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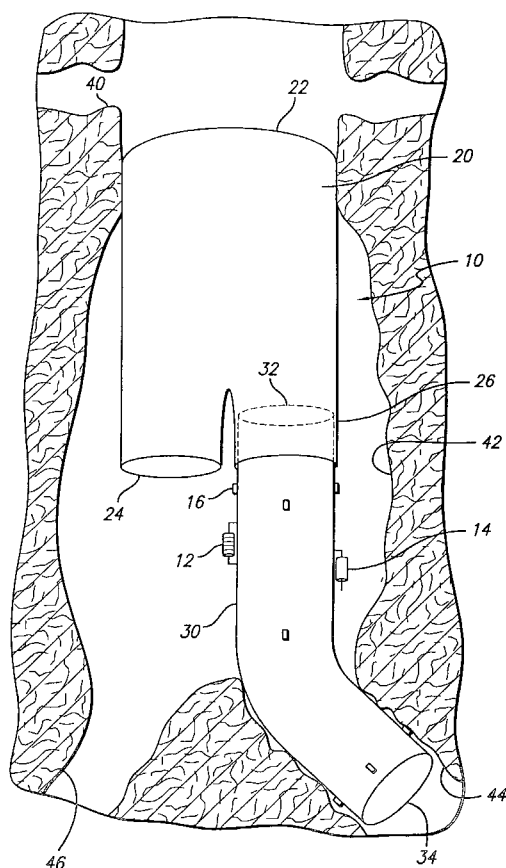
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(54) Title: ENDOVASCULAR GRAFT WITH SENSORS DESIGN AND ATTACHMENT METHODS



(57) Abstract: A endovascular graft (30) having sensing devices (16) attached thereto to facilitate measurement of pertinent parameters within the vasculature into which the graft (30) is implanted. Power sources and transmitters (12) may be attached to the graft to facilitate transmission of measurements to a receiving device outside the patient's body. The sensing devices (16) may be electrically passive or integrated devices with measurement and transmission capability. The sensing devices may be attached to specific locations on the graft material or attached to the lumen, thereby providing pertinent parameters from critical points inside the vasculature, or may be dispersed over the surface of the graft material or within the lumen to provide a profile of pertinent parameters. The sensing devices (16) may be attached to the graft material with one suture (70) using a running stitch to minimize graft bulk and may be coated with a material to inhibit or control tissue growth.

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## ENDOVASCULAR GRAFT WITH SENSORS

### DESIGN AND ATTACHMENT METHODS

#### BACKGROUND OF THE INVENTION

This invention relates to the treatment of body lumens and, more particularly, to the endovascular placement of a prosthetic graft within vasculature for the purpose of repairing the same.

5           Ruptured abdominal aortic aneurysms (AAA) are a leading cause of death in the United States. Treatment options to repair AAA include conventional open surgery and implantation of an endovascular graft. Conventional open surgical repair of AAA involves major abdominal surgery with associated high rates of morbidity. Endovascular grafts have been developed to endoluminally bypass

10   abdominal aortic aneurysms through minimally invasive surgery. Many patients that are unacceptable surgical risks for open repairs are eligible for endovascular graft implantation. Deployment of transfemoral, endovascular grafts to treat AAA is appealing for many reasons: avoidance of an abdominal incision, lack of aortic cross clamping, the potential for regional anesthesia, and a shortened hospital stay.

15           Untreated AAA have been shown to continue to expand until rupture, with an associated high mortality rate. Implantation of endovascular grafts have also been associated with high complication rates, including perioperative death,

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conversion to open repair, the need for further intervention, the need for hemodialysis, a failure to cure the AAA, and wound complications.

The inability to obtain or maintain a secure seal between the vessel wall and the endovascular graft is a complication unique to endovascular aneurysm exclusion. Because the term "leak" has been associated with aneurysm rupture following conventional surgery, the term "endoleak" has been proposed as a more definitive description of this complication. It is believed that persistent endoleaks result in continued aneurysm expansion, which may eventually lead to aneurysm rupture. Aneurysms that have been successfully excluded have shown a tendency towards a reduction in aneurysm diameter. Failure to properly exclude the aneurysm from systemic arterial blood pressure keeps the patient at risk of impending rupture. Endoleaks have been classified according to the source of the leaks. Current classifications of endoleaks include four categories. Type I endoleaks are "perigraft" or "graft-related" leaks that involve a persistent channel of blood flow due to inadequate or ineffective sealing at the ends of the endovascular graft, or between overlapping components of a modular system. Type II endoleaks are retrograde flow into the aneurysm sac from patent lumbar arteries, the inferior mesenteric artery, or other collateral vessels. Type III endoleaks result from fabric tears, graft disconnection, or graft disintegration. Finally, Type IV endoleaks are flow through the graft fabric associated with graft wall porosity or

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permeability. It has been recognized that preoperative patent side branches are not a good predictor of postoperative endoleaks.

There have been a number of reported cases of aneurysm rupture following implantation of an endovascular graft. Some of the ruptures occurred in  
5 patients without a documented endoleak.

A number of studies have focused on measurement of pressure within the aneurysm sac following implantation of an endovascular graft, both in the human patient, an animal model, or an in vitro model. Properly implanted endovascular grafts have been shown to reduce the pressure within the aneurysm sac while an  
10 endoleak, with or without detectable blood flow, continues to pressurize the sac at pressures equivalent to the systemic arterial pressure. Animal studies utilizing a predictable rupturing aneurysm model have shown that non-excluded aneurysms will rupture. Thrombosed aneurysm sacs may still receive pressurization from a sealed endoleak and this continued pressurization keeps the aneurysm at risk for  
15 rupture.

Current methods of patient follow-up include arteriography, contrast-enhanced spiral computed tomography (CT), duplex ultrasonography, abdominal X-ray, and intravascular ultrasound. All of these methods are costly and involve invasive procedures with associated morbidity that may need to be performed in a  
20 hospital. None of the imaging methods are completely successful in detecting endoleaks. Therefore, the potential exists for an endoleak to go undetected until

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eventual rupture. An increase in aneurysm diameter is detectable, and should be considered an indication of endoleak. To avoid aneurysm rupture an increase in aneurysm diameter must be detected in a timely fashion to identify patients in need of corrective endovascular procedures.

5           An endovascular graft with the ability to measure pressure within the aneurysm sac and provide feedback to the physician could provide acute confirmation of a procedure and identify those patients with persistent pressurization of their aneurysm, and subsequent risk of rupture. Some physicians are advocating that the follow-up examinations of AAA patients focus on pressure  
10   measurements, but that this is not currently clinically feasible. Furthermore, follow-up examinations may be performed in the physician's office as opposed to a hospital. Moreover, clinicians will have a new method to study the pathology of post-endovascularly treated AAA disease.

          Accordingly, there exists a need for an endovascular graft that facilitates  
15   non-invasive measurement of pressure, as well as other pertinent parameters, within the aneurysm sac and along the endovascular graft itself as a means for confirming the success of a procedure as well as identifying patients at risk for aneurysm rupture after the endovascular graft is implanted.

          However, providing devices on an endovascular graft to facilitate the  
20   measurement of pertinent parameters poses problems. The measurement device increases bulk, which can significantly effect the delivery profile of the

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endovascular graft and increase the force necessary to deploy the device, such as jacket or release wire retraction forces. Increased bulk is a significant issue for an endovascular graft. Furthermore, attachment of measurement devices to an endovascular graft may require sutures and the suture knots not only provide  
5 increased bulk, but are also potential graft wear points. Additionally, tissue growth around a measuring device attached to an implanted endovascular graft may interfere with its function and inaccurate data may result. The present invention addresses these problems and other needs.

### SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is embodied in an endovascular graft with sensors attached thereto. The endovascular graft has the ability to be delivered endovascularly and measure pertinent parameters within the lumen in which it is implanted. The endovascular graft has the ability to transmit data about intra-lumen parameters to an external monitoring device. Confirmation of a successful implant procedure is quickly and easily obtained. Patient follow-up is less costly (conducted in the physician office), non-invasive, and more accurate, allowing prompt intervention in those patients most at risk for acute AAA rupture.

10 The invention would also allow for more frequent patient follow-up, increasing the potential to diagnose and treat aneurysms at risk before acute rupture.

In one aspect of the invention, a modular endovascular graft having a main body component and one or more limb components is provided. One or more sensors are attached to the limb component(s). By attaching at least one sensor near the superior end of the limb component and sizing the main body component such that the sensor is adjacent to the aneurysm sac when the endovascular graft is implanted, measurement of pertinent parameters within the aneurysm sac is facilitated. The meaning of the term "adjacent" as used herein encompasses the sensor being located within the aneurysm sac or at a location where the parameters or properties being detected indicate conditions within the aneurysm sac.

20 Measurements of pertinent parameters within the aneurysm sac may allow early

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confirmation of a successful procedure and identification of areas of the patient's vasculature at risk for aneurysm rupture, thrombus formation, infection, inflammation or other anomalies without the need for invasive procedures.

An antenna or other data transmitter and a power source also may be  
5 attached to the limb component adjacent to the aneurysm sac, allowing a physician or technician to monitor graft and vessel health without the need for an invasive procedure. The transmitter transmits measurements made by the sensors to a receiver located outside the patient's body. With the main body component unencumbered with sensors, transmitters or power sources, the bulk of the main  
10 body component is minimized and thereby, catheter diameter, jacket retraction and deployment complications are kept to a minimum.

In another aspect of the invention, an endovascular graft is provided that has attached thereto at least one integrated sensor/transmitter device capable of measuring a pertinent parameter and transmitting the measurements to an external  
15 monitoring device. Although having more bulk than a sensor, the integrated sensor/transmitter device has less total bulk than a sensor and independent transmitter device, thereby facilitating less total bulk for the endovascular graft.

Furthermore, the integrated sensor/transmitter device may be designed to allow one or more "satellite" sensors, having no function other than measurement,  
20 to be connected thereto. A single integrated sensor/transmitter device and smaller "satellite" sensors facilitate a smaller total bulk than multiple integrated

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sensor/transmitter devices. Attaching the integrated sensor/transmitter at a central location such as the graft crotch and “satellite” sensors at various locations on the endovascular graft facilitates measurement and transmission to an external monitoring device of pertinent parameters at multiple locations along the

5 endovascular graft and within the lumen. The “satellite” sensors allow a complete profile of pertinent parameters to be obtained and may provide more accurate identification of anomalies. Measurement of pertinent parameters at multiple locations along the endovascular graft or within the aneurysm sac may allow early

10 detection of a defective seal between endovascular graft components, graft wear or changes in aneurysm geometry. The smaller “satellite” sensors may also allow pertinent parameters to be measured from locations on the endovascular graft where local graft bulk is a constraint of the design, such as the graft contra limb or near the superior attachment system that holds the graft in the patient’s aorta.

Additionally, it is contemplated that “satellite” sensors may be attached

15 directly to the lumen of a patient. The integrated sensor/transmitter device also may be attached directly to the lumen or attached to an implanted endovascular graft.

Moreover, it is contemplated that passive devices, or monuments, which perform no sensing function may be attached to the implanted endovascular graft or directly attached to the aneurysm sac. By tracking the location of the monuments

20 with a monitoring device, changes in the position of the endovascular graft within the lumen or changes in the geometry of the tissue outside the endovascular graft

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may be detected without the problems of encapsulation or thrombus isolation associated with the measurement of pertinent parameters. Such changes may provide early detection of endovascular graft displacement or aneurysm re-dilation due to an endoleak.

5           Sensors with pressure measurement capability may be used to detect pressure changes in the aneurysm sac indicative of graft failure or endoleak due to an inadequate seal between the endovascular graft and the vasculature. Sensors with temperature measurement capability may be used to detect temperature differentials associated with “hot spots” related to inflammation, infection or

10   thrombus formation in the vessel. Sensors with the capability to measure oxygen and other blood constituents such as enzymes, proteins, and nutrients, may be used to detect minute blood flow indicative of endoleak. Sensors with the capability to measure electrical potential or magnetic fields may be used to detect differences in potential associated with areas of the vessel at risk for thrombus formation. Sensors

15   also may be provided to facilitate other sensing applications such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

          In yet another aspect of the invention, sensors are attached to an

20   endovascular graft using one continuous suture. Starting at one location on the sensor, a running stitch around the sensor is used to attach the sensor to the graft

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fabric, thereby minimizing the number of knots necessary for attachment, in this case a single knot. It is contemplated that the running stitch may start at any location on the sensor depending on the location of the sensor on the endovascular graft. Minimizing the number of knots is advantageous because knots are potential  
5 graft wear points and add bulk. Additionally, a single knot attachment design may allow the sensor to be placed close to the graft crotch due to the lack of a knot at the end closest the crotch.

In an additional aspect of the invention, the sensors may be covered in a coating that either inhibits tissue growth or promotes a known or controlled amount  
10 and/or type of tissue growth. Because tissue growth may interfere with the ability of a sensor to perform its measurement function, inhibiting tissue growth or restricting tissue growth to a known type and/or amount may increase the reliability of measurements obtained.

The invention is applicable to all applications of endovascular grafts to  
15 treat aneurysmal segments of blood vessels. Furthermore, the invention and methods disclosed herein may be applied any time it is desired to measure intraluminal parameters in a non-invasive manner. It is contemplated that the invention may be used with all shapes of endovascular grafts known within the art.

Other features and advantages of the present invention will become  
20 apparent from the following detailed description taken in conjunction with the

accompanying drawings, which illustrate, by way of example, the principles of the invention.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a partial cross-sectional view of one embodiment of the invention showing a partially assembled bifurcated endovascular graft implanted across an aneurysm sac;

FIG. 2 is a perspective view of another embodiment of the present invention showing a bifurcated graft with an integrated sensor/transmitter device and “satellite” sensors;

FIG. 3 is a perspective view of a typical integrated sensor/transmitter device of the present invention;

FIG. 4 is a partial cross-sectional view of an alternate embodiment of the invention shown in FIG. 2 showing a bifurcated graft implanted across an aneurysm sac into which an integrated sensor/transmitter device and “satellite” sensors have been attached;

FIG. 5 is a schematic view of another embodiment of the present invention showing an endovascular graft with monuments attached thereto implanted in a patient's body and an external source/receiver; and

FIG. 6 is an enlarged view of a portion of graft fabric showing a sensor of the present invention attached using a single suture and running stitch.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

As shown in the exemplary drawings and for purposes of illustration, the invention is embodied in a prosthetic endovascular graft having the ability to measure pertinent parameters inside the lumen into which it is implanted and transmit the measurements to a receiver located external to the patient.

Referring to FIG. 1, an embodiment of the invention is shown in which a modular bifurcated endovascular graft 10 of the type known within the art is implanted in a body vessel 40 across an aneurysm sac 42 in the area of the contra-lateral 44 and ipsi-lateral 46 iliac arteries using methods known within the art (only the contra-lateral limb is shown). The bifurcated endovascular graft 10 may be assembled in-vivo from a tubular trunk component 20 and two limb components 30. The trunk component 20 has a superior end 22 adapted to be secured above the aneurysm and an inferior end 24 adapted to accept the limb components 30. The limb component 30 has a transmitter 12, power source 14, and sensors 16 attached external the graft material. The transmitter 12, power source 14 and sensors 16 can be integrated into one device as described below. The limb component 30 has a superior end 32 adapted to mate with the trunk component 20 inferior end 24 and an inferior end 34 adapted to be secured to the ipsi-lateral 44 iliac artery.

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The sensors 16 measure pertinent parameters outside the endovascular graft 10 and the power source 14 provides power for the transmitter 12 which transmits the measurements to a receiver (not shown) located outside the patient's body. The transmitter 12, power source 14 and receiver (not shown) may be of any type known in the art of surgical implants or other systems utilizing miniaturized power sources and transmitters. The power source 14 and transmitter 12, for example, may be of the type used in pacemaker technology or passive power sources such as ultrasonic chargeable capacitors.

One or more sensors 16 are located near the superior end 32 of the limb component 30 but inferior the attachment/sealing area 26 between the trunk component 20 and limb component 30 such that the seal between the trunk component 20 and limb component 30 is not jeopardized. Note that the attachment/sealing area 26 is such that one or more of the sensors 16 on the limb component 30 is adjacent the aneurysm sac 42, thereby facilitating measurement of pertinent parameters within the aneurysm sac 42 without encumbering the trunk component 20 with sensors 16. Note also that the transmitter 12 and power source 14 are attached to the limb component 30 such that they are also adjacent the aneurysm sac 42. Minimizing the bulk of the trunk component facilitates a smaller delivery profile for the endovascular graft 10.

The sensors 16 may measure pressure, with the measurements used as an aid in endovascular graft 10 placement or to identify anomalies that occur after

endovascular graft 10 implantation but before aneurysm rupture occurs. The sensors 16 may detect changes in pressure resulting from blood leakage between the endovascular graft 10 and the vessel wall 40, an endoleak resulting from an inadequate seal between them. Furthermore, the sensors 16 may detect changes in pressure resulting from leakage from an endoleak between the trunk 20 and vessel wall 40. Because sensors 16 are located in the area of the aneurysm sac 42, there may be multiple sensors 16 disbursed over the graft material outer wall since local thrombus or calcification may shield one or more of the sensors 16 from blood flow and render their measurements erroneous. Moreover, the sensors 16 may allow pressure differences throughout the “excluded” aneurysm sac 42 to be mapped. It is contemplated that pressure measurements in the aneurysm sac may be obtained to an accuracy range of  $\pm 1$  to 30 mm Hg and preferably of  $\pm 10$  mm Hg.

Alternatively, the sensors 16 may measure temperature. Differences in temperature may identify “hot spots” associated with infection, inflammation, thrombus formation or other anomalies that indicate an increased risk for aneurysm rupture. Methods known in the art of pathology and physiology may be used to relate temperature to changes in the vessel walls within which the endovascular graft is implanted.

Alternatively, the sensors 16 may detect blood flow by measuring oxygen or other constituents, such as enzymes, proteins and nutrients, which are altered by the presence of blood flow. Such sensors may allow detection of minute blood

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flow, often missed by conventional imaging modalities, and, therefore, allow endoleaks to be detected earlier. One method is to obtain a baseline of the constituents upon implantation of the endovascular graft. Thereafter, changes in the amount of the measured constituents may be used to identify anomalies.

Alternatively, the sensors 16 may measure electrical potential or magnetic field strength. Changes in electrical potential may identify areas of the patient's vasculature that are at risk for thrombus formation. Induced magnetic fields indicate motion at a charged portion of the aneurysm such as would occur from pulsatile pressure.

Sensors also may be provided to facilitate other sensing applications such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

Although shown external the limb component 30 in FIG. 1, it is contemplated that the transmitter 12, power source 14 and sensors 16 may be located internal the graft material of the limb component 30. It is further contemplated that the number of transmitters 12, power sources 14 and sensors 16 shown in FIG. 1 may be varied to meet the requirements of the individual patient. It is further contemplated that sensors 16 which measure different pertinent

parameters may be used together. Moreover, the invention shown in FIG. 1 may be utilized in any type of endovascular graft implant known in the art.

Referring to FIG. 2, another embodiment of the invention is shown in which an integrated sensor/transmitter 50 is attached to the endovascular graft 110 and “satellite” sensors 52 are attached at various locations on the endovascular graft 110. The integrated sensor/transmitter 50 is capable of measuring a pertinent parameter as well as transmitting measurements to a receiver (not shown) outside that patient’s body. The “satellite” sensors 52 only measure pertinent parameters and their measurements are transmitted by the integrated sensor/transmitter, to which they are connected by leads 54. The “satellite” sensors 52 may provide a complete profile of pertinent parameters over the surface of the endovascular graft 110 and, therefore, facilitate better identification of anomalies.

Because the “satellite” sensors 52 are smaller than the integrated sensor/transmitter 50, the overall bulk of the endovascular graft 110 is smaller than if multiple integrated sensor/transmitter devices 50 were utilized. Furthermore, the smaller “satellite” sensors 52 may be placed such that measurements may be obtained from multiple locations, such as near the superior attachment area or within the aneurysm sac 42. Moreover, the smaller “satellite” sensors 52 facilitate measurements from places on the endovascular graft 110 where local graft bulk is a constraint of the design, such as the contra limb, or near the superior attachment system that holds the graft in the patient’s aorta.

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A separate power source 114 may be provided. The power source can be integrated into the sensor/transmitter as described previously and further below. The leads 54 which connect the integrated sensor/transmitter 50 to the "satellite" sensors 52 may be woven into the graft fabric or attached external to the endovascular graft 110.

It is contemplated that the location and number of integrated sensor/transmitter devices 50, power sources 114 and "satellite" sensors 52 shown in FIG. 2 may be varied to meet the requirements of the individual patient. In the embodiment shown, the integrated sensor/transmitter device 50 is located at the crotch, thereby allowing it to be near the center of the aneurysm sac 42 (see FIG. 2) while still being located furthest away from the aneurysm wall during shrinkage. It is further contemplated that the invention shown in FIG. 2 may be utilized in any type of endovascular graft implant known in the art.

Moreover, the integrated sensor/transmitter 50 and "satellite" sensors 52 may be of any type known in the art used to measure pressure, temperature, oxygen and other blood constituents, electrical potential or any other pertinent parameter indicative of endovascular graft or lumen health. One such integrated sensor/transmitter 50 to measure pressure is disclosed in U.S. Pat. Application Publication No. 2002/0045921 (Wolinsky et al.), the contents of which are hereby incorporated by reference. Again, other sensing applications may be supported such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or

hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

FIG. 3 shows a typical integrated sensor/transmitter 50 for use with the present invention. The integrated sensor/transmitter 50 includes a control chip 55 with a transmitter/receiver, energy exchanger 56, capacitor 57 and sensor 58. An external receiver (not shown) may contain a transducer, computer, LCD display and measurement display devices, such as barometers if the sensor 58 measures pressure. In operation, the transducer in the external receiver charges the capacitor 57 using ultrasonic energy and activates the sensor 58 to measure a pertinent parameter and ultrasonically transmit the measured parameter. The external receiver receives the transmitted pertinent parameter, assesses the measurement and displays the measurement, for example, as a pressure pulse curve.

Although FIG. 2 shows an integrated sensor/transmitter 50 and “satellite” sensors 52 connected by leads 54 and attached to the endovascular graft 110, alternate embodiments of the invention may utilize an integrated sensor/transmitter 50 as the sole implant. Furthermore, the “satellite” sensors 52 may be attached to the vessel 40 with the integrated sensor/transmitter 50 either attached to the vessel 40 or attached to the endovascular graft 110. FIG. 4 shows an endovascular graft 110 implanted across an aneurysm sac 42 into which an integrated sensor/transmitter 50 connected to “satellite” sensors 52 by leads 54 have been attached. It

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is contemplated that pressure measurements in the aneurysm sac 42 may be obtained to an accuracy range of  $\pm 1$  to 30 mm Hg and preferably  $\pm 10$  mm Hg utilizing either an integrated sensor/transmitter 50 alone or in conjunction with one or more "satellite" sensors 52 or integrated sensor/transmitters 50.

In an alternate embodiment of the invention illustrated in FIGS. 2 and 4, micro devices having the capability to sense their location relative to each other are either attached to the endovascular graft 110 or attached to the vessel 40. The micro devices may be excited by an external energy source, sense their relative location and transmit the data to a receiver located outside the patient's body. The data may then be interpreted to determine if displacement of the endovascular graft 110 or changes in the geometry of the vessel 40 has occurred. Such changes may provide early detection of endovascular graft 110 displacement or aneurysm 42 re-dilation due to an endoleak. Additional micro devices could be provided for better resolution. Detecting location of the micro devices rather than measuring a pertinent parameter minimizes reliability problems due to encapsulation or thrombus isolation. It is contemplated that the micro devices may be an ultrasonic crystal attached or integral to a MEM chip having the ability to read, interpret and transmit data. The micro devices also may be ultrasonic or other energy reflectors utilized in conjunction with an energy source. Using ultrasound to show or image reflector location would be much easier than creating an ultrasound image of the tissue.

In a further embodiment of the invention illustrated in FIGS. 2 and 4, devices or monuments which perform no sensing function may be attached to the implanted endovascular graft 110 or directly attached to the aneurysm sac 42. The location of the monuments may be tracked with a monitoring device to detect changes in the position of the endovascular graft 110 within the vessel 40 or changes in the geometry of the tissue outside the endovascular graft 110. It is contemplated that the monitoring device may be located external the patient's body or attached to an implanted endovascular graft. FIG. 5 illustrates an external monitoring device 54 being used to sense the location of an endovascular graft 310 having monuments 60 attached thereto which has been implanted in a patient's body. It is contemplated that the monuments may be electrically passive devices or magnetic sensors. The use of RF or magnets to sense the position of monuments is contemplated.

In one example, the position of magnetic sensors attached to the aneurysm sac 42 are measured using an external magnet of known magnetic field strength and shape. By moving the external magnet to multiple positions and orientations outside the body and polling the magnetic sensors with ultrasound, a baseline of magnetic sensor positions is established. Subsequent polling of the magnetic sensor positions allows changes in aneurysm sac 42 geometry to be detected.

In yet another embodiment of the invention shown in FIG. 6, sensors 16 or integrated sensor/transmitters 52 are attached to the endovascular graft 110 fabric

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using one continuous suture 70 with a running stitch, from a starting point 72 on sensor 16, which continues around the sensor 16 and back to an end point 74 (the dashed lines in FIG. 6 indicate where the suture 70 is on the inner diameter of the endovascular graft 110 fabric). Suture loops 71 are provided on the sensor 16 to facilitate attachment. A single knot 75 may be used to join the ends of the suture 70. It is contemplated that the running stitch may start and end at either end of the sensor and utilize more or less stitches depending on the location of the sensor 16 on the endovascular graft 110 and the attachment requirements. Minimizing the number of knots not only reduces bulk but also reduces potential graft wear points and may allow the sensor to be placed close to the graft crotch due to the lack of a knot at the distal end. It is further contemplated that the continuous suture 70 attachment method may be utilized with sensors 16 having suture holes or any other attachment mechanism.

In yet another embodiment of the invention, the sensors 16 may be covered in a coating, such as Teflon or heparin, to inhibit tissue growth or covered in a coating, such as Thrombin, to promote a known or controlled amount of tissue growth. Inhibiting or controlling tissue growth, which may interfere with performance, increases the reliability of the measurements made by the sensors 16.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without

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departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

**CLAIMS**

What is claimed is:

1. A modular endoluminal prosthesis for repairing an aneurysm in vasculature, comprising:

a first endovascular graft component; and

5 a second endovascular graft component for attachment to the first endovascular graft component, the second endovascular graft component having one or more sensors attached thereto;

wherein at least one sensor is located on the second endovascular graft component such that the sensor is adjacent the aneurysm when the first and second endovascular graft components are implanted within the vasculature.

2. The prosthesis of claim 1, further comprising:

one or more power sources attached to the second endovascular graft component; and

5 one or more transmitting devices attached to the second endovascular graft component, each transmitting device capable of transmitting signals containing the parameters measured by one or more sensors to a location outside a patient's body.

3. The prosthesis of claim 2, wherein the power sources and

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transmitting devices are adjacent the aneurysm when the first and second endovascular graft components are implanted within the vasculature.

4. The prosthesis of claim 1, further comprising one or more receiving devices located outside a patient's body, each receiving device capable of receiving signals transmitted by one or more transmitters.

5. The prosthesis of claim 1, wherein one of the first and second endovascular graft components is generally tubular and each has a superior end, an inferior end and a midsection.

6. The prosthesis of claim 5, wherein one or more sensors are located on the second endovascular graft component at a midsection thereof.

7. The prosthesis of claim 1, wherein the first endovascular graft component has a trunk portion and at least one limb portion.

8. The prosthesis of claim 1, wherein at least one of the sensors measure pressure.

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9. The prosthesis of claim 1, wherein at least one of the sensors measure temperature.

10. The prosthesis of claim 1, wherein at least one of the sensors measure fluid flow.

11. The prosthesis of claim 1, wherein at least one of the sensors measure blood flow.

12. The prosthesis of claim 1, wherein at least one of the sensors measure blood chemistry.

13. The prosthesis of claim 1, wherein at least one of the sensors measure fluid chemistry.

14. The prosthesis of claim 1, wherein at least one of the sensors measure position.

15. The prosthesis of claim 1, wherein at least one of the sensors detect motion.

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16. The prosthesis of claim 1, wherein at least one of the sensors measure acoustics.

17. The prosthesis of claim 1, wherein at least one of the sensors measure a constituent altered by the presence of minute amounts of blood flow.

18. The prosthesis of claim 1, wherein at least one of the sensors measure electrical potential.

19. The prosthesis of claim 1, wherein at least one of the sensors measure magnetic fields.

20. The prosthesis of claim 1, wherein one or more sensor(s) are located on the external surface of the second endovascular graft component.

21. The prosthesis of claim 1, wherein one or more sensor(s) are located on the internal surface of the second endovascular graft component.

22. A modular endoluminal prosthesis for repairing an aneurysm in vasculature, comprising:

a first endovascular graft component; and

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a second endovascular graft component for attachment to the first  
5 endovascular graft component, the second endovascular graft component having  
one or more sensors attached thereto and wherein at least one sensor is located on  
the external surface of the second endovascular graft component.

23. The prosthesis of claim 22, further comprising:

one or more power sources attached to the second endovascular  
graft component; and

one or more transmitting devices attached to the second  
5 endovascular graft component, each transmitting device capable of transmitting  
signals containing the parameters measured by one or more sensors to a location  
outside a patient's body.

24. The prosthesis of claim 23, wherein one or more of the power  
sources are located on the external surface of the second endovascular graft  
component.

25. The prosthesis of claim 23, wherein one or more of the transmitting  
devices are located on the external surface of the second endovascular graft  
component.

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26. The prosthesis of claim 22, further comprising one or more receiving devices located outside a patient's body, each receiving device capable of receiving signals transmitted by one or more transmitters.

27. The prosthesis of claim 22, wherein one of the first and second endovascular graft components is generally tubular and each has a superior end, an inferior end and a midsection.

28. The prosthesis of claim 27, wherein one or more sensors are located on the second endovascular graft component at a midsection thereof.

29. The prosthesis of claim 22, wherein the first endovascular graft component has a trunk portion and at least one limb portion.

30. An endoluminal prosthesis for repairing vasculature, comprising:  
an endovascular graft having one or more sensing devices attached thereto, each sensing device capable of providing information regarding a pertinent parameter inside the vasculature; and

5 at least one receiving device located outside a patient's body, each receiving device capable of receiving the information provided by one or more sensing devices.

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31. The prosthesis of claim 30, wherein at least one sensing device comprises an integrated sensor/transmitter device capable of measuring and transmitting a pertinent parameter to the receiving device.

32. The prosthesis of claim 31, wherein the integrated sensor/ transmitter device comprises a control chip, a transmitter/receiver, an energy exchanger, a capacitor and a sensor.

33. The prosthesis of claim 31, wherein the receiving device comprises a transducer, a computer, an LCD display and one or more measurement display devices.

34. The prosthesis of claim 33, wherein one of the measurement display devices is a barometer.

35. The prosthesis of claim 31, further comprising one or more sensors attached to the endovascular graft, each sensor capable of measuring a pertinent parameter and connected to the integrated sensor/transmitter device by electrical leads, and wherein the integrated sensor/transmitter device is capable of sensing the

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5 parameter measured by each sensor device and transmitting the parameter to the receiving device.

36. The prosthesis of claim 35; wherein the electrical leads are woven into the endovascular graft fabric.

37. The prosthesis of claim 35, wherein the electrical leads are attached external the fabric of the endovascular graft.

38. The prosthesis of claim 35, wherein the sensors are located at multiple positions along the length of the endovascular graft.

39. The prosthesis of claim 35, wherein the sensors are located at multiple positions along the circumference of the endovascular graft.

40. The prosthesis of claim 30, wherein the pertinent parameter is pressure.

41. The prosthesis of claim 30, wherein the pertinent parameter is temperature.

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42. The prosthesis of claim 30, wherein the pertinent parameter is fluid flow.

43. The prosthesis of claim 30, wherein the pertinent parameter is blood flow.

44. The prosthesis of claim 30, wherein the pertinent parameter is fluid chemistry.

45. The prosthesis of claim 30, wherein the pertinent parameter is blood chemistry.

46. The prosthesis of claim 30, wherein the pertinent parameter is positional data.

47. The prosthesis of claim 30, wherein the pertinent parameter is motion data.

48. The prosthesis of claim 30, wherein the pertinent parameter is acoustics.

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49. The prosthesis of claim 30, wherein the pertinent parameter is a constituent altered by the presence of minute amounts of blood flow.

50. The prosthesis of claim 30, wherein the pertinent parameter is electrical potential.

51. The prosthesis of claim 30, wherein the pertinent parameter is magnetic field.

52. The prosthesis of claim 30, wherein the sensing devices measure different pertinent parameters.

53. The prosthesis of claim 30, wherein the sensing devices comprise electrically passive devices and the receiving devices detect the location of the sensing device(s) within the vasculature in which the endovascular graft is implanted.

54. The prosthesis of claim 53, wherein the receiving devices comprise RF.

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55. The prosthesis of claim 53, wherein the receiving devices comprise magnets.

56. The prosthesis of claim 53, wherein the sensing devices comprise energy reflectors.

57. The prosthesis of claim 56, wherein the sensing devices comprise ultrasonic reflectors.

58. The prosthesis of claim 30, wherein the sensing devices comprise micro devices capable of detecting their position with respect to other micro devices and transmitting the detected positional information to the receiving devices.

59. The prosthesis of claim 58, wherein the micro devices are ultrasonic crystals attached or integral to a MEM chip.

60. The prosthesis of claim 30, wherein the sensing devices comprise a receiver/transmitter capable of receiving data from one or more devices implanted in the lumen of the patient and transmitting the data received to the receiving devices.

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61. The prosthesis of claim 60, wherein the sensing devices further comprise an energy source capable of exciting one or more devices implanted in the lumen of the patient.

62. The prosthesis of claim 60, wherein the sensing devices further comprise RF.

63. The prosthesis of claim 60, wherein the sensing devices further comprise magnets.

64. The prosthesis of claim 30, wherein the endovascular graft is generally tubular.

65. The prosthesis of claim 30, wherein the endovascular graft is bifurcated.

66. The prosthesis of claim 65, wherein at least one sensing device is located at the crotch of the bifurcation.

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67. The prosthesis of claim 30, wherein each sensing device is attached to the endovascular graft by one continuous suture forming a running stitch starting from one location along the device, around the device, and back.

68. The prosthesis of claim 67, wherein the ends of the suture are connected together external the endovascular graft by a single knot.

69. The prosthesis of claim 67, wherein each sensing device comprises suture loops.

70. The prosthesis of claim 67, wherein each sensing device comprises suture holes.

71. The prosthesis of claim 30, wherein each sensing device is covered in a coating that inhibits tissue growth.

72. The prosthesis of claim 71, wherein the coating is Teflon.

73. The prosthesis of claim 71, wherein the coating is heparin.

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74. The prosthesis of claim 30, wherein each sensing device is covered in a coating that promotes a known amount or type of tissue growth.

75. The prosthesis of claim 74, wherein the coating is Thrombin.

76. A method of measuring pertinent parameters in the vasculature of a patient, comprising:

providing one or more sensors in the vasculature, each sensor capable of measuring a pertinent parameter and transmitting the measurement to a  
5 receiving device;

providing a receiving/transmitting device capable of receiving measurements from the sensors and transmitting the measurements to a receiving device outside the patient's body; and

10 providing one or more receiving devices outside the patient's body, each receiving device capable of receiving the measurements transmitted by the receiving/transmitting device.

77. The method of claim 76, wherein the sensors are attached to an endoluminal prosthesis implanted in the vasculature.

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78. The method of claim 76, wherein the sensors are attached to a lumen wall of the vasculature.

79. The method of claim 77, the endoluminal prosthesis further comprising a first endovascular graft component and a second endovascular graft component for attachment to the first endovascular graft component, the second endovascular graft component having one or more sensors attached thereto and  
5 wherein at least one sensor is adjacent an aneurysm when the first and second endovascular graft components are implanted within the vasculature.

80. The method of claim 77, the endoluminal prosthesis further comprising a first endovascular graft component and a second endovascular graft component for attachment to the first endovascular graft component, the second endovascular graft component having one or more sensors attached thereto and wherein at least one sensor is located on the external surface of the second endovascular graft component.

81. The method of claim 77, the endoluminal prosthesis further comprising at least one integrated sensor/transmitter device capable of measuring and transmitting a pertinent parameter to the receiving device.

82. The method of claim 81, wherein the integrated sensor/transmitter device is connected to one or more sensors by electrical leads and wherein the integrated sensor/transmitter device is capable of sensing the parameter measured by each sensor and transmitting the parameter to the receiving device.

83. The method of claim 76, wherein the receiving/transmitting device is attached to a lumen wall of the vasculature.

84. The method of claim 76, wherein the receiving/transmitting device is attached to an endovascular graft implanted in the vasculature.

85. The method of claim 76, wherein the pertinent parameter is pressure.

86. The method of claim 76, wherein the pertinent parameter is temperature.

87. The method of claim 76 wherein the pertinent parameter is fluid flow.

88. The method of claim 76, wherein the pertinent parameter is blood flow.

89. The method of claim 76, wherein the pertinent parameter is fluid chemistry.

90. The method of claim 76, wherein the pertinent parameter is blood chemistry.

91. The method of claim 76, wherein the pertinent parameter is positional data.

92. The method of claim 76, wherein the pertinent parameter is motion data.

93. The method of claim 76, wherein the pertinent parameter is acoustics.

94. The method of claim 76, wherein the pertinent parameter is a constituent altered by the presence of minute amounts of blood flow.

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95. The method of claim 76, wherein the pertinent parameter is electrical potential.

96. The method of claim 76, wherein the pertinent parameter is magnetic field.

97. A method of determining the changes in the geometry of the vasculature of a patient, comprising:

implanting one or more location detection devices in the lumen wall;

5 providing one or more monitoring devices outside the patient's body, each monitoring device capable of determining the position of one or more location detection devices in the lumen; and

monitoring the location of the location detection device(s) to detect changes in their position.

98. The method of claim 97, wherein the location detection device(s) comprise micro devices powered by an energy source external the patient's body.

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99. The method of claim 97, wherein the location detection device(s) comprise micro devices powered by an energy source attached to an endovascular graft implanted in the vasculature.

100. The method of claim 97, wherein the location detection device(s) comprise micro devices capable of detecting their position with respect to other micro devices and transmitting the detected positional information to the monitoring device(s).

101. The method of claim 100, wherein the micro devices are ultrasonic crystals attached or integral to a MEM chip.

102. The method of claim 97, wherein the location detection device(s) comprise energy reflectors.

103. The method of claim 102, wherein the location detection device(s) comprise ultrasonic reflectors.

104. The method of claim 97, wherein the location detection device(s) comprise electrically passive devices and the monitoring device(s) comprise RF.

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105. The method of claim 97, wherein the location detection device(s) comprise electrically passive devices and the monitoring device(s) comprise magnets.

106. The method of claim 97, wherein the location detection device(s) comprise magnetic sensors and the monitoring device(s) comprise a magnetic source.

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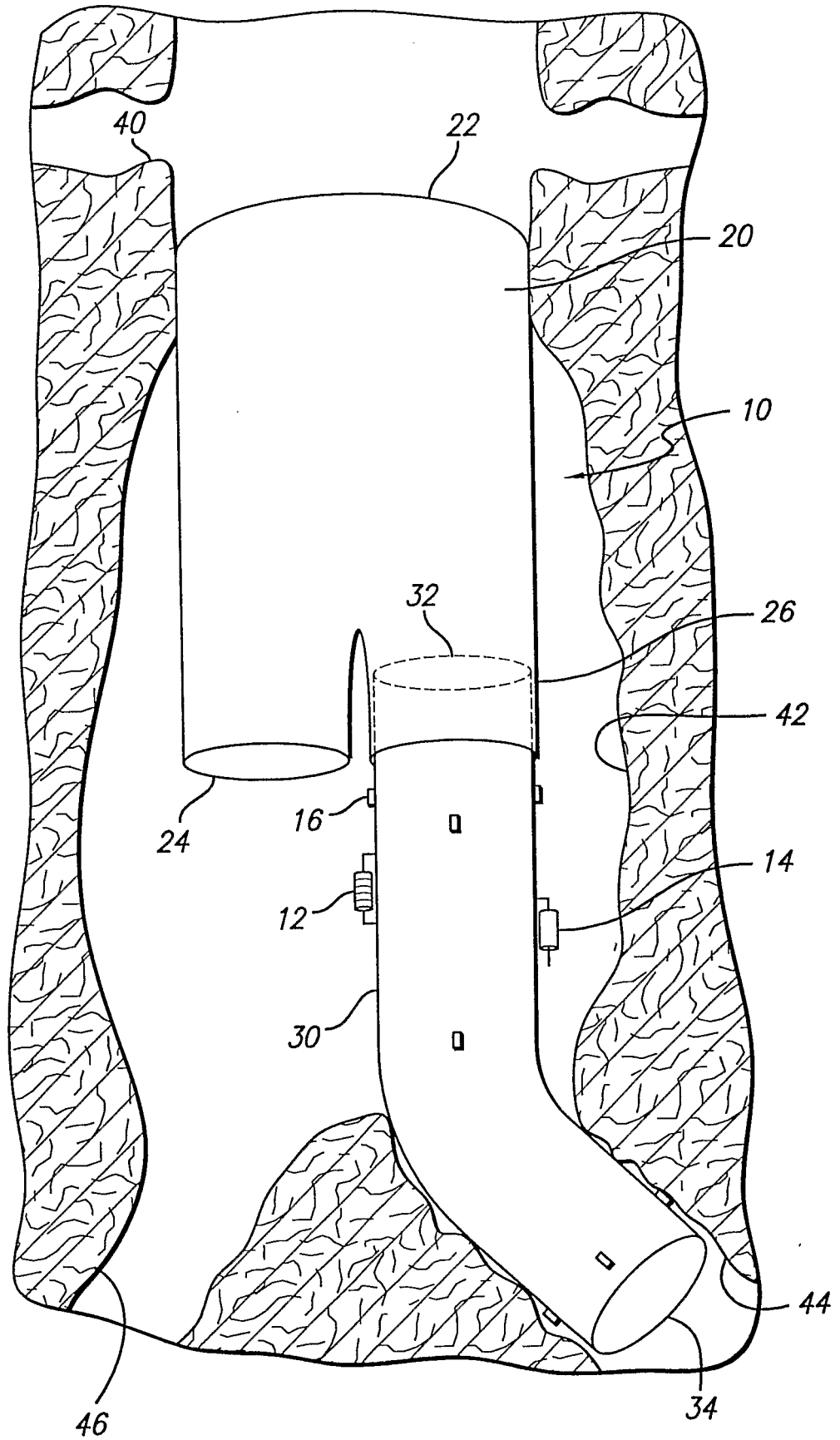


FIG. 1

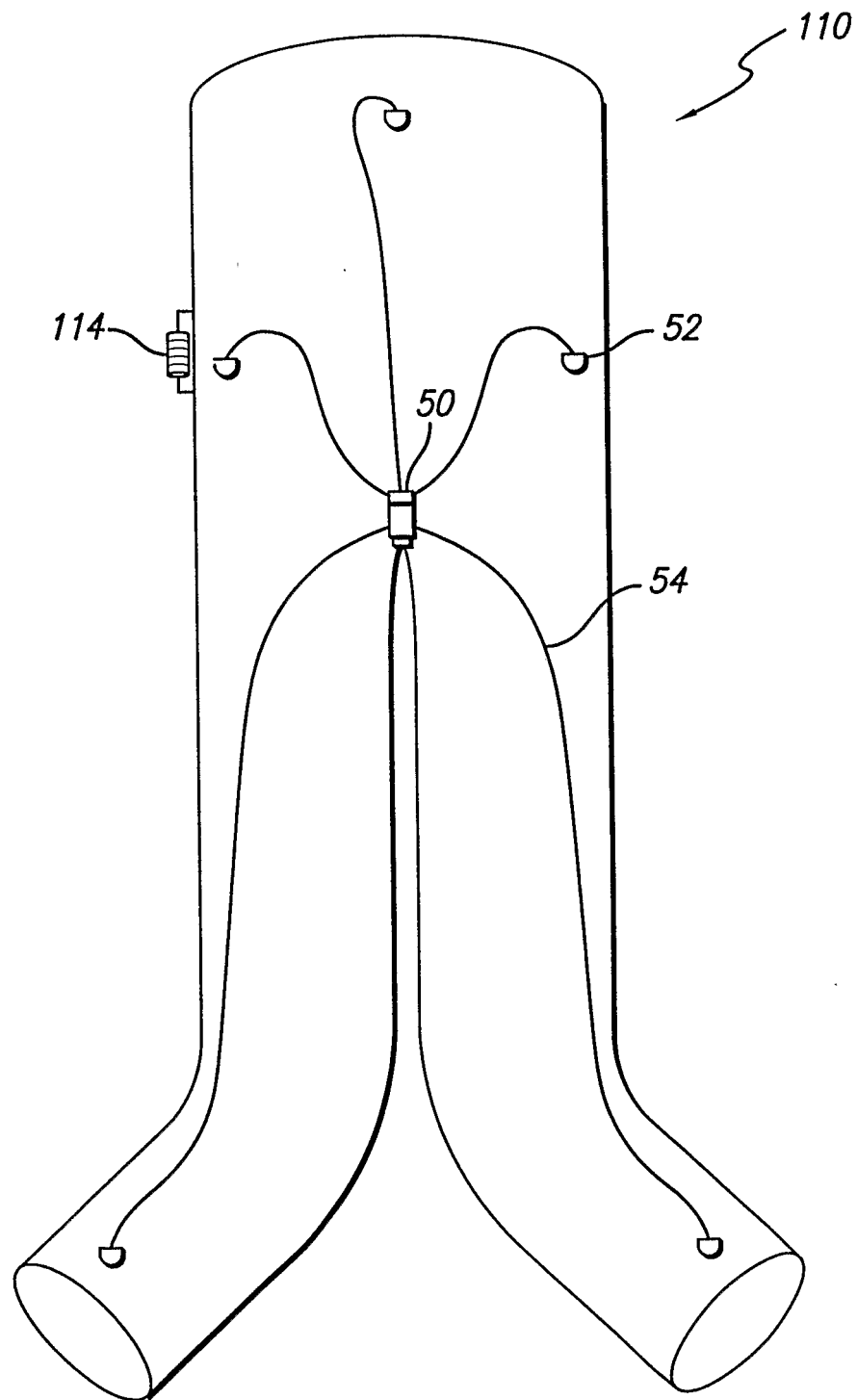


FIG. 2

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FIG. 3

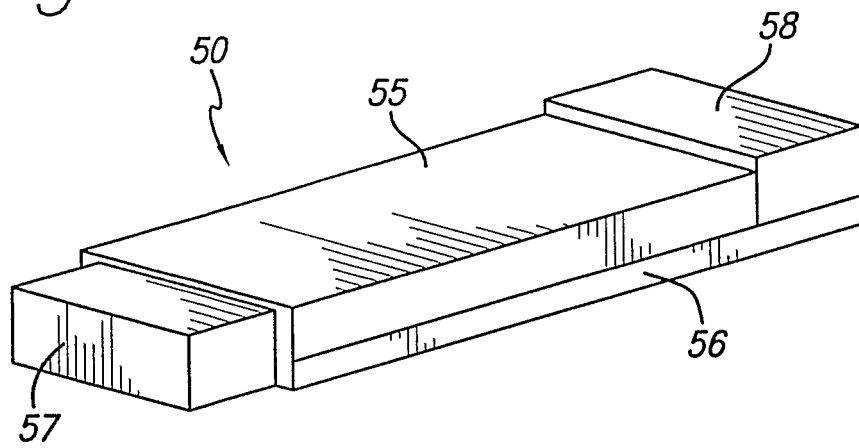
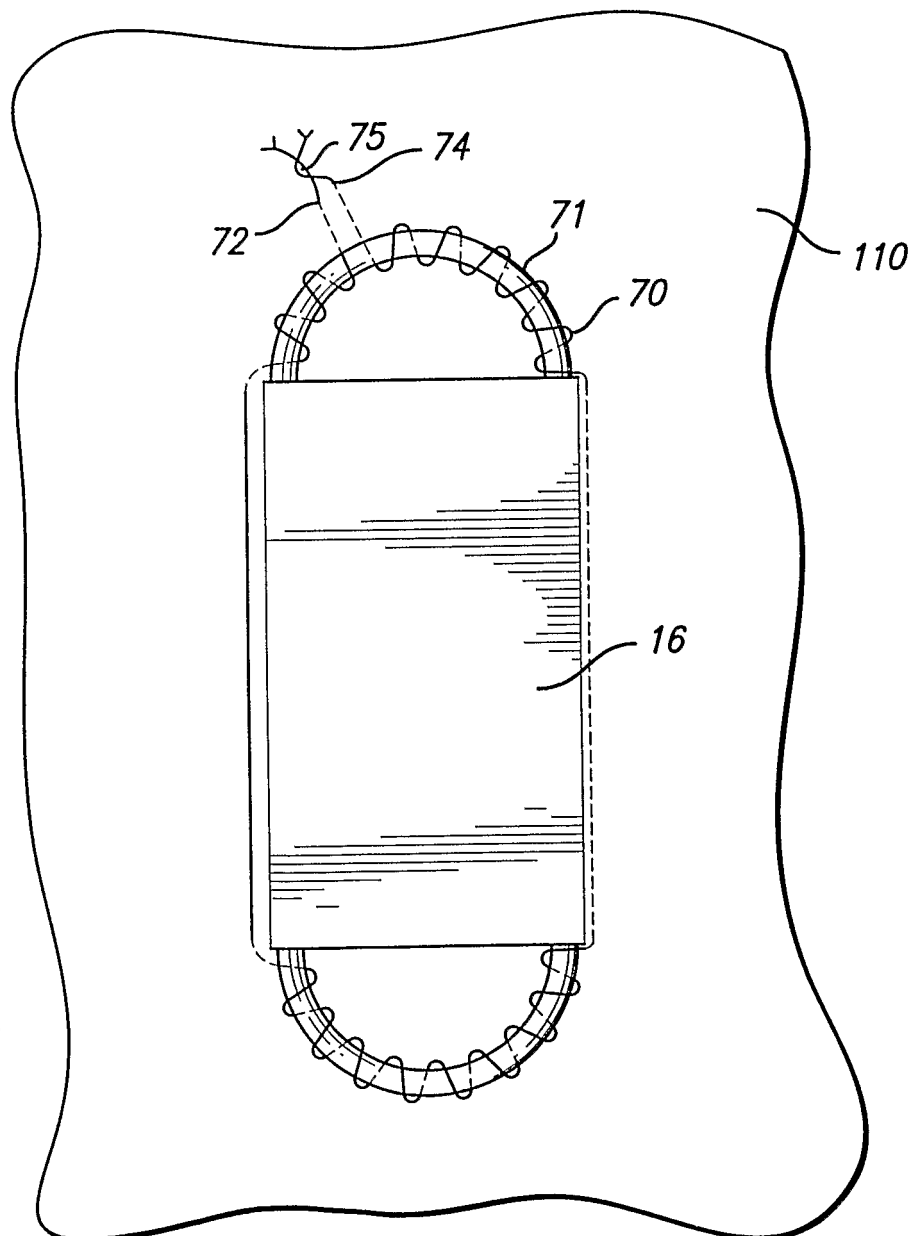


FIG. 6



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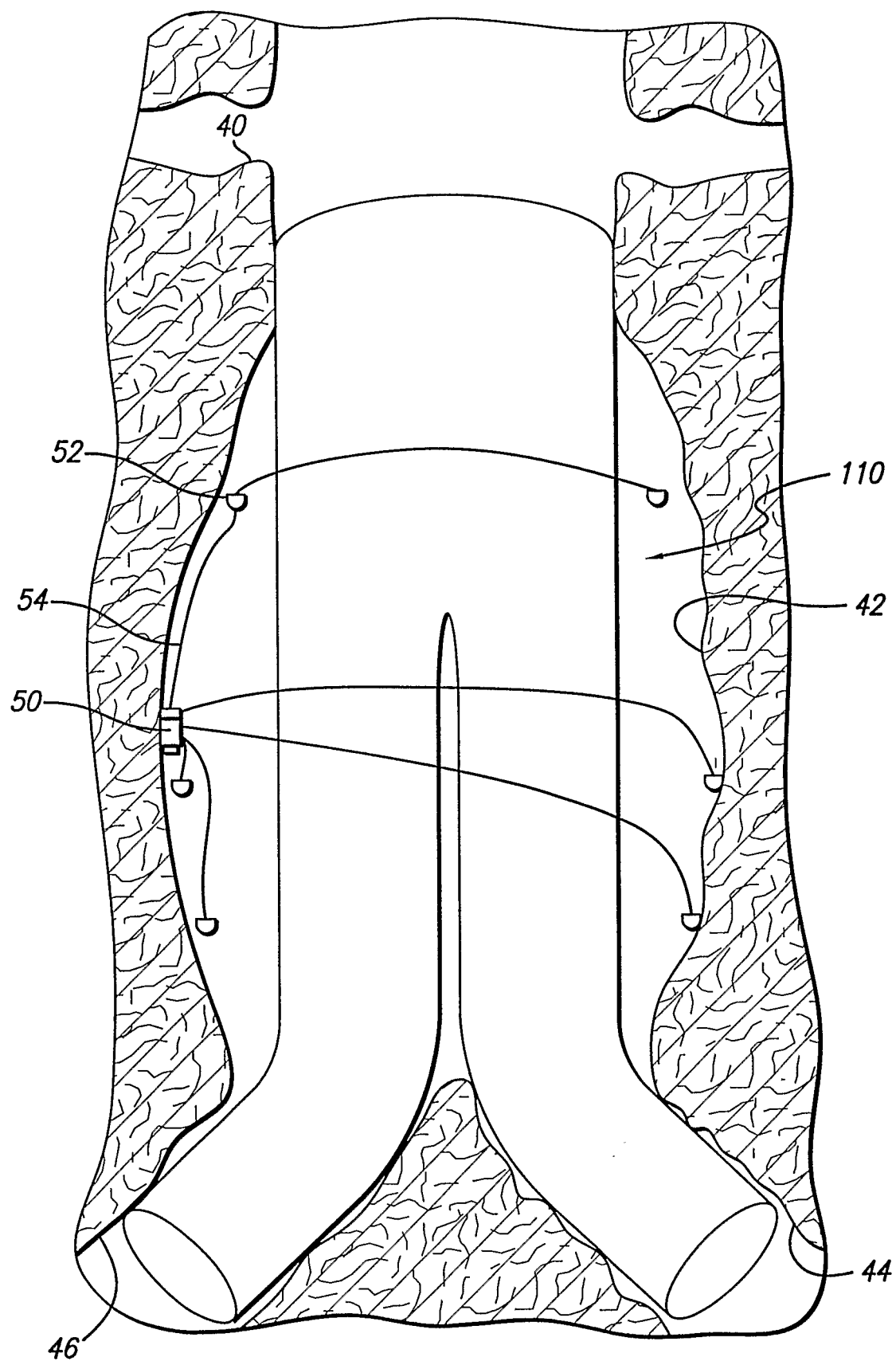


FIG. 4

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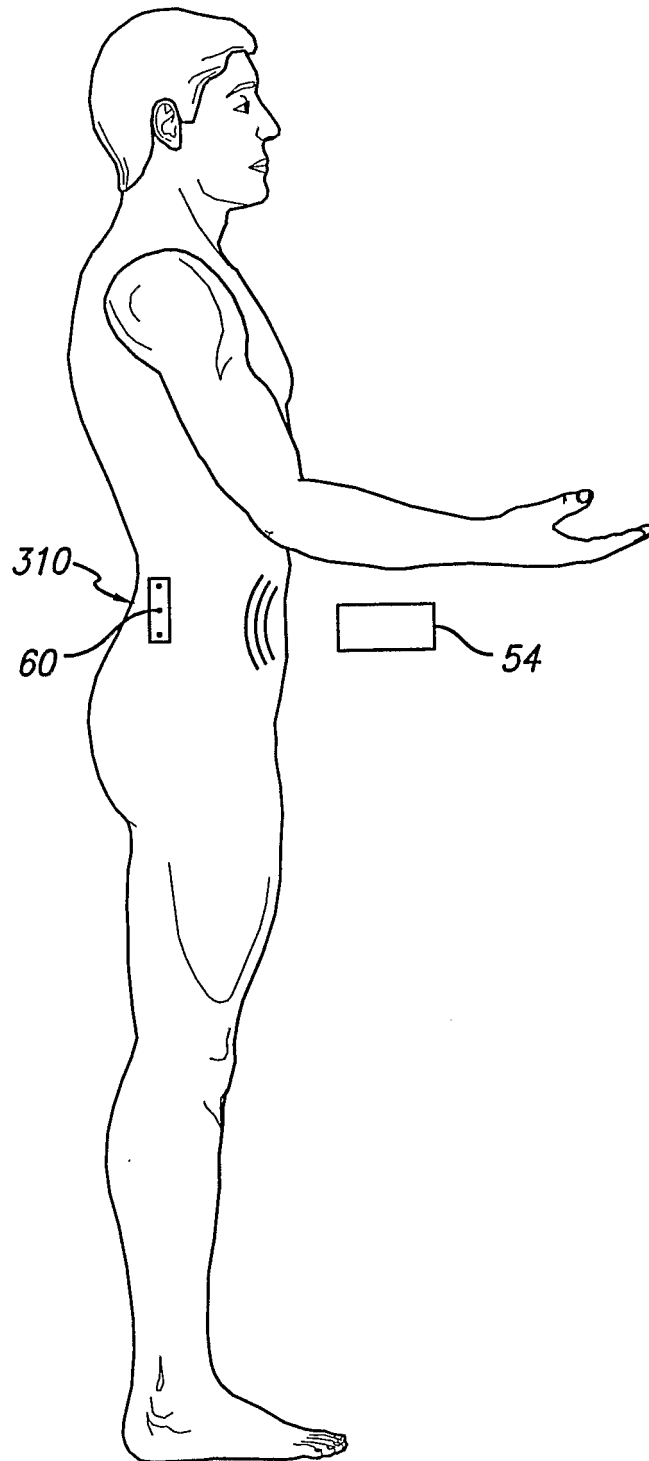


FIG. 5

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/17755

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/00; 2/06; A61B 5/103

US CL : 623/1.35; 600/587

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. : 623/1.35; 600/587

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.
Y, P	US 6,475,170 B1 (DORON et al.) 05 November 2002 (05.11.2002), see columns 1-13	1-106
Y, P	US 6,486,588 B2 (DORAN et al.) 26 November 2002 (26.11.2002), see columns 1-13, and figure 10	1-106
Y	US 6,140,740 A (PORAT et al.) 31 October 2000 (31.10.2000), see columns 1-14	1-106
Y	US 6,077,298 A (TU et al.) 20 June 2000 (20.06.2000), see columns 1-12, and figures 1 and 3-5	1-106
Y	US 6,053,873 A (GOVARI et al.) 25 April 2000 (25.04.2000), see columns 1-20	1-106
y	US 6,206,914 B1 (SOYKAN et al.) 27 March 2001 (27.03.2001), see columns 1-22, and figures 1-5	1-106

☐ 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 application or patent 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

15 September 2003 (15.09.2003)

Date of mailing of the international search report

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*Deane Russell for*

专利名称(译)	带有传感器设计和附着方法的血管内移植物		
公开(公告)号	<a href="#">EP1511443A1</a>	公开(公告)日	2005-03-09
申请号	EP2003757358	申请日	2003-06-06
[标]申请(专利权)人(译)	血管内TECH		
申请(专利权)人(译)	血管内TECHNOLOGIES , INC.		
当前申请(专利权)人(译)	血管内TECHNOLOGIES , INC.		
[标]发明人	BROWN PETER S LEMERE MARK T BARKMAN KIMBERLY KOVAC TIM		
发明人	BROWN, PETER, S. LEMERE, MARK, T. BARKMAN, KIMBERLY KOVAC, TIM		
IPC分类号	A61B5/00 A61F2/02 A61F2/06 A61F2/00 A61B5/103		
CPC分类号	A61B5/076 A61B5/0028 A61B5/0031 A61B5/02007 A61B5/02014 A61B7/001 A61B2560/0219 A61F2/07 A61F2002/065 A61F2002/067 A61F2250/0002		
优先权	10/165763 2002-06-07 US		
其他公开文献	EP1511443B1 EP1511443A4		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

一种血管内移植物 ( 30 ) , 其具有附接到其上的传感装置 ( 16 ) , 以便于测量移植物 ( 30 ) 植入其中的脉管系统内的相关参数。电源和发射器 ( 12 ) 可以连接到移植物上, 以便于将测量结果传输到患者体外的接收装置。传感装置 ( 16 ) 可以是电无源或具有测量和传输能力的集成装置。传感装置可以附接到移植物材料上的特定位置或附接到腔, 从而从脉管系统内的关键点提供相关参数, 或者可以分散在移植物材料的表面上或腔内, 以提供轮廓。相关参数。传感装置 ( 16 ) 可以使用一个缝合线 ( 70 ) 使用运行针脚附接到移植物材料以使移植物体积最小化并且可以涂覆有抑制或控制组织生长的材料。