



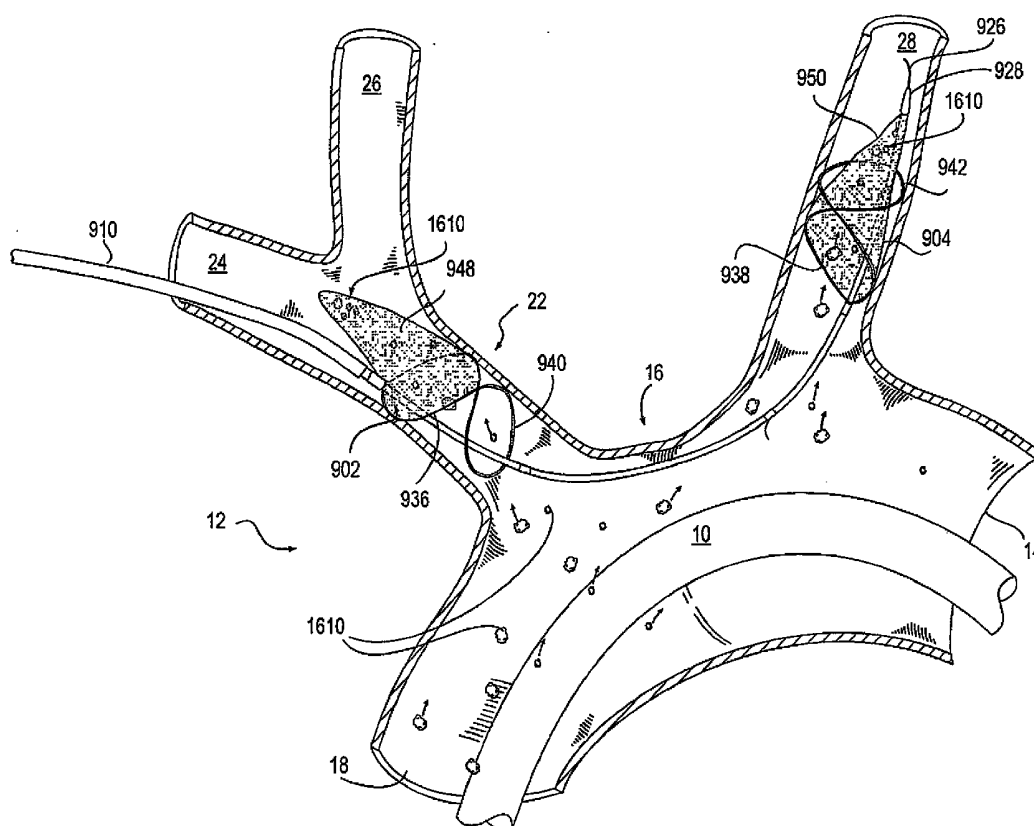
US 20160066880A1

(19) **United States**(12) **Patent Application Publication**
Stigall et al.(10) **Pub. No.: US 2016/0066880 A1**(43) **Pub. Date: Mar. 10, 2016**(54) **DISTAL PROTECTION SYSTEMS AND
METHODS WITH PRESSURE AND
ULTRASOUND FEATURES****Publication Classification**(51) **Int. Cl.***A61B 8/08* (2006.01)*A61B 8/12* (2006.01)*A61B 8/00* (2006.01)*A61F 2/01* (2006.01)(52) **U.S. Cl.**CPC *A61B 8/0841* (2013.01); *A61F 2/013*(2013.01); *A61B 8/12* (2013.01); *A61B 8/468*(2013.01); *A61B 8/461* (2013.01); *A61B**8/5207* (2013.01); *A61F 2002/011* (2013.01);*A61F 2250/0098* (2013.01)(71) Applicant: **CRUX BIOMEDICAL, INC.**, San
Diego, CA (US)(72) Inventors: **Jeremy Stigall**, San Diego, CA (US);
Eric Johnson, Woodside, CA (US)(21) Appl. No.: **14/858,484**(22) Filed: **Sep. 18, 2015****Related U.S. Application Data**(63) Continuation-in-part of application No. 14/777,232,
filed as application No. PCT/US14/30240 on Mar. 17,
2014.(60) Provisional application No. 61/794,222, filed on Mar.
15, 2013, provisional application No. 62/052,408,
filed on Sep. 18, 2014.

(57)

ABSTRACT

Embodiments of the invention relate generally to systems and methods for providing embolic protection to a medical procedure by filtration of debris generated by the medical procedure. The system and methods include an embolic protection device having an ultrasound transducer for assisting in intravascular navigation of the device.



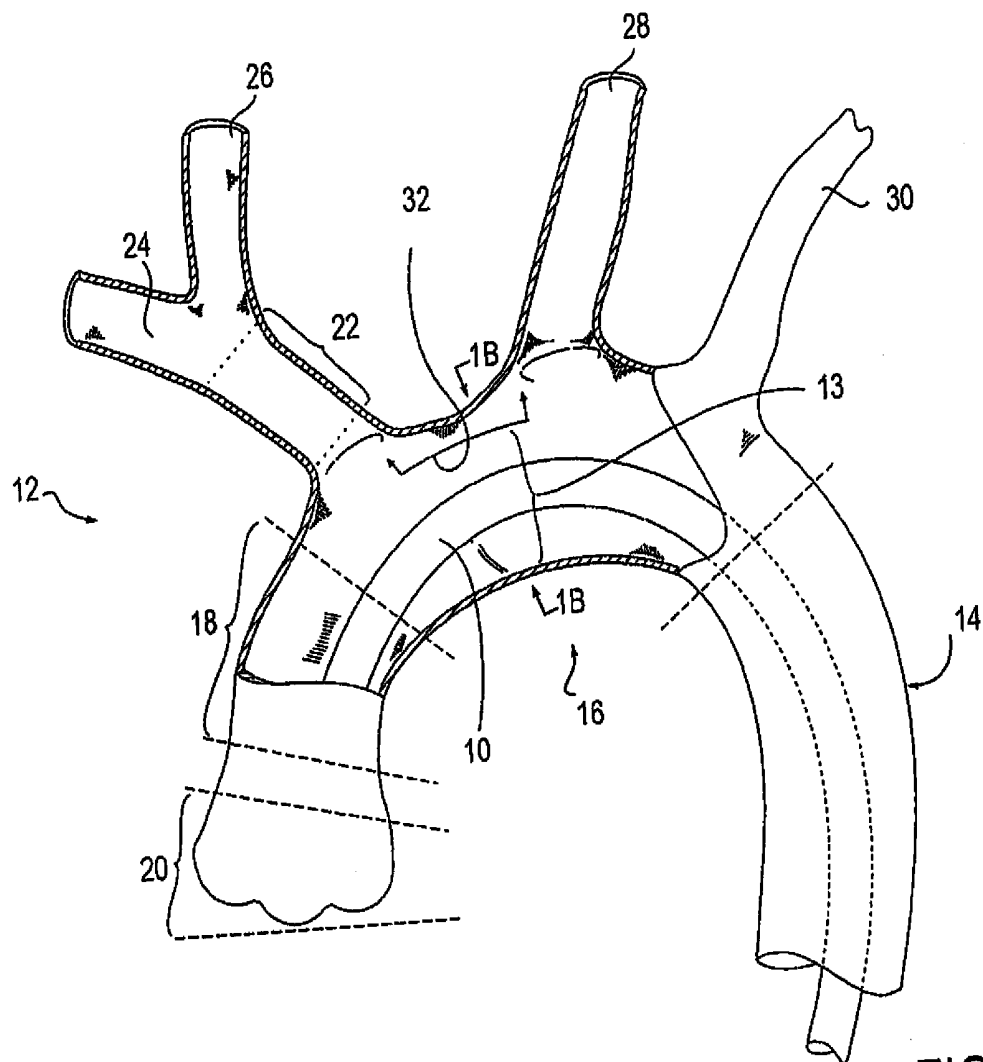


FIG. 1A

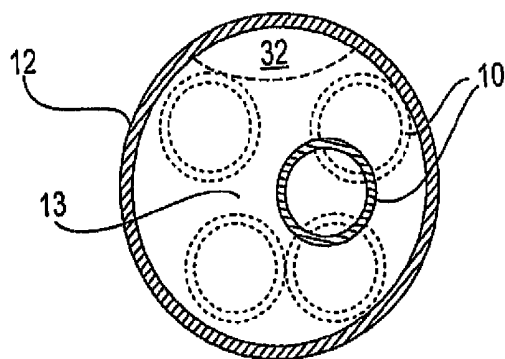


FIG. 1B

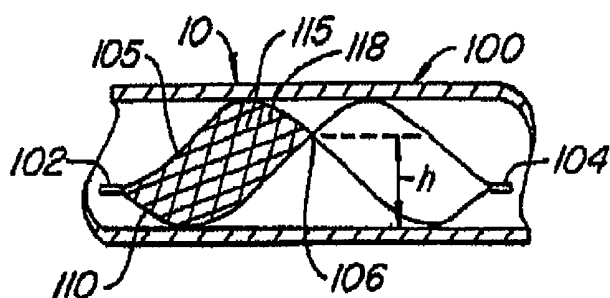


FIG. 2A'

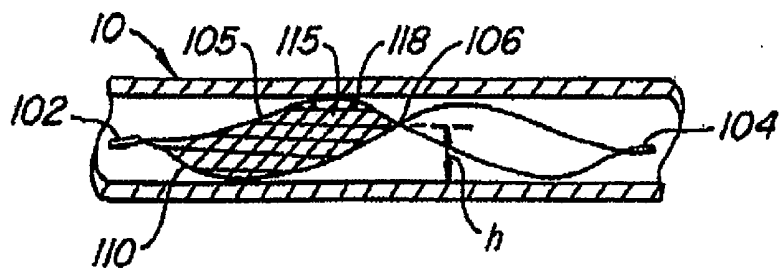


FIG. 2B

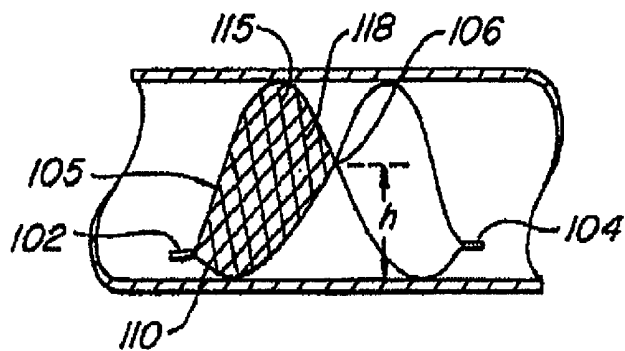


FIG. 2C

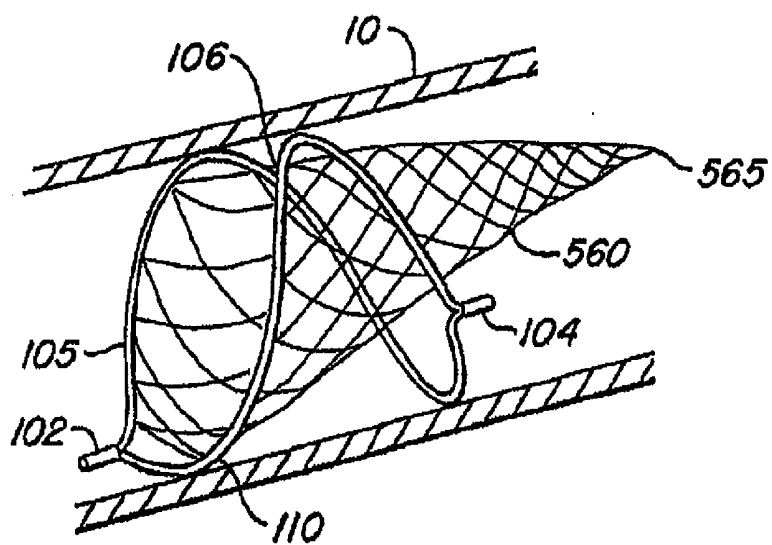


FIG. 3A

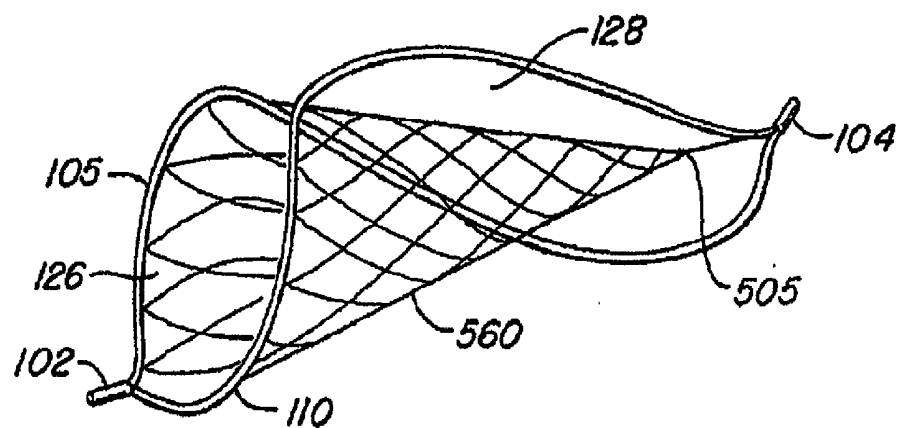


FIG. 3B

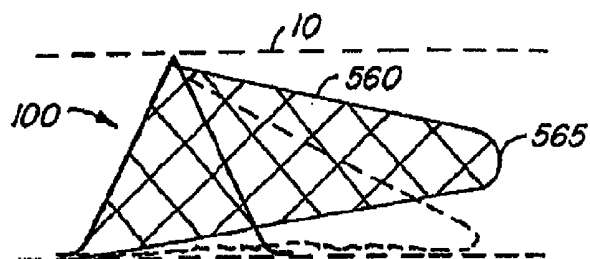


FIG. 4A

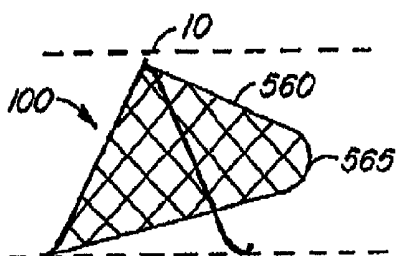


FIG. 4B

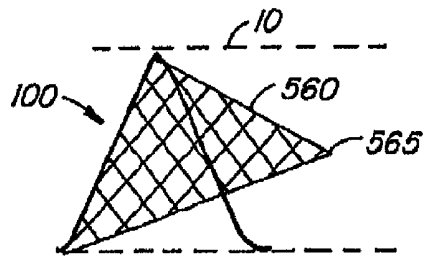


FIG. 4C

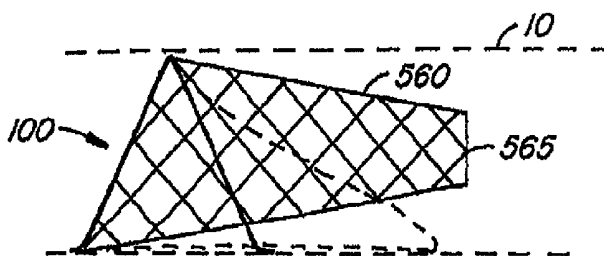


FIG. 4D

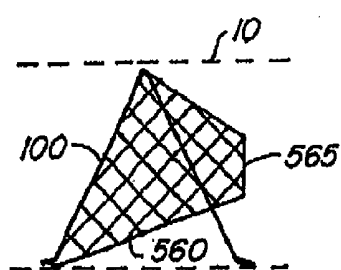


FIG. 4E

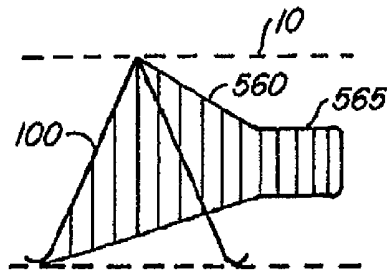


FIG. 4F

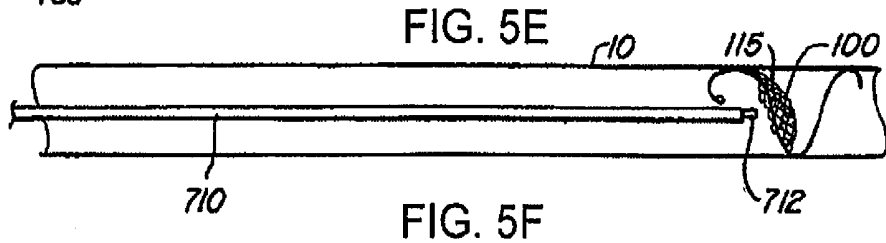
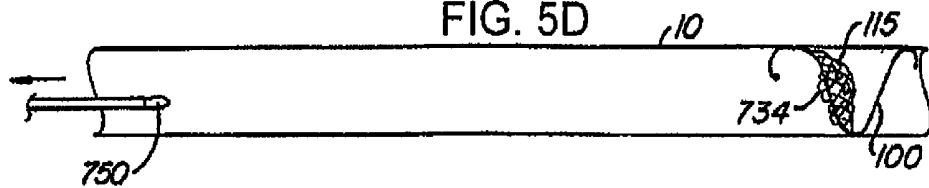
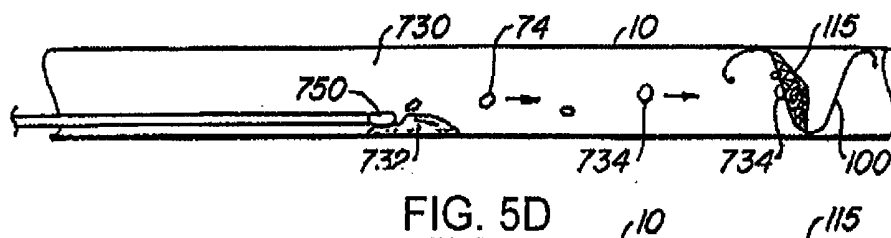
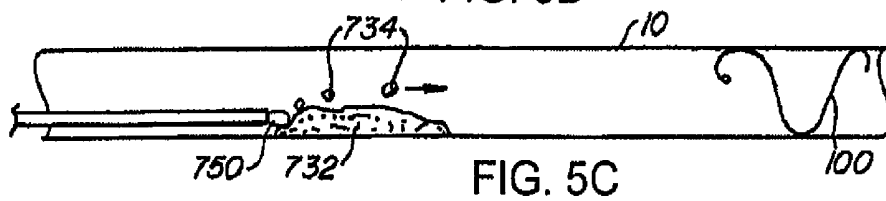
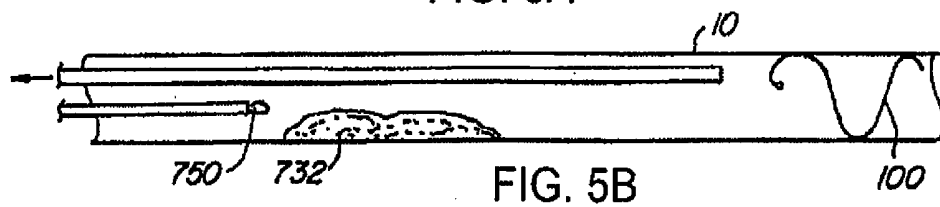
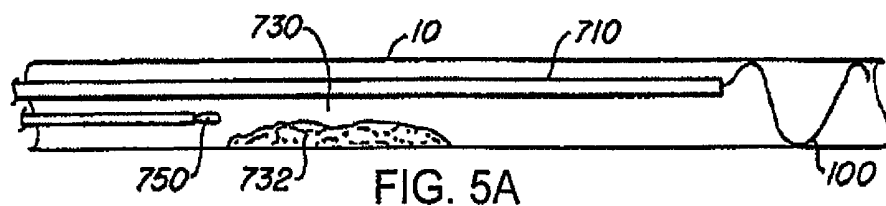




FIG. 5G



FIG. 5H



FIG. 5I

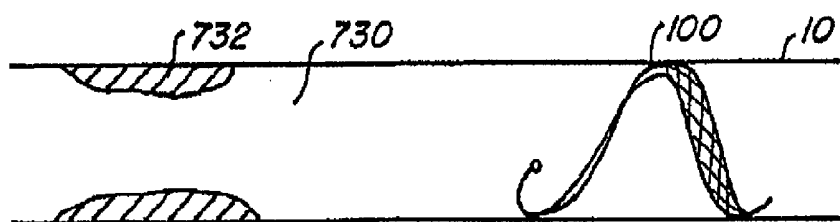


FIG. 6A

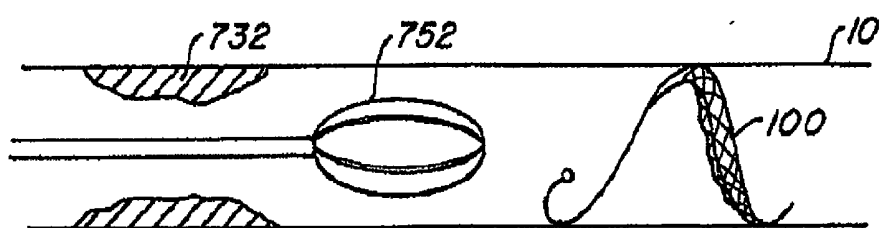


FIG. 6B

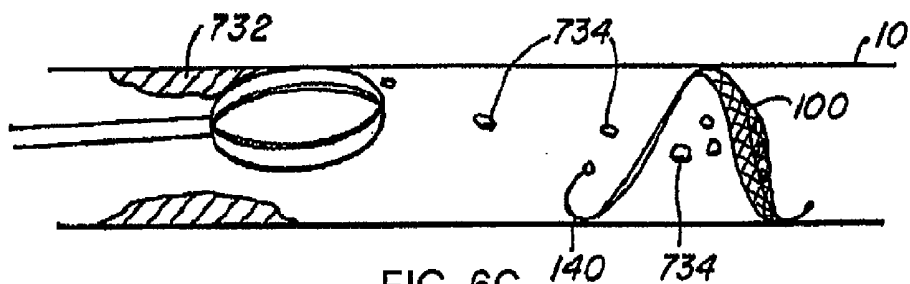


FIG. 6C

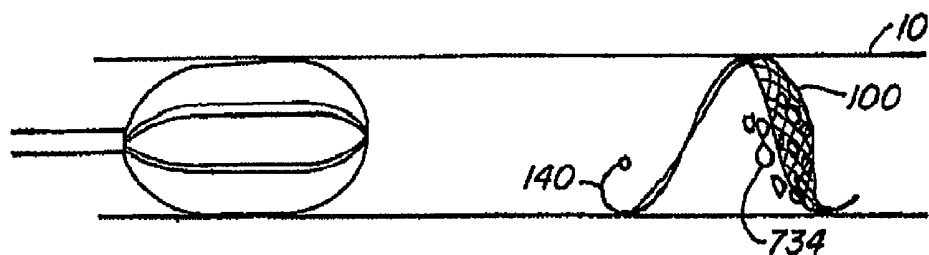


FIG. 6D

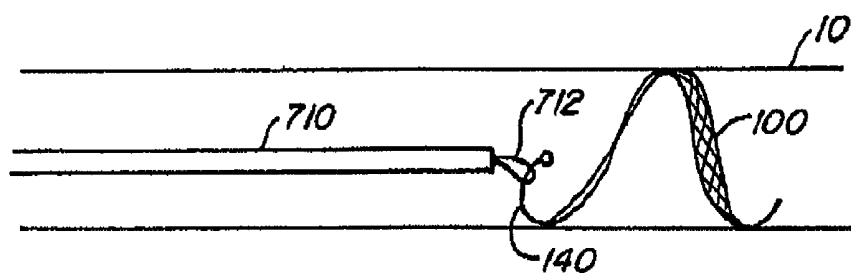


FIG. 6E

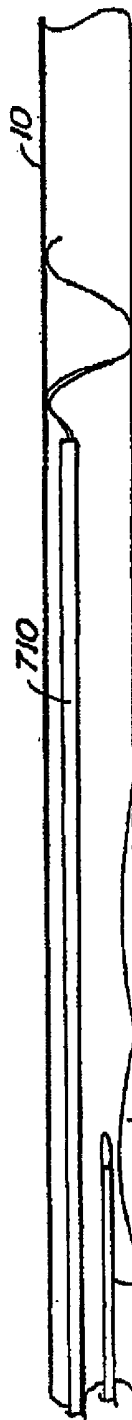


FIG. 7A

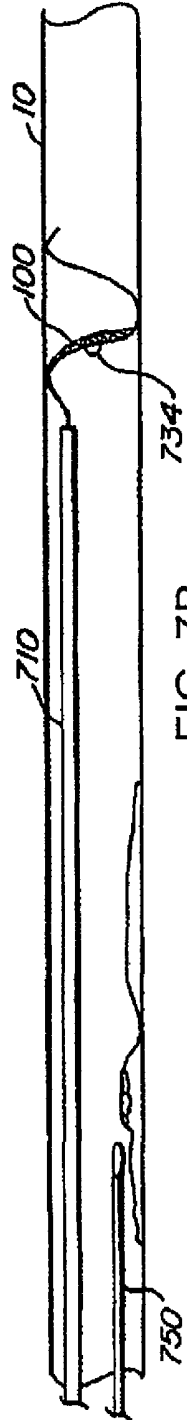


FIG. 7B



FIG. 7C

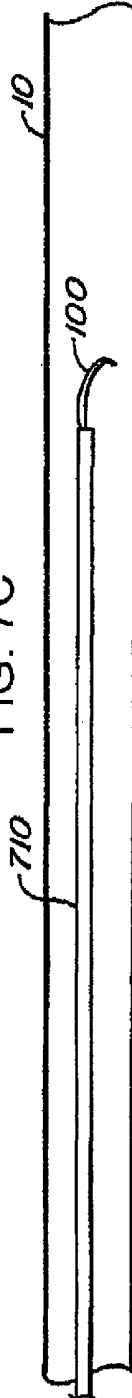


FIG. 7D



FIG. 7E

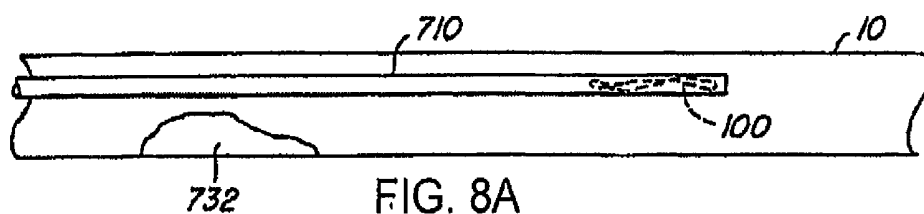


FIG. 8A

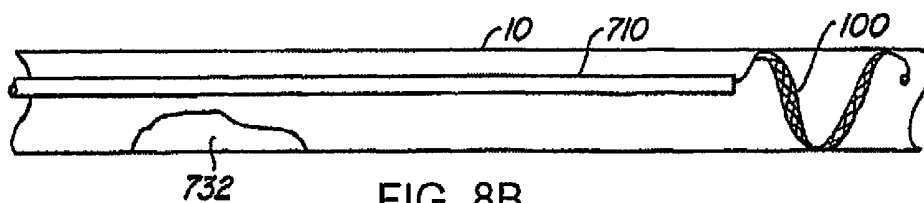


FIG. 8B

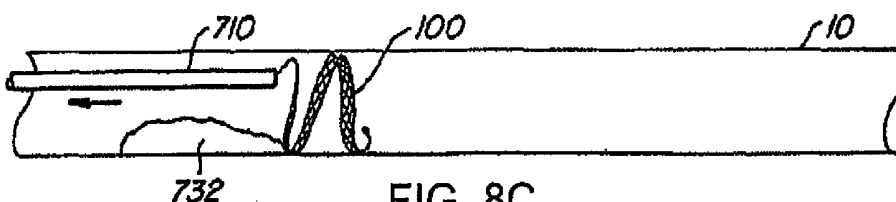


FIG. 8C

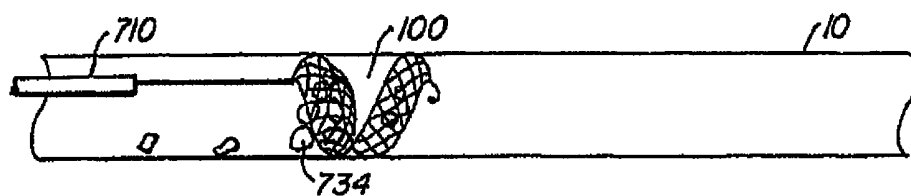


FIG. 8D

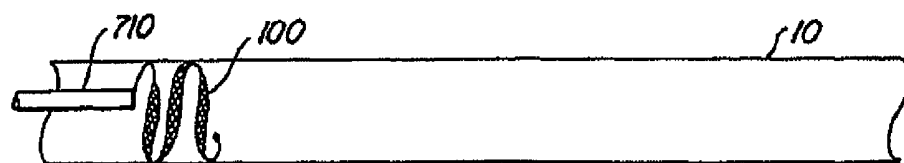


FIG. 8E

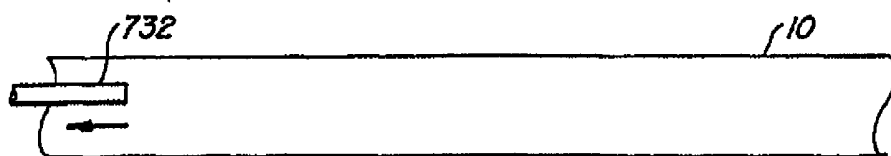
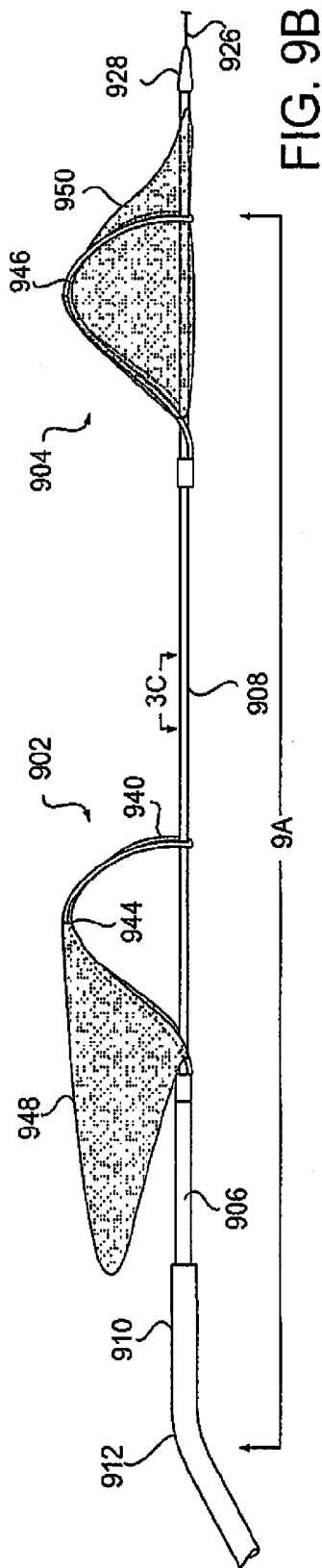
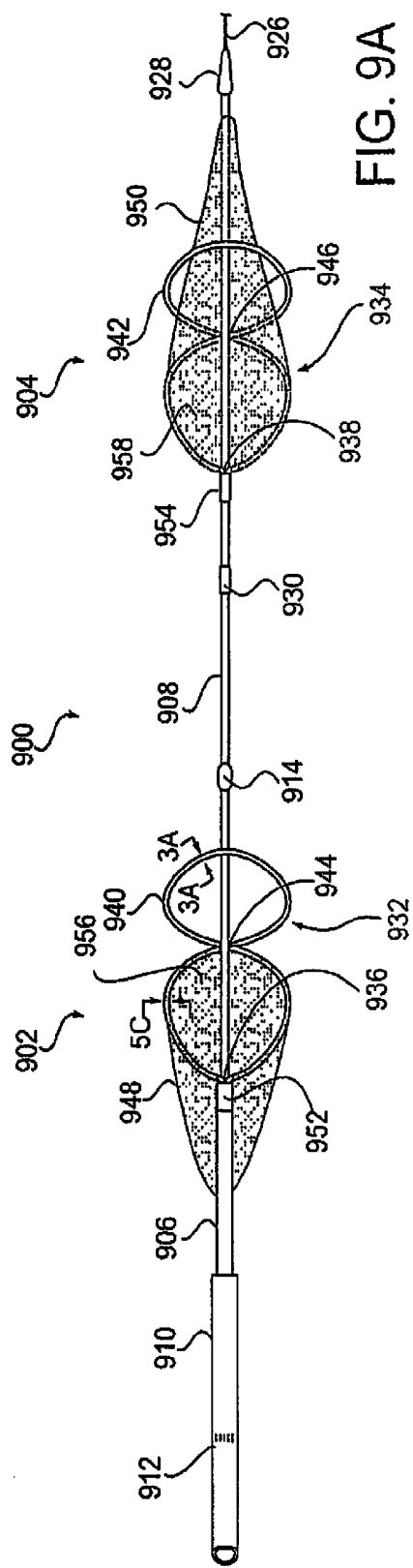


FIG. 8F



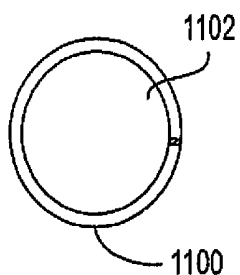


FIG. 11A

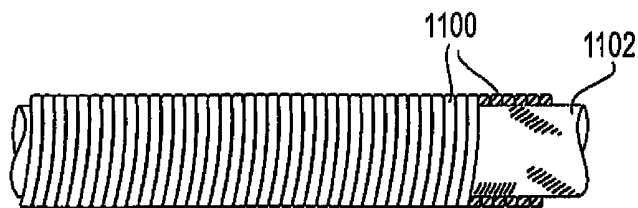


FIG. 11B

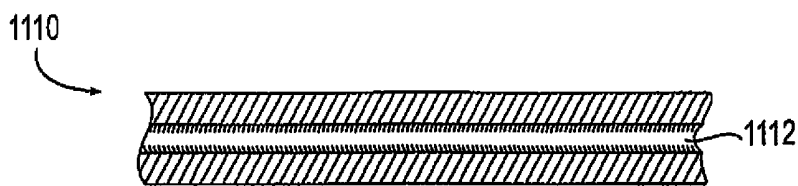


FIG. 11C

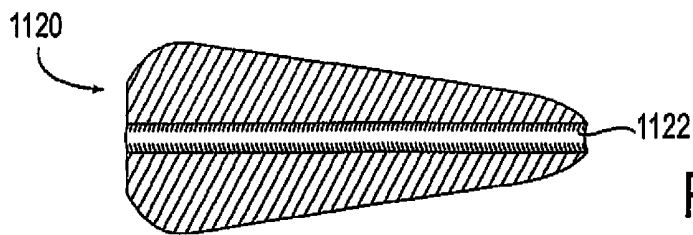


FIG. 11D

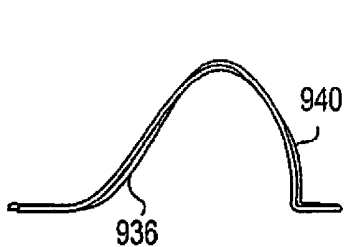


FIG. 9E

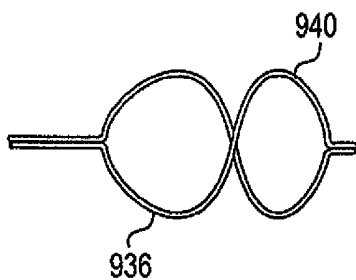


FIG. 9F

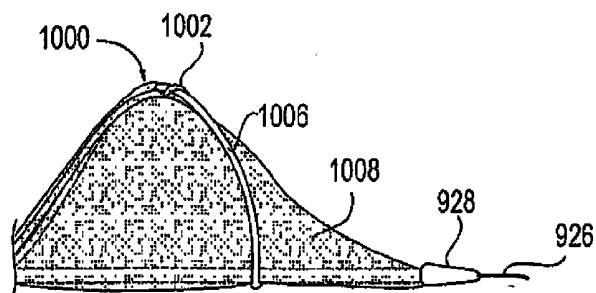


FIG. 10A

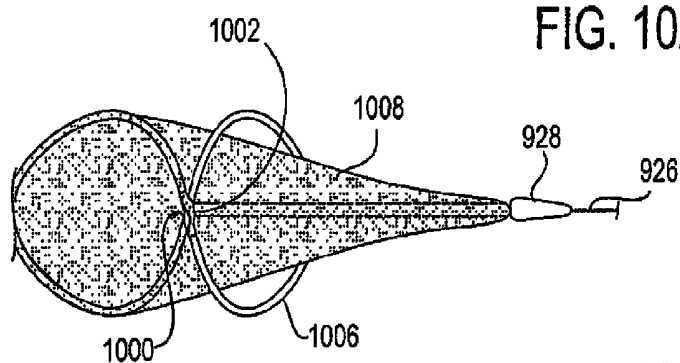


FIG. 10B

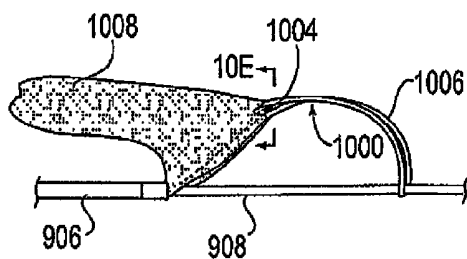


FIG. 10C

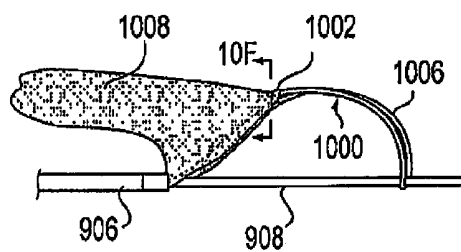


FIG. 10D

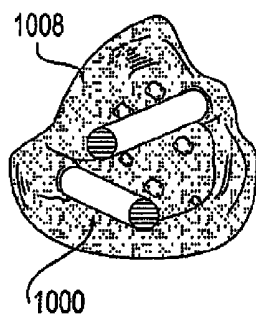


FIG. 10E

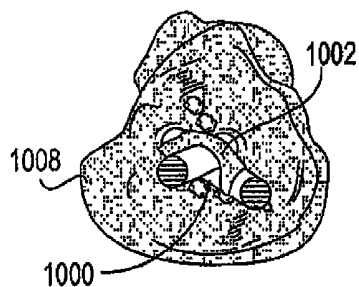


FIG. 10F

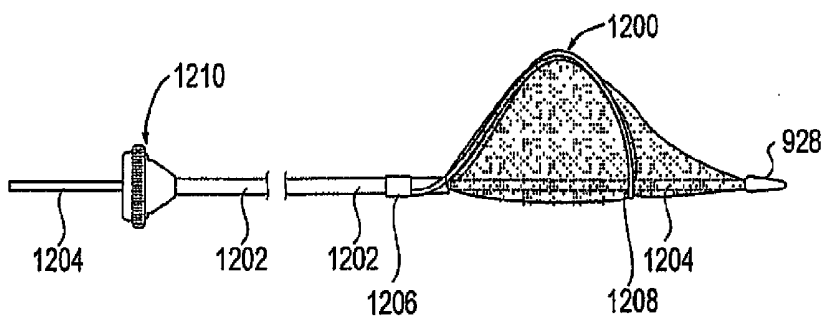


FIG. 12A

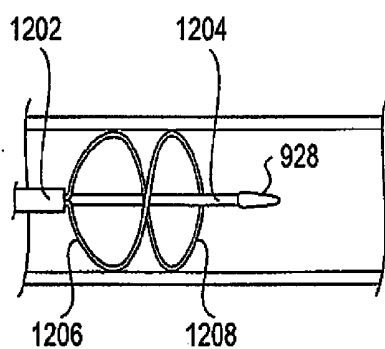


FIG. 12B

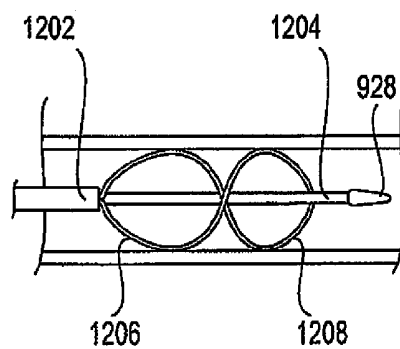


FIG. 12C

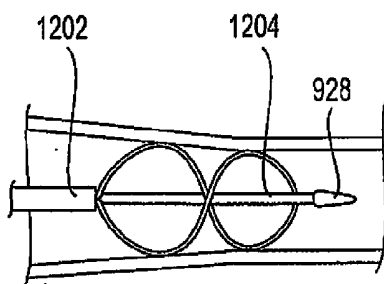


FIG. 12D

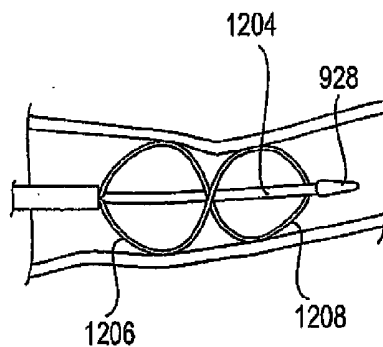


FIG. 12E

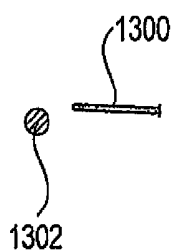


FIG. 13A

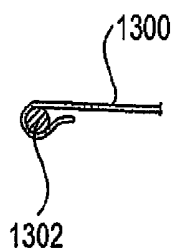


FIG. 13B

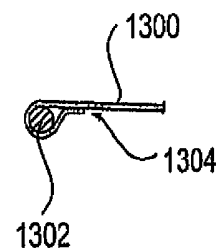


FIG. 13C

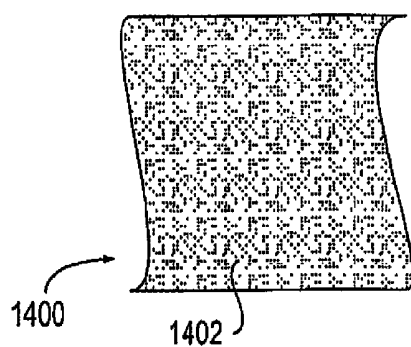


FIG. 14A

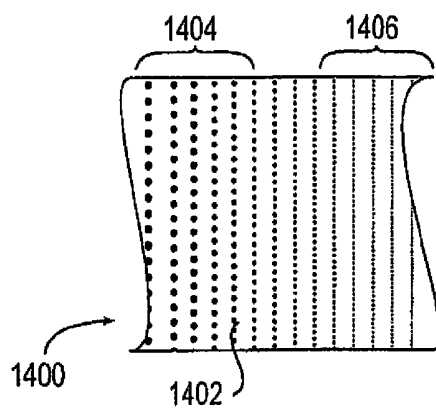


FIG. 14B

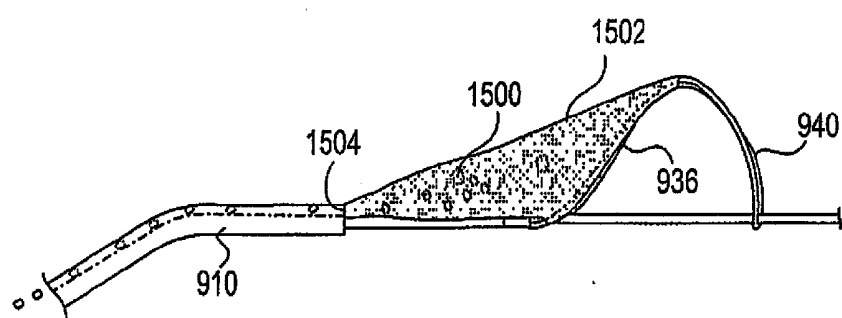


FIG. 15A

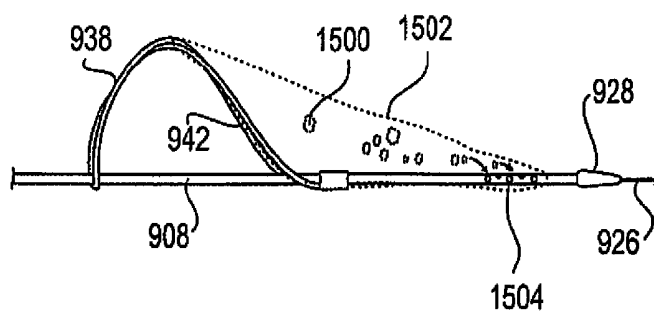


FIG. 15B

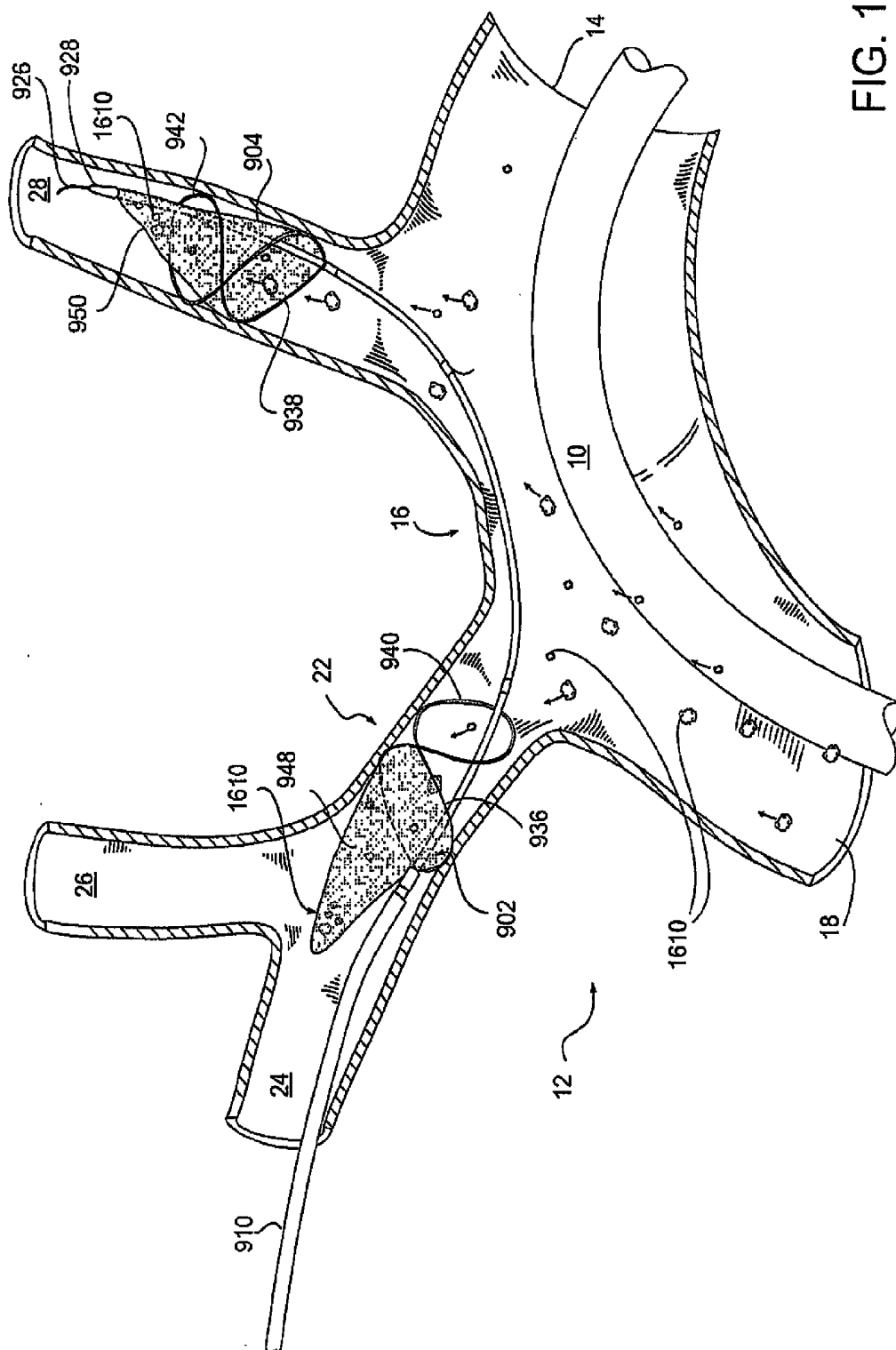


FIG. 16

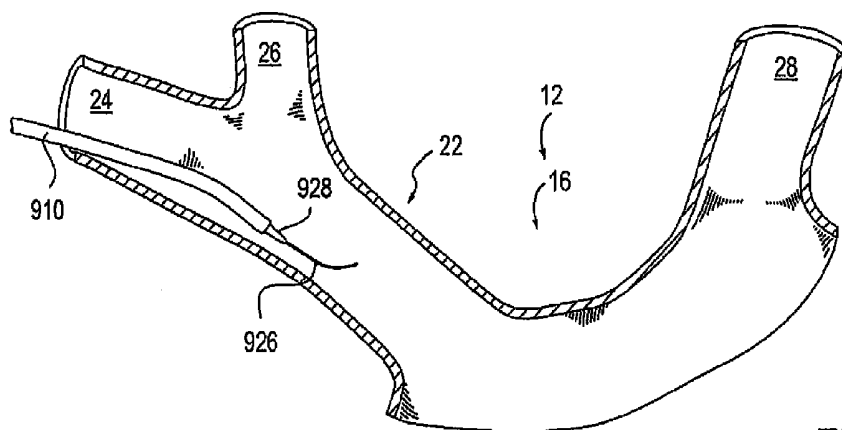


FIG. 17A

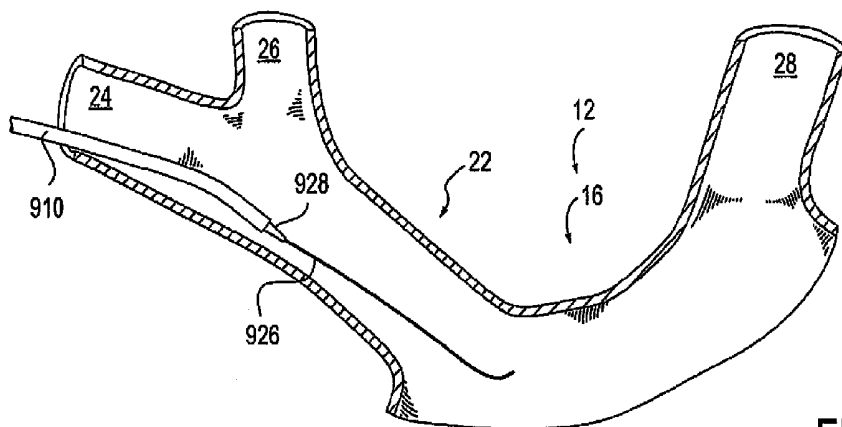


FIG. 17B

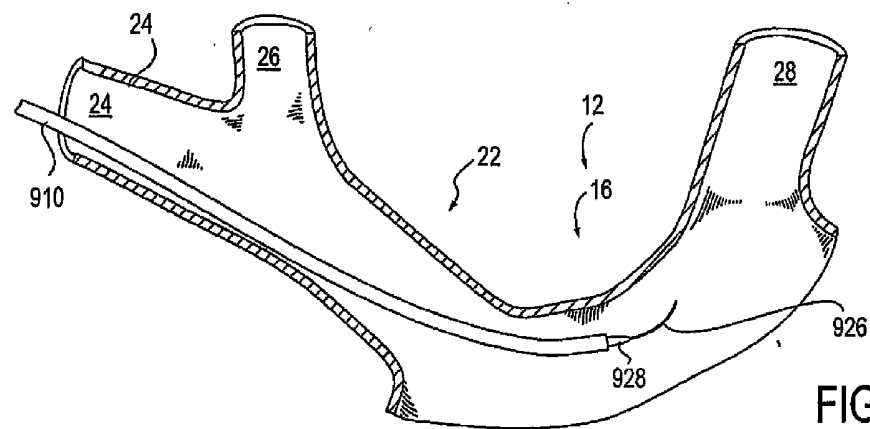


FIG. 17C

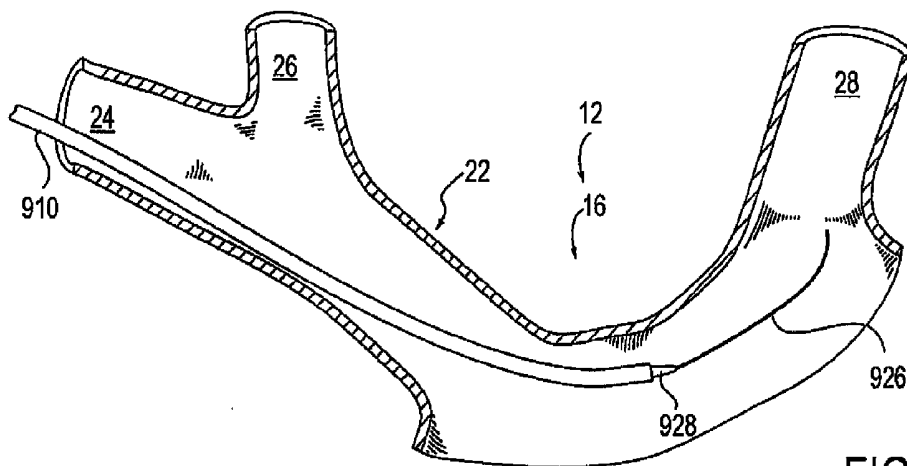


FIG. 17D

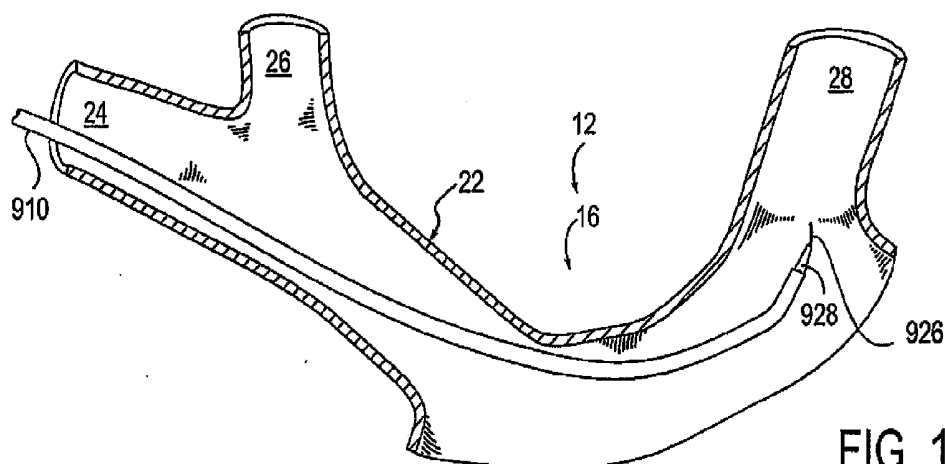


FIG. 17E

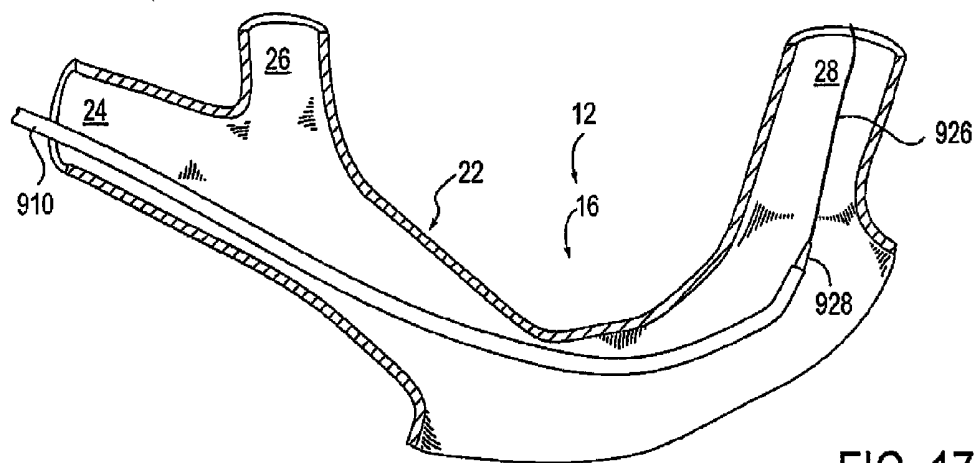


FIG. 17F

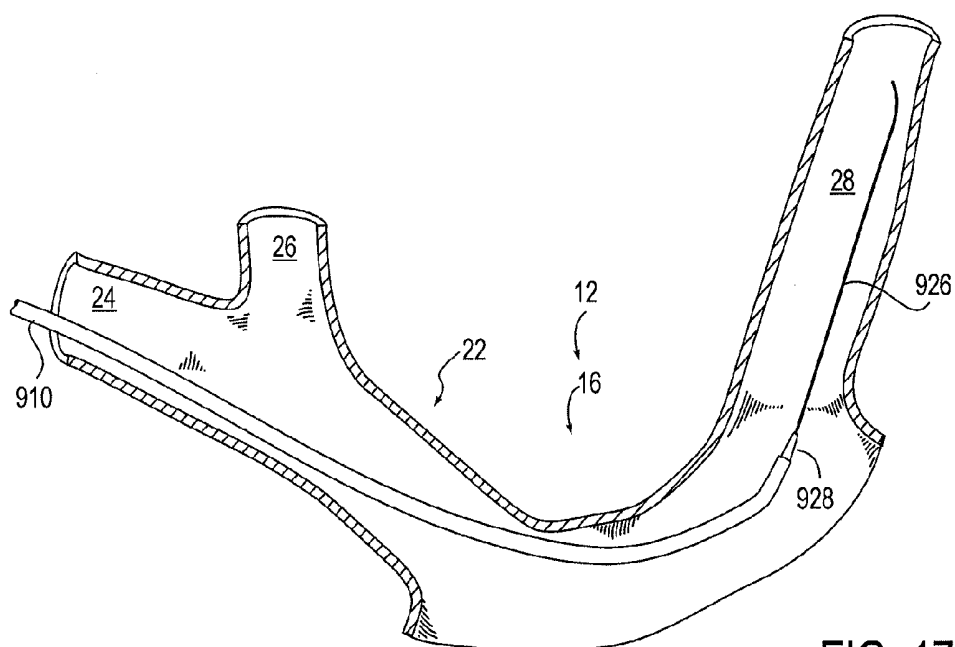


FIG. 17G

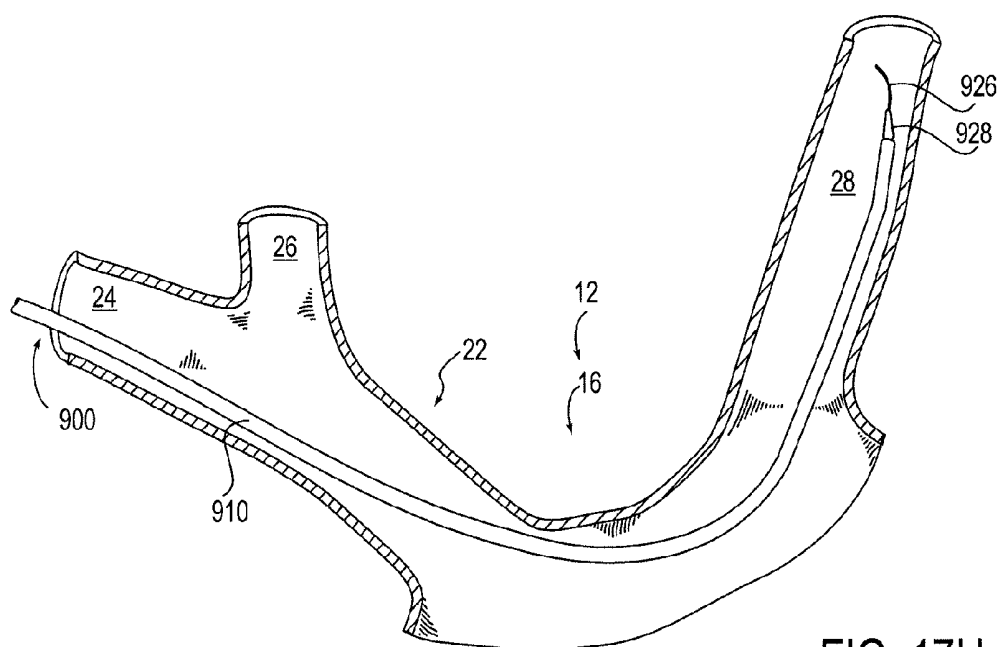


FIG. 17H

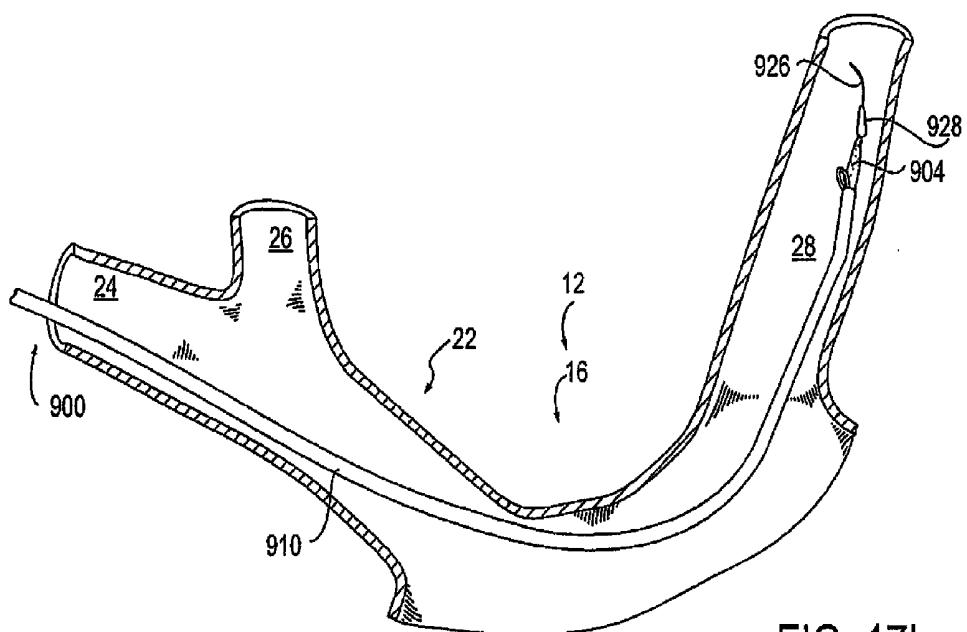


FIG. 17I

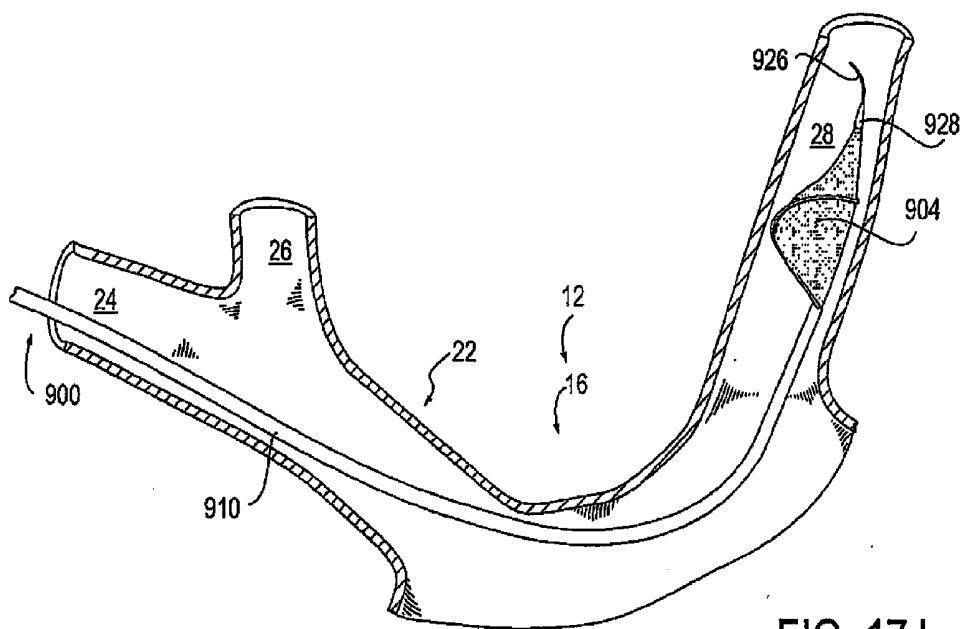
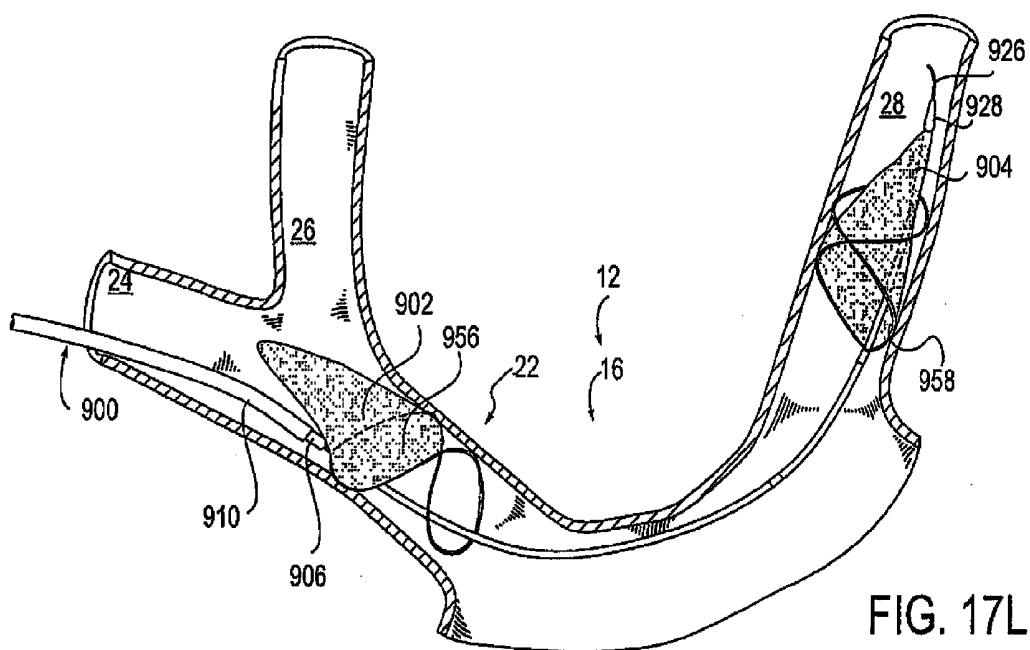
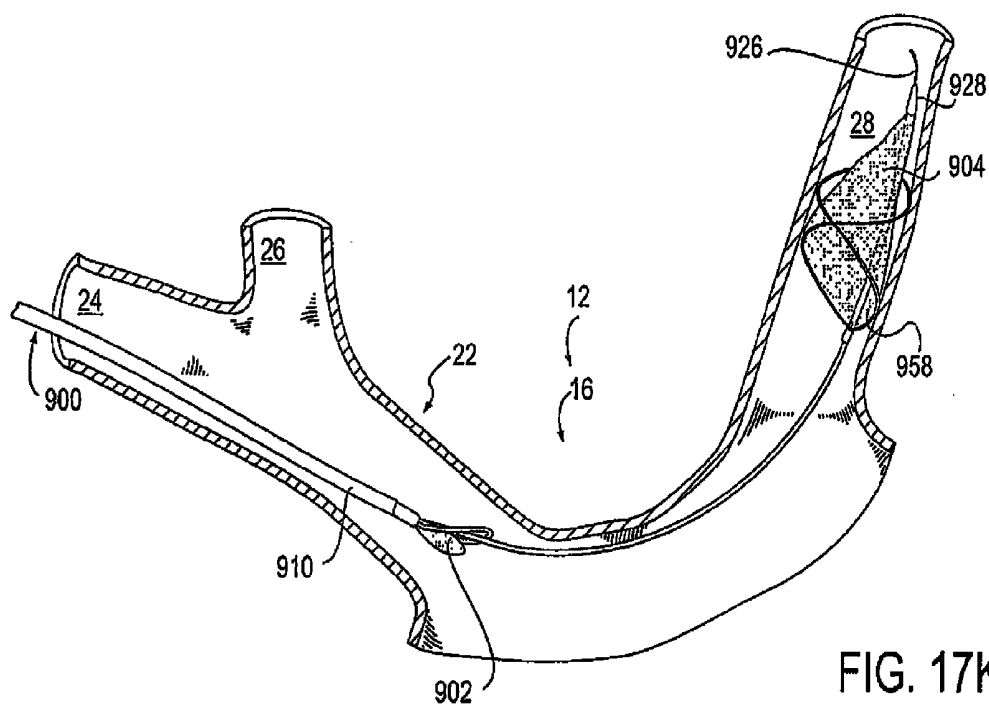


FIG. 17J



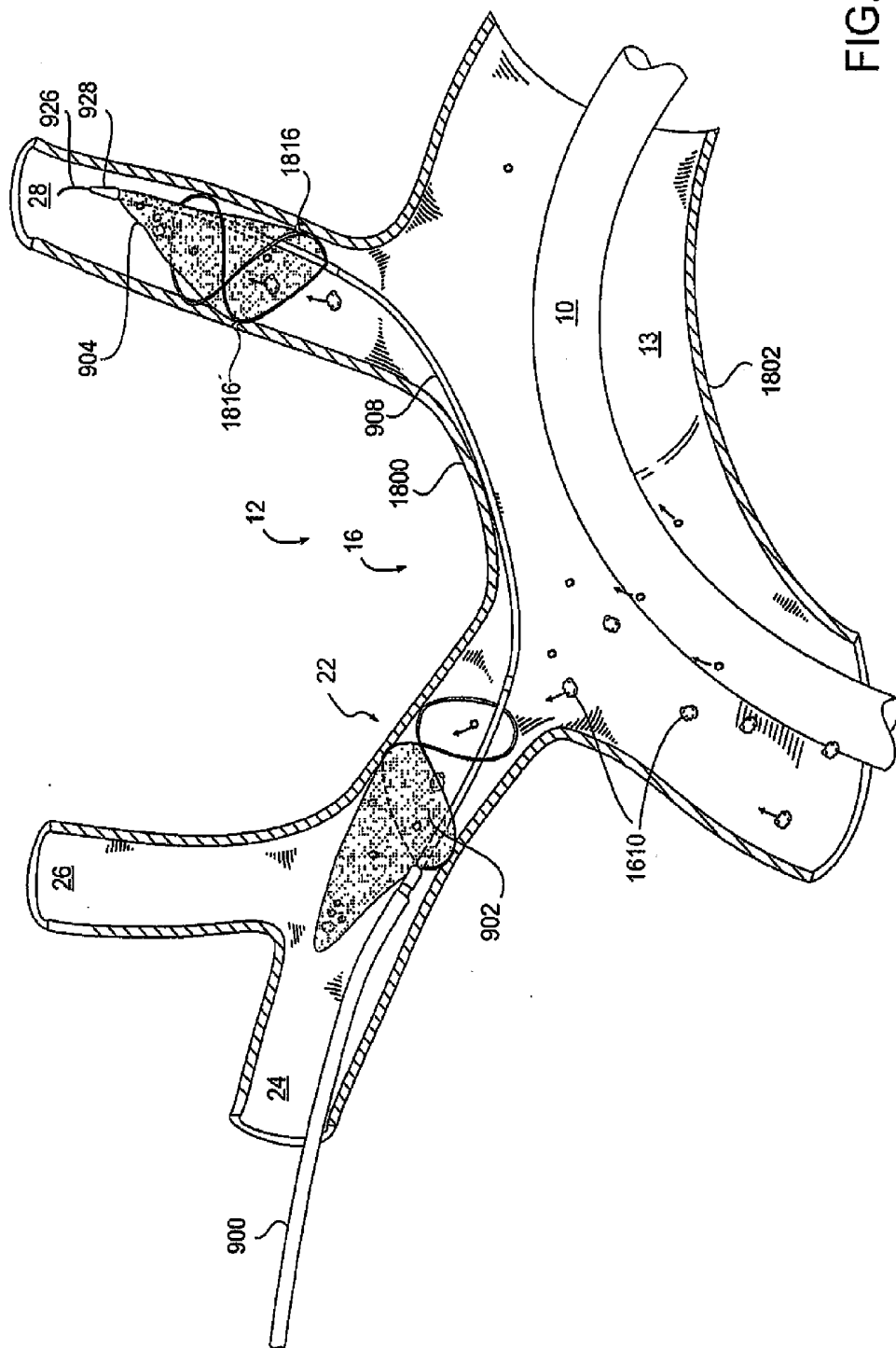


FIG. 18A

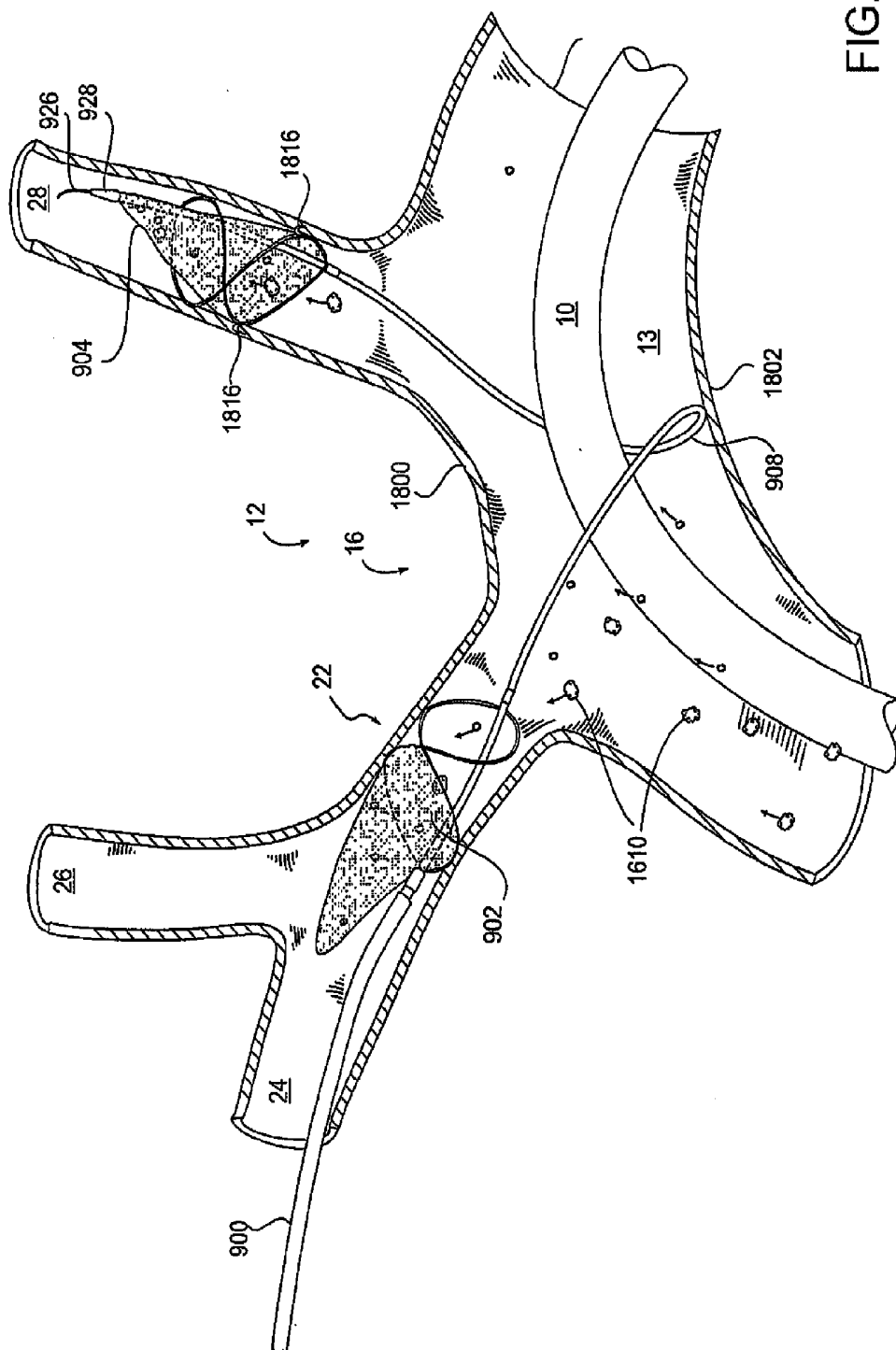


FIG. 18B

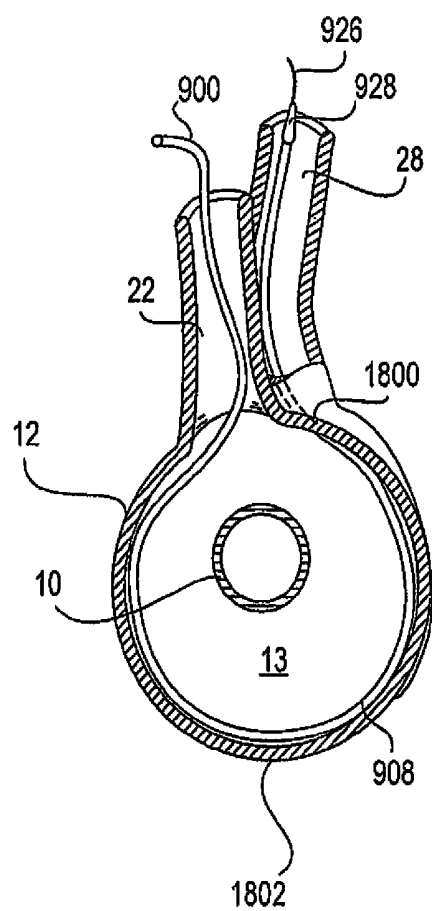


FIG. 18C

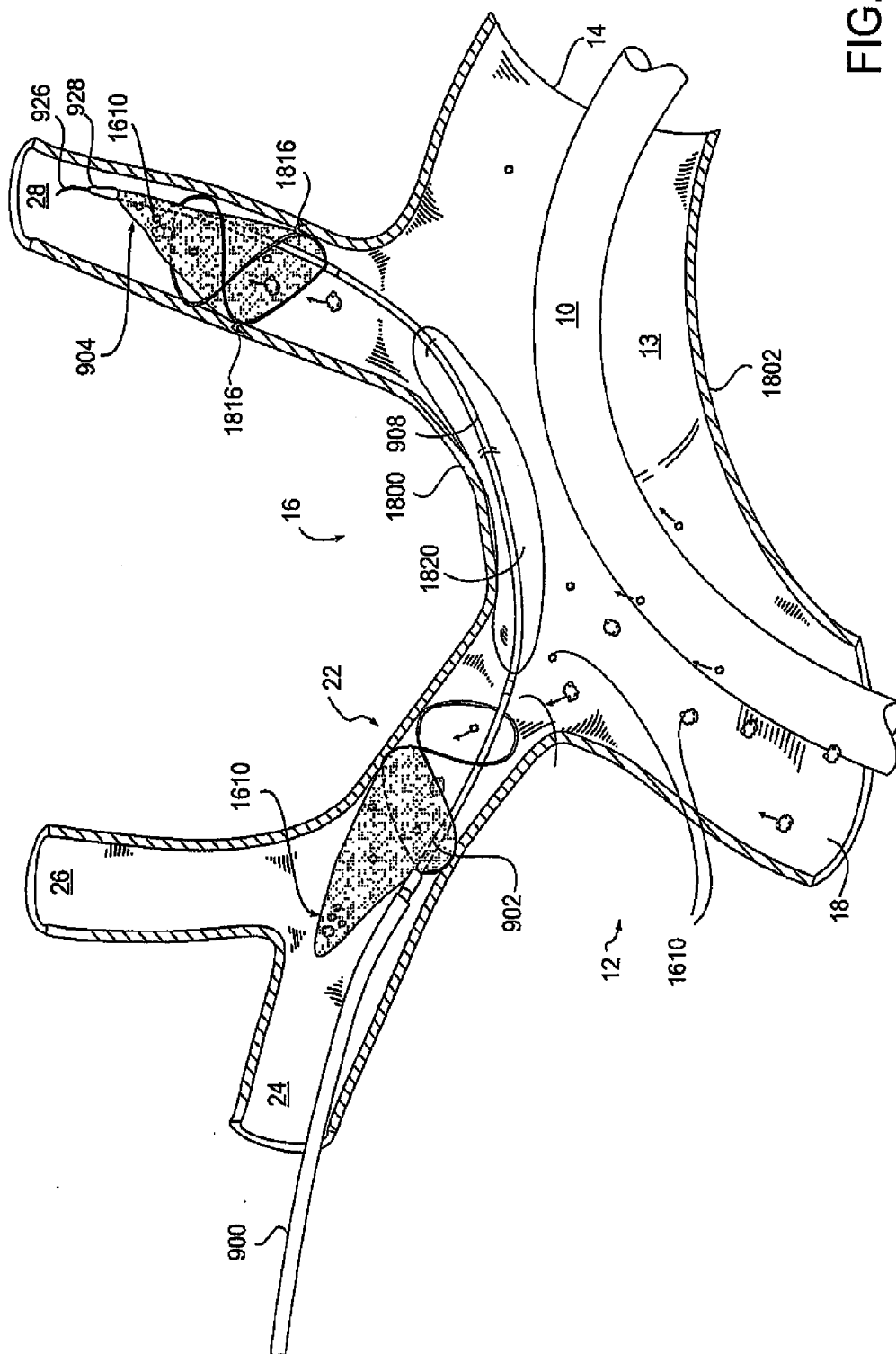


FIG. 18D

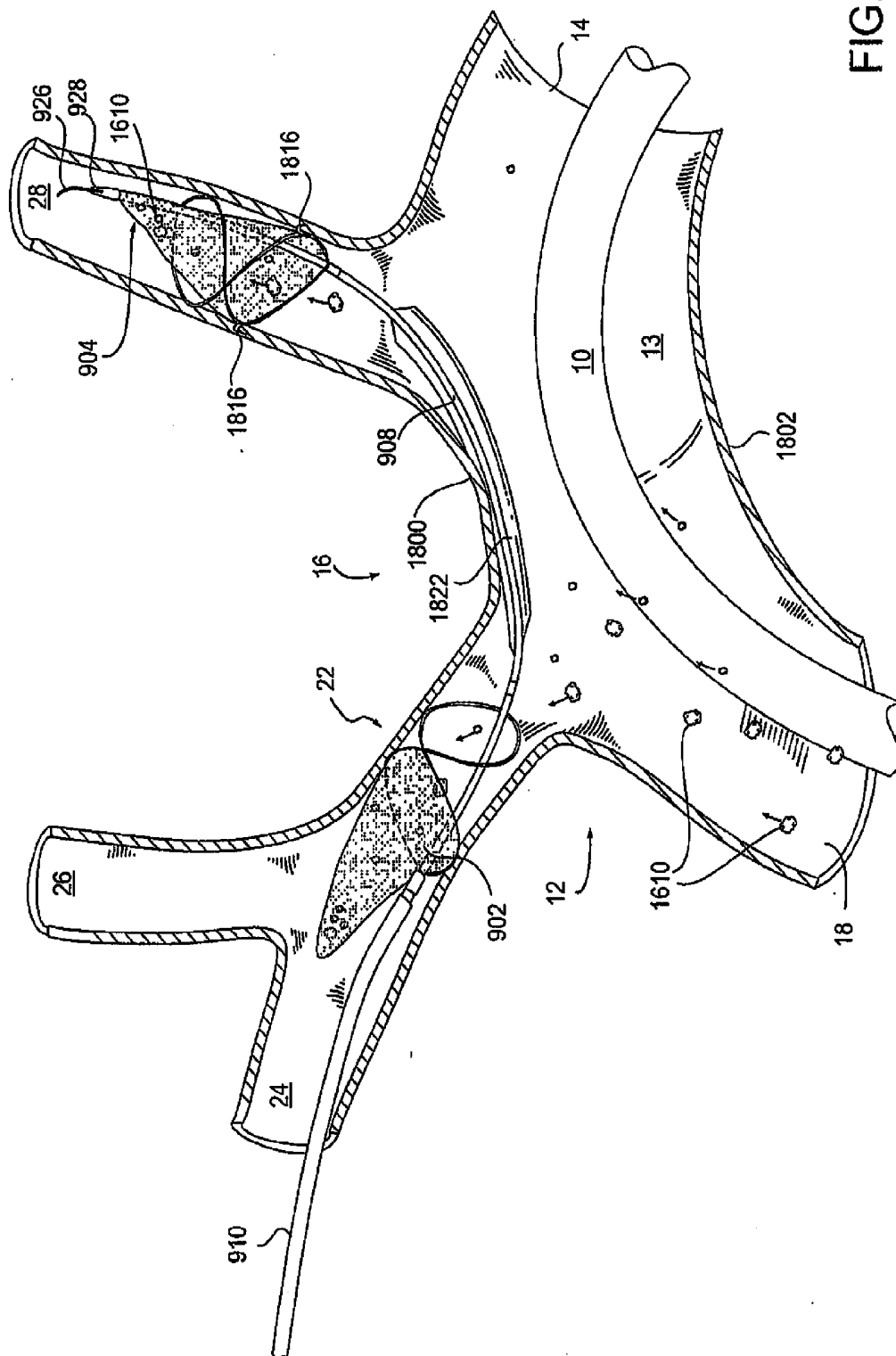
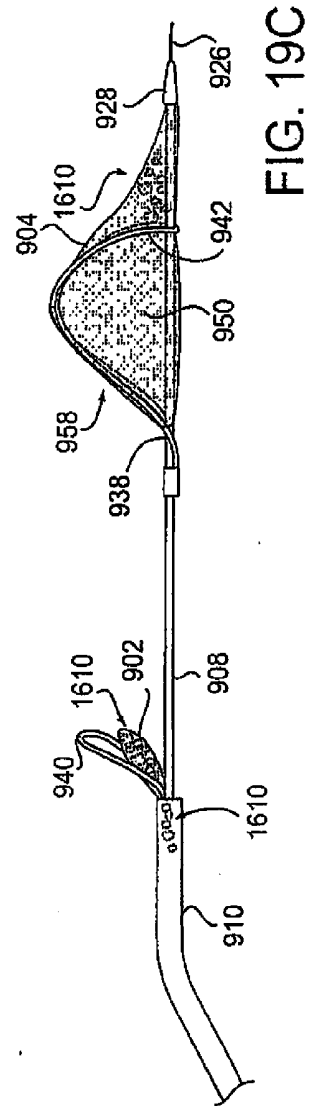
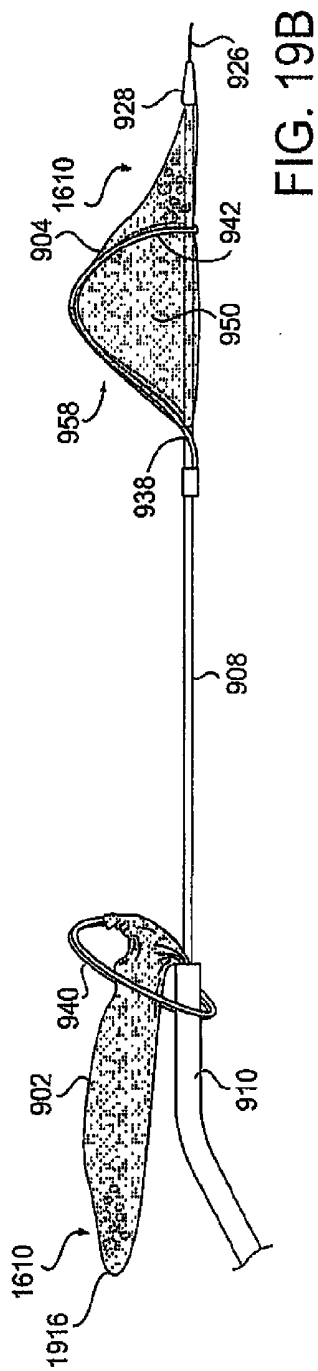
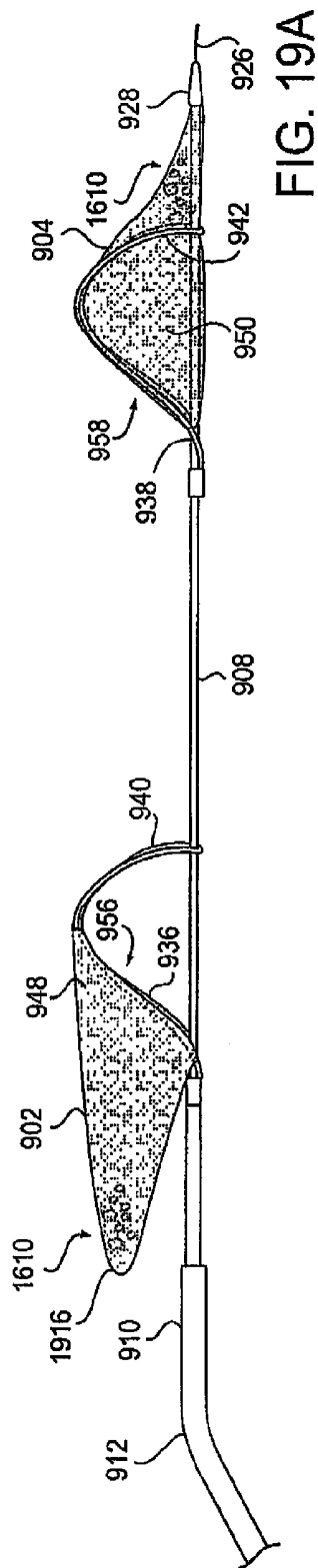


FIG. 18E



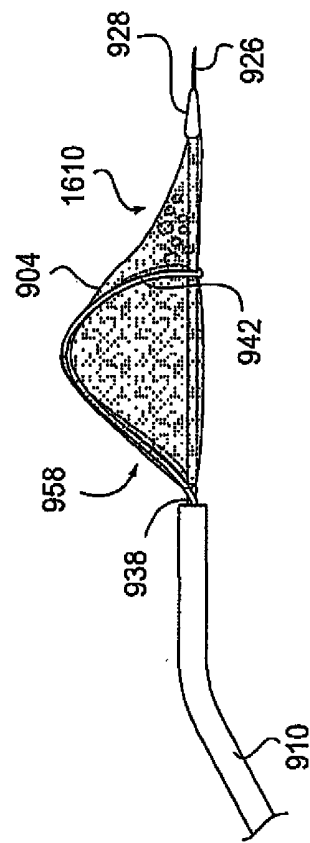


FIG. 19D

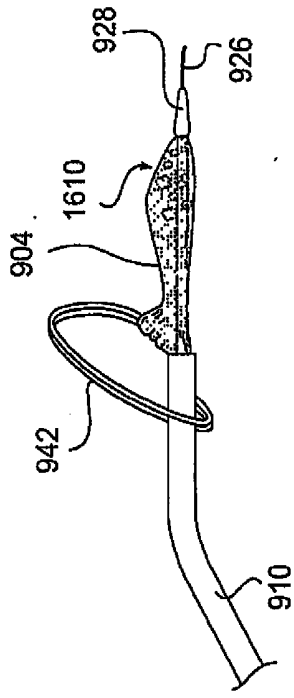


FIG. 19E

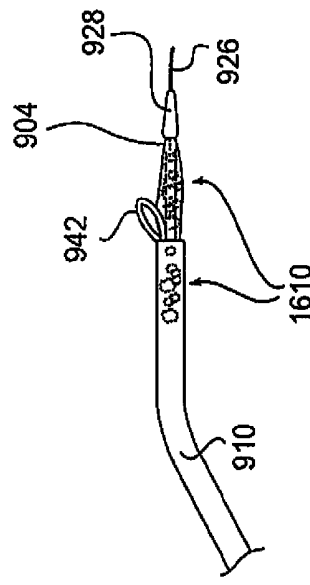


FIG. 19F

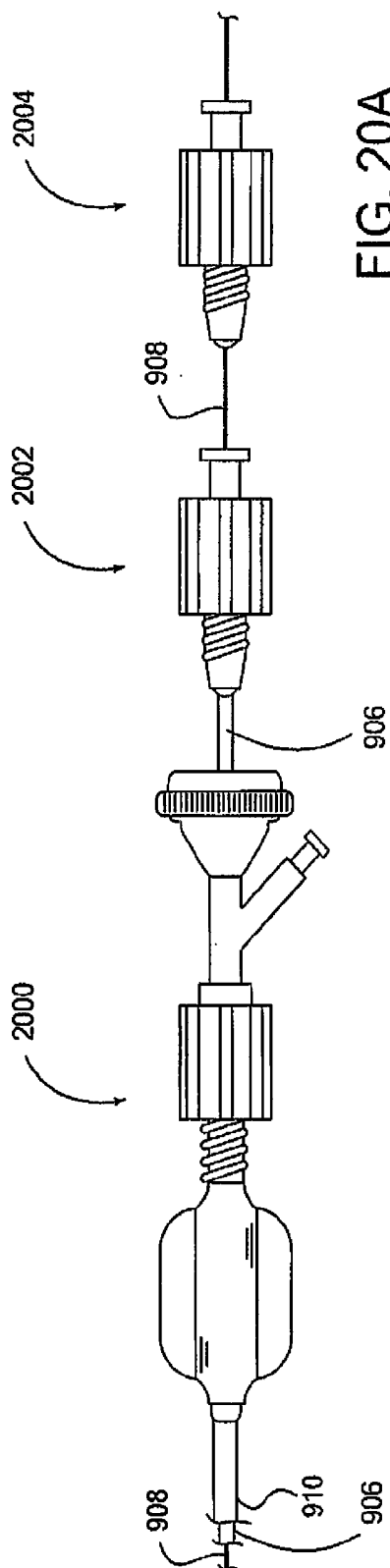


FIG. 20A

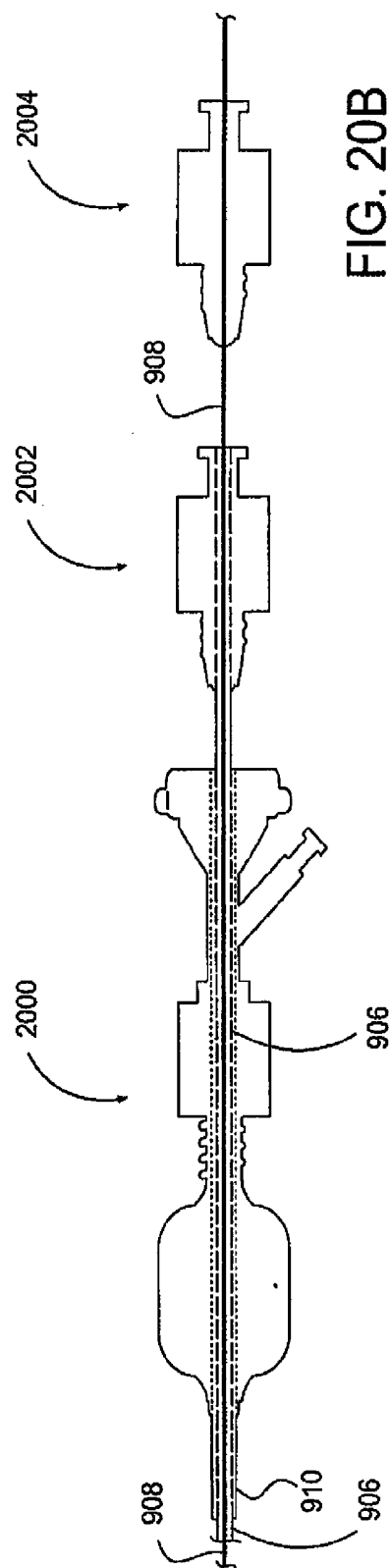


FIG. 20B

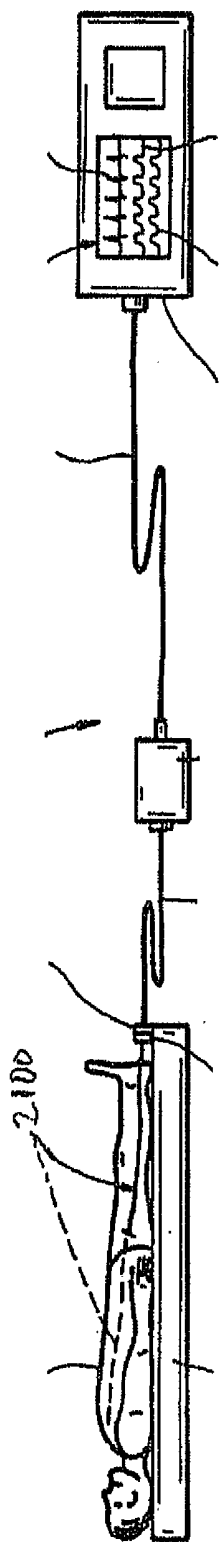


FIG. 21A

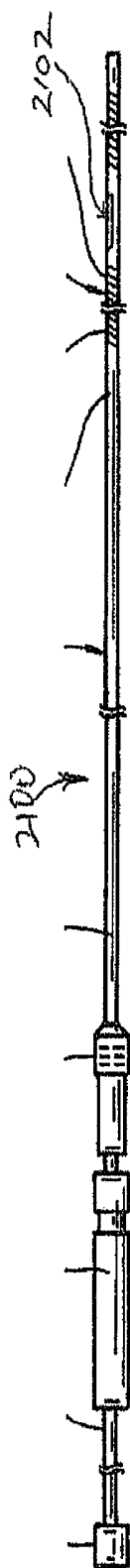


FIG. 21B

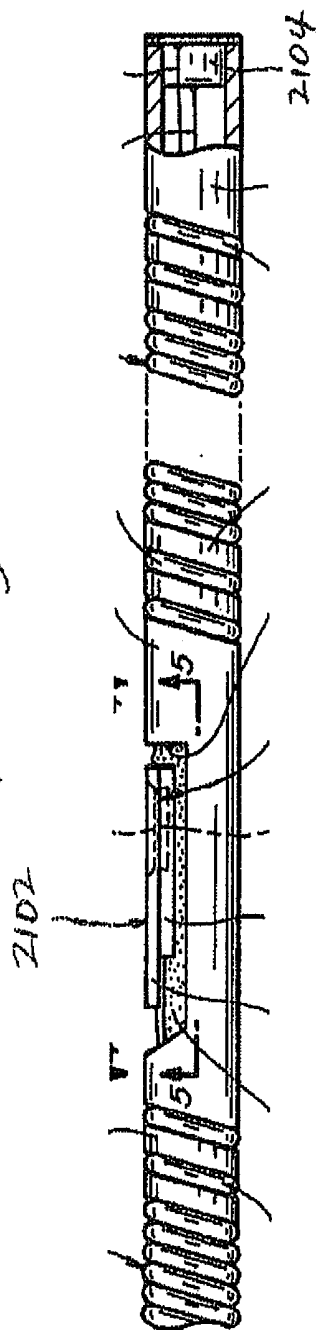


FIG. 21C

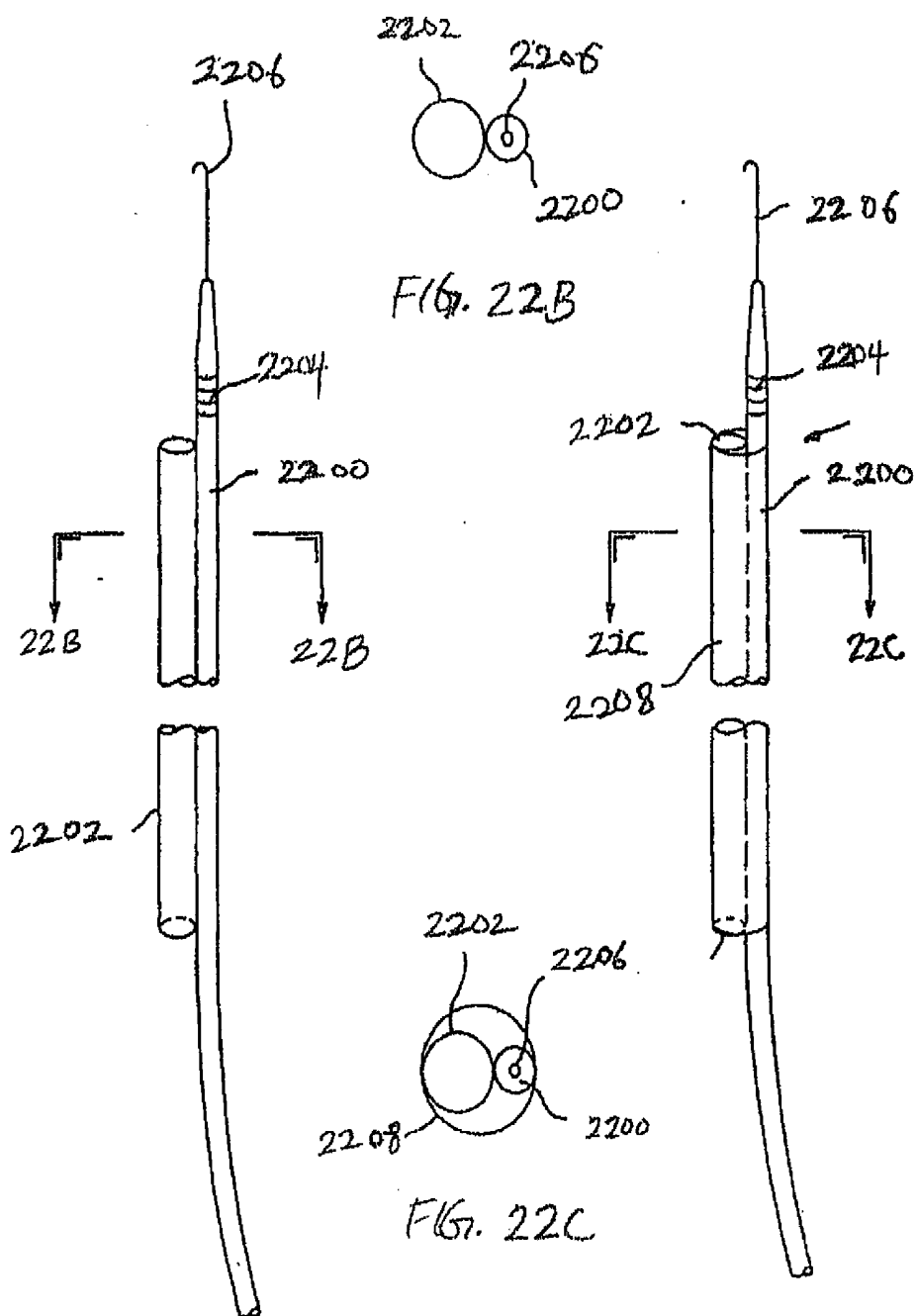
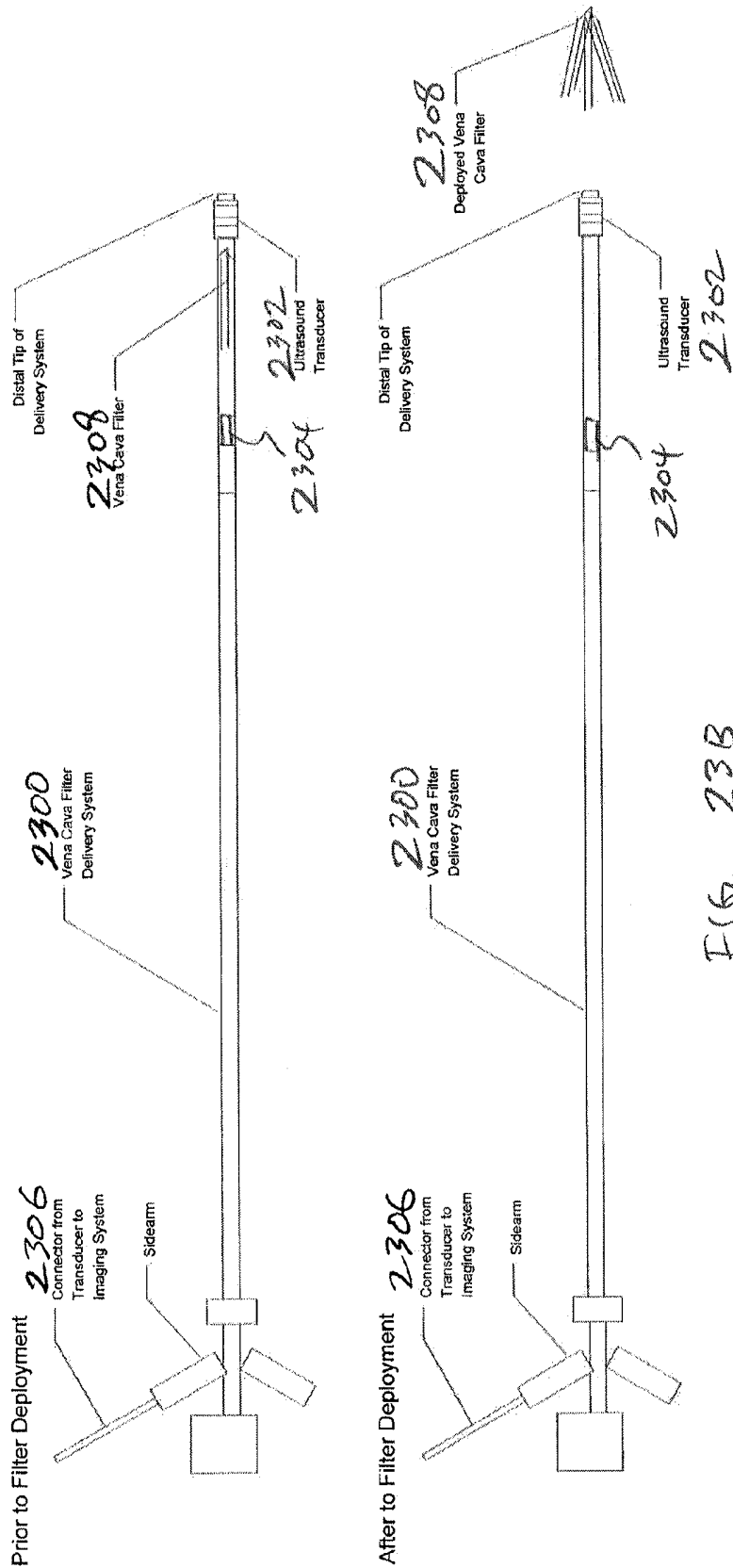


FIG. 22A

FIG. 22D

IVC Filter Delivery System w/
Ultrasonic Transducer

FIG. 23A



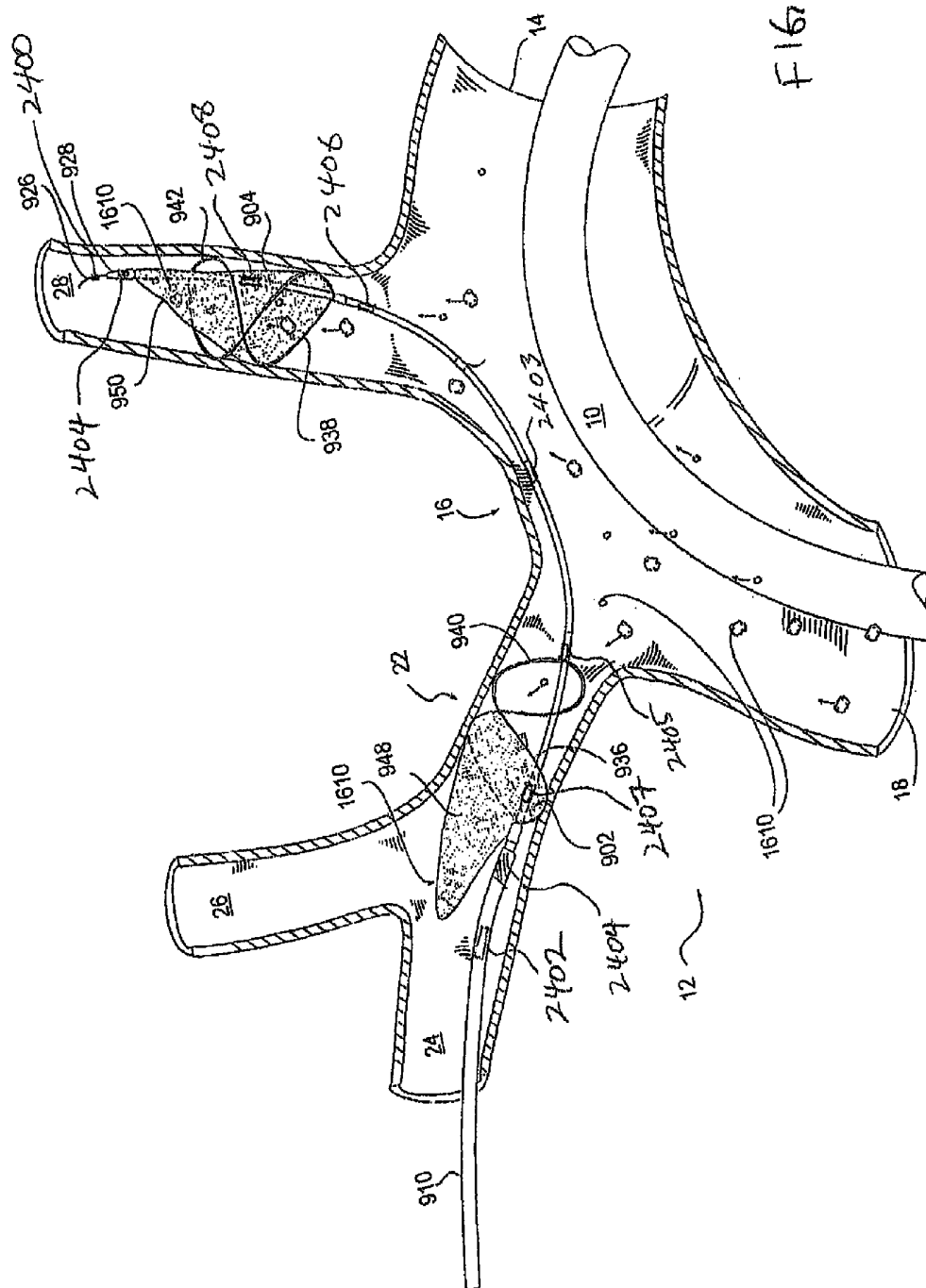
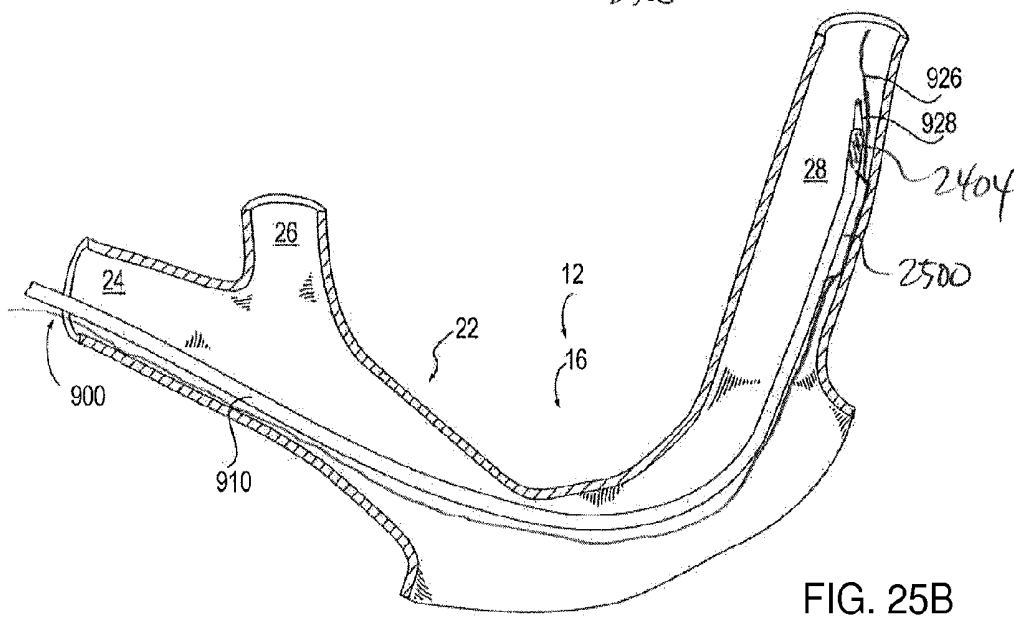
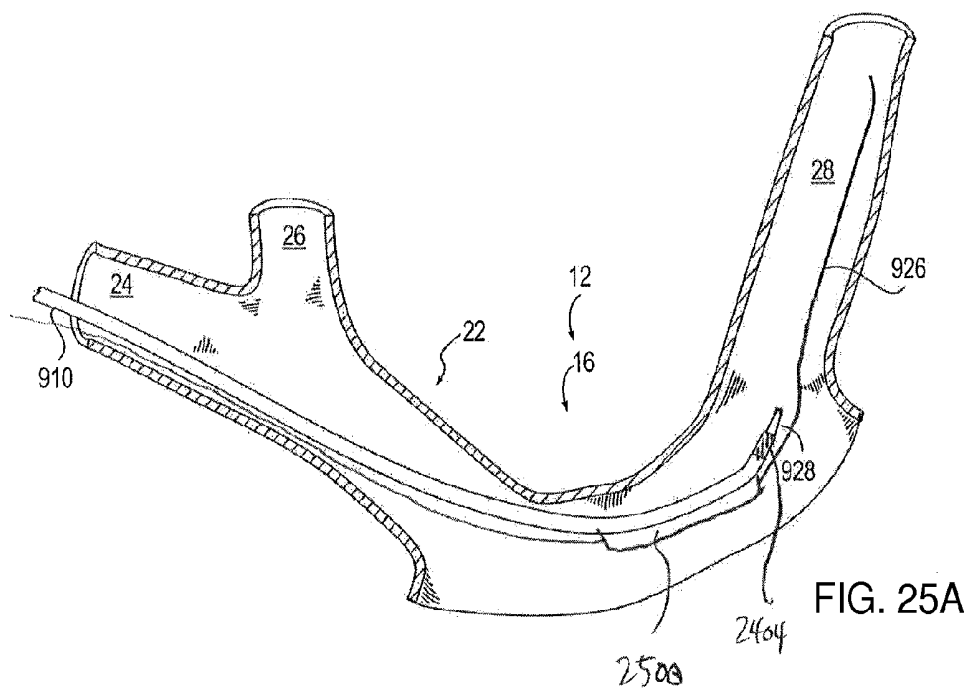


FIG. 24



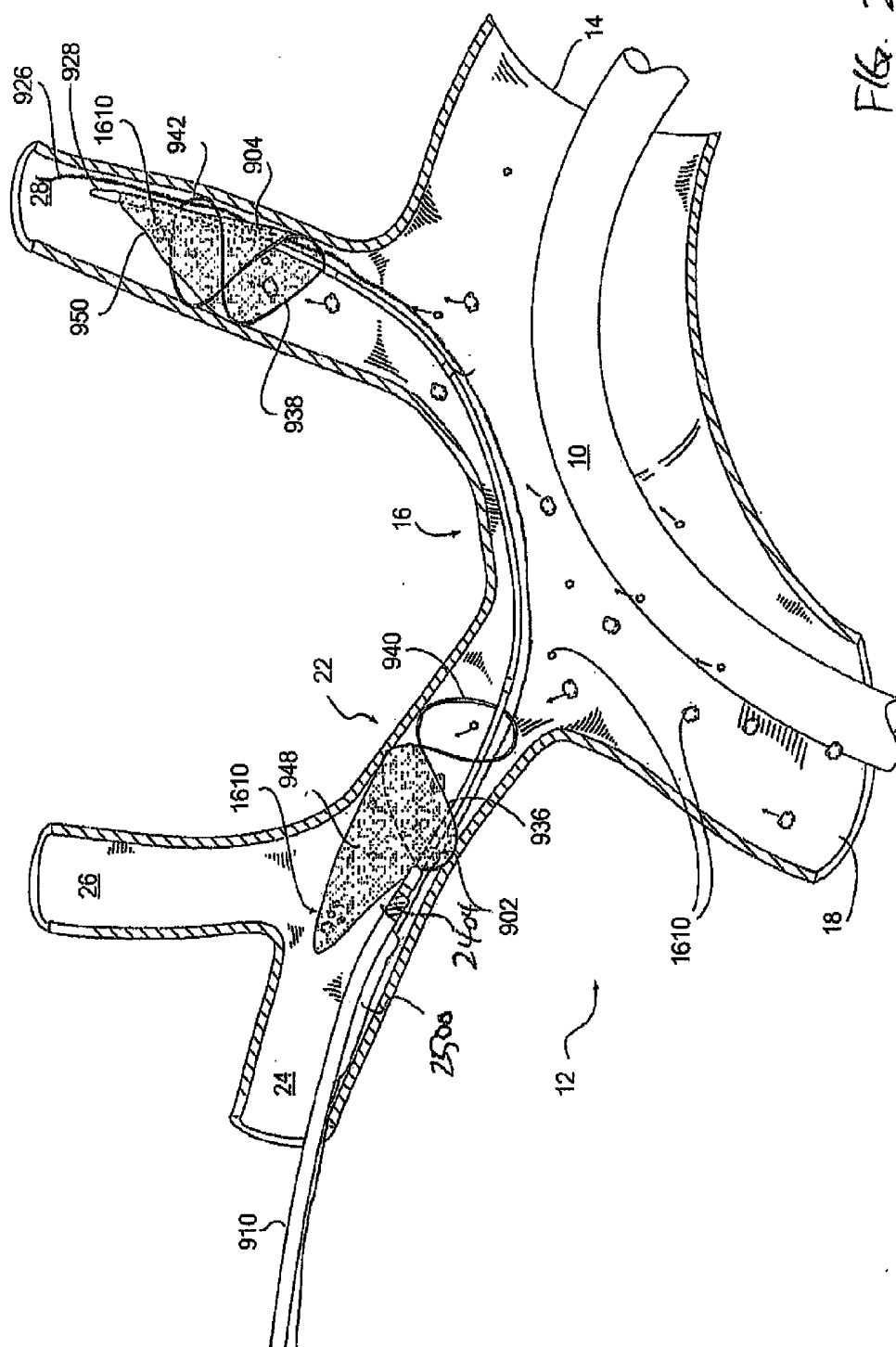
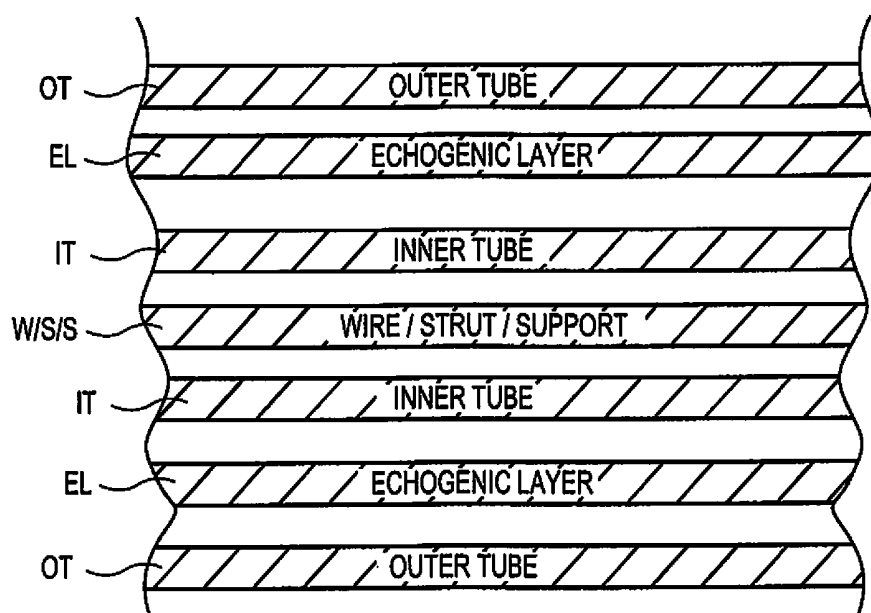
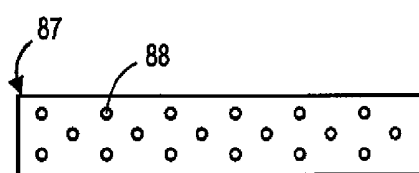


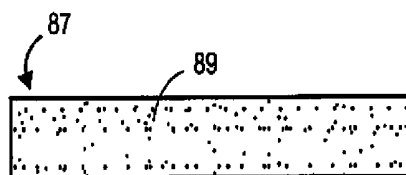
FIG. 25C

**FIG. 26**



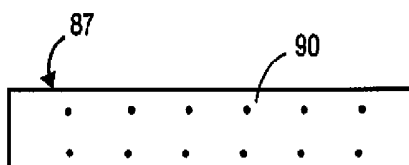
TUBE WITH LASER DRILLED HOLES

FIG. 27



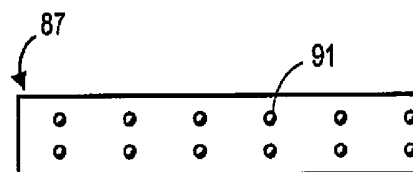
TUBE WITH ROUGH SURFACE
RAISED FEATURES

FIG. 28



TUBE WITH BUBBLES

FIG. 29



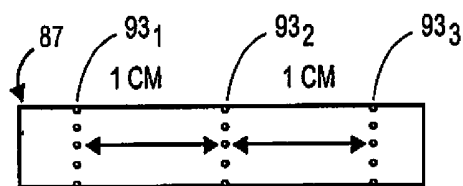
DIMPLES IN TUBE

FIG. 30



TUBE SANDWICH WITH
COIL/BRAID

FIG. 31



MEASUREMENT

FIG. 32

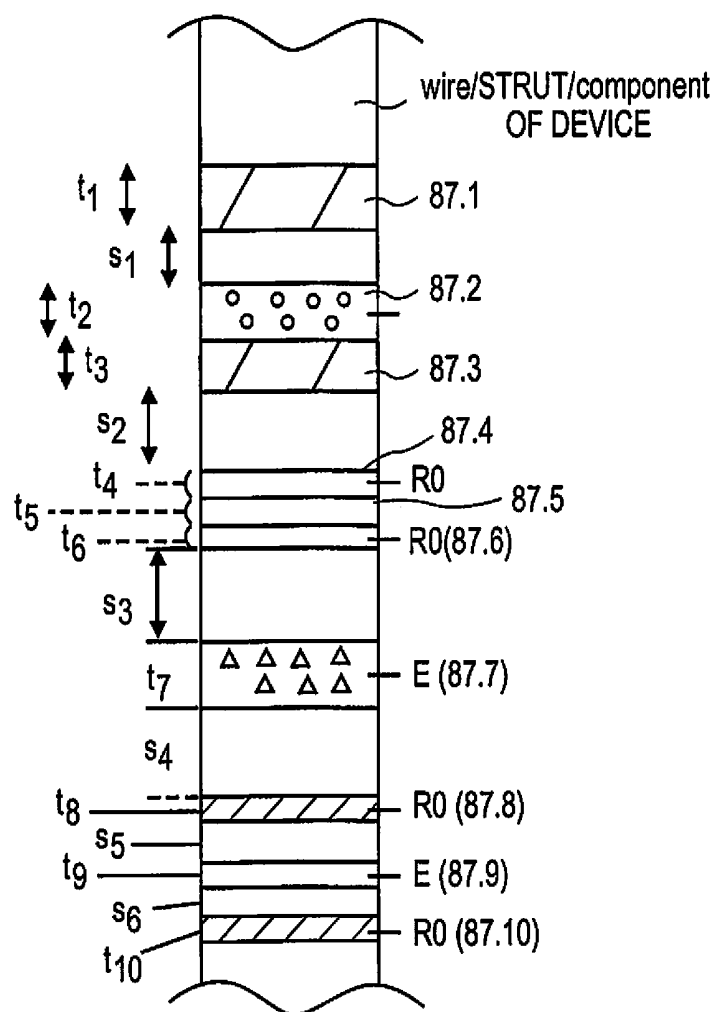
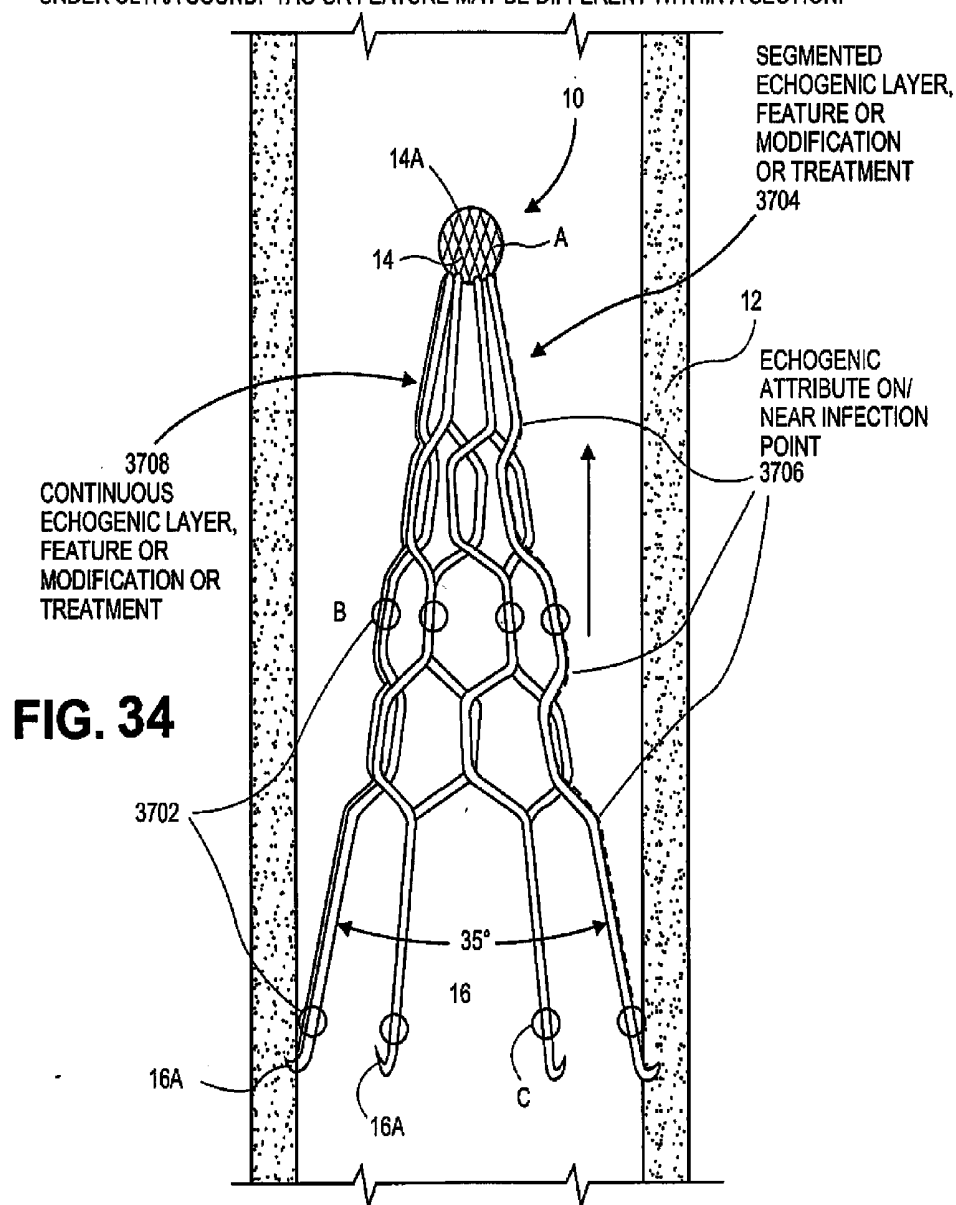


FIG. 33

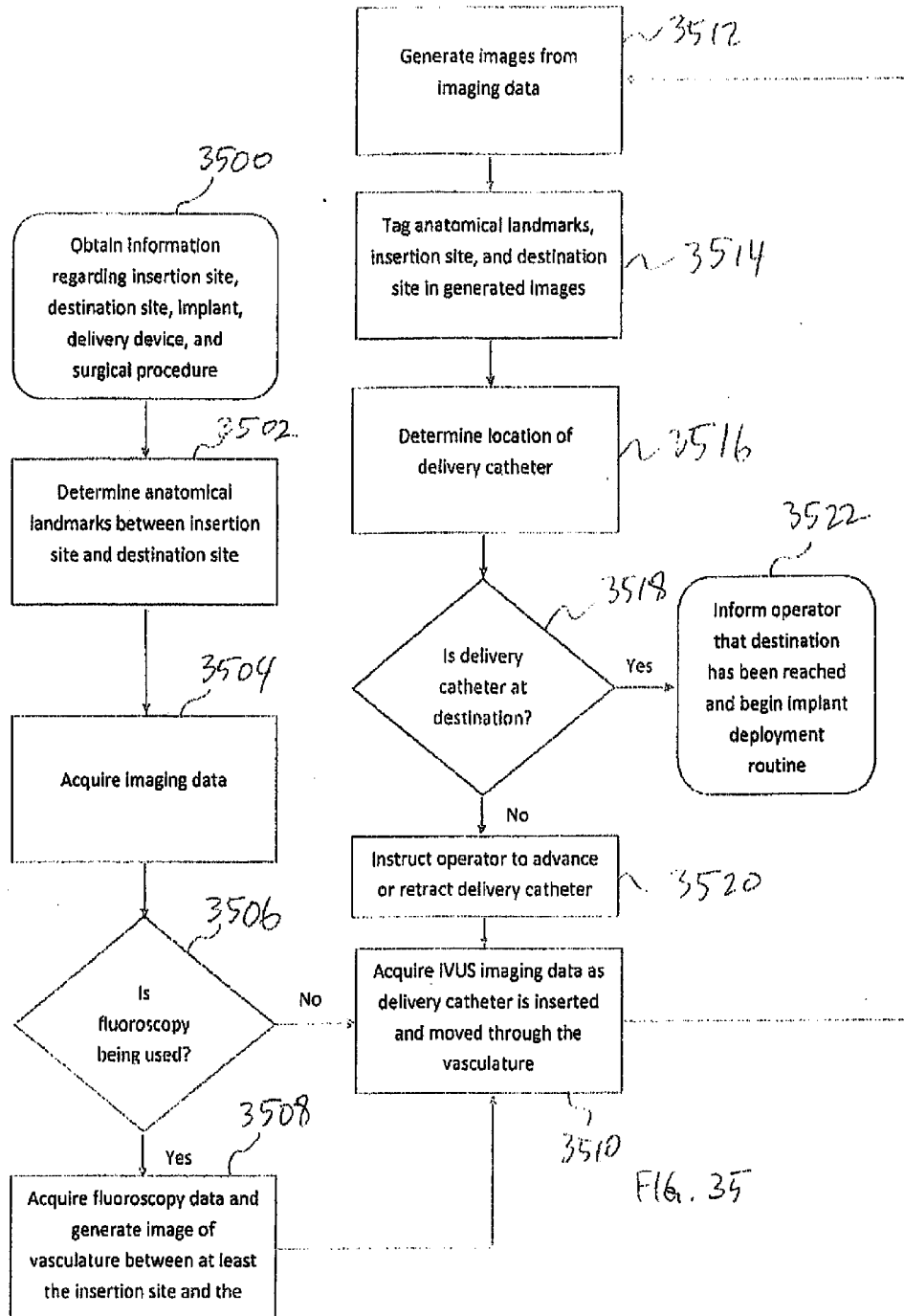
Ⓐ ECHOGENIC FEATURE/TAG/MARKER/MODIFICATION. SECTIONS A, B, C MAY BE THE SAME TYPE OR DIFFERENT FROM ONE ANOTHER IN DETECTION, RESPONSE OR APPEARANCE UNDER ULTRA SOUND. TAG OR FEATURE MAY BE DIFFERENT WITHIN A SECTION.

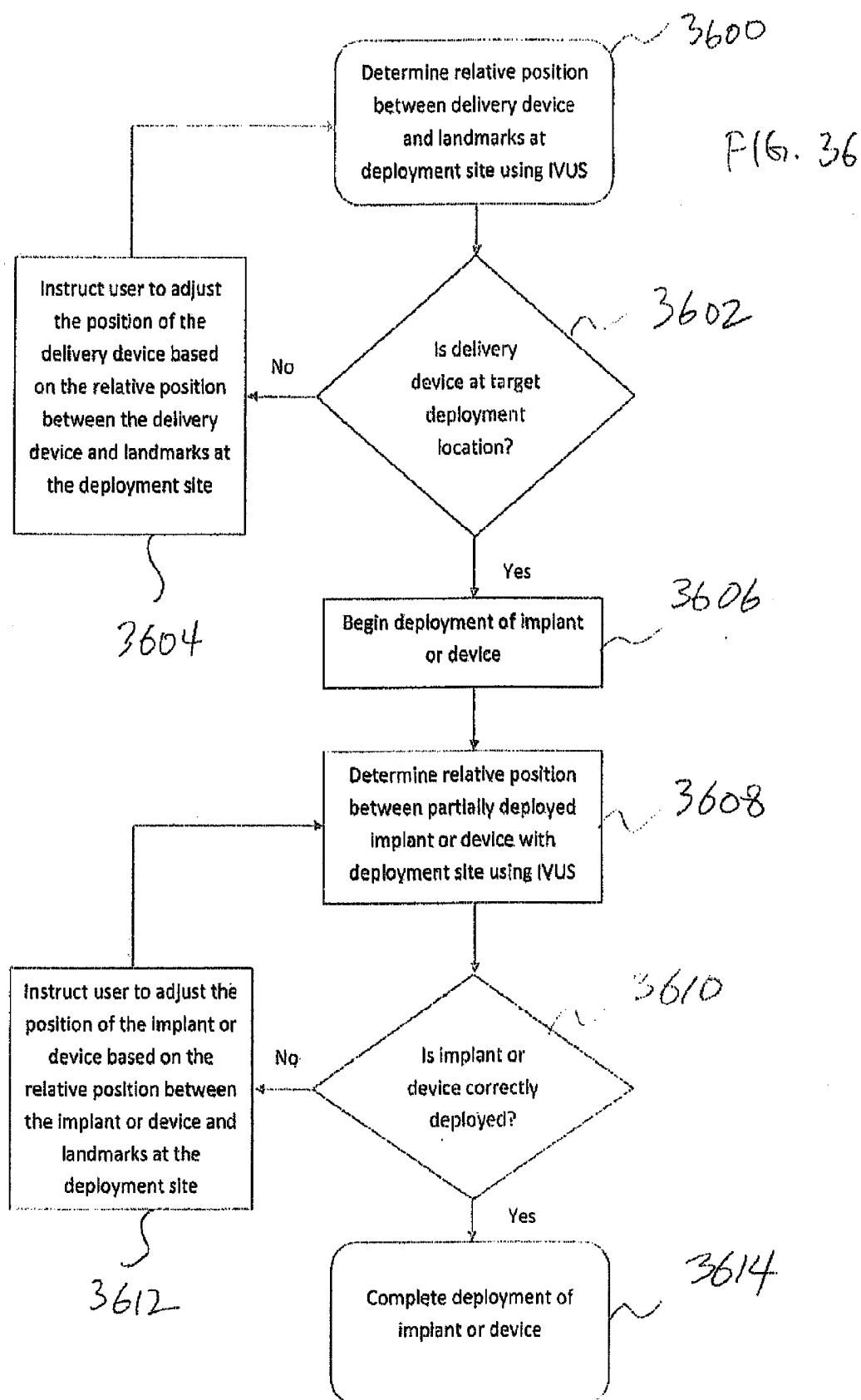


SECTION A: APEX/TIP/TERMINAL END/: PROVIDES ID OF END OF FILTER FOR RETRIEVAL, POSITIONING, ATTITUDE DETERMINATION, LOCALIZATION ETC.

SECTION B: MID STRUT/MIDDLE/FILTRATION OR CAPTURE REGION/: PROVIDES SIZING, CENTERING, SYMMETRY OF IMPLANT, APPPOSITION, CLOT BURDEN, DEPLOYMENT, GAUGE OF FILTER CAPACITY, FILTER CONTENTS

SECTION C: REAR PORTION/TERMINAL END/ANCHOR/FIXATION/PERFORATION: PROVIDES SIZING, CENTERING, SYMMETRY OF IMPLANT, LEGS, ANCHOR INSERTION OR DEPTH.





DISTAL PROTECTION SYSTEMS AND METHODS WITH PRESSURE AND ULTRASOUND FEATURES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation in part of U.S. patent application Ser. No. 14/777,232 filed on Sep. 15, 2015, which claims the benefit of PCT Application No. PCT/US2014/030240 filed on Mar. 17, 2014, which claims priority to U.S. Provisional Application No. 61/794,222 filed on Mar. 15, 2013. This application also claims priority to U.S. Provisional Application No. 62/052,408 filed on Sep. 18, 2014.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

[0003] The following patent and patent application is herein incorporated by reference in its entirety: U.S. application Ser. No. 11/325,247, now issued as U.S. Pat. No. 7,789,892, of which is hereby incorporated by reference in its entirety.

FIELD

[0004] Embodiments of the invention relate generally to devices and methods for providing filtration of debris within a body lumen. More particularly, embodiments of the invention are related to devices and methods for providing distal protection to a medical procedure by filtration of debris generated by the medical procedure and use of an ultrasound transducer to assist with navigation of the device.

BACKGROUND

[0005] Embolic protection is utilized throughout the vasculature to prevent the potentially fatal passage of embolic material, calcium deposits, and other debris in the bloodstream to smaller vessels where it can obstruct blood flow. The dislodgement of embolic material, calcium deposits, and other debris is often associated with procedures which open blood vessels to restore natural blood flow such as stenting, angioplasty, arthroectomy, valve replacement or repair, endarterectomy or thrombectomy. Used as an adjunct to these procedures, embolic protection devices trap debris and provide a means for removal from the body.

[0006] For example, in a percutaneous aortic valve replacement procedure as shown in FIGS. 1A and 1B, a valve delivery catheter **10** can be inserted through the lumen **13** of the aorta **12**, via the descending aorta **14**, the aortic arch **16**, the ascending aorta **18**, and to the native aortic valve **20** of the heart. During insertion through the aortic arch **16**, the valve delivery catheter **10** has a tendency to make contact with the upper portion **32** of the aortic arch **16** as it traverses the bend between the descending aorta **14** and ascending aorta **18**. During the aortic valve replacement procedure, embolic debris, calcium deposits and other debris can be generated and/or loosened from the native valve leaflets. This debris can travel through arteries branching off the aorta **12**, such as the brachiocephalic trunk **22**, which splits into the right subclavian artery **24** and the right common carotid artery **26**, the left common carotid artery **28**, and the left subclavian artery **30**.

Debris that passes into the right common carotid **26** and left common carotid artery **28** can travel to and get lodged within vessels supplying blood to the brain, potentially causing a stroke.

[0007] Accordingly, it would be desirable to provide a system and method for providing embolic protection to the right common carotid artery and the left common carotid artery in order to reduce complications, such as stroke, that may occur during a variety of medical procedures as described herein.

SUMMARY OF THE DISCLOSURE

[0008] The present invention relates generally to devices and methods for providing filtration of debris within a body lumen. More particularly, embodiments of the invention related to devices and methods for providing distal protection to a medical procedure by filtration of debris generated by the medical procedure.

[0009] Variations and modifications of the devices and methods disclosed herein will be readily apparent to persons skilled in the art. As such, it should be understood that the foregoing summary, detailed description and the accompanying illustrations, are made for purposes of clarity and understanding, and are not intended to limit the scope of the invention, which is defined by the claims appended hereto. Any feature described in any one embodiment described herein can be combined with any other feature of any of the other embodiment whether preferred or not.

[0010] In some embodiments, a system for providing embolic protection is provided. The system can include an embolic protection device including a guidewire having a proximal end, a distal end, and a first pressure sensor located near the distal end of the guidewire; a first sheath having a proximal end, a distal end and a lumen, the lumen configured to receive the guidewire; a first distal protection filter attached to a distal portion of the first sheath; a second sheath having a proximal end, a distal end and a lumen, the second sheath disposed over the first sheath, wherein the distal end of the second sheath is located proximally the first distal protection filter; a second distal protection filter attached to a distal portion of the second sheath; an outer sheath disposed over both the first sheath and the second sheath; and an intravascular ultrasound transducer disposed at the distal end of one of the first sheath, second sheath, or outer sheath. The system can also include a user interface configured to receive input from an operator regarding a surgical procedure including an insertion site and a destination site; a display; a processor programmed to receive input from the user interface regarding the surgical procedure, determine anatomical landmarks between the insertion site and the destination site, receive an intravascular ultrasound signal from the intravascular ultrasound transducer, process the intravascular ultrasound signal into an image, and send the image to the display.

[0011] In some embodiments, the processor is further programmed to identify any anatomical landmarks in the image and tag the anatomical landmarks in the displayed image.

[0012] In some embodiments, the processor is further programmed to determine a location of the embolic protection device based on the identified anatomical landmarks in the image.

[0013] In some embodiments, the processor is further programmed to determine whether the location is the destination site.

[0014] In some embodiments, the processor is further programmed to send a visual indicator to the display when the location has been determined to be the destination site.

[0015] In some embodiments, the visual indicator is color coded.

[0016] In some embodiments, the processor is further programmed to determine an orientation of the embolic protection device with respect to anatomical landmarks using the processed intravascular ultrasound imaging signal.

[0017] In some embodiments, the processor is further programmed generate instructions for adjusting the position of the embolic protection device based on the determined orientation of the embolic protection device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0019] FIG. 1A is a side view of the aorta and its branch arteries with a catheter inserted within the aortic lumen;

[0020] FIG. 1B is a cross-section view of the aorta with a catheter within the aortic lumen;

[0021] FIGS. 2A-2C illustrate the response of an embodiment of a filtering device to changes in lumen size;

[0022] FIGS. 3A and 3B illustrate embodiments of the distal protection filter with a filter element having an attached apex and an unattached apex;

[0023] FIGS. 4A-4F illustrate various alternative filtering structures;

[0024] FIGS. 5A-8F illustrate several exemplary methods of using a filtering device;

[0025] FIGS. 9A and 9B illustrate an embodiment of a filtering device with two distal protection filters;

[0026] FIGS. 9C and 9D illustrate an embodiment of the frame of a distal protection filter;

[0027] FIGS. 9E and 9F illustrate another embodiment of the frame of a distal protection filter;

[0028] FIGS. 10A-10F illustrate an embodiment of a gap reducing feature on a distal protection filter;

[0029] FIGS. 11A and 11B illustrate an embodiment of the construction of a frame element;

[0030] FIG. 11C illustrates a side cross-sectional view of an embodiment of a sheath;

[0031] FIG. 11D illustrates a side cross-sectional view of an embodiment of an atraumatic tip;

[0032] FIGS. 12A-12E illustrate an embodiment of a telescoping distal protection filter that allows control of the length of the filter;

[0033] FIGS. 13A-13C illustrate an embodiment of the attachment of a filter material to the frame of the filter;

[0034] FIGS. 14A and 14B illustrate embodiments of a filter membrane with various pore distributions;

[0035] FIGS. 15A and 15B illustrate embodiments of a filter device with a built-in aspiration mechanism;

[0036] FIG. 16 illustrates an embodiment of the filtering device with a distal protection filter deployed in the left common carotid artery and another distal protection filter deployed in the brachiocephalic trunk;

[0037] FIGS. 17A-17L illustrate an embodiment of a method of deploying distal protection filters to two arteries;

[0038] FIGS. 18A-18C illustrate embodiments of various orientations of the sheath within the aorta to minimize or reduce interference with a procedure catheter;

[0039] FIGS. 18D and 18E illustrate embodiments of various deflection mechanisms for deflecting a procedure catheter away from the filtering device;

[0040] FIGS. 19A-19F illustrate an embodiment of a method of capturing the distal protection filters using an outer sheath; and

[0041] FIGS. 20A and 20B illustrate an embodiment of the various hubs used to manipulate the various components of the filtering device.

[0042] FIGS. 21A-21C illustrate an embodiment of guidewire having both a pressure sensor and an IVUS transducer.

[0043] FIGS. 22A-22D illustrate two embodiments of an intravascular ultrasound catheter joined together in parallel with a catheter.

[0044] FIGS. 23A and 23B illustrate an embodiment of a filter delivery system where the pressure sensor and/or IVUS transducer are integrated into a delivery catheter, a retrieval catheter or a device itself.

[0045] FIG. 24 illustrates an embodiment of a distal protection filtering device having one or more ultrasound transducers and one or more pressure sensors.

[0046] FIGS. 25A-25C illustrates an embodiment of a distal protection filtering device having a rapid exchange guidewire lumen for receiving a guidewire having one or more pressure sensors.

[0047] FIG. 26 is a section view of a wire strut or support element of a filter (w/s/s) having multiple segments in a concentric arrangement.

[0048] FIG. 27 is an embodiment of a segment having one or a plurality of laser drilled holes formed therein.

[0049] FIG. 28 is an embodiment of a segment having one or a plurality of raised features or alternatively roughed portions formed thereon.

[0050] FIG. 29 is an embodiment of a segment having one or a plurality of bubbles formed therein.

[0051] FIG. 30 is an embodiment of a segment having one or a plurality of dimples formed therein.

[0052] FIG. 31 is an embodiment of a segment having a coil or braided structure within or about the segment.

[0053] FIG. 32 is an embodiment of a segment having a plurality of echogenic markers arrayed in rings about the segment to provide an indication of measurement via the spacing between adjacent rings.

[0054] FIG. 33 illustrates various alternative configurations for a segment used alone or in conjunction with other segments.

[0055] FIG. 34 is a view of an exemplary filter illustrating various alternative aspects of providing a filter with improved echogenic characteristics.

[0056] FIG. 35 is a flow chart illustrating an embodiment of a method of navigating the distal protection device through the vasculature.

[0057] FIG. 36 is a flow chart illustrating an embodiment of a method of deploying the distal protection device at a deployment site.

DETAILED DESCRIPTION

[0058] FIG. 2A illustrates an embodiment of a filtering device 100 of the present invention positioned within a lumen 10. The lumen 10 is cut away to show the position of filter 100

deployed into within a lumen and in contact with the lumen wall. The filter **100** includes a first elongate member **105** and a second elongate member **110**. In some embodiments, the two elongate members can be opposing helical spirals. The elongate members are joined to form ends **102**, **104**. The elongate members cross but are not joined to one another at crossover **106**, which can be slidable. In one embodiment, the elongate members have first and second sections. First sections extend between the end **102** and the crossover **106** and the second sections extend from the crossover **106** to the second end **104**. While some embodiments contact the lumen in different ways, the illustrated embodiment has the ends **102**, **104** against one side of the lumen interior wall while the crossover **106** contacts the other side of the lumen interior wall with the elongate bodies in constant or nearly constant apposition along the lumen interior wall between the ends **102**, **104**. In some embodiments, the diameter of the elongate members can be about 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, or 0.010 inches. Using a smaller diameter wire allows the filter to have a lower collapsed profile. In some embodiments, the filters can be collapsed into a 10Fr, 9Fr, 8Fr, 7Fr, 6Fr, or 5Fr or smaller delivery catheter. In some embodiments, the elongate members can be made from a flexible, biocompatible, fatigue-resistant material such as but not limited to nickel-titanium alloys, stainless steel, cobalt chrome, other shape memory alloys, other metal alloys, and various polymers such as PEEK, PTFE, and the like.

[0059] FIGS. 2B and 2C illustrate how the elongate support structure elements of embodiments of the present invention are configured to collapse and expand with natural vessel movements while maintaining constant apposition with the vessel wall. FIGS. 2A, 2B and 2C also illustrate how devices according to embodiments of the present invention are both radially and axially elastic. In response to vessel size changes, ends **102**, **104** move out as the vessel size decreases (FIG. 2B) and then move in as the vessel size increases (FIG. 2C). In addition, the device height “h” (measured from the lumen wall in contact with ends **102**, **104** to crossover) also changes. Device height “h” changes in direct relation to changes in vessel diameter (i.e., vessel diameter increases will increase device height “h”). As such, device height (“h”) in FIG. 2C is greater than device height (“h”) in FIG. 2A which is in turn greater than the device height (“h”) in FIG. 2B.

[0060] FIGS. 2A, 2B and 2C also illustrate how a single sized device can be used to accommodate three different lumen diameters. FIG. 2C illustrates a large lumen, FIG. 2A a medium sized lumen and FIG. 2B a small sized lumen. As these figures make clear, one device can adapt to cover a range of vessel sizes, thereby forming a better seal and providing good wall apposition over a wide range of vessel diameters. Also illustrated is the static or nearly static filter capacity of the material capture structure **115** in some embodiments. In these embodiments, in each different vessel size, the material capture structure **115**, the filaments **118** and filter cell **119** maintain the same or nearly the same shape and orientation within the support frame formed by the elongate bodies. These figures also illustrate the dynamic shape changing aspect of the device that may also be used to accommodate and conform to vessel irregularities, tortuosity, flares and tapers and while remaining in apposition to the wall. Because each elongate body may move with a high degree of independence with respect to the other, the loops or support frames formed by the elongate bodies can also independently match the shape/diameter of the lumen section in which it is placed.

[0061] For example, a single sized device can be used in a variety of vessels, such as the brachiocephalic trunk and left common carotid artery. The brachiocephalic trunk generally has a diameter between about 6 mm to about 20 mm or larger, and usually between about 8 mm to about 12 mm, or about 8 to 10 mm. The left common carotid artery generally has a diameter between about 5 mm to about 11 mm, and usually between about 6 mm to about 10 mm, or about 7 to 8 mm. Examples of the diameters of the aorta and its major branch arteries are disclosed in Kahraman et al., *The Diameters of the Aorta and Its Major Branches in Patients with Isolated Coronary Artery Ectasia*, Tex Heart Inst J 2006; 33:463-8, which is hereby incorporated by reference in its entirety. In some embodiments, a filter device with a nominal diameter size of about 6 mm, 9 mm, 12 mm, 15 mm, or 18 mm or between about 6 to 18 mm, can be used in the brachiocephalic trunk or left common carotid artery. Because these filter devices cover a dynamic range of sizes, as illustrated in FIGS. 2A-2C, a single filter can used to cover all or a wide range, such as the lower half/upper half or the lower third/middle third/upper third, of typical brachiocephalic trunk and/or left common carotid artery sizes. In some embodiments, the filter devices placed in the brachiocephalic trunk and left common carotid artery can have the same nominal diameter size, while in other embodiments the filter device placed in the left common carotid artery can be smaller than the filter device placed in the brachiocephalic trunk.

[0062] FIGS. 3A-4F illustrate the use of nets or other web structures within the filtering device. The various net structure embodiments described herein are used as material capture structures within filter device embodiments of the present invention. Each of these alternative is illustrated in a support structure similar to that of device **100** in FIG. 2A and elsewhere. When deployed within the lumen **10**, the material capture structure **560** has a defined shape such as a cone with a discrete apex **565** (FIG. 3A). In this embodiment, the net structure is long enough to contact the sidewall of the lumen **10** when deployed in the lumen **10**. Alternatively, the apex **565** may be attached to the end **104** to keep the net **560** in the lumen flow path and out of contact with the lumen sidewall (FIG. 3B).

[0063] In some embodiments, the apex can be attached to the delivery device, such as the sheath, tube or wire of the delivery device. In other embodiments, the apex can be free, or in other words is unattached to the sheath, tube or wire of the delivery device or the frame of the filter. In some embodiments with a proximal filter and a distal filter, as illustrated in FIG. 9A, the apex of the proximal filter can remain free while the apex of the distal filter can be attached to the delivery device. In some embodiments, the apex of the distal filter can also remain unattached to the sheath. Allowing the apex of the proximal filter to remain free allows a sheath to be advanced first over the mouth of the filter to close the filter before being advanced over the rest of the filter. This prevents or reduces the extrusion of trapped debris within the filter during the recovery of the proximal filter. The net **565** may also have a rounded apex **565** (FIG. 4A) or a truncated cone (flat bottom) (FIG. 4D) or a reservoir apex. Alternatively, the net **560** may have a discrete apex **565** so short that it will not contact the lumen sidewall when deployed (FIG. 4B). The short net may also have a rounded apex **565** (FIG. 4B), a flat apex (FIG. 4E) or a sharp apex (FIG. 4C). In addition, the net **560** may have a compound apex **565** (FIG. 4F).

[0064] Embodiments of filter devices of the present invention may be used in methods of providing distal protection in procedures such as, for example, thrombectomy, arthroscopy, stenting, angioplasty, valve repair or replacement, stent grafting and other procedures taking place in the heart or circulatory system. It is to be appreciated that embodiments of filter devices of the present invention may be used in veins and arteries. An exemplary procedure is illustrated in FIGS. 5A-I and FIGS. 6A-E. In each procedure, the device **100** is positioned in an un-tethered fashion adjacent to the treatment region **730**. The sequence FIGS. 5A-I illustrate the delivery sheath **710** positioning FIG. 5A, complete deployment FIG. 5B into the lumen **10**. A conventional treatment device **750** using mechanical, electrical energy or other suitable method is used to clear the undesired material **732** from the lumen wall (FIG. 5C). Some debris **734** removed from the lumen wall through the use of treatment device **750** is subsequently embolized into the blood stream (FIG. 5C) and trapped by the filter **100** (FIG. 5D). The conventional treatment device **750** is removed (FIG. 5E) and thereafter the advancement of recapture sheath **710** is advanced into recovery position (FIG. 5F).

[0065] The entrapped debris **734** is then removed prior to recapturing the device with methods such as, for example, aspiration, delivery of therapeutic agents or maceration. Additionally, the device and entrapped debris can be recaptured in whole and removed via the same sheath used to recapture the device as illustrated in FIG. 5G. The device **100** and debris **734** are then withdrawn into the sheath **710** (FIG. 5H), and the sheath withdrawn from the vasculature (FIG. 5I).

[0066] Similarly, an additional use of the invention as un-tethered distal protection is illustrated in FIGS. 6A-E, in which a balloon is used to expand the lesion **732** such as in the case of balloon angioplasty, often performed prior to stenting a vessel to keep it open. For this procedure a balloon catheter is advanced to the lesion site and inflated FIG. 6B, plaque **732** is pushed outward by the balloon (FIG. 6C), thus reestablishing normal blood flow. Any particulate matter **734** embolized by the procedure is trapped by the filter (FIG. 6D). The debris **734** can then be removed prior to filter retrieval as previously described or the device with trapped debris can be removed together.

[0067] Untethered filter embodiments can have a retrieval feature **140**, such as at the ends of the filter where the elongate members of the frame attach, and anchors, which can be located on the body of the frame to help the filter to maintain its location. In some embodiments, the untethered distal protection filters **100** can be left in the blood vessel to provide protection for up to 12, 24, 48, or 72 hours. In some embodiments, the untethered filters **100** can be left in the blood vessel to provide protection for up to 1 week, 2 weeks, 3 weeks, 4 weeks, 2 months, 3 months, 4 months, 5 months or 6 months. In some embodiments, the untethered filters **100** can be left in the blood vessel perioperatively, i.e. for the duration of the patient's surgical procedure, or sub-chronically, i.e. for a predetermined period of time postoperatively. In some embodiments, periodic aspiration of the debris captured by the filter **100** can be performed to prevent or reduce blockage of the blood flow through the filter **100**.

[0068] An additional method practiced widely in the art is the use of tethered distal protection adjunctive to the previously described procedures (i.e., the device **100** remains tethered during the procedure). Embodiments of the filtering device of the present invention may also be used for this purpose as illustrated in FIGS. 7A-7E. Positive control of the

filter **100** is maintained via an integral wire or snare connected to the device **100**. The connection between the integral wire or snare to the device **100** is maintained during the procedure and may be, in some embodiments, used as a guidewire. As illustrated in FIG. 7B, connection to the device **100** is maintained a while performing a procedure to treat the vasculature in proximity to the location (i.e., treat the lesion **732**).

[0069] An example of a tethered distal protection method is illustrated in FIGS. 7A-7E. An embodiment of a filter device **100** is deployed distal to the lesion **732** to be treated (FIG. 7A), the treatment is initiated (FIG. 7B), and embolized material **734** is captured in the filter **100** (FIG. 7C). Thereafter, the debris **734** is removed prior to filter recapture or, alternatively, with treatment in the filter **100** via a sheath as previously described. The device **100** is recovered into the sheath (FIG. 7D) and removed from the lumen **10** (FIG. 7E).

[0070] A tethered device (FIG. 7A, 8A) can also be employed to mechanically dislodge and remove embolic material **732** from a vessel **10**, such as in the case of a thrombectomy. This offers a simple means of removing and trapping debris without requiring multiple devices to achieve the same goal. For this method, the tethered device is advanced downstream of the lesion site (FIG. 8A), and deployed (FIG. 8B). The tethered, deployed filter **100** is then drawn across the lesion **732** (FIG. 8C) to pull the thrombus from the vessel wall and into the filter **100** (FIG. 8D). The embolized material **734** is then removed via the methods previously described (FIG. 8E), tethered device is drawn into the sheath and removed from the lumen (FIG. 8F).

[0071] In some embodiments, as illustrated in the FIGS. 9A-9B, the distal protection device or system **900** can include two filters, a proximal filter **902** and a distal filter **904**. In other embodiments, more than two filters can be used. In some embodiments, the two filters can be independently tethered to a delivery device, which can be a tube or sheath with a guide wire lumen or simply a wire, while not being tethered to each other. In some embodiments, the filters are tethered directly, i.e. are attached directly, to the delivery device. In some embodiments, such a configuration allows the distance or length between the two filters to be independently adjusted by the user by manipulating a separate hub for each filter. In addition, in some embodiments the filters can be independently oriented within a vessel by rotating the filters using a corresponding portion of the hub. For example, rotating the corresponding portion of the hub can cause the filter to rotate in a similar manner. In general, the opening of the filter is oriented to face the direction of blood flow such that blood and any debris, such as emboli, plaque fragments, calcium deposits and/or other mineral deposits, in the blood flows into the opening of the filter and into the material capture structure.

[0072] In some embodiments, the proximal filter **902** can be tethered or attached to a first sheath **906** and the distal filter **904** can be tethered or attached to a second sheath **908** that is coaxial with the first sheath **906**. In some embodiments, the second sheath **908** is disposed within the first sheath **906** and extends past the distal end of the first sheath **906**. This double sheath design allows each filter to be independently manipulated by manipulation of the corresponding sheath on which the filter is attached. In some embodiments, the sheaths can be braid or coil reinforced to reduce kinking. In some embodiments, the first and second sheaths can be microcatheters. In addition, the double sheath design allows the distance between the two filters to be adjusted, which allows the filters

to be properly placed in the brachiocephalic trunk and the left common carotid artery. Because the distance and anatomy between the left common carotid artery and the brachiocephalic trunk is highly variable between patients, it is very helpful to be able to adjust the distance between the filters to maintain wall apposition.

[0073] In addition, in some embodiments the first and second sheaths are disposed within an outer sheath **910**. In some embodiments, the outer sheath **910** can be advanced over both the first and second sheaths **906**, **908** to effect capture of the attached filters **902**, **904**. In some embodiments, the outer sheath **910** can have a curved, deflecting, steerable distal tip portion **912** adapted to aid in navigating the curvature of the vasculature. In some embodiments, the curvature of the distal tip portion **912** can be between about 10 to 60 degrees, or between about 20 to 45 degrees, or be about 15, 20, 25, 30, 35, 40, or 45 degrees.

[0074] In some embodiments, a stop **914** is provided between the filters. In some embodiments, the stop **924** is located on the second sheath **908** at a predetermined distance proximal of the distal filter **904**, which can be located on or proximal the distal end of the second sheath **908**. The stop **924** can be an enlarged section of the second sheath **908**, such as a thick band or other raised structure that cannot be retracted within the lumen of the first sheath **906**. Therefore, the stop **924** can provide a minimum separation distance between the two filters to prevent collisions and entanglements between the two filters during the deployment or removal/recovery phases.

[0075] In some embodiments, the sheaths can be over-the-wire type sheaths and can be advanced over a guidewire **926**. In other embodiments, the smaller diameter second sheath **908** with the distal filter **904** can have a rapid exchange type guidewire lumen located on the distal portion of the sheath to allow the second sheath to be exchanged in a rapid exchange type manner (not shown).

[0076] In some embodiments, the distal end of the second sheath **908** can have an atraumatic tip **928** to prevent accidental puncture of the vessel wall and to atraumatically advance the sheath.

[0077] In some embodiments, the proximal filter **902** and the distal filter **904** can be made from a frame **932**, **934** having a proximal loop **936**, **938**, a distal loop **940**, **942** and a slidable crossover point **944**, **946** between the two loops, and a material capture structure **948**, **950** attached to one of the loops two loops. In some embodiments, the sheaths pass through the interior of the loops. In some embodiments as illustrated in FIGS. 9C and 9D, the frame can be formed from a single wire or structural element that is oriented in a figure eight configuration. In some embodiments, the slidable crossover point is offset from an axis that connects the proximal end and the distal end of the frame. This offset can define the height of the filter structure. In some embodiments, the two ends of the single wire frame can be attached to one of the sheaths of the device by a fastener **952**, **954** such that the sheath is located within the loop. In some embodiments as illustrated in FIGS. 9E and 9F, the frame can be formed from two wires or structural elements with opposing spirals that form a figure eight structure with a slidable crossover point that is offset from an axis that connects the proximal end and the distal ends of the frame.

[0078] In some embodiments, the proximal filter **902** can have an orientation with an opening **956** that faces towards the distal end of the device **900** and can have a material capture

structure **948** attached to the trailing edge or proximal loop **936** of the proximal filter structure, while the distal filter **904** can have an orientation with an opening **958** that faces towards the proximal end of the device **900** and can have a material capture structure **950** attached to the leading edge or proximal loop **938** of the filter structure. In some embodiments, the material capture structure is attached to the proximal edge or loop of each filter.

[0079] In some embodiments, the material capture structure is pleated to accommodate the movement of the elongate members and crossover point while maintaining emboli and debris protection across the entire cross-sectional area of the lumen. In some embodiments, the material capture structure can have one or more pleats located adjacent or near the crossover point. In some embodiments, the material capture structure can have an overlapping portion at the crossover point that functions similarly to the pleat to provide material capture structure coverage in the event of separation of the elongate members at the crossover point. In some embodiments, as illustrated in FIGS. 10A-10F, the crossover point **1000** can include a crossover loop **1002** or some other restraining feature that keeps the elements of the frame that form the crosspoint point **1000** in substantial apposition or contact while still allowing the crossover elements to slide against one another. Like the pleat, the crossover loop **1002** prevents or reduces the gap **1004** that can form in between the frame **1006** and the material capture structure **1008** when the frame elements separate from one another. Such a gap may allow embolic debris to leak through the filter. Therefore, preventing or reducing the gap **1004**, by for example providing additional material capture structure in the form of a pleat or by preventing or reducing the separation of the frame elements at the crossover point, can improve the capture efficiency of the filter.

[0080] In some embodiments, as illustrated in FIG. 9A, radiopaque markers **930** can be provided on the sheaths and/or filters in order to visualize the location of the sheaths and filters during the delivery and recovery process. In some embodiments, the radiopaque marker **903** can be discrete bands incorporated in the sheaths and/or filters. In other embodiments, the sheaths and/or filters can include a coil of radiopaque wire or ribbon, such as platinum wire or ribbon, that can be incorporated into the sheaths and/or filters, making entire portions of the sheaths and/or filter radiopaque. For example, as illustrated in FIGS. 11A and 11B, a radiopaque wire or ribbon **1100** can be wrapped around a superelastic shape memory metal wire or frame core **1102**, made from Nitinol for example, to form the filter frame. Similarly, a radiopaque wire or ribbon **1100** can be wrapped around distal portions of the sheaths where visualization is desired. The wrapped radiopaque wire or ribbon can also provide an irregular surface that facilitates attachment of the filter membrane to the filter frame.

[0081] FIGS. 11C and 11D illustrate close up cross-sectional views of a sheath **1110** and the atraumatic tip **1120**. The sheath **1110** has a lumen **1112** that can receive a guidewire or another sheath. Similarly, the atraumatic tip **1120** has a lumen **1122** that can receive a guidewire.

[0082] In some embodiments, the end of the filter with the material capture structure, such as the loop in which the material capture structure is attached, can be tethered or attached to the delivery device, while the end of the filter without the material capture structure, such as the loop that is not attached to the material capture structure, can remain free.

In some embodiments, tethering only one end of the filter to the delivery device allows the filter greater flexibility in its deployed orientation with respect to the orientation of the delivery device, which can improve the seal or fit of the filter within the vessel. In some embodiments, both ends of the filter can be tethered to the delivery device. In some embodiments, the end of the filter without the material capture structure can be tethered to the delivery device. In some embodiments, the openings of the two filters face each other. In some embodiments, the opening of the two filters face in the same direction, which can be either towards the distal end of the filter or the proximal end of the filter. In some embodiments, the openings of the two filters face away from each other.

[0083] As illustrated in FIGS. 12A-12E, in some embodiments each filter **1200** can be attached to an outer sheath **1202** and an inner sheath **1204**, such that the proximal loop **1206** is attached to the outer sheath **1202** and the distal loop **1208** is attached to the inner sheath **1204**. This configuration allows longitudinal length and compression of the filter **1200** to be controlled by the user by manipulating a hub at the proximal end of the sheath or by manipulating the proximal end of the sheath directly. By decreasing the filter length, the height of the filter **1200** is increased allowing the filter to provide complete or substantial wall apposition in a larger diameter vessel, as shown in FIG. 12B. The slidable crossover point allows the filter to dynamically adapt to the shape of the anatomy. Once the desired filter length or height is obtained, a locking mechanism **1210**, such as a Touhy-Borst lock or ratchet lock or the like which can be incorporated into or with the hub portions, can be used to lock the outer sheath **1202** to the inner sheath **1204** to fix the filter dimensions. A locking mechanism **1210** can also be used in other embodiments described herein, by for example incorporation with the hub and hub portions illustrated in FIG. 20, to lock the position of one sheath to another sheath or to the guidewire. Similarly, by increasing the filter length, the height of the filter **1200** is decreased allowing the filter to more easily provide complete or substantial wall apposition in a smaller diameter vessel, as shown in FIG. 12C. As illustrated in FIGS. 12D and 12E, the height of the filter, including the size of each individual loop, can be customized by manipulating the telescoping sheath to increase or decrease the length of the filter, where the height of the filter or individual loop is inversely related to the length of the filter or individual loop.

[0084] In some embodiments, the material capture structure, which can be conical for example, can be formed from a flat filter membrane or film sheet. The filter sheet can be cut and folded into the desired shape, such as a cone for example, and the seam can be thermally bonded, mechanically stitched together, or bonded together at the surface using an adhesive. In some embodiments as illustrated in FIGS. 13A-13C, the filter sheet **1300** can be attached to a loop on the filter frame **1302** by stitching with a biocompatible thread or suture, by adhesive bonding, or by thermal bonding. In some embodiments, a portion of the mouth of filter sheet **1300** can be folded over the loop on the filter frame **1302** before attachment **1304**.

[0085] In some embodiments, the material capture structure **1400** contains a number of filter cells or pores **1402**, as illustrated in FIG. 14A-14B. Filter cells or pores may be formed in a number of different ways and have a number of different shapes and sizes. The shape, size and number of filter cells or pores in a specific filter may be selected based on the use of a particular filter. For example, a filter device of the

present invention configured for distal protection may have a filter cell size or pore size on the order of tens to hundreds of microns to less than 5 millimeters, or less than or equal to about 1000, 900, 800, 700, 600, 500, 400, 300, 200, 100, 90, 80, 70, 60 or 50 microns. In some embodiments, the filter cell size or pore size is formed by a selecting a filter material with a cell size or pore size suited to the desired filtration level. In some embodiments, the filter material can be a polymer membrane or film or mesh. The polymer can be polyurethane, polyethylene, nylon or the like. The polymer membrane can be between about 0.5 to 3 mil thick, or about 0.75 to 1.5 mil thick, or about 0.5, 1.0, 1.5, or 2.0 mil thick. Using a thin membrane allows the filter membrane to be easily collapsed or folded into a delivery catheter and also facilitates retrieval back into the catheter.

[0086] In some embodiments, the pores are laser drilled into the membrane. In some embodiments, the filter cells are formed from a mesh. In some embodiments, the pore size, shape, density, orientation, and distribution on the membrane can be adjusted to control the flow rate profile through the filter membrane. For example, in some embodiments, the shape of the pore can be circular, ellipsoid, oval or oblong. In a conical filter for example, an oval pore with its major axis aligned with the filter axis can present a more circular cross-sectional opening when viewed along the longitudinal axis. In addition, the pore distribution can be adjusted to provide higher pore density and/or larger pores at or near the periphery of the membrane, which is generally adjacent to the blood vessel wall after implantation. In some embodiments, the pores can be ellipsoid, oval or oblong towards the periphery of the membrane. For example as illustrated in FIG. 14B, the peripheral portions **1404** of the filter membrane that resides at or near the periphery of the blood vessel lumen can have a greater pore density and/or greater pore size than the central portions **1406** of the filter membrane that resides in the central portion of the vessel lumen. This configuration provides increased debris protection for the central portion of the filter membrane, which tends to receive debris that can be deflected from the periphery toward a central holding zone of, for example, a conical filter. As debris fills the central holding zone, the central portion of the membrane can become clogged or blocked, which can reduce or stop flow of blood through the central portion of the membrane. To compensate for the blocked central portion, the peripheral portions of the membrane can have larger pores and/or a higher pore density in order to allow a sufficient amount of blood through the debris filled filter membrane.

[0087] In some embodiments, the filter membrane has an open area between 25 to 75 percent, or between about 33 to 66 percent, or between about 40 to 60 percent, or about or at least about 35, 40, 45, 50, 55, 57, 60 or 65 percent, where the open area refers to the area occupied by the pores. Sufficient open space is important to allow an adequate flow of blood through the filter membrane and to the brain, if used to protect the neurovasculature. In some embodiments, a contrast dye or radiopaque fluid can be introduced upstream of a deployed filter to determine whether the filter membrane is occluded and the degree of occlusion. In some embodiments, the contrast dye or radiopaque fluid can be delivered through a lumen and fluid delivery port in the distal filter delivery device. In other embodiments, the contrast dye or radiopaque fluid can be delivered by a separate catheter.

[0088] In some embodiments as illustrated in FIGS. 15A and 15B, the embolic debris **1500** can be aspirated from the

material capture structure **1502** using an aspiration port **1504** included with the filter device. In some embodiments, the aspiration port **1504** can be located at or near the apex of the material capture structure **1502** where the debris **1500** is generally funneled to. In some embodiments, the aspiration port **1504** can be located on the distal end of a sheath which is connected to the apex of the material capture structure **1502**. In other embodiments, the aspiration port **1504** can be located along the length of the sheath on which the material capture structure **1502** is attached. In some embodiments, one or more aspiration ports **1504** are used to aspirate the debris. In some embodiments, a separate aspiration catheter can be used to aspirate debris **1500** from the material capture structure **1502**.

[0089] In some embodiments, the material capture structure, filter membrane or mesh can be coated with an anticoagulant such as heparin. In some embodiments, the other portions of the device in contact with blood, such as the catheter and tether and filter frame, can be coated with an anticoagulant. In some embodiments, the filter and/or filter membrane or mesh can be coated with a drug or pharmaceutical compound.

[0090] In some embodiments, the frame of the filter does not have any additional anchoring structures that penetrate into the vessel wall. The force exerted by the self expanding frame against the vessel wall along with the attachment of the filter to the delivery sheath during the entire procedure can provide sufficient stability to the filter and prevent substantial migration of the filter during the procedure. Relative to the venous vessels such as the vena cava, the arterial vessels are less compliant and can undergo less change in diameter over time. This makes it less necessary to provide relatively invasive fixation means. In some embodiments, the frame of the filter can include one or more anchors that do not penetrate completely through the vessel wall. In the branch arteries off the aorta, puncture through the vessel wall may lead to excessive bleeding or rupture. Therefore, in some embodiments, the anchors can be sized and designed to penetrate only part way through the vessel wall. For example, the anchors can extend radially outwards for a distance that is less than the thickness of the vessel wall, which can be less than about 0.75, 0.5, or 0.25 times the thickness of the vessel wall. In other embodiments, the anchors are designed to engage the vessel wall in an atraumatic manner.

[0091] In some embodiments as illustrated in FIG. 16, the dual filter configuration allows the user to place one filter **902** in a first location in the vasculature, such as in the brachiocephalic trunk **22**, and the second filter **904** can be placed in a second location in the vasculature, such as a portion of the left common carotid artery **28** that branches off the aorta **12**. In some embodiments, a filter can also be placed in the left subclavian artery (not shown). In some embodiments, the goal is to provide protection of the neurovasculature by protecting the left and right common carotid artery **26**, **28**. Placement of filters in both the brachiocephalic trunk **22** and the left common carotid artery **28** provides emboli and debris protection for the arteries that supply blood to the brain, where emboli or debris **1610** can cause severe adverse events such as stroke. By preventing procedure related emboli and debris **1610** from reaching the neurovasculature, the risk of stroke can be reduced.

[0092] In other embodiments, the filters can be placed in other vessels branching off the aorta, such as the left subclavian artery, the right and left coronary artery, the mesenteric

arteries and the renal arteries. In some embodiments, one or more of the filters can be deployed in the vasculature according to the configurations disclosed in U.S. Pat. No. 6,485,502 to Don Michael et al., U.S. Pat. No. 7,806,906 to Don Michael, U.S. Publication No. 2006/0100658 to Obana et al., and U.S. Publication No. 2008/0004687 to Barbut et al., which are hereby incorporated by reference in their entireties.

[0093] In some embodiments, the distal filter **904** can be placed first at the second location, such as the left common carotid artery **28**, and then the proximal filter **902** can be retracted to the first location, such as the brachiocephalic trunk **22**, and placed next. In some embodiments, the filter delivery device can access the first location and/or the second location through one of the arteries that branches off the aortic arch **16**, such as the brachiocephalic trunk **22**, the left common carotid artery **28** or the left subclavian artery, for example. In other embodiments, the proximal filter **902** can be placed first at the first location and then the distal filter can be advanced to the second location and placed next.

[0094] In some embodiments as illustrated in FIGS. 17A-17L, filters can be introduced into a patient's blood vessels as follows. In some embodiments as illustrated in FIGS. 17A-17G, a guidewire **926** can be introduced into a peripheral artery, such as the right brachial or radial artery, and then advanced into the right subclavian artery **24**. From the right subclavian artery **24**, the guidewire **926** can be further advanced into the brachiocephalic trunk **22**, then into the aortic arch **16** of the aorta **12**, and then into the left common carotid artery **28**. In other embodiments, the filters can be delivered to the left common carotid artery and brachiocephalic trunk through the femoral artery.

[0095] In some embodiments, a sheath can be optionally advanced over the guidewire to allow the guidewire to be exchanged for a stiffer guidewire. The stiffer guidewire may be better able to maintain its position in the left common carotid artery than a more flexible guidewire when the catheter or sheath carrying the filter is advanced over the guidewire. Because the catheter or sheath carrying the filter tends to be stiffer than the first, flexible guidewire, the operator can inadvertently dislodge the first guidewire from the left common carotid artery as the catheter or sheath carrying the filter is advanced into the aortic arch and is forced to make a bend towards the left common carotid artery. Increasing the stiffness of the guidewire with the stiffer second guidewire helps resist this dislocation force exerted by the filter catheter. In addition or alternatively, a sheath with an appropriately curved tip portion can be used to help steer the guidewire **926** through the vasculature. In some embodiments, the sheath can be the outer sheath **910** of the filter delivery device **900**. In other embodiments, the sheath can be separate from the filter delivery device **900** and can be removed after the guidewire **926** has been placed into the left common carotid artery **28** or other target location, and then be replaced by the filter delivery device **900**.

[0096] Once the guidewire **926** is in place in the left common carotid artery **28**, the filter delivery device **900** can be introduced over the guidewire **926** and advanced to the left common carotid artery **28**, where the filter deployment process can begin, as illustrated in FIGS. 17G-17L. More specifically, the filter delivery device **900**, which includes the plurality of sheaths with attached filters as described above, can be introduced over the guidewire **926** and into the brachiocephalic trunk **22** and then advanced towards the aorta **12**. The distal filter **904** can then be advanced into the aortic

arch 16, while covered by the outer sheath 910, and into the left common carotid artery 28, where the distal filter 904 can be deployed by retracting the outer sheath 910 over the distal filter 904. As the outer sheath 910 is retracted over the distal filter 904, the distal filter 904 can self-expand to engage the left common carotid artery wall. The distal filter 904 is deployed such that the mouth 958 of the distal filter 904 resides within the left common carotid artery 28. Next, the first sheath 906, which is attached to the proximal filter 902, is manipulated such that the mouth 956 of the proximal filter 902 resides in the brachiocephalic trunk 22. This manipulation can be done within the outer sheath 910, and depending on the location of the proximal filter 902 after the distal filter 904 has been deployed, can require the proximal filter 902 to be retracted or advanced into the brachiocephalic trunk 22.

[0097] Once the proximal filter 902 is in place within the brachiocephalic trunk 22, the proximal filter 902 can be deployed from the delivery device 900 to reside in the brachiocephalic trunk 22 by retracting the outer sheath 910 over the proximal filter 902. As the outer sheath 910 is retracted over the proximal filter 902, the proximal filter 902 can self-expand to engage the brachiocephalic trunk wall. As illustrated in the FIGS. 9A and 17L, both filters have openings that face each other in the stowed configuration and when deployed face the aortic arch. Such a delivery method and device configuration reduces and/or minimizes the amount of the distal protection device that occupies the aorta, thereby reducing and/or minimizing any interference with the main operational procedure to be performed, such as a percutaneous aortic valve replacement.

[0098] The length of the spacing between the two filters, which can be adjusted using the stop feature, can have an effect on whether the proximal filter will need to be retracted or advanced into the correct location in the brachiocephalic trunk. In some embodiments, the spacing between the filters is relatively long such that after deployment of the distal filter, the proximal filter resides within the brachiocephalic trunk. In some embodiments, the proximal filter may be then advanced into position such that the mouth of the proximal filter is located within desired location within the brachiocephalic trunk. In other embodiments, the spacing between the filters is relatively short such that after deployment of the distal filter, the proximal filter resides within the aortic arch, which means that the proximal filter can then be retracted into brachiocephalic trunk.

[0099] Furthermore, the spacing between the two filters can have an effect on the amount and/or the configuration of the sheath or catheter than remains in the aortic arch when the filters are in place. It can be important to minimize or reduce the obstruction of the aortic lumen by the sheath or catheter in order to minimize or reduce interference with subsequent surgical procedures, such as percutaneous aortic valve repair PAVR that require insertion of catheters and other medical devices through the aortic arch. Collision of the PAVR catheter with the sheath or catheter of the distal protection filter, can cause dislodgement of the filters and/or entanglement between the devices and/or otherwise interfere with the surgical procedure. Various embodiments of the system and method that minimize or reduce obstruction of the aortic lumen are illustrated in FIGS. 18A-18E. In some embodiments as illustrated in FIG. 18A, in order to minimize or reduce the obstruction of the aortic lumen 13 by the sheath 908 or catheter of the filter device 900, the sheath 908 or catheter portion between the proximal filter 902 and the distal

filter 904 can be kept taut or under tension to minimize or reduce the length of the sheath 908 or catheter between the two filters. In this configuration, the sheath 908 or catheter tends to abut or conform to the top 1800 of the aortic arch 16, also referred to as the outer radius 1800 of the aortic arch 16, between the left common carotid artery 28 and the brachiocephalic trunk 22. In some embodiments, the frame of the proximal filter 902, the distal filter 904 and/or sheath 908 or catheter portion between the two filters can include one or more anchors or securement elements 1816 that helps secure the sheath 908 or catheter to the top portion of the aortic arch 16 by allowing the user to apply tension to the sheath 908 which and/or by using anchors 1816 to secure the sheath 908 to the outer radius 1800. The anchors 1816 can be configured to extend towards the aortic arch wall, or can be manipulated to face the aortic arch wall, so that the likelihood that the anchors 1816 interfere with the surgical procedure catheter 10 or device is minimized or reduced. In some embodiments, anchors 1816 can have relatively short length to ensure that the anchors do not puncture the wall of the aortic arch. In some embodiments where the sheath 908 has an anchor, anchors 1816 can be located on the portion of the sheath opposite the crossover point of the proximal filter 902 and/or the crossover point of the distal filter 904. In some embodiments, the filter device 900 can have a plurality of anchors 1816 located in any of the locations described herein.

[0100] In other embodiments as illustrated in FIGS. 18B and 18C, the portion of the sheath 908 or catheter in the aortic arch 16 can extend downwards from the left common carotid artery 28, staying against inner wall the aortic arch and traversing from the outer radius 1800 of the aortic arch 16 proximate the left common carotid artery 28 to the inner radius 1802 of the aortic arch 16, before extending upwards towards the outer radius 1800 of the aortic arch 16 proximate the brachiocephalic trunk 22 and then into the brachiocephalic trunk 22, again staying against the aortic arch inner wall. This configuration results in a U shaped configuration for the sheath 908 or catheter while staying substantially out of the aortic arch lumen 13. In this embodiment, the distal filter 904 and/or sheath 908 or catheter can also have anchors 1816 as described above.

[0101] In other embodiments as illustrated in FIGS. 18D and 18E, which are modifications of the embodiment illustrated in FIG. 18A, a deflection mechanism can be incorporated on the portion of the sheath 908 or catheter between the two filters that resides against outer radius 1800 of the aortic arch 16. For example, FIG. 18D shows a balloon deflection mechanism 1820 that can be inflated after the filters are positioned in order to deflect the procedure catheter 10 from entanglement with the sheath 908 of the filter device 900. As the procedure catheter 10 is inserted into the aortic arch 16, it makes contact with the balloon deflection mechanism 1820 instead of the getting potentially entangled with the sheath 908. FIG. 18E shows various embodiments of the deflection mechanism, where a deflection shield 1822 is used in place of the balloon deflection mechanism 1820. The deflection shield 1822 can be flexible and flat and can be rolled up around the sheath 908 during delivery of the distal filter 904. As the outer sheath is further retracted, the deflection shield 1822 can be deployed and can unfurl into its flat configuration.

[0102] In other embodiments, the portion of the sheath 908 between the two filters can have a suture tether that allows the sheath 908 to be sutured against the aortic arch wall.

[0103] After completion of the main operation procedure, the process of removing the distal protection filters and any captured debris can be initiated, as illustrated in FIGS. 19A-19F. For example, in some embodiments, an outer sheath **910** can be advanced over the proximal filter **902** and the distal filter **904**. As the outer sheath **910** is advanced over the first sheath **906**, it first contacts the proximal edge or loop **936** of the proximal filter **902**, which in some embodiments, also serves as the attachment for a material capture structure **948**. As the outer sheath **910** is advanced over the proximal edge or loop **936** of the proximal filter **902**, it causes the proximal edge or loop to collapse **936** and close the mouth or opening **956** of the material capture structure **948**, thereby sealing the debris **1610** within the material capture structure **948** while not causing extrusion of the debris **160** out of the proximal filter **902**. As explained above, this can occur because the apex **1916** of the material capture structure **948** is unattached to the first sheath **906**. The outer sheath **910** can then be further advanced over the sealed off portion of the material capture structure **948** containing the trapped debris **1610** such that the apex **1916** is the last part of the material capture structure **948** to be encompassed by the outer sheath **910**. In some embodiments, as shown in FIGS. 19B and 19E, the distal loop **940**, **942** of the proximal filter **902** and/or the distal filter **904** can move proximally during the closure of the mouth of the material capture structure such that the distal loop can be proximal the crossover point during a portion of the mouth closure procedure. As the mouth closure procedure progresses, the distal loop can move distally such that the distal loop is again distal the crossover point before being completely withdrawn into the outer sheath. The outer sheath **910** can then be advanced over the second sheath **908** to the distal filter **904**, where it first contacts the proximal edge or loop **938** of the distal filter **904**, which in some embodiments also serves as the attachment for a material capture structure **950**. Next, the outer sheath **910** can be advanced over the proximal edge or loop **938** of the distal filter **904** to close the opening **958** the material capture structure **950** to trap the debris **1610** within the material capture structure **950** without causing extrusion of the debris **1610** out of the distal filter **904**. The outer sheath **910** can then be advanced over the sealed off portion of the material capture structure **950** of the distal filter **904** and the distal protection device and/or system can be removed from the patient.

[0104] In some embodiments, the outer sheath of the distal protection device can be swapped out for a larger sheath or smaller sheath by removing the hub, then removing the original sheath, then inserting the new larger or smaller sheath, and then reattaching the hub. In some embodiments, the hub can be simply twisted off and twisted back on. The ability to swap out one sheath for a larger or smaller sheath can be useful for using the smallest sheath that is capable of enclosing the filter and the debris captured by the filter. However, if a large amount of debris is captured by the filter, it may be desirable to use a larger sheath to recover the filter, especially if the operator has difficulty or cannot advance the smaller sheath over the trapped debris. For example, FIG. 20 illustrates an embodiment of a plurality of removable hubs. There is an outer sheath hub **2000** that controls manipulation of the outer sheath **910**, a proximal filter hub **2002** that controls the first sheath **906** and the proximal filter attached to the first sheath, and a distal filter hub **2004** that controls the second sheath **908** and the distal filter attached to the second sheath. Each of these hubs is detachable, which allows the outer sheath to be

removed and replaced if desired. In some embodiments, the hubs can be lockable to lock the position of the sheaths. For example, one hub can be used to lock the position of the attached sheath while the other sheaths can be advanced or withdrawn, allowing the distance between the filters to be manipulated.

[0105] In some embodiments, the distal protection filters can be removed after the medical procedure is complete. In other embodiments, the distal protection filters can be left in for a predetermined amount of time before the filters are removed from the blood vessels. In some embodiments, the filters can be left in for up to 12, 24, 48, or 72 hours before removal. In some embodiments, a clogged filter can be swapped out with a new filter. In some embodiments, the filters can be left in the blood vessels to provide protection for up to 1 week, 2 weeks, 3 weeks, 4 weeks, 2 months, 3 months, 4 months, 5 months or 6 months when used in conjunction with periodic aspiration of the debris captured by the filters to prevent or reduce blockage of the blood flow through the filter. In some embodiments, the filters can be left in the blood vessel perioperatively, i.e. for the duration of the patient's surgical procedure, or sub-chronically, i.e. for a predetermined period of time postoperatively.

[0106] The distal protection filters described above can be used to capture debris that is generated by any medical procedure performed in the heart or circulatory systems, such as percutaneous aortic valve replacement (PAVR), transcatheter aortic valve implantation (TAVI), thoracic endovascular aortic repair (TEVAR), coronary artery bypass graft surgery (CABG), off-pump coronary artery bypass surgery (OP-CAB), mitral valve replacement (MVR), aortic valve replacement (AVR), left ventricle assist device, maze procedures, left ventricle catheterization, mitral valve procedure, electrophysiology (EP) ablation, closure of atrial septal defect (ASD), closure of patent foramen ovale (PFO), and closure of left atrial appendage (LAA).

[0107] In some embodiments, a pressure sensor and/or an intravascular ultrasound (IVUS) transducer can be added to or incorporated into the delivery system and method. The pressure sensor can be used to measure the pressure at various positions within the vasculature, which can be used to determine blood flow, while the intravascular ultrasound (IVUS) transducer can be used to measure fluid flow and/or provide imaging within the vessel. In some embodiments, the pressure sensor and/or IVUS transducer can be incorporated into the guidewire at one or more locations, such as the distal end or distal portion of a guidewire, as described in U.S. Pat. No. 8,277,386, U.S. Pat. No. 6,106,476 and U.S. Pat. No. 6,780,157 which are hereby incorporated by reference in their entireties for all purposes, as well as being incorporated into intermediate and proximal portions of the guidewire. The guidewire with the pressure sensor and/or the IVUS transducer can be used much like a normal guidewire to help navigate the delivery device through the vasculature, with the added benefit of providing pressure measurements and ultrasound imaging to help in the navigation, to visualize the device placement site, and to monitor and ensure proper device deployment. In some embodiments, the IVUS transducer generates image slices as it is advanced and retracted which can then be assembled together to form a three dimensional reconstruction of the vasculature and/or the device within the vasculature. In some embodiments, the guidewire with the pressure sensor and/or IVUS transducer can be fastened to a catheter in a similar manner to that described below

for a catheter having a pressure sensor and/or IVUS transducer that is fastened to another catheter.

[0108] FIGS. 21A-21C illustrate an example of a guidewire 2100 having both a pressure sensor 2102 and an IVUS transducer 2104 located at the distal portion of the guidewire 2100. In some embodiments, the pressure sensor 2102 can be made from a semiconductor material, such as silicon, that is formed into a diaphragm and can be located proximally of the distal tip, while the IVUS transducer 2104 can be located at the distal tip of the guidewire 2104.

[0109] In some embodiments, the pressure sensor and/or IVUS transducer can be located on a catheter in a similar configuration to the guidewire. For example, the IVUS transducer can be located on the distal tip of the catheter while the pressure sensor(s) can be located proximally of the IVUS transducer at one or more locations along the catheter body, from the distal portion of the catheter to an intermediate portion of the catheter to the proximal portion of the catheter. The pressure and/or imaging catheter can be used in parallel with the delivery or retrieval device or any other catheter that is inserted into the vasculature. In some embodiments, the pressure and/or imaging catheter can be fastened to the delivery or retrieval device or other catheter by, for example, enclosing both catheters in a sheath or larger catheter or by fusing the two catheters together. For example, U.S. Pat. No. 6,645,152 and U.S. Pat. No. 6,440,077, both to Jung et al. and hereby incorporated by reference in their entireties for all purposes, discloses an intravascular ultrasound catheter joined together in parallel with a vena cava filter delivery device to guide placement of the filter in the vena cava. The pressure and/or imaging catheter can be used for the same purposes as the pressure and/or imaging guidewire.

[0110] FIGS. 22A-22D illustrate two embodiments of an intravascular ultrasound catheter 2200 joined together in parallel with a catheter 2202 that can be used, for example, to deliver a device to a location with the vasculature, such as a vena cava filter to the vena cava. The intravascular ultrasound catheter 2200 can have an IVUS transducer 2204 located on the distal portion of the IVUS catheter 2200. The IVUS transducer 2204 can be a solid state transducer that is disk shaped or cylindrically shaped with a hole to allow passage of a guidewire 2206 or other device through the IVUS catheter 2200. As shown in FIGS. 22A and 22B, the IVUS catheter 2200 and the delivery catheter 2202 can be joined together in parallel without a sheath by adhering or fusing the two catheters together. FIGS. 22C and 22D illustrate the same IVUS catheter 2200 and delivery catheter 2202 fastened together using a sheath 2208.

[0111] In some embodiments as illustrated in FIGS. 23A and 23B, the pressure sensor and/or IVUS transducer can be integrated into the delivery or retrieval catheter 2300 or device itself. For example, the IVUS transducer 2302 can be integrated into the distal tip or end of the catheter 2300 or device. The pressure sensor 2304 can be located on a distal portion of the catheter shaft proximally of the IVUS transducer 2302. A wire can extend from the IVUS transducer 2302 and/or pressure sensor 2304 to one or more connectors 2306 located at the proximal end of the catheter 2300. The connector(s) 2306 can be used to connect the IVUS transducer 2302 and/or pressure sensor 2304 to an imaging system and/or processing system. In the illustrated embodiment, the catheter 2300 can be used to deliver a vena cava filter 2308 to the vena cava. The catheter 2300 can additionally have a telescoping sleeve or pusher rod to deploy the vena cava filter

2308, or alternatively, the outer catheter sheath can be retracted to deploy the filter. The IVUS transducer can provide positioning guidance and determine the relative location of the filter by advancing and retracting the IVUS transducer 2302 on the catheter 2300 to generate a plurality of image slices that can be assembled to reconstruct a three dimensional image.

[0112] Use of the ultrasound imaging system allows the operator to deliver the device without fluoroscopy or using less fluoroscopy, thereby reducing the radiation exposure to the patient, while allowing more accurate evaluation of the vasculature, aiding placement of the device and allowing confirmation that device placement was proper. The imaging can be used to aid in the deployment of the filters or other devices. The vasculature and implant location can be imaged prior to deployment, after deployment and/or during deployment. The imaging can be used to aid in positioning of the filter or device within the vasculature. The imaging can be used to image the deployment location and determine the appropriate sizing of the filter or other device. The imaging can be used to help estimate treatment duration.

[0113] Although an imaging systems described above have been ultrasound based, other imaging systems can be used instead or in addition. For example, the imaging system can be based on intravascular ultrasound (IVUS), Forward-Looking IVUS (FLIVUS), optical coherence tomography (OCT), piezoelectric micro-machined ultrasound transducer (PMUT), and FACT.

[0114] In some embodiments as shown in FIG. 24, the pressure sensor(s) and IVUS transducer can be alternatively or additionally added to the delivery catheter. For example, the pressure sensor(s) can be added to one or more locations on the outer sheath and/or the inner sheath of the delivery catheter, while the IVUS transducer 2404 can be added to the distal end of the delivery catheter, at for example, the tracking tip 928 and/or at the distal end of the outer sheath 910.

[0115] In some embodiments, a first pressure sensor 2400 can be located distally the distal filter 904 on the guidewire 926 or the tracking tip 928. The first pressure sensor 2400 can be used to measure the pressure within the left common carotid artery 28 downstream of the distal filter 904. As debris 1610 is captured within the distal filter 904, the pores of the distal filter 904 can become clogged, thereby impeding blood flow through the distal filter 904. As the distal filter 904 becomes clogged by debris, the blood pressure downstream of the distal filter 904 can drop. Thus, blood pressure, such as peak systolic pressure or an average pressure over the course of a heartbeat for example, can be continuously monitored by the first pressure sensor 2400, and when a predetermined drop in blood pressure is detected, the operator can be alerted that the distal filter 904 is clogged and should be removed in order to restore blood flow to the brain.

[0116] Similarly, a second pressure sensor 2402 can be located on the outer sheath 910, such that when the outer sheath 910 is retracted to deploy the proximal filter 902, the second pressure sensor 2402 is located downstream of the proximal filter 902 and can measure the pressure in the brachiocephalic trunk 22 or right subclavian artery 24, depending on the location of the second pressure sensor 2402. As the proximal filter 902 becomes clogged by debris 1610, the blood pressure downstream of the proximal filter 902 can drop. Thus, blood pressure, such as peak systolic pressure or an average pressure over the course of a heartbeat for example, can be continuously monitored by the second pres-

sure sensor **2402**, and when a predetermined drop in blood pressure is detected, the operator can be alerted that the proximal filter **902** is clogged and should be removed in order to restore blood flow to the brain.

[0117] In some embodiments, when at least one filter is determined to be clogged, the operator is instructed to recover and remove both filters from the patient. A new distal protection device with clean filters can then be redeployed into the patient. In other embodiments, when both filters are determined to be clogged, the operator is instructed to recover and remove both filters from the patient, and a new distal protection device with clean filters can then be redeployed into the patient.

[0118] In some embodiments, a third pressure sensor **2403** can be located on the inner sheath **908** between the proximal filter **902** and the distal filter **904** such that the third pressure sensor **2403** is located within the aortic arch when the two filters are deployed. In some embodiments, additional pressure sensors **2405**, **2406** can be located on the inner sheath just upstream of the opening to the filters in order to determine the pressure drop across each filter. In some embodiments, the pressure drop across each filter can be estimated by subtracting the pressures measured downstream of the filters from the pressure measured in the aortic arch. In some embodiments, additional pressure sensors **2407**, **2408** can be located on the portion of the inner sheath that lies within each filter. In some embodiments, instead of placing or integrating pressure sensors within the sheaths, the inner and/or outer sheaths can have pressure measuring ports that allow a guidewire having a plurality of pressure sensors to measure the pressure along various locations as described above. The pressure measuring ports can provide fluid communication from the exterior of the sheaths to the guidewire that is disposed within the sheath.

[0119] In some embodiments, as illustrated in FIGS. **25A-25C**, the outer sheath **910** can have a rapid exchange guidewire lumen **2500** for receiving the guidewire **926** in a rapid exchange configuration. The rapid exchange guidewire lumen **2500** can be located along a distal portion of the outer sheath **910** in parallel to the main outer sheath lumen. In some embodiments, the length of the rapid exchange guidewire lumen **2500** is greater than about 6 cm. In other embodiments, the length of the rapid exchange guidewire lumen **2500** is less than about 6 cm. In some embodiments, the distal end of the rapid exchange guidewire lumen **2500** is located proximally of the IVUS transducer **2404** located at the distal end of the outer sheath **910**. In some embodiments, particularly in embodiments having the rapid exchange guidewire lumen, the inner sheath on which the distal filter **904** is attached to can instead be a wire, guidewire or elongate member without a lumen. Replacing the inner sheath with a wire allows the profile of the distal protection device to be reduced, thereby facilitating minimally invasive insertion and reducing the potential to cause obstructions within the aortic arch. Using the rapid exchange guidewire lumen **2500** allows the distal portion of the guidewire **926** to be exposed directly to the blood as the outer sheath **910** is retracted to deploy the filters. This allows placement of a plurality of pressure sensors on the guidewire **926** instead of on the inner and/or outer sheaths. The placement of the pressure sensors on the guidewire **926** can correspond to all the positions described above, allowing the pressure across each filter to be determined. In some embodiments, the guidewire **926** can have an alignment feature to align the pressure sensors to the desired locations relative to the deployed filters. For example, the guidewire

can have a radiopaque marker and/or echogenic marker that can be aligned with a corresponding radioopaque marker and/or echogenic marker on the outer sheath, inner sheath, and/or tracking tip. In some embodiments, the rapid exchange guidewire lumen can be located on the distal portion of the inner sheath that extends beyond the distal end of the outer sheath when the filters are in the loaded configuration. In addition, if one or more of the distal protection filters is determined to be clogged, use of the rapid exchange guidewire lumen facilitates the exchange of a clogged distal protection device with a new, unclogged distal protection device. In some embodiments, the guidewire can be retracted proximally of the distal protection filters before or after the filters are deployed, in order to reduce the risk that the guidewire interferes with apposition of the filter against the vessel wall. In other embodiments, the guidewire can be left in place and the filters can still expand and achieve wall apposition by pushing the guidewire against the vessel wall.

[0120] The IVUS transducer **2404** can be used to provide image based navigation of the delivery catheter through the vasculature to the deployment locations in the left common carotid and brachiocephalic trunk, for example. In addition, the IVUS transducer **2404** can be used to visualize deployment of the filters within the target locations and verify proper deployment including complete wall apposition of each filter within the target locations. As mentioned above, the IVUS transducer **2404** can be added to the distal end of the outer sheath **910**. As the outer sheath **910** is retracted to deploy the filters **902**, **904**, the IVUS transducer **2404** can be used to image the filters **902**, **904** as they are being deployed, allowing the operator to verify proper deployment of each filter. If imaging reveals improper deployment, the filters can be recaptured within the outer sheath by advancing the outer sheath back over the filters and then redeploying the filters.

[0121] To improve visualization of the filters using IVUS imaging, echogenic materials and/or features can be incorporated into various components of the filters including the filter frame and/or the material capture structure. The echogenic materials and/or features can be incorporated throughout the filter components or at discrete locations on the filter as more fully described below.

[0122] Filters are more complex structures in contrast to the relatively simple designs found in catheters and needles. In a more complex device like a filter there is a need to identify specific portions within the device during some medical procedures. In addition, it would be advantageous as well to determine the orientation of the device including components within the device to one another (as used for determining deployment, retrieval and the various intermediate stages thereof) as well as the overall filter orientation to the surrounding lumen or vessel. In contrast to the conventional techniques using location of the tip or start or end of the entire length, a more complex structure such as a filter position, orientation or relative placement information would yield specific benefits. In some cases, aspects, portions or attributes of the overall filter or filter components or portions will enable more useful determinations about the filter in relation to the physiological environment. In one aspect, an intravascular ultrasound (IVUS) catheter and processing system or signal processing algorithm is used to confirm filter sizing selection, guidance for filter placement, filter implantation steps, filter and/or vessel measuring using IVUS before during and/or after steps to confirm sizing selection and fit is appropriate under the physiologic environment and for con-

firmation and/or documentation of proper sizing selection, placement, engagement or degree of engagement of fixation elements (if present), clot burden, orientation and/or deployment in a patient or physician medical record.

[0123] In one aspect, embodiments of the present invention are directed toward medical devices having a complex shape or that are configured to move from stowed to deployed configurations that may also have specific orientation and placement criteria for proper use in a lumen, vessel or hollow organ. One such complex device is an IVC filter. Aspects of the present invention include such devices employed within the human body which have enhanced ultrasound visibility by virtue of incorporation of an echogenic material using any of the techniques described herein alone or in any combination.

[0124] Imaging System and Method for Navigation

[0125] One or more imaging modalities can be used to assist the navigation of the catheter through the vasculature and to assist in the surgical procedure at the surgical site. For example, fluoroscopy can be used to determine the location of the catheter in the vasculature and to assist in navigation. However, fluoroscopy involves the exposure of the patient to x-rays, which over time may increase the risk to a variety of diseases such as cancer, and may also cause burns to tissue such as the skin. The long procedure times for some operations can exacerbate these problems. In addition, medical personnel can also be exposed to incidental x-rays. Although the incidental exposure to the medical personnel is much lower than the patient during a given procedure, the numerous procedures using fluoroscopy conducted by the medical personnel during the course of the year can result in significant x-ray exposure to the medical personnel over time.

[0126] Therefore, the use of an additional or alternative imaging modality, such as intravascular ultrasound (IVUS) imaging, can be used to assist in navigation and assist in the surgical procedure at the surgical site, which can allow the use of fluoroscopy to be reduced, thereby lowering the x-ray exposure to both the patient and medical personnel. Another imaging modality that can be used is optical coherence tomography (OCT). Although the following embodiments have been described primarily using IVUS imaging, OCT imaging can be used by adding a fiber optic element and optical sensor to the catheter.

[0127] The multiple imaging modalities can generate different images that can be displayed separately on one or more displays and/or overlaid and combined or coregistered into a single image and for display on a single display.

[0128] In some embodiments, the imaging devices can be in communication with a computer system having a processor for executing instructions and software, memory for storing the instructions and software, one or more input devices such as a keyboard and mouse, and a display.

[0129] FIG. 35 illustrates an embodiment of a method of navigating the delivery device from the insertion site to the destination site. In some embodiments, the method can be implemented by software that is executed on a computing device. At step 3500, the software and computing device can obtain information from the operator regarding the insertion site, implant or therapeutic device, delivery device, and surgical procedure.

[0130] For example, the software can be imaging software that is designed for use to assist in various surgical procedures. For example, the imaging software can include a representative digital model of the cardiovascular system that includes all the blood vessels and the structures of the heart.

In addition, the software can include a list of standard surgical procedures and allow the creation of custom surgical procedures, which can be a modification of the standard surgical procedures or can be created from scratch. The surgical procedures in the software contain information regarding the insertion site, the path of travel through the vasculature, the destination, and information regarding the performance of the procedure itself. For example, the surgical procedure can be linked to various instructions for use (IFU) associated with the devices used in the procedure. Also, given a particular insertion site and destination, the imaging software can anticipate the pathway through the vasculature that the surgeon will likely navigate and can determine the anatomical landmarks between the insertion site and destination site, as shown in step 3502. For example, the software can identify the vessel junctions that the guidewire, catheter, guide sheath, or other device will encounter and pass as it is advanced from the insertion site to the destination.

[0131] The software can also have information regarding the implant, such as the size and shape of the implant, the echogenic markings on the implant, the fluoroscopic markings on the implant, and the like. The software can also have information regarding the delivery device including whether the delivery device is equipped with one or more IVUS transducers, pressure sensors, and the like. In one aspect, the various markings on the implant may be adapted and configured as an identification designation. In one embodiment, the identification designation includes a color designation selected by the user or provided by the system. For example, one or more markers in a distal portion of may be in a first color, a mid-portion may be in a second color and in a proximal portion in still a third color. In contrast to designating regions of the device, the user or the system may designate individual markers each with a different color or grouped into zones of color. In still another aspect, the entire model or representation of the implant or device or portion thereof may be in color to permit easier identification in the navigation display. In still other embodiments, the color of all or a portion of the device or the color indicated for one or more markers is determined by whether or not the device or marker is in a proper or expected position or in an improper or unexpected position. In one embodiment, proper or expected positions may display as green, improper positions as red and unexpected or indeterminate positions as yellow. In each of the above examples, colors are exemplary of a kind of identification designation and other indicia such as numbers, letters, pictograms (e.g., check marks, X, thumb up, thumb down and the like) may be used. In some embodiments, the imaging software can construct a two dimensional and/or three dimensional reconstruction of the patient's vasculature in real time using the acquired imaging data from the one or more imaging modalities, as shown in step 3504. For example, in steps 3506 and 3508, fluoroscopy, if used, can be used to construct an initial two dimensional reconstruction of the patient's circulatory system and vasculature between at least the insertion site and the destination site. In addition, echocardiography, such as trans-esophageal echocardiography (TEE) and trans-thoracic echocardiography (TTE), can be used to generate images and/or determine blood velocity and tissue velocity. An intravascular imaging modality, such as IVUS and/or OCT, can be used to generate a two dimensional and/or three dimensional reconstruction of the patient's circulatory system and vasculature as the imaging device is moved through the vasculature, as shown in steps

3510 and **3512**. The images can have an included scale that allows the distance between the vessels and other anatomical markers to be determined. The imaging device can have an outside surface with length or distance markings that allow the surgeon to determine what length of the imaging device has been inserted into the patient. In addition, the outside surface of the imaging device can include a longitudinal line along its length that allows the rotational orientation of the device to be determined.

[0132] Imaging data can be acquired as the imaging device is advanced through the vasculature, and also while the imaging device is retracted in reverse. In some embodiments, it can be desirable to scan a portion of the vasculature one or more times, such as two or three times for example, in order to enhance the resolution and/or accuracy of the reconstructed image.

[0133] In some embodiments, the imaging software can detect the presence of vessel junctions and/or other landmarks. In addition, as stated above, given a particular insertion site and destination, the imaging software can anticipate the pathway through the vasculature that the surgeon will likely navigate, and therefore, the software can identify the vessel junctions and/or other landmarks that the guidewire, catheter, guide sheath, or other device will encounter and pass as it is advanced from the insertion site to the destination. In some embodiments, for each detected vessel junction or other anatomical landmark, the imaging software can preliminarily tag, assign or suggest the name of the detected vessel junction and/or other landmark, as shown in step **3514**. The surgeon can accept the recommendation of the imaging software, or can override the recommendation by assigning a different vessel or landmark name to the detected vessel junction and/or other landmark. In some embodiments, the software can provide the recommended name along with one or more alternative names for the detected vessel junction and/or other landmark, and the surgeon can select the recommended name or alternative name with a single mouse click or keyboard click. The recommendations can be placed over the image of the detected vessel junction and/or landmark. In addition or alternatively, the surgeon can be provided a list of potential names identified by the imaging software that can be selected by the surgeon. The surgeon can click or drag the name on top of the detected vessel junction and/or other anatomical landmark. In addition, the surgeon can manually enter in a name for the vessel junction and/or anatomical landmark, if, for example, the name does not appear in the recommendation or list. As the surgeon confirms and locks in the names of each detected vessel junction and/or other anatomical landmark, the imaging software can reevaluate and update its recommendations. The recommendations from the imaging software can be based on the insertion site, the destination, the anticipated pathway through the vasculature, the length of the device that has been inserted into the vasculature, the flow rate of blood, the blood pressure, the vessel diameter, the distance between other vessel junctions and/or anatomical landmarks, and the distance from and/or relative position to a confirmed or locked vessel junction and/or anatomical landmark.

[0134] This imaging procedure involving the identification of the vessel junctions and/or anatomical landmarks can be done either as a preliminary step before the catheter, which can be the distal protection device described herein, is inserted, or can be done concurrently with a catheter that doubles as an imaging device. In some embodiments, the guidewire and/or guide sheath and/or the catheter can include

an imaging device, such as an imaging IVUS transducer located at the distal portion or tip of the device. The identified vessel junctions and/or anatomical landmarks can assist the surgeon in navigation the device through the vasculature to the destination site.

[0135] In some embodiments, the destination site, or a plurality of destination sites, can also be imaged in detail to assist the surgeon in accurately placing the device in the vasculature. For example, the aortic arch and the branch vessels off the aortic arch, such as the left common carotid artery, the brachiocephalic junction, and the right common carotid artery, for example, can be imaged along with the aortic valve. The locations of the vessels, the size and shapes of the vessel openings, the spacing between the openings, and abnormalities in the vasculature can be imaged and determined by the system and method.

[0136] In step **3516**, the location of the delivery catheter can be determined. In some embodiments, the system can determine the location of the delivery catheter using one or more of the following: identification of anatomical landmarks in a previous step, the length of the delivery device that has been inserted into the vasculature, and identification by the user. If the delivery catheter is not at the destination site, the system and software can instruct the operator to advance, retract, and/or rotate the delivery catheter, as shown in step **3520**, based on the determined location of the delivery catheter. After or as the delivery catheter is moved through the vasculature, the system again acquires IVUS imaging data, as shown in step **3510**. As shown in FIG. **35**, the system and method enters a loop until the system and method determines that the delivery catheter is at the destination site in step **3518**. When the system and method determines that the delivery catheter is at the destination site, the operator can be informed, through a visual and/or audible notification for example, that the destination has been reached and that deployment of the implant or device can begin, as shown in step **3522**.

[0137] Imaging Systems and Methods for Implant Deployment

[0138] In some embodiments, the software can further include a module for assisting in the deployment of the implant. As described above, the user can select a medical procedure from a list or menu, at either the prompting of the software, or by manually selecting the option from a menu.

[0139] Each preprogrammed medical procedure includes information regarding the standard procedure steps, including for example, the access points, the typical routes of navigation, the equipment required or recommended, and information regarding the echogenic implant, including models of the implant and color sections or other identification designations described above. The user can be presented with a plurality of fields which each present one aspect of the medical procedure. For example, one field can present access points and can present as a default the most common access point typically used in the medical procedure. If the user desires to use a different access point, the user can click on the access point field to select from a plurality of different predetermined access points, or can manually customize an access point by dragging a marker over a schematic drawing of the human body or a representation of the patient's vasculature generated by patient specific imaging data.

[0140] For a given procedure, the destination is generally known, and therefore, the navigation route through the vas-

culature can be determined by the system based on the access point and the destination, as described above.

[0141] Another field can allow the user to select the implant being used in the medical procedure from a predetermined list. The software can be preprogrammed with all the features of the various implants, including size, three-dimensional shape, location of echogenic features, pattern of echogenic features, and nature of the echogenic features. Additionally or optionally, one or more of the identification designations associated with the device may be preprogrammed or provided by the user such that the display information relating to the position, orientation or placement of an implant is provided according to the user's preferred color or other identification designation. Once the particular implant to be used is selected, the system will be able to automatically identify the implant and its location and orientation within the vasculature using one or more imaging modalities, such as IVUS imaging or FLIVUS imaging, by identifying the various features of implant in the ultrasound imaging data and mapping the data to a model of the implant that is prestored in the software database. By determining the three dimensional location of each of these features within the vasculature, the location and orientation of the implant or device within the vasculature can be determined. The output presented to the user may also be updated to include one or more of the device identification designations.

[0142] The imaging system can also be used to image the deployment site and can automatically identify the anatomical structures of interest, such as the aortic arch, the right common carotid artery, the left common carotid arteries, and the brachiocephalic junction. The system can provide real-time imaging and implant deployment guidance by imaging the implant throughout the deployment procedure, displaying the real-time images to the user that includes a reconstruction of the deployment site and the current implant location and orientation within the deployment site, and by providing instructions or recommendations to the user to achieve correct implant deployment. The real time display may also be updated to include one or more identification designations or changes to an identification designation depending upon the stage of the procedure, user actions or other factors.

[0143] For example, FIG. 36 illustrates an embodiment of a deployment procedure, which can begin after the destination site has been reached. In step 3600, the system and software can determine the relative position between the delivery device and one or more landmarks at the deployment site using IVUS and/or other imaging modalities. Based on the determined relative position, the system and software can determine whether the delivery device is at the target deployment location, as shown in step 3602. If the delivery device is not at the target deployment location, the operator can be instructed to adjust the position of the delivery device based on the relative position between the delivery device and landmarks at the deployment site, as shown in step 3604. After the operator adjusts the position of the delivery device, the method can then loop back to step 3600 by again determining the relative position of the delivery device to the landmarks. This portion of the procedure is an iterative loop for fine tuning the position and orientation of the delivery device before deployment of the implant or device that terminates when the delivery device is determined by the system and software to be at the target deployment location. Optionally or additionally, one or more identification designations may be

updated or altered depending on the result of the operator action, adjustments to the device or subsequent determination (s) of the system.

[0144] When the delivery device is determined to be at the target deployment location, as shown in step 3606, the operator can be instructed to begin deployment of the device or implant. During deployment of the device or implant, the system and software can determine the relative position between the partially deployed implant or device with the deployment site using IVUS, as shown in step 3608. The system and method can then determine whether the implant or device is correctly deployed based on the previous determination in step 3608. If the system and method determines that the implant or device is not correctly placed, the system and method can instruct the user to adjust the position of the implant or device based on the relative position between the implant or device and landmarks at the deployment site, as shown in step 3612. The system and method then loops back to step 3608. This loop can continue until the system and method determines that the implant or device is correctly deployed, upon which the system and method can instruct the user to complete the deployment of the implant or device, as shown in step 3614. Optionally or additionally, one or more identification designations may be updated or altered depending on the result of the operator action, adjustments to the device or subsequent determination(s) of the system.

[0145] In one aspect, there are described herein various alternative echogenic features designs for increasing the echogenicity of the device. It is to be understood that the term device includes any device or portion of a device, such as a filter. A device with enhanced echogenic characteristics may include one or more than one of: (a) a modification to one or more components of the device to enhance the echogenic characteristics of the component; (b) formation of dimples into a component surface of sufficient number and scaled to a suitable size, shape, orientation and pattern for use with intravascular ultrasound systems; (c) protrusions formed in, placed on or joined to a device surface; (d) roughening one or more surfaces of a device, for example using a chemical process, a laser or bead blasting technique; and (e) altering one or more steps of a device manufacturing technique to introduce cavities, voids or pockets to locally modify or adapt one or more acoustic reflection characteristics to improve echogenicity in one or more specific regions of a device. One example of the manufacturing alteration is to introduce gaps between the segments of tubing or coverings whereby the gap provides the echogenic enhancement. In addition, cavities, voids, pockets, dimples, gaps and the like may be left empty or, optionally, filed, partially filed or lined with any of the echogenic materials described herein.

[0146] In one aspect, there are provided embodiments of a device having enhanced echogenic characteristics in or related to at least one or a portion of: an proximal end, a distal end, a terminal proximal end, a terminal distal end, a retrieval feature, an atraumatic tip on a retrieval feature, a mid-strut region, a leg or strut portion having at least one orientation attribute to another portion of the device, an indicia of a location of a fixation element or a retrieval feature, a location on a portion of the device selected such that in use with a particular fixation element the marker in a location that indicates that the fixation element is fully deployed into a wall of a lumen or portion of a vessel or hollow organ (i.e., the marker is against the lumen wall or nearly so when the fixation element is fully engaged. As such, see the marker against

the wall indicates proper deployment, spaced from or not visible would indicate, respectively, not fully engaged or over penetration); a portion of the distal tip and/or an elongated portion. The above described methods may also be applied to the other techniques and alternatives described herein.

[0147] In still further embodiments, a portion, component or aspect of an intraluminal device may have enhanced echogenic attributes by applying a coating or sleeve containing one or more of the echogenic materials disclosed herein or fabricated according to any of the techniques or having any of the attributes to enhance echogenic qualities as described herein. In some aspects, the enhanced echogenic attributes are provided by the incorporation into, application onto or within a component or portion of a device one or more echogenic materials or echogenic markers in a specific configuration, location, orientation or pattern on the device.

[0148] Enhanced echogenic markers or locations may be devised and placed for use individually or in combinations such as to facilitate the identification to an IVUS system or ultrasound imaging modality an indication or signature for a specific location on a device, such as, for example, a retrieval feature, a terminal proximal end, a terminal distal end, a location of a fixation element or a location of some other indicia that identifies a specific aspect of a particular device design. In addition or alternatively, two or more enhanced echogenic markers or portions may be used in combination to provide additional information about a device such as orientation within a vessel, confirmation of deployment or a portion of a deployment sequence, confirmation of final placement, confirmation of migration or lack of migration, confirmation of retrieval or progress in a retrieval sequence and the like according to the various processes and used for devices within the vasculature or in lumens of the body. In another specific embodiment, the use of IVUS techniques with embodiment of the echogenic enhanced devices describe herein may also be used to measure the diameter of the vessel at specific device locations indicated by the echogenic markers during or after deployment or retrieval of a filter.

[0149] In still further aspects, the use of IVUS techniques with embodiment of the echogenic enhanced devices describe herein may also be used to determine, detect or indicate inadequate dilation, adequate dilation, filter expansion, degree of filter expansion, filter—vessel engagement and degree of engagement, strut/leg/anchor position and other attributes relating to the interaction between the device and the surrounding physiological environment.

[0150] Still further, the echogenic markers are positioned with regard to the likely or planned positioning of the IVUS transducer and/or likely pathways for acoustic energy used by the imaging system. By way of example, if the IVUS transducer is forward looking, then those forward looking aspects of the device will be provided with the enhanced echogenic aspects. In another example, if the IVUS transducer is cylindrically shaped and will be positioned through the interior portion of a device then the device will be provided with enhanced echogenic aspects on interior surfaces or portions that would receive acoustic energy from such as transducer in such a position. Other modifications are within the scope of the invention based on the particular style of IVUS transducer used, the position relative to the device and the placement and type of echogenic feature incorporated into the device. Put another way, the echogenic enhancements of the devices described herein are selected, designed and positioned on the

device with regard to the IVUS sensor type, acquisition mode and position relative to the device. Additional details in the use of IVUS with devices is further described in U.S. Pat. Nos. 6,645,152 and 6,440,077, both of which are incorporated herein by reference in their entirety for all purposes.

[0151] In one aspect, the placement and signature of such enhanced echogenic markers are discernible to a human user viewing an ultrasound output alone or in combination with being discernible to a computer system configured for the processing of an ultrasound return including a return from the enhanced echogenic device. Additional aspects of the formation and use of echogenic materials is made with reference to the following US Patents and Patent Publications, each of which is incorporated herein by reference in its entirety: US 2010/0130963; US 2004/0230119; U.S. Pat. Nos. 5,327,891; 5,921,933; 5,081,997; 5,289,831; 5,201,314; 4,276,885; 4,572,203; 4,718,433; 4,442,843; U.S. Pat. No. 4,401,124; U.S. Pat. Nos. 4,265,251; 4,466,442; and 4,718,433.

[0152] In various alternatives, the echogenic material may either be applied to a portion of or a component of a device in any of a number of different techniques.

[0153] In one example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as a selective coating applied to a portion or component of a device.

[0154] In one example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as a mold formed to be placed over or joined to a portion of component of a device.

[0155] In one example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as an extruded sleeve or cover formed in a continuous segment to cover a portion or component of a device. In one embodiment, one of the inner tubular member or the outer sleeve or coating may be fabricated of a material according to the present invention, having increased echogenicity, with the other of the inner tubular member fabricated of a biocompatible polymer such as polyurethane or silicone rubber, for example.

[0156] In one example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as a compound or two layer structure comprising an inner tube and an outer tube or sleeve or covering with one or both of the tubes made from or including or incorporating one or more echogenic materials or modifications as described herein. In addition or alternatively one or both sleeves, tubes described herein may include or encapsulate an echogenic marker or component of specific shape or geometry, for example, as in the case of a tube structure having within the sidewall of the tubing a coiled structure. In one aspect, the coiled structure is made from an echogenic material and the windings are provided in a manner that is useful in any of the aspects of the device described herein. The coil may have a particular size or variation in size, pitch or variation in pitch or other attribute useful in providing an echo identifiable aspect of the device property being determined. In one specific embodiment, the dimensions of the coil or other echogenic material has dimensions selected for increasing acoustic reflection with regard to the resolution or processing algorithms used in the imaging ultrasound system.

[0157] In one example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as a braided structure incorporated into a compound or two layer structure comprising an inner tube and an outer tube

or sleeve with one or both of the tubes made from or including or incorporating one or more braid comprising echogenic materials or modifications as described herein. In addition or alternatively one or both sleeves, tubes described herein may include or encapsulate an braid formed into an echogenic marker or component of specific shape or geometry, for example, as in the case of a tube structure having within the sidewall of the tubing a braided structure. In one aspect, the braided structure is made from an echogenic material and the braided is a small diameter that is when wound around the tubes or sleeve or directly onto a portion of or component of a device. The winding pattern and spacing of the braided materials are provided in a manner that is useful in any of the aspects of the device described herein. The braid may have a particular braid strand composition, structure, size or variation in size, pitch or variation in pitch or other attribute useful in providing an echo identifiable aspect of the device property being determined. One or more of the strands in the braid may be formed from an echogenic material. One or more of the strands may be formed from a material having improved radiopaque characteristic. One or more of the strands may be formed from a material having both echogenic and radiopaque properties. The strands of a braid may be combined using any of the above described strand characteristics.

[0158] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as the a series of short segments placed adjacent to one another along a portion or component of a device in either a close packed or spaced arrangement. In another embodiment, the spacing or voids between adjacent segments may also be adjusted or selected so as to enhance echogenic capabilities of the device using the material difference introduced by the spacings or voids.

[0159] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a device or portion of a device as a tubing or sleeve or covering suited to heat shrink operations. In one aspect, there is a manufacturing or assembly steps of sliding one or more sleeves or coverings over portion of the device then apply heat to shrink down the segment about the portion of the device. In particular, various embodiments provide for the specific placement of such a shrink fit tubing or covering having enhanced echogenic characteristics as described herein.

[0160] It is to be appreciated that the sleeves, segments, coverings or tubes may be provided from or have echogenic modifications or elements incorporated into suitable materials such as, for example, ePTFE, PTFE, PET, PVDF, PFA, FEP and other suitable polymers. Still further, these and other materials may be formed in shapes other than tubes but may also take the form of strands, lines, fibers and filaments to be applied in accordance with the echogenic enhancement techniques described herein. In some embodiments, the tubes, coverings or segments applied to a device may have the same or different composition as well as have the same width or different widths. In one aspect, the width or thickness of a plurality of bands is used to provide a code or information about the device. The use of echogenic bands of different widths is a marking technique similar to the way that different size and color rings on a resistor are arranged in a pattern to describe the resistor's value.

[0161] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a device or portion of a device is extruded over a portion of or a component of the device.

[0162] In another alternative, in still another example, an echogenic component or additive is applied to or incorporated into a device or portion of a device is by bonding an echogenic material or components to the device using a suitable adhesive or bonding technique.

[0163] In any of the above described configurations, the portion or component of the device may be modified with dimples, grooves, pockets, voids. In other aspects, there may be one or more full or partial circumferential recesses, rings, surface diffraction gratings or other surface features to selectively enhance or provide an echogenic property in that portion of the device, to aid in or foster the application of the echogenic materials. In still further aspects, any of above described surface modifications may also be used to uniquely identify a portion of a device or any of the above in any combination.

[0164] In still further aspects of any of the above echogenic markers or attributes the thickness of the sleeve or coating or component may decrease at its proximal and distal ends to provide for a smooth outer surface. As yet an additional alternative, a coating, marker or other echogenic material may extend proximally to or closely adjacent to the distal end or the distal end or both of the device or component thereof.

[0165] In still other alternatives or combinations, some device design embodiments alter components of the device to enhance echogenicity such as, for example, material selection to incorporate echogenic materials. Examples of echogenic materials include palladium, palladium-iridium or other alloys of echogenic materials.

[0166] In some embodiments, echogenic microbubbles are provided in a portion of a device to enhance the acoustic reflections of that aspect of the device. Echogenic microbubbles may be prepared by any convenient means and introduced into the component or portion thereof or by a coating, sleeve, shell, covering or other transferring means or mixed with a polymer or other suitable base compound prior to extension of extrusion, molding casting or other technique. The echogenic microbubbles may be pre-prepared or prepared inside the component or element or marker as appropriate. Aspects of the preparation or use of microbubbles are described in U.S. Pat. Nos. 5,327,891; 4,265,251; 4,442,843; 4,466,442; 4,276,885; 4,572,203; 4,718,433 and 4,442,843. By way of example, echogenic microbubbles can be obtained by introducing a gas, e.g. carbon dioxide, into a viscous sugar solution at a temperature above the crystallization temperature of the sugar, followed by cooling and entrapment of the gas in the sugar crystals. Microbubbles can be formed in gelatin and introduced into a component or portion of a device. Microbubbles can also be produced by mixing a surfactant, viscous liquid and gas bubbles or gas forming compound, e.g. carbonic acid salt, under conditions where microbubbles are formed.

[0167] In still further alternatives, there is also the incorporation of dual mode materials (radiopaque and echogenic) into a polymer then used to form part of, be applied or otherwise incorporated with a device device as described herein. Some of these polymer compounds may be fabricated to enhance aging and shelf life and have other beneficial attributes. In one aspect, a device or portion thereof includes one or more selected segments that are constructed using visibility materials compounded with one or more polymeric materials that make the selected segments visible using both fluoroscopy and ultrasonic imaging. In one specific example, the visibility material may take the form of tungsten and/or

tungsten carbide particles dispersed within a polymeric material. In one specific aspect, the radiopaque and echogenic material includes tungsten and/or tungsten carbide particles distributed within a base polymeric material.

[0168] In one embodiment, a portion of or a component of a device includes or has been modified to have an inner layer including a radiopaque and echogenic material. In one alternative, the radiopaque and echogenic material includes particles distributed within a base polymeric material (i.e., a first polymeric material) including a polyether block amide; and an outer layer including an additional polymeric material (i.e., a second polymeric material). In certain embodiments, the additional polymeric material is a thermoplastic elastomer. Optionally, the additional polymeric material is more resistant to hydrolysis and/or oxidation than the base polymeric material.

[0169] In still further aspects, a component, a portion or an element added to a device may be regarded as an echogenic body member that is a part of an echogenic device to be sonically imaged. The echogenic body member is at least partially made up of a composite material which is echogenically imageable in the patient, such as by the use of ultrasonic imaging equipment used either within the patient or external to the patient. In one aspect, a composite material includes matrix material with discrete acoustic reflective particles embedded in matrix material. In one aspect, the matrix material is a biocompatible plastic. Examples of suitable plastics may include urethane, ethylene, silicone, polyethylene, tetrafluoroethylene. In one aspect, a matrix is a formable, pliable material which may be molded and/or extruded to a variety of shapes, depending upon a specific application. The sound reflective particles are embedded in matrix material. Particles are, by way of example, made of a hard material, such as small glass particles that are solid or filled with an acoustically reflective medium. In one aspect, glass particles having a generally spherical shape forming glass microspheres. Glass microspheres with an outer diameter of about 5 microns is one acceptable size. Other sized particles may be utilized as, for example, ranging between 1 and 50 microns and beyond. Particles sized below the resolution size of the imaging ultrasound system in use may be arranged into patterns of sufficient size and orientation to the acoustic waves that result in a discernible feature by the imaging ultrasound system. Furthermore, the particles do not necessarily have to be spherical, or may be partially spherical. Still further, the shape of the particle could be altered to enhance acoustic reflection by presenting different shapes of particles, sizes of particles and combinations thereof to modify acoustic characteristics of the matrix material. By way of example, the particles may be shaped into an "Ordered array." "Ordered arrays" can take the form of a macrostructure from individual parts that may be patterned or unpatterned in the form of spheres, colloids, beads, ovals, squares, rectangles, fibers, wires, rods, shells, thin films, or planar surface. In contrast, a "disordered array" lacks substantial macrostructure.

[0170] By way of example, an echogenic marker may comprise particles that individually are below the resolution of the imaging ultrasound system. The echogenic marker is the combination of these below imaging ultrasound resolution particles in combination, in 1D, 2D or 3D patterns, in graphic arrays, or in machine readable combinations to make a signature. Based on the specific characteristics of the combination of particles, the acoustic returns from an echogenic marker or combination of echogenic markers may be visually

perceptible in a display for interpretation by a user or may be detected and interpreted by one or more acoustic reflection or spectral processing algorithms within a imaging ultrasound processing system.

[0171] In one aspect, the echogenic material is fabricated by incorporating nanometer sized particles of sonically reflective materials, for example iron oxide, titanium oxide or zinc oxide into a biocompatible polymer. In one method of fabrication, the acoustically reflective particles are mixed with a powdered thermoplastic or thermosetting material such as a polyether amide, a polyurethane or an epoxy, or polyvinylchloride followed by thermal processing of the mixture to provide a material of increased sonic reflectance which may be applied as a coating on medical devices of the type discussed above or may be incorporated as a structural component of the medical devices as described herein.

[0172] In still further embodiments and aspects, the particles included to provide echogenic enhancements may be selected, arranged or incorporated to provide acoustically geometrically tuned nanostructures, microstructures or macrostructures. The particles provided herein are formable in all shapes currently known or to be created for acoustic reflection enhancement. In non-limiting examples, the nano-, micro- or macro-particles are shaped as spheres, ovals, cylinders, squares, rectangles, rods, stars, tubes, pyramids, stars, prisms, triangles, branches, plates or comprised of an acoustically reflective surface or where one or more surfaces is adapted such as by roughening or dimpling or other technique used to alter acoustic reflection properties. In non-limiting examples, the particles comprise shapes and properties such as plates, solid shells, hollow shells, rods, rice shaped, spheres, fibers, wires, pyramids, prisms, or a combination thereof.

[0173] In one specific aspect, a partially spherical surface may be provided on the outside and/or the inside of particles, as for example a particle with a hollow spherical space therein. Particles are made up of a different material than the matrix. While desiring not to be bound by theory, it is believed that a spherical shape provides for sound reflections at a variety of angles regardless of the direction from which the ultrasonic sound waves are emanating from, and accordingly, are more likely to reflect at least a portion of the transmitted signal back to the ultrasonic receiver to generate an image. Since many of matrix materials available are relatively ultrasonically transparent in a patient, sound reflective particles provide adequate reflection. The use of a composite, rather than a solution, provides adequate size for acoustic reflection off of the discrete particles embedded in the matrix. As indicated, a variety of materials may be utilized for the sound reflective particles, such as aluminum, hard plastic ceramics, and metal and/or metal alloys particles, and the like. Additionally, liquids, gases, gels, microencapsulants, and/or suspensions in the matrix may alternatively be used either alone or in combination, so long as they form a composite with the desired ultrasonically reflective characteristic.

[0174] Any of the above embodiments, alternatives or device modifications to enhance echogenic characteristics may also be designed or implemented in such a way as to provide an echogenic identifiable or unique trait or acoustic reflection signature that may be registered by a human operator looking at a display or identified using signal processing techniques of a return containing acoustic reflections from the device in an imaging ultrasound system. In one example, there is a surface of the device having one or more echo registerable or identifiable feature, mark or indication in a

position useful for determining one or more of: a location of an end of a device; a location of a fixation element on a device; a location of a retrieval feature on a device; an orientation of one or more of a leg, a strut, a filter or an end of a filter relative to another of a leg, a strut, a filter or an end or the orientation of the overall filter to a lumen, vessel or hollow organ in a body. Moreover, in another widely applicable aspect of providing enhanced imaging characteristics to a device as described herein, the characteristic or modification—however added or incorporated into the device—enable a device, a device component or a specified portion of a device to be more readily imaged by intravascular ultrasound as described herein. In still another aspect, the characteristics or modification to the device are oriented and positioned in order to facilitate IVUS imaging via an IVUS probe borne by a filter deployment or retrieval catheter, snare, or other implement provided to facilitate the use of intravascular filters.

[0175] FIG. 26 is a section view of a wire strut or support element of a device (w/s/s) having multiple segments in a concentric arrangement. In this illustrative embodiment, the wire is encased in alternating tube segments. There is an inner tube (IT) directly adjacent to the wire. There is an echogenic segment layer (EL) adjacent to the inner layer. The inner tube may be selected to act as bonding layer to increase adhesion between the echogenic layer and the device wire, strut or support member. In this embodiment, there is an outer tube (OT) over the echogenic layer. In alternative configurations, either or both of the inner tube or the outer tube may be omitted. The echogenic layer is a segment having one or more of the echogenic characteristics described herein.

[0176] FIGS. 27-32 provide various exemplary embodiments of a segment 87 having one or a plurality of one or more than one type of echogenic characteristic, property or feature added thereto. Each of the illustrated echogenic adaptations applied to segment 87 along with segment 87 itself may be sized, scaled and/or shaped as described herein as needed based upon the requirements of the portion of the device and the echogenic characteristic.

[0177] FIG. 27 is an embodiment of a segment 87 having one or a plurality of laser drilled holes 88 formed therein. The diameter and the shape of the holes may be selected based upon the size of the device or device component to which the segment 87 will be attached. The holes 88 may be completely through the wall of the segment or only partially through the wall. The holes 88 may be formed in any pattern, spacing or orientation as described herein.

[0178] FIG. 28 is an embodiment of a segment 87 having one or a plurality of raised features or alternatively roughed portions 89 formed thereon. The size and shape of the raised features or the roughness of the surface may be selected based upon the size of the device or device component to which the segment 87 will be attached. The raised features or portions of roughness 89 may be formed in any pattern, spacing or orientation as described herein.

[0179] FIG. 29 is an embodiment of a segment 87 having one or a plurality of bubbles 90 formed therein. The size, shape, pattern, and manner of incorporating one bubble 90 or a plurality of bubbles 90 into the segment 87 may be selected based upon the size of the device or device component to which the segment 87 will be attached. The bubbles 90 may be formed within the segment sidewall, near the surface of the segment sidewall or near the inner surface of the sidewall. The bubble or bubbles 90 may be formed in any pattern, spacing or orientation as described herein.

[0180] FIG. 30 is an embodiment of a segment 87 having one or a plurality of dimples 91 formed therein. The diameter and the shape of the dimples may be selected based upon the size of the device or device component to which the segment 87 will be attached. The dimples 91 may be formed in any pattern, spacing or orientation as described herein.

[0181] FIG. 31 is an embodiment of a segment 87 having a coil or braided structure 92 within or about the segment 87. The size, shape, pattern, and manner of incorporating the coil or braid 92 into the segment 87 may be selected based upon the size of the device or device component to which the segment 87 will be attached. The coil or braid 92 may be formed within the segment sidewall, near the surface of the segment sidewall or near the inner surface of the sidewall. The coil or braid 92 may be part of a sandwich structure as illustrated and described in FIG. A. The coil or braid 92 may be formed in any pattern, spacing or orientation as described herein to enhance the echogenic characteristics of the device or device portion attached to the segment 87. The coil or braid 92 may be continuous along the entire length of a segment 87 or, alternatively, the coil or braid 92 may be in short lengths selected so that a plurality of coils or braids are provided within a single segment 87.

[0182] FIG. 32 is an embodiment of a segment 87 having a plurality of echogenic markers 93 arrayed in rings 93.1, 93.2 and 93.3. For purposes of illustration the rings are shown in an orientation that is generally orthogonal to the central longitudinal axis of the segment 87. The rings are shown with a sample spacing of 1 cm between them. The spacing may be any suitable distance based on the factors described herein such as device size and physiological environment. Similarly, the rings may be angled in other orientations relative to the longitudinal axis of the segment. For example, some ring may be in one angular orientation while other rings may be in a different angular orientation where the angular orientation or patent of orientation is utilized to provide one or more of the device functionality or echogenic characteristics described herein. In some specific configurations, the spacing and sizes used are in the millimeter range. In some specific configurations, the spacing and sizes are in the micron range. In some specific configurations, the size and/or spacing of a ring or between adjacent rings are in a combination of mm and micron ranges for sizes, spacings and features. The size and spacing of the echogenic markers 93 may be selected based upon the size of the device or device component to which the segment 87 will be attached. The markers 93 may be formed in any pattern, spacing or orientation as described herein in order to facilitate a measurement using the markers. Still further, the markers 93.1, 93.2 and 93.3 may be utilized for provide for other device characteristics as described herein.

[0183] FIG. 33 illustrates various alternative configurations for a segment used alone or in conjunction with other segments. The segments are illustrated along an exemplary wire, strut, or component of a filtering device. The segments may have different characteristics to enable the segment to be more readily imaged by a medical imaging modality used externally, internally or intraluminally. In one aspect, the segment characteristics are selected to provide for imaging enhancements for a device being used within a vein or an artery. In another aspect, the segments may have different characteristics to enable the segment to be readily imaged by intravascular ultrasound as described herein. In still another aspect, the segments are oriented and positioned in order to facilitate IVUS imaging via an IVUS probe borne by a filter

deployment or retrieval catheter, snare, or other implement. In one illustrative embodiment, the segments are selected and arrayed to facilitate imaging utilizing IVUS and an external medical imaging modality. In one exemplary embodiment, the external imaging modality is x-ray.

[0184] Also illustrated in FIG. 33 is the use of a combination of different echogenic characteristics (designated E) and radio-opaque characteristics (designated RO). These characteristics may be any of those described herein in any combination. The echogenic characteristic of a segment may be the same as another segment in a grouping such as in the E segments 87.9 and 87.5. Alternatively, the echogenic characteristic of a segment may be different from those in an adjacent group as with segments 87.2, 87.5 and 87.7.

[0185] FIG. 33 also illustrates not only that different characteristic and properties of segments may be used but also how variable segment dimensions may be used to aid in echogenic enhancement of a device. As illustrated, the segments have different widths or thicknesses as indicated along the longitudinal axis of the wire, strut or component. As such, FIG. 33 illustrates a series of imagine enhancing segments 87.1-87.10 having a variety of width or thickness values t1-t10. In one embodiment, the segments are configured as short rings or bands. The thickness of segments in groups may be similar as illustrated in segments 87.1, 87.2 and 87.3 where the thicknesses t1, t2 and t3 are about the same. Similarly, segments 87.4, 87.5 and 87.6 illustrate segments of similar width or thickness where t4, t5 and t6 are about the same value. Similarly, segments 87.8, 87.9 and 87.10 illustrate segments of similar width or thickness where t8, t9 and t10 are about the same value.

[0186] FIG. 33 also illustrates how segments within a group or groups of segments may have a variety of different spacing (s1-s6) to provide enhancements to a device for improving medical imaging modality characteristics. For example, in the segment grouping of 87.1, 87.2 and 87.3, there is a spacing s1 between segment 87.1 and segment 87.2 but then no spacing between segments 87.2 and 87.3. A spacing s2 is shown between segment 87.3 but then no spacing in the combination segment grouping formed by segments 87.4, 87.5 and 87.6. A spacing of s3 is shown between the three segment combination of 87.4, 87.5 and 87.6 to the single segment 87.7. The single segment 87.7 is spaced apart by spacing s4 from the equally sized (i.e., t8=t9=t10) and equally spaced (i.e., s5=s6) group of segments 87.8, 87.9 and 87.10. It is to be appreciated that in various alternative embodiments, the spacing used in groups of segments or between groups of segments may be the same or variable.

[0187] FIG. 34 is a view of an exemplary device illustrating various alternative aspects of providing a device with improved echogenic characteristics. The device illustrated is a conical filter. It is to be appreciated that the device of FIG. 34 is merely representative of one type of device. It is to be appreciated that the various alternative enhancement, modifications and treatments described herein may be provided to any intravascular or intraluminal device. The exemplary device is dividing into three general sections A, B and C. Sections A, B and C may be the same type of enhancement or have an enhancement different from one another section. In addition, the type of enhancement in each section may be the same or different from one another in detection, response or appearance under ultrasound. In addition, a tag, feature or enhancement may be different within a section. Circles 3402 are used to indicate exemplary locations for an echogenic

feature, tag, marker or modification to an enhanced filter 10. The illustrative embodiment in FIG. 34 also illustrates a continuous echogenic layer, feature or modification or treatment 3408. The illustrative embodiment in FIG. 34 also illustrates an echogenic attribute on/near an inflection point 3406 in an enhanced filter structure 10. The illustrative embodiment in FIG. 34 also illustrates a segmented echogenic layer, feature or modification or treatment 3404 on an enhanced filter structure 10. Section A is considered the apex, tip, distal portion or terminal end depending upon device configuration. Section B is considered the mid-strut, middle, filtration portion, debris capture portion, or thrombus collection or lysing portion depending upon specific device configuration. Section C is considered the rear portion, proximal portion, proximal terminal portion, anchor, fixation or perforation portion depending upon a specific device configuration. It is to be appreciated as well that the echogenic features, tags, markers or modifications illustrated for sections A, B and/or C may be of the same type or different types depending upon the echogenic signature or attribute intended for that section, group or sections or device. As such, the echogenic features, tags, markers or modifications for a particular section may be selected from any of the various alternatives described herein.

[0188] Echogenic characteristics may be added to each of the sections based on the type of function being measured or characterized. For example, echogenic markers, features or tags may be added to Section A in order to provide, for example: identification of the terminal end, end portion or retrieval portion of a device. Echogenic characteristics of Section A may also be used for determinations related to Section A specifically or the device generally of device position, positioning, attitude within the lumen, localization of the device within the vasculature and other traits common to the characterization of intravascular devices. For example, echogenic markers, features or tags may be added to Section B in order to provide, for example: identification of the mid strut portion, middle or capture region. Echogenic characteristics of Section B may also be used for determinations related to Section B such as for sizing, centering, symmetry of implantation, placement, apposition of implant to vessel walls, clot burden, deployment status or completion, gauge of filter capacity and/or filter contents as well as filter position, positioning, attitude within the lumen, localization of the device within the vasculature and other traits common to the characterization of intravascular devices. For example, echogenic markers, features or tags may be added to Section C in order to provide, for example: identification of the rear portion, terminal end, retrieval feature, anchor location or depth of insertion, perforation indication or other aspects of the rear or proximal portion of a device. Echogenic characteristics of Section C may also be used for determinations related to Section C such as for sizing, centering, symmetry of implantation or placement of legs struts and the like, as well as for determination of wall apposition, anchor penetration or perforation. Still further, the markers or tags may be added to aid in determining or evaluating device position, positioning, attitude within the lumen, localization of the device within the vasculature and other traits common to the characterization of intravascular devices.

[0189] A filter having enhanced echogenic properties is illustrated in FIG. 34 as it appears when it is in operative position within the vasculature. In one specific aspect the filter is in use in a large blood vessel. One exemplary vessel is the vena cava. Still further, a modified filter may be employed

in a different vein or even an artery. The filter is designated generally by reference numeral **10**, and the wall of the blood vessel in which it is located is designated by reference numeral **12**. The filter **10** includes an apical hub **14** of overall egg-shaped or tear drop configuration and which has a generally hemispherically shaped end portion **14a**.

[0190] The filter **10** includes a plurality of elongated legs **16** which are of equal length and are identically configured to each other. The legs **16** are collectively arrayed in a conical geometric configuration so that the legs converge to the apical hub **14**, and are symmetrically spaced about a central axis extending through the hub. Each of the legs is of equal diameter over its entire length and is made of a relatively resilient material, such as tempered stainless steel wire or the like. In addition to the echogenic attributes described herein, the legs may be coated with a polymeric, synthetic resin material having anti-thrombogenic properties. FIG. **34** illustrates an echogenic marker at the tip **14**. Exemplary continuous echogenic layers, features or modifications are also illustrated along one or more legs of the filter. In addition, FIG. **34** illustrates the use of echogenic tags, features or markers at, along or near inflection points in a filter element or component. In addition, FIG. **34** illustrates to application of echogenic markers, tags or features near the fixation elements of the filter.

[0191] In still other alternative embodiments, the device may have a covering. The covering may be comprised of any biocompatible material, such as polyethylene terephthalate, polyester, cotton, polyurethane, expanded polytetrafluoroethylene (ePTFE), silicon, or various polymers or fibers and have any suitable form, such as a fabric, mesh, textured weave, felt, looped or porous structure. The covering may alternatively be comprised of a polymer or other suitable materials dipped, sprayed, coated or otherwise adhered to the surfaces of the device. Optionally, the polymer coating may include pores or contours to assist in grasping the tissue and/or to promote tissue ingrowth.

[0192] In addition, in some embodiments, the textures, mesh, contours and/or porous structure may provide enhanced echogenicity for IVUS imaging. For example, the covering can be roughened to enhance its echogenicity. Alternatively, the covering can incorporate pores or microbubbles to enhance its echogenicity. The echogenic materials and/or features can be incorporated throughout the covering or underlying structural components or at discrete locations on the covering or underlying structural components as more fully described below.

[0193] In still other alternative embodiments, there is provided a material capture structure having one or more echogenic enhancements alone or in combination with radiopaque enhancements. In one aspect, the filter structure used in a filter includes both echogenic and radio opaque enhancements.

[0194] An one aspect, the filter includes material capture structure in the IVC filter will be viewable under fluoroscopic and ultrasound imaging modalities, including appropriate echogenic characteristics to enhance the view of the status or condition of the material capture structure while using IVUS. Enabling the material capture structure to be viewed will allow the physician to appropriately center and verify placement of a filter.

[0195] In one aspect, the device elements or structures are doped to incorporate one or more of echogenic or radio opaque materials or treatments. In one aspect, the membrane, filaments or strands or other structures used to form the filter

structure or webbing of the filter includes a radiopaque material having high echogenic properties, such as tungsten or gold, but not limited to either.

[0196] In other embodiments, one or more membranes, filaments or portions of a filament within a material capture structure includes one or more non-metallic echogenic features, such as those described elsewhere in this specification. For example, a membrane or filament or portion thereof may include air pockets either added to the material or by the use of materials with entrained air or gas that are used. Another example may include a membrane with a plurality of holes. In one embodiment, an ePTFE suture has echogenic properties due to air content of the ePTFE material. In other aspects, a suture material or a filament or polymer strand may also include dimpled/roughened/matrix/sponge materials, additives, or modifications to provide or enhance the overall echogenic nature of the suture, filament, material or material capture structure, in whole or in part.

[0197] In one aspect, these additional materials may assist the physician in centering or placing a device within a vessel. In another aspect, this improvement is used in conjunction with IVUS will enable the adequate viewing of the filter portion of the device and will allow for co-registration of filter placement along with an accurate entry/removal of the catheter through the webbing of the filter.

[0198] The advantages of this inventive aspect of a device include, for example and not limitation, device placement, accurate representation of device location, ease of introducing/retracting catheter, more viewable space for more accurate assessments, ability to co-register device location with IVUS and/or ability to better place device in desired location.

[0199] Still other aspects of the use of the innovative device include, for example, deployment of filters, positioning of devices, including filters, sizing of devices, including filters, and estimated treatment lengths as well as suture and/or material capture structure visibility. In still other aspects of the use of the innovative device include, for example, deployment of a vena cava filter, positioning of an IVC filter, sizing of an IVC filter, and estimated treatment lengths as well as enhanced suture visibility.

[0200] In one embodiment, there is an IVC filter delivery system with an enclosed IVC filter. This filter would have a mesh, suture, web or other material capture structure suited to the anticipated device use. The mesh, suture, web or other material capture structure has one or more components that is doped with a highly radiopaque material for better visibility under fluoro and good echogenicity for better viewing under IVUS guidance. In still further alternative embodiments, the techniques described above may be applied to one or more material capture structure described in U.S. Patent Application Publication US 2008/0147111 entitled "Endoluminal Filter with Fixation" filed Jun. 4, 2008 as U.S. patent application Ser. No. 11/969,827, (the "7111 publication") incorporated herein by reference in its entirety for all purposes. In one particular aspect, the filament/strand/suture **461** shown in FIG. 58 of the '7111 publication may be coated or doped as described above alone or in combination with the illustrated pharmacological coating **466**.

[0201] Variations and modifications of the devices and methods disclosed herein will be readily apparent to persons skilled in the art. As such, it should be understood that the foregoing detailed description and the accompanying illustrations, are made for purposes of clarity and understanding, and are not intended to limit the scope of the invention, which is defined by the claims appended hereto. Any feature described in any one embodiment described herein can be combined with any other feature of any of the other embodiment whether preferred or not.

[0202] It is understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims. All publications, patents, and patent applications cited herein are hereby incorporated by reference for all purposes.

[0203] In addition, visual markings can also be added to the device in place or in addition to the echogenic markings in order to facilitate use with an OCT imaging system. The visual markings can be discrete and distinct patterns, each of which can be different from each other, so that the visual markings correspond to particular predetermined portions of the device.

[0204] Variations and modifications of the devices and methods disclosed herein will be readily apparent to persons skilled in the art. As such, it should be understood that the foregoing detailed description and the accompanying illustrations, are made for purposes of clarity and understanding, and are not intended to limit the scope of the invention, which is defined by the claims appended hereto. Any feature described in any one embodiment described herein can be combined with any other feature of any of the other embodiment whether preferred or not.

[0205] It is understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims. All publications, patents, and patent applications cited herein are hereby incorporated by reference for all purposes.

What is claimed is:

1. A system for providing embolic protection, the system comprising:

an embolic protection device comprising:

- a guidewire having a proximal end, a distal end, and a first pressure sensor located near the distal end of the guidewire;
- a first sheath having a proximal end, a distal end and a lumen, the lumen configured to receive the guidewire;
- a first distal protection filter attached to a distal portion of the first sheath;
- a second sheath having a proximal end, a distal end and a lumen, the second sheath disposed over the first sheath, wherein the distal end of the second sheath is located proximally the first distal protection filter;
- a second distal protection filter attached to a distal portion of the second sheath;
- an outer sheath disposed over both the first sheath and the second sheath; and
- an intravascular ultrasound transducer disposed at the distal end of one of the first sheath, second sheath, or outer sheath;

a user interface configured to receive input from an operator regarding a surgical procedure including an insertion site and a destination site;

a display;

a processor programmed to:

- receive input from the user interface regarding the surgical procedure;
- determine anatomical landmarks between the insertion site and the destination site;

- receive an intravascular ultrasound signal from the intravascular ultrasound transducer;
- process the intravascular ultrasound signal into an image; and
- send the image to the display.

2. The system of claim 1, wherein the processor is further programmed to:

- identify any anatomical landmarks in the image; and
- tag the anatomical landmarks in the displayed image.

3. The system of claim 2, wherein the processor is further programmed to:

- determine a location of the embolic protection device based on the identified anatomical landmarks in the image.

4. The system of claim 3, wherein the processor is further programmed to:

- determine whether the location is the destination site.

5. The system of claim 4, wherein the processor is further programmed to:

- send a visual indicator to the display when the location has been determined to be the destination site.

6. The system of claim 5, wherein the visual indicator is color coded.

7. The system of claim 1, wherein the processor is further programmed to:

- determine an orientation of the embolic protection device with respect to anatomical landmarks using the processed intravascular ultrasound imaging signal.

8. The system of claim 1, wherein the processor is further programmed to:

- generate instructions for adjusting the position of the embolic protection device based on the determined orientation of the embolic protection device.

9. A system for providing embolic protection, the system comprising:

an embolic protection device comprising:

- a first elongate member having a proximal end and a distal end;
- a first distal protection filter attached to a distal portion of the first elongate member;
- a first sheath having a proximal end, a distal end and a lumen, the first sheath disposed over the first elongate member, wherein the distal end of the first sheath is located proximally the first distal protection filter;
- a second distal protection filter attached to a distal portion of the first sheath; and

an outer sheath disposed over both the first elongate member and the first sheath, the distal portion of the outer sheath comprising a rapid exchange guidewire lumen.

an intravascular ultrasound transducer disposed at the distal end of one of the first sheath or outer sheath;

a user interface configured to receive input from an operator regarding a surgical procedure including an insertion site and a destination site;

a display;

a processor programmed to:

- receive input from the user interface regarding the surgical procedure;
- determine anatomical landmarks between the insertion site and the destination site;
- receive an intravascular ultrasound signal from the intravascular ultrasound transducer;
- process the intravascular ultrasound signal into an image; and
- send the image to the display.

10. The system of claim 9, wherein the processor is further programmed to:

identify any anatomical landmarks in the image; and
tag the anatomical landmarks in the displayed image.

11. The system of claim 10, wherein the processor is further programmed to:

determine a location of the embolic protection device
based on the identified anatomical landmarks in the
image.

12. The system of claim 11, wherein the processor is further programmed to:

determine whether the location is the destination site.

13. The system of claim 12, wherein the processor is further programmed to:

send a visual indicator to the display when the location has
been determined to be the destination site.

14. The system of claim 13, wherein the visual indicator is
color coded.

15. The system of claim 9, wherein the processor is further
programmed to:

determine an orientation of the embolic protection device
with respect to anatomical landmarks using the pro-
cessed intravascular ultrasound imaging signal.

16. The system of claim 9, wherein the processor is further
programmed to:

generate instructions for adjusting the position of the
embolic protection device based on the determined ori-
entation of the embolic protection device.

17. A system for providing embolic protection, the system
comprising:

an embolic protection device comprising:

a guidewire having a proximal end, and a distal end;

a first sheath having a proximal end, a distal end and a
lumen, the lumen configured to receive the guidewire;
a first distal protection filter attached to a distal portion
of the first sheath;

a second sheath having a proximal end, a distal end and
a lumen, the second sheath disposed over the first
sheath, wherein the distal end of the second sheath is
located proximally the first distal protection filter;

a second distal protection filter attached to a distal por-
tion of the second sheath;

an outer sheath disposed over both the first sheath and
the second sheath; and

an intravascular ultrasound transducer disposed on an
atraumatic tip, the atraumatic tip extending from the
distal end of the first sheath.

a user interface configured to receive input from an opera-
tor regarding a surgical procedure including an insertion
site and a destination site;

a display;

a processor programmed to:

receive input from the user interface regarding the sur-
gical procedure;

determine anatomical landmarks between the insertion
site and the destination site;

receive an intravascular ultrasound signal from the intra-
vascular ultrasound transducer;

process the intravascular ultrasound signal into an
image; and

send the image to the display.

* * * * *

专利名称(译)	具有压力和超声功能的远端保护系统和方法		
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申请(专利权)人(译)	CRUX生物医学, INC.		
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优先权	62/052408 2014-09-18 US PCT/US2014/030240 2014-03-17 WO 61/794222 2013-03-15 US		
其他公开文献	US9986967		
外部链接	Espacenet USPTO		

摘要(译)

本发明的实施例总体上涉及用于通过过滤由医疗过程产生的碎屑来为医疗过程提供栓塞保护的系统和方法。该系统和方法包括具有超声换能器的栓塞防护装置, 用于辅助装置的血管内导航。

