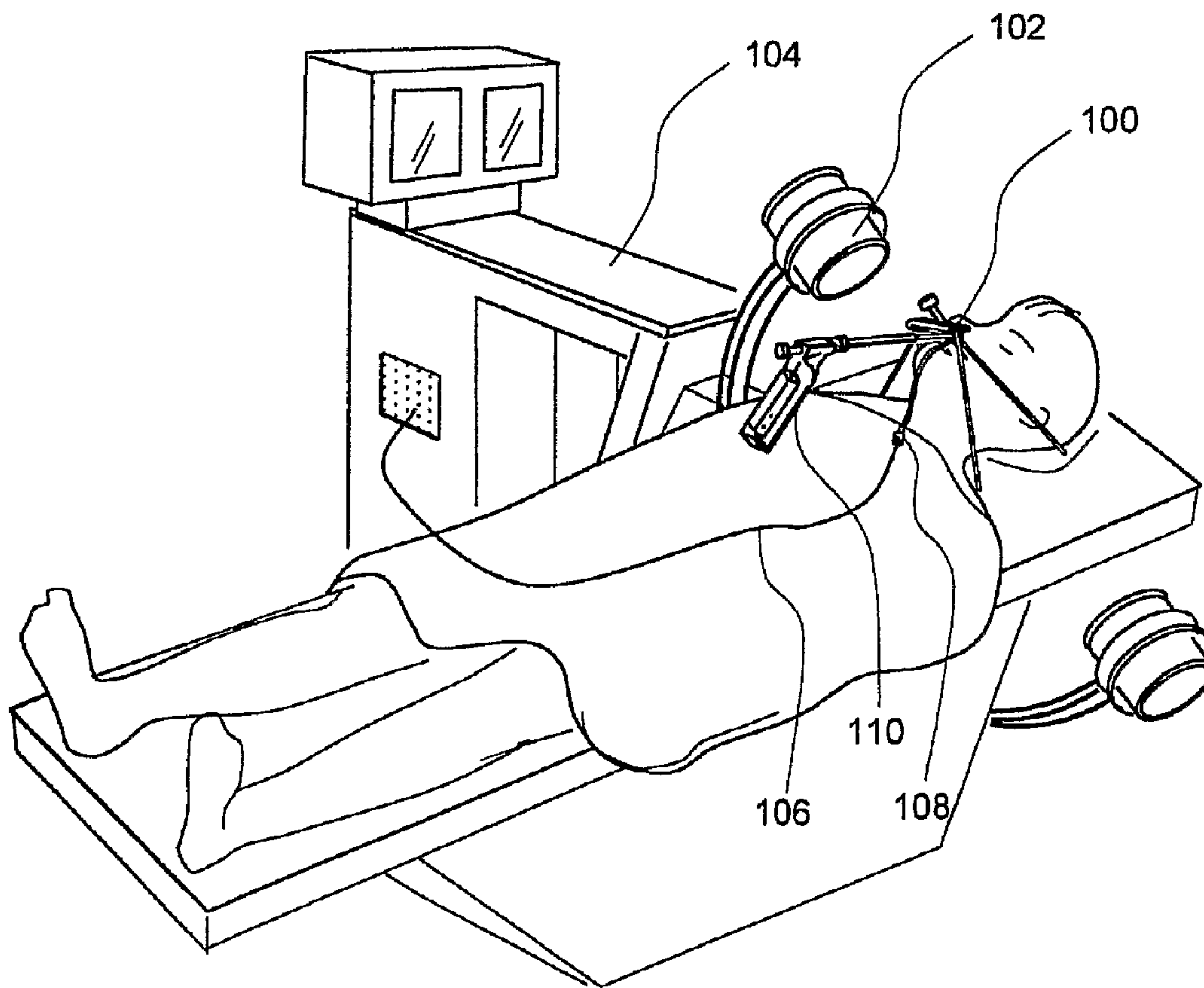




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structures within the ear, nose, throat or paranasal sinuses, navigation devices for use in conjunction with image guidance or navigation system and hand held devices having pistol type grips and other handpieces.

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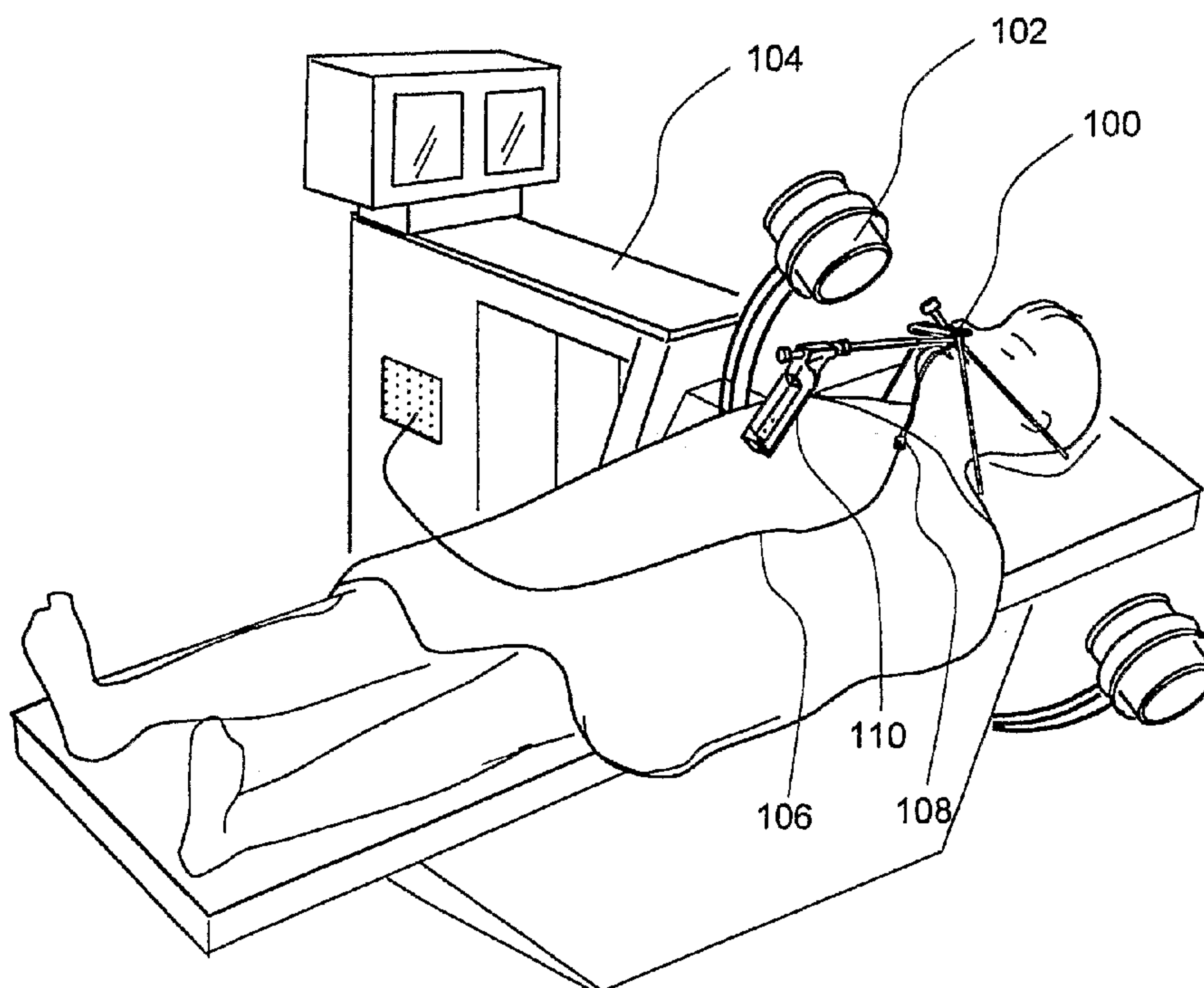
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(54) Title: METHODS AND APPARATUS FOR TREATING DISORDERS OF THE EAR, NOSE AND THROAT



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# METHODS AND APPARATUS FOR TREATING DISORDERS OF THE EAR NOSE AND THROAT

## RELATED APPLICATIONS

This application is a continuation-in-part of copending United States Patent Application Serial Nos. 10/829,917 entitled Devices, Systems and Methods for Diagnosing and Treating Sinusitis and Other Disorders of the Ears, Nose and/or Throat filed on April 21, 2004; 10/944,270 entitled Apparatus and Methods for Dilating and Modifying Ostia of Paranasal Sinuses and Other Intranasal or Paranasal Structures filed on September 17, 2004; 11/116,118 entitled Methods and Devices for Performing Procedures Within the Ear, Nose, Throat and Paranasal Sinuses filed April 26, 2005 and [Serial No. to be determined] entitled Devices, Systems And Methods Useable For Treating Sinusitis filed on June 10, 2005, each such application being expressly incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention relates generally to medical apparatus and methods and more particularly to devices and methods that are useable to treat disorders of the paranasal sinuses as well as other ear, nose & throat disorders.

## BACKGROUND OF THE INVENTION

Functional endoscopic sinus surgery (FESS) is currently the most common type of surgery used to treat chronic sinusitis. In a typical FESS procedure, an endoscope is inserted into the nostril along with one or more surgical instruments. The surgical instruments are then used to cut tissue and/or bone, cauterize, suction, etc. In most FESS procedures, the natural ostium (e.g., opening) of at least one paranasal sinus is surgically enlarged to improve drainage from the sinus cavity. The endoscope provides a direct line-of-sight view whereby the surgeon is typically able to visualize some but not all anatomical structures within the surgical field. Under visualization through the endoscope, the surgeon may remove diseased or hypertrophic

tissue or bone and may enlarge the ostia of the sinuses to restore normal drainage of the sinuses. FESS procedures can be effective in the treatment of sinusitis and for the removal of tumors, polyps and other aberrant growths from the nose.

5           The surgical instruments used in the prior art FESS procedures have included; applicators, chisels, curettes, elevators, forceps, gouges, hooks, knives, saws, mallets, morselizers, needle holders, osteotomes, ostium seekers, probes, punches, backbiters, rasps, retractors, rongeurs, scissors, snares, specula, suction canulae and trocars. The majority of such  
10 instruments are of substantially rigid design.

In order to adequately view the operative field through the endoscope and/or to allow insertion and use of rigid instruments, many FESS procedures of the prior art have included the surgical removal or modification of normal anatomical structures. For example, in many prior art FESS procedures, a  
15 total uncinectomy (e.g., removal of the uncinate process) is performed at the beginning of the procedure to allow visualization and access of the maxillary sinus ostium and/or ethmoid bulla and to permit the subsequent insertion of the rigid surgical instruments. Indeed, in most traditional FESS procedures, if the uncinate process is allowed to remain, such can interfere with endoscopic  
20 visualization of the maxillary sinus ostium and ethmoid bulla, as well as subsequent dissection of deep structures using the available rigid instrumentation.

More recently, new devices, systems and methods have been devised to enable the performance of FESS procedures and other ENT surgeries with  
25 minimal or no removal or modification of normal anatomical structures. Such new methods include, but are not limited to, uncinete-sparing Baloon Sinuplasty<sup>TM</sup> procedures and uncinete-sparing ethmoidectomy procedures using catheters, non-rigid instruments and advanced imaging techniques (Acclarent, Inc., Menlo Park, California). Examples of these new devices,  
30 systems and methods are described in incorporated United States Patent Application Nos. 10/829,917 entitled Devices, Systems and Methods for Diagnosing and Treating Sinusitis and Other Disorders of the Ears, Nose

and/or Throat; 10/944,270 entitled Apparatus and Methods for Dilating and Modifying Ostia of Paranasal Sinuses and Other Intranasal or Paranasal Structures; 11/116,118 entitled Methods and Devices for Performing Procedures Within the Ear, Nose, Throat and Paranasal Sinuses filed April 5 26, 2005 and [Serial No. to be determined] entitled Devices, Systems And Methods Useable For Treating Sinusitis filed on June 10, 2005, of which this application is a continuation-in-part.

There remains a need for further development of new and different devices and methodology for surgical treatment of sinusitis and other ear, 10 nose and throat disorders.

### SUMMARY OF THE INVENTION

The present invention provides apparatus and disorders for treating 15 sinusitis and other disorders of the ear, nose, throat and paranasal sinuses. The various devices and methods of the present invention may be used separately or in any possible and desirable combinations with each other.

In accordance with the invention, there is provided endoscopic guide systems that generally comprise tubular guides (e.g., rigid, flexible and/or 20 malleable guide catheters) that incorporate or are attachable to endoscopic apparatus. The endoscopic apparatus is useable to enable endoscopically view areas ahead of or adjacent to the distal end of the tubular guide. In some embodiments, such endoscopic guide systems are useable to facilitate trans-nasal advancement of a guidewire, catheter, instrument or other device 25 to a position within or near an opening or a paranasal sinus (e.g., any transnasally accessible opening in a paranasal sinus or air cell including but not limited to; natural ostia, surgically altered natural ostia, surgically created openings, antrostomy openings, ostiotomy openings, burr holes, drilled holes, ethmoidectomy openings, natural or man made passageways, etc.). To 30 facilitate this, the endoscopic guide system may comprise a) a tubular guide having a proximal end, a distal end and a lumen that extends longitudinally therethrough, said tubular guide having a distal portion that is more flexible than the remainder of the guide and said tubular guide being configured such that it may be i) inserted, distal end first, through a nostril of the subject's nose

and ii) advanced, without requiring substantial modification or removal of any normal anatomical structure, to a position where the distal end of the guide is within or adjacent to the ostium of the paranasal sinus; and b) an endoscopic device incorporated in or attached to the tubular guide, said endoscopic  
5 device being useable to view a visual field that includes an area beyond the distal end of the tubular guide. In some embodiments, a portion (e.g., a distal portion) of the tubular guide may be curved and the endoscopic apparatus may allow to user to essentially see around the curve. The endoscopic apparatus may comprise a rigid, flexible, deflectable or steerable endoscopes  
10 that is incorporated into, inserted into or through, or attached to the tubular guide. Or, the endoscopic apparatus may comprise a waveguide, periscope or other device that serves as an extension of a separate endoscope such that the endoscope may be connected (e.g., attached, inserted, coupled or otherwise associated) to the proximal end of the endoscopic apparatus and  
15 will receive an image from the distal end of the endoscopic apparatus.

Further in accordance with the invention, there are provided seeker devices that are useable to locate or access structures within the ear, nose and throat. In some embodiments, these seeker devices have lumens extending therethrough. In such embodiments having lumens, guidewires may  
20 be inserted or advanced through the lumen, thereby providing seeker/guidewire systems that are useable for placing guidewires into various anatomical structures (e.g., into a paranasal sinus). In embodiments having lumens, the proximal end of the seeker device may be attachable to a source of fluid for irrigation or substance delivery through the lumen and/or to a  
25 source of negative pressure to permit suction through the lumen. Also, in some embodiments that have lumens, a slot opening may extend along all or a portion of the lumen to allow a guidewire or other elongate device to be extracted laterally from all or a portion of the lumen. Additionally or  
30 alternatively, in some embodiments, the seeker device may have an expandable member (e.g., a balloon) that is useable to dilate anatomical structures, anchor the seeker and/or for other purposes. Structurally, a seeker device of the present invention may comprise an elongate substantially rigid (e.g., straight, pre-shaped, bent, curved, malleable) shaft,



optionally having a bulbous (e.g., enlarged) distal tip on one or both ends. Various curves may be formed or formable in the seeker shaft.

5 Still further in accordance with the invention, there are provided dilator devices (e.g., balloon dilators) that may be used to dilate anatomical structures within the ear, nose or throat of a human or animal subject (e.g., opening of paranasal sinuses as defined hereabove, metal passageways, other openings or passages). Such dilator devices may comprise a) a handpiece, b) an elongate shaft that extends from the handpiece, such elongate shaft having a distal portion that is insertable through a nostril of the subject's nose, c) a dilator having a non-expanded configuration and an expanded configuration and a dilator expansion control or trigger apparatus on or associated with the handpiece, such dilator expansion control or trigger apparatus being useable to move the dilator between its non-expanded configuration and its expanded configuration. In some embodiments, the dilator may be advanceable (or advanceable/retractable) from the elongate shaft. In such embodiments having an advanceable or advanceable/retractable dilator, the handpiece may additionally have a dilator advancement control or trigger. In some designs of these devices, the handpiece, dilator expansion control or trigger and/or dilator advancement control or trigger may be operable by one hand, thereby leaving the operators other hand free for handling other instruments or performing other tasks. In embodiments where the dilator comprises a balloon, the expansion of the dilator may result for the provision of a flow of infusion fluid into the balloon. Accordingly, such devices may incorporate pumps and/or sources of pressurized inflation fluid to facilitate inflation of the balloon. The balloon may be compliant or non-compliant. In embodiments having non-compliant balloons, the device may additionally comprise apparatus for applying negative pressure to the balloon thereby evacuating and collapse the non-compliant balloon.

30 Further still in accordance with the invention, there are provided devices for deterring unwanted movement of catheter(s) or other device(s) (e.g., guidewires, endoscopes, dilators, etc.) that have been inserted into the nose of a human or animal subject. Such support device may generally

comprise a support member (e.g., an elongate body) that is positionable adjacent to the subject's nose and an attachment substance or apparatus (e.g., adhesive, resilient or pliable projections, fingers, members, hook and loop connector material, other apparatus for frictional engagement, etc.). The attachment substance or apparatus is useable for releaseably holding the catheter(s) or other device(s) in substantially fixed position relative to the support member. Additionally, these devices may comprise positioning apparatus (e.g., legs, brackets, holders, adhesive) for holding the support member in position adjacent to the subject's nose.

Still further in accordance with the invention, there are provided balloon catheters that are constructed in new ways. Such balloon catheters have guidewire lumens that extend through some or all of the length of the catheter. In some embodiments, an optional slot opening may be formed along some or all of the length of the guidewire lumen to allow a guidewire or other device to be extracted laterally from all or part of that lumen.

Further still in accordance with the invention, there are provided balloon folding tools that are useable to facilitate folding of catheter-mounted balloons, such as non-compliant balloons. A balloon folding tool of this invention may comprise a) a rigid body having a central bore formed therein, the central bore having a diameter that is less than the fully inflated balloon diameter, b) a plurality of side channels located adjacent to and substantially parallel with the central bore, each of such side channels being connected to the bore through a slot. The balloon is insertable into the central bore while in a less than fully inflated state. Thereafter the balloon is inflatable to a fully or partially inflated state causing a separate portion of the balloon to pass through the each slot and into each side channel. Thereafter the balloon is deflatable such that each separate portion of the balloon that has passed into each side channel will form a separate wing of the deflated balloon. Those wings are, thereafter, foldable to a collapsed shape.

Even further in accordance with the invention, there are provided apparatus for compressing balloons to a low profile to facilitate subsequent insertion or reinsertion of the balloon into the body of a human or animal

subject. Such a balloon compression apparatus may comprise a plurality of compression members disposed radially about a central cavity, such compression members being spaced apart from each other such that gaps exist between adjacent compression members, such compression members  
5 being moveable from non-compressing positions to compressing positions. The balloon is insertable into the central cavity of the compression device while the compression members are in their non-compressing positions. The compression members are then moveable to their compressing positions, thereby compressing portions of the balloon causing any inflation fluid to be  
10 forced out of the balloon and causing portions of the balloon to protrude outwardly into the gaps between the compression members. This results in the formation of a plurality of wings on the deflated balloon, such wings being thereafter foldable into a collapsed shape.

Still further in accordance with the invention, there are provided inflator  
15 handpiece devices that are attachable to balloon catheters or other balloon equipped devices (e.g., balloon equipped tubular guides, seekers, guidewires, etc, as described herein and elsewhere) and useable to inflate the balloon. An inflator handpiece of the present invention may comprise a) a handpiece body configured to be grasped by a human hand, such handpiece body being  
20 attachable to the proximal end of a balloon catheter or other balloon equipped device, b) an inflator (e.g., a pump or source of compressed inflation fluid) and an inflation trigger useable to cause the inflator to inflate the balloon. These handpieces may facilitate precise handling and positioning of balloon catheters and other balloon equipped devices. In some embodiments, the  
25 handpiece may comprise an elongate body having a grip member that extends at an angle from the elongate body (e.g., generally similar to a pistol grip type of arrangement). In some embodiments, the handpiece and inflation trigger may be configured to be useable by a single hand, thereby freeing the operators other hand for handling of other instruments or performing other  
30 tasks. In embodiments where the catheter or other balloon equipped device has a lumen useable for passage of a guidewire or other device or substance, the inflator handpiece device may incorporate a port or passage to permit a guidewire or other device to be advanced through that lumen and/or to permit

fluids to be infused or suction applied through that lumen. Various valves, grippers, etc. may be associated with such passageway or port to provide hemostasis, prevent fluid leakage, deter unwanted movement of guidewires or devices, etc.

5 Further yet in accordance with the present invention, there are provided devices for breaking nasal turbinates or other bony anatomical structures in a human or animal subject. Such a breaking device may comprise a) first and second members positionable at spaced apart positions on one side of the turbinate or bony structure and a third member positionable  
10 on the other side of the turbinate or bony structure, between the first and second members. The third member and/or said first and second members are then moveable to exert pressure on the nasal turbinate or bony structure to cause the bone of the nasal turbinate or bony structure to break.

Still further in accordance with the invention, there are provided  
15 navigation adapters that are attachable to cannulae, catheters or elongate devices to facilitate their use in conjunction with navigation systems (e.g., optical, electromagnetic, etc.) of the type used in performing image guided surgery. Such navigation adapter may comprise a) an elongate adapter body that is attachable to the substantially rigid cannula, catheter or elongate  
20 device and b) apparatus useable by the image guidance system to determine the position of the substantially rigid cannula, catheter or elongate device within the body of a human or animal subject. The apparatus useable by the image guidance system may comprise various sensors, emitters, reflectors, transponders, reflective passive elements, light emitting diodes, transmitters  
25 or receivers of energy (e.g. optical energy, radiofrequency energy, etc.) or combinations thereof that are useable to enable a navigation system to track the position of catheter, cannula or other device within the body. Examples of commercially available navigation systems that may be useable in conjunction with these navigation adapters include but are not limited to (insert list from  
30 navigation application).

Still further in accordance with the invention, there are provided methods for using the above summarized devices.

Further yet in accordance with the present invention, there are provided methods where one or more anatomical structures (e.g. uncinata process, wall of ethmoid air cell, turbinate) and/or pathological structures (e.g., polyps, etc) are removed or modified in combination with a procedure  
5 where a dilator is inserted transnasally and used to dilate an opening of a paranasal sinus (as defined hereabove) or other anatomical structure within the ear, nose, throat or paranasal sinus of a human or animal subject. Such removal or modification of normal or pathological anatomical structures may facilitate visualization and/or access to various anatomical locations during  
10 and after the procedure.

Still further in accordance with the invention, there is provided a nasal introducer that comprises an introducer body (e.g., a plug) that insets into the nostril of a human or animal subject. One or more lumen(s) (e.g., passageway(s) or bore(s)) extend through the introducer body to allow one or  
15 more catheters or other devices (e.g., endoscopes, dilators, seekers, tubular guides, etc.) to be advanced through the introducer and into the nasal cavity or beyond. Various valves, grippers, etc. may be associated with such lumen(s) to provide hemostasis, prevent fluid leakage and/or deter unwanted movement of catheters or other devices that have been inserted through the  
20 lumen(s).

Further aspect, elements and advantages of the present invention will be understood by those of skill in the art upon reading of the detailed description set forth herebelow.

## 25 BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a human subject undergoing a procedure for treating sinusitis in accordance with the present invention.

Figure 2A shows a perspective view of an embodiment of a support  
30 device having finger members in the nature of bristles.

Figure 2B shows a perspective view of an embodiment of a support

device having finger members in the nature of pliable or resilient projections.

Figure 2C shows a perspective view of an embodiment of a support device comprising an adhesive surface.

5 Figures 2D through 2G show perspective views of various embodiments of a support device being used to support a working device.

Figures 3- 3A show an embodiment of a nasal introducer that is insertable in to nares of a human or animal subject and useable to facilitate subsequent insertion and handling of catheters and other devices.

10 Figure 4A shows a perspective view of an embodiment of a guidewire comprising an enlarged distal end.

Figure 4B shows a longitudinal sectional view of an embodiment of a guidewire comprising an anchoring balloon.

Figure 5A shows a cross sectional view of a first embodiment of a seeker device having a lumen.

15 Figure 5B shows a perspective view of a second embodiment of a seeker device having a lumen.

Figure 5C shows a cross section of the seeker in figure 5B through the plane 5C-5C.

20 Figure 5D shows a cross sectional view of a third embodiment of a seeker device comprising a lumen.

Figure 5E shows a longitudinal section of an embodiment of a seeker device comprising a deflectable or bendable distal tip.

Figure 5F shows a cross sectional view through plane 5F-5F in Figure 5E.

25 Figure 6A is a perspective, partially section view of a tubular guide having a balloon.

Figure 6B is a cross sectional view through line 6B-6B of Figure 6A.

Figure 6C shows a perspective view of a tubular guide having a separate lumen useable for insertion of an endoscope.

Figure 6D shows a perspective view of a tubular guide having clip(s) useable for attachment of an endoscope or other apparatus.

5 Figure 6E shows an embodiment of a combination endoscope and tubular guide.

Figure 6F shows another embodiment of a combination endoscope and tubular guide.

10 Figure 6G shows another embodiment of a combination endoscope and tubular guide.

Figures 6H and 6I show apparatus useable to hold a tubular guide and an endoscope in substantially fixed side-by-side positions.

15 Figure 6J shows a perspective view of a removable clip device useable for attaching a second device (e.g., an endoscope) to a tubular guide or other elongate device.

Figures 6K and 6L show steps in a method wherein the removable clip device of Figure 6J is used to attach an endoscope to a tubular guide.

20 Figures 6M through 6O show steps of a method of introducing one or more diagnostic or therapeutic devices through a tubular guide having an associated endoscope.

Figure 6P shows a method for introducing a dilator through a tubular guide that has an associated endoscope.

Figure 6Q shows a perspective view of a combination endoscope/tubular guide that is bendable or defelctable.

25 Figure 6R shows the distal end of the device of Figure 6Q in a bent or deflected state.

Figures 7A-7C show a method for advancing a guidewire or other device through the working lumen of an endoscope into an anatomical opening

viewed by the endoscope.

Figure 8A shows a perspective view of a tubular guide equipped for optional suctioning.

Figure 8B shows a perspective view of a guide having a handpiece that is configured to receive a detachable navigational modality to facilitate use of the device in an image guided surgical or interventional procedure.

Figure 9 shows a perspective view of a tubular guide having a tapered connector on its proximal end to facilitate attachment of a suction tube to the tubular guide.

Figure 10A is an exploded view showing the components of a tubular guide device formed of a straight proximal segment and a curved distal segment.

Figure 10B is an assembled view of the device shown in Figure 10A.

Figure 10C shows a distal portion of a tubular guide comprising a polymeric inner tube and an outer tube having apertures, wherein the polymeric material of the inner tube is caused to flow or protrude through the apertures thereby holding the inner tube in substantially fixed position within the outer tube.

Figure 11 shows a side-deflecting distal tip that may be formed on or attached to a tubular cannula or catheter.

Figure 12 shows the distal portion of a guide catheter having a plurality of lumens through which guidewires or other devices may be introduced on different trajectories.

Figure 12A is a cross sectional view through line 12A-12A of Figure 12.

Figure 13A shows a distal portion of a tubular guide having a curved endoscopic apparatus attached thereto.

Figure 13B is a longitudinal sectional view of an endoscopic apparatus in the nature of a periscope.



Figure 13C is a longitudinal sectional view of an endoscopic apparatus in the nature of a curved wave guide.

Figures 13D-E show steps in a method wherein the device of Figure 13A is used in combination with a straight endoscope to accomplish position of the distal tip of the tubular guide at an obscured anatomical location within the body of a human or animal subject.

Figure 14A is a perspective view of a straight tubular guide of the present invention having an endoscopic device attached thereto or integrated therewith and an optional balloon.

Figure 14B is a perspective view of a curved tubular guide of the present invention having an endoscopic device attached thereto or integrated therewith and an optional balloon.

Figure 14B' is a view of the distal portion of the tubular guide device of Figure 14B showing details of the curve formed therein.

Figure 14C is a perspective view of another curved tubular guide of the present invention having an endoscopic device attached thereto or integrated therewith and an optional balloon.

Figure 14C' is a view of the distal portion of the tubular guide device of Figure 14C showing details of the curve formed therein.

Figure 14D is a perspective view of another curved tubular guide of the present invention having an endoscopic device attached thereto or integrated therewith and an optional balloon.

Figure 14D' is a view of the distal portion of the tubular guide device of Figure 14D showing details of the curve formed therein.

Figure 14E is a perspective view of another curved tubular guide of the present invention having an endoscopic device attached thereto or integrated therewith and an optional balloon.

Figure 14E' is a view of the distal portion of the tubular guide device of Figure 14E showing details of the curve formed therein.

Figure 15 is a perspective view of a balloon catheter constructed of first and second tubes such that a short lumen (e.g., a rapid exchange guidewire lumen) extends through the balloon.

Figure 15A is a cross sectional view through line 15A-15A of Figure 15.

5 Figure 16 is a perspective view of a balloon catheter constructed of first, second and third tubes such that a short lumen (e.g., a rapid exchange guidewire lumen) extends through the balloon.

Figure 16A is a cross sectional view through line 16A-16A of Figure 16.

Figure 16B is a cross sectional view through line 16B-16B of Figure 16.

10 Figure 16C is a cross sectional view through line 16C-16C of Figure 16.

Figure 17 is a broken, partially sectional view of a balloon catheter having a stylet permanently positioned therein and a guidewire tip protruding from its distal end.

15 Figure 17A is a cross sectional view through line 17A-17A of Figure 17.

Figure 17B is a partial perspective view of the stylet of the balloon catheter shown in Figure 17.

Figure 18 is a broken, partially sectional view of a balloon catheter having a side slit.

20 Figure 18A is a cross sectional view through line 18A-18A of Figure 18.

Figure 18B is a cross sectional view through line 18B-18B of Figure 18.

Figure 19 shows a partial perspective view of the distal region of another balloon catheter that has capacitance measuring means for real time determination of balloon diameter.

25 Figure 19A shows a side view of the distal region of the balloon catheter of Figure 21.

Figure 19B is a cross sectional view through line 19B-19B of Figure

19A.

Figure 19C is a cross sectional view through line 19C-19C of Figure 19A.

5 Figure 20 shows a partial perspective view of the distal region of another balloon catheter that has capacitance measuring means for real time determination of balloon diameter.

Figure 20A shows a side view of the distal region of the balloon catheter of Figure 20.

10 Figure 20B is a cross sectional view through line 20B-20B of Figure 20A.

Figure 20C is a cross sectional view through line 20C-20C of Figure 20A.

Figure 21 shows a partial perspective view of a distal portion of balloon catheter having a malleable distal shaft.

15 Figure 22 shows a partial perspective view of a distal portion of balloon catheter having a flexible distal shaft.

Figure 23 shows a partial perspective view of a balloon folding tool of the present invention.

20 Figure 23A shows a balloon catheter being inserted into the balloon folding tool of Figure 23.

Figure 23B shows a cross sectional view of the balloon folding tool of Figure 23 with a fully deflated/collapsed balloon positioned therein.

25 Figure 23C shows a cross sectional view of the balloon folding tool of Figure 23 with a balloon partially inflated therein such that portions of the balloon protrude into side channels.

Figure 23 D shows a deflated/collapsed balloon after removal from the balloon folding tool of Figure 23.

Figure 24 is a front perspective view of a balloon compressing apparatus of the present invention.

Figure 24A is an exploded view of the balloon compressing apparatus of Figure 24.

5 Figure 25 shows a longitudinal sectional view of an embodiment of a catheter for simultaneous aspiration and irrigation of an anatomical region.

Figure 26 is a perspective view of a navigation adapter device that is attachable to a variety of other devices to facilitate use of those other devices in image guided surgical or interventional procedures.

10 Figure 26A is a perspective view of the navigation adaptor device of Figure 26 attached to the proximal end of a guide tube of the present invention and having an optical navigation assembly mounted on the navigation adapter device.

15 Figure 26B is a perspective view of the navigation adaptor device of Figure 26 attached to the proximal end of a guide tube of the present invention and having an electromagnetic navigation assembly mounted on the navigation adapter device.

20 Figure 27A is a top view of a dilation device useable to dilate the ostia of paranasal sinuses and other anatomical passages within the ear, nose and throat.

Figure 27B is a side view of the device of Figure 27A.

Figures 27C-27D show steps in a method for using the dilation device of Figures 27A-27B.

25 Figure 27E is a side view of another dilation device useable to dilate openings of paranasal sinuses and other anatomical passages within the ear, nose and throat.

Figure 27F is a side view of another dilation device which uses compressed inflation fluid to inflate a dilator balloon to dilate openings of paranasal sinuses and other anatomical passages within the ear, nose and

throat.

Figure 27G is a schematic diagram of the valving arrangement of the device shown in Figure 27F.

Figure 27H is a partial sectional view through a portion of the device of  
5 Figure 27A-B.

Figure 28A is a perspective view of a hand grip inflator device attached to a balloon catheter.

Figure 28B is a perspective view of a balloon dilation device having a hand grip inflator.

10 Figure 29 shows a perspective view of a hand-held squeezing device useable to break or deform anatomical structures such a nasal turbinates.

Figure 29A shows a distal portion of the device of Figure 29 in an open position.

15 Figure 29B shows a distal portion of the device of Figure 29 in a closed position.

Figures 29C-D show steps in a method for temporarily or permanently breaking or deforming a nasal turbinate using the squeezing device of Figure 29.

20 Figure 29E shows a broken perspective view of a twistable device that is useable to break or deform anatomical structures such a nasal turbinates.

Figures 29F-G show steps in a method for temporarily or permanently breaking or deforming a nasal turbinate using the twisting device of Figure 29E.

25 Figure 30 is a flow diagram of a method useable for treating sinus disorders by removal or modification of an anatomical or pathological structure in combination with dilation of an opening of a paranasal sinus.

Figure 31 is a flow diagram of a method useable for treating sinus disorders by dilation of an opening of a paranasal sinus in combination with

suction and/or irrigation of a sinus cavity.

Figure 32 is a flow diagram of a method useable for treating conditions where unwanted scar or adhesion tissue has formed by forming a puncture tract in the scar or adhesion tissue, inserting a dilator into the puncture tract  
5 and dilating the puncture tract.

Figure 33 a flow diagram of a method useable for treating sinus disorders by dilation of a natural opening of a paranasal sinus in combination with the creation of a new opening in the paranasal sinus.

10

### DETAILED DESCRIPTION

The following detailed description, the accompanying drawings and the above-set-forth Brief Description of the Drawings are intended to describe some, but not necessarily all, examples or embodiments of the invention. The  
15 contents of this detailed description do not limit the scope of the invention in any way.

A number of the drawings in this patent application may show anatomical structures of the ear, nose and throat. In general, these anatomical structures are labeled with the following reference letters:

20	Nasal Cavity	NC
	Nasopharynx	NP
	Nasal Turbinate	NT
	Frontal Sinus	FS
	Frontal Sinus Ostium	FSO
25	Ethmoid Sinus	ES
	Ethmoid Air Cells	EAC
	Sphenoid Sinus	SS
	Sphenoid Sinus Ostium	SSO
	Maxillary Sinus	MS
30	Maxillary sinus ostium	MSO
	Mucocyst	MC
	Middle turbinate	MT
	Inferior turbinate	IT

Uncinate UN  
Suprabullar ostium/recess SO  
Retro-bullar ostium/recess RO

The devices disclosed herein may be used alone or in various combinations to perform various procedures including, but not limited to, various transnasal procedures within paranasal sinuses and/or within openings of paranasal sinuses. As used herein, unless specified otherwise, the term "opening(s) of paranasal sinus(es)" shall include any transnasally accessible opening in a paranasal sinus or air cell including but not limited to; natural ostia, natural canals, surgically altered natural ostia, surgically created openings, antrostomy openings, ostiotomy openings, burr holes, drilled holes, puncture tracts, ethmoidectomy openings, fenestrations and other natural or man made passageways.

Figure 1 shows a human subject undergoing a procedure for treating sinusitis in accordance with one particular example of the present invention. The human subject is subjected to one or more diagnostic, therapeutic or access devices introduced through a support device 100. One example of a therapeutic device is a balloon catheter used to dilate openings of paranasal sinuses or other endonasal anatomical structures. One example of an access device is a guidewire used to access dilate natural ostia of paranasal sinuses or a natural or artificial passageway or tract leading to paranasal sinuses. In the embodiment shown in Figure 1, support device 100 comprises a support member that is stabilized by three or more legs that rest on the operating table. The one or more diagnostic, therapeutic or access devices may be tracked or navigated through the anatomy using one or more tracking or navigation modalities. In the embodiment shown in Figure 1, a C-arm fluoroscope 102 provides fluoroscopic visualization of anatomical regions during the procedure. An instrument console 104 comprising one or more functional modules may also be provided. Instrument console 104 can be controlled by console control means e.g. a foot pedal controller, a remote controller etc. Instrument console 104 may be fitted with wheels to enable an operator to change the position of the instrument console in an operating area. Instrument console 104 may comprise functional modules including, but

not limited to:

1. Suction pump for delivering a controlled amount of vacuum to a suction device,
2. Irrigation pump to deliver saline or other suitable irrigation medium,
- 5 3. Power module to supply power to drills or other electrical devices,
4. Storage modules for storing instruments, medications etc.,
5. Energy delivery module to provide radiofrequency, laser, ultrasound or other therapeutic energy to a surgical device,
6. Fluoroscope, MRI, CT, Video, Endoscope 106 or Camera or other imaging  
10 modules to connect or interact with devices used during various diagnostic or therapeutic procedures,
7. Display module e.g. a LCD, CRT or Holographic screen to display data from various modules such as an endoscope, fluoroscope or other data or imaging  
module,
- 15 8. Remote control module to enable an operator to control one or more parameters of one or more functional modules, and
9. Programmable Microprocessor that can store one or more operation settings for one or more functional modules etc.

In the embodiment shown in Figure 1, instrument console 104 is connected to  
20 endoscope 106. Endoscope 106 may be introduced in the anatomy through one or more introducing devices 108 such as guide catheters. A physician may use a hand held introducer 110 comprising a surgical navigation modality to introduce one or more diagnostic, therapeutic or access devices into the anatomy. Examples of surgical navigation modalities that may be located on  
25 introducer 110 include, but are not limited to navigation modalities comprising reflective passive elements, light emitting diodes, transmitters or receivers of energy (e.g. optical energy, radiofrequency energy, etc.), a combination of two or more of the abovementioned navigation modalities, etc.

One or more devices disclosed herein may be supported by one or  
30 more support devices while performing diagnostic, therapeutic or access procedures on a patient. For example, Figure 2A shows a perspective view of one embodiment of a support device 200 comprising an elongate, generally cylindrical body 202 having a plurality of projections 204 (e.g., strands, wires,



bristles, pliable or resilient members, etc.) extending therefrom. Projections 204 are located sufficiently close to each other and are made of a suitable material to frictionally grip a device that has been inserted between adjacent projections 204. For example, projections 204 may be made of polymers, rubber materials including, but not limited to neoprene, silicone rubber, ABS, Nylon, PVC, Pebax, etc. Projections 204 can be used to reversibly support one or more devices while performing diagnostic, therapeutic or access procedures on a patient. In some embodiments, one or more attachment substances or apparatus may be used to attach the body 202 to a region of the patient's body such as face, head, etc; a table; a flexible, rigid or repositionable arm mounted on a support; etc. In the embodiment shown in Figure 2A, body 202 is attached to four arms 206 that enable support device 200 to be placed on a suitable surface.

Figure 2B shows a perspective view of another embodiment of a support device. In this example, the support device 210 comprises a and elongate body 212 having having an adhesive material disposed on one or more regions of its outer surface to reversibly adhere the support device 216 to a surface, such as the patient's body, a table or a flexible arm, etc. The body 212 of this support device 210 further comprises two or more fingers 214 constructed and spaced in relation to each other to frictionally grip and substantially hold device(s) (e.g., catheter, cannula, endoscope, guidewire, etc.) that has been inserted between adjacent fingers 214. The fingers 214 may be formed of any suitable material, typically a pliable or resilient material such as certain polymer foams, elastomers, rubber materials including, but not limited to neoprene, silicone rubber, ABS, Nylon, PVC, Pebax, etc. Fingers 214 can be used to frictionally hold one or more device(s) (e.g., catheter, cannula, endoscope, guidewire, etc.) in substantially fixed position while performing diagnostic, therapeutic or access procedures on a patient. Body 212 is connected to one or more attachment mechanisms to attach body 212 to a region such as the patient's body, a table or a flexible arm, etc.

Figure 2C shows a perspective view of another embodiment of a support device 216 comprising an elongate body having one or more regions of its outer surface coated with an adhesive material to which one or more device(s) (e.g., catheter, cannula, endoscope, guidewire, etc.) may releasably

adhere. The body of this support device 216 may be made of any suitable biocompatible materials including, but not limited to silicone, nylon, DELRIN®, polycarbonate, stainless steel, ABS, etc. Typical examples of adhesives that may be disposed on the outer surface of the body to include, but are not limited to medical grade rubber pressure sensitive adhesives, acrylic adhesives such as 3M Emtech adhesive P1500™, 3M Emtech adhesive P1510™, etc. The adhesive coated regions may also be used to reversibly adhere the body of this support device 216 to another surface such as the patient's body, a table or a flexible arm, etc.

10 Figures 2D through 2G show perspective views of various embodiments of support devices being used to support working devices. In Figure 2D, support device 210 is reversibly attached to a the patient's face. Figure 2D also shows a guide catheter 226 introduced through the nose and supported between adjacent fingers 214 of the support device 210 with the elongate body of the support device being disposed transverseley (e.g., from side to side) inferior to the subject's nose (e.g., below the nares).

15 In the example of Figure 2E, a support device 230 comprises a body 232 and two or more thin strands, wires, or bristles 234 that are connected to body 232. Bristles 234 are designed to frictionally grip a device located between adjacent bristles 234. Body 232 is connected to one or more attachment mechanisms such as arms 236 that enable support device 230 to be placed on a patient's face. In the embodiment shown in Figure 2E, a guide catheter 238 is supported by support device 230.

25 In Figure 2F, a support device 240 comprises a body 242 and two or more thin strands, wires, or bristles 244 that are connected to body 242. One region of body 242 is in contact with a facial region of a patient. Bristles 244 are designed to frictionally grip a device located between adjacent bristles 244. Body 242 is connected to one or more attachment mechanisms such as arms 246 that enable support device 240 to be supported on a patient's face. In the embodiment shown in Figure 2F, a guide catheter 248 is supported by support device 240.

30 In Figure 2G, a support device 250 comprises a body 252 and two or more thin strands, wires, or bristles 254 that are connected to body 252. Bristles 254 are designed to frictionally grip a device located between

adjacent bristles 254. Body 252 is connected to one or more attachment mechanisms such as arms 256 that enable support device 250 to be placed on a mount table. In the embodiment shown in Figure 2G, a guide catheter 258 is supported by support device 250.

5 Similar support devices may also be designed using hook and loop fasteners such as Velcro™.

One or more devices disclosed herein may be introduced through one or more nasal introducers. Such nasal introducers may also be used for keeping catheters or devices separate from each other and/or for anchoring  
10 for deterring unwanted movement or slippage of one or more catheter or other devices that have been inserted into the nose. Such nasal introducers may also be used for plugging the nostrils to prevent leakage of fluids through the nostril. For example, Figures 3 - 3A show an embodiment of a nasal  
15 introducer that is insertable in to nares of a human or animal subject and useable to facilitate subsequent insertion and handling of catheters and other devices. Figure 3 shows a perspective view of an embodiment of the nasal  
20 introducer 300 comprising a body having a proximal region, a distal region and one or more lumens or bores extending therethrough to permit insertion of the desired device(s). The outer diameter of proximal region is larger than the outer diameter of the distal region. The outer diameter of nasal introducer  
25 300 gradually reduces or tapers in the distal direction, as shown in Figure 3. This nasal introducer 300 is placed in a nostril and one or more diagnostic, therapeutic or access devices may be introduced through nasal introducer 300. Examples of such diagnostic, therapeutic or access devices include, but  
30 are not limited to guide catheters, guidewires, endoscopes, etc. In the example shown in Figures 3 and 3A, the nasal introducer 300 has two lumens, a first device introducing lumen 302 and a second device introducing lumen 304. The proximal end of first device introducing lumen 302 emerges out of the proximal end of nasal introducer 300 through a first opening 306. The distal end of first device introducing lumen 302 emerges out of the distal end of nasal introducer 300 through a second opening 307. Similarly, the proximal end of second device introducing lumen 304 emerges out of the proximal end of nasal introducer 300 through a third opening 308. The distal end of second device introducing lumen 304 emerges out of the distal end of

nasal introducer 300 through a fourth opening 309. In one embodiment, first opening 306 and third opening 308 are provided with a locking mechanism such as a rotating hemostasis valve. The locking mechanism can be used to anchor one or more devices being introduced through nasal introducer 300 to the nose. Nasal introducer 300 may be made of suitable biocompatible materials including, but not limited to rubber, polymers, metals, etc.

Figure 4A shows a side view of an embodiment of a guidewire comprising an enlarged distal end. Guidewire 400 comprises an elongate body 402. Elongate body 402 may be made of a variety of biocompatible materials including, but not limited to stainless steel, Nickel-titanium alloy (e.g., Nitinol), etc. Elongate body 402 may be coated with a variety of guidewire coatings including, but not limited to lubricious coatings such as PTFE coatings, etc. The distal end of elongate body 402 comprises an enlarged region 404. In one embodiment, enlarged region 404 is substantially spherical in shape. The length of elongate body 402 may range from 65 to 75 cm. The distal region of guidewire 400 may comprise a curved, bent or angled region. In one embodiment, the distal region of guidewire 400 comprises a J-tip.

In some method embodiments of the invention disclosed herein, a guidewire may be inserted into a paranasal sinus or into/near the opening of a paranasal sinus and, thereafter, one or more diagnostic or therapeutic devices may be introduced over the guidewire. In some instances, forces generated during introduction of devices over the guidewire may tend to cause the position of the guidewire to change. The forces may also cause the guidewire to get dislodged from a desired position in a paranasal sinus or opening of a paranasal sinus. To prevent such unwanted movement of the guidewire, one or more anchoring or occlusion apparatus may be present on the guidewire. For example, Figure 4B shows a longitudinal sectional view of a guidewire 410 having an elongate body 412, a lumen 414 and a balloon 416 or other inflatable member that may be used to anchor the distal end of the guidewire 410 or for other purposes (e.g., dilation). Elongate body 412 may be made of a variety of biocompatible materials including, but not limited to stainless steel, Nickel-titanium alloy (e.g., Nitinol), etc. In one embodiment, elongate body 412 is made of a suitable hypotube. Elongate body 412 may be coated

with a variety of guidewire coatings including, but not limited to lubricious coatings such as PTFE coatings, etc. The outer diameter of elongate body 412 may range from 0.014 inches to 0.040 inches. In a preferred embodiment, the outer diameter of elongate body 412 is 0.035 inches.

5 Elongate body 412 comprises a lumen 414. The distal end of lumen 414 is in fluid communication with an anchoring balloon 416. Anchoring balloon 416 may be made of a compliant, semi-compliant or non-compliant material. Anchoring balloon 416 may be present on the distal end of elongate body 412 or on the distal region of elongate body 412. The proximal region of elongate

10 body 412 may comprise a microvalve located in lumen 414. The microvalve allows a user to inflate or deflate anchoring balloon 416 and also provide a fluid seal to lumen 414 when guidewire 410 is used to perform a diagnostic or therapeutic procedure. The distal region of guidewire 400 may comprise a curved, bent or angled region. In one embodiment, the distal region of

15 guidewire 400 comprises a J-tip. In one embodiment of a method of using guidewire 400, distal end of guidewire 400 is introduced into an anatomical region such as a paranasal sinus with anchoring balloon 416 deflated. Thereafter, anchoring balloon 416 is inflated. Guidewire 400 is then pulled in the proximal direction to anchor anchoring balloon 416 in the ostium of the

20 paranasal sinus. Thereafter, guidewire 400 is used to perform a diagnostic or therapeutic procedure. It will be appreciated that, as an alternative to a balloon 416, other anchoring apparatus such as deployable projections or expandable polymer or metal mesh structures may be incorporated into or on the guidewire 410.

25 Various diagnostic, therapeutic or access devices disclosed herein may be introduced in the anatomy through a seeker. Figure 5A shows a seeker device 500 that comprises an elongate body 502 having a lumen 506 extending therethrough. The elongate body 502 can be made of suitable biocompatible material(s) including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Pebax,

30 PEEK, Nylon, polyethylene, etc. Some or all of the elongate body 502 may be bent, angled, curved or malleable. The distal end of elongate body 502 may comprise a tip structure 504. Such tip member 504 may be constructed to be substantially atraumatic so as to prevent or reduce damage to adjacent

anatomy while using seeker 500. In the embodiment shown in Figure 5A, tip structure 504 comprises an enlarged, substantially spherical or bulbous region. Lumen 506 extends from the proximal end of elongate body 502 and to the distal end of the device. The lumen 506 can be used for introducing one or more elongate devices, suctioning, introducing one or more fluids, etc. The proximal end of elongate body 502 may comprise a suitable hub such as a luer lock. Seeker 500 may be introduced through an opening in the human body to determine the location of a cavity, sinus or other anatomical regions. Thereafter, one or more elongate devices such as guidewires may be inserted through lumen 506 and into the cavity, sinus or other anatomical regions. In one method embodiment, seeker 500 is inserted through the nose into the nasal cavity. Thereafter, seeker 500 is advanced such that optional tip structure 504 is located near a target anatomy e.g. an opening of a paranasal sinus. Seeker 500 is then moved by the user such that atraumatic tip 504 engages with the target anatomy. This provides the user information about the location and orientation of the target anatomy such as an ostium or passageway leading to a paranasal sinus. Seeker 500 is then used to introduce a guidewire through lumen 506 into the paranasal sinus. Thereafter, seeker 500 is removed leaving the guidewire in place. The guidewire is then used to introduce one or more diagnostic or therapeutic devices into the paranasal sinus. In another method embodiment, an endoscope may be incorporated within or introduced through lumen 506 and used to visualize anatomical structures and/or to guide the navigation of seeker 500. Optionally, a dilator (e.g., a balloon) may be mounted on the seeker 500 at or near the distal end of the device and may be used to dilate structures into which the seeker device 500 has been inserted. In instances where a balloon or other inflatable dilator is used, a second lumen may extend through the shaft 502 terminating distally in an opening within the balloon to permit inflation/deflation of the balloon.

Figures 5B-C show a second embodiment of a seeker device 510 comprising an elongate body 512 having a lumen 518 extending therethrough from end to end. Elongate body 512 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Pebax, PEEK, Nylon,

polyethylene, etc. The distal region of elongate body 512 may comprise a bent, angled or curved region. In some embodiments, some (e.g., a distal region) or all of the elongate body 512 may be substantially curved or malleable. The distal end of elongate body 512 may, in some cases, 5 comprise an atraumatic tip 514 to prevent or reduce damage to adjacent anatomy while using seeker 510. In the embodiment shown in Figure 5B, atraumatic tip 514 comprises an enlarged, substantially spherical region. The proximal region of elongate body 512 may comprise a handle 516 to enable a user to advance and/or twist seeker 510. In the particular example of Figure 10 5B, the lumen 518 extends from the proximal end of elongate body 512 to through distal end of the atraumatic tip 514. Also, in this particular example, the elongate body 512 further comprises a longitudinal slit 520 that extends into lumen 518. The proximal end of elongate body 512 may comprise a suitable hub such as a luer lock. In one method of use, this seeker 510 may 15 be inserted through the nose into the nasal cavity. Thereafter, seeker 510 is advanced such that atraumatic tip 514 becomes positioned near a target anatomy e.g. an ostium of a paranasal sinus. Seeker 510 is then moved by the user such that its atraumatic tip 514 touches adjacent anatomical structures. This provides the user with information about the location and 20 orientation of the target anatomy and/or surrounding anatomical structures. In some applications, after the atraumatic tip 514 of the seeker 510 has been inserted into or through an ostium of a paranasal sinus, a guidewire may be advanced through lumen 518 into the paranasal sinus. Thereafter, the seeker 510 may be removed leaving the guidewire in place. To facilitate removal of 25 the seeker 510 while leaving the guidewire in place, the proximal portion of the guidewire may be extracted laterally through slit 520. After the seeker 510 has been removed, the guidewire may be used to introduce one or more working devices (e.g., diagnostic or therapeutic devices) into the paranasal sinus. In some applications, an endoscope is introduced through lumen 518 30 to guide the navigation of seeker 510. Figure 5D shows Another seeker 530 comprising an elongate body 532 having a lumen 534 extending therethrough. The body 532 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Pebax, PEEK, Nylon, polyethylene, etc. The

distal region of elongate body 532 may comprise a bent, angled or curved region. In one embodiment, elongate body 532 is substantially malleable. Lumen 534 is an end-to-end lumen extending from the proximal end of elongate body 532 through an opening in the distal end of elongate body 532.

5 A guidewire 536, which may optionally have an atraumatic tip 538, is loaded in lumen 534 as shown. The distal region of guidewire 536 may be curved, bent or angled such that it forms an internal angle, for example an angle of about 30 degrees, about 60 degrees, about 90 degrees, about 110 degrees, etc. The proximal end of elongate body 532 may comprise a suitable hub

10 such as a rotating hemostasis valve to reversibly secure guidewire 536 to seeker 530. In one method embodiment, seeker 530 along with guidewire 536 is inserted through the nose into the nasal cavity. Thereafter, seeker 530 is advanced such that atraumatic tip 538 is located near a target anatomy e.g. an ostium of a paranasal sinus. Seeker 530 is then moved by the user such

15 that atraumatic tip 538 engages with the target anatomy. This provided the user information about the location and orientation of the target anatomy. Seeker 530 is then used to advance guidewire 536 through lumen 534 into the paranasal sinus. Thereafter, seeker 530 is removed leaving guidewire 536 in place. This step is performed by sliding seeker 530 in the proximal

20 direction over guidewire 536. Guidewire 536 is then used to introduce one or more diagnostic or therapeutic devices into the paranasal sinus.

Any of the seeker devices disclosed herein may comprise a deflectable or bendable distal tip. For example, Figure 5E shows a seeker device 540 having a deflectable or bendable distal tip. Seeker 540 comprises an

25 elongate body 542 having a first lumen 544 and a second lumen 546 extending therethrough. The elongate body 542 may be made from suitable biocompatible material(s) including, but not limited to Pebax, PEEK, Nylon, polyethylene, etc. The distal end of elongate body 542 may optionally comprise an atraumatic tip. In one embodiment, the distal end of elongate

30 body 542 comprises an enlarged, spherical region. . In the embodiment shown in Figure 5E, the inner diameter of the first lumen 544 is larger than the inner diameter of the second lumen 546. The proximal end of elongate body 542 may be connected to a suitable hub 548, such as a female luer lock. Hub 548 may comprise one or more wings 550 to enable a user to twist or torque



seeker 540. Seeker 540 further comprises a deflecting or bending mechanism. In this embodiment, the deflecting or bending mechanism comprises a deflecting handle 552 attached to a pivot 554. One end of deflecting handle 552 is connected to a pull wire 556. The distal end of pull wire 556 is attached to the distal region of elongate body 542 by an attachment means 558. In one embodiment, attachment means 558 is glue. To cause deflecting or bending of the distal tip of elongate body 542, a user pulls deflecting handle 552. Deflecting handle 552 in turn pulls pull wire 556. This causes deflecting or bending of the distal tip of elongate body 542. Figure 5F shows a cross sectional view through plane 5F-5F in Figure 5E. Figure 5F shows elongate body 542 comprising first lumen 544 and second lumen 546. Pull wire 556 passes through second lumen 546. Similar deflecting mechanisms may also be used for constructing one or more guide catheters disclosed herein. Such guide catheters may be used for introducing one or more diagnostic, therapeutic or access devices into the anatomy.

Any of the seeker devices disclosed herein may be used to open or puncture scar tissue or adhesions of paranasal sinus ostia or passageways leading to paranasal sinuses. Such scar tissue or adhesions may be caused for example due to infection, prior surgery, etc.

Figure 6A shows a tubular guide or guide catheter 600 having an elongate guide shaft 602, a lumen 603 extending therethrough and an expandable dilator such as a balloon 606. Guide shaft 602 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloy (e.g., Nickel-titanium alloy (e.g., Nitinol)), etc.; polymers e.g. Pebax, PEEK, Nylon, polyethylene, etc. The distal region of guide shaft 602 may comprise an angled, curved or bent region. In one embodiment, the distal tip of guide catheter 600 comprises a soft, atraumatic tip to reduce or prevent damage to surrounding anatomy. The distal region of guide shaft 602 may comprise a navigational marker 604 such as a radiopaque marker band or a sensor/emitter usable with an electromagnetic or other type of navigation or image guidance system. Balloon 606 may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyurethane, silicone, etc. Balloon 606 can be inflated by a hollow balloon inflation tube 608. Balloon inflation tube 608 is

attached to guide shaft 602 and is substantially collinear to guide shaft 602. The proximal end of balloon inflation tube 608 is in fluid connection to a balloon inflation port 610. The proximal end of guide shaft 602 may comprise a suitable hub such as a female luer lock 612. Guide catheter 600 can be  
5 used for introducing one or more devices or fluids through lumen 603. Lumen 603 can also be used for suctioning fluids. Balloon 606 may be used for dilating anatomical regions including, but not limited to anatomical passageways, ostia of paranasal sinuses, etc. Figure 6B shows a cross sectional view through the plane 6B – 6B of Figure 6A. Figure 6B shows  
10 balloon inflation tube 608 is attached to guide shaft 602.

Figure 6C shows a guide catheter 620 that has an elongate body 622 comprising a lumen and a side channel, such as a side tube 626. Elongate body 622 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, etc. or polymers e.g. Pebax, PEEK, etc.  
15 The distal end of elongate body 622 may comprise a curved, angled or bent region. The distal end of elongate body 622 may comprise a malleable region or may be actively deflectable by a user. The proximal end of elongate body 622 comprises a hub 624. In one embodiment, hub 624 is a female luer lock. The side lumen 626 may be aligned substantially parallel to the lumen of  
20 elongate body 622 and may extend distally to be flush with the distal end of the elongate body 622 or, in some cases, may terminate proximal to the distal end of the elongate body. In the particular example shown in the drawings, side lumen 626 extends from a proximal region of guide catheter 620 to a location that is substantially flush with the distal end of the elongate body 622.  
25 Side lumen 626 may be permanently or detachably attached to elongate body 622. A suitable endoscope 628 or other imaging device or imaging probe can be introduced through elongate side lumen 626 such that the distal end of endoscope 628 emerges out of the distal end of elongate side lumen 626. Examples of suitable endoscopes 628 that can be used with guide catheter  
30 620 include Karl Storz Flexible Rhino-Laryngoscope (11101RP), made by Karl Storz Endoscopy – America, Culver City, California. The proximal end of endoscope 628 is connected to a video camera 630 to enable a user to view the anatomy around the distal region of guide catheter 620. This combination of guide catheter 620 and endoscope 628 is introduced in a target anatomy.

Thereafter, one or more diagnostic, therapeutic or access devices are introduced through the lumen of elongate body 622 under endoscopic guidance. The curved, angled or bent region in the distal end of elongate body 622 is especially useful to navigate endoscope 628 around a tight bend  
5 in the anatomy.

Figure 6D shows a guide catheter 650 having an elongate body 652, a lumen that extends through the elongate body and one or more attachment apparatus such as side clip(s) 656. Elongate body 652 may be made of suitable biocompatible materials including, but not limited to metals e.g.  
10 stainless steel, etc. or polymers e.g. Pebax, PEEK, etc. The distal end of elongate body 652 may comprise a curved, angled or bent region. The proximal end of elongate body 652 may comprise a hub 654. In one embodiment, hub 654 is a female luer lock. Side clips 656 may be permanently or removably attached to the outer surface of elongate body 652  
15 as shown in Figure 6C. The one or more side clips 656 may form a channel through which an endoscope may be introduced or may otherwise hold an endoscope in a position beside the elongate body 652 such that the endoscope may view a field ahead of or adjacent to the distal end of the device 650. Thus, one or more diagnostic, therapeutic or access devices may  
20 be introduced through the lumen of elongate body 652 under endoscopic guidance using an endoscope (or other imaging device or probe) that has been inserted or otherwise positioned within or supported by side clips 656. In one embodiment, side clips 656 may be cylindrical. In another embodiment, side clips 656 may be ring shaped.

Figure 6E shows an endoscope 660 or other imaging device or imaging probe is combined with a guide catheter 662. Guide catheter 662 has a lumen. Guide catheter 662 may comprise a bent, angled or curved distal tip 664. In this particular example a magnet 666 causes the endoscope 660 to be attached by magnetic force to the guide catheter 662, as shown in Figure  
25 6D. This combination of endoscope 660 and guide catheter 662 is then introduced in the anatomy. Thereafter, one or more diagnostic, therapeutic or access devices may be introduced through the lumen of guide catheter 662 under endoscopic guidance or other image guidance using an endoscope 660 or other imaging device or imaging probe attached by magnetic force to the  
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guide catheter 662.

Figure 6F shows an endoscope 670-guide catheter 672 combination device or system. In this example, the guide catheter 672 has a lumen. Guide catheter 672 may comprise a bent, angled or curved distal tip 674. In this embodiment, endoscope 670 is combined with guide catheter 672 by an attachment apparatus that comprises a collar, such as a rubber collar 676. Rubber collar 676 comprises two parallel lumens. Endoscope 670 fits in the first lumen of rubber collar 676. Rubber collar 676 may be made of suitable biocompatible rubber materials including, but not limited to silicone, Pebax, PVC, etc. Similarly, guide catheter 672 fits in the second lumen of rubber collar 676. Thus, endoscope 670 is combined with guide catheter 672 to enable simultaneous introduction of endoscope 670 and guide catheter 672 into a target anatomy. Thereafter, one or more diagnostic, therapeutic or access devices are introduced through the lumen of guide catheter 672 under endoscopic guidance.

Figure 6G shows an endoscope 680-guide catheter 682 combination device or system. Guide catheter 682 has a lumen and may comprise a bent, angled or curved distal tip 684. In this embodiment, endoscope 680 is combined with guide catheter 682 by a removable band 686 that ties endoscope 680 with guide catheter 682. In one embodiment, removable band 686 comprises a hook and loop type of attaching mechanism such as Velcro. Removable band 686 may be made of suitable biocompatible materials including, but not limited to silicone, Pebax, nylon, stainless steel, Nickel-titanium alloy (e.g., Nitinol<sup>TM</sup>), etc. Thus, endoscope 680 is combined with guide catheter 682 to enable simultaneous introduction of endoscope 680 and guide catheter 682 into a target anatomy. Thereafter, one or more diagnostic, therapeutic or access devices are introduced through the lumen of guide catheter 682 under endoscopic guidance.

Figures 6H and 6I show another endoscope-guide catheter combination device or system 698. As seen in Figure 6H, the guide catheter comprises an elongate shaft 690. In some cases, a distal region of elongate shaft 690 may further comprise a curved, bent or angled region 692. The guide catheter further comprises a hub 694 located on the proximal end of elongate shaft 690. In one embodiment, hub 694 is a female luer lock. The

guide catheter is attached to an endoscope 696 such as a fiber-optic endoscope by an adjustable connector 698 comprising a hollow body 699. Hollow body 699 comprises two channels: a first channel comprising a first proximal orifice 6000 and a first distal orifice 6002 and a second channel  
5 comprising a second proximal orifice 6004 and a second distal orifice 6006. The first channel allows the guide catheter to pass through adjustable connector 698. The second channel allows endoscope 696 to pass through adjustable connector 698. Adjustable connector comprises a first gripping mechanism 6008 and a second gripping mechanism 6010. First gripping  
10 mechanism 6008 enables adjustable connector 698 to grip the guide catheter. Similarly, second gripping mechanism 6010 enables adjustable connector 698 to grip endoscope 696. In the embodiment shown in Figure 6H, first gripping mechanism 6008 comprises an elongate lever 6012 pivoted on a pivot 6014 located on adjustable connector 698. One end of elongate lever 6012 is  
15 attached by a spring mechanism 6016 to adjustable connector 698. Spring mechanism 6016 causes the distal end of elongate lever 6012 to press on the guide catheter. This in turn causes the guide catheter to press on an edge of first proximal orifice 6000 and first distal orifice 6002. This in turn causes adjustable connector 698 to grip the guide catheter. Similarly, second  
20 gripping mechanism 6010 comprises an elongate lever 6018 pivoted on a pivot 6020 and a spring mechanism 6022 to cause adjustable connector 698 to grip endoscope 696. To adjust the relative positions of the guide catheter and/or the endoscope 696, a user presses the proximal regions of elongate lever 6012 and/or elongate lever 6018 as shown in Figure 6I. Pressing the  
25 proximal region of elongate lever 6012 causes the distal region of elongate lever 6012 to move away from the guide catheter. This in turn releases the guide catheter from adjustable connector 698. Similarly, pressing the proximal region of elongate lever 6018 releases endoscope 696 from adjustable connector 698. Thus, adjustable connector 698 can be used to  
30 maintain the relative position of the guide catheter and endoscope 696 during introduction or removal of the guide catheter in the anatomy and/or while performing a diagnostic, therapeutic or access procedure. If needed, the relative position of the guide catheter and endoscope 696 can be adjusted before during or after a procedure. Various regions of adjustable connector

may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, Nickel-titanium alloy (e.g., Nitinol), titanium, etc.; suitable polymers, etc. Similarly, other embodiments of adjustable connectors can be used to maintain the relative position of the guide catheter and  
5 endoscope 696 during introduction or removal of the guide catheter in the anatomy and/or while performing a diagnostic, therapeutic or access procedure.

Figure 6J shows a perspective view of an embodiment of a removable attachment apparatus comprising a clipping device 6030 useable to introduce  
10 or support an endoscope, image apparatus or various other devices along side a guide catheter 6020. In the example shown, guide catheter 6020 comprises an elongate hypotube 6022 enclosing an elongate tubular member 6024. Elongate tubular member 6024 encloses a lumen to allow for insertion of one or more devices through guide catheter 6020. The distal end of tubular  
15 member 6024 may be angled, bent or curved. The distal end of tubular member 6024 may comprise an atraumatic tip 6026. The proximal end of tubular member 6024 comprises a hub. In one embodiment, the hub is a female luer lock. A removable clipping device 6030 can clip on to guide catheter 6020. Clipping device 6030 can be made of suitable biocompatible  
20 materials such as metals, rubbers, polymers, etc. Clipping device 6030 comprises a first clip 6032 and a second clip 6034. First clip 6032 is adapted to attach to the outer surface of guide catheter 6020. Second clip 6034 is adapted to attach to the outer surface of an endoscope. Such a combination of an endoscope and a device such as a guide catheter can be introduced by  
25 a physician using a single hand.

Figures 6K and 6L show the steps of a method of accessing an anatomical region using the removable clipping device shown in Figure 6J. In Figure 6K, clipping device 6030 is attached to guide catheter 6020. Thereafter, guide catheter 6020 is introduced in an anatomical region such as  
30 the nasal cavity. An endoscope 6036 is introduced in the anatomy along with guide catheter 6020. Endoscope 6036 helps to visualize the anatomy to facilitate the introduction and/or the navigation of guide catheter 6020 in the anatomy. If desired, endoscope 6036 may be attached to guide catheter 6020 using clipping device 6030 as shown in Figure 6L. This enables the

relative position of endoscope 6036 and guide catheter 6020 to be relatively fixed during a procedure. Endoscope 6036 and guide catheter 6020 can thus be co-introduced in an anatomical region. In one embodiment, clipping device 6030 is made of a flexible material such as a suitable rubber to allow for angular displacement of the axis of endoscope 6036 relative to the axis of guide catheter 6020. In another embodiment, the contact surface between clipping device 6030 and one or both of endoscope 6036 and guide catheter 6020 is smooth. This allows endoscope 6036 to slide relative to guide catheter 6020. In another embodiment, endoscope 6036 and/or guide catheter 6020 can be rotated around their axes even when attached to clipping device 6030. In another embodiment, clipping device 6030 allows minimal motion of endoscope 6036 relative to guide catheter 6020.

Figures 6M through 6O shows various steps of a method of introducing one or more diagnostic or therapeutic devices along or beside another device such as an endoscope or other imaging device or imaging probe. In the example of Figure 6M, the introducing device 6040 comprises an endoscope 6042 and an attachment or receiving apparatus comprising a side lumen 6044. Introducing device 6040 is introduced in a desired region of the anatomy. This introduction may be performed using endoscope 6042, using a separate endoscope or using fluoroscopy or other imaging/guidance techniques. Thereafter, a guidewire 6046 is introduced through side lumen 6044. Guidewire 6046 is navigated through the anatomy under endoscopic visualization by endoscope 6042. Thereafter, guidewire 6046 is placed in a desired target region. In one method embodiment, guidewire 6046 is placed across an ostium of a paranasal sinus. Thereafter, in Figure 6N, a working device such as a balloon catheter 6048 comprising a dilating balloon 6050 is introduced over guidewire 6046 into the target anatomy. Thereafter, in Figure 6O, balloon 6050 is inflated to dilate a region of the target anatomy. In one method embodiment, balloon 6050 is inflated to dilate an ostium of a paranasal sinus. Thereafter, balloon 6050 is deflated and balloon catheter 6048 and introducing device 6040 are removed from the anatomy. Similarly, other diagnostic or therapeutic devices may be introduced through side lumen 6044 to perform one or more diagnostic or therapeutic procedures.

Figure 6P shows an embodiment of a method of introducing a dilator

through the introducing device of Figure 6M. In this embodiment, dilator 6052 comprises a flexible shaft and a rounded distal end to dilate or displace tissue.

Figure 6Q shows a deflectable introducing device 6054 that generally comprises an endoscope and an introducing lumen. Introducing device 6054  
5 comprises a proximal handle 6056. Proximal handle 6056 encloses an elongate tubular element 6058. In one embodiment, the proximal region of tubular element 6058 is substantially rigid. In another embodiment, the distal region of tubular element 6058 comprises a bent region. In another embodiment, the distal region of tubular element 6058 is malleable or  
10 plastically deformable. In Figure 6Q, the distal region of tubular element 6058 is removed to show structures enclosed by the distal region of tubular element 6058. Tubular element 6058 encloses an endoscope 6060 and an introducing lumen 6062. Endoscope 6060 is used to visualize the anatomy or one or more diagnostic or therapeutic devices while performing a diagnostic or  
15 therapeutic procedure. The proximal end of introducing lumen 6062 may comprise a suitable hub 6064. In one embodiment, hub 6064 is a female luer hub. Introducing lumen 6062 can be used to introduce one or more diagnostic, therapeutic or access devices into the anatomy. In one embodiment, introducing device 6054 comprises a steering or deflecting  
20 mechanism to allow a user to controllably bend or deflect the distal region of tubular element 6058. In the embodiment shown in Figure 6Q, introducing device 6054 comprises a sliding button 6066 that is attached to a pull wire. The pull wire in turn is attached to one or more distal rings 6068 located on the distal region of tubular element 6058. A user can move sliding button  
25 6066 to cause a distal region of tubular element 6058 to controllably bend or deflect. In another embodiment of a steering or deflecting mechanism, the distal region of endoscope 6060 is attached to a distal region of tubular element 6058. The distal region of endoscope 6060 may be attached to a distal region of tubular element 6058 by one or more distal rings 6068. In this  
30 embodiment, pulling endoscope 6060 causes a distal region of tubular element 6058 to controllably bend or deflect. Figure 6R shows a perspective view of the distal region of the introducing device of Figure 6Q in a bent or deflected state. A distal region of tubular element 6058 has been removed to show structures enclosed by the distal region of tubular element 6058.



Introducing device 6054 may be used to introduce one or more diagnostic, therapeutic or access devices into the anatomy. In one embodiment, introducing device 6054 is used to introduce a balloon catheter. In another embodiment, introducing device 6054 is used to introduce a guidewire into the anatomy. The guidewire is thereafter used to introduce one or more diagnostic, therapeutic or access devices into the anatomy.

Figures 7A through 7C show various steps of a method of accessing an anatomical opening using an introducing device 700 that generally comprises an endoscope 702 and an introducing lumen 704. The introducing device 700 may be inserted into the body through an orifice or opening such as a nostril. Thereafter, introducing device 700 is positioned, possibly under endoscopic visualization or other image guidance, such that the distal end of introducing device 700 is positioned near a target of interest such as an opening of a paranasal sinus. Thereafter, in Figure 6S, a diagnostic, therapeutic or access device is inserted through introducing lumen 704 into the target of interest. In the example shown in Figure 7B, the target of interest is an opening of a paranasal sinus and a guidewire 706 is being inserted through introducing lumen 704 into a retro-bullar ostium or recess. Guidewire 706 may then be used to introduce one or more diagnostic, therapeutic or access into the retro-bullar ostium or recess, as shown. Figure 7C shows a perspective view of a region of the human face showing the manner in which the introducing device 700 may be transnasally inserted in the method shown in Figures 7A and 7B. After the introducing device 700 has been inserted and positioned, various guidewires or other diagnostic, therapeutic or access devices may be inserted through introducing lumen 704.

Any of the guide catheters or other luminal devices disclosed herein may comprise an arrangement for suctioning an anatomical region through the distal end of the guide catheter or device unless to do so would render the device unuseable for its intended purpose. For example, Figure 8A shows a guide catheter 800 comprising an elongate tube 802 that may be made of suitable biocompatible materials including, but not limited to metals such as stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; plastics such as Pebax, PEEK, Nylon, polyethylene, etc. The distal region of elongate tube 802 may comprise a curved, bent or angled region. In some embodiments,

the distal end of elongate tube 802 may comprise an atraumatic tip 804. Although various modes of construction may be used, in the example shown, an elongate hypotube 806 is disposed on the outer surface of elongate tube 802 and the proximal end of guide catheter 800 comprises a branched or Y-  
5 connector 808. The proximal region of Y-connector 808 comprises a straight arm 810 and a side arm 812. The proximal end of straight arm 810 comprises a suitable hub 814. In one embodiment, hub 814 is a female luer hub. In another embodiment, hub 814 comprises a rotating hemostasis valve such as a Touhy-Borst adapter. The proximal end of side arm 812 comprises a  
10 suitable hub 816. In one embodiment, hub 816 comprises a rotating hemostasis valve such as a Touhy-Borst adapter to adjust the amount of suction. Hub 816 is connected to a suction tube 818 that provides suction to guide catheter 800. Thus, guide catheter 800 can be used to provide suction as well as introduce one or more diagnostic, therapeutic or access devices  
15 into the anatomy.

Various devices being introduced in the anatomy may comprise a detachable navigation apparatus (e.g., a navigation module or localizer) useable in conjunction with a navigation or image guidance system to track and/or navigate the devices through the anatomy. For example, Figure 8B  
20 shows a perspective view of a guide catheter 820 having a navigation adapter 830 that is designed to receive detachable navigation apparatus such as a navigation module or localizer containing sensor(s), emitter(s), transmitter(s), reflector(s), etc. that are useable in conjunction with a navigation system. The navigation apparatus may be selected from the various navigation apparatus  
25 disclosed herein or in one of the patent applications incorporated herein by reference. In the embodiment shown in Figure 8B, guide catheter 820 comprises an elongate body 822 having a lumen. Elongate body 822 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers  
30 e.g. Pebax, PEEK, Nylon, polyethylene, etc. The distal end of elongate body 822 may comprise a bent, curved or angled region. The proximal region of elongate body 822 may comprise a hypotube 824 located on the external surface of elongate body 822. The distal end of elongate body 822 may comprise an atraumatic tip 826. The proximal end of guide catheter 820

comprises a first attachment mechanism 828. In one embodiment, first attachment mechanism 828 is a female luer lock. First attachment mechanism 828 is used to attach guide catheter 820 to a navigational adaptor 830. Navigational adaptor 830 comprises a second attachment mechanism 832 that attached to first attachment mechanism 828 on the proximal end of guide catheter 820. In one embodiment, second attachment mechanism 832 is a male luer lock. Navigational adaptor 830 further comprises a proximal hub 834 that is in fluid communication with second attachment mechanism 832. Navigational adaptor 830 further comprises a handle 836 to enable a user to hold and navigate guide catheter 820. The outer surface of handle 836 may be roughened to increase the grip of a user on handle 836. In one embodiment, outer surface of handle 836 is roughened by knurling. Handle 836 comprises a bay to attach a suitable navigational localizer 838 to navigational adaptor 830. Examples of navigational localizer 838 are encoded passive manipulator, active manipulator, ultrasound localizer, electromagnetic localizer, active optical localizer, passive optical localizer, etc. Navigation adaptor 830 may further comprise an identification module 840. Identification module 840 enables navigational localizer 838 to identify the type of navigational adaptor 830 that is being connected to navigational localizer 838. This enables the registration of the location and orientation of the distal tip of navigational adaptor 830 by navigational localizer 838. In the embodiment shown in Figure 8B, identification module 840 comprises a pair of magnets. The unique magnetic field generated by the pair of magnets is measured by navigational localizer 838. This enables navigational localizer 838 to identify the type of navigational adaptor 830 being attached to navigational localizer 838. Other examples of identification module 840 include, but are not limited to electrical modules e.g. a ROM that provides electrical information to navigational localizer 838; mechanical modules e.g. connector-pin arrangements that provide mechanical information to navigational localizer 838; other magnetic modules that provides magnetic information to navigational localizer 838; etc. In a particular embodiment, the distal end of elongate body 822 comprises a malleable or shapeable region. In this embodiment, the position and orientation of the distal tip of guide

catheter 820 is re-calibrated to navigational localizer 838 after performing a step of bending or shaping the distal end of elongate body 822.

In an alternate embodiment of navigational adaptor 830 of Figure 8B, handle 836 may comprise a non-detachable navigational localizer 838.

5       The devices disclosed herein, especially the guide catheters, may comprise a proximal region adapted to fit to a suction tube. For example, Figure 9 shows a perspective view of a tubular guide having a tapered connector on its proximal end to facilitate attachment of a suction tube to the tubular guide. Figure 9 shows a tubular guide 900 comprising an elongate shaft 902. The proximal end of elongate shaft 902 may comprise a suitable hub 904 to attach one or more devices to the proximal end of guide catheter 900. In one embodiment, hub 904 is a female luer lock. Tubular guide 900 further comprises a tapered region 906 on the proximal region of elongate shaft 902. Tapered region 906 comprises a wider proximal region and a narrower distal region to allow a suction tube to be fitted on the proximal end of tubular guide 900. One or more grooves or ridges of the external surface of tapered region 906 may be provided to increase the grip of the suction tube on tapered region 906. Tapered region 906 may also be used to attach a tube on the proximal end of tubular guide 900 to deliver a suitable flushing fluid. The distal region of tubular guide 900 may comprise a bent, curved or angled distal region 908.

15       Bent, curved or angled regions of one or more devices disclosed herein may be made by bending a portion of the device and, in some instances, the devices will be formed of malleable material or may incorporate a malleable region to permit the user to bend, curve, angle or otherwise configure the device as desired. Some of the devices disclosed herein may be made by joining two elements, one of which comprises a bent, curved or angled region. For example, Figure 10A is an exploded view showing the components of a tubular guide device of Figure 9 formed of a straight proximal segment 902 and a curved distal segment 908. In this example, the bent, curved or angled distal segment 908 is attached to the proximal segment 902 as shown in the assembled view of Figure 10B. The distal end of proximal region 902 may be joined to the proximal end of distal region 908 at any desired angle. This may be done, for example, by cutting the distal end of proximal segment 902 at

and angle and/or cutting the proximal end of distal segment 908 at an angle and then joining the segments in an end-to-end butt joint fashion. Optionally, a sleeve or covering may surround the joint between the proximal end of the distal segment 902 and the distal end of the proximal segment 908.

5 Embodiments where the distal segment 908 is joined to the proximal segment 902 at an angle may be used to make one or more of the devices disclosed herein that comprise a bent, curved or angled region.

In an alternate method of manufacture, bent, curved or angled regions of one or more devices disclosed herein are made by joining two molded parts. The two molded parts are made such that each molded part comprises a bent, curved or angled region. The two molded parts are then joined to each other to produce a tubular element enclosing a lumen.

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Figure 10C shows a tubular guide or guide catheter 1000 that comprises a first tube 1004 and a second tube 1002 that is formed of polymeric or other material that melts or softens so as to be flowable through openings 1006 formed in the first tube 1004. The second tube 1002 protrudes out of and beyond the distal end of the first tube 1004. Second tube 1002 may be made of suitable biocompatible materials including, but not limited to Pebax, PEEK, Nylon, polyethylene, etc. The first tube 1004 may also be formed of any suitable material such as hypotube made of a biocompatible metals including, but not limited to stainless steel, Nickel-titanium alloy (e.g., Nitinol), etc. During manufacture, the second tube 1002 is positioned such that a proximal portion of the second tube 1002 extends into or through the lumen of the first tube 1004 and the second tube 1002 is caused to melt or soften (e.g., by heating) in the area of the openings 1006. The melted or softened material of second tube 1002 thereafter enters the one or more openings (e.g., holes or notches) 1006 of first tube 1004 and is allowed to resolidify, thereby forming a bond or lock between the first tube 1004 and the second tube 1002. Such a method of manufacture may be used for manufacturing one or more devices comprising hypotubes disclosed herein or in the patent applications incorporated herein by reference.

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Figure 11 shows a perspective view of an embodiment of a guide catheter comprising a curved, bent or angled distal flap. Guide catheter 1100 comprises an elongate body 1102 comprising a lumen. Elongate body 1102

may be made from suitable biocompatible materials including, but not limited to metals such as stainless steel or Nickel-titanium alloy (e.g., Nitinol), or polymers such as Nylon, Pebax, PEEK, polyethylene, etc. The lumen of elongate body 1102 may be used to introduce one or more elongate devices  
5 through guide catheter 1100. The distal region of elongate body 1102 comprises a curved, bent or angled distal flap 1104. Flap 1104 is oriented at an angle to the axis of guide catheter 1100 as shown in Figure 11. In one embodiment, flap 1104 is created by removing material from the distal end of elongate body 1102 and bending the distal end of elongate body 1102. In  
10 another embodiment, flap 1104 is created by attaching an element comprising flap 1104 to the distal region of elongate body 1102. Such guide catheters may be used for introducing one or more elongate devices such as a guidewire 1106 at a desired angle to the guide catheter.

Similar flap regions may also be attached to the distal end of  
15 endoscopes comprising one or more endoscope lumens. This enables a user to introduce one or more devices through the one or more endoscope lumens at an angle to the axis of the distal region of the endoscope.

Figure 12 shows a perspective view of a guide catheter comprising an elongate body 1202, lumens 1206, 1210 terminating in openings 1208, 1212  
20 and an optional atraumatic distal tip 1204. Atraumatic distal tip 1204 prevents or reduces damage to the anatomy while introducing guide catheter 1200 into the anatomy. Elongate body 1202 may be made from suitable biocompatible materials including, but not limited to Nylon, Pebax, PEEK, polyethylene, etc. Guide catheter 1200 further comprises a lumen 1206 that extends from the  
25 proximal region of guide catheter 1200. The distal end of lumen 1206 emerges out of the distal region of guide catheter 1200 through a lumen opening 1208. The distal end of lumen 1206 comprises a bent, curved or angled region such that an elongate device introduced through lumen 1206 emerges out of lumen opening 1208 at an angle to the axis of guide catheter  
30 1200. Guide catheter 1200 may comprise one or more lumens. In the example shown in Figure 12, guide catheter 1200 further comprises a second lumen 1210 that extends from the proximal region of guide catheter 1200. The distal end of second lumen 1210 emerges out of the distal region of guide catheter 1200 through a second lumen opening 1212. Figure 12A shows a

cross section through the guide catheter shown in Figure 12 through the plane 12A-12A. Guide catheter 1200 comprises an elongate body 1202 comprising lumen 1206 and second lumen 1210. Such guide catheters may be used for introducing one or more elongate devices such as guidewires at a desired angle to the guide catheter. Such guide catheters may also comprise an endoscope lumen. In one embodiment, the endoscope lumen has a side opening to enable a user to introduce one or more elongate devices such as guidewires under endoscopic guidance.

Figure 13A shows a tubular guide or guide catheter 1300 comprises an elongate tubular body 1302 that may be substantially rigid and an endoscopic apparatus 1306 attached to the body 1302 and useable to facilitate endoscopic viewing of a field ahead or adjacent to the distal end of the tubular guide body 1302. Elongate body 1302 may be made of suitable biocompatible materials including, but not limited to metals such as stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; plastics such as Nylon, Pebax, PEEK, polyethylene, etc. The distal region of elongate body 1302 comprises a curved, bent or angled region to enable the user to introduce one or more devices into the target region around the anatomical obstruction. The curved, bent or angled region of elongate body 1302 may be bent by an angle ranging from 25 degrees to 130 degrees. The distal end of elongate guide 1302 may comprise an atraumatic tip 1304 to reduce or eliminate trauma to surrounding tissues while using device guide 1300. In this example, the endoscopic apparatus 1306 comprises a periscope or waveguide that is attached to the side of the tubular body 1302. The proximal end of this periscope 1306 comprises a socket 1308. Socket 1308 enables the distal end of an endoscope to attach to periscope 1306. Distal end of periscope 1306 comprises a curved, bent or angled region to enable the user to visualize the target region around the anatomical obstruction. The curved, bent or angled region of periscope 1306 may be bent by an angle ranging from 25 degrees to 130 degrees. In one embodiment of a method of using device guide 1300, the target region around the anatomical obstruction is visualized by an endoscope attached to periscope 1306. Thereafter, one or more diagnostic, therapeutic or introducing devices are introduced into the target region through elongate body 1302. Figure 13B shows a longitudinal sectional view

of the device guide shown in Figure 13A. Figure 13B shows device guide 1300 comprising an elongate body 1302 with an atraumatic tip 1304. The proximal end of periscope 1306 comprises a socket 1308. Socket 1308 comprises a gasket 1312 to substantially seal the interface between an endoscope and socket 1308. The distal end of periscope 1306 comprises lens 1310. Light entering lens 1310 is reflected by a mirror 1314 and is directed towards socket 1308. Thereafter, the light enters the endoscope to provide the user an image of the target anatomy to be visualized. In one alternate embodiment, the mirror may be polarized to improve image quality and reduce glare.

Figure 13C shows a longitudinal sectional view of a second embodiment of a device guide comprising a periscope to enable a user to endoscopically visualize a target region around an anatomical obstruction. Device guide 1320 comprises an elongate body 1322 comprising a lumen. Elongate body 1322 may be made of suitable biocompatible materials including, but not limited to metals such as stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; plastics such as Nylon, Pebax, PEEK, polyethylene, etc. The distal region of elongate body 1322 comprises a curved, bent or angled region to enable the user to introduce one or more devices into the target region around the anatomical obstruction. The curved, bent or angled region of elongate body 1322 may be bent by an angle ranging from 25 degrees to 130 degrees. The distal end of elongate guide 1322 may comprise an atraumatic tip 1324 to reduce or eliminate trauma to surrounding tissues while using device guide 1320. A periscope 1326 is attached lengthwise to elongate body 1320. Distal end of periscope 1326 comprises a curved, bent or angled region to enable the user to visualize the target region around the anatomical obstruction. The curved, bent or angled region of periscope 1326 may be bent by an angle ranging from 25 degrees to 130 degrees. The proximal end of periscope 1326 comprises a socket 1328. Socket 1328 enables the distal end of an endoscope to attach to periscope 1326. Socket 1328 comprises a gasket 1330 to substantially seal the interface between an endoscope and socket 1328. The distal end of periscope 1326 comprises a lens 1332. Periscope 1326 further comprises fiber optic fibers 1334 located proximal to lens 1332. Light passing through



lens 1332 passes through fiber optic fibers 1334. Thus, light emitted by the endoscope is transmitted by fiber optic fibers 1334 through lens 1332 to illuminate a field of view. The light is reflected from anatomical regions and enters lens 1332. Light entering lens 1332 is transmitted by fiber optic fibers 5 1334 to socket 1328. Thereafter, the light enters the endoscope attached to socket 1328 to provide the user an image of the target anatomy to be visualized. Fiber optic fibers 1334 of periscope 1326 are arranged such that they are substantially aligned with the fiber optic fibers of the endoscope attached to socket 1328. In one embodiment, a part of fiber optic fibers 1334 10 of periscope 1326 are designed to transmit light emitted from the endoscope to illuminate the field of view. Another part of fiber optic fibers 1334 of periscope 1326 are designed to transmit light reflected from anatomical structures to the endoscope. In one embodiment, periscope 1326 further comprises one or more intermediate lenses 1336 located between the ends of 15 adjacent bundles of fiber optic fibers 1334 as shown in Figure 13C. In one embodiment of a method of using device guide 1320, the target region around the anatomical obstruction is visualized by an endoscope that is attached to periscope 1326. Thereafter, one or more diagnostic, therapeutic or introducing devices are introduced into the target region through elongate body 1322.

20 Figures 13D and 13E show the various steps of an embodiment of a method to endoscopically visualize a target region around an anatomical obstruction using a device guide comprising a periscope. In this method embodiment, device guide 1320 shown in Figure 13A is used as an example of a device guide comprising a periscope. In Figure 13D, a user attempts to 25 visualize a target anatomical region around an anatomical obstruction using an endoscope 1340. In one embodiment, the target anatomical region is the ostium of a maxillary sinus and the anatomical obstruction is a nasal turbinate. If the attempt is unsuccessful, the method proceeds to the step shown in Figure 13E. In Figure 13E, the user fits the distal tip of endoscope 1340 into 30 the proximal end of periscope 1306. This enables the user to visualize the anatomy around the anatomical obstruction. Thereafter, one or more devices may be introduced through device guide 1320 into the anatomy.

The various devices described or incorporated herein may include one or more optical marker(s). Such optical marker(s) may be used for example

for optically determining the relative location of the balloon of the balloon catheter with respect to the distal end of a guide catheter through which the balloon catheter is introduced. Such optical marker(s) may enable a user to determine the location of the balloon of the balloon catheter with respect to  
5 the distal end of a guide catheter without using methods like fluoroscopy that used ionizing radiation. If the balloon is too close to the distal end of the guide catheter, there is a risk that the balloon may be inflated by a user while it is inside the guide catheter. If the balloon is too far from the distal end of the guide catheter, the guide catheter may not provide adequate support to  
10 the balloon catheter. Thus, the balloon of the balloon catheter should be located at an optimal distance with respect to the distal end of the guide catheter. In one embodiment, the optimal distance is ensured by providing an optical marker on the proximal region of the balloon catheter. The balloon catheter is inserted through a guide catheter such that the distal region of the  
15 balloon catheter emerges out of the distal end of the guide catheter. The location of the optical marker relative to the proximal region of the guide catheter is used to determine the relative location of the balloon of the balloon catheter with respect to the distal end of the guide catheter. In another embodiment, the optimal distance is ensured by providing an optical marker  
20 on the distal region of the balloon catheter. The balloon catheter is inserted through a guide catheter such that the distal region of the balloon catheter emerges out of the distal end of the guide catheter. The location of each optical marker may be tracked by an endoscope inserted in the anatomy. The location of the optical marker relative to the distal end of the guide catheter is  
25 used to determine the relative location of the balloon of the balloon catheter with respect to the distal end of the guide catheter.

Similar optical markers may be located on other balloon catheters disclosed herein. For example, an optical marker may be located on a balloon catheter proximal to a balloon on the balloon catheter. Such an  
30 optical marker is especially useful to determine the location of the balloon with respect to a paranasal sinus ostium after the balloon has been introduced in a paranasal sinus. After the balloon is inserted inside the paranasal sinus, the balloon can no longer be visually seen by an endoscope. The user can then

note the location of the optical marker proximal to the balloon. This information enables the user to determine the length of the balloon that is present inside the opening. This information in turn can be used by the user to accurately position the balloon with respect to the paranasal sinus ostium to  
5 achieve optimal dilation of the paranasal sinus ostium.

The optical markers disclosed herein may be combined optical – radiopaque markers. In one embodiment, the combined optical – radiopaque marker comprises a platinum coil or marker. Preferably, the combined optical – radiopaque marker comprises a coating of a colored polymer including, but  
10 not limited to colored heat shrink polyethylene terephthalate. The length of the combined optical – radiopaque marker ranges preferably from 0.5 mm – 10 mm.

While removing a balloon catheter from the anatomy, the balloon of the balloon catheter might accidentally pull anatomical structures like the uncinata  
15 and damage the anatomical structures. To prevent such damage, in the method embodiments where a balloon catheter is introduced through a guide device, the balloon catheter may be removed from the anatomy along with the guide device. This step may be performed after ensuring that an undesirably long distal region of the balloon catheter is not protruding from the distal end  
20 of the guide device. The guide device may have a suitable attachment mechanism such as a rotating hemostasis valve, a clip, etc. to temporarily attach the balloon catheter to the guide device. The attachment mechanism enables a user to remove the balloon catheter from the anatomy along with the guide device.

25 The flexible endoscopes disclosed herein may comprise one or more endoscope lumens. In one embodiment, the endoscope lumen is a side lumen. The side lumen is designed such that one or more diagnostic, therapeutic or access devices can be inserted in the anatomy through the side lumen under endoscopic guidance.

30 The guide catheters disclosed herein may comprise a bent, curved or angled distal region to allow easier access to a paranasal sinus ostium. Such guide catheters may further comprise mechanisms to introduce an endoscope along the guide catheters. For example, Figures 14A through 14E' show side

views of embodiments of guide devices comprising bent, curved or angled distal regions and mechanisms to introduce an endoscope along the guide catheters. One or more of these guide devices may be provided as a part of the system for diagnosing or treating paranasal sinus pathologies. Figure 14A

5 shows a side view of a first embodiment of a guide device comprising a substantially straight distal portion. Guide device 1400 comprises an elongate tube 1402. Elongate tube 1402 may be made of suitable biocompatible materials such as polymers e.g. Nylon, Pebax, etc. In a preferred embodiment, the material of elongate tube 1402 has Rockwell hardness in the range of

10 about 70R to about 110R. In this preferred embodiment, the distal portion is flexible enough to prevent or reduce damage to the anatomy. Yet, the distal portion is rigid enough to retain its shape as one or more devices are passed through guide device 1400. Furthermore, the distal portion is rigid enough to enable a user to use the distal portion to displace anatomical structures. The

15 distal portion of elongate tube 1402 comprises a curved, bent or angled region curved at an angle of less than 5 degrees. In one embodiment, distal portion of elongate tube 1402 is substantially straight. The inner surface of elongate tube 1402 may be lined by a lubricious coating or a tubular lubricious liner made of a suitable biocompatible material such as PTFE. In one embodiment,

20 the outer diameter of elongate tube 1402 is around 0.134 +/- 0.005 inches. An optional dilating balloon 1403 may be located on the distal region of guide device 1400. Dilating balloon may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, etc. The distal portion of elongate tube 1402 comprises an atraumatic tip 1404. Atraumatic tip 1404

25 may be made of suitable biocompatible materials including, but not limited to Pebax, etc. Atraumatic tip 1404 prevents or reduces damage to the anatomy caused by the distal end of guide device 1400. In one embodiment, length of atraumatic tip 1404 is 0.08 +/- 0.04 inches and the material of tip 1404 has Shore Durometer hardness in the range of about 35D to about 72D. Guide

30 device 1400 further comprises a hypotube 1406. Hypotube 1406 may be made of suitable biocompatible materials such as stainless steel 304, titanium, Nickel-titanium alloy (e.g., Nitinol), polymers such as Nylon etc. In one embodiment, the outer diameter of hypotube 1406 is 0.154 +/- 0.005 inches. In one embodiment of a method of constructing guide device 1400, a

stainless steel hypotube 1406 is bonded to an elongate tube 1402 such as a Nylon elongate tube 1402 to increase the strength of elongate tube 1402. In one embodiment, hypotube 1406 is heat bonded to elongate tube 1402. One or more openings, perforations or holes may be located on hypotube 1406 to enable material of elongate tube 1402 to melt into the one or more openings, perforations or holes. When the melted material of elongate tube 1402 solidifies, an additional mechanical bonding is created between hypotube 1406 and elongate tube 1402. Guide device 1400 further comprises an endoscope introducing mechanism for introducing an endoscope EN. In the embodiment shown in Figure 14A, the endoscope introducing mechanism comprises a side lumen 1407 through which a suitable flexible endoscope EN can be introduced in the anatomy. The proximal end of guide device 1400 comprises a hub 1408. In one embodiment, hub 1408 is a female luer hub. Hub 1408 may have wings 1409 to enable a user to turn guide device 1400. In one embodiment, the axial length of guide device 1400 is 5 +/- 0.25 inches. In one embodiment, the inner diameter of guide device 1400 is around 0.1 inches. The distal portion of guide device 1400 may comprise a radiopaque marker. In one embodiment, the radiopaque marker is a platinum/iridium marker band. The guide device design shown in Figure 14A is especially suited for trans-nasal access of the sphenoid sinuses.

Figure 14B shows a side view of a first embodiment of a guide device comprising a bent, angled or curved distal portion. Guide device 1410 comprises an elongate tube 1412. Elongate tube 1412 may be made of suitable biocompatible materials such polymers e.g. Nylon, Pebax, etc. Elongate tube 1412 comprises a substantially straight proximal portion enclosed by a hypotube and a distal portion comprising a curved, bent or angled region. The angle of the curved, bent or angled region of the distal portion can range from 5 degrees to 45 degrees. In this embodiment, distal portion of elongate tube 1412 is bent by an angle of around 30 degrees. The inner surface of elongate tube 1412 may be lined by a lubricious coating or a tubular lubricious liner made of a suitable biocompatible material such as PTFE. In one embodiment, the outer diameter of elongate tube 1412 is around 0.134 +/- 0.005 inches. An optional dilating balloon 1413 may be located on the distal region of guide device 1410. Dilating balloon may be

made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, etc. The distal portion of elongate tube 1412 comprises an atraumatic tip 1414. Atraumatic tip 1414 may be made of suitable biocompatible materials including, but not limited to Pebax, etc. Atraumatic tip 1414 prevents or reduces damage to the anatomy caused by the distal end of guide device 1410. In one embodiment, length of atraumatic tip 1414 is 0.08 +/- 0.04 inches. Guide device 1410 further comprises a hypotube 1416 covering the proximal portion of elongate tube 1412. Hypotube 1416 may be made of suitable biocompatible materials such as stainless steel 304, titanium, Nickel-titanium alloy (e.g., Nitinol), polymers such as Nylon etc. In one embodiment, the outer diameter of hypotube 1416 is 0.154 +/- 0.005 inches. In one embodiment of a method of constructing guide device 1410, a stainless steel hypotube 1416 is bonded to a Nylon elongate tube 1412. Guide device 1410 further comprises an endoscope introducing mechanism for introducing an endoscope EN. In the embodiment shown in Figure 14B, the endoscope introducing mechanism comprises a side lumen 1417 through which a suitable flexible endoscope EN can be introduced in the anatomy. The proximal end of guide device 1410 comprises a hub 1418. In one embodiment, hub 1418 is a female luer hub. Hub 1418 may have wings 1419 to enable a user to turn guide device 1410. Wings 1419 may be aligned in the plane of the curve of the distal tip as an indicator of the position and orientation of the distal tip in the anatomy. In one embodiment, the axial length of guide device 1410 is 5 +/- 0.25 inches. In one embodiment, the inner diameter of guide device 1410 is around 0.1 inches. The distal portion of guide device 1410 may comprise a radiopaque marker. In one embodiment, the radiopaque marker is a platinum/iridium marker band. Figure 14B' shows an enlarged view of the distal portion of the guide device in Figure 14B. Figure 14B' shows elongated tube 1412 enclosed by hypotube 1416. Distal end of elongated tube 1412 comprises atraumatic tip 1414. Several parameters defined hereafter characterize the design of the distal portion of guide device 1410. The width of the distal end of guide device 1410 is called W as shown. The length measured from the proximal-most point on the distal curved portion of elongate tube 1412 to the distal-most part of the distal tip is called L1. L1 is measured along the linear direction of the straight proximal portion of

guide device 1410 as shown in Figure 14B'. The length of the straight region of elongate tube 1412 from the distal end of the hypotube 1416 till the proximal most point on the curved region of the distal portion is called L2. In one particular embodiment, W is 0.34 +/- 0.08 inches, L1 is 0.46 +/- 0.08 inches, 5 L2 is 0 to 2 inches and the radius of curvature of the distal curved region of elongate tube 1412 is 0.180 inches. The guide device design shown in Figures 14B and 14B' is especially suited for trans-nasal access of the sphenoid sinuses.

Figure 14C shows a side view of a second embodiment of a guide 10 device comprising a bent, angled or curved distal portion. The design of guide device 1420 is similar to the design of guide device 1410. Guide device 1420 comprises an elongate tube 1422. The distal portion of elongate tube 1422 comprises a curved, bent or angled region curved at an angle ranging from 30 degrees to 140 degrees. In this embodiment, distal portion of elongate tube 15 1422 is bent by an angle of around 70 degrees. An optional dilating balloon 1423 may be located on the distal region of guide device 1420. Dilating balloon may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, etc. The distal portion of elongate tube 1422 comprises an atraumatic tip 1424. Guide device 1420 further comprises a 20 hypotube 1426. Guide device 1420 further comprises an endoscope introducing mechanism for introducing an endoscope EN. In the embodiment shown in Figure 14C, the endoscope introducing mechanism comprises a side lumen 1427 through which a suitable flexible endoscope EN can be introduced in the anatomy. The proximal end of guide device 1420 comprises 25 a hub 1428. In one embodiment, hub 1428 is a female luer hub. Hub 1428 may have wings 1429 to enable a user to turn guide device 1420. Figure 14C' shows an enlarged view of the distal portion of the guide device in Figure 14C. Figure 14C' shows elongated tube 1422 enclosed by hypotube 1426. Distal end of elongated tube 1422 comprises atraumatic tip 1424. In one 30 particular embodiment, W is 0.45 +/- 0.08 inches, L1 is 0.32 +/- 0.08 inches, L2 is 0 to 2 inches and the radius of curvature of the distal curved region of elongate tube 1422 is 0.180 inches. The guide device design shown in Figures 14C and 14C' is especially suited for trans-nasal access of the frontal sinuses.

Figure 14D shows a side view of a second embodiment of a guide device comprising a bent, angled or curved distal portion. The design of guide device 1430 is similar to the design of guide device 1410. Guide device 1430 comprises an elongate tube 1432. The distal portion of elongate tube 1432 comprises a curved, bent or angled region curved at an angle ranging from 70 degrees to 135 degrees. In this embodiment, distal portion of elongate tube 1432 is bent by an angle of around 90 degrees. An optional dilating balloon 1433 may be located on the distal region of guide device 1430. Dilating balloon may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, etc. The distal portion of elongate tube 1432 comprises an atraumatic tip 1434. Guide device 1430 further comprises a hypotube 1436. Guide device 1430 further comprises an endoscope introducing mechanism for introducing an endoscope EN. In the embodiment shown in Figure 14D, the endoscope introducing mechanism comprises a side lumen 1437 through which a suitable flexible endoscope EN can be introduced in the anatomy. The proximal end of guide device 1430 comprises a hub 1438. In one embodiment, hub 1438 is a female luer hub. Hub 1438 may have wings 1439 to enable a user to turn guide device 1430. Figure 14D' shows an enlarged view of the distal portion of the guide device in Figure 14D. Figure 14D' shows elongated tube 1432 enclosed by hypotube 1436. Distal end of elongated tube 1432 comprises atraumatic tip 1434. In one particular embodiment, W is 0.39 +/- 0.080 inches, L1 is 0.25 +/- 0.08 inches, L2 is 0 to 2 inches and the radius of curvature of the distal curved region of elongate tube 1432 is 0.180 inches. W may be as small as 5 mm with a corresponding reduction in the radius of curvature of the distal curved region of elongate tube 1432. The guide device design shown in Figures 14D and 14D' is especially suited for trans-nasal access of the maxillary sinuses.

Figure 14E shows a side view of a third embodiment of a guide device comprising a bent, angled or curved distal portion. The design of guide device 1440 is similar to the design of guide device 1410. Guide device 1440 comprises an elongate tube 1442. The distal portion of elongate tube 1442 comprises a curved, bent or angled region curved at an angle ranging from 140 degrees to 120 degrees. In this embodiment, distal portion of elongate tube 1442 is bent by an angle of around 110 degrees. An optional dilating



balloon 1443 may be located on the distal region of guide device 1440. Dilating balloon may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, etc. The distal portion of elongate tube 1442 comprises an atraumatic tip 1444. Guide device 1440 further comprises  
5 a hypotube 1446. Guide device 1440 further comprises an endoscope introducing mechanism for introducing an endoscope EN. In the embodiment shown in Figure 14E, the endoscope introducing mechanism comprises a side lumen 1447 through which a suitable flexible endoscope EN can be introduced in the anatomy. The proximal end of guide device 1440 comprises  
10 a hub 1448. In one embodiment, hub 1448 is a female luer hub. Hub 1448 may have wings 1449 to enable a user to turn guide device 1440. Figure 14E' shows an enlarged view of the distal portion of the guide device in Figure 14E. Figure 14E' shows elongated tube 1442 enclosed by hypotube 1446. Distal end of elongated tube 1442 comprises atraumatic tip 1444. In one particular  
15 embodiment, W is 0.46 +/- 0.08 inches, L1 is 0.25 +/- 0.08 inches, L2 is 0 to 0.5 inches and the radius of curvature of the distal curved region of elongate tube 1442 is 0.180 inches. L1 and W may be smaller than 0.25 +/- 0.08 inches and 0.46 +/- 0.08 inches respectively. The guide device design shown in Figures 14E and 14E' is especially suited for trans-nasal access of the  
20 maxillary sinuses.

Figure 15A shows a cross sectional view of a first embodiment of a balloon catheter comprising a short guidewire lumen. Balloon catheter 1500 comprises a hollow, elongate shaft 1502. Elongate shaft 1502 can be made of suitable biocompatible materials including, but not limited to metals e.g.  
25 stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. The proximal end of elongate shaft 1502 is connected to a suitable inflation port 1504 such as a female luer lock. In one embodiment, balloon catheter 1500 further comprises an elongate hypotube 1506 located between elongate shaft 1502 and inflation port 1504.  
30 The distal end of elongate shaft 1504 is attached to the proximal end of a balloon 1508 such that inflation port 1504 is in fluid communication with balloon 1508. Balloon 1508 can be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyethylene, polyurethane, Pebax, etc. Balloon 1508 also encloses a guidewire shaft 1510 enclosing a

guidewire lumen 1512. The length of guidewire shaft 1510 is less than the length of elongate shaft 1502. In one embodiment, the length of guidewire shaft 1510 ranges from 5 – 12 cm. The proximal region of guidewire shaft 1512 is connected sideways to elongate shaft 1502 such that guidewire shaft 1512 is substantially parallel to elongate shaft 1502. The proximal end of guidewire shaft 1512 is located in a region proximal to balloon 1508. The distal end of guidewire lumen 1512 is located in a region distal to balloon 1508. Guidewire shaft 1512 enables balloon catheter 1500 to be introduced over a suitable guidewire into an anatomical region. In one embodiment, the length of balloon catheter 1500 from the distal end of inflation port 1504 till the distal end of guidewire shaft 1510 is around 30 cm. In one embodiment, guidewire shaft 1512 comprises a navigational marker such as a radiopaque marker band 1514. Similar navigational markers may be present on other embodiments of balloon catheters disclosed herein and in the patent applications incorporated herein by reference. In one embodiment, two navigational markers are present on the balloon catheter shaft corresponding to the proximal and distal end respectively of the working length of the balloon. In another embodiment, a navigational marker is present on the balloon shaft corresponding to the proximal end of the balloon. Such a navigational marker is especially useful to determine the position of the proximal end of the balloon relative to the distal end of an introducing catheter when the balloon catheter is introduced through the introducing catheter. The user tracks the position of the navigational marker relative to the distal end of the introducing catheter to ensure that the balloon is not inflated within the introducing catheter. Examples of such a navigational marker include, but are not limited to a radiopaque marker band for fluoroscopic visualization, a colored ring for endoscopic visualization, etc.

Figures 16-16C show a balloon catheter 1600 constructed of a first shaft 1602 having a first lumen 1604, a second shaft 1612 and third shafts such that a short lumen (e.g., a rapid exchange guidewire lumen) extends through the balloon. Balloon catheter 1600 comprises a hollow, first elongate shaft 1602. First elongate shaft 1602 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium,

Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. First elongate shaft 1602 comprises a first lumen 1604. The proximal end of elongate shaft 1602 is connected to a suitable hub such as a female luer lock 1606 which is in fluid communication with first lumen 1604. A hypotube 1608 may be provided between female luer lock 1606 and first elongate shaft 1602. The distal end of first lumen 1604 is in fluid communication with a balloon 1610 located on the distal region of first elongate shaft 1602. Thus, first lumen 1604 can be used to inflate balloon 1610. Balloon 1610 can be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyethylene, polyurethane, Pebax, etc. The distal region of first elongate shaft 1602 is enclosed by a second elongate shaft 1612. Second elongate shaft 1612 further encloses a region of a third elongate shaft 1614 comprising a lumen. The proximal end of the lumen of third elongate shaft 1614 is located proximal to balloon 1610. The distal end of the lumen of third elongate shaft 1614 is located distal to balloon 1610. In one embodiment, the length of third elongate shaft 1614 may range from 5 - 12 cm. Third elongate shaft 1614 enables balloon catheter 1600 to be introduced over a suitable guidewire GW into an anatomical region. Third elongate shaft 1614 may further comprise a navigational marker such as a radiopaque marker band 1616 made of suitable radiopaque materials such as platinum-iridium alloys, etc. In one embodiment, the length of balloon catheter 1600 from the proximal end of female luer lock 1606 till the distal end of third elongate shaft 1614 is around 30 cm.

Figure 16A is a cross sectional view through line 16A-16A of Figure 16. Figure 16A shows a cross sectional view of elongate shaft 1602 comprising first lumen 1604. Figure 16B is a cross sectional view through line 16B-16B of Figure 16. Figure 16B shows second elongate shaft 1612 enclosing first elongate shaft 1602 and third elongate shaft 1614. Figure 16C is a cross sectional view through line 16C-16C of Figure 16. Figure 16C shows second elongate shaft 1612 enclosing third elongate shaft 1614.

Figure 17 shows a balloon catheter 1700 that comprises an elongate shaft 1702 having a mandrel 1712 positioned therein. The elongate shaft

1702 may be made of suitable biocompatible materials including, but not limited to polyethylene, Pebax, Nylon, etc. Elongate shaft 1702 encloses a lumen. The proximal end of elongate shaft 1702 comprises a suitable hub 1704. In one embodiment, hub 1704 is a female luer lock. A strain relief tubing 5 1706 may be present between hub 1704 and elongate shaft 1702. The distal region of elongate shaft 1702 comprises a balloon 1708. Balloon 1708 may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyethylene, polyurethane, Pebax, etc. The region of elongate shaft 1702 enclosed by balloon 1708 comprises an opening 1710 that 10 provides fluid communication between the lumen of elongate shaft 1702 and balloon 1708. The lumen of elongate shaft 1702 can thus be used to inflate balloon 1708. Elongate shaft 1702 may further comprise a navigational marker such as a radiopaque marker band 1711 located on the distal region of elongate shaft 1702. A mandrel 1712 is located in lumen 1703 such that a 15 distal region of mandrel 1712 emerges out of the distal end of elongate shaft 1702. The distal end of elongate shaft 1702 is connected to mandrel 1712 by a fluid-tight seal. Figure 17A shows a cross sectional view of balloon catheter 1700 of Figure 17 through plane 17A-17A. Figure 17A shows elongate shaft 1702 enclosing a lumen and mandrel 1712 located in the lumen.

20 Figure 17B shows an enlarged perspective view of the mandrel in Figure 8F. Mandrel 1712 comprises a proximal region 1714, a tapering region 1716, a distal region 1718 and a distal tip 1720. Proximal region 1714 may have an outer diameter ranging from 0.005 inches to 0.12 inches. Distal tip 1720 emerges out of the distal end of elongate shaft 1702 and can be used to 25 navigate balloon catheter 1700 through the anatomy or to insert balloon catheter 1700 through an anatomical opening or passageway. Distal tip 1720 further comprises a coil 1722 coiled around a region of or around the entire length of distal tip 1720. Coil 1722 can be made of suitable materials including, but not limited to platinum, stainless steel, nickel-titanium alloys 30 such as Nitinol, etc. In a particular embodiment, the distance from the proximal end of tapering region 1716 to the distal end of distal region 1718 ranges from 2 to 6 cm and the length of distal tip ranges from 1 to 3 cm. Mandrel 1712 may be made of suitable biocompatible materials including, but not limited to stainless steel, Nickel-titanium alloy (e.g., Nitinol), etc.

Figure 18 shows a balloon catheter 1800 comprising a shaft 1802 having a lumen 1804 with a side slit 1809 and a balloon 1810 or other expandable dilator. Elongate shaft 1802 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. In the particular example shown, the elongate shaft 1802 comprises a first lumen 1804 useable as a guidewire lumen and a second lumen 1806 useable to inflate the balloon 1810. The proximal end of first lumen 1804 may be occluded proximal to a slit 1809. The proximal region of elongate shaft 1802 may be connected to a hub 1808 which is in fluid communication with second lumen 1806. In this example, hub 1808 is a female luer lock. The slit 1809 extends along one side of the shaft 1802 proximal to the balloon 1810 and allows a guidewire to be pulled laterally out of the first lumen 1804 and through the slit 1809. This enables balloon catheter 1800 to be advanced or withdrawn over a suitable elongate devices such as a guidewire such that a portion of the suitable elongate device enters balloon catheter 1800 from the distal end of first lumen 1804 and exits out of balloon catheter 1800 through slit 1807. A balloon 1810 is located on the distal region of elongate shaft 1802. Balloon 1810 may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyethylene, polyurethane, Pebax, etc. A navigational marker 1812 such as a radiopaque marker band may be located on the region of elongate shaft 1802 enclosed by balloon 1810. The distal end of first lumen 1804 terminates in a region distal to balloon 1810. The distal end of second lumen 1806 is in fluid communication with balloon 1810 such that second lumen 1806 can be used to inflate or deflate balloon 1810. Figure 18A shows a cross sectional view of the balloon catheter in Figure 18 through the plane 18A – 18A. Figure 18A shows a cross section of elongate sheath 1802 showing first lumen 1804, second lumen 1806 and slit 1807. Figure 18B shows a cross sectional view of the balloon catheter in Figure 18 through the plane 18B – 18B. Figure 18B shows a cross section of elongate sheath 1802 showing first lumen 1804.

Figures 19-19C show a catheter device 1900 comprising an elongate catheter shaft 1902, a balloon 1906 or other expandable dilator mounted on

elongate shaft 1902 and apparatus such as capacitance plates 1908, 1910 located on opposite sides of the balloon or other dilator for determining its diameter. In the example shown, the elongate shaft 1902 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. Elongate shaft 1902 may comprise a guidewire lumen 1904 to enable balloon catheter 1900 to be advanced or withdrawn over a suitable guidewire. The distal region of balloon catheter 1900 comprises a balloon 1906 made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyurethane, etc. Balloon 1906 may be inflated or deflated by introducing or withdrawing fluid through a balloon inflation lumen present in elongate shaft 1902. Balloon 1906 further comprises a first capacitance plate 1908 and a second capacitance plate 1910. First capacitance plate 1908 and second capacitance plate 1910 may be made of suitable biocompatible metals sheets. First capacitance plate 1908 and second capacitance plate 1910 are electrically insulated from balloon 1906 and the fluid used to inflate balloon 1906. First capacitance plate 1908 is connected by a first insulated wire 1912 to a source of electrical supply. Second capacitance plate 1910 is connected by a second insulated wire 1914 to the source of electrical supply such that an electric field is generated between first capacitance plate 1908 and second capacitance plate 1910. This causes balloon 1906 to behave like a capacitor with a capacitance depending on various properties such as distance between first capacitance plate 1908 and second capacitance plate 1910, type of inflation fluid, size of first capacitance plate 1908 and second capacitance plate 1910, etc. As balloon 1906 is inflated or deflated, the distance between first capacitance plate 1908 and second capacitance plate 1910 changes. This in turn changes the capacitance. The change in capacitance can be measured through first insulated wire 1912 and second insulated wire 1914 to non-invasively measure the degree of inflation of balloon 1906. Using this method, the degree of inflation of balloon 1906 may be measured without the use of ionizing radiation. First insulated wire 1912 and second insulated wire 1914 may be further insulated from the surroundings by a layer of insulating covering 1916. Insulating covering 1916 covers first insulated wire 1912,

second insulated wire 1914 and elongate shaft 1902. Figure 19A shows a side view of the balloon catheter in Figure 19. Figure 19A shows balloon catheter 1900 comprising elongate shaft 1902, balloon 1906, first capacitance plate 1908 and first insulated wire 1912 connected to first capacitance plate 1908. Figures 19B and 19C show cross sectional views of the balloon catheter in Figure 19 through planes 19B-19B and 19C-19C respectively. Figure 19B shows a cross section of shaft 1902 comprising guidewire lumen 1904 and a balloon inflation lumen 1918. In this embodiment, balloon inflation lumen 1918 is annular and is coaxial to guidewire lumen 1904. Shaft 1902 further comprises first insulated wire 1912 and second insulated wire 1914 covered by insulating covering 1916. Figure 19C shows a cross section through balloon 1906 showing shaft 1902 enclosing guidewire lumen 1904. Also shown are first capacitance plate 1908 and second capacitance plate 1910 located on balloon 1906.

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Figures 20-20C show a balloon catheter 2000 comprising an elongate catheter shaft 2002, a balloon 2006 or other expandable dilator mounted on the catheter shaft 2002 and apparatus for determining the diameter of the balloon 2006, such as capacitance plates 2008, 2010, one of which is located on the wall of the balloon 2006 and the other of which is located on a portion of the catheter shaft 2016 that extends through the balloon 2006. The elongate shaft 2002 can be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. Elongate shaft 2002 may comprise a guidewire lumen 2004 to enable balloon catheter 2000 to be advanced or withdrawn over a suitable guidewire. Balloon 2006 made of suitable biocompatible materials including, but not limited to PET, Nylon, PVC, polyethylene, polyurethane, Pebax, etc. Balloon 2006 may be inflated or deflated by introducing or withdrawing fluid through a balloon inflation lumen present in elongate shaft 2002. First capacitance plate 2008 and second capacitance plate 2010 are electrically insulated from balloon 2006 and the fluid used to inflate balloon 2006. First capacitance plate 2008 is connected by a first insulated wire 2012

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to a source of electrical supply. Second capacitance plate 2010 connected by a second insulated wire 2014 to the source of electrical supply such that an electric field is generated between first capacitance plate 2008 and second capacitance plate 2010. This causes balloon 2006 to behave like a capacitor with a capacitance depending on various properties such as distance between first capacitance plate 2008 and second capacitance plate 2010, type of inflation fluid, size of first capacitance plate 2008 and second capacitance plate 2010, etc. As balloon 2006 is inflated or deflated, the distance between first capacitance plate 2008 and second capacitance plate 2010 changes. This in turn changes the capacitance. The change in capacitance can be measured through first insulated wire 2012 and second insulated wire 2014 to non-invasively measure the degree of inflation of balloon 2006. Using this method, the degree of inflation of balloon 2006 may be measured without the use of ionizing radiation. First insulated wire 2012 and second insulated wire 2014 may be further insulated from the surroundings by a layer of insulating covering 2016. Insulating covering 2016 covers first insulated wire 2012, second insulated wire 2014 and elongate shaft 2002. Figure 20A shows a side view of the balloon catheter in Figure 20. Figure 20A shows balloon catheter 2000 comprising elongate shaft 2002, balloon 2006, first capacitance plate 2008 and first insulated wire 2012 connected to first capacitance plate 2008. Figures 20B and 20C show cross sectional views of the balloon catheter in Figure 20A through planes 20B-20B and 20C-20C respectively. Figure 20B shows a cross section of shaft 2002 comprising guidewire lumen 2004 and a balloon inflation lumen 2018. In this embodiment, balloon inflation lumen 2018 is annular and is coaxial to guidewire lumen 2004. Shaft 2002 further comprises first insulated wire 2012 and second insulated wire 2014 covered by insulating covering 2016. Figure 20C shows a cross section through balloon 2006 showing shaft 2002 enclosing guidewire lumen 2004. Also shows are first capacitance plate 2008 and second capacitance plate 2010 located on balloon 2006.

In an alternate embodiment, a balloon catheter comprises a first capacitance plate located on or within the balloon material; a second capacitance plate located on or within the balloon material and one or more shaft plates located on or within the balloon shaft. A user measures a first



capacitance between the first capacitance plate and the one or more shaft plates. Also, the user measures a second capacitance between the second capacitance plate and the one or more shaft plates. The first capacitance and the second capacitance may be used to measure the degree of balloon inflation and also to measure the evenness of balloon inflation.

Any of the balloon catheters comprising capacitance measuring means disclosed herein may comprise a temperature sensor to measure the temperature of the inflation fluid. This is useful in cases where the dielectric constant of the inflation fluid varies significantly with temperature.

Figure 21 shows a balloon catheter 2100 having a proximal shaft 2104, a malleable distal shaft 2102, an expandable dilator such as a balloon 2106 and, optionally, a distal guide projection such as a wire 2108. This balloon catheter device is useable for a variety of applications including, but not limited to the diagnosis and treatment of certain Ethmoid sinus pathologies. The malleable distal region 2102 may be made of suitable biocompatible materials including, but not limited to stainless steel, Nickel-titanium alloy (e.g., Nitinol), polymer/metal composites, etc. Malleable distal region 2102 may be deformed or shaped by a user during a procedure to allow for easier access and navigation through a target anatomy. The proximal region of the catheter shaft may comprise a substantially non-malleable proximal region 2104. Malleable distal region 2102 comprises a balloon 2106. Balloon 2106 may be made of suitable biocompatible materials including, but not limited to PET, Nylon, PE etc. The length of balloon 2106 ranges from 3 to 40 mm and the inflated diameter of balloon 2106 ranges from 3 to 10 mm. In one embodiment adapted to treat Ethmoid sinuses, the length of balloon 2106 ranges from 3 to 10 mm and the inflated diameter of balloon 2106 ranges from 3 to 6 mm. Balloon catheter 2100 further comprises a navigation mechanism. In one embodiment, the navigation mechanism comprises a length of wire 2108 fixed to the distal end of balloon catheter 2100. The length of wire 2108 may range from 1 to 3 cm. In an alternate embodiment, the navigation mechanism is a rapid exchange lumen through the catheter shaft. In one embodiment, the length of rapid exchange lumen is more than half the total catheter length. For example, in a balloon catheter of total length around 20 cm, the length of the rapid exchange lumen may be about 10 cm.

In a balloon catheter of total length around 15 cm, the length of the rapid exchange lumen may be about 13.5 to 10 cm. In an alternate embodiment, the navigation mechanism is an end-to-end lumen through the catheter shaft to allow balloon catheter 2100 to be introduced over a guidewire.

5           Figure 22 shows balloon catheter 2200 having a proximal shaft 2202, a flexible distal shaft 2204, an expandable dilator such as a balloon 2206 and, optionally, a distal guide projection such as a wire 2208. This balloon catheter device 2200 is useable to perform a variety of diagnostic or therapeutic procedures, some of which are disclosed herein. Such a balloon catheter design comprising a flexible distal shaft is especially suitable for diagnosing or  
10           treating pathologies including, but not limited to Ethmoid sinus pathologies. The proximal region 2202 of this catheter is substantially stiff and the distal region 2204 is more flexible than the proximal region 2202. Flexible distal region 2204 may be made of suitable biocompatible materials including, but  
15           not limited to Nylon, Pebax, HDPE, LDPE, Polyimide, polymer/metal composites, braided materials, etc. Flexible distal region 2204 is deformed during a procedure to allow for easier access and navigation through a target anatomy. Flexible distal region 2204 comprises a balloon 2206. Balloon 2206 may be made of suitable biocompatible materials including, but not limited to  
20           PET, Nylon, PE etc. The length of balloon 2206 ranges from 3 to 40 mm and the inflated diameter of balloon 2206 ranges from 3 to 10 mm. In one embodiment adapted to treat Ethmoid sinuses, the length of balloon 2206 ranges from 3 to 10 mm and the inflated diameter of balloon 2206 ranges from 3 to 6 mm. Balloon catheter 2200 further comprises a navigation  
25           mechanism. In one embodiment, the navigation mechanism comprises a length of wire 2208 fixed to the distal end of balloon catheter 2200. The length of wire 2208 may range from 1 to 3 cm. In an alternate embodiment, the navigation mechanism is a rapid exchange lumen through the catheter shaft. The length of the rapid exchange lumen may range from 1 cm to 15  
30           cm. In one embodiment, the length of rapid exchange lumen is more than half the total catheter length. For example, in a balloon catheter of total length around 20 cm, the length of the rapid exchange lumen may be about 10 cm. In a balloon catheter of total length around 15 cm, the length of the rapid exchange lumen may be about 13.5 to 10 cm. In an alternate embodiment,

the navigation mechanism is an end-to-end lumen through the catheter shaft to allow balloon catheter 2200 to be introduced over a guidewire.

The balloon catheters disclosed herein and in the patent applications incorporated herein by reference may comprise a balloon of a working length adapted for dilating a particular region of the anatomy. For example, a balloon catheter comprising a balloon of working length ranging from 10 – 40 mm may be used for treating a disease of the frontal sinuses. Ideally, the balloon comprises a working length ranging from 20 – 30 mm. The inflated diameter of such balloons may range from 4 – 10 mm. In another example, a balloon catheter comprising a balloon of working length ranging from 6 – 10 mm may be used for treating a disease of the maxillary sinuses. In another example, a balloon catheter comprising a balloon of working length ranging from 3 – 10 mm may be used for dilating the Ethmoid sinuses.

The shafts of the balloon catheters disclosed herein and in the patent applications incorporated herein by reference may comprise one or more angled regions. Such balloon catheters may for example comprise an angled balloon located on an angled region of the shaft. Such balloon catheters are especially suited for treating diseases of the maxillary sinuses.

The balloon catheters disclosed herein and in the patent applications incorporated herein by reference may comprise a substantially compliant balloon. Such a substantially compliant balloon may be inflated at an inflation pressure preferably less than 4 atmospheres. Such balloon catheter may be used for example to dilate the mucosa of anatomical regions such as passageways leading to paranasal sinuses. The step of dilation of the mucosa may or may not include dilation of the underlying bony structures. Such balloon catheters may also be used for sizing anatomical regions such as passageways leading to paranasal sinuses. This is performed by inflating the substantially compliant balloon by a fluid comprising radiopaque contrast and observing the radiographic image of the balloon. The step of sizing an anatomical region may be performed before and/or after the step of dilating the anatomical region.

The balloon catheters disclosed herein and in the patent applications incorporated herein by reference may be introduced in the anatomy by a variety of manual introducing tools. Examples of such manual introducing

tools include, but are not limited to forceps (e.g. giraffe forceps), pincers, tweezers, tongs, etc. Such manual introducing tools may have curved, bent, angled or substantially straight distal regions. For example, a balloon catheter may be grasped in a region proximal to the balloon by a forceps and then  
5 introduced in the target anatomy.

The balloon catheters disclosed herein and in the patent applications incorporated herein by reference may be used to deliver heat or cold, a gas, electromagnetic energy in the visible spectrum, etc.

10 If a balloon catheter is used for performing multiple procedures, it may be useful to refold the balloon of the balloon catheter after each procedure to lower the profile of the balloon before the next procedure.

Figures 23-23D show a balloon folding tool 2300 useable to facilitate folding of a balloon 2308 mounted on a balloon catheter 2306. The balloon folding tool 2300 comprises a rigid body having a central bore or folding channel 2302 formed therein, such folding channel 2306 having a diameter that is less than the fully inflated balloon diameter. A plurality of side channels or parallel channels 2304 are located adjacent to and substantially parallel with the central bore or folding channel 2302 and are connected to the central  
15 bore or folding channel 2302 through slots or elongate openings. The balloon 2308 is insertable into the central bore or folding channel 2302 while in a less than fully inflated state and, thereafter, may be fully or partially inflated to cause separate portions of the balloon 2308 to pass through the each slot and into each side channel 2304 as seen in Figure 23C. Thereafter, the balloon  
20 may be deflated such that each separate portion of the balloon that has passed into each side channel will form a separate wing of the deflated balloon 2308, as seen in Figure 23D. The wings are thereafter foldable (e.g., to a creased, wrapped or furled state) to provide a collapsed balloon shape. The number of side or parallel channels 2304 and the resultant number of  
25 wings formed in the deflated balloon 2308 may vary depending of the size of the balloon 2308 and the manner in which it is intended to fold or furl the balloon. In some embodiments, about 2-6 side channels 2304 will be used, providing about 2-6 wings on the deflated balloon 2308.  
30

The elongate body of the folding tool 2300 may be made of suitable biocompatible materials including, but not limited to metals e.g. titanium, stainless steel, etc.; polymers e.g. PVC, Nylon, DELRIN®, Polycarbonate, ABS, etc. Folding tool 2300 further comprises a balloon folding channel 2302.

5 In one embodiment, the cross section of balloon folding channel 2302 is substantially uniform along the length of folding tool 2300. In another embodiment, the cross sectional size of balloon folding channel 2302 is larger at the proximal end of folding tool 2300. In this embodiment, the cross sectional size of balloon folding channel 2302 gradually reduces towards the

10 distal end of folding tool 2300 to facilitate loading a balloon catheter in balloon folding channel 2302. In one embodiment, balloon folding channel 2302 extends through the entire length of the elongate body. In another embodiment, balloon folding channel 2302 extends through a part of the length of the elongate body. Folding tool 2300 further comprises one or more

15 parallel channels 2304. Parallel channels 2304 are aligned substantially parallel to balloon folding channel 2302 and overlap lengthwise to balloon folding channel 2302 as shown in Figure 23. Figure 23A shows a perspective view of a balloon catheter 2306 comprising a balloon 2308 being introduced into folding tool 2300.

20 Figures 23B and 23C show an end view of the folding tool of Figure 23 showing the steps of an embodiment of a method of folding the balloon of a balloon catheter. Figure 23D shows a cross sectional view through a folded balloon 2308. In Figure 23B, balloon catheter 2306 is introduced into balloon folding channel 2302. Thereafter, in Figure 23C, balloon 2308 is partially

25 inflated such that regions of balloon 2308 extend in parallel channels 2304. Thereafter, balloon 2308 is deflated and a vacuum is created in balloon 2308. This creates one or more ridges in balloon 2308. Thereafter, folding tool 2308 is turned to obtain one or more folds in balloon 2308. Thereafter, balloon 2308 is pulled out of folding tool 2300 to obtain a folded balloon as shown in

30 Figure 23D. Such a folded balloon may thereafter be introduced in a small diameter tube to further reduce the profile of the balloon.

In an alternate method of folding balloon 2308, balloon catheter 2306 is introduced into balloon folding channel 2302. Thereafter, balloon 2308 is partially inflated such that regions of balloon 2308 extend in parallel channels

2304. Thereafter, balloon 2308 is deflated and a vacuum is created in balloon 2308. This causes one or more ridges to be created in balloon 2308. Thereafter, balloon 2308 is pulled out of folding tool 2300. Balloon 2308 is then folded manually to obtain a folded balloon with a low profile.

5 Similarly, other folding tools comprising one or more folding channels, folding grooves, folding cavities, folding slits, etc. may be used for folding one or more balloons of the balloon catheters disclosed herein.

Figure 24 shows a balloon compressing apparatus 2400 that is useable to facilitate folding of a balloon 2308 mounted on a catheter. This balloon  
10 compressing apparatus 2400 generally comprises a clamping element 2404 having a plurality of compression members 2416 disposed radially about a central cavity 2417. The compression members 2416 are spaced apart from each other such that gaps exist between adjacent compression members 2416. The compression members 2416 are moveable from non-compressing  
15 positions where the central cavity had a first diameter to compressing positions where the central cavity has a second diameter that is smaller than the first diameter. The balloon 2308 is insertable into the central cavity 2417 while the compression members are in their non-compressing positions and, thereafter, the compression members are moveable to their compressing  
20 positions, thereby compressing portions of the balloon 2308 and causing any inflation fluid to be forced out of the balloon and causing portions of the balloon to protrude outwardly into the gaps between the compression members. Such protrusion into the gaps between compression members 2416 forms a plurality of wings on the deflated balloon 2308. The wings are  
25 thereafter foldable (e.g., to a creased, wrapped or furled state) to provide a collapsed balloon shape. The number of gaps and the resultant number of wings formed in the deflated balloon 2306 may vary depending of the size of the balloon 2308 and the manner in which it is intended to fold or furl the balloon. In some embodiments, about 2-6 side gaps will be used, providing  
30 about 2-6 wings on the deflated balloon 2308.

In the particular example shown in the figures, folding tool 2400 comprises a screw cap 2402 that encloses a clamping element 2404. The distal end of clamping element 2404 and the distal end of screw cap 2402 are

in contact with a distal handle 2406. Clamping element 2404, screw cap 2402 and distal handle 2406 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, etc.; polymers e.g. PVC, Polycarbonate, Delrin®, Nylon, ABS, etc. Figure 24A shows an exploded view of the various components of the balloon folding tool of Figure 24. Distal handle 2406 comprises an elongate body comprising screw threads 2408 located on the proximal end of the elongate body. Distal handle 2406 may comprise a lumen 2410. The outer surface of distal handle 2406 may be roughened to increase the grip of a user on distal handle 2406. In one embodiment, outer surface of distal handle 2406 is roughened by knurling. Screw cap 2402 comprises a lumen 2412. The inner surface of screw cap 2402 comprises screw threads that screw over screw threads 2408 of distal handle 2406. The outer surface of screw cap 2402 may be roughened to increase the grip of a user on screw cap 2402. In one embodiment, outer surface of screw cap 2402 is roughened by knurling. Clamping element 2404 is enclosed by screw cap 2402 and distal handle 2406. Clamping element 2404 comprises a distal body 2414. The proximal end of distal body is connected to two or more clamping arms 2416. One or more gaps are located between two or more clamping arms 2416. Clamping arms 2416 enclose a central cavity 2417 that is substantially collinear with lumen 2412 of screw cap 2402. The proximal ends of clamping arms 2416 comprise a tapered region 2418. Tightening screw cap 2402 over distal handle 2406 causes a region of screw cap 2402 to slide over tapered region 2418. This in turn displaces the proximal regions of clamping arms 2416 in a radially inward direction. Thus, clamping arms 2416 can clamp on a device located in the hollow region that is enclosed by clamping arms 2416. Similarly, loosening screw cap 2402 over distal handle 2406 causes clamping arms 2416 to release a device located in the hollow region that is enclosed by clamping arms 2416. In one embodiment of a method of folding a balloon of a balloon catheter, an uninflated balloon is inserted in the hollow region that is enclosed by clamping arms 2416. Thereafter, the balloon is partially inflated such that portions of the balloon enter one or more gaps located between two or more clamping arms 2416. Thereafter, screw cap 2402 is tightened over distal handle 2406. Thereafter, the balloon is deflated. Simultaneously, folding

tool 2400 is rotated to create one or more folds in the balloon.

Folding tool 2300 and folding tool 2400 may comprise a centering element to align the shaft of a balloon catheter with the central axis of the folding tools. In one embodiment, the centering element comprises a centering wire attached to the folding tool. The shaft of the balloon catheter slides over the centering wire. This aligns the shaft of the balloon catheter with the central axis of the folding tool.

Figure 25 shows a catheter 2500 that is useable for simultaneous irrigation and aspiration. This catheter 2500 comprises an inner tube 2502 enclosing an inner lumen 2504. Inner tube 2502 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. The proximal end of inner tube 2502 comprises a suitable hub such as a female luer lock 2505. Inner tube 2502 is surrounded by an outer tube 2506. Outer tube 2506 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, Nickel-titanium alloy (e.g., Nitinol), etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. In one embodiment, inner tube 2502 has an inner diameter of 0.040 inches and an outer diameter of 0.050 inches and outer tube 2506 has an inner diameter of 0.080 inches and an outer diameter of 0.092 inches. The distal end of outer tube 2506 is attached to inner tube 2502 to create a fluid-tight distal seal 2508. The region between outer tube 2506 and inner tube 2502 encloses an outer lumen 2510. The distal region of outer tube 2506 comprises one or more openings or perforations 2512 that are in fluid communication with outer lumen 2510. The proximal end of outer tube 2506 is enclosed by a Y-connector 2514 as shown in Figure 25. A side arm of Y-connector 2514 is in fluid communication with outer lumen 2510. The proximal end of the side arm comprises a hub 2516 such as a luer lock. Y-connector 2514 is attached to female luer lock 2505 to create a fluid-tight proximal seal 2518. In one embodiment, catheter 2500 further comprises a hypotube surrounding outer tube 2506. Catheter 2500 may be used to simultaneously introduce fluids into and suction fluids out of a target anatomy such as a paranasal sinus, openings or passageways leading to a paranasal sinus, etc. In one method embodiment, outer lumen 2510 is used to introduce



one or more fluids into the target anatomy. Inner lumen 2504 is used to suction out one or more fluids from the target anatomy. In another embodiment, inner lumen 2504 is used to introduce one or more fluids into the target anatomy. Outer lumen 2510 is used to suction out one or more fluids  
5 from the target anatomy. In this embodiment, one or more openings or perforations 2512 may be made larger to prevent blockage by materials being suctioned into outer lumen 2510.

Image guided surgery (IGS) procedures (sometimes referred to as “computer assisted surgery”) were first developed for use in neurosurgery and  
10 have now been adapted for use in certain ENT surgeries, including sinus surgeries. See, Kingdom T.T., Orlandi R.R., *Image-Guided Surgery of the Sinuses: Current Technology and Applications*, Otolaryngol. Clin. North Am. 37(2):381-400 (April 2004). Generally speaking, in a typical IGS procedure, a digital tomographic scan (e.g., a CT or MRI scan) of the operative field (e.g.,  
15 the nasal cavities and paranasal sinuses) is obtained prior to surgery. A specially programmed computer is then used to convert the digital tomographic scan data into a digital map. During surgery, sensors mounted on the surgical instruments send data to the computer indicating the position of each surgical instrument. The computer correlates the data received from  
20 the instrument-mounted sensors with the digital map that was created from the preoperative tomographic scan. One or more image(s) is/are then displayed on a monitor showing the tomographic scan along with an indicator (e.g., cross hairs or an illuminated dot) of the real time position of each surgical instrument. In this manner, the surgeon is able to view the precise  
25 position of each sensor-equipped instrument relative to the surrounding anatomical structures shown on the tomographic scan. Various embodiments of adapter devices comprising image guidance sensors are disclosed herein. Such adapter devices are adapted to be fitted to one or more devices that are being introduced in the anatomy. This enables a user to view the real time  
30 position of the one or more devices that are being introduced in the anatomy. For example, Figures 26-26B show a navigation adapter adapter that may be attached to the proximal end of a catheter, seeker, cannula, or any other device to facilitate mounting of navigation unit (e.g., a navigation module, localizer or other apparatus such as sensor(s), emitter(s), transmitter(s),

reflector(s), etc. that are useable in conjunction with a navigation system. The particular navigation apparatus may be selected from the various navigation apparatus disclosed herein or in one of the patent applications incorporated herein by reference. In the example of Figure 26, the navigation adapter 2600  
5 comprises an elongate body 2602 comprising a lumen. Elongate body 2602 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. The outer surface of elongate body 2602 may be roughened. The distal end of elongate body 2602 comprises a first hub 2604.  
10 In one embodiment, first hub 2604 is a male luer lock. The proximal end of elongate body 2602 comprises a second hub 2606. In one embodiment, second hub 2606 is a female luer lock. Navigation adapter 2600 further comprises a tracking system for image guided surgery. Navigation adapter 2600 is adapted to be fixed to a device being introduced in the anatomy. The  
15 position of the device can then be tracked using the tracking system located on navigation adapter 2600. Thus, suitable rigid catheters or guide devices may be tracked using existing tracking systems. Similarly, suitable devices with malleable regions may also be tracked using existing tracking systems. The outer surface of elongate body 2602 may be roughened to increase the  
20 grip of a user on navigation adapter 2600. In one embodiment, outer surface of elongate body 2602 is roughened by knurling.

Figure 26A shows a perspective view of an embodiment of a navigation adapter comprising an optical navigation unit. Navigation adapter 2610  
25 comprises an elongate body 2612 comprising a lumen. Elongate body 2612 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, nickel-titanium alloys such as Nitinol, etc.; polymers e.g. Pebax, PEEK polyimide, etc.; composites, etc. The distal end of elongate body 2612 comprises a first hub 2614. In one embodiment, first hub 2614 is a male luer lock. The proximal end of elongate body 2612  
30 comprises a second hub 2616. In one embodiment, second hub 2616 is a female luer lock. Navigation adapter 2610 further comprises a navigation unit 2618 for image guided surgery. In one embodiment, navigation unit 2618 is an optical navigation unit. One example of such an optical navigation unit is a BrainLAB surgical instrument adapter. Navigation unit 2618 comprises an

attachment region 2620. One end of attachment region 2620 is connected to a series of arms 2622 that extend radially outward from the axis of attachment region 2620. The outer ends of arms 2622 comprise one or more optical energy emitters 2624 that emit optical energy. In one embodiment, optical energy emitters 2624 comprise infrared light emitting LEDs. In another embodiment, optical energy emitters 2624 comprise a reflecting surface that reflects externally generated optical energy reaching the surface of optical energy emitters 2624. A camera is positioned such that it receives the optical energy emitted from optical energy emitters 2624. The camera is then used to track the position and orientation of navigation adapter 2610. Other examples of navigation unit 2618 include, but are not limited to navigation units comprising reflective passive elements, light emitting diodes, transmitters or receivers of energy (e.g. optical energy, radiofrequency energy, etc.), a combination of two or more of the abovementioned navigation technologies, etc. Navigation adapter 2610 is adapted to be fixed to a diagnostic, therapeutic or access device 2626 being introduced in the anatomy. Device 2626 may comprise a curved, angled or bent distal end 2628. The position of the device can then be tracked using the navigation unit 2618 located on navigation adapter 2610. Thus, suitable rigid catheters or guide devices may be tracked using existing image guidance systems. One example of an optical image guidance system that is useable in ENT and sinus surgery is the LandmarX Evolution<sup>®</sup> ENT II Image Guidance System available from Medtronic Xomed Surgical Products, Inc., Jacksonville, Florida. The outer surface of elongate body 2612 may be roughened to increase the grip of a user on navigation adapter 2610. In one embodiment, outer surface of elongate body 2612 is roughened by knurling. In one method embodiment, a surgical navigation modality is attached to a rigid device disclosed herein, and the position and orientation of the distal tip of the rigid device is calibrated to the position and orientation of the imaging modality. Thereafter, the rigid device is used to perform a diagnostic, therapeutic or access procedure. If the position or orientation of the rigid device changes with respect to the position or orientation of the surgical navigation modality, the position and orientation of the distal tip of the rigid device may be re-calibrated to the position and orientation of the imaging modality. Such a re-calibration may be

necessary for example when a user bends or shapes the distal tip of a rigid device comprising a malleable or shapeable distal tip.

Figure 26B shows a perspective view of an embodiment of a navigation adapter comprising an electromagnetic navigation unit. In image guidance systems that employ electromagnetic sensors/tracking systems, radiofrequency electromagnetic sensors (e.g., electromagnetic coils) are placed on the surgical instruments and on a localizer frame worn by the patient. A transmitter is positioned near the operative field. The transmitter transmits signals that are received by the instrument-mounted sensors. The tracking system detects variations in the electromagnetic field caused by the movement of the instrument-mounted sensors relative to the transmitter. Examples of commercially available electromagnetic IGS systems that have been used in ENT and sinus surgery include the ENTrak Plus™ and InstaTrak ENT™ systems available from GE Medical Systems, Salt Lake City, Utah. Other examples of electromagnetic image guidance systems that may be modified for use in accordance with the present invention include but are not limited to those available from Surgical Navigation Technologies, Inc., Louisville, Colorado, Biosense-Webster, Inc., Diamond Bar, California and Calypso Medical Technologies, Inc., Seattle, Washington. Navigation adapter 2630 comprises an elongate body 2632 comprising a lumen. Elongate body 2632 may be made of suitable biocompatible materials including, but not limited to metals e.g. stainless steel, titanium, etc.; polymers e.g. Nylon, Pebax, PEEK, polyethylene, etc. The distal end of elongate body 2632 comprises a first hub 2634. In one embodiment, first hub 2634 is a male luer lock. The proximal end of elongate body 2632 comprises a second hub 2636. In one embodiment, second hub 2636 is a female luer lock. Navigation adapter 2630 further comprises a radiofrequency electromagnetic sensor 2638 for image guided surgery. Radiofrequency electromagnetic sensor 2638 is attached to elongate body 2632 by an attachment region 2640. In one embodiment, radiofrequency electromagnetic sensor 2638 is attached to an electrical cord 2642 to transmit data from radiofrequency electromagnetic sensor 2638 to an electromagnetic image guidance system. Navigation adapter 2630 is adapted to be fixed to a diagnostic, therapeutic or access device 2644 being introduced in the anatomy. Device 2644 may comprise a

shapeable or malleable distal tip 2646. The position of the device can then be tracked using radiofrequency electromagnetic sensor 2638 located on navigation adapter 2630. Thus, suitable rigid catheters or guide devices may be tracked using existing image guidance systems. The outer surface of elongate body 2632 may be roughened to increase the grip of a user on navigation adapter 2630. In one embodiment, outer surface of elongate body 2632 is roughened by knurling.

Similar navigation adapters can be designed wherein electromagnetic sensor 2638 is replaced by other surgical navigation units. Examples of such surgical navigation units include, but are not limited to navigation units comprising reflective passive elements, light emitting diodes, transmitters or receivers of energy (e.g. optical energy, radiofrequency energy, etc.), a combination of two or more of the abovementioned navigation technologies, etc.

One or more of the devices disclosed herein may comprise a magnetic navigation element located at the distal region of the devices. Such a magnetic navigation element may comprise a permanent magnet or an electromagnet. The distal region of the devices can then be navigated through the anatomy by providing a magnetic field of specified direction and magnitude, positioned externally to the patient.

Figures 27A and 27B show top and side views respectively of a surgical hand tool comprising a balloon catheter. Figure 27A shows a surgical hand tool 2700 comprising a hollow proximal body 2702 made of biocompatible materials including, but not limited to ABS, nylon, polyurethane, polyethylene, etc. Proximal body 2702 encloses a balloon catheter 2704. Balloon catheter 2704 comprises a balloon inflation port 2706 to inflate a balloon on balloon catheter 2704. Balloon inflation port 2706 emerges out of proximal body 2702 through a longitudinal slit 2708 through proximal body 2702 such that balloon catheter 2704 can slide along the axis of proximal body 2702. Balloon inflation port 2706 is connected to a suitable inflating device to inflate the balloon of balloon catheter 2704. In this embodiment, balloon catheter 2704 is introduced into a desired region of the anatomy over a guidewire 2710. The proximal region of guidewire 2710 may comprise a

torquing device 2712. A user can use torquing device 2712 to rotate, advance, retract, or torque guidewire 2710. The distal region of proximal body 2702 comprises a suitable hub that allows a guide catheter 2714 to attach to proximal body 2702. In an alternate embodiment, guide catheter 2714 is permanently attached to proximal body 2702. In this embodiment, guide catheter 2714 comprises an elongate tubular element 2716 made of suitable biocompatible materials including, but not limited to PEEK, Pebax, Nylon, Polyimide, ABS, PVC, polyethylene, etc. The proximal region of tubular element 2716 may be covered by a hypotube 2718 made of suitable biocompatible metals or polymers. The proximal end of tubular element 2716 is attached to a suitable hub 2720. Hub 2720 allows the reversible attachment of guide catheter 2714 to proximal body 2702. In one embodiment, hub 2720 is a female luer lock that attached to a suitable hub on proximal body 2702. Thus, various guide catheters can be attached to the distal region of proximal body 2702 to provide access to various anatomical regions. The distal end of tubular element 2716 may comprise an atraumatic tip 2722. The distal end of tubular element 2716 may comprise a curved, bent or angled region. Figure 27B shows the side view of surgical hand tool 2700 showing a handle 2724 attached to proximal body 2702.

Figures 27C through 27D show various steps of a method of dilating an anatomical region using the surgical hand tool shown in Figures 27A and 27B. In Figure 27C, surgical hand tool 2700 is introduced in the anatomy. Surgical hand tool 2700 is positioned such that the distal tip of surgical hand tool 2700 is located near an anatomical region to be accessed. Thereafter, a guidewire 2710 is introduced through surgical hand tool 2700 such that the distal tip of guidewire 2710 is located near an anatomical region to be accessed. During this step, guidewire 2710 may be navigated through the anatomy using torquing device 2712. In one embodiment, guidewire 2710 is positioned across a paranasal sinus ostium to be dilated. Thereafter, in Figure 27D, balloon catheter 2704 is advanced over guidewire 2710 into the anatomy. This is done by pushing balloon inflation port 2706 in the distal direction. Thereafter, balloon catheter 2704 is used to perform a diagnostic or therapeutic procedure. In one embodiment, balloon catheter 2704 is used to dilate an opening leading to a paranasal sinus such as a paranasal sinus

ostium.

Figure 27E shows a side view of a first alternate embodiment of a surgical hand tool comprising a balloon catheter. The design of surgical hand tool 2726 is similar to the design of surgical hand tool 2700. Surgical hand tool 2726 comprises a hollow elongate body 2727 made of biocompatible materials including, but not limited to ABS, nylon, polyurethane, polyethylene, etc. Elongate body 2727 is attached to a handle 2728 to allow a user to grasp surgical hand tool 2726. Elongate body 2727 comprises a longitudinal slit 2729. Elongate body 2727 encloses a balloon catheter 2730. Balloon catheter 2730 comprises a balloon inflation port 2731 to inflate a balloon on balloon catheter 2730. Balloon inflation port 2731 emerges out of elongate body 2727 through longitudinal slit 2729 such that balloon catheter 2730 can slide along the axis of elongate body 2727. Balloon catheter 2730 is further connected to a trigger 2732. Trigger 2732 is pivoted on elongate body 2727 such that pulling trigger 2732 in the proximal direction causes balloon catheter 2730 to move in the distal direction. Similarly, pushing trigger 2732 in the distal direction causes balloon catheter 2730 to move in the proximal direction. Thus balloon catheter 2730 can be moved by moving trigger 2732. The distal region of elongate body 2727 comprises a suitable hub that allows a guide catheter 2733 to attach to elongate body 2727. In this embodiment, guide catheter 2733 comprises an elongate tubular element 2734 made of suitable biocompatible materials including, but not limited to PEEK, Pebax, Nylon, polyethylene, etc. The proximal region of tubular element 2734 may be covered by a hypotube 2735 made of suitable biocompatible metals or polymers. The proximal end of tubular element 2734 is attached to a suitable hub 2736. Hub 2736 allows the reversible attachment of guide catheter 2733 to elongate body 2727. In one embodiment, hub 2736 is a female luer lock that attached to a suitable hub on elongate body 2727. Thus, various guide catheters can be attached to the distal region of elongate body 2727 to provide access to various anatomical regions. The distal end of tubular element 2734 may comprise an atraumatic tip 2737. The distal end of tubular element 2734 may comprise a curved, bent or angled region. In this embodiment, balloon catheter 2730 is introduced into a desired region of the anatomy over a guidewire 2738. The proximal region of guidewire 2738 may

comprise a torquing device 2739. A user can use torquing device 2739 to rotate, advance, retract, or torque guidewire 2738. Surgical hand tool 2726 can be used to introduce balloon catheter 2730 into a desired anatomical region to perform a diagnostic or therapeutic procedure in the anatomical  
5 region.

Figure 27F shows a side view of a second alternate embodiment of a surgical hand tool comprising a balloon catheter. The design of surgical hand tool 2740 is similar to the design of surgical hand tool 2726. Surgical hand tool 2740 further comprises a fluid delivery mechanism to deliver inflating fluid  
10 for inflating the balloon of balloon catheter 2730. The fluid delivery mechanism comprises an elongate tube 2741 connected to balloon inflation port 2731. Elongate tube 2741 is further connected to a fluid reservoir 2742. In one embodiment, fluid reservoir 2742 comprises a pressurized gas such as air, nitrogen, carbon dioxide, etc. The delivery of fluid from fluid reservoir 2742  
15 to balloon catheter 2730 is controlled by a valve 2743.

Figure 27H shows partial sectional view of the surgical hand tool shown in Figure 27F. The proximal region of elongate body 2727 comprises longitudinal slit 2729. Elongate body 2727 encloses balloon catheter 2730. The proximal end of balloon catheter 2730 comprises a Y shaped hub. The  
20 Y-shaped hub comprises balloon inflation port 2731. Balloon inflation port 2731 in turn is connected to elongate tube 2741. Guidewire 2738 enters elongate body 2727 through an opening in the proximal end of elongate body 2727.

Figure 27G shows a perspective view of an embodiment of the valve arrangement of the device shown in Figure 27F. The valve arrangement  
25 comprises a three way valve 2743. In one embodiment, three way valve 2743 is a three way luer valve. A first arm 2744 of three way valve 2743 is connected by elongate tube 2741 to fluid reservoir 2742. A second arm 2745 of three way valve 2743 is in fluid communication with the balloon of balloon  
30 catheter 2730. A third arm 2746 of three way valve 2743 is connected to a drain or is open to the atmosphere. Third arm 2746 may be connected to a syringe or a source of vacuum to deflate balloon of balloon catheter 2730. Such an arrangement comprising a syringe or a source of vacuum connected to third arm 2746 is especially useful to deflate a non-compliant balloon.



Three way valve 2743 further comprises a control knob 2747. In a first position of control knob 2747, a fluid communication is created between first arm 2744 and second arm 2745. In a second position of control knob 2747, a fluid communication is created between second arm 2745 and third arm 2746.

5 A user can turn control knob 2747 in the first position to inflate the balloon of balloon catheter 2730. The user can then turn control knob 2747 in the second position to deflate the balloon of balloon catheter 2730. Other suitable valve arrangements may also be used instead of a three way valve for controllably inflating or deflating the balloon of balloon catheter 2730.

10 Figure 28A shows a perspective view of an embodiment of a handheld balloon catheter tool. Balloon catheter tool 2750 comprises a proximal region 2751. Proximal region 2751 comprises a handle 2752 to enable a user to hold balloon catheter tool 2750. Balloon catheter tool 2750 further comprises a balloon catheter shaft 2753. In one embodiment, balloon catheter shaft  
15 2753 extends distally from the distal region of proximal region 2751. In another embodiment, balloon catheter shaft 2753 extends till the proximal end of proximal region 2751. Balloon catheter shaft 2753 may further comprise a hypotube 2754 surrounding a region of balloon catheter shaft 2753. The distal region of balloon catheter shaft 2753 comprises an inflatable balloon  
20 2755 that can be used to dilate one or more regions of the anatomy. Balloon 2755 is inflated by a trigger 2756 located adjacent to handle 2752. Trigger 2756 is connected to a plunger that is further connected to an inflating fluid reservoir. Pulling trigger 2756 causes the inflating fluid stored in an inflating fluid reservoir to be delivered to balloon 2755 under pressure. Balloon  
25 catheter tool 2750 may further comprise a flushing port 2757 to flush a lumen of balloon catheter shaft 2753. During a procedure, a user inflates balloon 2755 to a desired pressure using the inflating fluid stored in the inflating fluid reservoir. The pressure in balloon 2755 can be measured by a pressure sensor or gauge 2758 that is in fluid communication with the inflating fluid  
30 within balloon 2755. Balloon catheter tool 2750 may further comprise a ratcheting mechanism 2759 to allow a user to pull trigger 2756 in incremental steps. This allows the user to inflate balloon 2755 in incremental steps. Similarly, balloon catheter tool 2750 may comprise a ratcheting mechanism to allow a user to release trigger 2756 in incremental steps after inflating balloon

2755. This allows the user to deflate balloon 2755 in incremental steps. In one embodiment, balloon catheter tool 2750 can be advanced over a guidewire to a desired target location in the anatomy. In this embodiment, balloon catheter tool 2750 may further comprise a proximal guidewire port  
5 2760 that is in fluid communication with a guidewire lumen in balloon catheter shaft 2753. This enables balloon catheter tool 2750 to be introduced over a guidewire into the anatomy. In another embodiment, balloon catheter tool 2750 comprises a fixed guidewire 2761 at the distal tip of balloon catheter tool 2750 to navigate balloon catheter tool 2750 through the anatomy. In one  
10 embodiment, balloon catheter tool 2750 comprises a rotation knob 2662. Rotation knob 2762 allows a user to rotate balloon catheter shaft 2753. Balloon catheter tool 2750 may further comprise one or more navigational modalities including, but not limited to radio opaque markers, electromagnetic navigational sensors, etc. The distal region of balloon catheter tool 2750 may  
15 be introduced in the anatomy through a variety of introducing devices disclosed herein including, but not limited to guide catheter 620 of Figure 6C.

Figure 28B shows a perspective view of an embodiment of a detachable handheld balloon catheter inflation tool. Detachable inflation tool 2770 comprises a body 2771 comprising a handle 2772 to enable a user to  
20 hold inflation tool 2770. Detachable inflation tool 2770 attaches to a balloon catheter 2773. In one embodiment, a user is provided with a kit comprising a detachable inflation tool 2770 and multiple balloon catheters. In the embodiment shown in Figure 28B, balloon catheter 2773 comprises an elongate balloon catheter shaft 2774. The distal region of balloon catheter  
25 shaft 2774 comprises an inflatable balloon 2775 that can be used to dilate one or more regions of the anatomy. The proximal region of balloon catheter shaft 2774 is connected to a suitable hub 2776 comprising a side port for inflating balloon 2775. In one embodiment, balloon catheter shaft 2774 comprises a hypotube 2777 surrounding a region of balloon catheter shaft 2775. Balloon  
30 2775 is inflated by a trigger 2778 located adjacent to handle 2772. Trigger 2778 is connected to a plunger that is further connected to an inflating fluid reservoir. Pulling trigger 2778 causes an inflating fluid stored in the inflating fluid reservoir to be delivered to balloon 2755 under pressure. The inflating fluid is delivered through a fluid delivery port 2779 that attaches to the side

port of hub 2776. During a procedure, a user inflates balloon 2775 to a desired pressure using the inflating fluid stored in the inflating fluid reservoir. The pressure in balloon 2775 can be measured by a pressure sensor or gauge 2780 that is in fluid communication with the inflating fluid within balloon 2775. Detachable inflation tool 2770 may further comprise a ratcheting mechanism 2781 to allow a user to pull trigger 2778 in incremental steps. This allows the user to inflate balloon 2775 in incremental steps. Similarly, detachable inflation tool 2770 may comprise a ratcheting mechanism to allow a user to release trigger 2778 in incremental steps after inflating balloon 2775. This allows the user to deflate balloon 2775 in incremental steps. In one embodiment, the combination of balloon catheter 2773 and balloon catheter tool 2770 can be advanced over a guidewire to a desired target location in the anatomy. In this embodiment, balloon catheter tool 2770 may further comprise a proximal guidewire port 2782 that is in fluid communication with a guidewire lumen in balloon catheter shaft 2774. This enables balloon catheter tool 2770 to be introduced over a guidewire 2783 into the anatomy. In another embodiment, balloon catheter 2773 comprises a fixed guidewire at the distal tip of balloon catheter 2773 to navigate balloon catheter 2773 through the anatomy. In another embodiment, balloon catheter 2773 comprises a rapid exchange lumen. The rapid exchange lumen enables balloon catheter 2773 to be introduced over a suitable guidewire. Balloon catheter tool 2770 may further comprise a flushing port 2784 to flush a lumen of balloon catheter 2773. Balloon catheter tool 2770 may further comprises one or more navigational modalities including, but not limited to radio opaque markers, electromagnetic navigational sensors, etc. The distal region of balloon catheter 2773 may be introduced in the anatomy through a variety of introducing devices disclosed herein including, but not limited to guide catheter 620 of Figure 6C.

The balloon catheter tool of Figure 28A or the detachable handheld balloon catheter inflation tool of Figure 28B may be designed to inflate a balloon to a fixed pressure. Alternatively, they may be designed to deliver a fixed volume of inflating fluid to inflate a balloon.

Any of the handle assemblies of the tools described herein and in the patent applications incorporated herein by reference may comprise a rotatable

handle. Such a rotatable handle may be designed to convert a part of a rotational force exerted by a user to a rectilinear force to draw components of the handle assembly towards each other. One embodiment of a rotatable handle is disclosed in United States Patent No. 5,697,159 (Lindén) titled  
5 'Pivoted hand tool', the entire disclosure of which is expressly incorporated herein by reference. Such designs of rotatable handles may be used for handle assemblies including, but not limited to a) handle 2752 and trigger 2756 in Figure 28A, b) handle 2772 and trigger 2778 in Figure 28B, etc.

Figure 29 shows a perspective view of a hand-held squeezing device  
10 to break or deform one or more anatomical structures such as nasal turbinates. Squeezing device 2800 comprises two or more distal squeezing elements that are used by a user to squeeze tissue located between the distal squeezing elements. Squeezing device 2800 can be used to temporarily or permanently deform tissue, break tissue, etc. In the embodiment shown in  
15 Figure 29, squeezing device 2800 comprises a proximal handle element 2802 and a distal handle element 2804. Distal handle element 2804 may comprise an opening 2806 to enable a user to insert one or more fingers through opening 2806 to pull distal handle element 2804. Proximal handle element 2802 and distal handle element 2804 are hinged together by a first hinge  
20 2808. A spring device 2810 is used to bias proximal handle element 2802 and distal handle element 2804 such that the proximal regions of proximal handle element 2802 and distal handle element 2804 are spaced apart. In this embodiment, spring device 2810 comprises a bent, elastic metal strip as shown. One end of the strip is fixed to proximal handle element 2802 and the  
25 other end of the strip slides over a surface of distal handle element 2804. The distal region of proximal handle element 2802 is connected by a second hinge 2812 to the proximal region of an elongate first distal element 2814. The distal region of first distal element 2814 may comprise one or more compression arms 2816 to compress tissue. Compression arms 2816 may be  
30 substantially straight or may comprise one or more bent, curved or angled regions. In this embodiment, the distal region of first distal element 2814 comprises a single compression arm 2816. The distal region of distal handle element 2804 is connected by a third hinge 2818 to the proximal region of an elongate second distal element 2820. The distal region of second distal

element 2820 may comprise one or more compression arms 2822 to compress tissue. Compression arms 2822 may be substantially straight or may comprise one or more bent, curved or angled regions. In this embodiment, the distal region of second distal element 2820 comprises a two  
5 compression arm 2822. The curved middle regions of first distal element 2814 and second distal element 2820 are connected to each other by a fourth hinge 2824. In one embodiment of a method of using squeezing device 2800, a user squeezes proximal handle element 2802 and distal handle element 2804 towards each other. This causes the distal ends of proximal handle  
10 element 2802 and distal handle element 2804 move away from each other. This in turn causes the proximal ends of first distal element 2814 and second distal element 2820 to move apart from each other. This in turn causes compression arm 2816 and compression arms 2822 to move closer to each other. This squeezes tissue located between compression arm 2816 and  
15 compression arms 2822. In one method embodiment, squeezing device 2800 is used to crush or break a region of a nasal turbinate to gain access to a paranasal sinus ostium. The various components of squeezing device 2800 may be made using suitable biocompatible materials including, but not limited to stainless steel, titanium, etc. Figures 29A and 29B show enlarged views of  
20 the distal region of the squeezing device of Figure 29. Figure 29A shows the orientation of compression arm 2816 and compression arms 2822 when squeezing device 2800 is in an undeployed configuration. Figure 29B shows the orientation of compression arm 2816 and compression arms 2822 when squeezing device 2800 is being used to squeeze tissue.

25 Figures 29C and 29D show a coronal section through a region of a human head showing the steps of temporarily or permanently breaking or deforming a nasal turbinate NT using the squeezing device of Figure 29. In Figure 29C, squeezing device 2800 is introduced in the nasal cavity. Thereafter, squeezing devices 2800 is positioned such that compression arm  
30 2816 is located on one side of the nasal turbinate NT and compression arms 2822 are located on the other side of the nasal turbinate. In Figure 29D, a user deploys squeezing device 2800. This causes compression arm 2816 and compression arms 2822 to squeeze the region of the nasal turbinate NT located between compression arm 2816 and compression arms 2822.

Figure 29E shows a perspective view of a hand-held device to twist one or more anatomical structures such as nasal turbinates. Twisting device 2830 comprises two or more distal arms that are placed around an anatomical structure. Thereafter, the two or more arms are twisted to temporarily or permanently deform or break the anatomical structure. In the embodiment shown in Figure 29E, twisting device 2830 comprises a proximal handle 2832, a middle region 2834 and two distal arms 2836. Proximal handle 2832 may have a substantially larger outer diameter than the maximum width of the distal region of twisting device 2830 to enable a user to easily twist the anatomical structure. The various components of squeezing device 2800 may be made using suitable biocompatible materials including, but not limited to stainless steel, titanium, etc. In one method embodiment, twisting device 2830 is used to deform or break a region of a nasal turbinate to gain access to a paranasal sinus ostium.

Figures 29G and 29G show a coronal section through a region of a human head showing the steps of temporarily or permanently breaking or deforming a nasal turbinate NT using the squeezing device of Figure 29. In Figure 29G, twisting device 2830 is introduced in the nasal cavity. Thereafter, twisting device 2830 is positioned such that one of arms 2836 is located on one side of the nasal turbinate NT and the other of arms 2836 is located on the other side of the nasal turbinate. In Figure 29G, a user twists twisting device 2830. This causes arms 2836 to twist the region of the nasal turbinate NT located between arms 2836 to temporarily or permanently break or deform the nasal turbinate NT.

The devices disclosed in Figures 298 through 29G are especially useful to treat patients with narrow noses to controllably fracture a nasal turbinate to allow access to a paranasal sinus ostium.

The rigid or flexible endoscopes disclosed herein may have a range of view ranging from 0 degrees to 145 degrees. The embodiments of endoscopes comprising a curved, bent or angled region may be manufactured by curving or bending the optical fibers before fusing the optical fibers. The optical fibers may be fused for example by heating them to a temperature ranging from 500 to 700 degrees Celsius or by using suitable epoxy adhesives to attach the optical fibers to each other. The endoscopes may be

made using reduced cladding thickness optical fibers to allow curved, bent or angled regions with a large angle or curvature but a small radius of curvature. The endoscopes may also be made using glass/glass/polymer (GGP) multimode fiber such as the ones made by 3M to allow curved, bent or angled regions with a large angle or curvature but a small radius of curvature. For example, in embodiments of endoscopes that have a bent, curved or angled region enclosing an angle of 90 degrees or more, the radius of curvature of the bent, curved or angled region may preferably be less than or equal to 1.5 cm. Such endoscopes comprising curved, bent or angled regions with a large angle or curvature but a small radius of curvature are especially useful to enable a user to access the maxillary sinuses.

The embodiments herein have been described primarily in conjunction with minimally invasive procedures, but they can also be used advantageously with existing open surgery or laparoscopic surgery techniques. For example, the methods and devices disclosed herein may be combined with one or more techniques of Functional Endoscopic Sinus Surgery (FESS). In FESS, a surgeon may remove diseased or hypertrophic tissue or bone and may enlarge the ostia of paranasal sinuses to restore normal drainage of the sinuses. It is typically performed with the patient under general anesthesia using endoscopic visualization.

Although FESS continues to be the gold standard therapy for severe sinuses, it has several shortfalls such as post-operative pain and bleeding associated with the procedure, failure to relieve symptoms in a significant subset of patients, risk of orbital, intracranial and sinonasal injuries, etc. Replacing one or more steps of FESS may reduce the shortfalls associated with the traditional FESS. The following are some examples of procedures involving a combination of FESS and the procedures disclosed in this patent application and the patent applications incorporated herein by reference.

1. In one combination procedure, a maxillary sinus is treated by balloon dilation with or without total or partial removal of the uncinate. Total or partial removal of the uncinate may make it easier or faster for some physicians to visualize and access the maxillary sinus.

2. In another combination procedure, a maxillary sinus is treated by balloon dilation in conjunction with removal of a nasal turbinate. During this

combination procedure, a part or the entire nasal turbinate e.g. the middle turbinate may be removed. Removing a part or the entire middle turbinate provides additional working space in the region medial to the uncinate for instruments. This may potentially make the combination procedure easier or  
5 faster.

3. In another combination procedure, a sphenoid sinus ostium is treated by balloon dilation in conjunction with ethmoidectomy. The step of ethmoidectomy may enable a physician to introduce a guide catheter through the middle meatus to the sphenoid sinus ostium. This may potentially enable  
10 easy access to the sphenoid sinus ostium.

4. In another combination procedure, a frontal sinus is treated by balloon dilation in conjunction with middle turbinate resection and/or ethmoidectomy. This combination procedure may make easier for a physician to find, visualize or access the frontal sinus once anatomical structures like  
15 Ethmoid bulla, turbinate, etc. are removed or reduced.

5. In another type of combination procedures, multiple sinuses are treated by balloon dilation with no or minimal tissue or bone removal. This is then followed by standard techniques to treat sinus disease. Examples of such combination procedures include:

20 5A. Frontal, maxillary, or sphenoid sinuses are treated by balloon dilation. Also, ethmoidectomy is performed while preserving the uncinate. The presence of the uncinate may preserve the natural function of the uncinate. This in turn may lead to lower incidence of complications like infection, etc. in the sinuses.

25 5B. Any paranasal sinus may be treated by balloon dilation combined with a second procedure including, but not limited to ethmoidectomy, septoplasty, reduction of a turbinate (e.g. inferior turbinate, middle turbinate, etc.), etc.

30 6. Any of the procedures disclosed herein may be performed in conjunction with irrigation and suction of one or more paranasal sinuses with a flexible catheter or rigid instrument. A flexible catheter is particularly useful to reach regions that are difficult to access by rigid instruments. Such regions may be located in lateral aspects of the frontal sinuses, the inferior or medial aspects of the maxillary sinuses, etc.



7. Any of the procedures disclosed herein may further include removal of one or more polyps. Polyp removal by standard techniques such as using shavers can be combined with balloon dilation of various paranasal sinus ostia. Once one or more polyps are removed, one or more ostia of paranasal sinuses may be dilated by balloon dilation.

8. In another type of combination procedures, balloon dilation of one or more paranasal sinus ostia may be performed to revise a previously performed surgery or in conjunction with standard endoscopic sinus surgery techniques. Examples of such procedures include:

8A. Treating scar formation over frontal recess: In this combination procedure, an attempt is made to access frontal recess with a guidewire. A balloon catheter is then passed over the guidewire. If the guidewire is unable to access the frontal sinus ostia because of scarring or because the frontal sinus ostia are too small, a surgical instrument e.g. curette or seeker may be used to open or puncture scar tissue or adhesions or the frontal sinus ostia. Such scar tissue or adhesions may be caused for example due to infection, prior surgery, etc. Thereafter, the frontal sinus ostia may be dilated by balloon dilation.

8B. Combination procedures similar to the abovementioned combination procedure may be performed to treat scarring near sphenoid sinuses and maxillary sinuses.

9. In another type of combination procedures, one or more paranasal sinuses e.g. a maxillary sinus may be accessed by an artificially created opening leading to the sinuses. Thereafter, a diagnostic or therapeutic procedure disclosed herein or in the patent documents incorporated herein by reference may be performed. The artificially created opening may be used to endoscopically visualize the placement of devices such as balloon catheters, guidewires, or other devices through a natural ostium of the paranasal sinus. The artificially created opening may also be used to introduce one or more diagnostic, therapeutic or access devices. The artificially created opening may be used to introduce liquids including, but not limited to solutions of antibiotics, solutions of anti-inflammatory agents, etc. The artificially created opening may be made by using suitable devices including, but not limited to drilling devices, chopping devices, puncturing devices, etc.

Some specific examples of hybrid procedures of the present invention are shown in the flow diagrams of Figures 30-33.

Figure 30 shows steps in a method wherein an anatomical or pathological structure, such as the uncinata process, a turbinate, the wall of an ethmoid air cell, a polyp, etc. is removed or substantially modified and a dilator (e.g., the balloon of a balloon catheter) is positioned within an opening of a paranasal sinus and used to dilate that opening. Removal or modification of the anatomical or pathological structure may provide clearer access to and/or visibility of certain anatomical structures during the procedure or during post-operative examinations and follow-up.

Figure 31 shows steps in a method where a dilator such as the balloon of a balloon catheter is positioned in the opening of a paransal sinus and used to dilate that opening and, either before or after such dilation, the cavity of the paranasal sinus is suctioned or irrigated. In cases where a balloon catheter or other dilator device having a through lumen is used to accomplish the dilation step, the irrigation and/or suction step may be carried out by passing fluid or negative pressure through the through lumen of the dilation catheter. Or, a guidewire may be advanced into or near the sinus cavity during the dilation step and, thereafter, a suction and/or irrigation device may be advanced over such guidewire and used to carry out the suction and/or irrigation step.

Figure 32 shows steps in a method where scar or adhesion tissue has formed in a location that obstructs a lumen, orifice, or passageway (e.g., scar tissue obstruction the opening of a paranasal sinus) and a puncture tract is initially formed in the scar or adhesion tissue. This may be accomplished by pushing a needle, seeker, probe, guidewire or other penetrator through the tissue. Thereafter, a dilator (e.g., a balloon catheter) is advanced into the puncture tract and is used to dilate the puncture tract, thereby relieving the obstruction caused by the aberrant scar or adhesion tissue.

Figure 33 shows steps in a method wherein a dilator (e.g., the balloon of a balloon catheter) is placed in a pre-existing opening of a paranasal sinus, such as the natural ostium of the sinus (or a previously surgically altered ostium) and is used to dilate that opening. Also, a separate opening is created in that paranasal sinus, either from the nasal cavity or through the exterior of the face (e.g., a bore hole, antrostomy or trephination). This may

provide improved ventilation and/or drainage of the sinus cavity. Optionally, the two openings may then be used to perform other procedures. For example, a "flow through" lavage may be carried out by passing lavage solution through one of the openings and out of the other. Or, a device may  
5 be inserted through one of the openings, leaving the other opening unobstructed. Or, the physician may visualize (e.g., through an endoscope) through the newly created opening while treated the pre-existing opening or performing other diagnosis or treatment of the sinus cavity.

It is to be appreciated that the devices and methods of the present  
10 invention relate to the accessing and dilation or modification of sinus ostia or other passageways within the ear nose and throat. These devices and methods may be used alone or may be used in conjunction with other surgical or non-surgical treatments, including but not limited to the delivery or implantation of devices and drugs or other substances as described in  
15 copending United States Patent Application Serial No. 10/912,578 entitled Implantable Devices and Methods for Delivering Drugs and Other Substances to Treat Sinusitis and Other Disorders filed on August 4, 2004, the entire disclosure of which is expressly incorporated herein by reference.

It is to be appreciated that the invention has been described hereabove  
20 with reference to certain examples or embodiments of the invention but that various additions, deletions, alterations and modifications may be made to these examples and embodiments without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another  
25 embodiment or example, unless to do so would render the embodiment or example unsuitable for its intended use. All reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

## CLAIMS

What is claimed is:

- 1 1. An endoscopic guide system useable to facilitate trans-nasal  
2 advancement of a guidewire, catheter, instrument or other device to a position  
3 within or near the ostium of a paranasal sinus of a human or animal subject,  
4 said system comprising:
  - 5 a) a tubular guide having a proximal end, a distal end and a lumen  
6 that extends longitudinally therethrough, said tubular guide having a distal  
7 portion that is more flexible than the remainder of the guide and said tubular  
8 guide being configured such that it may be i) inserted, distal end first, through  
9 a nostril of the subject's nose and ii) advanced, without requiring substantial  
10 modification or removal of any normal anatomical structure, to a position  
11 where the distal end of the guide is within or adjacent to the ostium of the  
12 paranasal sinus; and
  - 13 b) an endoscopic device incorporated in or attached to the tubular  
14 guide, said endoscopic device being useable to view a visual field that  
15 includes an area beyond the distal end of the tubular guide.
  
- 1 2. A system according to claim 1 wherein the endoscopic device is  
2 attached to the exterior of the tubular guide.
  
- 1 3. A system according to claim 2 wherein the endoscopic device is  
2 detachable from the tubular guide.
  
- 1 4. A system according to claim 5 wherein an attachment apparatus is  
2 used to attach the endoscopic device to the tubular guide.

1 5. A system according to claim 4 wherein the attachment apparatus  
2 comprises a clip.

1 6. A system according to claim 4 wherein the attachment apparatus is  
2 integrated in or permanently attached to the tubular guide.

1 7. A system according to claim 4 wherein the attachment apparatus is  
2 removable from the tubular guide.

1 8. A system according to claim 1 wherein the tubular guide has a first  
2 lumen and a second lumen, said endoscopic device being insertable into or  
3 advanceable through the first lumen and a guidewire, catheter, instrument or  
4 other device being advanceable through the second lumen.

1 9. A system according to claim 1 wherein a curve is formed in the tubular  
2 guide and wherein the endoscopic device is constructed and positioned to  
3 receive an image from a location that is distal to said curve and to transmit  
4 said image to a location proximal to the curve.

1 10. A system according to claim 9 wherein the endoscopic device  
2 comprises a curved wave guide.

1 11. A system according to claim 9 wherein the endoscopic device  
2 comprises a periscope.

1 12. A system according to claim 9 wherein the proximal end of the  
2 endoscopic device is configured to communicate with a separate endoscope  
3 such that a visual image may be received by the distal end of the endoscopic  
4 device, transmitted around the curve by the endoscopic device and then  
5 received by the endoscope such that an operator may view the image through  
6 the endoscope.

1 13. A system according to claim 12 in combination with an endoscope that  
2 communicates with the endoscopic device.

1 14. A system according to claim 12 wherein the endoscopic device has a  
2 proximal end that is located proximal to the curve and a distal end that is  
3 located distal to the curve, the proximal end of the endoscopic device being  
4 configured to couple with the distal end of a separate endoscope.

1 15. A system according to claim 1 further comprising a balloon located on  
2 at least one of said tubular guide and endoscopic device.

1 16. A system according to claim 15 wherein the balloon is useable to dilate  
2 the ostium of a paranasal sinus.

1 17. A system according to claim 1 wherein at least a portion of the tubular  
2 guide is bendable.

1 18. A system according to claim claim 1 wherein at least a portion of the  
2 endoscopic device is bendable.

1 19. A system according to claim 1 wherein the tubular guide is substantially  
2 straight.

1 20. A system according to claim 1 wherein a curve of less than about 30  
2 degrees is formed in a distal portion of the tubular guide.

1 21. A system according to claim 1 wherein a curve of about 30 degrees is  
2 formed in a distal portion of the tubular guide.

1 22. A system according to claim 1 wherein a curve of about 70 degrees is  
2 formed in a distal portion of the tubular guide.

1 23. A system according to claim 1 wherein a curve of about 90 degrees is  
2 formed in a distal portion of the tubular guide.

1 24. A system according to claim 1 wherein a curve of about 110 degrees is  
2 formed in a distal portion of the tubular guide.

1 25. A system according to claim 1 wherein a distal portion of the tubular  
2 guide has a curve of angle (A) and a distal tip, said distal portion having a  
3 width (W) and a first length ( $L_1$ ) measured from the proximal-most point on the  
4 curve to the distal tip.

1 26. A system according to claim 25 wherein A is less than about 30  
2 degrees, W is less than approximately 0.034 inch and  $L_1$  is less than  
3 approximately 0.046 inch.

1 27. A system according to claim 26 wherein the distal portion has a second  
2 length  $L_2$  measured from the distal end of the proximal portion to the proximal-  
3 most point on the curve of the distal portion, said second length  $L_2$  being less  
4 than approximately 2 inches.

1 28. A system according to claim 25 wherein  $A$  is approximately 30  
2 degrees,  $W$  is approximately 0.34 inches and  $L_1$  is approximately 0.46 inches.

1 29. A system according to claim 28 wherein the distal portion has a second  
2 length  $L_2$  measured from the distal end of the proximal portion to the proximal-  
3 most point on the curve of the distal portion, said second length  $L_2$  being less  
4 than approximately 2 inches.

1 30. A system according to claim 25 wherein  $A$  is approximately 70  
2 degrees,  $W$  is approximately 0.48 inches and  $L_1$  is approximately 0.32 inches.

1 31. A system according to claim 30 wherein the distal portion has a second  
2 length  $L_2$  measured from the distal end of the proximal portion to the proximal-  
3 most point on the curve of the distal portion, said second length  $L_2$  being less  
4 than approximately 2 inches.

1 32. A system according to claim 25 wherein  $A$  is approximately 90  
2 degrees,  $W$  is approximately 0.39 inches and  $L_1$  is approximately 0.25 inches.

1 33. A system according to claim 32 wherein the distal portion has a second  
2 length  $L_2$  measured from the distal end of the proximal portion to the proximal-



3 most point on the curve of the distal portion, said second length  $L_2$  being less  
4 than approximately 2 inches.

1 34. A system according to claim 25 wherein  $A$  is approximately 110  
2 degrees,  $W$  is less than approximately 0.25 inch.

1 35. A system according to claim 34 wherein the distal portion has a second  
2 length  $L_2$  measured from the distal end of the proximal portion to the proximal-  
3 most point on the curve of the distal portion, said second length  $L_2$  being less  
4 than approximately 2 inches.

1 36. A system according to claim 34 or 35 wherein the distal portion has an  
2 outer surface and a third length  $L_3$  measured from the distal-most point on the  
3 outer surface of the distal portion to the proximal-most point on the distal tip,  
4 wherein  $L_3$  is approximately 0.18 inches.

1 37. A system according to claim 1 wherein a distal portion of the guide tube  
2 is more flexible than a proximal portion of the guide tube.

1 38. A system according to claim 1 wherein a distal portion of the guide tube  
2 is substantially transparent.

1 39. A system according to claim 1 wherein the guide tube comprises a  
2 straight metal tube having a distal end and a plastic tube that extends through  
3 the metal tube, a distal portion of the plastic tube protruding out of and  
4 beyond the distal end of the metal tube.

1 40. A system according to claim 39 wherein a curve is formed in the distal  
2 portion of the plastic tube.

1 41. A system according to claim 39 wherein the plastic tube is formed  
2 substantially of a material selected from the group consisting essentially of  
3 nylon, nylon 11, nylon 12, pebax, pebax 72D, polyimide,  
4 poly(etheretherketone) (PEEK), poly(butylene terephthalate) (PBT) and  
5 combinations or blends thereof.

1 42. A system according to claim 41 further comprising a liner that lines at  
2 least a portion of the plastic tube.

1 43. A system according to claim 42 wherein the liner is affixed to the plastic  
2 tube.

1 44. A system according to claim 42 wherein the liner is formed  
2 substantially of material selected from the group consisting of;  
3 polytetrafluoroethylene, poly (vinylidene fluoride) (PVDF) and high density  
4 polyethylene (HDPE).

1 45. A system according to claim 39 further comprising a distal tip member  
2 on the distal end of the plastic tube.

1 46. A system according to claim 45 wherein the distal portion of the plastic  
2 tube has a Rockwell hardness in the range of about 70R to about 110R and  
3 the distal tip member has a Shore Durometer hardness in the range of about  
4 35D to about 72D.

1 47. A system according to claim 45 wherein the plastic tube comprises  
2 nylon and the distal tip member comprises elastomeric polyether block amide.

1 48. A system according to claim 39 further comprising an outer cover that  
2 substantially surrounds the outer surface of the metal tube and the protruding  
3 distal portion of the plastic tube.

1 49. A system according to claim 48 wherein the outer cover is formed  
2 substantially of nylon or other thermoplastic material.

1 50. A system according to claim 49 wherein the outer cover deters leakage  
2 from a joint between the metal tube and the plastic tube.

1 51. A system according to claim 1 further comprising a connector on the  
2 proximal end of the guide tube to facilitate attachment of a suction tube to the  
3 guide tube.

1 52. A seeker/guide system useable for use in ear, nose and throat  
2 surgery, said system comprising:

3 a luminal seeker apparatus comprising i) an elongate, substantially  
4 rigid or malleable shaft having a distal end and ii) a lumen extending through  
5 the shaft and terminating distally in an opening in the distal end; and

6 a guidewire, catheter or other elongate device that is advanceable  
7 through the lumen of the luminal seeker apparatus.

1 53. A system according to claim 52 further comprising a balloon on the  
2 shaft proximal to the bulbous distal end.

1 54. A system according to claim 52 further comprising an expandable  
2 dilator on the shaft proximal to the bulbous distal end.

1 55. A system according to claim 52 further comprising a substantially  
2 atraumatic tip structure at the distal end of the shaft.

1 56. A seeker device useable for use in ear, nose and throat surgery, said  
2 device comprising:

3 a seeker apparatus comprising an elongate substantially rigid shaft  
4 having a bulbous distal end; and

5 an expandable member on the shaft proximal to the distal end.

1 57. A device according to claim 56 wherein the expandable member  
2 comprises a balloon.

1 58. A device according to claim 56 wherein the expandable member is  
2 sized and constructed to dilate an anatomical structure.

1 59. A device according to claim 56 wherein the expandable member is  
2 sized and constructed to dilate the ostium of a paranasal sinus.

1 60. A device according to claim 56 further comprising a lumen extending  
2 through the shaft and terminating distally in an opening in the bulbous distal  
3 end.

1 61. A system comprising a device according to claim 60 in combination  
2 with a guidewire, catheter or other elongate device that is advanceable  
3 through the lumen of the seeker apparatus.

1 62. A device useable to dilate an anatomical structure within the ear, nose  
2 or throat of a human or animal subject, said device comprising:

3 a handpiece;

4 an elongate shaft that extends from the handpiece, said elongate shaft  
5 having a distal portion that is insertable through a nostril of the subject's nose;

6 a dilator having a non-expanded configuration and an expanded  
7 configuration; and

8 a trigger apparatus on or associated with the handpiece, said trigger  
9 apparatus being useable to move the dilator between its non-expanded  
10 configuration and its expanded configuration.

1 63. A device according to claim 62 wherein the dilator comprises a balloon.

1 64. A device according to claim 62 wherein the balloon is inflated and  
2 deflated by a pumping apparatus and wherein the trigger apparatus is  
3 useable to cause the pumping apparatus to pump inflation fluid into or out of  
4 the balloon.

1 65. A device according to claim 64 wherein the pumping apparatus  
2 comprises a cylinder and plunger and wherein the trigger apparatus is usable  
3 to cause the plunger to move back and forth within the cylinder.

1 66. A device according to claim 62 wherein the balloon is connected to a  
2 source of compressed inflation fluid and wherein the trigger apparatus is  
3 useable to cause the pressurized inflation fluid to flow into the balloon.

1 67. A device according to claim 62 wherein the trigger is operable by the  
2 same hand that grasps the handpiece.

1 68. A device according claim 62 wherein the dilator is additionally  
2 moveable from a retracted position to an advanced position and wherein the  
3 device further comprises apparatus on or associated with the handpiece for  
4 moving the device.

1 69. A device for deterring unwanted movement of a catheter or other  
2 device that has been inserted into the nose of a human or animal subject, said  
3 device comprising:

4 a support member;

5 an attachment substance or apparatus for releaseably holding the  
6 catheter or other device in a substantially fixed position relative to the support  
7 member; and

8 positioning apparatus for substantially holding the support member in a  
9 position adjacent to the subject's nose.

1 70. A device according to claim 69 wherein the support member comprises  
2 and elongate body that is positionable such that it extends transversely  
3 inferior to the subject's nose.

1 71. A device according to claim 69 wherein the attachment substance or  
2 apparatus comprises an adhesive that causes the catheter or device to  
3 adhere to the support member.

1 72. A device according to claim 69 wherein the attachment substance or  
2 apparatus comprises a plurality of finger members protruding from the support  
3 member, said finger members being constructed such that when the catheter  
4 or device is inserted between adjacent ones of said finger members the  
5 catheter or device will be releasably held in a substantially fixed position  
6 relative to the support member.

1 73. A device according to claim 69 wherein the attachment substance or  
2 apparatus comprises at least one clip for holding a catheter or device in a  
3 substantially fixed position relative to the support member.

1 74. A device according to claim 69 wherein the positioning apparatus  
2 comprises one or more legs attached to the support member.

1 75. A device according to claim 69 wherein the positioning apparatus  
2 comprises apparatus for attaching the support member to the subject's upper  
3 lip or face.

1 76. A balloon catheter device comprising:  
2 a first tube having a lumen, a proximal end, a distal end and a distal  
3 region adjacent its distal end;  
4 a second tube having a lumen, a proximal end, a distal end and a  
5 proximal region adjacent its proximal end; and  
6 a balloon having a proximal end and a distal end;  
7 the first and second tubes being positioned such that the proximal  
8 region of the second tube is beside and substantially parallel to the distal  
9 region of the first tube;  
10 the balloon being mounted on the catheter device such that the  
11 proximal end of the balloon is affixed in substantially fluid tight fashion to the  
12 distal region of the first tube and the proximal region of the second tube and  
13 the distal end of the balloon being affixed in substantially fluid tight fashion to  
14 the second tube;  
15 such that inflation fluid may be passed into the balloon through the  
16 lumen of the first tube and a guidewire may pass through the lumen of the  
17 second tube from a location proximal to the proximal end of the balloon to a  
18 location distal to or coterminus with the distal end of the balloon.

1 77. A balloon catheter device comprising:  
2 a first tube having a lumen, a proximal end, a distal end and a distal  
3 region adjacent its distal end;  
4 a second tube having a lumen, a proximal end, a distal end and a  
5 proximal region adjacent its proximal end;  
6 a third tube having a lumen, a proximal end and a distal end; and  
7 a balloon having a proximal end and a distal end;  
8 the distal region of the first tube and the proximal region of the second



9 tube being positioned beside each other within the lumen of the third tube  
10 such that the first tube extends out of the proximal end of the third tube and  
11 the second tube extends out of the distal end of the third tube; and

12 the proximal end of the balloon being affixed in substantially fluid tight  
13 fashion to a proximal location on the third tube and the distal end the balloon  
14 being affixed in substantially fluid tight fashion to a distal location on the third  
15 tube;

16 such inflation fluid may be passed into the balloon through the lumen of  
17 the first tube and the lumen of the second tube forms a guidewire lumen that  
18 extends from a location proximal to the proximal end of the balloon to a  
19 location distal to or coterminus with the distal end of the balloon.

1 78. A balloon catheter device comprising:

2 a catheter shaft;

3 a balloon mounted on the catheter shaft;

4 an inflation lumen extending through the catheter shaft into the balloon  
5 such that inflation fluid may pass through the inflation lumen and into the  
6 balloon; and

7 a guidewire lumen that extends through the catheter shaft and through  
8 the balloon, a portion of the guidewire lumen having a slit formed therein.

1 79. A balloon catheter device comprising:

2 a catheter shaft;

3 a balloon mounted on the catheter shaft;

4 an inflation lumen extending through the catheter shaft into the balloon  
5 such that inflation fluid may pass through the inflation lumen and into the  
6 balloon; and

7 apparatus located on or in the balloon for determining the diameter of  
8 the balloon.

1 80. A device according to claim 79 wherein the apparatus located on or in  
2 the balloon for determining the diameter of the balloon comprises first and  
3 second capacitance plates located on the balloon such that the distance  
4 between the capacitance plates varies with the degree of inflation of the  
5 balloon.

1 81. A balloon folding tool useable to facilitate folding of a balloon that  
2 inflates to a fully inflated balloon diameter, said tool comprising:

3 a rigid body having a central bore formed therein, the central bore  
4 having a diameter that is less than the fully inflated balloon diameter;

5 a plurality of side channels located adjacent to and substantially  
6 parallel with the central bore, each of said side channels being connected to  
7 the bore through a slot;

8 the balloon being insertable into the central bore while in a less than  
9 fully inflated state, thereafter the balloon being fully or partially inflatable  
10 causing a separate portion of the balloon to pass through the each slot and  
11 into each side channel and, thereafter, the balloon being deflatable such that  
12 each separate portion of the balloon that has passed into each side channel  
13 will form a separate wing of the deflated balloon, said wings being thereafter  
14 foldable to a collapsed shape.

1 82. A tool according to claim 81 having 2-6 side channels such that 2-6  
2 wings are formed on the balloon.

1 83. A system comprising a tool according to claim 81 in combination with a  
2 balloon catheter having a balloon that may be folded using the tool.

1 84. A system according to claim 83 wherein the balloon is formed of non-  
2 compliant material.

1 85. A balloon compressing apparatus useable to facilitate folding of a  
2 balloon mounted on a catheter; said balloon compressing apparatus  
3 comprising:

4 a plurality of compression members disposed radially about a central  
5 cavity, said compression members being spaced apart from each other such  
6 that gaps exist between adjacent compression members, said compression  
7 members being moveable from non-compressing positions to compressing  
8 positions;

9 the balloon being insertable into the central cavity while the  
10 compression members are in their non-compressing positions, the  
11 compression members being thereafter moveable to their compressing  
12 positions, thereby compressing portions of the balloon causing any inflation  
13 fluid to be forced out of the balloon and causing portions of the balloon to  
14 protrude outwardly into the gaps between the compression members, thereby  
15 forming a plurality of wings, said wings being thereafter foldable into a  
16 collapsed shape.

1 86. A balloon compressing apparatus according to claim 85 further  
2 comprising a screw cap that, when rotated, causes the compression members  
3 to move from their non-compressing positions to their compressing positions.

1 87. A balloon compressing apparatus according to claim 85 having 2-6  
2 gaps such that 2-6 wings will be formed in the balloon.

1 88. A system comprising a balloon compressing apparatus according to  
2 claim 85 in combination with a balloon catheter having a balloon that may be  
3 folded using the balloon compressing apparatus.

1 89. A system according to claim 88 wherein the balloon is formed of non-  
2 compliant material.

1 90. An inflator handpiece device that is attachable to a balloon catheter or  
2 other balloon equipped device and useable to inflate the balloon, said inflator  
3 handpiece device comprising:

4 a handpiece body configured to be grasped by a human hand, said  
5 handpiece body being attachable to the proximal end of a balloon catheter or  
6 other balloon equipped device;

7 an inflator housed on or in the handpiece body; and

8 an inflation trigger on the handpiece body, said inflation trigger being  
9 useable to cause the inflator to inflate the balloon.

1 91. A device according to claim 90 wherein the handpiece body comprises  
2 an elongate body having a grip member extending at an angle from the  
3 elongate body, said grip member being graspable by a human hand.

1 92. A device according to claim 90 wherein the inflator comprises a pump.

1 93. A device according to claim 92 wherein the inflation trigger comprises a  
2 trigger arm that is pulled to cause the pump to pump fluid into the balloon.

1 94. A device according to claim 92 wherein the pump is constructed to  
2 deliver a predetermined volume of fluid into the balloon.

1 95. A device according to claim 92 wherein the pump is constructed to  
2 inflate the balloon to a predetermined pressure.

1 96. A device according to claim 90 wherein the inflator comprises a source  
2 of compressed inflation fluid.

1 97. A device according to claim 96 wherein the inflation trigger opens a  
2 valve allowing compressed fluid to flow from the source of compressed fluid  
3 into the balloon.

1 98. A device according to claim 92 wherein the pump is constructed to  
2 deliver a predetermined volume of fluid into the balloon.

1 99. A device according to claim 92 wherein the pump is constructed to  
2 inflate the balloon to a predetermined pressure.

1 100. A device useable for breaking a nasal turbinate in a human or animal  
2 subject, said device comprising:

3 first and second members positionable at spaced apart positions on  
4 one side of the turbinate; and

5 a third member positionable on the other side of the turbinate between  
6 the first and second members;

7 the third member and/or said first and second members being  
8 moveable to exert pressure on the nasal turbinate causing the bone of the  
9 nasal turbinate to break.

1 101. An adapter attachable to a substantially rigid cannula, catheter or  
2 elongate device to facilitate use of that cannula, catheter or elongate device in  
3 conjunction with a navigation system of the type used in performing image  
4 guided surgery, said adapter comprising:

5 an elongate adapter body that is attachable to the substantially rigid  
6 cannula, catheter or elongate device; and

7 apparatus useable by the image guidance system to determine the  
8 position of the substantially rigid cannula, catheter or elongate device within  
9 the body of a human or animal subject.

1 102. An adapter according to claim 101 wherein the adapter body is  
2 configured to be grasped by the operator's hand.

1 103. An adapter according to claim 101 wherein the apparatus useable by  
2 the image guidance system comprises optical sensors that receive light from  
3 a light source of an optical image guidance system.

1 104. An adapter according to claim 101 wherein the apparatus useable by  
2 the image guidance system comprises electromagnetic sensors that receive  
3 electromagnetic energy from a transmitter of an electromagnetic image  
4 guidance system.

1 105. An adapter according to claim 101 further comprising a lumen that  
2 extends through the elongate adapter body.

1 106. An adapter according to claim 101 further comprising a lumen that  
2 extends through the elongate adapter body.

1 107. A device for dilating an ostium, passageway or anatomical structure  
2 within an ear, nose, throat or paranasal sinus of a human or animal subject,  
3 said device comprising:

4 a handpiece comprising an elongate body having a distal end and a  
5 proximal end and a grip member extending at an angle from the elongate  
6 handpiece body, said grip member being configured to be grasped by a  
7 human hand;

8 an elongate shaft attached to and extending from the distal end of the  
9 elongate body of the handpiece, said shaft having a lumen and an open distal  
10 end;

11 a dilator advanceable from the distal end of the shaft, said dilator  
12 having a collapsed configuration and an expanded configuration;

13 a dilator advancement control on the handpiece useable to control  
14 advancement of the dilator out of the distal end of the shaft;

15 a dilator expansion control on the handpiece useable to control  
16 expansion of the dilator.

1 108. A device according to claim 107 wherein the dilator is on a tubular  
2 member having a lumen and wherein the device further comprises;

3 a guidewire that is advanceable through the lumen of the tubular  
4 member; and

5 a guidewire advancement control on the handpiece for controlling  
6 advancement of the guidewire.

1 109. A device according to claim 107 wherein the dilator comprises a  
2 balloon and wherein the dilator expansion control is operative to cause the  
3 balloon to inflate.

1 110. A device according to claim 109 further comprising apparatus on the  
2 handpiece for deflating the balloon such that the balloon returns to the  
3 collapsed configuration.

1 111 A device according to claim 109 wherein the dilator expansion control  
2 is connected to a pump that pumps inflation fluid into the balloon.

1 112. A device according to claim 111 wherein the pump is located in or on  
2 the handpiece.

1 113. A device according to claim 111 wherein the pump is operative to  
2 alternately i) inflate the balloon to its expanded configuration and ii) deflate the  
3 balloon to its collapsed configuration, and wherein the dilator expansion  
4 control is useable to alternately cause such inflation and deflation of the  
5 balloon.

1 114. A device according to claim 113 wherein the balloon is non-compliant  
2 and wherein the pump is operative to apply sufficient negative pressure to the  
3 balloon to cause the balloon to assume the collapsed configuration.



1 115. A device according to claim 109 wherein the dilator expansion control  
2 is connected to a source of compressed inflation fluid and is useable to cause  
3 pressurized inflation fluid to flow into the balloon.

1 116. A device according to claim 115 wherein the balloon is non-compliant  
2 and wherein the device further comprises apparatus for applying sufficient  
3 negative pressure to the balloon to cause it to assume the collapsed  
4 configuration.

1 117. A device according to claim 116 wherein the apparatus for applying  
2 sufficient negative pressure to the balloon comprises a port to which a  
3 negative pressure source may be connected to apply negative pressure to the  
4 balloon.

1 118. A device according to claim 107 wherein the handpiece, dilator  
2 advancement control and dilator expansion control are constructed such that  
3 the operator may grasp the handpiece, operate the dilator advancement  
4 control and operate the dilator expansion control with one hand.

1 119. A device according to claim 107 wherein the shaft has a proximal  
2 portion and a distal portion, the distal portion being more flexible than the  
3 proximal portion.

1 120. A device according to claim 107 wherein at least a portion of the shaft  
2 is malleable.

1 121. A device according to claim 107 wherein the dilator is located on an  
2 elongate member that is advanceable out of the distal end of the shaft, said

3 elongate member having a distal portion and a proximal portion, the distal  
4 portion of said elongate member being more flexible than the proximal portion  
5 of said elongate member.

1 122. A device according to claim 121 further comprising a guidewire tip that  
2 extends distal to the dilator.

1 123. A device according to claim 122 wherein the guidewire tip is  
2 substantially fixed.

1 124. A method for modifying the ostium of or other passageway leading into  
2 a paranasal sinus of a human or animal subject, said method comprising the  
3 steps of:

4 A) providing a guide wire having a distal end and an anchoring  
5 member at or near its distal end;

6 B) advancing the guidewire through the ostium or passageway and  
7 into the paranasal sinus such that the anchoring member is located within the  
8 paranasal sinus;

9 C) using the anchoring member to anchor the guidewire in the  
10 paranasal sinus;

11 D) advancing at least one working device over the guidewire to a  
12 position with the ostium or passageway to be modified; and

13 E) using said at least one working device to modify the ostium or  
14 passageway.

1 125. A method according to claim 124 wherein the anchoring member  
2 comprises a balloon and wherein Step C comprises inflating the balloon.

1 126. A method according to claim 125 wherein Step C comprises i) inflating  
2 the balloon and then ii) pulling the guidewire in the proximal direction to cause  
3 the balloon to become anchored.

1 127. A method for adapting a device that is insertable into the body of a  
2 human or animal subject to render that device useable in conjunction with a  
3 navigation system such that the navigation system may determine the location  
4 of the device within the subject's body, said method comprising the steps of:

5 A) providing a working device having a proximal portion that  
6 remains outside of the subject's body, a distal portion that is insertable into  
7 the subject's body and a reference location on said distal portion;

8 B) providing an adapter that is attachable to the proximal portion of  
9 the working device, said adapter comprising, or being attachable to, a  
10 navigation module that is useable by a navigation system to determine the  
11 position of the reference location within the subject's body;

12 C) attaching the adapter to the proximal portion of the working  
13 device; and

14 D) inserting the distal portion of the working device into the  
15 subject's body; and

16 E) using a navigation system in conjunction with the navigation  
17 module to determine the position of the reference location within the subject's  
18 body.

1 128. A method according to claim 127 wherein the navigation module is  
2 integrated into or mounted on the adapter before the adapter is attached to  
3 the working device.

1 129. A method according to claim 128 wherein the adapter is constructed to  
2 permit attachment of a navigation module to the adapter and wherein the  
3 method further comprises the step of attaching the navigation module to the  
4 adaptor.

1 130. A method according to claim 127 further comprising the step of  
2 calibrating or registering the reference location with the navigation system.

1 131. A method for inserting a device into a target ostium, passageway or  
2 other anatomical location within an ear, nose, throat or paranasal sinus of a  
3 human or animal subject, said method comprising the steps of:

4 A) providing an endoscopic guide system that comprises i) a  
5 tubular guide having a proximal end, a distal end and a lumen that extends  
6 longitudinally therethrough and ii) an endoscopic device incorporated in or  
7 attached to the tubular guide;

8 B) trans-nasally inserting the endoscopic guide system;

9 C) using the endoscopic device to guide the placement of the distal  
10 end of the tubular guide within or near the target ostium, passageway or other  
11 anatomical location; and

12 D) advancing the device through the lumen of the tubular guide and  
13 into the target ostium, passageway or other anatomical location.

1 132. A method according to claim 131 wherein the device comprises a  
2 guidewire and wherein Step D comprises advancing a guidewire through the  
3 lumen of the tubular guide and into the target ostium, passageway or other  
4 anatomical location.

1 133. A method according to claim 132 further comprising the step of:

2 E) advancing another device over the guidewire.

1 134. A method according to claim 132 wherein the endoscopic device  
2 comprises an endoscope that is attached to or integrated with the tubular  
3 guide and wherein Step C comprises obtaining a visual image through the  
4 endoscope.

1 135. A method according to claim 132 wherein the endoscopic device  
2 comprises a periscope or waveguide apparatus having a proximal end that is  
3 adapted to be coupled to a separate endoscope and wherein Step C  
4 comprises coupling an endoscope to the proximal end of the endoscopic  
5 device.

1 136. A method for dilating an ostium, passageway or other anatomical  
2 structure within an ear, nose, throat or paranasal sinus of a human or animal  
3 subject, said method comprising the steps of:

4 A) providing a dilation device that comprises i) a handpiece; ii) an  
5 elongate shaft attached to and extending from the handpiece; iii) a dilator  
6 positioned on or advanceable from the shaft, said dilator having a collapsed  
7 configuration and an expanded configuration and iv) a dilator expansion  
8 control on the handpiece useable to control expansion of the dilator, said  
9 handpiece and said dilator expansion control being constructed such that one  
10 hand of a use may be employed to grasp the handpiece and use the dilator  
11 expansion control to expand the dilator;

12 B) grasping the handpiece with one hand;

13 C) inserting the shaft into the subject's ear, nose, throat or  
14 paranasal sinus and positioning the dilator within the ostium, passageway or

15 other anatomical structure to be dilated;

16 D) using the same hand used to grasp the handpiece to operate  
17 the dilator expansion control to cause expansion of the dilator and resultant  
18 dilation of the ostium, passageway or other anatomical structure.

1 137. A method according to claim 136 wherein the device provided in Step  
2 A has a dilator that is advanceable from the distal end of the shaft and a  
3 dilator advancement control for controlling advancement of the dilator from the  
4 distal end of the shaft and wherein the method further comprises the step of:

5 E) using the same hand used to grasp the handpiece and to  
6 operate the dilator expansion control to also operate the dilator advancement  
7 control to cause the dilator to advance from the distal end of the shaft.

1 138. A method according to claim 136 wherein the device provided in Step  
2 A has a dilator that is rotatable and wherein the handpiece further comprises  
3 a dilator rotation control for controlling rotation of the dilator, and wherein the  
4 method further comprises the step of:

5 E) using the same hand used to grasp the handpiece and to  
6 operate the dilator expansion control to also operate the dilator rotation  
7 control to cause the dilator to rotate.

1 139. A method for dilating an ostium or passageway leading into a  
2 paranasal sinus of a human or animal subject, said method comprising the  
3 steps of:

4 A) providing a device that comprises a tubular member having a  
5 distal end that is sized to pass through the ostium or passageway, a dilator  
6 locate proximal to the distal end and useable to dilate the ostium and a shape  
7 that enables such tubular member to be inserted through a nostril and  
8 advanced to position where its distal end extends through the ostium or  
9 passageway and the dilator is positioned within the ostium or passageway;

10 B) inserting the tubular member through a nostril and advancing

11 the tubular member to a position where its distal end extends through the  
12 ostium or passageway and the dilator is positioned within the ostium or  
13 passageway; and

14 C) expanding the dilator to dilate the ostium or passageway.

1 140. A method according to claim 139 further comprising the step of:

2 D) suctioning through the tubular member.

1 141. A method according to claim 139 further comprising the step of:

2 E) infusing irrigation fluid or a therapeutic substance through the  
3 tubular member.

1 142. A method according to claim 139 wherein the device provided in Step  
2 A further comprises at least one marker for verifying position of the dilator and  
3 wherein the method further comprises the step of:

4 F) verifying the position of the dilator.

1 143. A method for dilating an ostium, passageway or other anatomical  
2 structure within an ear, nose, throat or paranasal sinus of a human or animal  
3 subject, said method comprising the steps of:

4 A) removing or modifying an anatomical or pathological structure  
5 within the ear, nose, throat or paranasal sinus;

6 B) trans-nasally inserting a dilation device and using the dilation  
7 device to dilate the ostium, passageway or other anatomical structure.

1 144. A method according to claim 143 wherein the anatomical structure  
2 removed or modified in Step A is an anatomical structure that, if not removed  
3 or modified, would obstruct direct visualization of the ostium, passageway or

4 other anatomical structure.

1 145. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises the uncinata process.

1 146. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises the uncinata process.

1 147. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises a turbinate.

1 148. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises a wall of at least one ethmoid air cell.

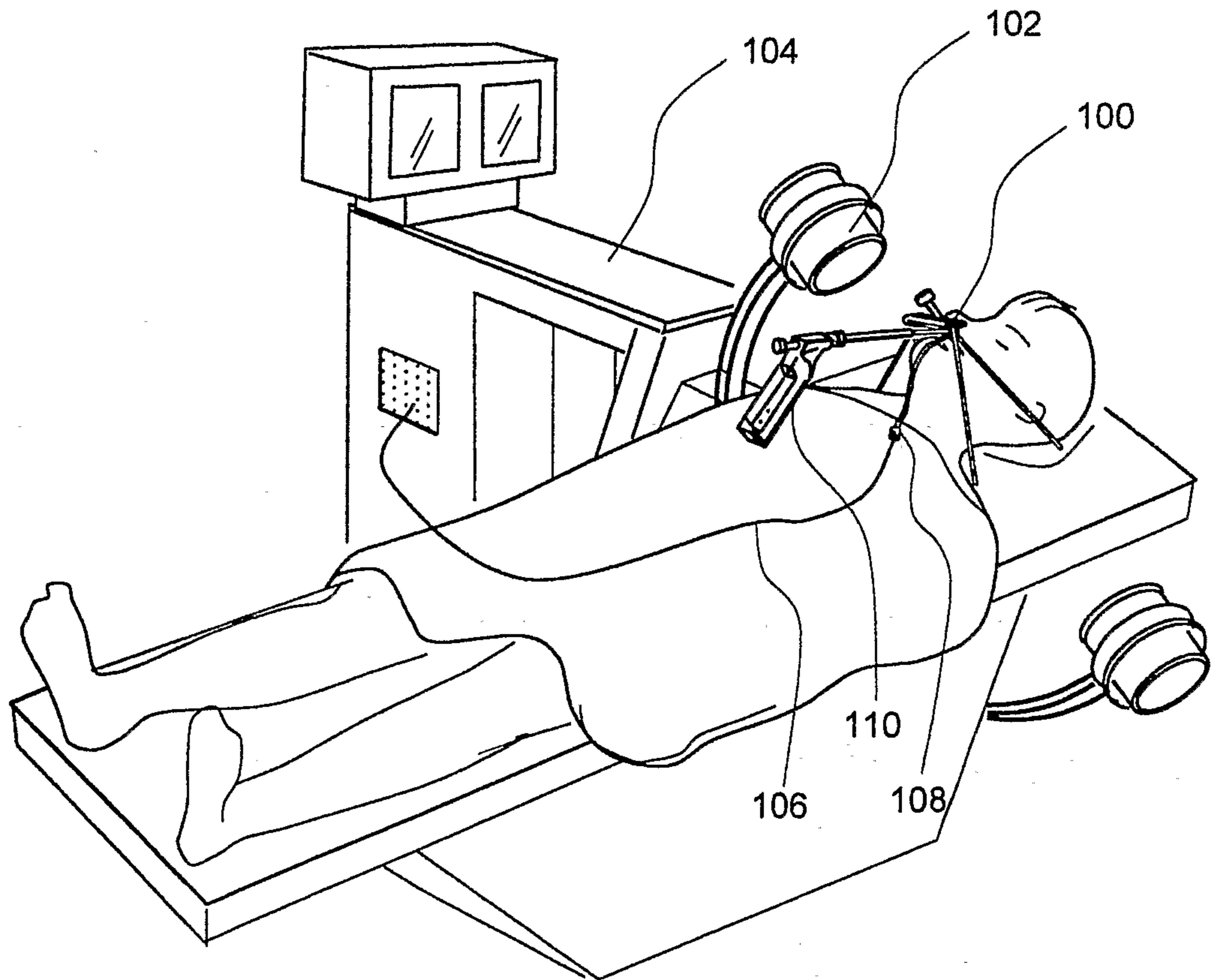
1 149. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises a polyp.

1 150. A method according to claim 143 wherein the structure removed or  
2 modified in Step A comprises scar or adhesion tissue.

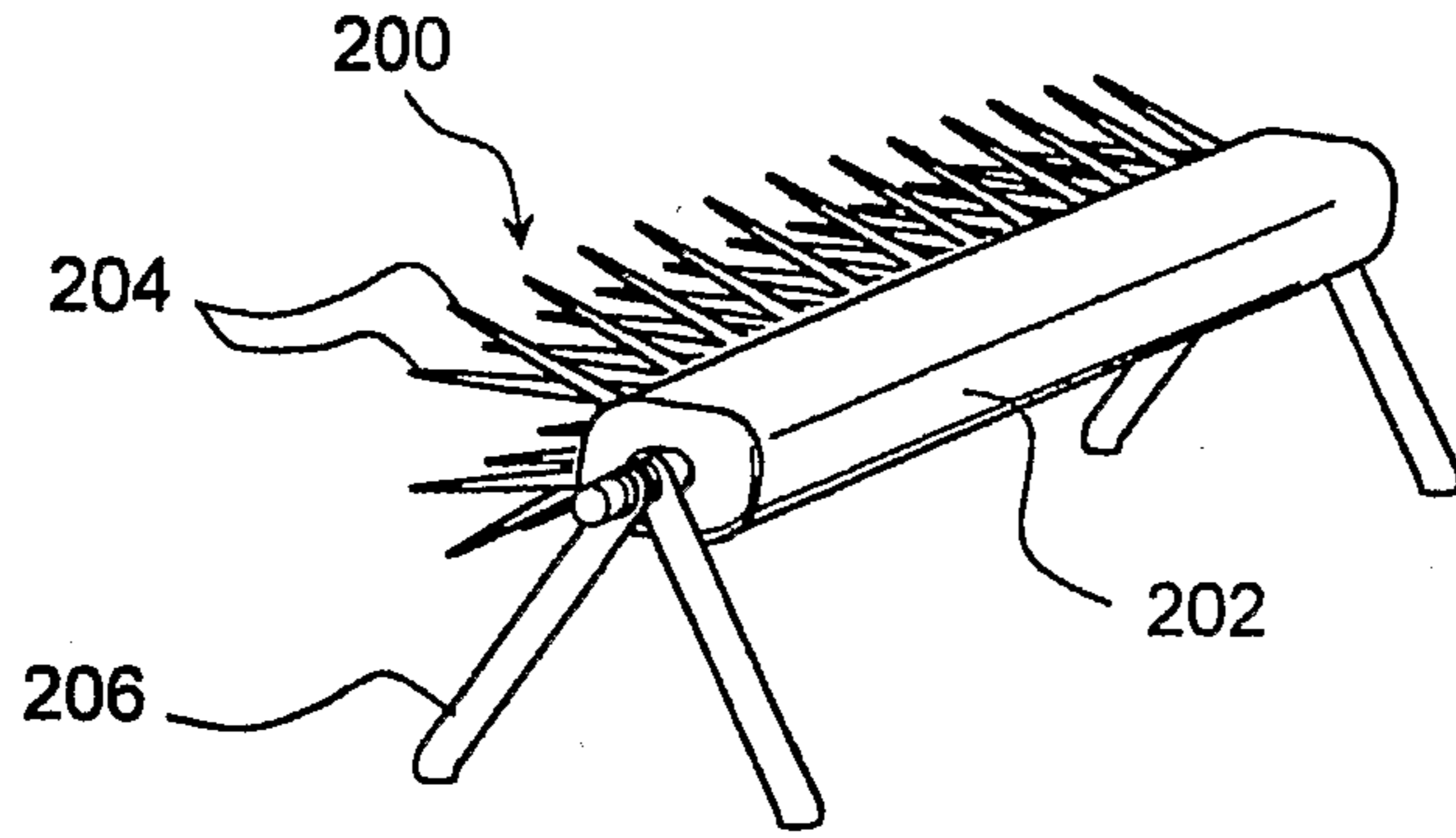
1 151. A method according to claim 143 wherein removal or modification of  
2 the structure in Step A permits visualization of the ostium, passageway or  
3 other anatomical structure after it has been dilated, and wherein the method  
4 further comprises the step of:

5 C) visualizing the ostium, passageway or other anatomical  
6 structure after it has been dilated.

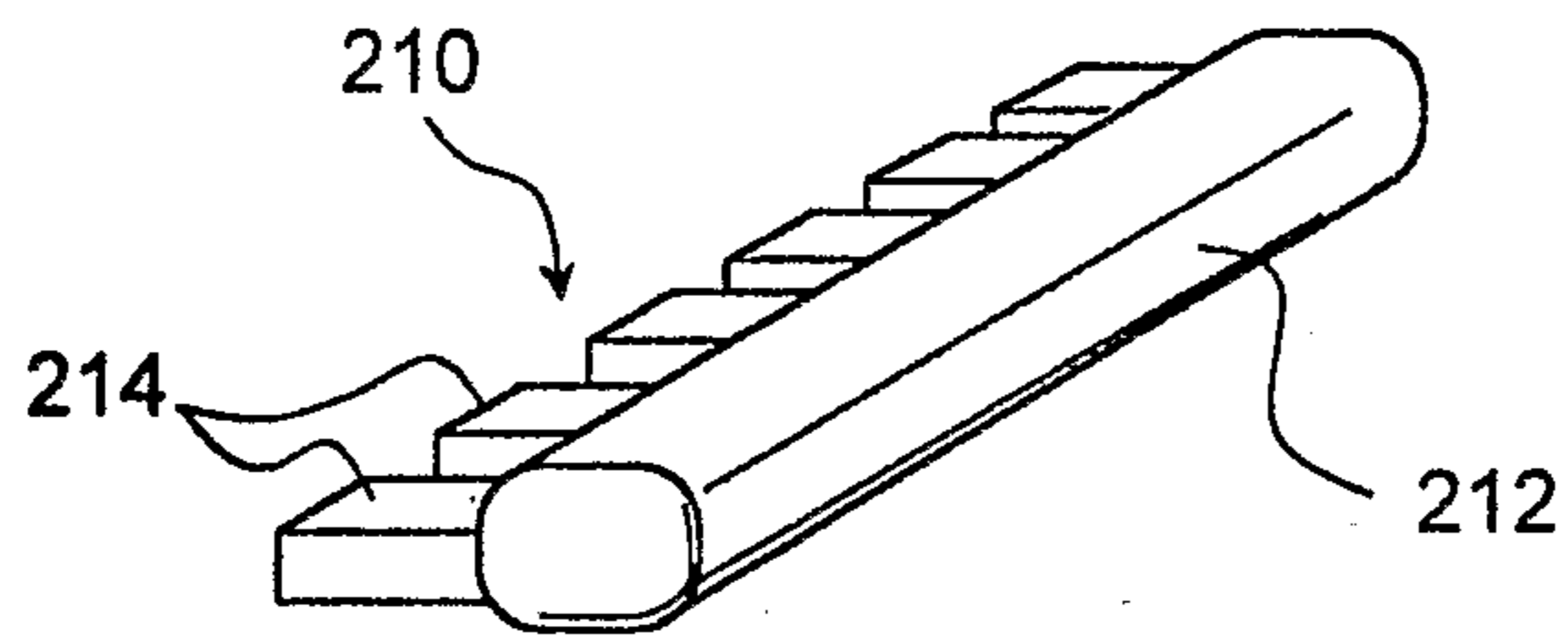




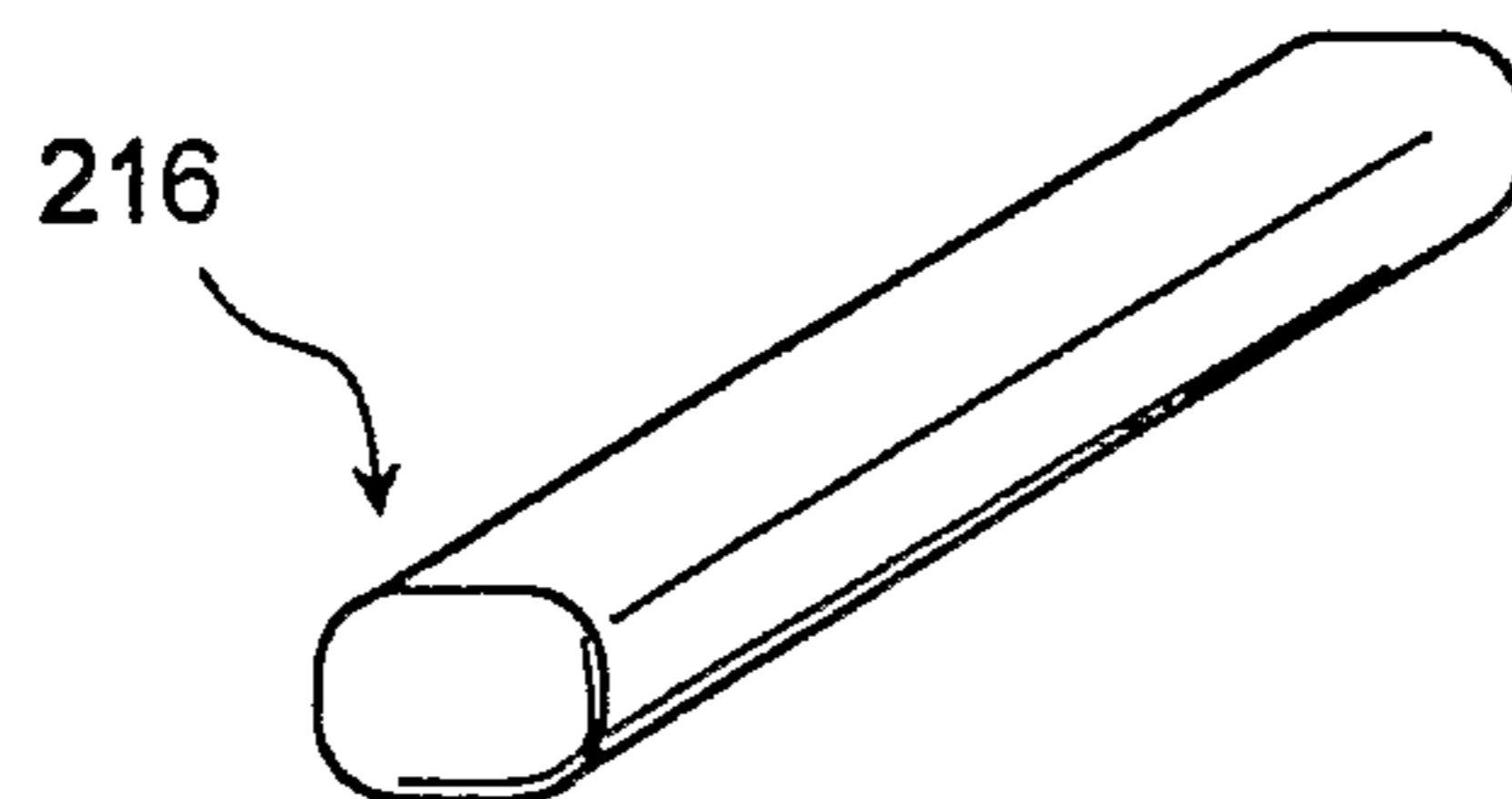
*Fig. 1*



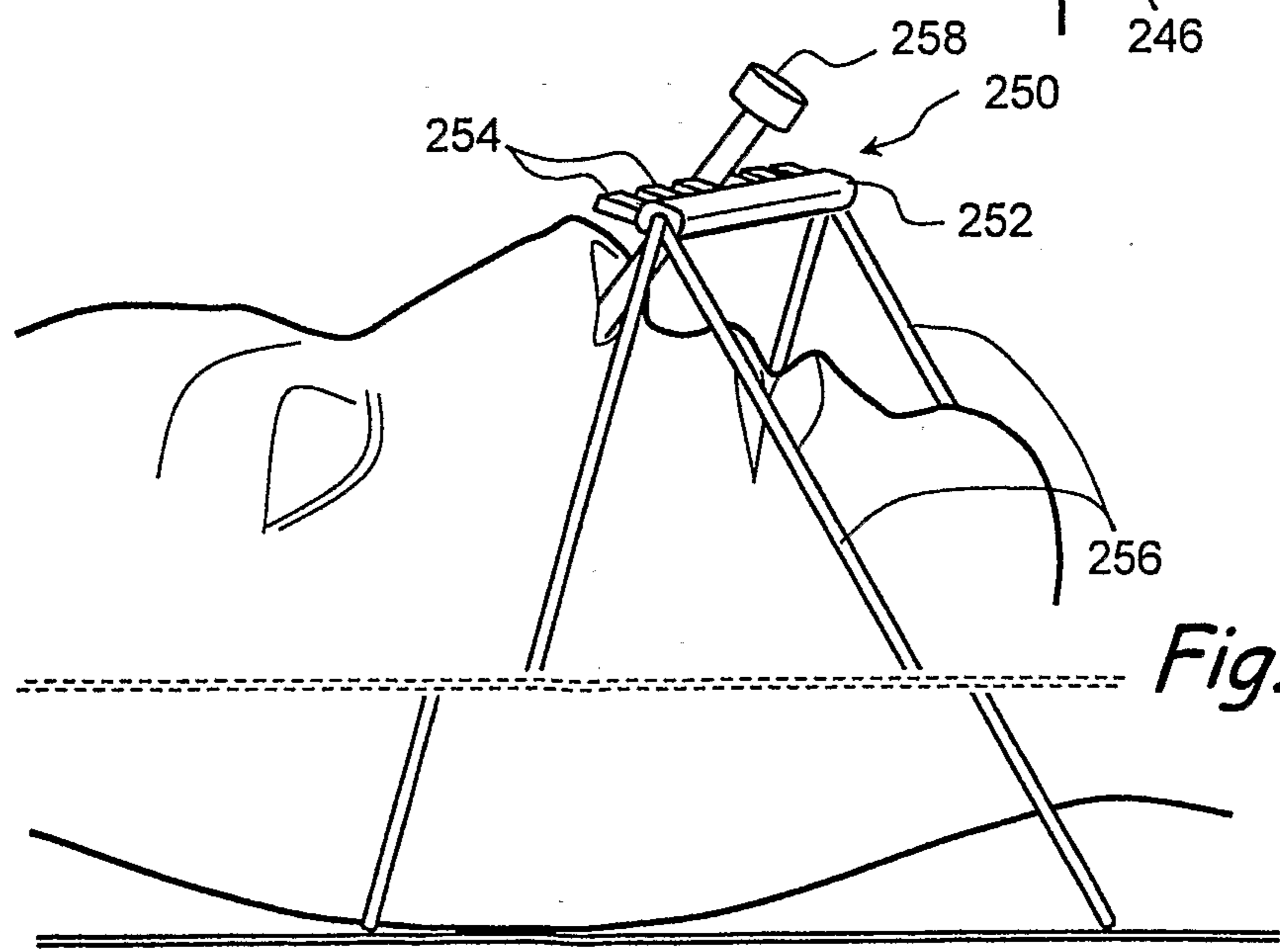
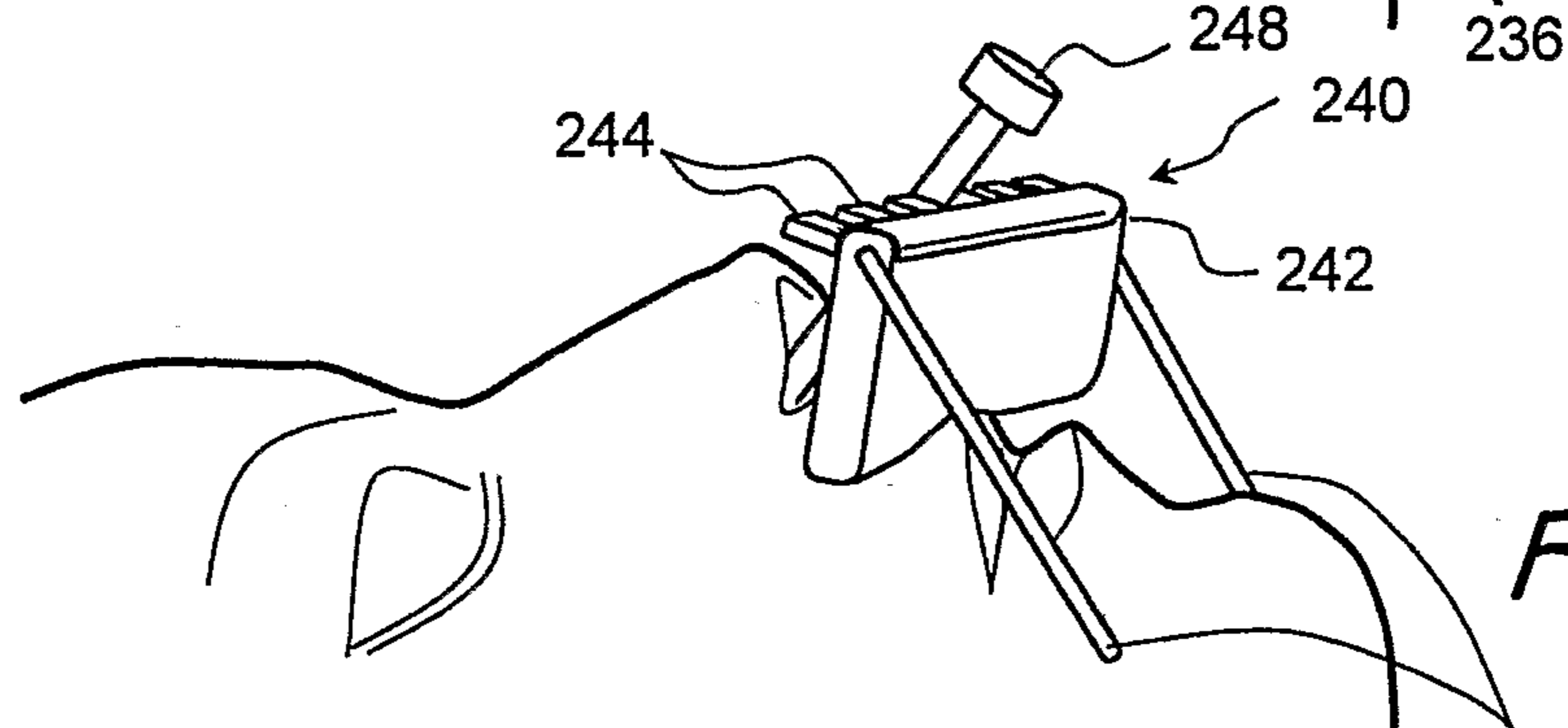
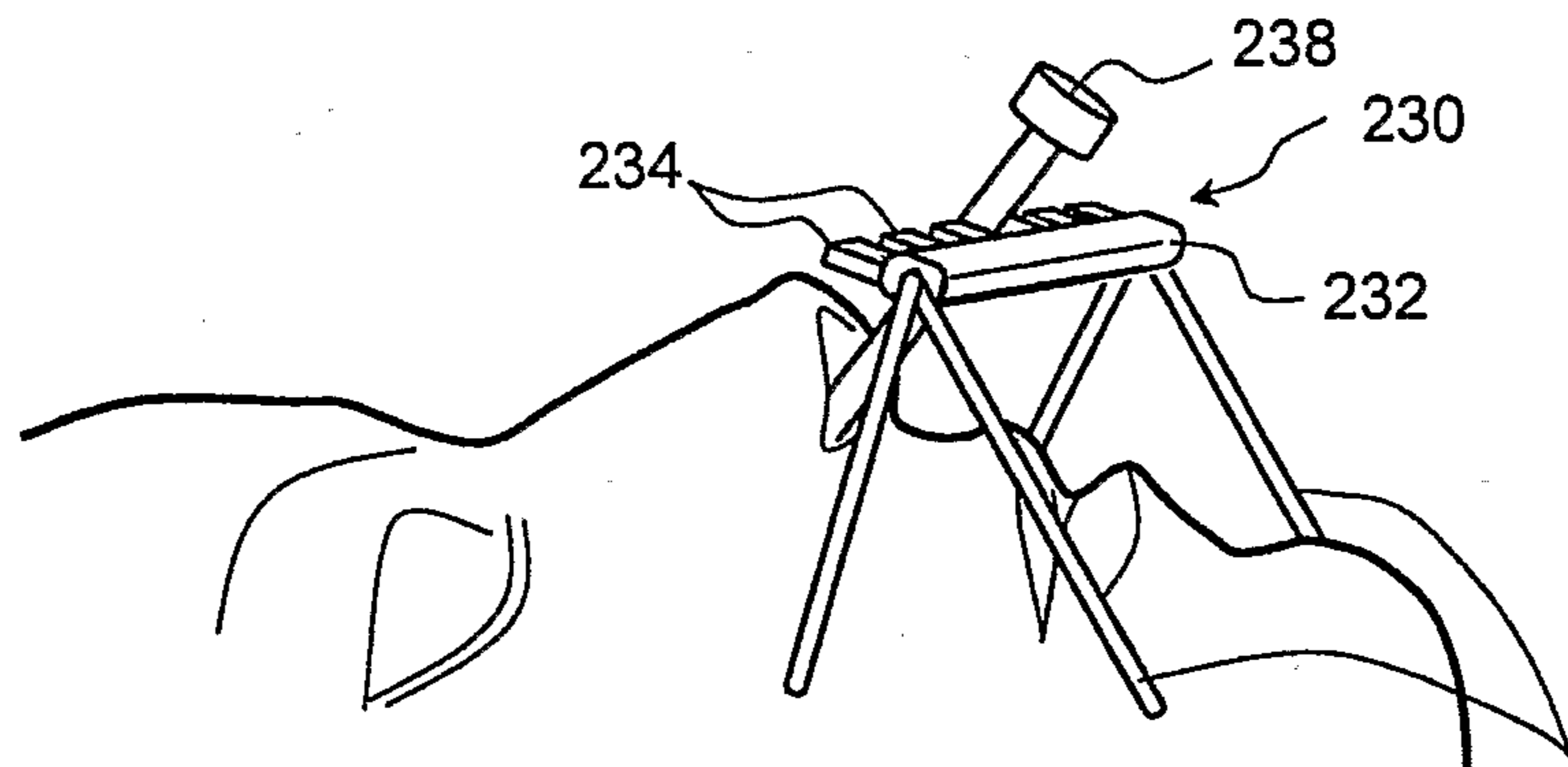
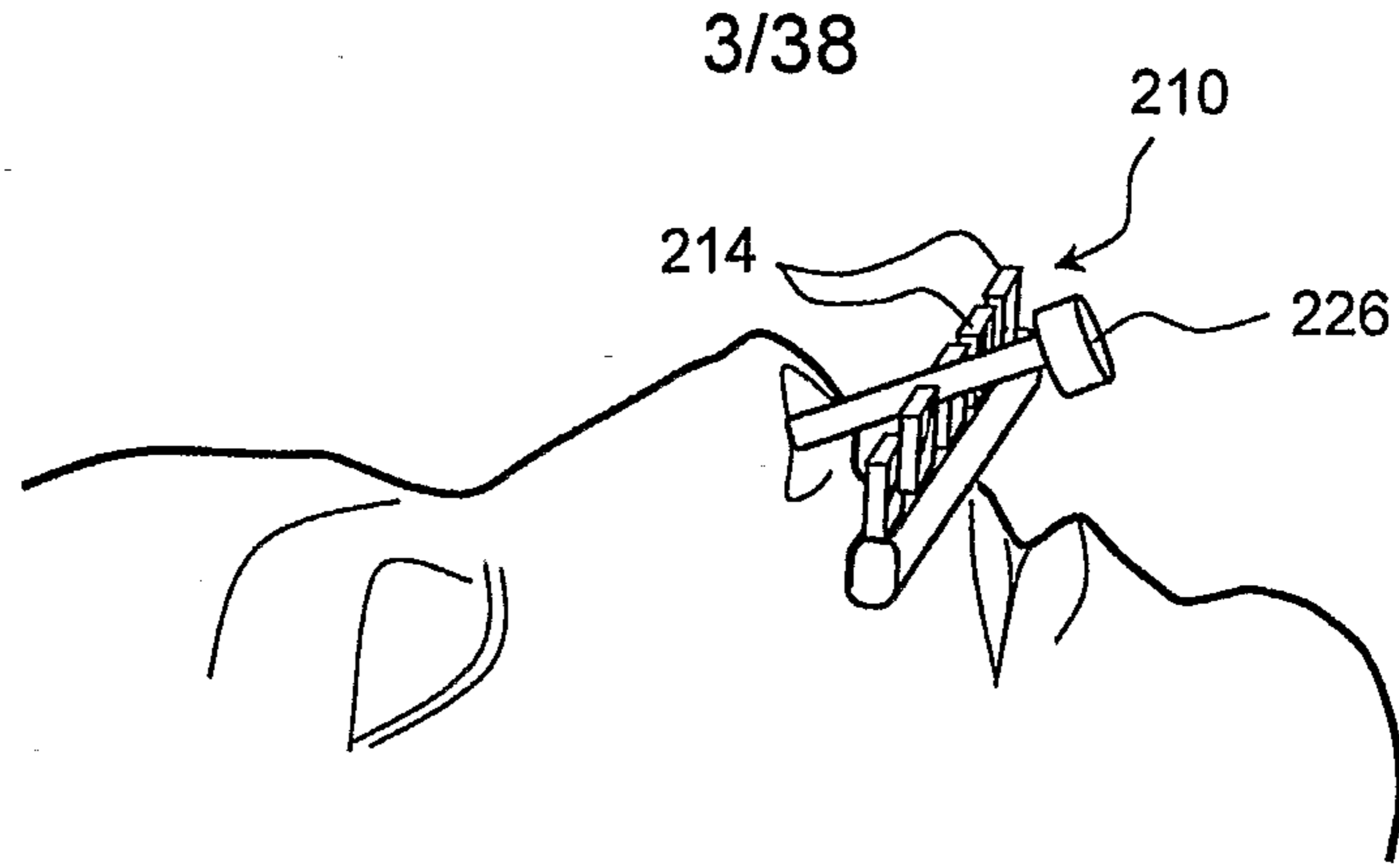
*Fig. 2 A*

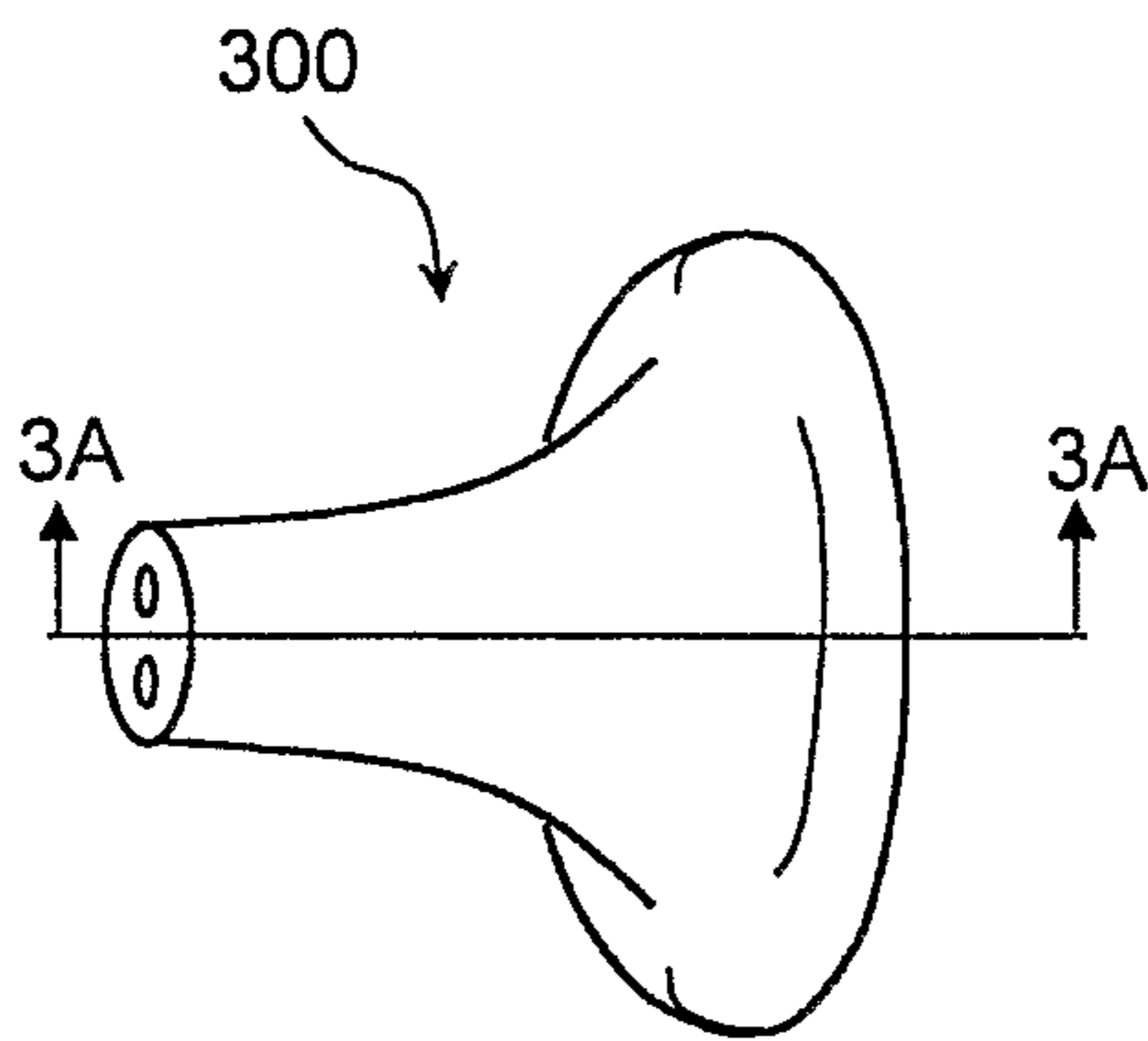


*Fig. 2 B*

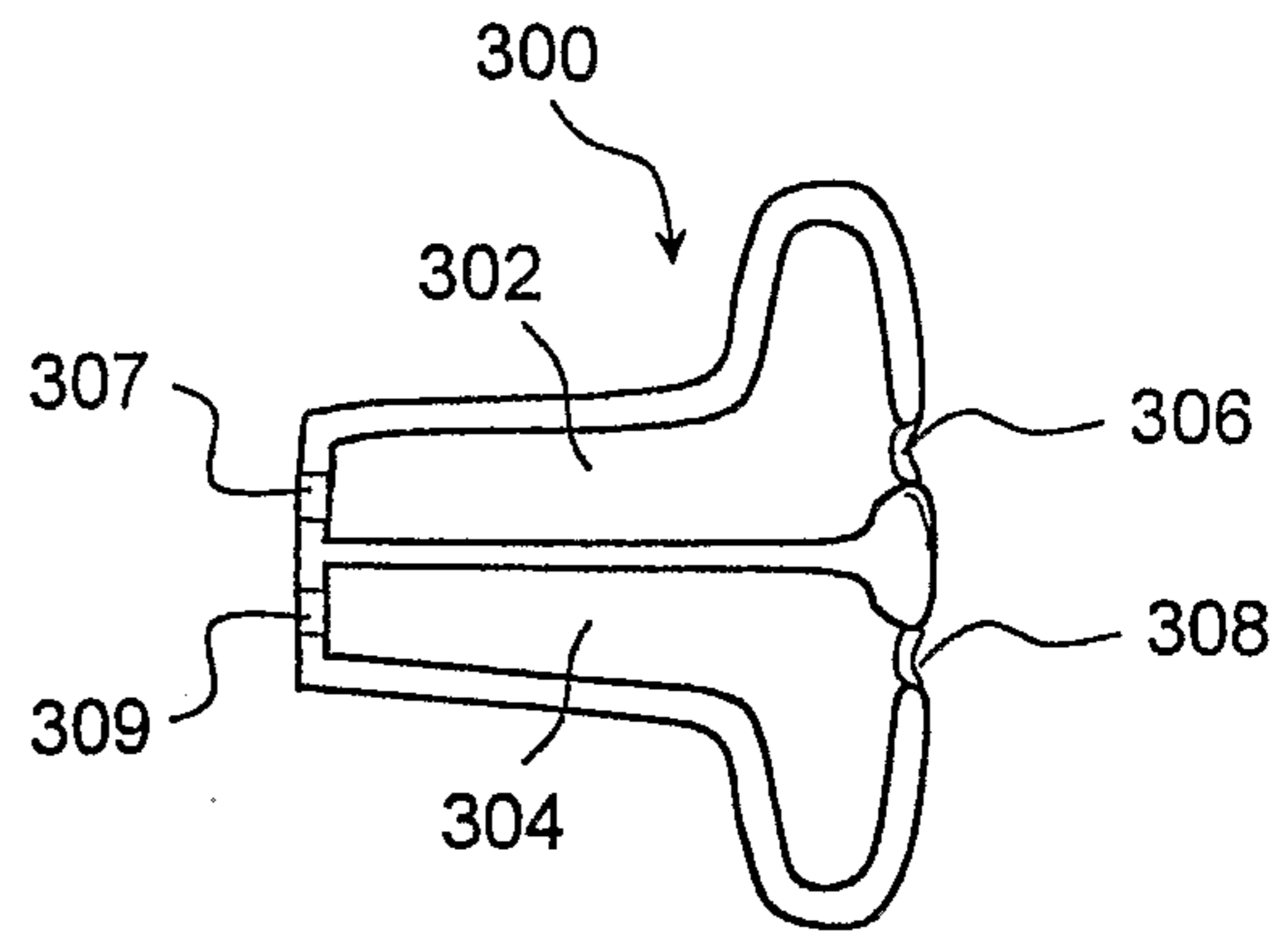


*Fig. 2 C*

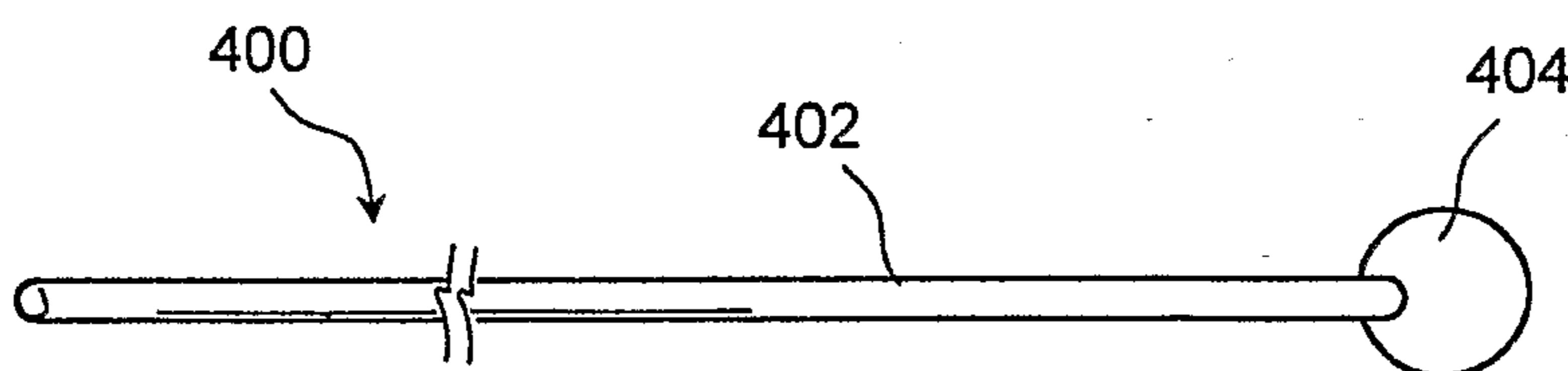




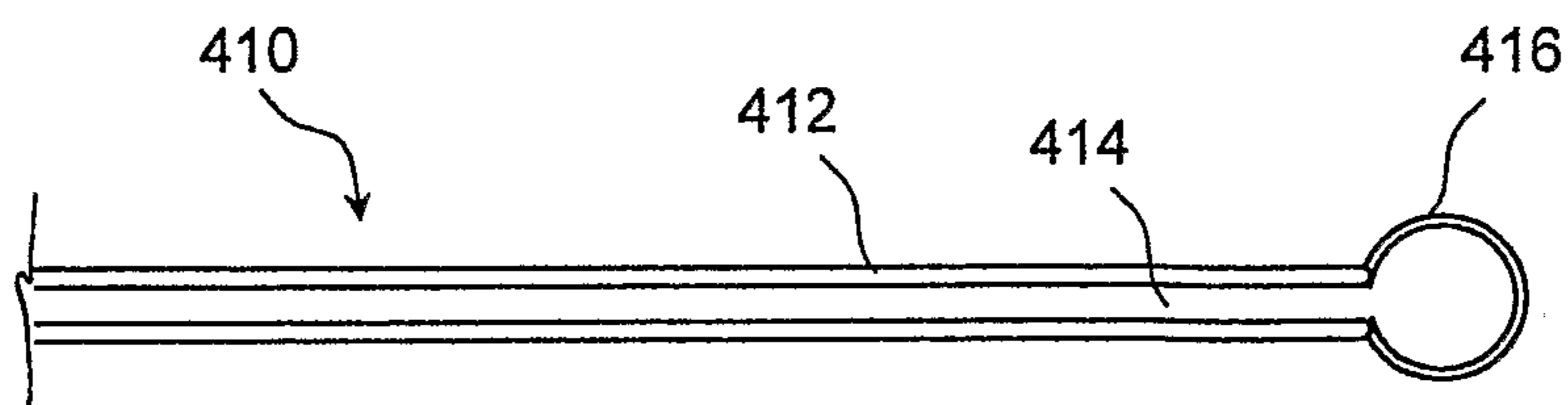
*Fig. 3*



*Fig. 3 A*

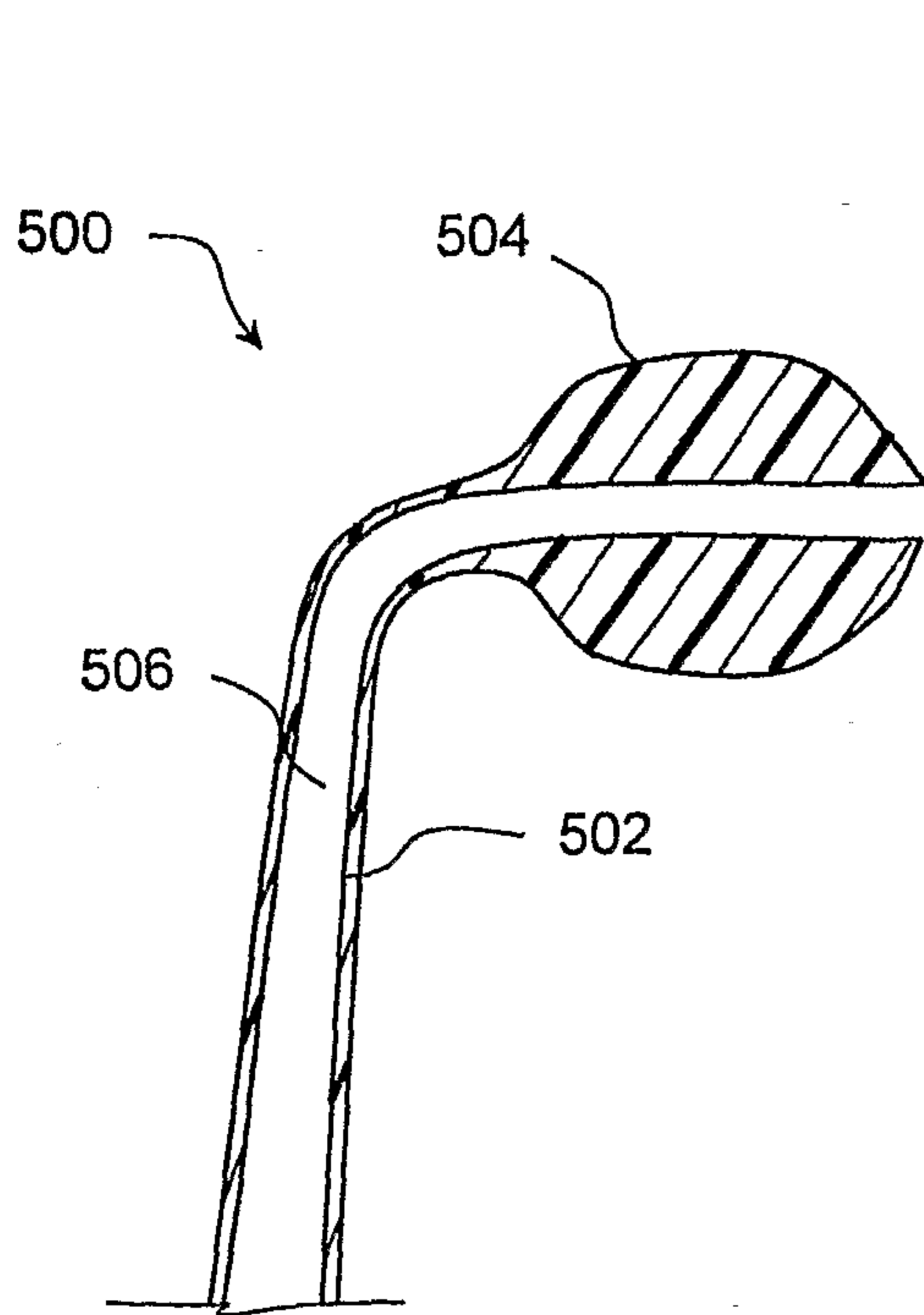


*Fig. 4 A*

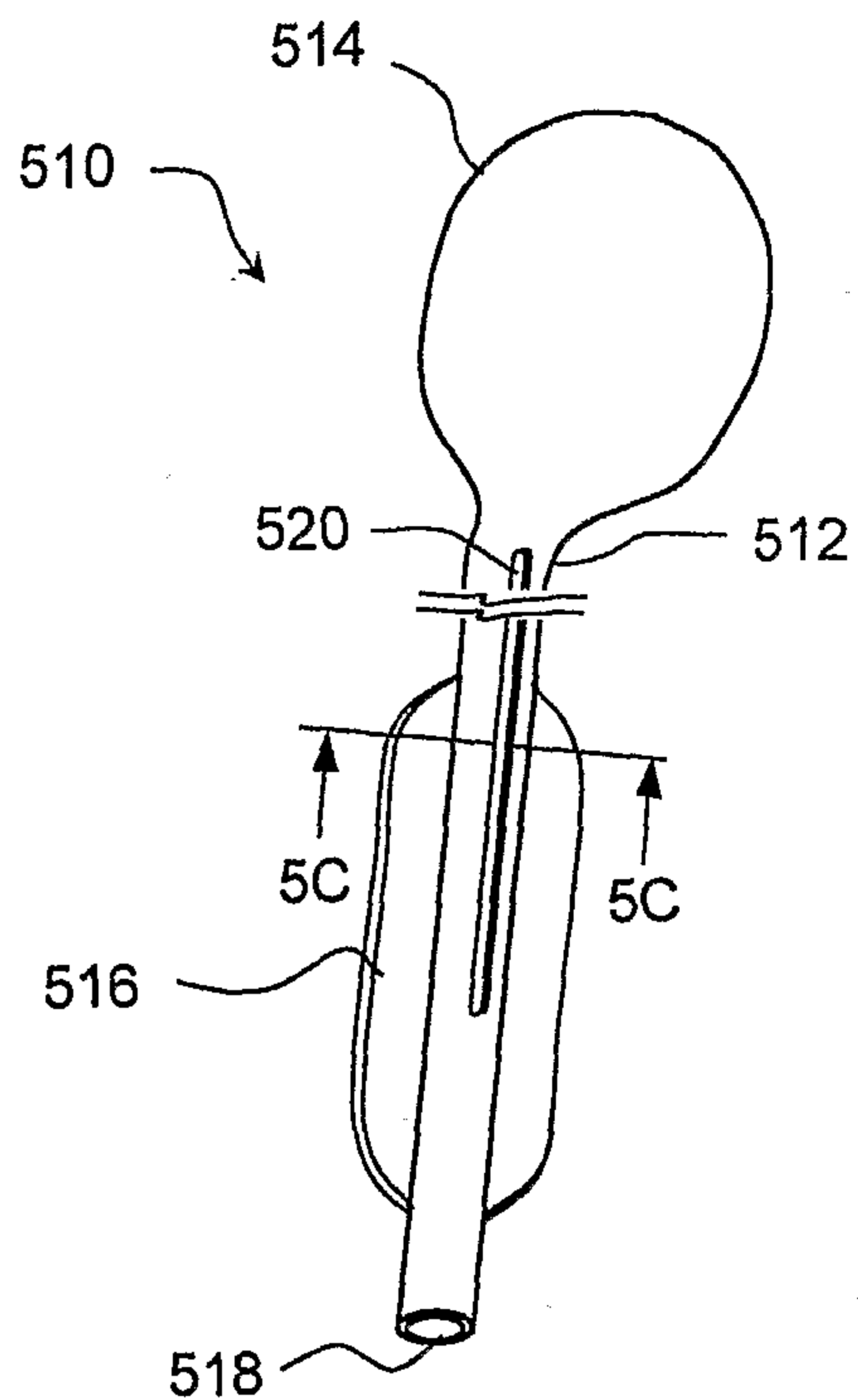


*Fig. 4 B*

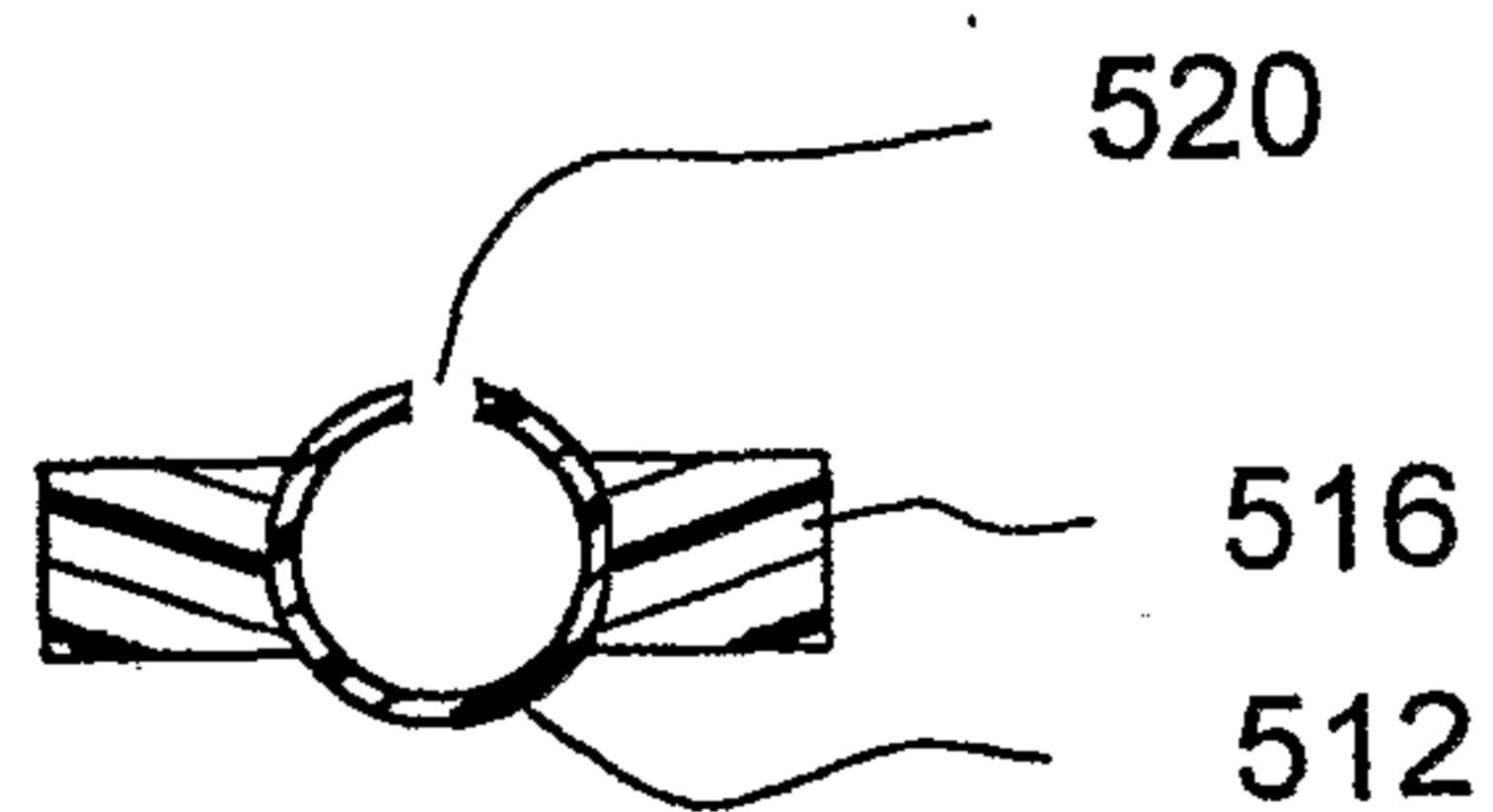
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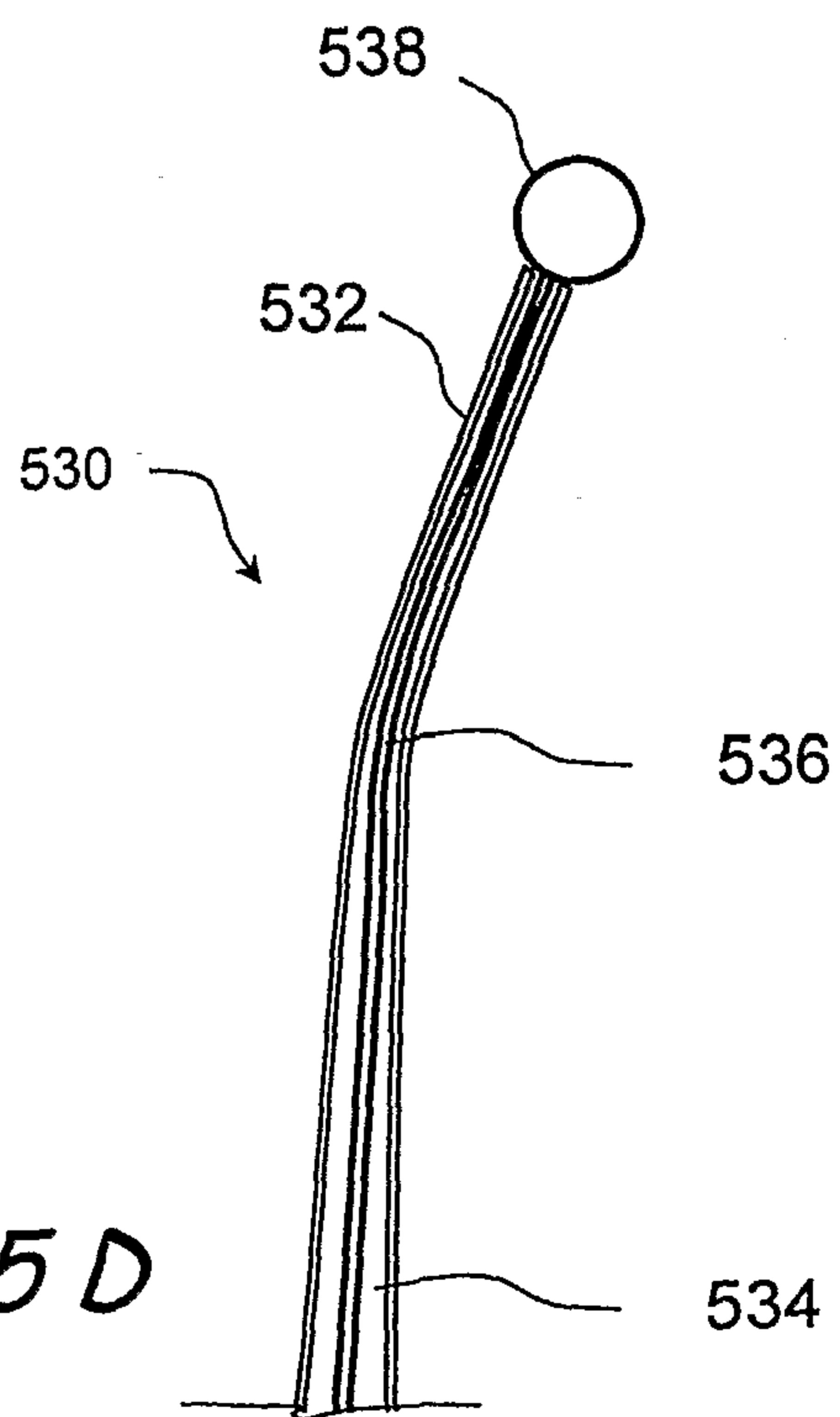
*Fig. 5 A*



*Fig. 5 B*

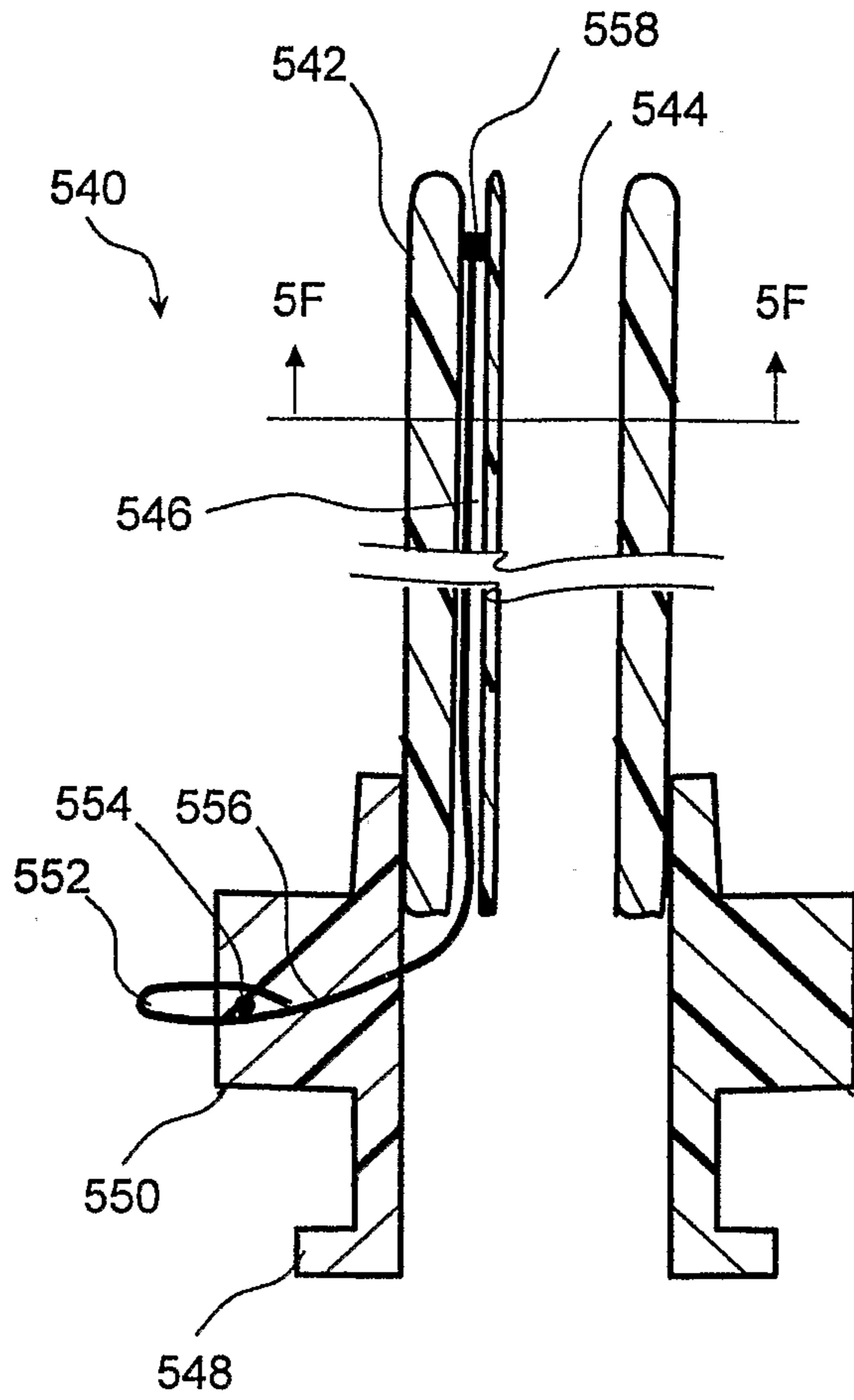


*Fig. 5 C*

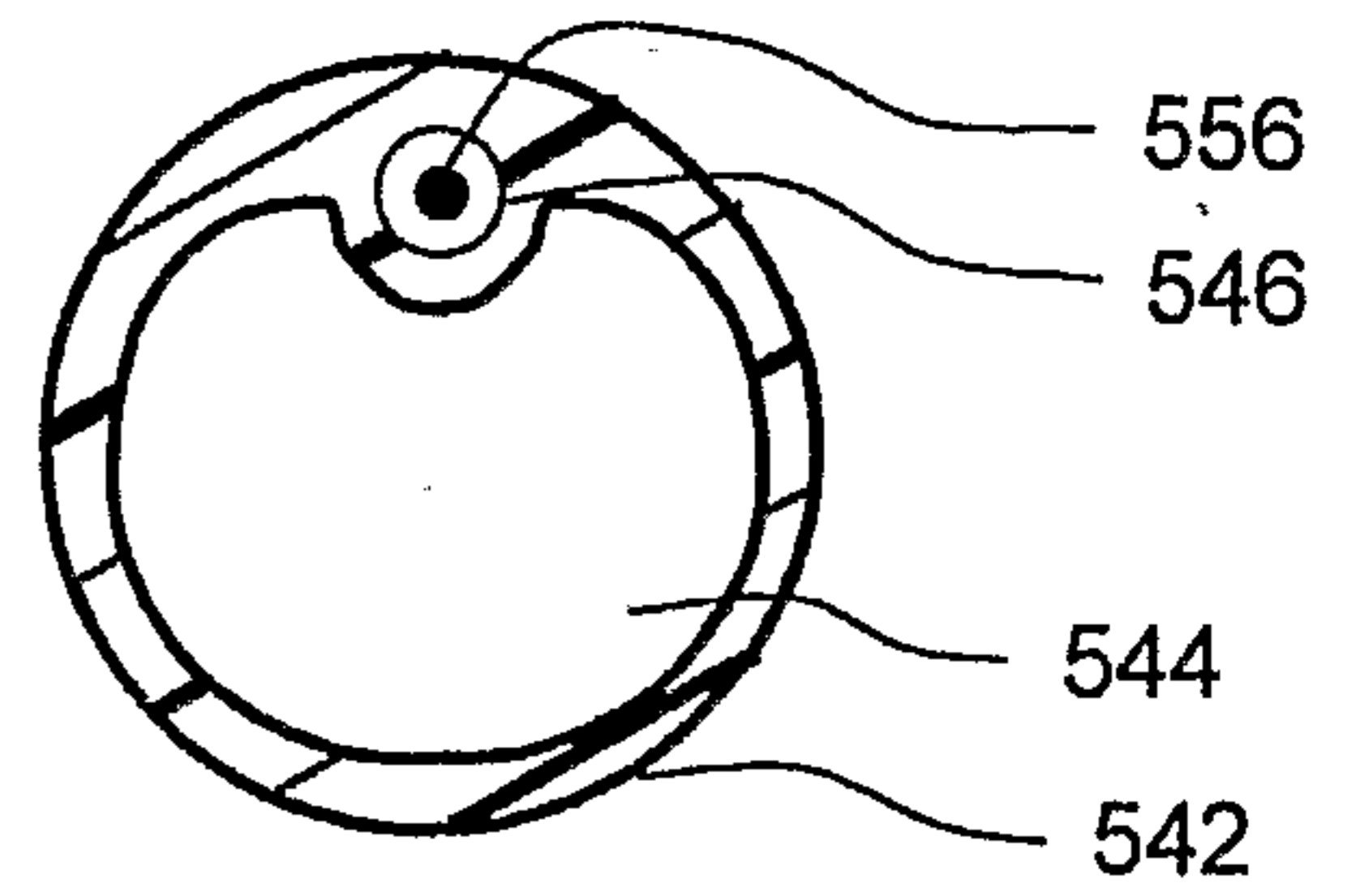


*Fig. 5 D*

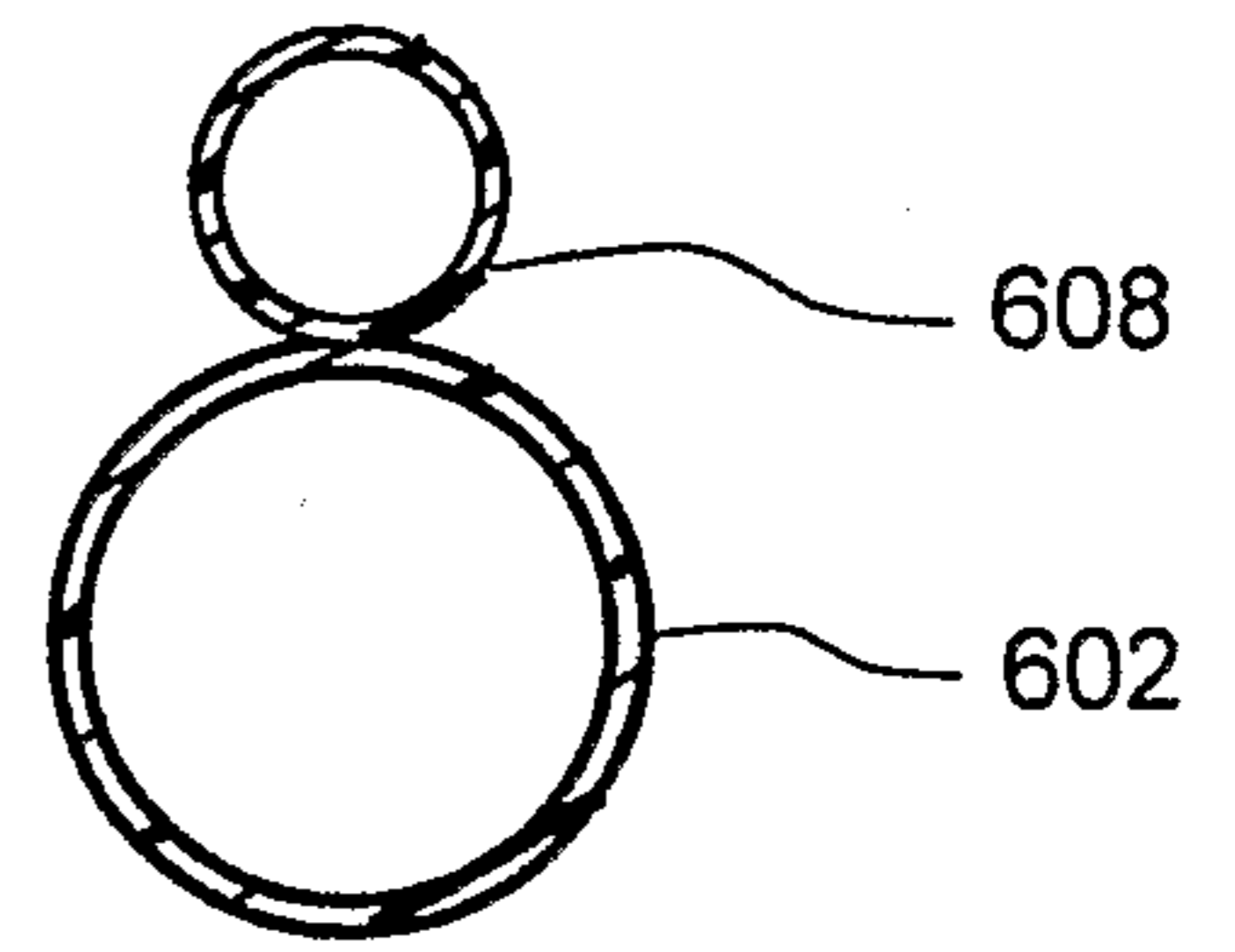
6/38



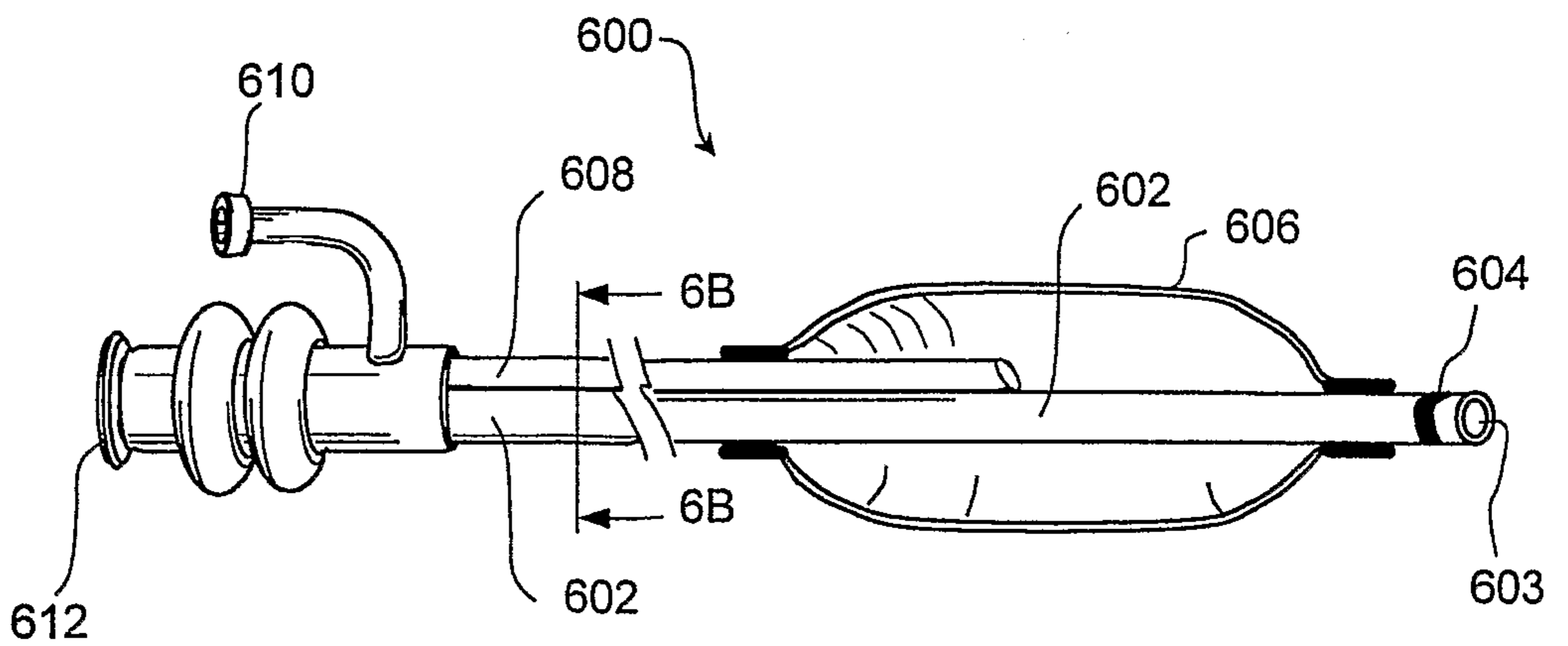
*Fig. 5 E*



*Fig. 5 F*

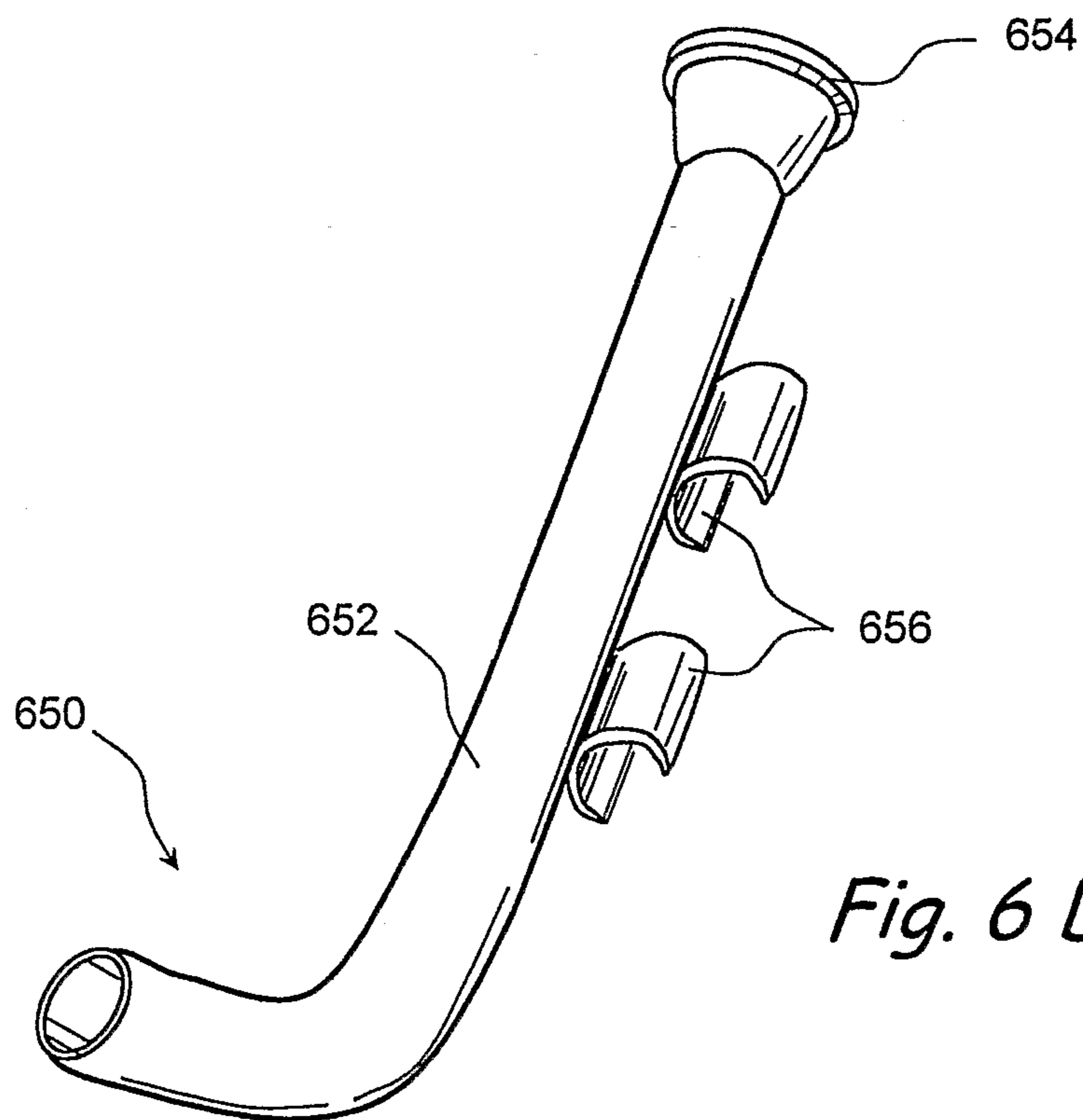
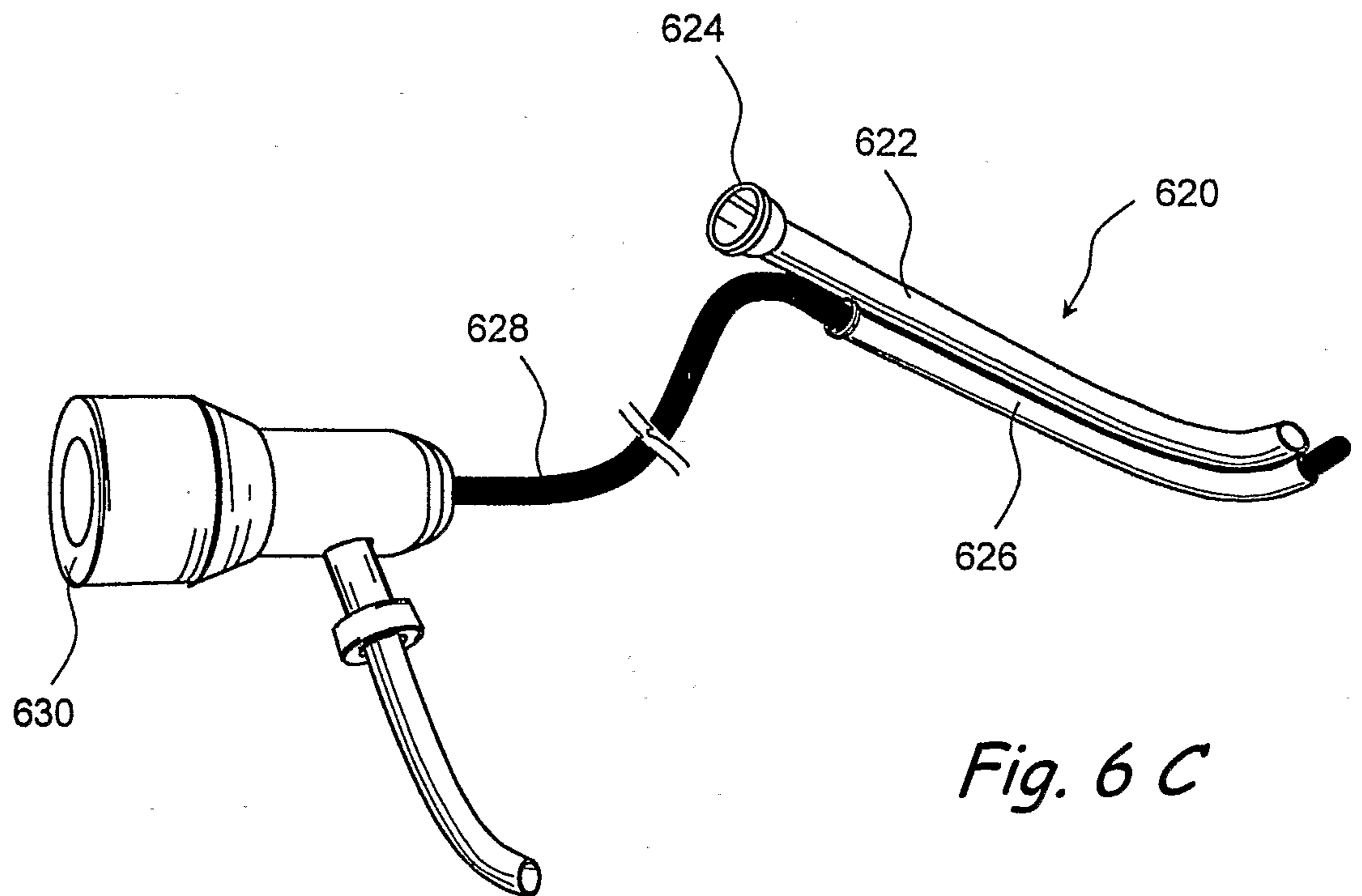


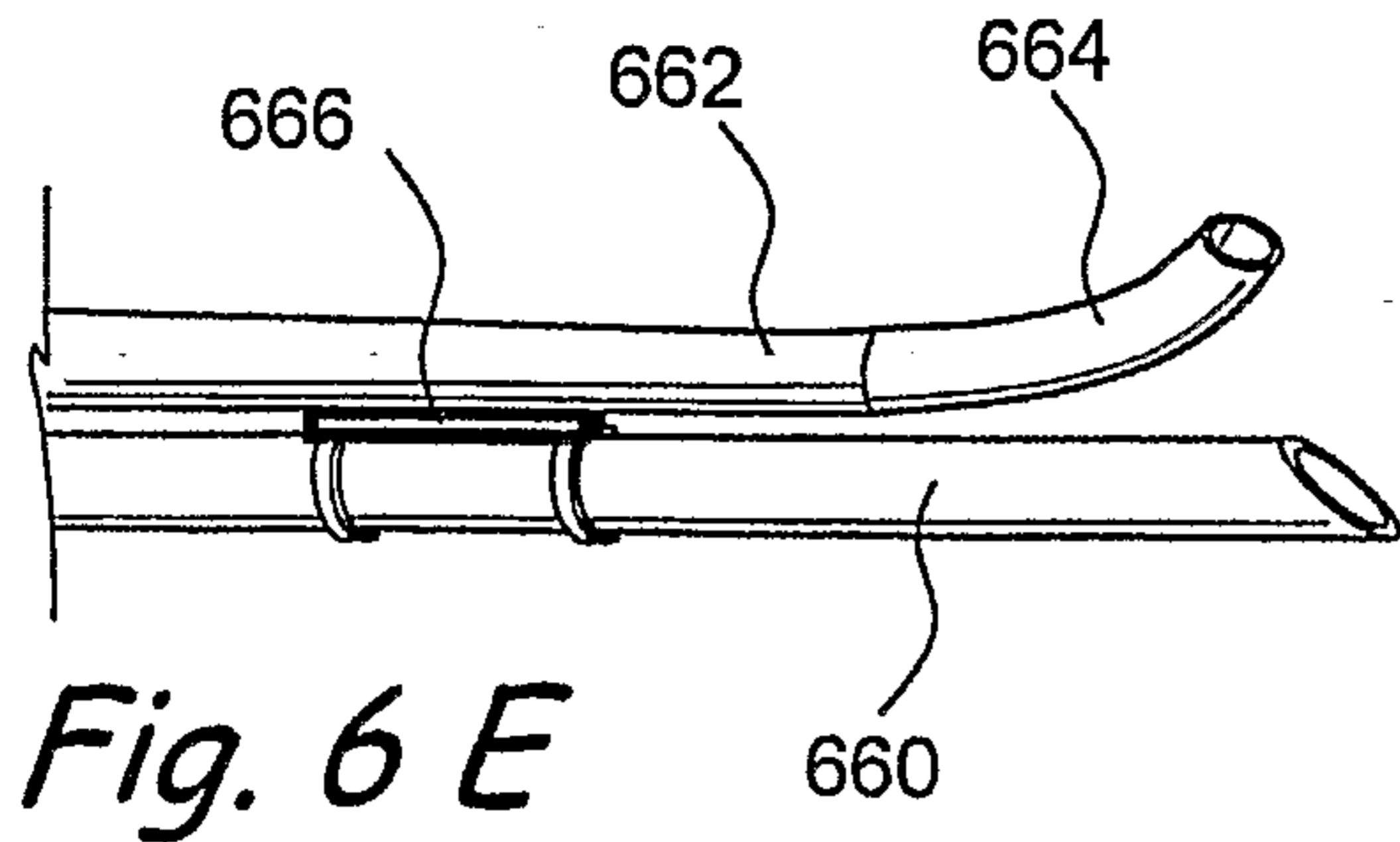
*Fig. 6 B*



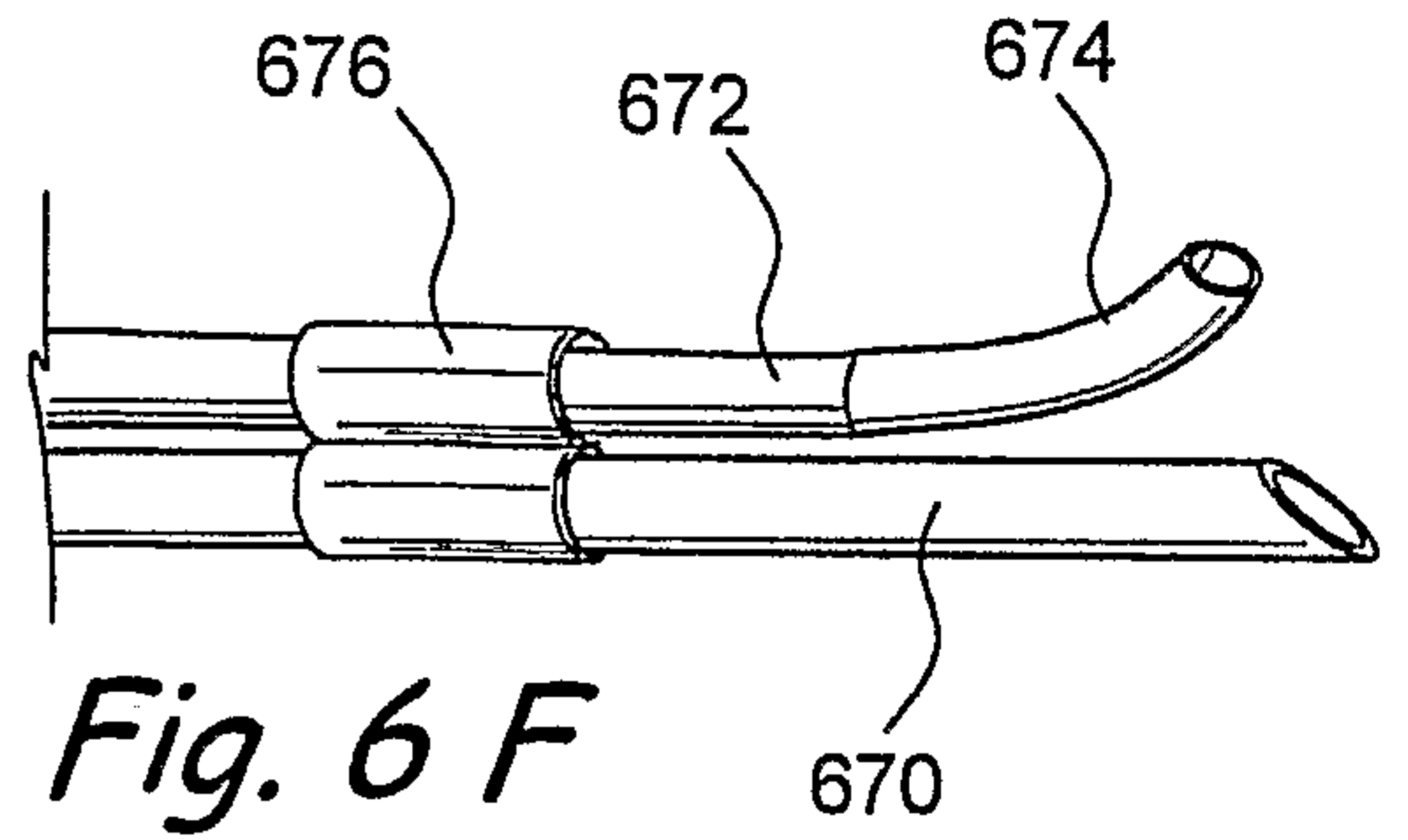
*Fig. 6 A*

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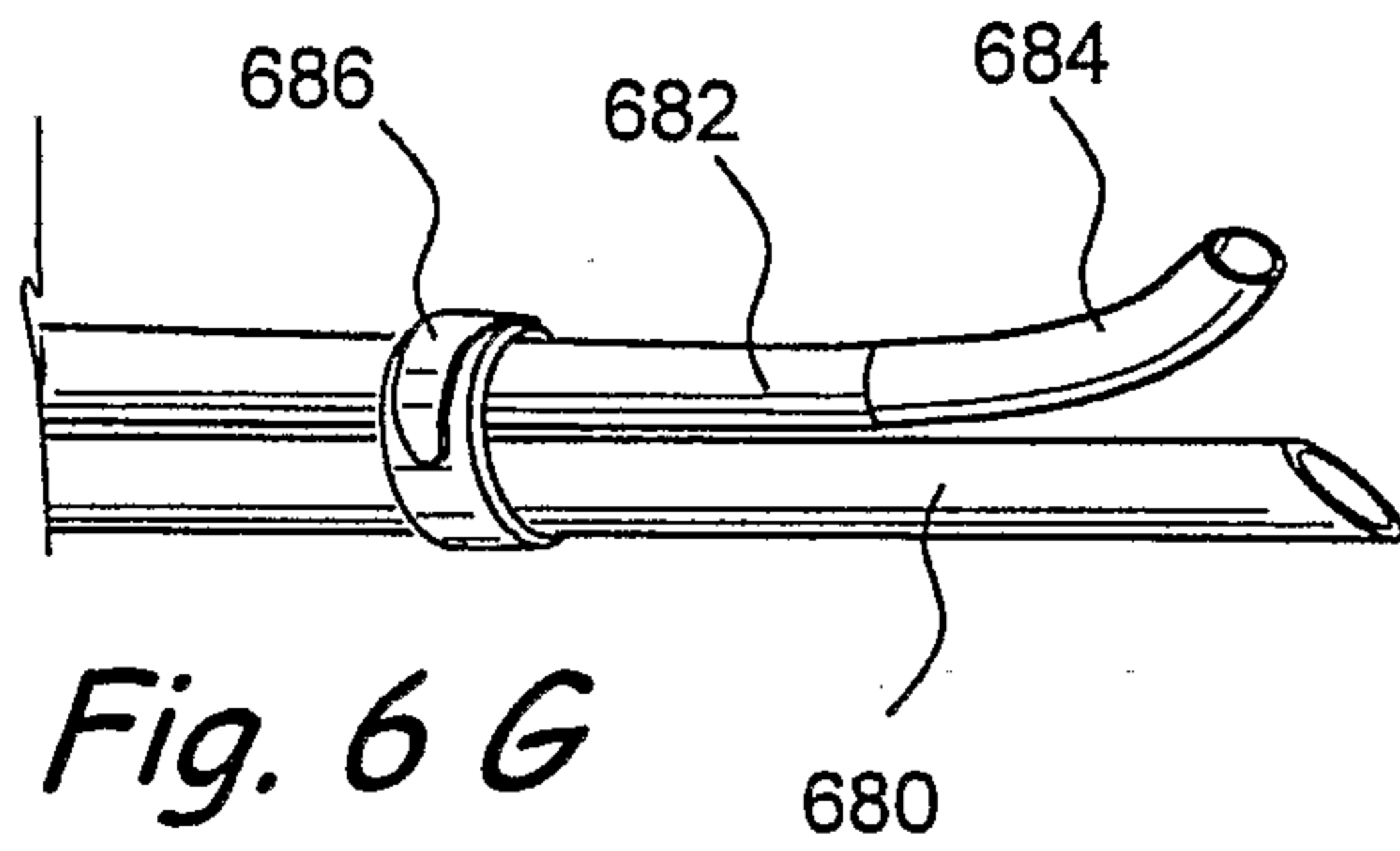




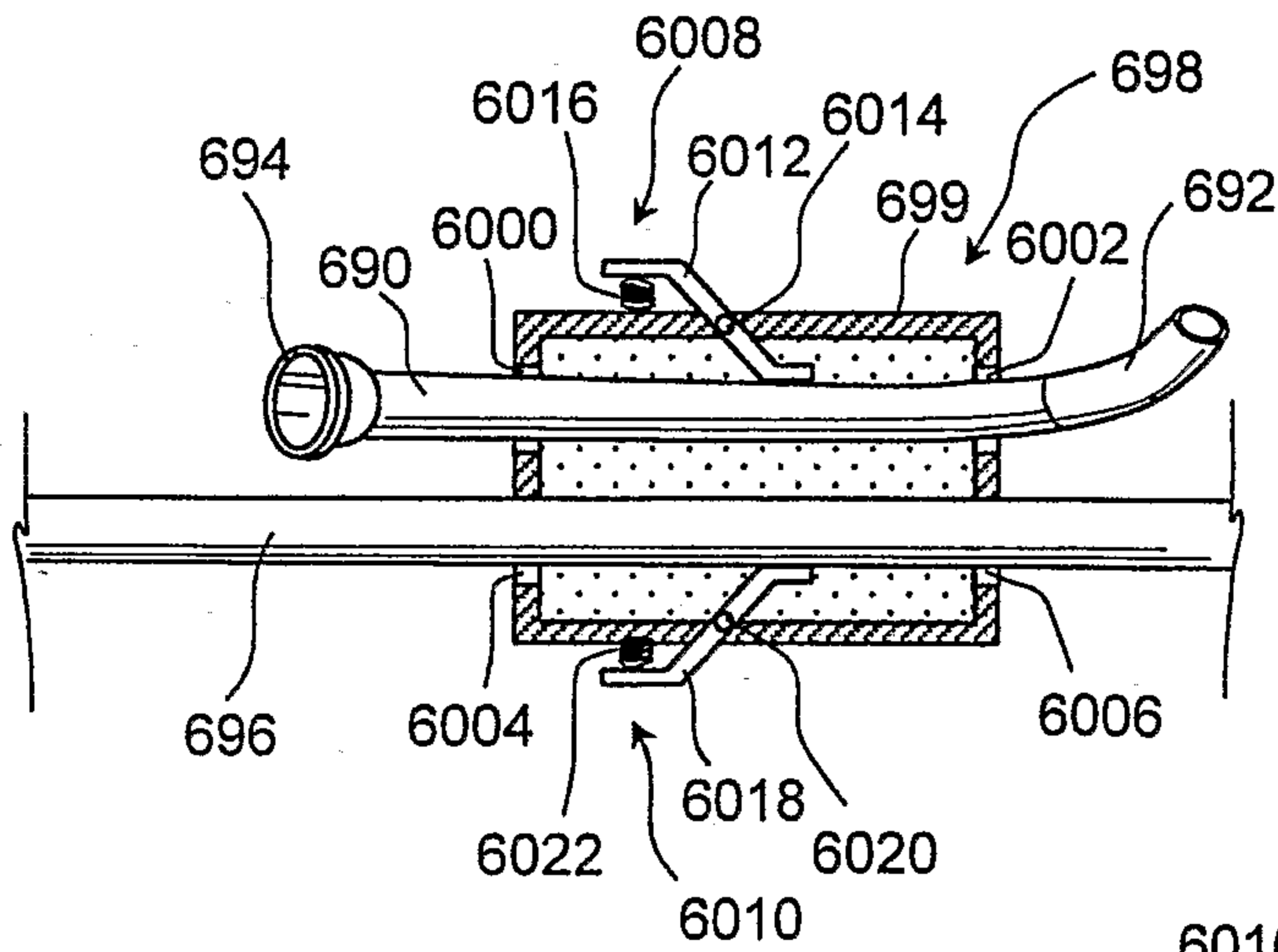
*Fig. 6 E*



*Fig. 6 F*

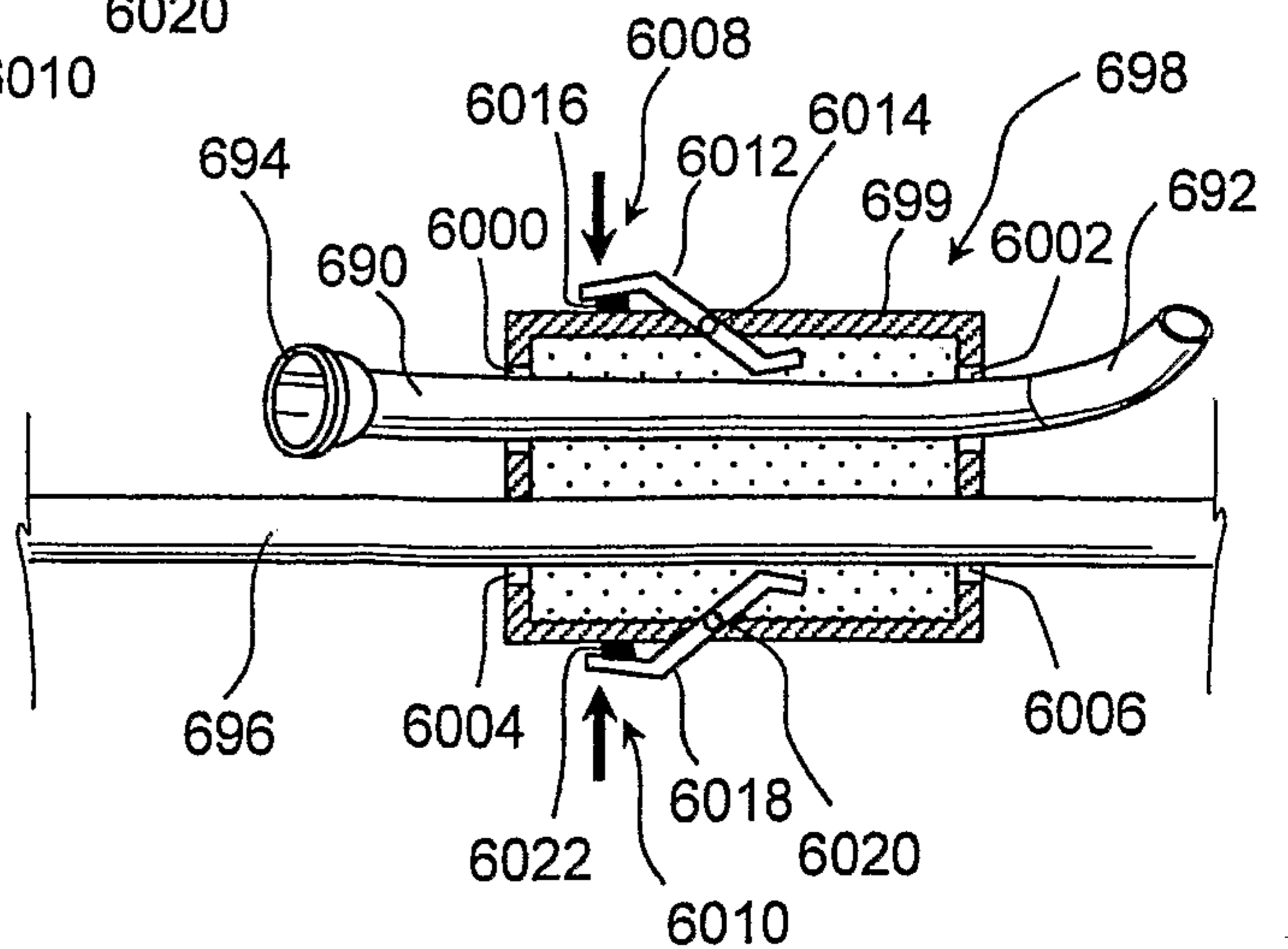


*Fig. 6 G*



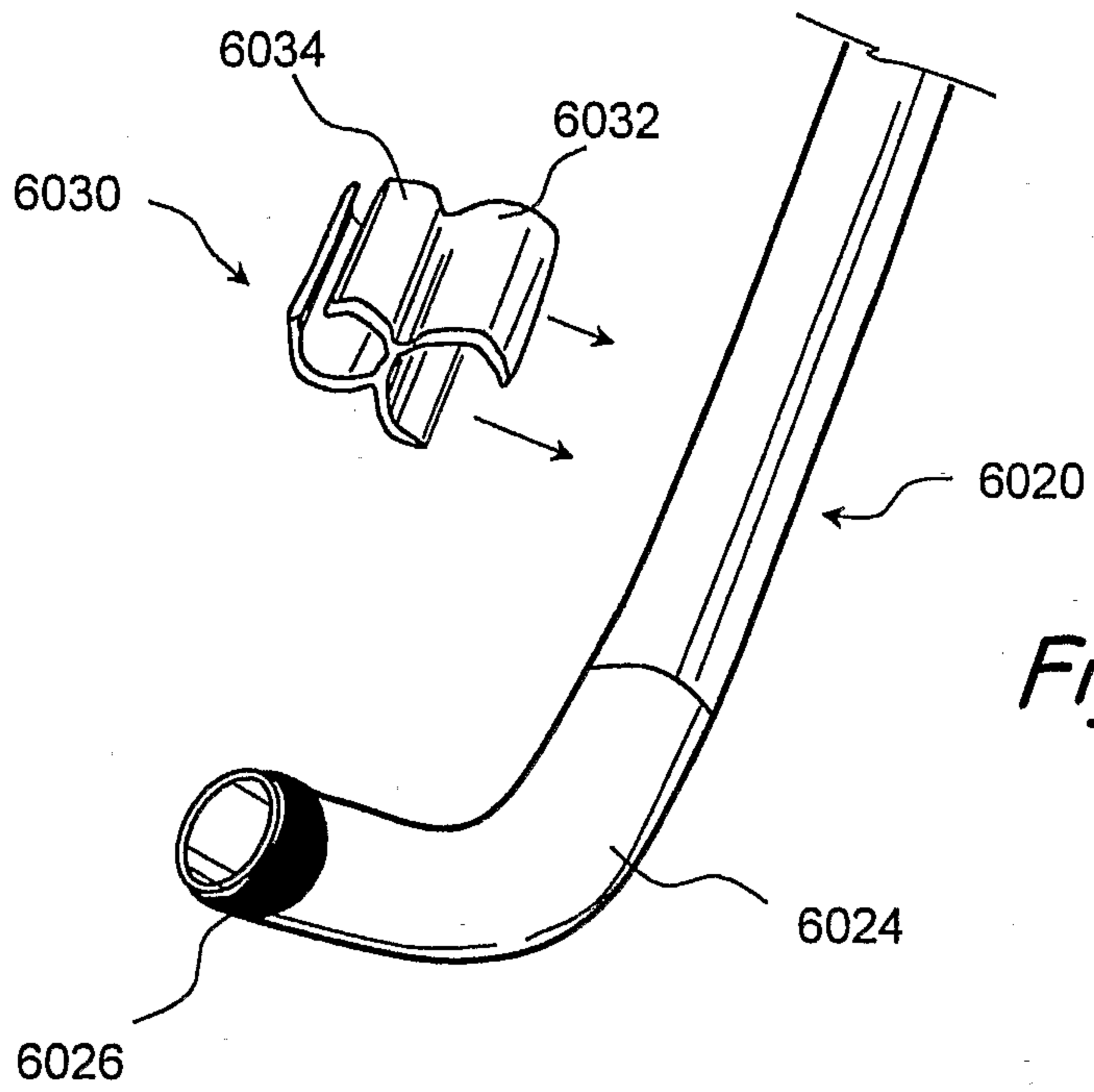
*Fig. 6 H*

*Fig. 6 I*

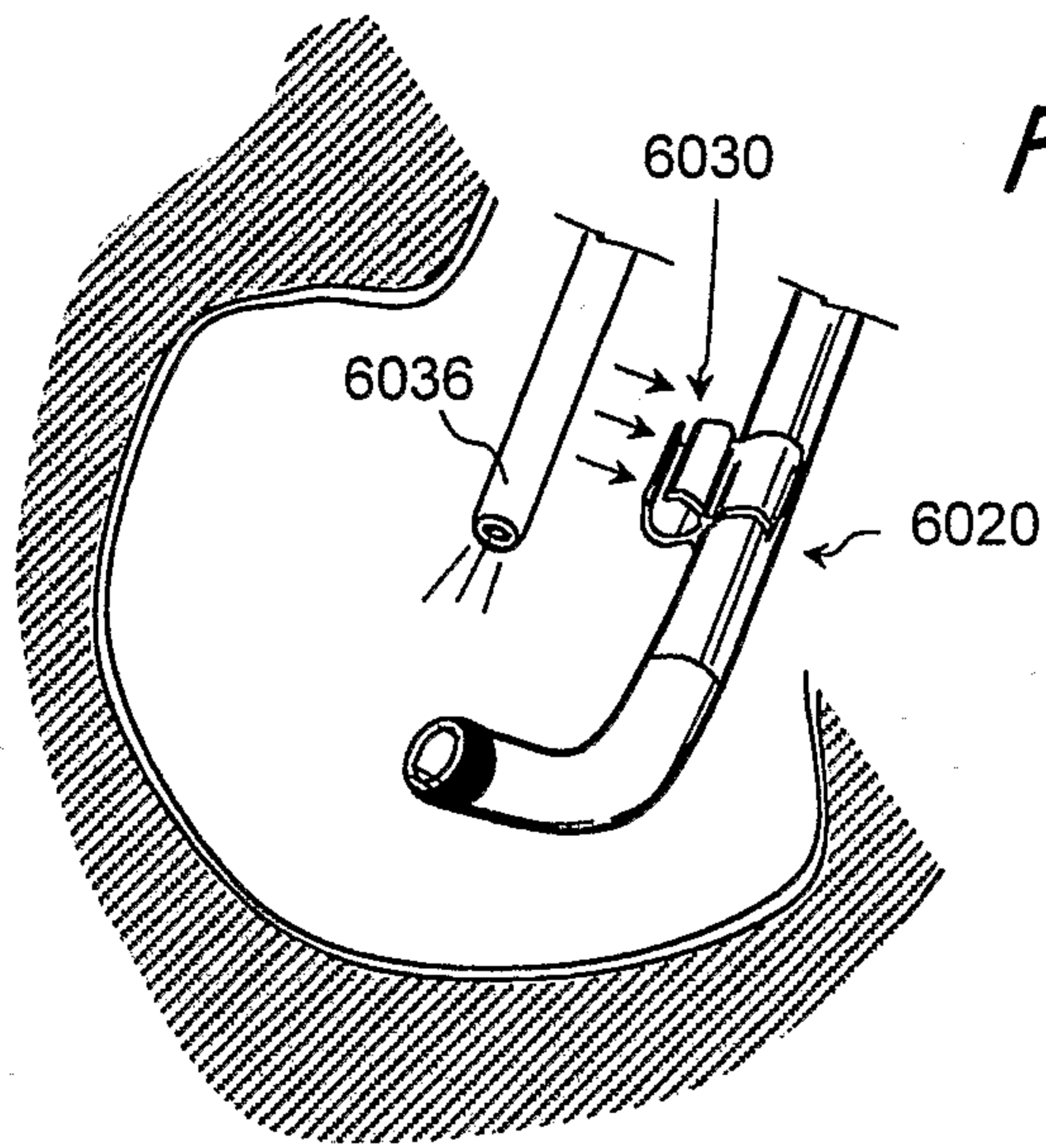




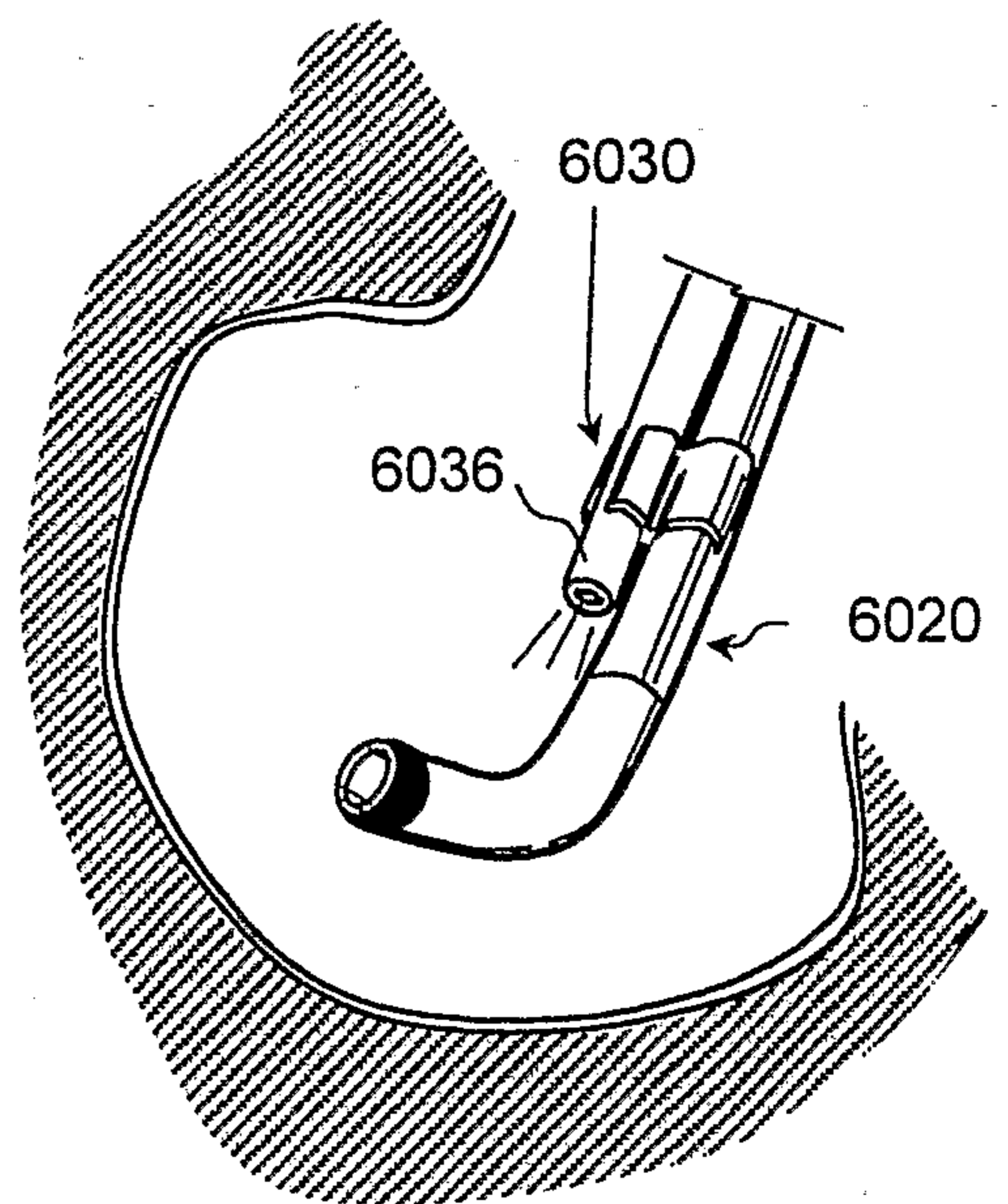
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*Fig. 6 J*

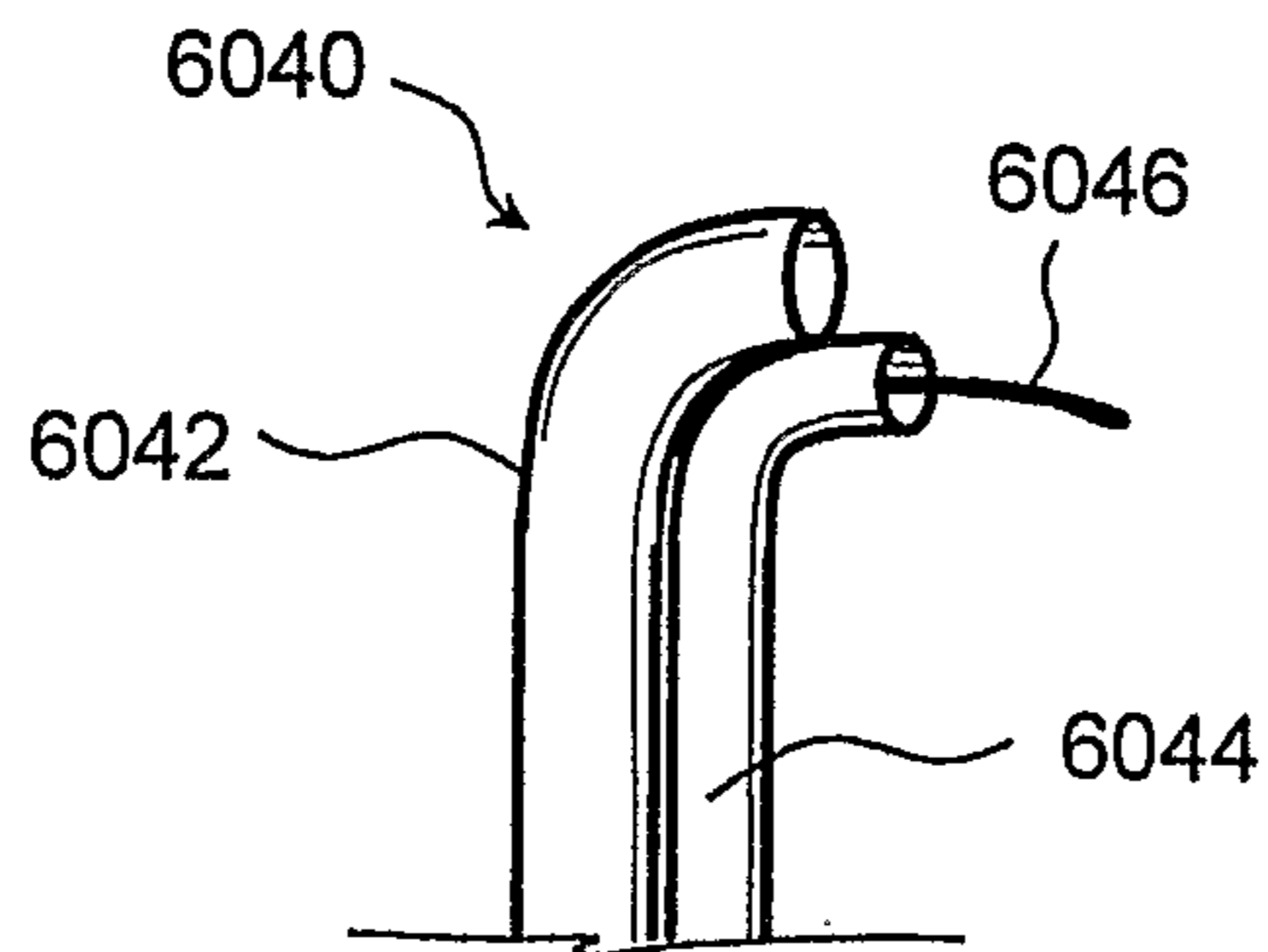


*Fig. 6 K*

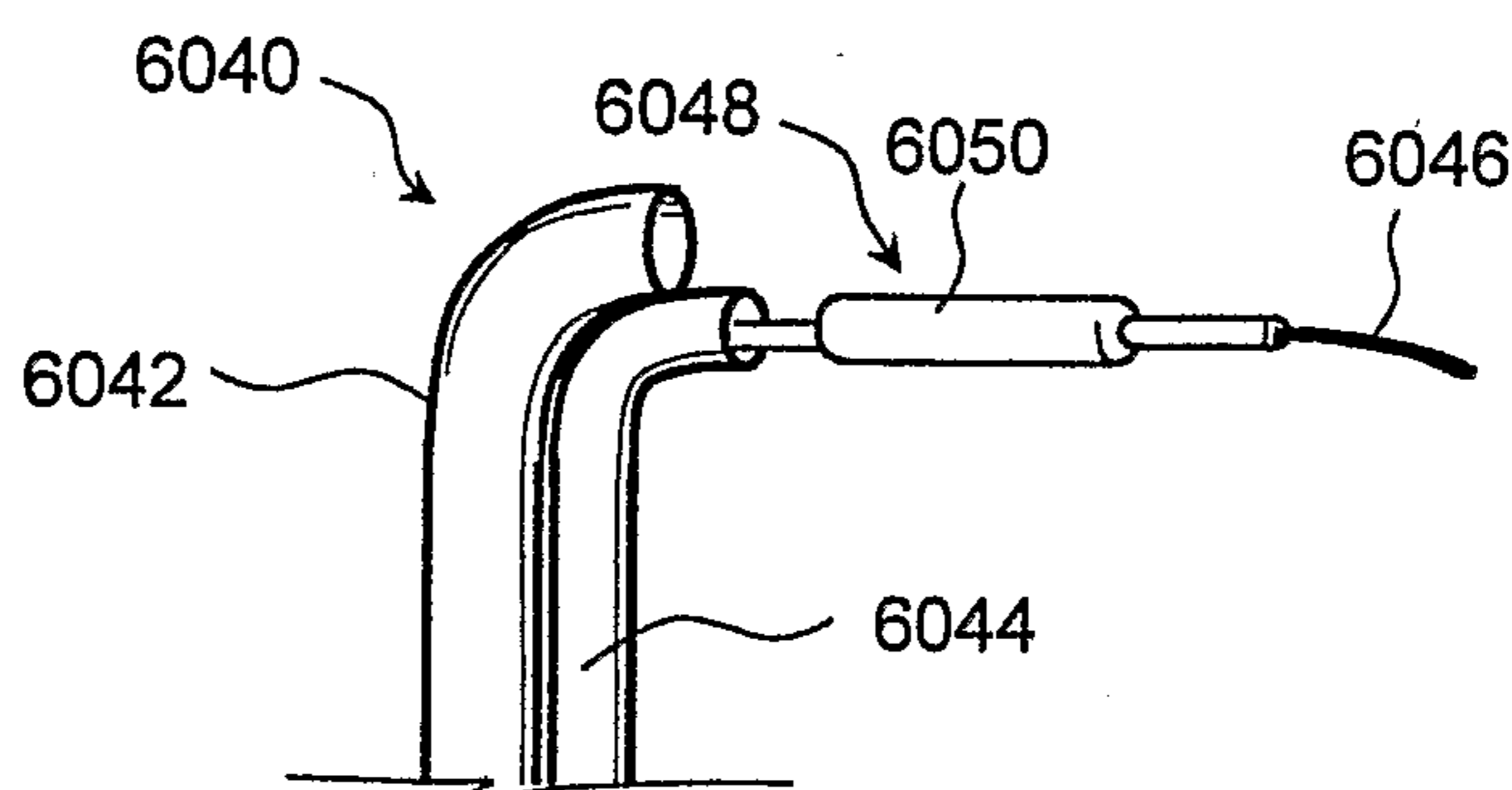


*Fig. 6 L*

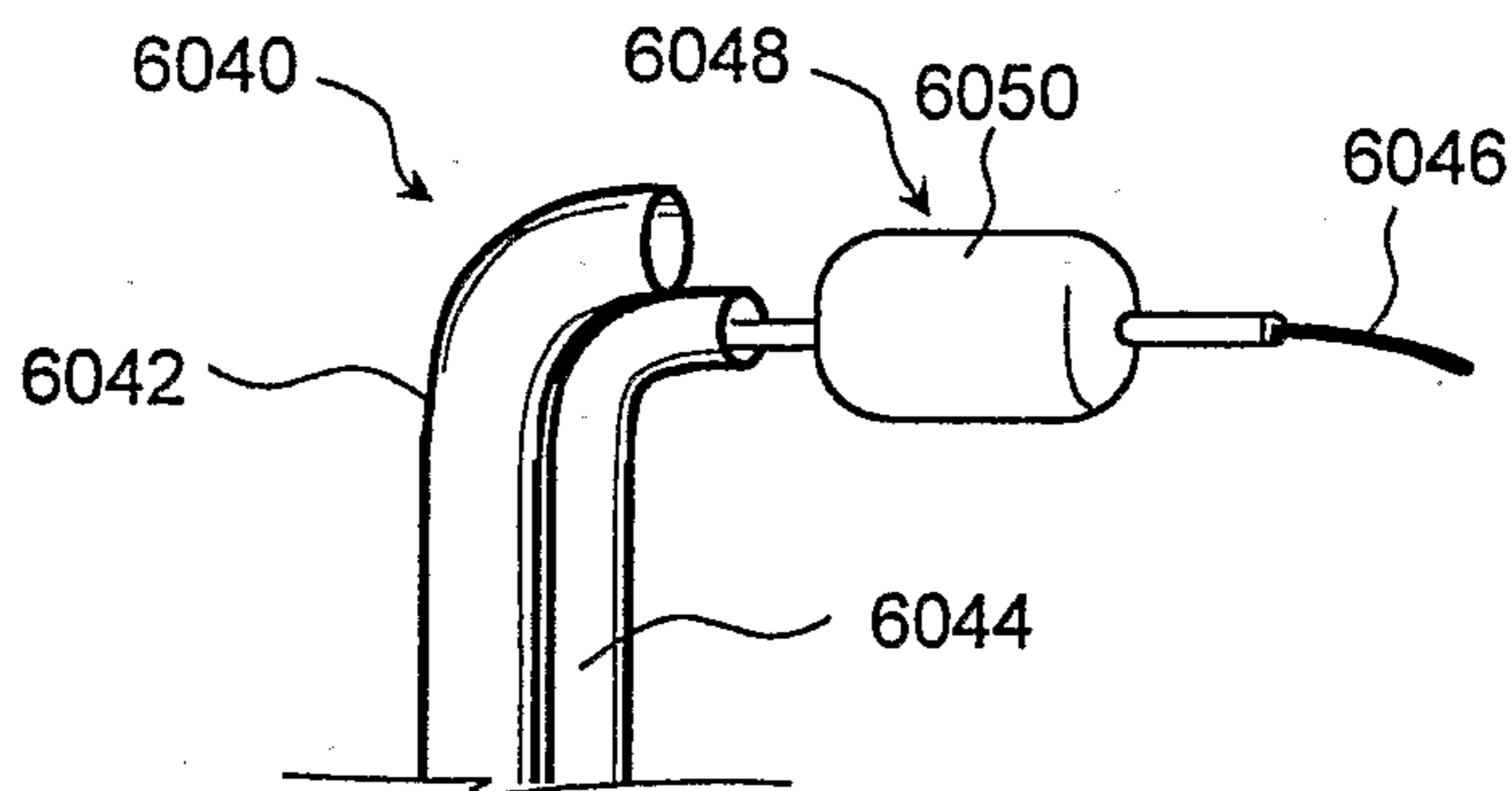
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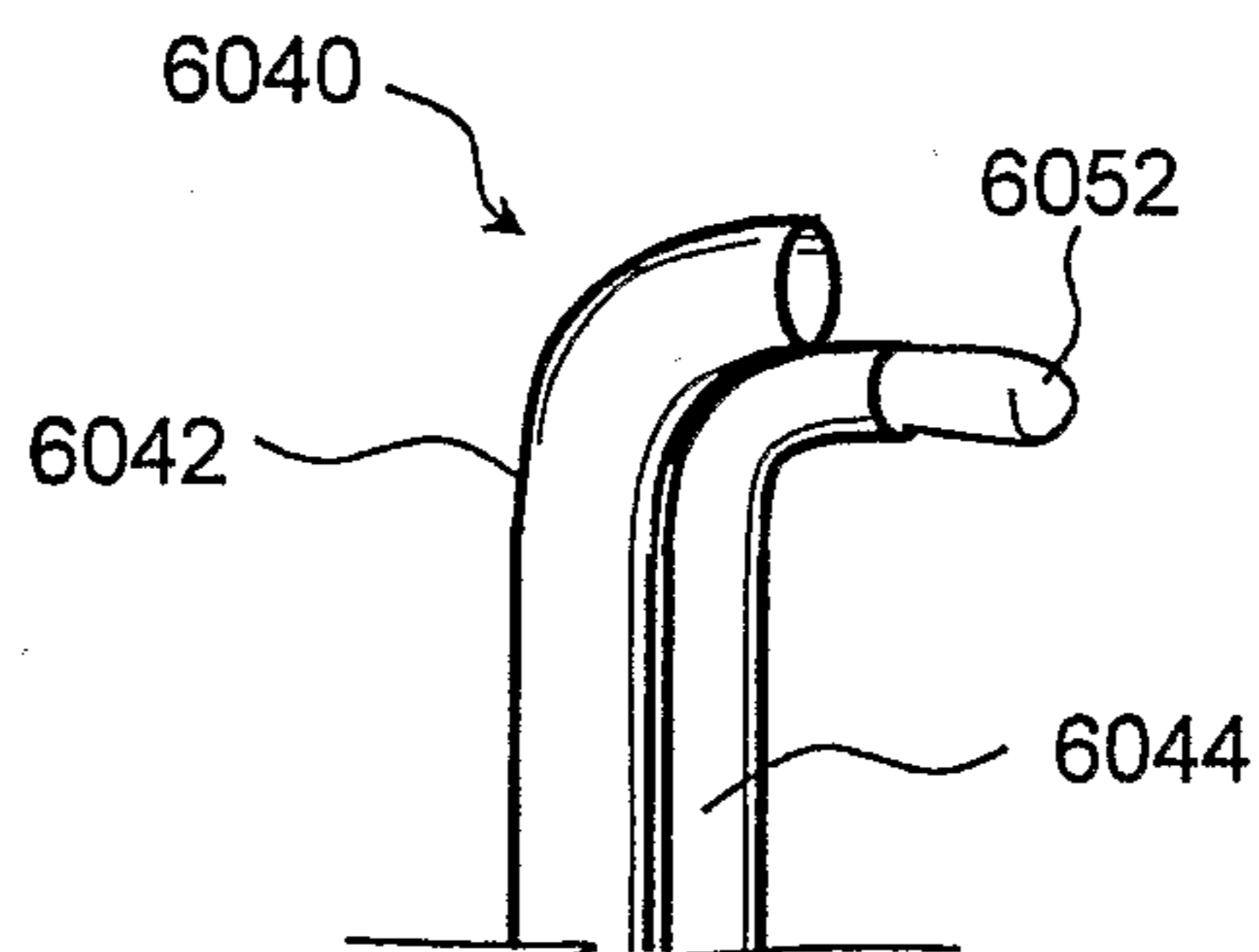
*Fig. 6 M*



*Fig. 6 N*

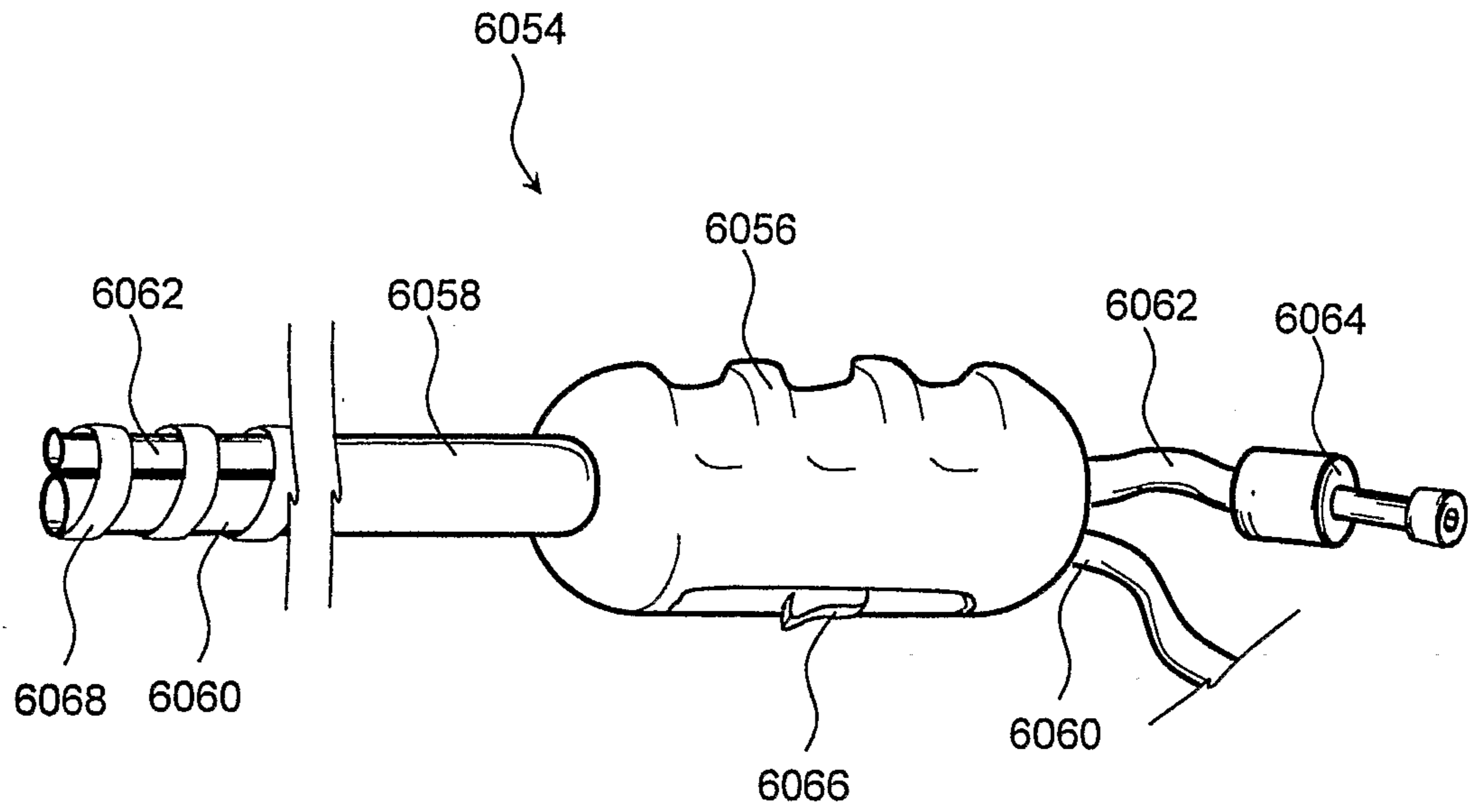


*Fig. 6 O*

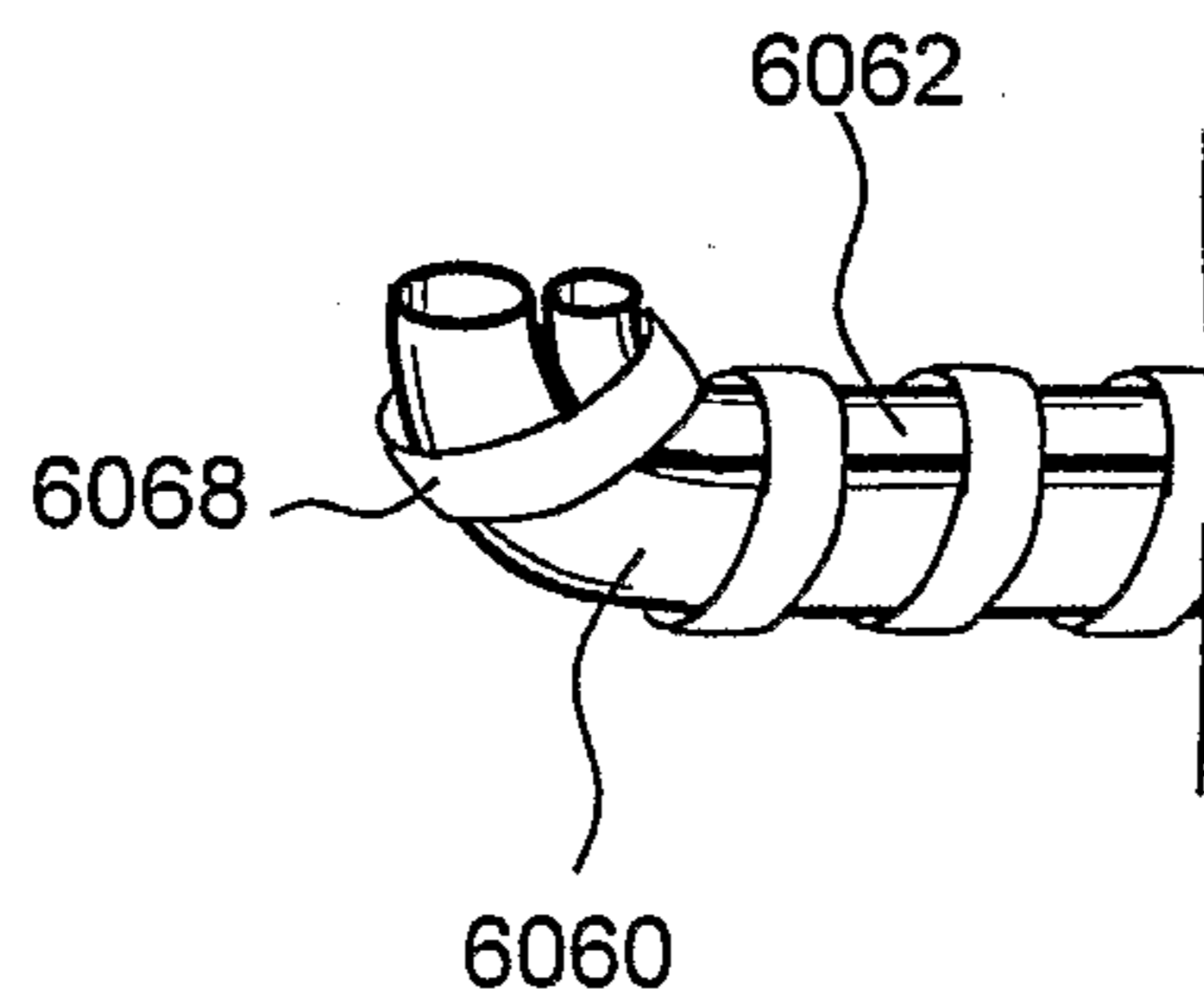


*Fig. 6 P*

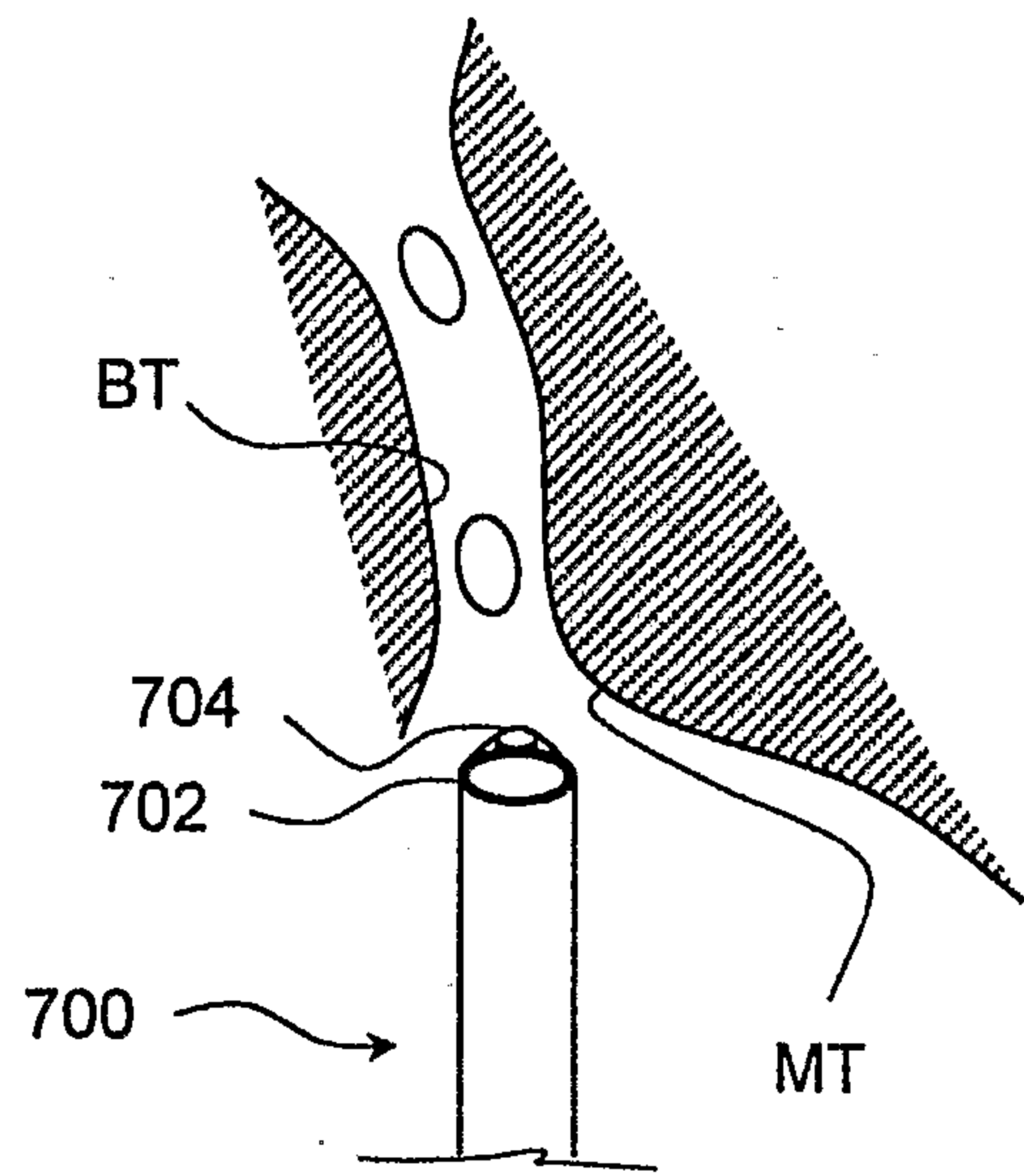
11/38



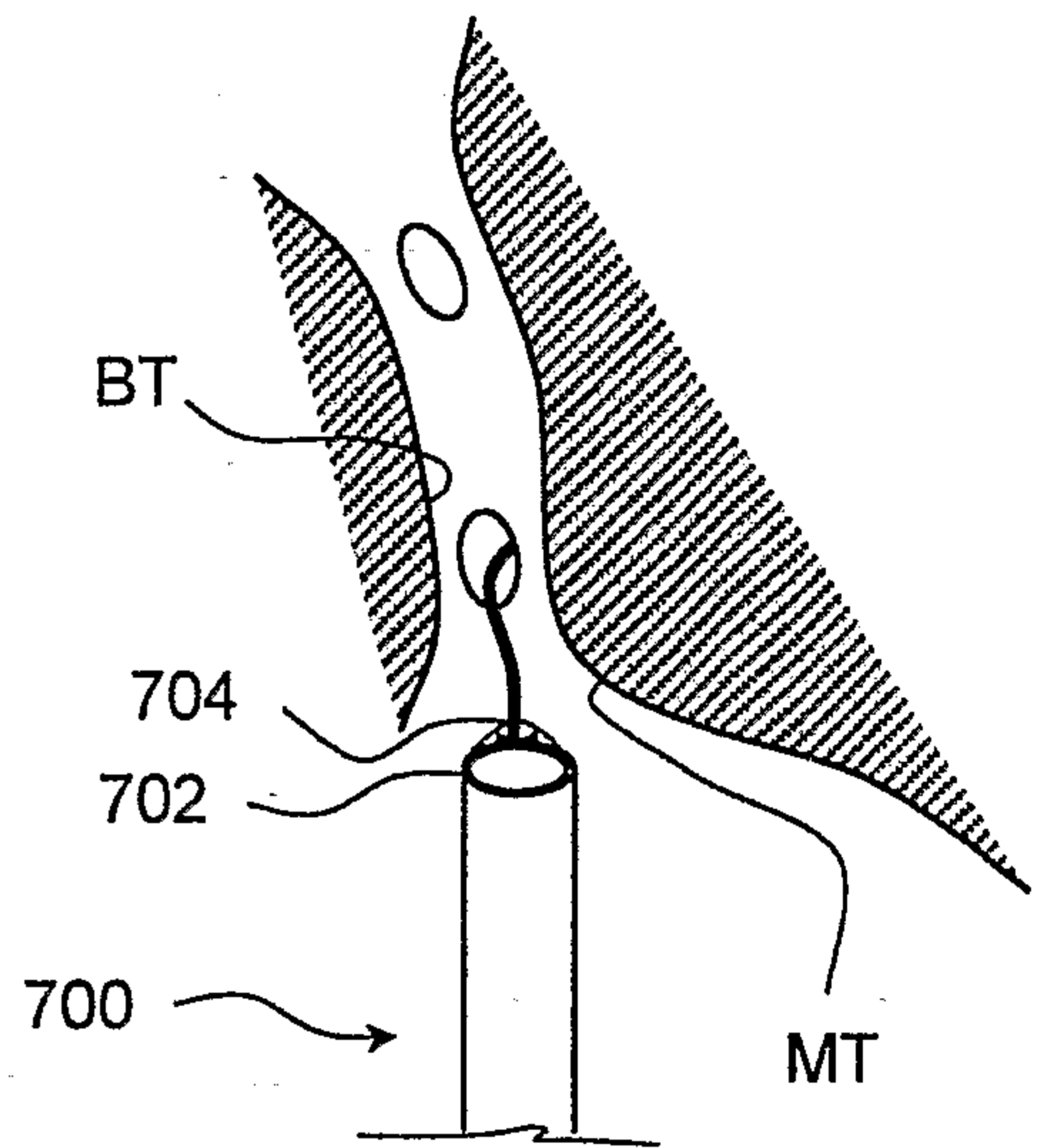
*Fig. 6 Q*



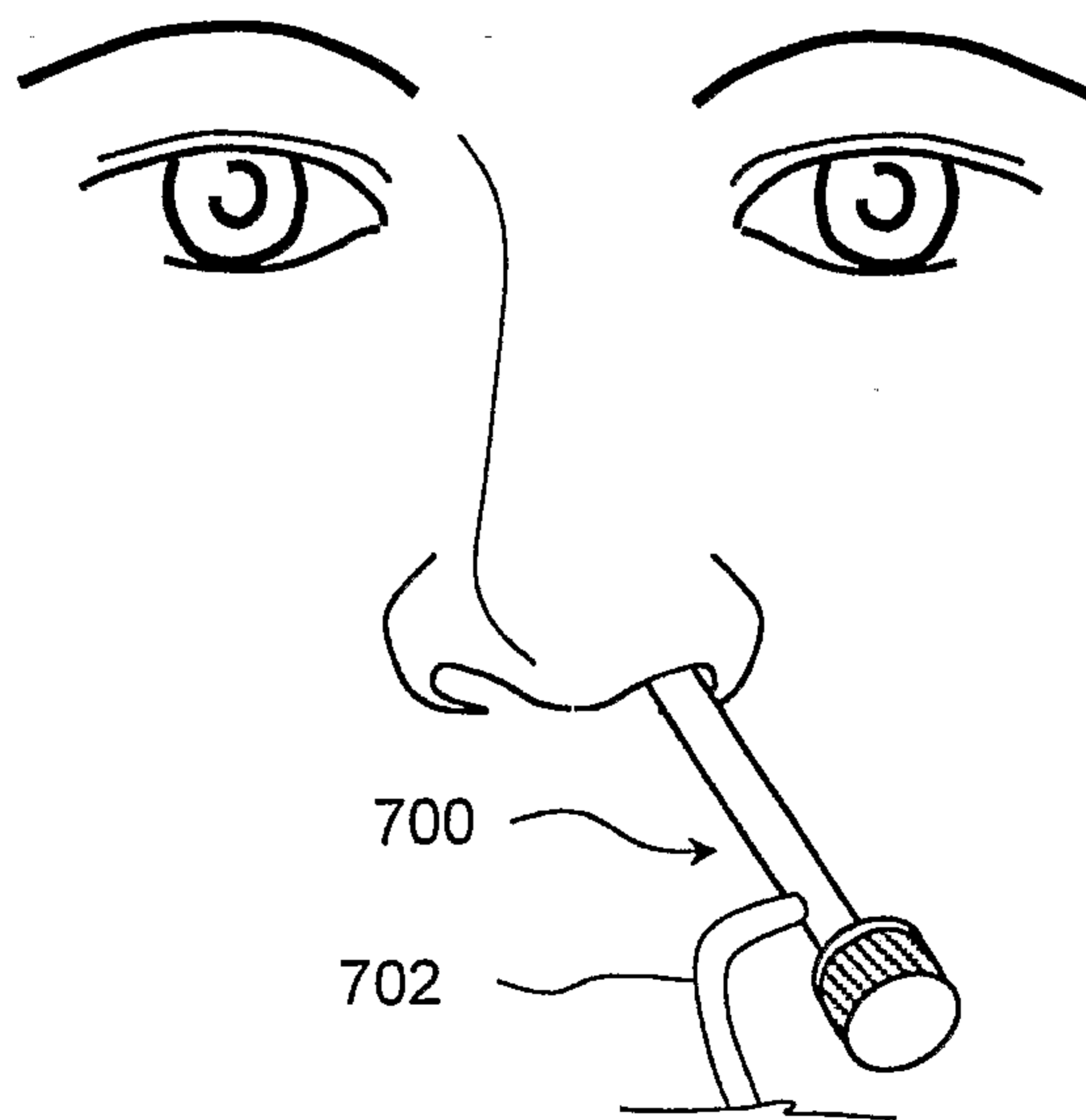
*Fig. 6 R*



*Fig. 7 A*

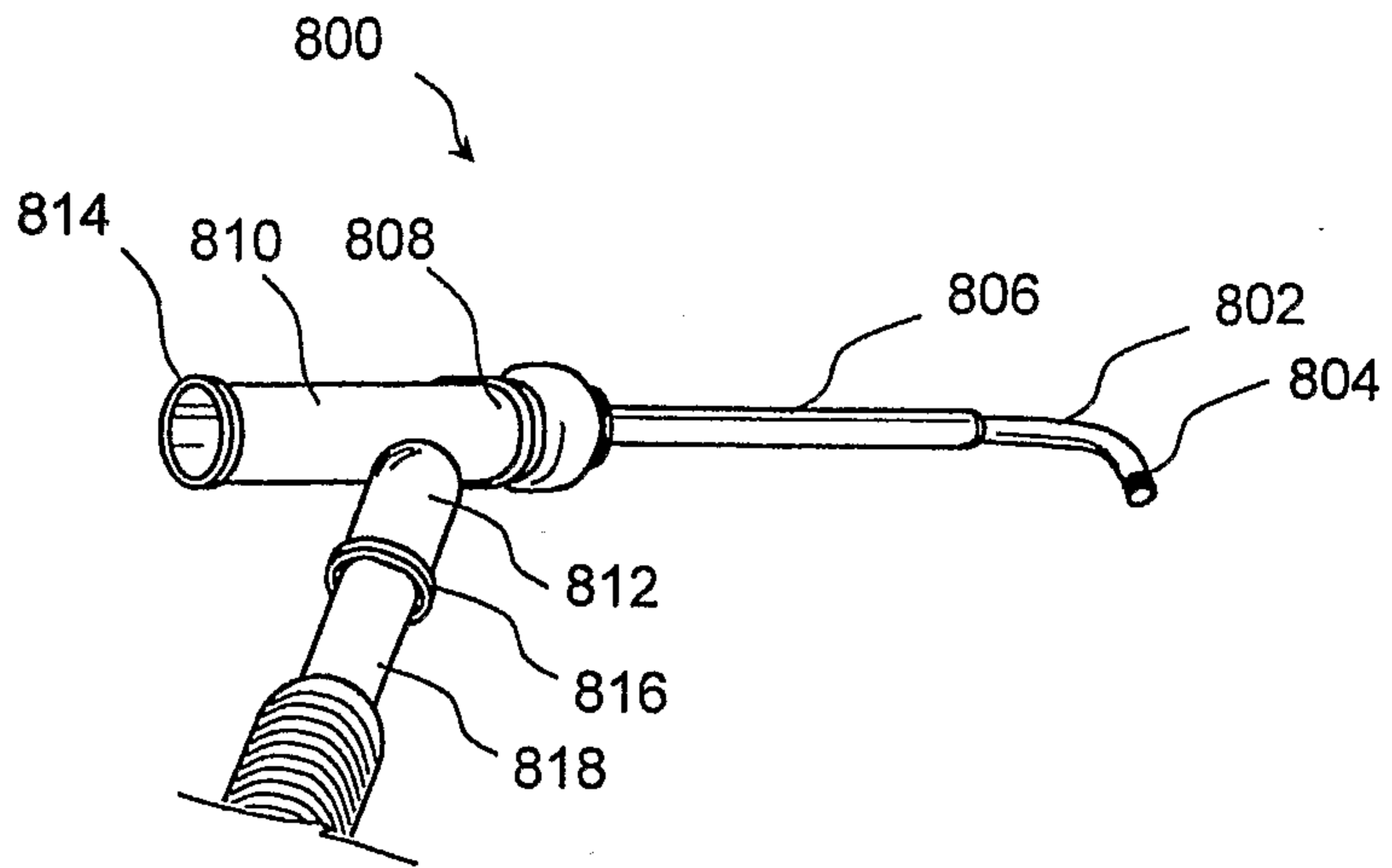


*Fig. 7 B*

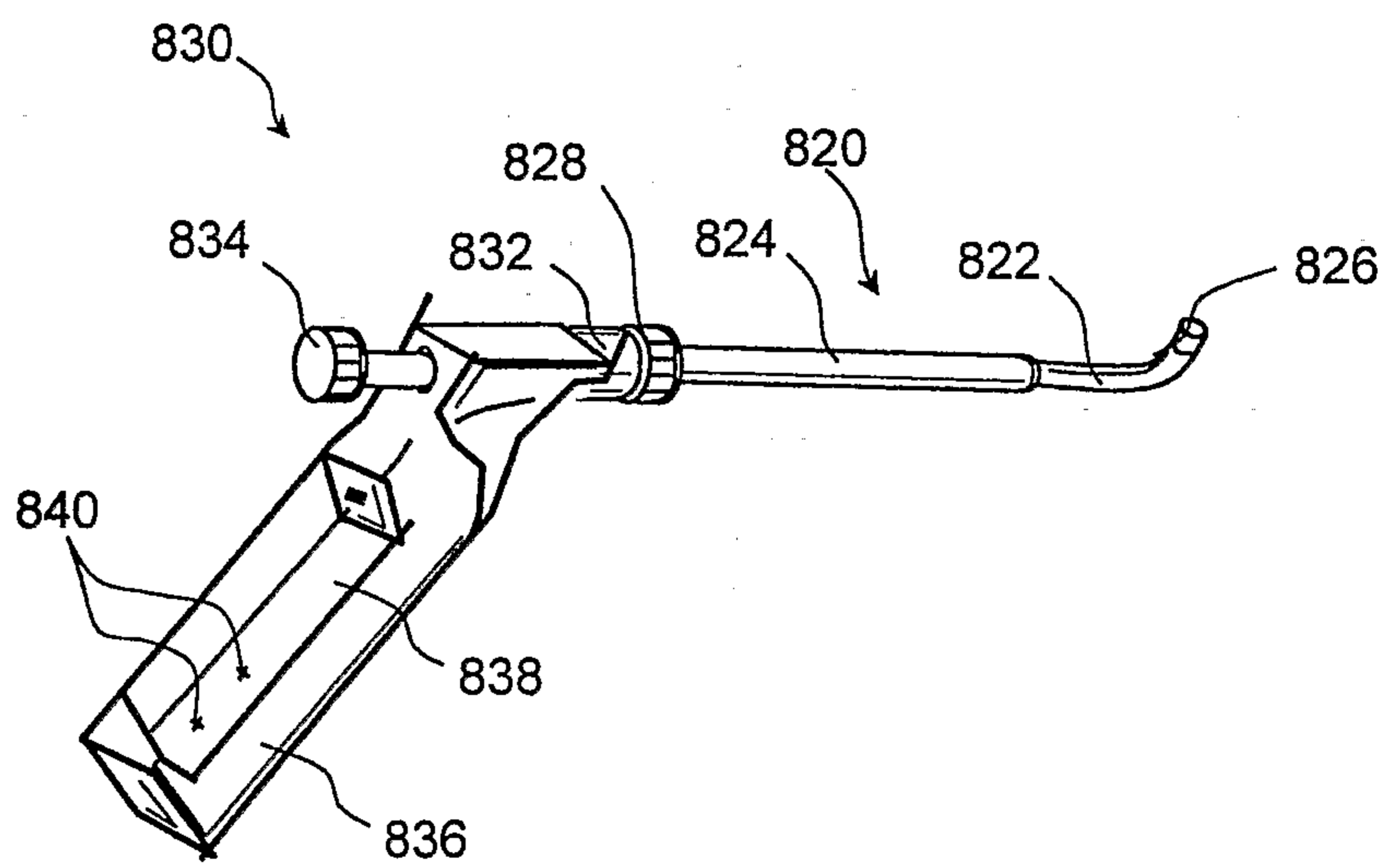


*Fig. 7 C*

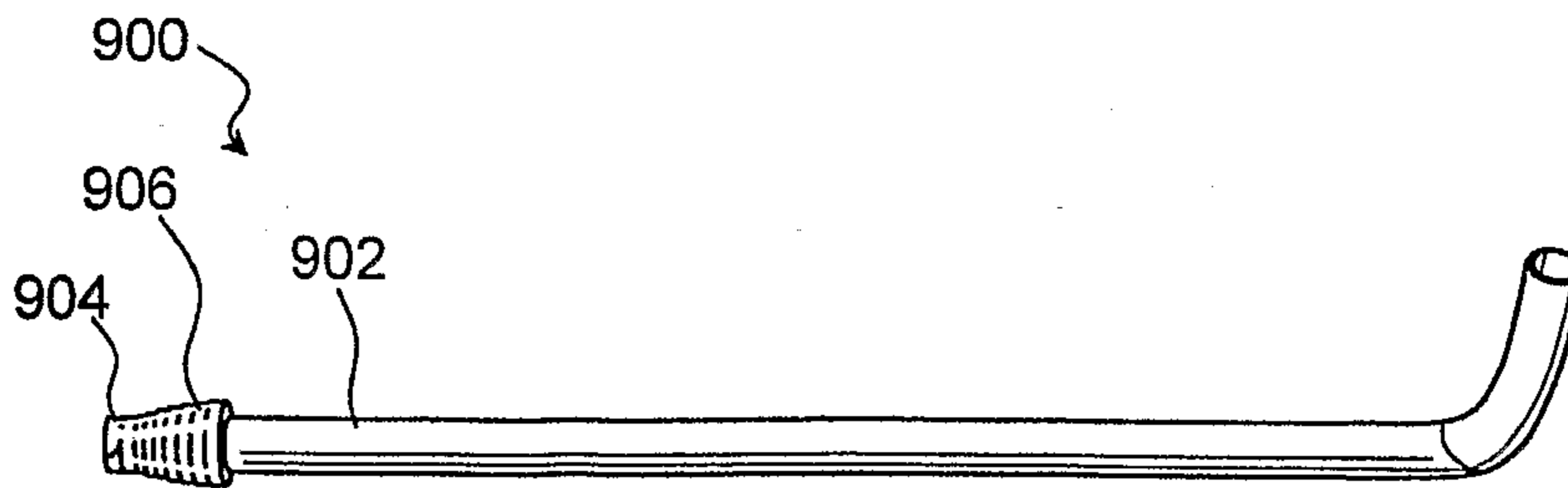
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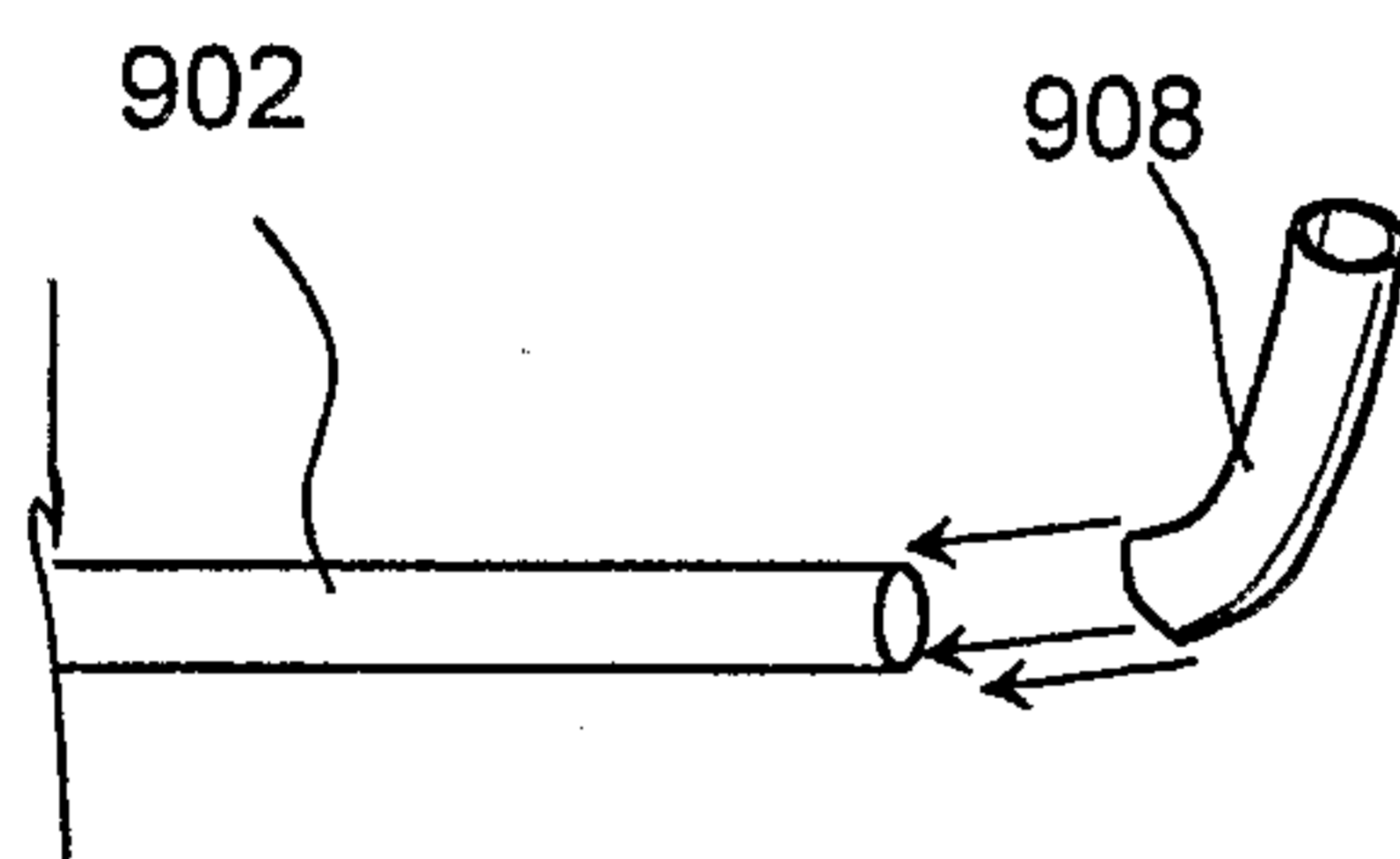
*Fig. 8 A*



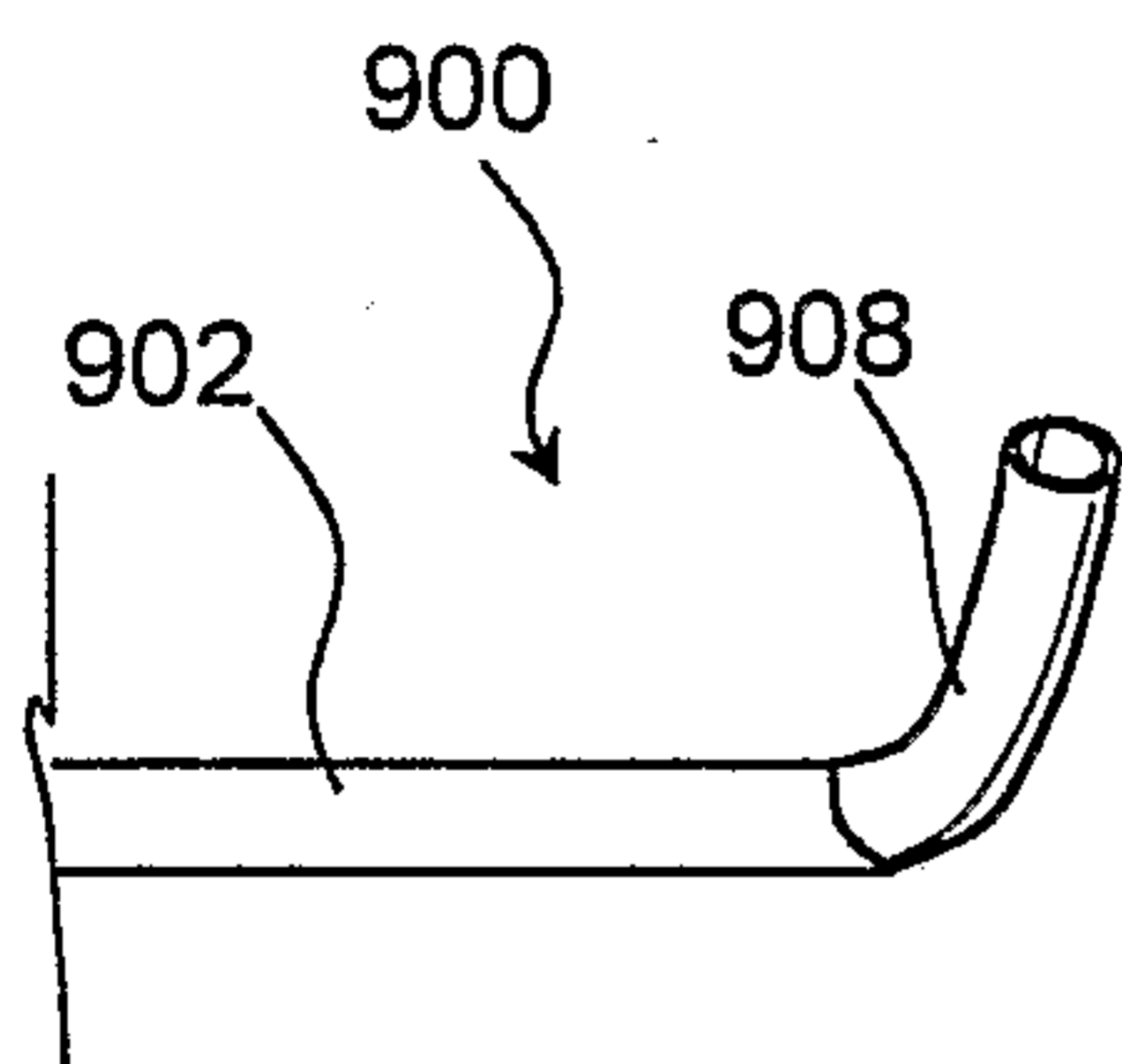
*Fig. 8 B*



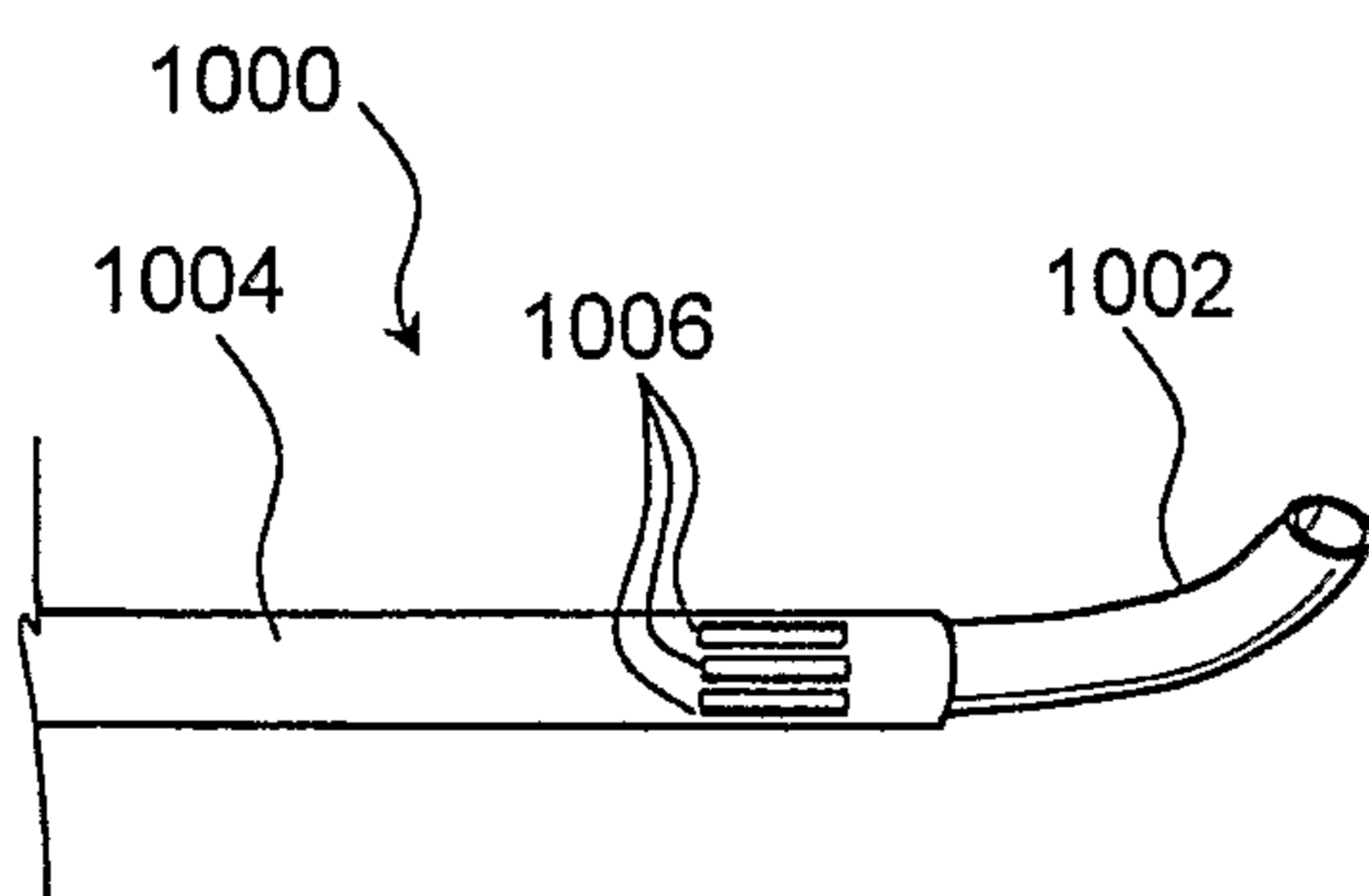
*Fig. 9*



*Fig. 10 A*

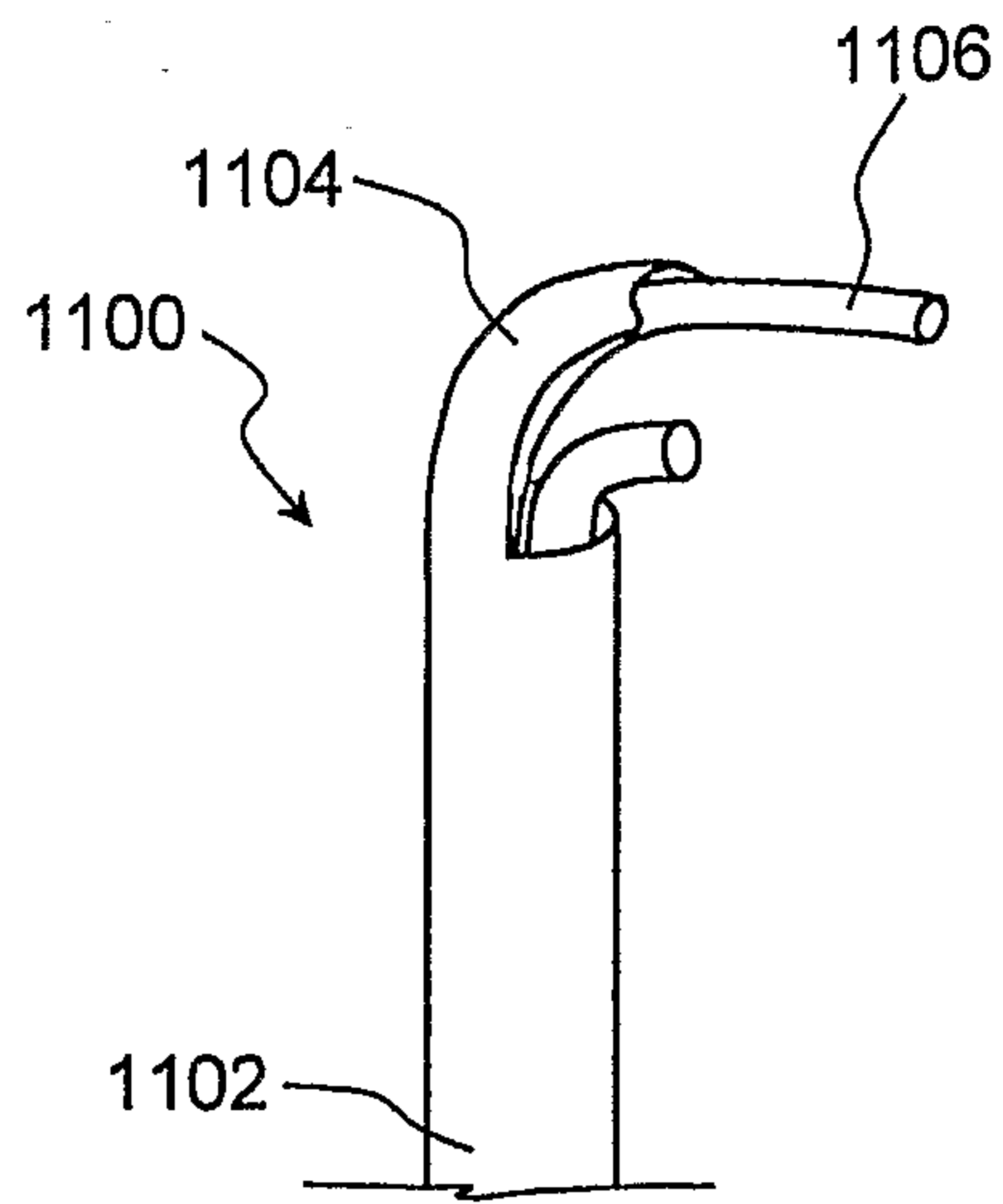


*Fig. 10 B*

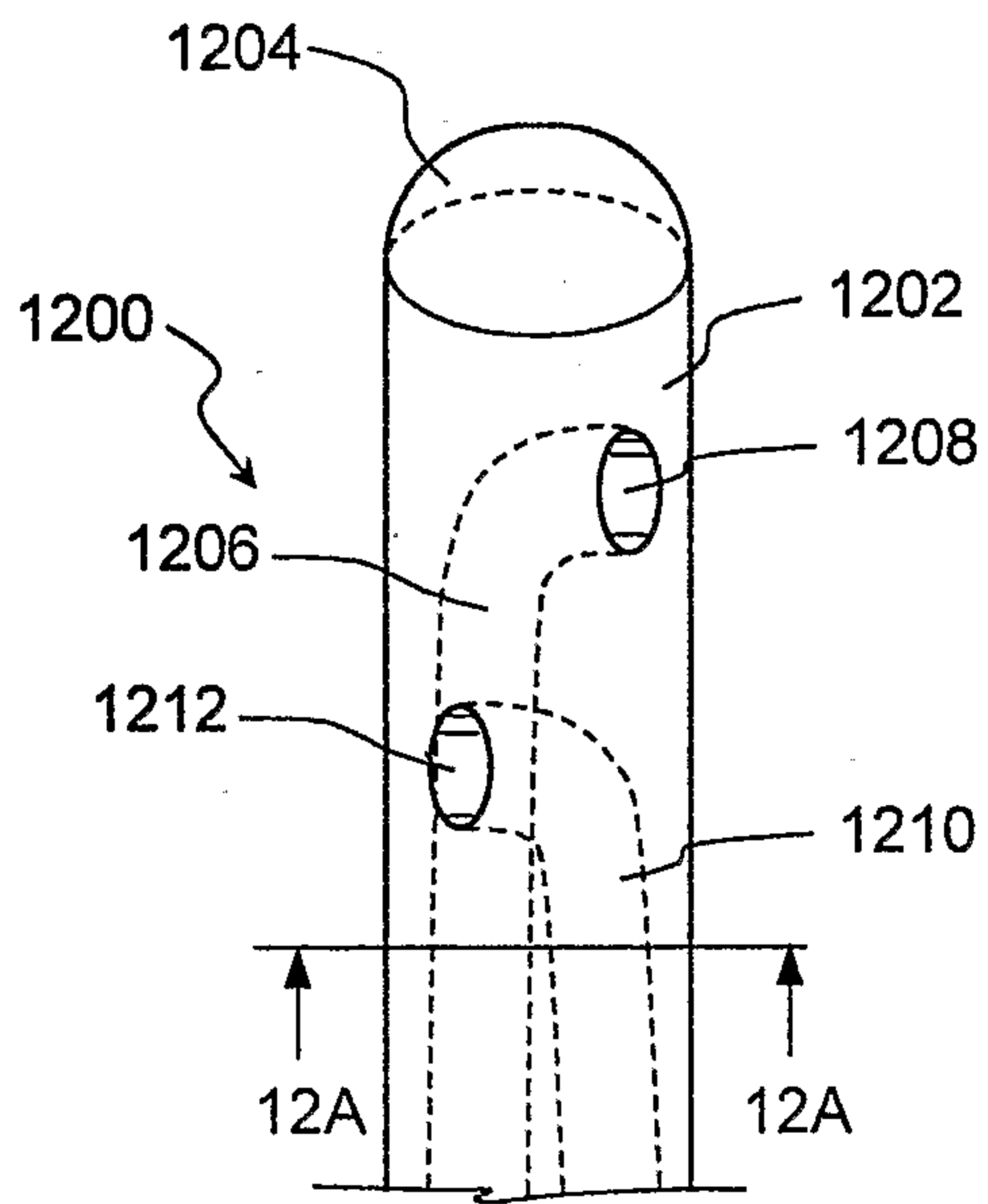


*Fig. 10 C*

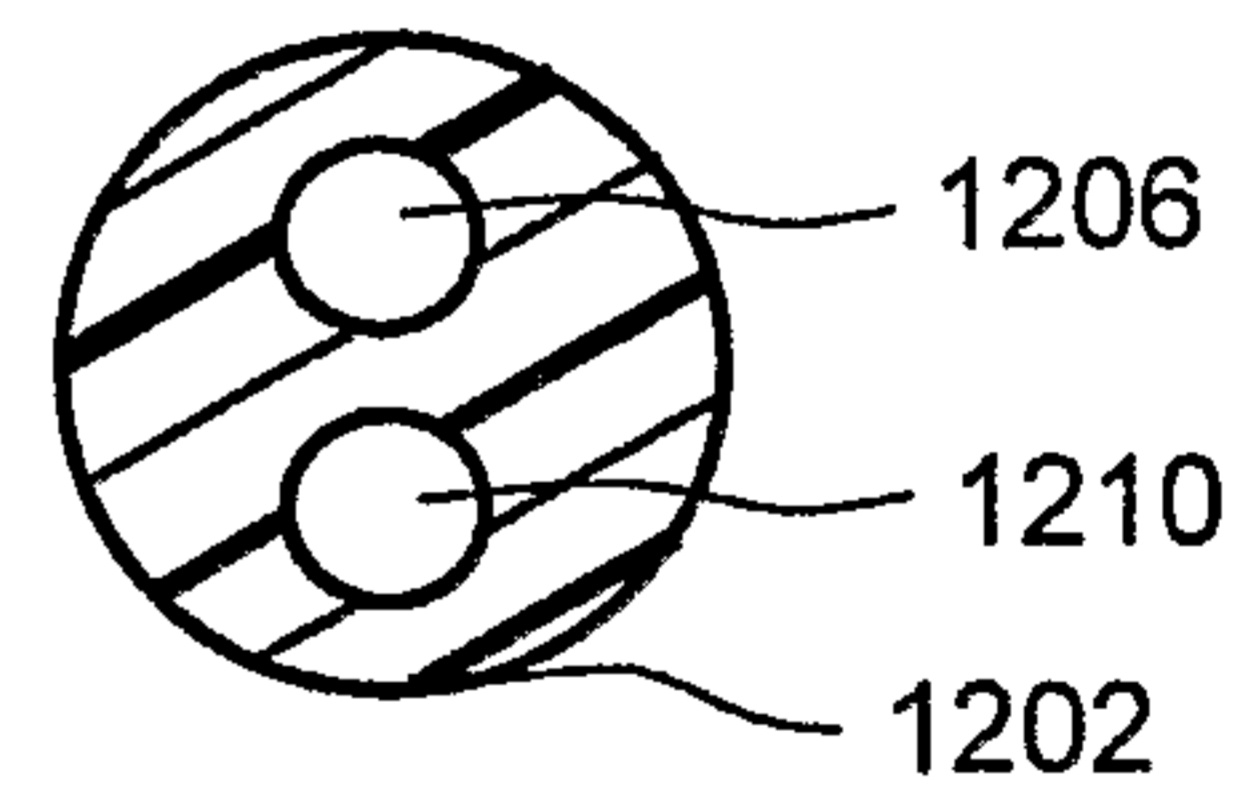
15/38



*Fig. 11*

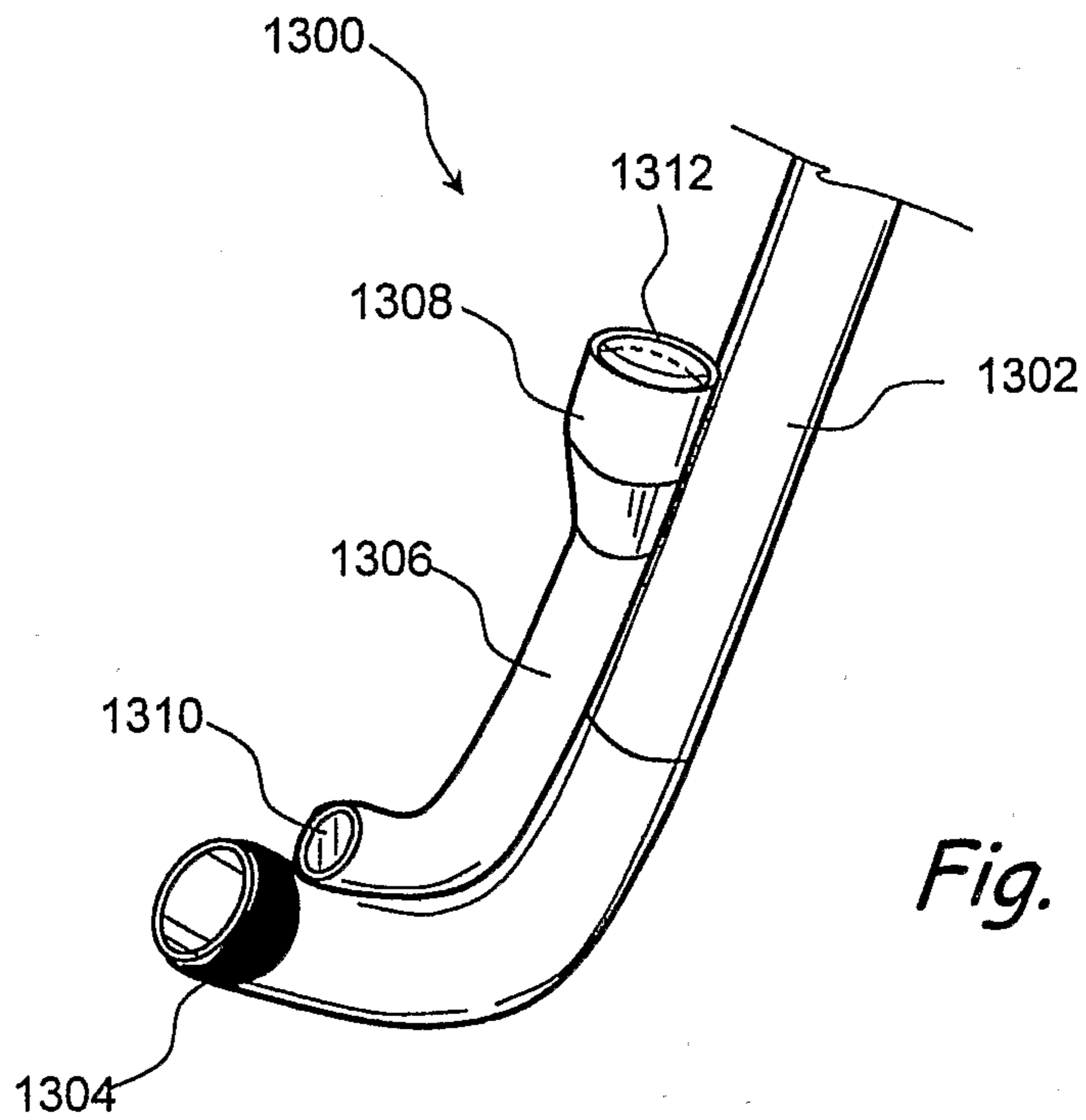


*Fig. 12*

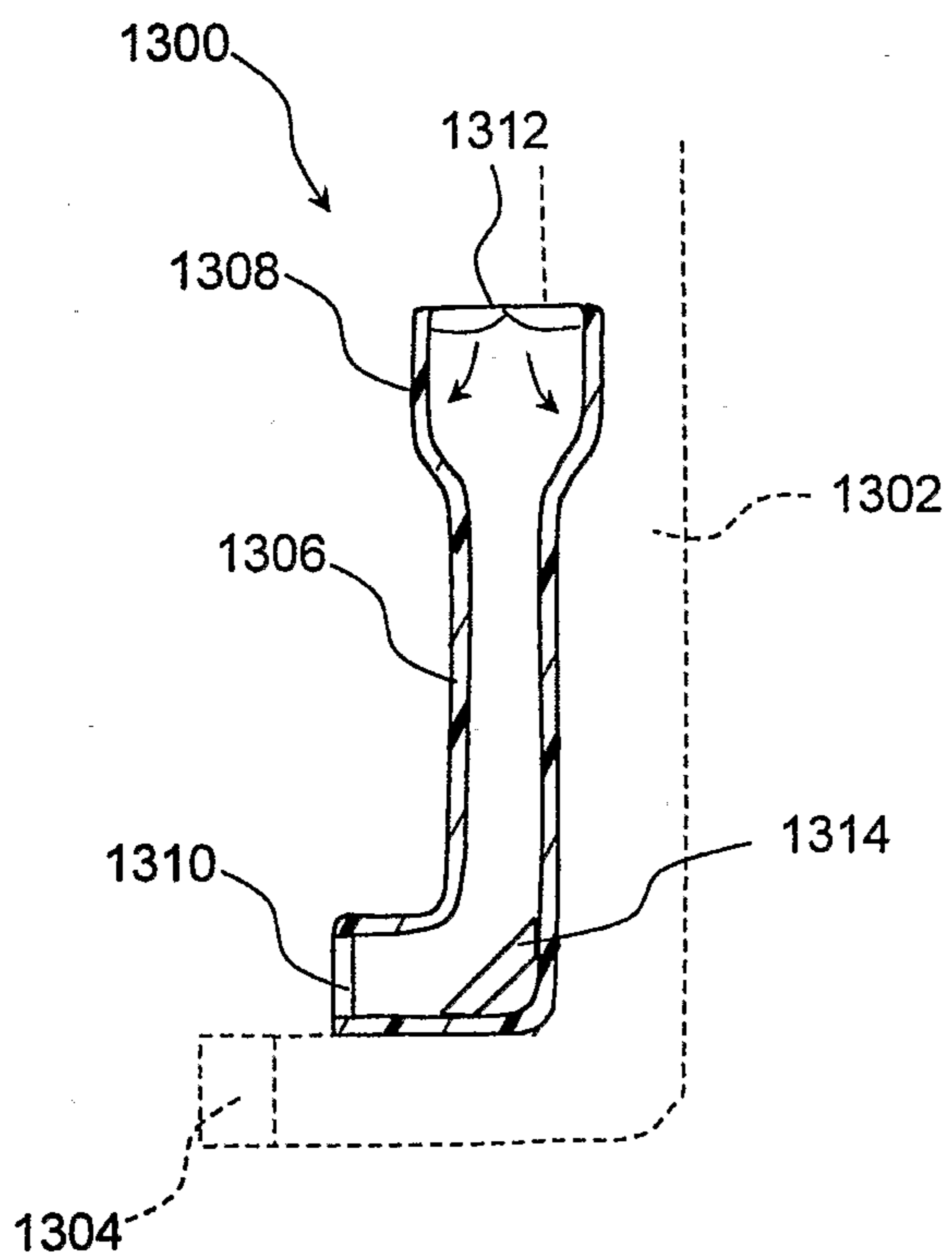


*Fig. 12 A*

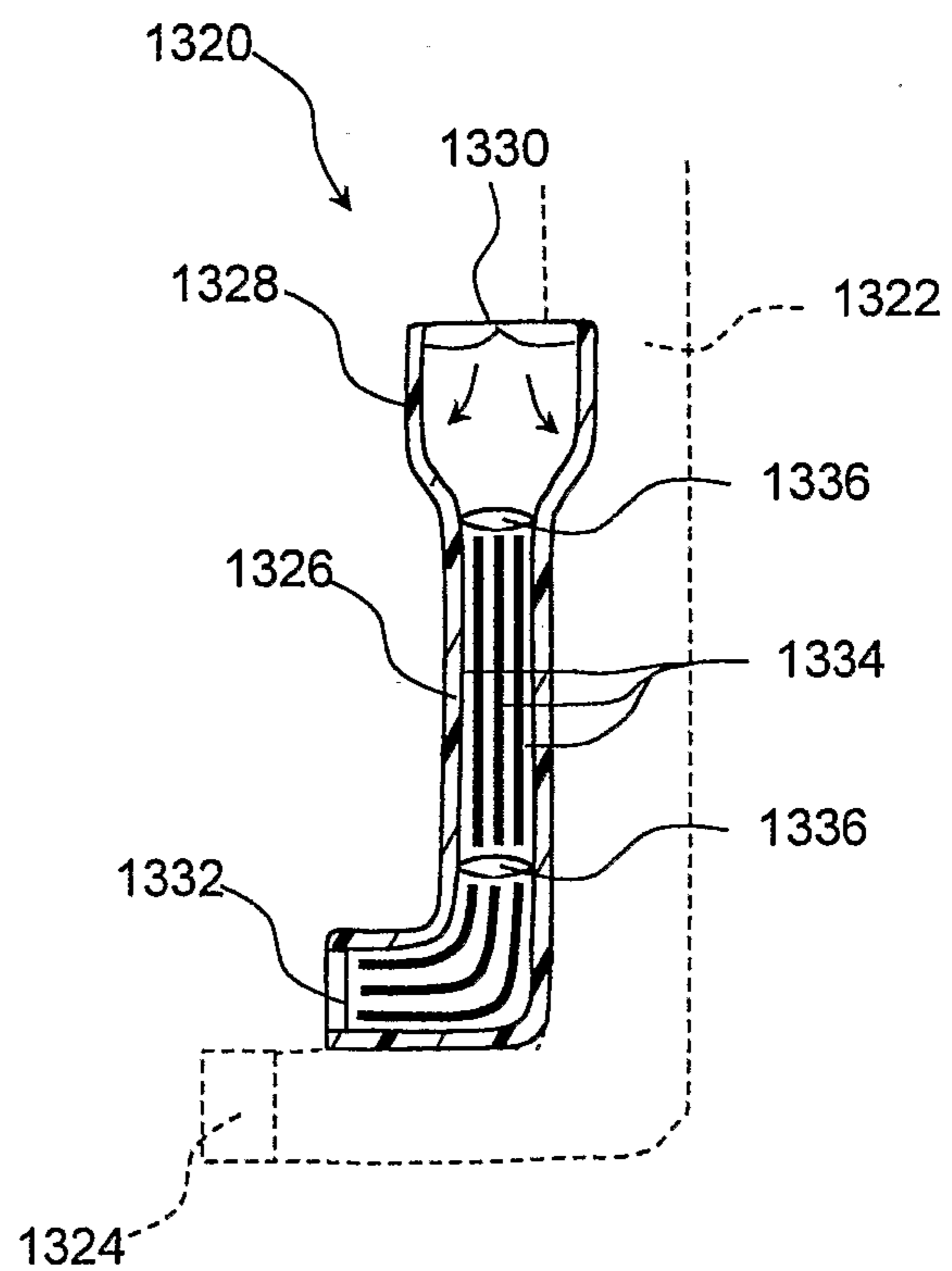
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*Fig. 13 A*

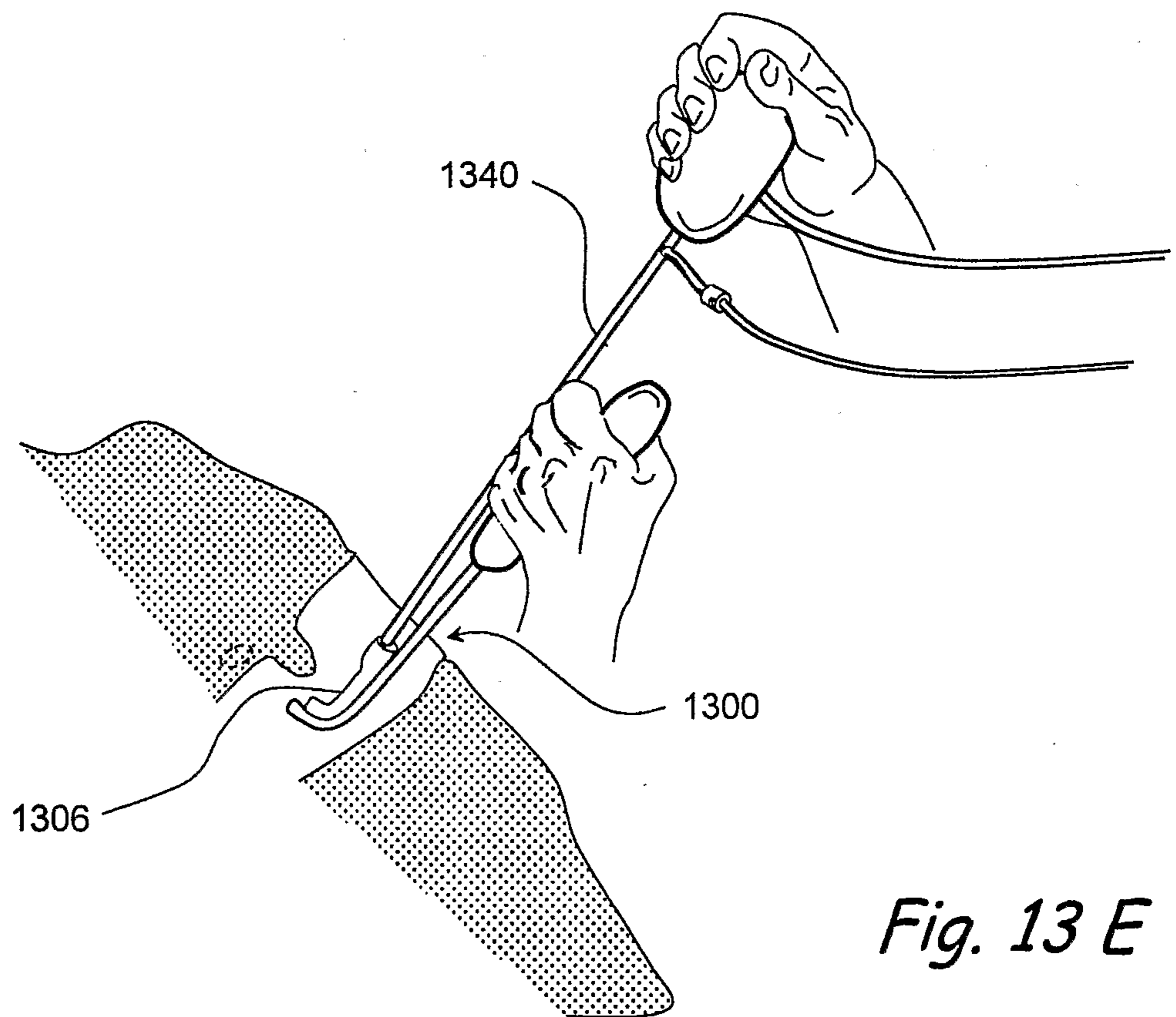
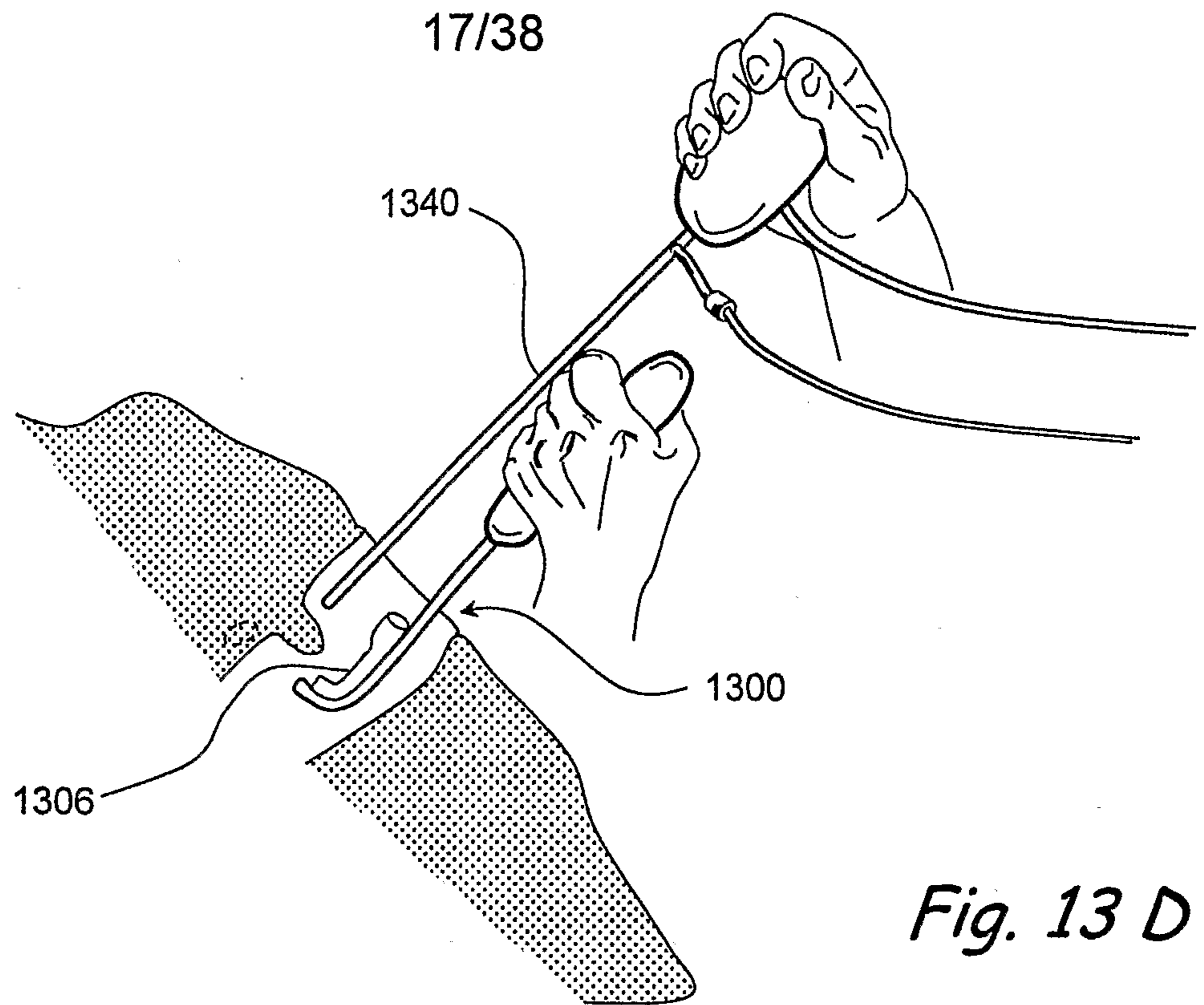


*Fig. 13 B*

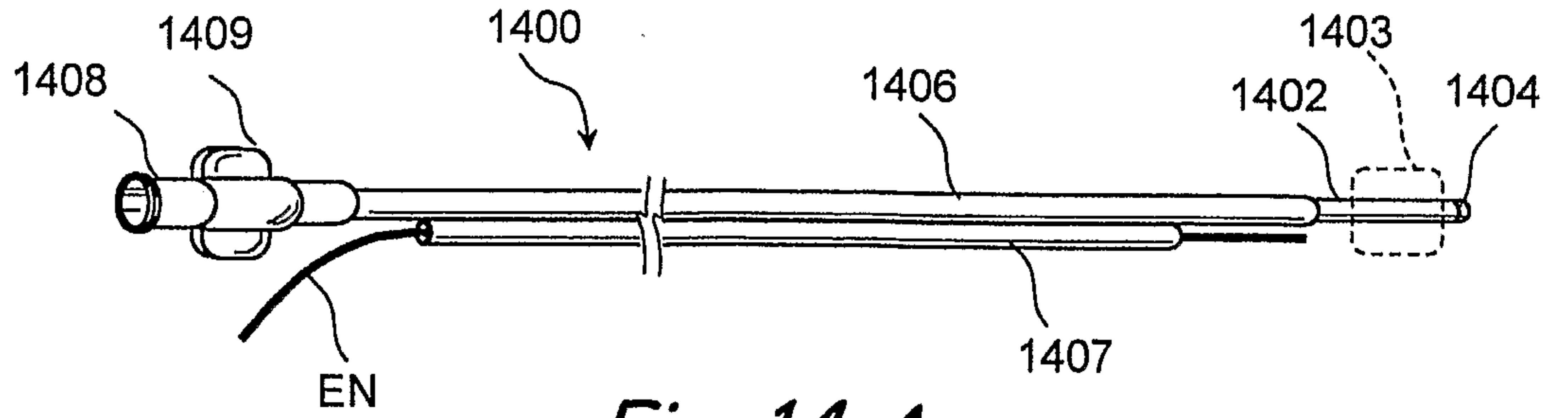


*Fig. 13 C*

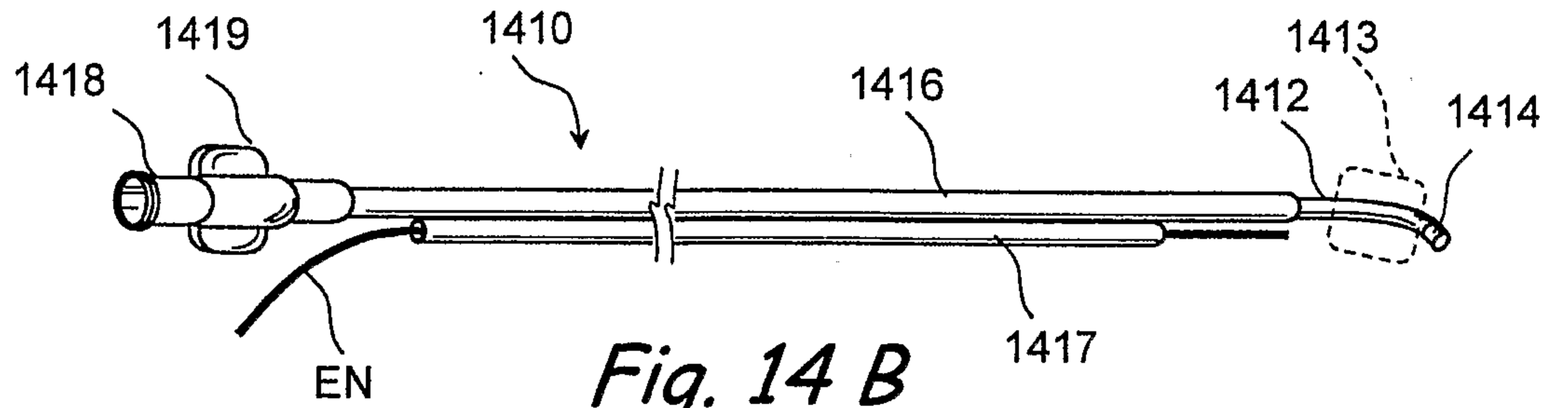




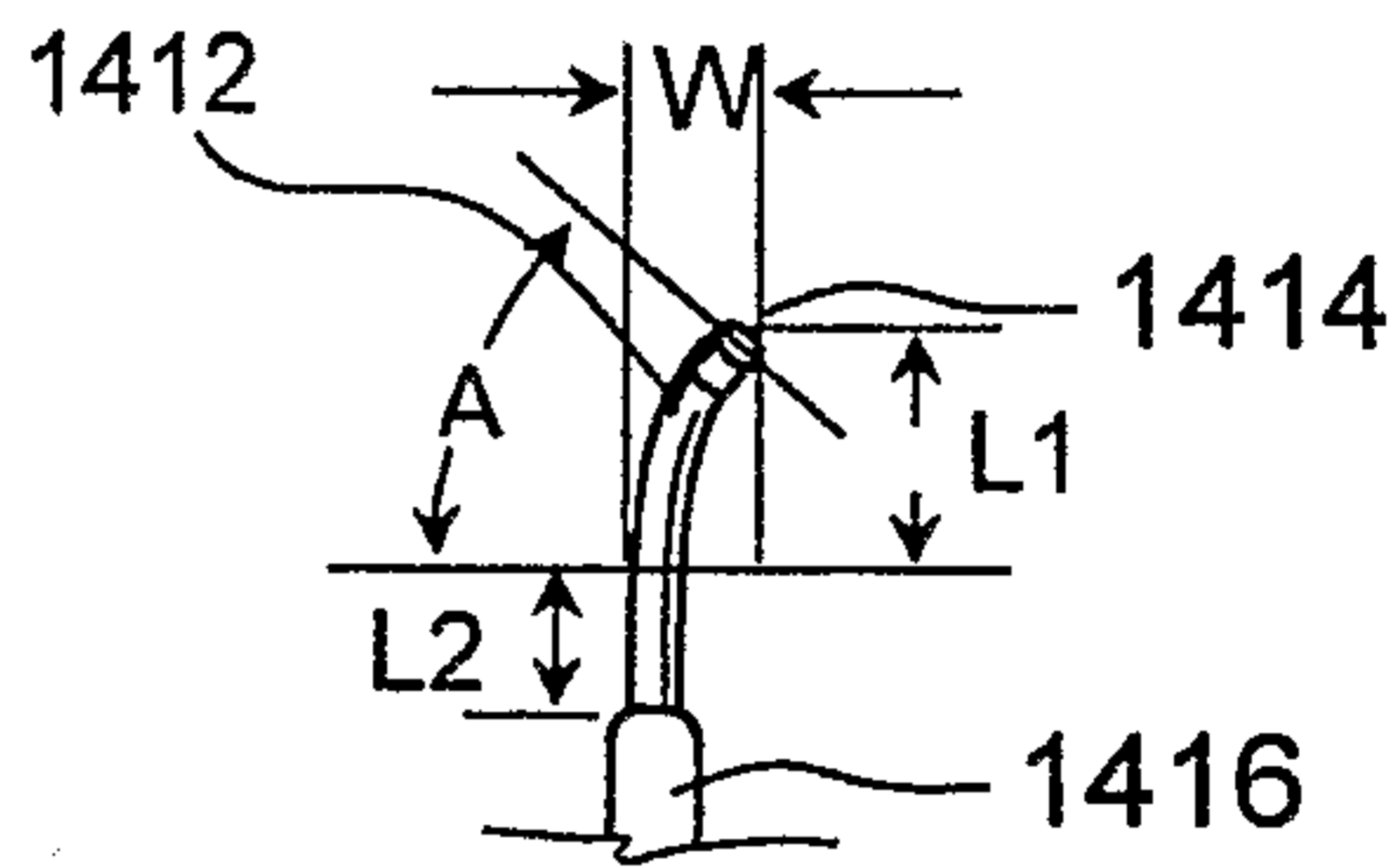
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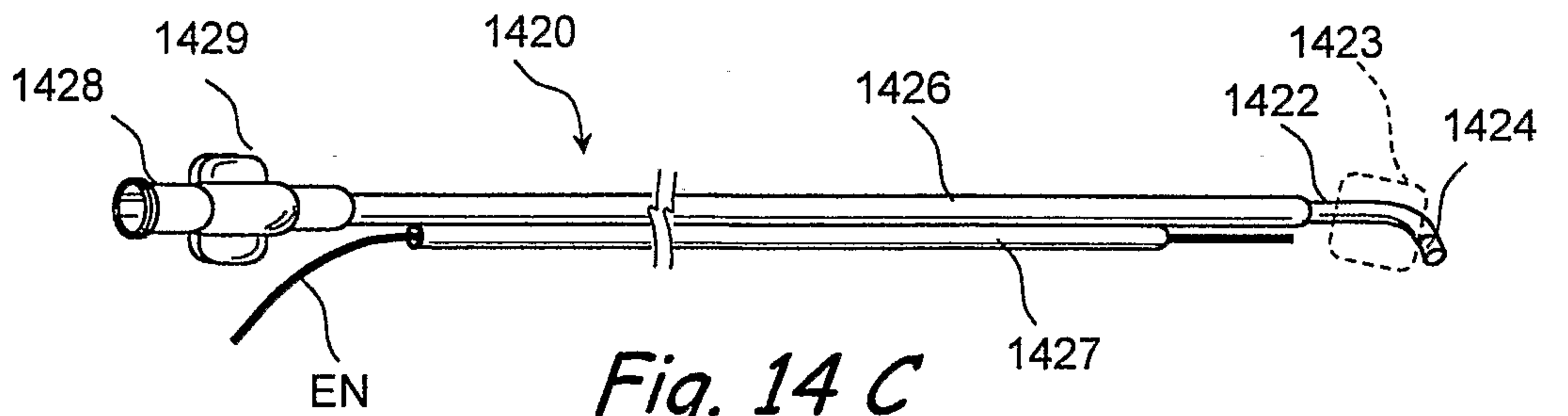
*Fig. 14 A*



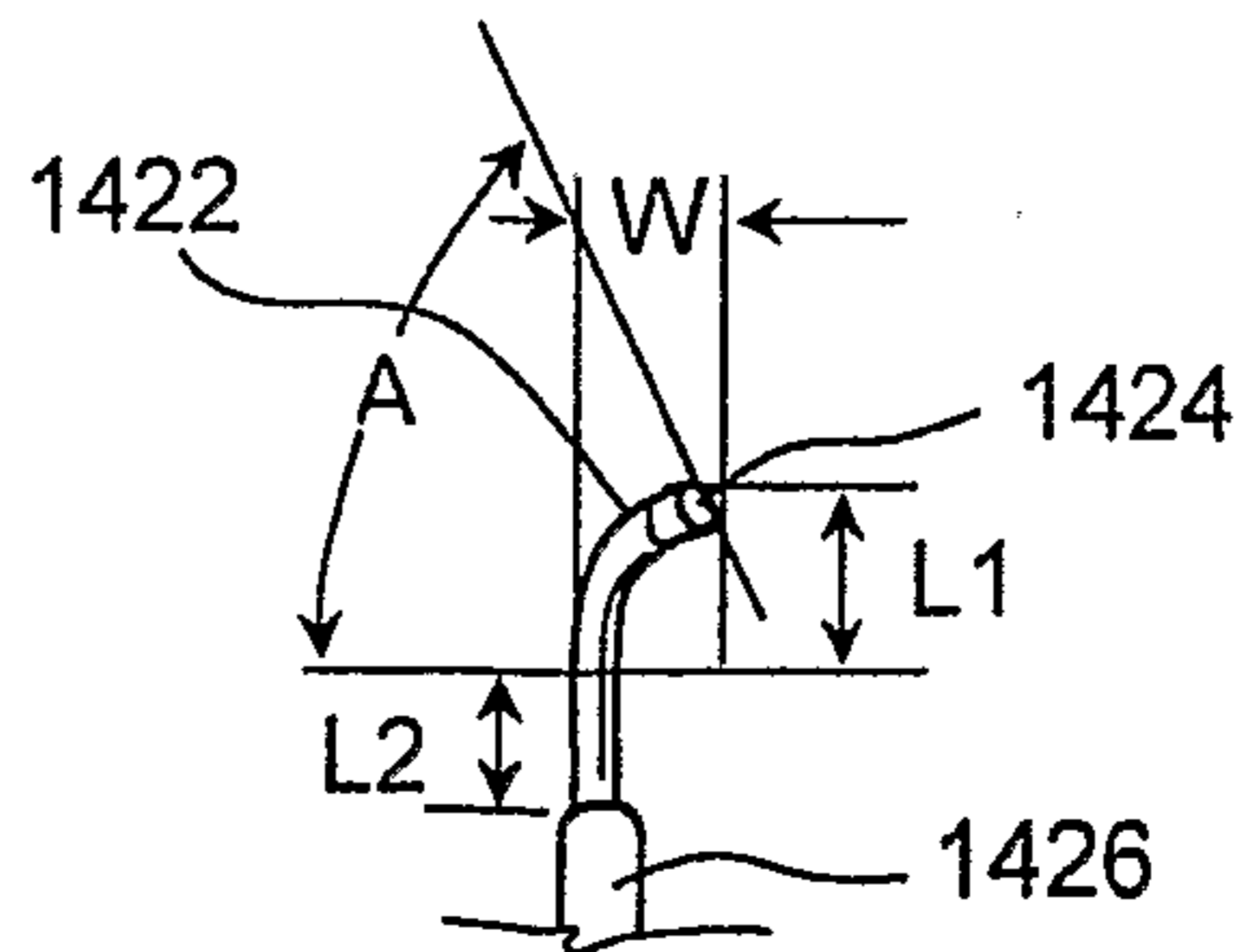
*Fig. 14 B*



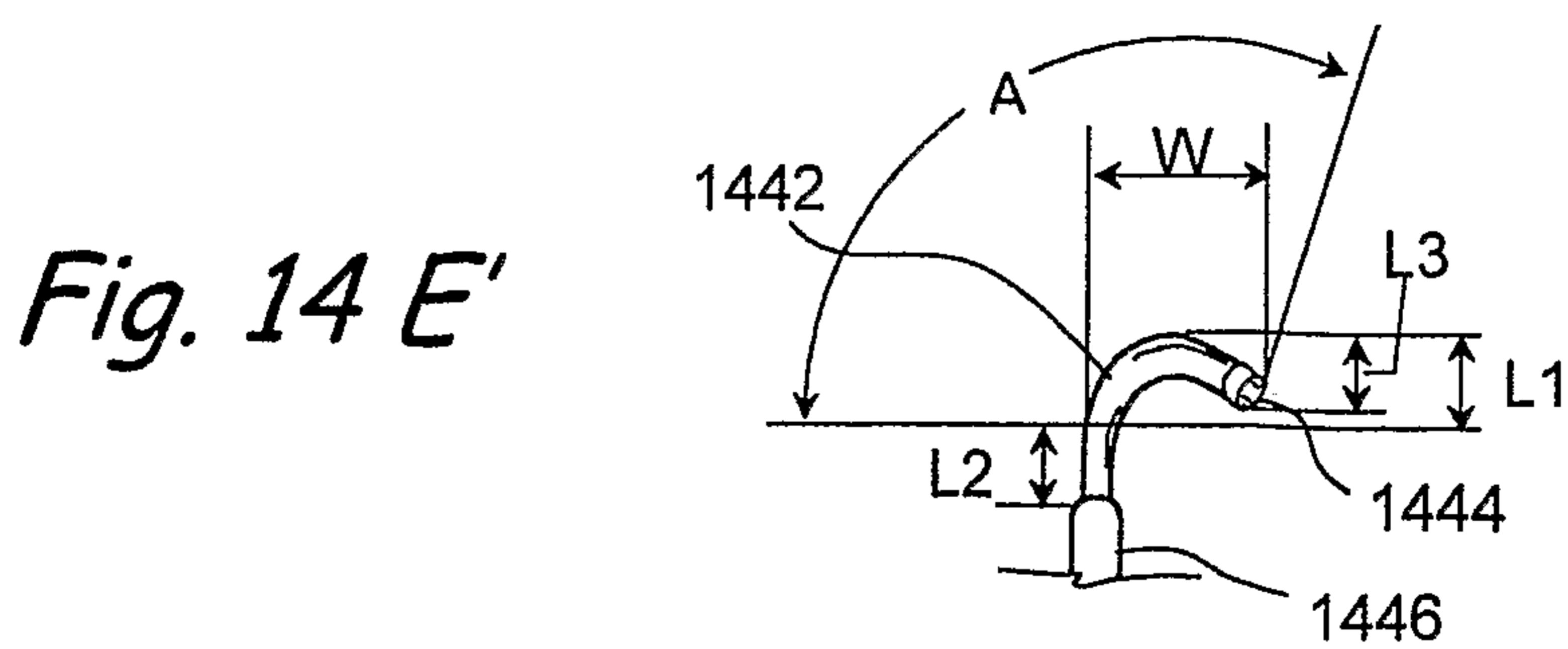
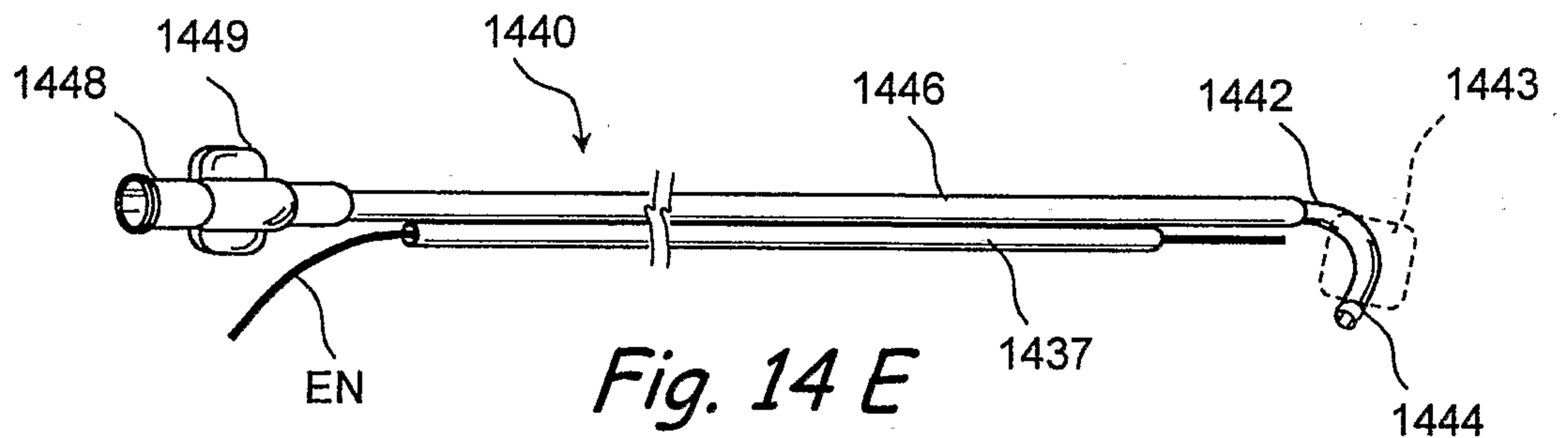
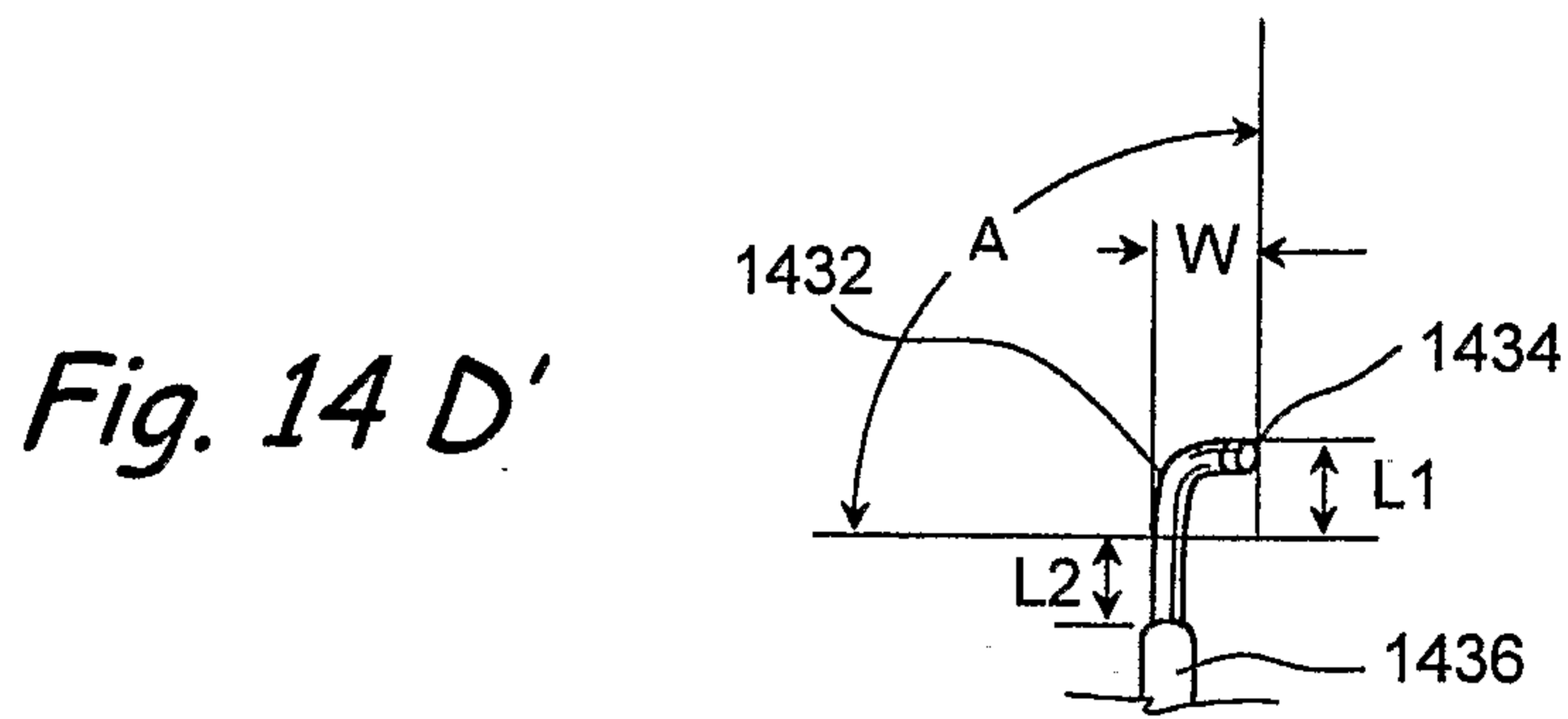
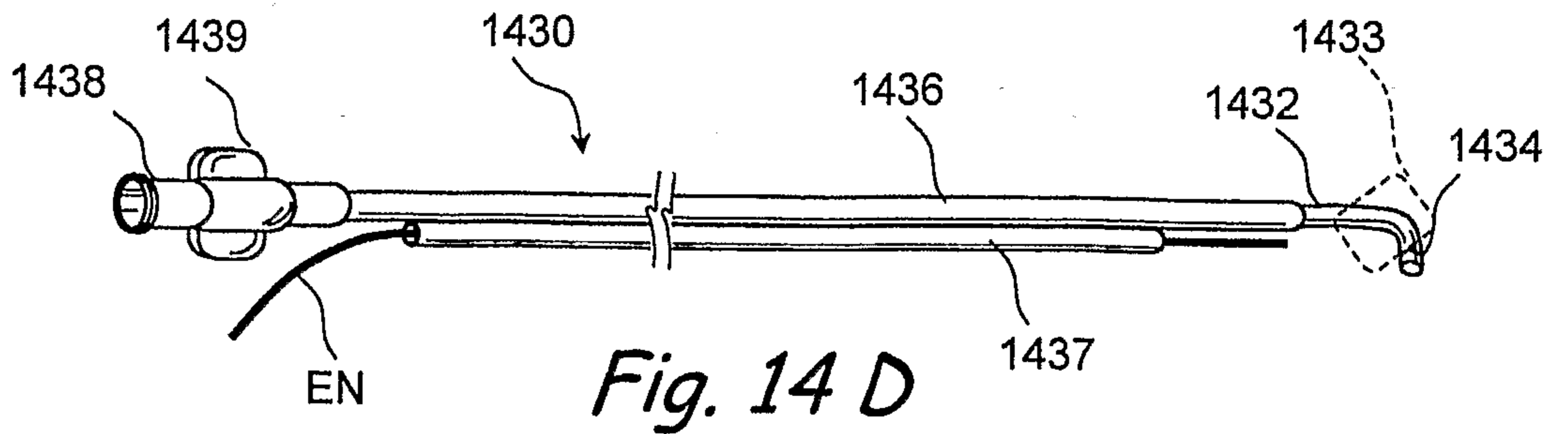
*Fig. 14 B'*

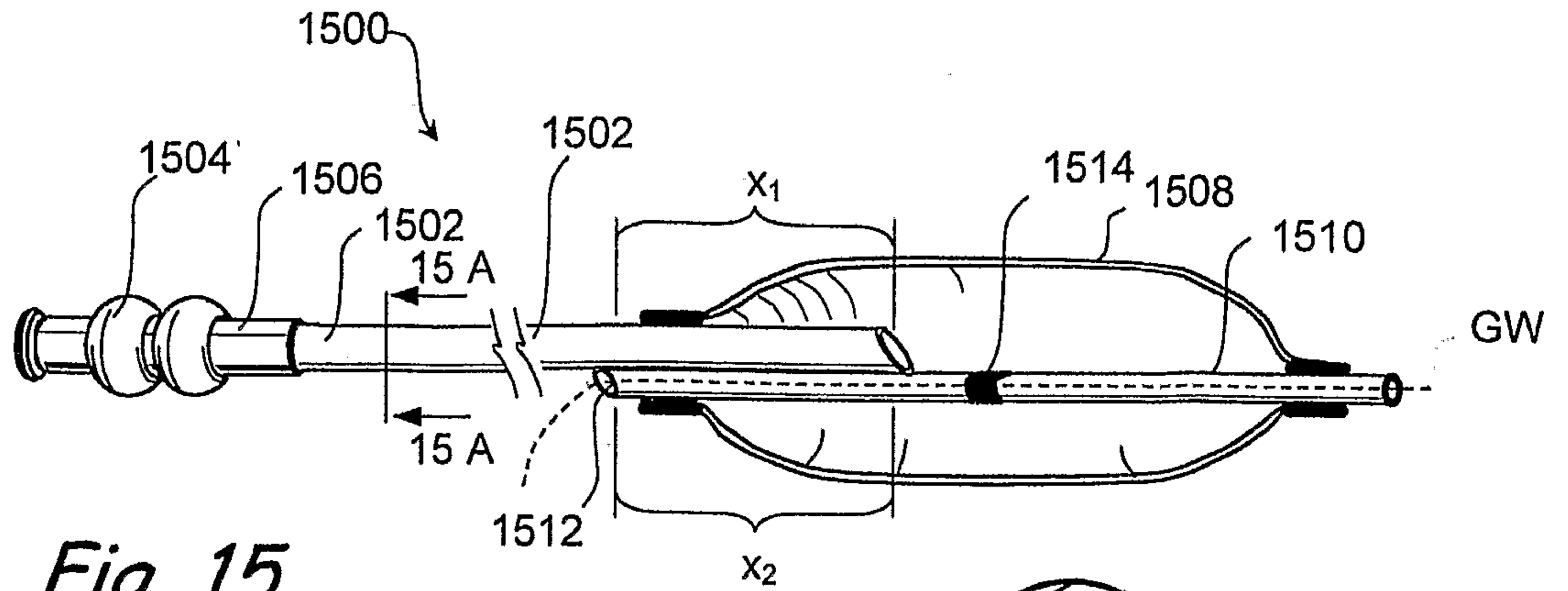


*Fig. 14 C*

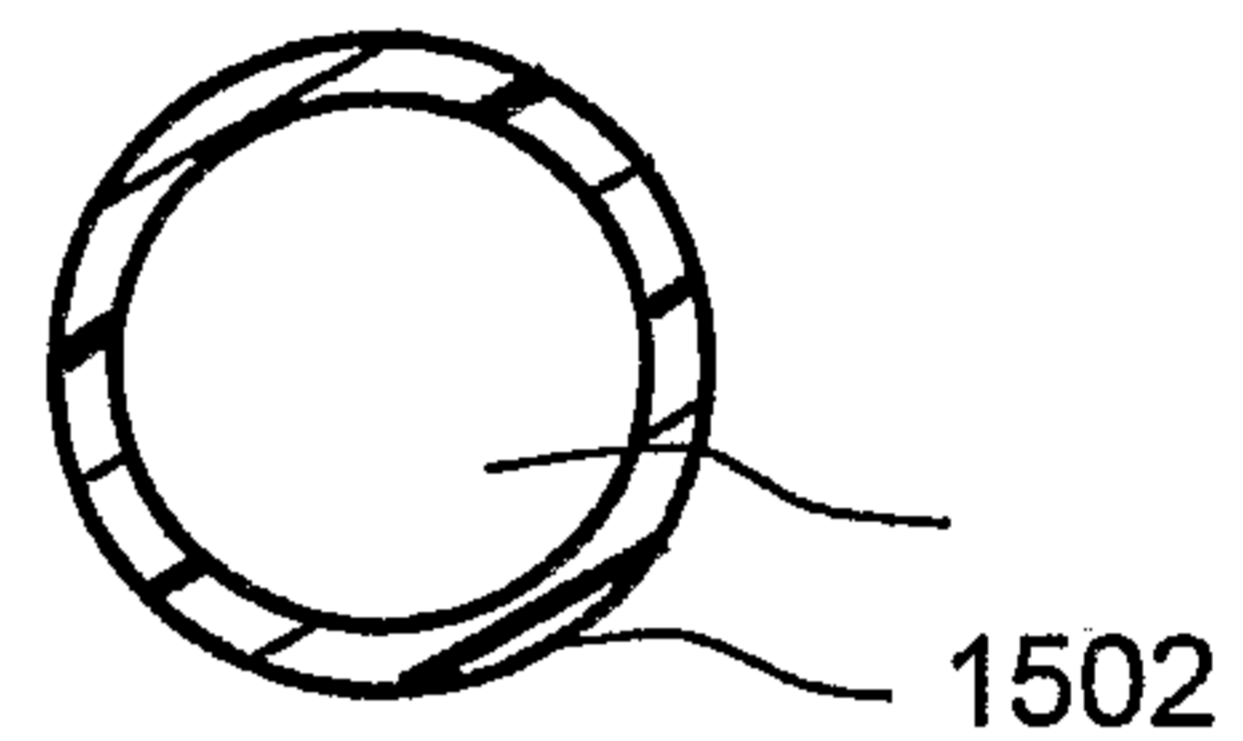


*Fig. 14 C'*

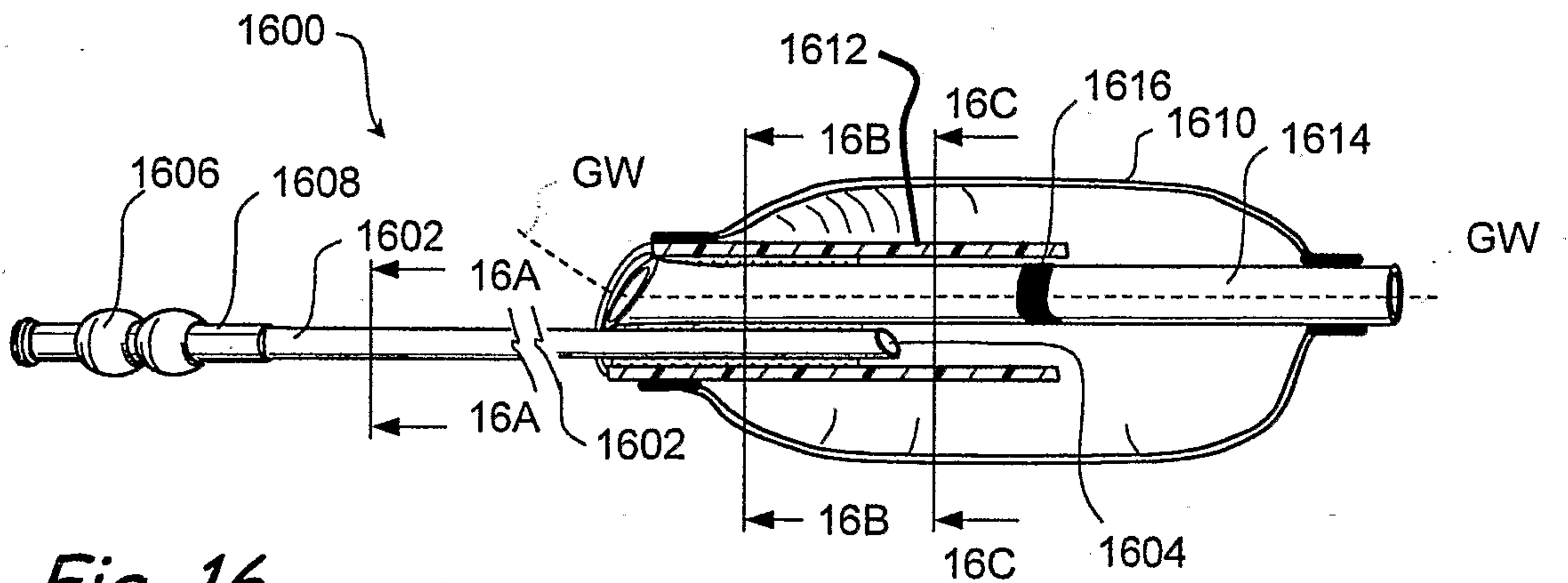




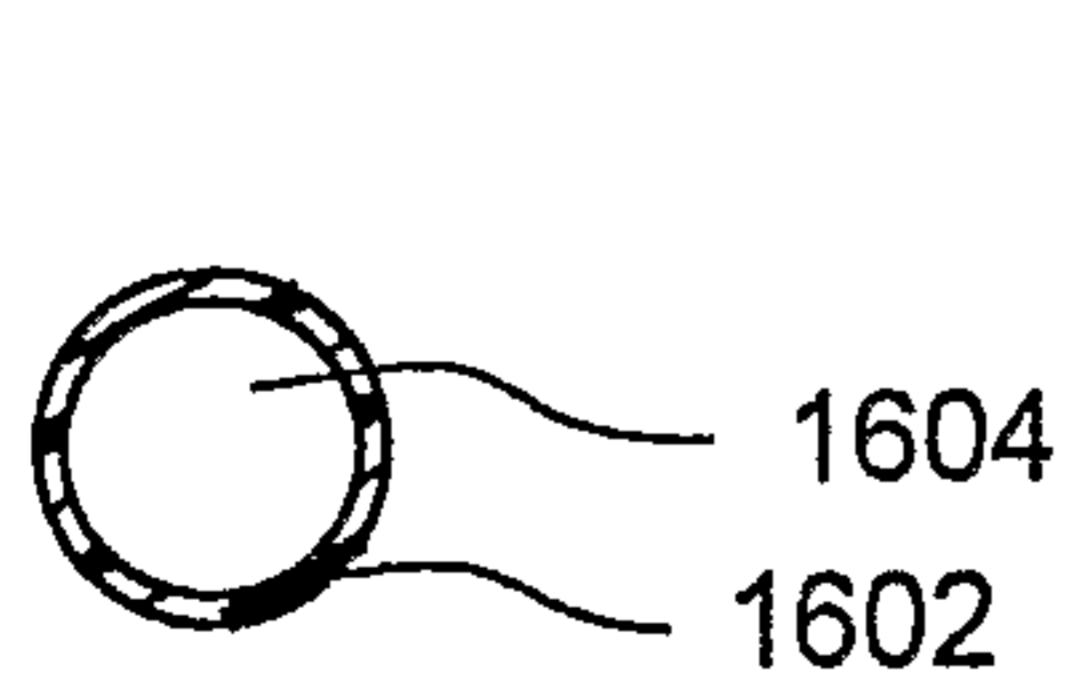
*Fig. 15*



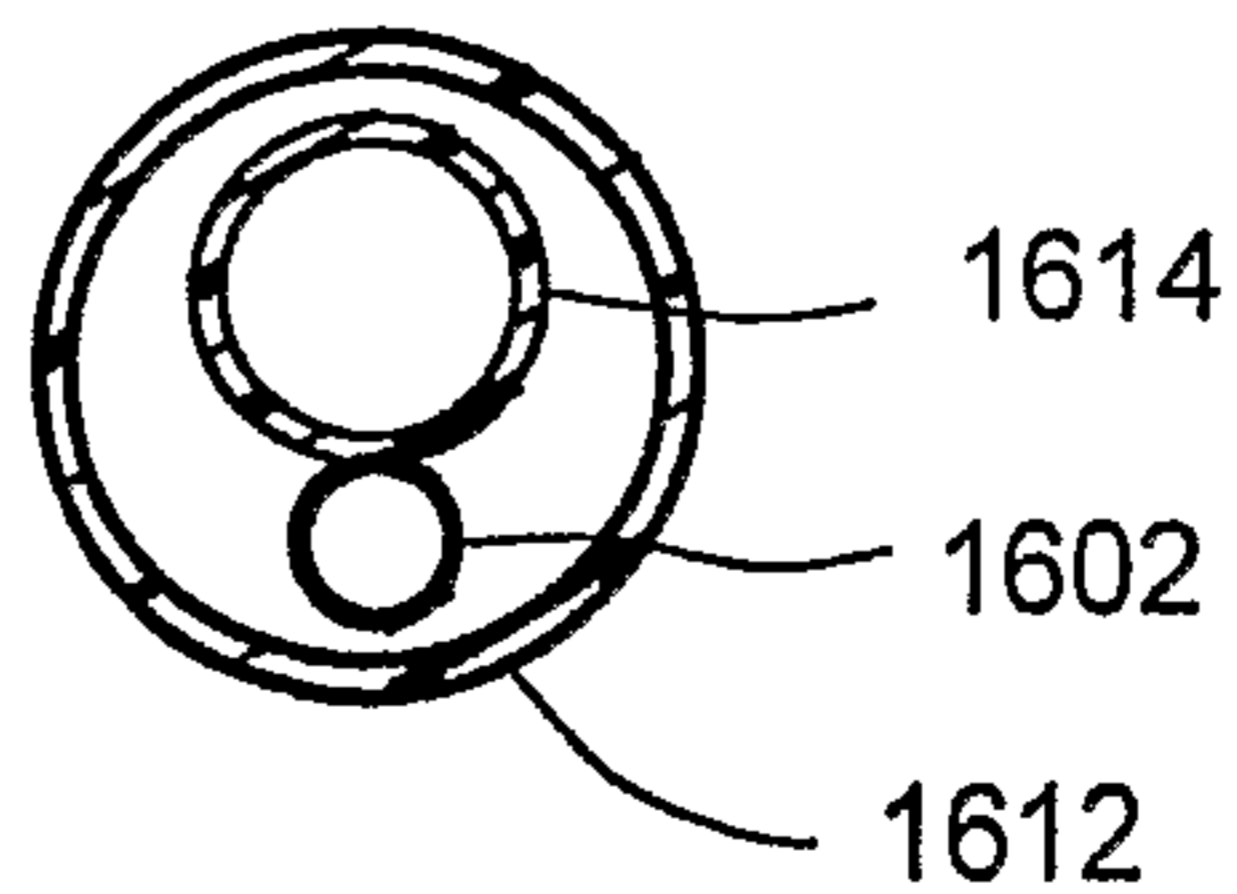
*Fig. 15 A*



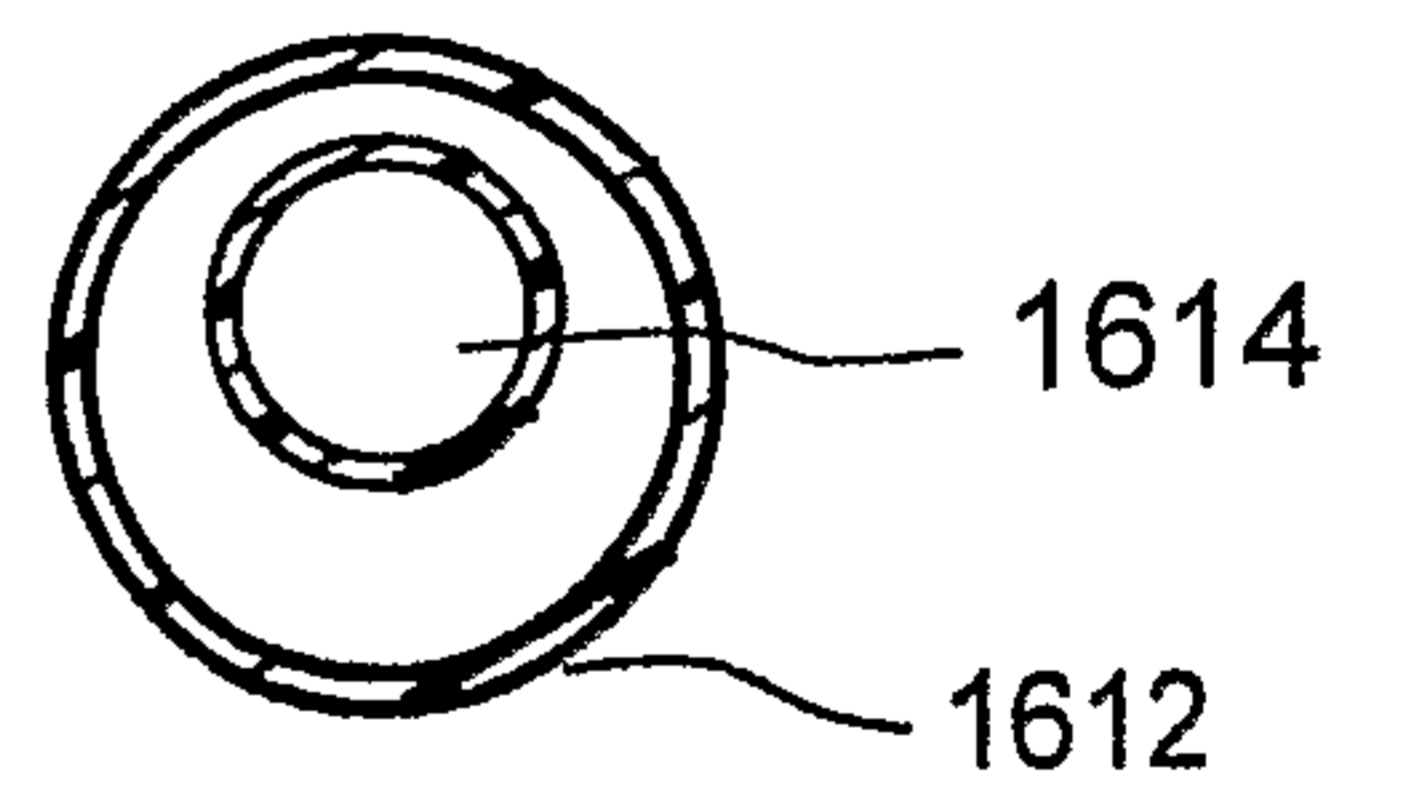
*Fig. 16*



*Fig. 16 A*



*Fig. 16 B*



*Fig. 16 C*

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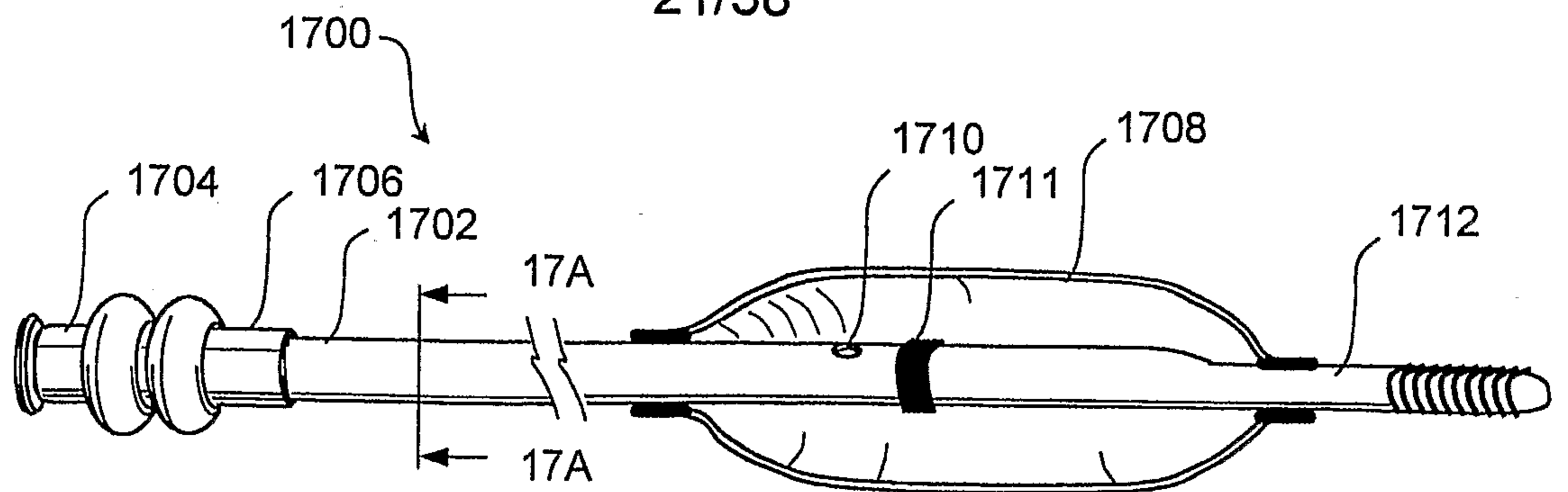


Fig. 17

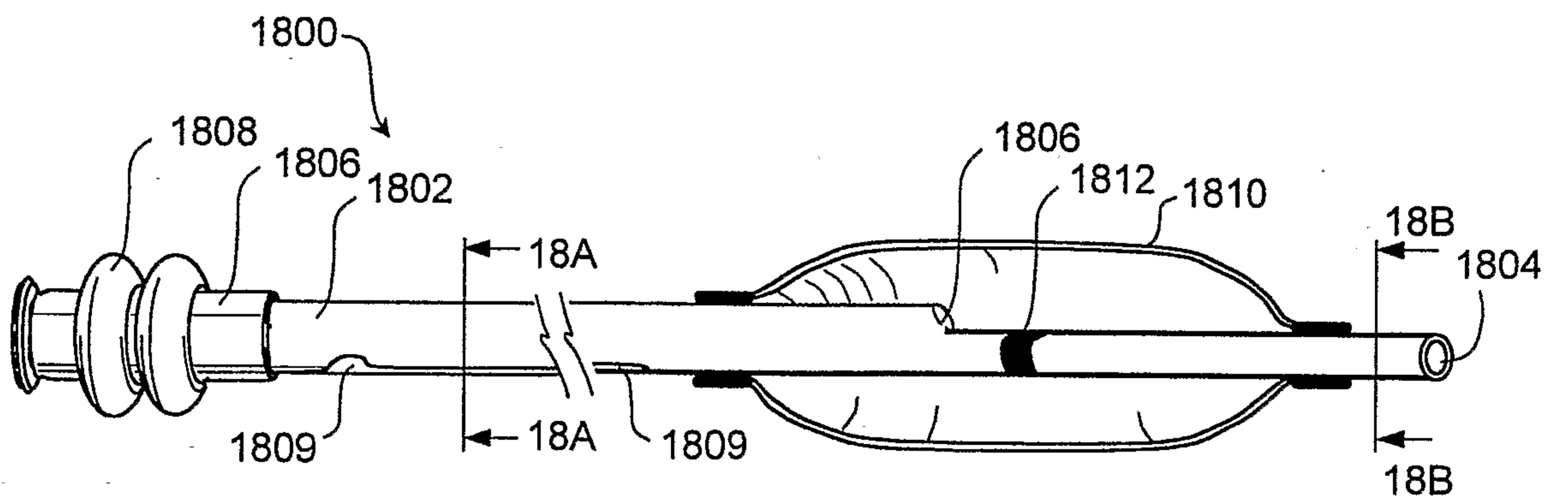
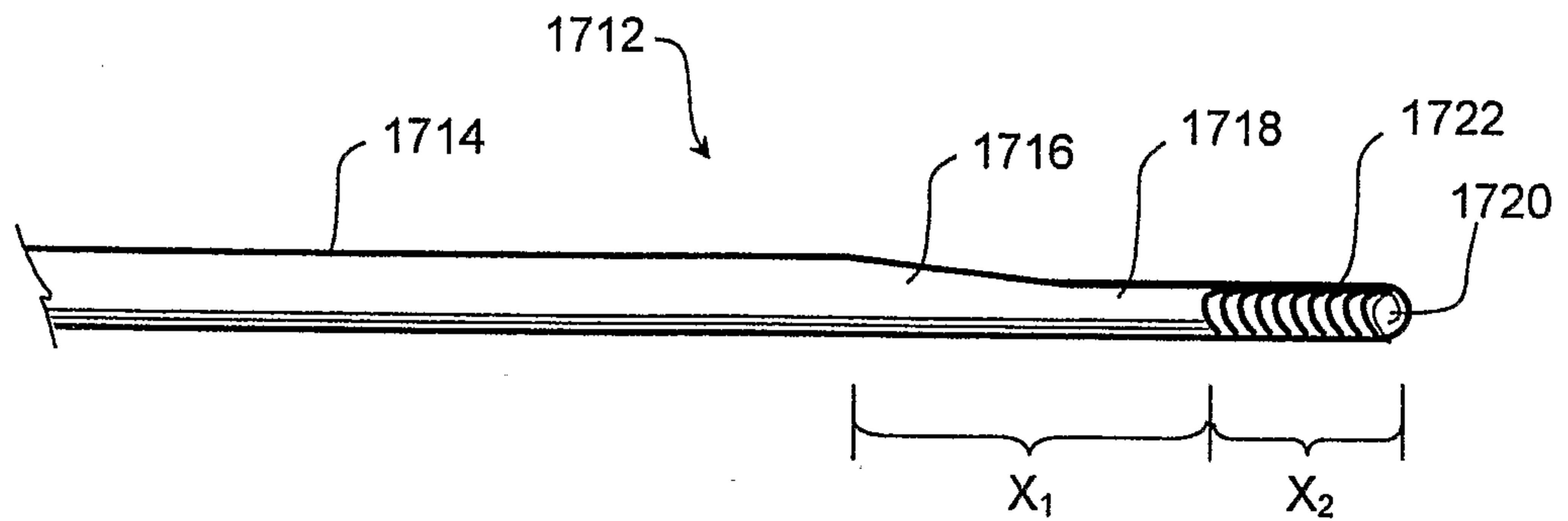


Fig. 18

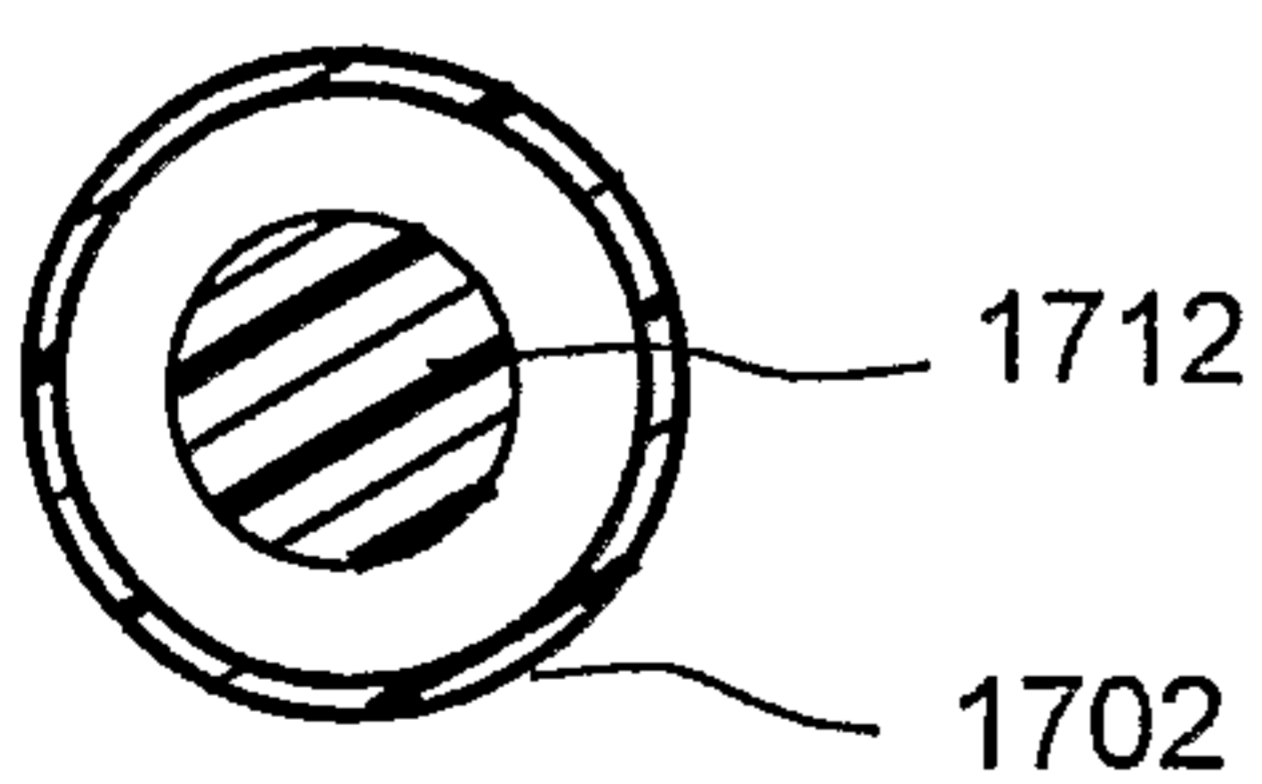


Fig. 17 A

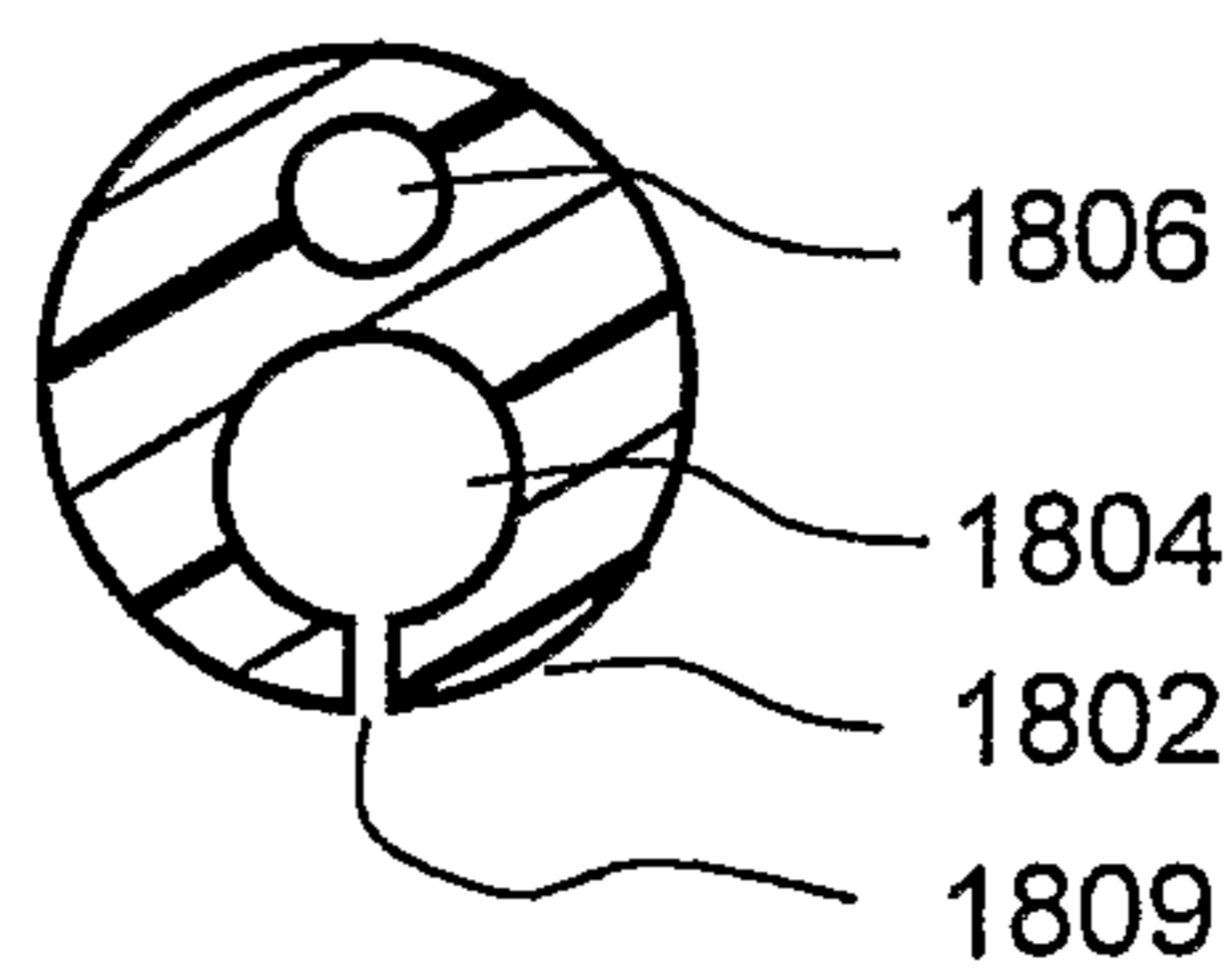


Fig. 18 A

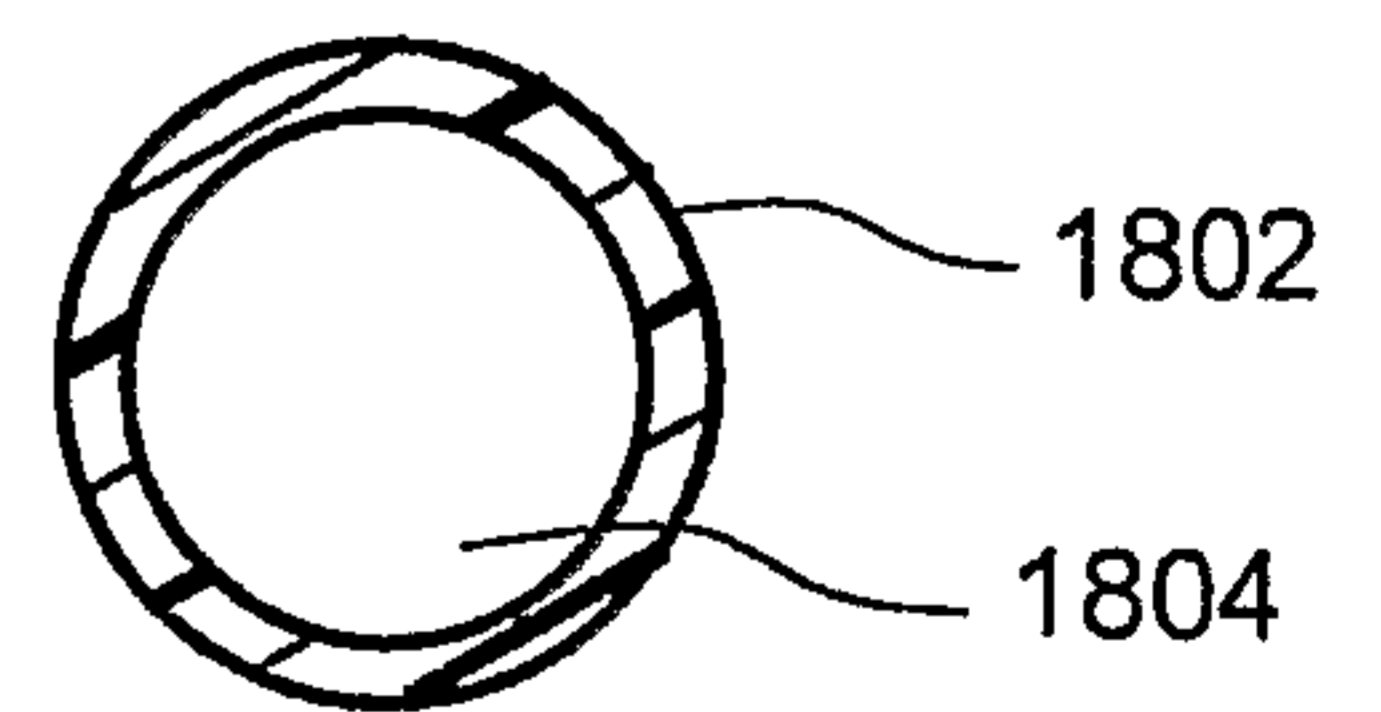
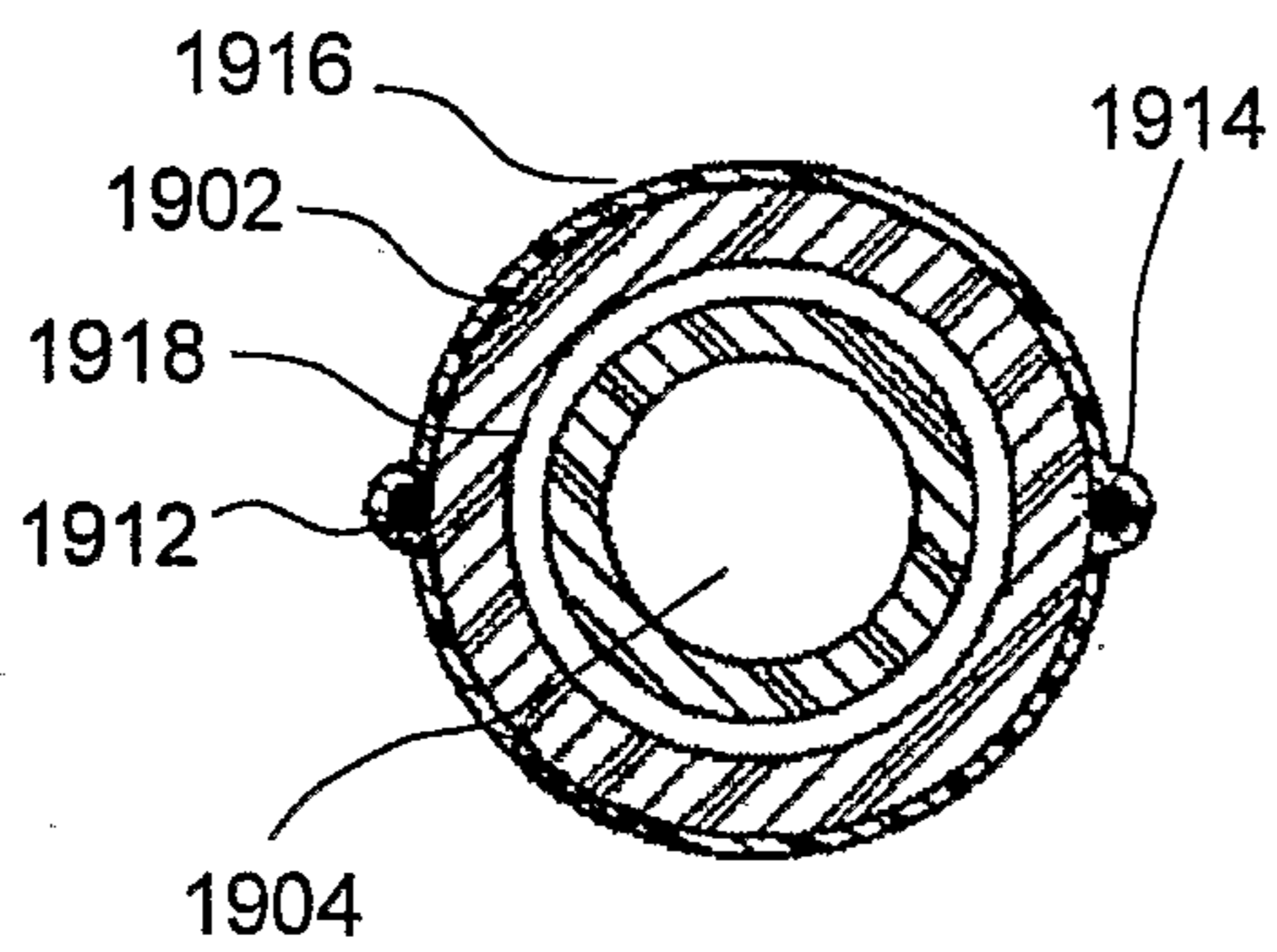
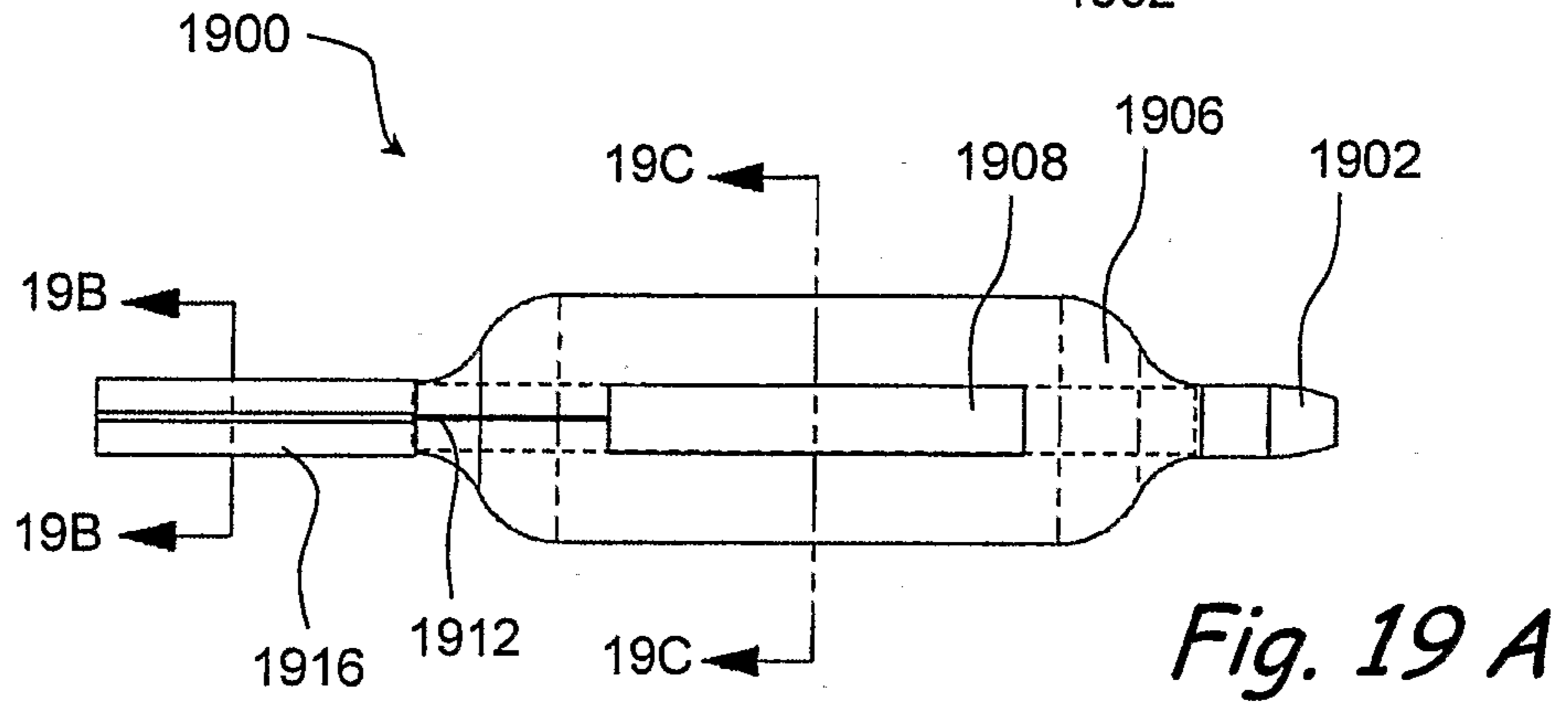
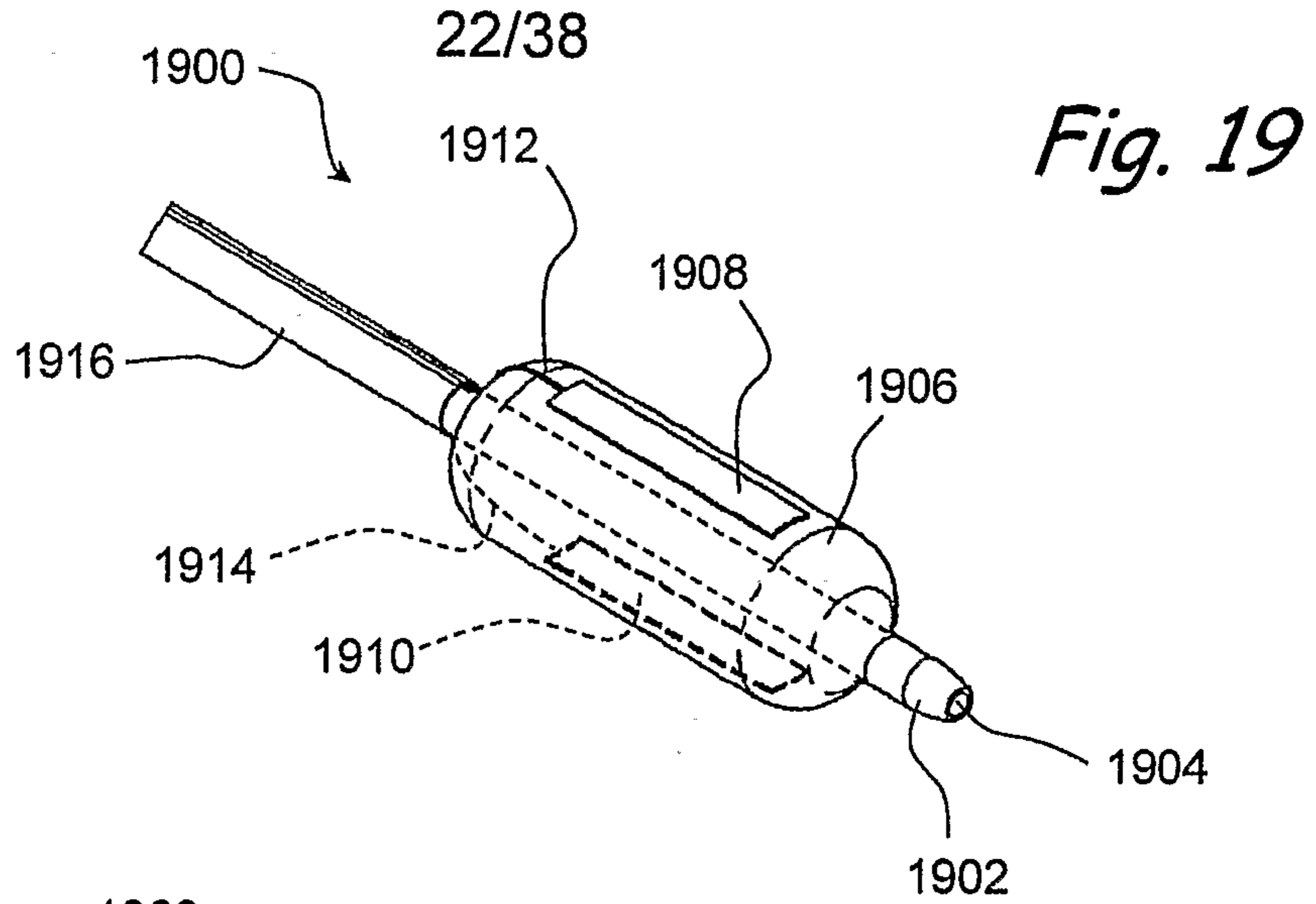
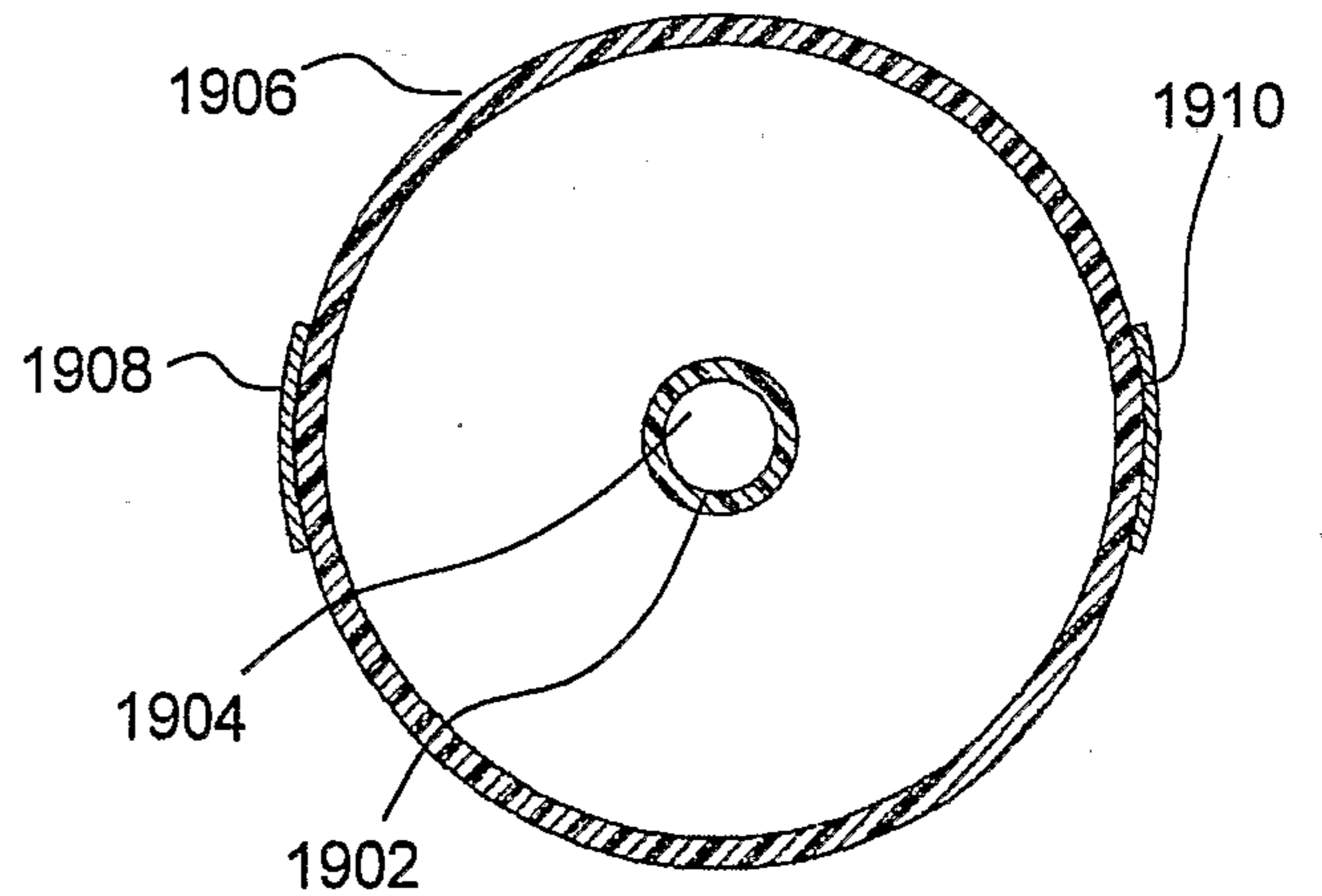


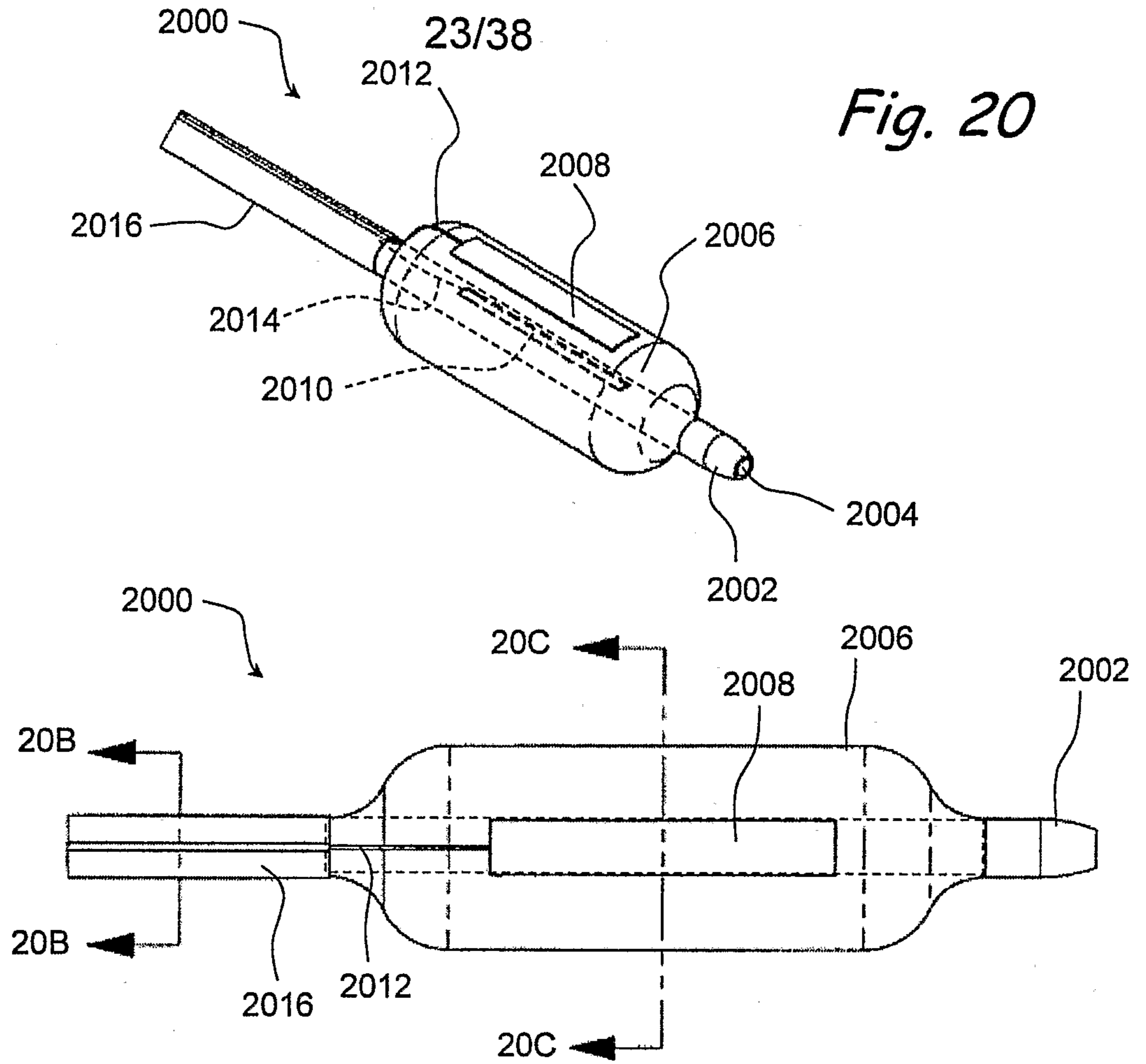
Fig. 18 B



*Fig. 19 B*

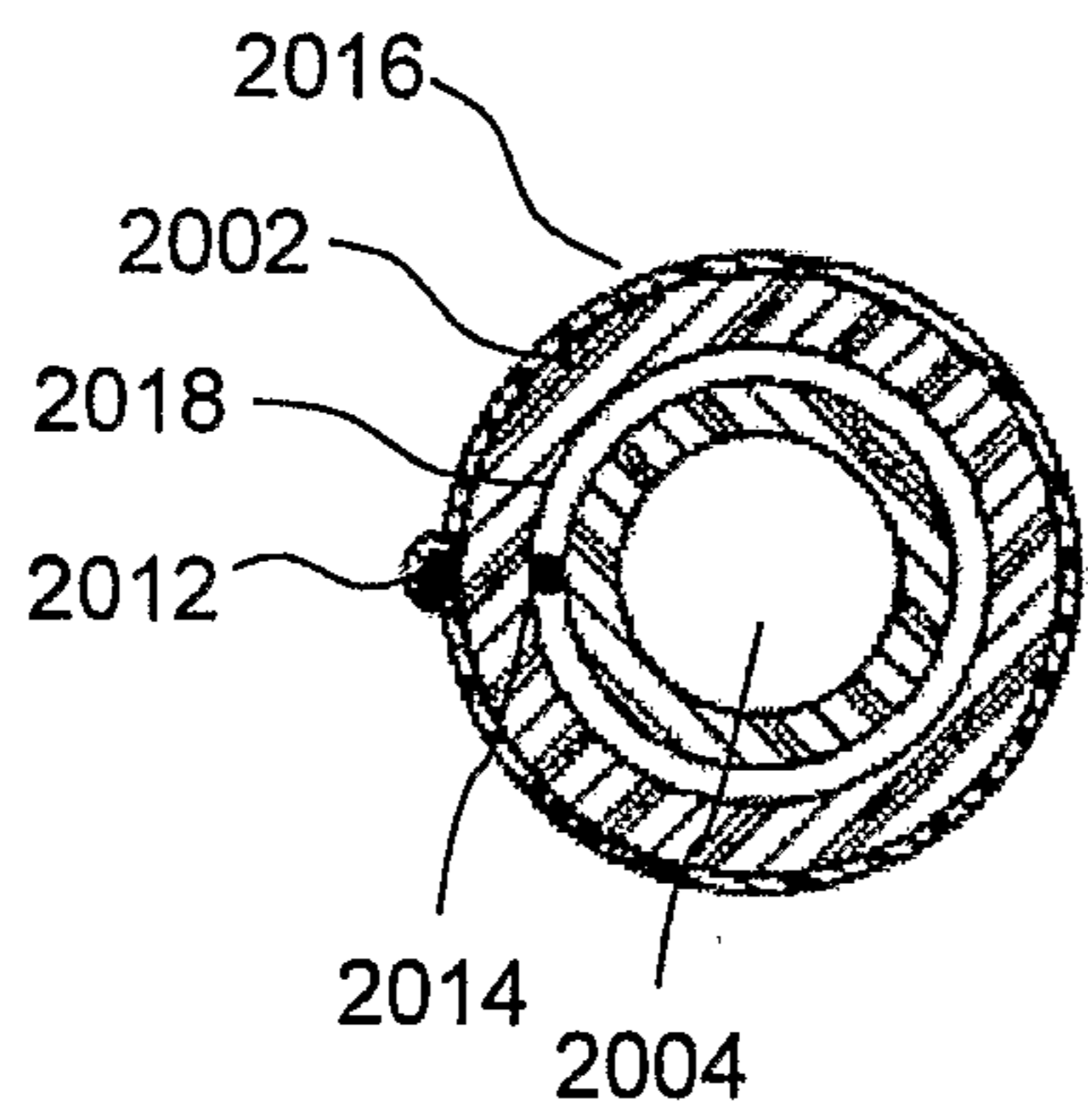


*Fig. 19 C*

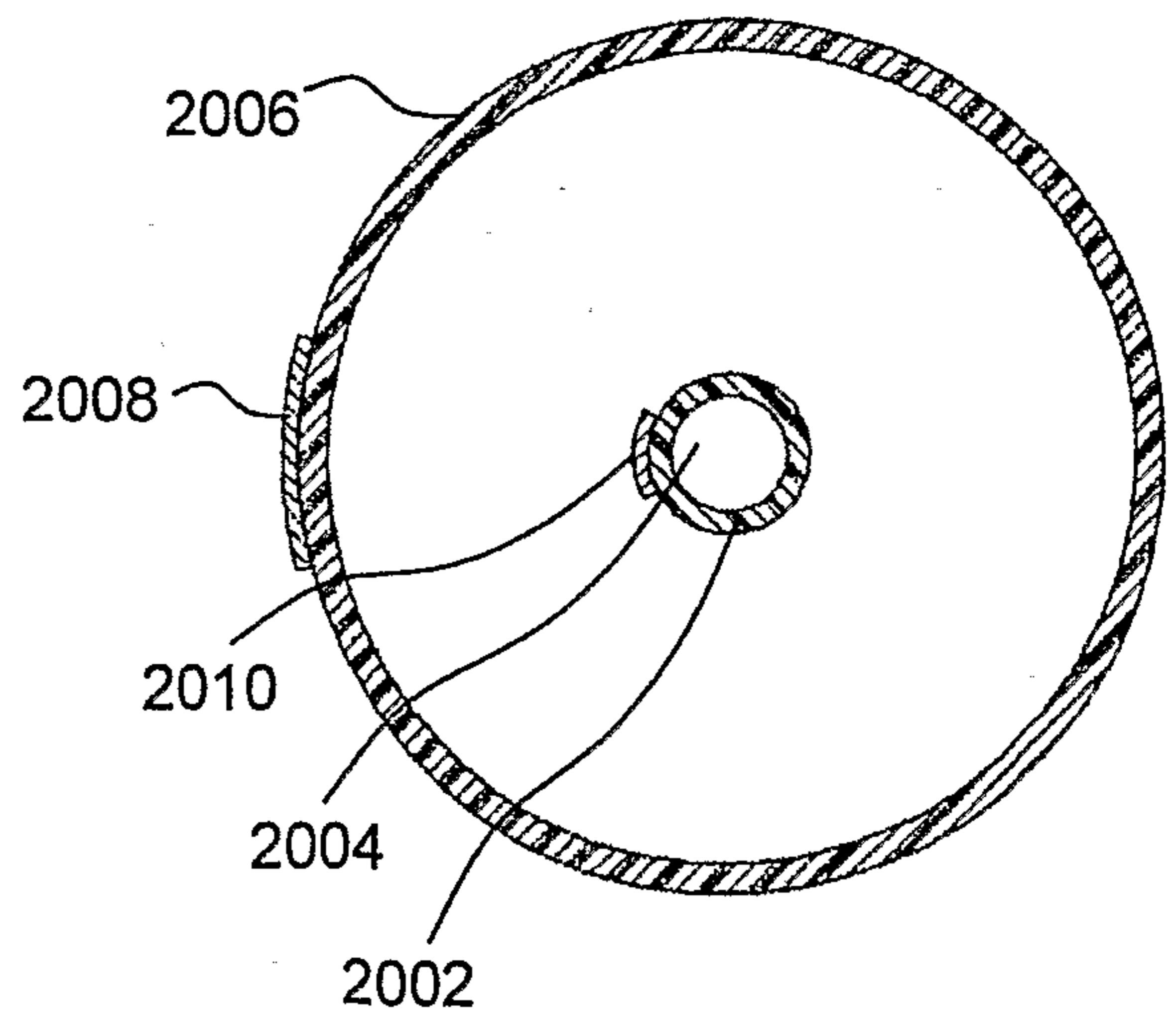


*Fig. 20*

*Fig. 20 A*

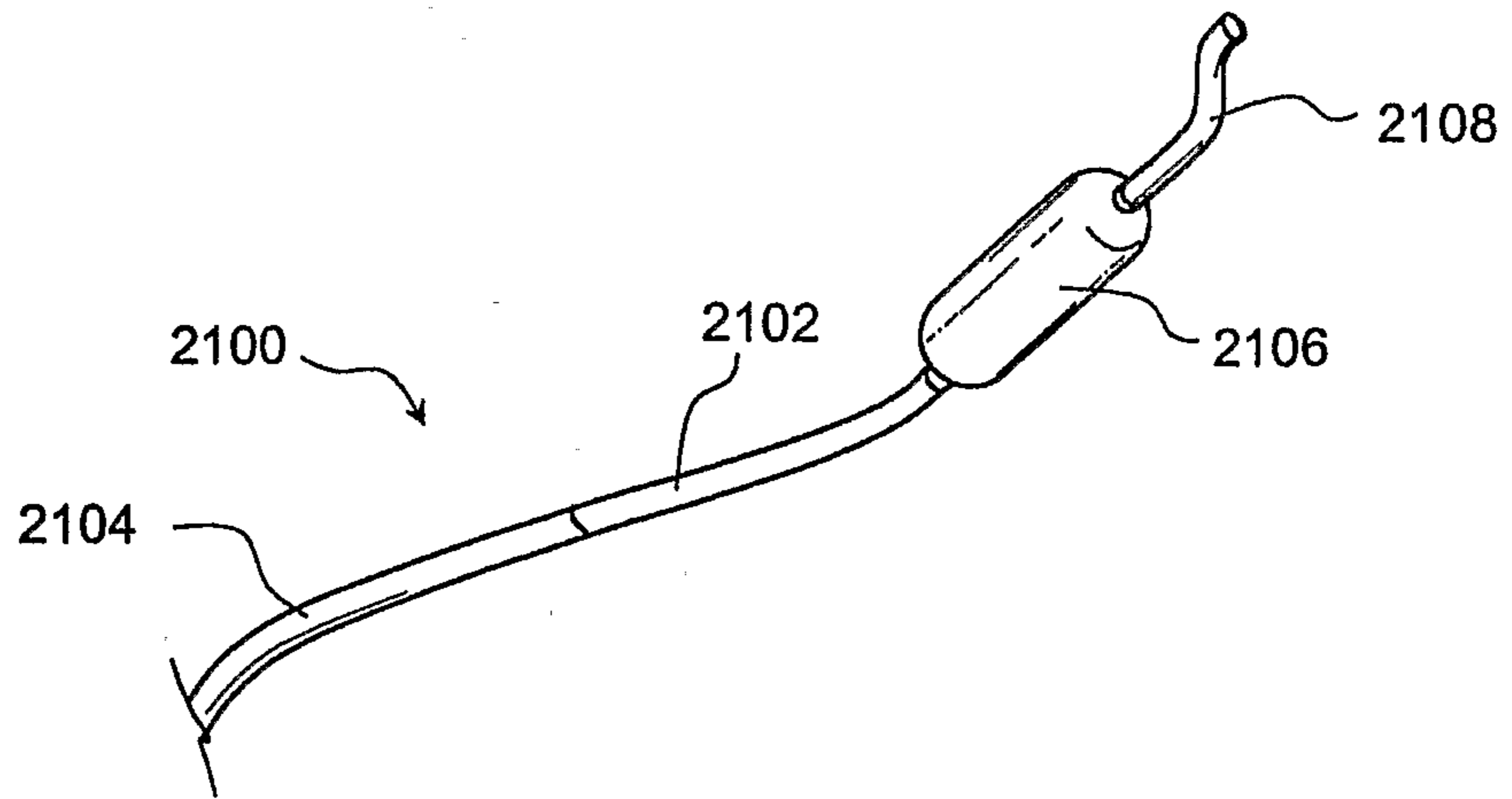


*Fig. 20 B*

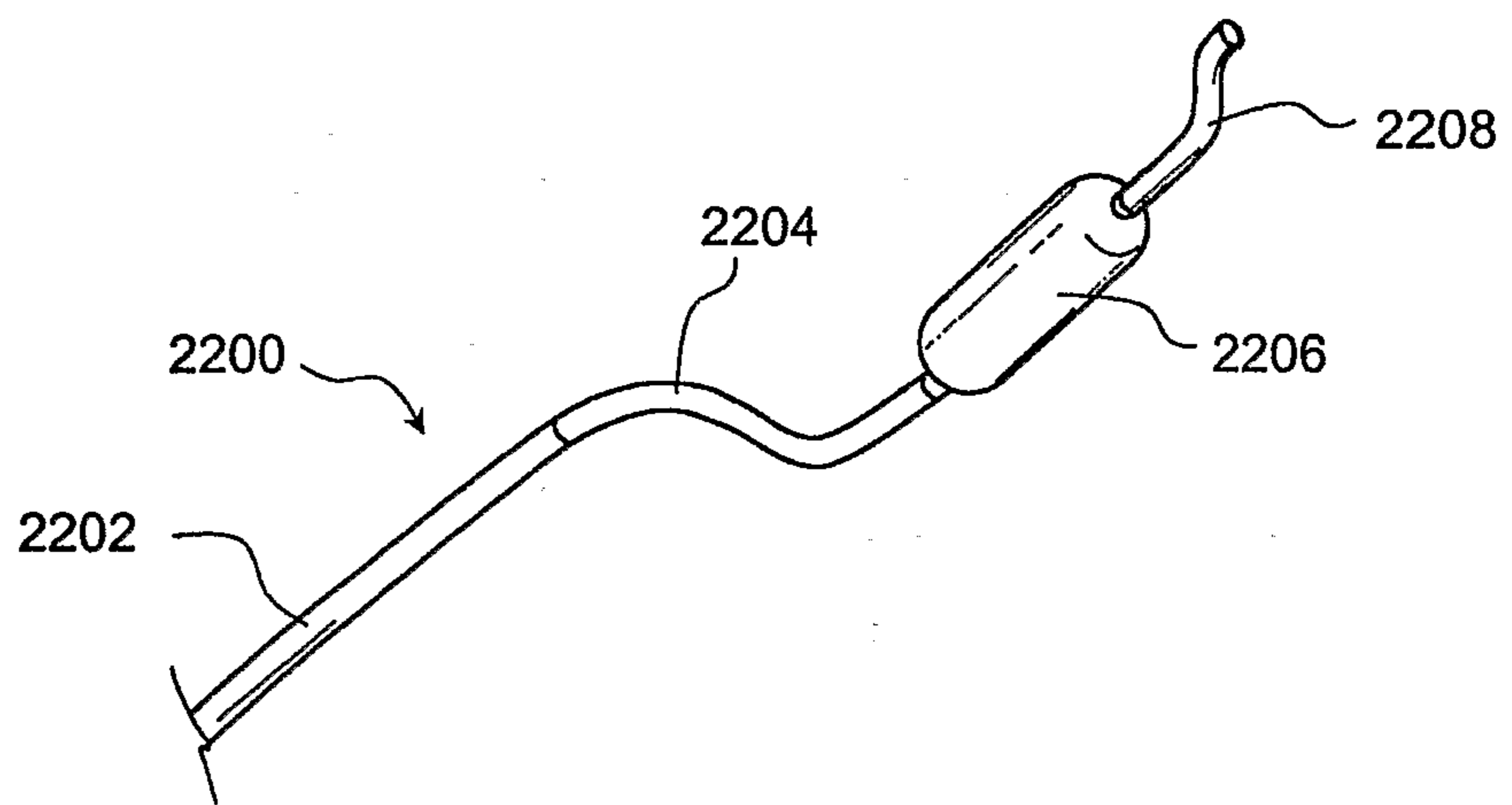


*Fig. 20 C*

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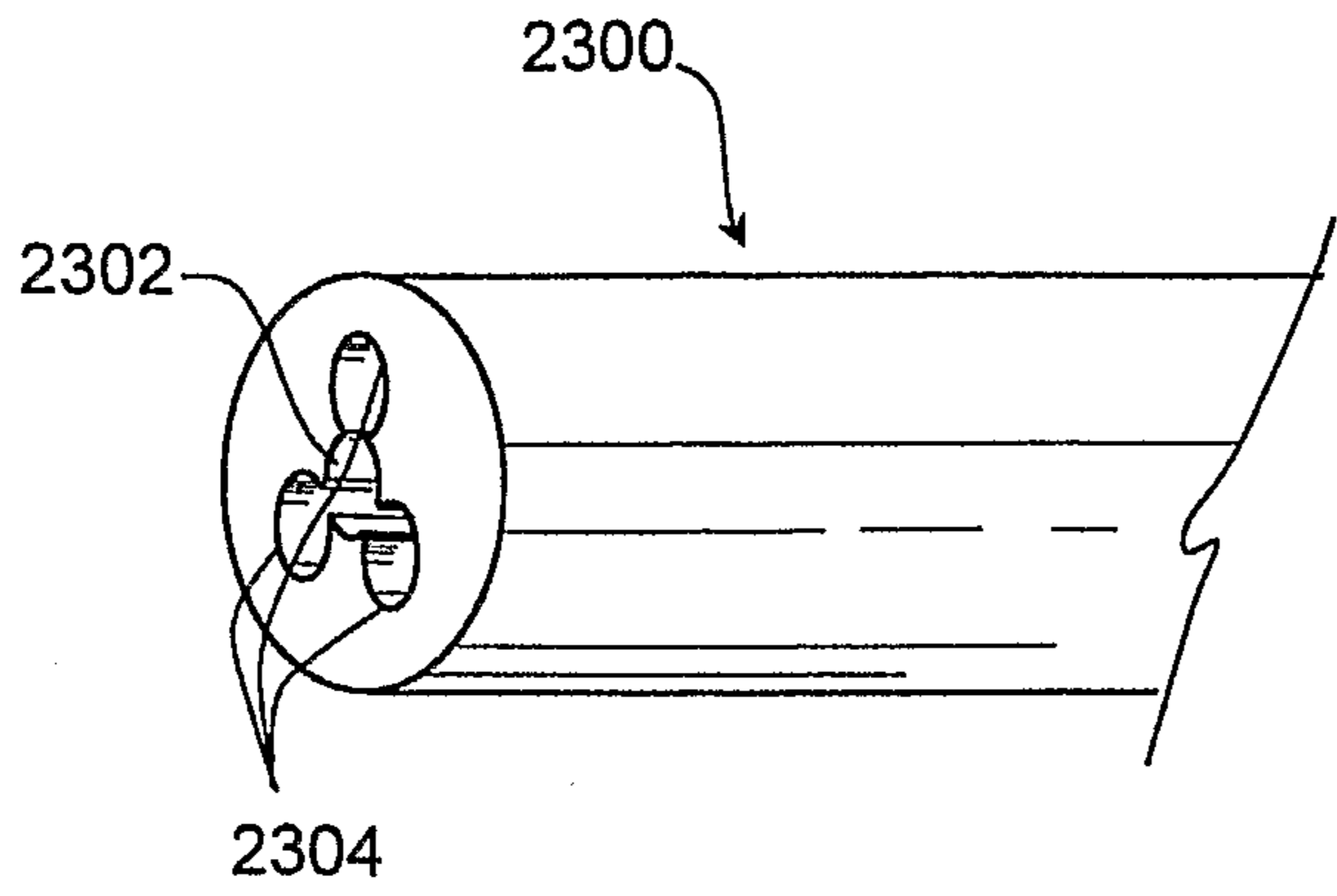
*Fig. 21*



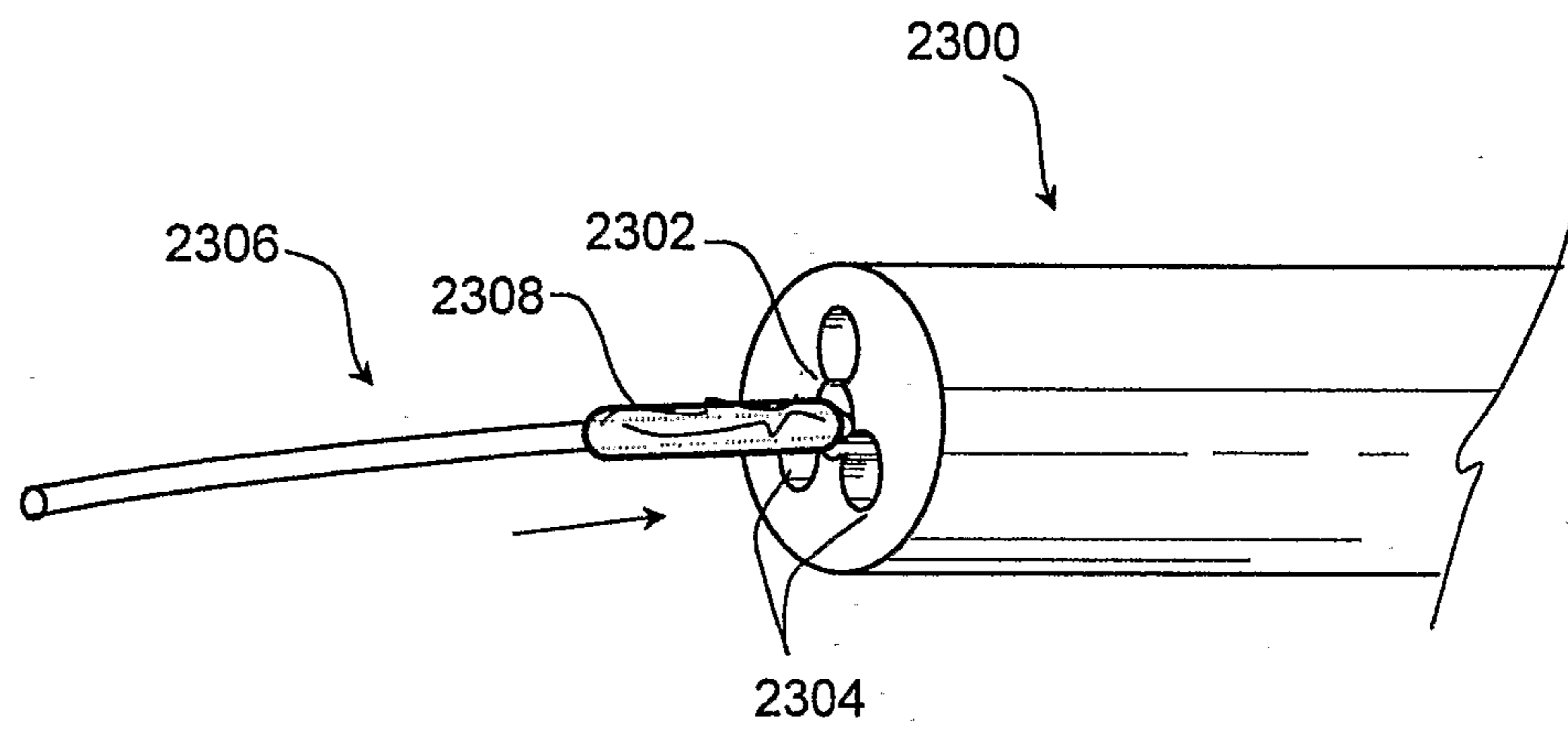
*Fig. 22*



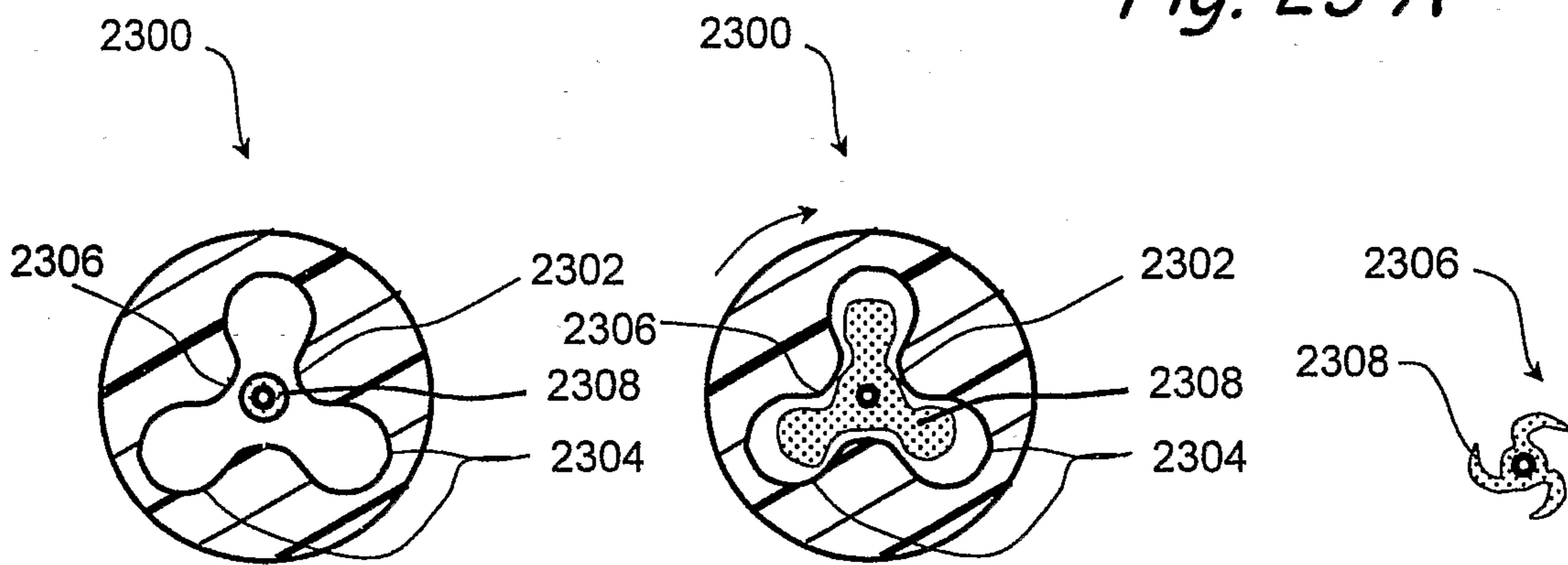
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*Fig. 23*



*Fig. 23 A*

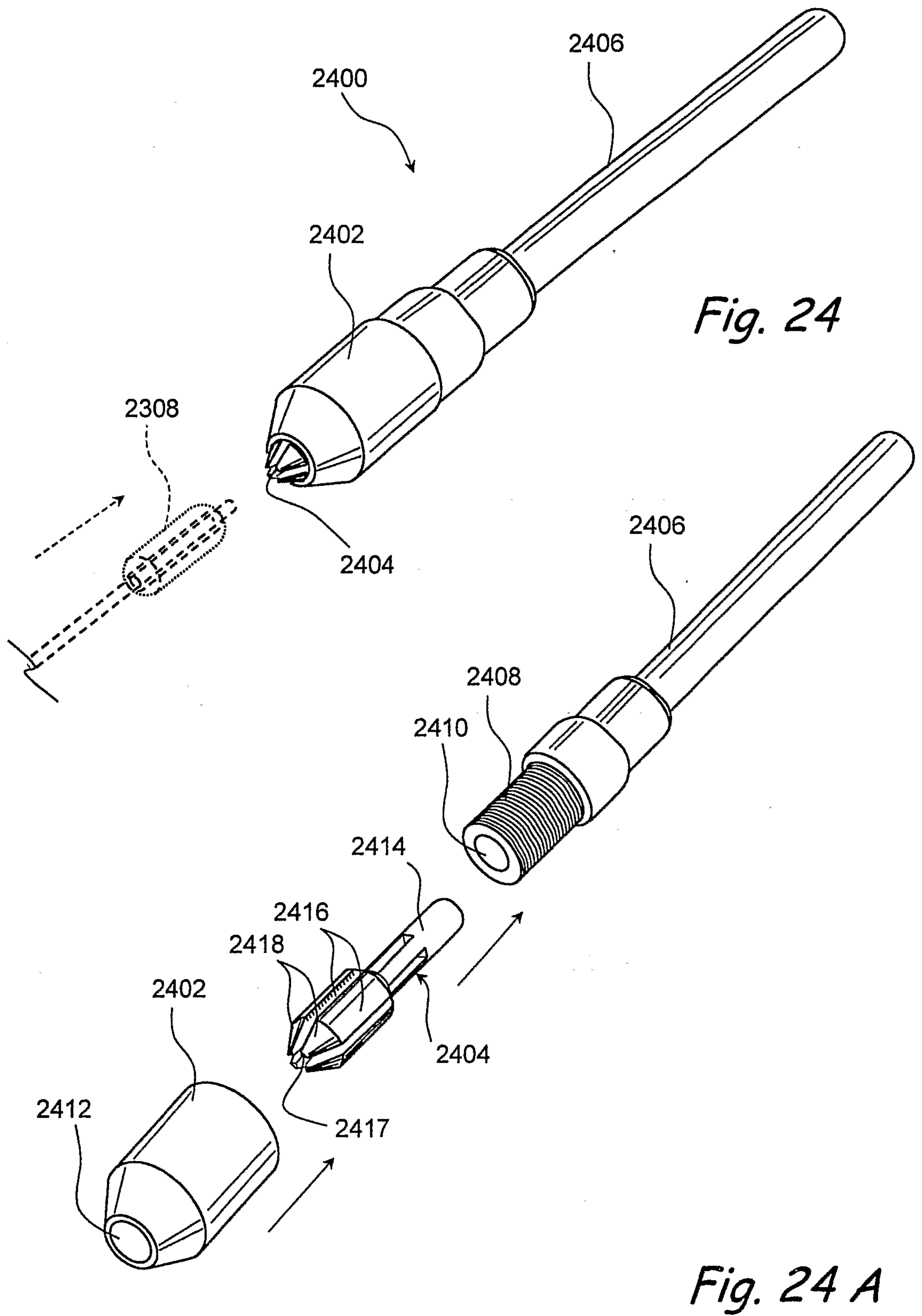


*Fig. 23 B*

*Fig. 23 C*

*Fig. 23 D*

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*Fig. 24*

*Fig. 24 A*

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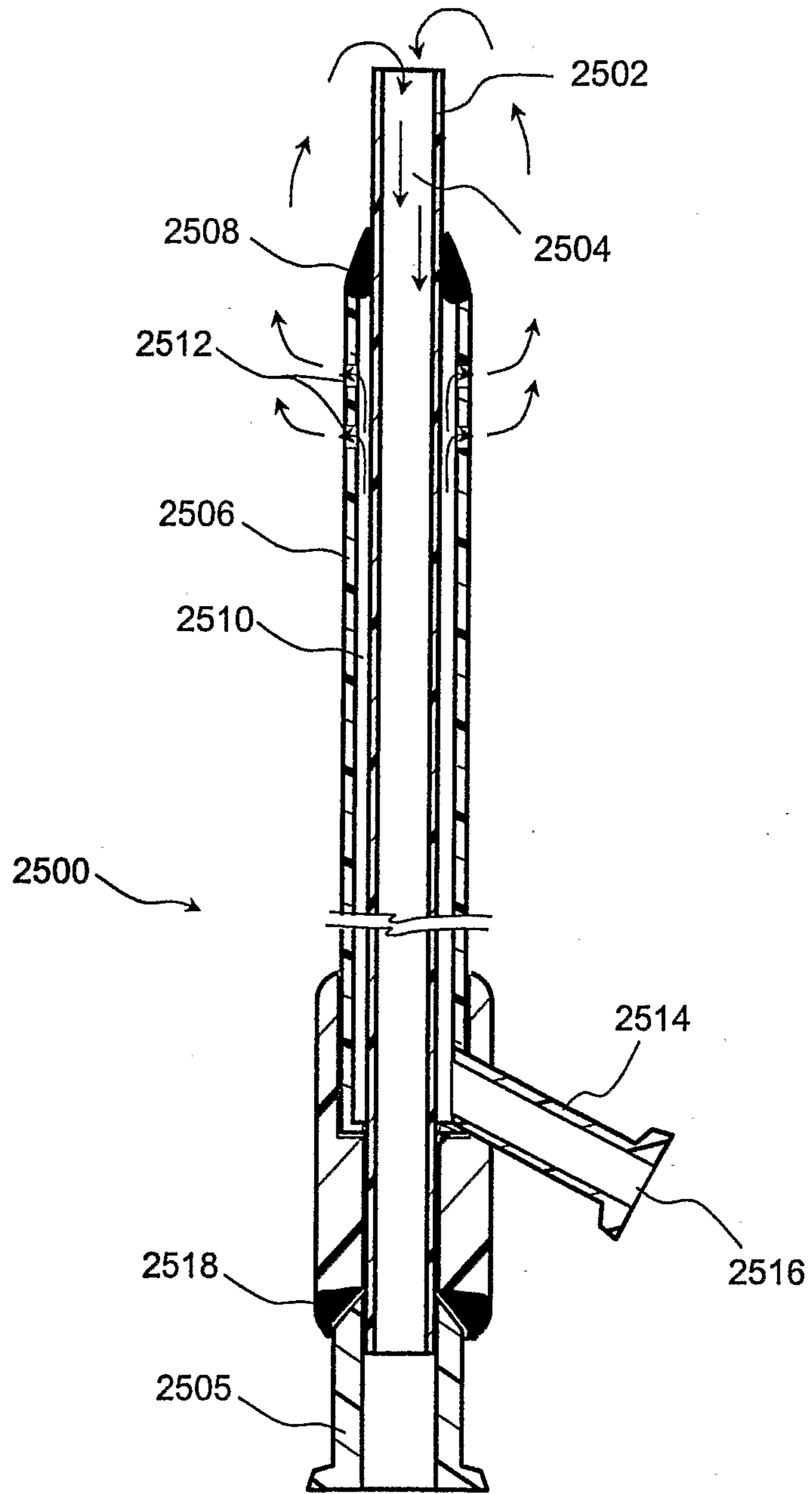
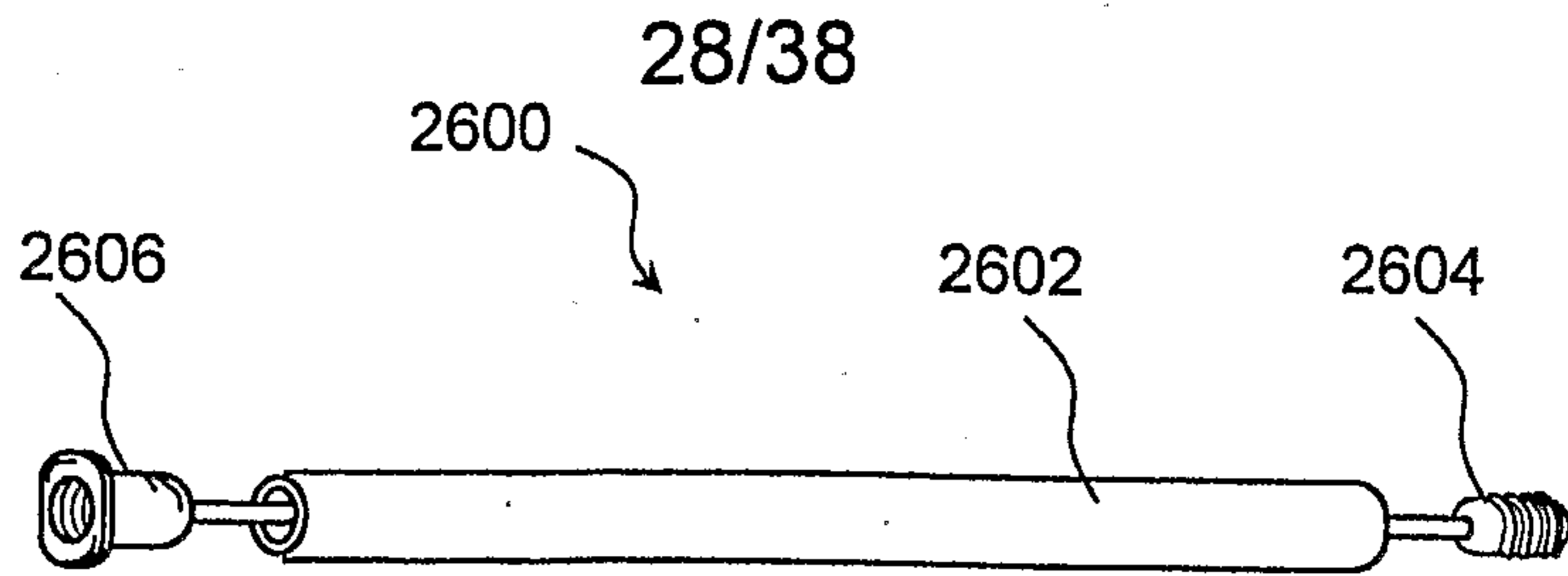
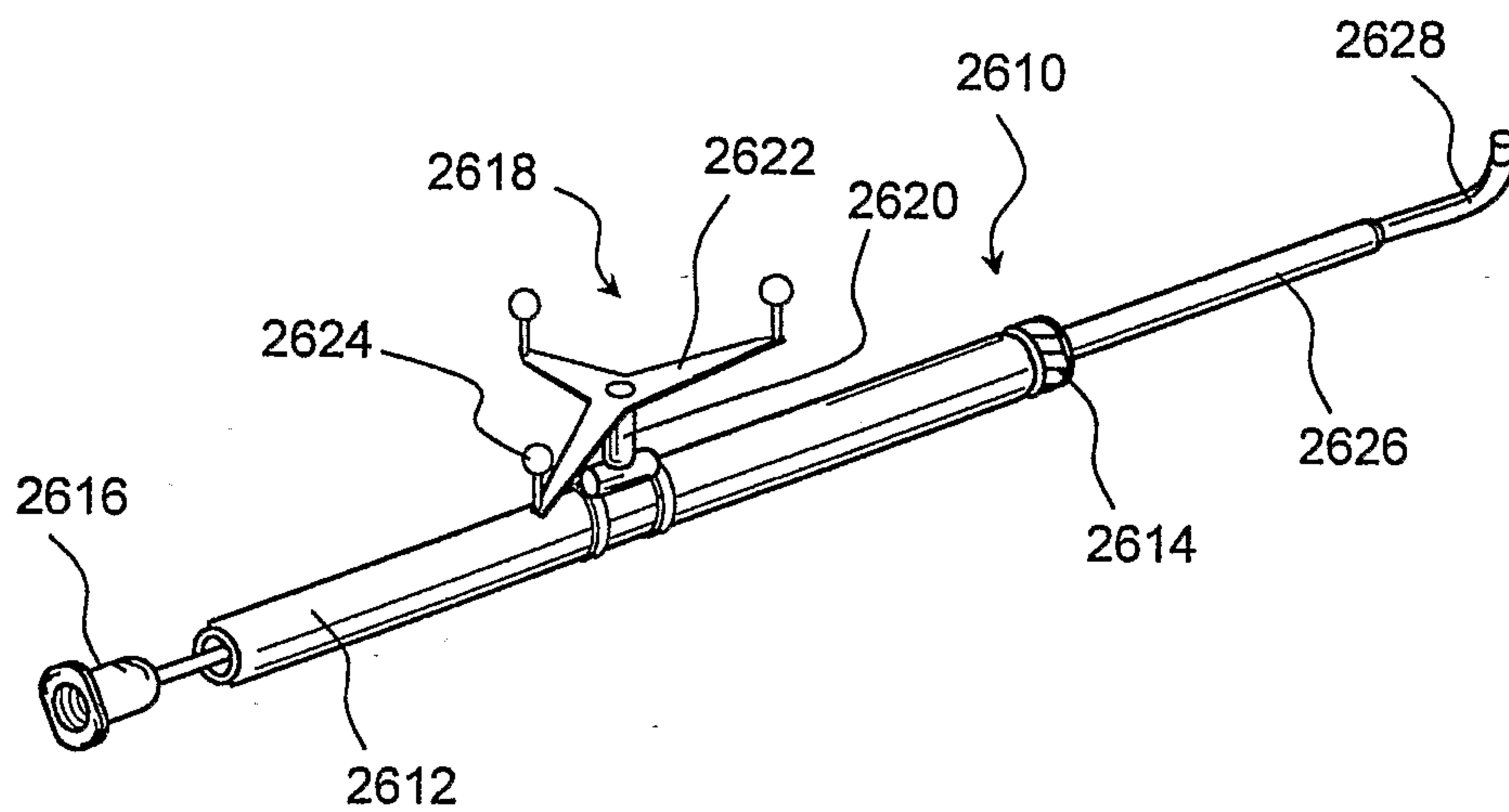


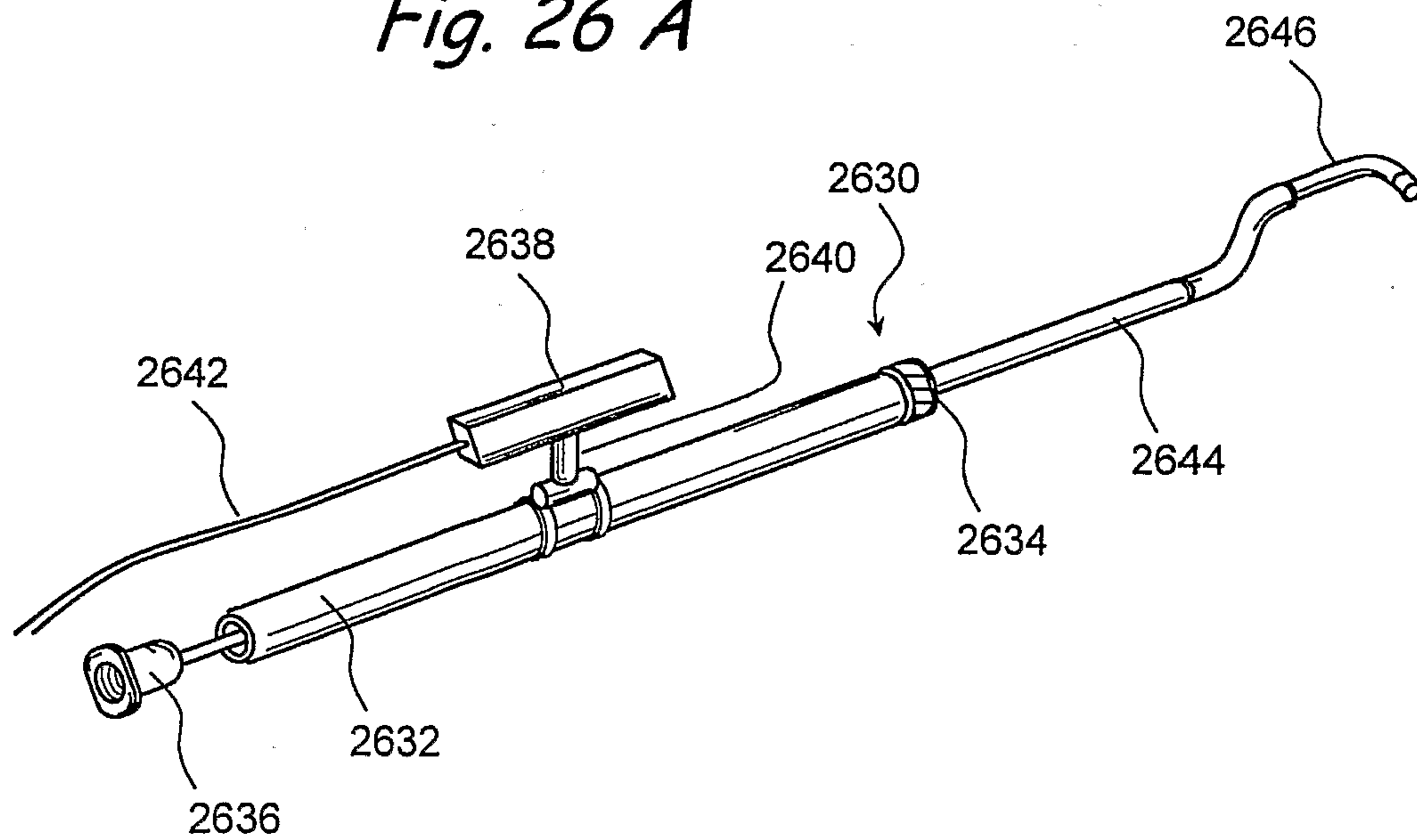
Fig. 25



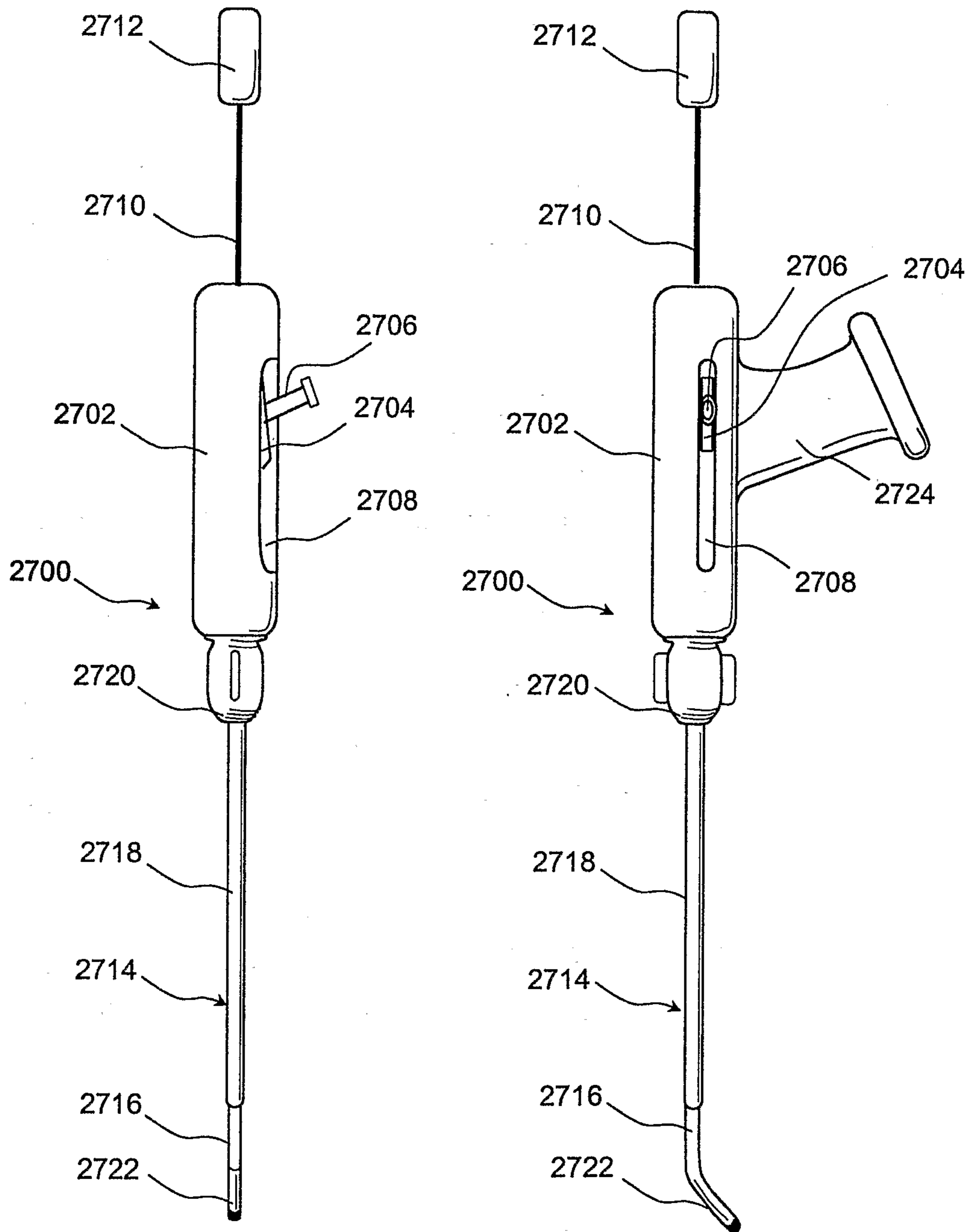
*Fig. 26*



*Fig. 26 A*



*Fig. 26 B*



*Fig. 27 A*

*Fig. 27 B*

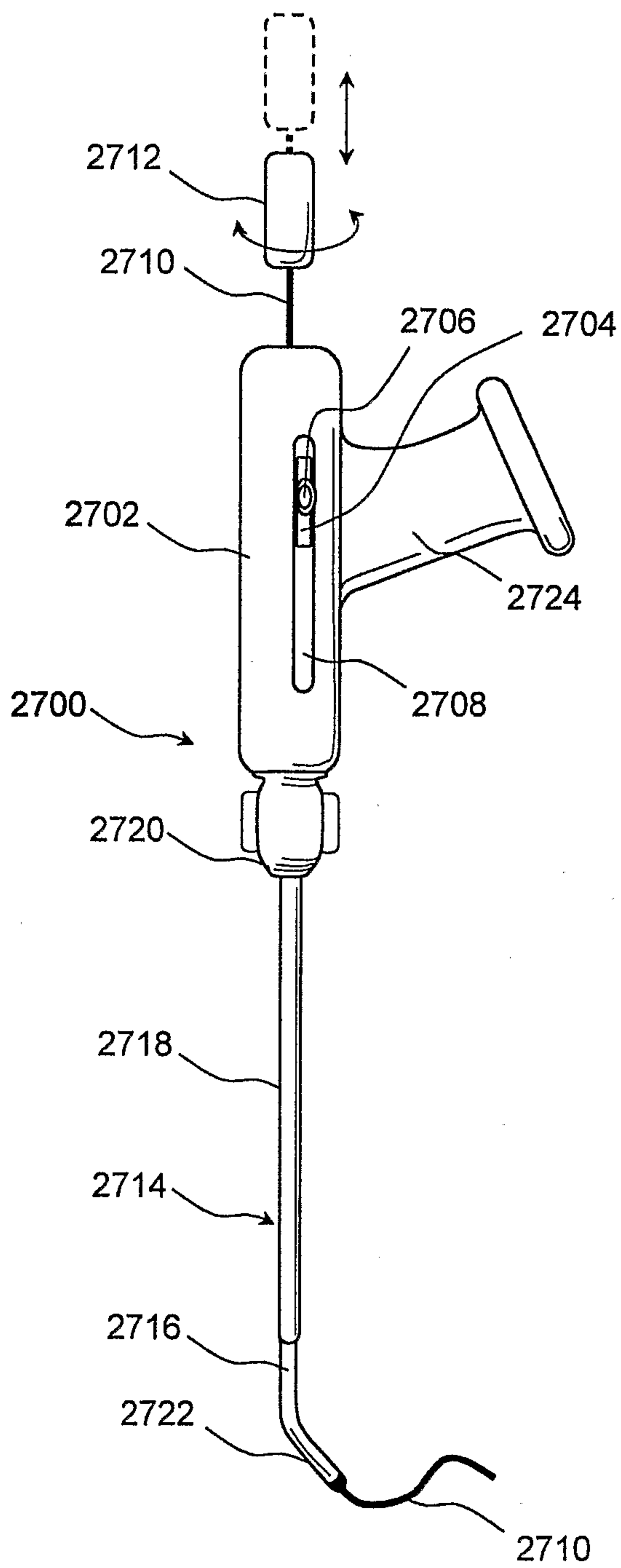


Fig. 27 C

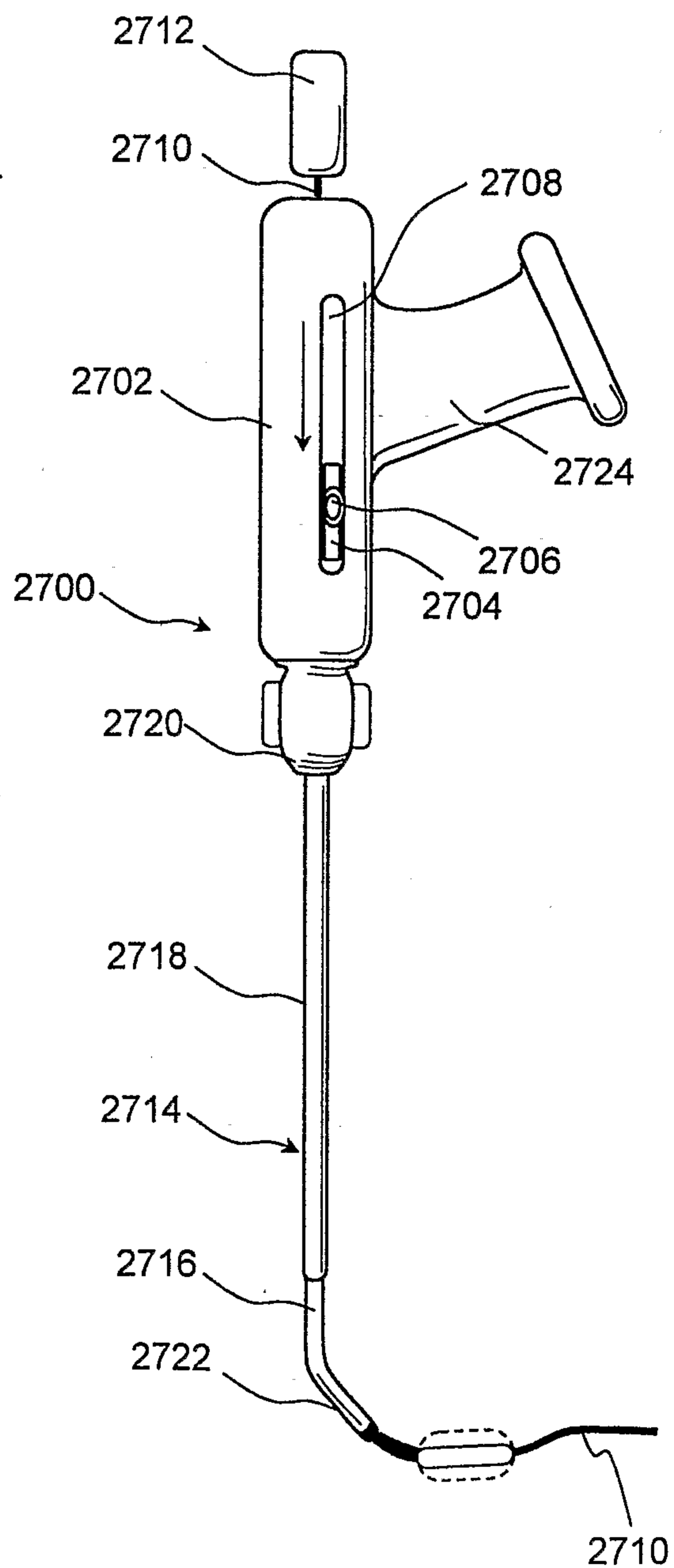


Fig. 27 D

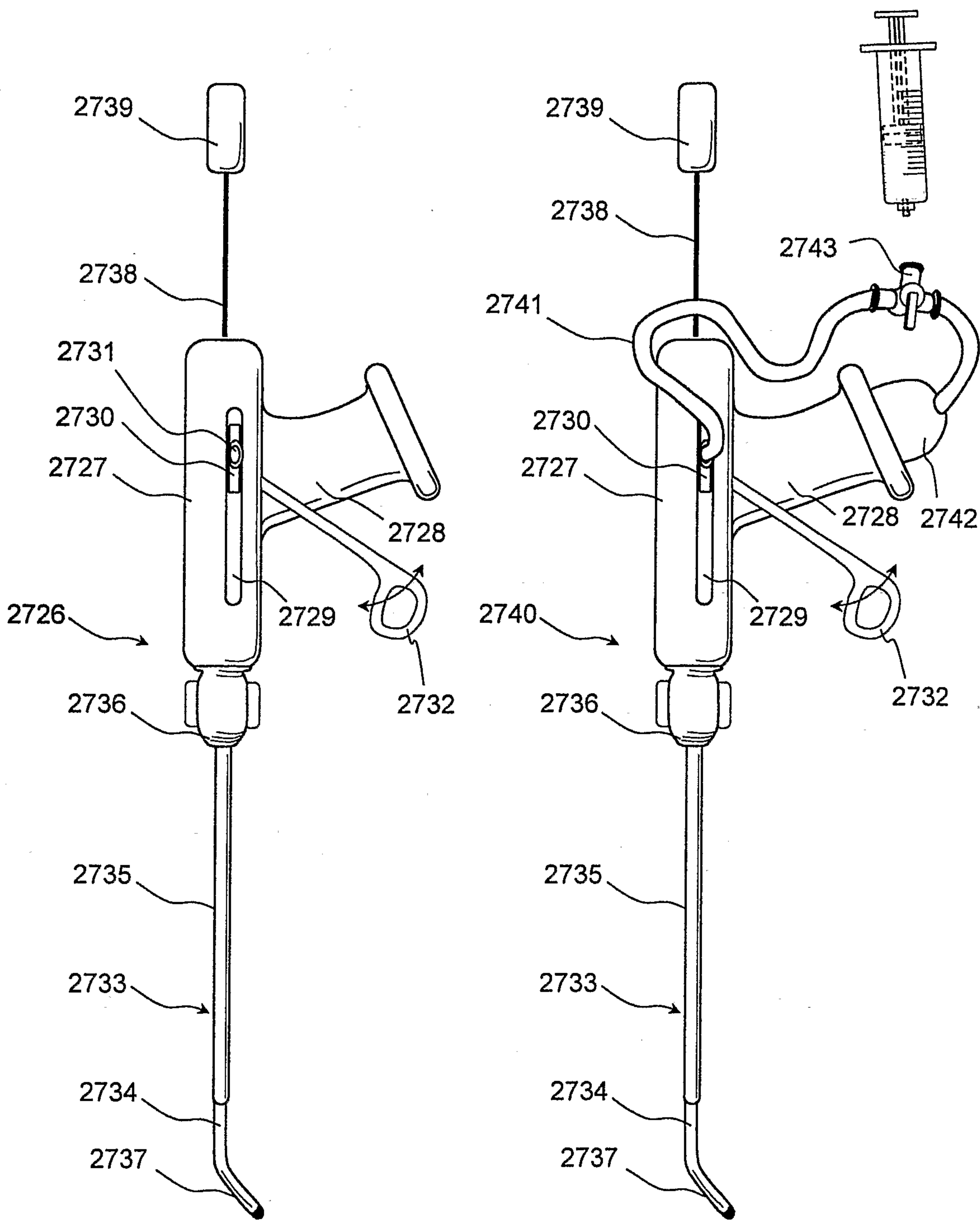
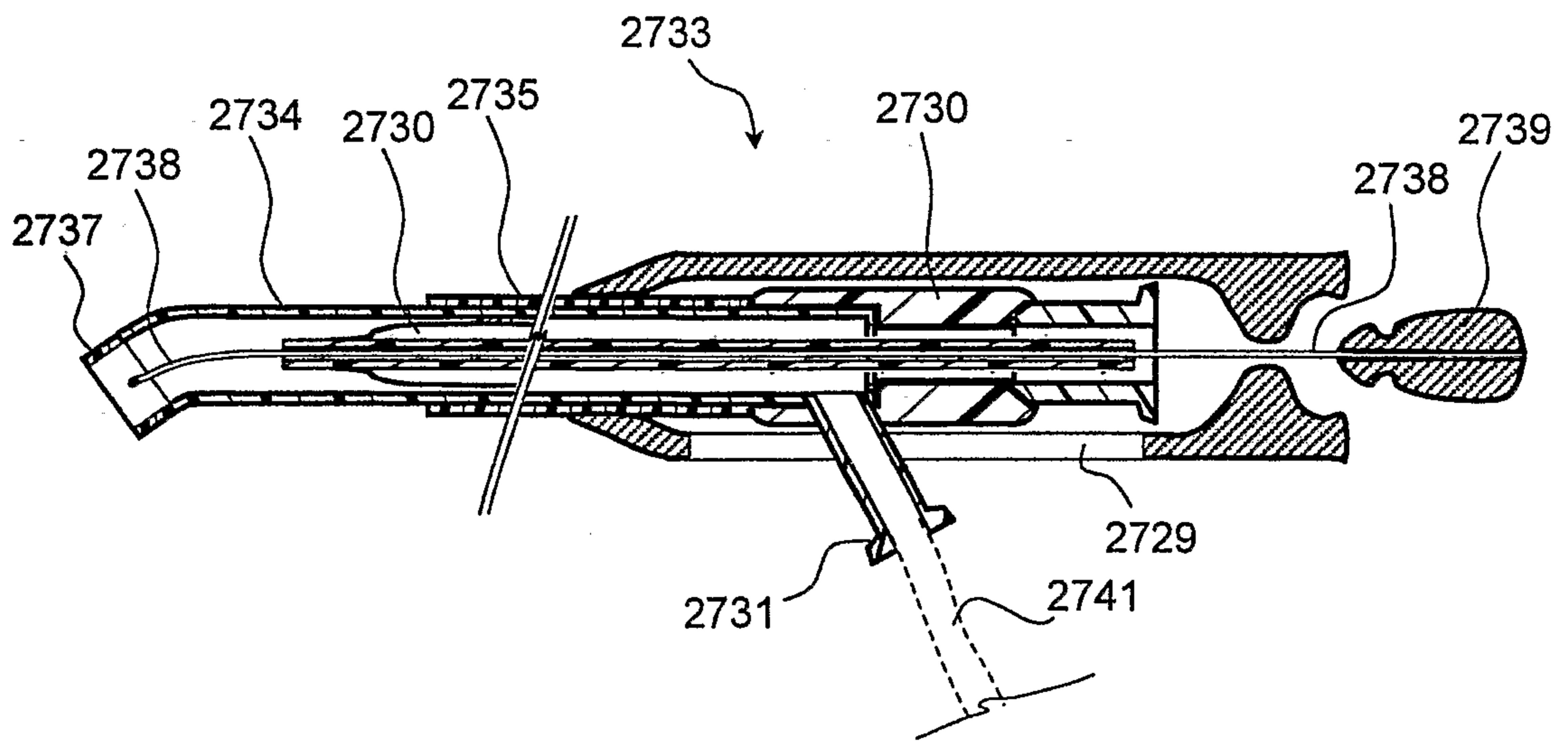
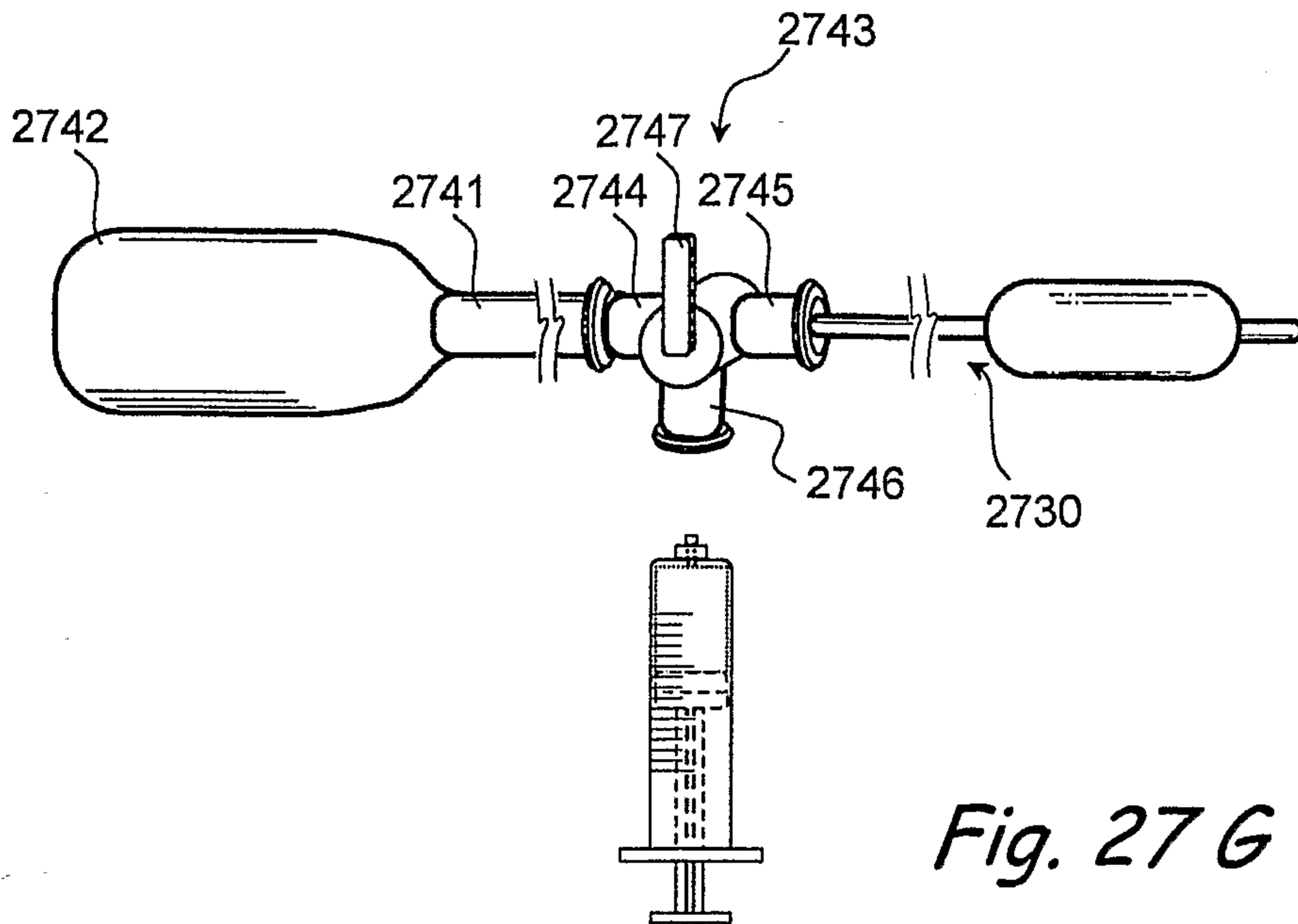


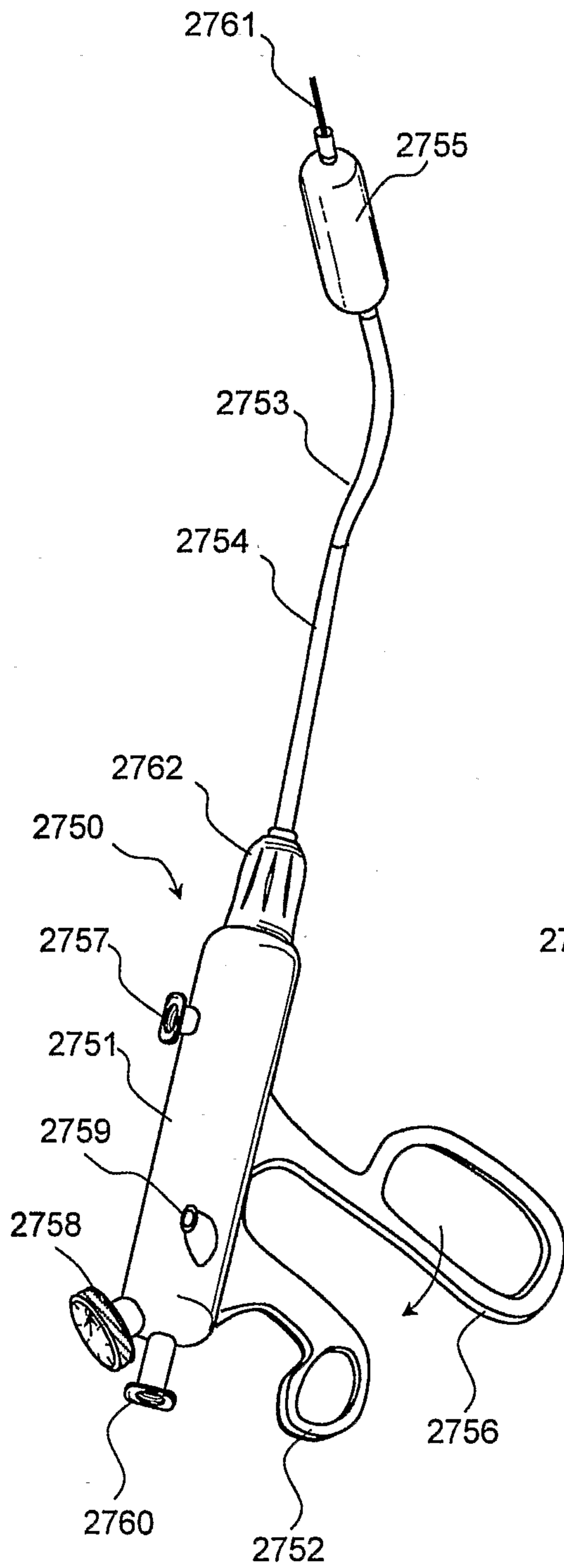
Fig. 27 E

Fig. 27 F

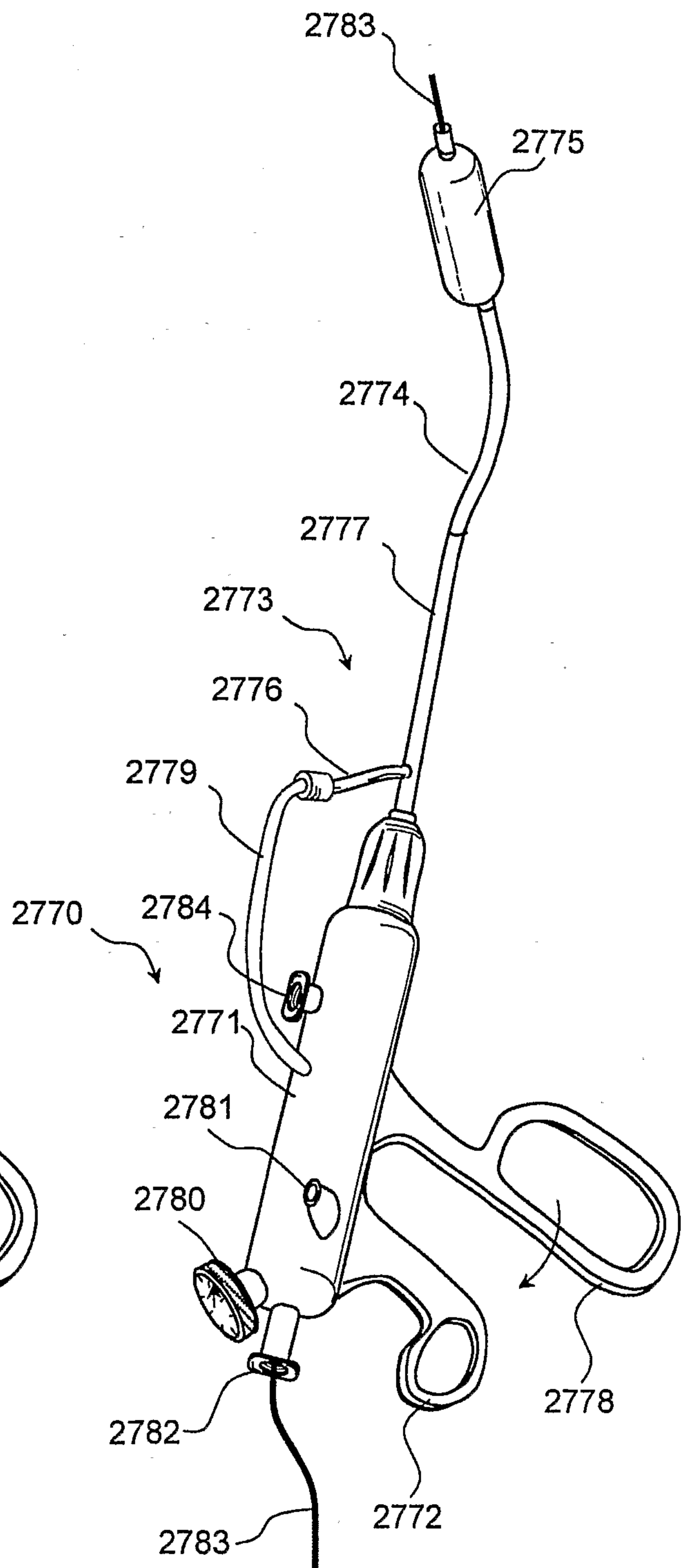
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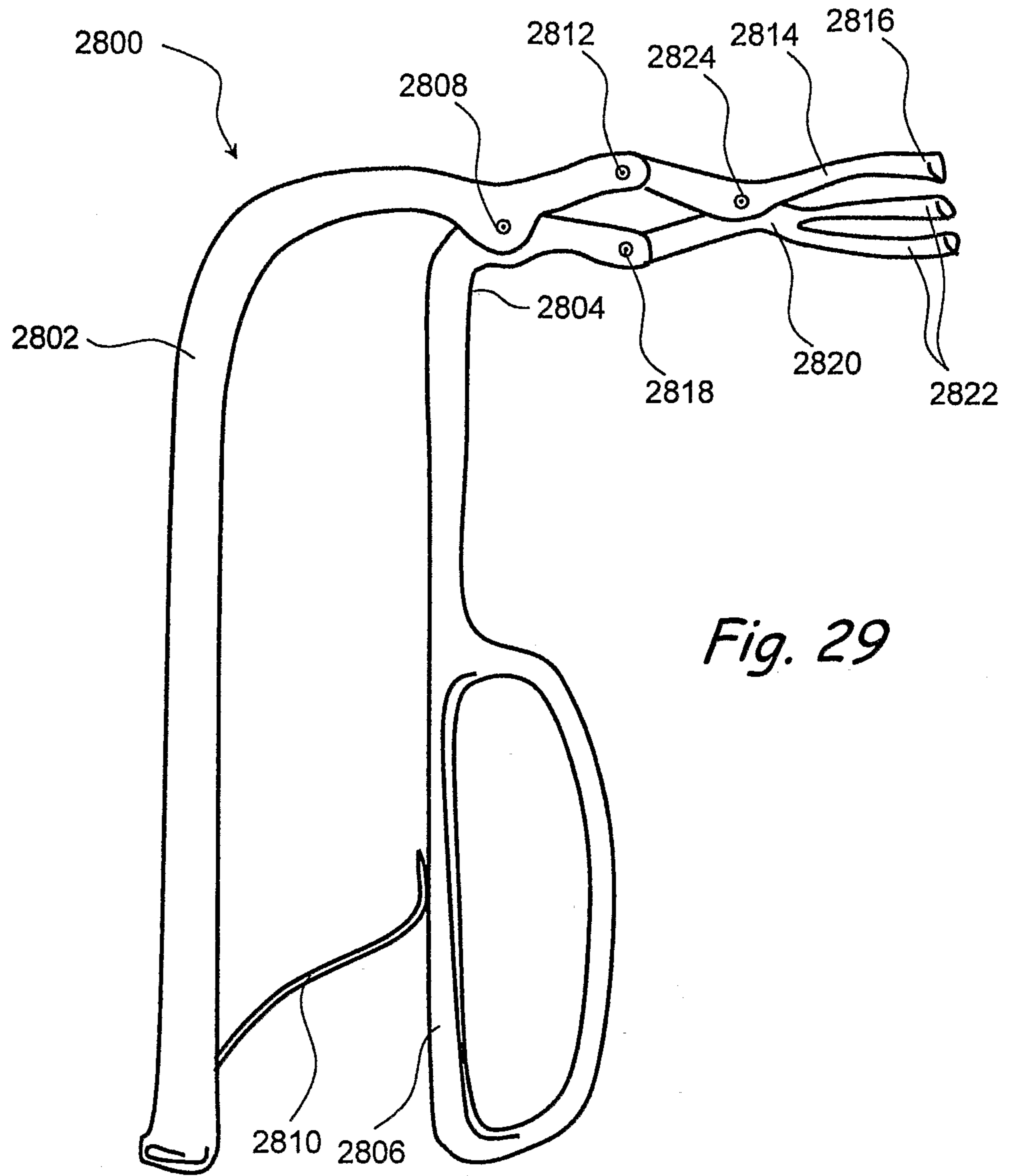


*Fig. 28 A*

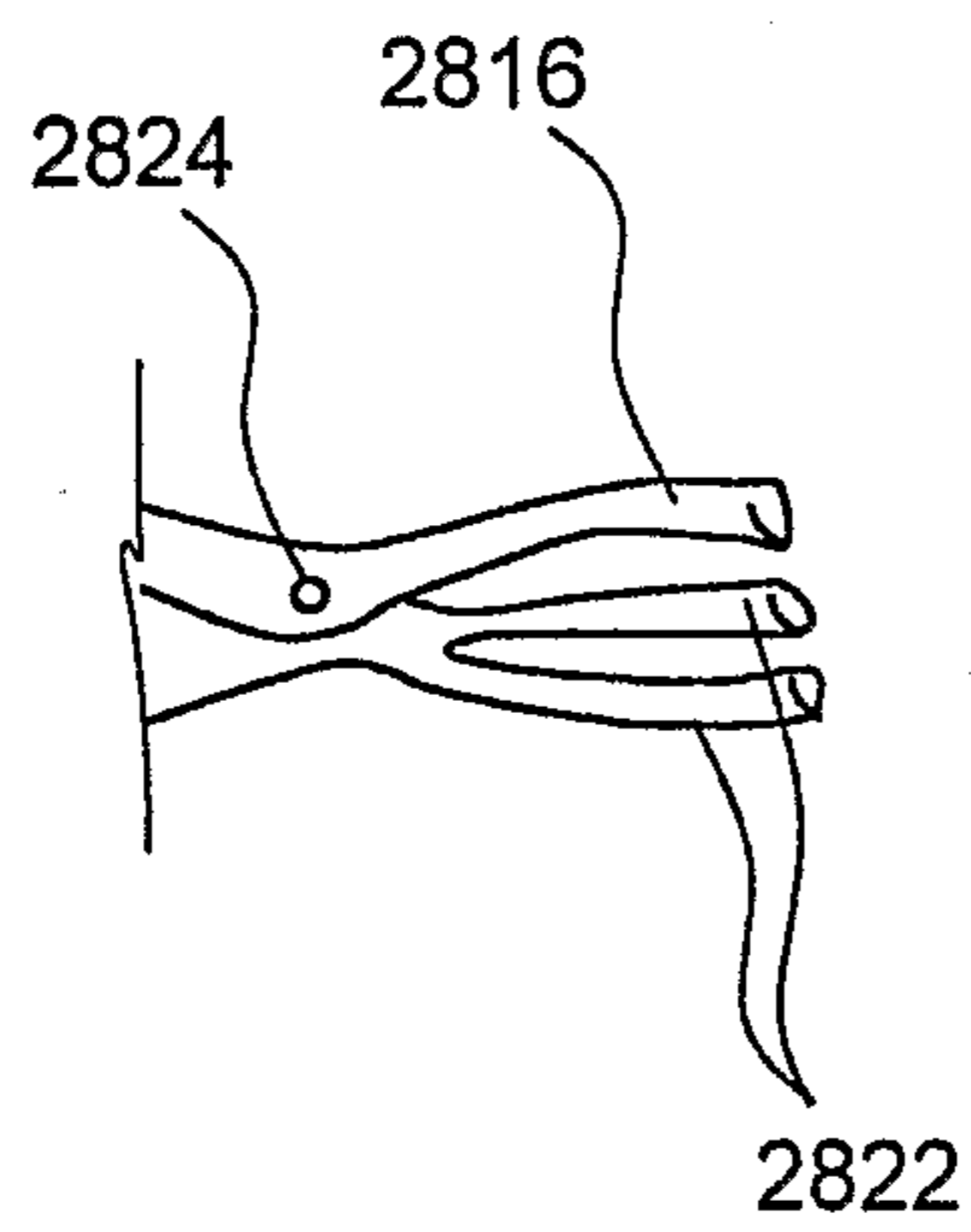


*Fig. 28 B*

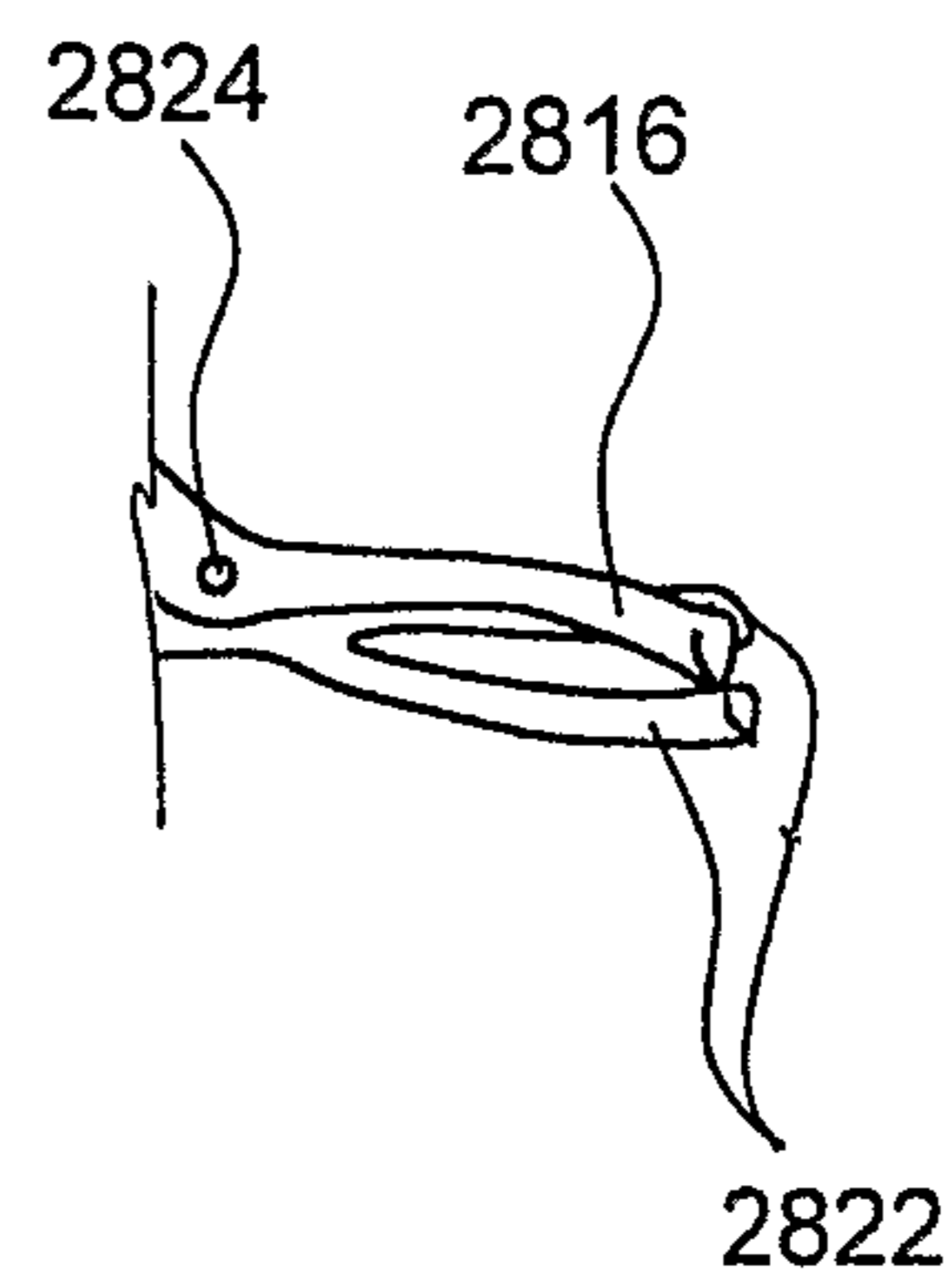
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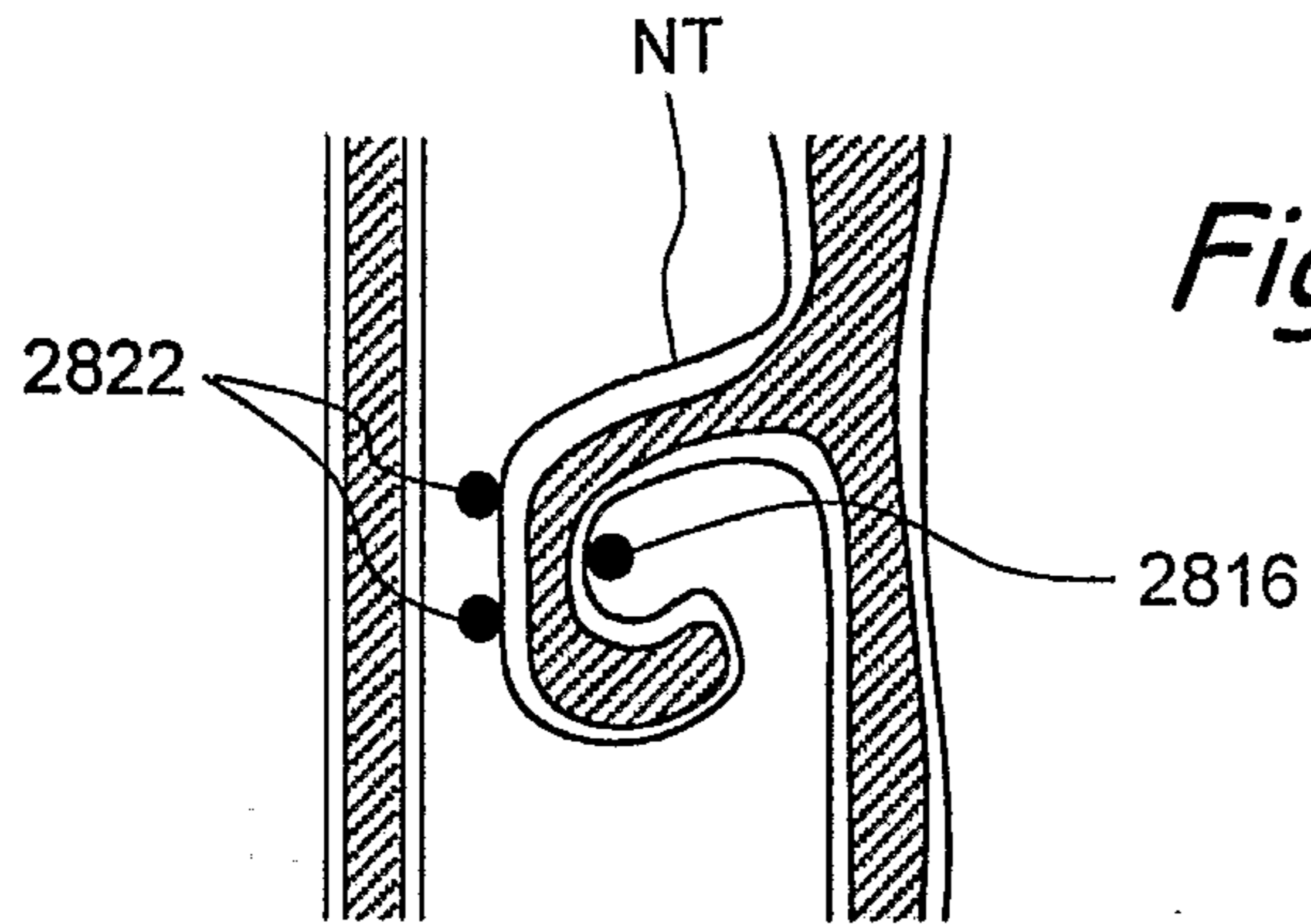
*Fig. 29*



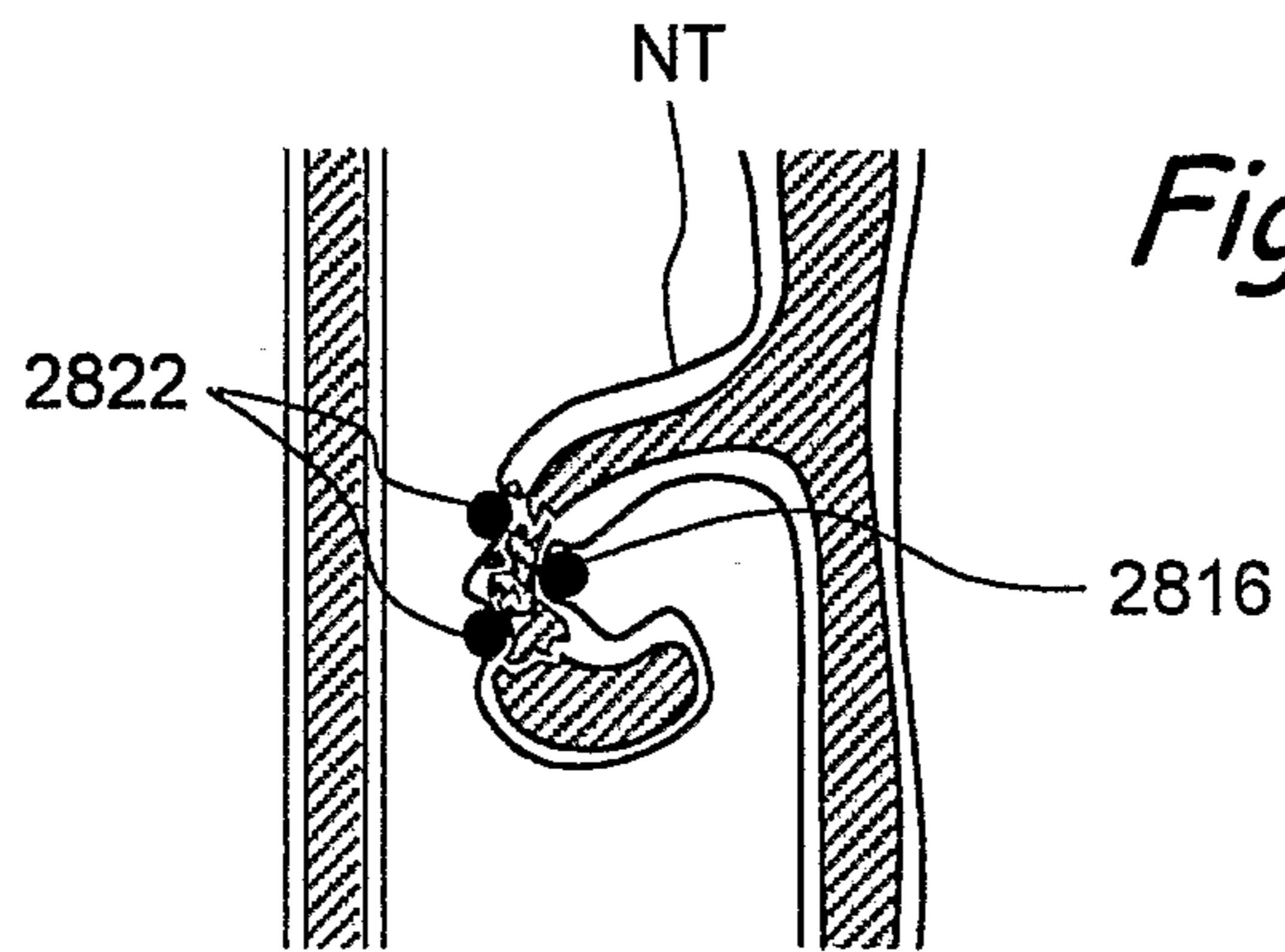
*Fig. 29A*



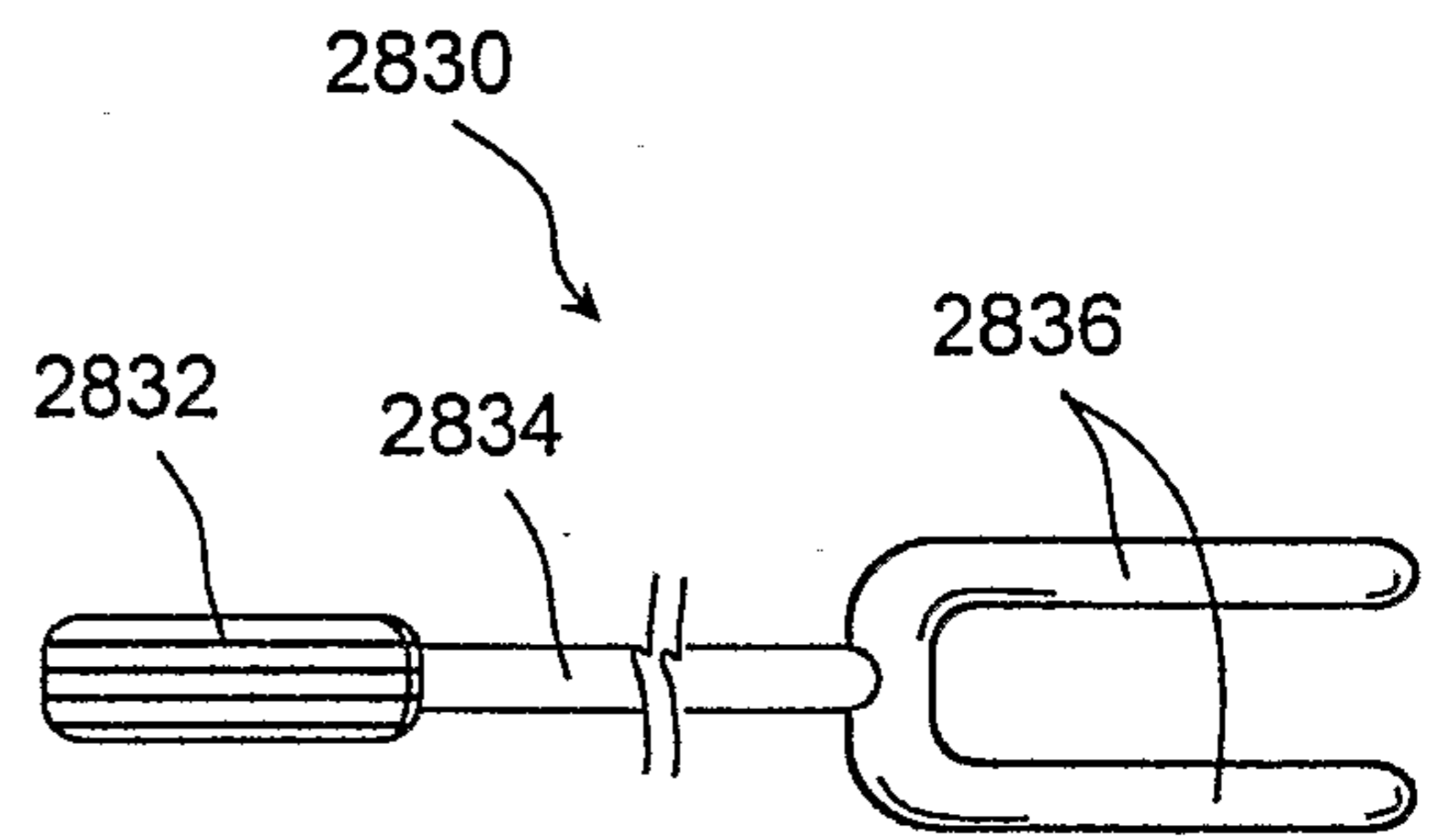
*Fig. 29B*



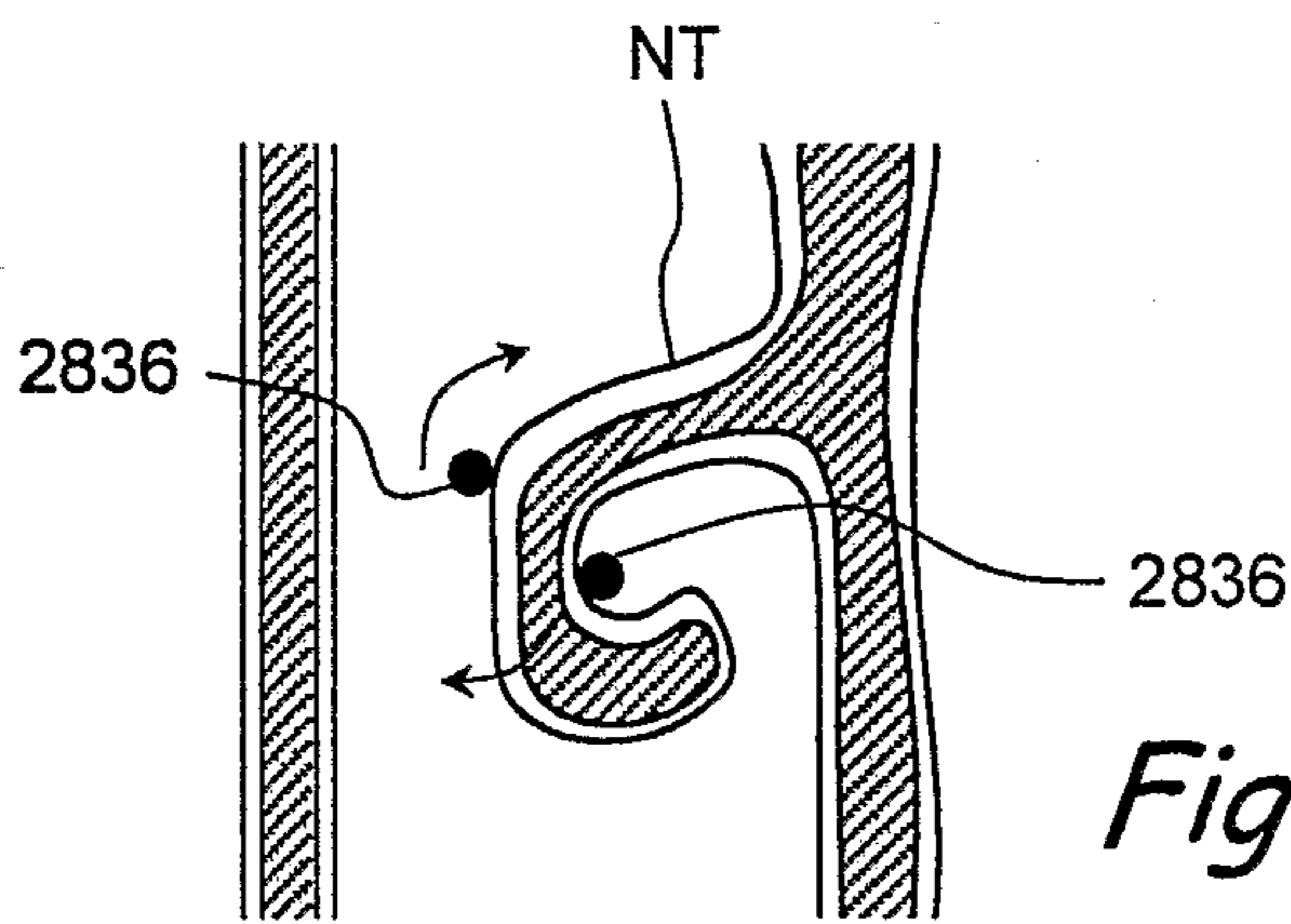
*Fig. 29 C*



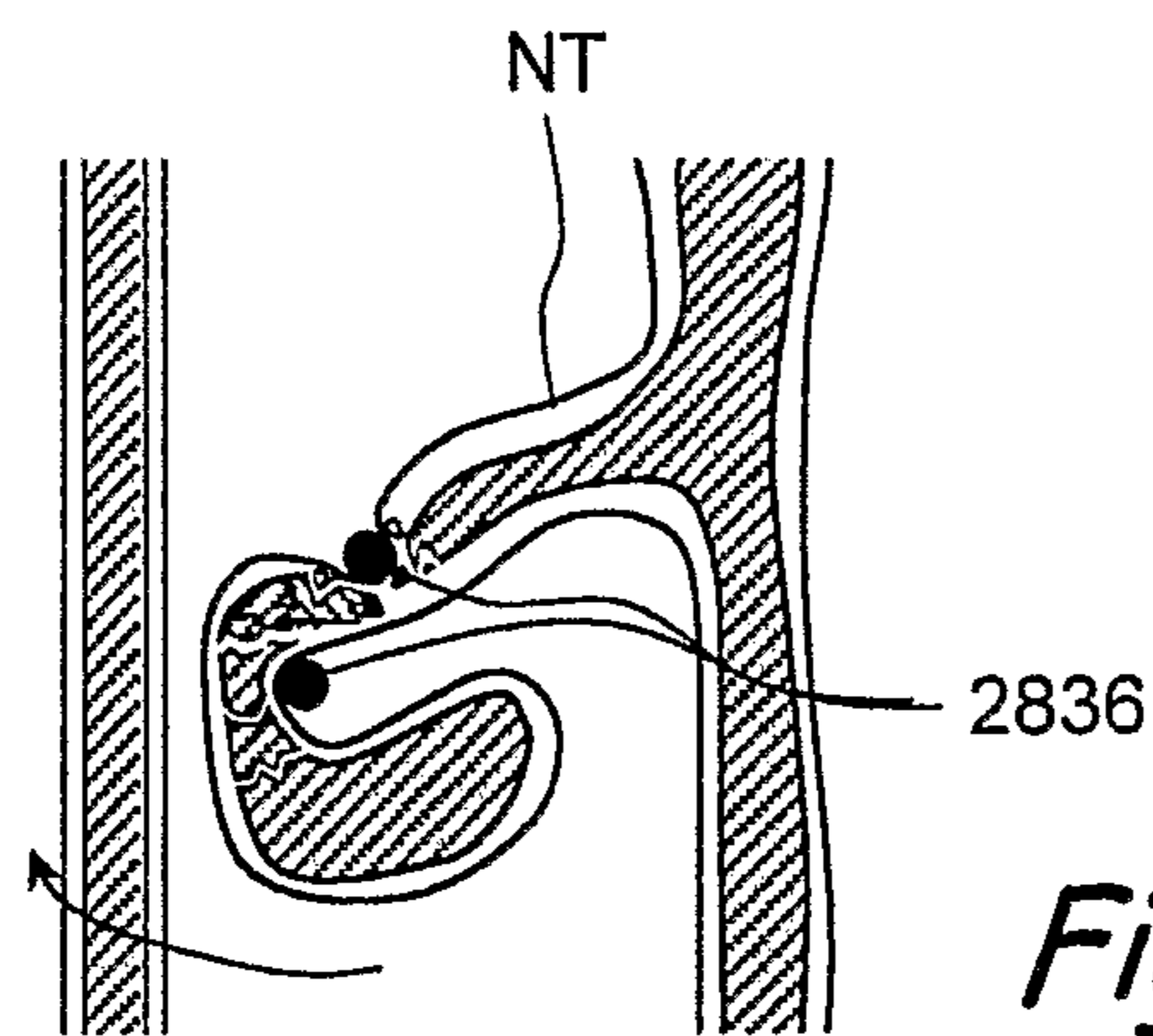
*Fig. 29 D*



*Fig. 29 E*

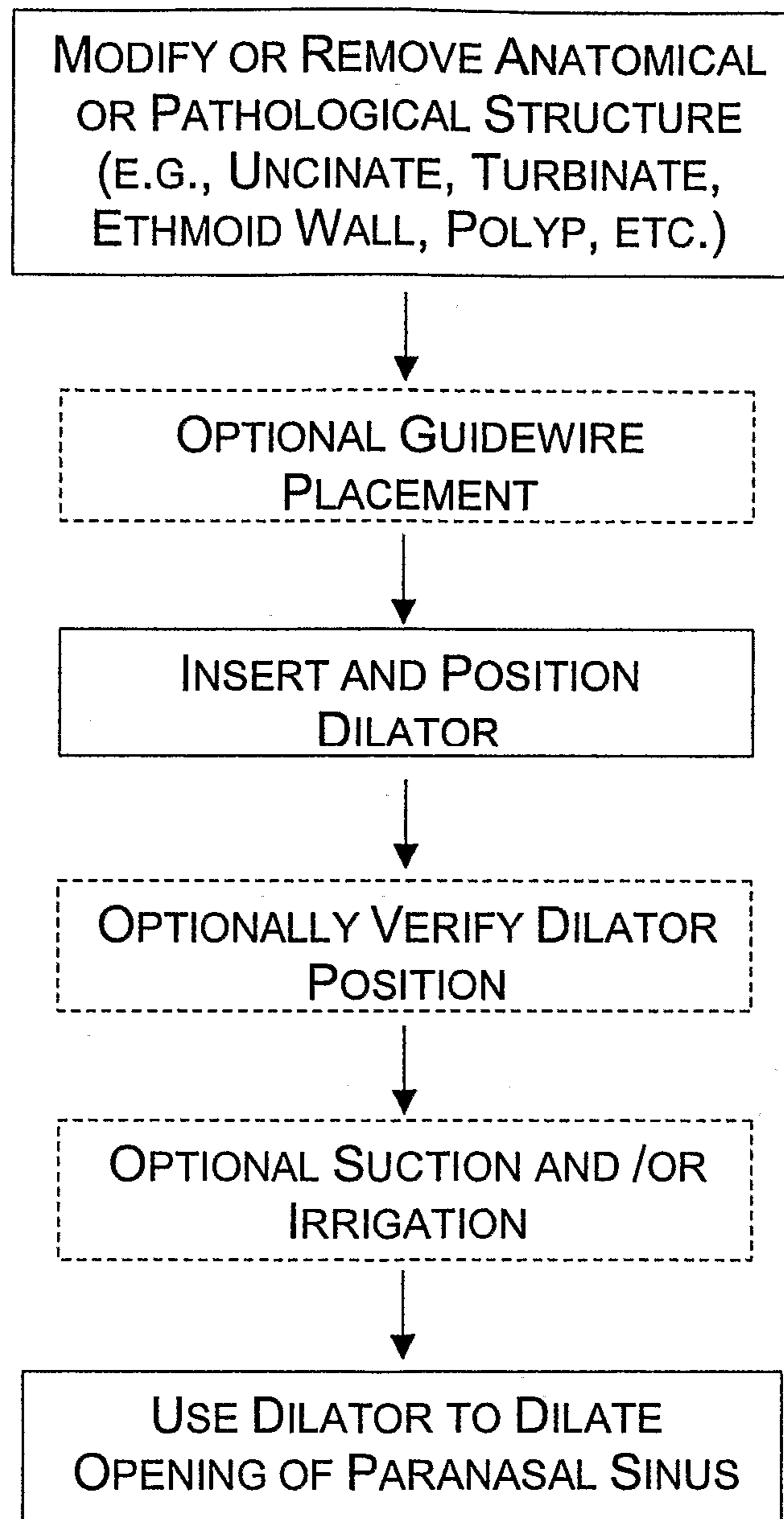


*Fig. 29 F*

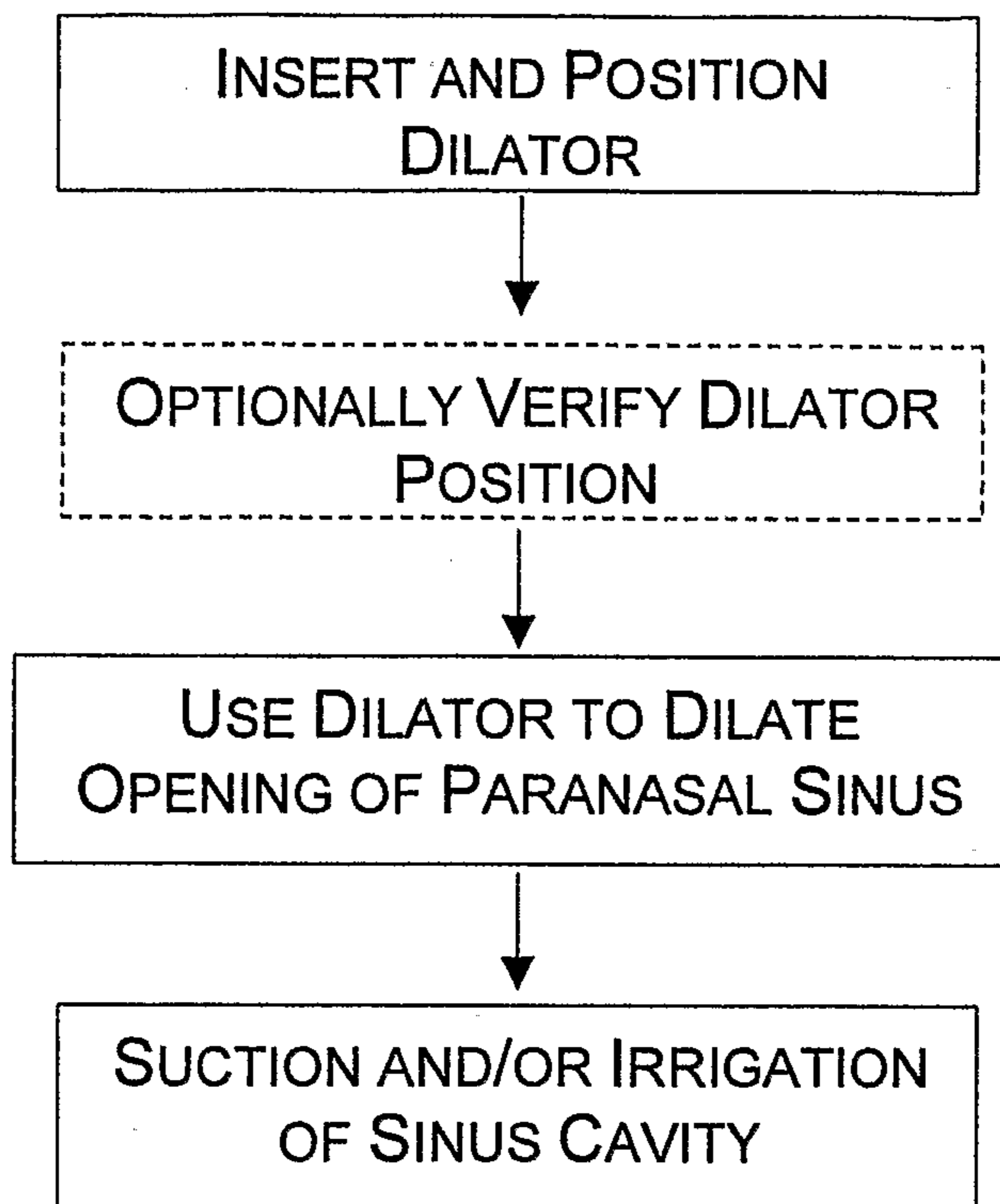
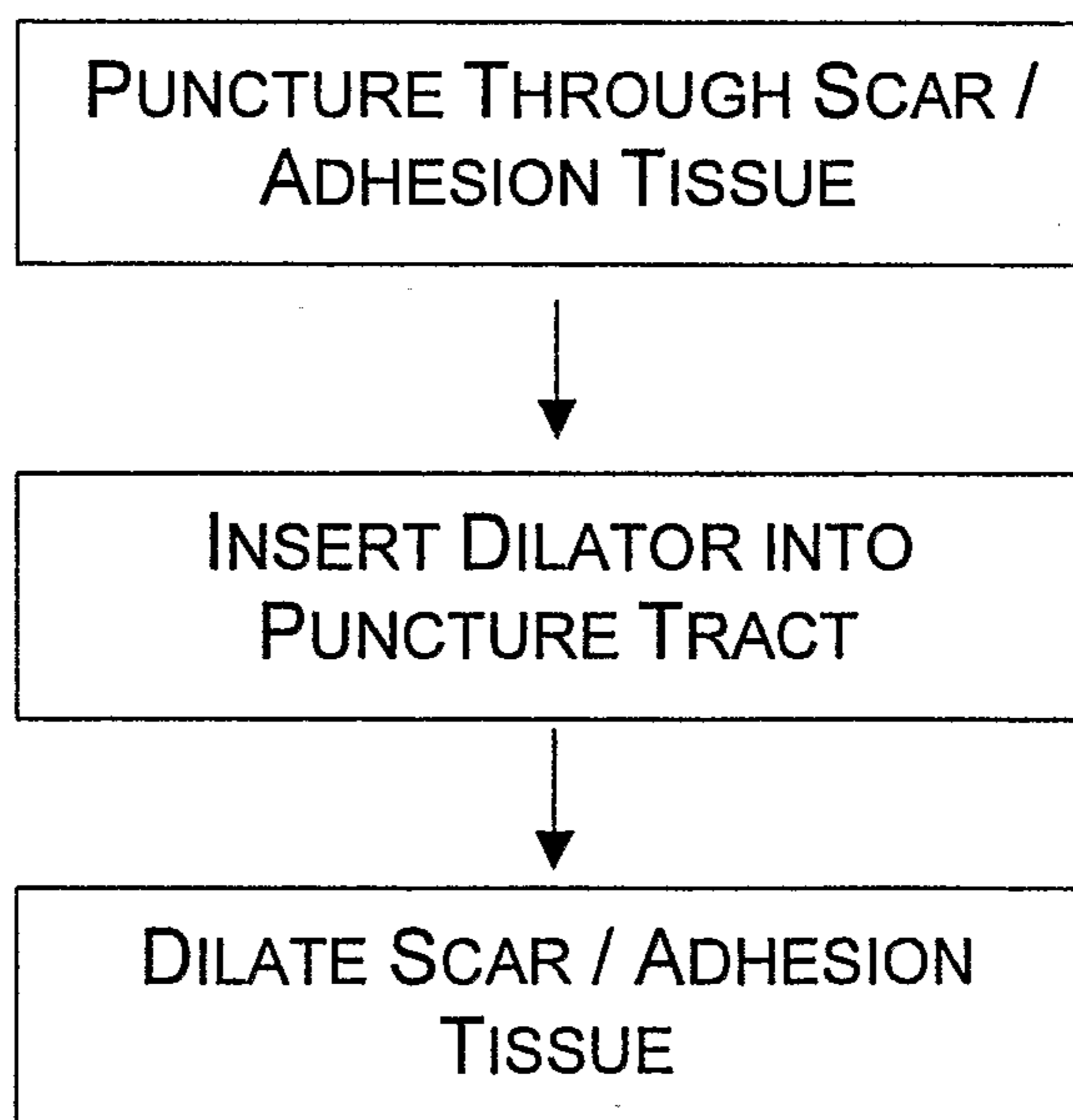


*Fig. 29 G*

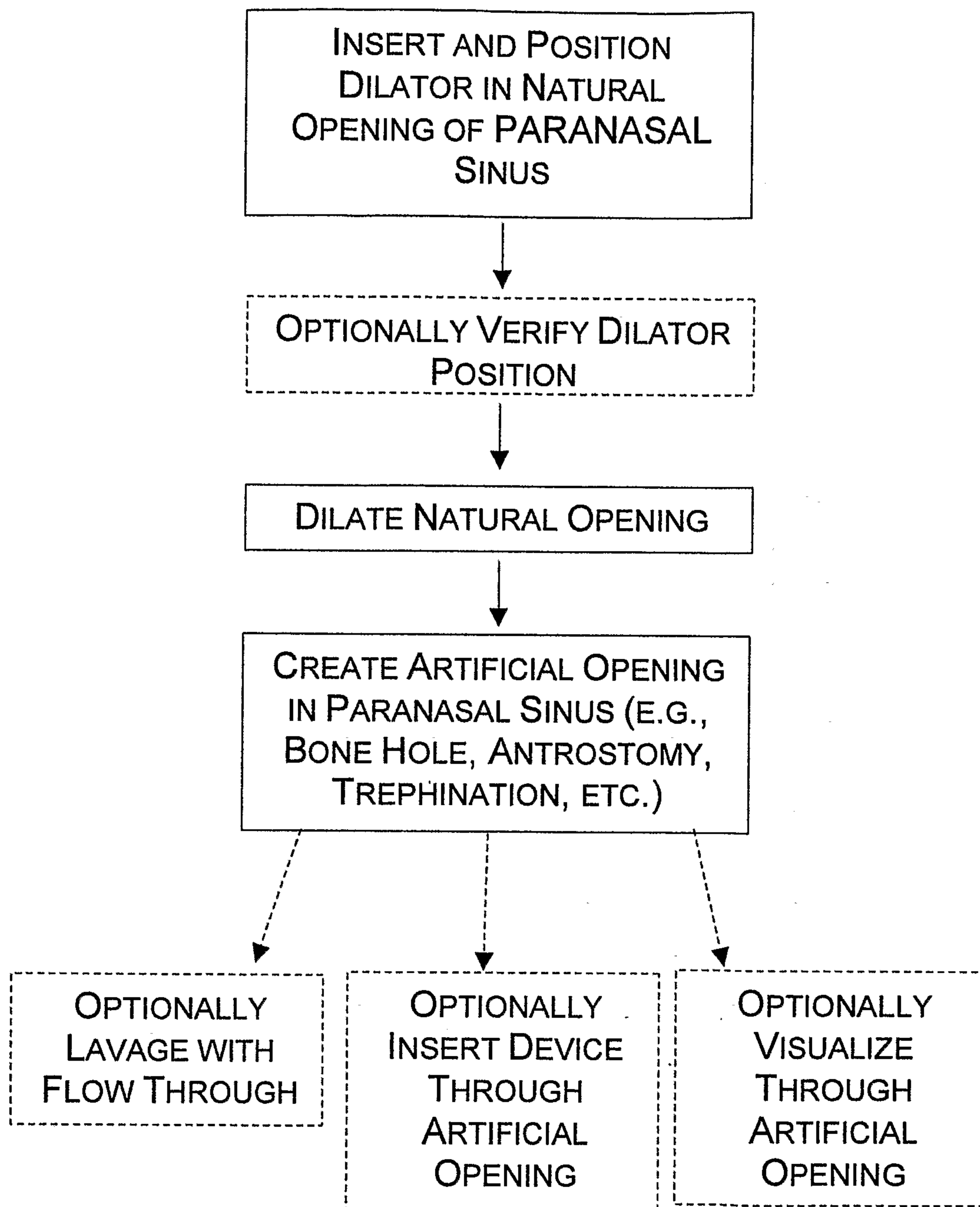
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*Fig. 30*

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*Fig. 31**Fig. 32*

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*Fig. 33*

