(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 January 2002 (03.01.2002)

PCT

(10) International Publication Number
WO 02/00118 A2

(51) International Patent Classification[7]: A61B 8/06, 17/11

(21) International Application Number: PCT/US01/20163

(22) International Filing Date: 25 June 2001 (25.06.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/214,706 27 June 2000 (27.06.2000) US

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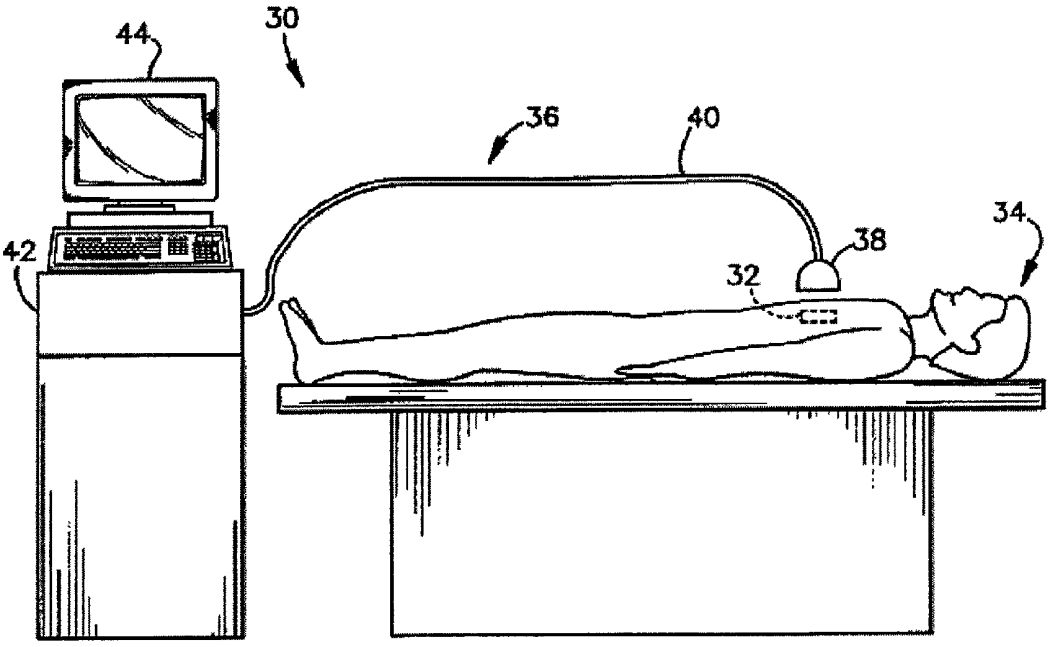
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

[Continued on next page]

(54) Title: PRESSURE GRADIENT MEASUREMENT FOR DETECTION OF SHUNT STENOSIS



(57) Abstract: The present invention relates to an implantable medical device, including a structure implantable within a living animal, at least one transducer/sensing element attached to vasculature adjacent the structure; the at least one transducer/sensing element being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and a communication element operatively coupled to the output of the at least one transducer/sensing elements, the communication element being configured to communicate information based on the output of the at least one transducer/sensing elements wirelessly to a remote element located outside the living animal.

WO 02/00118 A2

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TITLE: PRESSURE GRADIENT MEASUREMENT FOR DETECTION OF SHUNT STENOSIS

CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims priority to U.S. provisional application no. 60/214,706, filed June 27, 2000, which is incorporated by reference herein.

TECHNICAL FIELD

The present invention relates generally to medical devices which may be implanted in the body of a patient, and more particularly to devices which may be interrogated remotely from outside the patient's body.

BACKGROUND OF THE INVENTION

Various types of implantable medical devices have been developed over the years. In many instances, such devices enable humans to live longer, more comfortable lives. Implantable devices such as pacemakers, artificial joints, valves, grafts, stents, dialysis shunts, etc., provide a patient with the opportunity to lead a normal life even in the face of major heart, reconstructive, or other type surgery, or after suffering kidney failure, for example.

It has been found, however, that the introduction of such implantable devices can sometimes lead to complications. For example, the human body may reject the implanted device which can ultimately lead to infection or other types of complications. Alternatively, the implanted device may malfunction or become inoperative. Therefore, it is desirable to be able to monitor the condition of the implanted device. On the other hand, it is highly undesirable to have to perform invasive surgery in order to evaluate the condition of the device.

Still further, it is desirable to be able to monitor conditions related to the use of implanted devices. For example, in heart patients it may be helpful to know the extent of occlusion in a stent or graft in order to evaluate the health of the patient. In hemodialysis patients, in which development of stenosis in association with a dialysis shunt is expected, it is useful to know the degree or progress of stenosis which has developed in the vicinity of a dialysis shunt. Again, however, it is undesirable to have to perform invasive surgery in order to evaluate such conditions. Some prior art methods for estimating the development of stenosis in a dialysis shunt, e.g., that disclosed in U.S. Patent No. 5,690,115, require the insertion into the vasculature of a probe containing a Doppler catheter.

Techniques have been developed which enable the function of an implanted device to be monitored remotely from outside the body of the patient. These techniques involve including one or more sensors in the device for sensing the condition of the device. The device further includes a small transceiver for processing the output of the sensors and transmitting a signal based on the output. Such signal typically is a radio frequency signal

which is received by a receiver from outside the body of the patient. The receiver then processes the signal in order to monitor the function of the device.

Micro-miniature sensors have been proposed for use in implantable devices. For example, PCT Application WO 98/29030 to Govari et al. discusses the use of piezoelectric pressure sensors or micro-machined silicon strain gages in a stent. Pressure changes from one sensor to another are considered indicative of constriction of the stent. U.S. Pat. No. 5,807,258 to Cimochowski et al. describes using surface acoustic wave (SAW) sensors in a graft. Transit times or Doppler measurements using the SAW sensors enable one to determine fluid flow or velocity.

Peripheral and sometimes more central veins in the arm (or at times the leg) of patients with kidney failure who require regular hemodialysis can be "arterialized" by shunting blood directly from an anatomically adjacent artery to the vein, bypassing the normally intervening arteriolar and capillary bed. A dialysis or arteriovenous ("AV") shunt is a surgical construct which provides this bypass, connecting the artery to the adjacent vein subcutaneously in the arm. With this new blood flow path, most blood will bypass the high flow resistance of the downstream capillary bed, thereby producing a dramatic increase in the blood flow rate through the shunt. Furthermore, although it is not medically feasible to repeatedly puncture an artery, formation of the shunt "arterializes" the vein. The arterialized vein can be punctured repeatedly, and the high blood flow permits high efficiency hemodialysis to be conducted. Two fistula needles, connected to blood tubing leading to and from the hemodialysis machine, are used to puncture the skin to gain access to the arterialized vein. Blood is withdrawn from the arterial side of the vein, passes through the dialysis machine, where it is cleansed, and returns to the venous side of the access. The creation of this shunt can be performed using either native vessel, heterograft or synthetic materials. The dialysis shunt enables a high flow (typically 200 to 600 milliliters per minute) of blood to be removed from the circulation, passed through the dialyzer (artificial kidney) and returned to the venous system of the individual patient.

Due to a combination of blood turbulence, foreign body reaction, response to repeated venipuncture (needle sticks of blood vessels), inflammatory reactions from the dialyzer and other poorly understood complex biochemical phenomena, dialysis patients experience frequent vascular occlusions or stenoses caused by thromboses (blood clots) or from atherosclerotic-type lesions (referred to herein sometimes as partial occlusions) which form on the vessel wall, or, in the case of thromboses, also in the body of the dialyzer shunt. Such a vascular occlusion is generally referred to as a stenosis. The stenosis may result from proliferation of vascular smooth muscle and inflammatory cells, and connective tissue stroma.

The most common site of stenosis is the venous outflow tract, often in proximity to and usually downstream from the surgical anastomotic site. Occlusion of the graft requires emergency declotting and may often require repair of the vein, bypass of the diseased vessel and frequently replacement of the shunt with a new graft in a new anatomical venous position. Typical shunt life is two years, with declotting required even more frequently than graft replacement. Total occlusion results in an emergency situation that can have devastating consequences and may require emergency hemodialysis and temporary catheterization of blood vessels with attendant risks.

Due to the inevitability of formation of such stenoses in applications such as hemodialysis, a need exists for non-invasive, simple methods and apparatus for detection, estimation and monitoring of the size and progression of such stenoses in a patient or animal into which such device has been implanted.

SUMMARY OF THE INVENTION

The present invention is responsive to the aforementioned problems and to shortcomings with conventional devices, and is directed towards an implantable device to be implanted within a living animal and responsive to an interrogation circuit having an exciter/interrogator element which is located outside the living animal. The implantable device includes a structure to be implanted within the living animal and operatively configured to carry out or assist in carrying out a function within the living animal. The implantable device further includes an electrically passive sensing circuit operatively coupled to the structure for sensing a parameter associated with the function of the implant. In many cases, the structure is adapted for sensing a parameter associated with blood flow. The sensing circuit includes an inductive element in which the sensing circuit has a frequency dependent variable impedance loading effect on the interrogation circuit in response to an interrogation signal provided by the exciter/interrogator element, the impedance loading effect varying in relation to the sensed parameter. A transducer/sensing element is included in the electrically passive sensing circuit in the structure. The transducer/sensing element may itself provide the impedance loading effect, or the electrical circuit in which the transducer/sensing element is included may provide the impedance loading effect based on the output of the transducer/sensing element. As described in more detail below, the transducer/sensing element may be any of a variety of devices for sensing any of a variety of parameters. In one exemplary embodiment, the transducer/sensing element is a pressure transducer, in one an acoustic transducer, and in one an ultrasonic transducer.

In one embodiment, the invention enables detection and monitoring of stenotic regions in the vasculature of chronic hemodialysis patients by employing a transducer/sensing element which measures a parameter associated with blood flow.

Thus, as described more fully herein, in one embodiment, the present invention relates to an implantable device, including a shunt structure implantable within a living animal, the shunt structure adapted for blood flow from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end; a first transducer/sensing element attached to vasculature adjacent an end of the shunt structure; a second transducer/sensing element mounted on the shunt structure; the first and second transducer/sensing elements being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and a communication element operatively coupled to the output of the first and second transducer/sensing elements, the communication element being configured to communicate information based on the output of the first and second transducer/sensing elements wirelessly to a remote element located outside the living animal.

In another embodiment, the present invention relates to a detection system for blood flow, including a shunt structure implantable within a living animal, the shunt structure adapted for blood flow from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end; a first transducer/sensing element attached to the vasculature adjacent an end of the shunt structure; a second transducer/sensing element included as part of the shunt structure; the first and second transducer/sensing elements being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and a communication element operatively coupled to the output of the first and second transducer/sensing elements, the communication element being configured to communicate information based on the output of the first and second transducer/sensing elements wirelessly to a remote element located outside the living animal; the remote element configured to apply an interrogation signal and to receive the information from the communication element outside the living animal in response to the interrogation signal; and a processor programmed to process the information received by the remote element based on the parameter to provide an output indicative of blood flow.

In another embodiment, the present invention relates to a method for detecting in a living body blood flow associated with a dialysis shunt forming a fluid communication from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end, including the steps of implanting in the dialysis shunt or in vasculature adjacent the distal anastomosis at least two transducer/sensing elements for sensing a parameter associated with

blood flow; attaching each transducer/sensing element to a communication circuit producing an output signal for each transducer/sensing element based on the parameter associated with blood flow;

non-invasively detecting the output signal for each transducer/sensing element based on the parameter associated with blood flow; and determining the presence or absence of a stenosis based on a difference between the output signal for each transducer/sensing element.

In a further embodiment, the present invention relates to a method for detecting in a living body a leak in an aneurysm graft, including the steps of implanting in the living body an aneurysm graft having a transducer/sensing element for sensing a parameter associated with blood flow, wherein the transducer/sensing element is located on an outer surface of the aneurysm graft; attaching the transducer/sensing element to a communication circuit producing an output signal for the transducer/sensing element based on the parameter associated with blood flow;

non-invasively detecting the output signal from the transducer/sensing element based on the parameter associated with blood flow; and determining the presence or absence of a leak in the aneurysm graft based on a change in the output signal from the transducer/sensing element.

In another embodiment, the present invention relates to a method for determining in a living body a fluid flow rate through a natural or implanted vasculature, including the steps of attaching to the vasculature a first and a second transducer/sensing element for sensing a parameter associated with fluid flow, wherein the second transducer/sensing element is located downstream from the first transducer/sensing element; attaching each transducer/sensing element to a communication circuit producing an output signal for each transducer/sensing element based on the parameter associated with fluid flow; non-invasively detecting the output signal for each transducer/sensing element based on the parameter associated with fluid flow; and determining the fluid flow rate based on a difference between the output signal for each transducer/sensing element.

To the accomplishment of the foregoing and related ends, the invention, then, comprises the features hereinafter fully described and particularly pointed out in the claims. The following description and the annexed drawings set forth in detail certain illustrative embodiments of the invention. These embodiments are indicative, however, of but a few of the various ways in which the principles of the invention may be employed. Other objects, advantages and novel features of the invention will become apparent from the following detailed description of the invention when considered in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an environmental view illustrating a system including a remotely interrogated implantable medical device and exciter/interrogator unit in accordance with the present invention;

FIG. 2 is a simplified block diagram of the system of FIG. 1;

FIG. 3 is a schematic diagram of a dialysis shunt including a pair of transducer/sensing elements in accordance with one embodiment of the invention;

FIG. 4 is a schematic diagram of a dialysis shunt similar to that shown in Fig. 3, and showing exemplary stenoses, the embodiment of Fig. 3;

FIG. 5 is a schematic diagram of a dialysis shunt including transducer/sensing elements in accordance with another embodiment of the invention;

FIG. 6 is a schematic diagram of a dialysis shunt similar to that shown in Fig. 5, and showing exemplary stenoses, in the embodiment of Fig. 5;

FIG. 7 is a schematic diagram of an implanted device which includes both an annulus upon which a first transducer/sensing element is mounted and a patch upon which a second transducer/sensing element is mounted, in accordance with one embodiment of the invention;

FIG. 8 is a schematic diagram of one embodiment of an implantable annulus upon which a plurality of transducer/sensing elements are mounted transversely, in accordance with the invention;

FIG. 9 is a schematic diagram of another embodiment of an implantable annulus upon which a transducer/sensing element is mounted, in accordance with the invention;

FIG. 10 is a schematic diagram of yet another embodiment of an implanted annulus upon which a plurality of transducer/sensing elements are mounted longitudinally, in accordance with one embodiment of the invention;

FIG. 11 is a schematic diagram of still another embodiment of an implanted annulus upon which a pair of transducer/sensing elements are mounted longitudinally, in accordance with one embodiment of the invention;

FIG. 12 is a schematic diagram of an embodiment of the present invention in which a transducer/sensing element is mounted on an implanted aneurysm graft; and

FIG. 13 is a schematic diagram of an embodiment of the present invention in which a transducer/sensing element is mounted on an annulus on an implanted aneurysm graft.

DETAILED DESCRIPTION

The present invention will now be described with reference to the drawings, wherein like reference numerals are used to refer to like elements throughout.

Referring initially to FIG. 1, a system for remotely interrogating an implanted medical device in accordance with the invention is generally designated 30. The system 30 includes an implantable medical device 32 which may be implanted in a living animal such as a human patient 34. As is discussed in more detail below, the implantable medical device 32 can be any of a wide variety of different types of devices including, for example, a dialysis shunt, a stent, a graft, an artificial joint, etc.

The implantable device 32 is configured to carry out or assist in carrying out a function within the patient 34. For example, in the case of a dialysis shunt the device 32 provides a fluid connection between an artery and a vein which permits the flow of blood therethrough, and which may be used as a source and return path for dialyzed blood. In the case of a graft, the device 32 serves to couple blood flow between two separate ends of an artery. The device 32 may instead consist of a stent, which prevents the closing of an arterial wall and permits the flow of blood therethrough.

The implantable device 32 includes a sensing circuit (not shown in FIG. 1) which includes a transducer/sensing element which serves to sense a parameter associated with the function performed by the device. For example, in the case of a stent or graft the transducer/sensing element may be used to detect the degree of restenosis which occurs within the device 32. Alternatively, for example, the transducer/sensing element may detect an amount of strain or displacement which occurs in an artificial hip or knee. Still further, the transducer/sensing element may serve to sense the condition of the implanted device in carrying out its intended function. For example, in the case of a pacemaker the transducer/sensing element may detect the pulse rate. In particular, in one embodiment of the present invention, the device 32 includes transducer/sensing elements for sensing a parameter associated with the flow of blood through a dialysis shunt and in the adjacent vasculature.

The system 30 further includes interrogation instrumentation 36 for remotely interrogating the implanted device 32 in order to evaluate the device function. The instrumentation 36 includes an exciter/interrogator unit 38 which is positioned outside the patient 34 in close proximity to the implanted device 32. As will be discussed in more detail below, the exciter/interrogator unit 38 serves to excite or initiate communication with the sensing circuit within the device 32. The sensing circuit is designed to have a variable impedance loading effect on the exciter/interrogator unit 38, which varies in relation to the sensed parameter (e.g., blood pressure or flow, amount of restenosis, etc.).

The exciter/interrogator unit 38 is coupled via an electrical cable 40 to the main circuitry 42 included in the interrogation instrumentation 36. The main circuitry 42 includes suitable circuits for driving the exciter/interrogator unit 38 as described below, and for processing the

output of the exciter/interrogator unit 38 in order to provide an output to an operator (e.g., display 44). In particular, the variable impedance loading effect of the device 32 on the exciter/interrogator unit 38 is detected at different frequencies and processed to produce a display or the like indicative of the function performed using the device 32.

As will be better understood based on the description which follows, in one illustrative embodiment the present invention utilizes magnetic coupling between the exciter/interrogator unit 38 and the implanted device 32. The sensing circuit in the device 32 is a passive circuit designed to have an impedance loading effect on the exciter/interrogator unit 38. In this manner, the sensing circuit can be a very simple, low cost circuit which is less prone to failure. The device 32 does not require an active transmitter, mixer, amplifier, etc. as in other conventional devices. Moreover, the sensing circuit can be embedded within the device structure to reduce the amount of obstruction which occurs in the device and, for example, to increase performance.

FIG. 2 represents a simplified block diagram showing the positional relationship between the implanted device 32 and the exciter/interrogator unit 38. In one embodiment, the exciter/interrogator unit 38 is a hand-held device which is held by a doctor, nurse or medical assistant in close proximity to the implanted device 32. In one embodiment, the remote exciter/interrogator unit 38 may be disposed in a portable unit which the patient can use outside of a clinical setting. Since the system 30 is non-invasive, the exciter/interrogator unit 38 may be placed adjacent the implanted device 32 with the body 50 of the patient (e.g., skin, muscle tissue, etc.), disposed therebetween. The illustrated embodiment of the present invention relies on magnetic and/or electromagnetic coupling (represented by field lines 52) between the exciter/interrogator unit 38 and the implanted device 32 to interrogate the device 32 through the body 50 of the patient non-invasively.

More particularly, in one embodiment of the present invention, sensor technology developed in the aerospace industry is employed in the present implantable medical devices. Commonly owned U.S. Pat. No. 5,581,248 describes in detail how magnetic coupling between an interrogation circuit and a sensor coil, based on an impedance loading effect, can be used to interrogate an embedded sensor. The entire disclosure of U.S. Pat. No. 5,581,248 is incorporated herein by reference for this teaching. However, the remote interrogation methods which may be used with the present invention are not limited to those disclosed in U.S. Pat. No. 5,581,248. Other suitable remote coupling or communication means may be employed, including, for example, in the electromagnetic energy spectrum, radio frequency (Rf) radiation, visible radiation and microwave radiation. In addition, other communication means such as acoustic signals may also be employed as appropriate.

FIG. 3 presents a first embodiment of the present invention in which the implantable medical device 32 is a dialysis shunt. As is known and described briefly above, the dialysis shunt is a tubular connecting device surgically attached and forming a fluid connection between a major artery and a major vein, usually in a limb of a living animal, such as an arm or a leg of a human. The dialysis shunt 32 provides a high-flow source of blood for diversion to a dialysis unit outside the patient's body.

As used herein, the term "vasculature" refers to natural or implanted, generally tubular, vascular structures in a human or animal body. In particular herein, "vasculature" includes arteries and veins in the blood circulatory system, and may include implanted vasculature which is from either a natural or a synthetic source.

The implanted shunt 32 may be surgically implanted and attached to the vasculature at an anastomosis by any known means. The shunt 32 most commonly may be attached, for example, by suturing, stapling or gluing at the anastomosis. It is noted that the highly schematic drawings do not show any specific attachment method, it being understood however that the shunt 32 is attached by an appropriate surgical method. An exemplary shunt is shown in U.S. Patent No. 6,019,788, the disclosure of which is hereby incorporated by reference herein, for its disclosures of methods of implantation and attachment of a shunt to an anastomosis and of materials from which a dialysis shunt may be suitably formed.

In Fig. 3, an artery 54 in, e.g., a person's forearm, carries a flow of blood in a direction shown by an arrow 56 toward the person's hand. A return flow of blood is carried by a vein 58 in a second direction shown by a second arrow 60. A proximal end 61 of the shunt 32 is attached to the artery 54 at a first anastomosis 62 (indicated schematically by a dashed line in Figs. 3-6) and a distal end 63 of the shunt 32 is attached to the vein 58 at a second anastomosis 64 (indicated schematically by a dashed line in Figs. 3-6). As used herein, the terms proximal and distal are used in relation to the artery, such that, for example, the proximal end is that end nearest the artery 54, and the distal end is that end nearest the vein 58.

As described above, the shunt 32 provides a blood flow bypass from the artery 54 to the vein 58. Because the shunt 32 is implanted in the relatively large diameter artery 54, a significant quantity of blood may flow through the shunt 32 to the vein 58. This large flow of blood is thus made available for diversion into a dialysis apparatus (not shown). Attachment to the dialysis apparatus may be accomplished by any appropriate method known in the art, such as by suturing, stapling or gluing. The present invention is not limited to any particular method of such attachment. Exemplary attachments are shown and discussed in, e.g., U.S. Patent Nos. 6,210,591, 6,019,788 and 5,690,115. The methods of attachment disclosed in these patents are hereby incorporated by reference.

Referring again to Fig. 3, there are shown a first transducer/sensing element 66 and a second transducer/sensing element 68. The first transducer/sensing element 66 may be attached to the vasculature at a suitable location. In Fig. 3, the first transducer/sensing element 66 is attached to the vein 58 at a location downstream (referring to the direction of blood flow in the vein 58) from the second anastomosis 64. Since a thrombosis, stenosis or other partial occlusion of the vein 58 is most likely to occur in a turbulent region immediately adjacent and downstream from the anastomosis 64, the position of the first transducer/sensing element 66 is selected so as to be downstream from the turbulent region. The first transducer/sensing element 66 may be placed a distance ranging from about 1 to about 10 centimeters downstream from the second anastomosis 64. In one embodiment, the first transducer/sensing element 66 is placed a distance ranging from about 2 to about 8 centimeters downstream from the second anastomosis 64. In another embodiment, the first transducer/sensing element 66 is placed a distance ranging from about 2 to about 6 centimeters downstream from the second anastomosis 64.

One of the features of the present invention is that the transducer/sensing element may be mounted on an exterior surface of the vasculature with which it is used. This capability avoids the necessity of penetrating the vasculature wall, thereby avoiding a substantial source of potential problems which can result from penetration, including, e.g., both leaks and possible infections.

As shown in Fig. 3, the second transducer/sensing element 68 is mounted on the structure of the shunt 32. In the embodiment shown in Fig. 3, the second transducer/sensing element 68 is mounted on the structure of the shunt 32 at a position adjacent the first anastomosis 62, and is thus in the shunt 32 immediately downstream from the first anastomosis 62. Placing the second transducer/sensing element 68 on the shunt 32 at a position at or near the first anastomosis 62 provides information relating to the blood flow in the shunt 32, and provides "coverage" of the entire length of the shunt 32 for any thrombosis which may form therein. Since a likely site for a thrombosis which may result in reduction or prevention of blood flow in the shunt 32 is within the structure of the shunt 32 itself, placing the second transducer/sensing element 68 at this position provides the coverage of the full length of the shunt 32.

Referring still to Fig. 3, the apparatus further includes a communication element 70. The communication element 70 is operatively attached or connected to the first transducer/sensing element 66 by a first cable 72, and is operatively attached or connected to the second transducer/sensing element 68 by a second cable 74. The communication element 70 includes suitable electrical or electronic components to receive information from each

transducer/sensing element and to convert this information into a signal which can be detected by the external exciter/communicator 38.

The communication element 70 is operatively coupled to the implanted device 32, including the transducer/sensing elements 66, 68. The communication element 70 may be mounted near the implanted device 32 as shown in Fig. 3, or may be mounted integral to the implanted device 32 itself. The communication element 70 may be based on any of a variety of known techniques suitable for permitting non-invasive interrogation. For example, the communication element 70 may be configured to be interrogated non-invasively using a variable impedance loading effect. Such a configuration is described in detail in commonly assigned U.S. Patent No. 6,206,835. The entire disclosure of which with respect to such communication components is incorporated herein by reference.

Alternatively, the communication element 70 may be configured to utilize RF telemetry techniques, for example, to transmit a signal to an analyzer outside the body of the patient. The load measured by strain gage elements in the implanted device 32 may serve to change the oscillation frequency of an RF oscillator included in the communication element 70. An antenna (not shown) provided within the communication element 70 serves to transmit the RF signal output by the oscillator to the analyzer which in turn determines the measured load based on the frequency of the received signal. Details on the use of RF telemetry to non-invasively obtain information from medical implants can be found, for example, in United States Patent No. 5,807,258, the entire disclosure of which with respect to such communication components is incorporated herein by reference. As the particular configuration of the communication element 70 to permit non-invasive interrogation is not critical to the present invention, further details thereof have been omitted for sake of brevity.

In addition to the above-mentioned patents, suitable electrical or electronic components are also described, for example, in U.S. Patent Nos. 5,581,248, 6,053,873 and 6,092,530, the disclosures of which with respect to such communication components are incorporated herein by reference.

It is noted that while the communication element 70 is shown and described herein as a separate structure connected to the transducer/sensing elements 66 and 68 by the cables 72 and 74, the communication element 70 may be in communication with the transducer/sensing elements either integrally or by wireless means, by being formed as an integral structure with one or both of the transducer/sensing elements, or by other suitable methods known to those

of skill in the art for providing such communication. The present invention is not limited to any particular construct in this regard.

In operation, the transducer/sensing elements 66,68 associated with the implanted device 32 shown in Fig. 3 provide information relating to a parameter associated with blood flow in the shunt 32 or the adjacent vasculature 54, 58, by producing an output from each transducer/sensing element which varies as a function of the parameter. Thus, for example, if the transducer/sensing element is a pressure transducer, the implanted device provides information relating to the blood flow, i.e., blood pressure information, by producing an output from each transducer 66 and 68. In an embodiment in which the transducer/sensing elements 66, 68 are pressure transducers, if there is no restriction in the shunt 32 or in the portion of the vasculature (i.e., the vein 58) between the first transducer/sensing element 66 and the second transducer/sensing element 68, the pressure at each transducer should be substantially the same.

In general, since the blood is a viscous fluid and there is some small but finite restriction to the free flow thereof in the vasculature, the pressure at the first transducer/sensing element 66 may be slightly different than the pressure at the second transducer/sensing element 68. As with most fluids, the pressure at a downstream position is usually lower than that at an upstream position, although this is not always the case. See, for example, " A Primer of Venous Pressure" by George E. Burch, Charles C. Thomas Publishers, Springfield IL, 1972, which shows that the downstream pressure in venous flow may be higher, depending on various factors. However, for the purposes of the present invention, any such difference is considered negligibly small and is not of immediate concern. Thus, the statement that the pressure at these transducer/sensing elements is substantially the same ignores this small, inherent difference.

If a stenosis forms between the first transducer/sensing element 66 and the second transducer/sensing element 68, the pressure observed at the first transducer/sensing element 66 will be lower than the pressure observed at the second transducer/sensing element 68. Thus, when such a difference is observed, it may be diagnostic of a stenosis due, for example, to a thrombosis or a partial occlusion.

Fig. 4 shows a version of the implanted device of Fig. 3 in which exemplary, highly schematic stenoses are present in the device. In Fig. 4, a thrombosis 76 is shown in the structure of the shunt 32 itself. In addition, in Fig. 4, a highly schematic depiction of a partial occlusion of the vein 58 is shown, in which the occlusion is formed by an atherosclerotic-like lesion 78a and 78b. It is noted that while the lesions 78a and 78b are shown as similar size and shape, they may be of unequal size. As noted, the stenoses 76 and 78a, 78b are shown

highly schematically in Fig. 4. Furthermore, it is noted that while Fig. 4 shows both the thrombosis 76 and the partial occlusions 78a, 78b occurring simultaneously, any of these may occur singly, in any combination with each other, or in combination with other stenoses not specifically mentioned here. For example, the shunt 32 may collapse or be forced to close.

Both stenoses, the thrombosis 76 and the partial occlusion 78a, 78b shown in Fig. 4 would result in the observation of a reduction in the blood pressure at the first transducer/sensing element 66 relative to the pressure observed at the second transducer/sensing element 68. In this embodiment, the difference in the blood pressure observed at the two transducer/sensing elements would indicate the presence of some stenosis at some point between the two transducer/sensing elements.

In another embodiment, the transducer/sensing elements may be flow transducers such as magnetohydrodynamic flow transducers, in which a magnetic field applied to the body causes electrical changes in the blood flowing past the transducers which can be detected thereby. In this embodiment, as in the pressure transducer embodiment, the device is operatively configured to indicate a parameter associated with blood flow, here blood flow rate, by producing an output which varies as a function of the parameter.

Regardless of the specific type of device or parameter associated with blood flow which is measured thereby, the present invention provides the capability to observe differences between the outputs of the transducer/sensing elements. An observed difference between the outputs obtained from the first transducer/sensing element 66 and the second transducer/sensing element 68 may indicate the presence of a stenosis, or some other problem associated with blood flow, at some point between the two transducer/sensing elements, such as described above with reference to Fig. 4.

In another embodiment, the transducer/sensing elements are acoustic transducers which detect acoustic energy emitted as a result of the blood flowing past the acoustic transducer, which acoustic energy varies depending on the velocity of the blood. In this embodiment, as in the pressure transducer embodiment, the device is operatively configured to indicate a parameter associated with blood flow, here acoustic energy or sounds emanating from the blood as it flows past the acoustic transducers, by producing an output which varies as a function of the parameter. An observed difference between the outputs obtained from the first transducer/sensing element 66 and the second transducer/sensing element 68 may indicate the presence of a stenosis, or some other problem associated with blood flow at some point between the two transducer/sensing elements.

In a second embodiment of the present invention, as depicted in Fig. 5, the implanted device further includes a third transducer/sensing element 80, in addition to the first

transducer/sensing element 66 and the second transducer/sensing element 68. The components of the embodiment illustrated in Figs. 5 and 6 which are the same as those in Figs. 3 and 4 are indicated by the same reference numbers and are not separately described, except as necessary to describe the present embodiment. The third transducer/sensing element 80 is mounted on the structure of the shunt 32. In the illustrated embodiment, the third transducer/sensing element 80 is mounted near the distal end 63 of the shunt 32.

The third transducer/sensing element 80 is substantially the same as the first two transducer/sensing elements 66, 68. Thus, in separate embodiments, the third transducer/sensing element 80, like the first transducer/sensing element 66 and the second transducer/sensing element 68, may be, for example, a pressure transducer, a flow transducer or an acoustic transducer. The third transducer/sensing element 80, as shown in Fig. 5, is in operative communication with the communication element 70 by a third cable 82. As noted above with respect to the cables 72 and 74, the third cable 82 is illustrative of a communication means which may be in communication with the three transducer/sensing elements 66, 68 and 80 by wireless means, by being formed as an integral structure with one, two or all three of the transducer/sensing elements, or by other suitable methods known to those in the art for providing such communication.

Fig. 6 shows a version of the implanted device of Fig. 5 in which exemplary, highly schematic stenoses are present in the device similar to that shown in Fig. 4. In Fig. 6, a thrombosis 76 is shown in the structure of the shunt 32 itself. In addition, in Fig. 6, a highly schematic depiction of a partial occlusion of the vein 58 is shown, in which the occlusion is formed by an atherosclerotic-like lesion 78a and 78b. It is noted that while the lesions 78a and 78b are shown as similar size and shape, they may be of unequal size. As noted, the stenoses 76 and 78a, 78b are shown highly schematically in Fig. 6. As noted above with respect to Fig. 4, it is noted that while Fig. 6 shows both the thrombosis 76 and the partial occlusions 78a, 78b occurring simultaneously, any of these may occur singly, in any combination with each other, or in combination with other stenoses not specifically mentioned here. For example, the shunt 32 may collapse or be forced to close.

Both stenoses, the thrombosis 76 and the partial occlusion 78a, 78b shown in Fig. 6 would result in the observation of a reduction in the blood pressure at the first transducer/sensing element 66 relative to the pressure observed at the second transducer/sensing element 68. In addition, in this embodiment, the presence of the thrombosis 76 would result in the observation of a difference in the blood pressure observed at the third transducer/sensing element 80 relative to the second transducer/sensing element 68.

Thus, the presence of the third transducer/sensing element 80 allows the detection of a thrombosis or other stenosis in the structure of the shunt itself.

Thus, in this embodiment, the presence of a stenosis such as the partial occlusion 78a, 78b or a thrombosis in the vein 58 can be detected, as in the first embodiment. In this embodiment, in addition, the detected stenosis may be further differentiated as to location. Thus, the thrombosis 76 can be detected and determined to be within the body of the shunt 32, based on the difference in the pressures (or other parameter) observed in the second transducer/sensing element 68 and the third transducer/sensing element 80. Similarly, the partial occlusion 78a, 78b can be detected and determined to be within the vein 58, and not in the shunt 32, based on the difference in the pressures (or other parameter associated with blood flow) observed in the third transducer/sensing element 80 and the first transducer/sensing element 66.

Figs. 7, 10 and 11 illustrate exemplary embodiments of the invention in which the implanted devices 32 further include an annulus 84 which is fitted around the outer circumference of the respective implanted device 32. Figs. 8 and 9 show two embodiments of the annulus 84 which may serve as a carrier for one or more transducer/sensing elements 86 (e.g., transducer/sensing elements 66, 68 and 80 in Figs. 3-6).

In the embodiment shown in Fig. 7, the annulus 84 is mounted on an implanted device 32. The annulus 84 in Fig. 7 is attached to the communication element 70 by the cable 72. The embodiment shown in Fig. 7 further includes a patch type carrier for a transducer/sensing element described in more detail below.

In the embodiment shown in Fig. 8, the transducer/sensing elements 86 are mounted in or on the outer surface of a flat portion 88 in the annulus 84. In other embodiments including more than one transducer/sensing element 86, the elements 86 may be distributed about the outer circumference of the annulus 84. In another embodiment, for example, the transducer/sensing element 86 may be mounted on the outer surface of the annulus 84 or on both the inner and outer surfaces, depending on the type of transducer/sensing element used. The geometry of the annulus 84 is a function of the type of transducer/sensing element 86 actually used to measure a particular parameter associated with blood flow. The shape shown in Fig. 8, for example, is most suitable for strain gage transducers, where the creation of the flat region 88 insures that the implant 32 carries no load at the site of the annulus.

Fig. 9 shows an embodiment of an annulus 84 having a circular cross section. Such an annulus may include a collapsible portion, indicated schematically by a pair of dashed lines 85 drawn around a section of the annulus. The embodiment of the annulus 84 shown in Fig. 9 includes only a single transducer/sensing element 86, but additional transducer/sensing elements may be included as needed. The annulus 84 with a circular cross section could be used, for example, for magnetohydrodynamic or ultrasound transducer/sensing elements.

In the embodiment of the annulus 84 shown in Figs. 10 and 11, the transducer/sensing elements 86 are arrayed longitudinally along the length of the implanted annulus 84, rather than transversely as shown in Figs. 8 and 9. The embodiment shown in Fig. 10 optionally includes a flat portion, depending on the intended function of the transducer/sensing elements 86 employed thereon. The embodiment shown in Fig. 10 includes three transducer/sensing elements 86, which may all be of the same type or may be different. The embodiment shown in Fig. 11 includes two transducer/sensing elements 86, which may be the same or different. In an embodiment in which the elements 86 are the same, the device shown in Fig. 11 could be used as a flow sensing device as described in more detail below.

The annulus 84 with the transducer/sensing element(s) 86 is designed to sense changes in, e.g., pressure within the implanted device 32 which are indicative of blood flow. In an embodiment in which the transducer/sensing element 86 is a pressure transducer, when blood pressure within the implanted device 32 changes, it is detected by the transducer/sensing element 86 on the annulus 84. An output produced by the transducer/sensing element 86 varies in impedance as a function of the change in pressure, and the output is coupled to the communication element 70 via cables 72 or 82. Consequently, a change in pressure within the implanted device 32 results in a variation in the impedance presented to the communication element 70. It has been shown that a change in pressure exerted by the blood within a graft or shunt is a reliable indicator of vascular problems. Such problems may include clogging within the graft or shunt, for example, or clogging within the vessel.

In one exemplary embodiment, the implant 32 is made of a thin, compliant material which tends to deform measurably as a result of changes in blood pressure within the implant 32. As a particular example, the implant 32 is a conventional dialysis shunt made of a compliant woven fabric. The annulus 84 may be made of a thin material that is biologically inert, such as stainless steel or titanium, for example.

The annulus 84 includes the transducer/sensing elements 86 formed on the inner and/or outer surface of the annulus 84. In one embodiment, the transducer/sensing elements 86 are piezoresistive devices whose resistance changes as a function of mechanical strain of the annulus in the direction of its circumference. The piezoresistive devices are formed using MEMs technology, patterned lithography, etc., either directly on the annulus 84 material, or are subsequently mounted to the annulus 84 via a suitable adhesive, etc. The outputs of the transducer/sensing elements 86 are combined as desired in parallel, series, as a Wheatstone bridge, etc., via conductive lines 90 (Fig. 9) formed on the annulus 84, for example. The conductive lines 90 are coupled to cables 72 (or 82) to produce a resistance which varies as a function of the pressure exerted on the annulus 84 by the blood in the implant 32. The communication element 70, in turn, provides a means by which the measured pressure is communicated non-invasively to a receiving apparatus or analyzer outside of the body of the patient.

In one embodiment, the material of which the annulus 84 is made is stiffer than the implantable device 32. According to one embodiment, prior to the implantable device 32 being implanted in the patient, the annulus 84 is placed around the circumference of the implantable device 32 so as to slightly compress the tubular portion of the device. As a result, any increase in pressure which occurs in the tubular portion of the device 32 due to blood flowing therethrough will result in an expansion of the annulus 84 only, and hence causes a change in the output resistance of the transducer/sensing elements 86.

Although the exemplary embodiments involve a transducer/sensing elements 86 having a resistance which changes as a function of the amount of strain, another embodiment can incorporate a strain gage which produces a capacitance or inductance that changes as a function of strain as will be appreciated. Furthermore, other different types of transducer/sensor elements using cantilever beams, MEMs technology, etc. may be used. The present invention is not intended to be limited to any particular type of sensor element in its broadest sense.

For example, the transducer/sensing element 86 can be any of a variety of known types of sensors which may be used to sense a functional parameter within the living body. Such parameters may include, but are not limited to, vascular parameters such as blood flow rate, blood pressure, oxygen content, cholesterol, restenosis, glucose level, temperature, etc.; hematology parameters such as blood gases, blood chemistry, hemoglobin content, etc., and skeletal/muscular parameters such as force, strain, displacement, etc. As mentioned above, the element 86 itself may be characterized as a

sensor which is part of a circuit in which the impedance varies or can be varied in accordance with the output of the transducer/sensing elements in the circuit. In one embodiment, the sensor is an impedance based sensor whose resistance, capacitance and/or inductance varies directly with respect to frequency as a function of the sensed parameter. In another embodiment, the sensor is of a type whose output can be converted into a variable impedance. Exemplary sensor types include electrical, piezoelectric, sonic optical, microfluidic, chemical, membrane, thermal, magnetohydrodynamic, an NMR variant, magnetic, magnetostrictive, biological, microelectromechanical sensors (MEMs), etc.

In the particular examples discussed herein, the transducer/sensing element 86 may be a MEMs device whose impedance varies as a function of the amount or rate of blood flow through a stent or graft. Alternatively, the sensing element 86 may be a surface acoustic wave (SAW) device which can detect blood flow. In yet another alternative, the sensing element 86 may be a piezoelectric device within a stent or graft for detecting blood pressure.

In accordance with the present invention, the annulus 84 is mounted to the outer circumference of the implantable device 32 according to a number of different techniques. According to one embodiment, the annulus 84 is mounted to the implantable device 32 using a friction or interference fit. In one embodiment, an adhesive is provided along the edges of the annulus 84. The adhesive serves to bond the edges of the annulus 84 to the implantable device 32. In another embodiment, the annulus 84 is mechanically crimped to the implantable device 32 during manufacture of the device, by a mechanical attachment such as crimping or by a compression fitting. In another embodiment, the annulus 84 includes predrilled holes (not shown) about its circumference along each of the edges. The edges may be sutured or sewn to the wall of the implantable device 32.

The foregoing bonding methods allow for a simplification of the design of the apparatus for attaching the sensors to the implantable device 32 or to the vasculature. In actuality, only the flat portion 88 containing the transducer/sensing element 86 needs to be present and bonded to the implant or vasculature. This allows the annulus 84 to be dispensed with in another embodiment. In such an embodiment, the transducer/sensing element is reduced to a simple flat patch with the transducer sensing elements 86 mounted thereto. The shape of the patch can be rectangular similar to the flat portion 88, or the shape of the patch may be circular or some other shape, e.g., ovoid.

Fig. 7 shows a circular-shaped patch type sensor 92. The patch sensor 92 can be made of the same material as the annulus 84. The patch type sensor 92 shown in Fig. 7 includes a single transducer/sensing element 86, although in other embodiments additional transducer/sensing elements may be added as appropriate. In addition, the patch sensor 92 may be adhered to the vasculature or to the implantable device 32 along its perimeter using any of the methods described above. Particularly, the attachment to an implantable device 32 may be by the adhesive, crimping or suturing methods. When the patch type sensor 92 is attached to vasculature, the adhesive or suturing methods of attachment are most useful.

System

In one embodiment, the present invention relates to a system for detecting the flow of blood in or associated with an implanted device. The system 30 is a detection system for blood flow, including a shunt structure or implanted device 32 implantable within a living animal, i.e., a human patient 34. In one embodiment, the shunt structure 32 is adapted for blood flow from a proximal anastomosis 62 to a distal anastomosis 64 and has a proximal end 61 and a distal end 63. The system includes a first transducer/sensing element 66 attached to the vasculature 58 adjacent an end of the shunt structure 32. The implanted device 32 further includes a second transducer/sensing element 68 included as part of the shunt structure 32. The first and second transducer/sensing elements 66, 68 are operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter. The system further includes a communication element 70 operatively coupled to the output of the first and second transducer/sensing elements 66, 68. The communication element 70 is configured to communicate information based on the output of the first and second transducer/sensing elements 66, 68 wirelessly to a remote element 38 located outside the living animal 34. The remote element 38 is configured to apply an interrogation signal and to receive the information from the communication element 70 outside the living animal 34 in response to the interrogation signal provided to the communication element 70 by the remote element 38. The system further includes a processor 42 programmed to process the information received by the remote element based on the parameter, and to provide an output indicative of the parameter related to blood flow.

The implanted device 32, which in one embodiment is a shunt structure, the first transducer/sensing element 66, the second transducer/sensing element 68, the third transducer/sensing element 80 (when present), the communication element 70, and the associated connections 72, 74, and, when present the connection 82, provide one portion of a first embodiment of a system for detecting blood flow. The system further includes a remote

element 38 configured to apply an interrogation signal and to receive the information from the communication element 70. The remote element may be the external exciter/interrogator 38 described above. The system 30 further includes a processor programmed to process the information received by the remote element based on the parameter to provide an output indicative of blood flow. The processor may include, for example, suitable capability to apply a Fourier transform to the data obtained from the remote element in order to detect differences between the various transducer/sensing elements, thereby to provide information relating to possible stenoses, or other parameters associated with blood flow, in or associated with the implanted device.

Method

In one embodiment, the present invention relates to a method for detecting blood flow associated with a dialysis shunt. The method for detecting in a living body blood flow associated with a dialysis shunt forming a fluid communication from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end, including implanting in the dialysis shunt or in vasculature adjacent the distal anastomosis at least two transducer/sensing elements for sensing a parameter associated with blood flow; attaching each transducer/sensing element to a communication circuit producing an output signal for each transducer/sensing element based on the parameter associated with blood flow; non-invasively detecting the output signal for each transducer/sensing element based on the parameter associated with blood flow; and determining the presence or absence of a stenosis based on a difference between the output signal for each transducer/sensing element.

Thus, in one embodiment of the system, the blood flow information may be used in this method to determine the presence or absence of a stenosis in a dialysis shunt implanted device 32 or in the adjacent vasculature, i.e., the artery 54 or the vein 58.

Determination of Fluid Flow

In another embodiment of the present invention, the system may be employed in a method to determine fluid flow, such as blood flow, through a natural or implanted vasculature. In this embodiment, the use of two transducer/sensing elements for sensing a parameter associated with blood flow, e.g., two pressure transducers, separated by some distance on a graft as shown in Fig. 10, allows the detection of changes in blood flow based on the difference in, e.g., pressure between the two pressure transducers. As is well known, in any viscous fluid, the pressure at an upstream position, such as at the upstream position of the second transducer 68 in Figs. 5 and 6, is usually different from and most often is higher than the pressure at a downstream position, such as at the position of the third transducer 80 in Figs. 5 and 6, under constant flow conditions. Measuring the difference between the pressure at the

upstream and downstream positions, i.e., the pressure differential between the second transducer 68 and the third transducer 80, provides an indication of the blood flow therebetween, i.e., through the shunt 32. The structure shown in Fig. 11 shows an alternative apparatus for making such a determination.

The information obtained from the first transducer/sensing element 66 and the second transducer/sensing element 68, shown in Figs. 3-6, can also provide valuable information. In the presence of blood flow at the first transducer/sensing element 66 from both the vein 58 upstream of the anastomosis 64 and the implanted dialysis shunt 32, the difference in blood flow between the first transducer/sensing element 66 and the second transducer/sensing element 68 provides an indication of relative blood flow through the implanted dialysis shunt 32 and through the natural capillary bed between the artery 54 and the vein 58. This relative blood flow information provides a method for monitoring the amount of blood available for shunting to dialysis.

Fig. 11 shows an embodiment of the present invention in which fluid flow through a tubular graft 94 may be determined. In Fig. 11, the direction of fluid flow, e.g., blood flow, is shown by an arrow 96. The tubular graft 94 includes two transducer/sensing elements, a first, upstream transducer/sensing element 86a and a second, downstream transducer/sensing element, 86b. As noted above, the pressure at the first, upstream transducer/sensing element 86a may be different from the pressure at the second, downstream transducer/sensing element 86b. The very small but finite difference in pressure between the two transducer/sensing elements 86a, 86b allow calculation of the flow through the tubular graft 94.

Thus, with reference to the embodiment shown in Fig. 11, the method for determining in a living body a fluid flow rate through a natural or implanted vasculature 94, includes implanting in the vasculature a first transducer/sensing element 86a and a second transducer/sensing element 86b for sensing a parameter associated with fluid flow. The second transducer/sensing element 86b is located downstream from the first transducer/sensing element 86a. Each transducer/sensing element 86a, 86b is attached to a communication circuit for producing an output signal for each transducer/sensing element based on the parameter associated with fluid flow. The output signal for each transducer/sensing element 86a, 86b relating to the parameter associated with fluid flow is non-invasively detected by the remote exciter/interrogator 38. The fluid flow rate is then determined based on a difference between the output signal for each transducer/sensing element 86a, 86b.

Aneurysm Graft Leak Detection

In another embodiment of the present invention, the system may be employed to detect, e.g., a leak in an aneurysm graft. An aneurysm graft is a device which may be

implanted within an aneurysm, such as an aortic aneurysm. The aneurysm graft is intended to strengthen the vasculature in the vicinity of the aneurysm and thus to provide full blood flow through the affected vessel while avoiding a catastrophic rupture of the aneurysm. Aortic aneurysm grafts and various problems associated therewith are discussed in detail in U.S. Patent Nos. 6,162,246 and 6,203,779, the disclosures of which are incorporated by reference herein for such teachings. A problem which is may be presented by an aneurysm graft is a leak in the aneurysm graft, whereby blood bypasses the graft and enters the space between the graft and the aneurysm. Such a leak can also result in a rupture of the aneurysm. Thus, it is important to detect, as soon as possible, the presence of a leak in an aneurysm graft.

In order to meet the need for leak detection in aneurysm grafts, the present invention further relates to a method for detecting in a living body a leak in an aneurysm. The method includes the steps of implanting an aneurysm graft including a transducer/sensing element for sensing a parameter associated with blood flow, wherein the transducer/sensing element is located on an outer, aneurysm facing surface of the graft. The transducer/sensing element is attached to a communication circuit producing an output signal for the transducer/sensing element based on the parameter associated with blood flow. The output signal for each transducer/sensing element is non-invasively detected based on the parameter associated with blood flow. Based on the output signal, the presence or absence of a leak in the aneurysm graft is determined based on a change in the output signal for the transducer/sensing element.

Figs. 12 and 13 show two embodiments of an aneurysm graft in accordance with this embodiment of the present invention. In Figs. 12 and 13, there is shown an abdominal aorta 96, in which an aneurysm 98 has formed. As a treatment for the aneurysm 98, an aneurysm graft 100 has been implanted in the abdominal aorta 96. Implanting the aneurysm graft 100 in the aneurysm 98 forms an aneurysm space 102 between the outer wall of the aneurysm graft 100 and the inner wall of the aneurysm 98.

The aneurysm graft 100 may be any appropriate such graft as known in the art. This embodiment of the present invention is not limited to any particular type of aneurysm graft. The aneurysm graft 100 may be appropriately attached to the abdominal aorta 96 by any suitable means, such as suturing. Again, the present invention is not limited to any particular means of attachment of the aneurysm graft 100 to the aorta 96, so long as the graft 100 isolates the inner, blood flow surface of the graft 100 from the outer, aneurysm-facing surface of the aneurysm graft 100.

As shown in Fig. 12, in one embodiment, the aneurysm graft 100 includes an outwardly facing transducer/sensing element 86c attached to the body of the aneurysm graft 100 and disposed in the aneurysm space 102. Although not shown in detail in Fig. 12, the

transducer/sensing element 86c is connected to an appropriate communication element such as the communication element 70 shown in Figs. 3-7, 10 and 11. Also not shown, additional transducer/sensing elements 86 may be attached to the body of the aneurysm graft 100 as appropriate. For example, a further transducer/sensing element may be mounted on the inner, blood flow facing side of the aneurysm graft 100.

As shown in Fig. 13, in another embodiment, the aneurysm graft 100 includes an annulus 84, upon which is mounted the transducer/sensing element 86c and disposed in the aneurysm space 102. In this embodiment, the annulus 84 is attached to the aneurysm graft 100 and is implanted in the aneurysm 98 in the aorta 96 with the aneurysm graft 100. An aneurysm graft such as that shown in Fig. 13 may be implanted in a collapsed condition, since it is often undertaken via one of the iliac arteries below the aneurysm. In order to facilitate implantation of an aneurysm graft 100 including the annulus 84 such as shown in Fig. 13, the annulus 84 may be collapsible at appropriate locations indicated schematically by dashed lines 85 in Fig. 13. Although not shown in detail in Fig. 13, the transducer/sensing element 86c is connected to an appropriate communication element such as the communication element 70 shown in Figs. 3-7, 10 and 11. Also not shown, additional transducer/sensing elements 86 may be attached to the annulus 84, or to the body of the aneurysm graft 100 as appropriate. For example, a further transducer/sensing element may be mounted on the inner, blood flow facing side of the aneurysm graft 100, or on the inner side of the annulus 84 between the annulus 84 and the aneurysm graft 100.

The leak in the aneurysm graft to which the present embodiment is particulary applicable is a leak of blood around an end of the aneurysm graft 100 into the aneurysm space 102, in the area in which the transducer/sensing element 86c is located. When the aneurysm graft 100 has been implanted, in the absence of a leak, the pressure inside the aneurysm space 102 should remain relatively constant, although it may fluctuate slightly due to expansion and contraction of the body of the aneurysm graft 100 with the patient's heartbeat. Any observed baseline increase in the pressure in the aneurysm space 102 may be indicative of a leak in the aneurysm graft 100.

In one embodiment, the transducer sensing element 86c is a pressure transducer and is mounted on the outer surface of the aneurysm graft 100. The pressure transducer 86c measures the difference between blood pressure inside the graft and any pressure on the outside of the graft, i.e., pressure within the aneurysm space 102. In the absence of an aneurysm leak, the pressure measured by the pressure transducer 86c is the normal blood pressure inside in the aneurysm graft 100. If there is a leak in the aneurysm graft 100, as a result of which blood flows into the aneurysm space 102, the pressure observed by the

pressure transducer 86c will be reduced or offset by the amount of pressure in the aneurysm space 102. The pressure observed by the pressure transducer 86c will be reduced and may approach zero when an aneurysm leak allows blood to flow from the aorta 96 into the aneurysm space 102.

In another embodiment, the transducer/sensing element 86c is a pressure transducer mounted on the outer surface of the aneurysm graft 100 which directly measures the pressure inside the aneurysm space 102. In the absence of an aneurysm leak, the pressure in the aneurysm space 102 should be essentially ambient pressure, which is measured as zero pressure. In this embodiment, an observed increase in pressure in the aneurysm space 102 is measured directly by the pressure transducer 86c.

In both embodiments, the measured pressure is remotely, non-invasively sensed by the remote exciter/interrogator 38, and may be used by a physician to identify a possibly life-threatening leak in an implanted aneurysm graft.

While the invention has been described in conjunction with specific embodiments herein, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly it is intended to embrace all such alternatives and modifications in variations as for within the spirit and broad scope of the appended claims.

What is claimed is:

1. An implantable medical device, comprising:

a shunt structure implantable within a living animal, the shunt structure adapted for blood flow from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end;

a first transducer/sensing element attached to vasculature adjacent an end of the shunt structure;

a second transducer/sensing element mounted on the shunt structure;

the first and second transducer/sensing elements being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and

a communication element operatively coupled to the output of the first and second transducer/sensing elements, the communication element being configured to communicate information based on the output of the first and second transducer/sensing elements wirelessly to a remote element located outside the living animal.

2. A device as in claim 1, wherein the transducer/sensing elements are pressure transducers.

3. A device as in claim 1, wherein the transducer/sensing elements are flow transducers.

4. A device as in claim 1, wherein the transducer/sensing elements are acoustic transducers.

5. A device as in claim 1, wherein the remote element inductively couples with an inductive element in the communication circuit.

6. A device as in claim 1, wherein the first transducer/sensing element is attached to the vasculature at a location downstream from the distal end, and the second transducer/sensing element is attached to the shunt adjacent the proximal end.

7. A device as in claim 6, further comprising a third transducer/sensing element attached to the shunt adjacent the distal end, the third transducer/sensing element being coupled to the communication circuit.

8. A device as in claim 1, wherein the information relates to detection of a stenosis associated with the shunt.

9. A device as in claim 8, wherein the stenosis results from a thrombosis in one or both of the vasculature or the shunt.

10. A device as in claim 8, wherein the stenosis results from a partial occlusion in the vasculature adjacent the shunt.

11. A detection system for blood flow, comprising:

a shunt structure implantable within a living animal, the shunt structure adapted for blood flow from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end;

a first transducer/sensing element attached to the vasculature adjacent an end of the shunt structure;

a second transducer/sensing element included as part of the shunt structure;

the first and second transducer/sensing elements being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and

a communication element operatively coupled to the output of the first and second transducer/sensing elements, the communication element being configured to communicate information based on the output of the first and second transducer/sensing elements wirelessly to a remote element located outside the living animal;

the remote element configured to apply an interrogation signal and to receive the information from the communication element outside the living animal in response to the interrogation signal; and

a processor programmed to process the information received by the remote element based on the parameter to provide an output indicative of blood flow.

12. A system as in claim 11, wherein the transducer/sensing elements are pressure transducers.

13. A system as in claim 11, wherein the transducer/sensing elements are flow transducers.

14. A system as in claim 11, wherein the transducer/sensing elements are acoustic transducers.

15. A system as in claim 11, wherein the remote element inductively couples with an inductive element in the communication circuit.

16. A system as in claim 11, wherein the first transducer/sensing element is attached to the vasculature at a location downstream from the distal end, and the second transducer/sensing element is attached to the shunt adjacent the proximal end.

17. A system as in claim 16, further comprising a third transducer/sensing element attached to the shunt adjacent the distal end, the third transducer/sensing element being coupled to the communication circuit.

18. A system as in claim 11, wherein the information relates to detection of a stenosis associated with the shunt.

19. A system as in claim 18, wherein the stenosis results from a thrombosis in one or both of the vasculature or the shunt.

20. A system as in claim 18, wherein the stenosis results from a partial occlusion in the vasculature adjacent the shunt.

21. A method for detecting in a living body blood flow associated with a dialysis shunt forming a fluid communication from a proximal anastomosis to a distal anastomosis and having a proximal end and a distal end, comprising:

attaching to the dialysis shunt or to vasculature adjacent at least one said anastomosis at least two transducer/sensing elements for sensing a parameter associated with blood flow;

attaching each transducer/sensing element to a communication circuit producing an output signal for each transducer/sensing element based on the parameter associated with blood flow;

non-invasively detecting the output signal for each transducer/sensing element based on the parameter associated with blood flow; and

determining the presence or absence of a stenosis based on a difference between the output signal for each transducer/sensing element.

22. A method as in claim 21, wherein the output signal is detected in response to an interrogation signal externally applied by a remote element to the communication circuit.

23. A method as in claim 21, wherein the transducer/sensing elements are pressure transducers.

24. A method as in claim 21, wherein the transducer/sensing elements are flow transducers.

25. A method as in claim 21, wherein the transducer/sensing elements are acoustic transducers.

26. A method as in claim 21, wherein the remote element detects the output signal by inductively coupling with an inductive element in the communication circuit.

27. A method as in claim 21, wherein a first transducer/sensing element of the at least two transducer/sensing elements is attached to the vasculature at a location downstream from the distal end, and a second transducer/sensing element of the at least two transducer/sensing elements is attached to the shunt adjacent the proximal end.

28. A method as in claim 27, further comprising a third transducer/sensing element attached to the shunt adjacent the distal end, the third transducer/sensing element being coupled to the communication circuit.

29. A method as in claim 21, wherein the stenosis results from a thrombosis in one or both of the vasculature or the shunt.

30. A method as in claim 21, wherein the stenosis results from a partial occlusion in the vasculature adjacent the shunt.

31. A method as in claim 21, where the blood flow is used to diagnose the presence of a stenosis associated with the shunt.

32. A method for detecting in a living body a leak in an aneurysm graft, comprising:

implanting in the living body an aneurysm graft having a transducer/sensing element for sensing a parameter associated with blood flow, wherein the transducer/sensing element is located on an outer surface of the aneurysm graft;

attaching the transducer/sensing element to a communication circuit producing an output signal for the transducer/sensing element based on the parameter associated with blood flow;

non-invasively detecting the output signal from the transducer/sensing element based on the parameter associated with blood flow; and

determining the presence or absence of a leak in the aneurysm graft based on a change in the output signal from the transducer/sensing element.

33. A method as in claim 32, wherein the output signal is detected in response to an interrogation signal externally applied by a remote element to the communication circuit.

34. A method as in claim 32, wherein the transducer/sensing element is a pressure transducer.

35. A method as in claim 32, wherein the transducer/sensing element is an acoustic transducer.

36. A method as in claim 32, wherein the remote element detects the output signal by inductively coupling with an inductive element in the communication circuit.

37. A method for determining in a living body a fluid flow rate through a natural or implanted vasculature, comprising:

attaching to the vasculature a first and a second transducer/sensing element for sensing a parameter associated with fluid flow, wherein the second transducer/sensing element is located downstream from the first transducer/sensing element;

attaching each transducer/sensing element to a communication circuit producing an output signal for each transducer/sensing element based on the parameter associated with fluid flow;

non-invasively detecting the output signal for each transducer/sensing element based on the parameter associated with fluid flow; and

determining the fluid flow rate based on a difference between the output signal for each transducer/sensing element.

38. A method as in claim 37, wherein the output signal is detected in response to an interrogation signal externally applied by a remote element to the communication circuit.

39. A method as in claim 37, wherein the transducer/sensing elements are pressure transducers.

40. A method as in claim 37, wherein the transducer/sensing elements are acoustic transducers.

41. A method as in claim 37, wherein the transducer/sensing elements are acoustic transducers.

42. A method as in claim 37, wherein the remote element detects the output signal by inductively coupling with an inductive element in the communication circuit.

43. An implantable medical device, comprising

a structure implantable within a living animal;

at least one transducer/sensing element attached to the structure or to vasculature adjacent the structure; the at least one transducer/sensing element being operatively configured to indicate a parameter associated with blood flow by producing an output which varies as a function of the parameter; and

a communication element operatively coupled to the output of the at least one transducer/sensing elements, the communication element being configured to communicate information based on the output of the at least one transducer/sensing elements wirelessly to a remote element located outside the living animal.

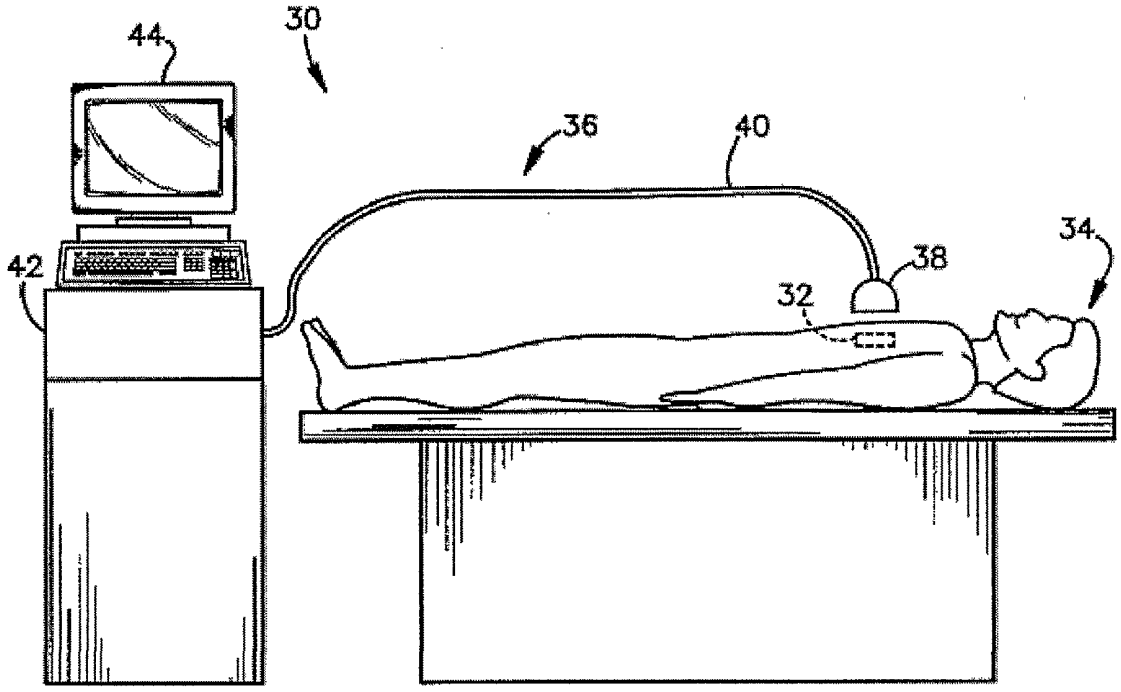
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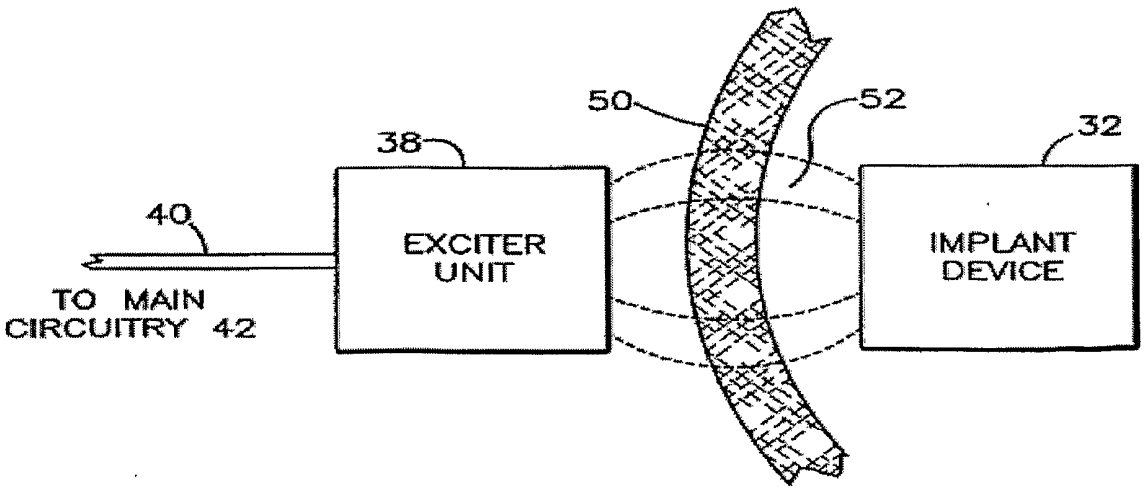
FIG. 1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32
40
EXCITER UNIT
IMPLANT DEVICE
TO MAIN CIRCUITRY 42

FIG. 2

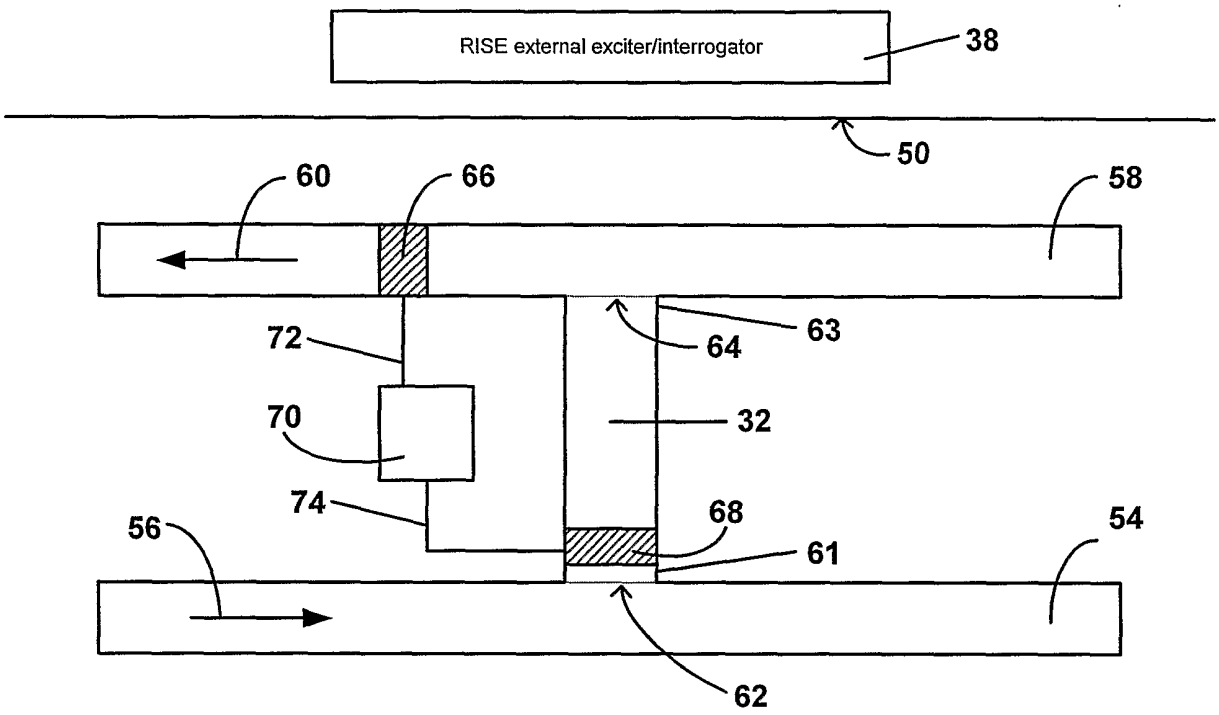
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FIG. 3

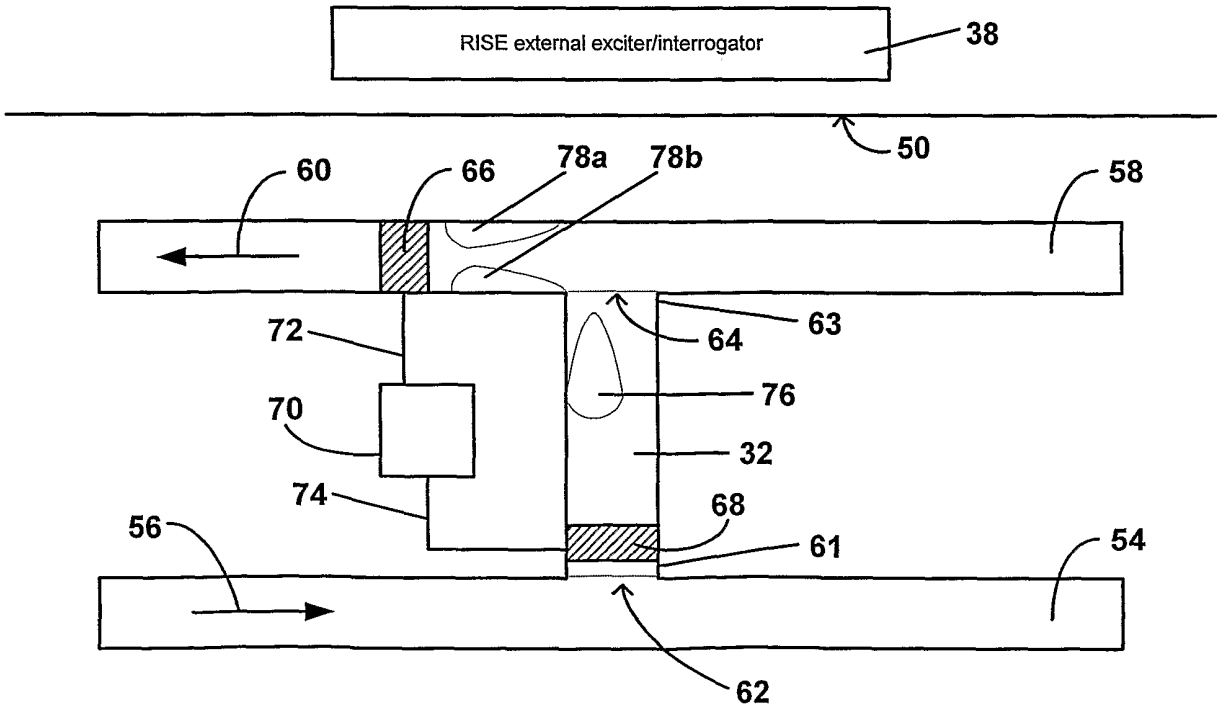
RISE external exciter/interrogator
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FIG. 4

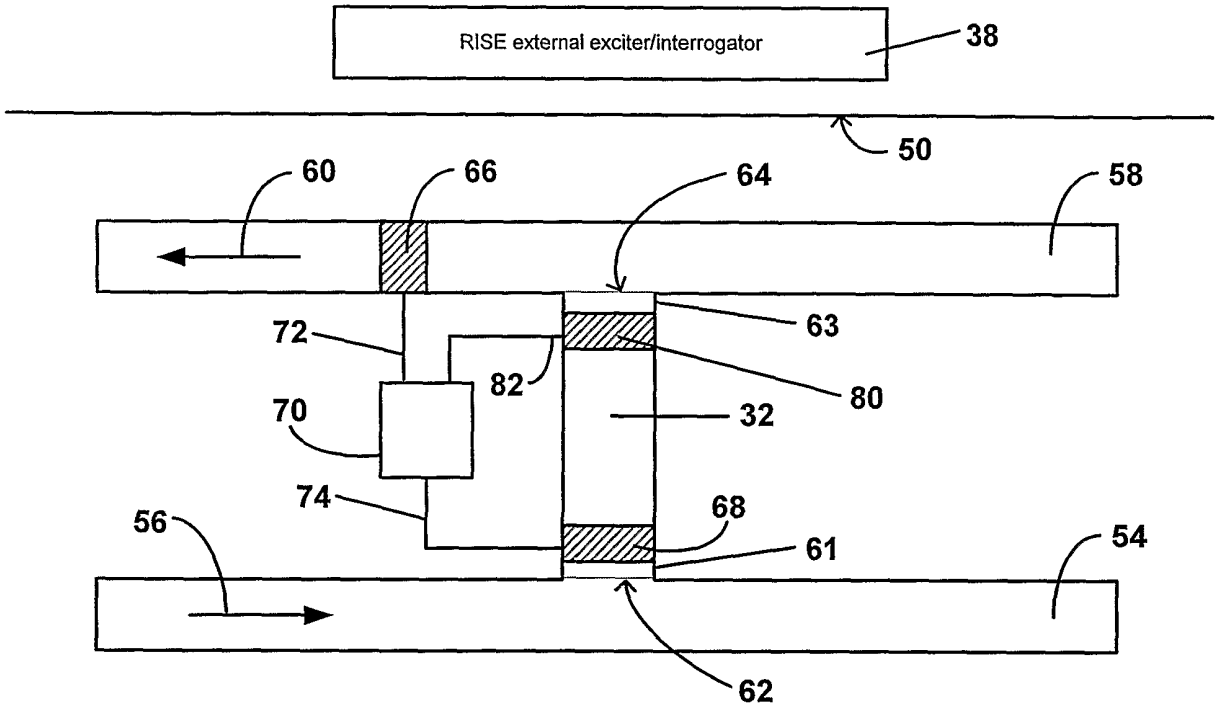
RISE external exciter/interrogator
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FIG. 5

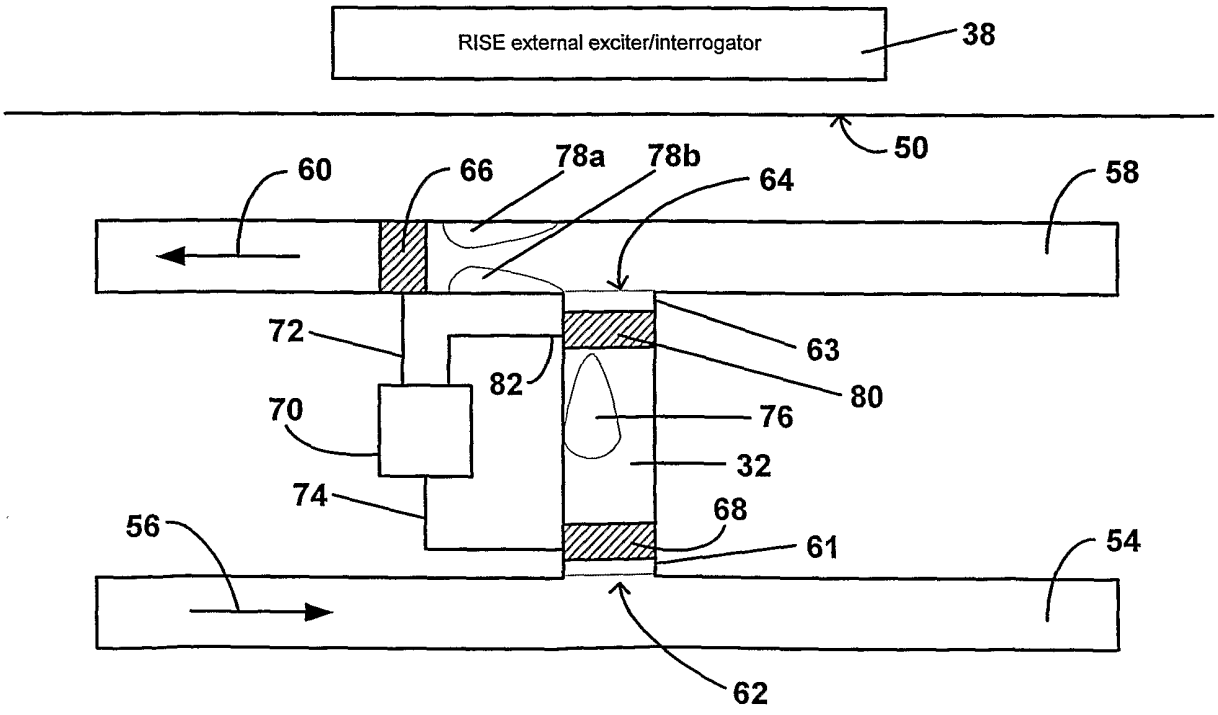
RISE external exciter/interrogator
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FIG. 6

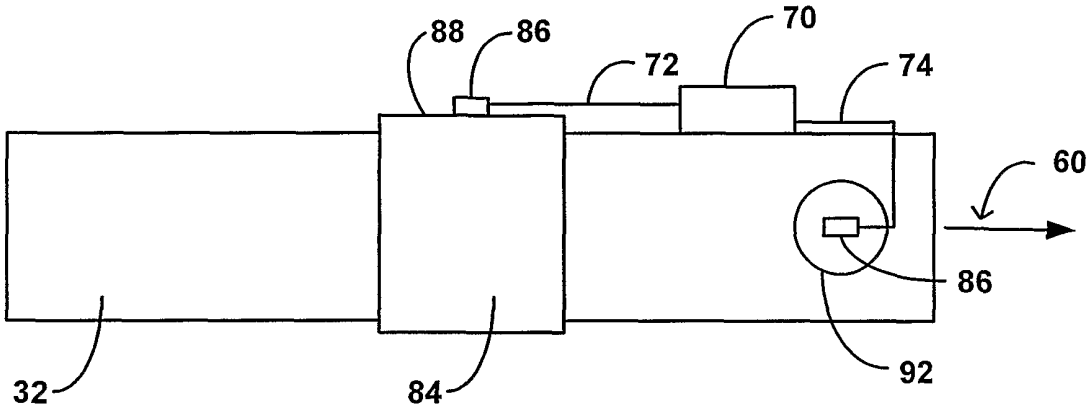

FIG. 7

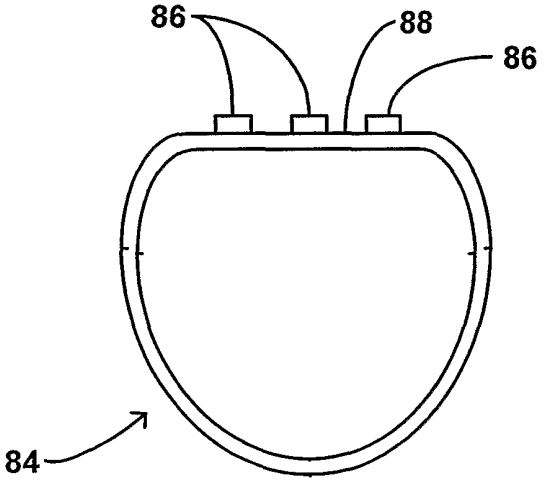

FIG. 8

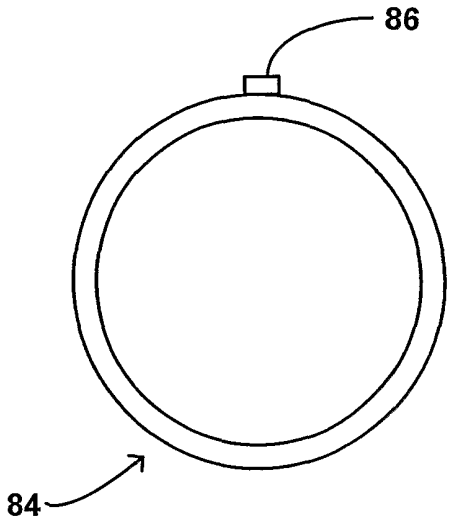

FIG. 9

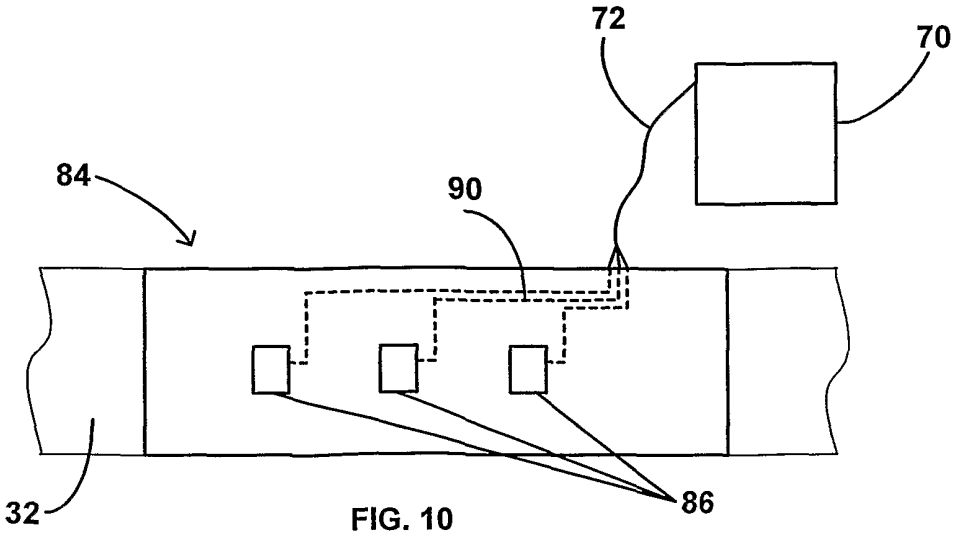

FIG. 10

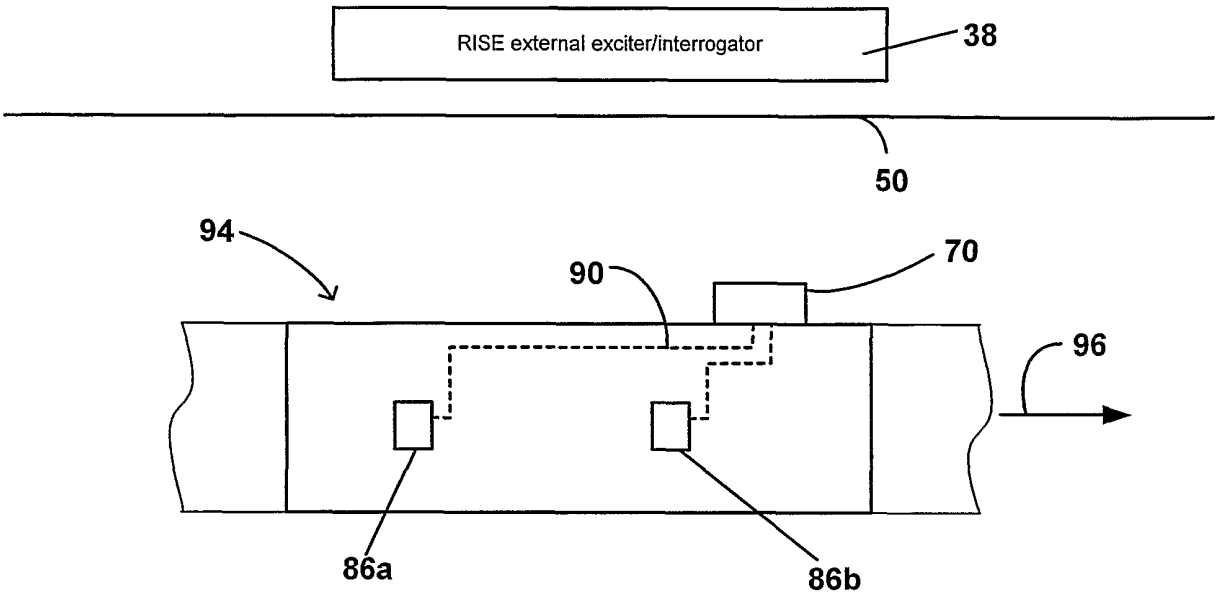

FIG. 11

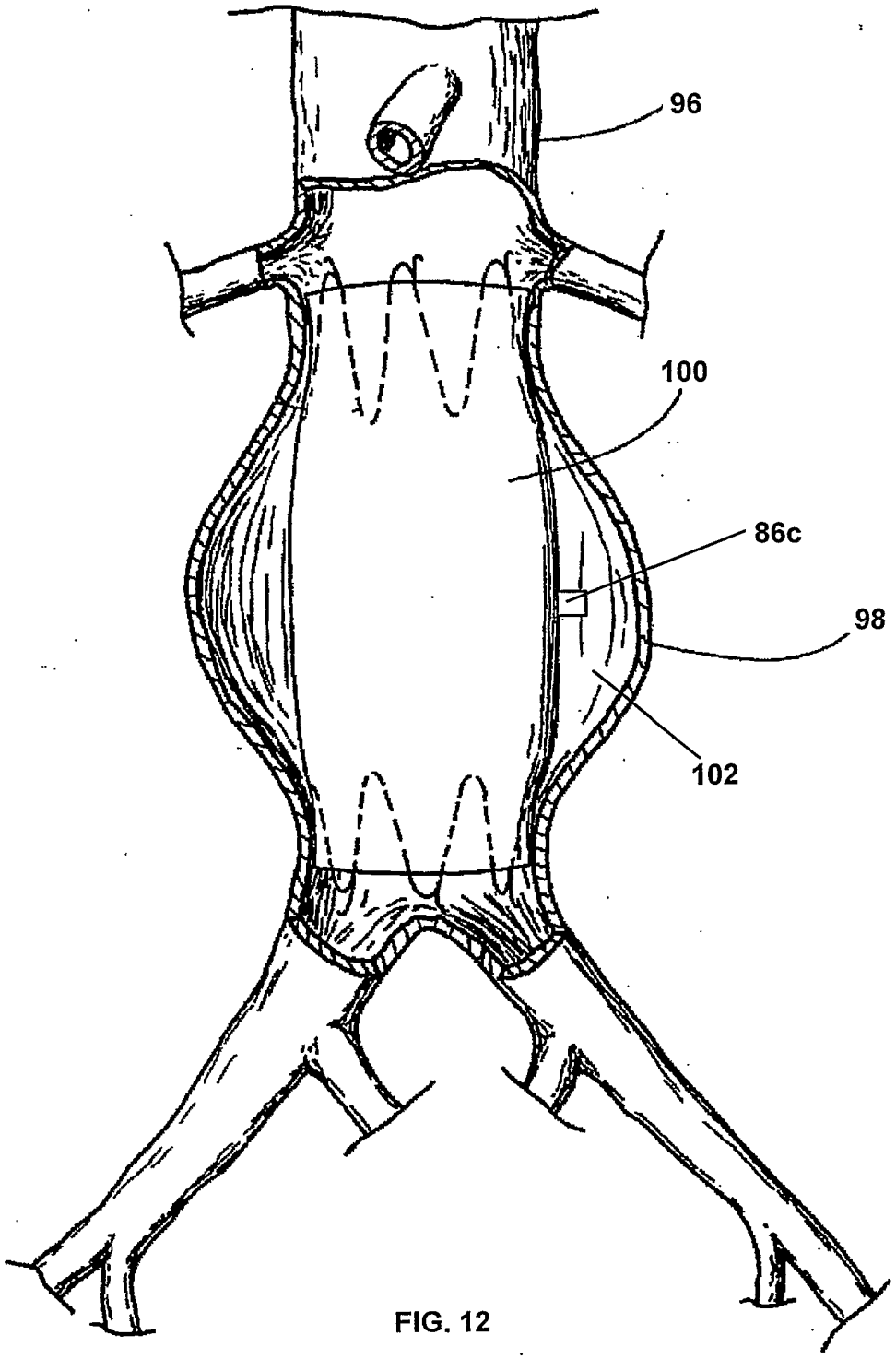

FIG. 12

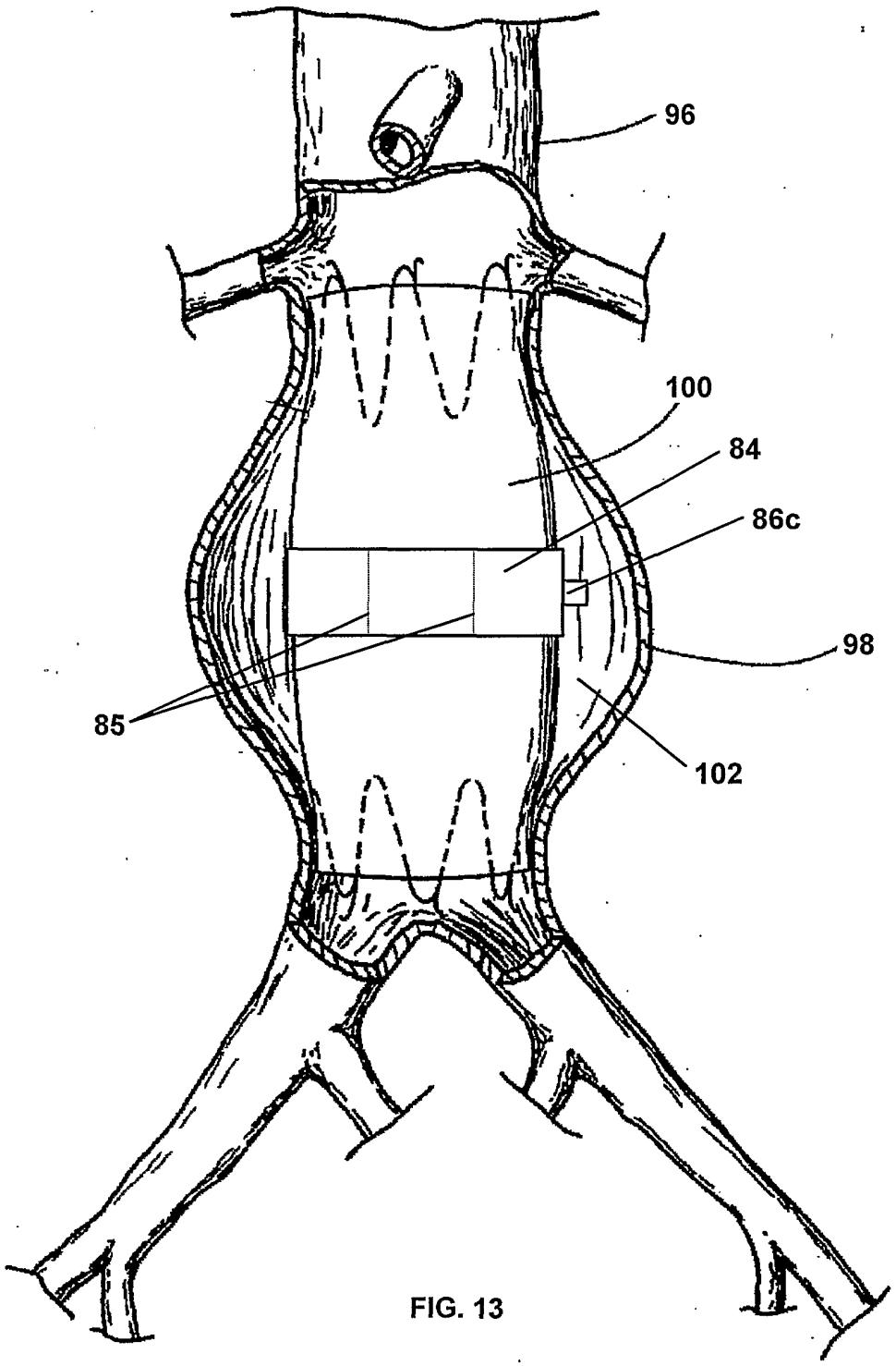

FIG. 13