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(54) Title: DEVICE AND METHOD FOR INTERNAL LIGATION OF TUBULAR STRUCTURES

(57) Abstract: A surgical device for performing internal ligation of a fallopian tube or other tubular anatomical structure, by application of one ore more ligating bands to a folded portion of the wall of the tubular structure. A method of using the device is also disclosed. The invention method and device may be used for sterilization to prevent undesired pregnancies, or for other medical applications. One embodiment of the device includes an elongated tubular element that is inserted into the fallopian tube, a grasper that extends out of the tubular element, grasps the interior of the fallopian tube and retracts into the tubular element in a folded bundle of the fallopian tube tissue; and a pusher balloon for pushing a ligating band from the tip of the tubular element into the tissue bundle. A fold assist mechanism may be included to help evert a section of a fallopian, or other, tube.

DEVICE AND METHOD FOR INTERNAL LIGATION OF TUBULAR STRUCTURES

TECHNICAL FIELD

The present invention relates to methods for blocking tubular anatomical structures. In particular, the present invention relates to methods for ligating the fallopian tube to achieve sterilization. The present invention pertains in addition to devices for performing tubal ligations.

BACKGROUND

Occlusion of tubular anatomical structures is desirable for various medical treatments. One important application of occlusion techniques is blockage of the fallopian tubes in the female or vas deferens in the male to achieve sterilization and prevent undesired pregnancies.

Various methods for producing occlusion or blockage of tubular anatomical structures have been considered for contraceptive purposes. A commonly used method for blocking the fallopian tube is to tie off or clamp the fallopian tube. The tube may be tied in two locations and the intermediate portion of tube removed. A similar result may be obtained by grasping and folding over a portion of the tube and tying off a loop of tube that does not communicate with the remainder of the tube. The folded segment of tube may be blocked by a loop of suture material, a elastic ligating band or O-ring, or a clamp. Access to the fallopian tube is usually gained through endoscopic surgery, either through the abdominal wall or, less commonly, through the wall of the vagina. Such methods are less invasive than conventional surgical methods, but still have an undesirably high risk of infection and tissue damage, and are accompanied by an undesirable recovery time and level of discomfort.

To eliminate the need for endoscopic or other, more invasive, surgery, a number of approaches have been devised for blocking the lumen of the fallopian tube after accessing the interior of the fallopian tube by inserting a catheter into the lumen of the tube via the vagina and uterus.

One approach is to block the fallopian tube by injecting an adhesive or sealant, typically a polymeric material, into the fallopian tube to form a plug. Another approach is to insert a pre-formed occlusive device or plug into the lumen of the fallopian tube or the utero-tubal junction. However, either type of plug may separate or dislodge from the wall of the fallopian tube, resulting in unreliable or impermanent blockage.

Another approach for blocking the fallopian tube or other tubular anatomic structures is to induce the formation of sclerosis or scar tissue to block the tube. Tissue damage may be induced chemically or thermally. However, this method is relatively difficult to accomplish successfully and requires skilled personnel and specialized equipment, making it unsuited for use in certain settings.

Improvements over the prior art desirably will provide a method and system for applying a ligating structure to the interior of a tubular anatomical structure. Desirable improvements will cause a reliable occlusion of a tubular anatomical structure. Such occlusion of a tubular anatomical structure desirably is permanent in certain applications, such as in reproductive contraception. An inexpensive method for occluding a tubular anatomical structure is also desired. An improvement may provide a partially or completely disposable device for performing occlusion of a tubular anatomical structure. It would be a further advance to provide an improved method for performing tubal ligations which requires only minimally invasive surgery, thereby reducing damage to vascular and reproductive tissues and reducing post-surgical discomfort and recovery time. A method for performing tubal ligations which further reduces the risk of infection is also desirable.

BRIEF SUMMARY OF THE INVENTION

In accordance with the invention as embodied and broadly described herein, a device is provided for applying ligating bands to tissue in the interior of a tubular anatomical structures. The invention also includes a method of using the device.

The device may be embodied as a surgical instrument for contraception of female reproduction by occluding the fallopian tubes. Such a device has a proximal and a distal end, the device being generally elongated and configured to permit insertion of the distal end into a fallopian tube via the vagina and uterus, while the device is held and controlled external to the patient, at the proximal end.

The female contraceptive device generally includes an elongated tube having a central, longitudinally extending lumen and a grasper carried on an end of an elongated member slidably disposed in the lumen. The grasper is capable of extending distally from the distal end of the tube, grasping tissue on the interior of a fallopian tube, and retracting proximally with the grasped tissue. Structure, including active mechanisms, may be provided at the distal end of the tube to assist in creating a circumferential fold, or an invagination of the fallopian tube, forming a tissue bundle or peduncle. One or more ligating bands are typically carried near the distal end of the tube. A ligating band may be released from the distal end of the tube to contract as a sphincter about the tissue bundle and thereby occlude a passageway through the fallopian tube. One way to release a ligating band is by driving the band distally, with a distal end of a sleeve slidably deployed around the tube, moving the band off from band supporting structure.

The proximal end of the device can be provided with a handle or base, and a number of controls thereon for controlling extension and retraction of the grasper with respect to the tube, actuation of the grasper, and release of ligating bands onto a tissue bundle, among other operations. The device may be provided with a current source for supplying current to cauterize tissue held by the grasper, or to separate the grasper from an extension member. The device may also be provided with an additional lumen for delivering drugs or other compounds, such as antibiotics, topical anesthetics, or chemical cauterizing agents, in the vicinity of the ligation.

A method of using the device includes the steps of inserting the distal end of the device into a tubular anatomical structure, causing the grasper to extend distally out of the tube, grasping tissue in the interior of the tubular anatomical structure with the grasper, retracting the grasper proximally, forming an inner tissue bundle, and releasing a ligating band from the distal end of the tube to contract as a sphincter around the inner tissue bundle. The method may further include the steps of withdrawing the device to a new position within the tubular anatomical structure and repeating the preceding steps to apply one or more additional ligating bands.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

In the drawings, which illustrate what are currently considered to be the best modes for carrying out the invention:

FIG. 1 is a view of an embodiment of the device inserted into the fallopian tube of a patient, with the controls for the device shown in schematic form;

FIG. 2 is a perspective view of an embodiment of the device positioned in a fallopian tube, with the grasper shaft unextended;

FIG. 3 is a longitudinal cross-sectional view taken along line 3-3 in FIG. 2;

FIG. 4 shows an alternative pusher mechanism for releasing a ligating band;

FIG. 5 is a transverse cross sectional view taken along line 5-5 in FIG. 3;

FIG. 6 a perspective view of the device of FIGS. 2 through 5, showing the balloon deflated and catheter extended;

FIG. 6.5 is a longitudinal cross section view of an alternative embodiment of the device;

FIG. 6.6 is a perspective view of an embodiment of the device utilizing suction tubes as graspers;

FIG. 7 depicts an alternative embodiment of the device tip having two o-rings carried on the device and an alternative grasper;

FIG. 8 depicts a further alternative embodiment of the device tip having two o-rings carried on the device and another alternative grasper;

FIG. 9 is a longitudinal cross-sectional view taken along line 9-9 in FIG. 6;

FIG. 10 is a longitudinal cross-sectional view of the device shown in FIGS. 2-9, depicting inflation of the balloon to force the barbs into the wall of the fallopian tube;

FIG. 11 is a longitudinal cross-sectional view of the device showing deflation of the balloon to draw the wall of the fallopian tube radially inward;

FIG. 12 is a longitudinal cross-sectional view of the device showing retraction of the grasper into the outer tube, drawing a fold of the fallopian tube with it into the outer tube;

FIG. 13 is a longitudinal cross-sectional view of the device showing expansion of the pusher balloon to push the ligating band off the end of the outer tube and onto the fold of fallopian tube;

FIG. 14 is a longitudinal cross-sectional view of the ligated fallopian tube;

FIG. 15 is a longitudinal cross-sectional view of the fallopian tube following application of a second ligating band;

FIG. 16 is a plan view of an alternate embodiment of the invention;

FIG. 17 is a longitudinal view, partially in section, of a tip portion of the device placed in a fallopian tube for tubal ligation;

FIG. 18 is a view similar to FIG. 17, but with the balloon expanded during a preliminary stage of tubal ligation;

FIG. 19 is a view similar to FIG. 18, but with the balloon partially retracted proximally in an intermediate stage of tubal ligation;

FIG. 20 is a cross-section view similar to FIG. 19, but in a configuration near completion of tubal ligation.

BEST MODE OF THE INVENTION

FIG. 1 depicts one embodiment of the inventive device, generally indicated at 20, for performing internal ligation of tubular structures. Device 20 includes an elongated tubular element 21 having a proximal end 22 and distal end 23. Proximal end 22 of tubular element 21 is connected to control segment 24, which includes controls 25, 26, 27, and 28 for controlling the device, and which also is used for supporting the device during use. Control segment 24 may be configured as a handle to be held in the hand of a person using device 20, or may be configured for mounting on an examination table or other base. Device 20 is supported and controlled by control segment 24 while distal end 23 is inserted into the lumen 30 of fallopian tube 31 of a patient via the vagina 32, lumen 33 of uterus 34, and uterine horn 35. Ovaries 36 are also shown in FIG. 1. Proximal end 22 may include an access port 37 to permit injection of anesthetics, antibiotics, or other substances into tubular element 21 for infusion into the fallopian tube in the vicinity of the ligation.

FIG. 2 shows detail of additional components of device 20 at distal end 23 of tubular element 21, from circled region 2 in FIG. 1. Tubular element 21 is shown positioned within the lumen 30 of fallopian tube 31, with the fallopian tube wall 39 shown in cross-section. Distal end 23 of tubular element 21 includes lip 40, on which is held a ligating band 41. Ligating band 41 may be of the type known for use in performing tubal ligations, formed of rubber, silicone, and other suitable materials. Other ligating structures, such as suture loops or clamps, may be used as well. Just proximal to ligating band 41 is pusher 42, which in this example is a pusher balloon having a generally toroidal shape. Pusher balloon 42 can be expanded distally to push

ligating band 41 off the distal end 23 of tubular element 21. The distal tip 43 of grasper shaft 44 of grasper 38 is visible in lumen 45 of tubular element 21. Grasper shaft 44 is shown in its unextended position, so that tip 43 does not project significantly beyond the distal end 23 of tubular element 21. Grasper shaft 44 is preferably maintained in an unextended position while device 20 is inserted into the fallopian tube of the patient.

FIG. 3 is a cross-sectional view of device 20 taken along section line 3-3 in FIG. 2. Grasper 38 is slidably disposed in lumen 45 of tubular element 21. In the embodiment of the invention shown here, grasper 38 includes grasper shaft 44, which is hollow with a central lumen 50, and balloon 51, which is attached to grasper shaft 44. Lumen 50 of grasper shaft 44 communicates with the interior 52 of balloon 51 via fluid channels 53a and 53b. In use, balloon 51 is inflated to a selected pressure or volume by the injection of a fluid with a syringe or other pressurized source. In this context, fluid is intended to mean liquids and gases. The fluid in grasper shaft 44 and the interior 52 of balloon 51 could be, for example, air or saline. Balloon 51 may be inflated in the same way as balloon angioplasty catheters. A plurality of barbs, of which only 54a and 54b are visible in the present cross section, are attached to the exterior of balloon 51. Channels 46a and 46b in tubular element 21 communicate with the interior 47 of pusher balloon 42. Air or fluid from a syringe or other pressurized source connected at the proximal ends of channels 46a and 46b is forced into pusher balloon 42 to cause it to expand and push ligating band 41 off of lip 40.

FIG. 4 depicts an alternative embodiment of the invention in which a pusher disk 48, driven by pusher rods 49a and 49b, is used in place of pusher balloon 42. Pusher rods 49a and 49b are slidably disposed in channels 46a and 46b and are driven by a mechanical actuator (not shown) located at the proximal end of the device, at control segment 24. Various actuation mechanisms may be devised by those of ordinary skill in the art for causing pusher rods 49a and 49b to move pusher disk 48 to push ligating band 41 (not shown) off of band support structure at lip 40.

FIG. 5 is a transverse cross section taken at section line 5-5 in FIG. 3. Channels 46a and 46b in tubular element 21 can be seen, as can as fluid channels 53a, 53b, 53c, and 53d, which provide fluid communication between grasper shaft lumen 50 and interior 52 of balloon 51. Fluid channels 53c and 53d were not visible in the cross section shown in FIG. 3. Also, all of the plurality of barbs 54a, 54b, 54c, etc., are

visible in this cross section. Although two channels 46a and 46b and four fluid channels 53a, 53b, 53c, and 53d are shown, the numbers of channels are merely exemplary, and embodiments of the device having different numbers of channels are considered to fall within the scope of the invention. Similarly, the number of barbs 54a, 54b, 54c, etc., attached to balloon 51 may be varied.

FIG. 6, which depicts grasper shaft 44 extended out of the distal end 23 of tubular element 21, more clearly shows the shape of balloon 51. Balloon 51 is generally cylindrical in shape, with its inner surface attached to the exterior of grasper shaft 44. A plurality of barbs 54a, 54b, 54c, etc., are attached to the exterior of balloon 51. As noted previously, when balloon 51 is inflated so that its outer diameter is substantially equal to the diameter of lumen 30 of fallopian tube 31, barbs 54a, 54b, 54c, etc. are forced into fallopian tube wall 39. Each barb has a shaft 90 that is attached to the exterior of balloon 51 at a first end 91 and which has a tip 55 at second end 92 which allows it to be readily pushed into the tissue of fallopian tube wall 39. Backward extending points 56 are attached at or near tip 55 and extend back toward first end 91 of shaft 90, and serve to engage the tissue to prevent withdrawal of the barb from the fallopian tube wall 39. These features are specifically pointed out on barb 54a, but all barbs 54a, 54b, 54c, etc. may include these features. The combination of balloon 51 and barbs 54a, 54b, 54c, etc. and grasper shaft 44 function together as grasper 38.

FIG. 6.5 depicts a further alternative embodiment of the invention in which ligating band 41 is pushed off of distal end 23 of tubular element 21 by sleeve 93, which is a tubular sleeve that is slidably disposed around tubular element 21 and can be slid distally to push ligating band 42 off of tubular element 21. In this and the other embodiments shown herein, ligating band 41 is released by being pushed off of distal end 23 of tubular element 21. However, the invention is not limited to embodiments in which the ligating band or other ligating structure is released by being pushed. Other mechanisms for releasing a ligating structure may be devised, for example, tubular element 21 could be retracted within sleeve 93, so that ligating band 41 is maintained in place while tubular element 21 is withdrawn from under it, thus allowing the ligating band to contract onto a grasped tissue bundle. Further, other means for holding a ligating band or other ligating structure at the end of tubular element 21 and then

releasing it onto the grasped tissue bundle may be devised and are considered to fall within the scope of the invention.

The embodiment of the invention shown in FIG. 6.5 also shows an alternative version of grasper 38, in which the elongated catheter formed by grasper shaft 44 and balloon 51, as shown in FIGS. 3, 5 and 6, is replaced by an elongated catheter comprising inflatable catheter 95, which has a closed end 96 and interior lumen 97. Inflatable catheter 95 is formed of a pliable material that is sufficiently elastic that when the pressure of the fluid in interior lumen 97 is increased, inflatable catheter 95 inflates or balloons out at end region 98. When the pressure of the fluid in interior lumen 97 is reduced, end region 98 of inflatable catheter 95 returns to its original diameter. Inflatable catheter 97 is substantially functionally equivalent to the combination of grasper shaft 44 and balloon 51 as shown in FIGS. 3, 5 and 6.

Also shown in FIG.6.5 are hooked wires 100, which provide an alternative hooking structure to the barbs used in the embodiment of FIGS. 3, 5, and 6. Two can be seen in the cross section, but a plurality of hooks (for example, four or five) would be used. When inflatable catheter 95 is uninflated, hooked wires 100 conform to the exterior of inflatable catheter 95, so inflatable catheter 95 and hooked wires 100 fit inside tubular element 21. When inflatable catheter 95 is inflated, hooked wires 100 are splayed outward to be pushed into and grasp the inner wall of the fallopian tube (not shown). When inflatable catheter 95 is deflated, hooked wires 100 return to their original position.

A further alternative grasper 38 is shown in FIG. 6.6. Inflatable catheter 95 is as shown in FIG. 7, as is sleeve 93. Hooked wires 100 shown in FIG. 6.5 are replaced by suction tubes 101, each of which has an opening at or near its tip 102. In FIG. 6.6, openings 103 are positioned laterally, and tip 102 is closed. When inflatable catheter 95 is inflated, suction tubes 101 are urged outward to contact the wall of the fallopian tube (not shown). Generation of a vacuum in suction tubes 101, from an external vacuum source connected to device 20 at control segment 24 and communicating with suction tubes 101, causes suction tubes 101 to grasp the fallopian tube by drawing the tissue of the fallopian tube to opening 103 and holding it there for as long as the vacuum is maintained.

The inventive device may be constructed with various other alternative grasper mechanisms. For example, a forceps-like mechanism could be used to grasp tissue in the interior of the fallopian tube, or other grasper mechanisms, for example, as shown in FIGS. 7 and 8, could be used. In FIG. 7, grasper 38 includes a grasper shaft 57 having a plurality of hooks 58a, 58b, 58c, and 58d. In this embodiment of the invention, grasping is accomplished when one or more of hooks 58a, 58b, 58c, and 58d catch on the wall of the fallopian tube. In the alternative embodiment of the invention shown in FIG. 8, grasper 38 includes grasper shaft 60 and a plurality of pivoting hooks 61a and 61b having angled points 62a and 62b. Pivoting hooks 61a and 61b would be held in a closed position (shown in dashed lines) while grasper 38 was in its retracted position in lumen 45 of tubular element 21, but when grasper 38 was extended, pivoting hooks 61a and 61b would be moved to their open position (shown in solid lines) and then closed again to grasp tissue on the interior of the fallopian tube. Pivoting hooks 61a and 61b pivot on pivot points 63a and 63b, actuated by actuation mechanisms 64a and 64b located in the lumen 65 of grasper shaft 60. Actuation mechanisms 64a and 64b could be, for example, drive rods which pass through grasper shaft 60 to control segment 24, where they are moved by a lever or trigger mechanism.

FIGS. 7 and 8 feature illustrate another variation in the design of the device, as well. More than one ligating band may be held at distal end 23 of tubular element 21, on lip 40 or in some other manner. In FIGS. 7 and 8, two ligating bands 41a and 41b are shown, but a larger number could be used as well. As will be described in below, by providing two ligating bands 41a and 41b, it is possible to make two ligations in a fallopian tube, in order to provide more reliable blockage of the tube. In order to release ligating bands 41a and 41b in sequence, pusher balloon 42 (in FIG. 7) or pusher disk 48 (in FIG. 8) must be extended a first distance sufficient to push ligating band 41a off lip 40, and then be extended a second distance sufficient to push ligating band 41b off lip 40. Pusher balloon 42 would be expanded to a first volume, and then to a second, larger volume in order to push the two ligating bands sequentially. Similarly, pusher disk 48 would be extended to two different positions sufficient to release ligating bands 41a and 41b sequentially. It would be possible to use the two ligating bands to perform ligation of the two fallopian tubes sequentially, with the same device, but this is not preferred, because the withdrawal of the device from one fallopian tube, followed by

reinsertion of the device into the second fallopian tube, provides an opportunity for contamination of the device and introduction of contaminants or infectious agents into the uterus or second fallopian tube.

It may be desirable to infuse antibiotics, topical anesthetics, or other drugs into the area of the ligation. Referring back to FIG. 2, drugs can be infused from the tip 23 of tubular element 21 into fallopian tube 31. One or more drug delivery lumens may be provided. For example, lumen 45 of tubular element 21 may function as a drug delivery lumen. Alternatively, one or more drug delivery lumens may be provided in the wall of tubular element 21, comparable to channels 46a and 46b shown in FIG. 5. As a further alternative, a drug delivery lumen may be provided by adding a second tubular element surrounding, and coaxial with tubular element 21, thereby forming a drug delivery lumen between tubular element 21 and the second tubular element. Drugs would be injected into the drug delivery lumen via access port 37, shown in FIG. 1, which would be connected to the drug delivery lumen.

If desired, an electrical current may be passed through grasper 38 to cauterize the grasped tissue. For example, current could be passed through barbs 54a, 54b, 54c, etc. of the device of FIGS. 2-6, hooked wires 100 of the device of FIG. 6.5, or through hooks 58a, 58b, 58c, 58d or 61a, 61b, etc. of the grasper as shown in FIGS. 7 and 8. Cauterization of tissue may be of use to reduce bleeding and to burn away small amounts of tissue to facilitate freeing of the fallopian tube from grasper 38. Cauterization of tissue may also be accomplished by delivery of a chemical cauterizing agent through a drug delivery lumen as discussed above.

The method of using the inventive device includes the following steps, described in the context of ligation of a fallopian tube, but applicable to the ligation of other tubular anatomical structures, as well. In the discussion of the methods steps, specific reference is made to the embodiment of the invention shown in FIGS. 1-3, 5 and 6, but the steps may be readily generalized to other embodiments of the invention.

1) INSERTION OF DEVICE. The first step is the insertion of the device into the fallopian tube, as shown in FIGS. 1 - 3. The grasper 38 maintained in the unextended position within tubular element 21 during the insertion step in order to prevent damage to the components of grasper 38 and to facilitate insertion of the device by having the relatively smooth, readily inserted distal end 23 of tubular element 21

leading during insertion. Referring now to FIG. 1, a person performing the procedure holds device 20 by control segment 24 and inserts distal end 23 into the vagina 31 of the patient, and then into the lumen 33 of the uterus 34. Distal end 23 is then guided into a uterine horn 35 and into the lumen 30 of fallopian tube 31. Correct placement of distal end 23 may be determined by monitoring the length of tubular element 22 inserted after distal end 23 has passed the uterine horn 35 and entered the fallopian tube 31, as determined by change in resistance to insertion. Insertion of tubular element 22 into uterus 34 and fallopian tube 31 may also be performed with hysteroscopic guidance. Device 20 may include control wires (not shown) for steering distal end 23, or other steering methods utilized with catheters, with steering control 25 on control segment 24 used for steering distal end 23 during insertion.

2) EXTENSION OF GRASPER. As shown in FIGS. 6 and 9, once the distal end 23 of tubular element 21 has been positioned properly within the fallopian tube 31, grasper 38 is extended out of tubular element 21. Grasper 38 is thus passed through the central opening of ligating band 41. FIG. 9 is a cross-section of the device, taken along section line 9-9 in FIG. 6. Extension and retraction of grasper shaft 44 may be controlled by extension control 26 on control segment 24 in FIG. 1 which may be, for example, a trigger causing movement of a mechanical linkage. Various mechanisms may be devised for causing grasper shaft 44 to extend out of tubular element 21 by a predetermined distance, and the practice of the invention is not limited to a particular mechanism.

3) GRASPING OF TISSUE. Once grasper 38 has been extended out of tubular element 21, grasper 38 is activated to grasp tissue on the interior of fallopian tube wall 39. Control segment 24, shown in FIG. 1, may include a grasp control 27 for controlling grasping. As shown in FIG. 8, balloon 51 is inflated by fluid flowing through grasper shaft 44 until the outer diameter of balloon 51 is substantially as large as the inner diameter of fallopian tube 31. Barbs 54a, 54b, etc. are then pushed into and grasp or engage fallopian tube wall 39. Naturally, grasping of tissue could also be accomplished with an alternative grasper mechanism, such as those shown in FIGS. 6.5, 6.6, 7, and 8.

4) RETRACTION OF GRASPER SHAFT AND GRASPED TISSUE. As shown in FIG. 11, once tissue has been grasped by barbs 54a, 54b, etc., balloon 51 is

deflated, drawing the fallopian tube wall 39 radially inward toward grasper shaft 44. Referring now to FIG. 12, following deflation of balloon 51, grasper 38 is retracted into distal end 23 of tubular element 21. A tissue bundle 70 from the fallopian tube wall 39, is drawn into distal end 23 of tubular element 21 by grasper 38. When tissue bundle 70 is drawn into distal end 23 of tubular element 21, it is at the same time drawn through the central opening of ligating band 41.

5) RELEASING OF LIGATING BAND ONTO TISSUE BUNDLE. As shown in FIG. 13, ligating band 41 is pushed off of lip 40 by the expansion of pusher balloon 42. Pusher balloon 42 may be expanded by air or liquid, such as water or saline solution, forced into pusher balloon 42 via channels 46a and 46b. Once pushed off of lip 40, ligating band 41 contracts around tissue bundle 70. An alternative release mechanism, such as the pusher mechanisms shown in FIG. 4 or 6.5, could be used at this step, instead. The pusher mechanism may be controlled by a push controller 28 located on control segment 24 in FIG. 1.

If tissue bundle 70 includes tissue from around the circumference of the tubular anatomical structure, application of ligating band 41 to tissue bundle 70 will produce blockage of fallopian tube 31. If, on the other hand, tissue bundle 70 includes tissue from only one side of the fallopian tube 31, ligation of tissue bundle 70 will only separate tissue bundle 70 from the remainder of fallopian tube 31, but not block fallopian tube 31. This may be desirable in certain medical applications, such as ligating damaged or cancerous tissue, but of course would not be effective for contraception. A grasper which grasps tissue around the circumference of the tube will form a tissue bundle 70 that includes tissue from around the circumference of the tube. It may also be possible to form a tissue bundle that includes tissue from around the circumference of the tube by grasping tissue around only a part of the circumference of the tube, if the amount of tissue grasped is large enough that the stiffness of the tube causes the entire circumference of the tube to fold in to form the tissue bundle.

6) FREEING OF GRASPED TISSUE. Following application of a ligating band or bands, tissue bundle 70 must be freed from grasper 38. This may be accomplished by simply tearing barbs 54a, 54b, etc. from tissue bundle 70. Since tissue bundle 70 is separated from the main portion of the fallopian tube by the ligation, tissue damage caused by tearing out of the barbs is not of great concern. Cauterization of the

tissue by passing current through the barbs, hooks, or other portion of the grasper contacting the tissue, or by delivering a chemical cauterizing agent, may facilitate freeing of tissue and reduce bleeding.

7) WITHDRAWAL OF DEVICE. Following ligation of tissue bundle 70 by ligating band 41, and freeing of tissue bundle 70 from grasper 38, the device may be withdrawn. FIG. 14 shows the ligated fallopian tube 31, with tissue bundle 70 secured by ligating band 41. The lumen of fallopian tube 31 is now divided into two sections separated by the ligation: distal lumen 71, on the side closer to the ovary; and proximal lumen 72, on the side closer to the uterus. If it is desired that only a single ligating band be applied to the fallopian tube, the device is now withdrawn completely from the fallopian tube.

8) APPLICATION OF ADDITIONAL LIGATING BANDS. Referring now to FIG. 15, if it is desired that more than one ligating band be applied to the fallopian tube, after the application of first ligating band 41a to first tissue bundle 70a, tubular element 21 is withdrawn only partially, to a new, more proximal position within the fallopian tube, and steps 2 through 5 are repeated at the new, more proximal position, to apply second ligating band 41b to second tissue bundle 70b to produce a double ligation. Lumen 72 is now between the first and second ligations, and lumen 73 is located most proximally on the side closer to the uterus. Steps 6 through 8 may be repeated as many times as desired to apply multiple ligating bands to one fallopian tube; however, it is anticipated that reliable ligation would be provided by one to three ligating bands, and larger numbers of ligating bands would not be necessary or desirable.

To accomplish sterilization, it is of course necessary to ligate both fallopian tubes. Thus the procedure would be repeated for the second tube in a similar manner. As noted above, it is preferred that the same device not be withdrawn from the first fallopian tube and then reinserted into the second fallopian tube, due to the risk of infection. Therefore, two sterilized devices are preferably provided to perform ligation of both fallopian tubes. It is within contemplation to manufacture the device having some or all components being disposable.

One alternate embodiment of the device, generally indicated at 200 in FIG. 16, is formed, in part, by three co-axial catheters 202, 204, and 206, referenced in numerical

order corresponding to increasing diameter. The device 200 has been designed for tubal ligation as an office procedure using locally applied topical anesthetics. Device 200 fits within the operating channel of a hysteroscope (2.2 mm ID), so that standard hysteroscopic techniques can be used to locate the fallopian tube opening (ostium) and feed the device 200 into the fallopian tube.

Placement of device 200 without hysteroscopic equipment may be effected to provide non-surgical sterilization options for women in rural or underdeveloped nations. Using a cannula bent at a 140° angle, the device 200's tip is manually guided through the uterine horn and grossly positioned near the utero tubal junction. The device 200 is then pushed from the cannula into the ostium and extended about 5 cm. Resistance to insertion requires tip manipulation to search for the tubal opening within the minimal surface area at the cannula tip. Verification of tubal entry can be achieved via 20 ml saline instillation through the catheter 204, where saline leakage into the cannula or cervical os is indicative of uterine (rather than tubal) catheter placement.

Catheters 202, 204, and 206 employed in devices 200 used for sterilization procedures desirably are formed from extruded nylon, or any other suitable medical grade polymer. The inner catheter 202 is an elongate member. The distal tip 208 of catheter 202 desirably is flexible and forms, or carries, an inflatable balloon 210. The distal end 212 of middle catheter 204 has an expandable tip, generally indicated at 214, and also carries an O-ring 216. The outer catheter 206 is used to push or deploy the O-ring 216 over an invaginated tissue peduncle (tissue bundles 70a and 70b in FIG. 15). Handles or grip-assisting structure, not illustrated, may be located on a proximal, or other convenient, location on each of catheters 202, 204, and 206, to facilitate manipulation of the device 200 and its components.

The distal tip 220 of the device 200 desirably includes about a 1 cm length of double hulled tubing 222. Tubing 222 desirably flexes to reduce the risk of tubal perforation during positioning of device 200, and also functions as an inflatable balloon 210 during a ligation procedure. Tubing 222 may be made from Silastic tubing, or some other operable material.

A minimal volume of cyanoacrylate or other adhesive may be contained between the double hulls of a Silastic balloon 210, to function as a grasping aide. Cyanoacrylate is the adhesive of choice based upon its minimal viscosity, long shelf life (in a dry

environment) and ability to cure upon tissue contact. Several cyanoacrylate compounds are approved for human use, but Trufill™ (Cordis Neurovascular) is currently approved for internal (non-superficial) use. Since scaring side effects are desirable for this application, the device 200 may not be limited to using Trufill adhesive.

An inner hull of balloon 210 may be nonporous, with the outer hull, in a relaxed state, having pores sized small enough to prevent premature passage of the adhesive. A syringe 225 can be provided in a device 200 to inflate the balloon 210. Other inflation devices are also operable. Inflation of the balloon 210 stretches the pores in the outer hull and allows local adhesive delivery through the pores in the outer balloon for adhesion of the balloon 210 to an inside wall section of a tube to be occluded. Pores in the outer hull may be arranged to produce spaced apart and axially aligned strips of adhesive on the balloon 210, to facilitate collapse of an inflated and adhered balloon 210.

FIGS. 17-20 illustrate operation of the device during a ligation procedure. In FIG. 17, distal tip 220 of device 200 has been inserted to a desired location for creation of an occlusion in a tube 230. The optimal sphincter location for female contraceptive ligation is just distal to the ampullary-isthmic junction (4-5 cm from the ostium), where the inner diameter of the fallopian tube abruptly increases from about 2 mm to about 5 mm. The ratio of wall thickness to inner diameter in the ampullary tube makes this the first region that is appropriate for invagination. Following positioning in the ampullary tube, the tip 214 of catheter 204 is expanded to 5 mm, approximating the inner diameter of the fallopian tube. The device 200 is then drawn back (proximally) until resistance to the expanded tip 214 prevents further withdrawal. This procedure ensures appropriate positioning at the ampullary-isthmic junction. FIG. 18 depicts inflation of balloon 210 to place adhesive in contact between the balloon 210 and an inner surface 232 of tube 230. Balloon 210 desirably is inflated with a formalin solution, such as 10% formalin. Furthermore, expandable tip 214 is illustrated in FIGS. 17 and 18 as having a plurality of legs 235, each leg 235 being in a substantially collapsed, or retracted, position for insertion into a tube.

FIG. 19 illustrates proximal retraction of the balloon 210 with respect to a fold mechanism 237 formed, in part, from structure of expanding tip 214. Fold mechanism 237 increases a diameter of tube 230, proximal to a grasped section, to

assist in everting the tube 230. In the illustrated device 200, proximal retraction of balloon 210 simultaneously activates fold mechanism 237. As shown in FIG 20, a balloon 210 desirably is collapsed to assist in forming a compact peduncle 250, although such is not a requirement. FIG. 20 also shows catheter 206 has been advanced distally to deploy O-ring 216 as a legator band around tissue bundle 250. In some cases, a distal end of catheter 206 may additionally act as a passive fold assist mechanism, or to compact the peduncle 250.

After the O-ring is deployed, the tube 230 immediately is sealed for a short term, at least until the peduncle 250 dies and its tissue sloughs off. The balloon 210 may be pulled from its attachment, promoting local scarring to provide a long term occlusion of tube 230. At present it is desired to leave balloon 210 attached, and for formalin leakage from balloon 210 to promote scarring in the tube proximal the O-ring to provide long term contraception. Permanent tubal occlusion is maintained through the formation of scar tissue at the site of the ligation sphincter. Chronic exposure to the elastomeric ligature 216 causes a sustained inflammatory response leading to more stable scar tissue formation. In addition, instillation of 10% formalin solution proximal to the tubal sphincter prevents epithelial regeneration and aids in permanent scar formation. It is within contemplation alternatively, or additionally, to provide a current source to cauterize tissue of the peduncle and potentially to assist in separating a balloon 210 from a catheter 202. Alternatively, catheter 202 may be coupled to a balloon 210 in a way preferentially to separate at a known weak link under a given amount of tension in catheter 202.

Illustrated fold mechanism 237 includes a plurality of legs 235 spaced apart around a centerline, each leg 235 having a knee 239 between a thigh 241 and a shin 243. A leg 235 desirably is sized such that a thigh 241 will have an axial length equal to, or greater than, a corresponding length of a shin 243. Such relative lengths assist in forming a circumferential fold in a wall of tube 230 during proximal retraction of balloon 210. A thigh 241 longer than a shin 243 causes a wrap to form in a wall of tube 230, thereby everting proximal and distal tubular portions of tube 230, as the shin 239 is displaced rotatingly towards the thigh 241. A long thigh 241 also forms a ramp, or surface guide, assisting in deployment of O-ring 216. Although such is not

currently preferred, it is within contemplation for a fold mechanism 237 to have a single active component, such as a single leg 235.

Illustrated active fold mechanism 237 may be considered as forming one or more four-bar linkages, and includes structure of catheter 202, expanding tip 214, and catheter 204. A distal portion of expanding tip 214 is rotatably attached to a distal end of catheter 202. A proximal displacement of catheter 202, while holding catheter 204 fixed, causes knees 239 to buckle and deflect radially outward, expanding the tip 214 and increasing a diameter of a localized portion of tube 230. In use, grasping structure, such as balloon 210, maintains (or even reduces) a diameter of a first tubular portion 245 of tube 230. A diameter of a second, and proximal, tubular portion 249 of tube 230 is increased by the transverse motion of knees 239. As illustrated in FIG. 20, the second portion 249 is folded over the first portion (everting the tube) to create a tissue bundle or peduncle 250.

An active mechanism generally can be defined as connected structure arranged actively to convert one form of work or a displacement in one direction, to another form of work or displacement in a different direction. In the case of the illustrated fold mechanism 237, a proximal (axial) displacement of catheter 202 is actively converted to a radial displacement of knees 239. In turn, knees 239 expand a cross-section of tube 230 to an effective diameter larger than a diameter grasped by the balloon 210. Such an active mechanism 237 can be contrasted to the essentially fixed geometry of a passive fold assist mechanism, such as a distal end of catheter 206. The distal open end of catheter 206 may assist in folding a tube 230, or in compacting a partially folded peduncle 250, but no active reduction in radial displacement occurs in the catheter 206 itself. In fact, a distal end of catheter 206 may be required to expand to accommodate insertion of a peduncle 250. In such case, thighs 241 may act as wedges to compact the diameter of a peduncle 250.

Although hysterosalpingography can be used to confirm complete tubal occlusion, these procedures are expensive and typically not available in developing nations. An inexpensive alternative to visualization exploits the fact that the distal end of the fallopian tube is naturally open to the peritoneal cavity. Following uterine injections of methylene blue, the dye dissipates into the peritoneal cavity then is

processed and excreted by the kidneys in less than 30 minutes. Only completely occluded tubes can prevent dye dispersion and excretion within this time frame.

While the present invention has been described and illustrated in terms of certain specific embodiments, those of ordinary skill in the art will understand and appreciate that it is not so limited. Additions to, deletions from and modifications to these specific embodiments may be effected without departing from the scope of the invention as defined by the claims. Furthermore, features and elements from one specific embodiment may be likewise applied to another embodiment without departing from the scope of the invention as defined herein.

CLAIMS

What is claimed is:

1. A method for blocking a passageway through a tubular anatomical structure, comprising the steps of:

grasping tissue on the interior of said tubular anatomical structure with a grasper, said grasper being carried at a distal end of an elongate member;

proximally retracting said grasper with respect to a fold mechanism operable to increase a diameter of said tubular anatomical structure at a location proximal to said grasper;

activating said fold mechanism to assist in formation of a tissue bundle comprising tissue from around the entire circumference of said tubular anatomical structure; and

applying a ligating structure to said tissue bundle to block said passageway.

2. The method according to claim 1, wherein said fold mechanism comprises a toggling leg having a knee adapted for radial translation to expand a first cross-section of said tubular anatomical structure, to a diameter larger than a diameter of a second cross-section of said tubular anatomical structure at a location being grasped by said grasper, so as to assist in forming a circumferential fold in said tubular anatomical structure when said grasper is proximally retracted with respect to said fold mechanism.

3. The method according to claim 2, wherein said grasper and said fold mechanism are cooperatively structured such that proximal retraction of said grasper simultaneously activates said fold mechanism.

4. The method according to claim 3, said fold mechanism being configured and arranged to assist in everting a first tubular section of said tubular anatomical structure, located adjacent and proximal to a second tubular section being grasped by said grasper, such that a vector, originating at one end and following a centerline of said tubular anatomical structure, is substantially coaxial, but reversed in direction, between said first and second tubular sections.

5. The method according to claim 1, said grasper comprising an inflatable section, the method further comprising the step of inflating said inflatable section whereby to adhere a portion of said inflatable section, carrying an adhesive, to a section of said tubular anatomical structure to perform said grasping.

6. The method according to claim 1, further comprising the step of detaching said grasper from said distal end of said elongate member, and removing said elongate member from inside said tubular anatomical structure.

7. A device for everting a first tubular section of a tubular anatomical structure to form a tissue bundle and applying at least one ligating structure to said tissue bundle, comprising:

an elongated conduit comprising a distal end, a proximal end, and a lumen therebetween, wherein said distal end is adapted for insertion into said tubular anatomical structure;

a grasper carried at a distal end of an elongate member, said elongate member being slidably disposed within said lumen, said grasper being capable of extending distally from said conduit, grasping grasped tissue on the interior of said tubular anatomical structure, and retracting proximally with said grasped tissue;

an active fold mechanism configured and arranged to assist said grasper in everting said first tubular section;

a ligating structure releasably carried near a distal end of said device; and

application structure disposed near said distal end of said conduit and adapted for applying said ligating structure to said tissue bundle.

8. The device of claim 7, wherein said grasper comprises a balloon structure disposable for inflation distal to said fold mechanism.

9. The device of claim 8, wherein said grasper further comprises an adhesive substance being released, by inflation of said balloon, to form an adhesive layer between said balloon and said grasped tissue.

10. The device of claim 9, wherein said balloon comprises a dual walled inflation structure having outer and inner walls with an adhesive substance disposed between said outer and inner walls, said outer wall of said inflation structure having pores being expandable on inflation of said balloon to permit passage through said expanded pores by said adhesive substance.

11. The device of claim 7, said fold mechanism comprising:

a leg having a knee adapted for radial translation to expand a first cross-section of said tubular anatomical structure, to a diameter larger than a diameter of a second cross-section of said tubular anatomical structure at a location being grasped by said grasper, whereby to assist in forming a circumferential fold in said tubular anatomical structure when said grasper is retracted proximally with respect to said fold mechanism.

12. The device of claim 11, wherein said leg comprises a shin portion distal to said knee; and a thigh portion proximal to said knee.

13. The device of claim 12, wherein said shin portion and said thigh portion are approximately of the same length.

14. The device of claim 12, wherein said shin portion having a length shorter than a length of a thigh portion, whereby to cause a first, outward, radial displacement of said knee, and a second, inward, radial translation of said knee as said grasper is moved proximally from a grasp engaging position to a folded position.

15. The device of claim 11, comprising a plurality of toggling legs, each leg having a knee, said legs being arranged to provide a plurality of knees spaced apart around a centerline and arranged in harmony for common action of said plurality of knees to expand said first cross-section.

16. The device of claim 7, said application structure comprising a portion of said distal end of said conduit.

17. The device of claim 7, wherein said ligating structure comprises a resilient o-ring.

18. A device for blocking a passageway of a flexible tube, at an internal and intermediate location between ends of the tube, comprising:

a conduit comprising a distal end, a proximal end, and a lumen therebetween, said distal end being adapted for insertion into one open end of said tube;

a balloon comprising a dual walled inflation structure having outer and inner walls with an adhesive substance disposed between said outer and inner walls, said outer wall of said inflation structure having pores being expandable on inflation of said balloon to permit passage through expanded said pores by said adhesive substance;

an elongate member with a distal end adapted to carry said balloon, said elongate member being slidably disposed within said lumen, said balloon being capable of extending distally from said conduit, inflating to create an adhesive grasp on a first tube section of the interior of said tube, and retracting proximally with said first tube section;

a ligating structure releasably carried near a distal end of said device; and

application structure disposed near said distal end of said conduit and adapted for applying said ligating structure to block said passageway.

19. The device of claim 18, further comprising: a fold assisting structure located, configured, and arranged to assist said balloon in everting a section of said tube.

20. The device of claim 19, said fold assisting structure comprising a mechanism operable to increase a diameter of a second tube section at a location proximal to said first tube section, thereby permitting said first tube section to be retracted proximally to a concentric position within said second tube section to create a circumferential fold in said tube and a resulting tissue peduncle.

21. The device according to claim 20, said mechanism comprising:
a plurality of legs, each leg having a knee, said legs being arranged to provide a plurality of knees spaced apart around a centerline and arranged in harmony for radial translation of said plurality of knees to increase a diameter of said second tube section.

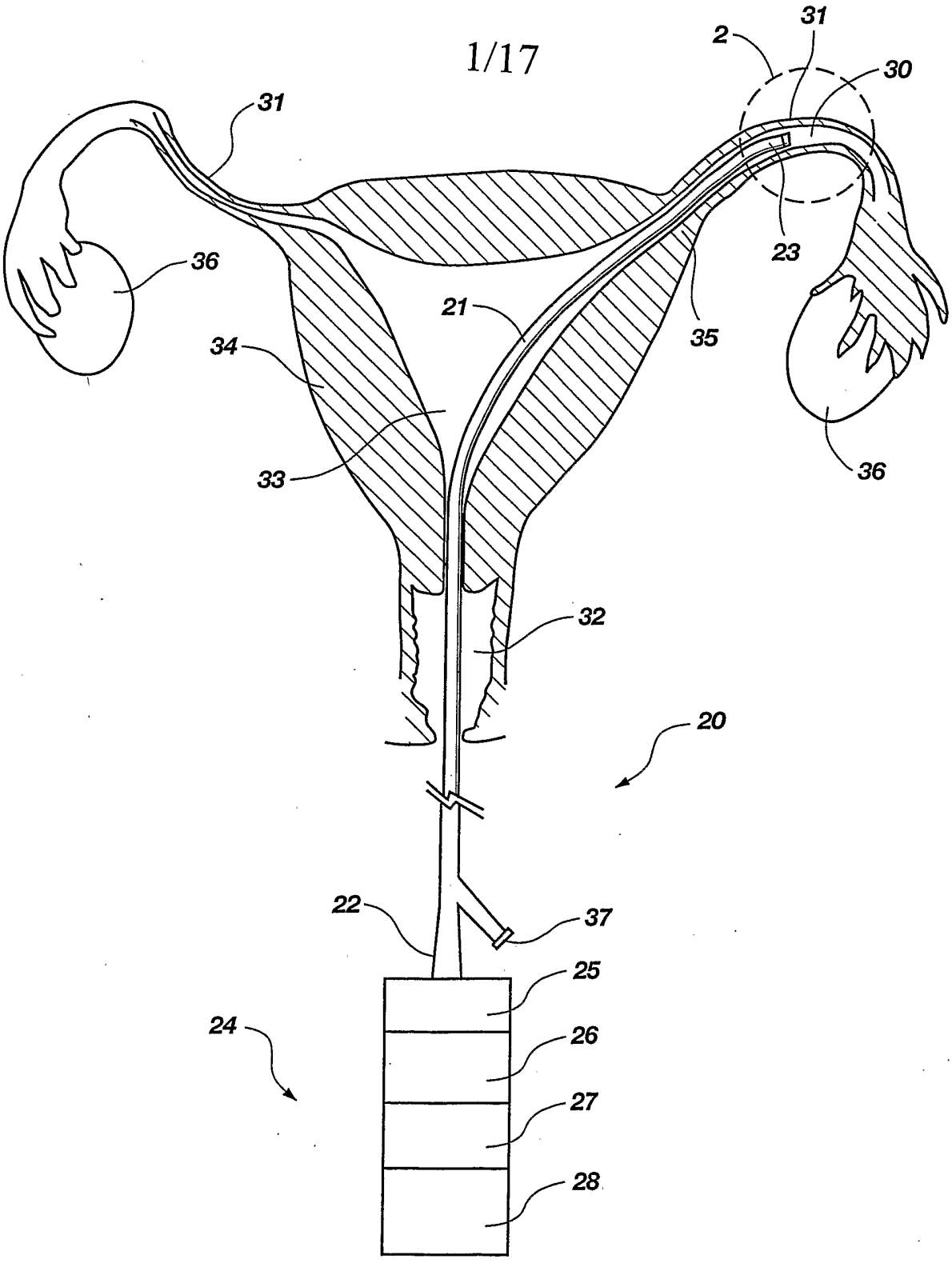

Fig. 1

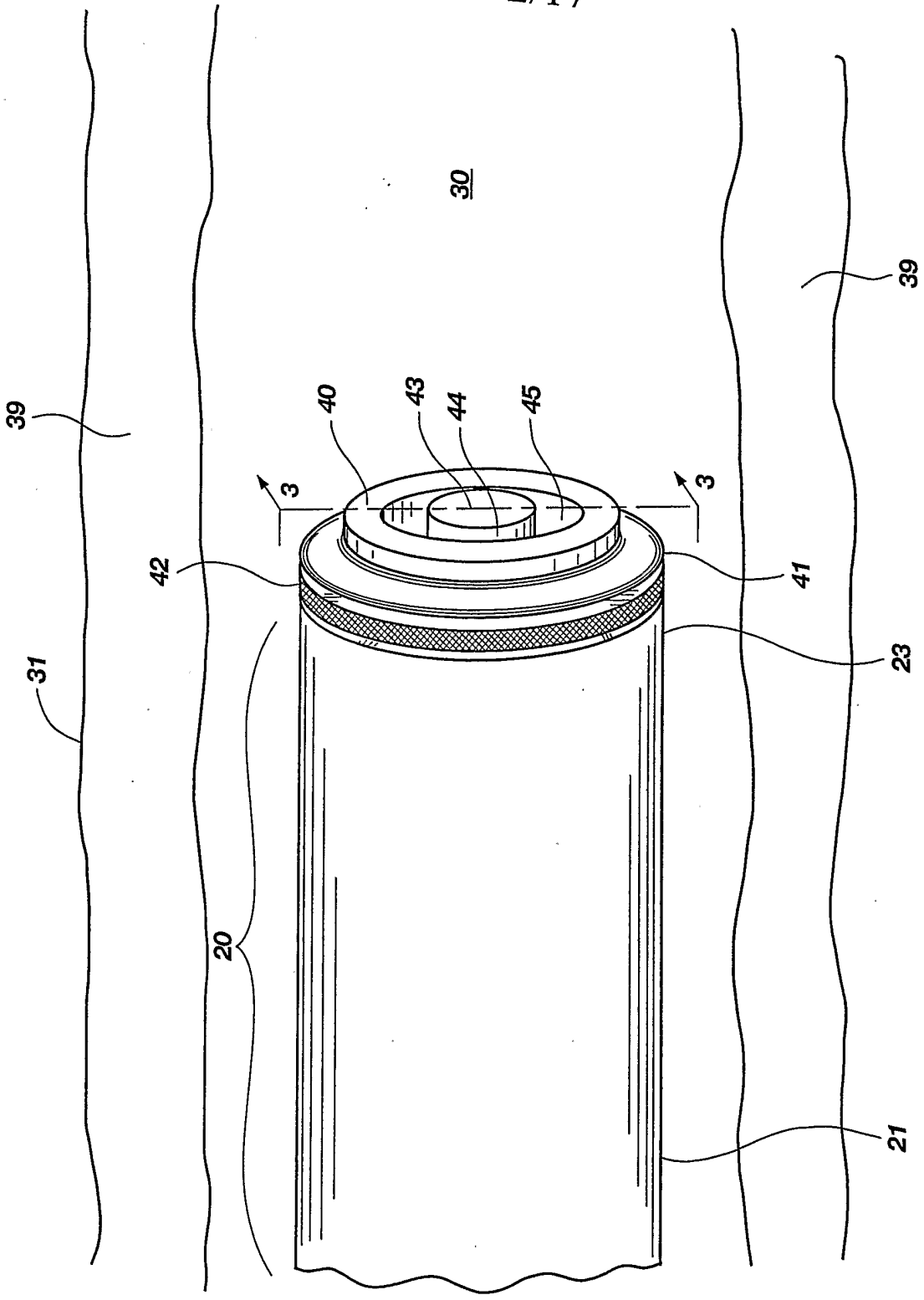

Fig. 2

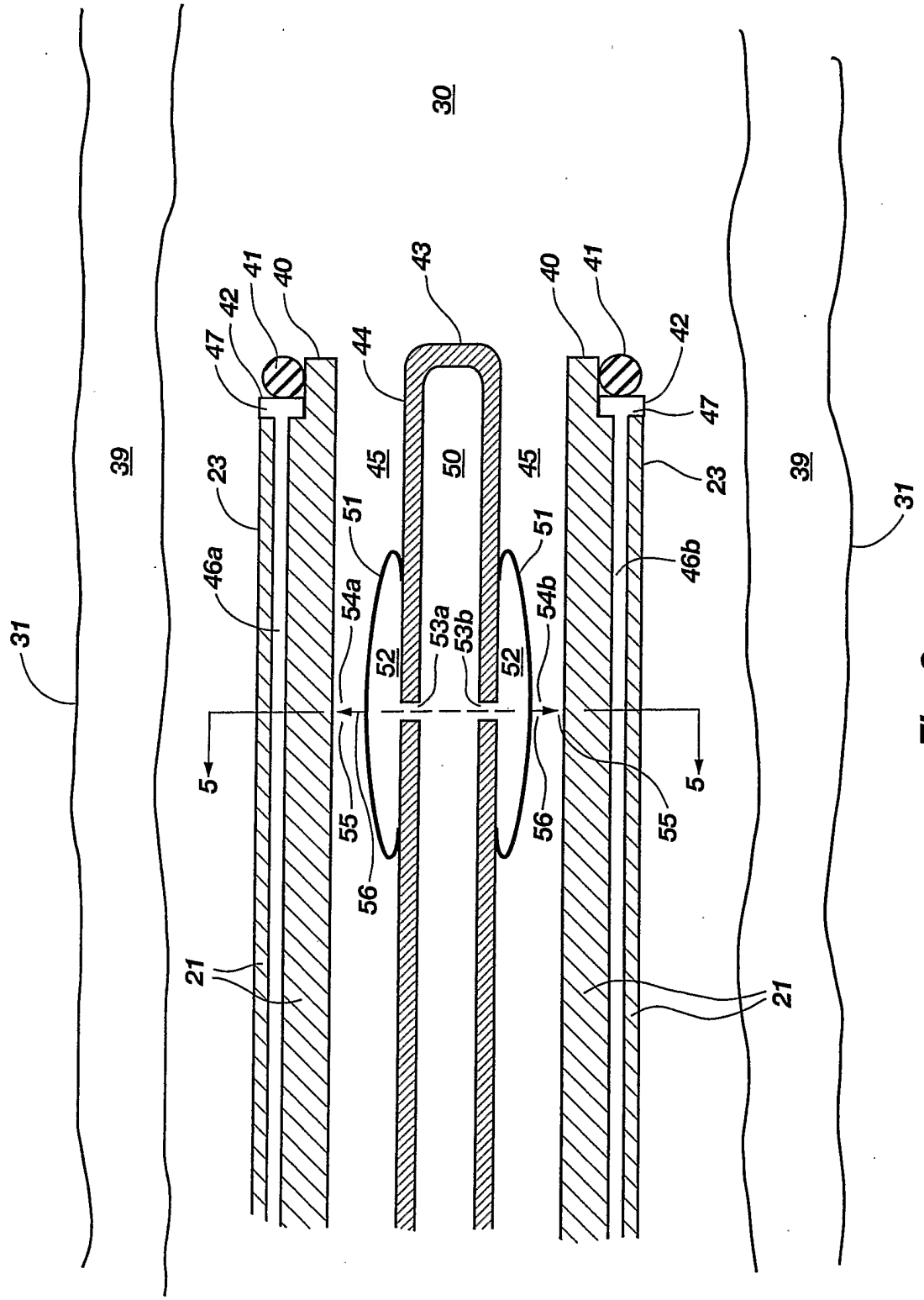
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Fig. 3

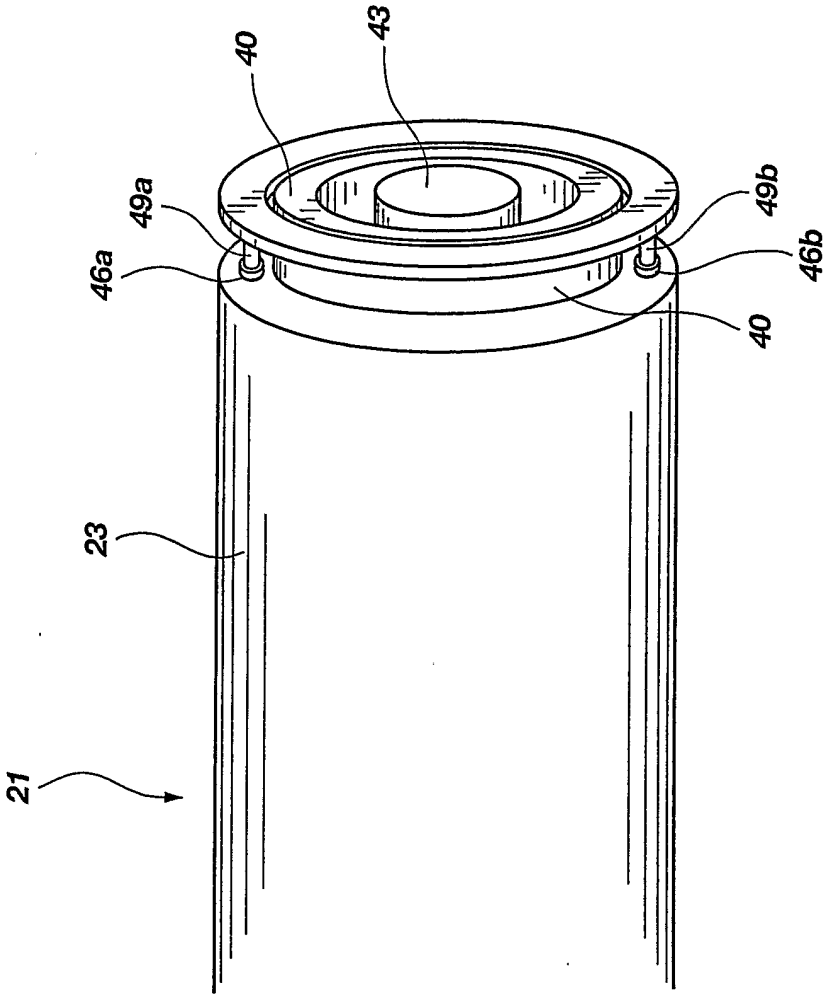

Fig. 4

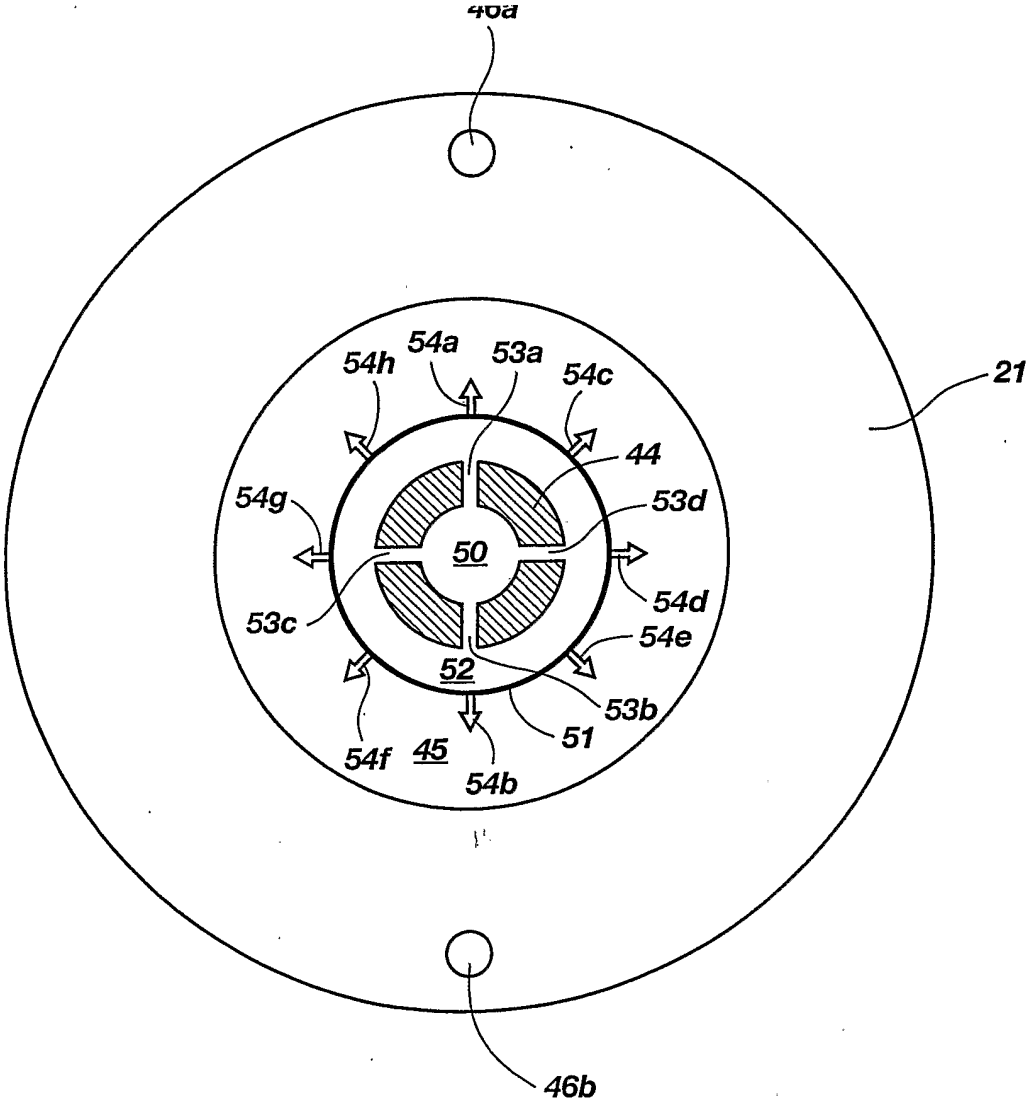
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Fig. 5

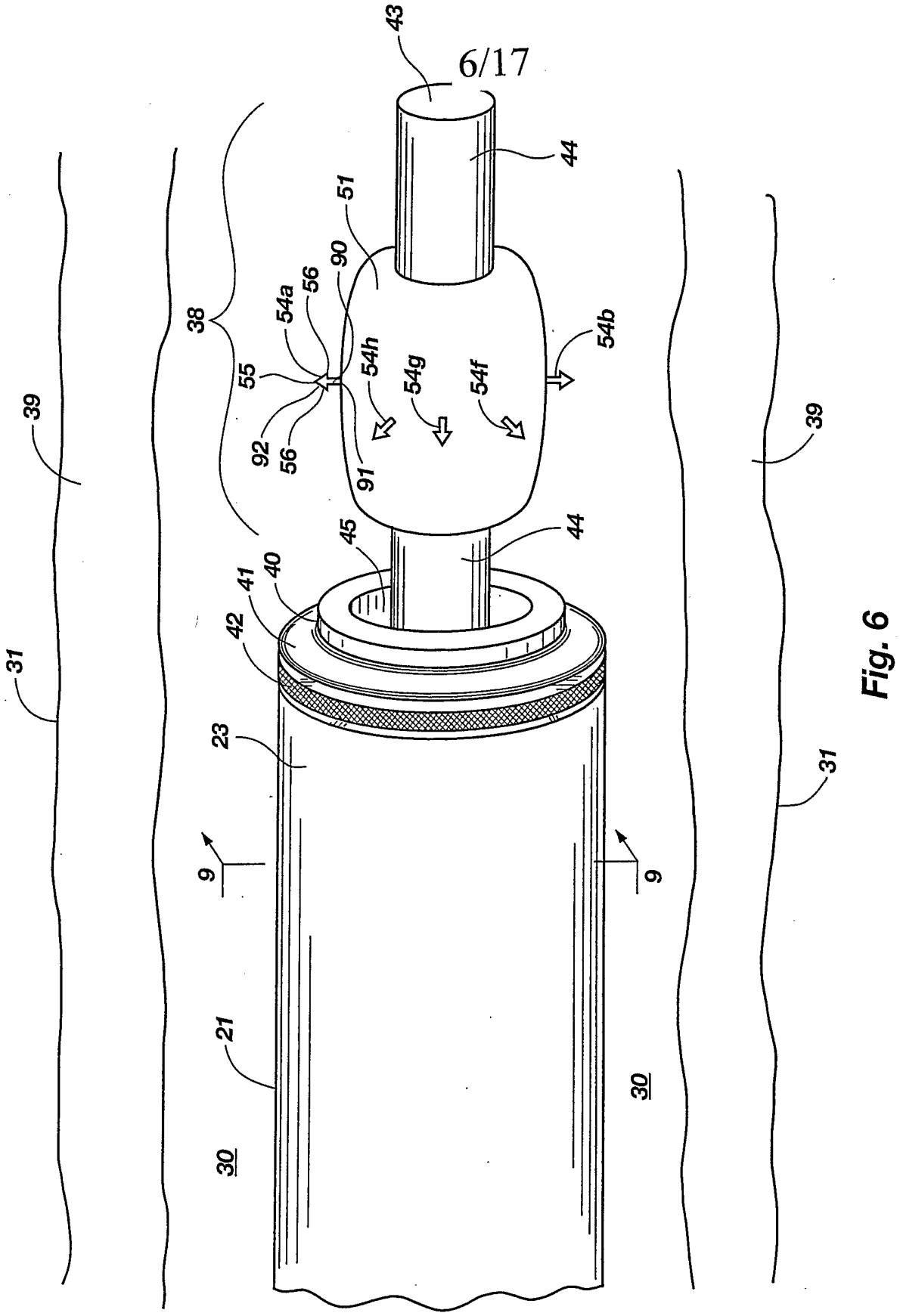
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Fig. 6

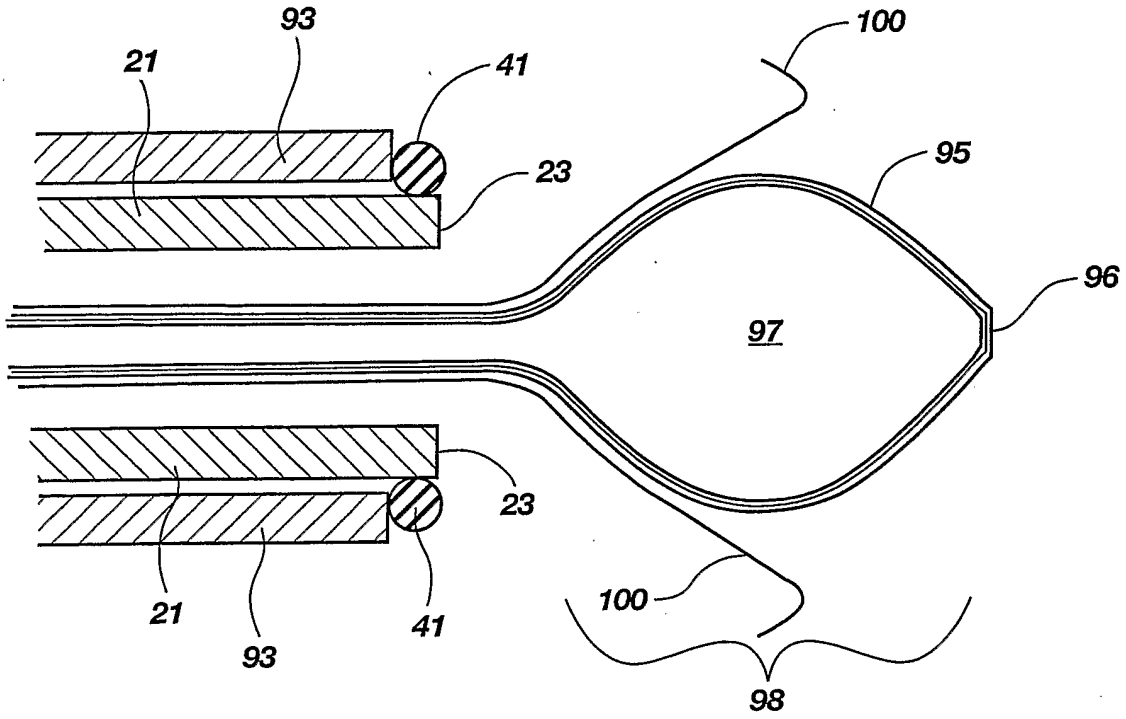
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Fig. 6.5

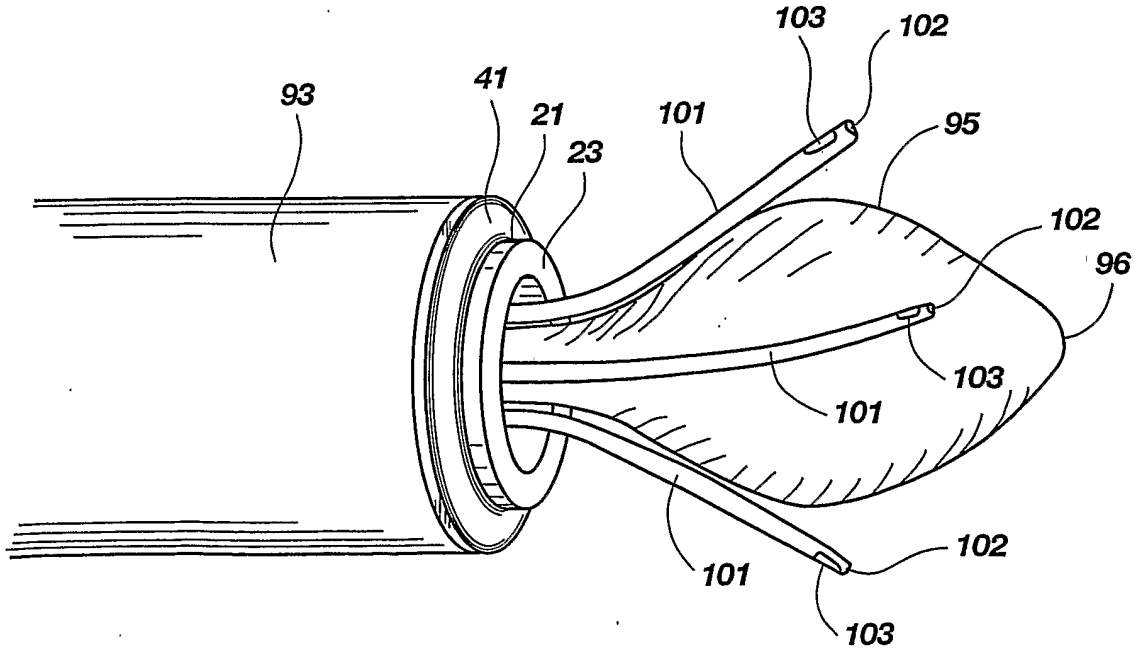
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Fig. 6.6

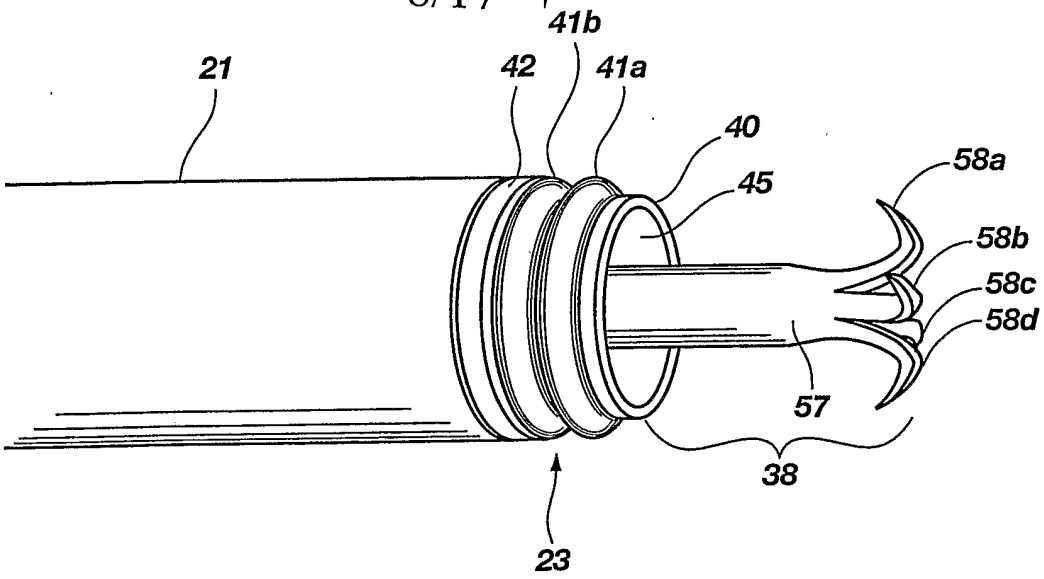
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Fig. 7

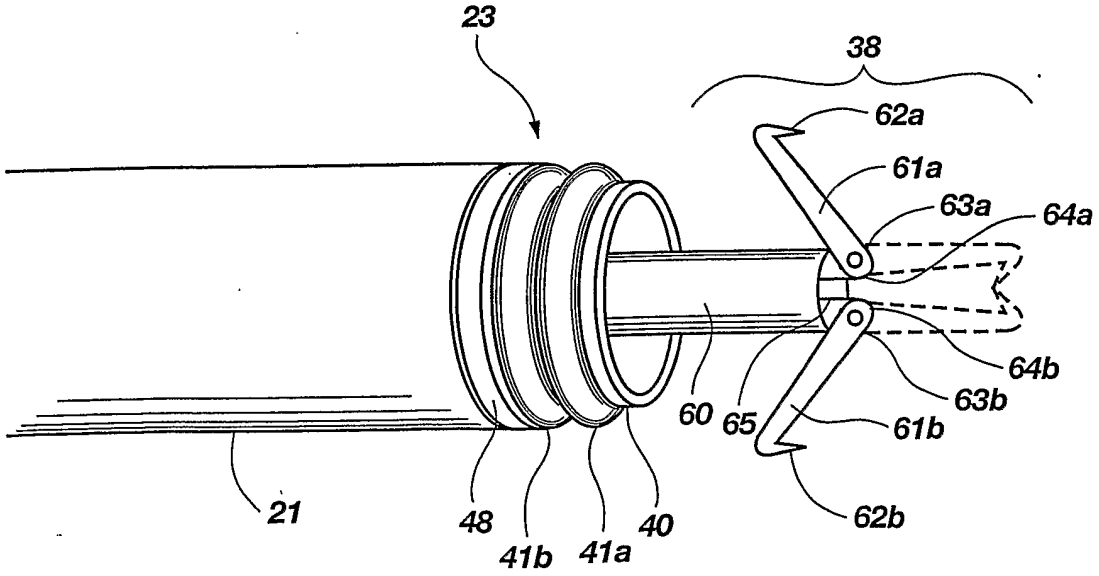
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Fig. 8

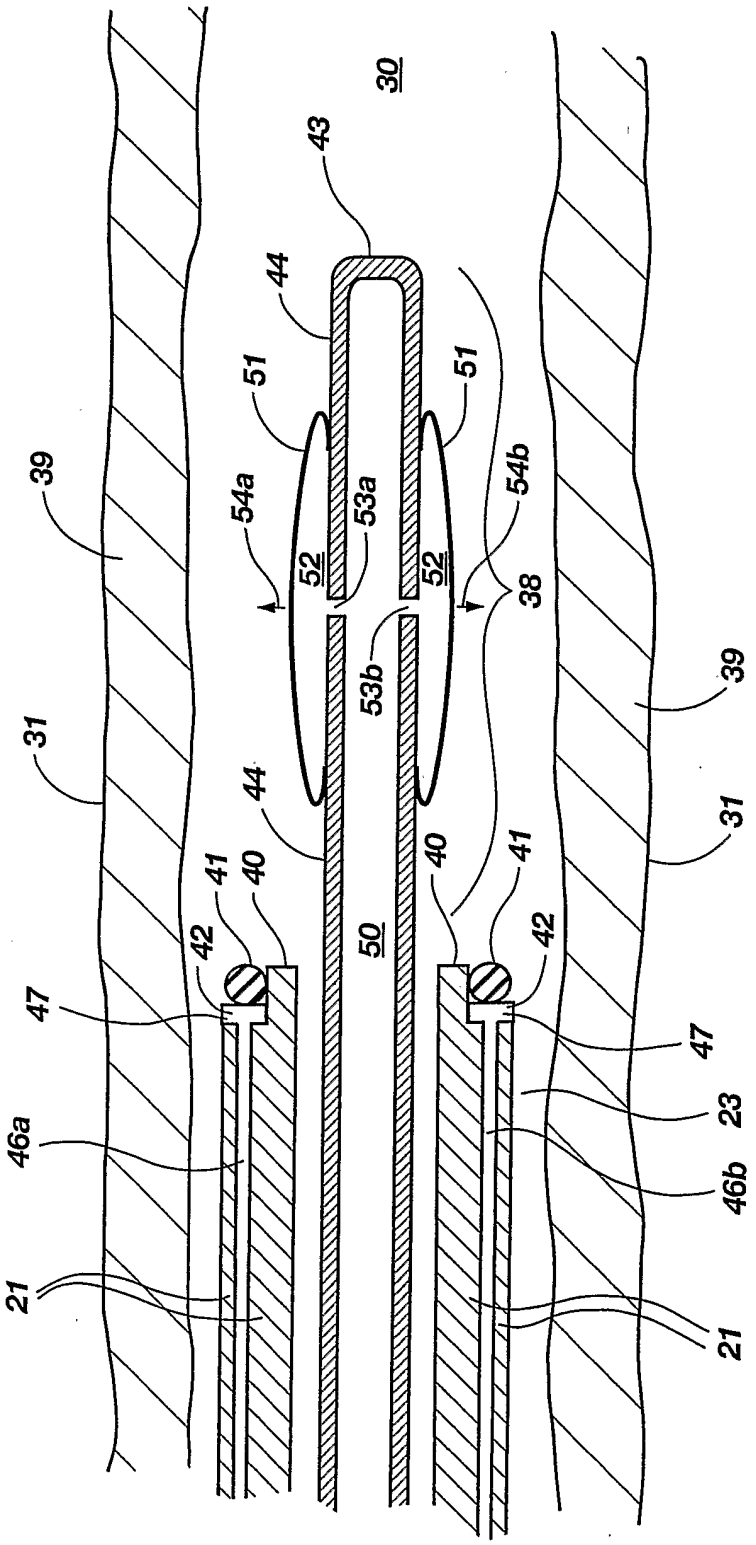
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Fig. 9

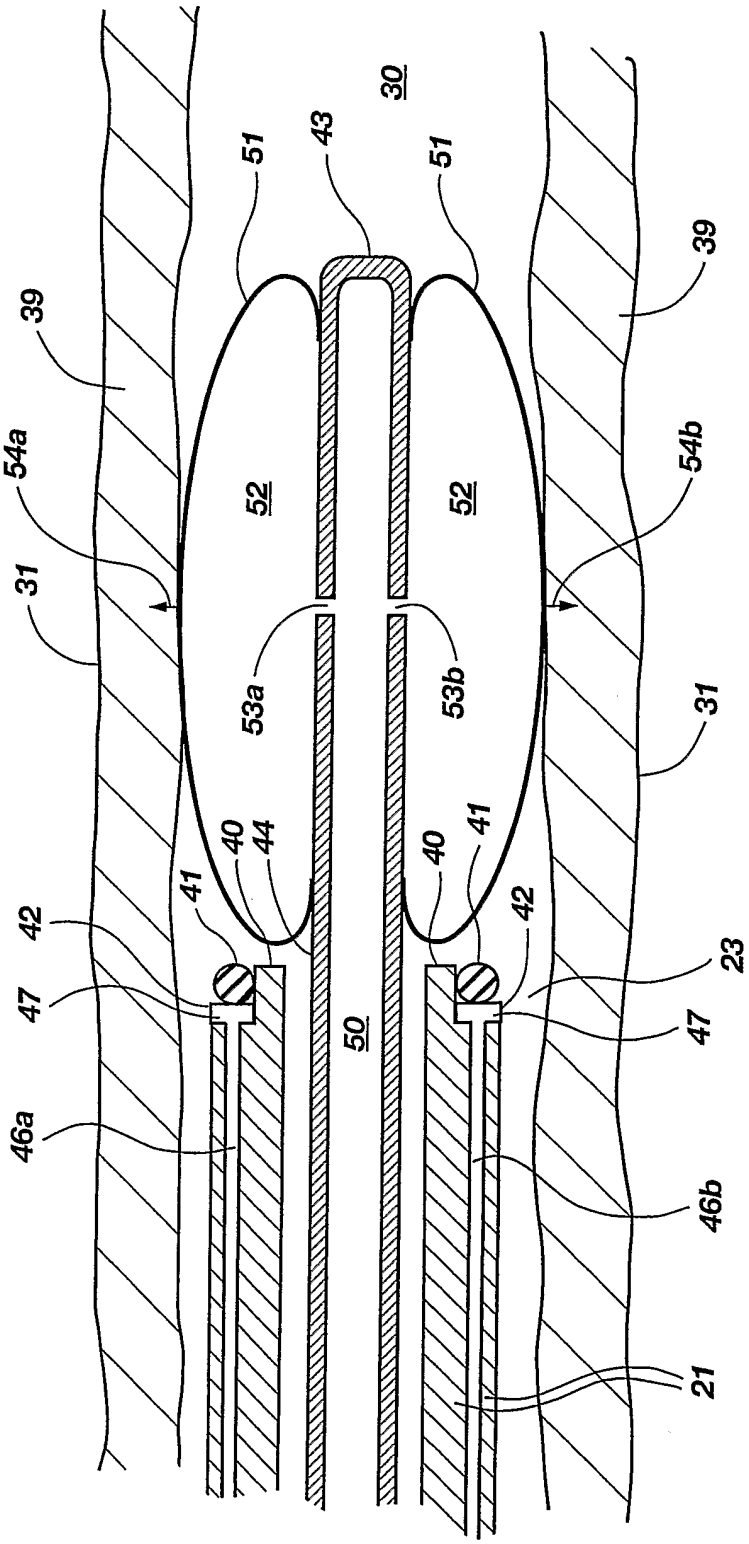
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Fig. 10

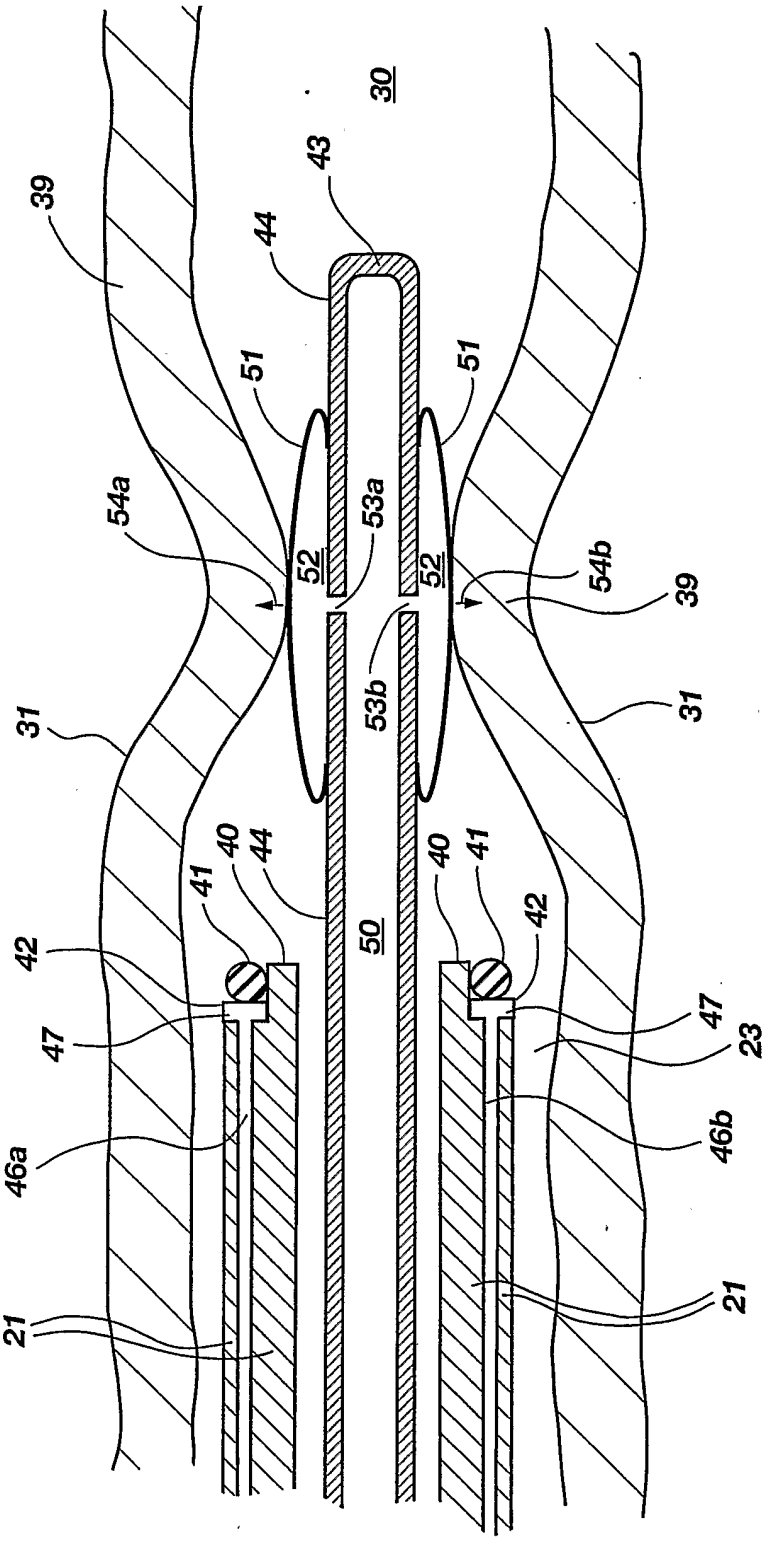
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Fig. 11

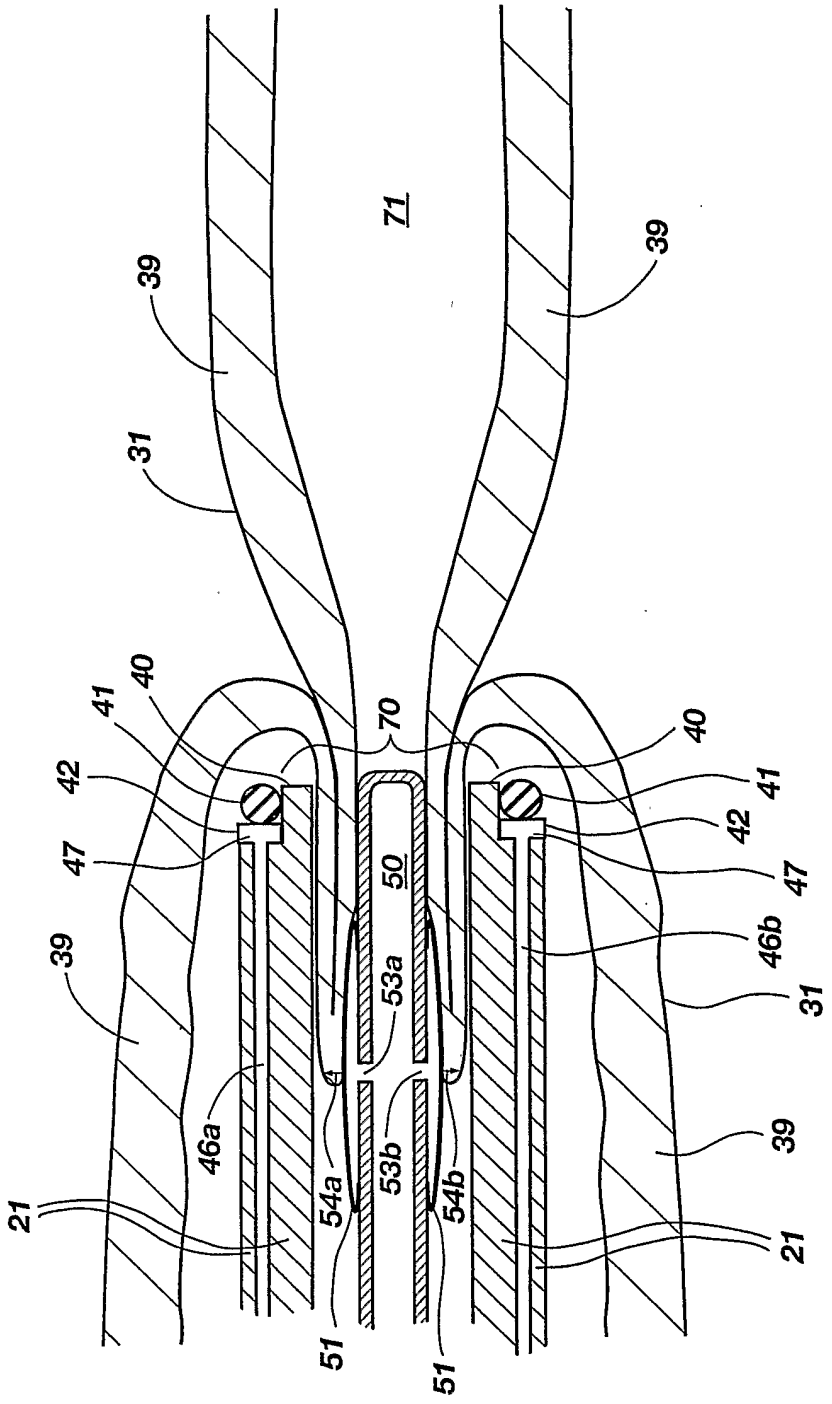
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Fig. 12

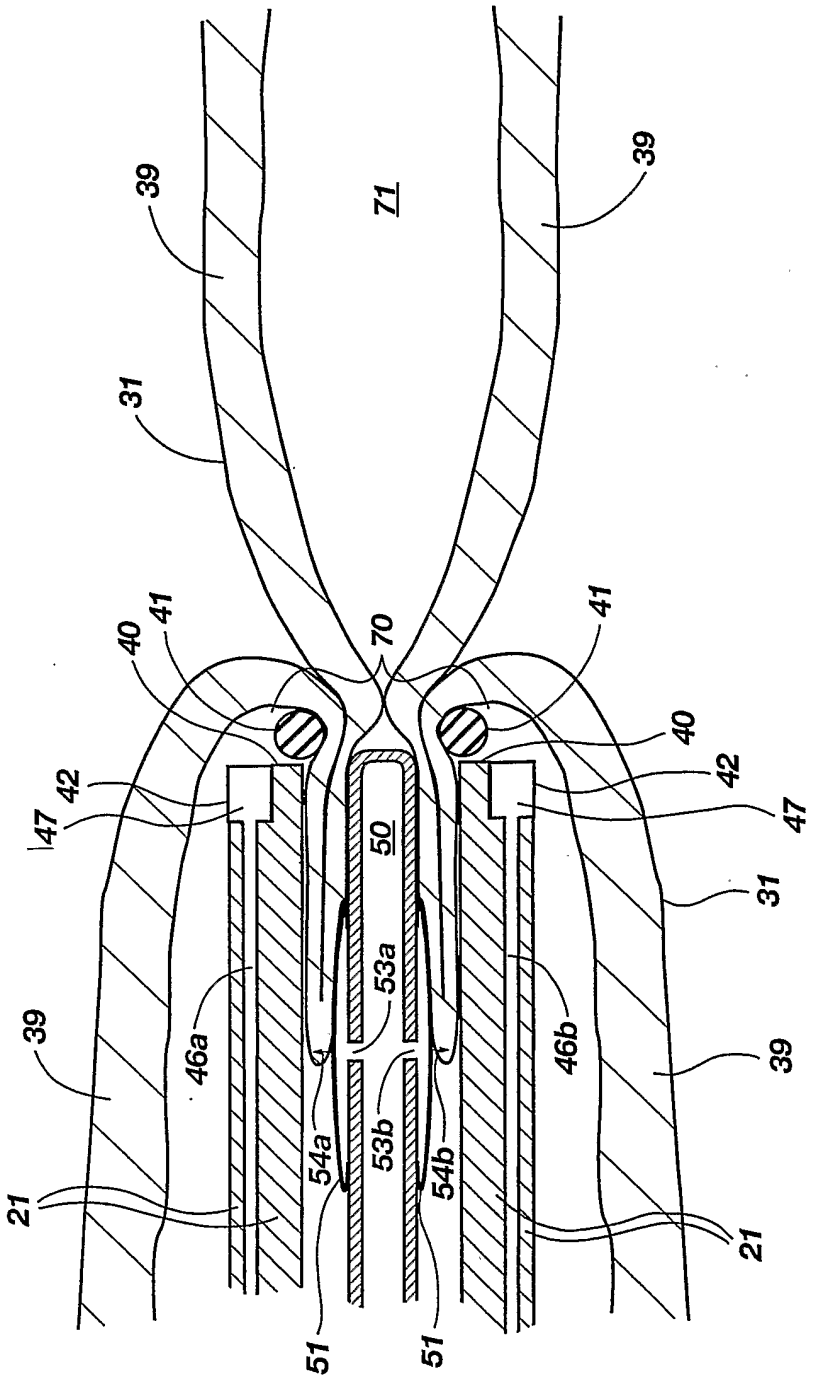
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Fig. 13

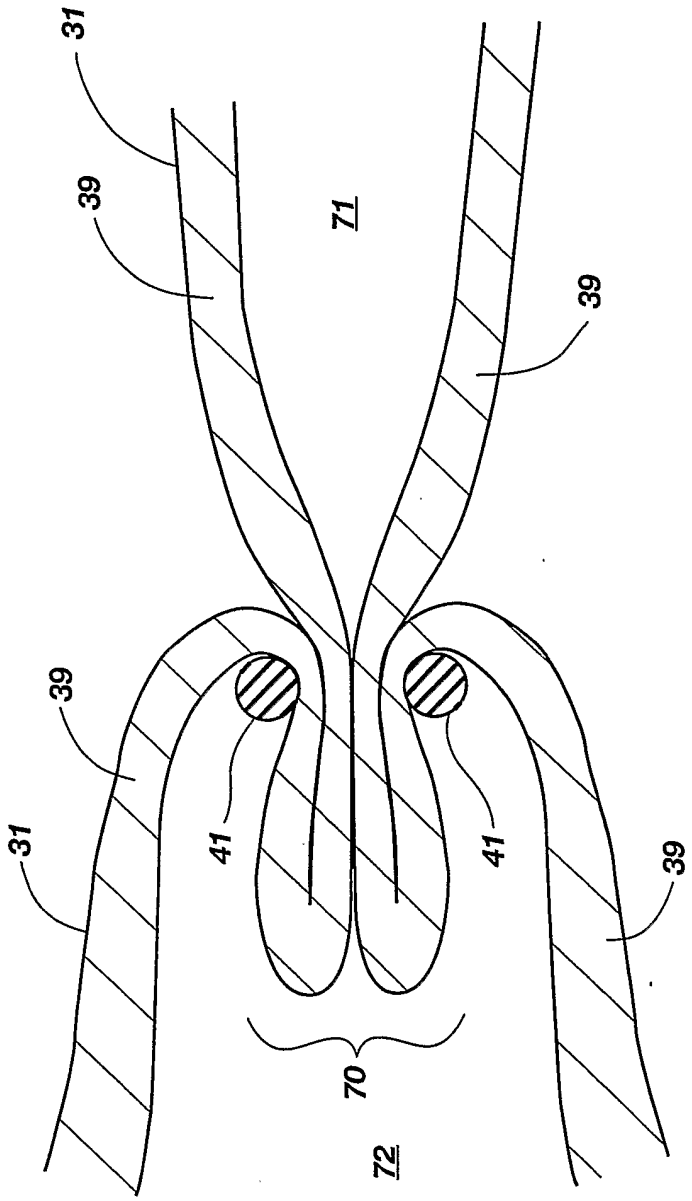

Fig. 14

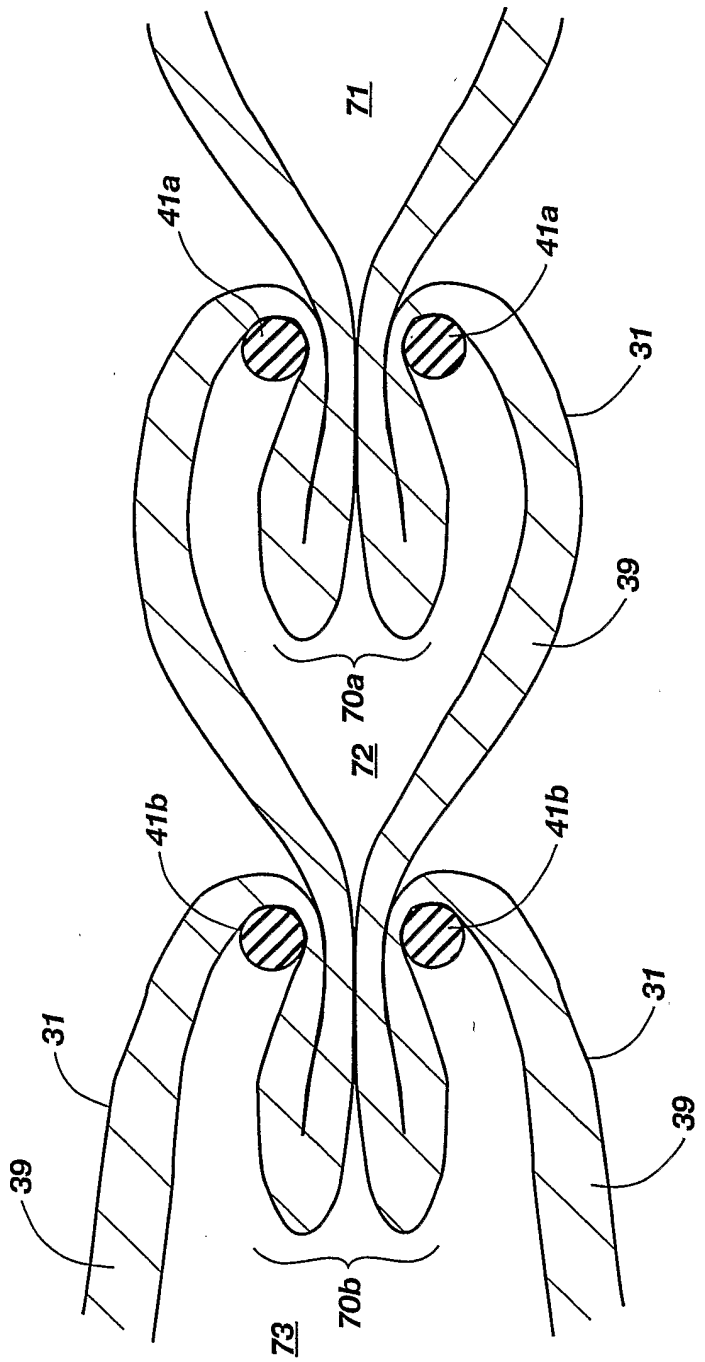

Fig. 15

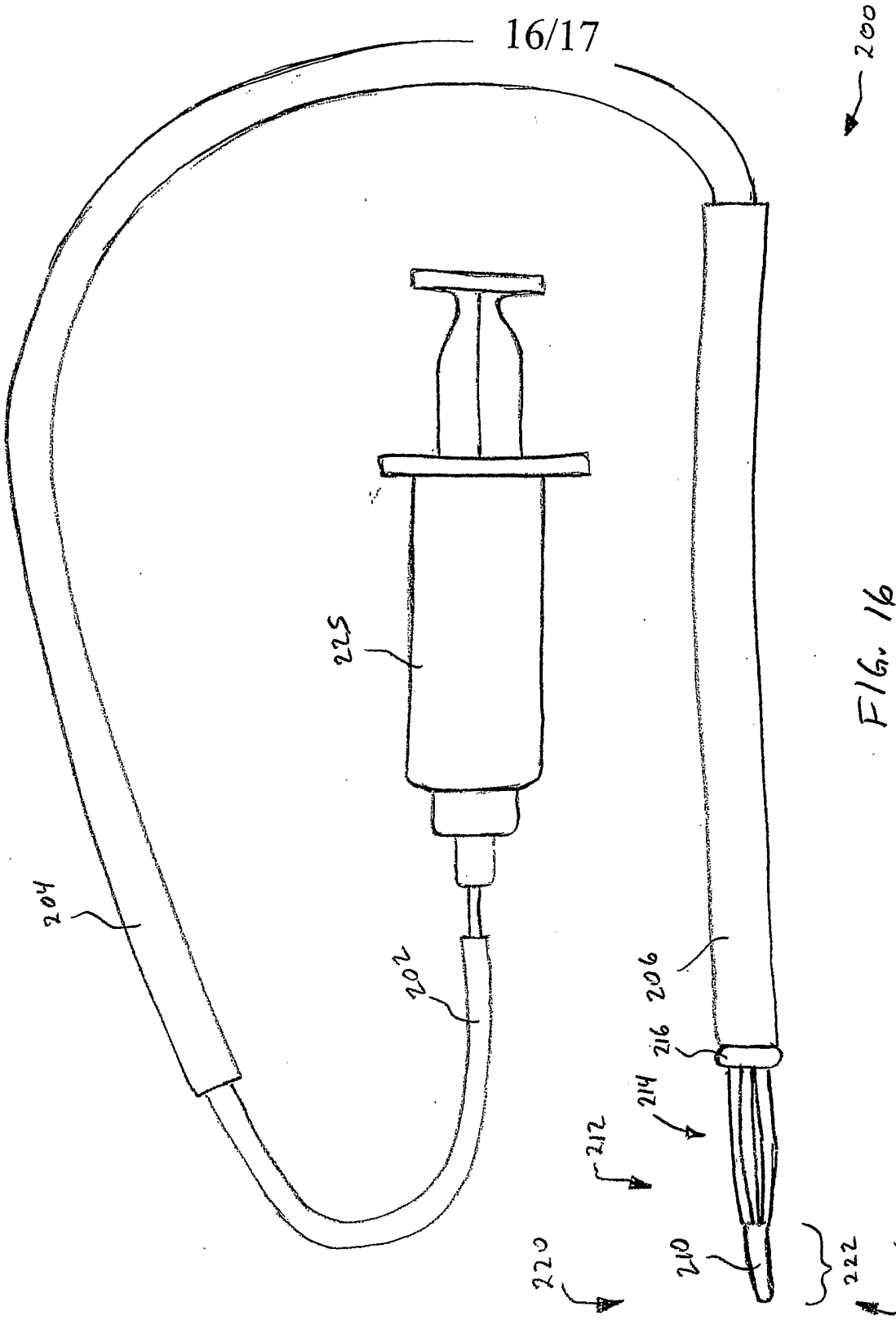

FIG. 16

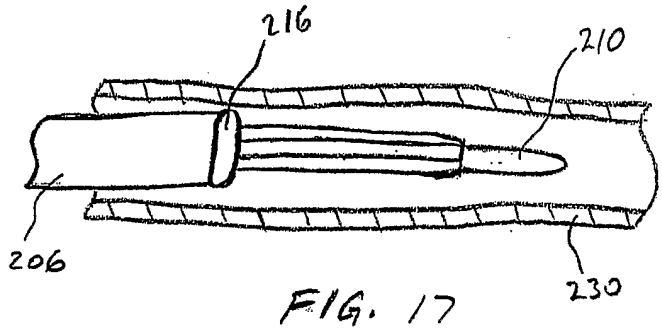

FIG. 17

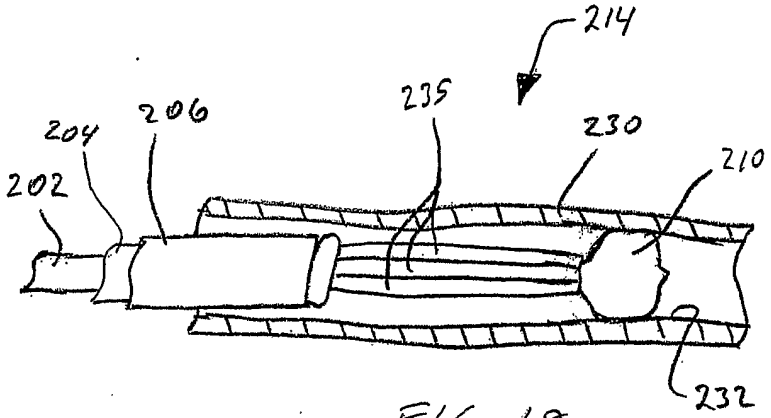

FIG. 18

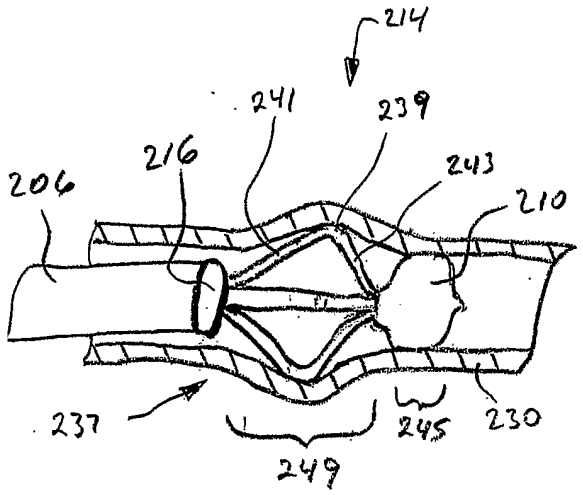

FIG. 19

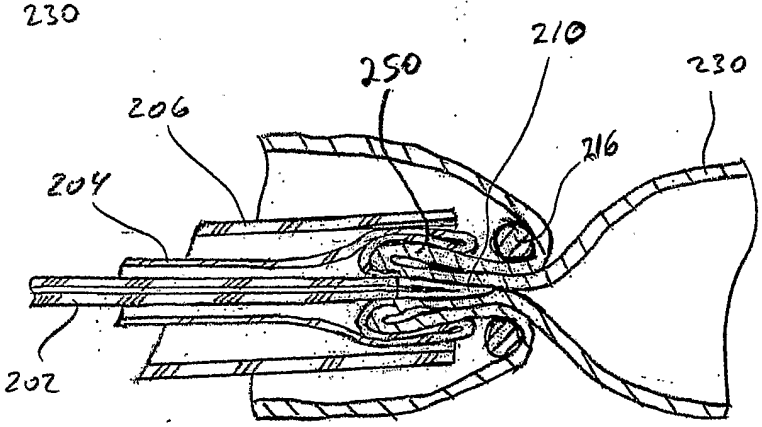

FIG. 20