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(54) **ENDOVASCULAR ANEURYSM DEVICES, SYSTEMS, AND METHODS**

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Continuation-in-part of application No. 10/786,465, filed on Feb. 25, 2004.  
Continuation-in-part of application No. 10/693,255, filed on Oct. 24, 2003, now Pat. No. 6,929,661.  
Continuation-in-part of application No. 10/307,226, filed on Nov. 29, 2002.

Continuation-in-part of application No. 11/166,411, filed on Jun. 24, 2005, which is a division of application No. 10/271,334, filed on Oct. 15, 2002, now Pat. No. 6,960,217.

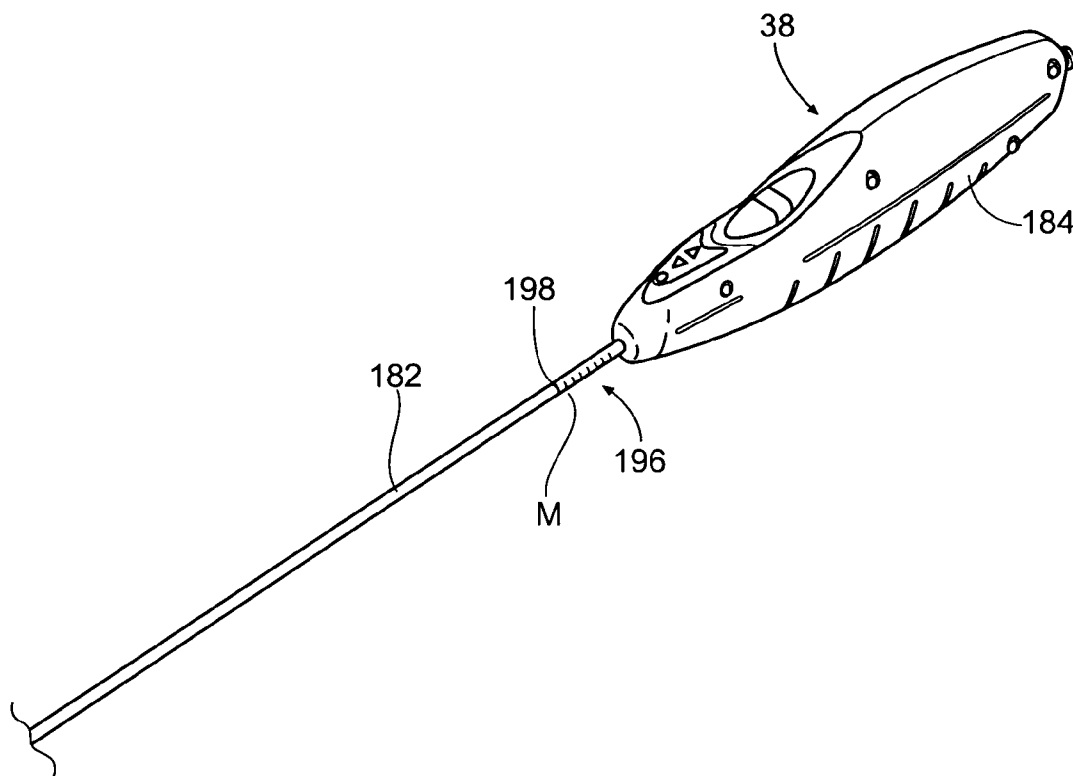
(60) Provisional application No. 60/488,753, filed on Jul. 21, 2003. Provisional application No. 60/489,011, filed on Jul. 21, 2003. Provisional application No. 60/333,937, filed on Nov. 28, 2001.

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(52) **U.S. Cl.** ..... **623/1.36; 623/1.11**

(57) **ABSTRACT**

Devices, systems, and methods for implanting prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least one prosthesis end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumferentially spaced-apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions.



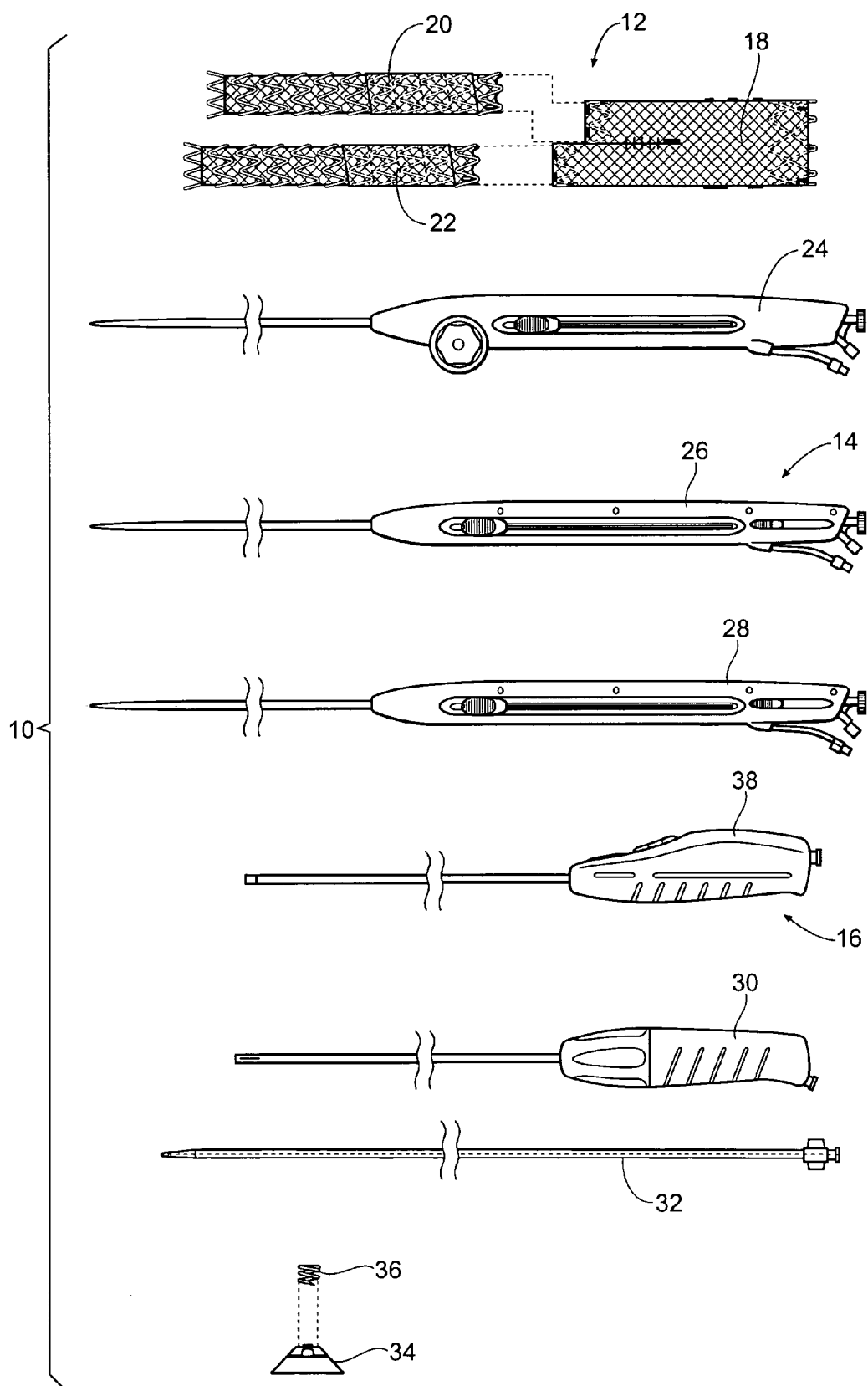


Fig. 1

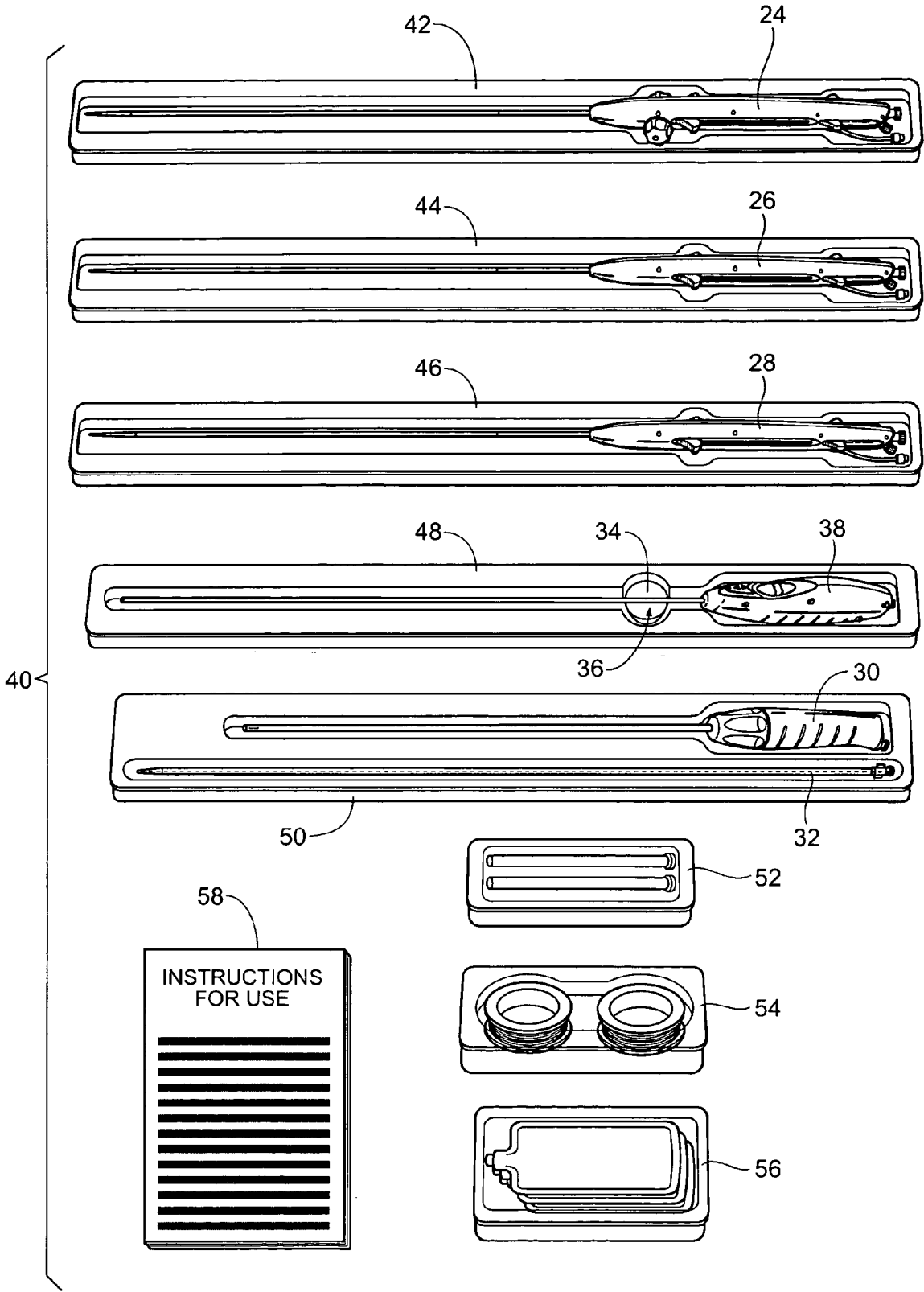


Fig. 2

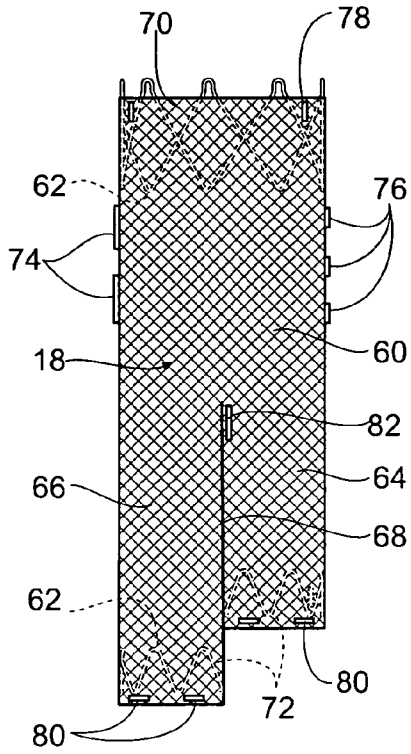


Fig. 3A

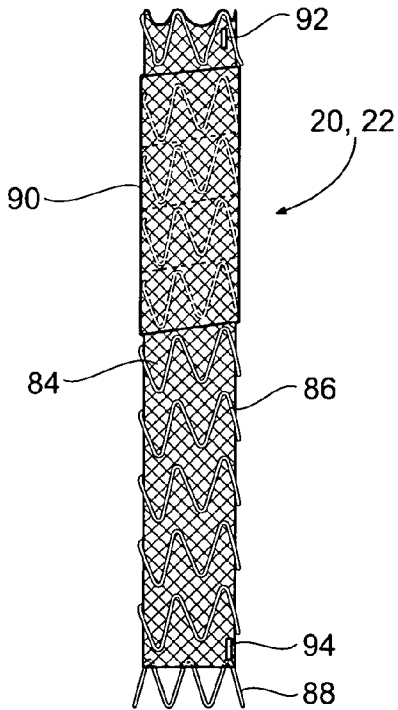


Fig. 3B

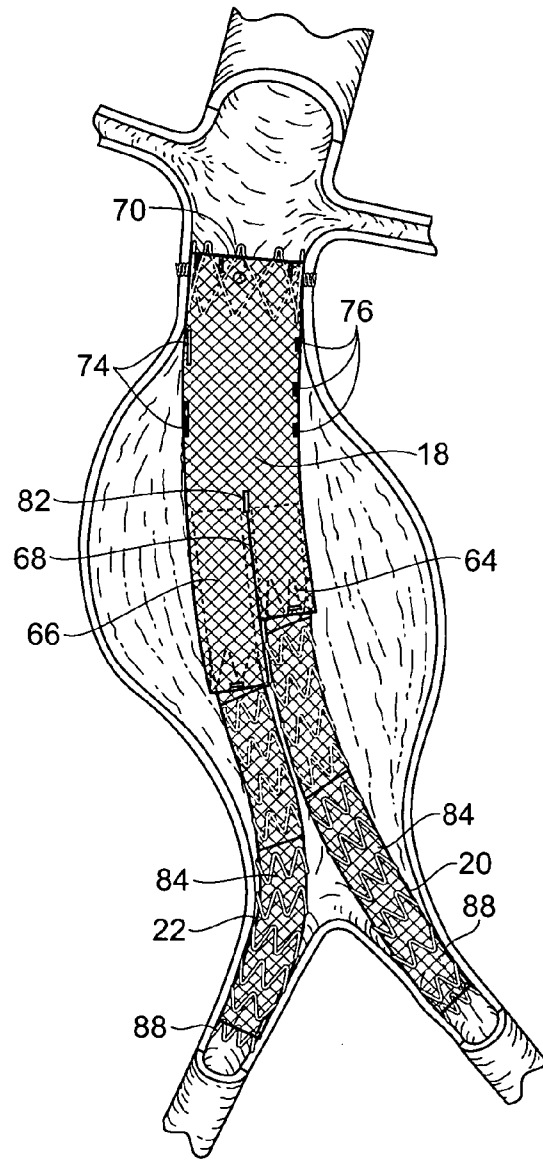
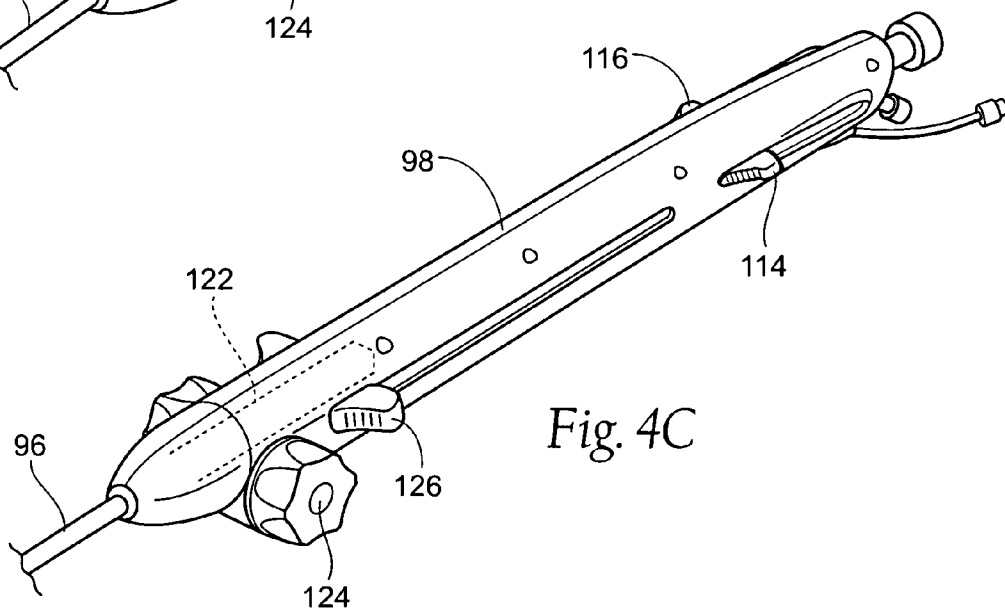
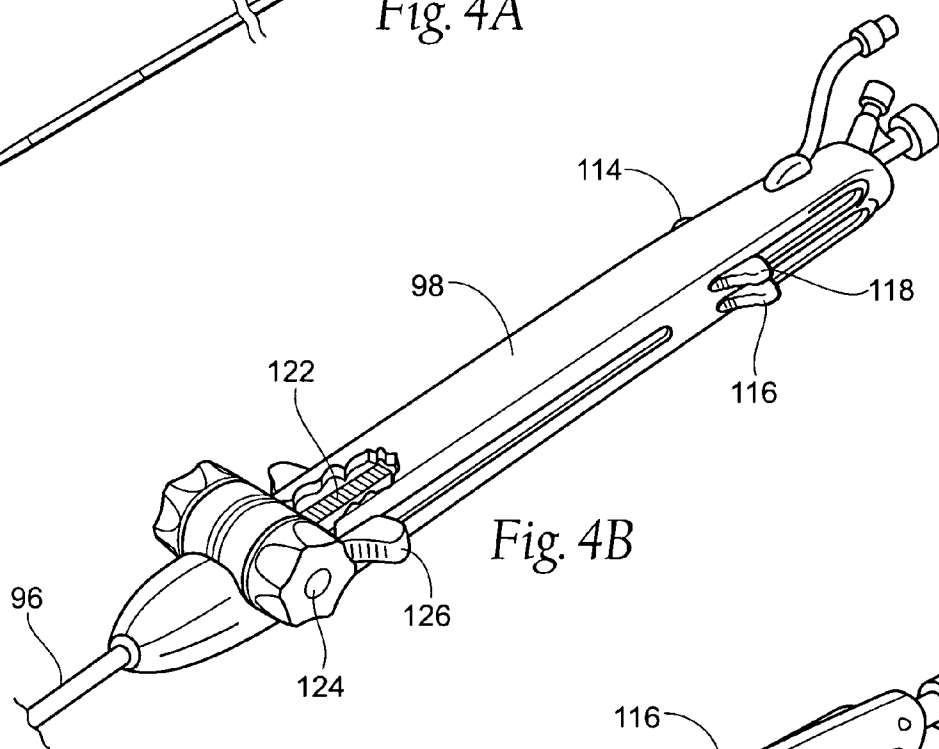
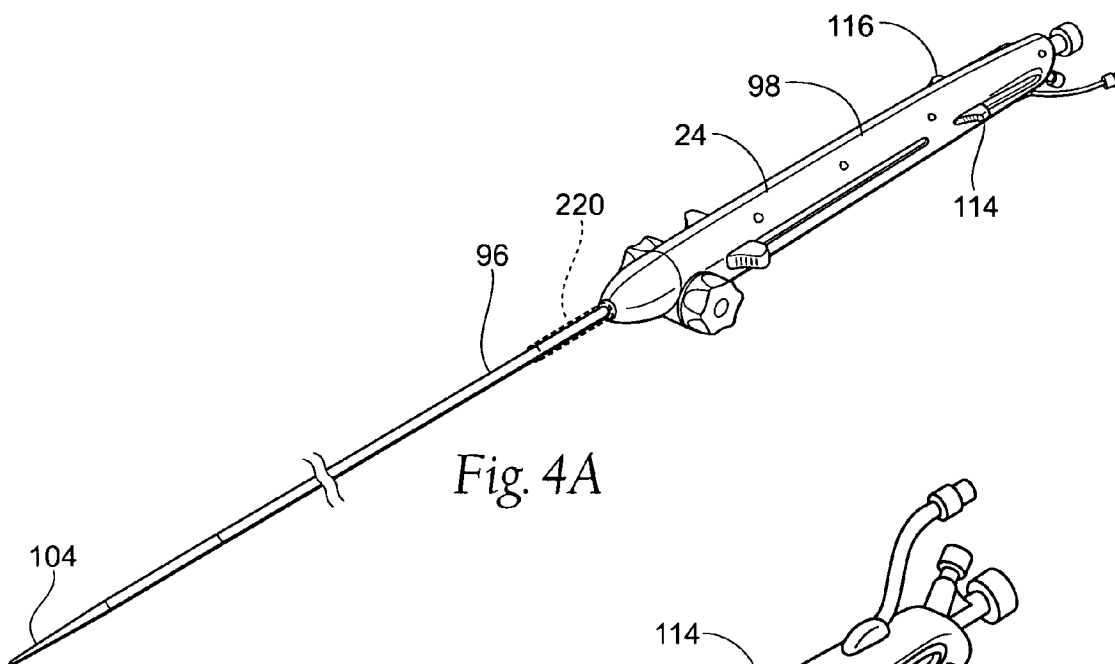


Fig. 3C



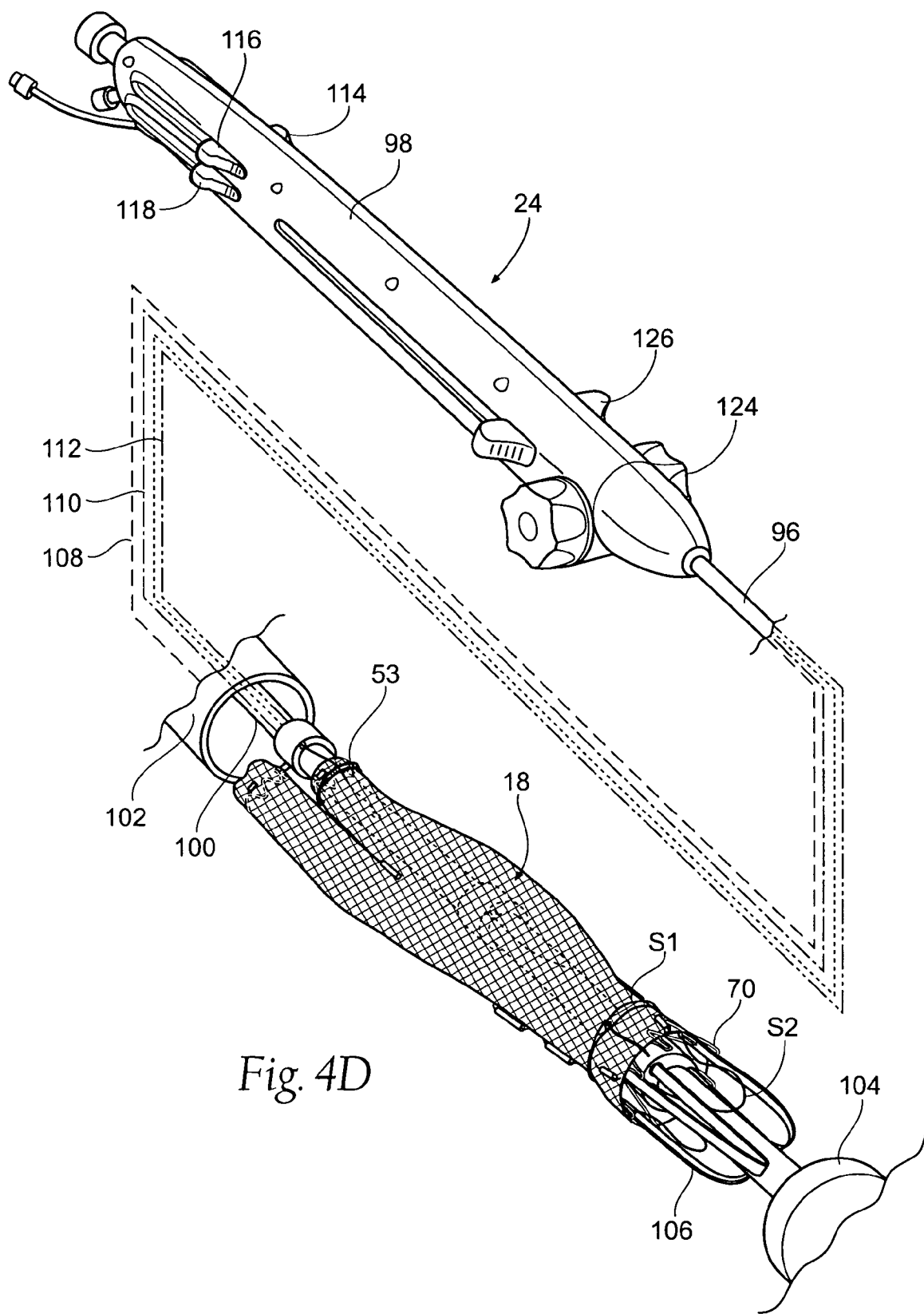


Fig. 4D

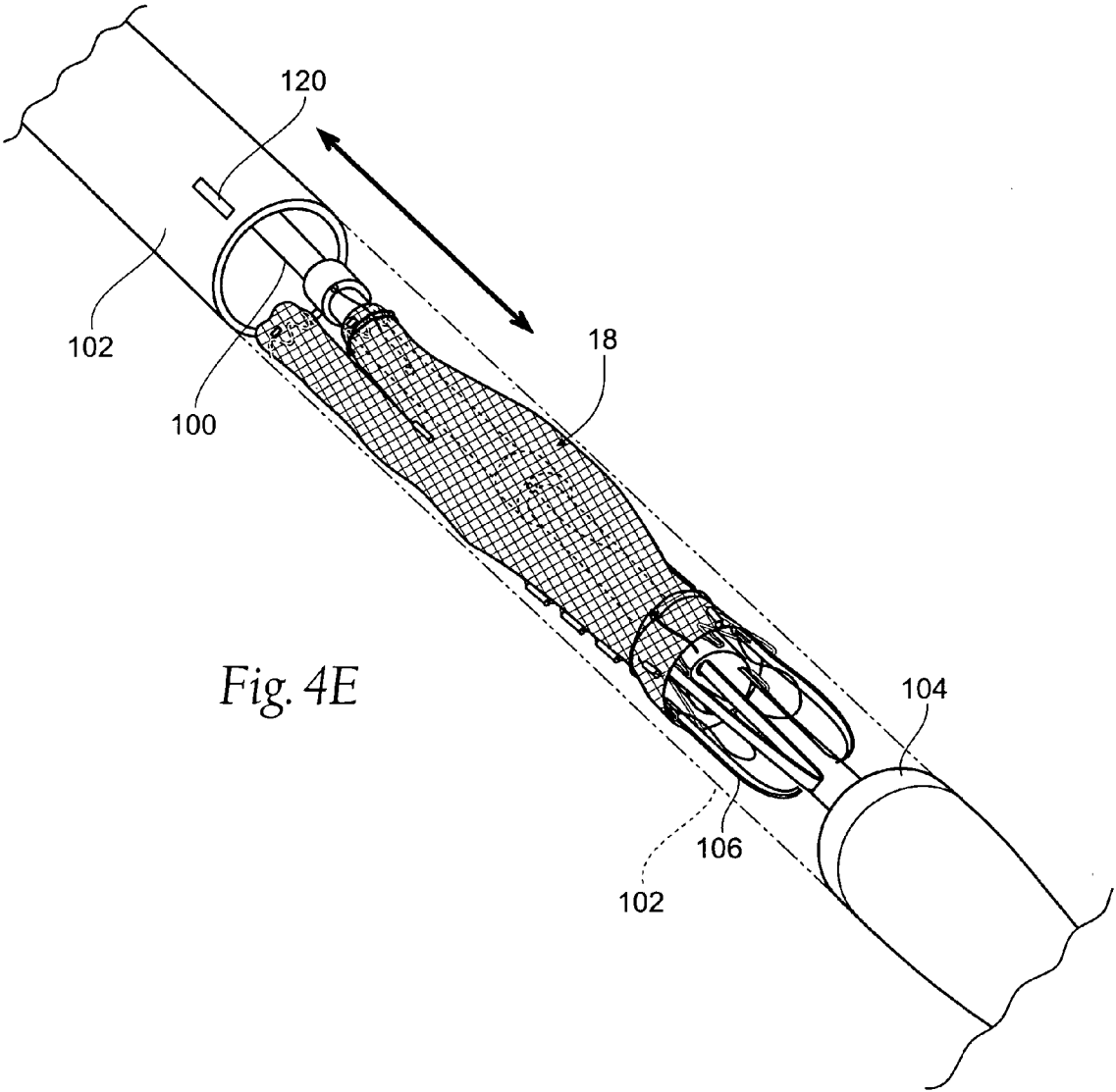


Fig. 4E

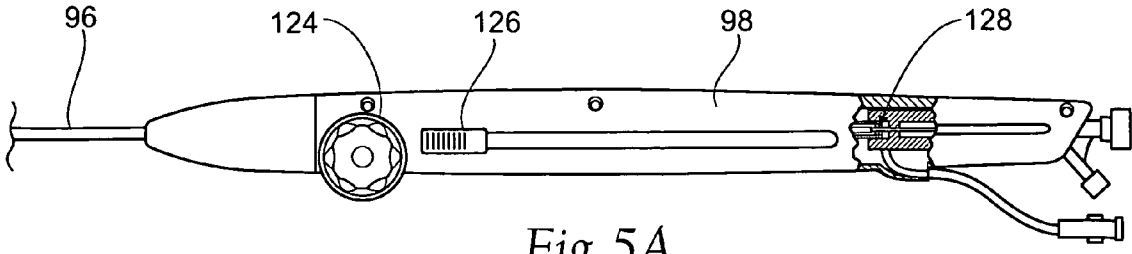


Fig. 5A

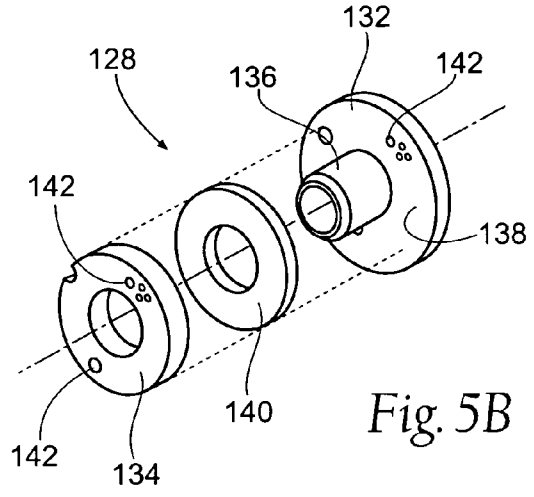


Fig. 5B

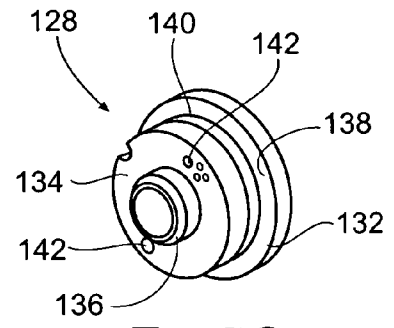


Fig. 5C

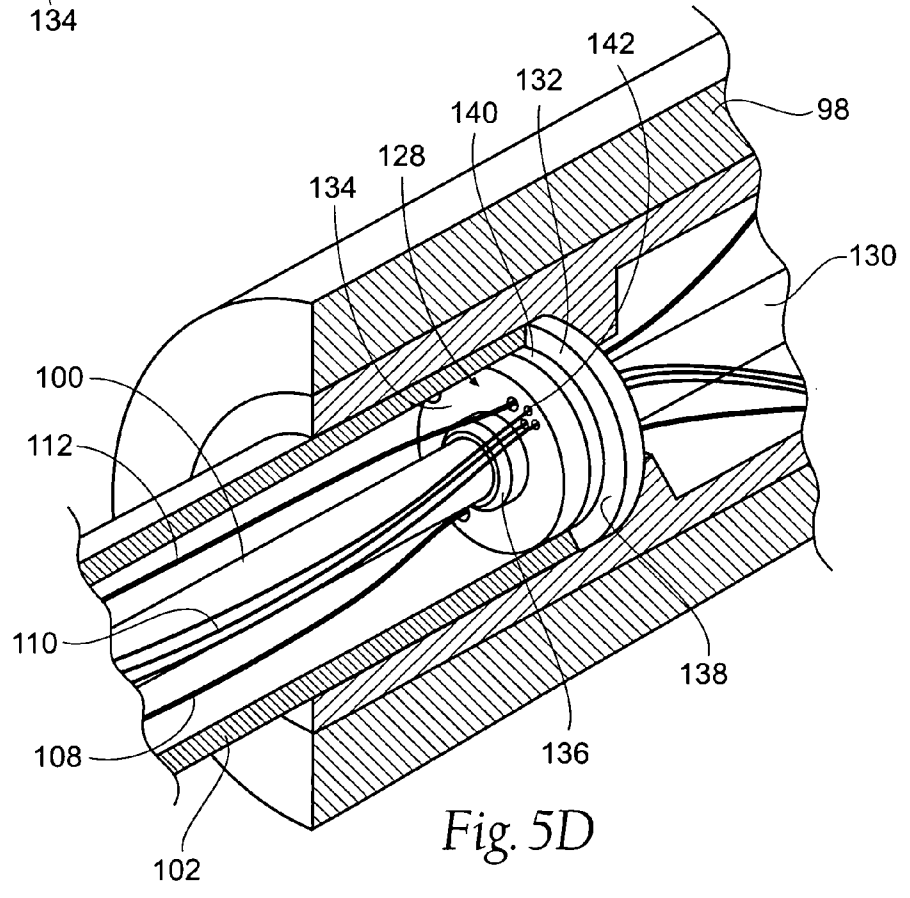
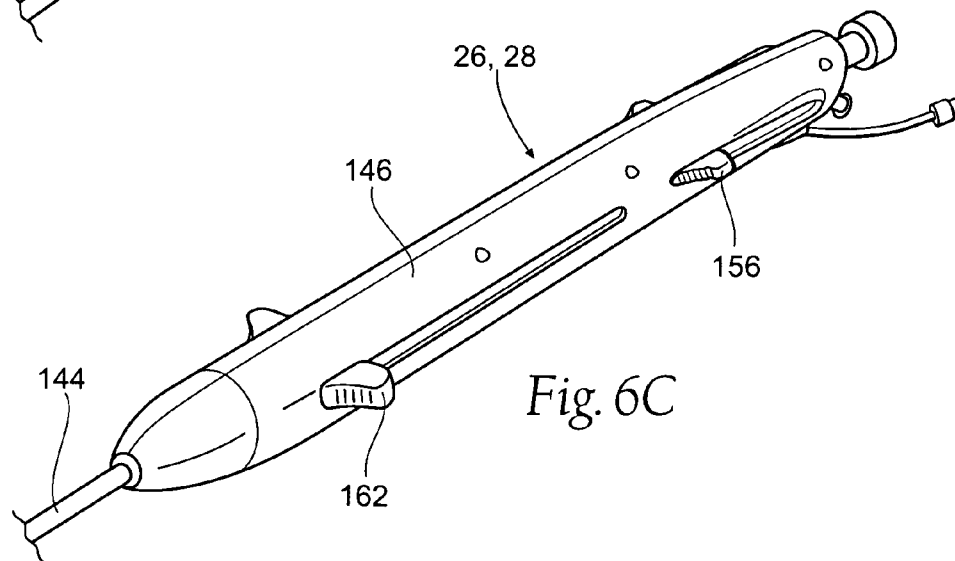
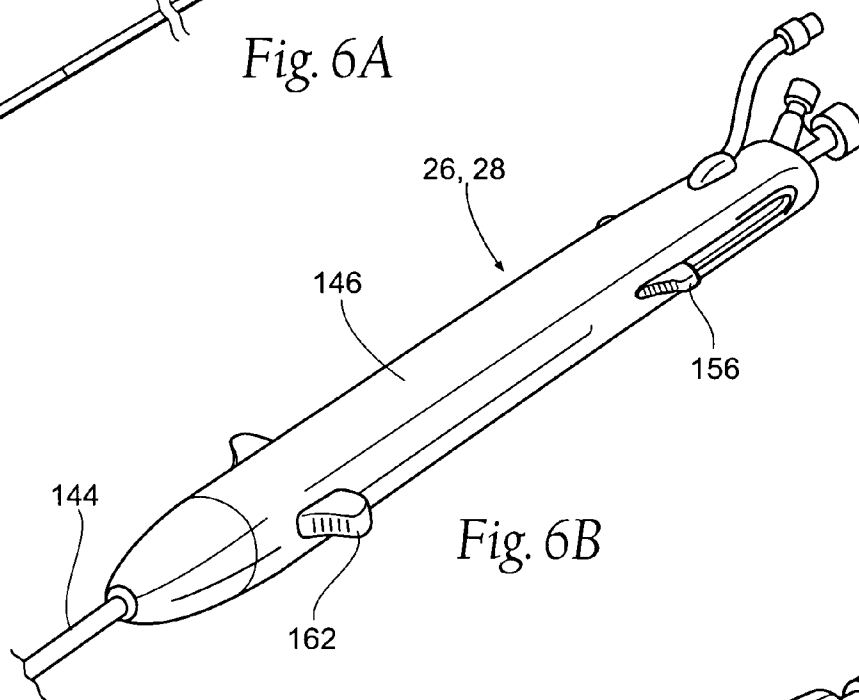
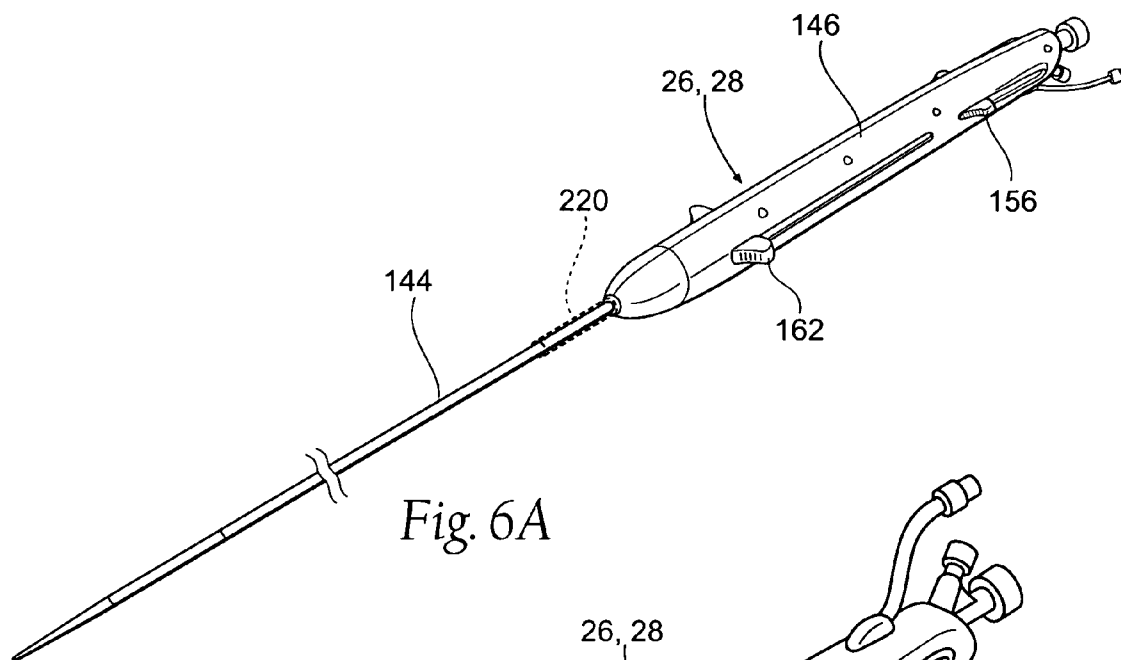
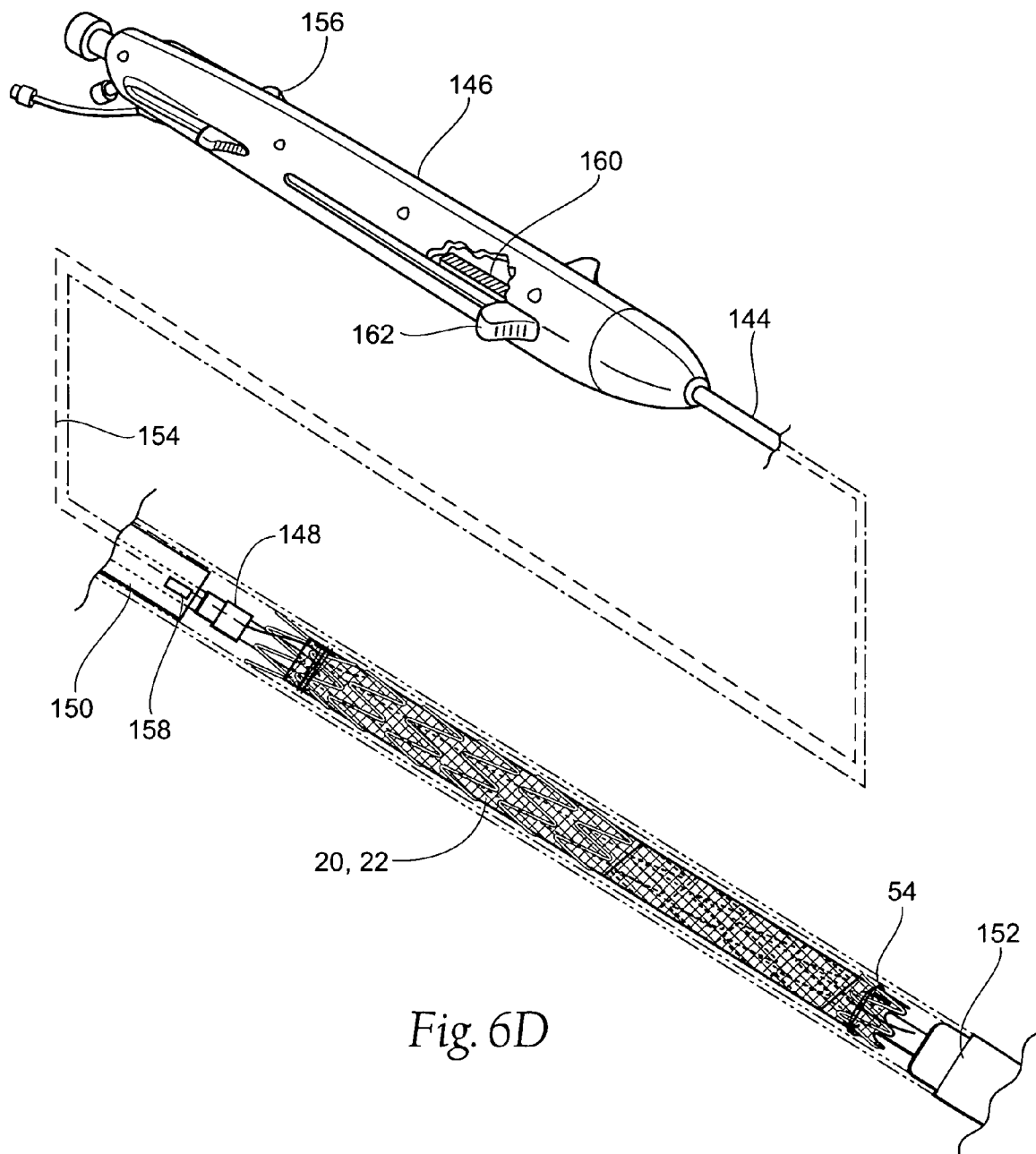
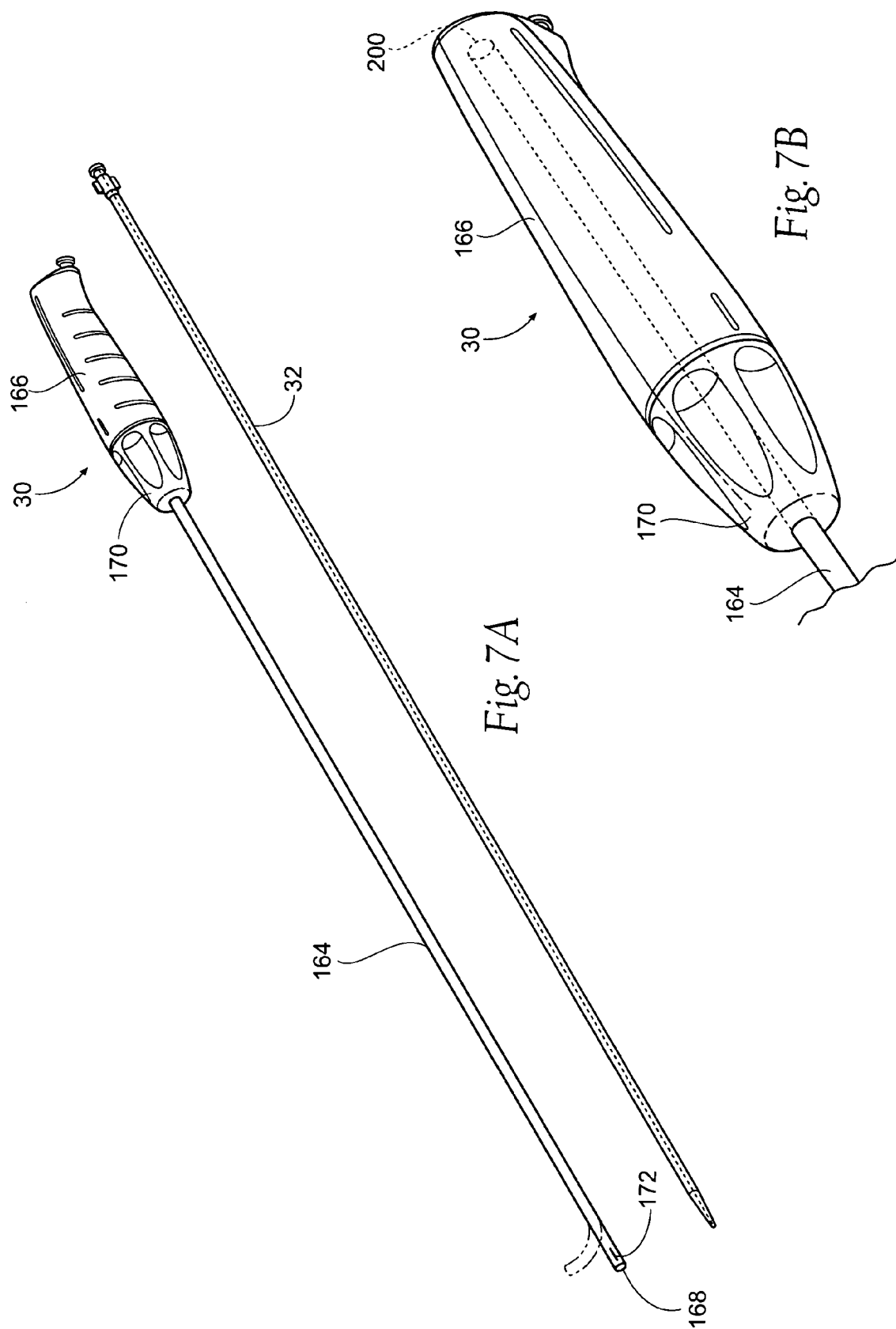


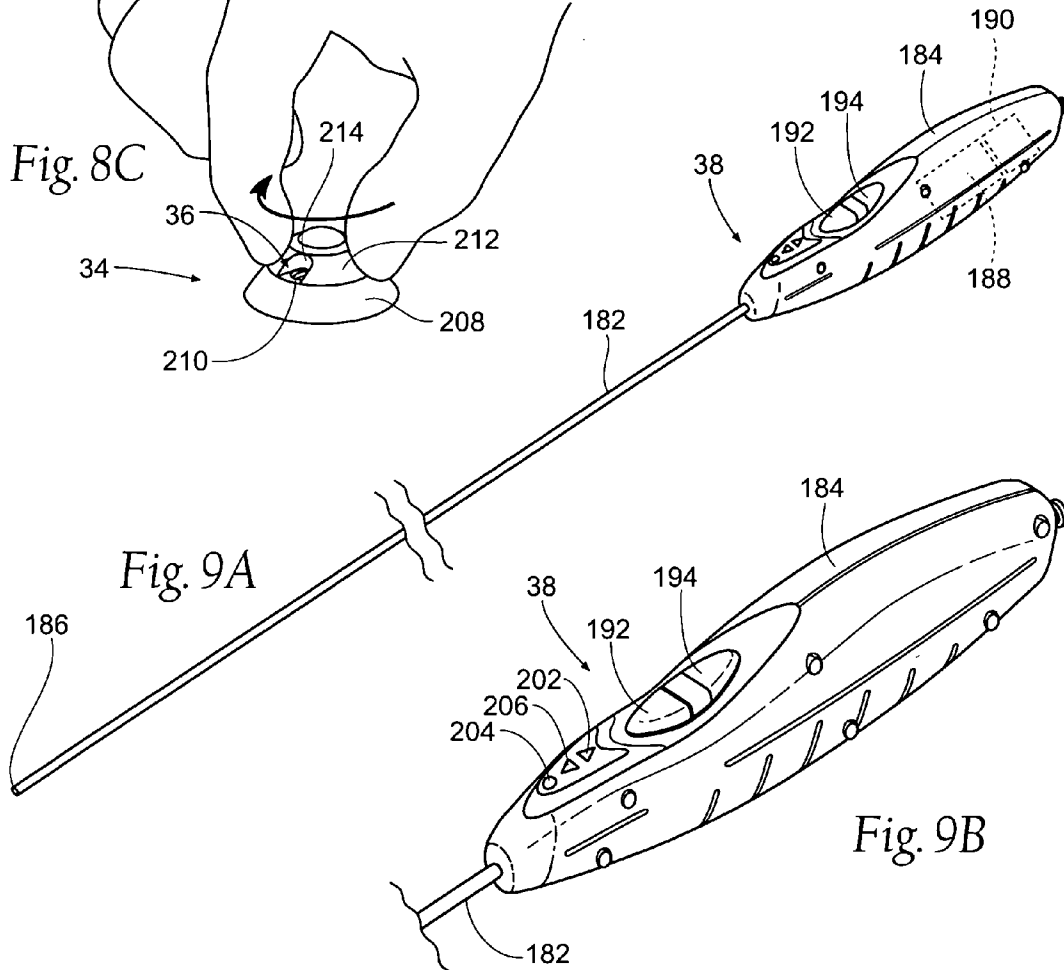
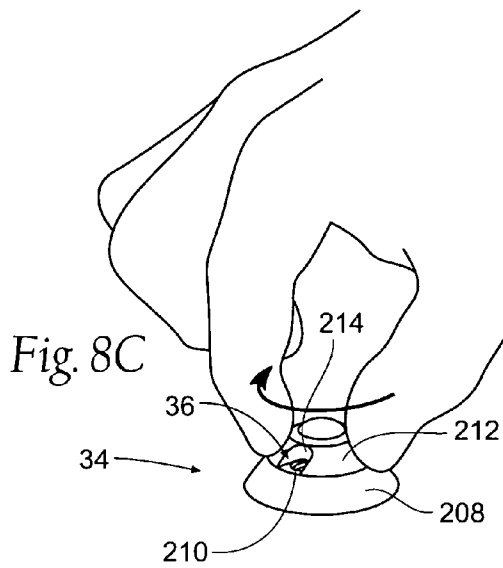
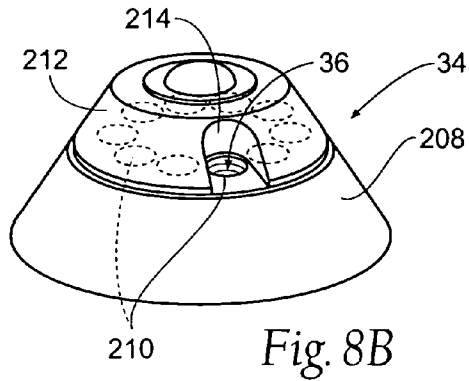
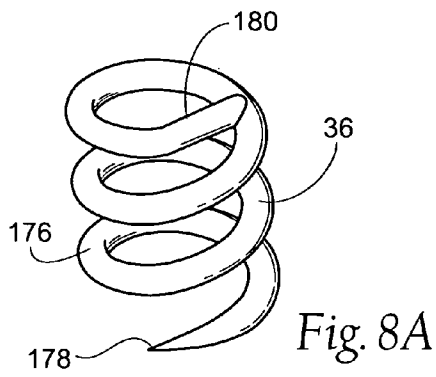
Fig. 5D

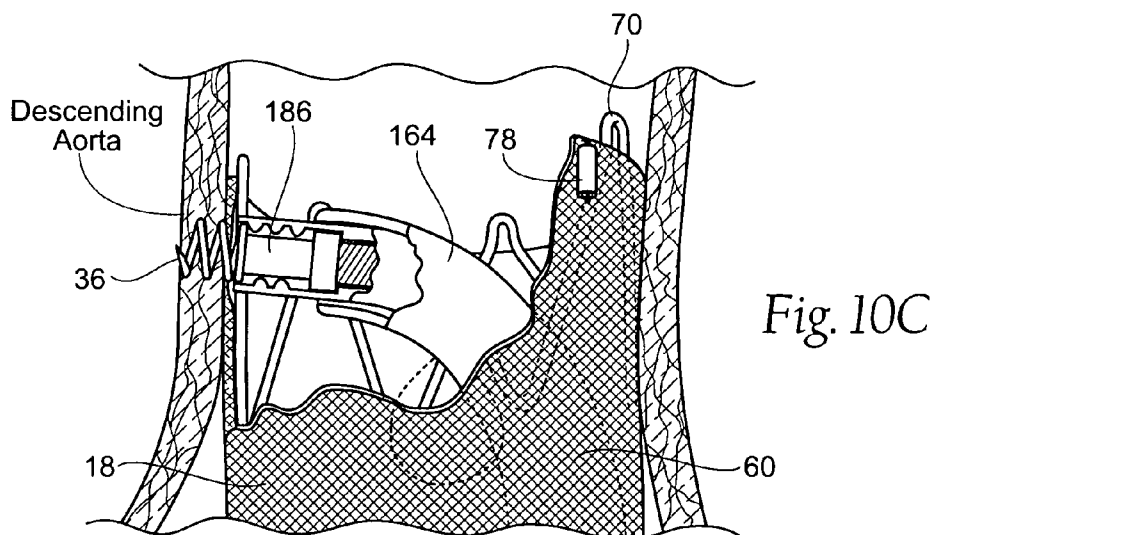
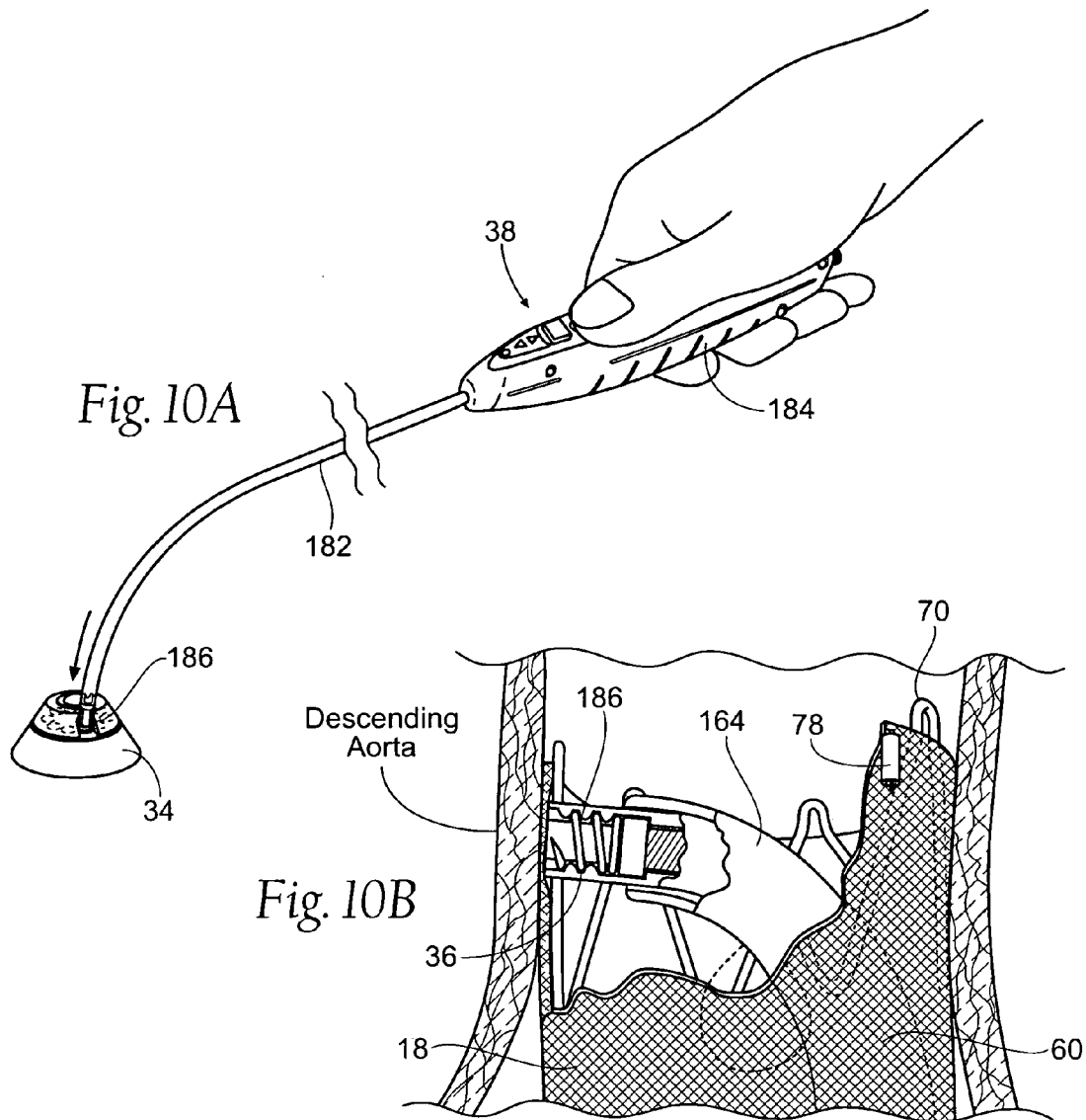












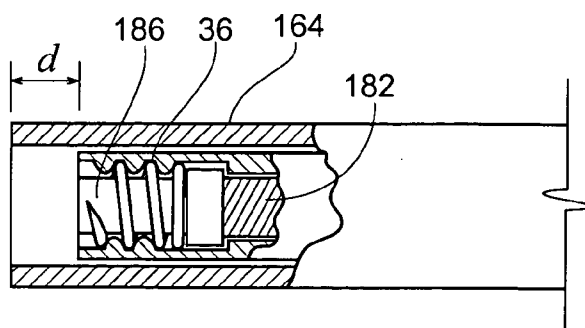
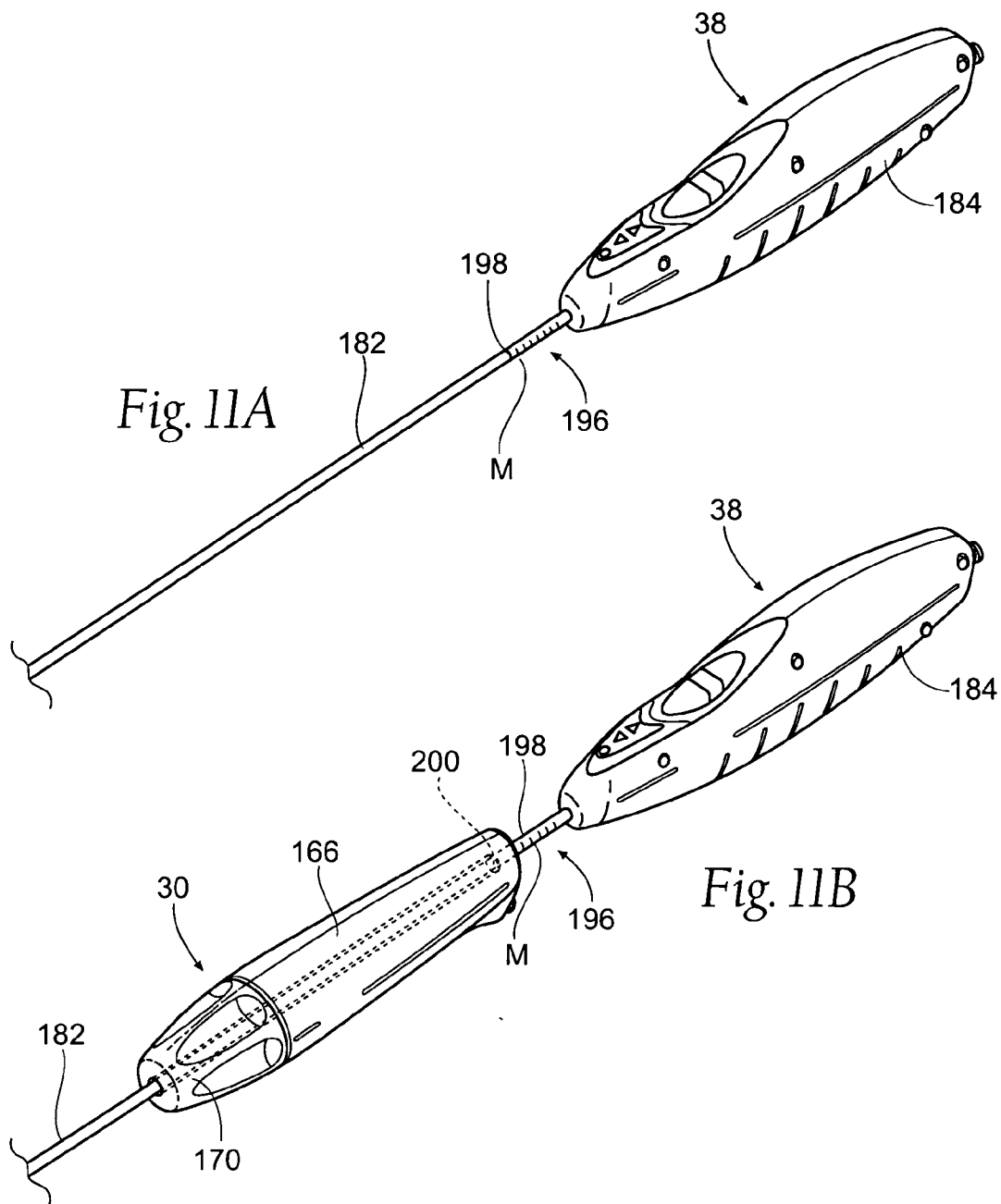


Fig. 11C

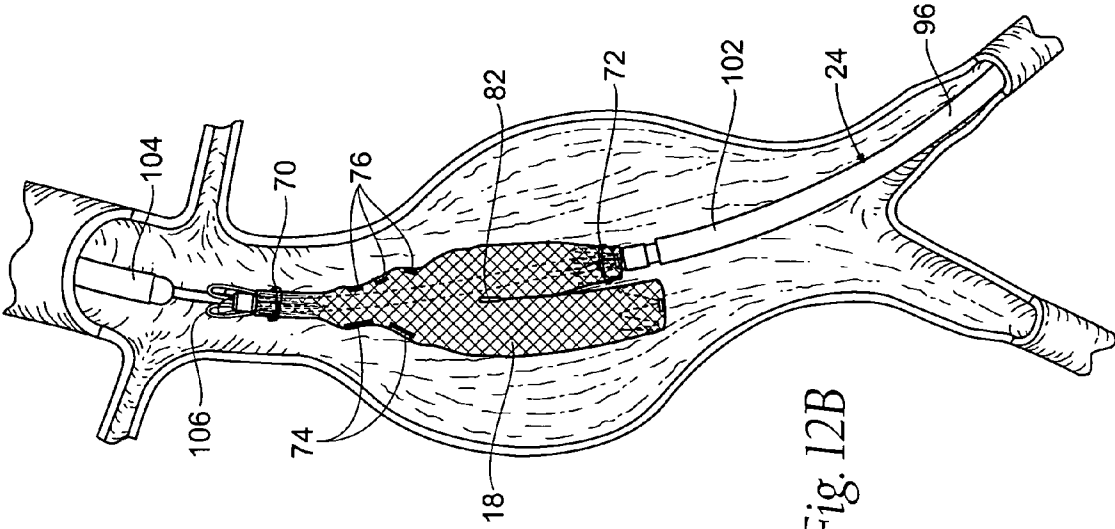


Fig. 12B

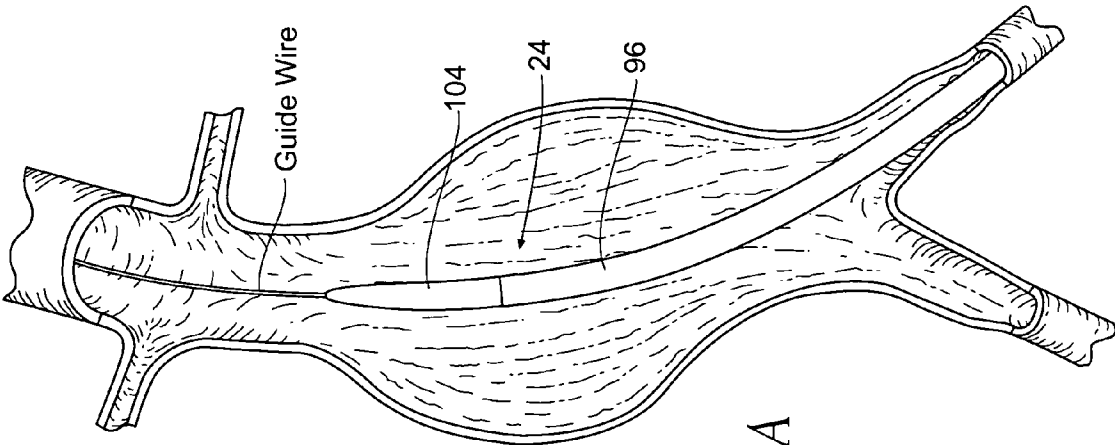
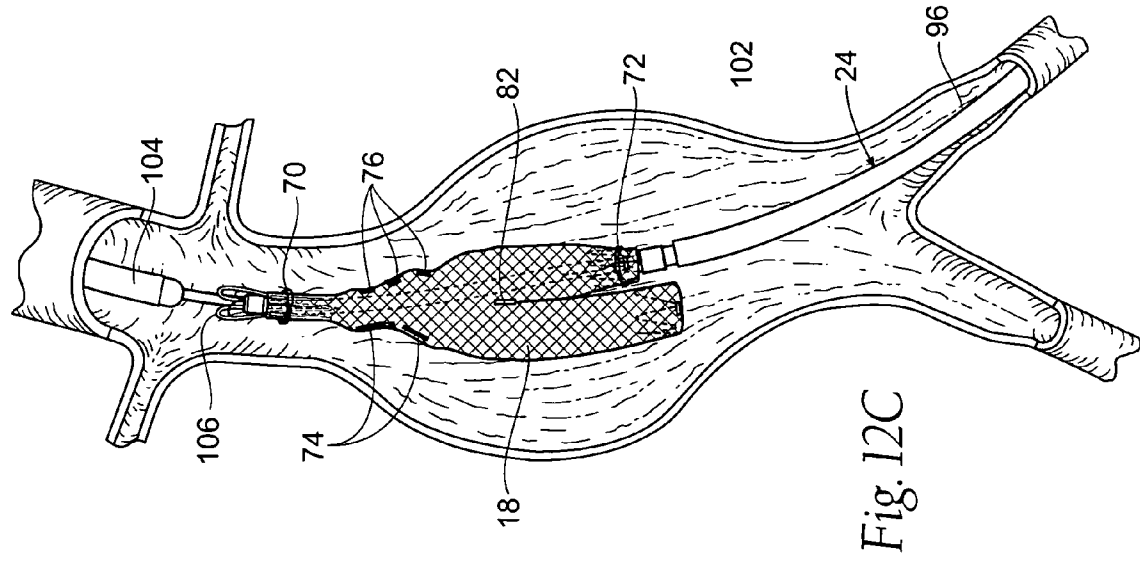
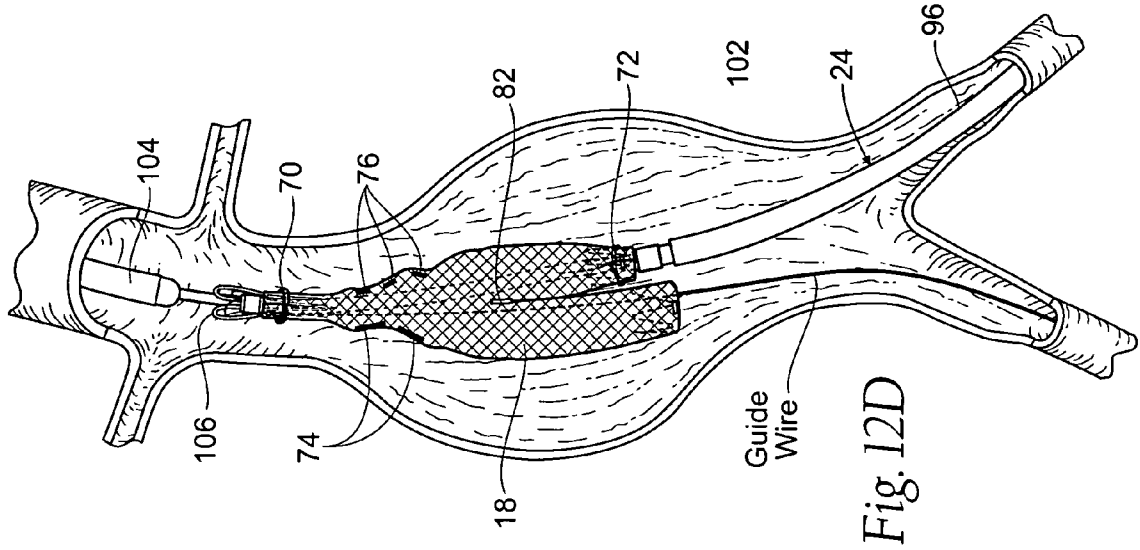


Fig. 12A





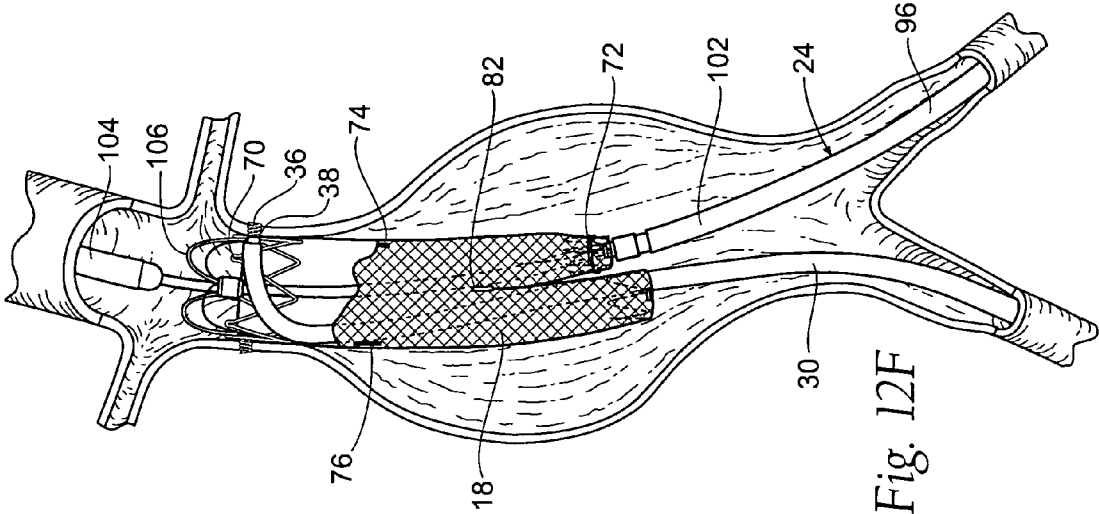


Fig. 12E

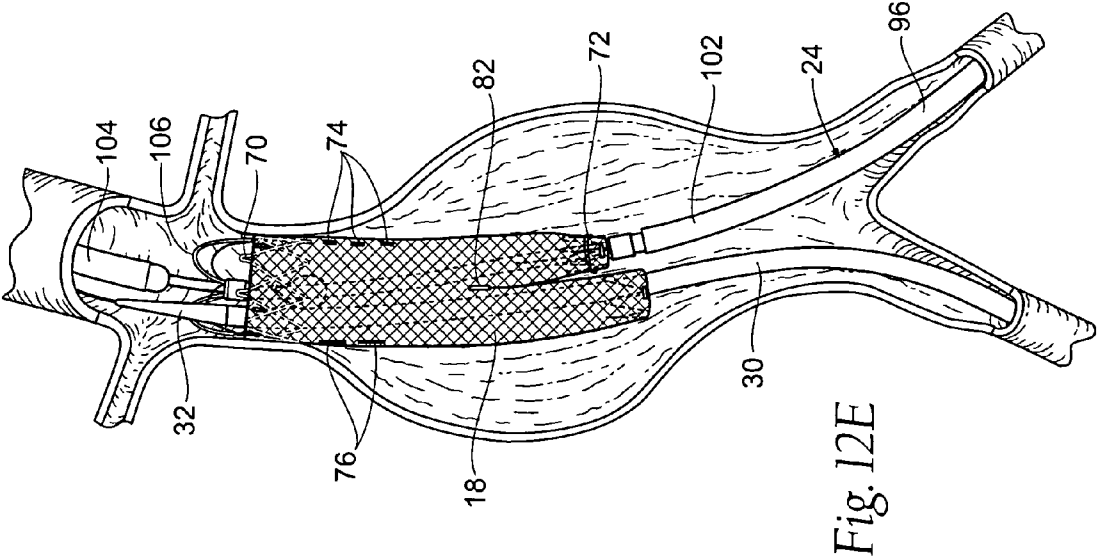


Fig. 12F

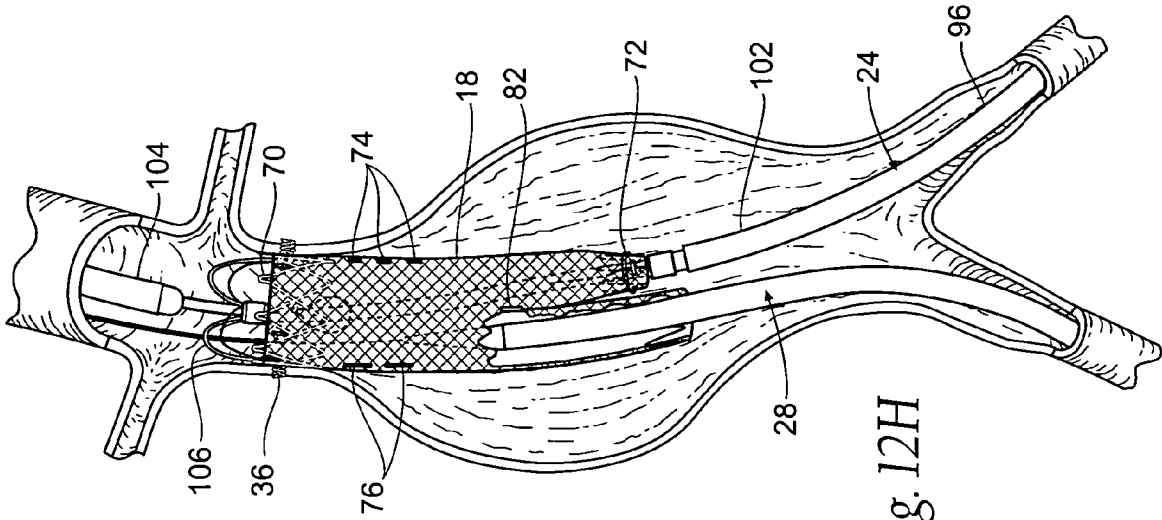


Fig. 12H

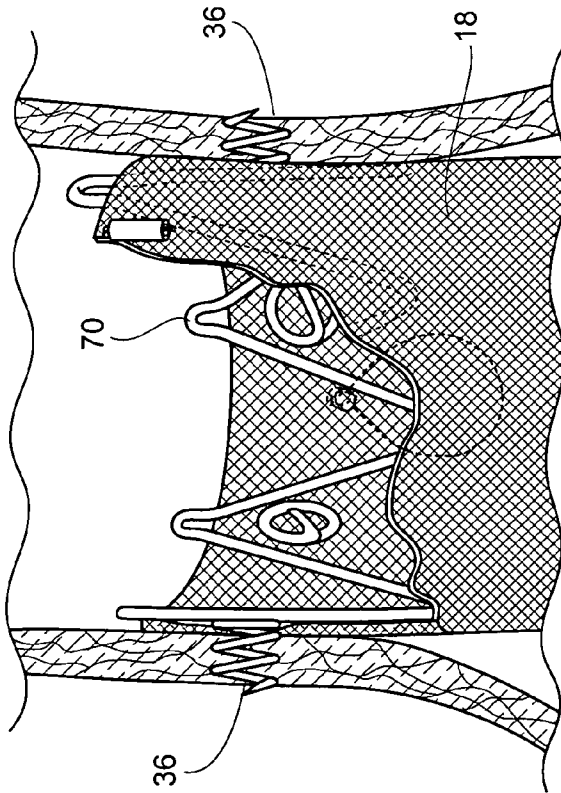


Fig. 12G

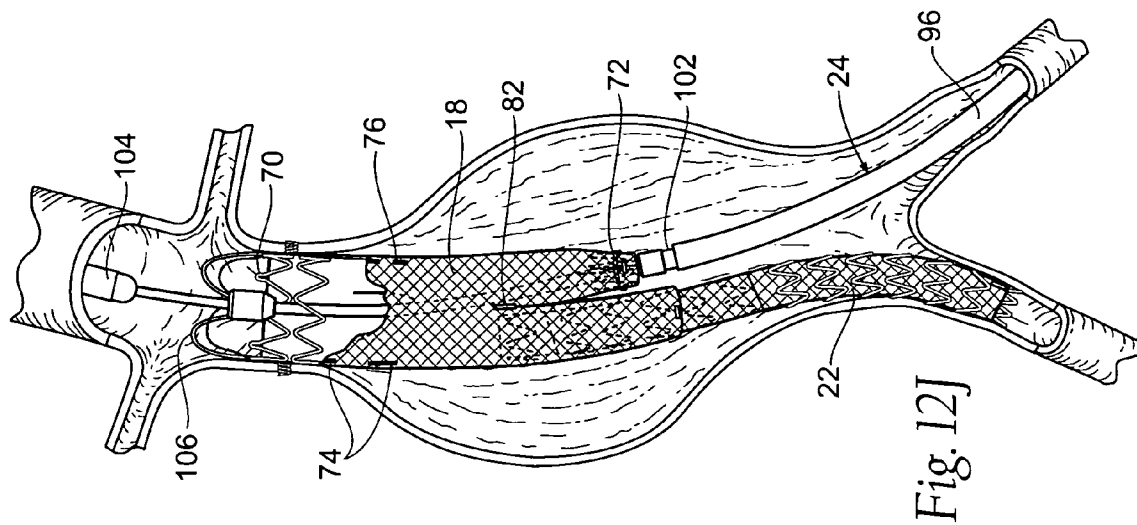
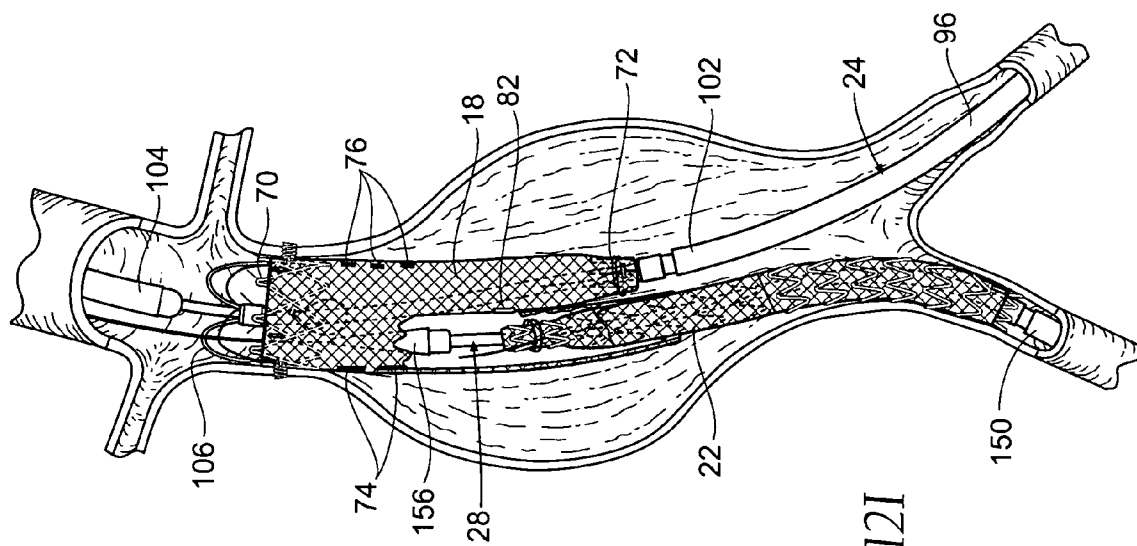


Fig. 12I



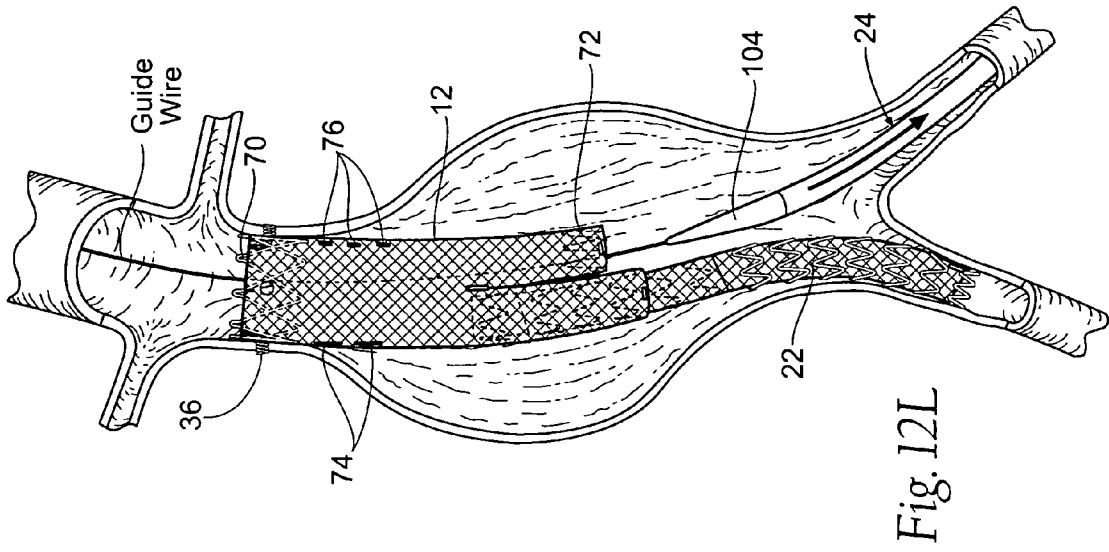


Fig. 12L

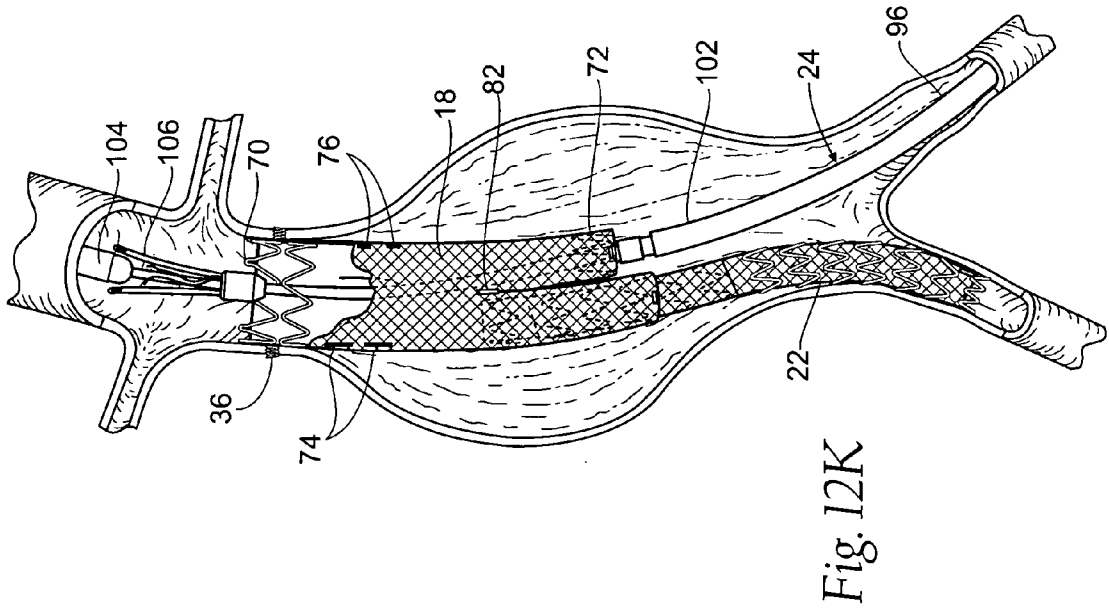


Fig. 12K

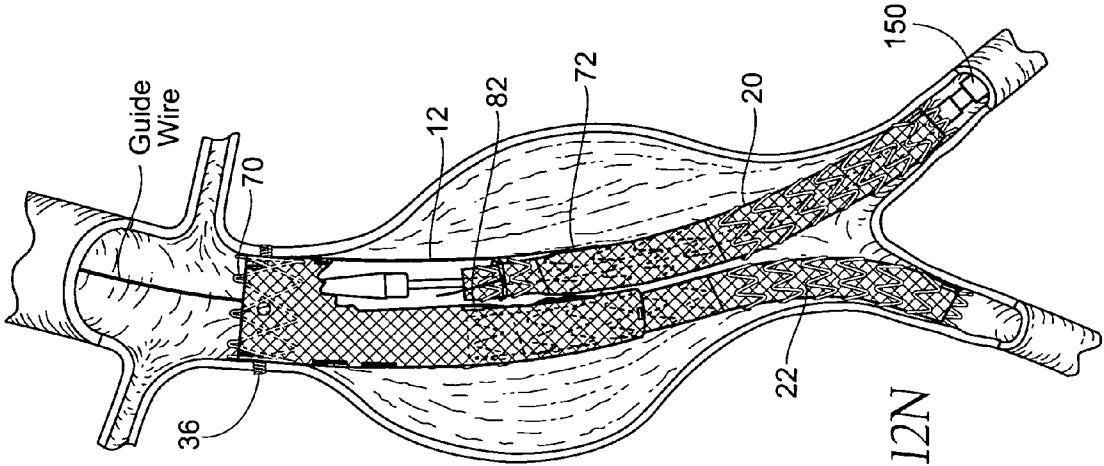


Fig. 12N

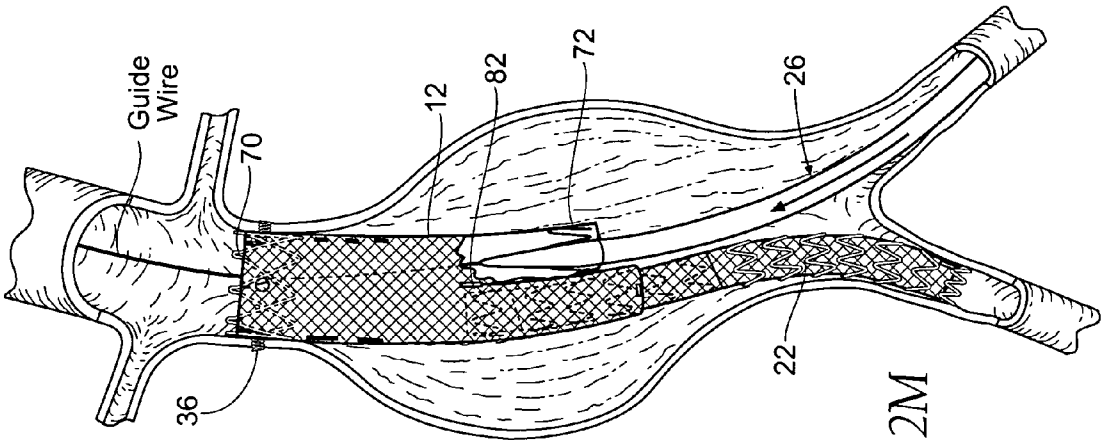


Fig. 12M

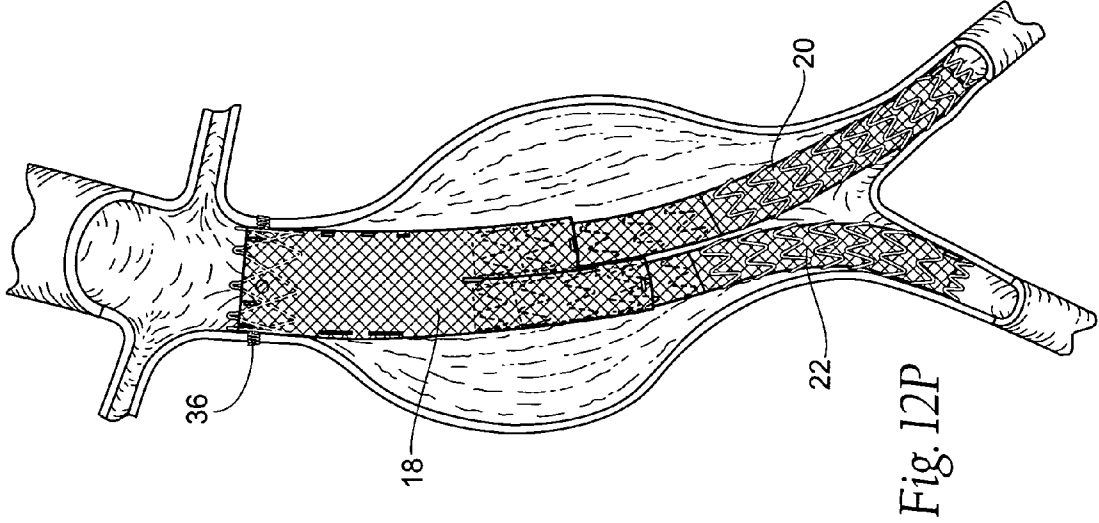


Fig. 12P

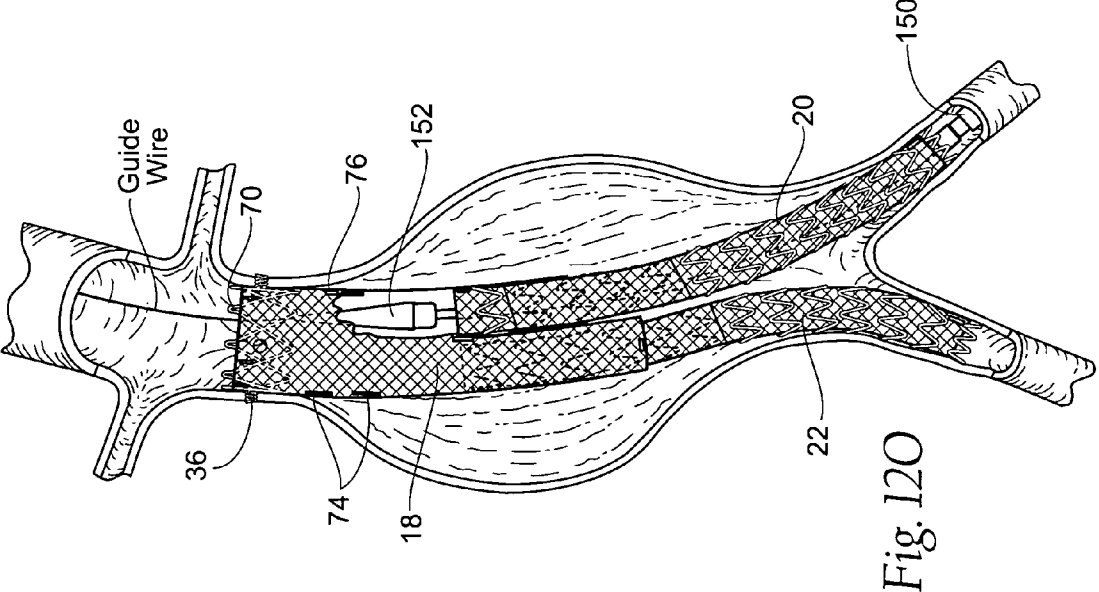


Fig. 12O

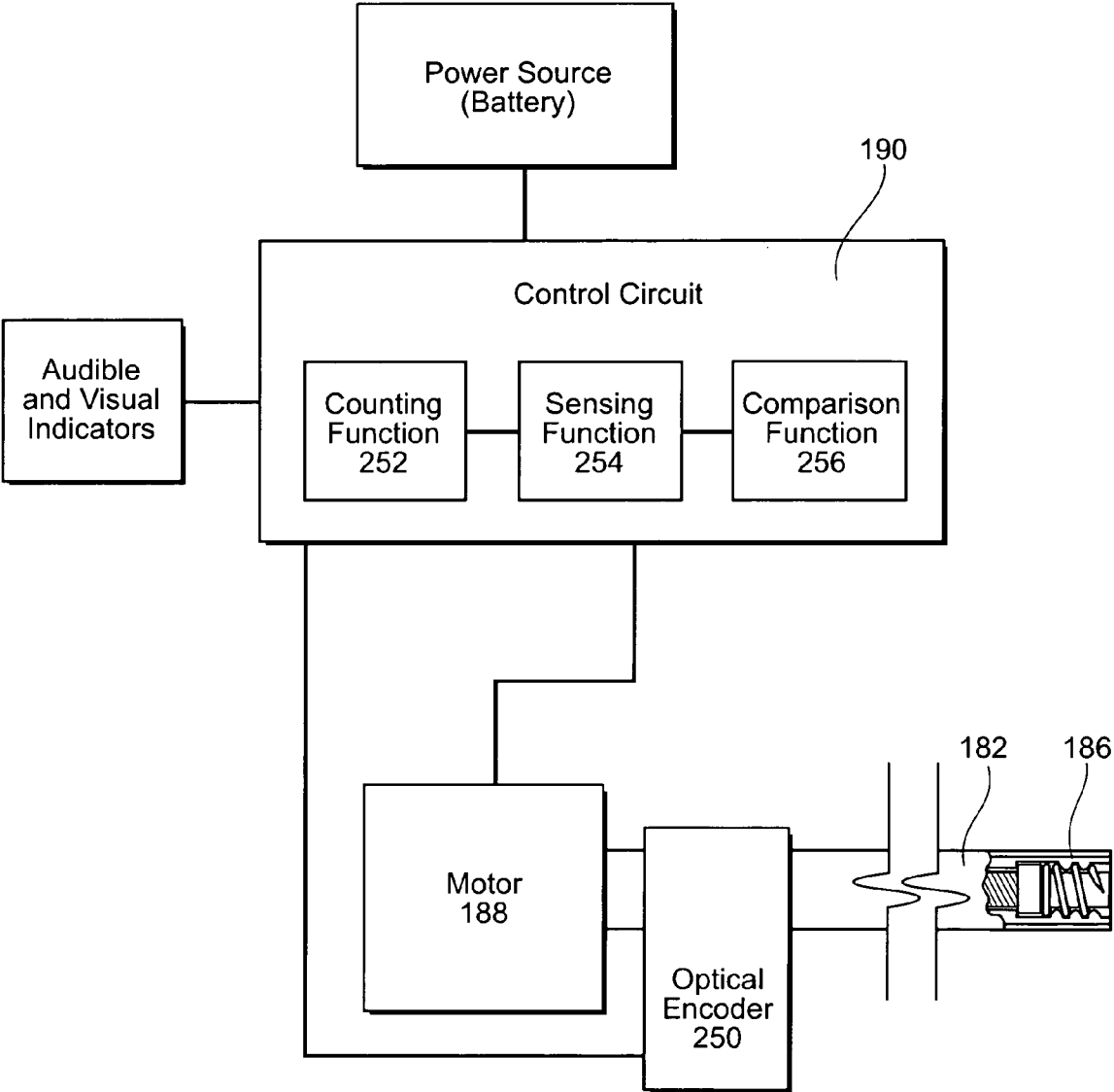
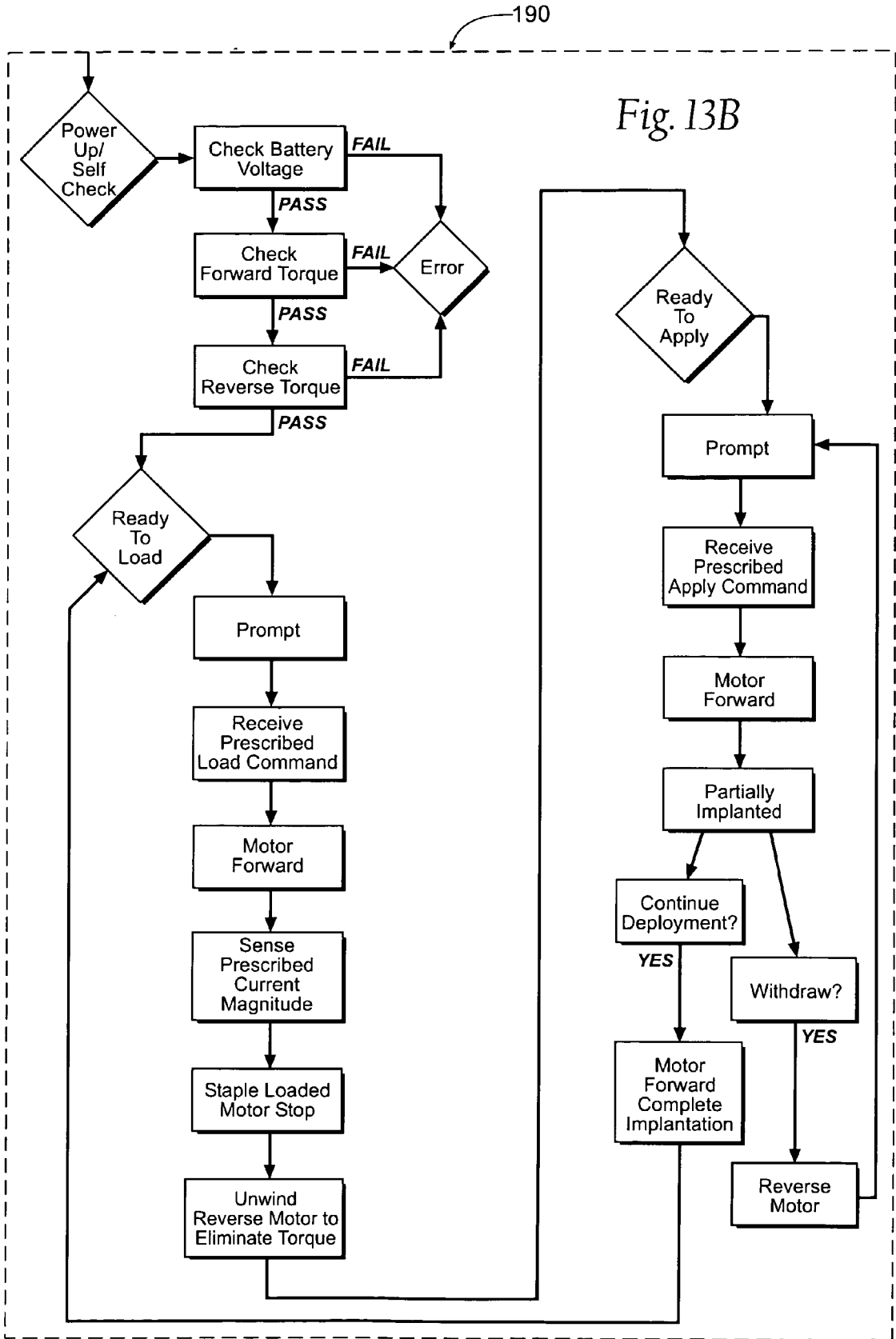


Fig. 13A





**ENDOVASCULAR ANEURYSM DEVICES,  
SYSTEMS, AND METHODS**

**RELATED APPLICATIONS**

[0001] This application is a continuation-in-part of co-pending U.S. patent application Ser. No. 11/254,116, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference. This application also is a continuation-in-part of co-pending U.S. patent application Ser. No. 10/692,283, filed Oct. 23, 2003, and entitled "Prosthesis Delivery Systems and Methods," which claims the benefit of U.S. Provisional Patent Application Ser. No. 60/488,753, filed Jul. 21, 2003, and entitled "Endoprosthesis Delivery Systems and Methods." This application also is a continuation-in-part of co-pending U.S. patent application Ser. No. 10/786,465, filed Feb. 25 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ." This application is also a continuation-in-part of co-pending U.S. patent application Ser. No. 11/693,255, filed Jun. 24, 2005, entitled "Multi-Lumen Prosthesis Systems and Methods," which is a division of U.S. patent application Ser. No. 10/693,255, filed 24 Oct. 2003 (now U.S. Pat. No. 6,929,661), which claims the benefit of U.S. Provisional Patent Application Ser. No. 60/489,011, filed Jul. 21, 2003, and entitled "Bifurcated Prosthesis Systems and Methods." This application also is a continuation-in-part of co-pending U.S. patent application Ser. No. 10/307,226, filed 29 Nov. 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods." This application is also a continuation-in-part of co-pending U.S. patent application Ser. No. 10/669,881, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution." This application is also a continuation-in-part of co-pending U.S. patent application Ser. No. 11/166,411, filed Jun. 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of U.S. patent application Ser. No. 10/271,334, filed 15 Oct. 2002 (now U.S. Pat. No. 6,960,217), which claims the benefit of U.S. Provisional Patent Application Ser. No. 60/333,937, filed 28 Nov. 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by reference.

**FIELD OF THE INVENTION**

[0002] The invention relates generally to devices, systems, and methods for the delivery and implantation of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

**BACKGROUND OF THE INVENTION**

[0003] The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

[0004] For example, aneurysms of the aorta primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

[0005] Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

[0006] Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prostheses for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed prostheses are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

[0007] Accordingly, there is a need for improved prosthesis delivery devices, systems, and methods that deliver a prosthetic graft to a body lumen, the prosthesis being able to adapt to changes in aneurysm morphology and able to be deployed safely and without damage to the native vessel.

**SUMMARY OF THE INVENTION**

[0008] One aspect of the invention provides a system comprising a guide defining an access path into a vessel or hollow body organ and a fastener applier comprising a catheter sized and configured for introduction along the access path to a site targeted for implantation of at least one fastener. The guide includes a distal region with terminus. The fastener applier includes an actuated member that is selectively operable to generate an implantation force to implant the at least one fastener within tissue at the site. According to this aspect of the invention, the catheter includes indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and is therefore still out of contact with tissue. The visible indicia makes it possible for the physician, without resort to fluoroscopic visualization or other visualizations techniques that augment human sight, to always know whether the fastener is within or outside the guide.

[0009] This aspect of the invention also provides instructions for using the guide and fastener applier in which, as the actuated member is being introduced along the access path toward the terminus, the operator or physician is instructed to view the indicia with a naked eye, to detect when the

actuated member rests at a desired distance along the access path short of the terminus of the distal region.

[0010] Another aspect of the invention provides for a fastener applier an electrically powered drive member coupled to the driven member and a controller coupled to the drive motor. According to this aspect of the invention, the controller includes a LOAD state. In the LOAD state, the controller operates in response to an input command for delivering electrical current to the drive member to drive the driven member in a first direction to load a fastener onto the driven member. The controller senses electrical current delivered to the drive member while loading the fastener onto the driven member. The controller terminates delivery of electrical current to the driven member when a prescribed amount of current is delivered to the drive member, thereby terminating the LOAD state.

[0011] On one embodiment, the controller also includes an UNWIND state that follows the LOAD state. In the UNWIND state, which is operative after termination of the LOAD state, the controller delivers electrical current to the drive member to drive the driven member in a second direction. The controller senses a period of operation of the driven member in the second direction which is sufficient to reduce torque windup on the driven member created during the LOAD state. The controller terminates delivery of electrical current to the driven member after the period of operation, thereby terminating the UNWIND state. According to this aspect of the invention, the fastener applier enters a READY TO APPLY state with a minimum of torque windup associated with the driven element.

[0012] Another aspect of the invention provides a fluid seal assembly usable in association with, e.g., a catheter assembly including an operative element that, in use, is exposed to a body fluid, a control element, a control filament coupled at one end to the control element and to an opposite end to the operative element. In this arrangement, the seal assembly is positioned between the control element and the operative element, and the control filament passes through the seal assembly to prevent contact between the body fluid and the control element.

[0013] According to this aspect of the invention, the seal assembly comprises a first seal component with at least one guide tube formed therein, and a second seal component with at least one guide tube formed therein. The second seal component registers with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component. A septum is sandwiched between the first and second seal components. The septum accommodates passage of the control filament from one of the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament that prevents the control element from contacting body fluid to which the operative element is exposed during use.

[0014] Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a view of the components of a system for repairing an endovascular aneurysm.

[0016] FIG. 2 is a view of the components of the system shown in FIG. 1 consolidated for use in a multiple piece kit, along with instructions for their use.

[0017] FIG. 3A is a view of the main body of the endovascular graft that forms a part of the system shown in FIG. 1.

[0018] FIG. 3B is a view of a lumen extension of the endovascular graft that forms a part of the system shown in FIG. 1.

[0019] FIG. 3C is an anatomic view of the main body and lumen extensions of the graft assembly assembled within an abdominal aortic aneurysm.

[0020] FIG. 4A is a view of the delivery system for the main body of the endovascular graft, which forms a part of the system shown in FIG. 1.

[0021] FIGS. 4B and 4C are views of the top and bottom of the control handle of the main body delivery system shown in FIG. 4A.

[0022] FIG. 4D is a view of the distal end of the main body delivery system shown in FIG. 4A, with parts broken away to show the attachment of the main body of the endovascular graft to the delivery system and the release wire and jacket controls that are coupled to the handle to affect a controlled stepwise release of the main body from the delivery system.

[0023] FIG. 4E is a view of the distal end of the main body delivery system showing the retracted and advanced positions of the slidable release jacket.

[0024] FIG. 5A is a view of the handle of the main body delivery system shown in FIG. 4A, with portions broken away to show a hemostatic seal assembly within the housing.

[0025] FIGS. 5B and 5C are, respectively, exploded and assembled views of the hemostatic seal assembly shown in FIG. 5A.

[0026] FIG. 5D is an enlarged view of the hemostatic seal assembly within the handle of the main body delivery system, showing the passage of the release wires through the seal assembly between the control mechanisms and the distal end of the main body delivery system (as shown in FIG. 4D).

[0027] FIG. 6A is a view of the delivery system for a lumen extension of the endovascular graft, which forms a part of the system shown in FIG. 1.

[0028] FIGS. 6B and 6C are views of the top and bottom of the control handle of the lumen extension delivery system shown in FIG. 6A.

[0029] FIG. 6D is a view of the distal end of the lumen extension delivery system shown in FIG. 6A, with parts broken away to show the attachment of a lumen extension of the endovascular graft to the delivery system and the release wire and jacket controls that are coupled to the handle to affect a controlled release of the lumen extension from the delivery system.

[0030] FIG. 7A is a view of the steerable endovascular guide and obturator that form a part of the system shown in FIG. 1.

[0031] FIG. 7B is an enlarged view of the handle of the steerable endovascular guide shown in FIG. 7A.

[0032] FIG. 8A is a view of a endovascular fastener or staple that forms a part of the system shown in FIG. 1.

[0033] FIGS. 8B and 8C are views of a cassette to hold the a plurality of endovascular fasteners, as shown in FIG. 8A, and to present the fasteners for loading in the staple applier, which also forms a part of the system shown in FIG. 1.

[0034] FIG. 9A is a view of a fastener applier for implanting a fastener as shown in FIG. 8A, which forms a part of the system shown in FIG. 1.

[0035] FIG. 9B is an enlarged view of the handle of the fastener applier shown in FIG. 9A.

[0036] FIG. 10A is a view showing the manipulation of the fastener applier shown in FIG. 9A in loading a fastener from the cassette shown in FIGS. 8B and 8C.

[0037] FIGS. 10B and 10C are anatomic views showing the actuated element at the distal end of the fastener applier being driven to implant a fastener in a graft and adjacent tissue, to secure the position of the graft.

[0038] FIG. 11A is a view showing a fastener applier of a type shown in FIG. 9A, which includes indicia visible to a naked eye.

[0039] FIG. 11B is a view showing the fastener applier shown in FIG. 11A in association with a steerable endovascular guide of a type shown in FIG. 7A, showing how the indicia, which is visible to a naked eye, marks when the actuated member rests at a desired distance within the guide short of the terminus of the guide and therefore out of contact with tissue.

[0040] FIG. 11C shown the distal end of the guide when the indicia visible at the proximal end of the guide marks when the actuated member rests at a desired distance within the guide short of the terminus of the guide and therefore out of contact with tissue.

[0041] FIGS. 12A to 12P are anatomic views of manipulation of the components of the system shown in FIG. 1 in placing a prosthesis in an abdominal aortic aneurism, which manipulations can be incorporated within an instruction for use associated with a kit like that shown in FIG. 2.

[0042] FIG. 13A is a schematic view of the motor control functions of a representative control circuit for the fastener applier shown in FIG. 9A.

[0043] FIG. 13B is a schematic flow diagram of the operational states of the control circuit shown in FIG. 13A.

#### DETAILED DESCRIPTION

[0044] This Specification discloses various catheter-based devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

[0045] The devices, systems, and methods are particularly well suited for treating aneurysms of the aorta that primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation, as well as aneurysms that also occur in the thoracic region between the aortic arch and renal arteries. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

[0046] When referring to an endovascular graft or its components that are intended to be implanted in a vessel or body organ, the terms “proximal” and “distal” will be used to describe the relation or orientation of the graft with respect to the heart after implantation. Therefore, the term “proximal” will be used to describe a relation or orientation of the graft that, when implanted, is toward the heart, and the term “distal” will be used to describe a position or orientation of the graft that, when implanted, is away from the heart, i.e., toward the feet.

[0047] When referring to implantation apparatus or devices that are manipulated by a physician or operator in order to implant the endovascular graft or its components, the terms “proximal” and “distal” will be used to describe the relation or orientation of the apparatus or device with respect to the operator as it is used. Therefore, the term “proximal” will be used to describe a relation or orientation of the apparatus or device that, when in use, is positioned toward to the operator (i.e., at the handle end of the device), and the term “distal” will be used to describe a position or orientation of the apparatus or device that, when in use, is positioned away from the operator (i.e., at the other end of a catheter or the like away from the handle).

#### I. System Overview

[0048] FIG. 1 shows a system 10 for repairing an endovascular aneurism, which is well suited for the repair of an abdominal aortic aneurism (AAA). The system 10 comprises three primary components 12, 14, and 16.

[0049] The first component 12 comprises an endovascular graft assembly. In use, the endovascular graft assembly 12 is placed within a vessel at the site of the aneurism. In the illustrated embodiment, the endovascular graft assembly 12 includes a main body 18 that is placed within the aorta adjacent the renal arteries (see FIG. 3C), and lumen extensions 20 and 22 that extend into the contralateral and ipsilateral branches of the iliac artery, as FIG. 3C shows.

[0050] The second component 14 comprises an endovascular delivery system for introducing and deploying in sequence the main body 18 and lumen extensions 20 and 22 of the endovascular graft assembly 12 using an endovascular approach. In the illustrated embodiment, in which the endovascular graft assembly 12 comprises three modular portions—the main body 18, the ipsilateral lumen extension 20, and the contralateral lumen extension 22—there are three corresponding endograft delivery components 24, 26, and 28.

[0051] The third component 16 comprises an endovascular stapling system. In use, the endovascular stapling system 16 attaches one or more regions of the endovascular graft assembly to the vessel wall with one or more endovascular

staples. In the illustrated embodiment, the endovascular stapling system **16** comprises a steerable endovascular guide **30**, an obturator **32**, a cassette **34** holding a plurality of endovascular staples **36**, and an endovascular staple applier **38**. In use, the steerable endovascular guide **30** establishes an endovascular path to the targeted site where the endovascular graft assembly **12** has been partially or fully deployed. The steerable endovascular guide **30** is manipulated by flexure and rotation to successive sites where individual endovascular staples **36** are to be implanted, to penetrate the endovascular graft assembly **12** and adjacent vessel wall. The endovascular staple applier **38**, carrying one or more endovascular staples **36**, is guided by the steerable endovascular guide **30** to the successive sites. The endovascular staple applier **38** is actuated to implant individual endovascular staples **36** into selected region or regions of the endovascular graft assembly **12** and adjacent vessel wall, to attach the endovascular graft assembly **12** to the vessel wall.

## II. The Kit

[0052] As FIG. 2 shows, the various tools and devices as just described, comprising the system **10**, can be consolidated for use in a multiple piece functional kit **40**.

[0053] The kit **40** can take various forms. In the illustrated embodiment, the kit **40** comprises an assemblage of individual packages **42**, **44**, **46**, **48**, **50**, **52**, **54**, and **56**, each comprising a sterile, wrapped, peel-open assembly. One or more the packages may include an interior tray made, e.g., from die cut cardboard, plastic sheet, or thermo-formed plastic material, which hold the contents. The kit **40** also preferably includes instructions or directions **58** for using the contents of the packages to carry out a desired procedure. A desired procedure using the contents of the kit **40** shown in FIG. 2 will be described in greater detail later.

[0054] The instructions for use **58** can, of course vary. The instructions for use **58** can be physically present in one or more of the packages, but can also be supplied separately. The instructions for use **58** can be embodied in separate instruction manuals, or in video or audio recordings. The instructions for use **58** can also be available through an internet web page.

### [0055] A. The Component Packages

[0056] The arrangement and contents of the packages can vary.

[0057] For example, as shown in FIG. 2, the kit **40** comprises eight packages **42**, **44**, **46**, **48**, **50**, **52**, **54**, and **56**. Five of these packages **42**, **44**, **46**, **48**, and **50** provide the main components of the endovascular repair system **10** as described. The remaining packages **52**, **54**, and **56** provide ancillary components used in the deployment of the system **10**, e.g., conventional vascular access sheaths (in package **52**); conventional 0.035 inch guide wires (in package **54**); and bags containing heparinized saline for catheter flushing and contrast for angiography (in package **56**).

[0058] In package **42**, the main body **18** of the endovascular graft assembly **12** is preloaded into the main body endograft delivery components **24**. In package **44**, the ipsilateral lumen extension **20** of the endovascular graft assembly **12** is preloaded into the ipsilateral extension endograft delivery component **26**. In package **46**, the contralateral lumen extension **22** of the endovascular graft assembly **12** is

preloaded into the contralateral extension endograft delivery component **28**. Housed within the packages **42**, **44**, and **46**, the components of the endovascular graft assembly **12** and the corresponding delivery components **24**, **26**, and **28** for the endograft components are supplied sterile to the user.

[0059] As further shown in FIG. 2, the kit **40** comprises an additional package **50** that provides the steerable endovascular guide **30** and at least one associated components; namely, the obturator **32**. The kit **40** also comprises an additional package **48** that provides the endovascular staple applier **38** and at least one associated component; namely, a cassette **34** holding a plurality of endovascular staples **36**. Housed within the packages **48** and **50**, the steerable endovascular guide **30** and the endovascular staple applier **38** and their associated components are supplied sterile to the user.

[0060] Further details of a representative construction of the contents of the packages will now be described.

### [0061] 1. The Endovascular Graft

#### [0062] a. The Main Body

[0063] In a representative embodiment (see FIG. 3A), the main body **18** of the endovascular graft is a multi-lumen endograft comprising two primary components: a graft **60** made of a biocompatible material, e.g., polyester, ePTFE, etc.; and one or more stents or scaffolds **62** made of a biocompatible metal or plastic material, e.g., Stainless steel, nickel-titanium (Nitinol), etc.

[0064] In a representative embodiment, the preferred length of the main body **18** is between 5 cm and 14 cm and most preferably between 7 cm and 10 cm. Desirably, different dimensions for the diameter of the main body **18** are provided to accommodate different anatomic dimensions of patients.

[0065] As illustrated, the multi-lumen endograft is a tube at the proximal end, which separates into two distal ipsilateral and contralateral lumens **64** and **66**. The ipsilateral and contralateral lumens **64** and **66** are separated by a septum **68** or "shared wall" between them. The septum **68** extends the length of the ipsilateral lumen **64** (in the representative embodiment, approximately 3 cm).

[0066] The main body **18** includes a proximal sealing stent **70**, e.g., with diamond or "V" shaped cells, which is sewn to the inside proximal end of the graft e.g., with braided or monofilament suture. The proximal sealing stent **70** is sized and configured to ensure secure apposition to the vessel wall just below the renal arteries. The stent **70** preferably extends beyond the fabric 0 mm to 15 mm and most preferably extends 1 mm to 10 mm .

[0067] The main body **18** includes a distal locking stent **72** located in each of the two lumens **64** and **66** at the distal end of the main body **18**. The stents **72** are sewn to the graft, e.g., with braided or monofilament suture. The distal locking stents **72** of the main body **18** engage with the tape covering the proximal spiral stent **86** on the lumen extensions **20** and **22** (see FIG. 3B) to help prevent component separation and provide support to the lumen openings of the main body **18**.

[0068] Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g., tantalum, platinum or gold) are desirably attached to the main body **18** to assist with visualization under fluoroscopy.

The markers, like the stents, are sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiment, there are two (2) long contralateral side markers **74**; three (3) short ipsilateral side markers **76**; four (4) proximal stent marker bands **78**; five (5) distal locking stent marker bands **80**; and an insertion depth marker **82** near the proximal end of the septum **68** for positioning of the lumen extension.

[0069] Further details of representative constructions of the main body **18** of the endovascular graft assembly **12** can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254,444, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

[0070] b. The Lumen Extensions

[0071] In a representative embodiment (see FIG. 3B), each lumen extension **20** and **22** is sized and configured to be inserted into the corresponding ipsilateral and contralateral lumens of the main body **18**, to complete the assembly of the endovascular graft **12** (see FIG. 3C). The lumen extensions **20** and **22** can be provided in various lengths and diameters to different anatomic dimensions of patients.

[0072] In a representative embodiment, each lumen extension comprises a biocompatible material **84**, e.g., polyester, ePTFE, etc., and two stent or scaffold components **86** and **88** made of a biocompatible metal or plastic material, e.g., Stainless steel, nickel-titanium (Nitinol), etc.

[0073] The first stent component **86** comprises a continuous, spiral sinusoidal stent that runs the length of the lumen extension **20** and **22**. The spiral stent component **86** is sized and configured to prevent kinking and maintain patency of the graft. The stent component can be sewn to the graft, e.g., with braided or monofilament suture. The proximal region of the spiral stent is further covered with material, e.g., polyester, ePTFE, etc. The covered proximal region **90** is sized and configured to engage the locking stent **72** in the main body **18** (see FIG. 3C) to prevent separation of the lumen extension from the main body **18**. The covered proximal region **90** also serves to prevent the metallic stent components from coming into contact with one another.

[0074] The other stent component **88** of each lumen extension comprises a distal sealing stent. The stent component **88** can be sewn to the graft, e.g., with braided or monofilament suture. The distal sealing stent **88** is sized and configured to ensure good apposition of the lumen extension to the wall of the iliac artery. The distal sealing stent **88** preferably extends beyond the distal end of the fabric portion of the lumen extension 0 mm to 15 mm and most preferably extends 1 mm to 10 mm .

[0075] Predetermined arrays of radiopaque markers made from biocompatible materials with high radiopacity (e.g., tantalum, platinum or gold) are desirably attached to each lumen extension to assist with visualization under fluoroscopy. The markers, like the stents, can be sewn to the graft, e.g., with braided or monofilament suture or can be attached to the stent. The arrays can vary. In the illustrated embodiment (FIG. 3B), there is a proximal insertion depth marker **92** at the proximal end of the graft material and a distal marker **94** at the distal end of the graft material.

[0076] Further details of representative constructions of the lumen extensions **20** and **22** of the endovascular graft assembly can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254,444, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including a Prosthesis Assembly," which is incorporated herein by reference.

[0077] 2. Endovascular Graft Delivery Components

[0078] a. The Main Body Delivery System

[0079] i. General Overview

[0080] The main body **18** of the endovascular graft assembly **12** is preloaded into the main body delivery system **24** (see FIG. 4A), which is a single use component that is supplied to the user within its package **42** in a sterile condition (see FIG. 2). The main body delivery system **24** is sized and configured to facilitate accurate placement of the main body **18** of the endovascular graft assembly **12** and to allow the physician to maintain control of the main body **18** while the endovascular staples **36** are applied.

[0081] In the illustrated embodiment (see FIG. 4A), the main body delivery system **24** comprises a delivery catheter **96** and a control handle **98** coupled to the proximal end of the delivery catheter **96**. The delivery catheter **96** (see FIG. 4D) comprises a flexible inner assembly **100** and an outer graft retention jacket **102**. The inner assembly **100** carries at its distal-most end a flexible radiopaque tracking nosecone **104**.

[0082] When preloaded (see FIG. 4D), the main body **18** of the endovascular graft assembly **12** is attached to the inner assembly **100** in three locations. Just proximal of the nosecone **104** (i.e., toward the handle **98**), the main sealing stent **70** of the main body **18** is secured by a releasable suture **S1** to the inner assembly **100**. Also just proximal of the nosecone **104**, the inner assembly **100** includes a set of main body stabilizing arms **106**. In the illustrated embodiment, there are three stabilizing arms **106**. The proximal end of the preloaded main body **18** of the endovascular graft assembly is attached to the three stabilizing arms by three releasable pull wires **S2**, each threaded through eyelets in a respective one of the distal ends of the stabilizing arms **106** and through adjacent graft material. The distal end of the ipsilateral lumen **66** of the preloaded main body **18** is also attached to the inner assembly **100** by a releasable suture **S3**. These sutures and release wires **S1**, **S2**, and **S3** secure the main body **18** of the endovascular graft assembly **12** to the inner assembly **100** for deployment to the targeted implantation site.

[0083] Separate wires **108**, **110**, and **112** extend from the handle **98** along the inner assembly **100**. The separate release wires **108** and **112** are independently coupled to the sutures **S1** holding the proximal sealing stent **70** (release wire **108**) and the suture **S3** at the distal end of the ipsilateral lumen **66** (release wire **112**). The release wires **110** are continuations of the release wires **S2** threaded through the stabilizing arms **106** (as previously described), so that, in the illustrated embodiment, there are actually three release wires **110**, one for each arm **106**. Controls **114**, **116**, and **118** on the handle **98** are coupled to the separate release wires **108**, **110** (commonly coupled to the three wires), and **112**, as will be described in greater detail later, to independently release the sutures or release wires at one location, without necessarily

releasing the sutures or release wires at another location. The separate and independently controllable release wires **108**, **110**, **112** and make it possible to release of the main body **18** of the endovascular graft assembly **12** in a prescribed order, to deploy the main body **18** of the endovascular graft assembly **12** in a desired sequence during the graft deployment process, as will be described in greater detail later.

[0084] The graft retention jacket **102** is sized and configured to slide over and along the inner assembly **100** from an advanced position over the main body **18** of the preloaded endovascular graft assembly **12** (shown in phantom Lines in FIG. 4E) to a retracted position spaced away from the main body **18** of the preloaded endovascular graft assembly **12** (shown in solid lines in FIG. 4E). A radiopaque marker **120** is positioned at the leading edge of the graft retention jacket **102** to assist in visualization under fluoroscopy. A jacket control mechanism **122** coupled to controls **124** and **126** on the handle **98** affects retraction of the graft retention jacket **102** in a stepwise fashion—using first control **124** and then control **126**, as will be described later—as well as the re-advancement of the retention jacket **102** using the single control **126** after the main body **18** has been fully deployed and it is time to withdraw the delivery system.

[0085] When in its advanced position, the graft retention jacket **102** protects the preloaded main body **18** of the endovascular graft assembly **12** as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket **102** frees the preloaded main body **18** of the endovascular graft assembly **12** for deployment by operation of the controls **124** and **126** on the handle **98** during the graft deployment process.

[0086] The actuating components on the control handle **98** (see FIGS. 4B and 4C) include a jacket retraction knob **124** and a jacket retraction slide **126**, which are coupled to the jacket control mechanism **122** just described (as shown in FIG. 4D). The jacket retraction knob **124** is actuated by rotation and is coupled to a rack and pinion component of the jacket control mechanism **122** within the handle **98**. The rack and pinion component applies a mechanical advantage in response to rotation of the knob **124** sufficient to overcome the initial resistance of the graft retention jacket **102** to axial movement beyond the proximal sealing stent **70** of the main body **18** of the endovascular graft assembly **12**. Once free of the proximal sealing stent **70**, the rack and pinion component of the jacket control mechanism **122** is automatically released from the jacket retraction knob **124** (the knob **124** will accordingly spin freely), and subsequent control passes to the jacket retention slide **126**. Pulling on the jacket retention slide **126** (which does not provide a mechanical advantage) suffices to complete the retraction of the jacket **102**. This control sequence provides the physician with tactile feedback during the retraction of the jacket **102**. After retracted in this manner, the jacket **102** can be advanced back toward the nosecone **104** using the jacket slide **126** when it is time to withdraw the delivery system.

[0087] The actuating components on the control handle (see FIGS. 4B and 4C) also include a proximal sealing stent release slide **114**, a graft release slide **116**, and an ipsilateral lumen release slide **118**. The proximal sealing stent release slide **114** is coupled to the release wire **110** for the proximal sealing stent **70** (see FIG. 4D). The graft release slide **116** is coupled to the three separate release wires **110** for the

stabilizing arms **106** (also shown in FIG. 4D). The ipsilateral lumen release slide **118** is coupled to the separate release wire **112** for the distal end of the ipsilateral lumen **66** (as further shown in FIG. 4D).

[0088] Once the graft retention jacket **102** is retracted (as just described), pulling on the proximal sealing stent release slide **114** opens the proximal sealing stent **70**. Despite opening the proximal sealing stent **70**, the proximal and ipsilateral ends of the main body **18** of the endovascular graft assembly **12** remain attached to the inner assembly **100** of the endovascular graft delivery system. The physician maintains control of the main body **18** of the endovascular graft assembly **12** for further final positioning and for the application of the staples **36**, as will be described in greater detail later.

[0089] Once positioned in a desired location and/or after insertion or implantation of staples to secure the main body **12** to the vessel wall, pulling on the graft release slide **116** releases the proximal end of the main body **18** of the endovascular graft assembly **12** from the stabilizing arms **106**. Despite opening the proximal sealing stent **70** and the stabilizing arms, the physician still maintains control of the ipsilateral end of the main body **18** of the endovascular graft assembly, which remains attached to the inner assembly **100**. Next pulling on the ipsilateral lumen release slide **118** opens and releases the ipsilateral lumen **66** from the delivery catheter **96**.

[0090] If desired, and as shown in phantom lines in FIG. 4A, a stationary outer jacket **220** may be provided that extends for a distance from the proximal end of the handle **98** over the delivery catheter **96** (the jacket **102** slides within the stationary outer jacket **220**). The stationary jacket **220** provides a seal interface with a hemostatic valve of the introducer sheath at the access site. The stationary jacket **220** can be made of a suitable medical grade plastic, such as Fluorinated Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket **220** provides column strength and lubricity to reduce friction during sliding actuation of the jacket **102**.

[0091] The delivery catheter **96** is desirably sized to present a minimum diameter according to the diameter of the main body **18** of the endovascular graft assembly **12** it carries. The delivery catheter **26** is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using a conventional 0.035 or 0.038 inch guide wire. In representative embodiment, the overall length of the delivery catheter is preferably between 40 and 120 cm and most preferably between 50 and 90 cm.

[0092] Further details of representative constructions of a main body delivery system **24** can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254, 116, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

[0093] ii. Hemostasis Control

[0094] In a representative embodiment (see FIG. 5A), the proximal end of the handle **98** (near the sliding controls **114**, **116**, and **118** just described) includes a hemostatic seal assembly **128**. As FIG. 5D shows, a flush passage **130** (for conveying heparinized saline to flush the delivery catheter

96 prior to deployment) communicates with the space between the inner assembly 100 and jacket 102 through the hemostatic seal assembly 128. As FIG. 5D also shows, the individual release wires 108, 110, and 112 for the proximal sealing stent release slide 114, the graft release slide 116 (one release wire 110 for each stabilizing arm 106), and the ipsilateral lumen release slide 118, as previously described, also pass from the slide controls 114, 116, and 118 within the handle in a sealed fashion through the hemostatic seal assembly 128 for passage along the inner assembly 100 to the distal end of the delivery catheter 96, where they connect to their respective components, as previously described. The hemostatic seal assembly 128 allows flushing to occur and prevents blood, which can enter the space between the outer jacket 102 and the inner assembly 100 catheter tube during use, from entering the interior of the handle 98.

[0095] In the illustrated embodiment (see FIGS. 5B and 5C), the hemostatic seal assembly 128 includes first and second substantially rigid seal components 132 and 134, made e.g. of an inert material. The first seal component 132 comprises a center post 136 and a collar 138 that extends radially from an end of the post 136. The collar 138 forms a mount for coupling the hemostatic seal assembly 128 within the confines of the handle 98, as FIG. 5D shows.

[0096] The center post 136 defines a passage that sealingly engages the flush passage 130 of the delivery catheter 96, to provide a fluid seal.

[0097] The second seal component 134 comprises an annular ring that fits about the post. As further shown in FIGS. 5B and 5C, the hemostatic seal assembly 128 further includes an annular septum or gasket 140 that also fits about the post 136. When assembled, the gasket 140 is sandwiched between the second seal component 134 and the collar 138 of the first seal component 132. The gasket 140 is made of a soft material, like silicone rubber. The collar 138 and the second seal component 134 include coaxial through-holes or guide tubes 142 to accommodate passage of the various release wires 108, 110, and 112 through the annular gasket 140. The through-holes 142 act as bearing surfaces or guides for the release wires 108, 110, and 112 on opposite sides of the annular gasket 140.

[0098] The gasket 140 provides a dynamic fluid seal for the release wires 108, 110, and 112. The fluid seal is maintained even if a release wire becomes tensioned during use in a non-axial direction. The length and diameter of the bearing surfaces of the through holes 142 and the thickness of the annular gasket 140 can vary depending upon the diameter of the release wires 108, 110, and 112 and direction or angle the release wires 108, 110, and 112 make as they exit the bearing through holes 142, to prevent tear out or sawing of the material of the gasket 140.

[0099] b. The Lumen Extension Delivery System

[0100] Each lumen extension 20 and 22 of the endovascular graft assembly is preloaded into a lumen extension delivery system, respectively 26 and 28 (see FIG. 6A), each of which is a single use component that is supplied to the user within its package 44 and 46 in a sterile condition. Each lumen extension delivery system 26 and 28 is sized and configured to facilitate accurate placement of its lumen extension 20 and 22 of the endovascular graft assembly 12.

[0101] In the illustrated embodiment (see FIG. 6A), each lumen extension delivery system 26 and 28 comprises a

delivery catheter 144 and a control handle 146 coupled to the proximal end of the delivery catheter 144. The delivery catheter 144 (see FIG. 6D) comprises a flexible inner assembly 148 and an outer graft retention jacket 150. The inner assembly 148 carries at its distal-most end a flexible radiopaque tracking nosecone 152.

[0102] When preloaded (see FIG. 6D), the lumen extension 20 or 22 of the endovascular graft assembly is attached to the inner assembly 148 by a releasable suture S4 at the proximal end of the spiral stent 86. A release wire 154 extends from the handle 98 along the inner assembly 148 and is coupled to the suture S4 holding the proximal end of the spiral stent 86. A sliding control 156 on the handle 146 is coupled to the release wire 154 (as will be described in greater detail later), to release the suture S4 and thereby release of the lumen extension 20 or 22 of the endovascular graft assembly 12 from the inner assembly 148 during the graft deployment process, as will be described in greater detail later.

[0103] The graft retention jacket 150 is sized and configured to slide over and along the inner assembly 148 from an advanced position over the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 (shown in phantom Lines in FIG. 6D) to a retracted position spaced away from the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 (shown in solid lines in FIG. 6D). A radiopaque marker 158 is positioned at the distal end of the graft retention jacket 150 to assist in visualization under fluoroscopy. A control mechanism 160 coupled to a sliding control 162 on the handle 146 affects advancement and retraction of the graft retention jacket 150, as will be described later.

[0104] When in its advanced position, the graft retention jacket 150 protects the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 as it is advanced through the patient's vasculature. When in its retracted position, the graft retention jacket 150 frees the preloaded lumen extension 20 or 22 of the endovascular graft assembly 12 for deployment by operation of the sliding control 162 on the handle 98 during the graft deployment process.

[0105] The actuating components on the control handle 146 (see FIGS. 6B and 6C) include a jacket retraction knob 162 (coupled to the jacket control mechanism 160) and a proximal spiral stent release slide 156 (coupled to the release wire 154 just described (as shown in FIG. 6D)). Pulling on the jacket retraction slide 162 suffices to retract the jacket 150. Once the graft retention jacket 150 is retracted (as just described), pulling on the proximal spiral stent release slide 156 opens and releases the lumen extension 20 or 22 from the inner assembly 148.

[0106] A stationary outer jacket 220 may also be provided for the lumen extension delivery systems 26 and 28 (as shown in phantom lines in FIG. 6A). As previously described with respect to the main body delivery system 24, the stationary outer jacket 220 extends for a distance from the proximal end of the handle 146 over the delivery catheter 144 (the jacket 150) slides within the stationary outer jacket 220). The stationary jacket 220 provides a seal interface with a hemostatic valve of the introducer sheath at the access site. As previously described, the stationary jacket 220 can be made of a suitable medical grade plastic, such as Fluorinated Ethylene Propylene (FEP) as non-limiting

example. The stationary outer jacket **220** provides column strength and lubricity to reduce friction during sliding actuation of the jacket **150**.

[**0107**] Each lumen extension delivery catheter **144** is desirably sized to present a minimum diameter according to the diameter of the lumen extension **20** or **22** of the endovascular graft assembly **12** it carries. The delivery catheter **144** is desirably sized and configured with a lumen accommodating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire. In representative embodiment, the over-all length of the lumen extension delivery catheter **144** is preferably between 40 and 120 cm and most preferably between 50 and 90 cm.

[**0108**] The lumen extension delivery catheter can include a hemostatic valve assembly of the type previously described and as shown in FIGS. **5A** to **5D**.

[**0109**] Further details of representative constructions of a lumen extension delivery system can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254,116, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

#### [**0110**] C. Endovascular Stapling System

[**0111**] The endovascular stapling system **16** comprises steerable endovascular guide **30** and a companion obturator **32** (see FIGS. **7A** and **7B**) for over-the-wire, intravascular deployment of the steerable endovascular guide **30**. The endovascular stapling system **16** also comprises a plurality of endovascular staples **36** (FIG. **8A**) and, desirably, a cassette **34** for holding the staples **36** (see FIG. **8B**), as well as an endovascular staple applier **38** (see FIGS. **9A** and **9B**).

#### [**0112**] d. Steerable Endovascular Guide and Companion Obturator

[**0113**] The steerable endovascular guide **30** is a single use component that is supplied with a companion obturator **32** to the user within its package **50** in a sterile condition. The steerable endovascular guide **30** is sized and configured to direct the endovascular staple applier **38** to the desired location for implantation of one or more endovascular staples **36**.

[**0114**] The steerable endovascular guide **30** (see FIGS. **7A** and **7B**) includes a guide tube **164** and a handle **166** coupled to the proximal end of the guide tube **164**. The guide tube defines an open interior lumen **168** accommodating passage of the obturator **32** (during deployment) and the endovascular staple applier **38** (during use).

[**0115**] The distal portion of the guide tube **164** can be deflected in one direction (as shown in phantom lines in FIG. **7A**) and straightened by a steering wire (not shown) coupled to a rotational deflector knob **170** on the handle **166**. In a representative embodiment, the over-all length of guide tube **164** and handle **166** is preferably between 40 and 120 cm and most preferably between 50 and 90 cm, and the length of the deflectable tip is preferably between 1 and 10 cm and most preferably between 2 and 5 cm. A C-shaped radiopaque marker **172** is located at the distal tip of the guide tube **164** to aid in orientation under fluoroscopy.

[**0116**] In a representative embodiment, the obturator **32** is desirably sized and configured with a lumen **174** accommo-

dating conventional over-the-wire delivery within a patient's vasculature, e.g., using an appropriately sized guide wire.

[**0117**] Further details of representative constructions of a steerable endovascular guide **30** can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254,619, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool into an Interior Body," and co-pending, commonly owned U.S. patent application Ser. No. 11/254,116, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which are both incorporated herein by reference.

#### [**0118**] B. The Endovascular Staple and Companion Cassette

[**0119**] The endovascular staple **36** (see FIG. **8A**) is a single use component that is supplied, desirably in a companion cassette, to the user within a package in a sterile condition. The endovascular staple **36** is sized and configured to attach the endovascular graft assembly **12** to a vessel wall.

[**0120**] In the illustrated embodiment (see FIG. **8A**) the endovascular staple **36** comprises a main staple body **176** that is helical-shaped. The helical-shape allows the endovascular staple **36** to pierce and engage tissue in response to rotation of the main staple body **176**, thereby securing attachment of the endovascular graft assembly **12** to a vessel wall.

[**0121**] In a representative embodiment, the main staple body **176** is manufactured from medical grade wire having a diameter of from 0.1 mm to 1 mm. In a representative embodiment, the endovascular staple **36** is approximately between 2 mm to 12 mm in over-all length and approximately from approximately 1 mm to 10 mm in maximum diameter. The leading end **178** of the main staple body **176** is desirably sharpened to facilitate atraumatic deployment through the graft materials and vessel wall. The proximal end **180** of the main staple body **176** is desirably closed to prevent over-penetration of the endovascular staple **36**.

[**0122**] Desirably, a plurality of staples **36** (e.g., ten) are provided in a cassette **34** (see FIG. **8B**), to allow easy and accurate loading into the endovascular staple applier **38**. The cassette **34** includes a base **208** having a plurality of spaced apart staple ports or stations **210**, each sized to house a staple **36**. A cover **212** rotates on the base **208** (see FIG. **8C**). The cover **212** overlies the ports **210**, closing them, except for an open notch region **214**, which permits access to a single one of the ports **210**. In use, an operator rotates the cover **212** to expose one port **210** and the staple **36** it contains. The operator operates the staple applier **38** to load the staple **36** from the exposed port **210**, as will be described in greater detail. After implanting the withdrawn staple **36**, the operator rotates the cover **212** to expose another one of the ports **210** and the staple **36** it contains. The operator again operates the staple applier **38** to load the staple **36** from the exposed port **210** for implantation. In this way, the cassette **34** aids the operator in loading individual staples on the staple applier **36** for implantation in a single fire (one at a time) fashion.

[**0123**] Further details of representative constructions of an endovascular staple **36** and companion cassette **34** can be found in co-pending, commonly owned United States patent



application Ser. No. 11/255,116, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation," which is incorporated herein by reference.

[0124] C. Endovascular Staple Applier

[0125] 1. Overview

[0126] The endovascular staple applier **38** (see FIGS. 9A and 9B) is a single use component that is supplied to the user within a package **48** in a sterile condition. In the illustrated embodiment, the endovascular staple applier **38**, a supply of endovascular staples **36**, and the staple cassette **34** are provided, for the sake of convenience, in a single package **48**. The endovascular staple applier **38** is sized and configured to pass through the lumen **168** of the steerable endovascular guide tube **164** and to be selectively operated to implant one or more endovascular staples **36** through the graft materials and vessel wall.

[0127] In the illustrated embodiment, the endovascular staple applier **38** comprises an applier catheter **182** and a control handle **184** coupled to the end of the applier catheter **182**. The applier catheter **182** carries a rotationally driven member **186** at its distal end. A battery powered motor **188** enclosed within the handle **184** is coupled to the driven member **186**, to selectively rotate the driven member **186** either in a forward (e.g., clockwise) direction and reverse (e.g., counterclockwise) direction. A control circuit **190** in the handle **184** is coupled to the motor **188** and to a forward control button **192** and a reverse control button **194** on the handle. The control circuit **190** governs operation of the operation of the motor **188** according to pre-programmed operating parameters in response to user commands received by manipulation of the buttons **192** and **194**.

[0128] In use (see FIGS. 10A to 10H), an endovascular staple **36** is loaded into the driven member **186** from the cassette **34**, e.g., by placing the distal end of the applier catheter **182** into an exposed staple port **210** in the cassette **34** and pressing the reverse control button **194** (FIG. 10A). The now loaded endovascular staple applier **38** is passed through the guide tube **164** of the endovascular guide **30** (FIG. 10B), which has been manipulated beforehand to be at an intended implantation site for the endovascular staple **36**.

[0129] Once the endovascular staple applier **38**, loaded with a staple, is positioned at the desired location (FIG. 10C), the physician presses the forward control button **192** to command rotation of the endovascular staple **36** in the forward direction (i.e., into tissue).

[0130] The control circuit **190** is desirably pre-programmed to require a two-stage implantation process. The first stage commands only a partial implantation of the staple **36**. In the first stage, the physician is allowed to ascertain whether the staple **36** is placed correctly at the desired location and that the desired located is suitable for implantation of the staple **36**. While in the first stage, the physician is allowed to retract the staple **36** (by pressing the reverse control button **194**) and to re-position the staple **36**.

[0131] The control circuit **190** commands a full final deployment of the staple **36** only after a deliberate entry of the second stage. In the first and second stages, the control circuit **190** generates audible tones and visual indicators e.g.,

blinking lights, during operation of the motor **188**, to indicate the position of the staple and available direction of motion.

[0132] Once the staple **36** is implanted, the endovascular staple applier **38** is withdrawn through the endovascular guide. The cassette cover **212** is rotated to reveal another staple port **210** and the staple **36** it contains. The staple applier **38** is reloaded. The endovascular guide **30** is manipulated to another desired implantation site, and the endovascular staple applier **38** (reloaded with another staple **36**) is redeployed and operated in the manner just described. The endovascular staple applier **38** is intended to be loaded, deployed, and reloaded in this way multiple times for a single patient.

[0133] Further details of representative constructions of an endovascular staple applier **38** and methods of its use can be found in co-pending, commonly owned U.S. patent application Ser. No. 11/254,950, filed Oct. 20, 2005, and entitled "Devices, Systems, and Methods for Prosthesis Delivery and Implantation, Including the Use of a Fastening Tool" which is incorporated herein by reference.

[0134] 2. Tracking the Relative Position of the Endovascular Staple Applier in the Endovascular Guide

[0135] Desirably, the endovascular staple applier **38** includes indicia **196**, which is visible to a naked eye (i.e., without resort to fluoroscopic visualization or other visualization techniques that augment human vision) the indicates the extent to which the driven distal end **186** of the applier catheter **182**, which carries the endovascular staple **36**, resides within the guide tube **164** of the steerable endovascular guide **30**. In particular, the visible indicia **196** indicates when the driven distal end **186** of the applier catheter **182** and the staple **36** it carries have arrived at a predetermined location within the guide tube near to but still within the distal end of the guide tube **164**. In this way (see FIG. 11C), the physician can quickly and accurately ascertain, without resort to fluoroscopic visualization, that the distal end of the applier catheter **182**, and the endovascular staple **36** it carries, are positioned wholly within the confines of the guide tube **164**, ready for final deployment, once the guide tube **164** is placed at the intended implantation site. The visible indicia **196** can also indicate to extend to which the driven distal end **186** of the applier catheter **182** has been extended outside the distal end of the guide tube **164**.

[0136] In the illustrated embodiment (see FIG. 11A), the indicia **196** comprises visible material or markings on the most proximal section of the applier catheter **182**, adjacent the handle **184**, that is marked or colored differently or is otherwise differentiated from the remainder of the applier catheter **182**. In a representative example, a prescribed length of contrast-colored tubing **198** can be placed at the most proximal end of the applier catheter **182**, where it exits the handle **184**.

[0137] The contrast-color tubing **198** has a prescribed length. The distal end of the tubing **198** marks a line of differentiation between the tubing **198** and the remainder of the applier catheter **182**. The length is selected so that the distal end of the tubing **198** registers with the insertion port/hemostatic seal **200** on the handle **166** of the steerable endovascular guide **30** (see FIG. 11B) when the driven distal end **186** of applier catheter **182** rests at a desired inset distance  $d$  within the distal end of the guide tube **164** (see FIG. 11C).

[0138] In this way, the indicia 196 indicates when the applier catheter 182 has reached a desired insertion depth within the guide tube, and is ready to be further advanced beyond the guide tube 164 to implant the endovascular staple 36. The contrast-color tubing 198 may further include additional markings M along its length by which the physician can gauge advancement of the applier catheter 182 beyond the endovascular guide 20.

[0139] The indicia 196 makes it possible for the physician, without resort to fluoroscopic visualization, to always know whether the endovascular staple 36 is within or outside the endovascular guide 30.

[0140] 3. The Motor Control Circuit

[0141] In a representative embodiment (see FIG. 13A), the control circuit 190 for the motor includes an optical encoder 250 coupled to a counting function 252, to enable counting the revolutions of the battery powered motor 188. The control circuit 190 also includes a sensing function 254 that senses the magnitude of current being drawn by the motor 188, for deriving torque that the motor 188 is encountering. The control circuit 190 also includes a comparison function 256 that compares the magnitude of the sensed torque (current) with set torque limits in either the forward or reverse direction, to change the state of operation should excess torque conditions be encountered.

[0142] The control circuit 190 carries embedded code, which expresses pre-programmed rules or algorithms under which different operation states are entered and motor command signals are generated in response to input from the external control sources and the counting, sensing, and comparison functions. The pre-programmed rules or algorithms of the control circuit 190 are designed to conserve power consumption, placing the circuit into a standby (wait) mode between staple loading and deployment cycles. This makes it possible to power up the staple applier just once and to leave the staple applier on during an entire procedure, avoiding time consumed in repeated power ups and power downs. The pre-programmed rules or algorithms of the control circuit also dictate that a desired sequence of steps is faithfully followed in loading, deploying, and reloading the staples, prompting the physician at the initiation of each step and not allowing any short-cuts or deviations along the way.

[0143] Features of the pre-programmed rules or algorithms of a representative control circuit 190 for the staple applier will now be described in greater detail.

#### Power Up/System Self-Check

[0144] In a representative implementation (see FIG. 13B), the pre-programmed rules or algorithms of the control circuit 190 enter a POWER UP state when an operator enters a prescribed power up command, e.g., when the operator presses and holds the reverse control button 194 for a prescribed amount of time. In the POWER UP state, the pre-programmed rules or algorithms of the control circuit 190 first check battery voltage against a set minimum. The POWER UP state proceeds if the battery voltage exceeds the set minimum. Otherwise, the pre-programmed rules or algorithms of the control circuit 190 enter a LOW BATTERY FATAL state.

[0145] Absent a LOW BATTERY FATAL state, the pre-programmed rules or algorithms of the control circuit 190

enable the optical encoder and drive the motor 188 in a forward direction for a set period of time. The counting and sensing functions of the control circuit 190 count the number of revolutions and sense forward current. If the forward current exceeds a set maximum current level (as determined by the comparison function), the pre-programmed rules or algorithms of the control circuit 190 enter a FORWARD TORQUE FATAL state. Otherwise, the sensed forward current is registered by the pre-programmed rules or algorithms of the control circuit 190 as a base line for forward torque.

[0146] Absent a FORWARD TORQUE FATAL state, the pre-programmed rules or algorithms of the control circuit 190 enable the optical encoder and counting function, and drive the motor 188 in a reverse direction for a set period of time. The counting function of the control circuit 190 counts the number of revolutions, while the sensing function senses reverse current. If the reverse current exceeds a set maximum current level (as determined by the comparison function), the pre-programmed rules or algorithms of the control circuit 190 enter a REVERSE TORQUE FATAL state. Otherwise, the sensed reverse current is registered by the pre-programmed rules or algorithms of the control circuit 190 as a base line for reverse torque.

[0147] Audible tones and visual indicators (e.g. blinking lights) coupled to the control circuit 190 desirably accompany the POWER UP state as the system self-check is accomplished. If no fatal states are encountered during the POWER UP sequence, the pre-programmed rules or algorithms of the control circuit 190 enter a READY TO LOAD state. The pre-programmed rules or algorithms of the control circuit 190 enable a ready to load prompt, e.g., blinking a reverse green arrow 202 (see FIG. 9B), to indicate to the user that the endovascular staple applier 38 is ready to load the first endovascular staple. If a fatal state is encountered, the pre-programmed rules or algorithms of the control circuit 190 enable a different prompt, e.g., illuminating a red error light 204 (see FIG. 9B), indicating that the endovascular staple applier 38 has encountered an error.

[0148] In addition, there are other checks that can be performed during the POWER UP state, including checking the encoder and the watchdog function for operation.

[0149] In a representative implementation, the pre-programmed rules or algorithms of the control circuit 190 allow the operator to clear the error state one time, e.g., by pressing the forward control button 192. After the error has been cleared, the self-check sequence of the POWER UP state will reinitiate. If during the second self check sequence, a fatal state is again encountered, the pre-programmed rules or algorithms of the control circuit 190 either disable the endovascular staple applier 38 from use, or again enable the error prompt. In the latter instance, the instructions for use 58 desirably will inform the operator not to use an endovascular staple applier 38 that has encountered a start-up error twice.

#### Ready to Load State: Load Staple

[0150] After the staple applier has been powered up and is in the READY TO LOAD state, the operator is able to load the endovascular staple by initiating a prescribed input command, e.g., by pushing the reverse control button 194. The distal end of the endovascular staple applier catheter

**182** is intended to be inserted into a staple port of the cassette at the time the input command is given.

[0151] When the prescribed input command is received, the pre-programmed rules or algorithms of the control circuit **190** command the motor **188** to rotate in a reverse direction for a set time period and generates a confirmation output with visual indicators (e.g., blinking the reverse green arrow **202**). The endovascular staple **36** will be drawn from the cassette **34** into the distal end of the staple applier **38**.

[0152] The sensing function of the control circuit **190** senses the magnitude of the current drawn by the motor **188** as the staple **36** is being loaded onto the distal end of the staple applier **38**. Once a prescribed amount of current has been reached, the pre-programmed rules or algorithms of the control circuit **190** consider the staple applier to have completed the loading state. The pre-programmed rules or algorithms of the control circuit **190** then automatically go into a UNWIND sequence, to reduce or eliminate amount of torque windup in the staple applier catheter and drive shaft developed during the LOAD state. The pre-programmed rules or algorithms of the UNWIND sequence run the motor in the reverse direction from the load direction a set number of turns and wait for a command input.

[0153] After the UNWIND sequence, the endovascular staple is presumed loaded, and the pre-programmed rules or algorithms of the control circuit **190** enter a READY TO APPLY state. The pre-programmed rules or algorithms of the control circuit **190** generate a confirmation output, e.g., audible and visual indicators (e.g., two short beeps and a forward green arrow **206** will blink (see FIG. 9B) to prompt the next step, which is to deploy the staple **36**.

[0154] The endovascular staple **36** is now loaded in the staple applier **38**, and the applier **38** can be removed from the cassette **34**. The physician is desirably urged by the instructions for use **58** to verify that the endovascular staple **36** is in place by visually inspecting the distal end of the applier **38**.

[0155] When the staple applier **38** has been powered up and is in the READY TO LOAD state, the pre-programmed rules or algorithms of the control circuit **190** desirably do not accept any command other than the command prescribed for loading (e.g., pushing the reverse control button **194**). If an operator provides a contrary command, e.g., by pushing on the forward command button **192**, the pre-programmed rules or algorithms of the command circuit will ignore the command. In this way, the pre-programmed rules or algorithms of the command circuit require an operator to follow a prescribed sequence in operating the staple applier.

#### Ready to Apply State: Deploy Staple

[0156] When the pre-programmed rules or algorithms of the control circuit **190** have entered the READY TO APPLY state, and the operator is ready to deploy the staple **36**, the operator is able to deploy the endovascular staple **36** by initiating a prescribed input command, e.g., by pressing the forward control button **192**. When the forward control button **192** is pushed, the pre-programmed rules or algorithms of the control circuit **190** command the motor **188** to rotate in a forward direction for a set number of rotations (sensed by the counting function), which, according to the pre-programmed rules or algorithms, are less than the num-

ber of rotations required to fully implant the staple. The pre-programmed rules or algorithms of the control circuit **190** suspend operation of the motor **188** at this point and await another input command. Thus, the pre-programmed rules or algorithms of the control circuit **190** only partially deploy the staple and generate a confirmation output, e.g., four beeps and/or alternatively blinking the forward and reverse arrows **202** and **206**, prompting the operator to make a choice. This indicates that the operator may chose to continue deployment or to withdraw the endovascular staple back into the applier.

[0157] If the operator inputs a prescribed withdraw command, e.g., by pushing the reverse control button **194**, the pre-programmed rules or algorithms of the control circuit **190** drive the motor **188** in the reverse direction for a set number of rotations (sensed by the counting function), to withdraw the staple **36**. The pre-programmed rules or algorithms of the control circuit **190** then return to the READY TO APPLY state.

[0158] If the operator inputs a prescribed complete the implantation command, e.g. by pushing the forward control button **192**, the pre-programmed rules or algorithms of the control circuit **190** will drive the motor **188** in the forward direction for a set number of rotations (monitored by the counting function), to complete the implantation of the staple. The pre-programmed rules or algorithms of the control circuit **190** generate a confirmation output, e.g., audio and visual indicators. The pre-programmed rules or algorithms of the control circuit **190** return to the READY TO LOAD state.

[0159] During the different operational states, the pre-programmed rules or algorithms of the control circuit **190** continue to check battery voltage against a set minimum. The operational states proceed as described as long as the battery voltage exceeds the set minimum. If, during an operational state the battery voltage falls below the set minimum, the pre-programmed rules or algorithms of the control circuit **190** enter a LOW BATTERY FATAL state.

[0160] D. The Instructions for Use

[0161] The instructions for use **58** can direct use of catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof.

[0162] FIGS. 12A to 12P show a representative embodiment of the steps that a representative instructions for use **58** can incorporate or direct.

[0163] In a representative embodiment, the instructions for use **58** may include the achievement of percutaneous vascular access by conventional methods into the femoral artery, for example. In this arrangement, the patient is placed on an imaging table, allowing fluoroscopic visualization from the aortic arch to the femoral artery bifurcations. Access is secured to both contralateral and ipsilateral branches by standard techniques using introducer sheaths (which can be supplied as part of the kit **40**). Using fluoroscopic guidance, access to the patient's abdominal aorta can be achieved with an appropriately sized guide wire through each femoral access sites.

[0164] 1. Position the Main Body Graft Assembly in the Targeted Endovascular Treatment Site

[0165] In this arrangement, the instructions 58 for use may include positioning of the main body 18 of the endovascular graft assembly to be deployed. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

[0166] (i) after flushing the main body delivery system 24 with heparinized saline, positioning the main body delivery system 24 within an aortic aneurysm over the guide wire via the ipsilateral femoral access site, which has been previously established in conventional fashion (FIG. 12A);

[0167] (ii) visualizing the proper rotation and orientation of the main body 18 using the ipsilateral and contralateral radiopaque markers on the main body 18. As previously described, the main body 18 includes three (3) short markers 76 on the ipsilateral side and two (2) long markers 74 on the contralateral side for this purpose. The two rows of markers 74 and 76 should be parallel to each other and not cross. The main body delivery system 24 can be rotated for re-alignment of the main body 18 of the graft assembly 12.

[0168] (ii) withdrawing the graft retention jacket 102 of the main body delivery system 24 by rotating the jacket retraction knob 124, until the knob 124 spins freely (which indicates that the rack and pinion mechanism has been released). This step only partially retracts the jacket 102 (about 63 mm), unsheathing the proximal stent 70, with the remaining portion of the main body 18 still constrained within the jacket 102. The instructions may note that the proximal sealing stent 70 will not open during retraction of the jacket 102.

[0169] (iii) completing the retraction of the graft retention jacket 102 by sliding the jacket retention slide 126 away from the patient. The instructions may note that the contralateral lumen of the main body 18 is now fully open, while the proximal sealing stent 70 and ipsilateral lumen remain collapsed and connected to the main body delivery system 24 (FIG. 12B);

[0170] (iv) verifying the position and orientation of the main body 18 using the radiopaque markers 74 and 76, to ensure that blood flow to the renal arteries is not obstructed and the main body 18 of the graft assembly 12 is not twisted; and

[0171] (v) opening the proximal sealing stent 70 by retracting the proximal sealing stent release slide 114 (FIG. 12C). The instructions may note that the proximal and distal ends of the main body 18 of the endovascular graft assembly 12 still remain secured to the main body delivery system 24. The physician thereby maintains control of the position and orientation of the main body 18 of the graft assembly 12.

[0172] 2. Deploy Endovascular Staples to Secure the Position of the Main Body of the Graft Assembly

[0173] The instructions for use 58 may next instruct securing of the position of the proximal end of the main body 18 of the endovascular graft assembly using endovascular staples 36. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

[0174] (i) placing an exchange length appropriately sized guide wire via the contralateral femoral access site into the

abdominal aorta (FIG. 12D). The main body 18 of the endovascular graft assembly includes distal end radiopaque markers that outline the opening of the contralateral lumen of the main body 18. The guide wire is to be placed through this opening and its position verified using standard endovascular techniques.

[0175] (ii) inserting the obturator 32 into the lumen 168 of the steerable endovascular guide 30.

[0176] (iii) using fluoroscopic guidance, advancing the steerable endovascular guide 30 with the obturator 32 over the guide wire into a position within the proximal neck of the aortic aneurysm (FIG. 12E). The C-shaped radiopaque marker 172 located at the distal tip of the steerable endovascular guide 30 will aid in fluoroscopic visualization.

[0177] (iv) removing the guide wire.

[0178] (v) removing the obturator 32 to open the lumen 168 of the steerable endovascular guide 30 for passage of the endovascular staple applier 38.

[0179] (vi) deflecting the distal end of the steerable endovascular guide 30 toward the first intended staple implantation area by rotating the deflector knob, while observing with fluoroscopic guidance. The instructions may note that the C-shaped fluoroscopic marker 172 will appear as a straight line when the catheter is oriented laterally, as a right curve “(” when oriented anteriorly, and as a left curve “)” when oriented posteriorly.

[0180] (vii) turning on the endovascular staple applier 38 by pressing and holding the reverse control button 194 for at least five (5) seconds. This initiates a self-checking sequence with audible tones and blinking lights. At the end of this sequence, the reverse green arrow 202 will be blinking, indicating that the endovascular staple applier 38 is ready to load the first endovascular staple 36. The instructions may note that, if at the end of the self check sequence, the red error light 204 is illuminated, the endovascular staple applier 38 has encountered an error. The error can be cleared by pressing the forward control button 192. After the error has been cleared, the self check sequence will initiate. If at the end of the second self check sequence, the red error light 202 is still illuminated, the endovascular staple applier 38 is not functional and should not be used.

[0181] (viii) after flushing the inner lumen of the endovascular staple applier 38 with heparinized saline via the flush port, loading the staple by pressing the reverse command button 194 on the handle. While the motor 188 is running, insert the distal end of the endovascular staple applier catheter 182 into the open staple port of the cassette 34. The reverse green arrow 202 will blink, and the endovascular staple will be drawn from the cassette into the distal end of the staple applier 38. When the endovascular staple 36 is loaded, an audible tone (e.g., two short beeps) will be heard, and the forward green arrow 206 will blink. This indicates that the endovascular staple 36 is now preloaded in the staple applier 38, and the applier 38 can be removed from the cassette 34. The instructions may urge the physician to verify that the endovascular staple 36 is in place by visually inspecting the distal tip of the applier 38.

[0182] (ix) while stabilizing the control handle 166 of the endovascular guide 30 relative to the patient, inserting the now-loaded endovascular staple applier 38 through the

hemostatic seal at the proximal end of the steerable endovascular guide control handle **166**. The instructions may direct the physician to observe the location of the visible contrast-color tubing **198** or other indicia on the proximal end of the applicator catheter **182** and to halt further insertion of the staple applicator **38** when the end of the contrast-color tubing **198** registers with the insertion port/hemostatic seal on the handle of the steerable endovascular guide (as shown in FIG. **11B**). This indicates that the distal end of applicator catheter **182** rests in a desired short inset distance within the distal end of the guide tube **164** (as shown in FIG. **11C**).

[**0183**] (x) inserting and positioning the steerable endovascular guide **30** at the desired location for endovascular staple implantation within a desired stapling zone, e.g., between the marker bands on the proximal sealing stent **70** and the bottom edge of the proximal sealing stent **70**. The instructions may note that the endovascular staples should be evenly distributed around the circumference of the proximal sealing stent **70**, typically about 4 to 6 endovascular staples per graft.

[**0184**] (xi) under fluoroscopic guidance, advancing the endovascular staple applicator **38** through the steerable endovascular guide **30** until the endovascular staple applicator **38** emerges from the distal end and contacts the endovascular graft assembly **12**. Slowly, continue to advance the endovascular staple applicator **38** until resistance is felt, indicating that the endovascular staple applicator **38** is firmly pushing against the main body **18** of the endovascular graft assembly **12** against the vessel wall.

[**0185**] (xii) using the control handle **184** of the endovascular staple applicator **38**, pressing the forward control button **192** for achieving the first stage of endovascular staple deployment. The endovascular step will partially deploy and pause. An audible tone is heard (e.g., four beeps) and the forward and reverse arrows **202** and **206** will alternatively blink, indicating that the operator may continue deployment or withdraw the endovascular staple **36** back into the applicator **38**. The instructions may note that, in the event of a power loss when the staple **36** is partially deployed, the staple may be removed by manually rotating the handle **184** and catheter **182** in a counter-clockwise direction until the staple **36** disengages from the graft and tissue. The staple applicator **38** can be removed from the endovascular guide **30** in this condition.

[**0186**] (xiii) If the endovascular staple **36** is not in the desired location, pressing the reverse control button **194** to re-house the staple inside the staple applicator **38** for re-positioning.

[**0187**] (xiv) If the endovascular staple **36** is in the desired position, completing the final stage of staple deployment by pressing the forward control button **192** (FIG. **12F**). When complete, an audible tone (e.g., three beeps) is heard and the reverse green arrow **202** will be blinking.

[**0188**] (xv) using fluoroscopy, carefully and slowly retracting the endovascular staple applicator **38** away from the graft wall to ensure it is released from the deployed staple.

[**0189**] (xvi) removing the endovascular staple applicator **38**, leaving the steerable endovascular guide **30** in place.

[**0190**] (xvii) using fluoroscopy, visually confirming that the endovascular staple **36** is in place.

[**0191**] (xviii) as needed, flush the steerable endovascular guide and the staple applicator with heparinized saline to prevent clotting in the lumens.

[**0192**] (xix) rotating the head of the cassette **34** (as shown in FIG. **8C**) clockwise to expose the next endovascular staple port. Load the next endovascular staple in the manner described above.

[**0193**] (xx) repositioning the steerable endovascular guide **30** to the next desired implantation site for an endovascular staple **36**. Desirably, the physician straightens the steerable endovascular guide **30** between rotating in within the main body **18**, to prevent accidental dislodgment or movement of the main body **18**.

[**0194**] (xxi) deploying the next endovascular staple **36** through the steerable endovascular guide **30** in the manner described above. Typically, 4 to 6 endovascular staples, evenly distributed about the circumference of the main body **18**, will serve to secure the position of the main body **18** within the vessel (FIG. **12G**).

[**0195**] (xxii) after deployment of the last endovascular staple, removing the endovascular stapler applicator **38** from the steerable endovascular guide **30**.

[**0196**] (xxiii) re-advancing the obturator **32** and then the guide wire into the steerable endovascular guide.

[**0197**] (xxiv) removing the steerable endovascular guide **30** and the obturator **32**, leaving the guide wire in position.

[**0198**] 3. Deploy the Contralateral Lumen Extension

[**0199**] The instructions for use **58** may next include the deployment of the contralateral lumen extension **22** of the endovascular graft assembly. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

[**0200**] (i) after flushing with heparinized saline, advancing the contralateral lumen extension delivery system **28** over the guide wire in the contralateral femoral access site (FIG. **12H**).

[**0201**] (ii) using fluoroscopic guidance, aligning the proximal marker **94** on the lumen extension **22** with the insertion depth marker **92** located medially on the main body **18**.

[**0202**] (iii) holding the lumen extension delivery system **28** stable relative to the patient, retracting the jacket retraction slide **162** away from the patient to unsheath the lumen extension **22** (FIG. **12I**). The distal end of the lumen extension **22** will deploy. The proximal end of the lumen extension **22** will remain collapsed and secured to the delivery system **28**.

[**0203**] (iv) retracting the proximal stent release slide **156** to release the proximal end of the lumen extension **22** and complete the deployment of the lumen extension (FIG. **12J**).

[**0204**] (v) re-jacketing the lumen extension delivery system by holding the jacket retention slide **162** and slowly retracting the delivery system **28**, until the nosecone seals into the proximal end of the jacket **150**.

[**0205**] (vi) maintaining forward pressure on the jacket retention slide **162**, removing the lumen extension delivery system **28** from the patient, leaving the guide wire and femoral access introducer sheath in place.

**[0206]** 4. Complete the Deployment of the Main Body

**[0207]** The instructions for use **58** may next include the completion of the deployment of the main body **18** of the endovascular graft assembly, which remains in a secured but partially deployed condition during the deployment of the contralateral lumen extension **22**, as above described. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

**[0208]** (i) moving to the ipsilateral femoral access site, where the main body delivery system **24** resides.

**[0209]** (ii) releasing the stabilizing arms **106** from the graft by retracting the graft release slide **116** on the handle of the delivery system away from the patient (FIG. **12K**).

**[0210]** (iii) releasing the main body ipsilateral lumen from the delivery system by retracting the ipsilateral release slide **118** on the handle away from the patient (FIG. **12L**). The main body **18** is now fully released (FIG. **12K**).

**[0211]** (iv) rejacketing the main body delivery system **24** by holding the jacket retention slide **126** and slowly retract the main body **18** delivery system, until the nosecone seals into the proximal end of the jacket **102**.

**[0212]** (vi) maintaining forward pressure on the jacket retention slide **126**, remove the main body delivery system **24** from the patient (FIG. **12L**), leaving the guide wire and femoral access introducer sheath in place.

**[0213]** 5. Deploy the Ipsilateral Lumen Extension

**[0214]** The instructions for use **58** may next include the deployment of the ipsilateral lumen extension **20** of the endovascular graft assembly **12**. The instructions may include a series of steps that can be followed to carry out this portion of the procedure. These steps may include:

**[0215]** (i) after flushing with heparinized saline, advancing the ipsilateral lumen extension delivery system **26** over the guide wire in the ipsilateral femoral access site (FIG. **12M**).

**[0216]** (ii) using fluoroscopic guidance, aligning the proximal marker **92** on the lumen extension **20** with the insertion depth marker **82** located medially on the main body **18**.

**[0217]** (iii) holding the lumen extension delivery system stable relative to the patient, retracting the jacket retraction slide **162** away from the patient to unsheath the lumen extension **20** (FIG. **12N**). The distal end of the lumen extension **20** will deploy. The proximal end of the lumen extension **20** will remain collapsed and secured to the delivery system **26**.

**[0218]** (iv) retracting the proximal stent release slide **156** to release the proximal end of the lumen extension **20** and complete the deployment of the lumen extension (FIG. **12O**).

**[0219]** (v) rejacketing the lumen extension delivery system **26** by holding the jacket retention slide **162** and slowly retracting the delivery system **26**, until the nosecone seals into the proximal end of the jacket **150**.

**[0220]** (vi) maintaining forward pressure on the jacket retention slide **162**, removing the lumen extension delivery system **26** from the patient, leaving the guide wire and femoral access introducer sheath in place.

**[0221]** 6. Completion of the Procedure

**[0222]** The instructions for use **58** may next include the completion of the procedure. The instructions may include a

series of steps that can be followed to carry out this portion of the procedure. These steps may include:

**[0223]** (i) performing post-implant aortic angiography to evaluate the implantation.

**[0224]** (ii) checking for endovascular leaks around the endovascular graft assembly. If a leak is observed, standard endovascular techniques can be used to resolve. Additional staples may be placed, in the manner described above.

**[0225]** (iii) checking for proper location, blood flow, and patency of the endovascular graft assembly.

**[0226]** (iv) removing the guide wires and femoral access sheaths and close the femoral arteriotomies according to standard practice (FIG. **12P**).

**[0227]** It is to be appreciated that the general steps just described do not necessarily need to follow the order in which they were described. It is also to be appreciated that fasteners may be applied to the lumen extensions as well to connect the lumen extensions to the iliac arteries.

**[0228]** It will also be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

**[0229]** The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

**[0230]** The desired embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

I/We claim:

1. A system comprising

a guide defining an access path into a vessel or hollow body organ and including a distal region having a terminus, and

a fastener applier comprising a catheter sized and configured for introduction along the access path and including an actuated member that is selectively operable to generate an implantation force to implant within tissue at least one fastener, the catheter including indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and is therefore out of contact with tissue.

2. A system according to claim 1

wherein the guide includes a passage that defines the access path, and

wherein the catheter is sized and configured for introduction through the passage, and

wherein the indicia marks when the actuated member rests at a desired distance inset within the passage from terminus of the distal region.

**3.** A system according to claim 2

wherein the passage comprises an interior lumen.

**4.** A system according to claim 1

wherein the access path includes a proximal region having a visible entry to receive the catheter, and

wherein the indicia includes a visible marking on the catheter that visibly registers with the entry of the proximal region when the actuated member rests at the desired distance short of the terminus of the distal region.

**5.** A system according to claim 1

wherein the distal region is deflectable.

**6.** A system according to claim 1

wherein the at least one fastener comprises a tissue-piercing fastener.

**7.** A system according to claim 6

wherein the tissue-piercing fastener comprises a helical fastener.

**8.** A system comprising

a guide defining an access path into a vessel or hollow body organ and including a distal region having a terminus,

a fastener applier comprising a catheter sized and configured for introduction along the access path and including an actuated member that is selectively operable to generate an implantation force to implant within tissue at least one fastener, the catheter including indicia visible to a naked eye to mark when the actuated member rests at a desired distance along the access path short of the terminus of the distal region and out of contact with tissue, and

instructions for using the guide and fastener applier comprising introducing the guide to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists, establishing the access path to a desired fastening site at the target site by manipulating the guide to orient the terminus with respect to the desired fastening site, introducing the actuated member along the access path toward the terminus; and viewing the indicia with a naked eye to detect when the actuated member rests at a desired distance along the access path short of the terminus of the distal region.

**9.** A method comprising

(i) providing a system as defined in claim 1 or 8

(ii) introducing the guide to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists;

(iii) establishing the access path to a desired fastening site at the target site by manipulating the guide to orient the terminus with respect to the desired fastening site;

(iv) introducing the actuated member along the access path toward the terminus; and

(v) viewing the indicia with a naked eye to detect when the actuated member rests at a desired distance along the access path short of the terminus of the distal region.

**10.** A method according to claim 9

(vi) after (v), advancing the actuated member to the terminus of the distal region, and

(vii) operating the actuated member to generate an implantation force to implant the into tissue at the desired fastening site.

**11.** A method according to claim 9

wherein (iii) includes rotating the guide and/or deflecting the distal region.

**12.** An apparatus comprising

a fastener applier comprising a catheter sized and configured for introduction along an access path into a vessel or hollow body organ and including an actuated member that is selectively operable in a first direction to load at least one fastener and in a second direction to generate an implantation force to implant the fastener within tissue,

an electrically powered drive member coupled to the driven member, and

a controller coupled to the drive motor including a LOAD state including means operable in response to an input command for delivering electrical current to the drive member to drive the driven member in a first direction to load a fastener onto the driven member, means for sensing electrical current delivered to the drive member while loading the fastener onto the driven member, and means for terminating delivery of electrical current to the driven member when a prescribed amount of current is delivered to the drive member, thereby terminating the LOAD state.

**13.** An apparatus according to claim 12

wherein the controller includes an UNWIND state including means, operative after termination of the LOAD state, for delivering electrical current to the drive member to drive the driven member in the second direction, means for sensing a period of operation of the driven member in the second direction sufficient to reduce torque windup on the driven member during the LOAD state, means for terminating delivery of electrical current to the driven member after the period of operation, thereby terminating the UNWIND state.

**14.** An apparatus according to claim 13

wherein the controller includes a READY TO APPLY state including means, operative after termination of the UNWIND state, to prompt a prescribed implant fastener input command.

**15.** An apparatus according to claim 14

wherein the READY TO APPLY state includes means operable in response to the prescribed implant fastener input command for delivering electrical current to the drive member to drive the driven member in the second direction, means for sensing a partial period of operation of the driven member in the second direction less

than a full period of operation sufficient to fully implant the fastener in tissue, means for terminating delivery of electrical current to the driven member after the partial period of operation, and means for prompting entry of either a continue implantation input command or a terminate implantation implant command.

16. An apparatus according to claim 15

wherein the READY TO APPLY STATE includes means, operative in response to the continue implantation command, for delivering electrical current to the drive member to drive the driven member in the second direction sufficient to fully implant the fastener in tissue.

17. An apparatus according to claim 15 or 16

wherein the READY TO APPLY STATE includes means, operative in response to the terminate implantation command, for delivering electrical current to the drive member to drive the driven member in the first direction sufficient to withdraw the fastener from tissue.

18. A method comprising

- (i) providing the apparatus as defined in claim 12,
- (ii) operating the fastener applier in the LOAD state to load a fastener onto the driven member, and
- (iii) after (ii), introducing the fastener applier to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists.

19. A method comprising

- (i) providing the apparatus as defined in claim 13,
- (ii) operating the fastener applier in the LOAD and UNWIND states to load a fastener onto the driven member, and
- (iii) after (ii), introducing the fastener applier to a location at a target site within a vessel or hollow body organ where a diseased or damaged section exists.

20. A seal assembly a first seal component with at least one guide tube formed therein,

a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component,

a septum sandwiched between the first and second seal components, the septum accommodating passage of a control filament from one the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

21. An assembly according to claim 20

wherein at least one of the first and second seal components is substantially rigid.

22. An assembly according to claim 21

wherein the septum comprises a soft material.

23. An assembly according to claim 21

wherein the septum comprises silicone rubber.

24. An assembly according to claim 21

wherein the septum comprises a gasket.

25. An assembly according to claim 20

wherein both of the first and second seal components are substantially rigid.

26. An assembly according to claim 25

wherein the septum comprises a soft material.

27. An assembly according to claim 25

wherein the septum comprises silicone rubber.

28. An assembly according to claim 25

wherein the septum comprises a gasket.

29. An apparatus comprising

a catheter assembly including an operative element that, in use, is exposed to a body fluid,

a control element,

a control filament coupled at one end to the control element and to an opposite end to the operative element, and

a seal assembly between the control element and the operative element through which the control filament passes to prevent contact between the body fluid and the control element, the seal assembly comprising

a first seal component with at least one guide tube formed therein,

a second seal component with at least one guide tube formed therein, the second seal component registering with the first seal component with at least one guide tube in the second component coaxially aligned with at least one guide tube in the first component, and

a septum sandwiched between the first and second seal components, the septum accommodating passage of the control filament from one the coaxially aligned guide tubes, through the septum, to the other one of the coaxially aligned guide tubes, thereby providing a fluid seal for the control filament.

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