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- (71) Applicant: VESALIUS CARDIOVASCULAR INC.
[CA/CA]; 506 - 2525 Willow Street, Vancouver, British Columbia, V5Z 3N8 (CA).
- (72) Inventor: SKARSGARD, Peter; 4650 Beverly Crescent, Vancouver, British Columbia V6J 4E6 (CA).
- (74) Agent: KWOK, Christina S.W. et al.; 480 - 601 West Cordova Street, Vancouver, British Columbia V6B 1G1 (CA).
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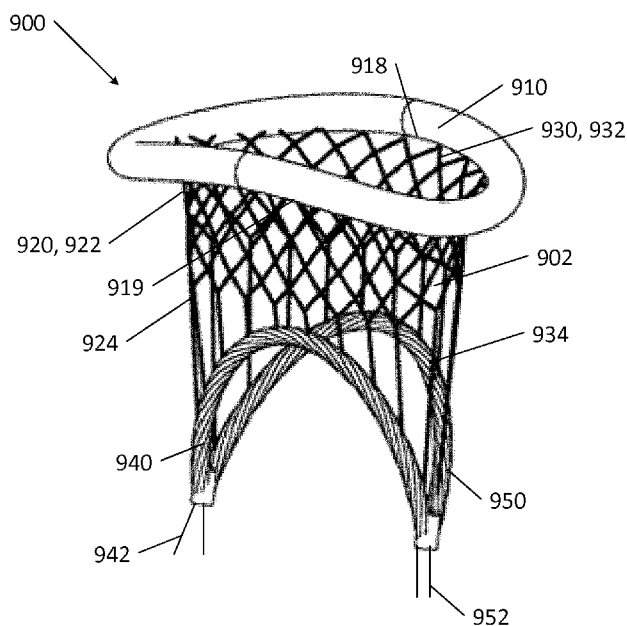


FIG. 22A

(57) Abstract: Apparatus for repairing a heart valve and methods for implanting anchors and repairing a heart valve are provided. The apparatus comprises a body, a member attached to the body at a first end and having a plurality of positioning cords spaced laterally across the member and extending away from a second end of the member opposed to the first end, a tube suspended from the plurality of positioning cords, and an adjustment cord extending through the tube. The method comprises implanting at least one annular anchor in a mitral annulus of the heart valve, implanting a papillary anchor through each papillary muscle of the heart, delivering and positioning an apparatus for repairing a heart valve inside the heart valve using the at least one annular anchor and the papillary anchors, and adjusting the apparatus to adjust the extent of atrial displacement of the heart's mitral leaflets during ventricular contraction.



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APPARATUS FOR USE IN REPAIRING MITRAL VALVES AND METHOD OF USE THEREOF

Technical Field

5 [0001] The present invention relates to apparatus for use in repairing heart valves and methods of use thereof. In particular, the present invention relates to apparatus for use in repairing mitral valves and methods of use thereof.

Background

10 [0002] The mitral valve is the most complex of the human heart's valves and is commonly associated with disease. Conditions affecting the normal functioning of the mitral valve include, for example, mitral valve regurgitation, mitral valve prolapse, and mitral valve stenosis. Mitral valve regurgitation refers to the condition whereby the leaflets of the mitral valve fail to coapt into apposition during ventricular contraction, resulting in abnormal leaking of blood from the left ventricle into the left atrium. Mitral valve prolapse refers to the
15 condition where the mitral leaflets bulge abnormally up into the left atrium causing irregular behaviour of the mitral valve. Mitral valve stenosis refers to the narrowing of the heart's mitral valve obstructing blood flow. A number of factors may affect the normal functioning of the mitral leaflets.

20 [0003] Although intermediate grades of impaired functioning of the mitral valve may not require treatment, severely impaired mitral valve function may result in symptoms (for example, breathlessness, fatigue, exercise intolerance), and may represent a threat to life expectancy. Often, invasive surgery must be performed to repair or replace an abnormal mitral valve.

25 [0004] Traditionally, repairing or replacing a mitral valve involves an open heart procedure. Open heart procedures present patients with morbidity and mortality risks and require a post-op period of convalescence that is typically several months in duration. Open heart surgery may pose prohibitive risks, or may otherwise not be ideal for some patients, including some elderly patients and patients with other health issues. Repairing or replacing the mitral valve without invasive open heart procedures may be attractive therapy for such
30 patients.

[0005] The foregoing examples of the related art and limitations related thereto are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

Summary

5 **[0006]** The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope. In various embodiments, one or more of the above-described problems have been reduced or eliminated, while other embodiments are directed to other improvements.

10 **[0007]** One aspect of the invention provides an apparatus for repairing a heart valve. The apparatus comprises a body, a member attached to the body at a first end and having a plurality of positioning cords spaced laterally across the member and extending away from a second end of the member opposed to the first end, a tube suspended from the plurality of
15 positioning cords, and an adjustment cord extending through the tube. The plurality of positioning cords is spaced laterally across the tube. The tube may be lengthened or shortened by tensioning the adjustment cord.

[0008] In some embodiments, the member has a net-like structure. The net-like structure can be defined by a plurality of cells. The plurality of cells extends radially and longitudinally from the body to the positioning cords. In some embodiments, the plurality of cells has a
20 diamond shape. In some embodiments, the plurality of cells has a square or rectangular shape.

[0009] In some embodiment tensioning the adjustment cord lengthens or shortens the tube consequently displacing the tube towards or away from the body causing corresponding displacement of the member.

25 **[0010]** In some embodiment the length of each positioning cord is selected to suspend the tube from the member in a parabolic or parabolic-like shape.

[0011] In some embodiment lengthening the tube consequently displaces a vertex of the parabolic or parabolic-like shaped tube towards the body.

30 **[0012]** In some embodiments shortening the tube consequently displaces a vertex of the parabolic or parabolic-like shaped tube away from the body.

[0013] In some embodiments the apparatus comprises an encircling member connectable to the body for radially compressing and/or radially expanding the body.

[0014] In some embodiments the body comprises a plurality of peaks and a plurality of troughs, the peaks and troughs defined interchangeably along the diameter of the body.

5 **[0015]** In some embodiments the body comprises a plurality of ring members, each ring member positioned on a corresponding peak.

[0016] In some embodiments the encircling member passes through the plurality of ring members.

[0017] In some embodiments the body defines at least one anchoring site.

10 **[0018]** In some embodiments the body comprises a skirt.

[0019] In some embodiments the skirt defines at least one anchoring site.

[0020] In some embodiments the apparatus is configured to extend from an atrial wall and a mitral annulus to an anterior-lateral papillary muscle and a posterior-medial papillary muscle of the heart valve when the apparatus is implanted in the heart valve.

15 **[0021]** In some embodiments the member comprises an anterior member attached to an anterior end of the body.

[0022] In some embodiments the member comprises a posterior member attached to a posterior end of the body.

20 **[0023]** In some embodiments the anterior member is configured to cover an anterior mitral leaflet of the heart valve when the apparatus is implanted in the heart valve.

[0024] In some embodiments the posterior member is configured to cover a posterior mitral leaflet of the heart valve when the apparatus is implanted in the heart valve.

[0025] In some embodiments the member comprises a biocompatible, blood-permeable material that permits the passage of blood therethrough.

25 **[0026]** Another aspect of the invention provides an annular anchor comprising an anchor pin, a tether connected to the anchor pin, and a guidewire connected to the tether. The length of the guidewire is at least sufficient to traverse a patient's circulatory system from a mitral annulus to an access site of the patient's circulatory system.

[0027] In some embodiments the anchor pin comprises a shape-memory material.

[0028] In some embodiments the anchor pin comprises a deformed configuration for advancing the anchor through a patient's circulatory system within a catheter.

5 [0029] In some embodiments the anchor pin comprises a pre-deformed configuration for anchoring the anchor in an annular tissue of a heart.

[0030] Another aspect of the invention provides an annular anchor catheter comprising a catheter body and a sensor attached to the body for detecting contact between the catheter and an annular wall of a mitral annulus of a heart.

10 [0031] In some embodiment the catheter comprises a needle housed within the catheter body and configured to retain an annular anchor.

[0032] Another aspect of the invention provides a method for implanting an annular anchor. The method comprises advancing a catheter to an anchor site located at an annular wall of a mitral annulus of a heart, detecting contact between the catheter and the anchor site, and advancing an annular anchor from the catheter and embedding the annular anchor in the
15 mitral annulus.

[0033] In some embodiments advancing the annular anchor comprises advancing a needle housing the annular anchor through the annular wall and advancing the annular anchor from the needle to embed the annular anchor in the mitral annulus.

20 [0034] Another aspect of the invention provides a papillary anchor comprising an anchor pin, at least one tether connected to the anchor pin, and a guidewire connected to each tether. The length of each guidewire is at least sufficient to traverse a patient's circulatory system from a papillary muscle to an access site of the patient's circulatory system.

[0035] In some embodiments the anchor pin comprises a shape-memory material.

25 [0036] In some embodiments the anchor pin comprises a deformed configuration for advancing the anchor through a patient's circulatory system within a catheter.

[0037] In some embodiments the anchor pin comprises a pre-deformed configuration for securing the anchor through a papillary muscle of a heart.

[0038] Another aspect of the invention provides a papillary anchor catheter comprising a body configured to house a papillary anchor, an arm extending away from the body, and a

receiver connected to the arm for receiving the papillary anchor. The body, arm, and receiver define an opening configured to receive a papillary muscle.

[0039] In some embodiments the receiver is detachable from the arm.

[0040] In some embodiments the arm is retractable inside the body.

5 **[0041]** In some embodiments the body comprises a retaining pin extendable from the body to close the opening.

[0042] In some embodiments the retaining pin is retractable inside the body to open the opening.

10 **[0043]** In some embodiments the catheter comprises a controller for operating one or more of the retaining pin and the arm externally.

[0044] Another aspect of the invention provides a method for implanting a papillary anchor. The method comprises advancing a papillary anchor catheter in a closed configuration through a patient's circulatory system to a papillary muscle, opening the catheter to receive a papillary muscle, positioning the papillary muscle within the opening, advancing the
15 papillary anchor from the catheter through the papillary muscle, receiving an anchor pin of the papillary anchor with a receiver of the catheter, detaching the receiver from the catheter leaving the papillary anchor implanted in the papillary muscle and secured to the papillary muscle with the receiver, and withdrawing the catheter from the patient's circulatory.

20 **[0045]** In some embodiments the method comprises advancing the retaining pin at least partially through the papillary muscle to stabilize the papillary muscle prior to advancing the papillary anchor through the papillary muscle.

[0046] In some embodiments the method comprises retracting the retaining pin prior to withdrawing the catheter from the patient's circulatory system.

25 **[0047]** Another aspect of the invention provides a papillary anchor catheter comprising a body configured to house a papillary anchor and a deformable arm extending away from the body.

[0048] In some embodiments the body comprises a needle for housing the papillary anchor and advancing the papillary anchor through a papillary muscle.

[0049] In some embodiments the arm comprises a tensioning wire extending lengthwise through the arm for deforming the arm in a deformed configuration and an extended configuration by applying tension to the wire.

5 [0050] In some embodiments the arm comprises a plurality of modular pieces arranged linearly, wherein the tensioning wire extends through the pieces to deform the arm by applying tension to the tensioning wire.

[0051] In some embodiments the catheter comprises a controller for operating one or more of the needle and the tensioning wire externally.

10 [0052] Another aspect of the invention provides a method for implanting a papillary anchor. The method comprises advancing a papillary anchor catheter in an extended configuration through a patient's circulatory system to a papillary muscle, deforming the catheter into a deformed configuration to at least partially encircle a papillary muscle, advancing the papillary anchor from the catheter through the papillary muscle, extending the catheter into the extended configuration, and withdrawing the catheter from the patient's circulatory
15 system in the extended configuration.

[0053] Another aspect of the invention provides a papillary anchor catheter comprising a body, a deformable arm extending from the body, and an anchor housing extending through the body and the arm, wherein the anchor housing is configured to house a papillary anchor.

20 [0054] In some embodiments the catheter comprises a guidewire extending through the body and alongside the arm, wherein the guidewire is extendable and retractable from the body.

[0055] In some embodiments a length of the guidewire is sufficient to traverse a patient's circulatory system from a papillary muscle to an access site to the patient's circulatory
25 system.

[0056] In some embodiments the arm comprises at least one deformable section.

[0057] In some embodiments the arm comprises a first deformable section deformable in a first plane and a second deformable section deformable in a second plane.

[0058] In some embodiments the first deformable section is deformable in a first direction
30 by about 0° to about 120° in the first plane.

[0059] In some embodiments the second deformable section is deformable in a second direction by about 0° to about 90° in the second plane and in a third direction by about 0° to about -90° in the second plane.

[0060] In some embodiments the first direction and the second direction are non-coplanar.

5 [0061] In some embodiments the catheter comprises a controller for operating one or more of the guidewire, the first deformable section, and the second deformable section externally.

[0062] Another aspect of the invention provides a method for implanting a papillary anchor. The method comprises advancing a papillary anchor catheter in an extended configuration through a patient's circulatory system to a papillary muscle, deforming the catheter in a first
10 direction into a deflected configuration, advancing a guidewire to at least partially encircle a papillary muscle, deforming the catheter in a second direction into a deformed configuration, advancing the catheter along the guidewire to at least partially encircle the papillary muscle with the catheter, advancing the papillary anchor from the catheter through the papillary muscle, and withdrawing the catheter from the patient's circulatory system in the extended
15 configuration.

[0063] In some embodiments advancing the papillary anchor through the papillary muscle comprises advancing the papillary anchor through a transverse dimension of the papillary muscle from an entrance site of the papillary muscle to an exit site of the papillary muscle.

[0064] In some embodiments advancing the papillary anchor through the papillary muscle
20 further comprises receiving an anchor tip of the papillary anchor with a receiver of the catheter adjacent to the exit site.

[0065] In some embodiments withdrawing the catheter comprises extending the catheter into the extended configuration.

[0066] Another aspect of the invention provides a method of repairing a heart valve. The
25 method comprises implanting at least one annular anchor in a mitral annulus of the heart valve, implanting a papillary anchor through each papillary muscle of the heart, delivering and positioning an apparatus for repairing a heart valve inside the heart valve using the at least one annular anchor and the papillary anchors, and adjusting the apparatus to adjust the extent of atrial displacement of the heart's mitral leaflets during ventricular contraction.

[0067] In some embodiments delivering the apparatus comprises externally connecting one or more guidewires of each annular anchor and one or more guidewires of each papillary anchor to the apparatus and advancing the apparatus along the guidewires to the heart valve.

5 [0068] In some embodiments delivering the apparatus further comprises externally advancing the one or more guidewires of each annular anchor through a body of the apparatus and advancing the body of the apparatus to an atrial wall of the mitral annulus of the heart valve.

10 [0069] In some embodiments delivering the apparatus comprises externally advancing the one or more guidewires of each papillary anchor through at least one compressible tube of the apparatus and advancing the at least one tube to extend between the papillary muscles of the heart valve in a parabolic or parabolic-like shaped configuration.

15 [0070] In some embodiments positioning the apparatus inside the heart valve comprises adjusting the length of the at least one tube to position the apparatus to cover an atrial surface of at least one mitral leaflet of the heart valve.

[0071] In some embodiments positioning the apparatus inside the heart valve further comprises adjusting the length of the at least one tube to adjust the position of at least one blood-permeable member of the apparatus to adjust the extent of atrial displacement of the at least one mitral leaflet during ventricular contraction.

20 [0072] In some embodiments delivering the apparatus comprises externally advancing a first guidewire of each papillary anchor through a first compressible tube of the apparatus and advancing a second guidewire of each papillary anchor through a second compressible tube of the apparatus and advancing the first and second tubes along the first and second guidewires to extend the first and second tubes between the papillary muscles of the heart
25 valve in a parabolic or parabolic-like shaped configuration.

[0073] In some embodiments positioning the apparatus inside the heart valve further comprises adjusting the length of the first tube to position an anterior member of the apparatus to cover an atrial surface of an anterior mitral leaflet of the heart valve.

30 [0074] In some embodiments positioning the apparatus inside the heart valve further comprises adjusting the length of the first tube to adjust the position of the anterior member

to adjust the extent of atrial displacement of the anterior mitral leaflet during ventricular contraction.

5 **[0075]** In some embodiments positioning the apparatus inside the heart valve further comprises adjusting the length of the second tube to position a posterior member of the apparatus to cover an atrial surface of a posterior mitral leaflet of the heart valve.

[0076] In some embodiments positioning the apparatus inside the heart valve comprises adjusting the length of the second tube to adjust the position of the posterior member to adjust the extent of atrial displacement of the posterior mitral leaflet during ventricular contraction.

10 **[0077]** In some embodiments the method comprises securing the apparatus to an atrial wall of the heart valve.

[0078] In some embodiments the method comprises securing the apparatus to each papillary muscle of the heart valve.

15 **[0079]** In some embodiments securing the apparatus to the atrial wall comprises advancing a lock in an open configuration to an anchor site of the apparatus and positioning the lock in a locked configuration adjacent the atrial wall at each anchor site.

[0080] In some embodiments securing the apparatus to the papillary muscles comprises advancing a lock in an open configuration along each papillary anchor and positioning the lock in a locked configuration adjacent the papillary muscle.

20 **[0081]** Another aspect of the invention provides a lock comprising a body defining opposed jaws and a channel extending lengthwise through the body and between the jaws. The lock is deformable in an open configuration by deflecting the jaws away from each other.

[0082] In some embodiments the jaws define a recess shaped concentrically about the channel and configured to receive a collar for retaining the lock in a locked configuration.

25 **[0083]** In some embodiments the collar comprises at least one notch configured to engage a lock catheter.

[0084] In some embodiments the body defines a groove shaped concentrically about the channel and configured to engage the lock catheter.

[0085] In some embodiments each jaw comprises a set of teeth.

[0086] Another aspect of the invention provides a lock catheter comprising a sleeve tube, a lock tube, and a deploying tube. The sleeve tube houses the lock tube and the lock tube houses the deploying tube.

5 [0087] In some embodiment the catheter comprises a needle extending through a channel defined by the deploying tube.

[0088] In some embodiments the sleeve tube defines a notch for engaging a lock.

[0089] Another aspect of the invention provides a method for securing an apparatus inside a heart valve. The method comprises advancing a lock in an open configuration along a guidewire to a lock site and advancing a collar along the lock at the lock site to lock the lock
10 in a closed configuration.

[0090] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed descriptions.

Brief Description of the Drawings

15 [0091] Exemplary embodiments are illustrated in referenced figures of the drawings. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

[0092] Figure 1 is a top cross-sectional view of a heart showing normal coaptation of the mitral valve.

20 [0093] Figure 2 is a side elevation cross-sectional view of the heart shown in FIG. 1.

[0094] Figure 3 is a side elevation cross-sectional view of a heart showing prolapse of a posterior mitral valve leaflet.

[0095] Figure 4A is a top posterior perspective view of an apparatus according to an example embodiment of the present invention.

25 [0096] Figure 4B is a partial top posterior perspective view of the apparatus shown in FIG. 4A.

[0097] Figure 4C is a partial top anterior perspective view of the apparatus shown in FIG. 4A.

[0098] Figure 4D is a posterior elevation view of the apparatus shown in FIG. 4A.

- [0099] Figure 4E is a side elevation view of the apparatus shown in FIG. 4A.
- [0100] Figure 4F is a top view of the apparatus shown in FIG. 4A.
- [0101] Figure 4G is a partial posterior illustration of the apparatus shown in FIG. 4A, wherein the tension from a cord is released thereby expanding and lengthening a tube.
- 5 [0102] Figure 4H is a partial posterior illustration of the apparatus shown in FIG. 4A, wherein the cord is tensioned thereby compressing and shortening the tube.
- [0103] Figure 5A is a perspective cross-sectional view of the heart shown in FIG. 1.
- [0104] Figure 5B is a perspective cross-sectional view of the heart shown in FIG. 5A showing normal coaptation of the mitral valve.
- 10 [0105] Figure 5C is a perspective cross-sectional view of the heart shown in FIG. 5A, wherein the apparatus shown in FIG. 4A is advanced into the mitral valve and anchored to the papillary muscles.
- [0106] Figure 5D is a perspective cross-sectional view of the heart and apparatus shown in FIG. 5C, wherein the apparatus is adjusted to fit the mitral valve.
- 15 [0107] Figure 5E is a top cross-sectional view of the heart and apparatus shown in FIG. 5C, wherein the apparatus is anchored to the mitral annulus.
- [0108] Figure 6A is a side elevation view of an annular anchor catheter according to an example embodiment of the present invention advanced towards an annular wall of the heart shown in FIG. 1.
- 20 [0109] Figure 6B is a side elevation view of the heart and catheter shown in FIG. 6A, wherein the needle is advanced into the annular wall of the heart.
- [0110] Figure 6C is a side elevation view of the heart and catheter shown in FIG. 6A having an anchor according to an example embodiment of the present invention advancing from the needle.
- 25 [0111] Figure 6D is a side elevation view of the heart, catheter, and anchor shown in FIG. 6C, wherein the anchor is advanced from the needle.
- [0112] Figure 6E is a side elevation view of the heart, catheter, and anchor shown in FIG. 6C, wherein the anchor is implanted into the mitral annulus of the heart.

[0113] Figure 6F is a side elevation view of the heart, catheter, and anchor shown in FIG. 6C, wherein the anchor is implanted into the mitral annulus of the heart and the needle is retracted into the catheter.

5 [0114] Figure 6G is a side elevation view of the heart, catheter, and anchor shown in FIG. 6C, wherein the anchor is implanted in the mitral annulus of the heart and the catheter is retracted from the annular wall of the heart.

[0115] Figure 7A is a side elevation view of an anchor according to an example embodiment of the present invention.

[0116] Figure 7B is a partial perspective view of the anchor shown in FIG. 7A.

10 [0117] Figure 7C is a perspective view of an anchor pin of the anchor shown in FIG. 7A.

[0118] Figure 7D is a partial front elevation partial view of the anchor shown in FIG. 7A.

[0119] Figure 7E is a top elevation view of the anchor shown in FIG. 7A.

[0120] Figure 7F is a partial side elevation view of the anchor shown in FIG. 7A.

15 [0121] Figure 8A is a side elevation view of an anchor according to an example embodiment of the present invention.

[0122] Figure 8B is a side perspective view of the anchor shown in FIG. 8A.

[0123] Figure 8C is side perspective cross-sectional view of the anchor shown in FIG. 8A taken along the line B-B.

[0124] Figure 8D is a side elevation view of the anchor shown in FIG. 8A.

20 [0125] Figure 8E is a side cross-sectional view of the anchor shown in FIG. 8D taken along the line D-D.

[0126] Figure 9A is a side perspective view of an anchor tip according to an example embodiment of the present invention.

25 [0127] Figure 9B is a side perspective view of an anchor tip according to an example embodiment of the present invention.

[0128] Figure 9C is a side perspective view of an anchor tip according to an example embodiment of the present invention.

[0129] Figure 9D is a side perspective view of an anchor tip according to an example embodiment of the present invention.

[0130] Figure 10A is a top view of an anchor fastener according to an example embodiment of the present invention.

5 [0131] Figure 10B is a side elevation view of the anchor fastener shown in FIG. 10A.

[0132] Figure 10C is a top side perspective view of the anchor fastener shown in FIG. 10A.

[0133] Figure 11A is a perspective view of an anchor and anchor fastener according to an example embodiment of the present invention.

10 [0134] Figure 11B is a perspective view of an anchor and anchor fastener according to an example embodiment of the present invention.

[0135] Figure 11C is a perspective view of an anchor and anchor fastener according to an example embodiment of the present invention.

[0136] Figure 11D is a perspective view of an anchor and anchor fastener according to an example embodiment of the present invention.

15 [0137] Figure 11E is a perspective view of the anchor and anchor fastener shown in FIG. 11D.

[0138] Figure 12A is a side elevation view of a papillary anchor catheter according to an example embodiment of the present invention in a closed configuration, wherein an anchor extends therethrough.

20 [0139] Figure 12B is a side elevation view of the catheter and anchor shown in FIG. 12A in an open configuration.

[0140] Figure 12C is a side elevation cross-sectional view of the catheter and anchor shown in FIG. 12A taken along the line A-A.

25 [0141] Figure 12D is a side elevation cross-sectional view of the catheter shown in FIG. 12A taken along the line H-H.

[0142] Figure 12E is a rear side perspective view of the catheter and anchor shown in FIG. 12A in an open configuration.

[0143] Figure 12F is a front side perspective view of the catheter and anchor shown in FIG. 12A in an open configuration.

[0144] Figure 12G is a partial rear side perspective view of the catheter and anchor shown in FIG. 12A in an open configuration.

5 [0145] Figure 12H is a partial front side perspective view of the catheter and anchor shown in FIG. 12A in an open configuration.

[0146] Figure 13A is a side elevation cross-sectional view of the catheter and anchor shown in FIG. 12A taken along the line A-A, wherein the catheter houses a papillary muscle.

10 [0147] Figure 13B is a side elevation cross-sectional view of the catheter, anchor, and papillary muscle shown in FIG. 13A, wherein a retaining pin of the catheter is advanced through the papillary muscle.

[0148] Figure 13C is a side elevation cross-sectional view of the catheter, anchor, and papillary muscle shown in FIG. 13A, wherein the retaining pin and the anchor are advanced through the papillary muscle.

15 [0149] Figure 13D is a side elevation cross-sectional view of the catheter, anchor, and papillary muscle shown in FIG. 13A, wherein the retaining pin is retracted from the papillary muscle.

20 [0150] Figure 13E is a side elevation cross-sectional view of the anchor and papillary muscle shown in FIG. 13A, wherein the catheter is retracted and a receiver is secured to the anchor.

[0151] Figure 14A is a front bottom perspective view of a papillary anchor catheter according to an example embodiment of the present invention in a deformed configuration, wherein an anchor extends therethrough.

25 [0152] Figure 14B is a rear top perspective view of the catheter and anchor shown in FIG. 14A.

[0153] Figure 14C is a front side perspective view of the catheter shown in FIG. 14A.

[0154] Figure 14D is a front side perspective view of the catheter shown in FIG. 14A in an extended configuration.

[0155] Figure 15A is a side elevation view of a papillary anchor catheter according to an example embodiment of the present invention in a deformed configuration.

[0156] Figure 15B is a front elevation view of the catheter shown in FIG. 15A in the deformed configuration.

5 **[0157]** Figure 15C is a rear elevation view of the catheter shown in FIG. 15A in the deformed configuration.

[0158] Figure 15D is a top view of the catheter shown in FIG. 15A in the deformed configuration.

10 **[0159]** Figure 15E is a front elevation view of the catheter shown in FIG. 15A in a deflected configuration.

[0160] Figure 15F is a rear elevation view of the catheter shown in FIG. 15A in the deflected configuration.

[0161] Figure 15G is a side elevation view of the catheter shown in FIG. 15A in the deflected configuration.

15 **[0162]** Figure 15H is a top view of the catheter shown in FIG. 15A in the deflected configuration.

[0163] Figure 15I is a front elevation view of the catheter shown in FIG. 15A in an extended configuration.

20 **[0164]** Figure 15J is a side elevation view of the catheter shown in FIG. 15A in the extended configuration.

[0165] Figure 15K is a top view of the catheter shown in FIG. 15A in the extended configuration.

[0166] Figure 15L is a rear elevation view of the catheter shown in FIG. 15A in the extended configuration.

25 **[0167]** Figure 16A is a perspective view of a papillary catheter receiver according to an example embodiment of the present invention.

[0168] Figure 16B is a perspective view of a papillary catheter receiver according to an example embodiment of the present invention.

[0169] Figure 17A is a rear elevation view of the papillary catheter shown in FIG. 15A in a deflected configuration extending a guidewire around a papillary muscle.

[0170] Figure 17B is a front elevation view of the catheter and papillary muscle shown in FIG. 17A.

5 [0171] Figure 17C is a side elevation view of the catheter and papillary muscle shown in FIG. 17A.

[0172] Figure 17D is a top view of the catheter and papillary muscle shown in FIG. 17A.

[0173] Figure 17E is a side elevation view of the papillary catheter shown in FIG. 15A in a deformed configuration encircling a papillary muscle.

10 [0174] Figure 17F is a front elevation view of the catheter and papillary muscle shown in FIG. 17E.

[0175] Figure 17G is a rear elevation view of the catheter and papillary muscle shown in FIG. 17E.

[0176] Figure 17H is a top view of the catheter and papillary muscle shown in FIG. 17E.

15 [0177] Figure 17I is a front elevation view of the papillary catheter shown in FIG. 17A in a deformed configuration advancing a papillary anchor through a papillary muscle.

[0178] Figure 17J is a side elevation view of the catheter, anchor, and papillary muscle shown in FIG. 17I.

[0179] Figure 17K is a top view of the catheter, anchor, and papillary muscle shown in FIG.
20 17I.

[0180] Figure 18 is a flow chart of a method of repairing a mitral valve according to an example embodiment of the present invention.

[0181] Figure 19A is a top elevation view of a lock according to an example embodiment of the present invention.

25 [0182] Figure 19B is a side elevation view of the lock shown in FIG. 19A.

[0183] Figure 19C is a front top side perspective view of the lock shown in FIG. 19A.

[0184] Figure 19D is a front elevation view of the lock shown in FIG. 19A.

[0185] Figure 19E is side elevation cross-sectional view of the lock shown in FIG. 19A taken along the line A-A.

[0186] Figure 20A is a top elevation view of a lock catheter according to an example embodiment of the present invention.

5 **[0187]** Figure 20B is a cross-sectional view of the catheter shown in FIG. 20A taken along the line F-F, wherein the catheter contains the lock shown in FIG. 19A.

[0188] Figure 20C is a top elevation view of the catheter shown in FIG. 20A advancing the lock shown in FIG. 19A along a guidewire in an open configuration.

[0189] Figure 20D is a side elevation view of the catheter and lock shown in FIG. 20C.

10 **[0190]** Figure 20E is a cross-sectional view of the catheter and lock shown in FIG. 20D taken along the line F-F.

[0191] Figure 20F is a top elevation view of the catheter shown in FIG. 20A advancing the lock shown in FIG. 19A further along the guidewire in an open configuration.

[0192] Figure 20G is a side elevation view of the catheter and lock shown in FIG. 20F.

15 **[0193]** Figure 20H is a cross-sectional view of the catheter and lock shown in FIG. 20G taken along the line F-F.

[0194] Figure 20I is a top elevation view of the lock catheter shown in FIG. 20A advancing the lock shown in FIG. 19A further along a guidewire in an open configuration.

[0195] Figure 20J is a side elevation view of the catheter and lock shown in FIG. 20I.

20 **[0196]** Figure 20K is a side cross-sectional view of the catheter and lock shown in FIG. 20I taken along the line D-D.

[0197] Figure 20L is a side elevation view of the lock catheter shown in FIG. 20A securing the lock shown in FIG. 19A in a closed configuration to a guidewire.

[0198] Figure 20M is a top elevation view of the catheter and lock shown in FIG. 20L.

25 **[0199]** Figure 20N is a side cross-section view of the catheter and lock shown in FIG. 20L taken along the line F-F.

[0200] Figure 21 is a side elevation view of a lock catheter according to example embodiment of the present invention advancing the lock shown in FIG. 18A along a guidewire in an open configuration.

5 [0201] Figure 22A is an anterior perspective view of an apparatus according to an example embodiment of the present invention.

[0202] Figure 22B is a partial side view of the apparatus shown in Figure 22A.

[0203] Figure 22C is a top view of the apparatus shown in Figure 22A.

[0204] Figure 22D is a posterior elevation view of the apparatus shown in Figure 22A.

[0205] Figure 22E is an isolated enlarged view of a cell shown in Figure 22A.

10 [0206] Figure 23A is a schematic diagram illustrating a mitral valve that is fully open.

[0207] Figure 23B is a schematic diagram illustrating a mitral valve that is fully closed.

Description

[0208] Throughout the following description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements
15 may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. Accordingly, the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

[0209] Unless context dictates otherwise, the term “anterior” (as used herein in relation to a patient’s body and parts thereof) refers to a position that is more near the front surface of
20 the patient’s body or part thereof than the rear surface of the patient’s body or part thereof.

[0210] Unless context dictates otherwise, the term “posterior” (as used herein in relation to a patient’s body and parts thereof) refers to a position that is more near the rear surface of the patient’s body or part thereof than the front surface of the patient’s body or part thereof.

[0211] Unless context dictates otherwise, the terms “percutaneous”, “percutaneously”, and
25 the like (as used herein) refer to a method of accessing a patient’s circulatory system and/or heart through the skin, such as by needle access.

[0212] Unless context dictates otherwise, the term “antegrade” (as used herein) refers to a percutaneous approach to a mitral valve via the femoral vein, right atrium, atrial septal

puncture, and left atrium (i.e. in the normal direction of blood flow through a patient's circulatory system).

[0213] Unless context dictates otherwise, the term "retrograde" (as used herein) refers to a percutaneous approach to the mitral valve via the femoral artery, wherein the left ventricle is accessed via the aortic valve (i.e. in reverse of the normal direction of blood flow through a patient's circulatory system).

[0214] Unless context dictates otherwise, the term "intravascular" (as used herein) means situated or occurring with a blood vessel or circulatory system.

[0215] Unless context dictates otherwise, the term "external" (as used herein in relation to a patient's body and parts thereof) means situated outside of a patient's circulatory system or body.

[0216] Unless context dictates otherwise, the term "transcatheter" (as used herein) refers to a method performed through the lumen of a catheter.

[0217] Unless context dictates otherwise, the term "circulatory system" (as used herein) refers to a system that circulates blood and/or lymph through a patient's body, consisting of one or more of the heart, blood vessels, blood, lymph, and the lymphatic vessels and glands.

[0218] Although the methods and apparatus of the present invention may be used for the percutaneous repair of any of the cardiac valves, the following description will focus on the repair of mitral valves. Further, while the methods and apparatus of the present invention will preferably be percutaneous and intravascular, such methods and apparatus may be used for performing open heart surgery where the heart is accessed through the myocardial tissue and/or in minimally invasive procedures where access to the heart is achieved thoroscopically. Further still, while the methods and apparatus of the present invention may be used with conventional transcatheter valve prostheses, such methods and apparatus may be used with prostheses implanted through the myocardial tissue of the heart and/or prostheses implanted using minimally invasive procedures where access to the heart is achieved thoroscopically. Further still, while the methods and apparatus of the present invention will use an antegrade approach (i.e. the access site of the patient's circulatory system being the femoral vein), the femoral artery may be favored in some embodiments as

the access site for one or more of its size, ease of insertion, and least tortuous path to the heart.

[0219] The human heart **10**, shown in FIGS. 1, 5A, and 5B, is a muscle pump which relies on heart valves to achieve blood flow. In normal physiology, oxygenated blood returning
5 from the lungs is collected in a left atrium **20**, and then passes through a mitral (inlet) valve **30** to enter a left ventricle **40** (i.e. the pumping chamber). With contraction of left ventricle **40**, the elevation of left ventricular pressure causes mitral valve **30** to close (FIGS. 2 and 5B), preventing reversal of blood flow back into atrium **20**. As ventricular pressure exceeds aortic pressure, aortic (outlet) valve **50** opens (FIGS. 1 and 5A), and blood is pumped
10 forward into aorta **60**. When left ventricle **40** relaxes, the ventricular pressure drops, mitral valve **30** reopens to permit flow of blood from left atrium **20** to left ventricle **40**, and the process repeats.

[0220] Mitral valve **30** separates left atrium **20** from left ventricle **40**, and is comprised of a mitral annulus **32**, leaflets (anterior **34** and posterior **36**), chordae tendinae **38**, and papillary
15 muscles **39**, **39a**, **39b**. During ventricular contraction (systole), the ventricular pressure rises, which forces displacement of mitral leaflets **34**, **36** towards atrium **20** (i.e. commonly known as atrial or leaflet displacement). The length and integrity of chordae tendinae **38** determines the degree of leaflet displacement. In normal physiology, equal displacement of anterior mitral leaflet **34** and posterior mitral leaflet **36** results in contact (coaptation)
20 between the leaflets, and consequent competence of mitral valve **30**.

[0221] In circumstances where mitral leaflet **34** and/or **36** is supported by chordae tendinae **38** which are elongated or ruptured, ventricular contraction may result in excessive atrial displacement of the leaflet(s), and this may prevent coaptation between the leaflets (FIG. 3). This is referred to as mitral leaflet prolapse. In this circumstance, the competency of mitral
25 valve **30** may be compromised and leakage may occur. Leakage through the mitral valve is referred to as mitral regurgitation, and when it is due to mitral leaflet prolapse it is referred to as degenerative mitral regurgitation. In other circumstances, the ventricular muscle itself can be diseased and its function impaired causing limited ventricular contraction and progressive ventricular dilation. Since mitral leaflets **34**, **36** are attached by chordae
30 tendinae **38** to the ventricular muscle, ventricular dilation can limit leaflet movement toward atrium **20** during contraction, resulting in poor leaflet coaptation and causing mitral regurgitation. This is referred to as functional mitral regurgitations.

[0222] An apparatus **100** for repairing a heart valve, such as a mitral valve, is shown in FIGS. 4A-4H. Apparatus **100** includes a radially compressible and radially expandable body **110**, an anterior member **120**, and a posterior member **130**. Although the term “radial” is most commonly used in connection with circular objects or features, it should be understood for the purpose of this description and accompanying aspects that the term “radial” is used in a broader context and is not limited to describing strictly circular objects or features or objects or features with strictly circular cross-section. In some embodiments, anterior member **120** and posterior member **130** form a single member (not shown). In some other embodiments, apparatus **100** includes either anterior member **120** or posterior member **130**, but not both.

[0223] In the embodiment shown in FIGS. 4A-4H body **110** comprises a radially compressible and radially expandable ring **112** attached to a skirt **114**. Ring **112** includes a plurality of apertures **113**, a plurality of peaks **115**, and a plurality of troughs **117**. Peaks **115** and troughs **117** are longitudinally spaced across ring **112**. Apertures **113** are positioned on the peaks **115** and/or troughs **117** for radially compressing and/or radially expanding body **110**. To radially compress and/or radially expand body **110**, an encircling member (not shown) may be provided. The encircling member extends through ring members **113**. By providing tension to first and second ends of the encircling member, body **110** may be radially compressed. Full radial expansion of body **110** is achieved by complete tension release of the encircling element within ring members **113**. A “purse-string” effect may be achieved when tension is applied to the encircling member to radially compress body **110**. Persons skilled in the art will recognize that body **110** may comprise any suitable radially compressible and radially expandable stent conventionally known. In some embodiments, the encircling element is not required to radially compress and/or radially expand body **110**. For example, an inflatable balloon may be used to radially expand and contract body **110**.

[0224] Anterior member **120** is connected to an anterior end **119** of body **110**. Posterior member **130** is attached to a posterior end **118** of body **110**. Each member **120**, **130** comprises a section **122**, **132** having a plurality of positioning cords **124**, **134** for positioning each member to cover an atrial surface of a mitral leaflet from a lateral commissure to a medial commissure thereof. Cords **124**, **134** are spaced laterally across each section **122**, **132** and extend from section **122**, **132** away from body **110**. In some embodiments, cords **124**, **134** are integrally formed with corresponding section **122**, **132**. Cords **124**, **134** each

terminate at and connect to a flexible, compressible tube **140, 150**. Cords **124, 134** are laterally spaced across tube **140, 150**. In some embodiments, the length of each cord **124, 134** is designed to suspend tube **140, 150** from section **122, 132** in a parabolic or parabolic-like shape. Thus, cords **124, 134** connect a ventricular perimeter **126, 136** of section **122, 132** with the corresponding tube **140, 150**. In the FIGS. 4G and 4H embodiment, apparatus **100** comprises five cords **124, 134** suspending tubes **140, 150** from members **120, 130**. Persons skilled in the art will recognize that apparatus **100** may comprises any number of cord(s) **124, 134** suitable for positioning member(s) **120, 130** to cover an atrial surface of a mitral leaflet as described elsewhere here.

[0225] Tubes **140, 150** each comprise an adjustment cord **142, 152** secured to an end of the tube and extending longitudinally through the tube. The length of each cord **142, 152** is sufficient to secure at a first end to the tube, extend through the tube, and traverse the patient's circulatory system from an implant site (e.g. papillary muscle **39**) to a femoral vein puncture (i.e. the access site to the patient's circulatory system). In this way, a second end of each cord **142, 152** is accessible external to the patient for delivering a device (e.g. a lock) to each tube **140, 150**. Tubes **140, 150** may be lengthened and shortened by externally delivering tension to cords **142, 152**. By tensioning cord **142/152**, tube **140/150** is compressed and shortened, consequently displacing the vertex of the parabolic or parabolic-like shaped tube away from body **110** and causing corresponding displacement of section **122/132** (FIG. 4H). By releasing tension from cord **142/152**, tube **140/150** is expanded and lengthened, consequently displacing the vertex of the parabolic or parabolic-like shaped tube toward body **110** and causing corresponding displacement of section **122/132** (FIG. 4G). Sections **122, 132** are displaced via cords **142, 152** to position members **120, 130** to cover an atrial surface of a mitral leaflet as described elsewhere here. When a desired amount of tension is delivered to cord(s) **142, 152** to position member(s) **120, 130** as desired, a lock **700** (described elsewhere herein) is advanced along cord(s) **142, 152** to abut against an end of tube(s) **140, 150**. In a locked configuration and abutting against tube(s) **140, 150**, tube(s) **140, 150** is secured in a desired length and member(s) **120, 130** is secured in a desired position covering an atrial surface of the mitral leaflet.

[0226] In some embodiments, anterior member **120** and/or posterior member **130** comprises a biocompatible blood-permeable material that permits the passage of blood therethrough. In some embodiments, anterior member **120** and/or posterior member **130**

comprises a mesh or a material like a net with spaces in it that permits the passage of blood therethrough. In some embodiments, anterior member **120** and/or posterior member **130** comprises a blood-permeable material made of one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a tissue engineered material. In some embodiments, anterior member **120** and/or posterior member **130** comprises a blood-permeable material having tissue ingrowth qualities. Persons skilled in the art will recognize that anterior member **120** and/or posterior member **130** may be made of other blood-permeable and biocompatible materials conventionally used in heart surgery.

[0227] In some embodiments, section **122** and/or section **132** comprises a biocompatible material that permits the passage of blood therethrough. In some embodiments, section **122** and/or section **132** comprises a mesh or a material like a net with spaces in it that permits the passage of blood therethrough. In some embodiments, section **122** and/or section **132** comprises a blood-permeable material made of one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a tissue engineered material. In some embodiments, section **122** and/or section **132** comprises a blood-permeable material having tissue ingrowth qualities. Persons skilled in the art will recognize that section **122** and/or section **132** may be made of other blood-permeable and biocompatible materials conventionally used in heart surgery.

[0228] In some embodiments, cords **124** and/or cords **134** comprise one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a tissue engineered material. In some embodiments, cords **124** and/or cords **134** comprise a material having tissue ingrowth qualities. Persons skilled in the art will recognize that cords **124** and/or cords **134** may be made of other biocompatible materials conventionally used in heart surgery.

[0229] In some embodiments, tube **140** and/or tube **150** comprises a biocompatible material, such as one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a metal alloy including (but not limited to) one or more of nickel and/or titanium and/or NitinolTM. Persons skilled in the art will recognize that tube **140** and/or tube **150** may be made of other biocompatible materials conventionally used in heart surgery. In some

embodiments, the material is braided, the braid defining an opening extending longitudinally through the tube for receiving an adjustment cord.

[0230] In some embodiments, cord **142** and/or cord **152** comprises one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a tissue engineered material. In some
5 embodiments, cord **142** and/or cord **152** comprises a material having tissue ingrowth qualities. Persons skilled in the art will recognize that cord **142** and/or cord **152** may be made of other biocompatible materials conventionally used in heart surgery.

[0231] In some embodiments, ring **112** comprises a biocompatible material, such as a
10 biocompatible, memory metal alloy including (but not limited to) nickel and/or titanium and/or Nitinol™. In some embodiments, skirt **114** comprises a biocompatible material, such as one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, and extracellular matrix biomaterial. In some
15 embodiments, body **110** and/or ring **112** and/or skirt **114** is blood-permeable. In some embodiments, body **110** and/or ring **112** and/or skirt **114** comprises a material having tissue ingrowth qualities. Persons skilled in the art will recognize that body **110** and/or ring **112** and/or skirt **114** may be made of other biocompatible materials conventionally used in heart surgery.

[0232] FIGS. 5C-5E show apparatus **100** implanted in heart **10**, wherein anterior member
20 **120** substantially prevents atrial displacement of anterior mitral leaflet **34** and posterior member **130** substantially prevents atrial displacement of posterior mitral leaflet **36**. Anterior member **120** is configured to cover an atrial surface **35** (FIG. 1) of anterior mitral leaflet **34** when apparatus **100** is implanted in the mitral valve. Posterior member **130** is configured to cover an atrial surface **37** (FIG. 1) of posterior mitral leaflet **36** when apparatus **100** is
25 implanted in the mitral valve. In some embodiments, anterior member **120** is sized and/or shaped like anterior mitral leaflet **34**. In some embodiments, posterior member **130** is sized and/or shaped like posterior mitral leaflet **36**.

[0233] Apparatus **100** is delivered and positioned within the heart using anchors (as described elsewhere herein). To implant apparatus **100**, a conventional endovascular
30 introducer (not shown) (or other device considered to be within the knowledge of persons skilled in the art of interventional cardiology) is inserted into a patient's circulatory system

and advanced using a transcatheter approach conventionally known. In some embodiments, the introducer is advanced using an antegrade transcatheter approach. In some other embodiments, the introducer is advanced using a retrograde transcatheter approach. Where the introducer is introduced into a patient's circulatory system via the femoral vein, the introducer is advanced to the patient's right atrium, through the atrial septum to the left atrium. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to guide the introducer through the patient's circulatory system and position the introducer in the heart.

[0234] Once transatrialseptal access of the introducer has been established, a papillary anchor is implanted into each papillary muscle and one or more annular anchors are implanted into the mitral annulus. To implant the papillary anchors, the introducer is advanced across the mitral valve, to the left ventricle of the patient's heart. A papillary anchor is introduced into each of the anterior-lateral papillary muscle and the posterior-medial papillary muscle using a catheter as described elsewhere herein. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to guide the catheter through the patient's circulatory system and position the papillary anchors in the papillary muscle.

[0235] To implant the annular anchor(s) into the mitral annulus, the introducer is positioned in the left atrium of the patient's heart. One or more annular anchors are introduced into the mitral annulus using a catheter as described elsewhere herein. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to guide the catheter through the patient's circulatory system and position the annular anchor(s) in the mitral annulus. Persons skilled in the art will recognize that the papillary anchors may be implanted in the papillary muscles before, after, or at approximately the same time that one or more annular anchors are implanted into the mitral annulus.

[0236] Example embodiments of an annular anchor are shown in FIGS. 7A-7C and 7D-7F. Anchor **500** (FIGS. 7A-7F) comprises an anchor pin **510**, a tether **520** connected to the anchor pin, and a guidewire **530** connected to the tether. The length of the guidewire is sufficient to traverse the patient's circulatory system from mitral annulus **32** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to advance apparatus **100** and a conventional transcatheter valve delivery system (e.g. an introducer) over the external end of guidewire **530**. In some embodiments, anchor **500** or one or more

of the parts thereof comprises a biocompatible material, such as polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, extracellular matrix biomaterial, and a metal alloy including (but not limited to) nickel and/or titanium and/or Nitinol™. In some embodiments, pin **510** comprises a bio-compatible, shape-memory material (e.g. one or more of SMA, smart metal, memory metal, memory alloy, muscle wire, smart alloy, Nitinol™, stainless steel) having a pre-deformed shape such as the shape shown in FIG. 7A or 7D for anchoring anchor **500** in mitral annulus **32**. In a deformed shape, pin **510** may be retained in a catheter for advancing anchor **500** to the mitral annulus. Persons skilled in the art will recognize that anchor **500** and the parts thereof may be made of other biocompatible materials conventionally used in heart surgery.

[0237] To secure each anchor **500** to mitral annulus **32**, an annular anchor catheter is used. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to advance the catheter through a patient's circulatory system to mitral annulus **32** through the introducer. The catheter is deflectable and steerable. An example embodiment of an annular anchor catheter **600** is shown in FIGS. 6A-6G. Catheter **600** comprises a catheter body **610** and a sensor **620** attached to body **610** for detecting contact between catheter **600** and the annular wall of mitral annulus **32**. Body **610** houses a needle **630** for piercing the annular wall and implanting anchor **500** into the annular wall tissue. Needle **630** is configured to house pin **510** of anchor **500** and advance anchor **500** through the annular wall.

[0238] To secure each anchor **500**, catheter **600** is advanced to a desired anchor site located at the annular wall of mitral annulus **32**. Sensor **620** detects contact between catheter **600** and the anchor site (FIG. 6A). Needle **630** is advanced through the annular wall into the mitral annulus tissue (FIG. 6B). Anchor **500** is advanced through needle **630** (FIG. 6C), with pin **510** resuming a pre-deformed shape as the anchor exits the needle (FIGS. 6D and 6E). In the pre-deformed shape, pin **510** is embedded in the mitral annulus tissue and is not retractable from mitral annulus **32** (FIG. 6F). With anchor **500** secured in mitral annulus **32**, needle **630** may be retracted into catheter **600** and catheter **600** may be withdrawn from the patient's circulatory via the introducer (FIG. 6G).

[0239] In some embodiments, catheter **600** comprises a controller (not shown) for operating the device extravascularly. When catheter **600** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some

embodiments the controller includes a handle and means for operating catheter **600** and the parts thereof.

[0240] Example embodiments of a papillary anchor are shown in FIGS. 8A-8E and 11A-11E. Anchor **200** comprises an anchor pin **210**, a tether **220** connected to the anchor pin, and a guidewire **230** connected to the tether. In the embodiment illustrated in FIGS. 8A-8E, anchor **200** comprises a pair of tethers **220**, each tether **220** connected to a guidewire **230**. In some embodiments, the anchor comprises one tether connected to a guidewire. The length of each guidewire **230** is sufficient to traverse the patient's circulatory system from the papillary muscle to the femoral vein puncture (i.e. the access site to the patient's circulatory system) and to advance apparatus **100** and a conventional transcatheter valve delivery system (e.g. an introducer) over the external end of guidewire **230**. In some embodiments, anchor **200** or one or more of the parts thereof comprises a biocompatible material, such as polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, extracellular matrix biomaterial, and a metal alloy including (but not limited to) nickel and/or titanium and/or Nitinol™. In some embodiments, the pin comprises a bio-compatible, shape-memory material (e.g. one or more of SMA, smart metal, memory metal, memory alloy, muscle wire, smart alloy, Nitinol™, stainless steel) that resumes a pre-deformed shape such as one of the shapes of pins **210A**, **210B**, **210C**, and **210D** shown in FIG. 9A-9D. Persons skilled in the art will recognize that anchor **500** and the parts thereof may be made of other biocompatible materials conventionally used in heart surgery. Many features and components of anchors **290**, **291**, **292**, and **293** (FIGS. 11A-11E) are similar to features and components of anchor **500**, with the same reference numerals being used to indicate similar features and components.

[0241] In some embodiments, anchor **200** includes a fastener for securing anchor **200** to papillary muscle **39**. Example embodiments of a fastener are shown in FIGS. 10A-10C and 11A-11E. Fastener **250** comprises a body **260** defining an aperture **270**. Anchor **200** is advanced through papillary muscle **39** and through aperture **270** of fastener **250**. When pin **210** abuts fastener **250**, fastener **250** disperses any retracting forces anchor **200** has on the papillary muscle thereby preventing anchor **200** from being retracted back through papillary muscle **39**. In some embodiments, fastener **250** comprises a biocompatible material, such as polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene,

polyethylene terephthalate, extracellular matrix biomaterial, and a metal alloy including (but not limited to) nickel and/or titanium and/or Nitinol™. Many features and components of fastener **280** (FIGS. 11A-11E) are similar to features and components of fastener **250**, with the same reference numerals being used to indicate similar features and components.

- 5 **[0242]** To secure each anchor **200** to a papillary muscle, a papillary anchor catheter is used (FIGS. 12A-12H, 13A-13E, 14A-14D, and 18A-18L and 20A-20L). Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to advance the catheter through a patient's circulatory system to a papillary muscle through the introducer. The papillary anchor catheter is deflectable and steerable.
- 10 **[0243]** An example embodiment of a papillary anchor catheter is shown in FIGS. 12A-12H and 13A-13E. Catheter **300** comprises a body **310** and a detachable receiver **320** removeably attached to body **310** by an arm **330**. Body **310**, arm **330**, and receiver **320** define an opening **340**. Opening **340** is configured to receive a transverse dimension of a papillary muscle **39** therein (FIG. 13A-13D). Body **310** is configured to house anchor **200**
- 15 having pin **210** and advance anchor **200** through the papillary muscle. In some embodiments body **310** comprises a retaining pin **350** for closing opening **340**. In a closed configuration shown in FIG. 12A, retaining pin **350** seals opening **340** and catheter **300** may be advanced through the patient's circulatory system and positioned adjacent the papillary muscle with minimal snaring and/or entangling surrounding tissues and/or valve structures.
- 20 In an open configuration shown in FIGS. 12B-12H, retaining pin **350** is at least partially retracted inside body **310** and opening **340** is exposed for receiving the papillary muscle. To advance and retract retaining pin **350** across opening **340**, retaining pin **350** comprises a wire **352** extending through body **310**. The length of wire **352** is sufficient to traverse the patient's circulatory system from papillary muscle **39** to a femoral vein puncture (i.e. the
- 25 access site to the patient's circulatory system) and to operate retaining pin **350** external the patient.

- [0244]** To secure anchor **200** to a papillary muscle, catheter **300** is advanced in the closed configuration through the patient's circulatory system to the papillary muscle. Adjacent the papillary muscle, retaining pin **350** is retracted into body **310** and catheter **300** (in the open
- 30 configuration) is advanced to position a transverse dimension of the papillary muscle within opening **340** (FIG. 13A). Retaining pin **350** may be extended (i.e. partially or fully closed) to contact or advance through the papillary muscle thereby stabilizing the muscle while anchor

200 is secured therein (FIG. 13B). Pin **210** of anchor **200** is advanced from body **310**, through the papillary muscle, to contact and/or secure to receiver **320** (FIG. 13C). In some embodiments anchor **200** is advanced through a transverse dimension of the papillary muscle from an entrance site **39e** of the papillary muscle to an exit site **39f** of the papillary muscle. Pin **210** is received by receiver **320** adjacent exit site **39f**. In some embodiments, anchor **200** is advanced from entrance site **39e** to exit site **39f** through the center of the papillary muscle. In some embodiments, anchor **200** is advanced from entrance site **39e** to exit site **39f** through the papillary muscle in such a way to enhance the grab on the papillary muscle to thereby minimize or avoid anchor **200** from being torn out of the papillary muscle.

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10 [0245] In some embodiments, pin **210** is connected to receiver **320** via a threaded screw-like mechanism. In some embodiments, receiver **320** houses fastener **250** for engagement with pin **210** as described elsewhere herein. However, persons skilled in the art will recognize that other conventional means for securing pin **210** to receiver **320** may be used. With pin **210** connected to receiver **320**, pin **210** is not retractable through the papillary muscle. Tether **220** extends through the papillary muscle and anchor **200** is thereby secured through the muscle.

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20 [0246] With anchor **200** secured to the papillary muscle, catheter **300** may be withdrawn from the patient's circulatory system by retracting (i.e. unscrewing) arm **330** (and retaining pin **350**) into body **310**, thereby releasing receiver **320** (FIGS. 13D-13E). Catheter **300** is then withdrawn from the patient via the introducer. To retract arm **330** from receiver **320**, arm **330** comprises a wire **332** extending through body **310**. The length of wire **332** is sufficient to traverse the patient's circulatory system from papillary muscle **39** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to operate arm **330** external the patient. In some embodiments, wire **352** and/or wire **332** are connected to a controller (not shown) external the patient for operating catheter **300** and/or the parts thereof internally. In the embodiment shown in FIGS. 12A-12H, arm **330** comprises a threaded wire **330a** that threadedly engages receiver **320** as described elsewhere herein and a pair of support posts **320b** on either side of wire **330a** that release from receiver **320** when wire **330a** is unthreaded from the receiver.

25
30 [0247] An example embodiment of a papillary anchor catheter is shown in FIGS. 14A-14D. Catheter **400** comprises a body **410** and a deformable arm **420** extending away from body **410**. Body **410** is configured to house pin **210** of anchor **200** and advance anchor **200**

through the papillary muscle. In some embodiments, body **410** includes a needle **440** for housing pin **210** in body **410** and advancing anchor **200** through the papillary muscle. The length of needle **440** is sufficient to traverse the patient's circulatory system from papillary muscle **39** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to operate needle **440** external the patient.

[0248] In the illustrated embodiment, arm **420** comprises a plurality of modular pieces **422** arranged linearly and at least one tensioning wire **450** extending through pieces **422**. Arm **420** is deformable into a hook-like or deformed configuration for receiving pin **210** when anchor **200** is advanced through the papillary muscle as described elsewhere herein. To deform arm **420**, tension is applied to a tensioning wire **450**, bringing the edges of adjacent modular pieces **422** together and forming a recess **430** for receiving a papillary muscle. Accordingly, modular pieces **422** are shaped to provide arm **420** with a desired configuration when wire **450** is tensioned. The length of wire **450** is sufficient to traverse the patient's circulatory system from papillary muscle **39** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to operate arm **420** external the patient.

[0249] Catheter **400** is shown in a deformed configuration in FIGS. 14A-14C. To return catheter **400** to an extended configuration shown in FIG. 14D, tension is removed from wires **450**. In the extended configuration, catheter **400** may be advanced through the patient's circulatory system and positioned adjacent the papillary muscle with minimal snaring and/or entangling surrounding tissues and/or valve structures. Persons skilled in the art will recognize that other conventional means for deforming arm **420** may be used.

[0250] To secure anchor **200** to a papillary muscle, catheter **400** is advanced in the extended configuration through the patient's circulatory system to the papillary muscle. Tensioning wires **450** are then tensioned to position the papillary muscle within recess **430** of catheter **400**. In this deformed configuration, arm **420** at least partially encircles the papillary muscle. Pin **210** of anchor **200** is then advanced from body **410**, through the papillary muscle, to contact arm **420**. Thus, catheter **400**, in the deformed configuration, prevents pin **210** from extending through the papillary muscle and piercing and/or damaging tissue of the left ventricle (i.e. the ventricular wall). In some embodiments anchor **200** is advanced through a transverse dimension of the papillary muscle from an entrance site (not shown) of the papillary muscle to an exit site (not shown) of the papillary muscle. Pin **210** is received by arm **420** adjacent exit site **39d**. In some embodiments, anchor **200** is advanced

from entrance site **39e** to exit site **39d** through the center of the papillary muscle. In some embodiments, anchor **200** is advanced from entrance site **39e** to exit site **39d** through the papillary muscle in such a way to enhance the grab on the papillary muscle to thereby minimize or avoid anchor **200** from being torn out of the papillary muscle.

5 **[0251]** Once advanced from body **410**, pin **210** resumes a pre-deformed shape (e.g. one of the shapes shown in FIGS. 9A-9D and 11A-11E). As such, pin **210** is not retractable through the papillary muscle. Tether **220** extends through the papillary muscle and anchor **200** is thereby secured through the muscle. With anchor **200** secured to the papillary muscle, catheter **400** may be withdrawn from the patient's circulatory system by releasing
10 the tension from wires **450** and withdrawing catheter **400** (in the extended configuration) from the patient via the introducer.

[0252] In some embodiments, a guidewire (not shown) may be used to advance catheter **300** and/or catheter **400** to a papillary muscle. In some embodiments, the guidewire comprises a J-shaped tip configured to engage the papillary muscle. The guidewire may be
15 advanced through the patient's circulatory system to the papillary muscle via the introducer. The papillary muscle is positioned about a recess defined by the tip. A balloon (not shown) may be advanced through the introducer, over the guidewire, and inflated to stabilize the guidewire in position and prevent the guidewire from becoming dislodged while catheter **300** and/or catheter **400** is advanced across the guidewire. In this way, catheter **300** and/or
20 catheter **400** may be advanced into a desired position around the papillary muscle.

[0253] In some embodiments, catheter **300** comprises a controller (not shown) for operating the device extravascularly. When catheter **300** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some
25 embodiments the controller includes a handle and means for operating catheter **300** and the parts thereof.

[0254] In some embodiments, catheter **400** comprises a controller (not shown) for operating the device extravascularly. When catheter **400** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some
30 embodiments the controller includes a handle and means for operating catheter **400** and the parts thereof.

[0255] In some embodiments, catheter **300** and/or the parts thereof comprise a sterilized or sterilisable material. In some embodiments, catheter **300** and/or the parts thereof comprise one or more of medical grade plastic, thermal plastic, stainless steel, metal, a metal alloy (e.g. Nitinol™ or another nickel/titanium alloy), and titanium. Persons skilled in the art will
5 recognize that catheter **300** and/or the parts thereof may be made of any sterilized or sterilisable material conventionally used to manufacture tools used in heart surgery.

[0256] In some embodiments, catheter **400** and/or the parts thereof comprise a sterilized or sterilisable material. In some embodiments, catheter **400** and/or the parts thereof comprise one or more of medical grade plastic, thermal plastic, stainless steel, metal, a metal alloy
10 (e.g. Nitinol™ or another nickel/titanium alloy), and titanium. Persons skilled in the art will recognize that catheter **400** and/or the parts thereof may be made of any sterilized or sterilisable material conventionally used to manufacture tools used in heart surgery.

[0257] An example embodiment of a papillary anchor catheter is shown in FIGS. 15A-15L and 17A-17L. Catheter **1000** comprises a body **1100**, a deformable arm **1200** extending
15 away from body **1100**, and an anchor housing **1300** connecting body **1100** and arm **1200**. Anchor housing **1300** is configured to house anchor **200** as catheter **1000** is advanced through a patient's circulatory system via a conventional endovascular introducer (not shown) (or other device considered to be within the knowledge of persons skilled in the art of interventional cardiology). Anchor housing **1300** extends through a channel **1310A** (FIG.
20 15D) defined by body **1100** and through a channel **1200A** (FIG. 15B) defined by arm **1200**. Catheter **1000** further comprises a guidewire **1400** extending from body **1100** alongside arm **1200** for directing catheter **1000** to a papillary muscle within the heart. Guidewire **1400** extends through a channel **1410A** (FIG. 15D) defined by body **1100**. The length of guidewire **1400** is sufficient to traverse the patient's circulatory system from papillary muscle
25 **39** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to operate guidewire **1400** external the patient. Guidewire **1400** may be soft and flexible for delivery about the papillary muscle without snaring or passing through the adjacent ventricular wall.

[0258] Catheter **1000** is deformable so that anchor **200** may be advanced through the
30 papillary muscle with minimal snaring and/or entangling tissues and/or valve structures in the heart and surrounding the papillary muscles. In the illustrated embodiment, arm **1200** comprises at least one deformable section **1210**. In some embodiments, each deformable

section **1210** comprises a plurality of modular pieces arranged linearly and a tensioning wire **1216**, **1218** extending through the pieces. To deform each section **1210**, tension is applied to wire **1216**, **1218**. In the illustrated embodiment, arm **1200** comprises a first deformable section **1212** and a second deformable section **1214**. In some embodiments, first

5 deformable section **1212** is deformable by about 0° to about 120° in a direction in a first plane. In some embodiments, second deformable section **1214** is deformable by about 0° to about 90° in a first direction in a second plane and by about 0° to about -90° in a second direction in the second plane. In some embodiments, the first plane and the second are non-coplanar. In some embodiments, the first plane is perpendicular to the second plane.

10 Persons skilled in the art will recognize that each deformable section may be deformable in a plurality of directions and/or in a plurality of planes. To deform arm **1200**, catheter **1000** comprises a wire for operating each deformable section. In the illustrated embodiment, catheter **1000** comprises a wire **1217** for operating first deformable section **1212** and wires **1216**, **1218** for operating second deformable section **1214**. In some embodiments wire **1217**

15 deforms first deformable section **1212** in a first direction (e.g. by about 0° to about 120°) in a first plane. In some embodiments wire **1216** deforms second deformable section **1214** in a first direction (e.g. by about 0° to about 90°) in a second plane and wire **1218** deforms second deformable section **1214** in a second direction (e.g. by about 0° to about -90°) in the second plane. In some embodiments, the first plane and the second plane are non-

20 coplanar. In some embodiments, the first plane and the second plane are perpendicular. Wires **1216**, **1217**, **1218** each extend through a respective channel **1216A**, **1217A**, **1218A** (FIG. 15D) defined by body **1100**. The length of each wire **1216**, **1217**, **1218** is sufficient to traverse the patient's circulatory system from papillary muscle **39** to a femoral vein puncture (i.e. the access site to the patient's circulatory system) and to operate arm **1200** external the

25 patient. In some embodiments, one or more of anchor housing **1300**, guidewire **1400**, wire **1216**, wire **1217**, and wire **1218** are connected to a controller (not shown) external the patient for operating catheter **1000** and/or the parts thereof internally.

[0259] Catheter **1000** is shown in an extended configuration in FIGS. 15I-15L. In the extended configuration, catheter **1000** may be advanced through a patient's circulatory

30 system and positioned adjacent a papillary muscle with minimal snaring and/or entangling tissues and/or valve structures in the heart and surrounding the papillary muscles. To implant anchor **200**, catheter **1000** is deformable as described elsewhere herein.

[0260] As shown in FIGS. 15E-15H, arm **1200** is deformable about first deformable section **1212** into a deflected configuration. Catheter **1000** may be deformed into the deflected configuration in the left ventricle to facilitate access to the papillary muscle and implantation of anchor **200**. In the deflected configuration, guidewire **1400** may be advanced about the papillary muscle to guide catheter **1000** in a position to implant anchor **200** with minimal snaring and/or entangling tissues and/or valve structures surrounding the papillary muscle. FIGS. 17A-17D show catheter **1000** deformed about first deformable section **1212** into the deflected configuration and delivery of guidewire **1400** to at least partially encircle the papillary muscle. With guidewire **1400** at least partially encircling the papillary muscle, catheter **1000** may be further advanced to implant anchor **200** with minimal snaring and/or entangling tissues and/or valve structures surrounding the papillary muscle.

[0261] As shown in FIGS. 15A-15D, arm **1200** is deformable about second deformable section **1214** into a hook-like or deformed configuration. Catheter **1000** may be deformed into the deformed configuration in the left ventricle to facilitate access to the papillary muscle. For example, in the deformed configuration, catheter **1000** may be positioned to advance anchor **200** through a papillary muscle and receive pin **210** so that minimal snaring and/or entangling of tissues and/or valve structures surrounding the papillary muscle occurs. In some embodiments, arm **1200** comprises a receiver **1230** for receiving pin **210**. Example embodiments of a receiver are shown in FIGS. 16A and 16B. Receiver **1230** (FIG. 16A) comprises a recess **1232** for receiving pin **210**. Receiver **1240** (FIG. 16B) comprises an anchor fastener **1242** for receiving pin **210** of anchor **200**. When pin **210** is in its pre-deformed shape, fastener **1242** disperses any retracting forces anchor **200** has on the papillary muscle thereby preventing anchor **200** from being retracted back through the papillary muscle.

[0262] FIGS. 17E-17K show catheter **1000** deformed in a first direction in a first plane about first deformable section **1212** and in a second direction in a second plane about second deformable section **1214**, wherein the first plane is perpendicular to the second plane. Deformed about first and second deformable sections **1212**, **1214**, arm **1200** may be advanced along guidewire **1400** to at least partially encircle the papillary muscle. With arm **1200** at least partially encircling the papillary muscle, anchor **200** may be advanced through the papillary muscle and pin **210** of anchor **200** may be received by receiver **1230**. In some embodiments anchor **200** is advanced through a transverse dimension of the papillary

muscle from an entrance site **39e** of the papillary muscle to an exit site **39f** of the papillary muscle. Pin **210** is received by receiver **1230** adjacent exit site **39f**. In this way, snaring and/or entangling tissues and/or valve structures surrounding the papillary muscle are minimized or avoided. Thus, catheter **1000**, prevents pin **210** from extending through the papillary muscle and piercing and/or damaging tissue of the left ventricle (i.e. the ventricular wall). In some embodiments, anchor **200** is advanced from entrance site **39e** to exit site **39f** through the center of the papillary muscle. In some embodiments, anchor **200** is advanced from entrance site **39e** to exit site **39f** through the papillary muscle in such a way to enhance the grab on the papillary muscle to thereby minimize or avoid anchor **200** from being torn out of the papillary muscle. In some embodiments, anchor housing **1300** is configured to advance anchor **200** through the papillary muscle in such a way to enhance the grab on the papillary muscle, thereby minimizing or avoiding anchor **200** from being torn out of the papillary muscle. For example, the diameter of anchor housing **1300** may be selected to house a rigid anchor **200** and advance the anchor through the papillary muscle with an optimal amount of grab on the papillary muscle.

[0263] Once advanced from anchor housing **1300**, pin **210** resumes a pre-deformed shape (e.g. one of the shapes shown in FIGS. 9A-9D and 11A-11D). As such, pin **210** is not retractable through the papillary muscle. Tether **220** extends through the papillary muscle and anchor **200** is thereby secured through the muscle. With anchor **200** secured to the papillary muscle, catheter **1000** may be withdrawn from the patient's circulatory system by withdrawing catheter **1000** (in the extended configuration) from the patient via the introducer. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to advance and retract the catheter through a patient's circulatory system and implant anchor **200** through the papillary muscle.

[0264] In some embodiments, catheter **1000** comprises a controller (not shown) for operating the device extravascularly. When catheter **1000** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some embodiments the controller includes a handle and means for operating catheter **1000** and the parts thereof.

[0265] In some embodiments, catheter **1000** and/or the parts thereof comprise a sterilized or sterilisable material. In some embodiments, catheter **1000** and/or the parts thereof comprise one or more of medical grade plastic, thermal plastic, stainless steel, metal, a

metal alloy (e.g. NitinolTM or another nickel/titanium alloy), and titanium. Persons skilled in the art will recognize that catheter **1000** and/or the parts thereof may be made of any sterilized or sterilisable material conventionally used to manufacture tools used in heart surgery.

5 **[0266]** To implant apparatus **100**, one or more annular anchors are secured to mitral annulus **32** as described elsewhere herein. In the embodiment illustrated in FIG. 5E, three anchors **500** are secured to mitral annulus **32**. Papillary anchors are secured to each of anterior-lateral papillary muscle **39a** and posterior-medial papillary muscle **39b** as described elsewhere herein. Once a first papillary anchor is implanted into a first papillary muscle, a
10 second papillary anchor may be implanted into a second papillary muscle. In the embodiment illustrated in FIGS. 5C-5D, one anchor **200** is secured to each papillary muscle. Persons skilled in the art will recognize that any suitable number of papillary anchors and annular anchors may be used to position apparatus **100** in a desired position and location in heart **10**. The papillary anchors may be implanted in the papillary muscles
15 before, after, or at approximately the same time that one or more annular anchors are implanted into the mitral annulus.

[0267] A method **900** for repairing a mitral valve of a heart according to an example embodiment is shown in FIG. 18. In block **910** a conventional transatrialseptal introducer (not shown) (or other device considered to be within the knowledge of persons skilled in the
20 art of interventional cardiology) is inserted into a patient's circulatory system and advanced using a transcatheter approach as described elsewhere herein. One or more papillary anchors and annular anchors are implanted respectively in the patient's mitral annulus and papillary muscle(s) in respective blocks **920** and **930**, as described elsewhere herein.

[0268] Once implanted in the heart, the papillary anchors and the annular anchor(s) are
25 used to advance and guide apparatus **100** through a patient's circulatory system to a desired implant site and to position apparatus **100** in the heart. In block **940** apparatus **100** is externally connected to the guidewires of the papillary and annular anchors. Guidewires **230** secured to the anterior-lateral papillary muscle are externally advanced through a first end **140A** of tube **140** of anterior member **120** and/or a first end **150A** of tube **150** of
30 posterior member **130**. Guidewires **230** secured to the posterior-medial papillary muscle are externally advanced through a second end **140B** of tube **140** of anterior member **120** and/or a second end **150B** of tube **150** of posterior member **130**. Guidewire(s) **530** secured to the

mitral annulus is/are advanced externally through body **110** at one or more anchor sites (not shown). In some embodiments, the guidewire of each anchor **500** is advanced through skirt **114** at one or more anchor sites (not shown). The anchor sites may be positioned anywhere through body **110** and/or skirt **114** so that body **110** may be advanced along guidewire(s)
5 **530** to mitral annulus **32** where the body is positioned against the atrial muscle (not shown) adjacent the mitral annulus. In some embodiments, body **110** is shaped like the mitral annulus of a heart for positioning body **110** against the atrial muscle.

[0269] With guidewires **230**, **530** connected to apparatus **100** externally, apparatus **100** may then be inserted inside the introducer by radially compressing body **110** (as described
10 elsewhere herein) to implant apparatus **100** inside the heart. In block **950** apparatus **100** is advanced endovascularly to an implant site to position apparatus **100** in heart **10**. Once positioned at the desired implant site, apparatus **100** is radially expanded as described elsewhere herein by releasing apparatus **100** from the introducer. In block **960** apparatus
15 **100** is adjusted to position anterior member **120** and/or posterior member **130** to adjust the extent of atrial displacement of the mitral leaflets during ventricular contraction and correct leaflet prolapse and/or restore mitral valvular competence. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to guide apparatus
100 along the guidewires through the patient's circulatory system to position apparatus **100** in the desired implant site (e.g. the mitral valve).

20 **[0270]** Body **110** is advanced along guidewire(s) **530** to mitral annulus **32** where the body is positioned against the atrial muscle (not shown) adjacent the mitral annulus. In some embodiments, body **110** is shaped like the mitral annulus of a heart for positioning body **110** against the atrial muscle. To secure body **110** to mitral annulus **32**, a lock **700** (described elsewhere herein) is advanced in an open configuration along each guidewire **530** to the
25 corresponding anchor site (not shown) of body **110** via a lock catheter **800** (described elsewhere herein). Lock **700** is secured in a locked configuration to tether **520** adjacent each anchor site. With lock **700** secured, tether **520** may be cut and guidewire **530** withdrawn from the patient.

[0271] Tube **140** and/or tube **150** is advanced along guidewire(s) **230** through the mitral
30 valve and into the left ventricle adjacent the corresponding papillary muscle. In this way, end **140A** and/or **150A** of tube **140** is connected to anterior-lateral papillary muscle **39a** via a first anchor **200** and end **140B** and/or **150B** of tube **150** is connected to posterior-medial

papillary muscle **39b** via a second anchor **200**. Thereby, tube **140** and/or tube **150** traverses the papillary muscles, from anterior-lateral papillary muscle **39a** to posterior-medial papillary muscle **39b** (FIGS. 5C-5D). By adjusting the length of tube **140** and/or tube **150** as described elsewhere herein, the extent of atrial displacement of the mitral leaflets during ventricular contraction can be adjusted. The tension of cord **142** and/or cord **152** may be adjusted as described elsewhere herein to adjust the extent of atrial displacement of the mitral leaflets during ventricular contraction. The length of tube **140** and/or tube **150** and the tension of cord **142** and/or cord **152** may be adjusted using ultrasound guidance. As described elsewhere herein, lock **700** may be advanced in an open configuration along cord(s) **142**, **152** to abut against an end of tube(s) **140**, **150**. Lock **700** is secured in a locked configuration to cord(s) **142**, **152** adjacent tube(s) **140**, **150** to secure tube(s) **140**, **150** in a desired length and member(s) **120**, **130** in a desired position covering an atrial surface of the mitral leaflet. With lock **700** secured, cord (s) **142**, **152** may be cut adjacent the lock and the free end withdrawn from the patient. When installed, apparatus **100** may correct leaflet prolapse and/or restore mitral valvular competence.

[0272] In some embodiments, to optimize the extent of atrial displacement of the mitral leaflets during ventricular contraction when apparatus **100** is implanted and under tension as described elsewhere herein, conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques are used to optimize a distance between an atrial edge 110a (FIG. 4A) of body **110** and an anchor point in papillary muscle **39**.

[0273] In block **960** one or more locks **700** (described elsewhere herein) may be advanced using a lock catheter (described elsewhere herein) to secure apparatus **100** in a desired location and position. Conventional Transesophageal Echocardiography (TEE) and/or fluoroscopy techniques may be used to advance lock **700** and the lock catheter through a patient's circulatory system to a desired location.

[0274] An example embodiment of lock **700** is shown in FIGS. 19A-19E. Lock **700** comprises a body **710** defining opposed jaws **720**, **730** and a channel **740** extending lengthwise through the body for receiving a guidewire and/or a tether of a papillary anchor and/or an annular anchor. In the embodiment shown in FIGS. 19A-19E, lock **700** is hairpin-shaped and body **710** tapers from jaws **720**, **730** to an opposed end **712** to facilitate delivery of lock **700** via a lock catheter (described elsewhere herein). In some embodiments body

end **712** defines a recess **742** shaped concentrically about channel **740** for engaging the catheter as described elsewhere herein.

[0275] Lock **700** is biased in a locked configuration shown in FIGS. 19A-19E. In the locked configuration, jaws **720**, **730** are operable to clasp a guidewire and/or a tether extending therebetween. To improve the strength of the clasp on the guidewire or tether, jaws **720**, **730** may define teeth **722**, **732** for gripping the guidewire or tether. In an open configuration (best shown in FIGS. 20C, 20F, 20J, and 20K) jaws **720**, **730** are deflected away from one another and lock **700** is free to move along the guidewire or tether. Each jaw **720**, **730** defines a flexible arm **724**, **734**. In some embodiments, pressure may be applied to arms **724**, **734** to deflect jaws **720**, **730** in the open configuration. In some embodiments, jaws **720**, **730** may be deflected away from one another by inserting a needle or other similar means between the jaws.

[0276] To secure lock **700** to a guidewire and/or tether, lock **700** is advanced in the open configuration along the guidewire and/or tether using a lock catheter (FIGS. 20A-20K). Example embodiments of a lock catheter are shown in FIGS. 20A-20N and 21. Lock catheter **800** (FIGS. 20A-20N) comprises a sleeve tube **810** housing a lock tube **820**. Lock tube **820** is configured to engage recess **742** of lock **700** to advance or retract lock **700** along guidewire and/or tether. Lock tube **820** houses a deploying tube **830** for disengaging lock **700** from lock tube **820** by advancing deploying tube **830** towards end **712** of lock **700**.

[0277] In some embodiment, lock tube **820** comprises at least one cut (not shown) longitudinally extending from a lock engaging end **820a** thereof through at least a portion of the lock tube. In some embodiments, deploying tube **830** comprises at least one cut (not shown) longitudinally extending from a lock abutting end **830a** thereof through at least a portion of the deploying tube. To deploy lock **700** from catheter **800**, a force is applied to deploying tube **830** to advance lock abutting end **830a** against end **712** of lock **700**. As end **830a** abuts against end **712**, deploying tube **830** splits open along the at least one cut, increasing the diameter of lock abutting end **830a**, and forcing end **830a** against lock tube **820**. As end **830a** abuts against lock tube **820**, lock tube **820** splits open along the at least one cut, increasing the diameter of lock engaging end **820a**, releasing lock tube **820** from recess **742** of lock **700**, and deploying lock **700** from catheter **800**.

[0278] In some embodiments, lock 700 may be retrieved using catheter 800 by forcing lock abutting end 830a of deploying tube 830 against lock tube 820 to split open lock tube 820, thereby increasing the diameter of lock engaging end 820a. Catheter 800 is advanced to position lock engaging end 820a of lock tube 820 with recess 742 of lock 700. To engage lock engaging end 820a with recess 742, deploying tube 830 is retracted away from lock engaging end 820a. As deploying tube 830 is retracted, the diameter of ends 820a, 830a decreases and lock engaging end 820 mates with and engages recess 742.

[0279] In some embodiments catheter 800 comprises a needle 840 (best shown in FIGS. 20B, 20E, 20H, and 20K) for retaining lock 700 in the open configuration. Needle 840 extends over the guidewire and/or tether through channel 740 and deflects jaws 720, 730 away from the guidewire and/or tether. To secure lock 700 to the guidewire and/or tether, needle 840 may be withdrawn from channel 740 thereby allowing jaws 720, 730 to bias towards one another and biasing lock 700 in the closed configuration.

[0280] In some embodiments lock 700 comprises a ring-shaped collar 750 for retaining lock 700 in closed configuration. In the example embodiment shown in FIGS. 19A-19E jaws 720, 730 define recesses 728, 738 shaped concentrically about channel 740 for receiving collar 750 and retaining lock 700 in the locked configuration. Collar 750, positioned in recesses 728, 738, is operable to prevent jaws 720, 730 from deflecting away from one another (FIGS. 20L-20N).

[0281] In some embodiments, to move collar 750 along lock 700, collar 750 comprises at least one notch 752. Sleeve tube 810 of catheter 800 defines at least one recess 812 configured to engage notch(es) 752. In the embodiment shown in FIGS. 20A-20N sleeve tube 810 comprises recess 812 configured to engage notch 752 of collar 750. To secure lock 700 to the guidewire/tether, sleeve tube 810 is advanced over lock tube 820 towards collar 750. Sleeve tube 810 is rotated about the guidewire and/or tether to align recess 812 with notch 752. With recess 812 and notch 752 aligned, collar 750 may be moved with sleeve tube 810. Sleeve tube 810 may be advanced across lock tube 820 to push collar 750 towards jaws 720, 730 and position collar 750 within recesses 728, 738. Collar 750 thereby clasps jaws 720, 730 together to close and retain lock 700 in the locked configuration (FIG. 20L-20N). In some embodiments lock 700 is irreversibly locked in the closed configuration once collar 750 is advanced along jaws 720, 730 and positioned within recesses 728, 738.

With lock **700** locked in the closed configuration and thereby secured to the guidewire and/or tether, catheter **800** may be withdrawn from the patient.

[0282] Many features and components of lock catheter **850** (FIG. 21) are similar to features and components of lock catheter **800**, with the same reference numerals being used to indicate similar features and components. Sleeve tube **810** of catheter **850** defines at least one aperture **862** configured to receive at least one notch **752** of lock **700**.

[0283] In some embodiments, catheter **800** comprises a controller (not shown) for operating the device extravascularly. When catheter **800** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some embodiments the controller includes a handle and means for operating catheter **800** and the parts thereof.

[0284] In some embodiments, catheter **400** comprises a controller (not shown) for operating the device extravascularly. When catheter **400** is situated intravascularly, as described elsewhere herein, the controller is located external to the patient's body. In some embodiments the controller includes a handle and means for operating catheter **400** and the parts thereof.

[0285] Lock **700** and the parts thereof may comprise one or more of medical grade plastic, thermal plastic, stainless steel, metal, a metal alloy (e.g. Nitinol™ or another nickel/titanium alloy), and titanium.

[0286] Catheter **800** and the parts thereof may comprise one or more of medical grade plastic, thermal plastic, stainless steel, metal, a metal alloy (e.g. Nitinol™ or another nickel/titanium alloy), and titanium. Persons skilled in the art will recognize that catheter **1000** and/or the parts thereof may be made of any sterilized or sterilisable material conventionally used to manufacture tools used in heart surgery.

[0287] FIGS. 22A-22D illustrate an apparatus **900** for repairing a heart valve, such as a mitral valve, according to an example embodiment of the invention. Apparatus **900** includes a radially compressible and radially expandable body **910**, an anterior member **920**, and a posterior member **930**. In the illustrated embodiments, body **910** is a tube. Alternatively, body **910** has a shape similar to body **110** of apparatus **100** as seen in FIG.4A. A radially compressible and radially expandable ring (not shown), having similar functions and properties as ring **112** discussed elsewhere here, may be arranged on or in body **910** to

facilitate the radial compression and expansion thereof. A compressible and expandable ring is not mandatory; body **910** may, for example, be provided in a self-expandable form (e.g., the body is constrained within a delivery device such as within a catheter until positioned and deployed). Body **910** may also be expanded and contracted directly using
5 external means such as an inflatable balloon.

[0288] Anterior member **920** is connected to an anterior end **919** of body **910**. Posterior member **930** may be attached to a posterior end **918** of body **910**. Each member **920**, **930** comprises a section **922**, **932**. Sections **922**, **932** may comprise a net-like structure defined by a plurality of cells **902**. The plurality of cells **902** extend radially and longitudinally from
10 body **910** to the plurality of positioning cords **924**, **934**. Cells **902** are hollow spaces that may permit the passage of blood therethrough.

[0289] Sections **922**, **932** may include a plurality of positioning cords **924**, **934** for positioning each member to cover an atrial surface of a mitral leaflet from a lateral commissure to a medial commissure thereof. Cords **924**, **934** are spaced laterally across
15 each section **922**, **932** and extend from section **922**, **932** away from body **910**. Cords **924**, **934** may be integrally formed with corresponding section **922**, **932**. Cords **924**, **934** each terminate at and connect to a flexible, compressible tube **940**, **950**. Cords **924**, **934** are laterally spaced across tube **940**, **950**. In some embodiments, cords **924**, **934** are evenly spaced across tube **940**, **950**. Tubes **940**, **950** may each comprise an adjustment cord **942**,
20 **952** secured to an end of the tube and extending longitudinally through the tube. In the illustrated embodiments, compressible tubes **940**, **950** are rounded hollow tubes that are constructed of braided threads. Threads can be made of one or more of polytetrafluoroethylene (PTFE), expanded PTFE, polyethylene, polypropylene, polyethylene terephthalate, an extracellular matrix biomaterial, and a tissue engineered material.
25 Compressible tubes **940**, **950** may however be provided in other suitable forms that are known in the art. Compressible tubes **940**, **950** and adjustment cords **942**, **952** are similar to tubes **140**, **150** and cords **142**, **152** respectively, which the latter have been discussed elsewhere here. The functions and properties of compressible tubes **940**, **950** and adjustment cords **942**, **952** are thus not repeated.

[0290] Cells **902** may be contractable between a relaxed position and an elongated position. Cells **902** may be elongated and/or contracted laterally and/or longitudinally with respect to body **910**. In some embodiments, each cell **902** has a diamond shape. A
30

diamond is a quadrilateral having four sides of substantially equal lengths and four vertices with opposite angles that are equal ($\theta_1 = \theta_2$ and $\theta_3 = \theta_4$), and that one set of angles is greater than the other set (θ_1, θ_2 is greater than θ_3, θ_4), a schematic diagram of a diamond-shaped cell **902** is shown in FIG. 22E. In the illustrated embodiments (FIG. 22A-22D), the diamond-shaped cells **902** are aligned such that the vertices with the smaller angles (θ_3, θ_4) are positioned longitudinally with respect to body **910**, and the vertices with the greater angles (θ_1, θ_2) are positioned laterally with respect to body **910**. This is not mandatory; however. In some embodiments, cells **902** may be aligned such that the vertices with the smaller angles (θ_3, θ_4) are positioned laterally, and the vertices having the greater angles (θ_1, θ_2) are positioned longitudinally with respect to body **910**.

[0291] When apparatus **900** is implanted in heart **10**, the shape of sections **922, 932** changes in response to the opening and closing of mitral valve **30** during ventricular contraction. Mitral valve **30** changes in shape during the opening and closing of the valve. FIG. 23A is a schematic diagram illustrating a fully opened mitral valve **30**. The arrow shows the direction of blood flow through the opened mitral valve **30**. As shown in FIG. 23A, a fully opened mitral valve can be defined by a substantially cylindrical shape. A cylindrical shape may be defined by two parallel circular bases connected by a curved surface. FIG. 23A is a schematic diagram illustrating a fully closed mitral valve **30**. The arrow shows that blood cannot flow backwards into atrium **20** through mitral valve **30**. As shown in FIG. 23B, a fully closed mitral valve can be defined by a substantially hourglass shape. An hourglass shape may be defined by a convex front face that tapers axially towards a constricted waist bottom.

[0292] In some embodiments, sections **922, 932** are transformable between a cylindrical configuration and an hourglass configuration in response to the respective opening and closing of mitral valve **30**. Sections **922, 932** conform to the shapes of mitral valve **30** by the transition of cells **902** between the relaxed position and the elongated position. The shapes and sizes of cells **902** change between the relaxed and the elongated positions.

[0293] Sections **922, 932** may be in the cylindrical configuration when mitral valve **30** is open. In such embodiments, cells **902** may be in the relaxed position. In the relaxed position, cells **902** may be substantially uniform in size and shape. For example, in embodiments in which cells **902** are diamond shaped, cells **902** have identical or substantially similar diagonal length p (i.e., the distance between opposing longitudinal

vertices), and have identical or substantially similar diagonal length q (i.e., the distance between opposing lateral vertices), as shown in the schematic diagram in FIG. 22E.

[0294] Sections **922**, **932** may be in the hourglass configuration when mitral valve **30** is closed. In such embodiments, some or all of cells **902** may be in the elongated position. In the elongated position, cells **902** may not be uniform in size and shape. In some
5 embodiments, the diagonal length p of cells **902** increases from posterior and anterior ends **918**, **919** of body **910** to compressible tubes **940**, **950**. Diagonal length q of cells **902** may decrease from posterior and anterior ends **918**, **919** of body **910** to compressible tubes **940**, **950**. In these embodiments, cells **902** near compressible tubes **940**, **950** are elongated and
10 narrow. The elongated and narrow cells **902** generally conform to the tapered waist bottom of the hourglass-shaped fully closed mitral valve.

[0295] Cells **902** that overlap with one another during ventricular contraction is undesirable. Some undesirable results include the occurrence of thrombosis, the prevention of adequate coaptation between the mitral leaflets, and the abrasion of sections **922**, **932** which could
15 eventually lead to disruption of apparatus **900** over time. Diamond-shaped cells **902** can conform to and transition between the cylindrical-shaped opened mitral valve **30** and the hourglass-shaped closed mitral valve **30** without cells **902** overlapping with one another during ventricular contraction. As discussed herein, when apparatus **900** is implanted in heart **10**, the diamond-shaped cells **902** near or at the tapered waist bottom of the
20 hourglass-shaped closed mitral valve **30** are elongated longitudinally and contracted laterally in response to the closing of mitral valve **30**. The elongation and narrowing of the diamond-shaped cells **902** near or at the tapered waist bottom of the hourglass-shaped closed mitral valve **30** avoids the overlapping of cells **902**.

[0296] It is understood that cells **902** may have other suitable shapes that could provide the
25 elongation and narrowing of cells similar to the diamond shaped cells discussed herein. Other suitable shapes, e.g., other types of polygons such as triangles, quadrilaterals other than diamonds, pentagons, hexagons, etc. For example, in the FIG. 4A-H embodiment, cells **102** of sections **122**, **132** have a square shape.

[0297] Apparatus **900** is delivered and positioned within the heart using the same methods
30 as described in respect of apparatus **100** elsewhere here.

Interpretation of Terms

[0298] Unless the context clearly requires otherwise, throughout the description and the claims:

• “comprise”, “comprising”, and the like are to be construed in an inclusive sense, as opposed to an exclusive or exhaustive sense; that is to say, in the sense of

5 “including, but not limited to”;

• “connected”, “coupled”, or any variant thereof, means any connection or coupling, either direct or indirect, between two or more elements; the coupling or connection between the elements can be physical, logical, or a combination thereof; elements which are integrally formed may be considered to be connected or coupled;

10 • “herein”, “above”, “below”, and words of similar import, when used to describe this specification, shall refer to this specification as a whole, and not to any particular portions of this specification;

• “or”, in reference to a list of two or more items, covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and

15 any combination of the items in the list;

• the singular forms “a”, “an”, and “the” also include the meaning of any appropriate plural forms.

[0299] Words that indicate directions such as “vertical”, “transverse”, “horizontal”, “upward”, “downward”, “forward”, “backward”, “inward”, “outward”, “vertical”, “transverse”, “left”, “right”,

20 “front”, “back”, “top”, “bottom”, “below”, “above”, “under”, and the like, used in this description and any accompanying claims (where present), depend on the specific orientation of the apparatus described and illustrated. The subject matter described herein may assume various alternative orientations. Accordingly, these directional terms are not strictly defined and should not be interpreted narrowly.

[0300] Specific examples of systems, methods and apparatus have been described herein for purposes of illustration. These are only examples. The technology provided herein can be applied to systems other than the example systems described above. Many alterations, modifications, additions, omissions, and permutations are possible within the practice of this invention. This invention includes variations on described embodiments that would be

30 apparent to the skilled addressee, including variations obtained by: replacing features,

elements and/or acts with equivalent features, elements and/or acts; mixing and matching of features, elements and/or acts from different embodiments; combining features, elements and/or acts from embodiments as described herein with features, elements and/or acts of other technology; and/or omitting combining features, elements and/or acts from described
5 embodiments.

[0301] It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions, omissions, and sub-combinations as may reasonably be inferred. The scope of the claims should not be limited by the preferred embodiments set forth in the examples, but should be
10 given the broadest interpretation consistent with the description as a whole.

[0302] While a number of exemplary aspects and embodiments are discussed herein, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof.

[0303] While a number of exemplary aspects and embodiments have been discussed
15 above, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are interpreted to include all such modifications, permutations, additions and sub-combinations as are within their true spirit and scope.

CLAIMS:

1. An apparatus for repairing a heart valve, the apparatus comprising:
 - a body;
 - 5 a member attached to the body at a first end and having a plurality of positioning cords spaced laterally across the member and extending away from a second end of the member opposed to the first end;
 - a tube suspended from the plurality of positioning cords, wherein the plurality of positioning cords is spaced laterally across the tube; and
 - 10 an adjustment cord extending through the tube, wherein the tube may be lengthened or shortened by tensioning the adjustment cord.
2. An apparatus according to claim 1, wherein tensioning the adjustment cord lengthens or shortens the tube consequently displacing the tube towards or away from the body causing corresponding displacement of the member.
- 15 3. An apparatus according to claim 2, wherein the length of each positioning cord is selected to suspend the tube from the member in a parabolic or parabolic-like shape.
4. An apparatus according to claim 3, wherein lengthening the tube consequently displaces a vertex of the parabolic or parabolic-like shaped tube towards the body.
5. An apparatus according to claim 3, wherein shortening the tube consequently
20 displaces a vertex of the parabolic or parabolic-like shaped tube away from the body.
6. An apparatus according to any one of claims 1 to 5, further comprising an encircling member connectable to the body for radially compressing and/or radially expanding the body.
7. An apparatus according to claim 6, wherein the body comprises a plurality of peaks
25 and a plurality of troughs, the peaks and troughs defined interchangeably along the diameter of the body.
8. An apparatus according to claim 7, wherein the body comprises a plurality of ring members, each ring member positioned on a corresponding peak.

9. An apparatus according to claim 8, wherein the encircling member passes through the plurality of ring members.
10. An apparatus according to any one of claims 1 to 9, wherein the body defines at least one anchoring site.
- 5 11. An apparatus according to any one of claims 1 to 10, wherein the body comprises a skirt.
12. An apparatus according to claim 11, wherein the skirt defines at least one anchoring site.
13. An apparatus according to any one of claims 1 to 12, wherein the apparatus is
10 configured to extend from an atrial wall and a mitral annulus to an anterior-lateral papillary muscle and a posterior-medial papillary muscle of the heart valve when the apparatus is implanted in the heart valve.
14. An apparatus according to any one of claims 1 to 13, wherein the member comprises an anterior member attached to an anterior end of the body.
- 15 15. An apparatus according to any one of claims 1 to 14, wherein the member comprises a posterior member attached to a posterior end of the body.
16. An apparatus according to claim 14, wherein the anterior member is configured to cover an anterior mitral leaflet of the heart valve when the apparatus is implanted in the heart valve.
- 20 17. An apparatus according to claim 15, wherein the posterior member is configured to cover a posterior mitral leaflet of the heart valve when the apparatus is implanted in the heart valve.
18. An apparatus according to any one of claims 1 to 17, wherein the member comprises a biocompatible, blood-permeable material that permits the passage of blood
25 therethrough.
19. An annular anchor comprising:
an anchor pin;
a tether connected to the anchor pin; and
a guidewire connected to the tether,
30 wherein the length of the guidewire is at least sufficient to traverse a patient's

circulatory system from a mitral annulus to an access site of the patient's circulatory system.

20. An annular anchor according to claim 19, wherein the anchor pin comprises a shape-memory material.
- 5 21. An annular anchor according to claim 20, wherein the anchor pin comprises a deformed configuration for advancing the anchor through a patient's circulatory system within a catheter.
22. An annular anchor according to claim 20 or 21, wherein the anchor pin comprises a pre-deformed configuration for anchoring the anchor in an annular tissue of a heart.
- 10 23. An annular anchor catheter comprising:
a catheter body; and
a sensor attached to the body for detecting contact between the catheter and an annular wall of a mitral annulus of a heart.
- 15 24. An annular anchor catheter according to claim 23, further comprising a needle housed within the catheter body and configured to retain an annular anchor.
25. A method for implanting an annular anchor, the method comprising:
advancing a catheter to an anchor site located at an annular wall of a mitral annulus of a heart;
detecting contact between the catheter and the anchor site;
20 advancing an annular anchor from the catheter and embedding the annular anchor in the mitral annulus.
26. A method for implanting an annular anchor according to claim 25, wherein advancing the annular anchor comprises advancing a needle housing the annular anchor through the annular wall and advancing the annular anchor from the needle to embed the
25 annular anchor in the mitral annulus.
27. A papillary anchor comprising:
an anchor pin;
at least one tether connected to the anchor pin; and
a guidewire connected to each tether,
30 wherein the length of each guidewire is at least sufficient to traverse a patient's

circulatory system from a papillary muscle to an access site of the patient's circulatory system.

28. A papillary anchor according to claim 27, wherein the anchor pin comprises a shape-memory material.
- 5 29. A papillary anchor according to claim 28, wherein the anchor pin comprises a deformed configuration for advancing the anchor through a patient's circulatory system within a catheter.
30. A papillary anchor according to claim 28 or 29, wherein the anchor pin comprises a pre-deformed configuration for securing the anchor through a papillary muscle of a heart.
- 10 31. A papillary anchor catheter comprising:
a body configured to house a papillary anchor;
an arm extending away from the body; and
a receiver connected to the arm for receiving the papillary anchor,
15 wherein the body, arm, and receiver define an opening configured to receive a papillary muscle.
32. A papillary anchor catheter according to claim 31, wherein the receiver is detachable from the arm.
33. A papillary anchor catheter according to claim 31 or 32, wherein the arm is retractable
20 inside the body.
34. A papillary anchor catheter according to any one of claims 31 to 33, wherein the body comprises a retaining pin extendable from the body to close the opening.
35. A papillary anchor catheter according to claim 34, wherein the retaining pin is retractable inside the body to open the opening.
- 25 36. A papillary anchor catheter according to claim 34 or 35, further comprising a controller for operating one or more of the retaining pin and the arm externally.
37. A method for implanting a papillary anchor, the method comprising:
advancing a papillary anchor catheter in a closed configuration through a patient's circulatory system to a papillary muscle;
30 opening the catheter to receive a papillary muscle;

- positioning the papillary muscle within the opening;
advancing the papillary anchor from the catheter through the papillary muscle;
receiving an anchor pin of the papillary anchor with a receiver of the catheter;
detaching the receiver from the catheter leaving the papillary anchor implanted
5 in the papillary muscle and secured to the papillary muscle with the receiver; and
withdrawing the catheter from the patient's circulatory.
38. A method according to claim 37, further comprising advancing the retaining pin at
least partially through the papillary muscle to stabilize the papillary muscle prior to
advancing the papillary anchor through the papillary muscle.
- 10 39. A method according to claim 38, further comprising retracting the retaining pin prior to
withdrawing the catheter from the patient's circulatory system.
- 40 A papillary anchor catheter comprising:
a body configured to house a papillary anchor; and
a deformable arm extending away from the body.
- 15 41. A papillary anchor catheter according to claim 40, wherein the body comprises a
needle for housing the papillary anchor and advancing the papillary anchor through a
papillary muscle.
42. A papillary anchor catheter according to claim 40 or 41, wherein the arm comprises a
tensioning wire extending lengthwise through the arm for deforming the arm in a
20 deformed configuration and an extended configuration by applying tension to the wire.
43. A papillary anchor catheter according to claim 42, wherein the arm comprises a
plurality of modular pieces arranged linearly, wherein the tensioning wire extends
through the pieces to deform the arm by applying tension to the tensioning wire.
44. A papillary anchor catheter according to claim 41, further comprising a controller for
25 operating one or more of the needle and the tensioning wire externally.
45. A method for implanting a papillary anchor, the method comprising:
advancing a papillary anchor catheter in an extended configuration through a
patient's circulatory system to a papillary muscle;
deforming the catheter into a deformed configuration to at least partially encircle
30 a papillary muscle;

advancing the papillary anchor from the catheter through the papillary muscle;
extending the catheter into the extended configuration; and
withdrawing the catheter from the patient's circulatory system in the extended
configuration.

- 5 46. A papillary anchor catheter comprising:
a body;
a deformable arm extending from the body; and
an anchor housing extending through the body and the arm, wherein the anchor
housing is configured to house a papillary anchor.
- 10 47. A papillary anchor catheter according to claim 46, further comprising a guidewire
extending through the body and alongside the arm, wherein the guidewire is
extendable and retractable from the body.
48. A papillary anchor catheter according to claim 47, wherein a length of the guidewire is
sufficient to traverse a patient's circulatory system from a papillary muscle to an
15 access site to the patient's circulatory system.
49. A papillary anchor catheter according to claim 47 or 48, wherein the arm comprises at
least one deformable section.
50. A papillary anchor catheter according to claim 49, wherein the arm comprises a first
deformable section deformable in a first plane and a second deformable section
20 deformable in a second plane.
51. A papillary anchor catheter according to claim 50, wherein the first deformable section
is deformable in a first direction by about 0° to about 120° in the first plane.
52. A papillary anchor catheter according to claim 50 or 51, wherein the second
deformable section is deformable in a second direction by about 0° to about 90° in the
25 second plane and in a third direction by about 0° to about -90° in the second plane.
53. A papillary anchor catheter according to any one of claims 50 to 52, wherein the first
direction and the second direction are non-coplanar.

54. A papillary anchor catheter according to claim 50, further comprising a controller for operating one or more of the guidewire, the first deformable section, and the second deformable section externally.
55. A method for implanting a papillary anchor, the method comprising:
- 5 advancing a papillary anchor catheter in an extended configuration through a patient's circulatory system to a papillary muscle;
- deforming the catheter in a first direction into a deflected configuration;
- advancing a guidewire to at least partially encircle a papillary muscle;
- deforming the catheter in a second direction into a deformed configuration;
- 10 advancing the catheter along the guidewire to at least partially encircle the papillary muscle with the catheter;
- advancing the papillary anchor from the catheter through the papillary muscle;
- and
- withdrawing the catheter from the patient's circulatory system in the extended
- 15 configuration.
56. A method according to claim 55, wherein advancing the papillary anchor through the papillary muscle comprises advancing the papillary anchor through a transverse dimension of the papillary muscle from an entrance site of the papillary muscle to an exit site of the papillary muscle.
- 20 57. A method according to claim 56, wherein advancing the papillary anchor through the papillary muscle further comprises receiving an anchor tip of the papillary anchor with a receiver of the catheter adjacent to the exit site.
58. A method according to any one of claims 55 to 57, wherein withdrawing the catheter comprises extending the catheter into the extended configuration.
- 25 59. A method of repairing a heart valve, the method comprising:
- implanting at least one annular anchor in a mitral annulus of the heart valve;
- implanting a papillary anchor through each papillary muscle of the heart;
- delivering and positioning an apparatus for repairing a heart valve inside the heart valve using the at least one annular anchor and the papillary anchors; and
- 30 adjusting the apparatus to adjust the extent of atrial displacement of the heart's mitral leaflets during ventricular contraction.

60. A method according to claim 59, wherein implanting the at least one annular anchor comprises the method according to claims 25 or 26.
61. A method according to claim 59 or 60, wherein implanting the papillary anchors comprises the method according to any one of claims 37 to 39 and 55 to 58.
- 5 62. A method according to any one of claims 58 to 61, wherein delivering the apparatus comprises externally connecting one or more guidewires of each annular anchor and one or more guidewires of each papillary anchor to the apparatus and advancing the apparatus along the guidewires to the heart valve.
- 10 63. A method according to claim 62, wherein delivering the apparatus further comprises externally advancing the one or more guidewires of each annular anchor through a body of the apparatus and advancing the body of the apparatus to an atrial wall of the mitral annulus of the heart valve.
- 15 64. A method according to any one of claims 58 to 63, wherein delivering the apparatus comprises externally advancing the one or more guidewires of each papillary anchor through at least one compressible tube of the apparatus and advancing the at least one tube to extend between the papillary muscles of the heart valve in a parabolic or parabolic-like shaped configuration.
- 20 65. A method according to claim 64, wherein positioning the apparatus inside the heart valve comprises adjusting the length of the at least one tube to position the apparatus to cover an atrial surface of at least one mitral leaflet of the heart valve.
- 25 66. A method according to claim 65, wherein positioning the apparatus inside the heart valve further comprises adjusting the length of the at least one tube to adjust the position of at least one blood-permeable member of the apparatus to adjust the extent of atrial displacement of the at least one mitral leaflet during ventricular contraction.
67. A method according to any one of claims 59 to 63, wherein delivering the apparatus comprises externally advancing a first guidewire of each papillary anchor through a first compressible tube of the apparatus and advancing a second guidewire of each papillary anchor through a second compressible tube of the apparatus and advancing the first and second tubes along the first and second guidewires to extend the first and

second tubes between the papillary muscles of the heart valve in a parabolic or parabolic-like shaped configuration.

- 5 68. A method according to claim 67, wherein positioning the apparatus inside the heart valve further comprises adjusting the length of the first tube to position an anterior member of the apparatus to cover an atrial surface of an anterior mitral leaflet of the heart valve.
- 10 69. A method according to claim 68, wherein positioning the apparatus inside the heart valve further comprises adjusting the length of the first tube to adjust the position of the anterior member to adjust the extent of atrial displacement of the anterior mitral leaflet during ventricular contraction.
70. A method according to any one of claims 67 to 69, wherein positioning the apparatus inside the heart valve further comprises adjusting the length of the second tube to position a posterior member of the apparatus to cover an atrial surface of a posterior mitral leaflet of the heart valve.
- 15 71. A method according to claim 70, wherein positioning the apparatus inside the heart valve comprises adjusting the length of the second tube to adjust the position of the posterior member to adjust the extent of atrial displacement of the posterior mitral leaflet during ventricular contraction.
- 20 72. A method according to any one of claims 59 to 71, further comprising securing the apparatus to an atrial wall of the heart valve.
73. A method according to any one of claims 59 to 72, further comprising securing the apparatus to each papillary muscle of the heart valve.
- 25 74. A method according to claim 72, wherein securing the apparatus to the atrial wall comprises advancing a lock in an open configuration to an anchor site of the apparatus and positioning the lock in a locked configuration adjacent the atrial wall at each anchor site.
- 30 75. A method according to claim 73, wherein securing the apparatus to the papillary muscles comprises advancing a lock in an open configuration along each papillary anchor and positioning the lock in a locked configuration adjacent the papillary muscle.

76. A lock comprising a body defining opposed jaws and a channel extending lengthwise through the body and between the jaws, wherein the lock is deformable in an open configuration by deflecting the jaws away from each other.
- 5 77. A lock according to claim 76, wherein the jaws define a recess shaped concentrically about the channel and configured to receive a collar for retaining the lock in a locked configuration.
78. A lock according to claim 77, wherein the collar comprises at least one notch configured to engage a lock catheter.
- 10 79. A lock according to claim 78, wherein the body defines a groove shaped concentrically about the channel and configured to engage the lock catheter.
80. A lock according to any one of claims 76 to 79, wherein each jaw comprises a set of teeth.
81. A lock catheter comprising:
a sleeve tube;
15 a lock tube; and
a deploying tube,
wherein the sleeve tube houses the lock tube and the lock tube houses the deploying tube.
- 20 82. A lock catheter according to claim 81, further comprising a needle extending through a channel defined by the deploying tube.
83. A lock catheter according to claim 81 or 82, wherein the sleeve tube defines a notch for engaging a lock.
- 25 84. A method for securing an apparatus inside a heart valve, the method comprising:
advancing a lock in an open configuration along a guidewire to a lock site; and
advancing a collar along the lock at the lock site to lock the lock in a closed configuration.
85. An apparatus according to claim 1, wherein the member comprises a net-like structure, the net-like structure being defined by a plurality of cells, the plurality of cells extend radially and longitudinally from the body to the positioning cords.

86. An apparatus according to claim 85, wherein the plurality of cells has a diamond shape.
87. An apparatus according to claim 85, wherein the plurality of cells has a square or rectangular shape.
- 5 88. An apparatus according to claim 86, wherein the diamond-shaped cells are contractable between a relaxed position and an elongated position.
89. An apparatus according to claim 88, wherein the diamond-shaped cells are uniform in shape and size in the relaxed position.
- 10 90. An apparatus according to claim 89, wherein the diamond-shaped cells are heterogeneous in shape and size in the elongated position.
91. An apparatus according to claim 90, wherein the diamond-shaped cells each comprises a first diagonal length extending between longitudinally opposing vertices, and a second diagonal length extending between laterally opposing vertices, the diamond-shaped cells positioned near the body have greater first longitudinal lengths than the diamond-shaped cells positioned near the positioning cords.
- 15 92. An apparatus according to claim 91, wherein the diamond-shaped cells positioned near the positioning cords have greater second longitudinal lengths than the diamond-shaped cells positioned near the body.

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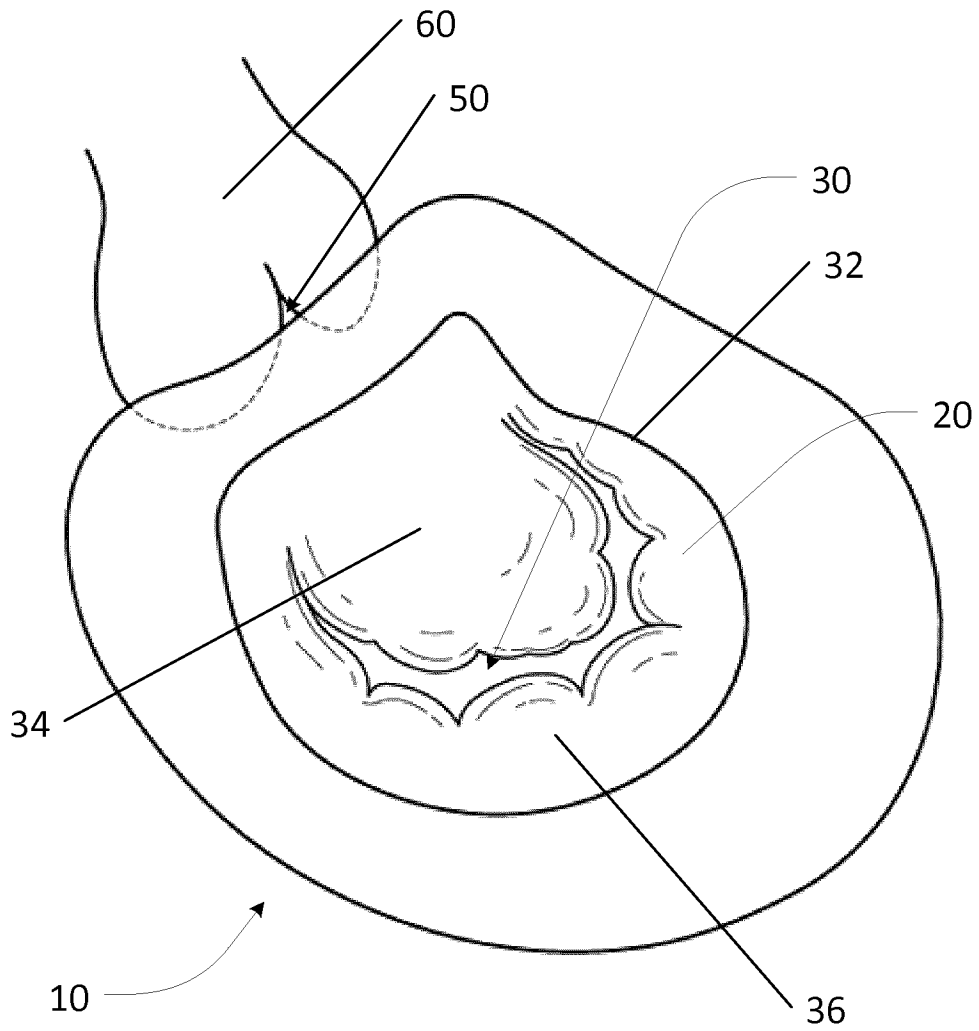


FIG. 1

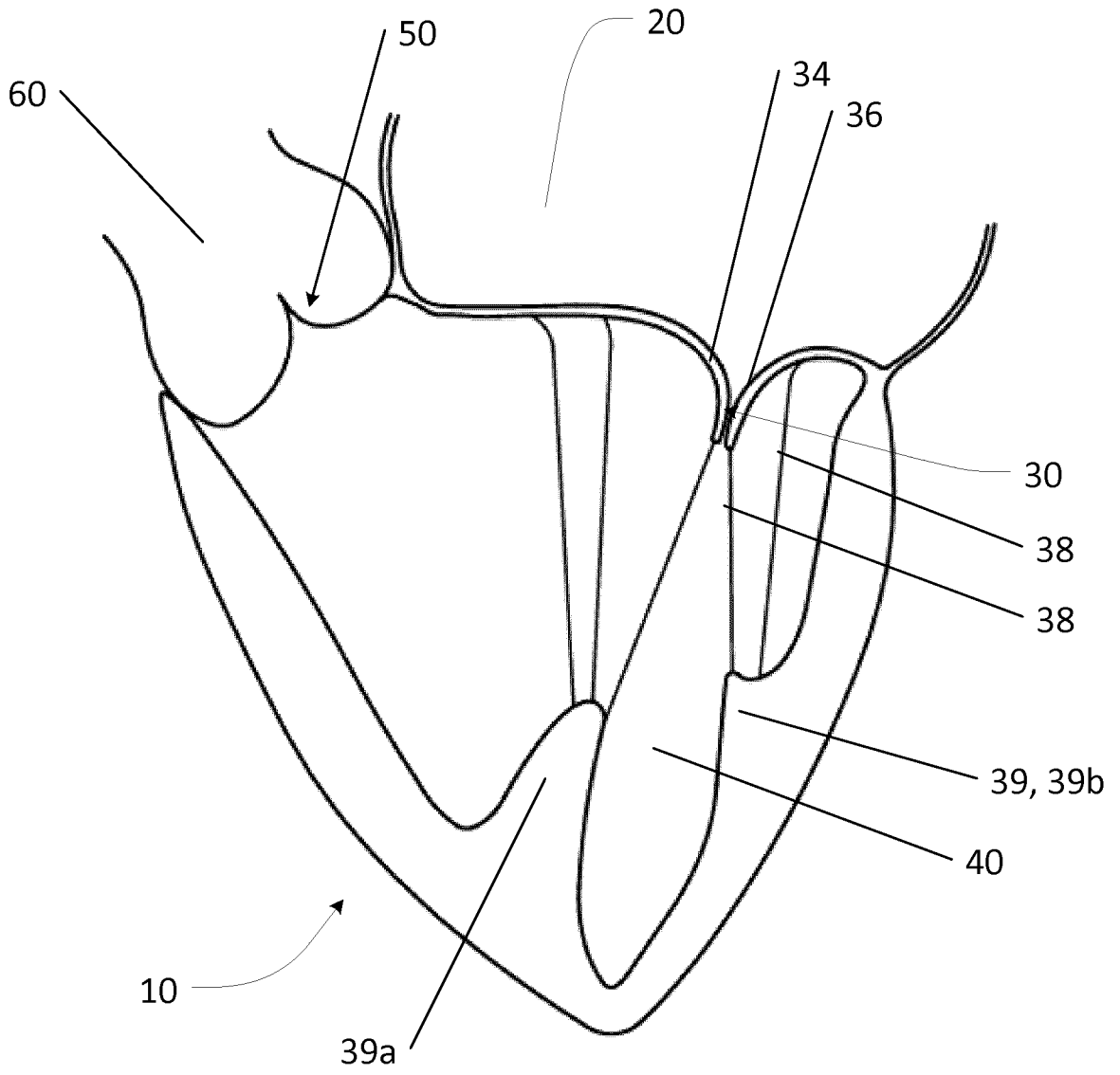


FIG. 2

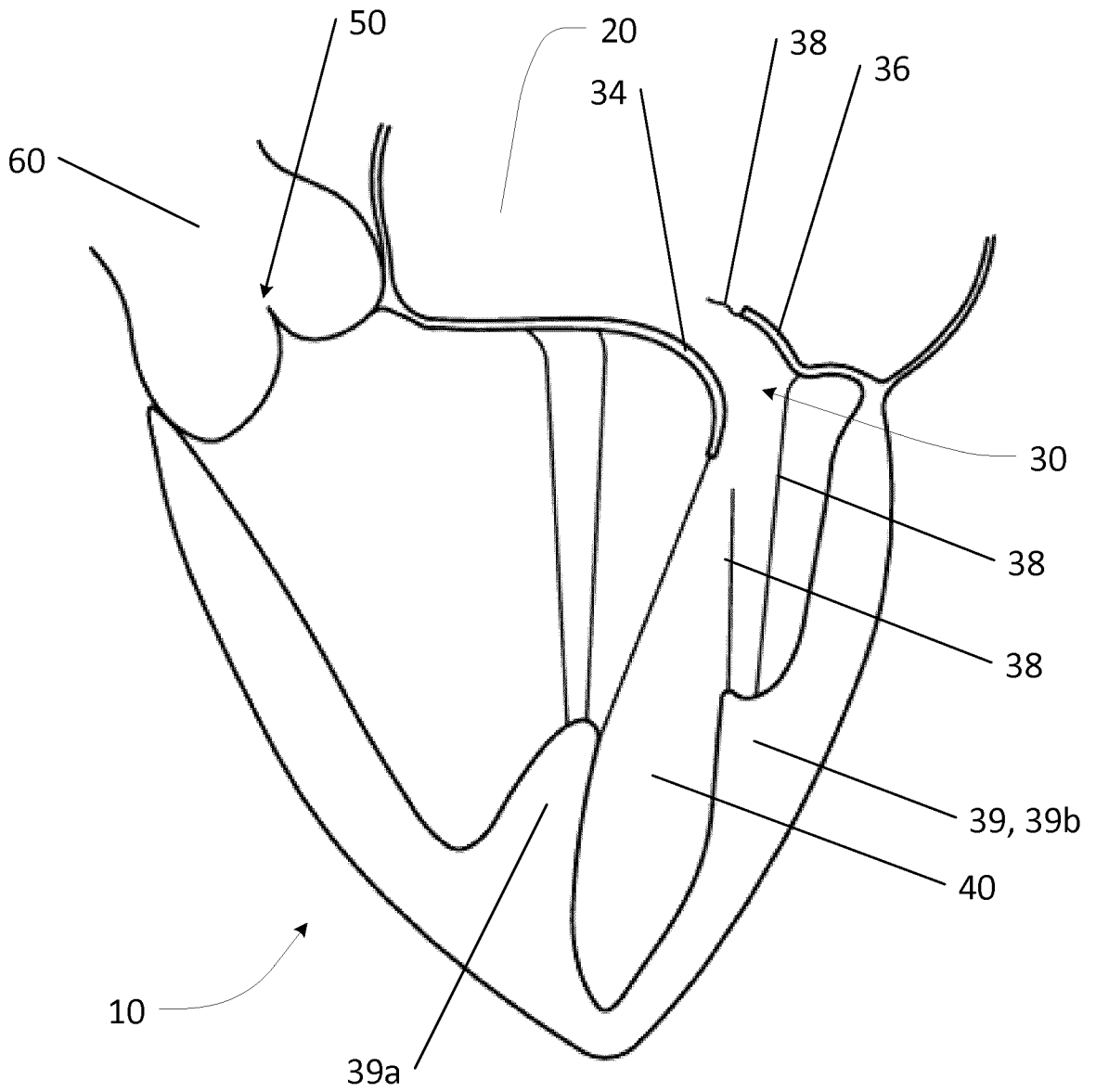


FIG. 3

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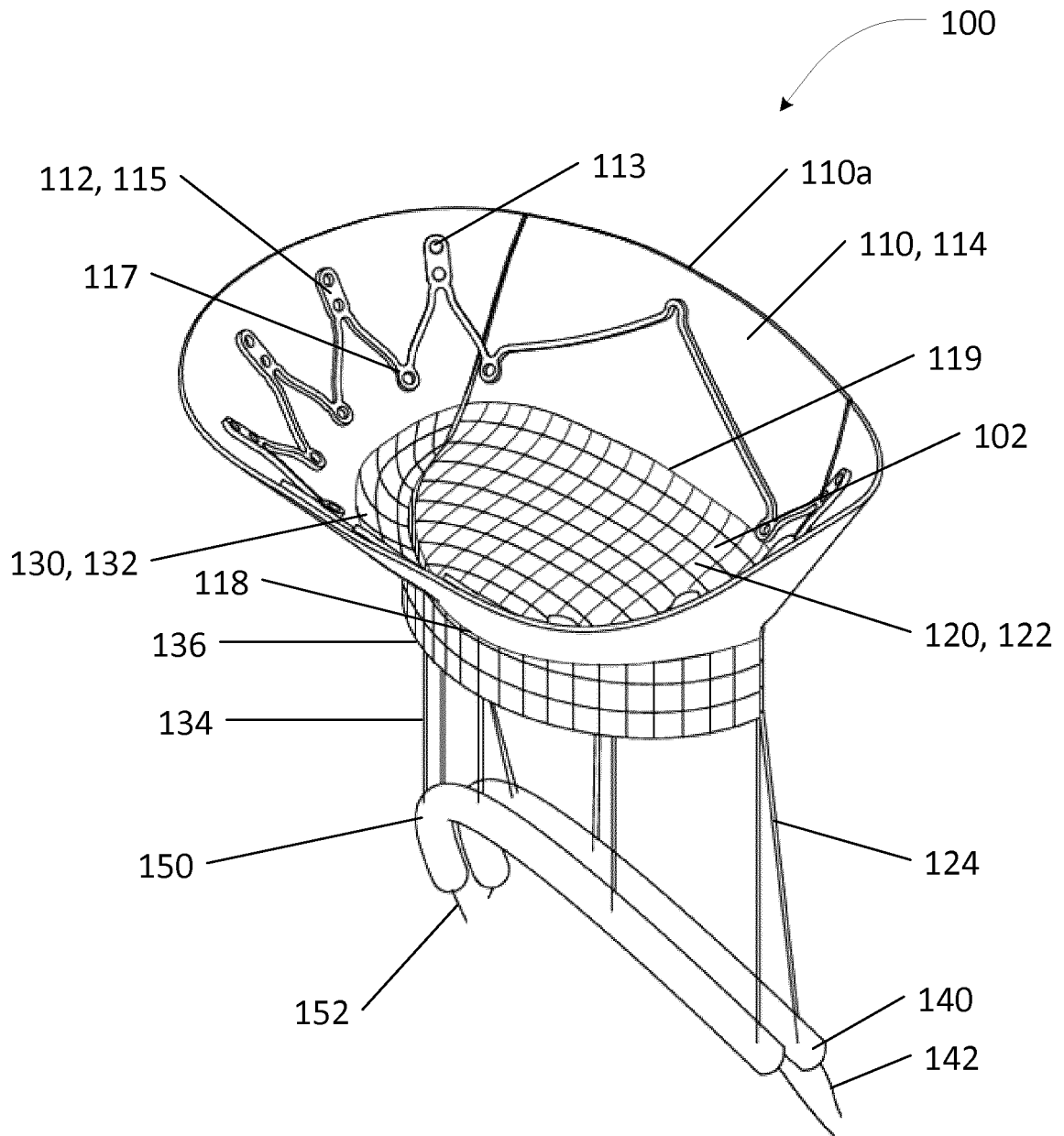


FIG. 4A

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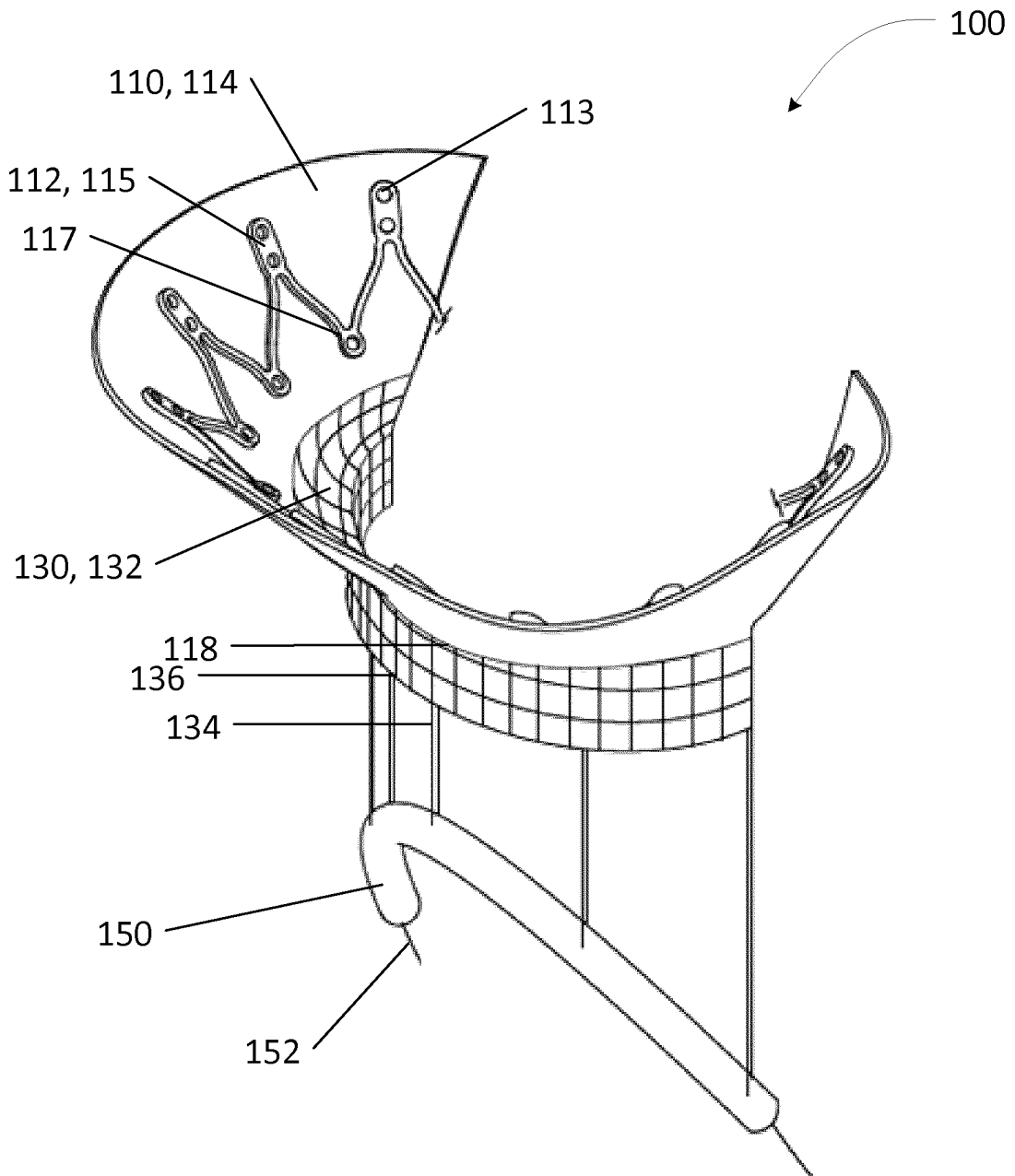


FIG. 4B

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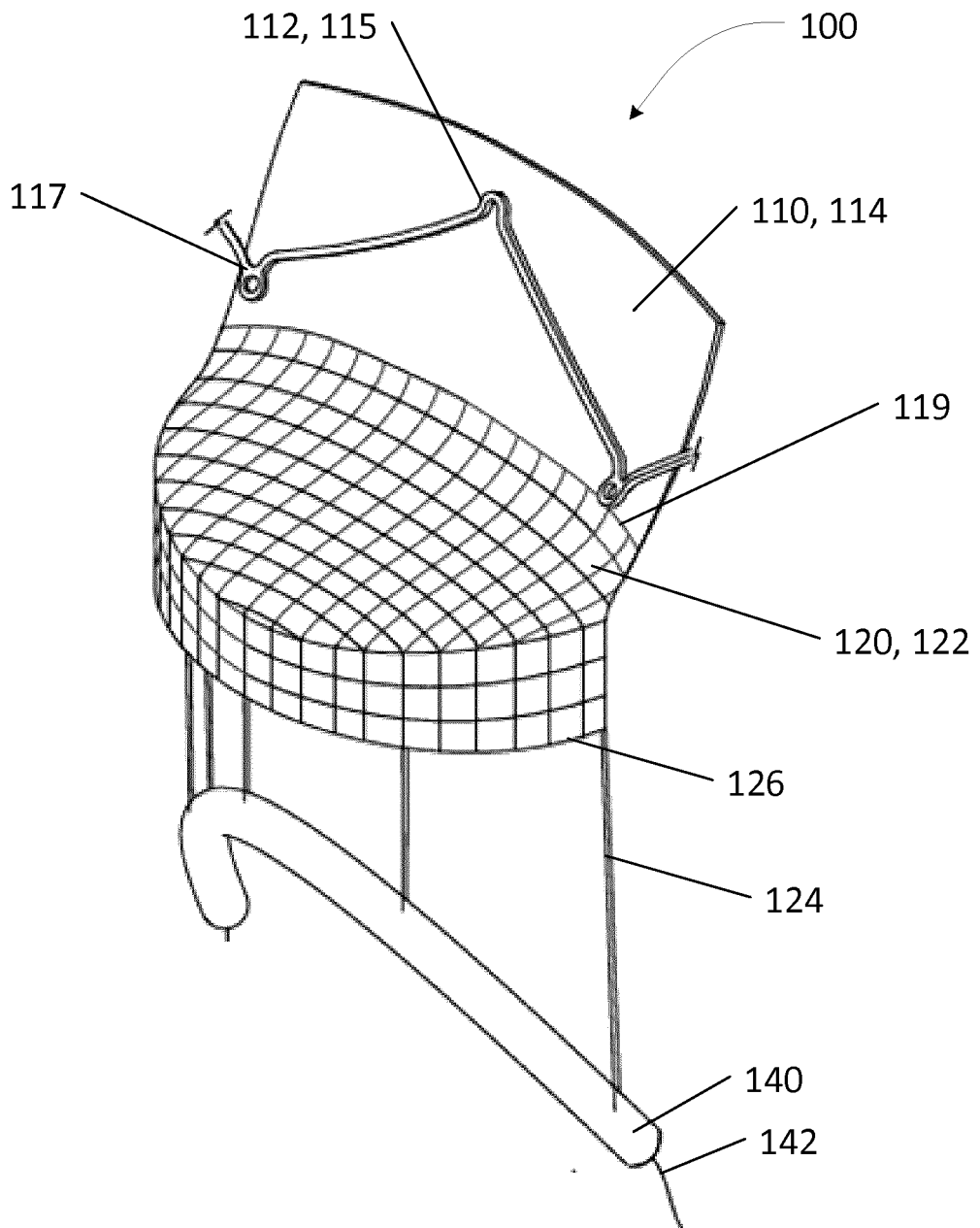


FIG. 4C

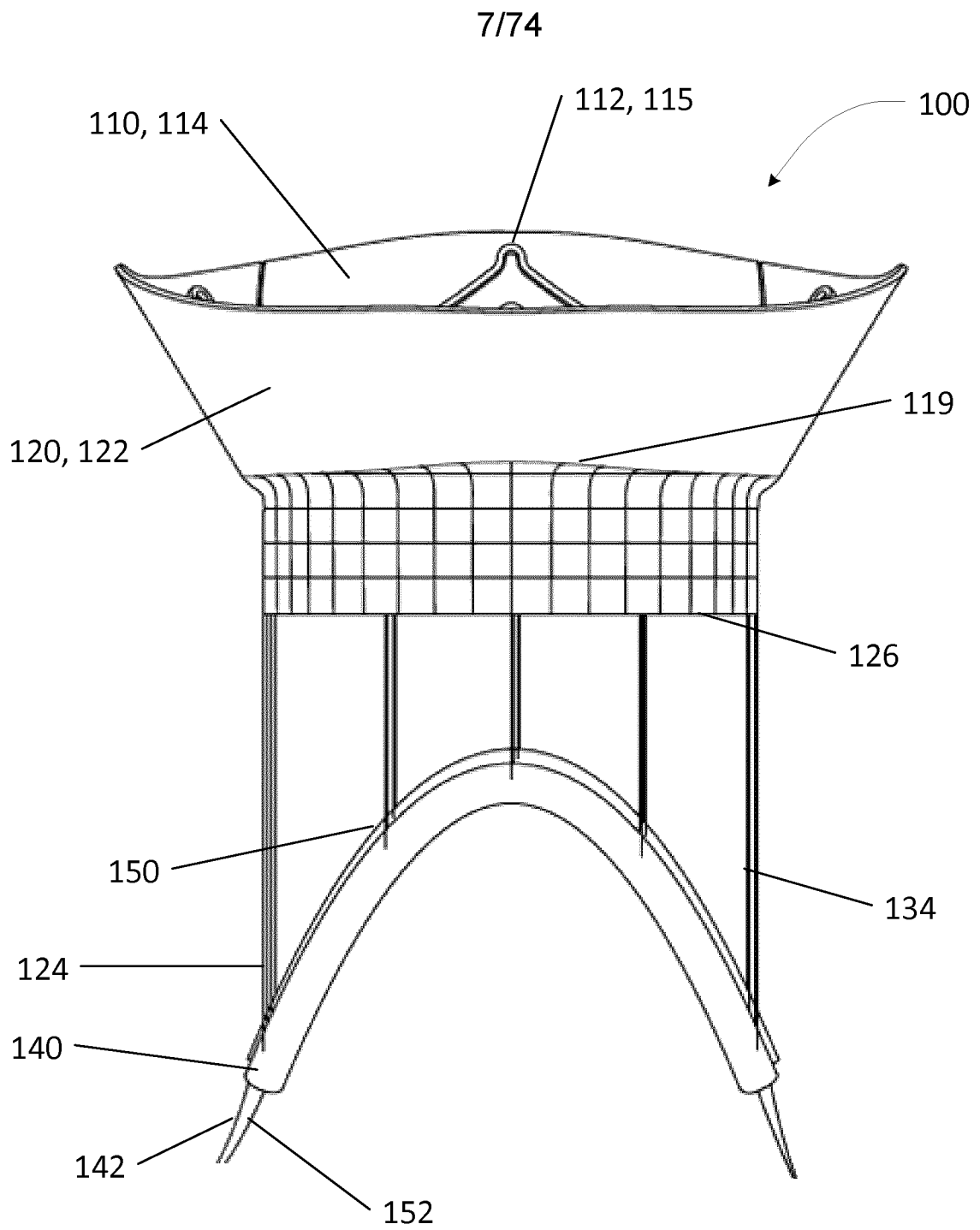


FIG. 4D

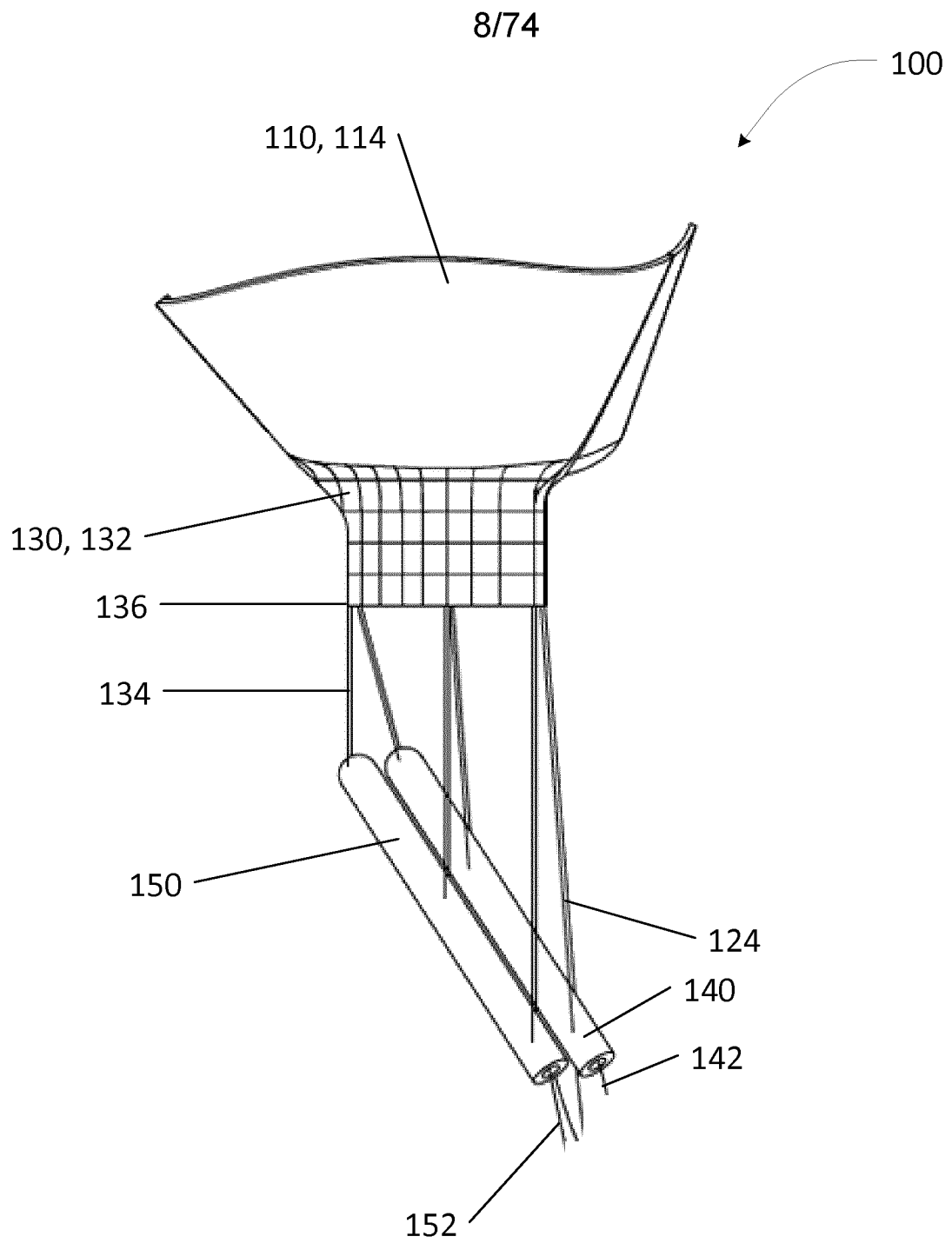


FIG. 4E

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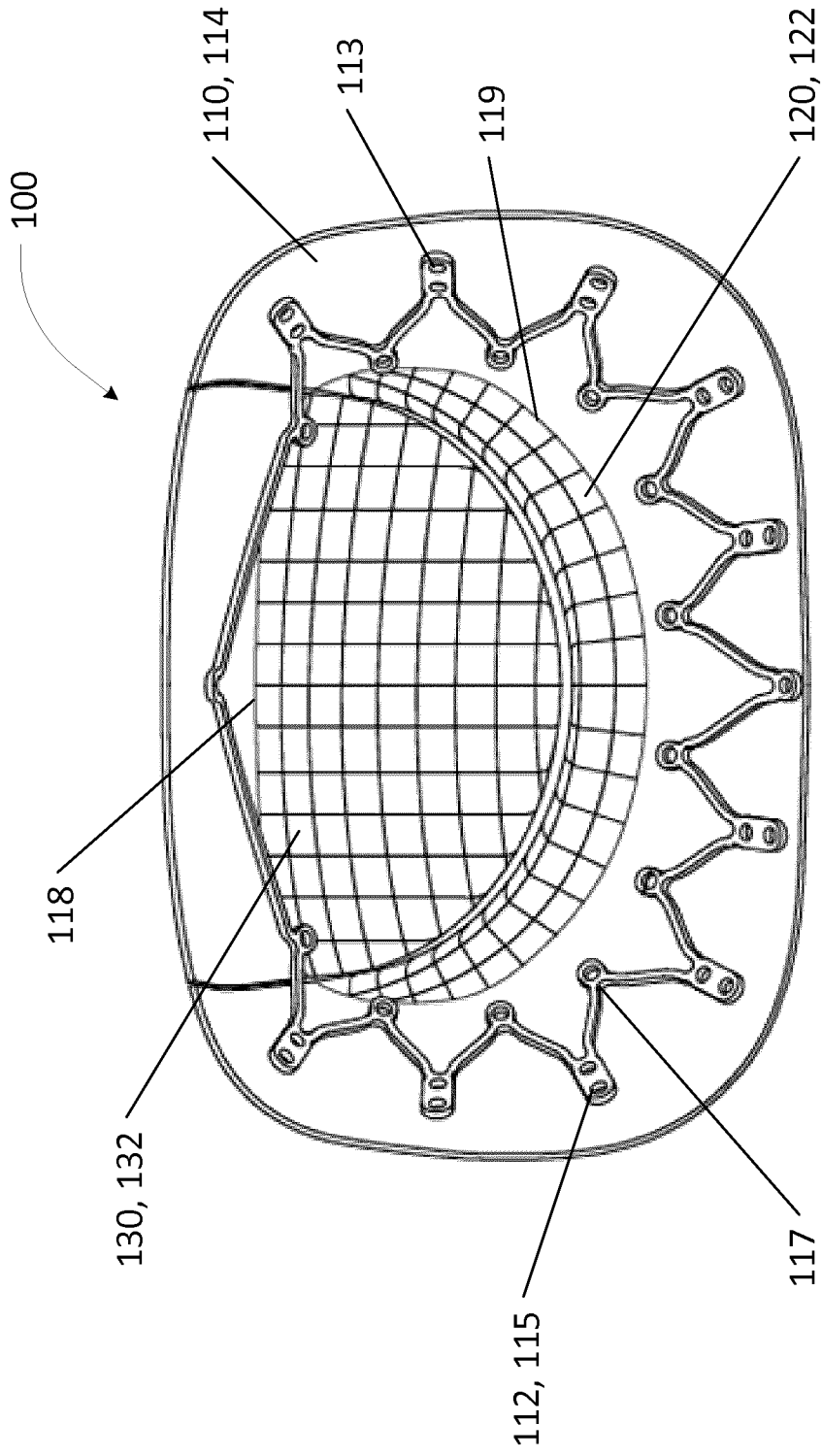


FIG. 4F

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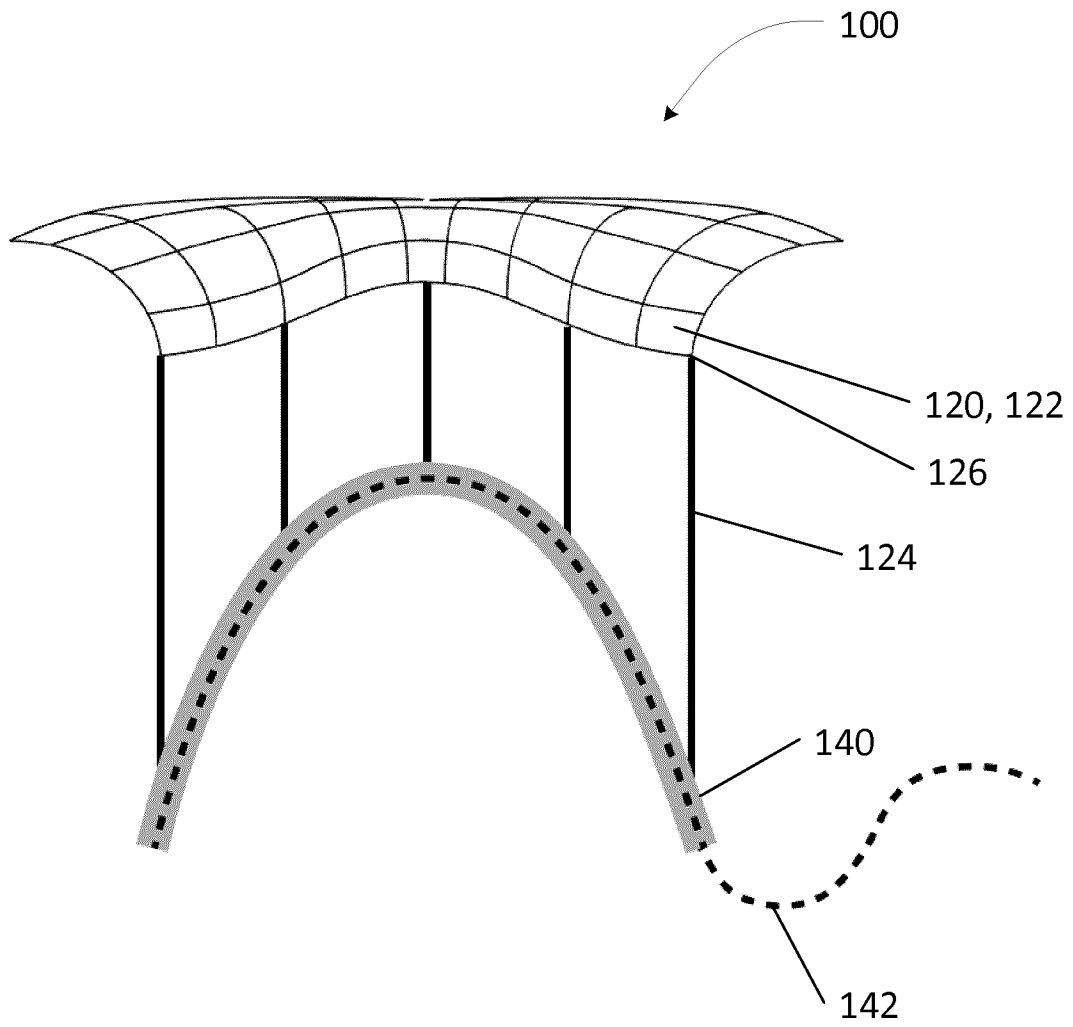


FIG. 4G

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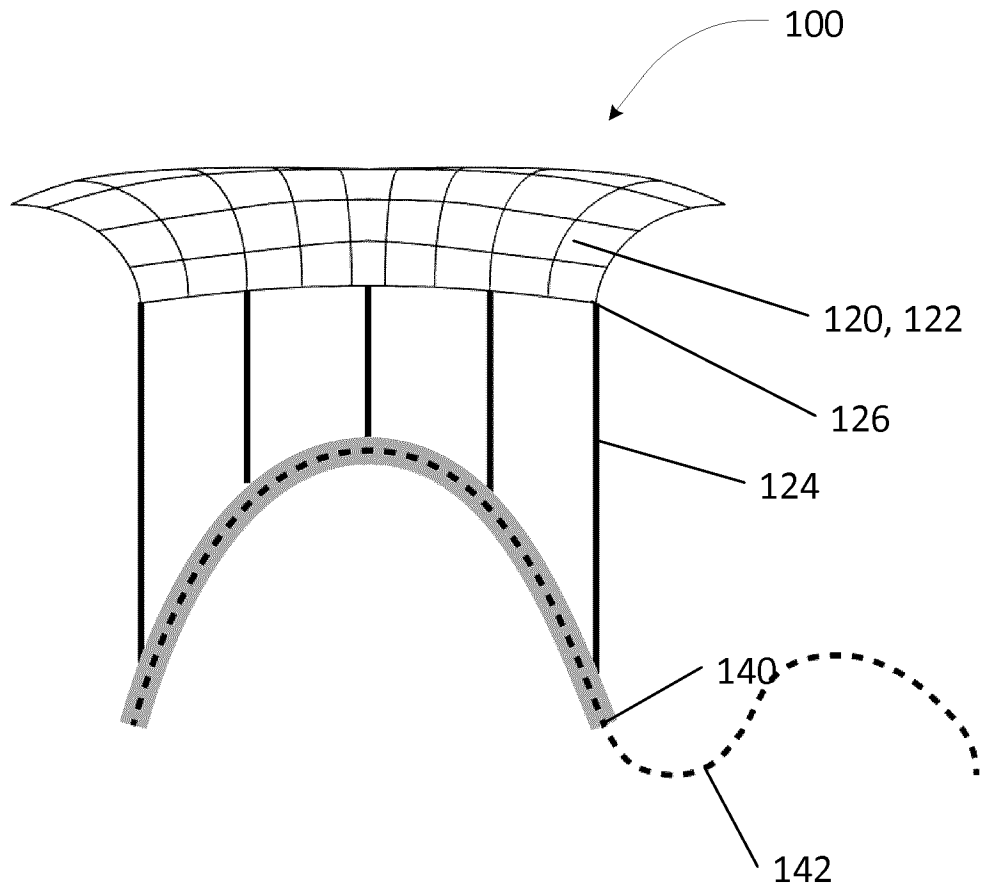


FIG. 4H

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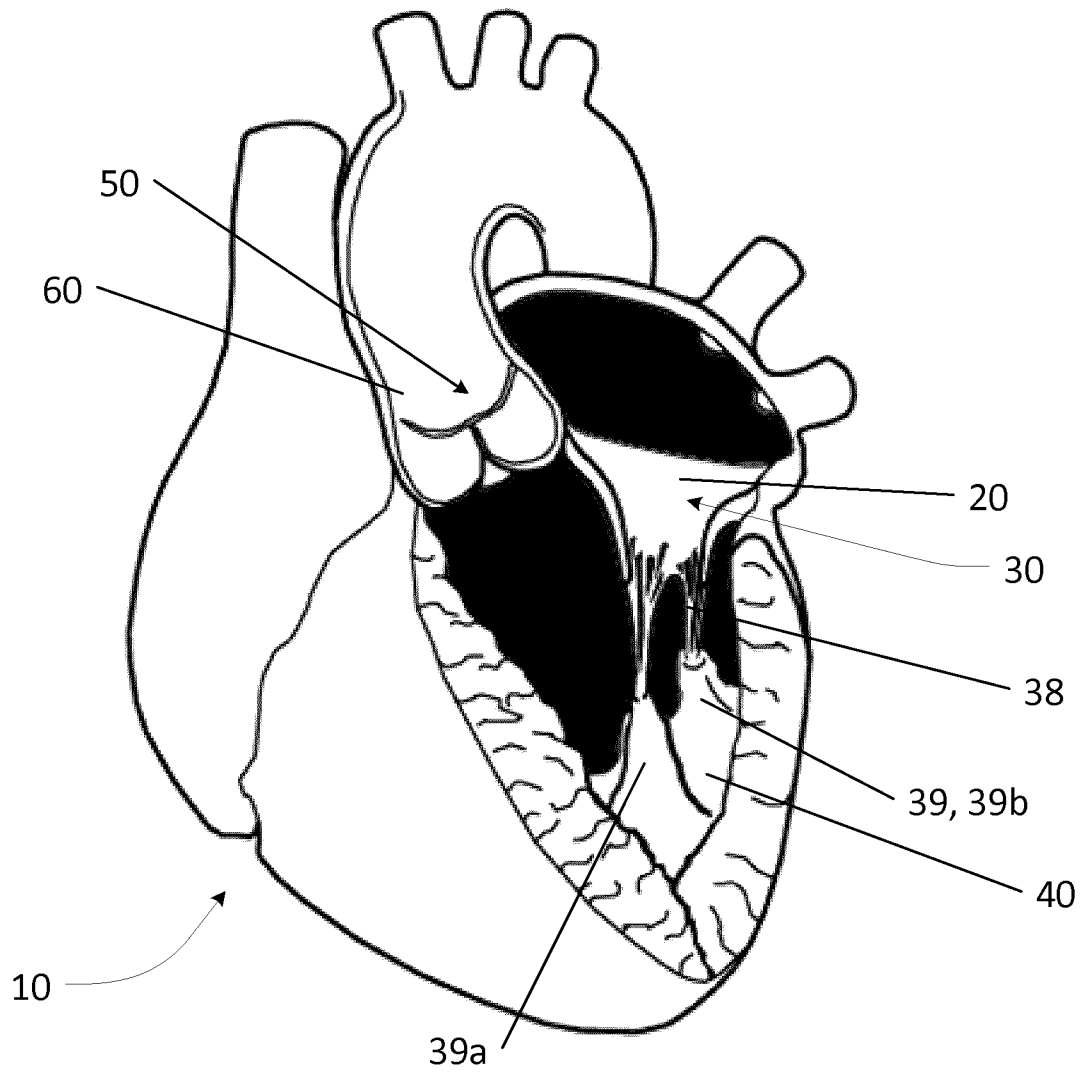


FIG. 5A

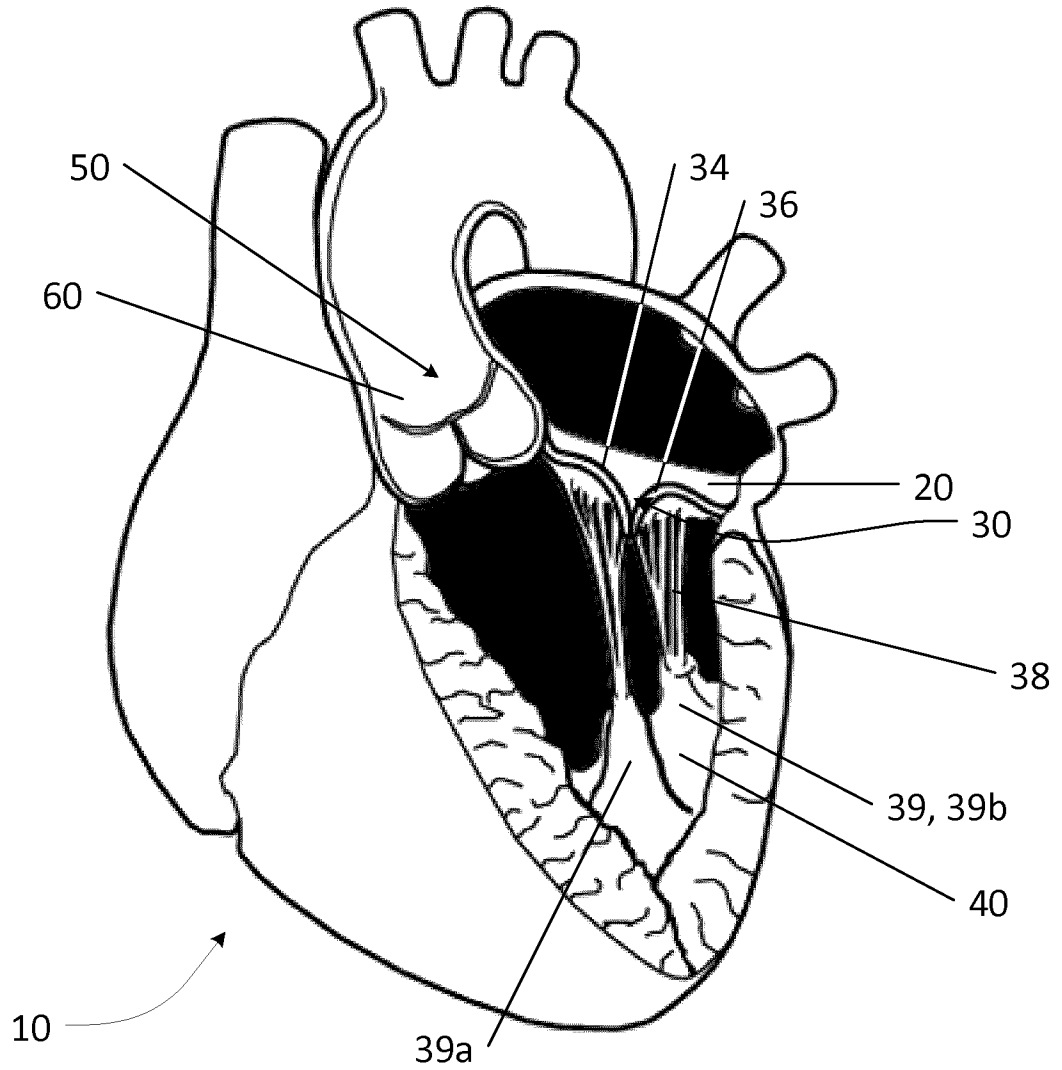


FIG. 5B

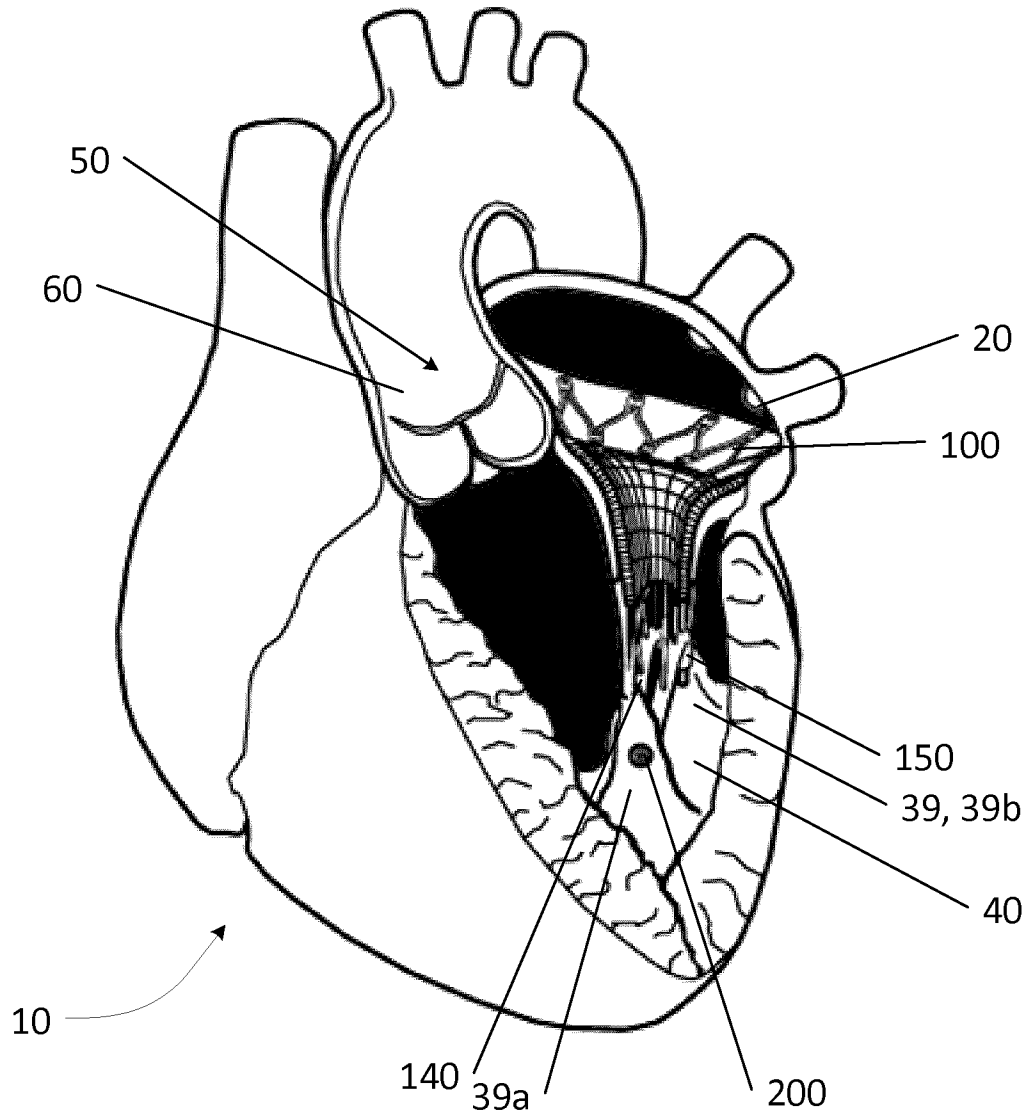


FIG. 5C

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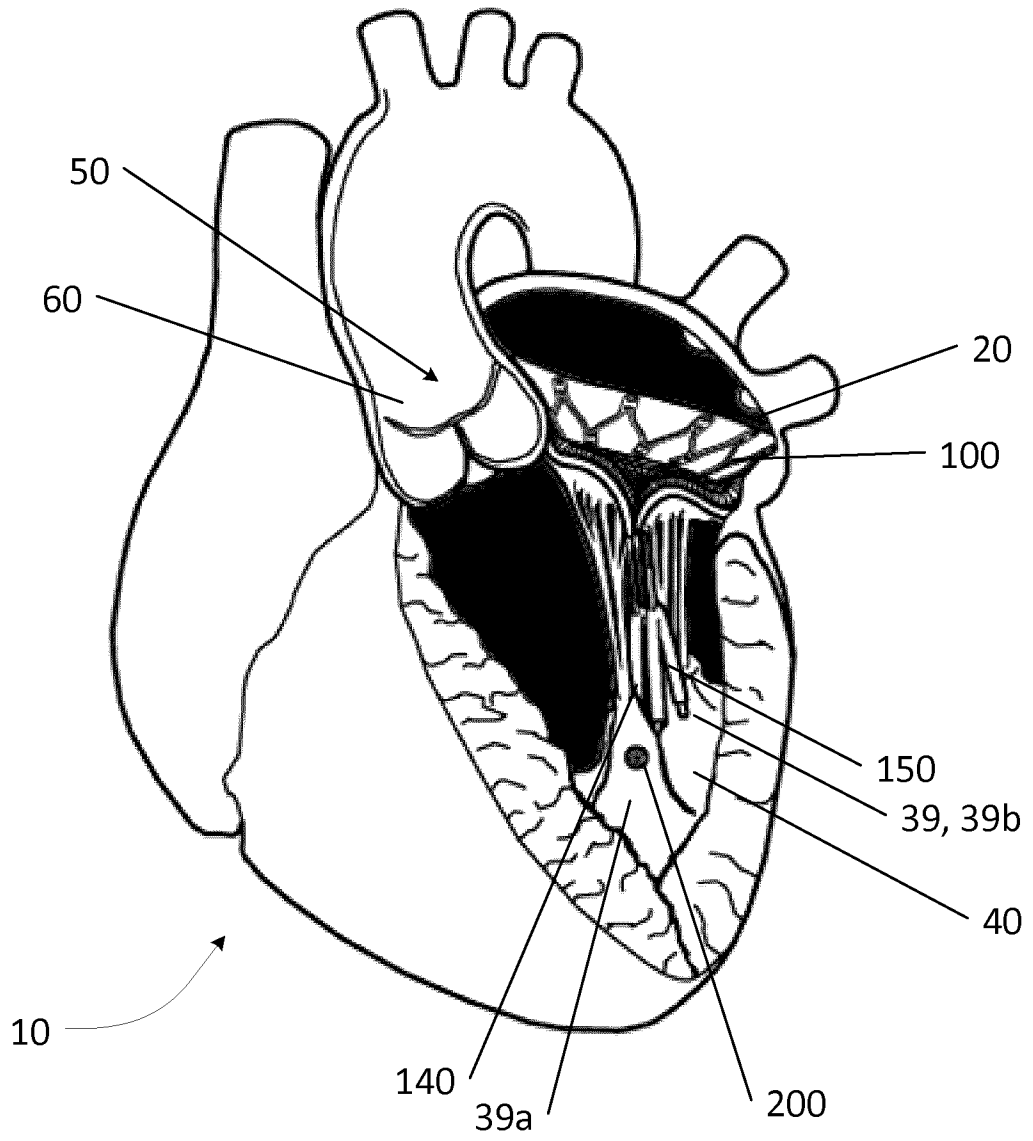


FIG. 5D

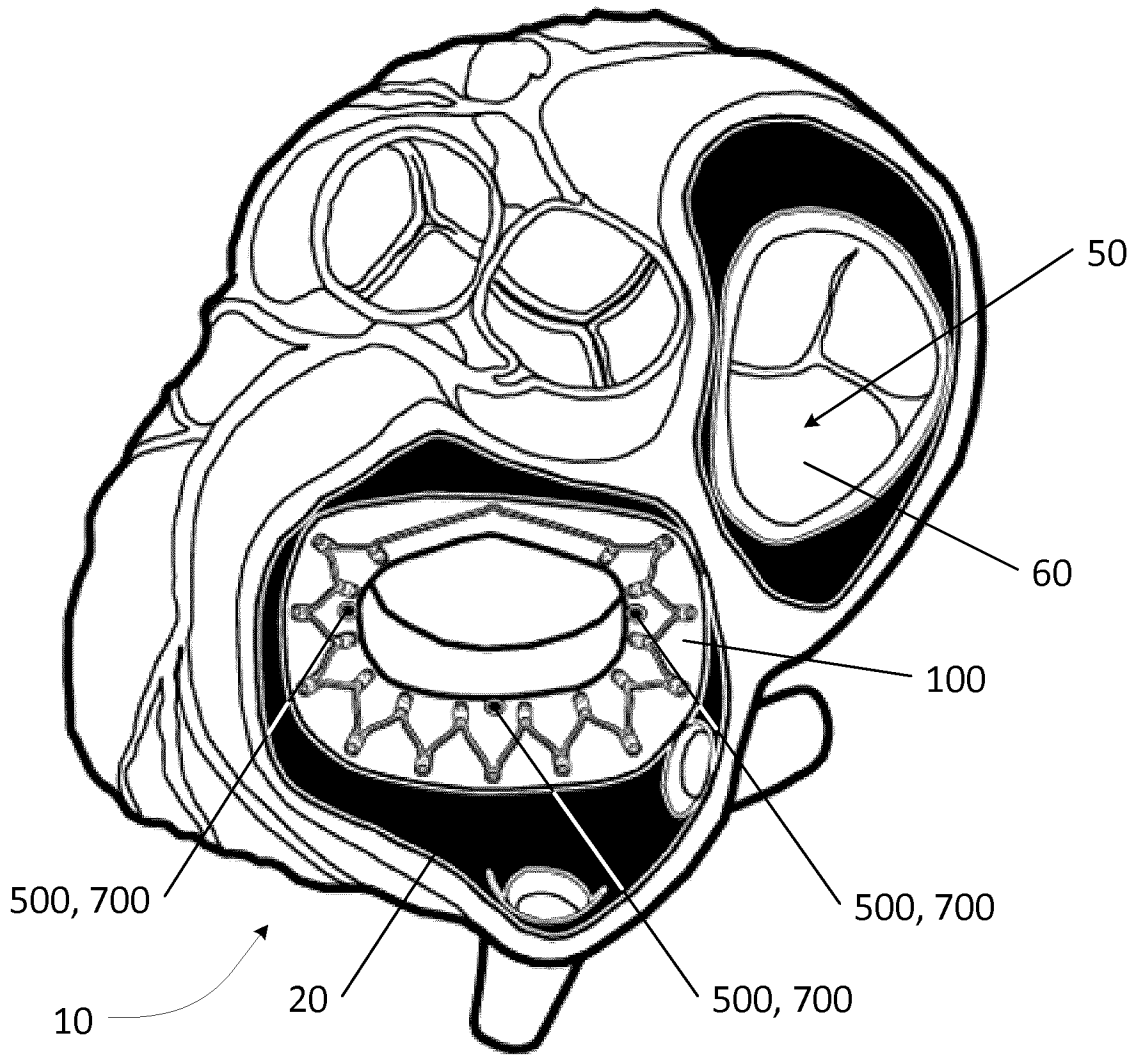


FIG. 5E

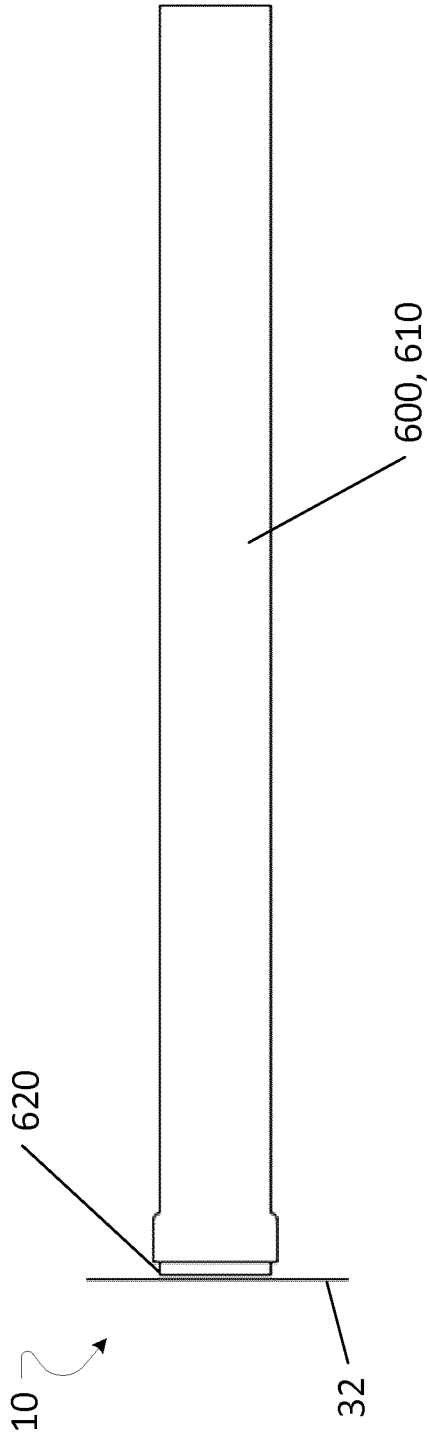


FIG. 6A

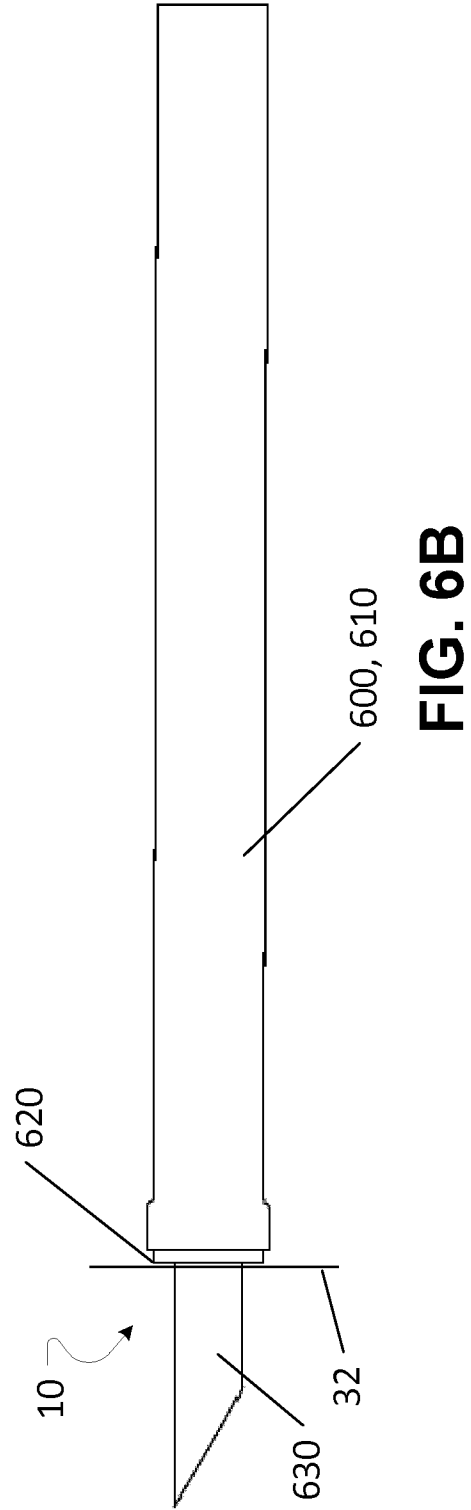


FIG. 6B

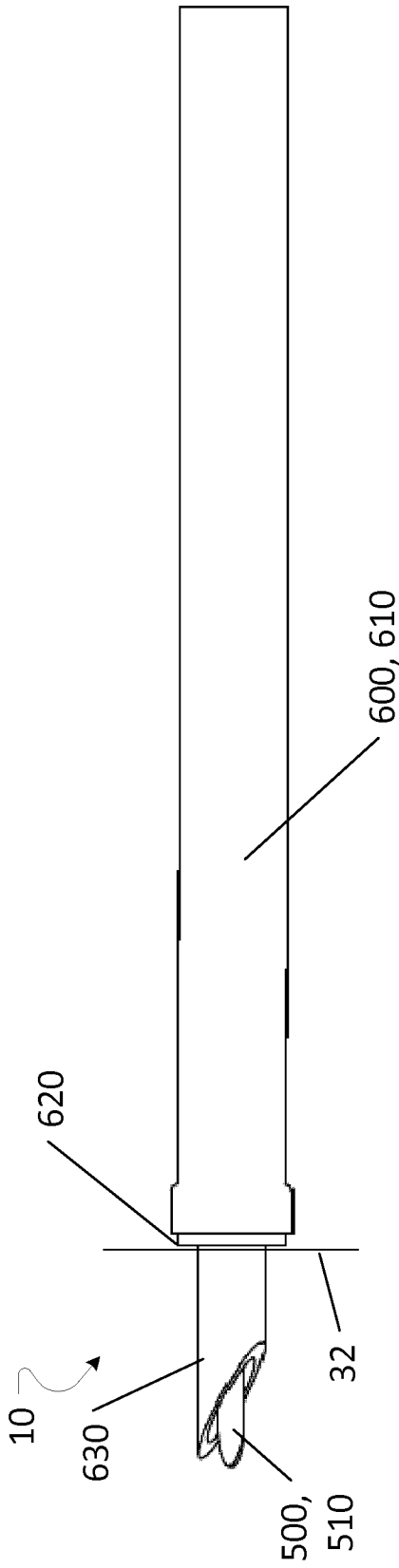


FIG. 6C

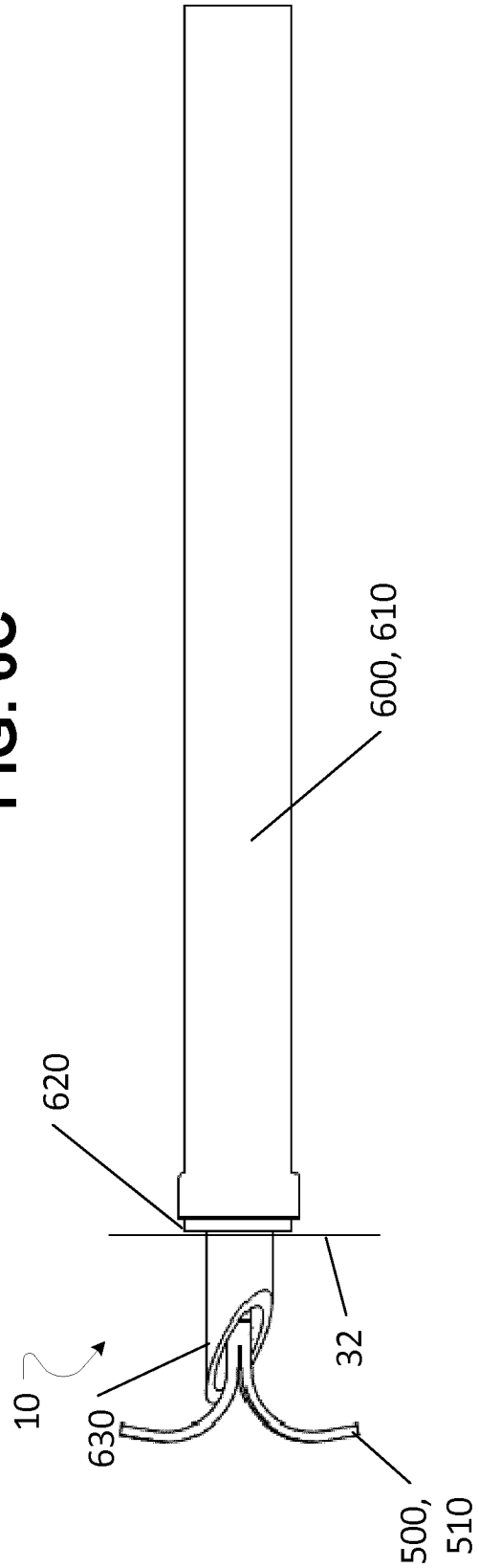
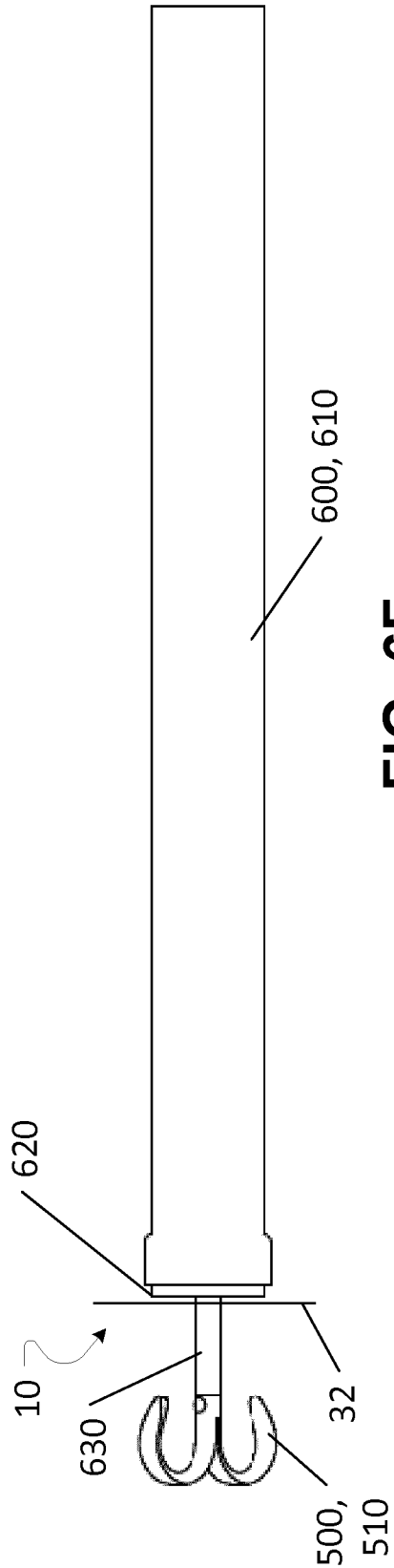
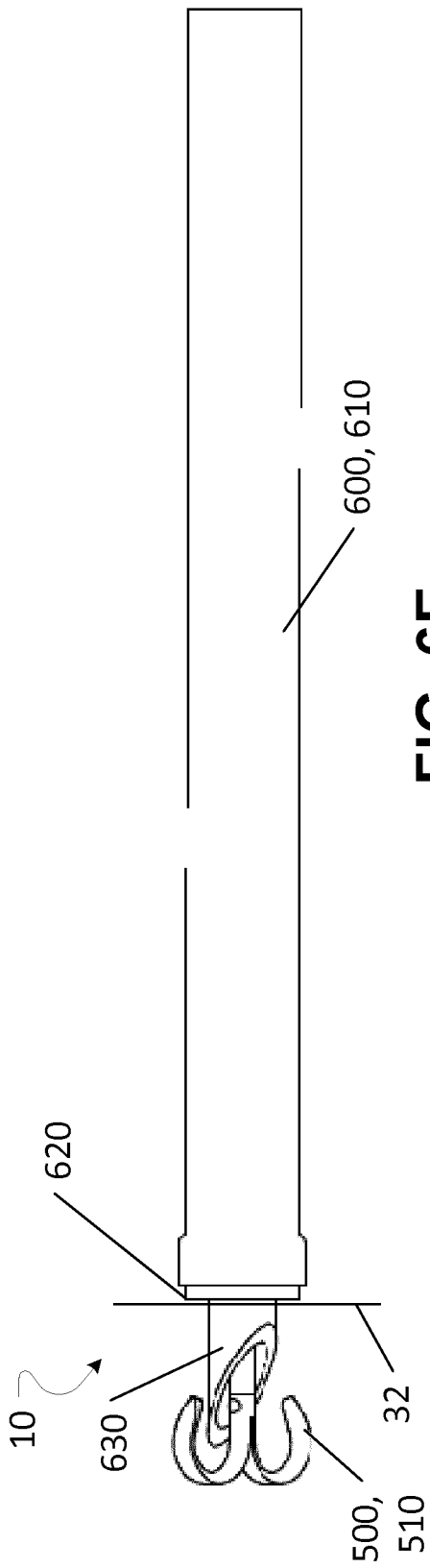


FIG. 6D



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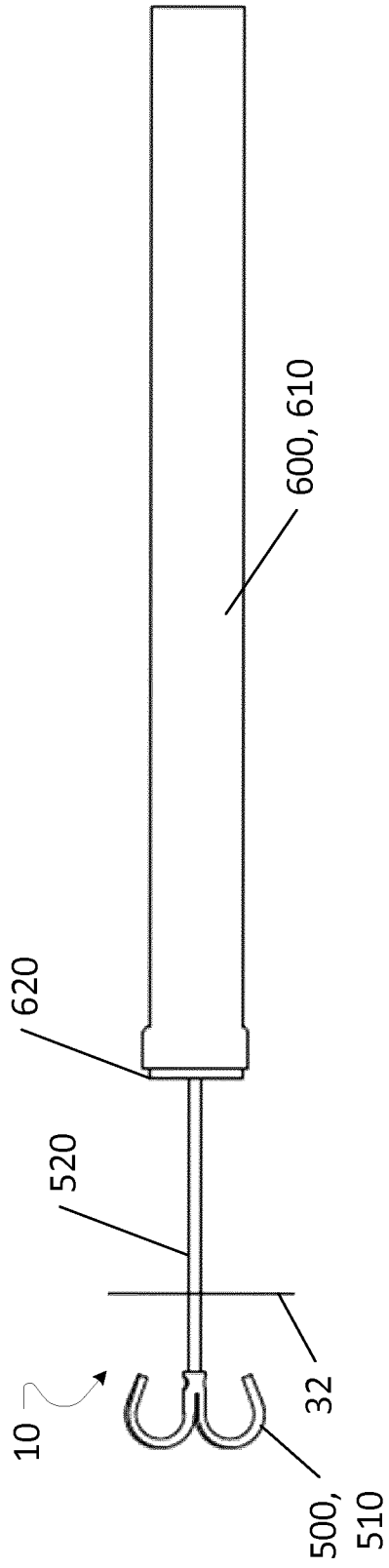


FIG. 6G

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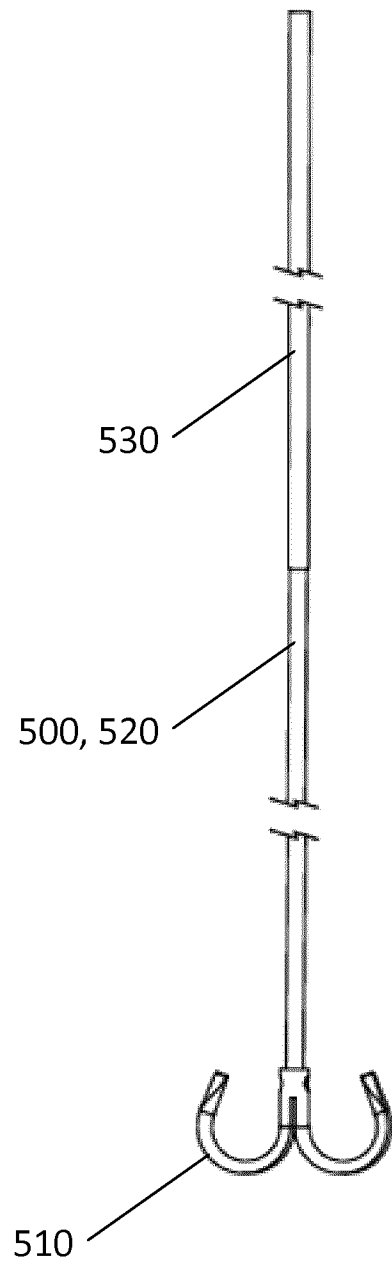


FIG. 7A

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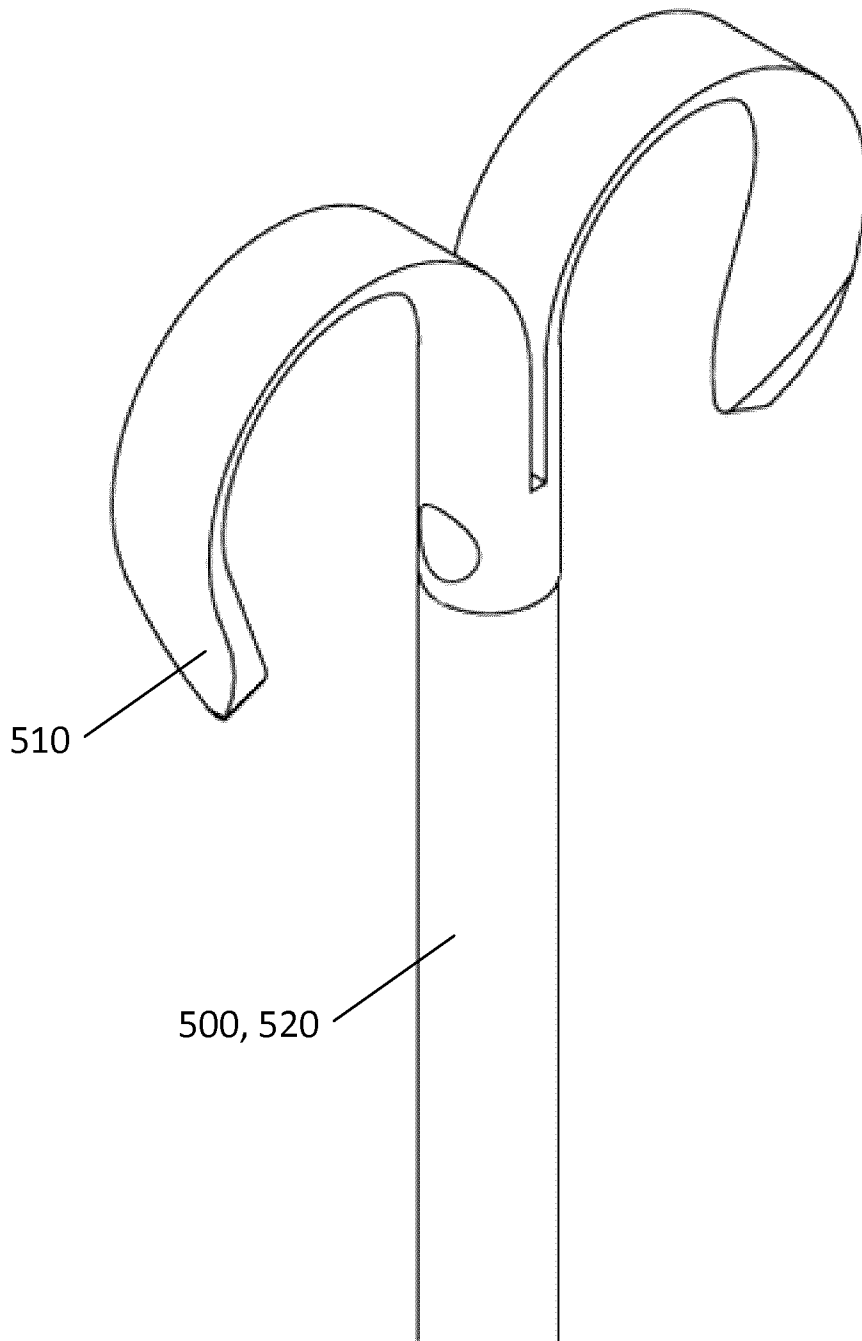


FIG. 7B

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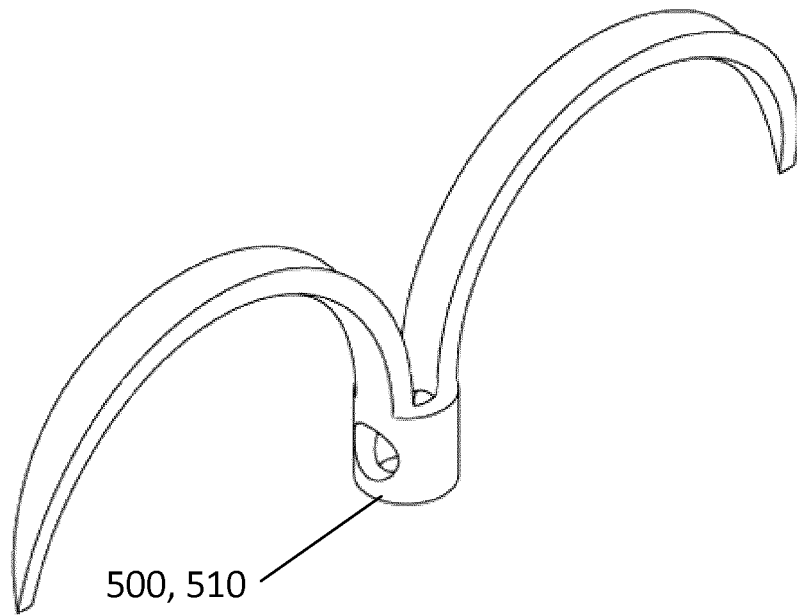
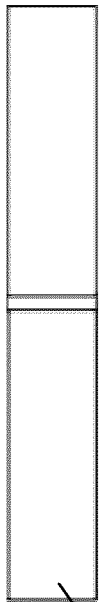
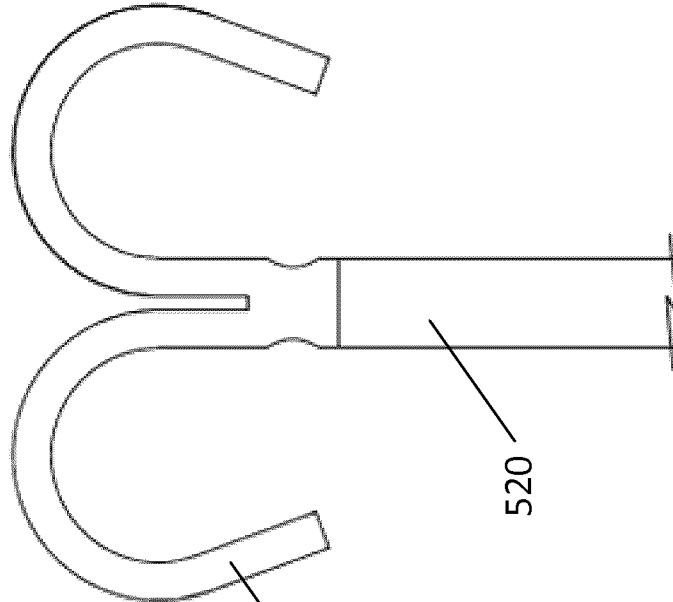


FIG. 7C

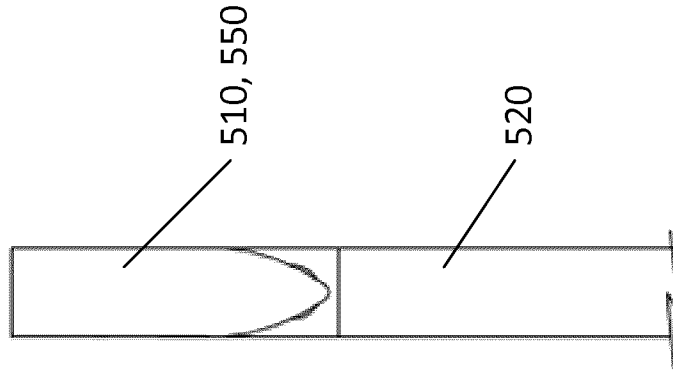
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510, 550
FIG. 7E



510, 550
520
FIG. 7D



510, 550
520
FIG. 7F

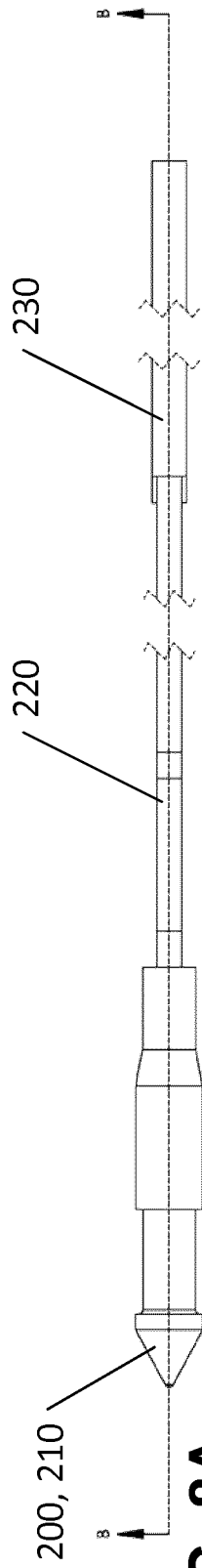


FIG. 8A

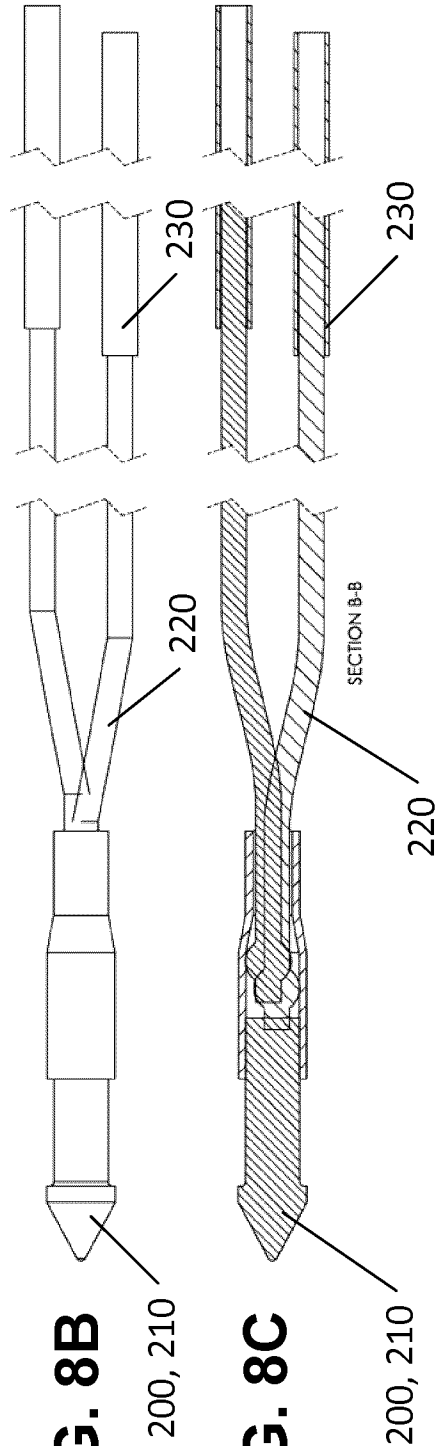


FIG. 8B

FIG. 8C

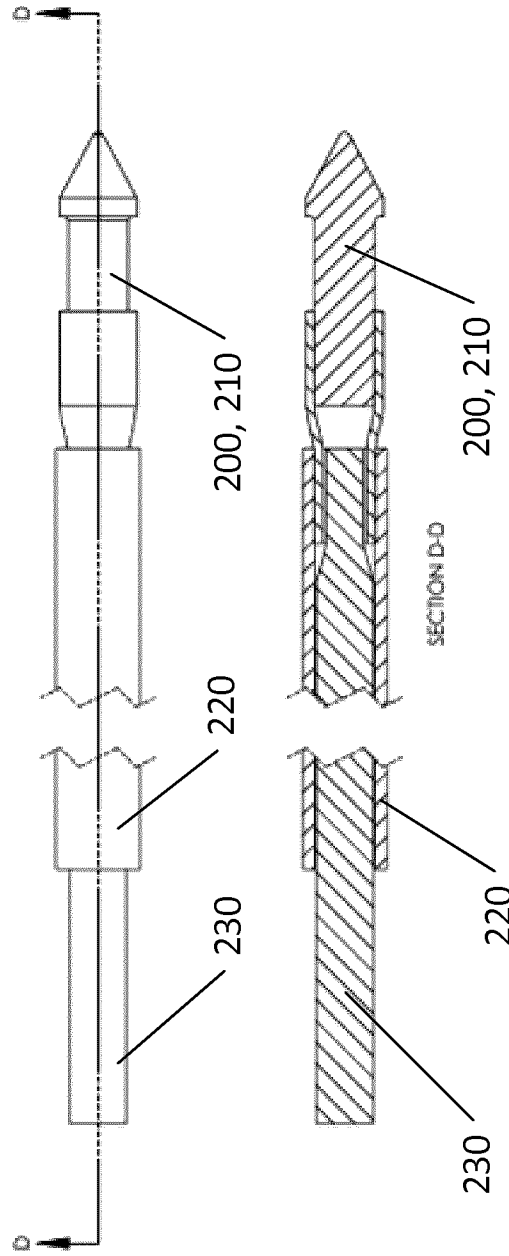


FIG. 8D

FIG. 8E

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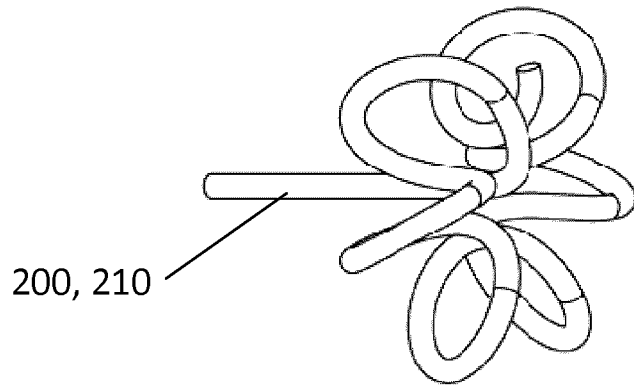


FIG. 9A

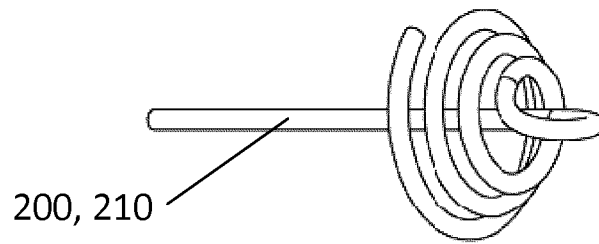


FIG. 9B

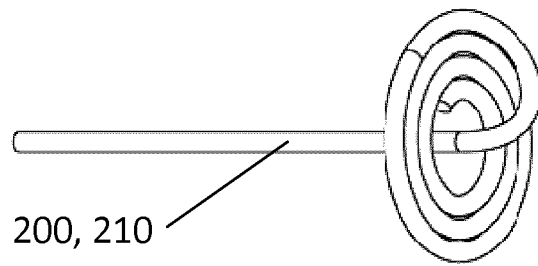


FIG. 9C

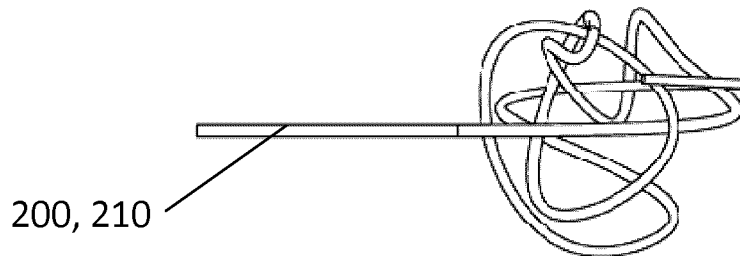


FIG. 9D

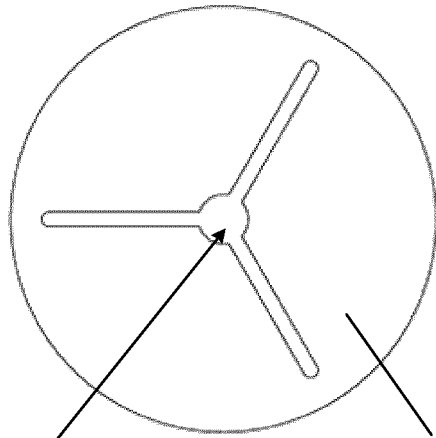


FIG. 10A

270

250, 260

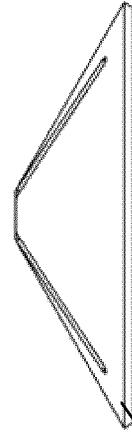


FIG. 10B

250, 260

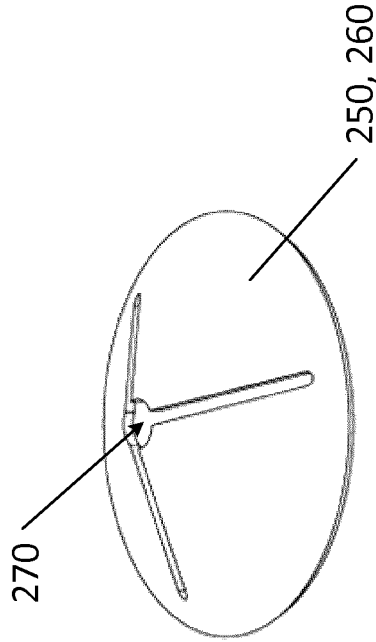


FIG. 10C

270

250, 260

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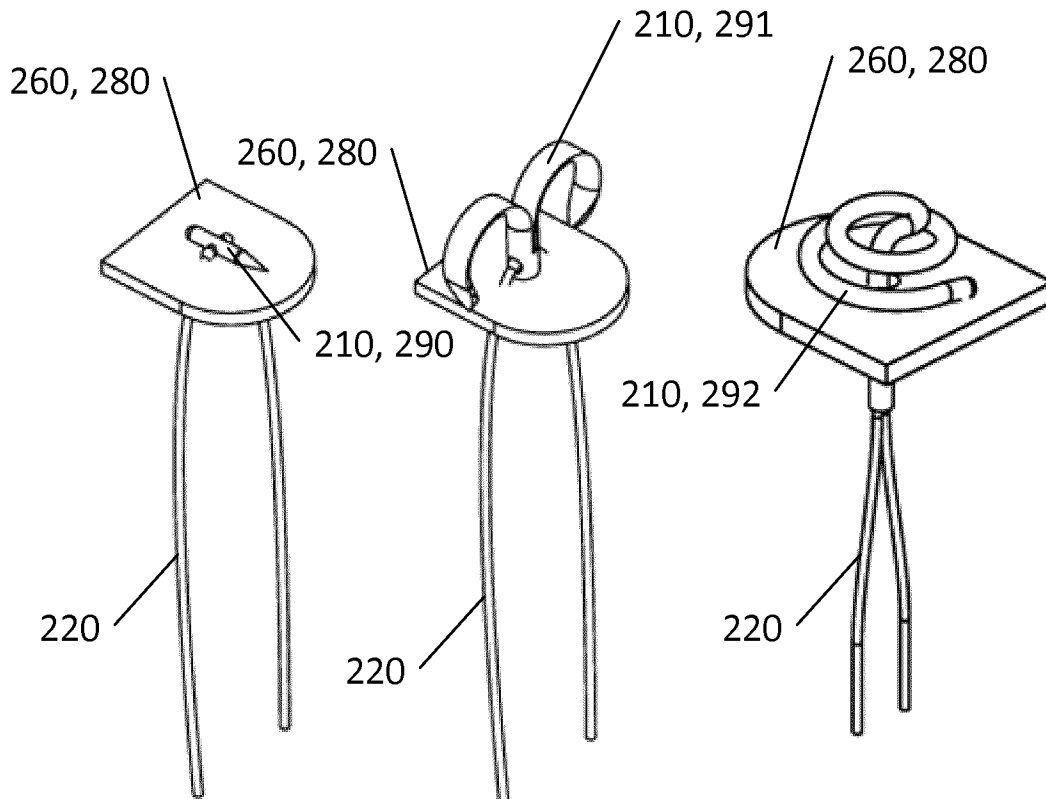


FIG. 11A

FIG. 11B

FIG. 11C

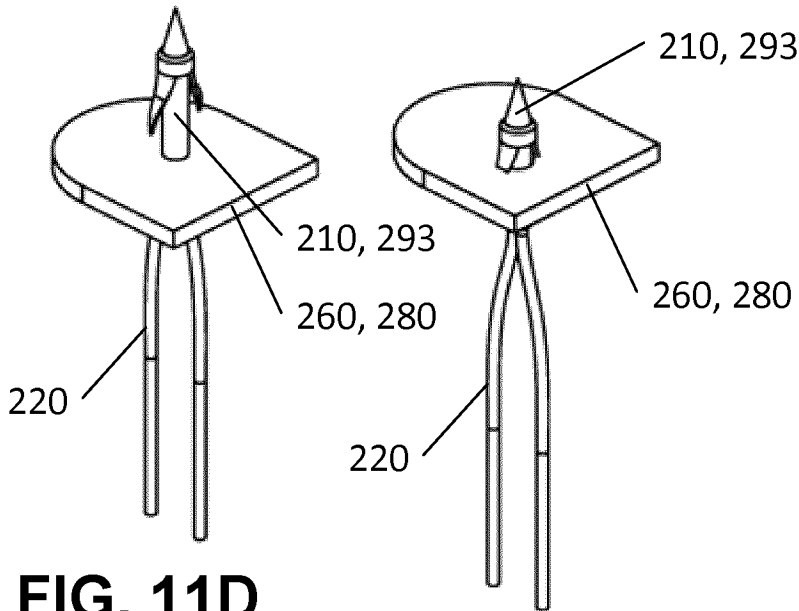


FIG. 11D

FIG. 11E

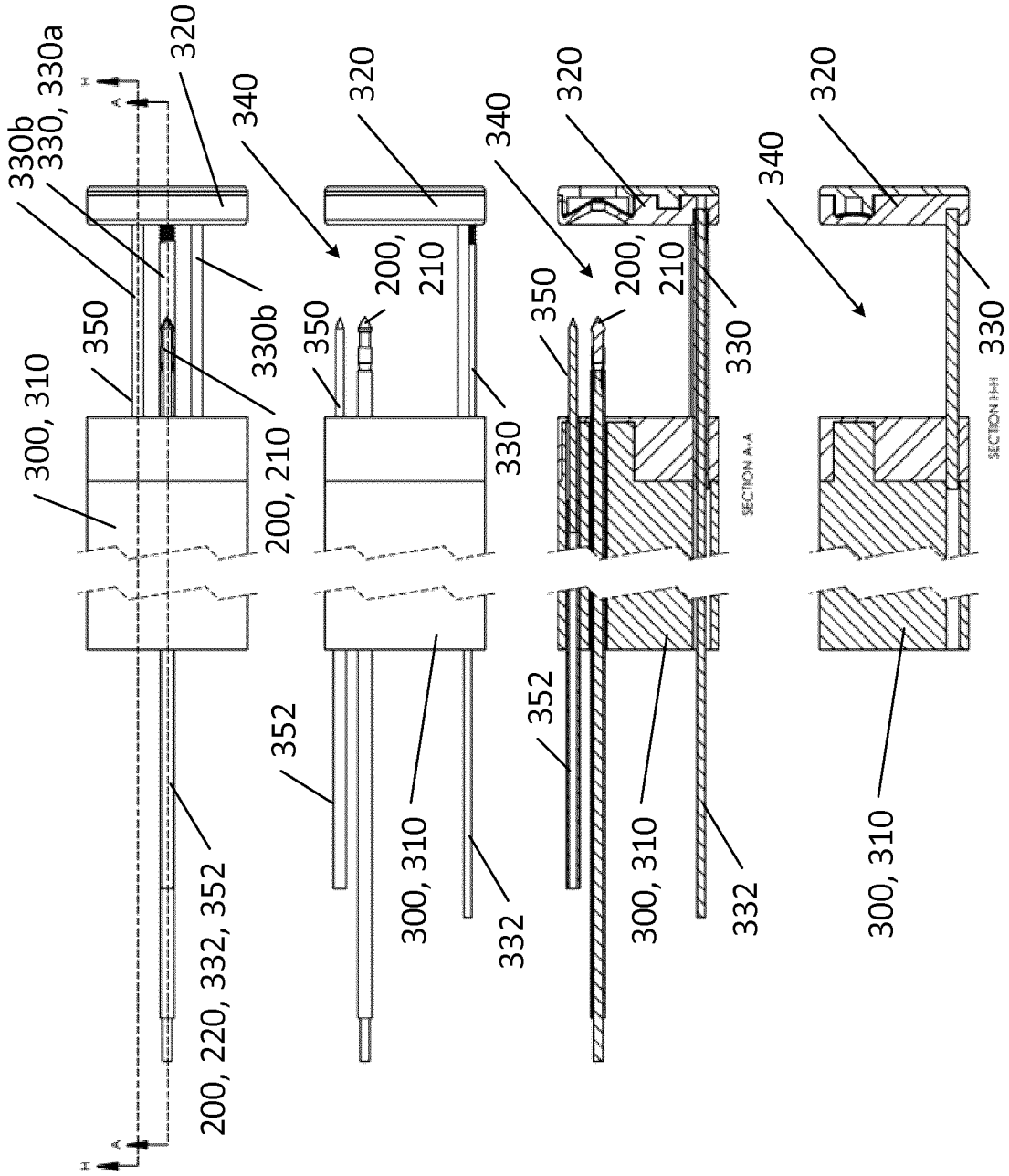


FIG. 12A

FIG. 12B

FIG. 12C

FIG. 12D

FIG. 12G

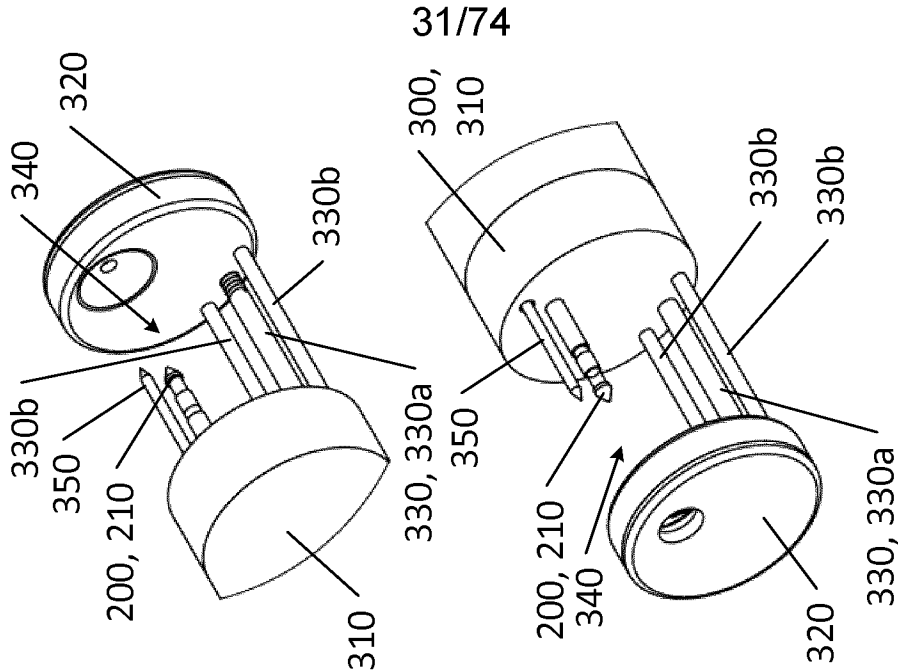


FIG. 12H

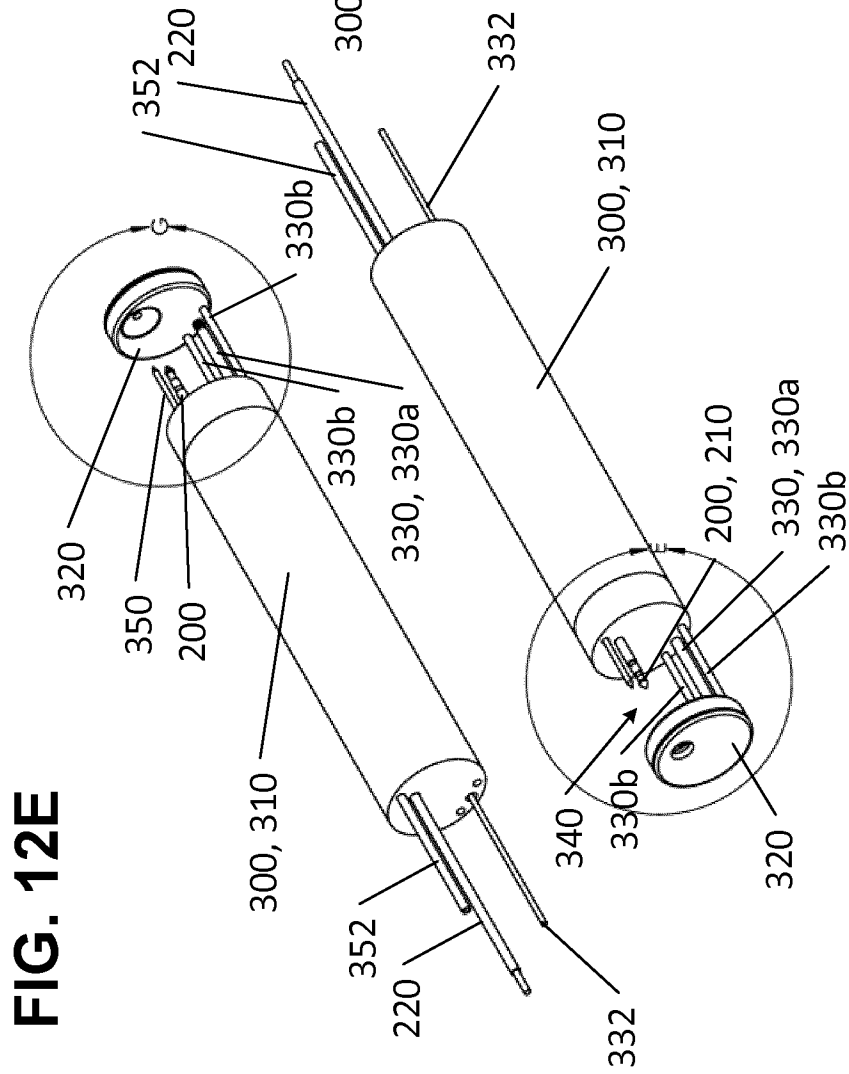


FIG. 12E

FIG. 12F

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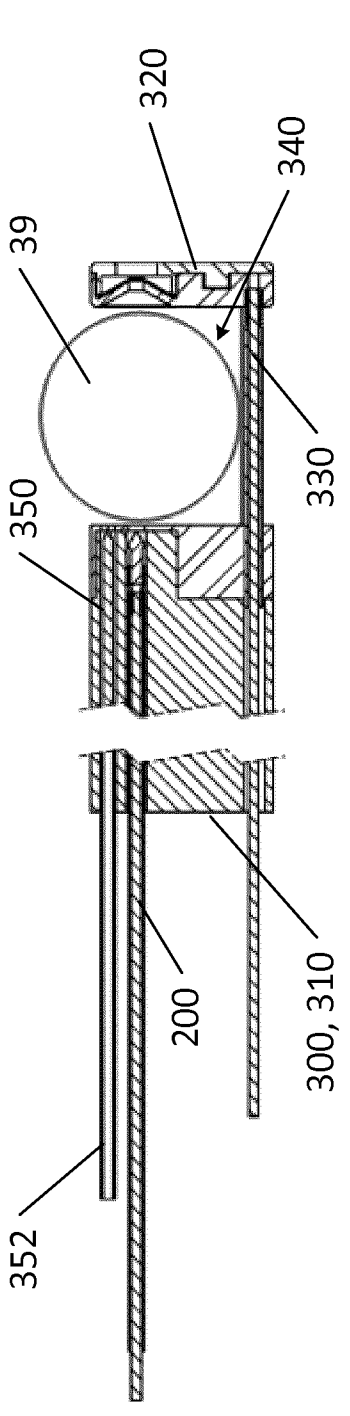


FIG. 13A

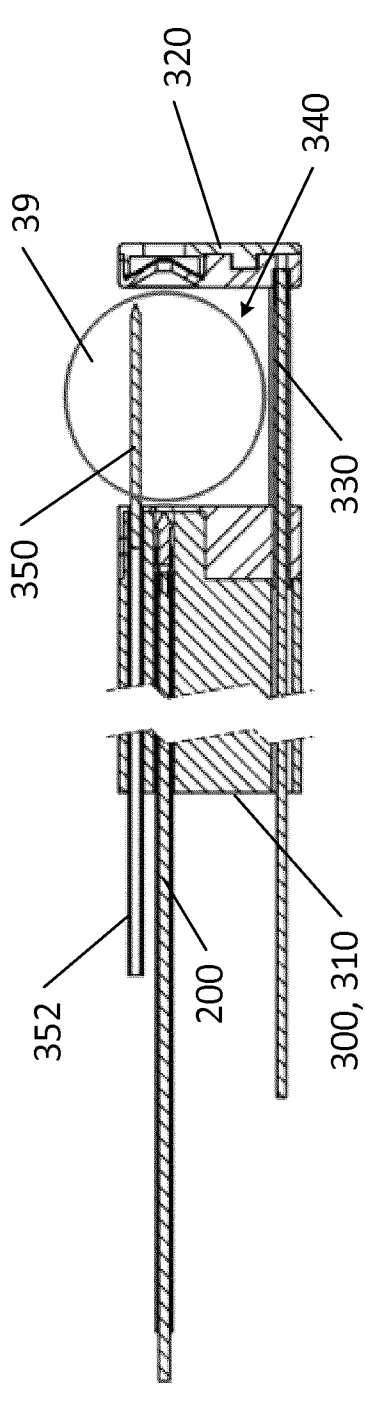


FIG. 13B

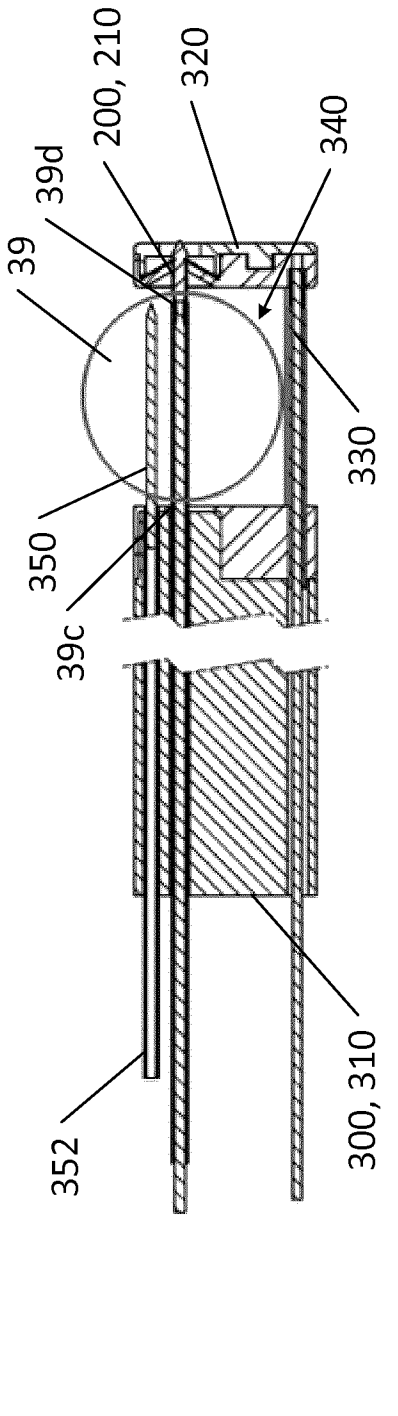


FIG. 13C

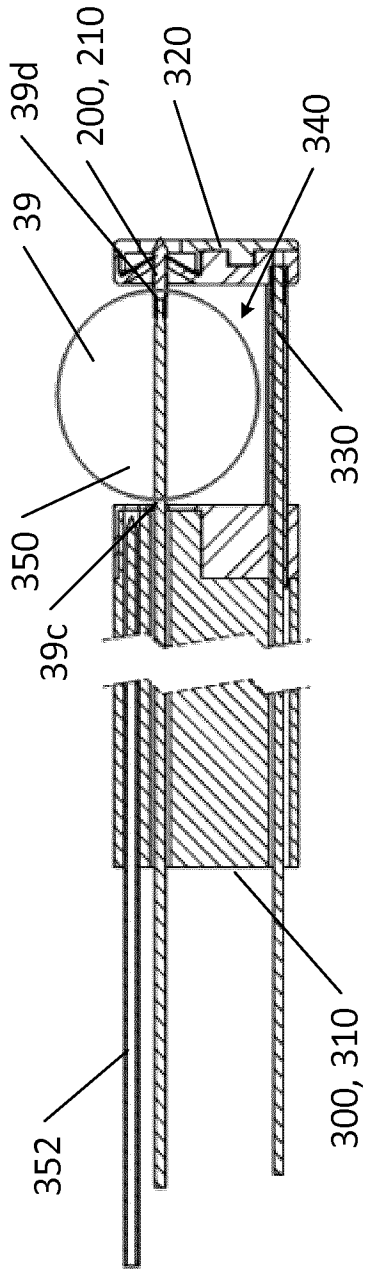


FIG. 13D

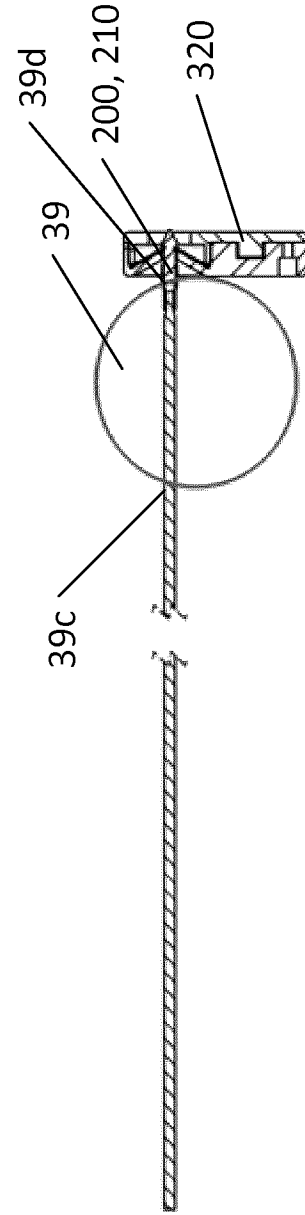


FIG. 13E

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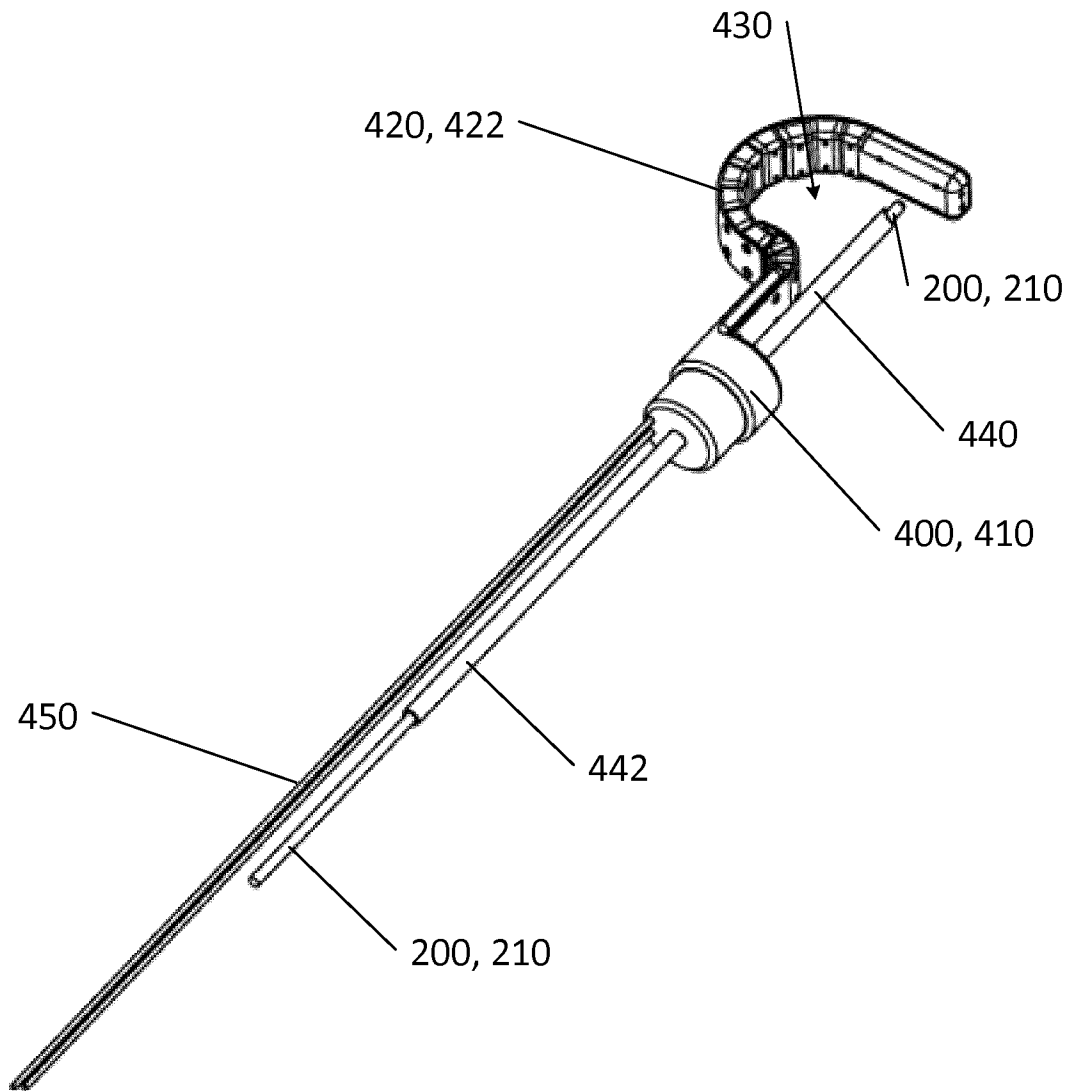


FIG. 14A

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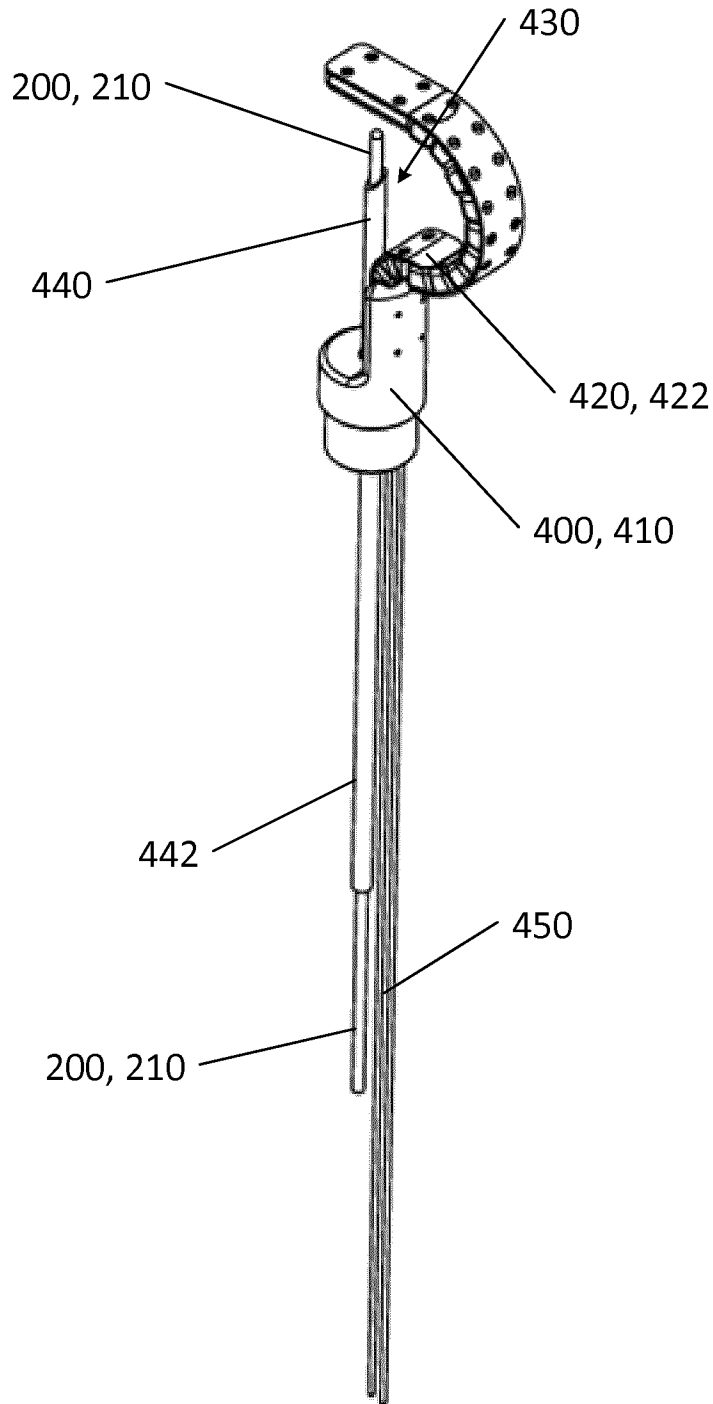


FIG. 14B

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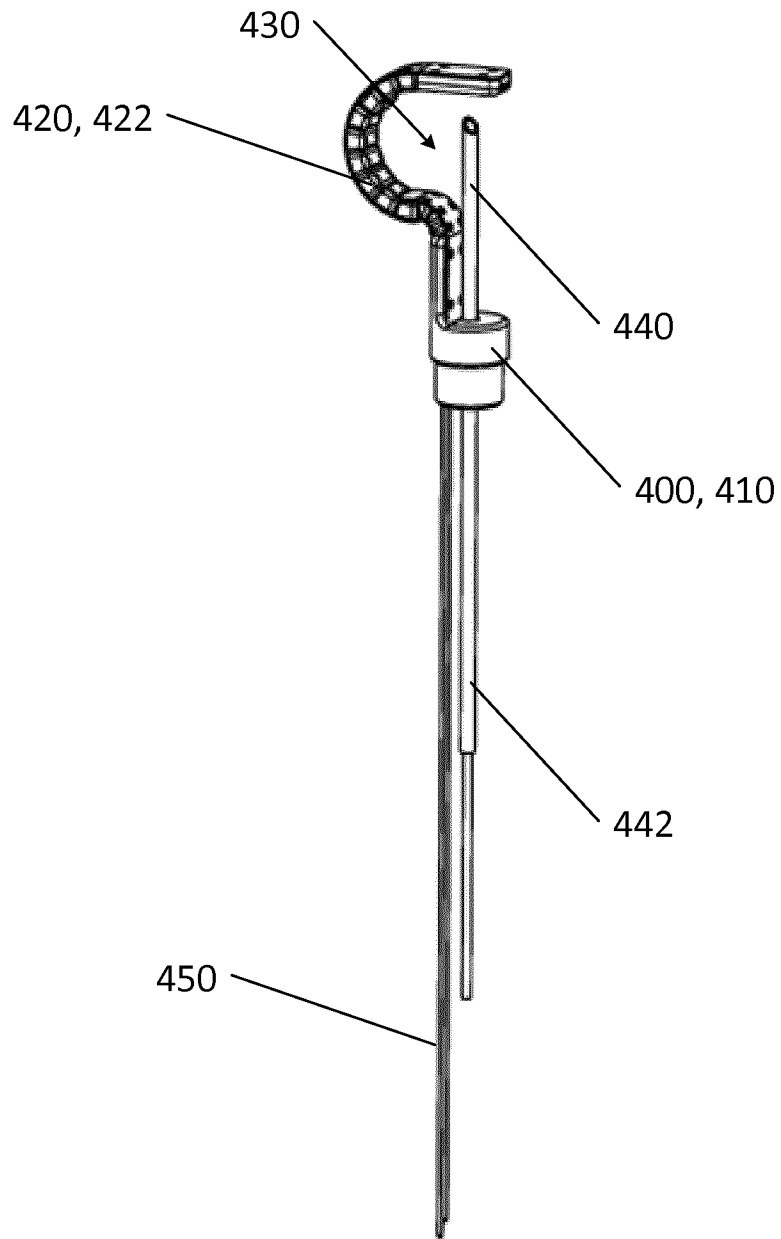


FIG. 14C

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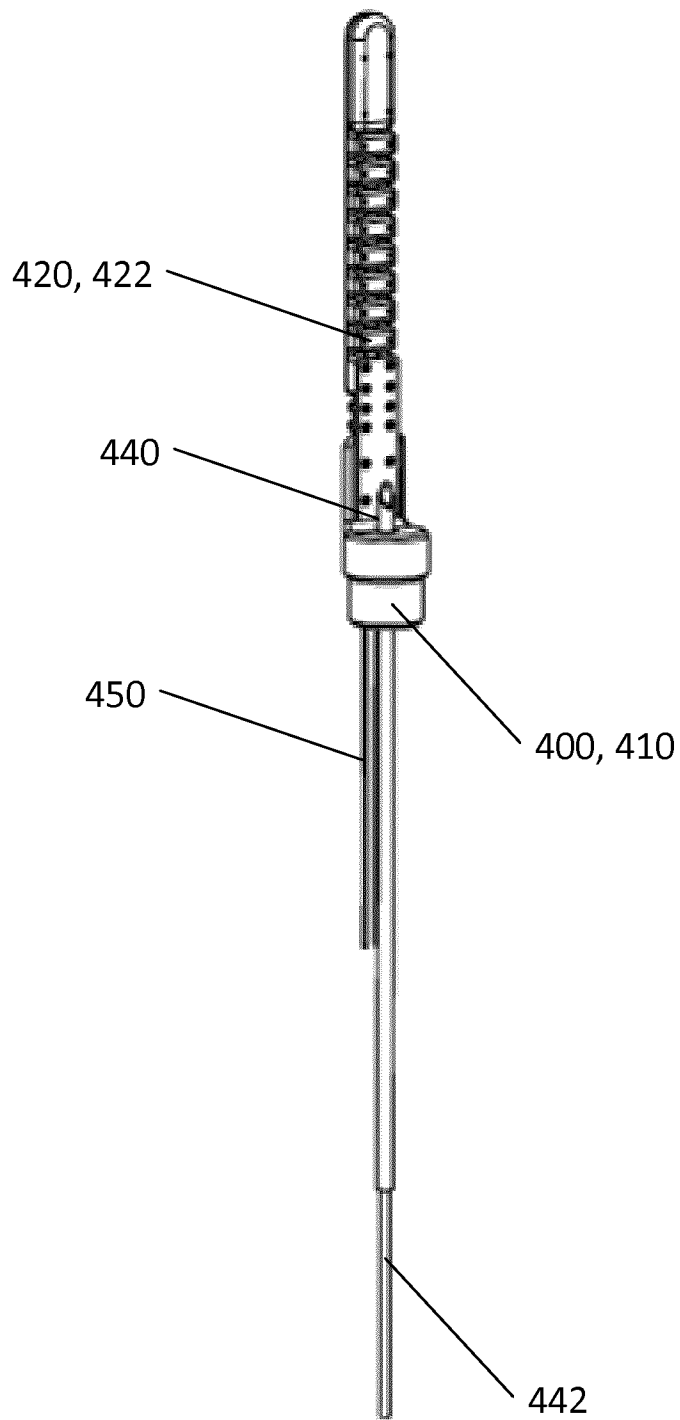


FIG. 14D

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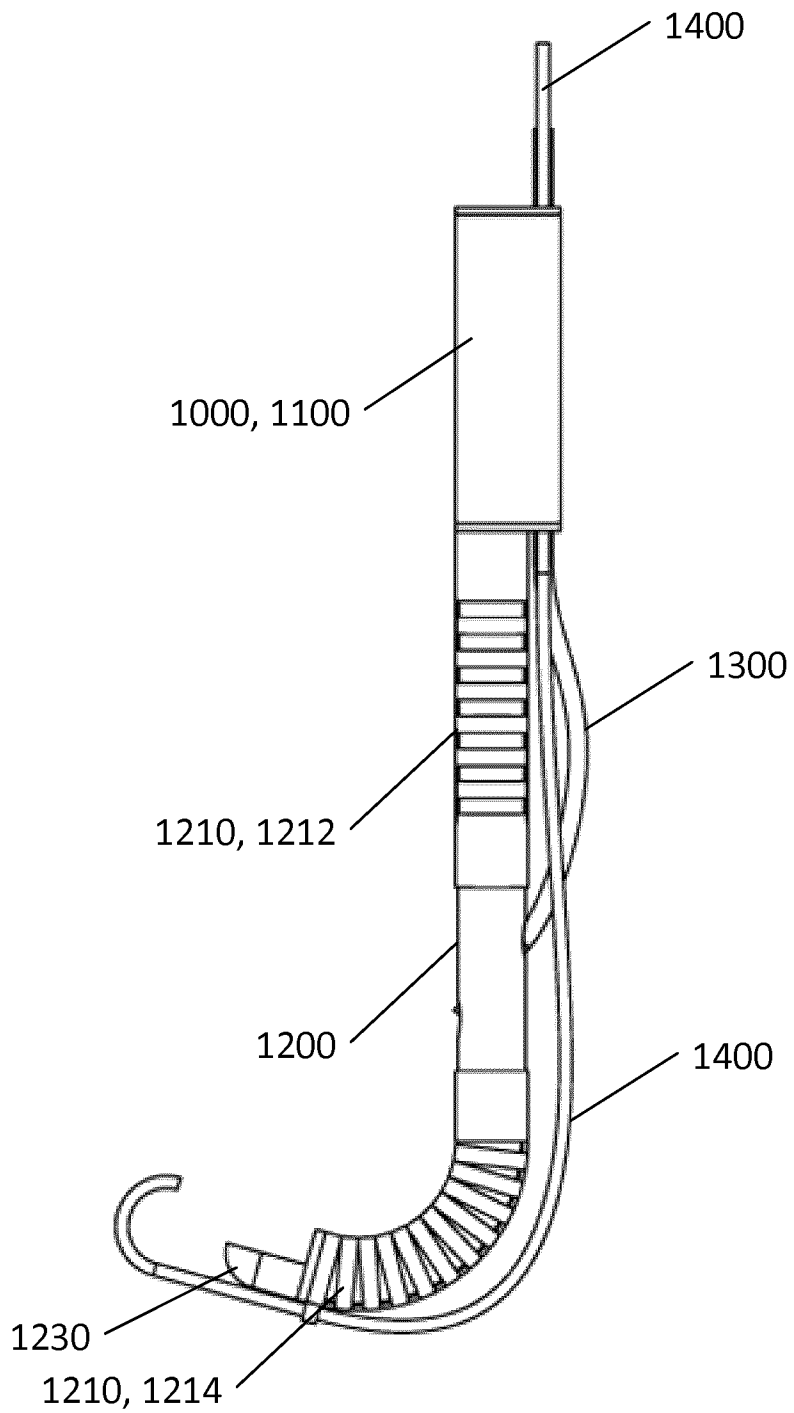


FIG. 15A

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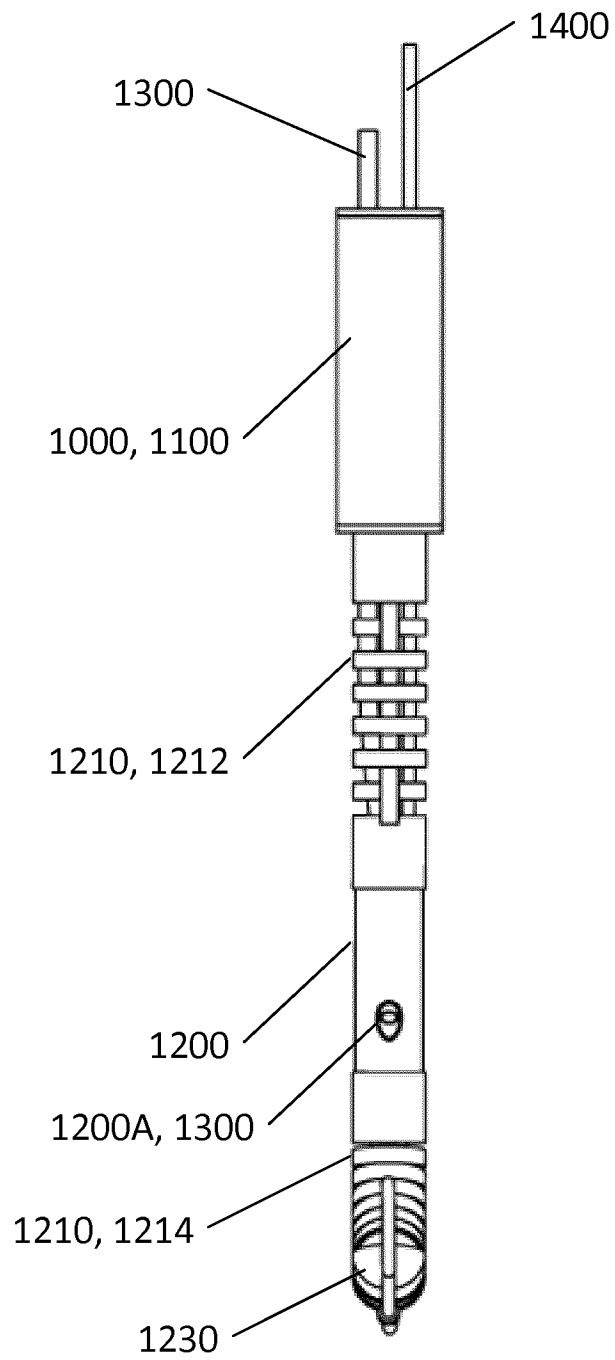


FIG. 15B

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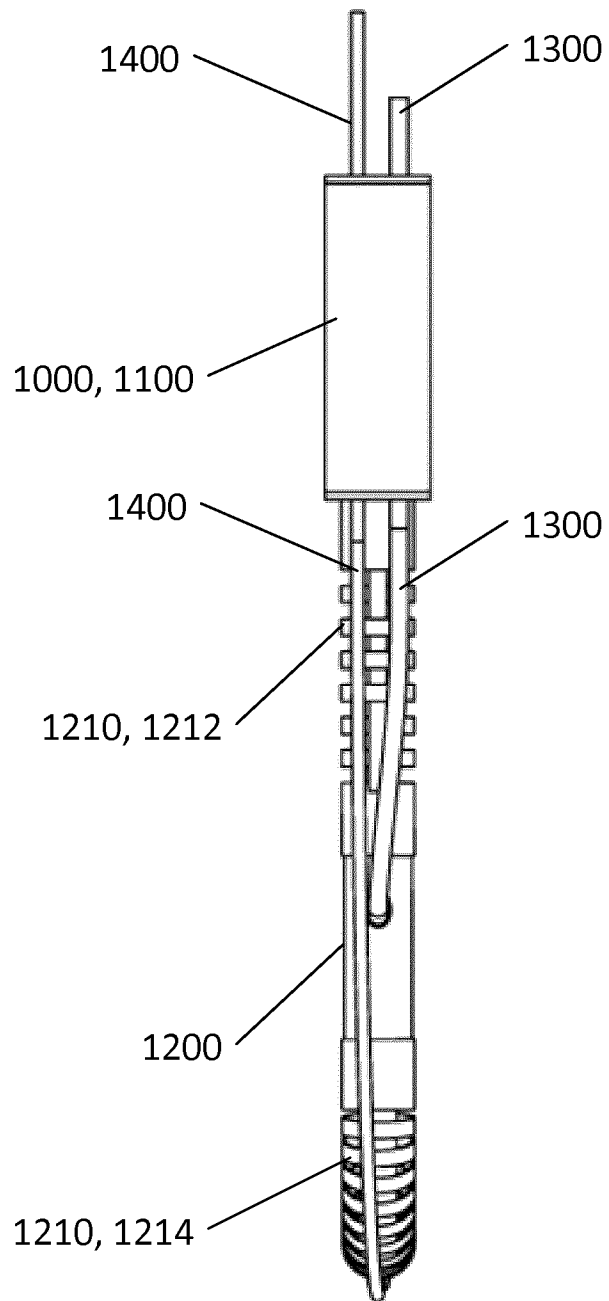


FIG. 15C

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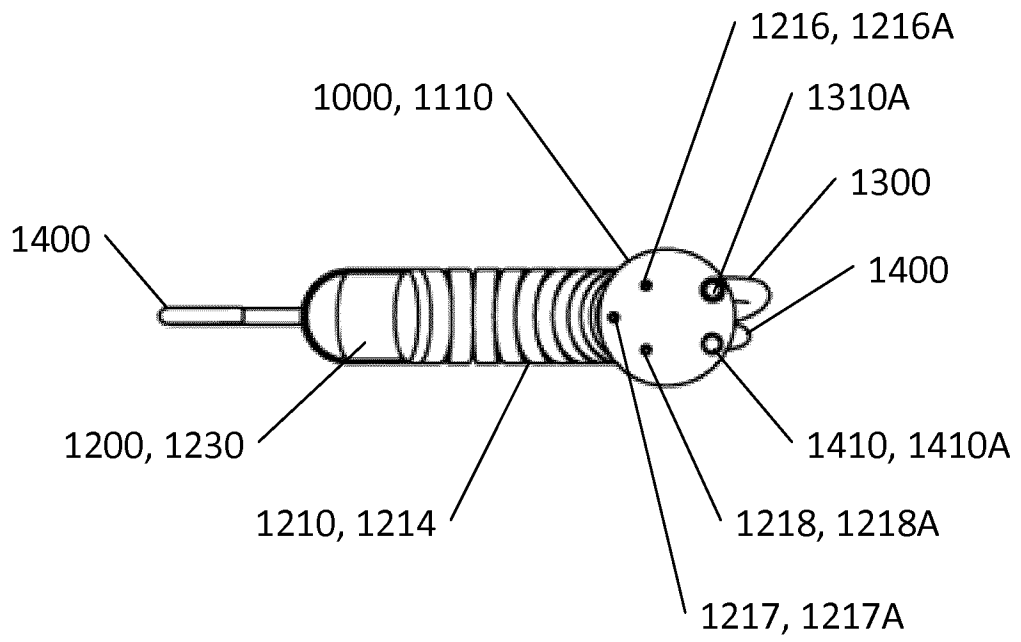


FIG. 15D

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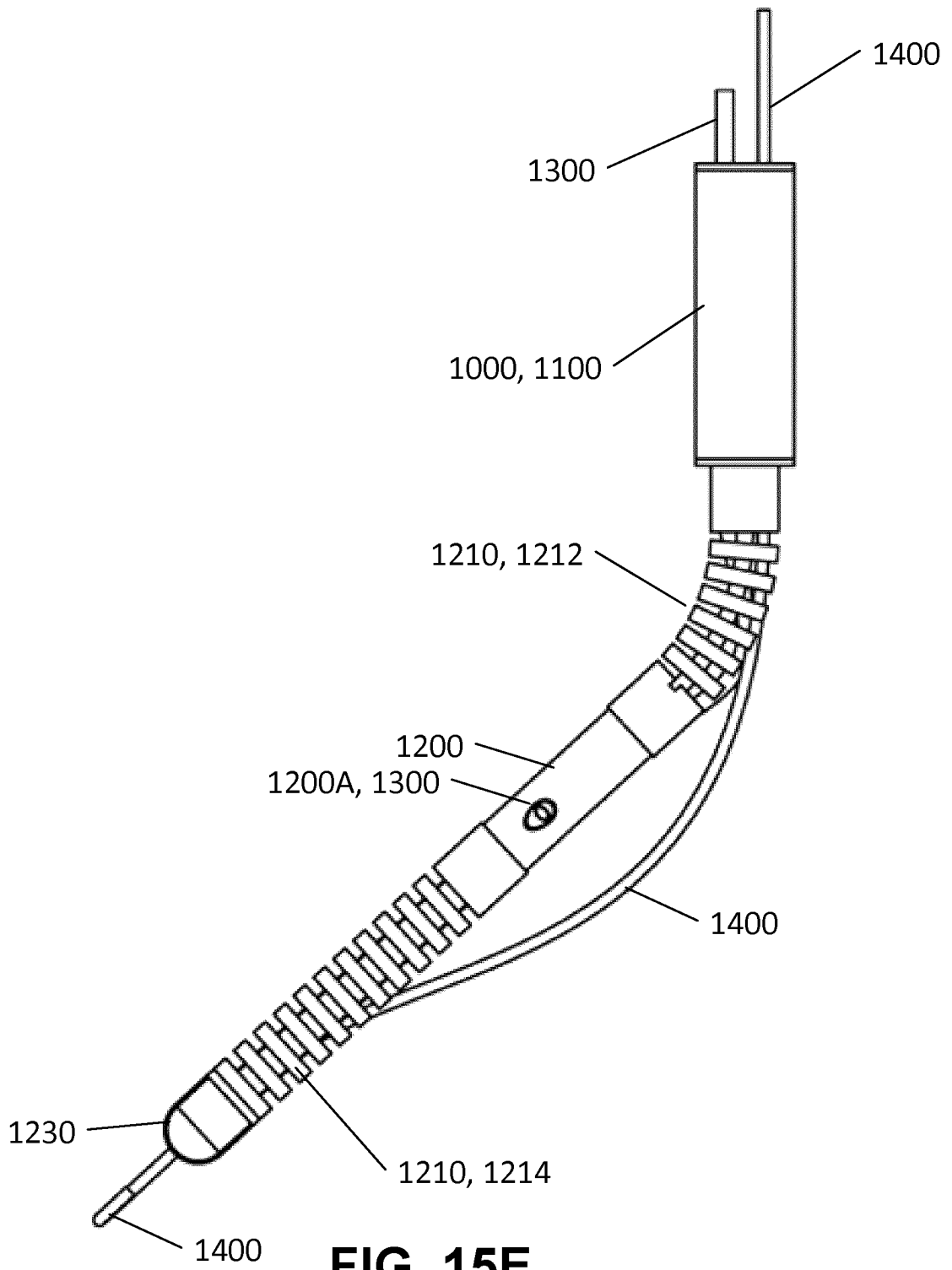


FIG. 15E

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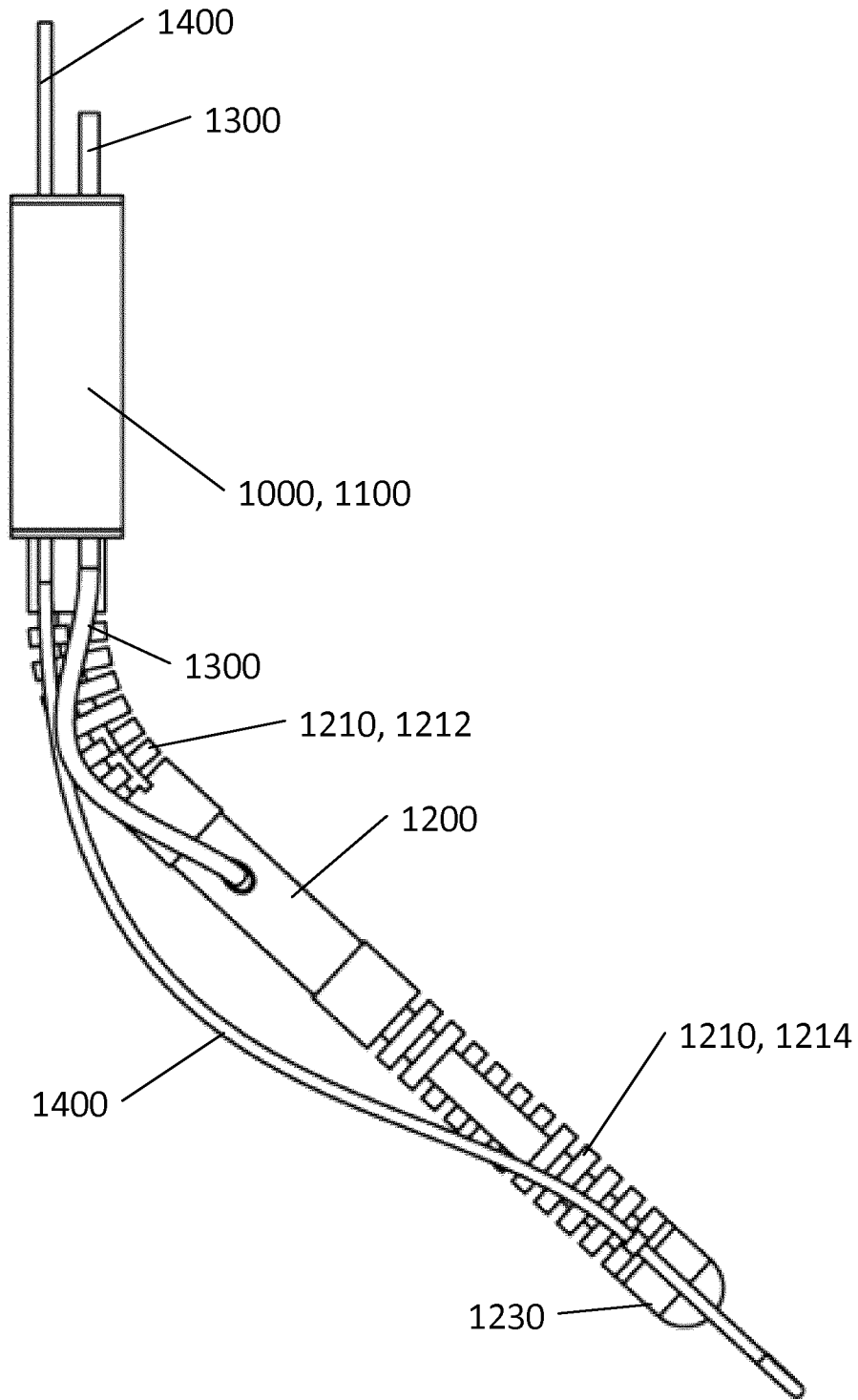


FIG. 15F

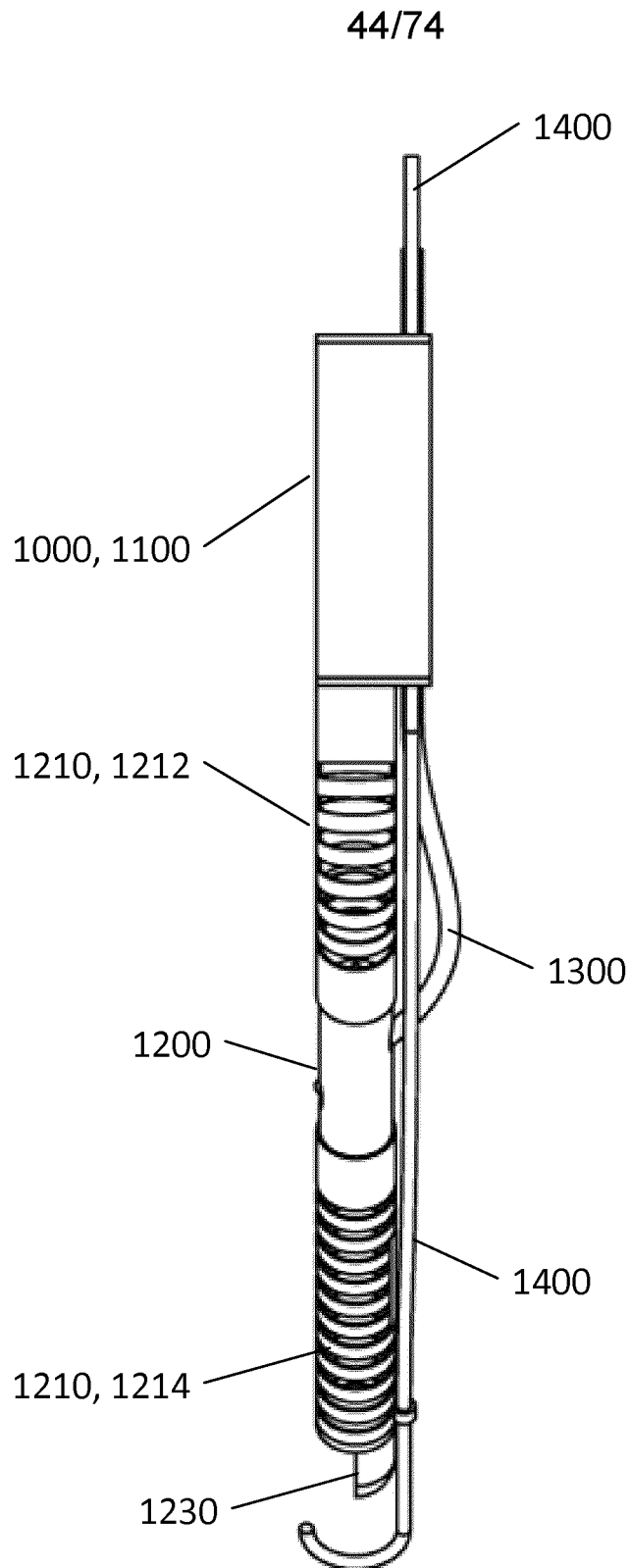


FIG. 15G

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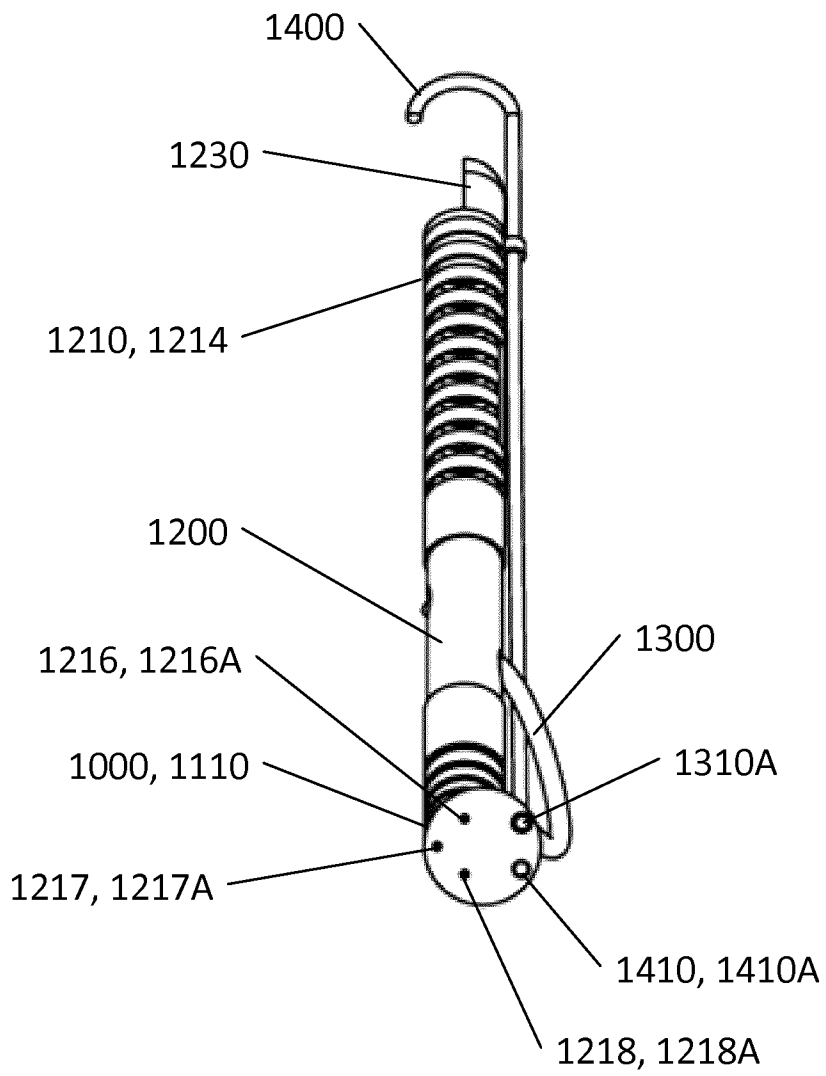


FIG. 15H

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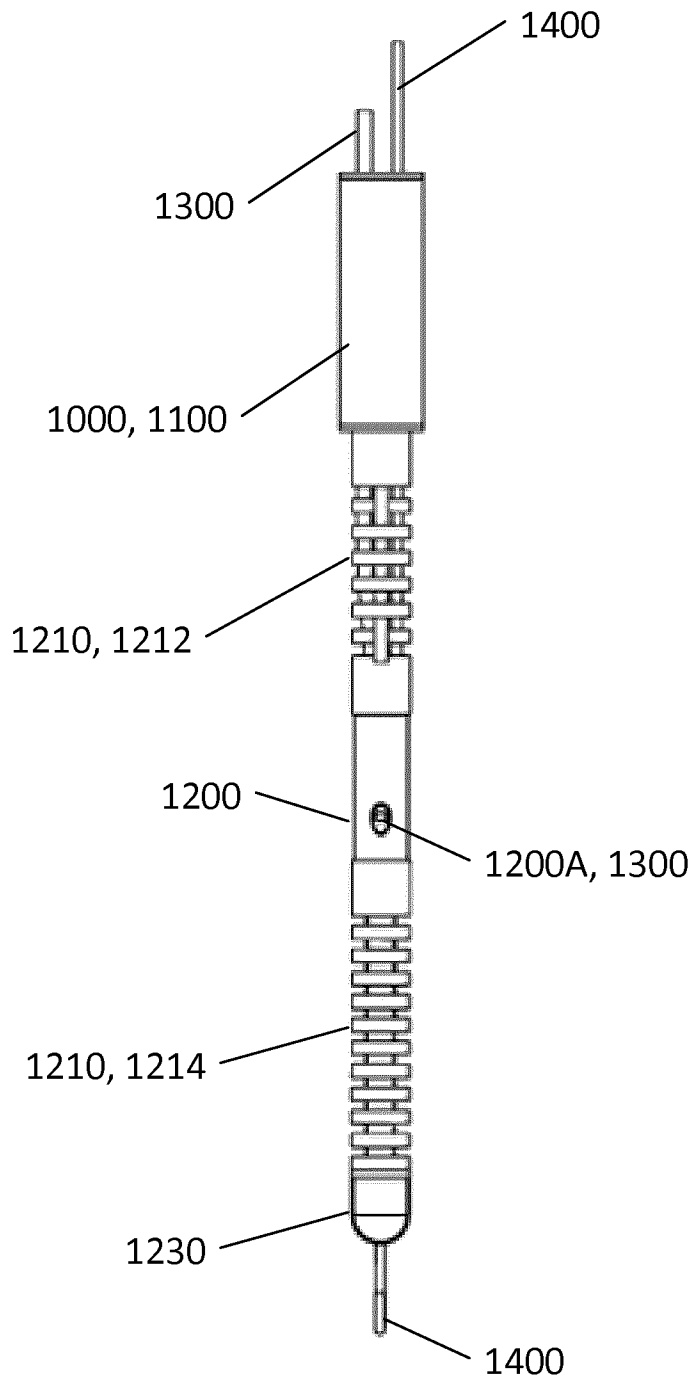


FIG. 15I

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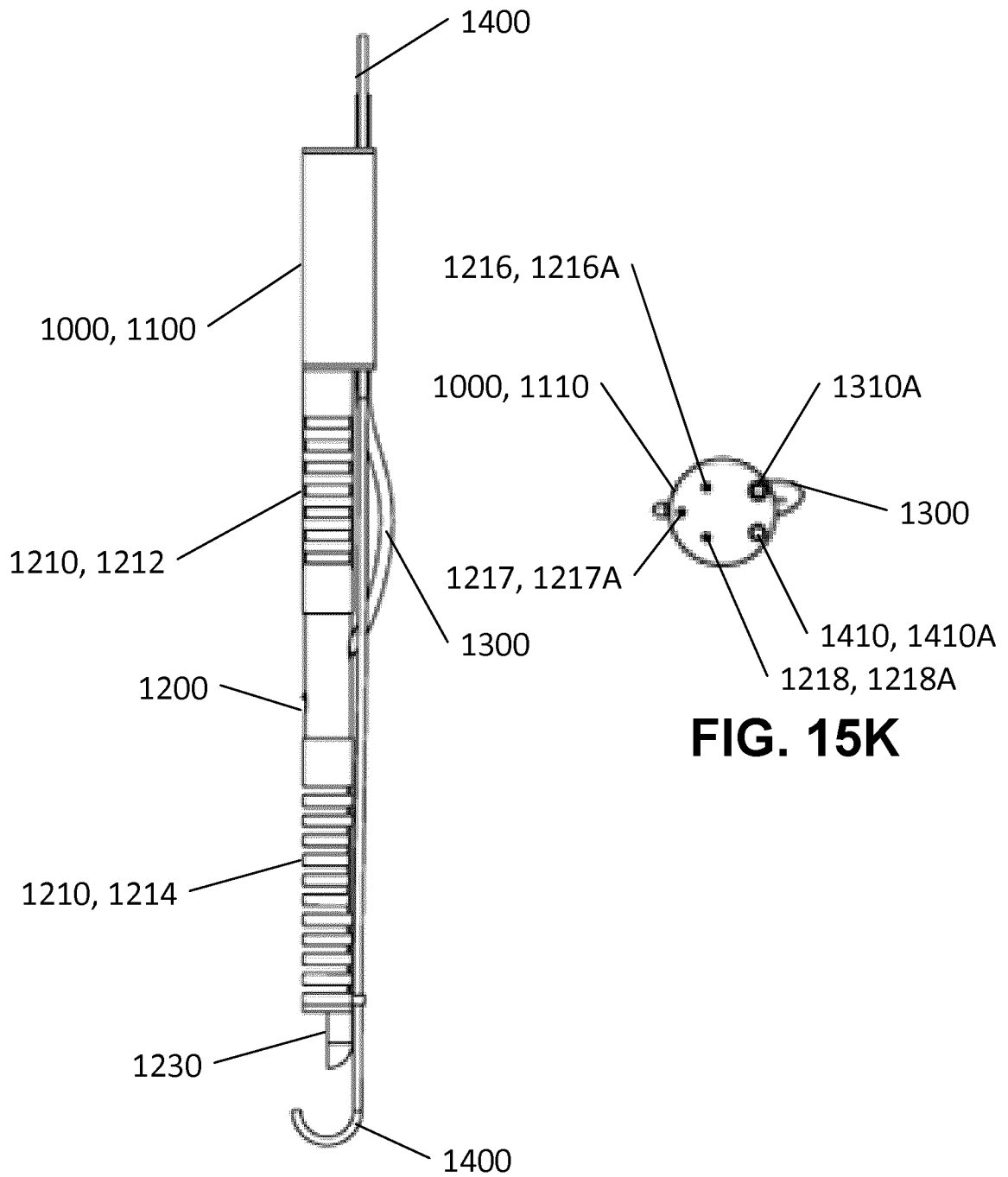


FIG. 15J

FIG. 15K

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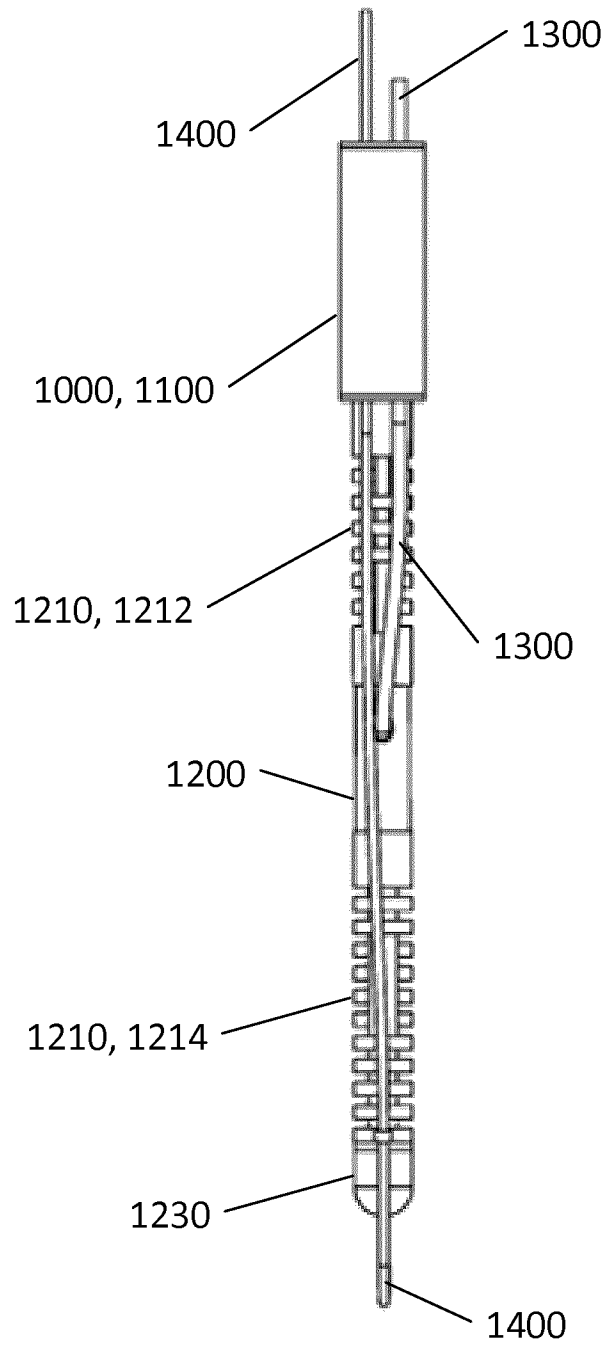


FIG. 15L

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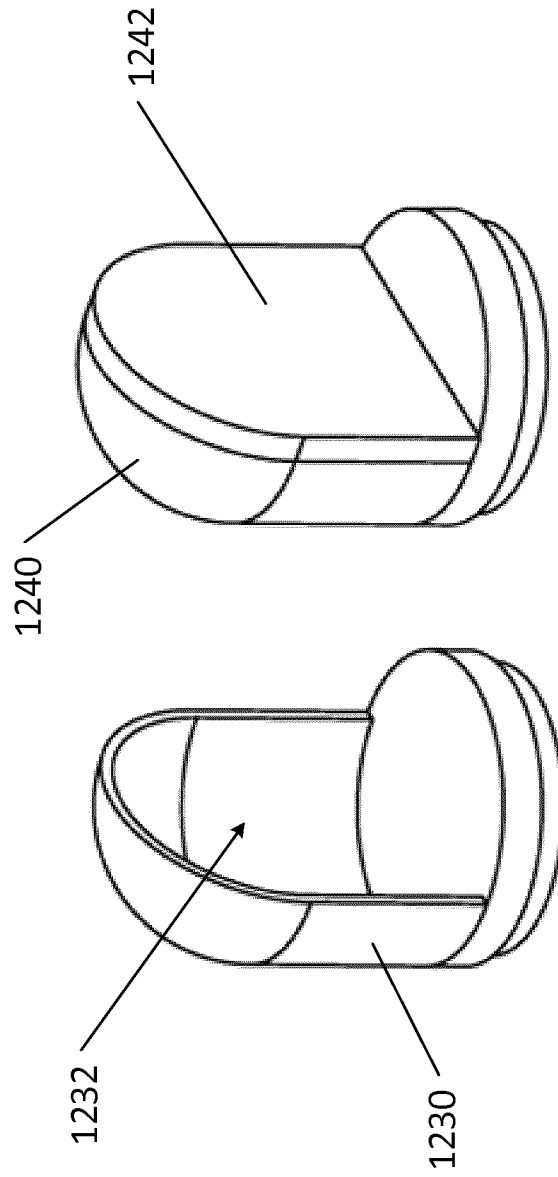


FIG. 16B

FIG. 16A

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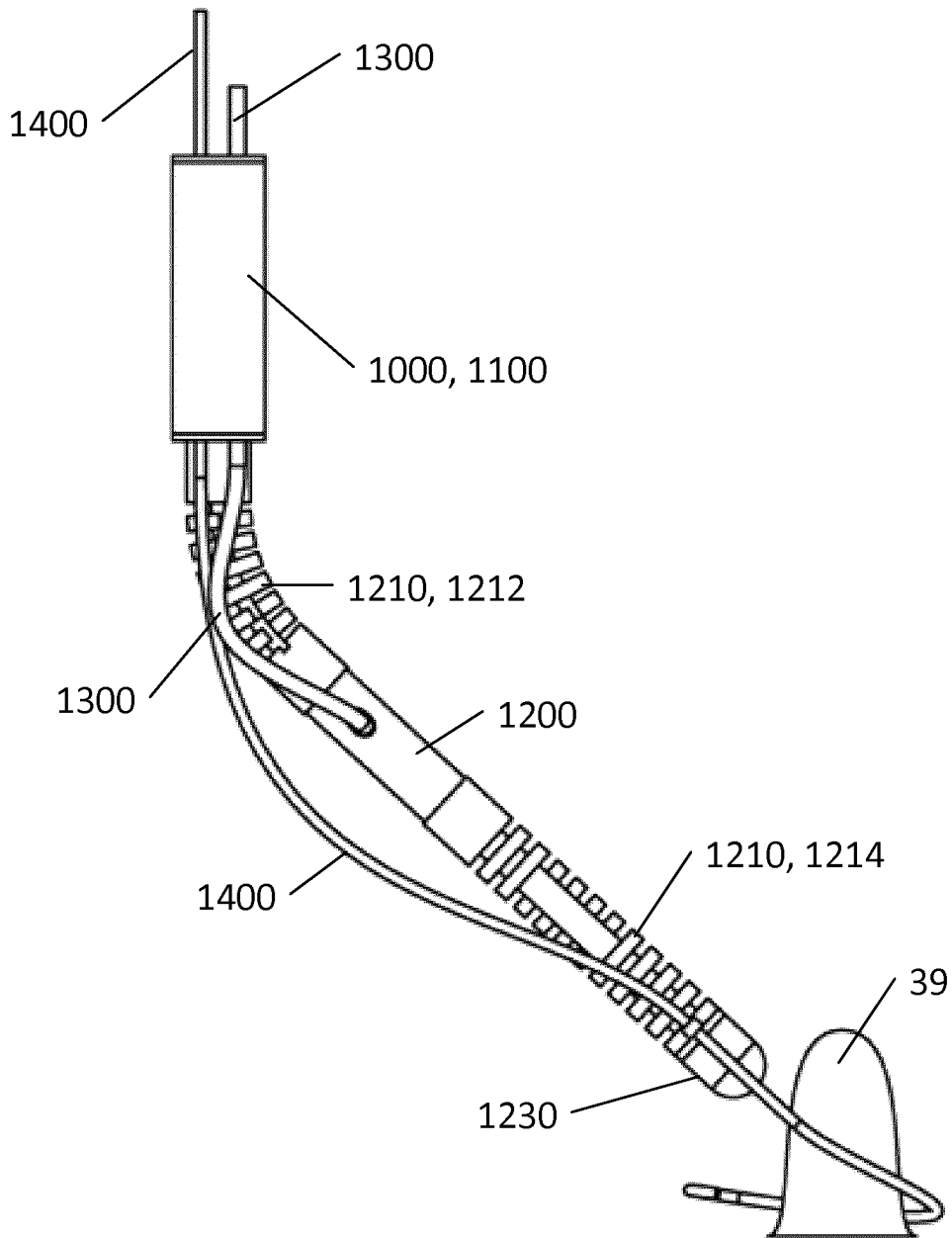


FIG. 17A

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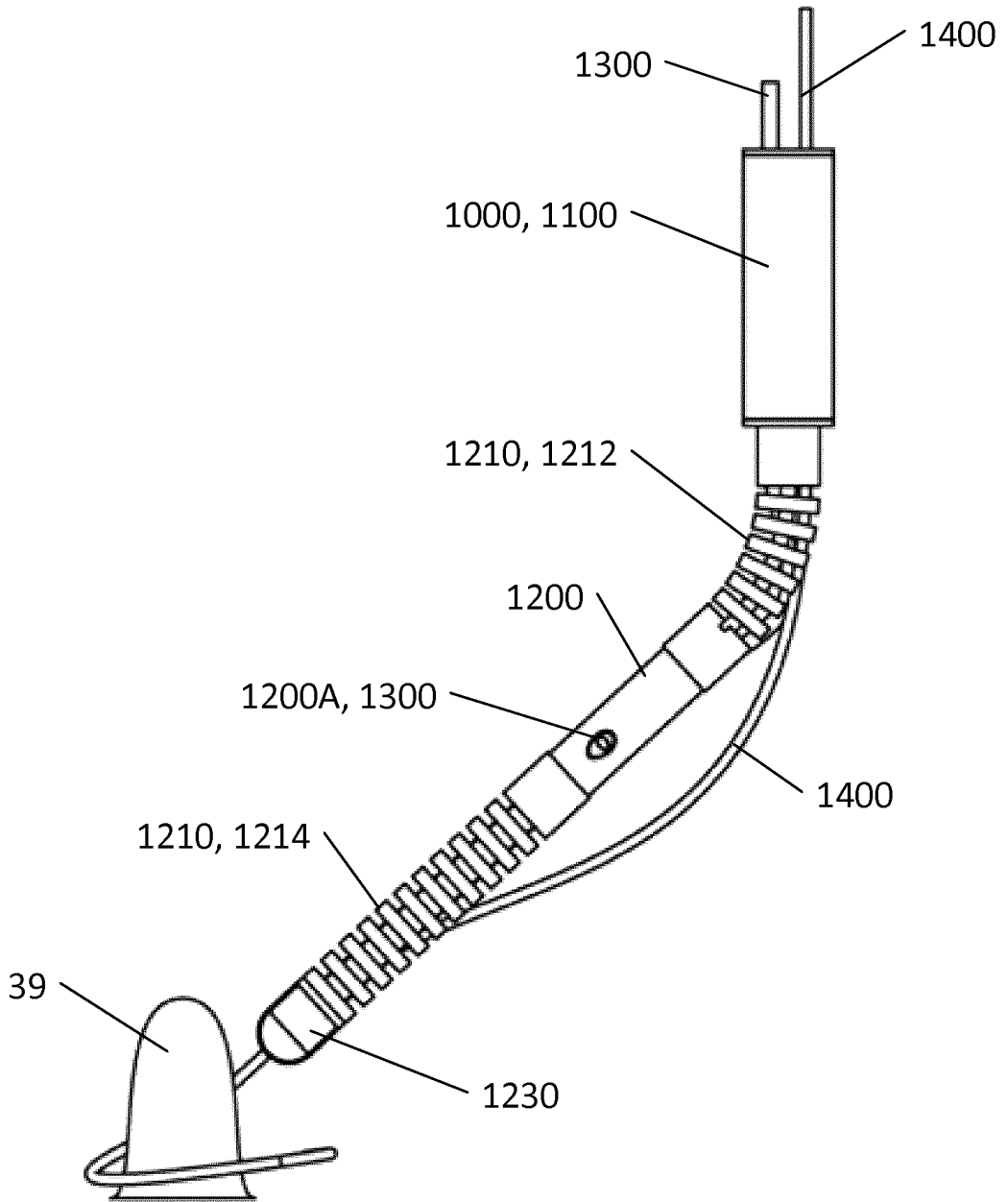


FIG. 17B

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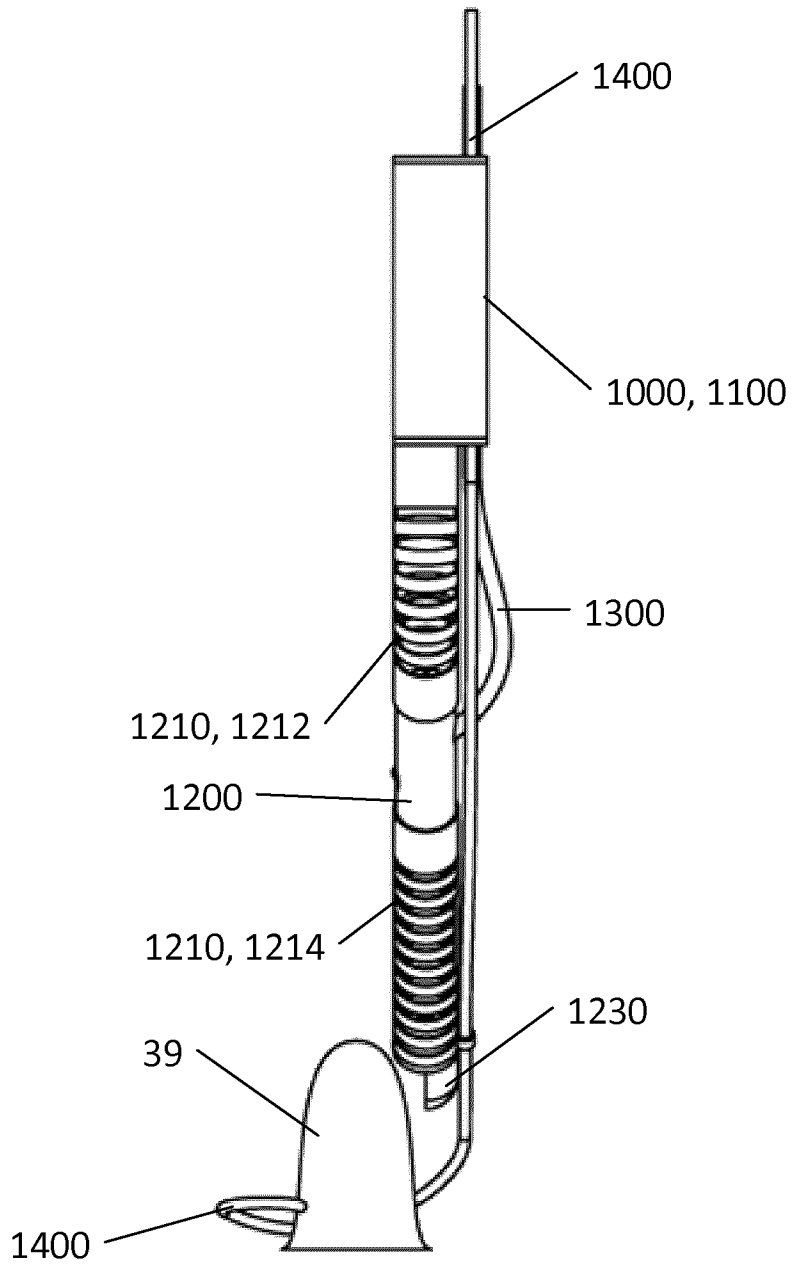


FIG. 17C

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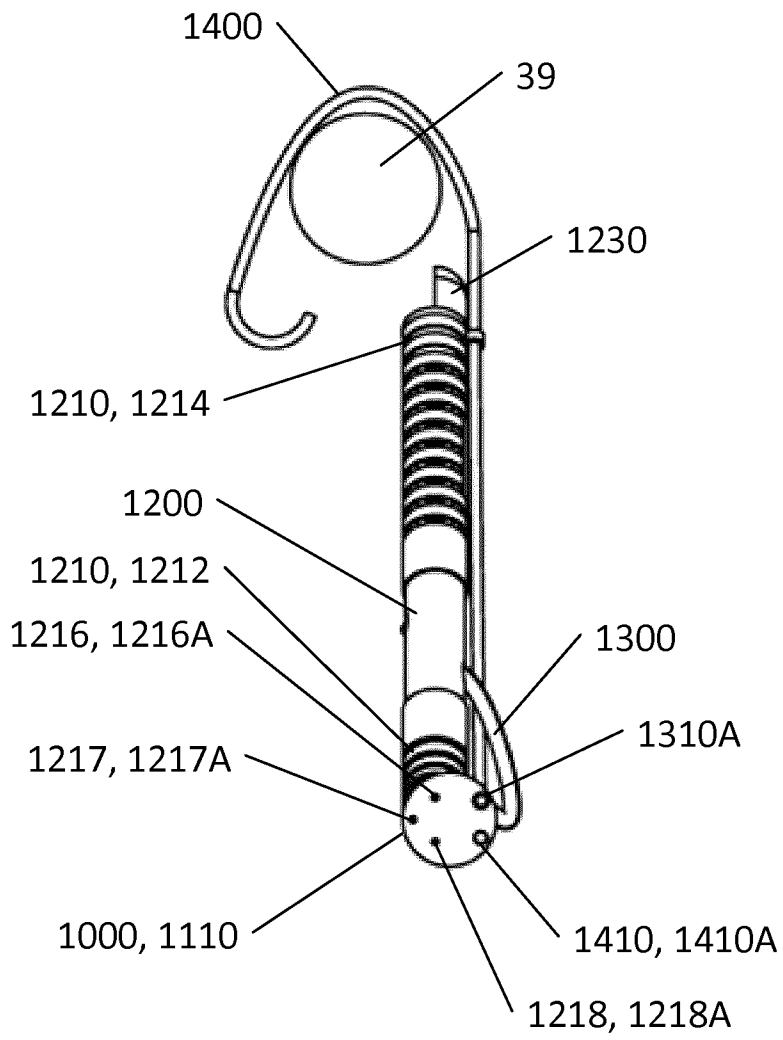


FIG. 17D

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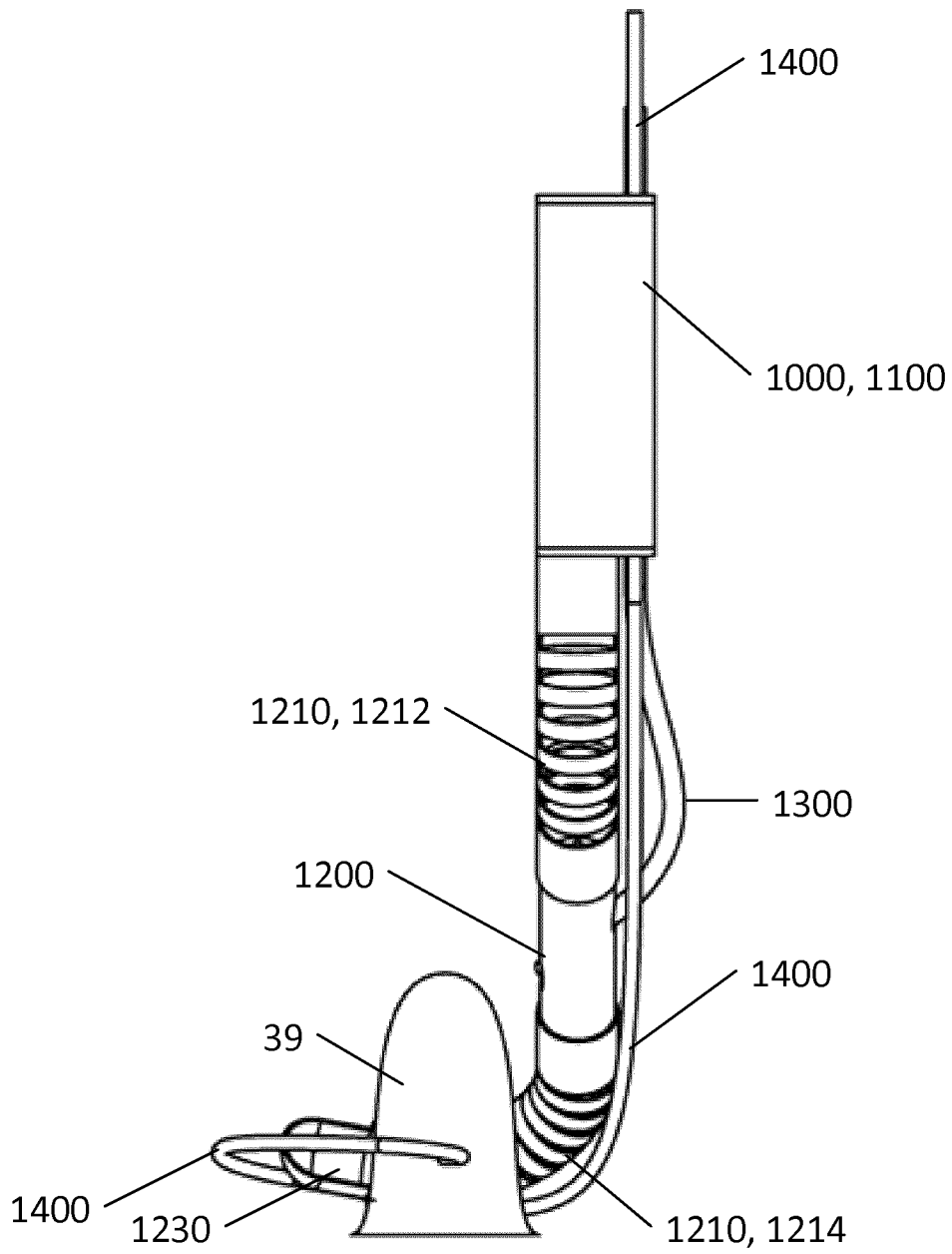


FIG. 17E

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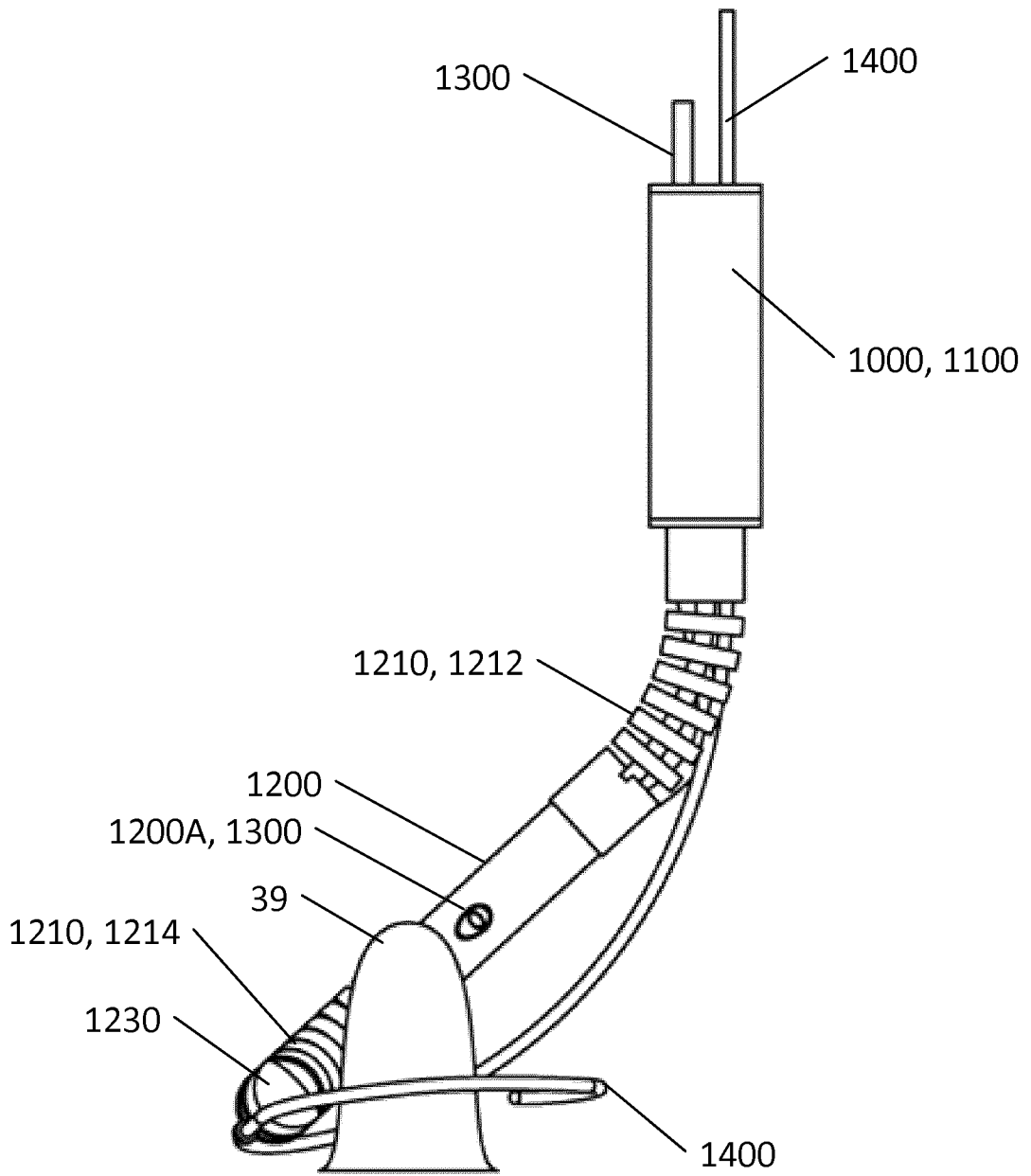


FIG. 17F

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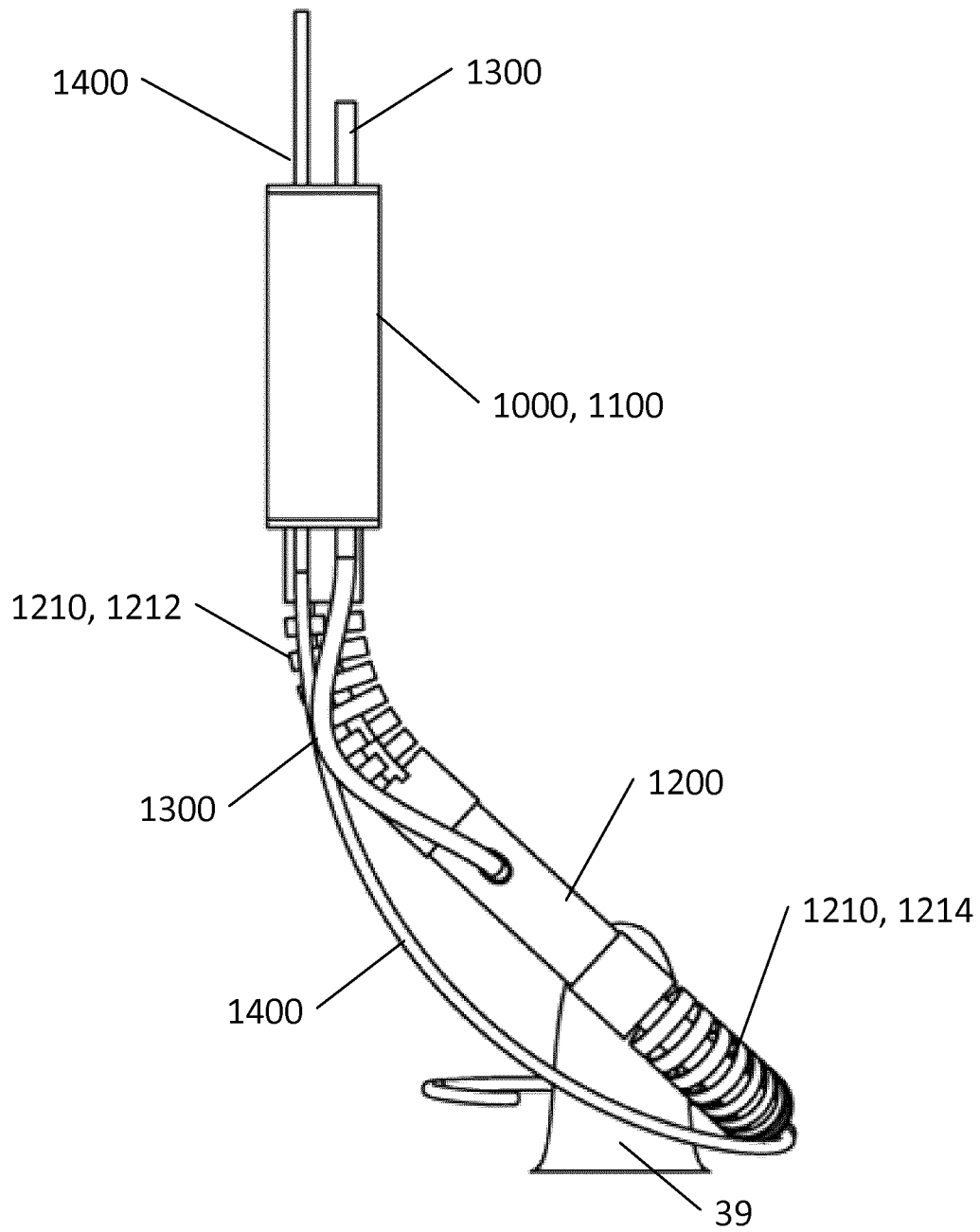


FIG. 17G

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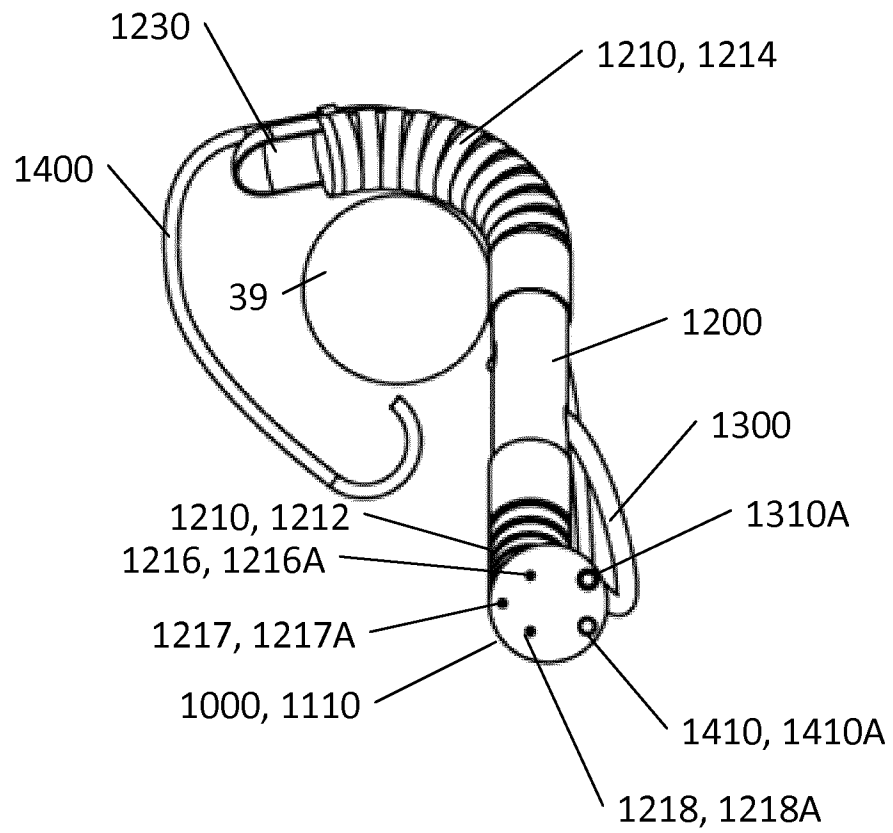


FIG. 17H

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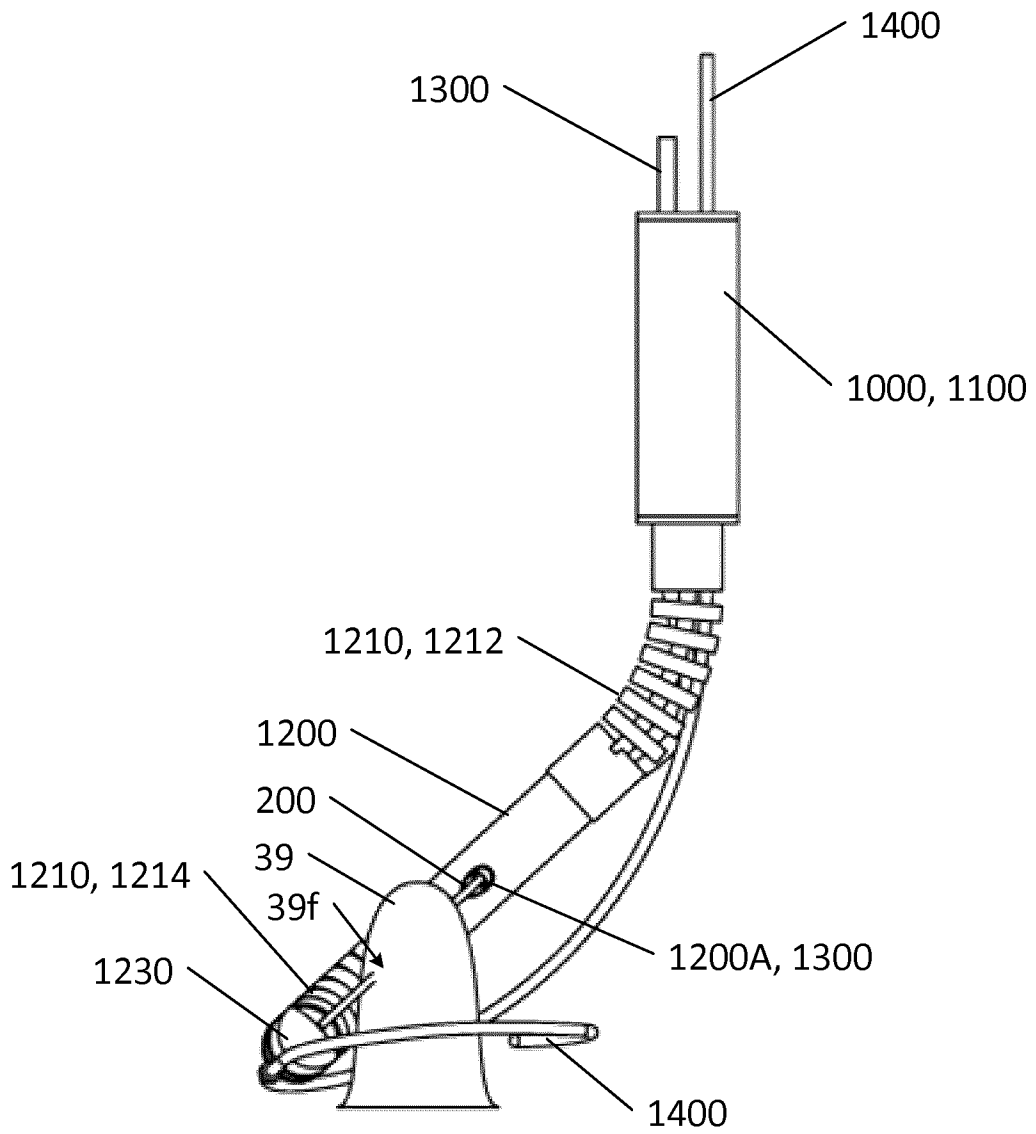


FIG. 171

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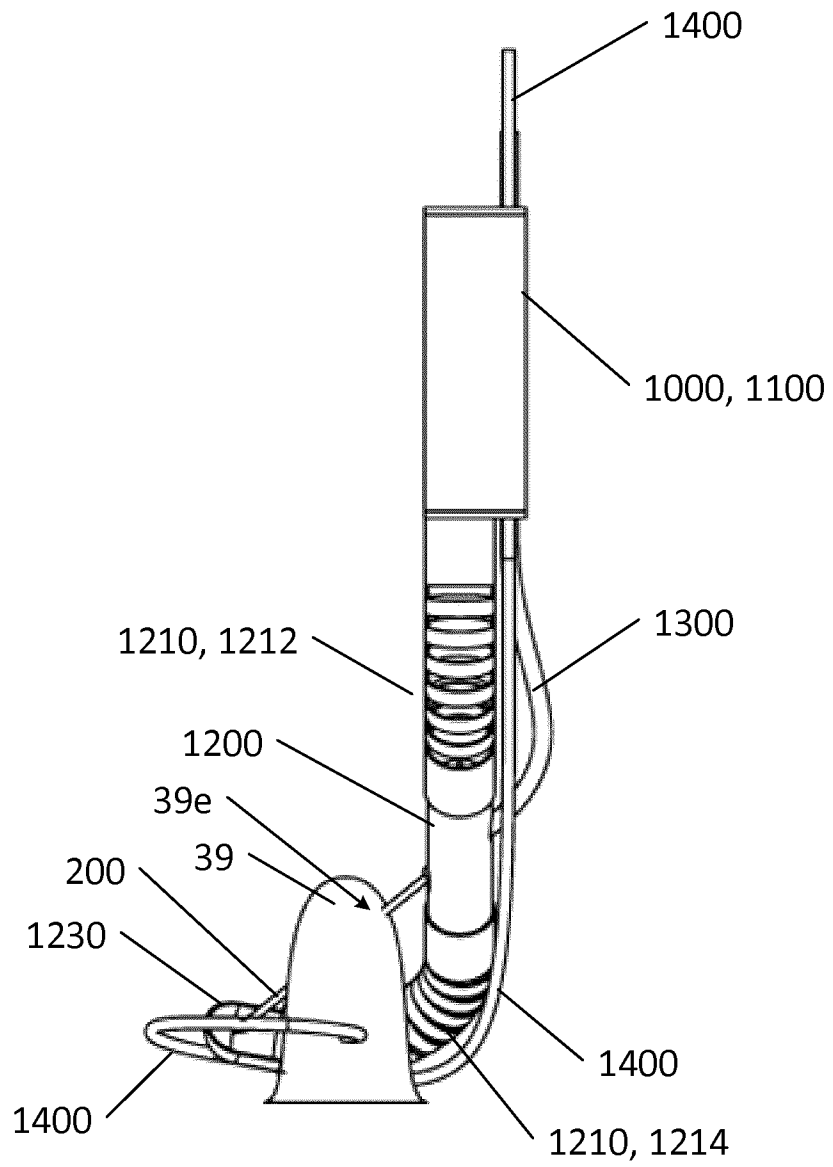


FIG. 17J

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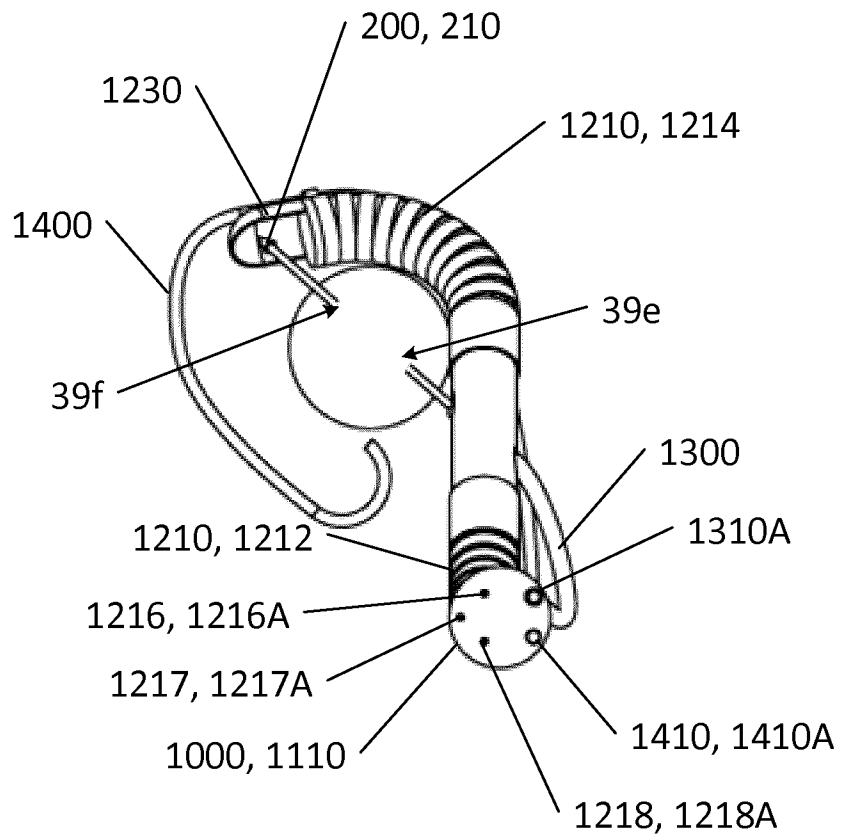


FIG. 17K

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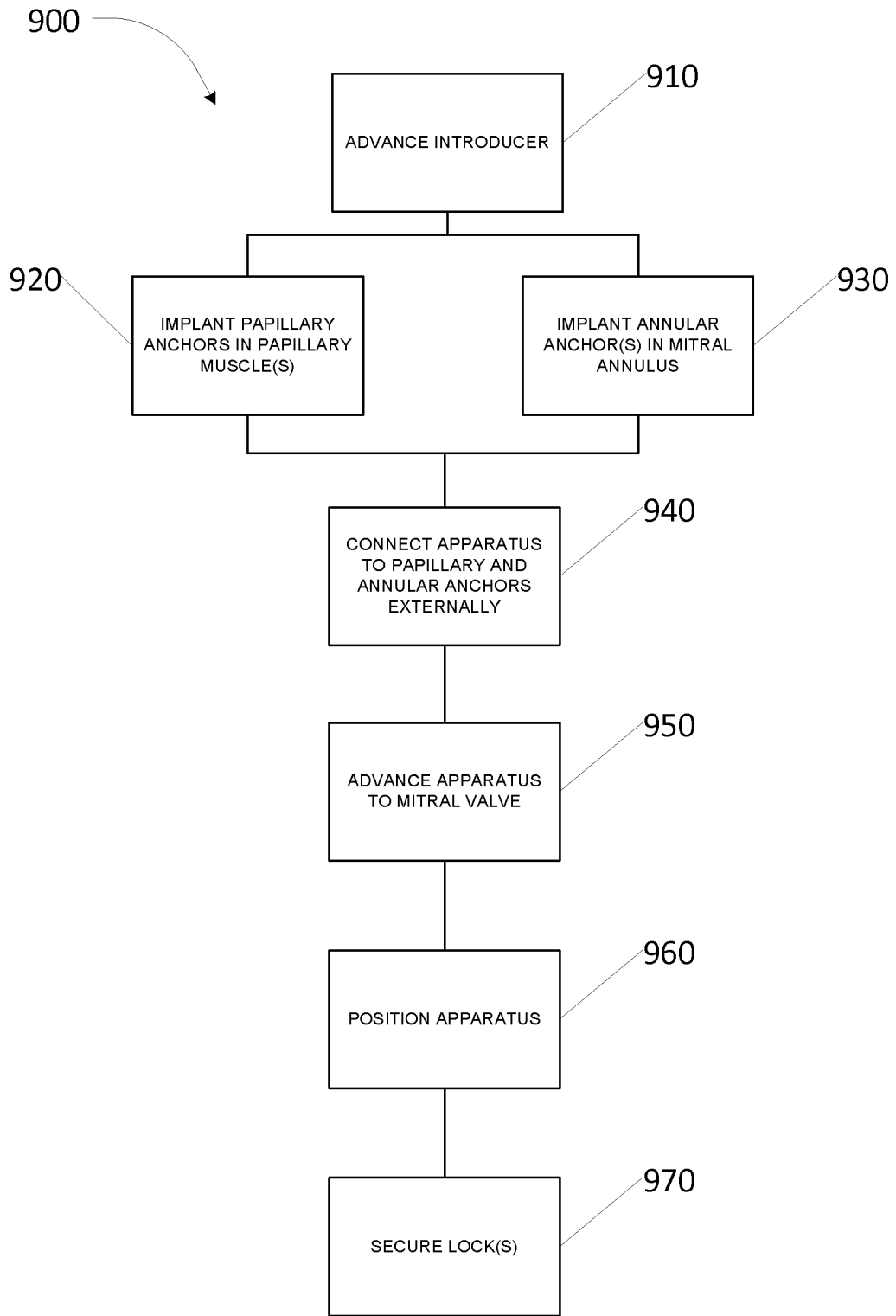


FIG. 18

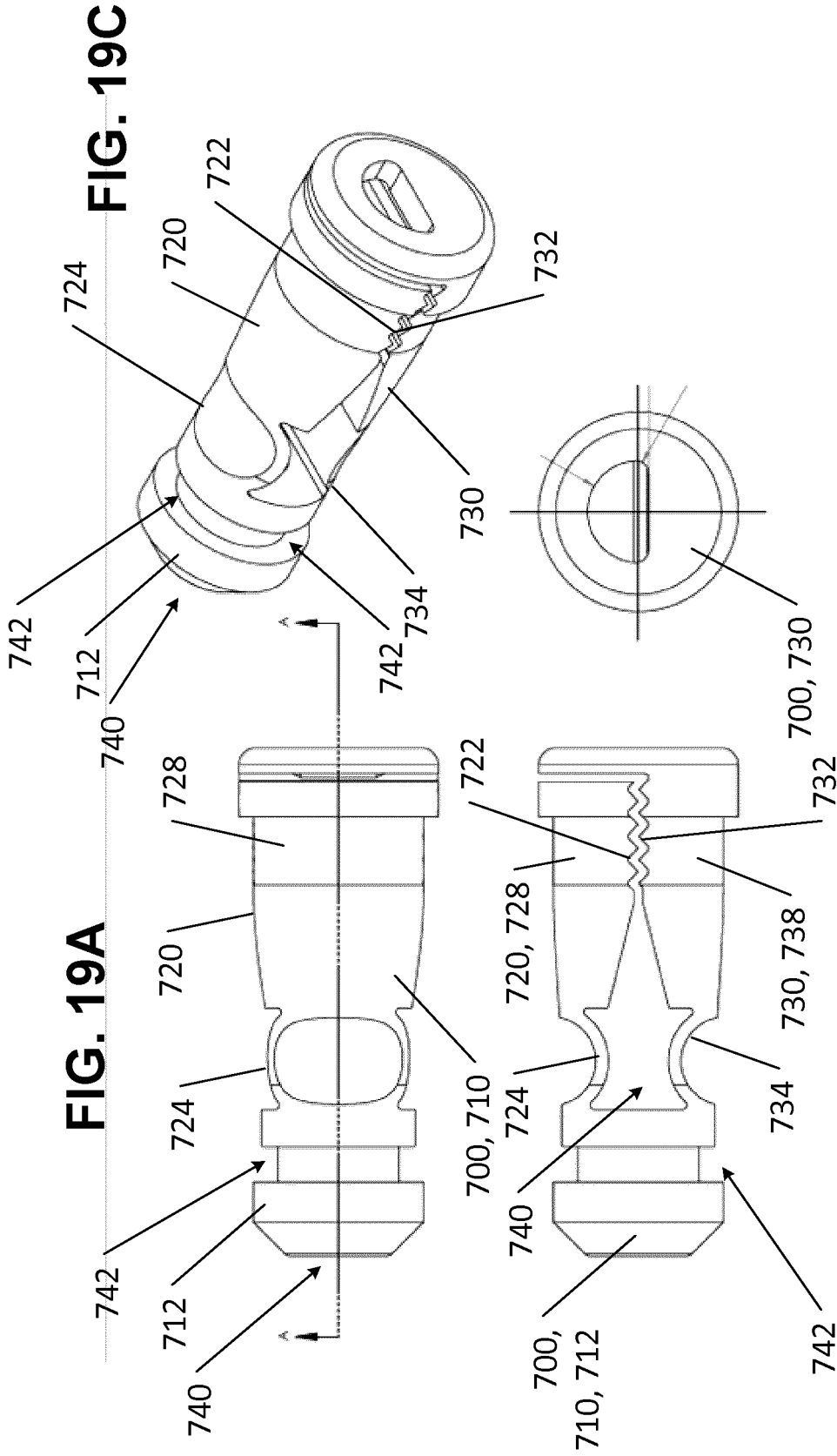


FIG. 19A

FIG. 19C

FIG. 19B

FIG. 19D

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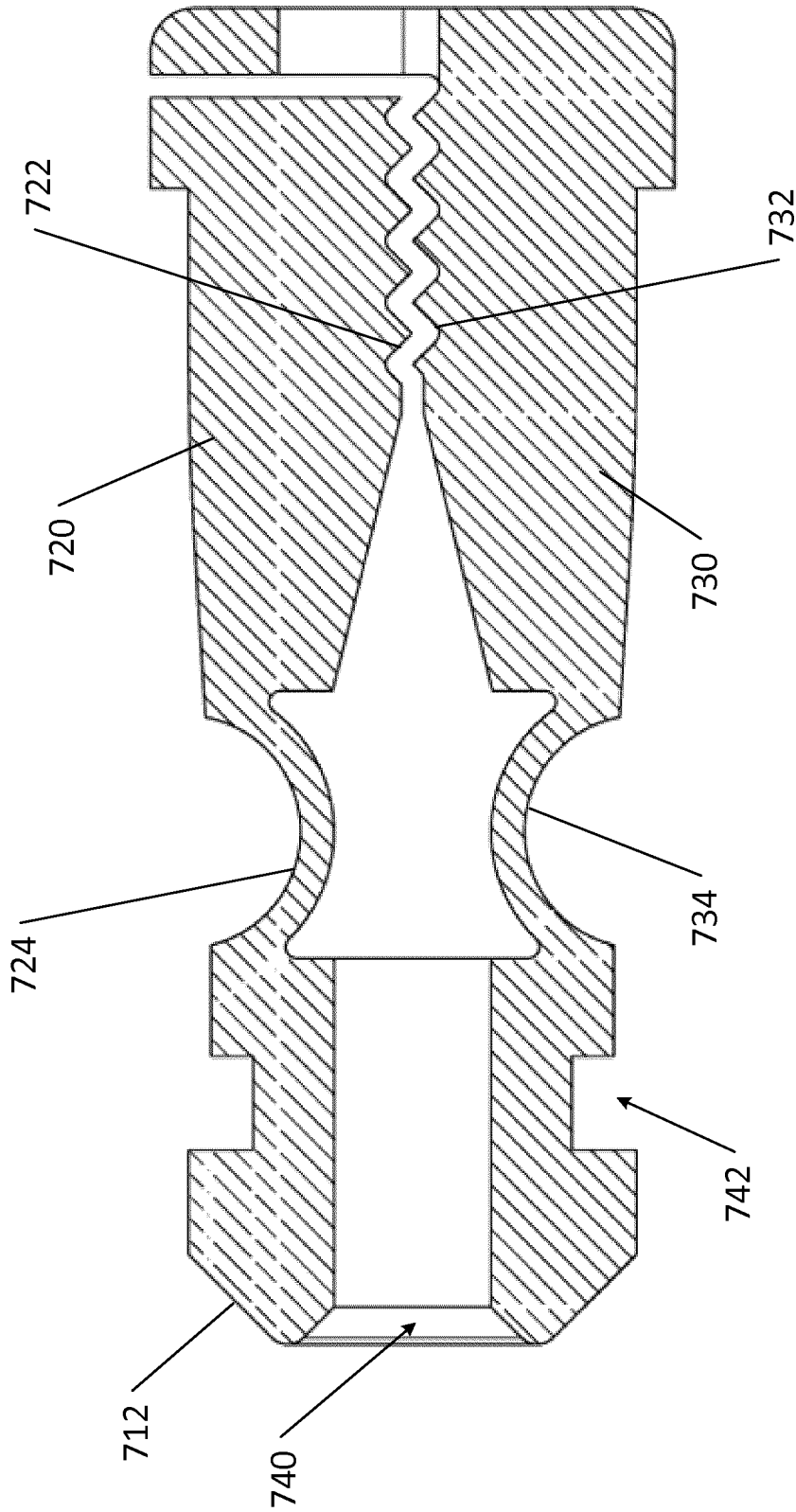


FIG. 19E

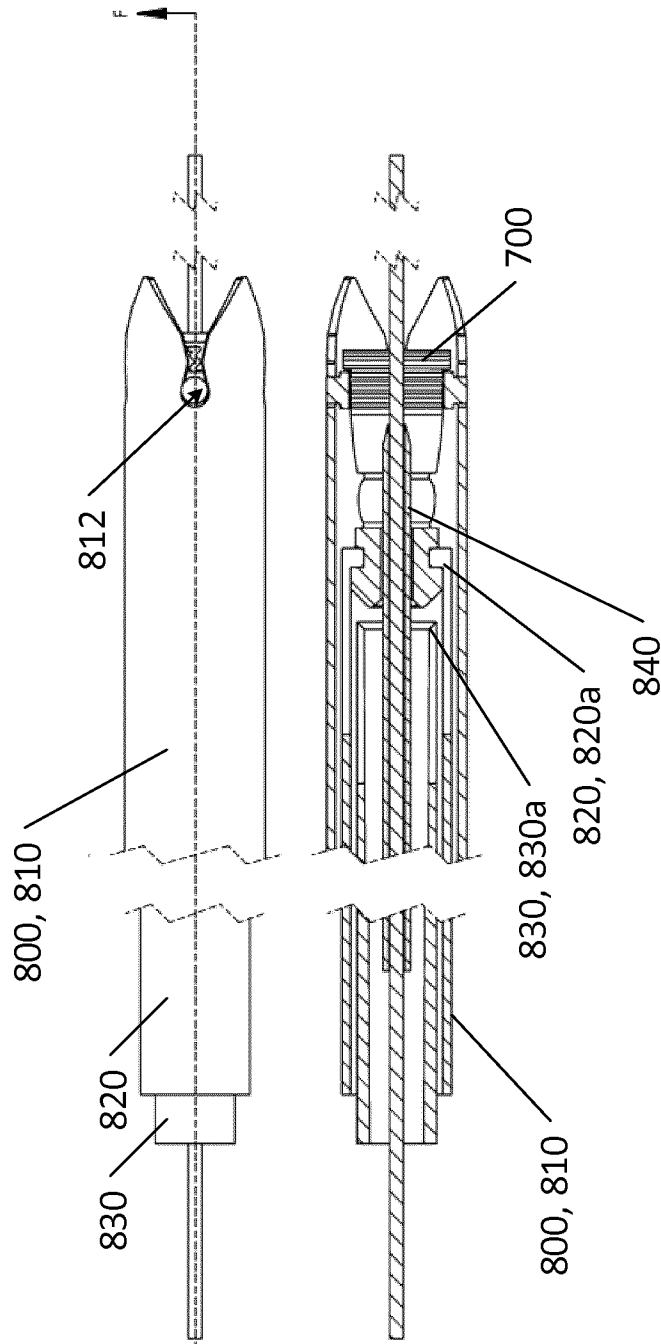


FIG. 20A

FIG. 20B

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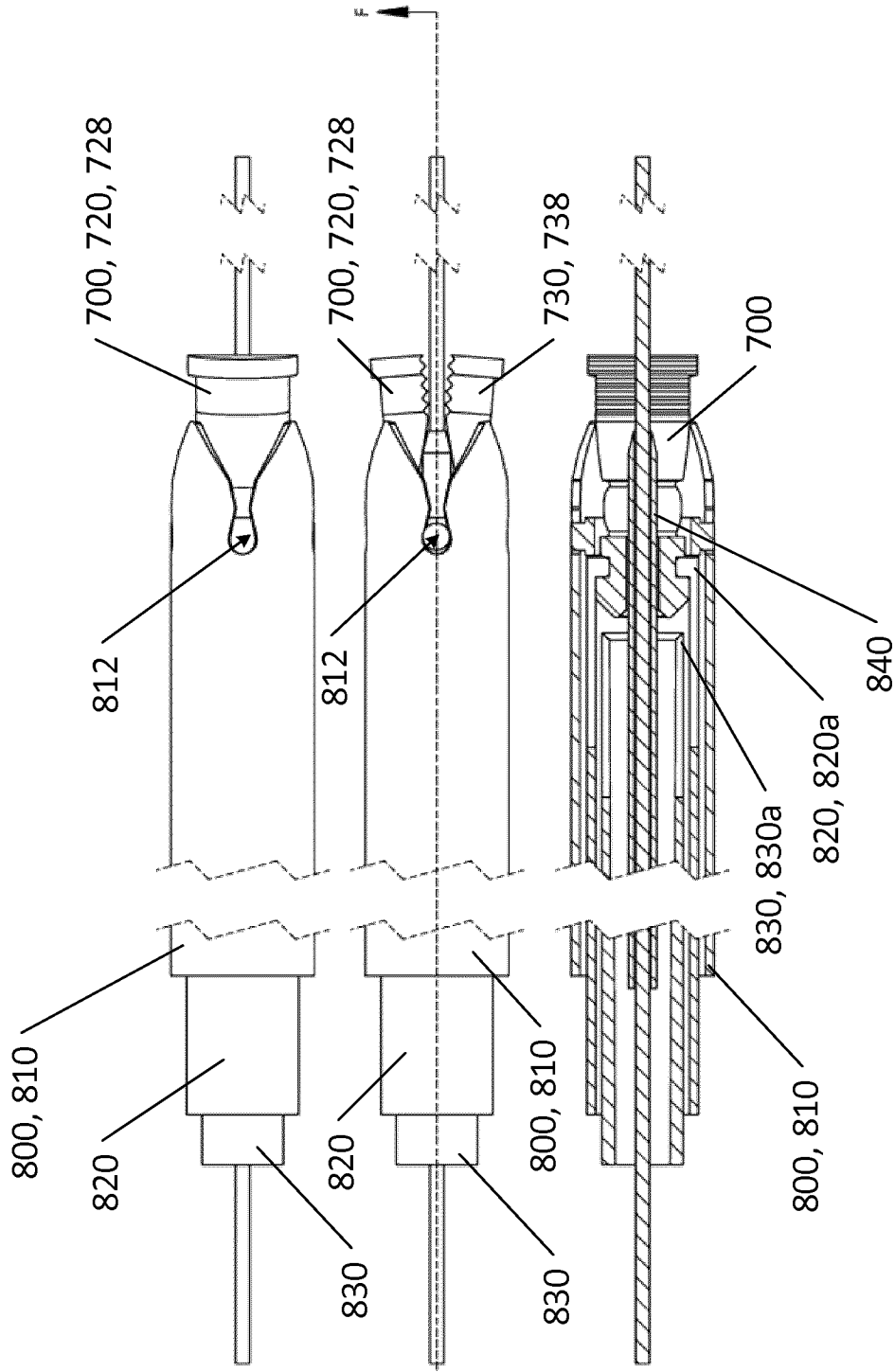


FIG. 20C

FIG. 20D

FIG. 20E

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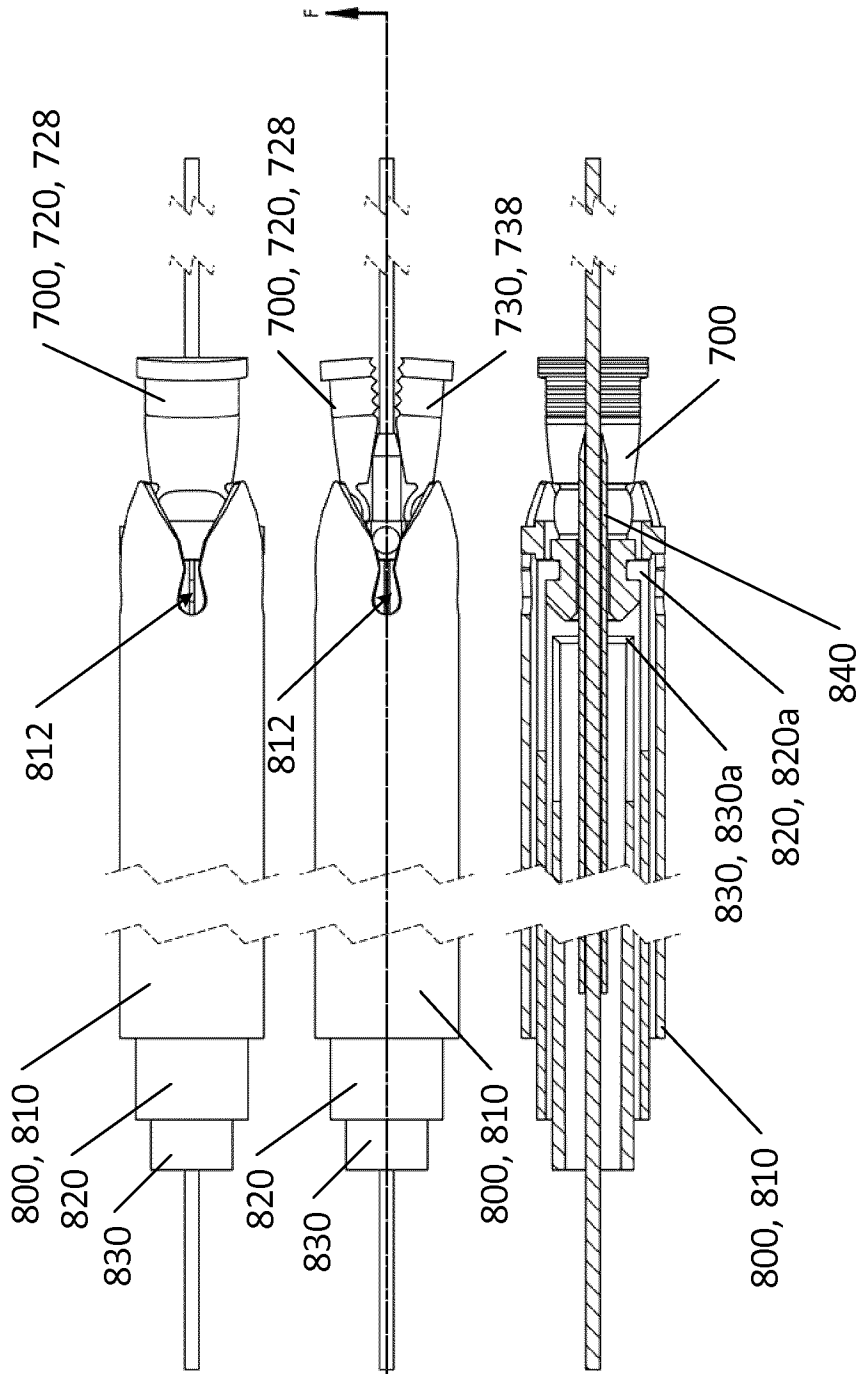
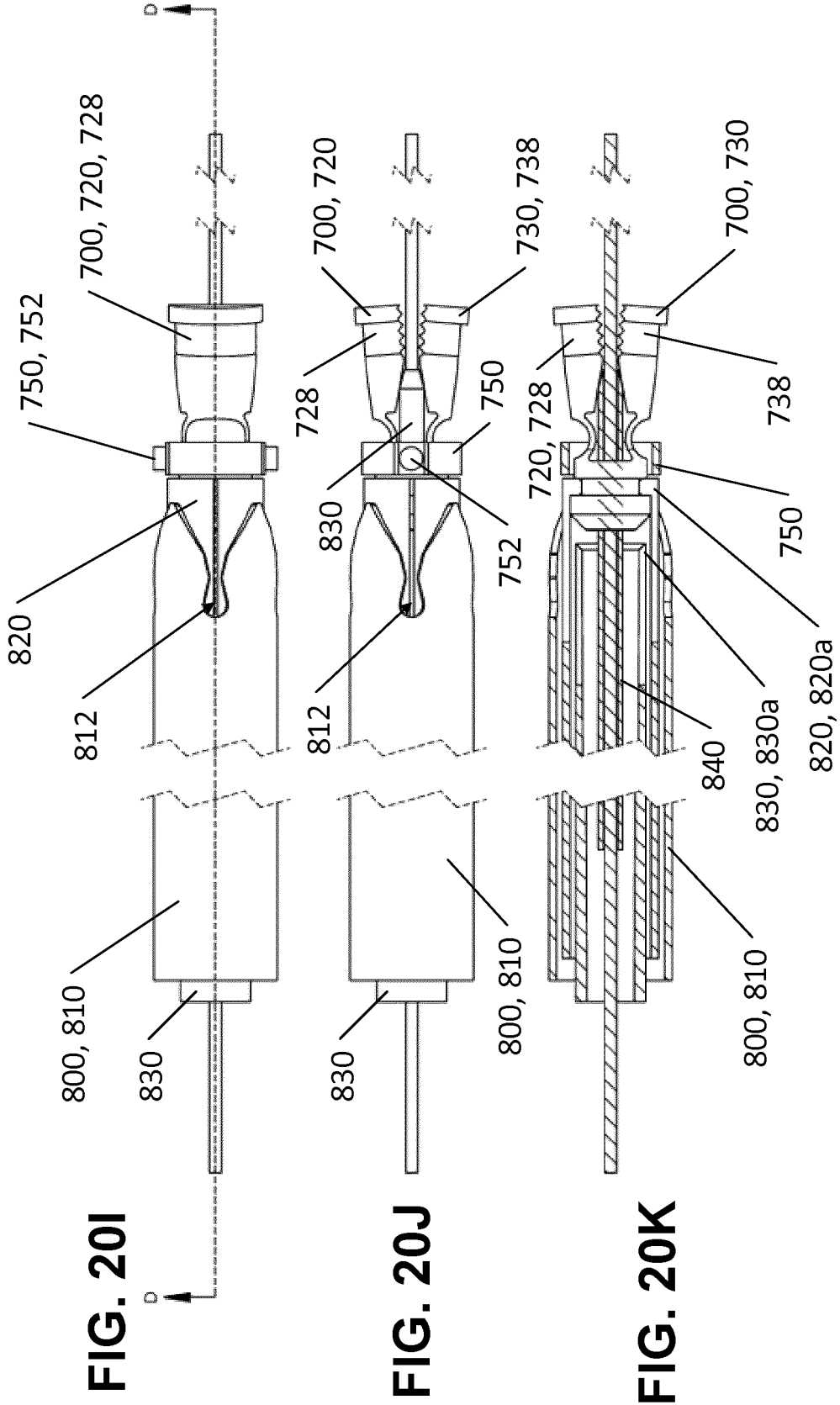


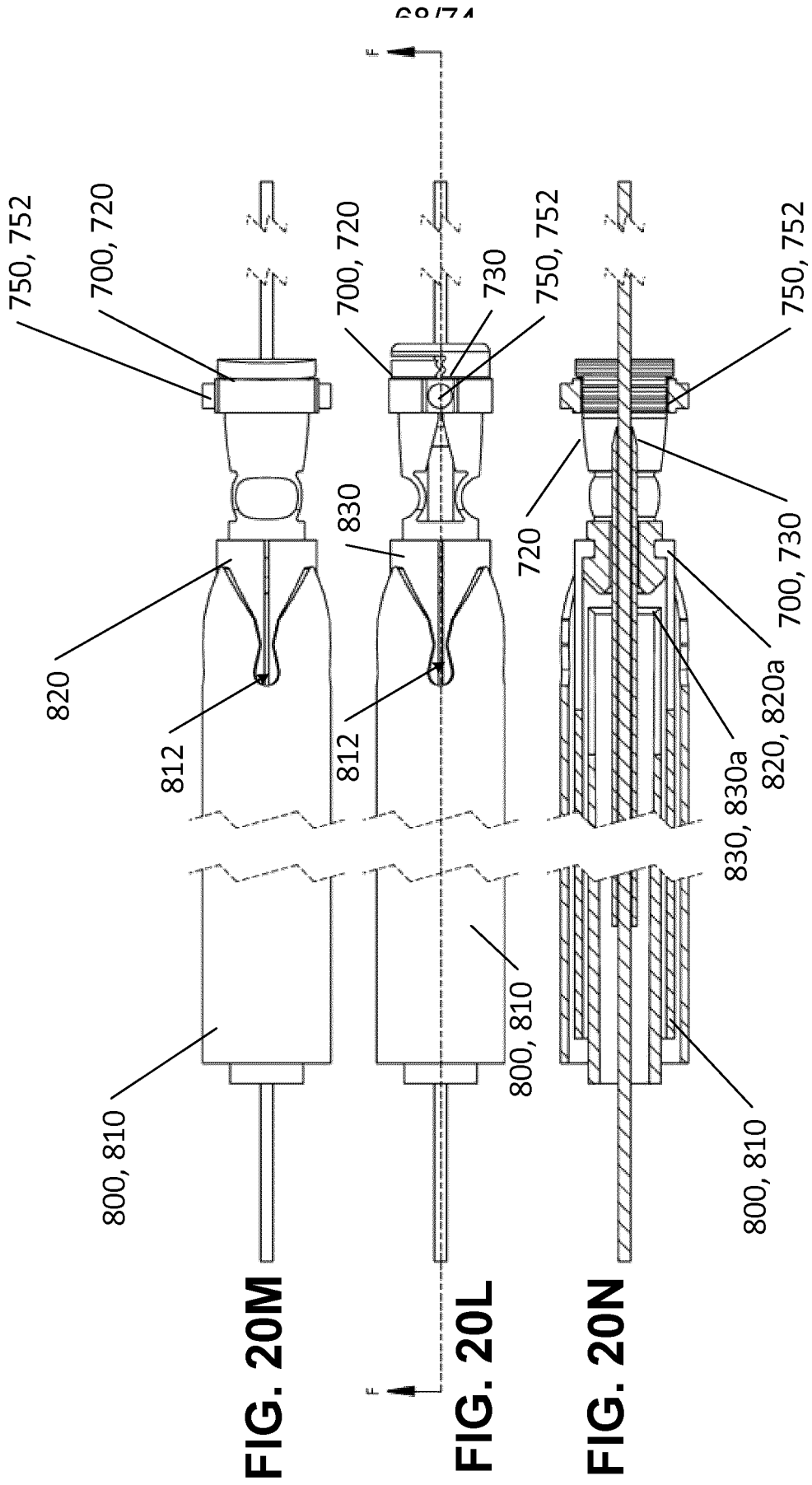
FIG. 20F

FIG. 20G

FIG. 20H

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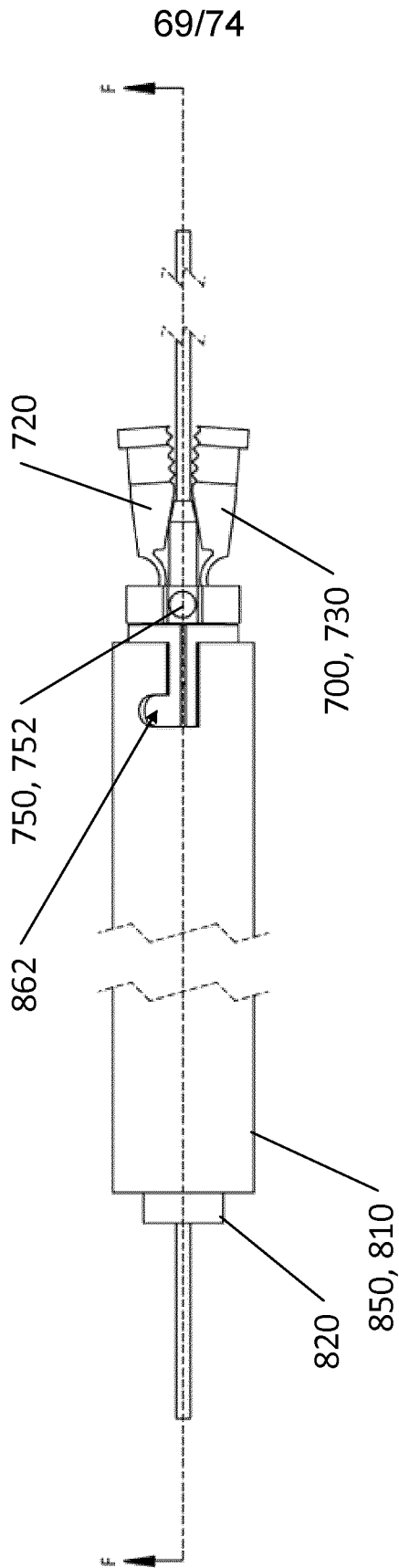


FIG. 21

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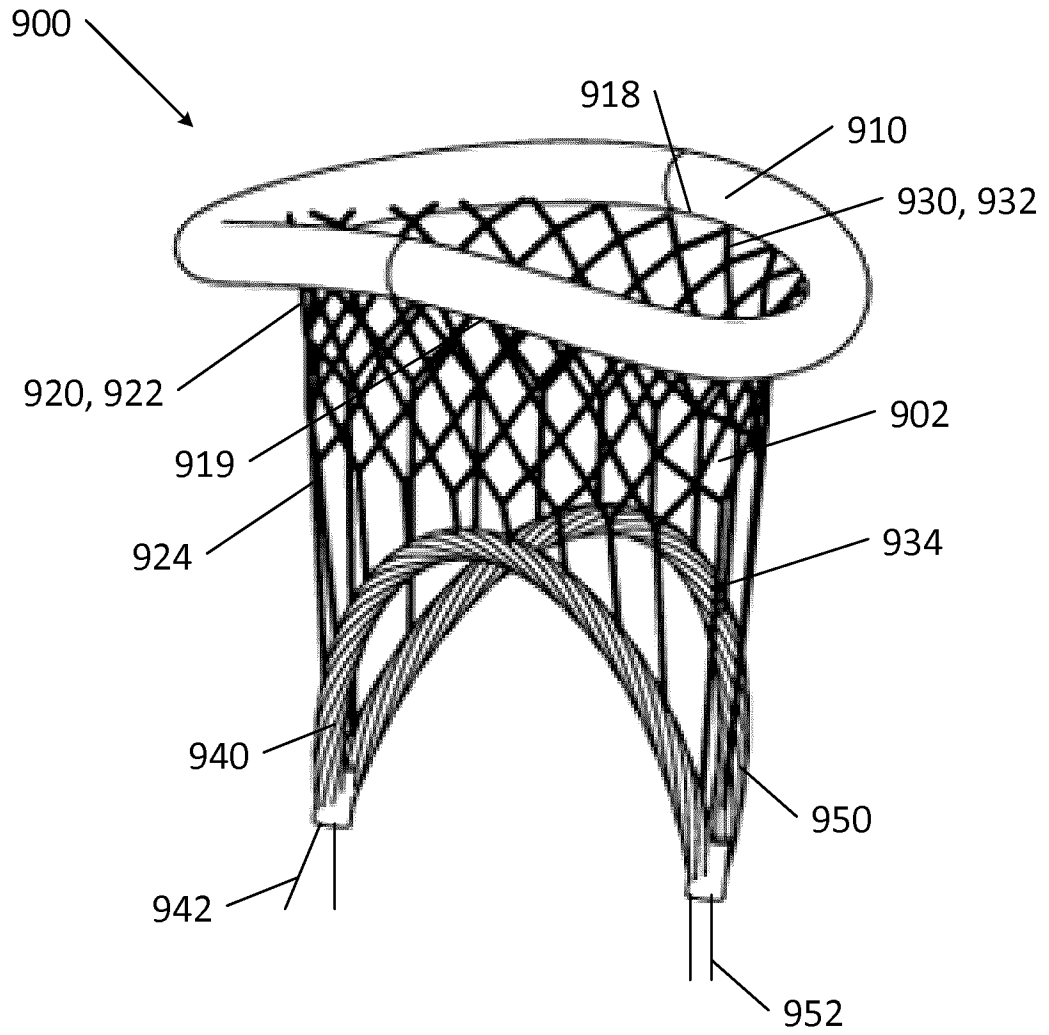


FIG. 22A

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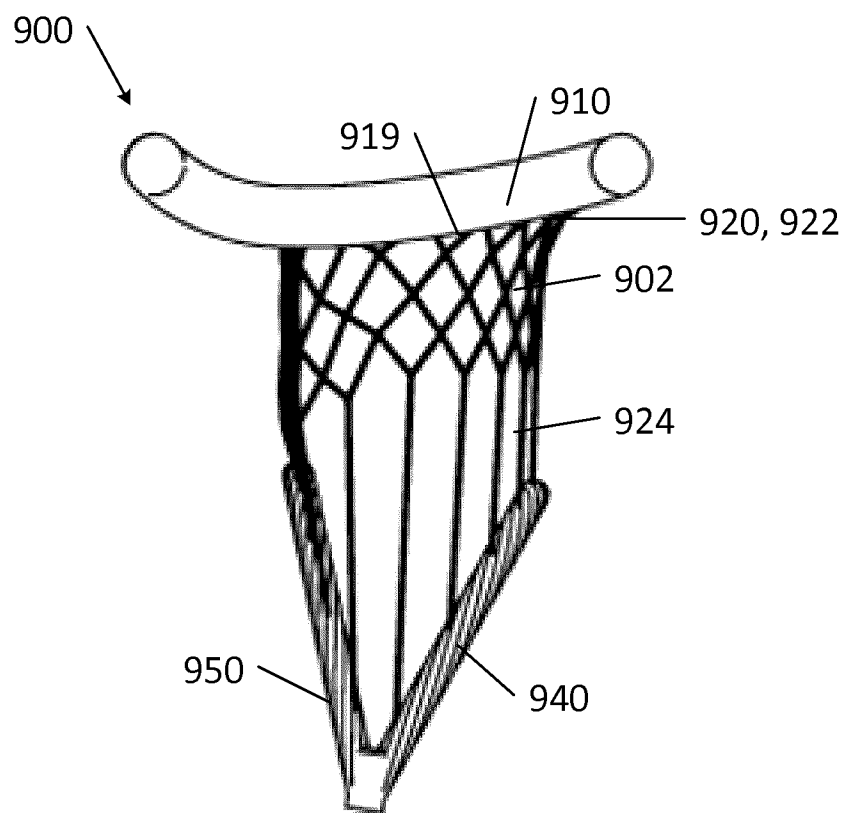


FIG. 22B

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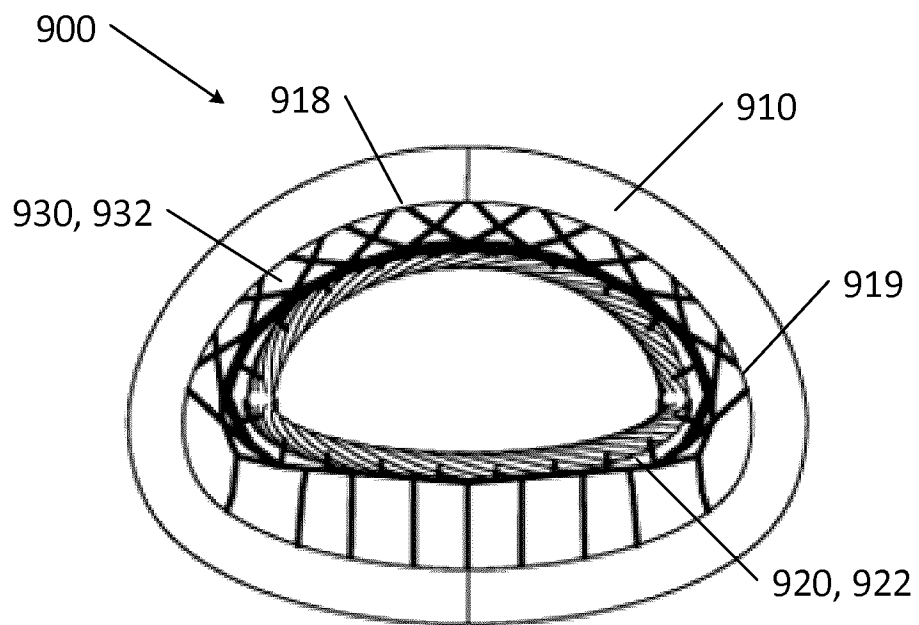


FIG. 22C

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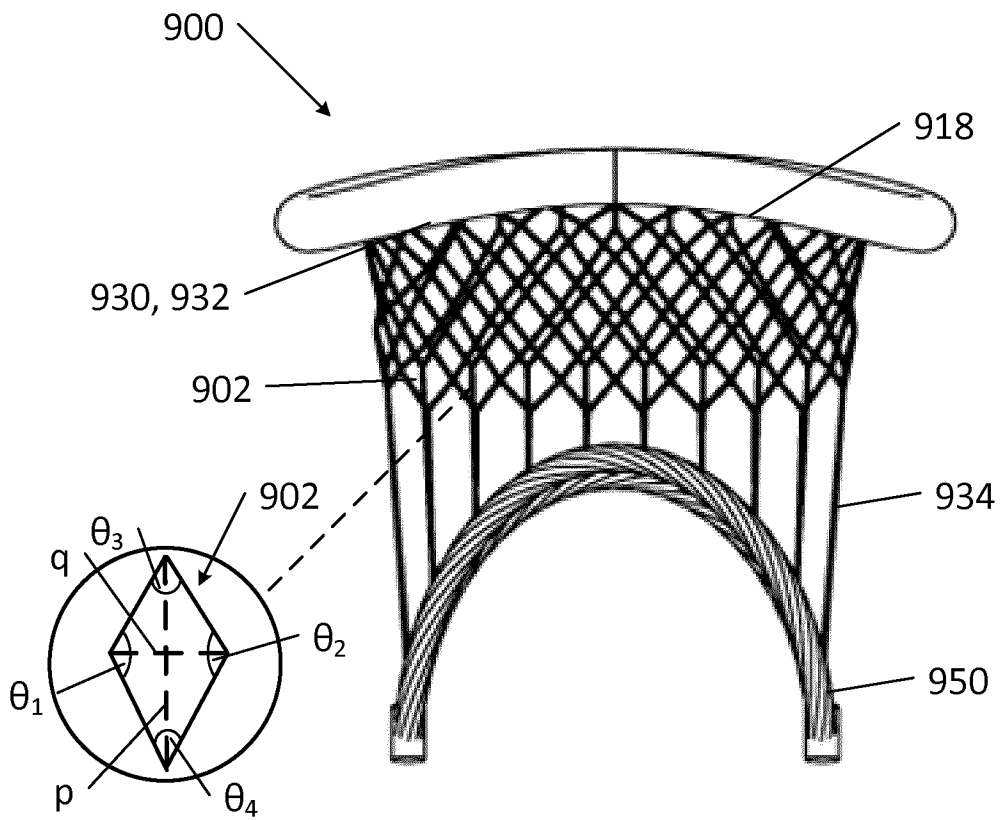


FIG. 22E

FIG. 22D

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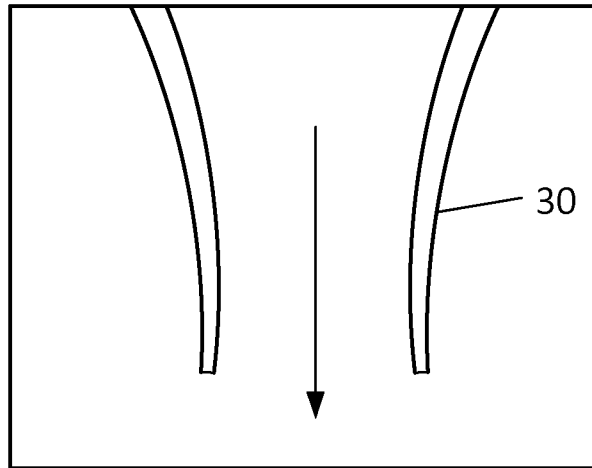


FIG. 23A

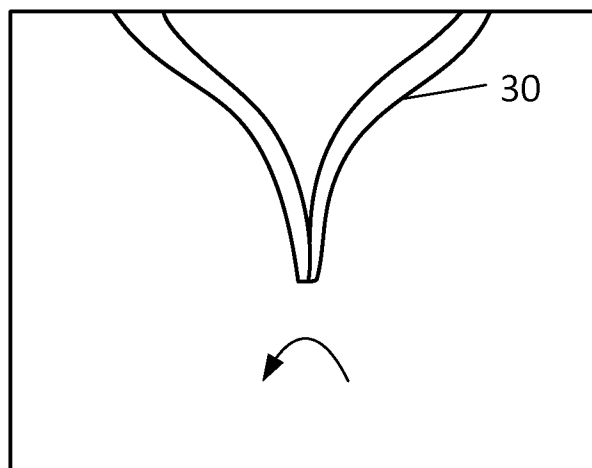


FIG. 23B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2020/050095A. CLASSIFICATION OF SUBJECT MATTER
IPC: *A61F 2/24* (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: *A61F 2/24* (2006.01)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
QUESTEL-ORBIT (FAMPAT database)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US20130172978A1 (VIDLUND et al.) 04 July 2013 (04-07-2013) - refer to figs.10-11	1
A	WO2018/057716A1 (SAAR et al.) 29 March 2018 (29-03-2018) - refer to entire document	1
A	WO2016/209970A1 (GREENE et al.) 29 December 2016 (29-12-2016) - refer to entire document	1
A	US20140358224A1 (TEGELS et al.) 04 December 2014 (04-12-2014) - refer to entire document	1
A	US20100082094A1 (QUADRI et al.) 01 April 2010 (01-04-2010) - refer to entire document	1

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	“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
“A” document defining the general state of the art which is not considered to be of particular relevance	“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
“D” document cited by the applicant in the international application	“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
“E” earlier application or patent but published on or after the international filing date	“&” document member of the same patent family
“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	

Date of the actual completion of the international search
17 April 2020 (17-04-2020)Date of mailing of the international search report
27 April 2020 (27-04-2020)Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 819-953-2476Authorized officer

Ishtiaque Ibne Rashid (819) 639-7889

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2020/050095

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2013/028387A2 (VIDLUND et al.) 28 February 2013 (28-02-2013) - refer to entire document	1
A	WO2011/072084A2 (SCHANKERELI et al.) 16 June 2011 (16-06-2011) - refer to entire document	1
A	EP3028668A1 (CENTOLA et al.) 08 June 2016 (08-06-2016) - refer to entire document	1
A	WO2015/152980A1 (BRAIDO et al.) 08 October 2015 (08-10-2015) - refer to entire document	1
A	US20040049262A1 (OBERMILLER et al.) 11 March 2004 (11-03-2004) - refer to entire document	1

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the 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. Claim Nos.: 25, 26, 37-39, 45, 55-75 and 84
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 25, 26, 37-39, 45, 55-75 and 84 are directed to a method of medical treatment that includes a surgical step, which the International Searching Authority is not required to examine under PCT Rule 67.1(iv).

2. Claim 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:

3. Claim 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:

see supplemental sheet

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 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 claim 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 claim Nos.:

1-18 and 85-92

- 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.

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

The claims are directed to a plurality of inventive concepts as follows:

Group A - Claims 1-18 and 85-92 are directed to an apparatus for repairing a heart valve, the apparatus comprising: a body; a member attached to the body at a first end and having a plurality of positioning cords spaced laterally across the member and extending away from a second end of the member opposed to the first end; a tube suspended from the plurality of positioning cords, wherein the plurality of positioning cords is spaced laterally across the tube; and an adjustment cord extending through the tube, wherein the tube may be lengthened or shortened by tensioning the adjustment cord.

Group B – Claims 19-24, 27-36, 40-44 and 46-54 are directed to an annular anchor and an annular anchor catheter.

Group C - Claims 76-83 are directed to a lock comprising a body defining opposed jaws and a channel extending lengthwise through the body and between the jaws, wherein the lock is deformable in an open configuration by deflecting the jaws away from each other and a lock catheter comprising: a sleeve tube; a lock tube; and a deploying tube, wherein the sleeve tube houses the lock tube and the lock tube houses the deploying tube.

The claims in the above groups fail to have a special technical feature linking the groups together to form a single inventive concept.

The claims must be limited to one inventive concept as set out in **PCT Rule 13**.

Claims 25, 26, 37-39, 45, 55-75 and 84 are directed to a method of medical treatment that includes a surgical step, which the International Searching Authority is not required to search under PCT Rule 39.1(iv).

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2020/050095

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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		US2018078368A1	22 March 2018 (22-03-2018)
WO2018057716A1	29 March 2018 (29-03-2018)	EP3515365A1	31 July 2019 (31-07-2019)
		EP3515365A4	25 September 2019 (25-09-2019)
		US2018078367A1	22 March 2018 (22-03-2018)
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		EP2419050A4	30 July 2014 (30-07-2014)
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International application No.

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		EP2901966B1	29 June 2016 (29-06-2016)
		EP3001978A1	06 April 2016 (06-04-2016)
		EP3001978B1	31 October 2018 (31-10-2018)
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		JP2014230797A	11 December 2014 (11-12-2014)
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2020/050095

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International application No.

PCT/CA2020/050095

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		EP1255510B3	04 March 2009 (04-03-2009)
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2020/050095

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		PL211544B1	31 May 2012 (31-05-2012)
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