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(54) **Titre : APPAREIL ET PROCEDES PERMETTANT DE FILTRER DES EMBOLES LORS DE PROCEDURES DE REMPLACEMENT ET DE REPARATION DE LA VALVULE AORTIQUE PAR VOIE PERCUTANEE AVEC UN SYSTEME DE FILTRATIONACCOUPLE A L'EXTREMITE DISTALE DU MANCHON**

(54) **Title: APPARATUS AND METHODS FOR FILTERING EMBOLI DURING PERCUTANEOUS AORTIC VALVE REPLACEMENT AND REPAIR PROCEDURES WITH FILTRATION SYSTEM COUPLED TO DISTAL END OF SHEATH**

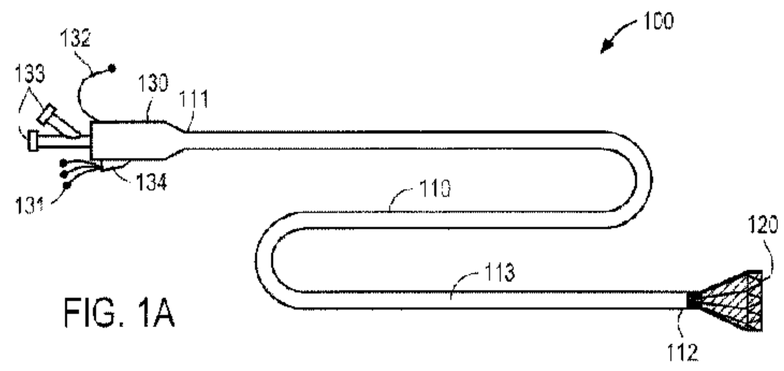

FIG. 1A

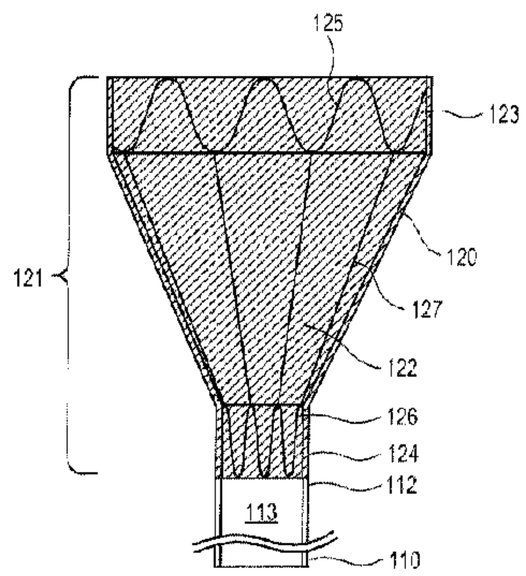

FIG. 1B

(57) **Abrégé/Abstract:**
J Embodiments of the present invention provide apparatus and methods for embolic filtering during percutaneous valve replacement and repair procedures. Under one aspect, an apparatus comprises a sheath and a filter. The sheath has proximal and distal ends and a lumen therebetween. The distal end may be introduced into the aortic arch via the peripheral arteries and ascending aorta, while the proximal end may be disposed outside of the body. The lumen permits percutaneous aortic valve replacement or repair therethrough. The filter has a frame with an inlet and an outlet and an emboli-filtering mesh attached to the frame. The inlet is substantially spans the aortic arch in a region between the aortic valve and the great arteries. The outlet is coupled to the distal end of the sheath without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath.

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[Continued on next page]

(54) **Title**: APPARATUS FOR FILTERING EMBOLI DURING PERCUTANEOUS AORTIC VALVE REPLACEMENT AND REPAIR PROCEDURES WITH FILTRATION SYSTEM COUPLED TO DISTAL END OF SHEATH

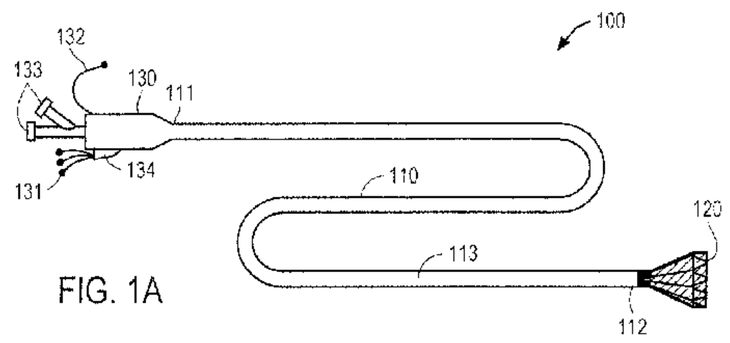

FIG. 1A

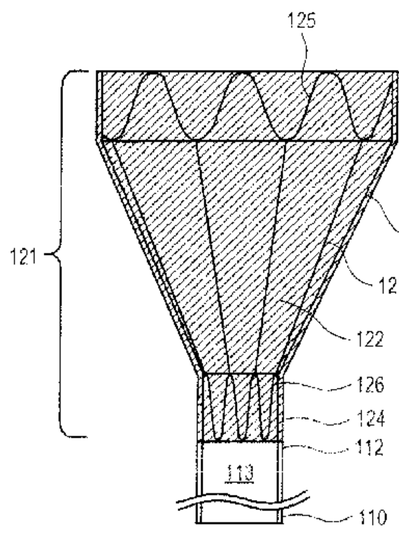

FIG. 1B

(57) **Abstract**: The present invention provides several embodiments of an apparatus for embolic filtering during percutaneous valve replacement and repair procedures. Under one aspect, an apparatus (100) comprises a sheath (110)and a filter (120). The sheath has proximal (111) and distal (112) ends and a lumen (113) therebetween. The distal end may be introduced into the aortic arch via the peripheral arteries and ascending aorta, while the proximal end may be disposed outside of the body. The lumen permits percutaneous aortic valve replacement or repair therethrough. The filter has a frame (121) with an inlet and an outlet and an emboli-filtering mesh (122) attached to the frame. The inlet substantially spans the aortic arch in a region between the aortic valve and the great arteries. The outlet is coupled to the distal end of the sheath without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath.

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APPARATUS AND METHODS FOR FILTERING EMBOLI DURING PERCUTANEOUS AORTIC VALVE REPLACEMENT AND REPAIR PROCEDURES WITH FILTRATION SYSTEM COUPLED TO DISTAL END OF SHEATH

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Provisional Application Ser. No. 61/613,896, filed March 21, 2012.

FIELD OF THE INVENTION

[0002] This application generally relates to filtering emboli during interventional procedures, particularly percutaneous aortic valve replacement and repair procedures.

BACKGROUND OF THE INVENTION

[0003] The recent development of prosthetic valves that can be placed through a catheter into the heart without thoracotomy represents a significant advance in the field of cardiovascular medicine. Early results are very promising and overall reduction in mortality has been achieved with transcatheter aortic valve implantation (TAVI) in high surgical risk patients when compared to medical therapy. One of the limitations for wide acceptance of this technology is the inherent risk of embolic complication during valve access, dilation and implantation. For example, each guidewire, introducer, balloon, cutter, or prosthetic valve that is introduced into the heart via the peripheral arteries and the ascending aorta may inadvertently dislodge one or more emboli, e.g., fragments of unstable plaque, irregular atherosclerotic calcified lesions, or mural thrombus, from the aortic arch, the area surrounding the aortic valve, or the chambers of the heart. The great vessels, which branch off the greater curve of the aortic arch, may transport such emboli to vulnerable locations like the eyes and brain causing stroke or blindness. In addition embolic material can flow past the arch and occlude vessels to the spinal cord causing paralysis, to the bowel causing life threatening mesenteric ischemia/ infarction, or to the renal vessels causing kidney failure, for example.

[0004] Numerous filters have been developed with the purpose of preventing emboli from entering the great vessels, particularly the carotid artery. For example, U.S. Patent No. 8,062,324 to Shimon et al. describes a filter that is supported by a skeleton having a horizontal plane, and that is pressed against the upper portion of the aortic arch by one or more bows so as to filter any blood passing into the great arteries. Shimon describes that the filter may be inserted using a catheter. However, Shimon does not disclose how to remove the filter in such a manner as to prevent filtered emboli from re-entering the blood stream, nor so as to prevent additional emboli from being dislodged by the edges of the skeleton or the bows during removal. Additionally, if additional devices are percutaneously introduced via the ascending aorta, such devices may scrape against the filter and thus potentially cause trauma to the aortic wall or dislodge emboli from the filter. In any such device designed to deflect particles by resting on the greater curve of the arch there is also the issue of device interaction and entanglement since the typical valve is a high profile stiff catheter that will have significant outward bias along the greater curve during advancement across the arch. This type of interaction could result in marriage of the devices together with catastrophic consequences as well as product incompetence if it folds up during catheter exchanges.

[0005] U.S. Patent No 8,052,713 to Khosravi et al. describes an apparatus for filtering emboli from the ascending aorta, that includes a thin, flexible, blood permeable sac having a mouth defined by a support hoop affixed to a guide wire, and a relatively short delivery sheath with a tapered proximal nose and a square distal end. Khosravi describes that the sac and support hoop may be disposed in the delivery sheath, which may be introduced to the ascending aorta via a guidewire. Khosravi describes that the sac may be deployed in the ascending aorta by retracting the support hoop proximally relative to the delivery sheath (in the direction away from the tapered nose), which draws the hoop out of the sheath and allows the sac to open across the aorta, proximal of the brachiocephalic trunk. Khosravi describes that the sac may be retrieved by advancing the support hoop back into the delivery sheath to collapse the sac, and then retracting the delivery sheath back down the ascending aorta. However, the square distal end of the delivery sheath may scrape the aortic arch as it is retrieved and thus potentially loosen additional occlusive material, such as emboli, from the aortic arch. Additionally, because the sac spans the aorta when deployed, the sac may impede the physician's ability to percutaneously introduce other devices to the aorta because such devices may become trapped in the sac, or alternatively may create a gap between the

edge of the sac and the aortic wall, thus providing an avenue for emboli or other occlusive material to bypass the sac.

[0006] Thus, there is a need in the art for embolic filters that may be deployed in the ascending aorta, that safely sequester any filtered occlusive material, such as emboli or thrombus, are shaped to avoid dislodging additional when retrieved, provide protection during all stages of the procedure and allow percutaneous valve replacement or repair procedures to be performed via the peripheral arteries and the ascending aorta without increasing the profile of the delivery sheath, which already may be at the limits of femoral vessel tolerance.

SUMMARY OF THE INVENTION

[0007] Embodiments of the present invention provide apparatus and methods for filtering occlusive material such as emboli or thrombus during percutaneous valve replacement and repair procedures. Such apparatus and methods may safely sequester any filtered emboli, are shaped to avoid dislodging additional emboli when retrieved, are fully compatible with percutaneous valve replacement or repair procedures performed via the peripheral arteries and the ascending aorta, and do not require use of a delivery sheath larger than those already adopted for such percutaneous procedures (e.g., 18 French).

[0008] Under one aspect of the present invention, an apparatus for filtering emboli during a percutaneous aortic valve replacement or repair procedure comprises a sheath and a filter. The sheath has proximal and distal ends and a lumen therebetween. The distal end is configured for introduction into the aortic arch via the peripheral arteries and ascending aorta, while the proximal end being configured to be disposed outside of the body. The lumen is sized to permit percutaneous aortic valve replacement or repair therethrough. The filter has a frame and an emboli-filtering mesh attached to the frame. The frame has an inlet and an outlet. The inlet is configured to substantially span the aortic arch in a region between the aortic valve and the great arteries. The outlet is coupled to the distal end of the sheath without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath.

[0009] In some embodiments, a release line is coupled to the frame of the filter and passes out of the body through the lumen, and is retractable from outside of the body to detach the outlet of the filter from the distal end of the sheath. A groove may be defined in

the lumen of the sheath and configured to receive the release line. A snare may be coupled to the frame of the filter and pass out of the body through the lumen, and may be retractable from outside of the body to draw the filter into the lumen. A groove may be defined in the lumen of the sheath and configured to receive the snare.

[0010] In an alternative embodiment, a snare may be coupled to the frame of the filter and pass out of the body through the lumen, and may be retractable from outside of the body to both detach the outlet of the filter from the distal end of the sheath and to draw the filter into the lumen.

[0011] In some embodiments, the frame comprises a distal, generally cylindrical ring defining the inlet and/or a proximal, generally cylindrical ring defining the outlet. The frame further may comprise a plurality of struts between the rings defining the inlet and the outlet.

[0012] In some embodiments, the sheath has an inner diameter of 18 French or less. The outlet of the filter may have an outer diameter that is greater than the inner diameter of the sheath. Alternatively, the outlet of the filter may have an inner diameter that is greater than an inner diameter of the sheath.

[0013] In some embodiments, the filter has a compressed state and a deployed state. The apparatus may further include a guidewire and an introducer for use in percutaneously introducing the filter and the distal end of the sheath into the aortic arch. The introducer may include a tapered distal nose, a proximal end, a guidewire lumen configured to receive the guidewire, and a recess between the distal nose and the proximal end. The recess may be configured to receive the filter in the compressed state. The introducer may be configured for insertion within the lumen at the distal end of the sheath when the filter is expanded and coupled distally. The filter may be crimped into the recess during the manufacturing process and retained the compressed state within the recess. The introducer, the filter, and the distal end of the sheath may be percutaneously introducible into the aortic arch by pushing the introducer and sheath in their married position (or coupled together) over the guidewire. A control wire may be coupled to the introducer, and the control wire may be configured to advance the introducer while the sheath is maintained in position, allowing for slow deliberate expansion of the filter and avoiding traumatic sudden expansion and advancement out the end of the sheath. The introducer may be retrievable through the outlet of the filter and the lumen of the sheath after the filter expands to the deployed state by retracting the

control wire. A portion of the sheath may be pre-curved to conform to the aortic arch, and the introducer may straighten the pre-curved portion of the sheath when inserted therein.

[0014] Under another aspect of the present invention, a method of filtering emboli during a percutaneous aortic valve replacement or repair procedure may include providing a sheath having proximal and distal ends and a lumen therebetween; and providing a filter coupled to the distal end of the sheath. The filter may have a compressed state and a deployed state, a frame, and an emboli-filtering mesh attached to the frame. The frame may have an inlet and an outlet, the inlet being configured to substantially span the aortic arch in a region between the aortic valve and the great arteries in the deployed state. The outlet of the filter is coupled to the distal end of the sheath within the aortic arch without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath. The filter may be advanced through the previously positioned sheath via an introducer with a recess that will accommodate the filter and a control wire mechanism coupled to the introducer may be used to control expansion during deployment of the filter.

BRIEF DESCRIPTION OF DRAWINGS

[0015] FIG. 1A illustrates a perspective view of a catheter for use in percutaneous aortic valve replacement or repair including an embolic filter and sheath assembly in an expanded configuration, according to some embodiments of the present invention.

[0016] FIG. 1B illustrates a detailed perspective view of the embolic filter and sheath assembly of FIG. 1A.

[0017] FIG. 2A illustrates a perspective view of an exemplary coupling/release mechanism that may be used with the embolic filter and sheath assembly of FIGS. 1A-1B.

[0018] FIG. 2B illustrates a perspective view of the distal end of an exemplary sheath that may be used with the embolic filter and sheath assembly of FIGS. 1A-1B.

[0019] FIG. 2C illustrates a plan view of a pre-curved sheath that optionally may be used with the embolic filter and sheath assembly of FIGS. 1A-1B.

[0020] FIGS. 3A-3F illustrate cross-sectional views of an introducer that may be used with the embolic filter and sheath assembly of FIGS. 1A-1B.

[0021] FIG. 4 illustrates steps in a method of using the embolic filter and sheath assembly of FIGS. 1A-1B and the introducer of FIGS. 3A-3F in an aortic arch during a percutaneous procedure.

[0022] FIGS. 5A-5C illustrate cross-sectional views of the embolic filter and sheath assembly of FIGS. 1A-1B and the introducer of FIGS. 3A-3F in an aortic arch during various steps of the method of FIG. 4.

[0023] FIGS. 6A-6C illustrate perspective views of an exemplary release mechanism that may be used to remove the embolic filter and sheath assembly of FIGS. 1A-1B.

[0024] FIGS. 7A-7I illustrate perspective views of another exemplary release mechanism that may be used to remove the embolic filter and sheath assembly of FIGS. 1A-1B.

[0025] FIGS. 8A-8C illustrate perspective views of another exemplary release mechanism that may be used to remove the embolic filter and sheath assembly of FIGS. 1A-1B.

[0026] FIGS. 9A-9D illustrate perspective views of the operation of an exemplary release mechanism that may be used to remove the embolic filter and sheath assembly of FIGS. 1A-1B.

DETAILED DESCRIPTION

[0027] Embodiments of the invention provide embolic filters that readily may be used during percutaneous aortic valve replacement and repair procedures and that overcome the above-noted shortcomings of previously-known systems. The inventive filters may be coupled to the distal end of a sheath suitable for percutaneous delivery into the aorta, e.g., an 18F sheath, and then compressed and mounted on an introducer that has a tapered nose and is disposed in the distal end of the sheath. The sheath, introducer, and compressed filter then are introduced to the aortic arch via the peripheral arterial system (e.g., femoral artery) and ascending aorta. The filter then is deployed from the distal end of the sheath by advancing the introducer relative to the sheath such that the filter expands to a deployed configuration at a location upstream of the great arteries, and the introducer then removed via the lumen of the sheath. The filter is securely coupled to the distal end of the sheath in such a manner that the full lumen of the sheath may be used for additional percutaneous procedures, e.g., to

percutaneously introduce a guidewire, introducer, balloon, cutter, and/or prosthetic valve to the heart via the sheath. Then, when the percutaneous procedure is complete and any other devices have been removed from the lumen of the sheath, a release line may be retracted from outside of the body to detach the filter from the end of the sheath, and a snare on the filter may be used to close the filter and retract the filter and any captured emboli into the lumen of the sheath after venting the sheath. The sheath then may be removed by retracting it from the ascending aorta and peripheral arterial system. As such, the inventive filters do not interfere with other percutaneously introduced devices, are compatible with 18 French sheaths, safely sequester filtered emboli when removed, and are shaped to avoid dislodging additional emboli when removed.

[0028] First, an overview of a catheter system including the inventive embolic filter and sheath assembly will be described. Then, further details will be provided on the construction of the sheath and embolic filter, respectively. Lastly, some alternative embodiments will be described.

[0029] FIG. 1A illustrates percutaneous catheter 100 including sheath 110, filter 120, and handle 130. Sheath 110 generally is in the form of an elongated tube having proximal end 111 and distal end 112, with lumen 113 therebetween. Preferably, sheath 110 has a diameter suitable for percutaneous use, e.g., has an inner diameter of 18 French or smaller. In some embodiments, sheath 110 includes reinforcing rings of metal or polymer to inhibit collapse of the sheath when curved around the aortic arch.

[0030] Filter 120 includes a frame and an emboli-filtering mesh attached to the frame. The frame defines an inlet and an outlet of filter 120. Preferably, the inlet has lateral dimensions approximately equal to those of the aortic arch between the aortic valve and the great arteries, where the filter will be deployed, so that the emboli-filtering mesh will filter substantially all of the blood passing through the aorta and remove emboli therefrom. The outlet of filter 120 is detachably coupled to distal end 112 of sheath 110, preferably without any gaps therebetween that would allow emboli to pass. The outlet of filter 120 also preferably has an inner lumen with a diameter that is at least as large as the inner diameter of sheath 110, so that filter 120 does not obstruct the lumen at the distal end of the sheath, thus allowing a physician to perform percutaneous procedures via the sheath without interference from filter 110.

[0031] Handle 130 is coupled to proximal end 111 of sheath 110, and includes release line 131 via which filter 120 may be detached from distal end 112 of sheath 110 while deployed, snare control 132 via which filter 120 may be retrieved by retracting the filter into the lumen at the distal end 112 of sheath 110, and various additional ports and passages, generally designated 139, via which a physician may introduce additional percutaneous devices. Handle 130 also may include a controller line (not shown) for controlling an introducer that may be used to deploy the filter, such as described below with reference to FIGS. 3A-3C.

[0032] Note that as used herein with reference to elements for insertion into the body, the term "distal" refers to the end that is inserted into the body first, e.g., the leading end of sheath 110 or filter 120 during advancement into the body, whereas the term "proximal" refers to the opposite end.

[0033] FIG. 1B illustrates a perspective view of an assembly including filter 120 and distal end 112 of sheath 110. Filter 120 includes frame 121 and mesh 122 attached thereto, e.g., by sutures, adhesives, dip molding, laser bonding, sandwich layers on each side of the struts melted or glued together, heat setting or the like. In the illustrated embodiment, frame 121 includes first and second generally cylindrical rings 123, 124. First ring 123 defines the inlet of filter 120, which as noted above preferably is of similar dimension to the ascending aorta in the region where the filter is to be deployed, e.g., between the aortic valve and the great arteries, so as to securely seat against the aortic wall and prevent emboli from slipping past the filter. Second ring 124 defines the outlet of filter 120, which is of similar dimension to distal end 112 of sheath 110. Specifically, second ring 124 is sized such that it does not obstruct lumen 113 of sheath 110 at distal end 112, so that the physician may conduct percutaneous procedures through lumen 113 without interference from filter 120. For example, second ring 124 may have an inner diameter that is equal to, or larger than, the inner diameter of lumen 113, and/or may have an outer diameter that is larger than the inner diameter of lumen 113.

[0034] First and second rings 123, 124 preferably are formed of a shape memory material, e.g., a metallic alloy such as Nitinol, stainless steel, MP35N, elgiloy or a shape memory polymer such as polyurethane or a block copolymer thereof, polyethylene terephthalate or a block copolymer thereof, polyethylene oxide or a block copolymer thereof, and the like. First and second rings 123, 124 respectively include struts 125, 126, which may

be sinusoids, zigzags, or other suitable shape that permits rings 123, 124 to be radially compressed into a compressed state for delivery and to return to a deployed state when expanded in the aortic arch. Optionally, frame 121 includes struts 127 that extend between first and second rings 123, 124. Struts 127 may have any suitable shape, including linear, sinusoids, or curves, and may extend within the interior surface of mesh 122 and/or may extend outside of the exterior surface of mesh 122. In other embodiments, only mesh 122 extends between first and second rings 123, 124, allowing the rings to freely move relative to one another so as to lessen the effect of blood-flow-induced torque that otherwise may cause filter 120 to tilt relative to sheath 110 and thus form a gap through which emboli may pass.

[0035] Mesh 122 preferably covers the entire outer surface of filter 120, including first and second rings 123, 124, such that substantially all of the blood in the aorta flows through filter 120 with no gaps. Mesh 122 has a surface area and pore size suitable to allow a sufficient volume of blood to pass therethrough to maintain the patient's blood pressure in a normal range, and also to avoid pressure buildup that otherwise may rupture mesh 122. Mesh 122 may include any suitable material known in the art, including a fabric, polymer, or flexible metal having pores of appropriate size to filter emboli having diameters of, e.g., 20 μm or greater, or 50 μm or greater, or 100 μm or greater, or 150 μm or greater, or 200 μm or greater. In one illustrative embodiment, mesh 122 is a polyurethane film of thickness 0.0003 inches to about 0.0030 inches and having holes defined therethrough, e.g., circular, square, or triangular holes in a suitable size and density to permit substantially the entire aortic blood flow to pass therethrough without a detrimental amount of resistance.

[0036] FIG. 2A illustrates an exemplary coupling/release mechanism that may be used to couple and subsequently detach filter 120 from distal end 112 of sheath 110 and pull the filter into lumen 113 of the sheath. Second ring 124 of filter 120 is coupled to a release line 131 that passes out of the patient's body through sheath 110 via lumen 135 and into handle 130 as illustrated in FIG. 1A. Release line 131 is coupled to, or includes, a wire or suture 133 that loops through sinusoids 126 of second ring 124, as well as through sheath elements 134 which are embedded in distal end 112 of sheath 110. Tension in wire/suture 133 causes second ring 124 to securely seat against distal end 112. As described in greater detail below with reference to FIGS. 6A-6C, retraction of release line 131 from outside the body may break wire/suture 133, releasing such tension and detaching ring 124 from distal end 112. In some embodiments, wire/suture 133 and/or release line 131 is formed of a relatively stiff

material such as stainless steel or a shape memory alloy, so as to maintain a relatively large amount of tension to retain second ring 124 against distal end 112. In other embodiments, wire/suture 133 and/or release line 131 may be formed of a relatively flexible material such as fiber or polymer, so that wire/suture 133 may easily be broken, thus detaching ring 124 from distal end 112. Sheath elements 134 may be formed of a relatively stiff material such as stainless steel or a shape memory alloy. Other possible configurations for sheath elements 134 are described further below with reference to FIGS. 7B-7C. Note also that instead of looping wire/suture 133 through sinusoids 126 as described with reference to FIG. 2A, a fabric ring may be coupled to second ring 124 and wire/suture 133 woven therethrough instead, such as described further below with reference to FIGS. 7A-7I.

[0037] As illustrated in FIG. 2A, second ring 124 also is coupled to snare 132, which is coupled to, or includes, wire 135 that loops about second ring 124 and passes out of the patient's body through groove 136 and into handle 130 as illustrated in FIG. 1A. Retracting snare 132 via handle 130 first causes wire 135 to radially contract second ring 124, and then pulls filter 120 into lumen 113 sheath 110 for removal from the body. Such a process is described further below with reference to FIGS. 6A-6C. In some embodiments, wire 135 and/or snare 132 is formed of a relatively stiff material such as stainless steel or a shape memory alloy, so as to impose relatively large compressive forces on second ring 124.

[0038] FIG. 2B illustrates distal end 112 of sheath 110 in greater detail. Release line 131 (not shown in FIG. 2B) may be disposed within lumen 135, and snare 132 (not shown in FIG. 2B) may be disposed within groove 136 defined in the inner surface 118 of sheath 110. Such an arrangement may inhibit interference between release line 131 or snare 132 and any devices that may be percutaneously introduced to the patient via sheath 110. In particular, groove 136 may be of such a depth that snare 132 does not reduce the effective inner diameter of lumen 113, thus allowing the physician to make full use of lumen 113 without obstruction during a percutaneous procedure. Alternative embodiments described below with reference to FIGS. 8A-9D use a combined snare/release mechanism that uses only a single groove through which filter 120 may be detached from distal end 112 of sheath 110 and pulled into lumen 113, thus further simplifying construction of sheath 110 and reducing the possibility of interference with instruments during the percutaneous procedure.

[0039] Optionally, sheath 110 is pre-curved to follow the curve of the patient's aortic arch, such as illustrated in FIG. 2C where bend 119 is disposed proximal of distal end 112.

Pre-curving sheath 110 as such may help to reduce tension the aortic arch may otherwise place on sheath 110 and/or filter 120 when deployed therein. Preferably, inserting introducer 300 (described further below with reference to FIGS. 3A-3F) into sheath 110 temporarily straightens bend 119; later, when introducer 300 is removed from sheath 110, bend 119 returns and generally follows the curve of the patient's aortic arch.

[0040] FIG. 3A illustrates an introducer 300 that may be used to introduce and deploy filter 120 into a patient's aortic arch. Introducer 300 includes tapered distal nose 301, proximal end 302, a guidewire lumen 303 configured to receive a guidewire (not illustrated in FIG. 3A), and a recess 304 between the distal nose and proximal end having cover 305 disposed thereover. Recess 304 is configured to receive filter 120 in a compressed state. For example, as illustrated in FIG. 3B, compressed state filter 120' may include radially compressed first ring 123', radially compressed second ring 124', folded mesh 122', and compressed struts 127'. Section 302 of introducer 300 may be tapered as shown to accommodate tilting of compressed second ring 124' caused by coupling of that ring to distal end 112 of sheath 110. Recess 304 of introducer 300 may be configured to have a length approximately equal to the length of compressed state filter 120', and an outer diameter (defined by the outer surface of cover 305) suitable for percutaneous insertion. Cover 305 may retain sliding of filter 120' in the proximal or lateral directions. Radiopaque markers (not shown) may be provided on introducer 300 and/or on filter 120/120' so as to assist the physician in properly positioning introducer 300 and filter 120/120' in the aortic arch.

[0041] As illustrated in FIG. 3B, when introducer 300 is inserted into lumen 113 of sheath 110, tapered nose 301 and cover 305 provide a smooth surface when introducer 300, compressed state filter 120', and distal end 112 of sheath 110 are percutaneously advanced into the aortic arch by pushing introducer 300 over the guidewire (not illustrated) via sheath 110. Preferably, introducer 300 also includes control line 306 which is coupled to proximal end 302 and which passes out of the body via lumen 113 of sheath 110 and an appropriate port (not illustrated). Control line 306 may be used to advance introducer 300 while sheath 110 is held in place so as to allow compressed state filter 120' to expand into the deployed state, e.g., filter 120 illustrated in FIGS. 1A-1B.

[0042] For example, FIG. 3C illustrates the relative positioning of introducer 300, filter 120, and sheath 110 when introducer 300 is partially advanced out of lumen 113 of sheath 110 by advancing control line 306 relative to sheath 110. As introducer 300 is moved

distally, partially deployed struts 127" of partially deployed filter 120" bow outwardly as the struts are no longer retained beneath cover 305. At the illustrated stage of deployment, first ring 123' of filter 120" is retained in the compressed state within recess 304 and beneath cover 305. However, second ring 124 of filter 120" is no longer in the compressed state because it is no longer within recess 304 or beneath cover 305.

[0043] As illustrated in FIG. 3D, when introducer 300 is further advanced out of lumen 113 of sheath 110 via control line 306, first ring 123 of filter 120 opens to a fully deployed state, as do struts 127, because first ring 123 is no longer within recess 304 or beneath cover 305. Then, as illustrated in FIG. 3E, introducer 300 may be removed via lumen 113 by retracting control line 306. Further details on the use of introducer 300 to deploy filter 120 are described in greater detail below with reference to FIGS. 4 and 5A-5C.

[0044] A method of percutaneously deploying filter 120 and distal end of sheath 112 in the aortic arch for filtering emboli during a percutaneous procedure will now be described with reference to FIG. 4, which illustrates steps in method 400, and FIGS. 5A-5C, which illustrate the relative positions of components of apparatus 100 and a patient's heart.

[0045] Method 400 includes providing a sheath having proximal and distal ends and a lumen therebetween (step 410), for example sheath 110 illustrated in FIGS. 1A-2C.

[0046] A filter is also provided having a compressed state and a deployed state, a frame having an inlet sized to span the aortic arch in the deployed state and an outlet, and an emboli-filtering mesh attached to the frame (step 420), for example filter 120/120' illustrated in FIGS. 1A-1B.

[0047] The filter then may be coupled to the distal end of the sheath (step 430), e.g., with a wire/suture such as illustrated in FIG. 2A. The filter then may be compressed within the recess of an introducer (step 440), e.g., as described above with reference to FIGS. 3A-3F.

[0048] The introducer, the filter, and the distal end of the sheath then may be introduced into the aortic arch (step 450). For example, introducer 300 may be inserted into lumen 113 at distal end 112 of sheath 110, and compressed state filter 120' may be crimped into recess 304 of the introducer and covered with cover 305. Then, as illustrated in FIG. 5A, assembly 300, 120', 112 (filter 120' not shown in FIG. 5A) may be percutaneously advanced into aortic arch 510 of a patient's heart 500 over guidewire 510 through guidewire lumen 303 of

introducer 300, by pushing on the proximal end 111 of sheath 110 from outside the patient's body. Assembly 300, 120', 112 (filter 120' not shown in FIG. 5A) is preferably pushed to a location in aortic arch 501 that is between aortic valve 502 and great arteries 503.

[0049] Referring again to FIG. 4, the filter then may be expanded from the compressed state to the deployed state within the aortic arch (step 460). For example, as illustrated in FIG. 5B, introducer 300 may be advanced from outside the patient's body, e.g., using control line 306 described above with reference to FIGS. 3A-3F, while the position of sheath 110 is maintained. Such advancement of introducer 300 allows compressed state filter 120' to expand to deployed state filter 120 which, as illustrated in FIG. 5B, substantially spans the aortic arch between aortic valve 502 and the great arteries 503. In particular, control line 306 maintains the relative positioning of compressed second (proximal) ring 124' of compressed filter 120' and introducer 300, thus facilitating slow, deliberate expansion of filter 120 as sheath 110 is retracted and avoiding traumatic sudden expansion of filter 120 out of sheath 110. Introducer 300 then may be removed via lumen 113, e.g., by retracting control line 306 from outside the body, leaving the lumen of sheath 110 unobstructed, as illustrated in FIG. 5C.

[0050] Referring again to FIG. 4, a percutaneous procedure may be performed on the aortic valve through the lumen of the sheath (470). Such percutaneous procedures may involve, for example, percutaneously introducing a guidewire, introducer, balloon, cutter, and/or prosthetic valve to the heart through sheath 110 and filter 120 as illustrated in FIG. 5C. For example, the physician may implant a prosthetic aortic valve that is specifically configured for percutaneous delivery via an 18 French sheath, such as the COREVALVE™ device manufactured by Medtronic, or the SAPIEN™ device manufactured by Edwards Lifesciences. Advantageously, filter 120, tensioning lines 131, and snare 132 do not obstruct lumen 113 of sheath 110, so that the physician may perform any desired percutaneous procedure using the full diameter of sheath 110. Filter 120 captures any emboli that may be freed from the region surrounding the aortic valve during such procedure, thus reducing the patient's risk of stroke from embolization.

[0051] An illustrative method of removing filter 120 and any filtered emboli from the body will now be described with reference to FIGS. 6A-6D. As illustrated in FIG. 6A, release line 131 may be retracted from outside the body, causing breakage of suture/wire 133' and allowing free end 133" of broken suture/wire 133' to come loose from sheath elements

134 and sinusoids 126 of second ring 124, thus detaching filter 120 from sheath 110. Then, as illustrated in FIG. 6B, retraction of snare 132 in the proximal direction causes wire 135 to radially compress proximal end 129 of second ring 124, resulting in partially compressed second ring 124''' having a generally hourglass shape as illustrated in FIG. 6B, and to begin to retract partially compressed second ring 124''' into lumen 113 of sheath 110. Further retraction of snare 132 in the proximal direction pulls proximal end 129 of second ring 124''' fully into lumen 113 of sheath 110 as illustrated in FIG. 6C. Further retraction of snare 132 in the proximal direction retracts the entirety of filter 120, including any emboli therein, into a compressed removal state within lumen 113 of sheath 110. Sheath 110 then may be withdrawn from the body by pulling the sheath in the proximal direction. Advantageously, sheath 110 does not have any sharp corners that would potentially loosen emboli during such removal. Additionally, any emboli within filter 120 advantageously remain within lumen 113 during the removal process, so as to further reduce the patient's chance of stroke due to embolization.

[0052] FIGS. 7A-7I illustrate an alternative mechanism that may be used to release filter 120 from sheath 110 prior to retraction with snare 132 into lumen 113. Referring to FIG. 7A, second ring 124 of filter 120 is coupled via sutures, adhesive, or the like to fabric ring 701, which is a ring of flexible, biocompatible fabric having a length sufficiently short to avoid folding-in of the fabric during device or introducer retraction. Wire/suture 733 is stitched or woven through fabric ring 701 and sheath elements 734, which secures filter 120 to distal end 112 of sheath 110. Sheath elements 734 may be closed arches having both ends embedded in distal end 112 of sheath 110, such as illustrated in FIGS. 7A-7B, or may have a construction similar to the eye of a needle, with an aperture spaced some distance away from distal end 112, such as illustrated in FIG. 7C.

[0053] The two ends of wire/suture 733 are coupled to locking mechanism 732, which in the illustrated embodiment includes a "J"-shaped hook 735 that is coupled to release line 731 within lumen 736. Hook 735 may be formed of a shape memory alloy such as described above. As can be seen in FIG. 7A, a first end of wire/suture 733 is coupled to one side of hook 735, which is disposed within pocket 737 defined within distal end 112 of sheath 110, while the second end of wire/suture 733 is coupled to the other side of hook 735. As such, hook 735 securely retains the ends of wire/suture 733 and thus maintains coupling between filter 120 and sheath 110 until hook 735 is retracted via release line 731. Further details on

coupling wire/suture 733 to hook 735 are provided further below with reference to FIGS. 7D-7G, and further details on detaching filter 120 from sheath 110 using wire/suture 711, hook 735, and release line 731 are provided further below with reference to FIGS. 7H-7I.

[0054] Referring now to FIG. 7D, hook 735 includes short end 738, and long end 739. Short end 738 may be moved relative to distal end 112 of sheath 110 by pushing or retracting release line 731, which may be integrally formed with hook 735, e.g., using a shape memory alloy. As illustrated in FIG. 7E, first end 741 of wire/suture 733 may include a loop through which short end 738 of hook 735 fits, while second end 742 of wire/suture 733 may include a loop through which long end 739 of hook 735 fits. FIG. 7F illustrates motion of hook 735 in the proximal direction when release line 731 is partially retracted, during which short end 738 of hook 735 becomes disposed in pocket 737 defined at distal end 112 of sheath 110. As illustrated in FIG. 7G, such motion of hook 735 secures the first and second ends 741, 742 of wire/suture 733, which as discussed above securely couples filter 120 to sheath 110. FIG. 7H illustrates further motion of hook 735 in the proximal direction when release line 731 is more fully retracted, during which short end 738 of hook 735 is pulled out of pocket 737 and drawn into release line lumen 736. As illustrated in FIG. 7I, such motion of hook 735 releases the first and second ends 741, 742 of suture, which as discussed above detaches filter 120 from sheath 110.

[0055] FIGS. 8A-8C illustrate another alternative mechanism that may be used to release filter 120 from sheath 110 prior to retraction into lumen 113. In this embodiment, a combined release/retraction mechanism permits both functions to be performed using only a single mechanism, thus simplifying the design of sheath 110 by obviating the need to provide multiple separate grooves or lumens to control release and retraction of filter 120. Referring to FIG. 8A, second ring 124 of filter 120 is coupled via sutures, adhesive, or the like to fabric ring 801, which is a ring of flexible, biocompatible fabric having a length sufficiently short to avoid folding-in of the fabric during device or introducer retraction. Wire/suture 833 is stitched or woven through fabric ring 801 and sheath elements 834, which secures filter 120 to distal end 112 of sheath 110. Wire/suture 833 passes through locking mechanism 832, which in the illustrated embodiment includes an release segment 835 configured to break wire/suture 833 by applying electrical current or voltage thereto.

[0056] As illustrated in FIGS. 8B-8C, in which filter 120 and sheath 110 are not shown, electrical current or voltage may be passed to release segment 835 along modified snare line

132', which is coupled to current generator 836. Current generator 836 may include a safety latch or cover 837 to protect against inadvertent application of electrical current to release segment 835. Release segment 835 includes first and second terminals 838, 839, across which electrical current or voltage may be applied by disabling safety latch or cover 837 and actuating current generator 836 such as illustrated in FIG. 8C. The resulting breakage of wire/suture 833' detaches filter 120 from sheath 110 and allows filter 120 to be retracted into lumen 113 of sheath 110 by retracting modified snare line 132' in a similar manner as described above.

[0057] Materials suitable for use in wire/suture 833, e.g., materials that may be formed into wires or sutures and that break when electrical current or voltage is applied thereto, are known in the relevant art.

[0058] FIGS. 9A-9D illustrate another alternative mechanism that may be used to release filter 120 from sheath 110 prior to retraction into lumen 113. In this embodiment, a combined release/retraction mechanism permits both functions to be performed using only a single mechanism, thus simplifying the design of sheath 110 by obviating the need to provide multiple separate grooves or lumens to control release and retraction of filter 120. Referring to FIG. 9A, second ring 124 of filter 120 is coupled via sutures, adhesive, or the like to fabric ring 901, which is a ring of flexible, biocompatible fabric having a length sufficiently short to avoid folding-in of the fabric during device or introducer retraction. Wire/suture 933 is stitched or woven through fabric ring 901, and the first and second ends 941, 942 of wire/suture 933 are looped around pull pin 935. Pull pin 935 is disposed in pouch 936 attached to fabric ring 901. The combination of elements 901, 933, 935, and 936 secures filter 120 to the distal end of sheath 110.

[0059] As illustrated in FIG. 9B, modified snare line 132" passes through loop 937 of pin 935, and is attached to segment 938 which has a larger outer diameter than the inner diameter of loop 937. Modified snare line 132" also includes slack portion 939 that facilitates detachment of filter 120 from sheath 110 before the filter is retracted into lumen 113 of sheath 110. Specifically, as illustrated in FIG. 9C, initial retraction of modified snare line 132" pulls segment 938 in the proximal direction, causing segment 938 to engage loop 937 of pin 935 while slack portion 939 is drawn taut. Such motion pulls pin 935 proximally out of pouch 936, which frees the first and second ends 941, 942 of wire/suture 933 and detaches

filter 120 from sheath 110. Further retraction of modified snare line 132" draws filter 120 into lumen 113 of sheath 110, such as described above and as illustrated in FIG. 9D.

[0060] While various illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made therein without departing from the invention. For example, although the embodiments above have been described primarily with respect to configurations suitable for use in the aortic arch, it should be appreciated that the apparatus and methods suitably may be modified for percutaneous use in other blood vessels and for other applications including but not limited to: treatment of atherosclerotic arterial disease, aneurysmal disease and venous thrombosis. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED:

1. Apparatus for filtering emboli during a percutaneous aortic valve replacement or repair procedure, the apparatus comprising:

a sheath having proximal and distal ends and a lumen therebetween, the distal end being configured for introduction into the aortic arch via the peripheral arteries and ascending aorta, the proximal end being configured to be disposed outside of the body, the lumen being sized to permit percutaneous aortic valve replacement or repair therethrough; and

a filter having a frame and an emboli-filtering mesh attached to the frame, the frame having an inlet and an outlet, the inlet being configured to substantially span the aortic arch in a region between the aortic valve and the great arteries, the outlet being coupled to the distal end of the sheath without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath.

2. The apparatus of claim 1, further comprising a release line coupled to the frame of the filter and passing out of the body through the lumen, the release line being retractable from outside of the body to detach the outlet of the filter from the distal end of the sheath.

3. The apparatus of claim 2, wherein a groove is defined in the lumen of the sheath and configured to receive the release line.

4. The apparatus of claim 2, further comprising a snare coupled to the frame of the filter and passing out of the body through the lumen, the snare being retractable from outside of the body to draw the filter into the lumen.

5. The apparatus of claim 4, wherein a groove is defined in the lumen of the sheath and configured to receive the snare.

6. The apparatus of claim 1, further comprising a snare coupled to the frame of the filter and passing out of the body through the lumen, the snare being retractable from outside of the body to detach the outlet of the filter from the distal end of the sheath and to draw the filter into the lumen.

7. The apparatus of claim 1, wherein the frame comprises a generally cylindrical ring defining the inlet.

8. The apparatus of claim 7, wherein the frame further comprises a generally cylindrical ring defining the outlet.

9. The apparatus of claim 8, wherein the frame further comprises a plurality of struts between the rings defining the inlet and the outlet.

10. The apparatus of claim 1, wherein the sheath has an inner diameter of 18 French or less.

11. The apparatus of claim 10, wherein the outlet of the filter has an outer diameter that is greater than the inner diameter of the sheath.

12. The apparatus of claim 10, wherein the outlet of the filter has an inner diameter that is greater than the inner diameter of the sheath.

13. The apparatus of claim 1, the filter having a compressed state and a deployed state, the apparatus further comprising a guidewire and an introducer for use in percutaneously introducing the filter and the distal end of the sheath into the aortic arch, the introducer comprising:

a tapered distal nose;

a proximal end;

a guidewire lumen configured to receive the guidewire; and

a recess between the distal nose and the proximal end, the recess being configured to receive the filter in the compressed state,

the introducer being configured for insertion within the lumen at the distal end of the sheath and to retain the filter in the compressed state within the recess,

the introducer, the filter, and the distal end of the sheath being percutaneously introducible into the aortic arch by pushing the introducer over the guidewire via the sheath.

14. The apparatus of claim 13, further comprising a control wire coupled to the introducer, the control wire configured to advance the introducer while the sheath is held in place, such advancement of the introducer allowing the filter to expand from the compressed state to the deployed state.

15. The apparatus of claim 14, the introducer being retrievable through the outlet of the filter and the lumen of the sheath after the filter expands to the deployed state by retracting the control wire.

16. The apparatus of claim 13, wherein a portion of the sheath is pre-curved to conform to the aortic arch, wherein the introducer straightens the pre-curved portion of the sheath when inserted therein.

17. A method of filtering emboli during a percutaneous aortic valve replacement or repair procedure, the method comprising:

providing a sheath having proximal and distal ends and a lumen therebetween;

providing a filter having a compressed state and a deployed state, the filter having a frame and an emboli-filtering mesh attached to the frame, the frame having an inlet and an outlet, the inlet being configured to substantially span the aortic arch in a region between the aortic valve and the great arteries in the deployed state, the outlet being coupled to the distal end of the sheath without leaving any gaps through which emboli could pass and without obstructing the lumen at the distal end of the sheath;

percutaneously introducing the distal end of the sheath into the aortic arch; and

expanding the filter from the compressed state to the deployed state within the aortic arch.

18. The method of claim 17, further comprising detaching the outlet of the filter from the distal end of the sheath by retracting a release line coupled to the frame of the filter and passing out of the body through the lumen.

19. The method of claim 18, further comprising retracting the filter into the lumen with a snare coupled to the frame of the filter and passing out of the body through the lumen.

20. The method of claim 17, further comprising:

providing a guidewire and an introducer having a guidewire lumen configured to receive the guidewire, the introducer having a recess configured to receive the filter in the compressed state;

compressing the filter to the compressed state within the recess of the introducer;

inserting the introducer into the lumen at the distal end of the sheath and retaining the filter in the compressed state within the recess and between the introducer and the sheath; and

percutaneously introducing the introducer, the filter, and the sheath into the aortic arch by pushing the introducer over the guidewire via the sheath.

21. The method of claim 20, wherein said expanding comprises advancing the introducer while maintaining the sheath in place so as to expose the filter and allow the filter to expand from the compressed state to the deployed state.

22. The method of claim 21, further comprising retrieving the introducer through the outlet of the filter and the lumen of the sheath after the filter expands to the deployed state.

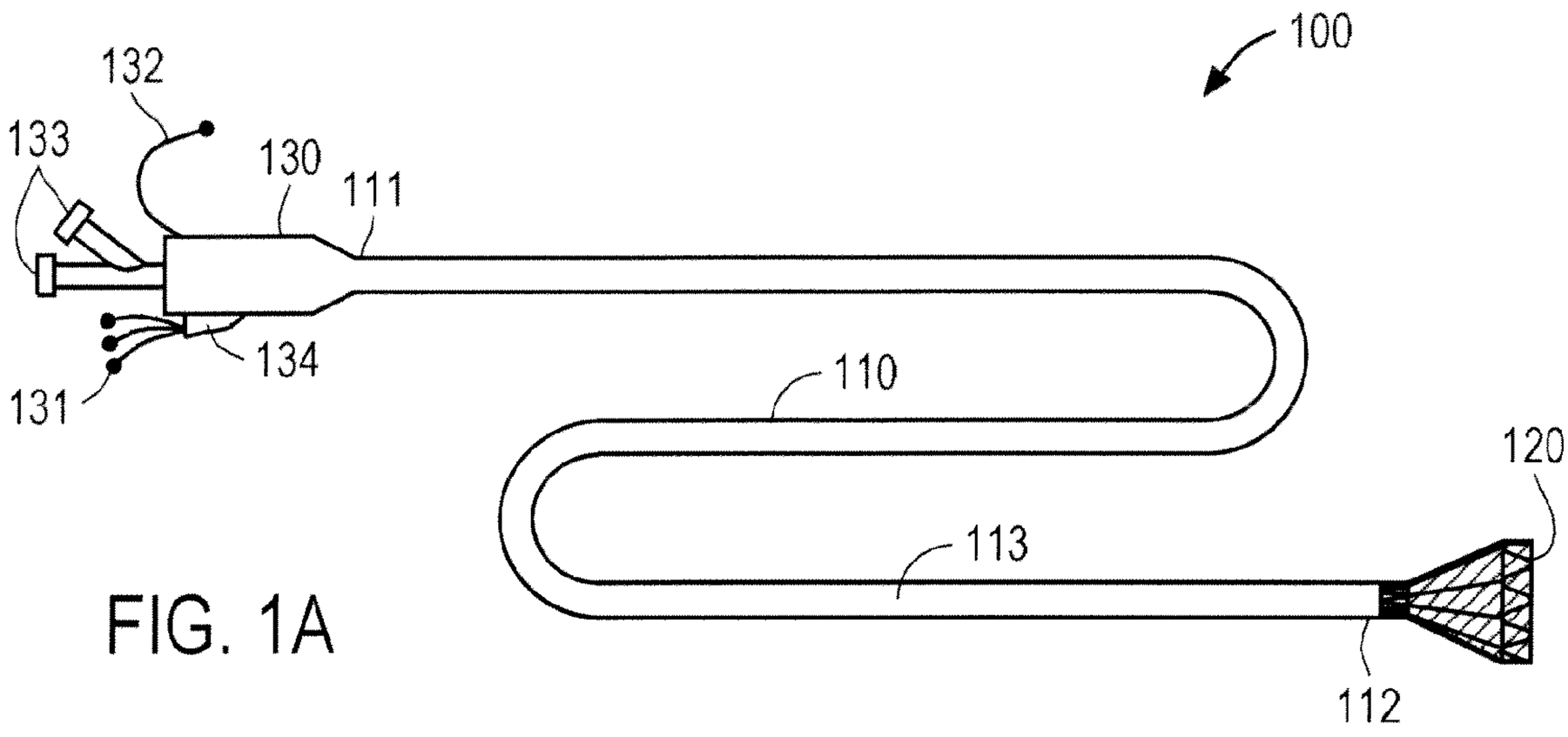
100
132
133
130
111
134
131
110
120
113
112

FIG. 1A

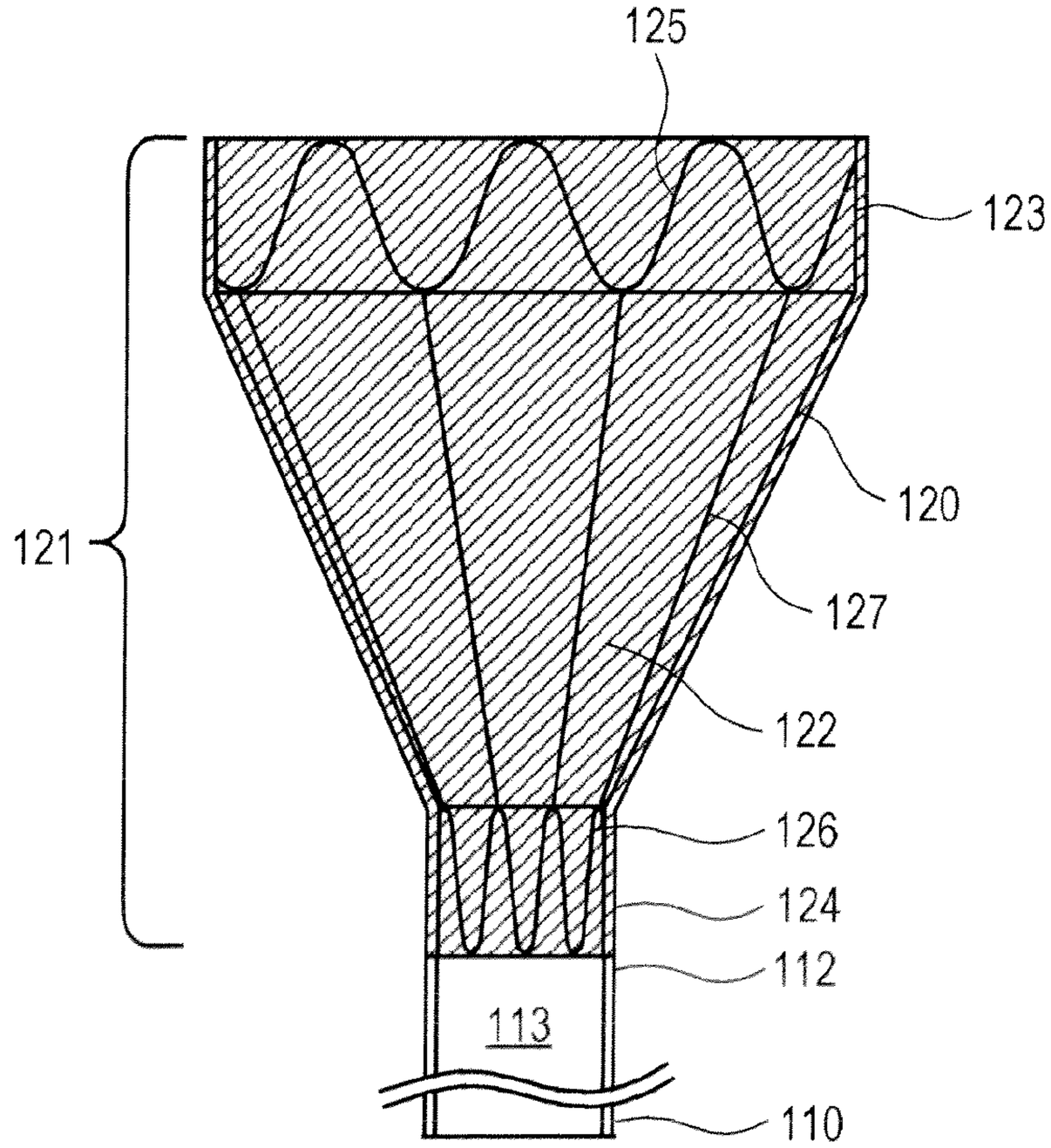
125
123
121
120
127
122
126
124
112
113
110

FIG. 1B

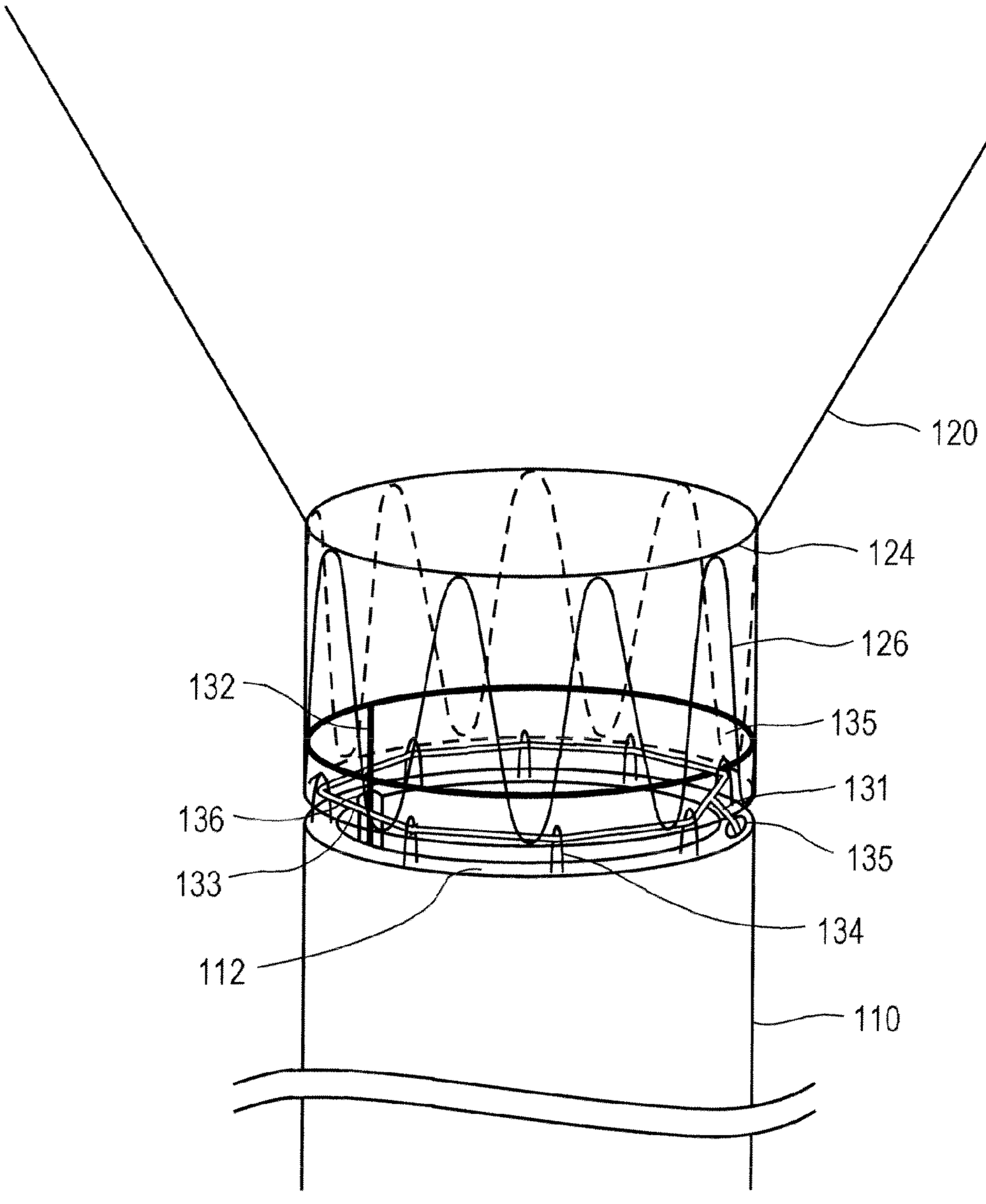

FIG. 2A

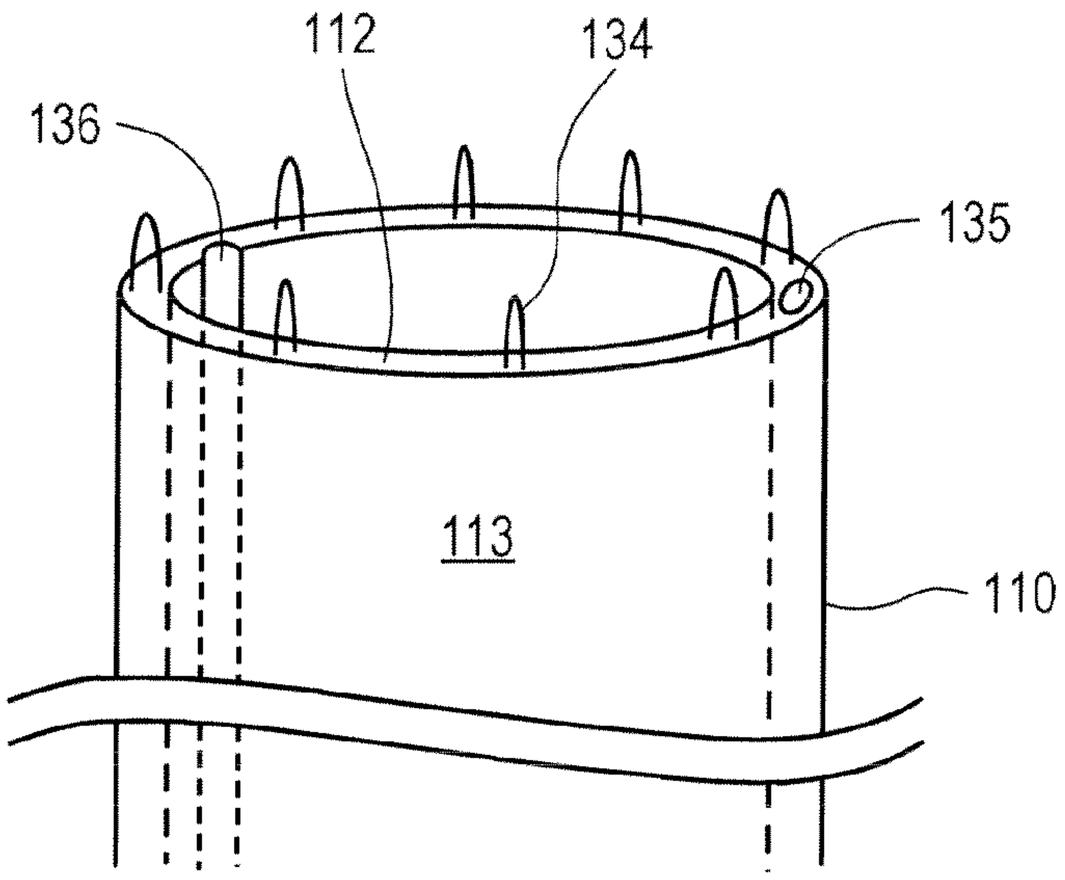

FIG. 2B

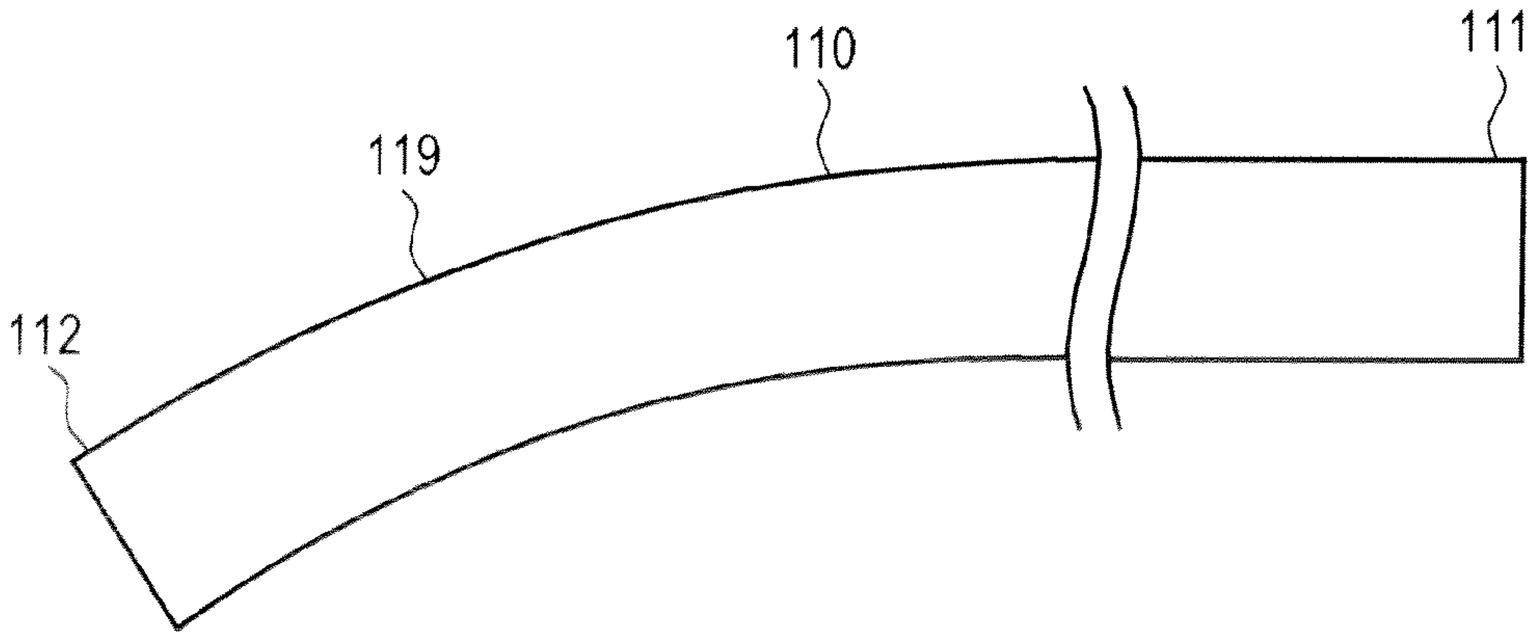

FIG. 2C

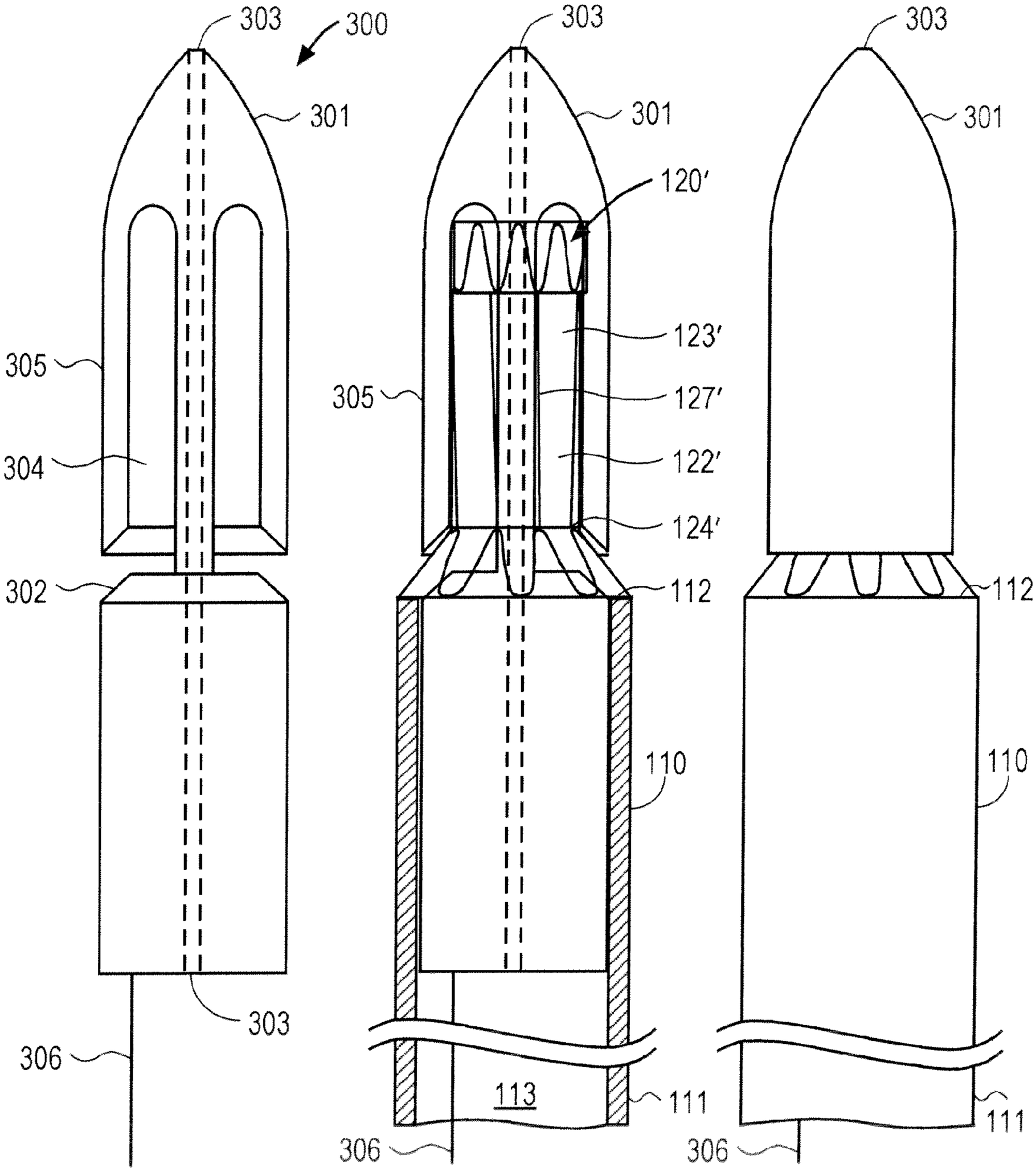

FIG. 3A FIG. 3B FIG. 3C

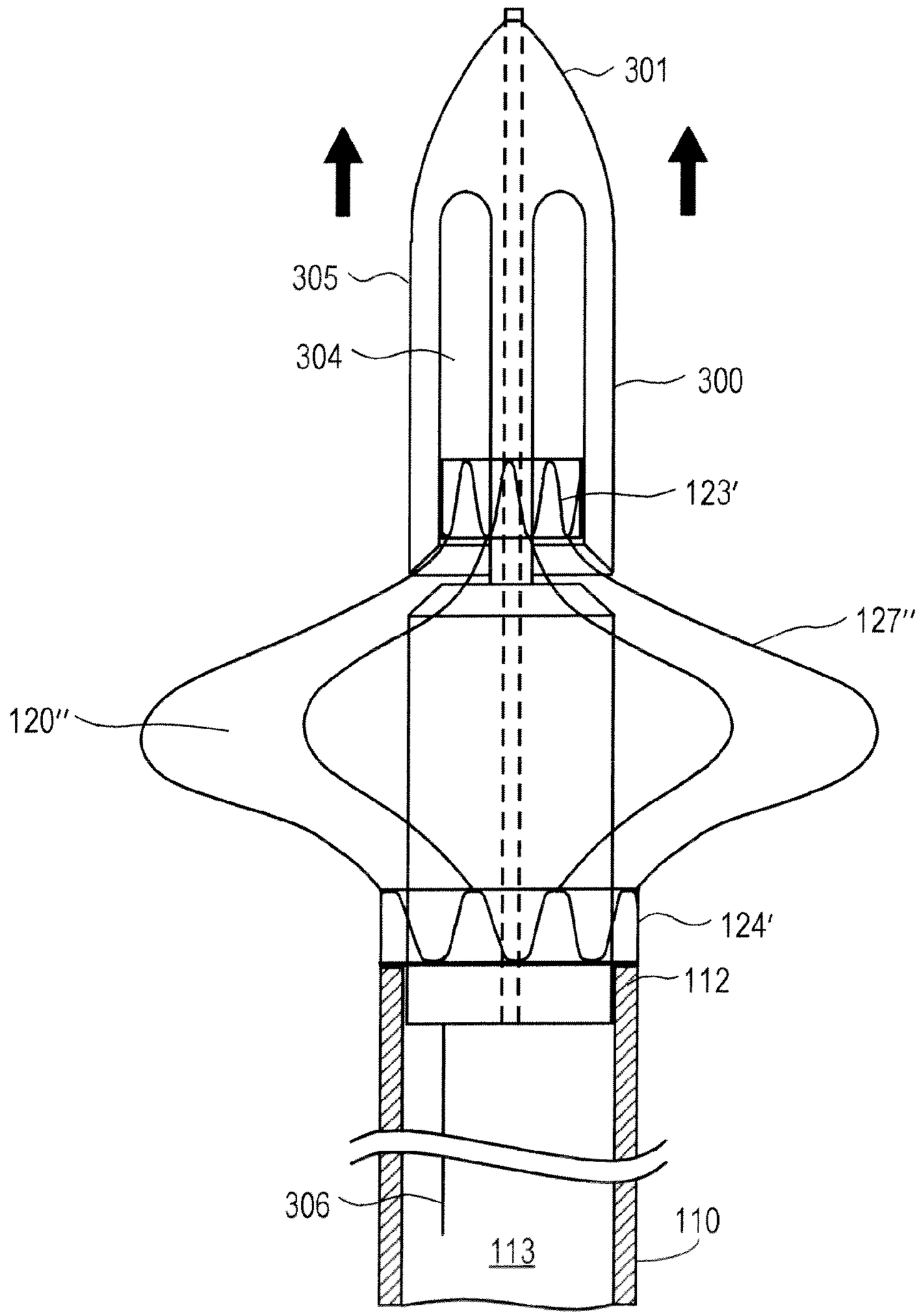

FIG. 3D

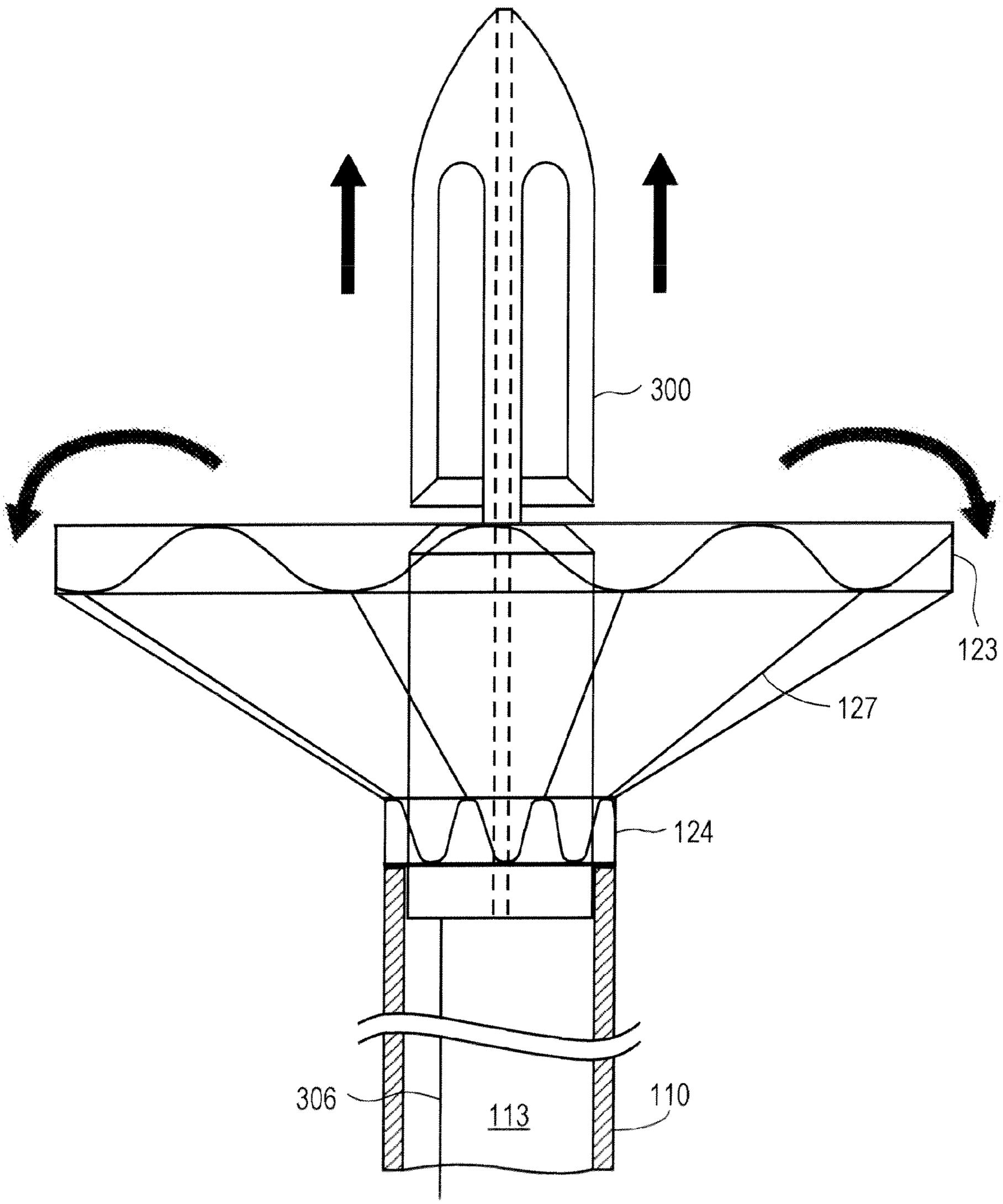

FIG. 3E

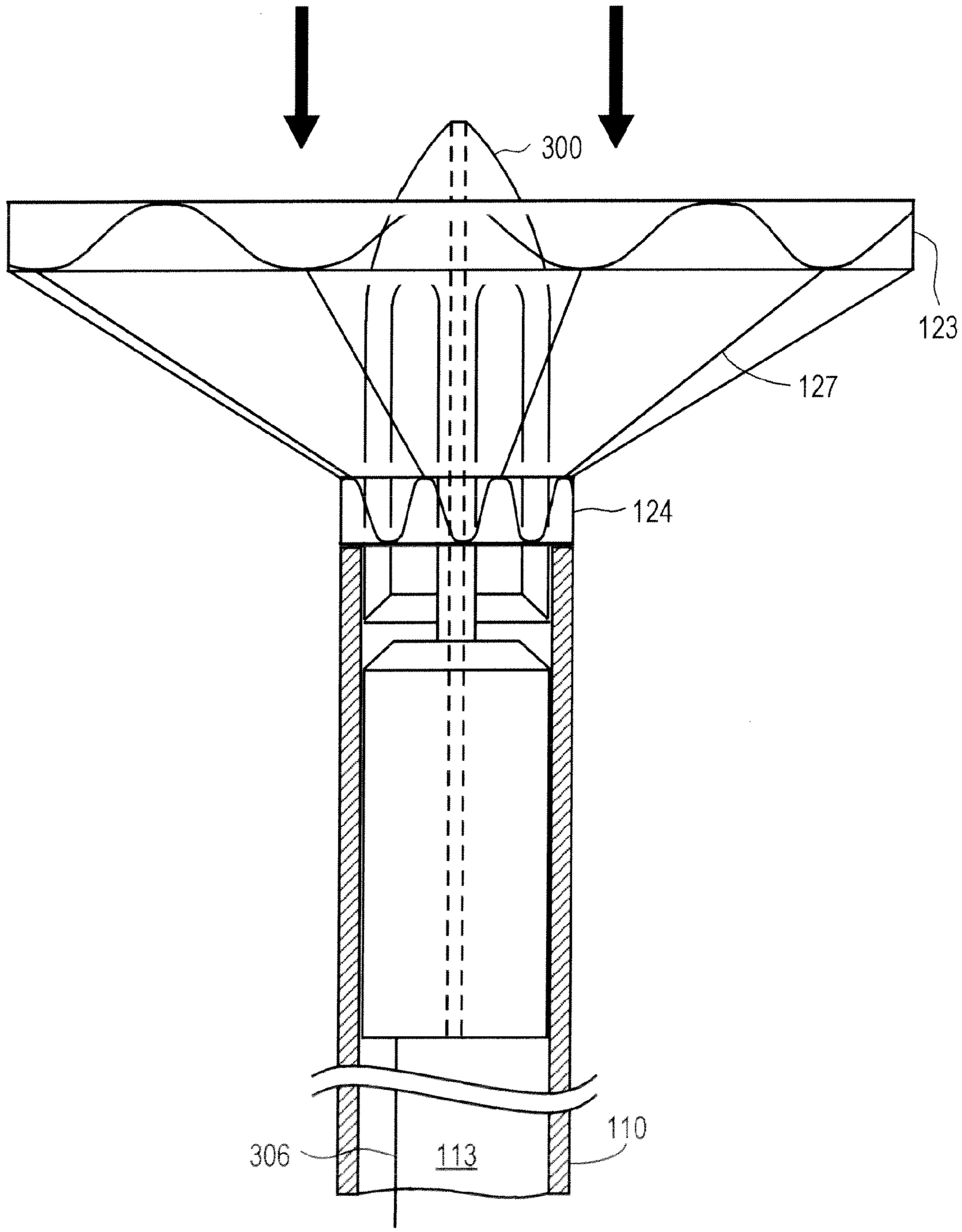

FIG. 3F

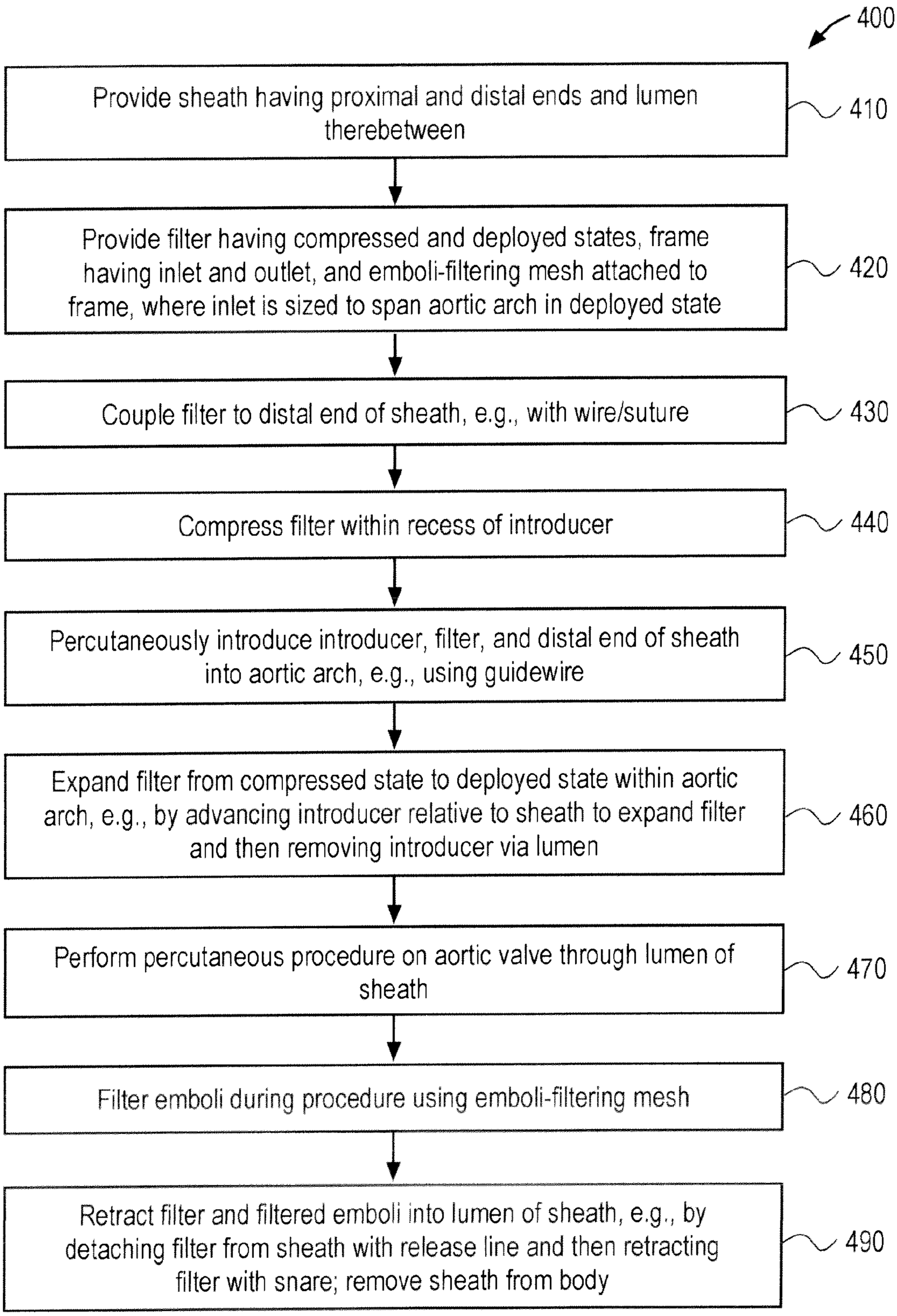
400
Provide sheath having proximal and distal ends and lumen therebetween
410
Provide filter having compressed and deployed states, frame having inlet and outlet, and emboli-filtering mesh attached to frame, where inlet is sized to span aortic arch in deployed state
420
Couple filter to distal end of sheath, e.g., with wire/suture
430
Compress filter within recess of introducer
440
Percutaneously introduce introducer, filter, and distal end of sheath into aortic arch, e.g., using guidewire
450
Expand filter from compressed state to deployed state within aortic arch, e.g., by advancing introducer relative to sheath to expand filter and then removing introducer via lumen
460
Perform percutaneous procedure on aortic valve through lumen of sheath
470
Filter emboli during procedure using emboli-filtering mesh
480
Retract filter and filtered emboli into lumen of sheath, e.g., by detaching filter from sheath with release line and then retracting filter with snare; remove sheath from body
490

FIG. 4

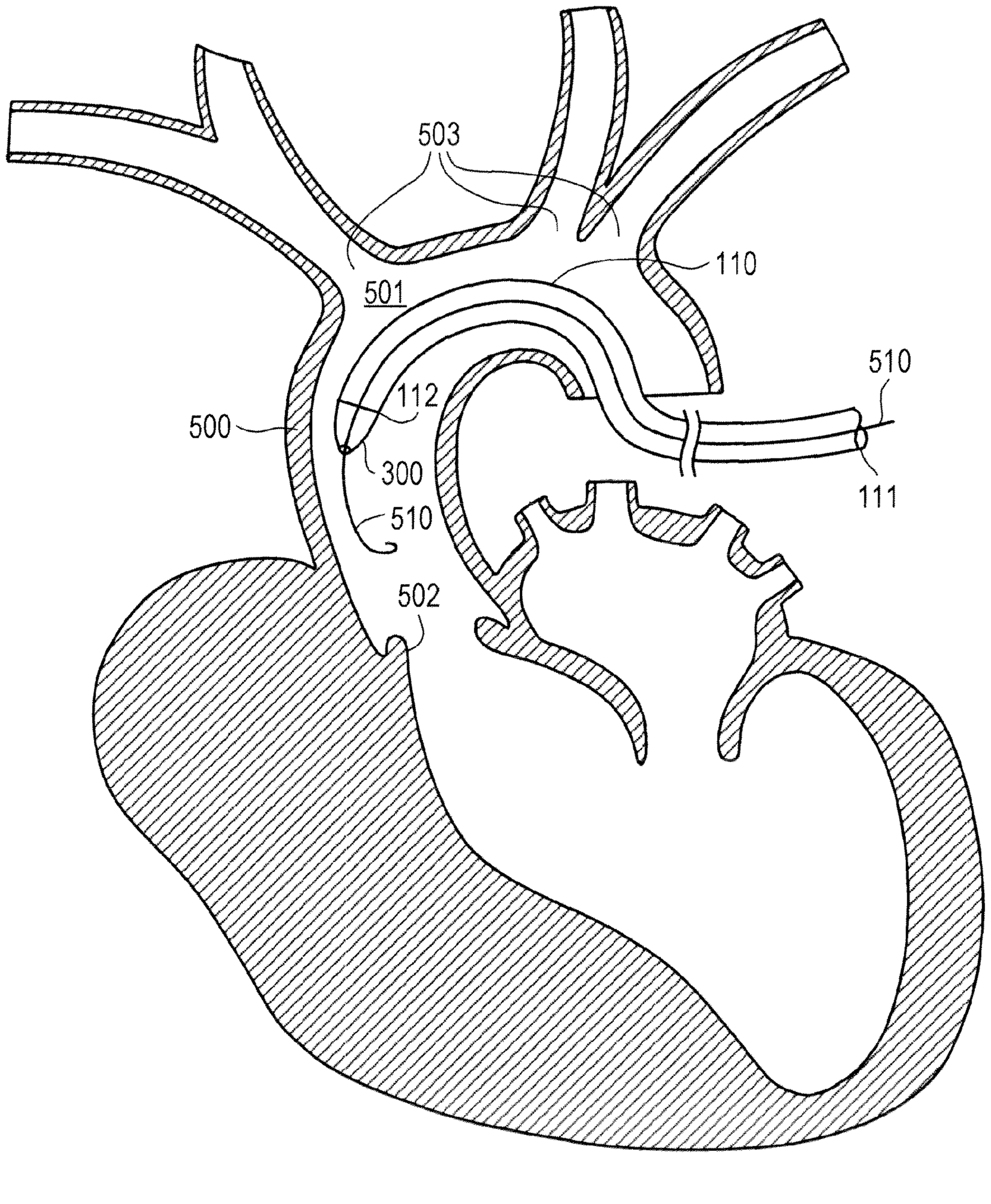

FIG. 5A

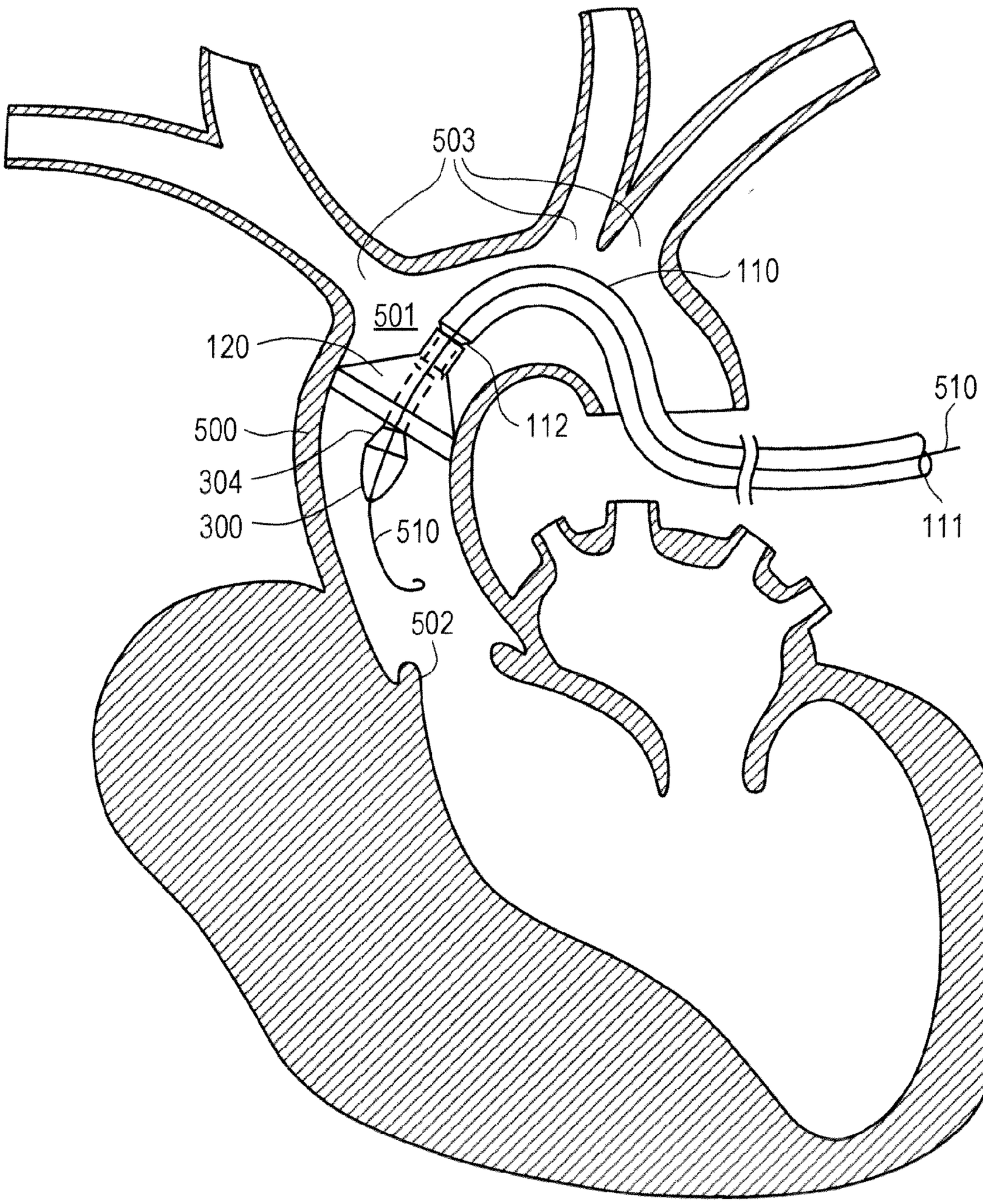

FIG. 5B

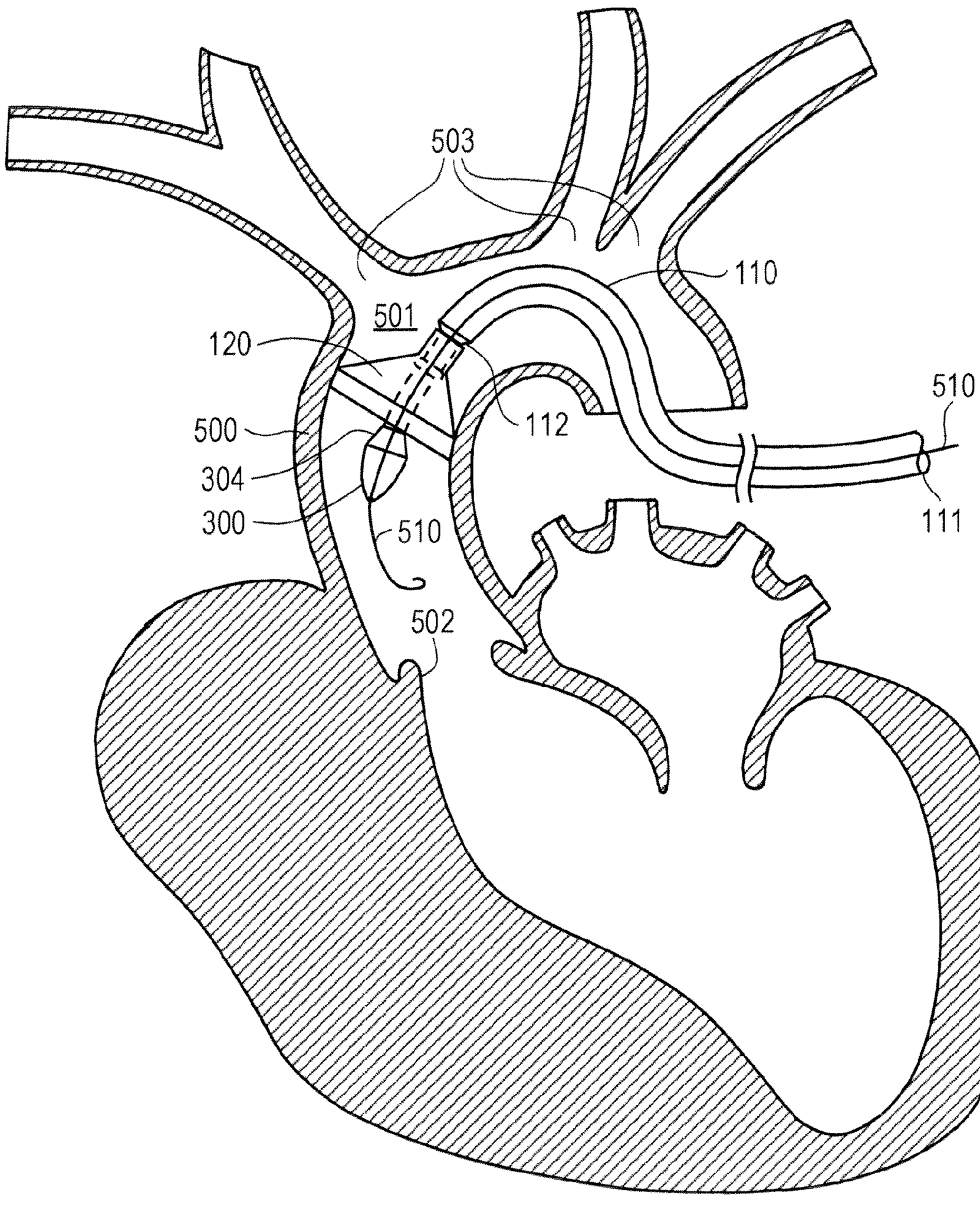

FIG. 5C

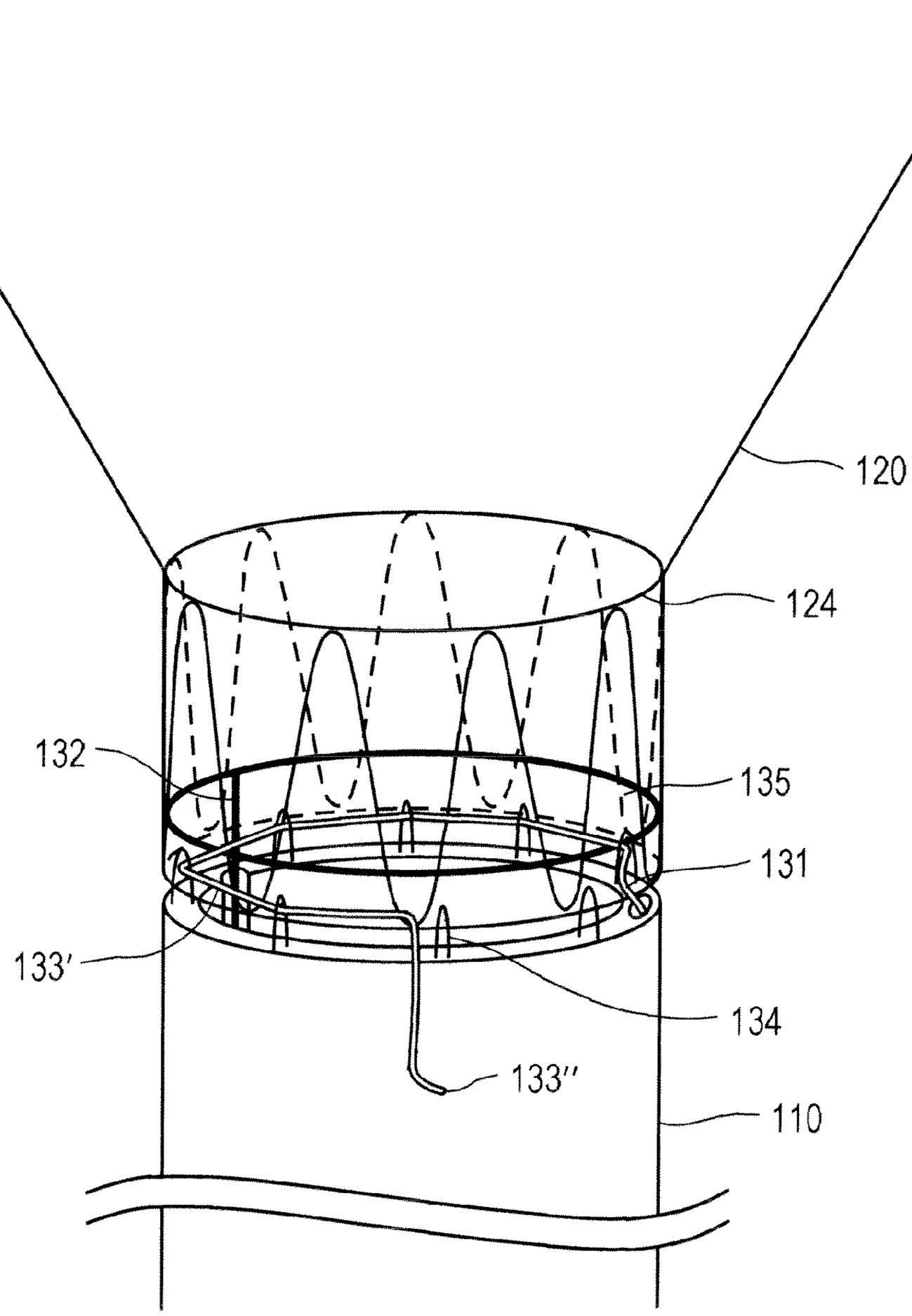

FIG. 6A

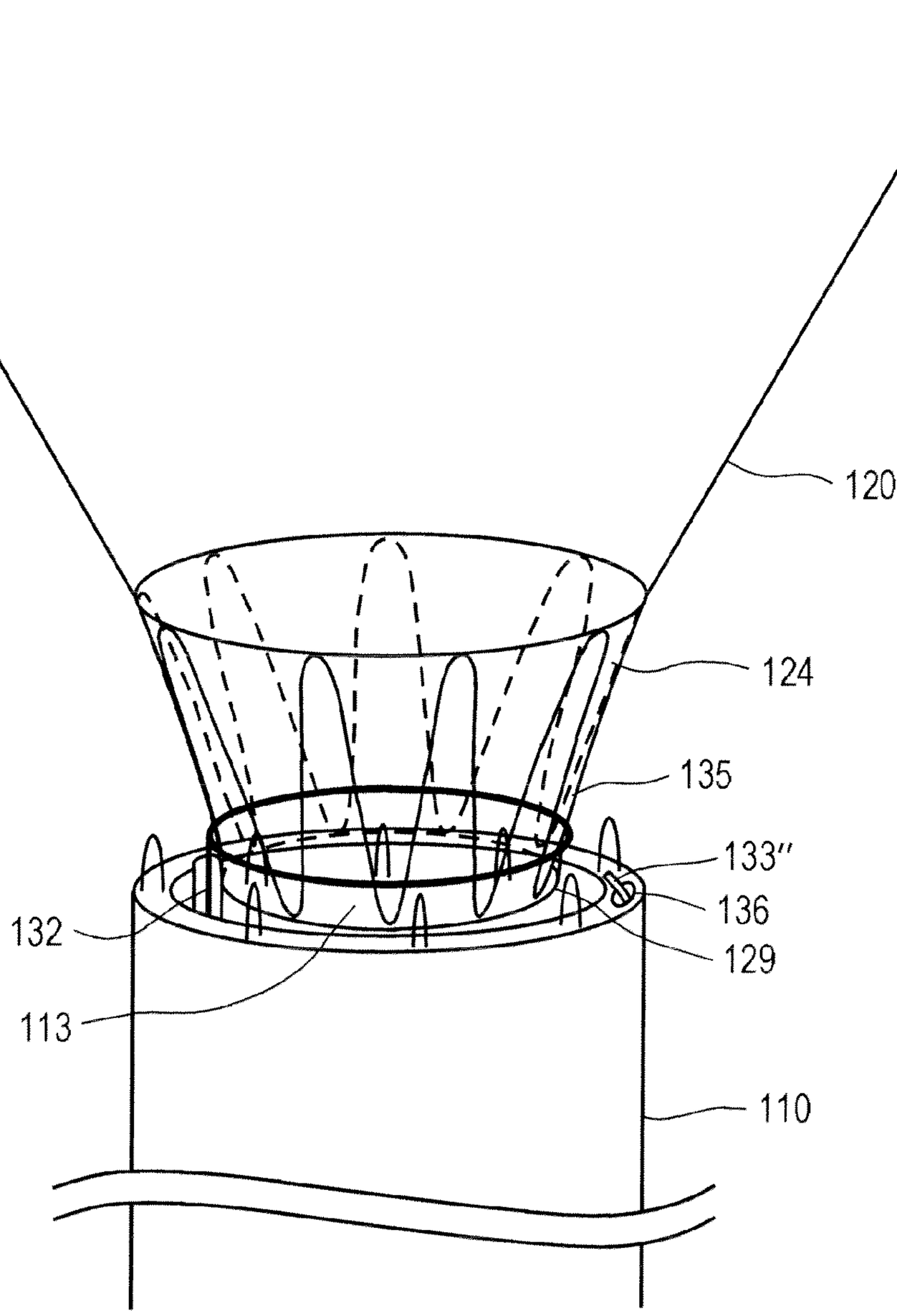

FIG. 6B

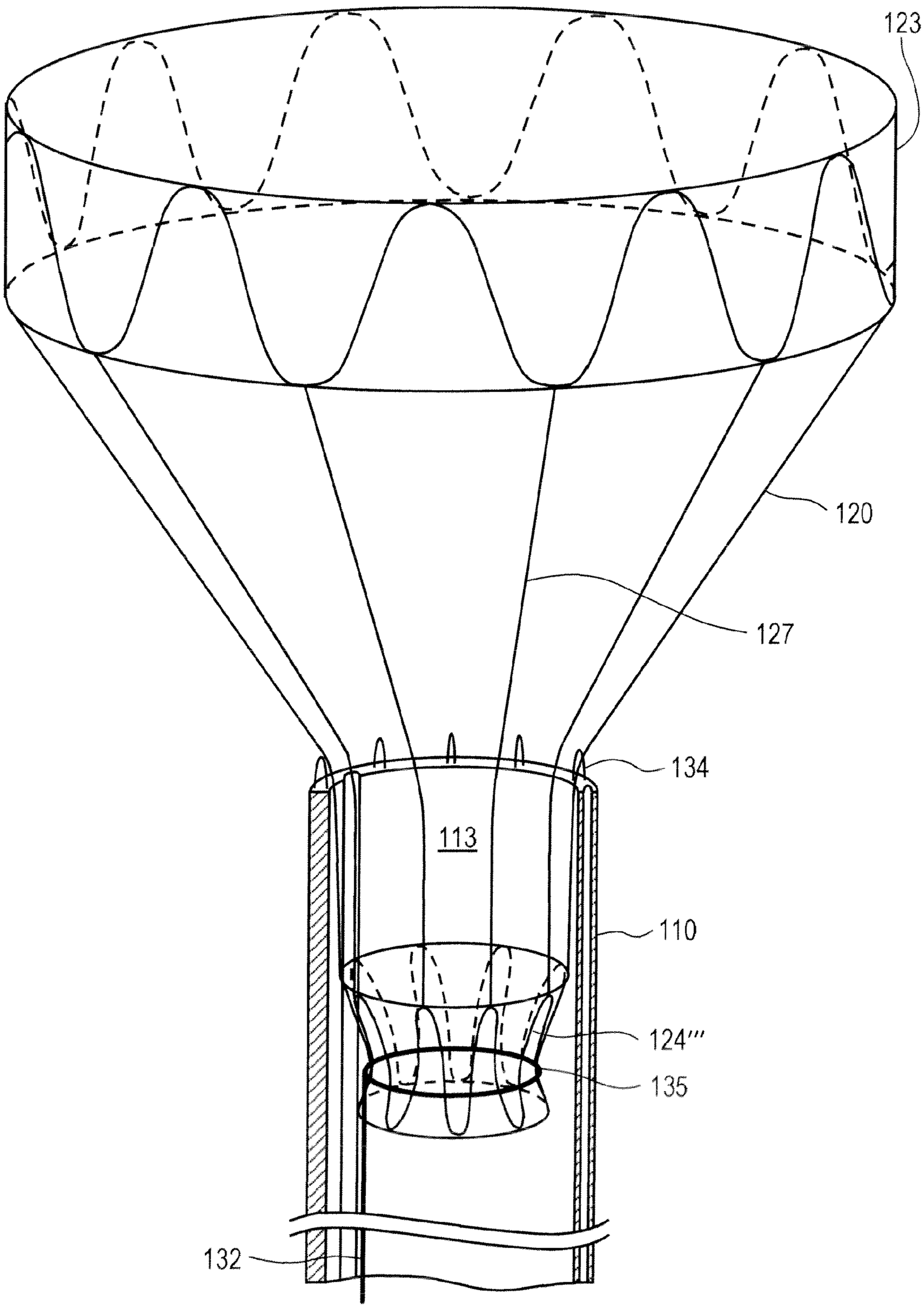

FIG. 6C

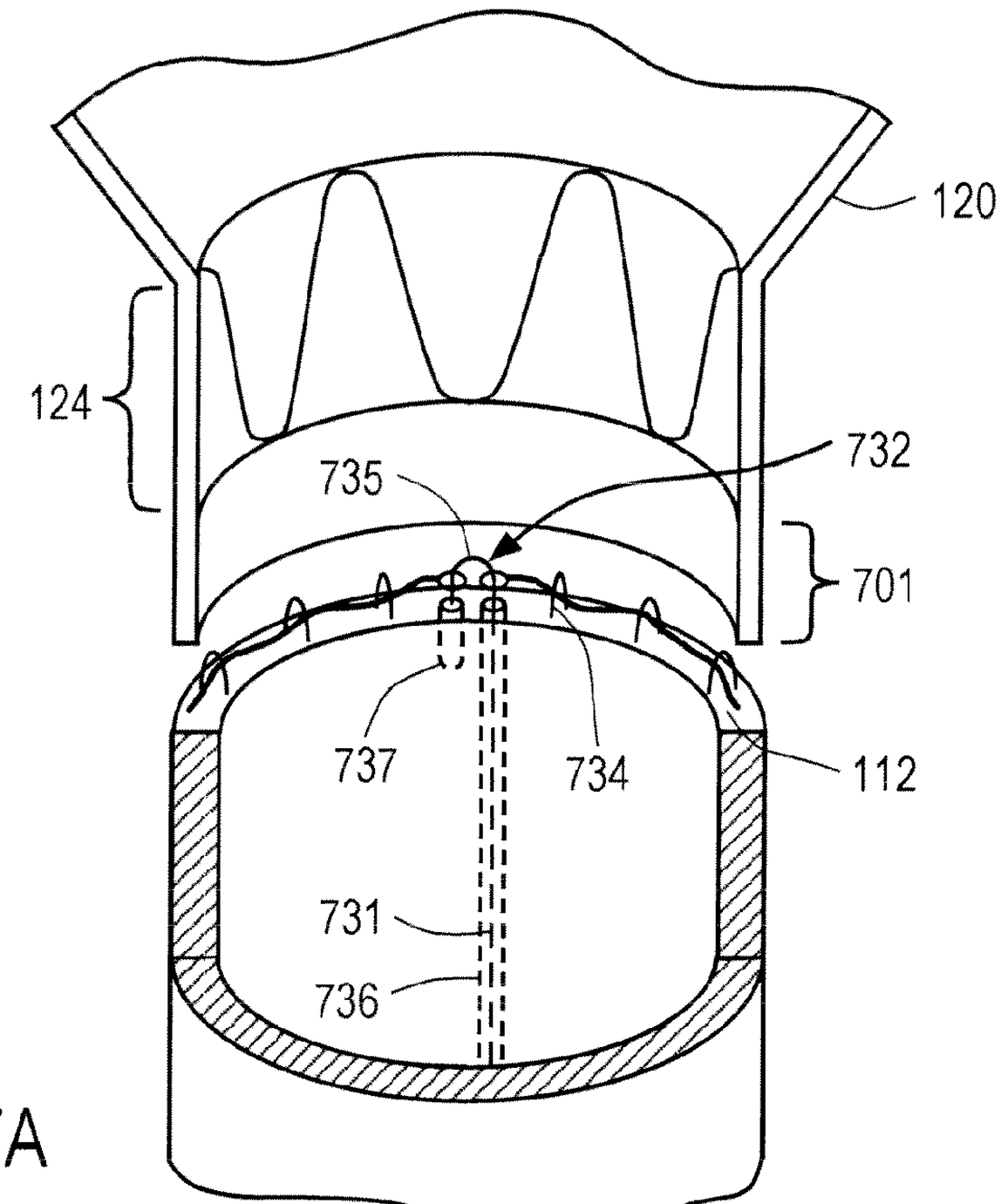

FIG. 7A

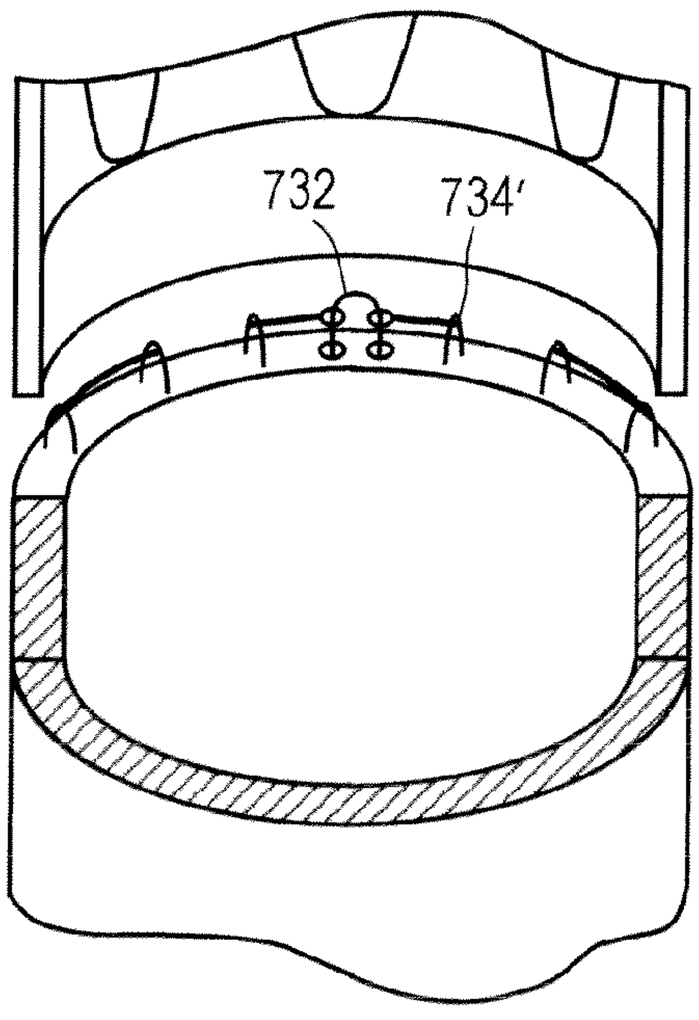

FIG. 7B

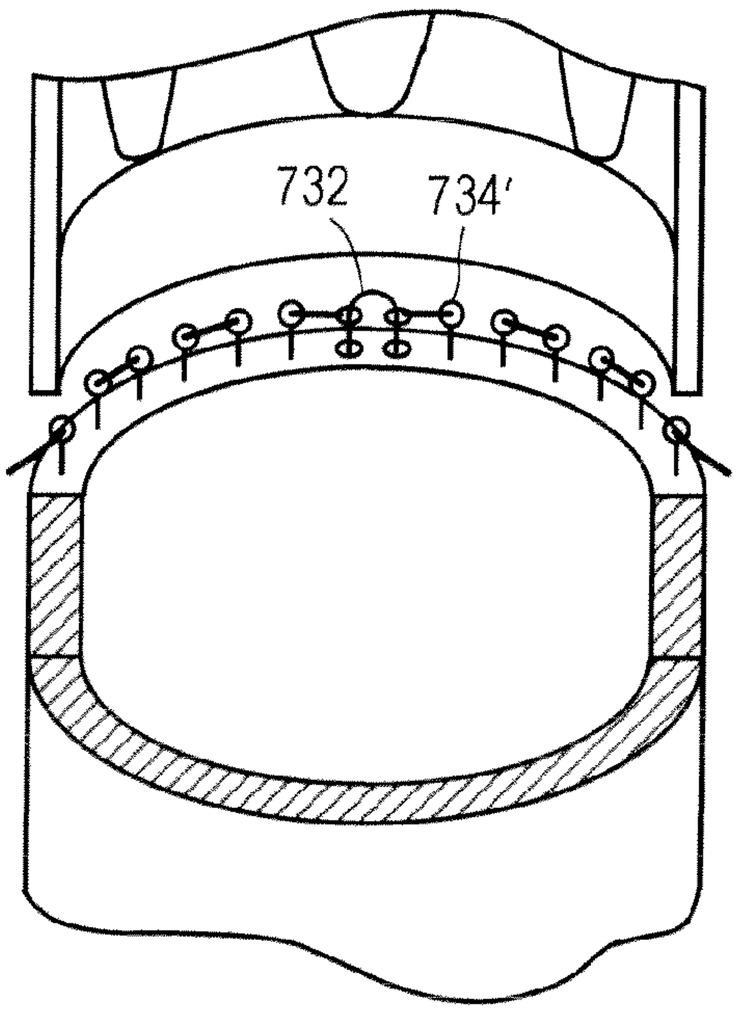

FIG. 7C

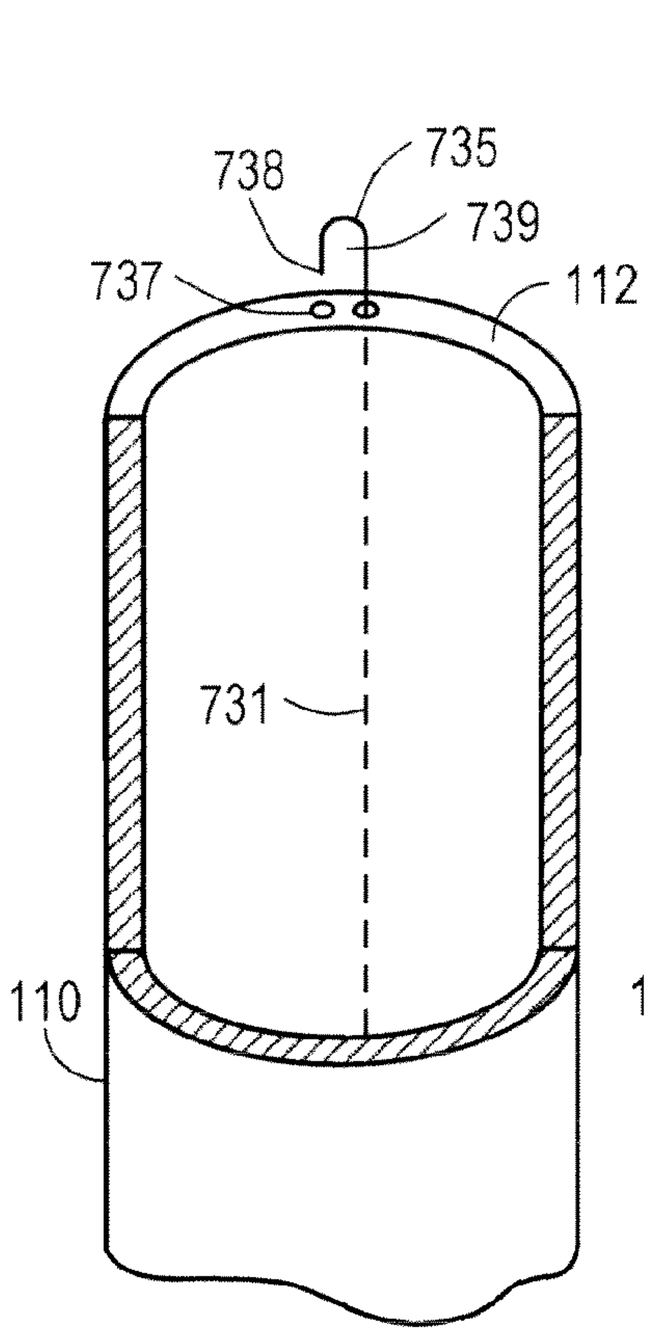

FIG. 7D

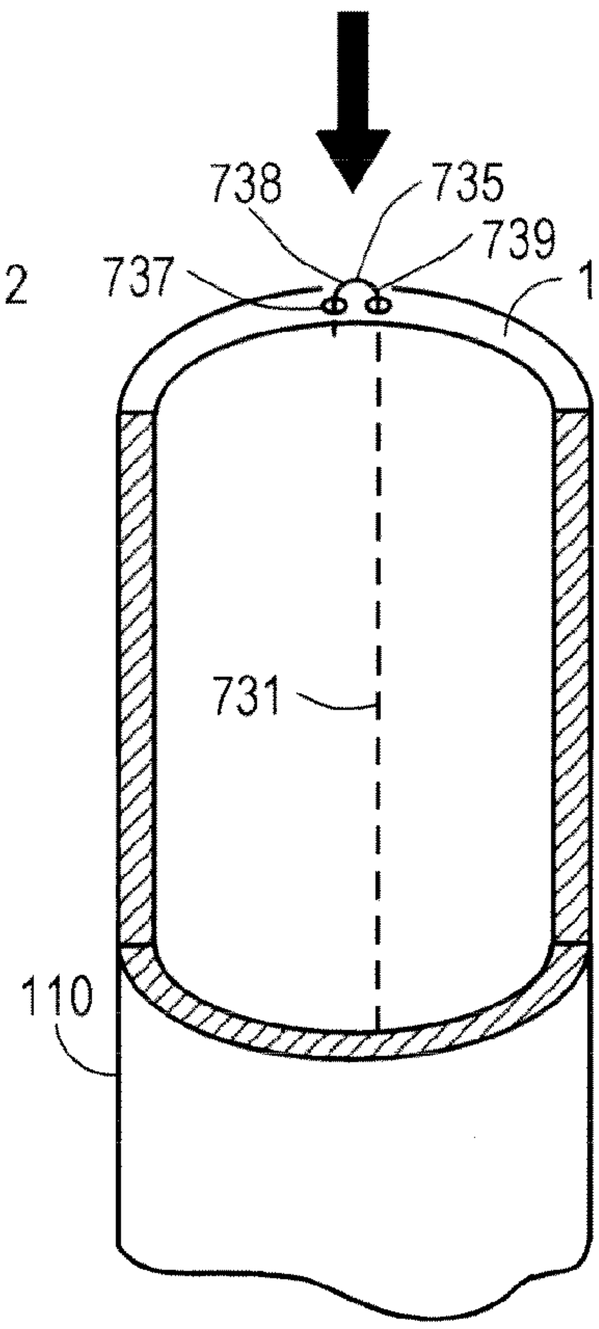

FIG. 7F

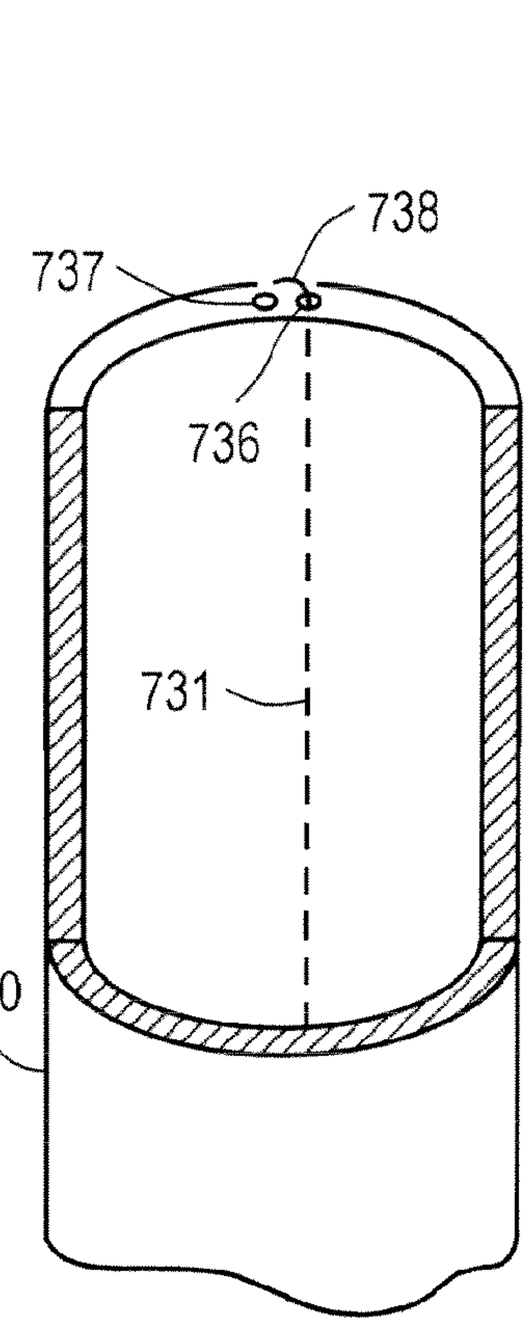

FIG. 7H

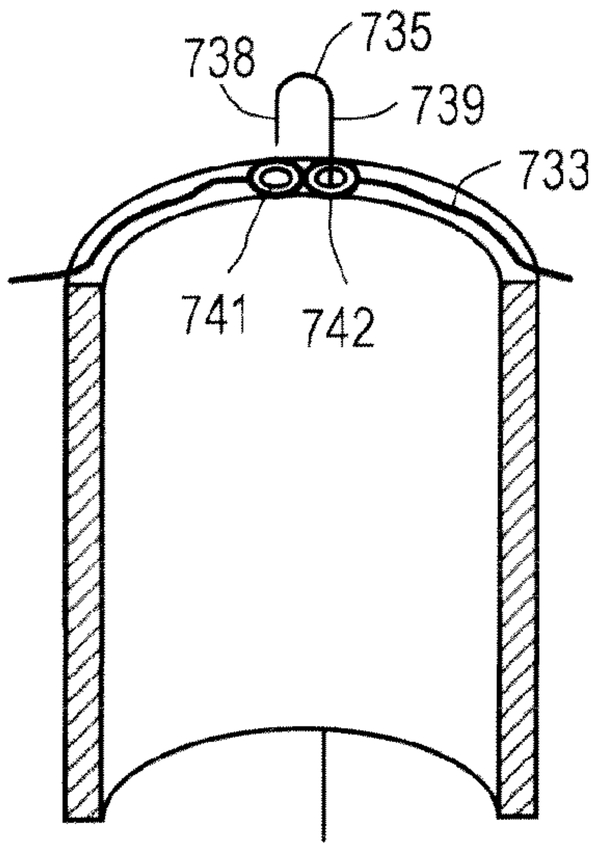

FIG. 7E

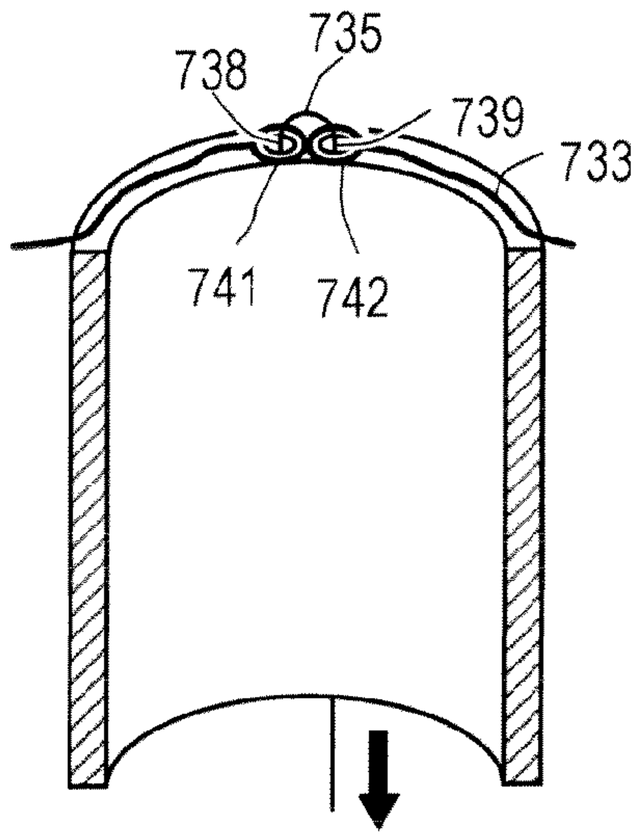

FIG. 7G

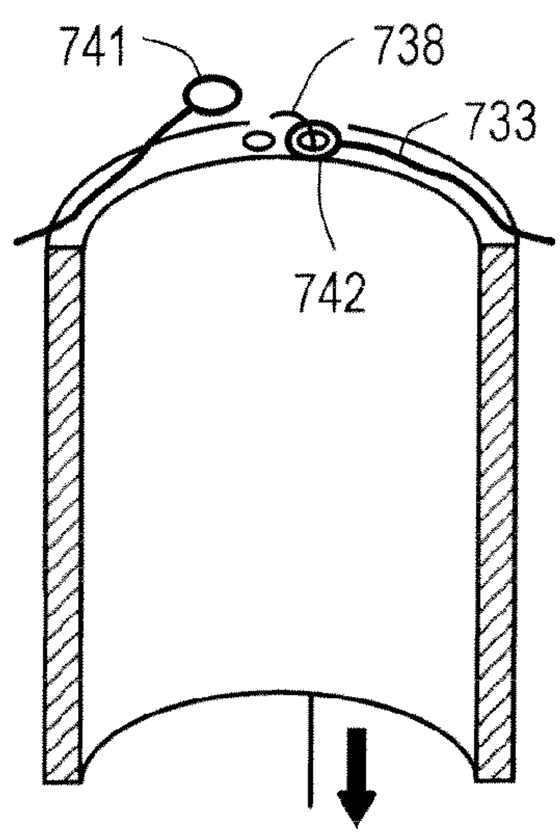

FIG. 7I

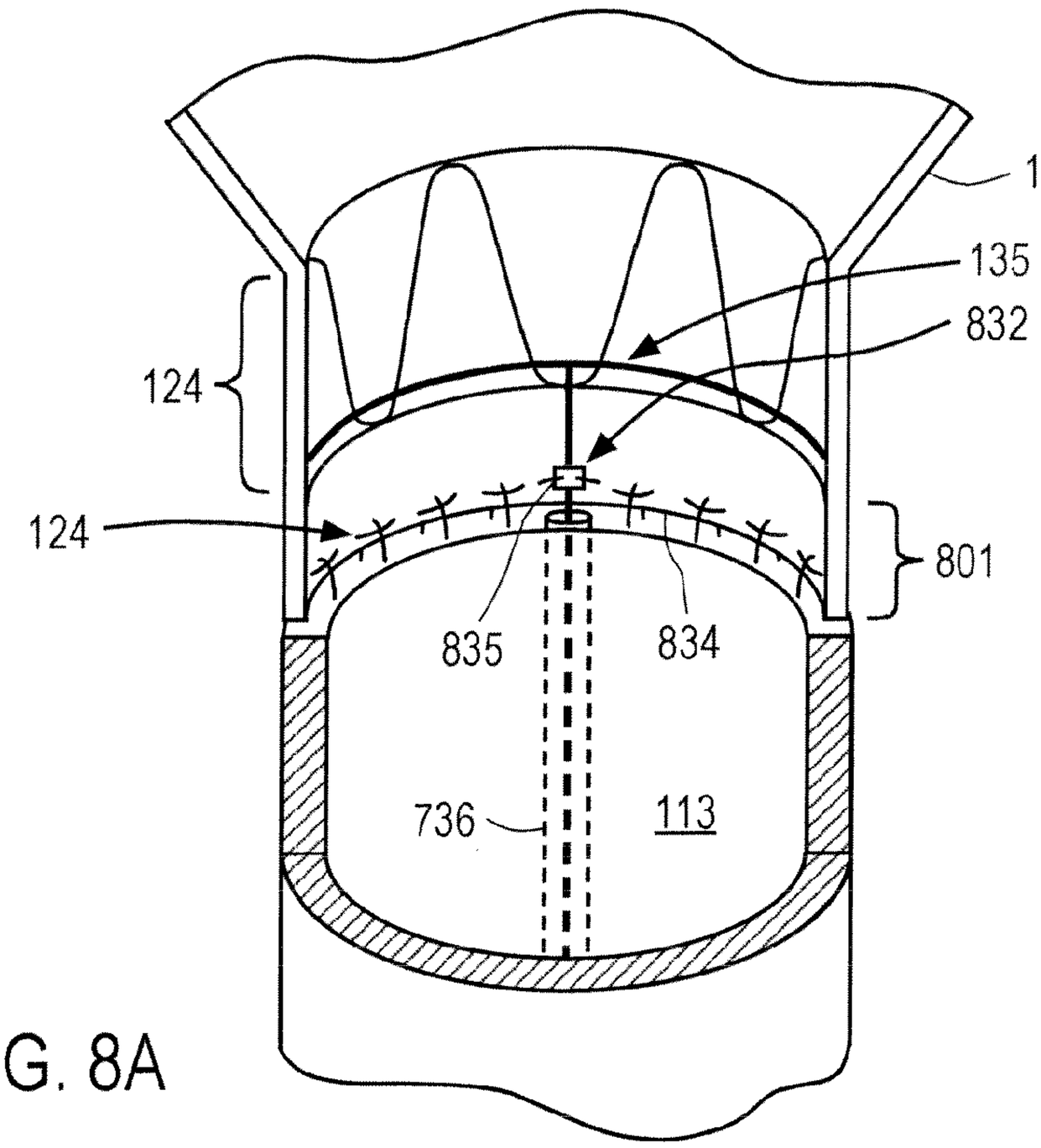

FIG. 8A

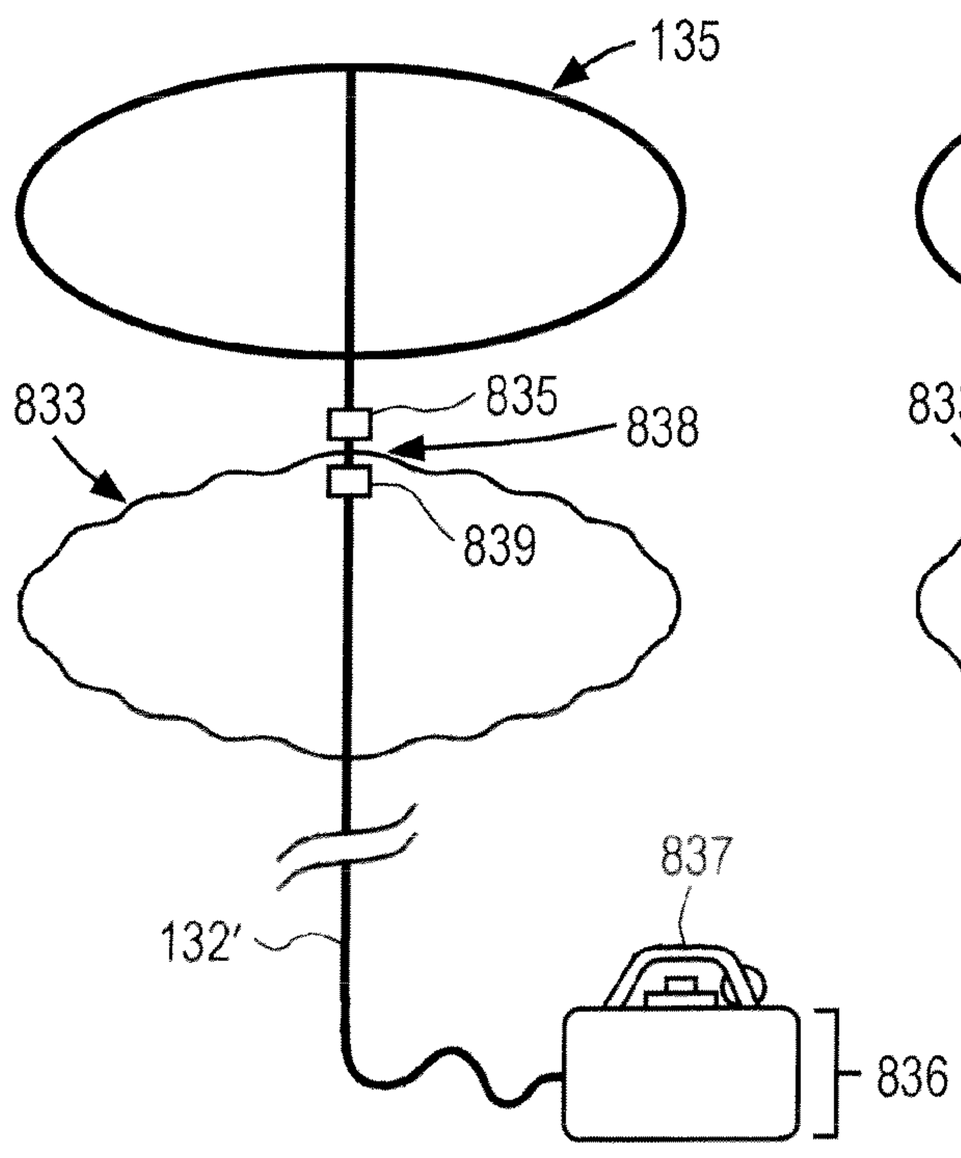

FIG. 8B

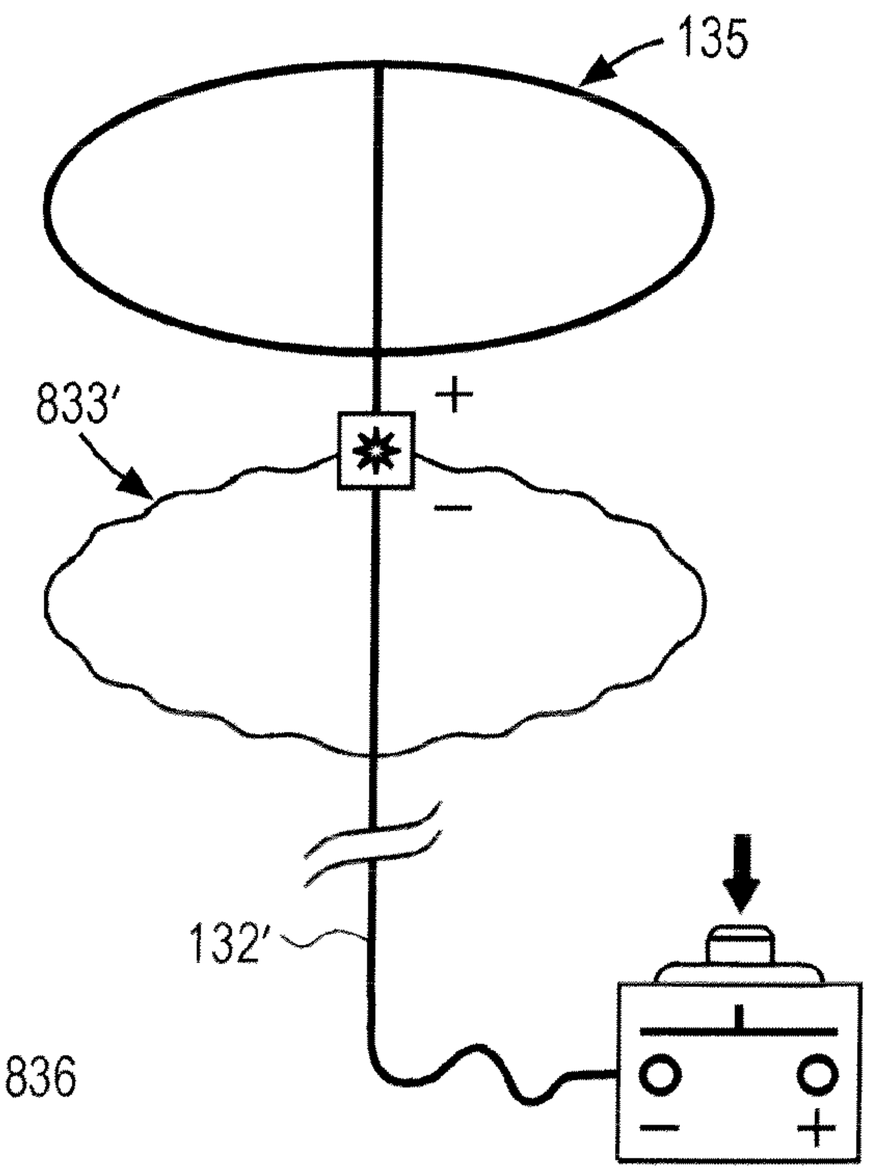

FIG. 8C

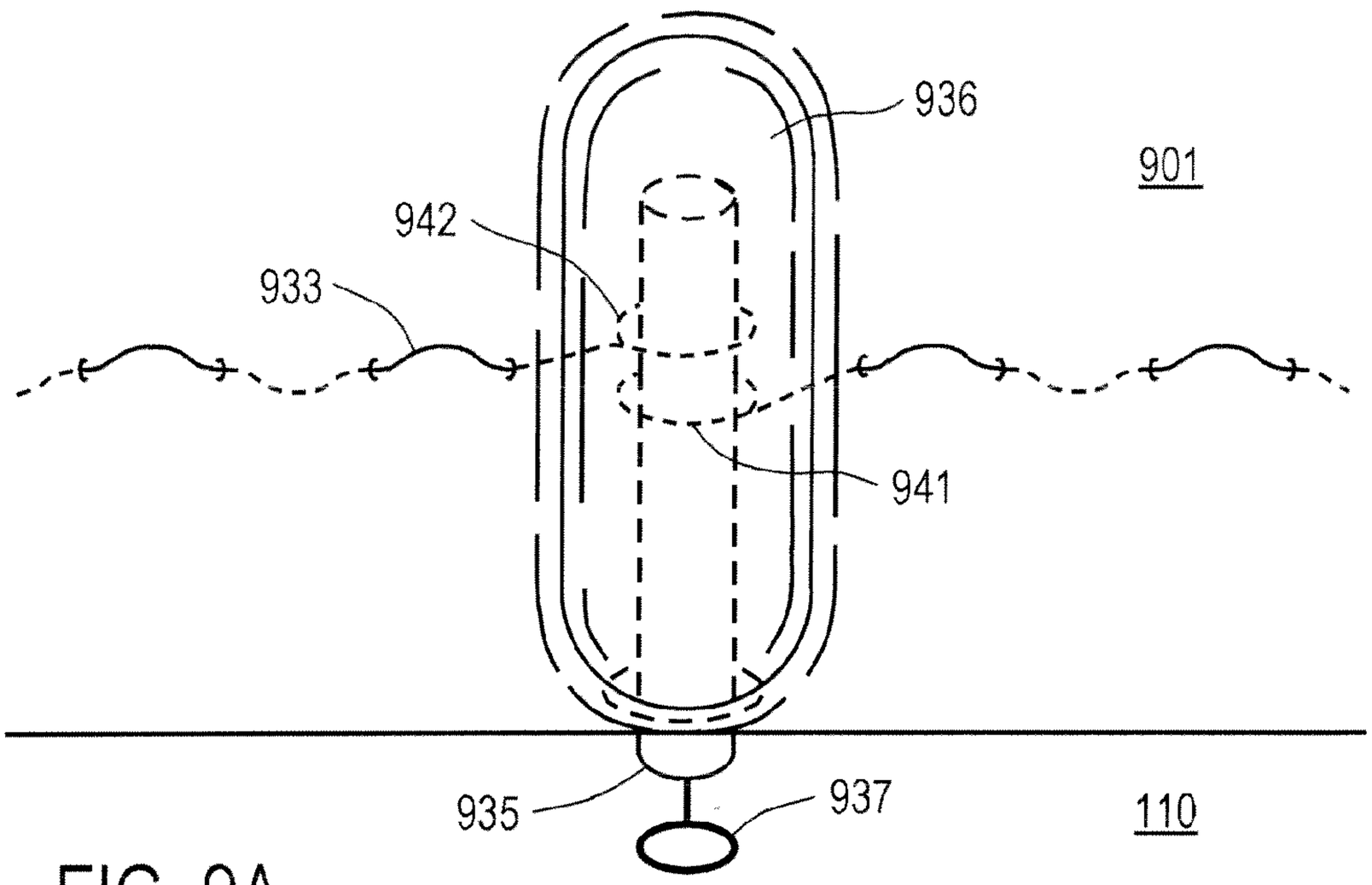
124
936
901
942
933
941
935
937
110

FIG. 9A

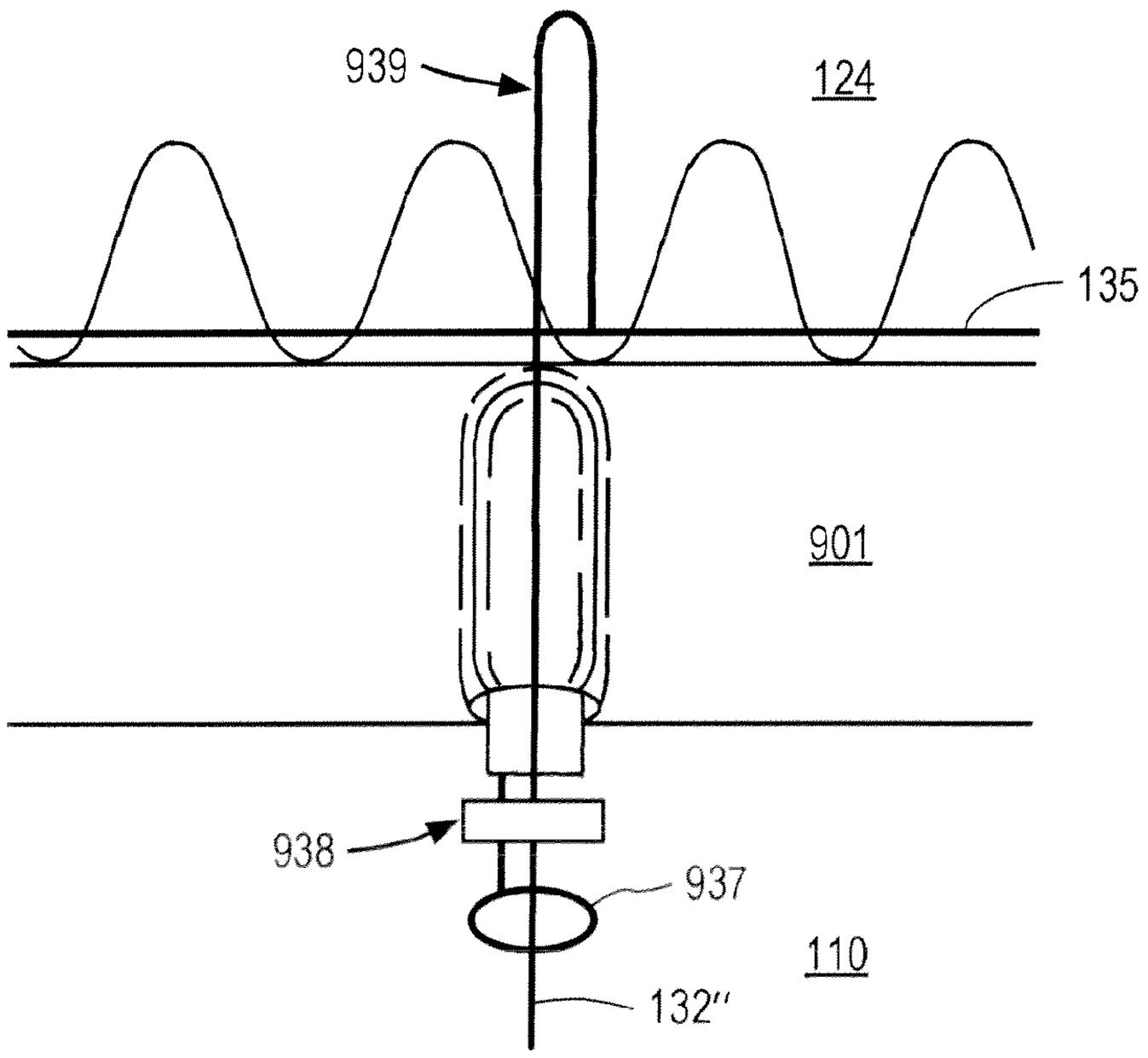
939
124
135
901
938
937
110
132''

FIG. 9B

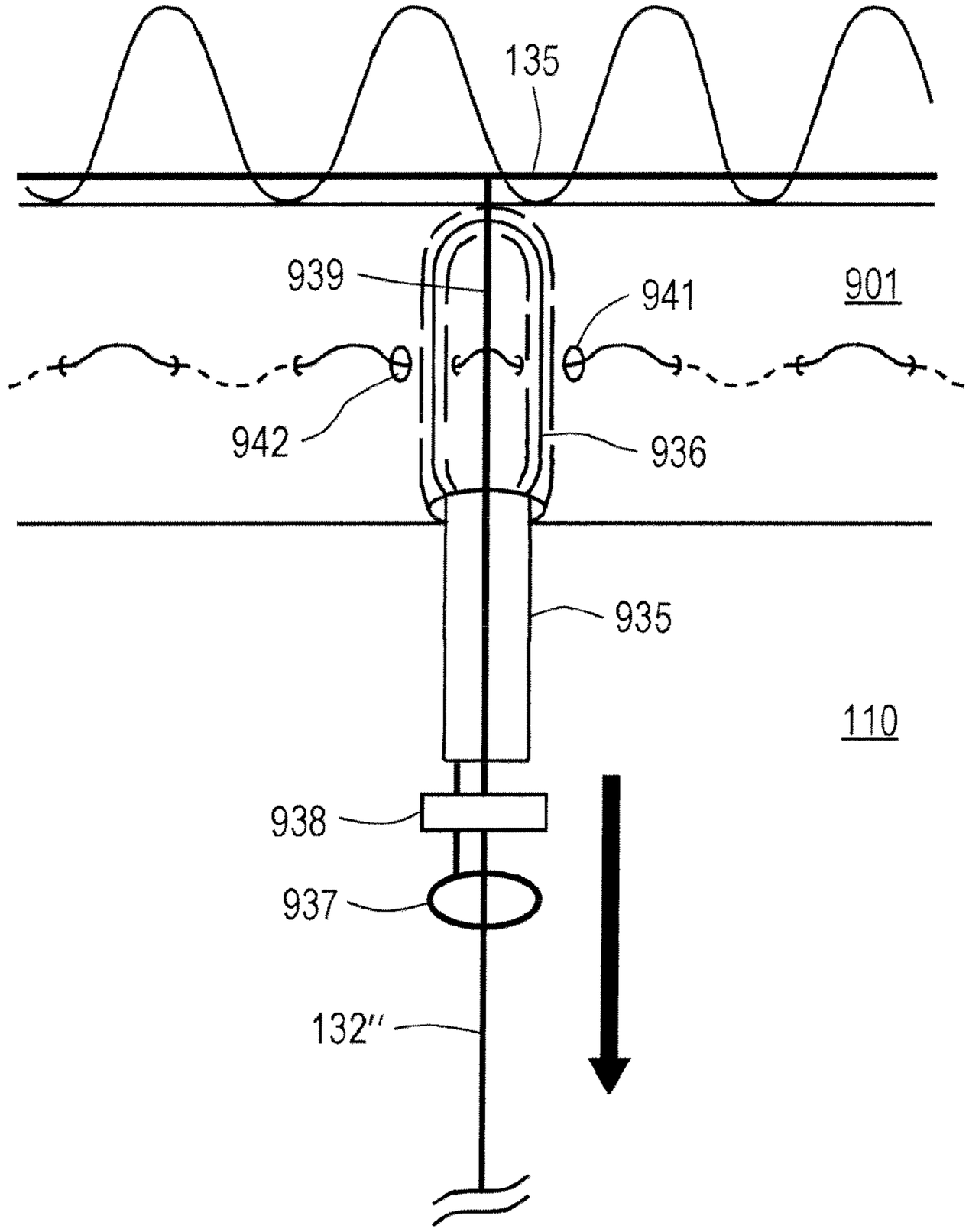

FIG. 9C

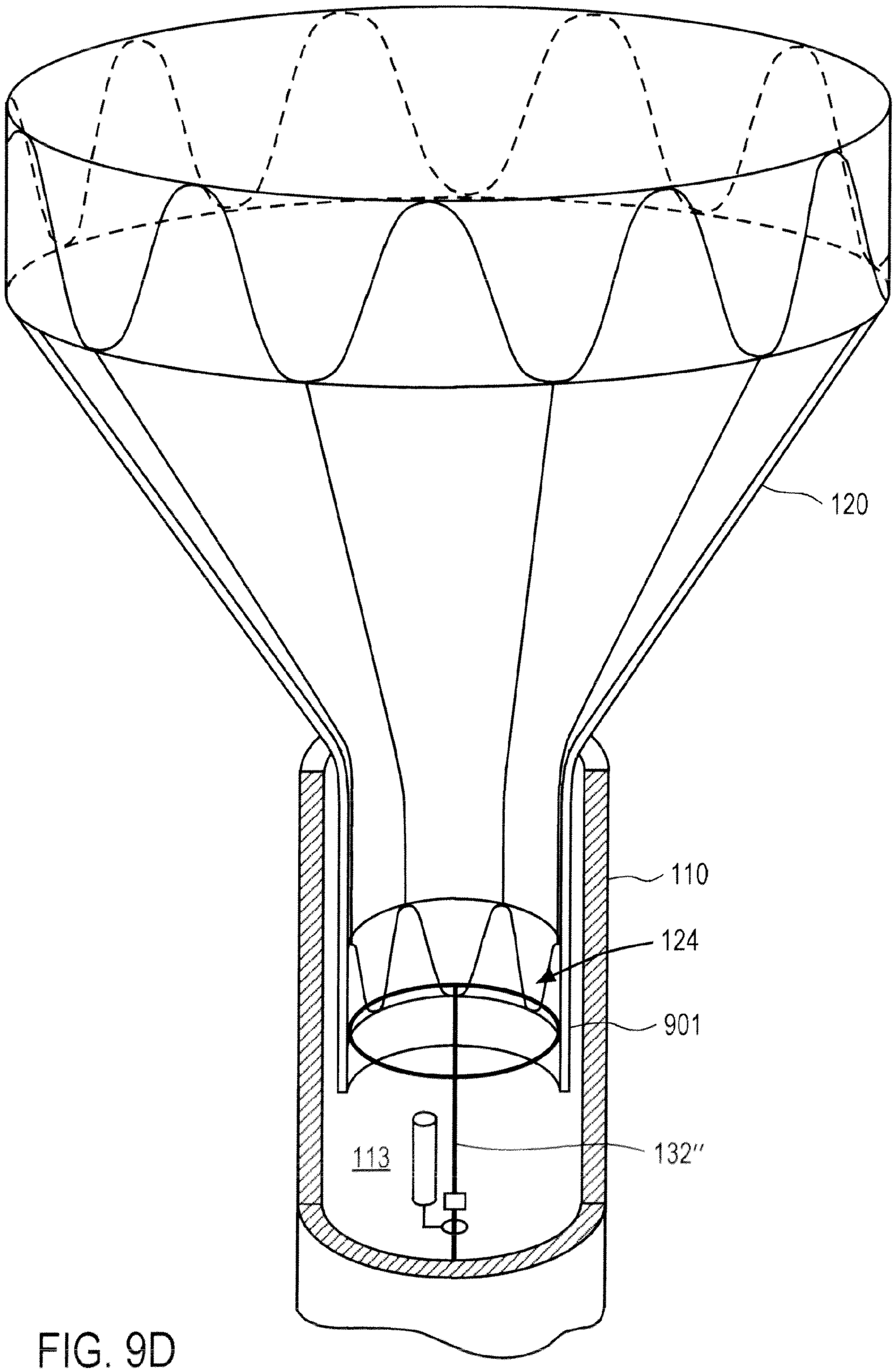

FIG. 9D

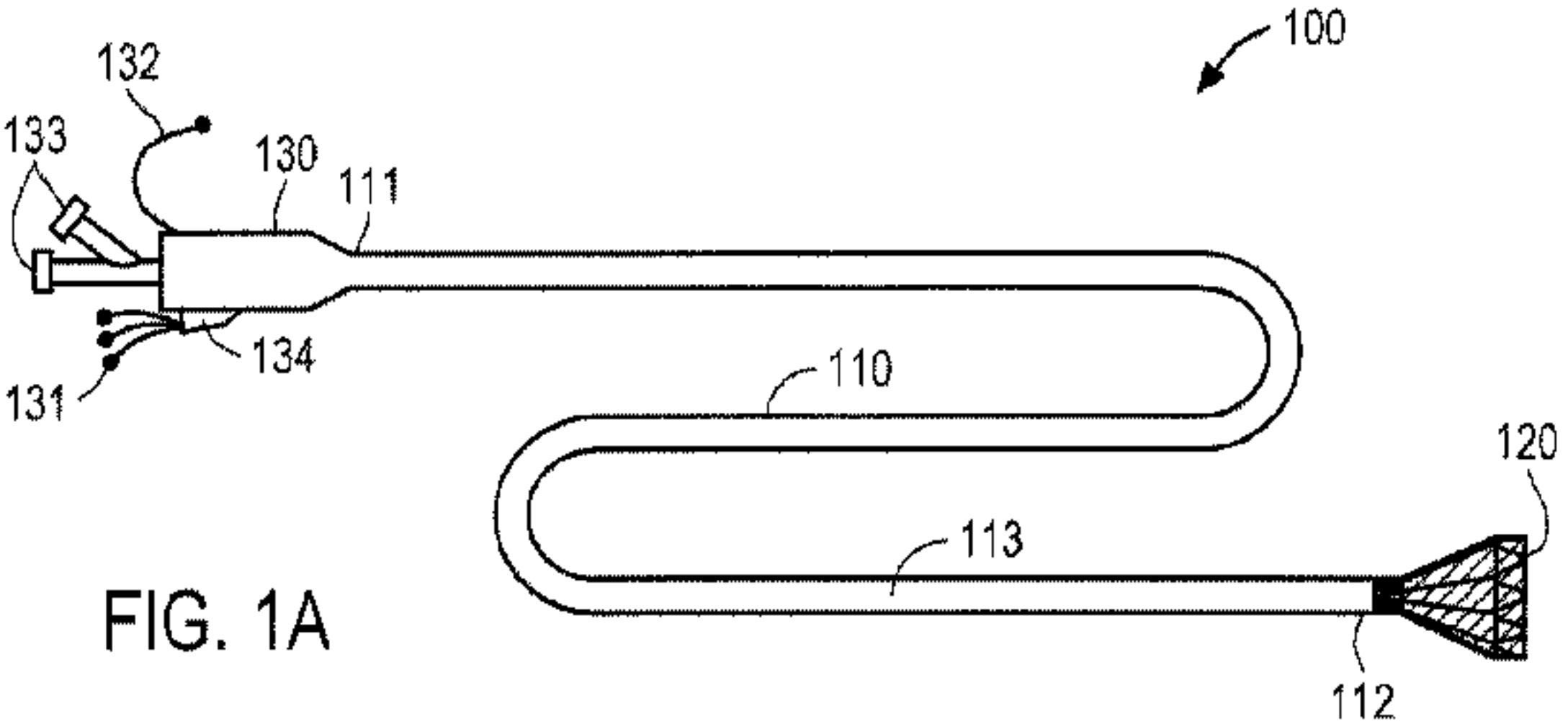
100
132
133
130
111
134
131
110
120
113
112

FIG. 1A

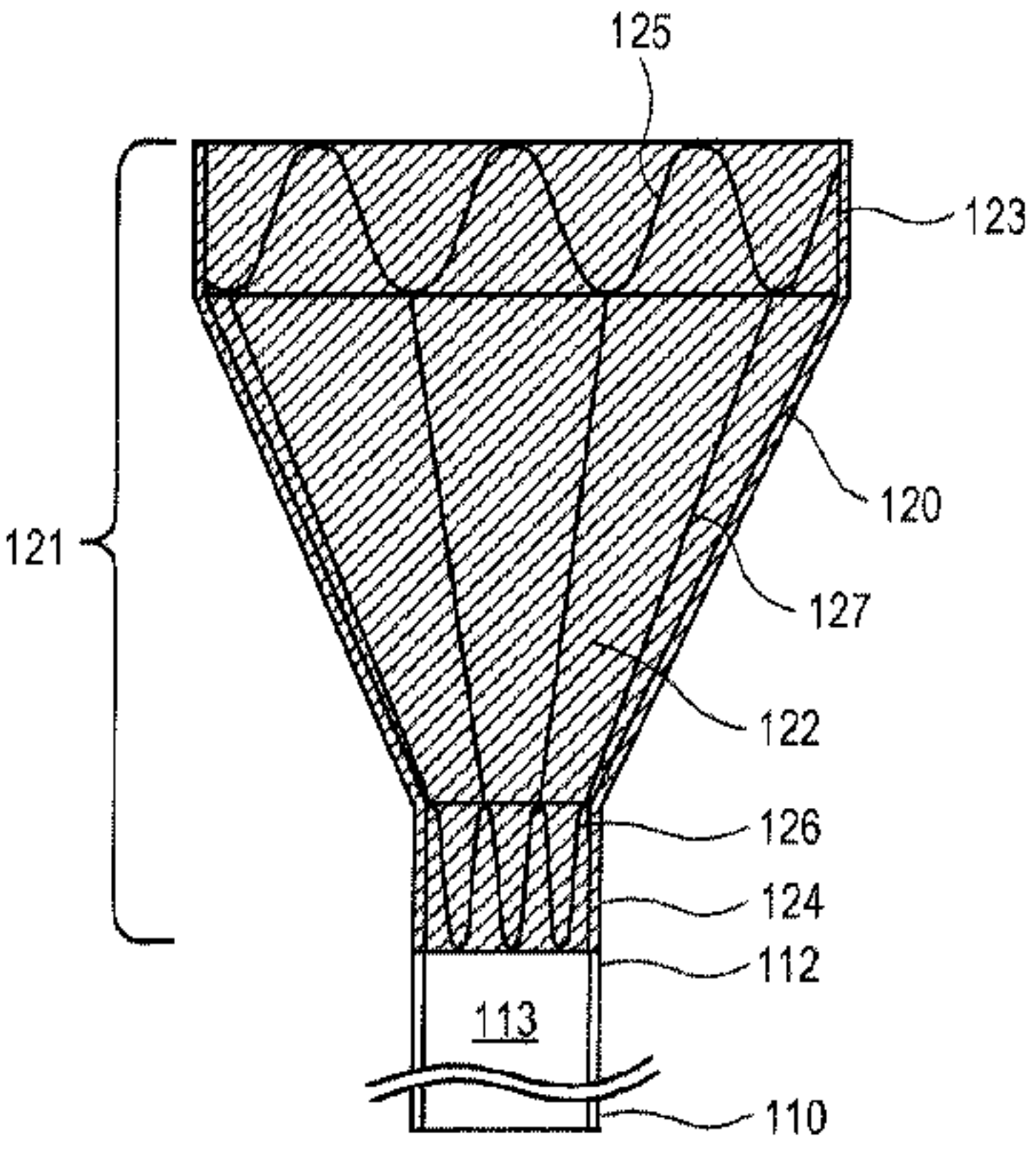
125
123
121
120
127
122
126
124
112
113
110

FIG. 1B