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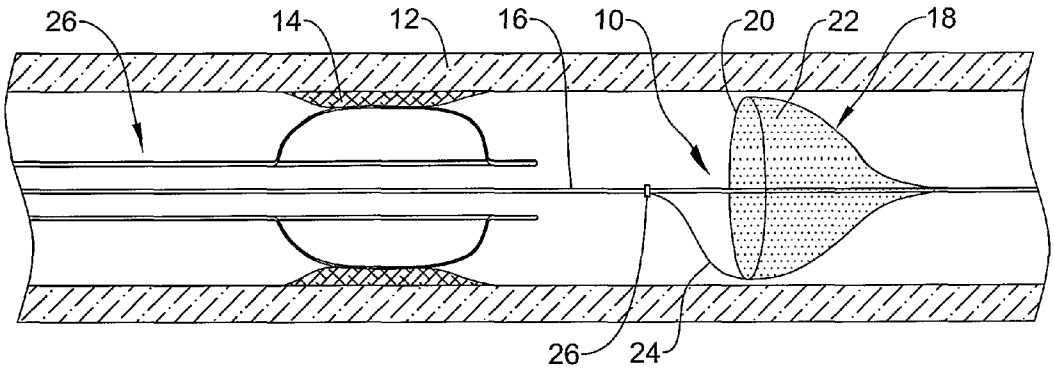
(54) **Title:** IMPROVED SHEATH FOR USE WITH AN EMBOLIC PROTECTION FILTER



(57) **Abstract:** An embolic protection filtering device and methods and making and using filtering devices. An example filtering device may include an elongate shaft or filter wire, a filter coupled to the filter wire, and a sheath. The methods for using the filtering device include using an introducer member to help back load a guidewire into the sheath and then advance the filtering device along the guidewire to a target region.

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IMPROVED SHEATH FOR USE WITH AN EMBOLIC PROTECTION FILTER

Field of the Invention

The present invention pertains to embolic protection filter devices. More particularly, the present invention pertains to filtering devices with a sheath and methods for making and using filtering devices with a sheath.

Background

Heart and vascular disease are major problems in the United States and throughout the world. Conditions such as atherosclerosis result in blood vessels becoming blocked or narrowed. This blockage can result in lack of oxygenation of the heart, which has significant consequences because the heart muscle must be well oxygenated in order to maintain its blood pumping action.

Occluded, stenotic, or narrowed blood vessels may be treated with a number of relatively non-invasive medical procedures including percutaneous transluminal angioplasty (PTA), percutaneous transluminal coronary angioplasty (PTCA), and atherectomy. Angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire such that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated and the restriction of the vessel is opened. During an atherectomy procedure, the stenotic lesion may be mechanically cut away from the blood vessel wall using an atherectomy catheter.

During angioplasty and atherectomy procedures, embolic debris can be separated from the wall of the blood vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural and pulmonary vasculature. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. Because of this debris, a number of devices, termed embolic protection devices, have been developed to filter out this debris. There is an ongoing need to provide alternative filtering devices as well as methods for making and using filtering devices.

Brief Summary

The invention provides design, material, and manufacturing method alternatives for embolic protection filtering devices. Exemplary filtering devices include an elongate shaft or filter wire, a filter coupled to the filter wire, and a sheath. The methods for using the filtering device include using an introducer member to help back load a guidewire into the sheath and then advance the filtering device along the guidewire to a target region. Once positioned, for example, the guidewire can be removed and the filtering device may be used for its intended purpose.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

Brief Description of the Drawings

Figure 1 is a partial cross-sectional plan view of an example filtering device disposed in a blood vessel;

Figure 2 is a side view of an example filtering device;

Figure 3 is a cutaway view of an example filtering device in suitable consumer packaging;

Figure 4 is a side view of an example filtering device where the filter is collapsed within a sheath;

Figure 5 is partial cross-sectional plan view depicting a guidewire disposed in a blood vessel adjacent a target region;

Figure 6 is a side view of an example filtering device having an introducer member coupled thereto;

Figure 7 is a partial cross-section side view depicting the guidewire of Figure 5 being back loaded through the introducer member;

Figure 8 is a partial cross-section side view depicting the introducer member being removed from the filtering device;

Figure 9 is a partial cross-section side view depicting the filtering device being advanced over the guidewire;

Figure 10 is a partial cross-sectional side view where the guidewire is removed; and

Figure 11 is a partial cross-sectional side view depicting the filter expanded in the blood vessel.

Detailed Description

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings illustrate example embodiments of the claimed invention.

When a clinician performs an intravascular intervention such as angioplasty, atherectomy, and the like, embolic debris may dislodge from the blood vessel that can travel in the bloodstream to a position where it may impair blood flow, possibly leading to tissue damage. A number of other situations and/or interventions may also result in the mobilization of embolic debris. Accordingly, embolic protection filtering devices have been developed that can be disposed in the blood vessel downstream of the treatment site and expanded to capture debris.

Figure 1 is a partial cross-sectional view of an example embolic protection filtering device 10 disposed within a blood vessel 12 adjacent an intravascular lesion 14. Device 10 may include an elongate shaft or filter wire 16 having an embolic protection filter 18 coupled thereto. Filter 18 may include a filter frame 20 and a filter material or fabric 22 coupled to filter frame 20. In general, filter 18 may be adapted to operate between a first generally collapsed configuration and a second generally expanded configuration for collecting debris in a body lumen. Frame 20 may be comprised of a "self-expanding" shape-memory material such as nickel-titanium alloy, which is capable of biasing filter 18 toward being in the second expanded configuration. Additionally, frame 20 may include a radiopaque material or include, for example, a radiopaque wire disposed about a portion thereof. Some further details regarding these and other suitable materials is provided below. Filter material 22 can be drilled (for example, formed by known laser techniques) or otherwise manufactured to include at least one opening. The holes or openings can be sized to allow blood flow therethrough but restrict flow of debris or emboli floating in the body lumen or cavity. One or more struts 24 may extend between frame 20 and filter wire 16 and be coupled to filter wire 16 by a coupling 26. Coupling 26 may be one or more windings of struts 24 about filter wire 16 or be a fitting disposed over an end of struts 24 to attach it to filter wire 16.

Filter wire 16 (or any other appropriate structure described herein such as filter frame 20) may include any suitable materials such as a metal, metal alloy, polymer, metal-polymer composite, and the like, or any other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic or super-elastic nitinol, nickel-chromium alloy, nickel-chromium-iron alloy, cobalt alloy, tungsten or tungsten alloys, MP35-N (having a composition of about 35% Ni, 35% Co, 20% Cr, 9.75% Mo, a maximum 1% Fe, a maximum 1% Ti, a maximum 0.25% C, a maximum 0.15% Mn, and a maximum 0.15% Si), hastelloy, monel 400, inconel 825, or the like; other Co-Cr alloys; platinum enriched stainless steel; or other suitable material.

As mentioned above, filtering device 10 or portions thereof, may also be doped with or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids the user of device 10 in determining its location. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, molybdenum, palladium, tantalum, tungsten or tungsten alloy, plastic material loaded with a radiopaque filler, and the like.

With filter 18 properly positioned in blood vessel 12, another medical device 26 may be advanced over filter wire 16 in order to treat and/or diagnose lesion 14. For example, a catheter 26 (such as the balloon catheter depicted in Figure 1) may be advanced over filter wire 16 in order to expand lesion 14. Of course numerous other devices could just as easily be passed over filter wire 16 including any device designed to pass through an opening or body lumen. For example, the device may comprise any type of catheter (e.g., therapeutic, diagnostic, or guide catheter), a stent delivery catheter, an endoscopic device, a laproscopic device, and the like, or any other suitable device.

Figure 2 depicts filtering device 10 along with a sheath 28. Sheath 28 comprises a generally tubular elongate structure having a proximal end region 30, a distal end region 32, and a lumen 34 extending at least partially the length therethrough. A port or opening 36 may be defined in sheath 28, which provide access to lumen 34 from the exterior surface 38 of sheath 28. For convenience, sheath

28 and filtering device 10, collectively, are referred to subsequently as the "filtering apparatus" and denoted with reference number 40.

Sheath 28 may be made from any suitable material including polymers or any other material described herein. Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont), polyether block ester, polyurethane, polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), Marlex high-density polyethylene, Marlex low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro(propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some embodiments sheath 26 can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6% LCP.

In some embodiments, sheath 26 may include a self-sealing material, for example, near port 36 such as a polymer, rubber, a rubber septum, and the like, or any other suitable material. By utilizing a rubber septum near port 36, object can pass through port 36 and, upon removal of the object, port 36 will self-seal. The phrase self-seal in relation to port 36 is understood to mean that the seal formed around port 36 remain substantially resistant to the passage of air or fluids after an object is removed from a rubber septum. Alternatively, a rubber septum or other suitable seal

can be disposed at port 36 to achieve the same result. In addition to the sealing characteristics described above, this structural feature may also help add column strength adjacent port 36.

In at least some embodiments, filtering apparatus 40 has a number of desirable design characteristics. For example, by including port 36, apparatus 40 may be used in conjunction with essentially any available guidewire or guiding structure including typical 0.014 inch diameter guidewires and the like. This feature is desirable given that many physicians tend to have a preference for a particular, commercially available guidewire. Thus, if another device is intended to be used with the guidewire, it must be "compatible" or usable with the guidewire. Apparatus 40 fits this need by being designed to have wide ranging compatibility with numerous devices. Therefore, physicians do not need to give up their preferred guidewire in order to take advantage of the diagnostic and therapeutic benefits of apparatus 40. Furthermore, by including port 36 instead of merely providing a separate guidewire lumen, the profile of apparatus 40 can be kept compact so that apparatus 40 can access deep vascular locations in an atraumatic manner. This may allow apparatus 40 to gain access to particularly small and/or sensitive regions of the anatomy such as the central nervous system.

Figure 3 depicts a package or kit 42 that an end user (i.e., physician or other clinician) might expect to see. Kit 42 may include a generally planar backing 44 that includes one or more depressions 46 formed therein that are designed to accommodate filter 18 and sheath . A covering (not shown) may be disposed over backing and apparatus 40 so as to maintain the sterility of apparatus 40. Numerous variations are contemplated for kit 42 according to the general practice and procedure for medical device packaging.

It can also be seen in Figure 3 that kit 42 allows filter 18 to packaged outside of sheath 28. This may desirably help filter 18 retain its expanded shape and help sheath 28 from being deformed or "stretched" by virtue of filter 18 being disposed therein for an extending period of time. Prior to use, a clinician needs only to open kit 42 and back load filter 18 into sheath 26. Back loading, a term that is used throughout this description, is understood to be a process in which an object is retracted or otherwise pulled into or through another object. For example, back loading filter 18 can occur by pulling filter wire 16 proximally so that filter 18 backs into distal end region 32 of sheath 26.

The result of back loading filter 18 into sheath 26 is depicted in Figure 4. Here it can be seen that filter 18 (shown in phantom) is collapsed and disposed within lumen 34 of sheath 26. In at least some embodiments, it may be desirable to back load filter 18 to a position that is proximal of port 36. This feature allows a guidewire 48 (not shown in Figure 4, best seen in Figure 5) to be more easily back loaded into sheath 26 and, ultimately, through port 36 without interference from filter 18.

With filter 18 properly back loaded into sheath 26, apparatus 40 can be advanced over guidewire 48. Guidewire 48, as suggested above, may be the clinician's preferred guidewire and can be advanced through blood vessel 12 to a position adjacent lesion 14 as seen in Figure 5. The proper positioning of guidewire 48 may include disposing a distal end 49 of guidewire 48 beyond or otherwise adjacent lesion 14 while a proximal end 50 (not shown in Figure 5, best seen in Figure 7) of guidewire 48 remains outside the body of the patient. In some embodiments, distal end 32 of sheath 26 may be tapered, strengthened, made more elastic, or otherwise configured to improve the ability of sheath 26 to cross lesion 14.

Proximal end 50 of guidewire 48 can be back loaded into sheath 26 by pulling proximal end 50 into lumen 34 and through port 36 so that proximal end 50 is generally disposed along exterior surface 38 of sheath 26. In order to improve the ability of the clinician to back load guidewire 48 into sheath 26, an introducer member 52 may be inserted through port 36 as shown in Figure 6. According to this embodiment, introducer member 52 may have a first end 54 disposed along exterior surface 38, a body portion 56 extending through port 36 and into lumen 34, and a second end 56 positioned distally of distal end 32 of sheath 26. For example, second end 56 may extend about 2 to about 10 millimeters distally beyond distal end 32. In some embodiments, first end 54 has a flared or trumpet-like shape. This shape may, for example, facilitate insertion and removal of introducer member 52 from port 36. Introducer member 52 may be made from any suitable material including any of those materials described herein. It should be noted that introducer member 52 could be placed in port 36 prior to packaging so that introducer member 52 is included with kit 42.

Proximal end 50 of guidewire 48 can be back loaded by extending it through second end 58, through body portion 56, and out of first end 54 so to a position along exterior surface 38 of sheath as shown in Figure 7. Once guidewire 48 is back loaded and proximal end 50 is accessible along exterior surface 38, introducer member 52

may be removed from port 36 as depicted in Figure 8. Removal of introducer member 52 may include grasping first end 54 and pulling introducer member 52 from port 36.

With guidewire 48 extending through port 36, apparatus 40 can be advanced over guidewire 48 to a suitable position adjacent lesion 14, for example, across or "downstream" of lesion 14. With apparatus 40 properly positioned, guidewire 48 can be removed by proximally retracting it as depicted in Figure 10. For example, the clinician may simply grasp proximal end 50 (which is accessible outside the patient's body) and pull guidewire 48 out from vessel 12. Finally, sheath 26 can be proximally retracted to allow filter 18 to be delivered or otherwise emerge from distal end 32 so as to expand and generally conform to blood vessel 12 as seen in Figure 11. With filter 18 deployed, another medical device may be advanced over filter wire 16 as shown in Figure 1 so that the desired diagnostic or therapeutic procedure may be performed. Upon completion of the intervention, filtering device 10 can be retrieved from the vasculature using a typical retrieval sheath. In some embodiments, the retrieval sheath is the same or similar to sheath 26.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

What is claimed is:

1. An embolic protection filter assembly, comprising:

a tubular sheath having a proximal end, a distal end, a lumen defined therein, and a port positioned distally of the distal end;

an elongate filter wire;

a filter attached to the filter wire;

wherein at least a portion of the filter wire is disposed within the lumen;

an introducer member releasably attached to the sheath adjacent the port, the introducer member having a first end, a body portion, and a second end; and

wherein the first end is disposed along an exterior surface of the sheath, the body portion extends through the port and into the lumen, and the second end is positioned distally of the distal end of the sheath.

2. The assembly of claim 1, wherein the first end of the introducer member is flared.

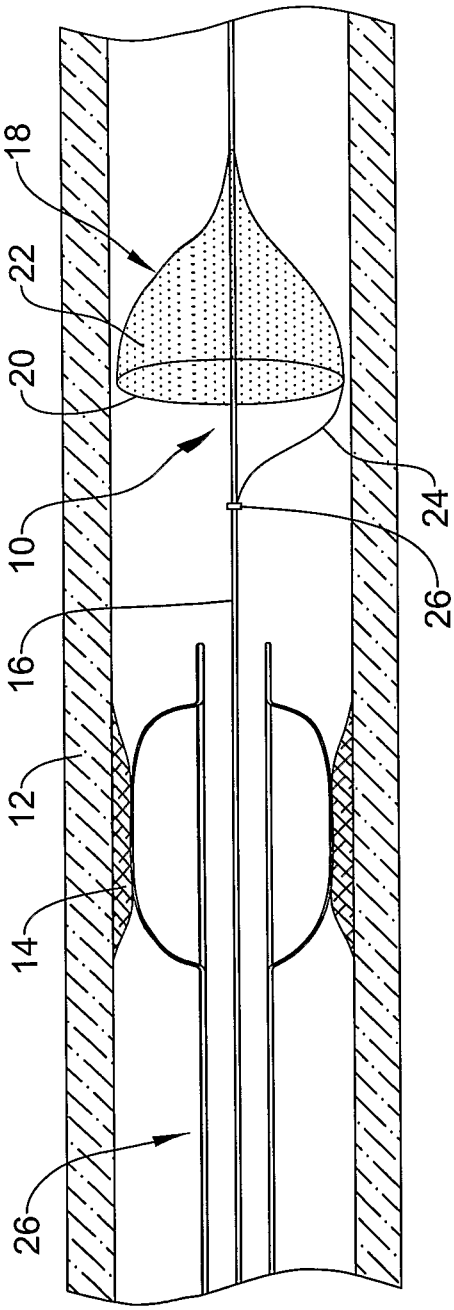

Figure 1

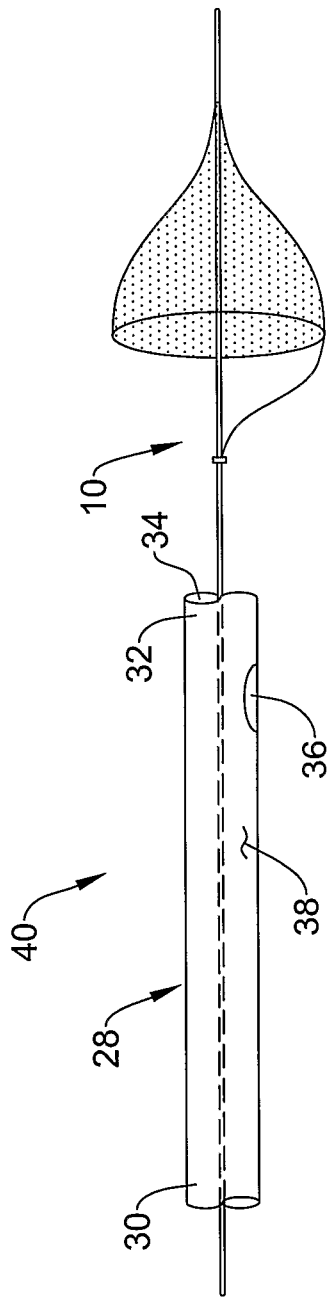

Figure 2

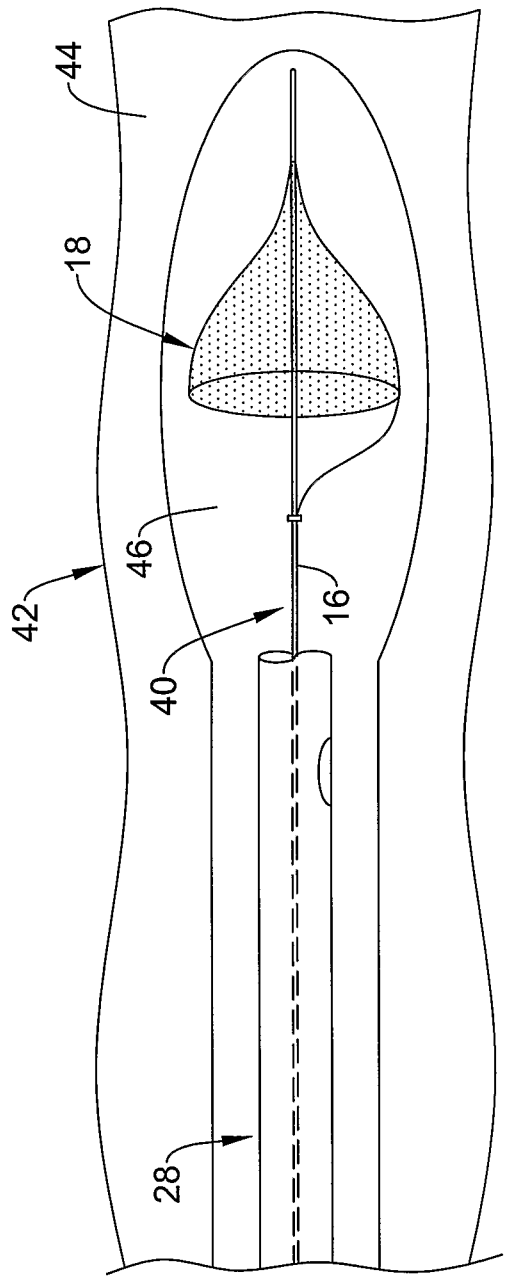

Figure 3

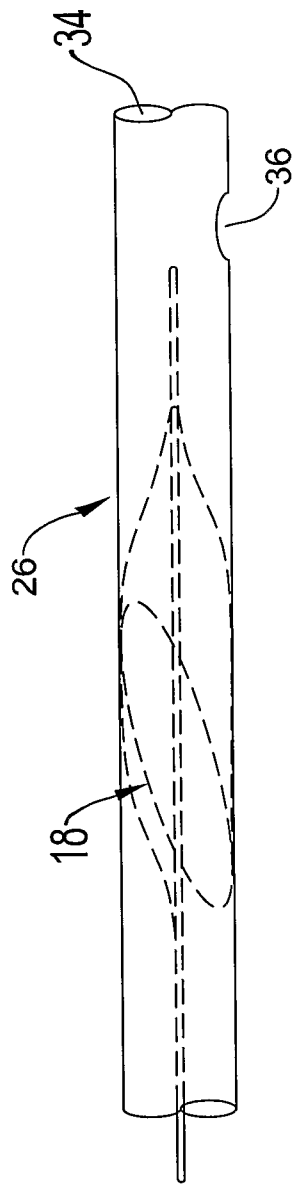

Figure 4

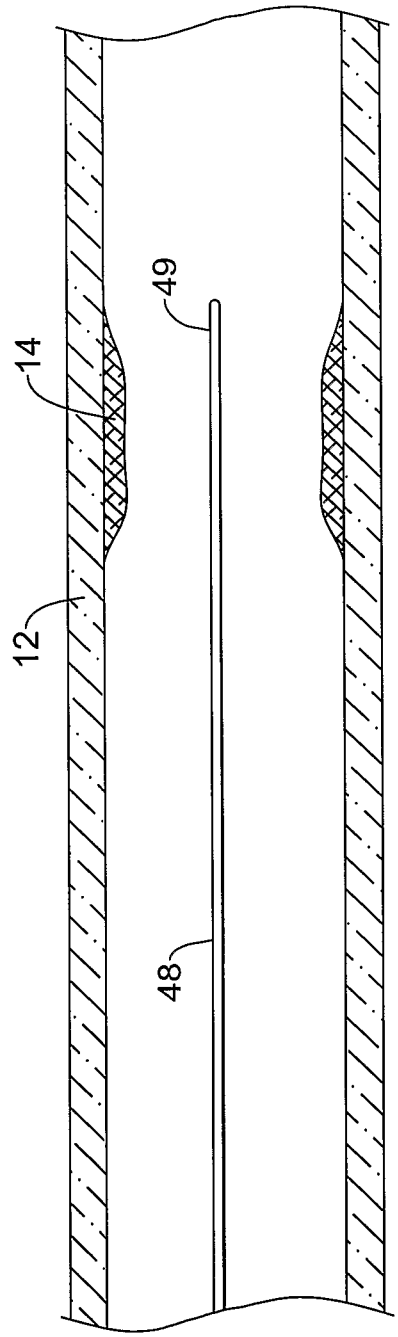

Figure 5

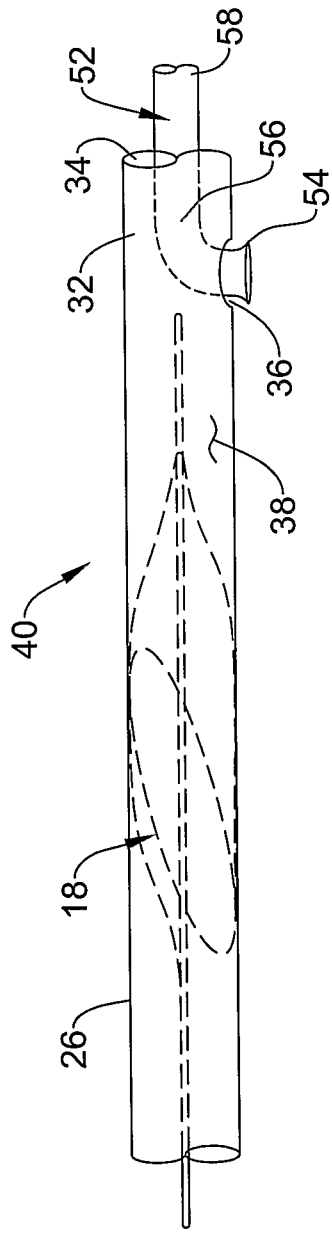

Figure 6

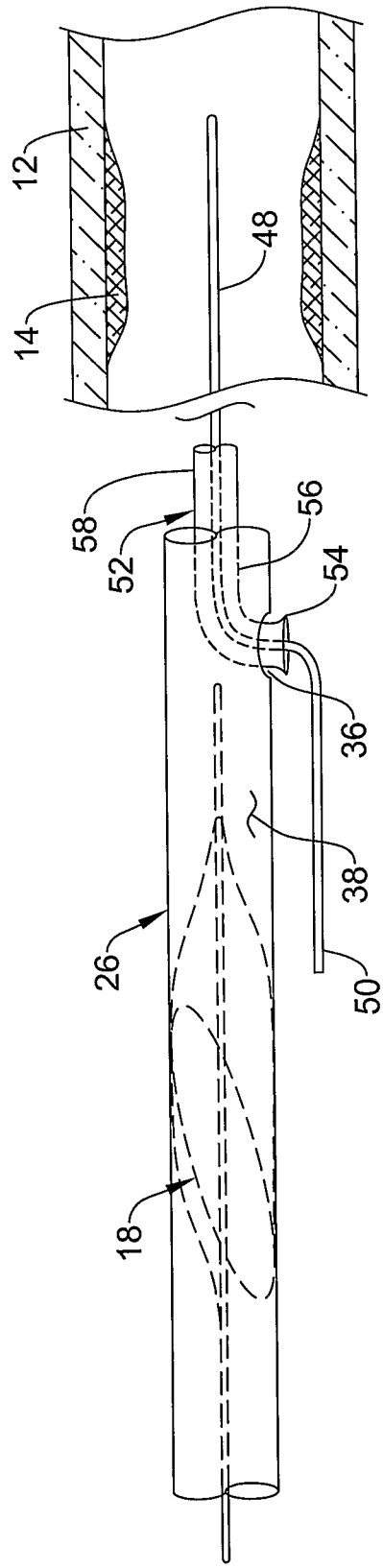

Figure 7

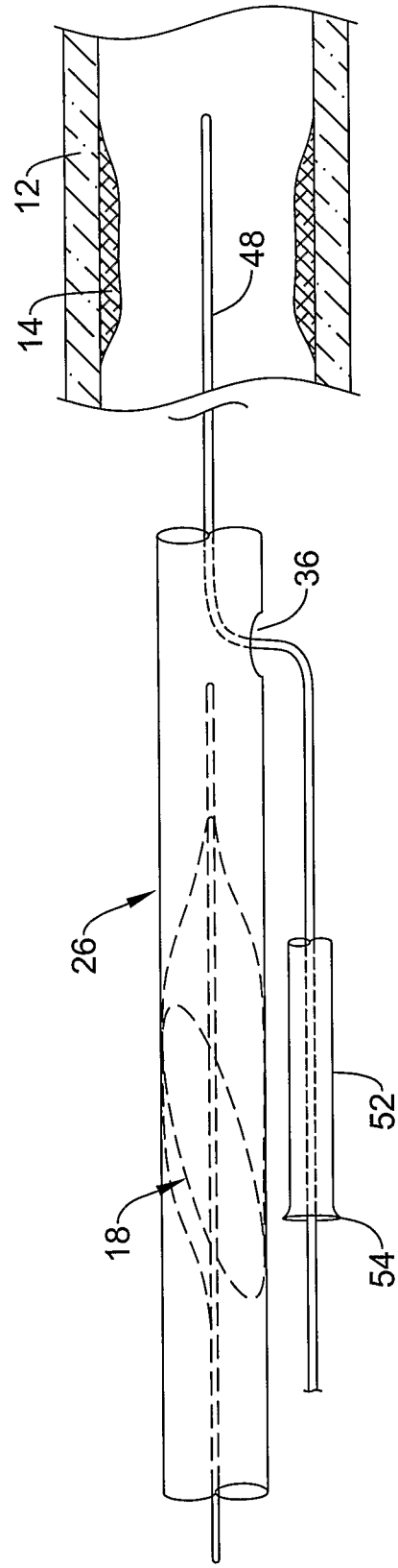

Figure 8

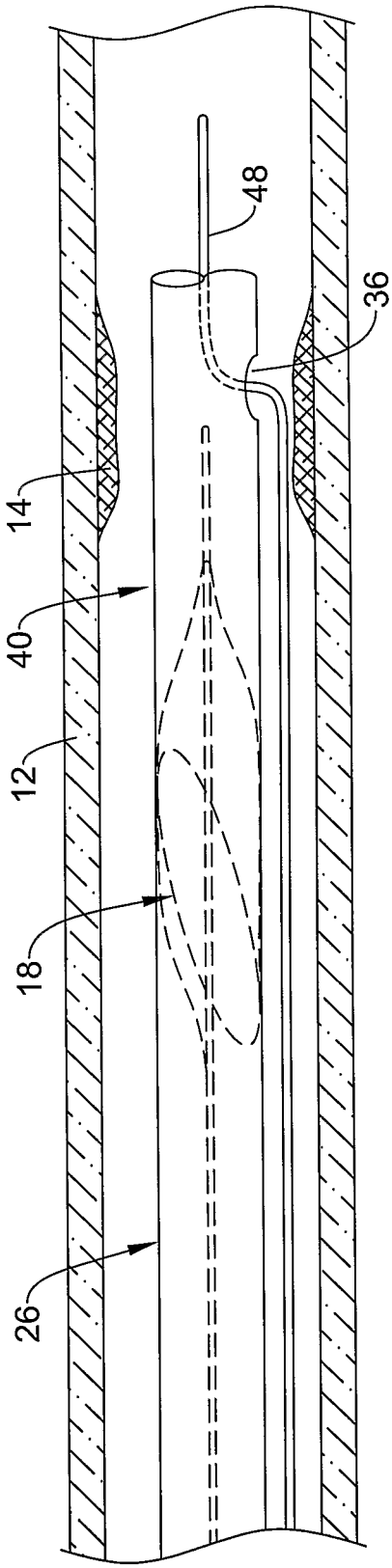

Figure 9

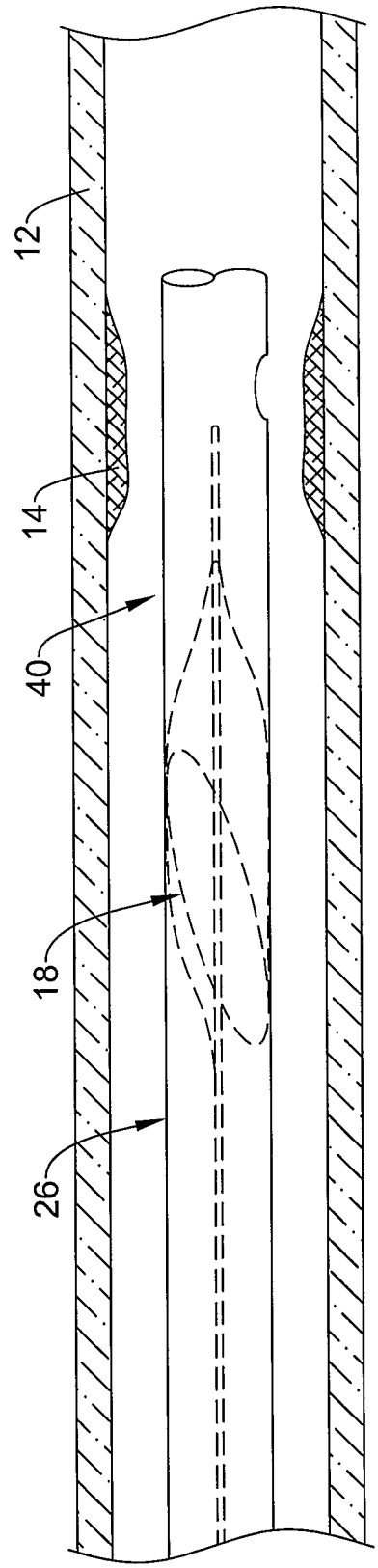

Figure 10

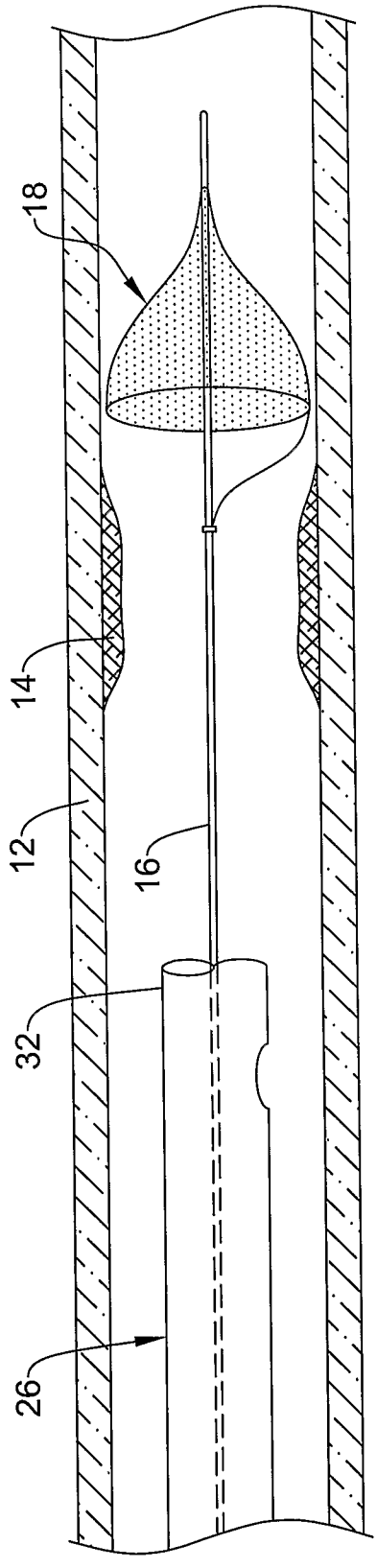

Figure 11