US 20100234880A1

(19) United States

(12) Patent Application Publication

Abbott et al.

(10) Pub. No.: US 2010/0234880 A1

(43) Pub. Date: Sep. 16, 2010

(54) **SYSTEMS AND METHODS FOR TREATING SEPTAL DEFECTS**

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(21) Appl. No.: **12/725,595**

(22) Filed: **Mar. 17, 2010**

Related U.S. Application Data

(60) Continuation of application No. 11/422,871, filed on Jun. 7, 2006, now Pat. No. 7,686,828, which is a division of application No. 11/175,814, filed on Jul. 5, 2005, which is a continuation-in-part of application No. 10/847,747, filed on May 17, 2004, now abandoned, which is a continuation-in-part of application No. 10/734,670, filed on Dec. 11, 2003, which is a division of application No. 09/948,453, filed on Sep. 7, 2001, now Pat. No. 6,702,835, which is a continuation-in-part of application No. 09/948,502, filed on Sep. 6, 2001, now Pat. No. 6,776,784.

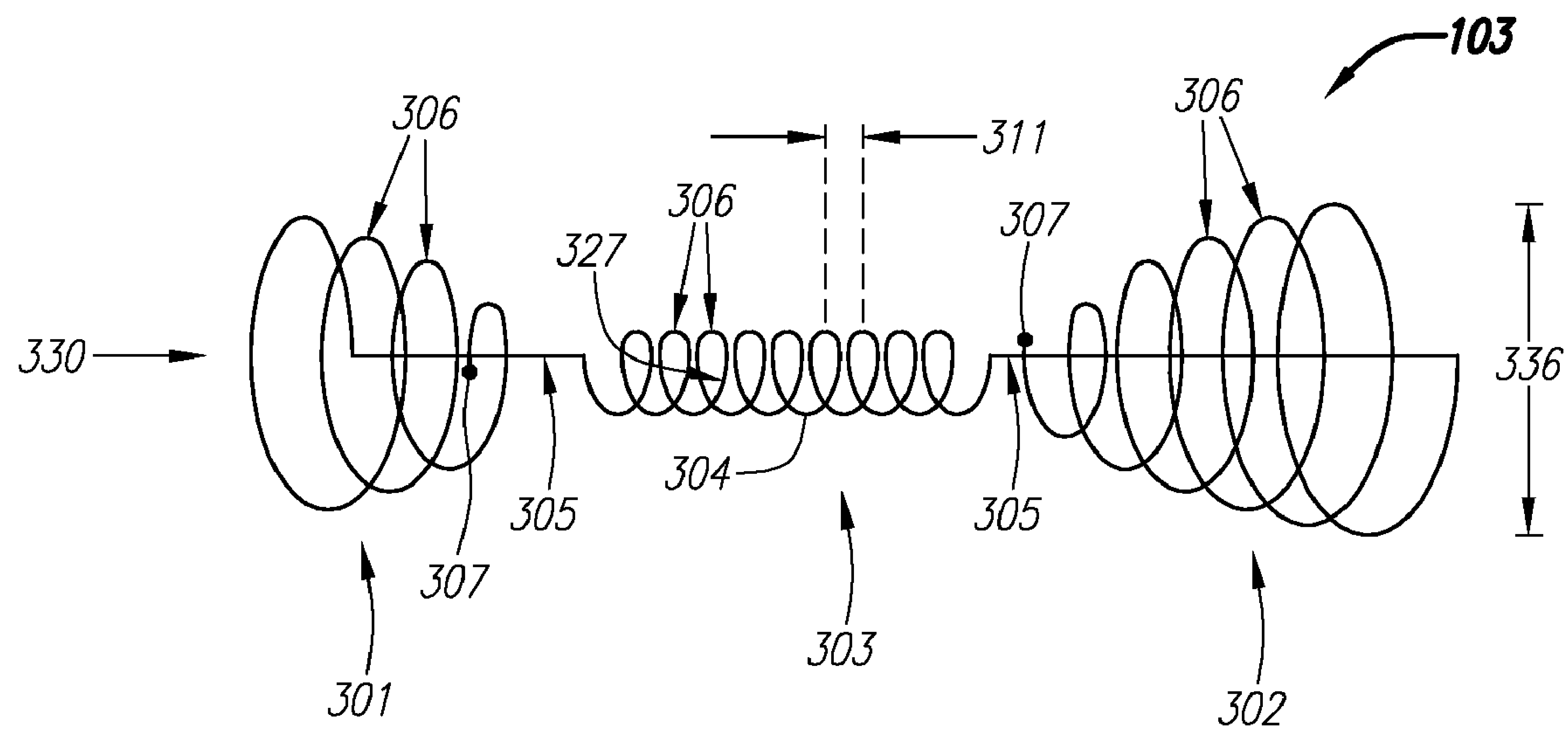
Publication Classification

(51) **Int. Cl.**
A61B 17/08 (2006.01)

(52) **U.S. Cl.** **606/213**

(57) **ABSTRACT**

A system for treating a septal defect having an implantable treatment apparatus and devices for delivering the implantable treatment apparatus and methods for treating a septal defect are provided. The implantable treatment apparatus is preferably implantable through a septal wall or portion thereof. The treatment system can include a flexible elongate body member, a delivery device configured to deliver the implantable apparatus, a stabilization device configured to stabilize the body member and a positioning device configured to position the delivery device in a desired location.



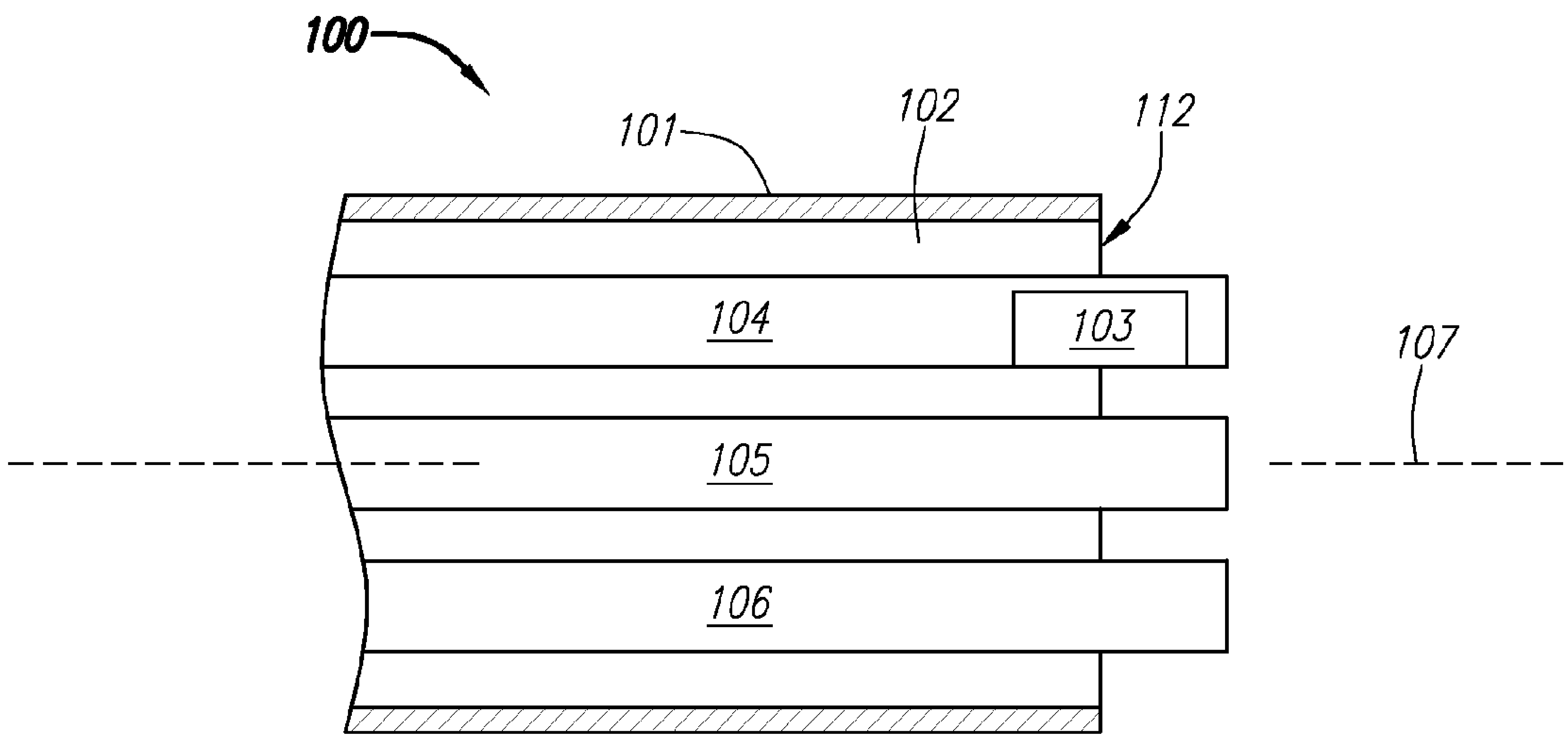


FIG. 1

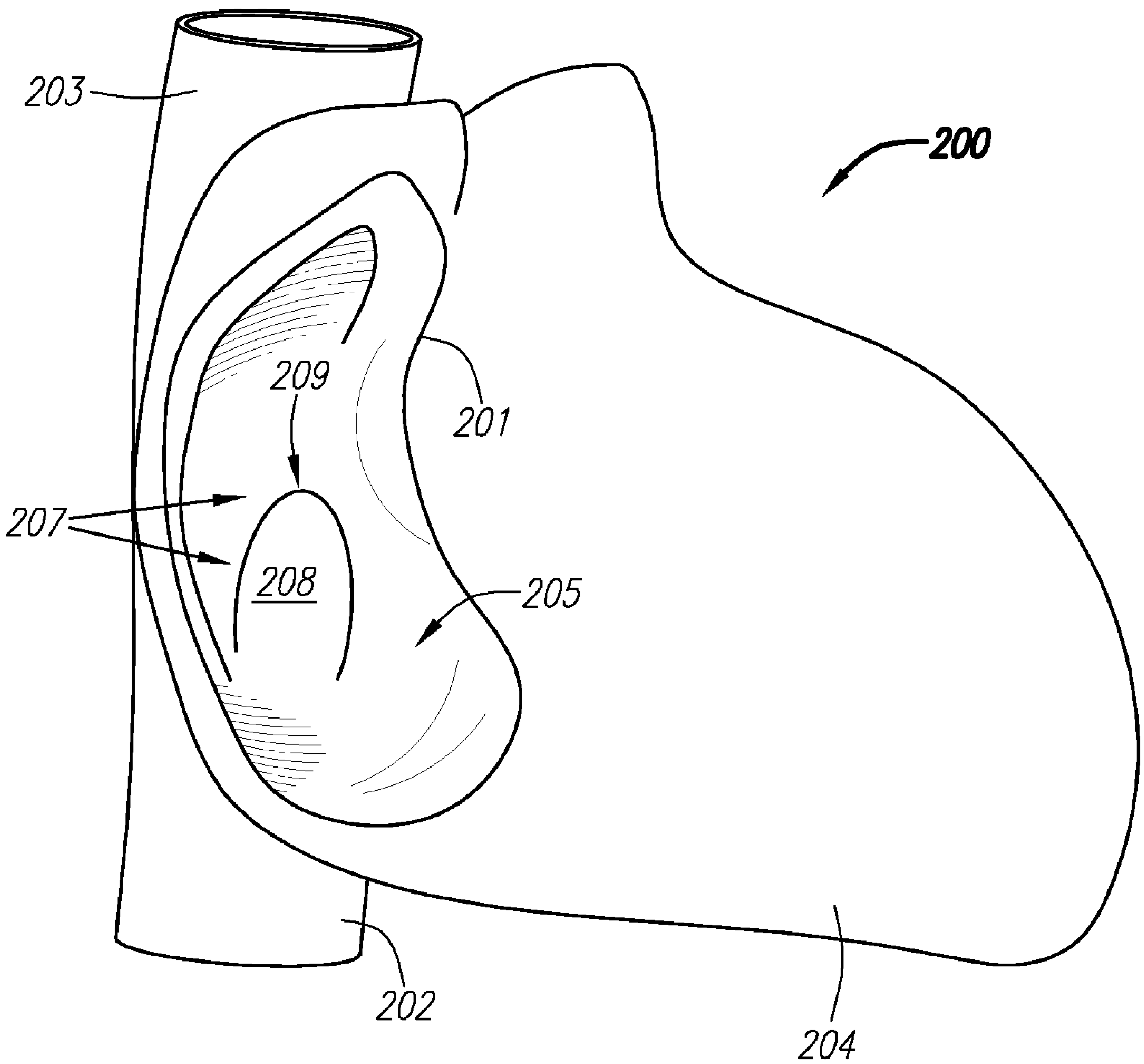


FIG. 2A

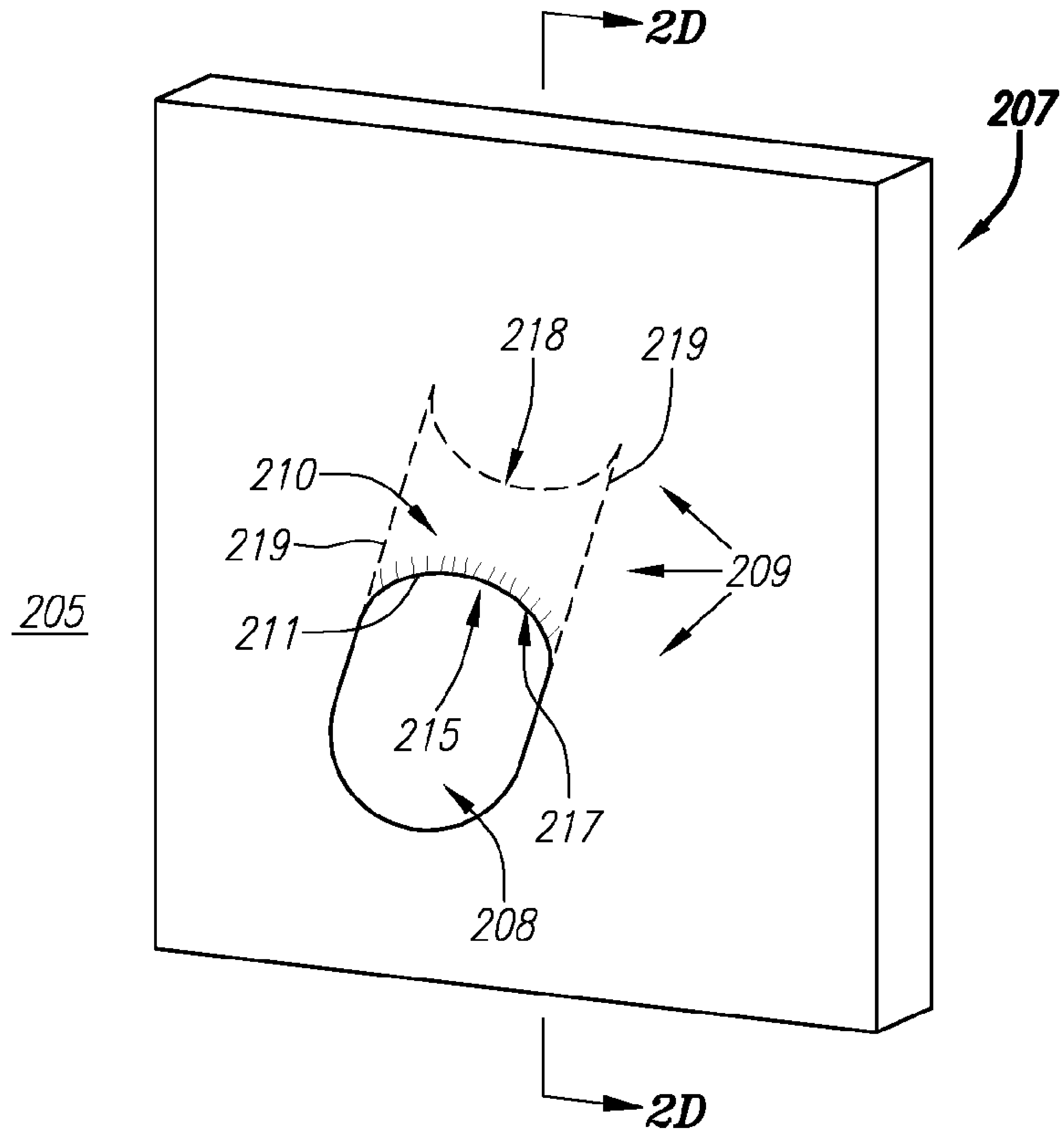

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FIG. 2B

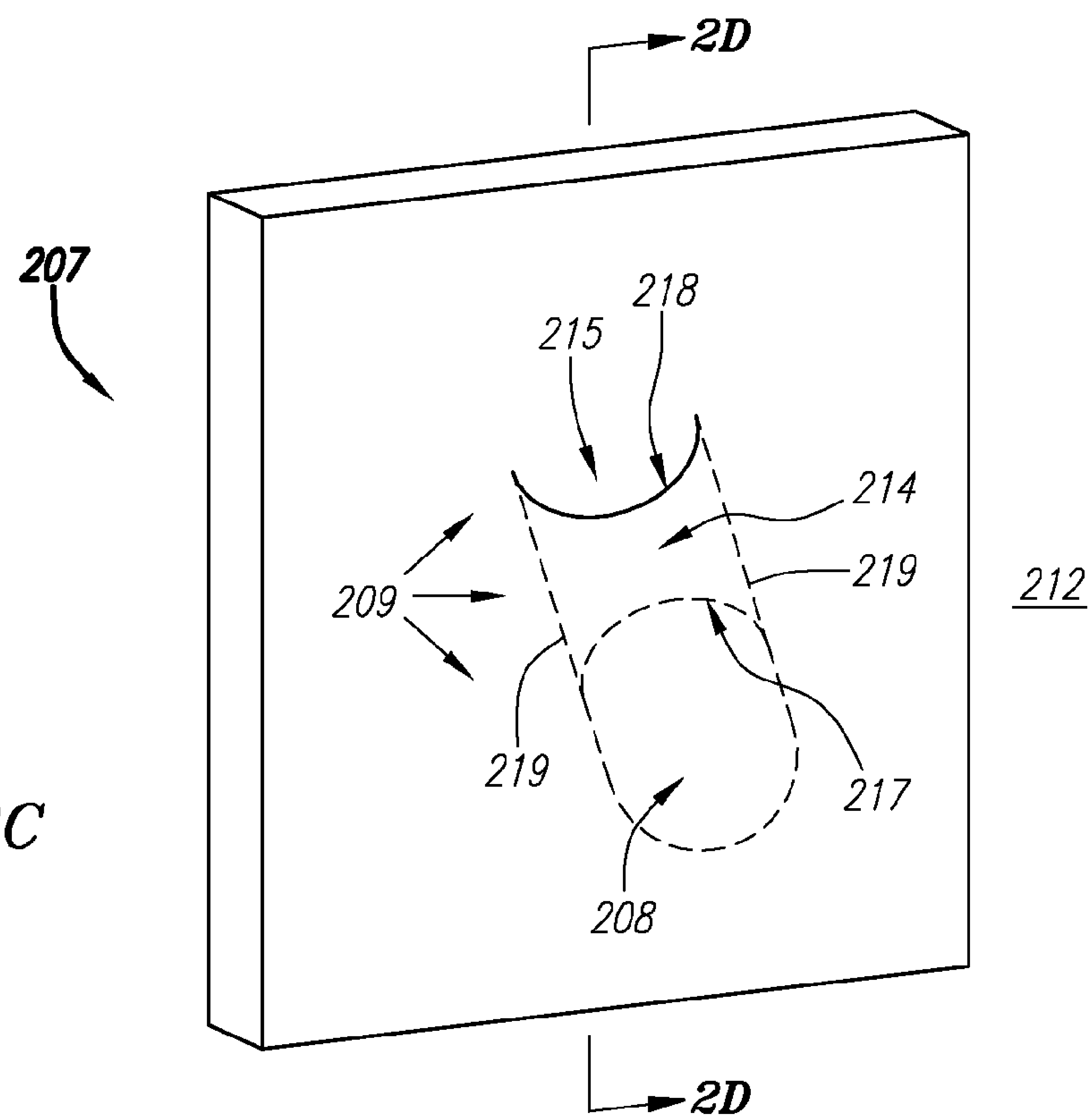
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FIG. 2C

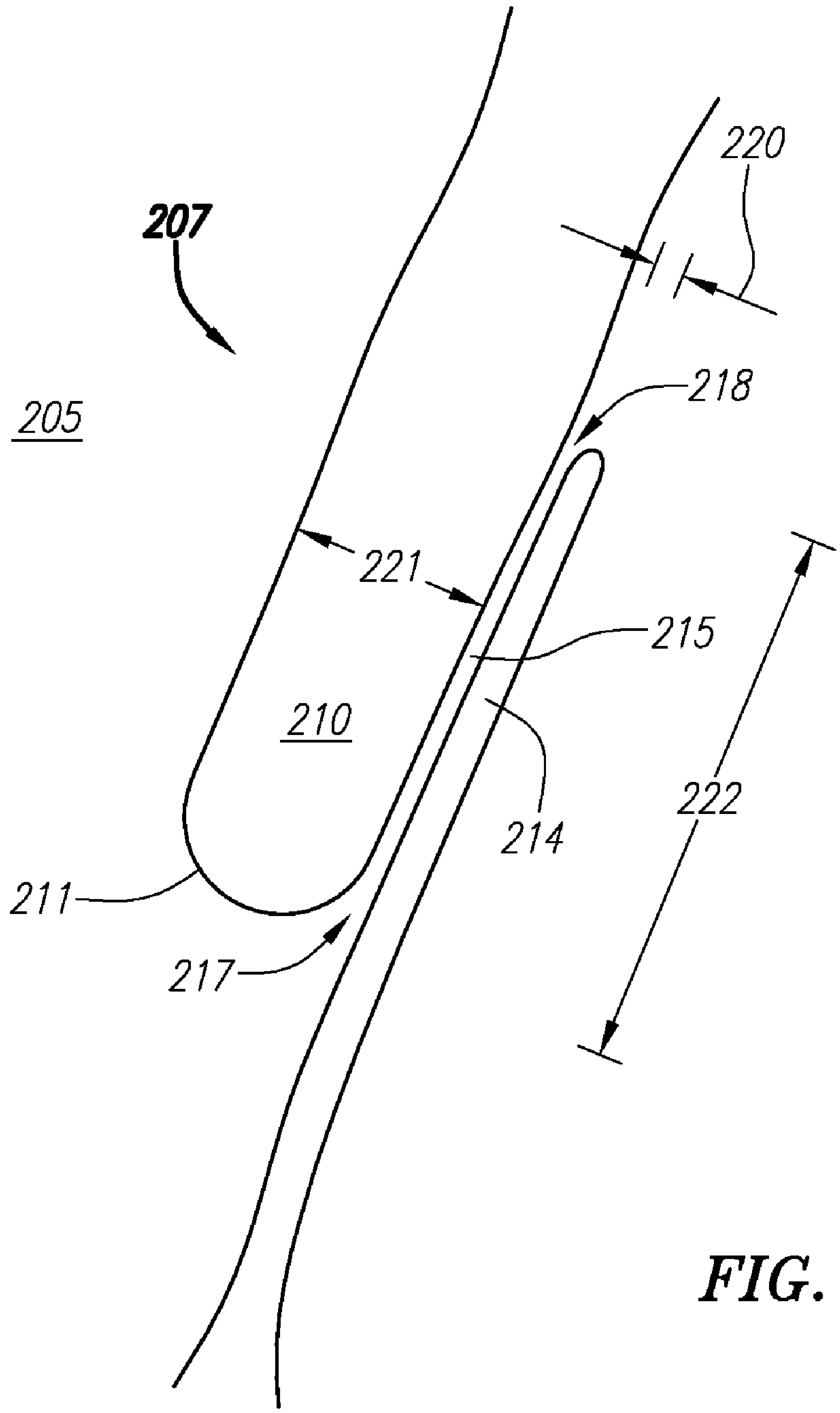
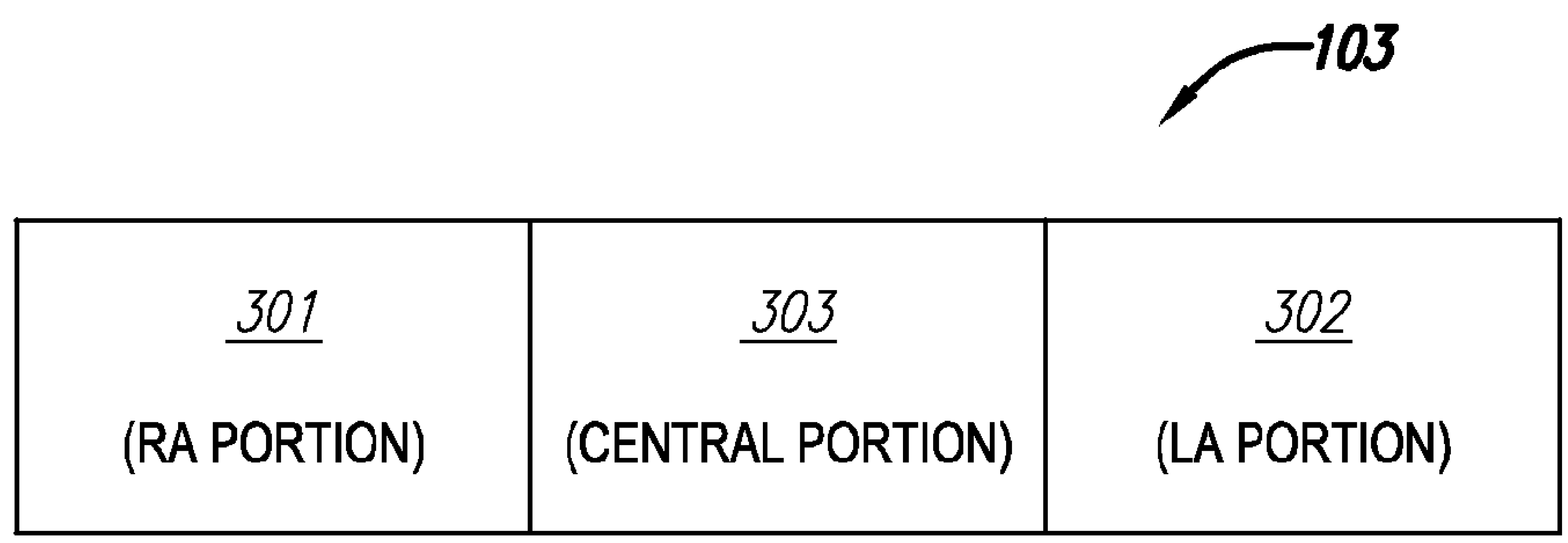


FIG. 2D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(RA PORTION)
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(LA PORTION)

FIG. 3

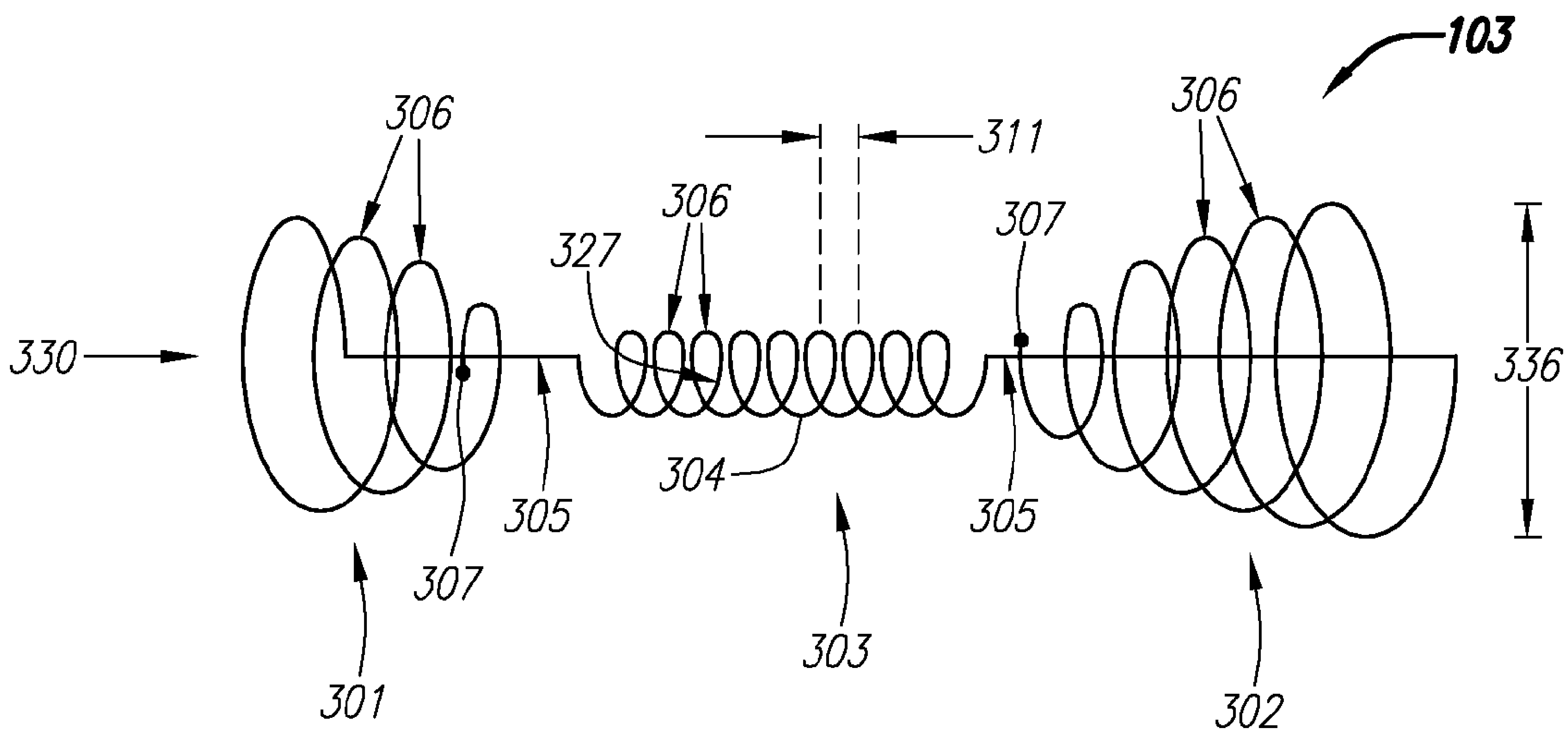
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FIG. 4A

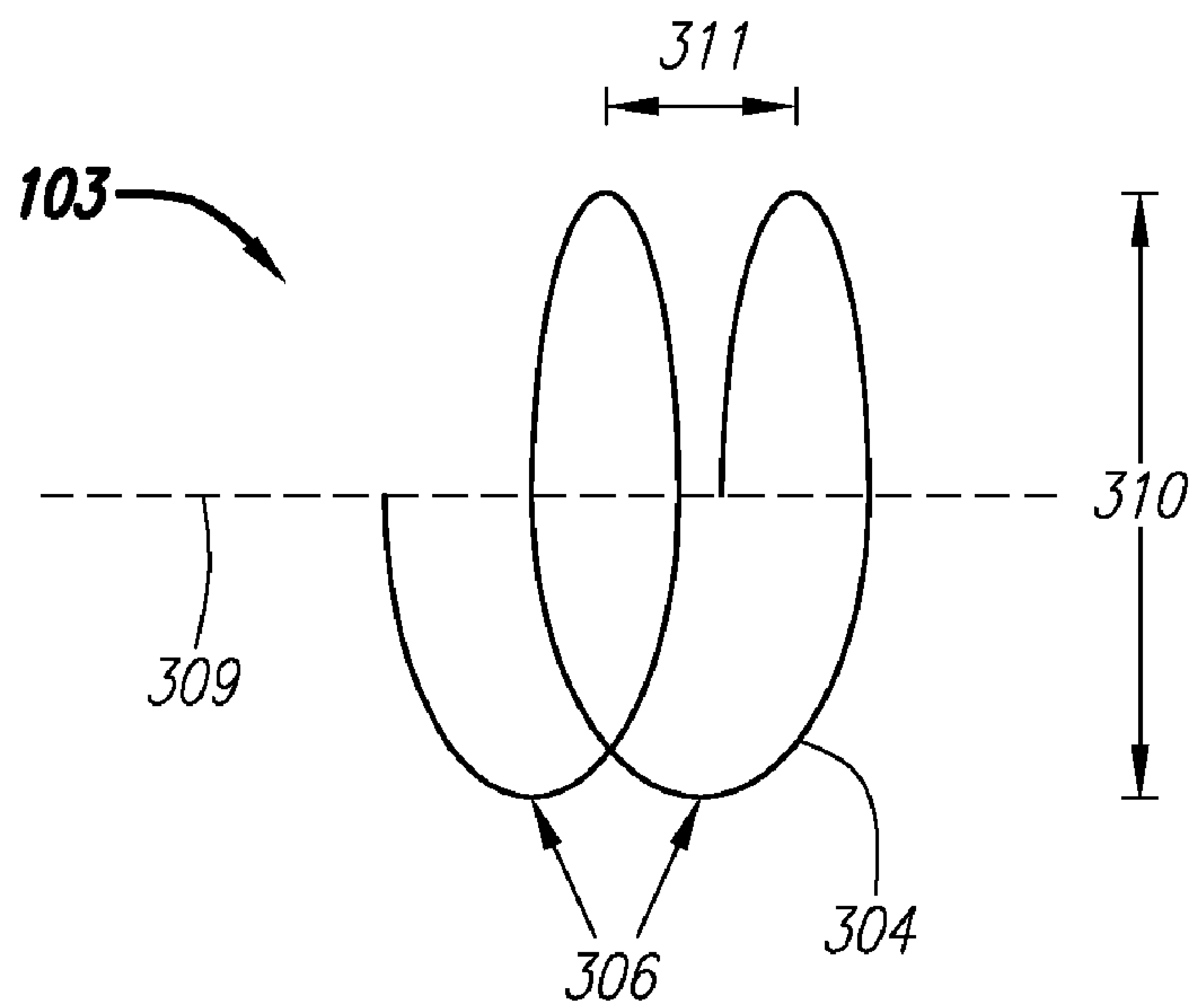

FIG. 4B

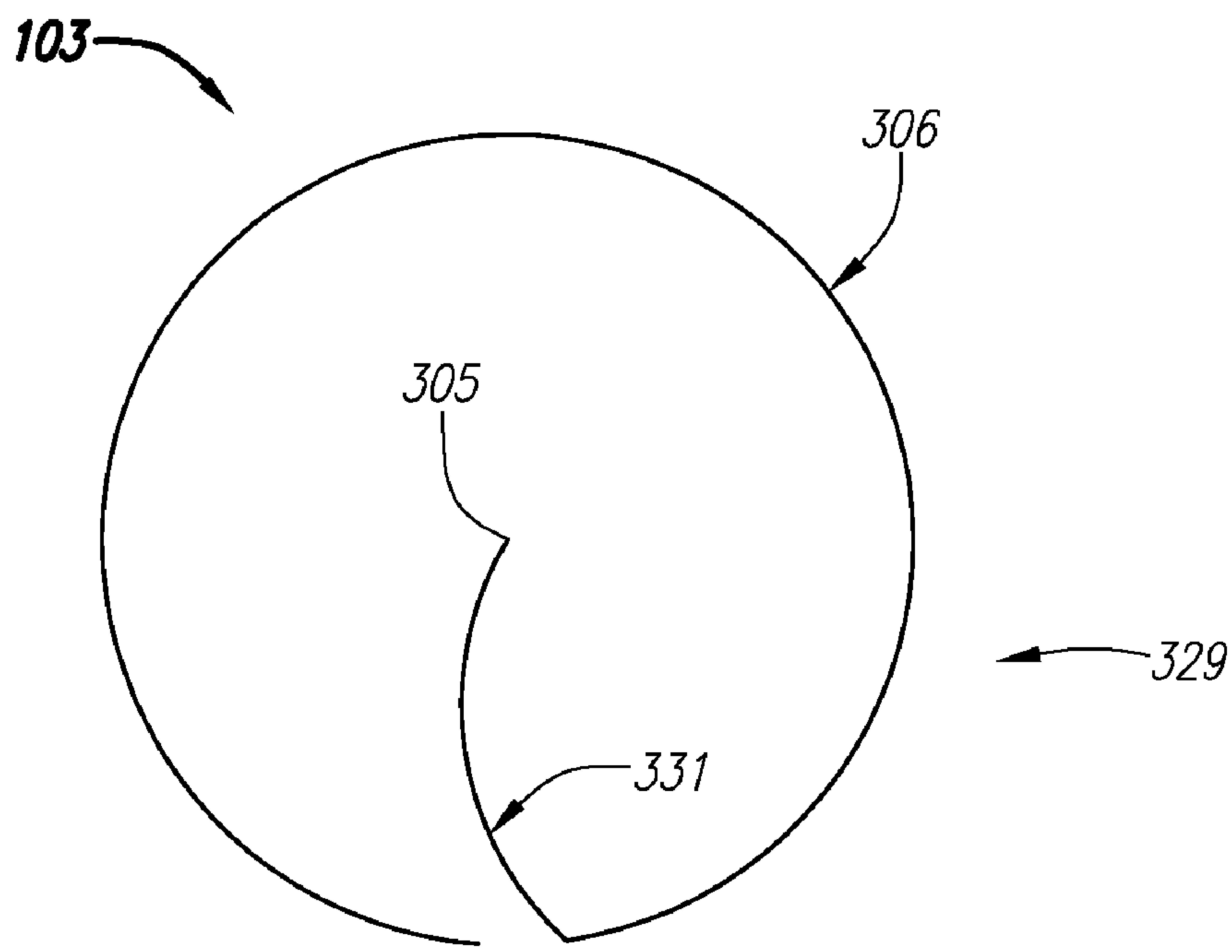

FIG. 4C

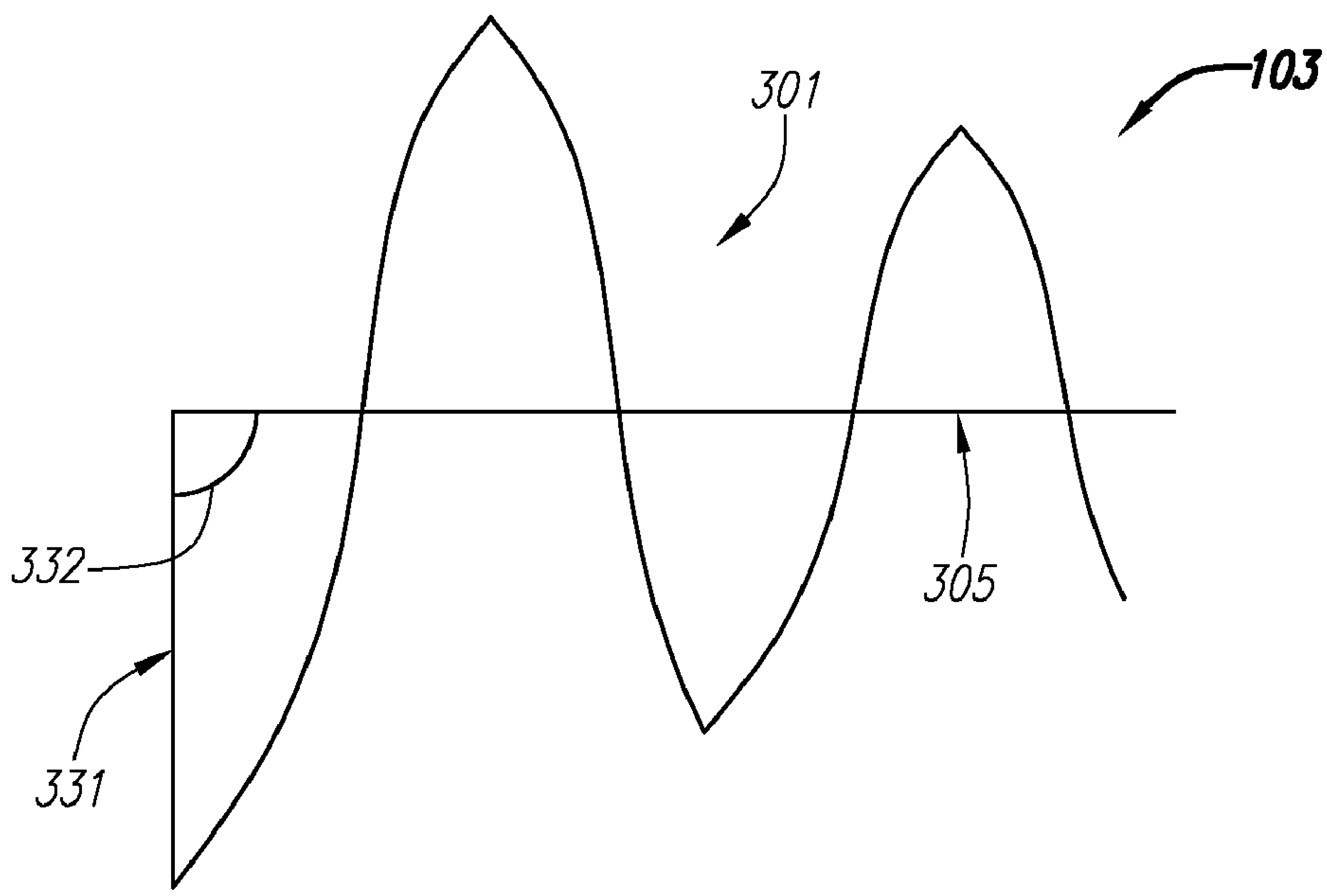

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FIG. 4D

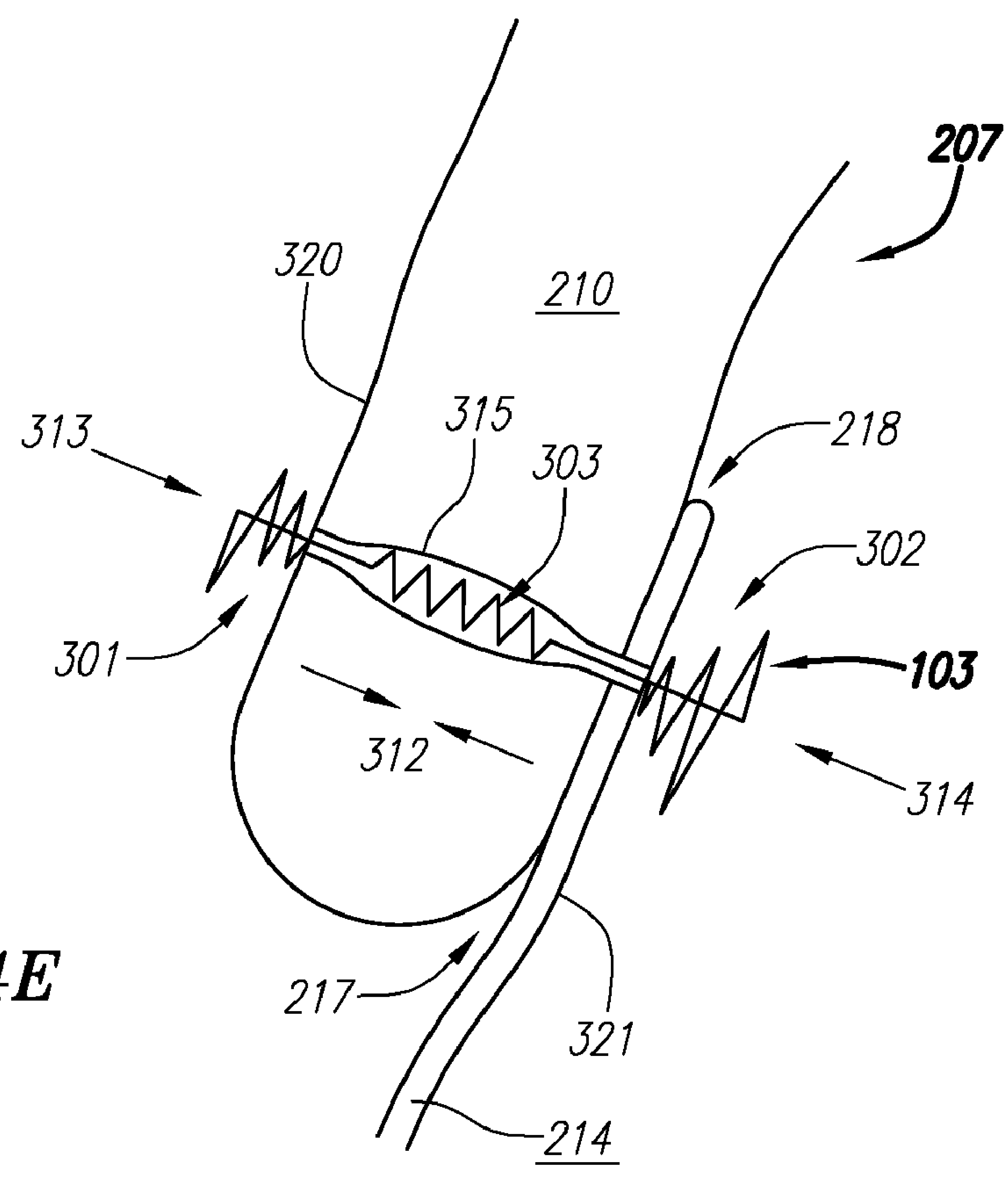

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FIG. 4E

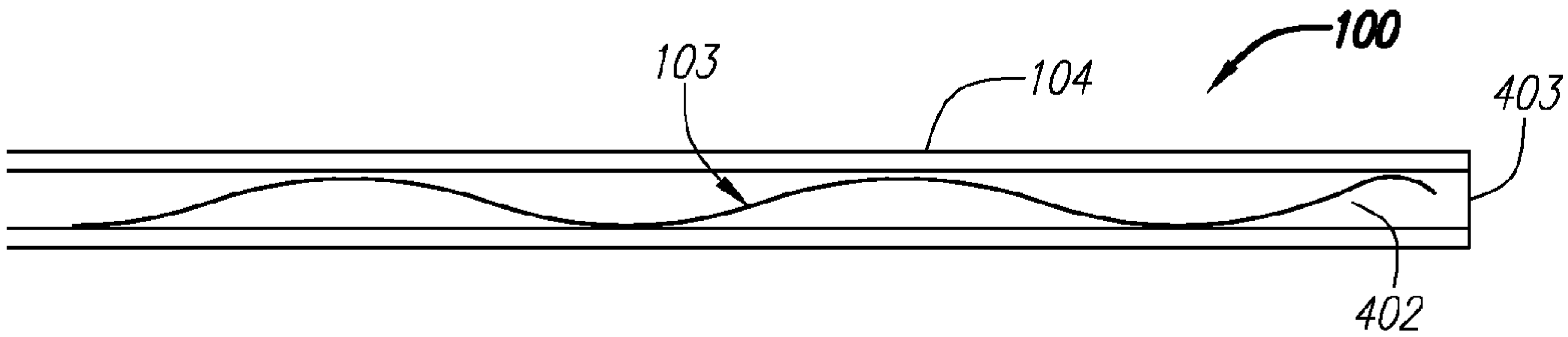

FIG. 4F

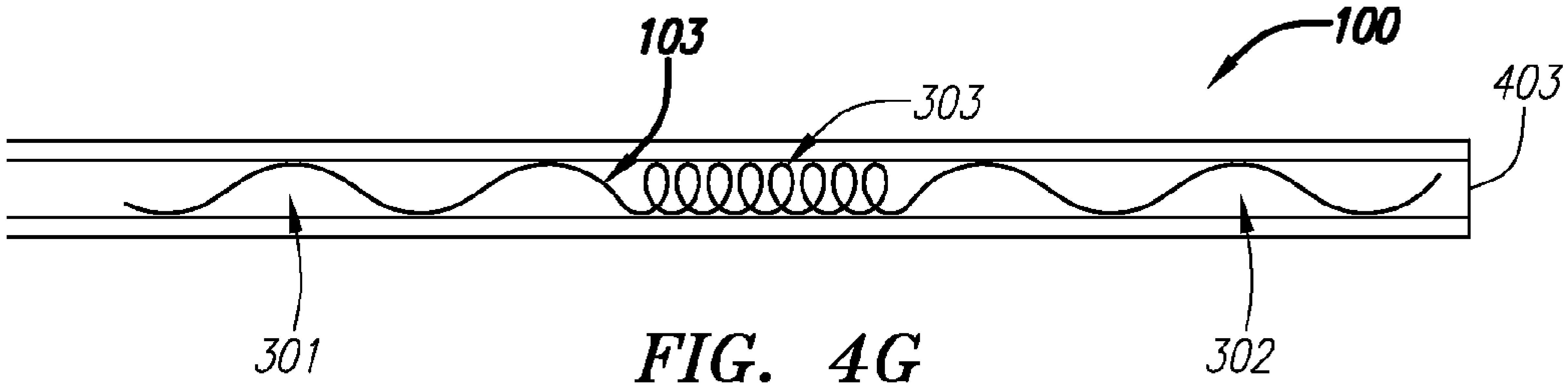

FIG. 4G

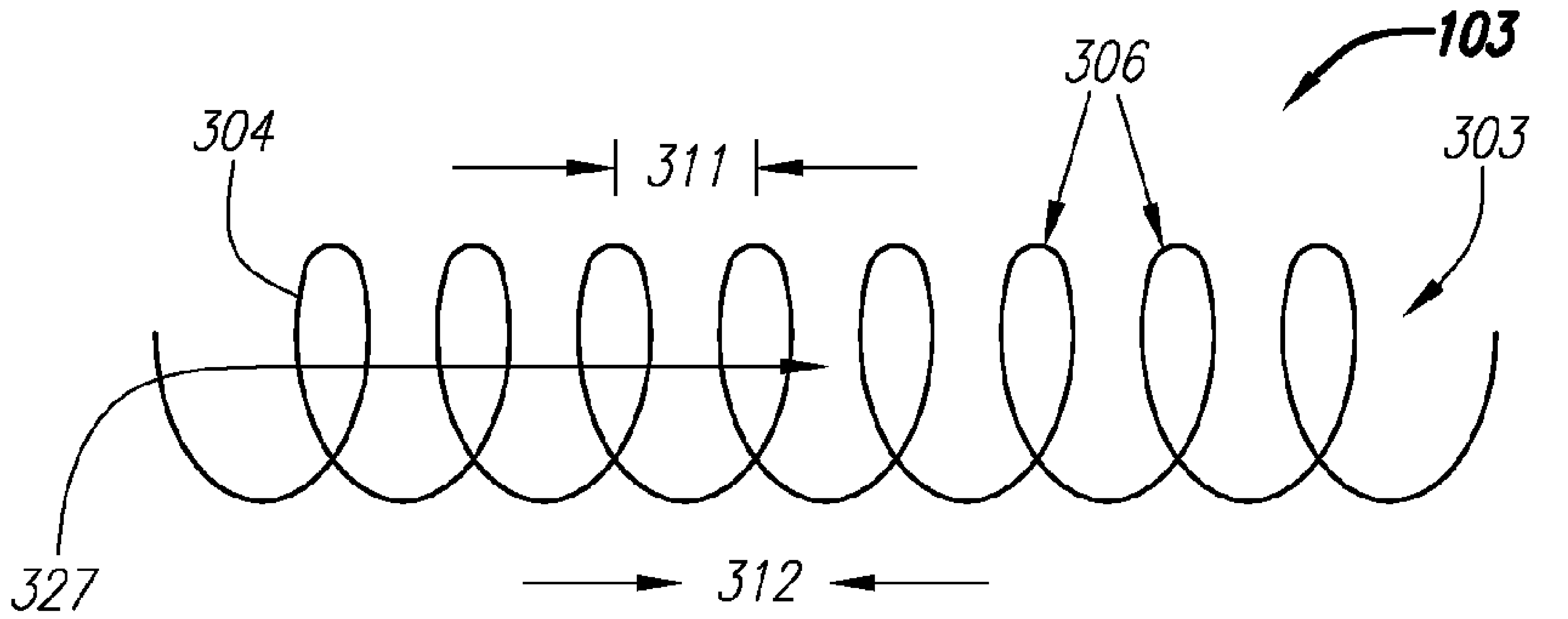

FIG. 5A

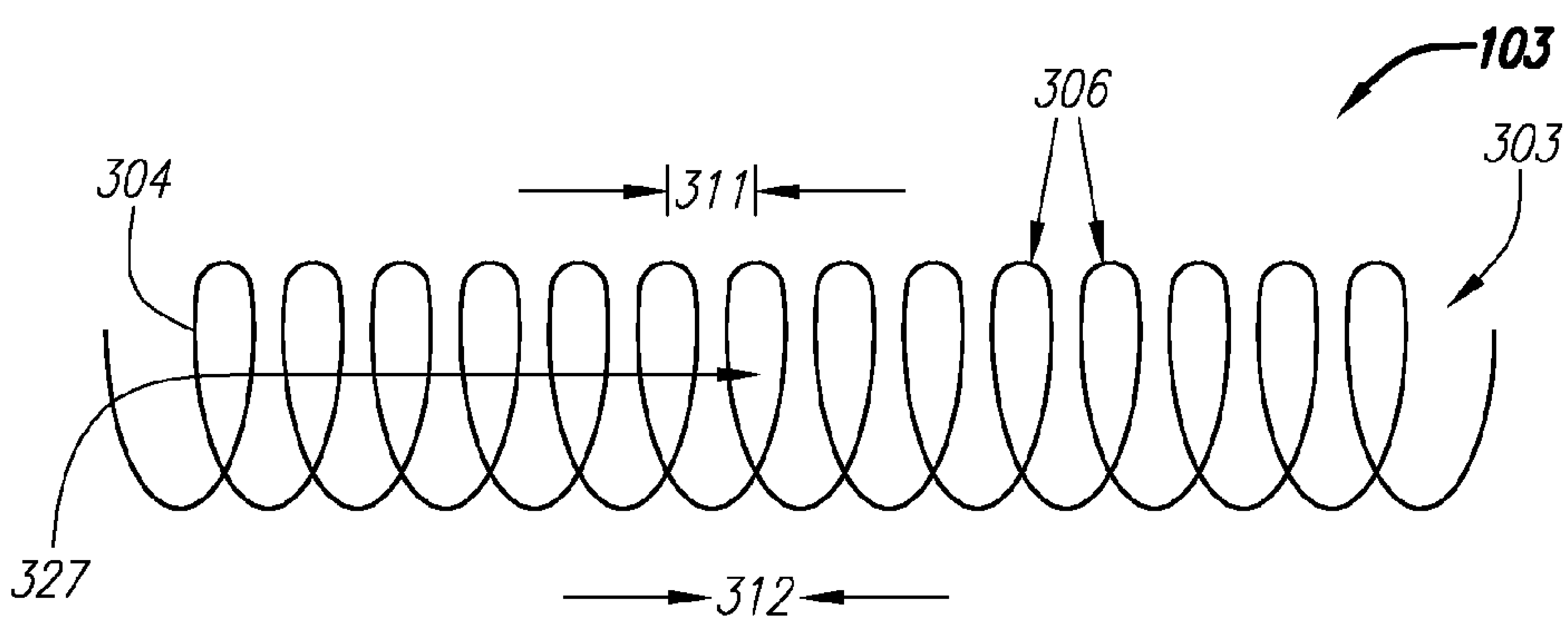

FIG. 5B

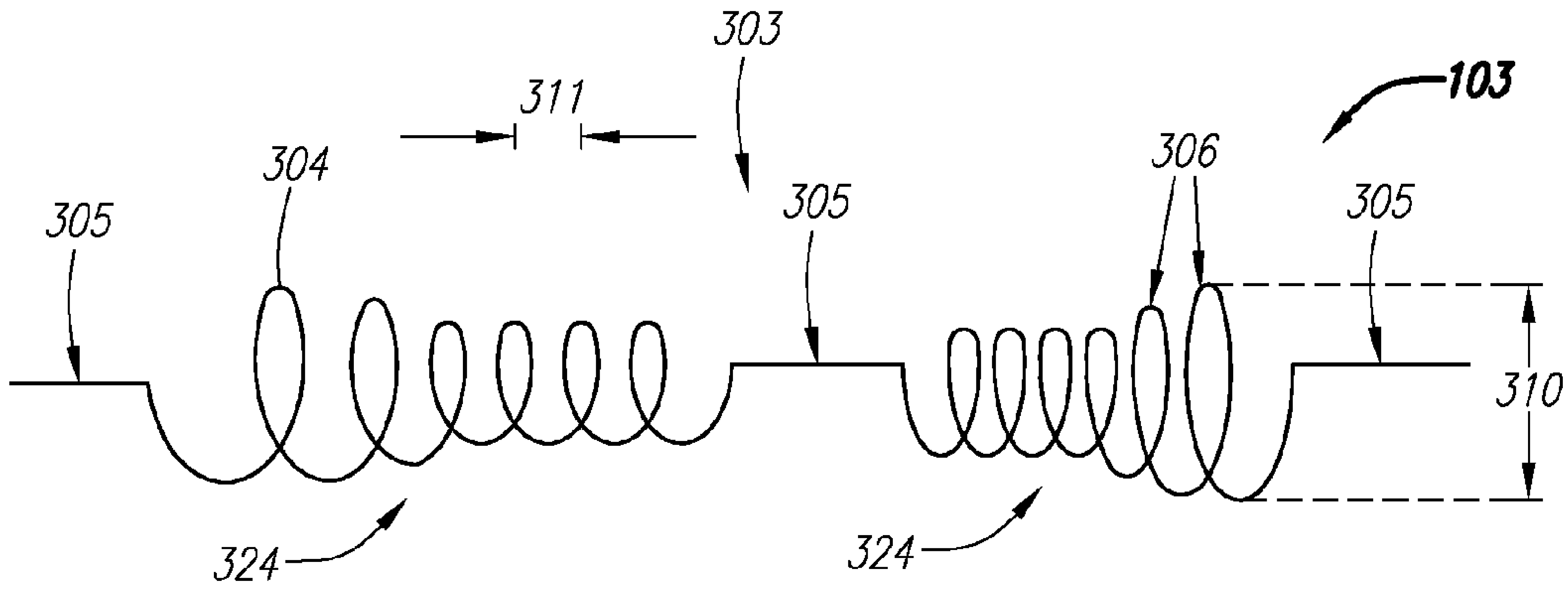

FIG. 5C

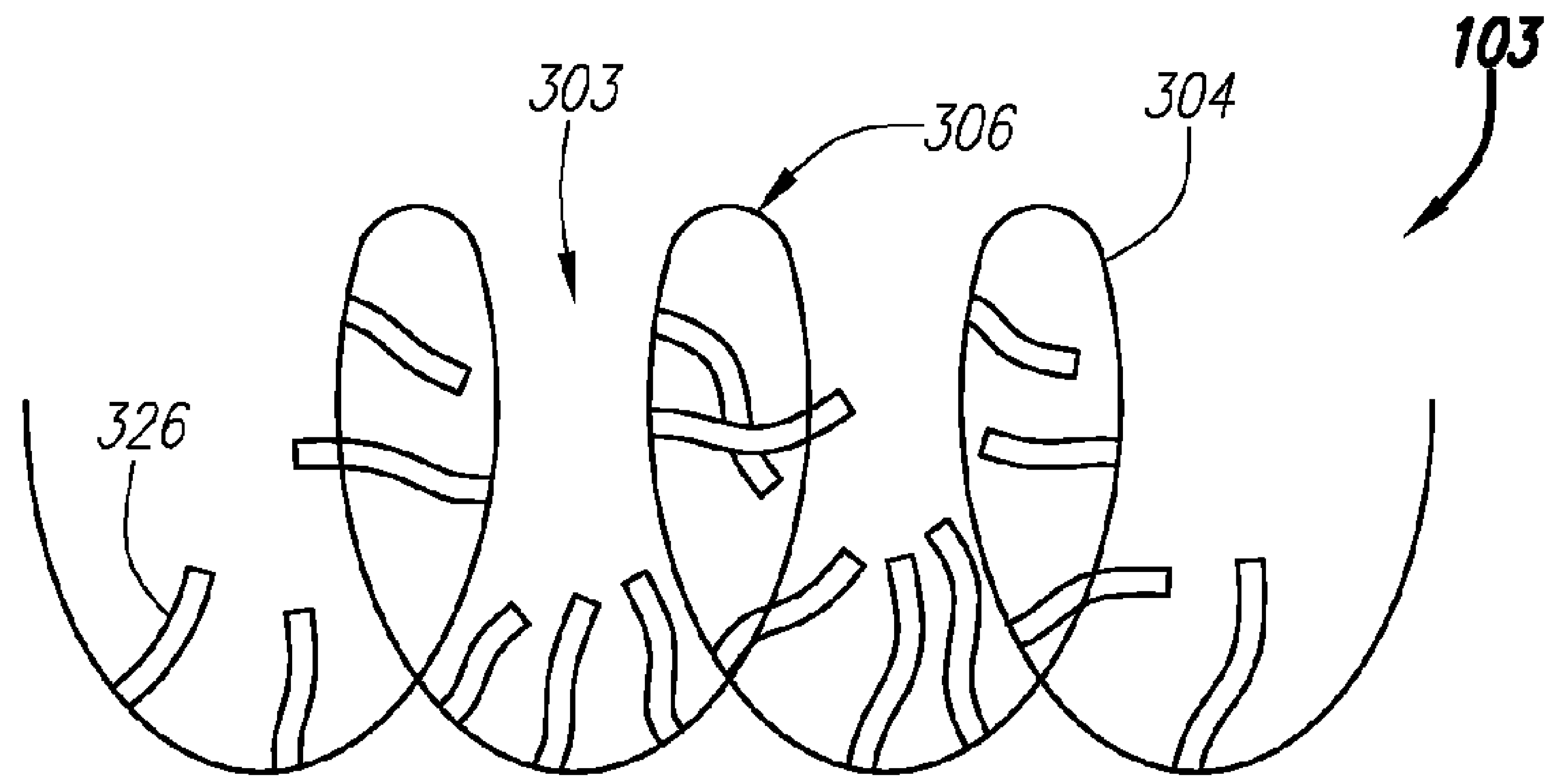

FIG. 5D

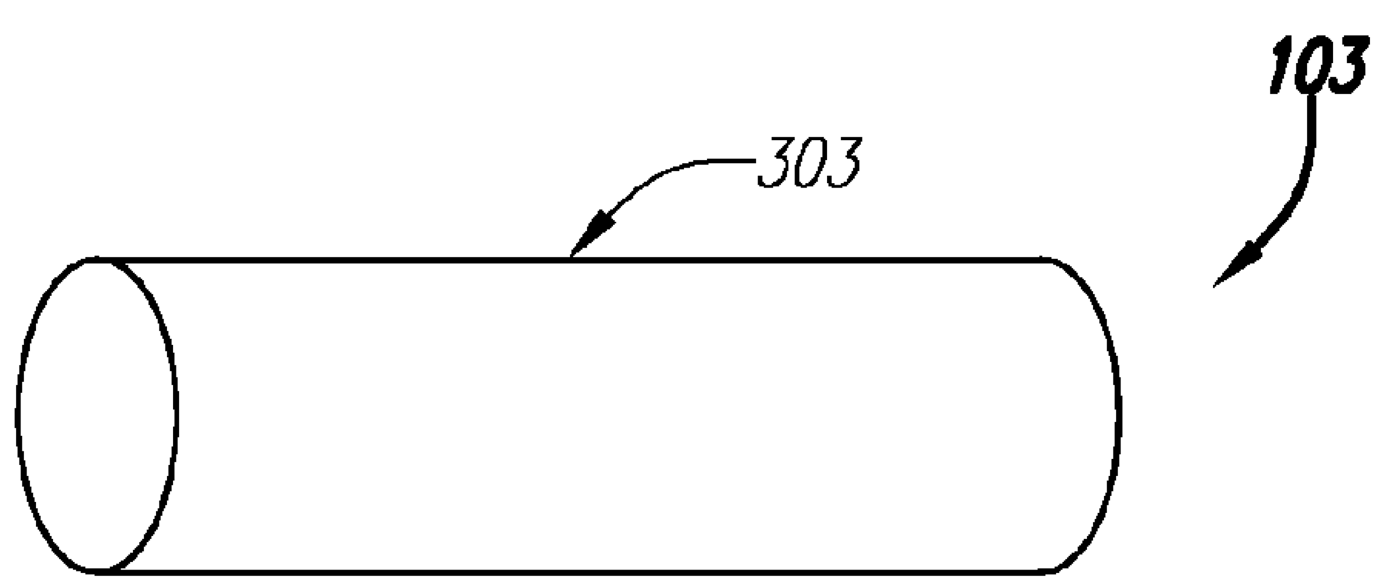

FIG. 5E

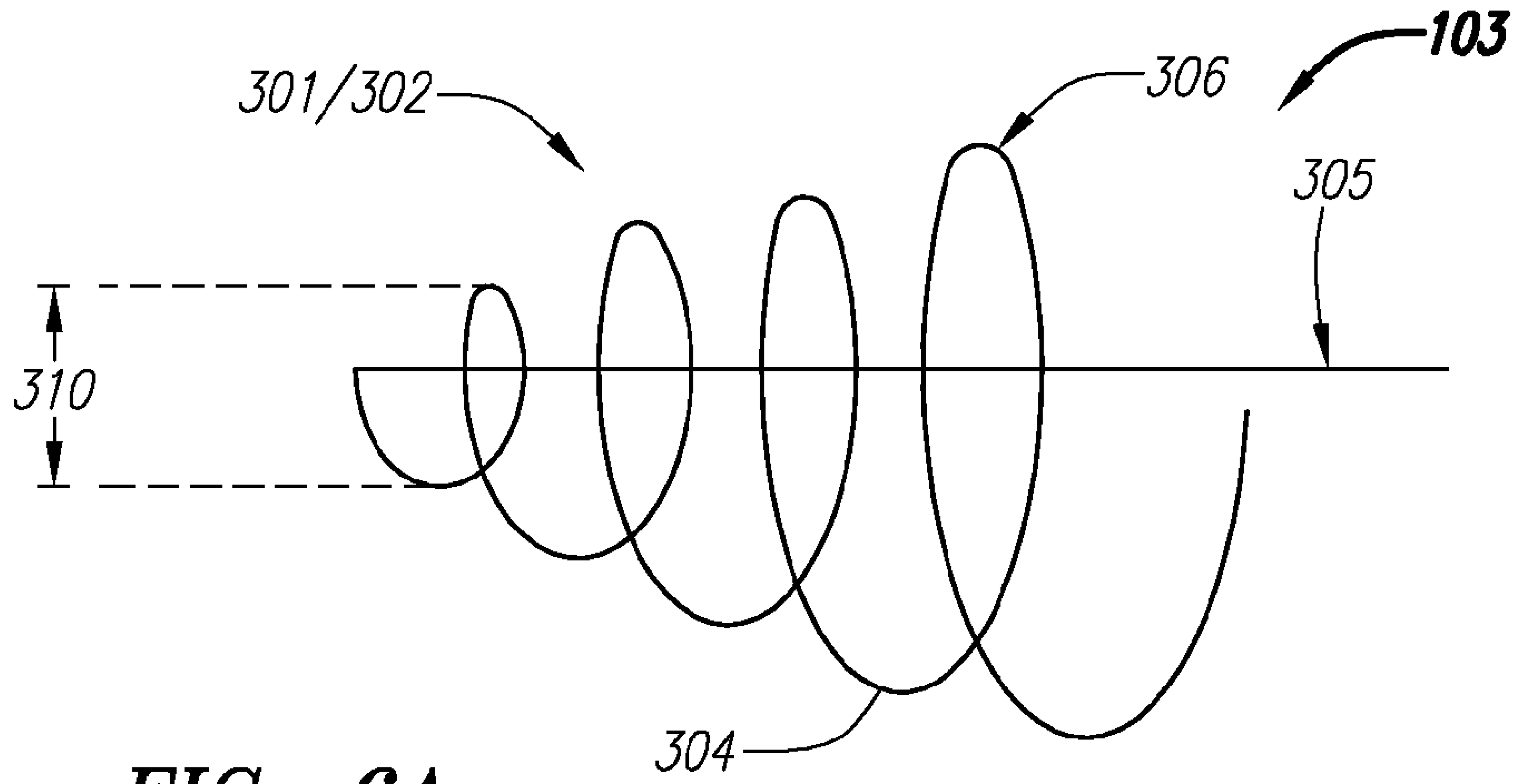

FIG. 6A

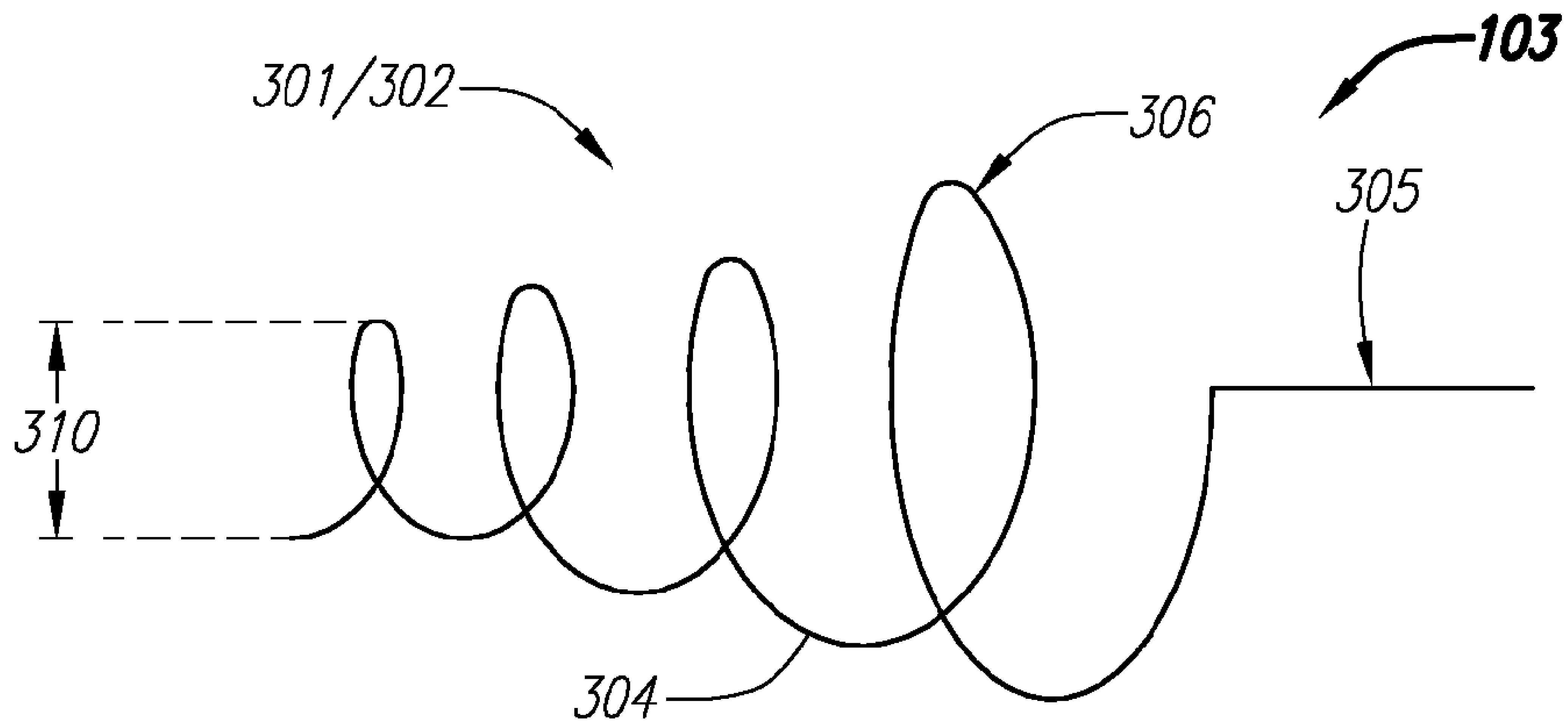

FIG. 6B

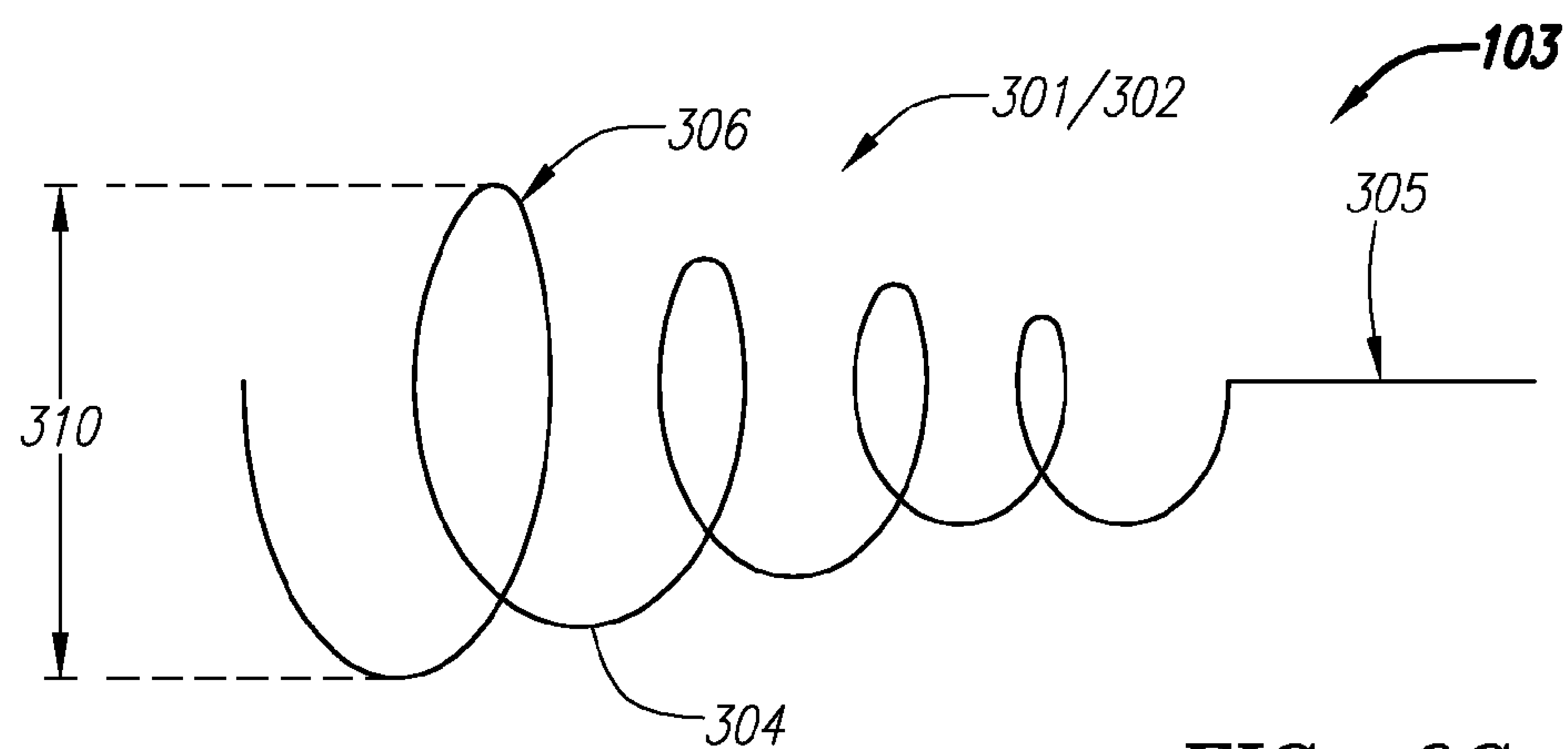

FIG. 6C

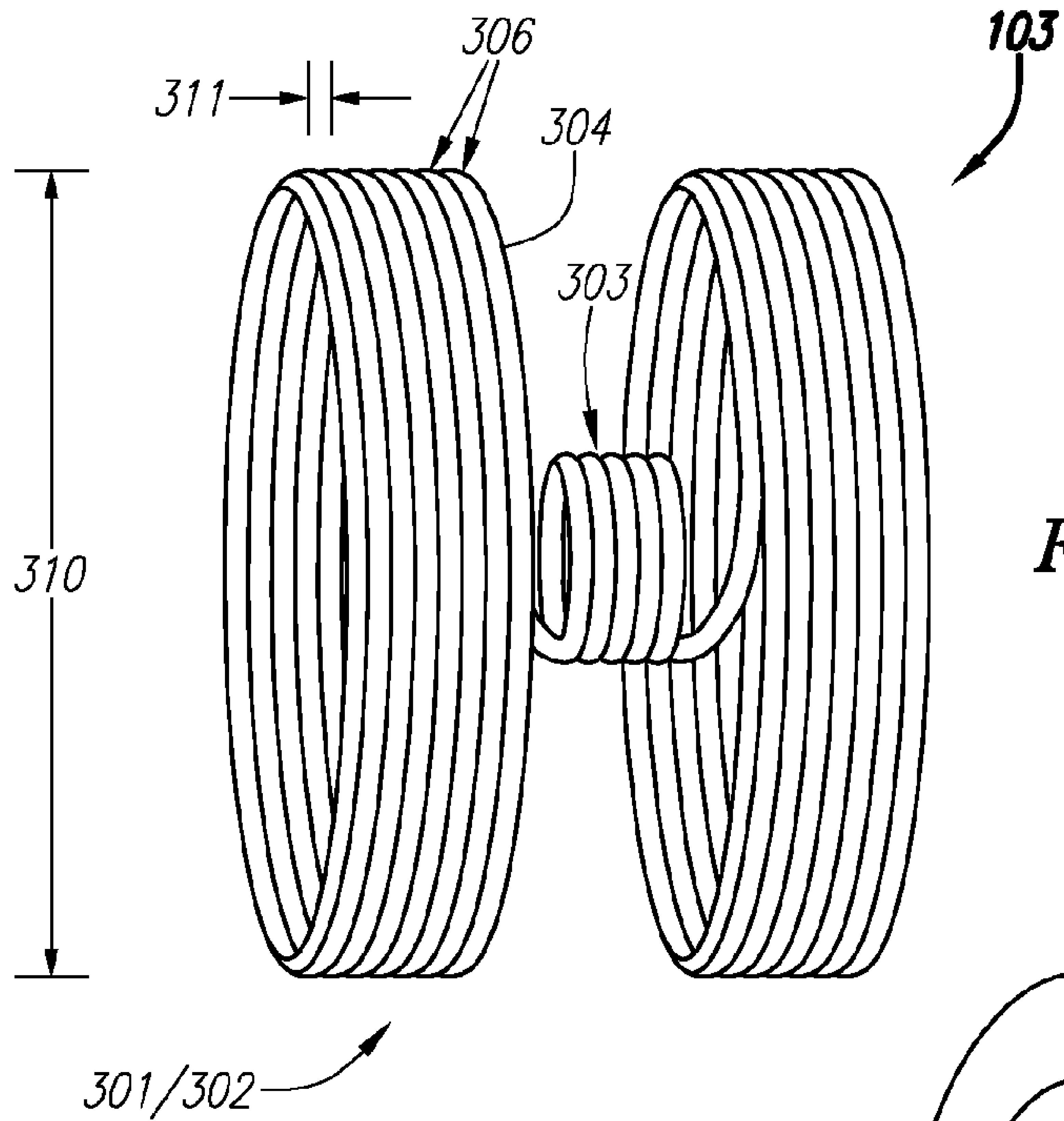

FIG. 6D

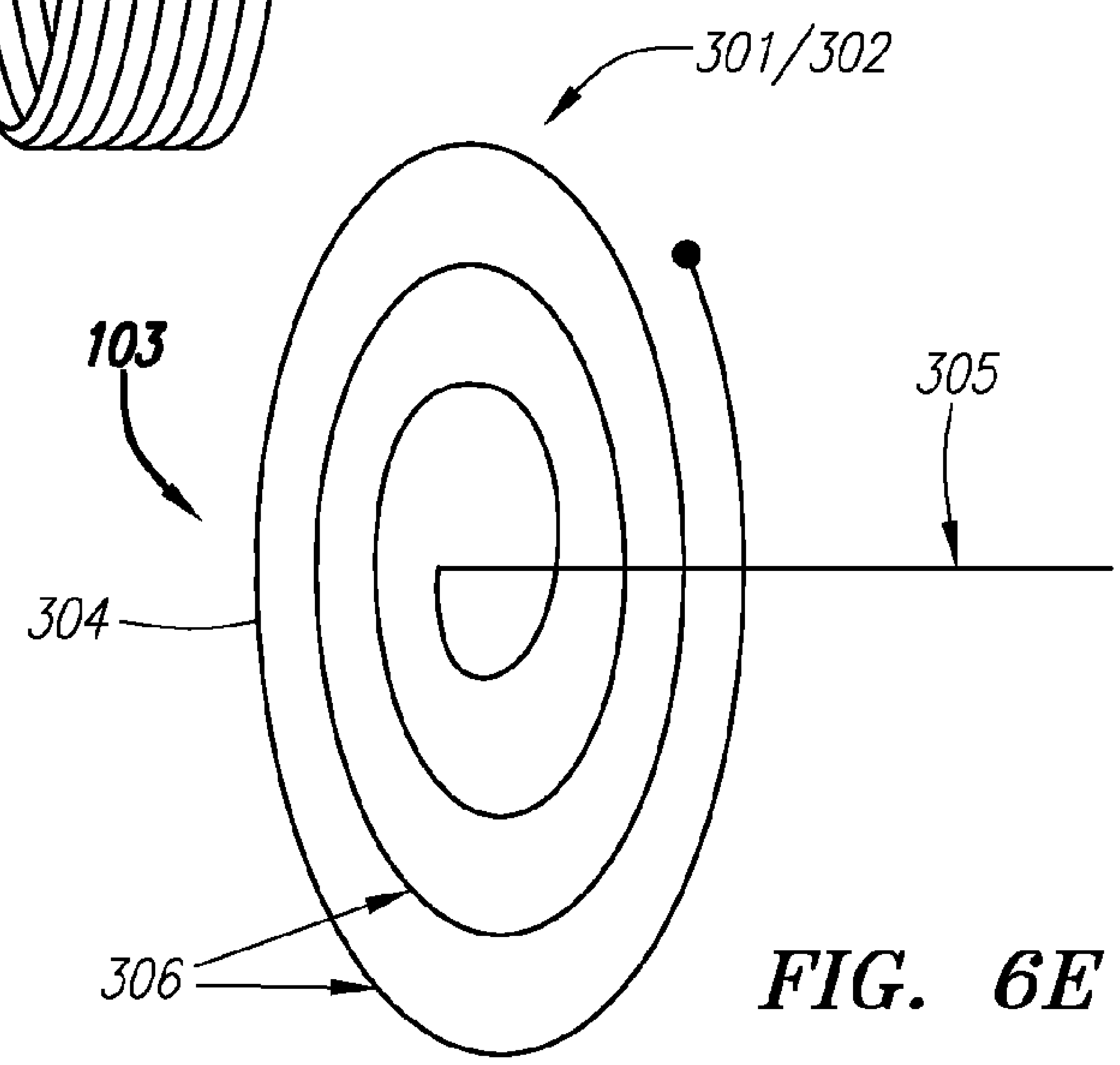

FIG. 6E

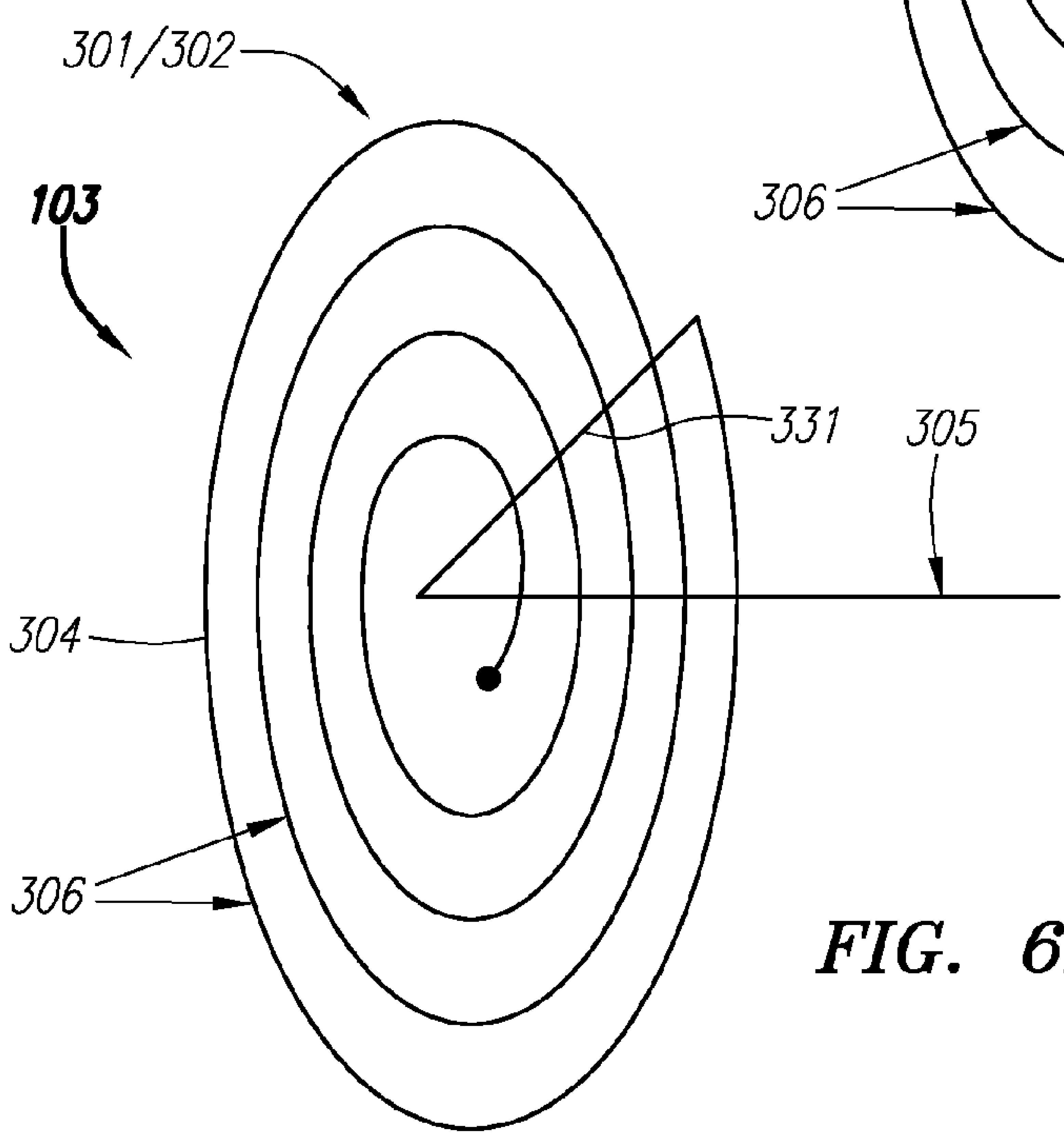

FIG. 6F

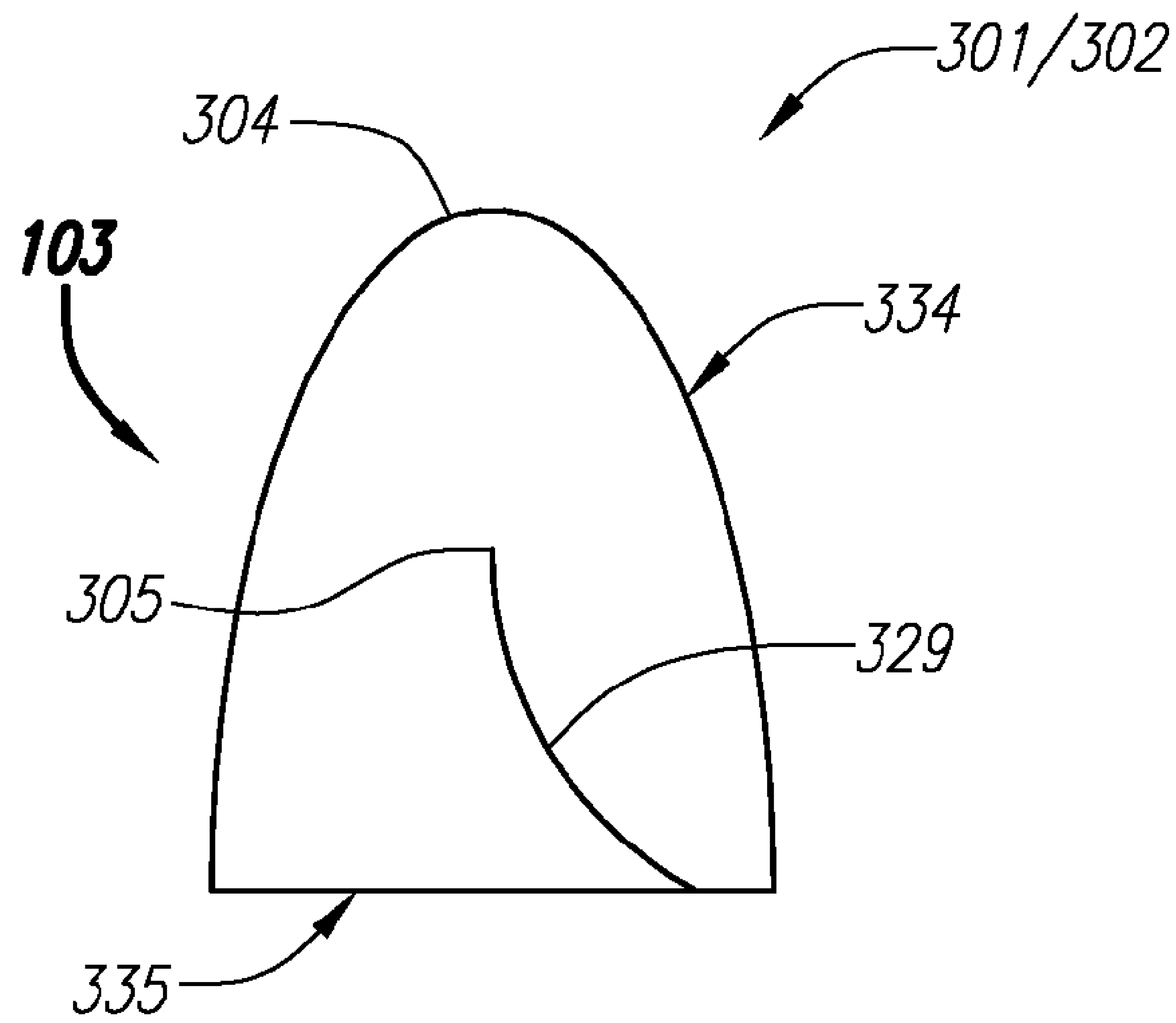

FIG. 6G

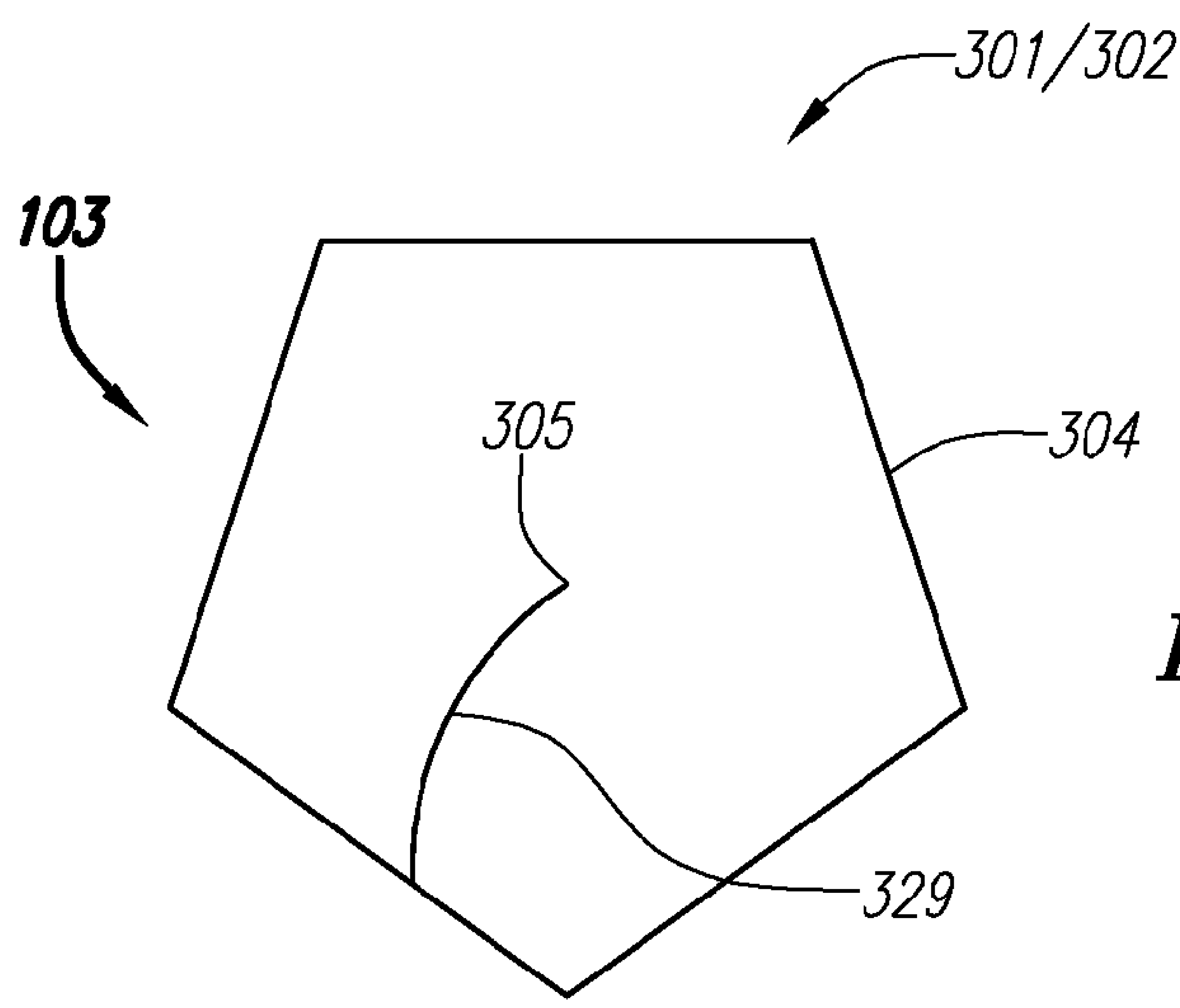

FIG. 6H

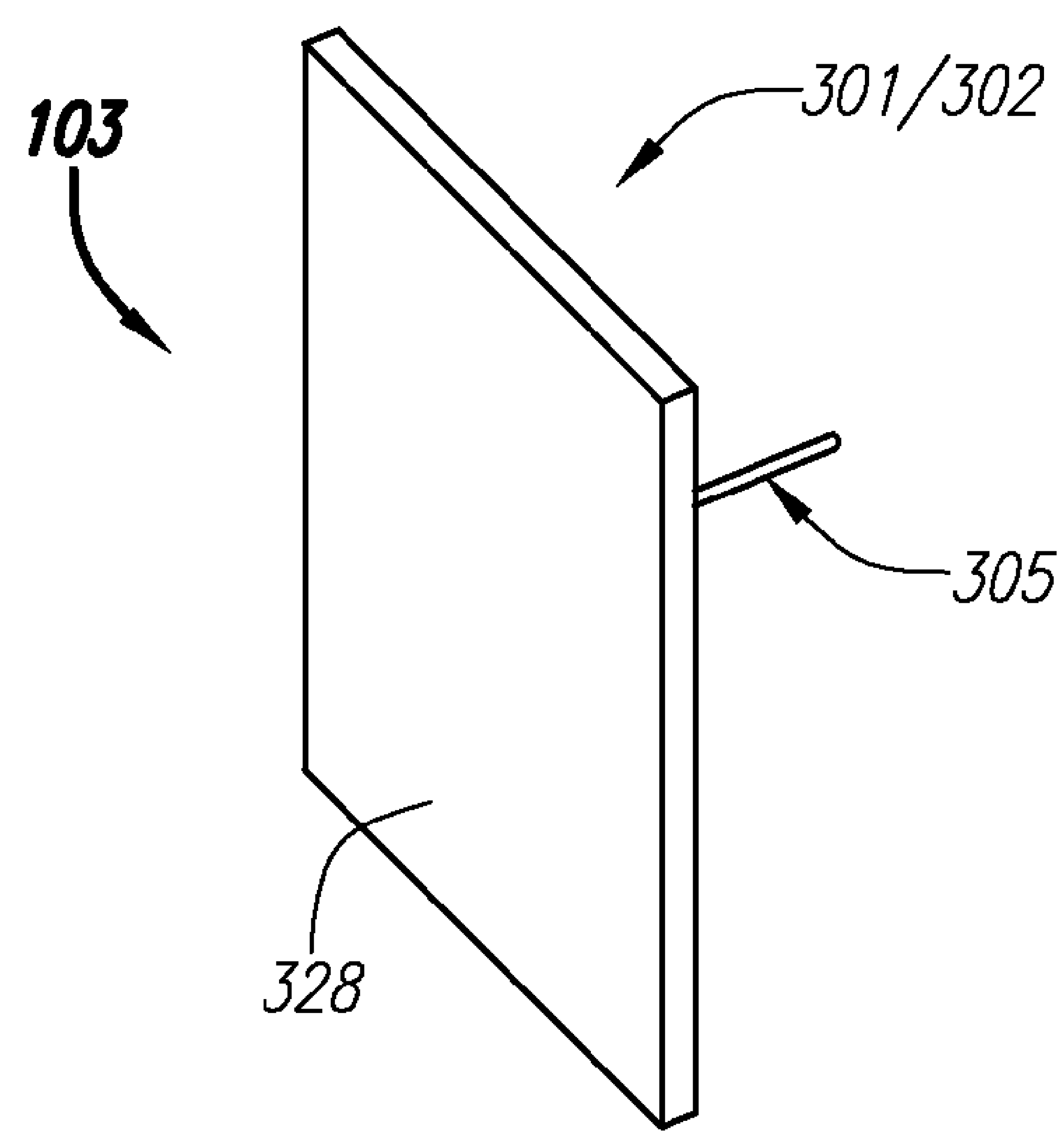

FIG. 6I

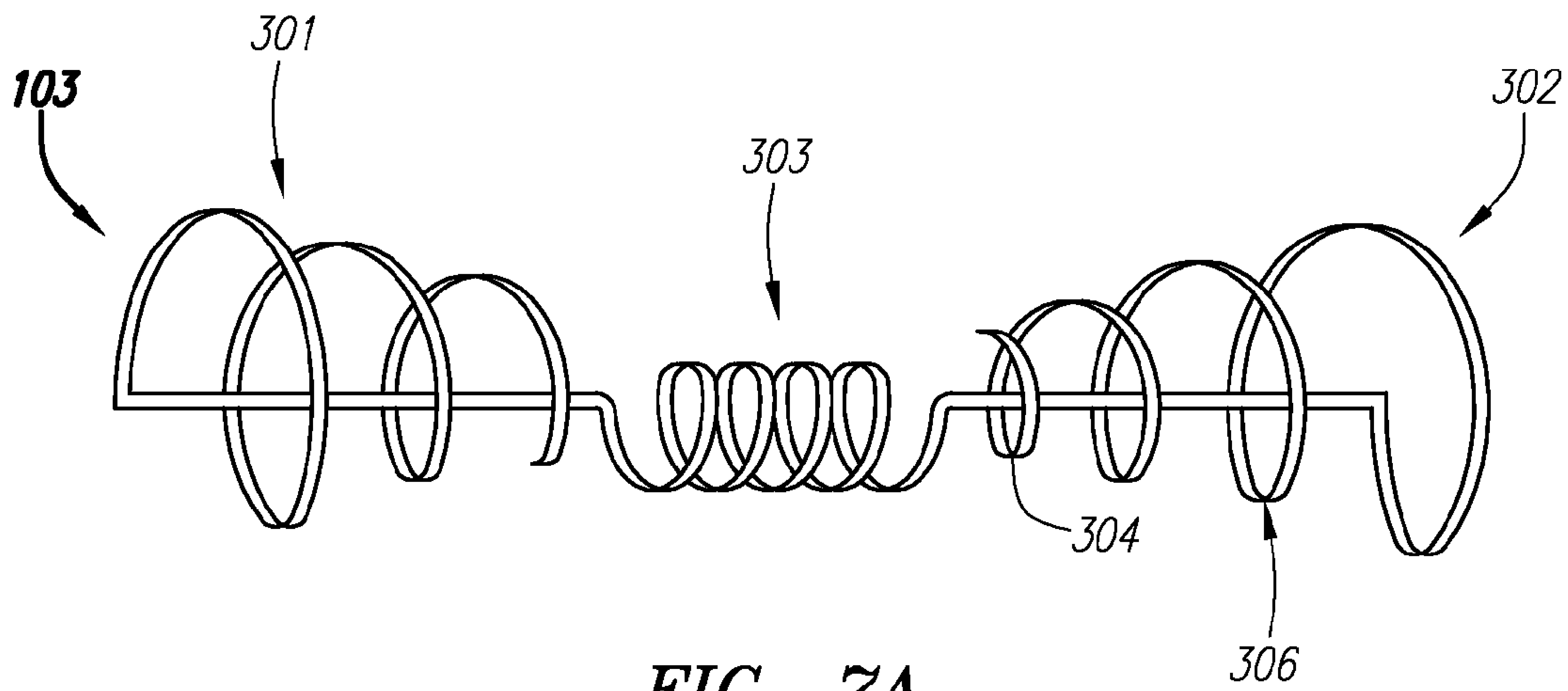

FIG. 7A

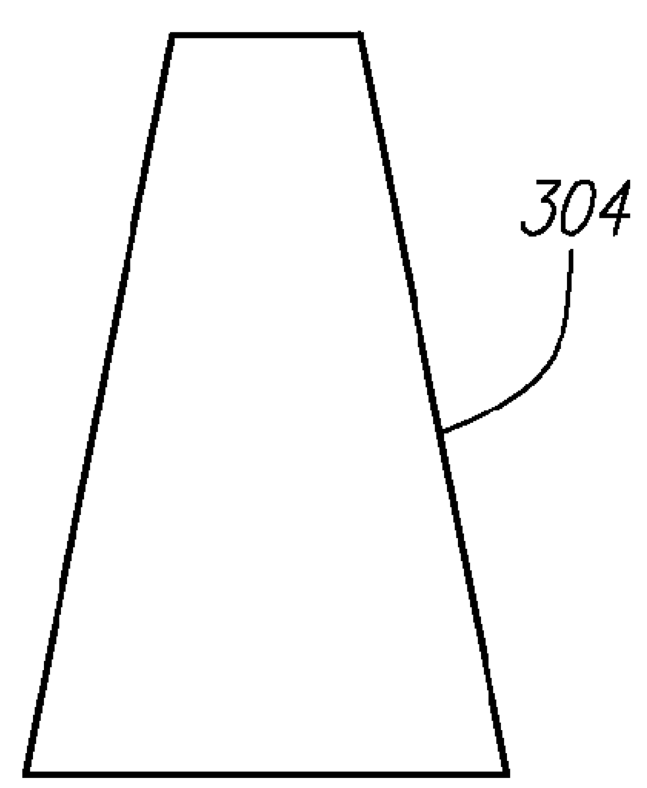

FIG. 7B

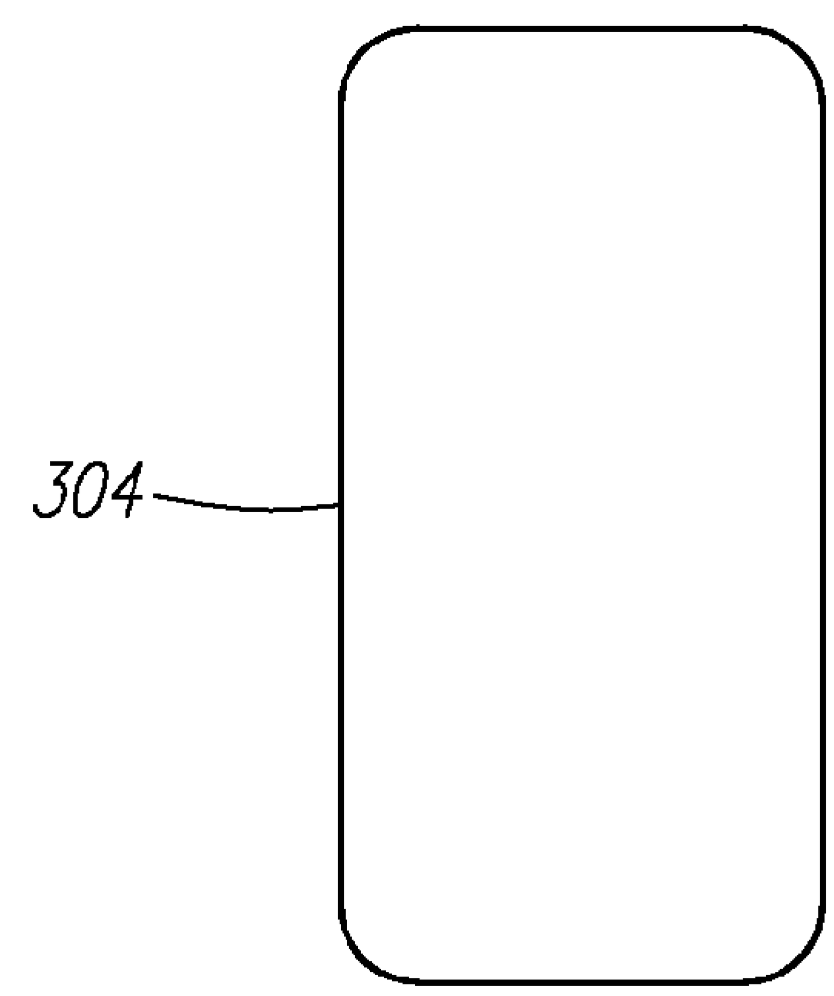

FIG. 7C

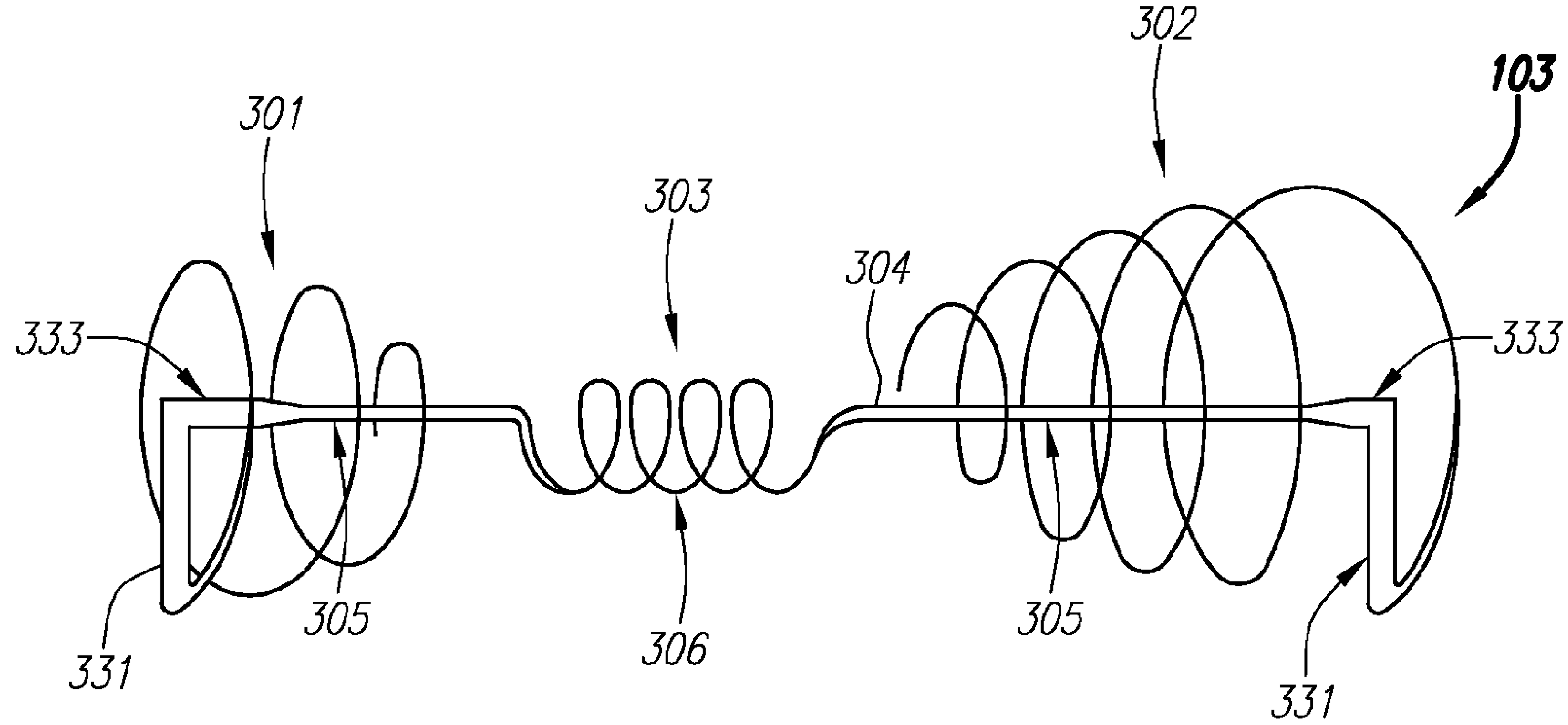
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FIG. 8

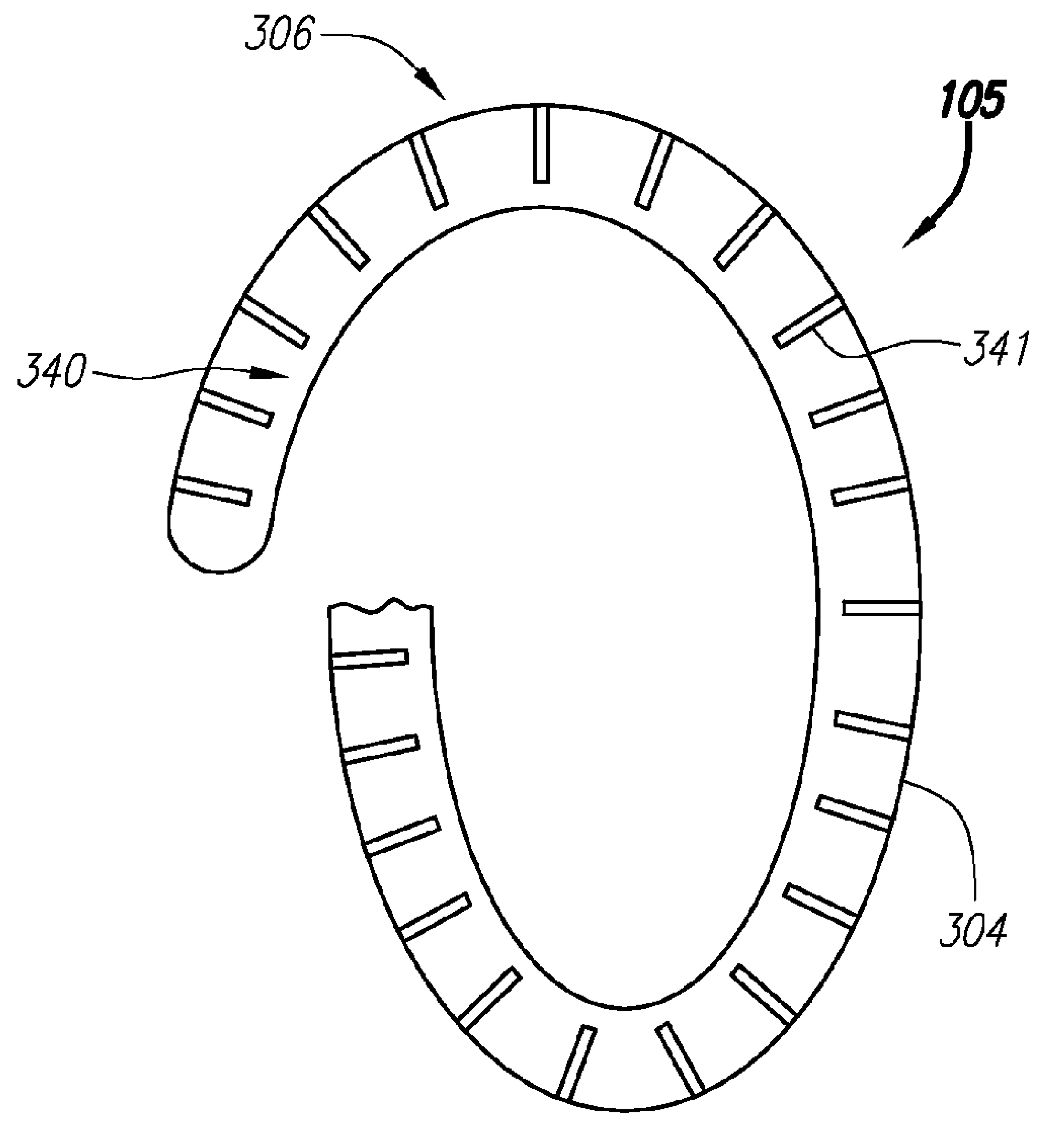
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FIG. 9A

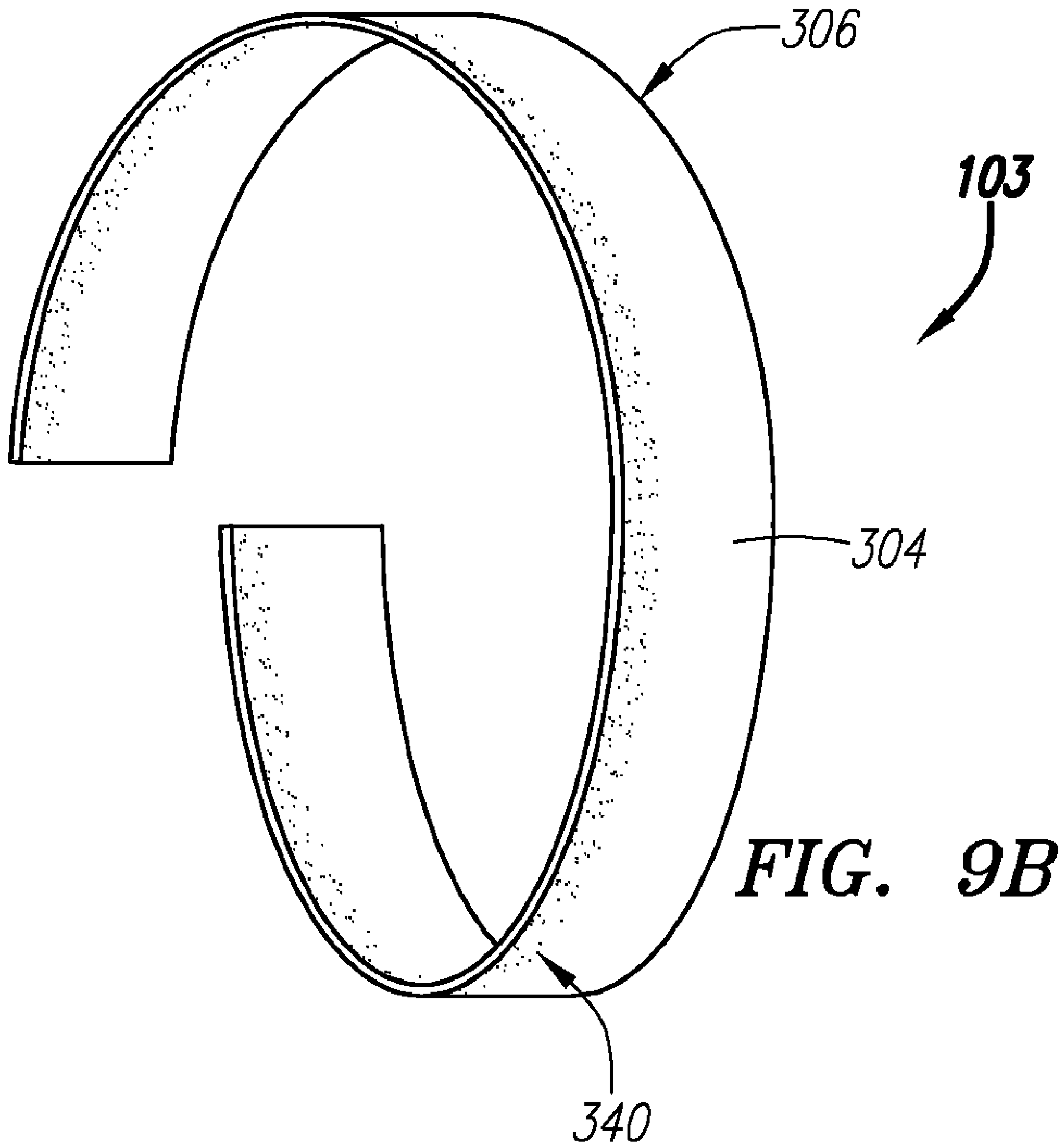

FIG. 9B

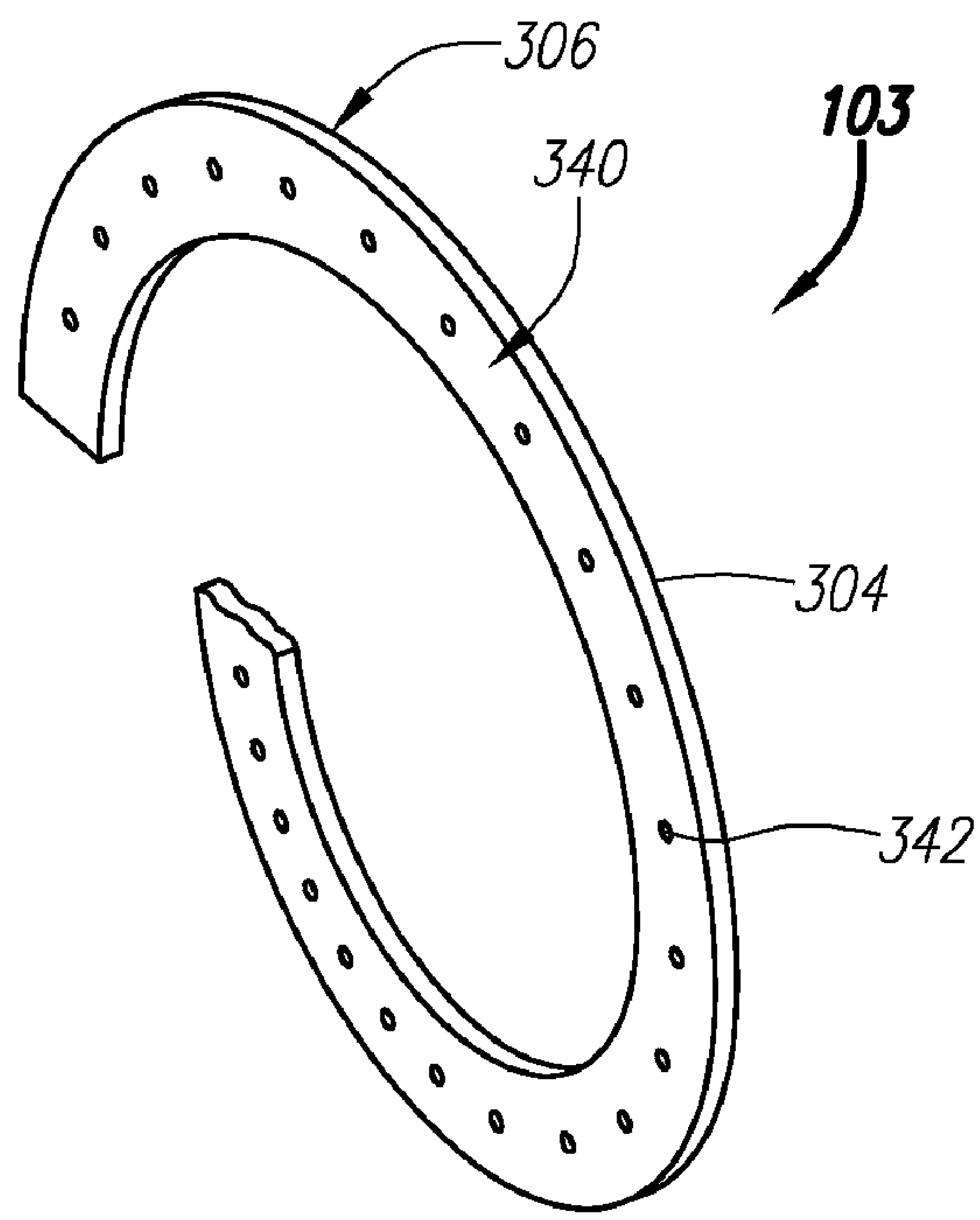

FIG. 9C

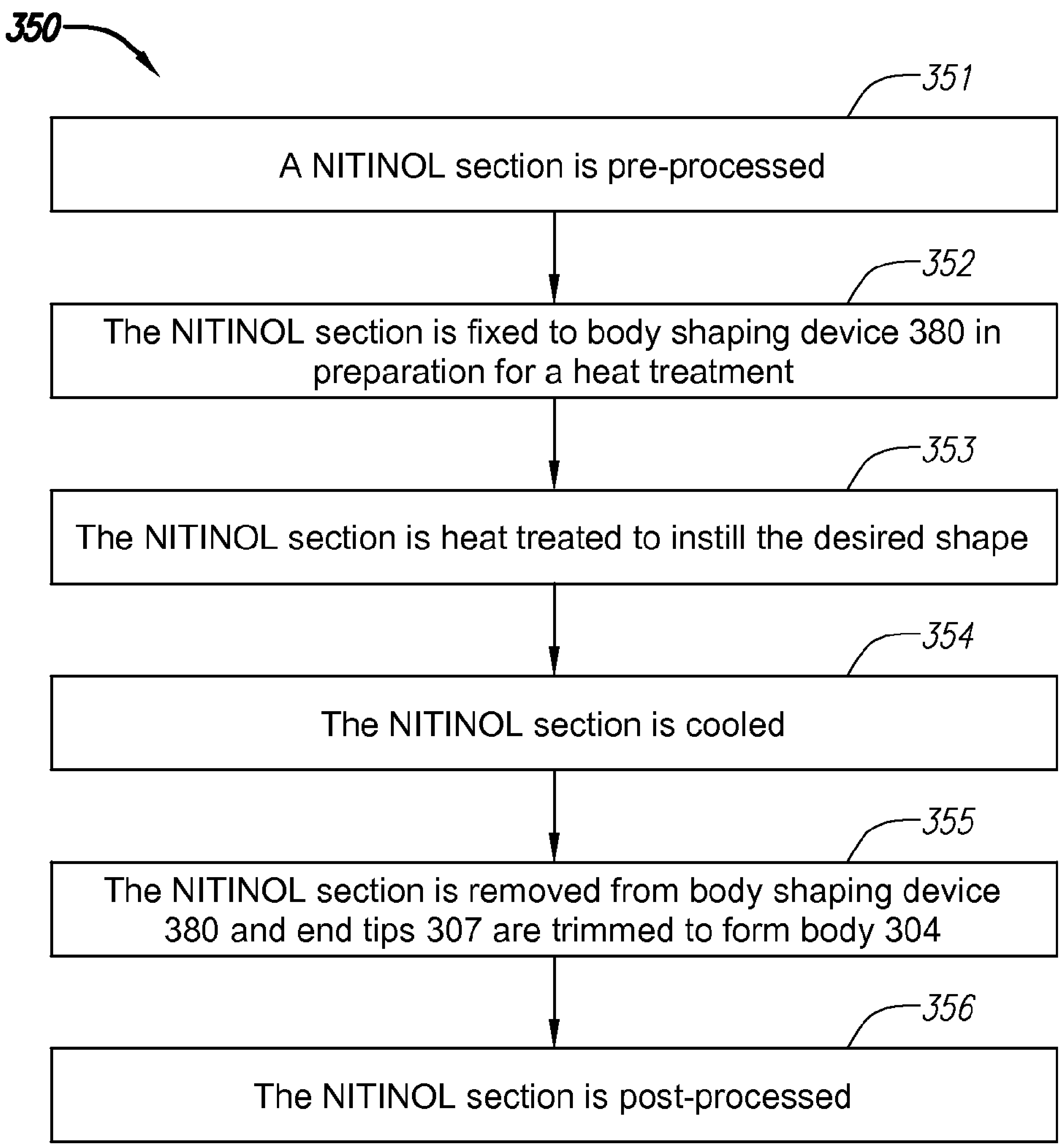

FIG. 10A

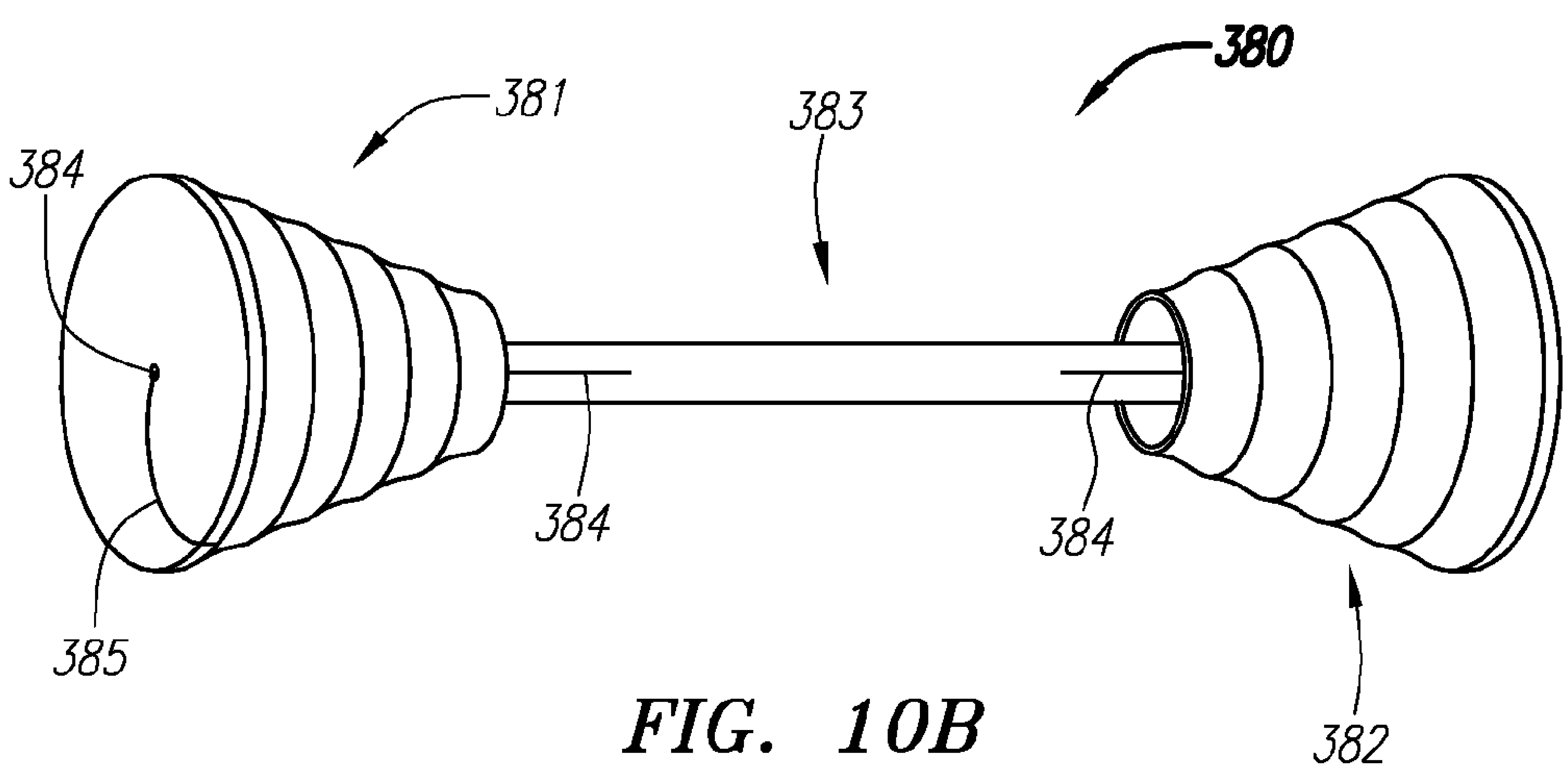

FIG. 10B

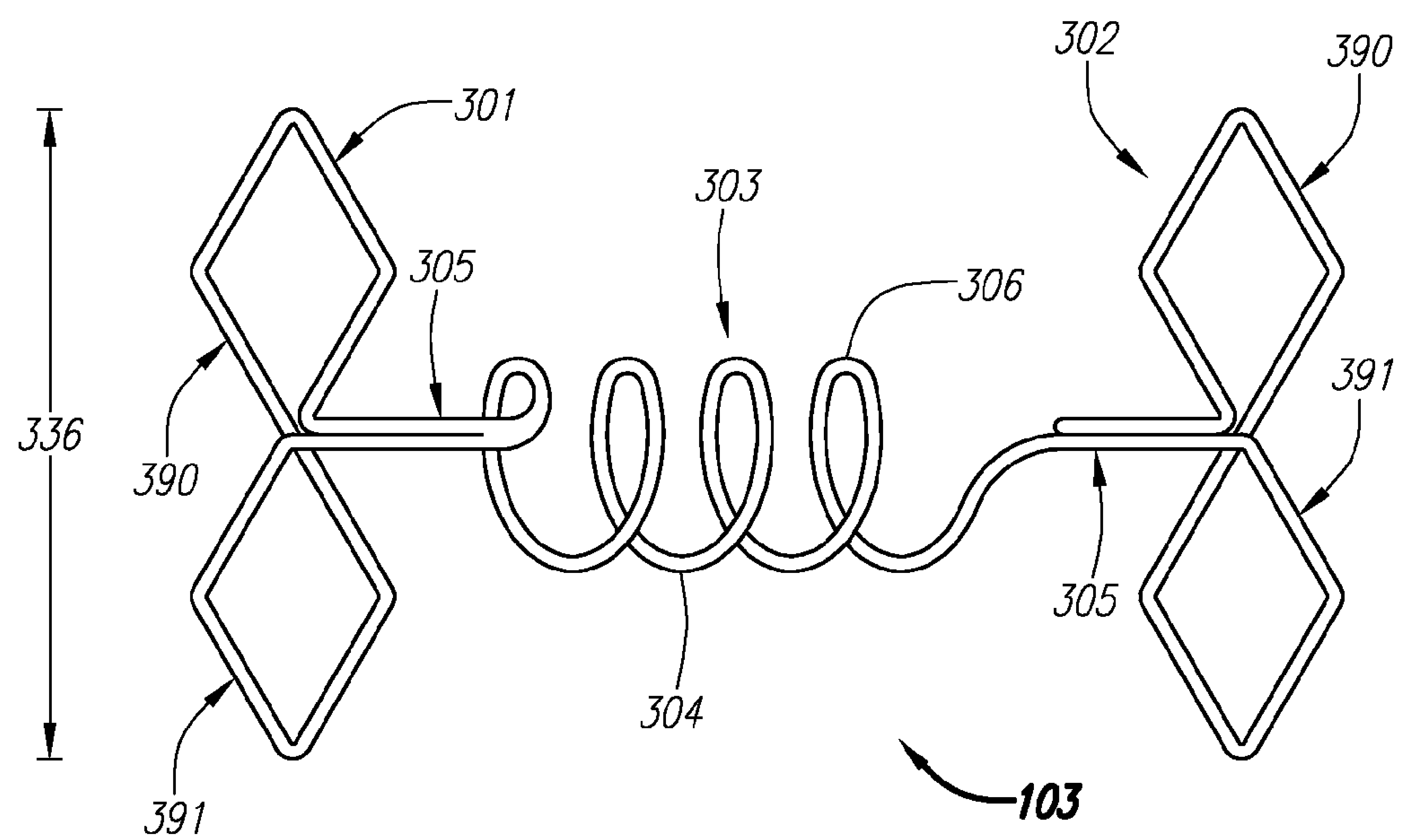

FIG. 11A

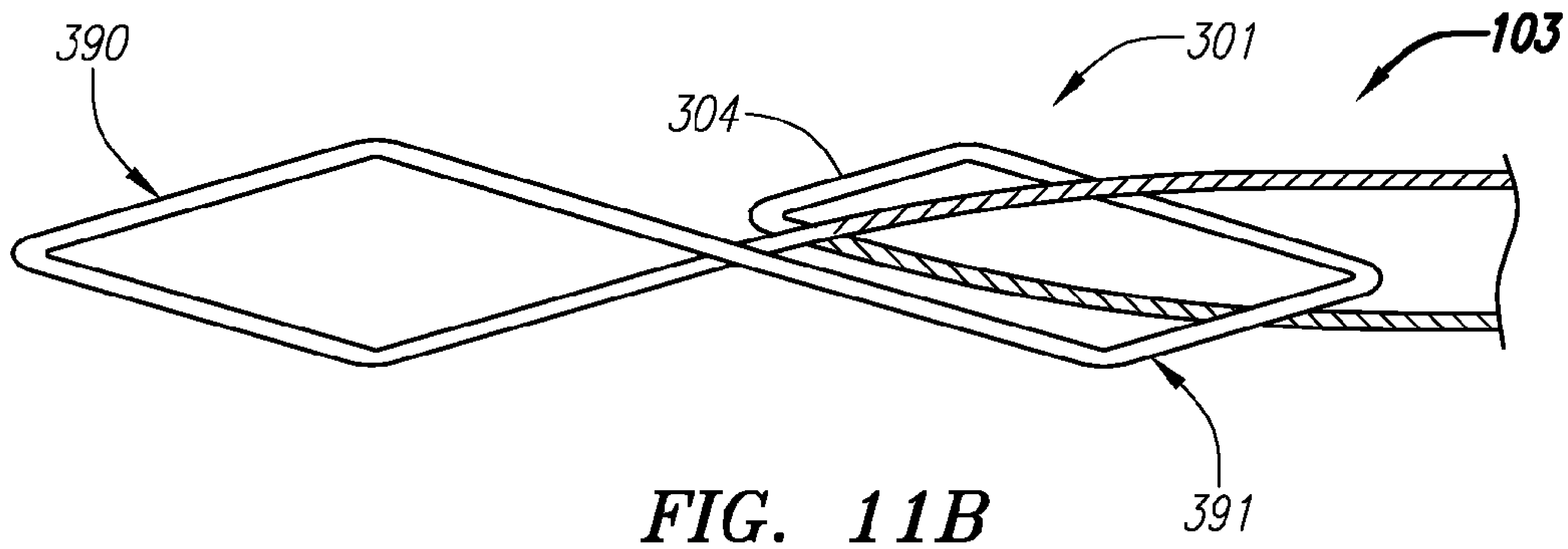

FIG. 11B

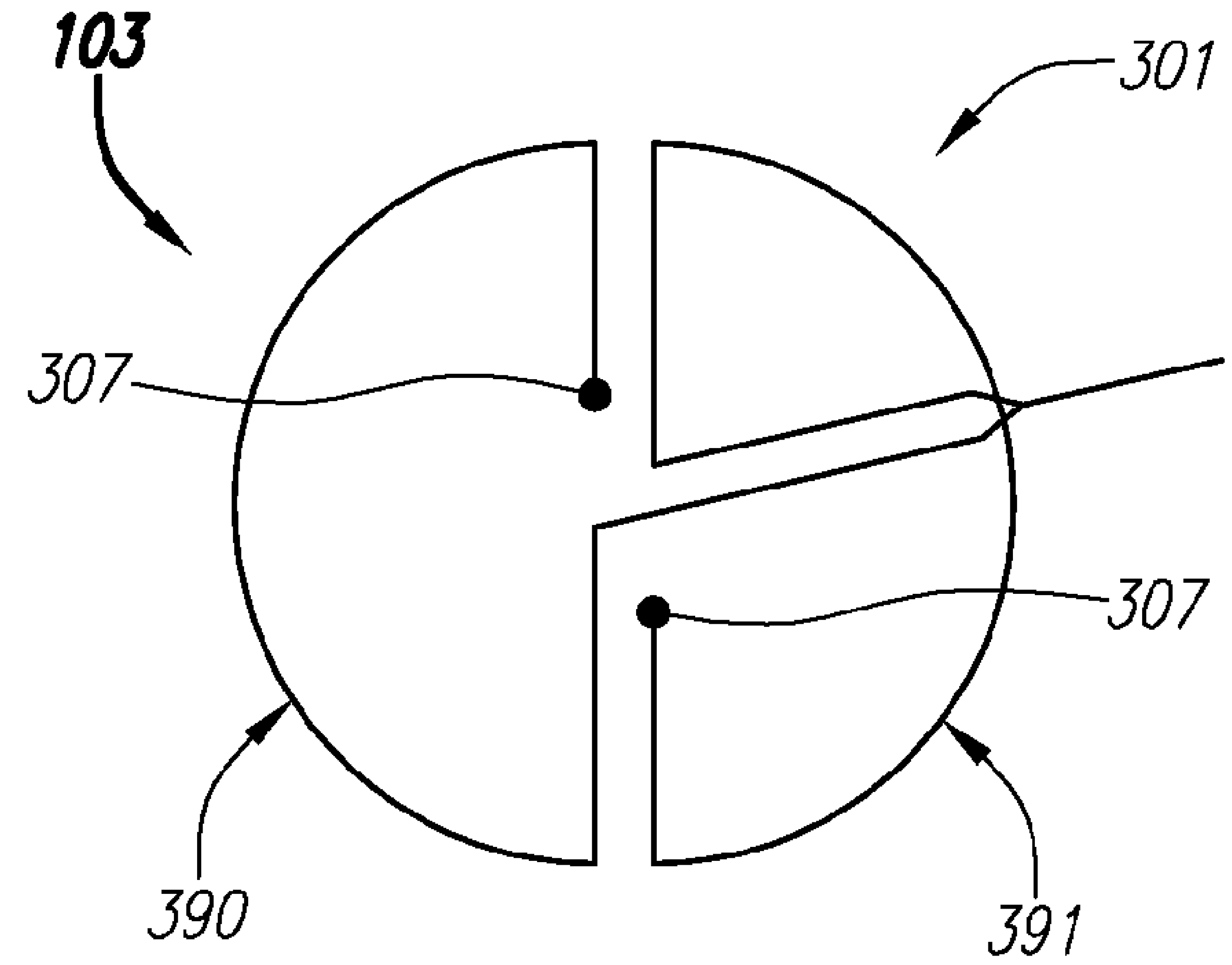

FIG. 11C

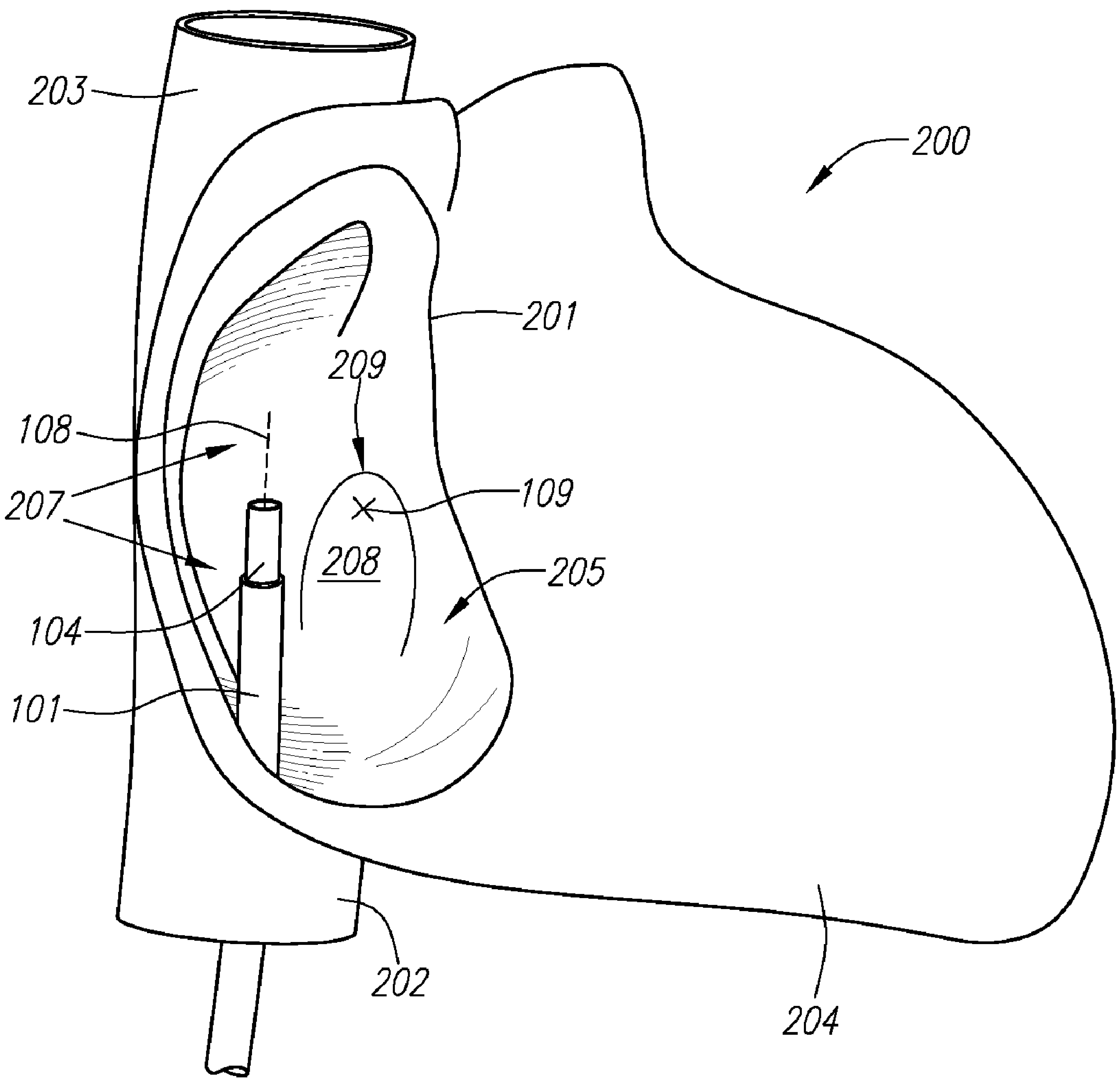

FIG. 12

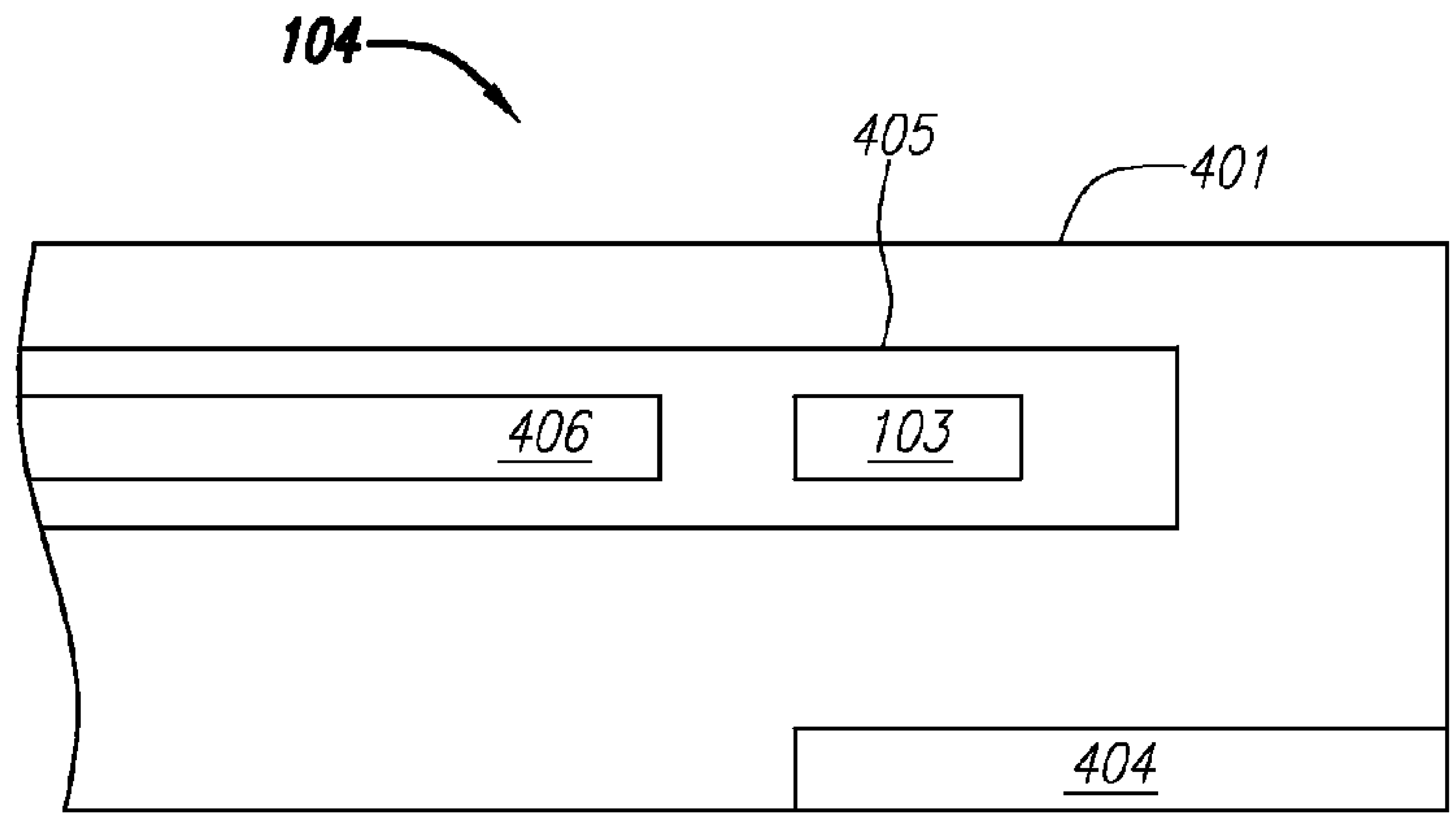

FIG. 13

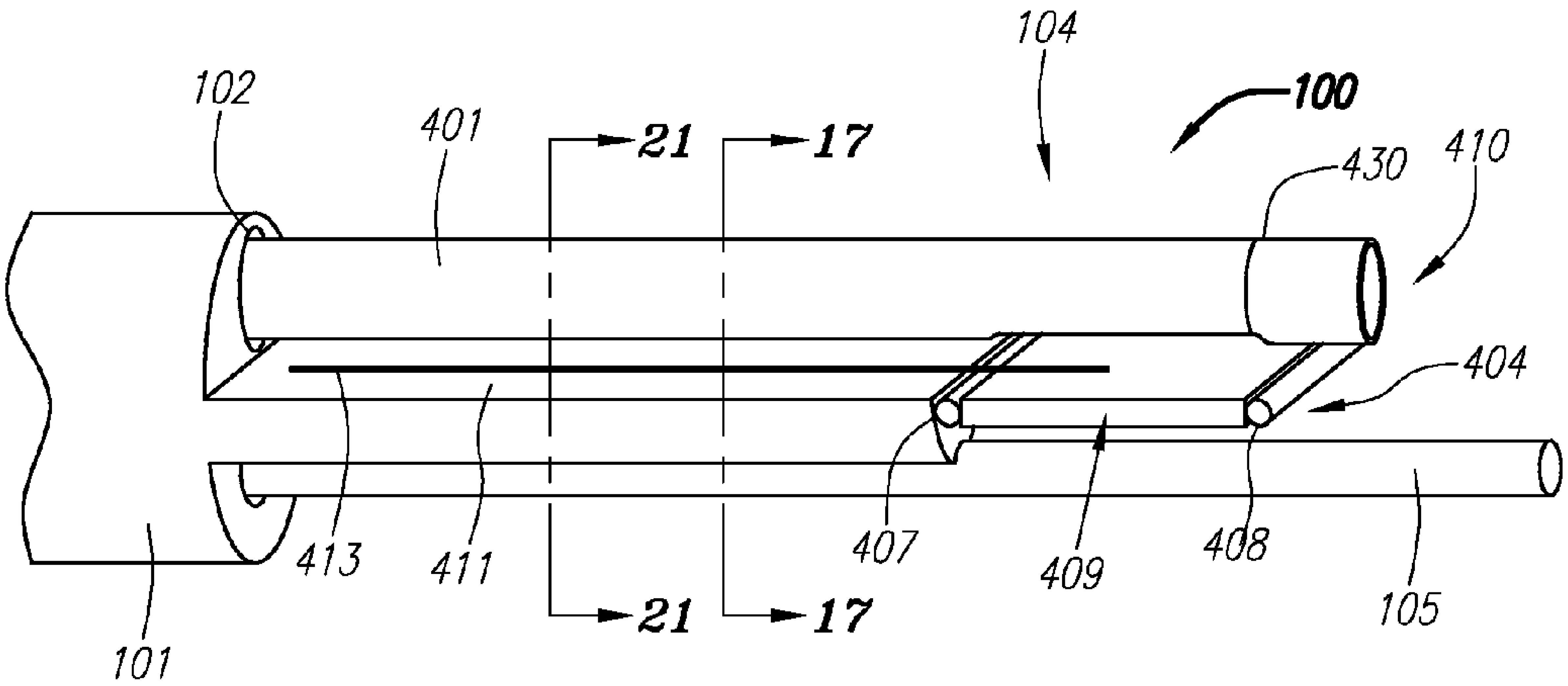

FIG. 14A

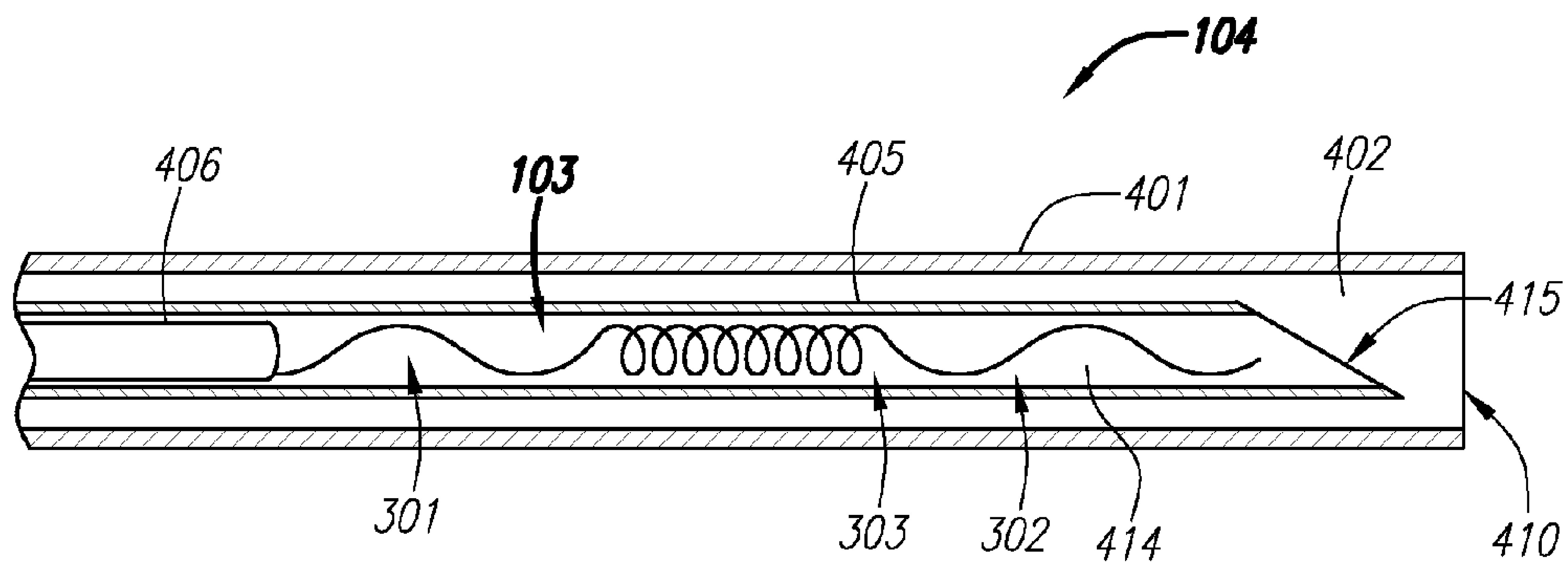

FIG. 14B

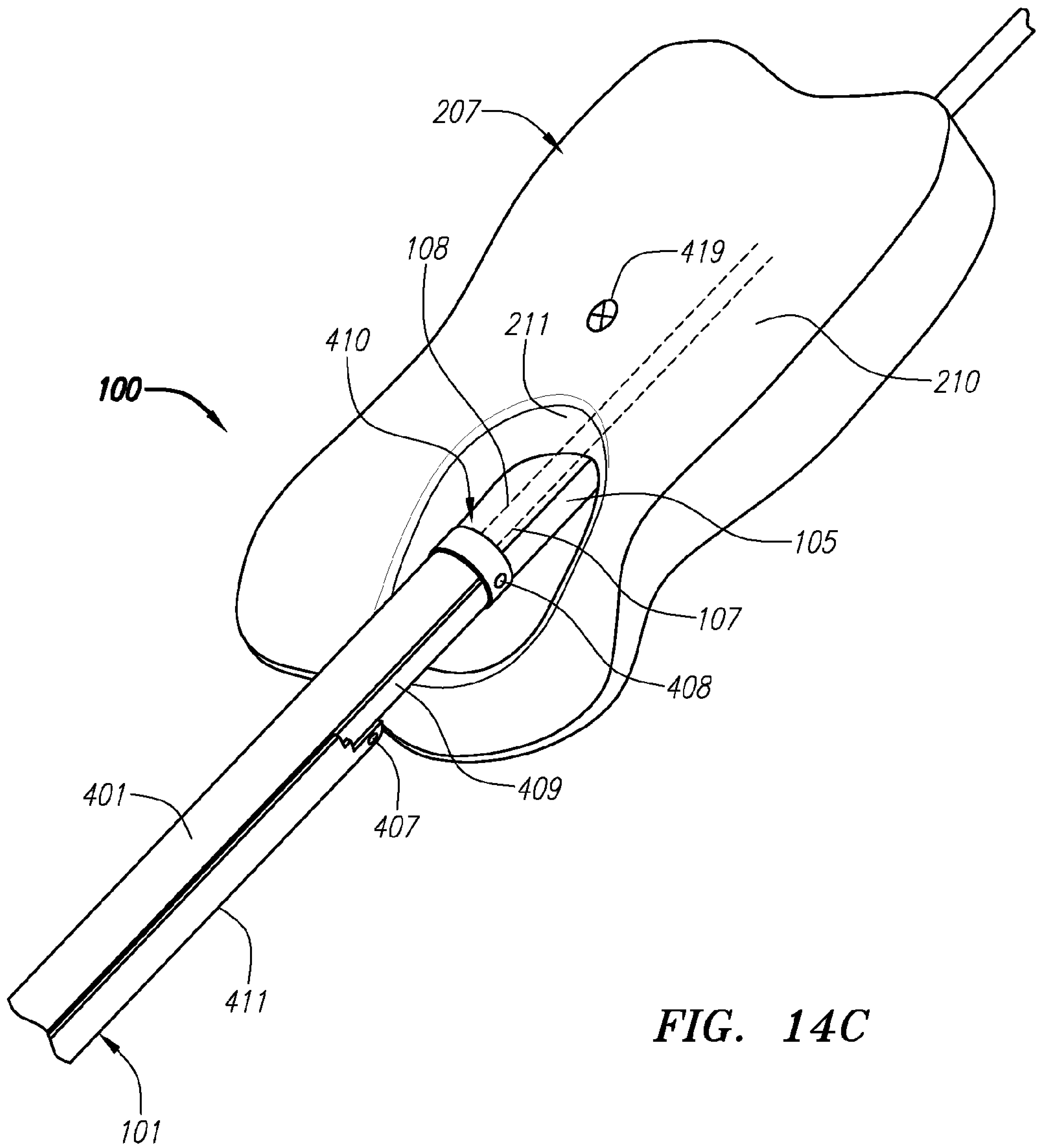

FIG. 14C

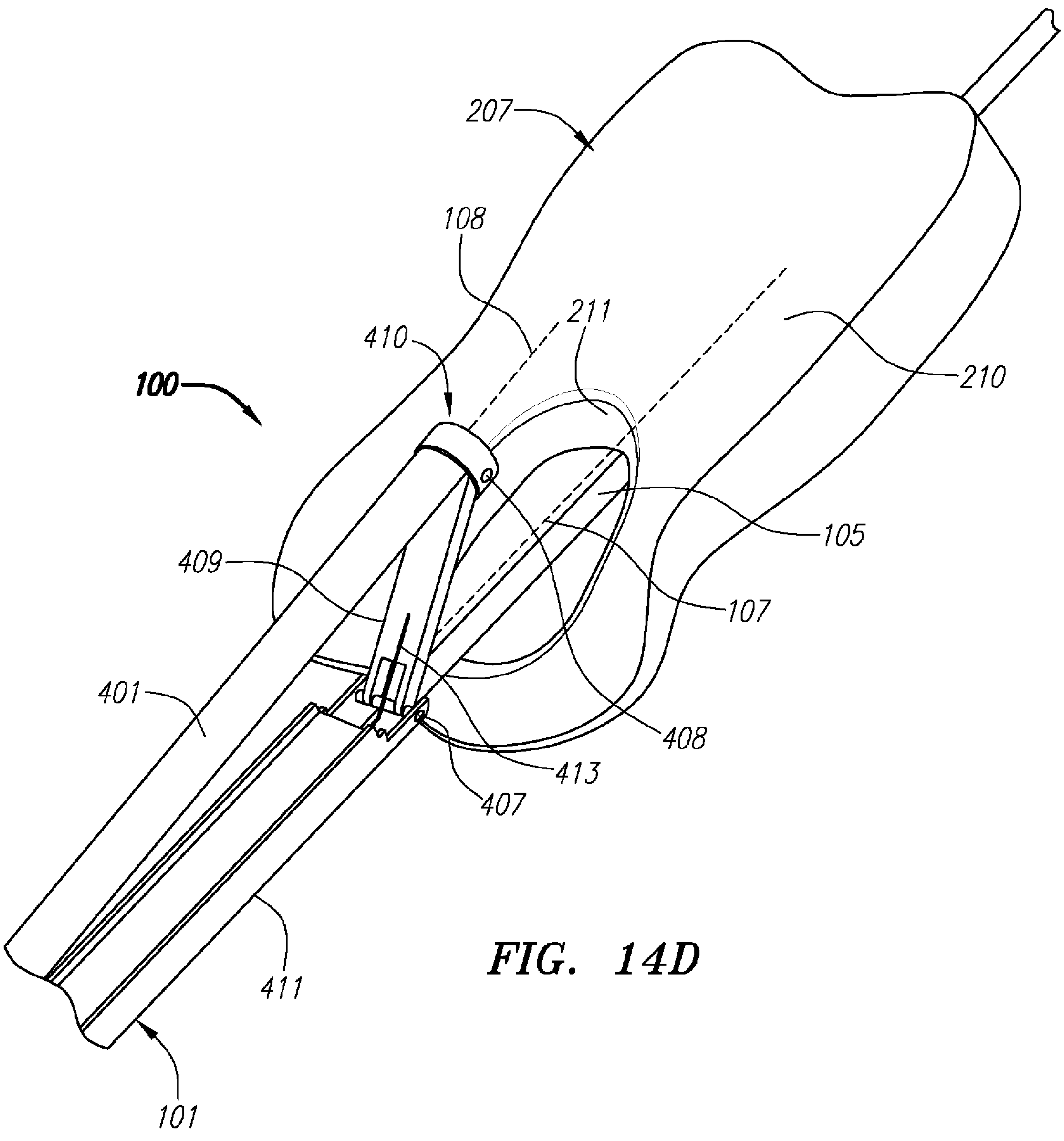

FIG. 14D

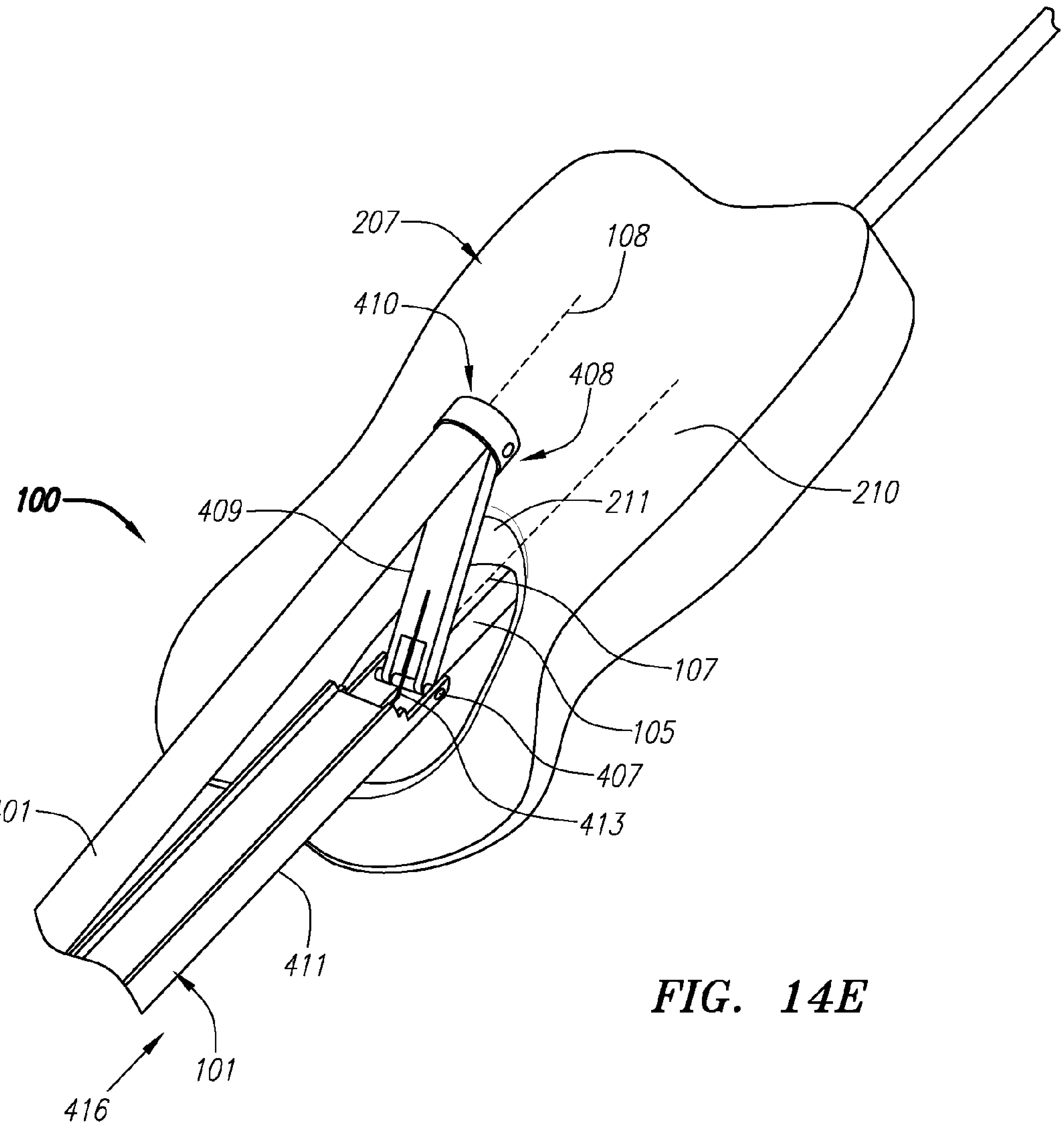

FIG. 14E

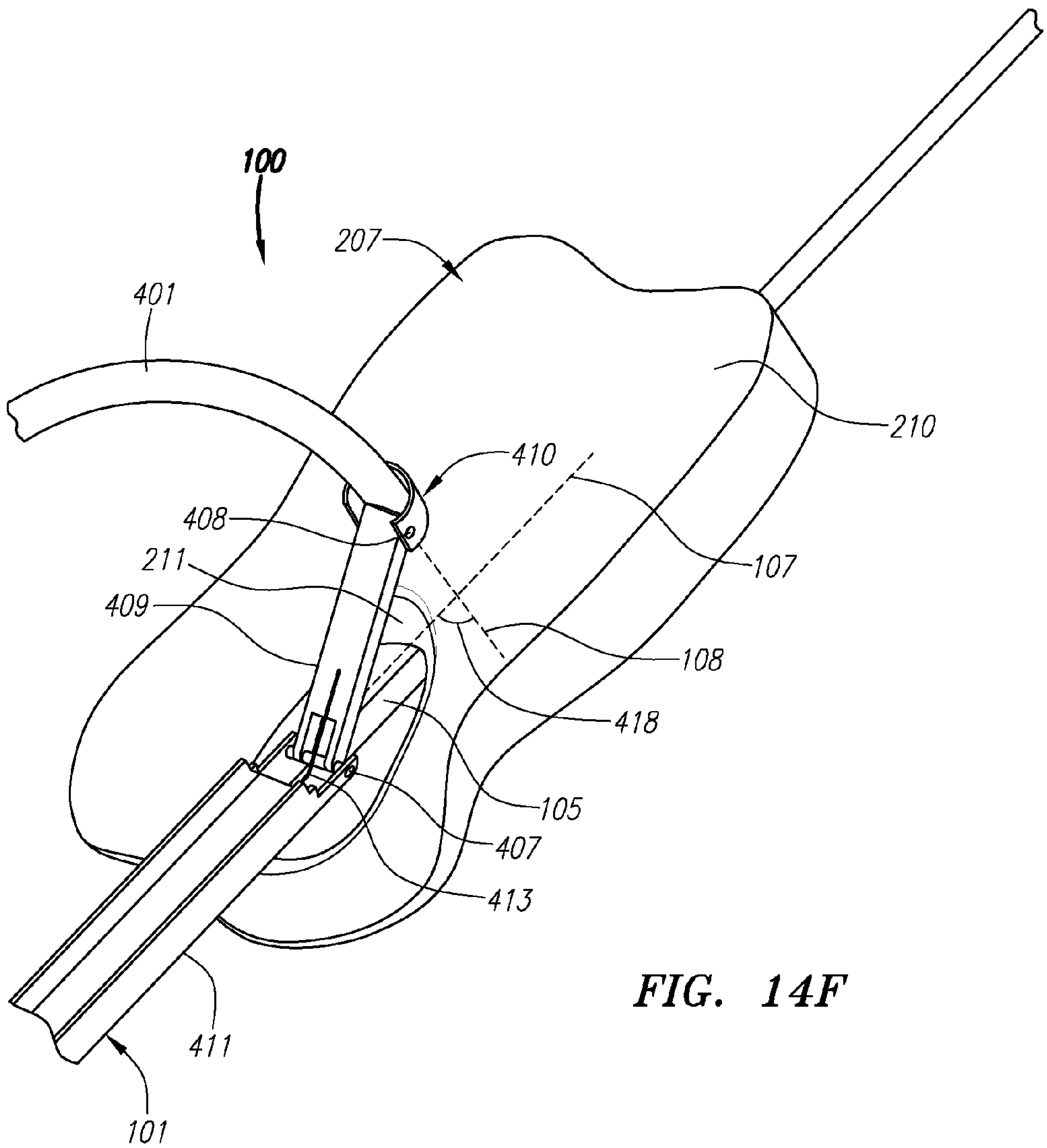

FIG. 14F

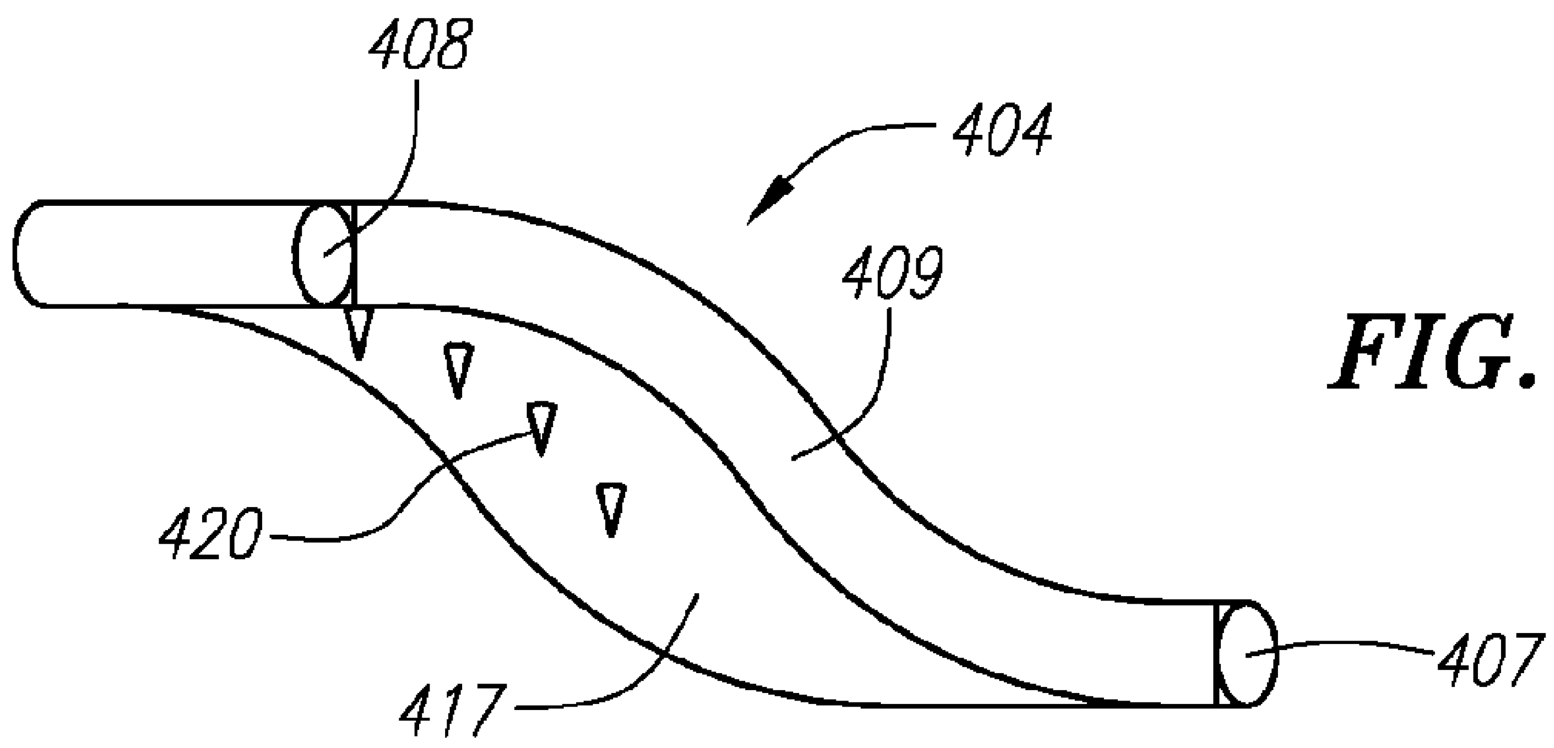

FIG. 15A

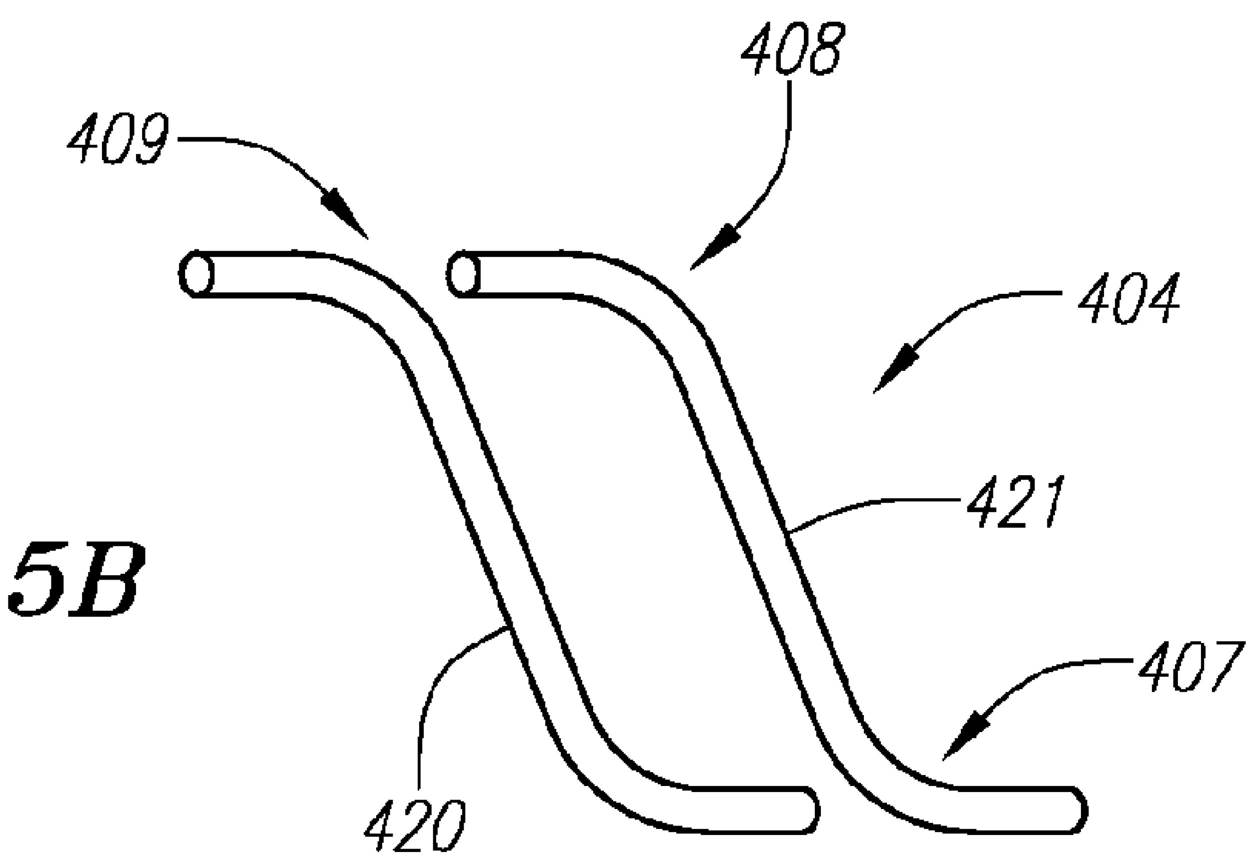

FIG. 15B

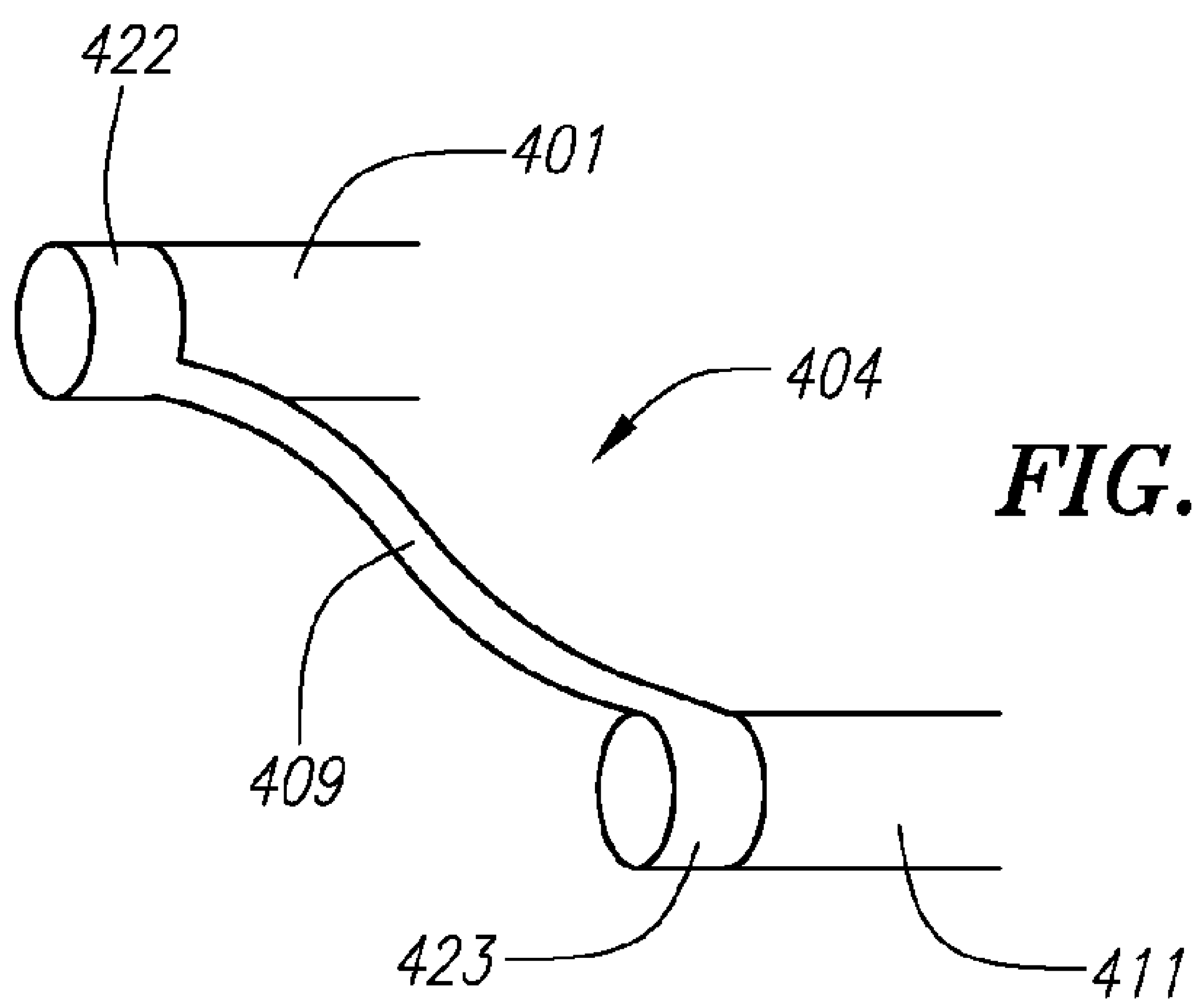

FIG. 15C

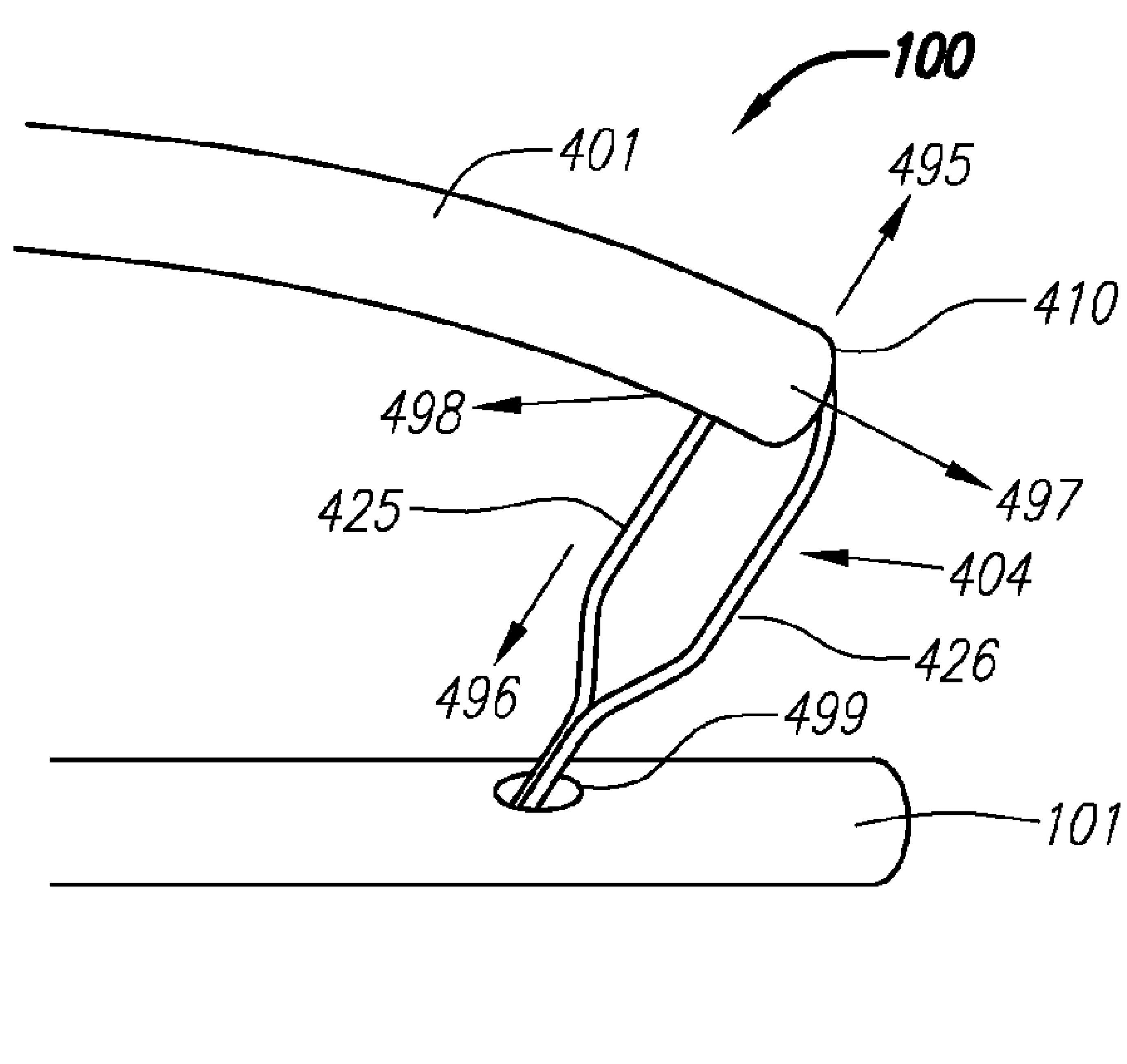

FIG. 15D

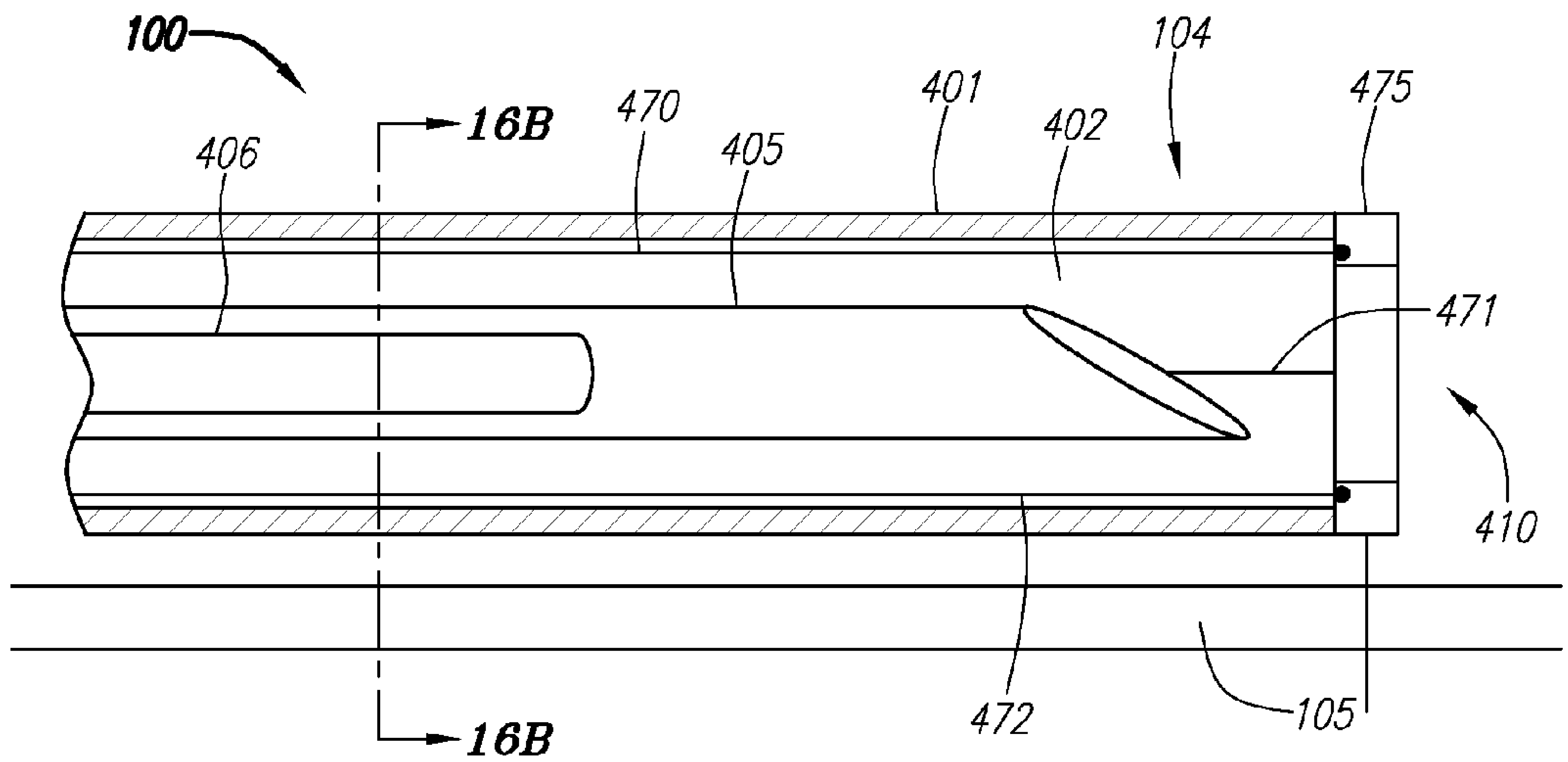

FIG. 16A

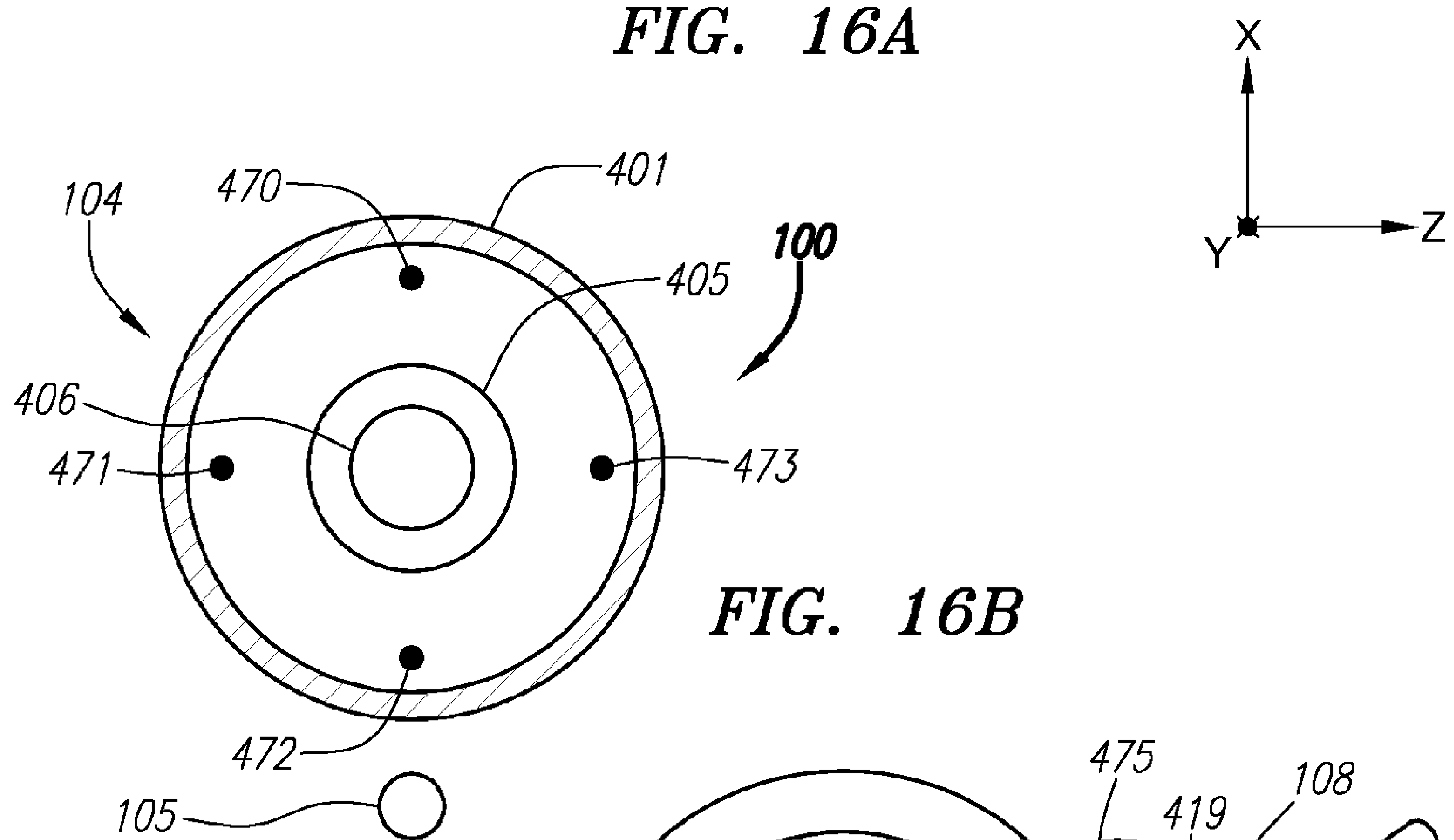

FIG. 16B

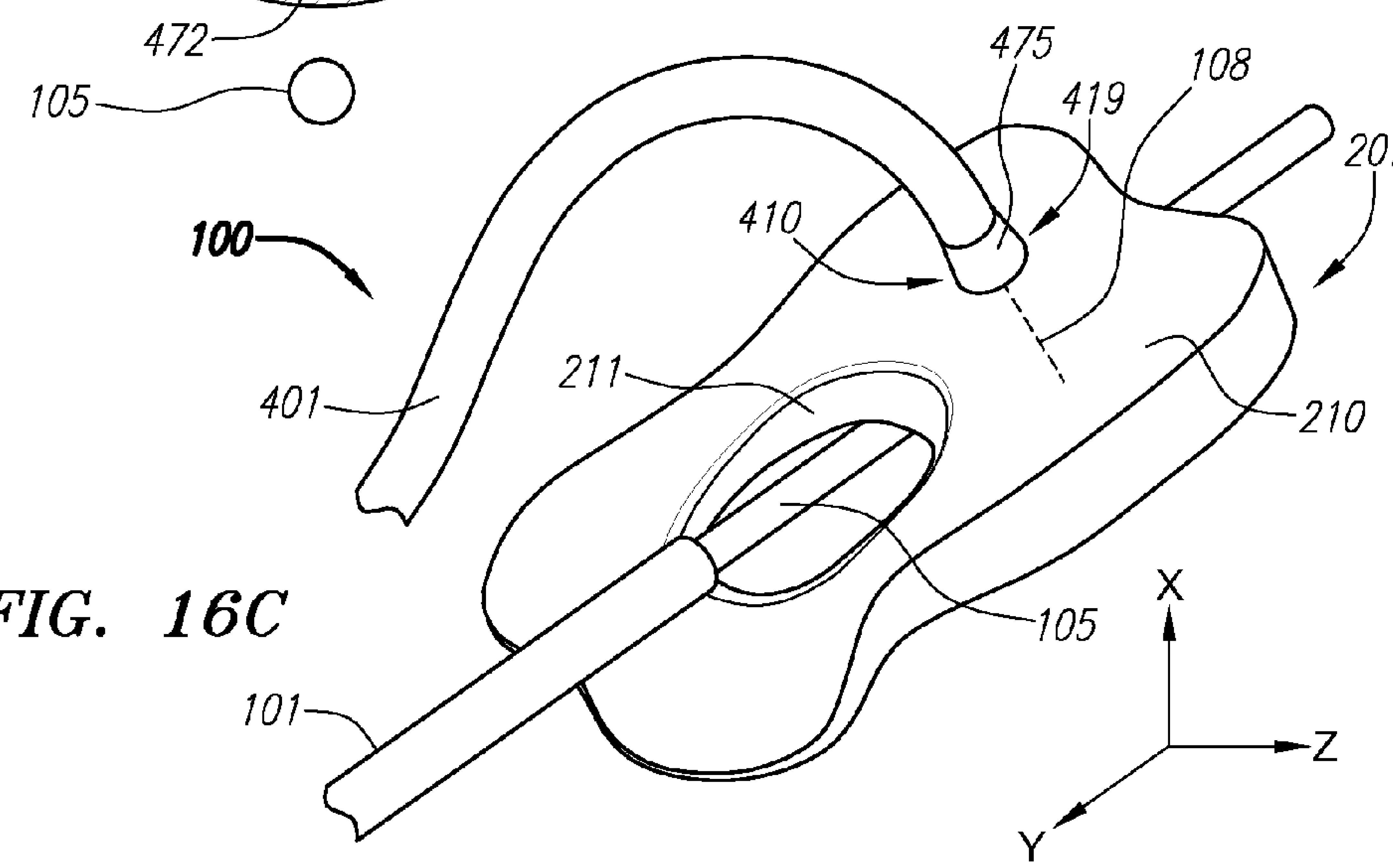

FIG. 16C

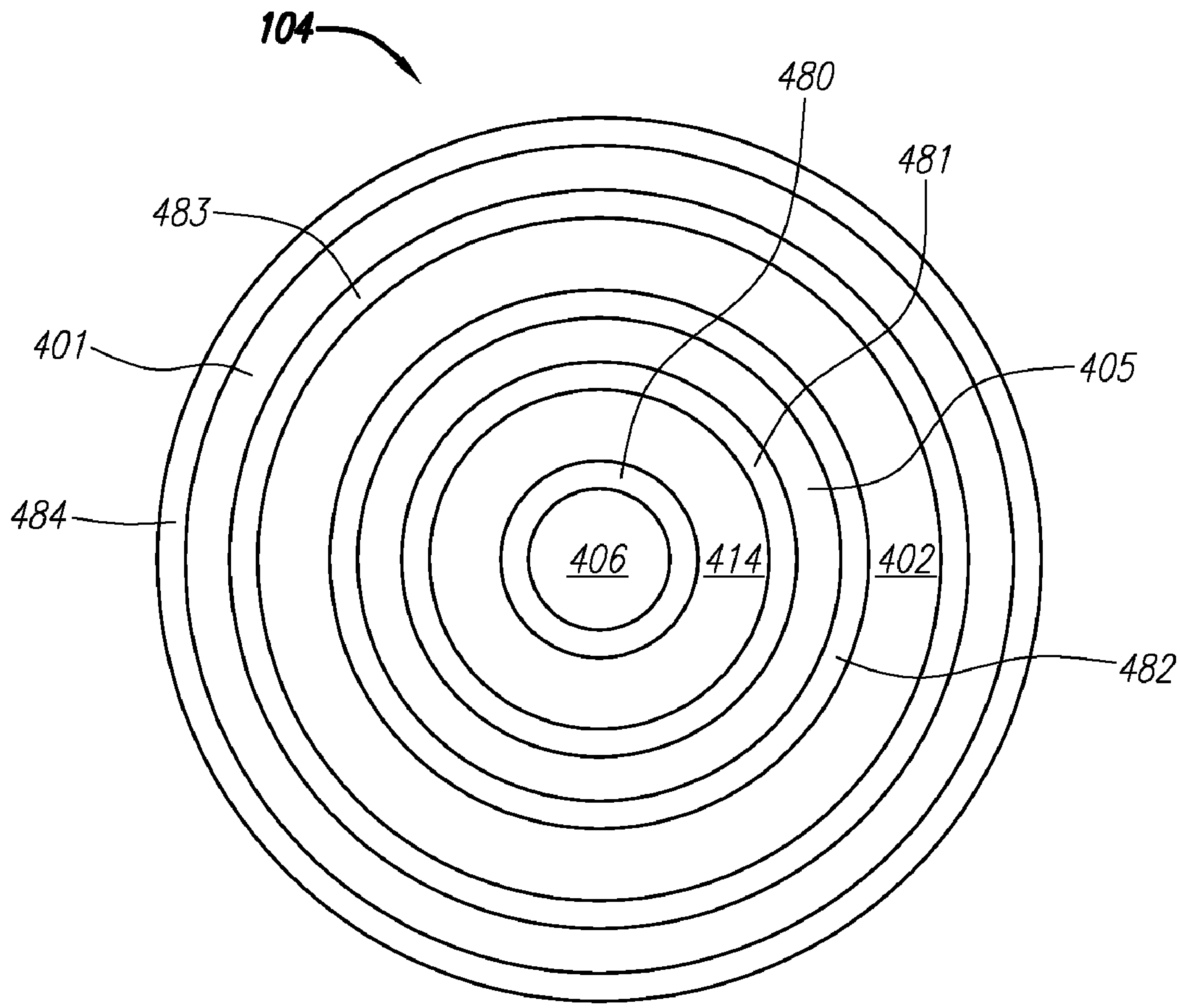

FIG. 17

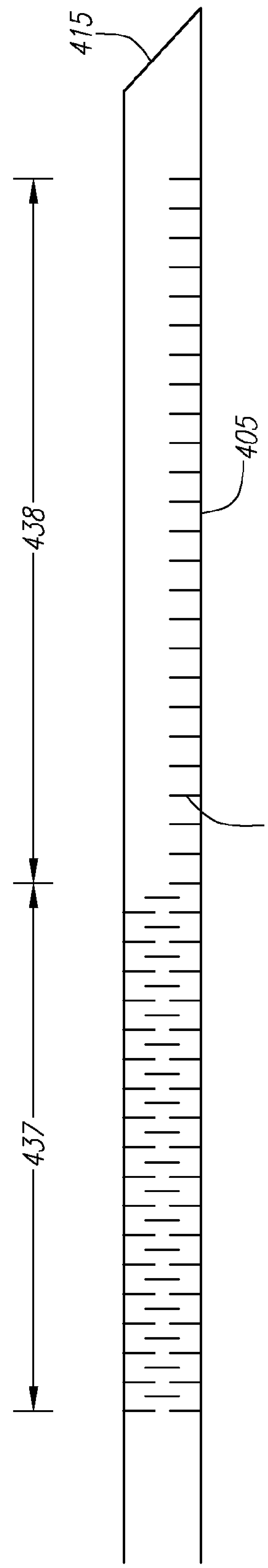

FIG. 18A

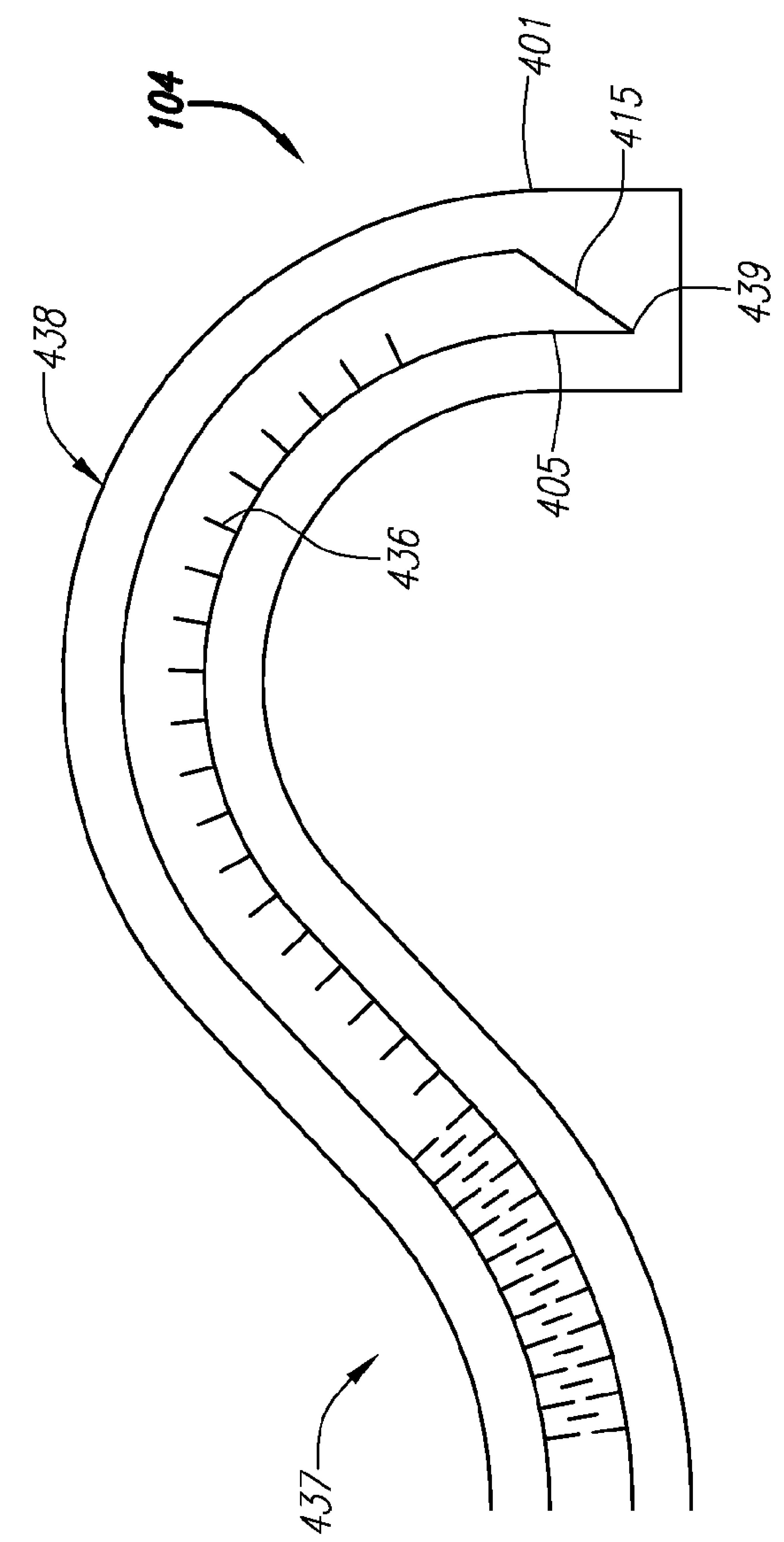

FIG. 18B

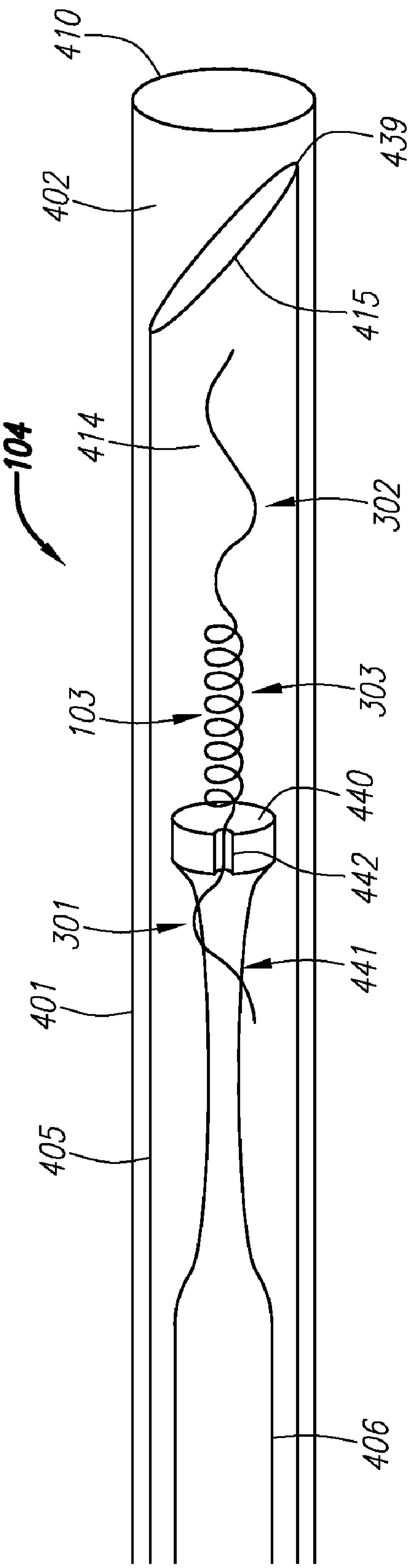

FIG. 18C

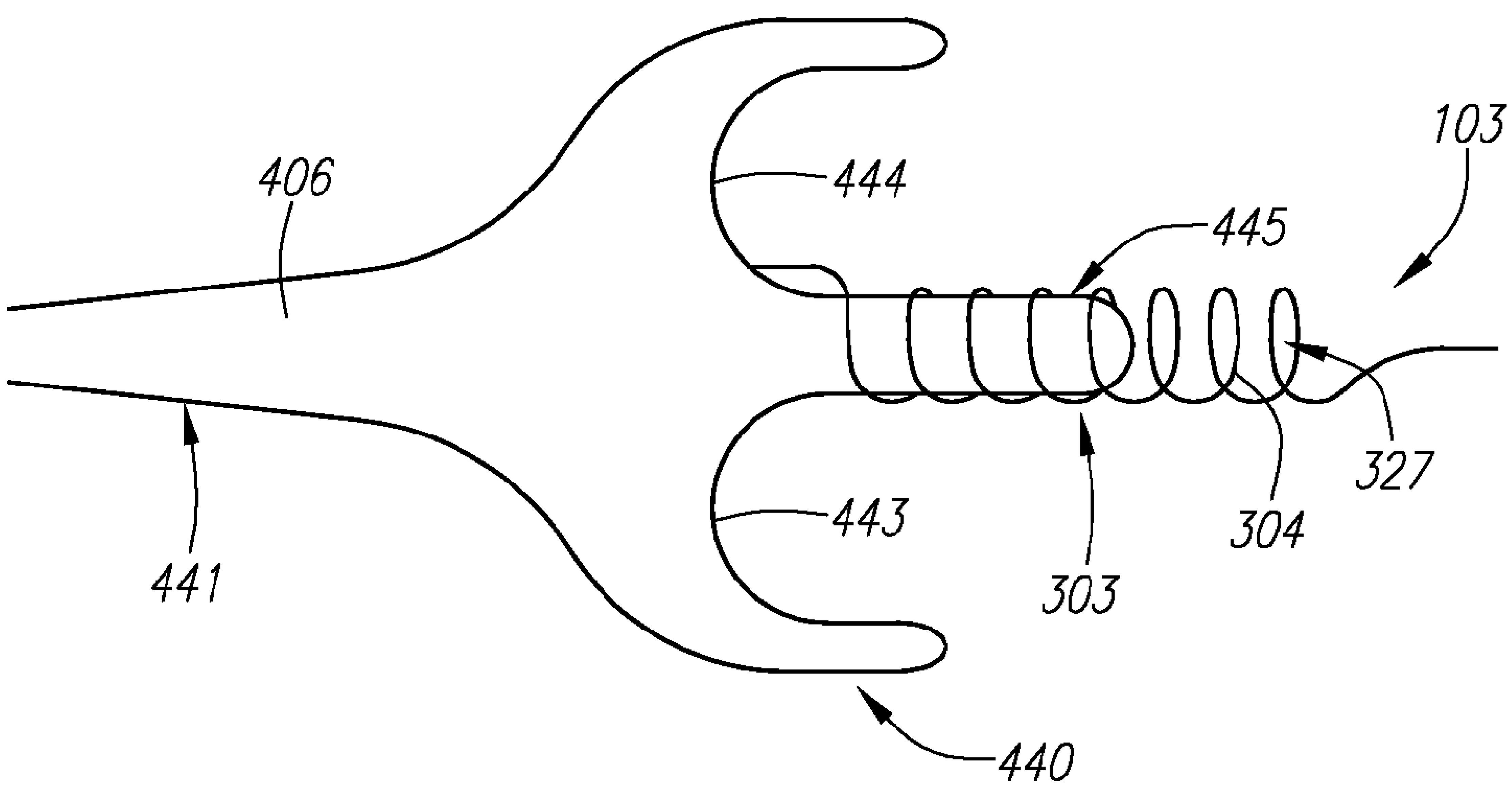

FIG. 19A

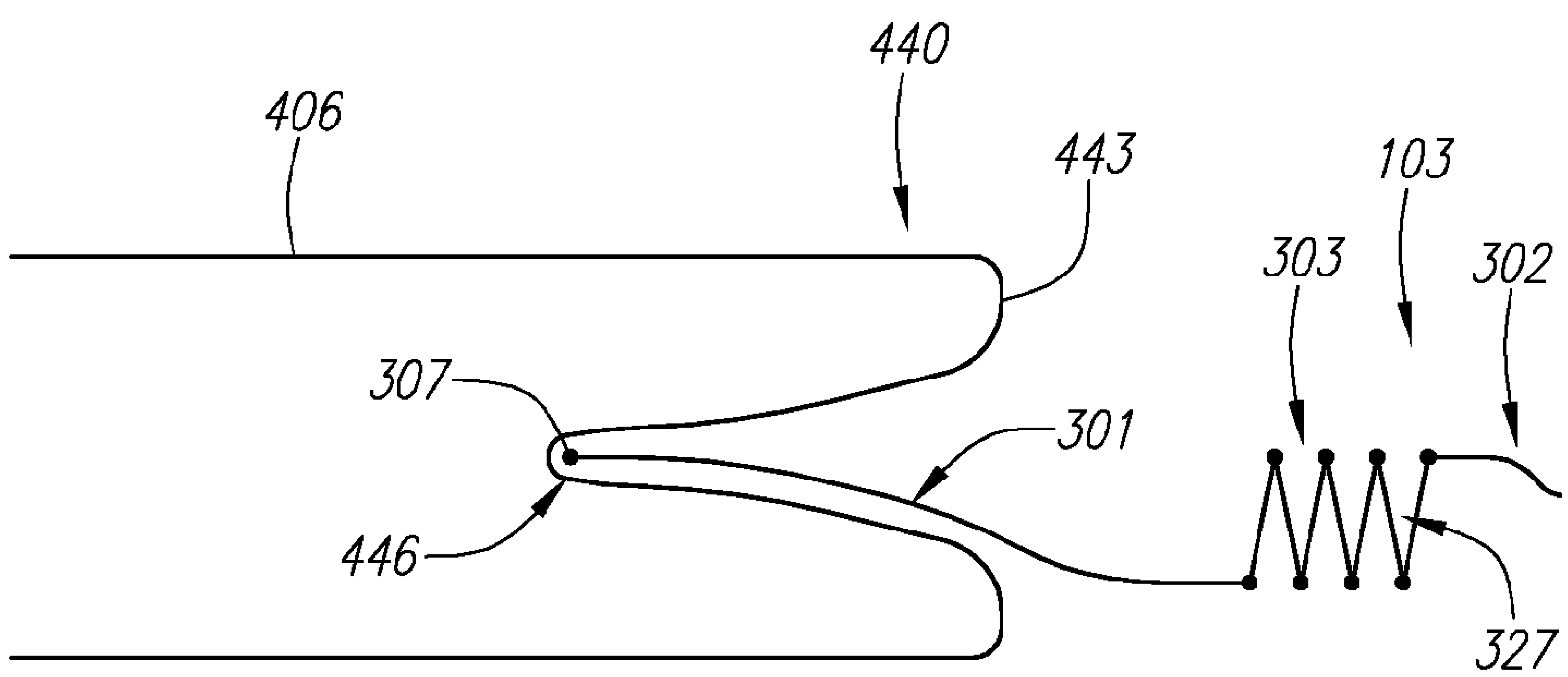

FIG. 19B

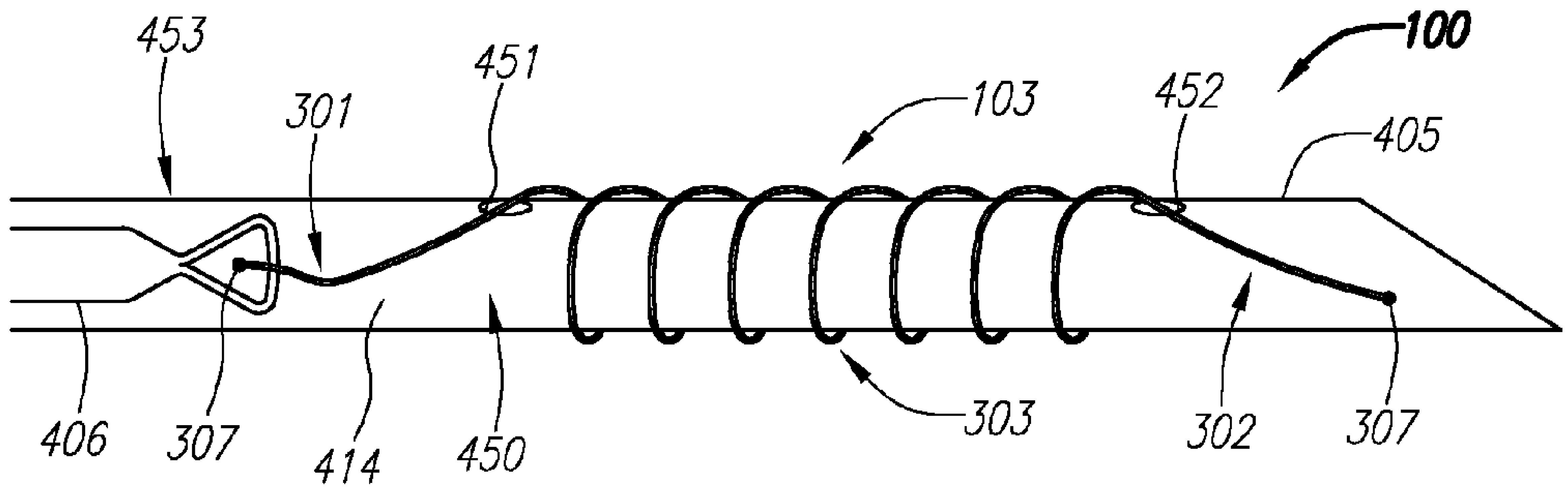

FIG. 20A

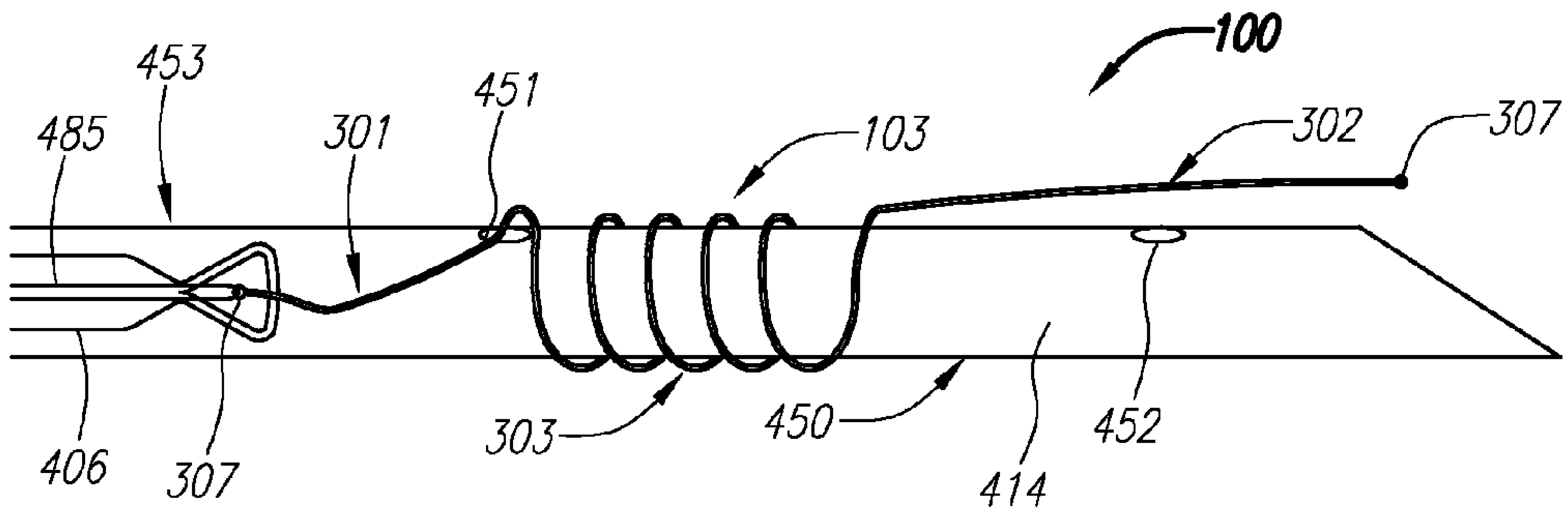

FIG. 20B

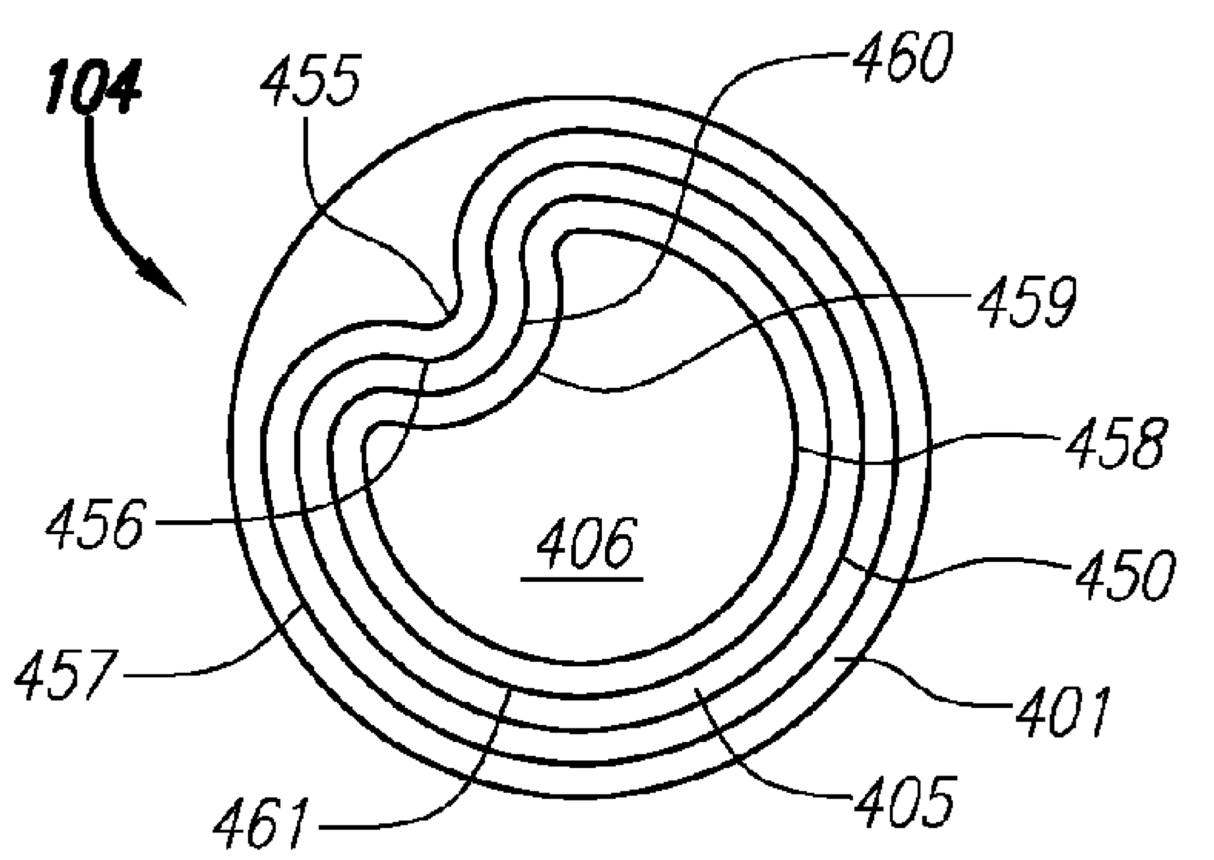

FIG. 21

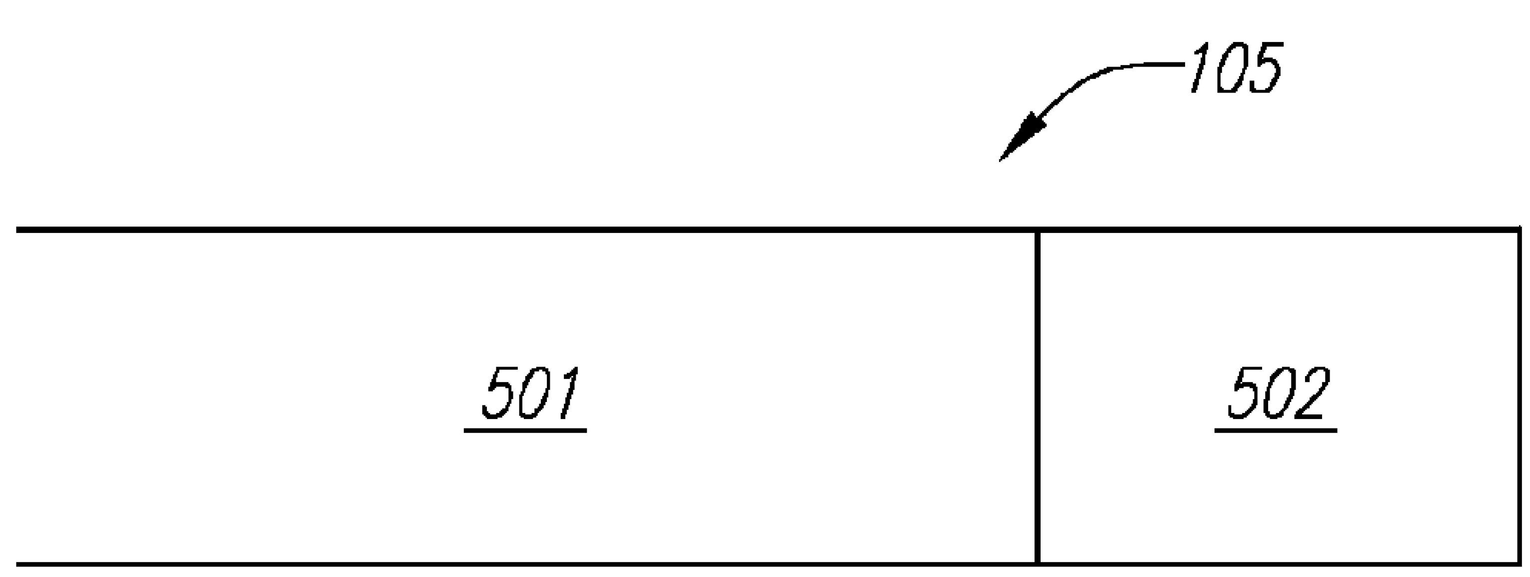

FIG. 22

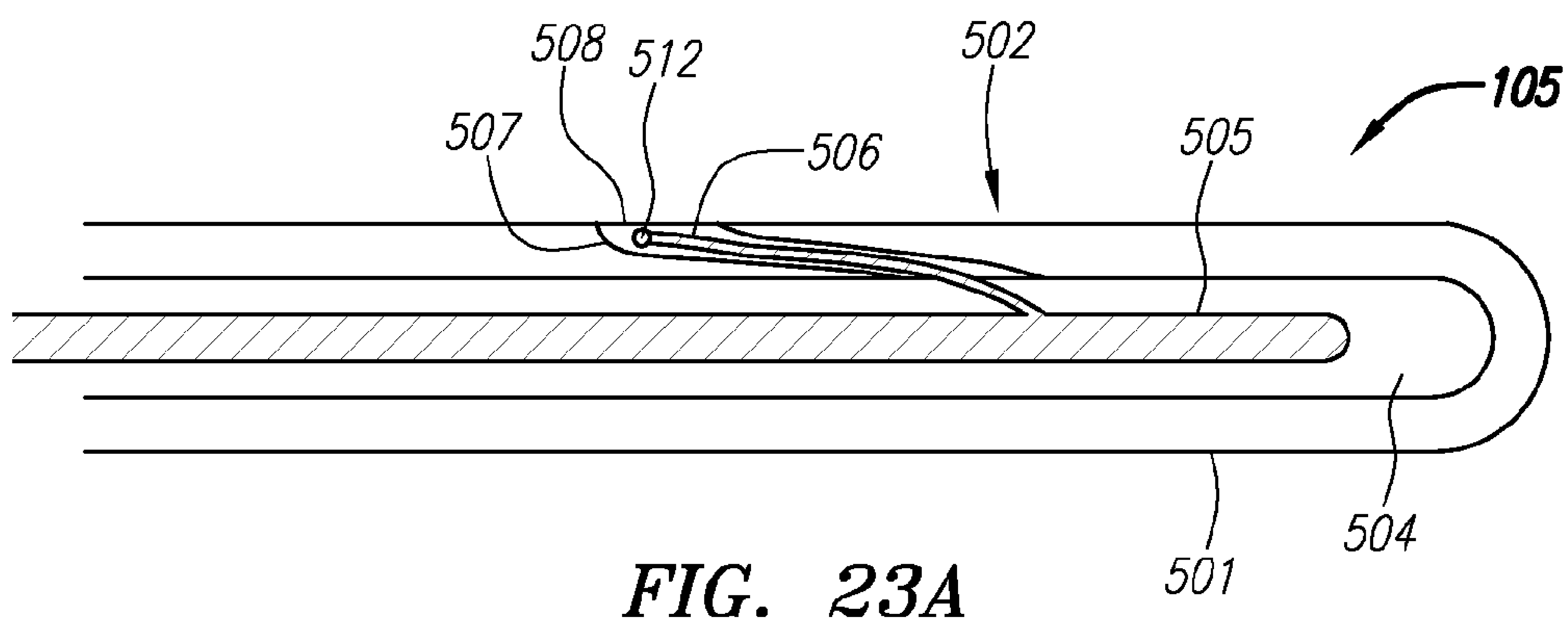

FIG. 23A

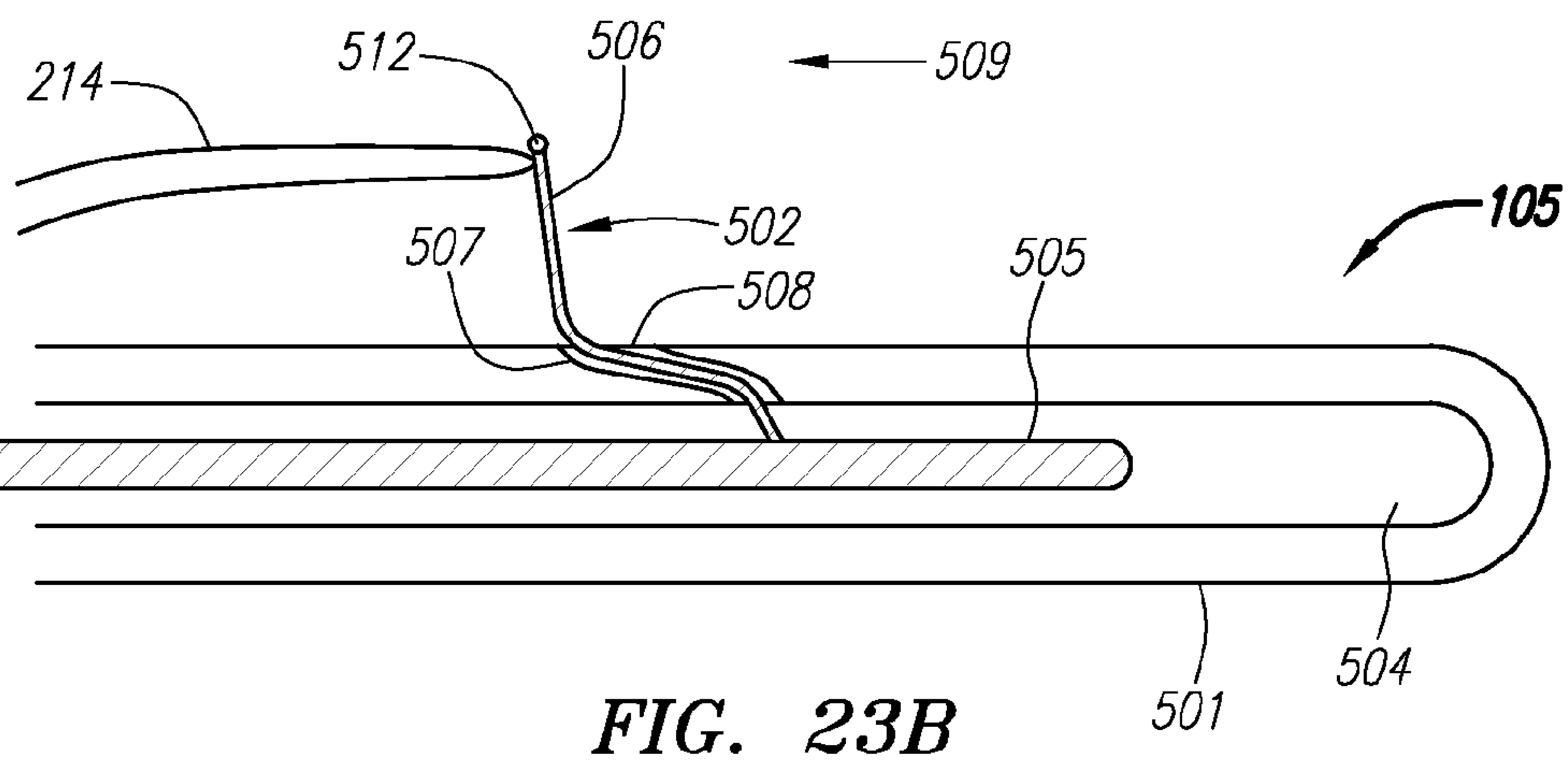

FIG. 23B

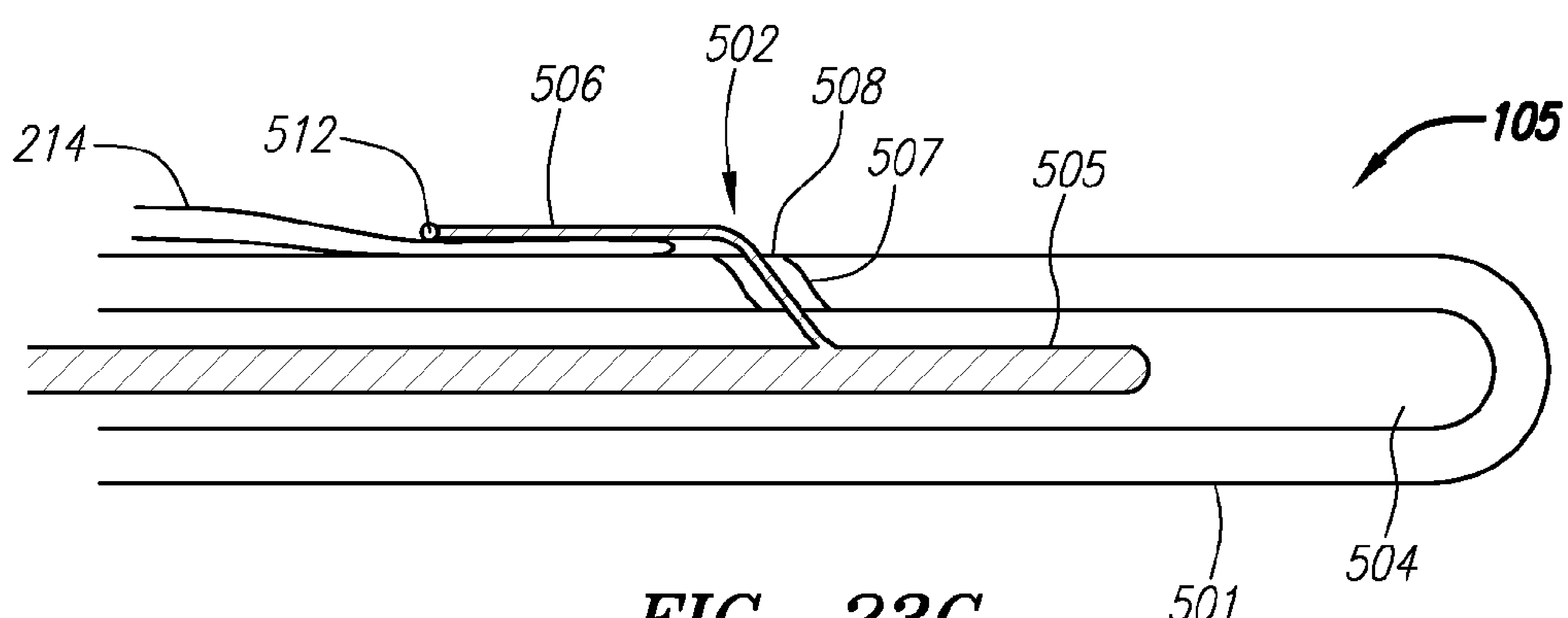

FIG. 23C

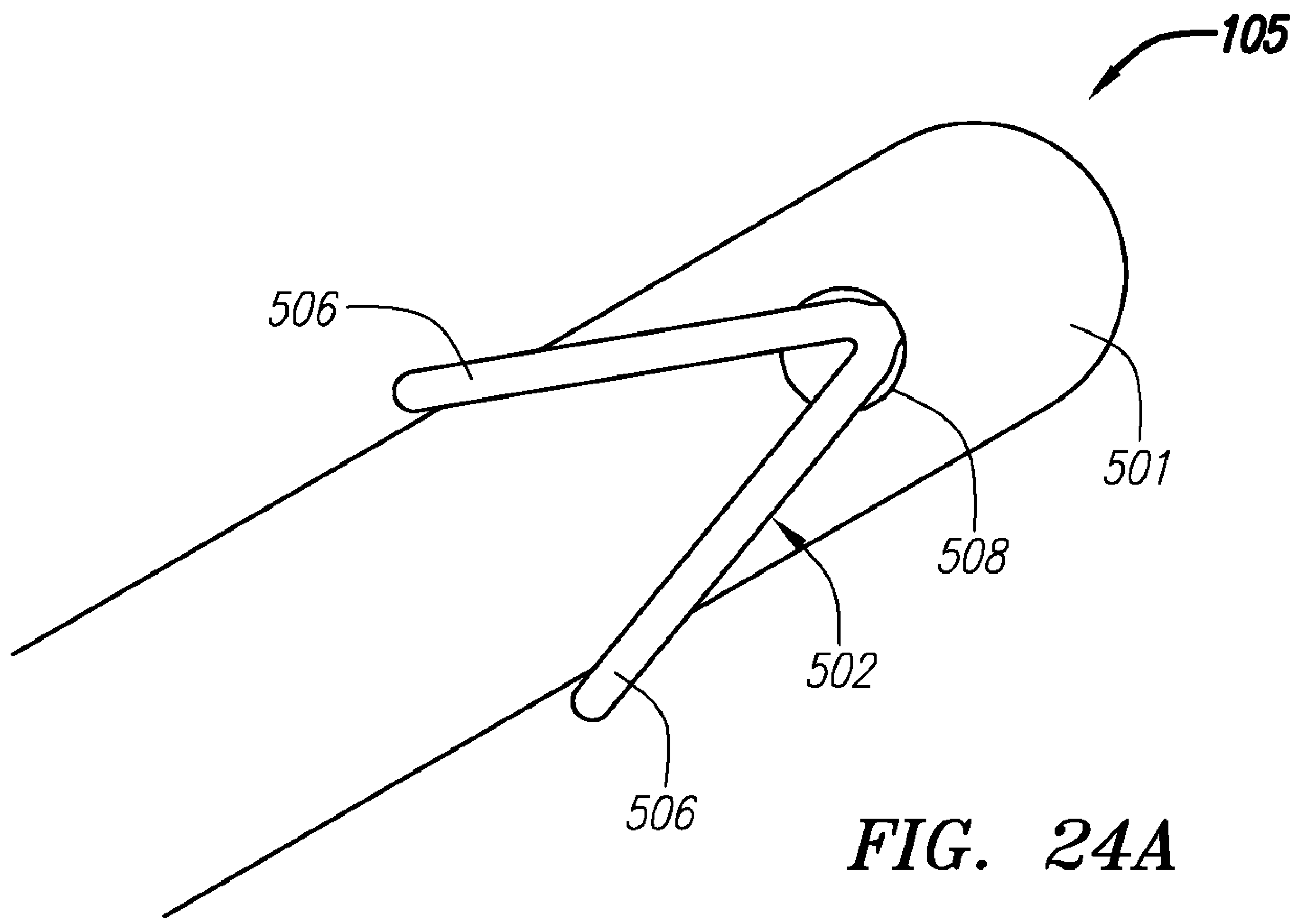

FIG. 24A

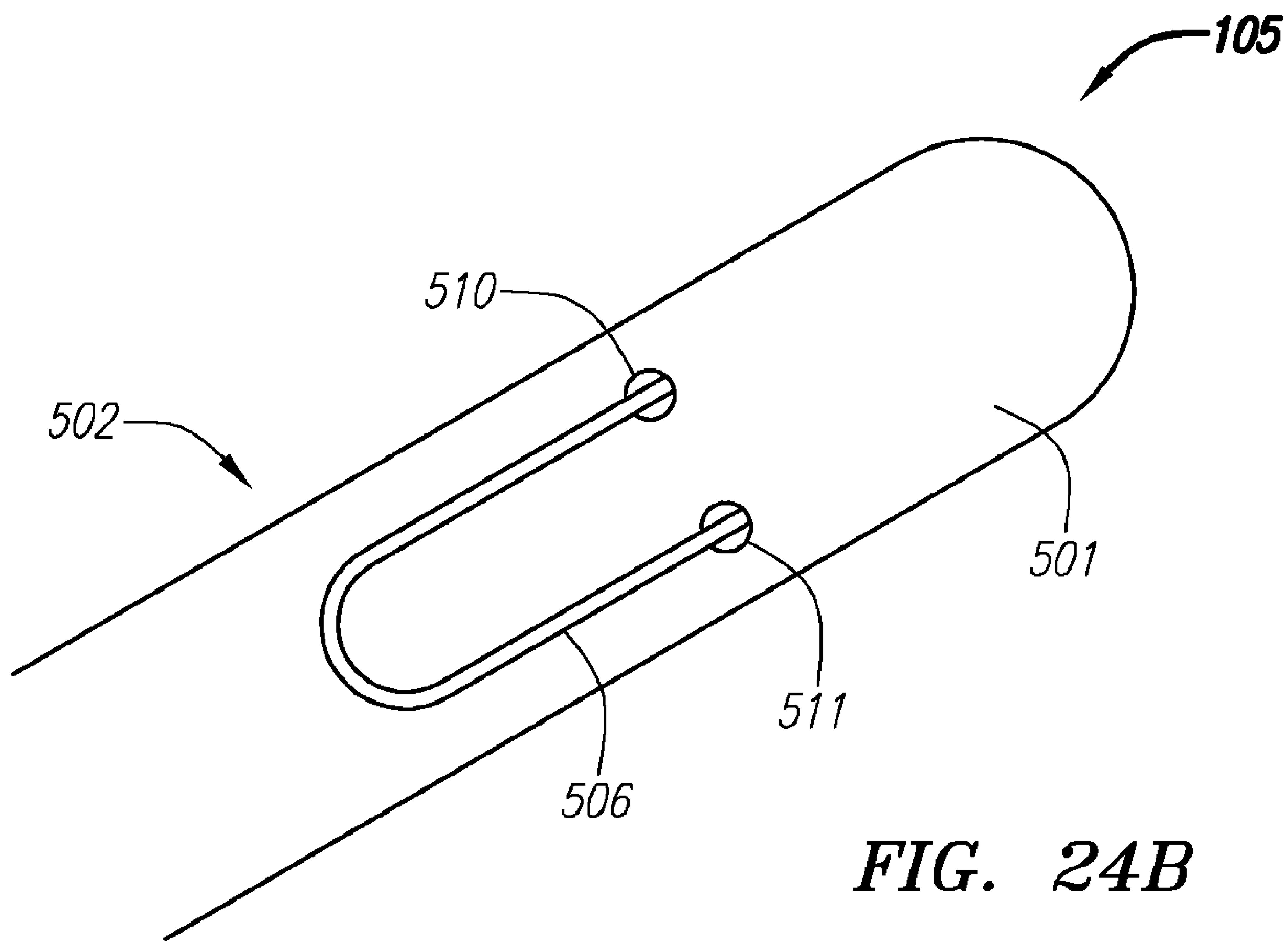

FIG. 24B

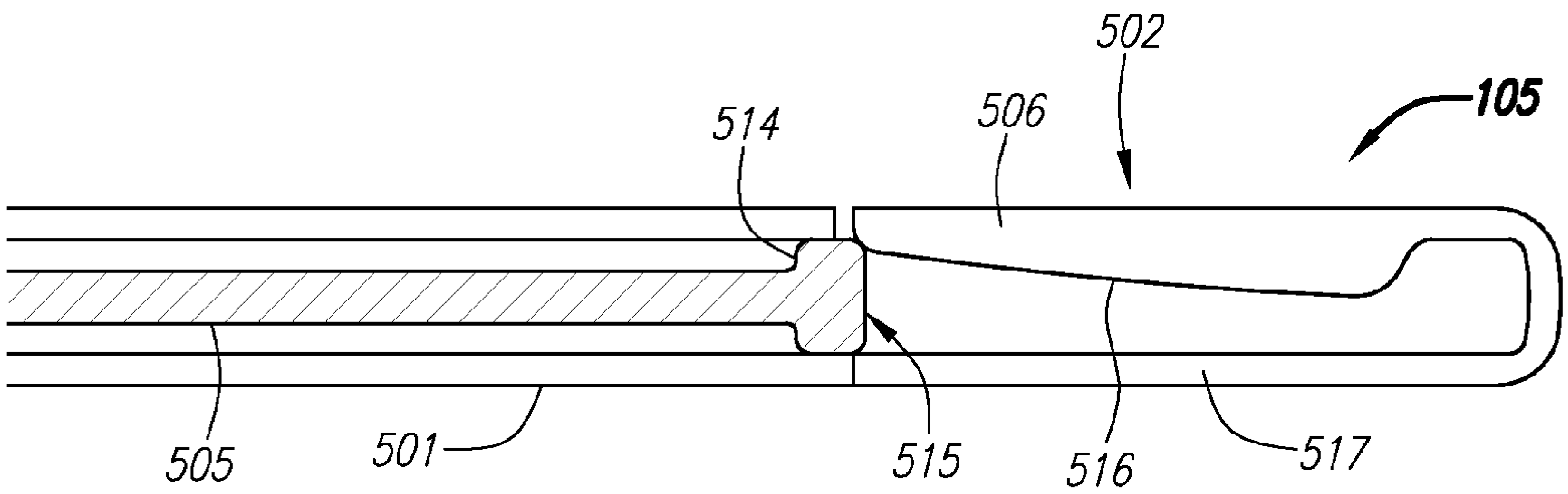

FIG. 25A

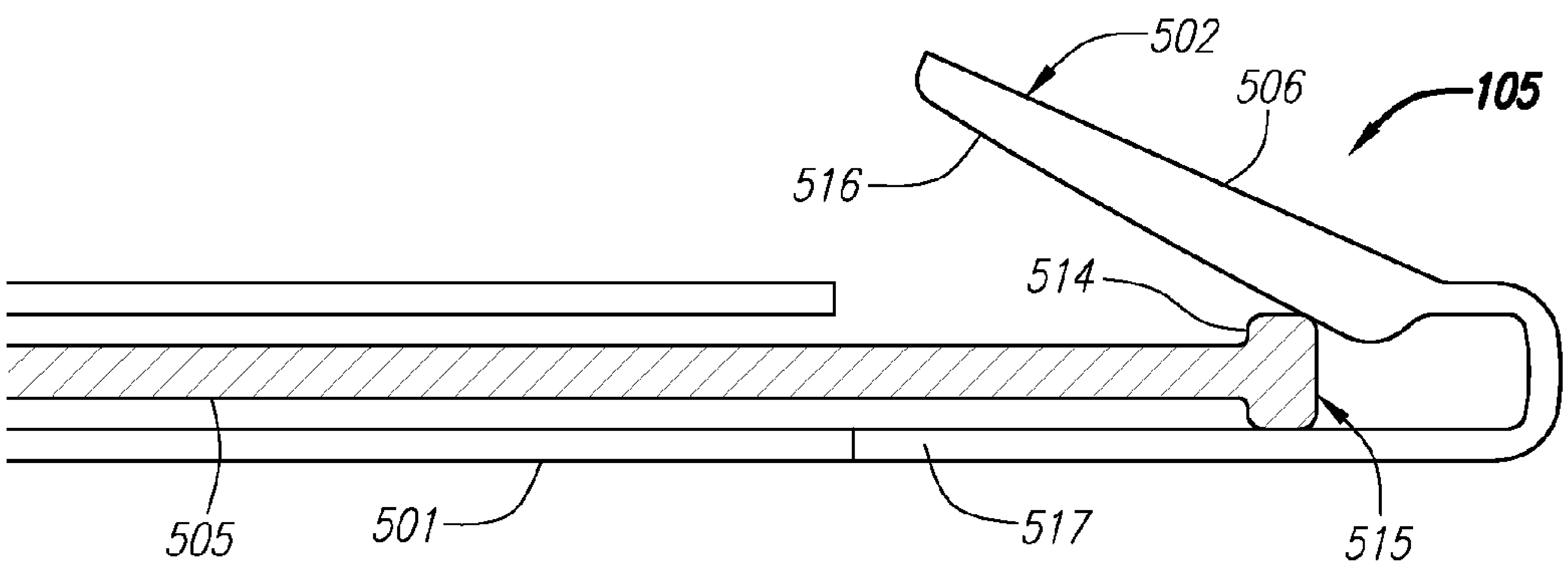

FIG. 25B

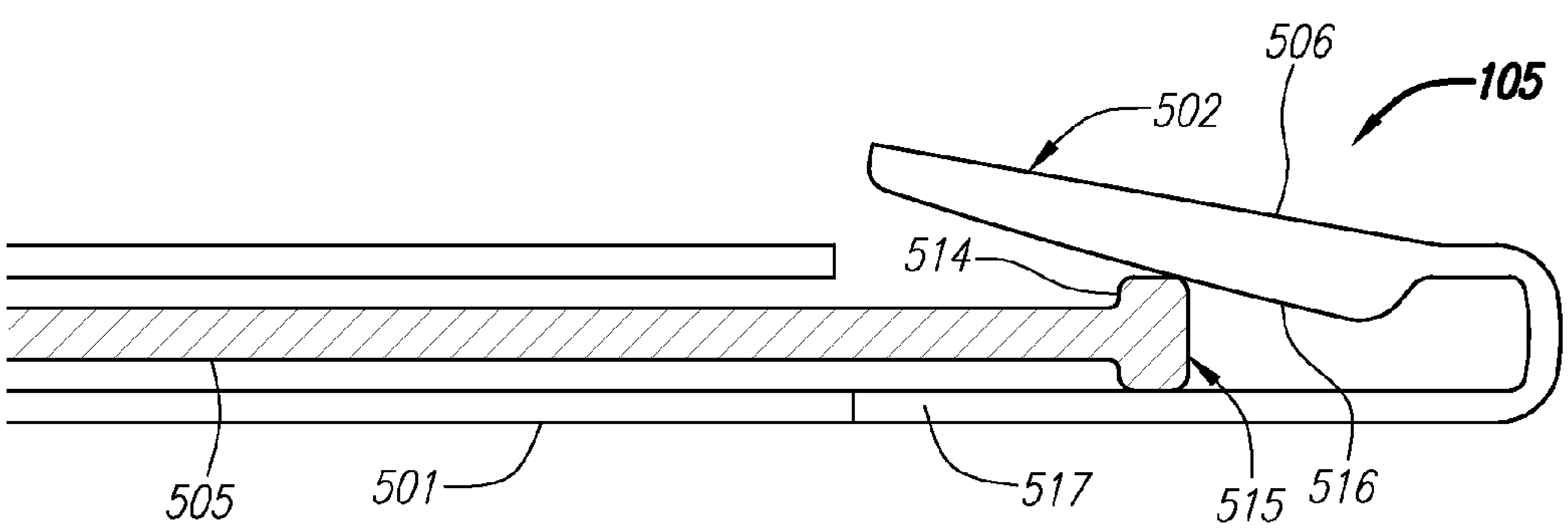

FIG. 25C

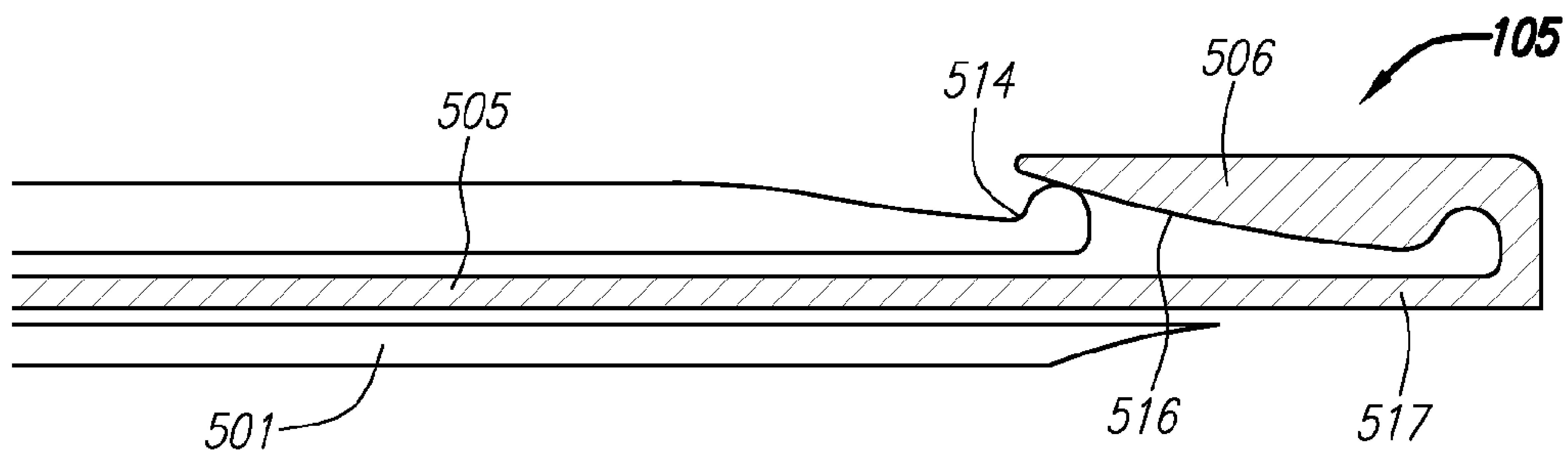

FIG. 25D

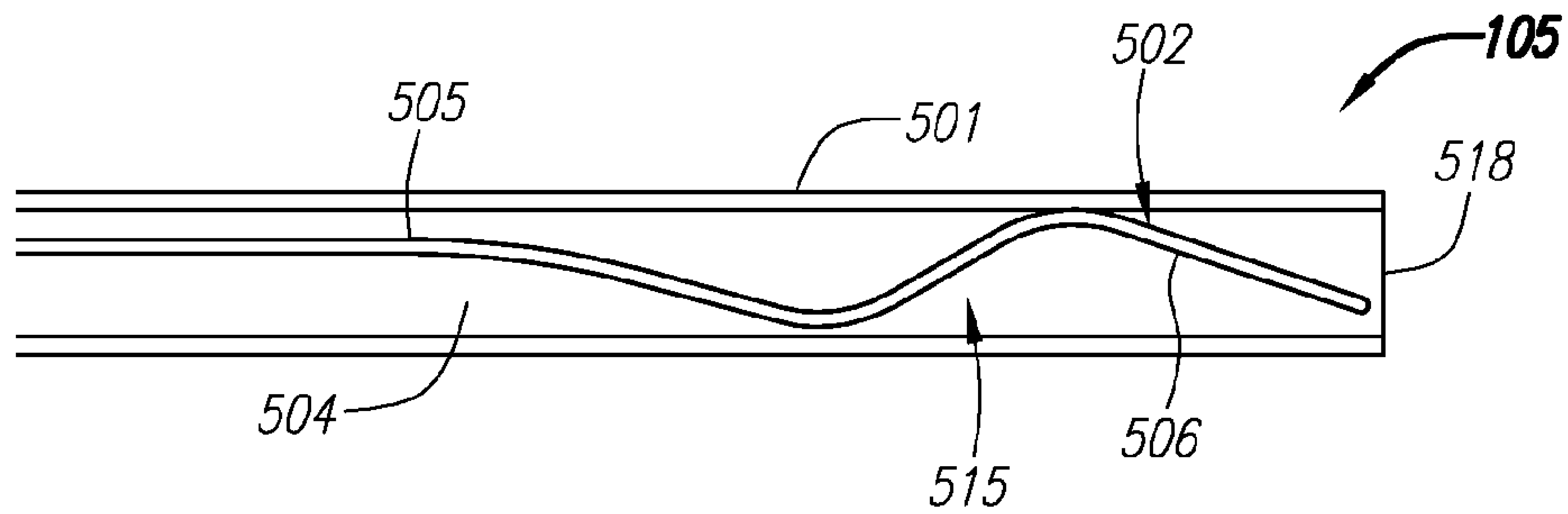

FIG. 26A

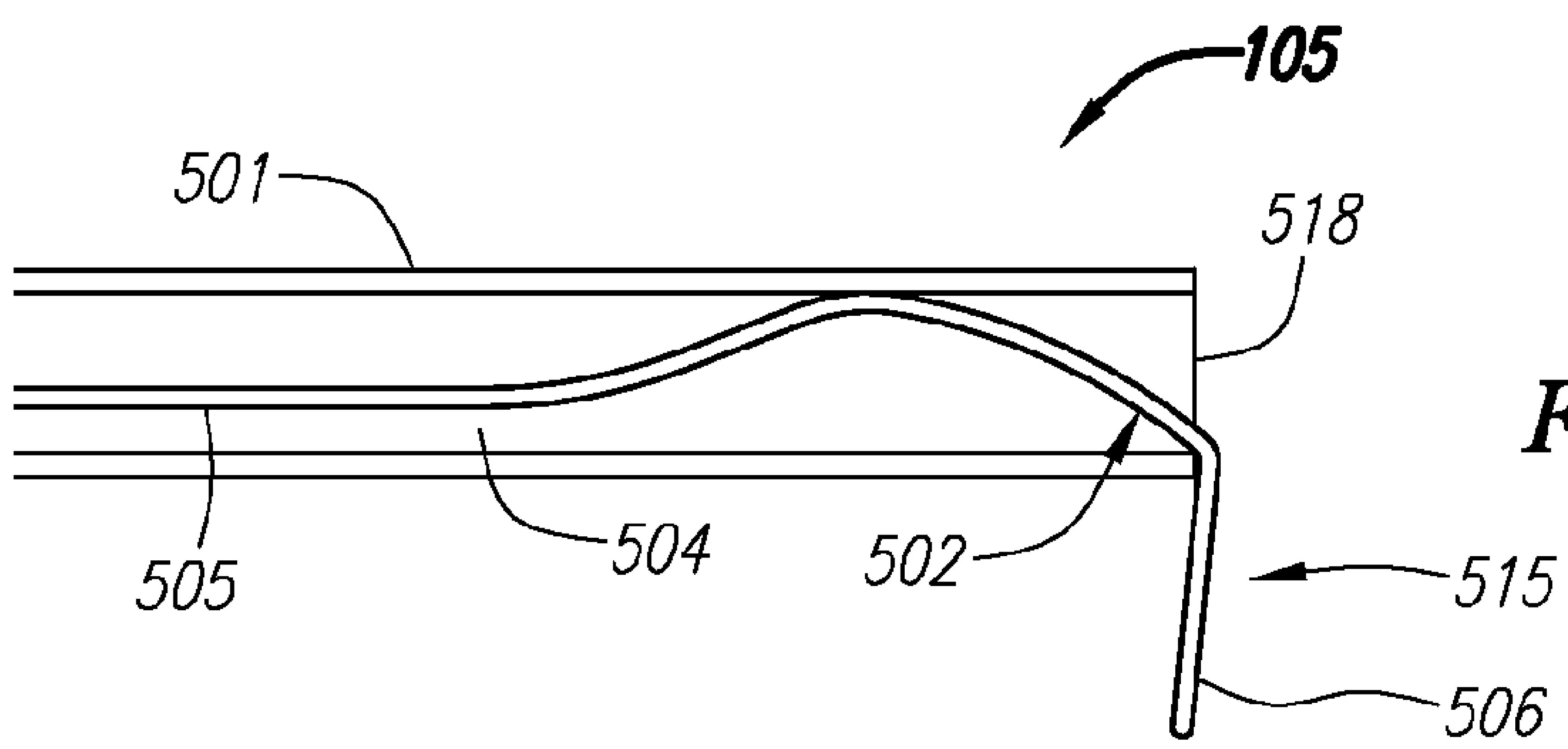

FIG. 26B

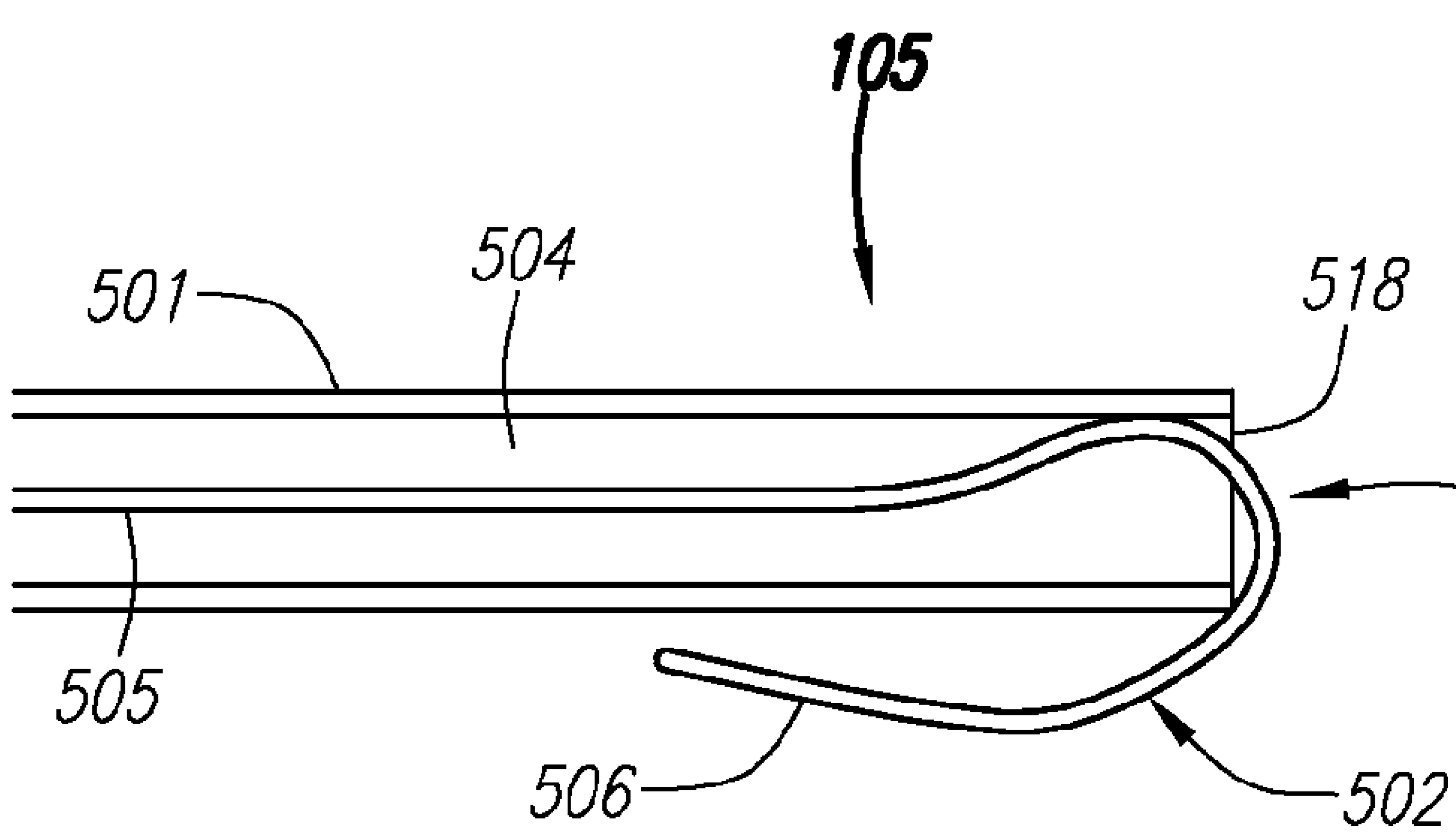

FIG. 26C

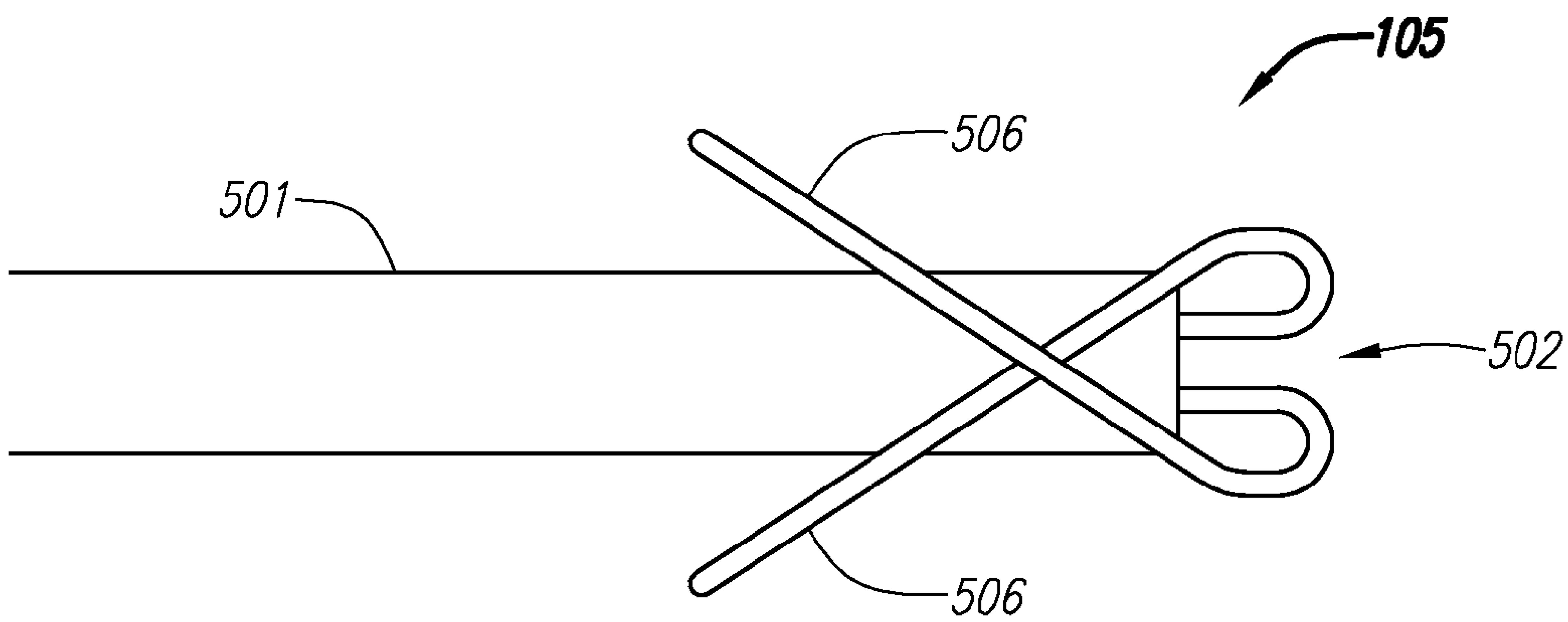

FIG. 27A

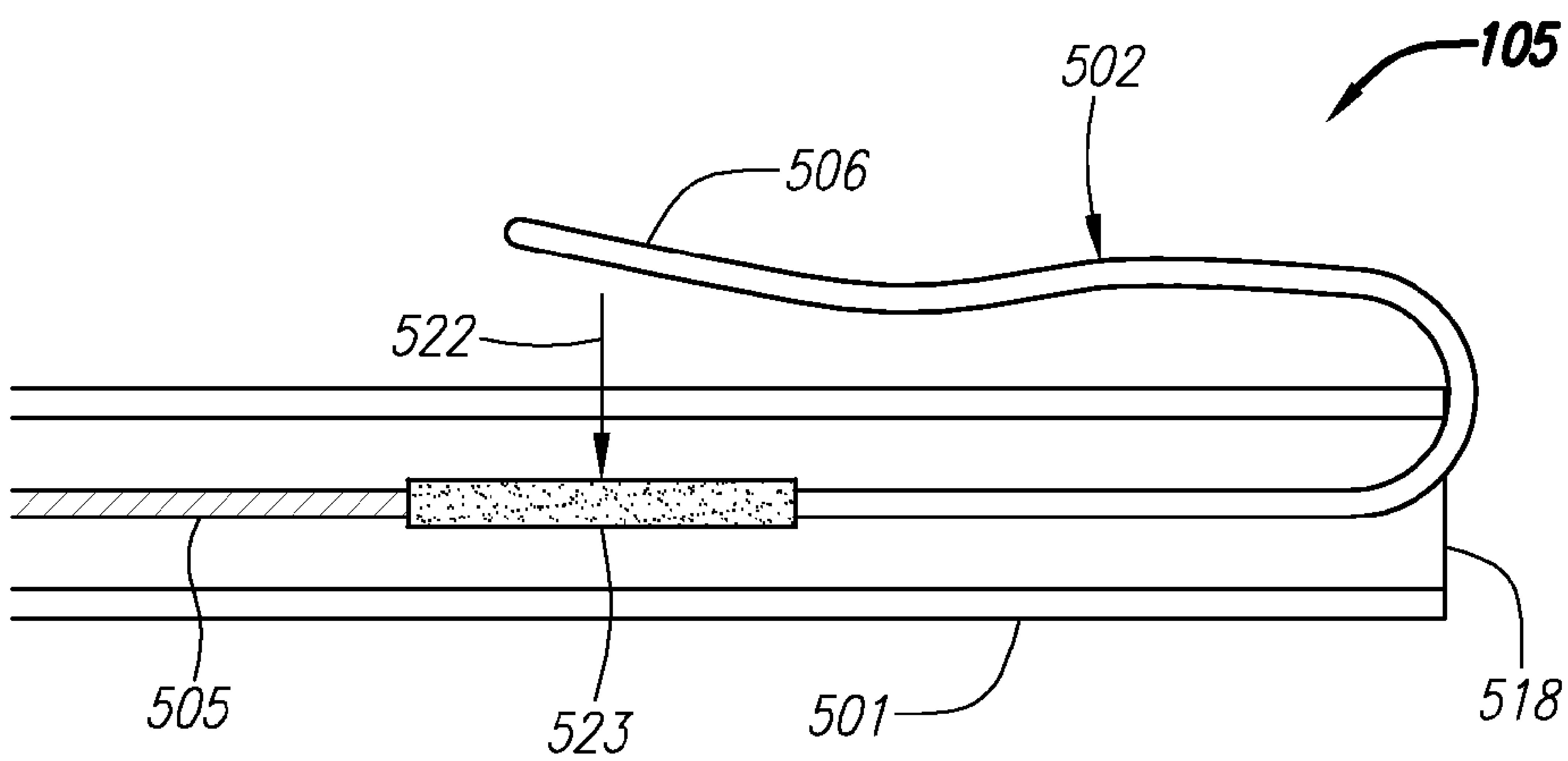

FIG. 27B

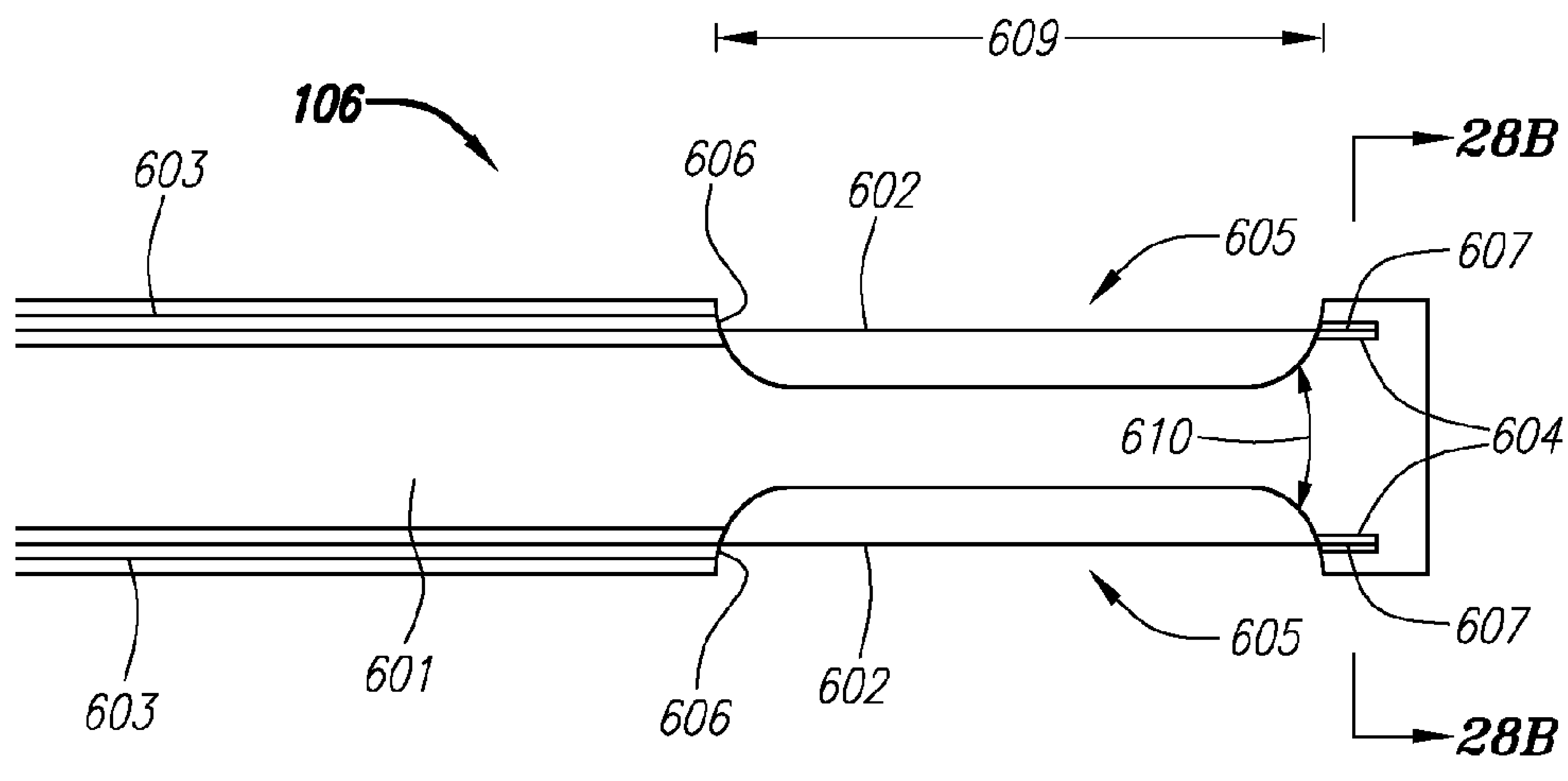

FIG. 28A

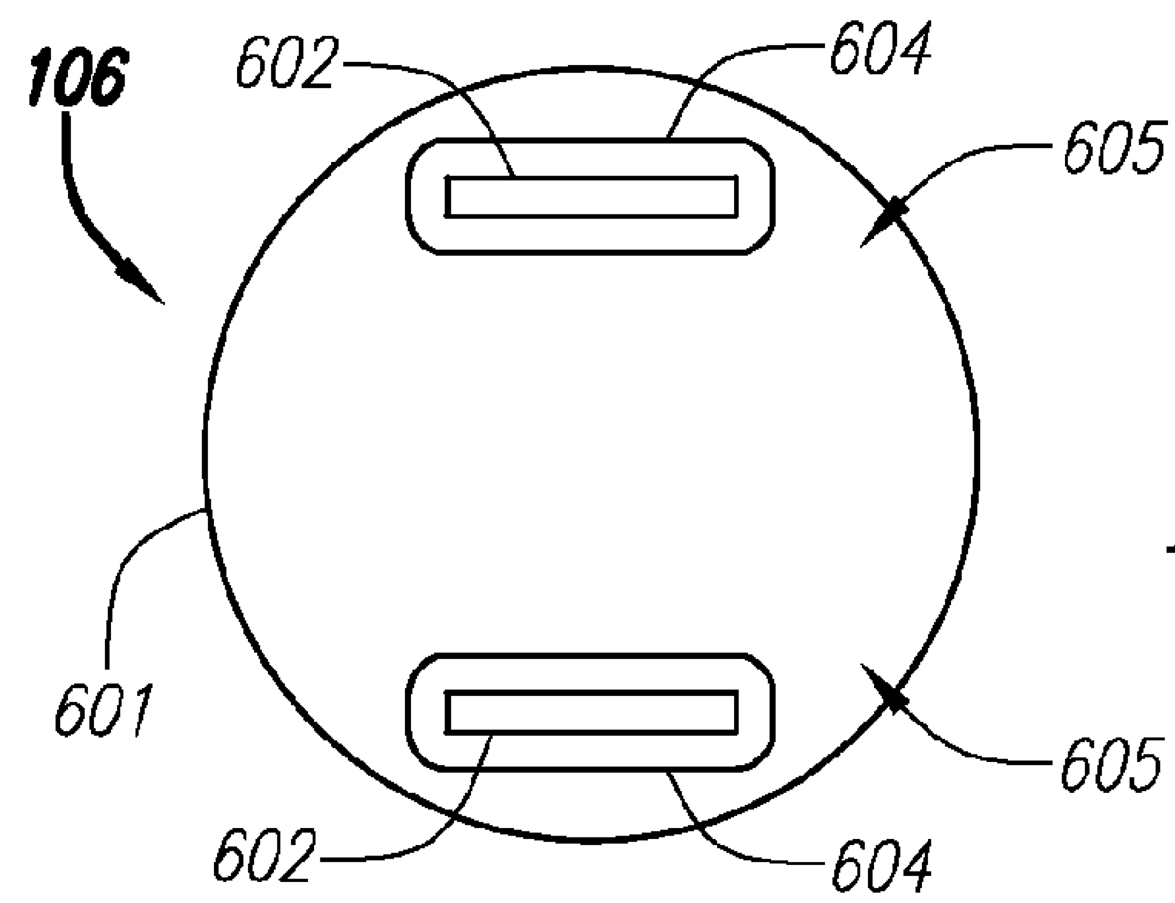

FIG. 28B

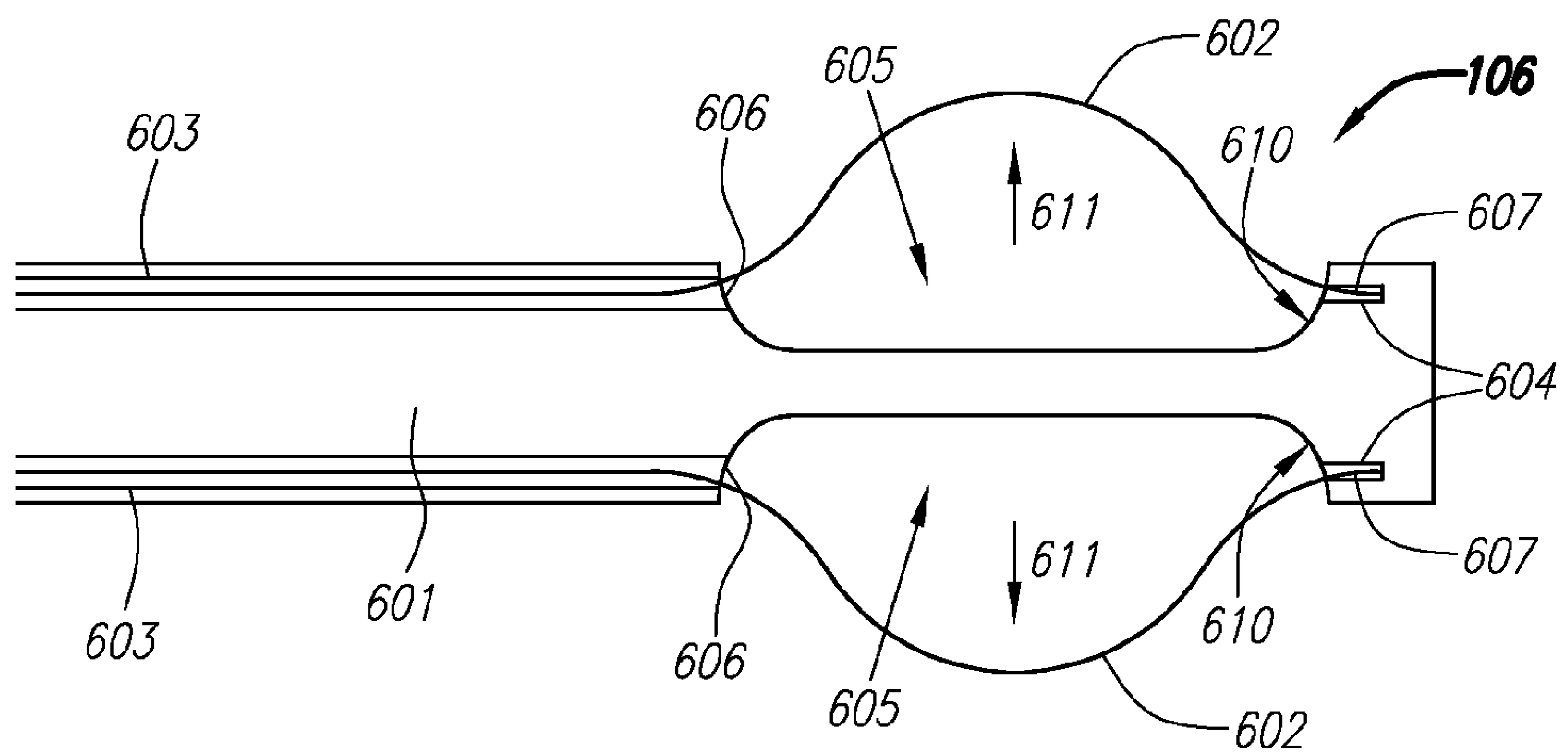

FIG. 28C

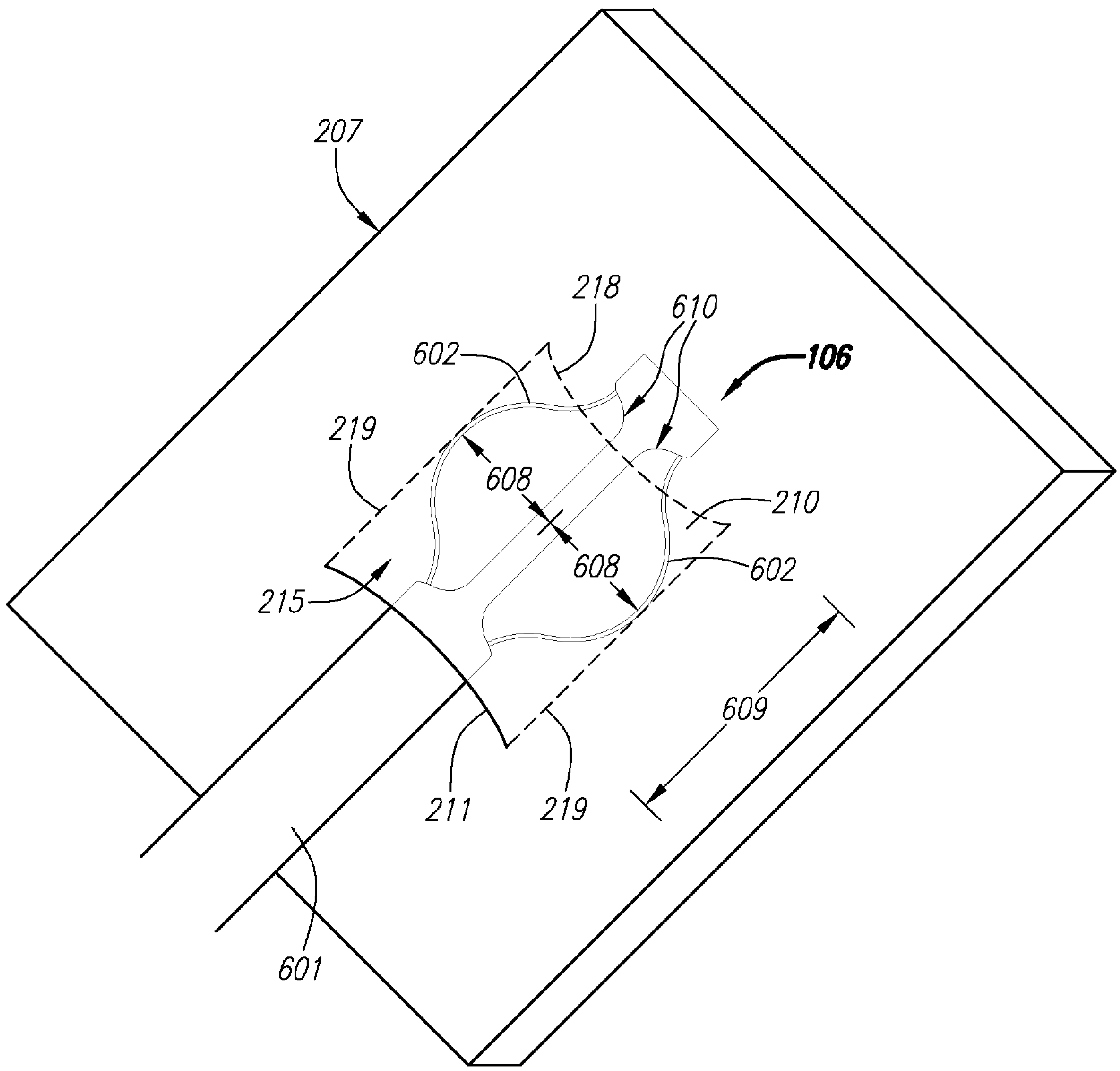

FIG. 28D

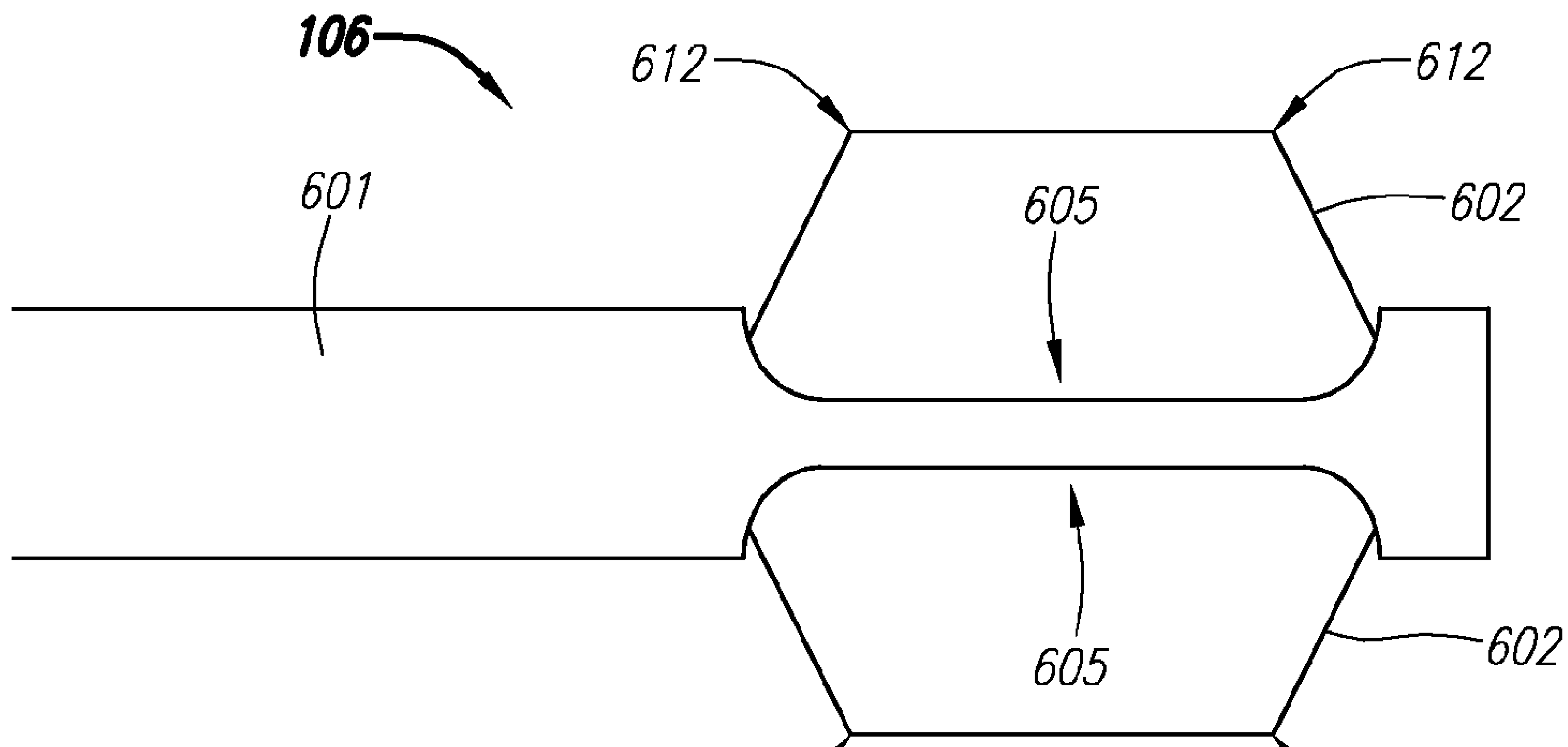

FIG. 29A

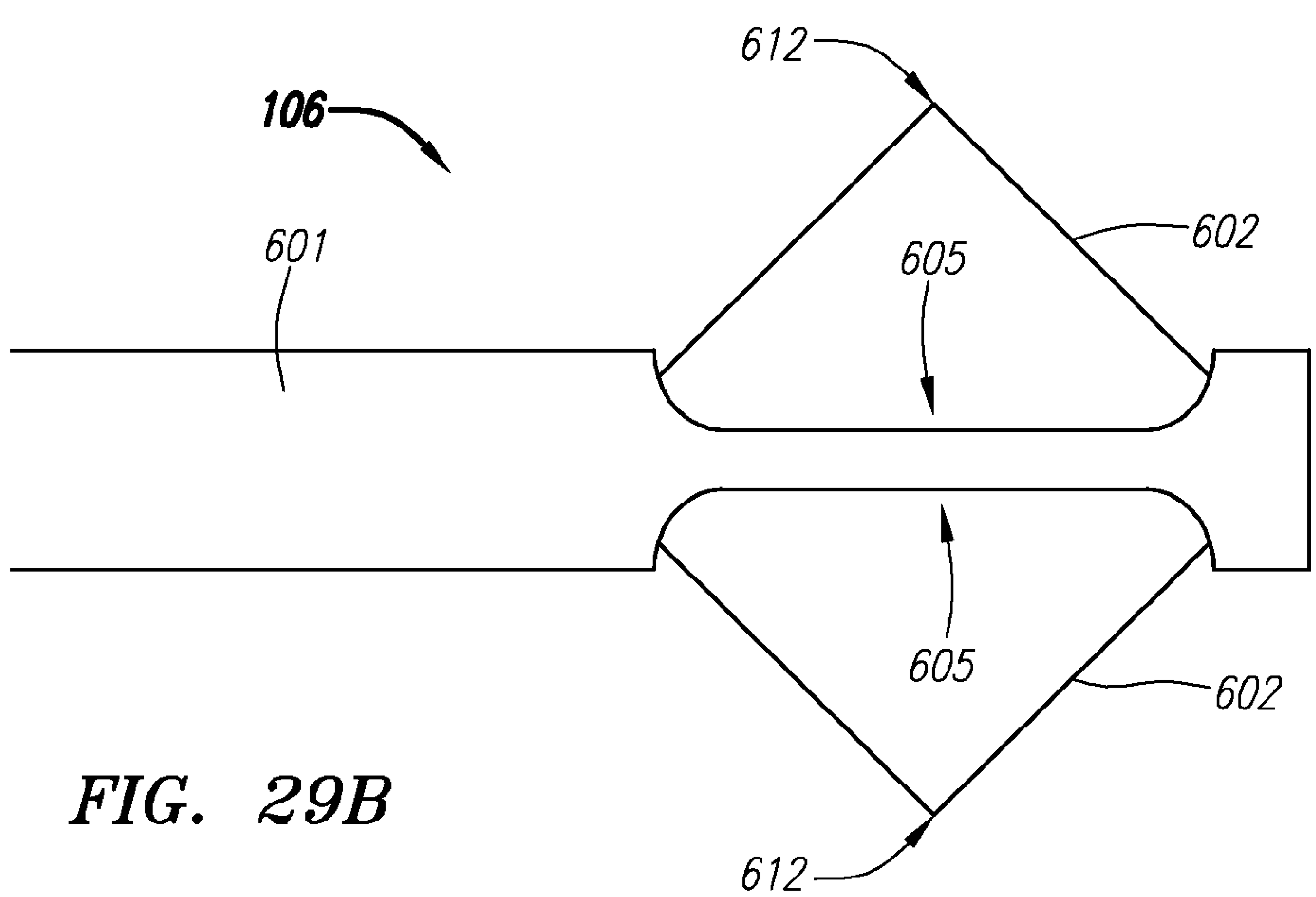

FIG. 29B

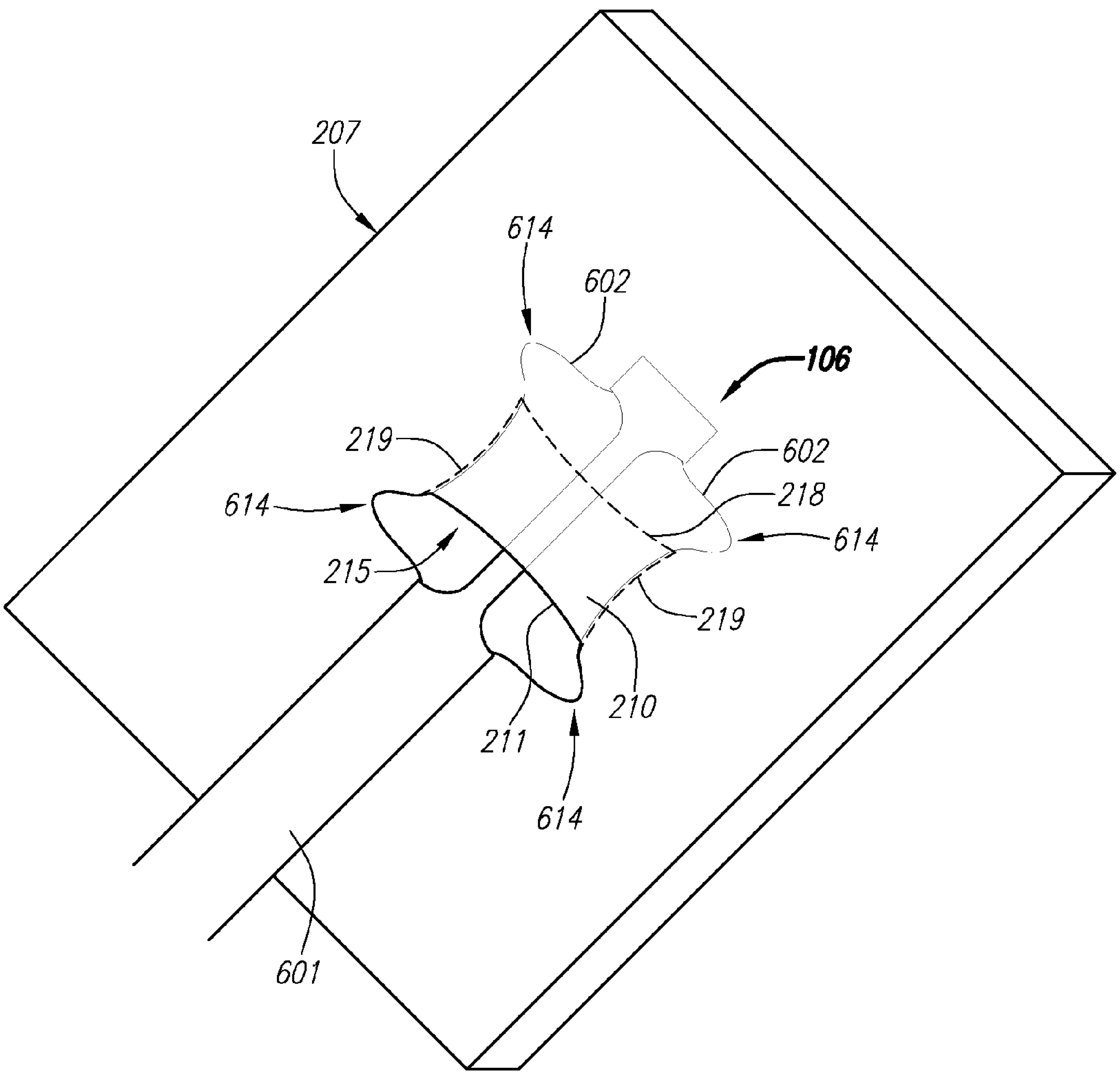

FIG. 29C

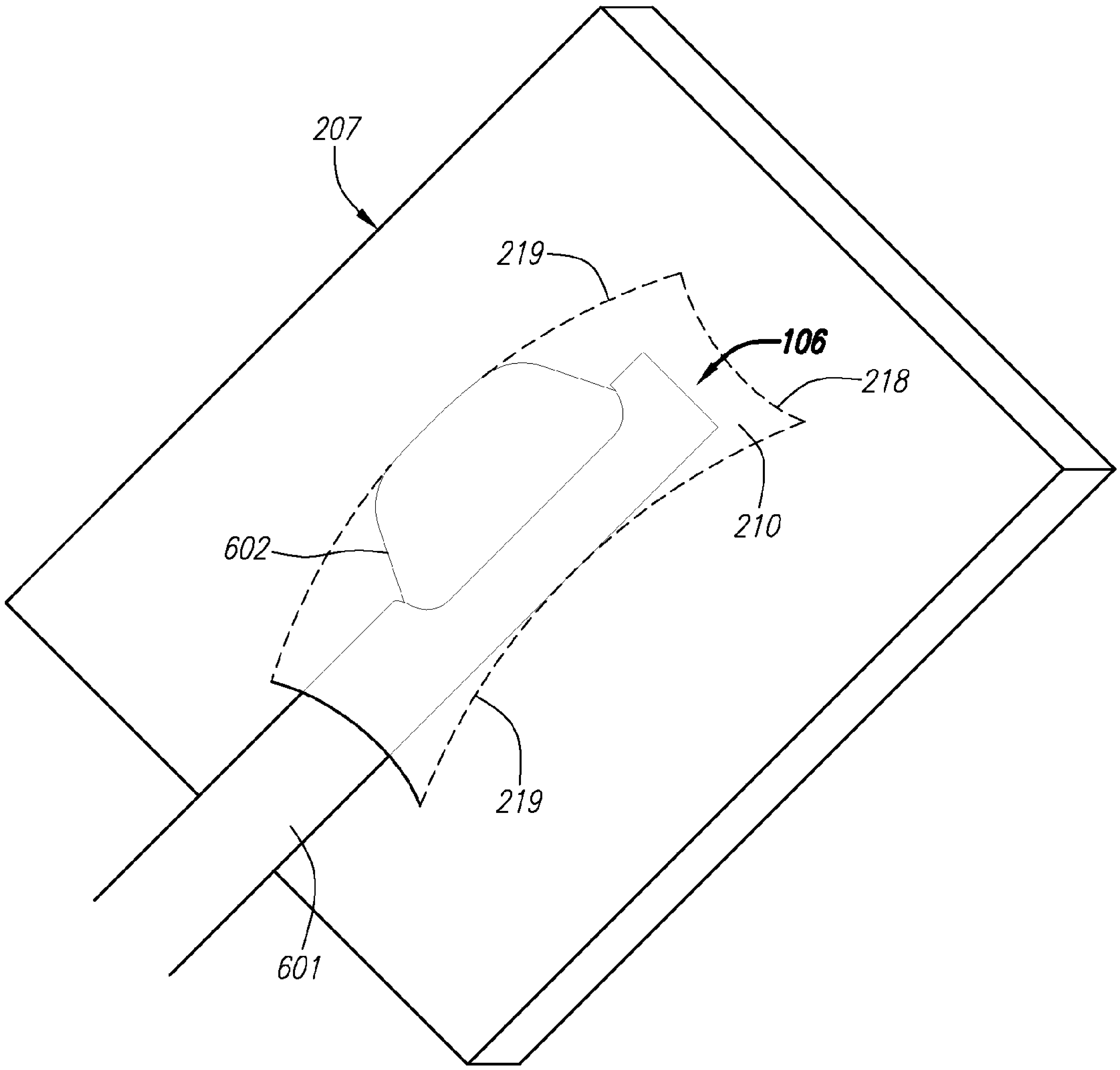

FIG. 30

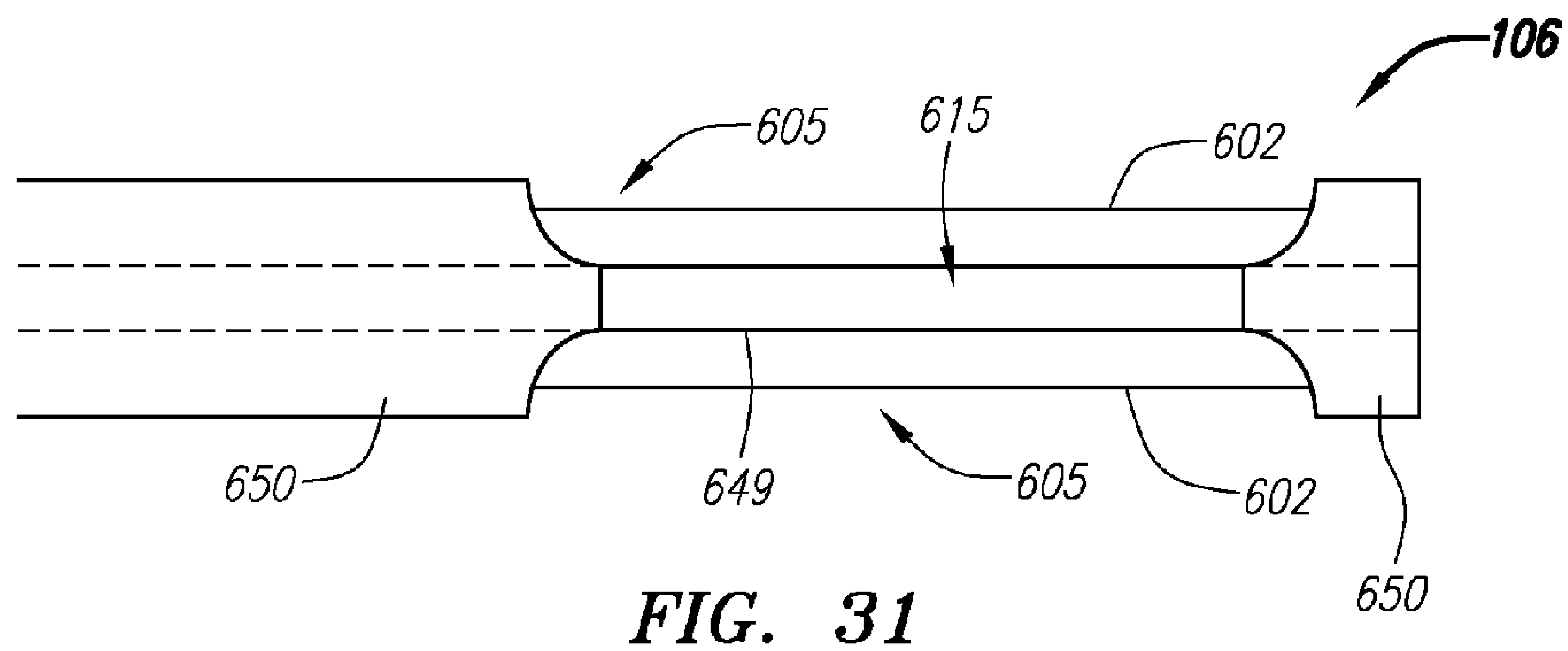

FIG. 31

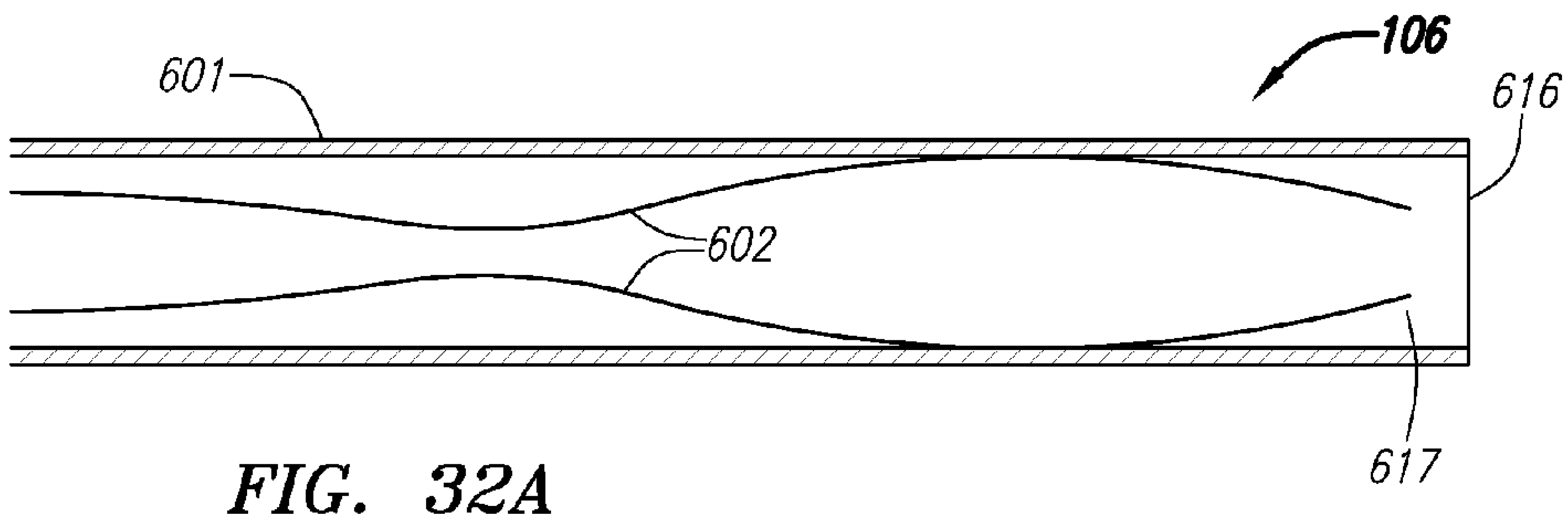

FIG. 32A

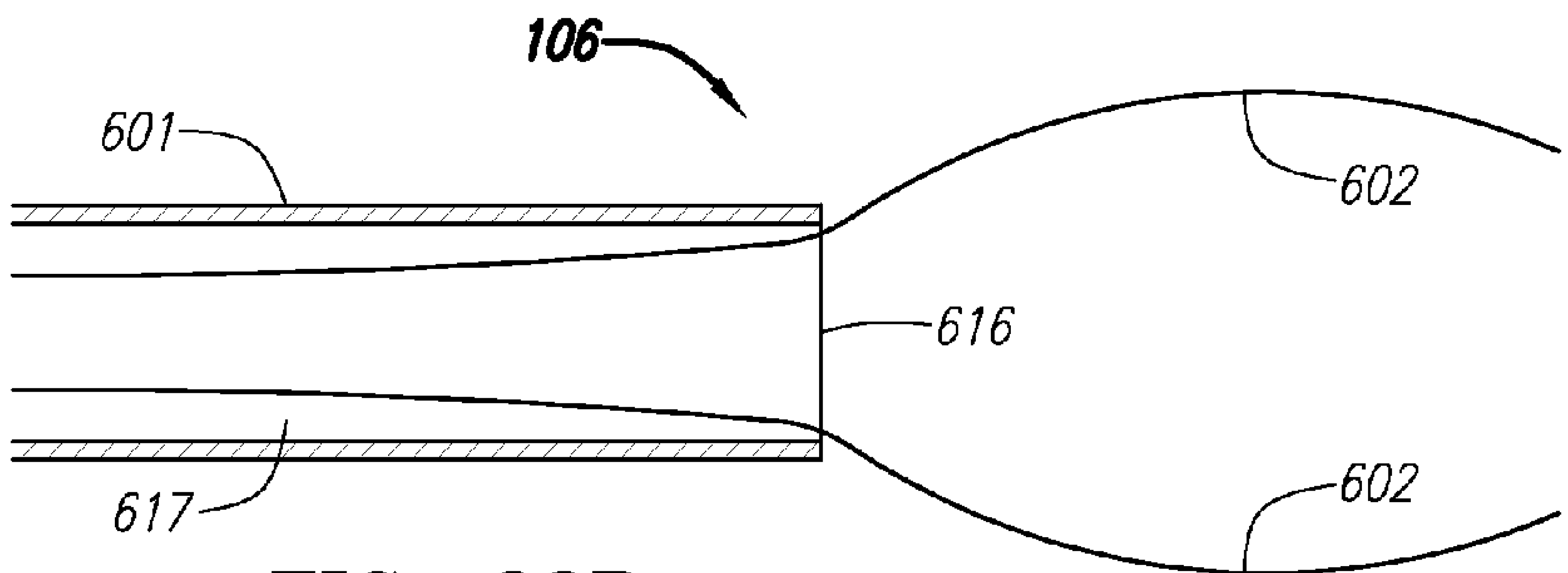

FIG. 32B

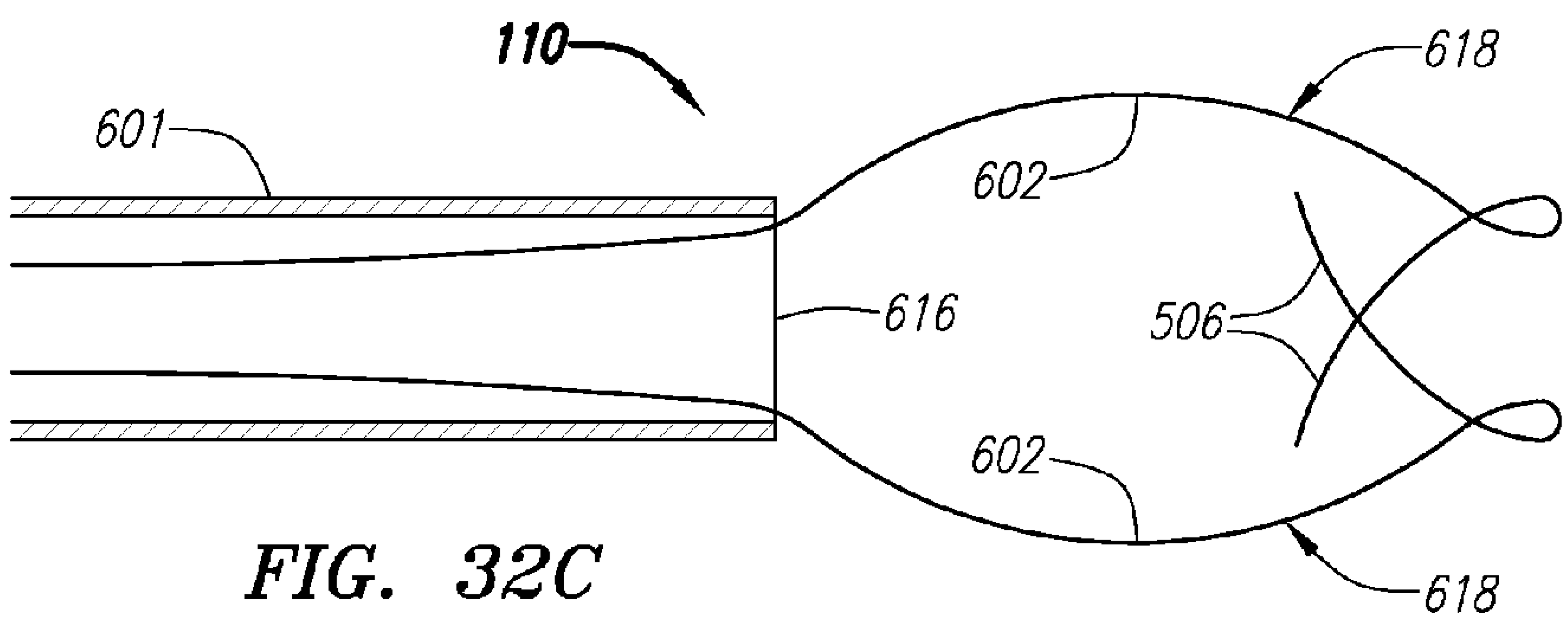

FIG. 32C

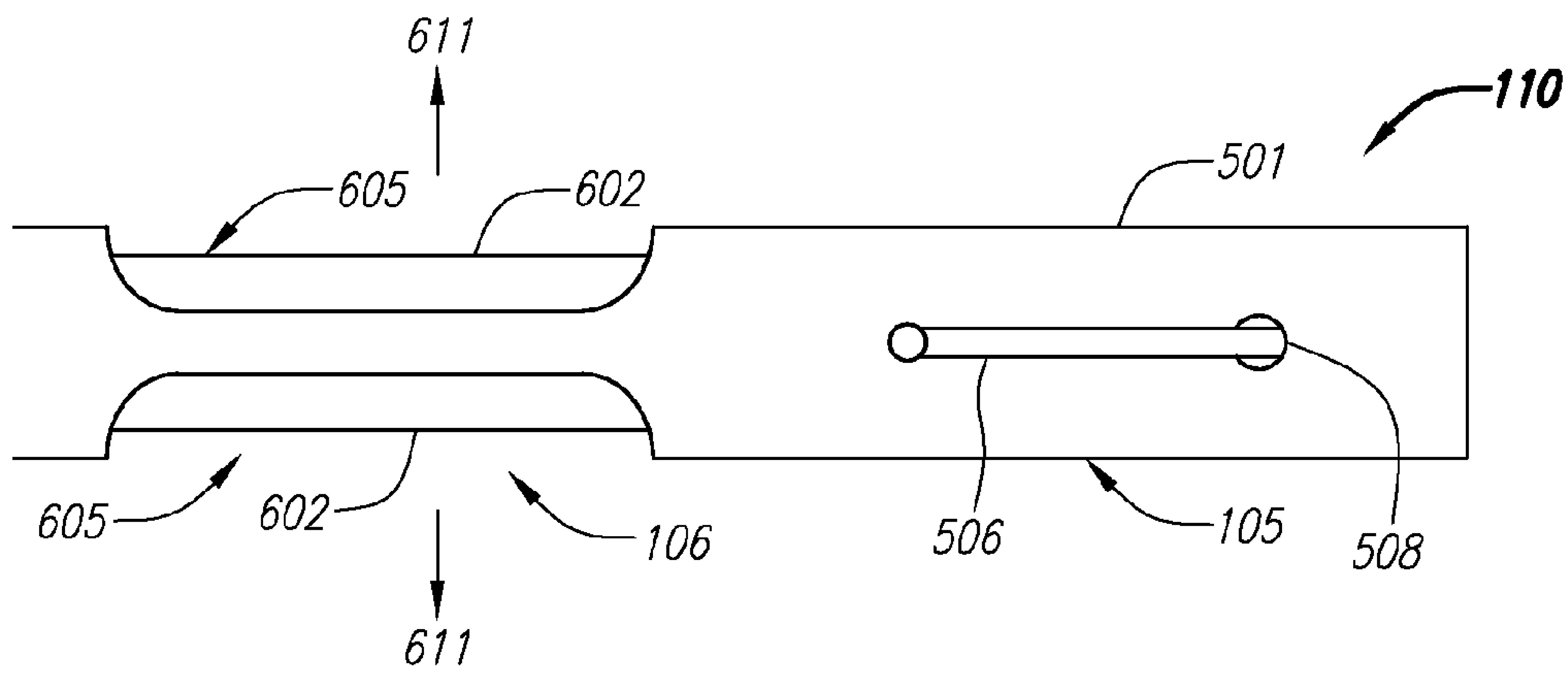

FIG. 32D

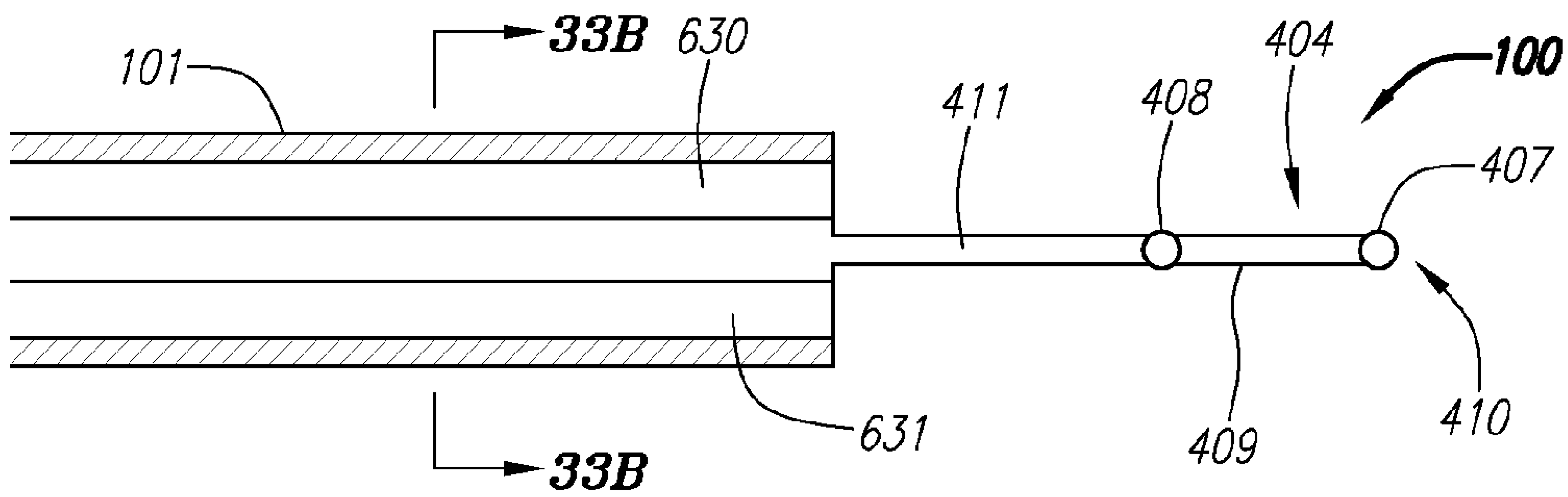

FIG. 33A

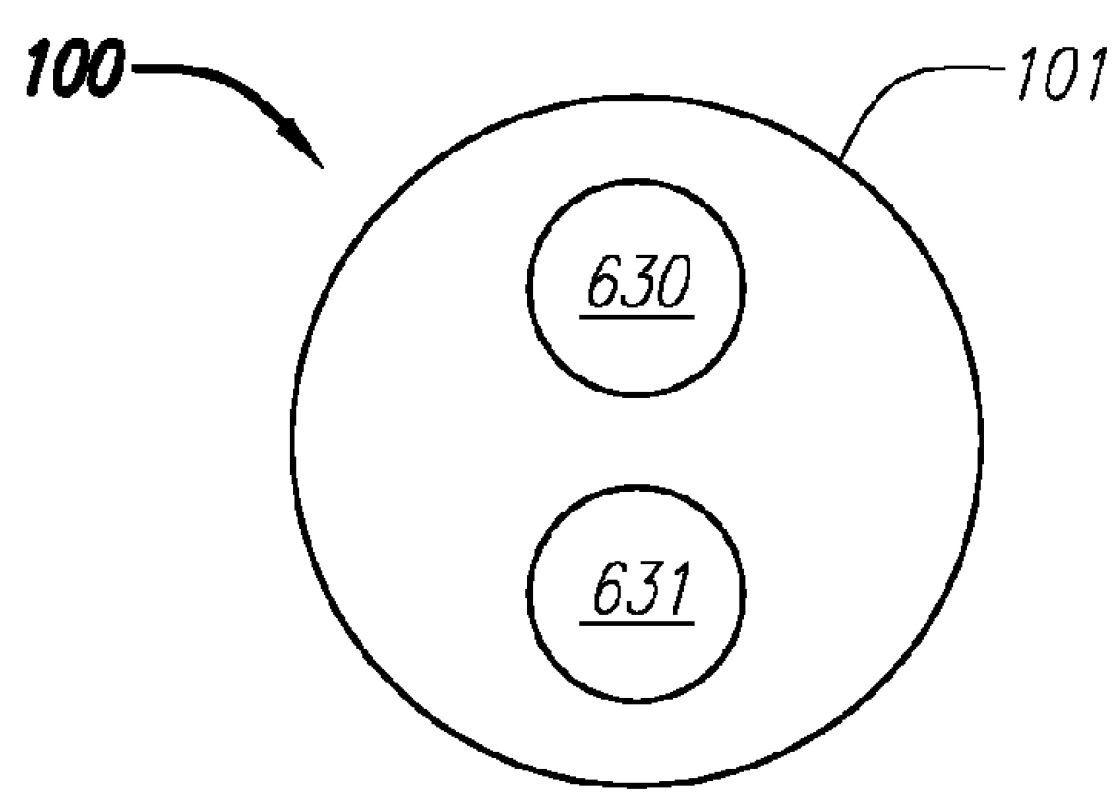

FIG. 33B

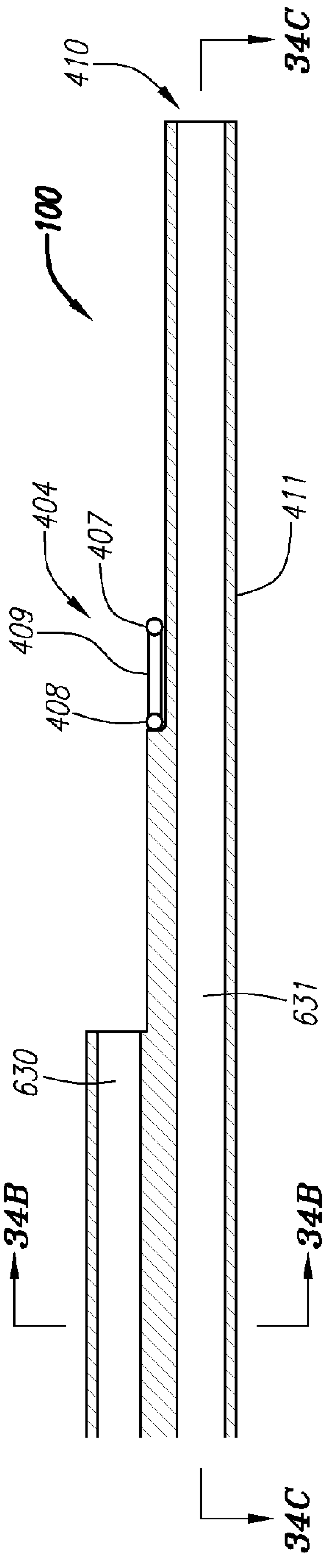

FIG. 34A

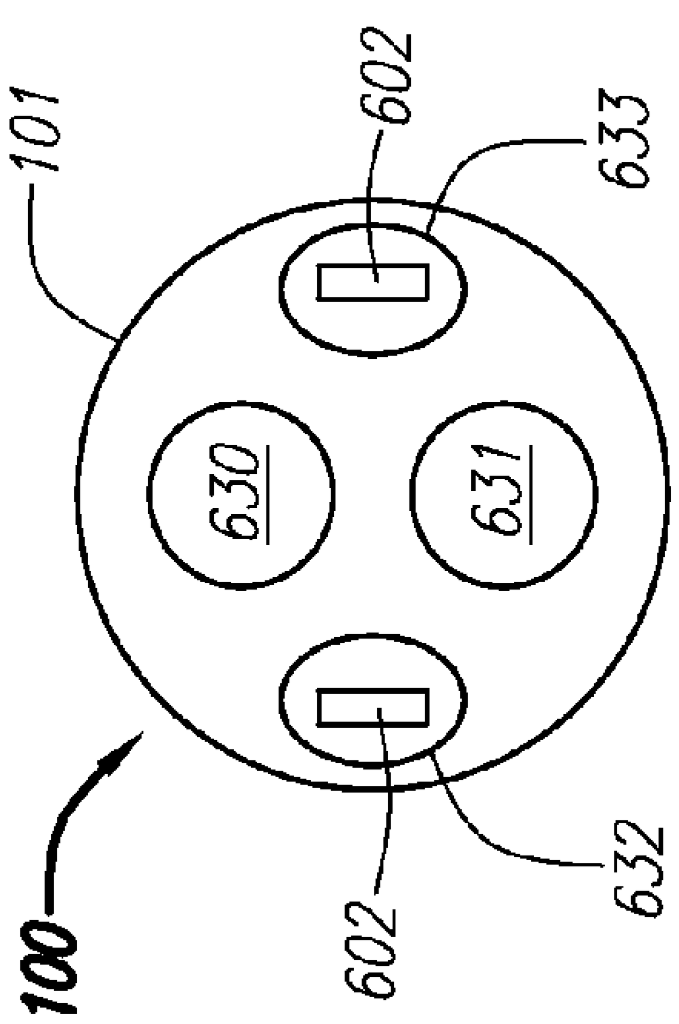

FIG. 34B

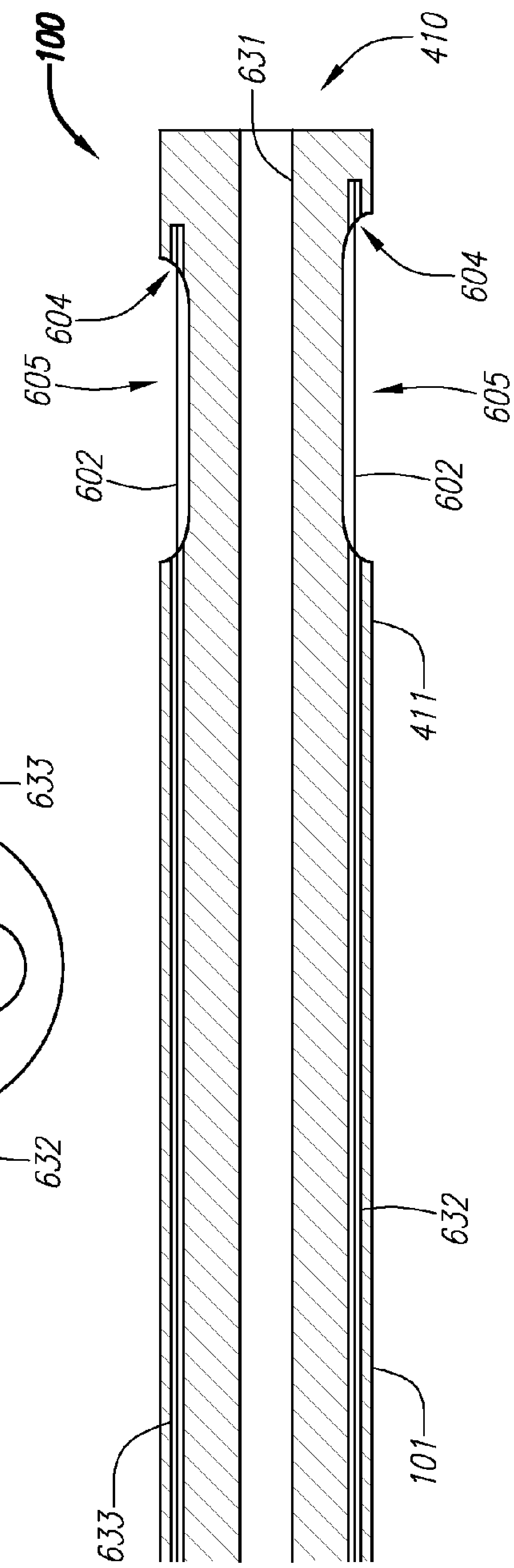

FIG. 34C

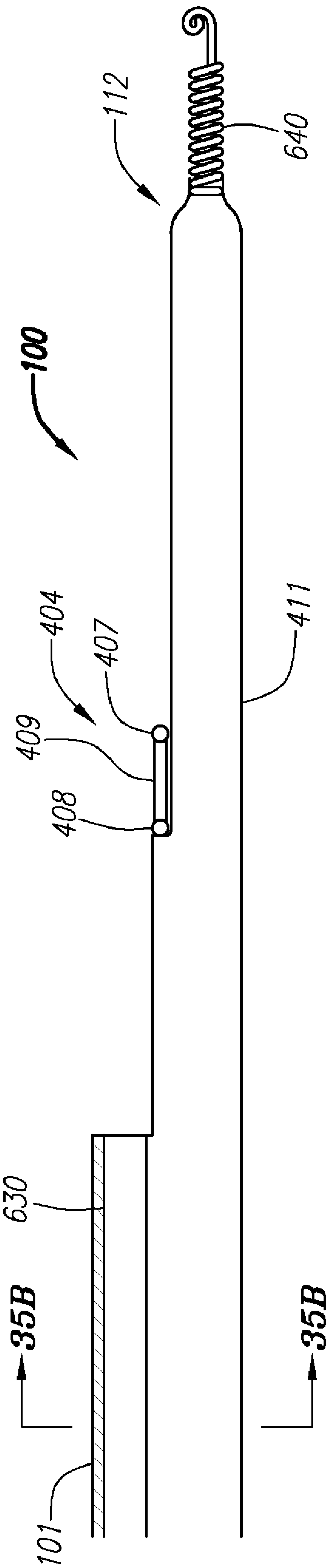

FIG. 35A

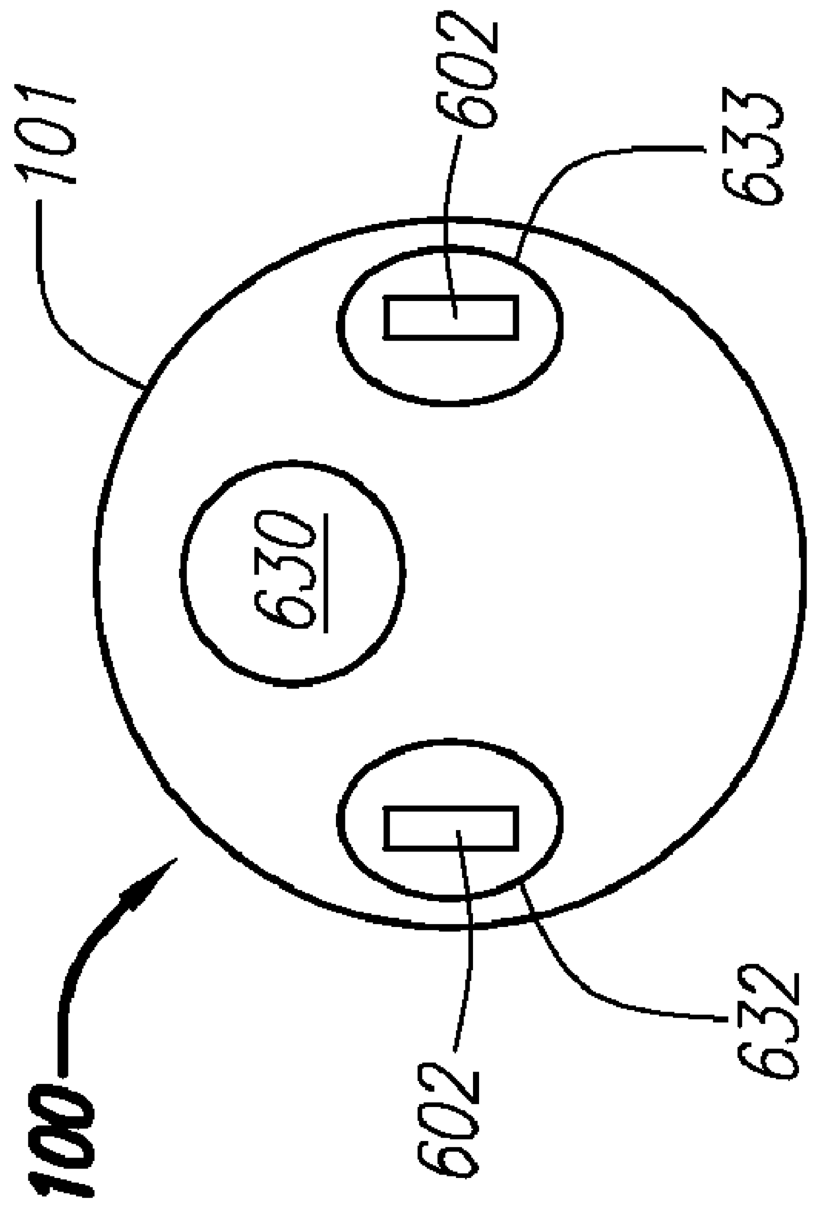

FIG. 35B

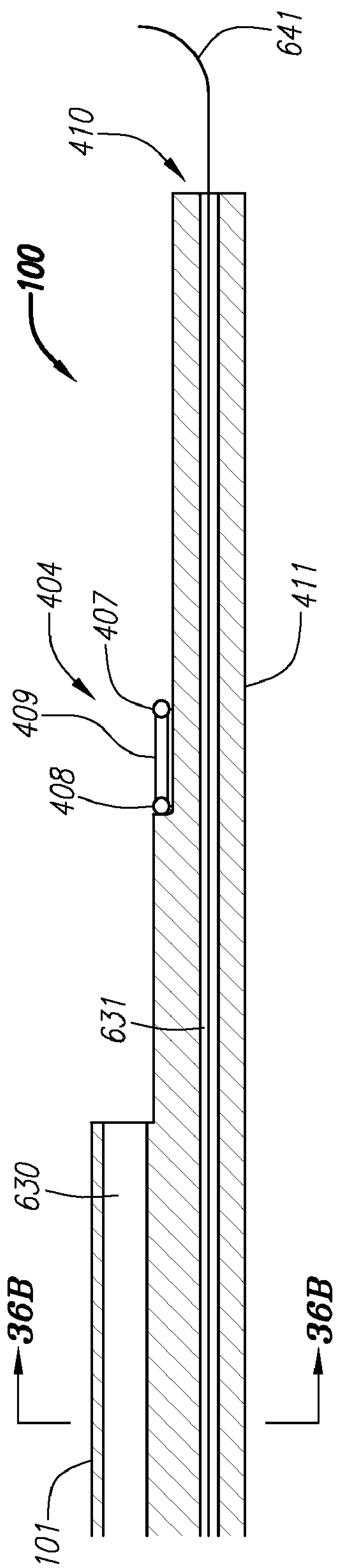

FIG. 36A

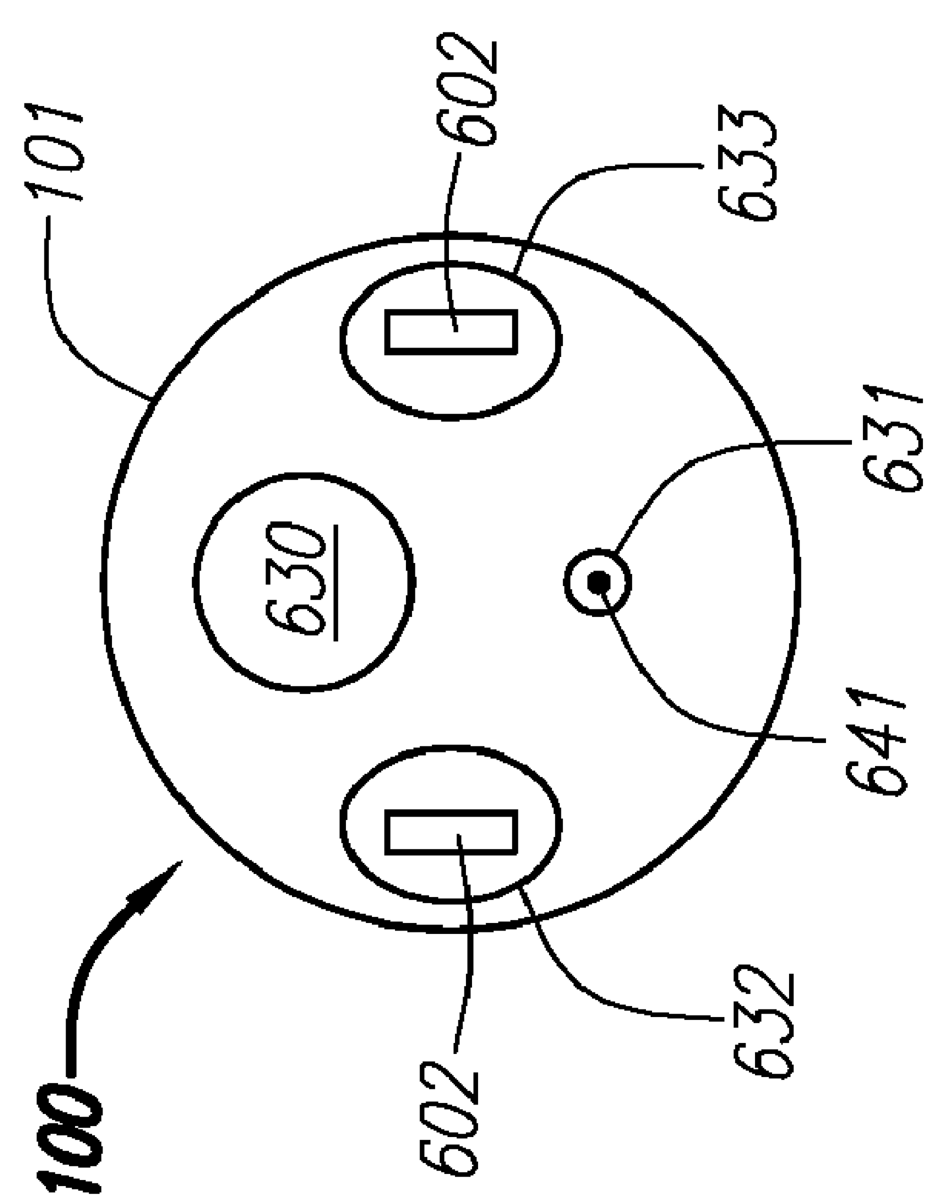

FIG. 36B

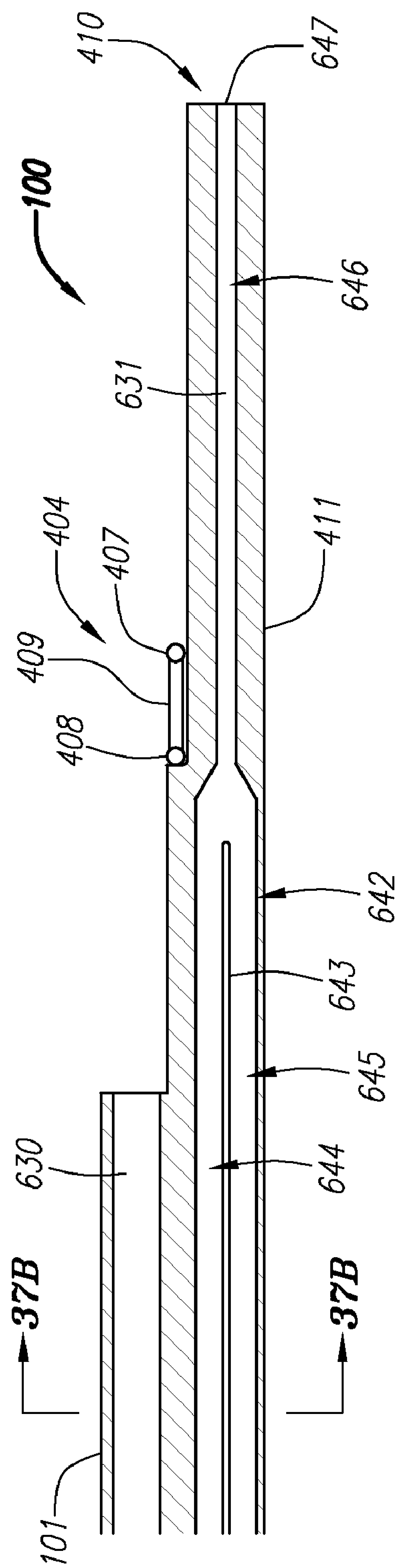

FIG. 37A

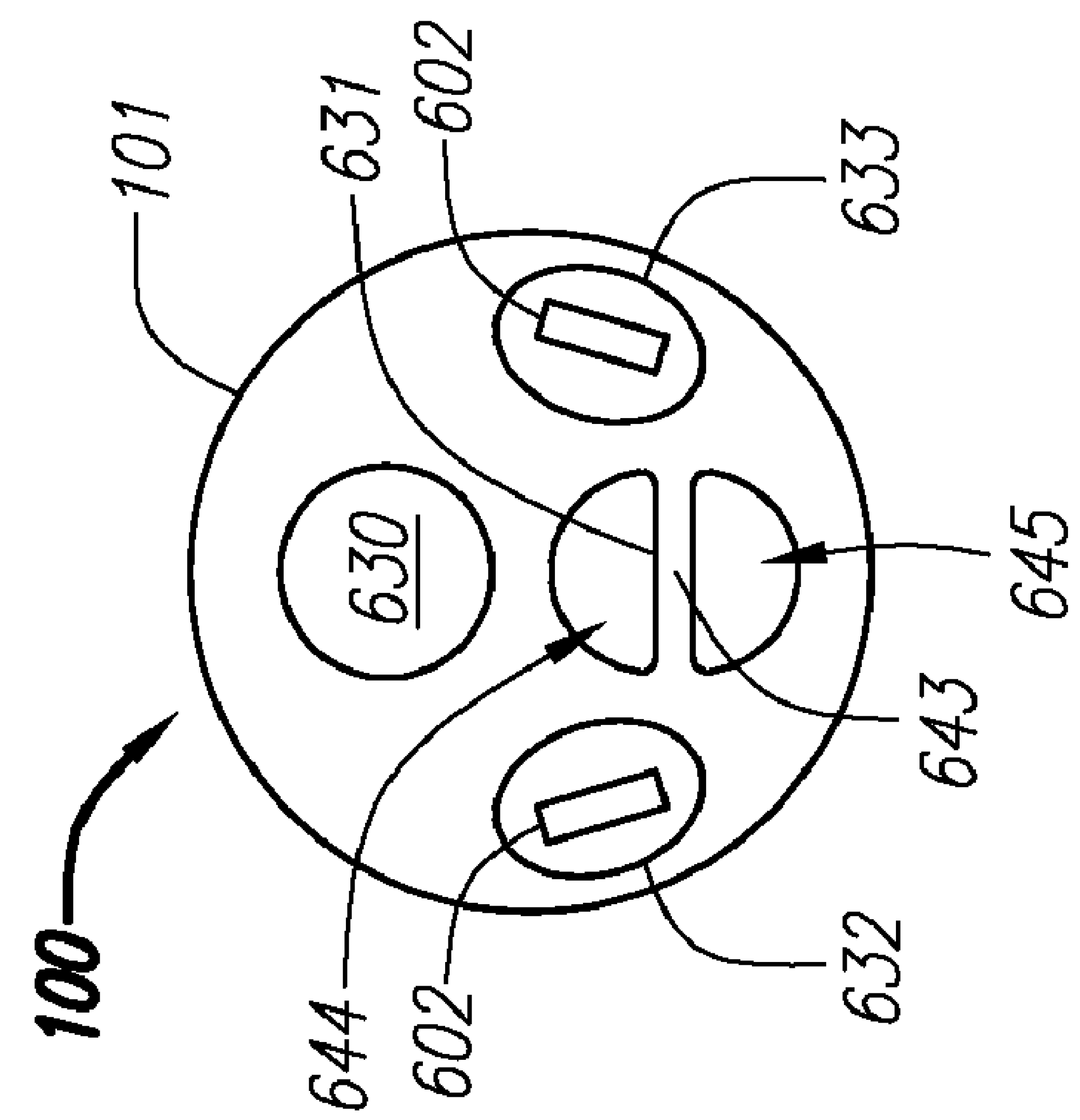

FIG. 37B

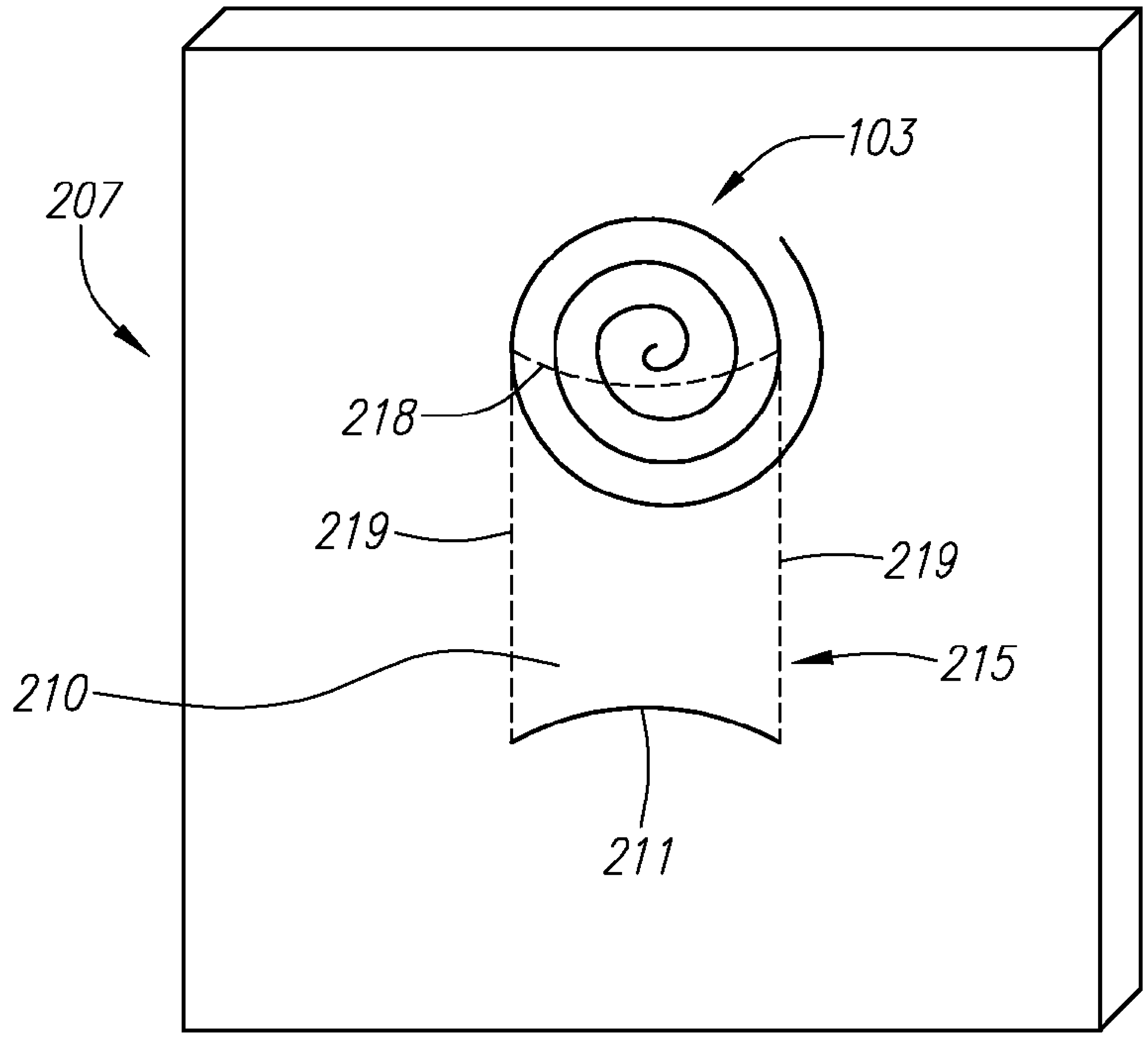

FIG. 38A

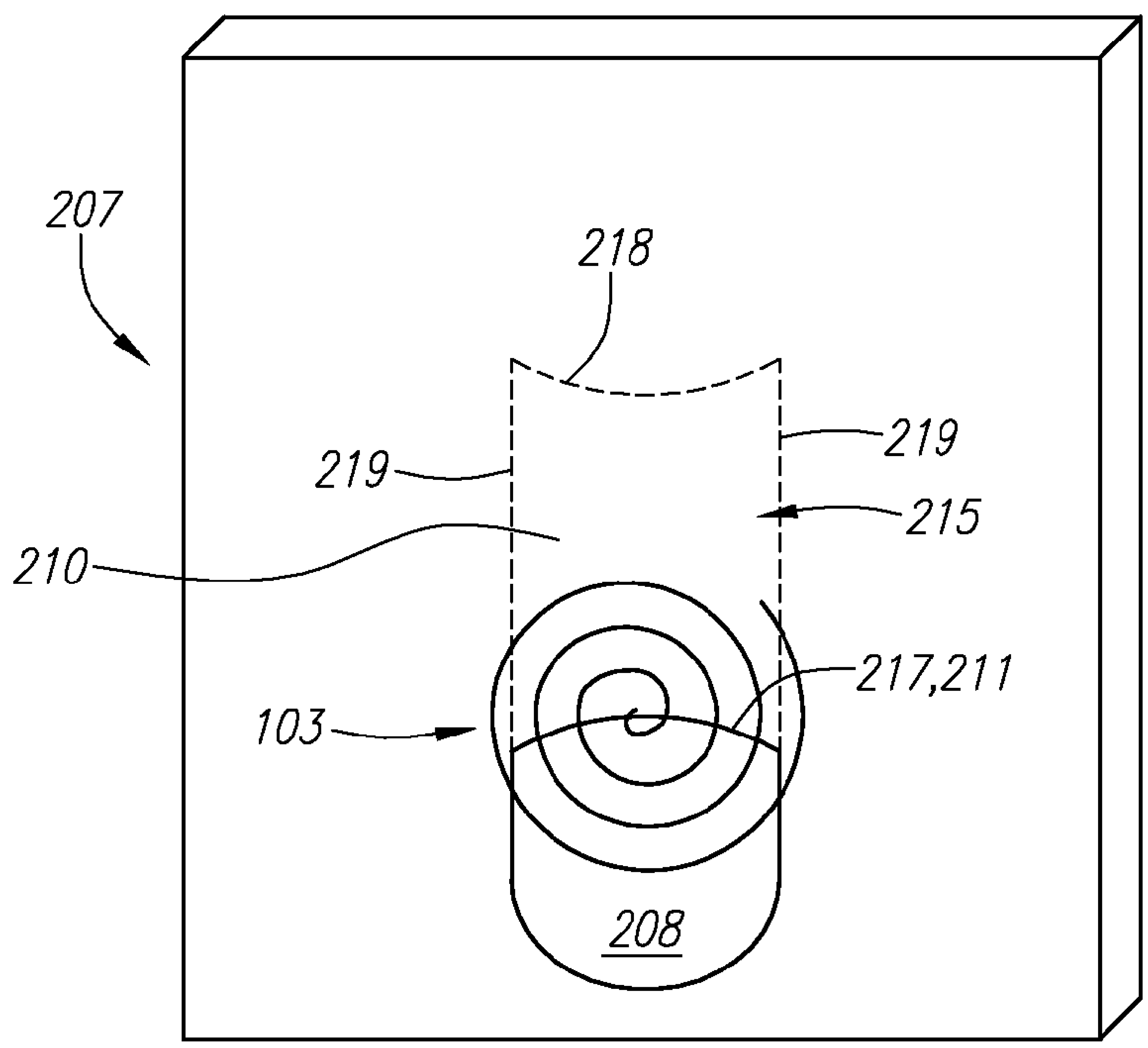

FIG. 38B

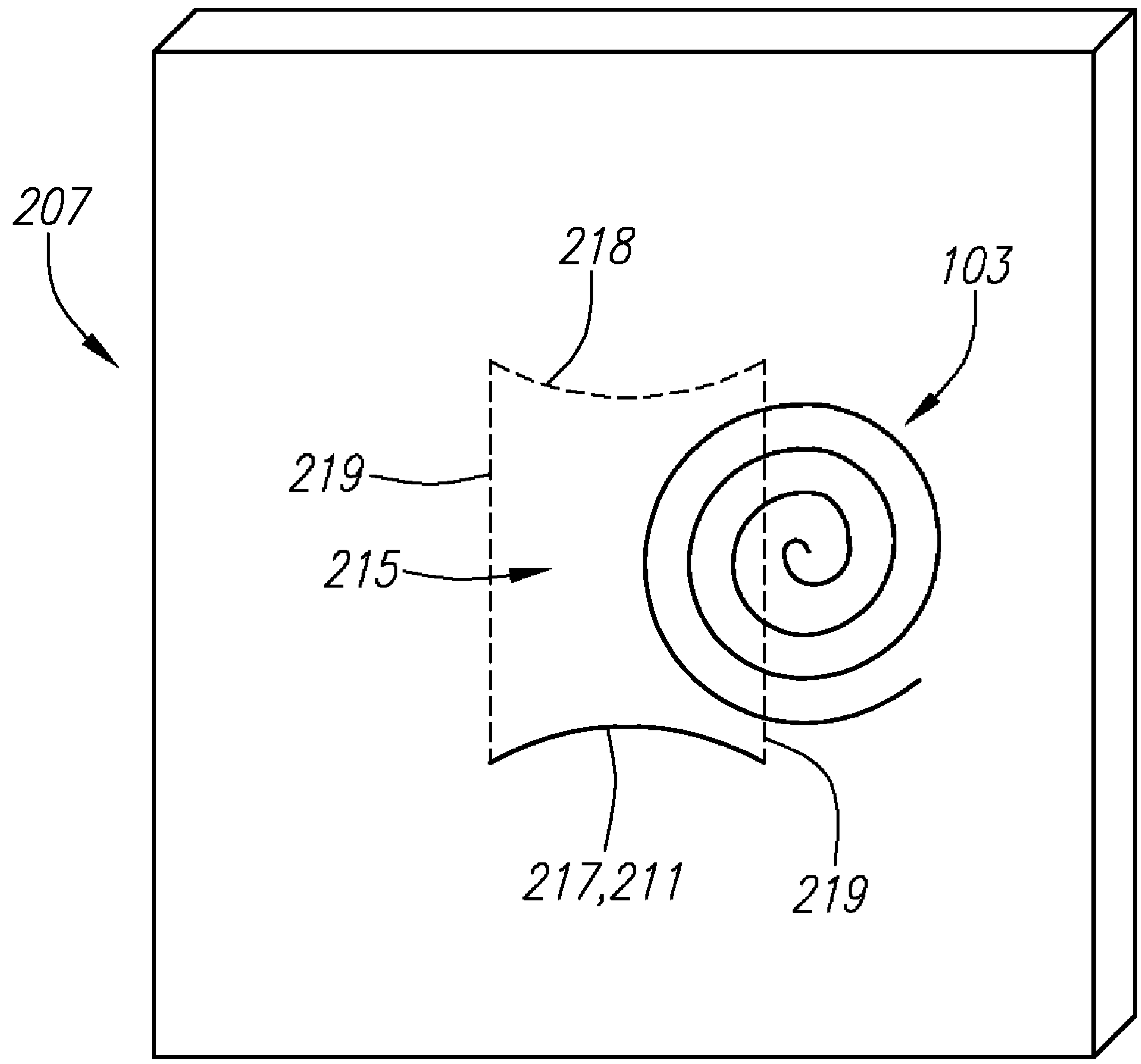

FIG. 38C

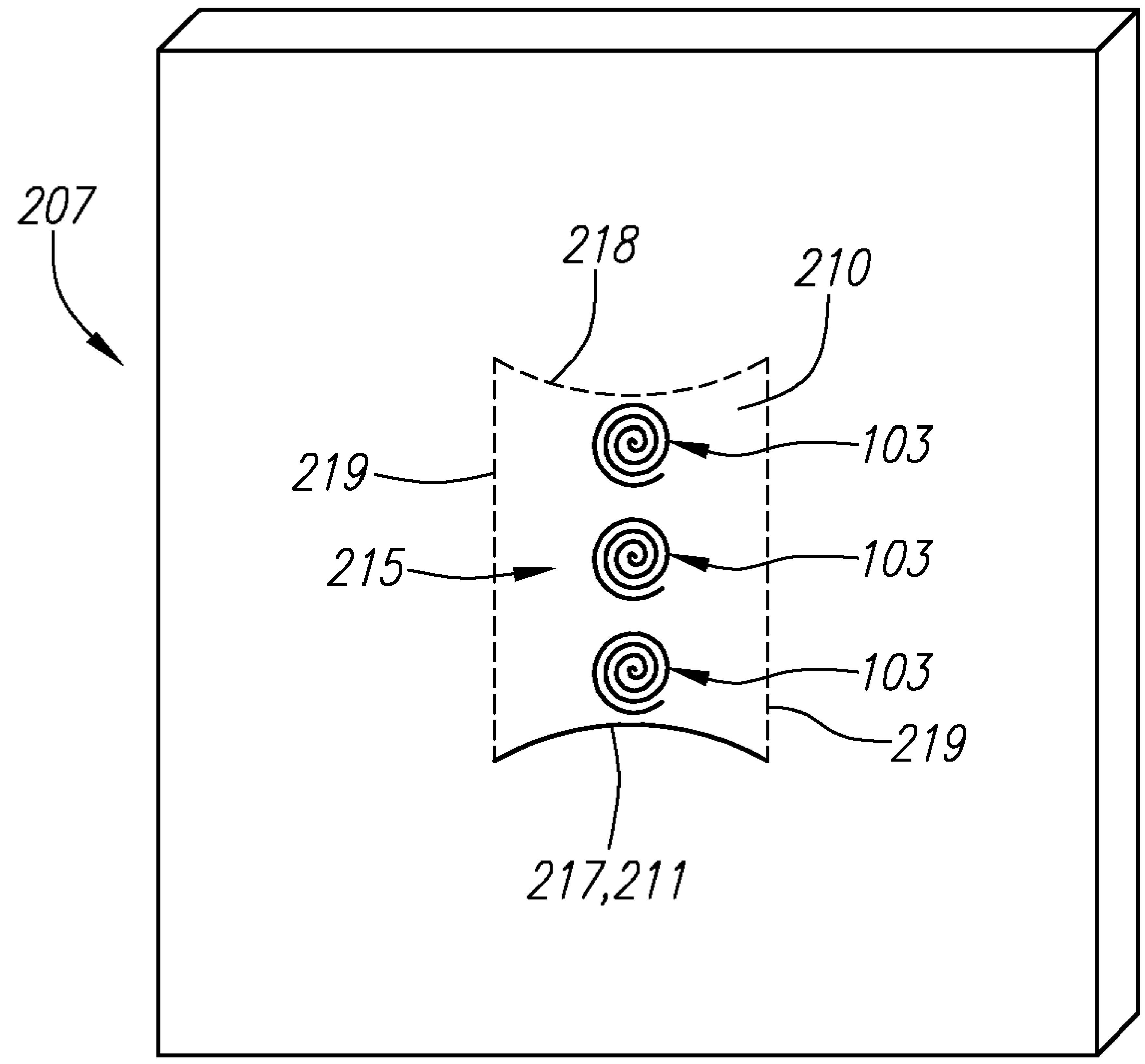

FIG. 38D

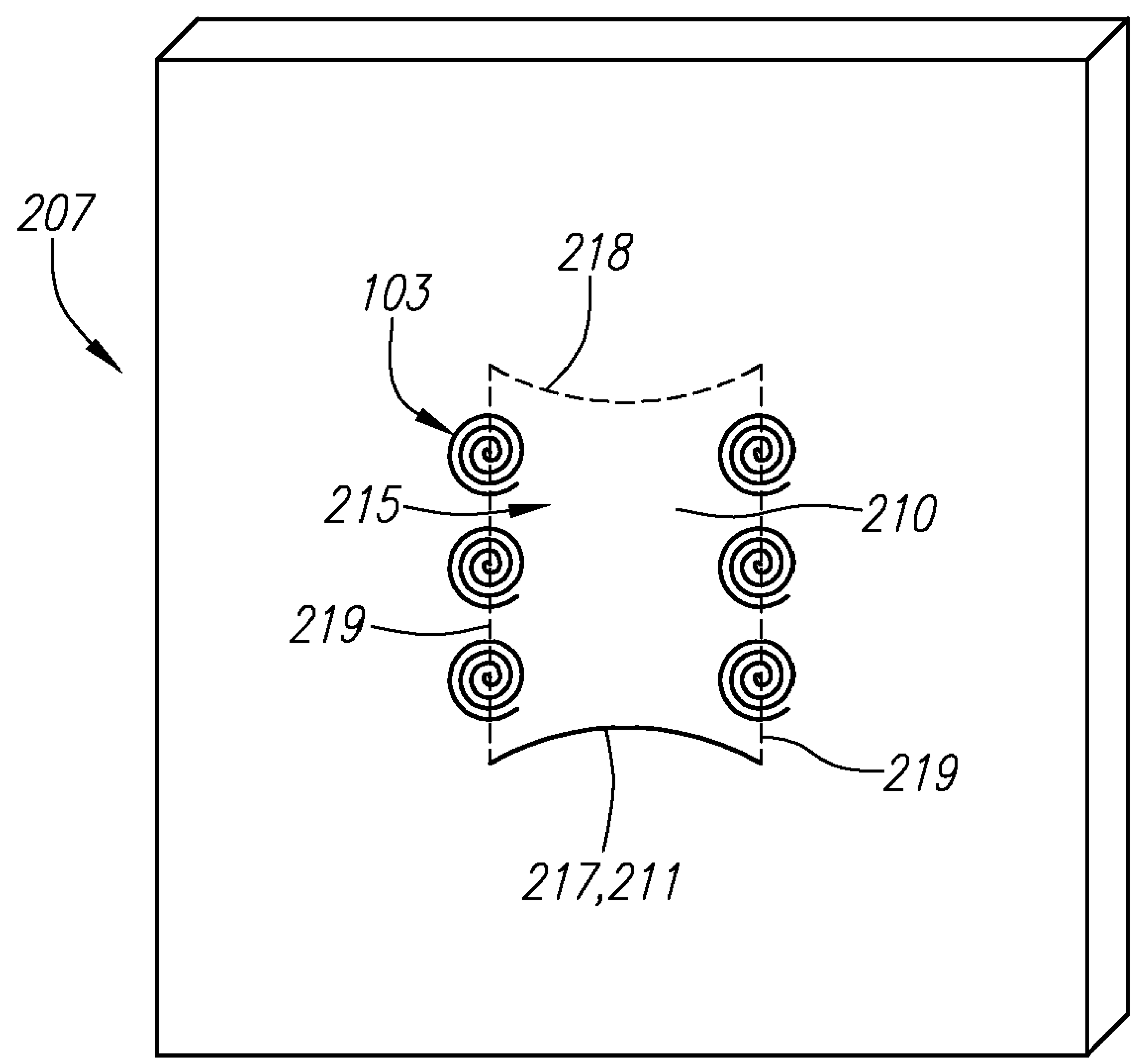

FIG. 38E

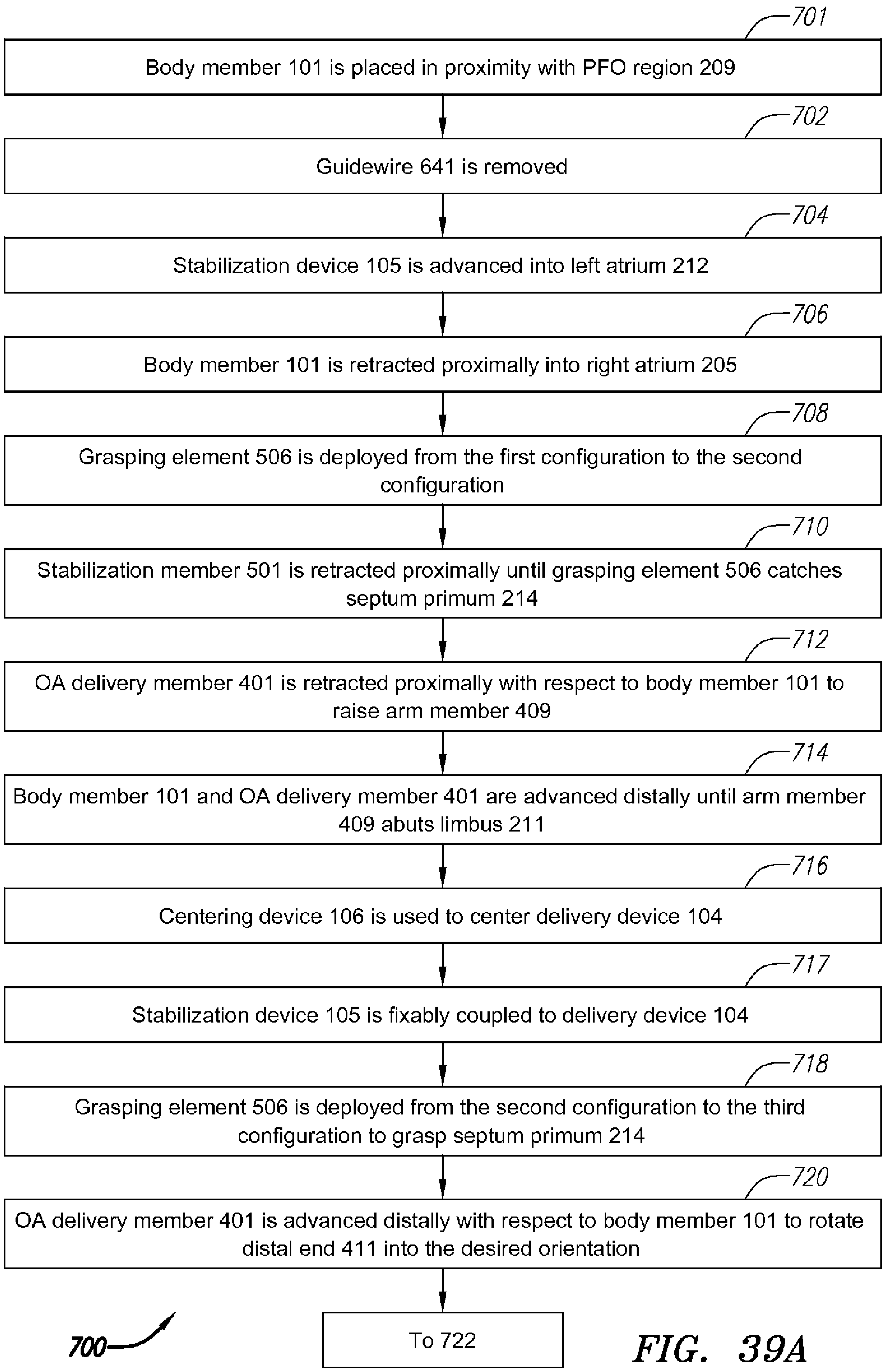
701
Body member 101 is placed in proximity with PFO region 209
702
Guidewire 641 is removed
704
Stabilization device 105 is advanced into left atrium 212
706
Body member 101 is retracted proximally into right atrium 205
708
Grasping element 506 is deployed from the first configuration to the second configuration
710
Stabilization member 501 is retracted proximally until grasping element 506 catches septum primum 214
712
OA delivery member 401 is retracted proximally with respect to body member 101 to raise arm member 409
714
Body member 101 and OA delivery member 401 are advanced distally until arm member 409 abuts limbus 211
716
Centering device 106 is used to center delivery device 104
717
Stabilization device 105 is fixably coupled to delivery device 104
718
Grasping element 506 is deployed from the second configuration to the third configuration to grasp septum primum 214
720
OA delivery member 401 is advanced distally with respect to body member 101 to rotate distal end 411 into the desired orientation
700
To 722

FIG. 39A

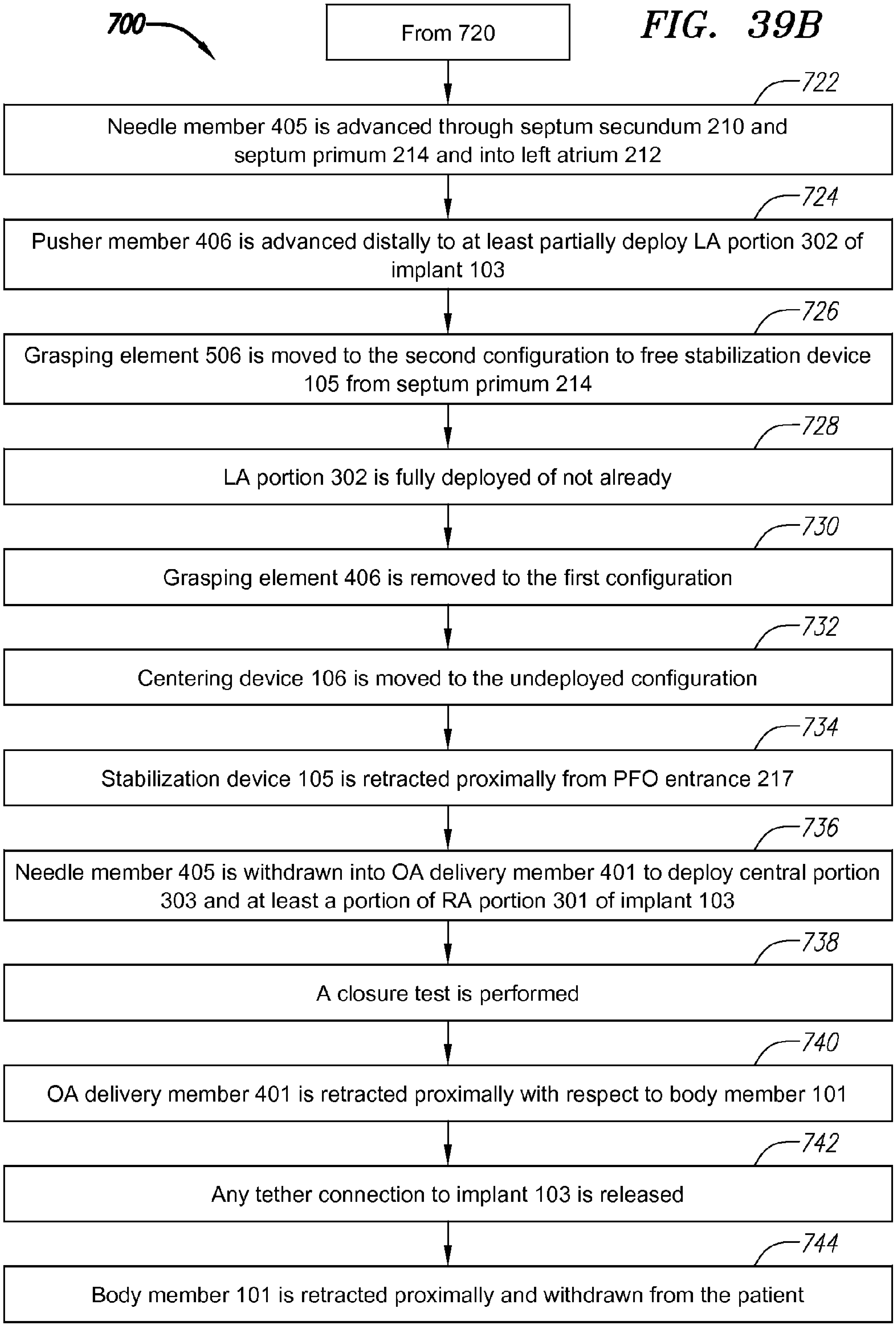
700
From 720
722
Needle member 405 is advanced through septum secundum 210 and septum primum 214 and into left atrium 212
724
Pusher member 406 is advanced distally to at least partially deploy LA portion 302 of implant 103
726
Grasping element 506 is moved to the second configuration to free stabilization device 105 from septum primum 214
728
LA portion 302 is fully deployed of not already
730
Grasping element 406 is removed to the first configuration
732
Centering device 106 is moved to the undeployed configuration
734
Stabilization device 105 is retracted proximally from PFO entrance 217
736
Needle member 405 is withdrawn into OA delivery member 401 to deploy central portion 303 and at least a portion of RA portion 301 of implant 103
738
A closure test is performed
740
OA delivery member 401 is retracted proximally with respect to body member 101
742
Any tether connection to implant 103 is released
744
Body member 101 is retracted proximally and withdrawn from the patient

FIG. 39B

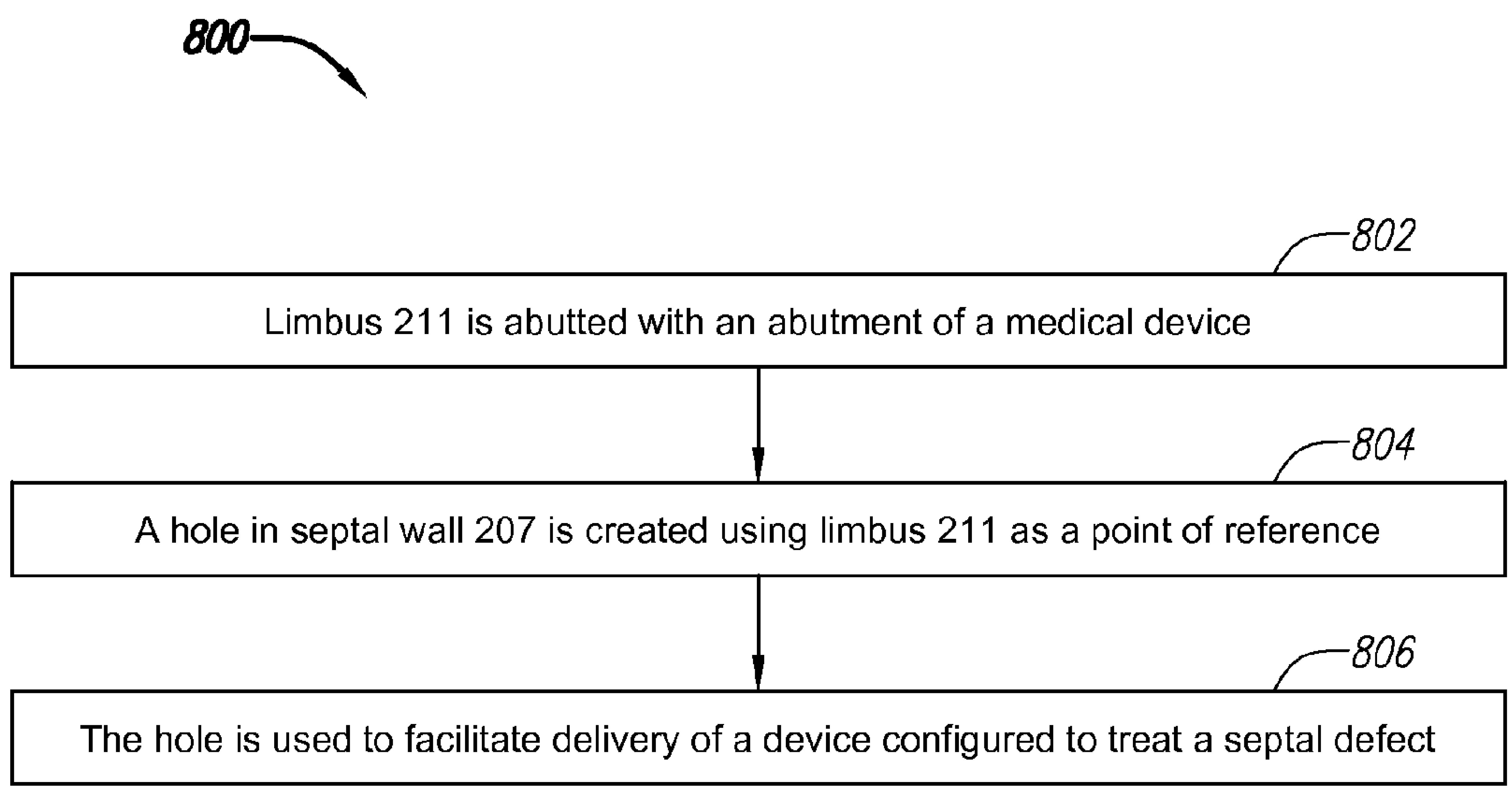
800
802
Limbus 211 is abutted with an abutment of a medical device
804
A hole in septal wall 207 is created using limbus 211 as a point of reference
806
The hole is used to facilitate delivery of a device configured to treat a septal defect

FIG. 40

SYSTEMS AND METHODS FOR TREATING SEPTAL DEFECTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 11/422,871, filed Jun. 7, 2006, now U.S. Pat. No. 7,686,828, which is a divisional of U.S. patent application Ser. No. 11/175,814, filed Jul. 5, 2005, which is a continuation-in-part of U.S. patent application Ser. No. 10/847,747, filed on May 7, 2004, which is a continuation-in-part of U.S. patent application Ser. No. 10/734,670, filed Dec. 11, 2003, which is a division of Ser. No. 09/948,453, filed Sep. 7, 2001, now U.S. Pat. No. 6,702,835 and which is a continuation-in-part of Ser. No. 09/948,502, filed Sep. 6, 2001, now U.S. Pat. No. 6,776,784, each of which are fully incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to systems and methods for closing internal tissue defects, and more particularly to systems and methods for closing a patent foramen ovale or other septal defect.

BACKGROUND OF THE INVENTION

[0003] By nature of their location, the treatment of internal tissue defects is inherently difficult. Access to a defect through invasive surgery introduces a high level of risk that can result in serious complications for the patient. Access to the defect remotely with a catheter or equivalent device is less risky, but treatment of the defect itself is made more difficult given the limited physical abilities of the catheter. The difficulty in accessing and treating tissue defects is compounded when the defect is found in or near a vital organ. For instance, a patent foramen ovale ("PFO") is a serious septal defect that can occur between the left and right atria of the heart and a patent ductus arteriosus ("PDA") is an abnormal shunt between the aorta and pulmonary artery.

[0004] During development of a fetus in utero, oxygen is transferred from maternal blood to fetal blood through complex interactions between the developing fetal vasculature and the mother's placenta. During this process, blood is oxygenated within the fetal lungs. In fact, most of the fetus' circulation is shunted away from the lungs through specialized vessels and foramens that are open during fetal life, but typically will close shortly after birth. Occasionally, however, these foramen fail to close and create hemodynamic problems, which, in extreme cases, can ultimately prove fatal. During fetal life, an opening called the foramen ovale allows blood to pass directly from the right atrium to the left atrium (bypassing the lungs). Thus, blood that is oxygenated via gas exchange with the placenta may travel through the vena cava into the right atrium, through the foramen ovale into the left atrium, and from there into the left ventricle for delivery to the fetal systemic circulation. After birth, with pulmonary circulation established, the increased left atrial blood flow and pressure causes the functional closure of the foramen ovale and, as the heart continues to develop, this closure allows the foramen ovale to grow completely sealed.

[0005] In some cases, however, the foramen ovale fails to close entirely. This condition, known as a PFO, can allow blood to continue to shunt between the left and right atria of the heart throughout the adult life of the individual. A PFO can pose serious health risks for the individual, including strokes and migraines. The presence of PFO's have been implicated as a possible contributing factor in the pathogenesis of migraine. Two current hypothesis that link PFO's with migraine include the transit of vasoactive substances or thrombus/emboli from the venous circulation directly into the left atrium without passing through the lungs where they would normally be deactivated or filtered respectively. Other diseases that have been associated with PFO's (and which could benefit from PFO closure) include but are not limited to depression and affective disorders, personality and anxiety disorders, pain, stroke, TIA, dementia, epilepsy, and sleep disorders.

[0006] Still other septal defects can occur between the various chambers of the heart, such as atrial-septal defects (ASD's), ventricular-septal defects (VSD's), and the like. To treat these defects as well as PFO's, open heart surgery can be performed to ligate and close the defect. Alternatively, catheter-based procedures have been developed that require introducing umbrella or disc-like devices into the heart. These devices include opposing expandable structures connected by a hub or waist. Generally, in an attempt to close the defect, the device is inserted through the natural opening of the defect and the expandable structures are deployed on either side of the septum to secure the tissue surrounding the defect between the umbrella or disc-like structure.

[0007] These devices suffer from numerous shortcomings. For instance, these devices typically involve frame structures that often support membranes, either of which may fail during the life of the patient, thereby introducing the risk that the defect may reopen or that portions of the device could be released within the patient's heart. These devices can fail to form a perfect seal of the septal defect, allowing blood to continue to shunt through the defect. Also, the size and expansive nature of these devices makes safe withdrawal from the patient difficult in instances where withdrawal becomes necessary. The presence of these devices within the heart typically requires the patient to use anti-coagulant drugs for prolonged periods of time, thereby introducing additional health risks to the patient. Furthermore, these devices can come into contact with other portions of the heart tissue and cause undesirable side effects such as an arrhythmia, local tissue damage, and perforation.

[0008] Accordingly, improved systems and methods for closing internal tissue defects within the heart are needed.

SUMMARY

[0009] Improved systems and methods for closing internal tissue defects, such as septal defects and the like, are provided herein by the way of exemplary embodiments. These embodiments are examples only and are not intended to limit the invention.

[0010] In one exemplary embodiment, a method of treating a septal defect includes placing a delivery device in proximity with a septal wall having a septal defect, stabilizing the delivery device with an elongate device placed at least partially within the septal defect, and positioning a distal end of the delivery device in a desired orientation with respect to the septal wall, where a first longitudinal axis of the delivery device at the distal end is transverse to a second longitudinal axis of the elongate device.

[0011] In another exemplary embodiment, an implantable apparatus for treating a septal defect is provided having a body with a first end portion, a second end portion and a central portion located therebetween. Preferably, the first end portion is configured to engage a first septal surface, the second end portion is configured to engage a second septal surface and the central portion is configured to fit within an opening in a septal wall.

[0012] In another exemplary embodiment, a treatment system is provided having a first elongate member and a second elongate delivery member having a distal end rotatably coupled with the first elongate member, wherein the orientation of the distal end is adjustable from a first orientation to a second orientation upon advancement of the elongate member in a distal direction.

[0013] In another exemplary embodiment, a treatment system is provided having an elongate tubular member having an inner lumen configured to slidably receive and interact with an inner elongate member. Preferably, the inner elongate member is configured to deploy a grasping device through an aperture in the elongate tubular member upon movement of the elongate inner member with respect to the elongate tubular member.

[0014] In yet another exemplary embodiment, a treatment system is provided having a flexible positioning member having a distal end and an elongate support member having an inner lumen configured to slidably receive the flexible positioning member. Preferably, the inner lumen has a distal end configured to abut the distal end of the flexible positioning member and an open portion located proximal to the distal end of the lumen. The flexible positioning member is also preferably configured to extend from the open portion upon advancement of the flexible positioning member distally against the distal end of the inner lumen.

[0015] In another exemplary embodiment, a method of treating a septal defect is provided, the method including abutting a limbus of a septum secundum with an abutment of a medical device, creating a hole in the septum secundum with the limbus as a point of reference, and using the hole to facilitate delivery of a device configured to treat a septal defect.

[0016] In another exemplary embodiment, a treatment system is provided having an implantable treatment device, a flexible elongate delivery device configured to deliver the implantable treatment device, a stabilization device insertable within an opening in a septum, or tunnel between two septa, and configured to stabilize an elongate body member, and the elongate body member configured for insertion within the vasculature of a patient, the body member configured to slidably receive the delivery device and stabilization device.

[0017] Other systems, methods, features and advantages of the invention will be or will become apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the invention, and be protected by the accompanying claims. It is also intended that the invention is not limited to require the details of the example embodiments.

BRIEF DESCRIPTION OF THE FIGURES

[0018] The details of the invention, both as to its structure and operation, may be gleaned in part by study of the accompanying figures, in which like reference numerals refer to like parts. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, all illustrations are intended to convey concepts, where relative sizes, shapes and other detailed attributes may be illustrated schematically rather than literally or precisely.

[0019] FIG. **1** is a block diagram depicting an exemplary embodiment of a treatment system.

[0020] FIG. **2**A is an exterior/interior view of the right atrium depicting an example human heart.

[0021] FIGS. **2**B-**2**C are enlarged views of an example atrial septal wall.

[0022] FIG. **2**D is a cross-sectional view taken along line **2**D-**2**D of FIGS. **2**B-**2**C depicting another example septal wall.

[0023] FIG. **3** is a block diagram depicting an exemplary embodiment of an implantable treatment device.

[0024] FIG. **4**A is a perspective view depicting another exemplary embodiment of an implantable treatment device.

[0025] FIG. **4**B is a perspective view depicting an exemplary embodiment of several coiled segments of an implantable treatment device.

[0026] FIG. **4**C depicts a side view of the embodiment of the implantable treatment device taken along direction **330** of FIG. **4**A.

[0027] FIG. **4**D is a schematic view depicting another exemplary embodiment of the implantable treatment device as viewed from direction **329** of FIG. **4**C.

[0028] FIG. **4**E is cross-sectional view depicting the exemplary embodiment of the implantable treatment device depicted in FIG. **4**A implanted within an example heart.

[0029] FIGS. **4**F-G are cross-sectional views of additional exemplary embodiments of the treatment system with a delivery device.

[0030] FIGS. **5**A-E are perspective views depicting additional exemplary embodiments of the central portion the implantable treatment device.

[0031] FIGS. **6**A-I are perspective views depicting additional exemplary embodiments of either the first and/or the second end portions of the implantable treatment device.

[0032] FIGS. **7**A-C, **8** and **9**A-C are perspective views depicting additional exemplary embodiments of the implantable treatment device.

[0033] FIG. **10**A is a flow diagram depicting one exemplary method of manufacturing another exemplary embodiment of the implantable treatment device.

[0034] FIG. **10**B is a perspective view of an exemplary embodiment of a body shaping device.

[0035] FIGS. **11**A-C are perspective views depicting additional exemplary embodiments of an implantable treatment device.

[0036] FIG. **12** depicts another exemplary embodiment of the treatment system within a heart.

[0037] FIG. **13** is a block diagram depicting an exemplary embodiment of a delivery device.

[0038] FIG. **14**A is a perspective view depicting another exemplary embodiment of the treatment system.

[0039] FIG. **14**B is a cross-sectional view depicting another exemplary embodiment of the delivery device.

[0040] FIGS. **14**C-F are perspective views depicting a portion of the septal wall and an additional exemplary embodiment of the treatment system.

[0041] FIGS. **15**A-D are perspective views depicting additional exemplary embodiments of the delivery device.

[0042] FIGS. **16**A-B are cross-sectional views depicting additional exemplary embodiments of the treatment system.

[0043] FIG. **16**C is a perspective view depicting the embodiment described with respect to FIGS. **16**A-B during delivery.

[0044] FIG. **17** is a cross-sectional view depicting an exemplary embodiment of the delivery device taken along line **17-17** of FIG. **14**A.

[0045] FIG. **18**A is a cross-sectional view of an exemplary embodiment of a needle member.

[0046] FIGS. **18**B-C are cross-sectional views depicting additional exemplary embodiments of a delivery device.

[0047] FIGS. **19**A-B are cross-sectional views depicting exemplary embodiments of a delivery device and an implantable treatment device.

[0048] FIGS. **20**A-B are schematic views depicting additional exemplary embodiments of a delivery device and an implantable treatment device.

[0049] FIG. **21** is a cross-sectional view depicting another exemplary embodiment of a delivery device taken along lines **21-21** of FIG. **14**A.

[0050] FIG. **22** is a block diagram depicting an exemplary embodiment of a stabilization device.

[0051] FIGS. **23**A-C are cross-sectional views depicting additional exemplary embodiments of a stabilization device.

[0052] FIGS. **24**A-B are perspective views depicting additional exemplary embodiments of a stabilization device.

[0053] FIGS. **25**A-D are cross-sectional views depicting additional exemplary embodiments of a stabilization device.

[0054] FIGS. **26**A-C are cross-sectional views depicting additional exemplary embodiments of a stabilization device.

[0055] FIG. **27**A is a perspective view depicting an additional exemplary embodiment of a stabilization device.

[0056] FIG. **27**B is a cross-sectional view depicting another exemplary embodiment of a stabilization device.

[0057] FIGS. **28**A-C are cross-sectional views depicting additional exemplary embodiments of a centering device.

[0058] FIG. **28**D is a schematic view depicting another exemplary embodiment of a centering device within a septal wall.

[0059] FIGS. **29**A-C, **30** and **31** are schematic views depicting additional exemplary embodiments of a centering device.

[0060] FIGS. **32**A-B are cross-sectional views depicting additional exemplary embodiments of a centering device.

[0061] FIG. **32**C is a cross-sectional view depicting another exemplary embodiment of a centering device with an exemplary embodiment of a stabilization device.

[0062] FIG. **32**D is a schematic view depicting another exemplary embodiment of a centering device with an exemplary embodiment of a stabilization device.

[0063] FIG. **33**A is a longitudinal cross-sectional view of an exemplary embodiment of a treatment system.

[0064] FIG. **33**B is a radial cross-sectional view of another exemplary embodiment of a treatment system taken along line **33**B-**33**B of FIG. **33**A.

[0065] FIG. **34**A is a longitudinal cross-sectional view of an exemplary embodiment of a treatment system.

[0066] FIG. **34**B is a radial cross-sectional view of another exemplary embodiment of a treatment system taken along line **34**B-**34**B of FIG. **34**A.

[0067] FIG. **34**C is a longitudinal cross-sectional view of another exemplary embodiment of a treatment system taken along line **34**C-**34**C of FIG. **34**A.

[0068] FIG. **35**A is a longitudinal cross-sectional view of an exemplary embodiment of a treatment system.

[0069] FIG. **35**B is a radial cross-sectional view of another exemplary embodiment of a treatment system taken along line **35**B-**35**B of FIG. **35**A.

[0070] FIG. **36**A is a longitudinal cross-sectional view of an exemplary embodiment of a treatment system.

[0071] FIG. **36**B is a radial cross-sectional view of another exemplary embodiment of a treatment system taken along line **36**B-**36**B of FIG. **36**A.

[0072] FIG. **37**A is a longitudinal cross-sectional view of an exemplary embodiment of a treatment system.

[0073] FIG. **37**B is a radial cross-sectional view of an exemplary embodiment of a treatment system taken along line **37**B-**37**B of FIG. **37**A.

[0074] FIGS. **38**A-E are cross-sectional views of a septal wall depicting exemplary embodiments of the implantable treatment device.

[0075] FIGS. **39**A-B are flow diagrams depicting an example of a method of treating a septal defect.

[0076] FIG. **40** is a flow diagram depicting another exemplary method of treating a septal defect.

DETAILED DESCRIPTION

[0077] Described herein are improved devices and methods for treating septal defects. For ease of discussion, the devices and methods will be described with reference to treatment of a PFO. However, it should be understood that the devices and methods can be used in treatment of any type of septal defect including ASD's, VSD's and the like, as well as PDA's or other structural cardiac or vascular defects.

[0078] FIG. **1** is a block diagram depicting a distal portion of an exemplary embodiment of a septal defect treatment system **100** configured to treat, and, preferably close, a PFO. In this embodiment, treatment system **100** includes an elongate body member **101** configured for insertion into the vasculature of a patient (human or animal) having a septal defect. Body member **101** has a longitudinal axis **107**, distal end **112** and can include one or more lumens **102**, each of which can be configured for achieving multiple functions. Preferably, treatment system **100** includes an implantable device **103** (referred to herein as an "implant") configured to at least partially close a septal defect. Treatment system **100** can include a flexible elongate delivery device **104** configured to house and deliver implant **103**. To minimize the width of body member **101**, implant **103** can be deformable from the configuration desired after implantation to a configuration having a smaller cross-section for storage and housing within delivery device **104** prior to implantation.

[0079] Treatment system **100** can also optionally include a stabilization device **105** for stabilization of body member **101** during delivery of implant **103** and a centering device **106** for facilitating the centering or the otherwise desired positioning of implant **103** for delivery. Although shown here as four separate components, any combination of body member **101**, delivery device **104**, stabilization device **105** and centering device **106** can be integrated together to reduce the number of components to three, two or one total components in treatment system **100**.

[0080] To better understand the many alternative embodiments of treatment system **100**, the anatomical structure of an example human heart having a PFO will be described in brief. FIG. **2**A is an exterior/interior view depicting an example human heart **200** with a portion of the inferior vena cava **202** and the superior vena cava **203** connected thereto. Outer tissue surface **204** of heart **200** is shown along with the interior of right atrium **205** via cutaway portion **201**. Depicted within right atrium **205** is septal wall **207**, which is placed between right atrium **205** and the left atrium located on the opposite side (not shown). Also depicted is fossa ovalis **208**, which is a region of septal wall **207** where the tissue is relatively thinner than the surrounding tissue. PFO region **209** is located near the upper portion beyond the fossa ovalis **208**.

[0081] FIG. **2**B is an enlarged view of septal wall **207** depicting PFO region **209** in more detail as viewed from right atrium **205**. PFO region **209** includes septum secundum **210**, which is a first flap-like portion of septal wall **207**. The edge of this flap above fossa ovalis **208** is referred to as the limbus **211**. FIG. **2**C is also an enlarged perspective view of septal wall **207**, instead depicting septal wall **207** as viewed from left atrium **212**. Here, PFO region **209** is seen to include septum primum **214**, which is a second flap-like portion of septal wall **207**. Septum primum **214** and septum secundum **210** partially overlap each other and define a tunnel-like opening **215** between sidewalls **219** (indicated as dashed lines in FIGS. **2**B-C) that can allow blood to shunt between right atrium **205** and left atrium **212** and is commonly referred to as a PFO.

[0082] FIG. **2**D is a cross-sectional view depicting an example PFO region **209** taken along line **2**D-**2**D of FIGS. **2**B-C. Here, it can be seen that septum secundum **210** is thicker than septum primum **214**. Typically, the blood pressure within left atrium **212** is higher than that within right atrium **205** and tunnel **215** remains sealed. However, under some circumstances a valsalva condition can occur where the blood pressure within right atrium **205** becomes higher than the blood pressure within left atrium **212** and blood shunts from right atrium **205** to left atrium **212**. Because most typical shunts occur in this manner and for purposes of facilitating the discussion herein, region **217** in FIG. **2**D will be referred to as PFO entrance **217**, and region **218** will be referred to as PFO exit **218**.

[0083] Many different variations of PFO's can occur. For instance, thickness **220** of septum primum **214**, thickness **221** of septum secundum **210**, overlap distance **222** and the flexibility and distensibility of both septum primum **214** and septum secundum **210** can all vary. In FIGS. **2**B-C, PFO entrance **217** and PFO exit **218** are depicted as being relatively the same size with the width of tunnel **215**, or the distance between sidewalls **219**, remaining relatively constant. However, in some cases PFO entrance **217** can be larger than PFO exit **218**, resulting in an tunnel **215** that converges as blood passes through. Conversely, PFO entrance **217** can be smaller than PFO exit **218**, resulting in an opening that diverges as blood passes through. Furthermore, multiple PFO exits **218** can be present, with one or more individual tunnels **215** therebetween. Also, in FIGS. **2**B-D, both septum primum **214** and septum secundum **210** are depicted as relatively planar tissue flaps, but in some cases one or both of septum primum **214** and septum secundum **210** can have folded, non-planar, highly irregular shapes.

[0084] As will be described in more detail below, treatment of a PFO preferably includes inserting treatment system **100** into the vasculature of a patient and advancing body member **101** through the vasculature to inferior vena cava **202**, from which access to right atrium **205** can be obtained. Once properly positioned within right atrium **205**, delivery device **104** can be used to deliver implant **103** to PFO region **209**, preferably by inserting implant **103** through septum secundum **210** and primum **214** such that implant **103** lies transverse to tunnel **215** and can at least partially close tunnel **215**.

[0085] FIG. **3** is a block diagram depicting one exemplary embodiment of implant **103**. Implant **103** can be configured in an almost limitless number of different ways, as this block diagram shows. Here, implant **103** includes a first end portion **301**, a second end portion **302** and a central portion **303** preferably coupled therebetween. First and second end portions **301-302** are each preferably configured to engage opposing surfaces of septal wall **207**. First end portion **301** can be configured to engage the surface of septal wall **207** on the right atrium (RA) side, while second end portion can be configured to engage the surface of septal wall **207** on the left atrium (LA) side. Although end portions **301-302** can be placed anywhere within heart **200** as desired, in order to facilitate the description of implant **103** herein, first end portion **301** will be referred to as RA portion **301** and second end portion will be referred to as LA portion **302**.

[0086] Central portion **303** is preferably configured to fit within a manmade or surgically created opening in either septum primum **214**, septum secundum **210** or both. Central portion **303** is also preferably configured to apply a force adequate to bring end portions **301-302** towards one another when implanted, to be implantable into septal walls **207** of varying thickness and to fit within elongate body member **101**, the diameter of which is preferably minimized for ease of insertion within the patient's vasculature.

[0087] Implant **103** can be configured in any manner desired to fit the needs of the application. Implant **103** can have any size and shape and can include additional portions not shown in FIG. **3** to achieve a different set of functions. Implant **103** can also be fabricated in any desired manner and from any materials suitable for implantation within the patient including, but not limited to, elastic materials, superelastic materials, shape-memory materials, composite materials, polymeric materials, coatings, drug containing materials, blends with radio-opaque materials and biodegradable materials.

[0088] FIG. **4**A is a perspective view depicting another exemplary embodiment of implant **103** shown in an "at rest" configuration. In this embodiment, implant **103** is configured in a coil-shaped manner with a wire-like body **304** composed of an elastic material. Wire-like body **304** can have any wire-like cross-sectional shape including, but not limited to circular, elliptical, oval, rounded, arcuate, polygonal and any combination thereof. Each portion **301-303** can be composed of one or more coiled segments **306**, with a coiled segment **306** being defined herein as a segment that is curved or otherwise shaped in any manner about one or more axes. Thus, rounded, straight, irregular and polygonal segments are all considered to be coiled. A coiled segment **306** can be curved or otherwise shaped less than 360 degrees about the one or more axes. FIG. **4**B is a perspective view depicting an exemplary embodiment of several coiled segments **306**, which could be used in any of portions **301-303**. In this embodiment, each coiled segment **306** is coiled with a constant rate of curvature about the same axis **309**. Coiled segments **306** have approximately the same width **310** and are stacked and separated by a distance **311**, which will be referred to herein as stacking distance **311**.

[0089] Referring back to FIG. **4**A, implant **103** has an overall width **336**. Central portion **303** includes a plurality of coiled segments **306** having substantially the same width **310**. Each end portion **301-302** includes a plurality of coiled segments having varied widths or diameters **310**. In this case, the width **310** of the outermost coiled segment **306** is the greatest and the widths **310** of each successive coiled segment **306** decreases as one approaches the innermost coiled segment **306**. Each end portion **301-302** is coupled with central portion **303** via optional generally straight sections **305**. Generally straight sections **305** can prevent blood from shunting between the right and left atria through open interior region **327** of coiled central portion **303**, by allowing the adjacent tissue to encroach upon and surround straight section **305**. Plugs of bioabsorbable or hydrophilic material may also be provided to minimize such shunting. Generally straight sections **305** can also prevent tissue from getting caught, or hung up, between central portion **303** and RA/LA portions **301/302**. Each generally straight sections **305** is not required to be straight and, in fact, can have any non-coiled shape. Central portion **303** can be placed approximately equidistant from end portions **301-302**, as depicted here, or central portion **303** can be placed closer to one of end portions **301-302** than the other. Generally straight sections **305** are optional and can be included on only one side of central portion **303** or omitted altogether, in which case the coiled segments **306** of central portion **303** extend directly up to a coiled segment **306** of each end portion **301-302**.

[0090] The end tips **307** of body **304** are preferably atraumatic so as to minimize injury to cardiac tissue. In this embodiment, end tips **307** are rounded and have a larger diameter than body **304**. End tips **307** can also be configured as floppy tips that are curled or coiled and can be flexible or non-flexible. Also, it should be noted that any part of implant **103** can be modified for imaging purposes. For instance, in this embodiment end tips **307** are radio-opaque to increase visibility of implant **103** during imaging. Also, end tips **307** can be configured to facilitate delivery. For instance, in one embodiment end tips **307** can be shaped to minimize the risk of becoming caught on any portion of the delivery device **104**. In another embodiment, end tips **307** are configured to interface with the delivery device **104** to allow manipulation of implant **103** before, during or after delivery.

[0091] FIG. **4**C depicts a side view of the embodiment of implant **303** taken along direction **330** of FIG. **4**A. For ease of illustration, FIG. **4**C depicts only the outermost coiled segment **306** of RA portion **301**, transition section **331** and the generally straight section **305** located between RA portion **301** and central portion **303**. Transition section **331** is an optional section of implant **103** that can be straight, curved or any other shape. FIG. **4**D depicts RA portion **301**, transition section **331** and the generally straight section **305** located between RA portion **301** and central portion **303** as viewed from direction **329** of FIG. **4**C. Here, it can be seen that transition section **331** connects to generally straight section **305** at **90** degree angle **332**. Angle **332** can be varied as desired, but values of angle **332** approaching 0 degrees or 180 degrees are less preferable due to the increased risk of RA portion **301** (or LA portion **302**) being drawn into manmade opening **315**, which is described in more detail below.

[0092] FIG. **4**E is cross-sectional view depicting the exemplary embodiment of implant **103** depicted in FIG. **4**A implanted within heart **200** using one exemplary method of implantation. Here, an opening **315** has been surgically created in septum primum **214** and septum secundum **210** and implant **103** has been positioned such that central portion **303** resides within the opening **315**. RA portion **301** and LA portion **302** are positioned on opposite sides of septal wall **207** to engage surface **320** of septum secundum **210** and surface **321** of septum primum **214**, respectively. Central portion **303** preferably exerts a contractile force **312** to bring portions **301-302** towards one another, which in turn preferably draws septum primum **214** and septum secundum **210** together to at least partially close PFO tunnel **215**. Typically, portions **301** and **302** will lie flat against the septa, but are illustrated as compressed conical coils for purposes of clarity. As mentioned above, the widths **310** of coiled segments **306** of RA and LA portions **301-302** get progressively larger from the innermost to the outermost segment **306**. If the rate of change of width **310** is large enough to allow coiled segments **306** to pass through each other, then portions **301** and **302** can exert additional closure forces **313** and **314**, respectively, which oppose each other and assist central portion **303** in closing PFO tunnel **215**.

[0093] LA portion **302** and RA portion **301** can each be sized in any manner desired. Preferably, LA portion **302** is configured to have relatively larger coiled segment widths **310**, include relatively more coiled segments **306** and exert a closure force over a relatively larger area **314** than RA portion **301**. This can be for one of at least two reasons. As will be described in more detail below, preferably, LA portion **302** is deployed in PFO region **209** first and, once in contact with septal wall **207**, LA portion **302** is used to help deploy, or pull, portions **303** and **301** from delivery device **104**. Also, septum primum **214** is typically thinner than septum secundum **210** and more likely to tear or deform to the extent that LA portion **302** can be pulled though septum primum **214**.

[0094] Preferably, implant **103** is configured to adjust to septal walls **207** having varying degrees of thickness. Accordingly, central portion **303** preferably has a compressibility sufficient to apply a closure force **312** to thinner septal walls **207** while at the same time having an expandability sufficient to accommodate thicker septal walls **207** without excessive permanent deformation. In one exemplary embodiment, which is for purposes of illustration only and should not be used to limit the scope of the invention in any way, central portion **303** is expandable from 3 to 8 millimeters (mm) without excessive permanent deformation.

[0095] As mentioned above, implant **103** can be deformable between a configuration suited for housing within delivery device **104** and the implanted configuration depicted in FIG. **4**E. FIG. **4**F is a cross-sectional view of an exemplary embodiment of treatment system **100** depicting delivery device **104** having an inner lumen **402** with implant **103** housed therein. Implant **103** is preferably housed within lumen **402** until body member **101** is advanced within the patient into the desired position within heart **200** for implantation, at which time implant **103** is delivered to PFO region **209** through open distal end **403**. Here, implant **103** is deformed from the at rest, i.e., unbiased, configuration depicted in FIG. **4**A into a generally straight configuration where coiled portions **301-303** are mostly unwound into a relatively straight state. This housed configuration significantly reduces the overall anchor width **336** of implant **103** and allows the size of delivery device **104** and, in turn, body member **101** to be minimized.

[0096] FIG. **4**G is a cross-sectional view of another exemplary embodiment of treatment system **100** depicting delivery device **104** with implant **103** in the housed configuration. Here, central portion **303** of implant **103** remains coiled in a state similar to the resting state of FIG. **4**A, while RA/LA portions **301/302** are partially unwound into a relatively straight state from the coiled rest state. Preferably, coiled segments **306** of central portion **303** generally have smaller widths **310** than most of the coiled segments **306** of RA/LA portions **301/302**. Coiled segments **306** having a smaller width, i.e., more tightly wound coils, can be permanently deformed more easily when unwound and, therefore, by maintaining central portion **303** in the coiled state, the risk of permanent deformation to central portion **303** is reduced. Implant **103** can be deformed in any manner when housed within delivery device **104**. For coil-like embodiments of implant **103**, this can include deforming any or all of coiled segments **306**, to any degree, in any portion **301-303**.

[0097] To facilitate the deformation of implant **103** between the housed configuration and the implanted configuration depicted in FIG. **4**E, implant **103** is preferably composed of an elastic material. Preferably, body **304** is composed of a titanium-nickel alloy such as NITINOL, although any elastic material can be used, including polymers, rubber-like materials, stainless steel, other metal alloys and the like. As one of skill in the art will recognize, the amount of closure force **312-314**, the degree of allowable deformation and the like will depend, in part, on the type of material used to form body **304**.

[0098] FIGS. **5**A-E are perspective views depicting additional exemplary embodiments of central portion **303** of implant **103**. Each of these embodiments can be used with any RA portion **301** and LA portion **302**. In FIG. **5**A, central portion **303** includes a plurality of coiled segments **306** where the stacking distance **311** between each segment **306** is relatively greater than the embodiment of central portion **303** depicted in FIG. **5**B. Generally, a smaller stacking distance **311** will provide a greater closure force **312**, if all other implant parameters remain the same. Any stacking distance **311** can be used in central portion **303** as desired, including configurations where there is no gap between each coiled segment **306**, i.e., each coiled segment **306** lies flush with any adjacent coiled segment **306**. Use of a larger stacking distance **311** that provides for gaps between adjacent coiled segments **306** allows the adjacent septal tissue to grow into the open interior region **327** of the coiled central portion **303**, which can provide positional stability to the device and reduce any risk of blood shunting through open region **327**.

[0099] In FIG. **5**C, central portion **303** includes a combination of coiled sections **324** and generally straight sections **305**. It should be noted that central portion **303** can include any number of one or more coiled sections **324** in any combination with any number of one or more generally straight sections **305**. As can be seen here, each coiled section **324** can be configured differently from any other coiled section **324**, i.e., each coiled portion can include a different number of coiled segments **306**, with different stacking distances **311** and different widths **310**, etc.

[0100] FIG. **5**D depicts another exemplary embodiment where blocking material **326** has been coupled with coil body **304**. Blocking material **326** preferably reduces any risk of blood shunting through the interior of coiled segments **306**, either by blocking blood flow directly or by facilitating the formation of blood clots within open interior region **327**. In one exemplary embodiment, blocking material **326** can include multiple DACRON fibers adhesively or mechanically coupled to the outer surface of body **304**. In another exemplary embodiment, a polymer or metal plug is placed in open interior region **327** to prevent blood flow. As one of skill in the art will readily recognize, any type of plug, device, material or coating can be used and attached to body **304** in any manner, the numerous combinations of which will not be listed here.

[0101] Central portion **303** is not required to include a coiled section **324** and can, in fact, be only a generally straight section **305**. Furthermore, central portion **304** is not required to be formed from a wire-like body **304** and can be configured in any manner desired as depicted in the block diagram of FIG. **3**. For instance, central portion **303** can be formed from an elastomeric or rubber-like stretchable member, as depicted in FIG. **5**E.

[0102] Referring in more detail to RA portion **301** and LA portion **302**, FIGS. **6**A-I are perspective views depicting multiple embodiments exemplary of either RA portion **301** or LA portion **302**. Any of the RA/LA portions **301/302** depicted here can be used with any embodiment of central portion **303** described with respect to FIGS. **5**A-E. For instance, an exemplary embodiment of implant **103** can have RA portion **301** configured in a manner similar to that described with respect to FIG. **6**A, central portion **303** configured in a manner similar to that described with respect to FIG. **5**A, and LA portion **302** configured in a manner similar to that described with respect to FIG. **6**B.

[0103] In FIG. **4**A, RA/LA portions **301/302** include multiple stacked coiled segments **306** having gradually decreasing widths **310** from the outermost to the innermost segment **306** (outermost being used to reference the segments **306** on the far left and right of FIG. **4**A). In FIG. **6**A, RA/LA portions **301/302** include multiple coiled segments **306** having gradually increasing widths **310** from the outermost to the innermost segment **306**. The embodiment of portions **301-302** described with respect to FIG. **4**A can be less susceptible to entering opening **315**, due to the presence of a relatively larger coiled segment **306** coupled with transition region **305**.

[0104] In both FIGS. **4**A and **6**A, coiled segments **306** of RA/LA portions **301/302** are stacked in an inwards manner, i.e., the outermost segment **306** is coupled with central portion **303** or generally straight section **305**, if present (as shown here) and RA/LA portion **301/302** overlaps central portion **303**. In FIGS. **6**B-C, RA/LA portions **301/302** include multiple coiled segments **306** stacked in an outwards manner, i.e., the innermost segment **306** is coupled with central portion **303** or generally straight section **305**, if present (as shown here). Generally, stacking segments **306** in an inwards manner will provide greater closure forces than stacking in an outwards manner. In FIG. **6**B, RA/LA portions **301/302** include multiple coiled segments **306** having gradually increasing widths **310** from the outermost to the innermost segment **306**, while in FIG. **6**C, RA/LA portions **301/302** include multiple coiled segments **306** having gradually decreasing widths **310** from the outermost to the innermost segment **306**.

[0105] In FIG. **6**D, RA/LA portions **301/302** are tightly stacked with a constant width **310** such that no gap exists between adjacent coiled segments **306**. This embodiment of RA/LA portions **301/302** exhibits a high resistance to the potential for being pulled into opening **315**.

[0106] RA/LA portions **301/302** are not required to be implemented in a stacked configuration. For instance, in FIGS. **6**E-F, RA/LA portions **301/302** each include multiple coiled segments **306** having varying widths **310** arranged in a generally co-planar fashion, i.e., for all segments **306** the stacking distance **311** is close to or equal to zero. In FIG. **6**E, the smallest coiled segment **306** is coupled with generally straight section **305**, while in FIG. **6**F, the largest coiled segment **306** is coupled with generally straight section **305**. To lessen the risk of RA/LA portions **301/302** being pulled into opening **315** in the embodiment depicted in FIG. **6**F, transition section **331** is preferably positioned on the outside of coiled segments **306** such that, when implanted, coiled segments **306** are located between transition section **331** and septal wall **207**.

[0107] In the embodiments discussed above, the radius of curvature of the coiled segments **306**, present in either RA/LA portions **301/302** or central portion **303**, is generally constant or varies at a constant rate, resulting in a circular, spiral or helical appearance when viewed from the side (e.g., direction **330** of FIG. **4**A). It should be understood that the radius of curvature can vary at any rate, abruptly or gradual, allowing coiled segments **306** to take any shape or form desired, whether in RA/LA portions **301/302** or central portion **303**. For instance, FIGS. **6**G-H are schematic views depicting additional exemplary embodiments of RA/LA portions **301/302** as viewed from the side. FIG. **6**G depicts RA/LA portion **301/302** having an elliptical D shape. Here, RA/LA portion **301/302** has an elliptical portion **334** and a generally straight portion **335**, which can be placed adjacent to fossa ovalis **208** to lessen the extent to which RA/LA portion **301/302** overlaps fossa ovalis **208** and minimize the risk of piercing or rupturing fossa ovalis **208**. FIG. **6**G depicts another exemplary embodiment of RA/LA portion **301/302** having a generally pentagonal shape.

[0108] RA/LA portions **301/302** are not required to include coiled segments **306** and are not required to be formed from a wire-like body **304**. As mentioned above, RA/LA portions **301/302** can be configured in any manner desired as depicted in the block diagram of FIG. **3**. For instance, RA/LA portions **301/302** can be formed from an elastomeric or rubber-like membrane **328** in an umbrella-like fashion, or a sheet-like fashion as depicted in the exemplary embodiment of FIG. **6**I.

[0109] FIG. **7**A-C are perspective views depicting additional exemplary embodiments of implant **103** having a ribbon-like body **304**. Ribbon-like bodies **304** can have a generally polygonal cross-section and can be differentiated from the wire-like bodies **304** depicted in FIGS. **4**A-**5**E, which can have generally circular, rounded etc. cross-sections as described above. FIG. **7**A is an embodiment of implant **103** having a ribbon-like body **304** configured similar to that of the embodiment depicted in FIG. **4**A. Generally, any of the embodiments described with respect to wire-like bodies **304** can also be implemented with ribbon-like bodies **304**. Ribbon-like bodies **304** can have any ribbon-like cross-sectional shape desired. FIGS. **7**B-C are cross-sectional views depicting ribbon-like body **304** having generally polygonal shapes. FIG. **7**B is a cross-sectional view depicting ribbon-like body **304** having a generally tapered trapezoidal shape. FIG. **7**C is a cross-sectional view depicting ribbon-like body **304** having a generally rectangular shape with rounded corners.

[0110] In addition to other parameters, the thickness of implant body **304** can vary as desired. For instance, FIG. **8** is a perspective view depicting another exemplary embodiment of implant **103** having a wire-like body **304** with varying thicknesses. Here, it can be seen that generally straight section **305** is relatively thicker than the coiled segments **306** of central portion **303**, while interface **333** between generally straight sections **305** and transition sections **331** is relatively thicker still. Relatively thicker regions of body **304**, whether formed from a wire, ribbon or other structure, generally have greater strength and less flexibility than relatively thinner regions of body **304**. Thus, relatively thicker regions can be used to add strength while relatively thinner regions can be used where added flexibility is desired.

[0111] Like the thickness, the surface of body **304** can also be varied as desired. The surface can be modified directly or through etching, grinding, additional coatings or add-ons, which are applied to the underlying body **304**. The surface can be modified for any purpose including, but not limited to increasing surface friction with tissue, increasing the ability to engage tissue, allowing tissue in-growth, promoting healing, promoting scarring, promoting thrombogencity, preventing blood passage or shunting around or through implant **103**, minimizing thrombus formation, promoting anti-coagulation (e.g., with drugs such as heparin and the like), modifying imaging characteristics (e.g., radio-opacity and the like) and decreasing body surface friction (e.g., with a hydrophilic coating and the like).

[0112] FIGS. **9**A-C are perspective views depicting just several additional exemplary embodiments of implant **103** having a modified surface region **340**. The surface of implant **103** can be modified in any location and in any manner desired, including, but not limited to, etching, grinding, coating, drilling, and cutting. For instance, FIGS. **9**A-C depict the innermost coiled segment **306** of exemplary embodiments of RA/LA portion **301/302**. In FIG. **9**A, wire-like body **304** has been etched or otherwise treated such that modified surface region **340** is a textured surface including multiple recesses **341** for increasing surface friction and allowing coiled segment **306** to more easily grasp septal wall **207**. It should be noted that any surface texture pattern can be used. In FIG. **9**B, a coating has been applied to ribbon-like body **304** to create an abrasive surface region **340**, also to increase surface friction. In FIG. **9**C, apertures **342** in ribbon-like body **304** are present to facilitate tissue in-growth on and around modified surface region **340**. Also, in this embodiment the orientation of ribbon-like body **340** has been rotated 90 degrees so that the widest surface is adjacent to the septal tissue.

[0113] As stated above, implant **103** can be configured in any manner desired in accordance with the needs of the application. The following is a non-exhaustive list of just some exemplary factors one of skill in the art may consider in designing, configuring, manufacturing and/or otherwise implementing implant **103**.

[0114] LA portion **302** can be configured to use compressive force **312** from center portion **303** to hold septum primum **214** against septum secundum **210** and at least partially close or seal PFO tunnel **215**. LA portion **302** can also be configured to maintain a stable position as central portion **303** and RA portion **301** are deployed without being pulled through septum primum **210**. LA portion **302** can be configured to lie flush against septum primum **214** when deployed and not to distort the native geometry of tunnel **215** to create residual shunts. LA portion **302** can be sized to provide adequate coverage over PFO tunnel **215**. (In one exemplary embodiment, which is included as an example only and should not be used to limit the invention, LA portion **302** has a maximum width **310** of 1.2 centimeters to accommodate most large PFO tunnels **215**.) LA portion **302**, in combination with central portion **303** and RA portion **301**, can be configured to exert enough closure force **314** to seal PFO tunnel **215** and prevent shunting during normal and valsalva atrial blood pressures. LA portion **302** can also be configured: to be deployable with minimal and consistent push force (e.g., push force on pusher member **406**, which will be described in more detail below); so that the shape before and after deployment is predictable; to be devoid of characteristics that cause chronic or excessive tissue irritation, inflammation, etc.; and/or for visibility during imaging procedures.

[0115] Central portion **303** can be configured to maintain LA portion **302** and RA portion **301** in a state of contact with septal wall **207** with enough closure force **312** to at least partially close and seal PFO tunnel **215**. Central portion **303** can also be configured: with an adequate spring constant (k) to prevent tunnel **215** from opening during normal and valsalva atrial blood pressures; not to distort the native geometry of tunnel **215** and create residual shunts; to be deployable with minimal and consistent push force (e.g., push force on pusher member **406**, which will be described in more detail below); for visibility during imaging procedures; to expand or stretch to accommodate variable septal wall thicknesses without excessive permanent deformation; with adequate strength to withstand any motion it may experience in vivo; to allow LA portion **302** or RA portion **301** to tilt, for instance, if the area of delivery is wedge shaped; so that central portion **303** does not pinch or sever any tissue that could embolize, for instance, with a spring constant low enough to prevent severing tissue; to exert adequate closure force **312** to close any residual shunts that exist; and/or with maximized width **310** and minimized strains to optimize fatigue performance.

[0116] RA portion **301** can be configured to hold septum secundum **210** against septum primum **214** and at least partially close or seal PFO tunnel **215**. RA portion **301** can also be configured: to lie flush against septum secundum **210** when deployed and not to distort the native geometry of tunnel **215** to create residual shunts; to be deployable with minimal and consistent push force (e.g., push force on pusher member **406**, which will be described in more detail below); so that the shape before and after deployment is predictable; to be devoid of characteristics that cause chronic or excessive tissue irritation, inflammation, etc.; for visibility during imaging procedures; and/or to resist being pulled through septal wall **207**.

[0117] Also provided herein are methods of manufacturing implant **103**. FIG. **10**A is a flow diagram depicting one exemplary method **350** of manufacturing an exemplary embodiment of a coil-like implant **103** having body **304**, which can be wire, ribbon or the like, composed of NITINOL. First, at **351**, a section of NITINOL, from which body **304** can be formed, is pre-processed. Pre-processing **351** can include adding a modified surface region **340** having a desired texture, adjusting body thickness, adjusting the cross-sectional shape of body **304** and the like.

[0118] With a ribbon-like implant **103**, pre-processing can include etching of the NITINOL section. Methods of etching NITINOL materials are readily understood to one skilled in the art. For instance, a sheet of NITINOL is first etched or grinded or otherwise altered to vary the cross-sectional shape, thickness, surface texture and the like of one or more sections present on the sheet. Etching of the NITINOL sheet can allow for the implementation of numerous different cross-sectional shapes, thicknesses, surface textures and combinations thereof. Afterwards, each section of NITINOL can be cut from the sheet and trimmed as desired.

[0119] At **352**, the NITINOL section is fixed to body shaping device **380** in preparation for heat treatment. Heat treatment of NITINOL can instill the desired at rest configuration to body **304** and is well known to those of skill in the art. Accordingly, body shaping device **380** is preferably shaped such that when the NITINOL section is coiled around body shaping device **380**, it is in the final desired at rest configuration. One exemplary embodiment of body shaping device **380** is depicted in FIG. **10**B. Here, body shaping device **380** is shaped for the exemplary embodiment of implant **103** depicted in FIG. **4**A. Body shaping device **380** includes a central body shaping portion **383** corresponding to the shape of central portion **303**, and two end body shaping portions **381** and **382** corresponding to the shape of RA portion **301** and LA portion **302**, respectively. End body shaping portions **381** and **382** are preferably configured to telescope over central body shaping portion **383** to allow for the inwards manner of coiling of RA/LA portions **301**/**302** over central portion **303**. Central portion **303** includes recesses **384** into which the NITINOL section can be placed to form generally straight sections **305**. End body shaping portions **381** and **382** also preferably include recess **385** that can allow for each transition section **331**.

[0120] Once wrapped around and fixed to body shaping device **380**, at **353**, the NITINOL section is then preferably heat treated to instill the desired shape. Heat treating can occur at any time and temperature sufficient to instill the desired at rest shape and level of elasticity in implant **103**. In one embodiment, which is included as an example only and should in no way be used to limit the invention, heat treating can occur at a temperature range of 500-550 degrees Celsius for approximately five minutes.

[0121] At **354**, the NITINOL section is preferably cooled, e.g., by rapid quenching in room temperature water, then at **355**, the NITINOL section is preferably removed from body shaping device **380** and end tips **307** are trimmed, if necessary, to the desired length to form body **304**. Finally, at **356**, any post-processing is performed, such as the addition of radio-opaque markers, the shaping of end tips **307** and the addition of any desired coatings or blocking material **326**.

[0122] FIGS. **11**A-C depict additional exemplary embodiments of implant **103**. Specifically, FIG. **11**A is a perspective view depicting an exemplary embodiment of implant **103** formed from multiple bodies **304**. More specifically, from central portion **303** to RA portion **301** and LA portion **302**, body **304** splits into separate wires which are then configured as shaped portions **390** and **391**, which in this embodiment have substantially polygonal shapes. The shape and size of polygonal shaped portions **390** and **391** can be configured as desired to facilitate PFO closure. Here, portions **390** and **391** are entirely connected such that implant **103** does not have discrete end tips **307**. Polygonal shaped portions **390** and **391** operate similar to coiled segments **306** and are deformable between a housed configuration and an "at rest" deployed configuration as shown here in FIG. **11**A. FIG. **11**B depicts RA portion **301** in the housed configuration. FIG. **11**C depicts another exemplary embodiment where portions **390** and **391** have "D" shapes. Each portion **390** and **391** is not entirely connected and each portion **390** and **391** has an atraumatic end tip **307**. It should be noted that body **304** can split into any number of separate portions having any number of configurations. Also, although not shown, implant **103** can include any number of separate bodies **304**.

[0123] Turning now to the devices and methods for delivering implant **103**, FIG. **12** depicts another exemplary embodiment of treatment system **100** within heart **200**. Implant **103** is preferably delivered from right atrium **205**, although delivery from left atrium **212** is also possible. Right atrium **205** is preferably accessed via inferior vena cava **202**.

In this embodiment, implant **103** is delivered from within delivery device **104**. To facilitate delivery in this manner, longitudinal axis **108** of delivery device **104** is preferably substantially parallel, i.e., at least close to parallel but not necessarily parallel, to the normal axis **109** of the surface of septal wall **207** into which implant **103** is to be delivered. However, as shown in FIG. **12**, longitudinal axis **108** of delivery device **104** is close to perpendicular to this normal axis **109** (shown here extending into the page). To accommodate for this, treatment system **100** is preferably configured for off-axis delivery, which allows the orientation of delivery device **104** to be changed so that the longitudinal axis **108** of delivery device **104** is transverse to the longitudinal axis **107** (not shown) of body member **101**.

[0124] FIG. **13** is a block diagram depicting one exemplary embodiment of delivery device **104** configured for off-axis delivery. Here, delivery device **104** includes an off-axis (OA) delivery member **401**. Delivery device **104** is preferably configured to grasp or engage cardiac tissue to support and/or facilitate orientation of delivery member **401**. Accordingly, an optional tissue engagement device **404** is included within delivery device **104**. Delivery device **104** can also include a needle member **405** for puncturing septal wall **207** and a pusher member **406** for pushing implant **103** from within delivery device **104**.

[0125] FIG. **14**A is a perspective view depicting another exemplary embodiment of treatment system **100**, including body member **101**, delivery device **104** and stabilization device **105**. Here, OA delivery member **401** is an elongate flexible tubular member having open distal end **410**. Inner lumen **102** of body member **101** is preferably configured to slidably receive OA delivery member **401**, such that OA delivery member **401** can be advanced both proximally and distally. Distal end **410** of OA delivery member **401** is coupled with an elongate support structure **411** of body member **101** via optional grasping device **404**. In this embodiment, grasping device **404** includes an arm member **409** coupled with support structure **411** and OA delivery member **401** with hinges **407** and **408**, respectively. A biasing element **413** can also be optionally included, to apply a bias force to maintain arm member **409** in the position shown here. Stabilization device **105** is also an elongate member preferably placed in a location to oppose arm member **401**.

[0126] FIG. **14**B is a cross-sectional view depicting another exemplary embodiment of OA delivery member **401** with embodiments of needle member **405**, pusher member **406** and implant **103** located within lumen **414**. Needle member **405** has an open distal end **415** and an inner lumen **414** in which pusher member **406** and implant **103** are slidably received and housed. In this embodiment, implant **103** is deformed to the housed configuration where RA/LA portions **301**/**302** are relatively straightened but central portion **303** remains in the coiled at rest configuration. As will be discussed in more detail below, delivery of implant **103** is accomplished by first orienting delivery device **104** in the desired orientation transverse to longitudinal axis **107** such that distal end **410** is in proximity with septal wall **207**, then advancing needle member **405** through septal wall **207** to create opening **315**. After needle member **405** has advanced through septal wall **207** into left atrium **212**, pusher member **406** is advanced distally to push LA portion **302** of implant **103** from within lumen **414**. Once LA portion **302** is outside lumen **414**, LA portion **302** returns to the coiled at rest configuration. Needle member **405** can then be retracted proximally such that LA portion **302** engages septal wall **207** and remains in left atrium **212**. As needle member **405** is refracted through septal wall **207**, central portion **303** deploys within opening **315**. Once needle member **405** is retracted back into lumen **402**, OA delivery member **401** can be refracted from septal wall **207**, for instance by pulling body member **101** proximally back, thereby allowing RA portion **301** to deploy and engage septal wall **207** in a coiled configuration.

[0127] FIGS. **14**C-F are perspective views depicting a portion of septal wall **207** and an additional exemplary embodiment of treatment system **100** during use of delivery device **104** prior to insertion of needle member **405**. Here, the preferred location for insertion of needle member **405** is indicated by location **419**. FIG. **14**C depicts treatment system **100** with delivery device **401** in the on-axis position, where the longitudinal axes **107**-**108** are generally or substantially parallel. Stabilization device **105**, the use and structure of which will be described in more detail below, is shown positioned within PFO tunnel **215**. In FIG. **14**D, OA delivery member **401** has been retracted proximally with respect to body member **101** and in opposition to bias member **413**, causing distal end **410** to move away from stabilization device **105** by way of arm member **409** and hinges **407**-**408**. In FIG. **14**E, treatment system **100** is advanced distally in direction **416** until the underside surface **417** of arm member **409** abuts limbus **211**, at which point OA delivery member **401** can be advanced distally with respect to body member **101** to force arm member **409** back towards stabilization device **105** to clamp, or grasp limbus **211** between arm member **409** and stabilization device **105**, which is preferably in a substantially fixed position with respect to arm member **409**. By grasping limbus **211** in this manner, treatment system is effectively anchored to septal wall **207**.

[0128] In FIG. **14**F, OA delivery member **401** is further advanced distally with respect to body member **101**, which causes OA delivery member to deflect, or arc outwards, in order to rotate distal end **410** about hinge **408** into the desired orientation with respect to septal wall **207**. Distal end **410** is now preferably in contact with septal wall **207** at the desired needle insertion location **419**. As shown here, OA delivery member **401** is in an outwardly arced state. The degree to which OA delivery member **401** arcs outwards can be adjusted by altering the length of OA delivery member **401** present outside of body member **101**. Because needle member **405**, pusher member **406** and implant **103** all preferably move within OA delivery member **401**, the radius of curvature of the arc is preferably kept large enough to allow movement within OA delivery member **401**. A very large radius of curvature can result in sharp angles or kinking in OA delivery member **401** that can make movement difficult.

[0129] As shown in FIG. **14**F, longitudinal axis **108**, as measured at distal end **410**, is now transverse to longitudinal axis **107**. Preferably, the delivery angle **418**, which is the angle between longitudinal axis **107** and longitudinal axis **108** as measured at distal end **410**, is approximately 90 degrees. Once distal end **410** is in the desired orientation, needle member **405** can be advanced into septal wall **207**.

[0130] The needle insertion location **419** can be placed in any desired location, but should be chosen based in part on the configuration and size of implant **103** and the degree of overlap between septum primum **214** and septum secundum **210**. For instance, in one exemplary embodiment, which is included for illustration only and in no way should be used to limit the invention, needle insertion location **419** is placed between 3 and 7 mm from limbus **211**. The position of needle insertion location **419** can be determined by the length of arm member **409**, which in turn can position distal end **410** using limbus **211** as a point of reference. To allow for added flexibility, the length of arm member **409** can be configured to be adjustable during the implantation procedure. Thus, arm member **409** is preferably configured for at least two functions: (1) to stop travel of body member **101** at limbus **211** by abutting limbus **211** and (2) to position distal end **410** in the desired needle insertion location **419**.

[0131] FIGS. **15**A-D are perspective views depicting additional exemplary embodiments of grasping device **404** in a pulled back position. In FIG. **15**A, arm member **409** is configured to engage limbus **211** with a contoured undersurface **417** that accommodates the shape of limbus **211** in order to facilitate grasping or engagement. Undersurface **417** can also be textured as desired to increase surface friction, or made lubricious to assist in friction-free centering, and, as shown here, undersurface can include abutments **420** configured to fixably grasp limbus **211**. Also, it should be noted that any type of hinges **407**-**408** can be used including, but not limited to, the swivel type hinges depicted here.

[0132] FIGS. **15**B-C depict exemplary embodiments of grasping device **404** where hinges **407** and **408** are integrated into arm member **409**. In FIG. **15**B, arm member **409** includes two elastic wires **421** each configured to flex at hinge positions **407** and **408**, e.g., by reducing the thickness of the material at the hinge positions. Arm member **409** is preferably biased towards a downwards position, which can allow elimination of any additional biasing element **413**. In FIG. **15**C, arm member **409** is configured to be both flexible and stretchable and can be composed of an elastomeric or rubber-like material or thin or slotted metal or polymeric material with the appropriate modulus. This flexibility and stretchability facilitates the conformance of arm member **409** to limbus **211**. Here, arm member **409** includes tubular portions **422** and **423** for coupling arm member **409** with OA delivery member **401** and support structure **411**, respectively.

[0133] FIG. **15**D is a perspective view depicting yet another exemplary embodiment of grasping device **404**. Here, arm member **409** again includes two flexible wires **420** and **421** that can be coupled with OA delivery member **401**. Like the embodiment described with respect to FIG. **15**B, hinges **407** and **408** can be integrated into wires **420** and **421**, which can be biased towards a downwards position. As shown in FIG. **15**D, wires **425** and **426** are preferably routed through aperture **499** into a lumen **102** within body member **101** and to the proximal end of body member **101**, where they can be independently adjusted to control, or steer, OA delivery member **401**. For instance, distal movement of both wires **425** and **426** moves distal end **410** of OA delivery member **401** in direction **495** and proximal movement of both wires **425** and **426** moves distal end **410** of OA delivery member **401** in direction **496**, as OA delivery member **401** permits. Distal advancement of wire **425** with respect to wire **426**, alone or in combination with proximal movement of wire **426** with respect to wire **425**, moves distal end **410** in lateral direction **497**, while reverse movement moves distal end **410** in lateral direction **498**, as OA delivery member **401** permits.

[0134] FIGS. **16**A-B are cross-sectional views depicting additional exemplary embodiments of treatment system **100** with delivery device **104**. FIG. **16**A depicts a longitudinal cross-sectional view of treatment system **100** and FIG. **16**B depicts a radial cross-sectional view of treatment system **100** taken along line **16**B-**16**B of FIG. **16**A. Here, delivery device **104** includes a steerable OA delivery member **401**, which is configured to be freely steerable to position distal end **410** in the desired orientation at needle insertion location **419**. Accordingly, distal end **410** is preferably left unconnected with any grasping device **404** (not shown). Preferably, steerability is provided through the use of one or more pull wires **424** coupled with distal end cap **475**. In this embodiment, four pull wires **470**-**473** are equally spaced apart from each other within lumen **402**. This configuration allows for manipulation of distal end **410** to any three-dimensional (X, Y, Z) orientation. For instance, pulling wire **470** back proximally with respect to wires **471**-**473**, or pulling wire **472** back proximally with respect to wires **470**-**471** and **473** allows movement of distal end **410** in the X-Z plane. Pulling wire **471** back proximally with respect to wires **470** and **472**-**473**, or pulling wire **473** back proximally with respect to wires **470**-**472** allows movement of distal end **410** in the Y-Z plane.

[0135] FIG. **16**C is a perspective view depicting the embodiment described with respect to FIGS. **16**A-B during delivery. Here, distal end **410** has been oriented in its needle insertion location **419** and longitudinal axis **108** lies within both the X-Z and Y-Z planes. The degree of steerability can be altered as desired for each individual application. For instance, the inclusion of additional pull back wires can provide for more finely controllable steerability, while the deletion of any of pull wires **470**-**473** can eliminate freedom of steerability, but can simplify the overall design of device **104**. The design and use of steerable devices is also discussed in parent U.S. patent application Ser. No. 10/847,747, filed on May 7, 2004.

[0136] As mentioned above, OA delivery member **401** is preferably configured to allow slidable movement of needle member **405**, pusher member **406** and implant **103** within inner lumen **402**. Preferably, OA delivery member **401** is configured so as to maintain a sufficient degree of structural integrity and kink resistance, while at the same time providing adequate torque or twist control. In one exemplary embodiment, OA delivery member **401** is composed of a flexible braided metal reinforced polymeric tube configured to provide the desired amount of kink resistance and torque control. In other exemplary embodiments, OA delivery member **401** can be composed of a braided or unbraided polymeric tube. In yet another exemplary embodiment, OA delivery member **401** is composed of a metal tube having apertures located therein to provide added flexibility. For instance, OA delivery member **401** can be a NITINOL slotted tube, with the size and spacing of each slot configured for optimal flexibility, kink resistance and torque control. The apertures are preferably placed in a location corresponding to the portion of OA delivery member **401** that extends or arcs out, while the portion of OA delivery member **401** proximal to this can be left solid without apertures to maintain resilience in OA delivery member **401** and provide resistance to push back from needle member **405** as it penetrates septal wall **207**.

[0137] Furthermore, OA delivery member **401** can be coated to provide low friction surfaces to facilitate advancement of OA delivery member **401** within body member **101** and the patient's body, as well as to facilitate movement of needle member **405** within lumen **402**. Pusher member **406** and needle member **405** can be coated as well. For instance, FIG. **17** is a cross-sectional view depicting an exemplary embodiment of OA delivery member **401** taken along line **17**-**17** of FIG. **14**A. Here, pusher member **406** includes an outer coating **480**, needle member **405** includes both an inner coating **481** and an outer coating **482** and OA delivery member **401** includes both an inner coating **483** and an outer coating **484**. Coatings **480-484** can be implemented for any purpose desired. For instance, in one embodiment, coatings **480-484** are composed of any material used to lower surface friction, including, but not limited to polymers such as polyethylene (PE), polytetrafluoroethylene, fluorinated ethylene/propylene copolymers, silicones, hydrogels, hydrophilic coatings or polyurethane (PU) and the like. Preferably, a high density PE material is used that is thin enough to provide the desired degree of flexibility while at the same time providing a low friction surface.

[0138] Like OA delivery member **401**, needle member **405** and pusher member **406** are also preferably flexible elongate members. FIG. **18**A is a cross-sectional view of an exemplary embodiment of needle member **405**. Distal end **415** of needle member **405** is preferably substantially sharp enough to penetrate the desired portion of septal wall **207**. In this embodiment, distal end **415** is tapered similar to a conventional needle. Also, needle member **405** is preferably flexible enough to move within OA delivery member **401** when deflected for off-axis delivery.

[0139] For instance, needle member **405** can include one or more openings, or apertures **436**, to increase flexibility. Here, needle member **405** includes multiple apertures **436** in various arrangements. Needle member **405** can be fabricated from any desired material including, but not limited to, NITINOL and stainless steel, and apertures **436** can be formed in any manner including, but not limited to, molding, milling, grinding, laser cutting, EDM, chemical etching, punching and drilling. The design and use of flexible needles is also discussed in parent U.S. patent application Ser. No. 10/847,747, filed on May 7, 2004.

[0140] A first region **437** of needle member **405** includes apertures **436** located at various intervals around the circumference of needle member **405**. A second region **438**, located distal to the first region **437**, includes apertures **436** on the lower portion of needle member **405**. FIG. **18**B is a cross-sectional view depicting an exemplary embodiment of needle member **405** in a deflected state within an exemplary embodiment of OA delivery member **401**. Because apertures **436** in region **437** are located around the circumference of needle member **405**, region **437** is relatively more flexible than region **438**. In region **438**, placement of apertures **436** on the lower surface, reduces the possibility that implant **103** will catch or snag an aperture **436** during advancement of needle member **405** from OA delivery member **401**. In addition, distal tip **439** of needle member **405** is also preferably aligned on the lower portion of needle member **405** to reduce the possibility that distal tip **439** will impact, catch, snag, or damage OA delivery member **401**.

[0141] Treatment system **100** can be configured to apply a suction-type force to any surface of septal wall **207** to allow needle member **405** to more easily penetrate the septal tissue without excessive "tenting" of septal wall **207** in response to the pressure applied by needle member **405**. For instance, the proximal end of OA delivery member **401** can be coupled with a vacuum or pressure adjustment device configured to lower the air or fluid pressure within OA delivery member **401**. The pressure is preferably lowered to a degree sufficient to create a suction-type force between OA delivery member **401** and septal wall **207** thereby keeping septal wall **207** in contact or in proximity with OA delivery member **401** while needle member **405** is advanced into septal wall **207**. Also, the suction-type force can be applied through needle member **405** instead of, or in addition to OA delivery member **401**.

[0142] Treatment system **100** preferably includes one or more sensors to facilitate determination of when needle member **405** has entered left atrium **212**. For instance, in one exemplary embodiment, needle member **405** includes a sensor at or near distal end **415**. The sensor can be any type of applicable sensor, such as a pressure sensor, thermal sensor, imaging device, acoustic device and the like. In one exemplary embodiment, a pressure sensor is included that is configured to sense the blood pressure change between right atrium **205** and left atrium **212**. The pressure sensor can be any type of pressure sensor including, but not limited to, an electrical sensor and a fluid feedback sensor such as a lumen within needle member **405** having an open distal end in fluid communication with the exterior environment. In an alternative exemplary embodiment, distal end **415** of needle member **405** is configured to be visible by an external or internal imaging device, which can then be used to track the position of distal end **415** with respect to septal wall **207**.

[0143] FIG. **18**C is a cross-sectional view of another exemplary embodiment of delivery device **104**. Here, distal end **440** of pusher member **406** is configured to push against central portion **303** of implant **103** as opposed to end tip **307** of RA portion **301**. This reduces the likelihood that RA portion **301** will coil when pushed within lumen **414**, which could result in bunching of implant **103** within lumen **414** making delivery more difficult. Because distal end **440** of pusher member **406** is located distal to RA portion **301**, pusher member **406** includes a relatively thinner portion **441** that can provide additional room for RA portion **301** within lumen **414** as well as provide added flexibility to pusher member **406**. Relatively thinner portion **441** is relatively thinner than distal end **440**, which is preferably thick enough to adequately engage central portion **303**. Distal end **440** can include a recess **442** to provide enough room for RA portion **301**. Recess **442** can also be used to help position implant **103** during delivery. For instance, rotation of pusher member **406** can cause implant **103** to rotate if implant **103** is still routed through recess **442**. This can allow the proper rotational orientation of implant **103** before or during delivery into septal wall **207**. Distal end surface **443** can be configured in any manner desired to facilitate proper contact and engagement of implant **103**.

[0144] For instance, FIGS. **19**A-B are cross-sectional views depicting exemplary embodiments of pusher member **406** and implant **103**. In FIG. **19**A, distal end surface **443** is contoured with a rounded recessed portion **444** into which a coiled central portion **303** can rest and an elevated portion **445** configured to fit within open interior region **327**. As one of skill in the art will readily recognize, the contours of distal end surface **443** are dependent on the type and housed configuration of implant **103**, as well as the desired point of contact on implant **103**. In FIG. **19**B, distal end surface **443** is contoured with a narrow recessed portion **446** into which end tip **307** of RA portion **301** can rest.

[0145] Pusher member **406** can also be configured to releasably couple with implant **103**. For instance, in one exemplary embodiment, pusher member **406** is tethered to implant **103** with a tether **485** in order to allow implant **103** to be drawn back into needle member **405** if needed, such as in a case of improper deployment. If implant **103** is properly deployed, tether **485** can be released from pusher member

406. In another exemplary embodiment, pusher member **406** can be configured to both push and pull implant **103** while within needle member **405**, as depicted in FIGS. **20**A-B.

[0146] FIGS. **20**A-B are schematic views depicting additional exemplary embodiments of needle member **405**, pusher member **406** and implant **103**. In FIG. **20**A, implant **103** is placed over outer surface **450** of needle member **405** and end tips **307** of RA portion **301** and LA portion **302** can be routed through apertures **451** and **452**, respectively, and housed within lumen **414**. To deliver implant **103**, after needle member **405** has traversed septal wall **207** into left atrium **212**, pusher member **406** is used to pull implant **103** back proximally to expose end tip **307** of LA portion **302** as depicted in FIG. **20**B. To grasp end tip **307**, pusher member **406** can include any type of grasping device desired. Here, pusher member **406** includes a clamp-type device **453**. Once removed from aperture **452**, LA portion **302** can enter the coiled state. As needle member **405** is withdrawn back through septal wall **207**, LA portion **302** engages septal wall **207** and cause implant **103** to slide off needle member **405**. Pusher member **406** can also be used to push end tip **307** of RA portion **301** to facilitate deployment. In this embodiment, proximally located end tip **307** includes an aperture through which a tether **485** is routed for use as described above.

[0147] Delivery device **104** can be configured to maintain the proper orientation of OA delivery member **401**, needle member **405**, pusher member **406** and implant **103** during delivery. FIG. **21** is a cross-sectional view depicting another exemplary embodiment of delivery device **104** taken along lines **21-21** of FIG. **14**A where delivery device **104** is configured to use a lock and key technique to maintain proper orientation. Here, the lock and keys are implemented with a combination of abutments and corresponding recesses. For instance, outer surface **450** of needle member **405** includes a recess **456** configured to receive an abutment **455** located on inner surface **457** of OA delivery member **401**. Recess **456** can extend longitudinally along needle member **405** for any desired distance to ensure proper orientation even when needle member **405** is advanced and refracted within OA delivery member **401**. Similarly, outer surface **458** of pusher member **406** includes a recess **459** configured to receive an abutment **460** located on inner surface **461** of needle member **405**. Like recess **456**, recess **459** can extend longitudinally along pusher member **406** for any desired distance to ensure proper orientation when pusher member **406** is advanced and refracted. As discussed above with respect to FIGS. **18**A-B, pusher member **406** can include recess **442** to accommodate for the presence of RA portion **301**. This recess **442** can also maintain implant **103** in the proper orientation with respect to pusher member **406**.

[0148] The distances that OA delivery member **401**, needle member **405** and pusher member **406** are moved proximally and distally with respect to body member **101**, can be relatively small. Manual movement of these components, while possible, can be difficult. Treatment system **100** can include one or more automated systems or devices at the proximal end of body member **101** to facilitate movement of these components and lessen the risk that each component is inadvertently advanced too far or not enough. The automated systems or devices can also be configured to apply the desired amount of force to move each component and sense if too much force is being used, which could be indicative of an error in the delivery process.

[0149] To further facilitate movement of OA delivery member **401**, needle member **405** and pusher member **406**, each can be optionally pre-shaped. For instance, in one exemplary embodiment, one or more of OA delivery member **401**, needle member **405** and pusher member **406** can include a curved section that corresponds to the desired deflected arc shape of OA delivery member **401** depicted in FIG. **14**F.

[0150] It should also be noted that needle member **405** can be excluded from system **100** altogether. Pusher member **406** can deploy implant **103** through a pre-existing hole, or implant **103** can be configured with a substantially sharp end tip **307** for creation of a hole while being deployed by pusher member **406**.

[0151] As described with respect to FIG. **1**, treatment system **100** can optionally include stabilization device **105**. FIG. **22** is a block diagram depicting an exemplary embodiment of stabilization device **105** within treatment system **100**. Here, stabilization device **105** is preferably configured to stabilize treatment system **100** during delivery of implant **103**. Stabilization device **105** can have any configuration desired in accordance with the needs of the application. For instance, stabilization device **105** can be configured as a body routed through PFO tunnel **215** or any portion of the patient's vasculature, such as superior vena cava **203**. Stabilization device **105** preferably includes an elongate stabilization member **501** and can optionally include grasping device **502**, which is preferably configured to grasp nearby tissue in order to facilitate stabilization.

[0152] FIGS. **23**A-C are cross-sectional views depicting additional exemplary embodiments of stabilization device **105** being used to in an exemplary method of stabilizing treatment system **100**. Here, stabilization member **105** is configured as an elongate member including an outer tubular sheath **501** having an inner lumen **504** configured to slidably receive inner elongate pull member **505**. Outer tubular sheath **501** and inner pull member **505** are preferably semi-rigid, having enough rigidity to stabilize treatment system **100** while at the same time having enough flexibility to allow movement and manipulation within the patient's vasculature and heart **200**. In these embodiments, stabilization device **105** is preferably configured to be routed from right atrium **205** through PFO tunnel **215** into left atrium **212**, where grasping device **502** can be used to cover a portion of septum primum **214** and anchor stabilization device **105** thereto.

[0153] The nature of the tissue forming septum primum **214** can be irregular, for instance including overlapping folds, variations in tissue thickness and variations in distensibility, each of which can cause septum primum **214** to move, or tent, when needle member **405** is advanced through. The inclusion of grasping device **502** can also provide the additional advantage of holding septum primum **214** in place and reducing the risk of tenting.

[0154] Grasping device **502** preferably includes a flexible grasping element **506** coupled with inner pull member **505**. Here, grasping element **506** is configured as a rectangular element. Outer tubular sheath **501** preferably includes lumen **507** having open distal end **508**, from which grasping element **506** can be deployed. Lumen **507** can be configured with contoured sidewalls to facilitate deployment of grasping element **506**. To deploy grasping element **506**, inner member **505** can be pulled in a proximal direction with respect to outer sheath **501**, causing grasping element **506** to advance through lumen **507** and out of distal end **508**. Grasping element **506** can optionally include an atraumatic end **512**, which in this embodiment is a radio-opaque element, which may be gold or platinum. In this embodiment, grasping element **506** is configured as a deformable, pre-shaped element having three main configurations.

[0155] FIG. **23**A depicts grasping element **506** in a first configuration housed within lumen **507**. This configuration is preferably used while treatment system **100** is moved through the patient's vasculature and as well as when stabilization device **105** traverses PFO tunnel **215**, as depicted here. FIG. **23**B depicts grasping element **506** in a second configuration partially deployed from within lumen **507**. Once stabilization device **105** is advanced through PFO tunnel **215** and out of PFO exit **218**, grasping element **506** is preferably deployed to this configuration by pulling inner member **505** proximally with respect to outer sheath **501**. In this configuration, grasping element **506** can be used to catch the edge of septum primum **214** as stabilization device **105** is pulled slightly back in proximal direction **509**. FIG. **23**C depicts grasping element **506** in a third, fully deployed configuration, after inner member **505** has been pulled back further. Grasping element **506** can optionally include a recess configured to engage an abutment on outer sheath **501** in this configuration, which is preferably used to more fully grasp or engage septum primum **214** to anchor stabilization device **105** thereto.

[0156] Once the delivery procedure is complete, inner member **505** can be advanced distally with respect to outer sheath **501** to draw grasping element **506** back within lumen **507**. Any component of treatment system **100** adequately coupled with stabilization device **105** is thereby also anchored to septum primum **214**. One of skill in the art will readily recognize that this and similar embodiments of stabilization device **105** can be used to engage any tissue flap or edge desired, not solely septum primum **214**.

[0157] Grasping device **502** can be configured in any manner desired in accordance with the needs of the application. FIGS. **24**A-B are perspective views depicting additional exemplary embodiments of stabilization device **105** with grasping device **502**. In FIG. **24**A, grasping device **502** includes multiple grasping elements **506** for grasping over a wider area. In FIG. **24**B, grasping device **502** includes a wire-like grasping element **506**. Here, grasping element **506** is looped into lumen **507** (not shown) via apertures **510** and **511**, which communicate with lumen **507**.

[0158] FIGS. **25**A-D are cross-sectional views depicting additional exemplary embodiments of stabilization device **105**. Here, grasping element **506** has a flap-like shape with tapered inner surface **516** and is located on distal end member **517** of outer sheath **501**. Inner member **505** includes an abutment **514** on distal end portion **515** and is configured to push against and apply a force to grasping element **506**. FIG. **25**A depicts grasping element **506** in the first, housed configuration. To deploy grasping element **506** to the second configuration for catching septum primum **214**, inner member **505** is advanced distally with respect to outer sheath **501** as depicted in FIG. **25**B. Because of tapered inner surface **516**, the more inner member **505** is advanced distally, the more outwards deflection of element **506** will occur. To more fully grasp septum primum **214**, inner member **505** (and body member **101**, if necessary) is refracted proximally by the desired amount, as depicted in FIG. **25**C. Manufacture of this embodiment can be made relatively simple. For instance, distal end member **517** and grasping element **506** can be formed by laser or EDM cutting a NITINOL tube. In FIG. **25**D, distal end member **517** is located on distal end of inner member **505** and abutment **514** is located on sheath **501**.

[0159] FIGS. **26**A-C are cross-sectional views of additional exemplary embodiments of stabilization device **105**. Here, outer sheath **501** preferably includes an open distal end **518**, from which grasping device **502** can be deployed. Grasping element **506** is preferably located on distal end portion **515** of inner member **505** and can be formed of a deformable elastic material such as stainless steel, NITINOL, shape memory polymers and the like. Grasping element **506** is preferably configured to be slidable within inner lumen **504** and is preferably pre-shaped, such as by heat-treating NITINOL, so that grasping element **506** can assume a desired shape when advanced from inner lumen **504**. In FIG. **26**A, grasping element **506** is depicted in the first, housed configuration within inner lumen **504**. In FIG. **26**B, inner member **505** has been advanced distally to deploy grasping element **506** in the second configuration for catching septum primum **214**. In FIG. **26**C, inner member **505** has been advanced further distally to place grasping element **506** in the third configuration for grasping septum primum **214**. Embodiments of stabilization device **105** where grasping device **502** can be deployed by pushing grasping device **502** out from within inner lumen **504**, such as that described with respect to FIGS. **26**A-C, will be referred to herein as "push out" embodiments.

[0160] FIG. **27**A is a perspective view depicting an additional exemplary embodiment of stabilization device **105** having a "push-out" grasping device **502**. Here, grasping device **502** is shown in the fully deployed third configuration having two grasping elements **506**. It should be noted that grasping device **502** can include any number of grasping elements **506**. Here, each grasping element **506** overlaps so as to provide additional grasping force at location **419** where needle member **405** insertion occurs. FIG. **27**B is a cross-sectional view depicting another exemplary embodiment where grasping element **506** is configured to attract to a magnetic force **522** provided by magnet **523** coupled with inner member **505**. Once deployed, the magnetic force is preferably great enough to penetrate outer sheath **501** and septum primum **214** and attract elements **506** to provide additional grasping force. Of course, magnet **523** can be placed in any desired location, for instance, on outer sheath **501** at distal end **518** or on grasping element **506**, in which case inner member **505** could be configured to attract to the magnetic force, or any combination thereof.

[0161] It should be noted that, in order to provide additional surface friction, additional abutments can be included on grasping element **506** and/or the surface of grasping element **506** can be etched or coated or otherwise textured.

[0162] As discussed with respect to FIG. **1**, treatment system **100** can include centering device **106** to facilitate proper placement of implant **103**. Centering device **106** can be configured to align delivery device **104** in the desired location with respect to the center of PFO tunnel **215**. Although the term "centering" is used, it should be understood that centering device **106** can be configured to align delivery device **104** in any location, not necessarily the center of PFO tunnel **215**.

[0163] FIGS. **28**A-C are cross-sectional views depicting additional exemplary embodiments of centering device **106**. In this embodiment, centering device **106** includes an elongate centering support member **601** having two elongate flexible positioning members **602**, referred to herein as centering arms **602**, located on opposite sides of and extending along the length of support member **601**. Support member **601** can include two lumens **603**, each configured to slidably receive a centering arm **602**. Each lumen **603** preferably has an open distal end **606** which opens to an open or recessed portion **605** of support member **601**. Each centering arm **602** preferably extends through this recessed portion **605** and into seat **604** preferably configured to receive distal end **607** of each centering arm **602**. Seat **604** is preferably located in recessed portion **605** in a position opposite to lumen **603**.

[0164] FIG. **28**A depicts centering arms **602** at rest within recessed portion **605** along the sides of support member **601**. The length of recessed portion **605** is indicated as length **609**. FIG. **28**B is a cross-sectional view of centering device **106** taken along line **28**B-**28**B of FIG. **28**A. As depicted here, centering arms **602** are preferably configured as rectangular wire bands, although any configuration can be used as desired. Advancement of centering arms **602** in a distal direction causes distal end **607** to contact seat **604** and forces centering arms **602** to extend outwards from recessed portion **605** as depicted in FIG. **28**C. Configuration of centering arms **602** as bands helps ensure that arms **602** extend directly away from support member **601** in direction **611**.

[0165] When centering device **106** is placed within PFO tunnel **215**, centering arms **602** can be extended until coming into contact with sidewalls **219**, as depicted in FIG. **28**D, which is a perspective view of centering device **106** within PFO tunnel **215**. Here, sidewalls **219** and PFO exit **218** are shown as dashed lines to indicate their presence underneath septum secundum **210**. When centering arms **602** are each advanced the same amount until contact with both sidewalls **219** is made, the extension distance **608** of each arm **602** will likewise be the same amount and support member **601** will be forced into a centered position within PFO tunnel **215**.

[0166] In this manner, centering device **106** can be centered within PFO tunnel **215** and can be used as a reference point for delivering implant **103**. Preferably, centering device **106** is coupled with delivery device **104**, so that centering of centering device **106** will also cause centering of delivery device **104**. Preferably, once implant **103** is delivered, centering arms **602** are retracted proximally into lumens **603** and centering device can then be retracted through PFO tunnel **215**. Surface **610** of recessed portion **605** is preferably curved, or tapered, to reduce the risk that support member **601** will catch or become hung up on any tissue in or around PFO tunnel **215**.

[0167] Here, the extended portions of centering arms **602** are shown as being located entirely within PFO tunnel **215**. One of skill in the art will readily recognize that variation of length **609** of recessed portion **605** will cause the extended portion of centering arms **602** to vary accordingly.

[0168] Support member **601** and centering arm **602** can each be composed of any desired material in accordance with the needs of the application. Preferably, support member **601** is composed of a flexible polymer, such as polyimides, polyamides, polyproylene and the like. Preferably, centering arms **602** are composed of a flexible polymer or metal, such as NITINOL, stainless steel and the like.

[0169] In the embodiment described with respect to FIGS. **28**A-D, centering arms **602** have a curved or arcuate shape when extended from support member **601**. As the FIGS. **29**A-C will show, centering arms **602** can be configured to have any desired shape when extended. FIGS. **29**A-B are schematic views depicting additional exemplary embodiments of centering device **106** with centering arms **602** extended in a three-sided and two-sided shapes, respectively. Preferably, portions **612** of centering arms **602** are made thinner than the surrounding portions, so that centering arms **602** have a tendency to flex first in portions **612**, allowing these polygonal shapes to be achieved.

[0170] Also, arms **602** can be pre-shaped to be biased to assume a desired shape when allowed to expand from recessed portion **605**. For instance, in one exemplary embodiment, arms **602** are composed of NITINOL and are heat-treated for pre-shaping. One of skill in the art will readily recognize, in light of this disclosure, that variation of the thickness of arms **602** and pre-shaping can allow an almost limitless number of shapes to be achieved, having curved portions, straight portions and any combination thereof which can be symmetric or asymmetric.

[0171] As mentioned above, in some cases, sidewalls **219** of PFO tunnel **215** are not equidistant along the length of PFO tunnel **215**, causing PFO tunnel **215** to diverge or converge from PFO entrance **217** to PFO exit **218**. Divergence or convergence of PFO tunnel **215** can cause centering device **106** to slip out from PFO tunnel **215** when arms **602** are extended. FIG. **29**C is a schematic view depicting another exemplary embodiment of centering device **106** where each centering arm **602** is configured to extend with two outcroppings **614**. These outcroppings **614** can be placed outside PFO tunnel **215** to prevent centering device **106** from slipping out of PFO tunnel **215**. Outcroppings **614** can be formed by making that portion of centering arm **602** relatively thicker than the surrounding portions, making outcropping **614** less likely to flex. A desired radius of curvature in centering arms **602** can be implemented by pre-shaping, or by gradually varying the thickness and/or width of centering arms **602**, where a relatively thinner portion will correspond to a relatively larger rate of curvature.

[0172] It should be noted that centering device **106** can include any number of one or more arms **602** for centering/positioning purposes. FIG. **30** is a schematic view depicting another exemplary embodiment of centering device **106** having one centering arm **602** extended within PFO tunnel **215**. In this embodiment, PFO tunnel **215** is curved to one side and centering arm **602** is positioned on the opposite side. Centering arm **602** can then be extended a predetermined distance to position centering device **106** in the desired location.

[0173] In another exemplary embodiment, centering device **106** includes multiple arms **602** configured for use independently of each other to allow the user to have increased control over the position of centering device **106** within PFO tunnel **215**. For instance, the user can adjust two opposing arms **602** to center device **106** between sidewalls **219** within tunnel **215**, and then adjust a third arm **602** to position device **106** as desired relative to septum secundum **210** and septum primum **214**. In another case, the user can use three or more arms **602** for centering based on the tunnel type or anatomy.

[0174] In some embodiments, it can be desirable to keep centering device **106** within PFO tunnel **215** while needle member **405** is advanced through septal wall **207**. To reduce the risk that needle member **405** will contact centering device **106** during this procedure, support member **601** can be configured to deflect needle member **405**. FIG. **31** is a schematic view depicting an exemplary embodiment of centering device **106** where support member **601** is a rigid cylindrical member **649** having a smooth, or polished, surface **615** between lumen **603** and seat **604** (as shown in FIG. **28**A), which are formed in rigid extrusions **650** which are preferable metal and located on member **649**. Here, if sharpened distal end **415** of needle member **405** comes into contact with support member **601**, it is more likely to be deflected from rigid cylindrical member **649**.

[0175] FIGS. **32**A-B are cross-sectional views depicting additional exemplary embodiments of centering device **106** where support member **601** includes an open distal end **616** from which one or more pre-shaped centering arms **602** can be extended. Centering arms **602** are preferably pre-shaped to the extended position allowing elimination of seat **604** and recessed portion **605**. Centering arms **602** are preferably deformable from a first configuration to allow housing within inner lumen **617** of support member **601** as depicted in FIG. **32**A. In FIG. **32**B, centering arms **602** are shown deployed from inner lumen **617** in their extended second configuration. Although in FIGS. **32**A-B, centering arms **602** are shown as separate elements, the proximal end of the pre-shaped portion of each arm **602** can be coupled together on a common elongate shaft.

[0176] It should be noted that the functionality of the various embodiments described herein can be combined and integrated together to reduce the number of components in treatment system **100**, simplify the design of treatment system **100** and so forth. For instance, FIG. **32**C depicts an exemplary embodiment of treatment system **100** where the embodiments described with respect to FIGS. **27**A and **32**A-B have been integrated together to form device **110**. Here, centering arms **602**, similar to that depicted in FIGS. **32**A-B each include grasping element **506** of stabilization device **105**, similar to that depicted in FIG. **27**A, located distal to the centering portion **618**. Here, centering device **106** is used for centering and stabilization, allowing the elimination of a separate stabilization device **105** from system **100**.

[0177] For stabilization and centering, support member **601** is preferably advanced through PFO exit **218**. Once in left atrium **212**, centering arms **602** can be advanced distally to deploy grasping elements **506** from the first, housed configuration, to the second and third configurations for catching and grasping septum primum **214**. Once septum primum **214** is grasped, support member **601** can be refracted proximally with respect to centering arms **602** in order to deploy centering portions **618** of each arm **602**. The centering portions **618** can then expand outwards and center device **106**, thereby preferably also centering body member **101** and delivery device **104**, while at the same time maintaining a grasp of septum primum **214**.

[0178] FIG. **32**D is a schematic view depicting another exemplary embodiment of treatment system **100** where centering device **106** and stabilization device **105** have been integrated together. Here, stabilization member **501** includes two lumens **603** and seats **604** (not shown), and recessed portions **605** for use with centering arms **602**. After stabilization with device **105**, centering arms **602** can be extended in directions **611** to center or otherwise place combined device **110** in the desired position.

[0179] As discussed with respect to FIG. **1**, delivery device **104**, stabilization device **105** and centering device **106** are each preferably used in conjunction with body member **101**. Body member **101** can be configured in any manner desired in accordance with the needs of the application. FIGS. **33**A-B are cross-sectional views depicting another exemplary embodiment of treatment system **100** where body member **101** includes two lumens **630** and **631**. FIG. **33**A is a longitudinal cross-sectional view and FIG. **33**B is a radial cross-sectional view taken along line **33**B-**33**B of FIG. **33**A. Preferably, lumen **630** is configured to slidably receive delivery device **104**, while lumen **631** is configured to slidably receive either stabilization device **105** or an optional guidewire to facilitate routing body member **101** through the patient's vasculature. The guidewire can be placed in lumen **631** until body member **101** is in the desired position within the patient, at which time the guidewire can be removed and stabilization device **105** can be inserted. Also, centering device **106** is preferably integrated with stabilization device **105**, such as in the embodiment described with respect to FIG. **32**D, in order to provide treatment system with both stabilization and centering capability. In order to prevent rotation of elongate body member **101** around stabilization device **105** during delivery, stabilization device is preferably fixably coupled with either body member **101** or delivery device **104**.

[0180] FIGS. **34**A-C are cross-sectional views depicting another exemplary embodiment of treatment system **100** where body member **101** includes four lumens **630**-**633** as well as centering arms **602**. Here, FIG. **34**A is a first longitudinal cross-sectional view, FIG. **34**B is a radial cross-sectional view taken along line **34**B-**34**B of FIG. **34**A and FIG. **34**C is a second longitudinal cross-sectional view taken along line **34**C-**34**C of FIG. **34**A. Preferably, lumen **630** is configured to slidably receive delivery device **104**, while lumen **631** is configured for any purpose, including reception of stabilization device **105**, a guidewire, dye infusion and the like. FIG. **34**B depicts centering arms **602** within lumens **632**-**633** and FIG. **34**C depicts centering arms **602** located within lumens **632**-**633**, recessed portions **605** and seats **604**. Here, recessed portions **605** and seats **604** are located distal to grasping device **404** on elongate support section **411**. The distal portion of support section **411** can be placed within PFO tunnel **215** where centering arms **602** can be deflected for centering prior to deployment of implant **103** in left atrium.

[0181] FIGS. **35**A-B are cross-sectional views depicting another exemplary embodiment of treatment system **100** where body member **101** includes three lumens **630**, **632** and **633** as well as centering arms **602**. Here, FIG. **35**A is a longitudinal cross-sectional view and FIG. **35**B is a radial cross-sectional view taken along line **35**B-**35**B of FIG. **35**A. In this embodiment, distal end **112** of body member **101** includes an atraumatic tip **640**, which in this embodiment is a floppy tip. Here, with the aid of atraumatic tip **640**, body member **101** is configured to be advanceable within the patient's vasculature without the aid of a guidewire. Accordingly, no additional lumen **631** is included for use with a guidewire. Also in this embodiment, stabilization device **105** has been optionally omitted, allowing body member **101** to achieve a relatively smaller radial cross-section size. In another exemplary embodiment, atraumatic tip **640** is omitted and body member **101** is configured to be slidably advanced through a tubular guide catheter placed within the patient's vasculature.

[0182] FIGS. **36**A-B are cross-sectional views depicting another exemplary embodiment of treatment system **100** where body member **101** includes four lumens **630**-**633** as well as centering arms **602**. Here, FIG. **36**A is a longitudinal cross-sectional view and FIG. **36**B is a radial cross-sectional view taken along line **36**B-**36**B of FIG. **36**A. This embodiment is similar to the embodiment described with respect to FIGS. **34**A-C except here, lumen **631** is configured for use with guidewire **641** only, which can be the same size as or relatively thinner than stabilization device **105**, allowing the radial cross-section size of lumen **631** and body member **101** to be reduced.

[0183] FIGS. **37**A-B are cross-sectional views depicting another exemplary embodiment of treatment system **100** where body member **101** includes four lumens **630-633** as well as centering arms **602**. Here, FIG. **37**A is a longitudinal cross-sectional view and FIG. **37**B is a radial cross-sectional view taken along line **37**B-**37**B of FIG. **37**A. This embodiment is similar to the embodiment described with respect to FIGS. **35**A-C except here, lumen **631** is configured to facilitate exchange of stabilization device **105** and guidewire **641**. Proximal portion **642** of lumen **631** includes a divider **643** to separate lumen **631** into a first portion **644** for stabilization device **105** and a second portion **645** for guidewire **641**. Distal portion **646** of lumen **631** is preferably tapered to minimize the radial cross-section size of lumen **631**. Exchange between stabilization device **105** and guidewire **641** is facilitated because both can reside within proximal portion **642** at the same time, with the desired one of stabilization device **105** or guidewire **641** being advanced distally through open distal end **647** for use.

[0184] It should be noted that in each of the embodiments described with respect to FIGS. 33A-37B, functionality can be added or removed as desired, while still remaining within the scope of treatment system **100**. For instance, treatment system **100** can be further configured for dye infusion, pressure sensing, imaging, drug delivery, ablation, the use of occlusive devices such as balloons and stents, facilitating the implantation of coronary sinus pacing or defibrillation leads, the use of a stylet and the like. These and other additional types of functionality can be added in any manner, including, but not limited to the addition of one or more lumens **102**, or the use of the existing lumens **102**, integration directly into body member **101**, or the addition of one or more extra body members **101**.

[0185] In addition, treatment system **100** can include multiple delivery devices **104** for delivery of multiple implants **103**, multiple stabilization devices **105** for stabilization on multiple tissue surfaces, multiple centering devices **106** and multiple body members **101** as desired. If treatment system **100** is used to access septal wall **207** via inferior vena cava **202**, the maximum radial cross-section size of body member **101** is preferably 13 French or less, although it should be noted that any size body member **101** can be used in accordance with the needs of the application. Body member **101** can be constructed from any material as desired, but is preferably constructed from a flexible polymer such as polyethylene, polypropylene, nylon and the like.

[0186] Furthermore, it should be noted that any component or component portion within treatment system **100** can be configured to facilitate any type of imaging, including, but not limited to, internal and external ultrasound imaging, optical imaging, magnetic resonance imaging (MRI), and flouroscopy. For instance, radio-opaque portions can be used to increase the visibility in flouroscopic applications while echolucent coatings can be used to increase visibility in ultrasound applications. As an example, in one exemplary embodiment OA delivery member **401** can be entirely radio-opaque, or can include portions that are radio-opaque, such as on distal tip **430** of FIG. **14**A.

[0187] Also described herein are methods **700** and **800** of treating PFO tunnel **215**, preferably by at least partially closing PFO tunnel **215**. Methods **700** and **800** are preferably used with treatment system **100**, but can be used with any medical system as desired. For ease of discussion, method **700** will be described with respect to treatment system **100** and method **800** will be described without reference to a particular treatment system, although it should be understood that methods **700** and **800** can be used with or without treatment system **100**. Generally, the steps of methods **700** will vary, in part, on the actual configuration of implant **103**, the number of implants **103** to be delivered, the location in which each implant **103** is to be delivered, the use of guidewire **641** or a guide catheter and the optional use of stabilization device **105** and/or centering device **106** or any combination thereof.

[0188] In FIG. **4**E, implant **103** is delivered through both septum primum **214** and septum secundum **210**. It should be noted, however, that implant **103** can be delivered in any location desired. FIGS. **38**A-C are cross-sectional views of septal wall **207** depicting exemplary embodiments of implant **103** in just several of the many alternate locations that can be used. In FIG. **38**A, implant **103** has been delivered through the upper portion of septum secundum **210** adjacent to PFO exit **218**. In FIG. **38**B, implant **103** has been delivered through the lower portion of septum primum **214**, adjacent to PFO entrance **217** and near (or in) fossa ovalis **208**. In FIG. **38**C, implant **103** has been delivered through septal wall **207** adjacent to sidewall **219**, septum primum **214** and septum secundum **210**.

[0189] Also, as many implants **103** can be used in any arrangement as desired. FIGS. **38**D-E are views of septal wall **207** depicting exemplary embodiments of multiple implants **103** in just several of the many alternate arrangements that can be used. In FIG. **38**D, three implants **103** have been delivered through both septum primum **214** and septum secundum **210**. In FIG. **38**E, six implants **103** have been delivered through septal wall **207** adjacent to both sidewalls **219**, septum primum **214** and septum secundum **210**.

[0190] Although there are many different implementations and variations of method **700**, for ease of discussion, method **700** will be described herein as using one implant **103**, delivered through both septum primum **214** and septum secundum **210**, using an exemplary embodiment of treatment system **100** similar to that described above with respect to FIGS. 33A-B, where body member **101** is configured for use with stabilization device **105** having centering device **106** integrated thereon.

[0191] FIGS. **39**A-B are flow diagrams depicting an example of method **700**. First, at **701**, body member **101** is placed in proximity with PFO region **209**. As mentioned above, implant **103** can be delivered from left atrium **212** or right atrium **205**. Preferably, implant **103** is placed into proximity with PFO region **209** by advancing body member **101** from the femoral vein to right atrium **205** in a conventional manner. For instance, in one example, a needle is inserted into the femoral vein and a guidewire is advanced through the needle into the femoral vein. The needle can then be removed and an access sheath can be routed over the guidewire, which can also then be removed. A J-tip guidewire, such as a 0.035"/0.038" guidewire, can be routed through the patient's vasculature into inferior vena cava **202** and right atrium **205**. From there, the guidewire can be routed through PFO tunnel **215** and into left atrium **212**. Next, an exchange sheath or multi-purpose guide can then be advanced over the J-tip guidewire into left atrium **212**, at which point the J-tip guidewire can be removed. A relatively stiffer guidewire **641** can then be advanced through the exchange sheath or multi-purpose guide and into left atrium **212** and optionally the pulmonary vein, which can act as an anchor for the guidewire. Body member **101** can then be advanced over the guidewire **641** into proximity with PFO region **209**, preferably through PFO tunnel **215** and into left atrium **212**. In addition, a catheter or guidewire having a sizing device, such as a balloon, can be placed within PFO tunnel **215** to measure the size of PFO tunnel **215**, for use in choosing a placement location, implant size, etc.

[0192] At **702**, guidewire **641**, if present, can be removed. At **704**, stabilization device **105** is preferably advanced through lumen **631** and into left atrium **212**. At **706**, body member **101** can be retracted proximally into right atrium **205**. Preferably, stabilization device **105** includes a stabilization member **501** and grasping device **502** with grasping element **506**. At **708**, grasping element **506** can be deployed from the first housed configuration to the second configuration for catching tissue, which, in this example, is preferably septum primum **214**.

[0193] Next, at **710**, stabilization member **501** is preferably moved distally until grasping element **506** catches septum primum **214**. Then, at **712**, OA delivery member **401** can be retracted proximally with respect to body member **101** to raise arm member **409**. At **714**, body member **101** and OA delivery member **401** are advanced distally until arm member **409** abuts limbus **211**. At **716**, centering device **106** can be used to center delivery device **104**, preferably by deflecting centering arms **602**. Once centered, if not already done so, at **717** stabilization device **105** can be fixably coupled to delivery device **104** (e.g., with a rotating hemostasis valve or Tuohy-Borst valve and the like). Next, at **718**, grasping element **506** can be further deployed to the third configuration to grasp septum primum **214** and lock stabilization device **105** to septum primum **214**. Alternatively, either **716**, **717**, **718** or any combination thereof can be implemented prior to **712**. Also, **716-718** can be implemented in any order desired with respect to each other.

[0194] Once stabilized, centered and locked in place, OA delivery member **401** is preferably advanced distally with respect to body member **101** to rotate distal end **410** into the desired orientation with surface **320** of septum secundum **210**. At **722**, needle member **405** can be advanced through septum secundum **210** and septum primum **214** and into left atrium **212**. Then, at **724**, pusher member **406** can be advanced distally to at least partially deploy LA portion **302** of implant **103** from distal end **415** of needle member **405**. In embodiments where centering arms **602** are in their deflected state for centering, it is possible for needle member **405** to pass between centering arms **602** and stabilization member **501** when inserted, based on needle insertion location **419**. To avoid capture of implant **103** between centering arms **602** and stabilization member **501**, centering arms **602** can be refracted proximally back into elongate body **101** thereby removing them from seats **604** and preventing implant **103** from being trapped between centering arms **602** and stabilization member **501**. Next, at **726**, grasping element **506** can be moved to the second configuration to free stabilization device **105** from septum primum **214**. Alternatively, **726** can be performed before 724 if desired.

[0195] Then, at **728**, LA portion **302** can be fully deployed if not already. At **730**, grasping element **506** can be removed to the first configuration, housed within stabilization member **501**. Next, at **732**, centering device **106** can be moved to the undeployed configuration if not already, preferably by collapsing centering arms **602**, after which stabilization device **105** can be refracted proximally from PFO entrance **217** at **734**. At **736**, needle member **405** can be withdrawn into OA delivery member **401** to deploy central portion **303** of implant **103** and at least a portion of RA portion **301**. Here, at **738**, an optional closure test can be performed to confirm at least partial closure, and preferably substantially complete closure, of PFO tunnel **215**. Any desired closure test can be performed including, but not limited to, the introduction of gaseous bubbles simultaneously with imaging using contrast enhanced trans-cranial doppler (CE-TCD), intracardiac echocardiography (ICE) and the like, or the infusion of a radio-opaque dye imagable via flouroscopy. The test may be performed by pulling back OA delivery member **401** as far as necessary to deploy RA coil **301** and then test while device is at PFO entrance.

[0196] At **740**, OA delivery member **401** can be refracted proximally with respect to body member **101** to complete deployment of RA portion **301**, release limbus **211** and place OA delivery member **401** in the original position. If the desired degree of closure is confirmed, then any tether connection to implant **103** can be released at **742**. Finally, at **744**, body member **101** can be retracted distally and withdrawn from the patient.

[0197] FIG. **40** depicts another exemplary method **800** of treating a septal defect. At **802**, limbus **211** is abutted with an abutment of a medical device. Preferably, limbus **211** is engaged with the medical device and optionally grasped such that the medical device is anchored to limbus **211**. Then, at **804**, a hole in septal wall **207**, preferably in septum secundum **210**, is created using limbus **211** as a point of reference. For instance, the hole can be created at a fixed or adjustable distance from limbus **211**. At **806**, the hole is used to facilitate delivery of a device configured to treat a septal defect. In one example, the device is deployed through the hole such that it causes at least partial closure of the septal defect. In this example of method **800**, limbus **211** is abutted and used as a reference. In another example of method **800**, the edge of septum primum **214** is abutted and used as a reference. In other examples of method **800**, one or both sidewalls **219** and/or fossa ovalis **208** are abutted and used as points of reference.

[0198] It should be noted that any feature, function, method or component of any embodiment described with respect to FIGS. **1-40** can be used in combination with any other embodiment, whether or not described herein. As one of skill in the art will readily recognize, treatment system **100** and the methods for treating a septal defect can be configured or altered in an almost limitless number of ways, the many combinations and variations of which cannot be practically described herein.

[0199] The devices and methods herein may be used in any part of the body, in order to treat a variety of disease states. Of particular interest are applications within hollow organs including but not limited to the heart and blood vessels (arterial and venous), lungs and air passageways, digestive organs (esophagus, stomach, intestines, biliary tree, etc.). The devices and methods will also find use within the genitourinary tract in such areas as the bladder, urethra, ureters, and other areas.

[0200] Furthermore, the off-axis delivery systems may be used to pierce tissue and deliver medication, fillers, toxins, and the like in order to offer benefit to a patient. For instance, the device could be used to deliver bulking agent such as collagen, pyrolytic carbon beads, and/or various polymers to the urethra to treat urinary incontinence and other urologic conditions or to the lower esophagus/upper stomach to treat gastroesophageal reflux disease. Alternatively, the devices could be used to deliver drug or other agent to a preferred location or preferred depth within an organ. For example, various medications could be administered into the superficial or deeper areas of the esophagus to treat Barrett's esophagus, or into the heart to promote angiogenesis or myogenesis. Alternatively, the off-axis system can be useful in taking biopsies, both within the lumen and deep to the lumen. For example, the system could be used to take bronchoscopic biopsy specimens of lymph nodes that are located outside of the bronchial tree or flexible endoscopic biopsy specimens that are located outside the gastrointestinal tract. The above list is not meant to limit the scope of the invention.

[0201] In some embodiments, the off-axis delivery system is used with an anchoring means in order to anchor the device to a location within the body prior to rotation of the off-axis system. This anchoring means may involve the use of a tissue grasper or forceps. It should be noted that any device or set of devices can be advanced within the lumen of the off-axis delivery system, including but not limited to needles, biopsy forceps, aspiration catheters, drug infusion devices, brushes, stents, balloon catheters, drainage catheters, and the like.

[0202] While the invention is susceptible to various modifications and alternative forms, a specific example thereof has been shown in the drawings and is herein described in detail. It should be understood, however, that the invention is not to be limited to the particular form disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit of the disclosure.

What is claimed is:

1. A method of treating a septal defect, comprising:

placing a delivery device in proximity with a septal wall having a septal defect;

stabilizing the delivery device with an elongate device placed at least partially within the septal defect;

positioning a distal end of the delivery device in a desired orientation with respect to the septal wall, wherein a first longitudinal axis of the delivery device at the distal end is transverse to a second longitudinal axis of the elongate device.

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