-annular flip). The proximal anchors **82**, if any, can remain within the delivery system **10**. In some embodiments, all of the distal anchors **80** can be flipped together. In other embodiments, a subset of the distal anchors **80** can be flipped while at a first position and another subset of the distal anchors **80** can be released while at a second position. For example, some of the distal anchors **80** can be flipped in the left atrium **1078** and some of the distal anchors **80** can be flipped while generally aligned with the mitral valve annulus **1106** or just below the mitral valve annulus **1106**.

[0378] In some embodiments, the distal anchors **80** may be positioned in line with the annulus **1106** or just below the annulus **1106** in the non-flipped position. In some embodiments, the distal anchors **80** may be position in line with the annulus **1106** or just below the annulus **1106** in the flipped position. In some embodiments, prior to flipping the distalmost portion of the implant **70** can be located within or below the mitral valve annulus **1106**, such as just below the mitral valve annulus **1106**. However, flipping the anchors can cause, without any other movement of the delivery system **10**, the distalmost portion of the implant **70**/anchors **80** to move upwards, moving it into the left atrium **1078** or moving it in line with the mitral annulus **1106**. Thus, in some embodiments the distal anchors **80** can begin flipping at the annulus **1106** but be fully within the left atrium **1078** upon flipping. In some embodiments the distal anchors **80** can begin flipping below the annulus **1106** but be fully within the annulus **1106** upon flipping.

[0379] In some embodiments, the distal anchors **80** can be proximal (e.g., toward the left atrium **1078**) of a free edge of the mitral leaflets **1108** upon release and flipping. In some embodiments, the distal anchors **80** can be aligned with (e.g., toward the left atrium **1078**) a free edge of the mitral leaflets **1108** upon release and flipping. In some embodiments, the distal anchors **80** can be proximal (e.g., toward the left atrium **1078**) of a free edge of the mitral valve annulus **1106** upon release and flipping. In some embodiments, the distal anchors **80** can be aligned with (e.g., toward the left atrium **1078**) a free edge of the mitral valve annulus **1106** upon release and flipping.

[0380] Thus, in some embodiments the distal anchors **80** can be released/flipped above where the chordae **1110** attach to the free edge of the native leaflets **1108**. In some embodiments the distal anchors **80** can be released/flipped above where some the chordae **1110** attach to the free edge of the native leaflets **1108**. In some embodiments the distal anchors **80** can be released/flipped above where all the chordae **1110** attach to the free edge of the native leaflets **1108**. In some embodiments, the distal anchors **80** can be released/flipped above the mitral valve annulus **1106**. In some embodiments, the distal anchors **80** can be released/flipped above the mitral valve leaflets **1108**. In some embodiments, the distal anchors **80** can be released/flipped generally in line with the mitral valve annulus **1106**. In some embodiments, the distal anchors **80** can be released/flipped generally in line with the mitral valve leaflets **1108**. In some embodiments, the tips of the distal anchors **80** can be released/flipped generally in line with the mitral valve annulus **1106**. In some embodiments, the tips of the distal anchors **80** can be released/flipped generally in line with the mitral valve leaflets **1108**. In some embodiments the distal anchors **80** can be released/flipped below where some the chordae **1110** attach to the free edge of the native leaflets **1108**. In some embodiments the distal anchors **80** can be released/flipped below where all the chordae **1110** attach to the free edge of the native leaflets **1108**. In some embodiments, the distal anchors **80** can be released/flipped below the mitral valve annulus **1106**. In some embodiments, the distal anchors **80** can be released/flipped below the mitral valve leaflets **1108**.

[0381] Once the distal anchors **80** are released and flipped, the delivery system **10** can be translated towards the left ventricle **1080** through the mitral valve annulus **1106** so that the distal anchors **80** enter the left ventricle **1080**. In some embodiments, the distal anchors **80** can compress when passing through the mitral valve annulus **1106**. In some embodiments, the implant **70** can compress when passing through the mitral valve annulus **1106**. In some embodiments, the implant **70** does not compress when it passes through the mitral annulus

1106. The distal anchors **80** can be delivered anywhere in the left ventricle **1080** between the leaflets **1108** and the papillary heads.

[0382] In some embodiments, the distal anchors **80** are fully expanded prior to passing through the mitral valve annulus **1106**. In some embodiments, the distal anchors **80** are partially expanded prior to passing through the mitral valve annulus **1106** and continued operation of the delivery system **10** can fully expand the distal anchors **80** in the left ventricle **1080**.

[0383] When the distal anchors **80** enter the left ventricle **1080**, the distal anchors **80** can pass through the chordae **1110** and move behind the mitral valve leaflets **1108**, thereby capturing the leaflets **1108**. In some embodiments, the distal anchors **80** and/or other parts of the implant **70** can push the chordae **1110** and/or the mitral valve leaflets **1108** outwards.

[0384] Thus, after release of the distal anchors **80**, the delivery system **10** can then be repositioned as needed so that the ends of the left distal anchors **80** are at the same level of the free edge of the native mitral valve leaflets **1108**. The delivery system **10** can also be positioned to be coaxial to the mitral annulus **1106** if possible while still reducing contact with the left ventricular wall, the left atrial wall, and/or the annulus **1106**.

[0385] In some embodiments, only the distal anchors **80** are released in the left atrium **1078** before the implant **70** is move to a position within, or below, the annulus. In some alternate embodiments, the distal end of the implant **70** can be further expanded in the left atrium **1078**. Thus, instead of the distal anchors **80** flipping and no portion of the implant **70** body expanding, a portion of the implant **70** can be exposed and allowed to expand in the left atrium **1078**. This partially exposed implant **70** can then be passed through the annulus **1106** into the left ventricle **1080**. Further, the proximal anchors, if any, can be exposed. In some embodiments, the entirety of the implant **70** can be expanded within the left atrium **1078**.

[0386] To facilitate passage through the annulus **1106**, the delivery system **10** can include a leader element (not shown) which passes through the annulus **1106** prior to the implant **70** passing through the annulus **1106**. For example, the leader element can include an expandable member, such as an expandable balloon, which can help maintain the shape, or expand, the annulus **1106**. The leader element can have a tapered or rounded shape (e.g., conical, frustoconical, semispherical) to facilitate positioning through and expansion of the annulus **1106**. In some embodiments, the delivery system **10** can include an engagement element (not shown) which can apply a force on the implant **70** to force the implant **70** through the annulus

1106. For example, the engagement element can include an expandable member, such as an expandable balloon, positioned within or above the implant **70**.

[0387] In some embodiments, to facilitate passage through the annulus **1106**, a user can re-orient the implant **70** prior to passing the implant **70** through the annulus **1106**. For example, a user can re-orient the implant **70** such that it passes through the annulus **1106** sideways.

[0388] However, if only the distal anchors **80** are flipped, and no other expansion occurs, the prosthesis can be partially expanded in the ventricle **1080**. Thus, when the implant **70** is in the proper location, the distal end can be allowed to expand to capture the leaflets **1108**. If the distal end is already expanded, no more expansion may take place or the distal end can be further expanded.

[0389] Further, the PML and AML **1106** can be captured, for example by adjusting the depth and angle of the implant **70**. If a larger prosthesis diameter is needed to capture the leaflets **1108**, the outer sheath assembly **22** can be retracted until the desired diameter of the implant **70** is achieved. Capture of the leaflets **1108** can be confirmed through echo imaging. In some embodiments, a user can confirm that the implant **70** is still in the appropriate depth and has not advanced into the left ventricle **1080**. The position can be adjusted as needed.

[0390] In some embodiments, once the distal anchors **80** enter the left ventricle **1080** the system **10** can be pulled backwards (e.g., towards the left atrium **1078**) to fully capture the leaflets **1108**. In some embodiments, the system **10** does not need to be pulled backwards to capture the leaflets **1108**. In some embodiments, systolic pressure can push the leaflets **1108** upwards to be captured by the distal anchors **80**. In some embodiments, systolic pressure can push the entire implant **70** up towards the mitral annulus **1106** after the leaflets **1108** are captured and the implant **70** is fully or partially released. In some embodiments, a user can rotate the delivery system **10** and/or implant **70** prior to and/or while pulling the delivery system **10** backwards. In some instances, this can beneficially engage a greater number of chordae tendineae.

[0391] The outer sheath assembly **22** can be further retracted to fully expand the prosthesis. Once the implant **70** is fully exposed, the delivery system **10** can be maneuvered to be coaxial and height relative to the mitral annulus **1106**, such as by flexing, translating, or rotating the delivery system **10**. As needed, the implant **70** can be repositioned to capture the free edge of the native mitral valve leaflets **1108**. Once full engagement of the leaflets **1108** is confirmed, the implant **70** can be set perpendicular (or generally perpendicular) to the mitral annular plane.

[0392] Following, the mid shaft assembly **21** can be withdrawn. The mid shaft assembly **21** can then be reversed in direction to relieve any tension on the delivery system **10**.

[0393] Below is a discussion of proximal anchors **82**, though some embodiments of the implant **70** may not include them. In some embodiments, proximal anchors **82** may not be released from the system **10** until the distal anchors **80** have captured the leaflets **1108**. In some embodiments, proximal anchors **82** may be released from the system **10** prior to the distal anchors **80** capturing the leaflets **1108**. In some embodiments, the proximal anchors **82** can be released when the distal anchors **80** are super or intra annular and the expanded implant **70** (either partially or fully expanded) can be translated through the mitral annulus **1106**. In some embodiments, the proximal anchors **82** could be released when the distal anchors **80** are sub-annular and the entire implant **70** can be pulled up into the left atrium **1078** such that the proximal anchors **82** are supra-annular prior to release. In some embodiments, the proximal anchors **82** could be intra-annular prior to release and the systolic pressure could push the implant **70** atrially such that the proximal anchors **82** end up supra-annular.

[0394] After, the leaflet capture and positioning of the implant **70** can be confirmed, along with the relatively perpendicular position with respect to the mitral annular plane. In some embodiments, the nose cone **28** can then be withdrawn until it is within the implant **70**. The mid shaft assembly **21** can be further retracted until the implant **70** is released from the delivery system **10**. Proper positioning of the implant **70** can be confirmed using TEE and fluoroscopic imaging.

[0395] Following, the delivery system **10** can be centralized within the implant **70**. The nose cone **28** and delivery system **10** can then be retracted into the left atrium **1078** and removed.

[0396] This intra-super annulus release can have a number of advantages. For example, this allows the distal anchors **80** to be properly aligned when contacting the chordae **1110**. If the distal anchors **80** were released in the left ventricle **1080**, this could cause misalignment or damage to heart tissue, such as the leaflets **1108** or chordae **1110**.

[0397] In an alternate delivery approach, the delivery system **10** can be translated into the left ventricle **1080** prior to release of the implant **70**. Thus, the distal end of the implant **70**, and thus the distal anchors **80**, can be released and flipped partially, or fully within the left ventricle **1080**. Accordingly, in some embodiments the anchors **82** can be released/flipped below the mitral annulus **1106**, just below the mitral annulus **1106**, and/or below the free edges

of the leaflets **1108**. Further, the anchors **82** can be released above the papillary heads. Similar methodology as discussed above can then be used to properly position the implant **70** and remove the delivery system **10** to deliver the implant **70**. Further, in some embodiments the distal anchors **80** can be released without expanding the prosthesis initially in the ventricle **1080**.

[0398] Although many of the systems and methods disclosed herein have been discussed in regard to implantation of a prosthetic mitral valve implant, it is understood that the systems and methods may be utilized to deliver a variety of implants, including implants for repair of a heart valve. For example, other types of heart valve implants that may be utilized are shown in FIGS. 68-69, among other types of implants (e.g., aortic valve implants and other repair implants).

[0399] The methods and systems disclosed herein may in certain embodiments not be limited to delivery of implants, but may extend to any medical intervention or insertion into a patient's body, which may include performing a medical procedure within the body. The methods and systems disclosed herein may be utilized in general use of a catheter as desired. For example, the handle shown in FIGS. 35 and 37 and components disclosed therein may comprise a general catheter handle in certain embodiments. Further, the configuration of the delivery apparatus may be modified in other embodiments. For example, for an aortic valve delivery apparatus, the configuration of the implant retention area and other features of the delivery apparatus may be modified.

[0400] With reference next to FIGS. 68–69, an alternative embodiment of an implant **1600** in an expanded configuration is illustrated. The implant **1600** can include an inner frame **1620**, an outer frame **1640**, a valve body **1660**, and one or more skirts, such as an outer skirt **1680** and an inner skirt **1690**.

[0401] With reference first to the outer frame **1640** illustrated in FIGS. 68–69, the outer frame **1640** can be attached to the inner frame **1620** using any known fasteners and/or techniques. Although the outer frame **1640** is illustrated as a separate component from the inner frame **1620**, it is to be understood that the frames **1620**, **1640** can be unitarily or monolithically formed.

[0402] As shown in the illustrated embodiment, the outer frame **1640** can include an outer frame body **1642**. The outer frame body **1642** can have an upper region **1642a**, an intermediate region **1642b**, and a lower region **1642c**. At least a portion of the upper region **1642a** of the

outer frame body **1642** can be sized and/or shaped to generally match the size and/or shape of an upper region **1622a** of the inner frame **1620**. As shown in the illustrated embodiment, the upper region **1642a** of the outer frame body **1642** can include one or more struts which generally match the size and/or shape of struts of the inner frame **1620**. This can locally reinforce a portion of the implant **1600** by effectively increasing the wall thickness of the combined struts.

[0403] When in an expanded configuration such as in a fully expanded configuration, the intermediate region **1642b** and the lower region **1642c** can have a diameter which is larger than the diameter of the upper region **1642a**. The upper region **1642a** of the outer frame body **1642** can have a decreasing diameter from a lower end to an upper end such that the upper region **1642a** is inclined or curved radially inwards towards the longitudinal axis of the implant **1600**. Although the outer frame body **1642** has been described and illustrated as being cylindrical or having circular cross-sections, it is to be understood that all or a portion of the outer frame body **1642** can have a non-circular cross-section such as, but not limited to, a D-shape, an oval or an otherwise ovoid cross-sectional shape.

[0404] With continued reference to the outer frame **1640** illustrated in FIGS. 68–69, the outer frame body **1642** can include a plurality of struts with at least some of the struts forming cells **1646a-c**. Any number of configurations of struts can be used, such as rings of undulating struts shown forming ellipses, ovals, rounded polygons, and teardrops, but also chevrons, diamonds, curves, and various other shapes.

[0405] The upper row of cells **1646a** can have an irregular octagonal shape such as a “heart” shape. This additional space can beneficially allow the outer frame **1640** to retain a smaller profile when crimped. The cell **1646a** can be formed via a combination of struts. As shown in the illustrated embodiment, the upper portion of cells **1646a** can be formed from a set of circumferentially-expansible struts **1648a** having a zig-zag or undulating shape forming a repeating “V” shape. The struts **1648a** can extend radially outwardly from an upper end to a lower end. These struts can generally match the size and/or shape of struts of the inner frame **1620**.

[0406] The middle portion of cells **1646a** can be formed from a set of struts **1648b** extending downwardly from bottom ends of each of the “V” shapes. The struts **1648b** can extend radially outwardly from an upper end to a lower end. The portion of the cells **1646a**

extending upwardly from the bottom end of struts **1648b** may be considered to be a substantially non-foreshortening portion of the outer frame **1640**.

[0407] The lower portion of cells **1646a** can be formed from a set of circumferentially-expandable struts **1648c** having a zig-zag or undulating shape forming a repeating “V” shape. As shown in the illustrated embodiment, the struts **1648c** can incorporate a curvature such that the lower end of struts **1648c** extend more parallel with the longitudinal axis than the upper end of the struts **1648c**. One or more of the upper ends or tips of the circumferentially-expandable struts **1648c** can be a “free” apex which is not connected to a strut. For example, as shown in the illustrated embodiment, every other upper end or tip of circumferentially-expandable struts **1648b** is a free apex. However, it is to be understood that other configurations can be used. For example, every upper apex along the upper end can be connected to a strut.

[0408] The middle and/or lower rows of cells **1646b-c** can have a different shape from the cells **1646a** of the first row. The middle row of cells **1646b** and the lower row of cells **1646c** can have a diamond or generally diamond shape. The diamond or generally diamond shape can be formed via a combination of struts.

[0409] The upper portion of cells **1646b** can be formed from the set of circumferentially-expandable struts **1648c** such that cells **1646b** share struts with cells **1646a**. The lower portion of cells **1646b** can be formed from a set of circumferentially-expandable struts **1648d**. As shown in the illustrated embodiment, one or more of the circumferentially-expandable struts **1648d** can extend generally in a downward direction generally parallel to the longitudinal axis of the outer frame **1640**.

[0410] The upper portion of cells **1646c** can be formed from the set of circumferentially-expandable struts **1648d** such that cells **1646c** share struts with cells **1646b**. The lower portion of cells **1646c** can be formed from a set of circumferentially-expandable struts **1648e**. Circumferentially-expandable struts **1648e** can extend generally in a downward direction.

[0411] As shown in the illustrated embodiment, there can be a row of nine cells **1646a** and a row of eighteen cells **1646b-c**. While each of the cells **1646a-c** are shown as having the same shape as other cells **1646a-c** of the same row, it is to be understood that the shapes of cells **1646a-c** within a row can differ. Moreover, it is to be understood that any number of rows of cells can be used and any number of cells may be contained in the rows.

[0412] As shown in the illustrated embodiment, the outer frame **1640** can include a set of eyelets **1650**. The upper set of eyelets **1650** can extend from an upper region **1642a** of the

outer frame body **1642**. As shown, the upper set of eyelets **1650** can extend from an upper portion of cells **1646a**, such as the upper apices of cells **1646a**. The upper set of eyelets **1650** can be used to attach the outer frame **1640** to the inner frame **1620**. For example, in some embodiments, the inner frame **1620** can include one or more eyelets which correspond to the eyelets **1650**. In such embodiments, the inner frame **1620** and outer frame **1640** can be attached together via eyelets **1650** and corresponding eyelets on the inner frame **1620**. For example, the inner frame **1620** and outer frame **1640** can be sutured together through said eyelets or attached via other means, such as mechanical fasteners (e.g., screws, rivets, and the like).

[0413] As shown, the set of eyelets **1650** can include two eyelets extending in series from each “V” shaped strut. This can reduce the likelihood that the outer frame **1640** twists along an axis of the eyelet. However, it is to be understood that some “V” shaped struts may not include an eyelet. Moreover, it is to be understood that a fewer or greater number of eyelets can extend from a “V” shaped strut.

[0414] The outer frame **1640** can include a set of locking tabs **1652** extending from at or proximate an upper end of the upper region **1642a**. As shown, the locking tabs **1652** can extend upwardly from the set of eyelets **1650**. The outer frame **1640** can include twelve locking tabs **1652**, however, it is to be understood that a greater number or lesser number of locking tabs can be used. The locking tabs **1652** can include a longitudinally-extending strut **1652a**. At an upper end of the strut **1652a**, the locking tab **1652** can include an enlarged head **1652b**. As shown, the enlarged head **1652b** can have a semi-circular or semi-elliptical shape forming a “mushroom” shape with the strut **1652a**. The locking tab **1652** can include an eyelet **1652c** which can be positioned through the enlarged head **1652b**. It is to be understood that the locking tab **1652** can include an eyelet at other locations, or can include more than a single eyelet.

[0415] The locking tab **1652** can be advantageously used with multiple types of delivery systems. For example, the shape of the struts **1652a** and the enlarged head **1652b** can be used to secure the outer frame **1640** to a “slot” based delivery system, such as the inner retention member **40** described above. The eyelets **1652c** and/or eyelets **1650** can be used to secure the outer frame **1640** to a “tether” based delivery system such as those which utilize sutures, wires, or fingers to control delivery of the outer frame **1640** and the implant **1600**. This can advantageously facilitate recapture and repositioning of the outer frame **1640** and the implant **1600** in situ.

[0416] The outer frame **1640**, such as the outer frame body **1642** can be used to attach or secure the implant **1600** to a native valve, such as a native mitral valve. For example, the intermediate region **1642b** of the outer frame body **1642** and/or the outer anchoring feature **1644** can be positioned to contact or engage a native valve annulus, tissue beyond the native valve annulus, native leaflets, and/or other tissue at or around the implantation location during one or more phases of the cardiac cycle, such as systole and/or diastole. As another example, the outer frame body **1642** can be sized and positioned relative to the inner frame anchoring feature **1624** such that tissue of the body cavity positioned between the outer frame body **1642** and the inner frame anchoring feature **1624**, such as native valve leaflets and/or a native valve annulus, can be engaged or pinched to further secure the implant **1600** to the tissue. As shown, the inner frame anchoring feature **1624** includes nine anchors; however, it is to be understood that a fewer or greater number of anchors can be used. In some embodiments, the number of individual anchors can be chosen as a multiple of the number of commissures for the valve body **1660**. For example, for a valve body **1660** have three commissures, the inner frame anchoring feature **1624** can have three individual anchors (1:1 ratio), six individual anchors (2:1 ratio), nine individual anchors (3:1 ratio), twelve individual anchors (4:1 ratio), fifteen individual anchors (5:1 ratio), or any other multiple of three. In some embodiments, the number of individual anchors does not correspond to the number of commissures of the valve body **1660**.

[0417] With continued reference to the prosthesis **1600** illustrated in FIGS. 68–69, the valve body **1660** is attached to the inner frame **1620** within an interior of the inner frame body **1620**. The valve body **1660** functions as a one-way valve to allow blood flow in a first direction through the valve body **1660** and inhibit blood flow in a second direction through the valve body **1660**.

[0418] The valve body **1660** can include a plurality of valve leaflets **1662**, for example three leaflets **1662**, which are joined at commissures. The valve body **1660** can include one or more intermediate components **1664**. The intermediate components **1664** can be positioned between a portion of, or the entirety of, the leaflets **1662** and the inner frame **1620** such that at least a portion of the leaflets **1662** are coupled to the frame **1620** via the intermediate component **1664**. In this manner, a portion of, or the entirety of, the portion of the valve leaflets **1662** at the commissures and/or an arcuate edge of the valve leaflets **1662** are not directly coupled or attached to the inner frame **1620** and are indirectly coupled or “float” within the inner frame **1620**.

[0419] With reference next to the outer skirt **1680** illustrated in FIGS. 68–69, the outer skirt **1680** can be attached to the inner frame **1620** and/or outer frame **1640**. As shown, the outer skirt **1680** can be positioned around and secured to a portion of, or the entirety of, the exterior of the outer frame **1640**. The inner skirt **1690** can be attached to the valve body **1660** and the outer skirt **1680**. As shown in FIG. 69, a first end of the inner skirt **1690** can be coupled to the valve body **1660** along portions of the valve body **1660** which are proximate the inner frame **1620**. A second end of the inner skirt **1690** can be attached to the lower region of the outer skirt **1680**. In so doing, a smooth surface can be formed along under each of the leaflets. This can beneficially enhance hemodynamics by allowing blood to more freely circulate and reducing areas of stagnation.

[0420] Although the implant **1600** has been described as including an inner frame **1620**, an outer frame **1640**, a valve body **1660**, and skirts **1680**, **1690**, it is to be understood that the implant **1600** need not include all components. For example, in some embodiments, the implant **1600** can include the inner frame **1620**, the outer frame **1640**, and the valve body **1660** while omitting the skirt **1680**. Moreover, although the components of the implant **1600** have been described and illustrated as separate components, it is to be understood that one or more components of the implant **1600** can be integrally or monolithically formed. For example, in some embodiments, the inner frame **1620** and the outer frame **1640** can be integrally or monolithically formed as a single component.

[0421] The systems, apparatuses, and methods disclosed herein may be utilized in a recapture of an implant that has been fully or partially deployed. For example, in the methods disclosed in regard to FIGS. 61–67B, the capsule **106** may be configured to slide distally for recapture of an implant **70** that has been partially or possibly fully deployed. The capsule **106** may accordingly move distally to pull all or a portion of the implant **70** back into the capsule **106** to recapture the implant **70**.

[0422] With reference to FIG. 64, for example, an implant **70** is shown to be partially deployed from the capsule **106**. The arms of the implant **70**, in the form of distal anchors **80**, have extended outward from the capsule **106** and have bent in a proximal direction relative to their orientation when positioned within the capsule **106** (for example as shown in FIG. 2A). Notably, in this configuration, the distal anchors **80** may extend between chordae **1110** as shown for example in FIG. 62.

[0423] FIG. 70 illustrates a cross sectional view of the capsule **106** in a plane transverse to the axis of the capsule **106**. The distal anchors **80** are shown to extend radially outward from the outer surface of the capsule **106** as shown in a perspective view in FIG. 64 for example. The tips **3610** of the distal anchors **80** extend proximally as shown in a perspective view in FIG. 64 for example.

[0424] As shown in FIG. 70, the chordae **1110** may be positioned within a narrow spacing **3612** between adjacent distal anchors **80**. If the capsule **106** is advanced distally to recapture the implant **70** after full or partial deployment of the implant **70** then the distal anchors **80** may pinch the one or more chordae **1110** positioned within the narrow spacing **3612**. As the distal anchors **80** are pulled into the capsule **106**, the chordae **1110** may press against the capsule **106** at a radial distance that cause the chordae **1110** to pinch within the narrow spacing **3612**. This possible complication may produce injury to the chordae **1110** including possibly severing one or more chordae **1110**.

[0425] FIG. 71 illustrates a side cross sectional view of an embodiment of a capsule **3614** that has a distal end **3616** that is configured to expand radially outward. The capsule **3614** may otherwise be configured similarly as the capsule **106** or any other embodiment of capsule disclosed herein. For example, the capsule **3614** may be configured to surround an implant retention area.

[0426] The distal end **3616** may be configured to bend radially outward. The distal end **3616** as shown in FIG. 71 may be configured to bend radially outward relative to a proximal portion **3618** of the capsule **3614**. The distal end **3616** may include an opening **3620** for an implant **70** to be deployed from.

[0427] The distal end **3616** may be configured to flare outward relative to the proximal portion **3618** of the capsule **3614**. The distal end **3616** may include a contact surface **3622** that is configured to contact and apply a force to the chordae **1110** to wipe any chordae **1110** off of the anchors **80** as the anchors **80** are being retracted back into the capsule **3614** during recapture. The flaring of the distal end **3616** may allow the contact surface **3622** to contact the chordae **1110** at a greater radial position than the position of the chordae **1110** shown in FIG. 70, and as such the chordae **1110** may be less likely to be pinched within a narrow spacing **3612** between the anchors **80**. As such, the possibility for damage to the chordae **1110** may be reduced during a recapture of the implant **70**.

[0428] The distal end **3616** may be configured to flare outward passively, which may be caused by the outward force of the anchors **80** upon the interior surface of the distal end **3616**. In other embodiments, the distal end **3616** may be configured to be controlled to flare the distal end **3616** in a desired manner.

[0429] The distal end **3616** may be made of a flexible material, which may comprise an elastomer or another form of flexible material. The distal end **3616** may be configured to be pliable, and as such may form a large contact surface area against the anchors **80** to wipe the chordae **1110** off of the anchors **80**. The distal end **3616** may be pliable to pass within spacings between the anchors **80**. The distal end **3616** may be resilient to return back towards an initial shape of the distal end **3616** upon recapture of the implant **70**, and to resist permanent deformation during flaring of the distal end **3616**. Other configurations of distal ends **3616** may be utilized as desired.

[0430] FIG. 72 illustrates a side cross sectional view of an embodiment of a capsule **3624** that has a distal end **3626** that is configured to expand radially outward. The capsule **3624** may otherwise be configured similarly as the capsule **106** or any other embodiment of capsule disclosed herein. For example, the capsule **3624** may be configured to surround an implant retention area. The distal end **3626** of the capsule **3624** may be configured to expand radially outward by being inflated radially outward.

[0431] The distal end **3626** may include an inflatable body **3628** that is configured to inflate. The inflatable body **3628** may comprise a balloon or other form of inflatable body that is configured to inflate to cause the distal end **3626** to flare radially outward. The distal end **3626** may include a contact surface **3630** (marked in FIG. 73) that operates similarly as the contact surface **3622** shown in FIG. 71. As such, the contact surface **3630** of the distal end **3626** may be configured to contact and wipe any chordae **1110** off of the anchors **80** as the anchors **80** are being retracted back into the capsule **3624** during recapture. The flaring of the distal end **3626** may allow the contact surface **3630** to contact the chordae **1110** at a greater radial position than the position of the chordae **1110** shown in FIG. 70, and as such the chordae **1110** may be less likely to be pinched within a narrow spacing **3612** between anchors **80**. As such, the possibility for damage to the chordae **1110** may be reduced during a recapture of the implant **70**. The inflatable body **3628** may be compliant, to allow a portion of the inflatable body **3628** to be positioned between the anchors **80**.

[0432] The distal end **3626** may be configured to vary in size. FIG. 72 illustrates the distal end **3626** in an unexpanded, uninflated, or undeployed configuration, and FIG. 73 illustrates the distal end **3626** in an expanded, inflated, or deployed configuration. The distal end **3626** in the expanded, inflated, or deployed configuration has a greater size and a greater radial extent than in the unexpanded, uninflated, or undeployed configuration. At least one inflation conduit **3632** may extend along the elongate shaft of the delivery system and be configured to inflate the inflatable body **3628** of the distal end **3626** with fluid or other substances for inflating the distal end **3626**. The inflation conduits **3632** may be controlled from a proximal portion of the delivery system to inflate or deflate the distal end **3626** and thus control the size and radial extent of the distal end **3626**.

[0433] The distal end **3626** may be configured to be expanded, inflated, or deployed at a desired time for recapture of the implant, and may then be unexpanded, deflated, or undeployed following recapture, or following a time for withdrawal of the delivery system from a portion of the patient's body. As such, the distal end **3626** may move from a configuration shown in FIG. 73 back to a configuration shown in FIG. 72. Other configurations of distal ends **3626** may be utilized as desired.

[0434] The embodiments disclosed herein may be utilized in a method including deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule surrounding an implant retention area retaining an implant for implantation within the patient's body. The capsule may be moved proximally to expose a portion of the implant within the patient's body. The capsule may then be moved distally to recapture a portion of the implant within the patient's body and to pass a distal end **3616**, **3626** of the capsule that is expanded radially outward over the portion of the implant that is recaptured. The portion of the implant that is recaptured may include arms of the implant, which may comprise anchors of the implant. The distal end **3616**, **3626** of the capsule may be positioned between the arms of the implant, to allow the distal end **3616**, **3626** to press against chordae between the arms of the implant. The method may include pushing chordae off of the arms of the implant with the distal end **3616**, **3626** of the capsule.

[0435] The embodiments of distal ends disclosed in FIGS. 71–73 may be utilized solely or with any embodiment of a delivery system or other system, apparatus, or method disclosed herein.

[0436] FIGS. 74A and 74B illustrate an embodiment in which a delivery system may utilize a pull tether **3700** that is coupled to a portion of the elongate shaft of the delivery system at or distal the implant retention area and is configured to deflect the distal end of the elongate shaft. Referring to FIG. 2B, for example, the implant retention area **16** is shown to be surrounded by the capsule **106** and has the nose cone shaft **27** extending within the implant retention area **16**. The steerable rail assembly **20**, however, is positioned proximal of the implant retention area **16**. As such, upon bending of the steerable rail assembly **20**, the nose cone **28** at the distal end of the elongate shaft follows the bend created by the steerable rail assembly **20** at a position proximal of the implant retention area **16**. The embodiment of FIGS. 74A and 74B, however, couples the pull tether **3700** at a position that is at or distal the implant retention area **16**. As such, greater torque and control of the distal end of the delivery system may result.

[0437] In the embodiment shown in FIGS. 74A and 74B, for example, a distal end of the pull tether **3700** is coupled to the nose cone **28**. The distal end of the pull tether **3700** may be positioned at a distal portion of the nose cone **28**. For example, the nose cone **28** may include a proximal portion **3702** and a distal portion **3704** and the pull tether **3700** may be coupled to the distal portion **3704** of the nose cone **28**. The distal coupling position of the pull tether **3700** may increase the torque that is provided upon the nose cone **28**. In other embodiments, other coupling positions may be utilized, such as on the proximal portion **3702** of the nose cone **28**.

[0438] The pull tether **3700** may have a variety of forms and may comprise a pull wire as disclosed herein or another form of tether. The pull tether **3700** as shown in FIGS. 74A and 74B may have at least a portion that extends external to the elongate shaft. Such a configuration may allow for increased torque upon the distal end of the elongate shaft. At least a portion of the pull tether **3700** may then extend within a channel **3706** internal to the elongate shaft such that the pull tether **3700** does not extend entirely external to the elongate shaft. For example, as shown in FIGS. 74A and 74B, the pull tether **3700** may extend external to the capsule **106**. The pull tether **3700** may be pulled and released to control the deflection of the distal end of the elongate shaft.

[0439] The distal end of the pull tether **3700** may be coupled to other locations as desired. For example, referring to FIG. 2B, the distal end of the pull tether **3700** may be coupled to the interior nose cone shaft **27** that is coupled to the nose cone **28**. The implant retention area **16** may include a proximal portion **3708** and a distal portion **3710**, and the pull tether **3700** may be coupled to a portion of the elongate shaft within the distal portion **3710** of the implant retention area **16**. As such, the pull tether **3700** may provide torque to the distal end of the

elongate shaft that is in addition to any torque provided by the steerable rail assembly **20** that is positioned proximal of the implant retention area **16** and is configured to deflect a portion of the elongate shaft that is positioned proximal of the implant retention area **16**.

[0440] The innermost assembly of the elongate shaft, as shown in FIG. 2B as the nose cone assembly **31** may accordingly be steerable. The pull tether **3700** may extend proximally from the distal end of the elongate shaft for manipulation at a proximal end of the delivery system to control the deflection of the distal end of the delivery system.

[0441] The coupling of the pull tether **3700** to a portion of the elongate shaft of the delivery system at or distal the implant retention area may allow for greater control of the distal end of the elongate shaft. As such, the nose cone **28** forming the tip of the elongate shaft and the nose cone shaft **27** may have additional directions and degrees of flex than provided by the steerable rail assembly **20**. Further, the pull tether **3700** may provide for flex distal of the steerable rail assembly **20**. The pull tether **3700** may thus allow for tighter turns and greater precision of control of the distal end of the elongate shaft. In embodiments, the pull tether **3700** may be configured to allow for flex in a same plane as provided by the steerable rail assembly **20**, or in a different plane.

[0442] The pull tether **3700** may also allow the use of a guide wire to be eliminated if desired. For example, the nose cone shaft **27** may lack an internal lumen for the guide wire. The additional control provided by the pull tether **3700** may allow the distal end of the elongate shaft to be controlled such that a guide wire is not needed to direct the distal end of the elongate shaft. In other embodiments, a guide wire may be utilized. The configuration of the pull tether **3700** may be varied in other embodiments.

[0443] In embodiments herein, the delivery system may include two elongate shafts, or at least two elongate shafts, that may be utilized in combination to deliver an implant to a location within a patient's body. A first elongate shaft may be steerable, and another or second elongate shaft may include an implant retention area that is configured to retain the implant and may include a deployment mechanism. Each elongate shaft may include a respective axis that the shaft extends along. A coupler may couple the elongate shafts to each other such that the elongate shaft including the implant may slide relative to the steerable elongate shaft, with the axes of the shafts offset from each other.

[0444] FIG. 79, for example, illustrates an embodiment of a steerable elongate shaft **3900** of a delivery system. The elongate shaft **3900** may be steerable utilizing mechanisms disclosed

herein, for example via the use of pull tethers, or may be steerable via another mechanism. The elongate shaft **3900** may be configured to form one or more bends in the elongate shaft **3900** and may be configured to be steerable and bend in at least one plane, or at least two planes as disclosed herein. The steerable elongate shaft **3900** may be configured to be inserted into the patient's body and moved to the desired implantation site for the implant.

[0445] The elongate shaft **3900** may be configured to be steerable and may be constructed in a similar manner as a rail assembly **20** as disclosed herein. For example, pull tethers may be utilized to control the deflection of the elongate shaft **3900** in one or more planes, or at least two planes as desired. Unlike the rail assembly **20** disclosed herein, the elongate shaft **3900** may be inserted into the patient's body without the implant and that capsule retaining the implant.

[0446] The embodiments disclosed herein may be utilized in a method including deploying an elongate shaft to a location within a patient's body, the elongate shaft including a proximal end and a distal end and an implant retention area retaining an implant for implantation within a patient's body. The method may include deflecting the distal end of the elongate shaft utilizing a pull tether to a portion of the elongate shaft at or distal the implant retention area. The pull tether **3700** and configuration of the pull tether **3700** may be utilized solely or with any of the other apparatuses, systems, or methods disclosed herein.

[0447] The elongate shaft **3900** may include an interior lumen **3902** that may be configured to retain components for the delivery system, such as an imaging sensor **3904**, such as an ultrasound intra-cardiac echo (ICE) sensor, or other form of imaging sensor as desired that is configured to be positioned within the interior lumen **3902**. A distal end **3906** of the shaft **3900** may include an inflatable body **3908** that may be configured to inflate to secure the distal end **3906** of the shaft **3900** in a position and/or determine if the pathway formed by the shaft **3900** is clear of obstructions (e.g., the distal end **3906** does not pass between chordae of a patient's heart).

[0448] The elongate shaft **3900** may be introduced first into a patient's body and steered to the desired implantation site.

[0449] Referring to FIG. 80, the elongate shaft **3910** may comprise a shaft configured to retain the implant for deployment. The shaft **3910**, for example, may include a capsule **3912** at a distal end that retains the implant. The capsule **3912** may surround the implant retention area and retain the implant therein, as disclosed herein. The shaft **3910** may include a

deployment mechanism for deploying the implant from the capsule **3912** as disclosed herein. For example, the capsule **3912** may be retracted to expose and deploy the implant. The shaft **3910** may be flexible, and passively flexible, to allow the shaft **3910** to follow the path that is formed by the steerable elongate shaft **3900**.

[0450] A coupler **3914** may couple the elongate shaft **3910** to the steerable elongate shaft **3900**. The coupler **3914** may have a variety of forms and may include a loop as shown in FIG. 80, or may comprise one or more of a magnet, a hook, a loop, or a joint between the shafts **3910**, **3900**. The coupler **3914** may be configured to allow the elongate shaft **3910** to slide relative to the shaft **3900**. In embodiments, the coupling may occur within the patient's body, or may occur outside the patient's body as desired.

[0451] The elongate shafts **3900**, **3910** may be coupled together such that the respective axes of the shafts **3900**, **3910** are offset from each other. The coupler **3914** may be configured to couple the shafts **3900**, **3910** to each other such that the shafts **3900**, **3910** may slide with the respective axes of the shafts **3900**, **3910** parallel with each other, and with the outer surfaces of the shafts **3900**, **3910** adjacent to each other. As such, the deployment mechanism (utilized with elongate shaft **3910**) may be separated into a separate shaft than the steering mechanism (utilized with elongate shaft **3900**). The complexity of each shaft accordingly may be reduced from an embodiment shown in FIG. 1. Further, the capsule **3912** in such an embodiment is not positioned distal of a bend portion, which may enhance the maneuverability of the capsule **3912** in an embodiment as shown in FIG. 80.

[0452] In embodiments, the coupler **3914** may be configured to couple the shafts **3900**, **3910** together in a defined orientation. For example, a joint such as a dovetail joint may be provided on either shaft **3900**, **3910** such that the shafts **3900**, **3910** may only couple in a defined orientation. As such, a circumferential position of the **3900** relative to the shaft **3910** may be defined. Such a feature may be beneficial in an embodiment in which an asymmetric implant is deployed. Such an implant may be deployed with the steerable shaft **3900** in a defined position that may aid the deployment of the asymmetric implant. In embodiments, the coupler **3914** may be configured such that the coupling may be rotated to orient the implant to optimize the position of the implant for deployment. In other embodiments, other forms of coupling may be utilized.

[0453] Referring back to FIG. 79, in operation, the steerable elongate shaft **3900** may be advanced to the desired location for implantation within the patient's body. The steerable

elongate shaft **3900** may be bent in a desired configuration, and may retain that configuration within the patient's body. The distal end **3906** of the elongate shaft **3900** for example, may be steered to the mitral valve, or other valve as desired. In embodiments, as shown in FIG. 80, the inflatable body **3908** may be inflated to secure the distal end **3906** of the shaft **3900** in a position and/or determine if the pathway formed by the shaft **3900** is clear of obstructions.

[0454] The steerable elongate shaft **3900** in position within the patient's body may serve as a rail that the elongate shaft **3910** having the implant is slid along. The elongate shaft **3910** may be passed through a separate entry point in the patient's body, for example, a separate leg or separate venous body of the patient's body. In embodiments, the coupler **3914** may couple the shafts **3900**, **3910** together within the patient's body such that the shaft **3910** may slide along the steerable shaft **3900**. The shaft **3910** may be advanced through the patient's body along the steerable shaft **3900** to the desired implantation site as shown in FIG. 80.

[0455] The shaft **3910** may be configured to deflect about any bend in the steerable shaft **3900** as shown in FIG. 81. The deflection of the shaft **3910** may be passive if desired. The shaft **3910** may then be utilized to deploy the implant from the capsule **3912**. A deployment mechanism as disclosed herein may be operated and the capsule **3912** may be retracted to deploy the implant. Following deployment, the shaft **3910** may be withdrawn, and then the shaft **3900** may be subsequently withdrawn. The configuration of the shafts **3900**, **3910** may be utilized solely or with any of the other apparatuses, systems, or methods disclosed herein.

[0456] From the foregoing description, it will be appreciated that an inventive product and approaches for implant delivery systems are disclosed. While several components, techniques and aspects have been described with a certain degree of particularity, it is manifest that many changes can be made in the specific designs, constructions and methodology herein above described without departing from the spirit and scope of this disclosure. The disclosure is not limited to the system and apparatuses disclosed herein, but also the methods of utilizing such systems and apparatuses.

[0457] Certain features that are described in this disclosure in the context of separate implementations can also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation can also be implemented in multiple implementations separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations, one or more features from a claimed combination can, in some cases, be excised from the

combination, and the combination may be claimed as any subcombination or variation of any subcombination.

[0458] Moreover, while methods may be depicted in the drawings or described in the specification in a particular order, such methods need not be performed in the particular order shown or in sequential order, and that all methods need not be performed, to achieve desirable results. Other methods that are not depicted or described can be incorporated in the example methods and processes. For example, one or more additional methods can be performed before, after, simultaneously, or between any of the described methods. Further, the methods may be rearranged or reordered in other implementations. Also, the separation of various system components in the implementations described above should not be understood as requiring such separation in all implementations, and it should be understood that the described components and systems can generally be integrated together in a single product or packaged into multiple products. Additionally, other implementations are within the scope of this disclosure.

[0459] Conditional language, such as “can,” “could,” “might,” or “may,” unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include or do not include, certain features, elements, and/or steps. Thus, such conditional language is not generally intended to imply that features, elements, and/or steps are in any way required for one or more embodiments.

[0460] Conjunctive language such as the phrase “at least one of X, Y, and Z,” unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such conjunctive language is not generally intended to imply that certain embodiments require the presence of at least one of X, at least one of Y, and at least one of Z.

[0461] Language of degree used herein, such as the terms “approximately,” “about,” “generally,” and “substantially” as used herein represent a value, amount, or characteristic close to the stated value, amount, or characteristic that still performs a desired function or achieves a desired result. For example, the terms “approximately,” “about,” “generally,” and “substantially” may refer to an amount that is within less than or equal to 10% of, within less than or equal to 5% of, within less than or equal to 1% of, within less than or equal to 0.1% of, and within less than or equal to 0.01% of the stated amount. If the stated amount is 0 (e.g., none, having no), the above recited ranges can be specific ranges, and not within a particular

% of the value. For example, within less than or equal to 10 wt./vol. % of, within less than or equal to 5 wt./vol. % of, within less than or equal to 1 wt./vol. % of, within less than or equal to 0.1 wt./vol. % of, and within less than or equal to 0.01 wt./vol. % of the stated amount.

[0462] Some embodiments have been described in connection with the accompanying drawings. The figures are drawn to scale, but such scale should not be limiting, since dimensions and proportions other than what are shown are contemplated and are within the scope of the disclosed inventions. Distances, angles, etc. are merely illustrative and do not necessarily bear an exact relationship to actual dimensions and layout of the devices illustrated. Components can be added, removed, and/or rearranged. Further, the disclosure herein of any particular feature, aspect, method, property, characteristic, quality, attribute, element, or the like in connection with various embodiments can be used in all other embodiments set forth herein. Additionally, it will be recognized that any methods described herein may be practiced using any device suitable for performing the recited steps.

[0463] While a number of embodiments and variations thereof have been described in detail, other modifications and methods of using the same will be apparent to those of skill in the art. Accordingly, it should be understood that various applications, modifications, materials, and substitutions can be made of equivalents without departing from the unique and inventive disclosure herein or the scope of the claims.

WHAT IS CLAIMED IS:

1. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:
 - an elongate shaft having a proximal end and a distal end, and including:
 - an implant retention area configured to retain the implant, and
 - a capsule configured to surround the implant retention area and including a hypotube having one or more cuts forming a plurality of rings.
2. The delivery system of claim 1, wherein the hypotube includes one or more spines connecting at least two of the plurality of rings.
3. The delivery system of claim 2, wherein the one or more spines extend longitudinally along the hypotube.
4. The delivery system of any of claims 1–3, wherein the one or more cuts bias a flexibility of the hypotube in a direction.
5. The delivery system of claim 4, wherein the hypotube includes two spines each configured to extend along a neutral axis of bend when the hypotube is bent in the direction.
6. The delivery system of any of claims 1–5, wherein the one or more cuts include a first cut circumferentially spaced from a second cut, with a size of the first cut being larger than a size of the second cut.
7. The delivery system of any of claims 1–6, wherein the one or more cuts include a first plurality of cuts each being longitudinally aligned and having a larger size than a second plurality of cuts that are each longitudinally aligned and are each circumferentially spaced from the first plurality of cuts.
8. The delivery system of claim 7, wherein the first plurality of cuts are located on the hypotube on an opposing side of the hypotube than the second plurality of cuts.

9. The delivery system of any of claims 4–8, wherein the direction is a first direction, and the one or more cuts bias a flexibility of the hypotube in a second direction.
10. The delivery system of any of claims 1–9, wherein the one or more cuts include a repeating pattern of staggered cuts.
11. The delivery system of any of claims 1–10, wherein the hypotube includes a first pair of spines positioned 180 degrees from each other, and a second pair of spines positioned 180 degrees from each other and offset 90 degrees from the first pair of spines.
12. The delivery system of any of claims 1–11, wherein the hypotube includes a distal section in which the one or more cuts bias a flexibility of the distal section in a single direction, and the hypotube includes a proximal section in which the one or more cuts bias a flexibility of the proximal section in at least two directions.
13. The delivery system of any of claims 1–12, wherein the one or more cuts form a spiral.
14. The delivery system of any of claims 1–13, wherein the hypotube includes one or more spines connecting at least two of the plurality of rings.
15. The delivery system of any of claims 1–14, wherein the plurality of rings are configured to contact each other when a force is applied to the hypotube in a distal direction.
16. The delivery system of any of claims 1–15, wherein the one or more cuts include a repeating pattern of staggered cuts that each have an equal size.
17. The delivery system of any of claims 1–16, wherein the one or more cuts provide equal flexibility of the hypotube in all radial directions.
18. The delivery system of any of claims 1–17, wherein the hypotube includes a first pair of spines positioned 180 degrees from each other, and a second pair of spines offset 90 degrees from the first pair of spines.

19. The delivery system of any of claims 1–18, wherein the capsule is configured to move proximally relative to the implant retention area to allow the implant to deploy.
20. The delivery system of any of claims 1–19, wherein the capsule is configured to move distally relative to the implant retention area to recapture the implant.
21. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:
- an elongate shaft having a proximal end and a distal end, and including:
 - an implant retention area configured to retain the implant, and
 - a capsule configured to surround the implant retention area and including a hypotube having one or more cuts that bias a flexibility of the hypotube in a direction.
22. The delivery system of claim 21, wherein the hypotube includes two spines each configured to extend along a neutral axis of bend when the hypotube is bent in the direction.
23. The delivery system of claim 21 or claim 22, wherein the one or more cuts include a first cut circumferentially spaced from a second cut, with a size of the first cut being larger than a size of the second cut.
24. The delivery system of any of claims 21–23, wherein the one or more cuts include a first plurality of cuts each being longitudinally aligned and having a larger size than a second plurality of cuts that are each longitudinally aligned and are each circumferentially spaced from the first plurality of cuts.
25. The delivery system of claim 24, wherein the first plurality of cuts are located on the hypotube on an opposing side of the hypotube than the second plurality of cuts.
26. The delivery system of claim 24 or claim 25, wherein a size of the first plurality of cuts is configured to be reduced when the hypotube is bent in the direction.
27. The delivery system of any of claims 21–26, wherein the direction is a first direction, and the one or more cuts bias a flexibility of the hypotube in a second direction.

28. The delivery system of any of claims 21–27, wherein the one or more cuts include a repeating pattern of staggered cuts.

29. The delivery system of any of claims 21–28, wherein the hypotube includes a first pair of spines positioned 180 degrees from each other, and a second pair of spines offset 90 degrees from the first pair of spines.

30. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant, and

a capsule configured to surround the implant retention area and including a hypotube having one or more cuts forming a spiral.

31. The delivery system of claim 30, wherein the hypotube includes one or more spines extending longitudinally along the hypotube.

32. The delivery system of claim 31, wherein the one or more spines includes a first spine and a second spine that is offset circumferentially from the first spine.

33. The delivery system of any of claims 30–32, wherein the spiral forms a plurality of rings that are configured to contact each other when a force is applied to the hypotube in a distal direction.

34. The delivery system of any of claims 30–33, wherein the spiral provides equal flexibility of the hypotube in all radial directions.

35. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule surrounding an implant retention area retaining an implant for implantation within the patient's body, the capsule including a hypotube having one or more cuts forming a plurality of rings;

moving the capsule proximally to expose a portion of the implant within the patient's body; and

moving the capsule distally to recapture a portion of the implant within the patient's body.

36. The method of claim 35, wherein the one or more cuts bias a flexibility of the hypotube in a direction.

37. The method of claim 36, further comprising bending the capsule in the direction when moving the capsule proximally.

38. The method of any of claims 35–37, wherein the plurality of rings contact each other when the capsule is moved distally.

39. The method of any of claims 35–38, wherein the one or more cuts provide equal flexibility of the hypotube in all radial directions.

40. The method of any of claims 35–39, wherein the one or more cuts form a spiral.

41. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant,
a capsule configured to surround the implant retention area,
a shaft portion positioned proximal of the capsule, and
a coupler configured to couple the capsule to the shaft portion and configured to allow the capsule to rotate relative to the shaft portion.

42. The delivery system of claim 41, wherein the coupler includes a protrusion positioned within a channel.

43. The delivery system of claim 42, wherein the protrusion includes material deflected into the channel.

44. The delivery system of claim 42 or claim 43, wherein the channel comprises a window, and the protrusion comprises a pin configured to slide along the window.

45. The delivery system of any of claims 41–44, wherein the elongate shaft includes a rail assembly configured to bend in at least one plane.

46. The delivery system of claim 45, wherein the capsule includes a hypotube having one or more cuts that bias a flexibility of the hypotube in a direction.

47. The delivery system of claim 46, wherein the coupler is configured to allow the capsule to rotate to align the direction with a direction of bend of the rail assembly.

48. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule and a shaft portion positioned proximal of the capsule and a coupler coupling the capsule to the shaft portion and configured to allow the capsule to rotate relative to the shaft portion, the capsule surrounding an implant retention area retaining an implant for implantation within the patient's body; and

moving the capsule proximally to expose a portion of the implant within the patient's body while the capsule rotates relative to the shaft portion.

49. The method of claim 48, wherein the capsule has a flexibility that is biased in a direction, and the capsule rotates to align the direction with a direction of bend of a rail assembly of the elongate shaft.

50. The method of claim 49, wherein the capsule passively rotates to align the direction of bias of the capsule with the direction of bend of the rail assembly of the elongate shaft.

51. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant,

a sheath having an interior lumen,

an interior shaft positioned within the interior lumen, and

an inflatable body positioned between the interior shaft and the sheath and configured to inflate to support the sheath.

52. The delivery system of claim 51, wherein the inflatable body includes one or more balloons.

53. The delivery system of claim 51 or claim 52, wherein the sheath includes a capsule configured to surround the implant retention area, and the inflatable body is configured to support the capsule.

54. The delivery system of any of claims 51–53, wherein the elongate shaft includes an inner shaft, and the interior shaft comprises a middle shaft positioned between the inner shaft and the sheath.

55. The delivery system of claim 54, wherein the middle shaft includes a retention ring for retaining the implant within the implant retention area.

56. The delivery system of any of claims 51–55, wherein the elongate shaft is steerable and configured to bend, and the inflatable body is configured to support the sheath at a bend of the elongate shaft.

57. The delivery system of any of claims 51–56, wherein the sheath includes a hypotube having one or more cuts forming a plurality of rings, and the inflatable body is configured to support the plurality of rings of the hypotube.

58. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a sheath and an interior shaft positioned within an interior lumen of the sheath and an implant retention area retaining an implant for implantation within the patient's body;

moving the sheath proximally to expose a portion of the implant within the patient's body;

inflating an inflatable body between the sheath and the interior shaft; and

moving the sheath distally to recapture a portion of the implant within the patient's body while the inflatable body is inflated between the sheath and the interior shaft to support the sheath.

59. The method of claim 58, wherein the sheath includes a capsule that is moved distally to recapture the portion of the implant.

60. The method of claim 58 or claim 59, wherein the inflatable body when inflated fills a space between the sheath and the interior shaft.

61. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

- an elongate shaft having a proximal end and a distal end, and including:

- an implant retention area configured to retain the implant, and

- a wall of the elongate shaft including:

- an outer jacket layer,

- an interior liner layer,

- a braid layer positioned between the outer jacket layer and the interior liner layer, and

- a metal layer positioned between the braid layer and the interior liner layer.

62. The delivery system of claim 61, further comprising a buffer layer positioned between the outer jacket layer and the braid layer to prevent flow of the outer jacket layer into the braid layer.

63. The delivery system of claim 62, wherein the buffer layer is made of a polymer and the outer jacket layer is made of polymer.

64. The delivery system of claim 62 or claim 63, wherein the buffer layer is made of expanded polytetrafluoroethylene.

65. The delivery system of any of claims 61–64, wherein the metal layer includes one or more of a coil or a hypotube having one or more cuts forming a plurality of rings.

66. The delivery system of any of claims 61–65, wherein the braid layer is configured to compress against the metal layer upon an axial force being applied to the braid layer.

67. The delivery system of any of claims 61–66, wherein the elongate shaft includes a sheath having an interior lumen, and an interior shaft positioned within the interior lumen, and wherein one or more of the sheath or the interior shaft includes the wall.

68. The delivery system of any of claims 61–67, wherein the elongate shaft includes a capsule configured to surround the implant retention area, and the capsule includes the wall.

69. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

- an elongate shaft having a proximal end and a distal end, and including:

- an implant retention area configured to retain the implant,

- a sheath configured to bend in at least one plane, and

- a cable having a first end portion, a second end portion, and an intermediate portion extending between the first end portion and the second end portion, the first end portion coupled to a first side of the sheath and the second end portion coupled to a second side of the sheath opposite the first side;

- a cable router configured to engage the intermediate portion of the cable and allow the cable to move along the cable router when the sheath is bent in the at least one plane; and

- a control mechanism for retracting the cable router and the sheath relative to the implant retention area.

70. The delivery system of claim 69, wherein the cable router comprises one or more of a pulley wheel or a channel.

71. The delivery system of claim 69 or claim 70, wherein the intermediate portion of the cable loops about the cable router.

72. The delivery system of any of claims 69–71, wherein the cable router is configured to engage the intermediate portion of the cable such that a length of the cable between the cable router and the first end portion of the cable increases and a length of the cable between the

cable router and the second end portion of the cable simultaneously decreases when the sheath is bent in the at least one plane.

73. The delivery system of claim 72, wherein an amount of the increase of the length of the cable between the cable router and the first end portion of the cable is equal to an amount of the decrease of the length of the cable between the cable router and the second end portion of the cable.

74. The delivery system of any of claims 69–73, wherein the sheath includes a capsule configured to surround the implant retention area.

75. The delivery system of any of claims 69–74, wherein the first side of the sheath and the second side of the sheath are both positioned in the at least one plane and are separated by an interior lumen of the sheath.

76. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a sheath and a cable having a first end portion, a second end portion, and an intermediate portion extending between the first end portion and the second end portion, the first end portion coupled to a first side of the sheath and the second end portion coupled to a second side of the sheath opposite the first side, the intermediate portion engaged with a cable router;

bending the sheath in a plane such that a length of the cable between the cable router and the first end portion increases and a length of the cable between the cable router and the second end portion decreases; and

retracting the cable router and the sheath relative to the implant retention area.

77. The method of claim 76, wherein the cable router is positioned in a handle coupled to the elongate shaft and comprises one or more of a pulley wheel or a channel.

78. The method of claim 76 or claim 77, wherein the intermediate portion of the cable loops about the cable router.

79. The method of any of claims 76–78, wherein an amount of the increase of the length of the cable between the cable router and the first end portion of the cable is equal to an amount of the decrease of the length of the cable between the cable router and the second end portion of the cable.

80. The method of any of claims 76–79, wherein the sheath includes a capsule configured to surround the implant retention area.

81. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

- an elongate shaft having a proximal end and a distal end, and including:

- an implant retention area configured to retain the implant,

- a sheath having an interior lumen and a capsule configured to surround the implant retention area,

- an interior shaft positioned within the interior lumen, and

- a stop positioned on the interior shaft and configured to impede proximal movement of the capsule relative to the interior shaft.

82. The delivery system of claim 81, wherein the stop includes a protrusion extending radially outward from the interior shaft.

83. The delivery system of claim 82, wherein the protrusion is configured such that a proximal force overcomes the protrusion and allows the capsule to move proximally relative to the interior shaft.

84. The delivery system of any of claims 81–83, wherein the stop includes a threading on the interior shaft.

85. The delivery system of any of claims 81–84, wherein the interior shaft is configured to rotate relative to the capsule to allow the capsule to move proximally relative to the interior shaft.

86. The delivery system of any of claims 81–85, wherein the stop includes a keyed shape on the interior shaft, and the sheath is configured to move relative to the interior shaft to

accommodate the keyed shape to allow the capsule to move proximally relative to the interior shaft.

87. The delivery system of any of claims 81–86, wherein the stop is positioned on the interior shaft such that the capsule may move proximally to only partially expose the implant upon the stop impeding proximal movement of the capsule relative to the interior shaft.

88. The delivery system of claim 87, wherein the capsule is configured to allow for full exposure of the implant upon the proximal movement of the capsule impeded by the stop being overcome.

89. The delivery system of any of claims 81–88, wherein the elongate shaft includes an inner shaft, and the interior shaft comprises a middle shaft positioned between the inner shaft and the sheath.

90. The delivery system of any of claims 81–89, wherein the sheath includes a shaft portion positioned proximal of the capsule and coupled to the capsule, and the stop is configured to contact the shaft portion to impede proximal movement of the capsule relative to the interior shaft.

91. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a sheath having an interior lumen and a capsule retaining an implant for implantation within the patient's body, the sheath including an interior shaft and a stop positioned on the interior shaft;

moving the capsule proximally to expose a first portion of the implant within the patient's body until the sheath contacts the stop; and

overcoming the stop and moving the capsule proximally to expose a second portion of the implant within the patient's body that is positioned proximal of the first portion of the implant.

92. The method of claim 91, wherein the stop includes a protrusion extending radially outward from the interior shaft.

93. The method of claim 92, wherein overcoming the stop includes applying a proximal force to the sheath to overcome a contact force applied by the stop.

94. The method of any of claims 91–93, wherein the stop includes a threading on the interior shaft.

95. The method of any of claims 91–94, wherein overcoming the stop includes rotating the interior shaft relative to the capsule.

96. The method of any of claims 91–95, wherein the stop includes a keyed shape on the interior shaft, and overcoming the stop includes moving the sheath relative to the interior shaft to accommodate the keyed shape.

97. The method of any of claims 91–96, wherein the stop is positioned on the interior shaft at a location that defines an amount of the implant that is exposed by the capsule.

98. The method of any of claims 91–97, further comprising fully releasing the implant from an implant retention area.

99. The method of any of claims 91–98, wherein the elongate shaft includes an inner shaft, and the interior shaft comprises a middle shaft positioned between the inner shaft and the sheath.

100. The method of any of claims 91–99, wherein the sheath includes a shaft portion positioned proximal of the capsule and coupled to the capsule, and the stop is configured to contact the shaft portion to impede proximal movement of the capsule relative to the interior shaft.

101. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and an implant retention area, and an assembly configured to retain at least a portion of the implant within the implant retention area; and

a handle coupled to the proximal end of the elongate shaft and including a control knob configured to be rotated to move the assembly to release at least the portion of the implant from

the implant retention area, the control knob including an outer grip surface that is exposed for gripping around an entire outer circumference of the control knob.

102. The delivery system of claim 101, wherein the assembly includes a capsule configured to surround the implant retention area and be moved proximally by the control knob to release at least the portion of the implant from the implant retention area.

103. The delivery system of claim 101 or claim 102, wherein the assembly includes a sheath that extends around an interior shaft of the elongate shaft.

104. The delivery system of any of claims 101–103, wherein the assembly includes a retention ring configured to extend over at least the portion of the implant and be moved proximally by the control knob to release at least the portion of the implant from the implant retention area.

105. The delivery system of any of claims 101–104, wherein the assembly includes an interior shaft positioned within a sheath of the elongate shaft.

106. The delivery system of any of claims 101–105, wherein the control knob is a first control knob, and the assembly is a first assembly, and the delivery system further comprises:

- a second assembly including a capsule configured to surround the implant retention area to retain at least a portion of the implant within the implant retention area; and

- a second control knob configured to be rotated to move the capsule to release at least the portion of the implant retained by the capsule from the implant retention area, the second control knob including an outer grip surface that is exposed for gripping around an entire outer circumference of the second control knob.

107. The delivery system of claim 106, wherein the first control knob and the second control knob are both coupled to a housing of the handle.

108. The delivery system of any of claims 101–107, wherein the handle includes:

- a housing having an interior cavity,

- a beam positioned within the interior cavity and including a channel, and

- a slider positioned within the channel and coupled with the assembly; and

wherein the control knob is configured to rotate to cause the slider to slide along the channel to move the assembly.

109. The delivery system of claim 108, wherein the beam has a “u” shape.

110. The delivery system of claim 108 or claim 109, wherein the control knob couples to a body having threading that engages threading of the slider, to allow rotation of the control knob to rotate the body and axially slide the slider.

111. The delivery system of any of claims 108–110, wherein the control knob includes a stop configured to stop axial movement of the slider.

112. The delivery system of any of claims 108–111, wherein the beam is suspended between the threading of the body and the slider.

113. The delivery system of any of claims 108–112, wherein the housing includes one or more supports for supporting the beam.

114. The delivery system of any of claims 108–113, wherein the housing includes a wall for preventing rotation of the beam within the interior cavity.

115. The delivery system of any of claims 101–114, wherein the elongate shaft includes a nose cone positioned distal of the implant retention area, and the control knob is a first control knob, and the handle includes a second control knob configured to be rotated to move the nose cone proximally or distally relative to the implant retention area, the second control knob including an outer grip surface that is exposed for gripping around an entire outer circumference of the second control knob.

116. A method comprising:

deploying a delivery apparatus to a location within a patient’s body, the delivery apparatus including an elongate shaft and a handle coupled to a proximal end of the elongate shaft, the elongate shaft including an implant retention area retaining an implant for implantation within the patient’s body and an assembly configured to retain at least a portion of the implant within the implant retention area, the handle including a control knob configured

to be rotated to move the assembly to release at least the portion of the implant from the implant retention area and including an outer grip surface that is exposed for gripping around an entire outer circumference of the control knob;

gripping the grip surface of the control knob; and

rotating the control knob to move the assembly to release at least the portion of the implant from the implant retention area.

117. The method of claim 116, wherein the control knob is not gripped over a bridge of the handle.

118. The method of claim 116 or claim 117, wherein the assembly includes a capsule configured to surround the implant retention area and rotating the control knob moves the capsule proximally to release at least the portion of the implant from the implant retention area.

119. The method of any of claims 116–118, wherein the assembly includes a retention ring configured to extend over at least the portion of the implant and rotating the control knob moves the retention ring proximally to release at least the portion of the implant from the implant retention area.

120. The method of any of claims 116–119, wherein the handle includes:

a housing having an interior cavity;

a beam positioned within the interior cavity and including a channel; and

a slider positioned within the channel and coupled with the assembly; and

wherein rotating the control knob causes the slider to slide along the channel to move the assembly.

121. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant, and

a marker configured to enhance an echogenicity of the elongate shaft to define a location of a portion of the elongate shaft when viewed with ultrasound imaging.

122. The delivery system of claim 121, wherein the marker includes a contoured portion forming an edge of the portion of the elongate shaft.

123. The delivery system of claim 121 or claim 122, wherein the marker includes a planar surface facing distally.

124. The delivery system of any of claims 121–123, wherein the marker includes one or more edges forming a spiral.

125. The delivery system of any of claims 121–124, wherein the elongate shaft includes a tip positioned distal of the implant retention area, and the tip includes the marker.

126. The delivery system of any of claims 121–125, wherein the marker includes a contoured portion forming a pattern on the portion of the elongate shaft.

127. The delivery system of claim 126, wherein the pattern includes a plurality of indentations on the portion of the elongate shaft.

128. The delivery system of any of claims 121–127, wherein the marker includes a first material having an acoustic impedance that differs from an acoustic impedance of a second material of the elongate shaft that is adjacent the first material.

129. The delivery system of claim 128, wherein the marker includes a ring including a plurality of apertures.

130. The delivery system of claim 129, wherein the second material is positioned within the plurality of apertures.

131. The delivery system of claim 129 or claim 130, wherein the ring extends about a longitudinal axis of the elongate shaft, and the plurality of apertures are positioned circumferentially about the longitudinal axis.

132. The delivery system of any of claims 129–131, wherein each of the plurality of apertures have an oblong shape and are positioned on the ring such that adjacent apertures overlap in an axial dimension and in a transverse dimension.

133. The delivery system of any of claims 121–132, wherein the elongate shaft includes a capsule configured to surround the implant retention area, and the capsule includes the marker.

134. The delivery system of any of claims 128–133, wherein the first material is encapsulated within the second material.

135. The delivery system of any of claims 128–134, wherein the elongate shaft includes a nose cone having a smooth tapered profile, and the marker is encapsulated within the nose cone such that the second material forms an outer surface of the nose cone.

136. The delivery system of any of claims 121–135, wherein the marker includes a plurality of fins extending radially.

137. The delivery system of any of claims 121–136, wherein the marker is configured to be activated.

138. The delivery system of claim 137, wherein a first portion of the elongate shaft is configured to move relative to a second portion of the elongate shaft to activate the marker.

139. The delivery system of claim 138, wherein the first portion of the elongate shaft is configured to move relative to the second portion of the elongate shaft to form a gap.

140. The delivery system of claim 138 or claim 139, wherein the first portion of the elongate shaft is configured to move axially or rotate relative to the second portion of the elongate shaft to activate the marker.

141. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's

body and a marker that enhances an echogenicity of the elongate shaft to define a location of a portion of the elongate shaft when viewed with ultrasound imaging.

142. The method of claim 141, wherein the marker includes a contoured portion forming an edge of the portion of the elongate shaft.

143. The method of claim 141 or claim 142, wherein the marker is coupled to a tip of the elongate shaft and appears more brightly viewed with ultrasound imaging than remaining portions of the tip.

144. The method of any of claims 141–143, wherein the marker includes a first material having an acoustic impedance that differs from an acoustic impedance of a second material of the elongate shaft that is adjacent the first material.

145. The method of any of claims 141–144, wherein the marker includes a ring including a plurality of apertures.

146. The method of claim 145, wherein the ring extends about a longitudinal axis of the elongate shaft, and the plurality of apertures are positioned circumferentially about the longitudinal axis.

147. The method of any of claims 141–146, wherein the elongate shaft includes a capsule configured to surround the implant retention area, and the capsule includes the marker.

148. The method of any of claims 141–147, further comprising activating the marker.

149. The method of claim 148, further comprising moving a first portion of the elongate shaft relative to a second portion of the elongate shaft to activate the marker.

150. The method of claim 149, further comprising forming a gap by moving the first portion of the elongate shaft relative to the second portion of the elongate shaft.

151. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:
an implant retention area configured to retain the implant, and
a capsule configured to surround the implant retention area and including a distal end configured to expand radially outward.

152. The delivery system of claim 151, wherein the distal end is configured to bend radially outward.

153. The delivery system of claim 151 or claim 152, wherein the capsule includes a proximal portion, and the distal end is configured to bend radially outward relative to the proximal portion.

154. The delivery system of any of claims 151–153, wherein the distal end includes an opening for the implant to be deployed from.

155. The delivery system of any of claims 151–154, wherein the distal end is made of a flexible material.

156. The delivery system of any of claims 151–155, wherein the distal end is made of a pliable material.

157. The delivery system of any of claims 151–156, wherein the distal end includes a contact surface configured to apply a force to chordae of the patient's heart.

158. The delivery system of any of claims 151–157, wherein the distal end is configured to inflate radially outward.

159. The delivery system of any of claims 151–158, wherein the distal end includes an inflatable body that is configured to inflate.

160. The delivery system of claim 159, further comprising at least one inflation conduit extending along the elongate shaft and configured to inflate the inflatable body.

161. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a capsule surrounding an implant retention area retaining an implant for implantation within the patient's body;

moving the capsule proximally to expose a portion of the implant within the patient's body; and

moving the capsule distally to recapture a portion of the implant within the patient's body and to pass a distal end of the capsule that is expanded radially outward over the portion of the implant that is recaptured.

162. The method of claim 161, wherein the portion of the implant that is recaptured includes arms of the implant.

163. The method of claim 162, further comprising positioning the distal end of the capsule between the arms of the implant.

164. The method of claim 162 or claim 163, wherein the arms of the implant comprise anchors.

165. The method of any of claims 161–164, wherein the distal end of the capsule is bent radially outward.

166. The method of any of claims 161–165, wherein the distal end of the capsule is made of a flexible material.

167. The method of any of claims 161–166, wherein the distal end of the capsule is inflated radially outward.

168. The method of any of claims 161–167, wherein the distal end of the capsule includes an inflatable body that is configured to inflate.

169. The method of any of claims 161–168, wherein the distal end of the capsule includes a contact surface, and the method further comprises applying the contact surface to chordae of the patient's heart.

170. The method of any of claims 161–169, wherein the portion of the implant that is recaptured includes anchors of the implant, and the method further comprises pushing chordae off of the anchors of the implant with the distal end of the capsule.

171. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant, and

a pull tether coupled to a portion of the elongate shaft at or distal the implant retention area and configured to deflect the distal end of the elongate shaft.

172. The delivery system of claim 171, wherein the elongate shaft includes a nose cone at the distal end of the elongate shaft and the pull tether is coupled to the nose cone.

173. The delivery system of claim 172, wherein the nose cone includes a proximal portion and a distal portion and the pull tether is coupled to the distal portion of the nose cone.

174. The delivery system of any of claims 171–173, wherein at least a portion of the pull tether extends external to the elongate shaft.

175. The delivery system of any of claims 171–174, wherein at least a portion of the pull tether extends within a channel internal to the elongate shaft.

176. The delivery system of any of claims 171–175, wherein the elongate shaft includes a capsule surrounding the implant retention area, and at least the portion of the pull tether extends external to the capsule.

177. The delivery system of any of claims 171–176, wherein the elongate shaft includes a nose cone at the distal end of the elongate shaft and an interior shaft coupled to the nose cone and extending within the implant retention area, and the pull tether is coupled to the interior shaft.

178. The delivery system of any of claims 171–177, wherein the implant retention area includes a distal portion and a proximal portion, and the pull tether is coupled to the portion of the elongate shaft within the distal portion of the implant retention area.

179. The delivery system of any of claims 171–178, wherein the elongate shaft includes a steerable rail assembly positioned proximal of the implant retention area.

180. The delivery system of claim 179, wherein the steerable rail assembly is configured to deflect a portion of the elongate shaft positioned proximal of the implant retention area.

181. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including:

an implant retention area configured to retain the implant,

a nose cone positioned at the distal end of the elongate shaft, and

a pull tether coupled to the nose cone and configured to deflect the nose cone.

182. The delivery system of claim 181, wherein the nose cone includes a proximal portion and a distal portion and the pull tether is coupled to the distal portion of the nose cone.

183. The delivery system of claim 181 or claim 182, wherein at least a portion of the pull tether extends external to the elongate shaft.

184. The delivery system of any of claims 181–183, wherein at least a portion of the pull tether extends within a channel internal to the elongate shaft.

185. The delivery system of any of claims 181–184, wherein the elongate shaft includes a capsule surrounding the implant retention area, and at least the portion of the pull tether extends external to the capsule.

186. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including a proximal end and a distal end and an implant retention area retaining an implant for implantation within the patient's body; and

deflecting the distal end of the elongate shaft utilizing a pull tether coupled to a portion of the elongate shaft at or distal the implant retention area.

187. The method of claim 186, wherein the elongate shaft includes a nose cone at the distal end of the elongate shaft and the pull tether is coupled to the nose cone.

188. The method of claim 186 or claim 187, wherein at least a portion of the pull tether extends external to the elongate shaft.

189. The method of any of claims 186–188, wherein the elongate shaft includes a capsule surrounding the implant retention area, and at least the portion of the pull tether extends external to the capsule.

190. The method of any of claims 186–189, wherein the elongate shaft includes a nose cone at the distal end of the elongate shaft and an interior shaft coupled to the nose cone and extending within the implant retention area, and the pull tether is coupled to the interior shaft.

191. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

- a first elongate shaft having a proximal end and a distal end and extending along a first axis and being steerable;

- a second elongate shaft having a proximal end and a distal end and extending along a second axis and including an implant retention area configured to retain the implant; and

- a coupler configured to couple the second elongate shaft to the first elongate shaft such that the second elongate shaft may slide relative to the first elongate shaft with the second axis offset from the first axis.

192. The delivery system of claim 191, wherein the coupler is configured to couple the second elongate shaft to the first elongate shaft such that the second elongate shaft may slide relative to the first elongate shaft with the second axis parallel with the first axis.

193. The delivery system of claim 191 or claim 192, wherein the first elongate shaft includes an outer surface and the second elongate shaft includes an outer surface, and the coupler is configured to couple the second elongate shaft to the first elongate shaft such that the outer surface of the first elongate shaft is adjacent to the outer surface of the second elongate shaft.

194. The delivery system of any of claims 191–193, wherein the second elongate shaft includes a capsule configured to surround the implant retention area and retain the implant therein.

195. The delivery system of any of claims 191–194, wherein the coupler comprises one or more of a magnet, a hook, a loop, or a joint.

196. The delivery system of any of claims 191–195, wherein the first elongate shaft is configured to be steerable in at least one plane.

197. The delivery system of any of claims 191–196, wherein the first elongate shaft is configured to be steerable in at least two planes.

198. The delivery system of any of claims 191–197, wherein the second elongate shaft is configured to deflect about a bend in the first elongate shaft.

199. The delivery system of any of claims 191–198, further comprising an inflatable body at the distal end of the first elongate shaft.

200. The delivery system of any of claims 191–199, wherein the first elongate shaft includes an interior lumen, and further comprising an imaging sensor configured to be positioned within the interior lumen.

201. A method comprising:

deploying a first elongate shaft to a location within a patient's body, the first elongate shaft extending along a first axis and being steerable; and

sliding a second elongate shaft along the first elongate shaft to a location within the patient's body, the second elongate shaft being coupled to the first elongate shaft and extending along a second axis that is offset from the first axis and including an implant retention area retaining an implant therein.

202. The method of claim 201, further comprising sliding the second elongate shaft with the second axis parallel with the first axis.

203. The method of claim 201 or claim 202, wherein the first elongate shaft includes an outer surface and the second elongate shaft includes an outer surface, and the method further comprises sliding the second elongate shaft such that the outer surface of the first elongate shaft is adjacent to the outer surface of the second elongate shaft.

204. The method of any of claims 201–203, wherein the second elongate shaft includes a capsule surrounding the implant retention area, and the method further comprises retracting the capsule to deploy the implant.

205. The method of any of claims 201–204, wherein a coupler couples the second elongate shaft to the first elongate shaft and comprises one or more of a magnet, a hook, a loop, or a joint.

206. The method of any of claims 201–205, further comprising steering the first elongate shaft in at least one plane.

207. The method of any of claims 201–206, further comprising steering the first elongate shaft in at least two planes.

208. The method of any of claims 201–207, further comprising deflecting the second elongate shaft about a bend in the first elongate shaft.

209. The method of any of claims 201–208, further comprising inflating an inflatable body at a distal end of the first elongate shaft.

210. The method of any of claims 201–209, wherein the first elongate shaft includes an interior lumen, and the method further comprises positioning an imaging sensor within the interior lumen.

211. A delivery system for delivering an implant to a location within a patient's body, the delivery system comprising:

an elongate shaft having a proximal end and a distal end, and including an implant retention area configured to retain the implant, and

a covering layer on the elongate shaft including reinforcing fibers or beads.

212. The delivery system of claim 211, wherein the covering layer includes polytetrafluoroethylene (PTFE) mixed with the reinforcing fibers or beads.

213. The delivery system of claim 211 or claim 212, wherein the covering layer forms an interior liner of the elongate shaft.

214. The delivery system of any of claims 211–213, wherein the elongate shaft includes an outer sheath, and the covering layer forms an interior liner of the outer sheath.

215. The delivery system of any of claims 211–214, wherein the elongate shaft includes a capsule configured to surround the implant retention area, and the covering layer forms an interior liner of the capsule.

216. The delivery system of any of claims 211–215, wherein the reinforcing fibers or beads comprise one or more of silicate or carbon.

217. The delivery system of any of claims 211–216, wherein the reinforcing fibers or beads comprise glass.

218. A method comprising:

deploying an elongate shaft to a location within a patient's body, the elongate shaft including an implant retention area retaining an implant for implantation within the patient's body and a covering layer including reinforcing fibers or beads.

219. The method of claim 218, wherein the covering layer includes polytetrafluoroethylene (PTFE) mixed with the reinforcing fibers or beads.

220. The method of claim 218 or claim 219, wherein the covering layer forms an interior liner of the elongate shaft.

221. The method of any of claims 218–220, wherein the elongate shaft includes a capsule configured to surround the implant retention area, and the covering layer forms an interior liner of the capsule.

222. The method of claim 221, further comprising retracting the capsule and sliding the interior liner along the implant.

223. The method of any of claims 218–222, wherein the reinforcing fibers or beads comprise one or more of silicate or carbon.

224. The method of any of claims 218–223, wherein the reinforcing fibers or beads comprise glass.

225. A method comprising:

preparing a mixture of polytetrafluoroethylene (PTFE) with reinforcing fibers or beads;
and

providing an elongate shaft for a delivery system for delivering an implant to a location within a patient's body, the elongate shaft including the mixture of the polytetrafluoroethylene (PTFE) with the reinforcing fibers or beads as a covering layer of the elongate shaft.

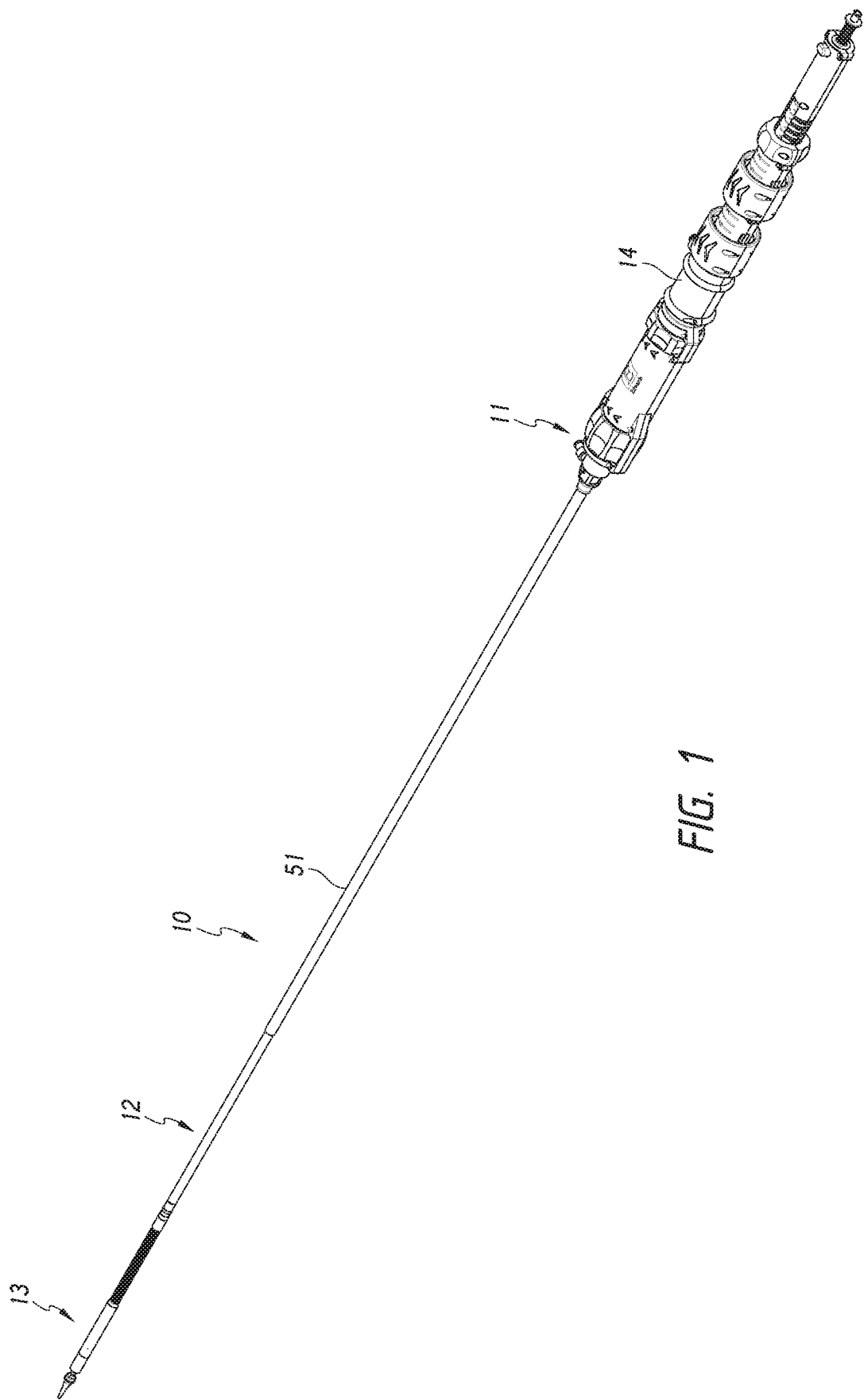
226. The method of claim 225, further comprising extruding the mixture of the polytetrafluoroethylene (PTFE) with the reinforcing fibers or beads.

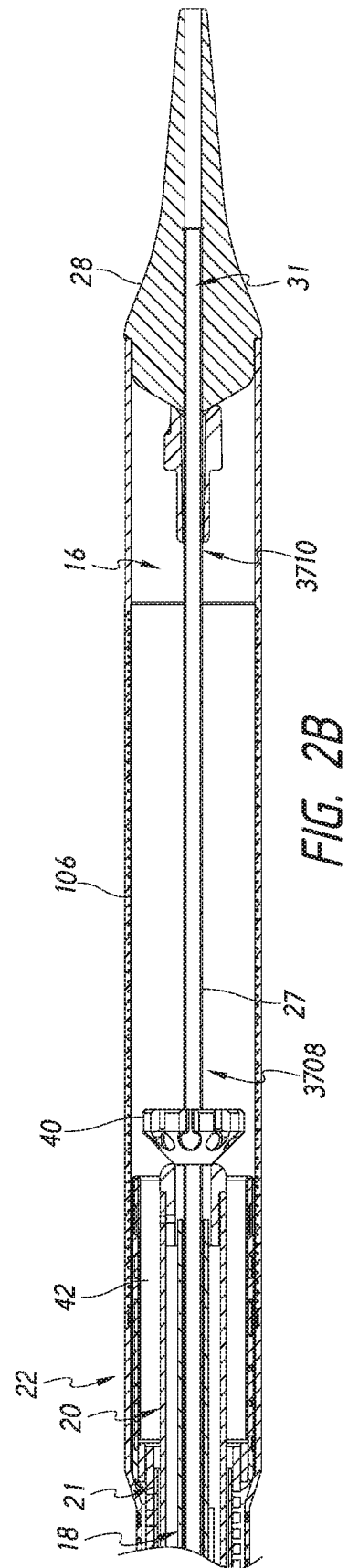
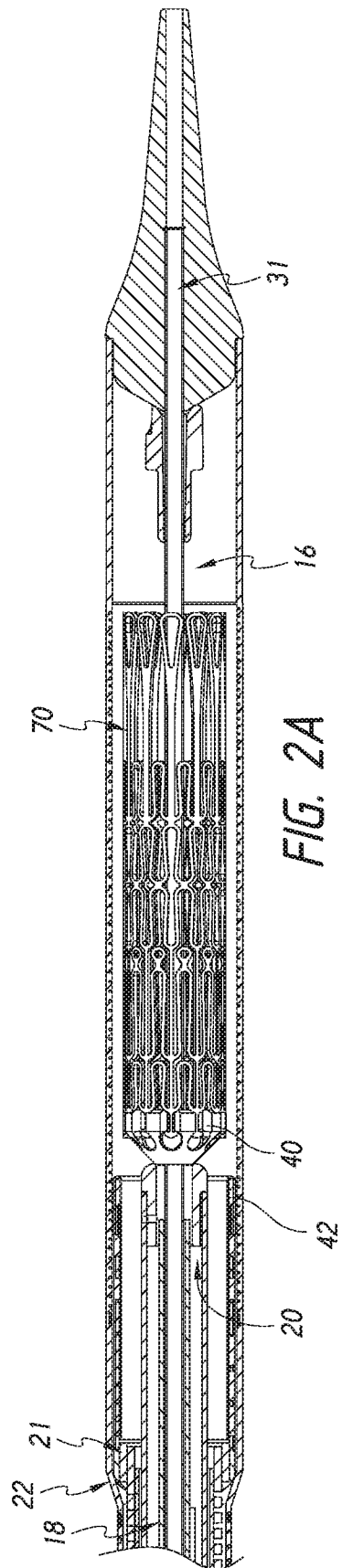
227. The method of claim 225 or claim 226, wherein the elongate shaft includes an outer sheath, and the covering layer forms an interior liner of the outer sheath.

228. The method of any of claims 225–227, wherein the elongate shaft includes a capsule configured to surround an implant retention area for retaining the implant, and the covering layer forms an interior liner of the capsule.

229. The method of any of claims 225–228, wherein the reinforcing fibers or beads comprise one or more of silicate or carbon.

230. The method of any of claims 225–229, wherein the reinforcing fibers or beads comprise glass.





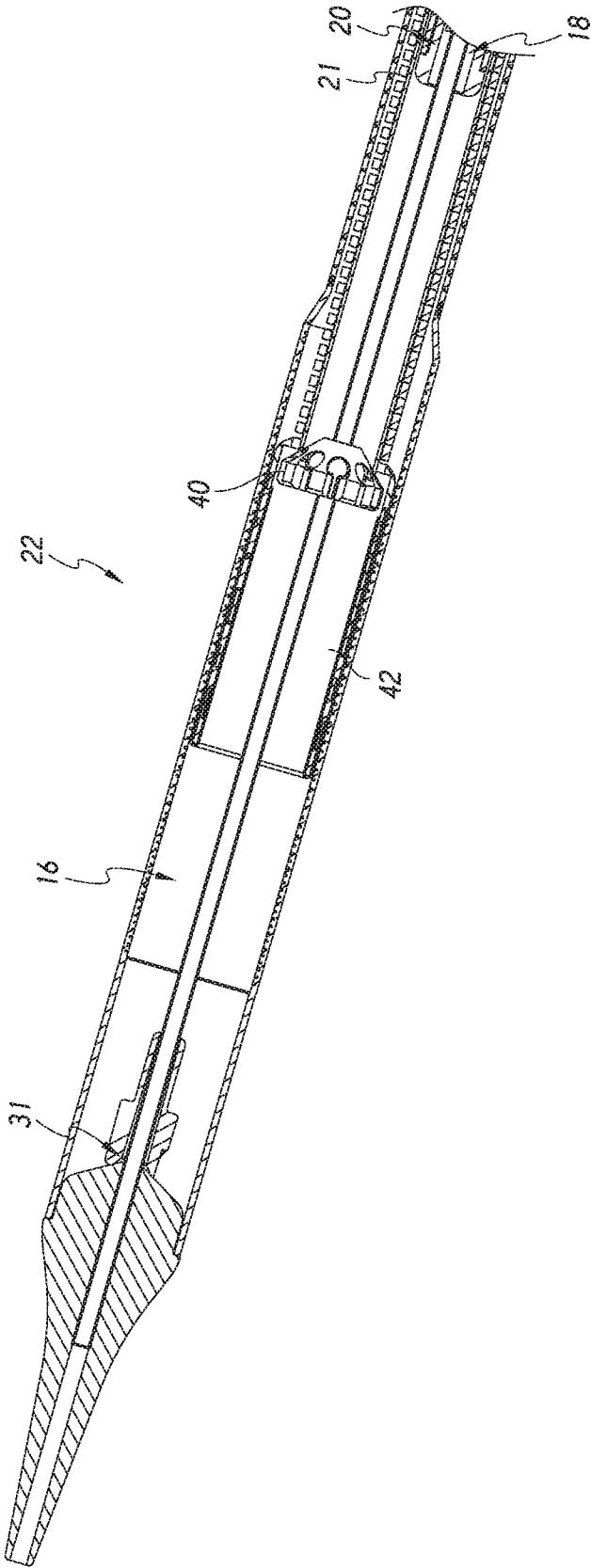


FIG. 2C

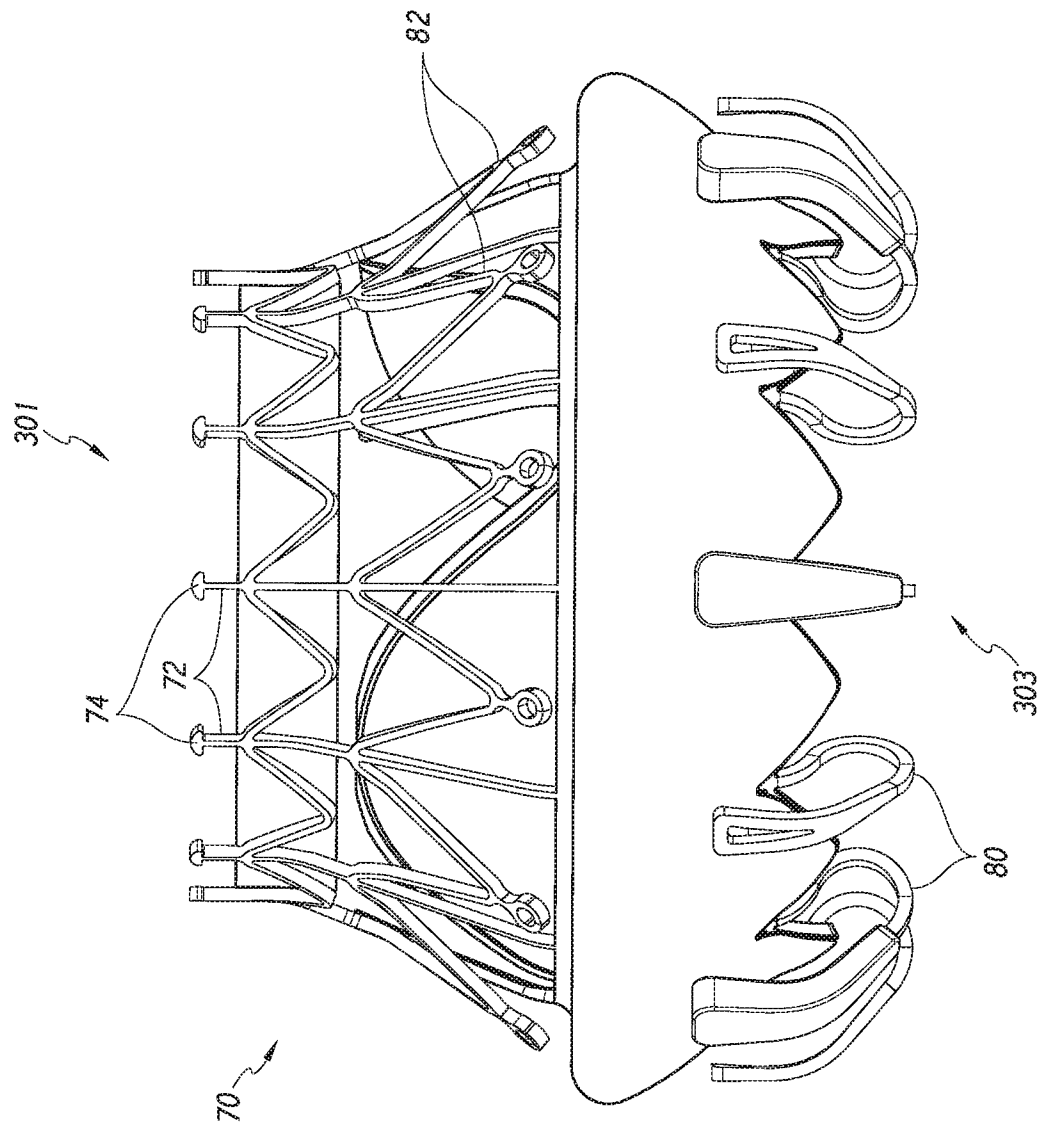


FIG. 3A

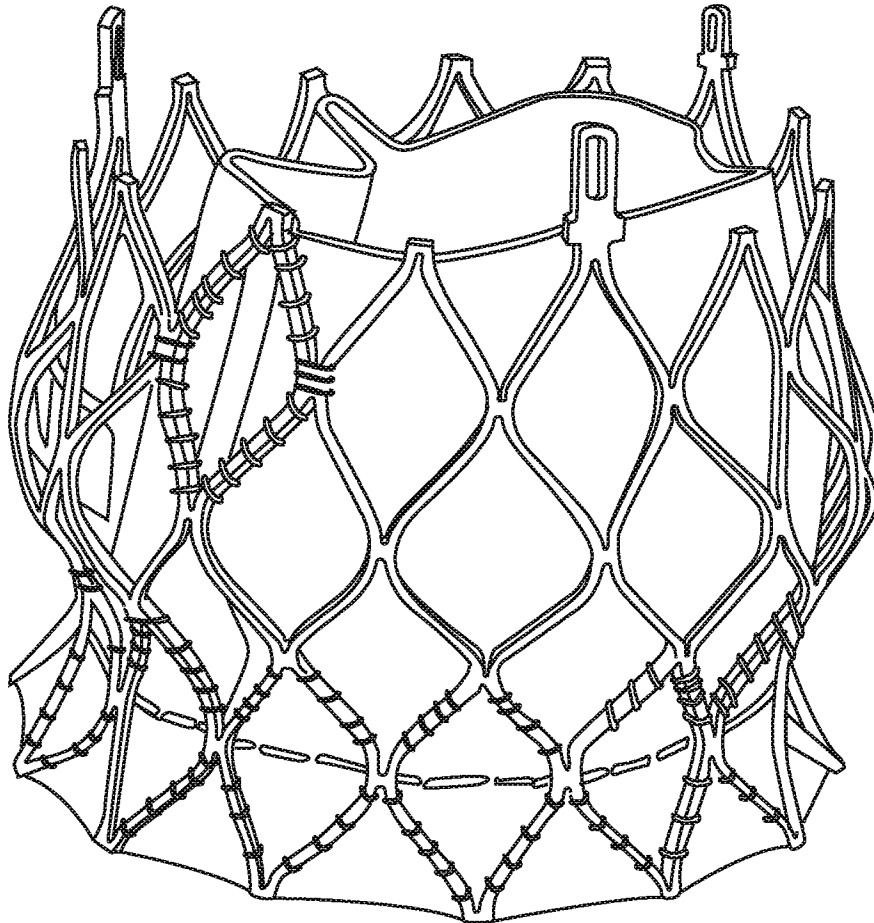


FIG. 3B

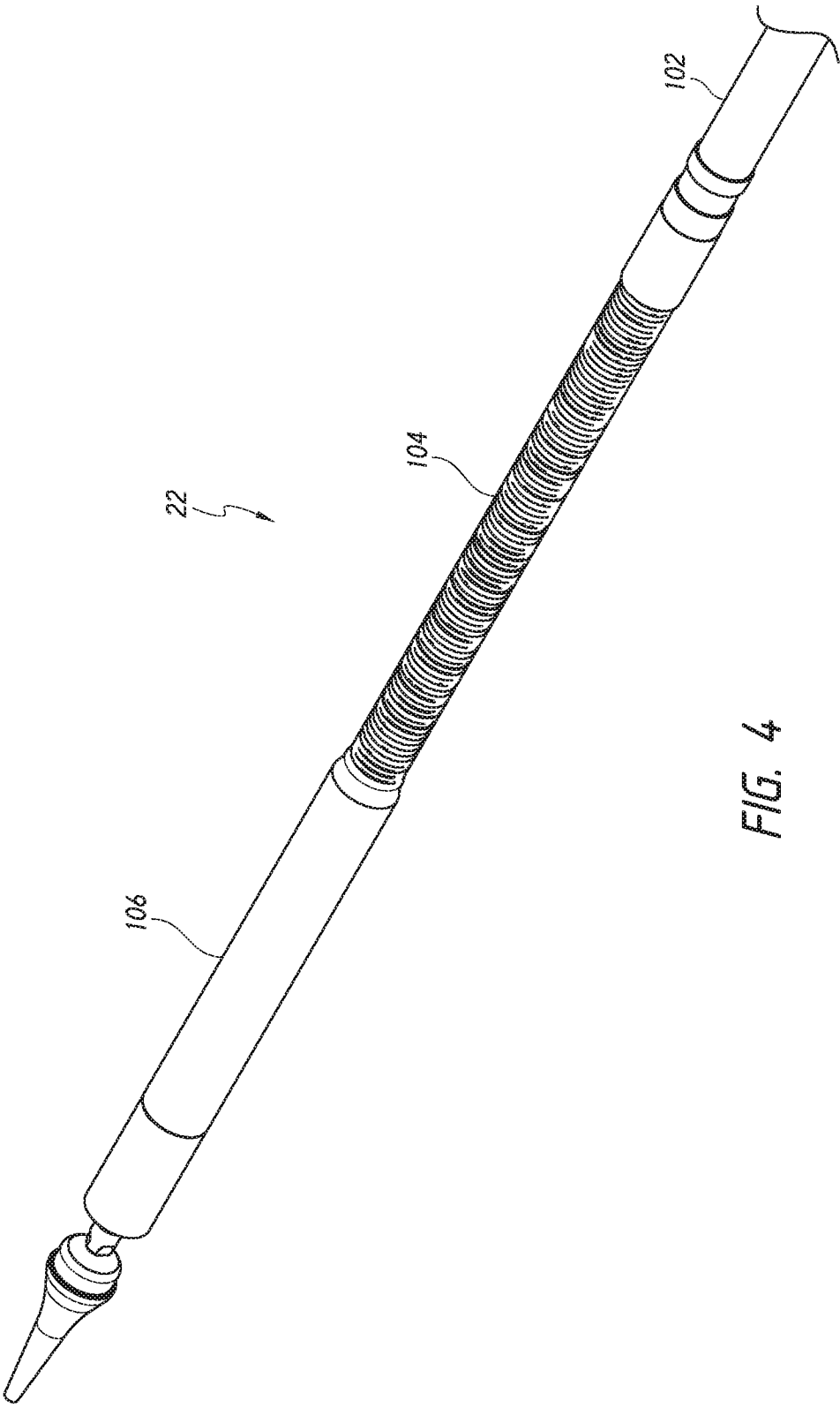


FIG. 4

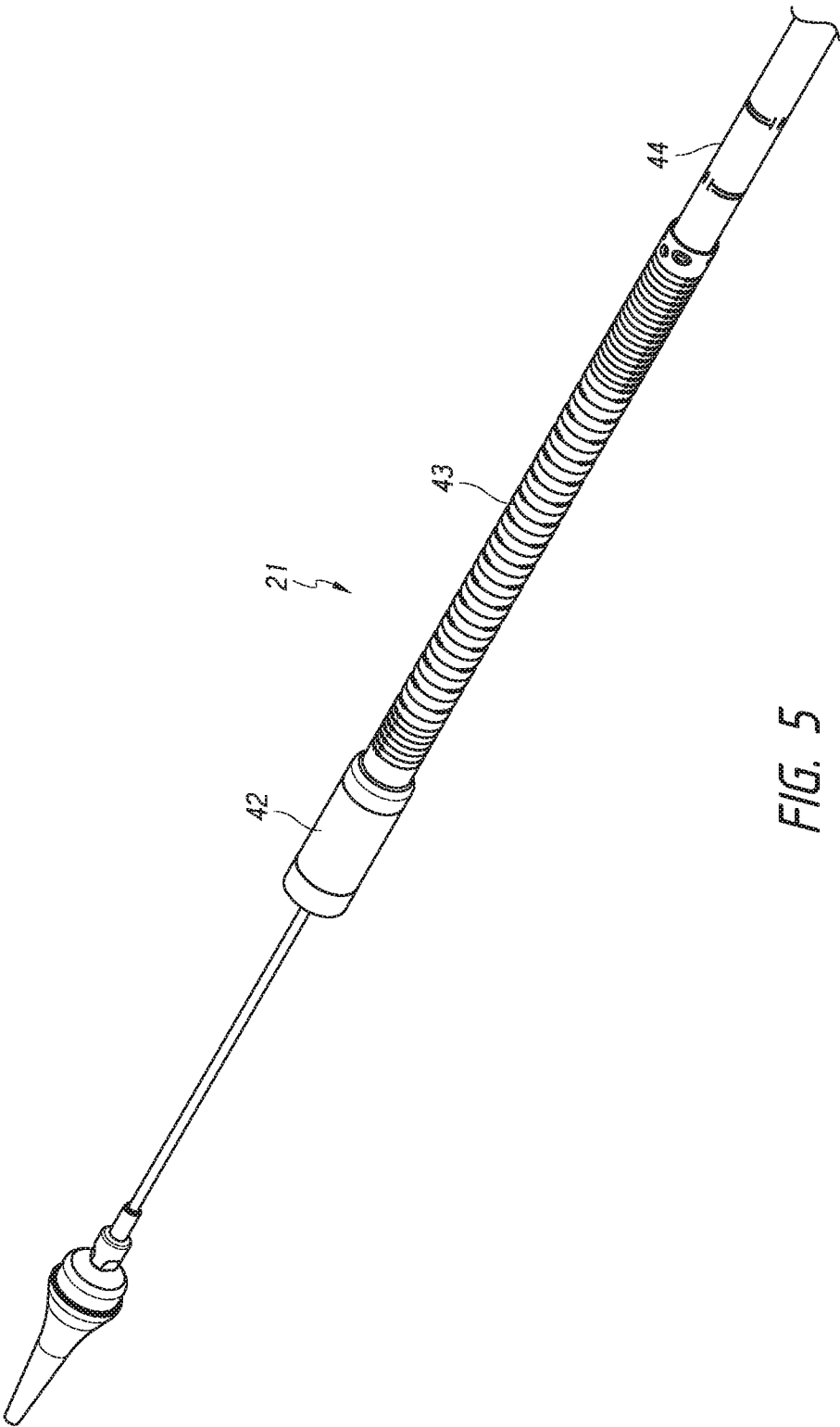


FIG. 5

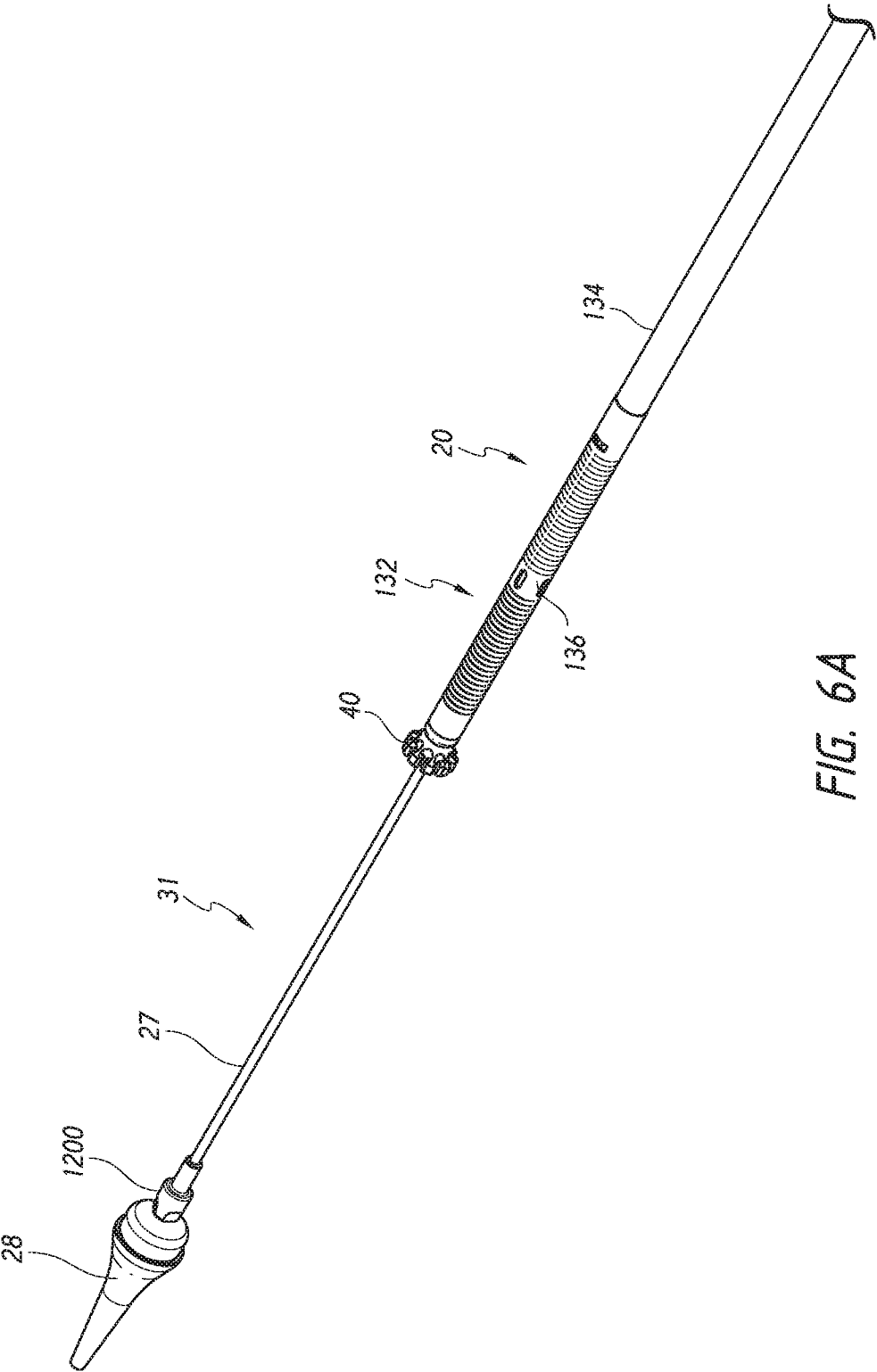


FIG. 6A

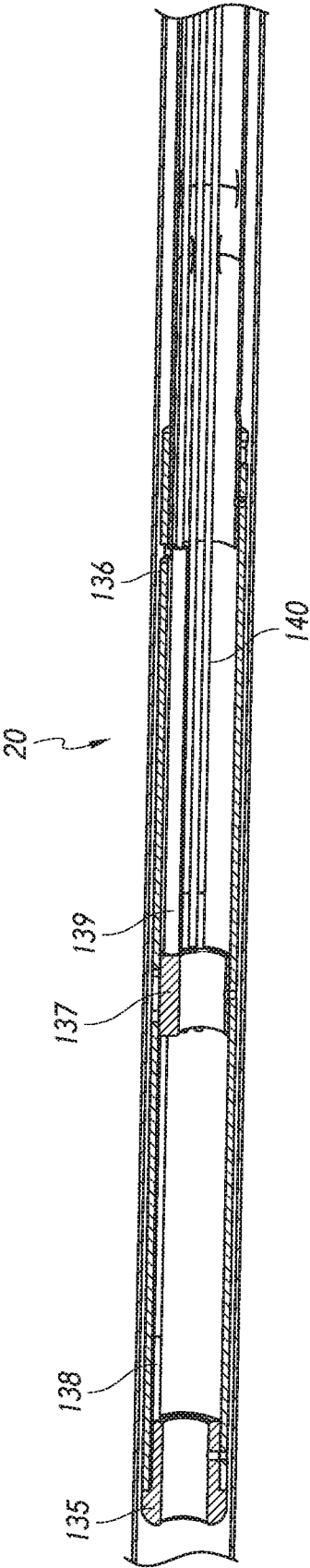
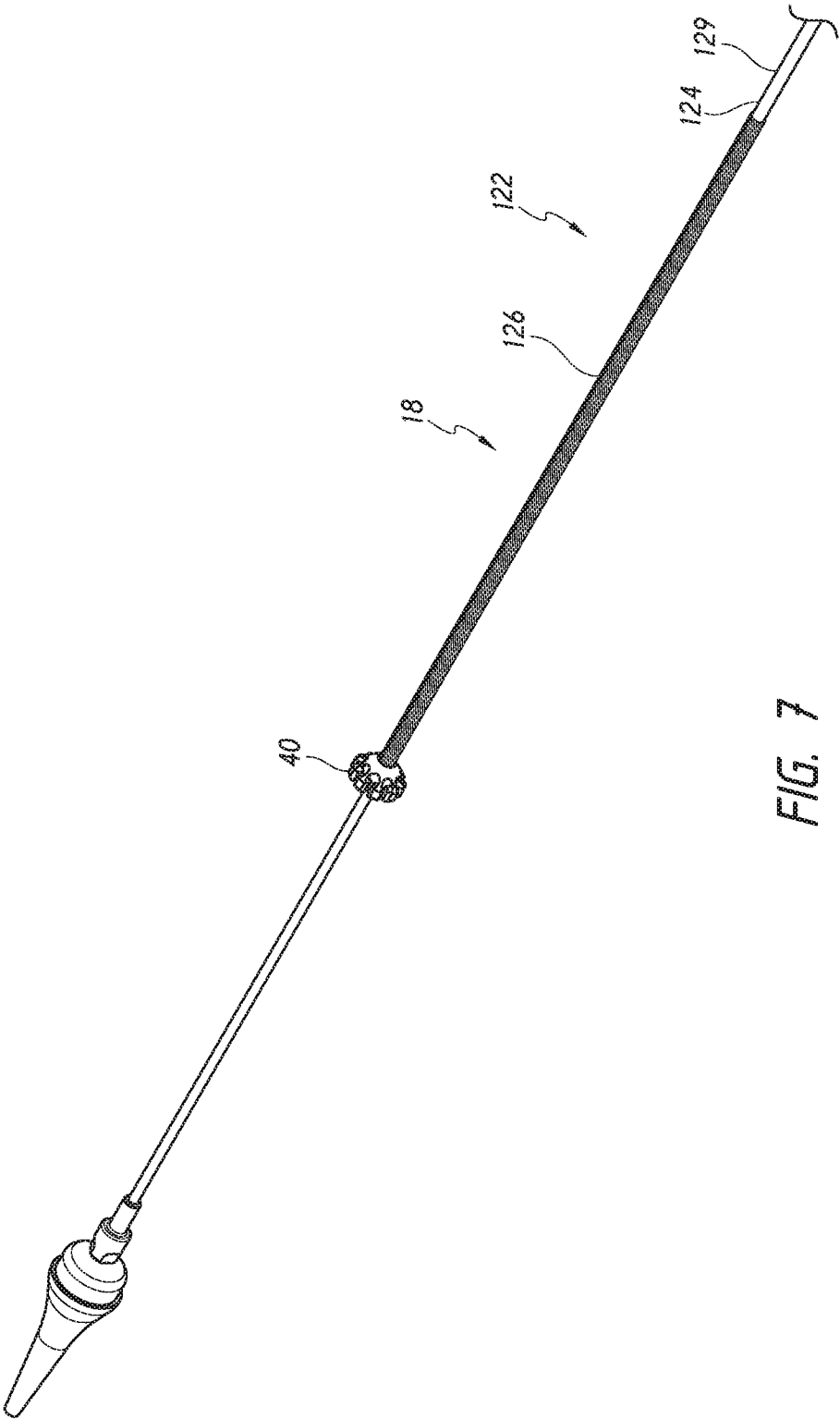


FIG. 6B



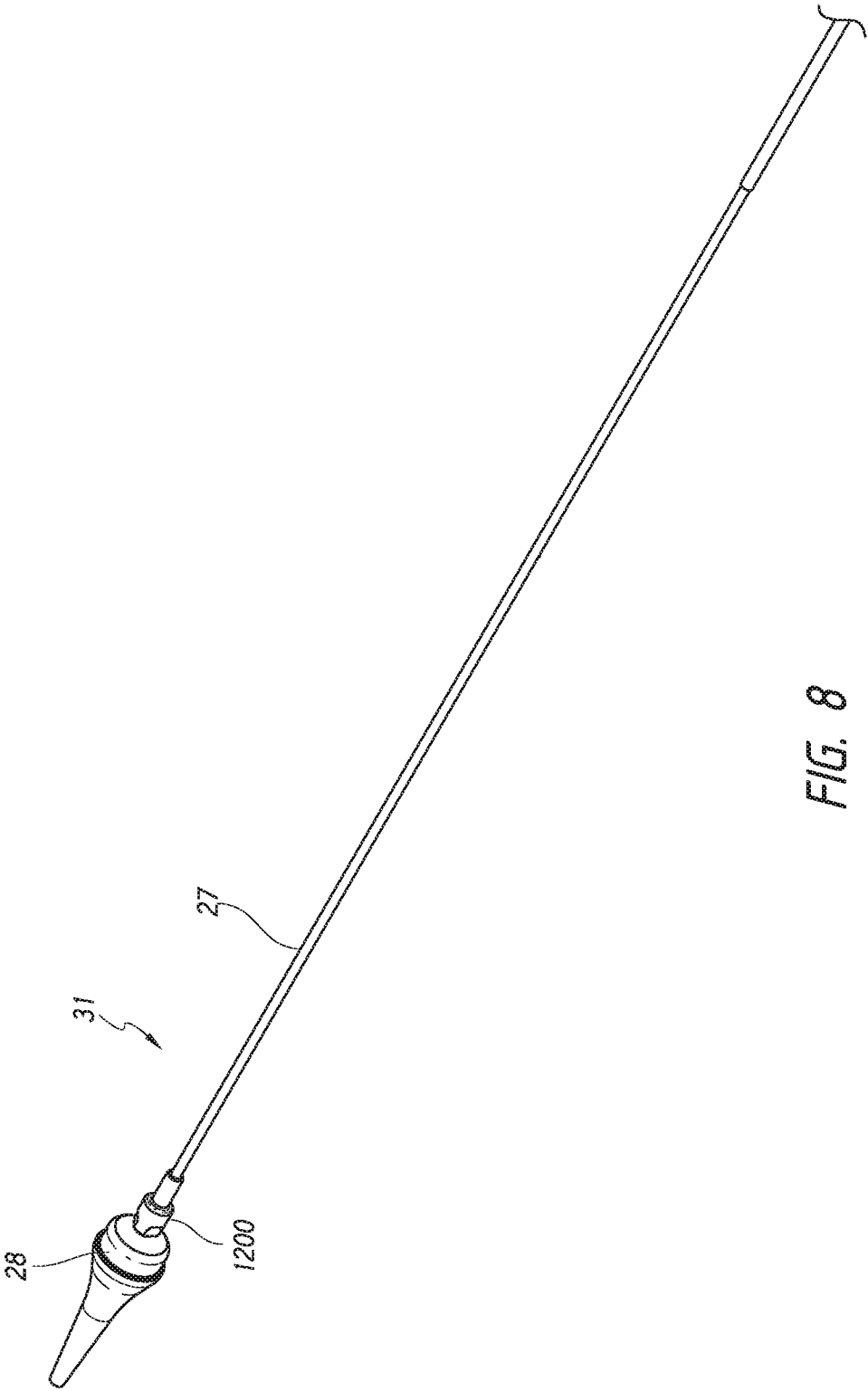


FIG. 8

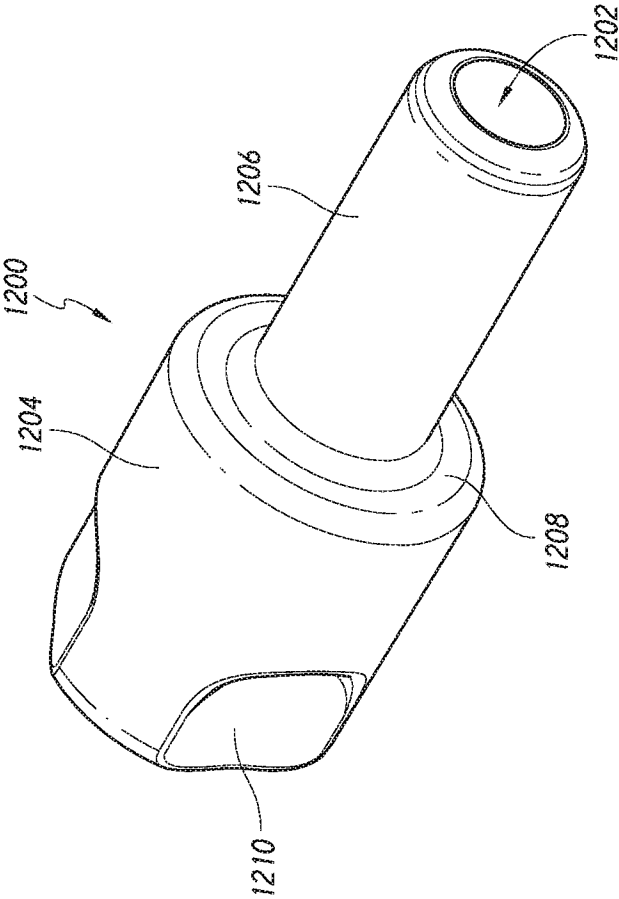


FIG. 9A

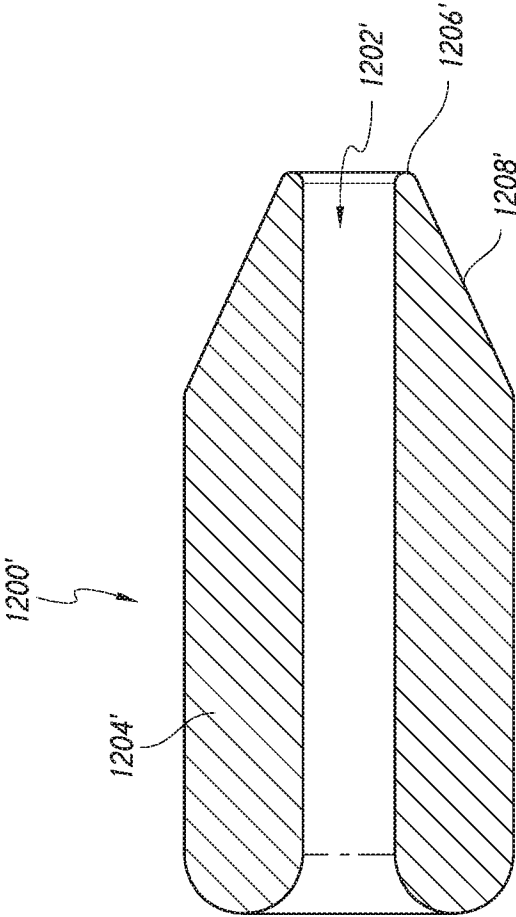


FIG. 9B

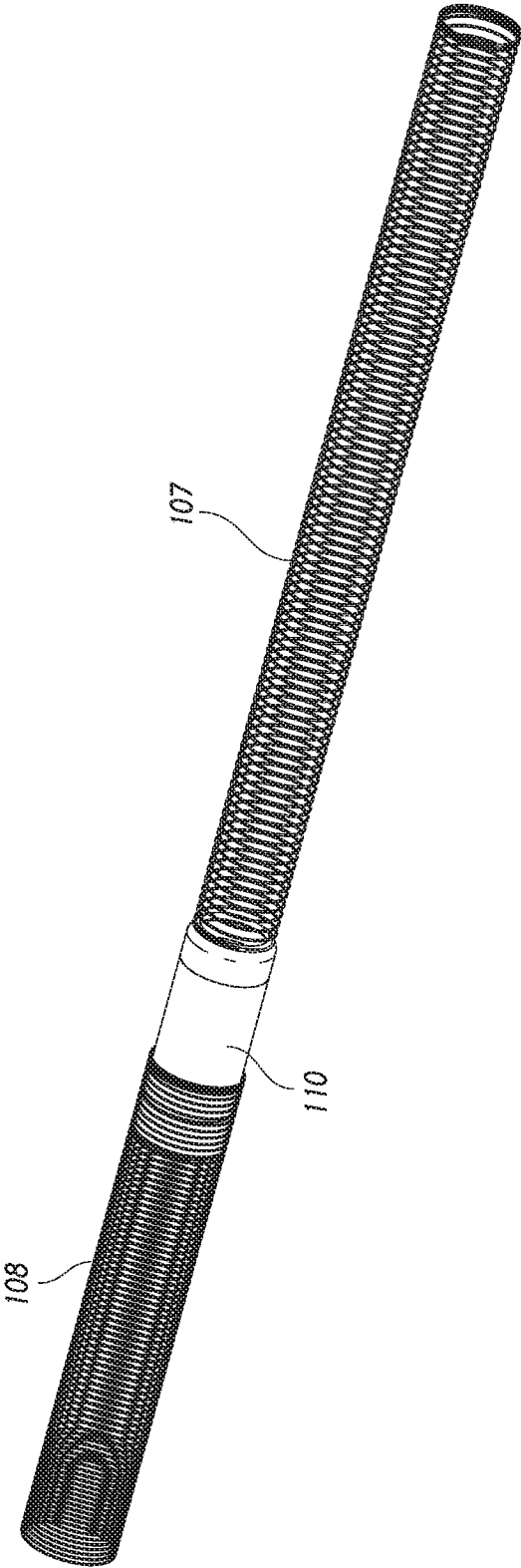


FIG. 10

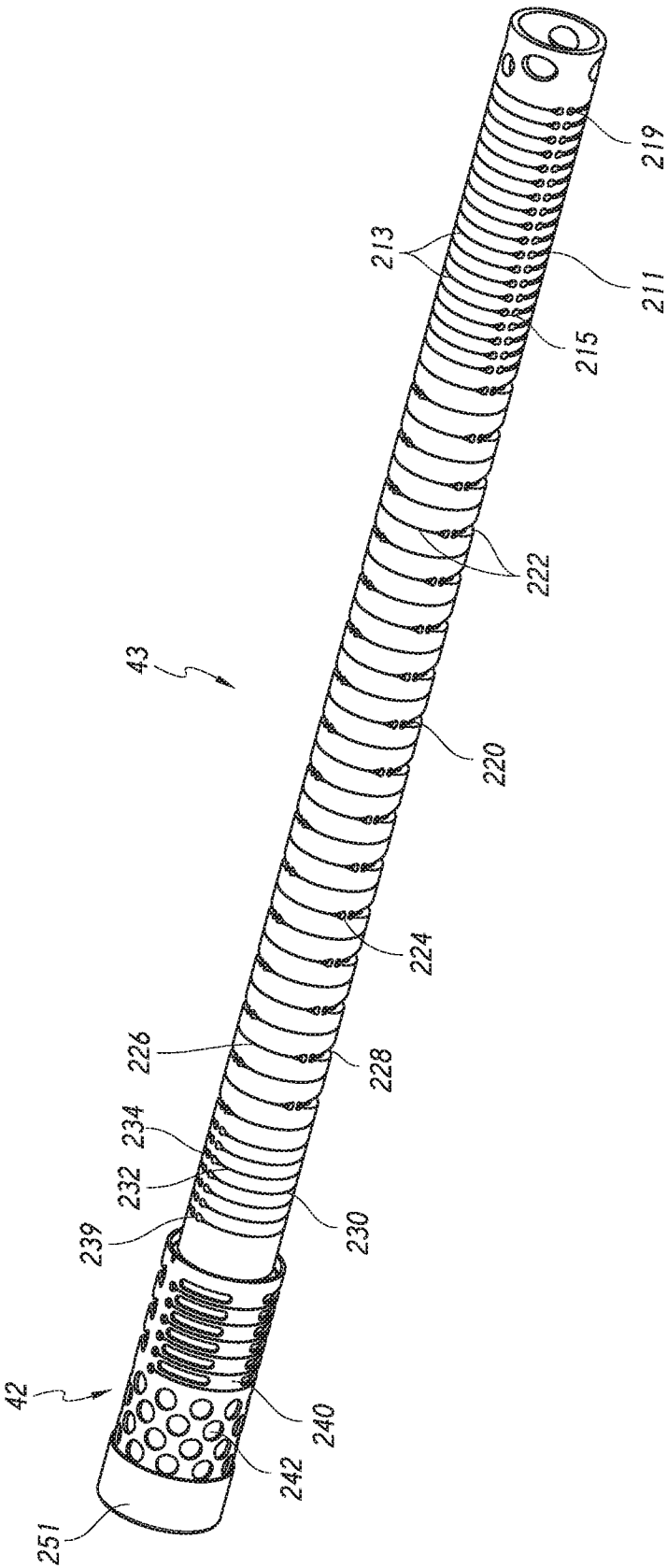


FIG. 11

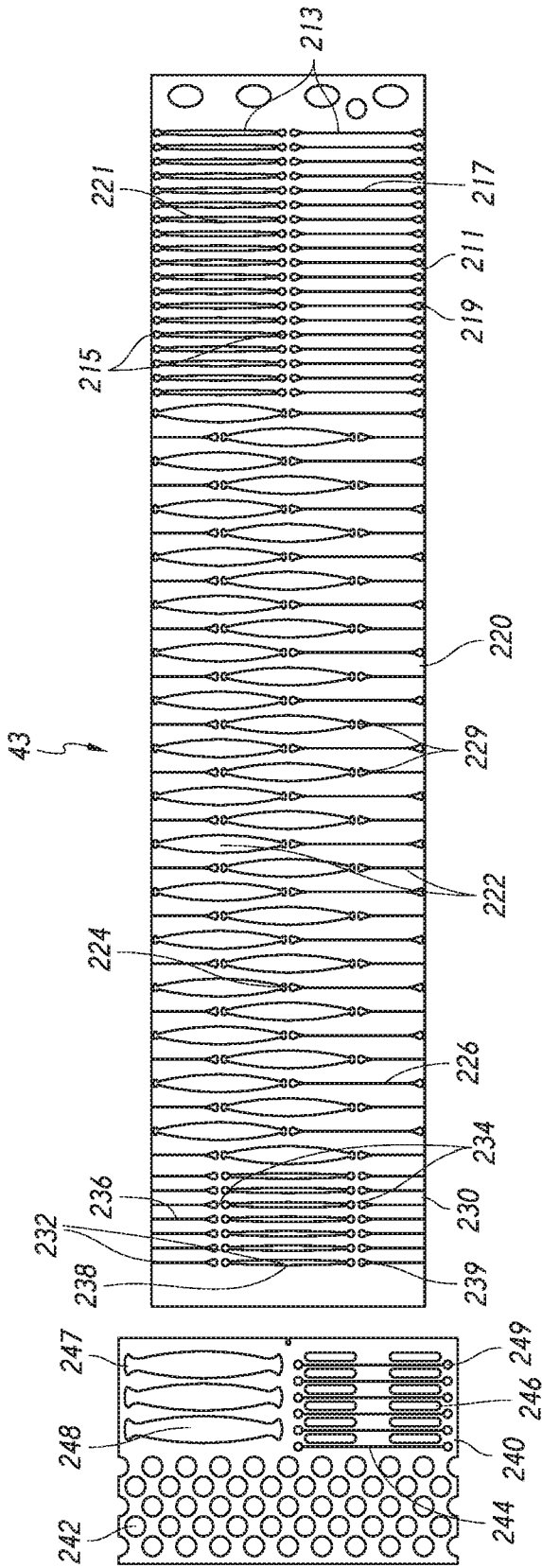


FIG. 12A

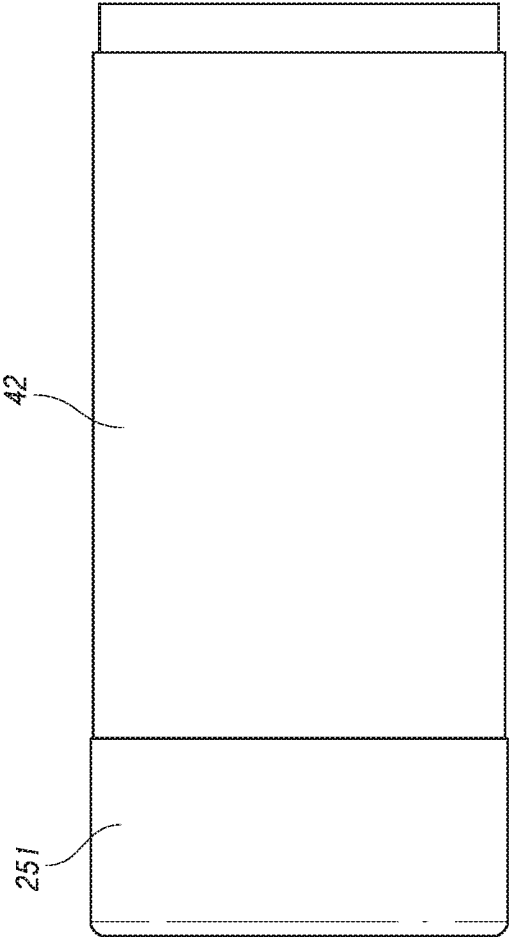


FIG. 12B

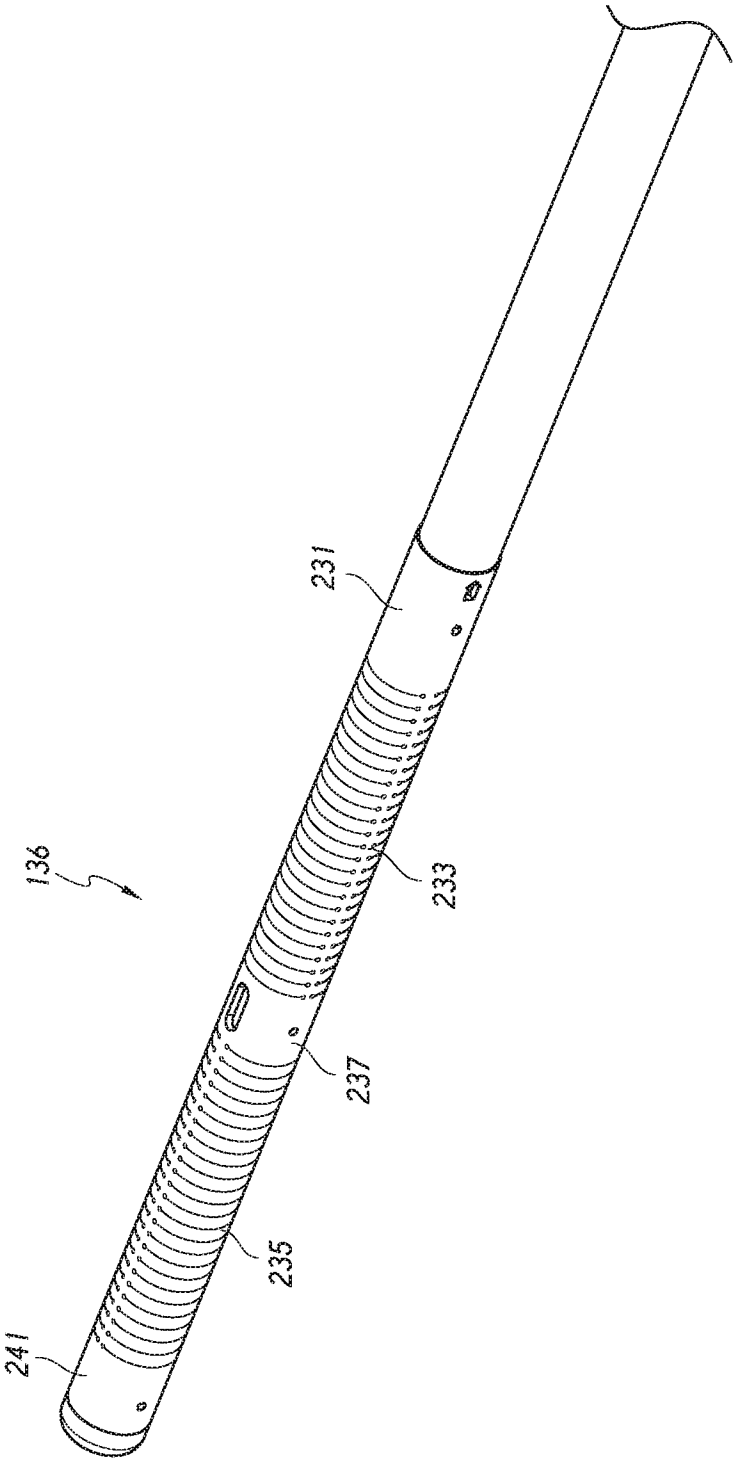


FIG. 13

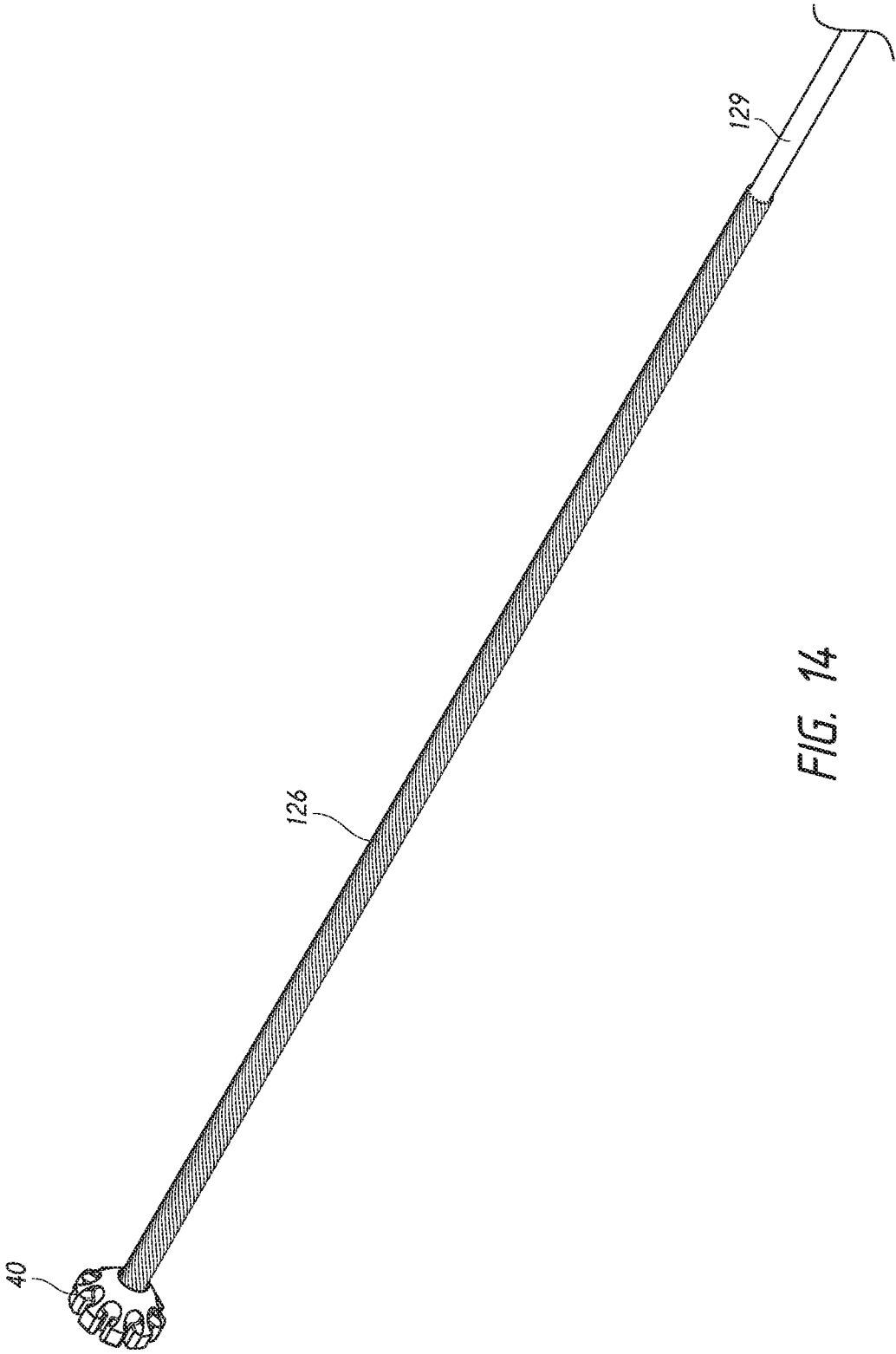


FIG. 14

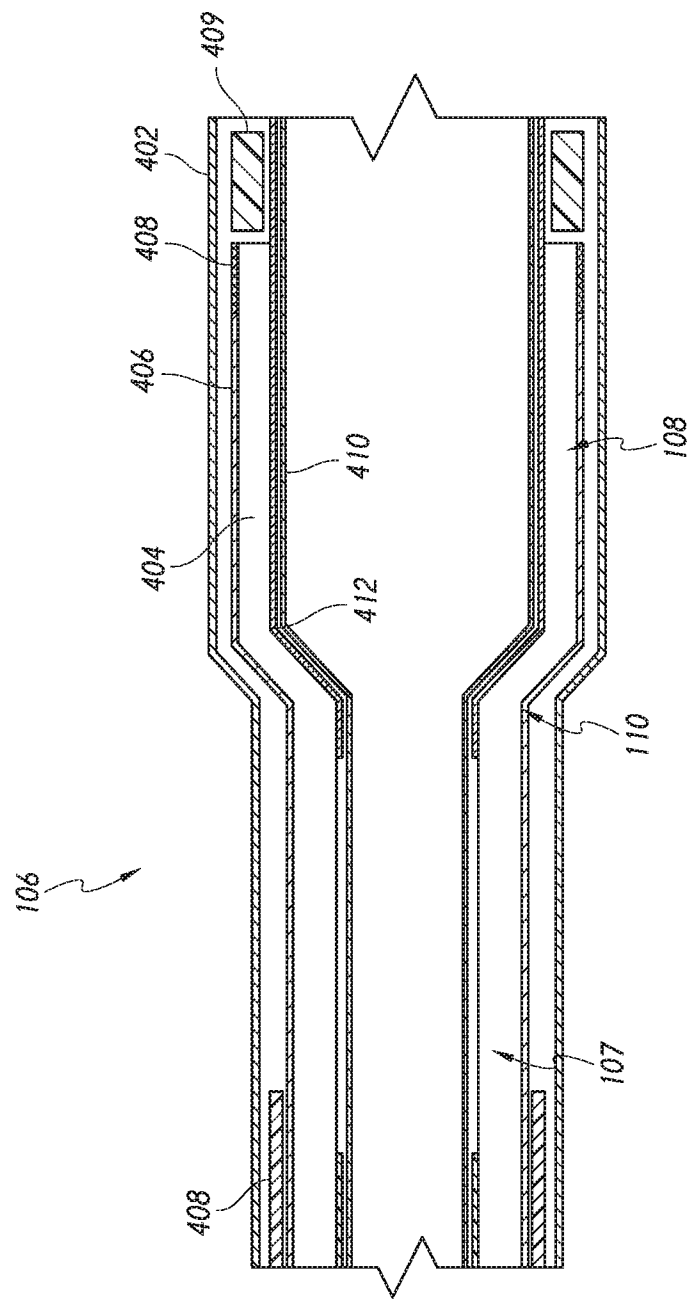


FIG. 15

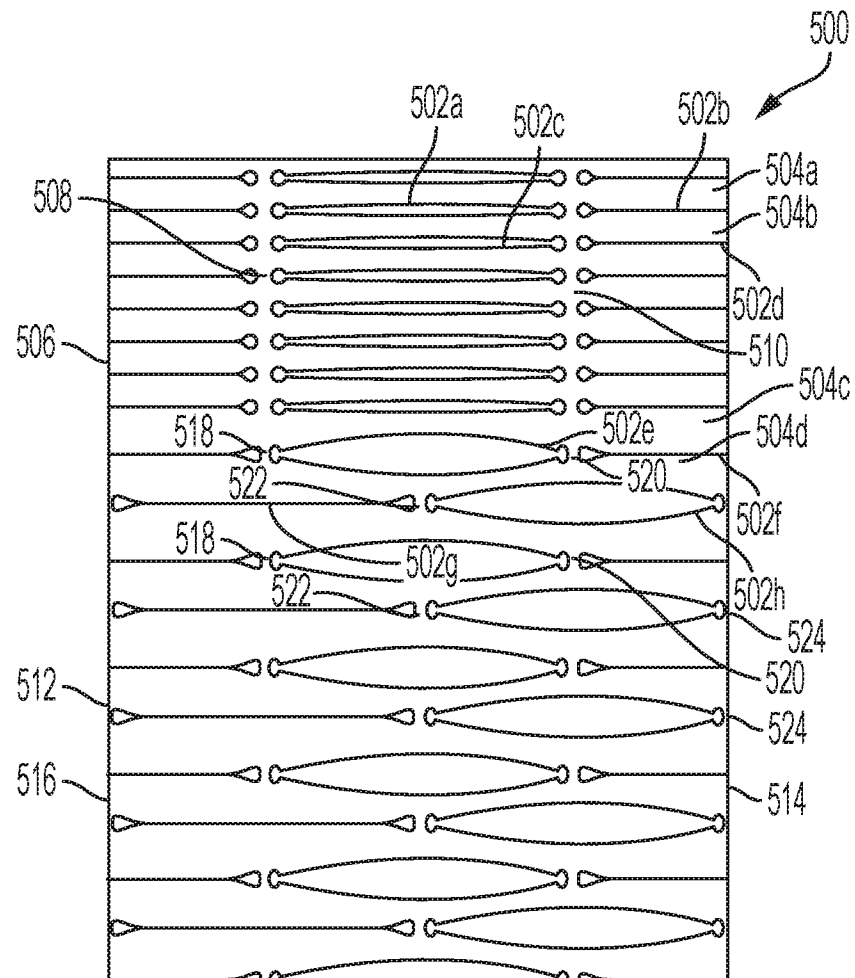


FIG. 16

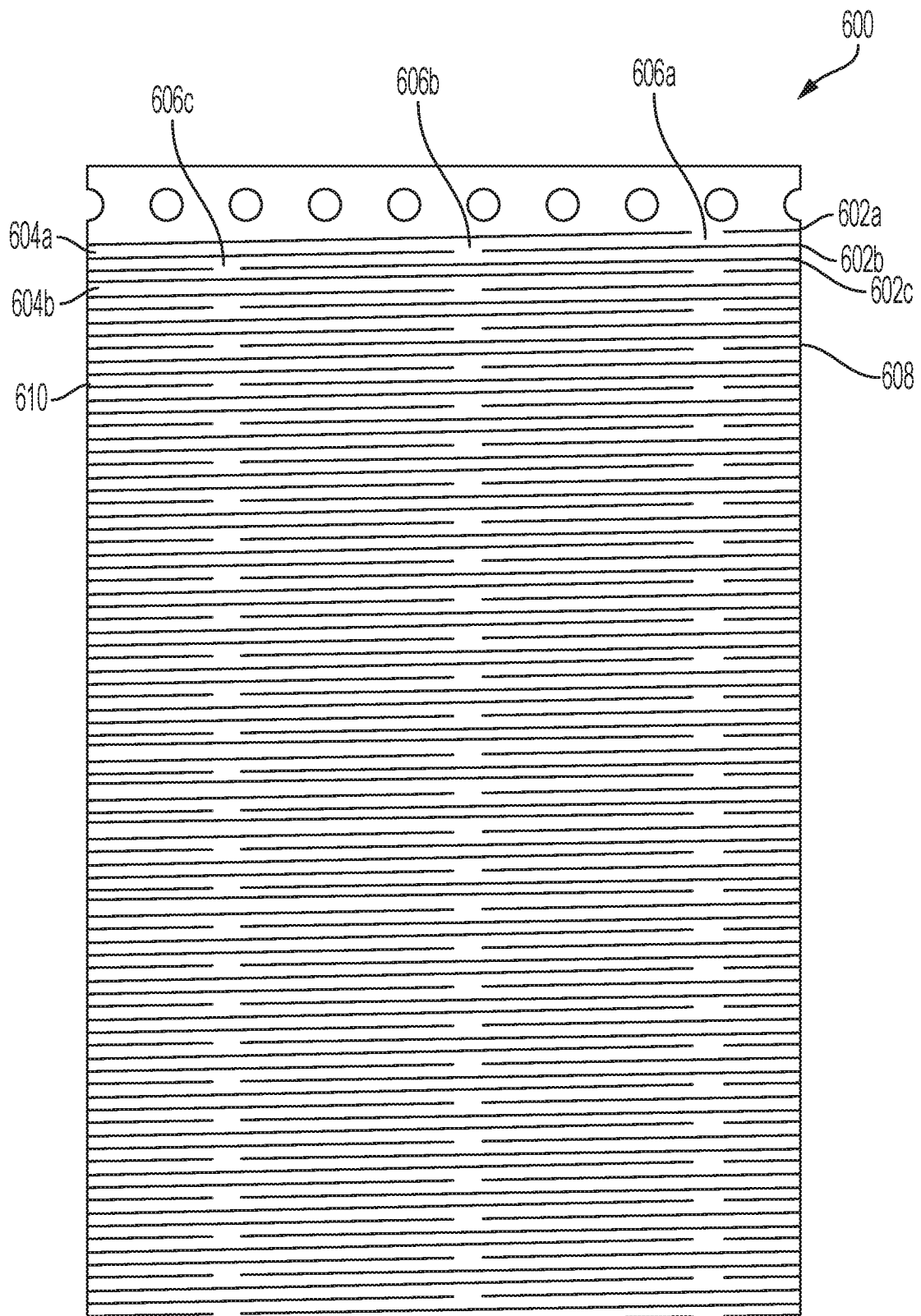


FIG. 17

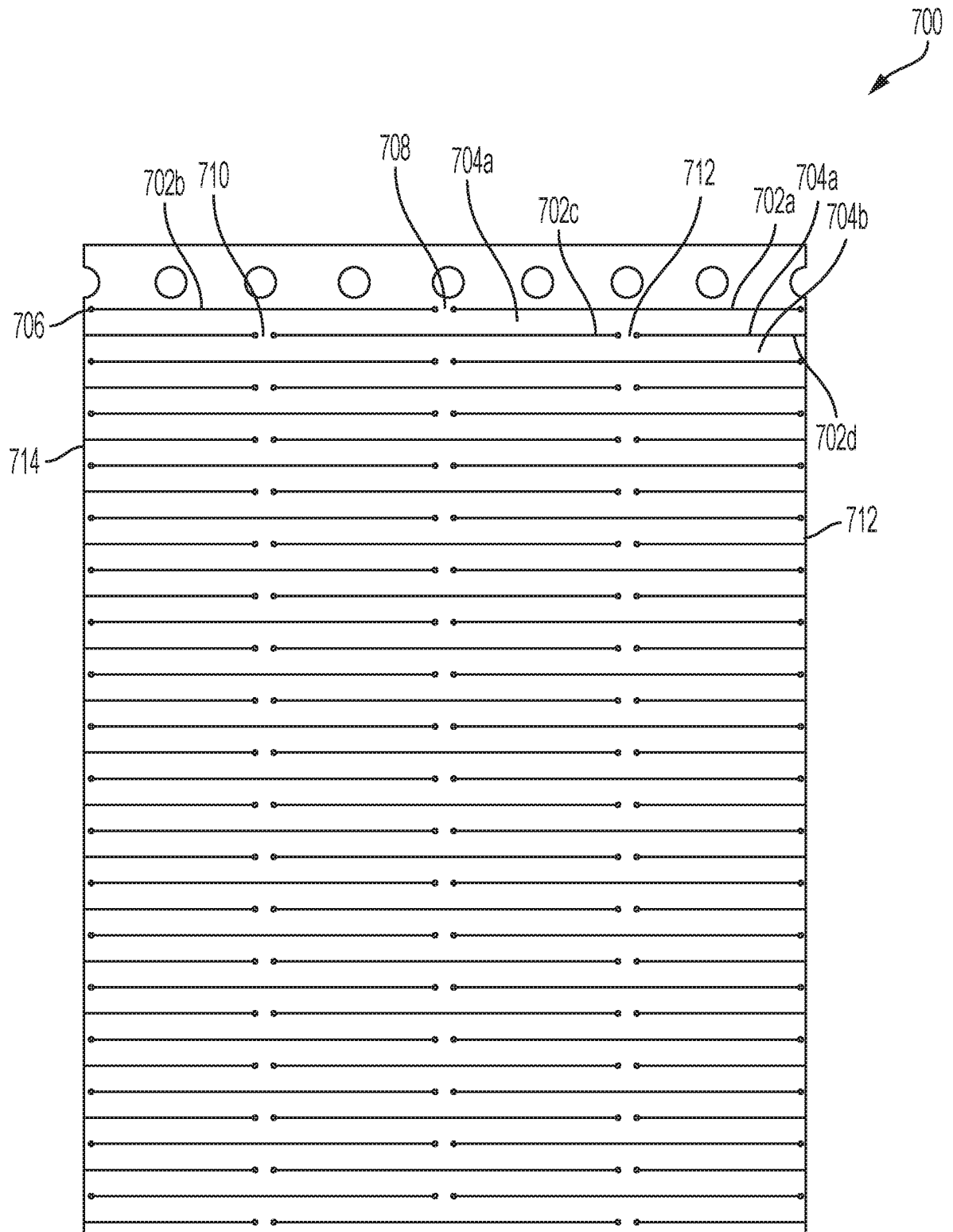


FIG. 18

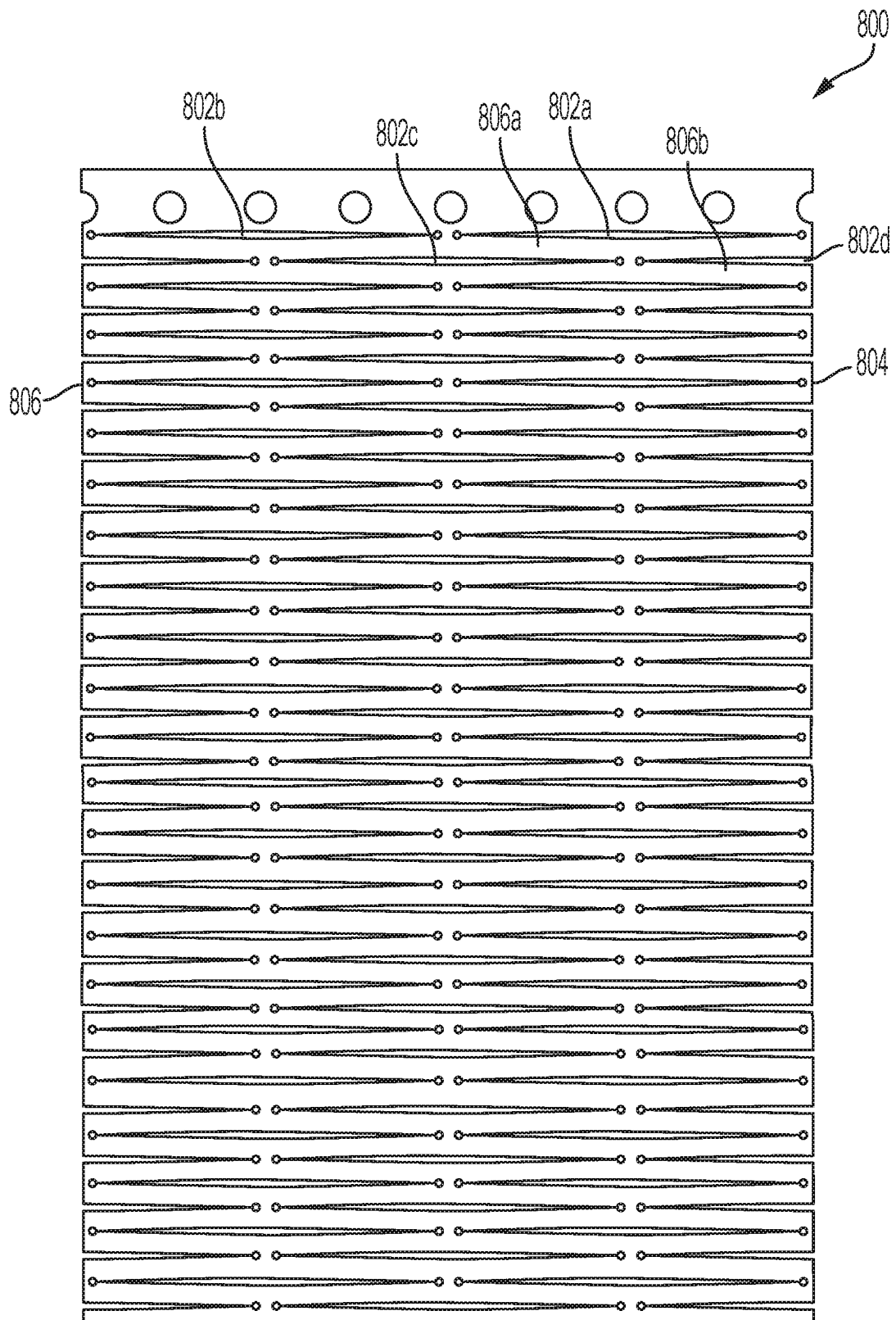


FIG. 19

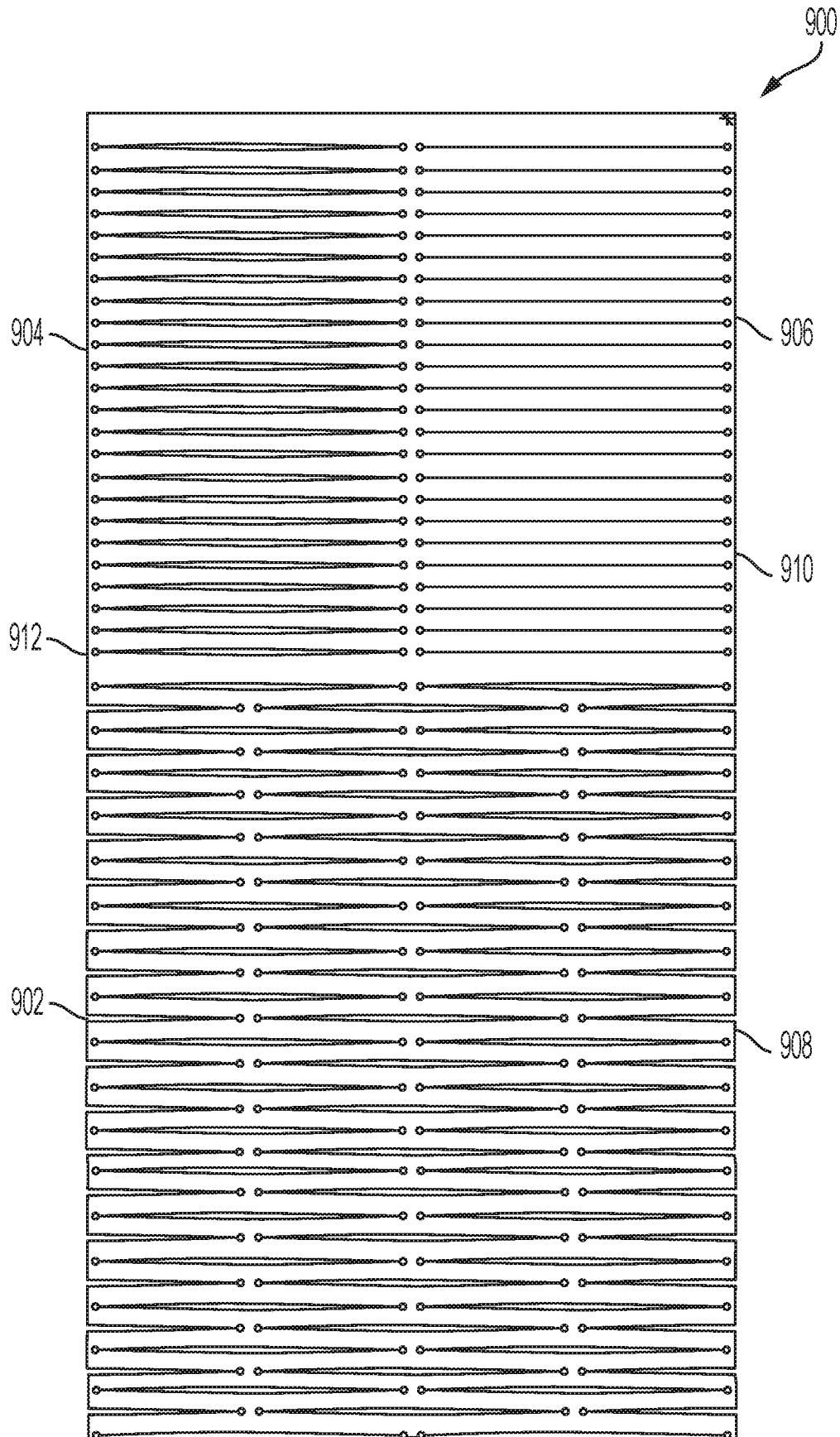


FIG. 20

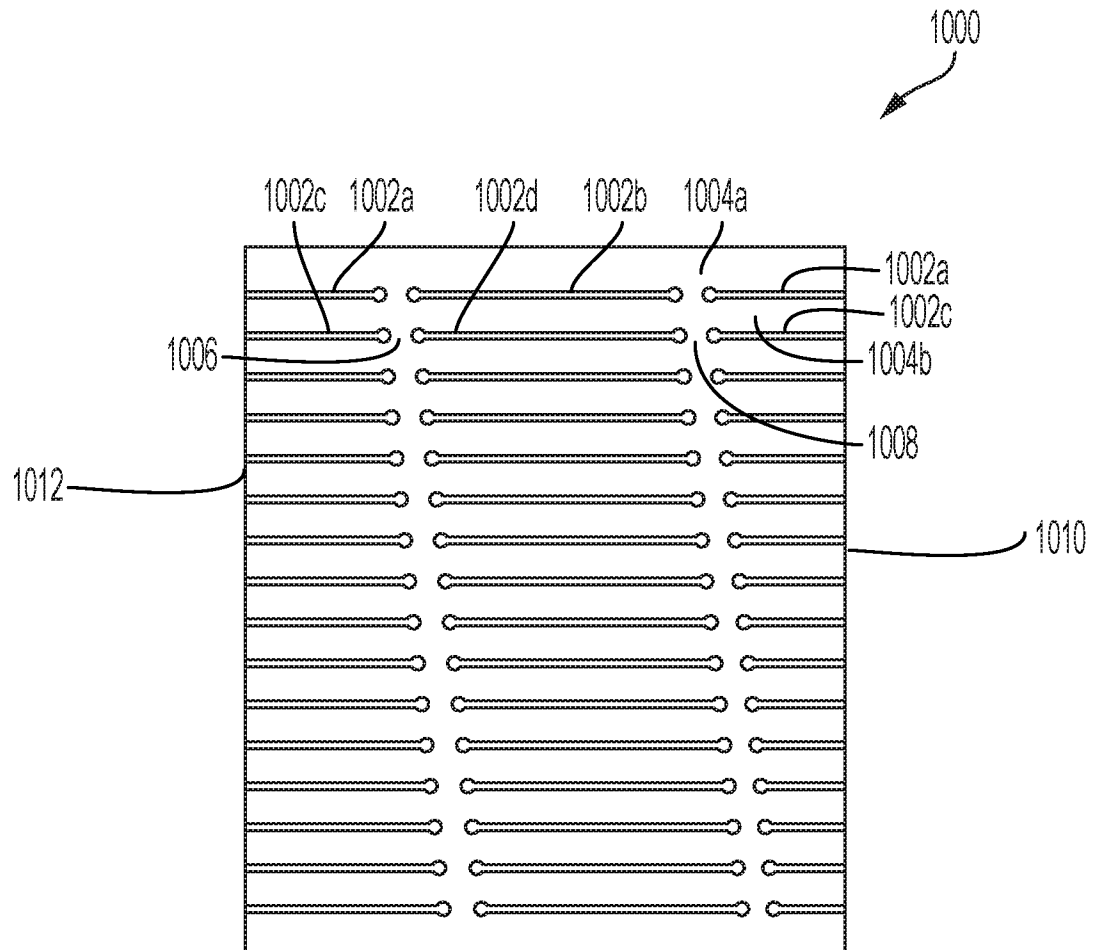


FIG. 21

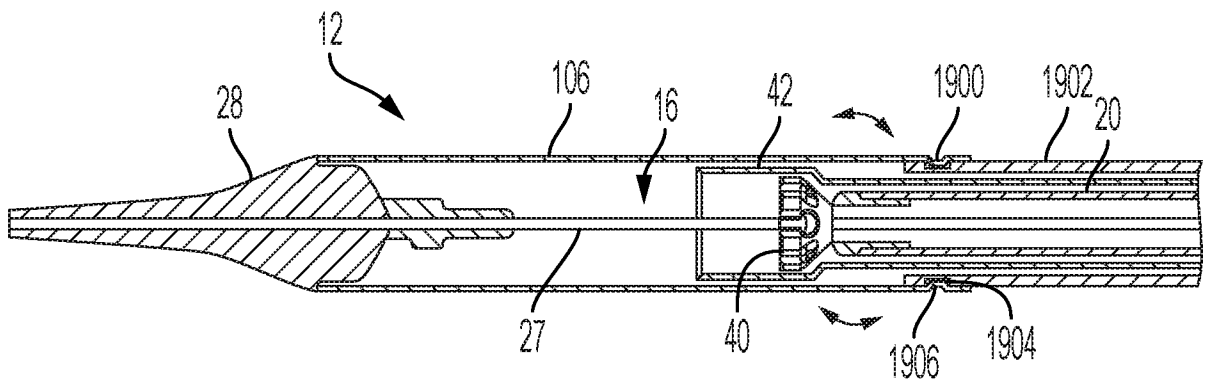


FIG. 22

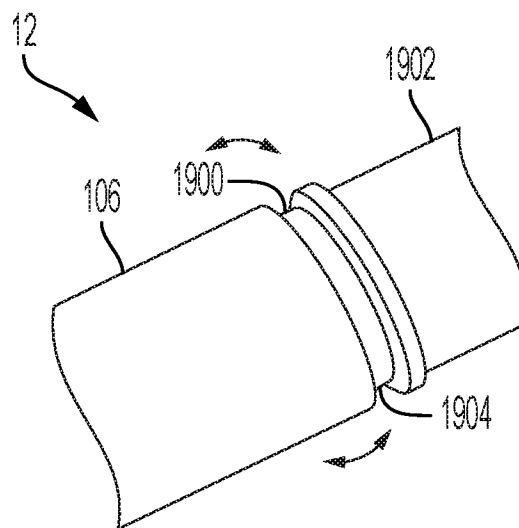


FIG. 23

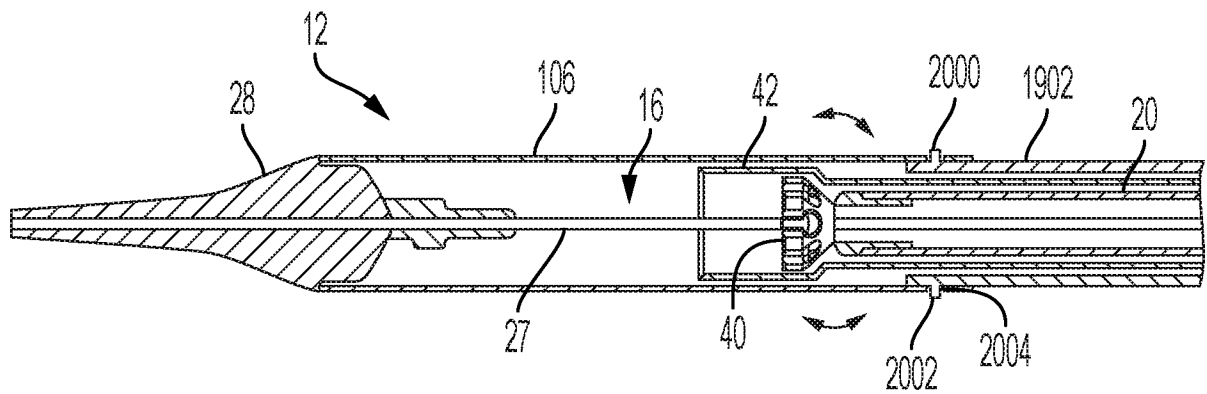


FIG. 24

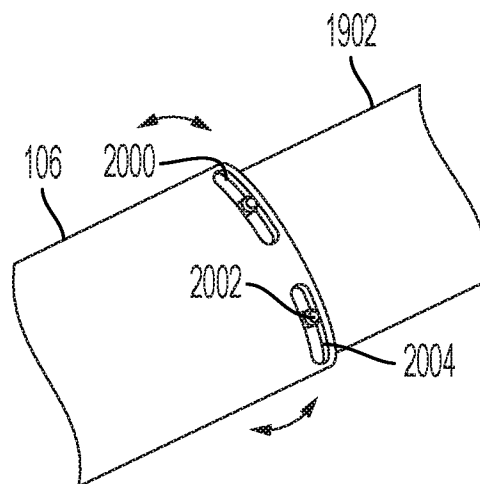


FIG. 25

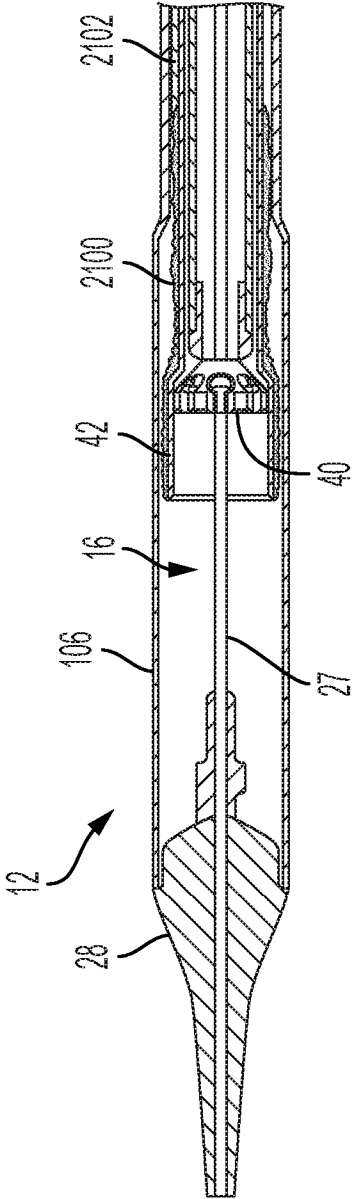


FIG. 26

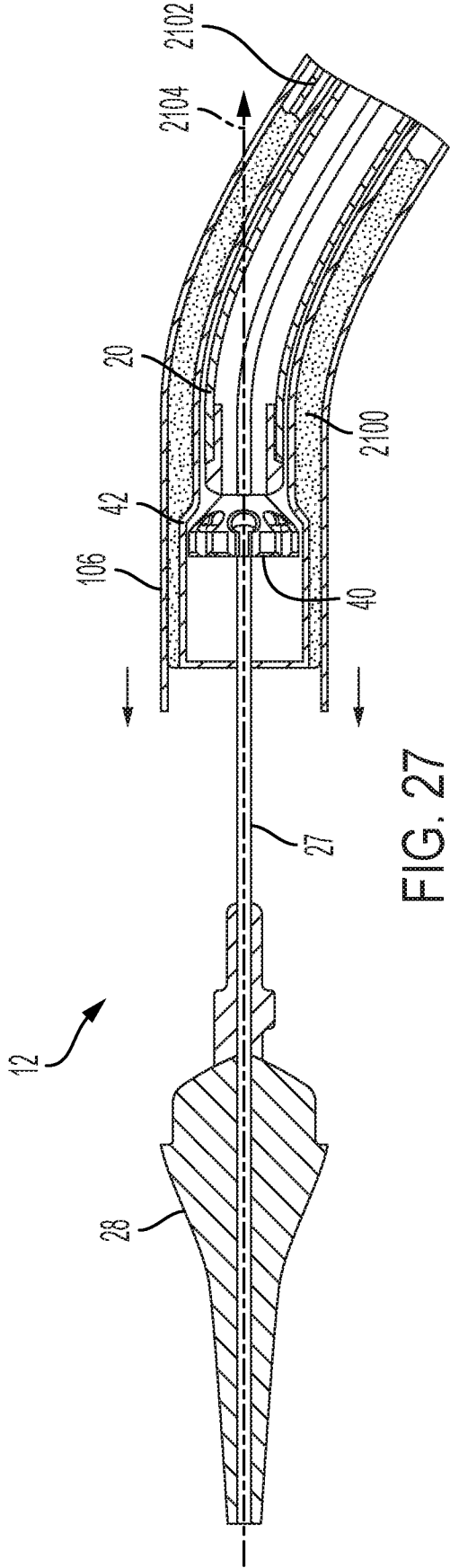


FIG. 27

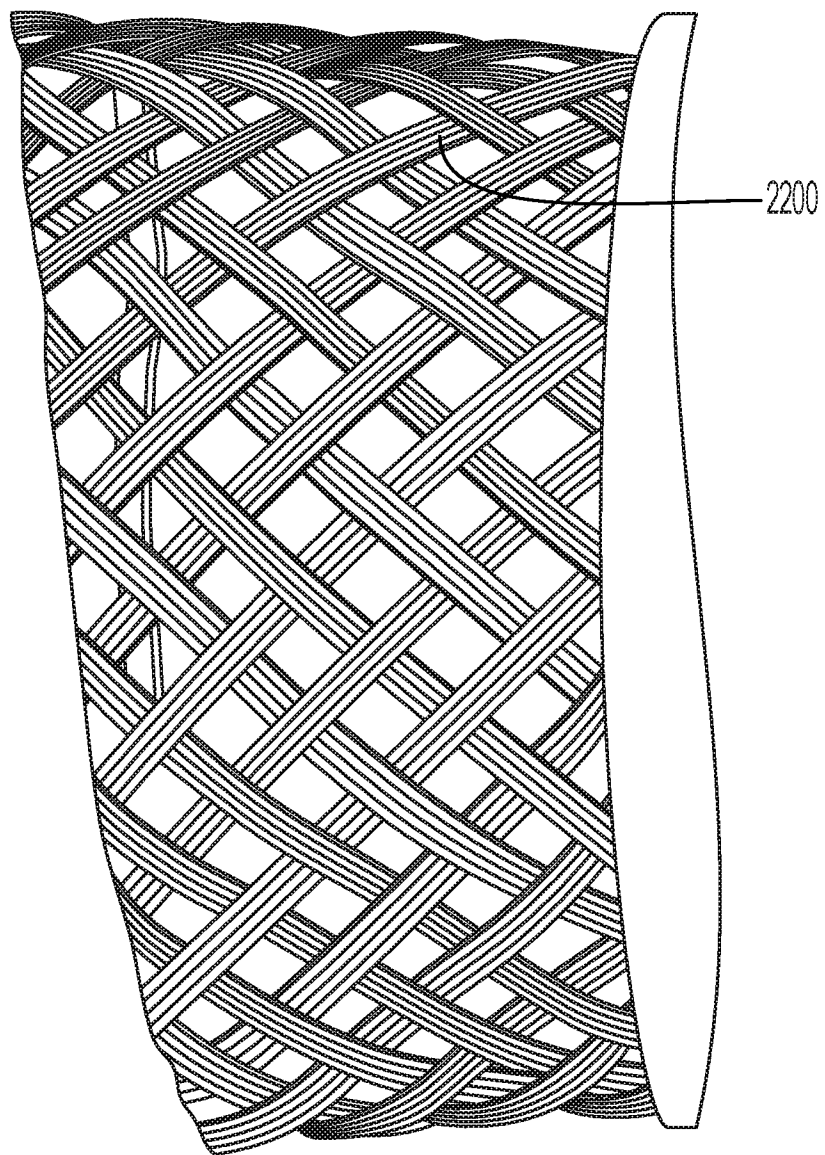


FIG. 28

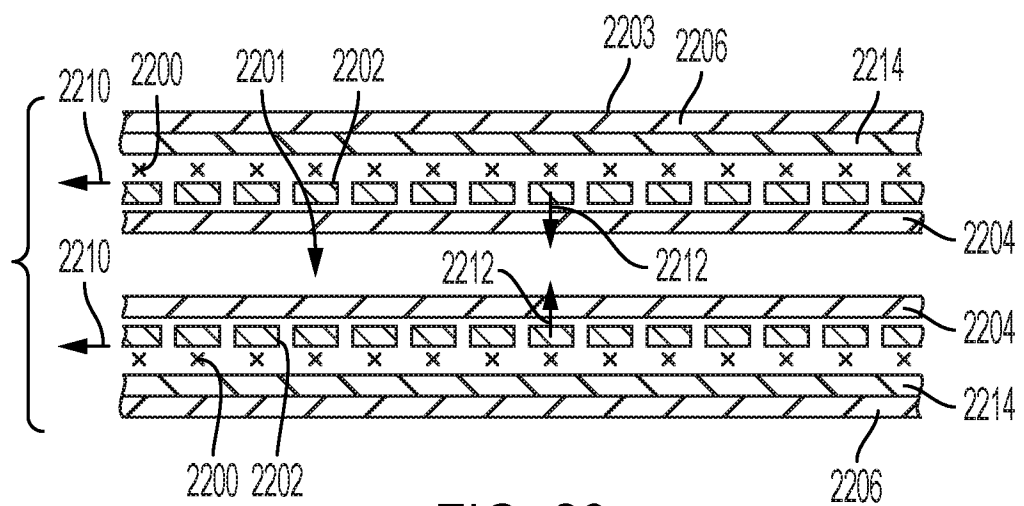


FIG. 29

31/69

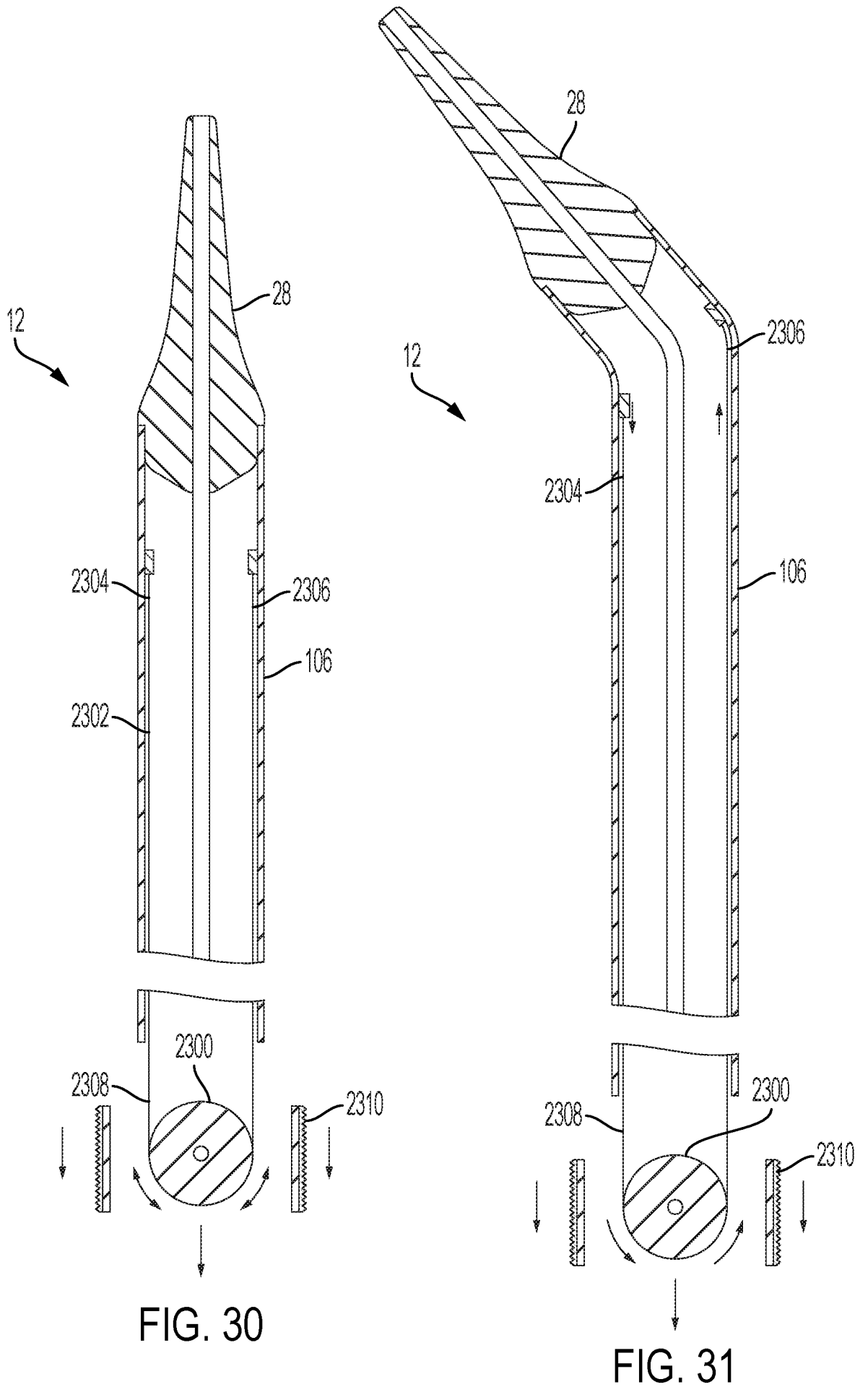


FIG. 30

FIG. 31

32/69

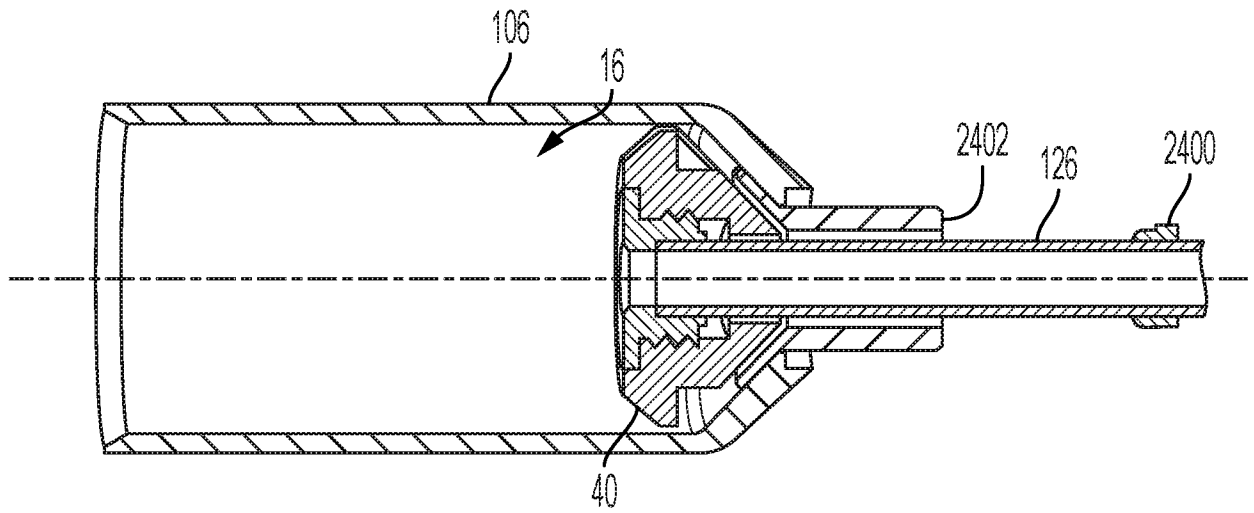


FIG. 32A

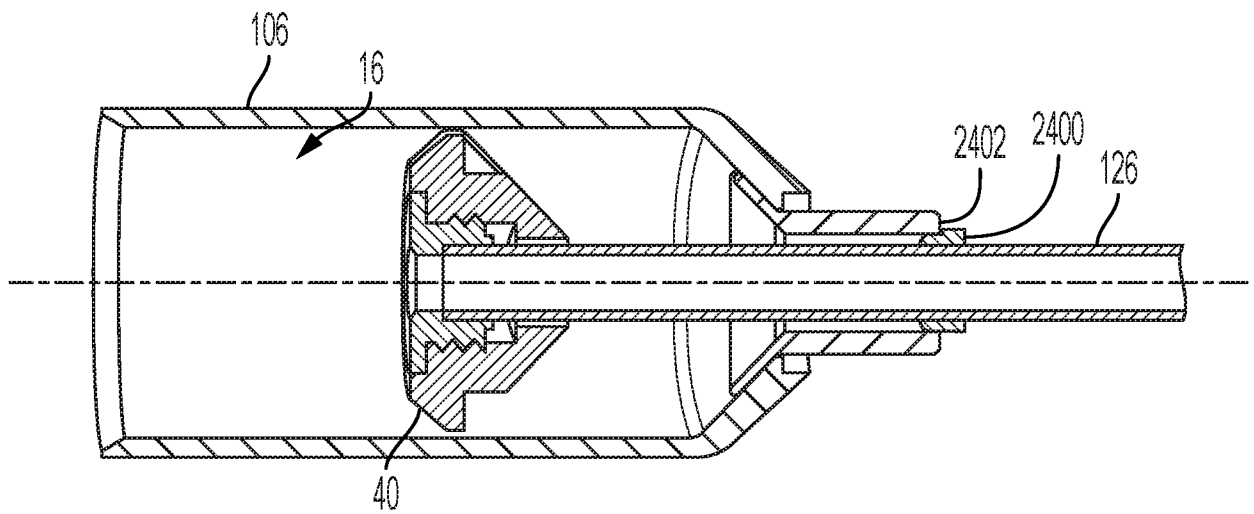


FIG. 32B

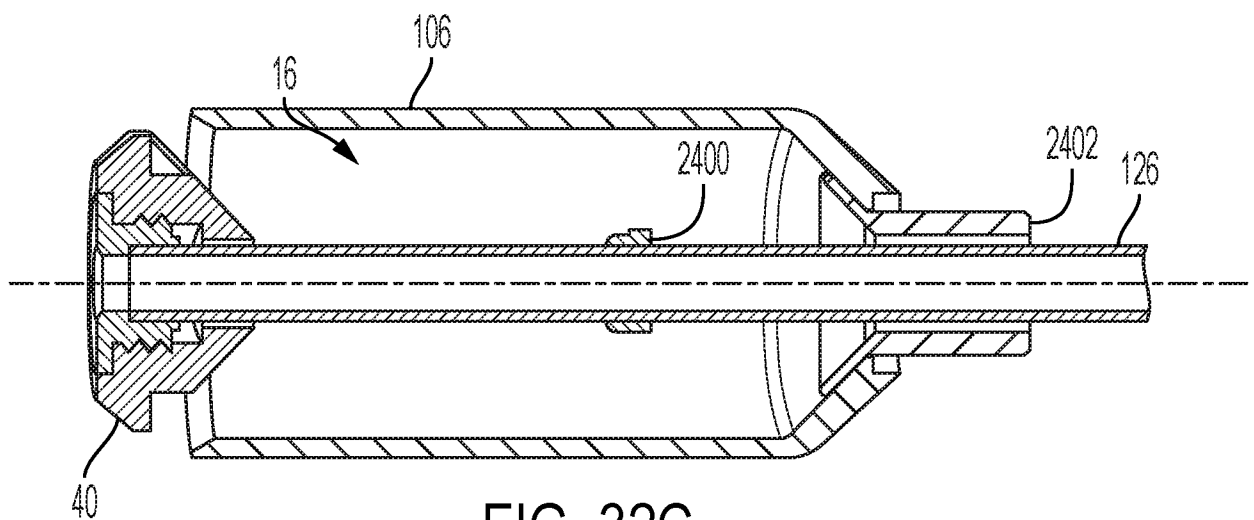


FIG. 32C

33/69

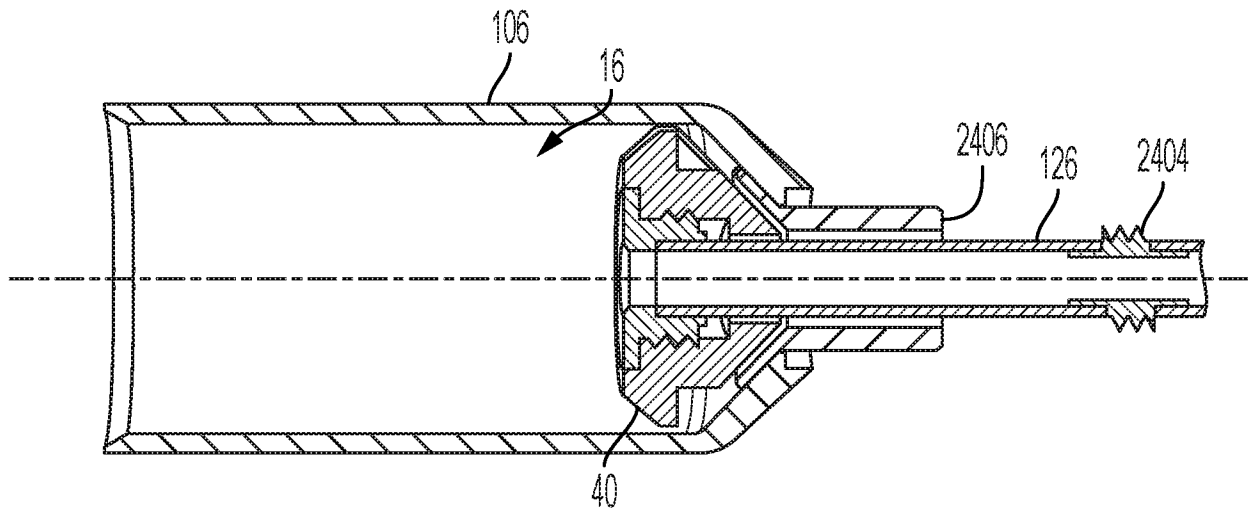


FIG. 33A

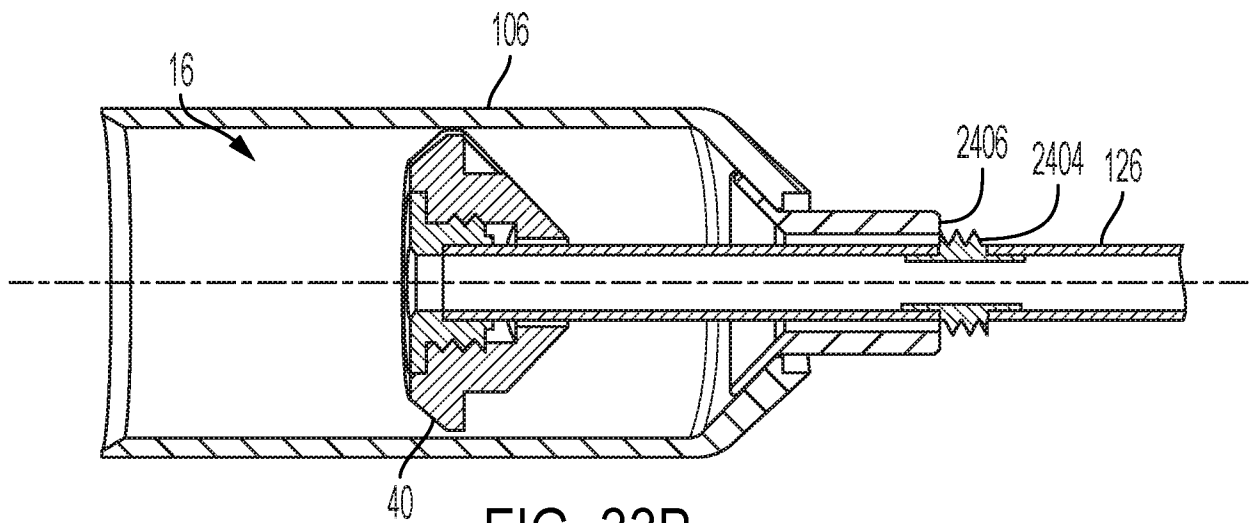


FIG. 33B

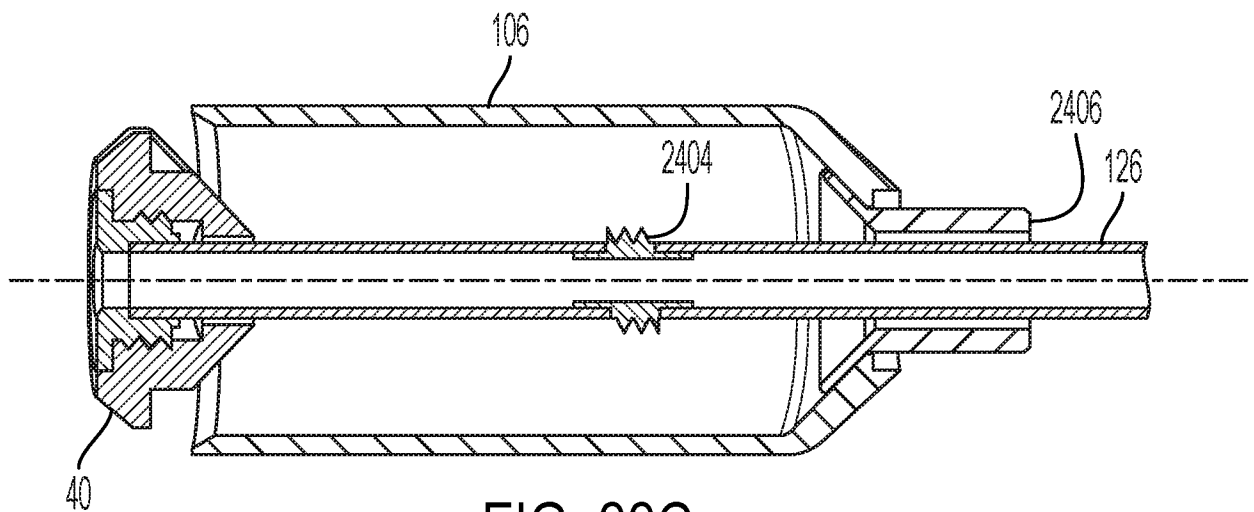
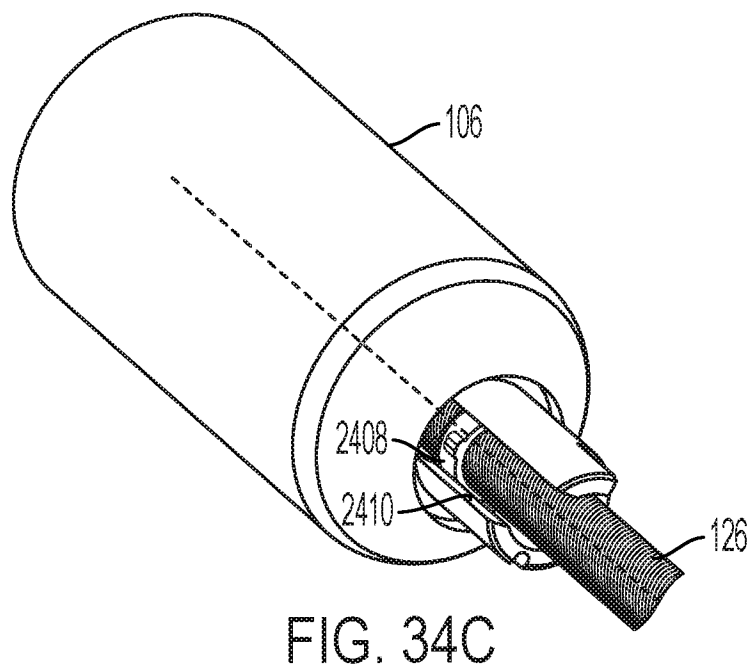
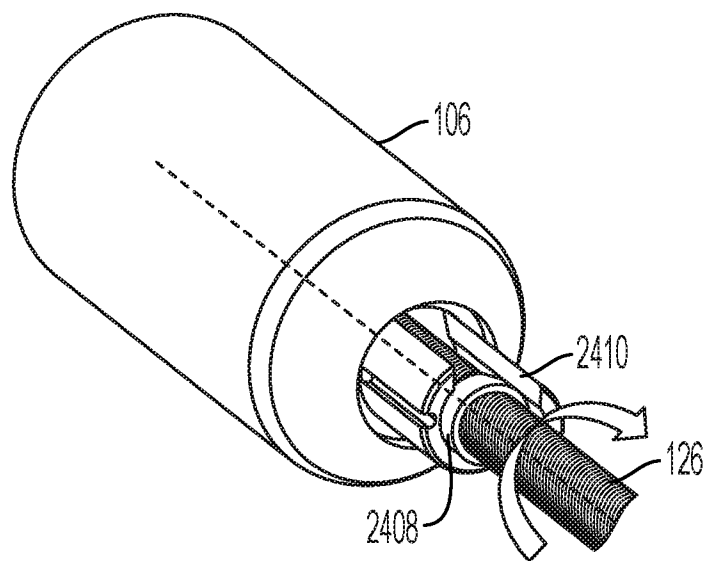
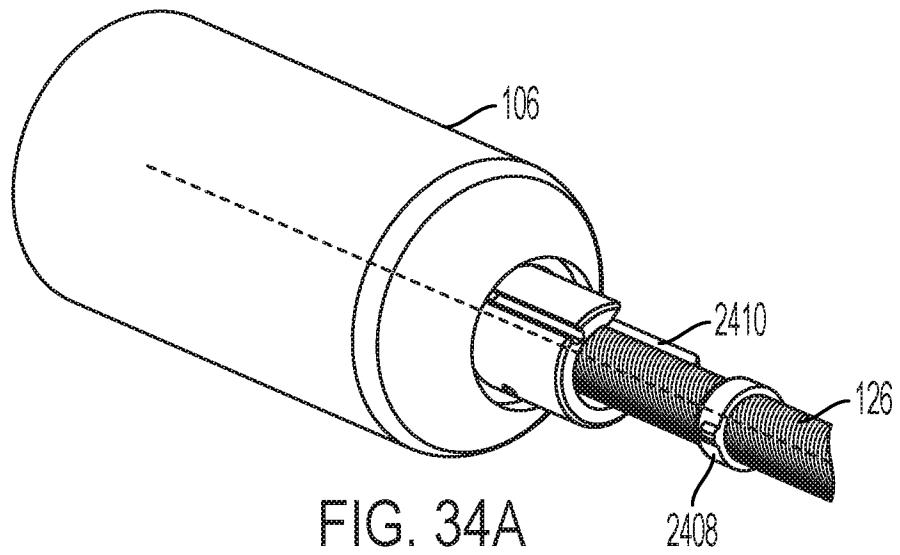


FIG. 33C

34/69



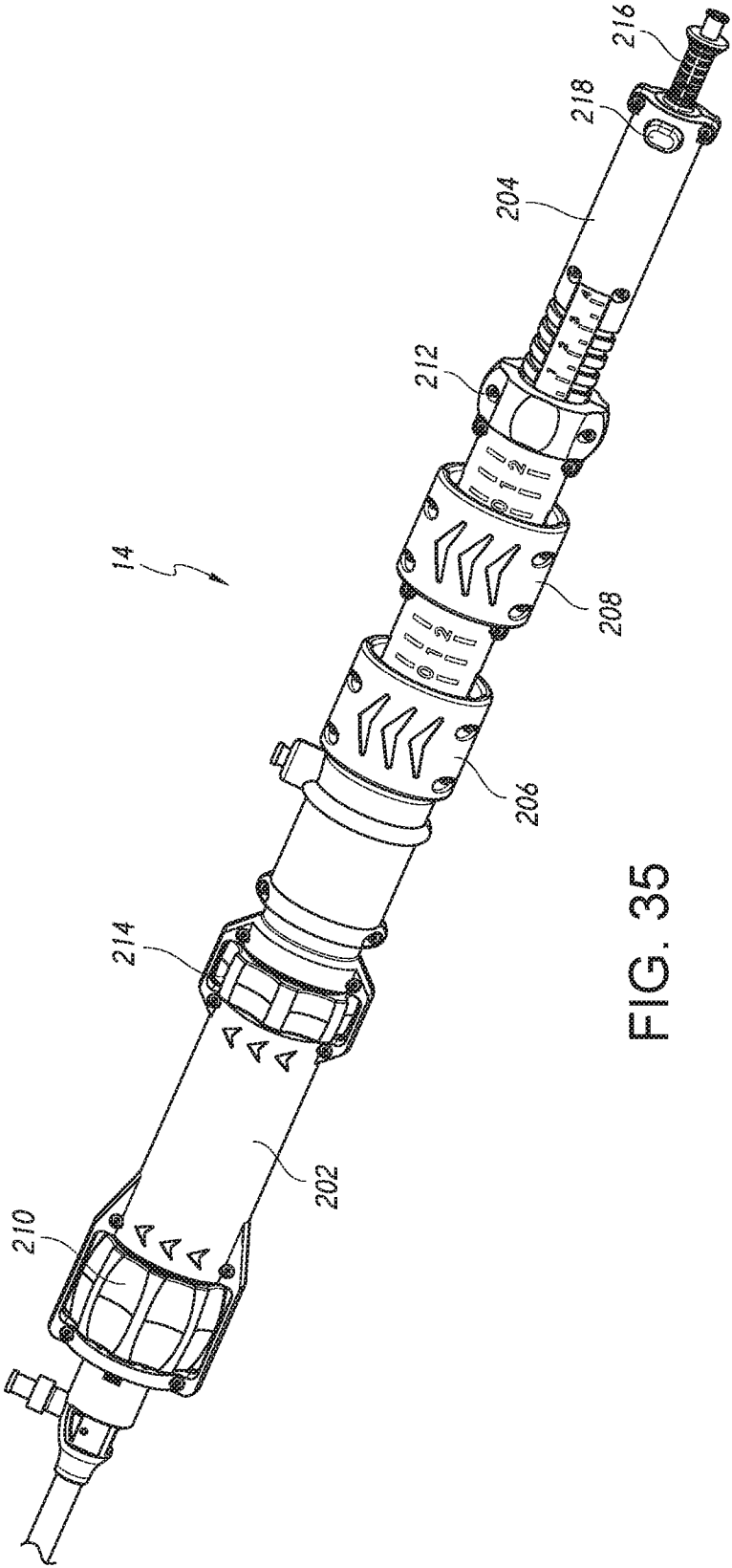


FIG. 35

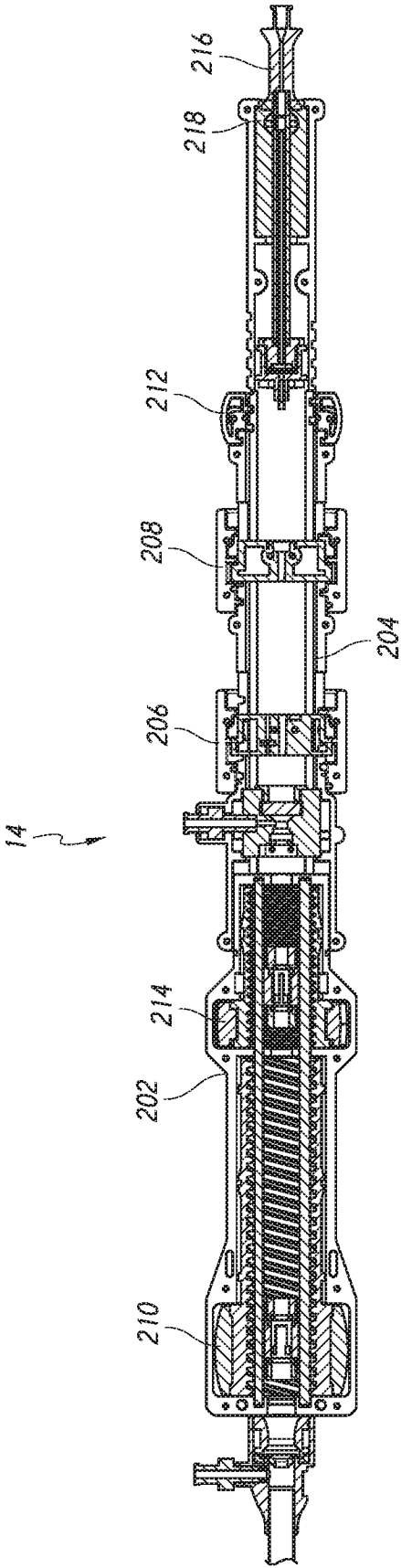


FIG. 36

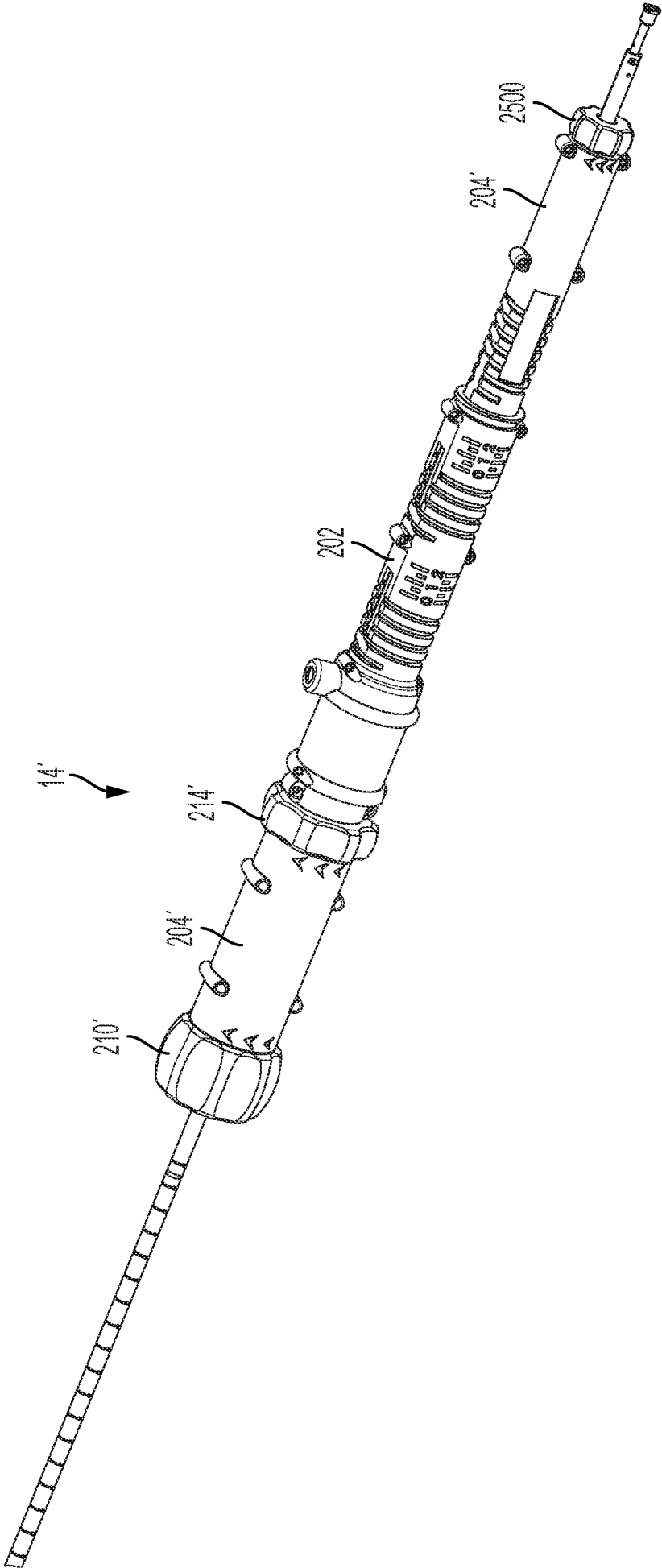


FIG. 37

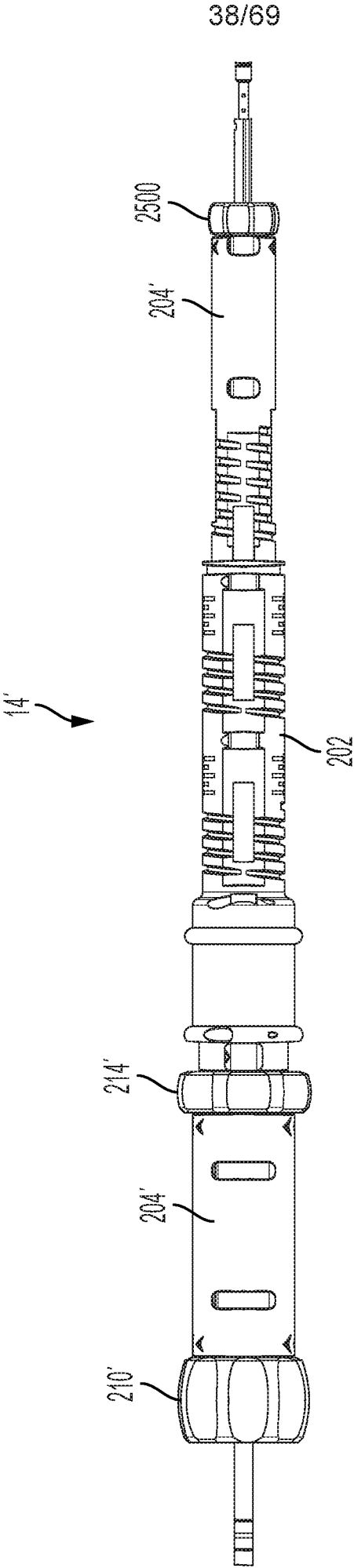


FIG. 38

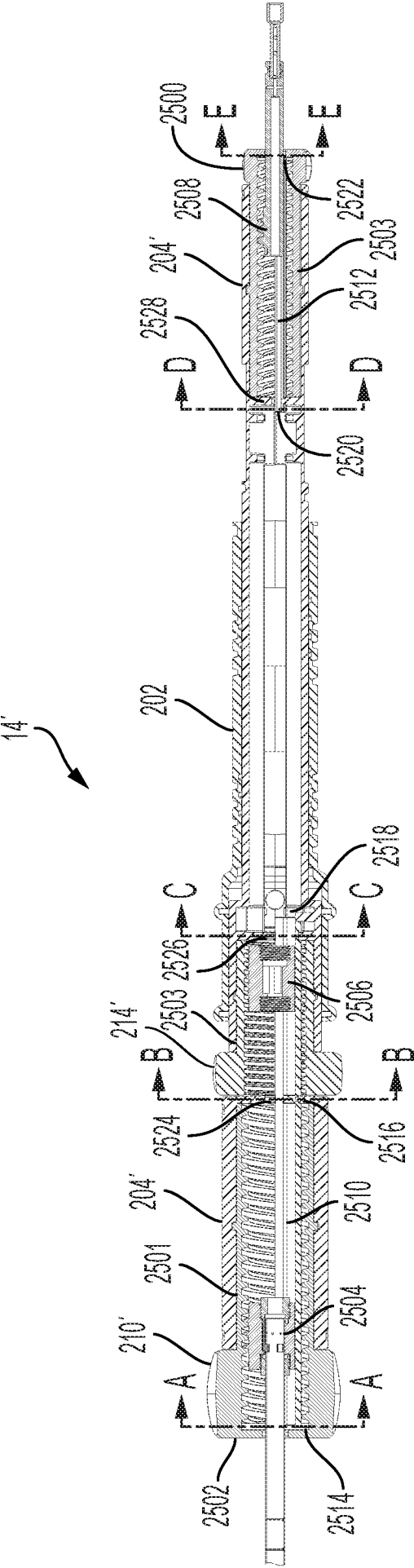


FIG. 39

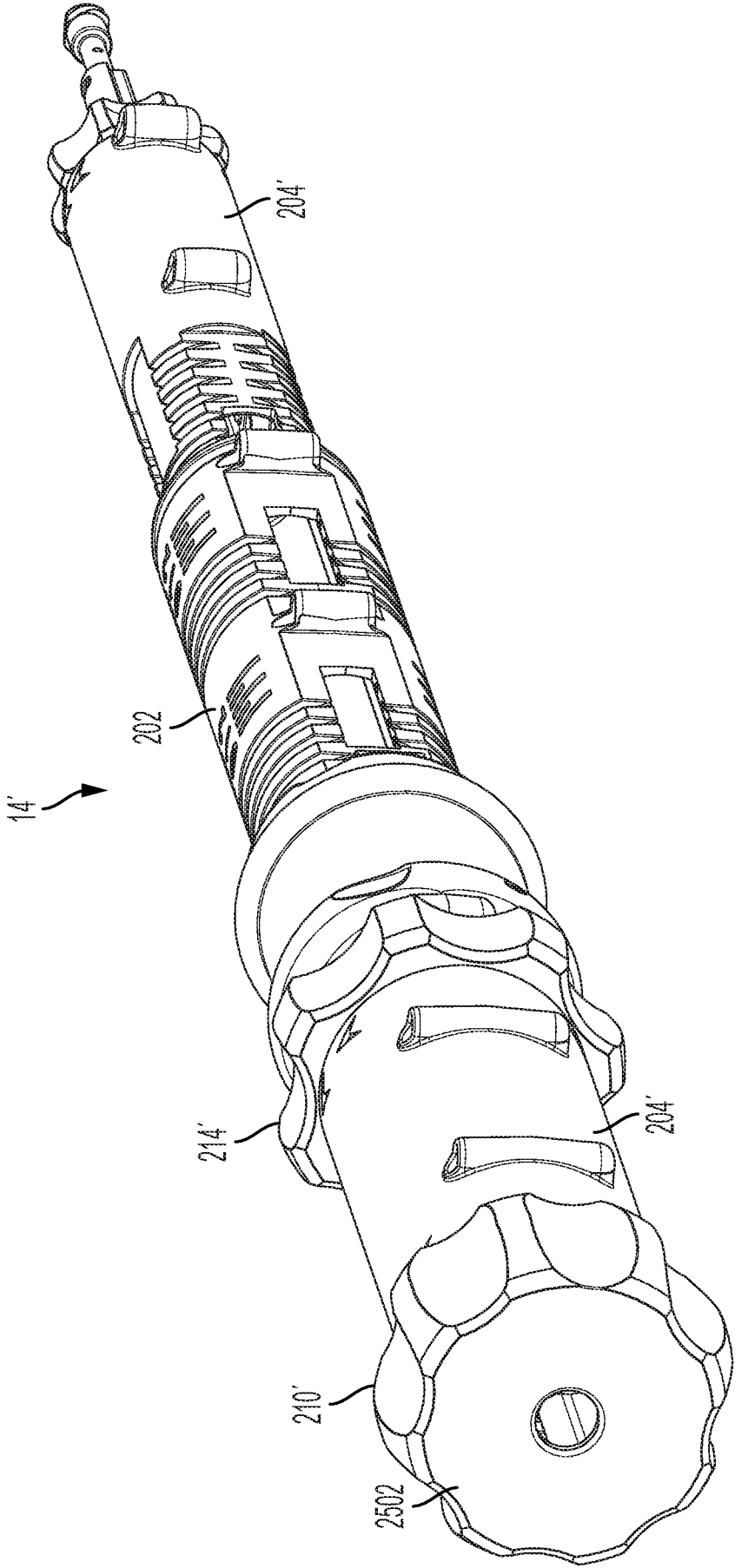


FIG. 40

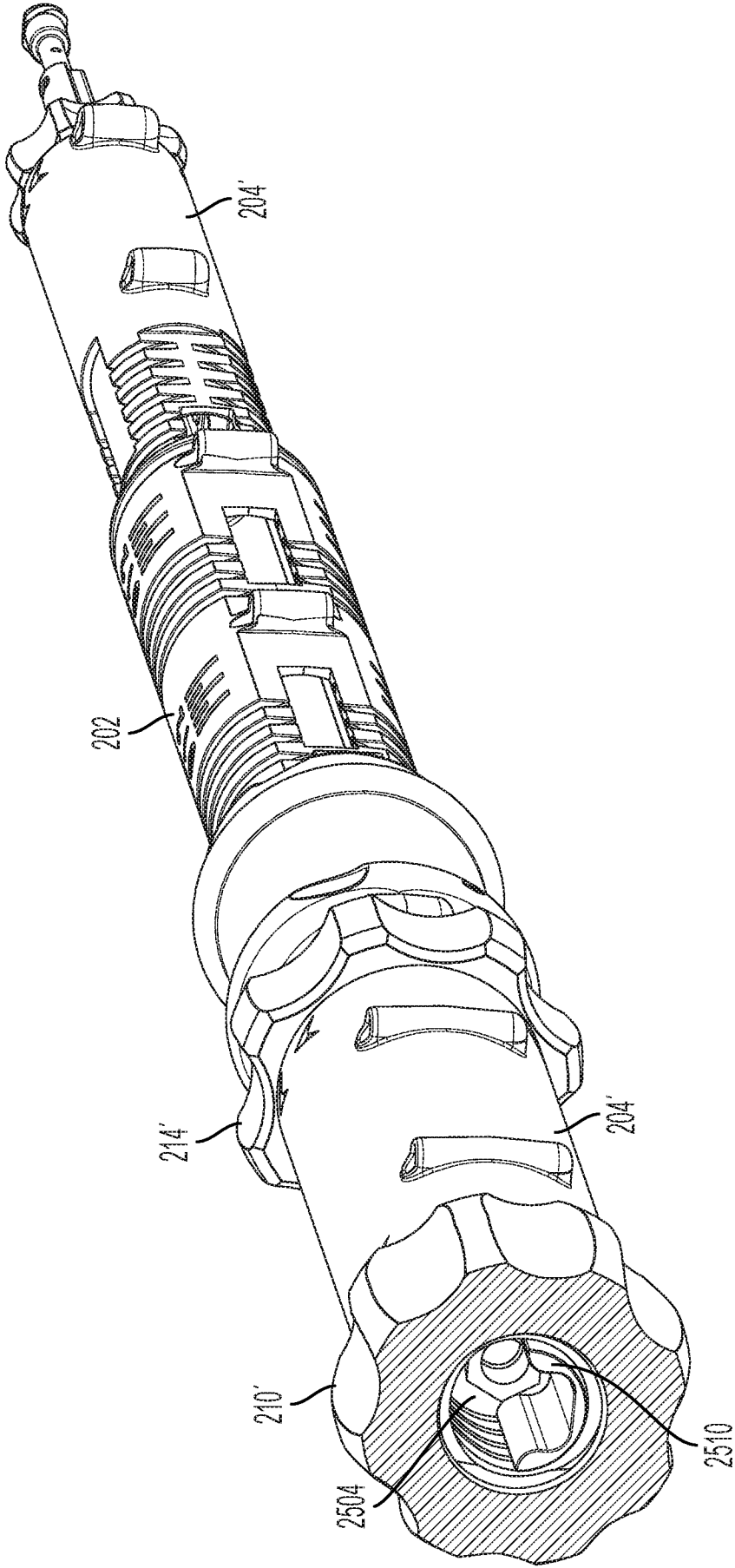


FIG. 41

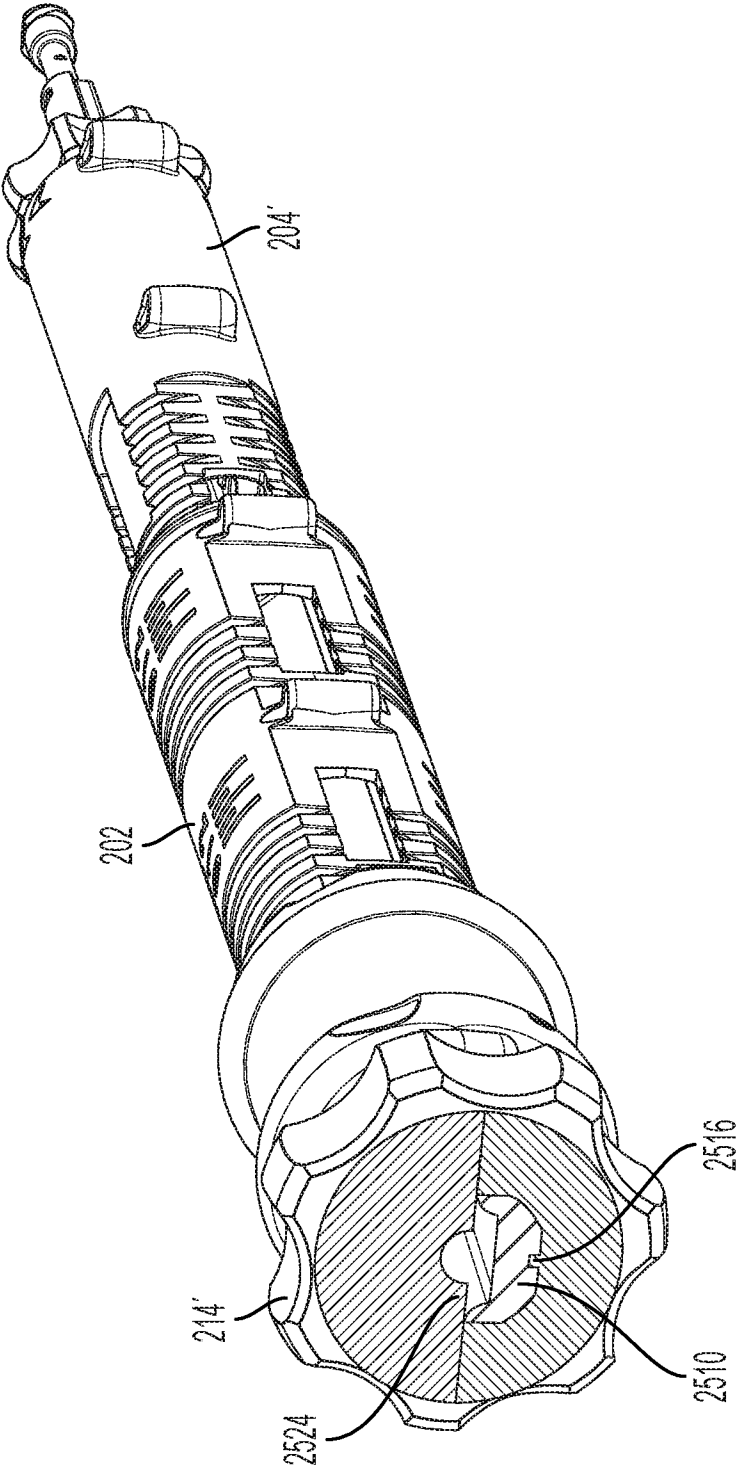


FIG. 42

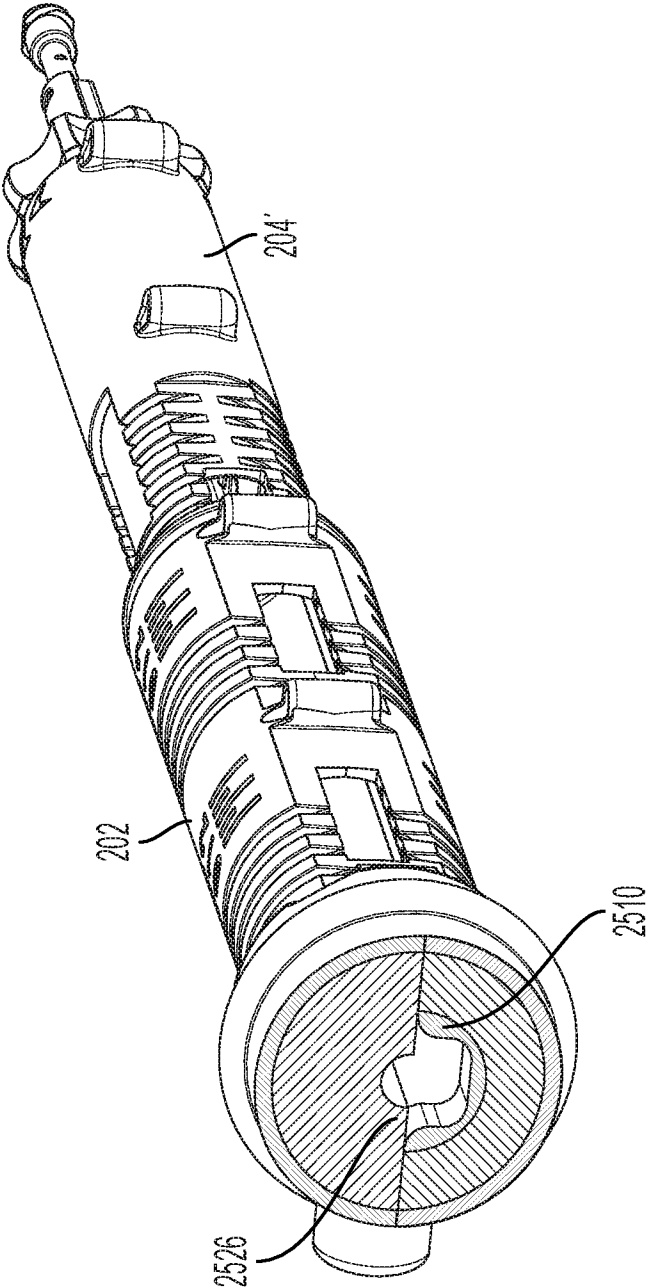


FIG. 43

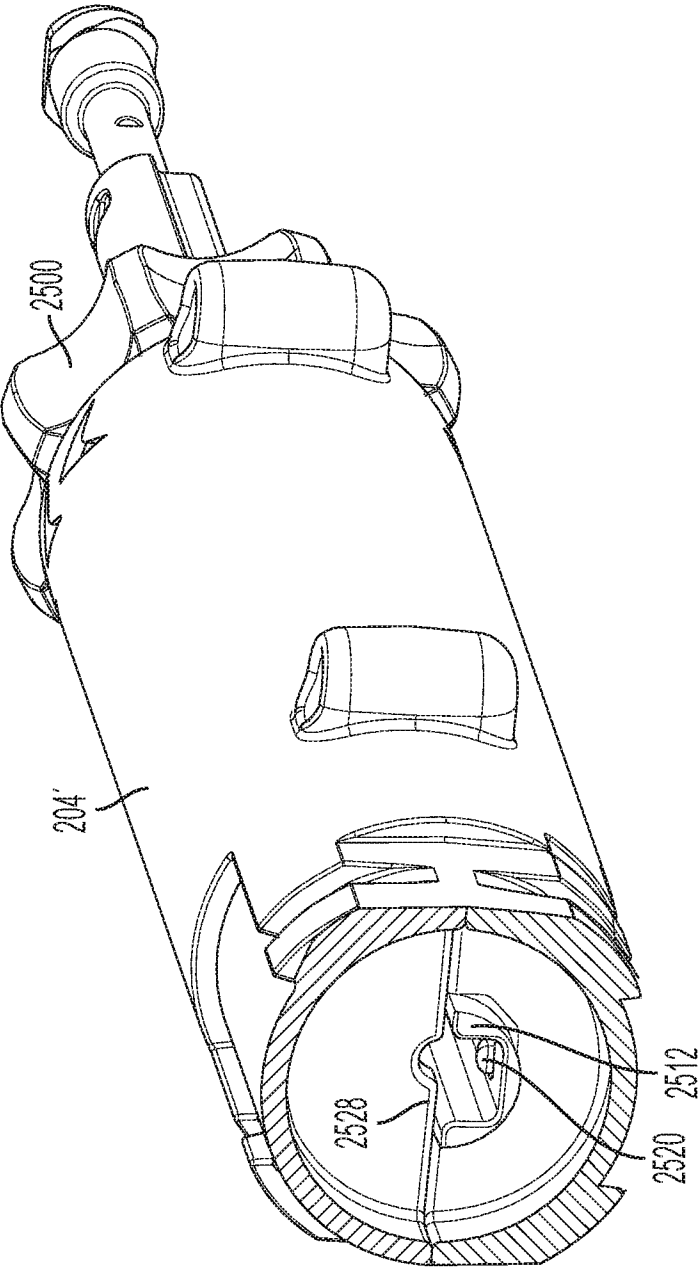


FIG. 44

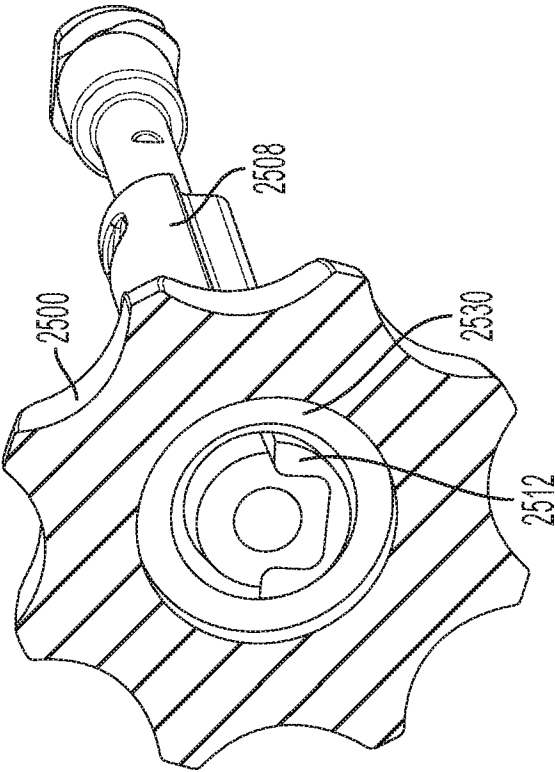


FIG. 45

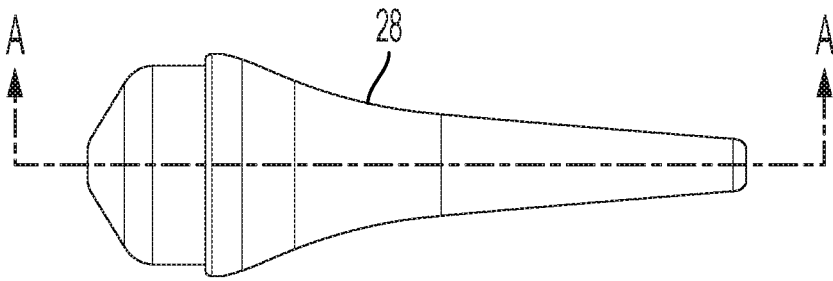


FIG. 46

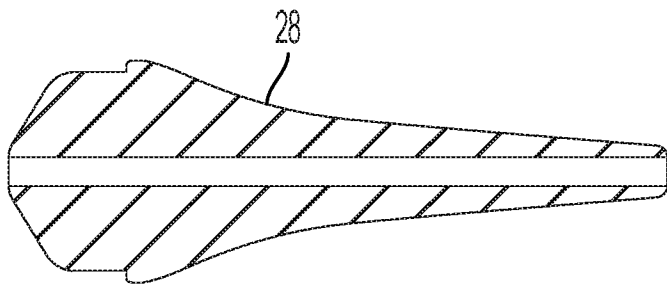
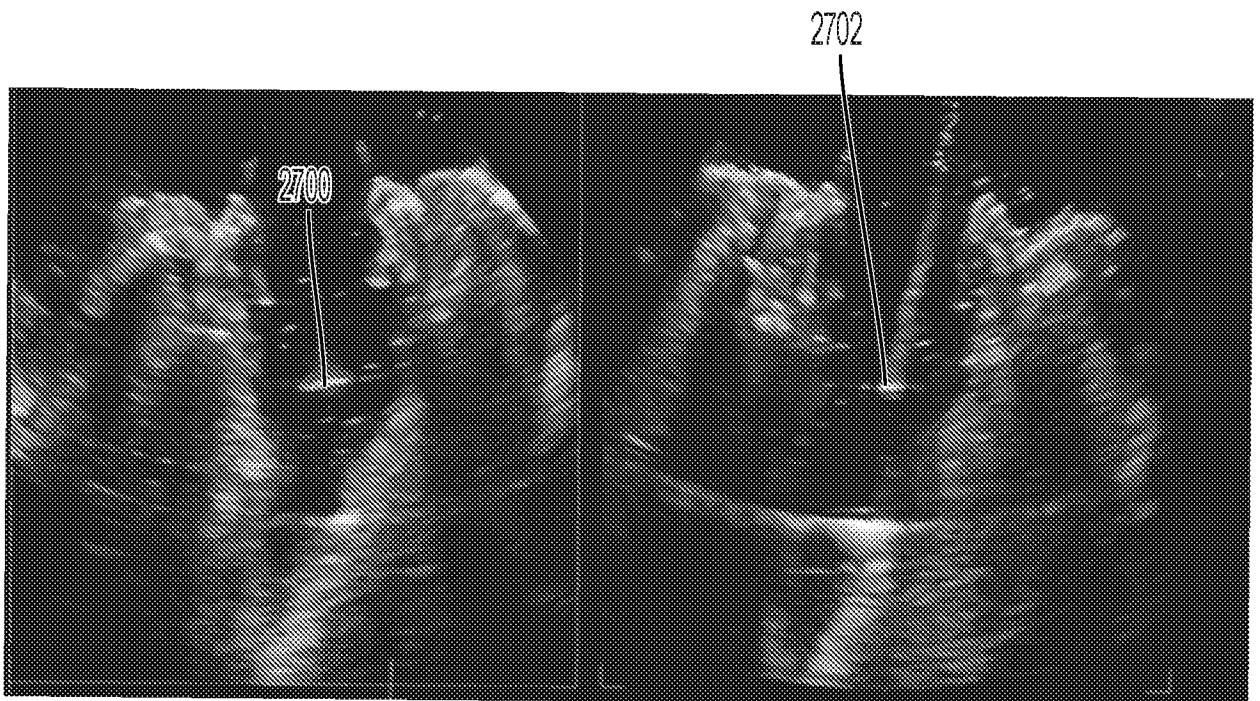
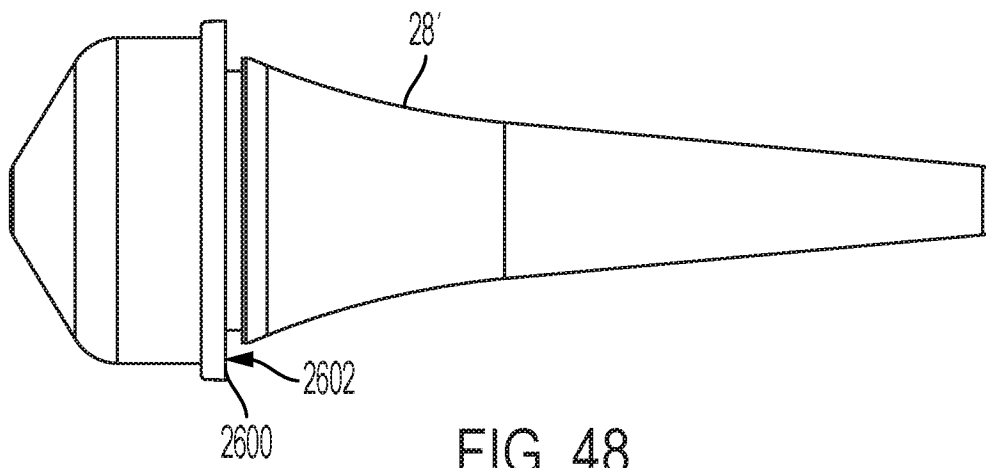
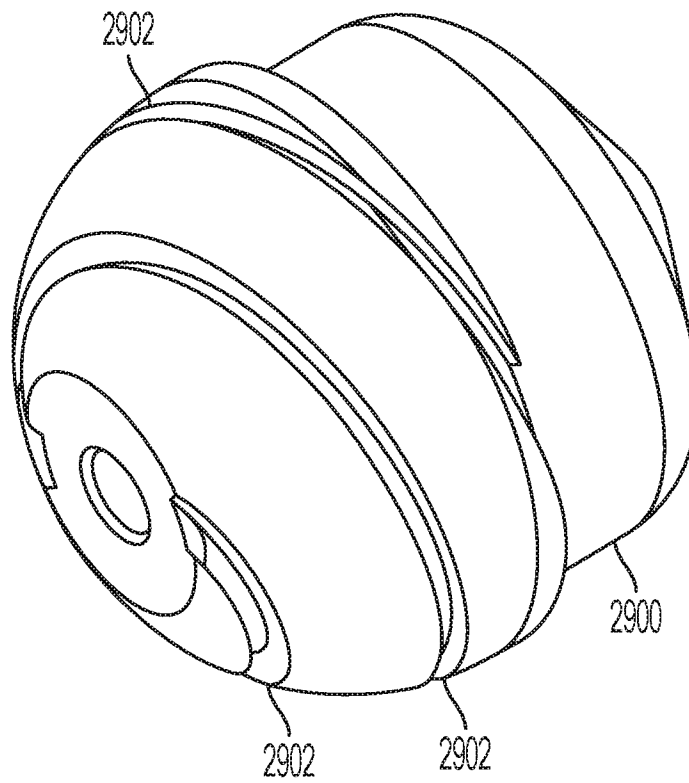
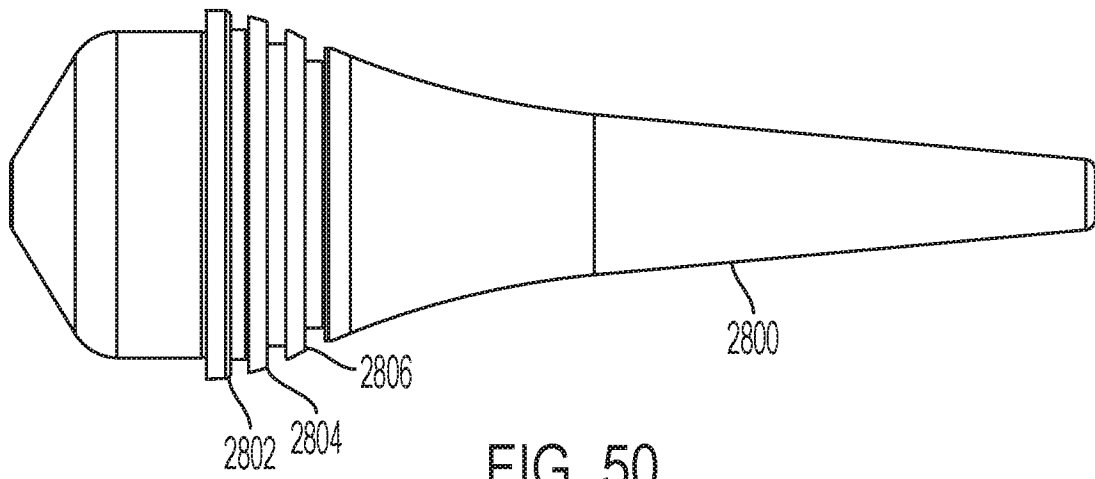


FIG. 47

47/69





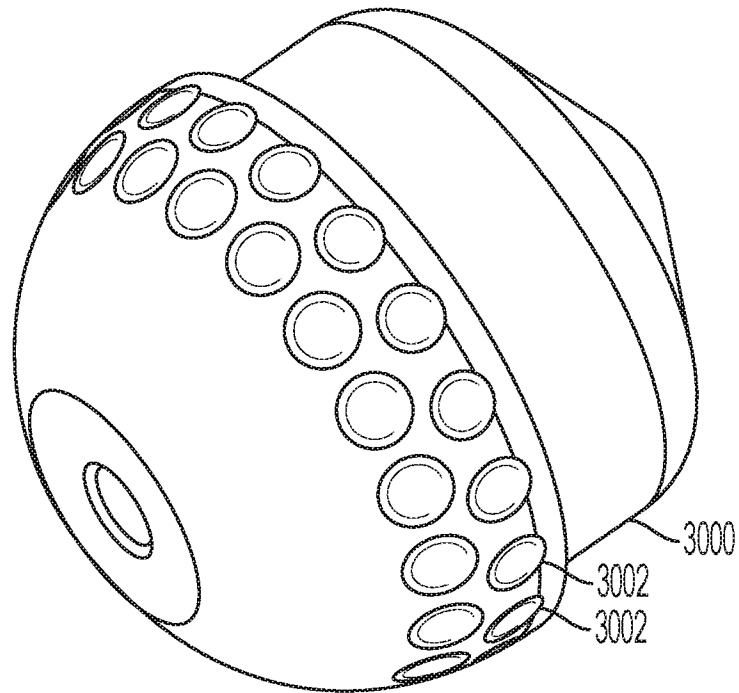


FIG. 52

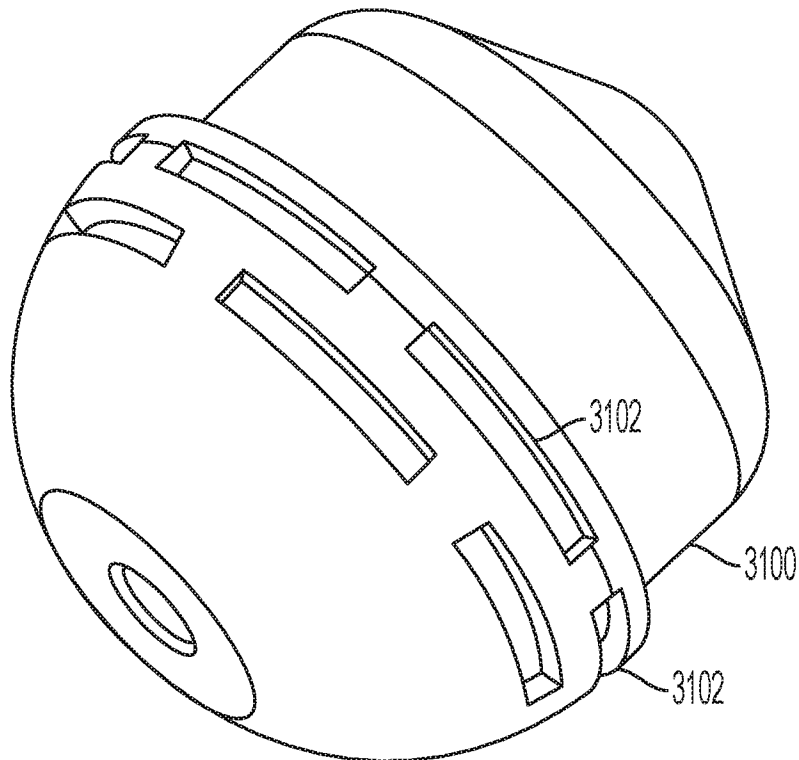


FIG. 53

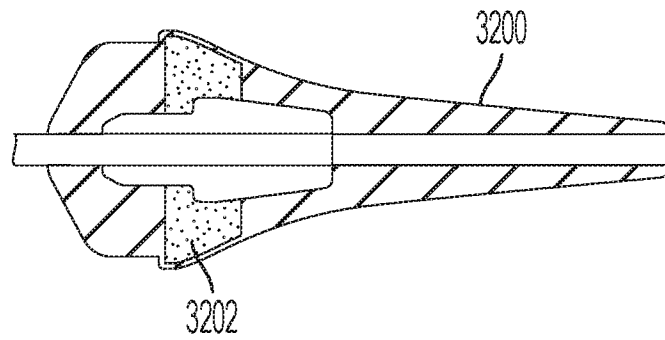


FIG. 54

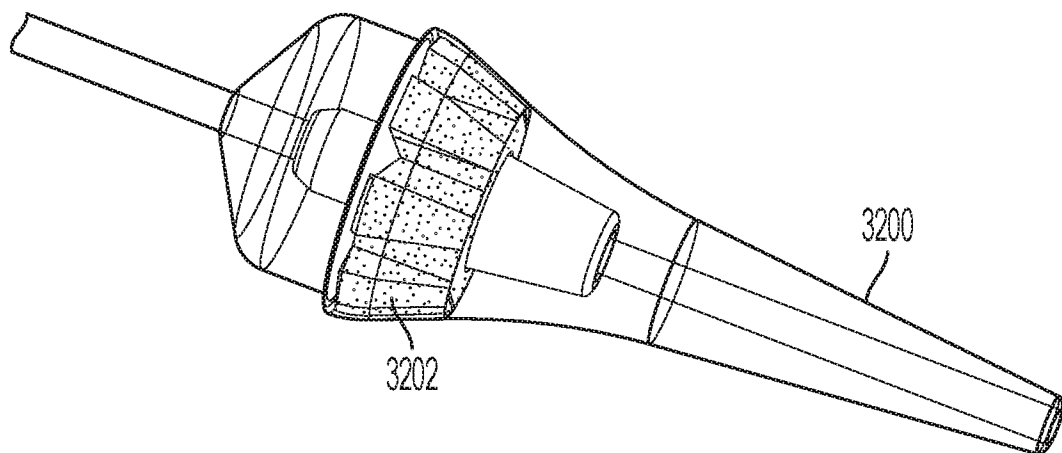


FIG. 55

51/69

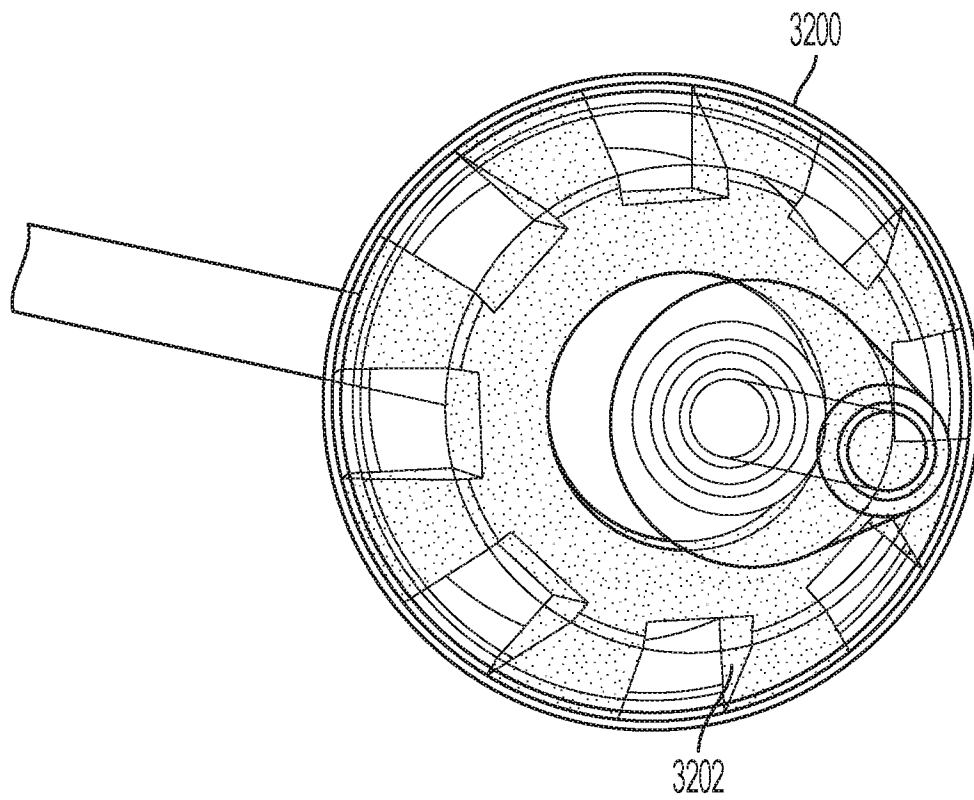


FIG. 56

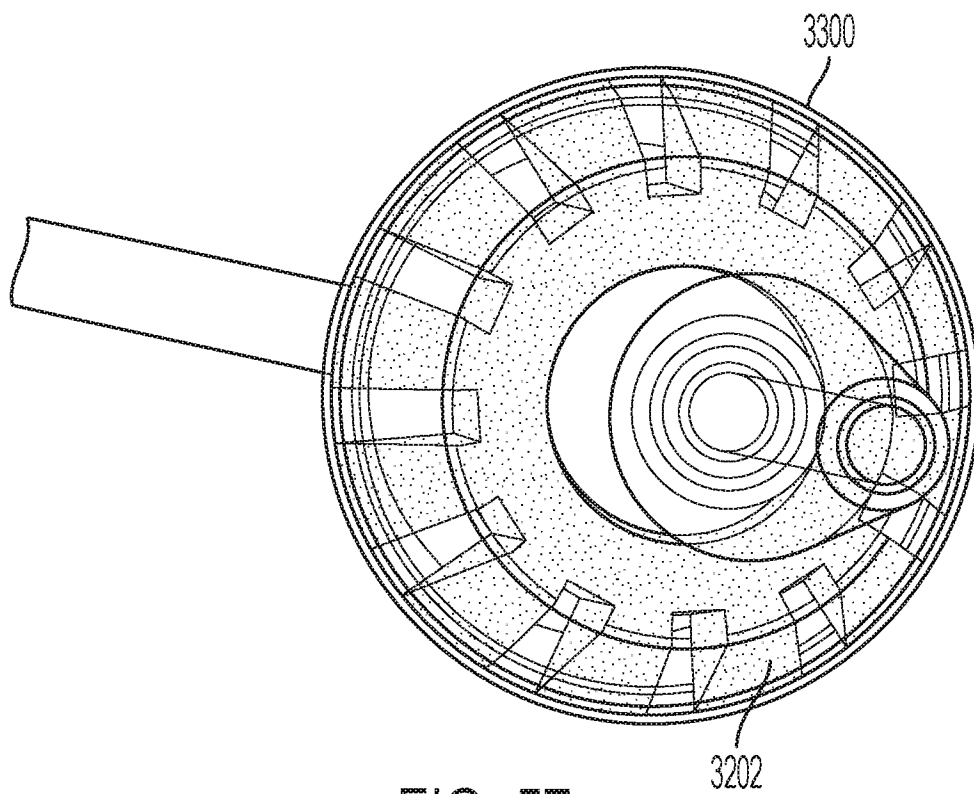


FIG. 57

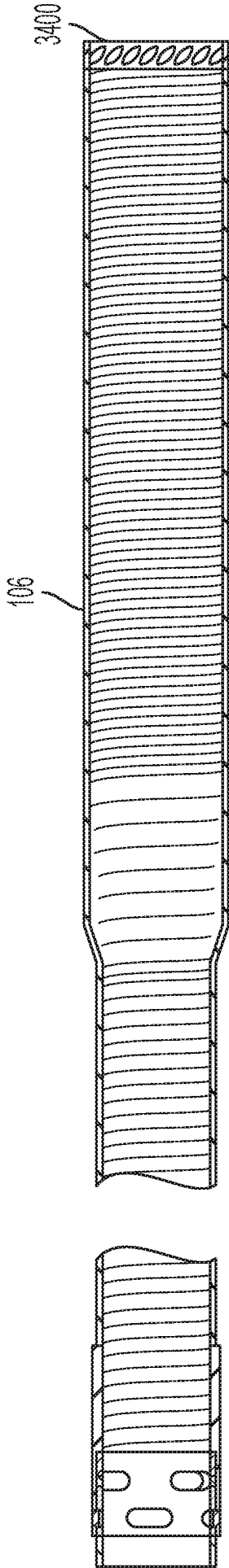


FIG. 58

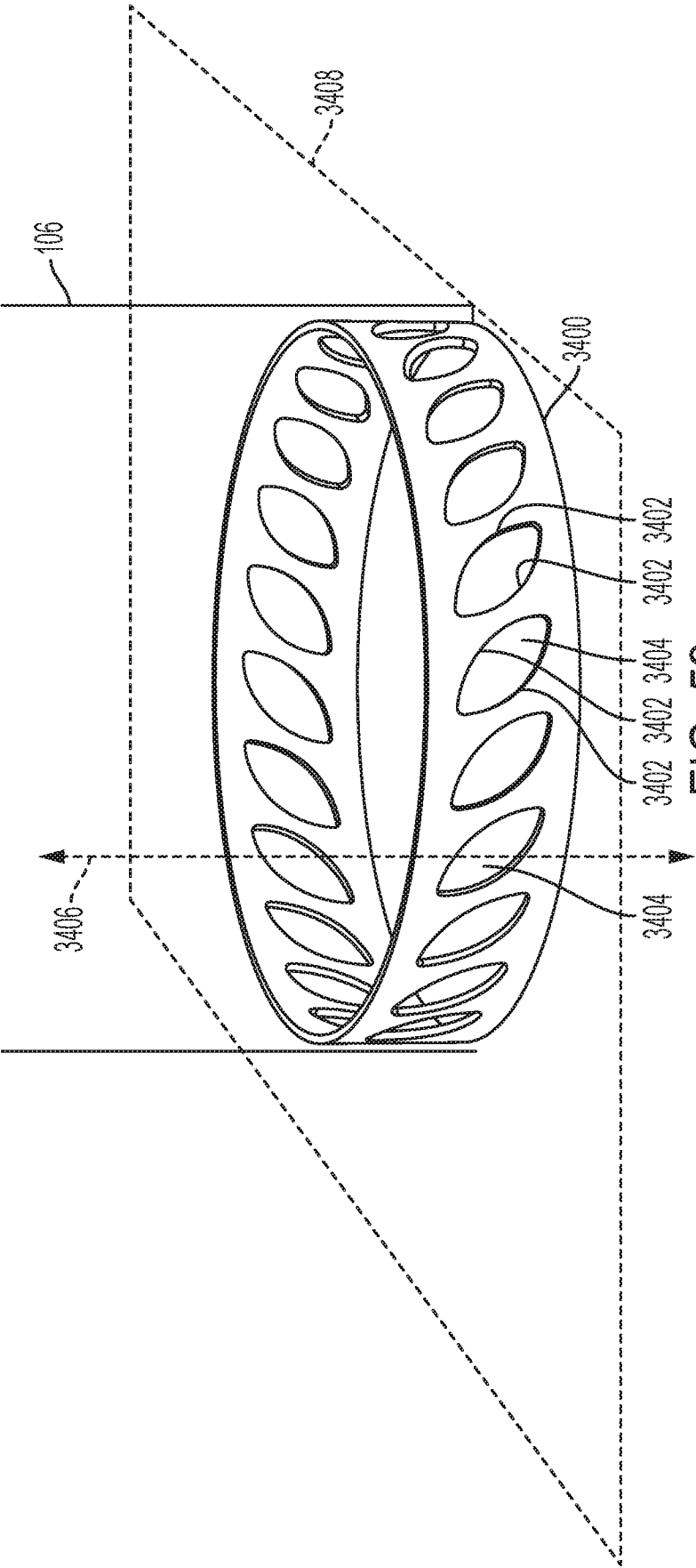


FIG. 59

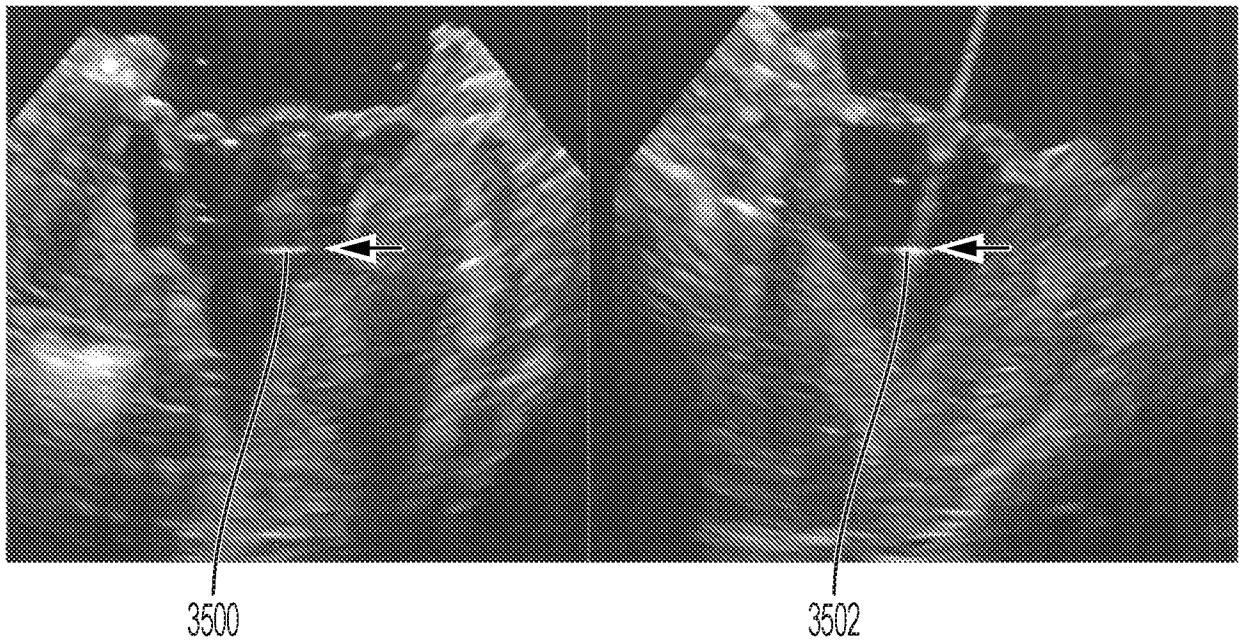


FIG. 60

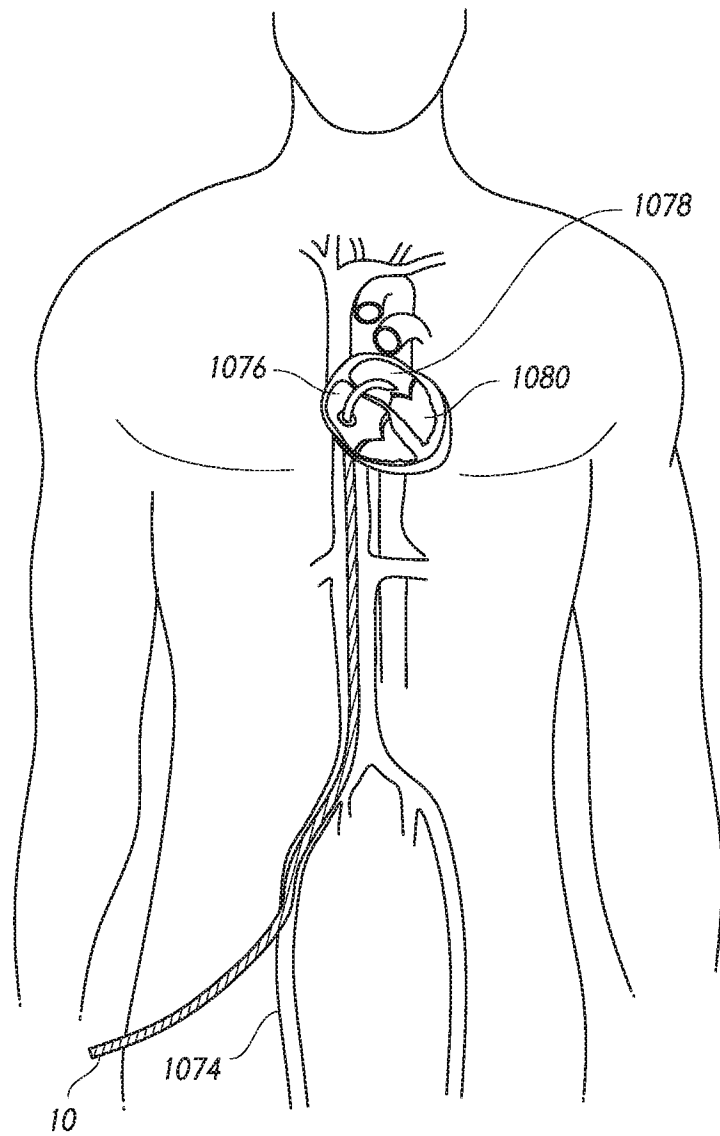
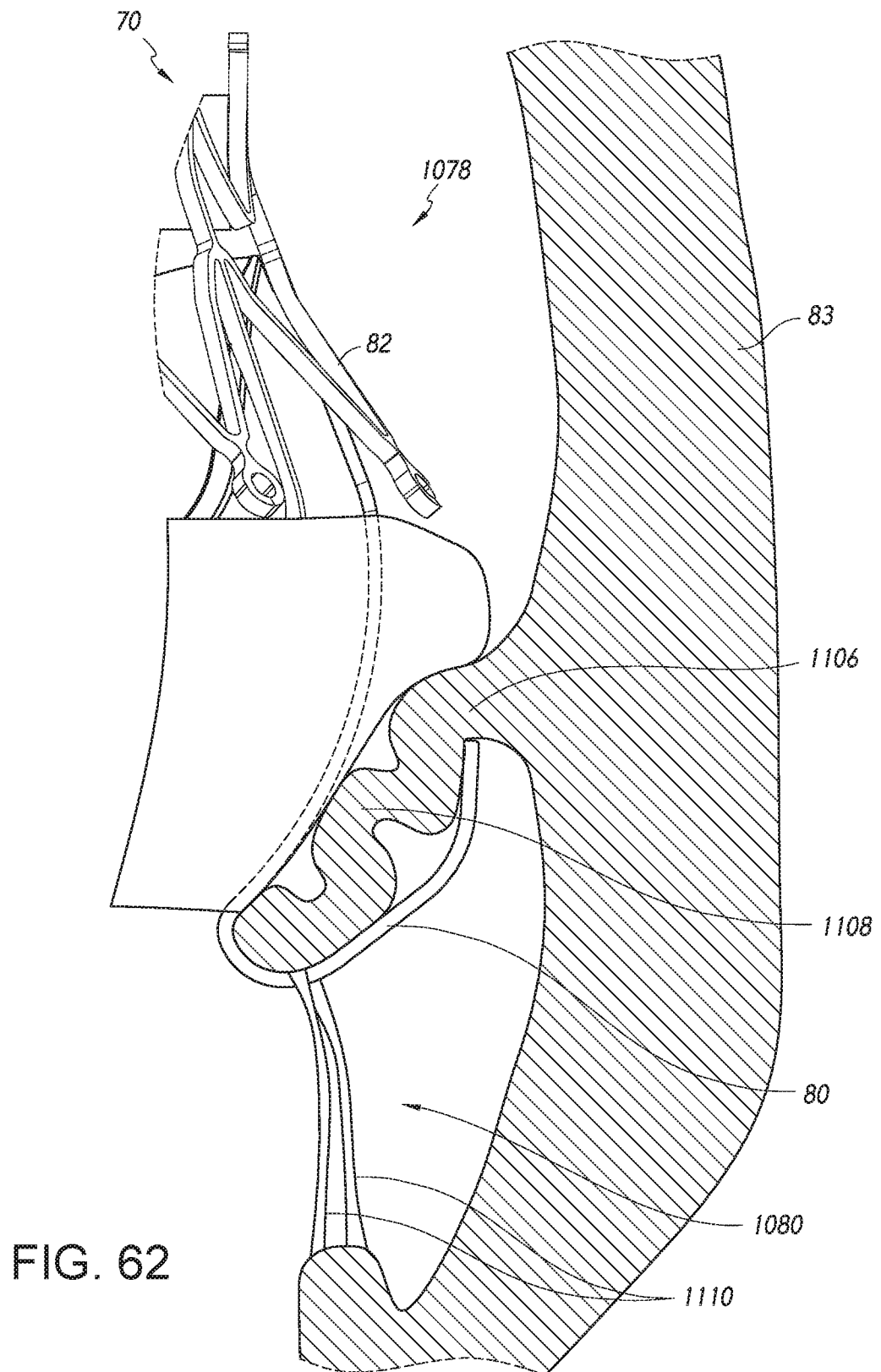


FIG. 61



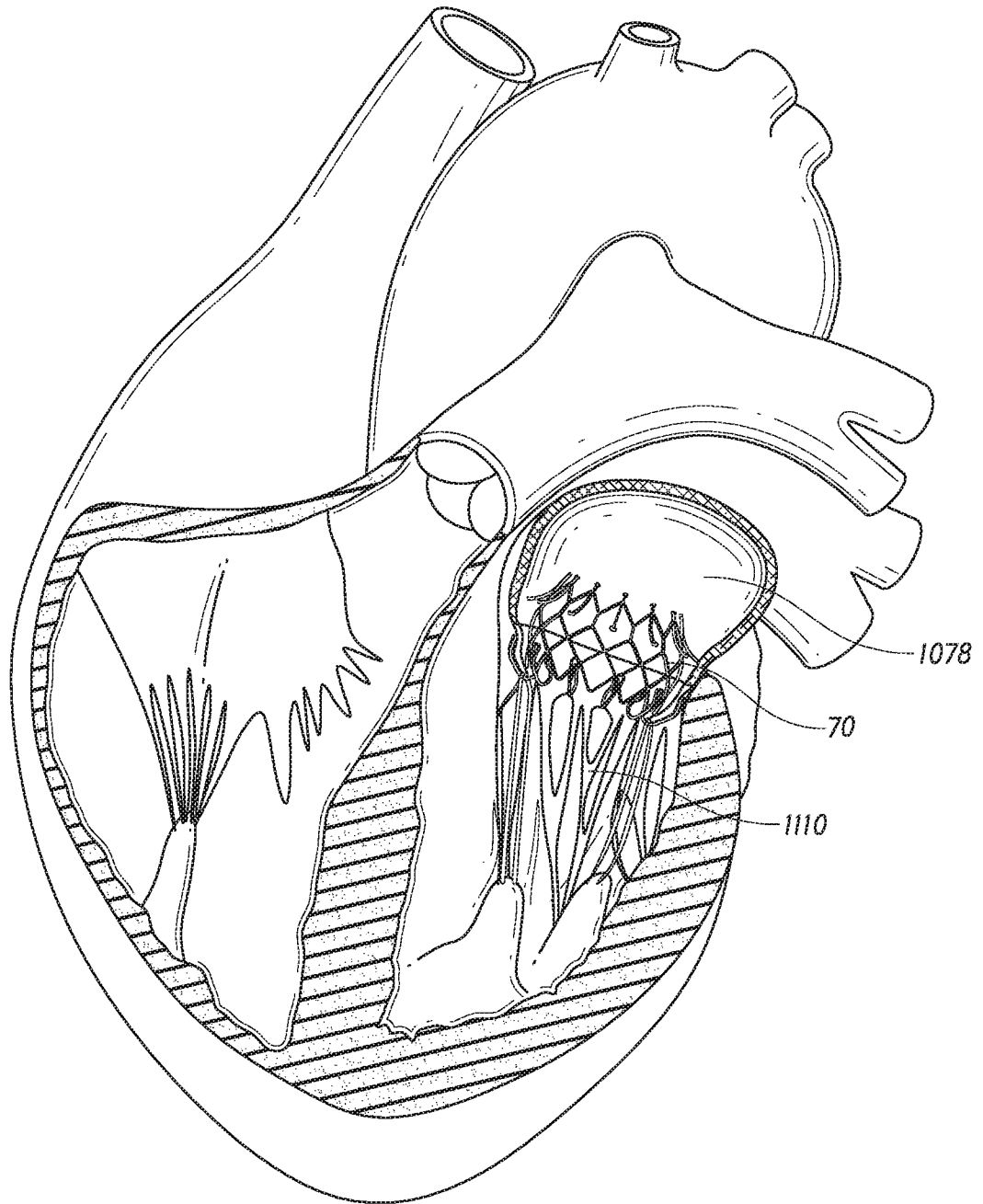


FIG. 63

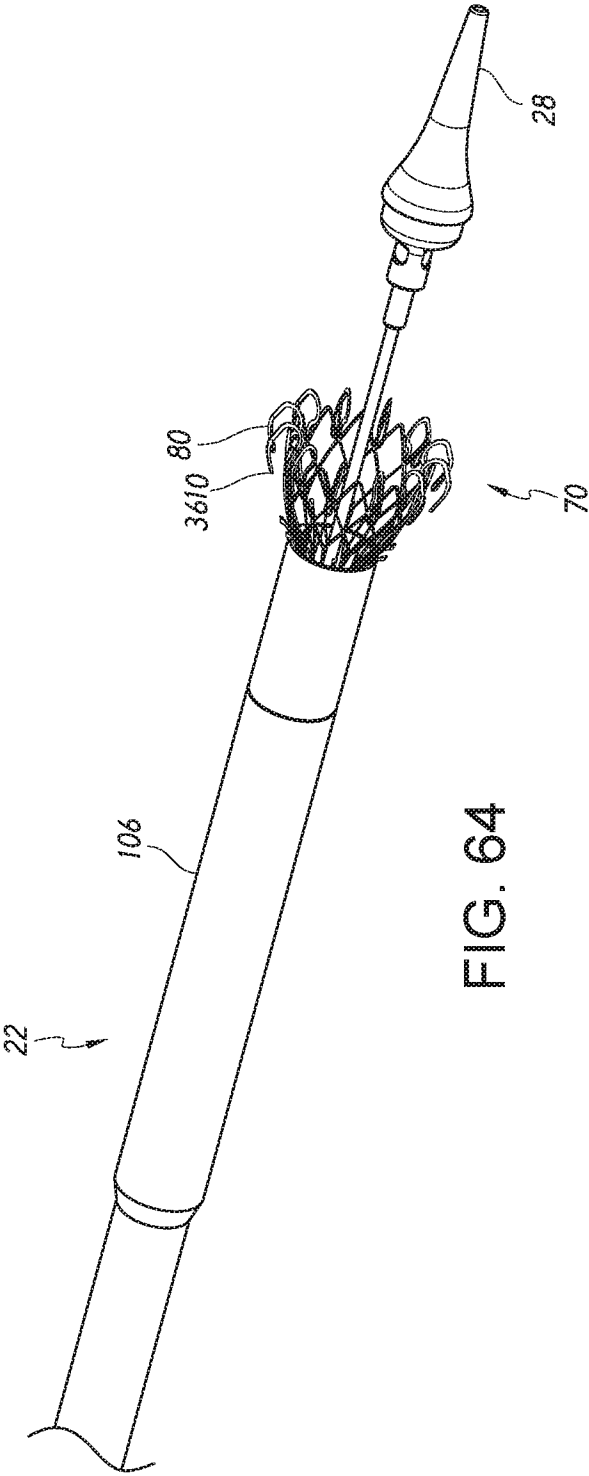


FIG. 64

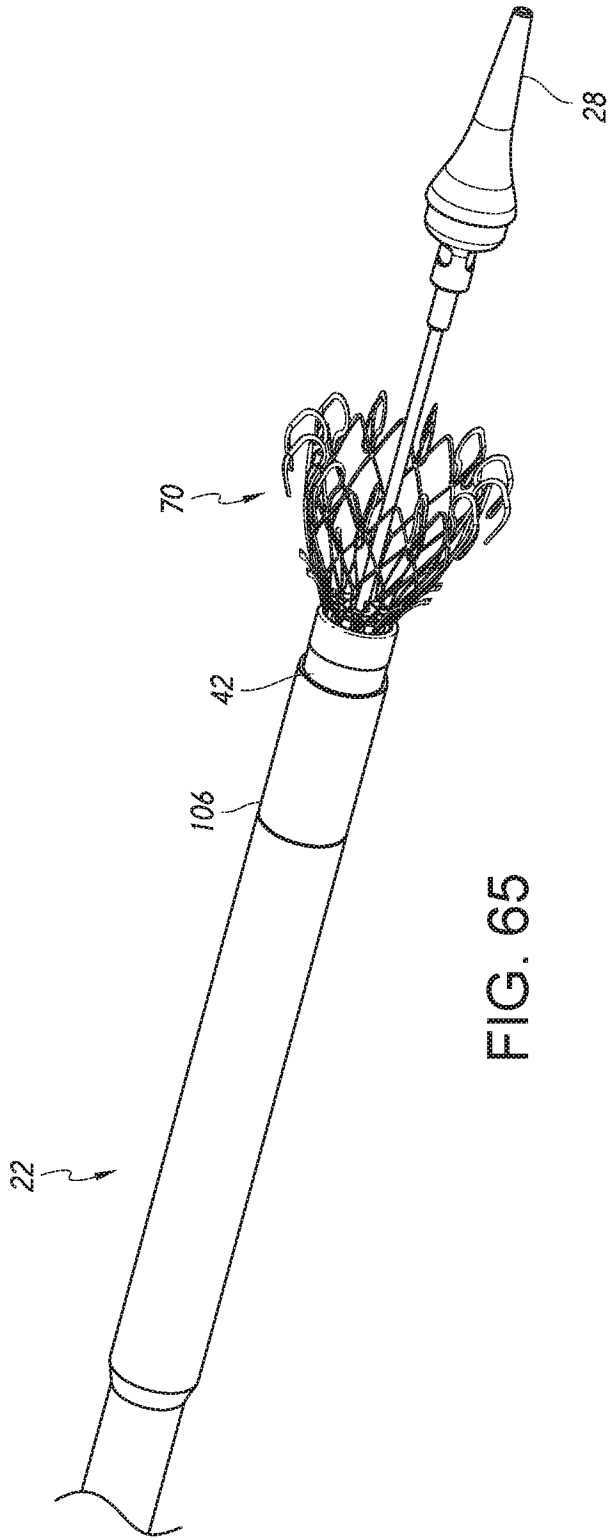


FIG. 65

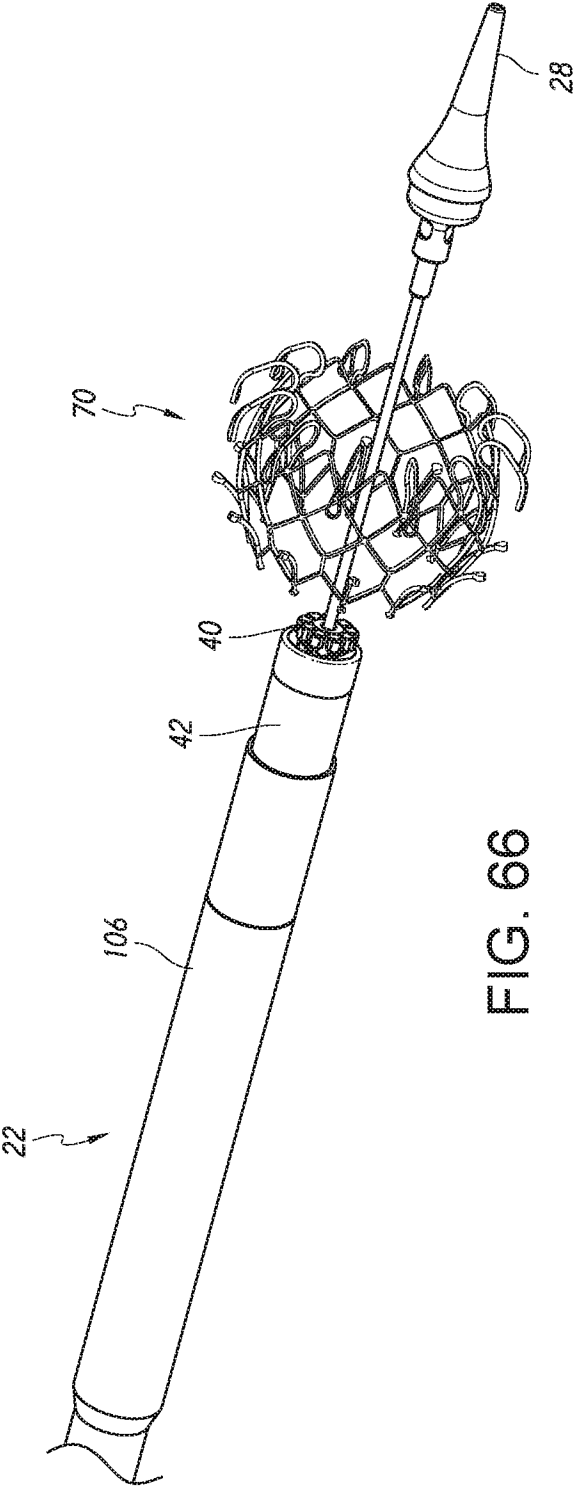


FIG. 66

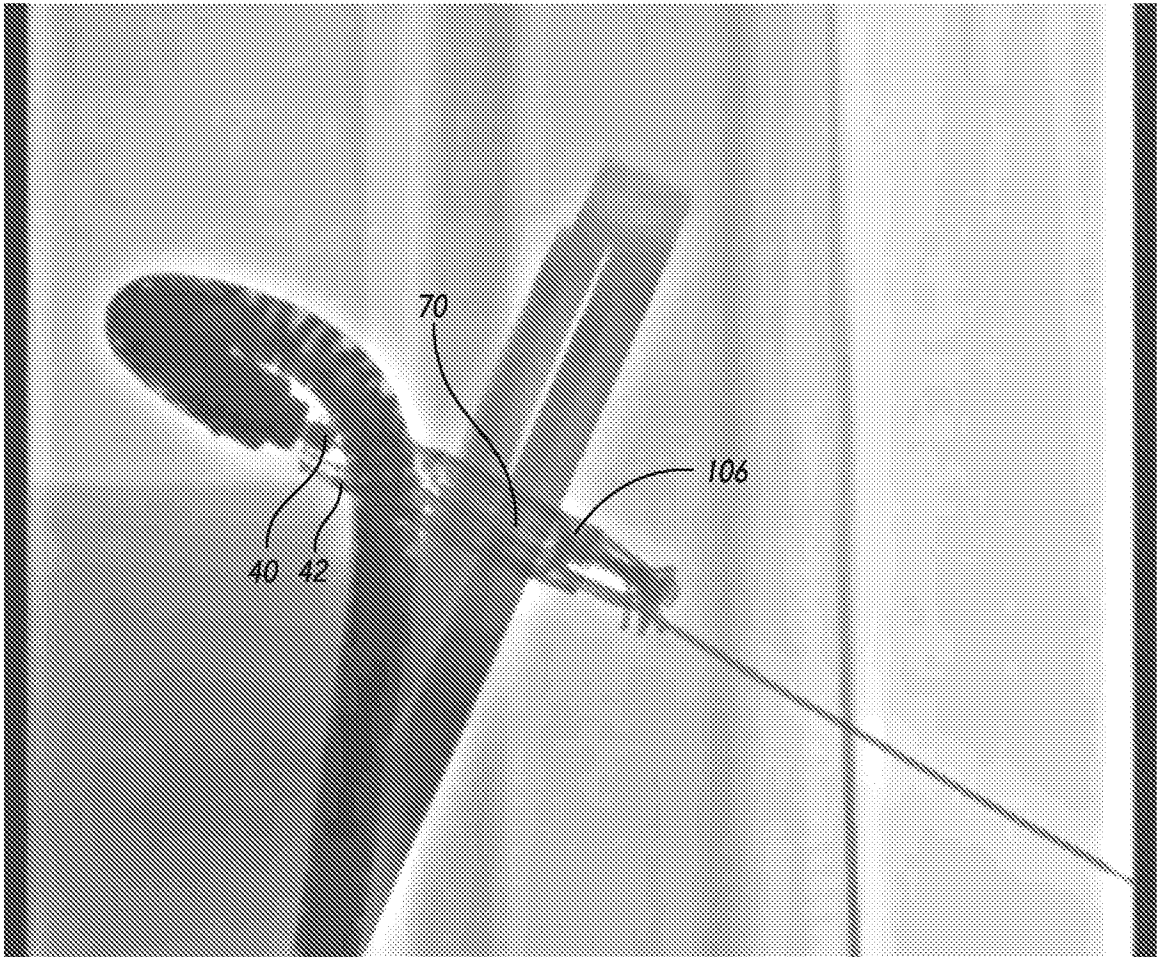


FIG. 67A

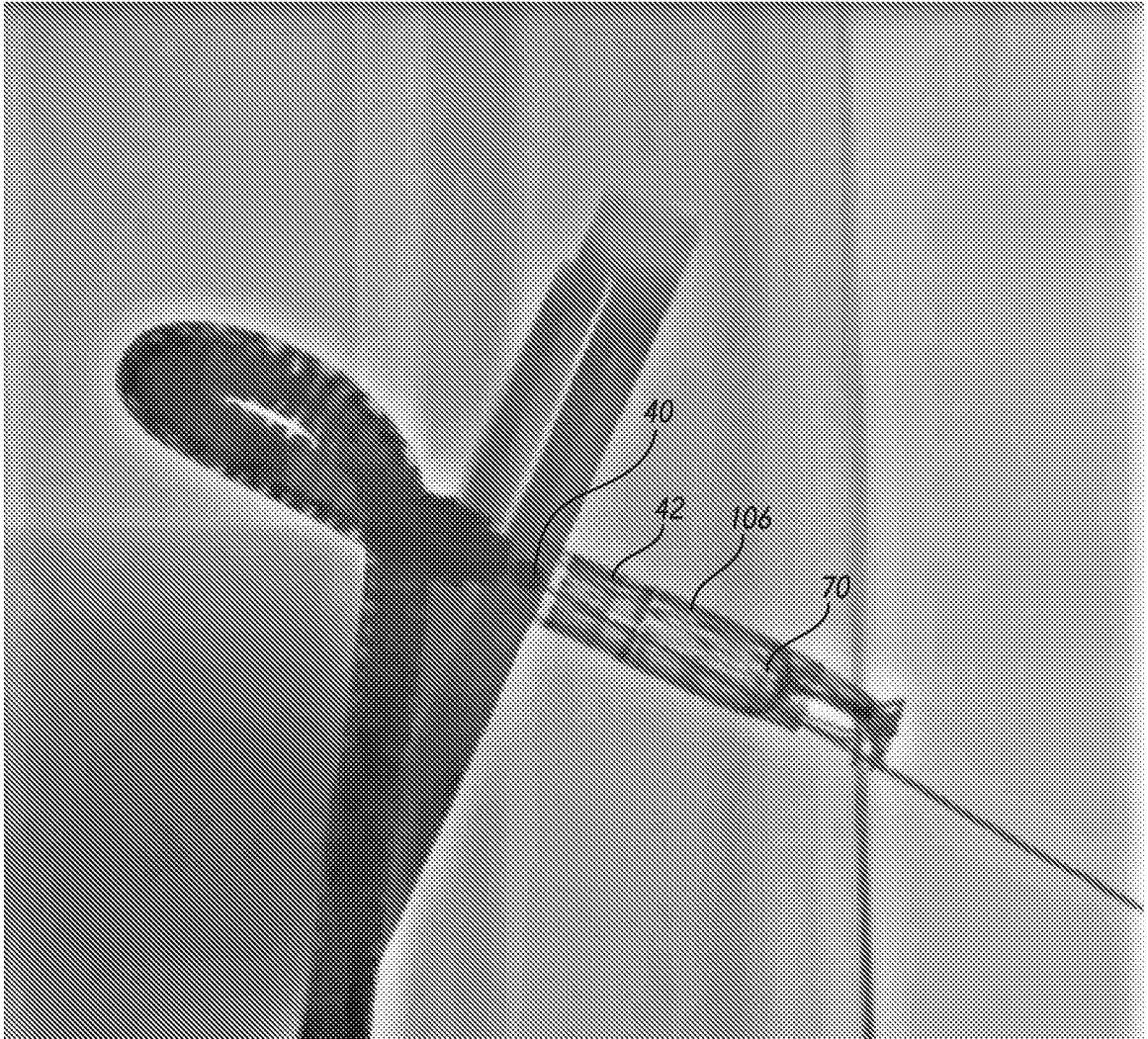


FIG. 67B

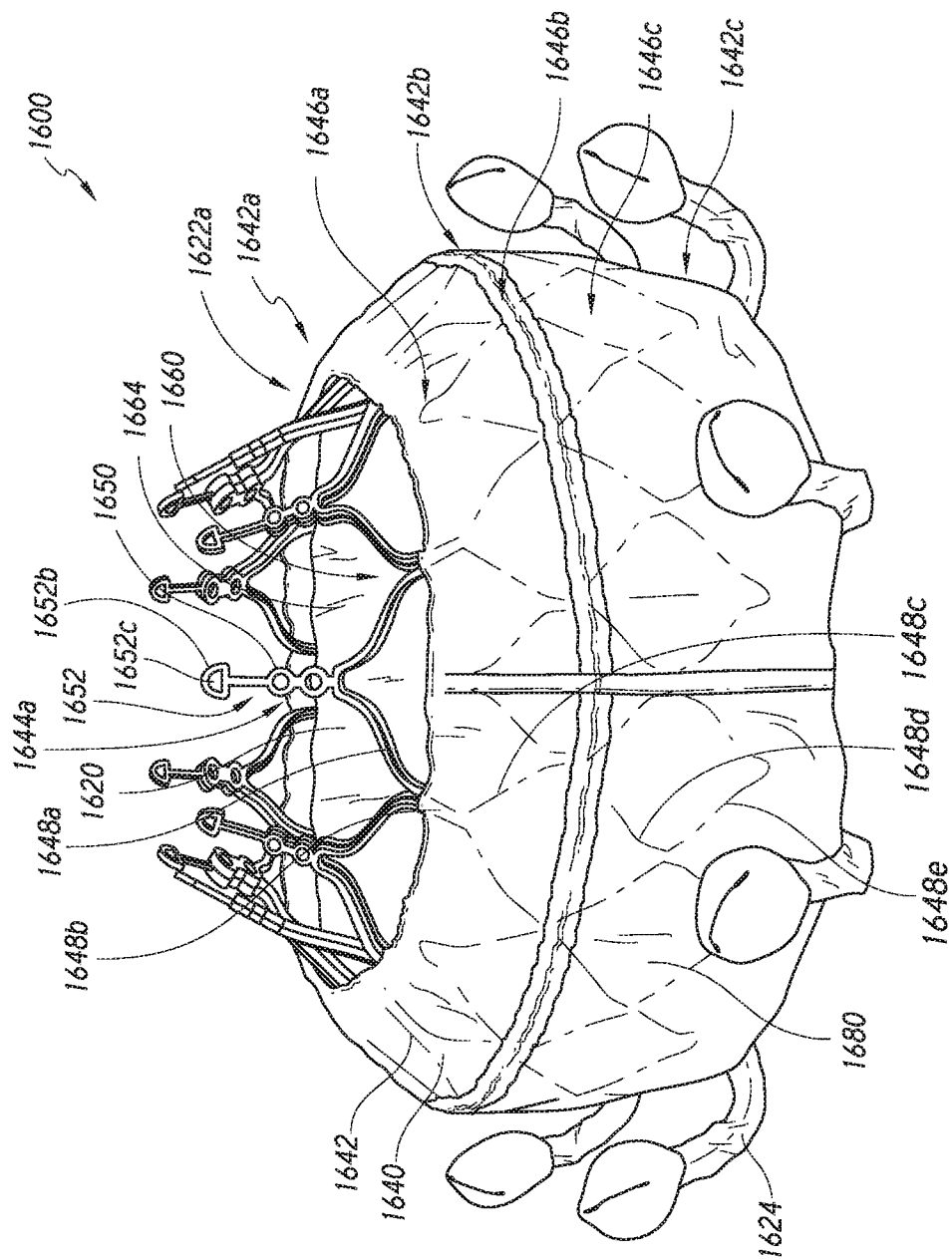


FIG. 68

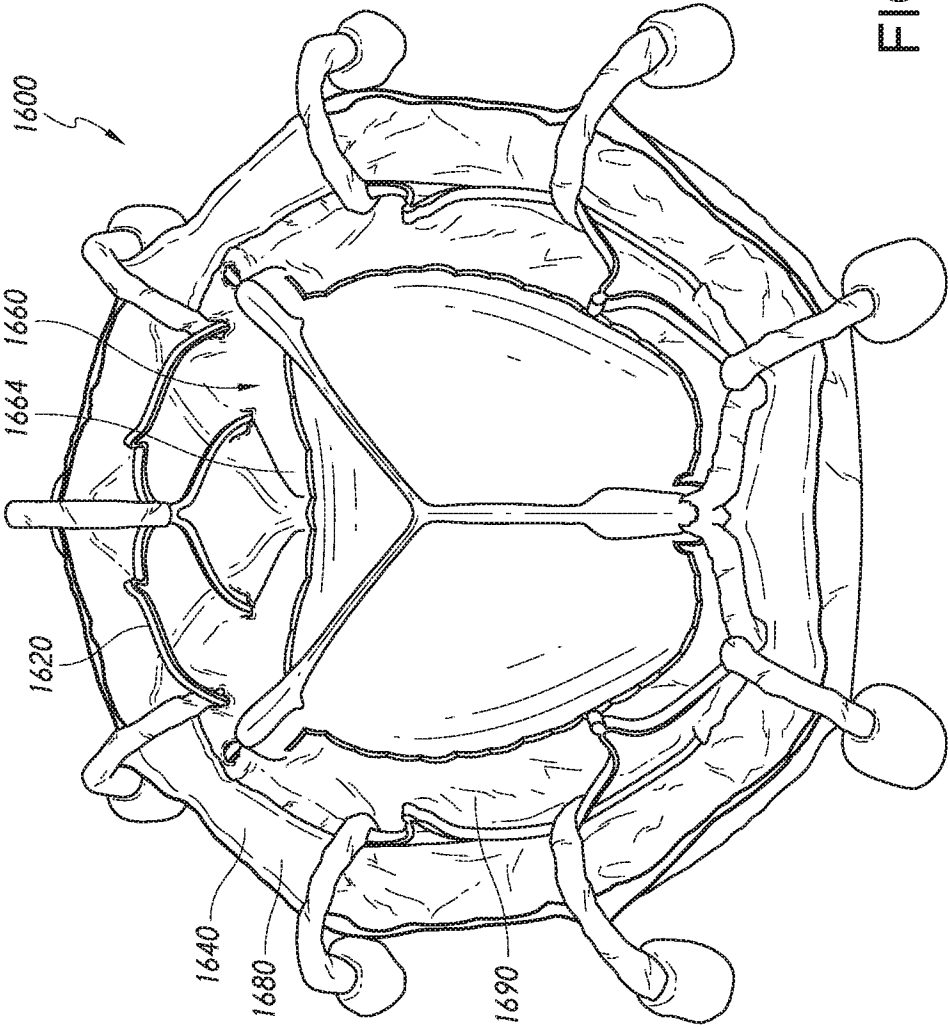


FIG. 69

64/69

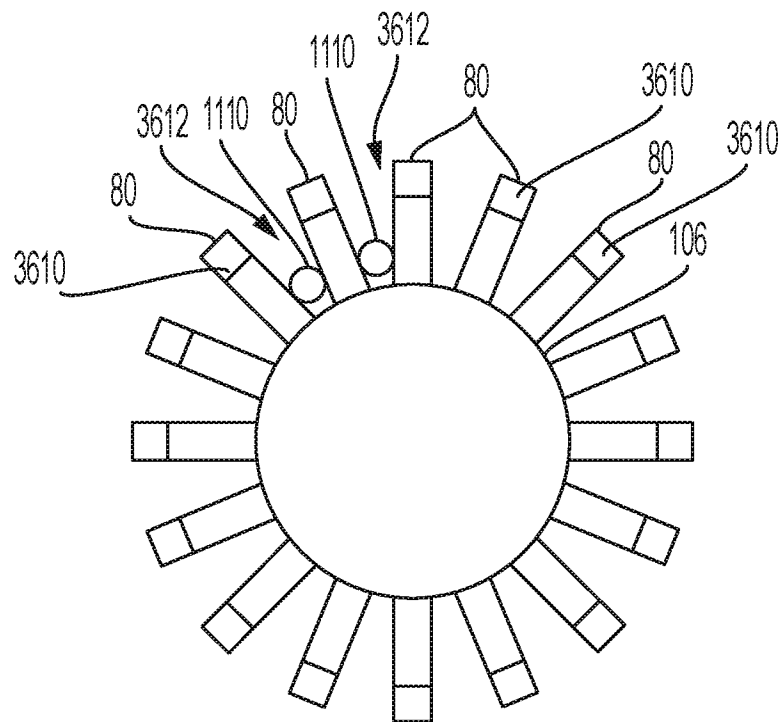


FIG. 70

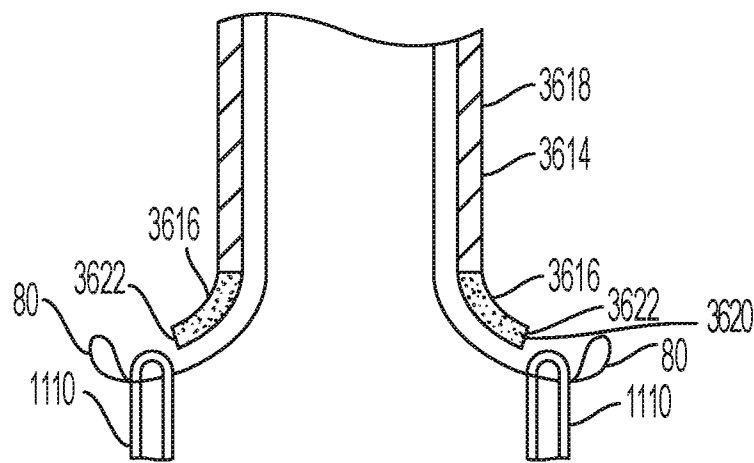


FIG. 71

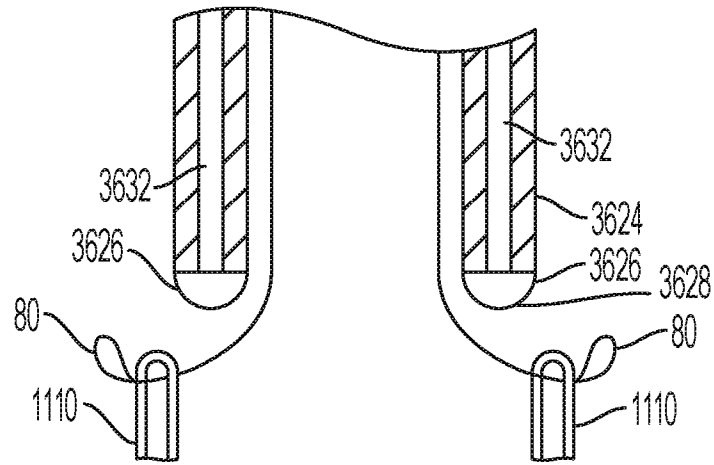


FIG. 72

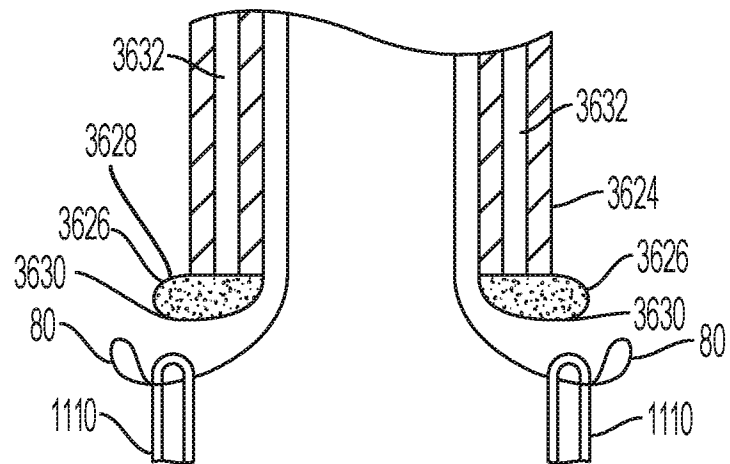
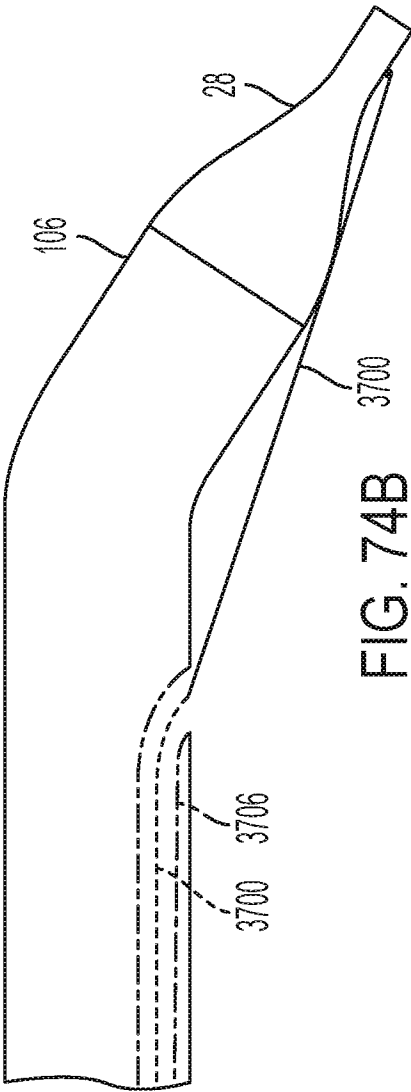
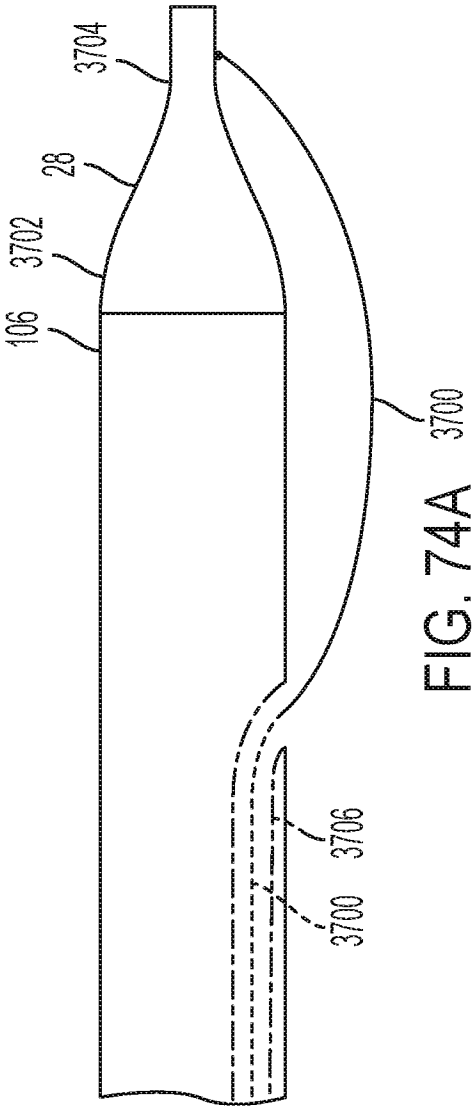


FIG. 73



67/69

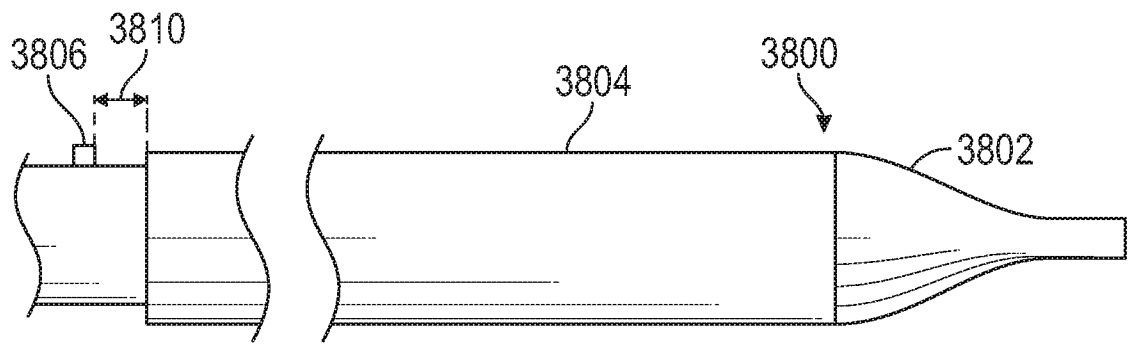


FIG. 75A

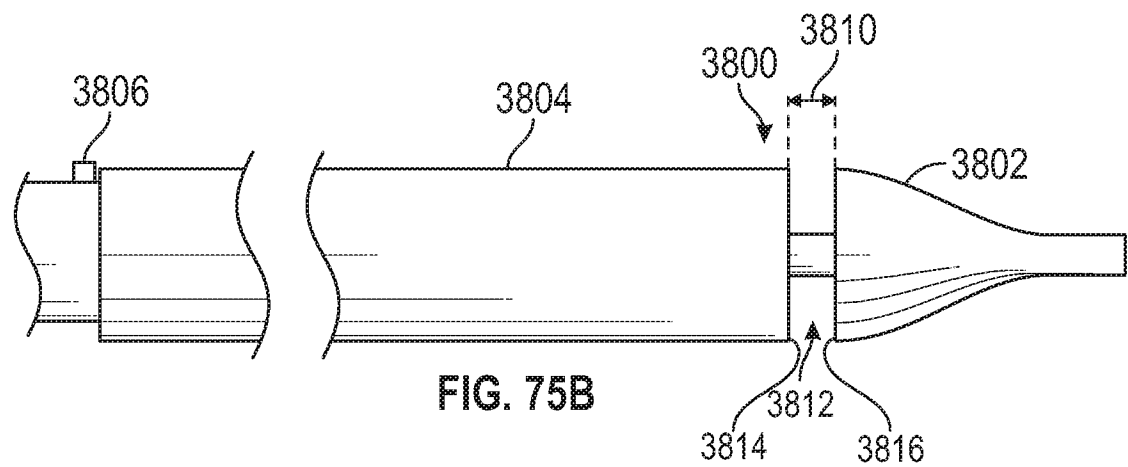


FIG. 75B

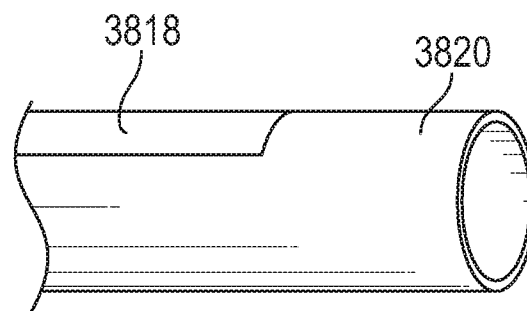


FIG. 76A

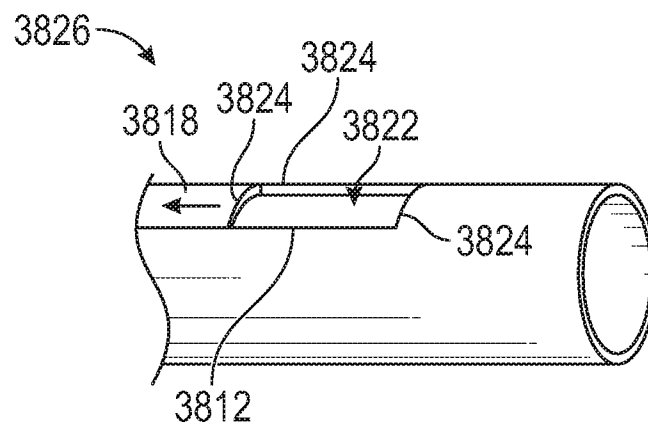


FIG. 76B

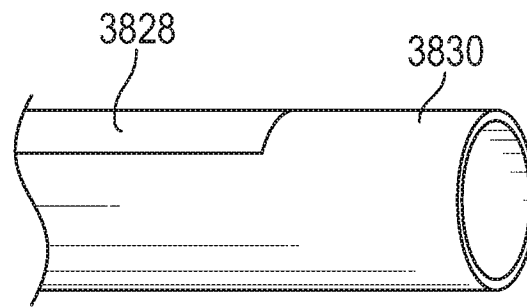


FIG. 77A

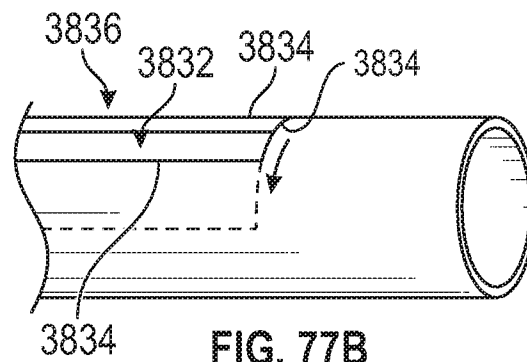


FIG. 77B

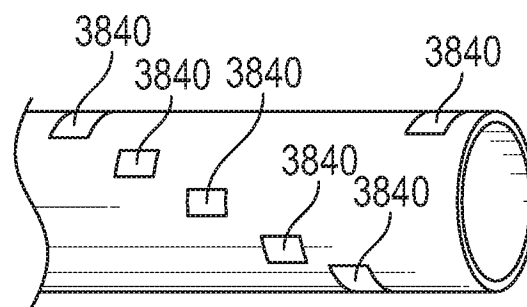


FIG. 78A

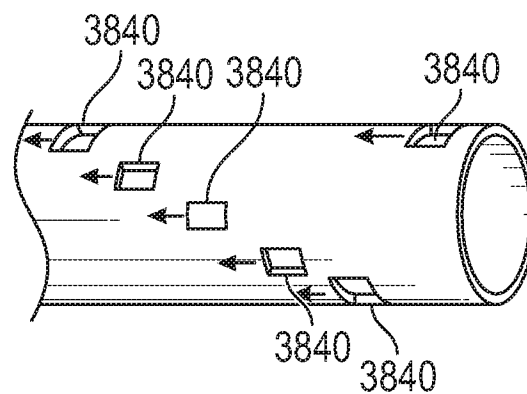


FIG. 78B

69/69

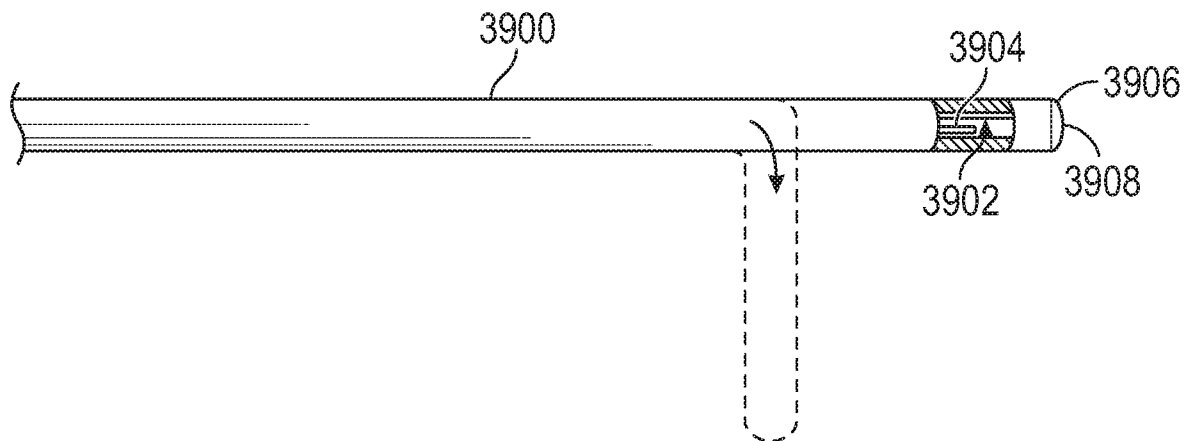


FIG. 79

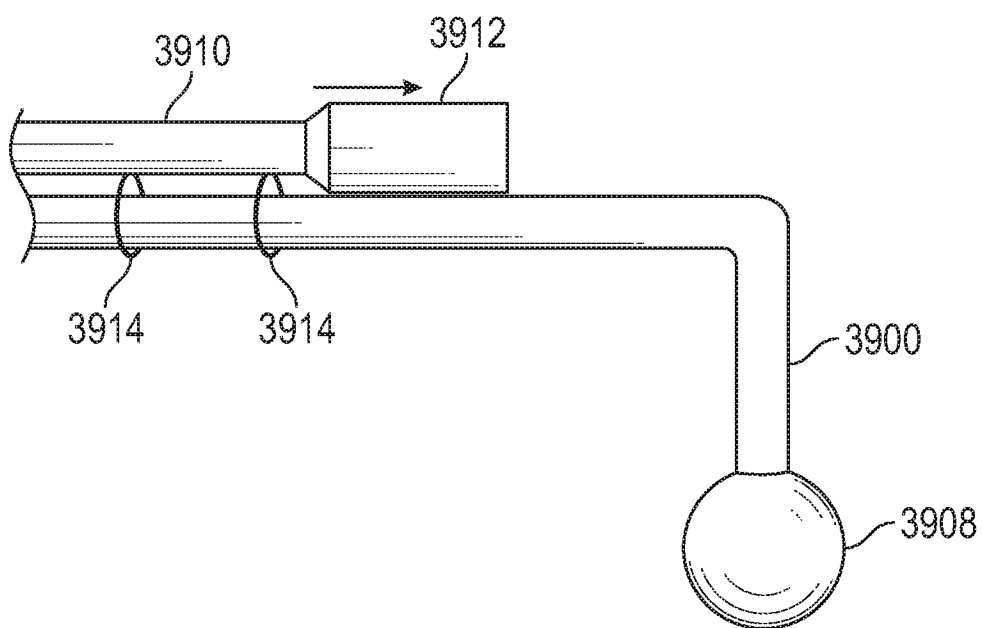


FIG. 80

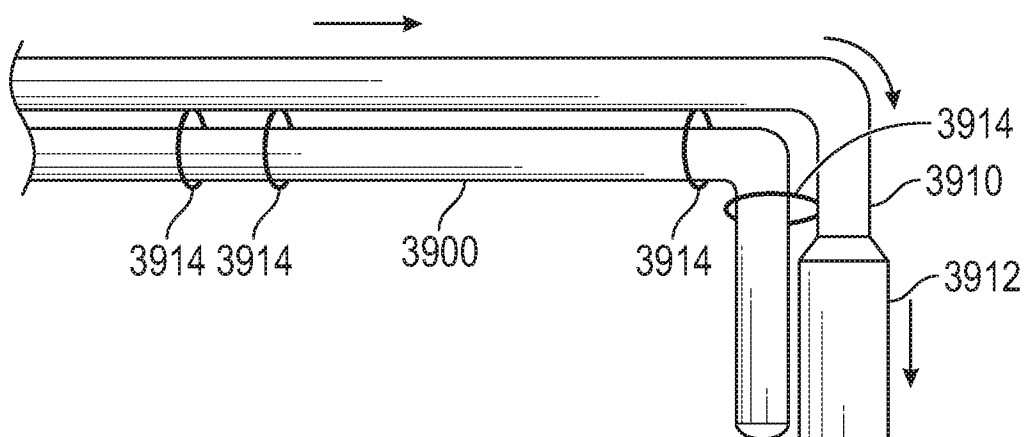


FIG. 81

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/040329

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☒ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/040329

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/24 A61F2/966 A61M25/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2019/008640 A1 (COOPER ALEXANDER H [US] ET AL) 10 January 2019 (2019-01-10) paragraphs [0119], [0151], [0152], [0288]; figures 1, 4, 5, 11, 12A, 13 -----	1-20



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

30 October 2020

Date of mailing of the international search report

09/11/2020

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Kun, Karla

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2020/040329

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2019008640	A1	10-01-2019	CA 3067150 A1 10-01-2019
			CN 110996854 A 10-04-2020
			CN 110996855 A 10-04-2020
			EP 3648708 A1 13-05-2020
			EP 3648709 A1 13-05-2020
			US 2019008639 A1 10-01-2019
			US 2019008640 A1 10-01-2019
			WO 2019010303 A1 10-01-2019
			WO 2019010321 A1 10-01-2019

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 35-40, 48-50, 58-60, 76-80, 91-100, 116-120, 161-170, 186-190, 201-210, 218-230

Since claims 35-40, 48-50, 58-60, 76-80, 91-100, 116-120, 141- 150, 161-170, 186-190, 201-210, 218-230 include the step of "deploying [...] to a location within a patient's body", they are to be construed as methods of treatment of the human body by surgery. No search and no opinion are required for this method claims (Rules 39.1(iv) and 67.1(iv) PCT).

Continuation of Box II.2

Claims Nos.: 21-34, 41-47, 51-57, 61-75, 81-90, 101-115, 121-160, 171-185, 191-200, 211-217

Claims 1-20, 21-34, 41-47, 51-57, 61-75, 81-90, 101-115, 121-160, 171-185, 191-200, 211-217 are drafted and ordered in such a way that the claims are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

In addition, even if some of the claims could be grouped, there is no clear distinction between claims within one group because of overlapping scope.

There is a multitude of equally likely permutations of features providing as many fall-back positions, making it impossible to foresee which subject-matter from the claims and the description is most likely to provide the basis for prosecution of the application.

It is thus not possible to clearly distinguish between the embodiments in the subject-matter claimed, making a search unduly burdensome.

An informal clarification request (PCT-CLAR) was sent to the applicant, on 02-10-2020. No reply was given to the communication within the time limit, therefore the search was limited to claims 1-20 as indicated in the PCT-CLAR.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

overcome.