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(54) Title: COMMUNICATION DIPOLE FOR IMPLANTABLE MEDICAL DEVICE

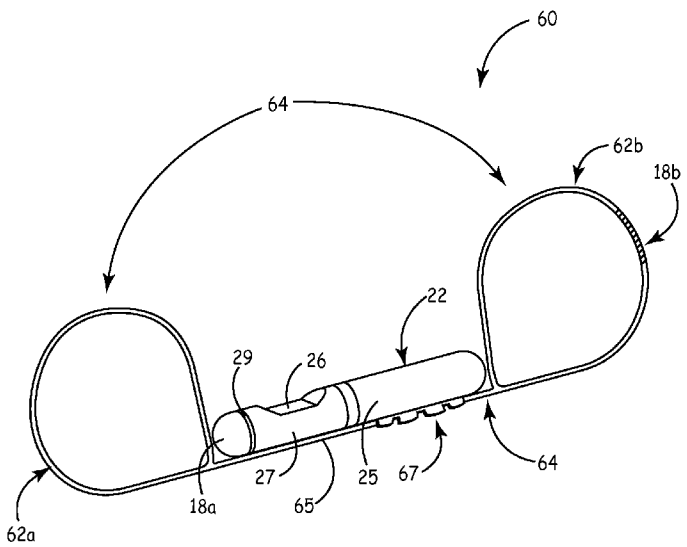

FIG. 5B

(57) Abstract: This disclosure is directed to an implantable medical device having a communication dipole configured in accordance with the techniques described herein. In one example, the disclosure is directed to an implantable medical device comprising a housing that encloses at least a communication module, a first electrode of a communication dipole electrically coupled to the communication module and an electrically conductive fixation mechanism that is electrically coupled to a portion of the housing and wherein a portion of the fixation mechanism is configured to function as at least part of a second electrode of the communication dipole. The electrically conductive fixation mechanism includes a dielectric material that covers at least part of a surface of the fixation mechanism. The communication module is configured to transmit or receive a modulated signal between the first electrode and second electrode of the communication dipole.

WO 2012/103433 A1

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COMMUNICATION DIPOLE FOR IMPLANTABLE MEDICAL DEVICE

TECHNICAL FIELD

The disclosure relates generally to implantable medical devices and, in particular, to a communication dipole for implantable medical devices.

BACKGROUND

A wide variety of implantable medical devices (IMDs) that sense one or more parameters of a patient, deliver a therapy to the patient, or both have been clinically implanted or proposed for clinical implantation in patients. An IMD may deliver therapy to or monitor a physiological or biological condition with respect to a variety of organs, nerves, muscles, tissues or vasculatures of the patient, such as the heart, brain, stomach, spinal cord, pelvic floor, or the like. The therapy provided by the IMD may include electrical stimulation therapy, drug delivery therapy or the like.

The IMD may exchange communications with another device. The IMD may exchange communications with another device that is implanted, attached to (e.g., worn by) the patient or otherwise located near the patient. The information exchanged may be information related to a condition of the patient, such as physiological signals measured by one or more sensors, or information related to a therapy delivered to the patient. The IMD may also receive information from the other device, such as information that may be used to control or configure a therapy to be provided to the patient. The IMD and the other device may exchange information using any of a variety of communication techniques, including inductive telemetry, magnetic telemetry, radio frequency (RF) telemetry or the like.

SUMMARY

Intra-body communication is one communication scheme that may be used to communicate information to and from an implantable medical device. Intra-body communication uses the body of the patient as the communication channel. The human body has dielectric properties that allow the body to act as a transmission medium for electrical currents. Thus, intra-body wireless communication exploits the transmission channel of electrolytic-galvanic coupling with the device electrodes and the ion medium

(or other properties) of cellular fluids of the patient. A transmitter of either an IMD or an external device applies a modulated electrical current between a pair of electrodes to transmit a modulated signal. A pair of electrodes of the receiving device, which are also in contact with the body of the patient, receive the modulated signal as an electric potential difference across a pair of electrodes of the receiving device. The pair of electrodes of either the transmitting device or the receiving device may be referred to herein as a "communication dipole," a "transmit dipole," or a "receive dipole" due to its operation resembling that of a dipole antenna.

Due to the small size of IMDs, and especially devices configured for implantation within the vasculature of the patient, the distance between electrodes forming the communication dipole is typically limited. Electrodes used for intra-body communication may, for example, typically be placed at opposite ends of a housing of the IMD. It is desirable, however, to increase the distance between the electrodes of the communication dipole to increase the strength of the communication signal transmitted and received via intra-body communication. In accordance with the techniques of one aspect of this disclosure, the IMD is configured to utilize a portion of a fixation mechanism of the IMD as part of one or both of the electrodes of the communication dipole, thereby increasing the distance separating the electrodes. In one example, a portion of the fixation mechanism is utilized as at least a part of a first of the dipole electrodes and the other dipole electrode may be formed on or integrated in the housing of the IMD. In some instances, the portion of the fixation mechanism and a second portion of the housing may be mechanically and/or electrically coupled to function as the first of the dipole electrodes.

Additionally, the location of the portion of the fixation mechanism forming part of the first of the dipole electrodes may be selected to provide at least some control of the orientation of the transmitting dipole when the IMD is rotated, e.g., around a central axis of a vasculature during implantation. In instances in which the communication dipole is formed from electrodes placed at opposite ends of a relatively cylindrical housing of the IMD there is very little control over the orientation of the communication dipole. However, selecting a portion of fixation mechanism that functions as part of the first electrode of the communication dipole such that the orientation of the axis of the communication dipole (axis defined between the portion of the housing configured to function as the second electrode of the communication dipole and the portion of fixation

mechanism configured to function as part of the first electrode of the communication dipole) is offset from the central axis of the vasculature when the IMD is positioned within the vasculature provides the capability to have more control of the orientation of the dipole. In this case, rotation of the IMD within the vasculature of the patient may change the directionality at which the current is radiated by the transmitting communication dipole.

In one example, the disclosure is directed to an implantable medical device comprising a housing that encloses at least a communication module, a first electrode of a communication dipole electrically coupled to the communication module and an electrically conductive fixation mechanism that is electrically coupled to a portion of the housing and wherein a portion of the fixation mechanism is configured to function as at least part of a second electrode of the communication dipole. The electrically conductive fixation mechanism includes a dielectric material that covers at least part of a surface of the fixation mechanism. The communication module is configured to transmit or receive a modulated signal between the first electrode and second electrode of the communication dipole.

This summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the techniques as described in detail within the accompanying drawings and description below. Further details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the statements provided below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a conceptual diagram illustrating an example medical system.

FIG. 1B is a conceptual diagram illustrating another example medical system.

FIG. 2 is a conceptual diagram illustrating an IMD implanted in a heart of a patient.

FIGs. 3A–3D are schematic diagrams illustrating enlarged views of the IMD of FIG. 2 from various viewpoints.

FIG. 3E is a schematic diagram illustrating another example IMD.

FIG. 3F is a schematic diagram illustrating another example IMD.

FIG. 4A and 4B are schematic diagrams illustrating other example IMDs.

FIG. 5A–5C are schematic diagrams illustrating other example IMDs.

FIGs. 6A–6C are graphs illustrating an example plot of effective dipole length and impedance versus the amount of fixation mechanism that is exposed.

FIGs. 7A and 7B are a schematic diagram illustrating other example IMDs.

FIGs. 8A–8C are schematic diagrams illustrating a further example of an IMD.

FIG. 9 is a functional block diagram illustrating components of an implantable medical device in further detail.

DETAILED DESCRIPTION

FIG. 1A is a conceptual diagram illustrating an example medical system 10. Medical system 10 includes an implantable medical device (IMD) 14 and an external device 16. Medical system 10 may, however, include more of fewer implanted or external devices.

IMD 14 may be any of a variety of medical devices that sense one or more parameters of patient 12, provide therapy to patient 12 or a combination thereof. In one example, IMD 14 may be a leadless IMD. In other words, IMD 14 is implanted at a targeted site with no leads extending from IMD 14, thus avoiding limitations associated with lead-based devices. Instead, sensing and/or therapy delivery components are integrated within IMD 14. In the case of a leadless sensor, IMD 14 includes one or more sensors that measure the physiological parameter(s) of patient 12. In one example, IMD 14 may comprise an implantable device incorporating a pressure sensor that is placed within a vasculature or chamber of a heart of patient 12.

IMD 14 may, in some instances, provide therapy to patient 12. IMD 14 may provide the therapy to patient 12 as a function of sensed parameters measured by the sensor of IMD 14 or sensed parameters received from another device, such as another IMD or a body worn device. As one example, IMD 14 may be a leadless cardiac IMD that provides electrical stimulation therapy (e.g., pacing, cardioversion, defibrillation, and/or cardiac resynchronization therapy) to the heart of patient 12 via one or more electrodes as a function of sensed parameters associated with the heart. In yet a further example, IMD 14 may provide therapy to patient 12 that is not provided as a function of the sensed parameters, such as in the context of neurostimulation. Although described above in the

context of electrical stimulation therapy, IMD 14 may provide other therapies to patient 12, such as delivery of a drug or other therapeutic agent to patient 12 to reduce or eliminate the condition of the patient and/or one or more symptoms of the condition of the patient, or provide no therapy at all.

External device 16 communicates with IMD 14 using intra-body communication. Intra-body communication as used herein refers to a data transmission scheme that uses the human body as the communication channel. The human body has dielectric and conductive properties that allow the body to act as a transmission medium for electrical currents. Intra-body wireless communication exploits these properties of body tissue and fluid as a transmission channel. In some instances, the intra-body wireless communication scheme may exploit the transmission channel of electrolytic-galvanic coupling with the device electrodes and the ion medium (or other properties) of extra and intracellular fluids of patient 12. External device 16 and IMD 14 may communicate using intra-body communication over frequencies ranging from a few kilohertz to a few megahertz. Higher frequency communication signals may be used to increase data transmission rates.

IMD 14 and external device 16 each include respective electrodes 18 used for intra-body communication. Electrodes 18a and 18b of IMD 14 form a communication dipole that may be used as both a receive dipole and a transmit dipole of IMD 14. Electrodes 18c and 18d of external device 16 form a communication dipole that may be used as both a receive dipole and a transmit dipole of external device 16, each for use in intra-body communication. A transmit dipole of either IMD 14 or external device 16 injects modulated electrical current between the pair of electrodes forming the transmit dipole, which introduces a modulated current into the body of patient 12. In general, the modulated current is radiated in a generally toroid shape about the axis of the dipole. The axis of the dipole may be defined by an imaginary line extending from electrode 18a to electrode 18b. If $r >> d$, where r is the distance between the observation point and the center of the dipole and d equals the transmit dipole length, then the potential ($\emptyset$) at a point in space can be approximated by the equation:

$$\emptyset = \frac{I_{tx} d}{4\pi\sigma r^2}\cos\theta \quad ,$$

where I_o is the dipole current, σ is the conductivity of the surrounding medium, and θ is the polar angle. The polar angle generally refers to the angle between the line depicting the axis of the dipole and the line drawn from the center of the dipole to one of the receive electrode positions. The value of d corresponds to the distance between the electrodes of the transmitting dipole, which is generally on the order of millimeters to centimeters for IMD 14.

A receive dipole of the other one of IMD 14 or external device 16, also in contact with the body of patient 12, receives the modulated signal as an electric potential difference across the pair of electrodes which are also in contact with the body of patient 12. Electrodes 18a and 18b of IMD 14 and the electrodes 18c and 18d of external device 16 can each be configured to function as either the transmit dipole or the receive dipole. Electrodes 18c and 18d of external device 16 may be arranged on the body of patient 12 such that they are oriented in a manner to provide sufficient coupling to the communication dipole of IMD 14. For example, an optimal or at least acceptable orientation may be determined at time of implantation and provided to patient 12 such that patient 12 can place external electrodes 18c and 18d in appropriate positions to enable intra-body communication with IMD 14.

External device 16 may communicate with IMD 14 via intra-body communication to retrieve information from IMD 14, such as the parameters measured by the one or more sensors of IMD 14 or information related to therapies delivered to patient 12. For example, information relating to monitored physiological parameters of patient 12 can be stored in a memory of IMD 14 and periodically transmitted to external device 16. Information can also be transmitted in the opposite direction (i.e. from the external device 16 to IMD 14), for example, when external device 16 provides programming information to IMD 14.

External device 16 may process the information from IMD 14 to monitor a condition of patient 12. In the case of an implantable device incorporating a pressure sensor, for example, external device 16 may receive pressure measurements from IMD 14 and process pressure measurements to monitor for a cardiac condition, such as heart failure. As another example, external device 16 may process sensed cardiac signals to monitor for a cardiac condition, such as tachycardia or bradycardia.

External device 16 may present the information to patient 12 via a display or other user interface. External device 16 may also relay the information received from IMD 14 to another IMD using intra-body communication or other type of communication, e.g., inductive, magnetic or radio frequency (RF) communication. Likewise, external device 16 may relay the information received from IMD 14 to an external device via another wireless communication scheme, such as RF communication, Bluetooth or the like. External device 16 may also transmit information to IMD 14, such as information identifying a condition of patient 12, information sensed by a sensor of external device 16 or information sensed by a sensor of another IMD implanted within patient 12. The information transmitted to IMD 14 may, in some instances, control delivery of therapy by IMD 14.

External device 16 may be a body worn device, such as a watch, necklace, armband, belt, ring, bracelet, patch, or other device that is configured to be attached to, worn by, placed on or otherwise coupled to a body of patient 12 in order to contact electrodes 18c and 18d to the skin of patient 12. Alternatively, external device 16 may be a handheld computing device, such as a cellular telephone, smart phone, pager, or personal digital assistant (PDA), that includes electrodes 18c and 18d configured to be placed in contact with the skin of patient 12.

Although FIG. 1A is described in the context of a medical system 10 having an IMD 14 communicating with an external device 16, IMD 14 may also communicate with another implantable medical device using intra-body communication in a similar manner to that described above.

FIG. 1B is another conceptual diagram illustrating an example medical system 10' that includes another IMD 2 and another external device 4 in addition to IMD 14 and external device 16. IMD 14 is illustrated in FIG. 1B as being implanted within a pulmonary artery of the heart of patient 12. Placement elsewhere throughout the vasculature of patient 12 is also contemplated by this disclosure. IMD 2 may, for example, be an implantable pacemaker, implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy defibrillator (CRT-D), neurostimulator or a combination thereof.

IMD 2 may be connected to one or more leads, such as leads 6a and 6b (collectively "leads 6") implanted within a heart of patient 12 to provide electrical

stimulation therapy to the heart. Lead 6a extends from IMD 2 into a right atrium of patient 12 and lead 6b extends from the IMD into the right ventricle of patient 12. Leads 6 each include one or more electrodes. In the example illustrated in FIG. 1B, leads 6 each include a respective tip electrode 7a,b (collectively "tip electrodes 7"), ring electrode 8a,b (collectively "ring electrodes 8"), and defibrillation electrode 9a,b (collectively "defibrillation electrodes 9") located toward a distal end of their respective leads 6. When implanted, tip electrodes 7, ring electrodes 8 and defibrillation electrodes 9 are placed relative to or in a selected tissue, muscle, nerve or other location within patient 12. Leads 6 may include more or fewer electrodes than shown in FIG. 1B. As one example, one or both of leads 6 may include a plurality of defibrillation electrodes, such as a right ventricular (RV) defibrillation electrode and a superior vena cava (SVC) defibrillation electrode. In another example, one or both of the leads may include multiple ring electrodes as is commonly used in multipolar left ventricular leads. The configuration of electrodes, e.g., location, size, shape or the like, may vary based on the target implant location, type of disorder being treated, or the like.

Leads 6 are connected at a proximal end to IMD 2. IMD 2 illustrated in FIG. 1B includes a housing 11 within which electrical components and a power source of IMD 2 are housed. Housing 11 can be formed from conductive materials, non-conductive materials or a combination thereof. IMD 2 and/or housing 11 may include a connector block 13 configured to couple to leads 6. Connector block 13 may include one or more receptacles that interconnect with one or more connector terminals located on the proximal end of leads 6. Leads 6 are ultimately electrically connected to one or more of the electrical components within housing 11. One or more conductors (not shown in FIG. 1B) extend within each of leads 6 from connector block 13 along the length of the lead to engage the respective tip electrode 7, ring electrode 8 and defibrillation electrode 9 of leads 6. In this manner, each of tip electrodes 7, ring electrodes 8 and defibrillation electrodes 9 is electrically coupled to a respective conductor within its associated lead bodies. The respective conductors may electrically couple to electrical circuitry, such as a therapy module or a sensing module, of IMD 2 via connections in connector block 13.

In other examples, IMD 2 may be connected to more or fewer leads extending from IMD 2. For example, IMD 2 may be coupled to three leads, e.g., a third lead implanted within a left ventricle of the heart of patient 12. In another example, IMD 2

may be coupled to a single lead that is implanted within either an atrium or ventricle of the heart of patient 12. As such, IMD 2 may be used for single chamber or multi-chamber cardiac rhythm management therapy. In further examples, implantable medical system 10 may include leads that are not implanted within the heart, but instead are implanted subcutaneously. In still further examples, the IMD 2 may include no leads, but instead be implanted within a chamber of the heart to provide leadless pacing.

As indicated above, housing 11 encloses a power source and electrical components of IMD 2, such as one or more processors, memories, transmitters, receivers, transceivers, sensors, sensing circuitry, charging circuitry, therapy circuitry, antennas, and/or other components. In the case of an implantable cardiac system, IMD 2 may receive electrical signals corresponding to electrical activity of the heart sensed using different electrode configurations and may process the electrical signals to identify an arrhythmia of the heart. In response to detecting an arrhythmia, IMD 2 selects a programmed therapy to treat the arrhythmia, e.g., pacing and/or defibrillation, and delivers the therapy to the heart via the electrical conductors and one or more of electrodes 7, 8 or 9. In the case of defibrillation therapy, for example, IMD 2 may deliver defibrillation shocks via defibrillation electrodes 9.

IMD 2 may communicate with one or more other devices, including IMD 10, external device 6, and/or external device 4 to exchange data with the other devices. External device 4 may communicate with IMD 2 to configure IMD 2 to operate within a particular operating mode. For example, communications received from external device 4 may include one or more operating parameters for operation of IMD 2. IMD 2 may also transmit sensed physiological data, diagnostic determinations made based on the sensed physiological data, IMD performance data and/or IMD integrity data to external device 4. IMD 2 and external device 4 may communicate via wireless communication using any techniques known in the art, including inductive telemetry or RF telemetry. However, other communication techniques are also contemplated.

IMD 14 and IMD 2 may communicate using intra-body communication. IMD 14 may utilize a pair of electrodes in accordance with any of the examples set forth herein as a communication dipole to transmit and, in some instances, receive intra-body communications. IMD 2 may utilize also utilize a pair of electrodes as a communication dipole for receiving and, in some instances, transmitting intra-body communications. The

pair of electrodes utilized by IMD 2 to transmit and receive communications may be the same electrodes used to provide electrical stimulation therapy, e.g., a pair of electrodes selected from electrodes 7, 8, 9, and/or a housing electrode. In this case, electrodes 7, 8, 9 and the housing electrode may be electrically connected to an intra-body communication module, e.g., by way of one or more switching modules. In other examples, IMD 2 may have separate electrodes dedicated for use as a communication dipole for intra-body communication.

In one example, IMD 14 may transmit parameters measured by the one or more sensors of IMD 14 to IMD 2. For example, information relating to monitored physiological parameters of patient 12, such as the measured pressure within the pulmonary artery, can be periodically transmitted from IMD 14 to IMD 2. IMD 2 may analyze the monitored physiological parameters measured by IMD 14 to identify any existing heart conditions, such as heart failure, and, if desirable, provide therapy and/or notify patient 12 or physician of the condition. IMD 2 may analyze the monitored physiological parameters from IMD 14 independently or in conjunction with the electrical signals measured via electrodes 7, 8, 9 of leads 6. IMD 2 may also relay the information received from IMD 14 to an external device, such as either of external device 6 and external device 4. IMD 2 may relay the information via another communication scheme, such as inductive telemetry, RF telemetry, Bluetooth or other scheme. Alternatively, IMD 2 may relay the information to external device 16 using intra-body communication.

As described above with respect to FIG. 1A, the radiation pattern of the intra-body communication emitted from IMD 10 is a generally toroid shape about the axis of the dipole, e.g., which may be defined by an imaginary line extending between the effective location of electrodes of IMD 14. As such, the directionality of the radiation pattern is highly dependent on the orientation of the communication dipole. Unlike electrodes 18c and 18d of external device 16, the location of electrodes 7, 8, and 9 of leads 6 may not be arranged in a particular orientation to provide optimal intra-body communication. Instead, the location of electrodes 7, 8 and 9 are selected to provide optimal or at least adequate electrical stimulation therapy to the heart. As such, the communication dipole of IMD 14 may be designed in accordance with some aspects of this disclosure to allow for at least some control of directionality of the radiation pattern relative to electrodes of leads 6 of IMD 2.

As will be described in further detail herein, the location of the portion of fixation mechanism used as part of the dipole may be selected such that the orientation of the axis of the communication dipole is offset from the central axis of the vasculature when the IMD is positioned within the vasculature. The term "offset" as used herein refers to the notion of the axis of the communication dipole is not substantially parallel with the central axis of the vasculature when the IMD is positioned within the vasculature. Instead, the axis of the communication dipole and the central axis of the vasculature when the IMD is positioned within the vasculature are offset at an angle relative to one another at their point of intersection. Offsetting the axis of the communication dipole relative to the central axis of the vasculature when the IMD is positioned within the vasculature provides the capability to have more control of the orientation of the communication dipole. For example, IMD 14 may be rotated during implantation to control the orientation of the communication dipole and thus the directionality of the radiation pattern emitted by the communication dipole of IMD 14. In instances in which housing of IMD 14 has a longitudinal axis that is substantially parallel to the vasculature when the IMD is positioned within the vasculature, the location of the portion of fixation mechanism used as part of the dipole may be selected such that the axis of the communication dipole is offset from a longitudinal axis of the housing of IMD 14. In this manner, IMD 14 may be oriented during implantation such that the directionality of intra-body communication signals transmitted by the communication dipole of IMD 14 are most likely to provide adequate coupling to the communication dipole of IMD 2 formed by electrodes of leads 6 or dedicated communication electrodes.

Although IMD 2 is described in the context of cardiac implantable devices, the techniques of this disclosure are not so limited. For example, IMD 2 may alternatively be a non-cardiac implantable device, such as an implantable neurostimulator, drug pump, or other device that provides electrical stimulation therapy, drug therapy or any other therapy to patient 12.

FIGs. 2 and 3A–3D are schematic diagrams illustrating an example IMD 20. IMD 20 may correspond with IMD 14 of FIGs. 1A or 1B. FIG. 2 illustrates IMD 20 implanted in a heart 21 of a patient 12. In the example illustrated in FIG. 2, IMD 20 is implanted in the pulmonary artery of heart 21. However, IMD 20 may be placed within or near other portions of heart 21, such as in one of the chambers (atrial or ventricular), veins, vessels,

arteries or other vasculature of heart 21, such as the aorta, renal arteries, or inferior or superior vena cava. FIGs. 3A–3D illustrate enlarged views of IMD 20 from various viewpoints. In particular, FIG. 3A illustrates an angled view from an aerial perspective, FIG. 3B illustrates a side view and FIGs. 3C and 3D illustrate end views.

IMD 20 includes a housing 22 and a fixation mechanism 24. Housing 22 and fixation mechanism 24 of IMD 20 may be sized and shaped to fit within a target location. In the example illustrated in FIGs. 2 and 3A–3D, housing 22 has a long, thin cylindrical shape (e.g., capsule-like shape) with rounded ends and a cylindrical sidewall extending between the ends to accommodate placement in the pulmonary artery of heart 21. This shape, for example, is considered to present low resistance to blood flow. Other housing configurations may be employed, however, to accommodate placement within or near other portions of heart 21 or other locations within the body of patient 12, the size and shape of IMD 20 may vary based on the desired implant location. Additionally, the size and shape of housing 22 may vary depending on the number and type of sensors incorporated within housing 22. For example, housing 22 may be formed in a different shape to accommodate placement within a chamber of heart 21, along a spine, in a brain, or other location within or on patient 12. As such, the techniques described in this disclosure should not be limited by the shape of housing 22 described herein.

Housing 22 hermetically encloses components of IMD 20. Housing 22 may be formed in two sections 25 and 27 that can be hermetically sealed to protect the components of IMD 20. Section 25 may contain a battery for powering the electronics and section 27 may contain the electronics, e.g., at least one processor, memory, power source, communication circuitry, sensing circuitry, therapy circuitry or the like. For ease of illustration, however, FIG. 3B illustrates only a communication module 42 within section 27 of housing 22. However, other components of IMD 20, such as those described with respect to FIG. 9, may also be enclosed within section 27 of housing 22.

Housing 22 (or each of the sections 25 and 27) may be formed of any of a variety of biocompatible materials including biocompatible conductive materials and biocompatible non-conductive materials. Examples of biocompatible, conductive materials include titanium (e.g., unalloyed titanium with an American Society for Testing and Materials (ASTM) grade 1 to grade 4 or an alloyed titanium (grade 5) that includes aluminum and vanadium), stainless steel, superalloy (such as a nonmagnetic, nickel-

cobalt-chromium-molybdenum alloy), platinum or the like. Examples of biocompatible, non-conductive materials include silicone, poly(p-xylylene) polymer sold under the trademark PARYLENE, polyurethane, epoxy, acetyl co-polymer plastics, PolyEtherEtherKetone (PEEK), liquid crystal polymer (LCP) plastics, ceramic, or the like. Housing 22 as well as some portions of fixation member 24 may be encapsulated in a biologically inert material such as a film of silicone or poly(p-xylylene) polymer sold under the trademark PARYLENE.

Housing 22 also includes a sensor for sensing one or more parameters of patient 12. In the example illustrated in FIGs. 2 and 3A–3D, housing 22 includes a pressure sensor 26 that obtains pressure measurements of an environment surrounding housing 22. Thus, IMD 20 may be an active leadless pressure sensor system designed to continuously monitor blood pressure and transmit the pressure measurements to external device 16 or another implanted device. However, IMD 20 may sense pressure measurements of other locations of heart 21 depending on the location of implantation.

In the example illustrated in FIGs. 2 and 3A–3B, housing 22 is formed to have an opening that exposes pressure sensor 26 to the environment at the target location. The opening of housing 22 is illustrated in FIGs. 2 and 3A–3B as being located along a length of housing 22. However, in other embodiments, the opening of housing 22 may be located on either end of housing 22. In any case, pressure sensor 26 is exposed to the surrounding environment to obtain pressure measurements of the surrounding environment.

Pressure sensor 26 may include a deformable diaphragm that moves in response to changes in the pressure of the environment to which it is exposed. Accordingly, there is a direct relationship between the movement of the diaphragm and the change in pressure. The diaphragm of pressure sensor 26 may be positioned adjacent to the opening of housing 22 so that pressure from the surrounding environment will act upon the diaphragm through the opening of housing 22. It is understood that in accordance with one or more embodiments, the diaphragm may be a component of a capacitor structure used in generating capacitive measurements indicative of the pressure of the surrounding environment. In other words, pressure exerted on the diaphragm causes a corresponding movement of the diaphragm which in turn alters a measured capacitance. As such, the measured capacitance corresponds to the pressure from the surrounding environment acting on the diaphragm. By way of example only and without limitation, pressure sensor

26 may comprise a pressure sensor constructed in a manner similar to that described in commonly assigned U.S. Patent No. 6,221,024, entitled "Implantable Pressure Sensor and Method of Fabrication," U.S. Patent Application No. 12/512,869 filed July 30, 2009 and entitled "Implantable Pressure Sensor with Membrane Bridge," and U.S. Patent No. 7,591,185, entitled "Pressure Sensor Configurations for Implantable Medical Electrical Leads" the contents of each of which are hereby incorporated by reference for their description of pressure sensors.

Although described above as a capacitive pressure sensor, pressure sensor 26 may be any sort of pressure sensing device, such as an electromagnetic pressure sensor that measures displacement of the diaphragm by means of changes in inductance (reluctance), linear variable differential transformer (LVDT), Hall Effect or eddy currents, a piezoelectric pressure sensor, optical pressure sensor, or any other pressure sensor. Housing 22 may include other types of sensors instead of or in addition to pressure sensor 26, such as pH sensor, oxygen sensor, temperature sensor, electrode, or any other type of sensor.

Fixation mechanism 24 affixes IMD 20 to the target location, such as the wall of the pulmonary artery in the example illustrated in FIG. 2. Fixation mechanism 24 of FIGs. 2 and 3A–3D is a generally tubular or cylindrical stent-like structure that is configured to lodge against a vessel wall when implanted. Fixation mechanism 24 is configured such that housing 22 of IMD 20 is substantially adjacent to the wall of the vasculature when implanted. In other embodiments, fixation mechanism 24 is configured such that housing 22 of IMD 20 is not in contact with the wall of the vasculature when implanted. Instead, housing 22 of IMD 20 may be substantially radially centered within vasculature when implanted or otherwise offset from the wall of the vasculature.

Fixation mechanism 24 includes a plurality of struts 38a-h that are arranged to form fixation mechanism 24. In particular, struts 38a-h are arranged to form the stent-like structure having a lumen 40. The number of struts and arrangement of struts may vary depending upon the desired length and structural rigidity of fixation mechanism 24. For example when the target implant site is relatively short, it would be desirable for fixation mechanism 24 to have a smaller number of struts arranged to form a short fixation mechanism. The material from which struts 38a-38h are made may be capable of being manipulated such that fixation mechanism 24 may be radially compressed or otherwise

manipulated to aid in delivery of IMD 20 to the target location. When located at the target location, fixation mechanism may be expanded in situ, e.g., via inflation of a balloon (not shown), such that at least a portion of struts 38 securely engage the vessel wall. Struts 38a-h may, for example, be made from a variety conductive materials suitable for implantation, including, but not limited to, nickel-titanium (nitinol), stainless steel, tantalum, nickel, titanium, nickel-cobalt-chromium-molybdenum "superalloy," combinations of the above, and the like.

In some embodiments, at least a portion of housing 22 of IMD 20 is positioned within lumen 40 defined by fixation mechanism 24. The diameter of lumen 40 is greater than the diameter of housing 22 such that the portion of housing 22 may be positioned within lumen 40 while still allowing blood to flow within the pulmonary artery. In the example illustrated in FIGs. 3A–3D, housing 22 of IMD 20 is completely located within lumen 40 defined by fixation mechanism 24. In other embodiments, only a portion of housing 22 may be located within lumen 40. For example, a portion of housing 22 forming first electrode 18a may be extend beyond lumen 40. Disposing at least a portion of housing 22 within lumen 40 reduces the overall length of IMD 20, which may be particularly advantageous when IMD 20 is implanted at a target site having a relatively short landing zone within the vessel. In further embodiments, however, none of housing 22 of IMD 20 may be positioned within lumen 40 defined by fixation mechanism 24.

Fixation mechanism 24 is mechanically coupled to housing 22 via strut 38h. In the example illustrated in FIGs. 3A and 3B, strut 38h is coupled to the battery section 25 of housing 22. Strut 38h may be mechanically coupled via crimping, welding or other technique. As described above, battery section 25 of housing 22 and fixation mechanism 24 may be constructed from conductive material. In such instances, the mechanical connection between housing 22 and fixation mechanism 24 also results in an electrical coupling of housing 22 and fixation mechanism 24. Section 25 of housing 22 may also serve as a ground plane for the electrical components of IMD 14. In other instances, fixation mechanism 24 may be electrically coupled to communication module 42 by one or more electrical interconnects within housing 22. In one embodiment, the electrical connection to communication module 42 is made when strut 38h is mechanically coupled to housing 22.

As indicated with respect to FIGs. 1A and 1B, IMD 20 transmits and/or receives wireless signals via intra-body communication using electrodes 18a and 18b. To transmit wireless signals via intra-body communication, IMD 20 applies a modulated current signal between electrodes 18a and 18b, which causes a current to propagate into the conductive parts of the body (e.g., ion medium of extra- and intra-cellular fluids). The current induced in the body by electrodes 18a and 18b results in a potential difference between electrodes 18c and 18d of external device 16 (FIGS. 1A AND 1B) which are in contact with the body of patient 12. To receive wireless signals via intra-body communication, electrodes 18a and 18b of IMD 20 detect a potential difference caused by the introduction of current by external device 16.

As described above, IMD 20 is typically a small size to fit within the vasculature of patient 12. Conventionally, electrodes 18a and 18b used for intra-body communication are placed at opposite ends of housing 22. In this case, the maximum distance between electrodes 18a and 18b is limited to the length of housing 22. It is desirable, however, to increase the distance between electrodes 18a and 18b to increase the strength of the communication signal transmitted via intra-body communication. In accordance with the techniques of this disclosure, IMD 20 is configured to utilize a portion of fixation mechanism 24 as one or both of the electrodes, thereby increasing the distance (L) separating the electrodes (sometimes referred to as the dipole length). In accordance with one aspect of this disclosure, a portion of housing 22 is configured as first electrode 18a and a portion of fixation mechanism 24 is configured as second electrode 18b.

Housing 22 and fixation member 24 may be constructed of a biocompatible conductive material, biocompatible non-conductive material or a combination thereof. In one example, housing 22 and fixation member 24 may be constructed of a biocompatible conductive material that is partially covered by a biocompatible non-conductive material. The portions of housing 22 or fixation member 24 that are intended to serve as poles for intra-body wireless communication (e. g., to transmit or receive RF signals) may remain uncovered. First electrode 18a of the communication dipole may be formed by an end of housing 22. For example, housing 22 may be formed of a conductive material coated with a non-conductive coating that covers all of housing 22 except the end portion of housing 22 forming electrode 18a (and possibly the exposed portion of sensor 26). The end portion of housing 22 may be electrically isolated from the rest of the conductive housing

via a non-conductive spacer 29. Electrode 18a is electrically connected to communication module 42 enclosed within housing 22 via an electrical interconnect, including, but not limited to a wire or conductive trace that extends through the non-conductive spacer 29. In another example, housing 22 may be constructed of a biocompatible, non-conductive material, such as borosilicate or other glass varieties, silicone or doped silicone, sapphire or ceramic (e.g., low temperature ceramic cofire (CLCC) materials) or a combination or conductive and non-conductive materials with an electrode 18a formed from a conductive material.

In the example illustrated in FIGs. 2 and 3A–3C, a portion of fixation mechanism 24 functions as second electrode 18b of the communication dipole. As described above, struts 38a–h of fixation mechanism 24 may be formed from an electrically conductive material 30 at least partially coated with a non-conductive dielectric material 28. In accordance with the techniques of this disclosure, dielectric material 28 may be selectively applied such that only a portion of conductive material 30 of fixation mechanism 24 is exposed to the surrounding environment. The rest of the conductive material 30 of fixation mechanism 24 is covered by the dielectric material 28. Dielectric material 28 may include silicone, parylene, polyurethane, epoxy, acetyl co-polymer plastics, PolyEtherEtherKetone (PEEK), liquid crystal polymer (LCP) plastics, or the like, or a combination of dielectric materials. The thickness of dielectric material 28 may depend on a number of factors, including the properties of the dielectric material and the current amperage used for communication. In one example, the coating of dielectric material of parylene may have a thickness of between approximately 2–20 microns. Again, however, the thickness of dielectric material 28 may vary and this is just one example.

The exposed portion of fixation mechanism 24 (i.e., the electrically conductive material 30 of fixation mechanism 24 not coated by dielectric material 28) therefore functions as the second electrode 18b for intra-body communication. Conductive material 30 of fixation mechanism 24 and, more particularly strut 38h of fixation mechanism 24, is mechanically and electrically coupled to housing 22, which serves as a ground plane. As such, the exposed portion conductive material 30 of fixation mechanism 24 is also at ground potential resulting in electrode 18b serving as a return path for the current injected into the body of patient 12 by the communication module 42 via electrode 18a.

In this manner, the only portion of the conductive fixation mechanism 24 that is exposed directly to the bodily fluid or tissue of patient 12 is the portion of fixation mechanism 24 that functions as the second electrode 18b. In the example illustrated in FIGs. 3A and 3B, a portion of electrically conductive material 30 of strut 38g is exposed to the surrounding environment while the remainder of the conductive material 30 strut 38g and the other struts 38 are covered by dielectric material 28. The portion of the conductive material 30 of strut 38 that is exposed (i.e., not covered by dielectric material 28) is represented by shading. A portion of conductive material 30 of strut 38h may also not be covered by dielectric material 28 such that a good mechanical and electrical connection may be made by way of the crimping or welding with housing 22. However, that portion of conductive material 30 of strut 38h is located within housing 22 and therefore will not function as a return path for the intra-body current injected by electrode 18a.

By using a portion of fixation mechanism 24 as second electrode 18b, the portion of fixation mechanism 24 forming second electrode 18b is a further distance from the first electrode than any other portion of housing 22, thus increasing the distance between electrodes 18a and 18b and the effective dipole length. In some instances, the portion of fixation mechanism 24 forming second electrode 18b is located at a position along fixation mechanism 24 that is the furthest distance from the portion of housing 22 forming first electrode 18a, thus maximizing the distance between electrodes 18a and 18b and the effective dipole length.

Additionally, the location of the portion of fixation mechanism 24 forming second electrode 18b may be selected to provide at least some control of the orientation of the communication dipole. In this manner, IMD 14 may be implanted with a more desirable orientation relative to a communication dipole of another device, e.g., electrodes of one of leads 6, which increases the robustness of communication between the devices. In instances in which electrodes 18a and 18b used for intra-body communication are placed at opposite ends of housing 22 there is very little control over the orientation of the transit dipole of IMD 20. This is because the axis of the communication dipole of the housing electrodes is substantially parallel with a central axis of the vasculature when the IMD is positioned within the vasculature. In the example illustrated in FIGs. 3A-3D, the longitudinal axis defined by housing 22 from one rounded end of housing 22 to the other

rounded end of housing 22 is substantially parallel with the central axis of the vasculature of the pulmonary artery when the IMD is positioned within the vasculature. Thus, even if IMD 20 was rotated within the vasculature of the heart during implantation, the orientation of electrodes 18a and 18b relative to another point within or on the body (e.g., at which the communication dipole of the other device is located) remains substantially unchanged. However, selecting the portion of fixation mechanism 24 forming second electrode 18b such that it is offset from the central axis of the vasculature when the IMD is positioned within the vasculature provides the capability to have more control of the orientation of the dipole (e.g., by rotating IMD 20 within the vasculature during implantation) relative to the other location within or on the body of the other communication dipole.

In the example described with reference to FIG. 3C and 3D, the longitudinal axis of housing 22 is substantially parallel with the central axis of the vasculature when the IMD is positioned within the vasculature. The portion of fixation mechanism 24 forming second electrode 18b is selected such that an axis of the dipole (labeled 42 in FIG. 3C and 42' in FIG. 3D) is offset relative to the longitudinal axis of the housing 22 of IMD 20. As such, when IMD 20 is rotated within the vasculature of the patient, the orientation of the dipole and the directionality of the radiation pattern of the dipole may be adjusted. FIG. 3C may be viewed as a first position of IMD 20 in which the radiation pattern of the dipole is a generally toroid shape about axis 42. FIG. 3D is a second position of IMD 20 within the vasculature, e.g., rotated between approximately 45 degrees and 90 degrees within the same location of the vasculature as the first position. Rotating IMD 20 to the second position within the vasculature rotates the axis of the dipole and thus the orientation of the dipole relative to a position in the body. As such, a physician may adjust the orientation of IMD 20 to provide better communication with a receive dipole of another device, e.g., by selecting an orientation that provides a desired directionality that has sufficient signal strength for transmitting to electrodes of one of leads 6 of IMD 2. In one example, the portion of fixation mechanism 24 configured to function as electrode 18b is selected such that there is a maximum offset relative to the central axis of the vasculature when the IMD is positioned within the vasculature.

In some instances, selecting a location of the portion of fixation mechanism 24 forming second electrode 18b that provides at least some control of the orientation of the transmitting dipole may result in a reduction of the dipole length. As such, selection of the

appropriate position along fixation mechanism 24 to use as part of electrode 18b may be a tradeoff between dipole length and orientation controllability. In some instances, the position along fixation mechanism 24 to use as part of electrode 18b may be selected to maximize both the offset and dipole length.

In addition to the distance between electrodes 18a and 18b and the axis of the dipole, the amount of conductive material 30 of fixation mechanism 24 that is exposed (i.e., not covered by the dielectric material 28) also affects the effective dipole length. Additionally, the amount of conductive material 30 of fixation mechanism 24 that is exposed further affects the impedance of the dipole. In some instances, the amount of conductive material 30 of fixation mechanism 24 that is exposed may be increased beyond and optimal impedance to account for some overgrowth effects, which would drive back the impedance to a desired range without having a significant effect on effective dipole length. Such effects will be described in further detail with respect to FIGs. 6A–6C.

FIG. 3E illustrates an angled view of an IMD 20' from an aerial perspective. IMD 20' conforms substantially to IMD 20 of FIGs. 3A-3D except that the portion of fixation mechanism 24 that functions as second electrode 18b is not exposed to the surrounding environment of the body. Instead, the portion of fixation mechanism 24 that functions as second electrode 18b of the communication dipole is also covered by a coating 31. Coating 31 may, for example, be deposited on the portion of fixation mechanism 24 that functions as second electrode 18b using any of a number of techniques known in the art, including plating, chemical or physical deposition.

Coating 31 may be designed to provide a capacitance associated with the portion of fixation mechanism 24 that functions as second electrode 18b that is significantly larger than a capacitance associated with the rest of fixation mechanism 24. In this manner, the capacitance associated with the portion of fixation mechanism 24 that functions as second electrode 18b dominates so that the effective impedance at the communication signal frequency does not limit the transmit signal amplitude. The desired minimum capacitance depends on the communication frequency, transmit amplitude, and output range of the transmitter. For example, with a 3 volt transmitter output range and a 1mA transmit amplitude using communications in the approximately 100 kilohertz frequency, a minimum capacitance of around 1 nanofarad would be desirable.

In one aspect of this disclosure, coating 31 may be a dielectric coating. For example, coating 31 may be the same material that covers the other portions of fixation mechanism 24. In other words, coating 31 may be the same dielectric material as dielectric material 28. In this case, the two materials have the same dielectric constant requiring a thickness of coating 31 will be substantially thinner than a thickness of dielectric material 28 to provide an increased capacitance. The thickness of coating 31 will depend partially on the ratio of the amount of fixation mechanism coated with the thicker dielectric material 28 to the amount of fixation mechanism coated with the thinner coating 31. If this ratio is about 10:1, for example, and it is desirable to have the capacitance of the portion of fixation mechanism 24 covered with coating 31 to dominate by about an order of magnitude, a thickness ratio of about 100:1 may be desirable. In other words, dielectric material 28 may be about 100 times thicker than coating 31. As such, the ratio of the amount of fixation mechanism covered by dielectric material 28 to the amount of fixation mechanism covered by coating 31 as well as the thickness of coating 31 or dielectric material 28 may be adjusted to achieve the desirable capacitance values.

In other instances, coating 31 may be a dielectric material having a different dielectric constant than dielectric material 28. In this case, the thicknesses of the coating 31 and dielectric material 28 may also be dependent on the dielectric constant of the materials used for coatings. For example, a dielectric material having a higher dielectric constant may be selected for use as coating 31 to increase the capacitance of the portion of fixation mechanism 24 that functions as second electrode 18b. Using a dielectric having an increased dielectric constant may allow for an increased thickness of the coating 31 covering the portion of fixation mechanism 24 that functions as second electrode 18b while still providing the ability to achieve the desirable capacitance ratios.

In one example, for an electrode 18b having a 0.5 inch length of a 15 mil fixation wire, a coating 31 having a thickness of 0.05 micrometers and dielectric constant of 3.4 may provide a capacitance of approximately 9.15 nanofarads at a frequency of approximately 100 kilohertz and an impedance magnitude of approximately 175 Ohms.

In other aspects, coating 31 may a fractal coating or other method that substantially increase surface area for a small section of the wire can make capacitance substantially larger than the capacitance associated with the rest of fixation mechanism 24. Coating 31

may, for example, be a coating made up of one or more of a titanium nitride (TiNi), a platinum oxide (e.g., PtO or Pt-black), iridium oxide (IrO), carbon nanotube, or other material. Fractal coatings that have been used on pacing and defibrillation electrodes may also be good candidates for use as coating 31 of fixation mechanism 24.

Although coating 31 is illustrated in FIG. 3E as coating only the portion of fixation mechanism 24 that is configured to function as electrode 18b, a similar coating (dielectric or fractal) may be applied over electrode 18a formed by the end of housing 22. Additionally, the portion of fixation mechanism 24 configured to function as part of electrode 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 3F illustrates an angled view of an IMD 20" from an aerial perspective. IMD 20" conforms substantially with IMD 20 of FIGs. 3A-3D except that a second portion of housing 22 functions in conjunction with the exposed portion of fixation mechanism 24 as second electrode 18b. In the example illustrated in FIG. 3F, the second end of housing 22, opposite the end that functions as electrode 18a, functions as part of second electrode 18b.

In this case, the coating of non-conductive material covering housing 22 may be applied or removed such that the other end of housing 22 is exposed. In one example, an overlay (e.g., of silicon or other insulator) may be placed over the sensor with backfilled adhesive. The overlay may be designed to make use of the entire length of the sensor for creating a further separation between the poles. In other words, a major portion of section 27 (which may be conductive) is covered leaving only the distal end to function as part of electrode 18b. In one instance, the overlay may be shaped for the features around the sensor so that excessive backfill is not required. In other examples, the coating covering housing 22 may be applied using other coating techniques including chemical vapor deposition, physical vapor deposition, chemical and electrochemical techniques, dip coating, or any other coating technique known in the field of coating.

This configuration may have several advantages. Forming second electrode 18b using a portion of housing 22 and a portion of fixation mechanism 24 may provide an increased reliability of communication dipole. For example, tissue growth over the exposed portion of fixation mechanism 24 may affect the impedance and transmission

efficiency of the communication dipole. Additionally, oxidation or corrosion over the connection between housing 22 and fixation mechanism 24 may affect the electrical connection with fixation structure 24. As another example, such a configuration may also provide the capability to provide some control over orientation of the communication dipole (e.g., during implant), as described in detail above.

These advantages, however, come with a reduction of the effective dipole length. The effective dipole length of the communication dipole may generally be defined as

$$\frac{D1*A1 + D2*A2}{A1+A2},$$

wherein D1 is the distance from electrode 18a to the second exposed portion of housing 22, A1 is the area of the second exposed portion of housing 22, D2 is the distance from electrode 18a to the exposed portion of fixation mechanism 24, and A2 is the area of the exposed portion of fixation mechanism 24. The sizes of the second exposed portion of housing 22 and the exposed portion of fixation mechanism 24 may be selected to maximize the effective impedance. D1 and D2 may, in some instance, be vector values.

In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 24 that is configured to function as part of electrode 18b, the portion of housing 22 configured to function as electrode 18b, and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 24 configured to function as part of electrode 18a may be selected such that the orientation of the axis of the communication dipole may be offset relative to the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

Although this disclosure is described with respect to IMD 20 being an implantable pressure sensor implanted within a heart of patient 12, IMD 20 be placed in locations within patient 12, such as within or proximate to a spinal cord, brain, stomach, or pelvic floor, and may sense, sample, and process any of a variety of parameters such as heart activity, muscle activity, brain electrical activity, intravascular pressure, blood pressure, blood flow, acceleration, displacement, motion, respiration, or blood/tissue chemistry, such as oxygen saturation, carbon dioxide, pH, protein levels, enzyme levels or other

parameter or combination of parameters. IMD 20 transmits the sensed parameters to another device, such as external device 16 (FIGS. 1A AND 1B) or another IMD 2 (FIG. 1B), which may in turn monitor a condition of patient 12 or provide therapy to patient 12 as a function of the sensed parameters.

Although illustrated as a stent-like fixation mechanism in FIGs. 2 and 3A–3B, fixation mechanism 24 may be a different fixation mechanism that exerts enough force against, embeds within, extends through or otherwise affixes IMD 20 to the target location. Other fixation mechanisms may include one or more tines, loops, or other mechanism that may be used to affix IMD 20 to the target location, some of which are illustrated and described in FIGs. 4, 5, 7 and 8.

FIG. 4A is a schematic diagram illustrating another example IMD 50. IMD 50 is similar to IMD 20 of FIGs. 3A–3D, but includes a different fixation element 54. Fixation element 54 is another stent-like fixation element composed of a number of conductive struts. In the example illustrated in FIG. 4A, housing 22 of IMD 50 is not positioned within the lumen defined by fixation mechanism 54.

Like fixation mechanism 24, a portion of fixation mechanism 54 is configured as second electrode 18b. In particular, fixation mechanism 54 includes a dielectric material that covers a majority of fixation mechanism 54, but is selectively applied or removed such that a portion of fixation mechanism 54 is exposed to the surrounding environment to function as the second electrode 18b for intra-body communication. The rest of fixation mechanism 54 is covered by the dielectric material, except possibly the portion of fixation mechanism that is mechanically and electrically coupled to housing 22. The portion of fixation mechanism 54 that is exposed is represented by the shaded portion of fixation mechanism 54.

In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 54 that is configured to function as electrode 18b and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 54 configured to function as part of electrode 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 4B is a schematic diagram illustrating another example IMD 50'. IMD 50' is similar to IMD 20" of FIG. 3F, but includes a different fixation element 54 similar the fixation element described above with respect to FIG. 4A. IMD 50' includes a second portion of housing 22 that functions in conjunction with the exposed portion of fixation mechanism 54 as second electrode 18b. In the example illustrated in FIG. 4B, the second end of housing 22, opposite the end that functions as electrode 18a, functions as part of second electrode 18b. In this case, the coating of non-conductive material covering housing 22 may be applied or removed such that the other end of housing 22 is exposed.

In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 54 that is configured to function as part of electrode 18b, the portion of housing 22 configured to function as electrode 18b, and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 54 configured to function as part of electrode 18a may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 5A and 5B are schematic diagrams illustrating another example IMD 60. IMD 60 includes a housing 22 that is described above with respect to IMD 20 of FIGs. 3A–3C. However, IMD 60 includes a different fixation mechanism 64. Fixation mechanism 64 includes a pair of longitudinally spaced loops 62a and 62b (collectively "loops 62") connected by an elongate linear attachment strut 65. Loops 62 are spaced apart sufficiently to receive and, in some instances, embrace housing 22 with the housing extending lengthwise between loops 62. First loop 62a extends from a first end of housing 22 and loop 62b extends from a second, opposite end of housing 22. Loops 62a and 62b affix IMD 60 within the vasculature due to force applied to the vessel wall by the respective loops 62a and 62b pushing radially against the vessel. Although illustrated in FIGs. 5A and 5B as including two loops 62a and 62b, fixation mechanism 64 of IMD 60 may include only a single fixation loop (e.g., only loop 62a) or more than two fixation loops.

Fixation member 64, including the attachment strut 65, may be formed from a sheet of conductive material by laser cutting or electrochemical etching or other

fabricating techniques known in the art. The resulting fixation member 64 is formed as a single, integral piece. In other examples, fixation member 64 may be formed of multiple pieces that are mechanically connected (e.g., via welding) to form an integral piece. The wire-like elements that make up the loops 62 and the attachment strut 65 may have a circular cross section or a non-circular cross section (square or rectangular) and may have a substantially uniform thickness.

The conductive material of loops 62 and attachment strut 65 are at least partially covered by a dielectric material. In the example illustrated in FIGs. 5A and 5B all of fixation member 64 is covered by a non-conductive dielectric material except a portion of loop 62b that is exposed (represented by the shaded portion of loop 62b) and functions as second electrode 18b for intra-body communication in conjunction with electrode 18a that is formed at the end of housing 22. The rest of loop 62b and the entire loop 62a are covered by the dielectric material. Attachment strut 65 is also covered by the dielectric material except for a portion of attachment strut 65 that is mechanically connected to housing 22. However, the portion of housing 22 that attaches to attachment strut 65 may be covered by a non-conductive material so that the point of fixation does not function as a return path for the current injected into the body of patient 12 by the communication module 42 via electrode 18a.

In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 64 that is configured to function as part of electrode 18b and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 64 configured to function as part of electrode 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 5C is a schematic diagram illustrating another example IMD 60'. IMD 60' is similar to IMD 60 of FIGs. 5A and 5B except IMD 60' includes a second portion of housing 22 that functions in conjunction with the exposed portion of fixation mechanism 64 as second electrode 18b. In the example illustrated in FIG. 5C, the second end of housing 22 that is opposite the end that functions as electrode 18a is utilized as part of

second electrode 18b. In this case, the coating of non-conductive material covering housing 22 may be applied or removed such that both ends of housing 22 are exposed.

In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 64 that is configured to function as part of electrode 18b, the portion of housing 22 configured to function as electrode 18b, and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 64 configured to function as part of electrode 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 6A is a graph illustrating an example plot of effective dipole length and impedance versus the amount of fixation mechanism 64 that is exposed. The plots in the graph of FIG. 6A are mathematically simulated results for an IMD having a communication dipole similar to that described above with respect to IMD 60' of FIG. 5C. In particular, one end of housing 22 is configured to function as electrode 18a and the combination of a second end of housing 22 and the exposed portion of fixation mechanism is configured to function as second electrode 18b.

The x-axis of the graph in FIG. 6A corresponds with the length (mm) of fixation mechanism that is exposed. The y-axis on the left hand side of the graph of FIG. 6A corresponds to effective dipole length (mm) and the y-axis on the right hand side corresponds with combined electrode impedance in blood (ohms). The effective dipole length is plotted as a solid line and the combined electrode impedance is plotted as a dotted line.

As illustrated in FIG. 6A, the effective dipole length increases somewhat exponentially as the length of the exposed fixation mechanism 64 increases. The increase in effective dipole length continues until the point at which the transition from exposed to insulated fixation is at the same point as the effective dipole length. After this point, exposing additional fixation material beyond this point will decrease the effective dipole length. As further illustrated in FIG. 6A, the impedance decreases somewhat exponentially as the length of the exposed fixation mechanism 64 increases. The decrease in impedance continues beyond the point at which the transition from exposed to insulated

fixation is at the same point as the effective dipole length. The amount of fixation mechanism 64 that is exposed may be selected to obtain a desired balance between effective dipole length and combined electrode impedance.

The relationship between the effective dipole length vs. exposed length is strongly dependent is highly dependent on the shape of the fixation mechanism. Different shapes of fixation mechanisms may have effective dipole length curves that vary considerably in shape. The example illustrated in FIG. 6A is just one example of a simulation of an IMD that is similar to IMD 60'.

FIG. 6B is a graph illustrating an example plot of effective dipole length and impedance versus the amount of fixation mechanism 64 that is exposed. The plots in the graph of FIG. 6B are mathematically simulated results for an IMD having a communication dipole similar to that described above with respect to IMD 60 of FIGs. 5A and 5B. In particular, one end of housing 22 is configured to function as electrode 18a and an exposed portion of fixation mechanism is configured to function as second electrode 18b.

The x-axis of the graph in FIG. 6B corresponds with the length (mm) of fixation mechanism that is exposed. The y-axis on the left hand side of the graph of FIG. 6B corresponds to effective dipole length (mm) and the y-axis on the right hand side corresponds with electrode impedance in blood (ohms). The effective dipole length is plotted as a solid line and the combined electrode impedance is plotted as a dotted line.

As illustrated in FIG. 6B, the effective dipole length decreases in a somewhat linear manner as the length of the exposed fixation mechanism 64 increases. As further illustrated in FIG. 6B, the impedance decreases somewhat exponentially as the length of the exposed fixation mechanism 64 increases. The amount of fixation mechanism 64 that is exposed may be selected to obtain a desired balance between effective dipole length and combined electrode impedance.

The relationship between the effective dipole length vs. exposed length is strongly dependent is highly dependent on the shape of the fixation mechanism. Different shapes of fixation mechanisms may have effective dipole length curves that vary considerably in shape. The example illustrated in FIG. 6B is just one example of a simulation of an IMD that is similar to IMD 60 of FIGs. 5A and 5B.

FIG. 6C is a graph illustrating an example plot of effective dipole length and impedance versus the amount of fixation mechanism that is exposed for an example IMD. The x-axis of the graph in FIG. 6C corresponds with percentage of the linear distance of fixation mechanism that is exposed. The y-axis on the left hand side of the graph of FIG. 6C corresponds to effective dipole length (mm) and the y-axis on the right hand side corresponds with impedance in blood (Ohms in blood).

As illustrated in FIG. 6C, the effective dipole length (represented by the dotted line) increases exponentially as the percentage of the linear distance of fixation mechanism 24 that is exposed increases until approximately 20% (which may correspond with the point at which the transition from exposed to insulated fixation is at the same point as the effective dipole length) and then begins to linearly decrease as the percentage of the linear distance of fixation mechanism 24 that is exposed continues to increase. As further illustrated in FIG. 6C, the impedance (represented by the solid line) decreases exponentially as the percentage of the linear distance of fixation mechanism 24 that is exposed increases. As such, the amount of fixation mechanism 24 that is exposed may be selected to obtain a balance between effective dipole length and impedance. In one example, the percentage of fixation mechanism 24 that is exposed may be between approximately 5–30% and, more preferably between approximately 10–20%. As will be described with respect to FIGs 8a-8c, more than one electrode formed by a portion of fixation mechanism 24 may be turned on to increase the linear distance of fixation mechanism 24 and thereby affect the impedance.

FIG. 7 is a schematic diagram illustrating another example IMD 70. IMD 70 is similar to IMD 60 of FIGs. 5A and 5B, but first electrode 18a is formed by a portion of loop 62a instead of by an end of housing 22. In this case, a portion of loop 62a is not covered by the dielectric material such that the exposed portion of loop 62a (represented as the shaded portion of loop 62a) functions as first electrode 18a for intra-body communication. To enable operation of this configuration, loops 62 are electrically isolated from one another, e.g., either by inserting a non-conductive material along a portion of attachment strut 65 or constructing loops 62 out of separate pieces of conductive material that are not electrically coupled to one another. The rest of loop 62a is covered by the dielectric material. Loop 62a is electrically connected to the communication module of IMD 70, e.g., utilizing one or more electrical interconnects or

feed throughs, to transmit and receive signals in conjunction with electrode 18b formed by loop 62b. Utilizing portions of fixation mechanism 64 as both electrodes 18a and 18b may result in an even larger distance between electrodes 18a and 18b, thereby further extending the effective dipole length. One or both of electrodes 18a or 18b may also utilize an exposed portion of housing 22 as described above with respect to FIG. 3F, FIG. 4B, and FIG. 5C as further illustrated in FIG. 7B.

In further aspects, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 64 that is configured to function as part of electrode 18a or the portion of fixation mechanism 64 that is configured to function as part of electrode 18b. In some instances, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 64 that is configured to function as part of electrode 18b, the portion of housing 22 configured to function as electrode 18b, and/or the portion of housing 22 configured to function as electrode 18a. Additionally, the portion of fixation mechanism 64 configured to function as part of electrode 18a or 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 7B is a schematic diagram illustrating another example IMD 70'. IMD 70' is similar to IMD 70 of FIG. 7A, but first electrode 18a is formed by a portion of loop 62a instead of by an end of housing 22. IMD 70' is similar to IMD 70 of FIG. 7A except IMD 70' includes a first exposed portion of housing 22 that functions in conjunction with the exposed portion of loop 62a as first electrode 18a and a second exposed portion of housing 22 that functions in conjunction with the exposed portion of loop 62b as second electrode 18b. In this case, loop 62a is electrically and possibly mechanically coupled to the first exposed end of housing 22 and loop 62b is electrically and possibly mechanically coupled to the second exposed end of housing 22.

In further aspects, a coating similar to coating 31 described with respect to FIG. 3E may cover the portion of fixation mechanism 64 that is configured to function as part of electrode 18a, the portion of fixation mechanism 64 that is configured to function as part of electrode 18b, the portion of housing 22 configured to function as electrode 18a, and/or the portion of housing 22 configured to function as electrode 18b. Additionally, the

portion of fixation mechanism 64 configured to function as part of electrode 18a or 18b may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIGs. 8A–8C illustrate a further example of an IMD 80. IMD 80 includes a housing 22 substantially similar to the housing described in detail above with respect to FIGs. 3A–3C. IMD 80 also includes a fixation mechanism 84 that is similar to fixation mechanism 24 of IMD 20 illustrated in FIGs. 3A–3C. Housing 22 of IMD 80 is positioned partially within the lumen defined by fixation mechanism 84 instead of being completely located within the lumen as illustrated in FIGs. 3A–3C.

In the example illustrated in FIGs. 8A–8C, the end of housing 22 does not function as an electrode used for intra-body communication. Instead, a plurality of struts 82a–d extend from the end of housing 22. Struts 82a–d are formed of a conductive material that is partially covered by a dielectric material such that only a portion of struts 82a–d are exposed to the surrounding environment to function as electrodes for use in intra-body communication. In the example illustrated in FIGs. 8A–8C, a distal end of each of struts 82a-d is exposed to the surrounding environment to form electrodes 18e-h, respectively. Struts 82a-d may or may not additionally function as part of the fixation mechanism for fixating IMD 80 to the target location.

As shown in the end view illustrated in FIG. 8C, each of struts 82a-d is attached to housing 22 by a separate feed through. In this manner, each of the electrodes 18e-h associated with respective struts 82a-d is electrically isolated from one another. Struts 82a-d are electrically coupled to the communication module of IMD 80 such that any of electrodes 18e-h may be used for intra-body communication in conjunction with electrode 18a formed by an exposed portion of fixation mechanism 24 or one another. Struts 82a-d may be electrically coupled to the communication module (not shown) via a switching device (not shown) that may selectively couple one of the electrodes 18e-h to the communication module of IMD 80. In this manner, IMD 80 has the ability to switch electrode configurations used for intra-body communication, thereby providing transmit dipole and receive dipole diversity.

The signal received by external device 16 at electrodes 18c and 18d (FIGS. 1A AND 1B), which corresponds to the electric potential difference between electrodes 18c and 18d, is a function of the length of the transmitting dipole, the length of the receive dipole, and the angle of orientation between the transmit dipole and receive dipole. The angle of orientation can be altered due to varying locations and orientations of IMD 80 or the different geometries of individual patients. Thus, no one single transmit or receive dipole will be optimal for all implant scenarios, particularly for enabling placement of external device 16 in an ergonomical manner.

Selecting among the plurality of electrodes 18e-h enables IMD 80 to adjust the angle of orientation between the dipole of IMD 80 and the dipole of external device 16. Even a slight adjustment of the angle of orientation, e.g., by switching from a dipole formed by electrodes 18a to 18e to a dipole formed by electrodes 18a and 18g may improve the quality and reliability of communication with external device 16. Moreover, such ability to adjust the angle of orientation between the dipole of IMD 80 and the dipole of external device 16 may allow for use of more ergonomical external devices, e.g., body-worn devices.

IMD 80 may selectively couple one of the electrodes 18e-h to the communication module of IMD 80 to function as the transmit and receive dipole in conjunction with electrode 18a. In one example, external device 16 may assess the signal quality of a received signal and send a command to IMD 80 to reconfigure the switch to couple to a different one of electrodes 18e-h when the signal quality is not sufficient. In another example, IMD 80 may assess the signal quality of a received signal and reconfigure the switch based on the assessment. In this manner, IMD 80 may be selectively configured between different dipole arrangements formed by electrodes positioned at different positions to provide a desirable signal quality for communication with an implantable medical device. The signal quality may be assessed using a variety of methods including but not limited to a transmission power required for signal detection, a received signal strength, a received signal-to-noise ratio, a bit error rate, a data throughput rate, a data dropout rate, a background noise floor, an optimum frequency, a correlation between a detected signal and a known template for a signal, or any combination of these measures.

It may be desirable to have a surface area of the electrodes used for intra-body communication be about the same size or a ratio of the larger electrode. In some

examples, IMD 80 may connect the communication module to more than two electrodes. For example, IMD 80 may connect the communication module to electrode 18a and two of electrodes 18e-h concurrently (for a total of three electrodes) to change the effective electrode surface area and thus the impedance. In other words, by electrically connecting to three electrodes, the total surface area of the exposed fixation mechanism is increased thereby affecting the impedance. In this manner, IMD 80 may selectively adjust the impedance by selecting more or fewer electrodes. This may be particularly advantageous if the surface area of one of the electrodes for communication changes, e.g., due damage to the dielectric material somewhere along the fixation mechanism causing additional surface area to be exposed or tissue overgrowth that covers a portion of the exposed fixation mechanism decreasing the surface area of conductive fixation mechanism exposed.

In the example illustrated in FIG. 8, the length of the exposed portion of struts 82a-d forming electrodes 18e-h, respectively, are approximately the same. However, in other instances, the length of the exposed portion of each of struts 82a-d forming electrodes 18e-h (or a portion thereof) may be of different lengths. IMD 80 may selectively couple one of the electrodes 18e-h (formed by the exposed portion of struts 82a-d, respectively) to the communication module of IMD 80 to achieve a desired impedance or dipole length. In this manner, IMD 80 may selectively change the effective electrode surface area and thus the impedance. IMD 80 may, for example, make such an adjustment automatically upon initiating communication, make the adjustment in response to a signal quality below a certain level, or make the adjustment in response to a command from an another device (external or implanted).

Although illustrated in FIGS. 8A–8C as including four struts 82a–d extending from the end of housing 22, IMD 80 may include more of fewer struts 82. In fact, in one example IMD 80 may include only a single strut 82 that extends from the end of housing 22 (e.g., strut 82d) to increase the length of the dipole. In such a case, however, the IMD 20 does not provide dipole diversity.

In further aspects, a coating similar to coating 31 described with respect to FIG. 3E may cover electrodes 18a-e and/or any portions of housing 22 configured to function as part of one of the electrodes. Additionally, the portion of struts 82a–e configured to function as part of electrodes 18a-e may be selected such that the orientation of the axis of the communication dipole may be offset from the central axis of the vasculature when the

IMD is positioned within the vasculature to provide more control of the orientation of the dipole as described in more detail with respect to FIGs. 3C and 3D.

FIG. 9 is a functional block diagram illustrating components of an implantable medical device in further detail. FIG. 9 will be described with respect to IMD 20 for purposes of illustration. However, the implantable medical device may correspond to any of the other implantable medical devices described herein.

IMD 20 includes a pressure sensor 26, communication module 42, electrodes 18a and 18b, processor 44, memory 46 and power source 48. The components of IMD 20 are shown to be interconnected by a data/communication bus 49, but may be interconnected by other means including direct electrical or non-electrical connections or a combination of different types of connections.

As described above, IMD 20 may sense one or more parameters (e.g., physiological or biological parameters) of patient 12 and/or detect one or more conditions from the sensed parameters. For example, pressure sensor 26 may be configured to obtain signals related to the pressure of the surrounding environment within which IMD 20 is implanted. Although described with respect to IMD 20 including pressure sensor 26, IMD 20 may include any number and type of sensors depending on the type of device, including a pH sensor, oxygen sensor, temperature sensor, electrodes, or any other type of sensor.

The parameters sensed by pressure sensor 26 may be stored in memory 46. In some instances, the sensed parameters may be stored in raw form. In other instances, the sensed parameters may be processed and the processed parameters may be stored in memory 46. For example, IMD 20 may include one or more analog or digital components that amplify and filter the sensed parameters and store the filtered parameters in memory 46. The parameters stored in memory 46 may, in some cases, be retrieved and further processed by processor 44. Processor 44 may, for example, process the sensed parameters to monitor or detect a condition of patient 12.

Processor 44 may control operation of IMD 20 with the aid of instructions associated with program information stored in memory 46. For example, the instructions may define the timing at which to sample signal from pressure sensor 26 or, in instances in which implantable medical device 20 delivery therapy, the timing of therapy delivery, waveform characteristics for electrical stimulation, and/or dosing programs that specify an

amount of a therapeutic agent to be delivered to a target tissue site within patient 12. Processor 44 may also control operation of communication module 42 to transmit communications to and/or receive communications from another medical device, such as external device 16 (FIGS. 1A AND 1B) or another implanted medical device.

Communication module 42 is coupled to at least two electrodes 18a and 18b configured to function as an electric dipole and transmit and receive information encoded in electrical signals to and from external device 16. The electrical signals are typically transmitted and received in a modulated format such as frequency shift keying, amplitude shift keying, phase shift keying, pulse width modulation, pulse amplitude modulation, quadrature amplitude modulation, orthogonal frequency division multiplexing, spread spectrum techniques, or in an analog signal format and/or modulation technique such as analog amplitude modulation or frequency modulation. In some embodiments, the communication module 42 of IMD 14 can be configured to operate for periods of time in a sleep state in order to conserve battery power. In such a configuration, communication module 42 may be configured to wake up periodically to listen to a communication request from external device 16 or to transmit the stored parameters sensed by pressure sensor 26.

Communication module 42 may include any suitable hardware, firmware, software or any combination thereof for communicating with another device for transmitting and receiving intra-body communications. For example, communication module 42 may include a current source, modulator, demodulator, encoder, decoder, amplifier, frequency converter, filter or any other component desired for communicating using intra-body communication techniques.

Power source 48 delivers operating power to various components of IMD 20. Power source 48 may include, for example, a small rechargeable or non-rechargeable battery and a power generation circuit to produce the operating power. In some examples, power requirements may be small enough to allow IMD 20 to utilize patient motion and implement a kinetic energy-scavenging device to trickle charge a rechargeable battery. In other examples, traditional batteries may be used for a limited period of time. As a further alternative, an external inductive power supply may transcutaneously power IMD 20 whenever measurements are needed or desired.

IMD 20 of FIG. 9 is provided for purposes of illustration. IMD 20 may include more or fewer components than those illustrated in FIG. 9. For example, IMD 20 may include more than two electrodes coupled to communication module 42. Such an embodiment is described with respect to FIGs. 8A–8C. In such an embodiment, communication module 42 may be selectively configured to couple to the two electrodes of the plurality of electrodes that provide an adequate orientation with respect to the dipole of external device 16. To this end, communication module 42 may be coupled to the electrodes via a switching device (not shown) that may be configured to couple to the selected electrodes. Processor 44 may, for example, control the configuration of the switching device in response to a command from external device 16. In another example, communication module 42 or processor 44 may be configured to operate as a signal quality monitor and assess the signal quality of an electrical signal received from external device 16. In this case, communication module 42 or processor 44 may control the configuration of the switching device in response to the signal quality assessment to achieve dipole diversity.

As another example, IMD 20 may be an implantable medical device configured to also provide therapy, such as electrical stimulation therapy or drug delivery therapy, in accordance with parameters of one or more selected therapy programs. In this case, implantable sensor may include a therapy module (not shown) to generate therapy according to one or more therapy programs. In the case of electrical stimulation therapy, the therapy module may include a stimulation generator that generates and delivers electrical stimulation therapy, e.g., in the form of pulses or shocks. Processor 44 may control the stimulation generator to deliver electrical stimulation pulses with amplitudes, pulse widths, frequency, and/or electrode polarities specified by the one or more therapy programs. In the case of drug delivery therapy, the therapy module may include a pump that delivers a drug or therapeutic agent, e.g., via a catheter or other delivery mechanism. Processor 44 may control the pump to deliver the drug or therapeutic agent with the dosage and frequency (or rate) specified by the one or more therapy programs. As such, the techniques of this disclosure should not be considered limited to the example described in FIG. 9.

The techniques described in this disclosure may be implemented, at least in part, in hardware, software, firmware or any combination thereof. For example, various aspects of

the techniques or components may be implemented within one or more processors, including one or more microprocessors, digital signal processors (DSPs), application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), programmable logic circuitry, or the like, either alone or in any suitable combination. The term "processor" or "processing circuitry" may generally refer to any of the foregoing circuitry, alone or in combination with other circuitry, or any other equivalent circuitry.

Such hardware, software, or firmware may be implemented within the same device or within separate devices to support the various operations and functions described in this disclosure. In addition, any of the described units, modules or components may be implemented together or separately as discrete but interoperable logic devices. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components.

When implemented in software, the functionality ascribed to the systems, devices and techniques described in this disclosure may be embodied as instructions on a computer-readable medium such as random access memory (RAM), read only memory (ROM), non-volatile RAM (NVRAM), electrically erasable programmable ROM (EEPROM), Flash memory, and the like. The instructions may be executed by a processor to support one or more aspects of the functionality described in this disclosure.

Various examples have been described. These examples, however, should not be considered limiting of the techniques described in this disclosure. These and other examples are within the scope of the following claims.

CLAIMS

1. An implantable medical device comprising:

a housing that encloses at least a communication module;

a first electrode of a communication dipole electrically coupled to the communication module; and

an electrically conductive fixation mechanism that is electrically coupled to a portion of the housing and that includes a dielectric material that covers at least part of a surface of the fixation mechanism,

wherein a portion of the fixation mechanism is configured to function as at least part of a second electrode of the communication dipole, and

wherein the communication module is configured to transmit or receive a modulated signal between the first electrode and second electrode of the communication dipole.

2. The implantable medical device of claim 1, wherein the portion of the electrically conductive fixation mechanism that is configured to function as at least part of the second electrode is not covered by the dielectric material.

3. The implantable medical device of any one of claims 1 and 2, wherein a portion of the housing not electrically coupled to the electrically conductive fixation mechanism is configured to function as the first electrode.

4. The implantable medical device of any one of claims 1–3, wherein the portion of the electrically conductive fixation mechanism that is configured to function as at least part of the second electrode is located at a position on the fixation mechanism that is a further distance from the first electrode than any other portion of the housing.

5. The implantable medical device of any one of claims 1–4, wherein an axis of the communication dipole between the portion of the housing configured to function as the first electrode of the communication dipole and the portion of fixation mechanism

configured to function as at least part of the second electrode of the communication dipole is offset from a central axis of a vasculature when the implantable medical device is positioned within the vasculature.

6. The implantable medical device of any one of claims 1–5, wherein the axis of the communication dipole and the central axis of a vasculature when the implantable medical device is positioned within the vasculature form an angle relative to one another at their point of intersection.

7. The implantable medical device of any one of claims 1–6, wherein the portion of the housing that is electrically coupled to the fixation mechanism is configured to function as part of the second electrode in conjunction with the portion of the electrically conductive fixation mechanism.

8. The implantable medical device of any one of claims 1–7, further comprising a second electrically conductive fixation mechanism that is electrically coupled to the first portion of the housing that is configured to function as the first electrode, wherein a portion of the second electrically conductive fixation mechanism is configured to function as at least part of a second electrode of the communication dipole.

9. The implantable medical device of any one of claims 1–8, wherein the portion of the housing electrically coupled to the electrically conductive fixation mechanism serves as a ground plane for the communication module.

10. The implantable medical device of any one of claims 1–9, wherein a thickness of the dielectric material covering the portion of the electrically conductive fixation mechanism that is configured to function as at least part of the second electrode is thinner than a thickness of the dielectric material covering other portions of the electrically conductive fixation mechanism.

11. The implantable medical device of any one of claims 1–10, wherein the portion of the electrically conductive fixation mechanism that is configured to function as at least

part of the second electrode is covered by a dielectric material that has a higher dielectric constant than a dielectric constant of the dielectric material covering other portions of the electrically conductive fixation mechanism.

12. The implantable medical device of any one of claims 1–11, wherein the portion of the electrically conductive fixation mechanism that is configured to function as at least part of the second electrode includes a fractal coating on a surface of the portion.

13. The implantable medical device of any one of claims 1–12,

further comprising a second electrically conductive mechanism that is mechanically coupled to the housing and electrically coupled to the communication module within the housing,

wherein the second electrically conductive mechanism includes a dielectric material that covers part of a surface of the second electrically conductive mechanism,

wherein a portion of the second electrically conductive mechanism is configured to function as at least part of the first electrode.

14. The implantable medical device of any one of claims 1–13, wherein the fixation mechanism is one of a cylindrical stent-like structure that is configured to lodge against a vessel wall, a loop fixation mechanism that includes at least two fixation loops mechanically coupled to the housing.

15. The implantable medical device of any one of claims 1–14, wherein the fixation mechanism is formed from a single, integral piece.

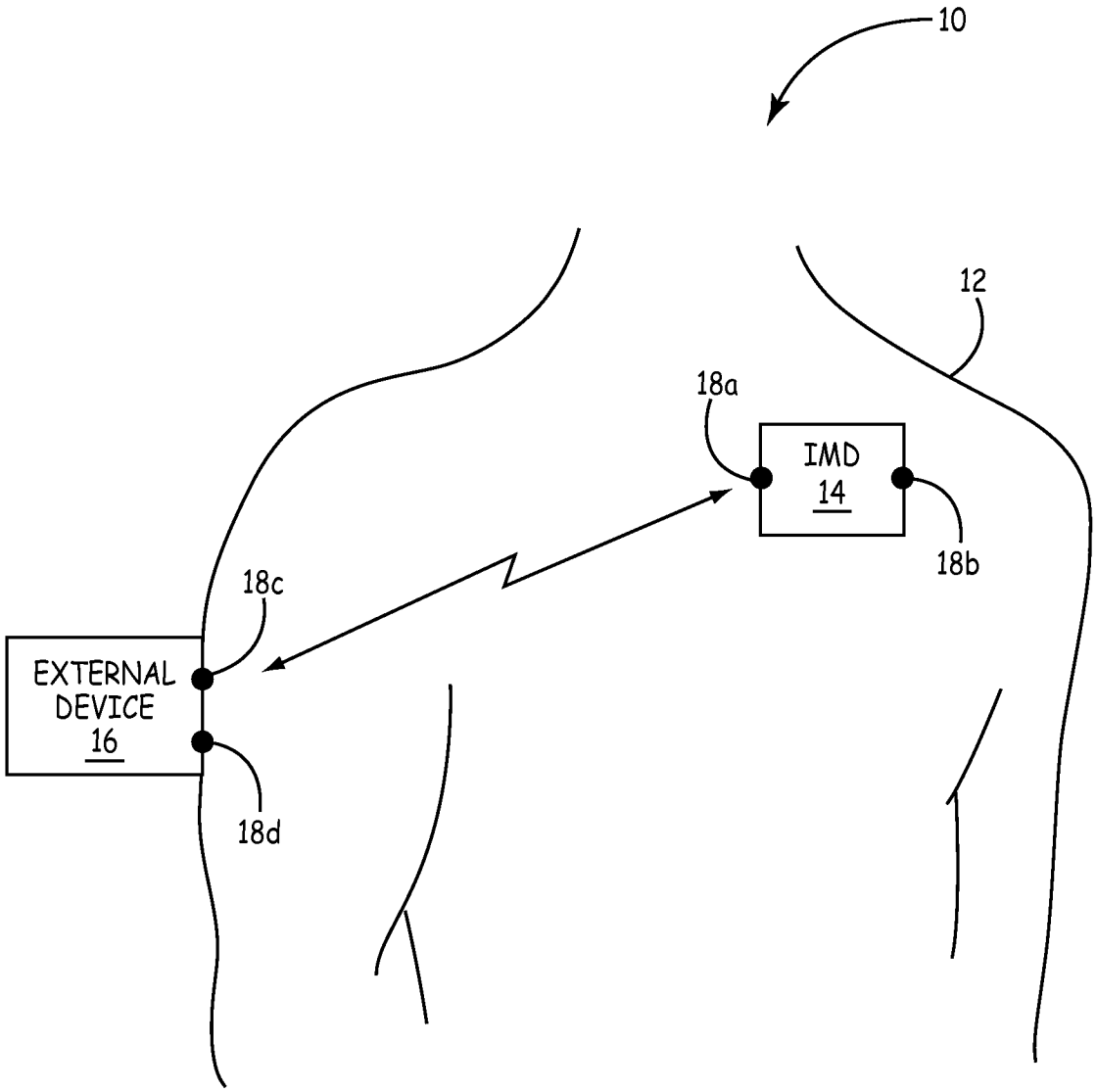


FIG. 1A

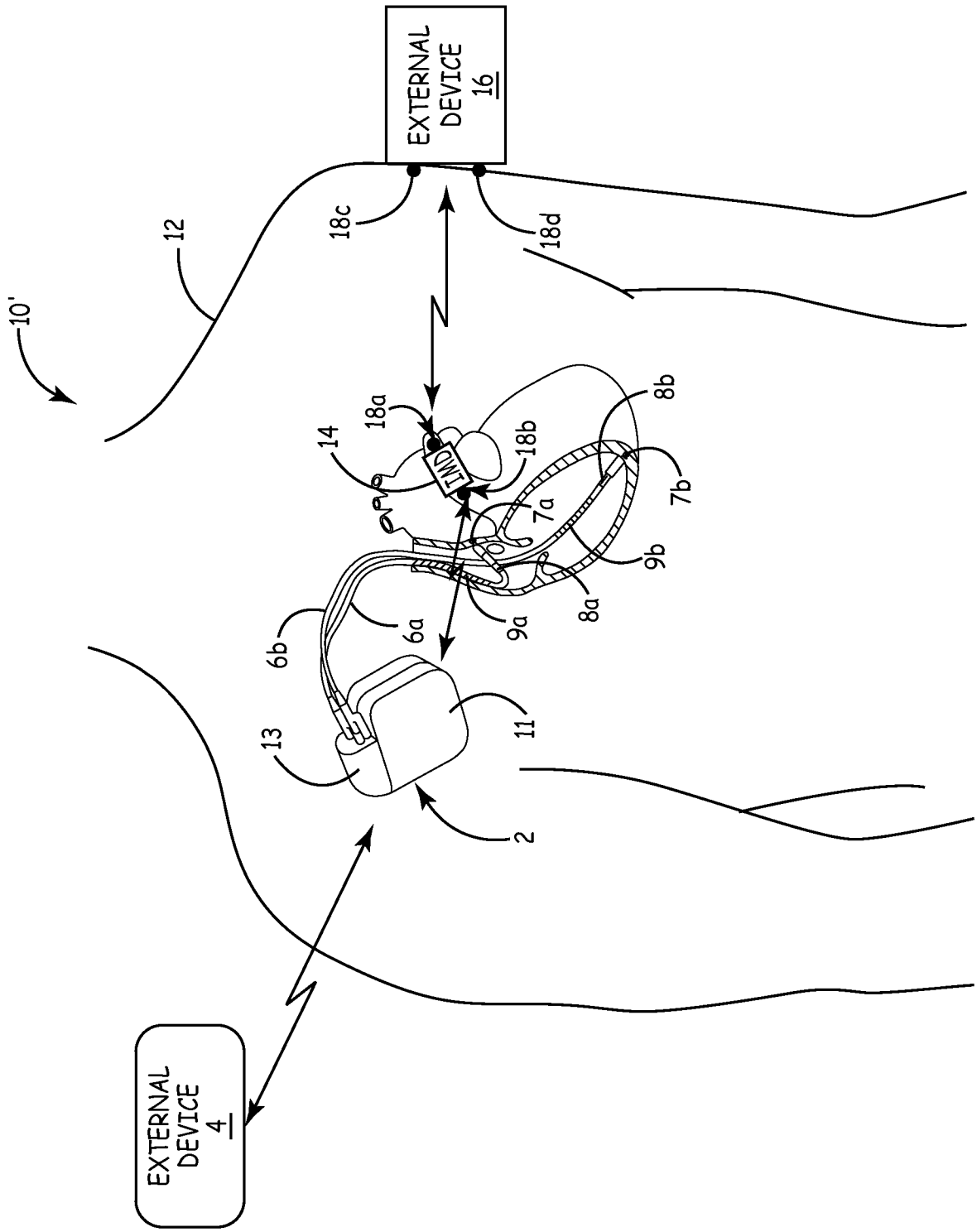

EXTERNAL DEVICE 16
EXTERNAL DEVICE 4
10'
12
18c
18d
18a
18b
14
TMD
7a
7b
8a
8b
9a
9b
6a
6b
11
13
2

FIG. 1B

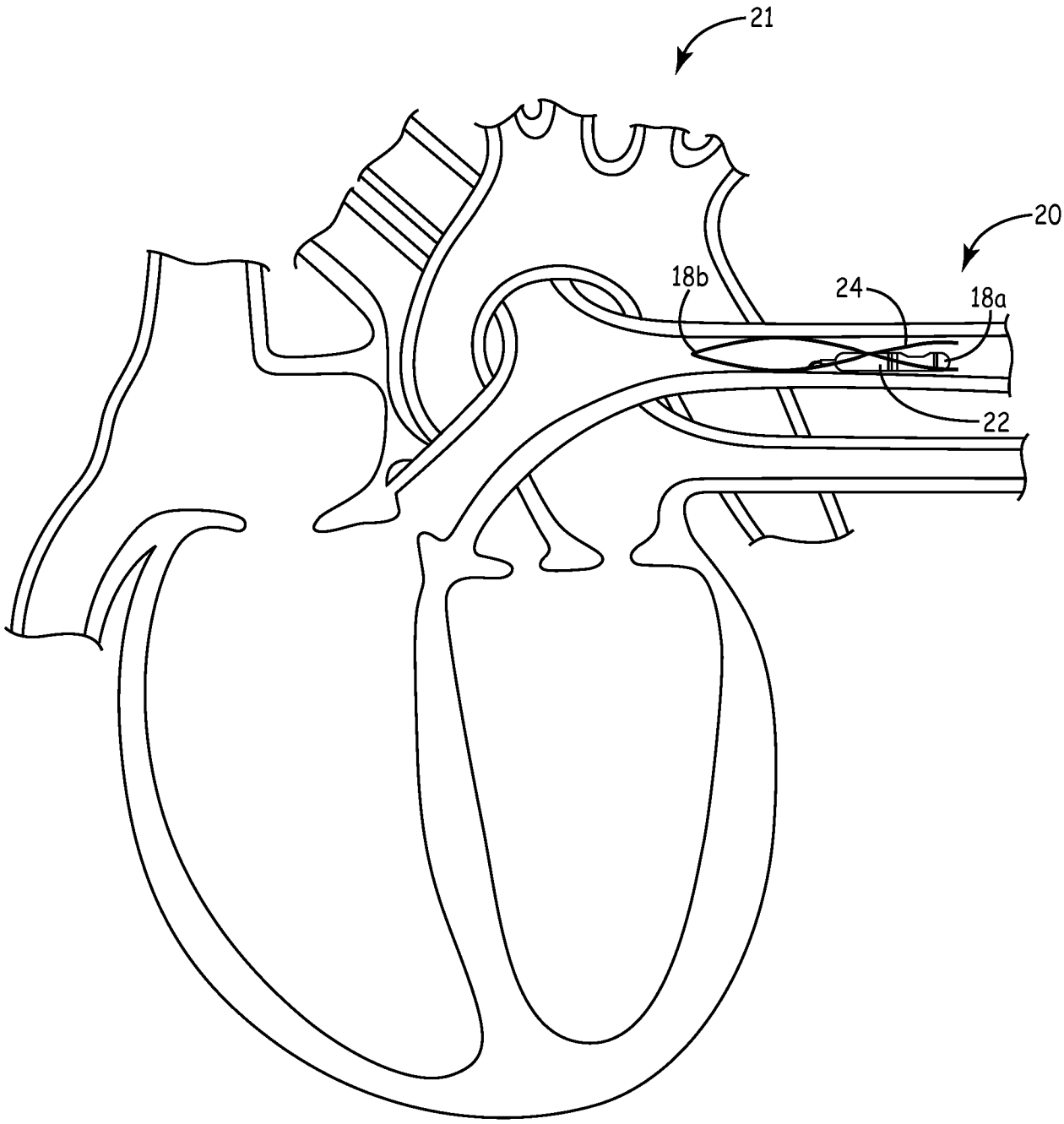
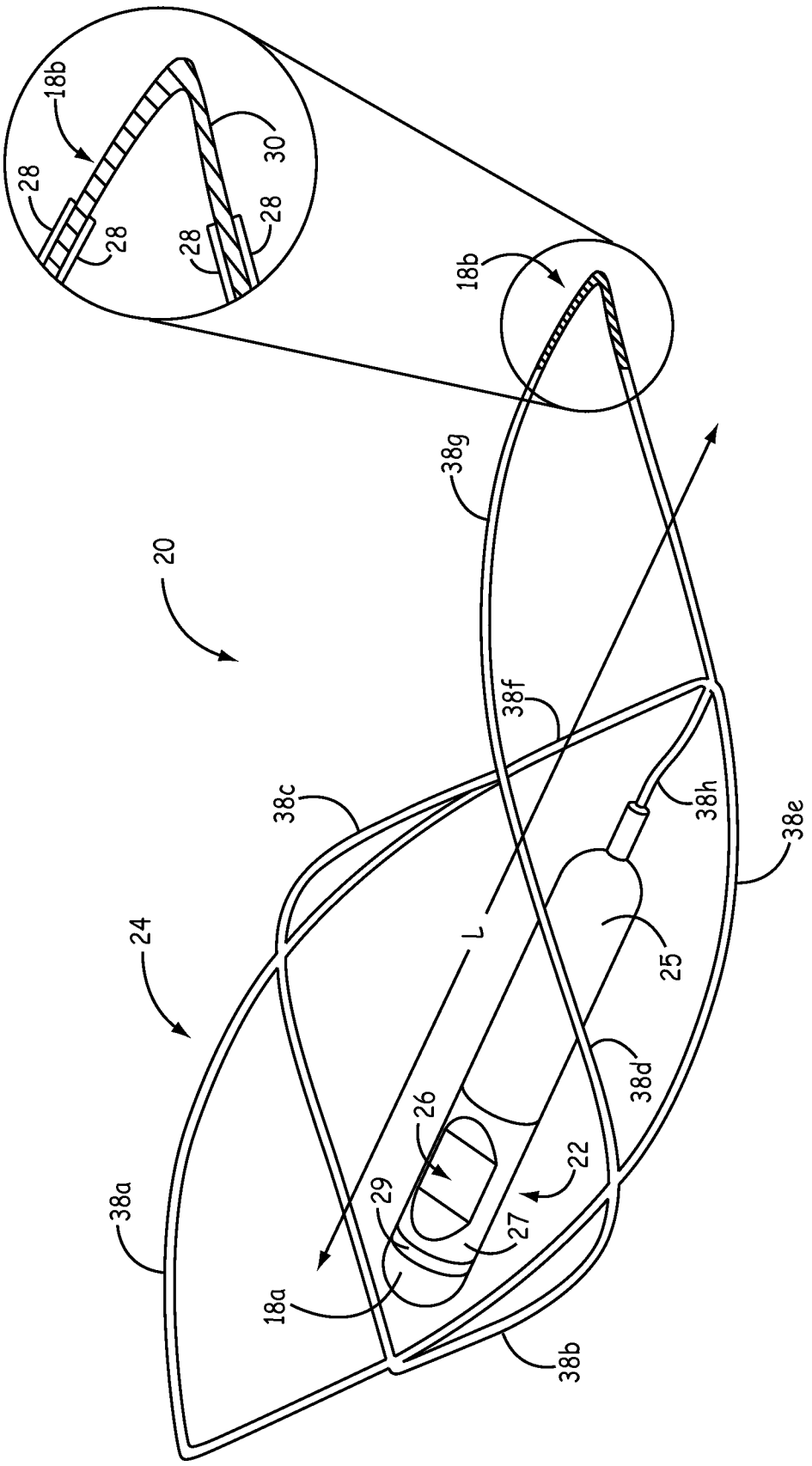


FIG. 2


18b
28
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30
18b
38g
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38f
38c
38h
38e
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L
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38d
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22
29
27
38a
18a
38b

FIG. 3A

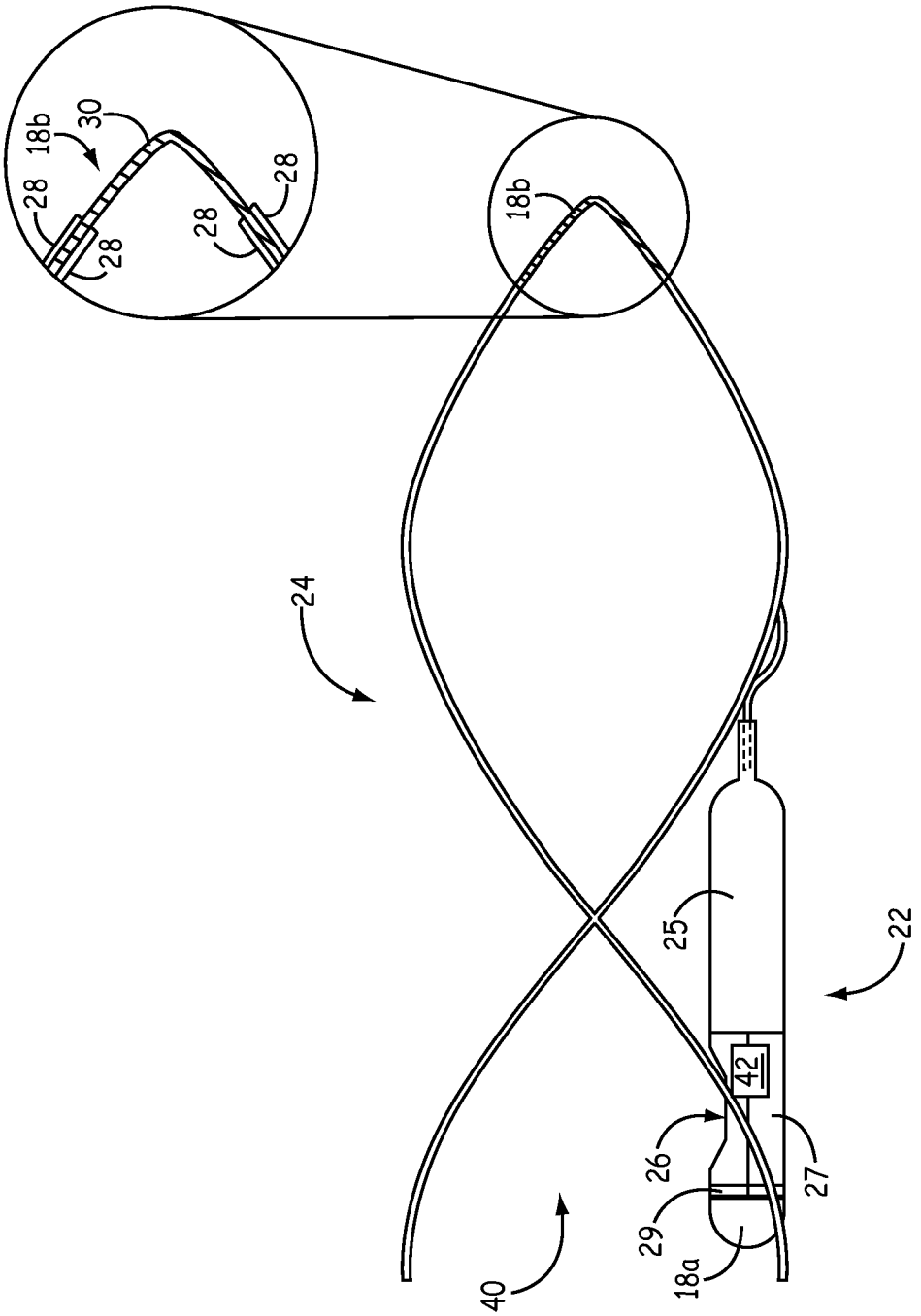


FIG. 3B

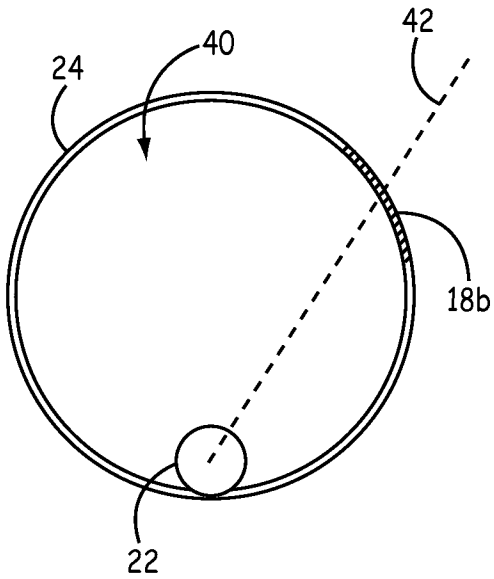


FIG. 3C

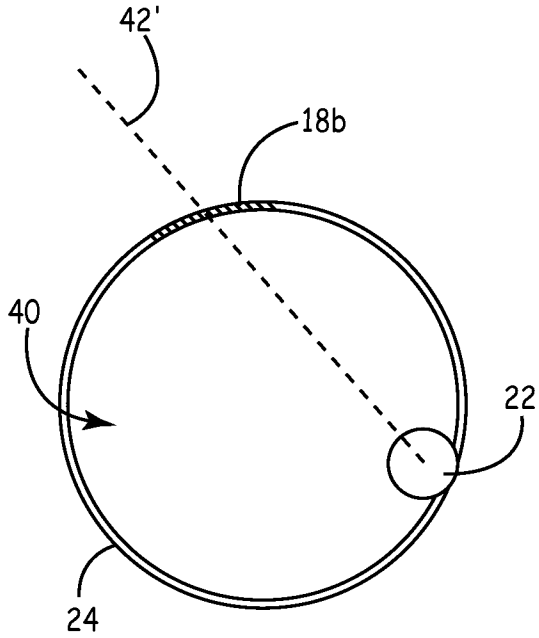
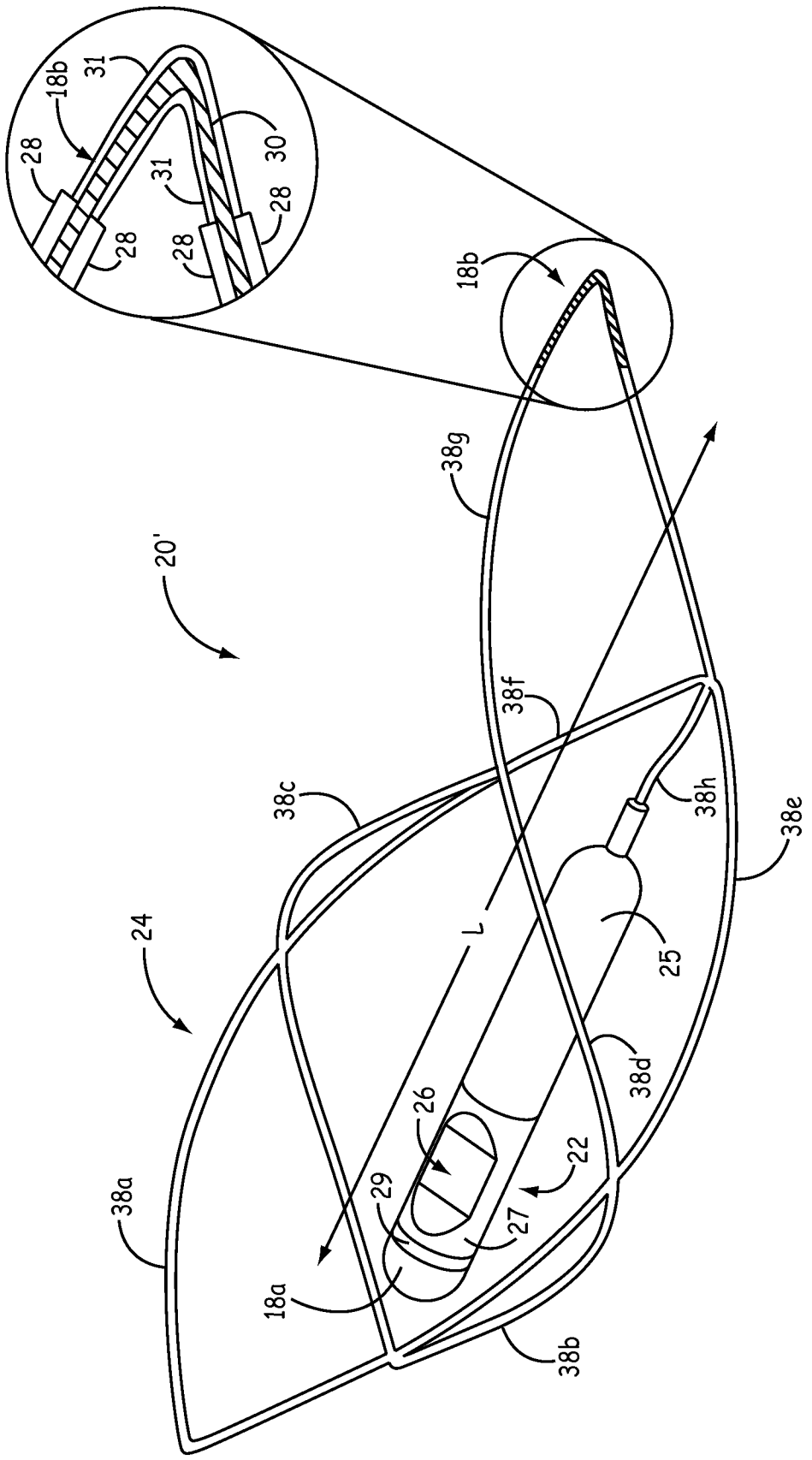


FIG. 3D


18b
31
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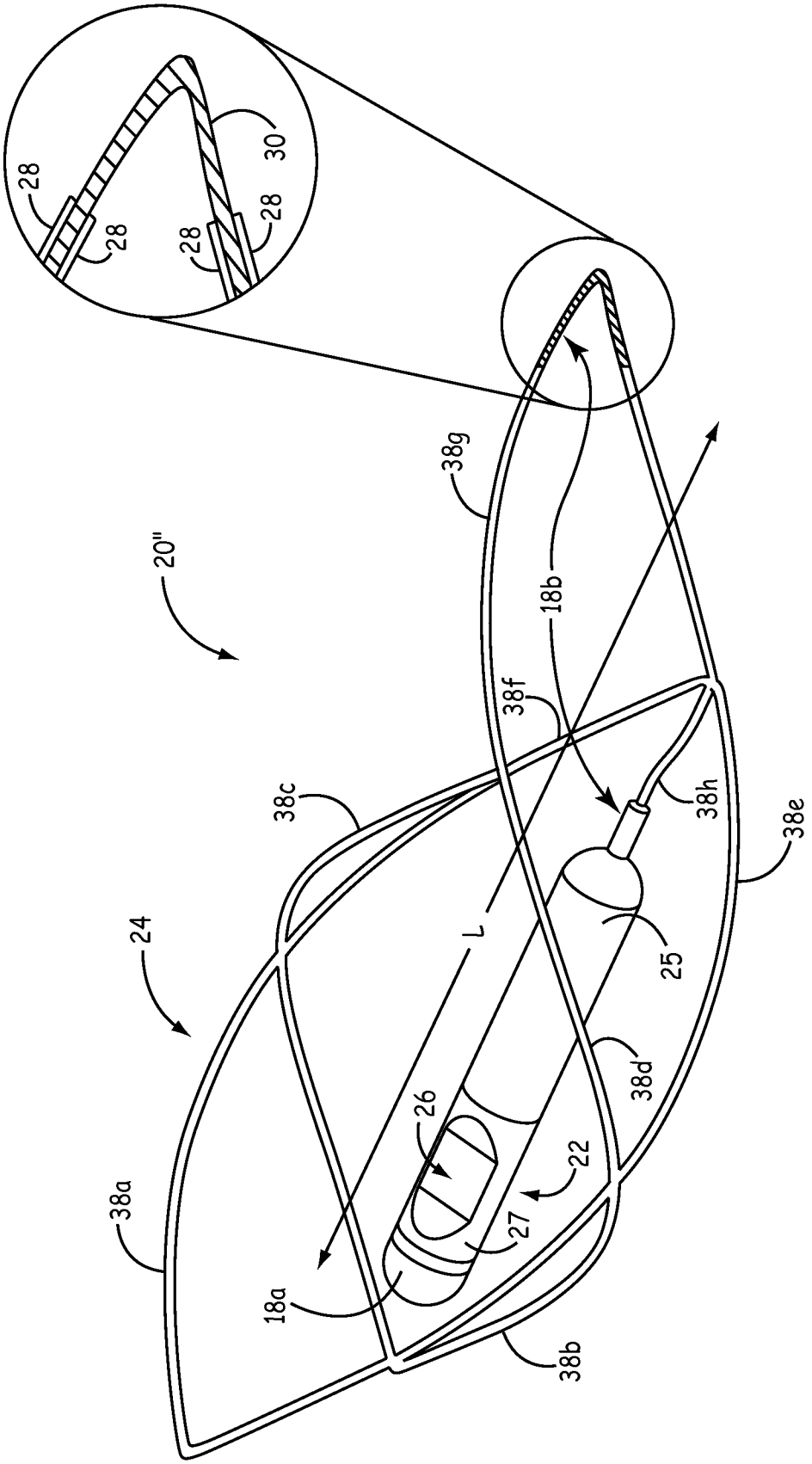
30
31
28
28
28
18b
38g
20'
38f
38c
38h
38e
24
L
25
38d
26
22
29
27
18a
38a
38b

FIG. 3E


28
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28
30
20"
24
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38b
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38d
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38g
38h
18a
18b
L
22
25
26
27

FIG. 3F

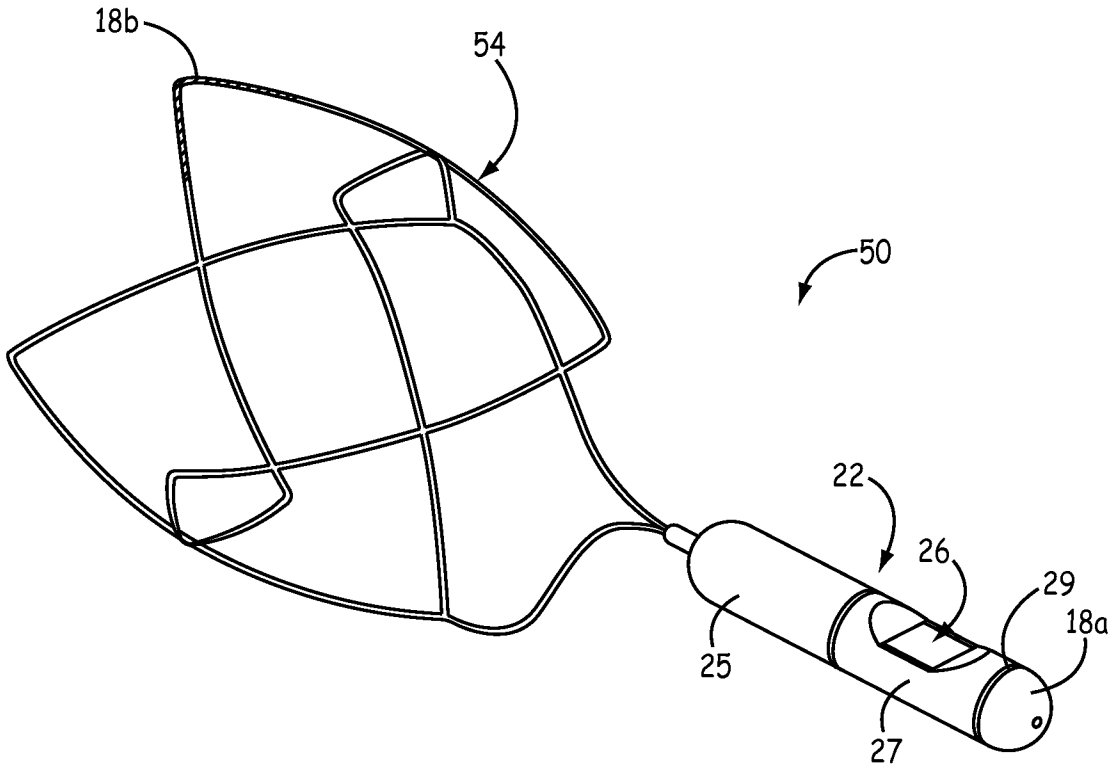

FIG. 4A

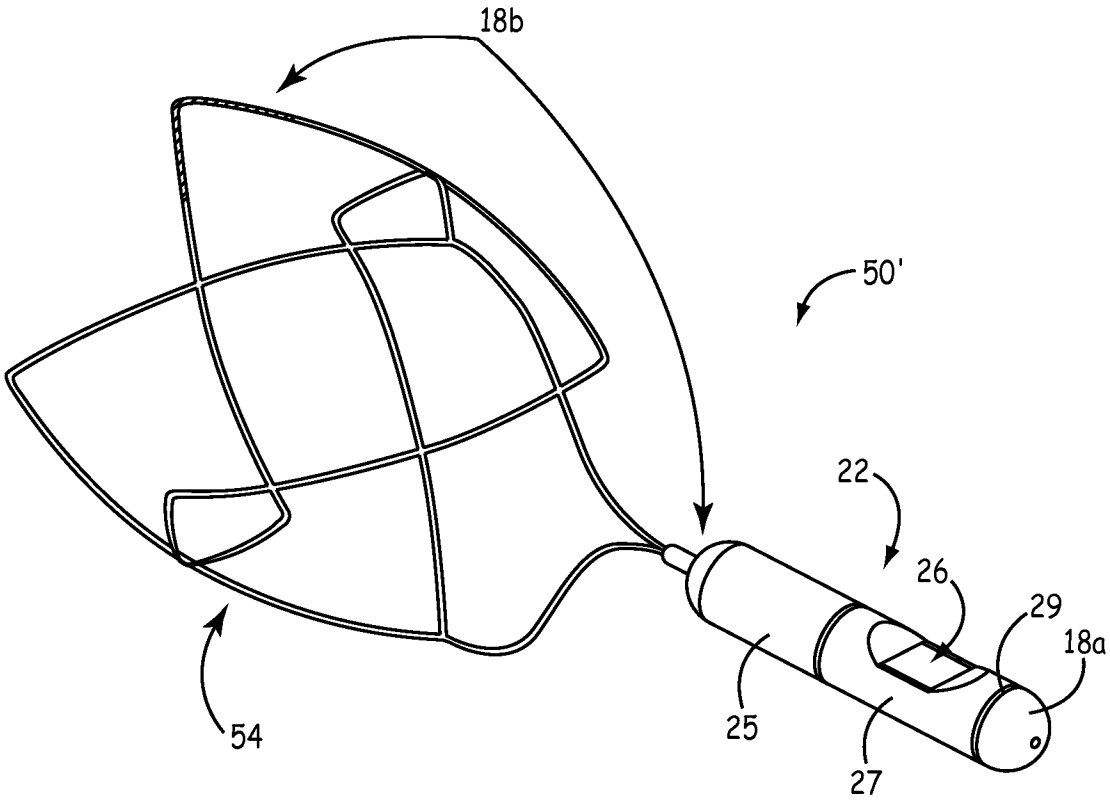

FIG. 4B

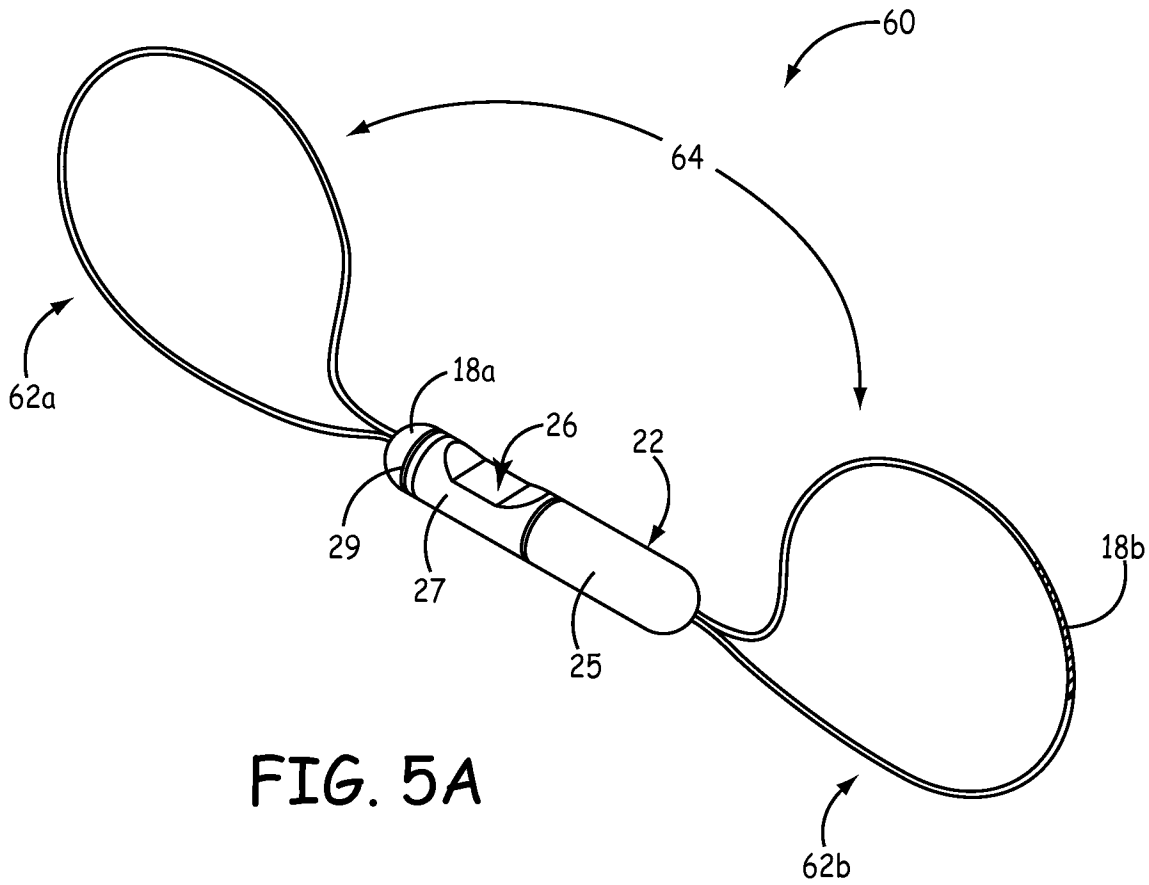

FIG. 5A

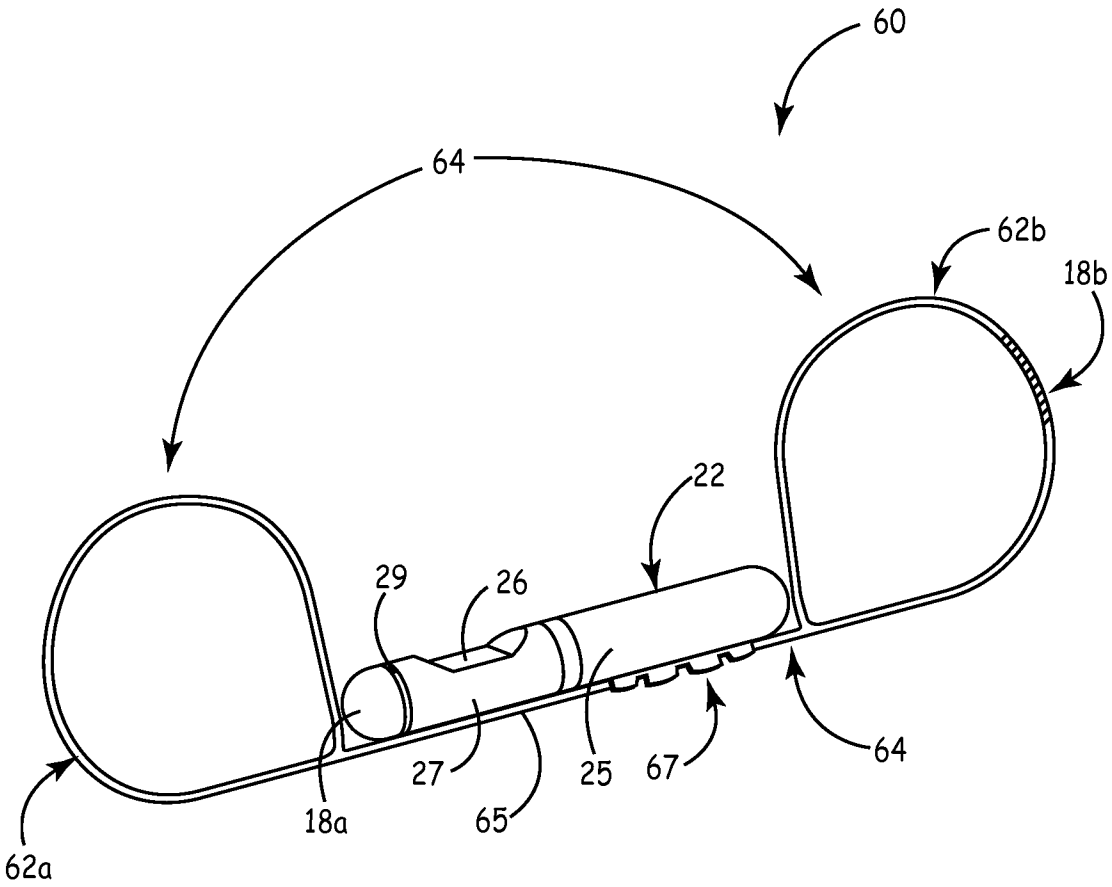

FIG. 5B

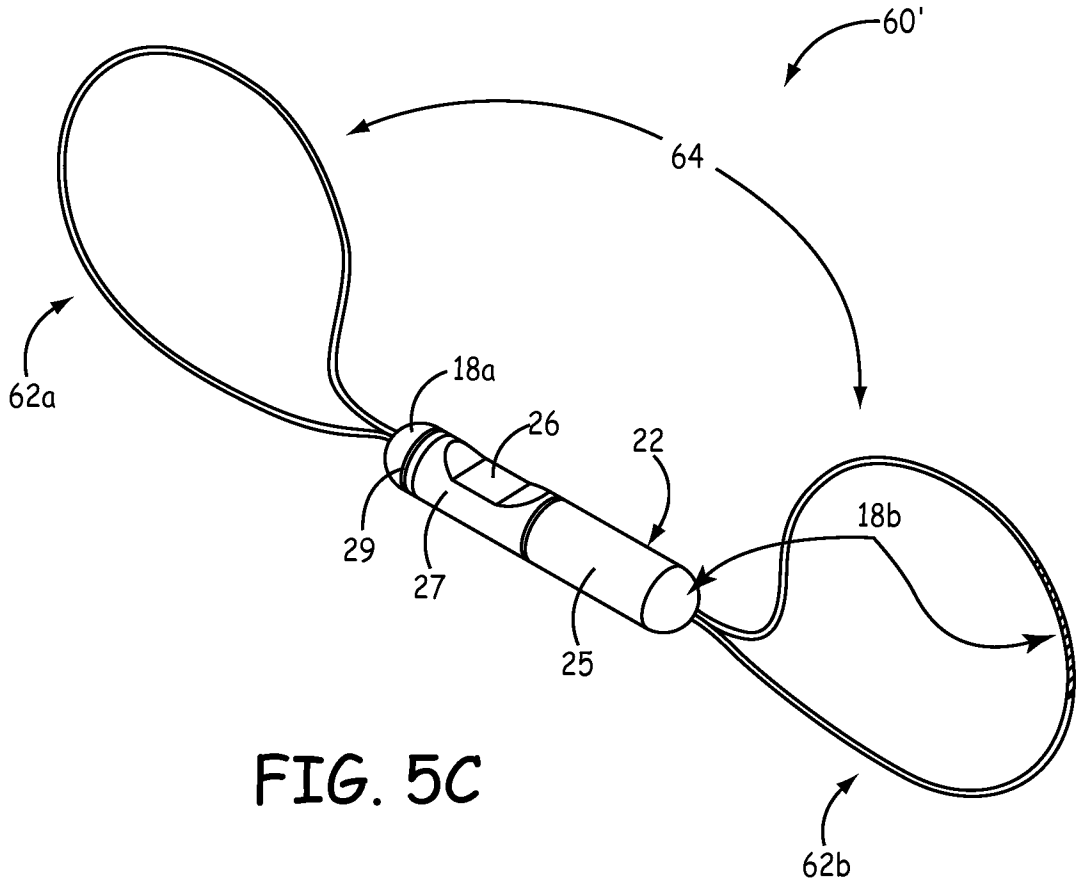

FIG. 5C

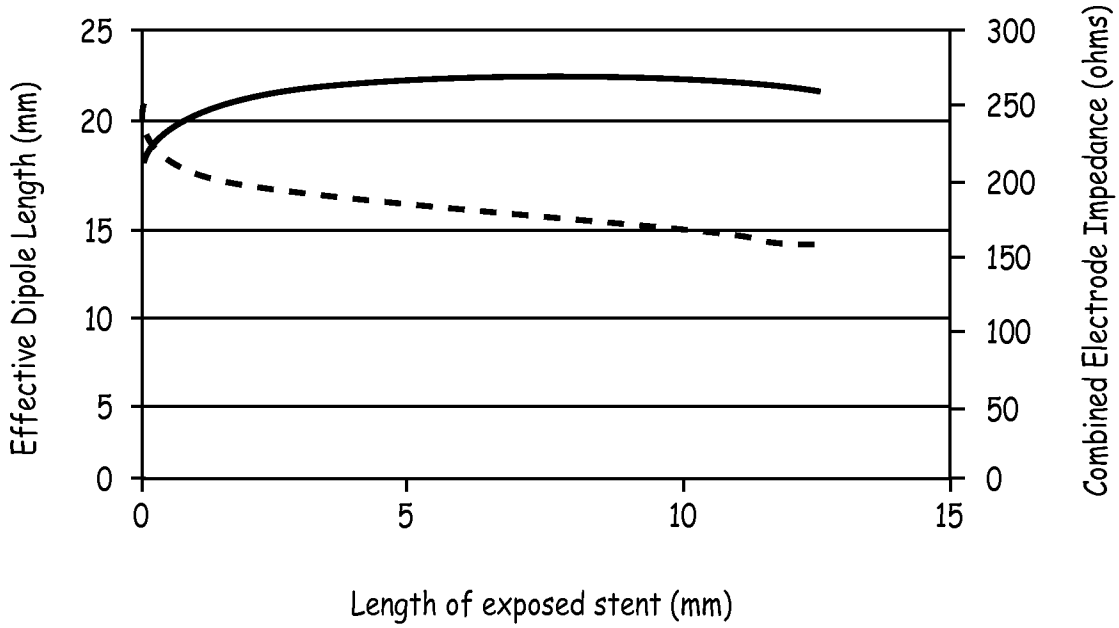
Effective Dipole Length (mm)
25
20
15
10
5
0
0
5
10
15
300
250
200
150
100
50
0
Combined Electrode Impedance (ohms)
Length of exposed stent (mm)

FIG. 6A

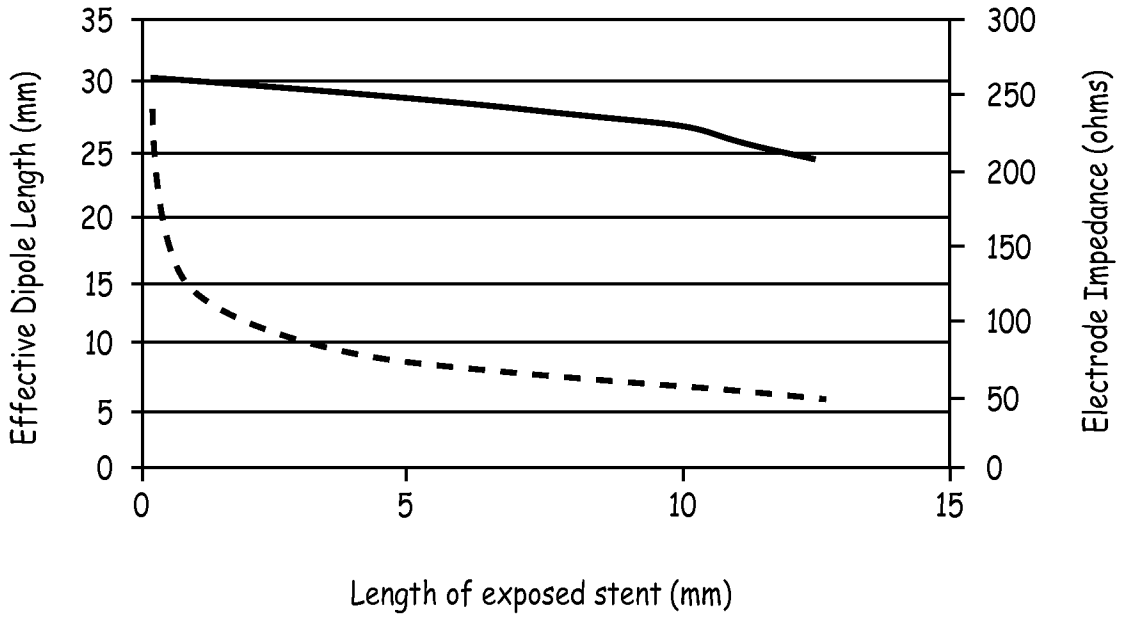
Effective Dipole Length (mm)
35
30
25
20
15
10
5
0
0
5
10
15
300
250
200
150
100
50
0
Electrode Impedance (ohms)
Length of exposed stent (mm)

FIG. 6B

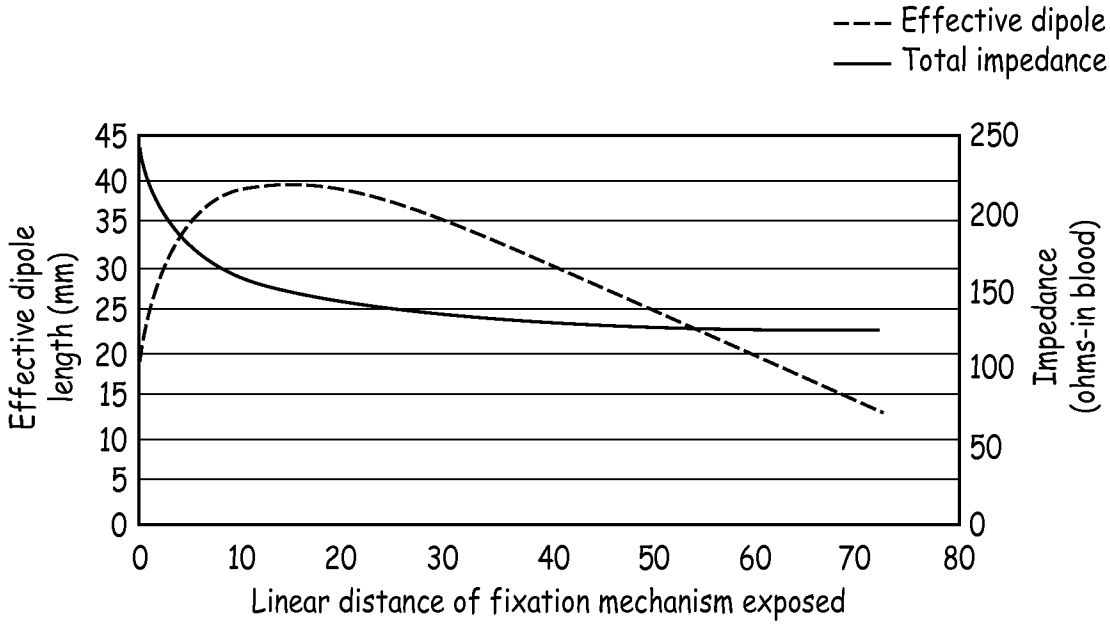
Effective dipole
Total impedance
Effective dipole length (mm)
Impedance (ohms-in blood)
Linear distance of fixation mechanism exposed
0
5
10
15
20
25
30
35
40
45
50
100
150
200
250
0
10
20
30
40
50
60
70
80

FIG. 6C

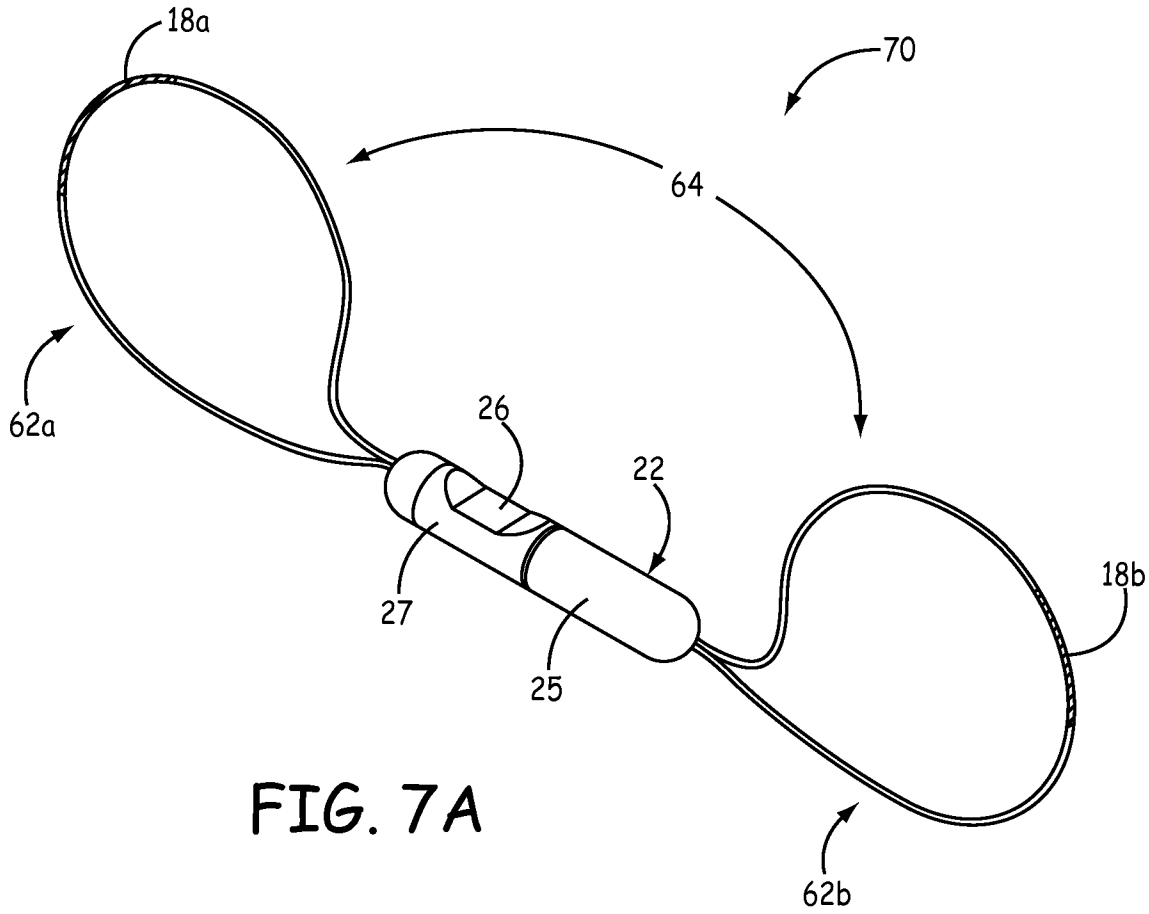

FIG. 7A

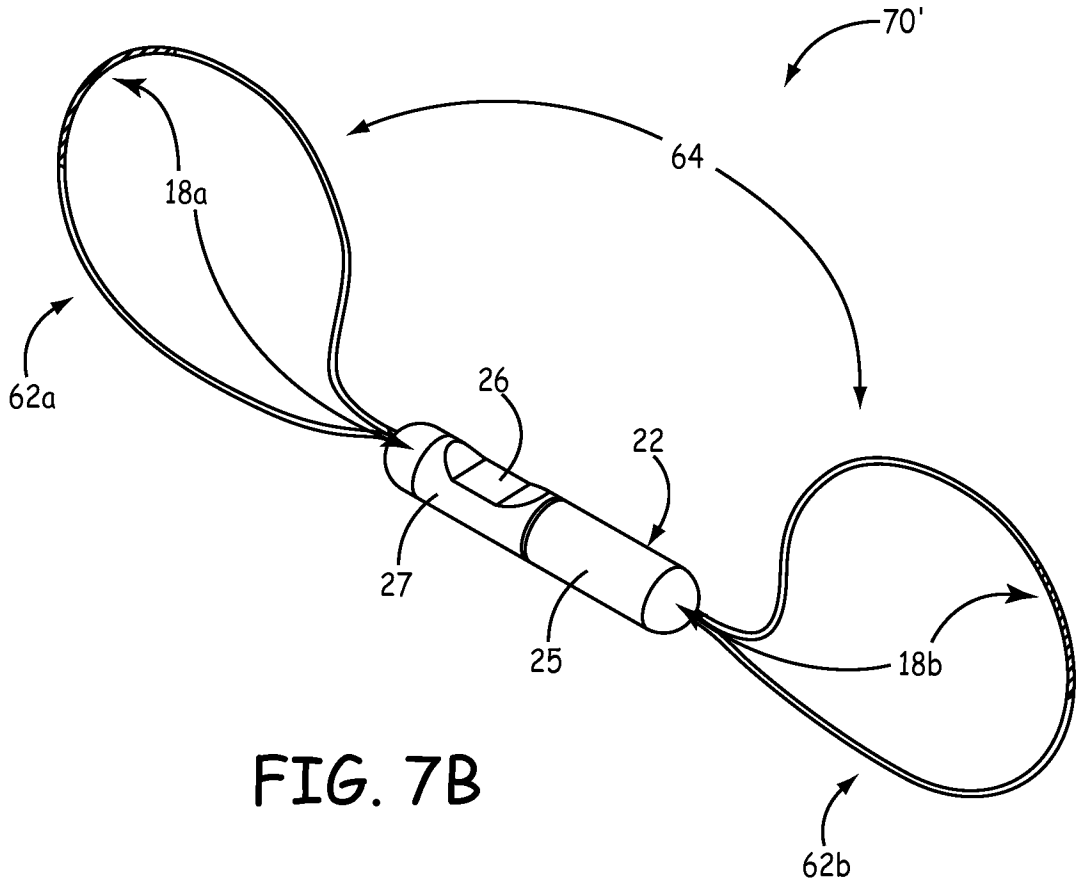

FIG. 7B

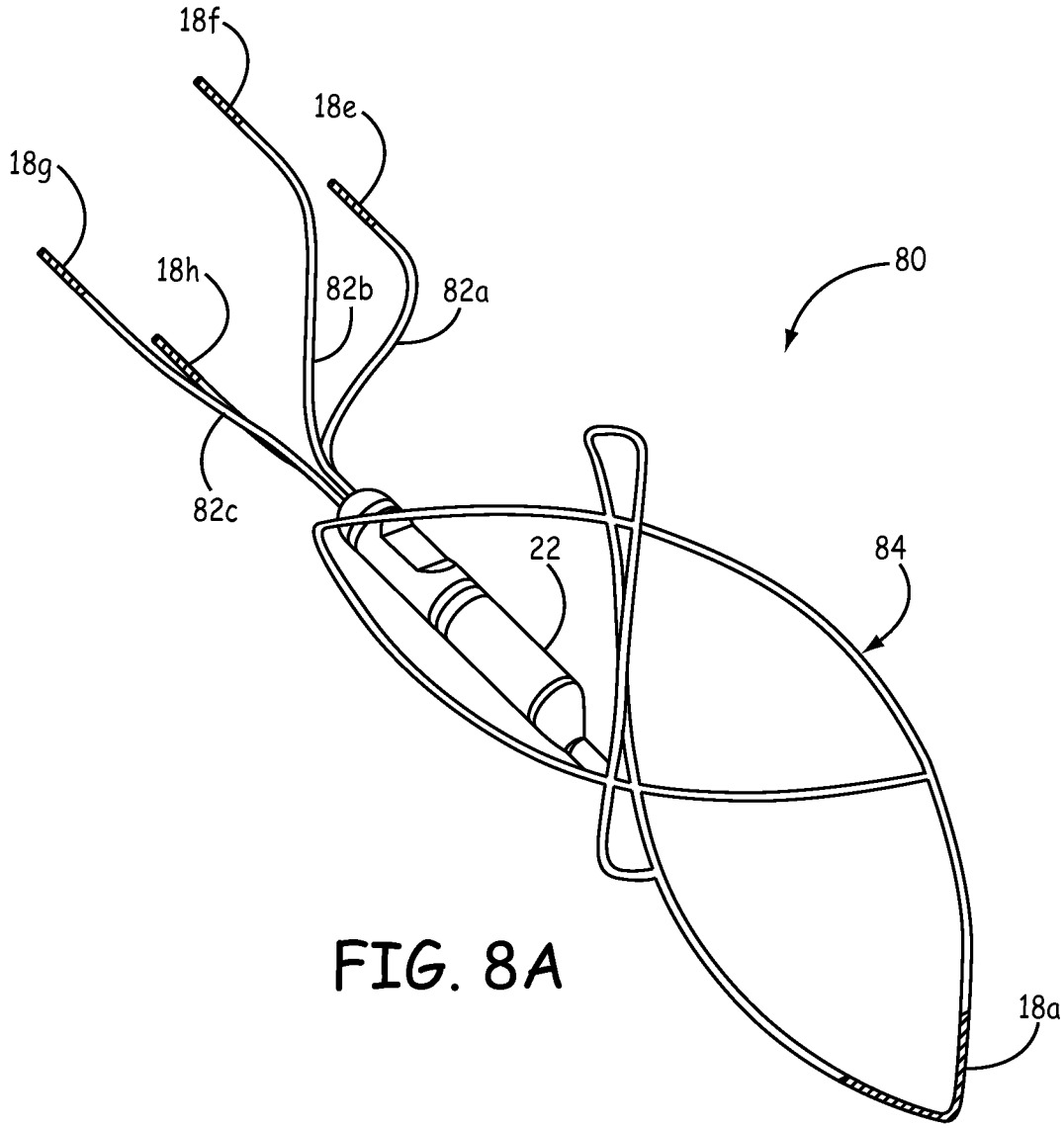

FIG. 8A

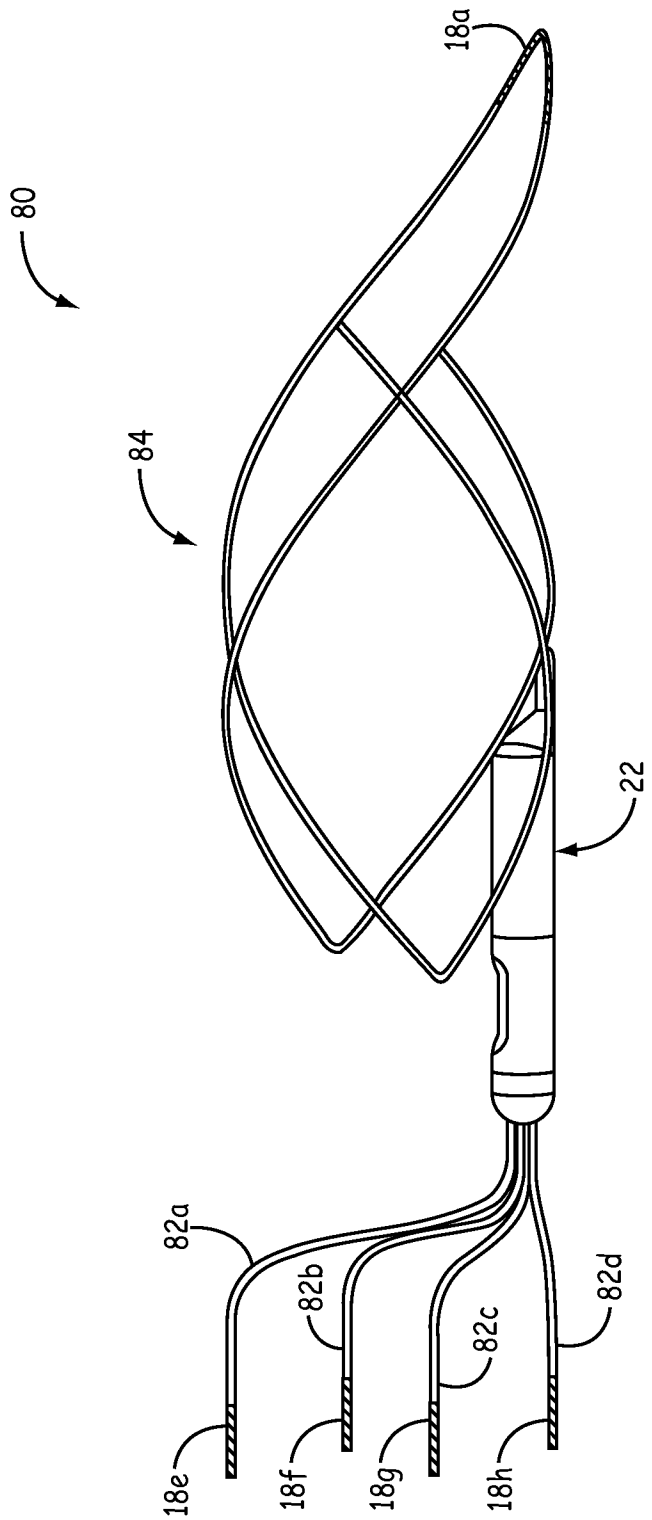

FIG. 8B

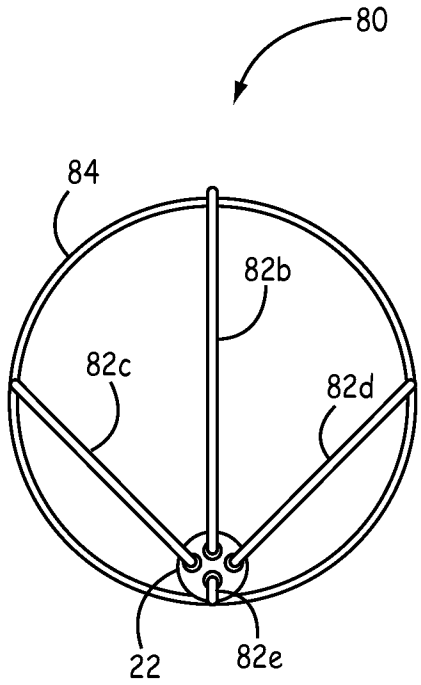

FIG. 8C

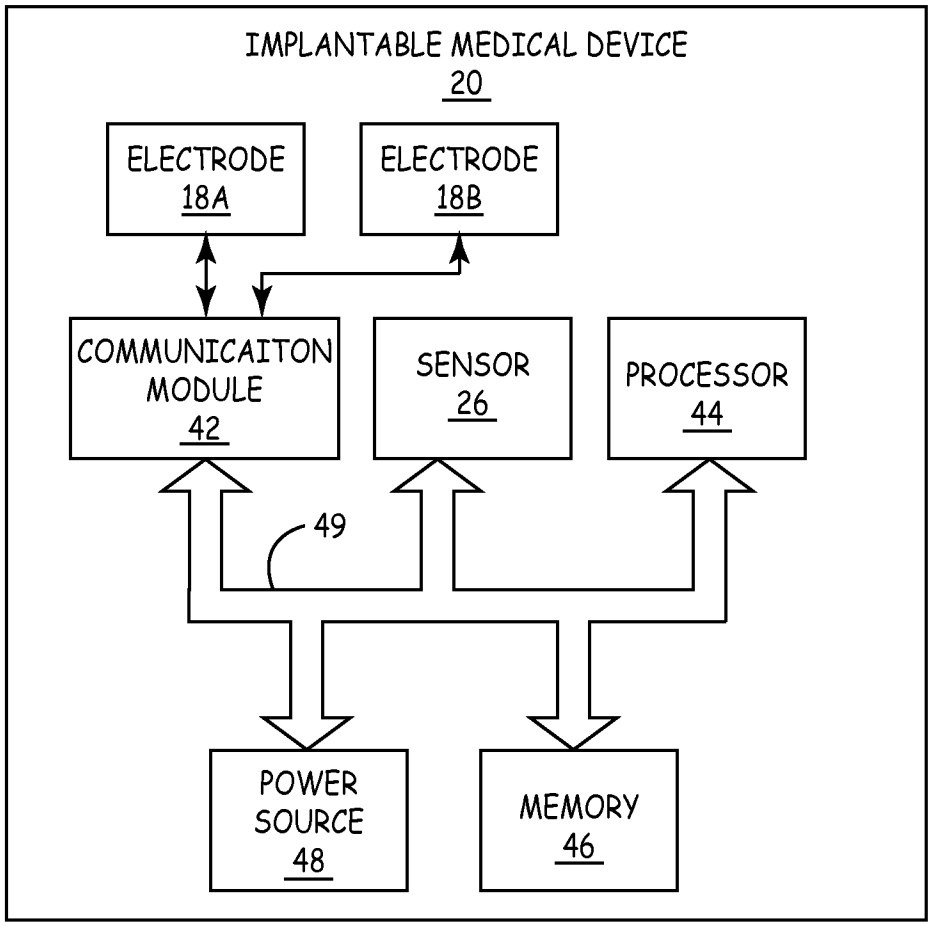
IMPLANTABLE MEDICAL DEVICE
20
ELECTRODE
18A
ELECTRODE
18B
COMMUNICAITON
MODULE
42
SENSOR
26
PROCESSOR
44
49
POWER
SOURCE
48
MEMORY
46

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/022889

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372 H04B13/00
ADD.

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)
A61N H04B

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/260294 A1 (SCHULMAN JOSEPH H [US] ET AL) 8 November 2007 (2007-11-08)	1-13,15
A	abstract; figures 1,2 paragraphs [0025] - [0036]	14
A	US 2006/259088 A1 (PASTORE JOSEPH M [US] ET AL) 16 November 2006 (2006-11-16) abstract; figure 6 paragraphs [0046] - [0048]	1-15
A	WO 2007/028035 A2 (PROTEUS BIOMEDICAL INC [US]; ZDEBLICK MARK [US]; ROBERTSON TIMOTHY [US) 8 March 2007 (2007-03-08) abstract; figures 19,20 page 16, line 24 - page 17, line 18 page 48, line 16 - page 49, line 23	1-15

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2012	24/05/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Pfeiffer, Uwe

1

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/022889

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00/13585 A1 (WOLFE RESEARCH PTY LTD [AU]; SORMANN GERARD WOLFE [AU]; WEST SIMON MIC) 16 March 2000 (2000-03-16) abstract; figure 7 page 4, line 29 - page 20, line 27 -----	1-15

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2012/022889

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