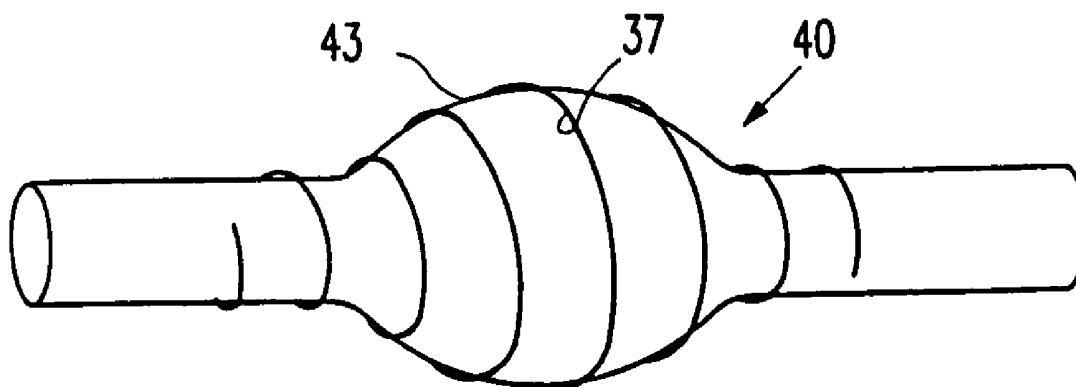


(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2004/0098104 A1**
Sirhan et al. (43) **Pub. Date: May 20, 2004**(54) **METHOD AND DEVICE FOR THE
TREATMENT OF VULNERABLE TISSUE
SITE**(76) Inventors: **Motasim Sirhan**, Sunnyvale, CA (US);
John Yan, Los Gatos, CA (US); **Kevin
Gertner**, Los Gatos, CA (US)

Correspondence Address:

Edward J. Lynch**DUANE MORRIS LLP****One Market****Spear Tower, Suite 2000****San Francisco, CA 94105 (US)**(21) Appl. No.: **10/621,126**(22) Filed: **Jul. 16, 2003****Related U.S. Application Data**(62) Division of application No. 09/717,910, filed on Nov.
20, 2000, now Pat. No. 6,648,911.**Publication Classification**(51) **Int. Cl.⁷** **A61F 2/06**(52) **U.S. Cl.** **623/1.15**(57) **ABSTRACT**

The present invention is directed to method and apparatus for treating vulnerable tissue sites, such as aneurysms in the abdominal area or in the thoracic cavity, and expanded tissues on various organs and body surfaces such as the heart. The apparatus of the present invention, are containment members for at least partially containing the vulnerable tissue site, thus preventing or minimizing the further vulnerability or growth of the site. Additionally, or alternatively, the containment members can apply resistive force to the vulnerable tissue site. The force can be compressive against the exterior surface of the tissue site. The containment members of the present invention can be used alone or in combination with support members, such as stent/grafts, in treating a tissue site. In this embodiment, the support member is disposed within the inner lumen of the vulnerable tissue site with the containment member disposed on the exterior surface of the lumen.



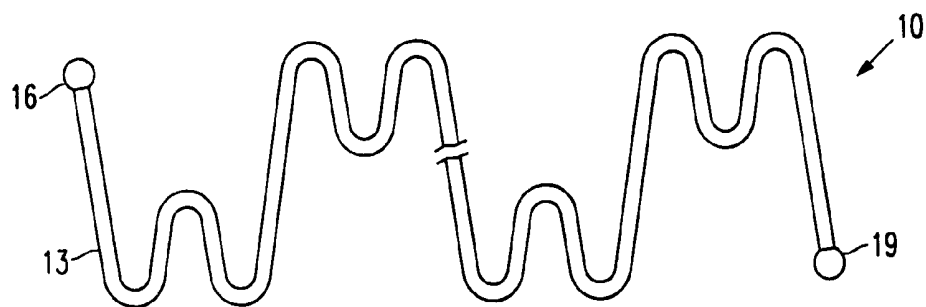


FIG. 1

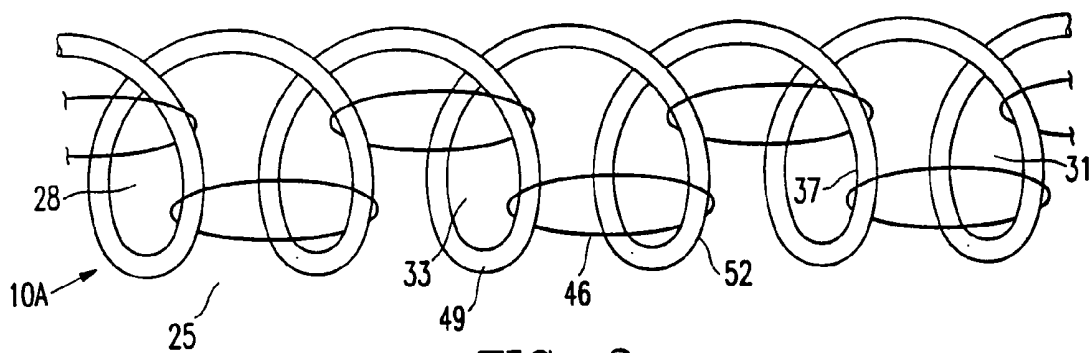


FIG. 2

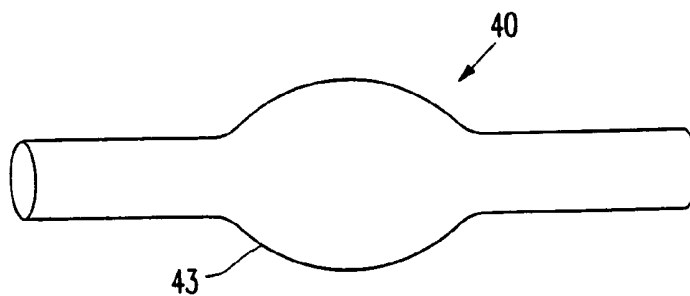


FIG. 3A

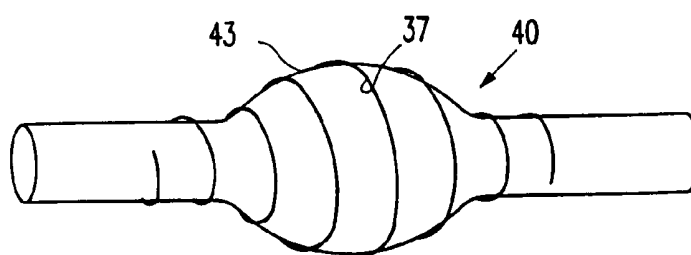


FIG. 3B

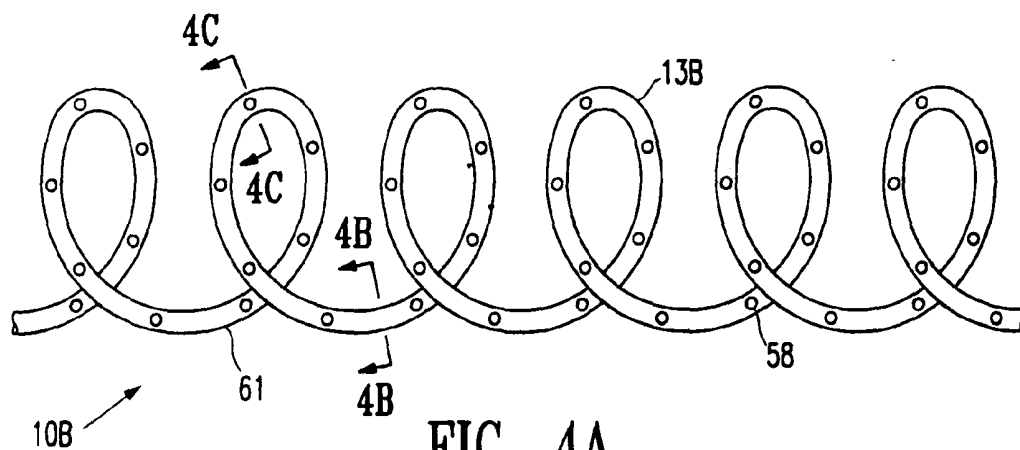


FIG. 4A

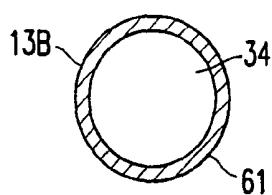


FIG. 4B

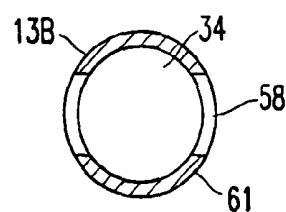


FIG. 4C

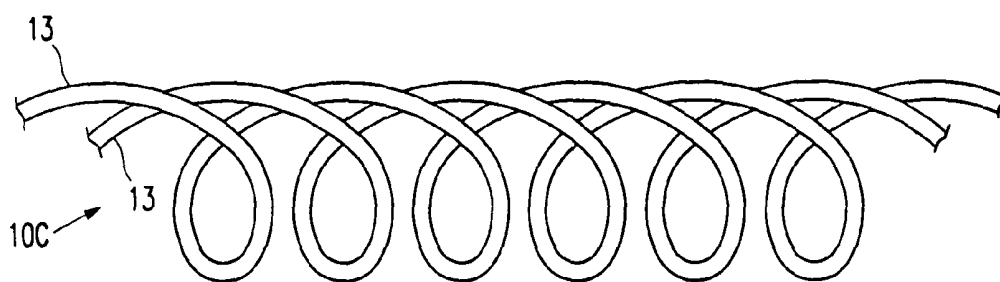


FIG. 5A

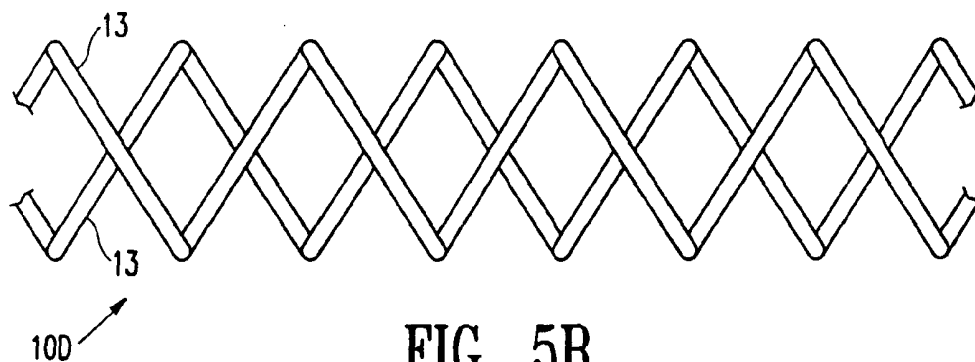


FIG. 5B

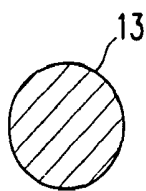


FIG. 6A

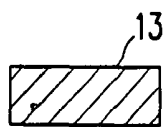


FIG. 6B

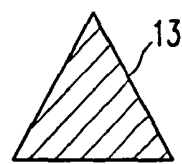


FIG. 6C

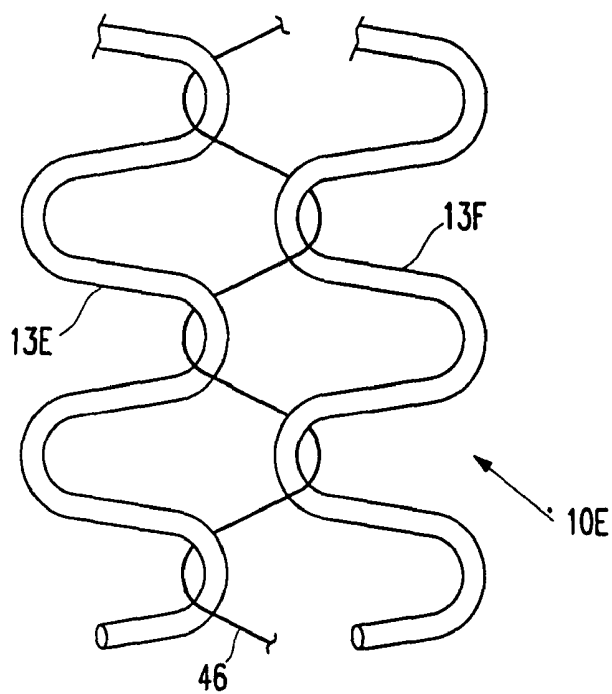


FIG. 7

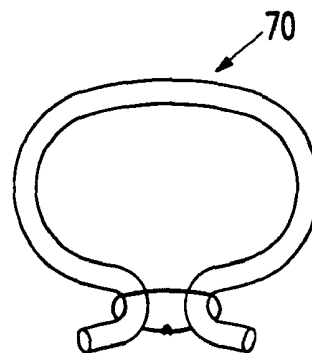


FIG. 8

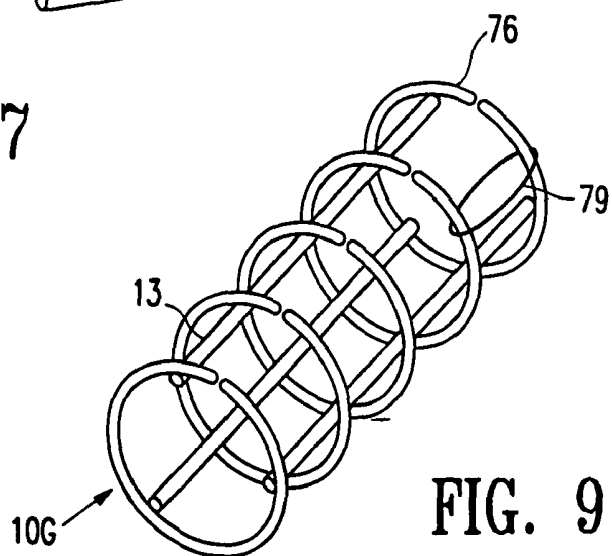
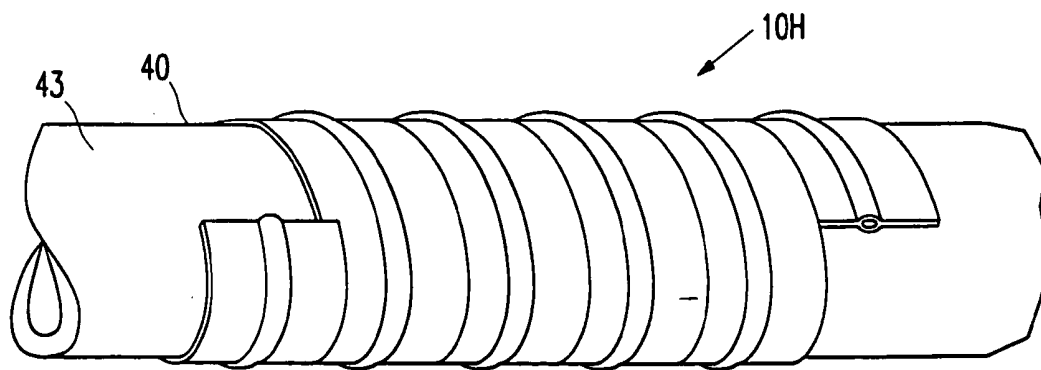
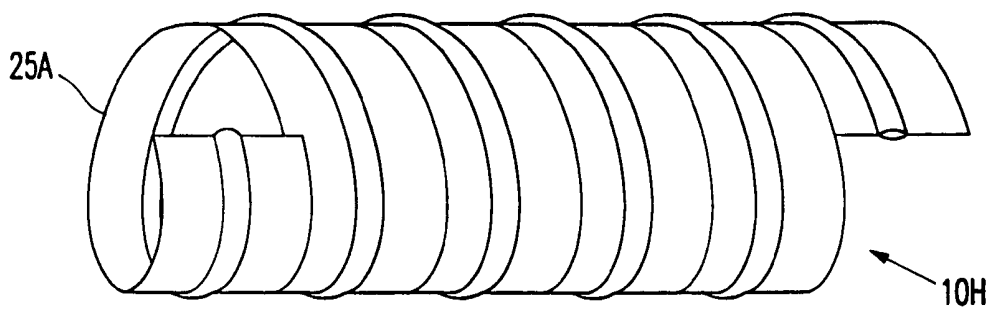
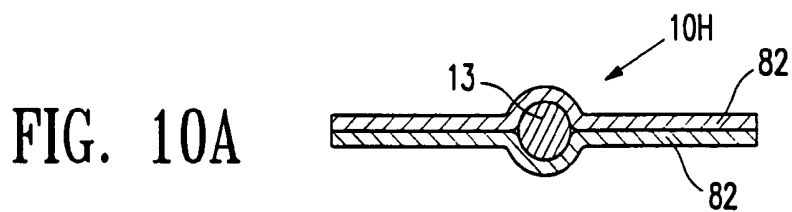
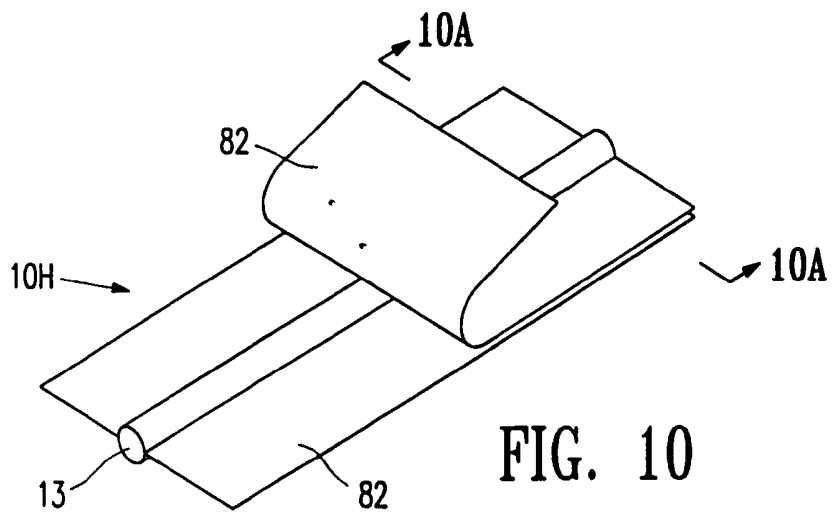


FIG. 9



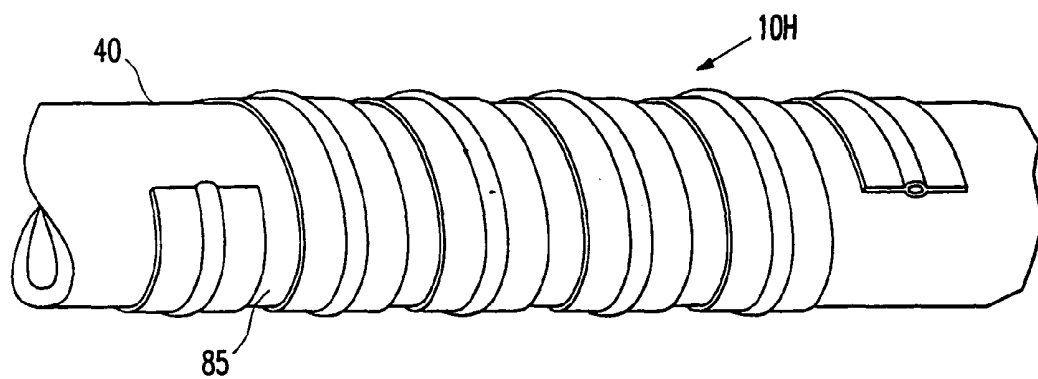


FIG. 11C

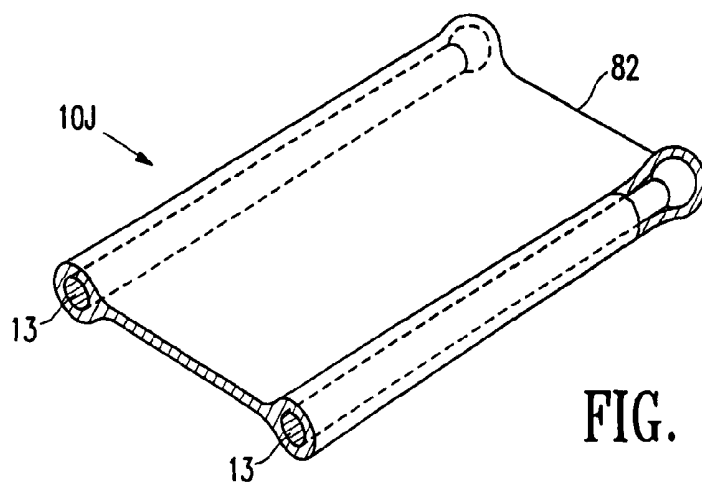


FIG. 12

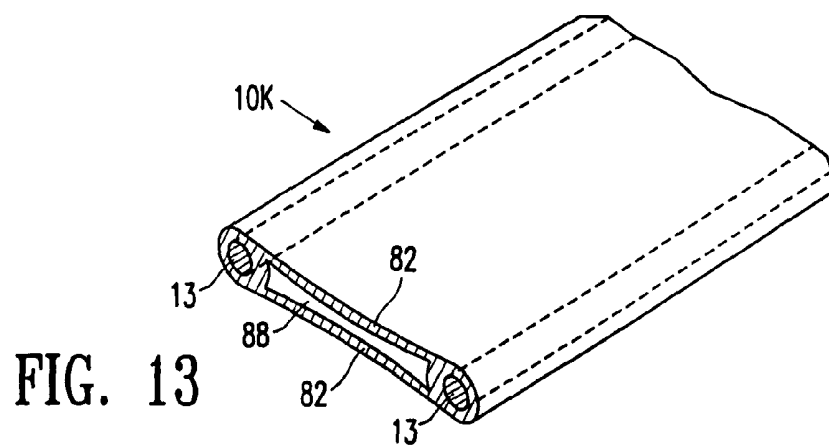
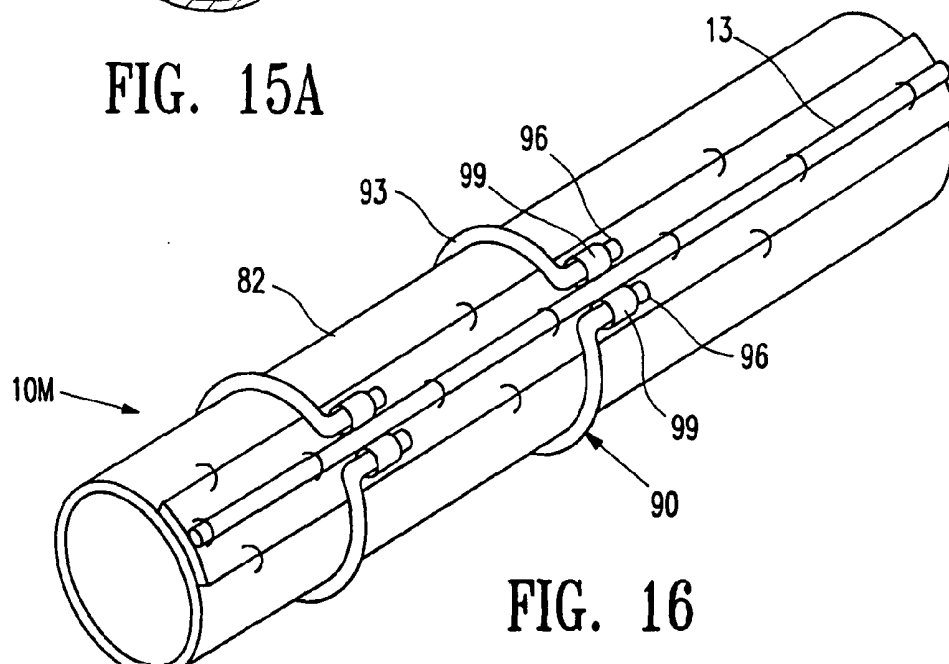
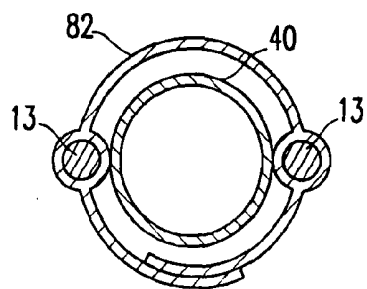
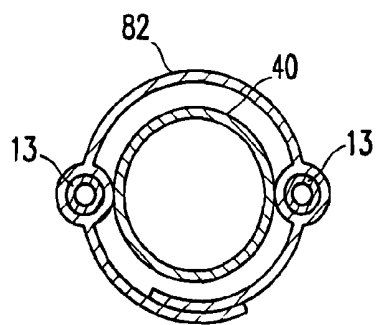
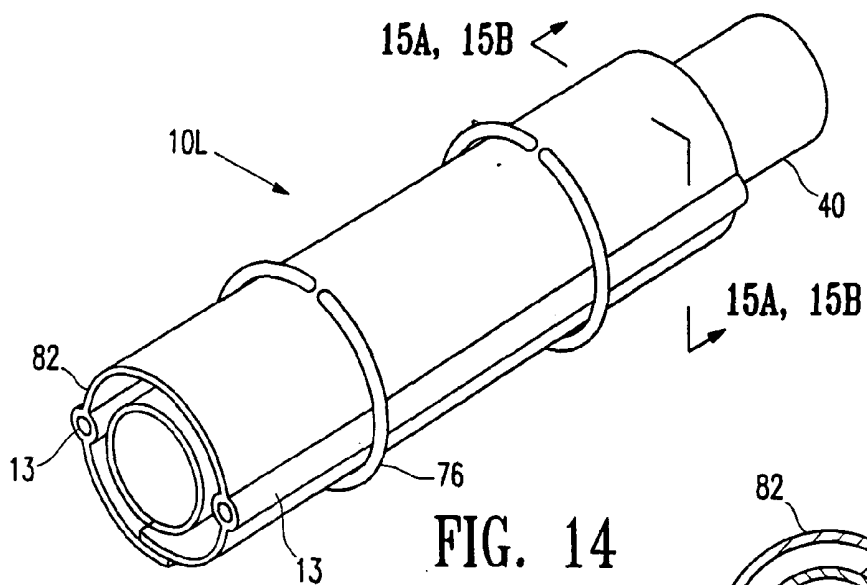


FIG. 13



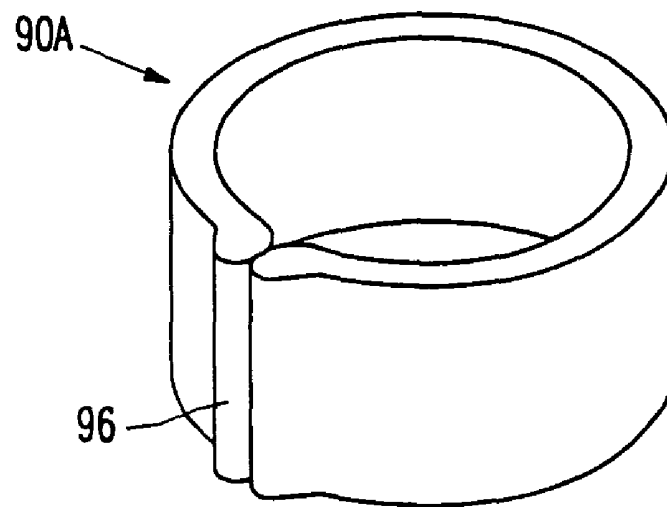


FIG. 17

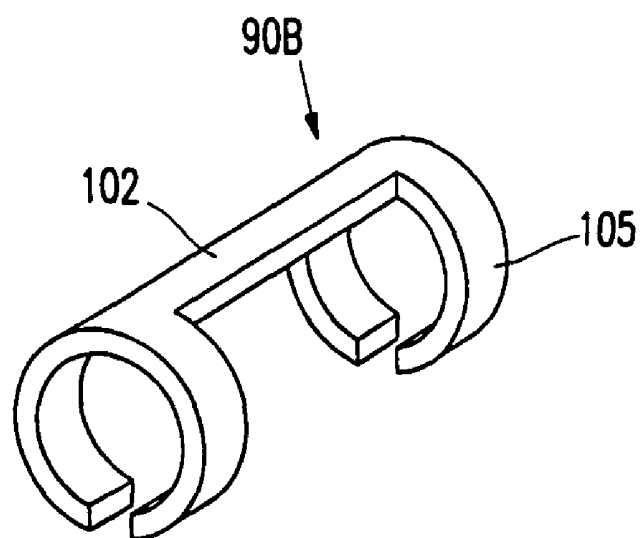


FIG. 18

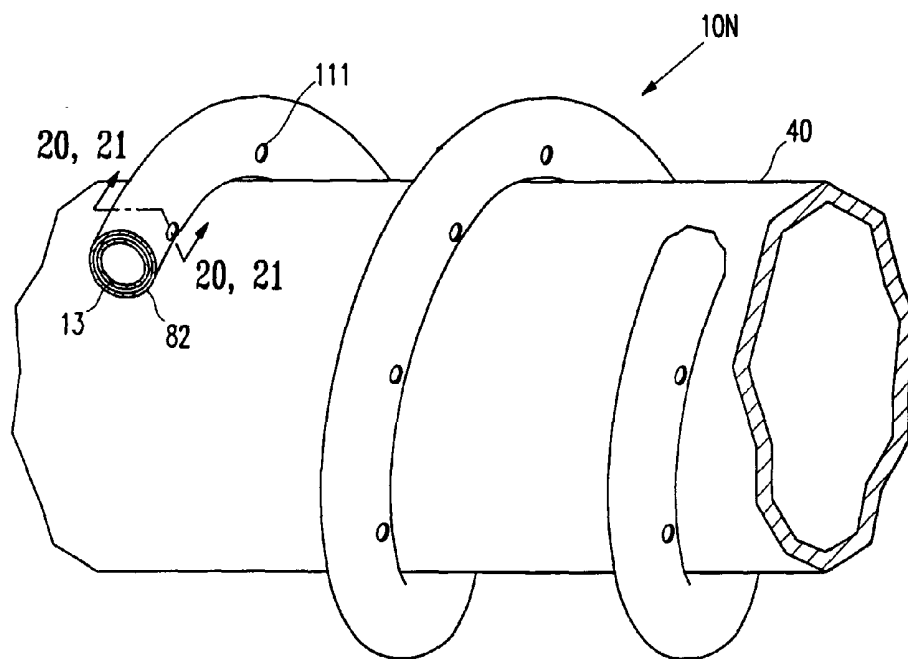


FIG. 19

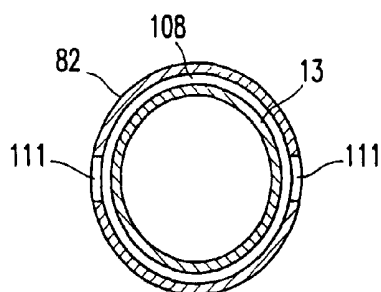


FIG. 20

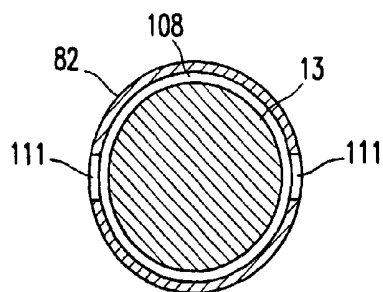
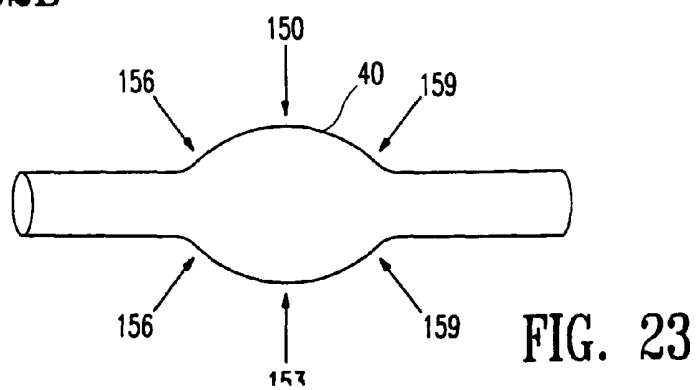
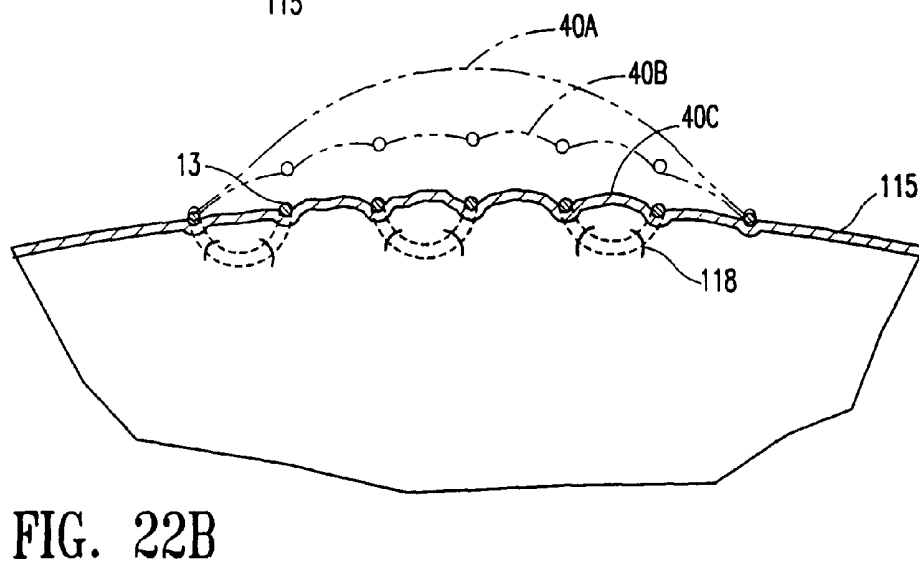
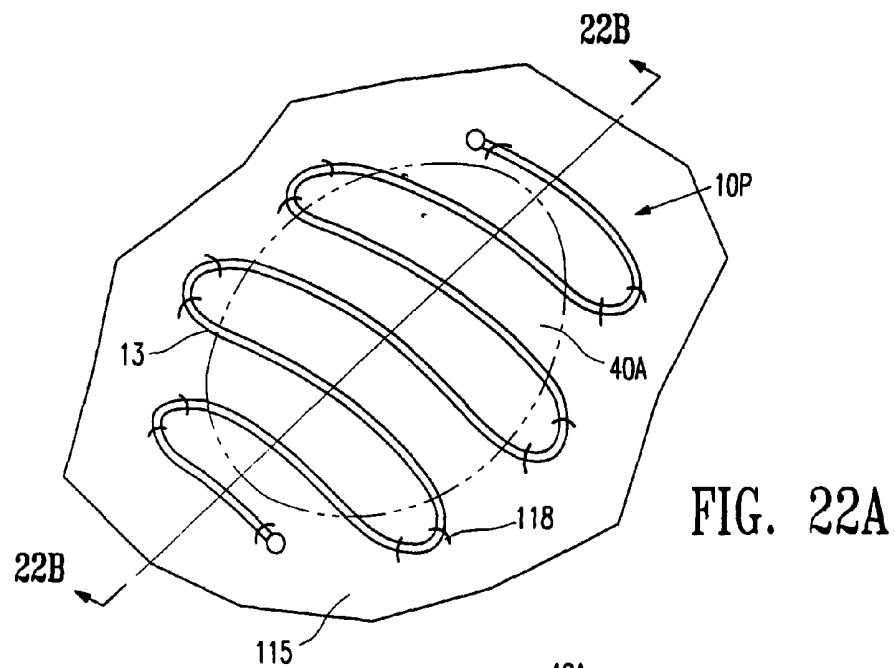


FIG. 21



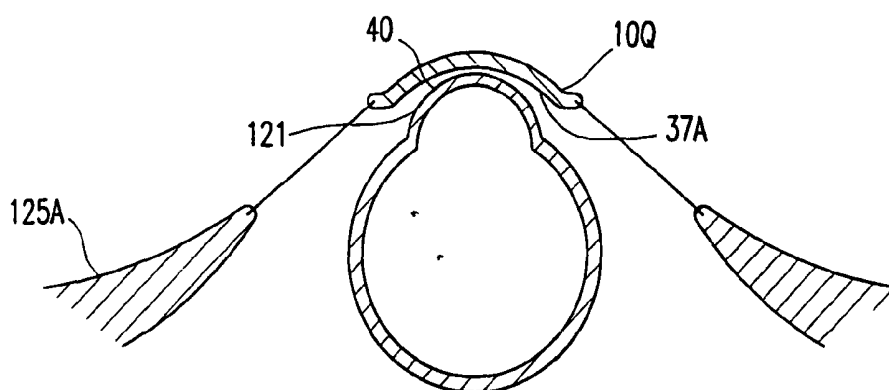


FIG. 22C

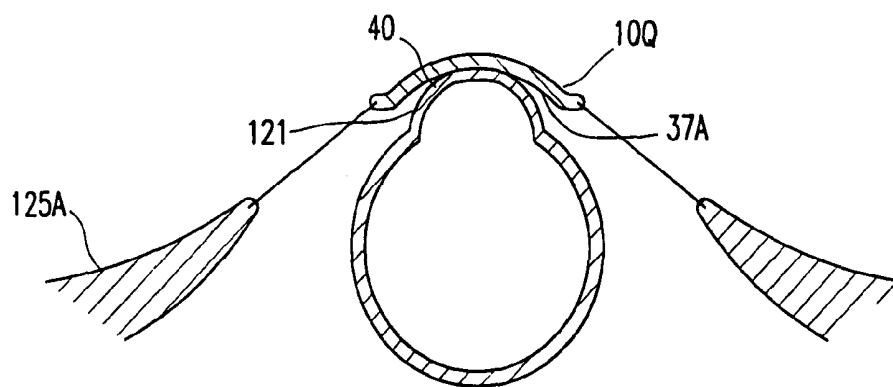


FIG. 22D

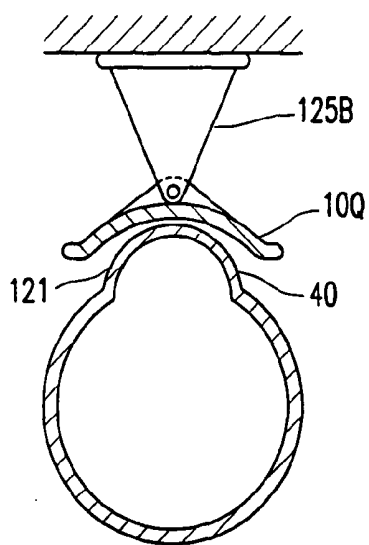


FIG. 22E

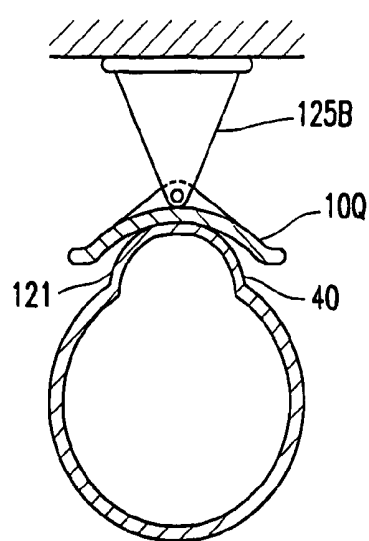
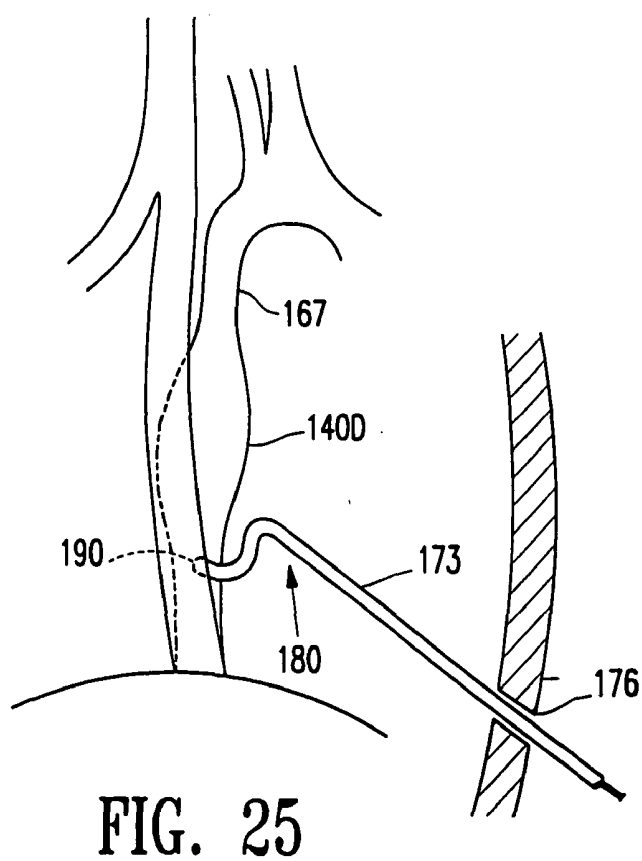
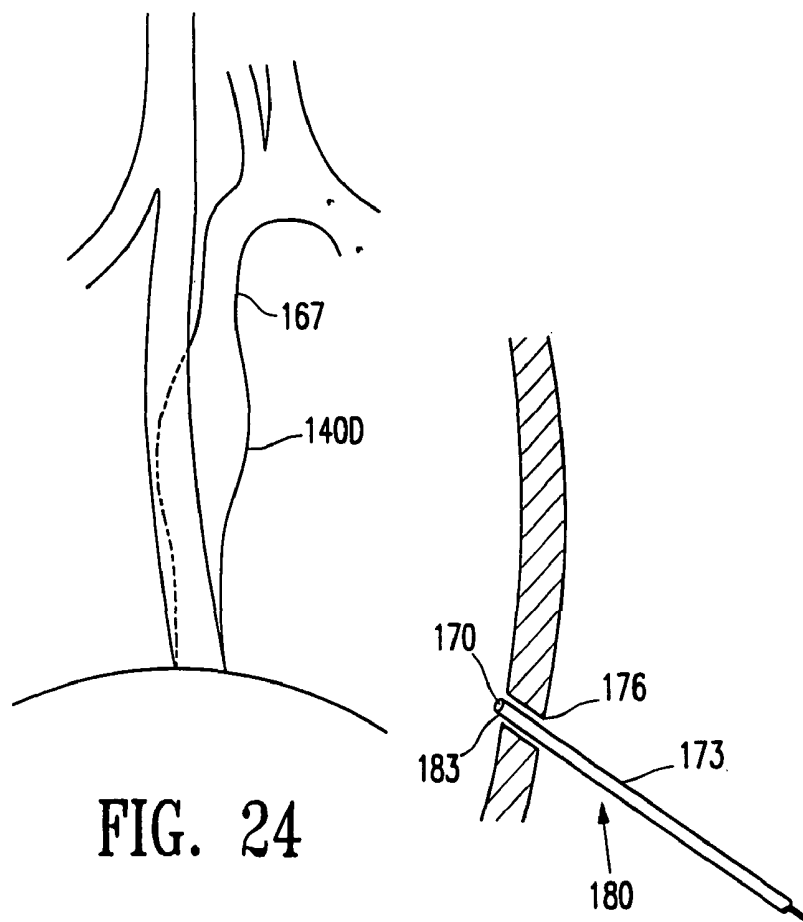


FIG. 22F



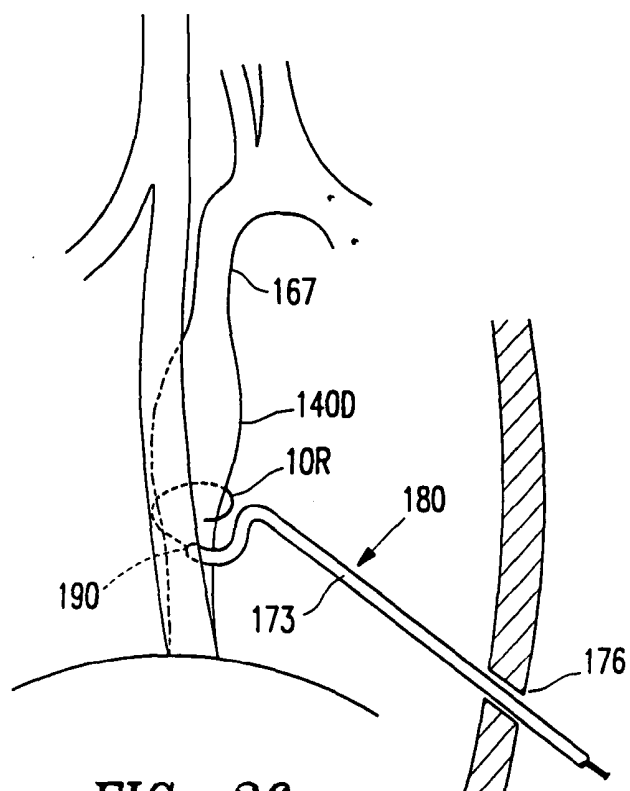


FIG. 26

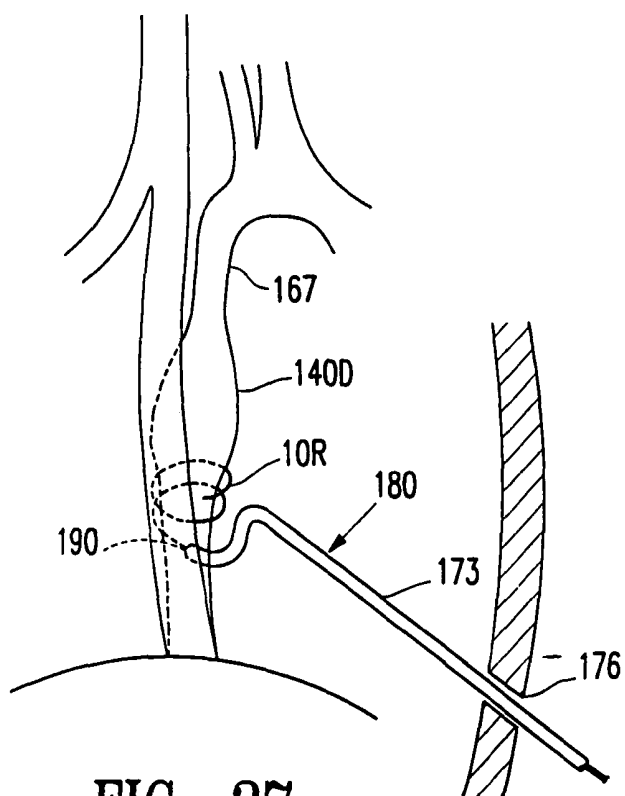
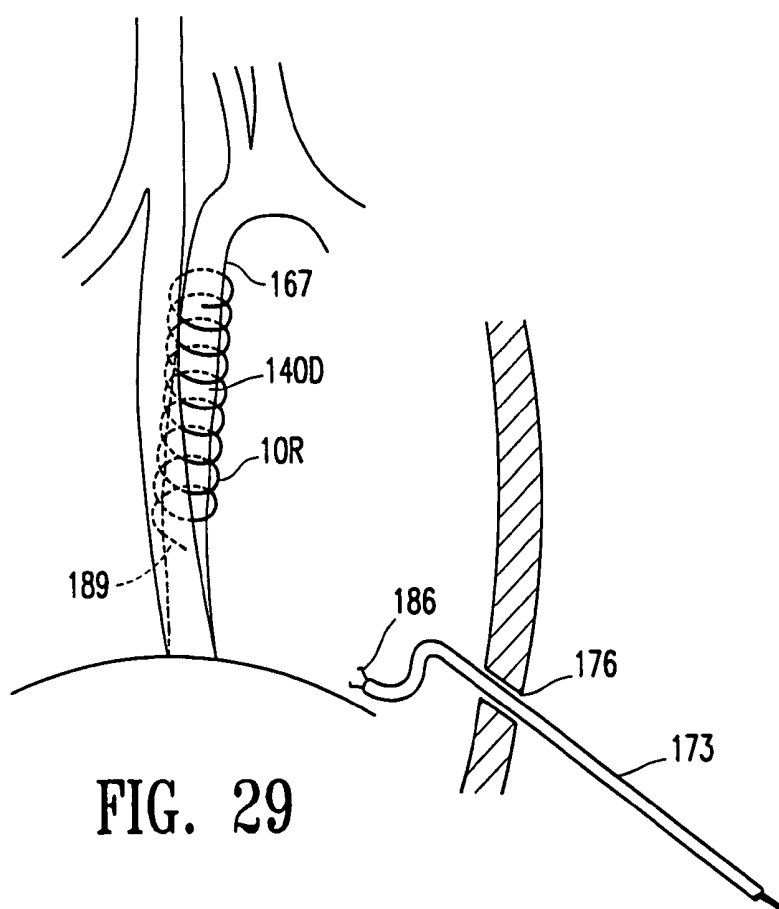
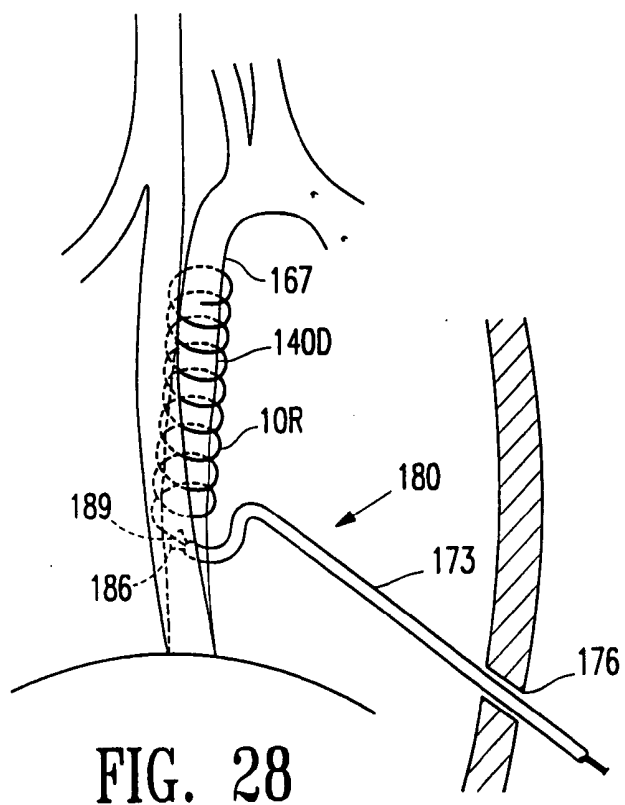


FIG. 27



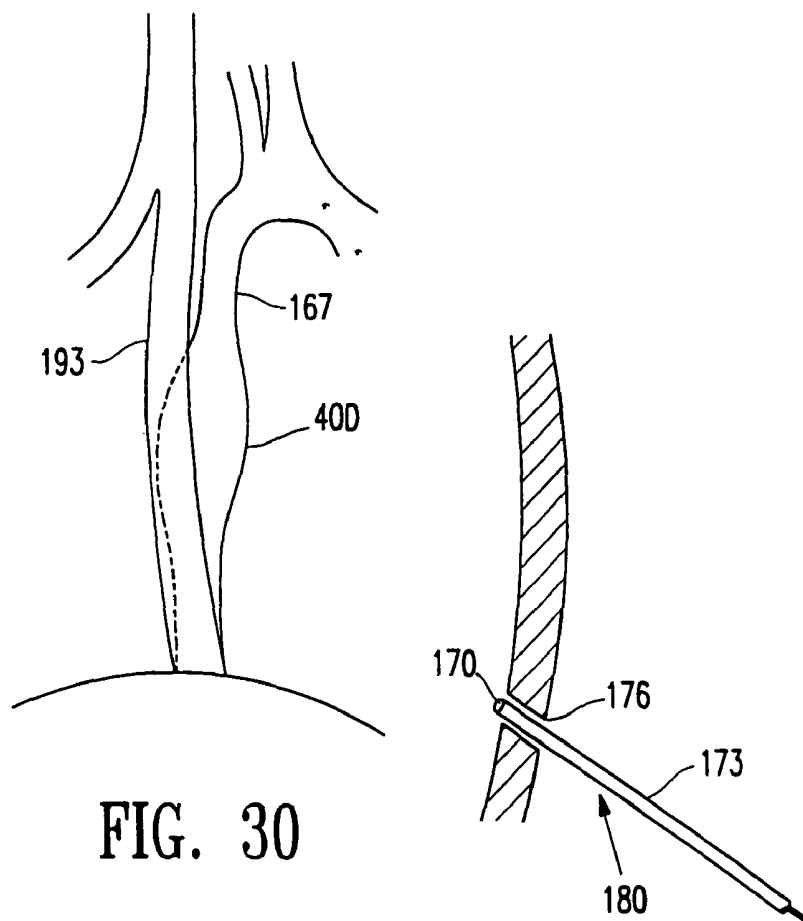


FIG. 30

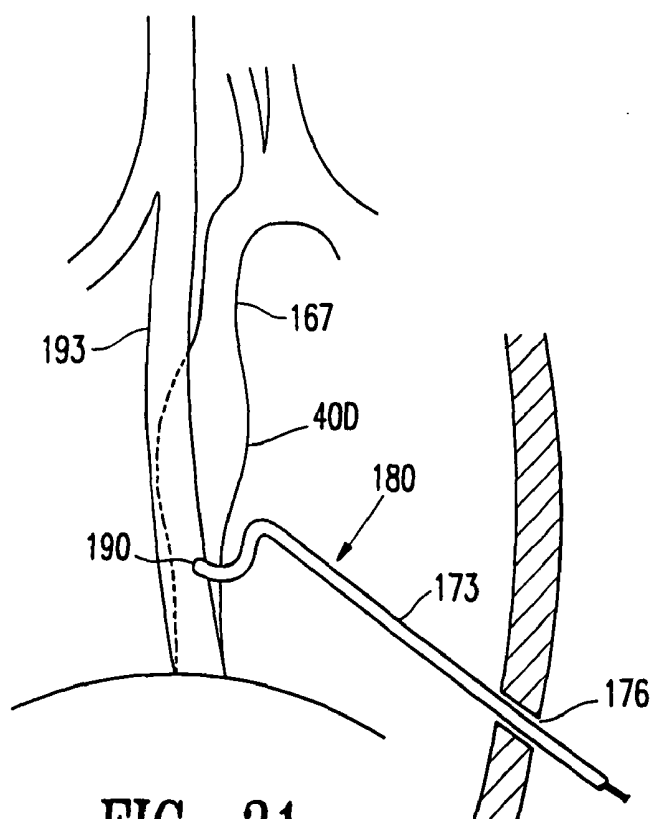


FIG. 31

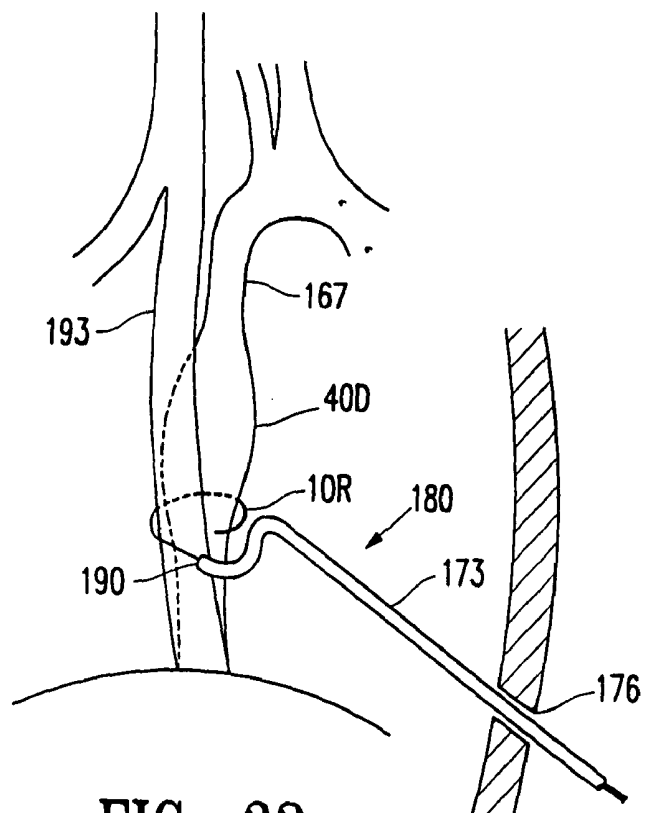


FIG. 32

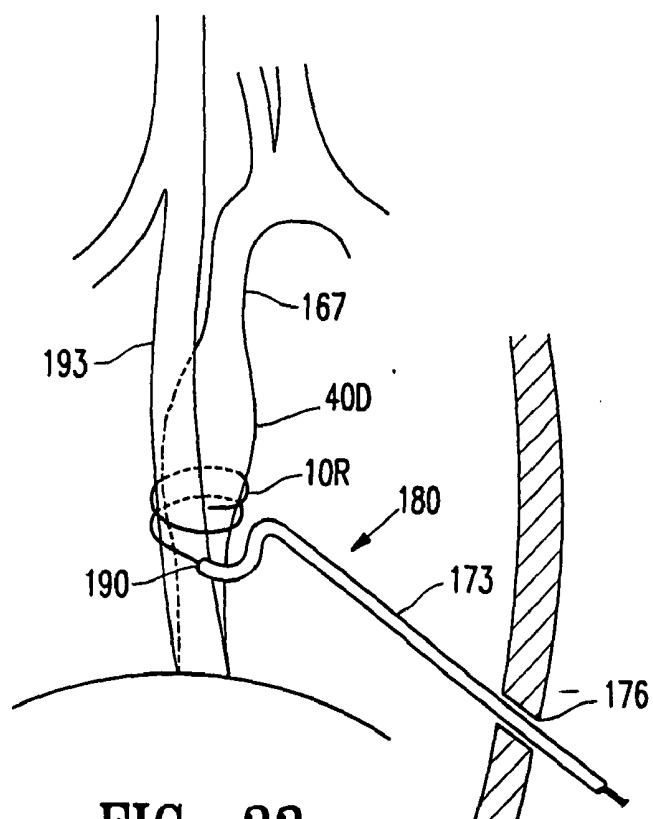
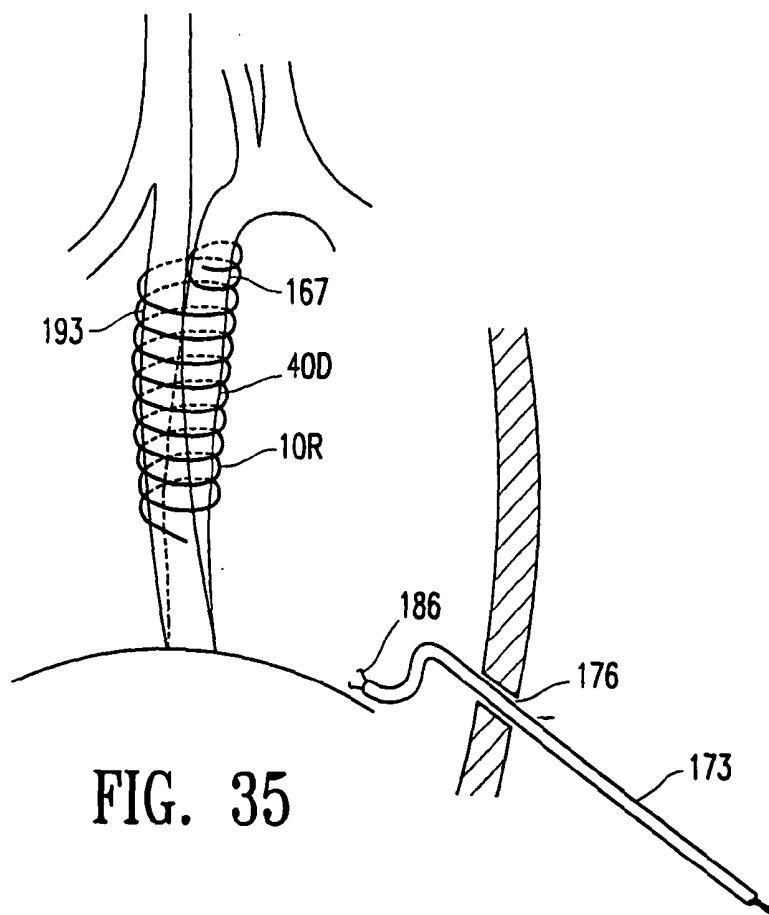
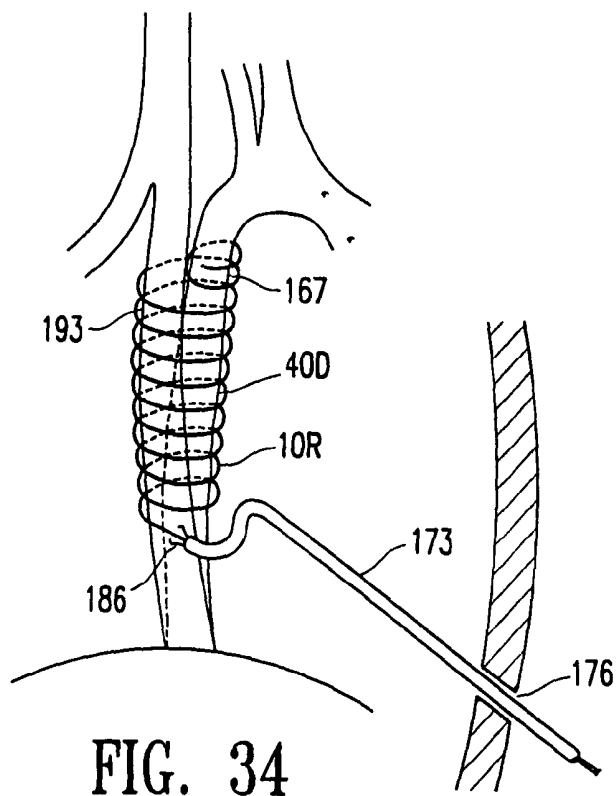
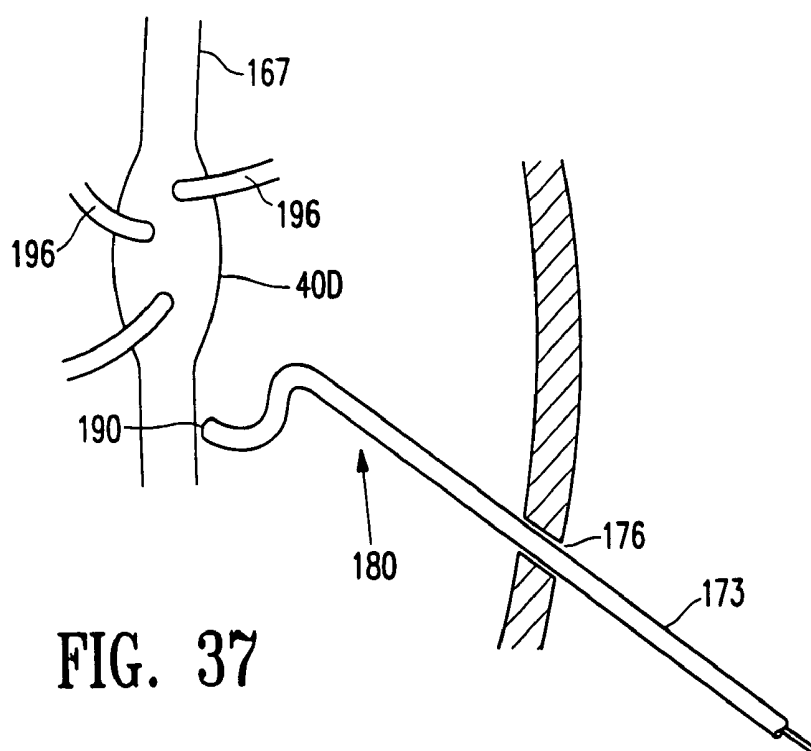
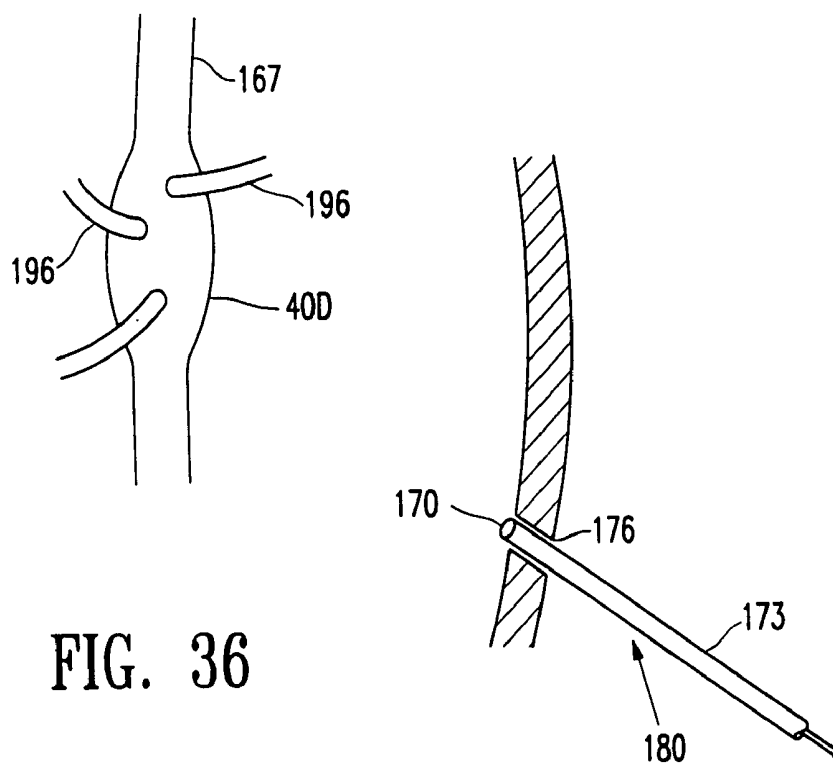
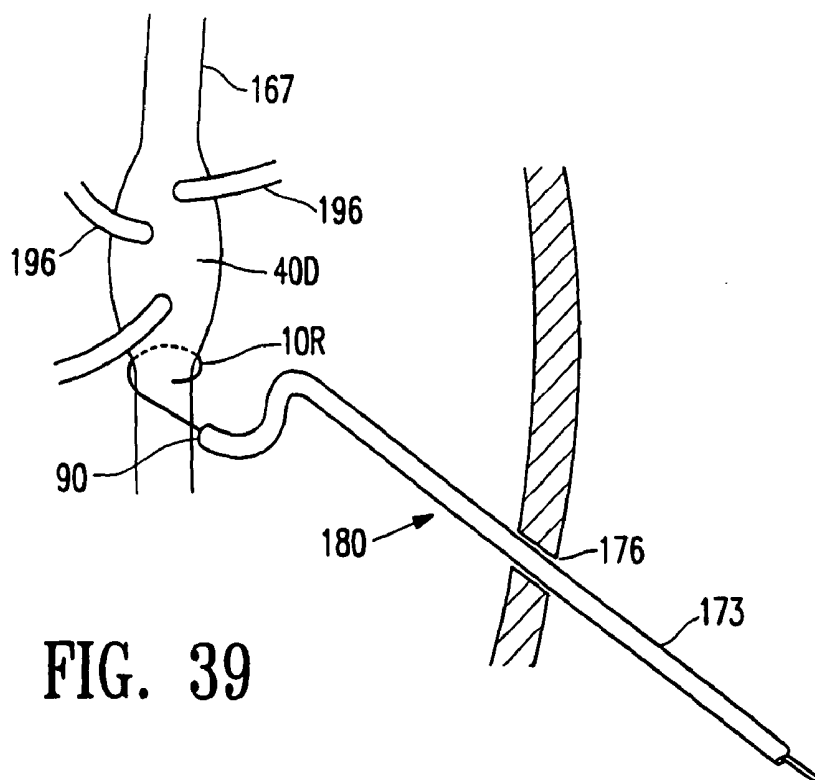
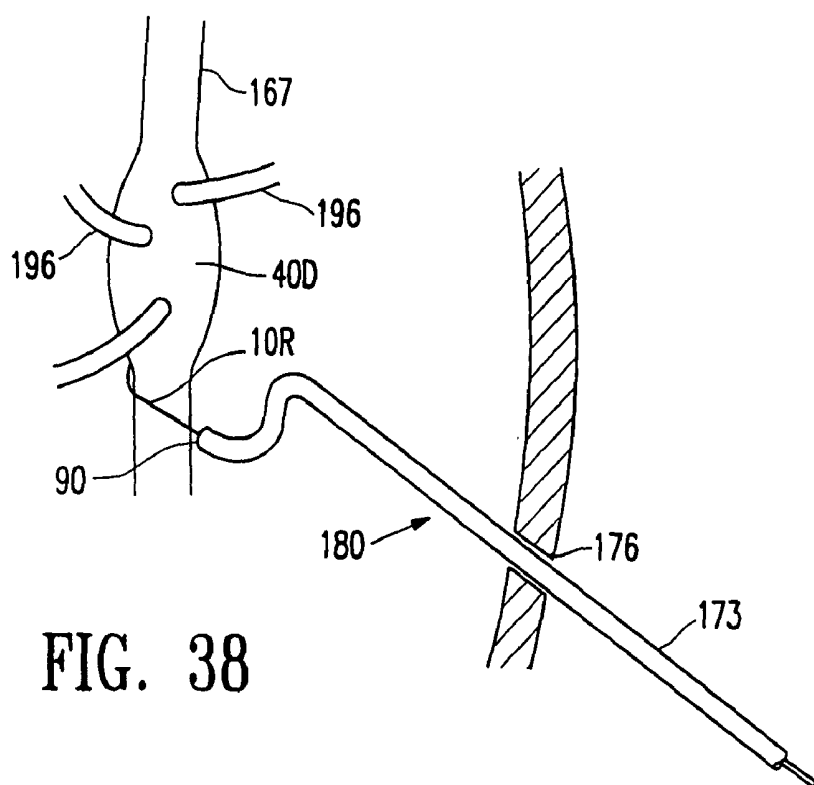


FIG. 33







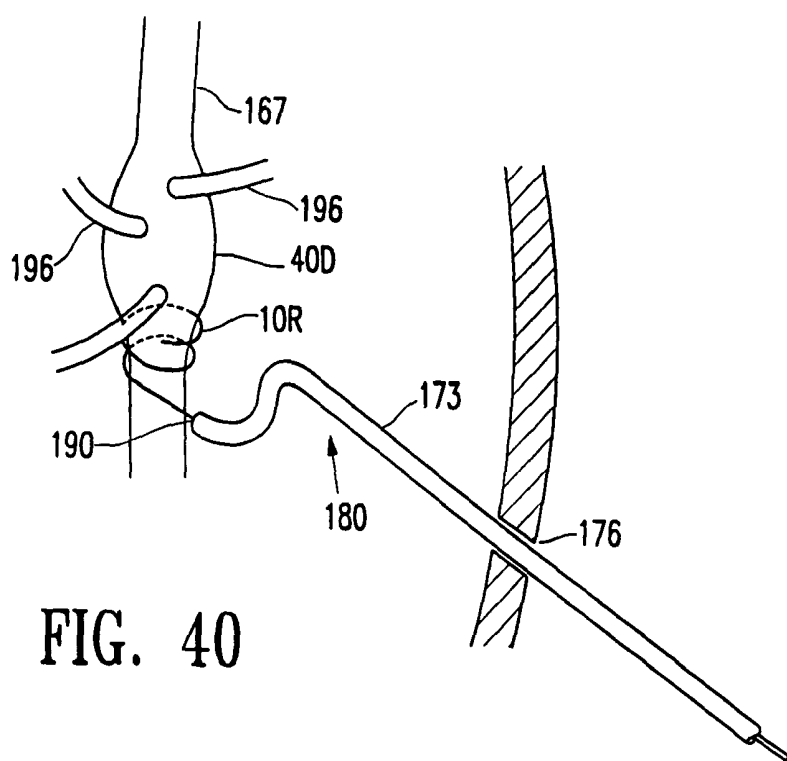


FIG. 40

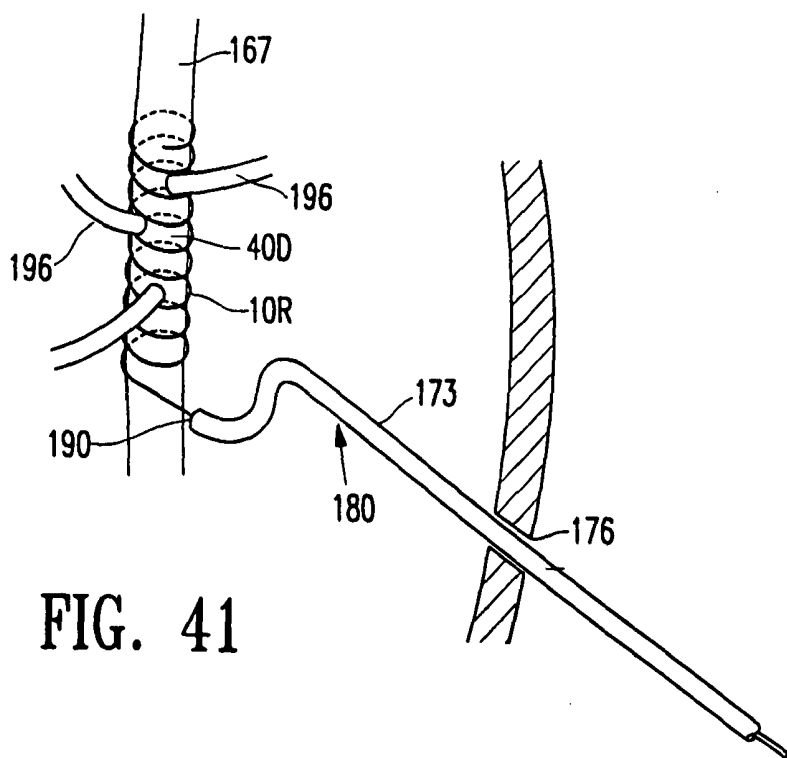


FIG. 41

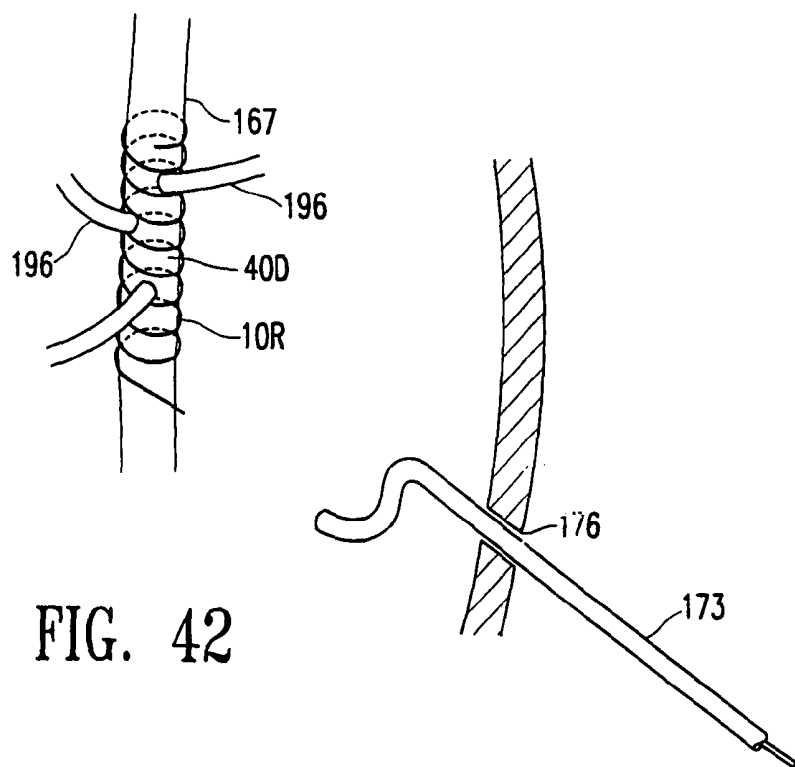


FIG. 42

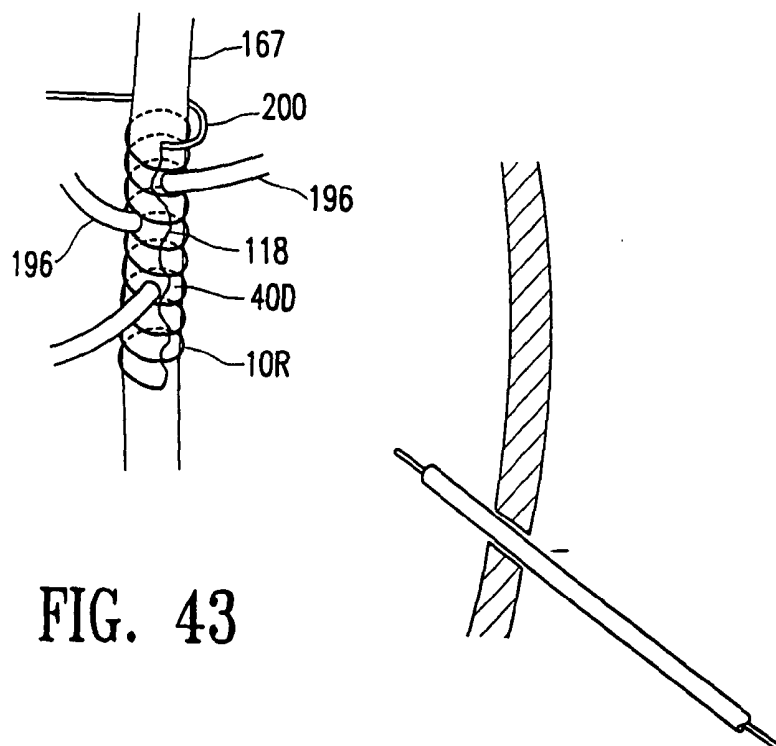


FIG. 43

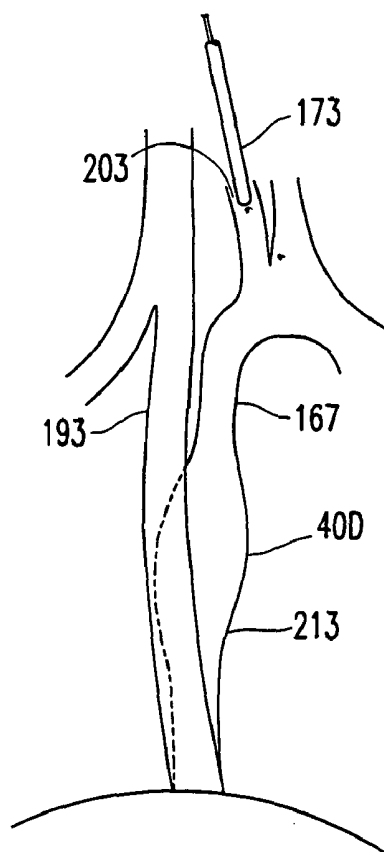


FIG. 44

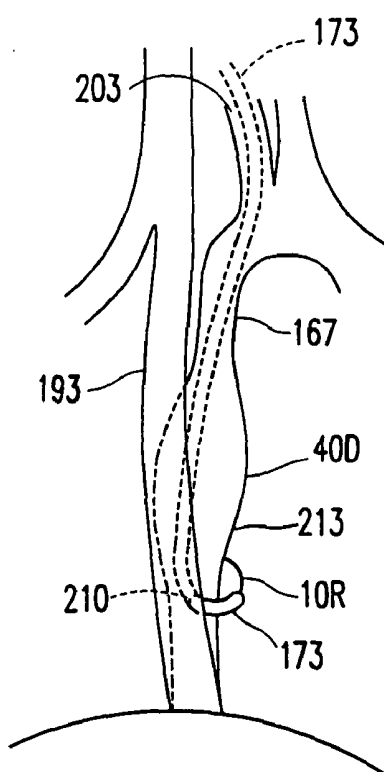


FIG. 45

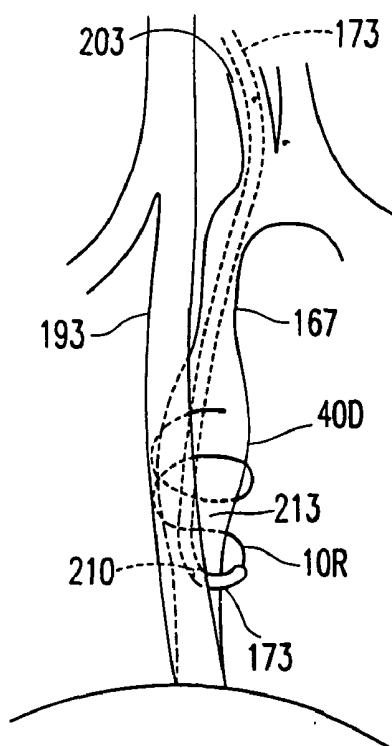


FIG. 46

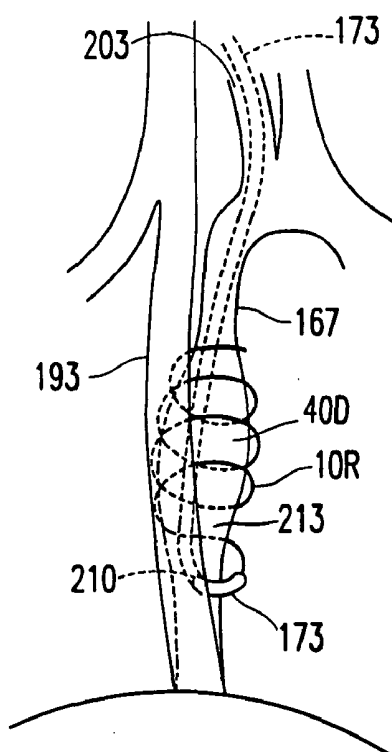


FIG. 47

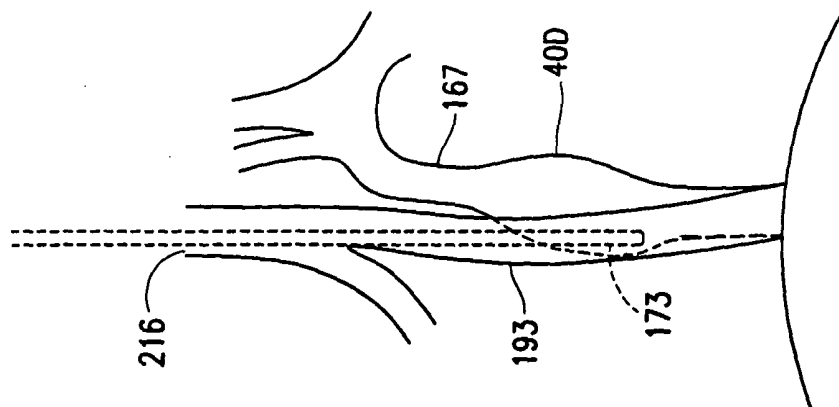


FIG. 48

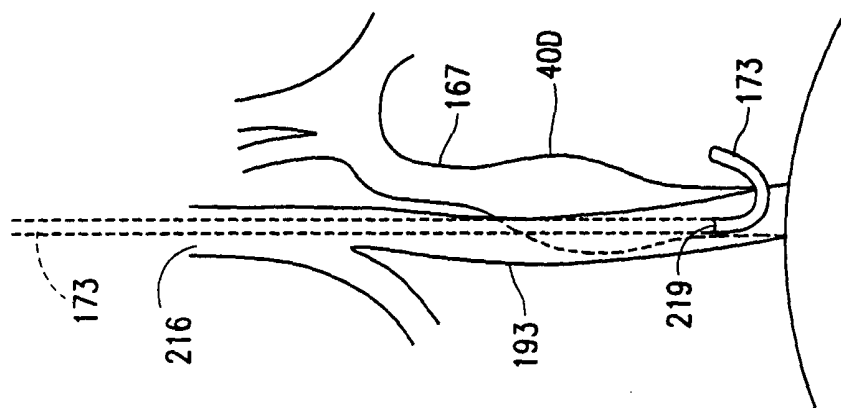


FIG. 49

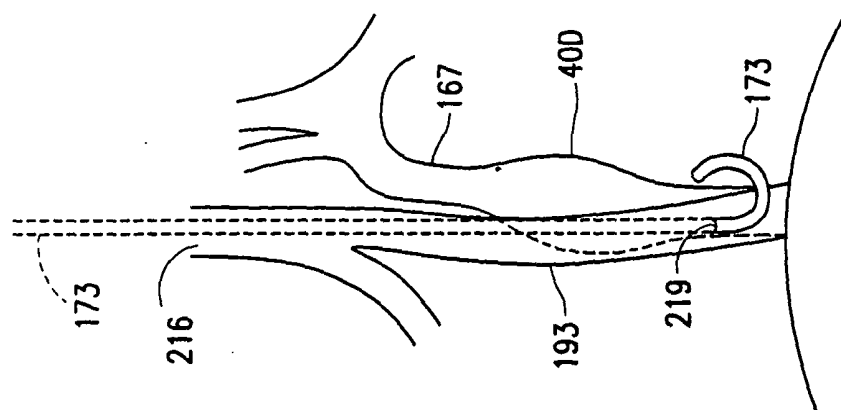


FIG. 50

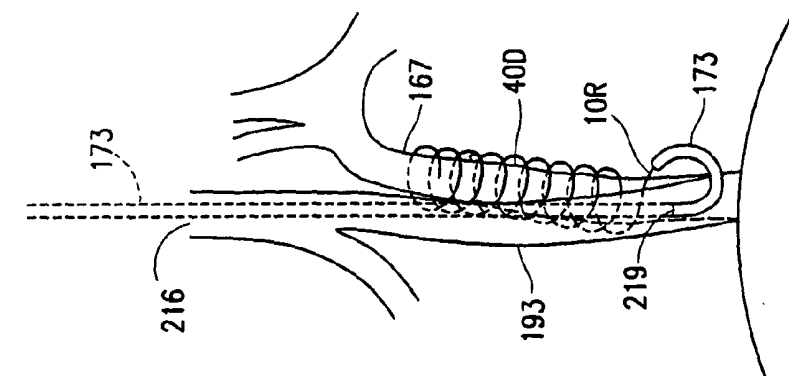


FIG. 51

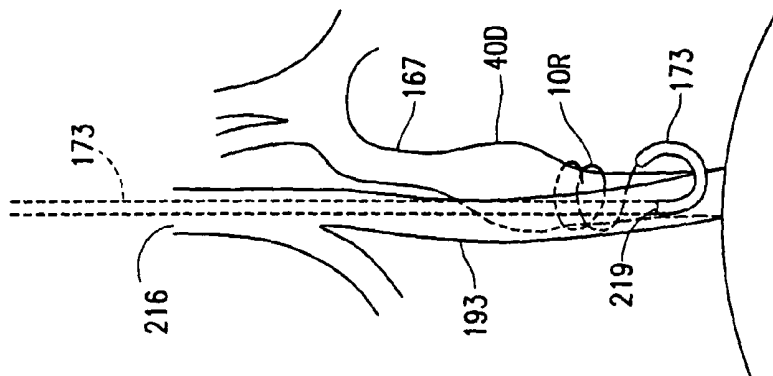


FIG. 52

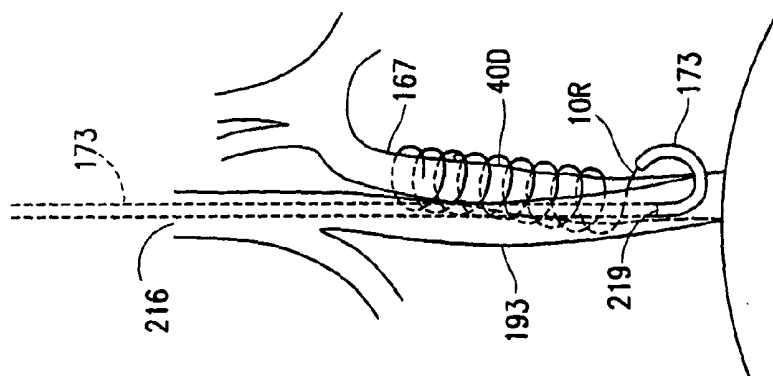


FIG. 53

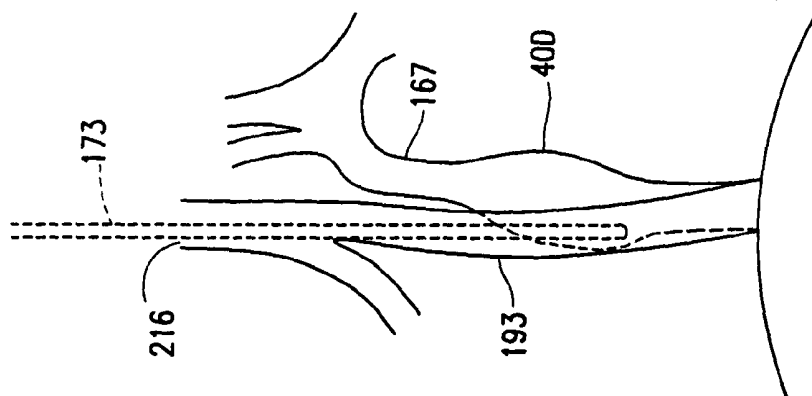


FIG. 54

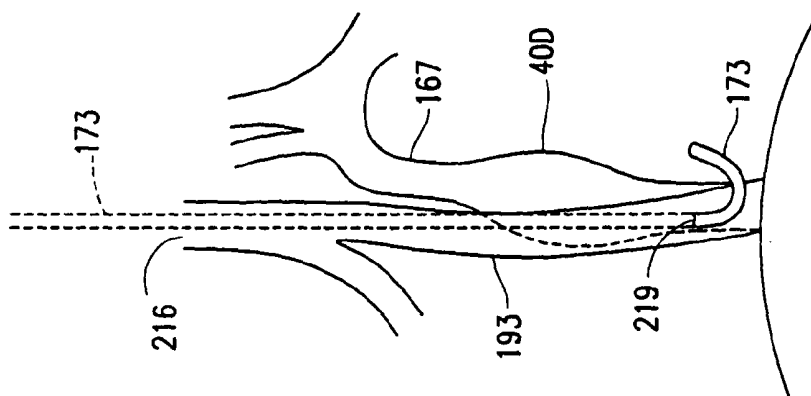


FIG. 55

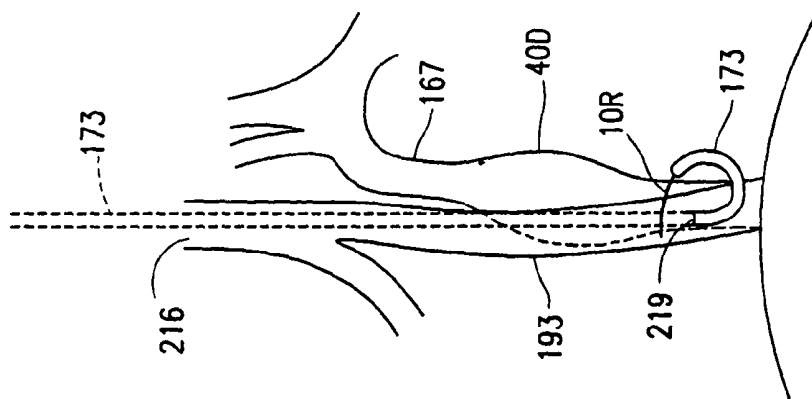


FIG. 56

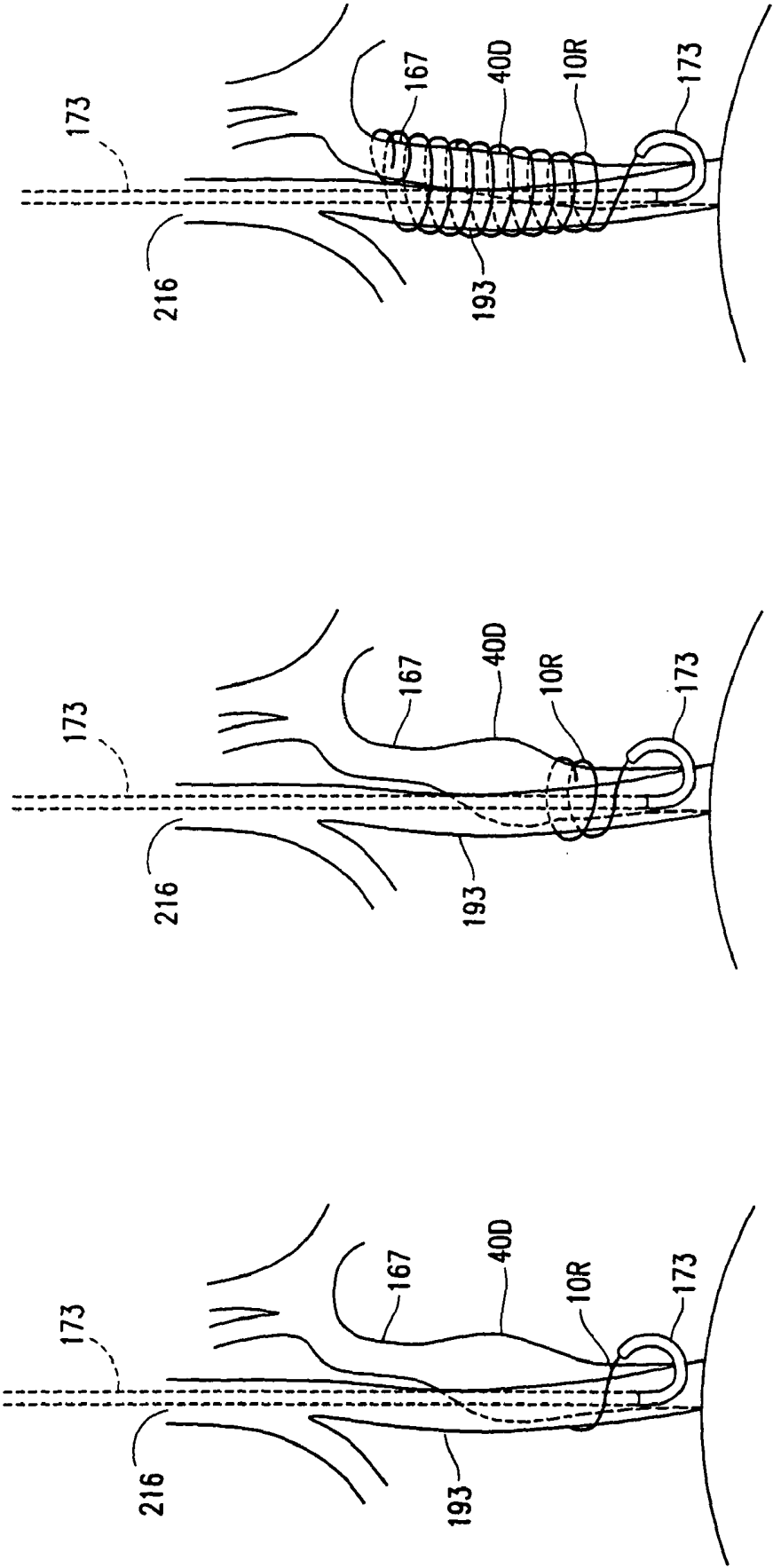


FIG. 59

FIG. 58

FIG. 57

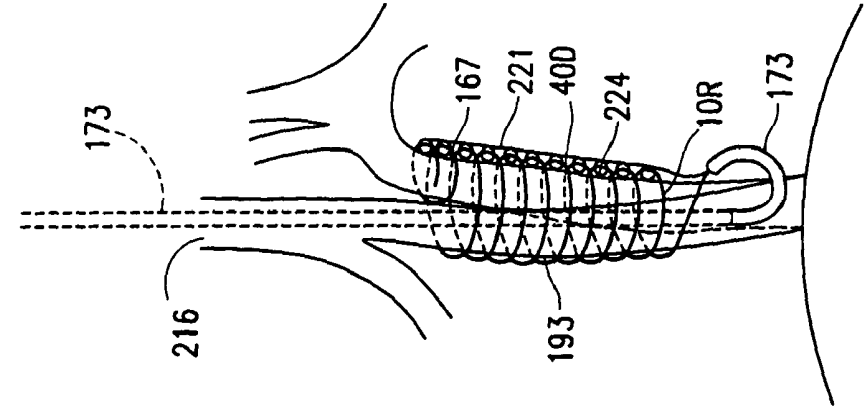


FIG. 60

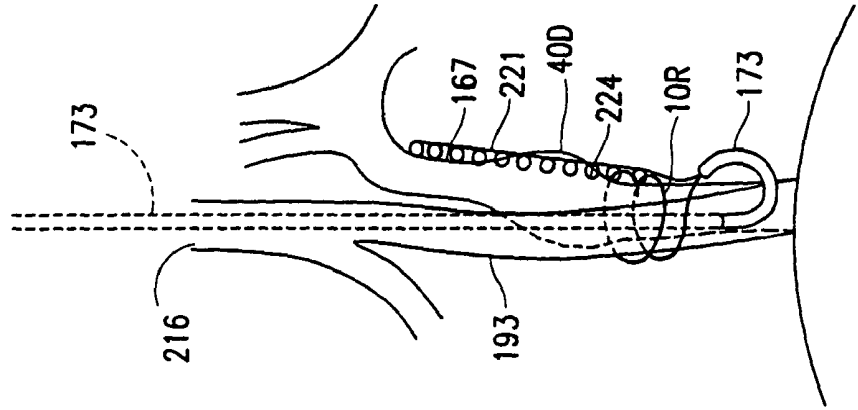


FIG. 61

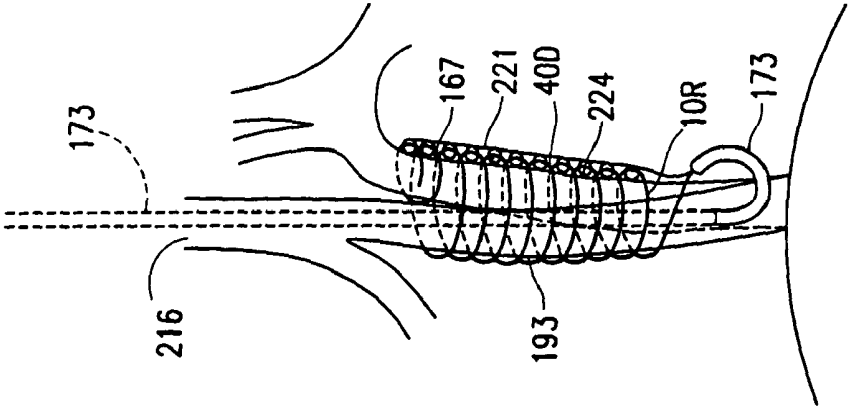


FIG. 62

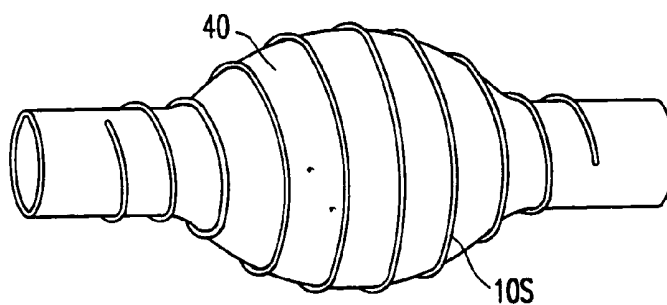


FIG. 63

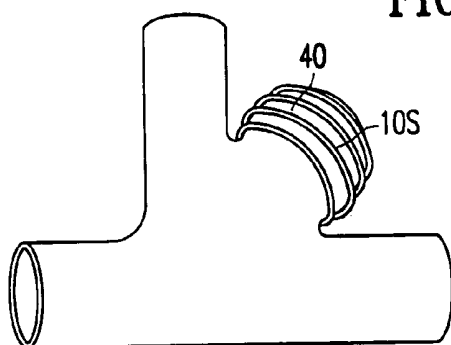


FIG. 64A

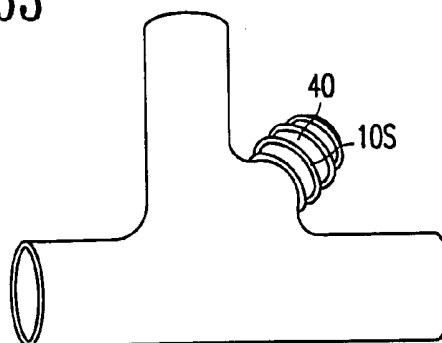


FIG. 64B

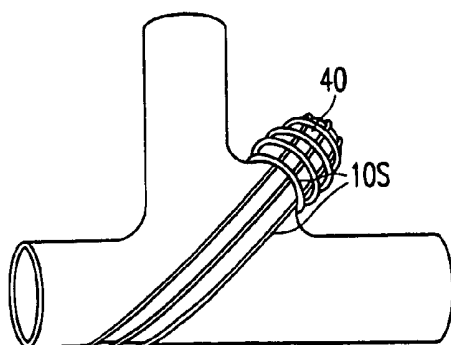


FIG. 64C

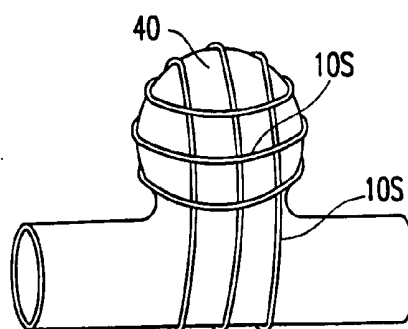


FIG. 65A

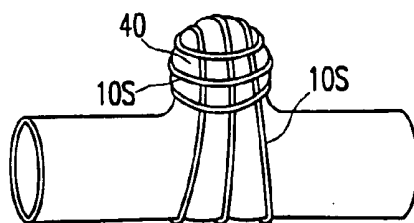


FIG. 65B

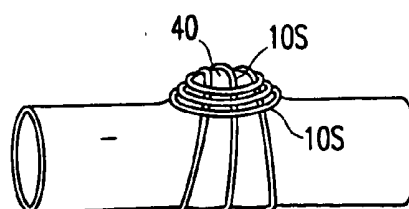


FIG. 65C

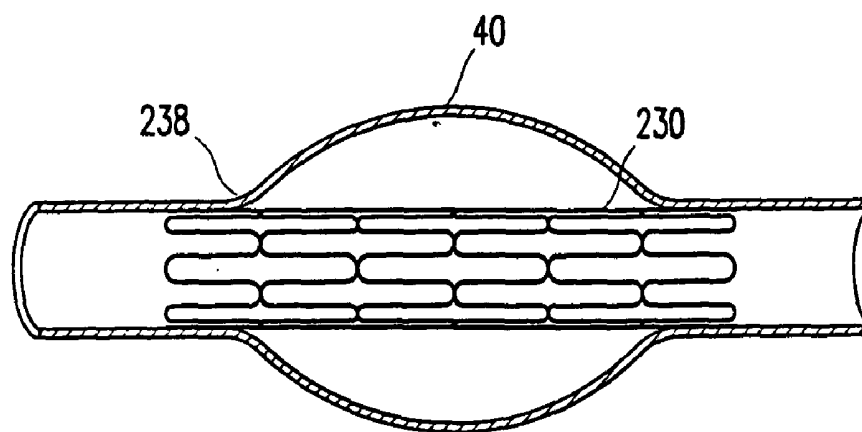


FIG. 66A

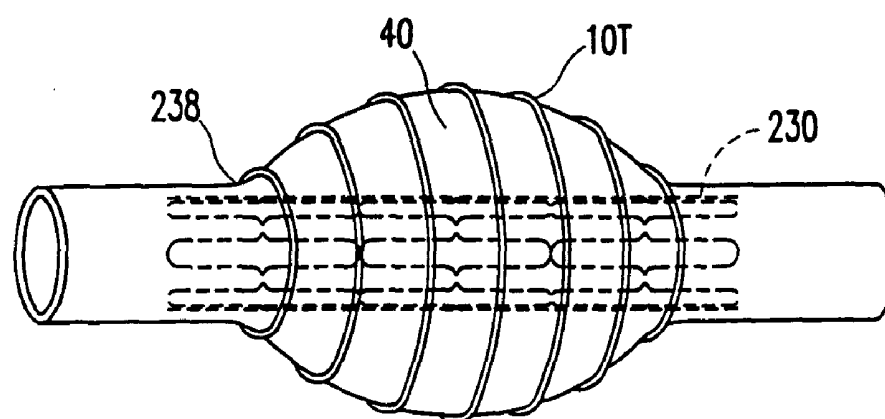


FIG. 66B

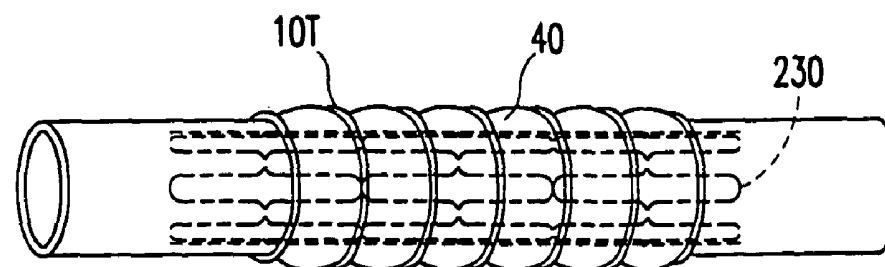


FIG. 66C

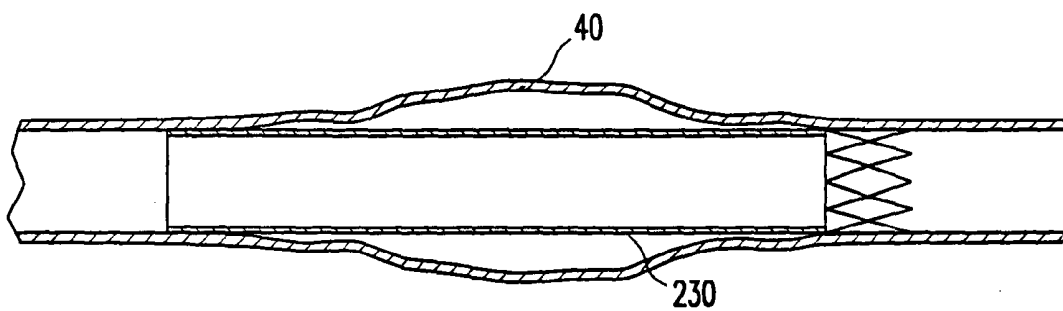


FIG. 67A

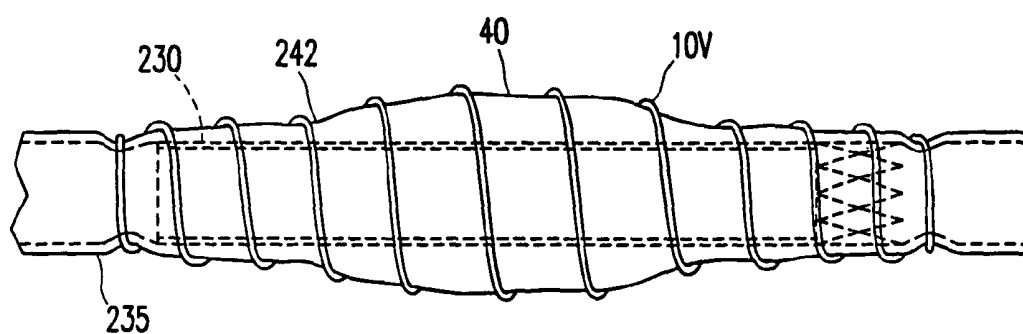


FIG. 67B

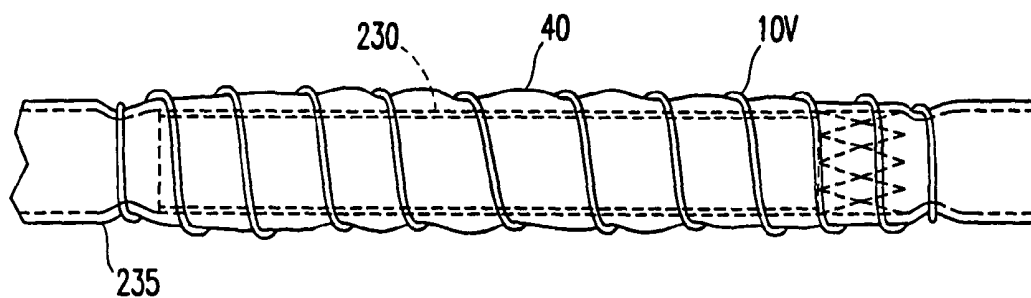


FIG. 67C

METHOD AND DEVICE FOR THE TREATMENT OF VULNERABLE TISSUE SITE

FIELD OF INVENTION

[0001] This invention relates to the fields of intervention, surgery, and more particularly to method and apparatus for treatment of aneurysms.

BACKGROUND OF THE INVENTION

[0002] An aneurysm is a condition in which a portion of a vessel has a weakened wall that results in the expansion of the vessel due to internal pressures. Aneurysm may be an aortic aneurysm occurring in the abdominal area or in other areas, including but not limited to: aneurysm in the thoracic aorta and neurovascular aneurysms.

[0003] Aortic aneurysm results from abnormal dilation of the artery wall and is often associated with arteriosclerotic disease. Unless treated, an aneurysm can rupture, leading to severe and often fatal hemorrhaging. Treating an aortic aneurysm generally involves transplanting a prosthetic graft to bridge or bypass the affected portion of the aorta. Surgical implantation of the graft is possible but this treatment causes considerable trauma, results in high mortality and morbidity and, even when completely successful, requires a lengthy recuperation period. Due to the difficulty of the operation, surgical replacement is even less attractive when it must be performed on an emergency basis after the aneurysm has ruptured.

[0004] A less invasive alternative involves the use of a catheter for intraluminal delivery of a graft. Graft delivery systems can employ a graft with expandable portions that anchor the graft in the aorta. Often, the systems use an inflatable balloon on the delivery catheter to expand the anchoring portion of the graft as disclosed in U.S. Pat. No. 5,275,622 (Lazarus et al.) which is hereby incorporated in its entirety by reference thereto. This latter example requires the use of a bulky capsule to store the graft and a complicated pushrod system to deploy the graft.

[0005] The success of a percutaneous vessel repair depends in large part on getting the graft to the location of the vasculature in need of repair and deploying the graft effectively. A difficulty associated with graft deployment and its effectiveness is blood flow-by which occurs when blood can pass between the graft and the patient's vessel wall, bypassing the graft.

[0006] Although the referenced prior art systems and others employ many different stent and graft configurations, the limitation of complete aneurysm containment has not been met.

[0007] These systems are frequently too bulky and inflexible to access many regions of a patient's vasculature. In addition when using endovascular stent grafting, it is important to know the diameter, length, and healthy neck length segment of the aneurysm in order to prevent perigraft leaks caused by poor arterial apposition or by foreshortening of the endovascular graft.

[0008] In the neurovascular applications, a particular example for aneurysm repair is the treatment of an aneurysm by placing radiopaque materials within an aneurysm pouch. For example, it is known to push embolic coils through an

introducer catheter. However, once the embolic coils leave the introducer catheter they are no longer under control and may become repositioned away from the desired location. This might occur, for example, when the treatment site is located near a vessel having a larger lumen, as when the embolic coil, having migrated to the larger vessel, would travel to a remote location. Other disadvantages include the possibility of the coils rupturing the wall of the aneurysm sac or the further expansion of the aneurysm.

[0009] Another example of vulnerable tissue sites other than aneurysms include vein grafts implanted as a bypass graft in CABG procedures. A disadvantage of a vein graft is that it may degrade over time as a result of the vein structure not being adept to effectively handle high arterial pressure (e.g., being a weaker structure against pressure), thereby degrading and occluding over time. Typically, by the time intervention takes place, the vein graft has degraded or occluded thus making it difficult to salvage or treat.

[0010] Thus, what has been needed is a method and device that can provide less invasive and more effective treatment of vulnerable tissue sites, in particular arterial and other aneurysms. The present invention satisfies at least some of this and other needs.

SUMMARY OF THE INVENTION

[0011] The present invention is directed to a method and apparatus for treating vulnerable tissue sites such as aneurysms in the abdominal or thoracic aorta. Other applications of for the method and apparatus of the present invention include neurovascular aneurysms, veins, vein grafts, and expanded or thinned tissues on various organs and body surfaces.

[0012] The apparatus of the present invention, is directed to containment members for at least partially containing a vulnerable tissue site, thus preventing or minimizing the further vulnerability or growth of the site. Additionally, or alternatively, the containment members can apply resistive force to the vulnerable tissue site. The force can be compressive against the exterior surface of the tissue site. The containment members of the present invention can be used alone or in combination with support members, such as stent/grafts, in treating a tissue site. In this embodiment, the support member is disposed within the inner lumen of the vulnerable tissue site with the containment member disposed on the exterior surface of the lumen.

[0013] The containment members may totally encircle the vulnerable tissue site or they may be disposed about less than the entire circumference of body lumen including the vulnerable tissue site. In one embodiment, the containment members have a containment surface of sufficient dimensions to at least partially encircle a region of the vulnerable tissue. In another embodiment, the containment member can be configured to provide a compressive force against the vulnerable tissue. The containment members may be configured for attachment to a positioning member. The positioning member can be configured for securing the containment member to an adjacent tissue site or body part to minimize further vulnerability of the tissue site. In another embodiment, the positioning member is configured to be biased against an adjacent healthy tissue site or body part.

[0014] The various embodiments of the containment members of the present invention can be configured to

deliver agents, such as therapeutic agents, to the tissue site. Additionally, the containment members can be configured to accommodate different anatomical settings having vulnerable tissue sites. The embodiments include but are not limited to strands, coils, sheaths, omega shaped coils for structures that can not be looped around entirely, and inflatable containment members.

[0015] The containment member may be formed of polymeric or metallic material to remain in place until the removal of the same, or in the alternative may be formed of bio-degradable material, degrading over a period of time.

[0016] In operation, the containment members of the present invention may be introduced to the vulnerable tissue site in one of several ways, including: (1) surgical methods, such as cut-down or laparoscopically; (2) intra-endoscopically, i.e., through the same body conduit or lumen as the one including the vulnerable tissue; and (3) inter-endoscopically, i.e., through, at least in part, a body conduit or lumen adjacent the conduit which has the vulnerable tissue.

[0017] In one embodiment, the containment member is advanced through the first lumen of the first tubular member including the vulnerable tissue site and through an access site in a wall of the first tubular member and is disposed about an exterior surface of the tissue site.

[0018] In another embodiment, the access site is part of a second tubular body member having a second lumen and disposed, at least in part, substantially parallel and adjacent the tissue site. In this embodiment, the containment member is advanced through the second tubular body and through the access site located in a wall of the second tubular body and disposed about an exterior surface of the tissue site. The containment member can be disposed about the exterior surface of the first body lumen which includes the vulnerable tissue site alone or together with the exterior surface of the second body lumen.

[0019] As defined herein, vulnerable tissue site includes, without limitation, any tissue site which is or can be weakened, enlarged, thickened, or thinned, either permanently or periodically (as for example during different phases, cycles, or conditions). The vulnerable tissue may be present in any area of a host body, such as but not limited to: cardiovascular or neurovascular arteries or veins, vein grafts such as saphenous vein graft for a pass surgery, aorta including abdominal and thoracic, vena cava including inferior and superior, organs such as stomach or glands. The vulnerable tissue site may be native to the intracorporeal body or it may be a transplanted intracorporeal body such as a saphenous vein graft introduced to the body as a result of a procedure such as bypass before it becomes weakened as a result of its new environment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 is an elevational view, partially cut away view of a containment member embodying features of the present invention.

[0021] FIG. 2 is another embodiment of a containment member embodying features of the present invention taking the form of a coil.

[0022] FIG. 3A is a side elevational view of a vulnerable tissue site.

[0023] FIG. 3B is a side elevational view of the vulnerable tissue site of FIG. 3A having the containment member disposed about its exterior surface.

[0024] FIG. 4A is a side elevational view of an embodiment of the containment member of FIG. 2 including apertures.

[0025] FIG. 4B is a transverse cross-sectional view of the containment member of FIG. 4A taken along lines 4B-4B.

[0026] FIG. 4C is a transverse cross-sectional view of the containment member of FIG. 4A taken along lines 4C-4C.

[0027] FIG. 5A is another embodiment of a containment member embodying features of the present invention and having a plurality of strands and having a circular cross section.

[0028] FIG. 5B is another embodiment of a containment member embodying features of the present invention and having a plurality of strands having a flat cross section.

[0029] FIGS. 6A-6C are transverse cross sectional views of containment members embodying features of the present invention and having different cross-sectional shapes.

[0030] FIG. 7 is an elevational view of another embodiment of a containment member having a double helix configuration.

[0031] FIG. 8 is an elevational view of an omega shaped containment member.

[0032] FIG. 9 is an elevation view of another embodiment of a containment member including longitudinal strands with transverse connecting member.

[0033] FIG. 10 is an elevational view of a containment member including two sheets disposed around the exterior surface of a strand.

[0034] FIG. 10A is a cross sectional view of the containment member of FIG. 10 taken along lines 10A-10A.

[0035] FIGS. 11A and 11B are side elevational views of the containment member of FIG. 10 in a disposed configuration.

[0036] FIG. 11C is a side elevational view of the containment member of FIG. 10 disposed around the exterior surface of a body lumen with the edges of the containment member being longitudinally set apart.

[0037] FIG. 12 is an elevational view of another embodiment of a containment member including a plurality of strands disposed substantially parallel to one another and sealed between two sheets.

[0038] FIG. 13 is an elevational view of another embodiment of the containment member of FIG. 12 including an inflation pocket defined between the two sheets.

[0039] FIGS. 14, 15A and 15B are side elevational views of containment members including sheets disposed about longitudinal strands and further including transverse connecting member, the longitudinal strands having solid or hollow cross-sections.

[0040] FIGS. 16-18 are side elevational views of different embodiments of transverse connecting.

[0041] FIG. 19 is a side elevational view of a containment member having a fluid pocket.

[0042] FIG. 20 is a cross sectional view of the containment member of FIG. 19 taken along line 20-20 with the strand being hollow.

[0043] FIG. 21 is a cross sectional view of the containment member of FIG. 19 taken along line 21-21 with the strand being solid.

[0044] FIG. 22A is a top elevational view of a containment member disposed on an exterior surface a vulnerable tissue site being secured to a body tissue mass.

[0045] FIG. 22B is a side elevational view of the tissue site of FIG. 22A showing the reduction in size of the tissue site at different time or phase intervals.

[0046] FIG. 22C is a front elevational view of a region of a vulnerable tissue site, with a containment member having a containment surface of sufficient dimensions to at least partially encircle the region of vulnerable tissue, the containment member being secured to adjacent healthy tissue by positioning member such as a suture.

[0047] FIG. 22D is a front elevational view of a region of a vulnerable tissue site, with a containment member having a containment surface of sufficient dimensions to at least partially encircle the region of vulnerable tissue and being in substantial contact with the vulnerable tissue site, the containment member being secured to adjacent healthy tissue by positioning member such as a suture.

[0048] FIG. 22E is a front elevational view of a region of a vulnerable tissue site, with a containment member having a containment surface of sufficient dimensions to at least partially encircle the region of vulnerable tissue, the containment member being secured to adjacent healthy body part by positioning member such as a strut.

[0049] FIG. 22F is a front elevational view of a region of a vulnerable tissue site, with a containment member having a containment surface of sufficient dimensions to at least partially encircle the region of vulnerable tissue and being in substantial contact with the vulnerable tissue site, the containment member being secured to adjacent healthy body part by positioning member such as a strut.

[0050] FIG. 23 is a side elevational view of a vulnerable tissue site showing the various access locations.

[0051] FIGS. 24-29 are schematic side elevational views of the steps of a surgical method of the present invention disposing a containment member about the exterior surface of a first body lumen including the vulnerable tissue site.

[0052] FIGS. 30-35 are schematic side elevational views of the steps of another surgical method disposing a containment member about the exterior surface of the first body lumen including the vulnerable tissue site and a second body lumen substantially parallel and adjacent the first body lumen.

[0053] FIGS. 36-43 are schematic side elevational views of the steps of another surgical method disposing a containment member about the exterior surface of the first body lumen which includes peripheral branches.

[0054] FIGS. 44-47 are schematic side elevational views of the steps of an intra-endoscopic method introducing a

containment member through an inner lumen of the first body lumen and being disposed about the exterior surface of the first body lumen.

[0055] FIGS. 48-53 are schematic side elevational views of the steps of an inter-endoscopic method introducing a containment member through an inner lumen of the second body lumen and being disposed about the exterior surface of the first body lumen.

[0056] FIGS. 54-59 are schematic side elevational views of the steps of another intra-endoscopic method introducing a containment member through an inner lumen of the first body lumen and being disposed about the exterior surface of the first and second body lumens.

[0057] FIGS. 60-62 are schematic side elevational views of the steps of another intra-endoscopic method introducing a containment member through an inner lumen of the first body lumen and being disposed about the exterior surface of the first and second body lumens and further including an elongate glide for securing the containment member to the tissue site.

[0058] FIGS. 63-65 are schematic side elevational views of the containment members embodying features of the present invention and disposed about the outer surface of host body such as an organ, showing the reduction in size of the organ at the vulnerable tissue site, immediately, over time, or at phase intervals.

[0059] FIGS. 66A-66C are side elevational views of the containment members embodying features of the present invention used in combination with a stent graft.

[0060] FIGS. 67A-67C are side elevational views of the containment members embodying features of the present invention used in combination with a stent graft with the two ends of the containment member defining a neck and extending onto the adjacent healthy tissue site.

DETAILED DESCRIPTION OF THE INVENTION

[0061] FIGS. 1 and 2 illustrate containment members 10 and 10A embodying features of the invention, generally including a strand 13, preferably having atraumatic proximal and distal tips, 16 and 19. The containment member 10, preferably, is wound in a helical configuration as generally depicted as 10A in FIG. 2. The containment member 10 forms, as in containment member 10A of FIG. 2, or, can be shaped to form, a tubular body 25 having open proximal and distal ends, 28 and 31, respectively, with a containment lumen 34 extending longitudinally therebetween, and defining an interior surface 37.

[0062] Upon disposing of the containment member 10 about a vulnerable tissue site 40, such as that shown in FIGS. 3A and 3B, the interior surface 37 of the containment member 10 comes into contact, at least in part, with an exterior surface 43 of the vulnerable tissue site 40, thus containing, at least in part, the vulnerable tissue site. In one embodiment, in the disposed configuration, the containment member 10 can apply resistive force to the tissue site, aiding in the minimizing the further vulnerability of the vulnerable tissue site. The containment member 10 can also apply a compressive force against the exterior of the vulnerable tissue. The strand 13 may be formed of any suitable material

such as polymeric or metallic materials, including thermoplastic and thermosets; stainless steel, nickel titanium alloys such as Nitinol, and precipitation hardenable material. The precipitation hardenable material, preferably, is formed of at least two material selected from the group consisting of nickel, cobalt, molybdenum, chromium, tungsten, and iron; and a combination thereof.

[0063] Specific example of such precipitation hardenable material include, but are not limited to, AISI (American Iron and Steel Institute) Type 600 series precipitation hardenable stainless steel; chromium-nickel based single stage martensitic precipitation hardenable stainless steel having modified proportions of chromium and nickel and with additional elements of copper and titanium, commercially available from Carpenter Steel Company of Reading, Pa., under the designation 455PH or 17-7PH; and a precipitation hardenable steel available under the trade designation 1RK91 from Sweden Steel. Other suitable precipitation hardenable stainless steel include those which are essentially "nickel free" such as those sold under the designation BioDur 108, available from Carpenter's Specialty Alloys Operations, Reading, Pa. By way of example, the nominal composition of BioDur is chromium (21%), manganese (23%), nitrogen (1%), nickel (less than 0.3%), and iron (balance).

[0064] Other suitable precipitation hardenable material include cobalt based alloys such as those including nickel, cobalt, molybdenum and chromium, also commercially available under the designation MP35N (UNS (Unified Numbering System) R30035) available from Carpenter Steel Co. Also useful in the practice of the invention is a similar alloy that contains a small amount of iron (less than about 10%) and is commercially available under the trade designation Elgiloy (UNS R30003) and L605 from Haynes International of Kokomo, In.

[0065] Alternatively, the strand 13 may be formed of biodegradable material, preferably degrading over a period of time, as for example few days to years, preferably within 1 to 10 months. The biodegradable material may be formed from any suitable bio-compatible material such as, but not limited to: enzymatically degradable polymers including polypeptides such as collagens, gelatin, poly(amino acids); polysaccharides such as amylose cellulose, dextran, chitin; polyesters such as poly(β -hydroxyalkanoates), PHB (poly β -hydroxybutyrate); and nucleic Acids; or nonenzymatically degradable polymers, including, polyesters such as aliphatic polyesters, as for example, PLA (polylactic acid), PGA (polyglycolic acid), co-polymer of PLA/PGA; poly(ester-ethers) such as PEG (poly(ethylene glycol)); poly caprolactones; and poly (amideesters).

[0066] As defined herein, vulnerable tissue site refers to any tissue site which is or can be weakened, enlarged, thickened, or thinned, either permanently or periodically (as for example during different phases, cycles, or conditions). The vulnerable tissue may be present in any area of a host body, such as but not limited to: cardiovascular or neurovascular arteries and veins, aorta including abdominal and thoracic, vena cava including inferior and superior, organs such as stomach or glands, and vein grafts.

[0067] The containment member 10 and other embodiments of the same, will be further discussed in reference to the figures below, wherein like reference represent like elements.

[0068] Optionally, and as shown in FIG. 2, the containment member 10, can, optionally, include, one or more connecting bodies 46, for connecting adjacent turns 49 and 52 of the containment member.

[0069] The containment member 10 for aortic aneurysms, preferably, has a disposed inner diameter ranging from about 0.25 to about 4 inches, more preferably, from about 0.75 to about 2.5 inches; with a disposed outer diameter ranging from about 0.27 to about 5 inches, more preferably, from about 0.77 to about 2.6 inches; and a disposed length ranging from about 1 to about 30 cm (with a straight length ranging from about 1 to about 50 cm), more preferably, from about 5 to about 20 cm. However, the containment member 10 inner and outer diameters and length may vary in size from those stated above for other applications and size of the vulnerable tissue site on which the containment member 10 is to be disposed.

[0070] For example, the containment member in a disposed but unstrained (or relaxed) condition can have an inner diameter substantially the same or slightly larger than a first thickness (outer diameter of the tissue site) of the vulnerable tissue site; substantially larger than the thickness of the vulnerable tissue site; about 25% larger than the thickness of the vulnerable tissue site; substantially between the first thickness of the vulnerable tissue site and second thickness of a healthy tissue site adjacent the vulnerable tissue site; substantially the same as the second thickness of the adjacent tissue site; or slightly smaller, for example 10% smaller than the second thickness of the adjacent tissue site. Adjacent tissue site, as used herein, refers to a tissue site which is adjacent the vulnerable tissue site and is substantially healthy, or adjacent body part, including but not limiting to tissue sites, bones, organs, etc.

[0071] The containment member 10A, preferably, has a pitch (distance between adjacent turns), ranging from about 0.01 to about 3 inches, more preferably, from about 0.04 to about 1 inch.

[0072] In an embodiment features of which are shown in FIGS. 4A through 4C, the containment member 10B is formed of a hollow strand 13B having a strand lumen 34 extending therein, and further including one or more apertures 58 extending between the lumen 34 and an strand outer surface 61. The strand lumen 34, and the apertures 58 when present, are configured to deliver fluids, such as therapeutic fluids, to and/or from the vulnerable tissue 40. Optionally, the apertures 58 may be used to deliver a hardenable material, including bio-degradable and permanent materials, preferably, bio-degradable over time (such as those described above in reference to strand material) to the outer surface of the vulnerable tissue site. In yet another embodiment, the hardenable material may be delivered to the exterior surface of the vulnerable tissue site by another delivery device, such as a catheter. It should be appreciated that the delivery of the hardenable material can occur, after, concurrently with, or prior to the placement of the containment member on the vulnerable tissue site. In yet another embodiment, the hardenable material itself can be the containment member left in place permanently, or degradable over time. In this embodiment, the containment member can take any suitable shape necessary for at least partially containing the vulnerable tissue site.

[0073] Now referring to FIGS. 5 through 6, the containment member 10, is generally shown in 10C and 10D

respectively and includes a plurality of strands **13**, **5A** in-phase and **5B** out of phase, having varying cross sections, as for example, substantially circular as shown in **FIG. 6A**, substantially flat as in **FIG. 6B**, substantially triangular as in **FIG. 6C**, or other shapes as dictated by a particular application or anatomy.

[0074] In another embodiment shown in **FIG. 7**, the containment member **10E** includes a multiple helix configuration having two counter helix strands **13E** and **13F**. The strands **13E** and **13F** can have identical or differing diameters (inner and/or outer). The counter helix strands **13E** and **13F** forming the double helix containment member **10E** can interlock by alternating inner and outer positions as shown in **FIG. 7**. Optionally, the proximal and distal ends of the counter helix strands **13E** and **13F**, or portions along their length, can be joined by suitable means, such as connecting member **46** as shown in **FIG. 7**, and means in the form of a ring **70** as shown in **FIG. 8**.

[0075] Also, the embodiment shown in **FIG. 8**, can be a containment member having a omega shape for containing vulnerable tissue sites, such as those attached to other tissue and or organs such as bones. One or more omega shaped containment members loops, at least partially, around the vulnerable tissue site, thus containing the site. The legs of the containment member can be affixed or secured to the vulnerable tissue site, or an adjacent structure such as a bone, with adhesive, staples suture, or strand; or when multiple containment members are used, each leg can be connected to a leg of another containment member.

[0076] Now referring to **FIG. 9**, the containment member **10G** includes a plurality of longitudinal strands **13** transversely set apart, with transverse connecting member **76** disposed about the inner or outer surface of the longitudinal strands **13** securing the relative position of the longitudinal strands **13**. The transverse connecting member **76** may be only secured to the corresponding underlying longitudinal strands **13**, or they may be additionally linked to one another through linking member **79**. Transverse connecting member **76** and linking member **79** can, independently, be made of any suitable material such as those described above with reference to the strand **13**.

[0077] Now referring to **FIGS. 10 through 16**, containment members of the present invention described above may further include one or more sheets disposed around the exterior surface of one or more strands.

[0078] In the embodiment shown in **FIGS. 10 and 10A**, an enlarged section of a containment member **10H** is shown having a strand **13** sealingly disposed between two sheets or strips of film or mesh **82**. Optionally, the exterior surface of one or more of the strips of film, or any strand or containment member, can include a securing material such as an adhesion promoting material or time-release adhesive, such as fibrin or cyanoacrylate, to aid in securing the containment member **10H** to the outer surface **43** of the vulnerable tissue **40**. As shown in **FIGS. 11A through 11C**, after the containment member **10H** is disposed about the vulnerable tissue, per the method described below, the containment member **10H** forms, preferably, a helical configuration with the edges of the attached films **82** overlapping, to form a tubular structure **25A**. When only one of the films includes the securing material, the containment member **10H** is, preferably, disposed about the exterior of the vulnerable

tissue site **40** such that the side having the securing material comes into contact, at least in part, with the outer surface **43** of the vulnerable tissue site **40**. Alternatively, and as shown in **FIG. 11C** the edges of the containment member **10H** may be longitudinally set apart by a gap **85**.

[0079] In an alternate embodiment, an enlarged section of a containment member **10J** prior to being disposed about the vulnerable tissue is shown in **FIG. 12**. A plurality of strands **13** of the containment member **10J** are disposed substantially parallel to one another and are sealed between two sheets or strips of film or mesh **82**, as described above in relation to **FIG. 10**. Alternatively, as shown in **FIG. 13**, in containment member **10K**, the two films **82** together define an inflation pocket **88** sealingly and fluidically connectable to a source of inflation fluid. Once the containment member **10K** has been disposed about the vulnerable tissue site **40**, the inflation pocket **88** can be used to inflate, with a fluid (liquid or gas), the containment member **10K** thus exerting pressure on the vulnerable tissue site **40**.

[0080] In another embodiment shown in **FIGS. 14, 15A and 15B**, an enlarged section of a containment member **10L** is shown having longitudinal strands **13** disposed between two sheets or strips of film or mesh **82**, with transverse connecting member **76** disposed on the outer or the inner sheets or therebetween. The longitudinal strands **13** may be solid or hollow (or have closed proximal and distal ends), as shown in **FIGS. 15A and 15B**, respectively.

[0081] In another embodiment of a containment member **10M** shown in **FIG. 16**, transverse connecting member **90** includes a generally annular body **93** with averted ends **96** which may be used to secure the transverse connecting member **90** about the longitudinal strand **13**. As shown in **FIG. 16**, the two averted ends **96** may be secured in place on either side of the longitudinal strand **13** in rings **99** located on an outer surface of the outer sheet **82**. Alternatively, and as shown in **FIG. 17**, ends **96** of transverse connecting member **90A** may hold sutures or other means for connecting the containment member to other containment members or tissue site. Alternatively, the member shown in **FIG. 17** can itself be a containment member to be disposed about the vulnerable tissue site individually or in multiples (as discussed in reference to **FIG. 8**). In this embodiment, the containment member can be held in place by suitable means such as sutures. In yet another embodiment as depicted in **FIG. 18**, transverse connecting member **90B** can include a substantially longitudinal portion **102** with a plurality of encircling portions **105** for encircling the longitudinal strands.

[0082] In another embodiment features of which are shown in **FIGS. 19-21**, containment member **10N** includes a fluid pocket **108** defined between the outer surface of strand **13** and inner surface of sheath **82**. The fluid pocket **108** is fluidically connectable to a source of therapeutic fluid for delivering the fluid to the vulnerable tissue and/or the surrounding tissue sites through sheath apertures **111**. The strand **13** may be hollow as shown in **FIG. 20** or solid as shown in **FIG. 21**.

[0083] Now referring to **FIGS. 22A and B**, features of a containment member **10P** are shown containing a vulnerable tissue site **40A** which is located on a body site **115** secured to body tissue mass. The containment member **10P** includes strands **13** and is disposed about less than the circumference

of the vulnerable tissue site **40A**. The containment member **10P** is secured to the vulnerable tissue site **40A** or adjacent tissue site by sutures **118** or other suitable securing means. As shown in **FIG. 22B**, the containment member **10P** may be used to apply pressure onto the vulnerable tissue site **40A**, thereby reducing its size as it is reduced from **40A** to **40B** to **40C**.

[0084] Now referring to **FIGS. 22C-D** and **22E-F**, the containment member **10R** can have a containment member surface **37A** of sufficient dimensions to at least partially encircle at least a region **121** of the vulnerable tissue **40**. The containment member **10R** is configured for attachment to a positioning member, such as **125A** in the form of a suture or C ring, or **125B** in the form of a strut. The containment members may be positioned to simply act as a means to minimize future vulnerability of the site (i.e., initially there is not substantial contact between the vulnerable tissue and the containment member), as for example depicted in **FIGS. 22C & E**; or to apply force against the vulnerable tissue (**FIGS. 22D and F**). As can be noted from the features of the embodiment shown in **FIG. 22F**, the containment member can be biased against adjacent healthy tissue site or body part (including bones).

[0085] In operation, the containment members of the present invention may be introduced to the vulnerable tissue site in one of several ways, including: (1) surgical methods, such as cut-down or laparoscopically; (2) intra-endoscopically, i.e., through the same body conduit or lumen as the one including the vulnerable tissue; and (3) inter-endoscopically, i.e., through, at least in part, a body conduit or lumen adjacent the conduit which has the vulnerable tissue.

[0086] By way of example, and not as a limitation, in describing the method of the present invention, only a subset of the various embodiments of the containment members of the present invention may be used. It should be appreciated by those skilled in the art that the more conventional steps of the method may not be individually described hereinafter.

[0087] Now referring to **FIG. 23** in a surgical method (cut-down or laparoscopically), an access site for accessing the vulnerable tissue site **40**, as for example, directly above or below, or proximal or distal to the site, as indicated by **150**, **153**, **156** and **159**, respectively.

[0088] **FIGS. 24-29** schematically depict a procedure whereby a containment member **10R**, under imaging guidance; such as fluoroscopic techniques, ultrasound (e.g. catheter-based on external), angioscope, direct visualization, MRI, (including catheter-based and external), and CT scan; is disposed about the exterior surface of an vulnerable tissue site **40D** of a patient included in a first body lumen **167**. The containment member **10R** is introduced over the surface of the aneurysm by percutaneous means through a lumen **170** of a catheter **173** through an access site **176**, the containment member **10R** and the catheter **173** together forming a delivery system **180**. The catheter may be in the form of a hypotube or tubular member. A distal end of the catheter may include a curve, or may form a curve on demand. The catheter can be formed of any conventional material for forming such devices. The distal end **183** of catheter **173** is advanced to a location, distal or proximal, to the aneurysm **10R**. Using a suitable mechanism such as a pusher rod, the containment member **10R** is then advanced within the inner

lumen **170** of the catheter **173**, preferably, the catheter having a detachment mechanism **186** disposed at the catheter distal end **183** (**FIG. 28**). The detachment mechanism **186** is detachably secured to a proximal end **189** of the containment member **10R** which allows proximal manipulation of the delivery system **180** to control axial advancement and retraction containment member **10R** within the catheter **173** and the patient. The containment member **10R** is then distally advanced out of a port **190** in the distal end **183** of the catheter **173** along the exterior surface of a body site which includes the vulnerable tissue **40**, so as to contain at least a portion of the length of the vulnerable tissue **40**. When the containment member **10R** is appropriately positioned, the containment member **10R** is detached from the delivery system **180** and is left in place and the catheter **173** is withdrawn from the body. The catheter **173** catheter can have multiple lumens (e.g. separate lumens for receiving the guidewire, containment member, light or visualization means, and drug delivery lumen). The catheter can also be inserted through a guiding catheter or sleeve having a pre-set shape at it is distal end according to the anatomy to be treated. Furthermore, the catheter can be a fixed wire type, over the wire type, or rapid exchange type.

[0089] It should be appreciated that the containment member **10R** may be advanced onto the exterior surface of the aneurysm in an ascending direction, as shown in the figures, or in a descending direction, depending on the location of the introduction of the catheter; from above or below the site.

[0090] Examples of suitable detachment mechanisms include polymeric links susceptible to chain cleavage upon degradation of the polymer link, mechanical detachment, electrolytic detachment, shape memory metal or polymer activation via a temperature change by application of RF energy, laser energy, ultrasonic energy, heating of a hot melt adhesive joint, ultrasonic joint degradation, hydrokinetic activation of a mechanical retaining device, and the like. Various detachment mechanisms known in the art are discussed in U.S. Pat. Nos. 5,722,989, J. Fitch et al., U.S. Pat. No. 5,108,407, G. Geremia et al., U.S. Pat. No. 5,217,484, M. Marks, and U.S. Pat. No. 5,423,829, P. Pham, which are hereby incorporated by reference.

[0091] Alternatively, and as shown in **FIGS. 30-35**, the containment member **10R** may be disposed about both the first body lumen **168** including the vulnerable tissue **40D** and a second body lumen **193** substantially parallel to or adjacent the first body lumen. In **FIGS. 30-35**, the containment member **10R** is laparoscopically introduced through the access site **176** and is advanced and disposed about, at least in part, both the esophagus as the second body lumen and the vulnerable tissue site **40D** (e.g. aneurysm) located in the aorta as the first body lumen.

[0092] Often, the vulnerable tissue **40D**, may be located in a part of the body which includes peripheral branches, as for example, peripheral branches of aorta. **FIGS. 36-43** show the steps associated with disposing the containment member **10R** about the exterior surface of the first body lumen **167** which includes peripheral branches **196**. In the practice of this method, it is particularly useful, to use a helical containment member **10A** similar to that previously shown in **FIG. 2** (or one or more omega shaped containment members such as that shown in **FIG. 8**). The helical configuration of

the containment member allows the advancement of the containment member along the exterior surface of the length of the first body lumen without being impeded by the peripheral branches. As shown in the figures, the containment member may optionally be secured in place by the use of a suitable device **200** to tie or tighten the coils with suture **118** or other means. Alternatively, when the containment member is formed from a shape-memory material, such as Nitinol, the containment member may be secured in place by the application of heat or energy, thus, transforming its size and dimensions. The containment member can be pre-shaped to the desired configuration (in the disposed configuration) and constrained to a secondary shape by the catheter such that upon release (e.g., disposing about the vulnerable tissue site) the containment member assumes the desired disposed shape.

[0093] Now referring to FIGS. 44-47 in an intra-endoscopic method, the catheter **173** is introduced through an inner lumen **203** of a first body lumen **167** which includes the vulnerable tissue **40D**, from a location proximal or distal (above or below) to the vulnerable tissue. Similar to the surgical method, the catheter **173** is advanced along the interior lumen **203** of the first body lumen **167** to an access point **210** being proximal or distal to the vulnerable tissue **40D**, at which point the catheter **173** is advanced through wall **213** of the first body lumen **167** and unto the exterior surface of the first body lumen (or body site). The containment member is then advanced onto the vulnerable tissue similar to the surgical method described above.

[0094] Now referring to FIGS. 48-53 in an inter-endoscopic method, the catheter **173** is introduced through an inner lumen **370** of the second body lumen **193** extending either or both substantially parallel, at least in part, and adjacent, at least in part, to the first body lumen **137** which includes the vulnerable tissue **40D**. The catheter **173** is then advanced through access site **219** located in a wall of the second body lumen and unto the exterior surface of the first body lumen (or body site). The containment member **10R** is then advanced onto the vulnerable tissue similar to the surgical method described above.

[0095] The inter-endoscopic method is particularly useful when a relatively easily accessible second body lumen lies substantially parallel or adjacent to the first body lumen having the vulnerable tissue. For example when the aneurysm is located in the thoracic cavity, the esophagus can be a suitable second lumen for accessing the aneurysm located in the thoracic aorta.

[0096] Alternatively, and as depicted in FIGS. 54-59, in the operation of the inter-endoscopic method, the containment member **10R** may be disposed, at least in part, along the exterior surface of both the first and the second body lumens, **167** and **193**, once it exits the wall of the second body lumen.

[0097] In yet another embodiment, shown in FIGS. 60-62, the catheter **173** may be equipped to deliver an elongate glide **221** used to secure the containment member **10R** along the exterior surface of the first body lumen **167**. The glide **221**, includes loops **224** along its length. Once advanced out of the catheter **173**, the glide **2210** is secured to the first body lumen at various points along its length. The containment member **10R** as it is being advanced along the exterior surface of the length of the vulnerable tissue, is looped

through the glide loops **224**, thus, becoming secure in place. For example, sutures can be passed through one or more of the glide loops to secure the glide to the first body lumen. Alternatively, the containment member **10R** may be secured to the exterior surface of the vulnerable tissue site by other suitable means, such as adhesives.

[0098] Now referring to FIGS. 63-65, when the vulnerable tissue **40** is on a body site such as an organ, containment member **10S** can be advanced by way of any one of the methods described above and disposed on the exterior surface of the organ. In operation, one or more individual containment members may be disposed on the organ in the same or differing orientations, as shown in the FIGS. 63-65. The containment member may only act to contain the vulnerable tissue site minimizing its further growth or it may apply pressure or compressive force on the vulnerable tissue site **40** thereby reducing its size, as depicted in FIGS. 63, 64A and 64B; and or 65A, 65B, and 65C.

[0099] As shown in FIGS. 66 through 67, the containment members of the present invention can be used in conjunction with a stent/graft **230**. In the embodiment shown in FIGS. 66B and 66C, the containment member **10T** is shown enclosing longitudinally, at least in part, the vulnerable tissue **40**. The containment member may only contain the vulnerable tissue site or it may act to reduce its size, immediately or over time, as shown in FIG. 66C. Alternatively, as shown in FIG. 67A, there may not be a well defined neck (such as **238** in FIG. 66A) on either or both sides of the vulnerable tissue site for having the stent/graft abutting against. In this configuration, as shown in FIGS. 67B and 67C, either or both the proximal and distal ends of the containment member **10V** can extend to cover healthy tissue **235** (i.e., not-vulnerable tissue) on either or both sides of the vulnerable tissue **40** or compress vulnerable tissue to define a neck, whereby, the compression of the containment member **10V** onto the vulnerable tissue site aids in creation of a neck **242** thereby aiding in the securing of the of the stent/graft **230** within the body lumen of the aneurysm. It should be noted that the containment members, may contain the vulnerable tissue site **40** with or without application of pressure to the site.

[0100] While particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited.

What is claimed is:

1. A method for treating a vulnerable tissue site of an intracorporeal body, comprising, providing a containment member adjacent to an exterior surface of the site.
2. The method of claim 1 wherein the member is positioned to apply resistive force to the tissue site.
3. The method of claim 2 wherein the force substantially minimizes the further vulnerability of the tissue site.
4. The method of claim 3 wherein the force is compressive against the exterior surface of the site.
5. The method of claim 1 wherein the containing is achieved by a containment member.
6. The method of claim 4 wherein the force is applied by a containment member.

7. The method of claim 5 wherein the containment member at least partially covers the exterior surface of the tissue site.

8. The method of claim 6 wherein the containment member at least partially covers the exterior surface of the tissue site.

9. The method of claim 5 wherein the containment member at least partially encloses the exterior surface of the tissue site.

10. The method of claim 6 wherein the containment member at least partially encloses the exterior surface of the tissue site.

11. The method of claim 5 wherein the containment member is secured at least in part to the tissue site.

12. The method of claim 6 wherein the containment member is secured at least in part to the tissue site.

13. The method of claim 5 wherein the containment member is further extended to an adjacent tissue site.

14. The method of claim 6 wherein the containment member is further extended to an adjacent tissue site.

15. The method of claim 13 wherein the containment member is further secured at least in part to the adjacent tissue site.

16. The method of claim 14 wherein the containment member is further secured at least in part to the adjacent tissue site.

17. The method of claim 1 wherein the vulnerable tissue site is not native to the intracorporeal body.

18. The method of claim 4 wherein the vulnerable tissue site is not native to the intracorporeal body.

19. A method for treating a vulnerable tissue site of an intracorporeal body, comprising:

providing a containment member;

disposing the containment member about the vulnerable tissue site so as to at least partially cover at least a portion of the exterior surface of the tissue site.

20. The method of claim 19 wherein the containment member at least partially encloses the tissue site.

21. The method of claim 19 wherein the containment member further disposed at least partially about a tissue site adjacent the vulnerable tissue site.

22. The method of claim 19 wherein the vulnerable tissue site is not native to the intracorporeal body.

23. The method of claim 19 further including the step of delivering the containment member to the tissue site through an access site.

24. The method of claim 19 wherein the access site is on the surface of the intracorporeal body.

25. The method of claim 19 wherein the access site is within the intracorporeal body.

26. The method of claim 20 wherein the tissue site is part of a first tubular body having a first lumen.

27. The method of claim of claim 26 wherein the containment member is advanced through the first lumen of the first tubular member and through the access site in a wall of the first tubular member and disposed about an exterior surface of the tissue site.

28. The method of claim 27 wherein the containment member at least partially contains at least a portion of the length of the tissue site.

29. The method of claim 25 or 26 wherein the access site is part of a second tubular body member having a second lumen and disposed, at least in part, substantially parallel or adjacent the tissue site.

30. The method of claim 29 wherein the containment member is advanced through the second tubular body and through the access site located in a wall of the second tubular body and disposed about an exterior surface of the tissue site.

31. The method of claim 23 wherein the tissue site is accessed laparoscopically.

32. The method of claim 23 wherein the containment member is advanced through the access site endoscopically.

33. The method of claim 23 wherein at least a portion of the containment member includes a radiopaque material.

34. The method of claim 23 further including the step of delivering therapeutic fluid to the tissue site.

35. The method of claim 23 wherein the intracorporeal body including the vulnerable tissue site includes any one of thoracic cavity, abdominal cavity, cerebral cavity, blood vessel, tissue, vein graft, vein, gland, heart, vessel, nerve, stomach, or liver.

36. The method of claim 29 wherein the second tubular body includes any one of esophagus, trachea, vena cava, vein, artery, sinus, aorta, heart, stomach, duct, or intestines.

37. The method of claim 19 further including providing a catheter for introducing the containment member into the intracorporeal body.

38. The method of claim 37 wherein the containment member is released into the intracorporeal body after the disposing step.

39. A method for treating a vulnerable tissue site of an intracorporeal tubular member, comprising:

providing a support member;

providing a containment member;

disposing the support member along the interior lumen of the tubular member along at least a portion thereof which includes the vulnerable tissue site;

disposing the containment member about an exterior surface of the vulnerable tissue site so as to at least partially cover at least a portion of the exterior surface of the tissue site.

40. The method of claim 39 wherein the containment member is further disposed in part on a tissue site adjacent the vulnerable tissue site.

41. The method of claim 40 wherein the containment member extends along at least a portion of the vulnerable tissue site.

42. The method of claim 41 wherein the containment member is longitudinally disposed on either side of the support member.

43. The method of claim 39 wherein the support member has an outer and an inner surface and an inner lumen defined by the inner surface and configured for passage of fluid therethrough.

44. The method of claim 40 wherein the containment member defines a neck on the vulnerable tissue site on at least one end of the containment member.

45. The method of claim 44 wherein the support member abuts the neck formed by the containment member.

46. A containment member for containing a region of a vulnerable tissue of predetermined dimensions, and provid-

ing a containment surface of sufficient dimensions to at least partially encircle the region of vulnerable tissue.

47. The containment member of claim 46 wherein the containment member includes at least one free end.

48. The containment member of claim 47 wherein the containment member includes at least one atraumatic end.

49. The containment member of claim 46 wherein the containment member comprises a strand.

50. The containment member of claim 49 wherein the strand forms a tubular member.

51. The containment member of claim 49 wherein the strand includes a wire member.

52. The containment member of claim 49 wherein the strand includes a ribbon member.

53. The containment member of any one of claims 49, 50, 51, or 52 wherein the strand includes a plurality of longitudinally oriented strands transversely spaced apart and attached to an adjacent strand with an attachment mean.

54. The containment member of claim 53 wherein the longitudinally oriented strands have a width ranging from about 0.001 to about 2 centimeters.

55. The containment member of any one of claims 49, 50, 51, or 52 wherein the strand includes a plurality of longitudinally oriented strands transversely spaced apart and a plurality of transversely oriented strands longitudinally spaced apart, the longitudinally oriented strands connected to one another by at least one of the transversely oriented strands.

56. The containment member of claim 55 wherein the longitudinally oriented and transversely oriented strands have a width, independently, ranging from about 0.0001 to about 2 centimeters.

57. The containment member of any one of claims 49, 50, 51, or 52 wherein the strand is formed of a material from the group consisting of polymers, metals, shape memory alloys, biodegradable material, and a combination thereof.

58. The containment member of claim 56 wherein the shape memory alloy includes nickel titanium.

59. The containment member of any one of claims 49, 50, 51, or 52 wherein the strand is in the form of a coil.

60. The containment member of claim 59 wherein the coil has a constant diameter.

61. The containment member of claim 59 wherein the coil has a variable diameter.

62. The containment member of claim 59 wherein the coil is tapered at either or both ends.

63. The containment member of claim 59 wherein at least some of the turns of the coil when disposed about the exterior of the tissue site wrap around the circumference of the tissue site.

64. The containment member of claim 59 wherein the turns of the coil when disposed about the exterior of the tissue site form an arcuate structure.

65. The containment member of claim 59 wherein the coil in a relaxed configuration has a pitch between adjacent turns ranging from about 0.002 to about 20 centimeters.

66. The containment member of claim 65 wherein the pitch ranges from about 0.002 to about 2 cm.

67. The containment member of claim 65 wherein the pitch ranges from about 2 to about 10 cm.

68. The containment member of claim 65 wherein the pitch ranges from about 10 to about 20 cm.

69. The containment member of claim 65 wherein the coil has a variable pitch.

70. The containment member of claim 65 wherein the containment member has means to secure the adjacent turns of the coil.

71. The containment member of claim 70 wherein the securing means includes any one of coil, wire, or strand.

72. The containment member of claim 49 wherein the containment member has a longitudinal dimension ranging from about 1 mm to about 50 cm.

73. The containment member of claim 49 wherein the containment member includes multiple lumens.

74. The containment member of claim 73 wherein at least one of the multiple lumens is configured to be an inflation lumen, a therapeutic fluid delivery lumen, or a strand lumen.

75. The containment member of claim 49 wherein the containment member has outer and inner surfaces defining at least in part a wall, a lumen disposed within the wall, and a containment surfaces defined at least in part by the inner surface of the wall.

76. The containment member of claim 75 wherein the containment member is configured to deliver therapeutic fluids to the tissue site.

77. The containment member of claim 75 wherein the lumen defined by the containment member inner and outer surfaces is a fluid lumen, either or both the containment member outer and inner surfaces including at least one aperture fluidically connectable to the containment member fluid lumen.

78. The containment member of claim 77 wherein the aperture size ranges from about 1 micron to about 2 millimeters.

79. The containment member of claim 78 wherein the aperture size ranges from about 1 micron to about 1 cm.

80. The containment member of claim 77 wherein the fluid lumen is fluidically connectable to a source of therapeutic fluid.

81. The containment member of claim 50 wherein the containment member has an outer diameter and an inner diameter defined by the inner surface.

82. The containment member of claim 81 wherein the inner diameter is configured to have a variable dimension.

83. The containment member of claim 82 wherein the containment member has outer and inner surfaces and a fluid lumen defined therebetween and a containment lumen defined by the inner surface, and the inner diameter of the containment member is decreased upon the expansion of the containment member fluid lumen.

84. The containment member of claim 83 wherein the fluid lumen is fluidically connectable to a source of inflation lumen.

85. The containment member of claim 49 wherein the containment member further includes a sleeve disposed on at least a portion of an exterior surface of the containment member.

86. The containment member of claim 85 wherein the sleeve includes multiple lumens.

87. The containment member of claim 86 wherein at least one of the multiple lumens of the sleeve is configured to be an inflation lumen.

88. The containment member of claim 85 wherein the sleeve has an inner and outer surface and an inner lumen disposed therebetween.

89. The containment member of claim 88 wherein the containment member has an inner diameter defined by an

inner surface of the containment member, the containment member inner diameter decreasing upon the expansion of the sleeve inner lumen.

90. The containment member of claim 89 wherein the sleeve inner lumen is fluidically connectable to a source of inflation fluid.

91. The containment member of claim 75 wherein the containment member is configured to at least partially encircle at least a portion of the tissue site.

92. The containment member of claim 91 wherein the containment member is configured to at least partially encircle at least a portion of a tissue site adjacent the vulnerable tissue site.

93. The containment member of claim 75 wherein the containment member inner surface has a curvature substantially less than 360°.

94. The containment member of claim 75 wherein the containment member inner surface includes an adhesion promoter.

95. The containment member of claim 94 wherein the adhesion promoter is selected from the group consisting of fibrin and cyanoacrylates.

96. The containment member of claim 50 wherein the containment member has an outer surface defining an outer diameter and an inner surface defining an inner diameter.

97. The containment member of claim 96 wherein the vulnerable tissue site has a first thickness and a tissue site adjacent the vulnerable tissue site has a second thickness.

98. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is substantially the same or slightly larger than the thickness of the vulnerable tissue site.

99. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is substantially larger than the thickness of the vulnerable tissue site.

100. The containment member of claim 99 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is about 25% larger than the thickness of the vulnerable tissue site.

101. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is substantially between the first thickness of the vulnerable tissue site and second thickness of the adjacent tissue site.

102. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is substantially the same as the second thickness of the adjacent tissue site.

103. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is slightly less than the second thickness of the adjacent tissue site.

104. The containment member of claim 97 wherein the dimension of the inner diameter of the containment member in a relaxed configuration is about 10% less than the second thickness of the adjacent tissue site.

105. The containment member of claim 101 wherein the vulnerable and adjacent tissue sites are part of a first tubular

member and the first and second thicknesses are defined by outer diameters of the vulnerable and adjacent tissue sites, respectively.

106. The containment member of claim 77 wherein the aperture is configured to delivered hardenable material to the exterior surface of vulnerable tissue site.

107. A containment member for containing a region of a vulnerable tissue of predetermined dimensions, and configured to provide a containment surface of sufficient dimensions to be at least partially disposed about a portion of an exterior surface of the region of vulnerable tissue.

108. The containment member of claim 107 wherein the containment member includes at least one free end.

109. The containment member of claim 108 wherein the containment member includes at least one atraumatic end.

110. The containment member of claim 107 further configured for attachment to a positioning means.

111. The containment member of claim 110 wherein the positioning means is configured for securing the containment member to an adjacent tissue site or body part to minimize further vulnerability of the tissue site.

112. The containment member of claim 111 wherein the containment member is configured to provide a compressive force against the vulnerable tissue.

113. The containment member of claim 112 wherein the positioning means is configured to be biased against an adjacent healthy tissue site or body part.

114. The containment member of claim 113 wherein the containment member is configured to provide a compressive force against the vulnerable tissue.

115. A containment member for containing a region of a vulnerable tissue of predetermined dimensions, providing a containment area of sufficient dimensions to cross over the region of the vulnerable tissue and be secured to healthy tissue adjacent to the region or two opposing sides of the region.

116. A delivery system for delivering a containment member to vulnerable tissue site of an intracorporeal body, comprising:

a catheter for slidably housing the containment member therein and further having proximal and distal portions and having a curve at a distal end thereof to bring about the desired deflection at the catheter distal end to negotiate the catheter through tortuous anatomy during treatment.

117. The system of claim 116 wherein the curve is formed within up to about 2 mm to 20 cm of the catheter distal end.

118. The system of claim 116 wherein the distal end has a curvature ranging from about 0.5 to about 3 cm.

119. The system of claim 116 wherein the distal end is configured to have an angle ranging from about -180 degrees to +180 degrees.

120. The system of claim 116 wherein the catheter has multiple deflection points.

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专利名称(译)	用于治疗脆弱组织部位的方法和装置		
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[标]申请(专利权)人(译)	索罕MOTASIM 闫JOHN Gertner教授KEVIN		
申请(专利权)人(译)	索罕MOTASIM 闫JOHN Gertner教授KEVIN		
当前申请(专利权)人(译)	索罕MOTASIM 闫JOHN Gertner教授KEVIN		
[标]发明人	SIRHAN MOTASIM YAN JOHN GERTNER KEVIN		
发明人	SIRHAN, MOTASIM YAN, JOHN GERTNER, KEVIN		
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外部链接	Espacenet USPTO		

摘要(译)

本发明涉及用于治疗脆弱组织部位(例如腹部区域或胸腔中的动脉瘤)和各种器官和身体表面(例如心脏)上的扩张组织的方法和装置。本发明的装置是用于至少部分地容纳易损组织部位的容纳构件,从而防止或最小化该部位的进一步脆弱性或生长。另外或替代地,容纳构件可以对易损组织部位施加阻力。该力可以压靠组织部位的外表面。本发明的容纳构件可单独使用或与支撑构件(例如支架/移植物)组合用于治疗组织部位。在该实施例中,支撑构件设置在易损组织部位的内腔内,容纳构件设置在腔的外表面上。

