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(54) **IMPLANTABLE MEDICAL DEVICE WITH A MOVABLE ELECTRODE BIASED TOWARD AN EXTENDED POSITION**

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(57) **ABSTRACT**

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An IMD may include a housing with a controller and a power supply disposed within the housing. A distal electrode may be supported by a distal electrode support that biases the distal electrode toward an extended position in which the distal electrode extends distally from the distal end of the housing and allows the distal electrode to move proximally relative to the extended position in response to an axial force applied to the distal electrode in the proximal direction. In some cases, the distal electrode support may include a tissue ingrowth inhibiting outer sleeve that extends along the length of the distal electrode support and is configured to shorten when the distal electrode moves proximally relative to the extended position and to lengthen when the distal electrode moves back distally toward the extended position in order to accommodate movement of the distal electrode.

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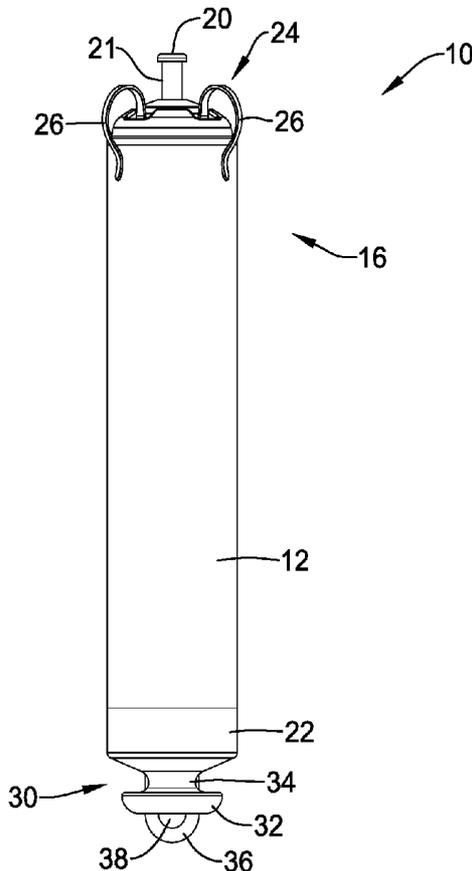
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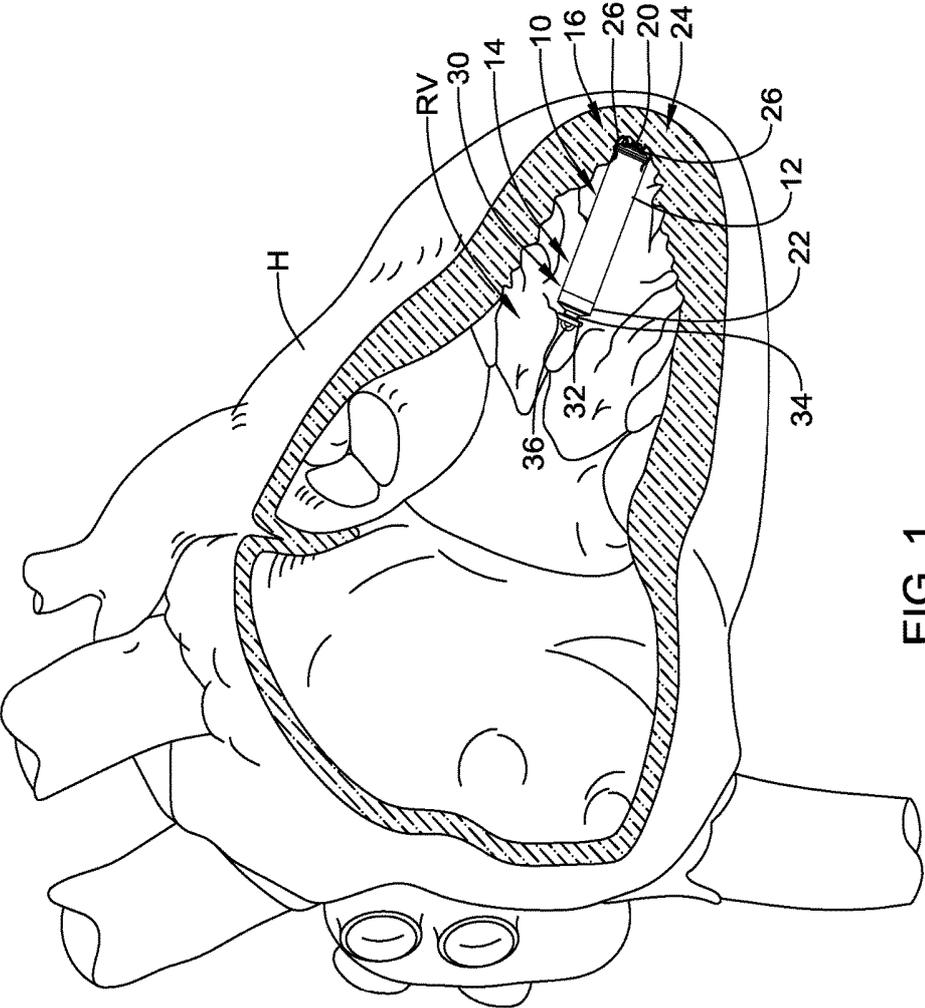


FIG. 1

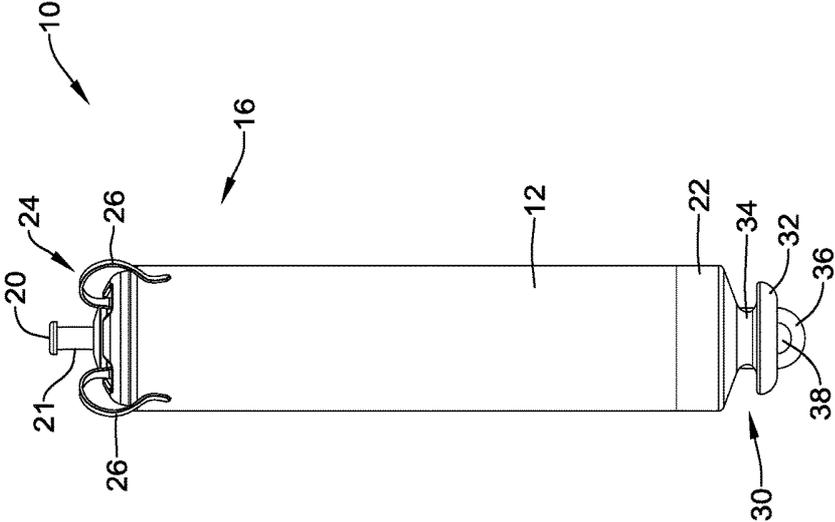


FIG. 2

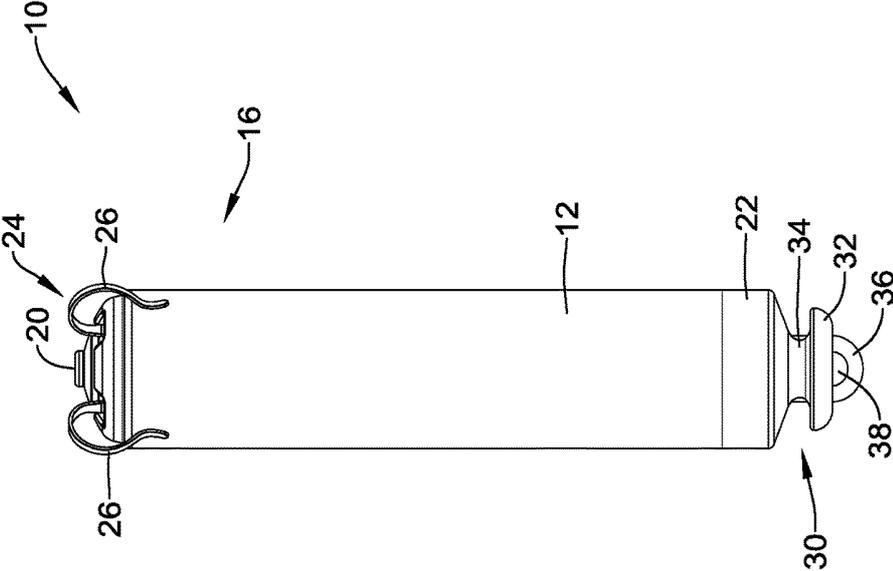


FIG. 3

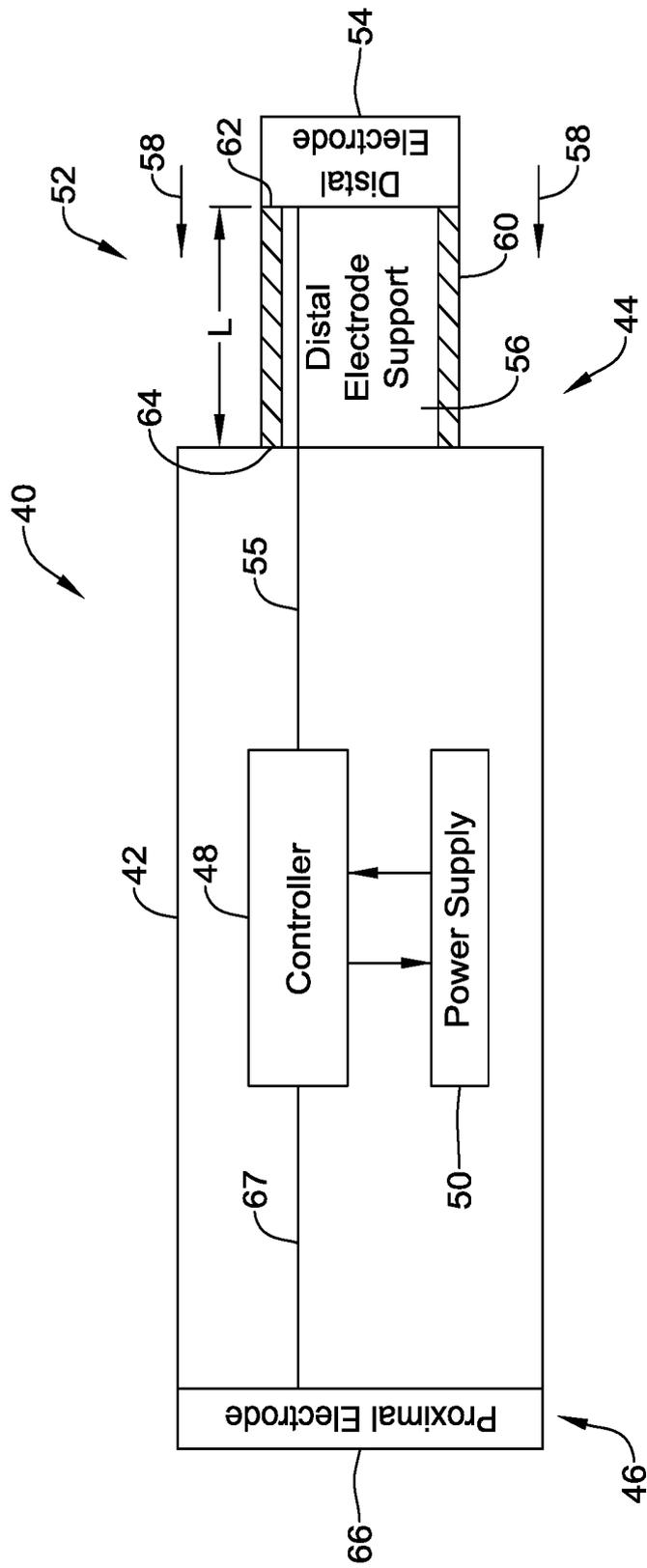


FIG. 4

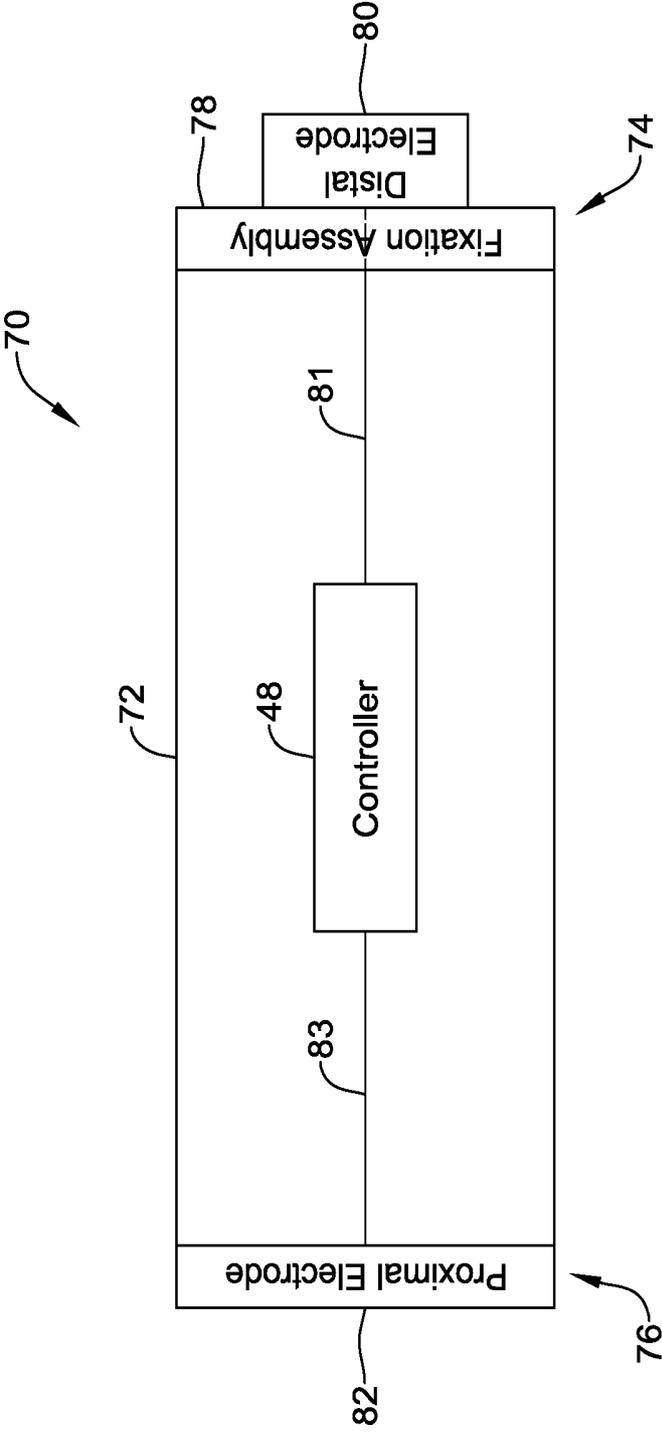


FIG. 5

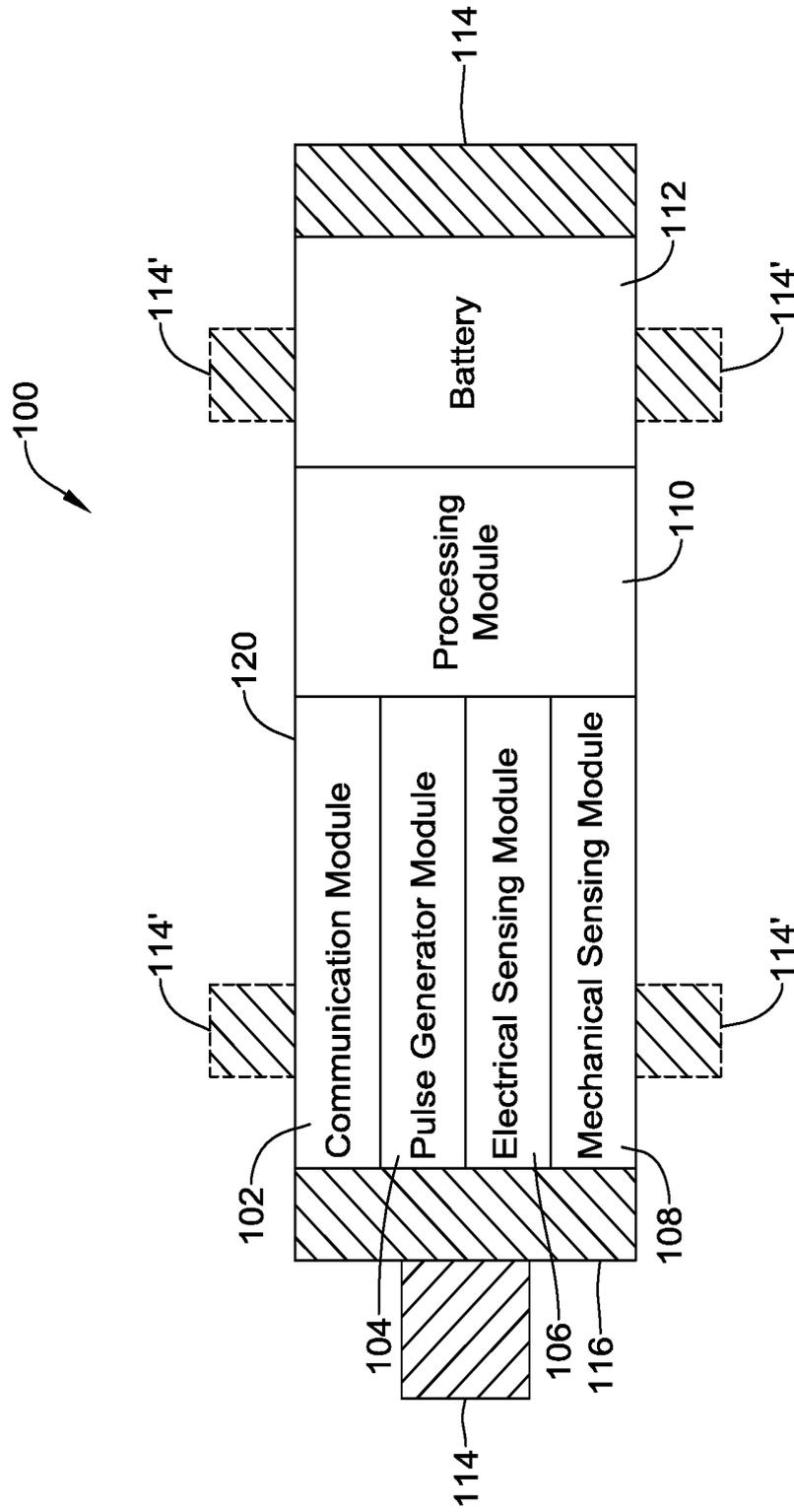


FIG. 6

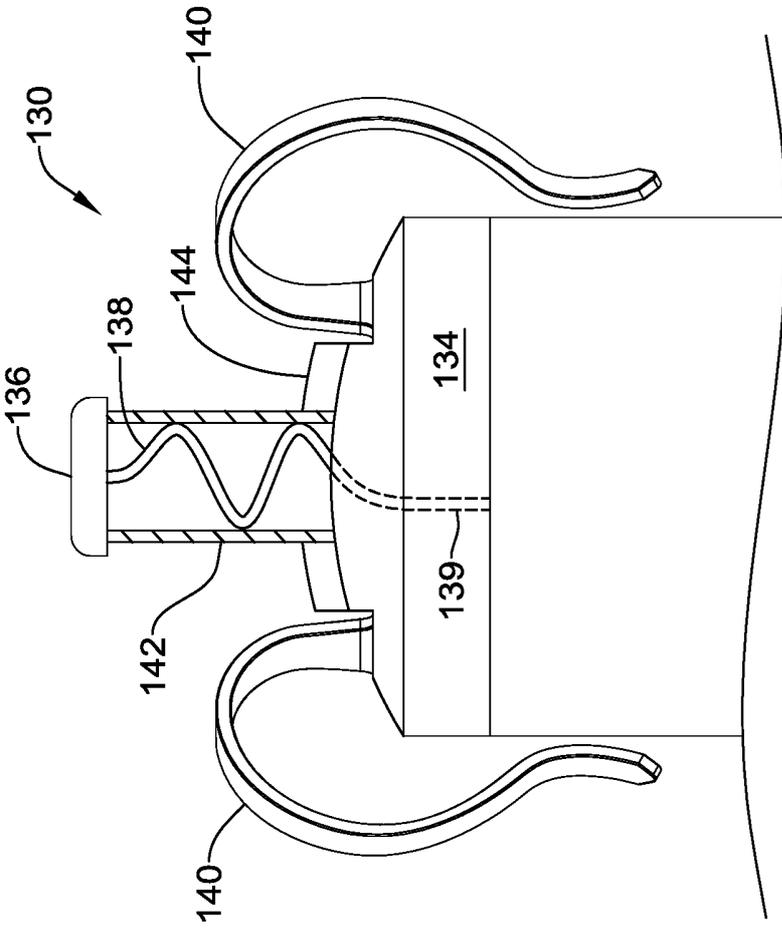


FIG. 7

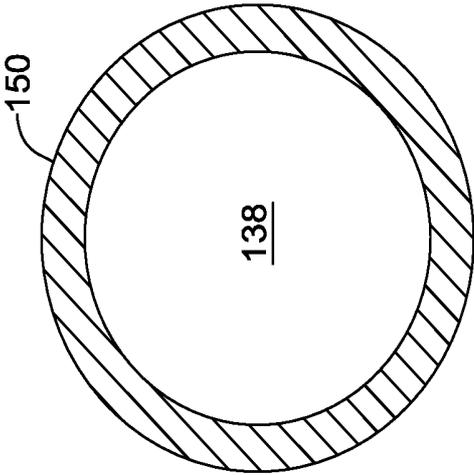


FIG. 8A

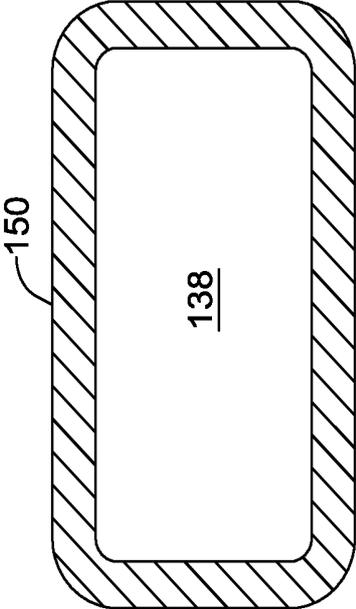


FIG. 8B

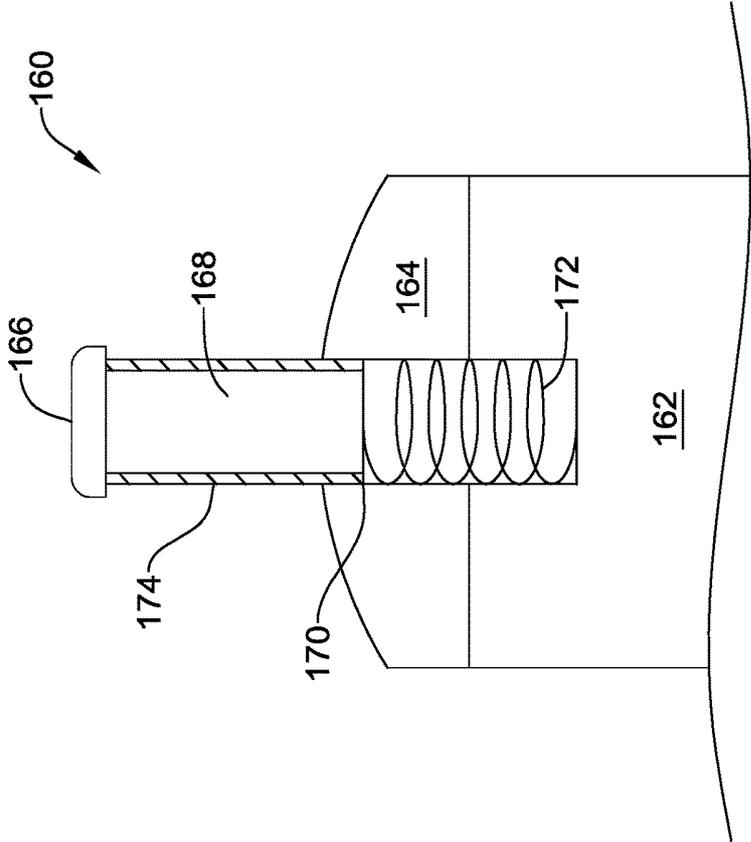


FIG. 9

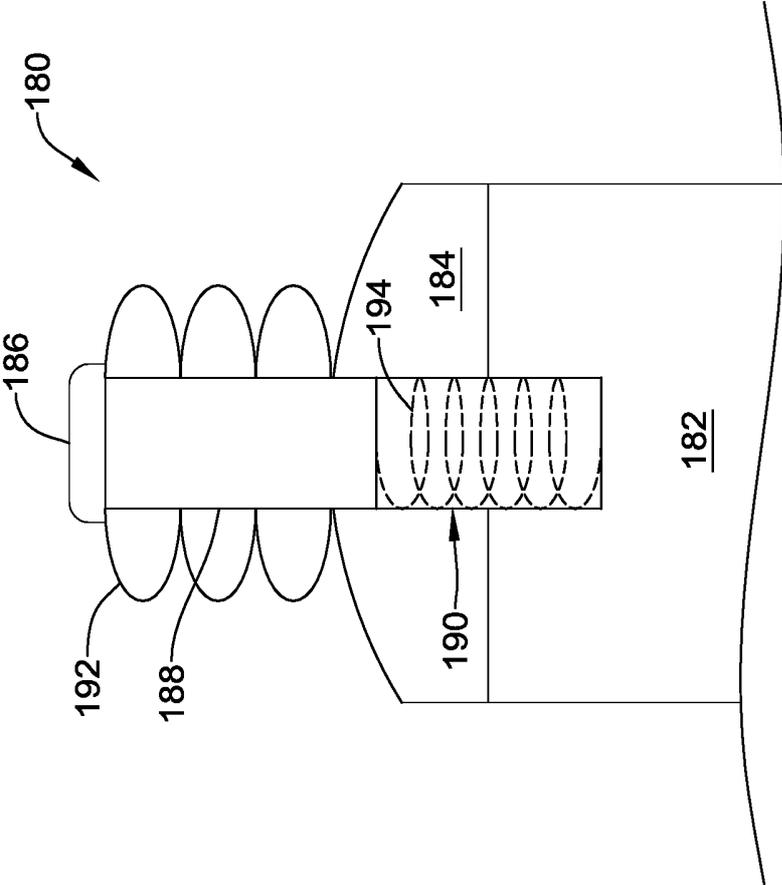


FIG. 10

**IMPLANTABLE MEDICAL DEVICE WITH A
MOVABLE ELECTRODE BIASED TOWARD
AN EXTENDED POSITION**

**CROSS REFERENCE TO RELATED
APPLICATIONS**

[0001] This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/480,741 filed on Apr. 3, 2017, the disclosure of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure pertains to medical devices, and more particularly to implantable medical devices that have an electrode for sensing physiological activity and/or for delivering therapy.

BACKGROUND

[0003] Implantable medical devices are commonly used today to monitor physiological or other parameters of a patient and/or deliver therapy to a patient. For example, to help patients with heart related conditions, various medical devices (e.g., pacemakers, defibrillators, etc.) can be implanted in a patient's body. Such devices may monitor and in some cases provide electrical stimulation (e.g. pacing, defibrillation, etc.) to the patient's heart to help the heart operate in a more normal, efficient and/or safe manner. In another example, neuro stimulators can be used to stimulate tissue of a patient to help alleviate pain and/or other condition. In yet another example, an implantable medical device may simply be an implantable monitor that monitors one or more physiological or other parameters of the patient, and communicates the sensed parameters to another device such as another implanted medical device or an external device.

SUMMARY

[0004] The present disclosure pertains to medical devices, and more particularly to implantable medical devices (IMD) that have an electrode for sensing physiological activity and/or for delivering therapy. The implantable medical devices (IMD) may be, for example, leadless cardiac pacemakers (LCP), subcutaneous implantable cardioverter defibrillators (SICD), transvenous implantable cardioverter defibrillators, neuro-stimulators (NS), implantable monitors (IM), and/or the like.

[0005] In one example, an implantable medical device (IMD) may be configured to deliver therapy to a patient's heart. The IMD may include a housing having a distal end and a proximal end and a controller that is disposed within the housing. A power supply may be disposed within the housing and may be operably coupled with the controller. The IMD may include a distal electrode assembly having a distal electrode supported by a distal electrode support. The distal electrode support may be secured relative to the housing and configured to bias the distal electrode toward an extended position in which the distal electrode extends distally from the distal end of the housing. The distal electrode support may further be configured to allow the distal electrode to move proximally relative to the extended position in response to an axial force applied to the distal electrode in the proximal direction. The distal electrode may be operably coupled to the controller. The distal electrode support may have a length, and in some cases may include

a tissue ingrowth inhibiting outer sleeve that extends along the length of the distal electrode support, wherein the tissue ingrowth inhibiting outer sleeve has a proximal end and a distal end and a length between the proximal end and the distal end. The length of the tissue ingrowth inhibiting outer sleeve may be configured to shorten when the distal electrode moves proximally relative to the extended position, and to lengthen when the distal electrode moves back distally toward the extended position in order to accommodate movement of the distal electrode. In some cases, the IMD may include a proximal electrode operably coupled to the controller. The controller may be configured to sense one or more cardiac signals and/or deliver therapy via the distal electrode and the proximal electrode.

[0006] Alternatively or additionally, the distal electrode support may include a spring that biases the distal electrode toward the extended position.

[0007] Alternatively or additionally, the distal electrode may be supported by the spring, which may be conductive and may form at least part of an electrical connection between the distal electrode and the controller.

[0008] Alternatively or additionally, an outer surface of the conductive spring may be electrically insulative so that the spring may be electrically isolated from blood or tissue of the patient.

[0009] Alternatively or additionally, an outer surface of the conductive spring may include an oxide layer.

[0010] Alternatively or additionally, an outer surface of the conductive spring may include a polymer layer.

[0011] Alternatively or additionally, the spring may include a coil spring, a leaf spring or a wave spring.

[0012] Alternatively or additionally, the spring may include a machined spring with a distal end of the machined spring forming the distal electrode.

[0013] Alternatively or additionally, the spring may include Nitinol.

[0014] Alternatively or additionally, the distal electrode support may include a post that is axially movable relative to the housing and that biases the distal electrode toward the extended position.

[0015] Alternatively or additionally, the tissue ingrowth inhibiting outer sleeve may include a polymeric tube that extends at least partially between the distal electrode and the distal end of the housing.

[0016] Alternatively or additionally, the tissue ingrowth inhibiting outer sleeve may include an electrospun polymer.

[0017] Alternatively or additionally, the tissue ingrowth inhibiting outer sleeve may be woven.

[0018] Alternatively or additionally, the tissue ingrowth inhibiting outer sleeve may include a bellows structure.

[0019] Alternatively or additionally, the IMD may further include one or more tines extending distally from the housing and then curling back proximally to engage the patient's tissue and to fix the IMD to the patient.

[0020] In another example, a leadless cardiac pacemaker (LCP) may be configured to sense and/or pace a patient's heart. The LCP may include a housing and a fixation assembly that extends distally from the housing in a deployed configuration in which the fixation assembly fixes the LCP to the patient's heart. In some cases, the fixation assembly may include one or more tines extending distally from the housing and then curling back proximally to engage the patient's heart and to fix the LCP to the patient's heart. A distal electrode may be secured relative to the housing and

may be biased to an extended position in which the distal electrode extends distally beyond the fixation assembly when the fixation assembly is in the deployed configuration. The LCP may also include a proximal electrode located proximally of the distal electrode. A controller may be disposed within the housing and may be operably coupled to the distal electrode and the proximal electrode such that the controller is able to sense cardiac electrical activity and/or deliver therapy via the distal electrode and the proximal electrode.

[0021] Alternatively or additionally, the LCP may further include a spring that biases the distal electrode to the extended position.

[0022] Alternatively or additionally, the LCP may further include a tissue ingrowth inhibiting outer sleeve that may be disposed between the housing and the distal electrode.

[0023] In another example, a leadless cardiac pacemaker (LCP) may be configured to sense and/or pace a patient's heart. The LCP may include a housing including a distal end, a controller disposed within the housing and a spring extending distally from the distal end of the housing. A distal electrode may be coupled to the spring and the spring may bias the distal electrode to an extended position in which the distal electrode extends distally from the distal end of the housing. The spring may be configured to allow the distal electrode to move in response to an applied force. The LCP may include a flexible polymeric tissue ingrowth inhibiting outer sleeve that is disposed about the spring. A proximal electrode may be operably coupled with the controller and may be located more proximal than the distal electrode. The controller may be configured to sense cardiac electrical activity and to deliver therapy via the distal electrode and the proximal electrode.

[0024] The above summary of some illustrative embodiments is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Description, which follow, more particularly exemplify some of these embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

[0026] FIG. 1 is a plan view of an example leadless pacing device implanted within a heart;

[0027] FIG. 2 is a side view of an example implantable leadless cardiac pacemaker with its distal electrode shown in an extended position;

[0028] FIG. 3 is a side view of the example implantable leadless cardiac pacemaker of FIG. 2, with its distal electrode shown in a retracted position;

[0029] FIG. 4 is a schematic block diagram of an example implantable medical device (IMD);

[0030] FIG. 5 is a schematic block diagram of another example implantable medical device (IMD);

[0031] FIG. 6 is a schematic block diagram of an example leadless cardiac pacemaker (LCP);

[0032] FIG. 7 is a partial cross-sectional view of an example leadless cardiac pacemaker (LCP);

[0033] FIG. 8A and 8B are schematic cross-sectional views of illustrative bias springs forming part of the LCP of FIG. 7;

[0034] FIG. 9 is a partial cross-sectional view of another example leadless cardiac pacemaker (LCP); and

[0035] FIG. 10 is a partial cross-sectional view of yet another example leadless cardiac pacemaker (LCP).

[0036] While the disclosure is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DESCRIPTION

[0037] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0038] All numeric values are herein assumed to be modified by the term "about," whether or not explicitly indicated. The term "about" generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (i.e., having the same function or result). In many instances, the terms "about" may include numbers that are rounded to the nearest significant figure.

[0039] The recitation of numerical ranges by endpoints includes all numbers within that range (e.g. 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

[0040] As used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0041] It is noted that references in the specification to "an embodiment," "some embodiments," "other embodiments," etc., indicate that the embodiment described may include one or more particular features, structures, and/or characteristics. However, such recitations do not necessarily mean that all embodiments include the particular features, structures, and/or characteristics. Additionally, when particular features, structures, and/or characteristics are described in connection with one embodiment, it should be understood that such features, structures, and/or characteristics may also be used in connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

[0042] The following detailed description should be read with reference to the drawings in which similar structures in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure. While the present disclosure is applicable to any suitable implantable medical device (IMD), the description below often uses pacemakers and more particularly leadless cardiac pacemakers (LCP) as particular examples.

[0043] Cardiac pacemakers provide electrical stimulation to heart tissue to cause the heart to contract and thus pump blood through the vascular system. Conventional pacemakers typically include an electrical lead that extends from a pulse generator implanted subcutaneously or sub-muscularly to an electrode positioned adjacent the inside or outside wall of the cardiac chamber. As an alternative to conventional pacemakers, self-contained or leadless cardiac pacemakers have been proposed. Leadless cardiac pacemakers are small capsules typically fixed to an intracardiac implant site in a cardiac chamber. The small capsule typically includes bipolar pacing/sensing electrodes, a power source

(e.g. a battery), and associated electrical circuitry for controlling the pacing/sensing electrodes, and thus provide electrical stimulation to heart tissue and/or sense a physiological condition.

[0044] FIG. 1 illustrates an example implantable leadless cardiac pacing device 10 (e.g., a leadless pacemaker) implanted in a chamber of a heart H, such as the right ventricle RV. In some cases, the implantable device 10 may be referred to as being a leadless cardiac pacemaker (LCP). A side view of the illustrative implantable device 10 is shown in FIG. 2. The implantable device 10 may include a shell or housing 12 having a proximal end 14 and a distal end 16. The implantable device 10 may include a first electrode 20 positioned adjacent to the distal end 16 of the housing 12 and a second electrode 22 positioned adjacent to the proximal end 14 of the housing 12.

[0045] In some cases, the first electrode 20 may be disposed on a distal electrode support 21 (see FIG. 2). In some cases, for example, the distal electrode support 21 may enable the first electrode 20 to extend relatively farther from the housing 12, and thus be able to reach through the trabeculae and/or other cardiac structures that can otherwise interfere with the first electrode 20 being able to make good electrical contact with the myocardium. As will be discussed with respect to subsequent Figures, in some cases the distal electrode support 21 may be configured to enable the first electrode 20 to move axially and/or radially relative to the housing 12. In some cases, this helps the first electrode 20 to make good and reliable electrical contact with cardiac tissue, while not exerting an excessive force on the cardiac tissue. Having good and reliable electrical contact with the cardiac tissue can reduce the impedance associated with the electrode, which can reduce the capture threshold and significantly increase the battery longevity of the implantable device. Having good and reliable electrical contact with the cardiac tissue can also improve the sensing capabilities of the electrode 20.

[0046] In FIG. 3, it can be seen that the first electrode 20 has moved axially to the point where the first electrode 20 is proximate the distal end 16 of the housing 12. This could be the result of, for example, the first electrode 20 making good contact with the myocardium of the patient's heart and the implantable device 10 being pushed further distally in order for a fixation mechanism 24 (as will be discussed) to penetrate the myocardium and anchor the implantable device 10 to the myocardium. Subsequent Figures will show possible varieties of the distal electrode support 21 shown in FIG. 2.

[0047] In some cases, and with respect to the second electrode 22, the housing 12 may include a conductive material and may be insulated along a portion of its length. A section along the proximal end 14 may be free of insulation so as to define the second electrode 22. The electrodes 20, 22 may be sensing and/or pacing electrodes to provide electro-therapy and/or sensing capabilities. The first electrode 20 may be capable of being positioned against or may otherwise contact the cardiac tissue of the heart H while the second electrode 22 may be spaced away from the first electrode 20, and thus spaced away from the cardiac tissue.

[0048] The implantable device 10 may include a pulse generator (e.g., electrical circuitry) and a power source (e.g., a battery) within the housing 12 to provide electrical signals to the electrodes 20, 22 and thus control the pacing/sensing electrodes 20, 22. Electrical communication between the

pulse generator and the electrodes 20, 22 may provide electrical stimulation to heart tissue and/or sense a physiological condition.

[0049] In the example shown in FIGS. 1-3, the implantable device 10 may include a fixation mechanism 24 proximate the distal end 16 of the housing 12. The fixation mechanism 24 may be configured to attach the implantable device 10 to a tissue wall of the heart H, or otherwise anchor the implantable device 10 to the anatomy of the patient. As shown in FIG. 1, in some instances, the fixation mechanism 24 may include one or more, or a plurality of hooks or tines 26 anchored into the cardiac tissue of the heart H to anchor the implantable device 10 to a tissue wall. In other instances, the fixation mechanism 24 may include one or more, or a plurality of passive tines, configured to entangle with trabeculae within the chamber of the heart H and/or a helical fixation anchor configured to be screwed into a tissue wall to anchor the implantable device 10 to the heart H. These are just examples.

[0050] In some cases, the implantable device 10 may include a docking member 30 proximate the proximal end 14 of the housing 12. The docking member 30 may be configured to facilitate delivery and/or retrieval of the implantable device 10. For example, the docking member 30 may extend from the proximal end 14 of the housing 12 along a longitudinal axis of the housing 12. The docking member 30 may include a head portion 32 and a neck portion 34 extending between the housing 12 and the head portion 32. The head portion 32 may be an enlarged portion relative to the neck portion 34. For example, the head portion 32 may have a radial dimension from the longitudinal axis of the implantable device 10 which is greater than a radial dimension of the neck portion 34 from the longitudinal axis of the implantable device 10. The docking member 30 may further include a tether retention structure 36 extending from the head portion 32. The tether retention structure 36 may define an opening 38 configured to receive a tether or other anchoring mechanism therethrough. While the retention structure 36 is shown as having a generally "U-shaped" configuration, the retention structure 36 may take any shape which provides an enclosed perimeter surrounding the opening 38 such that a tether may be securably and releasably passed (e.g. looped) through the opening 38. The retention structure 36 may extend though the head portion 32, along the neck portion 34, and to or into the proximal end 14 of the housing 12. The docking member 30 may be configured to facilitate delivery of the implantable device 10 to the intracardiac site and/or retrieval of the implantable device 10 from the intracardiac site. This is just one example, and other docking members 30 are contemplated.

[0051] FIG. 4 is a schematic block diagram of an illustrative implantable medical device (IMD) 40 that is configured to, for example, deliver therapy to a patient's heart. The illustrative IMD 40 includes a housing 42 having a distal end 44 and a proximal end 46. A controller 48 may be disposed within the housing 42. A power supply 50 may be disposed within the housing 42 and may be operably coupled to the controller 48 such that the power supply 50 may provide power for operation of the controller 48 as well as providing power for therapeutic functionality of the IMD 40. In some cases, the power supply 50 may be a battery.

[0052] The illustrative IMD 40 includes a distal electrode assembly 52 that includes a distal electrode 54 that is

supported by a distal electrode support 56. The distal electrode support 56, which may take various forms, is secured or securable to the housing 42 and is configured to bias the distal electrode 54 toward an extended position in which the distal electrode 54 extends distally from the distal end 44 of the housing 42. In some cases, the distal electrode support 56 may be configured to allow the distal electrode 54 to move proximally, as indicated by arrows 58, relative to the extended position in response to an axial force applied to the distal electrode 54 in the proximal direction. The distal electrode 54 may be operably coupled to the controller 48 via an electrical connector 55.

[0053] In some cases, the distal electrode support 56 may include a spring that biases the distal electrode 54 towards the extended position. In some cases, the distal electrode 54 may be supported by the spring, and the spring may be conductive and may form at least part of the electrical connection 55 between the distal electrode 54 and the controller 48. In some cases, particularly if the spring is conductive, an outer surface of the spring may include an insulative coating such as an oxide layer or a polymer layer, or otherwise may be rendered electrically insulating so that the spring may be electrically isolated from blood or tissue in the patient's heart. The distal end of the spring may be electrically coupled to the distal electrode 54. When the distal electrode support 56 is or otherwise includes a spring, the spring may for example be a coil spring, a leaf spring, a wave spring, or a machined spring with a distal end of the machined spring forming the distal electrode 54. In some cases, the distal electrode support 56 may include a post that is axially movable relative to the housing 42 against a bias, and the post may bias the distal electrode 54 toward the extended position.

[0054] In some cases, the spring may be formed of a shape memory material such as but not limited to Nitinol. It will be appreciated that some materials, such as Nitinol, demonstrate a reasonably constant force across a wide range of deflection as a result of the force plateauing within a region of transformation between its austenite state and its martensite state. In some cases, the spring may be configured to have a spring force that enables the distal electrode 54 to contact tissue without possibly damaging the tissue. In some cases, for example, the spring may exert a force on the distal electrode that is less than about 30 pounds per square inch (psi), or less than about 20 psi, or less than about 11 psi. It will be appreciated that the spring may exert a force that is at least about 1 psi, or at least about 5 psi.

[0055] In some cases, the distal electrode support 56 may be considered as having a length L and may include a tissue ingrowth inhibiting outer sleeve 60 that extends along the length L of the distal electrode support 56. The tissue ingrowth inhibiting outer sleeve 60 may have a distal end 62 and a proximal end 64, and a length therebetween (which may also be represented by the length L). In some cases, the length of the tissue ingrowth inhibiting outer sleeve 60 may be configured to shorten when the distal electrode 54 moves proximally relative to the extended position and to lengthen when the distal electrode 54 moves back distally toward the extended position in order to accommodate the movement of the distal electrode 54.

[0056] In some cases, the tissue ingrowth inhibiting outer sleeve 60 may include a polymeric tube that extends at least partially between the distal electrode 54 and the distal end 44 of the housing 42. In some instances, the tissue ingrowth

inhibiting outer sleeve 60 may include an electrospun polymer such as but not limited to PIB/PU (polyisobutylene/polyurethane). In some cases, the tissue ingrowth inhibiting outer sleeve 60 may be woven. In some cases, the tissue ingrowth inhibiting outer sleeve 60 may form a bellows structure. In some cases, the bellows structure itself may provide some or all of the bias force to bias the distal electrode 54 to the extended position.

[0057] The illustrative IMD 40 may include a proximal electrode 66 that is operably coupled to the controller 48 via an electrical connector 67. In some cases, the proximal electrode 66 may be at or near the proximal end 46 of the housing 42, but this is not required. It will be appreciated that the controller 48 may be configured to sense one or more cardiac signals and/or deliver therapy via the distal electrode 54 and the proximal electrode 66.

[0058] FIG. 5 is a schematic block diagram of an illustrative leadless cardiac pacemaker (LCP) 70 that is configured to sense and/or pace a patient's heart. The illustrative LCP 70 includes a housing 72 extending from a distal end 74 to a proximal end 76 and a fixation assembly 78 that extends distally from the housing 72 in a deployed configuration in which the fixation assembly 78 fixes the LCP 70 to the patient's heart. In some cases, the fixation assembly 78 includes a plurality of fixation tines (e.g. see FIGS. 1-3). A distal electrode 80 may be secured relative to the housing 72 and may be biased to an extended position in which the distal electrode 80 extends distally beyond the fixation assembly 78 when the fixation assembly 78 is in the deployed configuration in which the fixation assembly 78 fixes the LCP 70 to the patient's heart.

[0059] In some cases, the LCP 70 may further include a spring (not illustrated) that biases the distal electrode 80 to the extended position. In some cases, the LCP 70 may include a tissue ingrowth inhibiting outer sleeve (not specifically illustrated) that is disposed between the housing 72 and the distal electrode 80. A proximal electrode 82 may be secured relative to the housing 72. The controller 48 is disposed within the housing 72 and is operably coupled to the distal electrode 80 and to the proximal electrode 82 via electrical connections 81 and 83, respectively. The controller 48 may be configured to sense cardiac electrical activity and/or deliver therapy via the distal electrode 80 and the proximal electrode 82.

[0060] FIG. 6 depicts a more detailed block diagram of an illustrative leadless cardiac pacemaker (LCP) that may be implanted into a patient and may operate to deliver appropriate therapy to the heart, such as to deliver anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), bradycardia therapy, and/or the like. As can be seen in FIG. 6, the LCP 100 may be a compact device with all components housed within the or directly on a housing 120. In some cases, the LCP 100 may be considered as being an example of the implantable device 10 (FIGS. 1-3), the IMD 40 (FIG. 4) or the LCP 70 (FIG. 5).

[0061] In the example shown in FIG. 6, the LCP 100 may include a communication module 102, a pulse generator module 104, an electrical sensing module 106, a mechanical sensing module 108, a processing module 110, a battery 112, and an electrode arrangement 114. The LCP 100 may include more or fewer modules, depending on the application.

[0062] The communication module 102 may be configured to communicate with devices such as sensors, other

medical devices such as an SICD, and/or the like, that are located externally to the LCP 100. Such devices may be located either external or internal to the patient's body. Irrespective of the location, external devices (i.e. external to the LCP 100 but not necessarily external to the patient's body) can communicate with the LCP 100 via communication module 102 to accomplish one or more desired functions. For example, the LCP 100 may communicate information, such as sensed electrical signals, data, instructions, messages, R-wave detection markers, etc., to an external medical device (e.g. SICD and/or programmer) through the communication module 102. The external medical device may use the communicated signals, data, instructions, messages, R-wave detection markers, etc., to perform various functions, such as determining occurrences of arrhythmias, delivering electrical stimulation therapy, storing received data, and/or performing any other suitable function. The LCP 100 may additionally receive information such as signals, data, instructions and/or messages from the external medical device through the communication module 102, and the LCP 100 may use the received signals, data, instructions and/or messages to perform various functions, such as determining occurrences of arrhythmias, delivering electrical stimulation therapy, storing received data, and/or performing any other suitable function. The communication module 102 may be configured to use one or more methods for communicating with external devices. For example, the communication module 102 may communicate via radio-frequency (RF) signals, inductive coupling, optical signals, acoustic signals, conducted communication signals, and/or any other signals suitable for communication.

[0063] In the example shown in FIG. 6, the pulse generator module 104 may be electrically connected to the electrodes 114. In some examples, the LCP 100 may additionally include electrodes 114'. In such examples, the pulse generator 104 may also be electrically connected to the electrodes 114'. The pulse generator module 104 may be configured to generate electrical stimulation signals. For example, the pulse generator module 104 may generate and deliver electrical stimulation signals by using energy stored in the battery 112 within the LCP 100 and deliver the generated electrical stimulation signals via the electrodes 114 and/or 114'. Alternatively, or additionally, the pulse generator 104 may include one or more capacitors, and the pulse generator 104 may charge the one or more capacitors by drawing energy from the battery 112. The pulse generator 104 may then use the energy of the one or more capacitors to deliver the generated electrical stimulation signals via the electrodes 114 and/or 114'. In at least some examples, the pulse generator 104 of the LCP 100 may include switching circuitry to selectively connect one or more of the electrodes 114 and/or 114' to the pulse generator 104 in order to select which of the electrodes 114/114' (and/or other electrodes) the pulse generator 104 delivers the electrical stimulation therapy. The pulse generator module 104 may generate and deliver electrical stimulation signals with particular features or in particular sequences in order to provide one or multiple of a number of different stimulation therapies. For example, the pulse generator module 104 may be configured to generate electrical stimulation signals to provide electrical stimulation therapy to combat bradycardia, tachycardia, cardiac synchronization, bradycardia arrhythmias, tachycardia arrhythmias, fibrillation arrhythmias, cardiac synchronization arrhythmias and/or to produce any other suitable

electrical stimulation therapy. Some more common electrical stimulation therapies include anti-tachycardia pacing (ATP) therapy, cardiac resynchronization therapy (CRT), and cardioversion/defibrillation therapy. In some cases, the pulse generator 104 may provide a controllable pulse energy. In some cases, the pulse generator 104 may allow the controller to control the pulse voltage, pulse width, pulse shape or morphology, and/or any other suitable pulse characteristic.

[0064] In some examples, the LCP 100 may include an electrical sensing module 106, and in some cases, a mechanical sensing module 108. The electrical sensing module 106 may be configured to sense the cardiac electrical activity of the heart. For example, the electrical sensing module 106 may be connected to the electrodes 114/114', and the electrical sensing module 106 may be configured to receive cardiac electrical signals conducted through the electrodes 114/114'. The cardiac electrical signals may represent local information from the chamber in which the LCP 100 is implanted. For instance, if the LCP 100 is implanted within a ventricle of the heart (e.g. RV, LV), cardiac electrical signals sensed by the LCP 100 through the electrodes 114/114' may represent ventricular cardiac electrical signals. In some cases, the LCP 100 may be configured to detect cardiac electrical signals from other chambers (e.g. far field), such as the P-wave from the atrium.

[0065] The mechanical sensing module 108 may include one or more sensors, such as an accelerometer, a pressure sensor, a heart sound sensor, a blood-oxygen sensor, a chemical sensor, a temperature sensor, a flow sensor and/or any other suitable sensors that are configured to measure one or more mechanical/chemical parameters of the patient. Both the electrical sensing module 106 and the mechanical sensing module 108 may be connected to a processing module 110, which may provide signals representative of the sensed mechanical parameters. Although described with respect to FIG. 6 as separate sensing modules, in some cases, the electrical sensing module 106 and the mechanical sensing module 108 may be combined into a single sensing module, as desired.

[0066] The electrodes 114/114' can be secured relative to the housing 120 but exposed to the tissue and/or blood surrounding the LCP 100. In some cases, the electrodes 114 may be generally disposed on either end of the LCP 100 and may be in electrical communication with one or more of the modules 102, 104, 106, 108, and 110. The electrodes 114/114' may be supported by the housing 120, although in some examples, the electrodes 114/114' may be connected to the housing 120 through short connecting wires such that the electrodes 114/114' are not directly secured relative to the housing 120. In examples where the LCP 100 includes one or more electrodes 114', the electrodes 114' may in some cases be disposed on the sides of the LCP 100, which may increase the number of electrodes by which the LCP 100 may sense cardiac electrical activity, deliver electrical stimulation and/or communicate with an external medical device. The electrodes 114/114' can be made up of one or more biocompatible conductive materials such as various metals or alloys that are known to be safe for implantation within a human body. In some instances, the electrodes 114/114' connected to the LCP 100 may have an insulative portion that electrically isolates the electrodes 114/114' from adjacent electrodes, the housing 120, and/or other parts of

the LCP 100. In some cases, one or more of the electrodes 114/114' may be provided on a tail (not shown) that extends away from the housing 120.

[0067] The processing module 110 can be configured to control the operation of the LCP 100. For example, the processing module 110 may be configured to receive electrical signals from the electrical sensing module 106 and/or the mechanical sensing module 108. Based on the received signals, the processing module 110 may determine, for example, abnormalities in the operation of the heart H. Based on any determined abnormalities, the processing module 110 may control the pulse generator module 104 to generate and deliver electrical stimulation in accordance with one or more therapies to treat the determined abnormalities. The processing module 110 may further receive information from the communication module 102. In some examples, the processing module 110 may use such received information to help determine whether an abnormality is occurring, determine a type of abnormality, and/or to take particular action in response to the information. The processing module 110 may additionally control the communication module 102 to send/receive information to/from other devices.

[0068] In some examples, the processing module 110 may include a pre-programmed chip, such as a very-large-scale integration (VLSI) chip and/or an application specific integrated circuit (ASIC). In such embodiments, the chip may be pre-programmed with control logic in order to control the operation of the LCP 100. By using a pre-programmed chip, the processing module 110 may use less power than other programmable circuits (e.g. general purpose programmable microprocessors) while still being able to maintain basic functionality, thereby potentially increasing the battery life of the LCP 100. In other examples, the processing module 110 may include a programmable microprocessor. Such a programmable microprocessor may allow a user to modify the control logic of the LCP 100 even after implantation, thereby allowing for greater flexibility of the LCP 100 than when using a pre-programmed ASIC. In some examples, the processing module 110 may further include a memory, and the processing module 110 may store information on and read information from the memory. In other examples, the LCP 100 may include a separate memory (not shown) that is in communication with the processing module 110, such that the processing module 110 may read and write information to and from the separate memory.

[0069] The battery 112 may provide power to the LCP 100 for its operations. In some examples, the battery 112 may be a non-rechargeable lithium-based battery. In other examples, a non-rechargeable battery may be made from other suitable materials, as desired. Because the LCP 100 is an implantable device, access to the LCP 100 may be limited after implantation. Accordingly, it is desirable to have sufficient battery capacity to deliver therapy over a period of treatment such as days, weeks, months, years or even decades. In some instances, the battery 112 may be a rechargeable battery, which may help increase the useable lifespan of the LCP 100. In still other examples, the battery 112 may be some other type of power source, as desired.

[0070] To implant the LCP 100 inside a patient's body, an operator (e.g., a physician, clinician, etc.), may fix the LCP 100 to the cardiac tissue of the patient's heart. To facilitate fixation, the LCP 100 may include one or more anchors 116. The anchor 116 may include any one of a number of fixation

or anchoring mechanisms. For example, the anchor 116 may include one or more pins, staples, threads, screws, helix, tines, and/or the like. In some examples, although not shown, the anchor 116 may include threads on its external surface that may run along at least a partial length of the anchor 116. The threads may provide friction between the cardiac tissue and the anchor to help fix the anchor 116 within the cardiac tissue. In other examples, the anchor 116 may include other structures such as barbs, spikes, or the like to facilitate engagement with the surrounding cardiac tissue.

[0071] FIG. 7 is a partial cross-sectional view of an example leadless cardiac pacemaker (LCP) 130 that includes a housing 132 having a distal region 134. A distal electrode 136 extends distally from the distal region 134 and is operably coupled with a spring 138 that biases the distal electrode 136 to an extended position (illustrated) in which the distal electrode 136 extends further distally than fixation tines 140 when the fixation tines 140 are in a deployed configuration (as shown). As can be seen, the fixation tines 140 extend distally from the housing and then curl back proximally to engage the patient's tissue and to fix the LCP 130 to the patient.

[0072] In some cases, as noted with respect to FIG. 4, the spring 138 may be a coil spring, a leaf spring or a wave spring, for example. In some cases, as shown, the LCP 130 may include a tissue ingrowth inhibiting outer sleeve 142 that at least partially surrounds the spring 138 and protects the spring 138 from tissue ingrowth that could otherwise potentially limit the flexibility of the spring 138 and/or interfere with eventual removal of the LCP 130 from the patient. In some instances, the tissue ingrowth inhibiting outer sleeve 142 may include an electrospun polymer such as but not limited to PIB/PU (polyisobutylene/polyurethane) and in some cases may be woven. While not required in all cases, the LCP 130 may include a drug collar 144 that may be configured to elute any desired pharmaceutical drug or agent. In some cases, an elutable pharmaceutical drug or agent may be placed in other locations relative to the distal electrode 136.

[0073] In some cases, if the spring 138 is electrically conductive, the spring 138 may continue proximally, as indicated in phantom at 139, into the housing 132 in order to be electrically coupled with the controller 48. FIG. 8A and 8B are example schematic cross-sectional views of the spring 138. In FIG. 8A, the spring 138 can be seen as having a circular cross-section, and includes a coating 150 that may, for example be an oxide layer or a polymer layer, so that the spring may be electrically isolated from blood or tissue in the patient's heart. The distal end of the spring 138 may be in electrical contact with the distal electrode 136, and the proximal end of the spring may be in electrical contact with a controller in the housing 132. In FIG. 8B, the spring 138 can be seen as having a rectilinear cross-section. It will be appreciated that these examples are merely illustrative, as the spring 138 may take on any of a variety of different shapes and configurations. In some cases, the spring 138 may be a flexible polymeric material or block that embeds a plurality of conductive members extending from a proximal end to a distal end. The distal electrode 136 may be mounted on the distal end of the flexible polymeric material or block. The flexible polymeric material or block may compress when an axial force is applied to the distal electrode 136, allowing the distal electrode to move in a proximal direction. The distal ends of the plurality of

conductive members embedded in the flexible polymeric material or block may form an electrical connection with the distal electrode 136, and the proximal end of the plurality of conductive members may be in electrical communication with a controller in the housing 132. The flexible polymeric material or block may be similar to Zebra™ connectors often used in providing an electrical connection between printed circuit boards and LCD displays. However, the plurality of conductive members may be embedded within the flexible polymeric material or block such that they are not exposed to blood or other tissue during use.

[0074] FIG. 9 is a partial cross-sectional view of another illustrative leadless cardiac pacemaker (LCP) 160, and includes a housing 162 having a distal region 164. A distal electrode 166 extends distally from the distal region 164 and is operably coupled (or integrally formed) with a post 168 that extends proximally into an aperture 170 formed within the housing 162. A spring 172 may be disposed within the housing 162 and/or aperture 170 in order to bias the post 168, and hence the distal electrode 166, to an extended position. In some cases, the LCP 160 may include fixation tines, which for clarity are not illustrated in FIG. 9. The spring 172 may, for example, be a coil spring, a leaf spring or a wave spring. In some cases, the spring 172 may be a machined spring with the distal electrode 166 integrally formed as part of the machined screw. In some cases, the spring 172 could be a resilient polymeric material that can compress in response to an applied force. In some cases, as shown, the post 168 may include a tissue ingrowth inhibiting material 174 that may be a coating or an outer sleeve that protects the post 168 from tissue ingrowth that could otherwise interfere with the functionality of the post 168.

[0075] FIG. 10 is a partial cross-sectional view of another illustrative leadless cardiac pacemaker (LCP) 180, and includes a housing 182 having a distal region 184. A distal electrode 186 extends distally from the distal region 184 and is operably coupled (or integrally formed) with a post 188 that extends proximally into an aperture 190 formed within the housing 182. A bellows 192 may be disposed about the post 188 and may be configured to bias the distal electrode 186 into an extended position as shown. The bellows 192 may be configured to compress in response to an axial force applied to the distal electrode 186. In some cases, the bellows 192 protects the post 188 against tissue ingrowth. In some instances, the LCP 180 may also include a secondary spring 194 (shown in phantom) to help bias the post 188 (and hence the distal electrode 186) into the extended position. In some cases, the bellows 192 has sufficient structure so that the separate post 188 is not necessary. That is, the bellows 192 itself may be structurally sufficient to fully support the distal electrode, and to bias the distal electrode 186 toward the extended position.

[0076] The springs described herein may be made from a metal, metal alloy, a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 304V, 304L, and 316LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL®

400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R30035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R30003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

[0077] As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated “linear elastic” or “non-super-elastic” which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial “super-elastic plateau” or “flag region” in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear than the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed “substantially” linear elastic and/or non-super-elastic nitinol.

[0078] In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

[0079] In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about -60 degrees Celsius (° C.) to about 120° C. in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear

elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

[0080] In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Some examples of nickel titanium alloys are disclosed in U.S. Pat. Nos. 5,238,004 and 6,508,803, which are incorporated herein by reference. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

[0081] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. An Implantable Medical Device (IMD) configured to delivery therapy to a patient's heart, the IMD comprising:
 - a housing having a distal end and a proximal end;
 - a controller disposed within the housing;
 - a power supply disposed within the housing and operably coupled with the controller;
 - a distal electrode assembly having a distal electrode supported by a distal electrode support, the distal electrode support is secured relative to the housing and is configured to bias the distal electrode toward an extended position in which the distal electrode extends distally from the distal end of the housing, the distal electrode support is further configured to allows the distal electrode to move proximally relative to the extended position in response to an axial force applied to the distal electrode in the proximal direction, the distal electrode is operably coupled to the controller;
 - the distal electrode support having a length and further having a tissue ingrowth inhibiting outer sleeve that extends along the length of the distal electrode support, wherein the tissue ingrowth inhibiting outer sleeve has a proximal end and a distal end and a length between the proximal end and the distal end, and wherein the length of the tissue ingrowth inhibiting outer sleeve is configured to shorten when the distal electrode moves proximally relative to the extended position and to lengthen when the distal electrode moves back distally toward the extended position in order to accommodate movement of the distal electrode;
 - a proximal electrode operably coupled to the controller, the proximal electrode located more proximal than the distal electrode; and
 - the controller configured to sense one or more cardiac signals and/or deliver therapy via the distal electrode and the proximal electrode.

2. The IMD of claim 1, wherein the distal electrode support comprises a spring that biases the distal electrode toward the extended position.

3. The IMD of claim 2, wherein the distal electrode is supported by the spring, and the spring is conductive and forms at least part of an electrical connection between the distal electrode and the controller.

4. The IMD of claim 3, wherein an outer surface of the conductive spring is electrically insulative so that the spring is electrically isolated from blood or tissue in the patient's heart.

5. The IMD of claim 4, wherein an outer surface of the conductive spring includes an oxide layer.

6. The IMD of claim 4, wherein an outer surface of the conductive spring includes a polymer layer.

7. The IMD of claim 2, wherein the spring comprises a coil spring, a leaf spring or a wave spring.

8. The IMD of claim 2, wherein the spring comprises a machined spring with a distal end of the machined spring forming the distal electrode.

9. The IMD of claim 2, wherein the spring comprises Nitinol.

10. The IMD of claim 1, wherein the distal electrode support comprises a post that is axially movable relative to the housing, and the post biases the distal electrode toward the extended position.

11. The IMD of claim 1, wherein the tissue ingrowth inhibiting outer sleeve comprises a polymeric tube that extends at least partially between the distal electrode and the distal end of the housing.

12. The IMD of claim 11, wherein the tissue ingrowth inhibiting outer sleeve comprises an electrospun polymer.

13. The IMD of claim 11, wherein the tissue ingrowth inhibiting outer sleeve is woven.

14. The IMD of claim 11, wherein the tissue ingrowth inhibiting outer sleeve comprises a bellows structure.

15. The IMD of claim 1, further comprising two or more tines extending distally from the housing and then curling back proximally to engage the patient's heart and to fix the IMD to the patient's heart.

16. A leadless cardiac pacemaker (LCP) configured to sense and/or pace a patient's heart, the LCP comprising:

- a housing;

- a fixation assembly that extends distally from the housing in a deployed configuration in which the fixation assembly fixes the LCP to the patient's heart;

- a distal electrode secured relative to the housing and biased to an extended position in which the distal electrode extends distally beyond the fixation assembly when the fixation assembly is in the deployed configuration;

- a proximal electrode located proximally of the distal electrode;

- a controller disposed within the housing and operably coupled to the distal electrode and the proximal electrode;

- the controller configured to sense cardiac electrical activity and/or deliver therapy via the distal electrode and the proximal electrode.

17. The LCP of claim 16, wherein the fixation assembly comprises a plurality of fixation tines.

18. The LCP of claim 16, further comprising a spring that biases the distal electrode to the extended position.

19. The LCP of claim 16, further comprising a tissue ingrowth inhibiting outer sleeve disposed between the housing and the distal electrode.

20. A leadless cardiac pacemaker (LCP) configured to sense and/or pace a patient's heart, the LCP comprising:

- a housing including a distal end;
 - a controller disposed within the housing;
 - a spring extending distally from the distal end of the housing;
 - a distal electrode coupled to the spring, the spring biasing the distal electrode to an extended position in which the distal electrode extends distally from the distal end of the housing, the spring configured to allow the distal electrode to move in response to an applied force;
 - a flexible polymeric tissue ingrowth inhibiting outer sleeve disposed about the spring;
 - a proximal electrode operably coupled with the controller, the proximal electrode located more proximal than the distal electrode; and
- the controller configured to sense cardiac electrical activity and to deliver therapy via the distal electrode and the proximal electrode.

* * * * *

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摘要(译)

IMD可以包括具有控制器的壳体和设置在壳体内部的电源。远侧电极可以由远侧电极支撑件支撑, 该远侧电极支撑件将远侧电极朝向延伸位置偏置, 其中远侧电极从壳体的远端向远侧延伸并且允许远侧电极相对于延伸位置向近侧移动以响应于沿近端方向施加到远端电极的轴向力。在一些情况下, 远侧电极支撑件可包括沿着远侧电极支撑件的长度延伸的组织向内生长抑制外套管, 并且被配置为当远侧电极相对于延伸位置向近侧移动时缩短并且在远侧电极移动时延长向远侧朝向伸展位置, 以适应远端电极的运动。

