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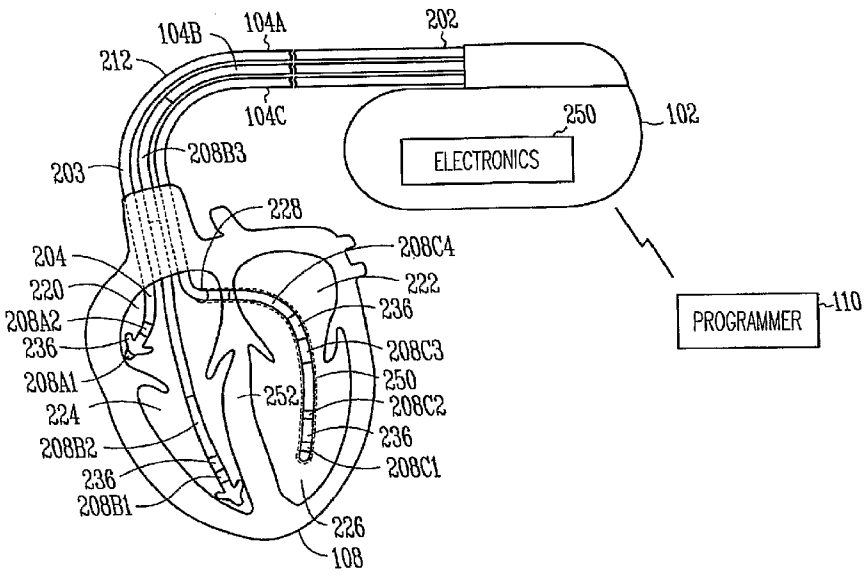
(54) **Title:** LEAD COMPRISING ELECTRODE-SHARED DRUG REGION



(57) **Abstract:** One or more multi-electrode leads couplable with a medical device, such as an implantable medical device, are discussed. Each lead includes a lead body extending from a lead proximal end portion to a lead distal end portion. The lead proximal end portion includes a connector assembly for connection to the implantable medical device. A lead intermediate or distal end portion includes two or more electrodes and a drug region shared by at least two of the electrodes. In one example, the drug region is positioned between two or more electrodes such each of the electrodes may benefit from a drug in the region. A method of forming a lead having a drug region shared by more than one electrode is also discussed.

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LEAD COMPRISING ELECTRODE-SHARED DRUG REGION

CLAIM OF PRIORITY

Benefit of priority is hereby claimed to U.S. Patent Application Serial Number 11/460,429, filed on July 27, 2006, which is herein incorporated by reference.

TECHNICAL FIELD

This patent document pertains generally to leads for linking medical devices with selected bodily tissue to be sensed or stimulated by such devices. More particularly, but not by way of limitation, this patent document pertains to a lead comprising a drug region shared by more than one electrode and systems and methods related thereto.

BACKGROUND

Leads represent the electrical link between a medical device, such as an implantable medical device (referred to as "IMD"), and a subject's cardiac or other bodily tissue, which is to be sensed or stimulated. A lead generally includes a lead body that contains one or more electrical conductors extending from a proximal end portion of the lead to an intermediate or distal end portion of the lead. The lead body includes insulating material for covering and electrically insulating the electrical conductors. The proximal end of the lead further includes an electrical connector assembly couplable with the IMD, while the intermediate or distal end portion of the lead includes one or more tissue sensing/stimulation electrodes that may be placed within, on, or near a desired sensing or stimulation site within the body of the subject.

The safety, efficacy, and longevity of an IMD depend, in part, on the performance and properties of the lead(s) used in conjunction with the device. For example, various properties of a lead and the one or more electrodes thereon will result in a characteristic lead impedance and stimulation threshold. Lead impedance corresponds to an electrical resistance of a lead to direct current. Stimulation threshold is the energy required in a stimulation pulse to depolarize, or "capture," the cardiac or other bodily tissue to which a pulse is directed. A

relatively low threshold and impedance is desirable to minimize the current drawn from a battery of the IMD in delivering a stimulation pulse. Maximizing the useful life of the battery is important to extend the useful life of the IMD, thereby reducing the need to replace the implanted device.

One factor that can affect the stimulation threshold, particularly during the first several weeks after implantation of a lead, is the natural immunological response of the subject's body to the lead as a foreign object. The presence of the lead activates macrophages, which attach themselves to the surface of the lead and any electrodes thereon and form multi-nucleated giant cells. These cells, in turn, secrete various substances, such as hydrogen peroxide as well as various enzymes, in an effort to dissolve the foreign object. Such substances, while intending to dissolve the foreign object, also inflict damage to the surrounding tissue. When the surrounding tissue is the myocardium, these substances cause necrosis. Areas of necrosis, in turn, impair the electrical characteristics of the electrode-tissue interface. Consequently, stimulation thresholds may rise.

Even after the microscopic areas of tissue die, the inflammatory response continues and approximately seven days after implant, the multi-nucleated giant cells cause fibroblasts to begin laying down collagen to replace the necrotic myocardium. Eventually, on the order of three weeks or so after implant, the lead and its associated electrodes are encapsulated by a thick layer of fibrotic tissue. Typically, the inflammatory response ends at this time. The fibrotic encapsulation of the lead and its tissue electrodes, however, remains. Since the fibrotic tissue is not excitable tissue, an elevated stimulation threshold can persist due to the degraded electrical properties of the electrode-tissue interface.

Another factor that can affect the stimulation and impedance thresholds pertain to the location of electrodes relative to the subject's cardiac or other bodily tissue to be sensed or stimulation, and in this way, pertains to the limited number of electrodes that a typical lead possesses. An electrode's ability to sense or stimulate the subject's cardiac or other bodily tissue depends, in part, on the relative location of the electrode(s) within, on, or near such tissue and the interface therebetween. Typically, the distal or intermediate portion of the lead body includes one or two electrodes arranged in a unipolar or bipolar

arrangement. A unipolar arrangement includes one tissue electrode, which represents one pole of an electrical circuit, while the other pole is represented by the body of the IMD itself. A bipolar arrangement includes a pair of tissue electrodes that form the single electrical circuit (i.e., one electrode is positive, while the other electrode is negative). Through the use of leads having only one or two tissue electrodes, the sensing or stimulation is limited, sometimes to a tissue location different from the optimum or acceptable position (e.g., a position having a lower stimulation and impedance parameter). Sensing or stimulating at such undesirable locations results in greater IMD battery drain, and thus, reduced IMD life.

SUMMARY

A lead comprises a lead body extending from a lead proximal end portion to a lead distal end portion, and having an intermediate portion therebetween. An electrical connector assembly is coupled to the lead proximal end portion, while at least a first and a second electrode are disposed along the lead intermediate or distal end portion. The first and second electrodes are electrically coupled to the connector assembly by way of one or more longitudinally extending conductors. A drug region is disposed between the first and second electrodes, such that a drug in the region may be shared by the electrodes.

Several options for the lead are as follows. In one example, the drug region comprises a polymeric material mixed with a drug. In another example, the drug region comprises a drug eluting matrix that elutes one or more drugs over time. In one such example, the drug eluting matrix comprises at least one drug and at least one drawing agent. The drawing agent has the ability to draw bodily fluid into the matrix for modulating a drug delivery rate of the at least one drug to nearby bodily tissue. In a further example, the lead body comprises a preformed biased portion, such as a helical or sinusoidal curve shape, at one or both of the lead intermediate or lead distal end portion.

A cardiac system includes a lead and a medical device, such as an IMD. The lead includes at least two electrodes and a shared drug region disposed near the at least two electrodes. In one such example, the lead includes four

electrodes and two shared drug regions. The medical device includes an electronics circuit configured to generate one or both of a sense signal or a stimulation signal, which are delivered using one or more of the lead electrodes. According to at least one example, a processing circuit of the medical device is adapted to select the delivering electrode(s) using, at least in part, one or a combination of a stimulation threshold parameter, a stimulation impedance parameter, a stimulation selection parameter, a heart chamber configuration parameter, or a spatial distance parameter.

An implantable lead includes a lead body extending form a proximal end portion to a distal end portion, and having an intermediate portion therebetween. The lead body includes at least one elongated electrical conductor contained therewithin. Two or more electrodes are disposed on the lead body and electrically coupled with the at least one conductor. A drug region is positioned and configured to dispense a drug adjacent the two or more electrodes.

Several options for the implantable lead are as follows. In one example, the drug region is positioned between the two or more electrodes. In another example, a structural strength or fixation mechanism is disposed on the lead body near an edge of the drug region. In yet another example, the two or more electrodes are electrically coupled to one another to provide an increased (effective) electrode sense surface area. In one such example, the electrodes are electrically coupled using a hard (wire) connection therebetween. In another such example, the electrodes are electrically coupled using a programmed software connection with an attached medical device.

A method of manufacturing a lead comprises forming a lead body encasing a substantial portion of one or more electrical conductors, including forming a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween. The method further comprises disposing a first and a second electrode on the lead body, such that the electrodes are separated a select distance away from one another. Further yet, the method comprises disposing a drug region on the lead body in a position such that the drug is shared by the first and second electrodes.

Several options for the method are as follows. In one example, disposing the drug region on the lead body includes spraying, dipping, or painting the drug

on the lead body. In another example, disposing the drug region on the lead body includes fusing a drug ring to the lead body. In yet another example, forming the lead body includes forming a bias portion at or near the lead intermediate or distal end portion. Additionally, the method may further include electrically coupling the first and second electrodes, or disposing a third and fourth electrodes and an associated drug region on the lead body.

The leads, systems, and methods discussed herein may overcome many deficiencies of current leads, systems, and methods. As one example, through the use of a lead including a drug region shared by more than one electrode, less drug may be used on a per lead basis in comparison to conventional leads in which a separate drug region is associated with each individual electrode (for which a drug and its associated benefits is desired). As another example, through the use of the drug shared region, additional regulatory approval may not be needed for a lead including three, four or more electrodes, as testing has already been conducted for leads including two drug regions. For instance, a lead including four electrodes and two drug regions shared by the four electrodes (e.g., a first and second electrode sharing a first drug region and a second and third electrode sharing a second drug region) need not require additional drug safety and efficacy testing, as such testing has already been performed for leads having two electrodes and two associated drug regions.

As yet another example, through the use of a lead including three, four or more electrodes, the opportunity exists for a caregiver (e.g., a physician) or an IMD itself to choose among numerous electrode configurations for sensing or stimulating the desired cardiac or other bodily tissue. The numerous possible electrode configurations allow the caregiver or the IMD to recurrently select one or more electrode configurations, which optimize or provide an acceptable balance of, among other things, one or a combination of a stimulation threshold parameter, a stimulation impedance parameter, a stimulation selection parameter (including reduction of phrenic nerve or diaphragmatic stimulation), a heart chamber configuration parameter, or a spatial distance parameter.

These and other examples, advantages, and features of the present leads, systems, and methods will be set forth, in part, in the detailed description that

follows, and in part, will become apparent to those skilled in the art by reference to the following description and drawings or by practice of the same.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

FIG. **1** is a schematic view of an implantable cardiac system and an environment in which the system may be used, as constructed in accordance with at least one embodiment.

FIG. **2** is an enlarged schematic view of the implantable cardiac system of FIG. **1**, as constructed in accordance with at least one embodiment.

FIG. **3** is a schematic view of an implantable neurological system and an environment in which the system may be used, as constructed in accordance with at least one embodiment.

FIGS. **4A-4I** are plan views of an intermediate or distal portion of a lead, each constructed in accordance with at least one embodiment.

FIG. **5** is a plan view of a lead, as constructed in accordance with at least one embodiment.

FIG. **6A-6B** are plan views of a lead, each constructed in accordance with at least one embodiment.

FIG. **7** is a cross-section view of a lead taken along a line, such as line **7-7** of FIG. **4A**, as constructed in accordance with at least one embodiment.

FIG. **8** is a schematic view illustrating portions of an implantable system, including circuitry of an IMD, as constructed in accordance with at least one embodiment.

FIG. **9** is a flow diagram illustrating a method of making a lead, as performed in accordance with at least one embodiment.

DETAILED DESCRIPTION

The following detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the present leads, systems, and methods may be practiced. These embodiments, which are also referred to herein as "examples," are described in enough detail to enable those skilled in the art to practice the present leads, systems, and methods. The embodiments may be combined, other embodiments may be utilized or structural, logical, and electrical changes may be made without departing from the scope of the present leads, systems, and methods. It is also to be understood that the various embodiments of the present leads, systems, and methods, although different, are not necessarily mutually exclusive. For example, a particular feature, structure or characteristic described in one embodiment may be included within other embodiments. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present leads, systems, and methods are defined by the appended claims and their legal equivalents.

In this document the terms "a" or "an" are used to include one or more than one; the term "or" is used to refer to a nonexclusive or, unless otherwise indicated; the term "subject" is used synonymously with the term "patient"; and the terms "implantable medical device," "implantable lead," and the like refer to elements that are to be at least partially placed within a subject's body for a period of time for which it would be beneficial to have a drug region present. In addition, it is to be understood that the phraseology or terminology employed herein, and not otherwise defined, is for the purpose of description only and not of limitation.

Leads, systems, and methods are provided herein for, among other things, minimizing an amount of drug needed on a per lead basis and minimizing new drug safety and efficacy testing, while still providing multiple vectors and electrode spacing for sensing and stimulation of a subject's bodily tissue. The foregoing is achieved, in part, by positioning two or more electrodes on a lead in such a way that the electrodes can share, thereby reaping the benefits of, a single drug region.

Turning now to the drawings, and initially to FIG. **1**, which illustrates an implantable cardiac system **100** and an environment (e.g., a subcutaneous pocket made in the wall of a subject's **106** chest, abdomen, or elsewhere) in which the system may be used. In varying examples, the cardiac system **100** may be used for receiving or delivering electrical signals or pulses to sense or stimulate, respectively, a heart **108** of the subject **106**. As shown in FIG. **1**, the cardiac system **100** may include an IMD **102**, at least one implantable lead **104** coupled with the IMD on a proximal end, and an external programmer **110** adapted to electrically communicate with the IMD, such as wirelessly through the use of a telemetry device **112**.

The IMD **102** generically represents, but is not limited to, cardiac function management (referred to as "CFM") systems such as pacemakers (also referred to as "pacers"), cardioverters/defibrillators, pacers/defibrillators, biventricular or other multi-site resynchronization or coordination devices such as cardiac resynchronization therapy (referred to as "CRT") devices, sensing instruments, or drug delivery systems. Among other things, the IMD **102** includes a source of power as well as an electronics circuitry portion **250** (*see, e.g.*, FIG. **2**). In varying examples, a housing of the IMD **102** may serve as an indifferent electrode for use in combination with an electrode disposed on the lead **104** (*see, e.g.*, FIG. **2**).

In one example, the IMD **102** is a pacemaker. Pacemakers deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart **108**, such as via the at least one lead **104** having one or more (typically ring-like) electrodes disposed within, on, or near the heart. Heart **108** contractions are initiated in response to such pace pulses (i.e., the pulses capture the heart **108**). By properly timing the delivery of pace pulses, the heart **108** can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacemakers are often used to treat subjects **106** with bradyarrhythmias, that is, hearts **108** which beat too slowly or irregularly. Pacemakers may also coordinate atrial and ventricular contractions to improve a heart's **108** pumping efficiency.

In another example, the IMD **102** is a CRT device for coordinating the spatial nature of heart depolarizations for improving a heart's pumping

efficiency, such as for subjects **106** experiencing CHF. In one such example, the CRT device may deliver appropriate timed pace pulses to different locations of the same heart **108** chamber to better coordinate the contraction of that heart chamber, or the CRT device may deliver appropriately timed pace pulses to different heart **108** chambers to improve the manner in which these different heart chambers contract together, such as to synchronize left and right side contractions.

In yet another example, the IMD **102** is a defibrillator that is capable of delivering higher energy electrical stimuli to the heart **108** (as compared to, for example, pacing pulses). Defibrillators may include cardioverters, which synchronize the delivery of such stimuli to sensed intrinsic heart activity signals. Defibrillators are often used to treat subjects with tachyarrhythmias, that is, hearts which beat too quickly. Such too-fast heart rhythms cause diminished blood circulation because the heart isn't allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart **108** is inefficient. A defibrillator is capable of delivering a high energy electrical stimulus via a (typically coil-like) electrode that is sometimes referred to as a defibrillation countershock, also referred to simply as a "shock." The countershock interrupts the tachyarrhythmia, allowing the heart **108** to reestablish a normal rhythm for the efficient pumping of blood.

When the IMD **102** is a defibrillator, it may also be used to treat subjects experiencing cardiac arrest in which the heart **108** stops beating or goes into fibrillation (i.e., inefficient pumping). The high energy defibrillation countershocks deliverable by a defibrillator may restart the heart **108** or stop fibrillation thereby allowing the heart **108** to re-establish normal sinus rhythm.

FIG. **2** illustrates an enlarged schematic view of the cardiac system **100** shown in FIG. **1**, for receiving and delivering electrical signals (e.g., via an electronics circuitry portion **250**) to sense or stimulate a subject's heart **108**, which includes a right atrium **220**, a left atrium **222**, a right ventricle **224**, a left ventricle **226**, a coronary sinus **228** extending from the right atrium, and a coronary vein **250**. The cardiac system **100** includes a medical device, such as an IMD **102**, and at least one lead **104*A***, **104*B***, **104*C***, where each lead extends from a proximal end portion **202** to a distal end portion **204**, and has an

intermediate portion **203** therebetween. The lead proximal end portion **202** includes an electrical connector assembly to connect to the IMD **102**, while the lead intermediate **203** or distal end portion **204** includes two or more electrodes **208**. Each lead includes a lead body **212** which, in one example, is comprised of a tubing material formed of a biocompatible polymer suitable for implementation within a subject's body **106** (FIG. **1**), such as silicone rubber. The lead body **212** of each lead includes at least one lumen (*see, e.g.*, FIG. **7**) which house longitudinally electrical conductors extending from the connector assembly to the tissue sensing/stimulation electrodes. The electrical conductors carry current and other signals between the IMD **102** and the electrodes **208**.

In this example, the atrial lead **104*A*** includes electrodes disposed in, around, or near the right atrium **220** of the heart, such as ring electrode **208*A2*** and tip electrode **208*A1***, for sensing signals (e.g., via a sense measurement circuit **806** (FIG. **8**)) or delivering pacing therapy (e.g., via a stimulation energy delivery circuit **804** (FIG. **8**)) to the right atrium. Atrial lead **104*A*** may also include additional electrodes, such as for delivering atrial or ventricular cardioversion/defibrillation or pacing therapy to the heart **108**. Also shown in this example, a right ventricular lead **104*B*** includes one or more electrodes, such as a ring electrode **208*B1***, for sensing signals or delivering pacing therapy. The right ventricular lead **104*B*** may also include additional electrodes, such as coil electrodes **208*B2*** or **208*B3*** for delivering right atrial or right ventricular cardioversion/defibrillation or pacing therapy to the heart **108**. As further shown in this example, the system **100** may also include a left ventricular lead **104*C***, which provides one or more electrodes such as tip electrode **208*C1*** and ring electrode **208*C2***, for sensing signals or delivering pacing therapy. The left ventricular lead **104*C*** may also include one or more additional electrodes, such as coil electrodes **208*C3*** or **208*C4*** for delivering left atrial or left ventricular cardioversion/defibrillation or pacing therapy to the heart **108**.

Although not shown in FIG. **2**, other dispositions of the lead intermediate **203** and distal end **204** portions within, on, or near the heart **108** are also possible. For instance, in one example a lead **104** includes at least one preformed biased portion or is otherwise configured to urge one or more of the electrodes **208** thereon against a septal wall **252** for pacing the of the same.

Disposed between the electrode pairs **208*A1*-208*A2***, **208*B1*-208*B2***, **208*C1*-208*C2***, and **208*C3*-208*C4*** is a drug region **236**, which may be shared by each electrode of the associated electrode pair. The incorporation of a shared drug region in a lead may provide for, among other things, lower lead impedances (as optimal electrode vectors with adjacent drug regions may be chosen), or lower peak and chronic stimulation thresholds by reducing, for example, inflammation or fibrotic growth. A reduction in lead impedance and stimulation thresholds increases the longevity of medical devices, such as the IMD **102**, because the current drain from the IMD's power source is reduced. In addition, a lead construction in which two or more electrodes share a drug region, such as a drug collar, advantageously minimizes an amount of drug needed on a per lead basis – resulting in a cost savings – and further minimizes new drug safety and efficacy testing which would be required for leads having more than two drug regions (there may be instances in which more drug would potentially be detrimental).

Previously tested leads comprised a separate drug region for each electrode for which an adjacent drug region and its associated benefits was desired. For instance, a lead including two electrodes would typically include two associated drug regions. As mentioned above, by having only two or less electrodes per lead limited sensing and stimulation to a limited number of electrode configurations. With the advent of quad-polar leads (i.e., leads having four electrodes, which may find utility in treating congestive heart failure by allowing switching of pacing electrodes) and the like, the question may arise as to what the proper dosage of drug per lead should be, and further, is it acceptable to include one drug ring per electrode. Placing an electrode on each side of a drug region eliminates the need to resolve the dosage question and thus, may eliminate any potential need for new clinical studies (e.g., by regulatory agencies, such as the Food and Drug Administration (FDA) or British Standards Institution (BSI)) as the dosage is the same as historical data.

Also shown in FIG. **2** is a programmer **110**. In this example, the programmer is an external-type programmer that may be used to program many of the parameters of the electronics circuitry portion **250** or other parameters of the IMD **102**. In another example, the programmer **110** may be an external

handheld-type programmer adapted for use by a subject **106**. Another type of programmer **110** might be one that a physician would have in his/her office, which can be used to program various parameters associated with, for example, stimulation signals produced by the IMD **102**. The programmer **110** may includes a feature allowing for a readout of the status of the IMD **102**.

The present leads, systems, and methods may be used in a wide variety of medical applications including, but not limited to, cardiac pacing, defibrillation, cardioversion, or as shown in FIG. **3**, neurostimulation. FIG. **3** illustrates an exemplary neurostimulator system **300** implanted in a subject **106**. The system **300** comprises an IMD **102** and a lead **104** extending from a lead proximal end portion **202** coupled with the IMD to a lead distal end portion **204**. The lead includes at least two electrodes **208** and a drug region **236** shared by the at least two electrodes. The IMD may be implanted subcutaneously in the subject **106**, such as in the abdomen or chest region. From the location of implantation of the IMD **102**, the lead distal end portion **204** is tunneled subcutaneously to the subject's neck region **306** and positioned in proximity to a desired therapy site. In the example of FIG. **3**, the target therapy site is the vagal nerve **308**. In another example, the target therapy site is one or more baroreceptor in a pulmonary artery. The lead **104** is positioned such that the at least two electrodes **208** and the drug region **236** are in close proximity to the desired therapy site.

FIGS. **4A-4I** illustrate various examples of a lead intermediate **203** or distal end **204** portion according to the present subject matter. Each lead intermediate **203** or distal end portion **204** extends from a proximal end portion **202** (FIG. **2**), which includes an electrical connector assembly adapted to couple to a medical device, such as an IMD **102** (FIG. **1**). The IMD contains an electronics circuitry portion **250** (FIG. **2**) and software necessary to detect, for example, certain types of arrhythmias and to correct for them. Each lead **104** also includes a lead body **212** to which two or more electrodes **208** and a shared drug region **236** are disposed. In varying examples, the drug region **236**, such as a drug collar, is shared by placing at least one electrode **208** adjacent or near each side of the drug region.

As discussed above, the implantation of a lead **104** into a subject's **106** body may, among other things, vitiate a stimulation pulse's desired effects. For example, reactions between the body and lead materials may encourage fibroses. In regards to pacing (i.e., one form of stimulation), fibrosis is considered a factor in the increase in chronic stimulation threshold, and thus increased device battery drain, that may be experienced over time. Also, the mechanical trauma of implantation can result in inflammation of the adjacent bodily tissue. This inflammation can further alter the response of the tissue to the pacing stimulus, both acutely and chronically. Other interactions between the lead **104** and body, while not directly affecting the tissue's response to stimulation, are nonetheless undesirable. In some circumstances, the body region to be stimulated may be irritable. The implantation of a lead **104** can compound this irritability. For example, the presence of an implanted lead **104** can promote thrombus formation. For at least these reasons, the present leads **104** comprise a drug region **236** shared by the at least two electrodes **208**.

In varying examples, the drug region(s) **236** is positioned between the at least two electrodes **208**. The drug region releases a selected drug, such as a steroid, adjacent to the point of sensing or stimulation. The selected drug or combination of drugs from the drug region is used to avoid acute and chronic increases in the stimulation threshold caused by inflammation or fibrosis, for example. In addition, thrombus formation may generally be avoided or reduced by the administration of suitable drugs. Regardless of each drug's purpose, a threshold dose of the drug must be provided in order to evoke a desired effect. Advantageously, the present leads include a drug region **236** configured and positioned to deliver (e.g., elude) the requisite amount of drug needed to come into contact with a desired electrode or to effectuate a desired outcome for actions of the at least two electrodes **208**.

In particular, FIG. **4A** illustrates a lead **104** having four electrodes **208** and two drug regions **236**. The drug regions **236** are disposed such that one region is between a first and second electrode (i.e., a first electrode pair), while the other drug region **236** is between a third and a fourth electrode (i.e., a second electrode pair). The electrodes comprising each electrode pair can be positioned close together on the lead body **212** to accommodate a (relatively) short drug

region **236**, or they can be spaced far apart for use with a (relatively) long drug region **236**. Even if the first and second or third and fourth electrodes are positioned close together on the lead body **212**, the distance between the first and third electrodes **410** or the second and fourth electrodes **420** can be set to a desired sensing or stimulation distance (e.g., 10-11 mm).

As shown in FIG. **4A**, the shared drug region (lead) construction still allows for multiple sensing or stimulation vectors, such as **430**, **432**, **434**, **436**, among others. Multiple sensing or stimulation vectors advantageously allow for an electrode configuration which provides a desirable combination of electrode contact with myocardial tissue, low stimulation thresholds, avoidance of unintended stimulation of the phrenic nerve or diaphragm, or beneficial heart remodeling. In addition, the first and second or third and fourth electrodes may be electrically coupled (e.g., a hard (wire) connection or in the IMD **102** electronically), thereby providing an increased surface area (and lower thresholds) to sense or stimulate from.

As illustrated in FIGS. **4B-4I**, the present subject matter is not limited to a lead **104** having four electrodes (i.e., a quad-polar lead) and two drug sharing regions **236**; rather, any number, type (e.g., ring-like or coil-like), or combination of electrodes **208** and drug regions **236** may be used, such that two or more of the electrodes share the same drug region **236**.

Referring specifically to FIGS. **4G-4H**, additional features **402** may be placed near an edge of a drug region **236** to provide structural strength or fixation mechanisms to the lead **104**. For instance, polyurethane rings may be placed adjacent to the one or more drug regions **236** to increase axial strength of the lead **104**. Such polyurethane rings may be fused or bonded to the underlying lead material, for example. As further shown in FIGS. **4G-4H**, the shared drug region **236** need not be directly adjacent the two or more electrodes **208** to which it is shared. Rather, the shared drug region **236** may be positioned a short distance **408** (e.g., between about 0 to about 0.75 cm, such as about 0.5 cm) away from one or both of the two or more electrodes **208** so long as it can provide an anti-inflammatory or other benefit to the electrodes at desired times.

As shown in FIG. **4I**, the two or more electrodes **208** that share a drug region **236** may comprise coil electrodes. Typically, it is the (ring-like) pacing

electrodes (as shown in FIG. **4H**) which have the most need for a drug region positioned nearby; however, coil-like electrodes (as shown in FIG. **4I**) may also have a need for a shared drug region in certain circumstances such as for reducing inflammation due to electrode abrasion on tissue or for reducing inflammation after trauma of shock. Some drug formulations may lower shocking thresholds. In one example, a biocompatible cable **404** (e.g., Pt-Clad Tantalum) goes from a straight cable to a wound coil electrode. This wound coil electrode could be made longer, as needed, to better ensure contact with myocardium or other bodily tissue.

Contents, structure, and size of the shared drug region **236** may vary depending on, among other things, the desired use of the region. As one example, the drug comprised in the drug region **236** may be one which is intended to counter thrombus formation, fibrosis, inflammation or arrhythmias, or any combination of drugs intended to accomplish one or more of these purposes, or any drug or combination of drugs intended to accomplish any other desirable localized purpose or purposes. As another example, the drug region **236** may be of any length or thickness to contain and apply the desired amount of drug to each electrode to which it is shared. As yet another example, the drug region **236** may be a separate element (e.g., a collar-like structure) secured to the lead body **212** (FIG. **2**) or may be integrally molded into the lead body.

In one specified example, the drug region **236** comprises a carrier material and a drug. Typically, the carrier material is selected and formulated for an ability to incorporate the desired drug during manufacture and release the drug within a subject **106** (FIG. **1**) after implantation. The carrier material may comprise, among other things, silicone rubber or other polymer (e.g., polyurethane, polyethylene, ethylene-tetrafluoroethylene (ETFE), polytetrafluoroethylene (PTFE), polyetheretherketone (PEEK)) or material (e.g., metal, porous ceramics) that can hold or elute a drug. Alternatively, the carrier material may comprise a porous or non-porous material onto which a drug may be collated. The amount of any particular drug incorporated into the drug region **236** is often determined by the effect desired, the drug's potency, or the rate at which the drug capacity is released from the carrier material, as well as other factors.

In another specified example, the drug region **236** comprises a drug eluting matrix that elutes over time. In one such example, the drug eluting matrix is a steroid compounded with an uncured silicone rubber. Upon curing, the steroid becomes incorporated into a hardened polymeric binder. The curing process, in one example, is performed within a mold to produce a desired matrix shape. For instance, for a pacing lead, a rod or tube of dexamethasone acetate in silicone rubber is cut to form a plug or ring, respectively.

FIG. **5** illustrates a lead **104** having a lead body **212** extending from a lead proximal end portion **202** to a lead distal end portion **204** and having a lead intermediate portion therebetween **203**. The lead proximal end portion **202** includes a connector assembly **502** adapted to couple with a medical device, such as an IMD **102** (FIG. **1**), and specifically an electronics circuitry portion **250** contained within the IMD (FIG. **2**). The lead distal end portion **204** includes one electrode **208** proximal and distal to a tine region **504**, used for fixing the lead **104** at a desired location within a subject **106** (FIG. **1**). The electrodes **208** are coupled with the connector assembly **502** via one or more electrical conductors **506** contained within the lead body **212**. FIG. **5** further illustrates that a drug region **236** may be disposed on, or integrated with, portions of the tine region **504** and be shared by each of the electrodes **208**.

As discussed above, it is advantageous that an electrode configuration used to stimulate bodily tissue have a low stimulation threshold to reduce device battery drain, and thus, increase device life, or eliminate phrenic nerve or diaphragmatic stimulation. FIGS. **6A-6B** illustrate leads **104** having a preformed bias portion **602** at a lead intermediate **203** or distal end portion **204**. The preformed bias portions **602** may help ensure a reliable and stable lead/vessel wall area interface, and in turn, lower stimulation thresholds. Specifically, FIG. **6A** illustrates a lead **104** having a helical preformed bias portion **602**, while FIG. **6B** illustrates a lead **104** having a sinusoidal curve preformed bias portion **602**. The leads **104** including the preformed bias portion **602** may include two or more electrodes **208** positioned on the lead body **212** to share a drug region **236**. As shown in FIG. **6A**, the electrodes **208** and shared drug region **236** may be positioned on the preformed bias portion **602** to contact a vessel (e.g., coronary

vein **250**) wall **604**. As shown in FIG. **6B**, the preformed bias portion **602** may include a curve height **606** of a variety of sizes.

Leads **104** having the preformed biased portion **602** will typically include a lumen **706** (FIG. **7**) into which a stylet or guidewire may be inserted. The stylet or guidewire are typically wires that straighten out the lead **104** while it is being placed within a heart **108** or other desired portion of a subject **106** (FIG. **1**). By removing the stylet or guidewire, the lead will take on its natural or preformed shape, which in the example of FIG. **6A** is a helical curve and in the example of FIG. **6B** is a sinusoidal curve.

FIG. **7** illustrates a cross-sectional view of a lead **104**, such as taken along line **7-7** of FIG. **4A**. The lead **104** shown in FIG. **4A** includes four electrodes **208** and two shared drug regions **236**, one of which is shown here in cross-section. The electrodes **208** are electrically coupled to an electronics circuitry portion **250** (FIG. **2**) of an IMD **102** via one or more conductors **506** carried by a plurality of lumens **702** within the lead body **212**. As the line along which the cross-section of FIG. **7** is distal to at least one electrode **208**, one of the plurality of lumens **702** is shown with a plug **704** therein. A coil conductor **708** optionally used includes a lumen **706** to allow passage of a guidewire or stylet therethrough.

Surrounding the lead body **212** is a first drug region **236** shared by the two most proximal electrodes **208** of the lead **104** shown in FIG. **4A**. Any means of depositing the drug region **236** on the lead body **212**, whether physical or chemical, may be used. In one example, the drug region **236** comprises a drug ring that is fused to the lead body **212**. In another example, the drug region **236** comprises a drug impregnated porous medium, such as ceramic metal or polymer. In yet other examples, the drug region **236** is sprayed, dipped, painted, or similarly deposited on an outer surface of the lead body **212**.

FIG. **8** is a schematic drawing illustrating portions of a system **100** adapted to sense or stimulate (e.g., pace, defibrillate, or cardiovert) a heart **108** of a subject **106** (FIG. **1**) at multiple locations within, on, or near the same. In the example shown, system **100** includes a hermetically sealed medical device, such as an IMD **102**, and an external programmer **110**. The IMD **102** is connected to the heart **108** by way of at least one lead **104**. In varying examples,

the at least one lead **104** includes at least two electrodes **208**, which share a drug region **236**. In one example, the lead **104** includes four electrodes **208** and two shared drug regions **236**. Through the use of shared drug regions **236**, the opportunity exists to use leads having more than two electrodes, while still providing the desired drug benefits to each electrode – all without requiring additional safety and efficacy testing and the expense associated with incorporating additional drug regions to a lead. Leads having more than the conventional one or two electrodes provide a greater number of electrode configurations to sense or stimulate across. As a result, an electrode configuration which prolongs the life of the IMD **102**, or other useful benefit, may be selected.

Among other things, the IMD **102** includes a signal processing circuit **802**, a sense/stimulation energy delivery circuit **804**, a sense measurement circuit **806**, an electrode configuration multiplexer **810**, a drug delivery circuit **824**, and a power source **812**. Among other things, external programmer **110** includes an external/internal sensor receiver **816** and an external user-interface **818** including a user-input device. The external/internal sensor receiver **816** is adapted to receive subject specific information from one or more internal or external sensor(s).

The signal processing circuit **802** is adapted to sense the heart **108** in a first instance and stimulate the heart in a second instance, each of which occur by way of one or more (optimal) electrode configuration selected from the two or more electrodes **208** of each lead **104** (FIG. **2**) implanted within the subject **108** (FIG. **1**) (including intralead and interlead combinations) and one or more indifferent electrode (e.g., a header or housing electrode of the IMD **102**). In one example, the IMD (specifically, the signal processing circuit **802**) is adapted (i.e., programmed) to automatically analyze all possible electrode configurations of the system **100** and select the one or more electrode configuration to be used in sensing or stimulating the heart **108**. The IMD **102** may be further adapted (e.g., via an ongoing evaluation/ selection module **823**) to monitor and re-select the one or more electrode configuration as necessary).

In another example, the programmer **110** is adapted (i.e., programmed) to automatically analyze all possible electrode configurations of the system **100** and

select the one or more electrode configuration to be used in sensing or stimulating the heart **108**. In yet another example, the one or more electrode configuration used to sense or stimulate the heart **108** is selected manually by a caregiver (e.g., an implanting physician), and communicated to the IMD **102** (e.g., signal processing circuit **802**) using a telemetry device **112** (FIG. **1**) and a communication circuit **820** of the IMD. In the example shown, such automatic or manual selection of the one or more electrode configuration is stored in a memory **822**. In yet another example, the one or more electrode configuration used to sense the heart **108** in a first instance and stimulate the heart in a second instance are the same. In a further example, the one or more electrode configuration used to sense the heart in a first instance and stimulate the heart in a second instance are different.

The one or more electrode configuration may be selected (either automatically or manually) using, at least in part, one or a combination of a stimulation threshold parameter, a stimulation impedance parameter, a stimulation selection parameter, a heart chamber configuration parameter, or a spatial distance parameter, all of which are further discussed below. Other parameters that may be used to select the one or more electrode configuration include a sense voltage parameter, a sense noise parameter, a tissue electrode location parameter, a heart chamber configuration parameter, a blood flow parameter, a posture parameter, a blood volume parameter, an acceleration or motion parameter, a timing parameter, an impedance parameter, a blood oxygen level parameter, or a stimulation energy parameter. In one example, at least one of the foregoing parameters are evaluated by way of a logic module **814** of the signal processing circuit **802** and is used in the selection of the one or more electrode configuration used to sense or stimulation the heart **108**.

In one example, a stimulation threshold parameter is used in the selection of the one or more electrode configuration for stimulating the heart **108**. In varying examples, some or all possible electrode configurations are or may be evaluated to determine which one or more configuration (optimally or acceptably) requires the lowest amount of output energy (i.e., stimulation pulse or shock) be applied to the heart **106** for capturing of the same. In one such example, capturing of the heart **108** is determined by monitoring electrical

activity of at least one of the right atrium **220** (FIG. **2**), the right ventricle **224** (FIG. **2**), the left atrium **222** (FIG. **2**), or the left ventricle **226** (FIG. **2**) in response to a stimulation pulse or shock of predetermined amplitude. Electrical activity may be determined by using one or more sensor, such as an ultrasound, an accelerometer, or the like, to measure the hemodynamic response to pacing. The presence or absence of such hemodynamic response during an appropriate time period following the stimulation pulse or shock indicates a resulting capture and no capture, respectively.

Advantageously, by providing a system **100** adapted to determine to which one or more electrode configurations require the lowest amount of energy be delivered while still ensuring reliable capture of the heart **108**, the life of the IMD **102** may be prolonged, thereby minimizing the risk and expense to the subject **106** (FIG. **1**) associated with early explantation and replacement of the IMD. In one example, the system **100** includes an autothreshold determination module **815** adapted to automatically determine whether a stimulation pulse or shock delivered through a first electrode configuration has evoked a desired response from the heart **108**, and if not, testing a second, third, . . ., etc. electrode configuration for the desired heart response.

In another example, a stimulation impedance parameter is used in the selection of the one or more electrode configuration for stimulating the heart **108**. In varying examples, some or all possible electrode configurations are or may be evaluated to determine which one or more configuration (optimally or acceptably) possess the lowest impedance at an electrode **208**/heart tissue **108** interface. Advantageously, by providing a system **100** adapted to determine which one or more electrode configuration possesses the best heart tissue contact, the life of the IMD **102** may be prolonged as result of less battery drain from stimulating the heart.

In another example, a stimulation selection parameter is used in the selection of the one or more electrode configuration for stimulating the heart **108**. In varying examples, some or all possible electrode configurations are or may be evaluated to determine which one or more configurations (optimally or acceptably) provides appropriate therapy to one or more chambers of the heart **108** while minimizing phrenic nerve or diaphragmatic stimulation.

Advantageously, by providing a system **100** adapted to determine which one or more electrode configurations provides an appropriate balance between pulse or shock stimulation to the heart **108**, while minimizing phrenic nerve or diaphragmatic stimulation ensures the subject **106** does not experience undesirable side effects.

In yet another example, a heart chamber configuration parameter is used in the selection of the one or more electrode configuration for stimulating the heart **108**. In varying examples, some or all possible electrode configurations are or may be evaluated to determine which one or more configuration (optimally or acceptably) allow for sequential or multi-chamber (e.g., four-chamber) stimulation of the heart for optimum hemodynamic responses. In still another example, a spatial distance parameter is used in the selection of the one or more electrode configuration for stimulating the heart **108**.

As illustrated in the example of FIG. **8**, the IMD **102** may include the sense/stimulation energy delivery circuit **804** and the sense measurement circuit **806** to sense intrinsic or responsive activity of (e.g., in the form of sense indication signals), and provide stimulation (e.g., pacing, defibrillation, or cardioversion) to, the heart **108**, respectively. In one such example, but not by way of limitation, the sense/stimulation energy delivery circuit **804** delivers a pacing pulse stimulation via a lead **104** (FIG. **2**) to one or more electrode **208** located in a right ventricle of the heart **108**. Such pacing stimuli are usually delivered at a time when the particular heart chamber is in a relaxed, passive state and is being filled with blood. If the delivered pacing stimulus captures the heart, myocardial tissue near the pacing site of the electrode **208** begins to contract, which may be detected by the sense measurement circuit **806**. If the delivered pacing stimulus does not capture heart **108** (which may also be detected by the sense measurement circuit**806**), such tissue does not begin to contract. Similarly, defibrillation or cardioversion stock stimulation may also be applied to the heart **108**, with responsive heart activity detected by the sense measurement circuit **806**. In addition, the IMD **102** may include the electrode configuration multiplexer **810** to electrically connect electronics of the IMD to the one or more selected electrode configuration.

FIG. **8** illustrates one conceptualization of various circuits, modules, and devices, which are implemented either in hardware or as one or more sequence of steps carried out on a (micro)processor or other controller. Such circuits, modules, and devices are illustrated separately for conceptual clarity; however, it is to be understood that the various circuits, modules, and devices of FIG. **8** need not be separately embodied, but may be combined or otherwise implemented, such as in hardware, software, or firmware. Although not shown in FIG. **8**, the IMD **102**, such as the signal processing circuit **802**, may further include amplification, demodulation, filter, analog-to-digital (A/D) conversion, digital-to-analog (D/A) conversion, and other circuits for extracting and storing information obtained through the system **100**.

FIG. **9** is a flow chart illustrating a method **900** of manufacturing a lead for use in a system adapted to sense or stimulate a heart, brain, or other desired region of a subject. At **902**, a lead body extending from a lead proximal end portion to a lead distal end portion, and having an intermediate portion therebetween, is formed. In one example, forming the lead body includes forming a preformed bias portion at one or both of the lead intermediate or distal end portion. In one such example, the preformed bias portion includes a two-dimensional shape, such as a sinusoidal curve or wave. In another such example, the preformed biased portion includes a three-dimensional shape, such as a helical or other shape that conforms to heart anatomy.

At **904**, a first and a second electrode are disposed on the lead body. The first and second electrodes are typically disposed on the lead intermediate or distal end portion. The preformed biased portion, as mentioned in association with **902**, is one option for increasing the probability of optimal or acceptable interfacing between the first and second electrodes and tissue or veins of the heart, such as a coronary vein. At **906**, the first and second electrodes are optionally electrically coupled. By coupling the first and second electrodes, a larger (effective) surface area is created, thereby increasing the probability of making a satisfactory electrical connection between the electrodes and desired bodily tissue to be sensed or stimulated. At **908**, a drug region is disposed on the lead body, such that a drug therein may be shared by the first and second

electrodes. In varying examples, the drug region is disposed between the first and second electrodes on the lead body.

At **910**, a third and a fourth electrode spaced from the first and second electrodes are optionally disposed on the lead body. At **912**, the third and fourth electrodes are optionally electrically coupled. At **914**, another drug region is disposed on the lead body, such that a drug therein may be shared by the third and fourth electrodes. Additionally, the method may further include coupling a terminal pin and at least one terminal ring (collectively, one example of a "connection assembly" as referred to herein) are coupled along the lead proximal end portion. The connection assembly is configured to electrically and mechanically couple with a cavity and electrical connections of a medical device, such as an IMD. Further yet, the method may comprise disposing two or more conductors within the lead body, thereby electrically coupling the electrodes and the connection assembly.

The lead constructions discussed herein provide numerous advantages over conventional lead designs including, among other things, a minimization of a drug amount needed (on a per lead basis) and a reduction or elimination of new drug safety and efficacy testing required (as drug dosage is similar to historical data), while still allowing multiple sensing/stimulation vectors and electrode spacing.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For instance, although a majority of the foregoing discusses lead characteristics individually or in specific combinations, any combination of the lead characteristics described herein is within the scope of the present subject matter. In addition, while the above text discusses and figures illustrate, for the most part, implantable leads for use in cardiac situations, the present subject matter is not so limited. Many other embodiments and contexts, such as for non-cardiac nerve and muscle situations (e.g., neurological situations) or for external nerve and muscle situations, will be apparent to those of skill in the art upon reviewing the above description. The scope should, therefore, be determined with reference to the appended claims, along with the full scope of legal equivalents to which such claims are entitled.

WHAT IS CLAIMED IS:

1. A lead comprising:

a lead body extending from a lead proximal end portion to a lead distal end portion, and having a lead intermediate portion therebetween;

an electrical connector assembly coupled to the lead proximal end portion;

at least a first and a second electrode disposed along the lead body, the electrodes electrically coupled to the connector assembly by way of one or more longitudinally extending conductors; and

a drug region disposed between the first and the second electrodes, the drug region configured to be shared by the electrodes.

2. The lead of claim 1, wherein the drug region extends from a first end to a second end, the first end being between about 0 – about 0.75 cm from the first electrode and the second end being between about 0 – about 0.75 cm from the second electrode.

3. The lead of claims 1 or 2, further comprising at least one of a structural strength or fixation mechanism disposed on the lead body near an edge of the drug region.

4. The lead of any of claims 1-3, wherein the drug region comprises a polymeric material mixed with a drug.

5. The lead of claim 4, wherein the drug is dispersed through the polymeric material and a combination thereof is formed into a solid shape couplable with the lead body.

6. The lead of any of claims 1-5, wherein the drug region comprises a drug eluting matrix that elutes one or more drugs over time.

7. The lead of claim 6, wherein the drug eluting matrix comprises at least one drug and at least one drawing agent, the drawing agent having the ability to draw bodily fluid into the matrix for modulating a drug delivery rate of the at least one drug to nearby bodily tissue.

8. The lead of any of claims 1-7, wherein the lead body comprises a preformed bias portion at one or both of the lead intermediate or the lead distal end portion.

9. The lead of claim 8, wherein the preformed bias portion urges one or more of the first electrode, the second electrode, or the shared drug region against a vessel wall, a septal wall, a heart wall, a pulmonary trunk wall, or a pulmonary artery wall.

10. The lead of claims 8 or 9, wherein the preformed bias portion comprises at least one of a helical or sinusoidal shape.

11. The lead of any of claims 1-10, further comprising a third and a fourth electrode; and

wherein a first drug region is positioned between the first and second electrodes and a second drug region is positioned between the third and fourth electrodes.

12. A method comprising:

forming a lead body encasing a substantial portion of one or more electrical conductors, including forming a lead body extending from a proximal end portion to a distal end portion and having an intermediate portion therebetween;

disposing a first electrode on the lead body near the lead intermediate or distal end portion;

disposing a second electrode on the lead body a selected distance away from the first electrode; and

disposing a drug region on the lead body in a position such that the drug is shared by the first and second electrodes.

13. The method of claim 12, wherein disposing the drug region on the lead body includes disposing the drug region on a portion of the lead body between the first and second electrodes, such that the electrodes straddle the drug region.

14. The method of claims 12 or 13, wherein disposing the drug region on the lead body includes spraying, dipping, or painting the drug on the lead body.

15. The method of claims 12 or 13, wherein disposing the drug region on the lead body includes impregnating a porous medium with drug on the lead body.

16. The method of claims 12 or 13, wherein disposing the drug region on the lead body includes fusing a drug ring to the lead body.

17. The method of any of claims 12-16, wherein forming the lead body includes forming a bias portion at or near the lead intermediate or distal end portion.

18. The method of any of claims 12-17, further comprising electrically coupling the first and second electrodes to provide an increased effective electrode surface area.

19. The method of any of claims 12-18, further comprising disposing a third and a fourth electrode on the lead body, and a second drug region therebetween.

20. The method of any of claims 12-19, further comprising disposing a structural strength member on the lead body near an edge of a drug region.

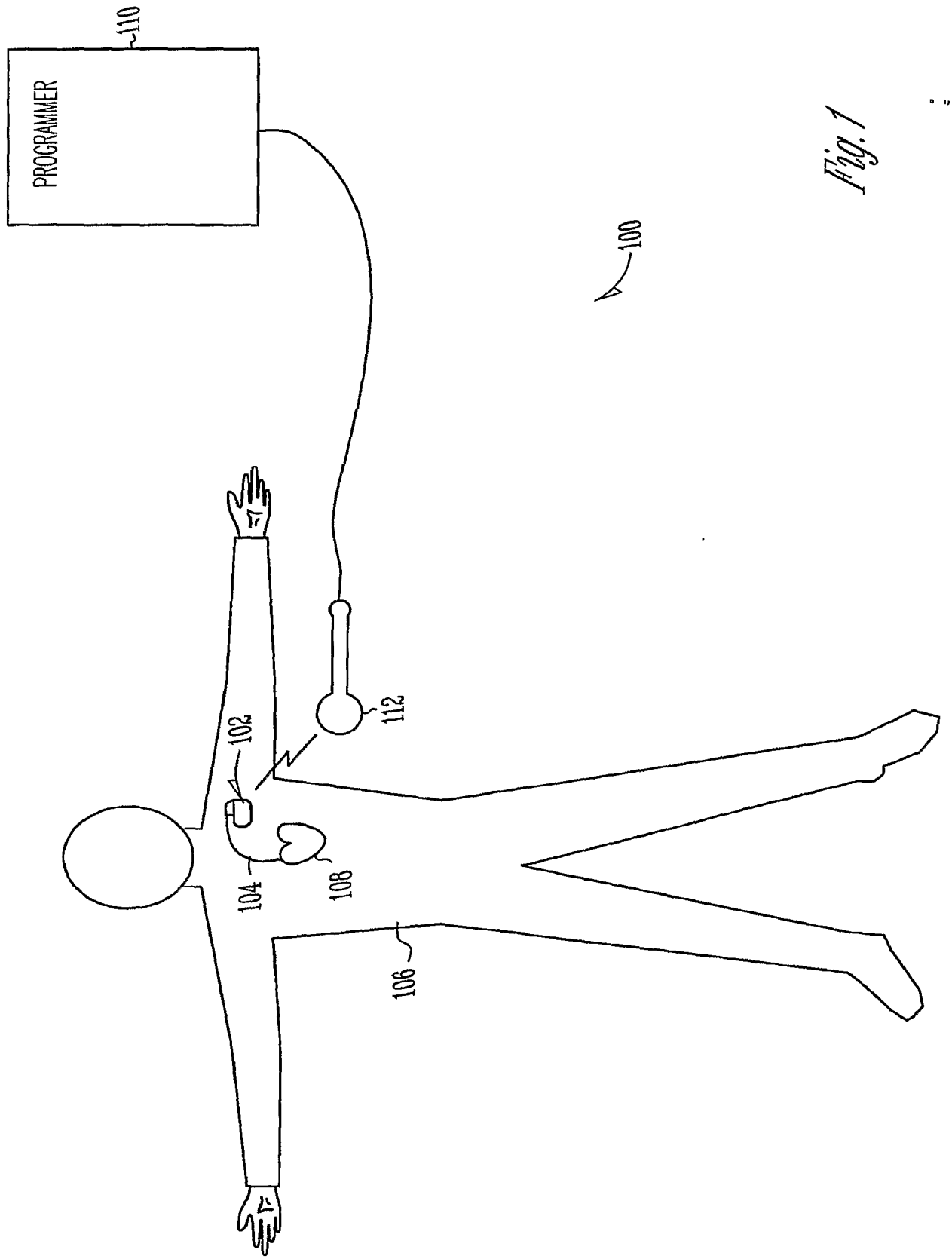
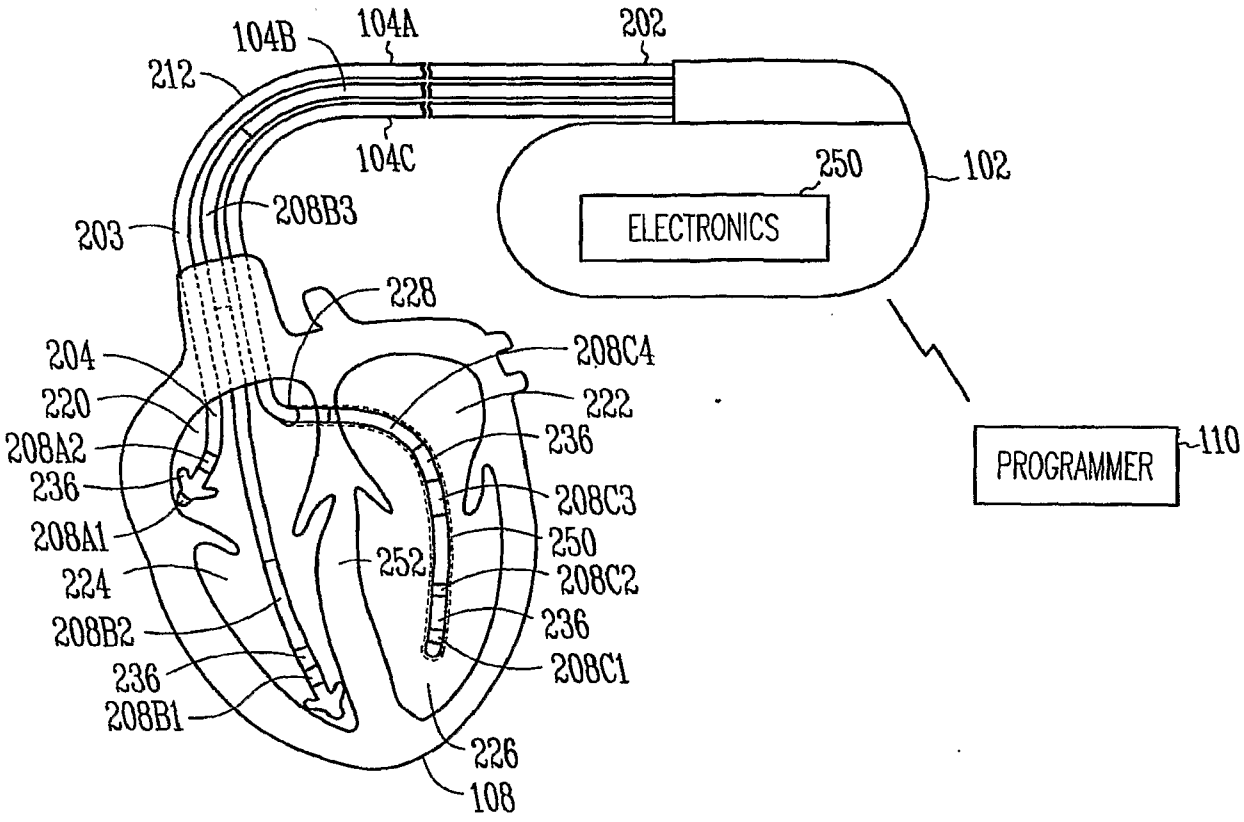


Fig. 1


104B
104A
202
212
104C
250
102
ELECTRONICS
208B3
203
228
204
208C4
220
222
208A2
236
236
208C3
208A1
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208B2
236
236
208C1
208B1
226
108
PROGRAMMER
110

Fig. 2

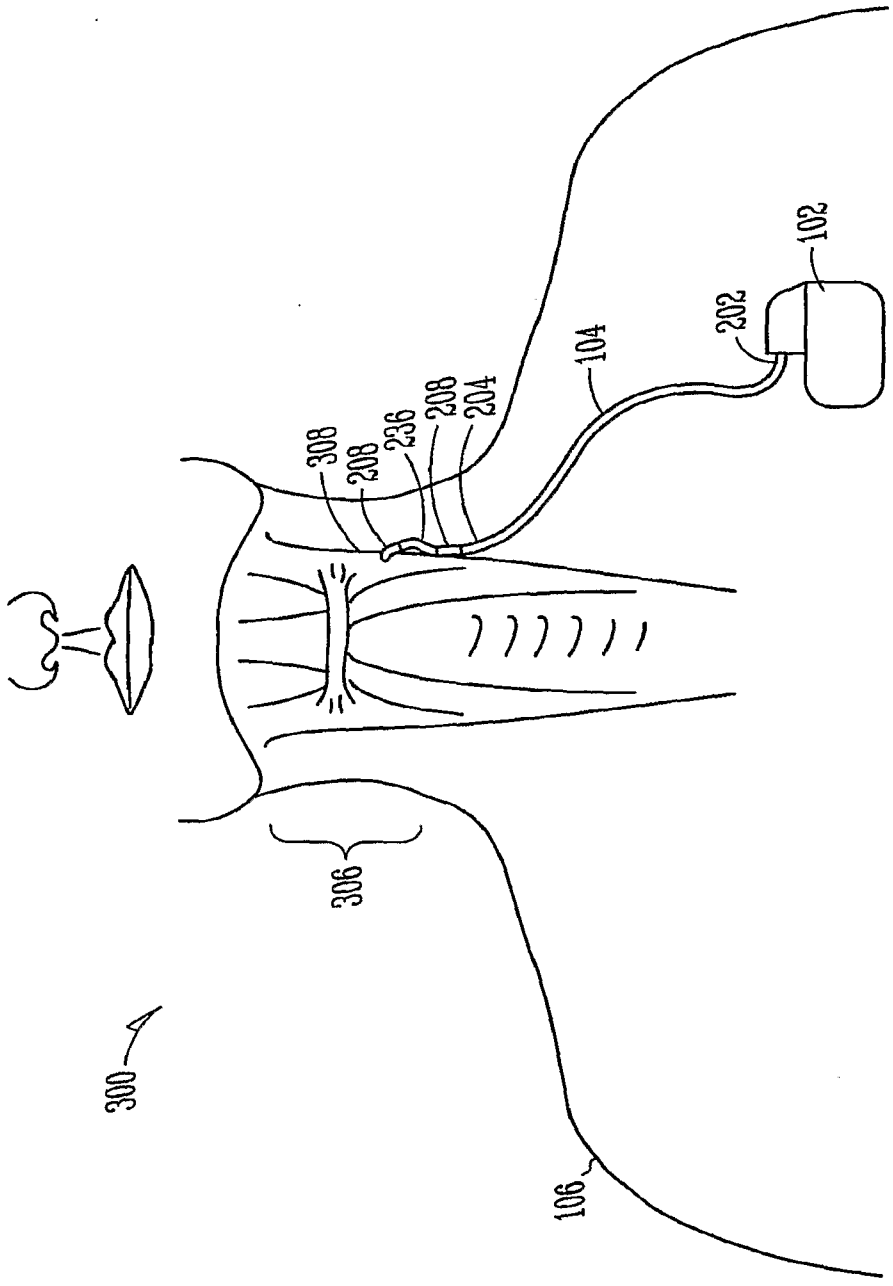

Fig. 3

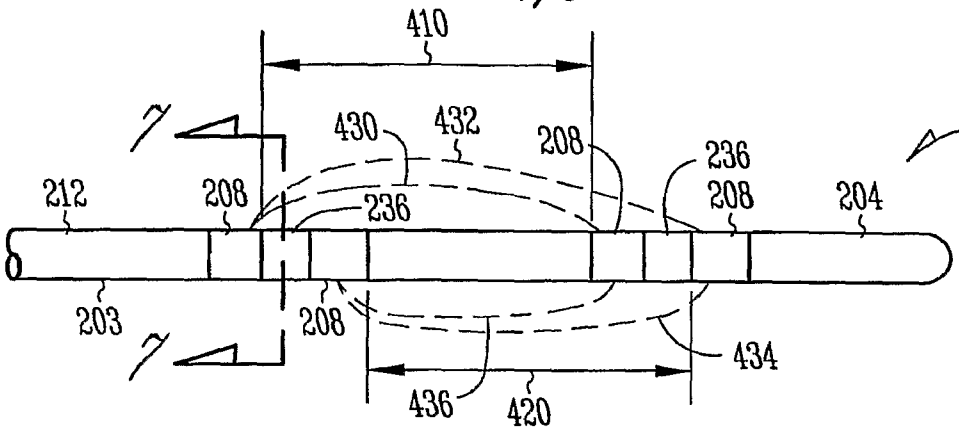

Fig. 4A

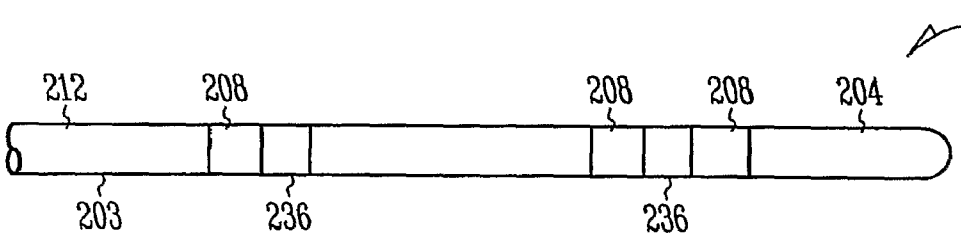

Fig. 4B

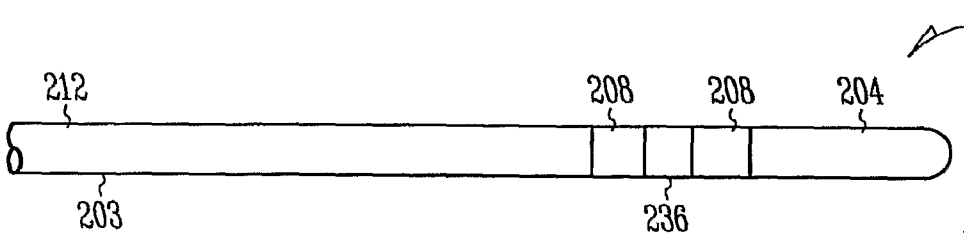

Fig. 4C

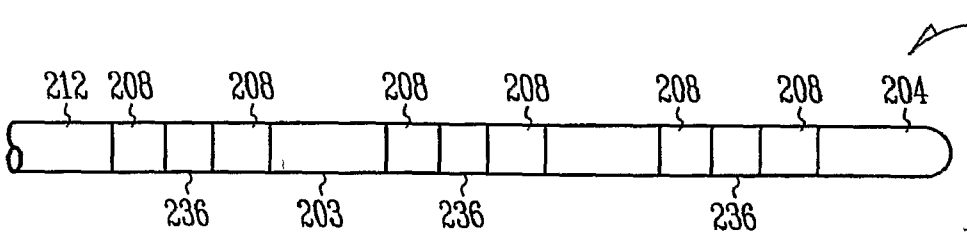

Fig. 4D

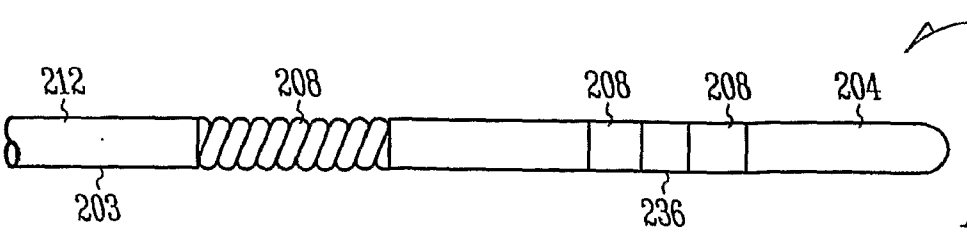

Fig. 4E

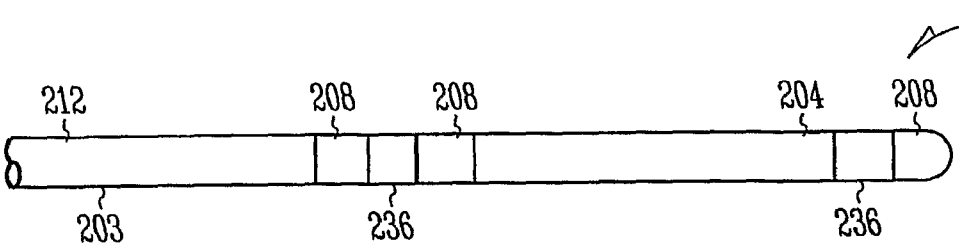

Fig. 4F

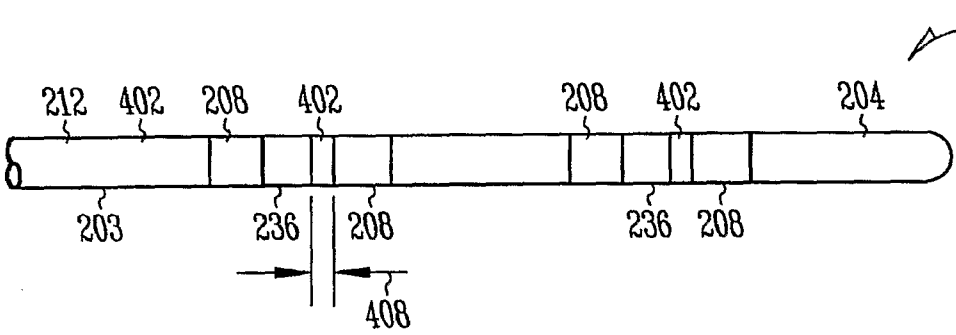

Fig. 4G

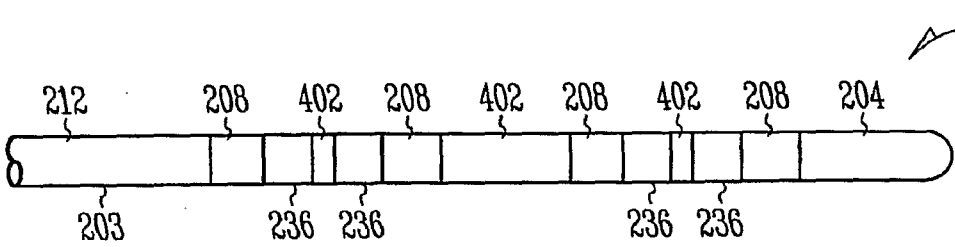

Fig. 4H

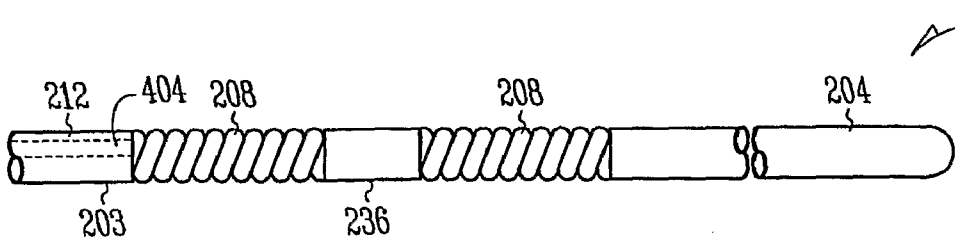

Fig. 4I

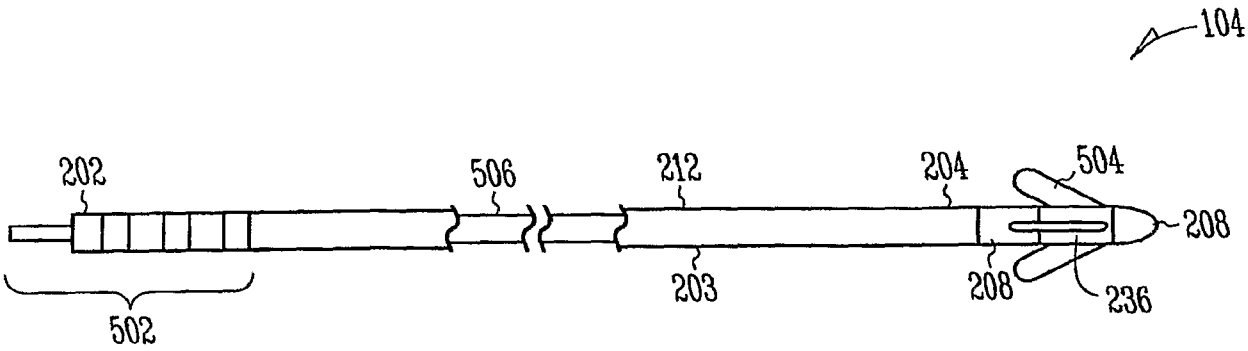

Fig. 5

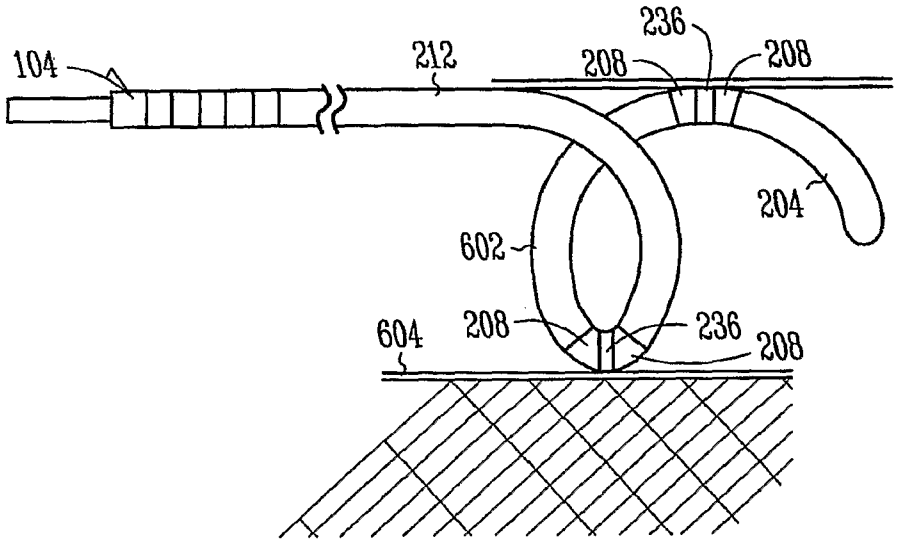

Fig. 6A

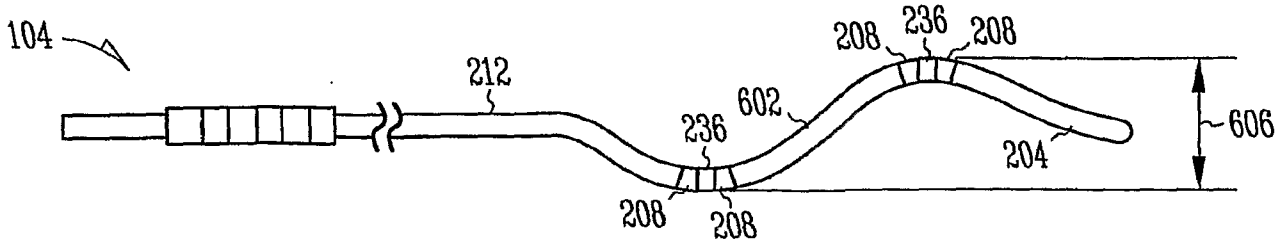

Fig. 6B

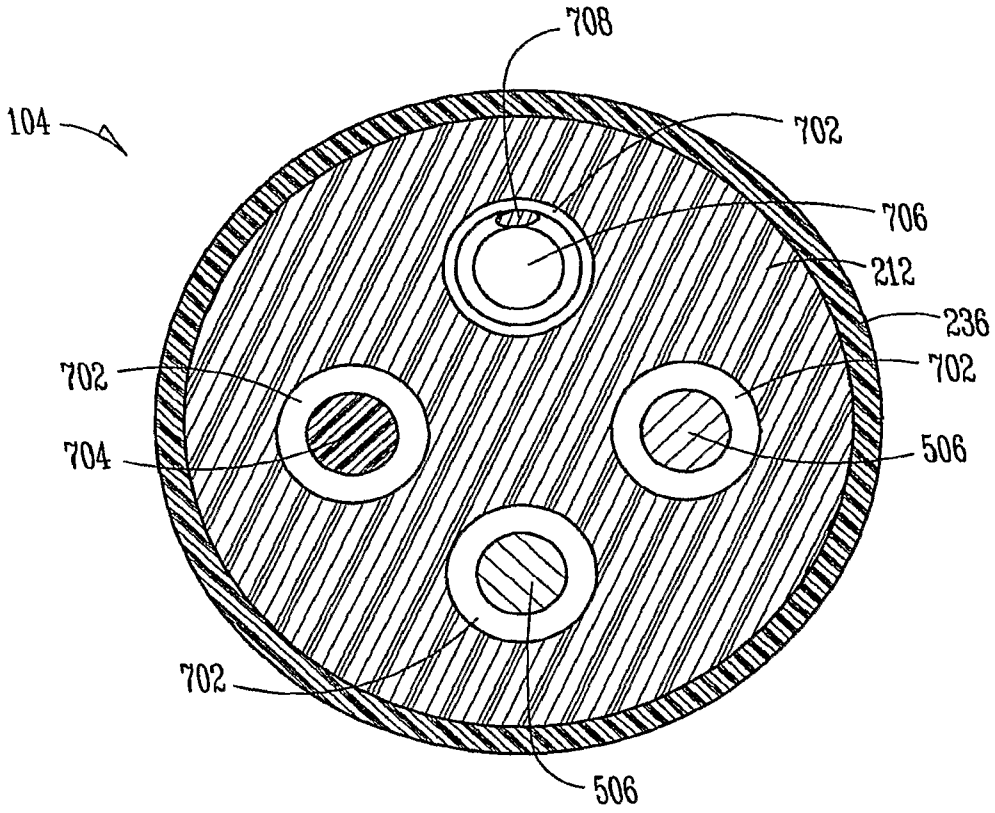

Fig. 7

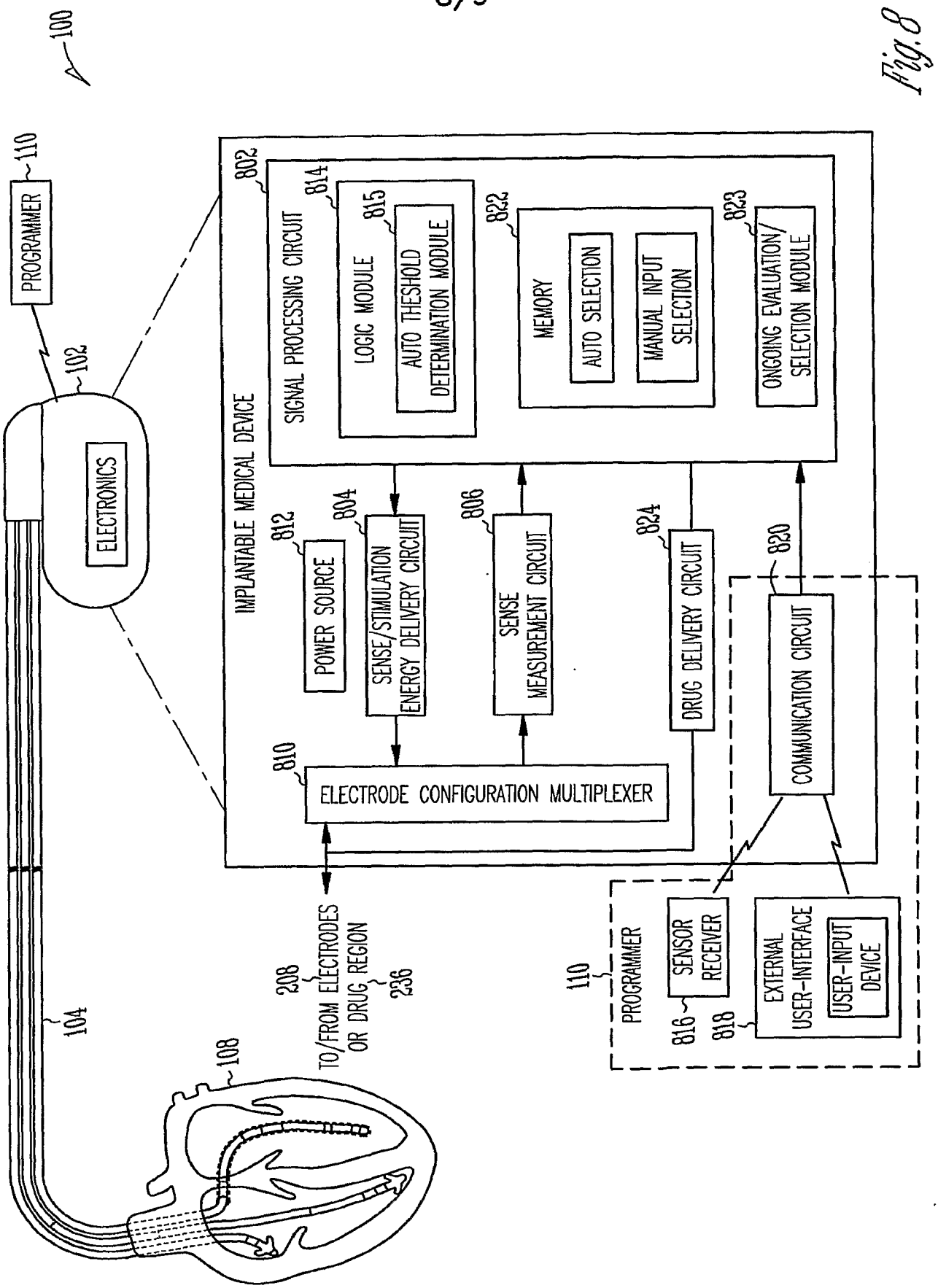
100
PROGRAMMER
110
102
ELECTRONICS
104
108
208
TO/FROM ELECTRODES OR DRUG REGION
236
IMPLANTABLE MEDICAL DEVICE
802
SIGNAL PROCESSING CIRCUIT
814
LOGIC MODULE
815
AUTO THESHOLD DETERMINATION MODULE
822
MEMORY
AUTO SELECTION
MANUAL INPUT SELECTION
823
ONGOING EVALUATION/ SELECTION MODULE
812
POWER SOURCE
804
SENSE/STIMULATION ENERGY DELIVERY CIRCUIT
806
SENSE MEASUREMENT CIRCUIT
824
DRUG DELIVERY CIRCUIT
820
COMMUNICATION CIRCUIT
810
ELECTRODE CONFIGURATION MULTIPLEXER
110
PROGRAMMER
816
SENSOR RECEIVER
818
EXTERNAL USER-INTERFACE
USER-INPUT DEVICE

Fig. 8

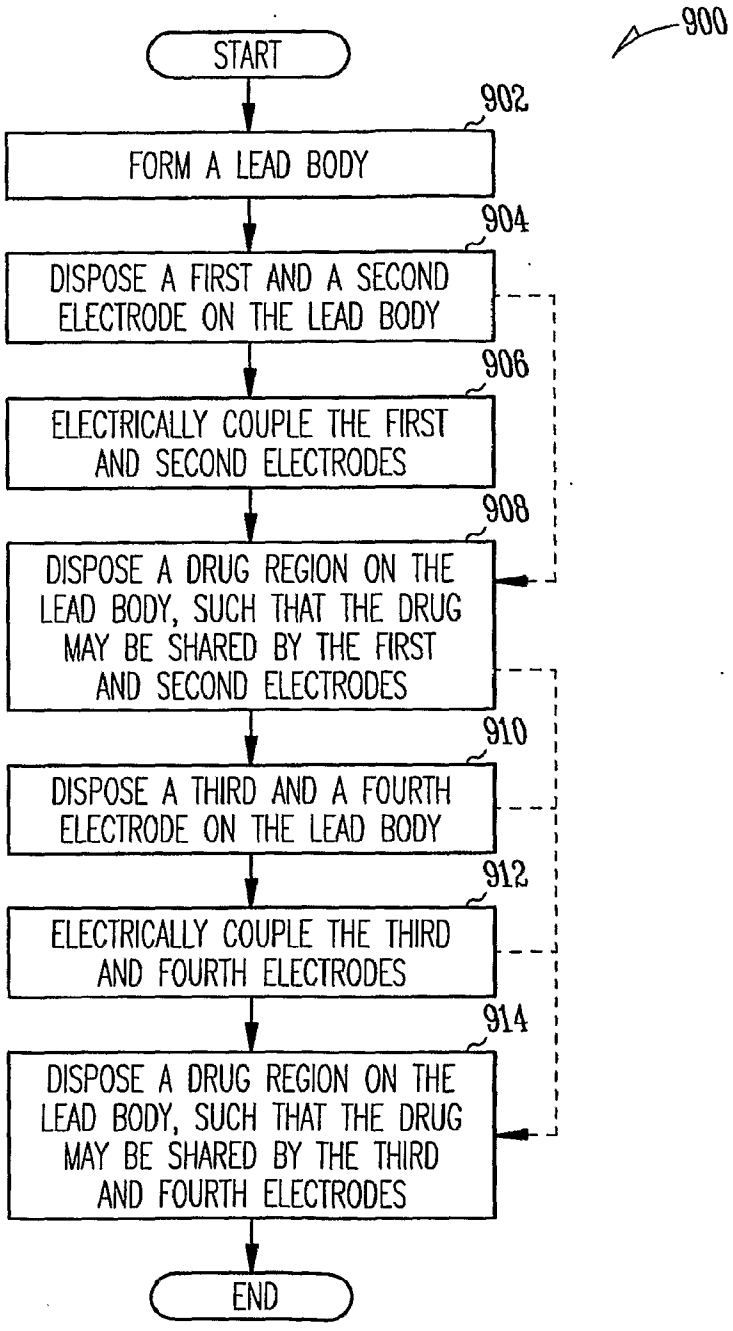
900
START
902
FORM A LEAD BODY
904
DISPOSE A FIRST AND A SECOND ELECTRODE ON THE LEAD BODY
906
ELECTRICALLY COUPLE THE FIRST AND SECOND ELECTRODES
908
DISPOSE A DRUG REGION ON THE LEAD BODY, SUCH THAT THE DRUG MAY BE SHARED BY THE FIRST AND SECOND ELECTRODES
910
DISPOSE A THIRD AND A FOURTH ELECTRODE ON THE LEAD BODY
912
ELECTRICALLY COUPLE THE THIRD AND FOURTH ELECTRODES
914
DISPOSE A DRUG REGION ON THE LEAD BODY, SUCH THAT THE DRUG MAY BE SHARED BY THE THIRD AND FOURTH ELECTRODES
END

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/016841

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05

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

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/064158 A1 (KLEIN GEORGE J [CA] ET AL) 1 April 2004 (2004-04-01) paragraphs [0031], [0033] - [0035], [0038]; figures	1-20
A	US 2006/041299 A1 (BAUER RYAN T [US] ET AL) 23 February 2006 (2006-02-23) paragraphs [0014], [0016], [0019]; figures	1-20

☐ Further documents are listed in the continuation of Box C.

☒ 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

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"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
5 December 2007	17/12/2007

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	RAKOTONDRAJAONA, C

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/016841

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004064158 A1	01-04-2004	WO 2004028621 A2	08-04-2004
		US 2006142814 A1	29-06-2006
US 2006041299 A1	23-02-2006	CN 101031331 A	05-09-2007