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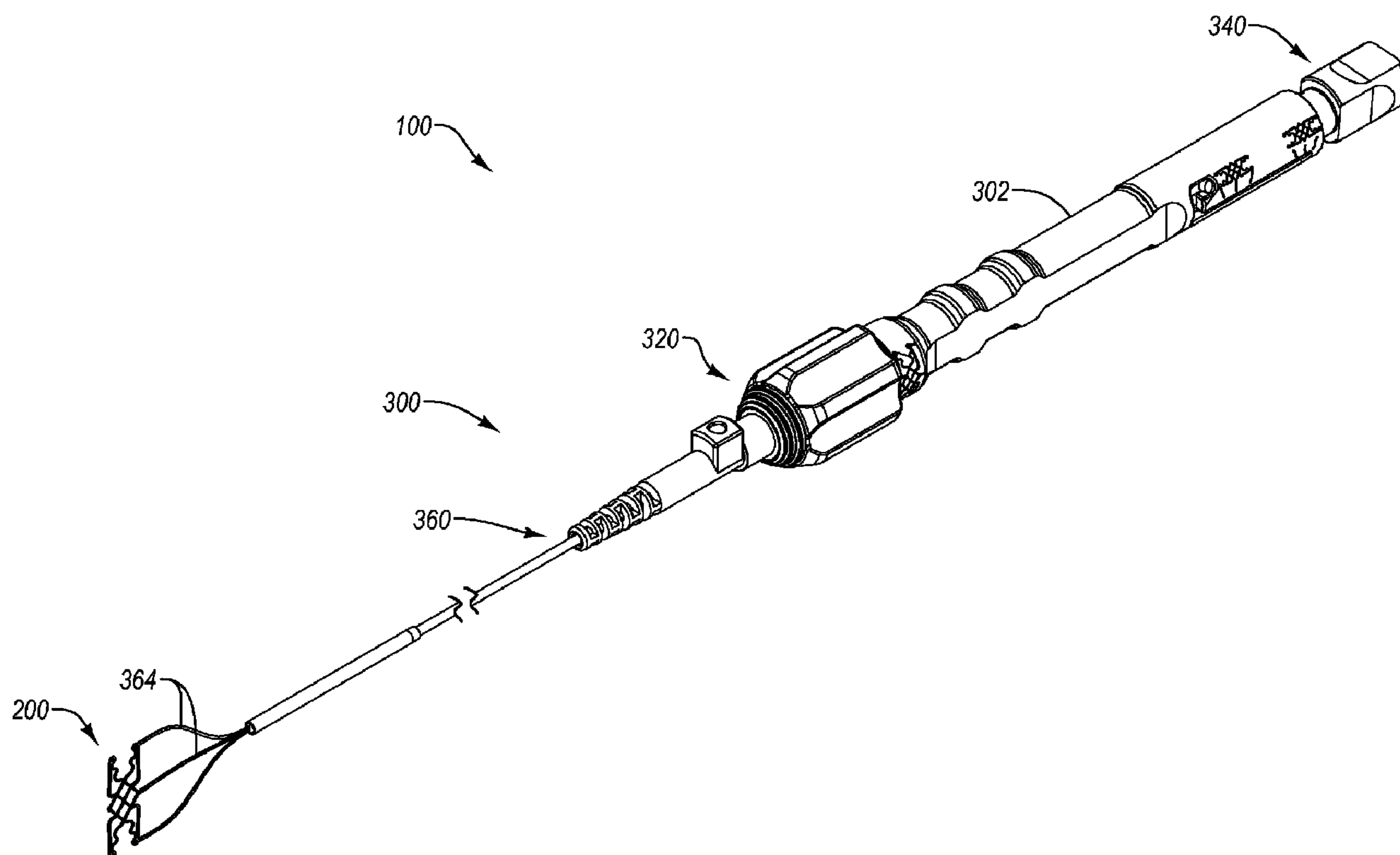
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(54) Title: DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING



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A medical system for treating an internal tissue opening can include a closure device and associated delivery device. The closure device can include a body portion operatively associated with a first anchor and a second anchor. The body portion can include a plurality of segments defining a multi-cellular structure. The closure device can be configured to apply lateral force to tissue of the internal tissue opening to bring tissue together. The closure device can have a substantially flat aspect, and have a depth thickness that is substantially greater than the thickness or width of a majority of the members forming the closure device to reduce out of plane bending. The closure device can also include a member adapted to induce tissue growth.

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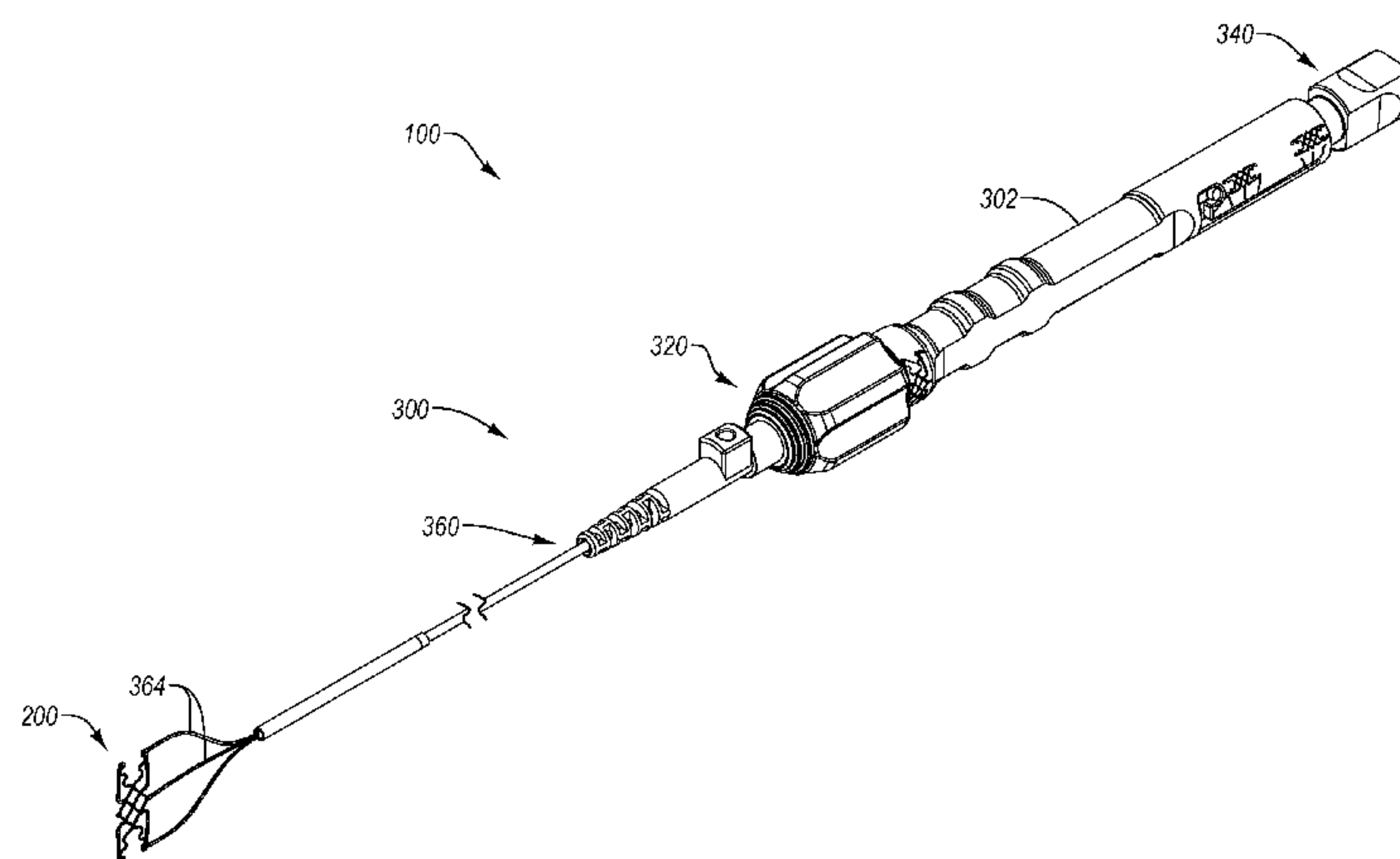
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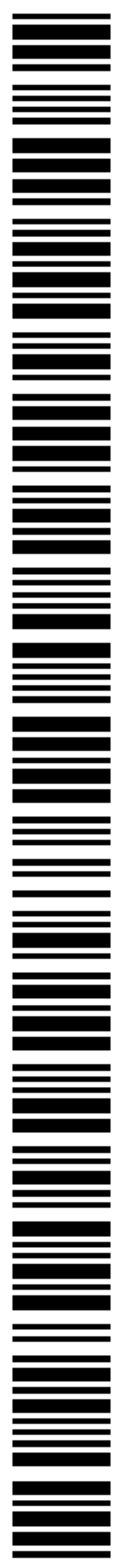
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(54) Title: DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING



(57) Abstract: A medical system for treating an internal tissue opening can include a closure device and associated delivery device. The closure device can include a body portion operatively associated with a first anchor and a second anchor. The body portion can include a plurality of segments defining a multi-cellular structure. The closure device can be configured to apply lateral force to tissue of the internal tissue opening to bring tissue together. The closure device can have a substantially flat aspect, and have a depth thickness that is substantially greater than the thickness or width of a majority of the members forming the closure device to reduce out of plane bending. The closure device can also include a member adapted to induce tissue growth.



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DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/821,947, filed August 9, 2006, U.S. Provisional Application No. 60/821,949, filed August 9, 2006, U.S. Provisional Application No. 60/829,507, filed October 13, 2006, U.S. Provisional Application No. 60/866,047, filed November 15, 2006, and U.S. Provisional Application No. 60/942,625, filed June 7, 2007, the contents of each of which are hereby incorporated by reference in their entirety. This application relates to U.S. Patent Application Serial No. 11/836,000, filed August 8, 2007, titled DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.1), U.S. Patent Application Serial No. 11/836,016, filed August 8, 2007, titled DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.2), U.S. Patent Application Serial No. 11/836,037, filed August 8, 2007, titled DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.3), U.S. Patent Application Serial No. 11/836,051, filed August 8, 2007, titled SYSTEMS AND DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.4), U.S. Patent Application Serial No. 11/836,013, filed August 8, 2007, titled SYSTEMS AND DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.5), U.S. Patent Application Serial No. 11/836,026, filed August 8, 2007, titled METHODS FOR DETERMINING CHARACTERISTICS OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.6), and U.S. Patent Application Serial No. 11/836,123, filed August 8, 2007, titled METHODS, SYSTEMS AND DEVICES FOR REDUCING THE SIZE OF AN INTERNAL TISSUE OPENING (Attorney Docket No. 16348.27.7), the contents of each of which are hereby incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present invention relates generally to medical devices and methods of use for treating an internal tissue structure. More particularly, the present invention

relates to medical devices, systems, and methods for reducing the size of an internal tissue opening.

2. The Relevant Technology

Physical malformations or defects that are present at birth can be detrimental and even lethal when left uncorrected. A PFO is an example of a cardiac birth defect that can be problematic and even result in death when combined with other factors such as blood clots or other congenital heart defects. A PFO occurs when an opening between the upper two chambers of the heart fail to close after birth.

Some of the problems associated with a PFO can occur when a blood clot travels from the right to the left atria of the heart through the PFO, and lodges in an artery that feeds blood to the brain. A blood clot in the left atrium can be passed through the aorta and travel to the brain or other organs, and cause embolization, stroke, or a heart attack. A PFO can be treated by being closed by a surgical procedure. Additionally, other similar defects (*e.g.*, septal or otherwise) where some tissue needs to be closed in order to function properly can include the general categories of atrial-septal defects (“ASDs”), ventricular-septal defects (“VSD’s”) and patent ductus arteriosus (“PDA”), and the like.

Figures 1A-1C depict various views of a heart having a PFO. The heart 10 is shown in a cross-section view in Figure 1A. In a normal heart 10, the right atrium 30 receives systemic venous blood from the superior vena cava 15 and the inferior vena cava 25, and then delivers the blood via the tricuspid valve 35 to the right ventricle 60. However, in the depicted heart 10 a septal defect, which is shown as a PFO 50, is present between right atrium 30 and left atrium 40.

The PFO 50 is depicted as an open flap on the septum between the heart’s right atrium 30 and left atrium 40. In a normal heart 10, the left atrium 40 receives oxygenated blood from the lungs via pulmonary artery 75, and then delivers the blood to the left ventricle 80 via the mitral valve 45. In a heart 10 having a PFO 50 some systemic venous blood can also pass from the right atrium 30 through the PFO 50 and mixes with the oxygenated blood in left atrium 40, and then is routed to the body from left ventricle 80 via aorta 85.

During fetal development of the heart 10, the interventricular septum 70 divides the right ventricle 60 and left ventricle 80. In contrast, the atrium is only

partially partitioned into right and left chambers during normal fetal development, which results in a foramen ovale fluidly connecting the right and left atrial chambers. As shown in Figure 1B, when the septum primum 52 incompletely fuses with the septum secundum 54 of the atrial wall, the result can be a tunnel 58 depicted as a PFO 50.

Figure 1C provides a view of the crescent-shaped, overhanging configuration of the septum secundum 54 from within the right atrium 30 in a heart 10 having a PFO 50. The septum secundum 54 is defined by its inferior aspect 55, corresponding with the solid line in Figure 1C, and its superior aspect 53 represented by the phantom line, which is its attachment location to the septum primum 52. The septum secundum 54 and septum primum 52 blend together at the ends of the septum secundum 54. The anterior end 56a and posterior end 56p are referred to herein as “merger points” for the septum secundum 54 and septum primum 52. The length of the overhang of the septum secundum 54, which is the distance between superior aspect 53 and inferior aspect 55, increases towards the center portion of the septum secundum as shown.

The tunnel 58 between the right atrium 30 and left atrium 40 is defined by portions of the septum primum 52 and septum secundum 54 between the merger points 56a and 56p which have failed to fuse. The tunnel 58 is often at the apex of the septum secundum 54 as shown. When viewed within right atrium 30, the portion of the septum secundum 54 to the left of tunnel 58, which is referred to herein as the posterior portion 57p of the septum secundum, is longer than the portion of the septum secundum 54 to the right of tunnel 58, which is referred to herein as the anterior portion 57a of the septum secundum 54. In addition to being typically longer, the posterior portion 57p also typically has a more gradual taper than the anterior portion 57a as shown. The anterior pocket 59a is the area defined by the overhang of the anterior portion 57a of the septum secundum 54 and the septum primum 52, and it extends from the anterior merger point 56a toward the tunnel 58. Similarly, the posterior pocket 59p is the area defined by the overhang of the posterior portion 57p of septum secundum 54 and the septum primum 52, and it extends from the posterior merger point 56p toward the tunnel 58.

Conventional treatments for PFO, and other related conditions have generally involved invasive surgery, which also presents a risks to a patient. Although there are some less invasive treatments for PFO, such treatments have been less efficient at closing the PFO opening than techniques involving invasive surgery.

BRIEF SUMMARY OF THE INVENTION

The invention relates to a medical system, devices and methods of use for reducing the size of an internal tissue opening, such as a Patent Foramen Ovale ("PFO"). In one embodiment of the invention, the medical system can include a closure device and an associated delivery device. The medical system can be configured to enable a practitioner to selectively position and deploy the closure device in an internal tissue opening to approximate, or in other words bring together the tissue of the opening.

According to one embodiment of the invention, the closure device can include a multi-cellular body portion operatively associated with a first anchor and a second anchor. The multi-cellular body portion can be configured to enable the closure device to collapse into a relatively narrow non-deployed orientation and expand into a deployed or expanded orientation without plastic deformation or failure of the closure device. The first and second anchors can be configured to engage at least a portion of a wall of the internal tissue opening and/or tissue, such as tunnel tissue, of the opening. In one embodiment of the invention, the closure device can be a non-tubular, substantially flat stent.

In one embodiment of the invention the closure device can include an ingrowth material to facilitate tissue growth. The closure device can also include one or more indicators to facilitate the estimation of the position and/or orientation of the closure device with respect to the internal tissue opening.

In accordance with the present invention, the delivery device can include a delivery assembly, an actuating assembly, and a release assembly operatively associated with a handle body. In one embodiment of the invention, the delivery assembly facilitates selective delivery of the closure device from the delivery device, and is operatively associated with the actuating assembly and the release assembly. The actuating assembly interacts with the handle body to selectively deploy the closure device from the delivery assembly. In one embodiment of the invention, the

actuating assembly can be configured to deploy at least a portion of the closure device by a first movement and deploy a second portion of the closure device by a second movement. The release assembly can be linked to the handle body to facilitate detachment of the closure device from the delivery device.

In one embodiment, the closure device is linked to the delivery device by one or more tethers and one or more wires, the tethers being coupled to the handle body and the wires being coupled to a biasing member of the release assembly. The tethers can be configured to receive a portion of the closure device therein to facilitate securement of the closure device to the delivery device. The wires can be detachably coupled to the closure device to enable selective detachment of the closure device from the delivery device by movement of the biasing member.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figures 1A-1C illustrate exemplary views of a heart having a Patent Foramen Ovale;

Figure 2 illustrates a perspective view of an embodiment of a medical system according to the present invention;

Figure 3A illustrates an embodiment of a closure device according to the present invention;

Figure 3B illustrates an embodiment of a closure device in a non-deployed orientation according to the present invention;

Figure 3C illustrates a cut-out view of a portion of a closure device according to the present invention;

Figure 4 illustrates an embodiment of a delivery device according to the present invention;

Figures 5A-5C illustrate cross-sectional views of a delivery device according to the present invention;

Figure 6 illustrates an exploded view of a delivery device according to the present invention;

Figure 7 illustrates an embodiment of a coupling system according to the present invention;

Figure 8A illustrates an embodiment of a closure device being partially deployed in an internal tissue opening;

Figure 8B illustrates an embodiment of a delivery device in an orientation corresponding to the partially deployed closure device of Figure 8A;

Figure 9 illustrates an embodiment of a partially deployed closure device according to the present invention;

Figure 10A illustrates an embodiment of a closure device positioned in an internal tissue opening;

Figure 10B illustrates an embodiment of a delivery device in an orientation corresponding to the deployed and detached closure device of Figure 10A;

Figure 11A illustrates an embodiment of a closure device having an ingrowth material according to the present invention; and

Figure 11B illustrates a side view of the closure device of Figure 11A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention extends to medical systems, methods, and apparatus for reducing the size of an internal tissue opening. By way of explanation, the devices disclosed herein can be used to treat a variety of internal tissue openings, such as a left atrial appendage, paravalvular leaks, PDA's, and VSD's, for example. Although, for purposes of simplicity, frequent reference is made herein to reducing the size of or closing an opening in heart tissue known as Patent Foramen Ovale ("PFO"). Accordingly, it will be understood that references to PFO openings are not limiting of the invention.

In the following description, numerous specific details are set forth to assist in providing an understanding of the present invention. In other instances, aspects of

delivery and/or closure devices, or medical devices in general have not been described in particular detail in order to avoid unnecessarily obscuring the present invention. In addition, it is understood that the drawings are diagrammatic and schematic representations of certain embodiments of the invention, and are not limiting of the present invention, nor are they necessarily drawn to scale.

Introduction of Medical System 100

Figure 2 is a perspective view of a medical system 100 configured to facilitate closure of an internal tissue opening according to one embodiment of the present invention. In the illustrated embodiment, the medical system 100 comprises a closure device 200 adapted to reduce the size of the internal tissue opening, and a delivery device 300 adapted to facilitate placement and deployment of the closure device 200 with respect to the internal tissue opening. The medical system 100 of the present invention can provide benefits. For example, the medical system 100 can be configured to be used with different sizes, shapes and types of internal tissue openings. Furthermore, the medical system 100 can provide various safety measures to increase the safety and effectiveness of positioning the closure device 200. In addition, the medical system 100 can be configured to provide distributed lateral force to tissue of the internal tissue opening.

In the illustrated embodiment, delivery device 300 comprises a handle body 302, an actuating assembly 320 operatively associated with handle body 302, a release assembly 340 operatively associated with the handle body 302 and a delivery assembly 360 operatively associated with the actuating assembly 320, the release assembly 340 and the handle body 302. Handle body 302 can be configured to provide a gripping surface for a user. Handle body 302 can be used to position closure device 200, as well as facilitate deployment of the closure device 200 from the delivery assembly 360. Actuating assembly 320 can be moved with respect to handle body 302 to selectively deploy portions of the closure device 200 from the delivery assembly 360, as will be discussed more fully herein below.

Release assembly 340 can be operatively associated with the handle body 302 to enable selective detachment of closure device 200 from the delivery assembly 360. Delivery assembly 360 can house closure device 200 in a non-deployed or constrained orientation, such as illustrated in Figure 3B for example, and facilitate deployment of

closure device 200. Delivery assembly 360 can include one or more tethers 364 linked to the closure device 200 to facilitate selective detachment of the closure device 200 from the delivery device 300.

Closure Device 200

With reference to Figure 3A, the closure device 200 is illustrated in a fully deployed, expanded, relaxed or non-constrained orientation. According to one embodiment of the invention, the closure device 200 can be configured to reduce the size of an internal tissue opening so as to close the internal tissue opening. In one embodiment, the closure device 200 can reduce the size of an internal tissue opening by approximating, or in other words bringing together tissue of the internal tissue opening, such as tunnel tissue in a PFO. The closure device 200 can approximate tissue by applying lateral force to tissue of the internal tissue opening, as will be discussed more fully herein after. Also, the closure device 200 can be configured to enable a user to estimate the position and/or orientation of the closure device 200 with respect to an internal tissue opening, during and after positioning of the closure device 200 in the internal tissue opening.

According to one embodiment of the invention, the closure device 200 can be a non-tubular stent. The closure device 200 can be configured to assume a substantially flat configuration, or in other words be configured to be substantially planar, such as illustrated in Figures 3A and 11B for example. Furthermore, the closure device 200 can be configured to resist movement out of plane, such as plane 260 of Figure 11B. However, the closure device 200 may bend out of plane when positioned in a tissue opening.

The closure device 200 according to one embodiment of the invention has many advantages. For example, the closure device 200 can be configured to be reliable and compliant. The configuration of the closure device 200 can enable the closure device 200 to be movable between a non-deployed orientation and a deployed orientation without causing failure or plastic deformation of the closure device 200. The closure device 200 can be used to close various types, shapes and sizes of internal tissue openings. Furthermore, the closure device 200 can accommodate for a range of PFO tunnel lengths, for example. Also, the closure device 200 can be partially or fully deployed from or received back into the delivery device 300. Closure device

200 can be configured to substantially conform to the size and shape of a tissue opening. For example, the undulations on the distal and proximal anchors can enable the anchors to substantially, or to a certain degree, conform to the anatomy of a tissue opening.

Generally, the closure device 200 can have a substantially flat aspect having a length and height greater than its depth or depth thickness. For example, in one embodiment, the closure device 200 has an overall length of 22mm, a height of 7.5mm and a depth thickness of 0.4mm. According to one embodiment of the present invention, when the closure device 200 is in the relaxed or completely expanded orientation, as illustrated in Figure 3A, the distance between the opposing ends of the proximal anchor 218 can be about 22mm, the distance between the most proximal attachment member 240 of the body portion 202 and the most distal indicator 220 of the body portion 202 can be about 7.5mm, and the depth thickness, designated as DT in Figure 11B, of the closure device 200 can be about 0.4mm.

Furthermore, the majority of segments comprising the closure device 200 can have a thickness or width that is substantially less than the depth thickness of the segments. The closure device 200 can resist out of plane movement due to the size and configuration of the segments. For example, the closure device 200 can be configured to assume a substantially flat configuration in a first plane. The configuration of the segments, for example the segments having a certain depth thickness, can facilitate the closure device 200 resisting movement out of the first plane in a manner similar to an I beam resisting bending in the direction of the web of the beam. The first plane can be plane 260 as illustrated in Figure 11B.

Also, the closure device 200, according to one embodiment of the invention, can have a unitary construction. For example, the closure device 200 can be cut from a single piece of material, such as cut by a laser, thereby removing the need to assemble or join different segments together. A unitary construction can provide advantages, such as ease of manufacturing and reliability. For example, assembly is not required for a closure device having a unitary construction. Also, a closure device having a unitary construction may not include distinct elements or segments which require joining by joints, thereby reducing a likelihood of failure. The closure device 200 can be made from a super-elastic material, such as a super-elastic metal or a

super-elastic polymer. Furthermore, the closure device 200 can be made from NiTiNol, stainless steel alloys, magnesium alloys, and polymers including bio-resorbable polymers.

In some embodiments according to the present invention, the closure device can be formed by utilizing a pressurized stream of water, such as a water jet, to remove material from a piece of material to form the closure device. Furthermore, it is contemplated that the closure device can be formed by utilizing one or more of the following: die casting, chemical etching, photolithography, electrical discharge machining, or other manufacturing techniques. It is contemplated that the closure device can be formed through use of a mill or some other type of device adapted to remove material to form a desired shape.

It will be appreciated by one of ordinary skill in the art in view of the disclosure provided herein that the closure device 200 can comprise multiple segments joined together by a known joining process, such as by an adhesive, by interference fits, crimping, by fasteners, or a weld, or some combination thereof. For example, in one embodiment, the closure device can include multiple segments joined together by various welds to form a closure device according to the present invention. In other embodiments, the segments can be joined together by a plurality of means, such as by the combination of welding, fasteners, and/or adhesives. The segments can be a wire or multiple joined or rolled wires crimped together or joined by a joining process to form the closure device 200.

In the illustrated embodiment, the closure device 200 includes a body portion 202, a first anchor 204 operatively associated with the body portion 202 and a second anchor 206 operatively associated with the body portion 202. The body portion 202 can be configured to facilitate application of lateral force against tissue of an internal tissue opening. Also, the body portion 202 can be configured to enable the closure device 200 be movable between a non-deployed and deployed orientation. For example, the closure device 200 can be configured to be self-expanding from the constrained or non-deployed orientation, as illustrated in Figure 3B for example, to the relaxed orientation, as illustrated in Figure 3A. In other words, the closure device 200 can have a preferential orientation, such that movement of the closure device 200 from a first orientation to a second orientation can create internal stresses in the

closure device 200. These internal stresses can serve to bias the closure device 200 to the first orientation. For example, in one embodiment, the closure device 200 can have a preferential orientation of the relaxed or fully deployed orientation as illustrated in Figure 3A. In this embodiment, movement of the closure device 200 to a constrained orientation, such as illustrated in Figure 3B for example, can create internal stresses in the closure device 200, thereby creating in the closure device 200 a bias to return to the relaxed orientation.

In the illustrated embodiment, body portion 202 includes one or more cells 208 defined by a plurality of segments 210. The body portion 202 can include one or more apertures. In one embodiment, an aperture is defined by the cell 208, or in other words by the plurality of segments 210. In one embodiment, segment 210 can be a strut or a body support segment. Cells 208 can be distinct, or can be at least partially defined by a common segment. For example, cell 208A, as the distal most cell, and cell 208C, as the proximal most cell of body portion 202, are distinct and defined by distinct segments 210 with respect to each other. However, cell 208B is partially defined by a segment 210C which also defines a portion of cell 208A. Similarly, cell 208B is partially defined by a segment 210G which also partially defines cell 208C. Likewise, cell 208D shares a segment 210D with cell 208A and shares a segment 210H with cell 208C.

Segments 210 can be shaped and configured to have a substantially uniform stress at any given point along a certain length, when the segment 210 is deflected. For example, segment 210A can include a first portion 230 having a width or thickness greater than a second portion 232, wherein the width or thickness decreases from the first portion 230 to the second portion 232, or in other words is tapered, in a manner which provides for substantially uniform stress levels along the certain length. In other embodiments, segments can have a substantially constant width along their length.

Figure 3C is a cut-out view of a portion of the closure device 200, including the first portion 230 and the second portion 232 of segment 210A. In the illustrated embodiment, the width or thickness of the segment 210A varies along the portion of the segment 210A from the location where segment 210A extends from the portion 254 which joins segment 210A to segment 210C to the intermediate portion 234. As

the closure device 200 moves between an expanded or otherwise related orientation and a constrained or otherwise collapsed orientation, the segments 210 are deflected, with the highest levels of stress in the segment 210 being concentrated at the joining portion 254 and decreasing towards the intermediate portion 234. The segments 210 can be configured in a manner so as to have a substantially equal stress level along the length of the segment 210 between the joining portion 254 and the intermediate portion 234. The uniform stress level can be accomplished by having the width of the segment 210 vary from the first portion 230 to the second portion 232 in a calculated manner. In one embodiment, the width of the first portion 230 of the segment can be about .1mm and the taper to a width of about .05mm at the second portion 232 of the segment.

In other embodiments, the uniform stress level can be accomplished by utilizing a gradient of material having varying properties. In other embodiments, the segment 210 can have varying widths along its length and comprise a gradient of material sufficient to achieve a substantially uniform stress level between the first portion 230 and the second portion 232 of the segment. In the illustrated embodiment, the first portion is adjacent the joining portion 254 and the second portion is adjacent the intermediate portion 234. In yet additional embodiments, the joints of the interconnecting segments can include a biasing member, such as a spring, thereby enabling the segments to move relative to each other to collapse or expand the closure device 200. Furthermore, the biasing member of the joint can cause the segments to have a preferential orientation with respect to each other.

With continued reference to Figure 3A, segments 210 can also be configured to have a rectangular cross-section. In other embodiments, segments 210 can have an oval shaped cross section. In yet another embodiment, sections 210 can have a round or rounded cross section. Furthermore, in one embodiment, the ratio, or aspect ratio, of the thickness or width to the depth thickness of the first and second portions 230, 232 can range between at least about 1:2 to about 1:20. In one embodiment, the aspect ratio of the width to the depth thickness of the first portion 230 can be at least 1:2 and the ratio of the width to the depth thickness of the second portion 232 can be at least 1:4. In an alternative embodiment, the aspect ratio of the first portion 230 can be about 1:4 and the aspect ratio of the second portion 232 can be about 1:8. In this

manner, the closure device 200 can substantially resist out of plane movement, while allowing in-plane movement during reorientation of various portions of the closure device 200.

Segments 210 can be configured to be compliant. Compliancy of segments 210 can enable cells 208, and thus the body portion 202, to be oriented in various orientations. For example, body portion 202 can be oriented, or in other words moved, between a non-deployed orientation, such as illustrated in Figure 3B, and a fully deployed orientation, such as illustrated in Figure 3A. The compliancy of segments 210 can facilitate the accommodation by the closure device 200 of a variety of types, shapes and sizes of internal tissue openings. For example, the size and configuration of the first and second anchors 204, 206 and the body portion 202 can enable the closure device 200 to accommodate varying sizes, shapes and types of internal tissue openings. In one implementation, the first anchor 204 can engage wall tissue of an internal tissue opening and the second anchor 206 can engage only the tunnel tissue of the internal tissue opening to approximate tissue. In an alternative implementation where the internal tissue opening has a shorter tunnel length, the second anchor 206 can engage the tunnel tissue and an opposing wall of the internal tissue opening to approximate tissue.

Segments 210 can include an intermediate portion 234 configured to facilitate securement of ingrowth materials to the closure device 200, or can be used as an indicator 220 to facilitate estimation of the position of the closure device 200 with respect to an internal tissue opening. Furthermore, intermediate portion 234 can be configured to facilitate measuring of a characteristic of an internal tissue opening. In one embodiment, intermediate portion 234 can include one or more apertures. The apertures can be configured to receive a securing element, such as a thread, therethrough to facilitate securing an ingrowth material to the closure device 200. Intermediate portion 234 can be configured to be stiffer or more rigid than first portion 230, second portion 232, or both. A stiffer intermediate portion 234 can increase the reliability of segments 210.

In another embodiment, the intermediate portion 234 can include an indicator 220, such as a dense metallic rivet or concentration of dense material, for use in estimating the orientation and/or position of the closure device 200. Understanding of

the orientation and/or position of the closure device 200 can facilitate estimating a physical characteristic of an internal tissue opening and/or the relative position of the closure device 200 with respect to the internal tissue opening. For example, if the distance between the indicators 220 is known, a practitioner can estimate a physical characteristic, such as the opening or tunnel width, by determining the new distance between the indicators 220 when the closure device 200 is positioned in the tissue opening. Similarly, indicators 220 can be positioned on the first and second anchors 04, 206. The indicators 220 can be configured and arranged on the closure device 200 such that when the first anchor 204 is deployed the indicators 220 are substantially aligned. In this manner, a practitioner can estimate whether the first anchor 204 has fully deployed.

In some cases, it may be difficult to view the closure device 200 in the event the closure device 200 is at a skewed angle with respect to the viewing plane, such as a fluoroscope. When the closure device 200 is skewed in this manner, it can be difficult to determine accurately the distance of interest. However, when various distances between indicators is known, a user can use the known distances to calculate the distances of interest by using geometry.

In one embodiment, segments 210 along a similar or common lateral plane can have substantially equal lengths. Substantially equal lengths of segments 210 in this manner can enable body portion 202 to be moved between the non-deployed and deployed orientation without failure of the segments 210. For example, in one embodiment, segments 210A and 210B have substantially the same length, segments 210E, 210C, 210D, and 210K have substantially the same length, segments 210F, 210G, 210H and 210L have substantially the same length, and segments 210I and 210J have substantially the same length. In this configuration, body portion 202 can be collapsed or oriented into the non-deployed orientation, as illustrated in Figure 3B, without causing damage to the body portion 202 of closure device.

The closure device 200 can be configured to have a preferential orientation of the fully deployed orientation as illustrated in Figure 3A. As the closure device 200 is deployed from the delivery device 300, the configuration of closure device 200 can cause the closure device 200 to preferentially move toward the fully deployed orientation. Thus, as the closure device 200 is deployed in an internal tissue opening,

the preferential orientation of the closure device 200 can cause the closure device 200 to apply lateral force to the tissue of the internal tissue opening. In other words, the body portion 202, first anchor 204 and the second anchor 206 are deflected by an applied force in order to reorient the closure device 200 from the fully deployed orientation to a non-deployed orientation, for example. In this manner, the closure device 200, because of the deflection of the body portion 202, first anchor 204 and the second anchor 206, will have tendency to return to the fully deployed orientation. When the closure device 200 is positioned in an internal tissue opening, the deflected body portion 202, first anchor 204 and the second anchor 206 can have a tendency to apply a lateral force to tissue of the opening as the closure device 200 attempts to return to the fully deployed orientation.

Body portion 202 can be operatively associated with the first anchor 204 and the second anchor 206. First and second anchors 204, 206 can be configured to move between a deployed and non-deployed orientation. First and second anchors 204, 206 can be configured to apply lateral force to tissue of an internal tissue opening, and to engage and/or contact a portion of wall tissue and/or tunnel tissue of an internal tissue opening. In one embodiment, the first anchor 204 can be a left atrial anchor, and the second anchor 206 can be a right atrial anchor.

In the illustrated embodiment, the first anchor 204 can include a first anchor segment 212 and an opposing second anchor segment 214. Likewise, the second anchor 206 can include a first anchor member 216 and an opposing second anchor member 218. The first anchor segment 212 can be configured to move relative to the second anchor segment 214. Likewise, the first anchor member 216 can be configured to move relative to the second anchor member 218. In this manner, the closure device 200 can accommodate for a variety of types, shapes and sizes of internal tissue openings. The first anchor segment 212 and the second anchor segment 214 can be configured to be substantially similar in size, shape and configuration. As such, reference to the configuration and/or function of one of the first or second anchor segments can apply to the other anchor segment. In one embodiment of the invention, the first anchor 204 and/or the second anchor 206 can include one or more undulations. The undulations can facilitate reorienting or movement of the anchors with respect to the body portion 202, for example, from a

deployed to a non-deployed configuration. Furthermore, the undulations can facilitate the anchor substantially conforming to the anatomy of the tissue opening.

The first anchor segment 212 can include a distal end 224 and a proximal end 226. The first anchor segment 212 can be defined by various segments and can include reinforced segments 228 and one or more engaging members 222. For example, in the illustrated embodiment, the first anchor segment 212 is at least partially defined by segment 210K of cell 208D. The engaging members 222 can be microposts or tines configured to contact and/or engage tissue. The engaging members 222 can include a sharp tip or can be blunt. The engaging members 222 can be configured to provide a degree of surface texture in order to increase engagement of the first anchor 204 with tissue.

The first anchor segment 212 can be configured to be moved between a non-deployed orientation, as illustrated in Figure 3B, and a fully deployed orientation, as illustrated in Figure 3A. The first anchor segment 212 can be configured such that the distance from the proximal end 226 to the distal end 224 of the segment which includes the engaging members 222 is substantially equal to the distance from the proximal end 226 to the distal end 224 of the segment which includes the reinforced segments 228 and segment 210K. The second anchor segment 214 can be configured similar to the first anchor segment 212.

First anchor segment 212 can be configured to define a closed periphery. For example, first anchor segment 212 can include the reinforced segment 228 extending from the body portion 202 to the segment having the engaging members 222 which is connected to segments 210K, 210L to define a closed periphery with segment 210K. Furthermore, two reinforced segments 228 can extend from the joining portion 254 of the body portion 202 and join together near the distal end 224 of the first anchor 204. As such, there are multiple anchor portions extending from the body portion 202. In this manner, anchors of the present invention are reinforced to provide greater rigidity and strength to facilitate stabilization and maintenance of the closure device 200 within a tissue structure.

First anchor member 216 can include a distal end 236 and a proximal end 238. The first anchor member 216 can be defined by various segments and can include one or more engaging members 222. For example, in the illustrated embodiment, the first

anchor member 216 is at least partially defined by segment 210L of cell 208D. The engaging members 222 can be microposts or tines configured to contact and/or engage tissue. The engaging members 222 can include a sharp tip or can be blunt. The engaging members 222 can be configured to provide a degree of surface texture to increase engagement of the second anchor 206 with tissue.

It will be understood by one of ordinary skill in the art in view of the disclosure provided herein that the engaging members 222 can vary in size and shape, and can be positioned at various locations on the closure device 200. In alternative embodiments, one or more engaging members can extend out of plane of the closure device so as to contact tissue which is perpendicular, for example, to the substantially flat plane, such as plane 260 of Figure 11B, of the closure device 200.

The first anchor member 216 can be configured to be moved between a non-deployed orientation, as illustrated in Figure 3B, and a fully deployed orientation, as illustrated in Figure 3A. The first anchor member 216 can be configured such that the distance from the proximal end 238 to the distal end 236 of the segment which includes the engaging members 222 is substantially equal to the distance from the proximal end 238 to the distal end 236 of the segment which includes segment 210L. In this manner, first anchor member 216 can be detachably coupled to the delivery device 300 when in a non-deployed orientation inside the delivery device 300 as illustrated in Figure 3B. The second anchor member 218 can be configured similar to the first anchor member 216.

The first anchor segment 212 can also include a first portion 256 and a second portion 258 configured to facilitate engagement of the internal tissue opening. For example, first anchor segment 212 can be configured to include one or more undulations causing the first portion 256 to be positioned in close proximity with second portion 258. In this manner, as tissue is positioned between the first and second portions 256, 258, the configuration of the first anchor segment 212 can engage, or to some degree, pinch the tissue therebetween to facilitate maintenance of the position of the closure device 200 with respect to the tissue opening.

The closure device 200 can also include attachment members 240 for use in detachably linking the closure device 200 to the delivery device 300, as will be discussed more fully herein after. The attachment members 240 can include an

aperture 242 for use in facilitating the linking of the closure device 200 to the delivery device 300.

Figure 3B illustrates the closure device 200 in a non-deployed or constrained orientation. The configuration of the body portion 202, and the first and second anchors 204, 206 enables the closure device 200 be reoriented from the fully deployed and preferential orientation, as illustrated in Figure 3A, to the non-deployed or collapsed orientation as illustrated. In the collapsed or non-deployed orientation, the first anchor 204 extends distally and the second anchor 206 extends proximally, with the attachment members 240 being the proximal most portions of the second anchor 206 and the body portion 202.

In the illustrated embodiment, the closure device 200 is positioned inside of a delivery portion 366 of the delivery device 300. The configuration of the closure device 200 can cause portions of the closure device to apply force to the wall of the delivery portion 366 due to the preferential orientation of the closure device 200. The closure device 200 is configured to be received into and deployable from the delivery portion 366.

Delivery Device 300

Figure 4 illustrates one embodiment of the delivery device 300. In the illustrated embodiment, the delivery assembly 360 includes a catheter 362 having a delivery portion 366, and a plurality of tethers 364 at least partially housed by the catheter 362. The tethers 364 can be configured to facilitate selective detachment of the closure device 200 from the delivery device 300. The delivery portion 366 can be configured to receive the closure device 200 therein. The catheter 362 can be coupled to the actuating assembly 320, such that movement of the actuating assembly 320 can cause movement of the catheter 362.

In the illustrated embodiment, the actuating assembly 320 includes a first member 322 operatively associated with the handle body 302, a second member 324 operatively associated with the first member 322 and the handle body 302, and a knob 338 linked to the first member 322. The actuating assembly 320 can be utilized by a user to selectively deploy the closure device 200 from the catheter 362.

The handle body 302 can include indicia 304 to enable a user to estimate the degree of deployment of the closure device 200 from the delivery device 300, as well

as predict detachment of the closure device 200 from the delivery device 300. For example, indicia 304 can include deployment indicia 306 and release indicia 308. Deployment indicia 306 can be utilized to enable a user to estimate the degree of deployment of the closure device 200 from the catheter 362, and the release indicia 308 can be utilized to predict the detachment of the closure device 200 from the delivery device 300. The handle body 302 can also include a release pin groove 310. The release pin groove 310 can be operatively associated with the release assembly 340 to facilitate the selective detachment of the closure device 200 from the tethers 364.

According to one embodiment of the invention, the release assembly 340 can include a biasing member 342 operatively associated with the handle body 302 to facilitate detachment of the closure device 200. A release knob 346 can be provided to manipulate the position of biasing member 342 in order to release or detach the closure device 200. In one embodiment, the release knob 346 is coupled to the biasing member 342, such that movement of the release knob 346 can cause movement of the biasing member 342. The biasing member 342 can include a release pin 344 configured to be received in, influenced by and movable in the release pin groove 310. In this manner, release pin groove 310 can restrict, and thereby influence the movement of the biasing member 342 with respect to the handle body 302.

The biasing member 342 is configured to interact with the handle body 302 such that when the release pin 344 is positioned in a terminating portion of the release pin groove 310, as illustrated in Figure 4, the biasing member 342 is biased in the proximal direction with respect to the handle body 302. In this manner, the release pin 344 can be moved from the terminating portion of the release pin groove 310, as illustrated in Figure 4, to the opposing terminating portion of the release pin groove 310 adjacent the release indicia 308B by applying force to the biasing member 342 through the release knob 346 in the distal direction, rotating the release knob 346 and then moving the release knob 346 in the proximal direction to release the closure device 200, as illustrated in Figure 10B.

Figure 5A is a cross-sectional view of the distal end of the catheter 362. In the illustrated embodiment, the catheter 362 includes a delivery portion 366 for use in positioning the catheter 362. The catheter 362 can be made from a resilient material

having sufficient axial stiffness to allow a practitioner to position the catheter 362 with respect to an internal tissue opening, and sufficient rotational stiffness to allow a practitioner to rotate the catheter 362 by rotating the handle body 302.

In one embodiment, the catheter 362 comprises a braided polyimide. In other embodiments, the catheter 362 can be made from a material having a sufficient axial stiffness, such as a braid reinforced polymer, axially reinforced polymer, metal reinforced polymer, carbon reinforced polymer, or some other type of axially stiff material. The delivery portion 366 can be made from a thermoplastic elastomer, such as PEBAX®. In other embodiments, the delivery portion or tip portion 366 can be made from a material having sufficient flexible properties, such as a polymeric material. In other embodiments, the delivery portion 366 can include a combination of materials, such as metallic materials and polymeric materials.

The delivery portion 366 can define a lumen 368 to facilitate placement of the catheter 362. For example, a guidewire can be received in the lumen 368 to guide the catheter 362 to a desired location. In this manner, the closure device 200 can be located proximate to the internal tissue opening in a quick and efficient manner. Furthermore, the delivery portion 366 can be shaped, such as including a bend, in order to facilitate placement of the delivery portion 366 through a PFO, for example. In one embodiment of the invention, the catheter 362 can be considered a rapid exchange catheter wherein the delivery or tip portion 366 enables a guidewire to be linked to the catheter 362 in a quick and efficient manner for placement of the catheter 362.

The catheter 362 and delivery portion 366 can be configured to at least partially house tethers 364 in a lumen which is distinct and separate from lumen 368. For example, lumen 368 can be in a spaced apart, non-coaxial arrangement from the lumen which houses tethers 364, such that a guidewire can be received through lumen 368 without being introduced into the lumen or space in which the tethers 364 are housed. In this manner, a user can introduce a guidewire into the lumen 368 at the distal end of the catheter 362, rather than the lumen which at least partially houses the tethers 364 which would require the guidewire to be introduced into the lumen at the proximal end of the catheter 362. In alternative embodiments, the lumen 368 configured to receive the guidewire therein can be positioned inside the lumen which

houses the tethers 364. In this embodiment, lumen 368 would include an opening and an exit at the distal end of the catheter 362 in order to facilitate the quick placement of a guidewire through the lumen 368.

In one embodiment, catheter 362 can include a rounded cross-section and the delivery portion 366 can include a rectangular cross-section. The rectangular cross-section of the delivery portion 366 can facilitate proper deployment of the closure device 200 from the delivery device 300, as well as facilitate the closure device 200 being reintroduced back into the delivery portion 366. The rectangular cross-section of the delivery portion 366 can be sized to orient the tethers 364 next to each other in a linear fashion. In this manner, the likelihood that the tethers 364 cross each other upon reintroduction of the closure device 200 into the delivery portion 366 can be reduced.

In one embodiment of the invention, tethers 364 includes three tethers 364A-C, each tether 364 being sized and configured to attach to and/or accommodate therein an attachment member 240 of the closure device 200. One example of a tether is a line or hollow tube coupled to the handle body 302. The tether 364 can comprise a flexible, hollow shaft having sufficient stiffness such that as actuating assembly 320 moves the catheter 362 proximally with respect to the handle body 302, the closure device 200 is forced out of the delivery portion 366. Likewise, the tether 364 can be configured to pull the closure device 200 back into the delivery portion 366 as the actuating assembly 320 is moved distally with respect to the handle body 302.

In one embodiment, the tether 364 can be a coil of stainless steel covered by a heatshrunk tubing to give the coil a degree of tensile strength and rigidity. In an alternative embodiment, the tether 364 can be a polymeric tube. In yet an additional embodiment, the tether 364 can be a combination of polymeric materials and metallic materials. In some embodiments, an additional heatshrunk tubing covers a proximal segment of the three tethers 364A-C. The heatshrunk covering can increase the column strength of the tether 364, which can enable the tethers 364 to assist with deployment and reintroduction of the closure device 200 from and into the delivery portion 366. The tethers 364 can have a distal tip configured to correspond to the shape and size of the attachment members 240 of the closure device, such that the

attachment member 240 can be received into the distal tip of the tether 364, as illustrated in Figure 7.

Tethers 364 can be made from a material having sufficient flexibility to substantially prevent distortion or otherwise influence the orientation of the closure device 200 when the closure device is deployed from the catheter 362, yet have sufficient axial strength to facilitate deployment of the closure device 200 when the catheter 362 is moved proximally with respect to the closure device 200. The tethers 364 can have a lumen extending therethrough of sufficient size and configuration to enable a plurality of wires 378 to be housed and movable therein.

Figures 5B-5C are cross-sectional views illustrating the delivery assembly 360 in association with the actuating assembly 320. However, for simplicity, Figure 5B does not include the biasing member 342 and associated release knob 346, and Figure 5C illustrates details about the interaction between the delivery assembly 360 and the actuating assembly 320 without illustrating the first member 322 and details about the handle body 302 and the second member 324. In the illustrated embodiment, the proximal end of the catheter 362 is coupled to the distal end of the second member 324. In this manner, movement of the second member 324 can cause a corresponding movement in the catheter 362. For example, as the second member 324 moves proximally with respect to the handle body 302, so also does the catheter 362 move proximally with respect to the handle body 302.

According to one embodiment of the invention, the tethers 364 can extend from the delivery portion 366, through the catheter 362 and the second member 324 and are coupled to the handle body 302. The tethers 364 can be coupled to the handle body 302 by, for example, an intermediate member 376. The tethers 364 can be covered with a first and second housing 370, 372 to provide a degree of rigidity to the portions of the tethers 364 located inside of the handle body 302 and the second member 324. For example, in one embodiment, the first housing 370 comprises a rigid, hollow, metal rod configured to house the three tethers 364A-C therein. The first housing 370 can extend from the intermediate member 376, which facilitates securement of the tethers 364 to the handle body 302, and terminate at some point beyond the handle body 302.

In the illustrated embodiment, the second housing 372 can extend from the distal end of the first housing 370 and extend into the catheter 362. The second housing 372 can comprise a resilient material configured to resist axial stretching while allowing a degree of bending. In one embodiment, the second housing 372 comprises a coil of metal, such as stainless steel, configured to resist axial stretching, yet allow a degree of bending. The second housing 372 can allow a practitioner to bend a portion of the catheter 362, if needed, in order to manipulate delivery device 300 for placement of the closure device 200. A seal 374 can be provided between the first housing 372 and the second member 324 in order to reduce or substantially prevent bodily fluid, which may have entered the catheter 362, from entering the handle body 302 or otherwise inappropriately being expelled from the delivery device 300.

In the illustrated embodiment, the second member 324 can comprise an elongate shaft defining an axial lumen 348 and a lumen 350 in fluid communication therewith. Lumen 350 can be configured to couple to a medical device for removal of fluid from the delivery device 300. The axial lumen 348 can be sized to accommodate and allow movement of the tethers 362, the first housing 370 and the second housing 372 therein. The second member 324 can include a guide 326. The guide 326 can be configured to cooperate with a first pin 352 and a second pin 354 to influence movement of the second member 324 with respect to the handle body 302, as will be discussed more fully herein below.

In the illustrated embodiment, the first member 322 comprises a hollow elongate tube sized and configured to enable the second member 324 to be received into and moveable within the first member 322. The first member 322 can be operatively associated with the handle body 302 and the second member 324 to facilitate deployment of the closure device 200. For example, the first member 322 is linked to the handle body 302 by a third pin 356. The third pin 356 is received in a guide 358 of the first member 322. The guide 358 is configured to interact with the third pin 356 in order to influence the movement of the first member 322 with respect to the handle body 302.

The first pin 352 can link the first member 322 to the second member 324. When the first pin 352 links the first member 322 to the second member 324, the

second pin 354 links the handle body 302 to the second member 324, and the third pin 356 links the handle body 302 to the second member 322, movement of the first member 322 can selectively deploy the closure device 200 from the delivery portion 366.

With reference to Figures 5A-C and 6, the association between the first member 322, the second member 324, the handle body 302 and the biasing member 342 will be discussed. Figure 6 is an exploded view of the actuating assembly 320 and the release assembly 340. In the illustrated embodiment, the second member 324 is received into the first member 322, and the first member 322 is received into the knob 338 and the handle body 302, as illustrated in Figures 4 and 5B-5C.

According to one embodiment of the invention, the second member 324 can include a guide 326 having a first portion 326a and a second portion 326b, which guide 326 can be defined by a slot formed on the outer surface of the second member 324. In the illustrated embodiment, the first portion 326a is straight and extends along at least a portion of the length of the first member 324 and joins with the second portion 326b of the guide 326. The second portion 326b can include a helical groove or slot that begins with and is contiguous with the first portion 326a and extends distally therefrom.

The guide 326 of the second member 324 is configured to interact with the handle body 302 and the first member 322 to selectively retract the catheter 362 in order to deploy the closure device 200. For example, the first portion 326a of the guide 326 is configured to interact with the second pin 354, which is secured into the handle body 302 by means of threads and extend into the first portion 326a of the guide 326. In this manner, the second member 324 can move laterally with respect to the handle body 302. Thus, rotation of the handle body 302 can translate to rotation of the second member 324, and thus, the catheter 362 and the delivery portion 366.

The second portion 326b of the guide 326 is configured to interact with the first pin 352, which is secured to the first member 322 by means of threads and extends into the second portion 326b of the guide 326. In this manner, as the first member 322 is rotated, the first pin 352 will interact with the second portion 326b to move the second member 324 in the proximal direction. As the second member 324 is moved in the proximal direction with respect to the handle body 302, the catheter

362 moves proximally with respect to the handle body 302 thereby exposing or deploying the closure device 200 from the delivery portion 366.

In the illustrated embodiment, the first member 322 can include a guide 358 defined by a slot or groove formed in the outer surface of the first member 322. In the illustrated embodiment, the guide 358 can include a first portion 358a connected to a second portion 358b. The first portion 358a of guide 358 can be straight and extend along at least a portion of the length of the first member 322, and then join and be contiguous with the second portion 358b. The second portion 358b of the guide 358 can be a helical groove that wraps around at least a portion of the outer surface of the first member 322 and extends along at least a portion of the length of the first member 322.

As described previously, the third pin 356, which is secured to the handle body 302 by means of threads, can extend into the guide 358 in order to influence movement of the first member 322 with respect to the handle body 302. For example, as the third pin 356 is positioned in the most proximal portion of the first portion 358a, the closure device 200 is completely received into and enclosed by the delivery portion 366. As the first member 322 is moved in the proximal direction as illustrated by the arrow in Figure 4, the third pin 356 moves in the first portion 358a of the guide 358 to deploy the first anchor 204 of the closure device 200 from the delivery portion 366.

The length of the first portion 358a can correspond with the distance that the first member 322, and thus the catheter 362, must move in order to deploy the first anchor 204 of the closure device 200 from the delivery portion 366. For example, a practitioner can move the knob 338, which is coupled to the first member 322, in the proximal direction. Movement of the knob 338 in the proximal direction can cause the third pin 356 to move linearly in the first portion 358a of the guide 358. In this manner, the second member 324 can move correspondingly with the first member 322 because of the first pin 352, which links the first member 322 to the second member 324. As the third pin 356 is positioned in the location of the guide 358 where the first portion 358a meets with the second portion 358b, the first member 322 can be rotated in order to selectively deploy the remaining portions of the closure device 200 from the delivery portion 366 of the delivery device 300.

As the first member 322 is rotated, the third pin 356 is positioned in the second portion 358b to influence movement of the first member 322 with respect to the handle body 302, and the first pin 352, which is coupled to the first member 322, interacts with the second portion 326b of the guide 326 to move the second member 324 in the proximal direction with respect to the handle body 302. Movement of the second member 324 in the proximal direction in this manner can cause further deployment of the closure device 200 from the delivery portion 366. As will be appreciated, the knob 338 can be coupled to the first member 322 to facilitate and enable movement of the first member 322 with respect to the handle body 302.

The dual movement required to deploy the closure device 200 can provide some efficiency and safety advantages. For example, a practitioner can move the knob 338 in a first direction (i.e., proximally in a linear fashion) to deploy the first anchor 204 from the delivery portion 366. Thereafter, the practitioner can move the handle body 302 to position the first anchor 204 against the wall tissue of an internal tissue opening, such as against the left atrial wall of a heart, for example. Once the first anchor 204 is positioned against the wall, the practitioner can move the knob 338 in a second direction (i.e., rotate the knob) to further deploy the closure device 200 from the delivery portion 366. The dual movement enables a user to predict the deployment of the closure device 200 to reduce the risk of premature deployment of the closure device.

It will be understood by one of ordinary skill in the art in view of the disclosure provided herein that other means of controlling movement of one member with respect to the other, such as the first member with respect to the second member, can be utilized without departing from the scope and spirit of the invention. For example, a structure configured to substantially restrict or control movement of the first element with respect to the second element and/or handle body can be utilized. In one embodiment, the structure can include a cam and a follower. In an alternative embodiment, the structure can include a slider.

The release assembly 340 can be configured to be received in the proximal end of the handle body 302. The release assembly 340 can be configured to provide additional safety features for the practitioner and patient by reducing the risk of premature detachment of the closure device 200 before it is positioned appropriately

in an internal tissue opening. For example, a practitioner using the medical system 100 of the present invention can manipulate the actuating assembly 320 to deploy the closure device 200 for positioning in an internal tissue opening. In order to deploy a first portion of the closure device 200, a user can move the knob 338, and thus the first member 322, in the proximal direction with a first movement, which is a linear movement, then deploy the remaining portions of the closure device 200 by a rotational movement. Once the closure device 200 is deployed, the practitioner can be required to move their hands in order to utilize the release assembly 340 to release the closure device 200 from the delivery device 300.

In the illustrated embodiment the release assembly 340 can include a release knob 346 coupled to a biasing member 342, which is received into the proximal end of the handle body 302. The biasing member 342 can be configured to include a plurality of slots 318 configured and arranged to act similar to a spring. The slots 318 can be configured and arranged in the biasing member 342 to enable at least a portion of the biasing member 342 to be compressed. Compression of the biasing member 342 can cause the release pin 344 to move toward the distal end of the biasing member 342.

The biasing member 342 can be configured such that when biasing member 342 is positioned in the handle body 302, the biasing member 342 naturally tends to maintain its position with the release pin 344 in the release pin groove 310 as illustrated in Figure 4. As force is applied to the release knob 346 in the distal direction (i.e., compress the biasing member 342), the release pin 344 can be moved out of a terminating portion of the release pin groove 310 and rotated and moved into a proximal terminating portion of the release pin groove 310 to release the closure device 200 from the delivery device 300.

The closure device 200 is released from the delivery device 300 by moving a plurality of wires 378 which are housed by a tether 364 and coupled to the biasing member 342. Illustrated in Figure 7 is a cross-sectional view of attachment member 240 of the closure device 200 received into a tether 364 and coupled by first and second wires 378a, 378b. In the illustrated embodiment, a second wire 378b can extend through and out of the tether 364 and form a loop. The loop can extend through an aperture 242 of the attachment member 240 of the closure device 200.

With the loop of second wire 378b positioned through the aperture 242 of the attachment member 240, a first wire 378a, which extends through and out of the tether 364, can extend through the loop of the second wire 378b to form a locking feature. When the first wire 378a extends sufficiently through the loop of the second wire 378b, the closure device 200 can remain coupled to the delivery device 300 until the first wire 378a is pulled through the loop of the second wire 378b, and the second wire 378b is pulled out of the aperture 242 of the attachment member 240.

The first wire 378a and the second wire 378b can be attached at their proximal ends to the biasing member 342. In this manner, movement of the biasing member 342 in the proximal direction can cause movement of the wires 378 also in the proximal direction. In one embodiment, the wires 378 can be coupled to the biasing member 342 such that movement of the biasing member 342 will cause the first wire 378a to move a distance sufficient to be removed from the loop of second wire 378b before the second wire 378b is moved by the biasing member 342. The wire 378 can comprise a metallic wire, such as a NiTiNol wire. The wire 378 can also include a stainless steel wire or some other type of metal or stiff polymer. The wires 378 can be made from a material having a sufficient tensile strength to secure the closure device 200 to the tethers 364 without causing the wires 378 to fail or substantially deform. In one embodiment of the invention, the wire 378B can include a stainless steel wire and wire 378A can include a NiTiNol wire.

Other types and configurations of biasing members can be utilized without departing from the scope and spirit of the invention. For example, in one embodiment, the release assembly can include a rotating member coupled to the securing elements. In this embodiment, rotation of the rotating member can cause the securing elements to wind around the rotating member thereby causing the distal ends of the securing elements to move proximally with respect to the handle body.

The method of use of the medical system 100 will now be described with reference to a particular internal tissue opening, namely a PFO. Figure 8a illustrates the positioning of the catheter 362 through the tunnel 58 of a PFO with the first anchor 204 of the closure device 200 deployed. The medical system 100 is utilized to close an internal tissue opening by positioning the catheter 362 through an internal tissue opening and moving the first member 322 by a first movement (i.e., linearly) in

the proximal direction to deploy the first anchor 204 of the closure device 200. After the first anchor 204 of the closure device 200 is deployed, the delivery device 300 can be moved in the proximal direction in order to seat the first anchor 204 against the wall of the tissue opening or otherwise engage the wall of the internal tissue opening, as illustrated in Figure 9. This can be done by moving the handle body 302 in the proximal direction.

After the first anchor 204 has been positioned against the wall of the internal tissue opening, the knob 338, and thus the first member 322, can be moved by a second movement, or in other words, rotated to deploy additional portions of the closure device 200 as illustrated in Figure 9. After the closure device 200 has been fully deployed and conforms to the anatomy of the internal tissue opening, the release assembly 340 can be actuated to selectively detach the delivery device 300 from the closure device 200 as illustrated in Figures 10a and 10b.

The release assembly 340 can be actuated by moving the biasing member 342 distally with respect to the handle body 302, then rotating the biasing member with respect to the handle body 302, and then moved proximally with respect to the handle body 302. In this manner, closure device 200 substantially conforms to the anatomy of the internal tissue opening. As noted previously, the configuration of the closure device 200 is such that when positioned in the internal tissue opening as illustrated, the members of the closure device 200 apply lateral force to the tissue of the internal tissue opening, such as the tunnel 58 of the PFO, to approximate tissue of the PFO for closure.

Figure 11A illustrates one embodiment of a closure device 200 that can include a member 250, such as an ingrowth material. The member 250 can be configured to induce tissue growth. The member 250 can be fixed to the closure device 200 by means of a securing element, such as a thread 252. For example, the thread 252 can extend through the member 250 and through the apertures in the intermediate portions 234 in order to secure the member 250 to the closure device 200. In other embodiments, the member 250 can be secured to the closure device 220 by a known securing means, such as by an adhesive, a heat weld, or some other known or hereafter developed means for securement.

The member 250 and the thread 252 can include a bio-resorbable material, such as polylactide or polyglycolide or collagen. The member 250 can be sized and configured to enable the closure device 200 to be deployed from and received into the delivery portion 366 of the delivery device 300. Furthermore, the member 250 can be configured to interact with tissue of the internal tissue opening to stimulate growth of tissue for closure of the internal tissue opening. For example, the member 250 can interact with the tunnel tissue 58 of a PFO in order to stimulate growth of tissue in the PFO tunnel 58.

The member 250 can be any suitable material which can or tends to promote tissue growth. Examples of such material can include a polymeric material, or a woven material, such as a woven metallic or biological material. In one embodiment, the member 250 can be a piece of foam. In alternative embodiments, the member 250 can be a piece of yarn, fabric or string, or some combination thereof. Other tissue growth promoting members can include a coating disposed on the closure device 200. In other embodiments, the member 250 can be a piece of foam, braided material such as a piece of yarn or string, or fabric which has a coating disposed thereon.

The member 250 can include materials such as a piece of polyurethane or some other biocompatible polymer, including bio-resorbable polymers. The member 250 can also include Dacron or polymeric threaded material which have been woven or knitted, or formed into compressed, non-woven fabrics. The member 250 can also include a metallic material, such as a NiTiNol, stainless steel or some other biocompatible alloy or bio-resorbable metal, such as magnesium alloy, or some combination thereof. In one embodiment, the member 250 comprises a metallic wire.

Figure 11B illustrates a side view of the closure device 200, and illustrates one example of the closure device having a substantially flat configuration. In the illustrated embodiment, the closure device 200 can include a depth or depth thickness designated as DT, and a plane 260 extending perpendicular into and out of the plane of the page. In this embodiment, the member 250 can extend beyond at least a first edge 262 of the closure device 200. Furthermore, the member 250 can extend beyond both the first edge 262 and a second edge 264 of the closure device 200. In this manner, member 250 can contact tissue adjacent the closure device 200 to promote tissue growth in the tissue opening.

The member 250 can be sized and configured to extend beyond at least the first edge 262 of the closure device 200 a sufficient distance to contact tissue of the tissue opening. In one embodiment, the member 250 can extend beyond at least the first edge 262 a sufficient distance to contact tissue adjacent the first edge 262, thereby causing the end of the member 250 which is in contact with the tissue to deflect or bend. In this manner, more surface area of the member 250 can be in contact with tissue to thereby facilitate an increase in tissue growth. In other embodiments, the member 250 can extend beyond both the first edge 262 and the second edge 264 a sufficient distance to cause both ends of the member 250 to bend, which can result in more surface area contacting the tissue. In one embodiment, the member 250 can extend between at least .5mm and 5mm beyond the first edge 262. In another embodiment, the member 250 can extend between at least .5mm and 5mm beyond the first edge 262, and can extend between at least .5mm and 5mm beyond the second edge 264. Furthermore, the member 250 can have a thickness of between at least .25mm and 2mm.

In addition, in some embodiments the member 250 can be configured to decrease the size of a remaining void in the tissue opening after the closure device 200 has been positioned in the tissue opening. Member 250 extending beyond the first edge 262 of the closure device 200 is an example of the member 250 extending substantially out of plane of the substantially flat configuration.

The present invention can also include the following methods, systems and devices.

A medical device comprising: a body portion comprising two or more cells, said body portion being movable between a deployed and non-deployed orientation; and at least one anchor linked to said body portion, said at least one anchor being adapted to reduce proximal movement of the medical device when the medical device is positioned in an internal tissue opening.

A medical device comprising: a multi-cellular structure adapted to selectively expand and contract between a deployed and non-deployed orientation; a first anchor operatively associated with said multi-cellular structure, said first anchor being adapted to selectively engage at least a portion of a wall of an internal tissue opening; and a second anchor operatively associated with said multi-cellular structure, said

second anchor being adapted to engage at least a portion of at least another portion of the wall of the tissue opening.

A method for closing a Patent Foramen Ovale, comprising the steps of: positioning at least a portion of a medical device into a left atrium of a heart, said medical device comprising a first anchor, a multi-cellular structure linked to said first anchor, and a second anchor linked to said multi-cellular structure, said first anchor, said multi-cellular structure and said second anchor being adapted to selectively move between a non-deployed and deployed orientation; locating at least a portion of said first anchor against at least a portion of a left atrial wall of the heart; and locating at least a portion of said second anchor against at least a portion of at least one of a tunnel of the Patent Foramen Ovale or a right atrial wall of the heart.

A medical device for approximating tissue of an internal tissue opening together, the medical device comprising: a body portion comprising two or more cells, said body portion being adapted to apply lateral force to tissue of an internal tissue opening; and at least one anchor operatively associated with said body portion.

A medical device for approximating tissue of an internal tissue opening together, the medical device comprising: a multi-cellular structure adapted to selectively expand and contract between a deployed and non-deployed orientation, said multi-cellular structure configured to preferentially expand; and at least one anchor operatively associated with said multi-cellular structure, said at least one anchor being adapted to move between a deployed and non-deployed orientation, at least a portion of said at least one anchor being adapted to apply lateral force to at least a portion of tissue of an internal tissue opening when said first anchor is deployed.

A method for reducing the size of an internal tissue opening, comprising the steps of: positioning at least a portion of a medical device through an internal tissue opening, said medical device comprising a multi-cellular structure and at least a first anchor associated with said multi-cellular structure, said at least one anchor and said multi-cellular structure being adapted to selectively move between a non-deployed and deployed orientation; and applying lateral force to tissue of the internal tissue opening by at least partially deploying said at least one anchor.

A medical device comprising: two or more cells forming a body portion, said body portion being adapted to move between a collapsed and expanded orientation to apply lateral force to tissue of an internal tissue opening; and at least one anchor linked to said body portion, said at least one anchor being adapted to extend distally when said at least one anchor is collapsed and extend laterally when said at least one anchor is moved from a collapsed to an expanded orientation.

A method for deploying a closure device, the method comprising the steps of: deploying a left anchor of a closure device from a delivery device, said delivery device comprising an actuating assembly operatively associated with a handle body, said left anchor being adapted to deploy by linearly moving at least a portion of said actuating assembly with respect to said handle body; and deploying a second anchor of said closure device from said delivery device by rotating at least a portion of said actuating assembly with respect to said handle body.

A delivery device for an internal tissue opening closure device, the delivery device comprising: a handle body including first and second guide members; a first member operatively associated with said handle body, at least a portion of said first member defining a guide, said first guide member cooperating with said guide to influence movement of said first member with respect to said handle body, said first member including a guide structure; and a second member operatively associated with said first member, at least a portion of said second member defining a second guide, said guide structure cooperating with said second guide to influence the movement of said second member with respect to said first member, and said second guide member cooperating with said second guide to influence the movement of said second member with respect to said handle body.

A delivery device for an internal tissue opening closure device, the delivery device comprising: a handle body; a first pin coupled to said handle body; a second pin coupled to said handle body; a first cam adapted to be at least partially received into and movable with respect to at least a portion of said handle body, said first cam including a slot formed on an external surface of said first cam, said slot including a first portion and a second portion, said first portion of said slot extending along at least a portion of the length of said first cam, said second portion of said slot extending at least partially around said first cam, said first pin received in said slot; a

third pin coupled to said first cam; and a second cam adapted to be at least partially received into and movable with respect to at least a portion of said first cam, said second cam including a first and second slot formed on an external surface of said second cam, said first slot of said second cam extending at least partially around said second cam and said second slot of said second cam extending along at least a portion of the length of said second cam, said third pin received in said first slot of said second cam and said second pin received in said second slot of said second cam.

A medical device for closing an internal tissue opening, the medical device comprising: a multi-cellular structure configured to assume a substantially flat configuration; at least one anchor operatively associated with said multi-cellular structure, said at least one anchor comprising a plurality of segments at least partially defining a closed periphery.

A medical device for closing an internal tissue opening, the medical device comprising: a multi-cellular structure adapted to be moveable between a first orientation and a second orientation; at least one anchor operably associated with said multi-cellular structure; and a tissue growth member associated with said multi-cellular structure, said tissue growth member being adapted to enhance tissue growth in the internal tissue opening.

In addition to the embodiments and configurations described above, the present invention can also related to various other medical devices, systems, and methods. For instance, in another configuration, disclosed is a medical device that has a multi-cellular structure being configured to be moved from a collapsed state to an expanded state, the multi-cellular structure including a waist portion and at least one anchor portion, wherein the anchor portion is wider in the expanded state of the device than the waist portion and the waist portion is configured to engage a tunnel of an internal tissue opening in the expanded state to close the internal tissue opening. This device can also include one or more distal anchors and/or proximal anchors. These anchors can be substantially the same width, or one may be wider than the other. These anchors may also include a plurality of elongate arms. One or more of the elongate arms may have a serrated edge, such as a serrated edge is configured to face toward the center of a tunnel of an internal tissue opening when the medical device is deployed. The elongate arms may also have smooth edges. The multi-

cellular structure may include a plurality of cellular portions having substantially the same size or the cellular portions may be of different sizes. The medical device may also be configured to shorten its overall length dimension upon deployment. If the medical device has a distal anchor and a proximal anchor, the proximal anchor may be configured to roll at least partially onto itself upon deployment to shorten the overall length of the medical device upon deployment. The medical device may a spring member secured to the waist and a solid anchor portion. The solid anchor portion may be a solid proximal anchor portion. In one example in which the medical device includes both proximal and distal anchor arms, the waist portion of the medical device may also include a hinged portion. The medical device may be formed of a resilient material such that the medical device is configured to expand from the compressed state to the expanded state due at least in part to spring forces associated with the resilient material. The medical device may also be configured to be expanded from the compressed state to the expanded state mechanically.

A medical device according to one example includes opposing expansion members and at least one connecting member coupling the opposing expansion members. The connecting member may be configured to move the opposing expansion members from a compressed state to an expanded state to seal an internal tissue opening. The medical device may also include a plurality of connecting members and pinned joints between adjacent connecting members and between the connecting members and the opposing expansion arms. The pinned joints may include a ratcheting mechanism configured to allow the connecting members to move relative to each other to allow expansion of the expansion members during deployment but to prevent the expansion members to collapse after deployment of the medical device. The medical device may further include an actuation member, such as a cable or tether, coupled to at least one connecting member. The expansion arms may be configured to be expanded from the compressed to the expanded state by drawing the actuation member proximally. The medical device may also include a locking member configured to lock the expansion member in the expanded state. The locking member may include a clasp operatively associated actuation member. Further, the connecting member may have a strut and piston configuration.

In yet another configuration, a medical device includes a plurality of elongate arms and an actuation member coupled to the elongate arms, the actuation member being configured to mechanically expand the elongate arms from a collapsed position to an expanded position. The actuation member may include alternating thinner portions between relatively thicker portions. Further, the actuation member may be configured to be drawn proximally and/or moved distally to mechanically expand the elongate arms. The medical device may also include a body portion operative associated with the elongate arms. The body portion may include flexing sections and/or pivots coupling the elongate arms to the body portion. The medical device may be a distal locator device, a proximal locator device, and/or a closure device.

In yet another configuration, a medical system includes a first medical device having expandable elongate arms, the expandable elongate arms being configured to expand from a collapsed state to an expanded state and to locate an opening of an internal tissue opening, and a second medical device operatively associated with the first medical device, the second medical device having a multi-cellular structure being configured to be moved from a collapsed state to an expanded state, the multi-cellular structure including a waist portion configured to engage a tunnel of an internal tissue opening in the expanded state to close the internal tissue opening. The first medical device may be a distal locator device or a proximal locator device. For example, the first medical device may be configured to locate a distal opening of the internal tissue opening. The system may further include a third medical device operatively associated with the second medical device, wherein the third medical device includes expandable elongate arms, the expandable elongate arms being to expand from a collapsed state to an expanded state and to locate a proximal opening of the internal tissue opening. The second medical device may include outwardly facing tines, first anchor portions, and/or second anchor portions.

A device for releasing an implant within a body lumen includes an attachment member coupled to the implant, a push member operatively associated with the attachment member. The device may be configured to secure the implant to a delivery device before release of the implant and to selectively release the attachment member. The attachment member may have a post configuration and the push member has a hole defined therein to receive the post. The attachment member may

include a loop of material coupled to the push member and a pin, the loop extending through a hole formed in the attachment member and being secured to the attachment member by the pin, wherein removing the pin releases the attachment member. The attachment member may also include a tab while the push member includes a pin configured to retain the tab in contact with the push member. The tab may have a dog-leg shape. The push member may include a slot defined therein configured to receive a portion of the tab while the device further includes a release wire configured to retain the tab in the slot and to be withdrawn to release the tab from the slot. The pin and tab may be interlocking members held in engagement while retained within the push member and that are released when moved from the push member. The push member may be formed from a meltable material. In such an example, the device may further include a coil of electrically conductive wire in which a portion of the push member extends at least partially through the coil. The device is configured to release the attachment member by heating the coil to melt a portion of the push member. Insulation may surround at least a portion of the coil. The device may also include a current source configured to provide a direct current and/or alternating current to the coil. The current source may be configured to provide an alternating current to the coil at a frequency up to radio frequencies. The coil may also be configured a resistive temperature device and may be formed from nickel, copper, and/or platinum or any other suitable material.

In another example, the device includes bimetallic actuator configured to release the attachment member from the push member at a specified temperature range. The bimetallic actuator may include a bimetallic strip and a securing member operatively associated with both the attachment member and the push member. The securing member may be configured to couple movement of push member to the attachment member when engaged and to be disengaged at a specified temperature range to decouple the attachment member from the push member. The push member and the attachment member may each include a receiving portion, such as a loop, defined therein which allows the securing member to pass at least partially through each of the receiving portions. The bimetallic actuator may be secured directly to the securing member and/or a linkage may couple the bimetallic strip and the securing member. A pivot may also be coupled to the linkage member. Example 66. A device

according to example 65, further including a pivot coupled to the linkage member. The linkage member may include a first portion proximate the bimetallic strip relative to the pivot and a second portion proximate the bimetallic strip relative to the pivot in which the first portion is shorter than the second portion.

In yet another example, a medical device further includes a shape-memory actuator configured to move between an initial shape below a transition temperature and a preset shape above the transition temperature to secure the attachment member in the initial shape and release the attachment member when moved to the preset shape. The push member may include a receiving portion. The shape memory actuator may extend through the receiving portion in the initial shape to secure the push member to the attachment member and wherein the shape memory actuator is drawn from engagement with the receiving portion when moved to the initial state to release the push member from attachment member. For example, the attachment member has a recess defined therein and the shape memory actuator engages the recess when in the initial state and is released from engagement with the recess when moved to the preset shape. Multiple shape memory actuators may engage the receiving portion from opposing sides of the attachment member in the preset shape. Further, the device may include a cutting feature secured to the shape memory actuator, the cutting feature being configured to cut a portion of the push member when the shape memory actuator is moved to the preset shape. For example, cutting feature may have an opening defined therein and at least a portion of the push member may extend through the opening. Additionally, the device may include a linkage and a securing member, the linkage coupling the shape memory actuator to the securing member. The securing member may couple the push member to the attachment member when the shape memory actuator is in the initial shape and release the push member from the attachment member when the shape memory actuator is in the preset shape. A pivot may also be operatively associated with the linkage. In another example, a device includes a cylinder and piston secured to the implant, a linkage, and a securing member. The securing member may be configured to release the push member in response to operation of the cylinder and piston, such as by expansion of the cylinder and piston. A phase change material may be expanded within an enclosed space of the cylinder to drive the piston. Phase change

materials may include a hydro-carbon fluid as well as formulations of waxes such as those used in the thermostats of common automotive engine thermostats. In one example, a cross hole is defined in the push member and a hole is defined in the attachment member. The device may further include a flexible filament extending through the cross hole through the hole and into a distal end of the push member. The device may include a cutting feature. The cutting feature may engage the filament at the cross hole to cut the filament.

A delivery device for delivering a closure device includes a handle body and a pusher handle operatively associated with the handle body, the pusher handle having a guide slot defined therein. The guide slot may be configured to allow the pusher handle to move linearly with respect to the handle body a first linear distance to deploy a first portion of the closure device. The guide slot may be further configured to allow the pusher handle to move linearly with respect to the handle body additional linear distances to deploy additional portions of the closure device, such as a second linear distance to deploy a second portion of the closure device. The guide slot may be configured to allow the pusher handle to rotate a rotational distance between the first linear distance and the second linear distance. First and second grooves may be defined in the handle body while first and second stops may be associated with the first and second grooves. The first and second stops may be associated with the guide slot. The first and second stops are configured to move between initial positions and rotated positions to constrain the movement of pusher handle. For example, rotating the first stop to the rotated position allows the pusher handle to move from the first position to the second position and rotating the second stop to the rotated position after rotating the first stop to the rotated position allows the pusher handle to move from the second position to the third position. The linear distance from the first position to the second position may correspond to the first linear distance and the distance between the second position and the third position may correspond to the second linear distance. Accordingly, in one example the guide slot includes a first linear portion, a transverse portion transverse to the first linear portion and in communication with the first linear portion, and a second linear portion substantially parallel to the first linear portion, the second linear portion in communication with the transverse portion. The delivery device may also include a release assembly

configured to release the closure device from the delivery device. The release assembly may include a release cap having a slot defined therein, the slot having a linear portion and a transverse portion transverse to the linear portion in which the linear portion extends proximally of the linear portion. The slot may also include a detent formed defined therein in communication with the transverse portion. In one example, a pin is coupled to the handle portion and is operatively associated with the pin. The delivery device may also include a drain lumen in fluid communication with the handle body.

A medical device has a multi-cellular structure being configured to be moved from a collapsed state to an expanded state, the multi-cellular structure including a waist portion configured to engage a tunnel of an internal tissue opening in the expanded state to close the internal tissue opening, and in-growth media having an in-growth configuration secured to the medical device. The in-growth configuration may include at least one filament secured to a central portion of the medical device, a filament coiled around the central portion of the medial device, and/or anchoring points configured to have the in-growth media secured thereto. The anchoring points may allow the filament to be secured to the medical device by sewing, fixing by adhesive, and/or knots. In another example, points at which the in-growth media is attached to the closure device are maintained at a constant distance from each other as the closure device is deployed. The in-growth media also include strips of in-growth media. The strips may be formed of a loosely woven gauze-like material that is woven into an interlocking structure. The strips may also be wrapped around a cellular portion of the closure device. The in-growth media may also include a membrane. The in-growth media may be located at least partially between the closure device and an adjacent closure device. The closure device and the adjacent closure device may be different or may be substantially similar.

In yet another configuration, a medical device has multiple chambers configured to be inflated from a collapsed state to an expanded state, the multiple chambers having a waist portion configured to engage a tunnel of an internal tissue opening in the expanded state to close the internal tissue opening. The multiple chambers may a distal anchor portion and/or a proximal anchor portion. The distal anchor portion may be configured to be inflated first and the proximal anchor portion

may be configured to be inflated subsequent to inflation of the proximal anchor portion, such as second. The multiple chambers may be interconnected, isolated or a mix of the two. The multiple chambers may also be formed of bioresorbable materials.

In another example a method for detaching a tether from an implant within a body lumen is provided that includes positioning an implant within a body lumen, a tether being coupled to the implant to aid with positioning the implant within the body lumen, and applying at least one of an electrical input or a thermal input to the tether to detach the tether from implant. Applying at least one of an electrical input or a thermal input may include applying electrical input to the tether to melt the tether and detach the tether from the implant, applying thermal input to a bimetallic actuator to remove a securing member from engagement with the tether and detach the tether from the implant, applying thermal input to a shape memory actuator releasably coupled to the implant to move a portion of the shape memory actuator relative to the implant to disengage from the tether and detach the tether from the implant, applying thermal input to a shape memory actuator, the shape memory actuator being mounted to a cutting structure that at least partially surrounds the tether, wherein the thermal input moves the shape memory actuator and the cutting structure to cut the tether and detach the tether from the implant, and/ or applying thermal input to a phase change assembly resulting detaching of the tether from the implant.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a framework configured to assume a substantially flat configuration, said framework comprising a central portion and at least one anchor extending from said central portion, said central portion including central frame portions having a length and a width, wherein the width of at least one of said central frame portions varies along at least a portion of the length of said at least one of said central frame portions.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a framework configured to assume a substantially flat configuration, said framework comprising a central portion and at least one anchor extending from said central portion, said central portion including a plurality of central frame portions, at least one of said plurality of central frame portions including

a first portion and a second portion, said first portion having a greater rigidity than said second portion.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a framework configured to assume a substantially flat configuration, said framework comprising a central portion and at least one anchor extending from said central portion, said central portion including central frame portions, at least one of said central frame portions having an aspect ratio of a depth dimension to a lateral width dimension of at least about 2 to 1.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a frame configured to assume a substantially flat configuration, said frame comprising a central portion and at least one anchor, said at least one anchor extending from said central portion and connecting to said frame, wherein said at least one anchor defines a closed periphery of said frame.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a frame configured to assume a substantially flat configuration, said frame including at least one anchor configured to adapt to different sizes of tissue structures, said at least one anchor including an undulation configured to facilitate movement of the medical device between an non-deployed orientation and a deployed orientation.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a frame configured to assume a substantially flat configuration, said frame comprising a central portion and at least one anchor, said at least one anchor including multiple anchor portions extending from said central portion, said multiple anchor portions being configured to position and stabilize said frame.

A medical device deployable at least partially within a tissue structure, the medical device comprising: a unitary frame configured to assume a substantially flat configuration, said unitary frame including a central portion and at least one anchor extending from said central portion.

A method of forming a medical device, the method comprising: positioning a material; and removing portions of said material to form a unitary medical device from said material, said medical device comprising a non-tubular body portion having

a plurality of interconnecting body support segments, said plurality of body support segments defining one or more cells, and an anchor operatively associated with said body portion.

A method for measuring characteristics of a tissue structure, comprising the steps of: positioning at least a portion of a medical device in the tissue structure, said medical device comprising a multi-cellular structure, at least one anchor linked to said multi-cellular structure, and two or more indicators; and measuring a physical characteristic of the tissue structure utilizing said two or more indicators of said medical device.

A method for measuring the tunnel width of a Patent Foramen Ovale, comprising the steps of: locating at least a portion of a medical device in a tunnel of the Patent Foramen Ovale of a heart, said medical device comprising a multi-cellular body portion, a first anchor linked to said multi-cellular body structure and a second anchor linked to said multi-cellular body structure; positioning said first anchor against a left atrial wall of the heart; deploying said second anchor; and measuring the tunnel width of at least a portion of the tunnel of the Patent Foramen Ovale utilizing at least one of said first anchor, said second anchor or said multi-cellular body portion.

A method for verifying the placement of a medical device, comprising the steps of: deploying at least a portion of a first anchor of a medical device in the left atrium of a heart, said medical device comprising a multi-cellular structure operatively associated with said first anchor, a second anchor operatively associated with said multi-cellular structure, and two or more indicators; deploying at least a portion of said second anchor in at least one of a tunnel of a Patent Foramen Ovale or the right atrium of the heart; and estimating placement of said medical device with respect to the Patent Foramen Ovale utilizing said two or more indicators.

A system reducing the size of an internal tissue opening, the system comprising: a handle body; and a release assembly operatively associated with said handle body, said release assembly comprising a release coupler extending at least partially through said handle body, said release coupler being selectively coupled to a closure device, and a release actuator coupled to said release coupler, said release actuator including one or more slots, said one or more slots being adapted to facilitate actuation of said release actuator.

A delivery device for positioning a closure device, the delivery device comprising: a handle body; one or more tethers coupled to said handle body; and a release assembly operatively associated with said handle body, said release assembly comprising a release mechanism extending through a first tether and engaging the closure device, and a release actuator coupled to said release mechanism, said release actuator being adapted to selectively draw at least a portion of said release mechanism proximally to release the closure device.

A method for detaching a closure device from a delivery device, the closure device being deployed within an internal tissue opening, the method comprising: positioning a closure device within an internal tissue opening, a tether and a release mechanism being operatively associated with said closure device to aid with positioning said closure device within the tissue opening, said release mechanism extending at least partially through said tether, wherein at least a portion of said closure device is positioned inside of said tether; and drawing at least a portion of said release mechanism proximally relative to said tether to thereby release said closure device.

A system for treating a tissue structure, the system comprising: a handle body; a catheter coupled to said handle body; a tip portion extending from a distal end of said catheter; one or more tethers coupled to said handle body and extending through said catheter; and a medical device configured to assume a substantially flat configuration, said medical device comprising a frame with a central portion and a proximal anchor extending from said central portion, said proximal anchor configured to be coupled to said one or more tethers and configured to deflect proximally from said central portion when constricted in said tip portion.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

What is claimed is:

1. An expandable medical device deployable at least partially within a tissue structure, the expandable medical device comprising:
a non-tubular multi-cellular body portion configured to self expand from a non-deployed orientation, said body portion comprising a plurality of interconnecting body support segments defining at least two apertures; and
at least one anchor linked to said multi-cellular body portion.
2. A medical device as recited in claim 1, wherein said body portion is configured to assume a substantially flat configuration.
3. A medical device as recited in claim 1, wherein said body portion comprises three or more cells.
4. A medical device as recited in claim 1, wherein said body portion is configured to apply lateral force to tissue of the tissue structure.
5. A medical device as recited in claim 1, wherein at least one of said body support segments has a width that varies along at least a portion of the length of said at least one body support segment.
6. A medical device as recited in claim 1, further comprising at least a second anchor operatively associated with said body portion.
7. A medical device as recited in claim 1, further comprising a member operatively associated with said body portion, wherein said member is configured to induce tissue growth.
8. An expandable medical device deployable at least partially within a tissue structure, the expandable medical device comprising:
a frame configured to assume a substantially flat configuration, said frame comprising a central portion adapted to move between a first orientation and a second orientation, said central portion comprising a plurality of struts defining a multi-cellular structure.
9. A medical device as recited in claim 8, wherein said frame comprises a superelastic material.
10. A medical device as recited in claim 8, wherein said frame is configured to assume said substantially flat configuration lying in a first plane, said

frame being configured to resist movement out of said first plane of the substantially flat configuration.

11. A medical device as recited in claim 8, wherein said central portion is configured to preferentially expand to said second orientation.

12. A medical device as recited in claim 8, further comprising a first anchor operatively associated with a distal portion of said central portion.

13. A medical device as recited in claim 12, wherein said first anchor is configured to reduce proximal movement of the medical device when the medical device is positioned in the tissue structure.

14. A medical device for reducing a size of a Patent Foramen Ovale ("PFO"), the medical device comprising:

a self-expanding frame configured to be constricted within a catheter and configured to assume a substantially flat configuration, said frame comprising a central portion with proximal and distal anchors extending from said central portion, said central portion comprising a multi-cellular structure configured to self-expand outwardly against a wall of the PFO.

15. A medical device as recited in claim 14, wherein said frame comprises a flat stent.

16. A medical device as recited in claim 14, wherein said proximal anchor is linked to said central portion.

17. A medical device as recited in claim 14, wherein said proximal anchor is adapted to engage at least a portion of a tunnel of the PFO and the right atrial wall of a heart.

18. A medical device as recited in claim 17, wherein said distal anchor is adapted to engage at least a portion the tunnel of the PFO.

19. A medical device as recited in claim 14, wherein at least one of said proximal or distal anchors comprises one or more engaging members.

20. A medical device for reducing the size of an internal tissue opening, the medical device comprising:

a frame including a central portion having a plurality of struts defining a multi-cellular structure, said central portion having at least one anchor

extending from said central portion, said central portion configured to assume a substantially flat configuration; and

a member associated with said frame, said member adapted to induce tissue growth in the internal tissue opening.

21. A medical device as recited in claim 20, wherein said central portion is configured to preferentially expand.

22. A medical device as recited in claim 20, wherein said member comprises an ingrowth member.

23. A medical device as recited in claim 20, wherein said member is secured to said central portion by a securement member.

24. A medical device as recited in claim 20, wherein said member is associated with said frame through an adhesive.

25. A medical device as recited in claim 20, wherein said member is configured to substantially extend out from said central portion.

26. A medical device as recited in claim 20, wherein said member comprises at least one of polylactide or polyglycolide or collagen.

27. A medical device as recited in claim 20, wherein said member comprises a bio-resorbable material.

28. A medical device for closing an internal tissue opening, the medical device comprising:

a frame including a central portion with at least one anchor extending from said central portion, said central portion configured to assume a substantially flat configuration; and

a tissue growth promoting member attached to said frame, said tissue growth promoting member configured to substantially extend out-of-plane from the substantially flat configuration and configured to enhance tissue growth in the internal tissue opening.

29. A medical device as recited in claim 28, wherein said frame comprises a flat stent.

30. A medical device as recited in claim 28, wherein said central portion comprises two or more cells.

31. A medical device as recited in claim 28, wherein said central portion comprises a plurality of support segments defining a multi-cellular structure.

32. A medical device as recited in claim 28, wherein said tissue growth promoting member comprises an ingrowth material.

33. A medical device as recited in claim 28, wherein said tissue growth promoting member is secured to said frame by a securing means.

34. A medical device as recited in claim 33, wherein said securing means includes at least one of a securement member or an adhesive.

35. A medical device as recited in claim 28, wherein said tissue growth promoting member comprises a bio-resorbable material.

36. A medical implant delivery system for delivering a medical device in a human body, the delivery system comprising:

a handle;

a catheter coupled to the handle with lines coupled to the medical device; and

a tip portion coupled to a distal end of the catheter, the tip portion defining at least a first passageway and a second passageway extending at least partially along a length through the tip portion, the first passageway configured to move over a guide wire and the second passageway configured to communicate with the catheter and configured to facilitate delivery of the medical device, the first passageway and the second passageway being in a spaced apart arrangement.

37. A medical system as recited in claim 36, wherein said first passageway includes a first opening and a second opening in communication with said first opening, wherein said first and second openings are positioned in said tip portion.

38. A medical system as recited in claim 36, wherein said first passageway defines a first lumen.

39. A medical system as recited in claim 38, wherein said second passageway defines a second lumen, wherein said first lumen is separate and distinct from said second lumen.

40. A medical system as recited in claim 36, wherein said second passageway is configured to enable the medical device to be received therein and deployed therefrom.

41. A medical system as recited in claim 36, wherein at least a portion of said lines extend at least partially through said second passageway.

42. A delivery device configured to be coupled to a catheter for delivering a medical device in a human body, the delivery device comprising:

a tip member configured to be coupled at a distal end of the catheter, the tip member defining at least a first passageway and a second passageway extending at least partially along a length through the tip member, the first passageway configured to move over a guide wire and the second passageway configured to communicate with the catheter and configured to facilitate delivery of the medical device, the first passageway and the second passageway being in a spaced apart arrangement.

43. A delivery device as recited in claim 42, further comprising a delivery assembly operably associated with said tip member to facilitate deployment of the medical device from said second passageway.

44. A delivery device as recited in claim 42, wherein said first passageway includes an inlet and an outlet in communication with said inlet.

45. A delivery device as recited in claim 44, wherein said inlet is positioned at a distal portion of the delivery device.

46. A delivery device as recited in claim 44, wherein said inlet and said outlet are positioned at a distal portion of the delivery device.

47. A delivery device as recited in claim 42, wherein said tip member defines said first passageway.

48. A delivery device as recited in claim 42, wherein said tip member comprises a distal end and a proximal end, wherein said second passageway extends from said distal end to said proximal end.

49. A medical implant delivery system for delivering a medical device in a human body, the delivery system comprising:

a handle;

a catheter coupled to the handle with lines coupled to the medical device; and

a tip portion coupled to a distal end of the catheter, the tip portion defining at least a first passageway and a second passageway extending at least partially along a length through the tip portion, the first passageway configured to move over a guide wire and the second passageway configured to communicate with the catheter and configured to deliver the medical device, the second passageway and the first passageway being in a non-coaxial arrangement.

50. A delivery system as recited in claim 49, further comprising an actuating assembly configured to facilitate delivery of the medical device.

51. A delivery system as recited in claim 49, wherein said first passageway is configured such that the guide wire can be received into and extended from said first passageway at a distal end of the delivery system.

52. A delivery system as recited in claim 49, wherein said first passageway includes an inlet and an outlet in communication with said inlet.

53. A delivery device as recited in claim 52, wherein said inlet is positioned at a distal portion of the delivery system.

54. A delivery system as recited in claim 49, wherein said first passageway defines a first lumen.

55. A delivery system as recited in claim 54, wherein said second passageway defines a second lumen, wherein said first lumen is separate and distinct from said second lumen.

56. A delivery device for delivering a medical device, the delivery device comprising:

a handle body; and

an actuating assembly operatively associated with said handle body, said actuating assembly being adapted to move linearly with respect to said handle body to deploy at least a portion of a medical device, and to rotate with respect to said handle body to deploy additional portions of the medical device.

57. A delivery device as recited in claim 56, wherein said actuating assembly comprises a first member adapted to move linearly with respect to said handle body to deploy said at least a portion of the medical device.

58. A delivery device as recited in claim 57, wherein said actuating assembly comprises a second member adapted to rotate with respect to said handle body to deploy said additional portions of the medical device.

59. A delivery device as recited in claim 56, further comprising a release assembly adapted to facilitate detachment of the medical device from the delivery device.

60. A delivery device as recited in claim 56, further comprising a delivery assembly adapted to facilitate delivery of the medical device.

61. A delivery device as recited in claim 56, further comprising a catheter linked to said actuating assembly, wherein said catheter comprises a first lumen and second lumen in a non-coaxial arrangement.

62. A delivery device for delivering a Patent Foramen Ovale closure device, the delivery device comprising:

a handle body;

a first member operatively associated with said handle body, said first member being adapted to move linearly with respect to said handle body; and

a second member linked to said handle body and said first member, said second member being adapted to move linearly with respect to said handle body and adapted to rotate with respect to said handle body and said first member.

63. A delivery device as recited in claim 62, wherein said first member is linked to said handle body by a pin.

64. A delivery device as recited in claim 62, wherein linear movement of said first member with respect to said handle body causes at least a first portion of the closure device to deploy.

65. A delivery device as recited in claim 62, wherein a first anchor of the closure device is deployed by linear movement of said first member with respect to said handle body.

66. A delivery device as recited in claim 62, wherein a second anchor of the closure device is deployed by rotating said second member with respect to said handle body.

67. A delivery device as recited in claim 62, wherein said first member is linked to said handle body by a pin.

68. A method for deploying an internal tissue opening closure device, the method comprising the steps of:

deploying a left anchor of a closure device from a delivery device, said delivery device comprising an actuating assembly linked to a handle body, said left anchor being adapted to deploy by a first movement of at least a portion of said actuating assembly with respect to said handle body; and

deploying a right anchor of said closure device from said delivery device by a second movement of at least a portion of said actuating assembly with respect to said handle body.

69. A method as recited in claim 68, where said deploying said left anchor comprises linearly moving said actuating assembly with respect to said handle body.

70. A method as recited in claim 68, where said deploying said second anchor comprises rotating at least a portion of said actuating assembly with respect to said handle body.

71. A method as recited in claim 68, where said actuating assembly comprises a first member configured to move linearly with respect to said handle body, and a second member.

72. A method as recited in claim 71, where said second member is configured to rotate and move linearly with respect to said handle body portion.

73. A method for closing an internal tissue opening, wherein the internal tissue opening includes first and second opposing tissue walls and a tunnel therethrough defining the internal tissue opening, the method comprising the steps of:

deploying a first anchor of a closure device from a delivery device by moving at least a portion of an actuating assembly of said delivery device in a linear direction with respect to a handle body of said delivery device;

positioning said first anchor against a first tissue wall of an internal tissue opening; and

deploying a second anchor of said closure device from said delivery device to engage at least a portion of at least one of a tunnel or a second tissue wall of the internal tissue opening by rotating at least a portion of said actuating assembly.

74. A method as recited in claim 73, wherein said deploying said first anchor comprises linearly moving a first member of said actuating assembly.

75. A method as recited in claim 73, wherein said deploying said second anchor comprises rotating a second member of said actuating assembly.

76. A method as recited in claim 73, wherein said positioning said first anchor comprising moving the delivery device.

77. A method as recited in claim 73, wherein said positioning said first anchor comprising moving the handle body.

78. A method as recited in claim 73, wherein said closure device comprises a multi-cellular body structure.

79. A method for closing a Patent Foramen Ovale, the method comprising the steps of:

translating at least a portion of an actuating assembly of a delivery device with respect to a handle body of said delivery device to deploy at least a first portion of a closure device from said delivery device, said closure device comprising a multi-cellular structure linked to said first portion and a second portion linked to said multi-cellular structure; and

rotating at least a portion of said actuating assembly to deploy said second portion of said closure device from said delivery device.

80. A method as recited in claim 79, further comprising positioning said first portion of said closure device against a left atrial wall of the hear.

81. A method as recited in claim 79, further comprising deploying said second portion of said closure device inside a tunnel of the PFO.

82. A method as recited in claim 79, further comprising detaching said closure device from said delivery device.

83. A method as recited in claim 82, wherein said detaching said closure device comprises utilizing a release assembly to selectively detach said closure device from said delivery device.

84. A medical system for treating an internal tissue opening, the system comprising:

a medical device comprising:

a multi-cellular structure, and

at least one anchor operatively associated with said multi-cellular structure; and

a delivery device comprising:

a handle body, and

an actuating assembly operatively associated with said handle body, said actuating assembly being adapted to selectively deploy at least a first portion of said closure device by a first movement, and said actuating assembly being adapted to selectively deploy at least a second portion of said closure device by a second movement.

85. A medical system as recited in claim 84, further comprising a second anchor operatively associated with said multi-cellular structure.

86. A medical system as recited in claim 84, wherein said first movement is a linear movement.

87. A medical system as recited in claim 84, wherein said second movement is a rotational movement.

88. A medical system as recited in claim 84, wherein said medical device comprises a flat stent.

89. A medical system for treating a tissue structure, the system comprising:

a medical device comprising a frame configured to assume a substantially flat configuration, said frame including a central portion and at least one anchor extending from the central portion, the central portion including a plurality of struts defining a multi-cellular structure; and

a delivery device comprising:

a handle body, and

an actuating assembly, said actuating assembly adapted to enable deployment of said at least one anchor by movement of at least a portion of said actuating assembly.

90. A medical system as recited in claim 89, wherein said actuating assembly comprises a first member adapted to facilitate selective deployment of a first portion of said medical device, and a second member adapted to facilitate selective deployment of a second portion of said medical device.

91. A medical system as recited in claim 89, wherein said medical device comprises a PFO closure device.

92. A medical system as recited in claim 89, wherein said medical device further comprises at least one anchor.

93. A medical system as recited in claim 89, wherein said medical device is adapted to apply lateral force to tunnel tissue of a PFO.

94. A medical system as recited in claim 89, wherein said medical device further comprises a tissue growth promoting member associated with said frame.

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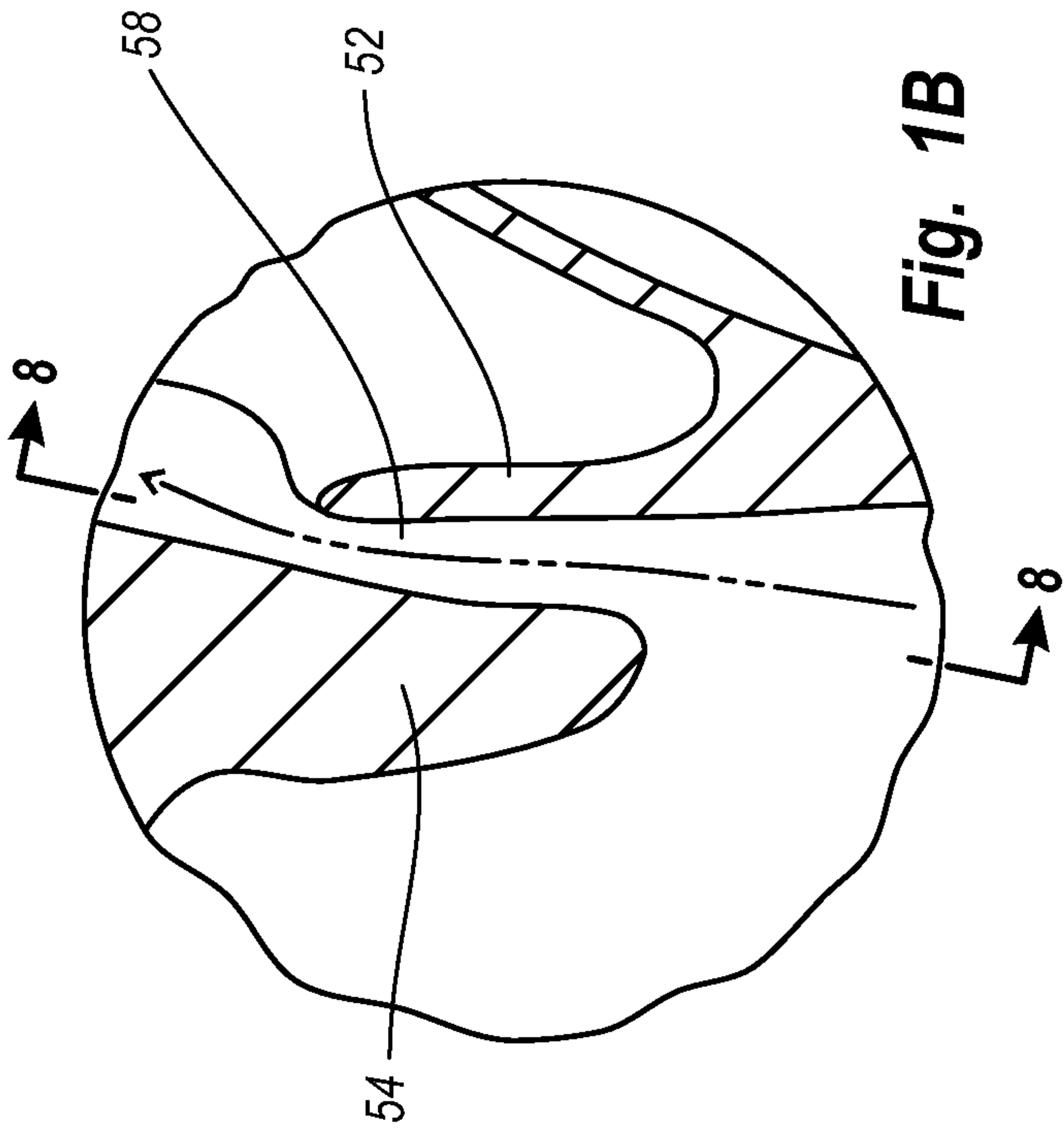


Fig. 1B

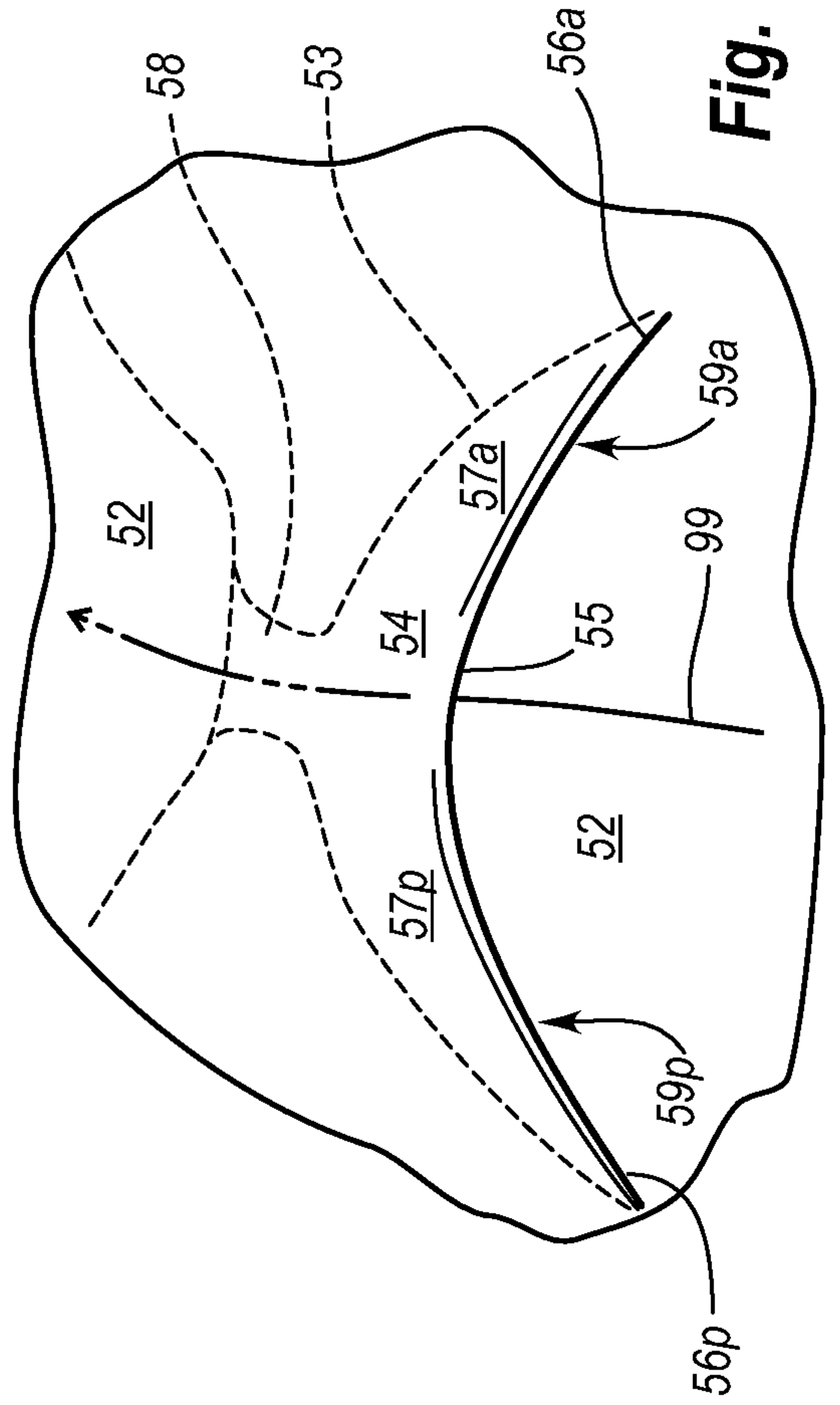


Fig. 1C

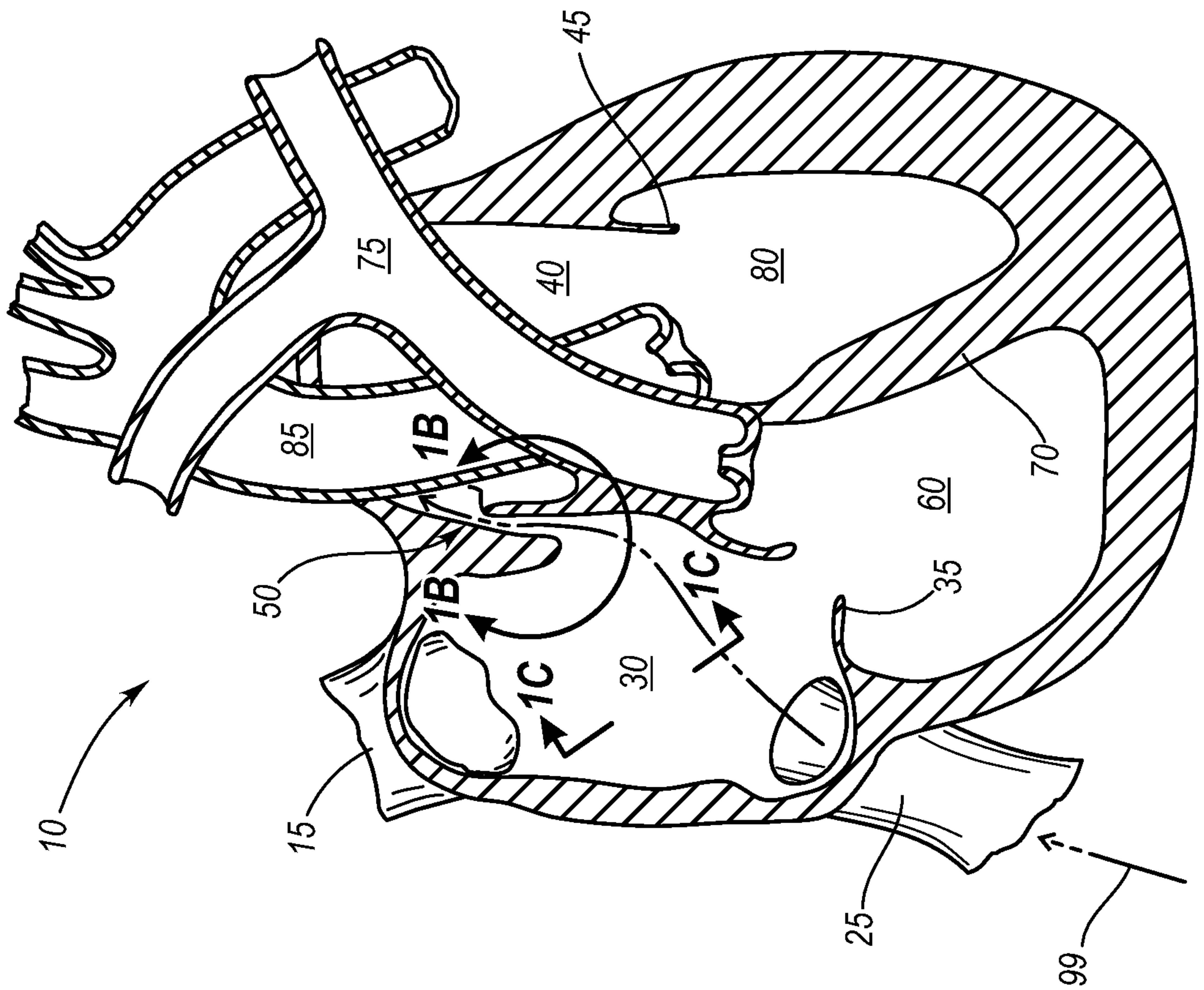


Fig. 1A

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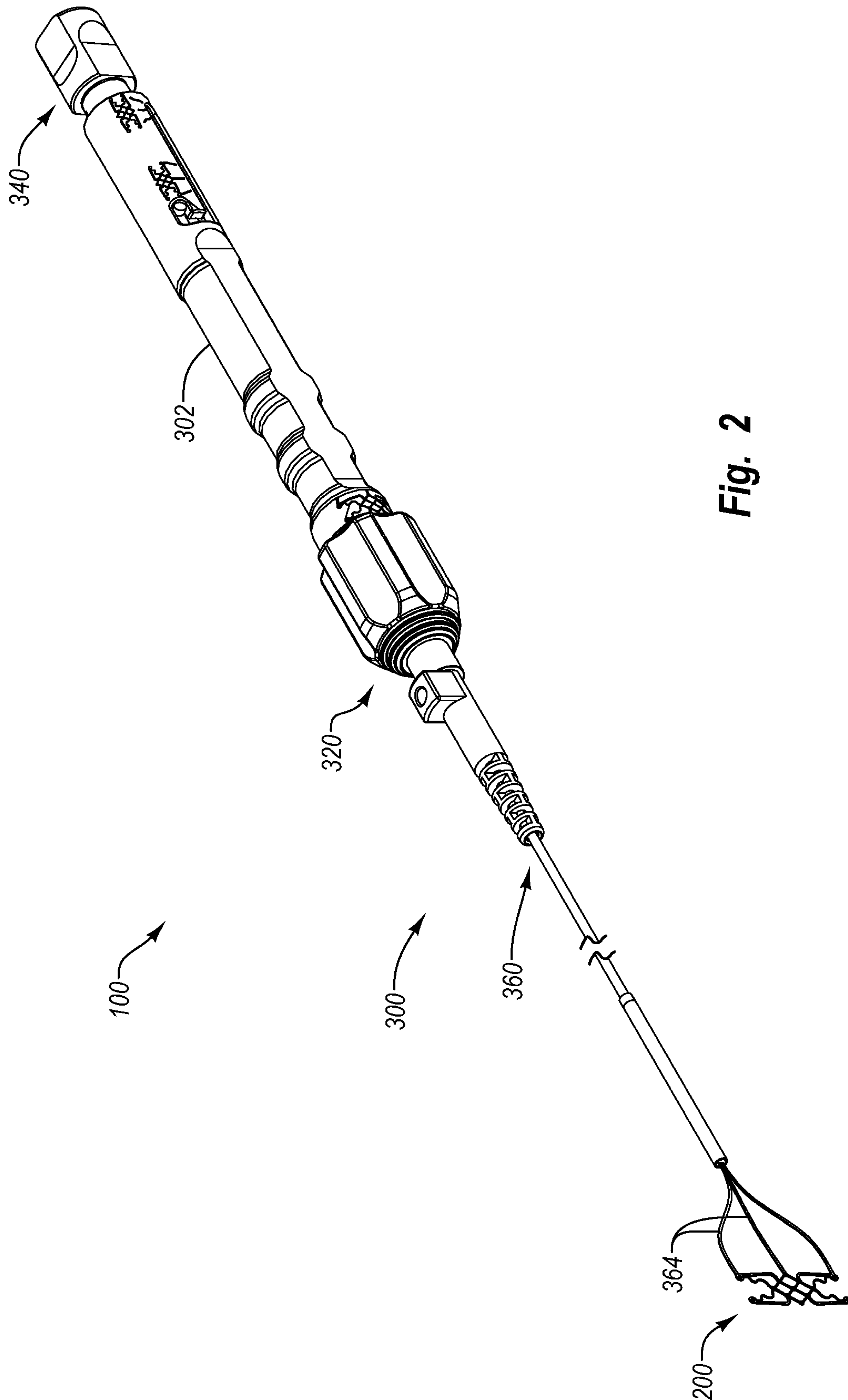


Fig. 2

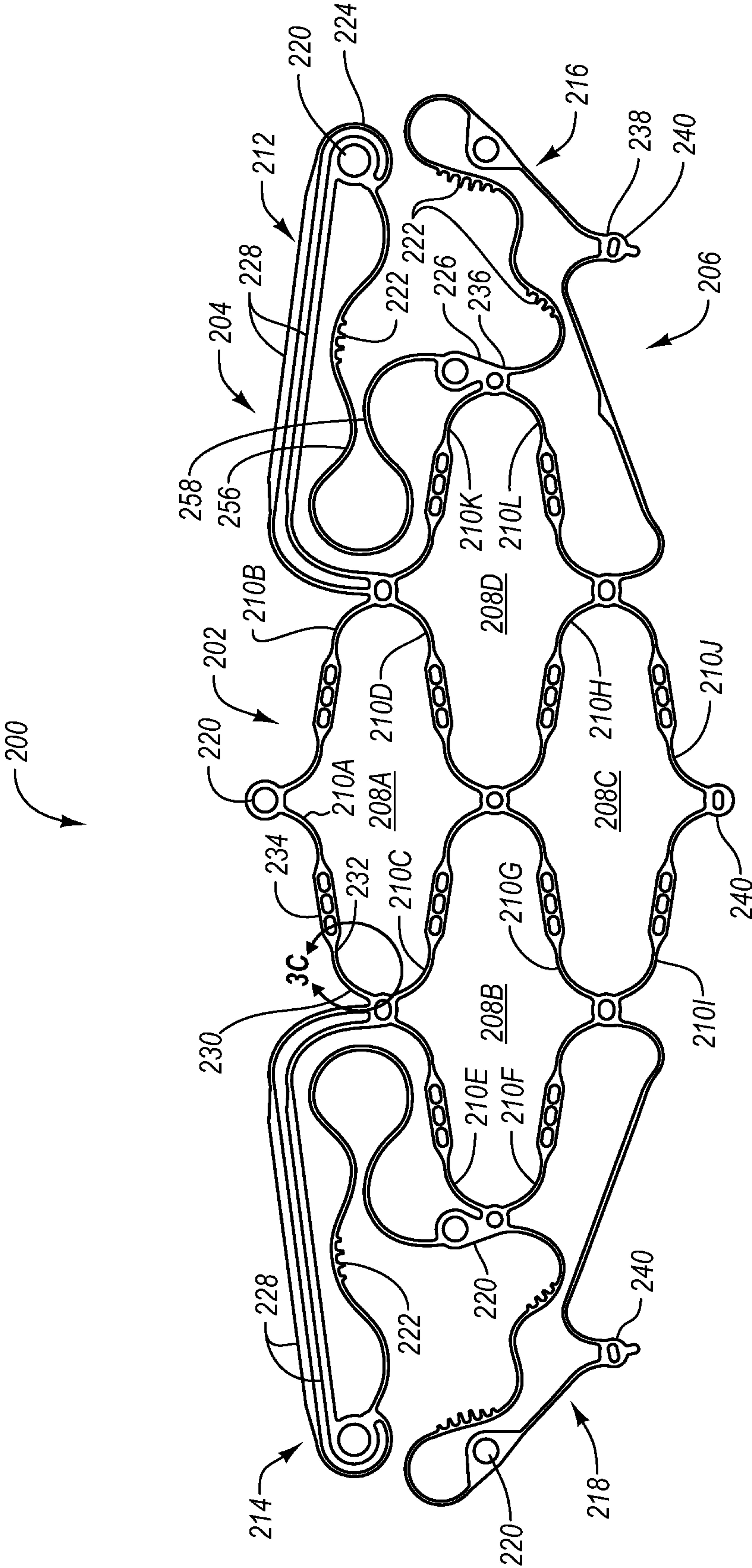


Fig. 3A

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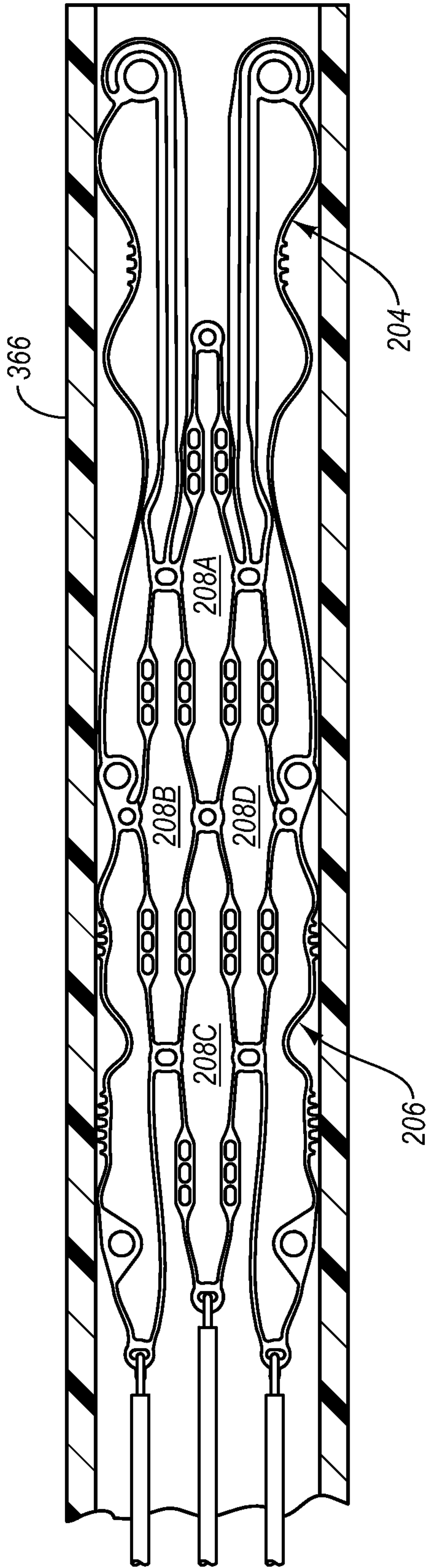


Fig. 3B

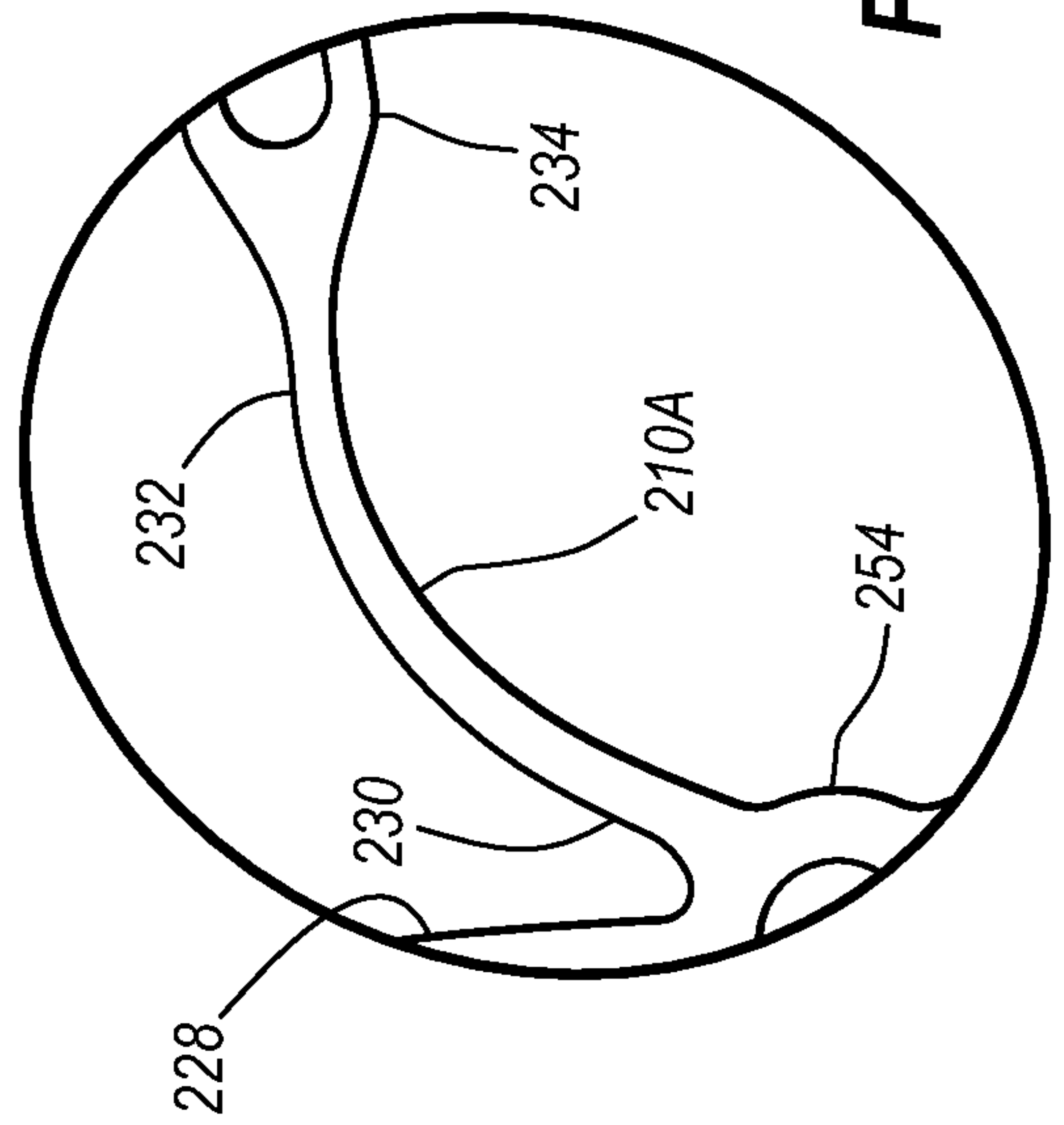


Fig. 3C

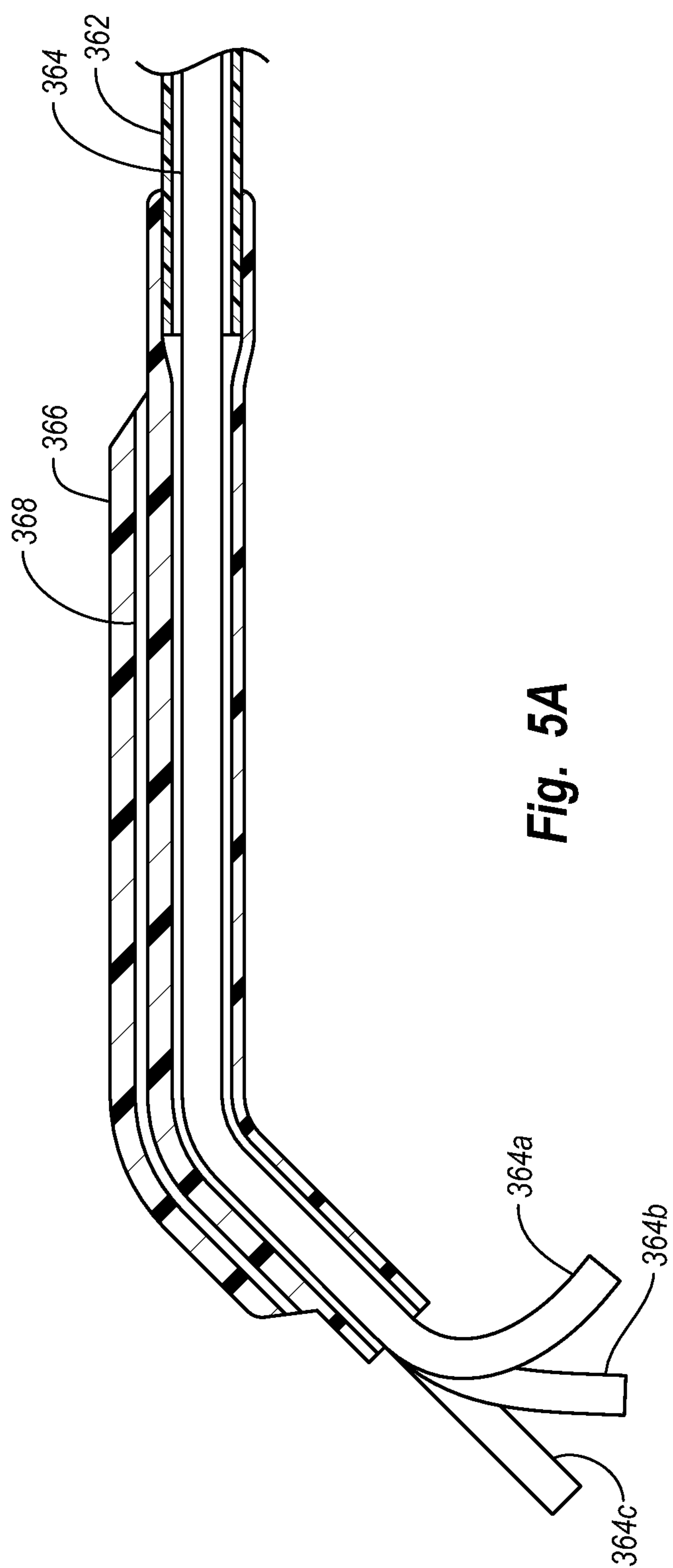
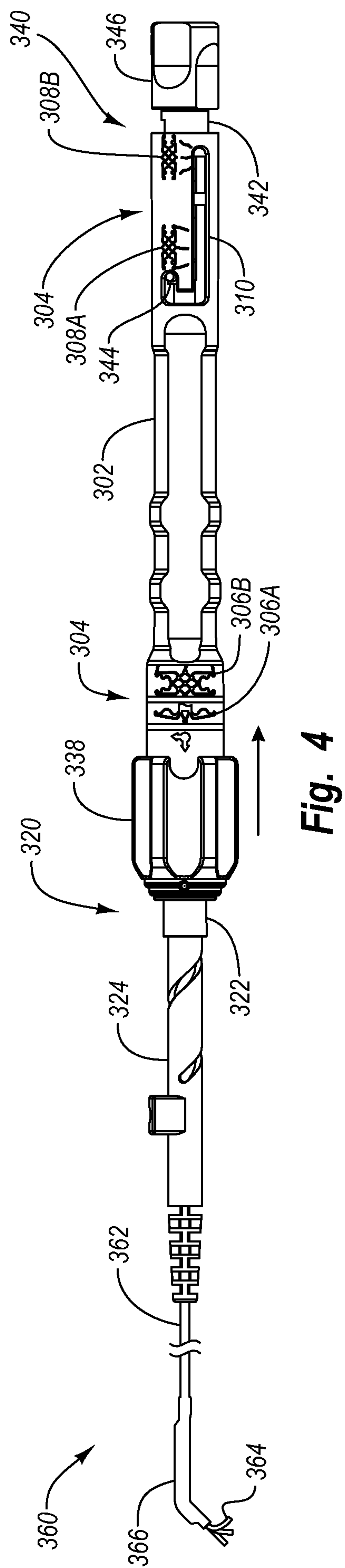


Fig. 5A

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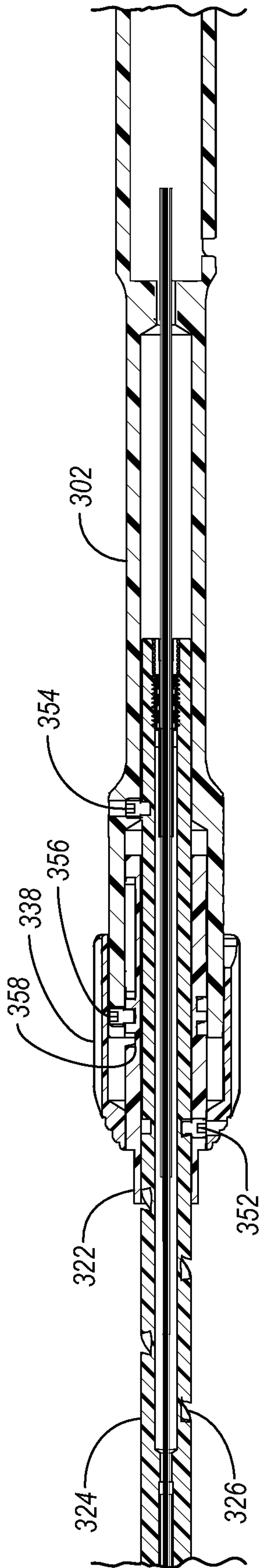


Fig. 5B

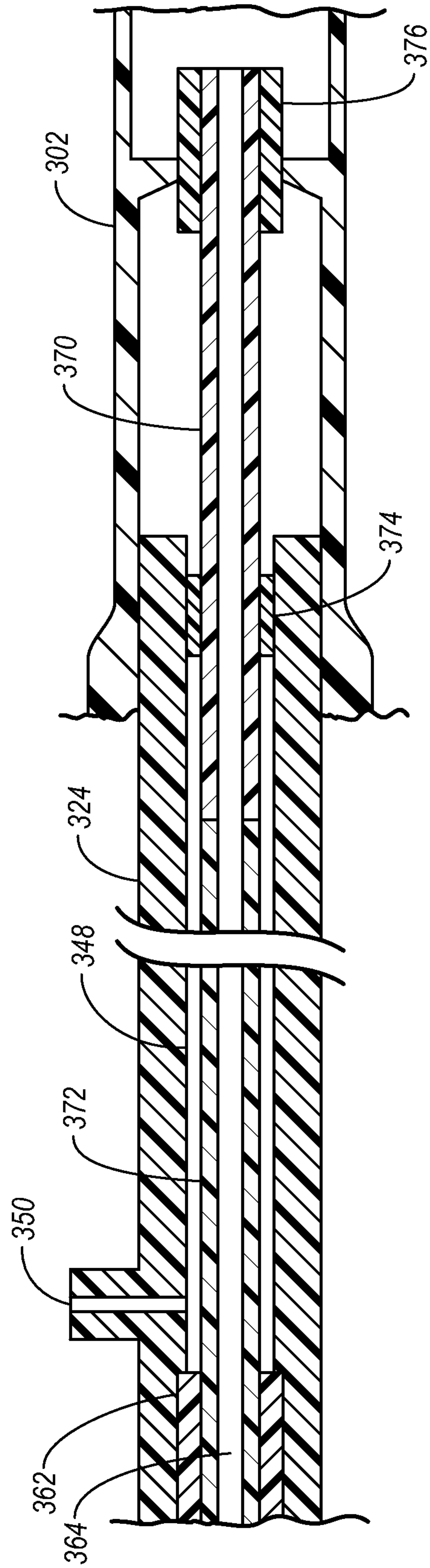


Fig. 5C

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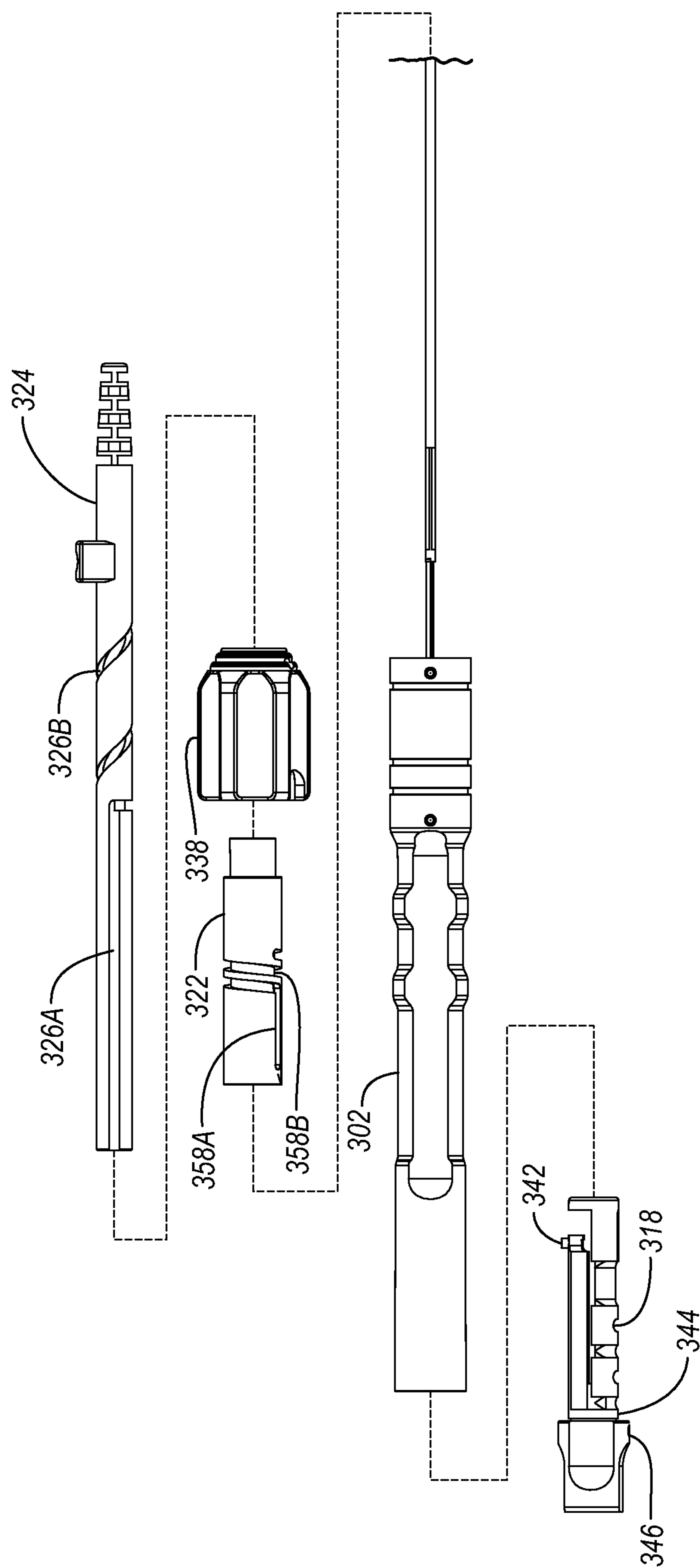


Fig. 6

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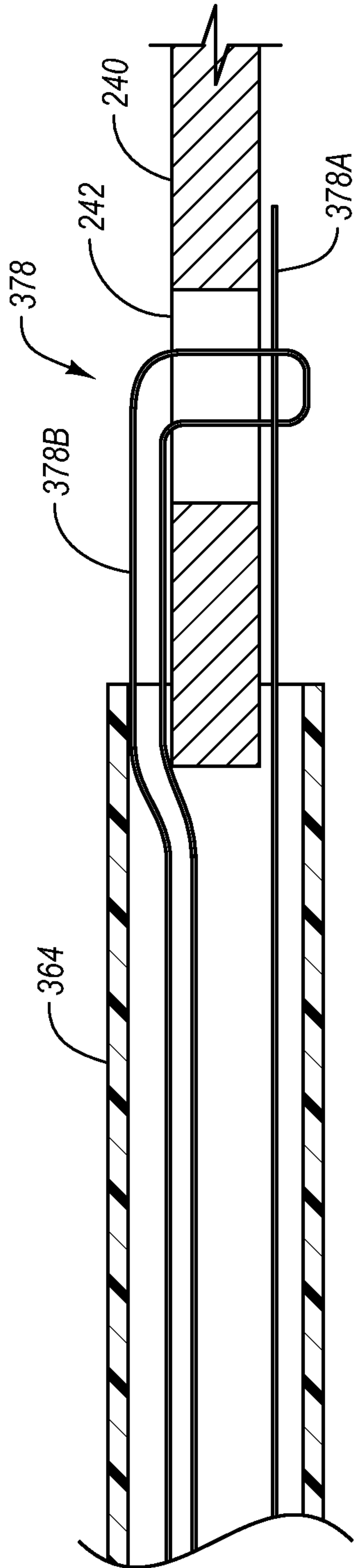
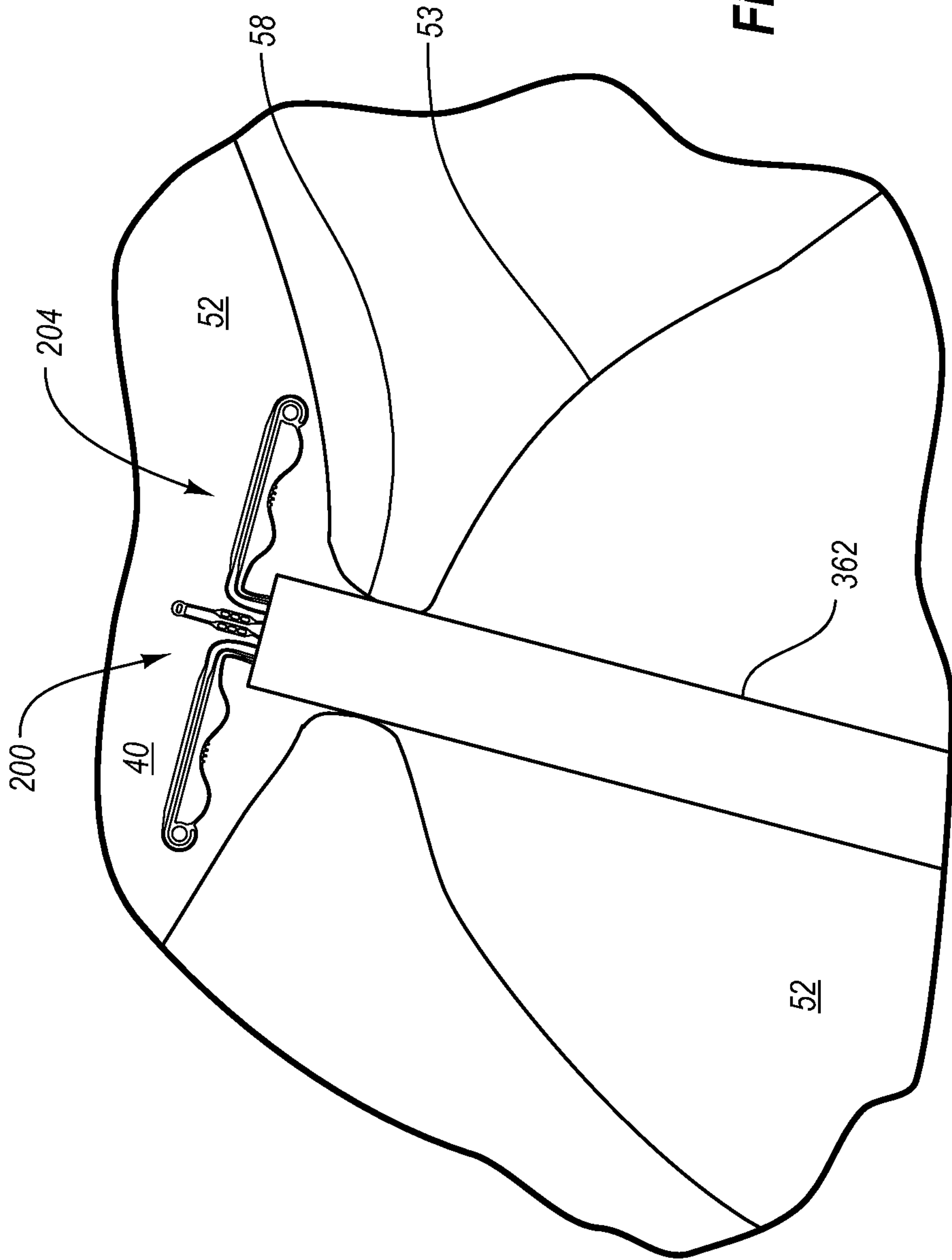
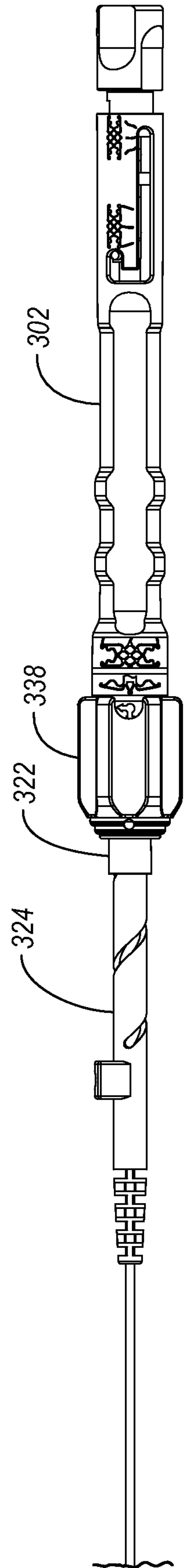


Fig. 7

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**Fig. 8A****Fig. 8B**

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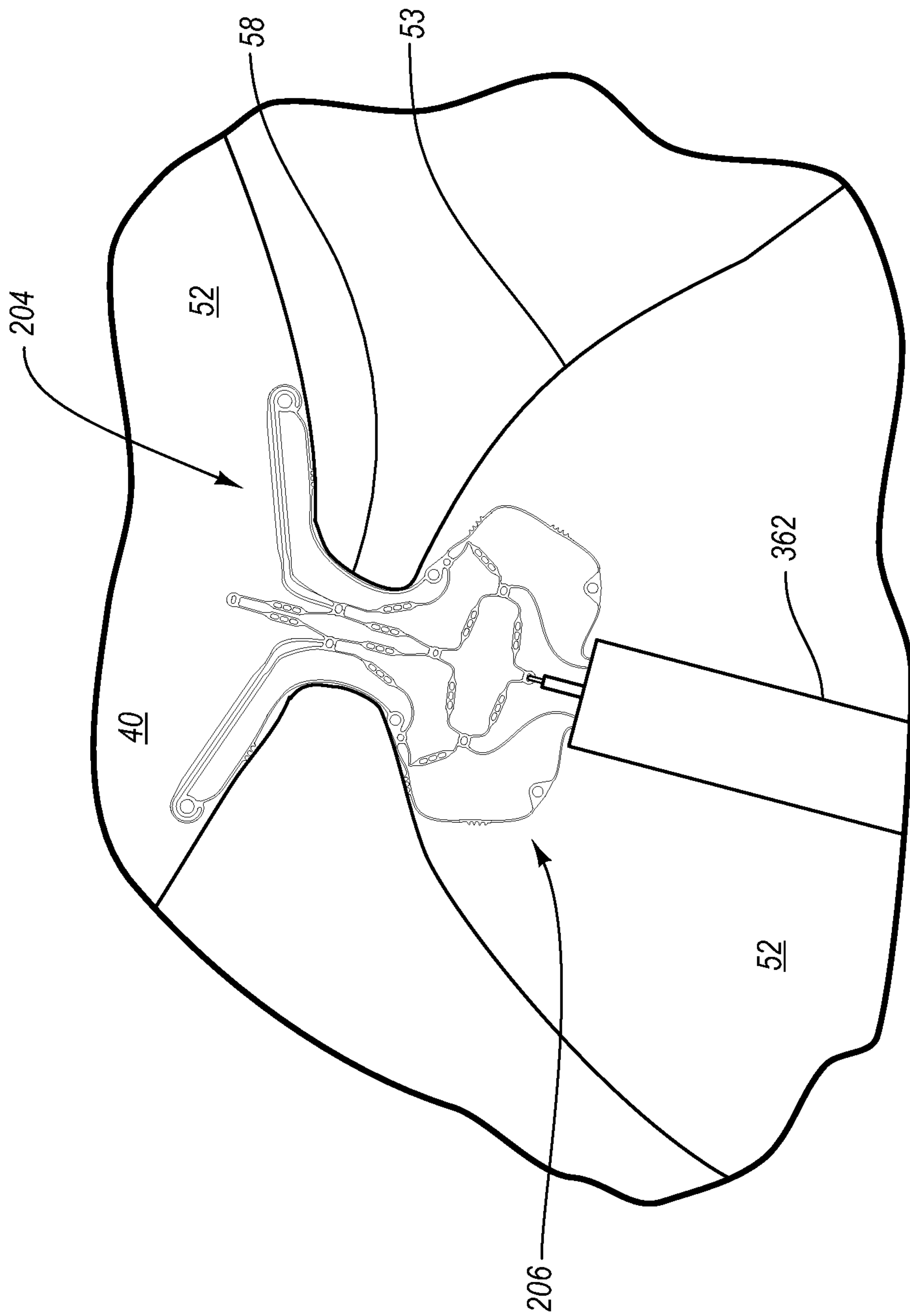
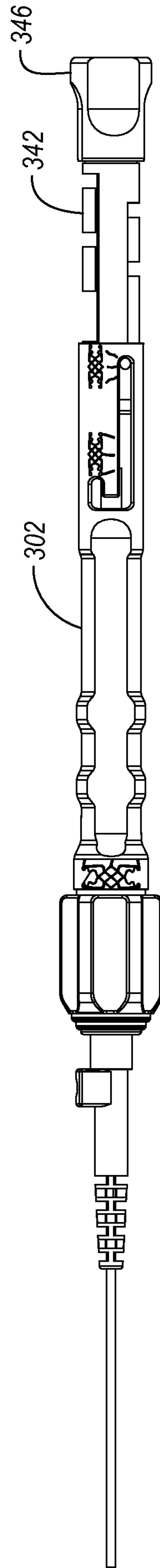
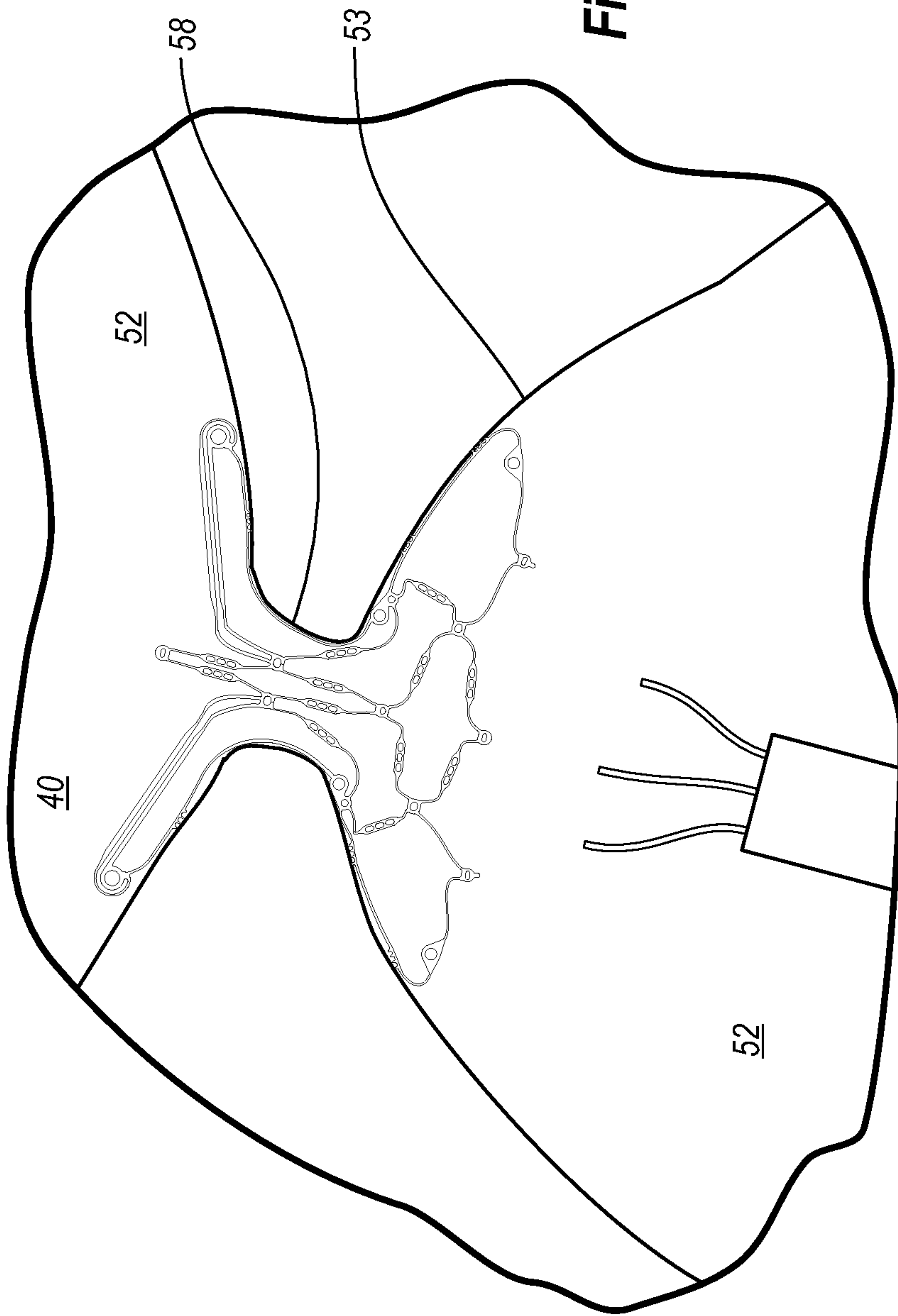


Fig. 9

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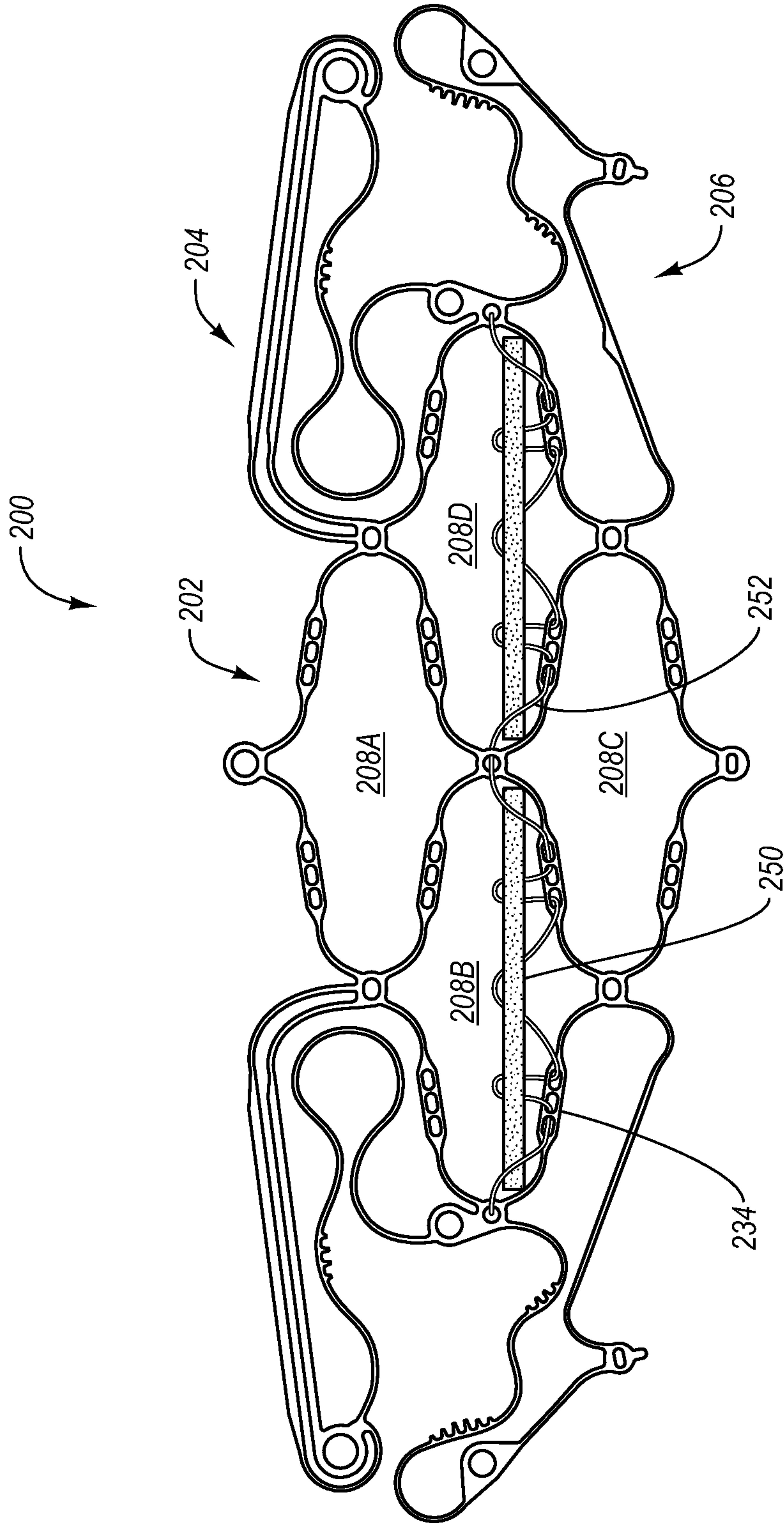


Fig. 11A

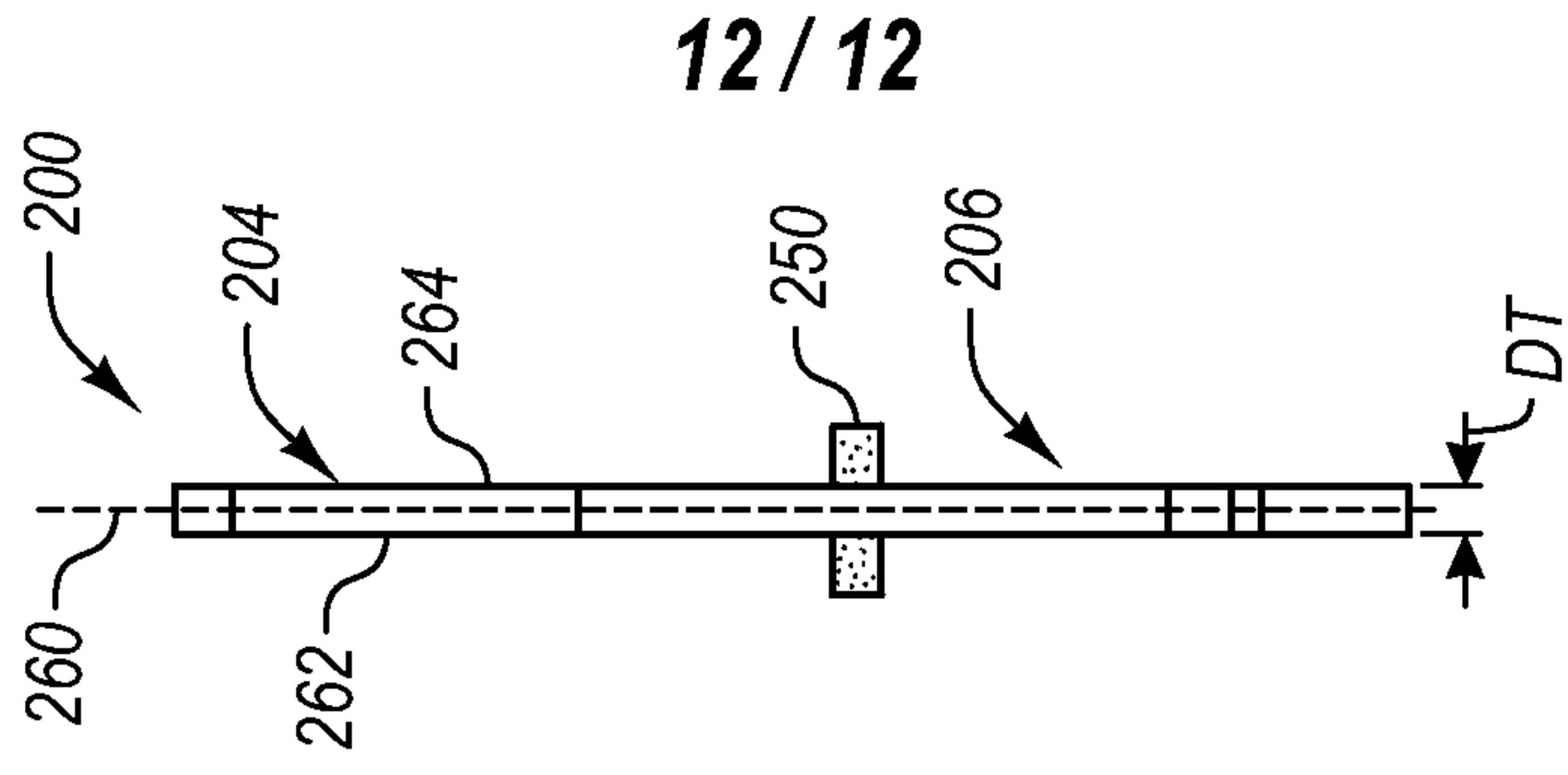


Fig. 11B

