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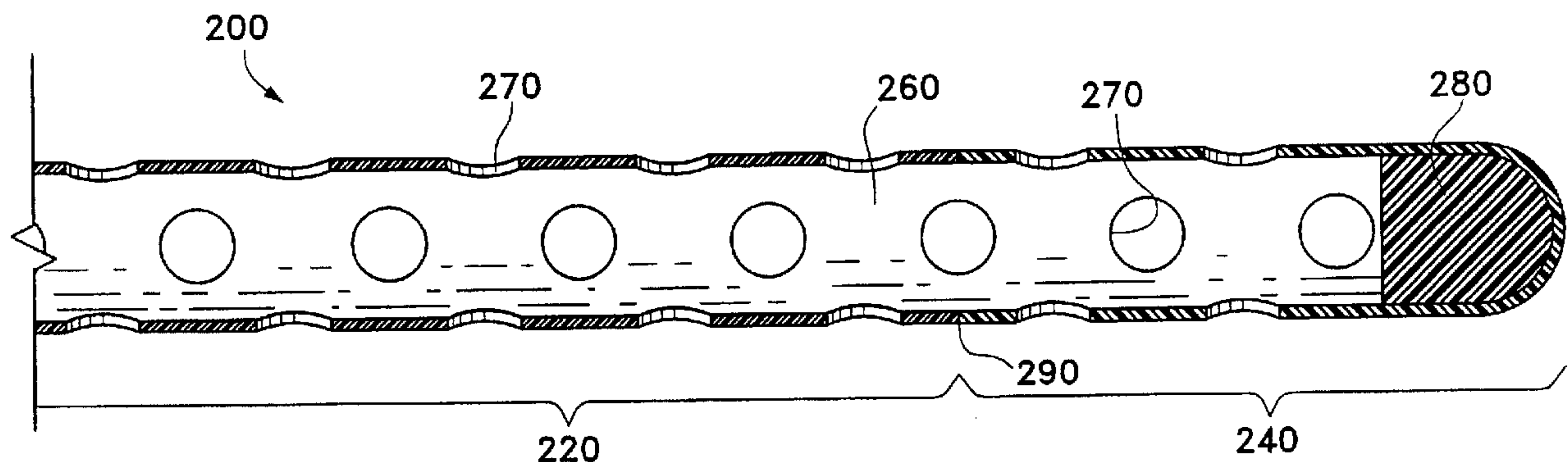
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(54) Titre : CATHETER DE DRAINAGE LOMBAIRE

(54) Title: LUMBAR DRAINAGE CATHETER



(57) **Abrégé/Abstract:**

This is a catheter assembly designed for accessing the cerebrospinal fluid circulation system and draining fluid therefrom. The polymeric thin-walled catheter has a soft, flexible distal region for minimizing trauma to tissue and angularly accessing the subarachnoid space in the cerebrospinal fluid pathway with an optional guidewire. A stiffer proximal region, which may optionally contain a reinforcing woven braid or coil ensures that the catheter does not kink or compress during use in the tough membranes around the spinal column. One or more apertures in the catheter wall for draining fluid proximally through the catheter central lumen allows for transport of fluid through the catheter at therapeutic flow rates and pressures. A soft polymeric plug that may be disposed in the distal end of the catheter assembly ensure minimal trauma to tissue upon entry. The entire catheter may be coated with hydrophilic coating to facilitate movement through an optional Touhy needle and tissue, and may be radio-opaque for greater visibility under fluoroscopy.

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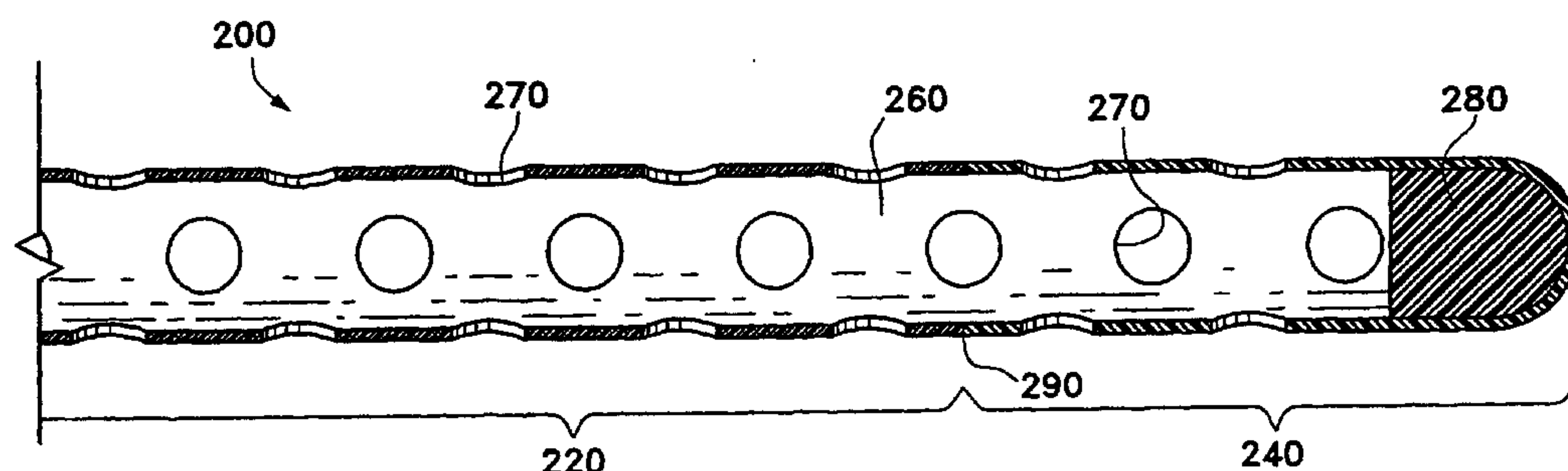
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LUMBAR DRAINAGE CATHETER

FIELD OF THE INVENTION

This invention generally relates to cerebral and lumbar catheterization apparatus for perfusing and draining fluids from the cerebral and spinal regions. In particular, this invention is a lumbar drainage catheter for accessing the cerebrospinal fluid (CSF) pathways and efficiently removing fluids from those passageways.

BACKGROUND OF THE INVENTION

Despite recent improvements in the understanding and treatment of stroke, this disease remains the third leading cause of death in the United States. It follows only heart disease and cancer. It is the largest single cause of neurologic crippling in the country, and kills nearly 160,000 Americans each year. It is also one of the leading causes of adult disability.

In addition to its tragic health consequences, stroke costs the United States about \$40 billion annually in treatment and rehabilitation expenses as well as lost job productivity. Therefore, there is still a critical need for further improvement in the prevention, detection, and treatment of stroke and stroke-related injury.

One difficulty with effective treatment is related to the speed with which a stroke inflicts cellular damage. For ischemic stroke, the cascade caused by the stroke-initiated infarct occurs rapidly. Without prompt medical treatment, typically within about six hours of the stroke event, brain cells in the penumbra surrounding the infarct will die.

Although neural tissue in this penumbra does not exhibit notable necrosis until about 24 hours after the stroke-causing occlusion is formed, vascular tissue and smaller arterioles are susceptible to irreparable damage within 30 minutes of occlusion. Edema also begins to occur throughout the penumbra due to reduced cellular ion pump activity; this will result in swelling of the neural tissue and accelerated neural tissue damage.

One method for providing timely therapy to neural tissue under such severe ischemic conditions is introducing an oxygenated fluorocarbon nutrient emulsion (OFNE) through a portion of the ventriculo-subarachnoid spaces surrounding the brain and spinal cord where the cerebrospinal fluid (CSF) exists. Emulsions such as those described in U.S. Patent No. 4,981,691, to Osterholm et al., the entirety of which is herein incorporated by

WO 01/13984

PCT/US00/40736

reference, are well-known in the art. OFNE treatment is intended to provide much-needed oxygen and nutrients to neural and vascular tissue until collateral circulation develops or the occlusion resolves. It offers a powerful emergency therapy for those individuals suffering the first symptoms of ischemic stroke.

5 There are a variety of methods for introducing and monitoring the introduction of fluids such as OFNE into the CSF pathway system. For example, circulation systems such as those disclosed in U.S. Patent Nos. 4,393,863 and. 4,378,797, both to Osterholm, the entirety of which are each incorporated by reference, have been taught for systems and methods for perfusing oxygenated nutrient emulsions into the brain ventricles and
10 withdrawing them from, e.g., the spinal sub-arachnoid space. These and other references also show how such emulsions are monitored and treated to adjust oxygen and carbon dioxide partial pressure, temperature, chemical composition, fluid flow rates, etc.

 Such fluids are introduced into the brain ventricles via specialized perfusion catheter arrangements such as those described in U.S. Patent No. 4,840,617, to Osterholm.
15 These catheters are specially designed for penetrating the skull, safely navigating brain tissue to the brain ventricle, and reliably delivering OFNE to the CSF pathway.

 Such fluids are removed from the CSF pathways by use of specialized drainage catheters. In addition to removing OFNE in a scheme such as that described above, there are various other reasons for the need to effectively drain fluid from the CSF pathways.
20 For instance, a type of hemorrhagic stroke known as a subarachnoid hemorrhage, in which an aneurysm bursts in a large artery on or near the dural matter surrounding the brain, blood may enter into the CSF pathway and present the need for draining the contaminated CSF.

 Disorders such as cerebral edema, neurosurgical sequelae, encephalitis, or neoplastic
25 disease, as well as severe head or spinal trauma may present the need for draining or tapping the CSF. For instance, patients with hydrocephalus, a condition in which there is an abnormal increase in the amount of CSF within the cranial cavity, are presented with life-threatening levels of elevated intracranial pressure that must be relieved by drainage.

 Such drainage may be accomplished by tapping into the CSF pathway via a
30 specialized drainage catheter in a number of locations, including the ventricles of the brain, the cisterna magna, and the subarachnoid space in the spinal column, for example. The exact location from which a physician chooses to access the CSF pathway will depend

upon a number of factors, including the indication being treated, the condition of the patient, the type of treatment selected, etc.

For drainage catheters designed to access the CSF pathway through the lumbar region, a number of considerations must be taken into account -- especially when they are used in conjunction with OFNE perfusion. For instance, the catheter must have appropriately-sized apertures and an internal lumen for allowing fluid flow to freely take place at designated flow rates and pressure ranges while preventing blockage by the cauda equina (spinal nerve roots) or the arachnoid membrane. The catheter diameter and the tip must be appropriately designed to access the subarachnoid space of the spine with minimal trauma to the patient, yet must be able to resist kinking or crushing upon entry through the dermal back tissue and the tough dura mater outside the subarachnoid space. The catheter should also be radiopaque so that its visibility can be maximized to verify placement.

What is needed is a lumbar drainage catheter for accessing the CSF pathway that meets these and other requirements.

SUMMARY OF THE INVENTION

This invention is a lumbar drainage catheter assembly made up of a polymeric single- or multiple-wall elongate tubular member forming a lumen and having an exterior wall, a distal end, and a proximal end. The tubular member, and in particular, a distal portion of the tubular member, is of a size and flexibility suitable for entry into a subarachnoid space without substantial trauma to neural tissue and yet is very resistant to crushing and to kinking during use. The tubular member typically has at least one aperture through its wall. The apertures are usually spaced away from the distal end of the catheter. The size of the lumen, the overall length of the catheter assembly, and the size, placement, and number of apertures through the tubular member wall and certain other variables related to fluid flow are chosen so that during normal use, the catheter can accommodate CSF flowrates of 3-150 ml/min (preferably greater than 50ml/min.) at driving pressures of about 15 cm H₂O.

The distal end of the catheter assembly may either be closed or open, depending on the particular application required. When the distal end is open, the catheter is adaptable for passage of a guidewire completely therethrough and allows for greater fluid flow from the exterior of the catheter through the lumen to assist in the drainage process.

A soft polymeric distal tip plug may, instead, be situated in the distal-most end of the catheter lumen to provide added mass and to minimize trauma to the tissue of the lumbar region surrounding the spinal column. This plug may be solid or have one or more channels or lumens to allow fluid to flow therethrough.

5 In general, the proximal section of the catheter elongate tubular member is stiffer than the distal section. This may be accomplished by the use of polymeric materials having a higher stiffness than those materials making up the softer, more flexible distal section. It may also be accomplished by varying the wall thickness of the elongate tubular member in the catheter proximal section, or by including a braid or coil in the proximal section interior
10 to the catheter exterior wall.

The catheter assembly elongate tubular member may also contain an inner polymeric liner defining the lumen and an outer cover coaxial to said inner polymeric liner which defines the exterior surface. In this variation, a woven braid or coil may be situated coaxially between the liner and cover. The proximal portion of the outer cover may be
15 stiffer than the distal portion of the outer cover.

The coil or braid may be of stainless steel, super-elastic alloys, polymers, or mixtures thereof. It should be MRI compatible. It may be made of filamentary components such as wire, ribbon, thread, or their mixtures.

At least a portion of the elongate tubular member may be radio-opaque. When the
20 tubular member is polymeric, a radio-opaque filler such as barium sulfate, bismuth oxide, bismuth oxychloride, bismuth carbonate, powdered tungsten, powdered tantalum and mixtures thereof may be used. Alternatively or in combination with filler material, one or more radio-opaque markers may be included to provide visibility to the catheter assembly.

This invention may also include a flexible guidewire which is inserted within the
25 catheter lumen from the catheter proximal end. It is preferred, but not necessary, that such a guidewire when unrestrained by the catheter lumen has a naturally nonlinear, semicircular, or "J" form. Once inserted into the catheter lumen, the catheter takes on a shape influenced by the nonlinear guidewire form. Preferably, such shape is presented as about a 5° to 15° bend in the distal portion of the catheter-guidewire combination. This
30 facilitates entry into the spinal subarachnoid space in the direction of the patient's head.

The flexible distal section of the catheter assembly may also have an unrestrained shape so that after deployment in the subarachnoid space and the guidewire is withdrawn, the elongate tubular member self-forms into an elbow that bends approximately 90°. This

elbow is preferably, but not necessarily, proximal of at least one of the catheter apertures so as to promote fluid drainage.

The catheter is also designed to work in conjunction with a Touhy needle to facilitate insertion of the catheter through the dermal, cartilaginous and other tissues surrounding the subarachnoid space. This Touhy needle generally has an interior lumen through which the inventive catheter and guidewire may be introduced.

The Touhy needle may have a curved distal end to guide or to urge the catheter, usually with an included guidewire, in the direction of the patient's head or feet, whichever is clinically indicated. To allow easier passage of the catheter assembly through the Touhy needle lumen and more importantly through the spinal tissue, the surface of the elongate tubular member exterior wall typically is coated with a lubricious, hydrophilic layer.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic lateral cross-section of the spinal column and nerve roots detailing various tissues in the region of the L4 and L5 vertebrae.

Figure 2A shows, in longitudinal cross section, one design of the lumbar catheter of the present invention.

Figure 2B is a longitudinal cross section of the distal end of a variation of the lumbar catheter of the present invention having a distal aperture and channel for fluid flow therethrough.

Figure 3A shows a partial sideview of an aperture having a modified entrance region.

Figure 3B shows a front view of the aperture of Figure 3A.

Figure 4A shows a partial sideview of a second variation aperture having a modified entrance region.

Figure 4B shows a front view of the aperture of Figure 4A.

Figure 5 shows a sideview of a portion of the inventive catheter with external spacing fibers.

Figure 6A shows a sideview of a portion of the inventive catheter with external spacing ribs.

Figure 6B shows a sideview of a portion of the inventive catheter with external spacing ribs.

Figure 6C shows a sideview of a portion of the inventive catheter with external spacing ribs.

Figure 7A shows, in partial longitudinal cross section, another design of the lumbar catheter of the present invention having a reinforced section.

5 Figure 7B shows the lumbar catheter of Figure 7A in transverse cross section along the line B-B.

Figure 7C shows the lumbar catheter of Figure 7A in transverse cross section along the line C-C.

10 Figure 7D shows the lumbar catheter of Figure 7A in transverse cross section along the line D-D.

Figures 8A-8C show partial cutaway views of the catheter of the present invention showing variations of the anti-kinking member.

Figures 9A and 9B show, respectively, sideview and top views of further variations of the catheter of the present invention.

15 Figures 10A and 10B show, respectively, sideview and top views of further variations of the catheter of the present invention.

Figure 11 depicts a kit made according to the present invention including a catheter of the present invention, a guidewire, a Touhy needle, and an obturator.

20 Figures 12A-12D show schematic views of the catheter of the present invention and how it assembles with a shaped guidewire and Touhy needle for insertion into the lumbar region.

Figure 13 is a depiction of the human cerebrospinal fluid circulation system and one configuration of using the lumbar catheter of the present invention in conjunction with an inflow catheter to perfuse and drain oxygenated fluorocarbon nutrient emulsion from the
25 cerebrospinal fluid circulation pathway.

Figures 14A and 14B show side views of a catheter stay suitable for use with this invention.

DESCRIPTION OF THE INVENTION

30 This invention includes a lumbar drainage catheter assembly for accessing the CSF pathway, or the subarachnoid space, via the lumbar region of the human spine. One single-wall variation includes a stiffer proximal section having a higher material hardness so to resist kinking and compression during deployment and use. A less stiff, softer distal section perhaps having a soft polymeric, distal plug provides needed flexibility and assures

minimal tissue damage. A number of openings through the catheter wall allows CSF, OFNE, or other therapeutics or diagnostics to drain from the spinal subarachnoid space into the catheter lumen out through an open proximal end.

A double-wall variation includes a braid, perhaps woven, or a coil or coils in the proximal section to provide added stiffness, and, more importantly added compression and kink resistance, to the catheter. Either variation may be used with a guidewire and Touhy needle for precise placement into the delicate subarachnoid space.

Figure 1 is a partial lateral cross-section of the human spinal column (100) in the area most appropriate for application of the lumbar catheter discussed below. In particular, this cross-section depicts the spinal column (100) around the L4 (designated with reference numeral (110)) and L5 (designated with reference numeral (120)) vertebrae. The tough and fibrous dura mater (130) is the outermost membrane protecting the spinal cord. Situated adjacent the dura mater (130) is the subdural space (150), which is bordered by arachnoid (140), another more delicate membrane covering the spinal cord. The pia mater is a further discrete membrane covering each individual nerve root.

The subarachnoid space through which CSF flows is designated in Figure 1 as element (160). The subarachnoid space (160) serves as a reservoir also housing the spinal cord, or, in the region depicted in Figure 1, the cauda equina (170). The cauda equina (170) are the collection of spinal roots that descend from the lower part of the spinal cord (not shown) in the lumbar region.

In a typical application, OFNE is perfused from the cerebral ventricles through the dural tube down along the spinal cord to the lumbar region as in Figure 1. The lumbar catheter of the present invention accesses the subarachnoid space (160) from, for instance, the gap between L4 (110) and L5 (120) and drains the OFNE therefrom.

One catheter assembly which incorporates the concepts of this invention is shown in longitudinal cross section in Figure 2A.

Catheter (200) is characterized by a single-wall elongate tubular member forming a lumen (260) and exterior wall and having a proximal end (205) and distal end (210). The elongate tubular member consists of a proximal tubular section (220) and a distal tubular section (240). Such a construction gives catheter (200) multiple bulk elastic moduli along its length.

The typical configuration shown in Figure 2A has a moderately stiff proximal section (220) to prevent its crushing or kinking when present in the ligature of the back, a

WO 01/13984

PCT/US00/40736

distal shaft section (240) which is typically more flexible to minimize kinking due to moduli differences, and soft polymeric tip plug (280) for minimizing trauma to the dural tissue and promoting proper placement of the catheter. Tip plug (280) resides in the lumen (260) shown in distal tubular section (240) and may also occupy a portion of lumen (260) in proximal section (220). These and other features of catheter (200) are described below in greater detail.

The typical dimensions of catheter (200) are:

Overall length:	150-450 mm
Proximal section (220) length	145-420 mm
Distal section (240) length	5-30 mm
Tip plug (280) length	0.025-5.0 mm

Obviously, the specific dimensions are not particularly critical to this invention except to the extent that they promote or inhibit flow of the CSF, as discussed below. The specific dimensions may be varied as the location of use and particular function required of the catheter vary.

In particular, we have found that a proximal section (220) length of between about 180 and 200 mm is suitable. Likewise, a distal section (240) length of between about 10 and 15 mm is desired. Plug (280) preferably has a length of between about 1.0 and 4.0 mm; more preferably about 1.5 to 2.0 mm. The overall length of catheter (200) is generally between about 190 and 210 mm.

Through judicious choice of physical parameters for the catheter sections, the components may also have varying physical parameters e.g., lubricity, flexibility, wall thickness, inner or outer layer member composition, etc. within the sections.

Proximal section (220) makes up the majority of the length of catheter (200), and serves several purposes. As described above, one particularly important purpose is to provide enough bulk stiffness and form to the catheter to ensure that the catheter is not kinked or crushed when the catheter is in use. The proximal portion (220) of catheter (200) should also be sufficiently stiff to allow the user to push the catheter (200) through the Touhy needle (discussed and shown below) during placement of the catheter. Passage through membranes such as the tough dura mater (130), associated muscles, tendons, and the arachnoid (140) to access the subarachnoid space (160) without such kinking or crushing is a requirement served by such a proximal section. It is also desirable that the

inner lumen (260) within at least a portion of the proximal section (220) be larger than the lumen in the distal section (240) so to enhance the overall flow capabilities of the catheter.

Another purpose of proximal section (220) is optionally to provide for one or more apertures (270) for the drainage of CSF or OFNE when the catheter is in place.

5 The proximal section (220) also provides an interface at proximal end (205) through which the catheter (200) may join or interact with other equipment, etc. in the manner appropriate for the particular application for which the catheter is being used.

10 The proximal section (220) of catheter (200) may be of a single-wall construction of a thin polymeric tubular member. The outer diameter of proximal section (220) may be between about 50 and 100 mils and more preferably between about 55 and 75 mils.

Likewise, to ensure that lumen (260) has the capacity to handle necessary CSF/OFNE flow rates and house guidewires or like elements, the inner diameter of proximal section (230) may be between about 30 and 70 mils and preferably between about 40 and 60 mils.

15 The optimal inner diameter of proximal section (220) will be ultimately determined to attain maximum volume of fluid flow over a given period of time while not compromising the structural integrity of the catheter assembly (200). It is contemplated that for application in the CSF pathway, the catheter should accommodate flow rates of between about 3 and 150 ml/minute, preferably between about 5 and 75 ml/minute, more
20 preferably about 40 ml/minute, and most preferably about 50 ml/minute each at approximately 15 cm H₂O of fluid driving pressure. Again, the size of the lumen (260), the overall length of the catheter assembly (100), and the size, placement, and number of apertures (270) through the tubular member wall and certain other variables related to fluid
25 flow are chosen so that during normal use, the catheter can accommodate the desired CSF and included drug flowrates. These dimensions are chosen and interrelated depending on the performance characteristics required.

Any biocompatible, polymeric material suitable for medical application that meets the requirements of the catheter assembly can be used for proximal section (220). Because we use this catheter with the Osterholm OFNE discussed above, the polymers chosen
30 should be compatible with those fluids, which contain significant fluorocarbon content. Particularly useful classes of polymers are polyurethanes, various polyethylenes (including low density polyethylene (LDPE), linear low density polyethylene (LLDPE)), polypropylene, polybutenes, polyamide (such as Nylons), high density polyethylene

(HDPE), polyimides, polyvinylchloride, fluorocarbon resins (e.g., PTFE, FEP, vinylidene fluoride, their mixtures, copolymers, block copolymers, etc.), etc., and other polymers of suitable hardness and modulus of elasticity. Blends, alloys, mixtures, copolymers and block copolymers of these materials are also suitable if desired. We have found that medical grade urethane sold under the name TECOFLEX (Thermedics, Inc., Waltham, MA) having a Shore hardness of approximately 80A-200A, preferably about 95A-125A is suitable.

In addition, proximal section (220) may be stiffened by increasing its wall thickness. This will alter its bulk elastic performance under the conditions contemplated.

The fenestrations or apertures (270) are shown, in this variation, to be situated both within the proximal and distal (240) sections of the catheter assembly (205). Typically, though, the apertures (270) are placed only in the distal section (240). In some variations of the invention, we have eliminated the fenestrae (270) from the distal-most 3mm of the distal section (240). The only substantial limitation of the aperture placement is that the apertures should not be either outside of the body or situated in the subdural space when finally and properly situated within the patient.

These openings (270) are necessary for fluid flow between, and preferably from, an area external to the catheter into the lumen (260) of proximal section (220). Ideally, they are of a diameter, spacing, and pattern that maximizes the flow rate of fluids such as CSF, OFNE, drugs or diagnostics from the subarachnoid space through lumen (260) towards proximal end (205). Once at proximal end (205), fluids may be collected from lumen (260) for diagnostic monitoring or the like.

Fenestrae (270) generally have a relatively small diameter so to optimize the twin goals of maximizing fluid flow rates and maintaining the structural integrity of catheter (200). Another consideration for application in the subarachnoid space is the possibility that individual nerve root fibers of the cauda equina could partially or completely block fluid flow through one or more apertures (270), hindering the efficiency of the catheter drainage function. The apertures (270) shown in Figure 2A typically have diameters in the range of 0.010" to 0.060" depending upon the diameter of the catheter and the ability of the catheter to maintain the CSF flow-rates discussed above. It is within the scope of this invention to utilize multiple apertures (270) having diameters down to, e.g., 25 microns or so. It is further within the scope of this invention that the distal section (240) comprise a fabric containing these micro-apertures (270). Again, since these inventive catheters are

preferably used with Osterholm's OFNE, discussed above, which is preferably an emulsion, the apertures must not be of a size so small that they upset the micellar structure of the emulsion.

Of course, inextricably related to the choice of opening diameter is their number, their spacing, and their pattern in the catheter shaft. Catheter (200) of Figure 2A depicts four rows of seven apertures (270). In this configuration, the apertures are spaced about 3.8 mm apart in each of four rows arranged symmetrically about the catheter's central axis. Note also that the centers of the apertures in a given row are aligned with those in the opposing row; however, these same centers are offset from those in any adjacent row along the catheter central axis. This pattern is merely exemplary as are the Figure 2A aperture (270) diameter and spacing. For instance, it is within the scope of this invention that the fenestrae (270) be arranged in a spiral or other nonlinear or random pattern, or have variable spacing or diameters as desired.

As was noted above, the spinal roots in this portion of the subarachnoid space are free to move about there. They are very soft in texture and may clog the fenestrae (270) when CSF is withdrawn at high rates. Consequently, to lessen the possibility of this happening, a number of things may be done. As shown in Figs. 3A, 3B, 4A, and 4B, the apertures may be modified to broaden the suction zones of the apertures. As shown in Figs. 5, 6A, 6B, and 6C projections may be placed on the outer surface of the catheter in the region of the apertures. As will be discussed below, the shape of the catheter may be selected (and the placement of the apertures carefully selected) to minimize the propensity of the apertures to draw the nerve roots to the flow region near those apertures.

Figure 3A shows a cross-sectional side-view of an aperture (280) having a depressed, perhaps generally conical, entrance (or exterior) region (282) in a catheter wall (284). The depressed region (282) will help to maintain the nerve root away from the higher flow rate aperture (280). Figure 3B shows a partial front view of the aperture (280), and the depressed entrance region (282) in the catheter wall (284).

Similarly, Figure 4A shows a cross-sectional side-view of an aperture (286) having a shaped depressed entrance region (288) in a catheter wall (284). The shaped depressed region (288) provides a region which has a substantial length in a generally circumferential groove around the catheter. This may be desirable since the nerve roots generally run parallel to the longitudinal axis of the catheter when the catheter is in use. Figure 4B shows

a partial front view of the aperture (286), and the depressed entrance region (288) in the catheter wall (284).

Figure 5 shows a catheter section (300) having various apertures (270) and a number of brush-like projections (302) near the apertures (270). These brushes (302) must be very soft and flexible. Specifically, they must not cause injury to the nerve roots in the subarachnoid space when moved through that space during the introduction of the catheter; the brushes must easily fold during their passage through the Touhy needle and therefor not add those problems to the introduction of the catheter section (300) into the spine. As was the case just above, these projections (302) will keep the nerve roots away from the apertures (270) and lessen the chances that the nerve roots will clog the apertures.

Similarly, Figure 6A shows a catheter section (300) having circumferential ribs (306) adjacent the apertures (270). Circumferential ribs (306) hold the nerve roots away from the apertures (270). The circumferential ribs (320), as shown in Figure 6B, may be inflatable using, e.g., a separate lumen for the inflation fluid. Similarly, the projecting nibs (322) shown in Figure 6C may be inflatable.

Returning to Figure 2A, proximal end (205) is generically illustrated as an open-ended termination point of catheter (200). As will be discussed in conjunction with Figure 13, this configuration allows catheter (200) to be connected to a variety of components. For instance, tubing may be placed over the outer diameter of proximal section (220) so to capture fluid flowing through apertures (270) into lumen (260) for further collection or disposal. It is within the scope of the invention to modify proximal end (205) so to adapt catheter (200) for connection to a wide variety of components with a number of different configurations as will be clear to those of skill in the art.

Distal section (240) is preferably made from a polymeric material largely as described above for proximal section (220). The most important factor distinguishing distal section (240) from proximal section (220) is the lower elastic modulus and/or hardness of distal section (240), which is desired so that the distal end (210) of catheter (200) may be adequately maneuvered into the subarachnoid space without significant trauma. We have found that TECOFLEX medical grade urethane having a Shore hardness of approximately 80A-190A and preferably about 85A-110A is suitable for distal section (240). Other types of polymeric materials discussed above with respect to proximal section (220) can comprise distal section (240) as long as the overall flexibility of the distal section (240) is higher than that of proximal section (220).

The physical dimensions (i.e. inner and outer diameters) of distal section (240) will generally be the same as those discussed with respect to the distal section (240) although it is sometimes desirable to utilize a comparatively smaller diameter distal section (240) to improve the flow capabilities of the catheter assembly.

5 Proximal section (220) and distal section (240) are joined together at joint (290). To make the joint (290), the tubing making up the two sections are butted (or overlapped) on a TEFLON-coated inner mandrel and beneath an outer glass retainer and heat welded, adhered, or solvent welded together. Alternatively, joint (290) may comprise a discrete material different from that of either proximal section (220) or distal section (240). Joint
10 (290) is preferably formed so as to maintain smooth and continuous interior and exterior surfaces of the catheter. Such an interior surface minimizes drag on, and turbulence created in, fluid flowing through lumen (260). It also ensures that materials or instruments such as a guidewire may be inserted and removed from lumen (260) with minimum effort or obstruction. A smooth exterior surface promotes easy insertion to and removal from a
15 Touhy needle and, more importantly, minimizes trauma to tissue.

Polymeric tip plug (280) is shown in the distal-most end of catheter (200) in Figure 2A. This soft insert is typically between about 0.25 and 5.0 mm in length; more preferably between about 1.5 and 2.0 mm. The diameter of plug (280) is chosen to be slightly smaller than the inner diameter of distal section (240).

20 Plug (280) is preferably made of a softer polymer than that of distal section (240). Particularly suitable, is the polyurethane copolymer sold as TECOFLEX having a Shore hardness between about 70A and 150A, preferably between about 75A and 95A.

Such a soft tip provides added mass to the blunt distal end (210) of the catheter, promoting correct placement in the subarachnoid space (160) with minimal trauma. This
25 allows for shorter healing times of the entry wound and helps to minimize risk of post-procedure infection.

Distal end (210) is depicted in Figure 2A as closed to the exterior and to lumen (260). It is within the scope of the present invention, however, that this section (210) be open so that fluid flows through one or more apertures (270) in distal section (220) in the vicinity of the distal end (210), through or around (via a channel, etc.) tip plug (280) and
30 into lumen (260). One such arrangement with a single distal aperture is shown in Figure 2B, where a central channel (284) is formed in plug (280). Channel or lumen (284) is aligned with distal aperture (292) in the center of distal end (210) through distal section

(220). It is understood that this is but one of many arrangements of an open-ended design that is within the scope of the invention. An open ended design has several advantages. For instance, drainage of fluid through catheter (200) can be enhanced. Such an arrangement could also allow for passage of a guidewire through the entire catheter.

5 Catheters such as that of the present invention are typically inserted into the subarachnoid space using a Touhy needle. The procedure will be discussed below. Since a significant amount of force is needed to insert the Touhy needle, and subsequently the catheter, through the tough dura mater and other membranes in the lumbar region, any additional friction between the catheter exterior surface and Touhy needle interior surface
10 makes the procedure all the more difficult. In addition, once the catheter exits the Touhy needle and enters the subarachnoid space, friction between the catheter surface and tissue can hinder smooth introduction, raising the potential for trauma. Abrasion of the catheter surface by the opening of the Touhy needle is also a risk when the catheter is withdrawn proximally through the needle.

15 With this in mind, it is preferred that at least a portion of the exterior wall of catheter (200) (and those of the other inventive catheter variations discussed herein) be coated with a lubricious and typically hydrophilic layer, which either is chemically bonded or physically coated onto the catheter exterior surface. A description of suitable procedures for producing such lubricious coatings is found in U.S. Patent No. 5,531,715 to Engelson et
20 al. and U.S. Patent No. 5,538,512 to Zenzen et al. the entirety of each are which incorporated by reference. A preferred hydrophilic coating is a polypyrrolidone-based material sold by Hydromer Co. Although less preferred, silicone oils such as MDX are suitable.

A second variation of the present invention is shown in Figures 7A-7D. This
25 catheter is similar to the variation of Figure 2A, with a proximal end (305), a proximal section (320), a closed distal end (310) and a distal section (330); however, the entire catheter (300) has a dual-tubing shaft over its entire length. In addition, the proximal section (320) contains a stiffener or kink-resisting member (340), e.g., a woven braid, a laid-up braid, or one or more coils, interposed between the two polymeric shafts to
30 reinforce, to provide kink resistance, and to provide additional stiffness to the proximal section (320) of the catheter. These and other features of catheter (300) are described below in greater detail.

It should be apparent that graduated changes in catheter stiffness may be accomplished by utilizing tubing components of different durometer values.

Many of the features of the variation of the inventive catheter shown in Fig. 7A are the same as those relating to the Fig. 2A variation discussed above. For instance, the
5 typical dimensions are the same .

A main tubular catheter body shaft or inner polymeric liner (325) is situated within at least a portion, and preferably over the entire length of catheter (300) and provides the basic structure of the device. This liner may be of any of the suitable polymers discussed above, but preferably made from TECOFLEX urethane tubing having a Shore hardness of
10 approximately 80A-190A and preferably about 85A-110A.

As with the Fig. 2A catheter, the inner diameter of tubular polymeric liner (325) is preferably between about 30 and 70 mils and more preferably between about 40 and 60 mils. The wall thickness of shaft (325) is thus sized accordingly. These dimensions are obviously not critical and may vary from those cited above depending on the performance
15 characteristics required. The optimal inner diameter of tubular member (325) will be ultimately determined to attain maximum volume of fluid flow in a given period of time while not compromising the structural integrity of the catheter assembly (300).

Turning now to the proximal section (320) of catheter (300), Figure 3B shows in radial cross-section the innermost tubular shaft (325) that often extends the entire length of
20 catheter (300).

Particular to proximal section (320) is woven braid or coil (340), which is interposed coaxially between liner (325) and a stiffer proximal outer cover or tubular shaft (330). Braid or coil (340) provides additional mass and stiffness, and serves to ensure that the catheter resists kinking or crushing when traversing the tough membranes such as the
25 dura mater (130), muscles, ligaments, and arachnoid (140) as previously discussed.

Figs. 8A, 8B, and 8C show variations of the kink resistant member in partial cross-section.

Fig. 8A shows a catheter section (342) having a coil kink-resistant member (344) situated between the inner liner (343) and an outer cover (345). This section (342) is
30 usually the proximal section of the catheter, although it need not be. Of special interest in Figure 8A are the optional features that apertures (347) are found in the proximal section, that the coil (344) has a varying pitch, and that the apertures (347) are in a generally spiral

formation. It should be apparent that the coil pitch (and the braid pitch) control the stiffness of the catheter for a given wire or ribbon size.

Fig. 8B shows a woven braid (349) situated in the wall of the catheter assembly (351). A "woven" braid means that the individual wires or ribbons cross each other radially, in-and-out, as they pass axially down the length of the catheter. This is in contrast to the "unwoven" braid (353), shown in Fig. 8C, in which one layer of individual wires or ribbons making up the braid (353) in the catheter section (354) are simply wound one-way and then another layer of wires or ribbons are wound the other way, i.e., left-handed and then right-handed, one layer of coil windings on top of the other layer.

Returning to Fig. 7A, woven braid or coil (340) may be made from various filamentary components, such as wire, ribbon, thread, etc. and mixtures thereof. The particular choice of filamentary components making up braid or coil (340) will depend on the particular mechanical properties desired, cost and manufacturing considerations, etc.

The coil or woven braid can be made from, in whole or in combination, metals such as platinum, palladium, rhodium, gold, tungsten, titanium, tantalum, nickel, alloys thereof, stainless steel, and polymers. Preferably, the material should be MRI compatible.

A particularly useful class of alloys for the filamentary components of woven braid or coil (340) are of a member of a class of alloys known as super-elastic alloys. Preferred super-elastic alloys include the class of titanium/nickel materials generically known as nitinol -- alloys discovered by the U.S. Navy Ordnance Laboratory. These materials are discussed at length in U.S. Patent Nos. 3,174,851 to Buehler et al., 3,351,463 to Rozner et al., and 3,753,700 to Harrison et al. Commercial alloys containing up to about 8% or more, of one or more other members of the Iron Group of the Periodic Table, e.g., Fe, Cr, Co, are considered to be encompassed within the class of super-elastic Ni/Ti alloys suitable for this service. Desirable alloys having a transition temperature below body temperature, and desirably of less than 0° C are useful.

When using stainless steels or especially super-elastic alloys, an additional step may be desirable to preserve the shape of the stiffening braid. For instance, when using a Ni/Ti super-elastic alloy which has been rolled into a ribbon and woven into a braid, some heat treatment is desirable. Braids which are not treated in this way may unravel during subsequent handling or may undertake changes in diameter or braid member spacing during that handling. In any event, the braid is placed onto a mandrel, usually metallic, of an appropriate size. The braid is then heated to a temperature of 650°-750°F for a few

minutes, possibly (but not necessarily) annealing the constituent ribbon. After heat treatment, the braid retains its shape and the alloy retains its super-elastic properties.

By the term "ribbon", we intend to include elongated shapes, the cross-section of which are not square or round and may typically be rectangular, oval or semi-oval. They should have an aspect ratio of at least 0.3 (thickness/width). In any event, for super-elastic alloys, particularly nitinol, the thickness and width may be at the lower end of the range, e.g., down to 0.30 mil and 1.0 mil, respectively.

The ribbons making up the braid or coil (340) shown in Figure 7B may also contain a minor amount of non-super-elastic alloy materials. Although metallic ribbons are preferred as the ancillary materials because of their strength-to-weight ratios, fibrous materials (both synthetic and natural) may also be used. Suitable non-metallic ribbons include high performance materials such as those made of polyaramids (e.g., KEVLAR), liquid crystal polymers (LCP's), and carbon fibers. Preferred, because of cost, strength, and ready availability are stainless steels (SS304, SS306, SS308, SS316, SS318, etc.) and tungsten alloys. In certain applications, more malleable metals and alloys, e.g., gold, platinum, palladium, rhodium, etc. may be used. A platinum alloy with a few percent added tungsten is preferred partially because of its radio-opacity.

The braids utilized in this invention may be made using commercially available tubular braiders. The term "woven braid" is meant to include tubular constructions in which the wires or ribbons making up the construction are woven radially in an in-and-out fashion as they cross to form a tubular member defining a single lumen. The braids may be made up of a suitable number of ribbons, typically six or more. Ease of production on a commercial braider typically results in braids having eight or sixteen ribbons.

Braid (340) can be either a single, double, or multiple-ribbon or -wire wind. Single-ribbon or wire winds permit the braid to contain the maximum amount of open area between ribbons in the braid. In a double-wind variation, a pair of ribbons or wires is placed side by side. This variation produces a braid which is denser than the single wind. It is also thicker. Typically, the regions between adjacent winds are smaller. The invention described herein is intended to encompass multiple-wind braids. Because the stiffness of the proximal section (320) substantially increases as the number of wires or ribbons used in a multiple-weave is increased, or as the spacing between coil windings is decreased, it is within the scope of this invention to tailor the braid or coil (340) so to obtain the desired stiffness of proximal section (320).

The braid or coil (340) typically will have a nominal pitch angle (to the catheter axis) of 45°. Clearly the invention is not so limited. Other angles from 7.5° to 60° are also suitable. A variation of this invention is the ability to vary the pitch angle of the braid or coil (340) either at the time the braid or coil (340) is produced or at the time the braid or coil is included in the catheter proximal section (320).

Woven braid or coil (340) is present throughout the entire proximal section (320) of catheter (300), and preferably extends from the most proximal end of the catheter to within approximately 10 mm of the most proximal aperture (360). However, the invention is not so limited, and braid or coil (340) can, if necessary, extend distally throughout the entire length of catheter (300).

It is also within the scope of this invention that catheter (200) of Figure 2A additionally comprise a braid or coil such as braid (340) discussed above. In this case, the braid or coil would preferably be disposed interior to proximal section (240), and even distal section (240), in lumen (260).

For both catheter (200) of Figure 2A and catheter (300) of Figure 7A, such braid or coil (340) may be simply press fit into the catheter shaft or may be bonded using available mechanical, thermal, and chemical bonding techniques. It is contemplated that for catheter (200), a polymeric layer may be bonded to braid or coil (340) in such a configuration so to present the lumen (260) with a continuous, smooth surface as discussed above.

Returning to catheter (300) of Figures 7A-7D, proximal outer cover or tubing (335) surrounds braid or coil (340) and is mechanically, thermally, or chemically bonded to braid or coil (340). Typically, when using polyurethane as the outer cover (335), the inner liner (325) and braid or coil (340) are slid into a polyurethane tubing. The assembly is then placed inside a temporary shrink-wrappable polymeric tubing of, e.g., polyethylene or Teflon, and the whole assembly is heated. The heating both shrinks the temporary shrink-wrappable polymeric tubing and preferably passes through the glass point of the polymer in the outer cover (335). The outer cover (335) is squeezed onto the braid or coil (340) and, upon cooling, the assembly is an integral whole. The temporary shrink-wrappable polymeric tubing is then peeled off.

Any of the biocompatible polymeric materials, particularly those materials discussed above, that are suitable for medical application and that meet the requirements of the catheter assembly can be used for outer cover (335). Particularly useful is the material

WO 01/13984

PCT/US00/40736

sold as TECOFLEX having a Shore hardness of approximately 85A-200A and preferably about 90A-110A.

Proximal outer cover (335) extends from the proximal end (305) of catheter (300) through proximal section (320) to joint (350) as shown in Figures 7A, 7B, and 7C. The
5 outer diameter of proximal outer cover (335) is preferably between about 50 and 80 mils. The inner diameter, will of course, be designed to best fit over liner (325) and braid or coil (340). Figure 7C details in cross section proximal outer cover (335) in relation to inner liner (325) in the region of the apertures.

At joint (350), cover (335) is joined to distal outer cover or tubular shaft (345),
10 which is in turn joined to liner (325) as previously described. It is desirable that joint (350) forms a continuous and smooth bond between liner (325) and cover (335). Joint (350) is shown in Figure 7A as located distal of the distal-most aperture (370) and proximal to polymeric tip plug (380). However, the location of joint (350) may be varied in either direction along the catheter axis depending on the performance requirements and
15 manufacturing concerns for the particular catheter in consideration.

Distal section (330) is that portion of catheter (300) distal to mid-section (320) and to proximal section (310). The outer layer (345 in Fig. 7D) of distal section (330) may be an extension of the proximal outer cover or tubular shaft (335), but need not be as shown where the distal outer cover or tubular shaft (345). Note that in this section, distal outer
20 cover (345) as shown in Figures 7A and 7D extends from joint (350) around the distal-most end of catheter (300) and encompasses polymeric tip plug (380). It preferably has an outer diameter of between about 50 and 80 mils.

Polymeric tip plug (380) is shown disposed in the lumen (360) of catheter (300), and serves the same purpose as tip plug (280) of catheter (200) as discussed with relation to
25 Figs. 2A and 2B. As with catheter (200), catheter (300) may also have an open distal end with one or more apertures to enhance drainage of fluid through the catheter lumen and to possibly allow passage of a guidewire therethrough.

All of the polymeric portions of the catheter assembly in the various Figures, including the proximal and distal shafts, both inner and outer, as well as the plug, may be
30 radio-opaque for visibility under fluoroscopic examination. This allows the physician to more readily verify placement of the catheter.

This may be accomplished, for example, by filling the polymers noted herein radio-opaque filler materials such as barium sulfate, bismuth oxide, bismuth trioxide, bismuth

oxychloride, bismuth carbonate, powdered tungsten, powdered tantalum, or the like. It is preferred, but not critical, that the radio-opaque material make up about 40% (wt) of the polymeric material so maximum visibility can be had.

Alternatively, though not shown in the figures, the catheters of the present invention may be made radio-opaque, if so desired, by the placement of rings or other markers of radio-opaque metals such as platinum, etc. at appropriate locations along the length of the catheter.

Figures 9A, 9B, 10A, and 10B show two other variations of the inventive catheter that may utilize either of the physical makeup discussed in relation to Figs. 2A and 7A.

Figure 9A shows a side view of a corkscrew-like catheter (362) with apertures (364) which are preferably within the inside of the turns of the cork-screw. The distal-most section (366) of the catheter (362) is straight. The depicted shape has the following benefits, and is specifically to help deny the nerve roots in the spine an opportunity to approach the apertures and, indeed, to push them away from the center of the catheter (362). The distal-most section (366) is to allow the catheter (362) to align with the nerve roots and prevent the catheter (362) from encircling a nerve root. Again, the catheter, when properly deployed, will have formed a small central area or central volume free of nerve roots and into which the apertures are directed.

Fig. 9B shows a top view of the Figure 9A catheter (362). The view shows an open volume (368) within the catheter (362) turns. There need not be an open area there, the shape of the catheter (362) may be wound tighter so that the corkscrew is very "tight." Obviously, the push to the outside of the catheter (368) is lessened for, e.g., young spines and for smaller cavities.

Figure 10A shows a catheter (372) having a design similar to that in Fig. 9A but in which the corkscrew portion is only in the distal section, much like a "pigtail." This form is often easier to insert through a Touhy needle because of the fewer number of turns. Again, the corkscrew may be wound quite tightly and the apertures are preferably within the inside of the turns of the corkscrew section. Fig. 10B shows a top view of the Figure 10A catheter (372).

The shaping of the catheters found in Figures 9A, 9B, 10A, and 10B may be produced by heat-shaping during production of the devices either by heating the formed device or by pre-shaping the anti-kinking members discussed above.

Figure 11 shows a typical kit having a catheter (382) made using the invention, a Touhy needle (383), an obturator (384), and a guidewire (385). The obturator (384) is a simple solid needle having a distal end cut at an angle approximating that of the distal end of the Touhy needle. The obturator (384) is fit into the Touhy needle (383) upon rotation
5 forms a circular opening in the affected area. Once the combination of obturator (384) and Touhy needle (383) is properly situated in the subarachnoid space, the obturator (384) is removed. The catheter (382) is then placed in the lumen of the Touhy needle (383). Catheter (382) includes apertures (386) and a variety of typical markers (387, 388, and 389). Marker (387) is a double marker which indicates to the user that the distal end of the
10 catheter (382) is at the distal end of the Touhy needle (383). Double marker (388) is a distance marker at, e.g., one inch. Markers (389) are also distance markers depicting, e.g., one-quarter inch.

Turning now to Figures 12A-12D, the catheter (420) of the present invention is shown in conjunction with guidewire (410) and Touhy needle (430).

15 As discussed above, during use, the catheter is typically inserted into the subarachnoid space via a Touhy needle such as needle (430) shown in Figure 12D. As the catheter exits the needle (430), the catheter typically turns to enter the subarachnoid space along the spinal column axis so that its direction of motion is towards the patient's head.

To accomplish this turn, three features may be used. The first is the curved
20 guidewire (410) as shown in Figure 12B. The second is a self-forming distal end on catheter (420). The third is Touhy needle (430) having an asymmetrically curved distal end (440).

During use, guidewire (410) having a generally nonlinear proximal end (412) or, as shown in Figure 12A, a "J" or semicircular-shaped distal end (414) is inserted into the
25 lumen of catheter (420) through its proximal end (Figure 12C). The distal portion of catheter (420) is flexible enough so that the elongate tubular member making up the catheter takes on an approximation of the shape of the guidewire (410) as shown in Figure 12C. The angle created by this shape can vary, and is preferably between about 35° and 150° so to best facilitate entry into the subarachnoid space.

30 When unaccompanied by a guidewire, the catheter (420) may have a straight configuration, yet it is flexible and unrestrained. It is within the scope of this invention that the unrestrained elongate tubular member making up the catheter can be self-forming into a

WO 01/13984

PCT/US00/40736

form having an elbow. Such an elbow is depicted in Figures 9A and 10A discussed above. The elbow facilitates catheter placement in the direction of the length of the subarachnoid space when the catheter is oriented properly in the subarachnoid space and the shaped guidewire has been withdrawn from the catheter lumen. It is preferred, but not necessary, that the elbow be proximal to at least one of the apertures herein described so that drainage can be facilitated by allowing fluid to flow into the catheter lumen in a direction other than that of fluid flowing into other apertures. The angle formed between the portions of the tubular member of the catheter distal and proximal to the elbow when deployed can be generally between 60° and 120°.

Next, the guidewire-catheter combination is inserted through the Touhy needle into the lumbar region of the spinal column. Again, the elongate tubular member of catheter (420) is flexible enough and sized so that it can pass through a 10 to 18 gauge and preferably a 12 to 15 gauge Touhy needle.

As shown in Figure 12D, when the guidewire-catheter combination exits the distal end of Touhy needle in the vicinity of bend (440), it is directed to move in the subarachnoid space typically in the direction of the patient's head. Proper orientation of the Touhy needle so that bend (440) guides the guidewire-catheter assembly in this direction is helpful.

After the guidewire-catheter combination is advanced into the subarachnoid space in the desired direction as shown in Figures 12D and 13, the guidewire (410) is proximally withdrawn from catheter (420) and the lumbar drainage procedure can begin.

Figure 13 depicts one possible system for use with the catheter of the present invention. This figure depicts a CSF perfusion-drainage system deployed in a human cerebrospinal system. Inflow catheter (560) is inserted into the brain ventricle (500) so that it accesses the CSF pathway system of the human body. This system allows CSF, or in the case of the perfusion-drainage system of Figure 13, OFNE, to pass through the various regions of the CSF pathway. This includes ventricles (500), aqueduct (510), cisterna magna (520) and the subarachnoid space (530) of the brain and spinal cord.

A lumbar drainage catheter (570) of the present invention is shown in Figure 13 deployed in the subarachnoid space (530) between L4 (reference numeral (540)) and L5 (reference numeral (550)) with an approximate 90° bend as previously described. During the drainage procedure as shown in this simplified figure, OFNE drains through catheter

WO 01/13984

PCT/US00/40736

(570) into collection reservoir (600). A sterile filter (380) and aseptic air break (590) are shown in the OFNE flowpath prior to its deposit in the reservoir (600). Of course, other configurations and applications of the collection system may be used with this catheter.

One further ancillary device useful with this invention is shown in Figs 14A and 14B. The catheter stay (620) snugly holds a catheter (622) in place during its placement in the human body. This catheter stay (620) is made up of a somewhat tacky or sticky self-elongating woven cage (624). The woven cage (624) is a variation of the children's toy ("Chinese Finger Puzzle"). To release the cage (624), a lanyard (626) is provided. The woven cage assembly (624) is held on the surface of the body by a base (628) fixedly attached to the woven cage (624). The base (628) may include suture openings (630) allowing the woven cage assembly (624) to be affixed to the body by sutures (632) through the skin (631). Pulling on the catheter (622) should not allow movement of the catheter relative to the body.

Figure 14B shows the cinching of the lanyard (626) against the lanyard holder (633) to collapse the loosen the woven cage (624) and allow the catheter (622) to move relative to the skin (631).

This invention has been described and specific examples of the invention have been portrayed. The use of those specific examples is not intended to limit the invention in any way. Additionally, to the extent that there are variations of the invention which are within the spirit of the disclosure and yet are equivalent to the inventions found in the claims, it is our intent that those claims cover those variations as well.

WE CLAIM AS OUR INVENTION:

1. A lumbar drainage catheter assembly comprising:

an elongate tubular member having an overall length, an exterior wall, a distal end,
a proximal end, said tubular member forming a lumen surrounded by said exterior wall,

5 said tubular member being of a size and flexibility suitable for entry into a
subarachnoid space without substantial trauma to neural tissue surrounded by said
subarachnoid space,

 said tubular member being more flexible in the vicinity of the distal end than is the
tubular member in the vicinity of the proximal end, and

10 said tubular member defining at least one aperture having an aperture diameter,
through said exterior wall, said aperture being spaced away from said distal end,

 whereby said length, lumen, and at least one aperture and aperture diameter
cooperate to allow liquid flowrates of 3-150 ml/min at driving pressures of about 15 cm
H₂O through said lumen and proximal end.

15 2. The catheter assembly of claim 1 wherein said distal end is closed.

 3. The catheter assembly of claim 1 wherein said distal end is open.

 4. The catheter assembly of claim 1 wherein said liquid flowrate is 10-150 ml/min
at driving pressures of about 15 cm H₂O through said lumen and proximal end.

 5. The catheter assembly of claim 1 further comprising a soft polymeric plug
20 terminating the lumen at the distal end.

 6. The catheter assembly of claim 5 wherein said distal tip plug further comprises
at least one channel for passage of fluid therethrough.

 7. The catheter assembly of claim 1 wherein the elongate tubular member has an
unrestrained shape that is self-forming into a form having an elbow, said elbow being
25 proximal of said at least one aperture.

WO 01/13984

PCT/US00/40736

8. The catheter assembly of claim 7 wherein the elbow is approximately 90°.

9. The catheter assembly of claim 1 wherein the elongate tubular member is of a size and flexibility such that said member will pass through a 14 gauge Touhy needle.

5 10. The catheter assembly of claim 9 wherein an inner diameter of said elongate tubular member is about 0.05 inch.

11. The catheter assembly of claim 9 wherein said Touhy needle is a 12 gauge Touhy needle.

12. The catheter assembly of claim 9 wherein said Touhy needle is a 13 gauge Touhy needle.

10 13. The catheter assembly of claim 1 wherein at least a portion of the elongate tubular member is radio-opaque.

14. The catheter assembly of claim 13 wherein at least a portion of the elongate tubular member is polymeric and filled with a radio-opaque filler.

15 15. The catheter assembly of claim 14 wherein the radio-opaque filler is selected from the group consisting of barium sulfate, bismuth oxide, bismuth oxychloride, bismuth carbonate, powdered tungsten, and powdered tantalum.

16. The catheter assembly of claim 13 further comprising at least one radio-opaque marker.

20 17. The catheter assembly of claim 1 further comprising a coil or woven braid situated interior to said exterior wall.

18. The catheter assembly of claim 17 wherein said coil or woven braid is comprised of a material selected from stainless steels, super-elastic alloys, and polymers.

19. The catheter assembly of claim 18 wherein said coil or woven braid is comprised of filamentary components.

20. The catheter assembly of claim 19 wherein said filamentary components are selected from wire, ribbon, thread, or their mixtures.

21. The catheter assembly of claim 1 further comprising a lubricious coating on the surface of the elongate tubular member exterior wall.

5 22. The catheter assembly of claim 21 wherein said lubricious coating comprises polyvinylpyrrolidone.

23. The catheter assembly of claim 1 wherein at least a portion of the elongate tubular member is polymeric.

10 24. The catheter assembly of claim 23 wherein said polymeric portion of the elongate tubular member comprises polyurethane.

25. The catheter assembly of claim 13 wherein the elongate tubular member comprises an inner polymeric liner defining the lumen and an outer cover coaxial to said inner polymeric liner and defining the exterior surface.

15 26. The catheter assembly of claim 25 wherein said outer cover comprises a proximal outer cover and a distal outer cover, said proximal outer cover having a higher stiffness than a stiffness of said distal outer cover.

27. The catheter assembly of claim 26 wherein said proximal outer cover and said distal outer cover are fused to each other.

20 28. The catheter assembly of claim 26 further comprising a lubricious coating on the surface of the outer cover.

29. The catheter assembly of claim 28 wherein said lubricious coating comprises polyvinylpyrrolidone.

30. The catheter assembly of claim 25 further comprising a polymeric plug terminating the lumen at the distal end.

WO 01/13984

PCT/US00/40736

31. The catheter assembly of claim 25 further comprising distal tip plug having at least one channel for passage of fluid therethrough.

32. The catheter assembly of claim 25 further comprising a coil or woven braid situated coaxially between said inner polymeric liner and said outer cover.

5 33. The catheter assembly of claim 32 wherein said coil or woven braid is comprised of a material selected from stainless steels, super-elastic alloys, and polymers.

34. The catheter assembly of claim 32 wherein said coil or woven braid is MRI-compatible.

10 35. The catheter assembly of claim 32 wherein said coil or woven braid is comprised of filamentary components.

36. The catheter assembly of claim 35 wherein said filamentary components are selected from wire, ribbon, thread, or their mixtures.

37. The catheter assembly of claim 1 further comprising a guidewire insertable within said lumen from said proximal end.

15 38. The catheter assembly of claim 37 wherein said guidewire, when unrestrained by said lumen, has a natural guidewire form which is nonlinear.

39. The catheter assembly of claim 38 wherein said guidewire has a proximal and a distal end and said natural guidewire form is semicircular at the guidewire distal end.

20 40. The catheter assembly of claim 37 further comprising a Touhy needle having a interior lumen through which said elongate tubular member and said guidewire may be introduced.

41. The catheter assembly of claim 1 wherein said elongate tubular member has a corkscrew shape with an interior corkscrew surface.

25 42. The catheter assembly of claim 41 wherein said corkscrew shape with an interior corkscrew surface in the vicinity of the distal end.

43. The catheter assembly of claim 41 wherein said corkscrew shaped elongate tubular member has said at least one aperture opening onto said interior corkscrew surface.

44. The catheter assembly of claim 1 wherein said elongate tubular member includes multiple apertures.

5 45. The catheter assembly of claim 1 wherein said at least one aperture is surrounded by a suction-breaking region.

46. The catheter assembly of claim 1 wherein said at least one aperture is surrounded by a depressed region.

10 47. The catheter assembly of claim 1 wherein said at least one aperture is surrounded by a depressed conical region.

48. The catheter assembly of claim 1 wherein said at least one aperture is surrounded by a depressed region having a partial circumferential groove.

49. The catheter assembly of claim 1 further comprising projections adjacent said at least one aperture.

15 50. The catheter assembly of claim 49 wherein said projections adjacent said at least one aperture are fibrous.

51. The catheter assembly of claim 49 wherein said projections adjacent said at least one aperture are brushlike.

20 52. The catheter assembly of claim 49 wherein said projections adjacent said at least one aperture are rib-like.

53. The catheter assembly of claim 52 wherein said rib-like projections are circumferential around said tubular member.

54. The catheter assembly of claim 52 wherein said rib-like projections are inflatable.

WO 01/13984

PCT/US00/40736

55. A catheter stay comprising:

a.) a tacky, woven braid member having two ends and a lumen there through between said two ends, said braid member being self extending for grasping a catheter section extending through said lumen,

5 b.) a base fixedly attached to one of said woven braid member ends, and having at least one suture sites for suturing said base to a skin site, and

c.) a lanyard looped through said woven braid member lumen for releasing said self extending woven braid member from grasping said catheter section.

1/11

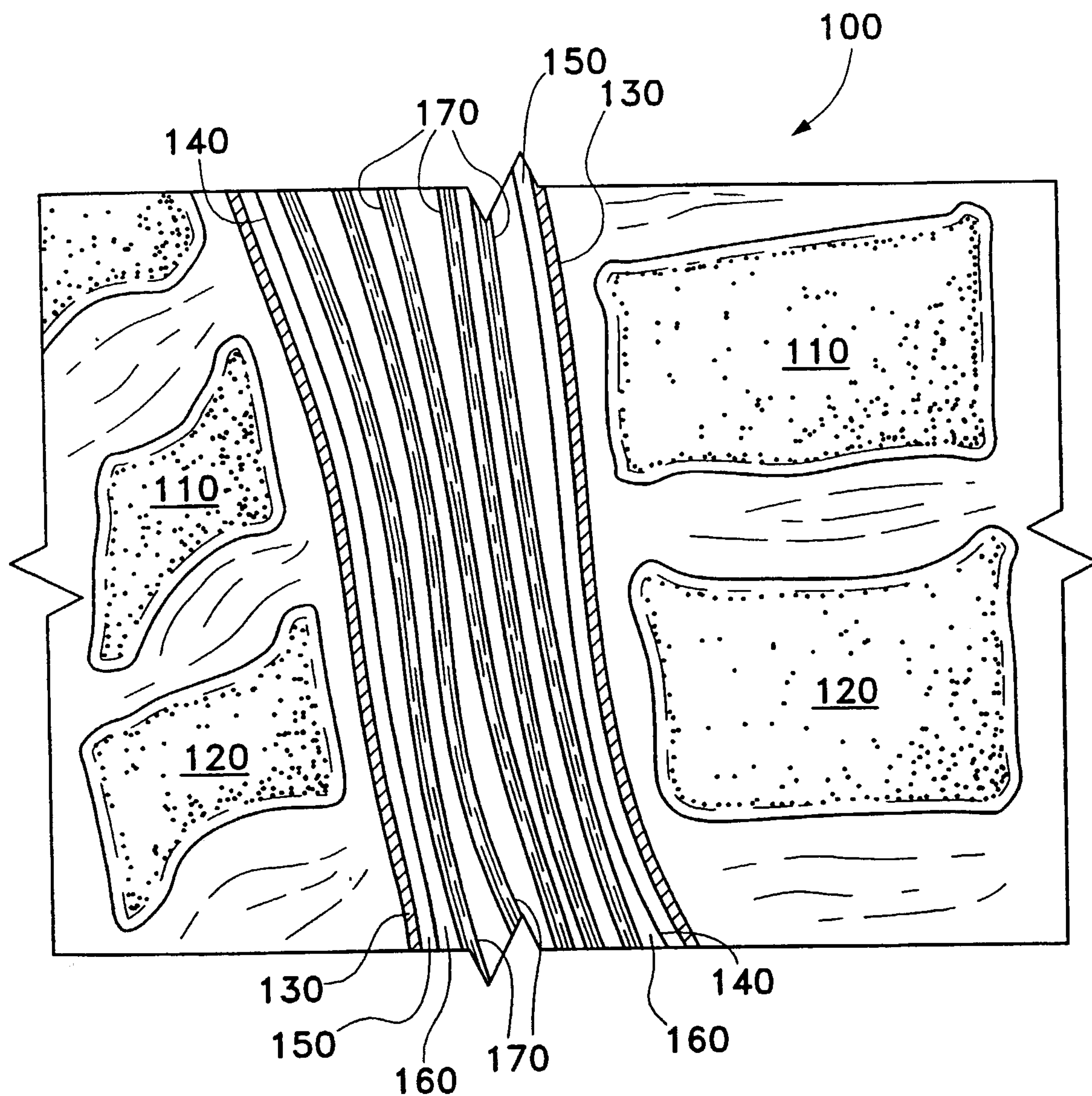


FIG. 1

2/11

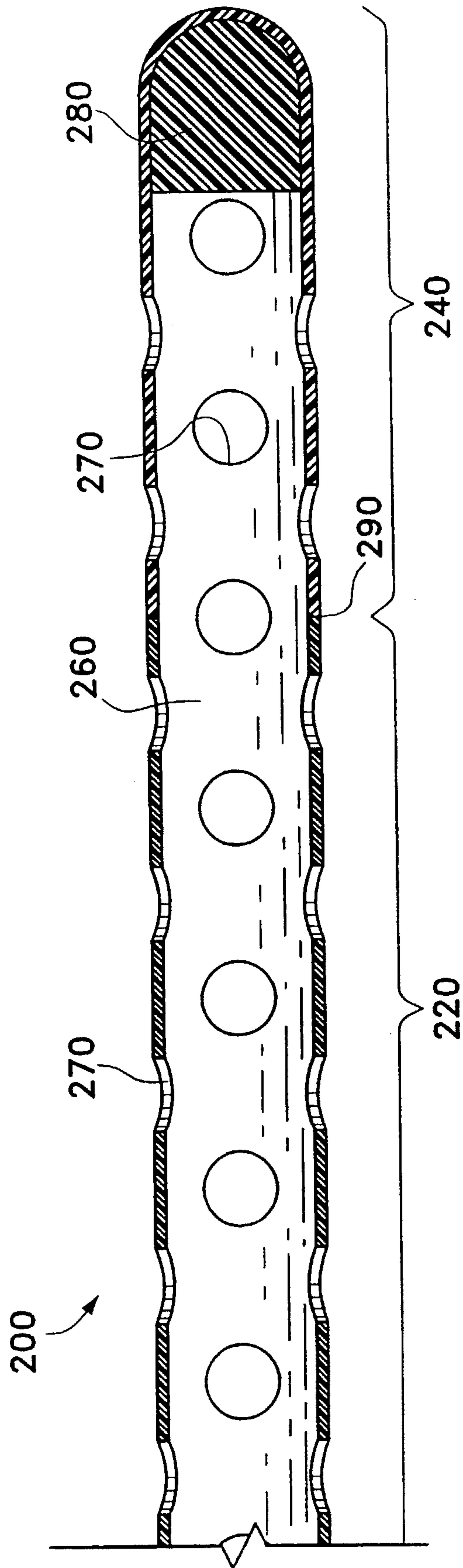


FIG. 2A

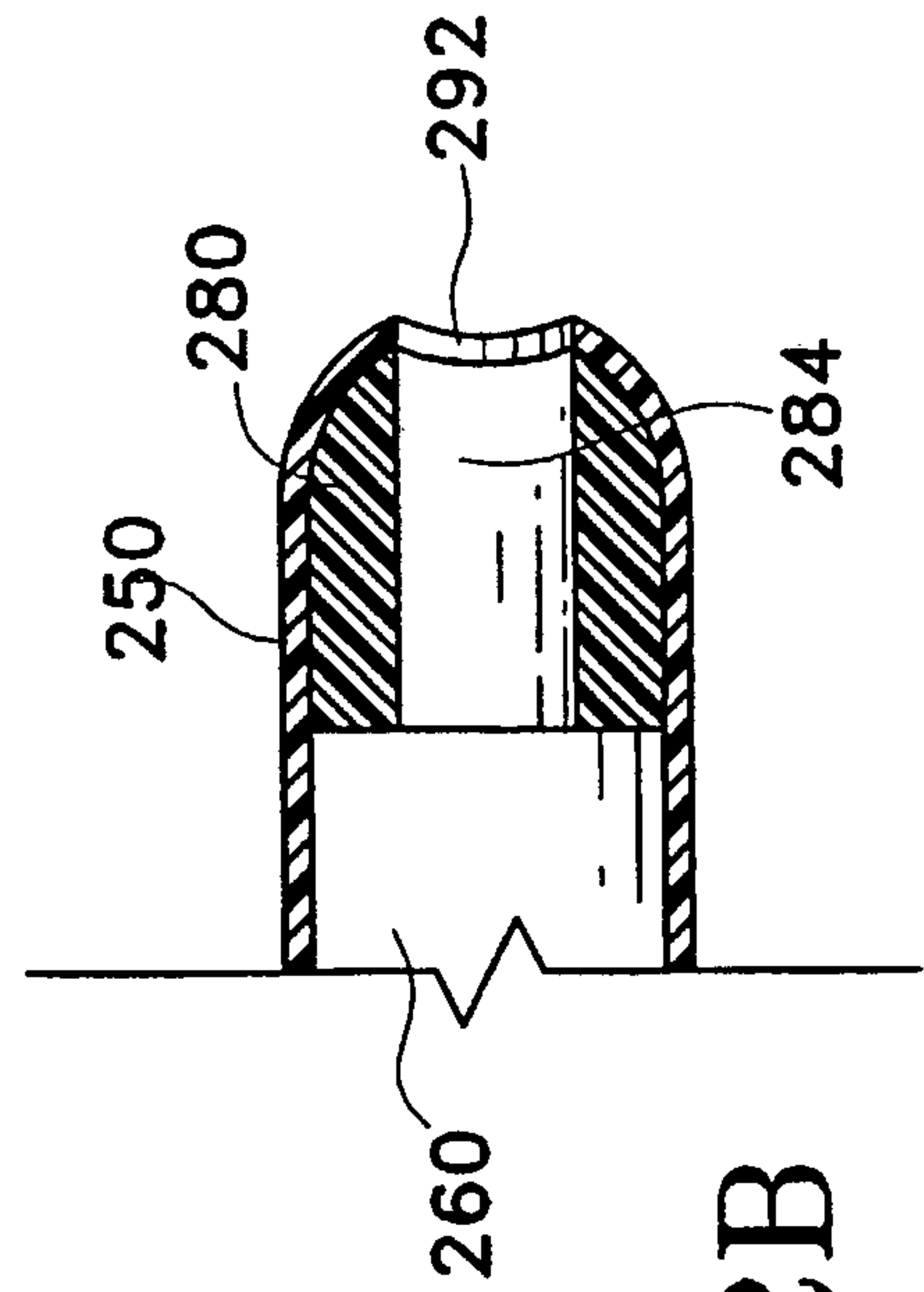


FIG. 2B

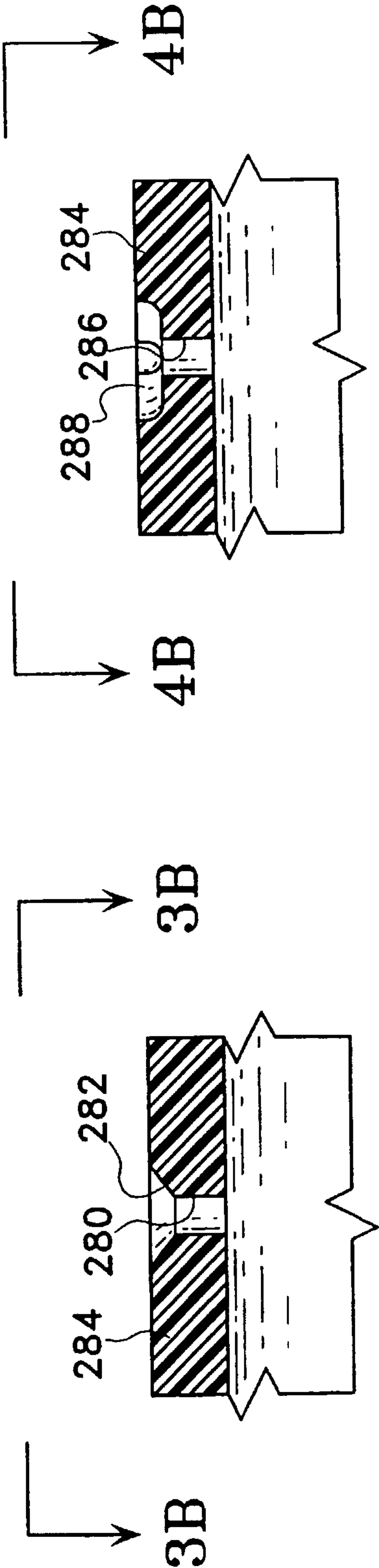


FIG. 3A

FIG. 3B

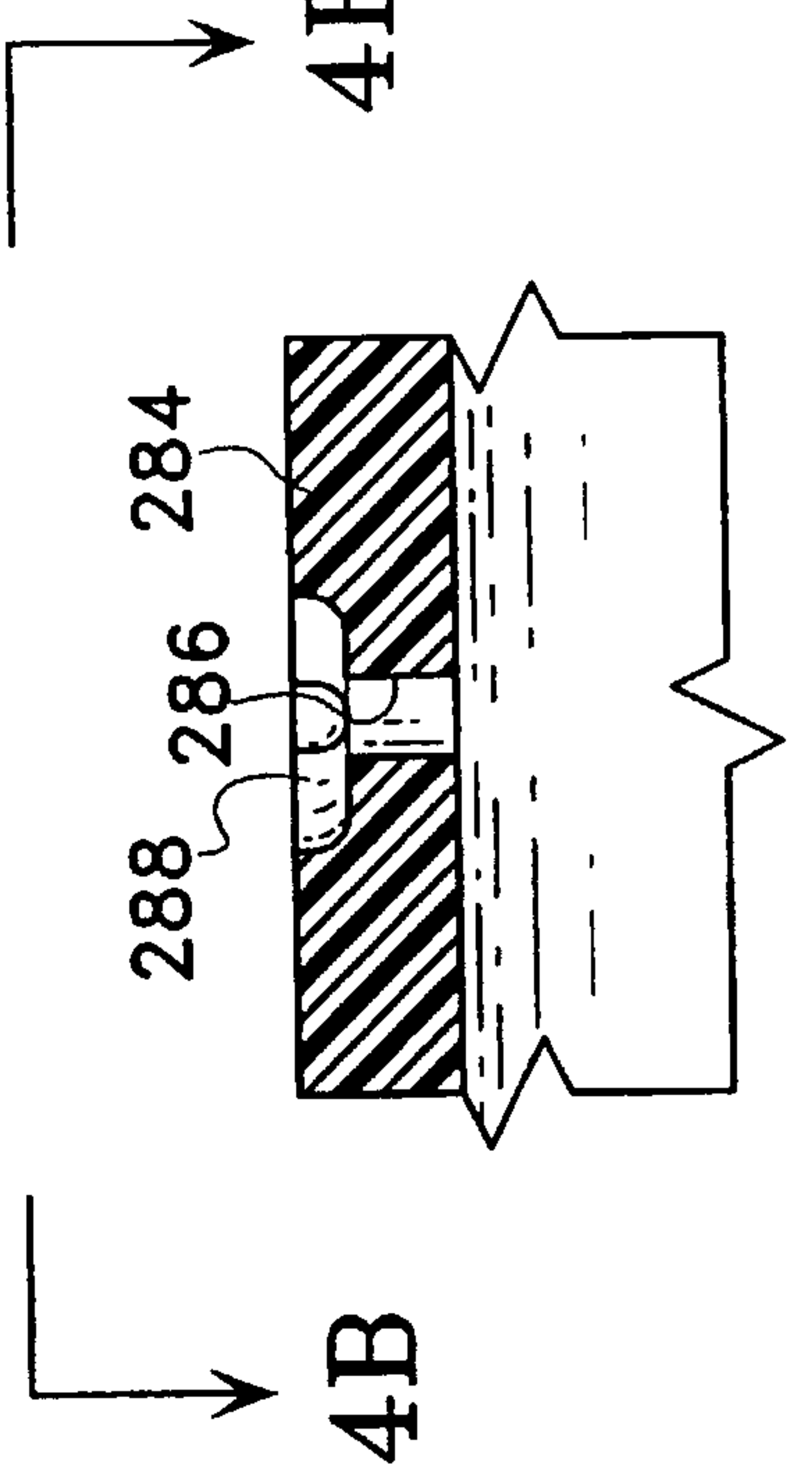


FIG. 4A

FIG. 4B

4/11

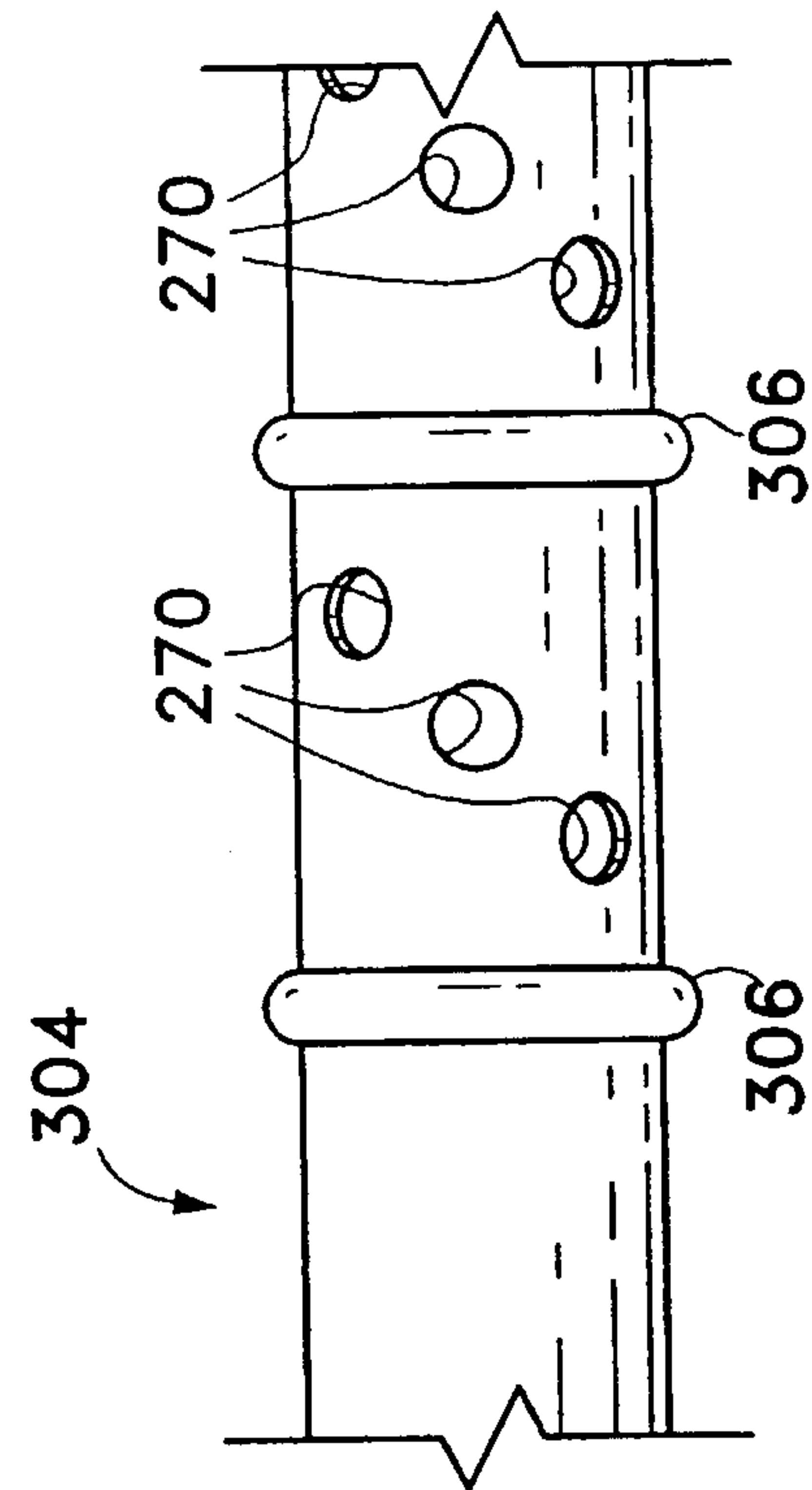


FIG. 6A

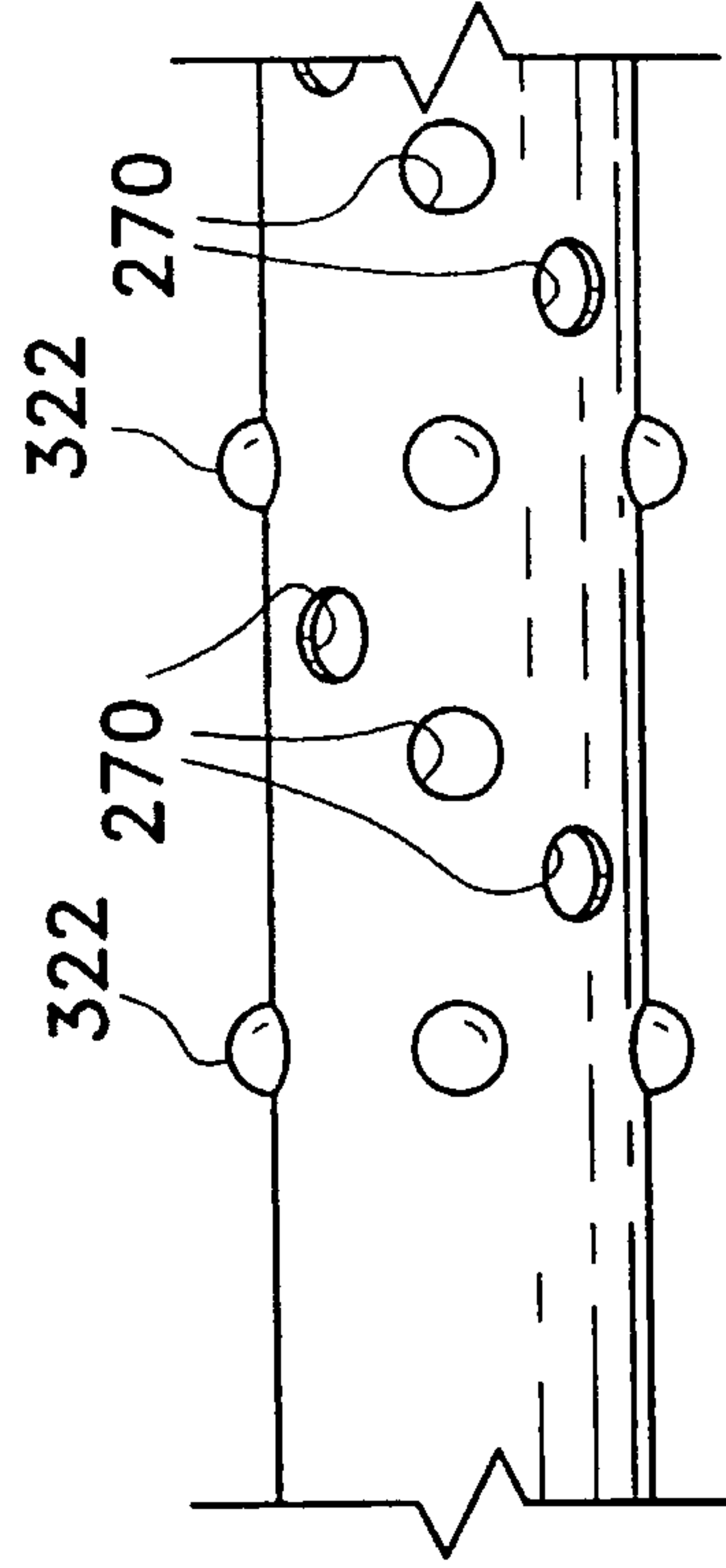


FIG. 6C

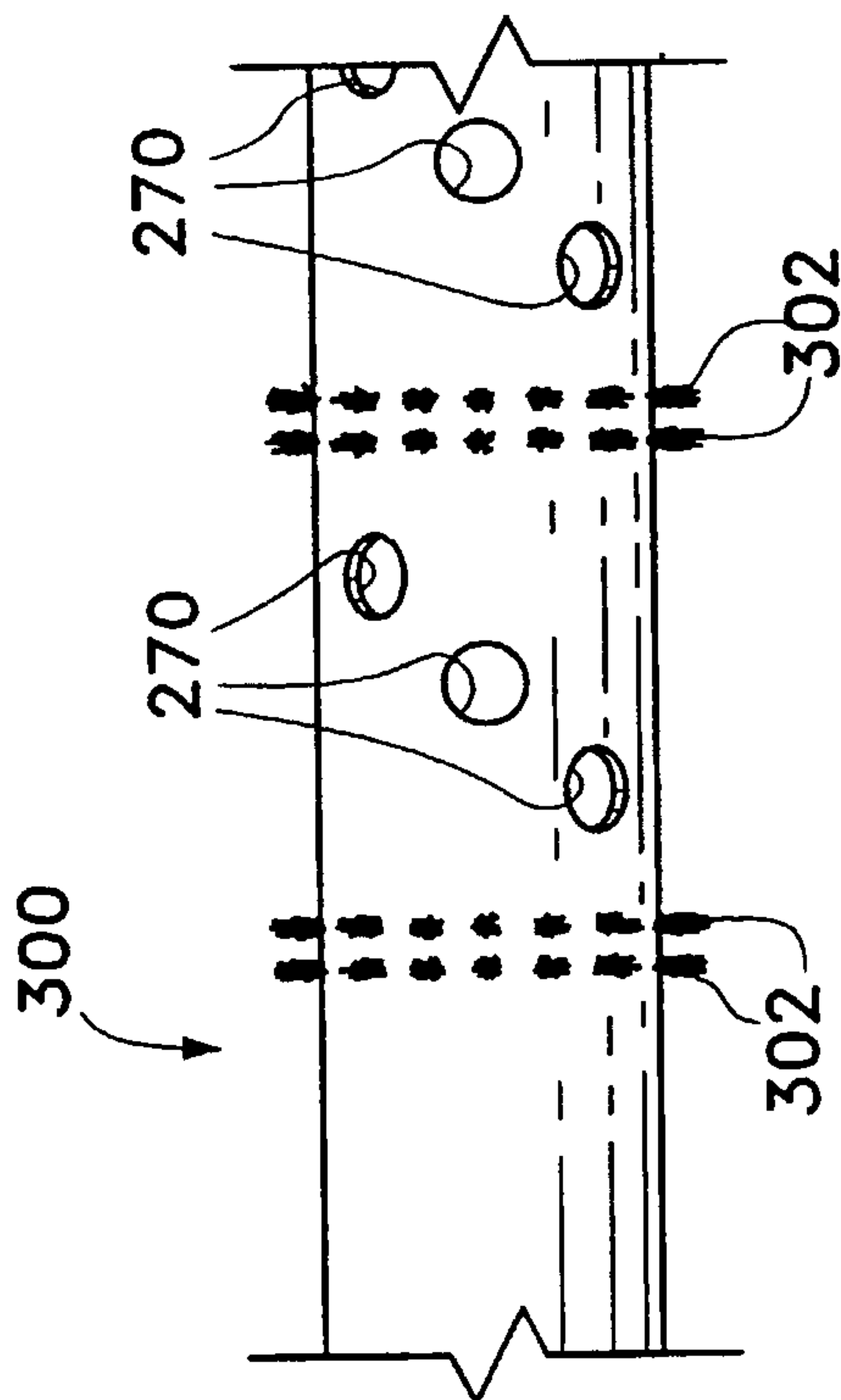


FIG. 5

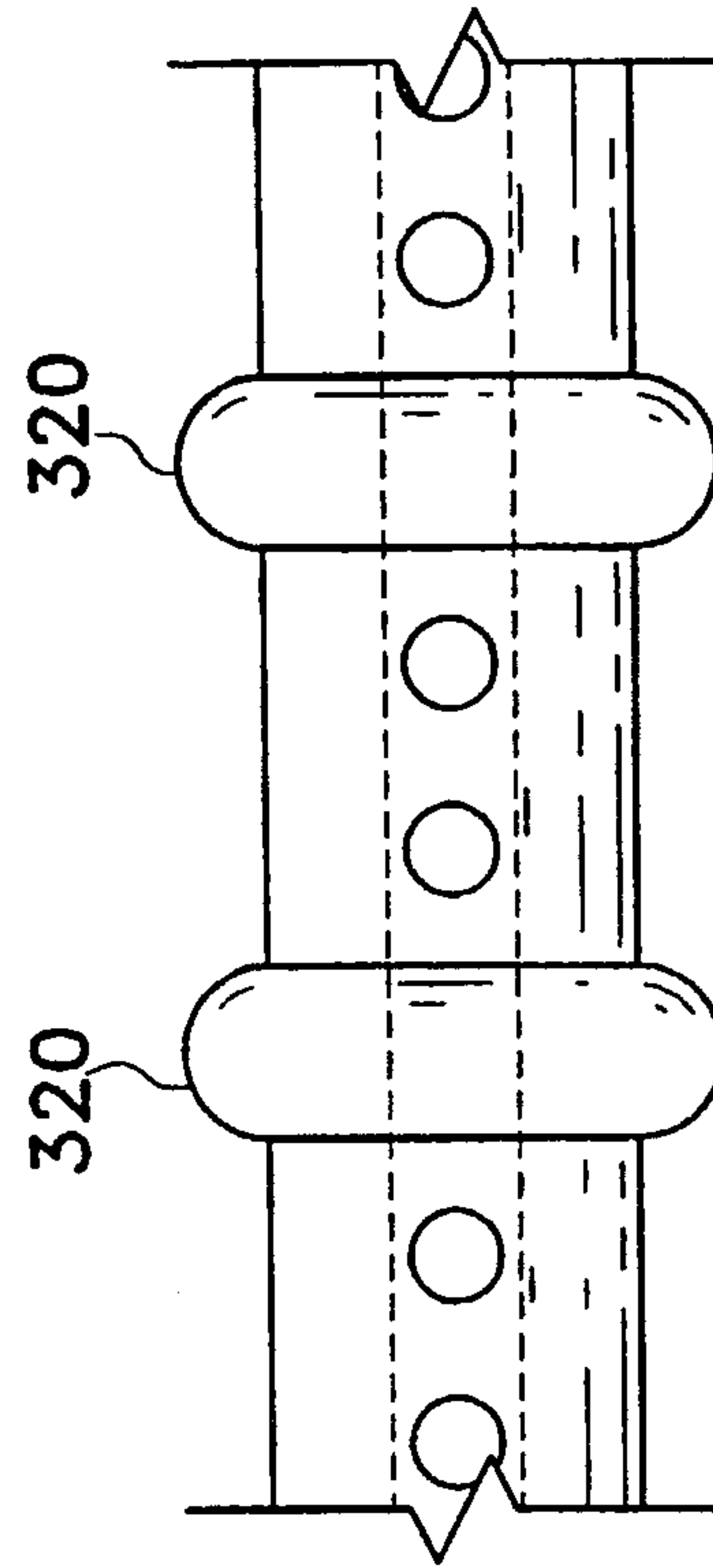
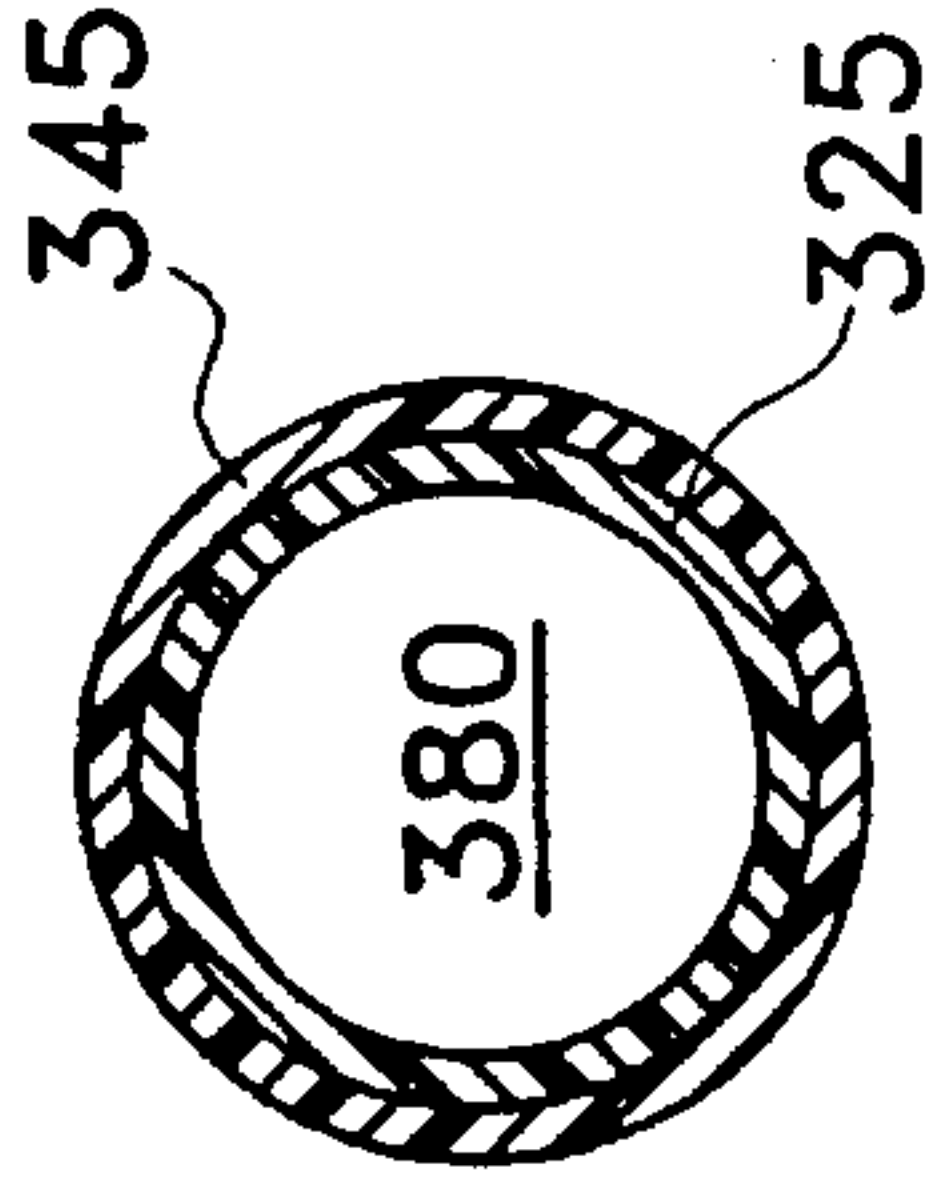
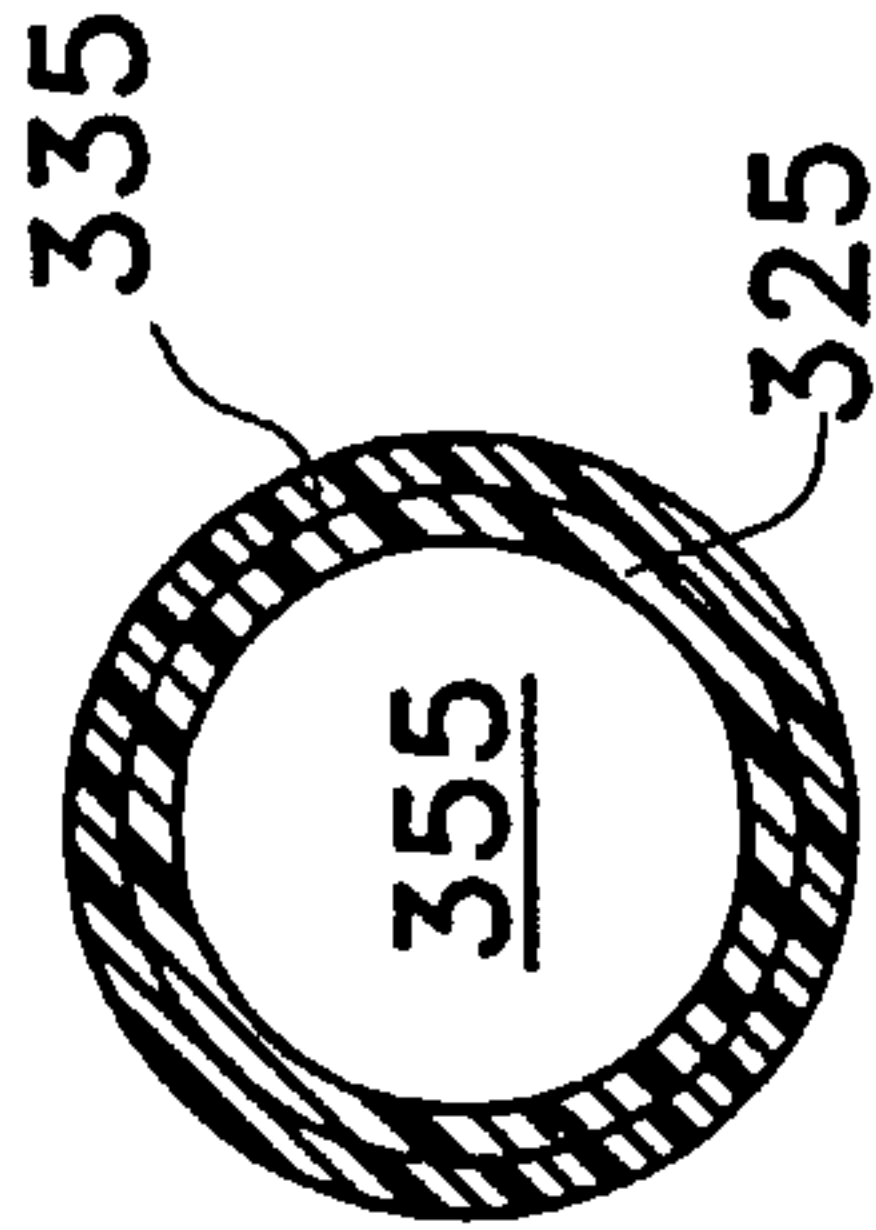
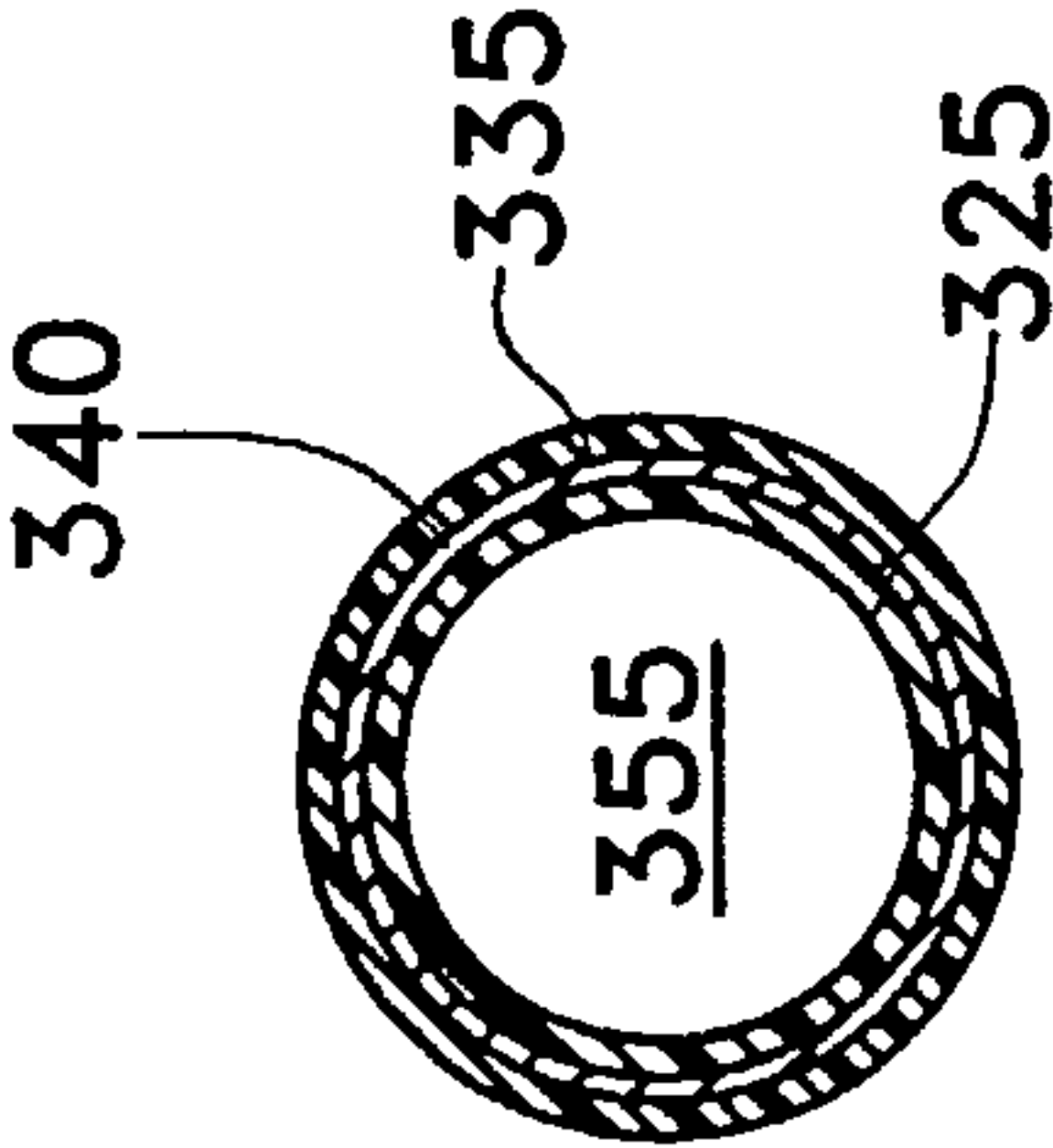
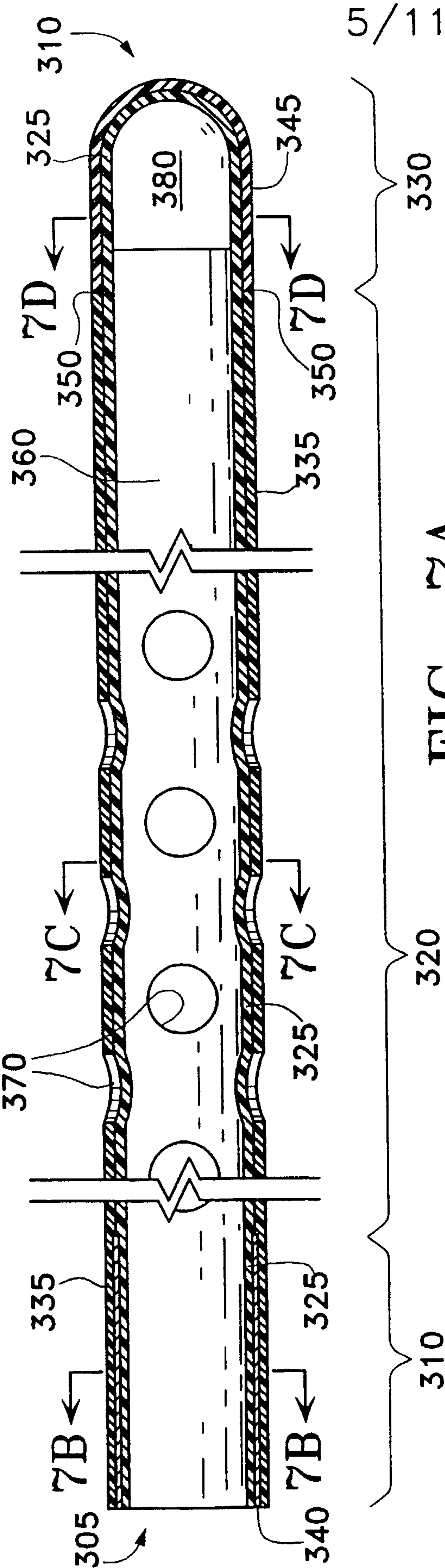


FIG. 6B



6/11

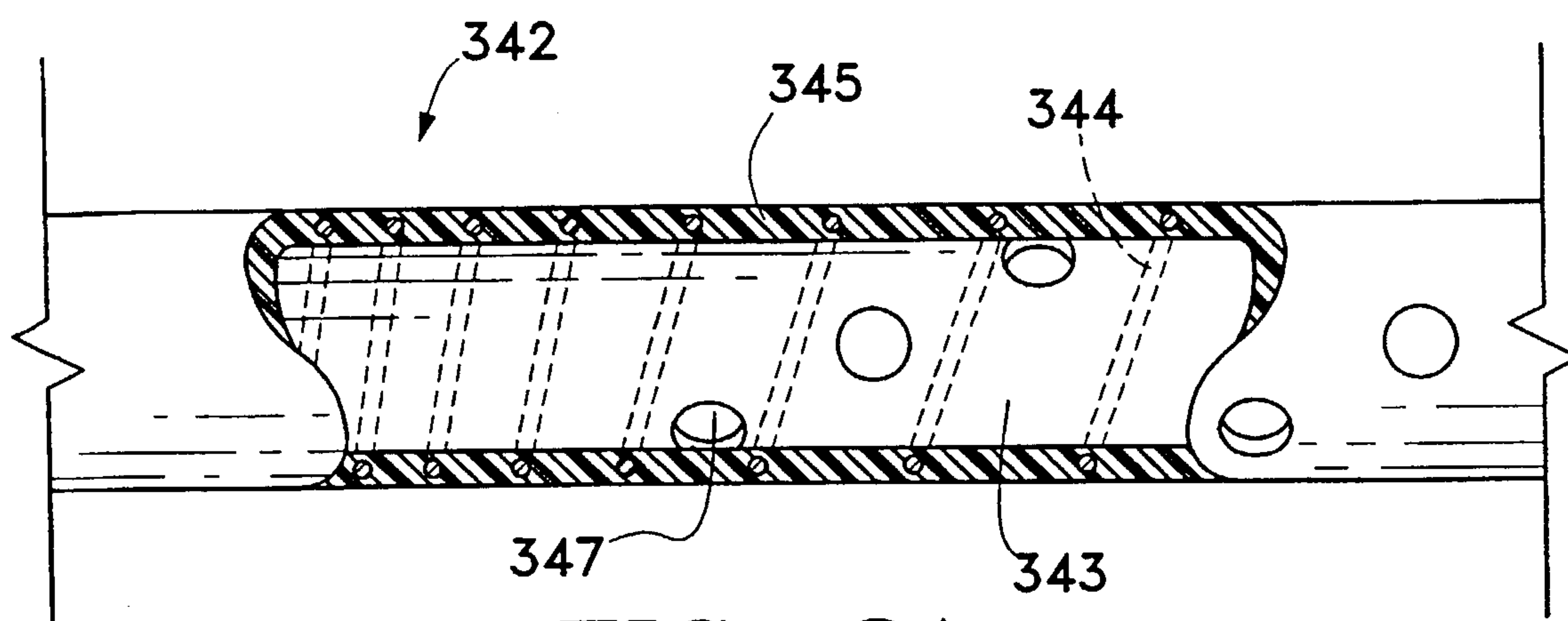


FIG. 8A

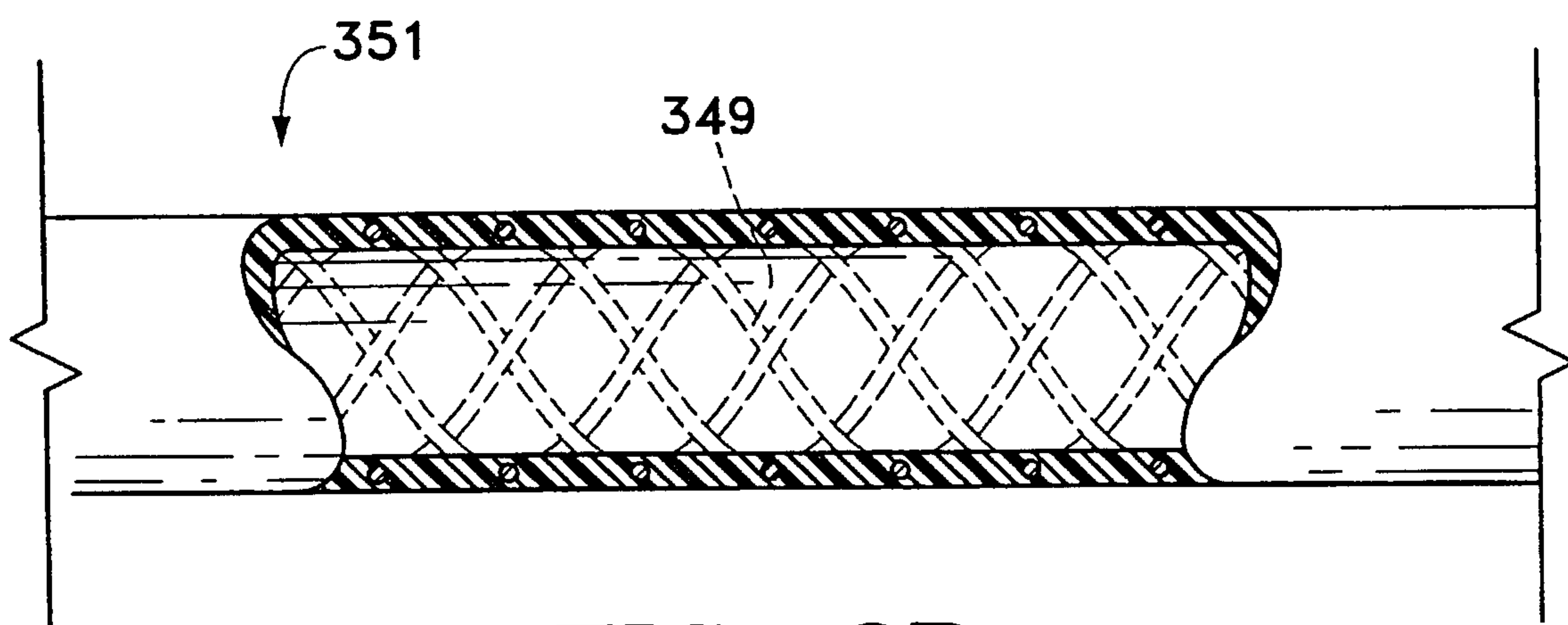


FIG. 8B

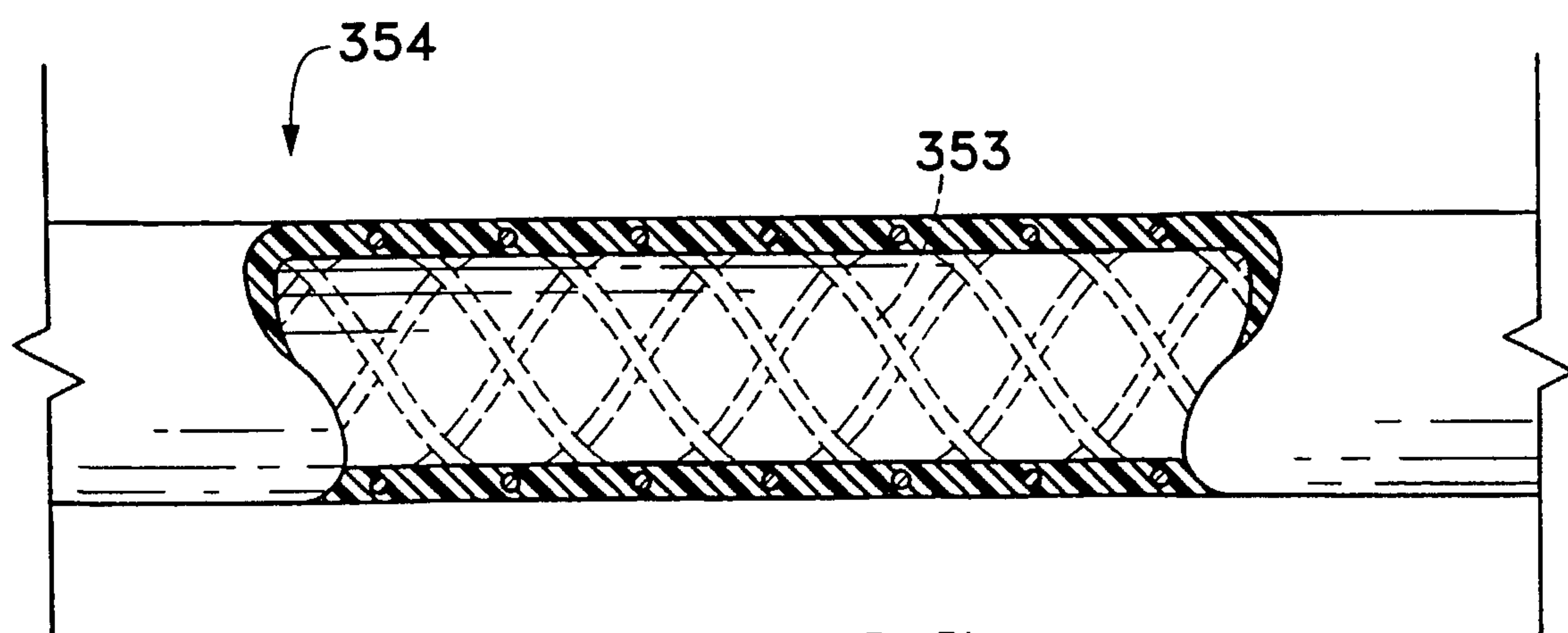
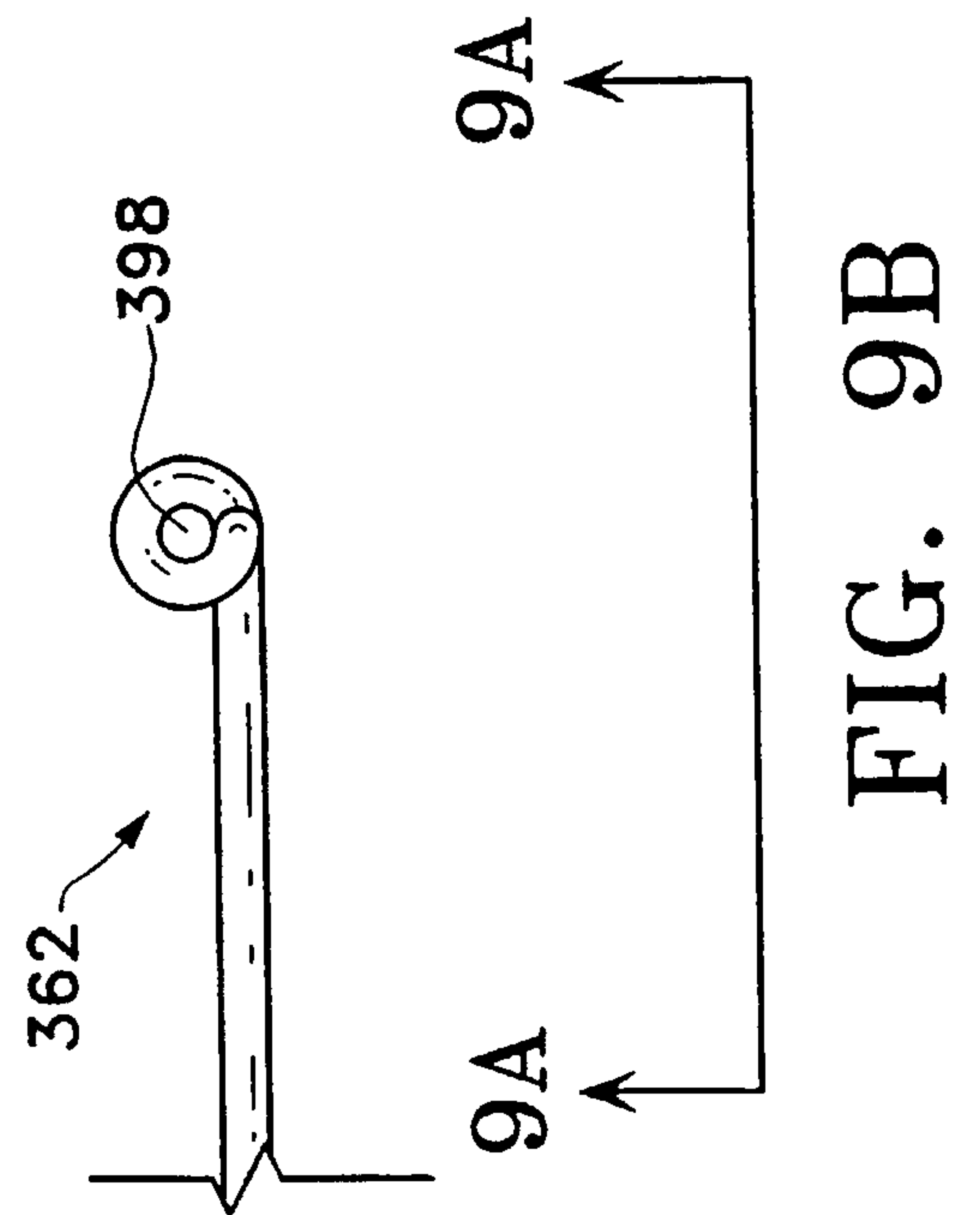
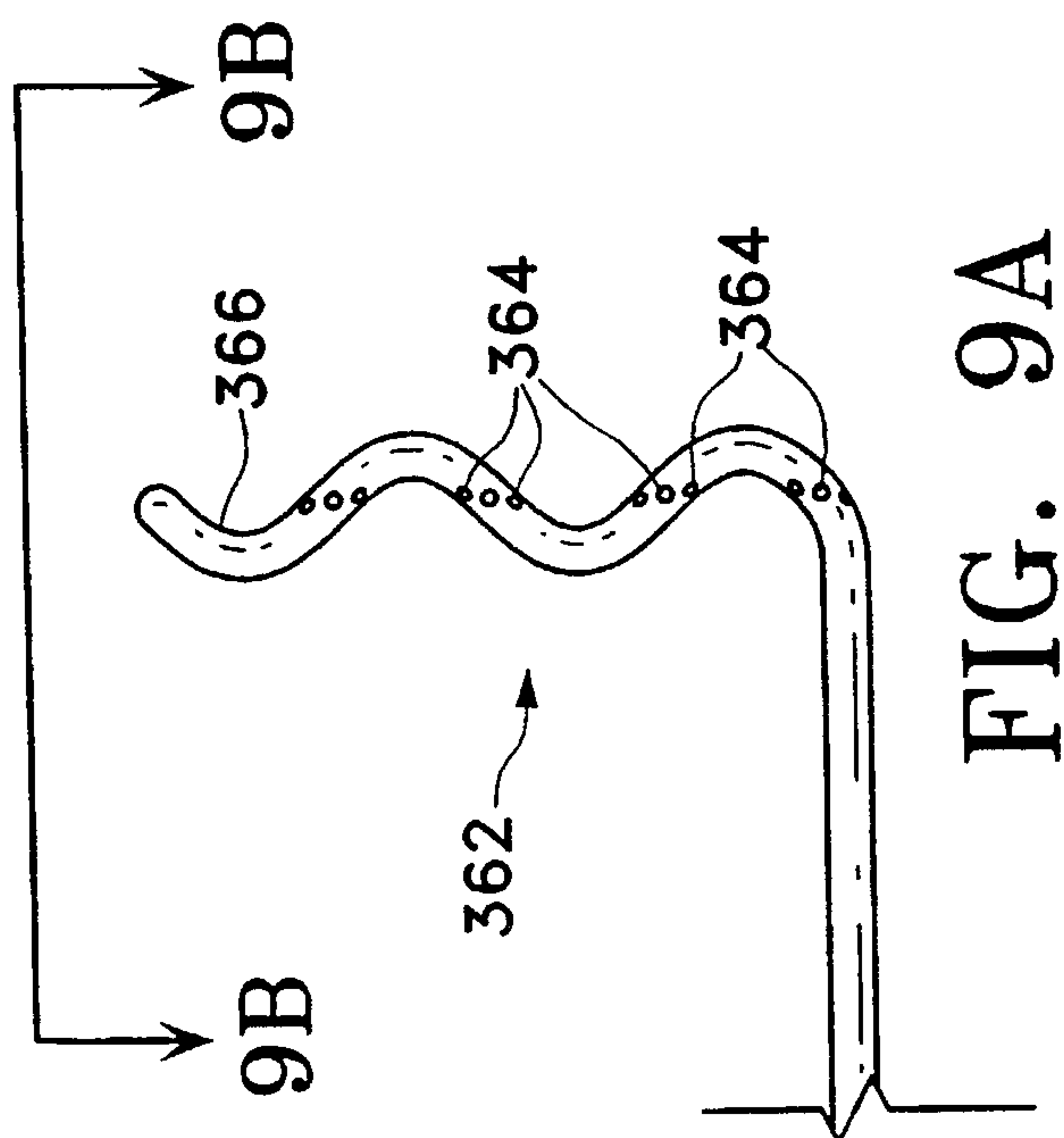
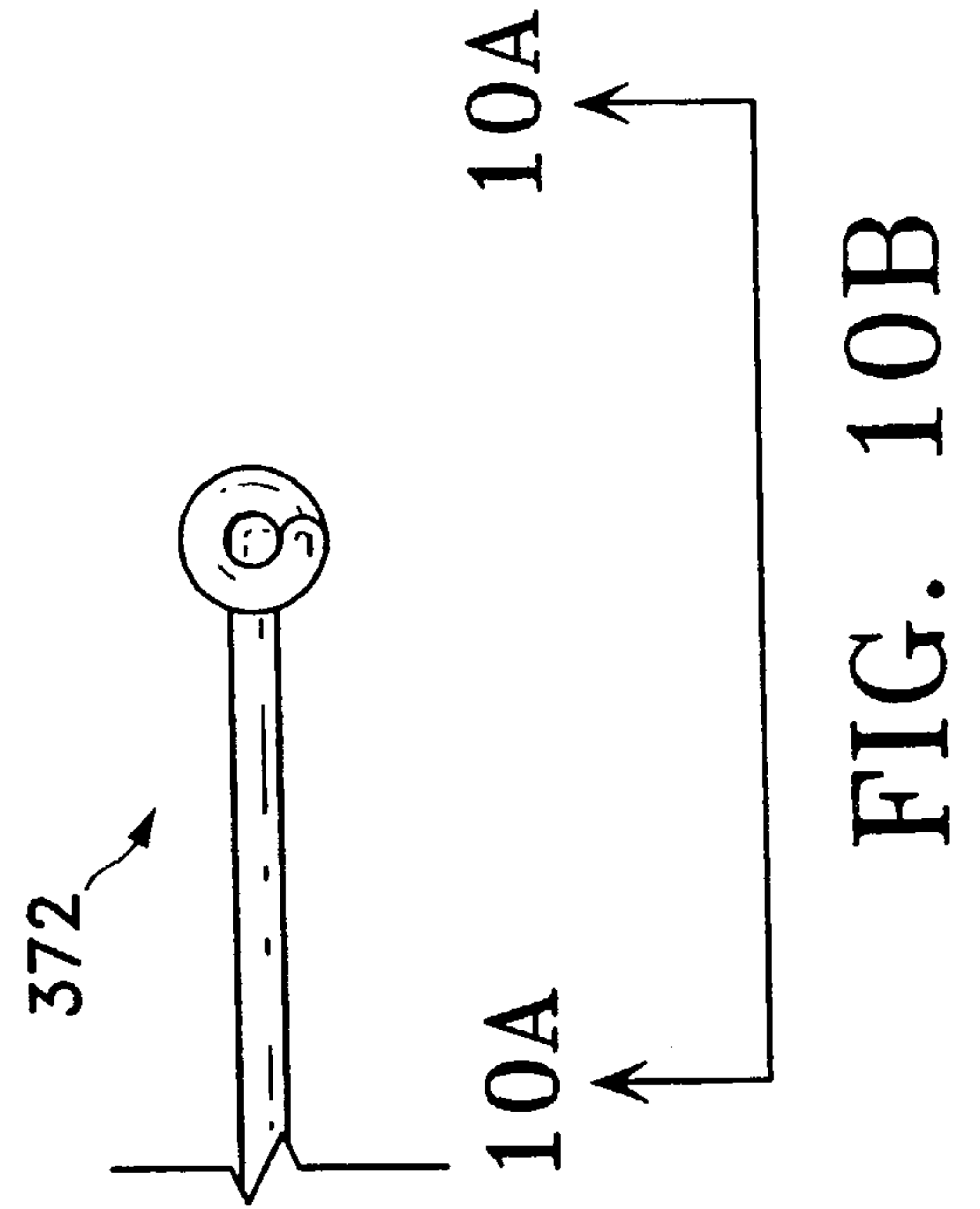
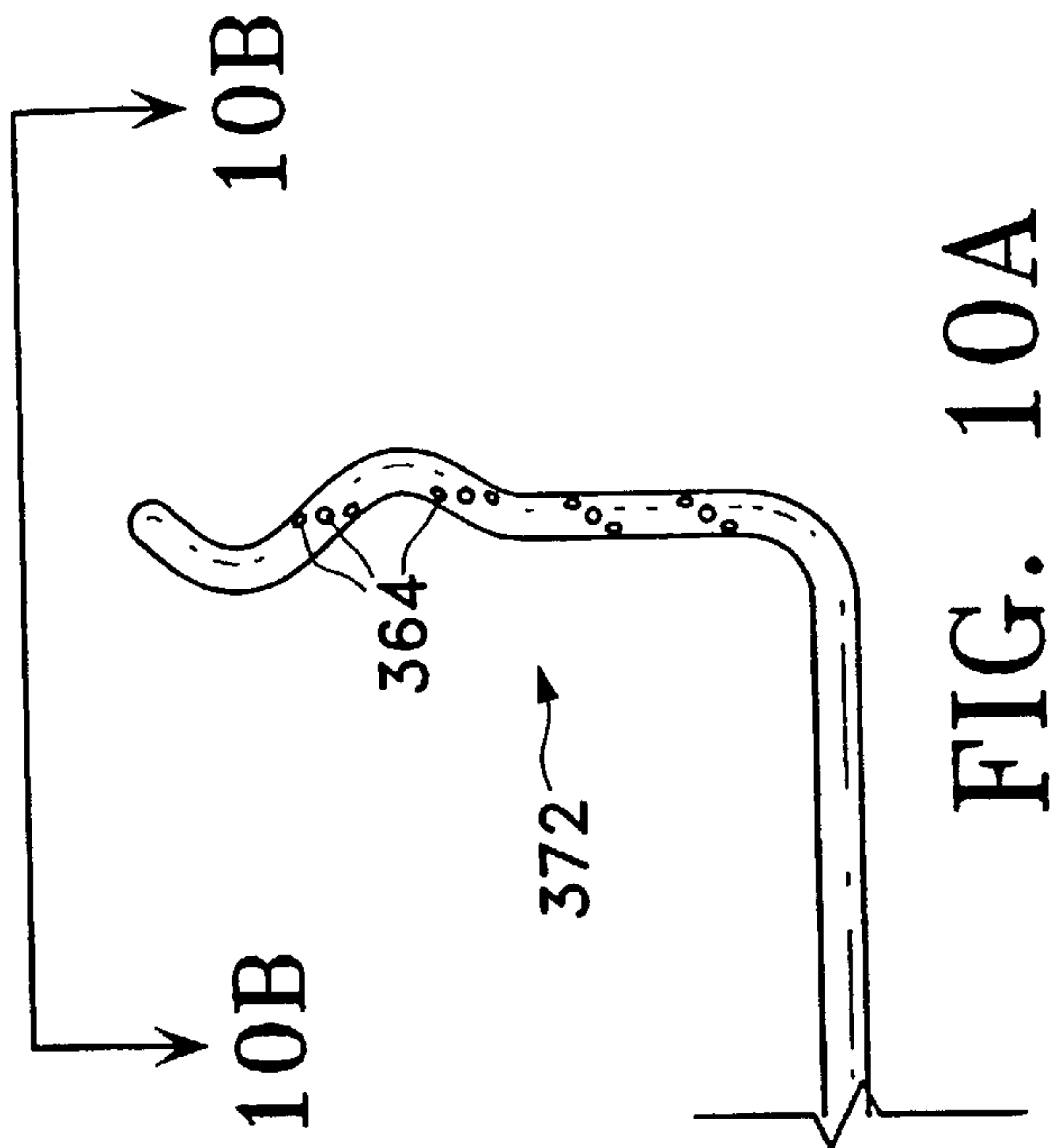


FIG. 8C

7/11



8/11

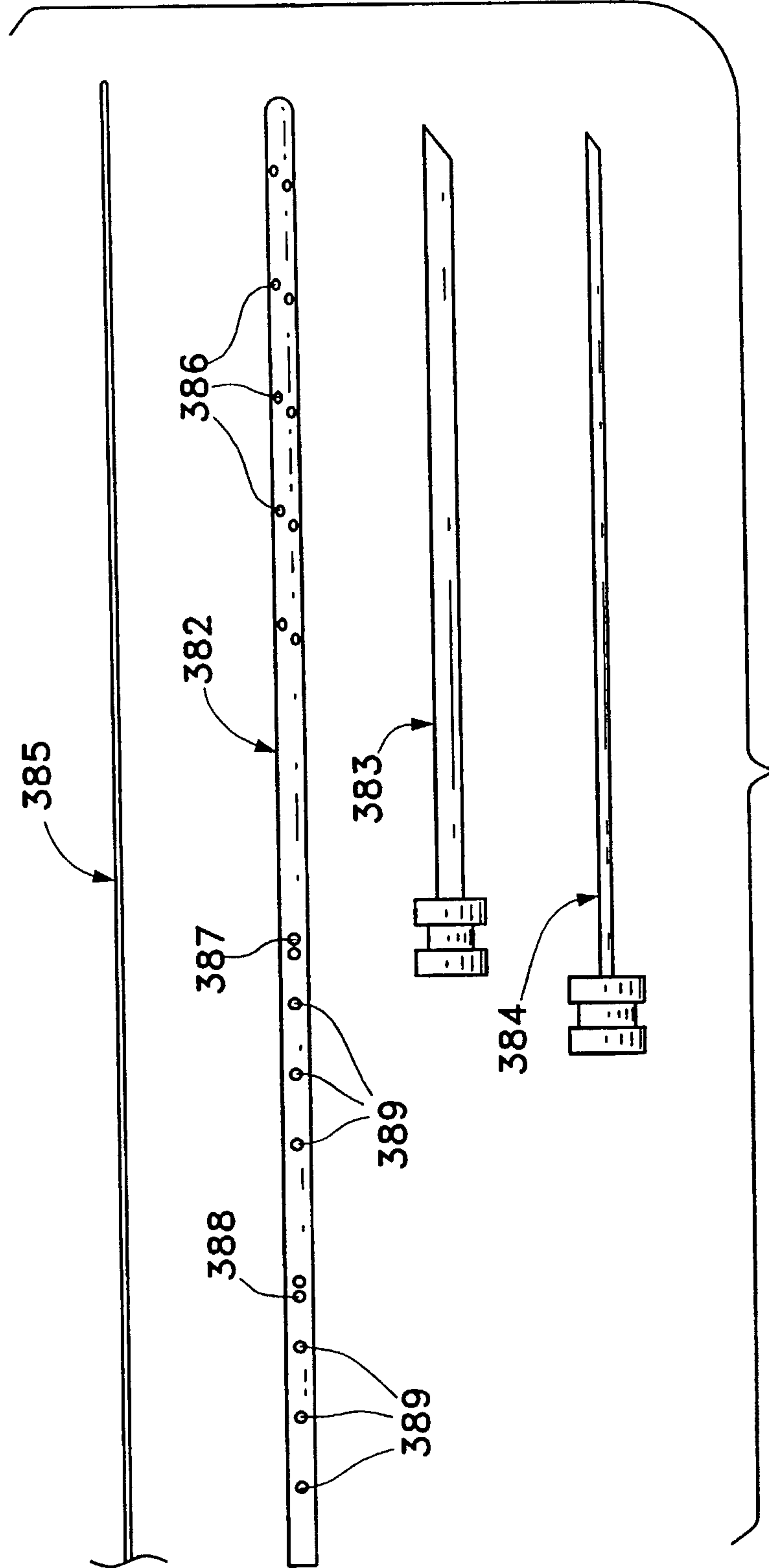


FIG. 11

9/11

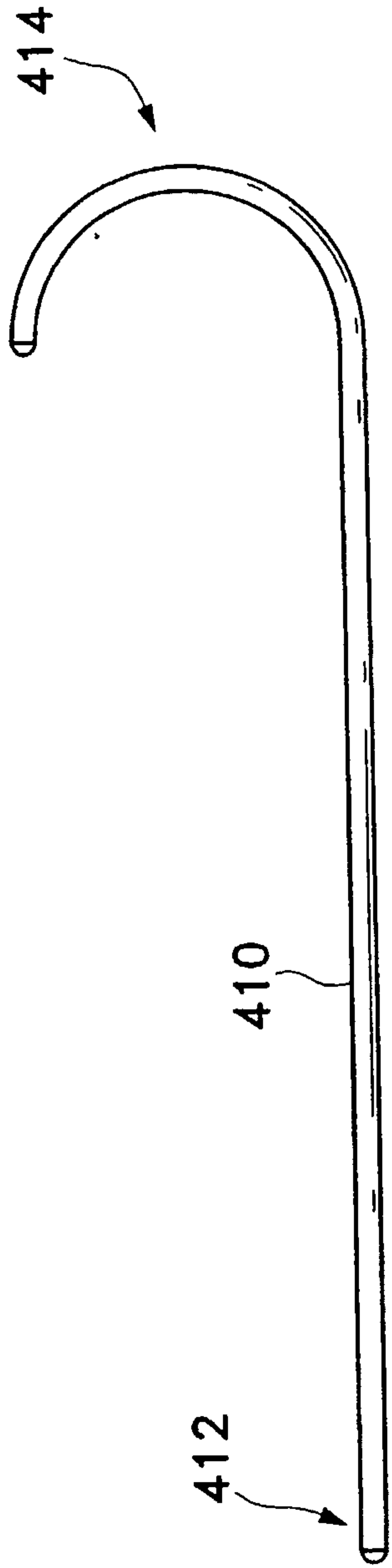


FIG. 12A

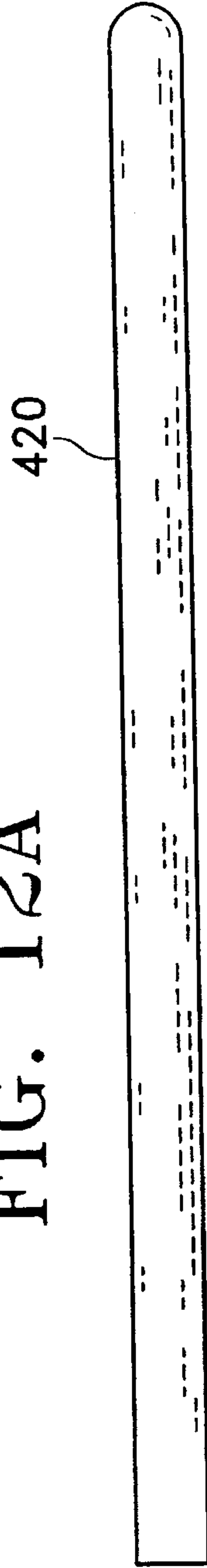


FIG. 12B

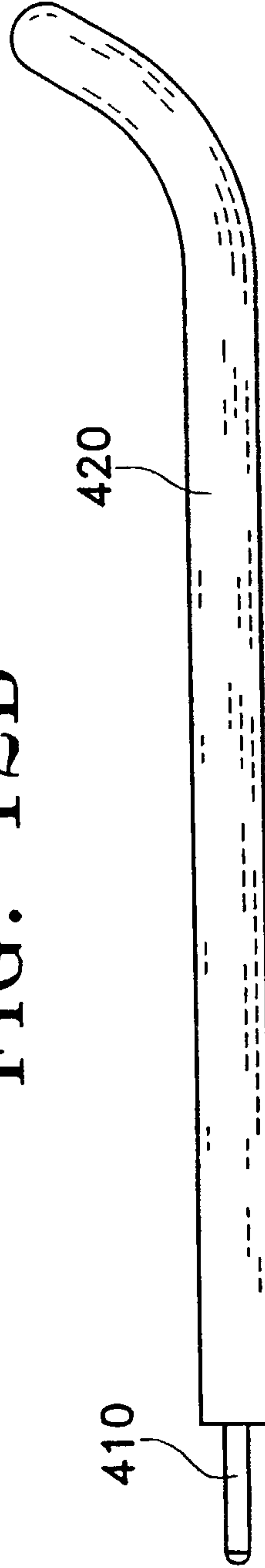


FIG. 12C

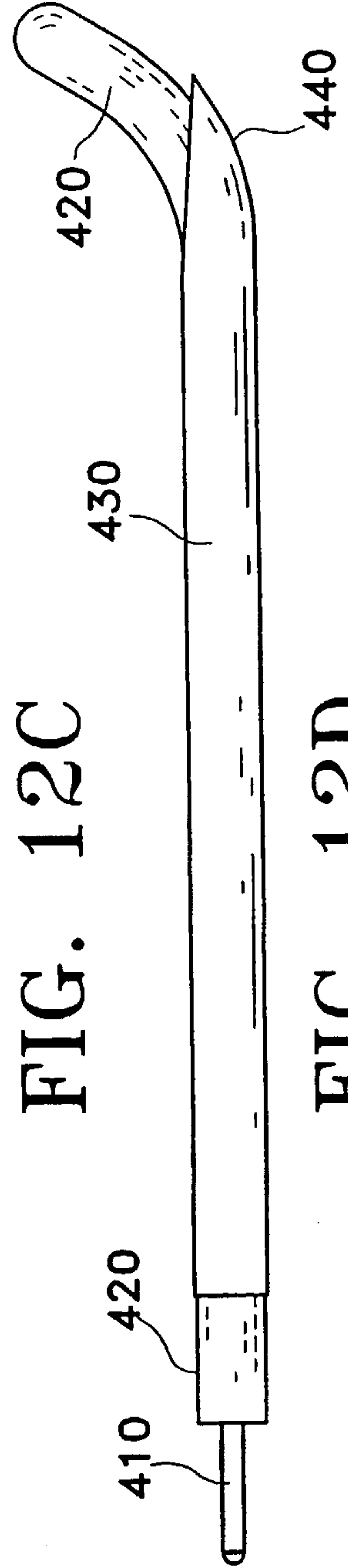
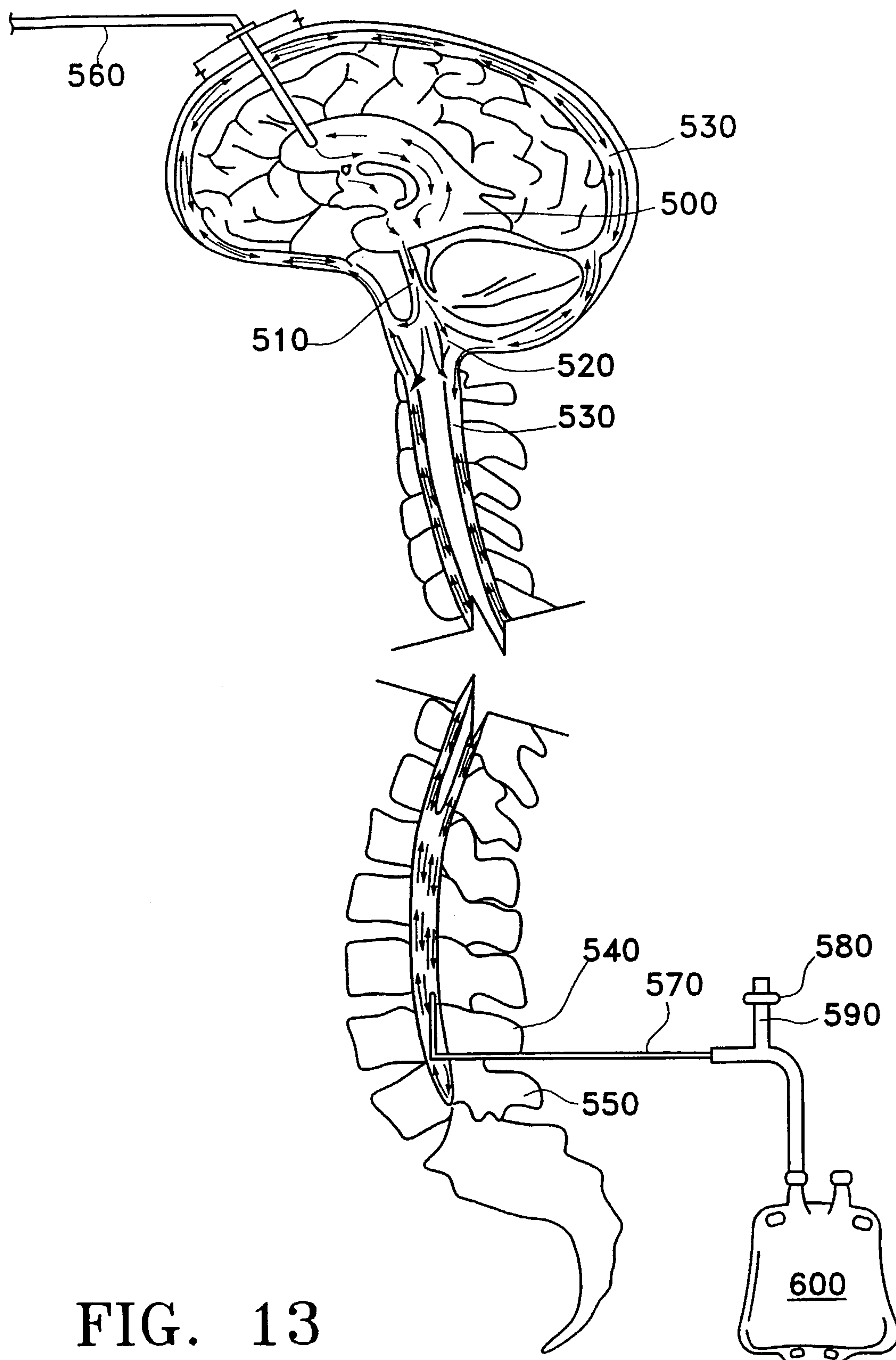


FIG. 12D

10/11



SUBSTITUTE SHEET (RULE 26)

11/11

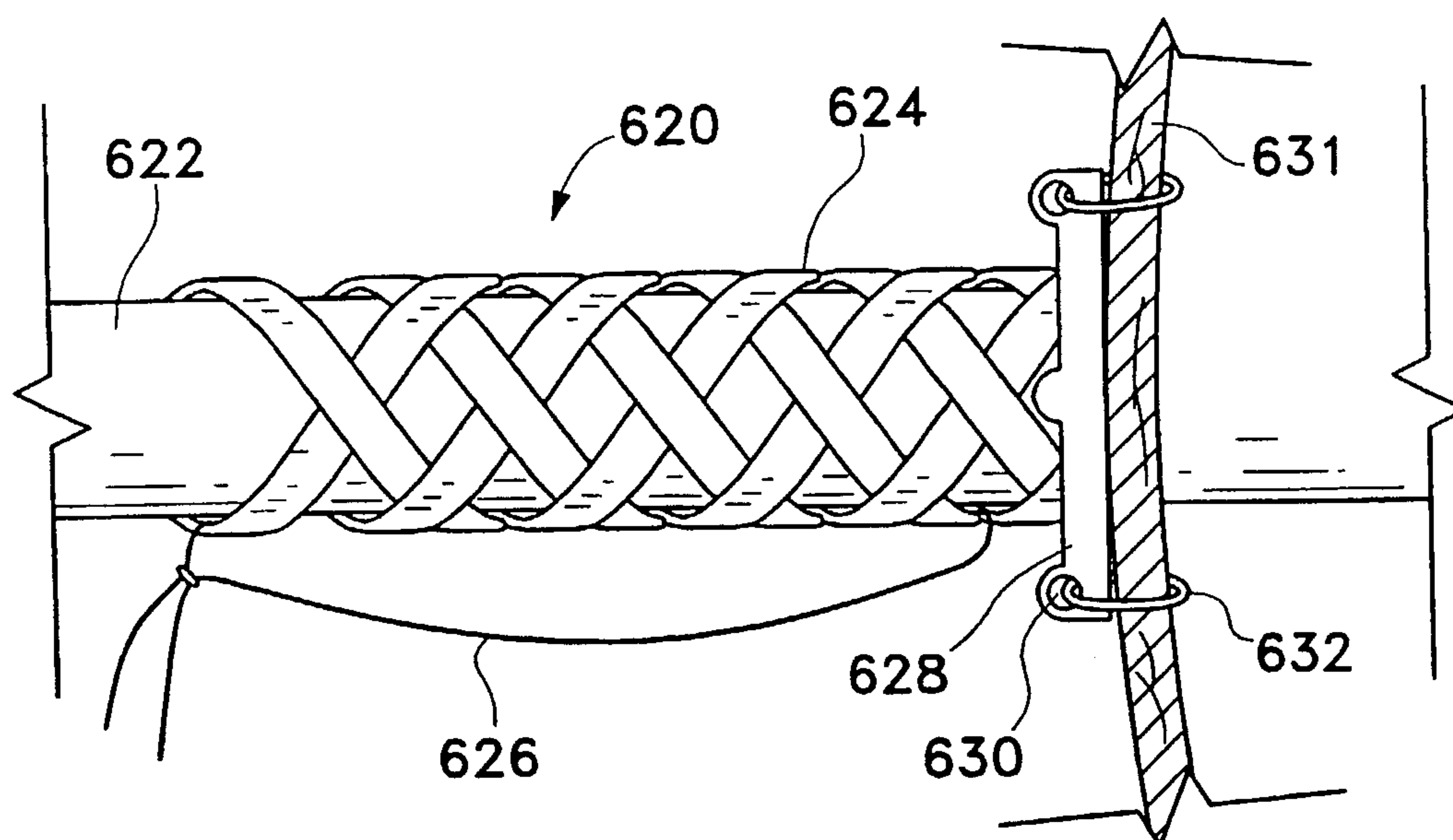


FIG. 14A

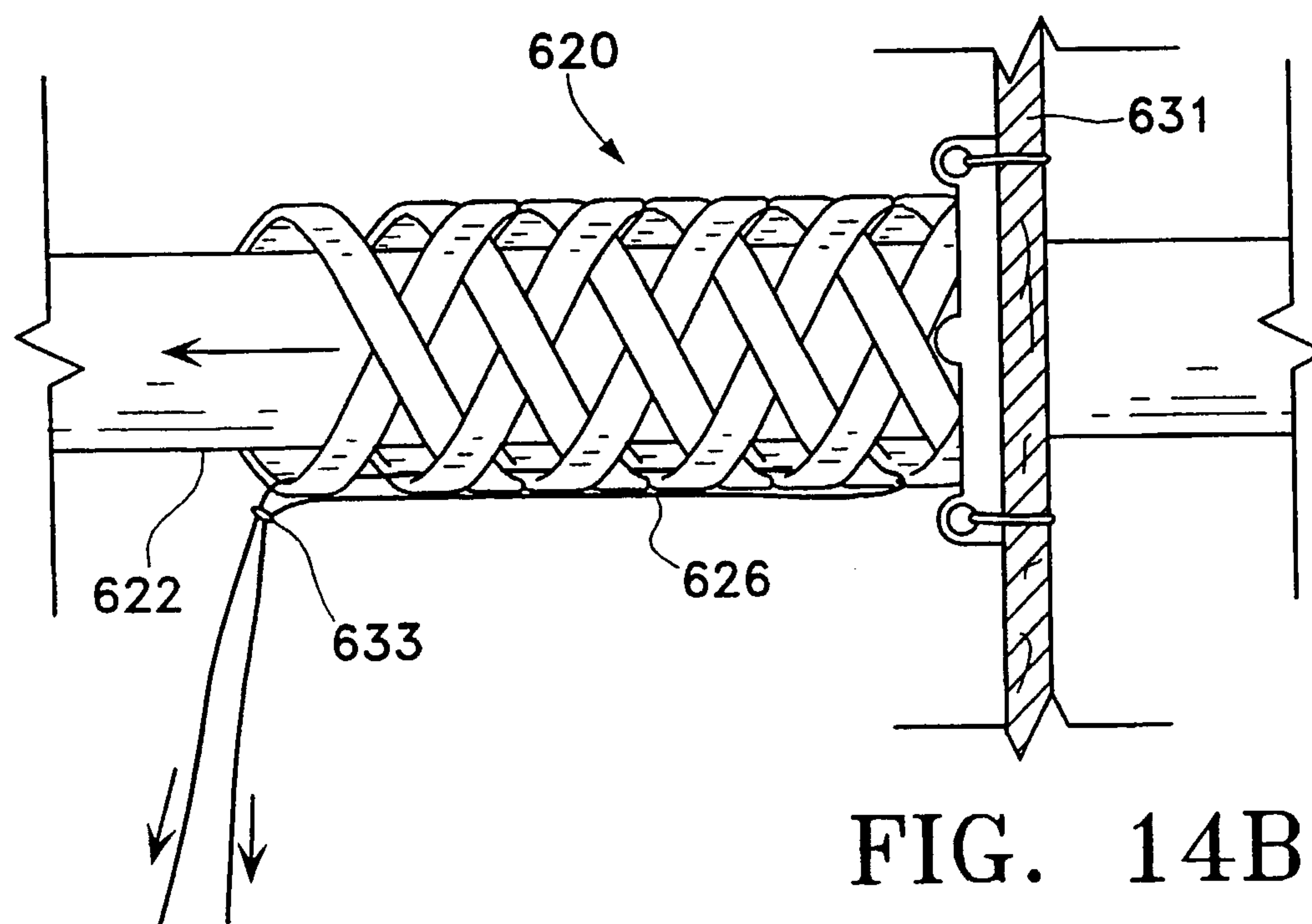


FIG. 14B

