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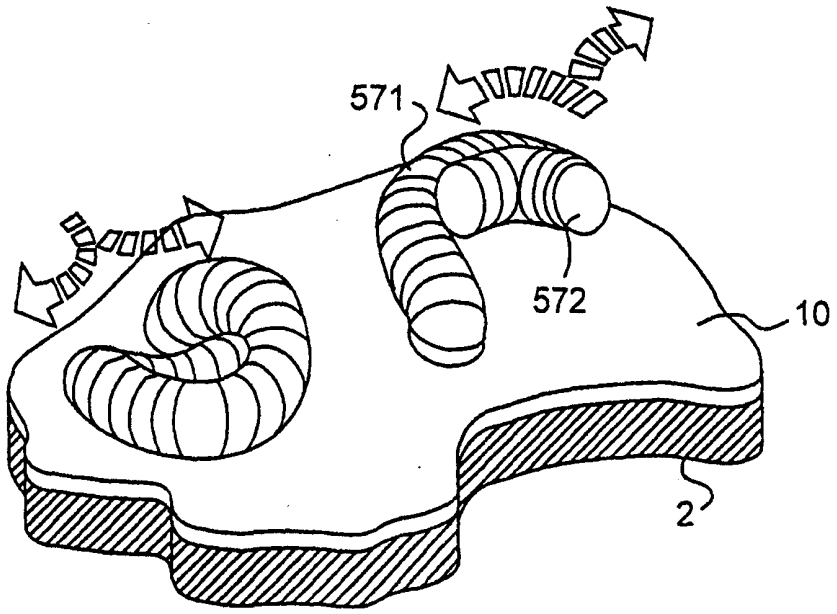

(57) Abstract

A fastener (510) comprises a flexible fastening assembly for securing a surgical component (20) to the vessel wall (2) under a compressive force. The fastening assembly has a first portion (542) located on one side of the surgical component (20), and the vessel wall (2); a second portion (543) located on another side of the surgical component (20); the vessel wall (2), and an intermediate portion (541) connecting to the first portion (542), and the second portion (543); the intermediate portion (541) extending through the vessel wall (2), and the surgical component (20). The fastener (510) further includes a control assembly for controlling the compression of the fastener (510).

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SURGICAL FASTENER

Background of the Invention

1. Field of the Invention

The present invention relates to methods and apparatus for the repair of abdominal aortic aneurysms using a novel prosthetic tube graft within the abdominal aorta.

2. Description of Related Art

An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. Such an aneurysm is often located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because no statistical benefit exists in performing such procedures.

Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm. This intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aortic aneurysm. A prosthetic device, typically a synthetic tube graft, is used for this purpose. The graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated and the surgery carries attendant risk, certain patients may not be able to tolerate the stress of intra-abdominal surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with intra-abdominal surgical intervention.

In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

Kornberg discloses an aortic graft comprising a flexible tubular material having a plurality of struts to lend the graft stability and resiliency. The struts have angled hooks with barbs at their upper ends which are securely attached to the inside of the aorta above the aneurysm. Kornberg's graft is inserted using a tubular device also disclosed in his patent. Kornberg, however, only anchors the proximal end of the graft. Kornberg claims that the downward flow of blood holds the distal graft securely in place, so that no mechanical attachment is necessary distally. The blood pressure in the abdominal aorta, however, is

typically in the magnitude of 130 mm of mercury (Hg). In spite of the direction of flow of blood through the graft, proximal to distal, substantial back pressure within the aneurysm will result unless the distal end is also mechanically attached to the aorta in a manner that prevents substantial leakage of blood between the graft and the aorta. Without distal attachment, the device of Kornberg will not effectively exclude the weakened arterial wall at the site of the aneurysm from the forces and stress associated with the blood pressure.

Lazarus discloses a grafting system that employs a plurality of staples mounted in the proximal end of the graft. Lazarus's staples are forced through the aorta wall by means of a balloon catheter. As does Kornberg, Lazarus discloses staples mounted only in the proximal end of the graft. There is no teaching or suggestion in Lazarus, U.S. Patent No. 4,787,899 as to the desirability of, let alone means for, mechanically attaching the graft to the distal aorta below the level of the aneurysm.

Taheri discloses an articulatable stapler for implanting a graft in a blood vessel. The stapler is in the form of an elongated catheter with a plurality of segments mounted on the distal end of the catheter. The segments have beveled faces and are connected to each other by hinges. A stylet runs through the catheter to the most distal segment. The most distal segment is moved, in conjunction with the other segments, into a firing position that is substantially perpendicular to the main catheter body by the action of pulling on the stylet. The staple is implanted by using two other stylets which act as fingers to bend the staple into its attachment position.

Taheri, however, appears to be a single-fire design which can only implant one staple at a time. After each stapler is implanted, Taheri's design apparently requires that the catheter be removed before another staple is loaded. In addition, Taheri's does not teach or suggest an appropriate density of staples to secure a graft against the pulsatile blood flow of the aorta. Pressures within the aorta range from 120 mm Hg pressure to 200 mm Hg pressure. Without adequate attachment, the graft may leak around the edges continuing to allow life threatening pressures to develop in the aneurysm, and may not even remain in place.

Hence, although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to

repair aortic aneurysms, none of the systems that have been developed effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with circulation. None of the devices disclosed in the references provide a reliable and quick means to reinforce an aneurysmal artery. In addition, all of the prior references require a sufficiently large section of healthy aorta surrounding the aneurysm to ensure attachment of the graft. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain a graft's attachment means. However, when an aneurysm is located near the iliac arteries, there may be an ill-defined neck or no neck below the aneurysm. Such an ill-defined neck would have an insufficient amount of healthy aortic tissue to which to successfully mount a graft. Furthermore, much of the abdominal aorta wall may be calcified which may make it extremely difficult to attach the graft to the wall.

There are a number of shortcomings with the presently available graft products and their fixation within the abdominal aorta. Although sizing of "tube" or "bifurcated" grafts is radiographically assessed prior to surgery, it is necessary for the surgeon to have a large selection of graft lengths and diameters on hand to ensure an appropriate surgical outcome. Additional shortcomings include the placement of a "circular" profile graft with an associated fixation device within an essentially "ovoid" profile vessel and the use of attachment means which fasten only to the insubstantial, structurally compromised (diseased) intima and media levels of the vessel wall. Research has exposed yet another problem which indicates that the necks of the post-surgical aorta increase in size for approximately twelve months, regardless of whether the aneurysm experiences dimensional change. This phenomenon can result in perigraft leaks and graft migration.

There are a number of currently available scanning technologies that facilitate the pre-surgical assessment of abdominal aortic aneurysms. These include: computed tomography; magnetic resonance angiography; computed angiography; sonography including Doppler, and color flow; abdominal aortography; contrast arteriography; magnetic resonance imaging (i.e., MRI); and echocardiography. The images gained by these scanning technologies are informative, but are open to multiple interpretations as they do not provide direct viewing of the portion of the aorta to be repaired. Furthermore, the performance of the

procedures for these technologies may be injurious to the patient and in other instances impractical.

Objects of the Invention

It is therefore an object of the present invention to provide a new and improved method of repairing an abdominal aortic aneurysm.

It is another object of the present invention to provide an apparatus for facilitating the repair of an abdominal aortic aneurysm.

It is another object of the present invention to provide a graft for the repair of an abdominal aortic aneurysm.

It is an object of the present invention to provide an apparatus for the repair of the aneurysm that facilitates direct viewing of the area of the aneurysm to be repaired.

It is another object of the present invention to reduce the amount of damage to the aorta and associated vasculature while repairing the aneurysm.

It is another object of the present invention to facilitate direct viewing of the vessel wall surface to assist the medical practitioner (i.e., surgeon or interventional radiologist) in the repair of vessel.

It is an object of the present invention to exclude an aneurysm from the circulatory system.

It is an object of the present invention to create a device for the repair of an aneurysm that can, without negative consequences, navigate the vessels extending to and from the aorta.

It is another object of the present invention to localize a graft within the abdominal aorta between the proximal and distal ends of the aorta.

It is an object of the present invention to firmly fasten a graft to the adventitia of the vessel wall to prevent migration of the graft.

It is another of object of the present invention to create a device to clearly visualize the surgical site during repair of the aneurysm.

It is another object of the present invention to create a uniform universal graft that is sized for use in a range of patients.

It is another object of the present invention to create a graft whose performance is not adversely effected by post surgical dimensional changes of the aortic necks.

It is another object of the present invention to create a device for the repair of the abdominal aortic aneurysm which may in addition to the classic femoral/common iliac introduction, also may be introduced via the axillary and/or brachial artery, which has not previously been contemplated.

It is another object of the present invention to provide a seal detail within an introducer sheath device that will significantly reduce blood loss during the repair procedure.

It is another object of the present invention to provide fastener assemblies that replace sutures.

It is another object of the present invention to provide a device that is capable of on board storage of a procedure specific quantity of fasteners so that it is not necessary to remove the device to reload during the repair procedure.

It is another object of the present invention to create a graft and a device for the repair of an aneurysm that reduces the invasiveness of current surgical procedures.

It is another object of the present invention to create a graft that is not dimension dependent (i.e., diameter/length) and which is adaptable to the patient environment.

Summary of the Invention

The present invention is directed to a fastener for use during a surgical procedure for securing a surgical component to a vessel wall. The fastener includes a flexible fastening assembly for securing the surgical component to the vessel wall under a compressive force. The fastening assembly has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to the first portion and the second portion, the intermediate portion extending through the vessel wall and the surgical component. The first portion, second portion and the intermediate portion act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall. The fastening assembly further includes at least one supplemental fastening assembly for securing the surgical component to the vessel wall, the

at least one supplemental fastening assembly being located on at least one of the first portion and the second portion.

The fastening assembly may include at least one spring assembly, and the supplemental fastening assembly may include at least one supplemental spring assembly. In accordance with present invention each of the first portion, the second portion and the at least one supplemental spring assembly may extend substantially parallel to the vessel wall.

The fastening assembly may a plurality of entwined coil springs.

The supplemental fastening assembly may include a first supplemental spring assembly connected to the first portion of the fastening assembly and a second supplemental spring assembly connected to the second portion of the fastening assembly. The fastener may further include an assembly for connecting at least a portion of the at least one supplemental spring assembly to the spring assembly.

The fastener has a first orientation for inserting the fastener through the vessel wall and the surgical component, and a second orientation when the fastener is in a secured position. The spring assembly and the at least one supplemental spring assembly may be aligned along a longitudinal axis when the fastener is in the first orientation. The spring assembly and the at least one supplemental spring assembly are displaced with respect to one another from the longitudinal axis when the fastener is in the second orientation.

The fastener is in tension when in the first orientation and relaxed when in the second orientation, the fastener further includes a control assembly for controlling the compression of the fastener in the first orientation. The spring assembly and the at least one supplemental spring assembly may be coil springs having a plurality of individual coils therein. The control assembly may be located between a plurality of the individual coils.

The control assembly may include a suture fiber or material disposed between the plurality of the individual coils. The suture material may be formed from a dissolvable material, such that the suture material dissolves after the fastener is in its second orientation.

The control assembly may include a dissolvable material formed on the fastener assembly and the supplemental fastener assembly.

The present invention is also directed to a fastener for use during a surgical procedure for securing a surgical component to a vessel wall. The fastener includes a flexible fastening assembly for securing the surgical component to the vessel wall under a compressive force. The fastening assembly has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to the first portion and the second portion, the intermediate portion extending through the vessel wall and the surgical component. The first portion, second portion and the intermediate portion act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall. The fastening assembly has a first orientation for inserting the fastening assembly through the vessel wall and the surgical component, and a second orientation when the fastening assembly applies the compressive force to the surgical component and the vessel wall. The fastening assembly may be in tension when in the first orientation. The fastener further includes a control assembly for controlling the compression of the fastening assembly in the first orientation.

The present invention is also directed to an attachment assembly for securing a graft to repair a vessel having an aneurysm therein. The vessel has a proximal neck or end and a distal neck or end. The graft has a proximal end and a distal end. The attachment assembly comprises attachment means for securing the distal end of the graft to the distal end of the vessel. The attachment assembly also comprises graft attachment means for securing the distal end of the graft to the attachment means. The attachment means permits expansion of the vessel necks and/or ends without negatively impacting the connection between the graft and the vessel wall. The attachment assembly may comprise a radially extending cuff. The attachment means may comprise at least one graft attachment tube for receiving the distal end of the graft. The attachment assembly is preferably formed from a flexible material.

The present invention is also directed to a repair graft assembly for repairing a vessel having an aneurysm therein. The repair graft assembly comprises a graft assembly for creating a passageway within the vessel and thereby reinforcing it. The graft assembly has a proximal end and a distal end. The repair graft assembly also comprises an attachment

assembly. The attachment assembly comprises attachment means for securing the distal end of the graft to the distal end of the vessel. The attachment assembly also comprises graft attachment means for securing the distal end of the graft to the attachment means. The attachment means permits expansion of the vessel without negatively impacting the connection between the distal end of the graft and the vessel. The attachment assembly may comprise a radially extending cuff. The attachment means may comprise at least one graft attachment tube for receiving the distal end of the graft. The repair graft assembly is preferably formed from a flexible material. The attachment means of the repair graft assembly preferably comprises at least one graft attachment tube for receiving the distal end of the graft assembly.

The repair graft assembly comprises proximal attachment means for securing the proximal end of the graft to the proximal neck or end of the vessel. The proximal attachment means comprises a radially extending cuff.

The present invention is also directed to a visualization apparatus for viewing the interior of a vessel prior to, during and following a surgical procedure. The visualization apparatus comprises a housing and image creating means for creating an image of the interior of the vessel from within the vessel. The image creating means is located within the housing. The image creating means comprises illumination means for illuminating an area within the vessel for viewing by a user. The image creating means also comprises diverting means for temporarily diverting blood away from the viewing area. The image creating means also comprises optical viewing means for viewing the area within the vessel.

The illumination means may comprise at least one optical fiber for illuminating the area within the vessel.

The visualization means comprises means for supplying a fluid to the area to direct the flow of blood away from the viewing area, and return means for draining the fluid from the area to permit the return of blood.

The optical viewing means comprises an optical fiber. The optical viewing means may alternatively comprise scanning means for scanning an area of the vessel for creating a

non optical image of the area. The scanning means may produce an ultrasound image. The scanning means may comprise a scanning catheter.

The present invention is also directed to a penetration apparatus for use in creating a plurality of treatment specific holes in the sometimes calcified vessel wall to aid in the attachment of a graft. The penetration apparatus comprises a housing, and penetration means for use in creating a plurality of treatment specific holes in the sometimes calcified vessel wall. The penetration means is located within the housing. The penetration means may comprise a laser. The laser may be an acousto optical laser or a Holmium-Yag laser. Alternatively, the penetration means may comprise a piezoelectric penetrating device. The penetration apparatus may also comprise insertion means for inserting a fastener through the opening in the vessel to secure a surgical component (e.g., graft and prosthesis) to the vessel. The penetration apparatus may also comprise secondary penetration means for forming at least one opening adjacent the opening in the sometimes calcified vessel wall. The secondary penetration means may comprise a laser or piezoelectric device. The secondary penetration means stabilizes the penetration apparatus as the insertion means inserts a fastener in the opening. The penetration apparatus may further comprise visual tracking means for identifying the location of the penetration apparatus within the vessel.

The present invention is also directed to repair apparatus for repairing a vessel during a surgical procedure. The apparatus comprises a housing and at least one of a penetration apparatus for use in forming an opening in a vessel having a calcified portion and a visualization apparatus for viewing an interior of a vessel during a surgical procedure. The penetration apparatus comprises a penetration housing, and penetration means for forming treatment specific holes in the sometimes calcified vessel wall. The visualization apparatus comprises a visualization housing, and image creating means for creating an image of the interior of the vessel from within the vessel.

The present invention is also directed to a fastener for use in a surgical procedure for securing a surgical component to a vessel. The fastener comprises fastening means for securing the surgical component to the vessel under a compressive force. The fastening means is either a wire fabrication or a coil spring fabrication.

The present invention is also directed to an introducer sheath device for use during a surgical procedure for introducing surgical components into a vessel. The introducer sheath device comprises a housing having a passageway that permits the passage of the surgical components therein. The introducer sheath device also comprises sealing means at the proximal end for preventing the loss of blood from the vessel during the insertion and subsequent removal of surgical components during the surgical procedure. The sealing means comprises a sealing cavity. The sealing cavity is filled with a sealing material, which forms a seal around the surgical components as they are inserted and removed from the introducer sheath device during the surgical procedure. The introducer sheath device further comprises positioning means for maintaining the position of the introducer sheath device within the vessel. The positioning means preferably comprises an inflatable cuff positioned at the distal end of the introducer sheath device.

Brief Description of the Drawings

The invention will now be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

Fig. 1 is a perspective view of a prosthetic bifurcated tube graft and bifurcated cuff according to a preferred embodiment of the present invention;

Fig. 2 is a perspective view of a prosthetic bifurcated tube graft and bifurcated cuff according to another embodiment of the present invention;

Fig. 3 is a perspective view of the prosthetic bifurcated tube graft and bifurcated cuff of Fig. 1 secured within the abdominal aorta;

Fig. 4 is a perspective view of the prosthetic bifurcated tube graft and bifurcated cuff of Fig. 2 secured within the abdominal aorta;

Fig. 5 is a perspective view of a prosthetic tube graft and cuff according to another embodiment of the present invention;

Fig. 6 is a perspective view of the prosthetic tube graft and cuff of Fig. 5 secured within the abdominal aorta;

Fig. 7 is a perspective view of the connection between the prosthetic tube graft and the cuff;

Fig. 8 is a side view of the prosthetic tube graft of Fig. 6 secured to a secondary cuff;

Fig. 9 is an exploded view of the connection between the prosthetic tube graft and secondary cuff as shown in Fig. 8;

Fig. 10 is a perspective view of attachment cuffs according to another embodiment of the present invention;

Fig. 11 is a perspective view of the flexible attachment cuff according to embodiments of the present invention;

Fig. 12 is a perspective view of the attachment cuffs of Fig. 10 having a prosthetic tube graft secured between the attachment cuffs;

Fig. 13 is a perspective view of an IntraVascular Endoscopy (I'VE) based repair system according to an embodiment of the present invention containing an embodiment of a visualization device according to the present invention;

Fig. 14 is an end view of the IntraVascular Endoscopy (I'VE) based repair system according to the embodiment of Fig. 13;

Fig. 15 is an end view of the visualization device depicted in Fig. 13;

Fig. 16 is another perspective view of the IntraVascular Endoscopy (I'VE) based repair system illustrating the guide wire and articulation cables exiting the housing of the repair system;

Fig. 17 is a perspective view of an IntraVascular Endoscopy (I'VE) based repair system according to an embodiment of the present invention containing an embodiment of a penetration device according to the present invention and an embodiment of a fastener cartridge according to the present invention;

Fig. 18 is a perspective view of an I'VE based repair system according to another embodiment of the present invention containing a penetration device and fastener cartridge according to the present invention;

Fig. 19 is a perspective view of an I'VE based repair system according to the embodiment of Fig. 18 containing a penetration device and fastener cartridge according to another embodiment of the present invention;

Fig. 20 is a perspective view of an I'VE based repair system according to another embodiment of the present invention containing a penetration device and fastener cartridge according to the present invention;

Fig. 21 is an end view of the penetration device according to an embodiment of the present invention;

Fig. 22 is an end view of the penetration device according to another embodiment of the present invention;

Fig. 23 is an end view of the fastener cartridge according to the embodiment of Fig. 17;

Fig. 24 is a perspective view of an advancing mechanism of a penetration device according to an embodiment of the present invention;

Fig. 25 is a schematic view of another advancing mechanism of a penetration device and fastener cartridge according to another embodiment of the present invention;

Figs. 26 and 27 are perspective views of an IntraVascular UltraSound (IVUS) based repair apparatus according to another embodiment of the present invention containing a visualization device and a penetration device;

Fig. 28 is a cross sectional view of a housing according to an embodiment of the present invention;

Fig. 29 is an end view of a penetration device depicted in Fig. 26;

Figs. 30 and 31 are perspective views of a wire fastener for securing the cuff detail of a surgical cuff to a vessel wall according to an embodiment of the present invention;

Figs. 32 and 33 are perspective views of a wire fastener according to another embodiment of the present invention for securing the cuff detail of a surgical cuff to a vessel wall;

Figs. 34 and 35 are perspective views of a wire fastener according to another embodiment of the present invention for securing the cuff detail of a surgical cuff to a vessel wall;

Figs. 36, 37, 38, 39, 40 and 41are perspective views of a fastener according to another embodiment of the present invention for securing the cuff to a vessel wall;

Fig. 42 is a schematic view of an embodiment of the penetration device according to the present invention having fasteners, as shown in Figs. 34, 37, 38 and 39 stored thereon;

Fig. 43 is a schematic view of an another embodiment of the penetration device according to the present invention having fasteners, as shown in Figs. 36, 37, 38 and 39 stored therein;

Figs. 44 and 45 are perspective views illustrating the fastener attachment of the cuff detail to the vessel wall using a fastener as shown in Figs. 34 and 35 according to an embodiment of the present invention;

Fig. 46 is a perspective view of another embodiment of an IntraVascular Endoscopy (I'VE) based repair system according to an another embodiment of the present invention;

Fig. 47 is a perspective view on an introducer sheath device according to the present invention;

Fig. 48 is a cross sectional view of a seal assembly for the introducer sheath device according to an embodiment of the present invention.

Figs. 49, 50, and 51 are perspective views of a fastener according to another embodiment of the present invention.

Figs. 52 and 53 are perspective views of a fastener according to another embodiment of the present invention for securing the cuff to a vessel wall;

Fig. 54 is a cross sectional view of a seal assembly for the introducer sheath device according to an embodiment of the present invention;

Fig. 55 is a perspective view of the introducer sheath device and seal assembly for the present invention;

Figs. 56, 57 and 58 are perspective views of a fastener according to another embodiment of the present invention; and

Fig. 59 is a perspective view of a fastener according to another embodiment of the present invention.

Detailed Description of Preferred Embodiments

The following descriptions of the preferred embodiments of the present invention are described, for purpose of example, in connection with the repair of an abdominal aortic

aneurysm. The inventors of the present subject matter contemplate that the embodiments described herein are capable of use in the repair of other vessels and in other procedures. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

Repair Graft

Reference will now be made in detail to preferred embodiments of grafts according to the present invention for repair of abdominal aortic aneurysms, an example of which is illustrated in Figs. 1-11.

Figs. 1 and 3 depict a preferred embodiment of the repair graft assembly of the present invention directed to a proximal graft assembly **10** and distal graft assembly **20** for repair of a vessel **1**. The proximal graft assembly **10** and distal graft assembly **20** are secured to a wall **2** of the vessel **1** to exclude the aneurysm from the circulatory system of the patient. In the preferred embodiment of the present invention, the proximal graft assembly **10** is a bifurcated tube graft.

The distal graft assembly **20** preferably comprises an attachment cuff **21**. The attachment cuff **21** is sized to secure the distal graft assembly **20** to the wall **2** of the vessel **1** at the distal end of the vessel **1**. The distal graft assembly **20** also comprises at least one graft attachment leg, tube or branch **22**. The attachment cuff **21** is secured to the wall **2** of the vessel **1** out to the adventitia using a suitable fastener, described in detail below.

The distal graft assembly **20** is positioned within the distal end of the vessel **1**, as shown in Fig. 1 using a guide wire, not shown, that extends between and through both common iliacs. The attachment cuff **21** is then secured to distal end of the vessel **1** out to the adventitia using a repair apparatus, described below. After the attachment cuff **21** is firmly secured to the wall **2**, attachment tubes **22** are invaginated to the position shown in Fig. 3. A proximal graft assembly **10** is then secured to the attachment legs **22** using suitable connectors, such as, a self-expanding stent **30**, as shown in Fig. 7.

The bifurcated proximal graft assembly **10** comprises a pair of tubular legs **11**. The tubular legs **11** are sized to be received within/without the graft attachment tubes **22**. The bifurcated proximal graft assembly **10** may also comprise an attachment cuff **12** for

attachment to the wall **2** of the vessel **1**. The attachment cuff **12** has a similar structure to the attachment cuff **21** of attachment device **20**. The tubular legs **11** are invaginated following the process of securing the attachment cuff **12** to the wall **2**. The attachment legs **22** may be positioned within the tubular legs **11**, as shown in Fig. 3. Alternatively, the tubular legs **11** may be positioned within the attachment legs **22**, as shown in the embodiment of Fig. 6.

It is also contemplated that the distal graft assembly **20** may be used with a standard tube graft **3**, as shown in Fig. 2 and 4. In this variation, the tube graft **3** is secured to the wall **2** of the vessel **1** while in an inverted position, as shown in Fig. 2 using fasteners, described below, and a self-expanding stent **30**, if desired. The tube graft **3** is then invaginated and secured to the distal graft assembly **20**, as described above. The benefit of the invagination of the graft **3** is that the fasteners securing the graft **3** to the vessel **1** are not in direct contact with the blood within the vessel **1**. This will reduce the possible build up of thrombus at the point of attachment and thereafter the creation of emboli.

The proximal graft assembly **10** and distal graft assembly **20** will enable the creation of a cross sectional area ratio between the common iliacs and the distal aorta that exists only at childhood. The ratio may be 1.1 to 1.0. This ratio minimizes the reflected wave that is instrumental in the creation of plaque deposits at the distal bifurcation.

Figs. 5 and 6 depict another embodiment of a repair graft for repair of an abdominal aortic aneurysm **1** according to the present invention. The proximal graft assembly **100** is secured to a wall **2** of the abdominal aorta to exclude the aneurysm **1** from the circulatory system of the patient. The proximal graft assembly **100** is used in connection with the distal graft assembly **20**, described above. In this embodiment, the distal graft assembly **20** comprises a single attachment leg or tube **22**. The proximal graft assembly **100** comprises a tube graft assembly **110** for forming a passageway within the vessel **1**.

The radially extending attachment cuff **121** provides a greater surface area for securing the proximal graft assembly **100** to the wall **2**. Additionally, the radially extending portion **121** is flexible, which permits some positioning adjustment of the proximal graft assembly **100** in the event the size of the passageway within the abdominal aorta changes after the surgical procedure. Fig. 11 illustrates the flexibility of the attachment cuff **21** which

is similar to attachment cuff **121**. Like the embodiment of Figs. 1 and 3, the proximal graft assembly **100** is secured to the vessel wall **2** in an invaginated manner, as shown in Fig. 5. After the attachment cuff **121** is secured to the vessel wall **2**, the proximal graft assembly **100** is invaginated to the position shown in Fig. 6. The tubular leg assembly **110** is then secured to the distal graft assembly **20**, as shown in Fig. 7. In a preferred embodiment, a self-expanding stent **30** is used to secure it to the attachment leg **22** of the distal graft assembly **20**. The self-expanding stent **30** applies radial pressure against an inner surface of tube graft assembly **110** to secure the tube graft assembly **110** to the distal graft assembly **20**.

The self-expanding stent **30** is a preferred method of securing the proximal tube assemblies **10** or **100** to the distal graft assembly **20**. However, it will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, surgical staples, sutures, adhesives or other methods may be used to secure the proximal graft assembly **10** to the distal graft assembly **20**. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

As described above in connection with Figs. 2 and 4, it is also contemplated that the distal graft assembly **20** may be used with a standard tube graft, not shown. The tube graft will also be secured to the wall **2** of the vessel **1** while in a cephalad position using either fastener devices, described below, or a self-expanding stent **30**. The tube graft is then invaginated and secured to the distal graft assembly **20**, as described above.

Figs. 8 and 9 depict a proximal attachment assembly **150** according to the present invention for securing the proximal graft assembly **10** or **100** to the proximal end of the vessel **1**. It is preferred that the proximal attachment assembly **150** be used in connection with securing the proximal graft assemblies **10** or **100** to the vessel wall **2** according to preferred embodiments of the present invention as shown, for example, in Figs. 5, 6, 8 and 9. The proximal attachment assembly **150** comprises a cuff attachment portion **151** and a vessel attachment portion **152**. The attachment cuff **12** or **121** is secured to the cuff attachment portion **151**, by sewing, for example. The vessel attachment portion **151** is then

secured to the vessel **1** using, for example, a fastener or a self-expanding stent **30** and fasteners, if necessary. Alternatively, the proximal attachment assembly **150** may be invaginated and secured to the vessel **1** in the manner described above in connection with Figs. 2 and 4. The cuff attachment portion **151** and the attachment cuff **12** or **121** interact in a manner such that the proximal graft assembly **10** or **100** are not impacted by the expansion of the neck of vessel **1** after the surgical procedure.

Another embodiment of the repair grafts according to the present invention are disclosed in Figs. 10 and 12. The embodiment of Figs. 10 and 12 utilizes a pair of distal graft assemblies **20**, which are secured at the proximal and distal ends of the vessel. A proximal graft assembly **1000**, which forms a passageway within the vessel **1** interconnects the distal graft assemblies **20**. As described above, the proximal graft assembly **1000** is secured to the attachment legs **22** of the distal graft assemblies **20** using a self-expanding stent **30** or other suitable fastening means. The attachment legs **22** may be inserted in the proximal graft assembly **1000**. Alternatively, the proximal graft assembly **1000** may be inserted in the attachment legs **22**, as shown in Fig. 12.

The above described repair grafts facilitates repair of a vessel in a manner that is neither profile nor dimension dependent. This is especially helpful in view of the fact that the necks of the post-surgical aorta typically increases in size for approximately twelve months. The above-described repair grafts accommodate such expansion without allowing leaks or graft migration. The attachment cuffs are capable of accommodating dimensional changes in the necks of the abdominal aorta. Furthermore, the use of the distal graft assembly **20** permits distal attachment removing the need for iliac/femoral attachment.

In accordance with the present invention, detailing and assembly of the graft within the abdominal aorta creates a situation in which the fasteners are positioned outside the blood flow and are therefore not a focal point for thrombus creation. Both distal and proximal bifurcated grafts in accordance with the present invention may be strategically marked with radiopaque materials to enable their visual tracking and correct positioning prior to fixation within the aorta. A frieze/band of platinum oxide is vacuum deposited, photo deposited, silkscreened, or otherwise adhered to the graft material at the location of the tube end

(proximal graft), tube end/halo transition (distal graft), and at the halo perimeter. Other noble metals such as gold, molybdenum and titanium may also be successfully used as marking material. Radiopaque wires or metal fragments have been woven or otherwise incorporated into grafts -- the coating methods listed above, have not. The ring details previously discussed titanium or polymeric (suitably impregnated) are also radiopaque.

In the above described embodiments, the proximal graft assemblies **10**, **100** and **1000**, distal graft assembly, and proximal attachment assembly **150** are preferably formed from a twill weave, non-crimped polyester, Gore-Tex® or equivalent biocompatible material. It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, in the embodiments mentioned above, various other suitable materials such as, Dacron®, and other biocompatible graft materials may be used to form the repair grafts. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

The attachment cuffs may include a ring located at the perimeter. This ring may comprise a metal spring wound into holes cut in the cuff of a polymeric spring which is molded directly to the cuff. The ring serves to keep the cuff fully expanded during the attachment process of the graft to the vessel wall. The ring has no negative impact on the insertion process, described below.

Similar to other graft procedures, the proximal graft assemblies **10**, **100**, or **1000** according to the present invention require attachment to the wall **2** of the vessel. Often, it is necessary to attach the distal end of the graft into material which is routinely calcified and therefore difficult to penetrate. When paired with the absence of a distal neck in the vessel, the presence of the plaque has forced others to promote the use of a bifurcated graft in which the graft limbs are fastened by stents within the common iliac or femoral arteries. This procedure may potentially damage the femoral arteries. Furthermore, the presence of a graft and stent within the iliac or femoral arteries potentially restricts the flow of blood within the

vessels. This is unnecessary when utilizing the repair grafts according to the present invention.

IntraVascular Endoscopy (I'VE) Based Repair System

Reference will now be made in detail to preferred embodiments of an apparatus according to the present invention for facilitating the repair of abdominal aortic aneurysms using above described grafts. An example of an intravascular endoscopy based system is depicted in Figs. 13-22.

The repair apparatus **5** comprises a housing **200** for alternately receiving a visualization apparatus **6** and a penetration apparatus **7**, as shown in Fig. 20. It, however, is contemplated by the inventors of the present invention that the visualization apparatus **6** and penetration apparatus **7** may be combined into a single assembly within the repair apparatus **5**. The housing **200** has a hollow construction, as illustrated in Fig. 14, which permits insertion of the visualization apparatus **6** or the penetration apparatus **7**, described in detail below. The housing **200** is divided into two primary portions: static housing portion **210**; and flexible housing portion **220**. The housing **200** has a sufficient length such that it extends from the repair site within the vessel **1** through the appropriate or chosen artery to a point outside the patient.

The housing **200** has a hollow interior **211** to permit passage of one of the interchangeable apparatus **6** and **7**. An inner surface of the hollow interior **211** comprises rotation prevention means **212** for properly orienting the interchangeable apparatus **6** and **7** within the housing **200**. In a preferred embodiment, the rotation prevention means **212** is a ridge, as shown in Fig. 14, that extends along the inner surface of the hollow interior **211**.

It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the rotation prevention means **211** mentioned above, may be located at different radial positions within the housing and may also be a ridge, a groove, a plurality of grooves, or other devices capable of preventing rotation of the interchangeable apparatus **6** and **7** within the housing **200**. Thus,

it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Positioned within the housing **200** is an apparatus guide means **214** for guiding the repair apparatus **5**, as shown in Figs. 13 and 17, within the vessel **1** during use. The guide means **214** preferably is a passageway or lumen extending within the housing wall through the static portion **210**. A guiding means **160** cooperates with guide means **214** to guide the apparatus **5** during use. The guiding means **160** is preferably a guide wire which is capable of extending from the femoral artery to the axillary artery. In a preferred embodiment, the guide wire **160** is a filament (e.g., stainless steel, titanium or a Kevlar®). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength, flexibility, and minimal thermal expansion may be used to form the guide wire **160**. The guide wire **160** projects from the flexible housing portion **220** through an aperture **226** in the housing **200**, as shown in Fig. 14.

Housing **200** also comprises an apparatus manipulation means **215** to aid in manipulating and orienting the apparatus **5** within the vessel **1** during the repair operation. The manipulation means **215** preferably comprises at least one passageway extending within the housing wall through the static housing portion **210** and terminating in the flexible housing portion **220**. A manipulating means **170** cooperates with manipulation means **215** to guide the apparatus **5** during use. The manipulating means **170** is preferably comprises at least one guide wire that is capable of extending from outside the patient through the housing **200**. The guide wires **170** extend through the manipulating means **215**. In a preferred embodiment, the guide wires **170** are filaments (e.g., stainless steel, titanium or a Kevlar®). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength and flexibility may be used to form the guide wires **170**.

The guide wires of the manipulating means **170** terminate within the flexible housing portion **220**. Operation of the manipulating means **170** results in the articulation of an end portion of the flexible housing portion **220**. The guide wires **170** maintain the flexible housing portion **220** in an articulated position, as shown in Figs 13 and 16, such that the

visualization apparatus **6** and the penetration apparatus **7** can be interchanged without altering the orientation of the repair apparatus **5** with respect to the surgical site.

The wall of the static housing portion **210** comprises an outer surface formed from silicone and an inner surface formed from Teflon®. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the housing wall may be formed from a suitable polymer (e.g., Pebax®) or other material having similar properties including, but not limited to biocompatability, flexural strength, low coefficient of friction. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

The flexible housing portion **220** may be formed in a manner similar to static housing portion **210**. For example, the housing may comprise an outer surface formed from silicon and an inner surface formed from Teflon®. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the lining may be formed from a suitable polymer or other material having similar properties including, but not limited to biocompatability, flexural strength, low coefficient of friction. Alternatively, the flexible housing portion **220** may comprise a coiled metallic spring outer casing **224** that surrounds a lining. The lining may be formed from Teflon®. The coiled metallic spring outer casing **224** may be formed from a biocompatible stainless steel or titanium. Furthermore, the spring outer casing **224** may be formed from other suitable spring materials. It is not necessary that the outer spring casing **224** extend along the entire length of the flexible housing portion **220**. Rather, the outer spring casing **224** may be positioned along the portion of the flexible housing portion **220** that is subject to bending. However, it is contemplated that an outer spring casing that extends along the entire length of the flexible housing portion **220** be within the scope of the present invention.

The flexible housing portion **220** and the static housing portion **210** are manufactured as separate components. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the static housing portion **210** and the flexible housing portion **220** may be formed as a single component. In a preferred embodiment, the static housing portion **210** is permanently secured to the flexible housing portion **220**. However, it is contemplated that the housing portions **210** and **220** may also be removably attached.

Figs. 18 and 19 illustrates another repair apparatus **500** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7** according to another embodiment of the present invention. The repair apparatus **500** comprises a housing **2000** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7**. The housing **2000** is flexible and has a sufficient length such that it extends from the repair site within the vessel **1** through the appropriate artery to a point outside the patient.

The housing **2000** is hollow, as described above in connection with housing **200**, to permit passage of one of the interchangeable apparatus **6** or **7**. The housing **2000** includes at least one guide means **2140** positioned at the exterior of the housing **2000** for guiding the repair apparatus **500** within the vessel **1** during use. The guide means **2140** preferably is a passageway extending along the exterior of the housing wall to a point adjacent the distal end **2001** of the housing **2000**.

Guide wires **160** extend within the guide means **2140**. The guide wires **160** extend from the end of guide means **2140** and are secured to the distal end **2001** of the housing **2000**, as shown in Figs. 18 and 19. Adjustment of the guide wires **160** manipulates the position of the repair apparatus **500** within the vessel **1**. The above described arrangement permits a wide range of articulation of the repair apparatus **500** within the vessel **1**.

An additional guide wire **161** is secured to the distal end **2001** of the housing **2000**. The guide wire **161** extends through the vessel **1** and appropriate artery to permit the positional adjustment of the repair apparatus **500** within the vessel.

Fig. 20 illustrates another repair apparatus **5000** for alternatively receiving a visualization apparatus **6** and a penetration apparatus **7** according to another embodiment of the present invention. The repair apparatus **5000** comprises a flexible hollow housing **2010** and has a sufficient length such that it extends from the repair site within the vessel **1** through the appropriate artery to a point outside.

The housing **2010** includes at least one guide wire **162** extending along the exterior of the housing **2010**, as shown in Fig. 20. The housing **2010** includes an inflatable portion **2011**, located adjacent the distal end **2001**. Inflation of the inflatable portion **2011** permits articulation of the repair apparatus **5000** within the vessel **1**. A passageway, not shown, extends within the housing **2010** to permit inflation of the inflatable portion **2011** with a suitable fluid, such as, saline or suitable liquid polymers or air. An additional guide wire **161** is secured to the distal end **2001** of the housing **2010**. The guide wire **161** extends through the vessel **1** and appropriate artery to permit the positional adjustment of the repair apparatus within the vessel.

The overall dimensions of the repair apparatus **5** allows axillary access. This previously was not possible. In this regard, the repair apparatus used in connection with the visualization apparatus **6** or penetration apparatus **7** is capable of being used in other surgical procedures not previously contemplated. The apparatus size permits insertion through an introducer sheath device **900**, described below. The apparatus **5** may also be introduced into a vessel percutaneously. This procedure is less invasive and/or intrusive when compared to other repair surgical procedures.

IntraVascular Endoscopy (I'VE) Visualization Apparatus

Reference will now be made in detail to preferred embodiments of the interchangeable apparatus **6** and **7** for use with the repair apparatus **5** according to the present invention for facilitating the repair of abdominal aortic aneurysms. The visualization apparatus **6** will now be described in connection with Figs. 13 and 15.

A visualization apparatus **6** may be inserted within the repair apparatus **5** to illuminate and permit real time direct viewing of the abdominal aorta to aid and the diagnosis and repair of the aneurysm. The visualization apparatus **6** is an intravascular endoscope based system

that comprises a housing **300** for housing various illuminating and viewing components. The housing **300** is preferably formed as a conduit that is sized to slide within housing **200**. In a preferred embodiment, the housing **300** is an extrusion of silicon, Teflon® or polymer or other material having similar properties.

The housing **300** extends through the hollow interior **211** of the housing **200**. The housing **300** may comprise orientation means **310** for orienting the visualization apparatus **6** within the housing **200**. The orientation means **310** cooperates with rotation prevention means **212**. In a preferred embodiment, the orientation means **310** is a channel that extends along an outer surface of the housing **300**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the orientation means **310** mentioned above may be located at different radial positions within the housing **300**. The orientation means **310**, may be a ridge, a groove, a plurality of grooves, or other devices that are complementary with the rotation prevention means **212** to prevent rotation of the visualization apparatus **6** within the housing **200**.

As shown in Fig. 15, housing **300** comprises a plurality of passageways **311**, **312**, **313**, **314**, and **315** formed therein. The passageways **311**, **312**, **313**, **314**, and **315** extend along the entire length of the housing **300**. Central passageway **311** is provided for the passage of optical viewing means **320** for viewing an abdominal aorta. In a preferred embodiment, the optical viewing means **320** is a fiber optic system. The system incorporates a fiber optic bundle. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the optical viewing means **320** mentioned above, may be any flexible optical system that is sized for use in surgical applications. The optical viewing means **320** permits real time direct viewing of the area of repair in the vessel **1**. The optical viewing means **320** may be connected to a video camera and monitor, not shown, that permits the surgeon to view the repair area. The images may be stored and recalled as desired by using either a video printer

or video cassette recorder. The penetration apparatus **7** will be located at the same position as the visualization apparatus **6**. The penetration apparatus **7** incorporates a radio opaque marker that will indicate the precise position of the penetration apparatus **7** on the monitor. This allows the surgeon to monitor and track the adjustments of the repair apparatus **5**.

Peripheral illumination passageways **312** and **313** are provided for the passage of illuminating means **330** for illuminating the abdominal aorta for viewing by the optical viewing means **320**. In a preferred embodiment, the illuminating means **330** is a fiber optic system including a fiber optic bundle. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the illuminating means **330** mentioned above, may be any system that is sized for use in surgical applications and capable of illumination within the aorta. Although a pair of passageways are illustrated, it is contemplated that a single illumination passageway will provide sufficient illumination. Additionally, more than two passageways may also be provided.

Peripheral fluid inflow passageway **314** and peripheral fluid outflow passageway **315** are provided for the passage of fluid lens media to and from the visualization tip **340**. The peripheral fluid inflow passageway **314** supplies a stream of optically clear fluid lens media from the visualization tip **340** in the area in front of the optical viewing means **320**. A control means, not shown, may be incorporated into passageway **314** to control the flow volume and velocity of the fluid lens media to the visualization tip **340**. The control means may be a valve or other suitable flow control devices. The control means controls the optically clear fluid lens media such that blood within the aortic cavity and the fluid lens media are pressure balanced. As a result, blood that is typically within the aorta is temporarily diverted away by the fluid lens media to a point adjacent the area of the wall **2** to be viewed by the optical viewing means **320**. The infusion of fluid lens media will dilute blood to an appropriate transparency in the immediate surgical site to exclude blood between the visualization tip **340** and the surgical site on the wall **2**. This permits the surgeon to clearly view the wall **2** through the optical viewing means **320**. In a preferred embodiment, the fluid lens is a

transparent fluid to permit viewing of the wall **2**. The fluid lens media may be a saline solution. It is preferred that the solution be used for a single application (i.e., it is not reused). Other media, such as CO_2 gas and Green Cross liquid fluorocarbon are contemplated to be within the scope of the present invention. The peripheral fluid outflow passageway **315** acts as a return duct for the fluid lens media within the aorta. Alternatively, the fluid lens media may then be filtered using an appropriate filtering means and recirculated using a pumping means through the peripheral fluid inflow passageway **314**.

In a preferred embodiment, it is contemplated that the visualization apparatus **6** be used in combination with the introducer sheath devices **900**, described below. The introducer sheath devices **900** and in particular the positioning assemblies **920** permit the isolation of a portion of the vessel during the repair procedure. Specifically, the positioning assemblies **920** within the common iliacs and femoral artery permit the control of blood within the vessel. With this arrangement, it is then possible to more readily divert blood away from a viewing area with the flow of fluid lens media from the fluid inflow passageway **314**.

A visualization tip **340** is securely mounted to the end of housing **300** in a fluid tight manner. The tip **340** may be snap fitted or permanently mounted to the housing **300**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the visualization tip **340** mentioned above, may be secured to the housing **300** by means other than the above described snap and permanent fittings. The visualization tip **340** may be formed by injection molding or other suitable manufacturing methods in silicone or similar polymer.

The visualization tip **340** comprises apertures **341**, **342**, **343**, **344**, and **345** that correspond to passageways **311**, **312**, **313**, **314**, and **315**, respectively. Aperture **341** contains a lens positioned therein to facilitate viewing of the wall **2** with the optical viewing means **320**. Apertures **342** and **343** may include windows therein whereby light from the illuminating means **330** passes through the windows to illuminate the wall **2**, although it is not necessary. Apertures **344** and **345** act as gates for the peripheral fluid inflow passageway **314** and peripheral fluid outflow passageway **315**. The aperture **344** may be inwardly

tapered, such that the inside diameter of the aperture adjacent the inflow passageway **314** is greater than the diameter on the outer surface of the tip **340** to concentrate the stream of fluid lens media from the fluid inflow passageway **314**. The aperture **345** may be outwardly tapered, such that the inside diameter of the aperture adjacent the inflow passageway **315** is less than the diameter on the outer surface of the tip **340**. It is contemplated that the tip **340** is optional.

Penetration Apparatus

A penetration apparatus **7** will now be described in connection with Figs. 17-25. The penetration apparatus **7** may be inserted within the repair apparatus **5**, **500**, **5000**, as shown in Figs. 17-20, for fastening a repair graft to the vessel wall **2**. The penetration apparatus **7** comprises several components for fastening a repair graft including penetration means **420**, secondary penetration means **430**, tracking means **440** and insertion means **450**. The penetration apparatus **7** comprises housing **410** for housing the penetration means **420**, secondary penetration means **430**, tracking means **440** and insertion means **450**. In a preferred embodiment, the housing **410** has a thin walled tri-limbed profile, as shown in Figs. 19, 21, and 22. In a preferred embodiment for increased flexibility, the housing **410** is positioned within the repair apparatus **5** such that two of the three limbs of the housing **410** are spaced from the side of housing **200** containing the guide wire **160**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the housing **410** mentioned above, may have more than three limbs. Alternatively, the housing **410** may be cylindrical having a plurality of inwardly projecting limbs. An alternative configuration for housing **4100** is depicted in Figs. 18 and 20. The housing **4100** comprises a central passageway **4110** containing penetration means **420**. Additional passageways **4210** and **4130** are provided for other components such as secondary penetration means, tracking means and insertion means.

The housing **410** is preferably formed from an extrusion of silicone, Teflon®, or polymer having similar properties. Housing **410** comprises a plurality of passageways **411**, **412**, **413**, and **414**, formed therein as shown in Fig. 21. An alternative arrangement is shown in Fig. 22. The passageways **411**, **412**, **413**, and **414** extend along the entire length of the

housing means **410**. Primary passageway **411** is provided for the passage of the penetration means **420**. The penetration means **420** is provided to create a treatment specific hole in the wall **2** of the abdominal aorta for securing the graft thereto with a suitable fastener device, described below. The penetration means **420** penetrates the potentially calcified vessel wall **2** to securely fasten the repair graft to the wall **2**. The penetration means **420** may be either a laser penetrating device or a piezoelectric penetrating device. It, however, is contemplated by the inventors of the present invention that other penetration means including but not limited to CO_2 penetration, micro electromechanical systems, and intraluminal suturing are considered to be within the scope of the present invention. The laser penetrating device **420** preferably is an IR fiber optic based system using laser energy to create treatment specific holes in the aorta wall **2**. The fused silica/quartz fibers that are utilized are in the 200-600 micron size range. Suitable lasers comprise but are not limited to an acousto optical laser having a wavelength of about 1.35 μm, and a Holmium-Yag laser having a wavelength of about 2.1 μm. The selected wavelength allows transition of laser energy through the fiber in the passageway **411**. The laser fiber will be in direct contact with the surgical site such that the fiber projects from the end of the housing **410**. It is contemplated that a single, or tri-pronged hole pattern will be created using penetration means **420** and secondary penetration means **430**.

The piezoelectric penetrating device preferably is a catheter based system, which utilizes acoustic vibrations to create treatment specific suture holes to aid in graft/tissue attachment. The piezoelectric penetrating device applies an "acoustic wave" effect to create holes in the graft and vessel wall. In this variation, the passageway **411** preferably contains a super elastic titanium catheter, in rod or tube form, which enables transmittance of energy through the sometimes tortuous vessels to the surgical site. The catheter will be in direct contact with the surgical site such that the catheter projects from the end of the housing **410** into the formed treatment specific hole. The secondary penetration means **430** creates one or more temporary hole(s). The piezo-electronic device preferably operates at a frequency of 20 KHz. Other frequencies, both higher and lower, are contemplated to be within the scope of the present invention. The primary penetration means **420** is coaxial with the

fastener devices such that the fastener devices may be inserted through the treatment specific hole created by the primary penetration means **420**.

Secondary passageway **412** is provided for the passage of the secondary penetration means **430**. The secondary penetration means **430** is also provided to create one or more temporary holes in the vessel wall **2**, in a manner similar to the primary penetration means **420**. Similarly, the secondary penetration means **430** may be either a laser penetrating device or a piezoelectric penetrating device, as described above in connection with the penetration means **420**. The secondary penetration means **430** serves to anchor and orient the penetration apparatus **7** while a fastener is inserted within the treatment specific hole formed by the primary penetration means **420**. After the secondary penetration means **430** is removed, the temporary holes will seal with blood that will coagulate.

Passageway **413** is provided within the housing **410** for passage of the insertion means **450**, described below. Passageway **414** is provided within the housing means **410** for passage of the tracking means **440**. In a preferred embodiment, the tracking means **440** is a radiopaque marker, which is utilized for the purpose of identifying the location of the penetration apparatus **7** within the image on the monitor. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the tracking means **440** mentioned above, may be a tip-tracking device or a fiber optic aiming beam.

Insertion means **450** for securing the repair graft to the wall **2** during repair of the aneurysm will be described in connection with Fig. 24. The insertion means **450** preferably comprises a mechanism that drives an individual fastener from a fastener cartridge **460**, shown in Figs. 17 and 23, into and through the treatment specific holes created by the penetration means **420** in the repair graft and wall **2**. The fastener cartridge **460** is capable of holding a plurality of fasteners such that more than one fastener may be sequentially displaced from the cartridge **460** to secure the repair graft to the abdominal aorta wall **2**. Fastener cartridge **460** is preferably detachably connected to housing **410**. The fastener cartridge **460** is a hollow housing, as shown in Fig. 23, preferably formed of injection molding HDPE or Liquid Crystal, manufactured by the RTP Co. of MN. The penetration

means **420** and **430**, the tracking means **440** and the insertion means **450** are appropriately accommodated within the interior of the cartridge structure **460**. The cartridge **460** is positioned about the housing **410**.

The insertion means **450** illustrated in Fig. 24 comprises a driving means **451** for driving the fastener devices to secure the repair graft to the vessel wall **2**. A gear **452** and fastener advancing means **453** are positioned within an opening **454** in housing **410**. In a preferred embodiment, the gear **452** is a worm gear. However, other suitable gear assemblies are contemplated to be within the scope of the present invention. The gear **452** is connected to the driving means **451**. The fastener advancing means **453** interacts with the gear **452** to advance a fastener device to secure the repair graft to the vessel wall **2**. In a preferred embodiment, the fastener advancing means **453** is an internally geared drive plate assembly. The drive plate assembly may be capable of limited angular adjustment. Operation of the insertion means **450** is controlled by a control device, not shown, such that upon actuation by the control device, the fastener advancing means **453** is advanced to eject a fastener device from fastener cartridge **460**. Alternatively, the insertion means **450** may be hand operated. The insertion means **450** is used, for example, in the embodiment illustrated in Fig. 19.

Another embodiment of the insertion means **4500** is illustrated in Fig. 25. An insertion cartridge **4510** is secured to the distal end of the repair apparatus **5**. The insertion cartridge **4510** may be snap fitted to the housing **200**. The insertion cartridge **4510** comprises a cavity **4511**. A spring means **4520** is positioned within the cavity **4511**. A fastener cartridge **460** is also located within the cavity **4511**. An opening **4530** is located at one end of the insertion housing **4510**. The housing **410** of the penetration apparatus **7** normally prevents the spring means **4520** from ejecting a fastener device through the opening **4530**. The insertion means **4500** comprises retraction means **4540** which retracts the housing **410** away from the opening **4530** which permits the fastener to be ejected into the treatment specific hole created by the primary penetration means **420**. The retraction means **4540** may be a cable that acts to retract the housing **410** away from opening **4530**. The release of the retraction means **4540** causes the housing **410** to return to the position adjacent the opening **4530** to prevent the discharge of a subsequent fastener device.

IntraVascular UltraSound (IVUS) Repair System

Reference will now be made in detail to preferred embodiments of an apparatus according to the present invention for facilitating the repair of abdominal aortic aneurysms using above described repair grafts. An example of an intravascular ultrasound based system is depicted in Figs. 26-29.

The repair apparatus **50** comprises housing **800**. The housing **800** comprises a major guide wire portion **810**, a cross-section of which is shown in Fig. 28, a spacer portion **820**, and a minor guide wire portion **830**.

Positioned within the housing **800** is an apparatus guide means **214** for guiding the repair apparatus **50** within the vessel **1** during use. The guide means **214** preferably is a passageway or lumen extending the length of the housing **800** through major guide wire portion **810**, the spacer portion **820**, and the minor guide wire portion **830**. A guiding means **160** cooperates with guide means **214** to guide the apparatus **50** during use. The guiding means **160** is preferably a guide wire which is capable of extending from the femoral artery to the axillary artery. In a preferred embodiment, the guide wire **160** is a filament (e.g., stainless steel, titanium or Kevlar® cable). It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength, flexibility, and minimal thermal expansion may be used to form the guide wire **160**.

Housing **800** also comprises an apparatus manipulation means **215** to aid in manipulating and orienting the penetration apparatus **700** within the vessel **1** during the repair operation. The manipulation means **215** preferably comprises at least one passageway extending within the housing **810**. The manipulation means **215** mates with complimentary passageways formed in housing **710**. A manipulating means **170** cooperates with manipulation means **215** to guide the apparatus **50** during use. The manipulating means **170** is preferably comprises at least one guide wire that is capable of extending from outside the patient through the housings **810** and **710**. The guide wire **170** extends through the manipulating means **215**. In a preferred embodiment, the guide wire **170** is a super elastic metal filament. It, however, will be apparent to those skilled in the art that various other materials having similar properties of physical integrity, high strength and flexibility may be used to form the guide wire **170**.

Operation of the manipulating means **170** results in the articulation of an end portion of the housing **710**. The guide wire **170** maintains the housing **710** in an articulated position, as shown in Fig. 26, during the repair operation.

The penetration apparatus **700** will now be described in connection with Figs. 26-29. The penetration apparatus **700** comprises several components for fastening a repair graft including penetration means **420**, secondary penetration means **430**, tracking means **440**, and insertion means **450**. The penetration apparatus **700** comprises housing **710** for housing the penetration means **420**, secondary penetration means **430**, and insertion means **450**. In a preferred embodiment, the housing **410** has a thin walled tri-limbed profile, as shown in Figs. 26, 27 and 29. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention.

The housing **710** is preferably formed from an extrusion of silicone, Teflon®, or polymer having similar properties. Housing **710** comprises a plurality of passageways **711**, **712**, **713**, **714**, and **715** formed therein as shown in Fig. 29. The passageways **711**, **712**, **713**, **714** and **715** extend along the entire length of the housing **710**. Primary passageway **711** is provided for the passage of the penetration means **420**. The penetration means **420** is provided to create an treatment specific hole in the wall **2** of the abdominal aorta for securing the graft thereto with a suitable fastener device. The penetration means **420** penetrates the calcified portions of the wall **2** to securely fasten the repair graft to the wall **2** in the same manner as described above in connection with the endoscopic based system. The penetration means **420** may be either a laser penetrating device or a piezoelectric penetrating device.

Secondary passageway **712** is provided for the passage of the secondary penetration means **430**. The secondary penetration means **430** is also provided to create one or more openings in the vessel wall **2**, in a manner similar to the primary penetration means **420**, as described above.

Passageway **713** is provided within the housing **710** for passage of the insertion means **450**. Passageway **714** is provided within the housing **710** for passage of the guide wire **170**. Passageway **715** is provided for tracking means **440**. The insertion means **450** preferably comprises a mechanism that drives an individual fastener from a fastener cartridge

470, shown in Figs. 26 and 27, into and through the treatment specific holes created by the penetration means **420** in the repair graft and wall **2**. The fastener cartridge **470** is capable of holding a procedure specific quantity of fasteners such that more than one fastener device may be sequentially displaced from the cartridge **470** to secure the repair graft to the wall **2**. Fastener cartridge **470** is preferably detachably assembled to housing **710**. The fastener cartridge **470** has a hollow housing **471**, as shown in Fig. 26. The penetration means **420** and **430**, and the placement/fastener means **450** are appropriately accommodated within the interior of the cartridge structure **460**. The cartridge structure **470** and associated fastener device are complimentary with the spacer portion **820** of the housing **800** such that the penetration apparatus **700** has a flush profile, as shown in Fig. 27.

A visualization apparatus **600** for viewing the abdominal aorta to repair the aneurysm is positioned within housing **800** adjacent the minor guide wire portion **830**. The visualization apparatus **600** is an intravascular ultrasound (IVUS) based system produced, for example, by Endosonics of Rancho Cordova, CA, that comprises a housing **601** for housing radial scanning components. The housing **601** may comprise a scanning window **602**, however, it is not essential for the effective operation of the visualization apparatus **600**. The visualization apparatus comprises scanning catheter positioned within the housing **601** such that it scans the area of the abdominal aorta. The housing **601** is an extrusion of silicon, Teflon® or polymer or other material having similar properties. The scanning catheter extends through the minor guide wire portion **830** of housing **800**. The scanning catheter creates an image of the repair that can be viewed on an external monitor, not shown.

The housing **800** also comprise transition portions **801** and **802** located on opposite ends of the penetration apparatus **700** to provide the repair apparatus **50** with a smooth profile, as shown in Fig. 27. This improves the movement of the repair apparatus **50** within the vessel **1** and adjacent arteries.

Fasteners

Reference will now be made in detail to embodiments of a fastener device, as depicted in Figs. 30-41, 49-53 and 56-59 according to the present invention for securing the attachment device **20** to the distal end of the vessel **1**. Although the fastener devices are described in connection with the repair of an aneurysm in a vessel, the use of the fastener

devices in other surgical procedures as a replacement for sutures is contemplated to be within the scope of the present invention.

Figs. 30 and 31 depict a fastener **510** according to an embodiment of the present invention. The fastener **510** comprises a pair of normally splayed fastening legs **512** and **513**. The fastener **510** also comprises an anchoring portion **514**, as shown in Fig. 31. The fastener **510** is preferably formed from a wire-like material. The anchoring portion **514** may be formed from a coil of the wire-like material. The legs **512** and **513** are temporarily reoriented, as shown in Fig. 30, for storage on a fastener cartridge **460** and for enabling the attachment of the attachment device **20** to the wall **2**. As the legs **512** and **513** are inserted through the attachment device **20** and the wall **2**, the legs **512** and **513** return to a normal, as manufactured, splayed position, as shown in Fig. 31. When the fastener **510** is in a fastened position within the vessel, the anchoring portion **514** is positioned on one side of the attachment device **20** and wall **2** (intima/graft) adjacent the attachment device **20**. The splayed legs **512** and **513** are positioned on the opposite side of the attachment device **20** and wall **2** (adventia) adjacent the wall **2**. The anchoring portion **514** and splayed legs **512** and **513** apply compressive forces to the wall **2** and the attachment device **20** to securely fastening the attachment device **20** to the vessel **1**.

The fastener **510** is preferably formed from a stainless steel, such that the legs **512** and **513** return to the splayed position to secure the attachment device **20** to the wall **2**. It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the fastener **510** may be formed from other suitable materials including but not limited to superelastic titanium, or other procedure/performance appropriate materials such as plastics having similar properties including, but not limited to biocompatability, elasticity, and flexural strength. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Figs. 32 and 33 depict a fastener **520** according to an another embodiment of the present invention. The fastener **520** comprises a pair of normally splayed fastening legs **522** and **523**. The fastener **520** also comprises an anchoring portion **524**. The fastener **520** is also

preferably formed from a wire-like material. The anchoring portion **524** may be formed from at least one coil of the wire-like material (i.e., a wound portion). The legs **522** and **523** are temporarily compressed, as shown in Fig. 32, for storage in a fastener cartridge **460** and for facilitating the attachment of the attachment device **20** to the wall **2**. Similar to the embodiment described above in connection with Figs. 30 and 31, as the legs **522** and **523** are inserted through the attachment device **20** and the wall **2**, the legs **522** and **523** return to a normally splayed position, as shown in Fig. 32. When the fastener **520** is in a fastened position within the vessel, the anchoring portion **524** is positioned on one side of the attachment device **20** and wall **2** adjacent the attachment device **20**. The splayed legs **522** and **523** are positioned on another side of the attachment device **20** and wall **2** adjacent the wall **2**. The anchoring portion **524** and splayed legs **522** and **523** apply compressive forces to the wall **2** and the attachment device **20** to securely fastening the attachment device **20** to the vessel **1**.

Figs. 34 and 35 depict a fastener **530** according to another embodiment of the present invention. Fastener **530** is a spring type fastener, which may comprise a coil spring. The fastener **530** is also formed from a wire-like material. The fastener **530** comprises a plurality of coils, as shown in Fig. 34. The end portions **531** and **532** of the wire-like material are preferably located on the same end of the fastener **530**, as shown in Figs. 29, 30, and 34-36. Unlike fastener **510** and **520**, the fastener **530** is temporarily elongated for storage in the fastener cartridge **535**, as shown in Figs. 42, 43, and 46. As the fastener **530** is inserted through the attachment device **20** and wall **2** using the insertion means **450** on the penetration device **7**, as shown in Fig. 44, the fastener **530** remains in an elongated position until the insertion means **450** is removed from the treatment specific hole **3** created in the wall **2** of the vessel **1** and the attachment device **20** formed by the penetration apparatus **7**. The fastener **530** then assumes a collapsed position, as shown in Fig. 35. When the fastener **530** is in a fastened position within the vessel **1**, the end portions **531** and **532** are positioned on one side of the attachment device **20** and wall **2** adjacent the attachment device **20**, as shown in Fig. 45. The remaining portion of the fastener **530** is positioned on another side of the attachment device **20** and wall **2** adjacent the wall **2**. The fastener **530** apply compressive forces to the wall **2** and the attachment device **20** to securely fastening the attachment device **20** to the

vessel **1**. Fastener **530** may be formed from stainless steel; a superelastic alloy, for example titanium; or any other procedure/performance-appropriate materials.

Figs. 36, 37, 38, and 39 depict a fastener **540** according to another embodiment of the present invention. Fastener **540** is a coil spring type fastener. Fastener **540** comprises a mid-section **541**, and semi-knotted end portions **542** and **543**. The fastener **540** is also formed from a coil spring using materials, as described above. Preferably the fastener **540** is formed from stainless steel or a superelastic alloy, for example titanium. The fastener **540** is substantially linear, as shown in Fig. 36, when stored in a fastener cartridge, not shown. As the fastener **540** is inserted through the attachment device **20** and wall **2**, the fastener **540** returns to its normally coiled configuration, as shown in Fig. 37. The fastener **540** applies compressive forces to the wall **2** and the attachment device **20** to securely fastening the attachment device **20** to the vessel **1** such that one semi-knotted overlapping end portion **542** is positioned adjacent the attachment device **20** and the other semi-knotted end portion **543** is positioned adjacent the wall **2** of the vessel **1**, as shown in Figs. 38 and 39. Fig. 28 depicts an axially wound fastener **540**. Fig. 40 depicts the fastener **540** of Fig. 38 secured to the wall **2**. Fig. 39 depicts a radially wound fastener **540**. Fig. 41 depicts the fastener **540** of Fig. 39 secured to the wall **2**. The fastener **540** is termed a coiled coil spring type fastener. The coil spring which makes up the fastener is itself coiled during manufacture to assume the coiled configuration shown in Figs. 38-40. Fastener **540** is inserted through the attachment device **20** and the wall **2** using an insertion means in manner described above for fastener **530**.

Figs. 49, 50, and 51 depict a fastener **550** according to another embodiment of the present invention. Fastener **550** is a coil spring type fastener formed from stainless steel, or a superelastic alloy, for example titanium, or any other procedure/performance appropriate materials. Fastener **550** is substantially linear, as shown in Fig. 36, when temporarily stored in a fastener cartridge, not shown.

The fastener **550** is a coiled coil spring type fastener which is coiled into its fastening shape during manufacture. Fastener **550** may comprise a plurality of coiled coil springs connected together. The embodiment shown in Fig. 49 comprises two entwined springs. The coil diameter and wire gauge for the depicted design are approximately .04 inches and .005 inches respectively. It, however, is contemplated that the present invention is not limited to

these dimensions. Outside coil diameters greater than 0.04 inches and less than 0.04 inches (such as, for example, 0.03 inches) are considered to be well within the scope of the present invention. The fastening force of the fastener **550** can be adjusted to suit a particular purpose by varying the coil diameter, wire gauge, number of coils, and number of coil springs. The fastener **550** is termed a coiled coil spring due to the fact that the coil spring is further coiled into a shape suitable for fastening during manufacture. The coiled coil springs that comprise the fastener **550** are spot welded together at at least one point along their lengths. Any suitable connection means that serves to keep the springs of the coiled coil in a fixed relationship with one another is within the scope of the present invention, and may be used in lieu of spot welding.

Fastener **550** comprises a midsection **551**, and underlapping end portions **552** and **553**. Prior to insertion the fastener **550** is temporarily straightened and placed about an insertion means. The fastener **550** is inserted through the attachment device **20** and the wall **2** using a process similar to that described above for fastener **530**. Following insertion the core is removed and the fastener **550** returns to its normally coiled configuration, as shown in Figs. 49-51. The manufactured configuration of the fastener **550** provides the innovative method for securing the attachment device. The end portions **552** and **553** underlap at point **554** providing a locking mechanism for the fastener **550**. The underlapping design of the fastener **550** prevents the attachment device **20** and the wall **2** from being pulled apart.

Figs. 52 and 53 depict a fastener **560** according to another embodiment of the present invention. Fastener **560** is a coiled coil spring type fastener formed from stainless steel, or a superelastic alloy, for example titanium, or any other procedure/performance appropriate materials. Similar to fastener **550**, fastener **560** also utilizes coiled coil springs. Fastener **560** comprises a plurality of springs entwined together. The fastener **560** may be a single coiled coil spring or a plurality of coiled coil springs entwined together such as in fastener **550** described above. The preferred embodiment, as shown in Figs. 52 and 53, comprises two coiled coil springs **562** and **563**. However, it is within the scope of the present invention that the fastener **560** may comprise more or less than two springs. The coil diameter and the wire gauge for the depicted design is approximately .04 inches and .005 inches respectively. The

fastening force of the fastener **560** can be adjusted to suit a particular purpose by varying the coil diameter, wire gauge, number of coils, and the number of springs.

Fastener **560** comprises a midsection **561**, and end portions **562**, **563**, **564** and **565**. Prior to insertion the fastener **560** is temporarily straightened and placed about an insertion means. The fastener **560** is inserted through the attachment device **20** and the wall **2**. Following insertion, the insertion means is removed and fastener **560** unravels allowing the coiled coil springs **562** and **563** to return to their manufactured configuration, as shown in Figs. 52 and 53. The springs **562** and **563** may be spot welded together at at least one point along the midlength **561**. The ends **564**, **565**, **566** and **567** of the springs are not welded together allowing them to separate when the insertion means is removed. Any suitable connection means that serves to keep the springs of the fastener **560** in a fixed relationship with one another is within the scope of the present invention, and may be used in lieu of spot welding.

Both fasteners **550** and **560**, described above, use coiled coil springs with elastic/mechanical memories. Following insertion through the attachment device **20** and the wall **2**, the coiled coil springs remember their manufactured form, and return to that form securing the attachment device **20** to the wall **2**.

The holding potential of the coiled-coil fastener **570** may be further enhanced according to the embodiment of Figs. 56-58. The fastener **570** includes a central coiled fastener **571**. The fastener **570** further includes at least one short coiled insert **572**. The coiled insert **572** is located adjacent the end portion of fastener **571**, as shown in Figs. 56 and 57. The short coiled insert **572** may be entwined with the fastener **571** at its ends to create unique head features. When the core over which the fastener **570** is temporarily positioned is removed the fastener **570** returns to its as-manufactured configuration. In this position, the at least one coiled insert **572** separates from the fastener **571** host creating a dimensional disturbance and additional resistance to fastener withdrawal. The at least one short coiled insert **572** is spot welded as shown at **573** to prevent complete separation from the fastener **571**.

It is contemplated that the above-described coil spring fasteners may be formed either axially or radially wound coil springs. Furthermore, it is contemplated that coil spring may

have a circular, rectangular, triangular or other cross sectional configuration. It is also contemplated that the above-described fasteners may be surface treated to increase friction between the fastener and the surrounding tissue. Furthermore, it is contemplated that a polymeric material may be used rather than metal. In addition to varying coil diameter, wire gauge, number of coils and number of interwound springs to modify the holding force of the coiled-coil fastener, changing the spring's pitch between coils will also enhance the fastener's performance.

The fasteners according to the present invention are advanced to the surgical site either over or within the penetration assembly **7**, as discussed above by activation of an advancing mechanism positioned remotely with respect to the patient. To minimize the complexity of the mechanism it is necessary to tightly control the over-mandrel length of the fastener. Compression of the fastener is inherent to its design as it transitions from its "as-manufactured" form to its "insertion-ready" form and will create significant functional problems unless anticipated in the fastener/fastener advance mechanism design. The inventors of the fasteners of the present invention have been able to remove fastener compression from the fastener advancement equation. According to one embodiment, the fastener can be dimensioned in such a way that the "slack" which is created within the fastener as it transitions from its "as-manufactured" to its "insertion-ready form," is taken up as it is wound over the insertion assembly **450**. The inside diameter of the coil spring is the same as or slightly smaller than the insertion assembly **450** over which or within which it is temporarily positioned. This "dimensioning" facilitates both the pre-compression of the fastener on or within the penetration assembly **7** and its uniform advancement to the surgical site.

According to another embodiment, the fastener may be insert molded within a gelatin or similar dissolvable medium while in its "insertion-ready" form. The resultant "tube-like" component is non-compressible and facilitates both the fastener's easy loading over or within the penetration means and thereafter its uniform advancement to the surgical site where ultimately it spans the graft/adventitia matrix. The blood present dissolves the gelatin coating about and within the interstices of the fastener enabling resumption of its "as-manufactured" form and the compressive attachment of graft to vessel wall.

According to another embodiment, the fasteners may incorporate a dissolvable suture material. As shown in Fig. 59, the fastener **580** incorporates a dissolvable suture **581** wound between the individual coils **582** of the fastener **580**. The provision of the dissolvable suture **581** prevents longitudinal compression the fastener **580** on the insertion assembly, described above. Furthermore, the use of the suture permits uniform advancement of the fastener **580** along the insertion assembly and penetration assembly during the surgical procedure. It is contemplated that the use of the dissolvable suture **581** is not limited to fastener **580**. Rather, the use of the dissolvable suture **581** with any fastener having at least a coiled spring portion, including but not limited to the above-described embodiments, is considered to be well within the scope of the present invention.

It, however, will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. For example, the fastening means mentioned above, may be pop-rivet fasteners, screw-type fasteners, and rapid hardening plastic extrudates, which are all contemplated to be within the scope of the present invention. Thus, it is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Introducer Sheath Devices

Reference will now be made to a preferred embodiment of an introducer sheath device according to the present invention for use in the repair of abdominal aneurysms, an example of which is illustrated in Figs. 47 and 48. The introducer sheath device creates a protective passageway through the vessel through which the graft and repair devices are inserted. The introducer sheath device protects the arteries from damage that may occur when the repair apparatus and other devices are passed through the tortuous artery passageways during a surgical procedure.

Existing methods for repairing aneurysms utilize introducer sheath devices only in the femoral and common iliac arteries. Typically, guide wires extend from a femoral arteriotomy to an occlusion balloon placed within the proximal neck of the aorta at a point cephalad with respect to the abdominal aorta. Typically, others have gained access to the abdominal aorta via a femoral or common iliac arteriotomy into which is inserted an

introducer sheath device of between 18-28 Fr. diameter. The size of these devices may cause damage to the vessels through which they pass.

By contrast, the inventors of the present invention contemplate the use of more than one unique introducer sheath device **900**, as shown in Fig. 47. The sheaths **900** are introduced over a femoral/axillary guide wire. One introducer sheath device **900** extends from either an axillary incision or a brachial incision to the proximal neck of the vessel **1**. Another introducer sheath device **900** extends from a femoral incision to the distal neck of the vessel or common iliac/distal aorta transition. The introducer sheath devices according to the present invention that extend through the axillary vessel and through the femoral artery have similar constructions. However, the introducer sheath device that extends through the axillary artery has a smaller size in the range between 9-12 Fr. and is able to navigate the arteriotomy/proximal aorta passageway without problem. The smaller size permits access to the aorta via either the left brachial or axillary artery, both of which are significantly smaller than the femoral or common iliac arteries. This procedure, previously, beyond consideration, may now significantly benefit these vascular procedures.

Each introducer sheath device **900** comprises a housing **910** having a hollow interior **911** that permits the passage of the tube graft and other repair apparatus through the introducer sheath device to the vessel **1**. The housing **910** preferably includes multiple lumen or passageways formed therein. The repair apparatus are introduced through a multiport introducer assembly an opening **912** in the end portion of the housing **910**. In a preferred embodiment, the housing **910** is a thin walled co-extrusion having an outer surface formed, for example, from silicon and an inner surface formed, for example, from Teflon®. Alternatively, the housing **910** may be formed of a suitable polymer having similar properties.

The introducer sheath device **900**, also, comprises positioning assembly **920** for maintaining the sheath **900** in proper orientation within the vessel. In a preferred embodiment, the positioning assembly **920** comprises an inflatable cuff **921** located at one end of housing **910**. The positioning assembly **920** further comprises an inflation device for inflating the cuff **921**. The inflation device in a preferred embodiment comprises a plurality of passageways **923** formed within the wall of housing **910**. A suitable fluid, such as saline,

is supplied from an external source through the passageways **923** to fill the cuff **921**. The passageways **923** terminate at inflatable cuff **921**, as shown in Fig. 47. The positioning assembly **920** includes a silicon balloon which is connected to the housing opposite the introducer assembly. The silicon balloon is preferred for several reasons. First, unlike other polymeric balloons, the silicon balloon is capable of material expansion of up to 800% and will upon deflation return to its original shape. Other materials require "pre-forming" before integration within a device; such a device is more bulky and less able to totally deflate once it has served its clinical purpose. Utilization of silicon facilitates a low profile balloon which can be made co-planar with the multi-lumen housing to which it is attached. Additionally, housing termination details and smooth transitions -- balloon to housing, may be affected.

The housing **910** includes a central channel. The housing is formed of a multi-layer assembly comprising a fluoronated polymer core over which a polyurethane layer is extruded. A multi-stranded wire braid is located on top of the polyurethane layer about which a multi-lumen polymeric profile is co-extruded. This housing configuration provides certain benefits. First, the internal surface of the housing also has a low coefficient of friction which aids in the intraluminal passage of both penetration and visualization devices. The braided layer provides kink resistance, torquability and flexibility to the housing. locating the braid within the multi-lumen co-extrusion allows non-destructive access to the peripheral lumen. Furthermore, the co-extruded assembly provides a thermoplastic exterior surface to which the positioning assembly may be readily attached.

Alternatively, the housing may include a multi-lumen polymeric profile about which a multi-stranded wire braid is attached. Thereafter the assembly receives a polymeric coating which binds the three tubular layers to one another.

Prior introducer sheath devices have not been able to control the loss of significant amounts of blood through the open end of the introducer sheath device that is positioned outside of the body. Others have attempted to prevent this blood loss through the use of complex clamping systems. The present invention provides a unique seal arrangement to prevent significant blood loss. The introducer sheath device **900** efficiently seals the smaller surgical devices of the present invention which are typically 3 mm in diameter. Presently available surgical devices used with similar procedures typically have diameters in the range

of 6-9 mm. The use of these larger diameter devices in combination with currently available introducer sheaths typically results in significant and problematic blood loss. The sheath **900** may be used with these larger diameter devices without significant blood loss due to its innovative sealing arrangement.

A seal **930** located at one end of the housing **910** adjacent opening **912** prevents significant blood loss. The seal **930** comprises an expanded housing assembly **931**. A self-sealing gel-like material **932** is located within the expanded housing assembly **931**. The material **932** permits the insertion of the repair apparatus through the material **932**, which forms a seal around the repair apparatus. As the repair apparatus is removed from the introducer sheath device **900** and the sealing material **932**, the material **932** forms a seal behind the repair apparatus as it is removed through opening **912**.

A detailed view of the seal **930** is shown in Fig. 54. The seal assembly **930** may comprise the expanded housing assembly **931** and an end cap **935**. The seal material **932** is preferably a polymeric gel, sphincter-like in shape, having a central opening for receiving a surgical device **940**. When the surgical device or repair apparatus **940** is removed from the sheath **900** the sphincter-like opening in material **932** closes, creating a tight seal and preventing the loss of blood. The seal material **932** rests on a ledge or seat **936** located in the housing assembly **931**. The seal material **932** is held in place by a retaining ring **933**, which is secured to the interior of the housing assembly **931**.

The expanded housing assembly **931** is permanently attached to the housing **910**, as shown in Fig. 55, at **915**. An infusion port **925** is provided to allow for the supply or removal of the fluid or gas, which inflates or deflates the cuff **921**. The fluid or gas travels from the infusion port **925** to the cuff **921** via the lumen **923** shown in Fig. 47.

The seal **930** may be used with or without the end cap **935**. The end cap **935** provides additional protection against blood loss. The end cap **935** is inserted into the opening **912** in the expanded housing assembly **931** opposite the housing **910**. The end cap includes a thumbwheel portion **938** to facilitate connection with the housing assembly **931**. The end cap **935** has both internal and external sealing means. The internal sealing means is comprised of a V-type sealing ring **937** which provides a fluid-tight seal between the surgical device **940** and the end cap **935**. The external sealing means is provided by an external groove **939** and

a sealing ring **934**. Sealing ring **934** is preferably an O-ring formed from polymeric material. The end cap **935** may be modified as required to accommodate different surgical devices. The expanded housing assembly **931**, however, is capable of accommodating a variety of devices without modification.

The multi-port introducer assembly includes lured entryways for balloon inflation (positioning assembly), pressure monitoring/fluid control. (IVA) and a seat-protected device entry. With the exception of seal and cap details, the multi-port introducer assembly is an insert molding about the housing. The seal includes a thermoplastic elastomer molding having a lubricious polymeric coating, which is able to form a blood-tight seal about inserted instruments having very small diameters while at the same time enabling their easy rotation within the introducer assembly. The cap component snap-fits to the introducer molding and holds the seal component in position.

The general arrangement of the sheath device **900** is shown in Fig. 55. The surgical device or repair apparatus **940** is inserted into the housing **910** through the seal **930** which is located outside the skin **950**. As described above, the positioning assembly **920** is located in the vicinity of the aneurysm so maintaining the sheaths **900** correct orientation within the vessel.

It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and configuration of the present invention without departing from the scope or spirit of the invention. It is intended that the present invention cover the modifications and variations of the invention, provided they fall within the scope of the appended claims and their equivalents.

Method of Repairing an Aneurysm

Reference will now be made in detail to a preferred embodiment of the method of repairing an aneurysm utilizing the above described components according to the present invention.

IntraVascular Endoscopy (I'VE) Based Repair Method

The IntraVascular Endoscopy (I'VE) based repair method will be described in connection with the use of a proximal graft assembly **10** and distal graft assembly **20**. Introducer sheath devices **900** are placed by femoral arteriotomy in both common iliacs under

radiological guidance such that the positioning assembly **920** is positioned at the common iliac/aortic bifurcation transition. A guide wire is fed from one femoral incision to the other, also under guidance. A distal graft assembly **20** is fed over the guide wire until the attachment cuff **21** appears directly above the carina at the bifurcation, as shown in Fig. 1.

A second guide wire **160** is now fed under radiological guidance between one femoral incision and the left axillary incision. Another introducer sheath device **900** is fed from the axillary until the positioning assembly **920** reaches the infrarenal aorta at which time it is inflated. The repair apparatus **5** is then fed through the introducer sheath device **900** over guide wire **160** from either the femoral or axillary access to the midpoint of the aortic aneurysm. The visualization apparatus **6** is then fed through the hollow interior **211** of housing **200** to the area of the wall **2** to which the attachment cuff **22** is to be attached. The guide wires **170** are then manipulated to adjust the orientation of the visualization apparatus **6** to permit viewing of the wall **2** as described above, such that an image appears on the monitor. An image of the wall **2** appears on the monitor. The visualization apparatus **6** is then removed and the penetration apparatus **7** is then inserted through the hollow interior **211**. The guide wires **170**, as described above, permit the penetration apparatus to be positioned in the same position as the visualization apparatus **6**. The tracking means **440** pinpoints the location of the penetration means **420** with respect to the wall **2** and attachment cuff **22** as viewed on the monitor. The primary and secondary penetration means **420** and **430** are then operated to form treatment specific holes within the cuff **22** and wall **2**, as described above. The primary penetration means **420** is then retracted and a fastener is then inserted within the treatment specific hole using the insertion means **450**. The location of the penetration apparatus **7** is then adjusted to repeat the process over the area previously viewed by the visualization apparatus **6**. The penetration apparatus **7** is then removed and the visualization apparatus **6** is reinserted. The viewing and fastening process is alternately repeated until the attachment cuff **22** is firmly attached to the wall **2**.

The repair apparatus **5** is removed once the attachment cuff **22** is secured to the wall **2**. The proximal graft assembly **10** is then inserted in an inverted manner through the femoral arteriotomy over the guide wire **160** to the position shown in Fig. 1. The repair apparatus **5** is then fed through the introducer sheath device **900** over the guide wire **160** from either a

femoral or axillary access to a position adjacent the attachment cuff **12**. The visualization apparatus **6** and the penetration apparatus **7** are then alternately inserted in the manner described above to secure the attachment cuff **12** to the wall **2**. In the event that a standard graft **3** is used, the inverted graft **3** is secured directly to the wall **2** in a similar manner. Alternatively, a self-expanding stent **30** may be used in combination with fasteners to secure the graft **3** to the wall **2**. The repair apparatus **5** is then removed.

Once the proximal graft assembly **10** or **3** are secured in place, the first guide wire is removed and the graft **3** or **10** is invaginated. The tubular legs **11** are then inserted into the attachment tubes **22**. Self-expanding stents **30** are then used to secure the attachment tubes **22** and tubular legs **11** firmly together. The guide wire **160** is then removed. The positioning assemblies **920** are deflated and the introducer sheath device **900** are removed from the femoral and axillary arteries. The incisions are then closed completing the repair process. The outlined procedure according to the present invention is far less intrusive than current known techniques. As a result, a patient's recovery period should decrease.

IntraVascular Ultrasound Repair Method

The intravascular ultrasound repair method will be described in connection with the use of a proximal graft assembly **10** and distal graft assembly **20**. Introducer sheath device **900** are placed by femoral arteriotomy in both common iliacs under radiological guidance such that the positioning assembly **920**, as described above in connection with the IntraVascular Endoscopy (I'VE) based repair method. A distal graft assembly **20** is fed over a guide wire, as described above, until the attachment cuff **21** appears directly above the carina at the bifurcation, as shown in Fig. 1.

A second guide wire **160** is now fed under guidance between one femoral incision and the left axillary incision. Another introducer sheath device **900** is fed from the axillary until the positioning assembly **920** reaches the infrarenal aorta at which time it is inflated. The repair apparatus **50** is then fed through the introducer sheath device **900** over guide wire **160** to the midpoint of the aortic aneurysm. The visualization apparatus **600** is then positioned adjacent the area of the wall **2** to which the attachment cuff **22** is to be attached. The scanning catheter is drawn caudad providing images of the distal aortal common iliac transition on an external monitor. The repair apparatus **50** is then oriented such that the

penetration apparatus **700** is adjacent the area where the attachment cuff **21** is to be attached to the wall **2.**

The primary and secondary penetration means **420** and **430** are then operated to form treatment specific holes within the cuff **22** and wall **2**, as described above. The primary penetration means **420** is then retracted and a fastener is then inserted within the treatment specific hole using the insertion means **450**. The location of the penetration apparatus **700** is then adjusted to repeat the process over the area previously viewed by the visualization apparatus **600**. The repair apparatus **50** is then oriented such that the visualization apparatus **600** may scan another portion of the wall **2**. The viewing and mounting process is alternately repeated until the attachment cuff **22** is firmly attached to the wall **2**.

The repair apparatus **50** is removed once the attachment cuff **22** is secured to the wall **2**. The proximal tube graft assembly **10** is then inserted in an inverted manner over the guide wire **160** to the position shown in Fig. 1. The repair apparatus **50** is then inserted through a femoral incision over the guide wire **160** to a position adjacent the attachment cuff **12**. The visualization apparatus **600** and the penetration apparatus **700** are then alternately operated in the manner described above to secure the attachment cuff **12** to the wall **2**.

Once the proximal graft assembly **10** is secured in place, the first guide wire and the repair apparatus **50** are removed and the proximal graft assembly **10** is invaginated. The tubular legs **11** are then inserted into the attachment tubes **22** or vice verse. Self-expanding stents **30** are then used to secure the attachment tube **22** and tubular legs **11** firmly together. The guide wire **160** is then removed. The positioning assemblies **920** are deflated and the introducer sheath devices **900** are removed from the femoral and axillary arteries. The incisions are then closed completing the repair process.

While this invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, the preferred embodiments of the invention as set forth herein are intended to be illustrative, not limiting. Various changes may be made without departing from the spirit and scope of the invention as defined in the following claims.

WE CLAIM:

1. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion act together to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall; and

wherein said fastening means further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

2. The fastener according to claim 1, wherein said fastening means includes at least one spring assembly, and said supplemental fastening means includes at least one supplemental spring assembly.

3. The fastener according to claim 2, wherein each of said first portion, said second portion and said at least one supplemental spring assembly extends substantially parallel to the vessel wall.

4. The fastener according to claim 2, wherein said fastening means comprises a plurality of entwined coil springs.

5. The fastener according to claim 2, wherein said supplemental spring assembly includes a coil spring.

6. The fastener according to claim 2, wherein said supplemental fastening means includes a first supplemental spring assembly connected to said first portion of said fastening means.

7. The fastener according to claim 6, wherein said supplemental fastening means includes a second supplemental spring assembly connected to said second portion of said fastening means.

8. The fastener according to claim 2, further comprising:

means for connecting at least a portion of said at least one supplemental spring assembly to said spring assembly.

9. The fastener according to claim 2, wherein said fastener has a first orientation for inserting said fastener through the vessel wall and the surgical component, and a second orientation when said fastener is in a secured position.

10. The fastener according to claim 9, wherein said spring assembly and said at least one supplemental spring assembly are aligned along a longitudinal axis when said fastener is in said first orientation.

11. The fastener according to claim 10, wherein said spring assembly and said at least one supplemental spring assembly are displaced with respect to each other and from said longitudinal axis when said fastener is in said second orientation.

12. The fastener according to claim 9, wherein said fastener is in tension when in said first orientation and a relaxed state when in said second orientation, said fastener further comprising:

control means for controlling the compression of said fastener in said first orientation.

13. The fastener according to claim 12, wherein said spring assembly and said at least one supplemental spring assembly are coil springs, wherein each of said coil springs has a plurality of individual coils.

14. The fastener according to claim 13, wherein said control means is located between a plurality of said individual coils.

15. The fastener according to claim 14, wherein said control means includes a suture material disposed between said plurality of said individual coils.

16. The fastener according to claim 15, wherein said suture material is formed from a dissolvable material, such that said suture material dissolves after said fastener has been secured in said second orientation.

17. The fastener according to claim 12, wherein said control means includes a dissolvable material formed on said fastener means and said supplemental fastener means.

18. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion act together to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall;

wherein said fastening means has a first orientation for inserting said fastening means through the vessel wall and the surgical component, and a second orientation when said fastening means applies the compressive force to the surgical component and the vessel, said fastening means being in tension when in said first orientation; and

control means for controlling the compression of said fastening means in said first orientation.

19. The fastener according to claim 18, wherein said control means includes a dissolvable material formed on said fastening means.

20. The fastener according to claim 19, wherein said fastener further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

21. The fastener according to claim 18, wherein said fastening means includes at least one coil spring assembly.

22. The fastener according to claim 21, wherein said at least spring assembly has a plurality of individual coils, wherein said control means is located between a plurality of said individual coils.

23. The fastener according to claim 22, wherein said control means includes a suture material disposed between said plurality of said individual coils.

24. The fastener according to claim 23, wherein said suture material is formed from a dissolvable material, such that said suture material dissolves after said fastener has been secured in said second orientation.

25. The fastener according to claim 23, wherein said fastener further includes at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion.

26. The fastener according to claim 25, wherein said supplemental fastening means includes at least one coil spring assembly having a plurality of individual coils.

27. The fastener according to claim 26, wherein said suture material is disposed between a plurality of said coils of said supplemental fastening means.

28. A fastener for use during a surgical procedure for securing a surgical component to a vessel wall, said fastener comprising:

flexible fastening means for securing the surgical component to the vessel wall under a compressive force;

wherein said fastening means has a first portion located on one side of the surgical component and the vessel wall, a second portion located on another side of the surgical component and the vessel wall, and an intermediate portion connecting to said first portion and said second portion, said intermediate portion extending through the vessel wall and the surgical component, whereby said first portion, second portion and said intermediate portion act to apply a compressive force to the surgical component and the vessel wall to secure the surgical component to the vessel wall;

at least one supplemental fastening means for securing the surgical component to the vessel wall, said at least one supplemental fastening means being located on at least one of said first portion and said second portion;

wherein said fastening means and supplemental fastening means have a first orientation for inserting said fastener through the vessel wall and the surgical component, and

a second orientation when said fastener applies the compressive force to the surgical component and the vessel, said fastener being in tension when in said first orientation; and

control means for controlling the compression of said fastener in said first orientation.

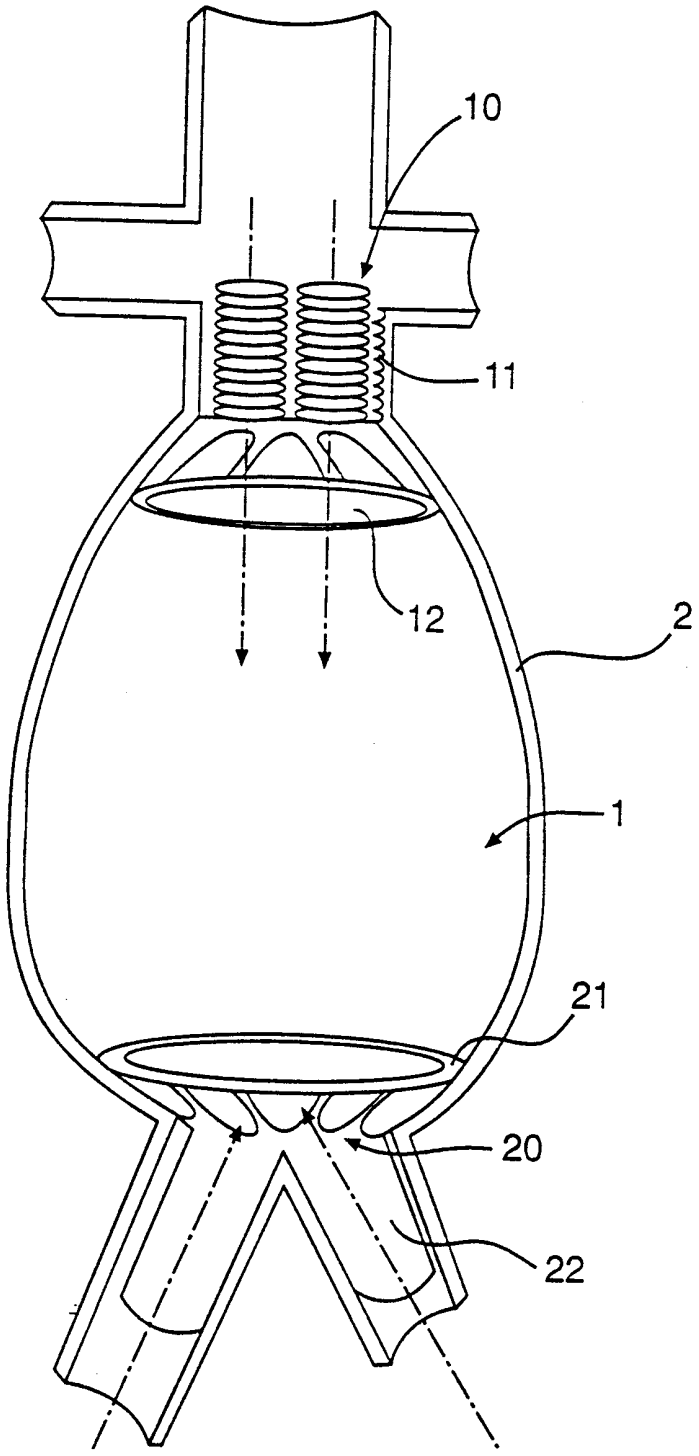


FIG. 1

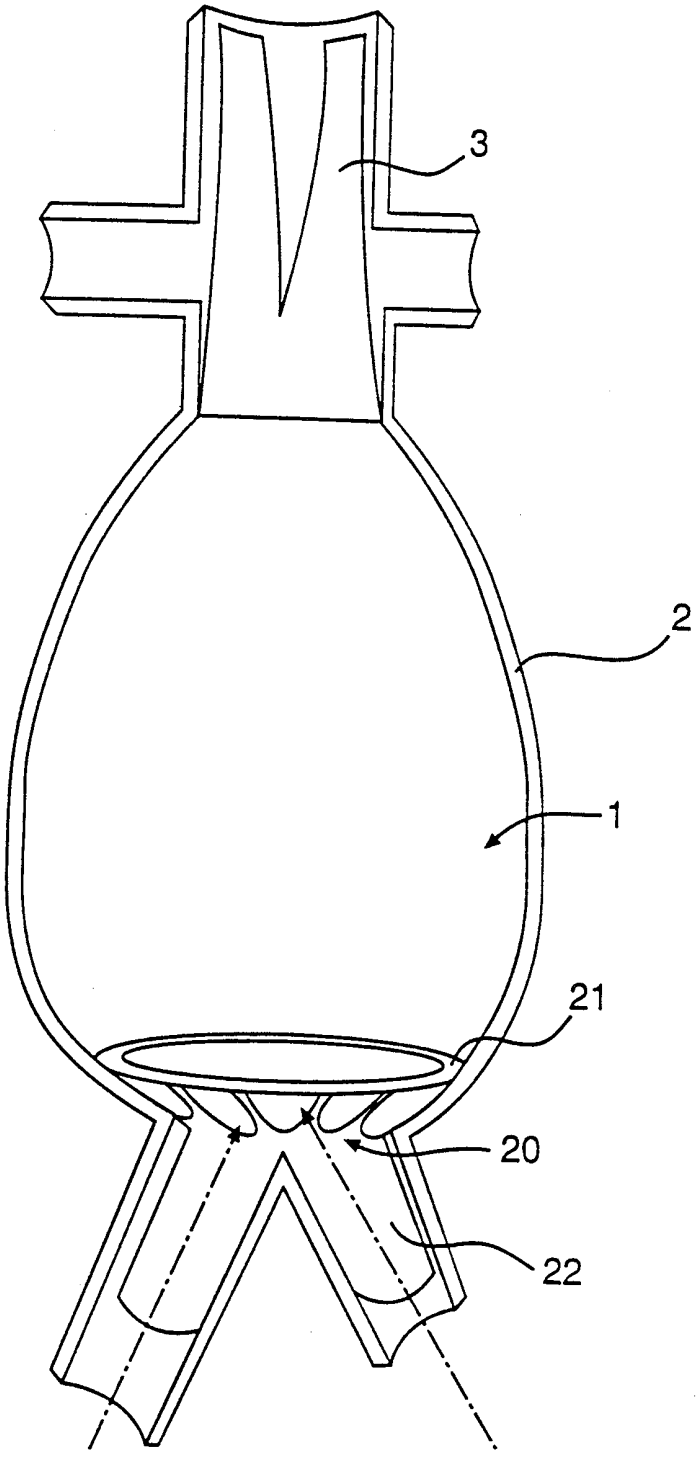


FIG. 2

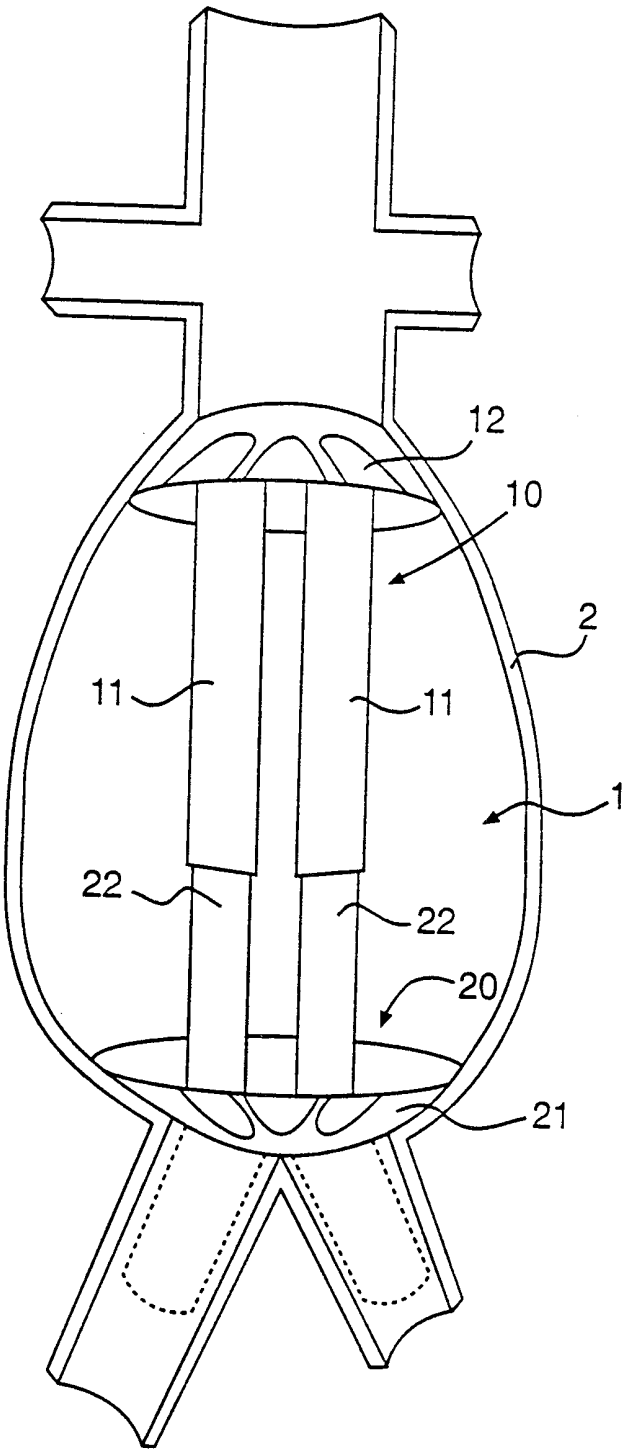


FIG. 3

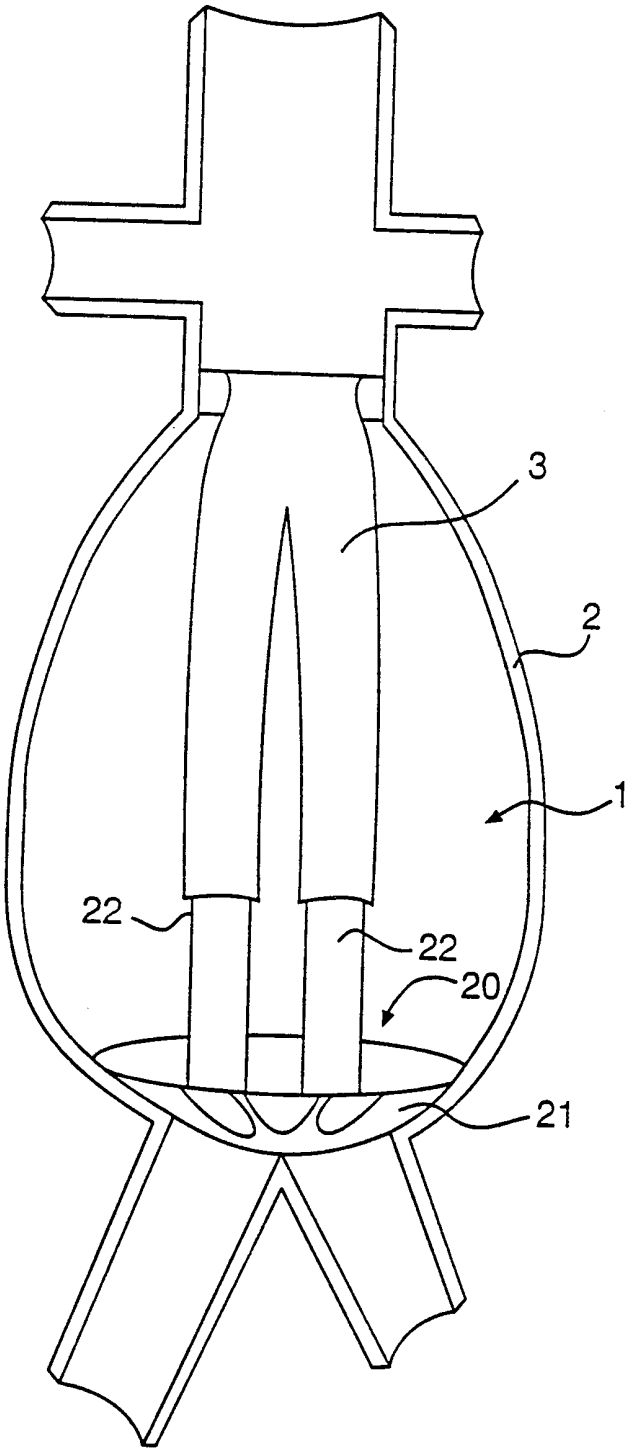


FIG. 4

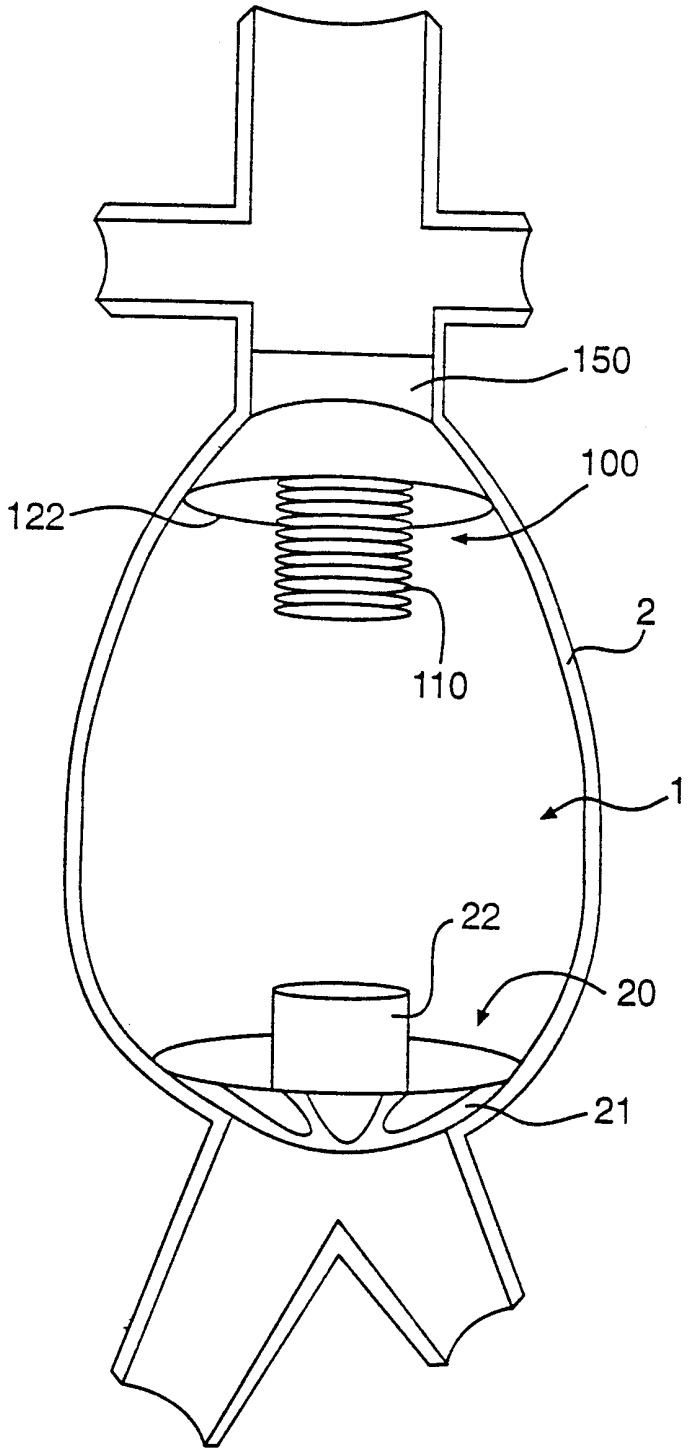


FIG. 5

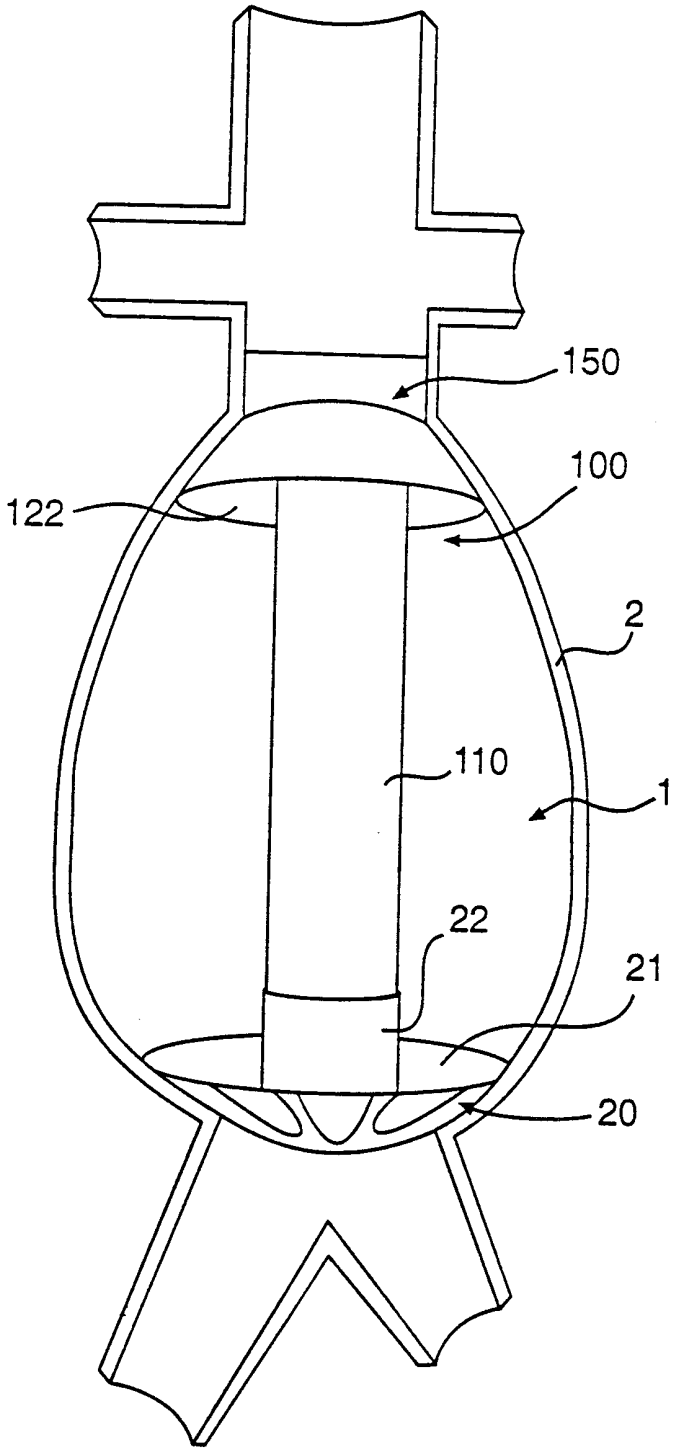


FIG. 6

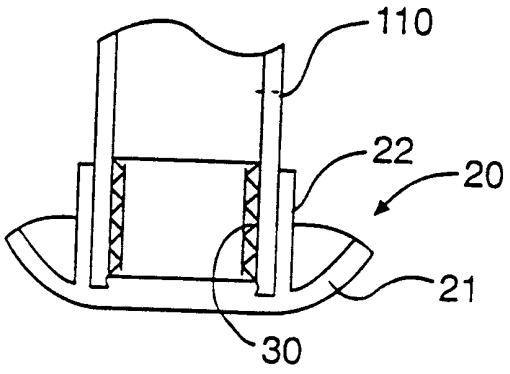


FIG. 7

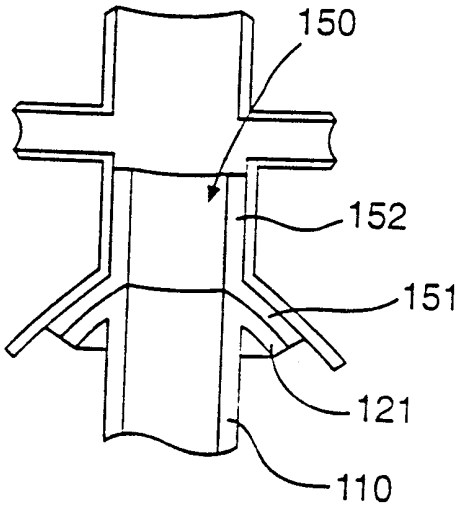


FIG. 8

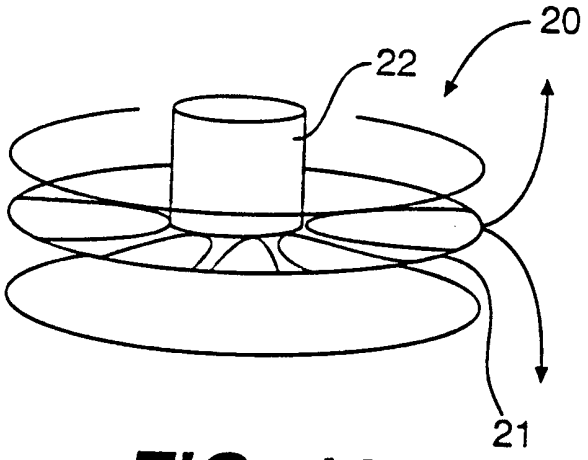


FIG. 11

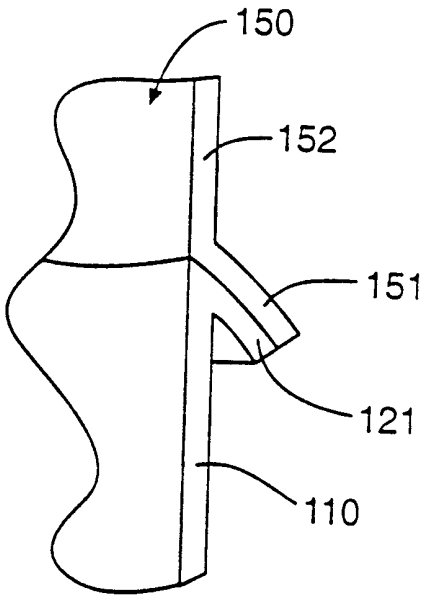


FIG. 9

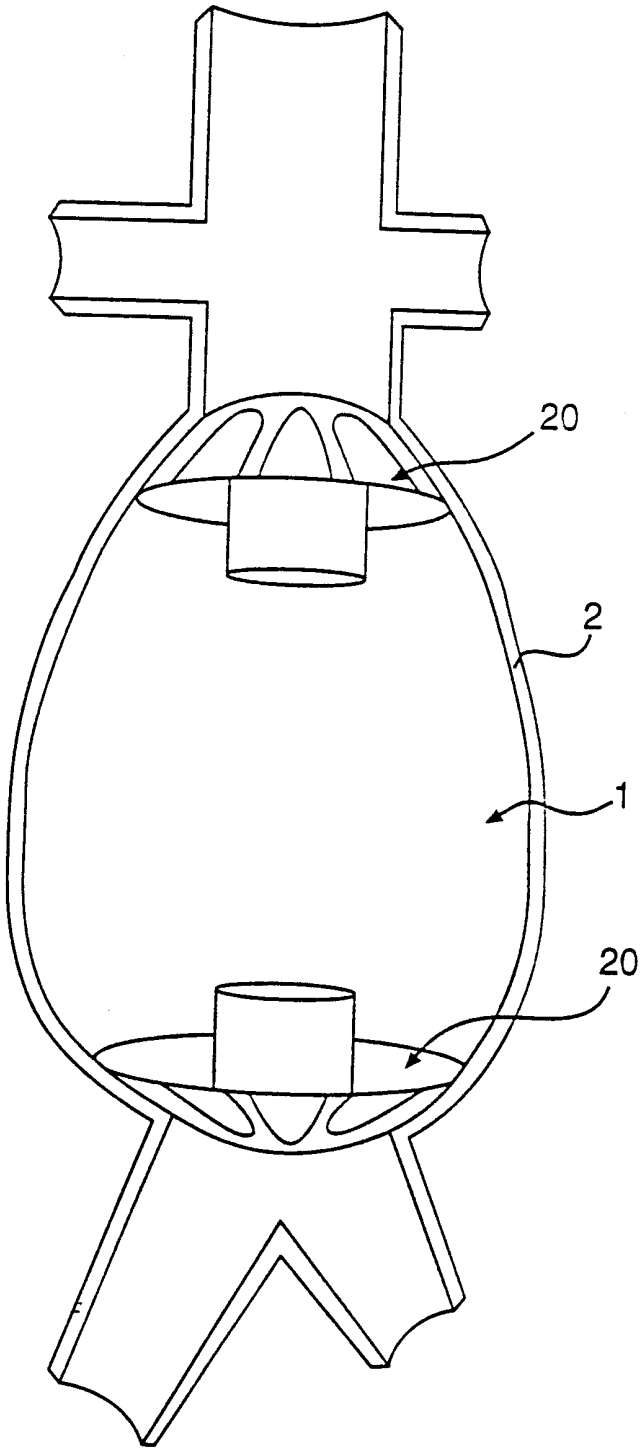


FIG. 10

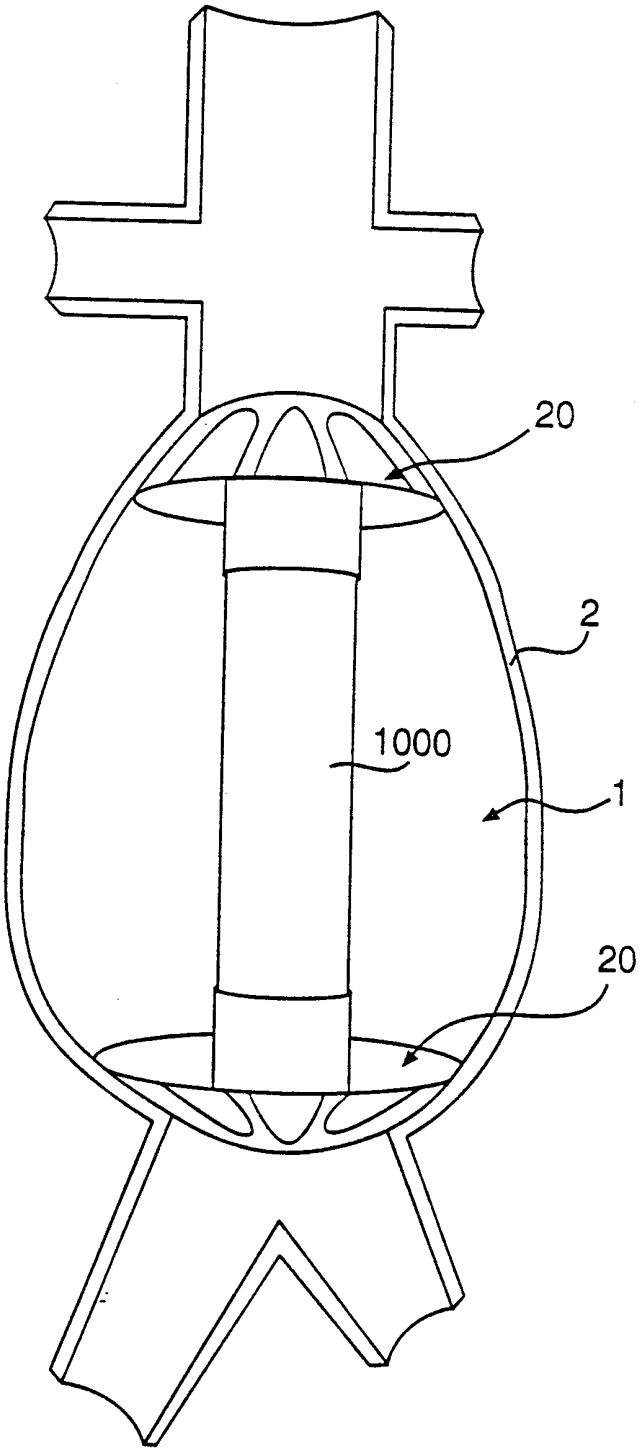


FIG. 12

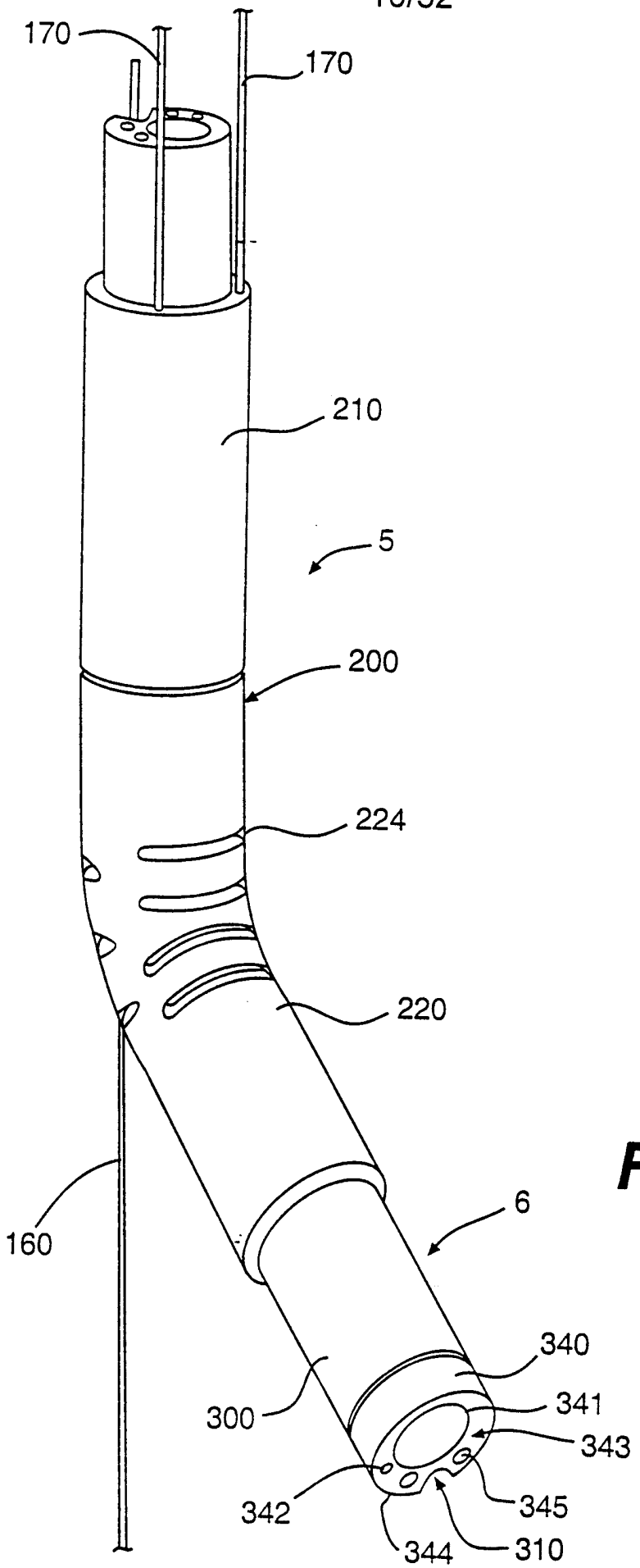


FIG. 13

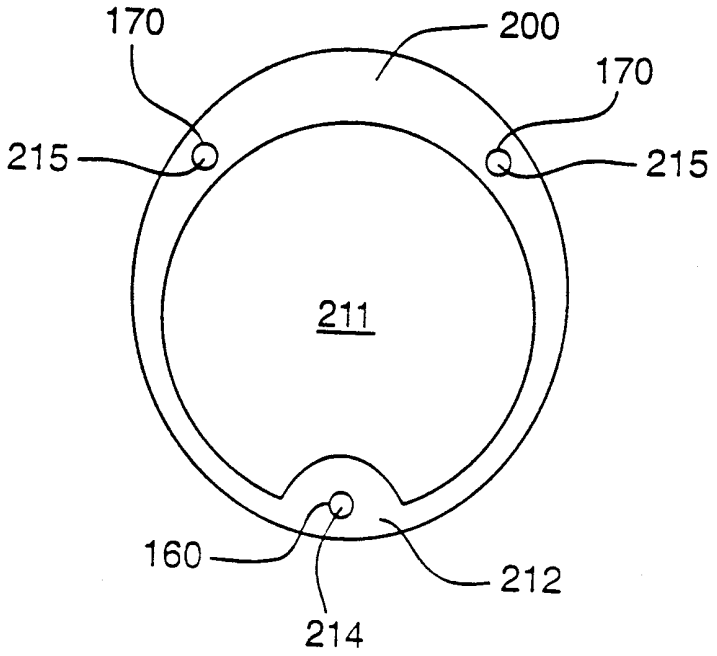


FIG. 14

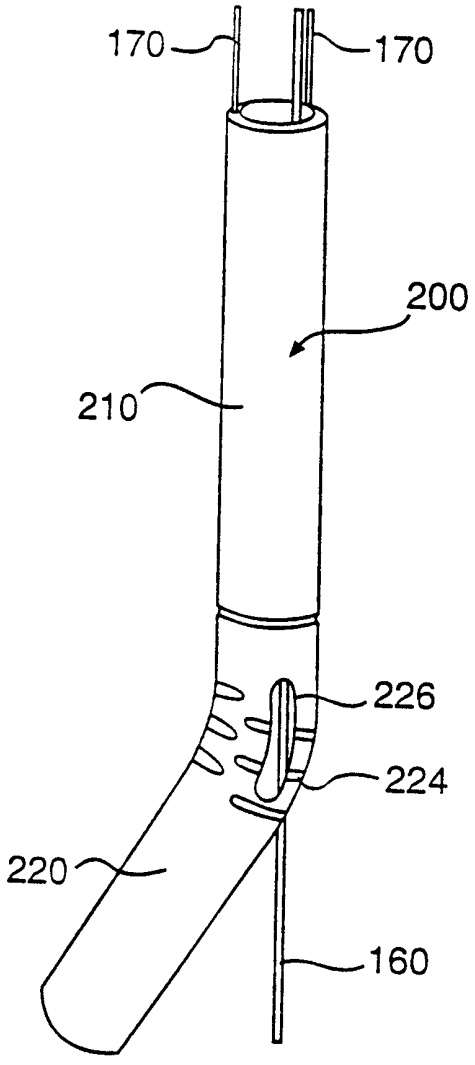


FIG. 16

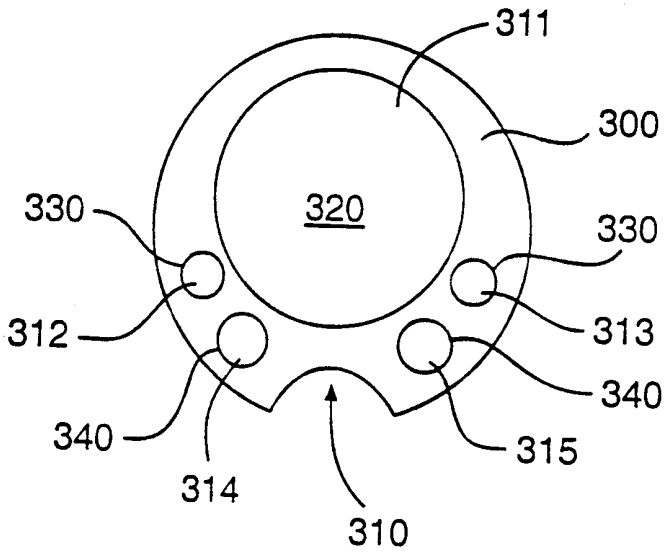


FIG. 15

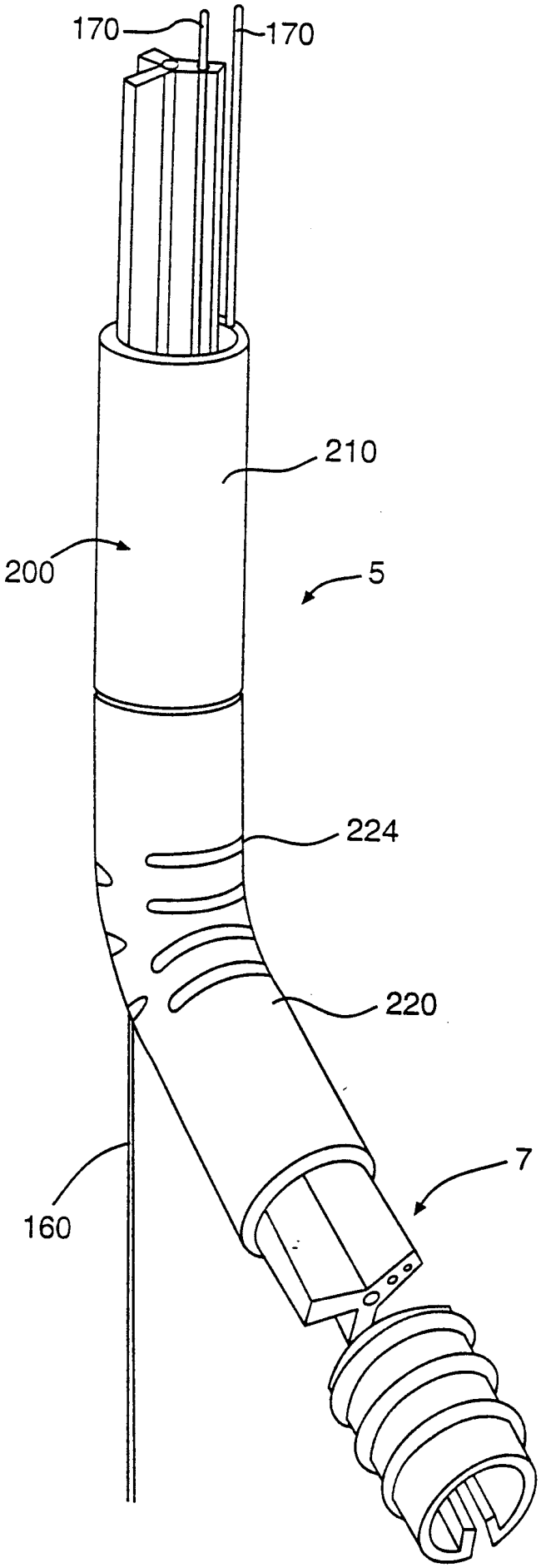


FIG. 17

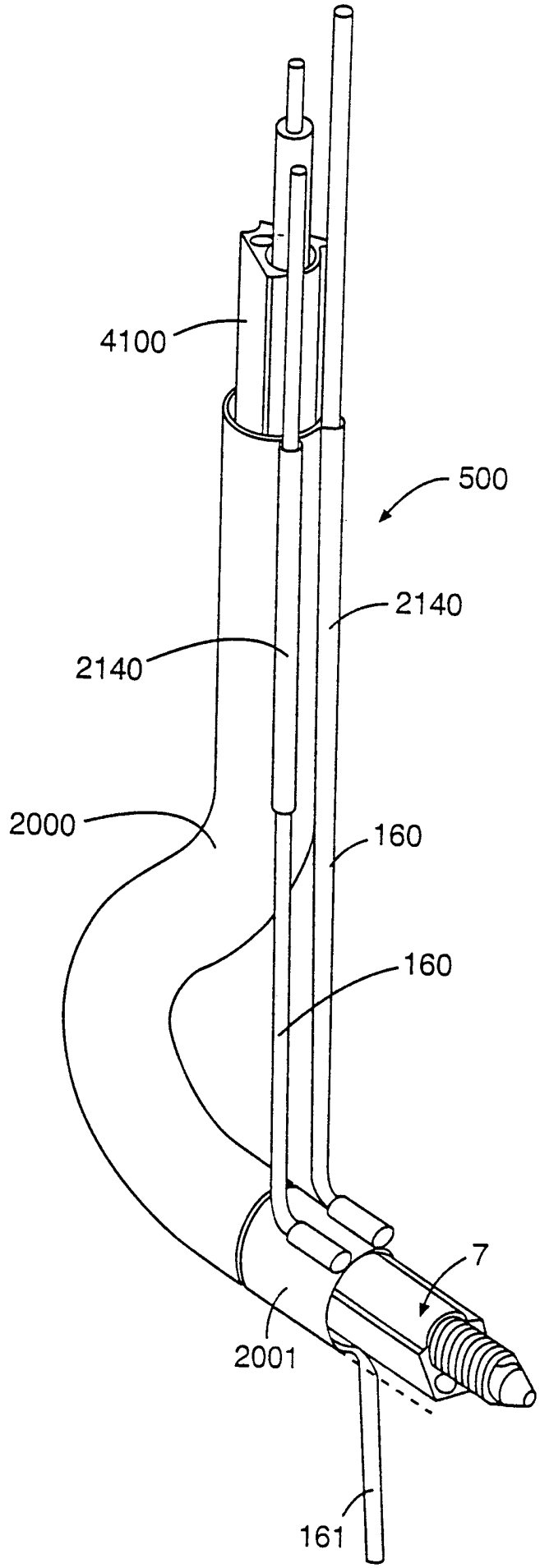


FIG. 18

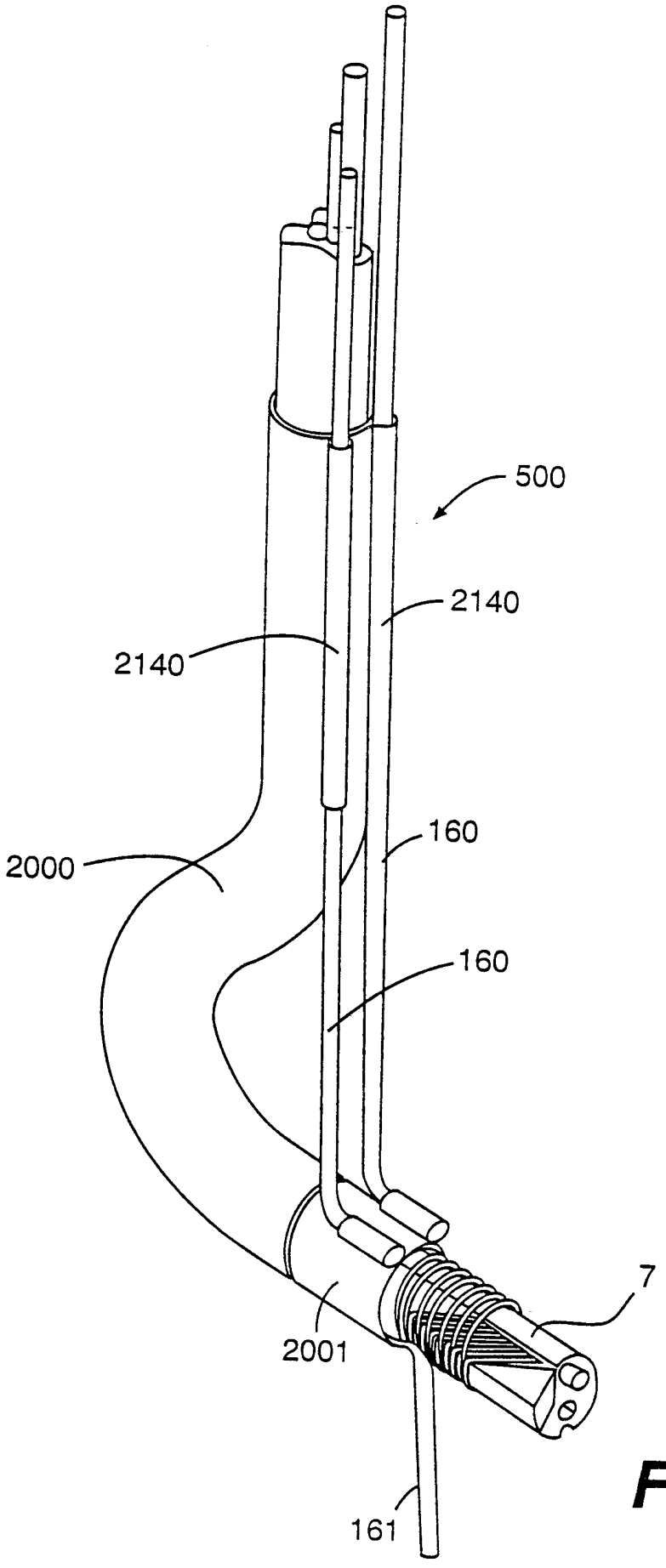


FIG. 19

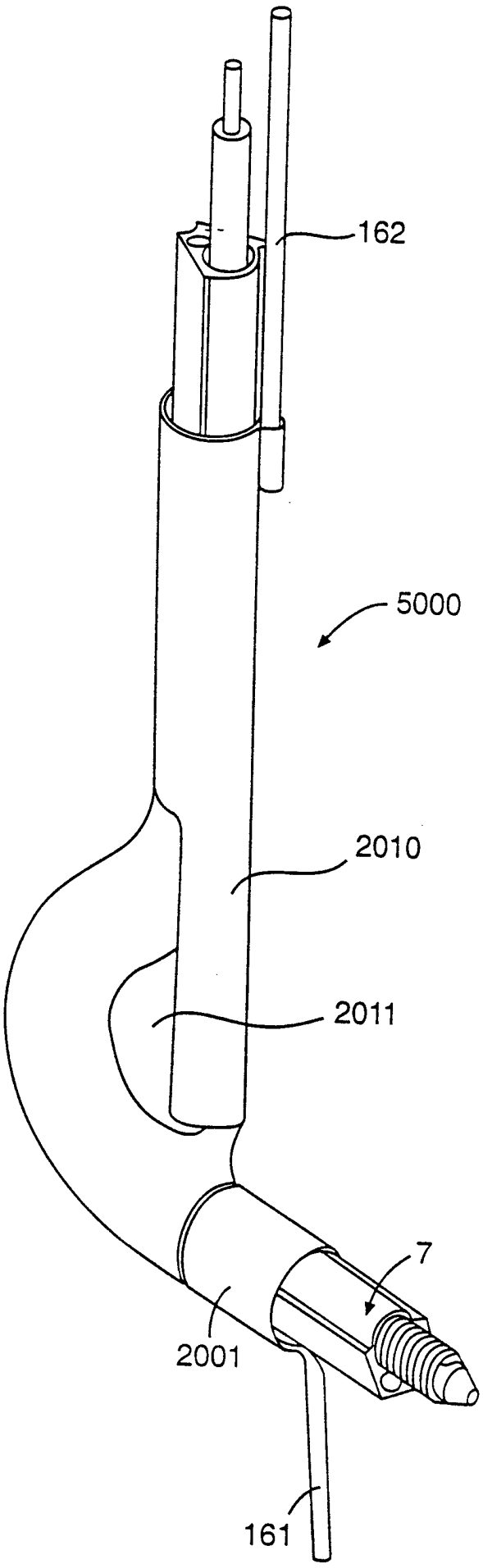


FIG. 20

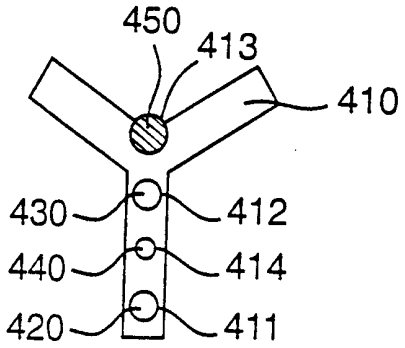


FIG. 21

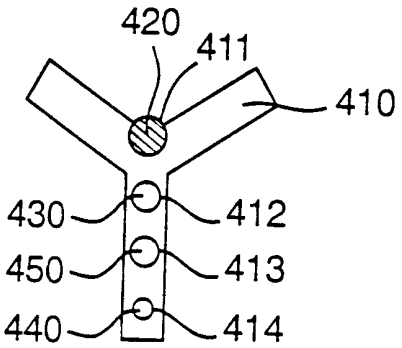


FIG. 22

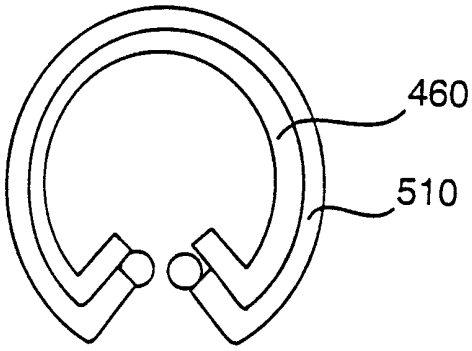


FIG. 23

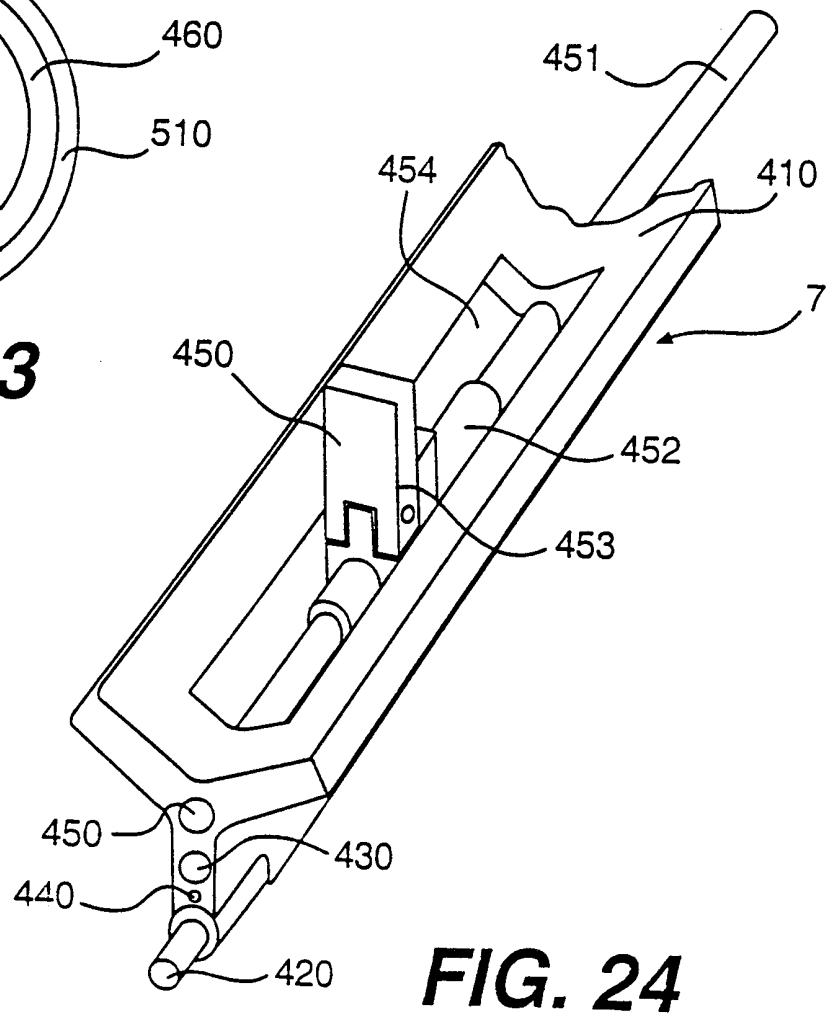


FIG. 24

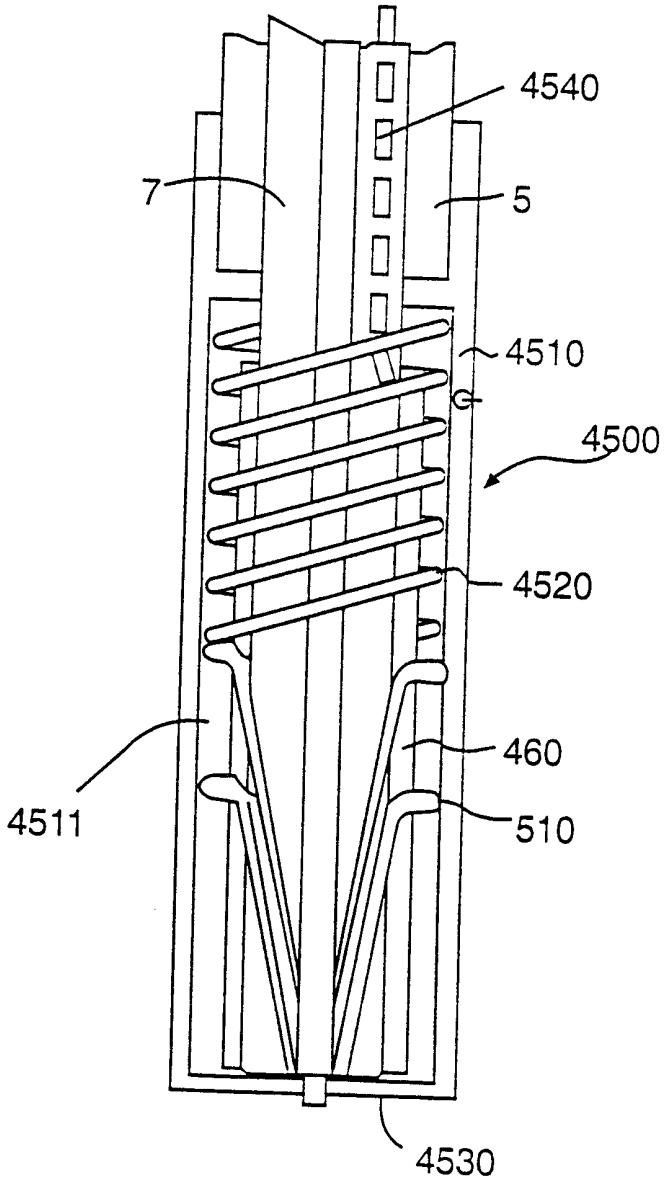
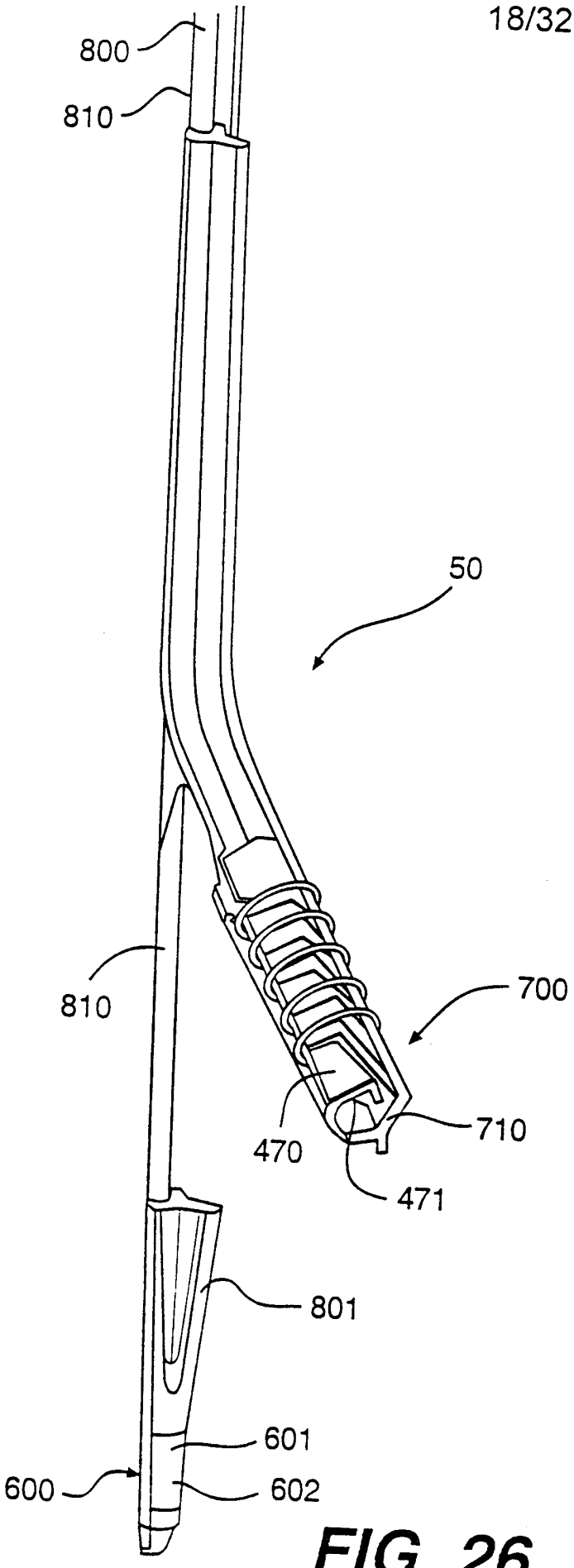


FIG. 25


800
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50
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710
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601
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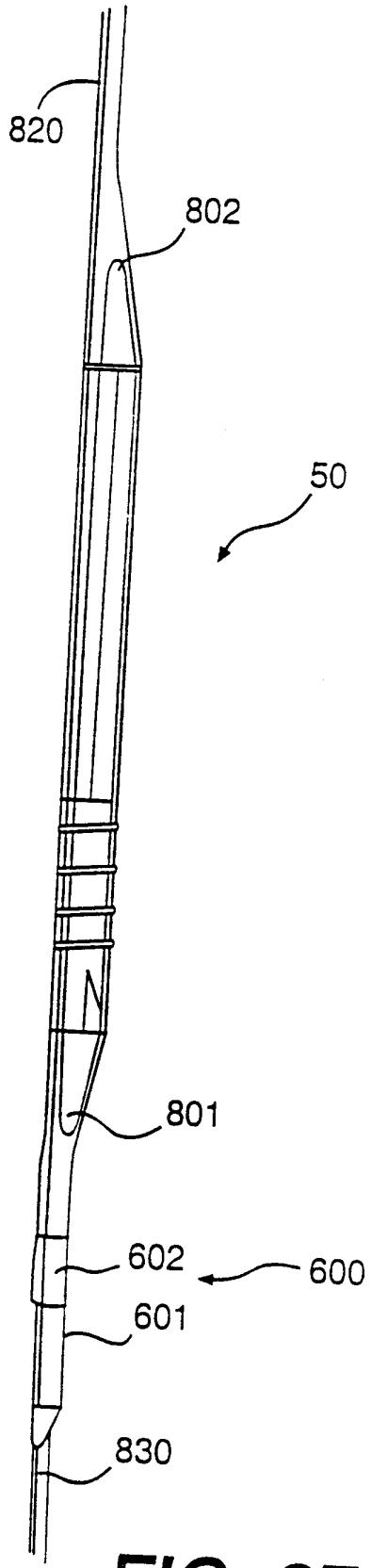
602

FIG. 26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600
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830

FIG. 27

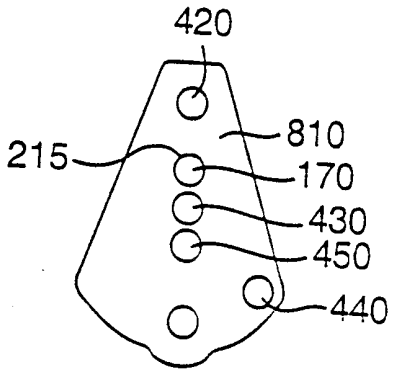
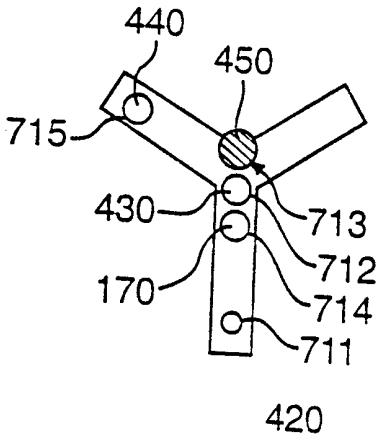

420
810
215
170
430
450
440

FIG. 28


440
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715
430
713
712
170
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711
420

FIG. 29

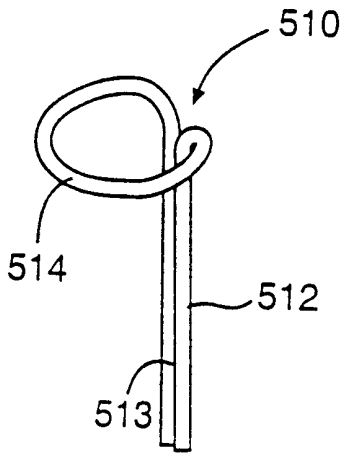

FIG. 30

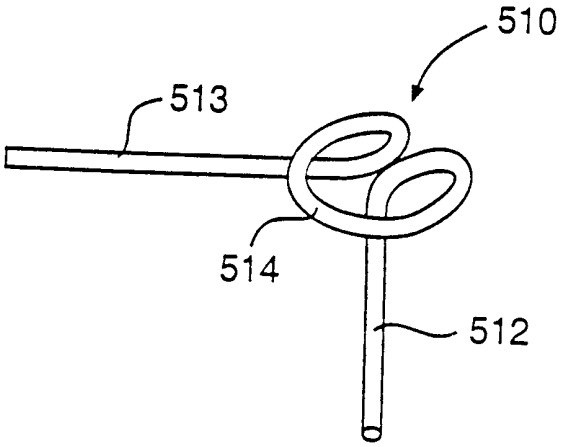

FIG. 31

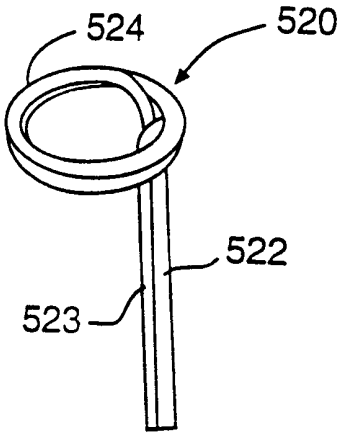

FIG. 32

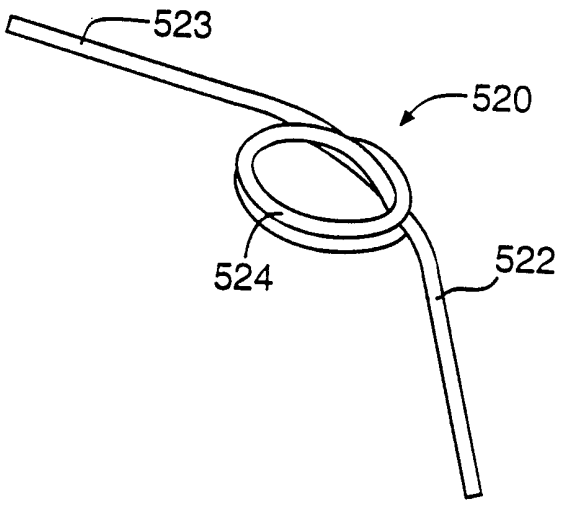

FIG. 33

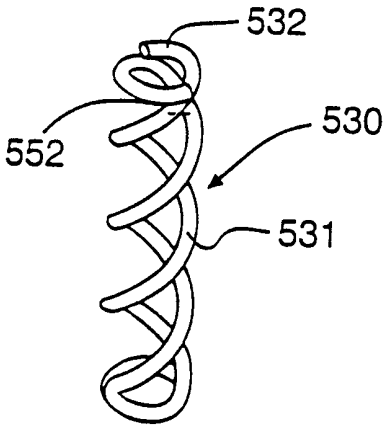

FIG. 34

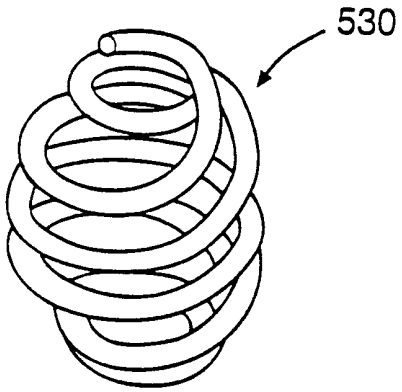

FIG. 35

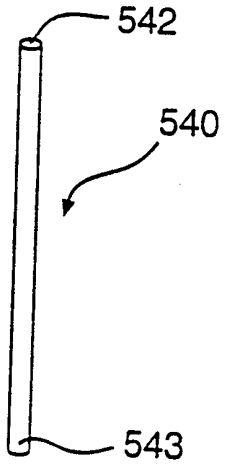

FIG. 36

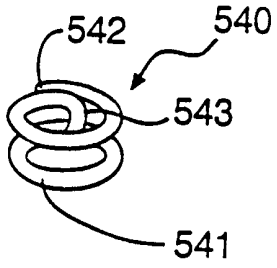

FIG. 37

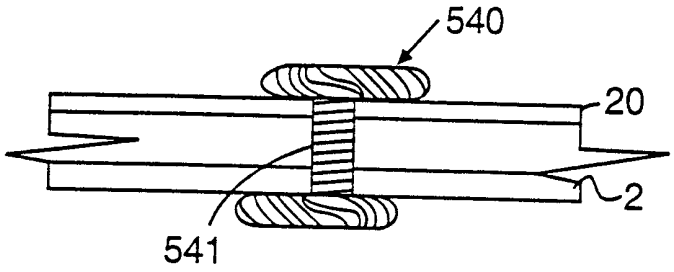

FIG. 38

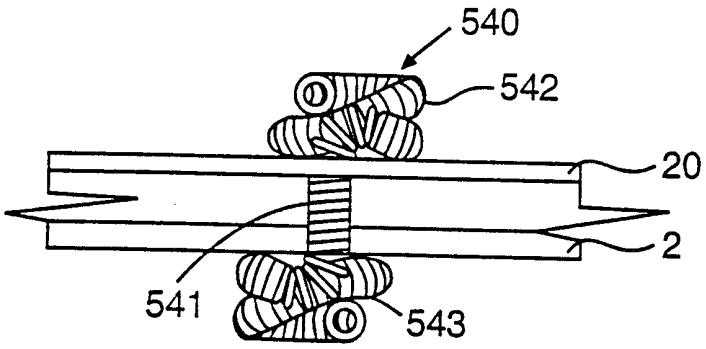

FIG. 39

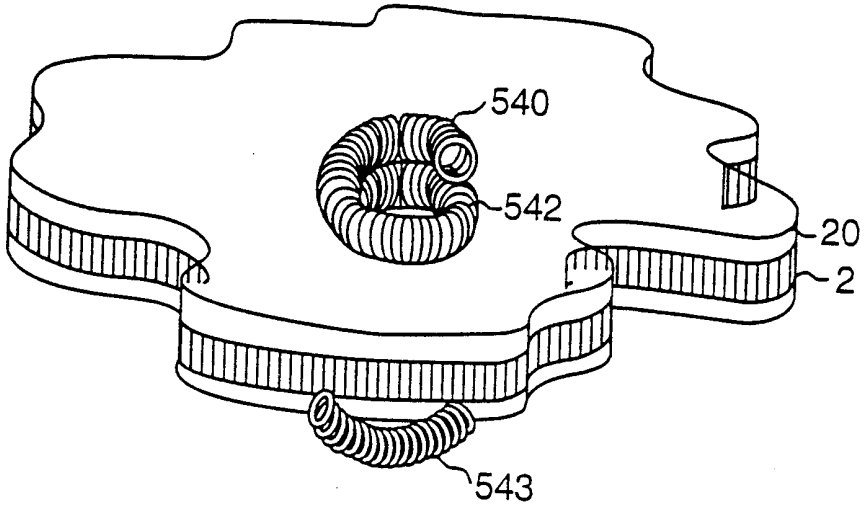

FIG. 40

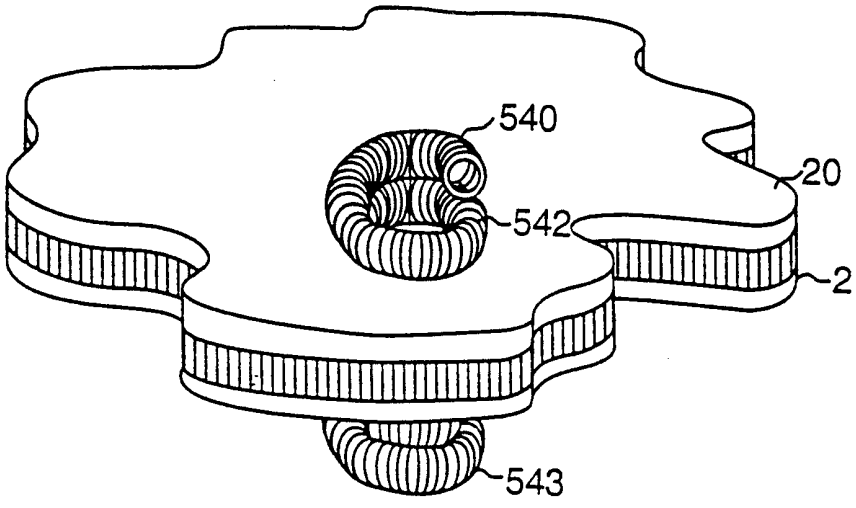

FIG. 41

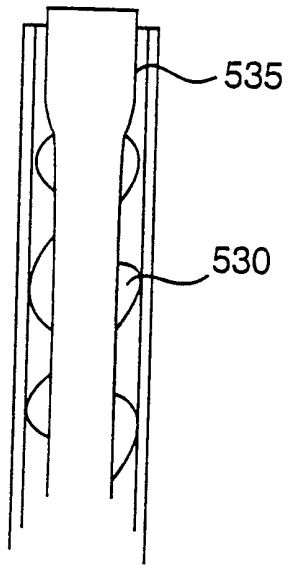

FIG. 42

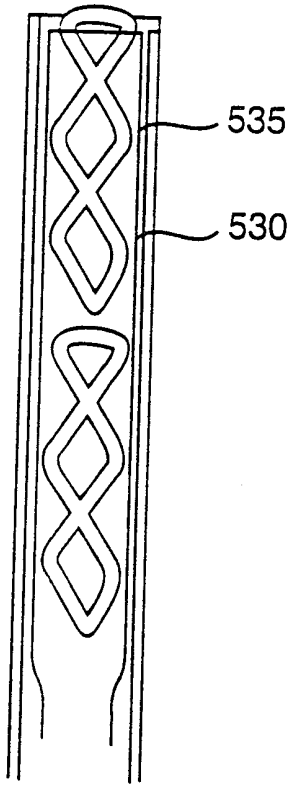

FIG. 43

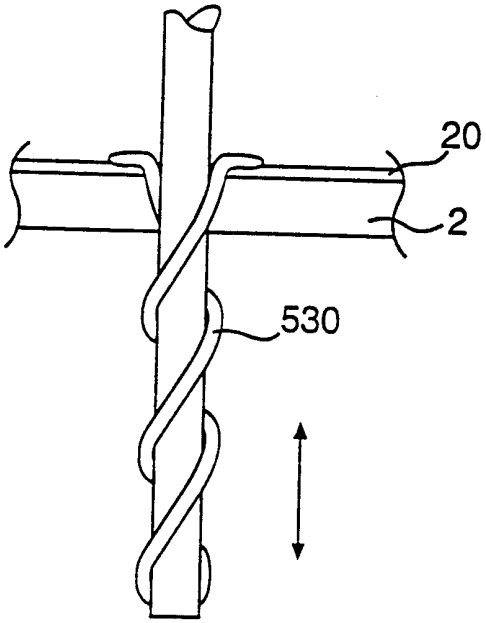

FIG. 44

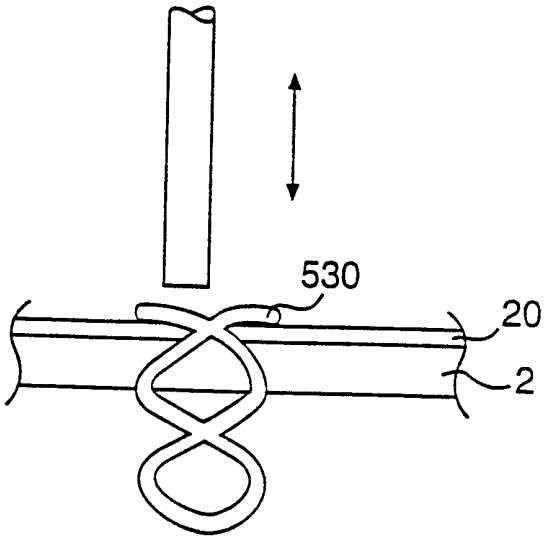

FIG. 45

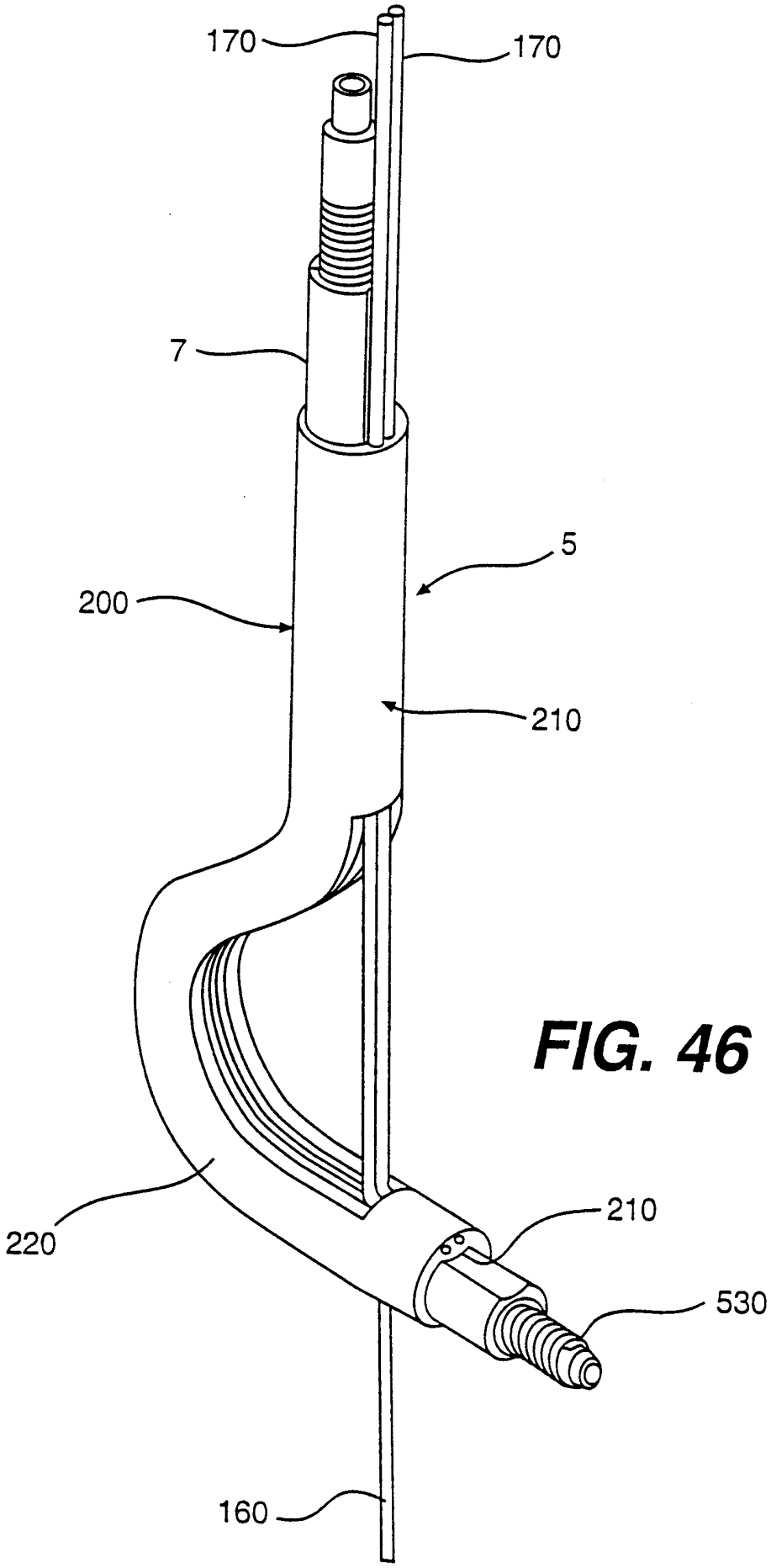

FIG. 46

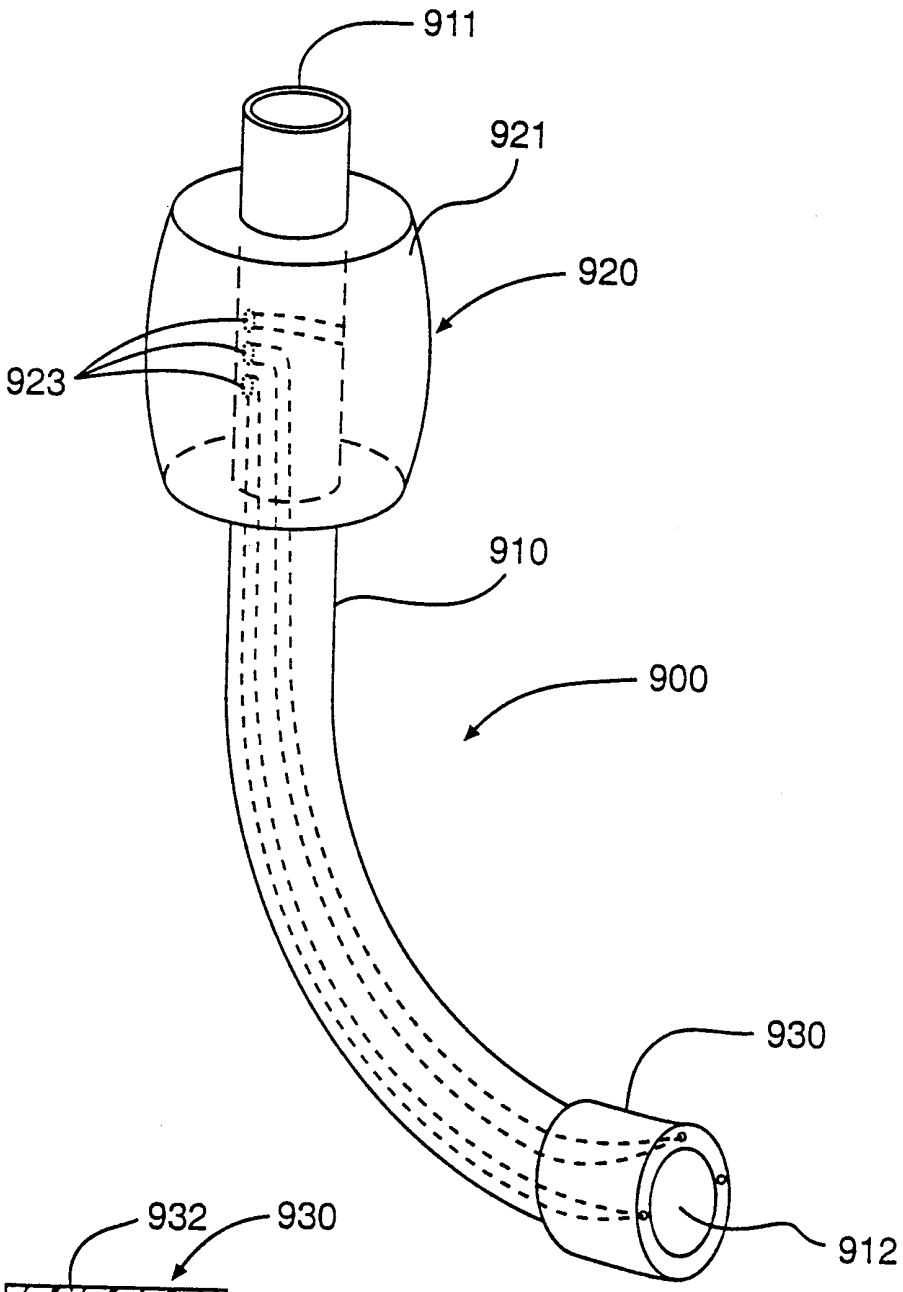

FIG. 47

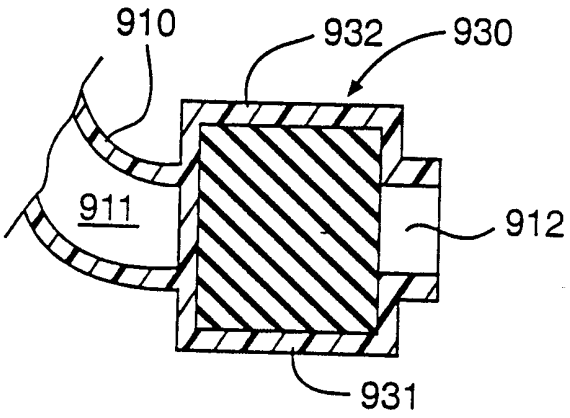

FIG. 48

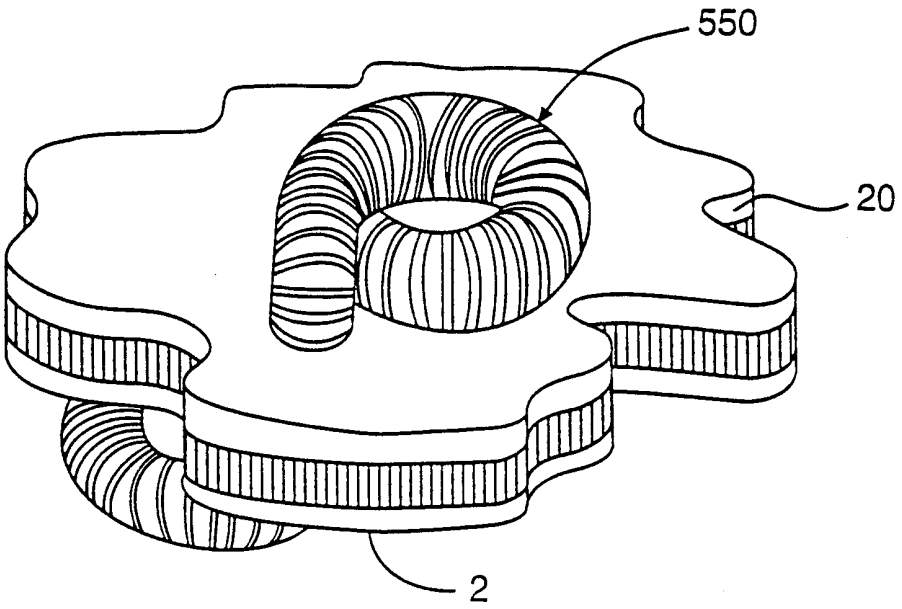

FIG. 49

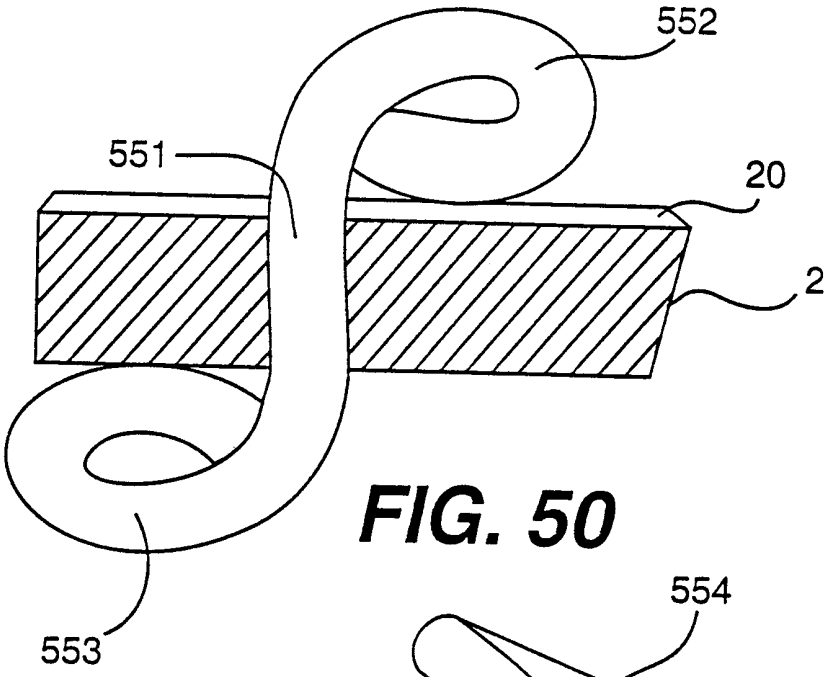

FIG. 50

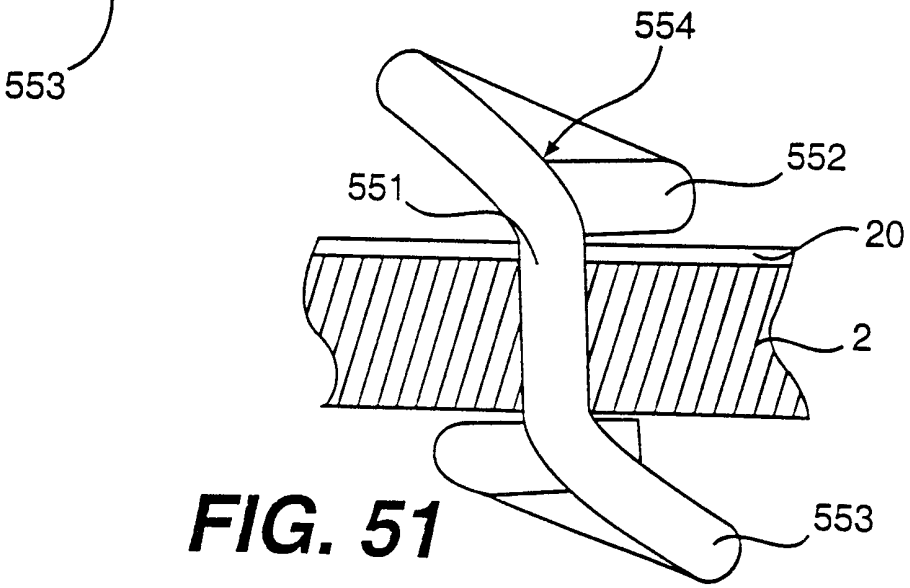

FIG. 51

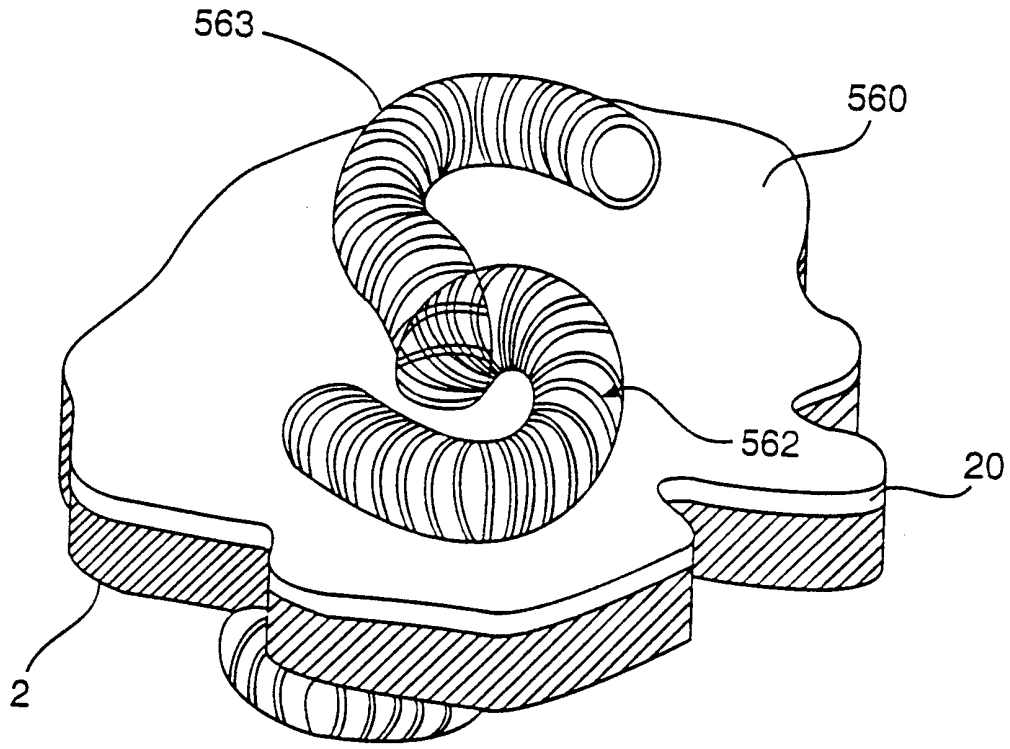

FIG. 52

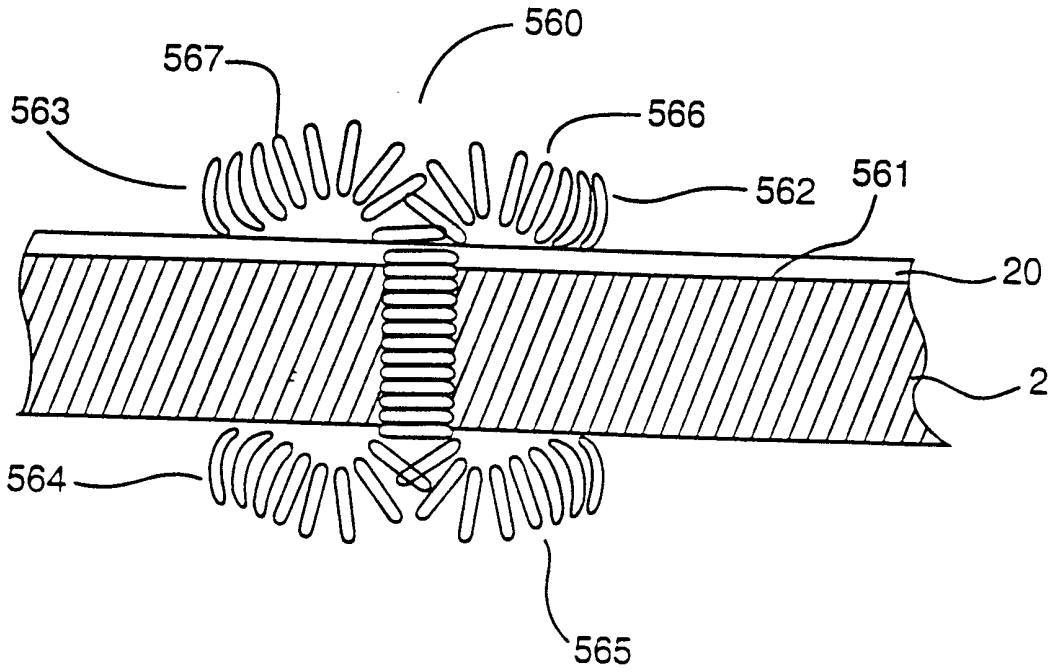

FIG. 53

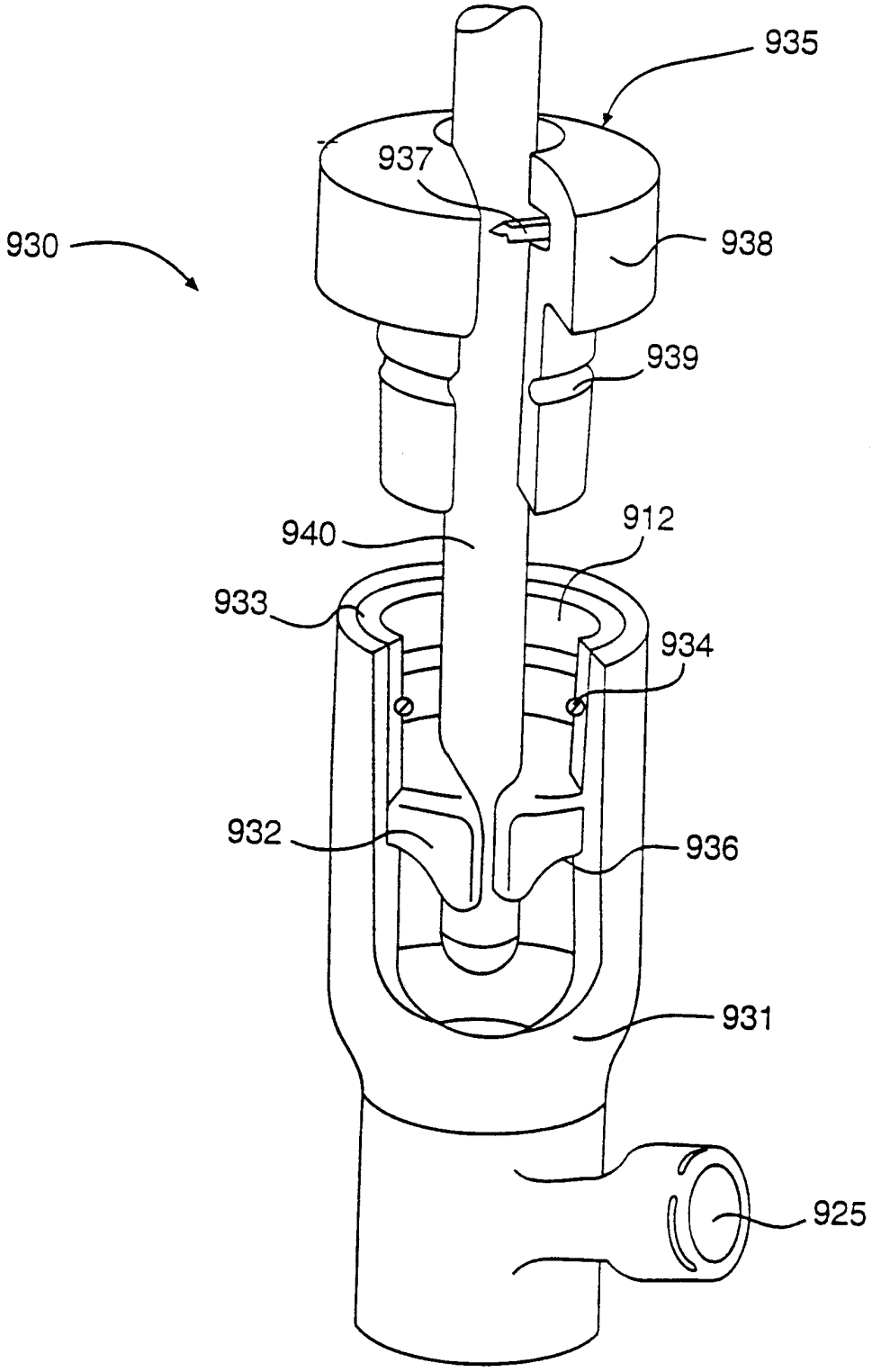

FIG. 54

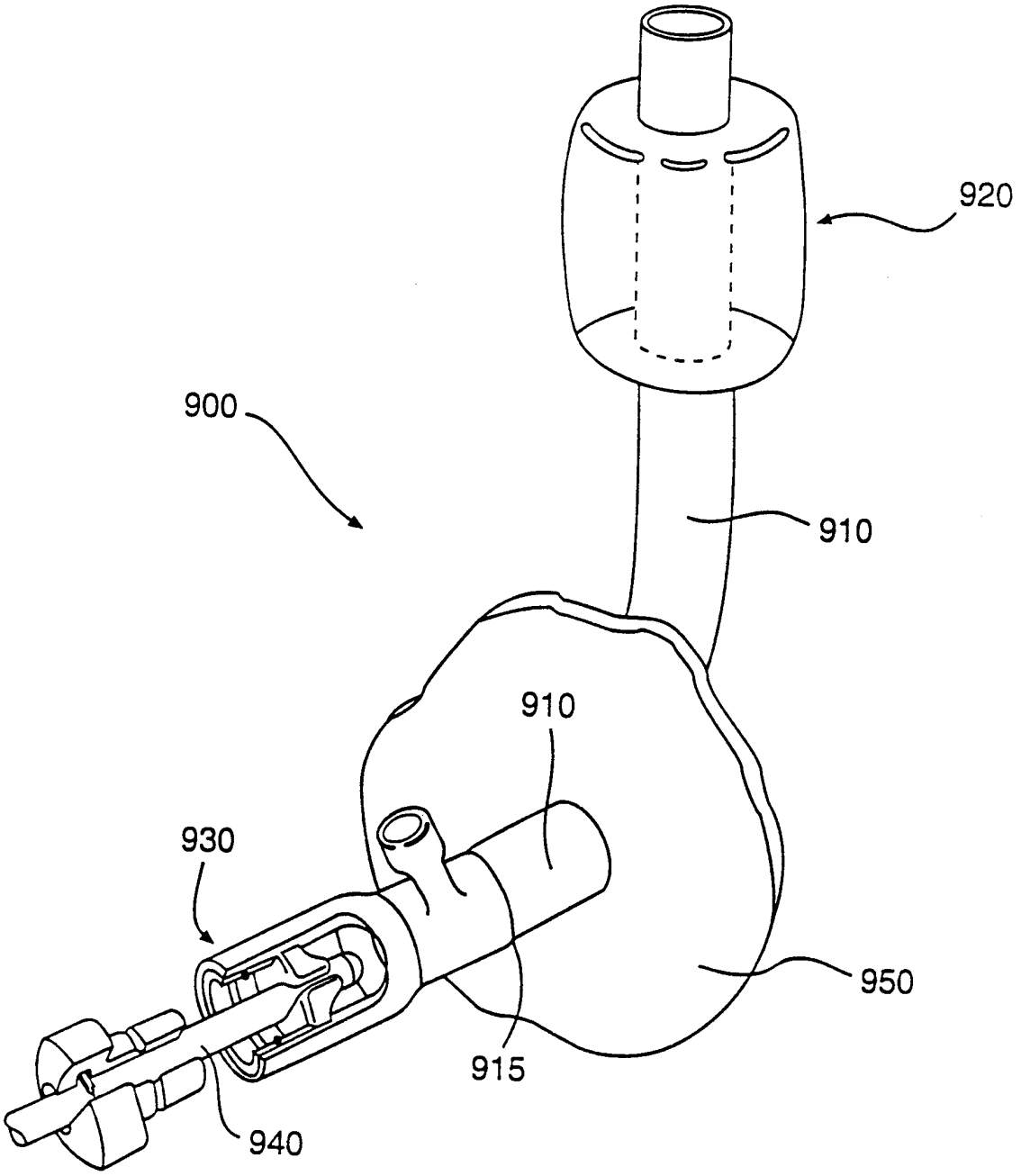

FIG. 55

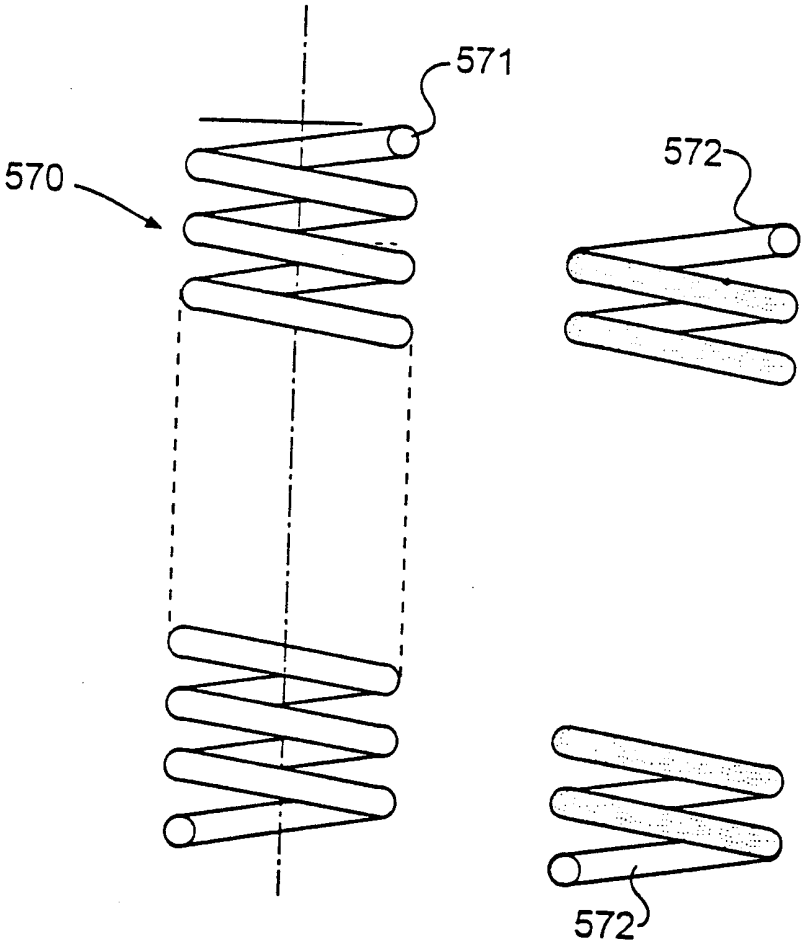

FIG. 56

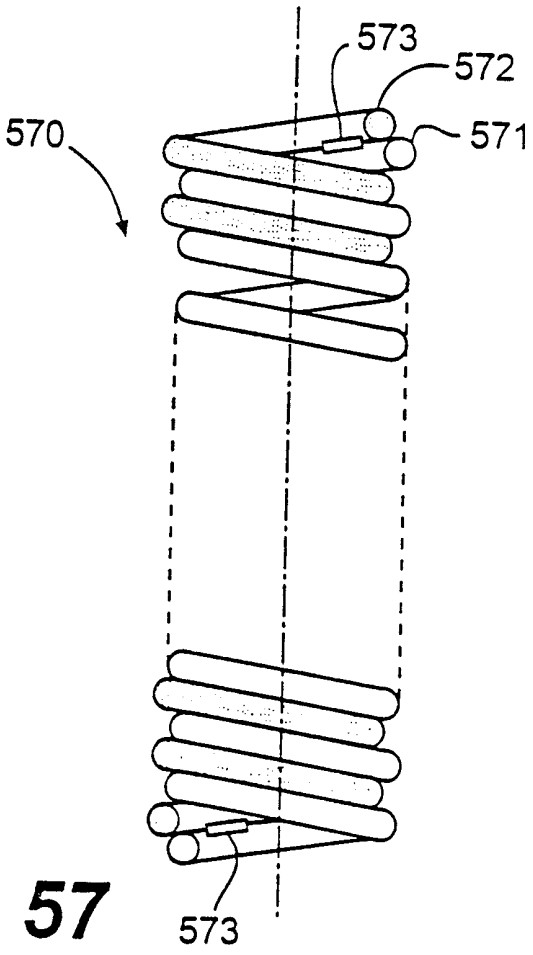

FIG. 57

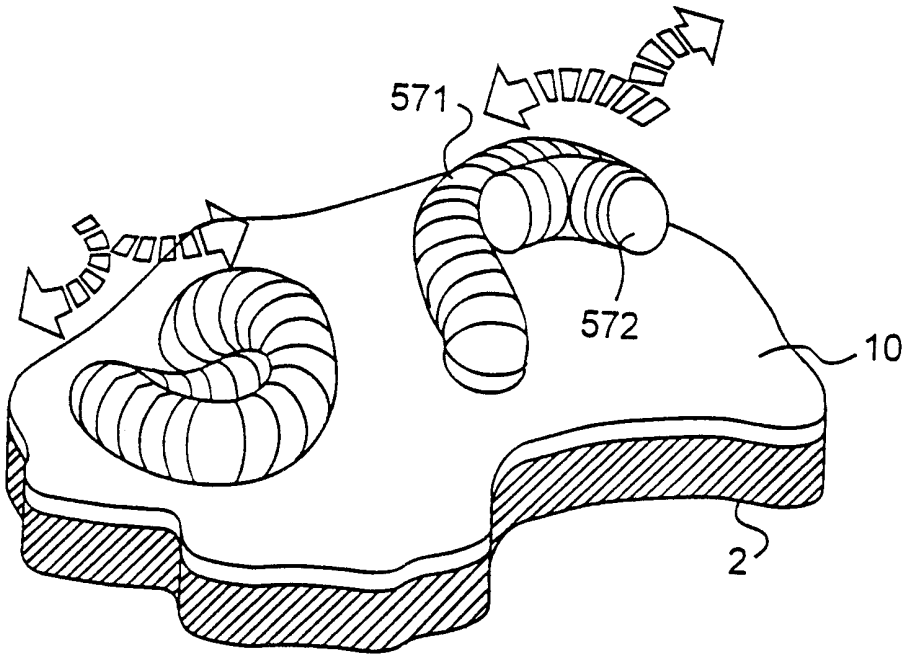

FIG. 58

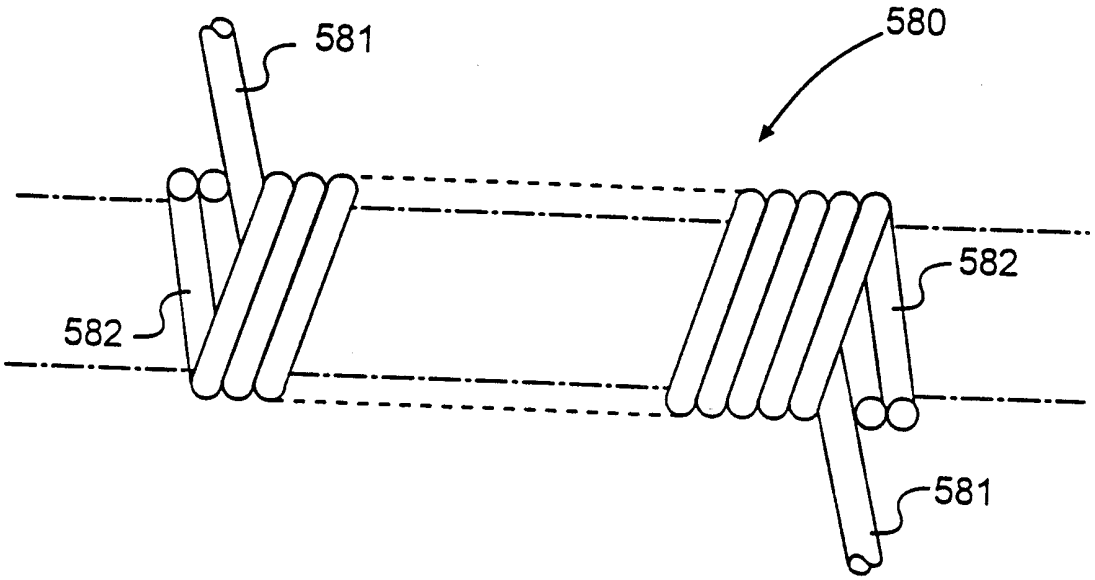

FIG. 59

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/29348

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/00
US CL :606/153
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/151, 153, 155, 157, 158

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,366,462 A (KASTER et al.) 22 November 1994, entire document.	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 16 FEBRUARY 2000	Date of mailing of the international search report 06 MAR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIKKI TRINH Telephone No. (703) 308-8238

Form PCT/ISA/210 (second sheet)(July 1992)★