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(54) **DEVICES AND METHODS FOR TREATING VASCULAR MALFORMATIONS**

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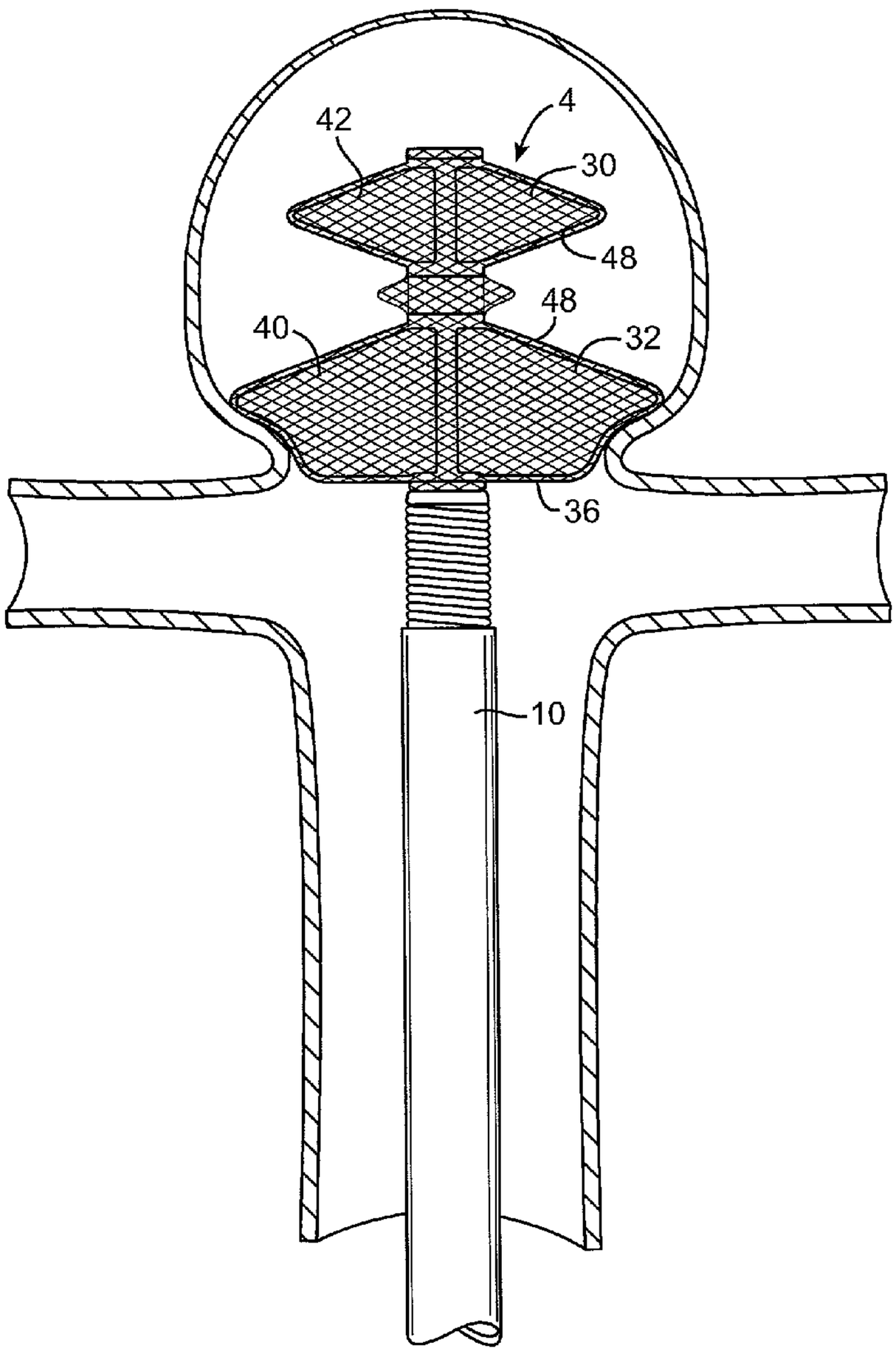
(57) **ABSTRACT**

A system for treating a vascular malformation has an expandable device and a heating device for heating and shrinking the malformation. The expandable device may have deformable elements which plastically deform in the expanded position. The balloon may be self-expanding, balloon expanded or expanded with an actuating rod. A fluid, such as saline, may be introduced during heating when using RF heating. A sealant may also be introduced into the expandable device to further seal the aneurysm.



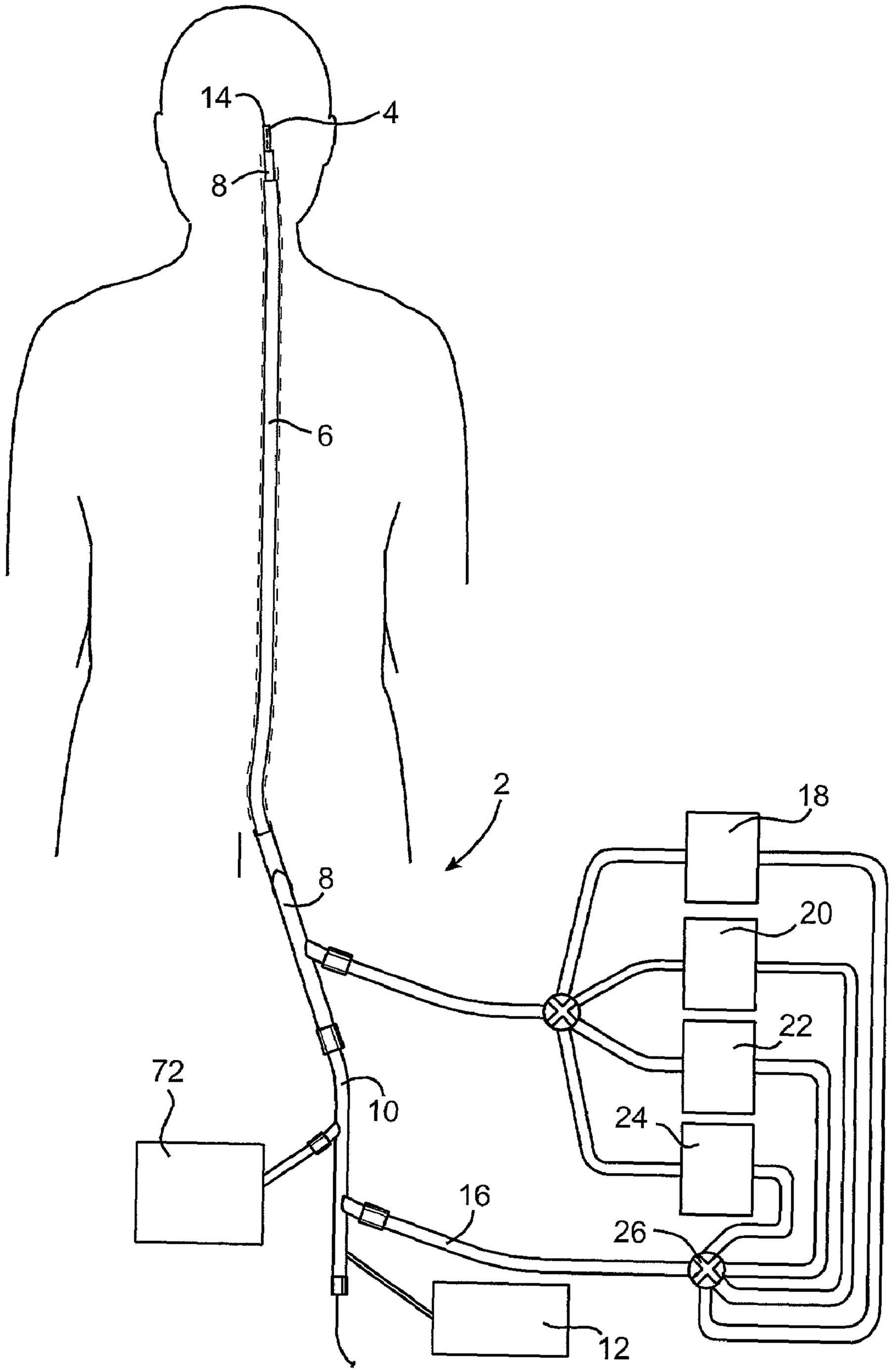


FIG. 1

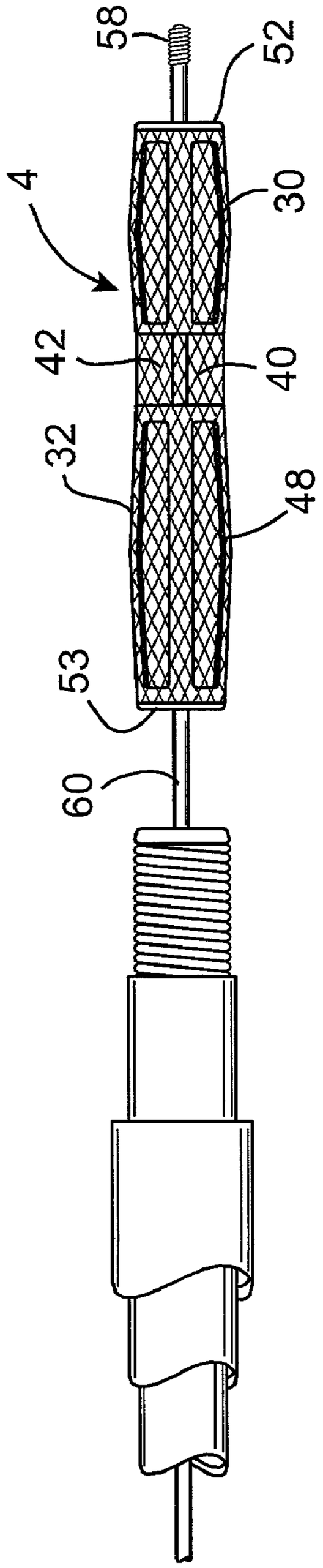


FIG. 2

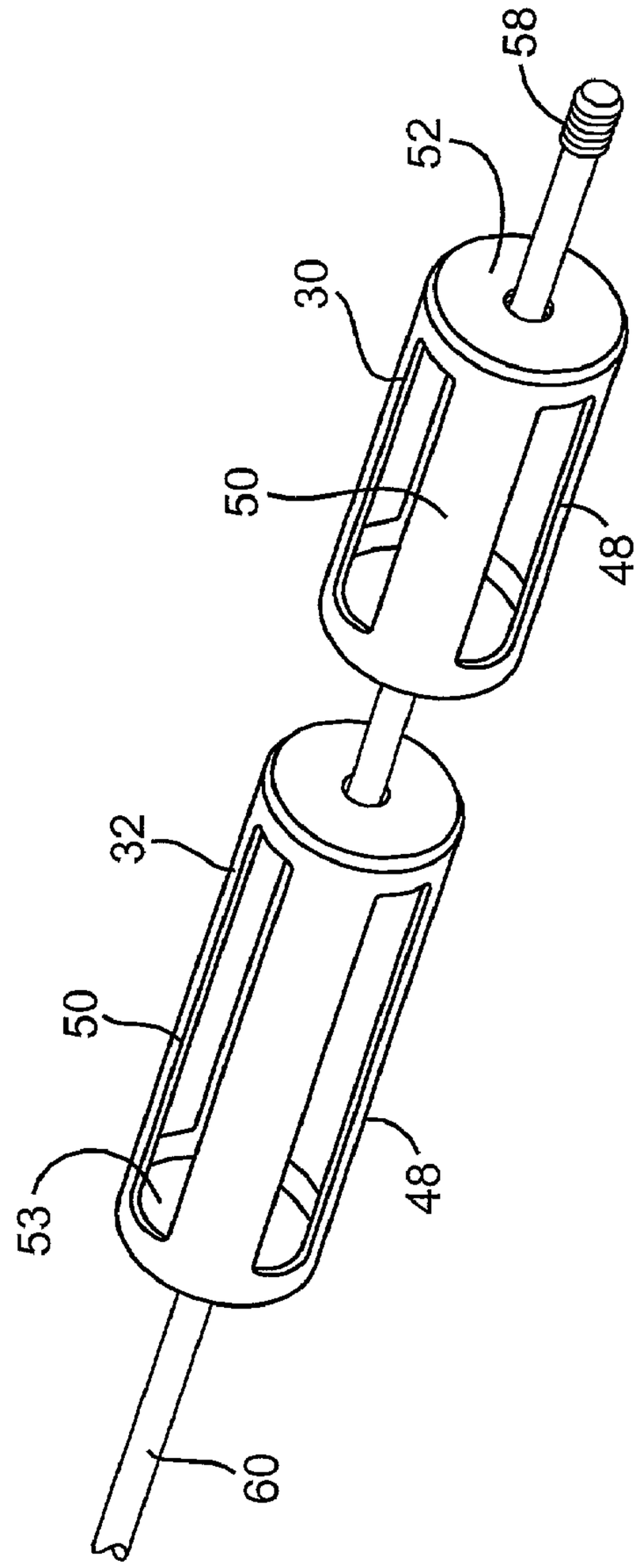
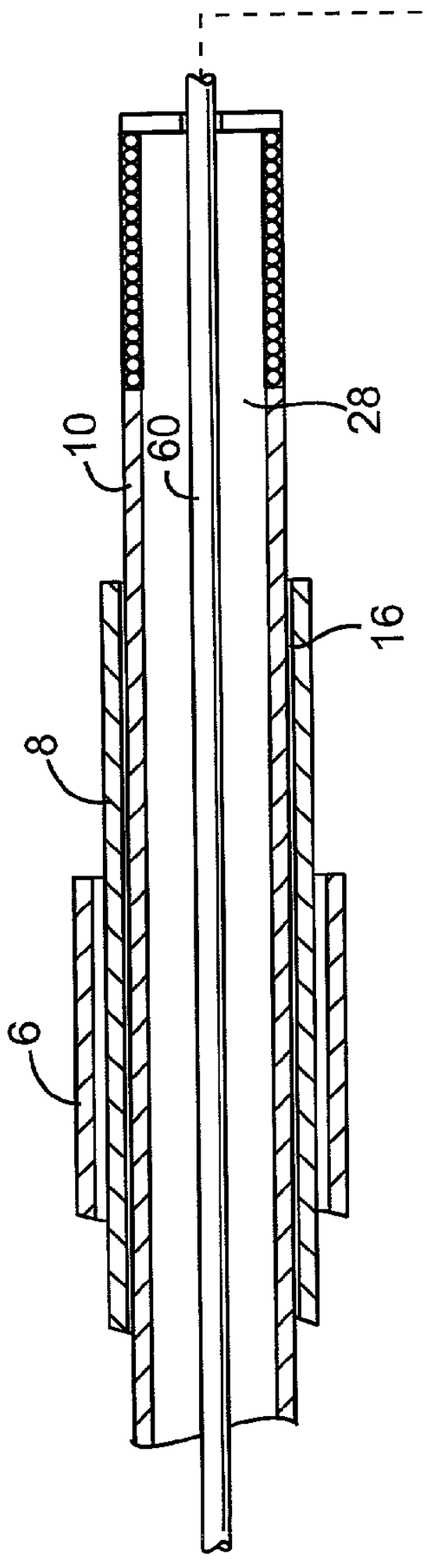
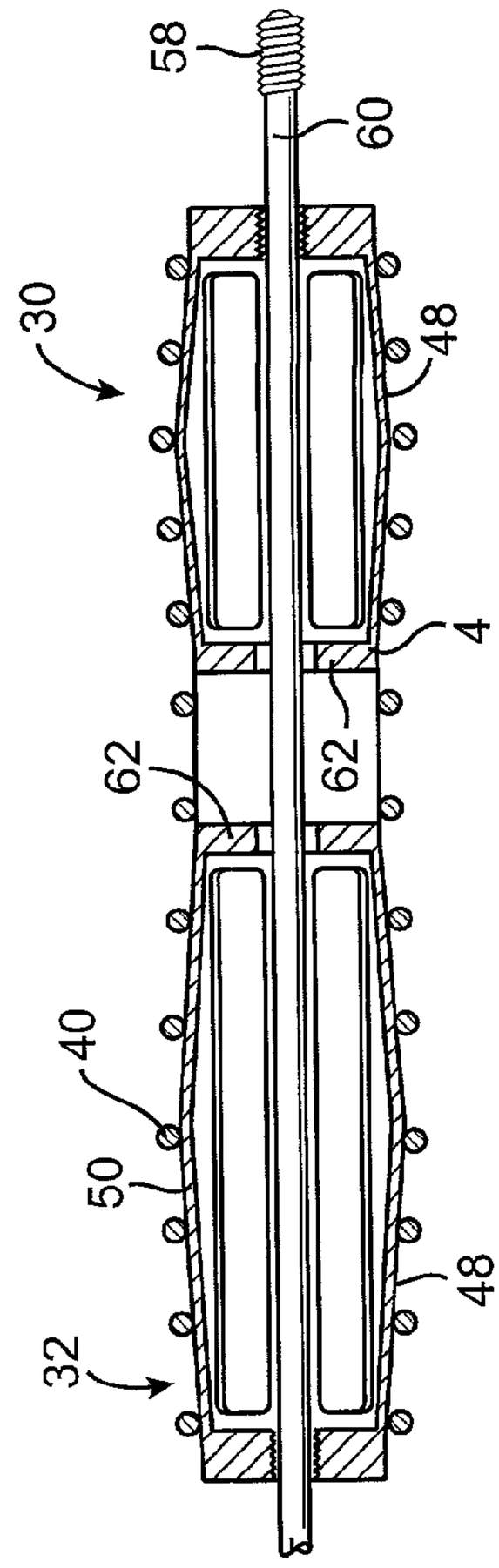


FIG. 3





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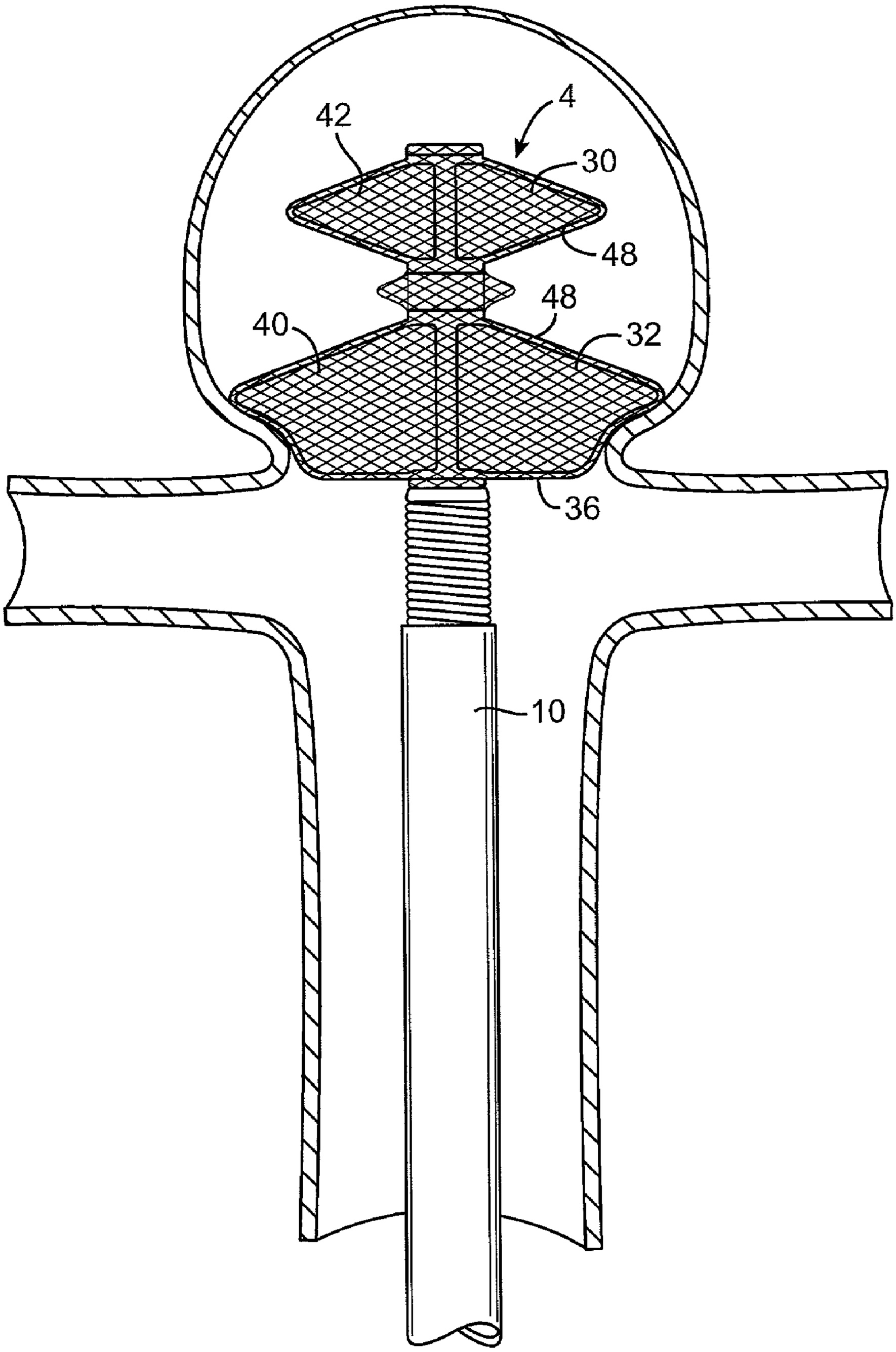

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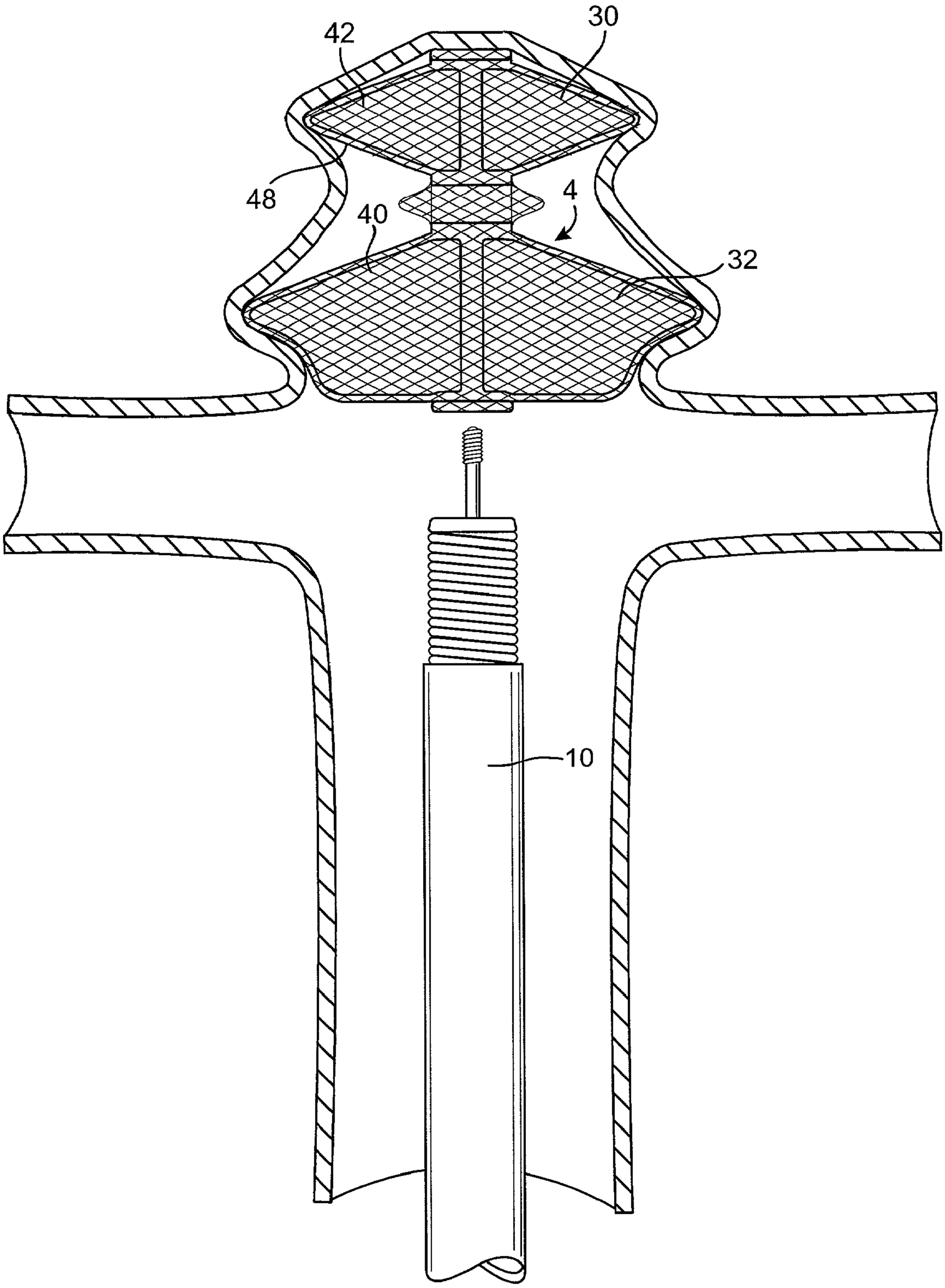

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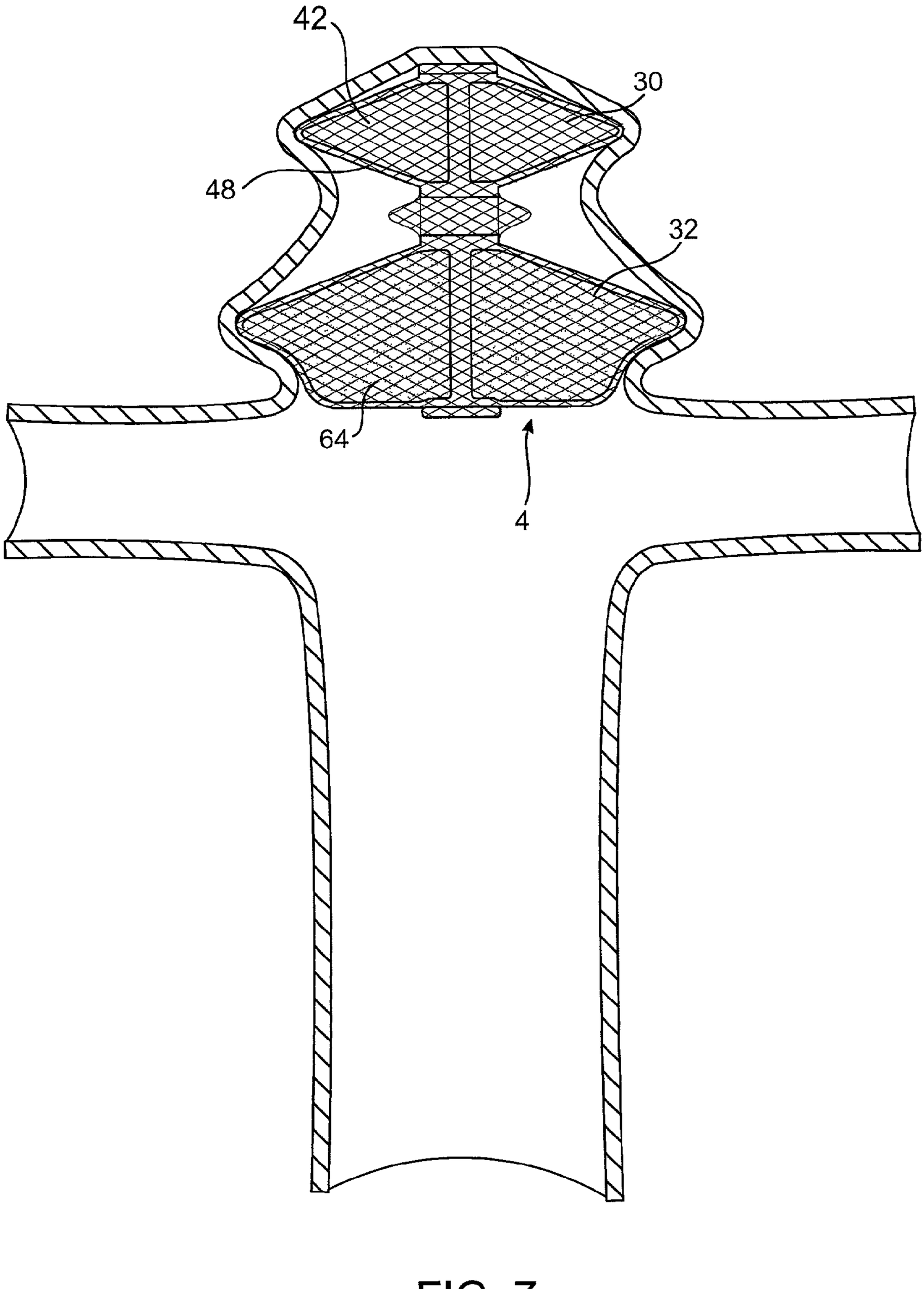
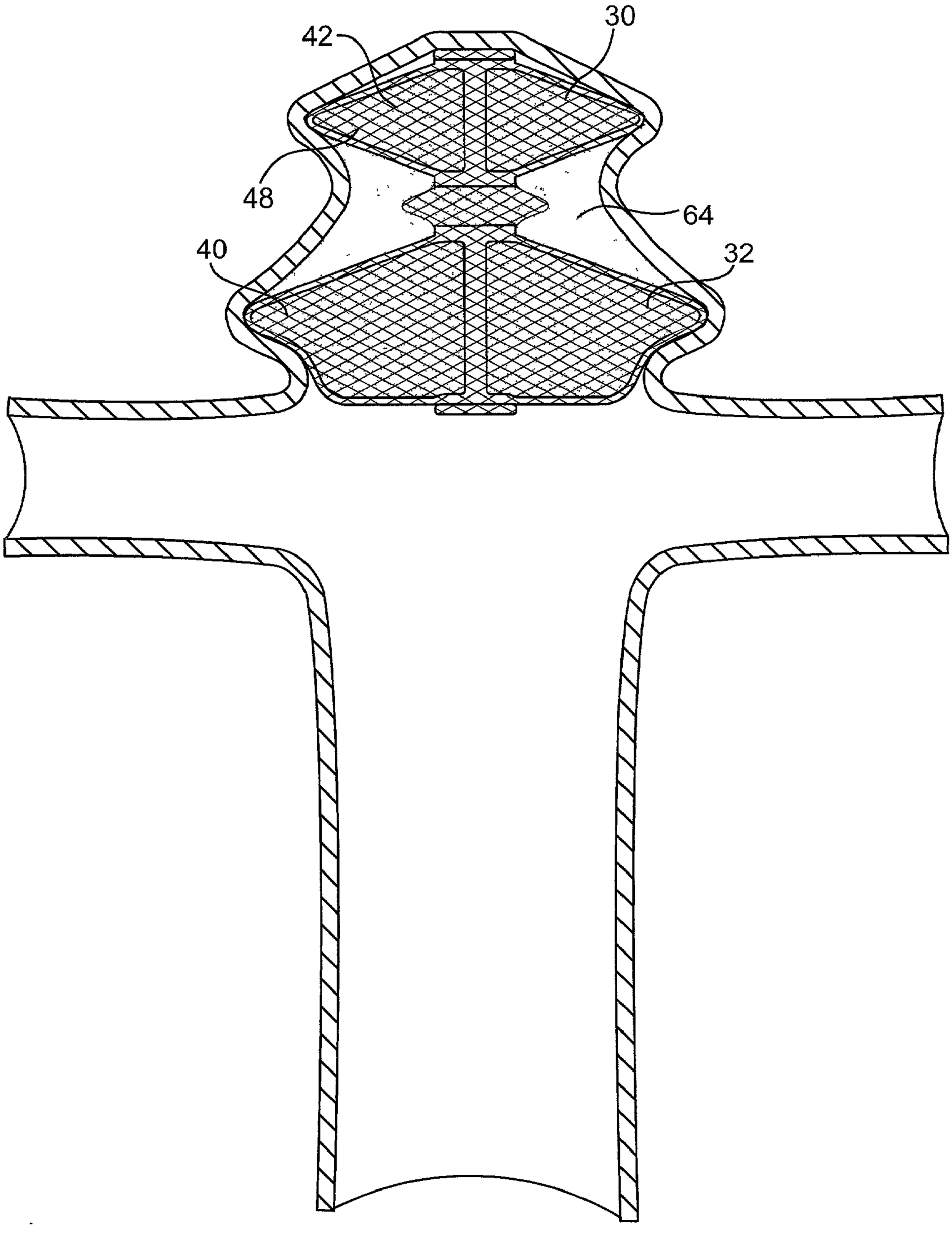


FIG. 7



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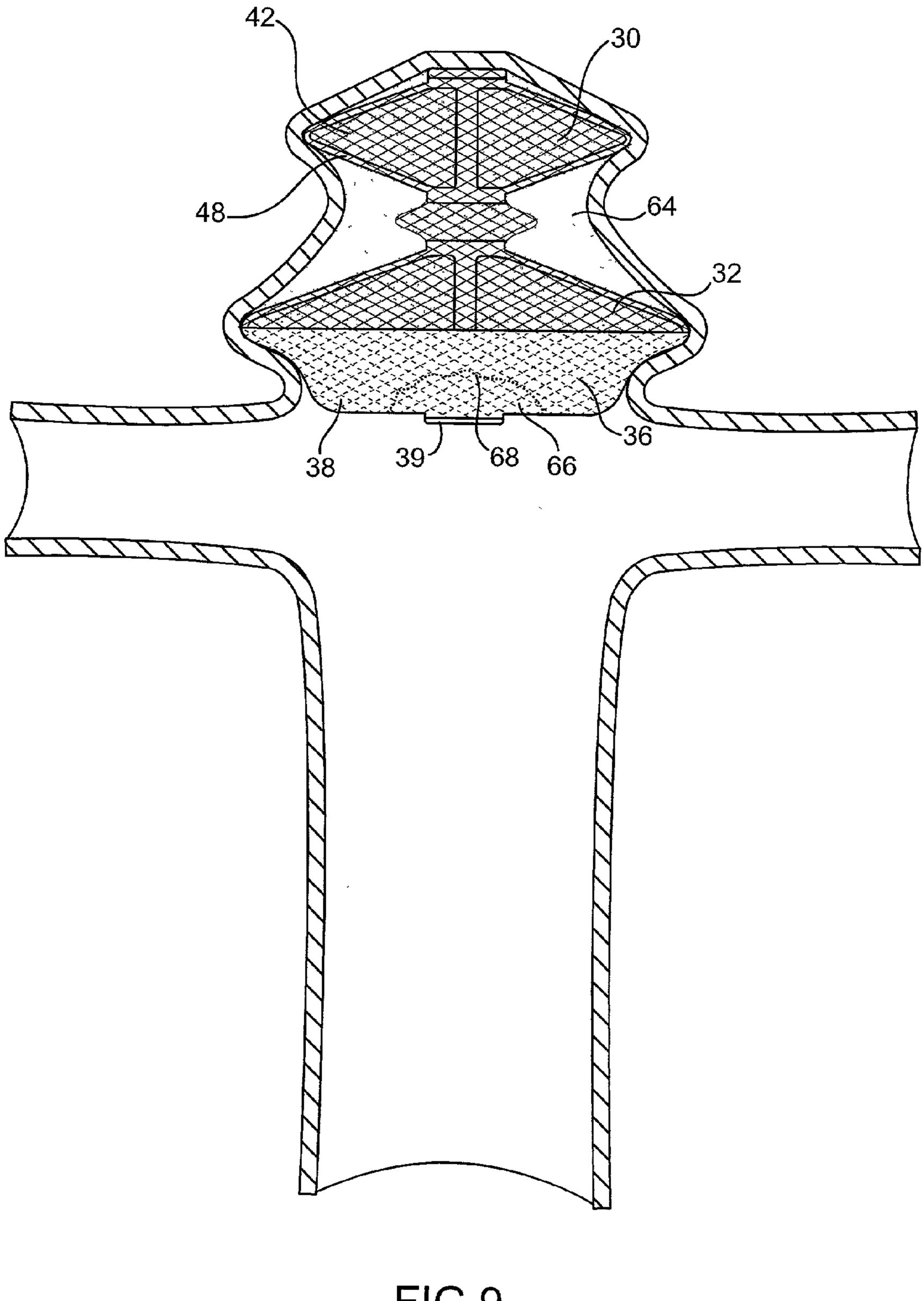

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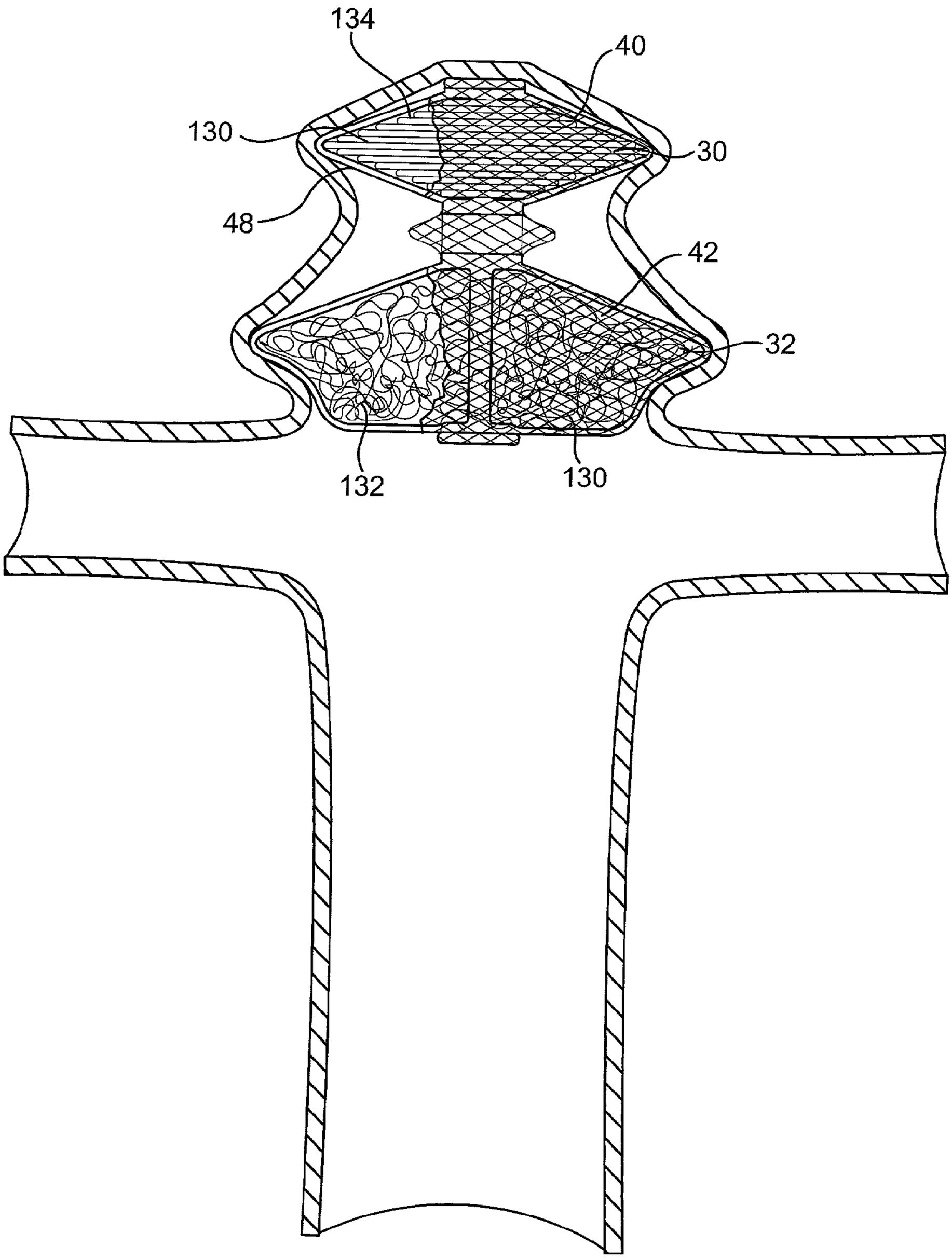
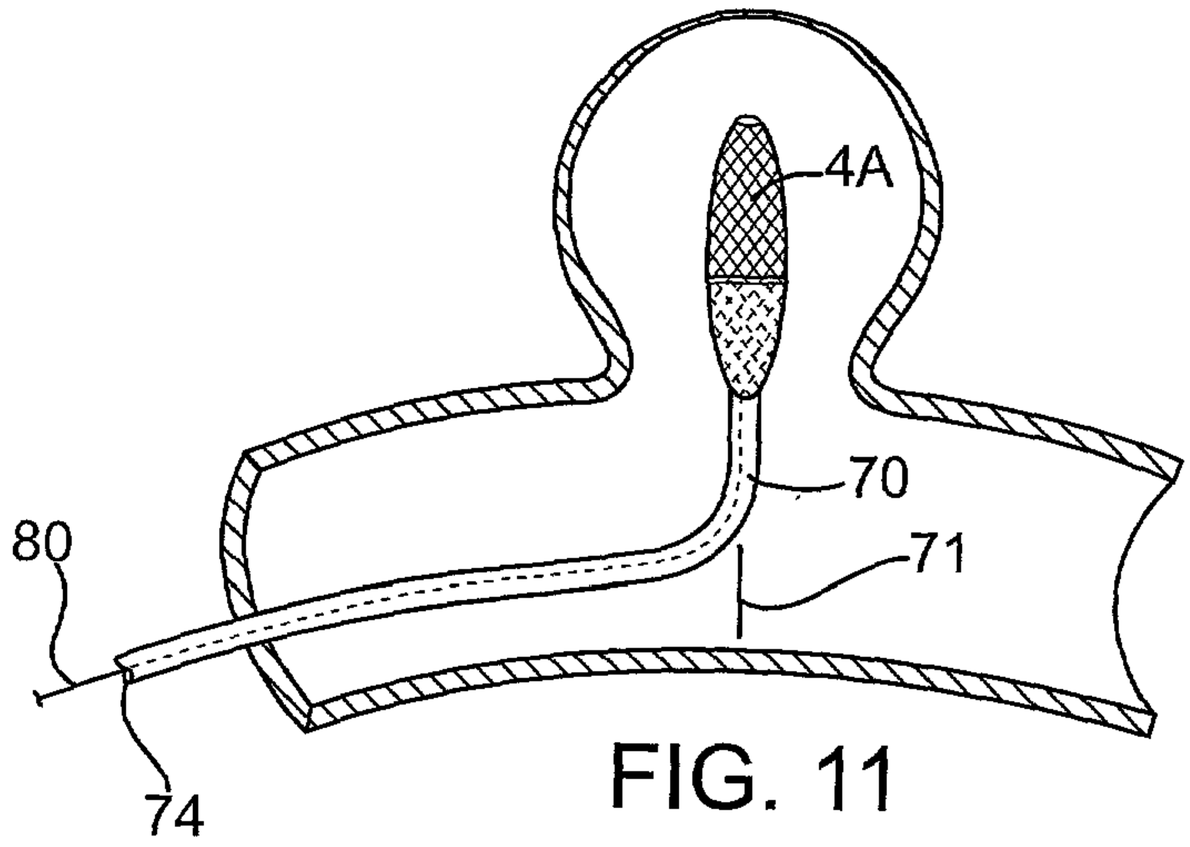


FIG. 10



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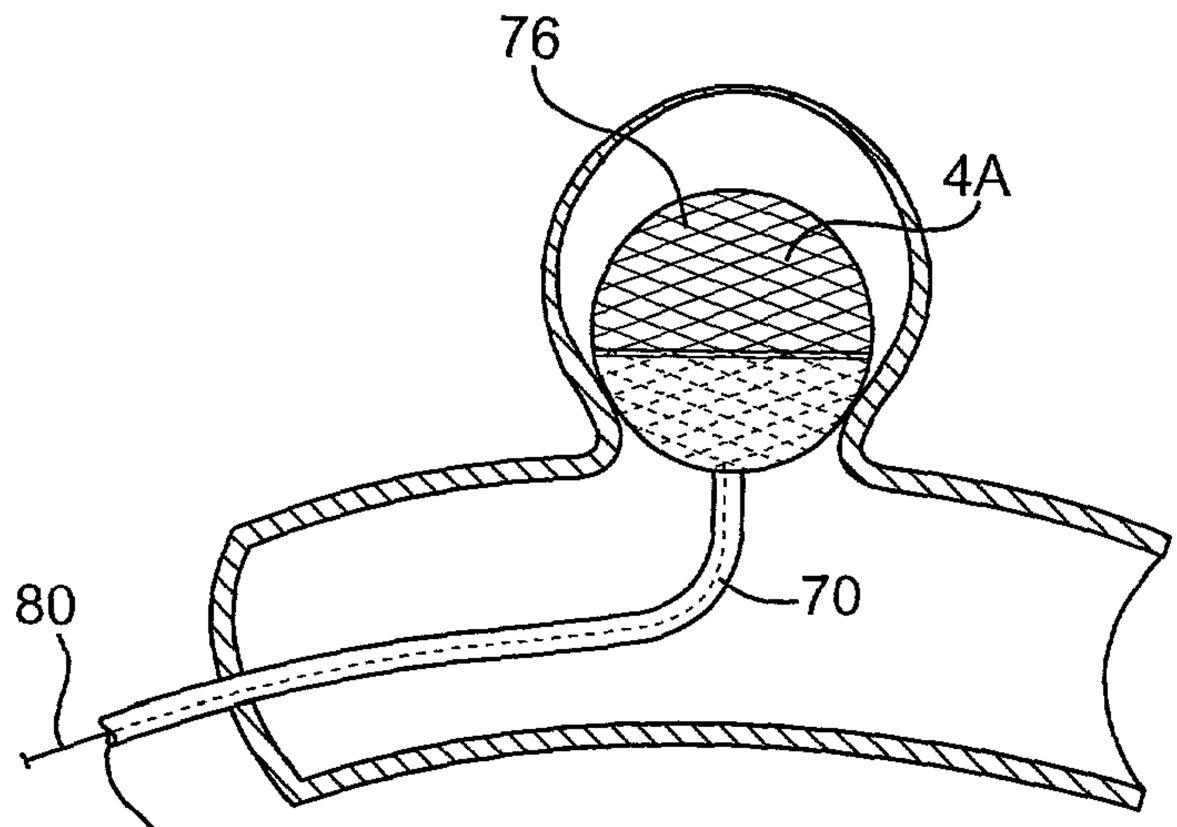

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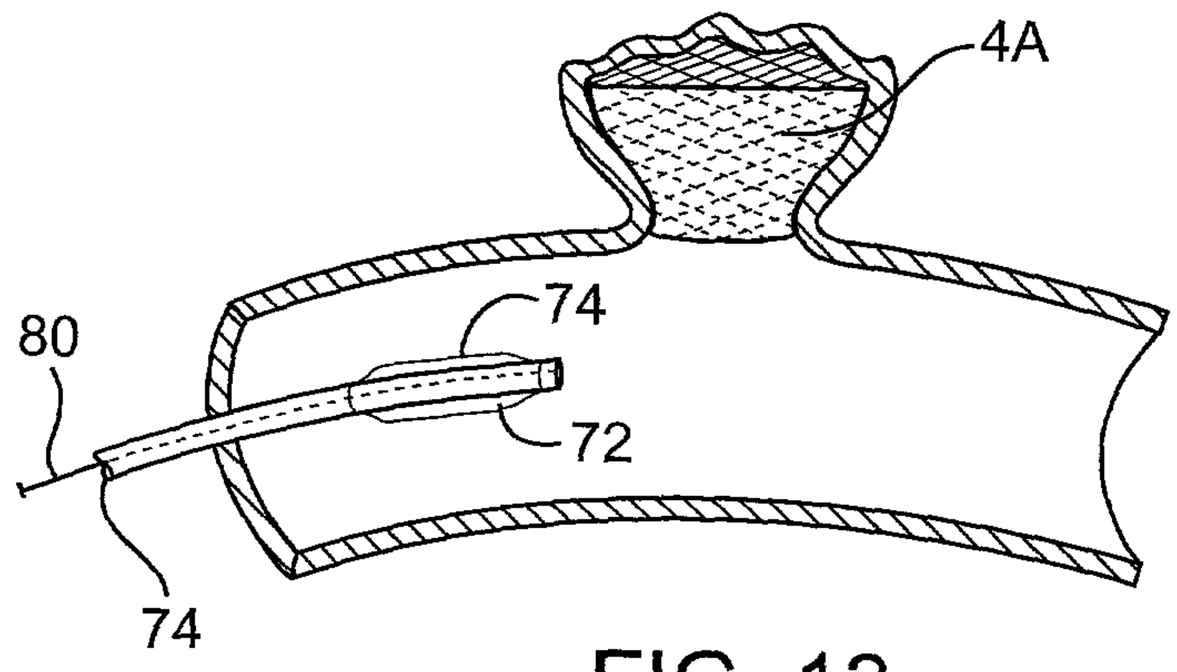
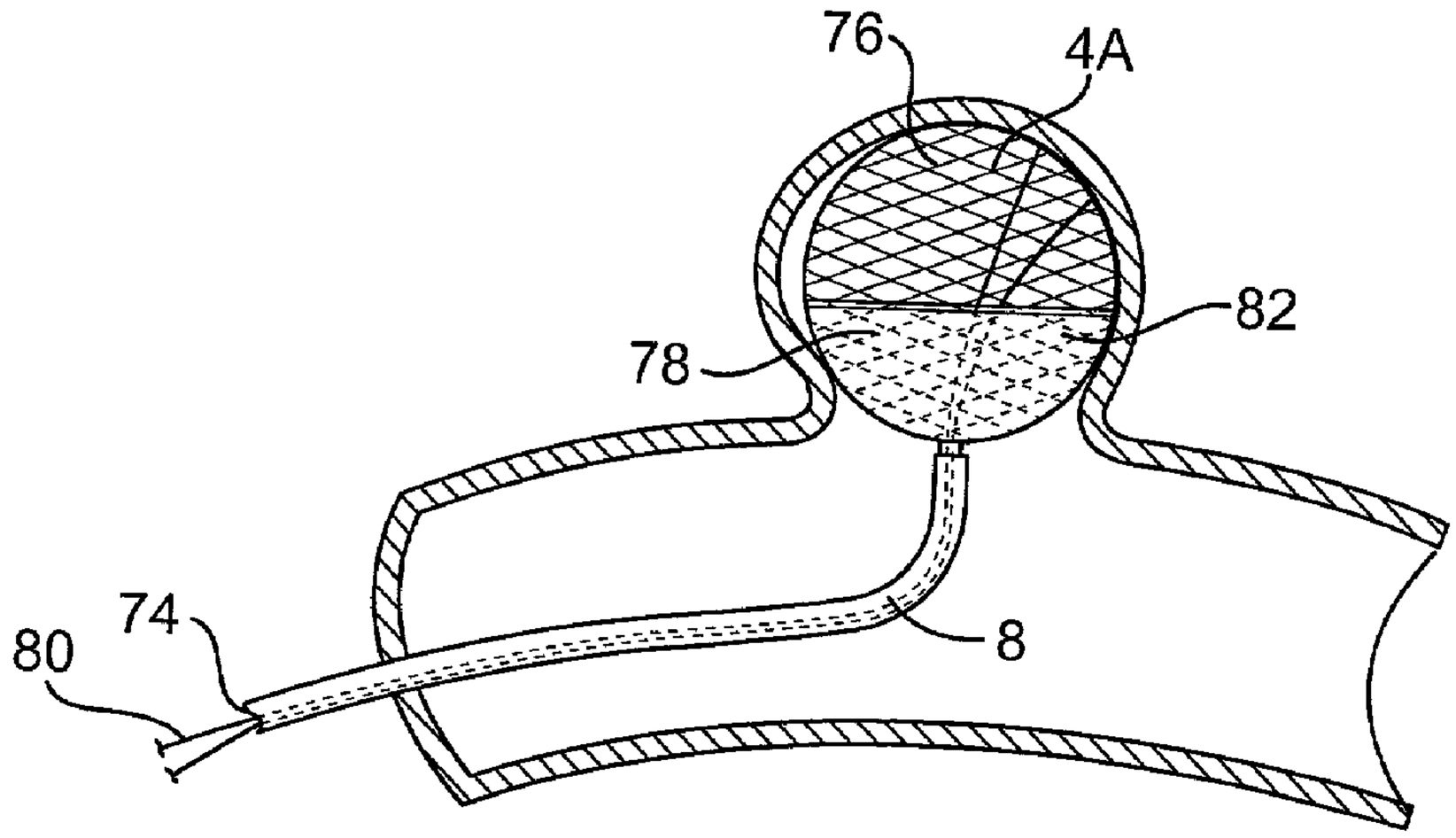


FIG. 13



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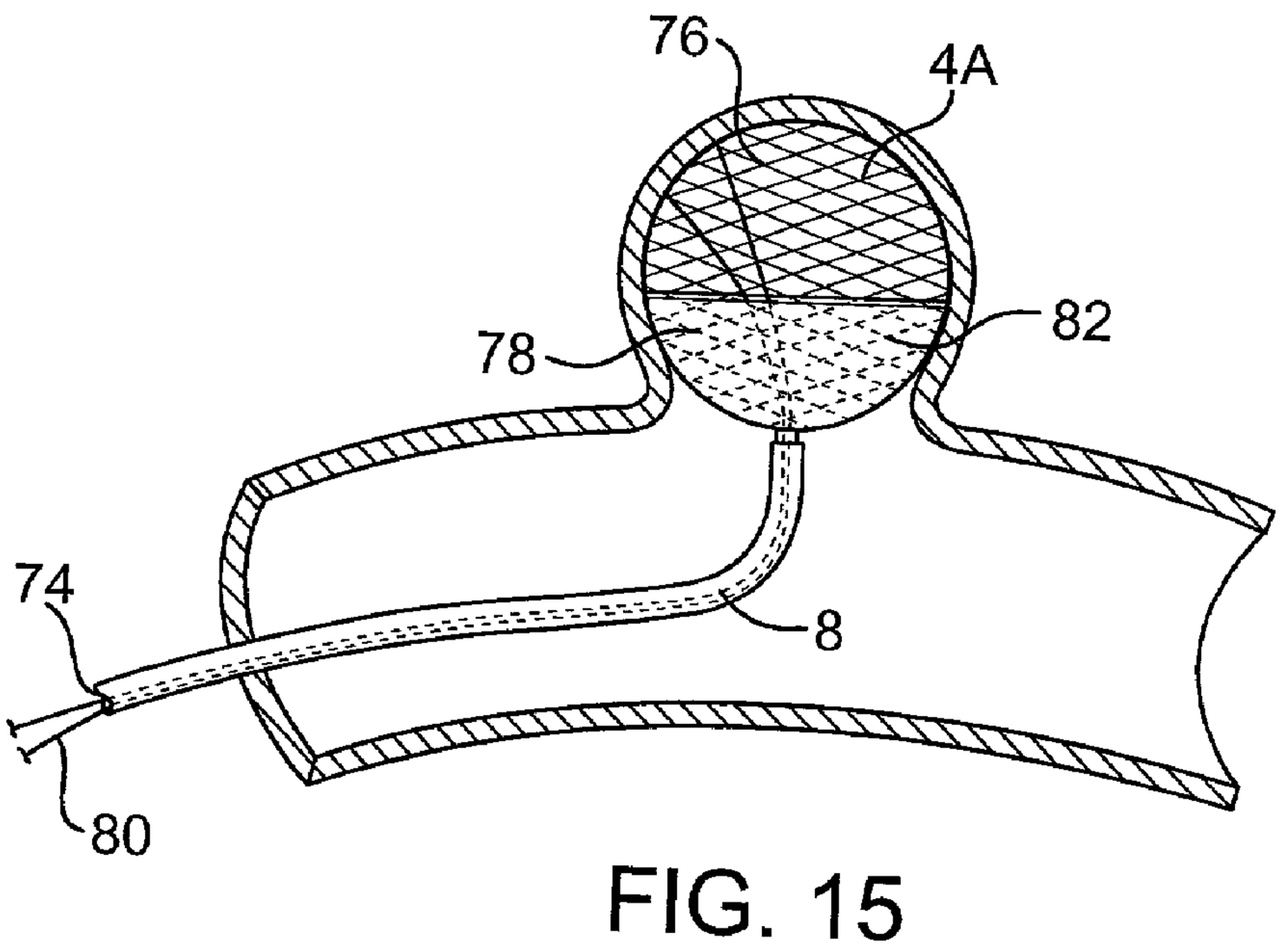

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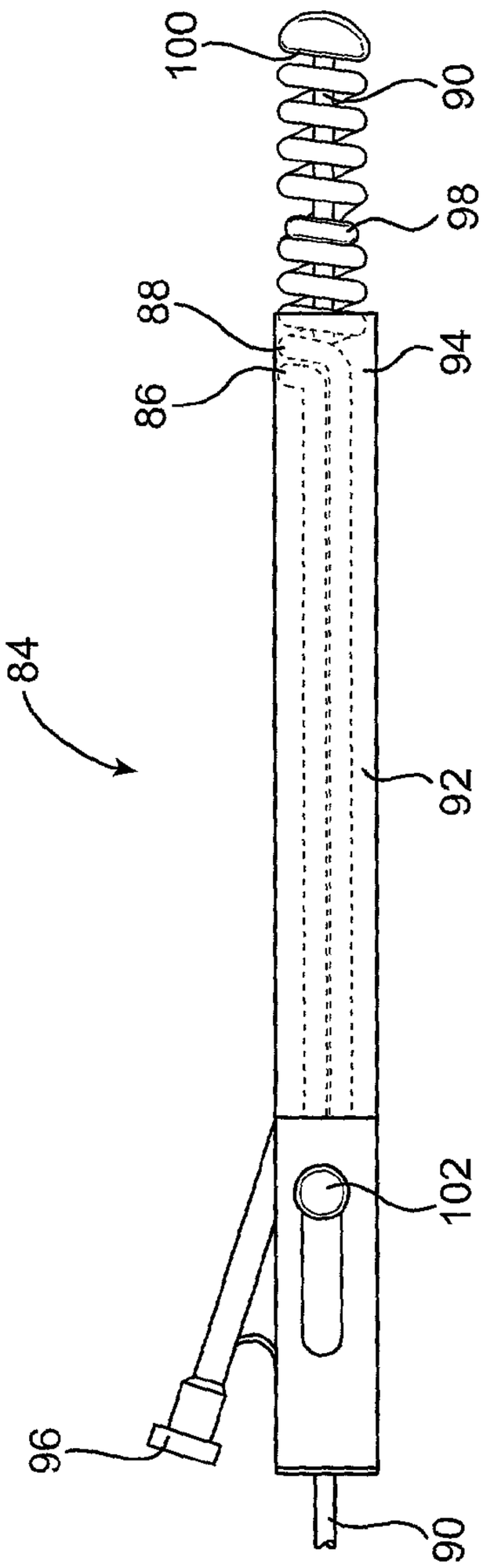

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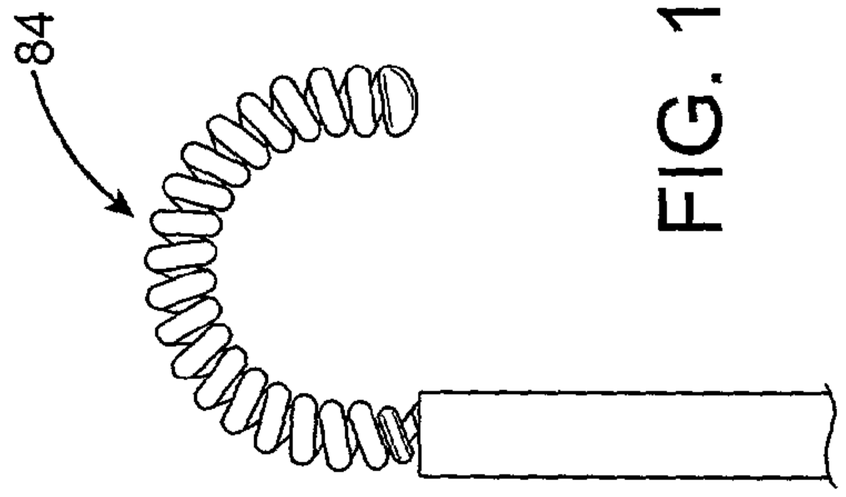

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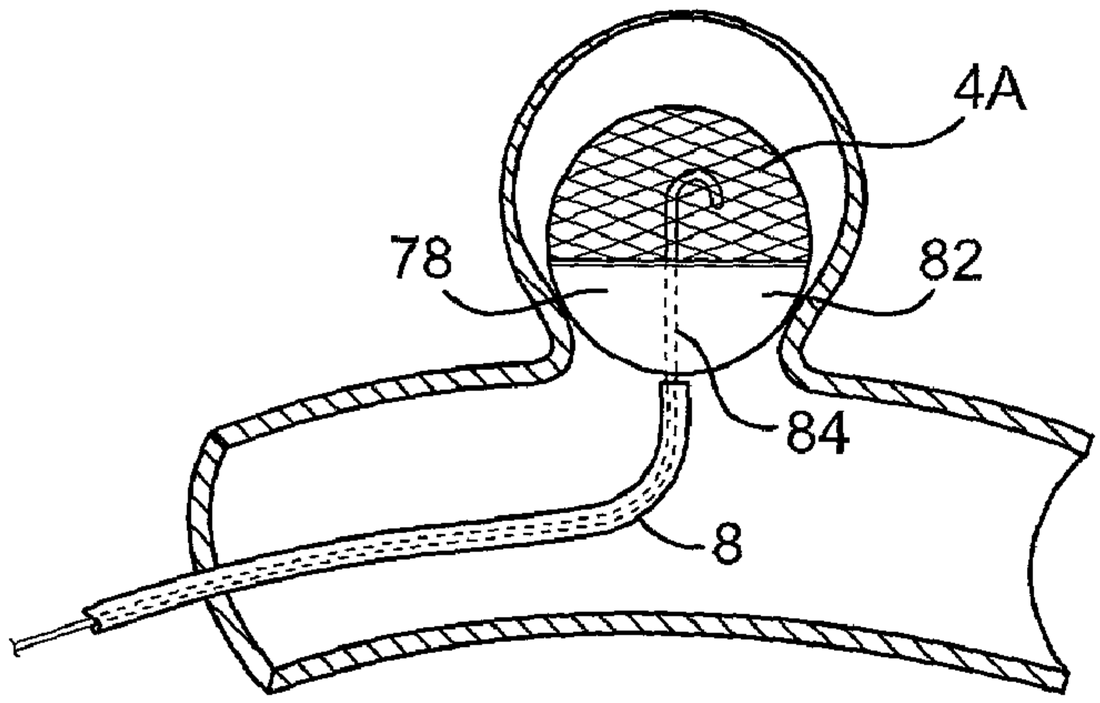

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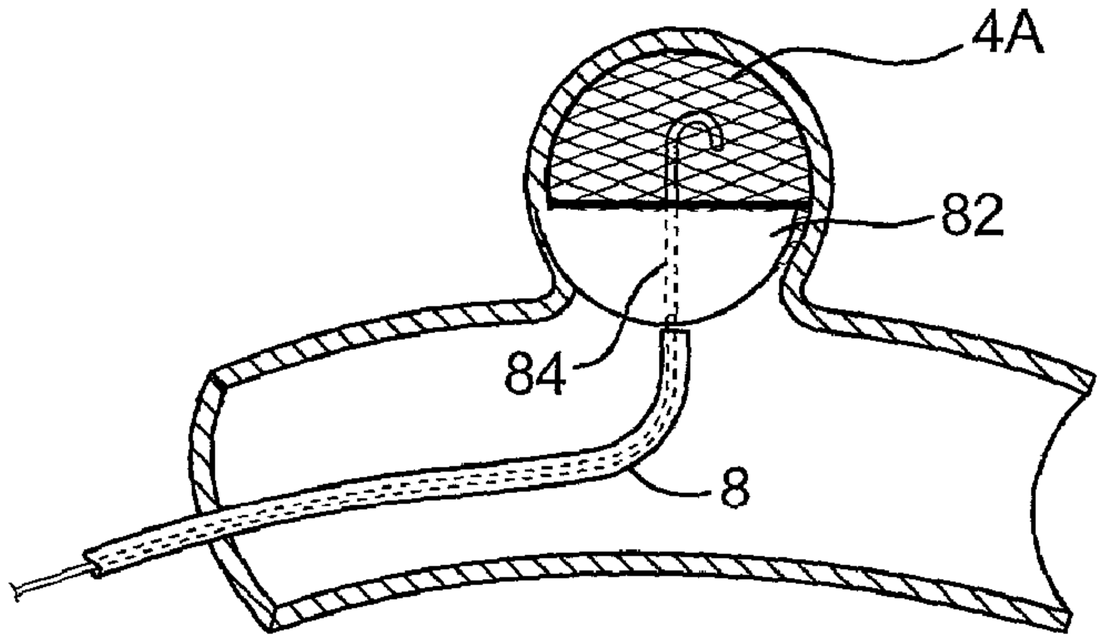

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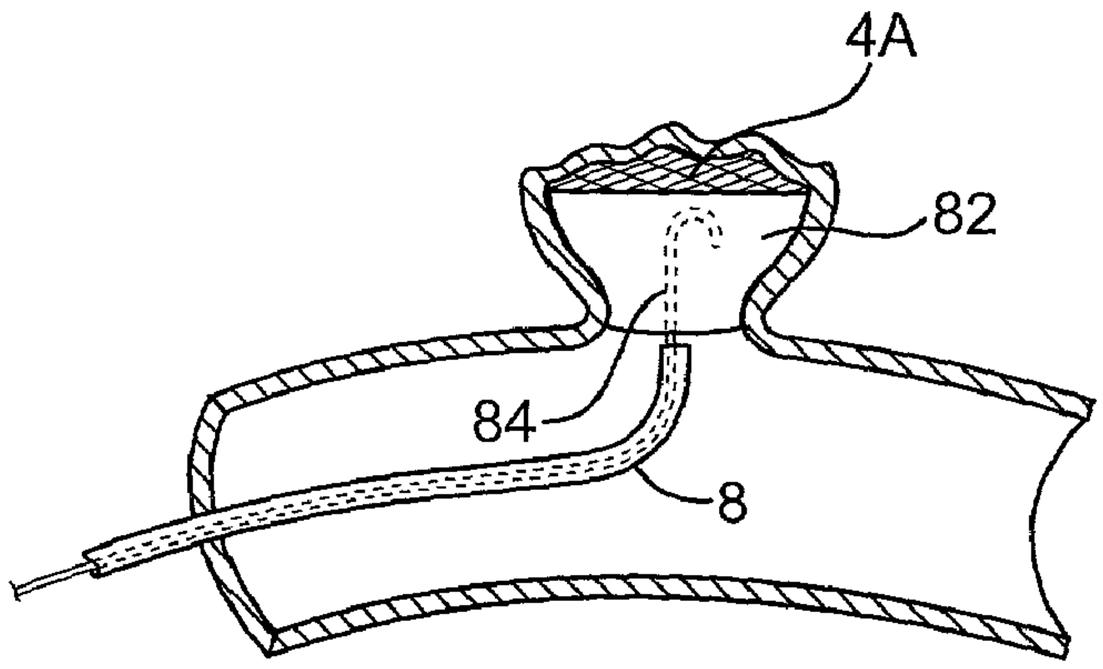

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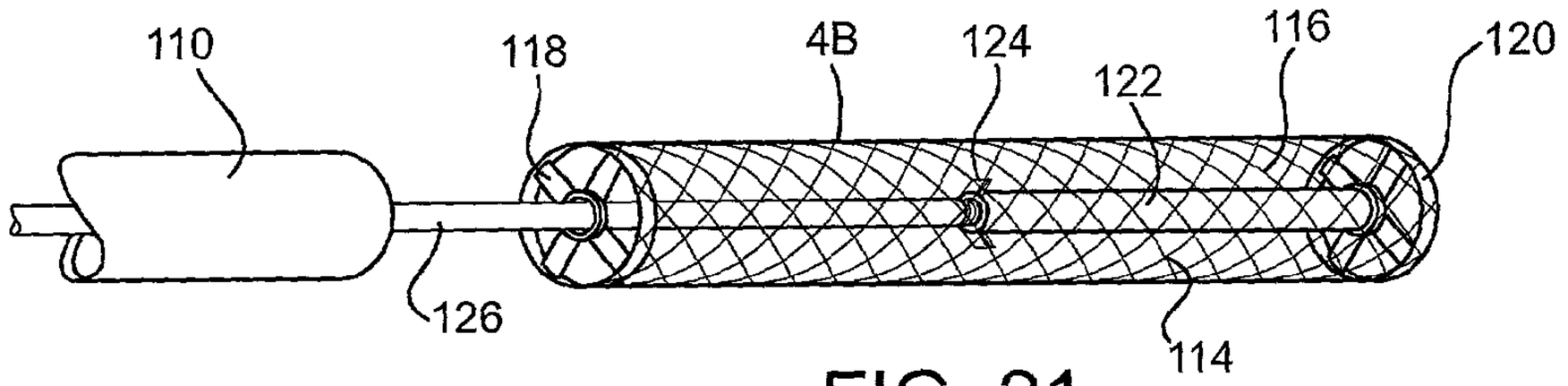

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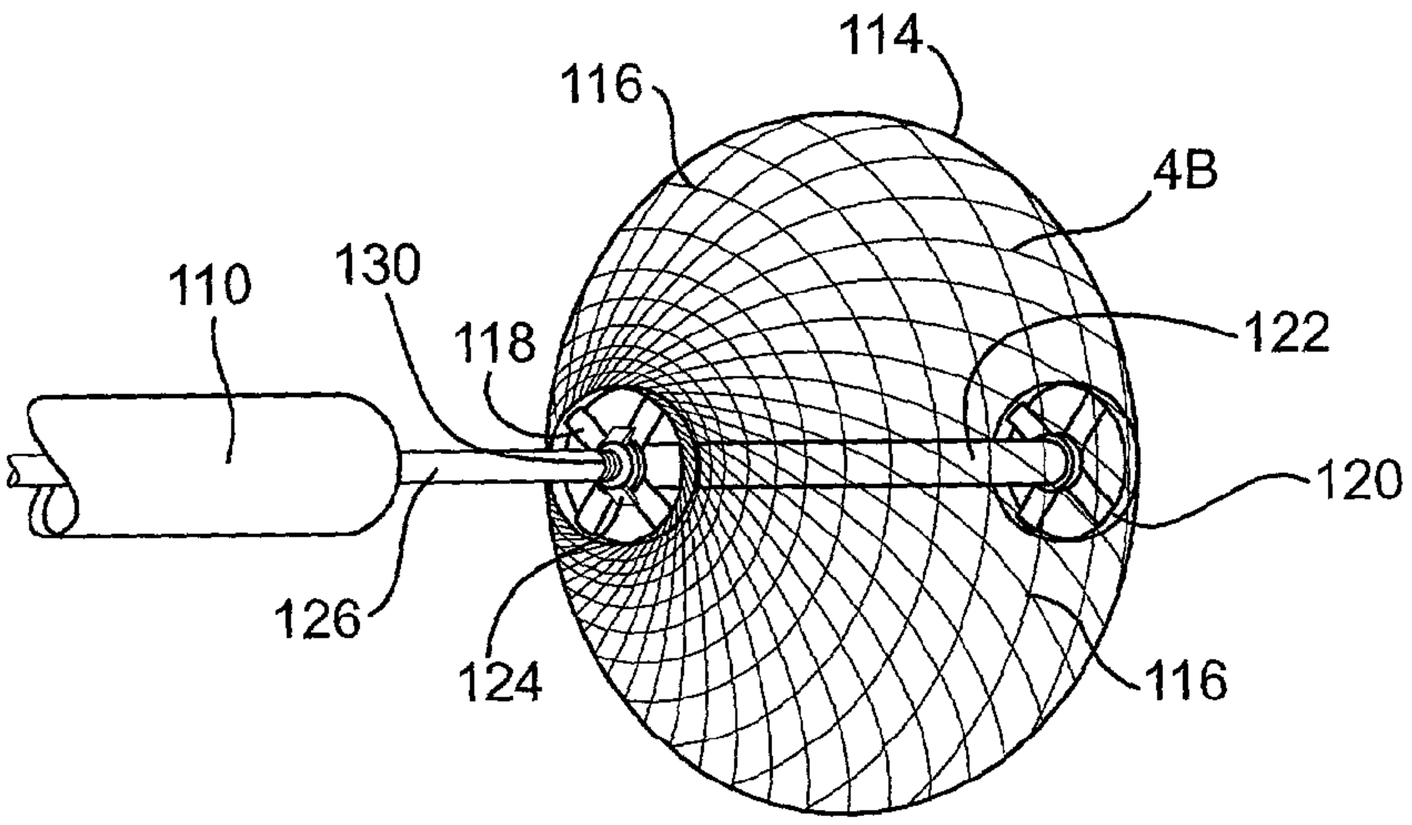

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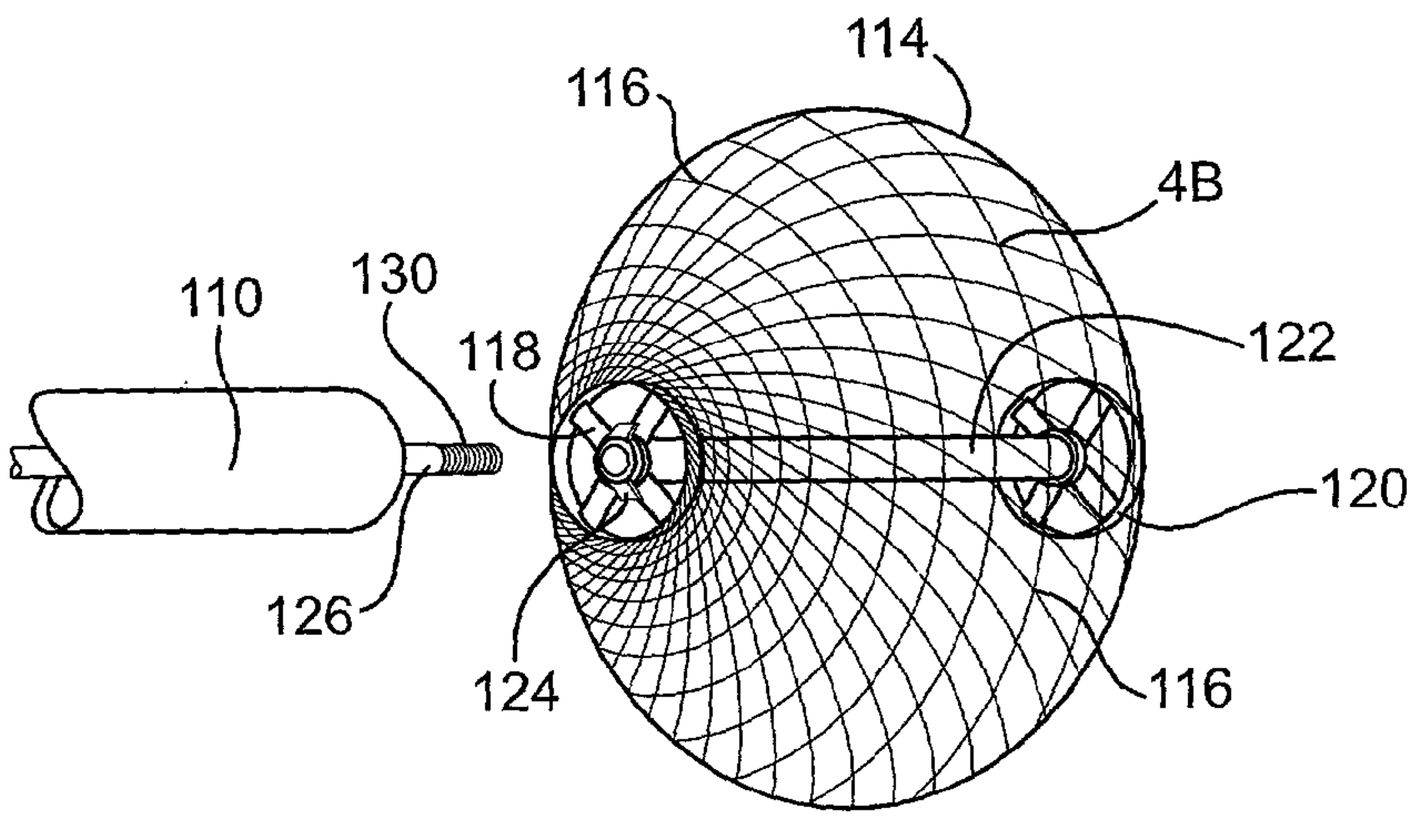

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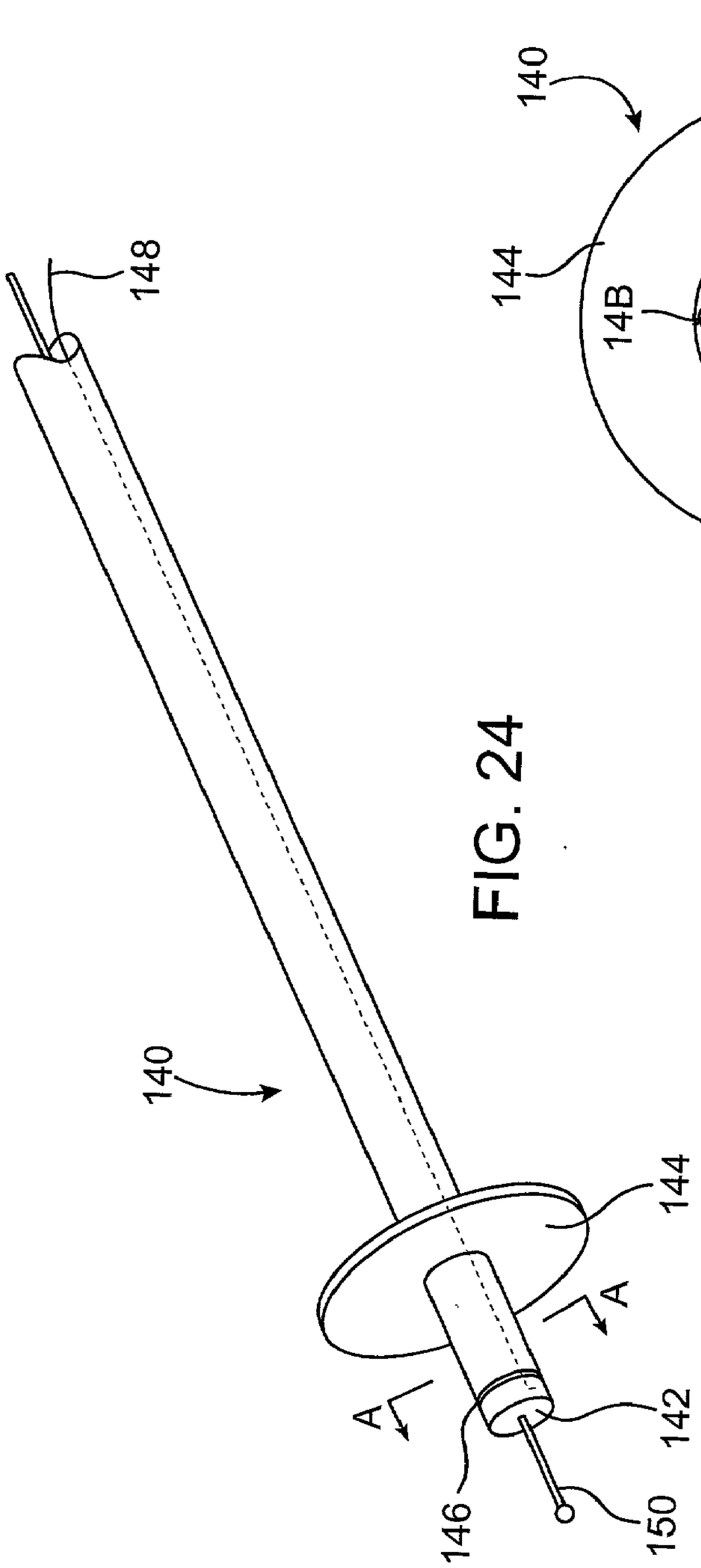

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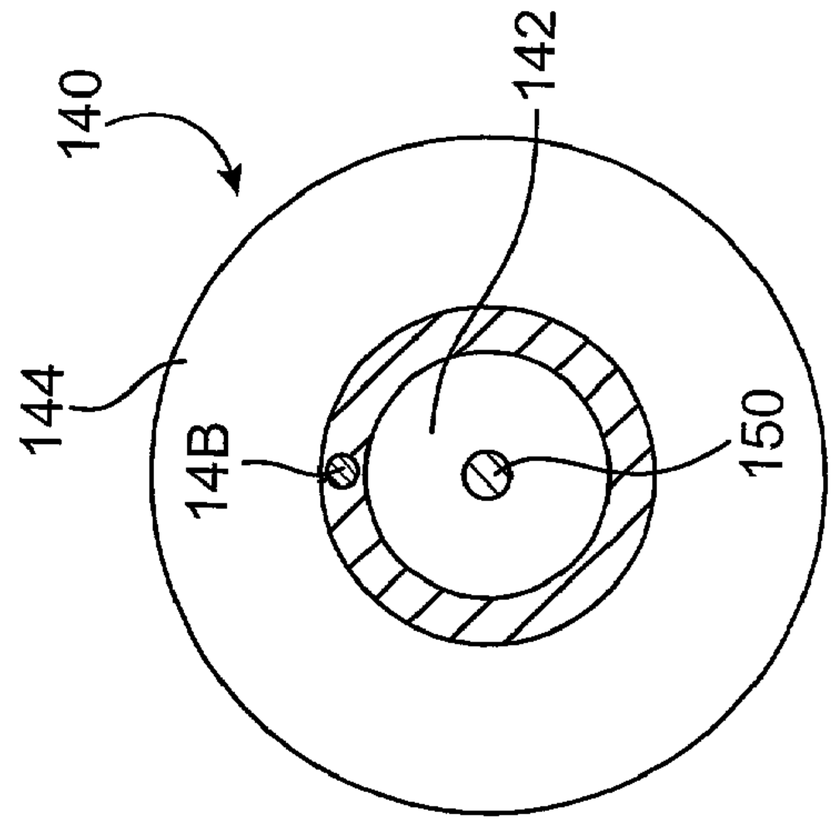

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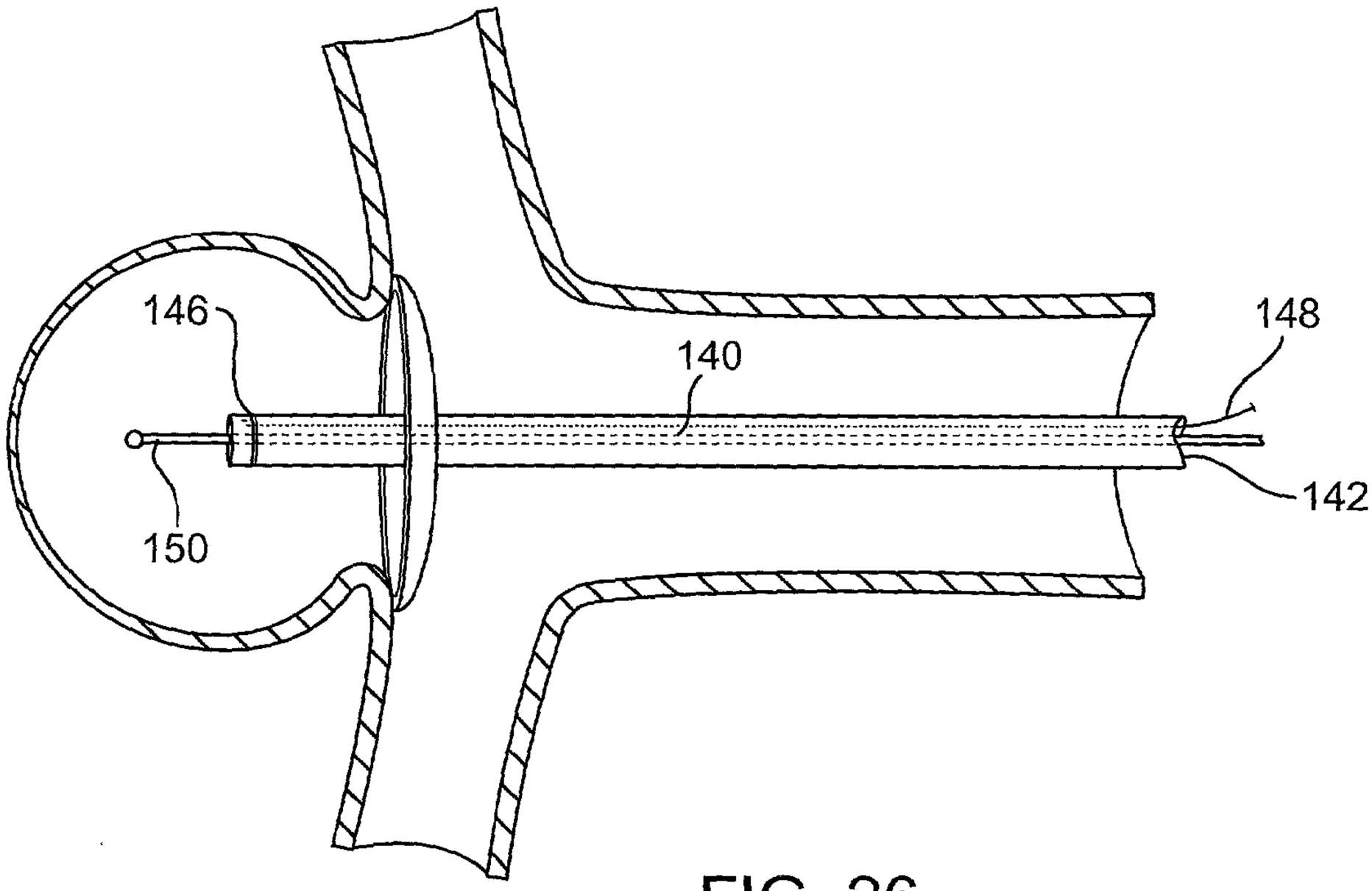

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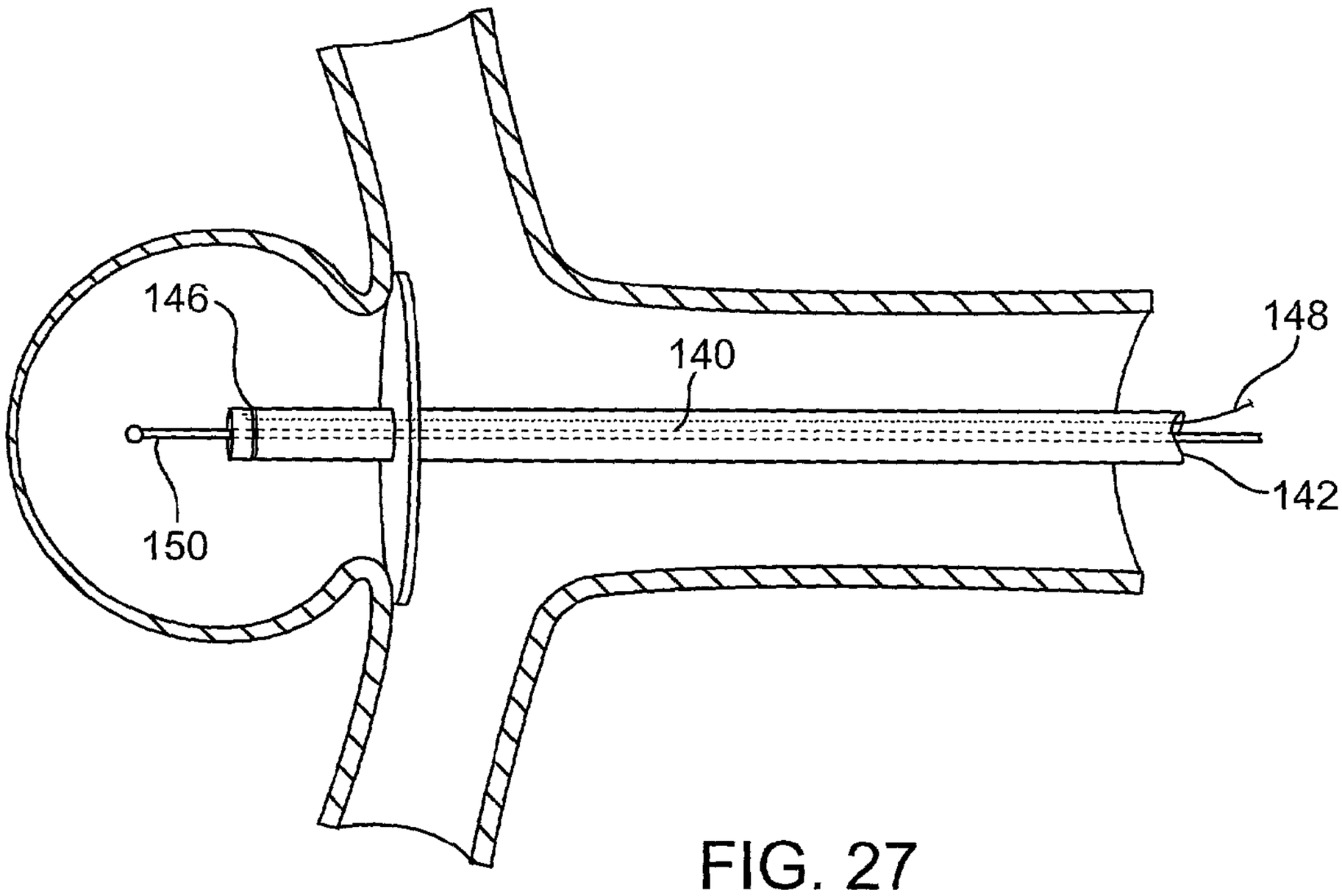

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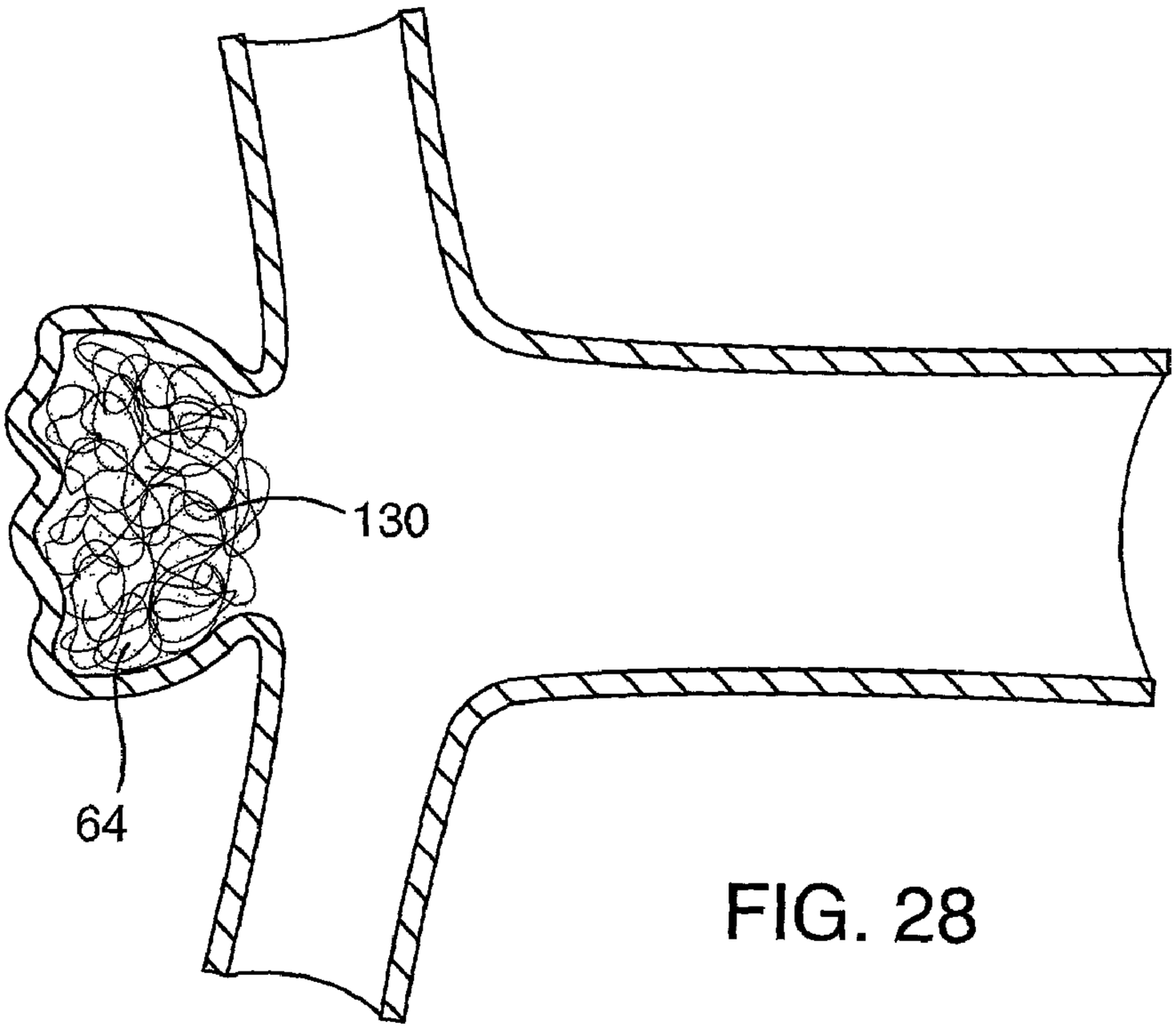

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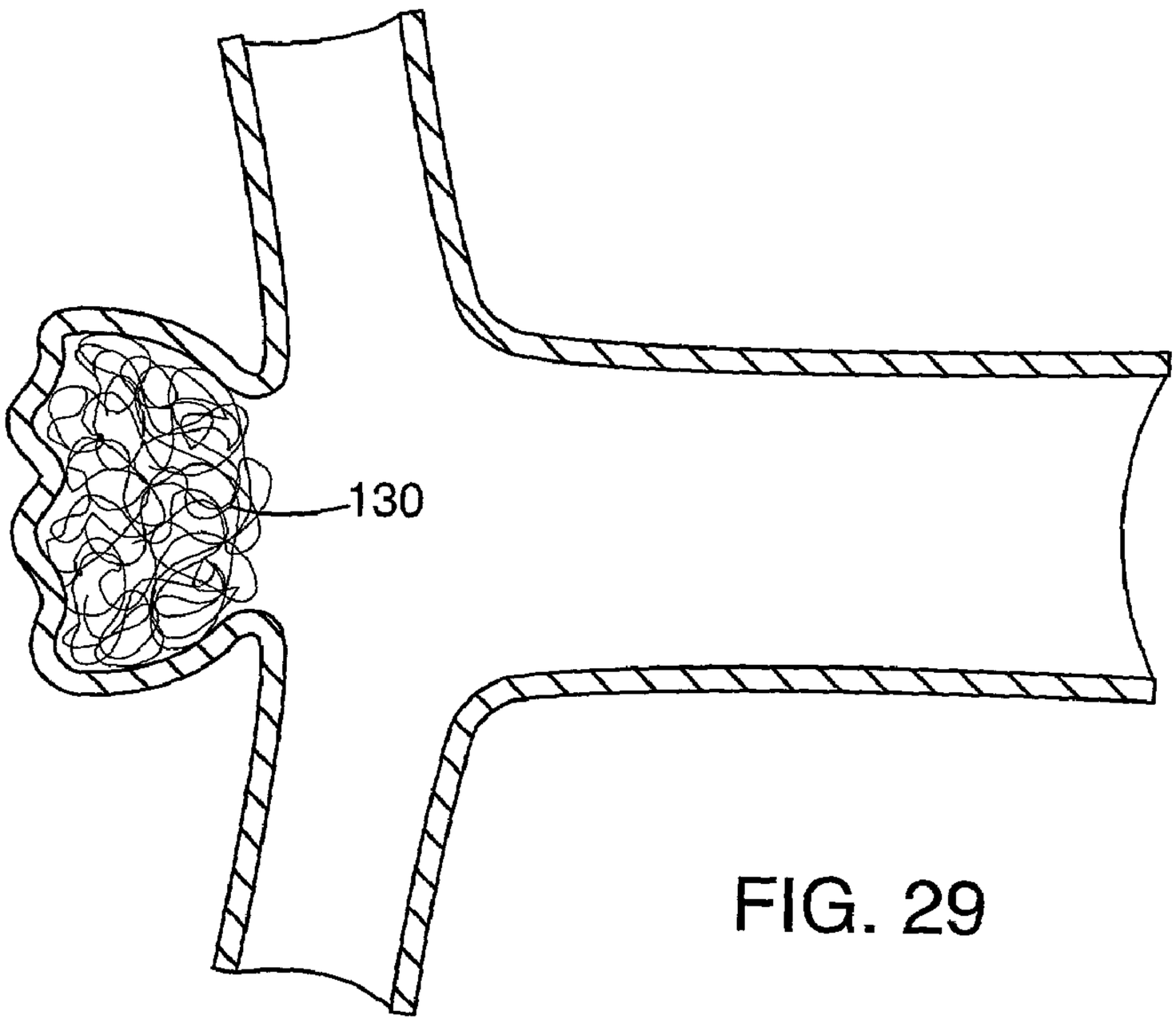


FIG. 29

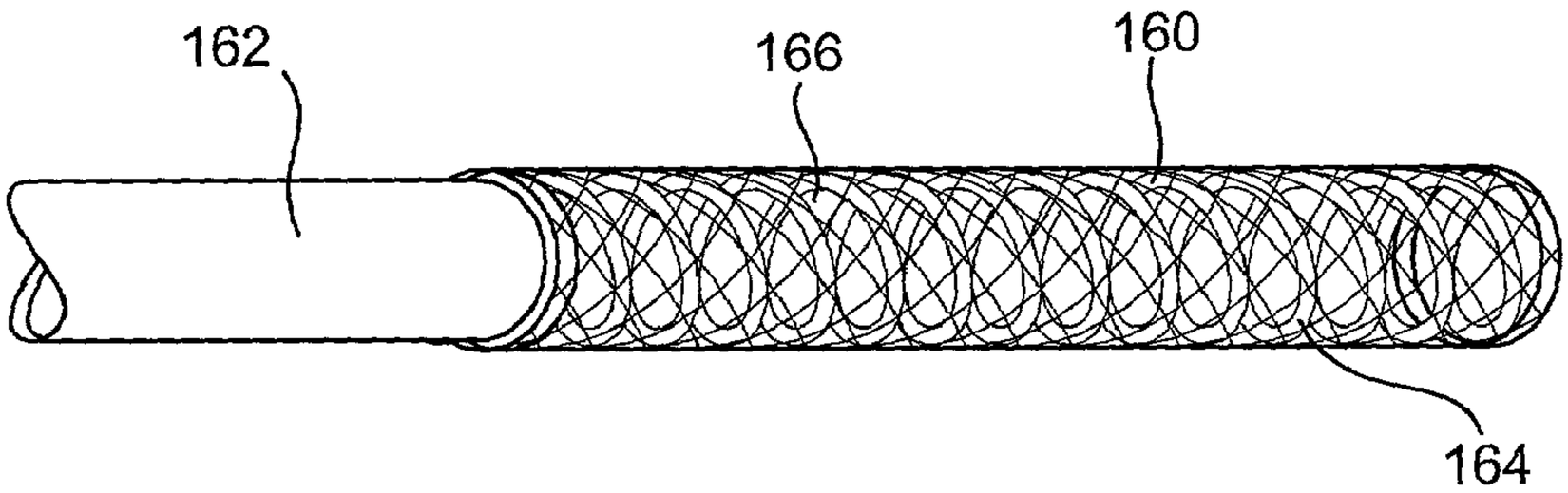


FIG. 30

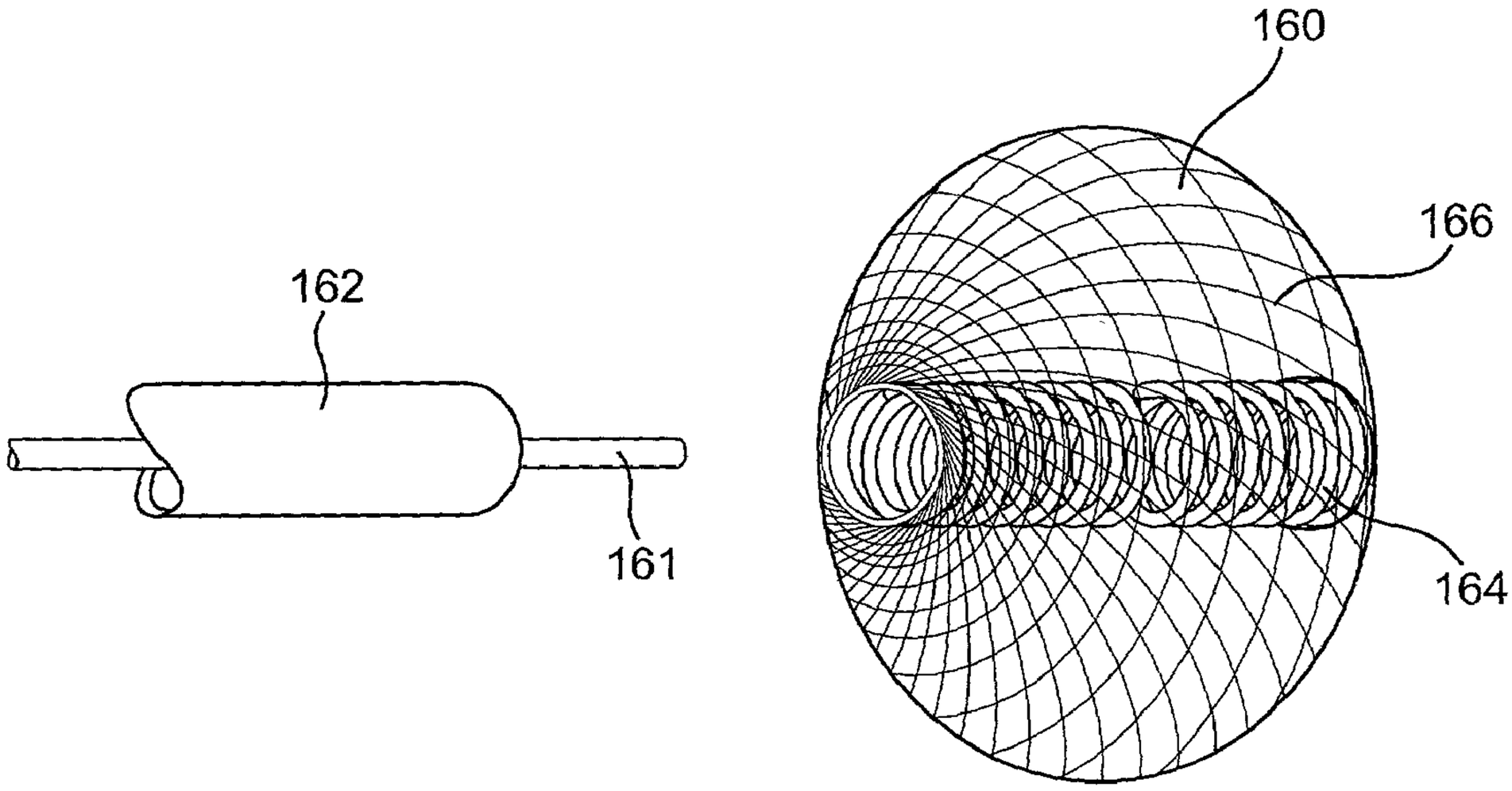


FIG. 31

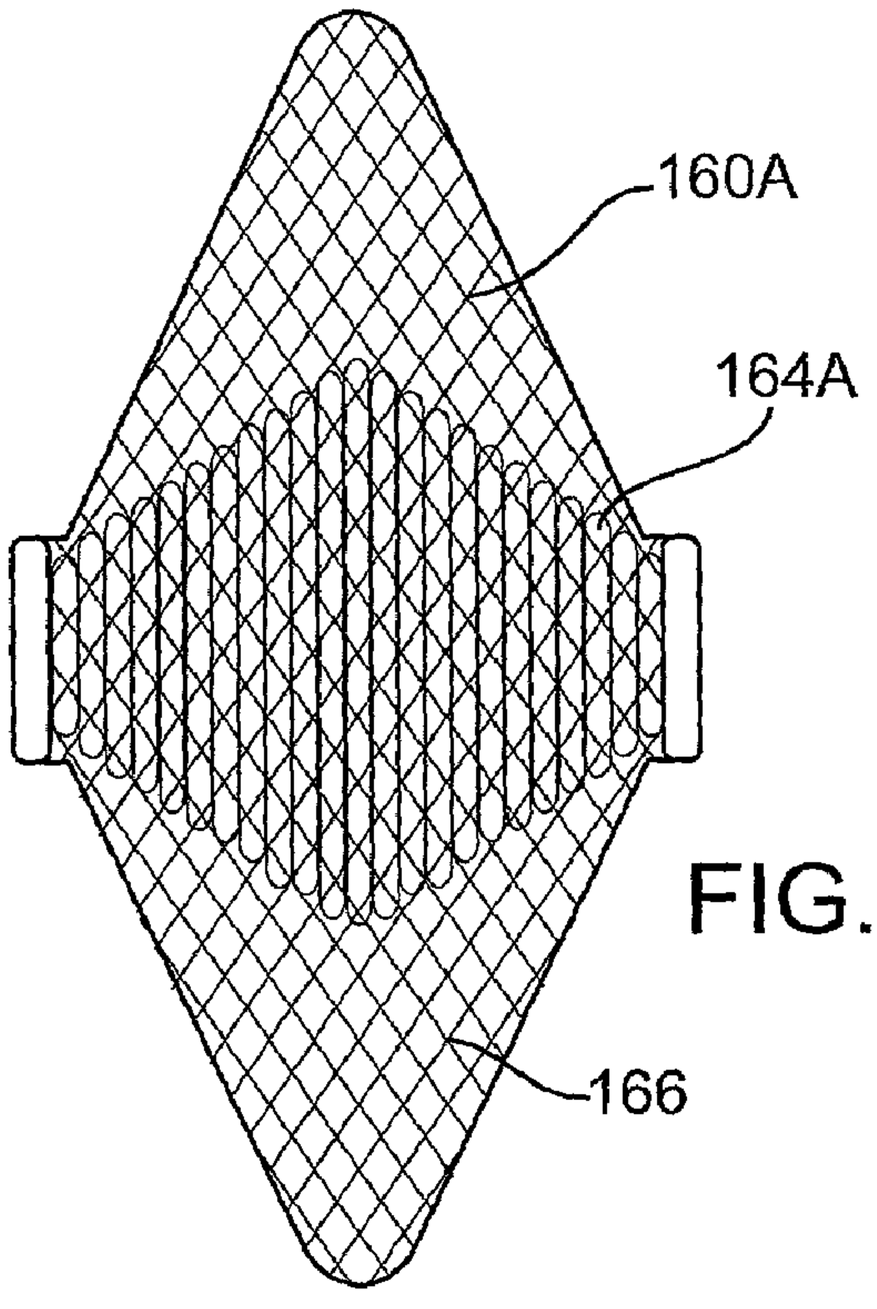


FIG. 32

FIG. 33

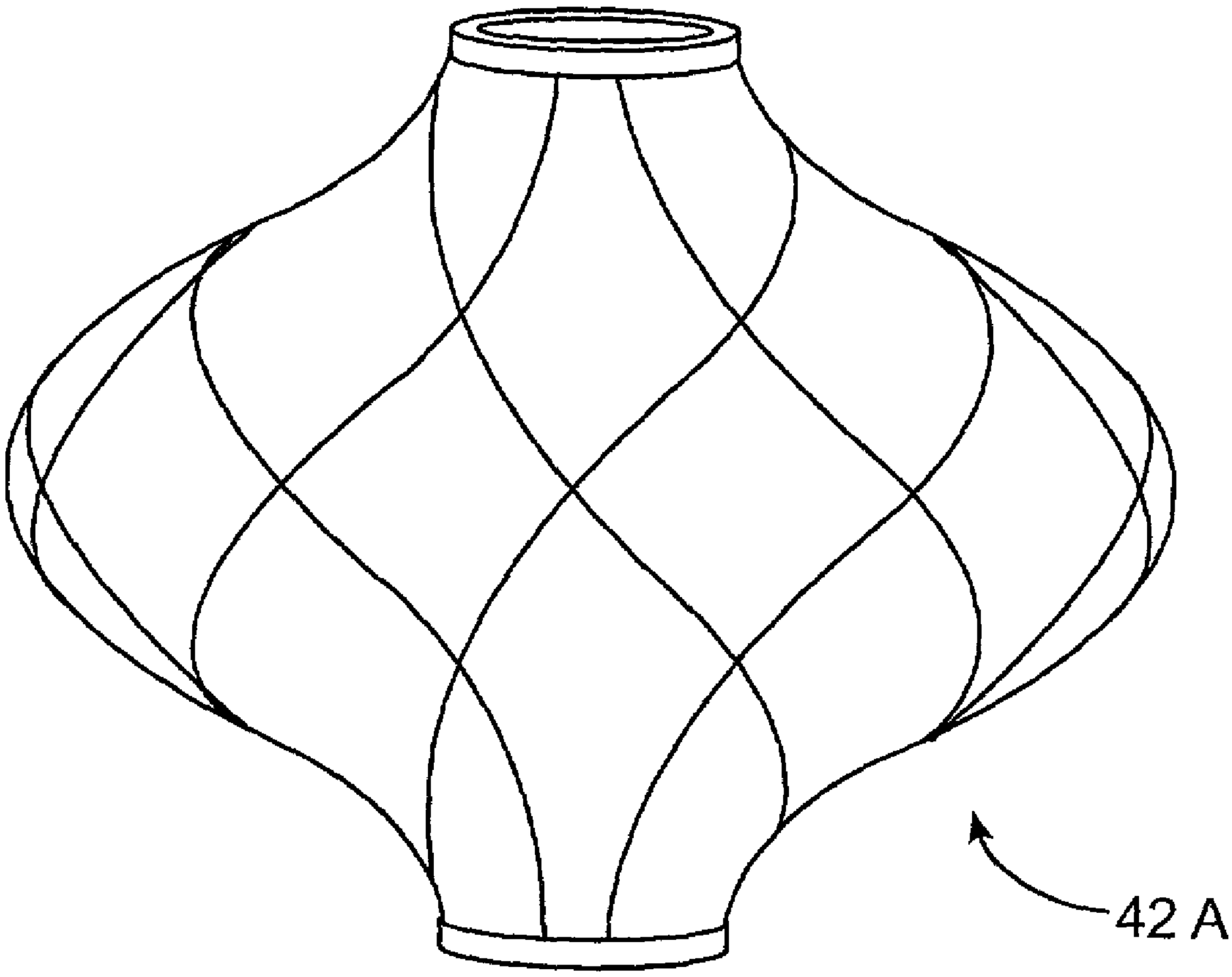


FIG. 34

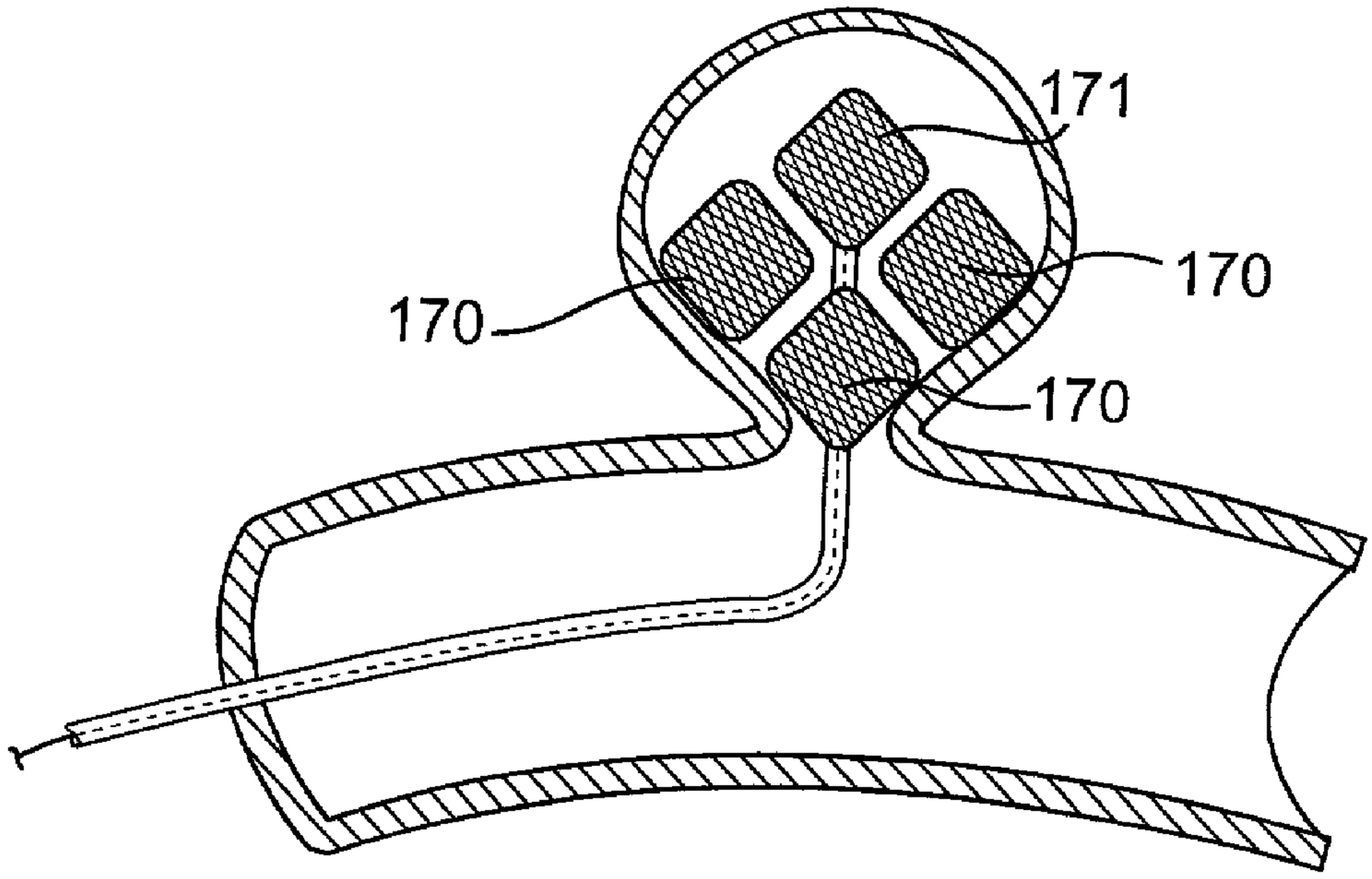


FIG. 35

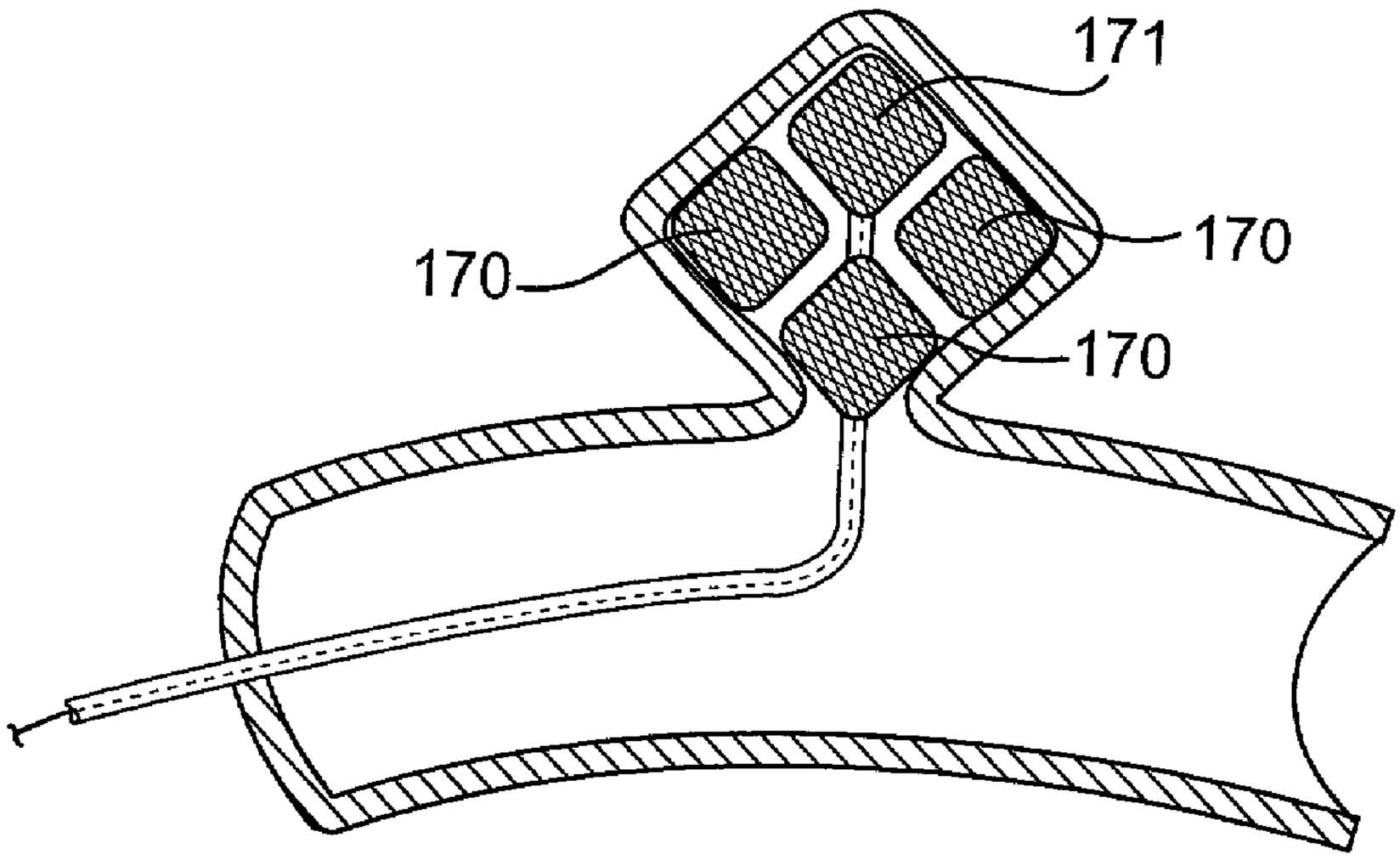
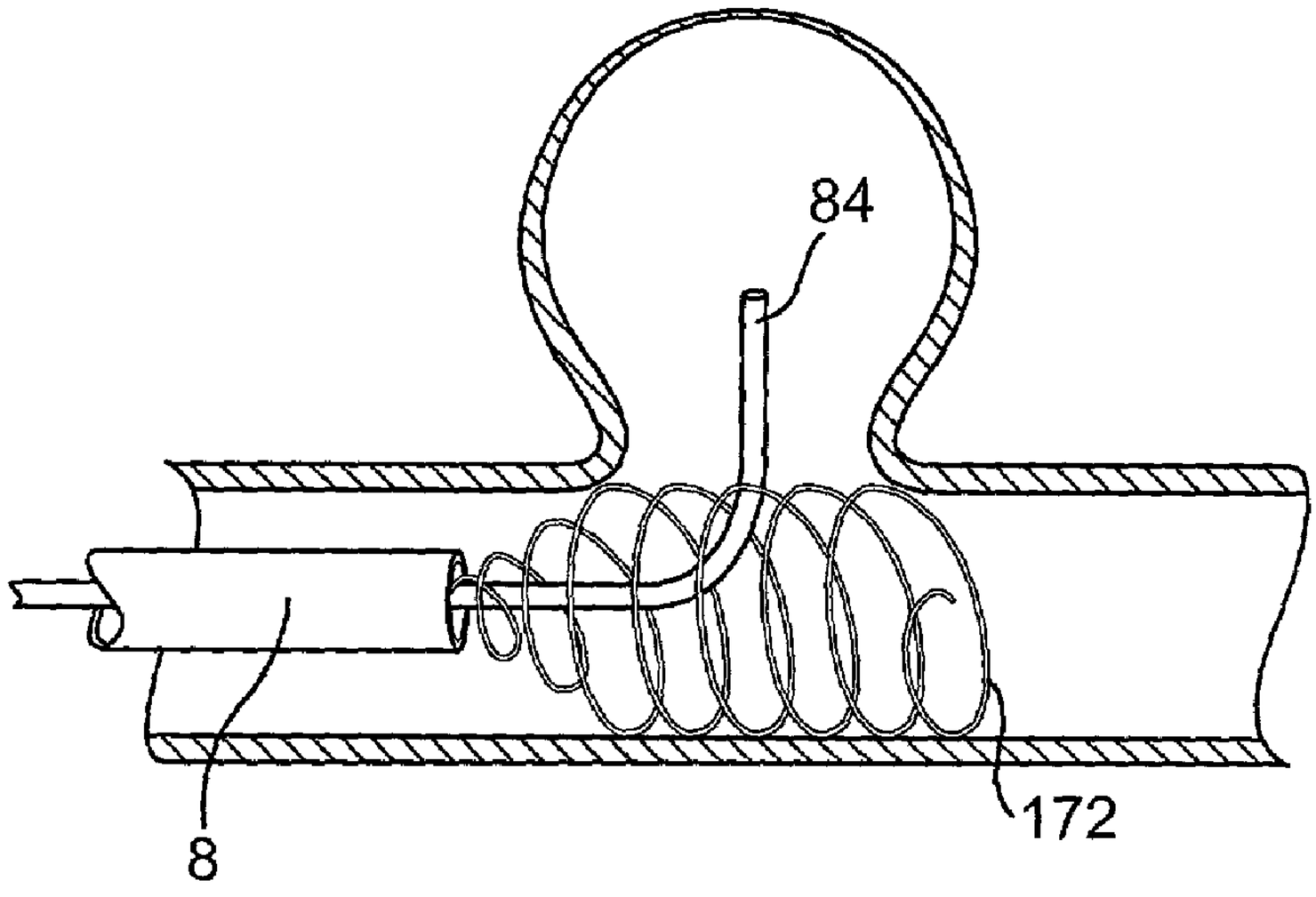


FIG. 36



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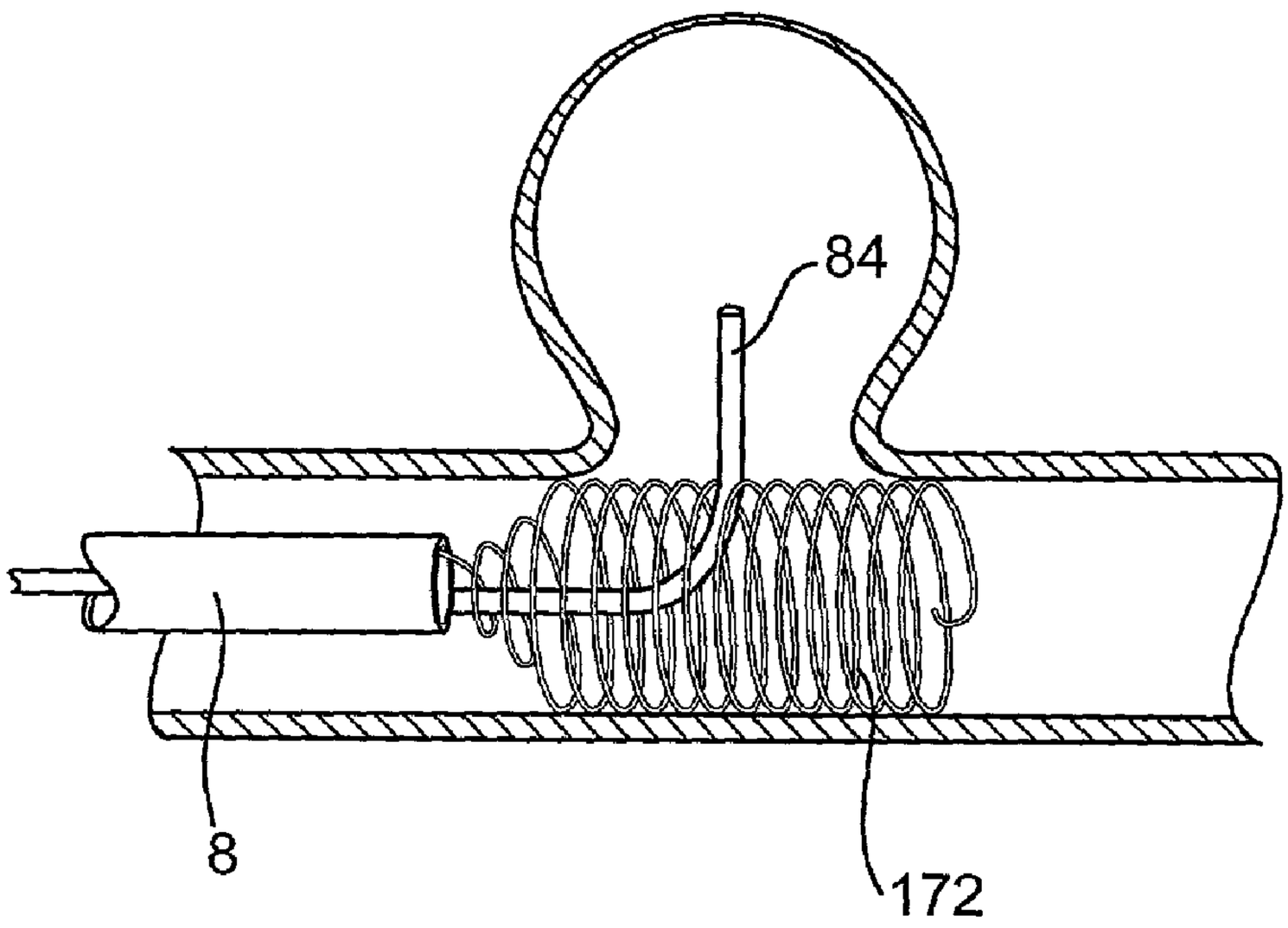

FIG. 38

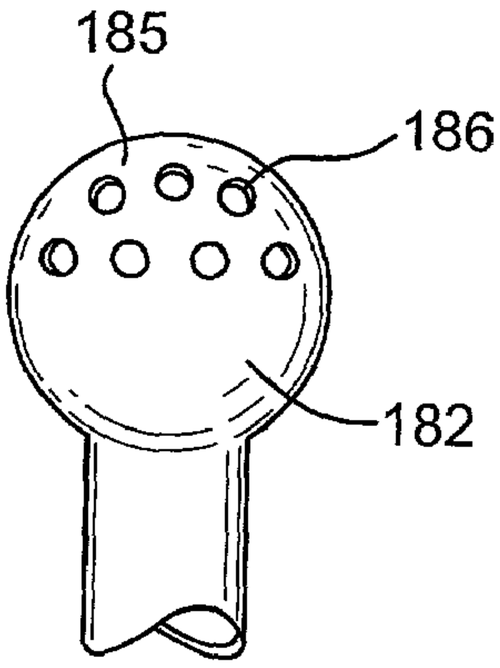

FIG. 41

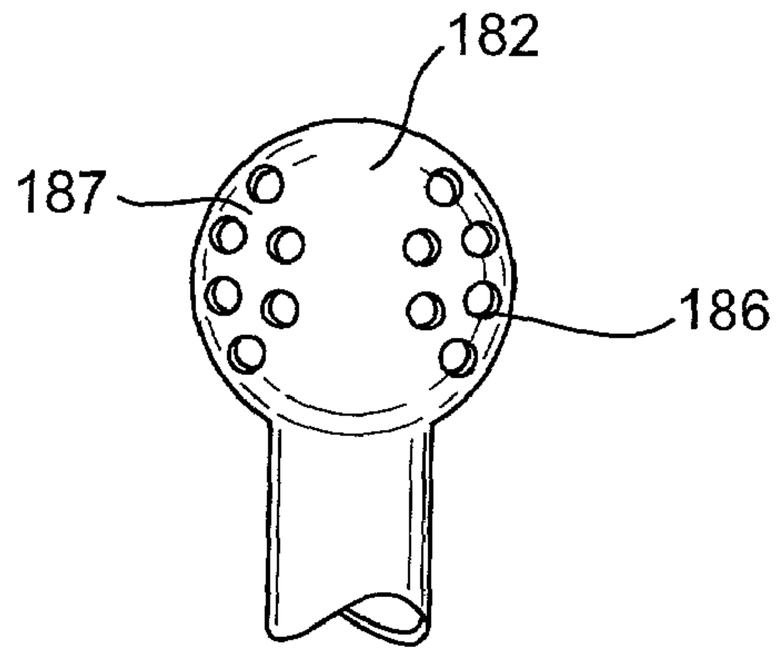

FIG. 42

FIG. 40

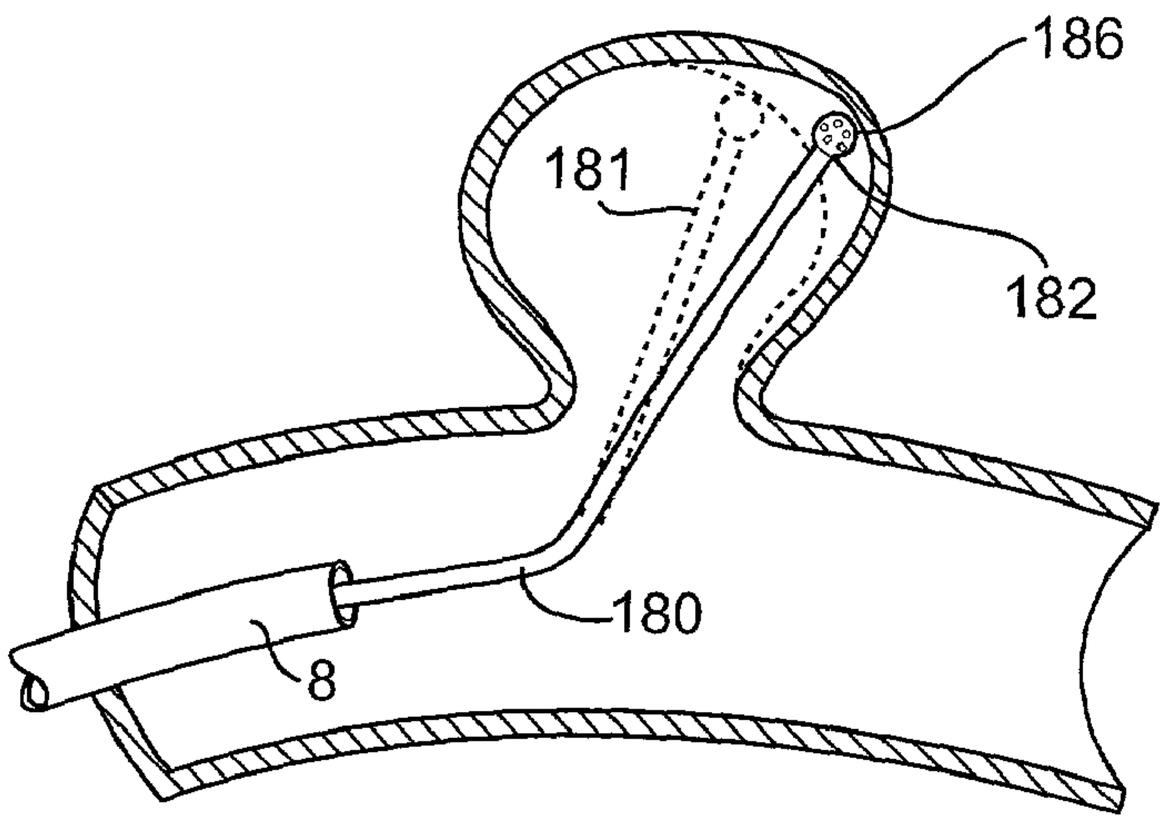

FIG. 39

DEVICES AND METHODS FOR TREATING VASCULAR MALFORMATIONS

BACKGROUND OF THE INVENTION

[0001] The present invention relates to treatment of abnormalities in a patient's vascular system. A specific use of the present invention described below is for the treatment of cerebral aneurysms although the various aspects of the invention described below may also be useful in treating other abnormalities such as arteriovenous malformations (AVM), hypervascular tumors, cavernous carotid fistulas, fibroid tumors, and non-reversible sterilization via fallopial occlusion.

[0002] Cerebral aneurysms are enlargements of the cerebral vasculature which protrude like a balloon from the wall of a cerebral artery. The cerebral aneurysm has a neck which leads to the parental vessel and a body or "dome" which can vary in diameter from 1-30 mm.

[0003] The wall of the aneurysm is often weak and can rupture, leading to hemorrhage. Rupture of the aneurysm can kill the patient or leave the patient with permanent or transitory mental and physical deficits.

[0004] Aneurysms are often treated to prevent rupture, leading to hemorrhage, or to prevent rebleeding of acutely ruptured aneurysms. A conventional method of treating aneurysms is to fill the aneurysm with coils. The coils are introduced into the aneurysm one at a time through a delivery catheter until the aneurysm is filled. The aneurysm eventually becomes a solid mass of coils and thrombus.

[0005] A problem with the conventional method of using coils to fill aneurysms is that the aneurysm becomes a relatively solid mass due to coils and thrombus contained therein. The mass of coil and thrombus exerts pressure on adjacent areas of the brain which may lead to other problems. Another problem with the conventional method is that the coils must be delivered one at a time into the aneurysm which increases the procedure time and risk to the patient. For large aneurysms, up to twenty coils may be required to fill the aneurysm.

[0006] It is an object of the invention to provide improved methods and devices for treating aneurysms. These and other objects of the invention will become evident from the description of the preferred embodiments described below.

SUMMARY OF THE INVENTION

[0007] In a first aspect of the present invention, a method of treating an aneurysm is provided. An expandable structure is delivered through the vasculature in a collapsed position. Once the expandable structure is at the desired location, such as within a cerebral aneurysm, the expandable structure is expanded. The structure and advantages of the expandable structure are described below. The aneurysm wall is also reduced in size so that the aneurysm does not need to be completely filled in the conventional manner. The expandable shape is sized to be smaller than the aneurysm to permit reducing the size of the aneurysm by at least 30% percent.

[0008] A preferred method of reducing the size of the aneurysm is to heat the aneurysmal wall, preferably to a temperature of at least 60° and preferably 60-80° C., which causes the aneurysmal wall to shrink. The aneurysm may be heated in any suitable manner and preferred methods are monopolar and bipolar RF, laser, microwave, and simple electrical resistance heating. In a preferred method, electrical energy is delivered to the expandable device itself to generate heat. A fluid may be introduced into the aneurysm to prevent clotting during heating and to provide thermal and/or electrical conductance. When using RF heating, for example, the fluid may be saline and more preferably hypertonic saline. Although it is preferred to heat the aneurysmal wall to reduce the size of the aneurysm, the aneurysm may also be reduced in size by chemical action.

[0009] The expandable structure forms a matrix of filaments in the expanded condition. The matrix preferably forms a woven or braided structure, however the filaments may also be randomly oriented, parallel, or non-intersection filaments. The matrix may be flexible filaments, such as platinum ribbon, extending randomly, radially or helically within an expandable, permeable, mesh-like enclosure. The material may also be an expandable material such as polymer, nitinol, stainless steel, tungsten or tantalum and alloys/composites thereof.

[0010] The expandable device preferably fills a volume of at least 10% of the aneurysm volume, more preferably at least 40% and most preferably at least 60% of aneurysm volume. The expandable device preferably has internal filaments within the volume to quickly form a stable thrombus. An advantage of the expandable device is that a three-dimensional structure forms without requiring separate delivery of a cage and coils as described in International Application WO 99/07293. In another aspect, the expandable device has a deforming portion which plastically deforms when moving to the expanded position. The deformable portion holds the flexible filaments in the expanded position.

[0011] The aneurysm may be reduced in size until the aneurysmal wall contacts the expandable structure so that the expandable structure supports and reinforces the aneurysmal wall. In a particularly advantageous embodiment of the invention, the expandable structure itself is used to transmit energy to heat the aneurysmal wall which causes the aneurysmal wall to fuse to the expandable structure, thereby reinforcing the aneurysmal wall and preventing migration of the expandable structure into the parental vessel.

[0012] In another aspect of the invention, the aneurysmal wall may be reduced in size together with the expandable device. In a preferred embodiment, the expandable structure is a soft mesh which easily collapses when the aneurysmal wall is shrunk.

[0013] Various optional steps and structure may also be provided. For example, a sealant may be delivered into the aneurysm to ensure that the aneurysm is isolated from the parental artery. An advantage of the present invention is that the sealant is held within a matrix formed by the expandable device which holds the sealant in the aneurysm.

[0014] The proximal portion of the expandable structure may be insulated to protect the neck of the aneurysm. The insulation may coat only the flexible filaments so that the structure is still permeable to fluid. Alternatively, the insulation may be impermeable to protect the neck from hot fluid

slowly expelled into the aneurysm or to isolate the aneurysm entirely from the parental vessel.

[0015] The expandable device may have one or more expandable sections. In an embodiment, the expandable device has two expandable sections wherein energy is delivered to the dome with one of the sections while the second section is insulated to protect the neck.

[0016] The expandable device may have a locking mechanism for locking the expandable device in the expanded position. The expandable device is naturally biased toward the collapsed position so that the operator may partially deploy the expandable device to determine whether the device has the appropriate size. If the device does not have the appropriate size, the device is collapsed and removed and another device having the appropriate size is introduced. The locking mechanism is then actuated when the user is satisfied with the size of the device.

[0017] In still another aspect of the present invention, a catheter has a cover which is positioned over the neck of the aneurysm to isolate the aneurysm from the parental vessel. The aneurysm is then reduced in size as explained above while the cover isolates the aneurysm. The cover also protects the patient from hemorrhage by isolating the aneurysm from the parental vessel. The cover may be periodically moved to expel heated fluid into the parental vessel when heating and shrinking the aneurysm.

[0018] In yet another aspect of the present invention, a coil is used to cover the neck of the aneurysm to regulate the flow of hot fluid out of the aneurysm and into the parental vessel. The pitch of the coil can be varied by the operator during deployment to allow faster or slower leakage of hot fluid out of the aneurysm and into the parent artery during heating.

[0019] A catheter is also provided which has a low-impedance coil, such as flat copper ribbon or other suitable material, disposed in the catheter tip. Upon infusion of saline through the catheter and passage of RF energy through the coil, the saline is heated and conducts electrical energy to heat the fluid.

[0020] These and other aspects and advantages of the invention will become evident from the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] **FIG. 1** is a system for treating a patient's vascular system.

[0022] **FIG. 2** shows an expandable device in a collapsed position.

[0023] **FIG. 3** is a perspective view of the expandable device with the mesh removed.

[0024] **FIG. 4** is a cross-sectional view of the expandable device.

[0025] **FIG. 5** shows the expandable device in an aneurysm.

[0026] **FIG. 6** shows the expandable device detached from the delivery catheter.

[0027] **FIG. 7** shows the expandable device of **FIG. 6** with a sealant introduced into a portion of the expandable device.

[0028] **FIG. 8** shows the sealant filling the aneurysm and the expandable device.

[0029] **FIG. 9** shows the expandable device having a proximal portion which is relatively impermeable to the sealant so that the sealant is retained in the aneurysm.

[0030] **FIG. 10** shows the expandable device filled with an expandable material such as random fibers or a coil.

[0031] **FIG. 11** shows another expandable device which is deployed with a balloon in a collapsed position.

[0032] **FIG. 12** shows the expandable device of **FIG. 11** in an expanded position.

[0033] **FIG. 13** shows the expandable device reduced in size and the expandable device having a proximal portion which is insulated to protect the neck of the aneurysm.

[0034] **FIG. 14** shows the expandable device of **FIG. 11** with simple resistance heating used to shrink a portion of the aneurysm into contact with the expandable device.

[0035] **FIG. 15** shows the use of simple resistance heating to shrink another portion of the aneurysm into contact with the expandable device.

[0036] **FIG. 16** shows a heating device.

[0037] **FIG. 17** shows a heating device with the tip curved.

[0038] **FIG. 18** shows the heating device used with the expandable device of FIGS. **11-14**.

[0039] **FIG. 19** shows the aneurysm shrunk into contact with the expandable device.

[0040] **FIG. 20** shows the expandable device reduced in size during shrinking of the aneurysm.

[0041] **FIG. 21** shows another expandable device having a locking mechanism for holding the device in the expanded position.

[0042] **FIG. 22** shows the expandable device of **FIG. 21** with the device in the expanded position.

[0043] **FIG. 23** shows the device of **FIGS. 21 and 22** released from the delivery catheter.

[0044] **FIG. 24** shows a catheter having a cover for isolating an aneurysm from the parental vessel.

[0045] **FIG. 25** is a cross-section of the catheter of **FIG. 21** along line A-A.

[0046] **FIG. 26** shows the catheter of **FIG. 21** with the cover having a curved shape.

[0047] **FIG. 27** shows the catheter of **FIG. 21** isolating an aneurysm.

[0048] **FIG. 28** shows the aneurysm reduced in size and a thrombogenic material and sealant introduced into the aneurysm.

[0049] **FIG. 29** shows only the thrombogenic material in the aneurysm.

[0050] **FIG. 30** shows another expandable device in a collapsed position.

[0051] **FIG. 31** shows the expandable device of **FIG. 30** in an expanded position.

[0052] **FIG. 32** is an alternative embodiment of the device of **FIGS. 30 and 31**.

[0053] **FIG. 33** is another alternative embodiment of the device of **FIGS. 30 and 31**.

[0054] **FIG. 34** shows a mesh structure for use with any of the expandable devices described herein.

[0055] **FIG. 35** shows a number of expandable device delivered to the aneurysm.

[0056] **FIG. 36** shows the aneurysm of **FIG. 35** reduced in size.

[0057] **FIG. 37** shows a coil for regulating flow between an aneurysm and a parent vessel.

[0058] **FIG. 38** shows the coil of **FIG. 37** with the windings spaced close together to further impede fluid flow between the aneurysm and the parent vessel.

[0059] **FIG. 39** shows another catheter for heating tissue.

[0060] **FIG. 40** is a cross-sectional view of the distal end of the catheter of **FIG. 39**.

[0061] **FIG. 41** shows the tip of the catheter of **FIGS. 39 and 40** with holes at the distal end of the tip.

[0062] **FIG. 42** shows the tip of the catheter of **FIGS. 39 and 40** with holes along the side of the tip.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0063] Referring to **FIG. 1, a** system **2** for introducing an expandable device **4** into a cerebral aneurysm is shown. A first catheter **6** extends through a penetration in the femoral artery and up to the carotid artery. A second catheter **8** is advanced through the first catheter **6** and into the cerebral vasculature to the site of the aneurysm or other abnormality. A delivery catheter **10** is then advanced through the second catheter **8**. The catheter **10** delivers an expandable device **4** which partially fills the aneurysm as will be described below. The system **2** also has an energy supply **12** for heating the aneurysm to shrink the aneurysm as will be described below.

[0064] After the expandable device **4** has been delivered to the aneurysm and expanded, the aneurysm is reduced in size as shown in **FIG. 6**. The aneurysm may be shrunk partially toward the expandable device **4**, into engagement with the expandable device **4**, or may even be shrunk until the expandable device **4** is also reduced in size. An advantage of shrinking the aneurysm is that the aneurysm does not need to be completely filled with coils in the conventional manner. The conventional method of filling the aneurysm with coils creates a relatively solid mass in the aneurysm which can press against adjacent structures leading to further problems. The expandable device **4** is removably mounted to the end of a shaft **5** in the manner described below so that the expandable device **4** may be released in the aneurysm. The expandable device may be released with a mechanical mechanism, a thermoadhesive bond, or an electrolytically or chemically severable bond.

[0065] The aneurysm may be shrunk in any suitable manner and a preferred method is to heat the aneurysmal wall. Shrinking of the aneurysm may also be accomplished through chemical action. The aneurysmal wall is preferably heated to a temperature of 60-80° C. and preferably at least 70° C. Depending upon the size of the aneurysm, the aneurysmal wall is preferably heated for at least 10 seconds and generally between 10 seconds and 5 minutes.

[0066] In the preferred system of **FIG. 1**, the energy supply **12** supplies RF energy to heat and shrink the aneurysm. The expandable device **4** is preferably configured as a mono-polar RF electrode **14** and the energy supply **12** is preferably an RF generator. A suitable second electrode (not shown) is placed in contact with the patients skin in the conventional manner. The aneurysm may, of course, be heated with the energy supply being a hot fluid, laser, microwave, bi-polar RF or a resistance heating device without departing from the scope of the invention.

[0067] Referring to **FIGS. 1 and 4**, the catheter **8** has a lumen **16** coupled to a source of fluid **18** which is preferably a conductive fluid such as saline and more preferably hypertonic saline. The lumen **16** may also be coupled to a source of sealant **20** which may be used to seal the aneurysm as described below. The sealant may be any suitable sealant such as cyanoacrylates, ethylene vinyl-alcohol, cellulose acetate polymers, fibrin glues and other liquid-type tissue sealants. The sealants may also be bioperodable and/or bio-absorbable. The lumen **16** is also coupled to a vacuum source **22** for suctioning fluids and reducing the size of the aneurysm. A source of contrast **24** is also provided for visualization of the aneurysm, vasculature and device positions. A valve **26** couples the lumen **16** to the various sources **18, 20, 22, 24**. The delivery catheter **10** also has a lumen **28** which may be coupled to the sources **18, 20, 22, 24** and discussion of use of the lumen **16** is equally applicable for the lumen **28**.

[0068] Referring to **FIGS. 2, 3** and **5**, the expandable device **4** has first and second expanding sections **30, 32**. Although it is preferred to provide both the first and second expanding sections **30, 32**, the expandable device **4** may include only one expanding section or three or more expanding sections without departing from the scope of the invention. The first section **30** acts as the electrode **14** to deliver RF energy from the energy source **12** to the aneurysm. The second section **32** is insulated and does not transmit energy to the aneurysm so that the neck of the aneurysm is protected. The second section **32** is preferably coated with PTFE, polyamide, FED, or PFA to prevent RF energy transmission. Protecting the neck of the aneurysm also protects peripheral vessels adjacent the neck of the aneurysm.

[0069] The second expandable section **32** may be permeable to fluid so that heated fluid in the aneurysm may be slowly expelled into the parental vessel to dissipate heat. The second section **32** may also have a fluid impermeable portion **36** adjacent the neck to further protect the neck of the aneurysm as shown in **FIG. 9**. The fluid impermeable portion **36** is preferably a flexible sheath **38** having a ring or annular shape. The ring shape may interrupted at a radially inner portion **39** so that heated fluid may still be slowly expelled into the parental vessel. Alternatively, the sheath **38** may completely isolate the aneurysm from the parental vessel.

[0070] The first and second expandable sections **30, 32** have a number of flexible filaments **40** which move from the collapsed position of **FIG. 2** to the expanded position of **FIG. 5**. The flexible filaments **40** are preferably woven or

braided to form a substantially closed-form mesh structure **42** in the expanded position. The filaments **40** and mesh **42** have the characteristics described below and are graphically depicted in the drawings for clarity. A preferred mesh structure **42** is also described with reference to **FIG. 34** below.

[**0071**] Referring again to **FIGS. 2 and 3**, the filaments **40** are positioned over deformable elements **48** which hold the flexible filaments **40** in the expanded position. Referring to **FIG. 3**, the deformable elements **48** have columns **50** extending between collars **52, 53** at the ends. The deformable elements **48** are formed from tubes which have four cut-out sections **54** to form the columns **50**. The collars **52** are then attached to the ends of the tube. The columns **50** are bent outward slightly so that they will buckle outwardly when compressed. As will be described in further detail below, the deformable elements **48** are plastically deformed when moving to the expanded position to hold the filaments **40** in the expanded position. The columns **50** may also be designed with curved or sinusoidal shaped sections to improve flexibility.

[**0072**] Referring to **FIG. 4**, the proximal and distal collars **52** are threaded to engage a threaded tip **58** of a guidewire **60** for manipulating the expandable device **4**. Intermediate collars **62** provide only throughholes to hold and guide the expandable device **4** on the guidewire **60**. When expanding the device **4**, the guidewire **60** is pulled until the device **4** is trapped between the delivery catheter **10** and the threaded tip **58**. The guidewire **60** is then rotated to engage the tip **58** with the distal threaded collar **52**. When the tip **58** is threaded into engagement with the distal collar **52**, the guidewire **60** can be pulled to expand the device. When the device **4** is partially expanded, the deformable elements **48** may still be within their elastic range so that the expandable device **4** will recover the collapsed position when tension is released on the guidewire **60**. The operator may then check to see if the device **4** has the appropriate size and shape for the aneurysm before fully deploying the device. If the operator determines that the device **4** is too small or too large, the device **4** is collapsed and removed and another expandable device of appropriate size advanced to the aneurysm.

[**0073**] When the operator is ready to deploy the device **4**, the operator pulls the guidewire **60** so that the deformable elements **48** undergo plastic deformation and move to the expanded position. Even if the device **4** is moved to the expanded position, the operator may still retrieve the device by engaging the proximal collar **53** with the threaded tip **58** and withdrawing the device into the second catheter **8**.

[**0074**] After the expandable device **4** has been moved to the expanded position, the aneurysm is then preferably reduced in size. In a preferred method, RF energy is delivered to the first expandable section **30** through the guidewire **60** and a conductive fluid, preferably hypertonic saline, is injected into the aneurysm through the lumen **16** or lumen **28**. **FIG. 6** shows the aneurysm reduced in size until the aneurysm engages the first section **30**. The threaded tip **58** is then disengaged from the device **4** leaving the device **4** in the shrunken aneurysm.

[**0075**] As an optional step, the sealant **64** from the source of sealant **20** may also be introduced into the entire aneurysm **(FIG. 8)** or into just the second section **32 (FIG. 7)** to seal the aneurysm. An advantage of the present invention over conventional methods is that the sealant **64** is contained within the closed-form mesh structure **42** to prevent escape of the sealant **64** into the parental vessel. Referring to **FIG. 9, a** proximal portion **66** may be impermeable to further isolate the aneurysm from the parental vessel. A small amount of the sealant **64** may also be delivered to completely isolate the aneurysm if necessary as shown at dotted-line **68**. The method of the present invention described above may, of course, be practiced with any suitable structure other than the structure of FIGS. **1-9** without departing from the scope of the invention.

[**0076**] Referring to FIGS. **11-15**, another delivery catheter **70** is shown for use with the system of **FIG. 1**. The delivery catheter **70** is delivered through the first and second catheters described above. The catheter delivers an expandable device **4**A to the aneurysm through the second catheter **8** (see **FIG. 1**).

[**0077**] The delivery catheter **70** has an expandable member **72**, preferably a balloon **74**, for deploying the expandable device **4**A. The device **4**A is configured to retain the expanded position of **FIG. 12** after the balloon **74** has been deflated. The delivery catheter **70** has an inflation lumen **72** coupled to a source of inflation fluid **74** for inflating the balloon **(FIG. 1)**.

[**0078**] The expandable device **4**A is preferably made of a number of flexible filaments **76**. The filaments **76** are preferably woven or braided but may also be a number of non-woven filaments. The filaments **76** may be any suitable material and a preferred material is platinum alloy (92% platinum, 8% tungsten) wire having a thickness of 0.005-0.003 inch.

[**0079**] The expandable device **4**A may take any shape and may have a number of predetermined shapes which can be selected depending upon the shape of the aneurysm and the nature of the patient's vasculature. Referring to **FIG. 12**, the expandable device **4**A has a simple spherical shape. Although the expandable device **4**A is shown as spherical, the expandable device **4**A preferably has a width to height ratio of more than 1.1, more preferably at least 1.2 and most preferably at least 1.8. The width and height are defined relative to the aneurysm **(FIG. 12)** and/or relative to a longitudinal axis **76** of the expandable device **4**A. The preferred dimensions provide a relatively large width so that the expandable device **4**A cannot escape through the neck of the aneurysm after expansion. The height of the expandable device **4**A provides clearance for shrinking the aneurysmal toward the expandable device. The width to height ratios are preferred dimensions for all of the embodiments described herein.

[**0080**] Once the expandable device **4**A has been delivered to the aneurysm, the aneurysm is preferably reduced in size in any manner described herein. A method of reducing the size of the aneurysm is to deliver energy to the expandable device **4**A from the energy source **12**. The energy may be delivered to the aneurysm by delivering RF energy to the expandable device **4**A with one or more wires **80** passing through the second catheter **8**. During RF delivery, the second catheter **8** may be used to deliver fluid, such as hypertonic saline, to the aneurysm.

[**0081**] Referring to **FIGS. 14 and 15**, simple resistance heating may also be used by moving the wires **80** into

contact with the expandable device **4A** to conduct electricity therebetween as shown in **FIG. 14**. An advantage of the system is that different portions of the aneurysm can be heated to shrink the aneurysm as shown in **FIGS. 14 and 15**.

[**0082**] The expandable device **4A** may be insulated at a proximal portion **82** so that energy is delivered to the aneurysm dome rather than toward the neck and parental artery. The flexible filaments **76** may be coated with any suitable insulation, such as paraline, and may be applied by spraying, dipping or etching. The expandable device **4A** may also have the flexible sheath **78** over the insulated region to further shield the neck of the aneurysm.

[**0083**] Referring to **FIG. 16, a** heating device **84** is shown which may be used to heat and shrink the aneurysm. The heating device **84** is advanced into the aneurysm to heat fluid in the aneurysm thereby heating and shrinking the aneurysmal wall. Two insulated wires **86, 88** are wrapped around a core wire **90** and covered with a sheath **92** along the proximal portion. The sheath **92** forms a lumen **94** therethough which may be coupled to the various sources **18, 20, 22, 24** described above with connector **96**. The distal end of the wires **86, 88** form proximal and distal electrodes **98, 100** for bipolar RF heating. The core wire **90** is attached to the distal electrode **100**.

[**0084**] An actuator **102** is manipulated to change the distance between the electrodes **98, 100** and to bend the tip in the manner shown in **FIG. 17**. The actuator **102** is coupled to the core wire **90**. The device may be configured so that the electrodes **98, 100** move toward another when the actuator **102** is manipulated, or the device may be configured so that the tip curves as shown in **FIG. 17**. The tip may be curved to navigate tortuous vessels and may be curved during heating. In use, the distal end of the device **84** is introduced into the aneurysm and the actuator **102** is manipulated to curve the distal end. RF energy is then delivered and a fluid, such as hypertonic saline, is delivered through the second catheter **8** or through the lumen **94**.

[**0085**] Referring to **FIGS. 18 and 19**, the aneurysm may be shrunk into contact with the expandable device so that the expandable device **4A** reinforces the aneurysmal wall to prevent rupture. The aneurysmal wall may also be shrunk further so that the expandable device **4A** itself shrinks as shown in **FIG. 20**. After the aneurysm has been reduced in size, the sealant **64** may also be delivered to further seal the aneurysm.

[**0086**] Referring to **FIGS. 1 and 21-24**, another delivery catheter **110** for treating an aneurysm with the system **2** of **FIG. 1** is shown. The catheter **110** is advanced to the carotid artery and the second catheter **8** is advanced through the first catheter **6** to the aneurysm. The delivery catheter **110** extends through the second catheter **8** to deliver an expandable device **4B** to the aneurysm. The delivery catheter **110** has a lumen **112** which may be coupled to one or more of the various sources **18, 20, 22, 24**. The expandable device **4B** is coupled to the energy source **12** for heating and shrinking the aneurysm as will be described below.

[**0087**] The expandable device **4B** is movable from the collapsed position of **FIG. 21** to the expanded position of **FIG. 22**. Flexible filaments **114** preferably form a woven or braided mesh structure **116** extending between first and second hubs **118, 120**. A central post **122** extends from the second hub **120** and has a locking mechanism **124** which engages the first hub **118** to hold the expandable device **4B** in the locked position. An actuator **126**, which is preferably a tapered rod **128**, has a threaded connection **130** with the central post **122**. The actuator **126** is pulled to move the locking mechanism **124** into engagement with the second hub **120**. The locking mechanism **124** has spring elements **126** which are naturally biased to the position of **FIG. 23**. The spring elements **126** are angled proximally so that they are displaced inwardly by the hub **118** when the post **122** and spring elements **126** pass through the hub **118**. After the spring elements **126** have passed through the hub **118** they assume their unbiased shape thereby locking the device **4B** in the expanded position. The locking mechanism **124** may be any suitable locking mechanism.

[**0088**] The flexible filaments **114** preferably bias the device **4B** toward the collapsed position so that the operator may partially expand the device to determine whether the device has the appropriate size. If the device is not the appropriate size, the device can be collapsed and withdrawn through the second catheter **8**. After the expandable device **4B** has been expanded, the aneurysmal wall may then be shrunk in any manner described herein. In the preferred embodiment of **FIG. 21**, the expandable device is a monopolar RF electrode with the energy source being an RF generator coupled to the actuator **126**. The expandable device **4B** may be insulated along a proximal portion **116** to protect the neck, parental vessel and adjacent vessels as mentioned above. After the aneurysmal wall has been reduced in size, the sealant **64** (**FIG. 8**) may be introduced to isolate the aneurysm from the parental vessel.

[**0089**] In another aspect of the present invention, the expandable devices **4, 4A**, and **4B** may be filled with an expandable thrombogenic material **130**. Referring to **FIG. 10**, the expandable device **4** is filled with the compressible, thrombogenic material **130** which may be randomly oriented fibers **132** or coils **134**. When the expandable device **4** is expanded, the material **130** expands to occupy the interior volume of the woven or braided mesh structure **42**. The material **130** may be used with any of the expandable devices described herein without departing from the scope of the invention. When the material **130** includes filaments **136**, the filaments **136** may be helically, radially or randomly oriented within the interior volume of the mesh or braided structure **42**.

[**0090**] Referring to **FIGS. 1 and 24-27**, another catheter **140** for treating an aneurysm with the system of **FIG. 1** is shown. The first catheter **6** is introduced through the femoral artery and advanced to the carotid artery. The second catheter **8** is advanced through the first catheter **6** to the aneurysm. The delivery catheter **140** is passed through the second catheter **8** to the aneurysm to treat the aneurysm.

[**0091**] The delivery catheter **140** has a lumen **142** which is coupled to the sources of fluid, contrast, sealant and vacuum **18, 20, 22, 24**. The distal end of the catheter **140** has a cover **144** which is positioned over the neck of the aneurysm as shown in **FIG. 27**. The cover **144** provides temporary isolation of the aneurysm from the parental vessel. The cover **144** is preferably a disc of relatively soft material such as silicone. The cover **144** is preferably configured to cover an area of about 0.8 mm^2 to 75 mm^2 and is relatively thin so that the cover **144** does not impede flow

through the parental vessel and so that the cover **144** can distort to a small profile when passing through the second catheter **8**. The cover **144** is also preferably impermeable so that the cover **144** can isolate the aneurysm from the parental vessel.

[**0092**] The catheter **140** has an electrode **146** which is coupled to the energy source **12** with a wire **148** extending through the catheter **140**. The electrode **146** may be configured as a monopolar RF electrode for delivery of RF energy with a second electrode (not shown) in contact with the patient's skin. Alternatively, a second electrode **150** may be passed through the lumen **142** to provide monopolar or bipolar RF with the first and/or second electrodes **146**, **150**. Shrinking of the aneurysm may, of course, be accomplished with any of the methods described above. For example, the heating device **84** (**FIG. 16**) may be advanced through the lumen **142** to heat and shrink the aneurysm.

[**0093**] Use of the delivery catheter **140** is now described, the delivery catheter **140** is advanced through the second catheter **8** to the aneurysm. The cover **144** is positioned over the neck of the aneurysm and the aneurysm is heated to shrink the aneurysm. When using RF heating, fluid such as hypertonic saline may be infused into the aneurysm through the catheter **140** or second catheter **8** (**FIG. 1**). The cover **144** may be flexible enough to deflect and permit hot fluid to be slowly expelled into the parental vessel. Alternatively, the cover **144** may be periodically moved away from the neck so that hot fluid in the aneurysm may be slowly expelled into the parental vessel. The aneurysm may be reduced to an acceptable size or partially shrunk and filled with the thrombogenic material **130** and sealant (**FIG. 28**) or just the material **130** (**FIG. 29**). Although the delivery catheter **140**, and particularly the cover **144**, have been described in connection with RF delivery, the cover **144** may be incorporated into any of the other catheters described herein or any other catheter without departing from the scope of the invention.

[**0094**] Referring to FIGS. **30-34**, another expandable device **160** is shown for use with the system of **FIG. 1**. The expandable device **160** is advanced through the second catheter **8** with a delivery catheter **162**. The expandable device has a mesh **166** which covers a spring **160** made of a shape memory material. The expandable device **160** is in the collapsed shape of **FIG. 30** when advanced through the second catheter **8**. After the expandable device **160** is within the aneurysm, a wire **161** or other device can be advanced to contact the device **160** to heat the device and the aneurysm. Upon heating, the coil collapses to the shape of **FIG. 31** to move the mesh **166** to the expanded condition. Heating of the coil may be undertaken in any manner described herein. An advantage of the device **160** is that the device may be heated together with the aneurysm to deploy the device **160** while shrinking the aneurysm. Referring to **FIG. 32**, another device **160**A is shown which is substantially the same as the device **160** except that spring **160**A expands in the middle. **FIG. 33** shows still another device **160**B which has a smaller diameter in the middle to impede fluid flow through the spring **160**.

[**0095**] Referring to **FIG. 34**, another mesh **42**A is shown. The mesh **42**A may be used with any of the expandable devices described herein and the mechanism for expanding and holding the mesh **42**A has been omitted from **FIG. 34** for clarity. Any of the actuating and delivery methods and devices described above or any other suitable device may be used with the mesh **42**A. The mesh **42**A preferably has 10-50 filaments, more preferably 20-50 filaments, extending between first and second ends **150**, **152**. The filaments **148** are preferably platinum alloy (such as 92% platinum, 8% tungsten). The filaments **148** preferably form a tube in the collapsed position which has a diameter of no more than 0.020 inch but expands to a diameter of at least 0.200 inch at a central portion **154**.

[**0096**] The devices described herein are preferably delivered to the aneurysm to occupy the remaining volume of the aneurysm after shrinking the aneurysm. Referring to **FIGS. 35 and 36**, a number of devices **170** may be delivered to the aneurysm with one of the devices **171** being used to heat and shrink the aneurysm. The devices **170** may be partially or completely insulated in the manner described above to protect the neck while heating and shrinking is accomplished with the device **171**. The devices **170** and **171** are shown spaced apart for clarity but, of course, will be closely packed together when filling the aneurysm. The devices **170** and **171** may be any of the expandable devices described herein or any other suitable device without departing from the scope of the invention.

[**0097**] Referring to **FIG. 37**, another system for reducing the size of an aneurysm is shown. A coil **172** is used to regulate flow of fluid between the aneurysm and the parent vessel. The coil **172** is particularly useful for holding heated fluid in the aneurysm to heat and shrink the aneurysm. The heating device **84** of **FIGS. 16 and 17**, or any other suitable device for heating the aneurysm, is introduced into the aneurysm to heat and shrink the aneurysm. The coil **172** is manipulated by pulling or pushing the coil to retract or deploy the coil **172** from the catheter **8** (see **FIG. 1**). The pitch of the coil **172** can be varied by pulling or pushing the catheter **8** relative to the coil **172**. The windings of the coil **172** may be close together so that the coil **172** substantially impedes flow between the aneurysm and the parent vessel (**FIG. 38**) or may be spaced-apart to permit slow leakage of fluid into the parent vessel. The coil **172** may be made of any suitable material and is preferably a shape-memory alloy such as nitinol.

[**0098**] Referring to **FIGS. 39 and 40**, another catheter **180** for heating and shrinking an aneurysm is shown. The catheter **180** is preferably less than 5 Fr, more preferably 2-4 Fr, and most preferably about 3 Fr in size so that it is small and flexible enough to shrink select portions of the aneurysm as shown by dotted lines **181** in **FIG. 39**. The catheter **180** may, of course, be sized larger to shrink larger portions of the aneurysm or other tissue structures. The catheter **180** has a tip **182** which is made of a heat-resistant, non-stick material (such as PTFE) so that the tip can contact the tissue during heating without sticking to the tissue. The catheter **180** may also be a hypotube, guidewire or similar device without departing from the scope of the invention. The tip **182** forms a chamber **183** and has holes **186** formed therein for delivery of a conductive fluid as described below.

[**0099**] The catheter **180** has a lumen **184** which communicates with the chamber **183** in the tip **182**. The lumen **184** is coupled to the source of fluid **18** (see **FIG. 1**) which is preferably hypertonic saline. An RF probe **188** passes through the lumen **184** and is coupled to the energy supply

12 (see **FIG. 1**) which is preferably an RF generator. The RF probe **188** has an electrode **189** positioned in the chamber while a second electrode (not shown) is positioned in contact with the patient's skin in the conventional manner. When the conductive fluid is delivered through the lumen **184**, electrical energy is conducted by the conductive fluid to heat the aneurysm. The holes **183** in the tip **182** may be distributed around the tip **182** (**FIGS. 39 and 41**), positioned at the distal end **185** (**FIG. 42**) or along the sides **187** (**FIG. 43**) of the tip **182**.

[**0100**] After the volume of the aneurysm has been reduced, the aneurysm may be treated in any other manner described herein. Furthermore, the catheter **180** of FIGS. **39-43** may be used to heat tissue or fluid in connection with any of the other embodiments described herein and in particular as a substitute for the device **84** of **FIGS. 16 and 17**. Finally, the catheter **180** may be used to heat tissue for any other suitable purpose including those described above. For example, the catheter **180** may be useful in treating venous insufficiency, deep vein reflux or for vein stripping. Furthermore, the catheter **180** may be useful for treating urinary incontinence.

[**0101**] While the above is a description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. For example, the expandable device may take any other shape and the sealant may be any other suitable sealant. Furthermore, the dimensions and characteristics of any of the expandable members may be incorporated into any of the other expandable devices described herein without departing from the scope of the invention. Finally, the expandable devices are preferably used when shrinking the aneurysm but the expandable devices may have various features which may be useful when simply filling the aneurysm in the conventional manner.

What is claimed is:

1. A method of treating a cerebral aneurysm, comprising the steps of:

providing an expandable structure movable from a collapsed shape to an expanded shape;

introducing the expandable structure into a blood vessel of a patient;

advancing the expandable structure through the patient's vasculature to a cerebral aneurysm while the expandable structure is in the collapsed position;

moving the expandable structure into the cerebral aneurysm;

expanding the expandable structure to the expanded position in the cerebral aneurysm;

shrinking the wall of the aneurysm; and

leaving the expandable structure in the aneurysm after the shrinking step.

2. The method of claim 1, wherein the shrinking step is carried out until the aneurysmal wall contacts the expandable structure.

3. The method of claim 1, wherein the shrinking step is carried out by delivering electrical energy to the expandable structure to generate heat which shrinks the aneurysm wall.

4. The method of claim 3, further comprising the step of:

delivering saline to the aneurysm while delivering the electrical energy.

5. The method of claim 3, wherein the shrinking step is carried out for at least 5 seconds.

6. The method of claim 1, wherein the shrinking step is carried out by providing a heated fluid in the aneurysm to heat the aneurysmal wall.

7. The method of claim 1, wherein the introducing step is carried out with the expandable structure having a permeable portion when in the expanded position.

8. The method of claim 7, wherein the shrinking step is carried out by delivering RF energy to the aneurysm wherein heated fluid in the aneurysm leaks through the permeable portion and into the parental vessel.

9. The method of claim 1, wherein the introducing step is carried out with the expandable structure being advanced through the patient's vasculature with a catheter, the catheter having a lumen.

10. The method of claim 1, further comprising the steps of:

coupling the lumen to a source of fluid; and

infusing the fluid into the aneurysm through the lumen.

11. The method of claim 10, wherein the infusing step is carried out so that the fluid seals the aneurysm to isolate the aneurysm from the parental vessel.

12. The method of claim 1, wherein the shrinking step is carried out so that the aneurysmal wall contacts the expandable structure and reduces the size of the expandable structure after the expanding step.

13. A method of isolating a cerebral aneurysm from the parental vessel, comprising the steps of:

providing a device movable from a collapsed position to an expanded position, the device having a proximal portion when in the expanded position;

introducing the device into the aneurysm in the collapsed position;

expanding the device to the expanded position after the introducing step;

shrinking the dome of the aneurysm so that that the proximal portion of the expandable device extends around the neck of the aneurysm.

14. The method of claim 13, wherein the providing step is carried out with the proximal portion being permeable, the proximal portion being configured to form a thrombus to isolate the aneurysm from the parental vessel.

15. The method of claim 14, wherein the providing step is carried out with the proximal portion forming a permeable barrier having an opening size of no more than 1 mm when viewed in a direction perpendicular to blood flow through the parental vessel.

16. A system for treating a cerebral aneurysm, comprising:

a shaft having a length and flexibility sufficient to extend into a patient's cerebral vasculature;

an expandable device movable from a collapsed shape to an expanded shape, the expandable device being removably coupled to the shaft;

means for shrinking the aneurysmal wall toward the expandable device when the expandable device is contained within the aneurysm.

17. The system of claim 16, wherein the shrinking means includes an electrical power supply coupled to the expandable device.

18. The system of claim 17, wherein the electrical power supply is an RF generator.

19. The system of claim 18, wherein the expandable device acts as an electrode and is electrically coupled to the RF generator.

20. The system of claim 16, wherein the shaft has a lumen passing therethrough.

21. The system of claim 20, further comprising:

a source of conductive fluid coupled to the lumen.

22. The system of claim 16, wherein the shrinking means is a device selected from the group consisting of RF, resistance heating, laser and chemical action.

23. The device of claim 16, wherein the shrinking means heats the fluid passing through the lumen so that the heated fluid shrinks the aneurysm.

24. A method of treating a cerebral aneurysm, comprising the steps of:

providing an expandable structure movable from a collapsed shape to an expanded shape, the expandable structure having a deforming portion which is displaced beyond the yield strength when moving from the collapsed position to the expanded position;

introducing the expandable structure into a blood vessel of a patient;

advancing the expandable structure through the patient's vasculature to a cerebral aneurysm while the expandable structure is in the collapsed position;

moving the expandable structure into the cerebral aneurysm;

expanding the expandable structure to the expanded position in the cerebral aneurysm; and

leaving the expandable structure in the aneurysm after the expanding step.

25. The method of claim 24, wherein the providing step is carried out with the expandable structure occupying a volume of at least 50-70%.

26. The method of claim 24, wherein the providing step is carried out with the expandable structure having a maximum opening size of no more than 15 mm when in the expanded position.

27. The method of claim 24, wherein the providing step is carried out with the expandable structure having first and second ends, the deforming portion extending between the first and second ends; and

the expanding step is carried out with the first and second ends moving toward one another so that the deforming portion plastically deforms.

28. The method of claim 27, wherein the providing step is carried out with the deforming portion including at least three posts extending between the first and second ends.

29. The method of claim 24, wherein the providing step is carried out with the deforming portion holding a number of flexible filaments in the expanded position, the flexible filaments being deformed elastically when in the expanded position.

30. A device for introduction into a cerebral aneurysm, comprising:

a first end having a first hub;

a second end having a second hub; and

an expandable structure extending between the first and second ends, the expandable structure being movable from a collapsed shape to an expanded shape, the expandable structure having at least two filaments extending between the first and second hubs, the first and second hubs moving toward one another when the expandable structure moves from the collapsed position to the expanded position.

31. The device of claim 30, further comprising:

a locking mechanism which locks the expandable structure in the expanded position.

32. The device of claim 30, further comprising:

a fluid flow path extending through the expandable structure for introduction of a fluid into the aneurysm.

33. The device of claim 30, wherein the expandable structure is naturally biased toward the collapsed condition.

34. A method of treating an aneurysm in the cerebral vasculature of a patient, comprising the steps of:

providing a device having first and second ends and an expandable structure extending between the first and second ends, the expandable structure being movable from a collapsed shape to an expanded shape, the device also having a locking mechanism for locking the expandable structure in the expanded position;

introducing the device into the patient's vascular system with the expandable structure in the collapsed position;

advancing the device through the patient's vascular system with the expandable structure in the collapsed condition;

positioning the device into an aneurysm in the patient's cerebral vasculature;

expanding the expandable structure of the device after the positioning step; and

locking the locking mechanism to hold the expandable structure in the expanded position.

35. The device of claim 34, wherein the providing step is carried out with the expandable structure being naturally biased toward the collapsed position when in the expanded position.

36. The device of claim 34, wherein the providing step is carried out with the expandable structure having a mesh structure.

37. The device of claim 34, wherein the providing step is carried out with the expandable structure having a number of elongate members extending between the first and second ends.

38. The device of claim 34, further comprising the step of:

heating the aneurysm to shrink the aneurysm.

39. The device of claim 34, wherein the heating step is carried out with a heated fluid.

40. The device of claim 34, wherein the heating step is carried out by delivering electrical energy to the expandable portion.

41. The device of claim 34, wherein the providing step is carried out with the expandable structure being substantially cylindrical in the collapsed position, the expandable structure having a longitudinal axis;

the expanding step being carried out with the expandable structure moving radially outward relative to the longitudinal axis.

42. The device of claim 34, wherein the first and second ends move towards one another by a distance of 10-15 mm, the expandable structure having a diameter, the diameter increasing at a portion of the expandable structure between 0.020 and 0.600 inch when moving from the collapsed position to the expanded.

43. A method of treating a cerebral aneurysm, comprising the steps of:

providing a catheter having a cover;

passing the catheter through a patient's cerebral vasculature to an aneurysm;

positioning the cover over the neck of the aneurysm; and

shrinking the aneurysmal wall.

44. The method of claim 43, wherein the shrinking step is carried out by heating the aneurysmal wall.

45. The method of claim 43, wherein the providing step is carried out with the catheter including a lumen having an outlet.

46. The method of claim 45, further comprising:

introducing a fluid into the aneurysm through the lumen.

47. The method of claim 43, further comprising the step of:

introducing an electrode in the aneurysm; and

the shrinking step being carried out by delivering electrical energy to the electrode to heat the aneurysmal wall.

48. The method of claim 47, wherein the electrode introducing step is carried out with the electrode being on a guidewire passing through a lumen in the catheter.

49. The method of claim 48, further comprising the step of:

introducing a second electrode into the patient.

50. The method of claim 49, wherein the second electrode is introduced on the guidewire.

51. The method of claim 49, wherein the second electrode is introduced on the catheter.

52. The method of claim 43, wherein the covering step is carried out with the cover being permeable.

53. The method of claim 43, further comprising the step of:

delivering a substance into the aneurysm after the shrinking step, the substance remaining in the aneurysm to seal the aneurysm.

54. The method of claim 53, wherein the delivering step is carried out with the substance being selected from the group consisting of cyanoacrylates, ethylene vinyl-alcohol, cellulose acetate polymers, and fibrin glues.

55. The method of claim 43, wherein the cover is composed of silicone.

56. A method of treating an aneurysm, comprising the steps of:

providing an expandable device movable from a collapsed position to an expanded position, the expandable device having a first section and a second section;

passing the expandable device through a patient's cerebral vasculature;

introducing the expandable device into an aneurysm in the patient's cerebral vasculature;

expanding the expandable device to the expanded position with the first section positioned adjacent to the neck of the aneurysm and the second section positioned further into the aneurysm;

coupling the expandable device to a source of electric power;

delivering the electric power to the expandable device so that the aneurysm is heated thereby shrinking the aneurysm, the heat being generated by the second section and not the first section so that the neck of the aneurysm is protected.

57. The method of claim 56, wherein the providing step is carried out with the expandable device being permeable when in the expanded position.

58. The method of claim 56, wherein the coupling step is carried out with the source of electric power being an RF generator.

59. The method of claim 56, wherein the delivering step is carried out with the electric power being monopolar RF with the second section acting as the electrode.

60. The method of claim 56, wherein the delivering step is carried out so that the aneurysm shrinks and contacts the expandable device so that the expandable device is reduced in size from the expanded position.

61. A method for treating an aneurysm and a parent vessel, comprising the steps of:

providing a catheter and a coil, the catheter having a lumen and the coil being positioned in the lumen, the coil being movable within the lumen to extend and retract the coil from the distal end of the catheter;

introducing the catheter into a patient's vascular system;

advancing the catheter to an aneurysm;

filling the aneurysm with a heated fluid;

positioning the coil in the parent artery so that windings are positioned adjacent the neck of the aneurysm to impede flow between the aneurysm and the parent artery.

62. The method of claim 61, wherein the filling step is carried out by introducing a catheter into the aneurysm through the windings in the coil, the catheter having means for heating fluid.

63. The method of claim 62, wherein the filling step is carried out with the heating means being an RF electrode.

64. The method of claim 61, wherein the providing step is carried out with the coil a first deployed position and a second deployed position, the second deployed position having more coil extended from the distal end of the catheter and having greater pitch than when the coil is in the first deployed position.

65. The method of claim 61, wherein the providing step is carried out with the coil being made of a shape memory alloy.

66. A device for regulating fluid flow between an aneurysm and a parent vessel, comprising:

a catheter including a lumen having a distal end; and

a coil positioned within the lumen, the coil being movable within the lumen to extend or retract the coil from the distal end of the lumen, the coil being extending from the lumen to form a coil.

67. The device of claim 66, wherein the coil is movable from a first deployed position to a second deployed position, the exposed portion of the coil extending from the catheter having a greater pitch in the second deployed position than in the first deployed position and being extended further from the distal end of the catheter.

68. The device of claim 67, wherein the coil forms windings having a diameter of 1 mm to 3 mm.

69. A device for heating tissue, comprising:

a shaft having a lumen;

a tip having a chamber therein and a plurality of holes leading to the chamber, the chamber being fluidly coupled to the lumen so that a fluid delivered through the lumen passes into the chamber and out the plurality of holes; and

an RF electrode configured to deliver RF energy from an RF generator, the RF electrode positioned in the chamber.

70. The device of claim 69, further comprising:

a source of conductive fluid coupled to the lumen.

71. The device of claim 69, wherein the shaft has a size of no more than 5 French.

72. The device of claim 69, wherein the plurality of holes in the tip are positioned along sides of the tip.

73. The device of claim 69, wherein the plurality of holes in the tip are positioned at a distal end of the tip.

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