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(54) **IMPLANTABLE MEDICAL DEVICE FIXATION**

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CPC ***A61N 1/05*** (2013.01); ***A61N 1/0573*** (2013.01); ***A61N 1/3756*** (2013.01)

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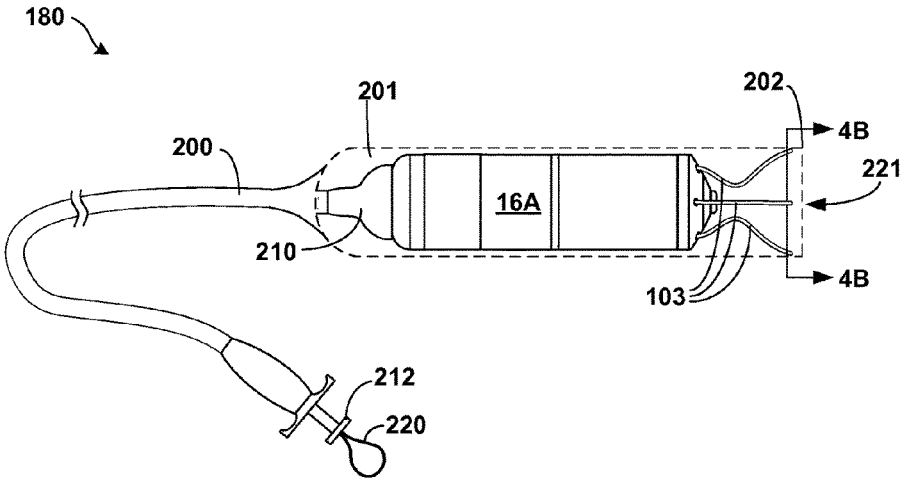
(57) **ABSTRACT**

Various fixation techniques for implantable medical device (IMDs) are described. In one example, an assembly comprises an IMD; and a set of active fixation tines attached to the IMD. The active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the IMD to a hooked position in which the active fixation tines bend back towards the IMD. The active fixation tines are configured to secure the IMD to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue.

18 Claims, 10 Drawing Sheets



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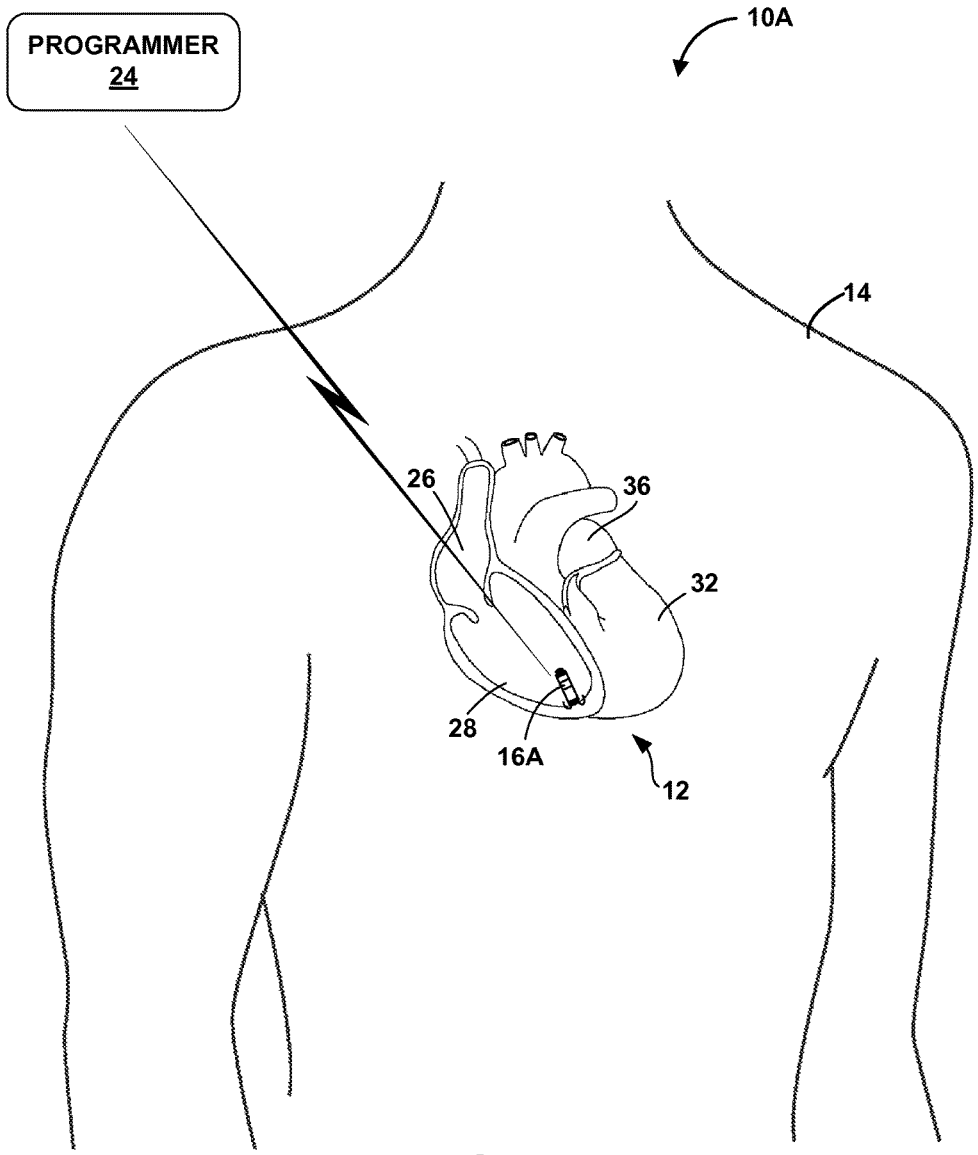

FIG. 1

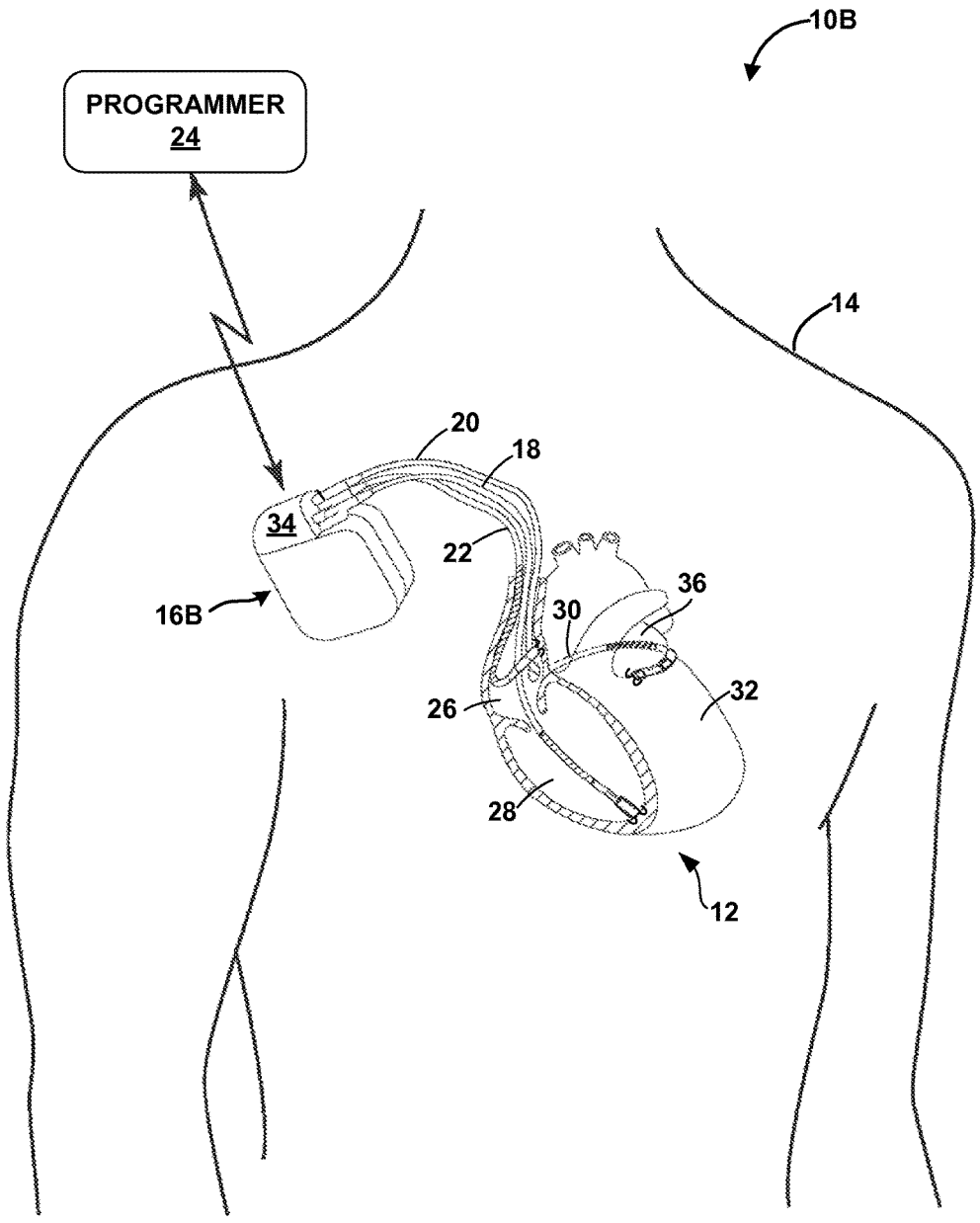

FIG. 2

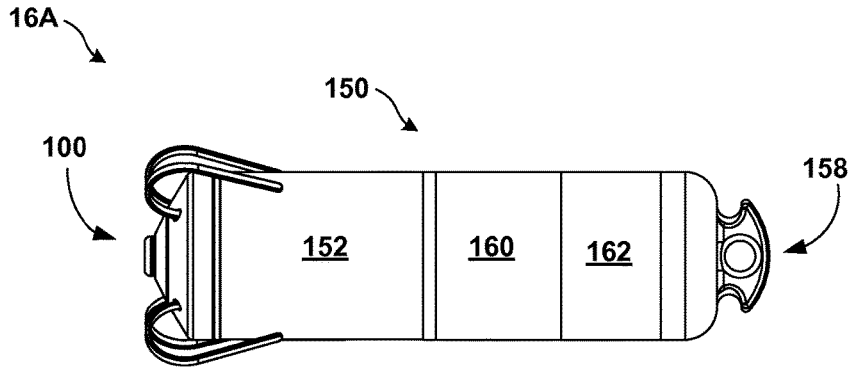
16A
150
100
158
152
160
162

FIG. 3A

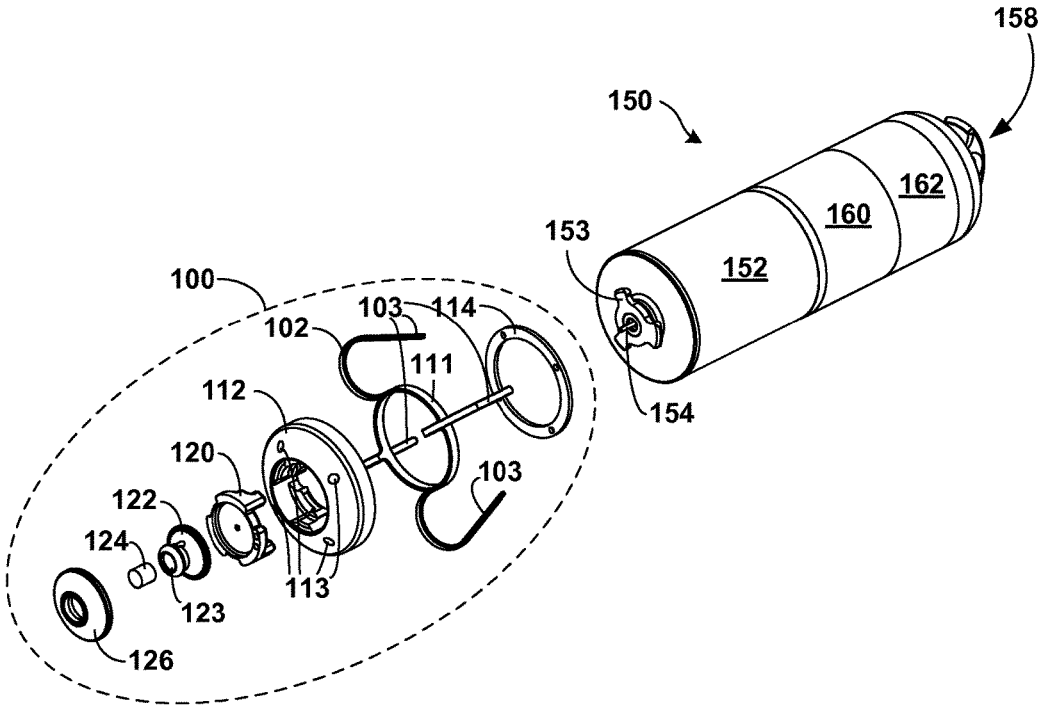
158
150
162
160
153
152
100
102
103
114
111
112
154
120
103
122
124
113
123
126

FIG. 3B

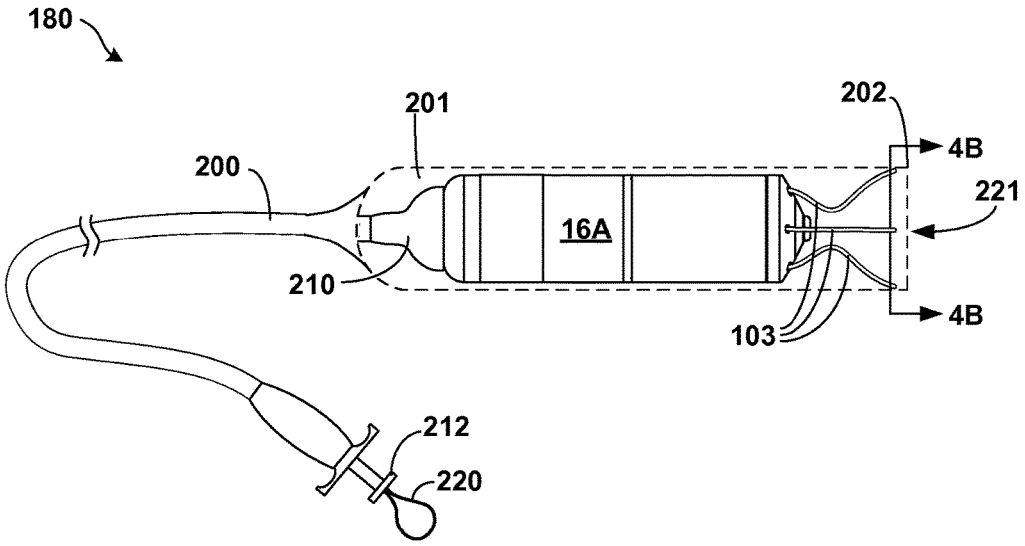
180
201
202
4B
200
221
16A
210
103
4B
212
220

FIG. 4A

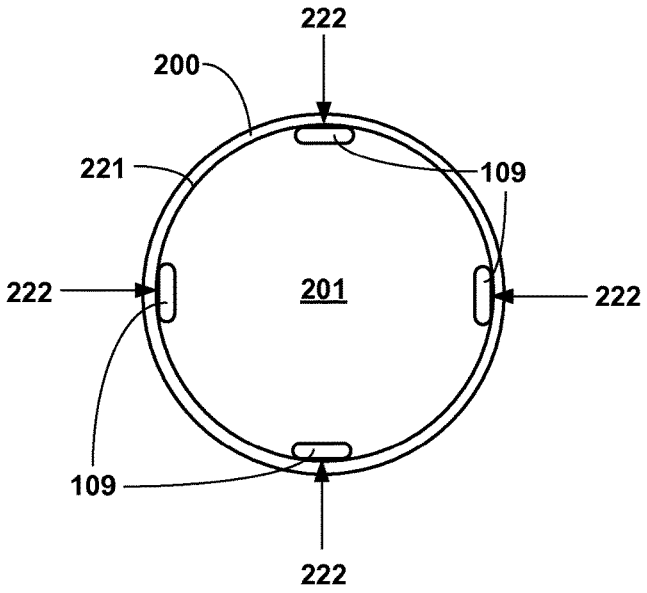
222
200
221
109
222
201
222
109
222

FIG. 4B

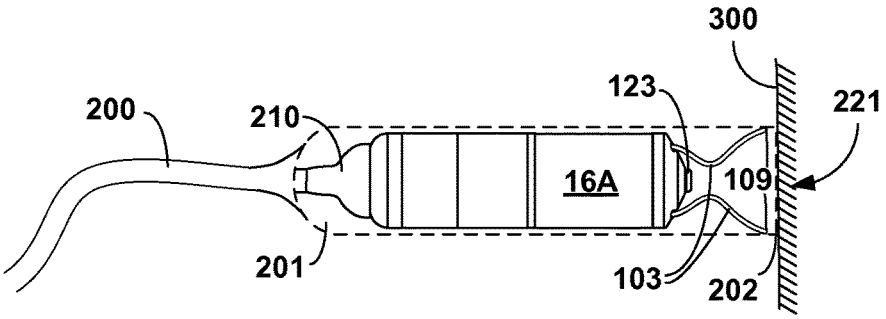

FIG. 5A

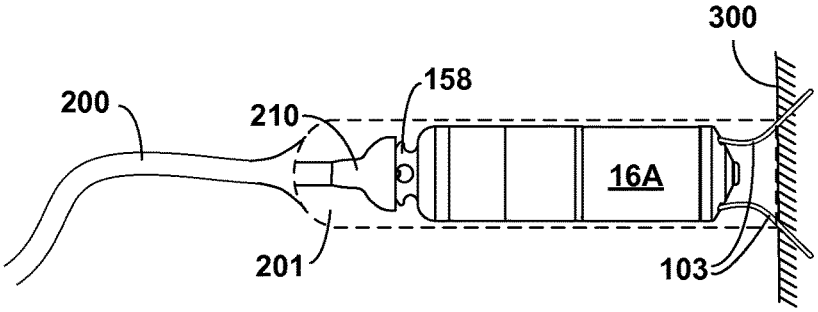

FIG. 5B

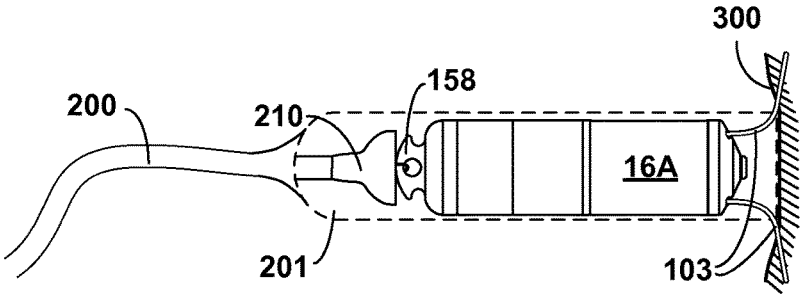

FIG. 5C

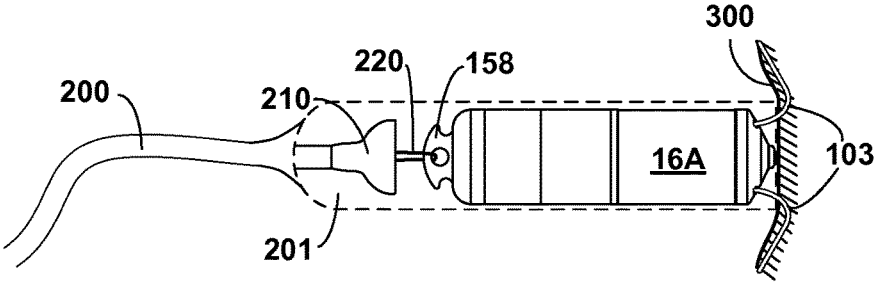

FIG. 5D

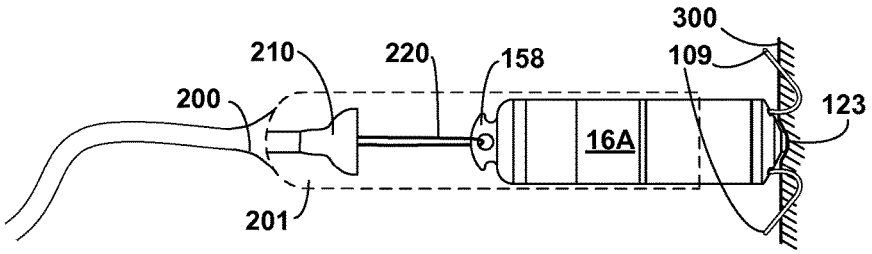

FIG. 5E

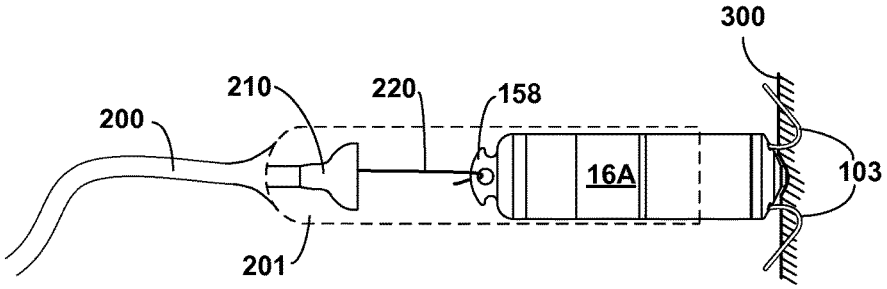

FIG. 5F

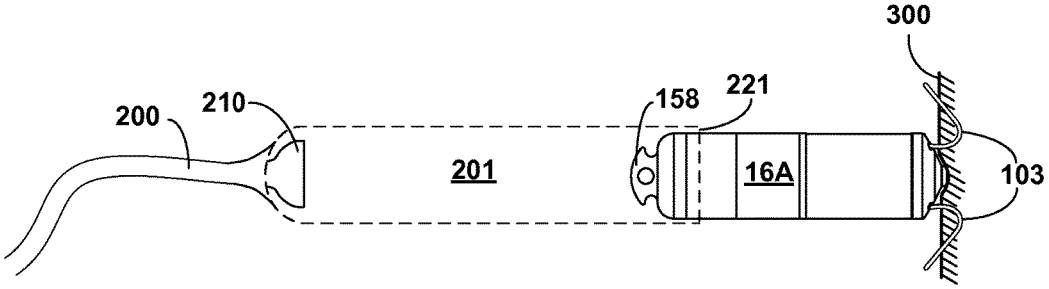

FIG. 5G

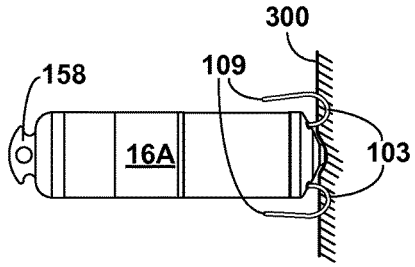

FIG. 5H

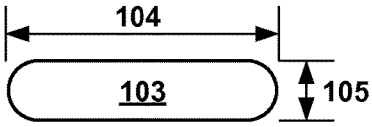

FIG. 6A

FIG. 6B

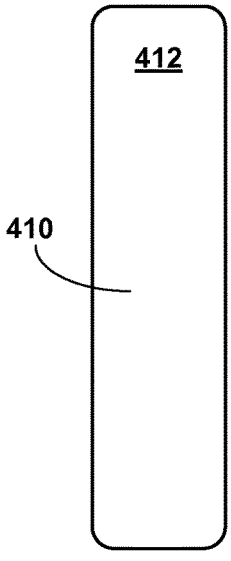

FIG. 7A

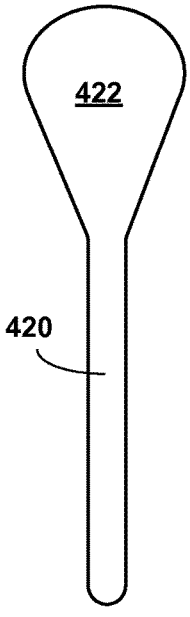

FIG. 7B

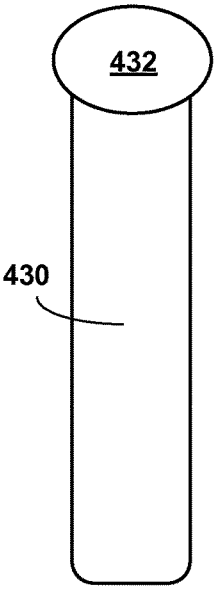

FIG. 7C

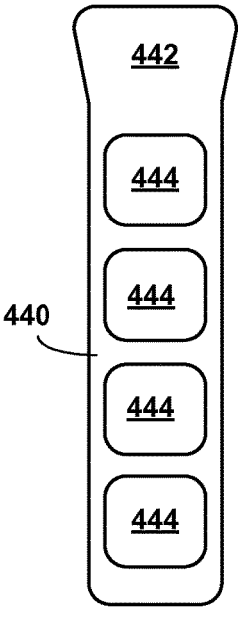

FIG. 7D

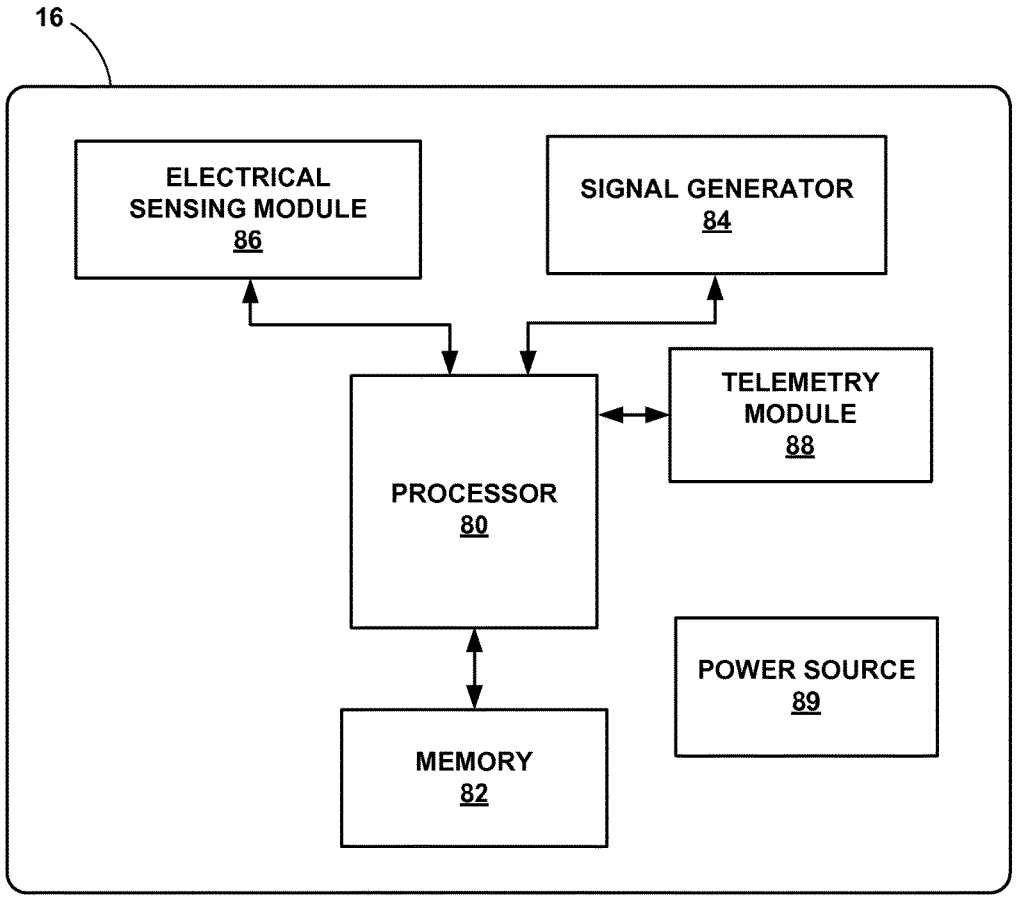
16
ELECTRICAL SENSING MODULE 86
SIGNAL GENERATOR 84
TELEMETRY MODULE 88
PROCESSOR 80
POWER SOURCE 89
MEMORY 82

FIG. 8

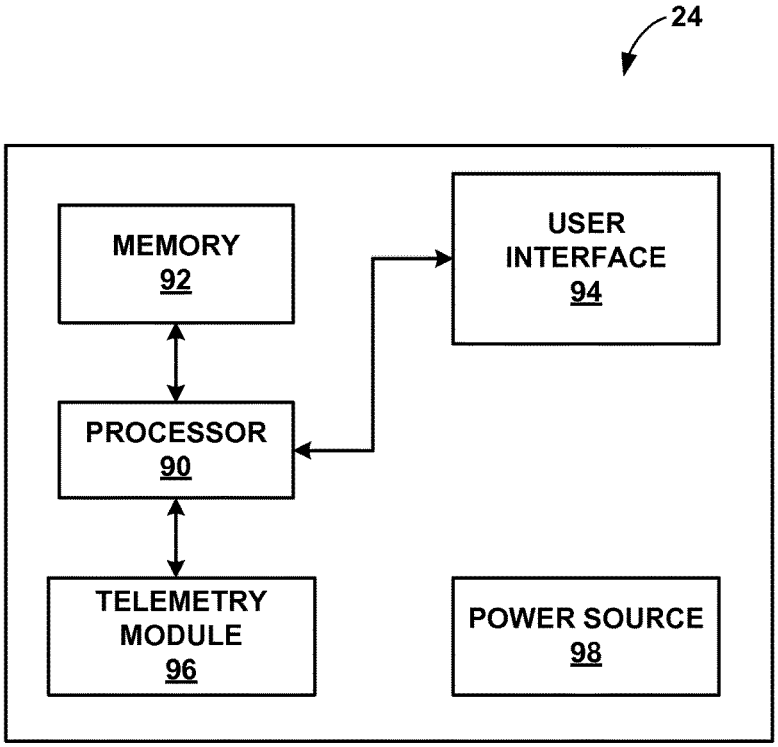
24
MEMORY
92
USER
INTERFACE
94
PROCESSOR
90
TELEMETRY
MODULE
96
POWER SOURCE
98

FIG. 9

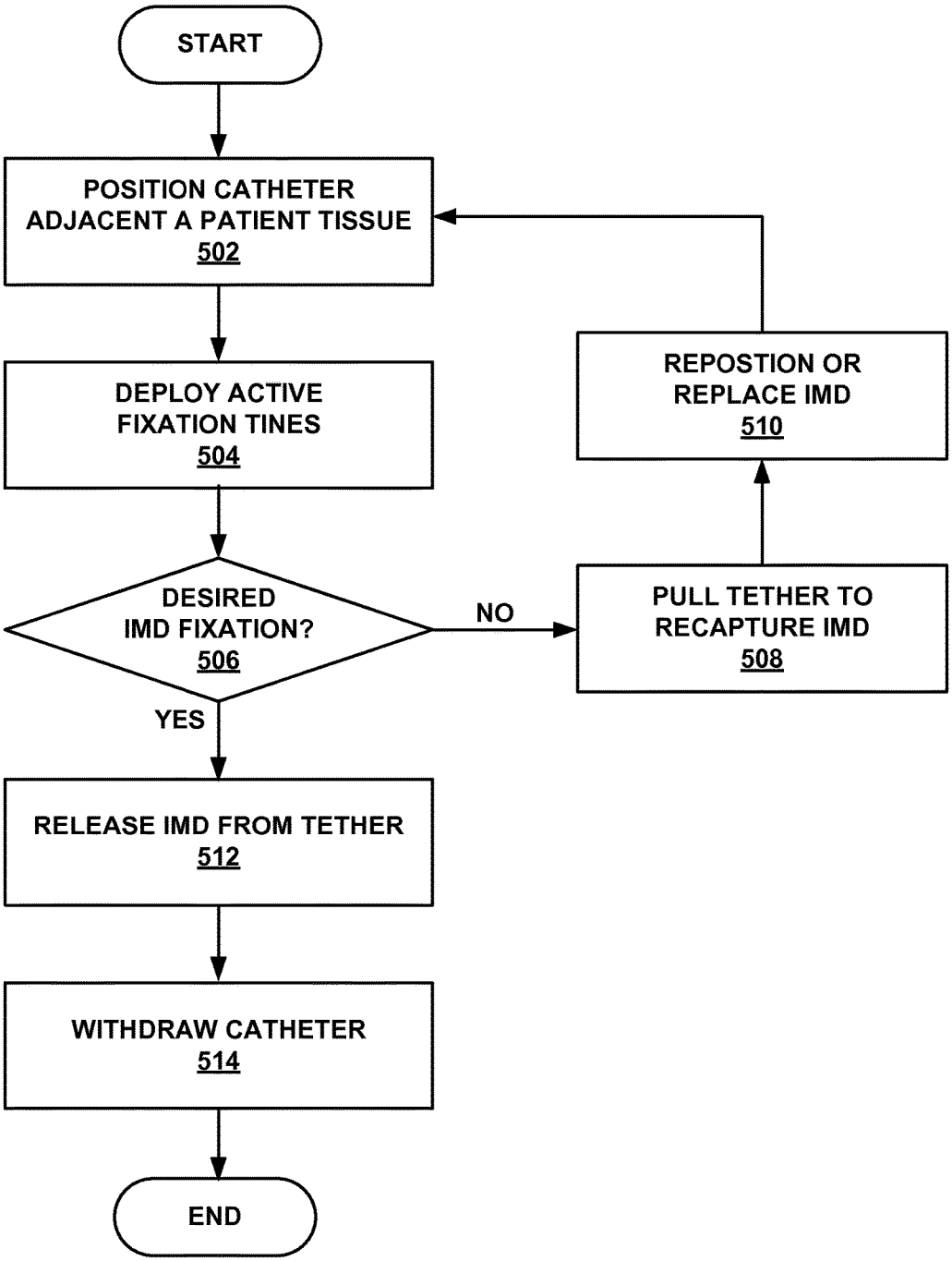
START
POSITION CATHETER ADJACENT A PATIENT TISSUE 502
DEPLOY ACTIVE FIXATION TINES 504
DESIRED IMD FIXATION? 506
NO
YES
PULL TETHER TO RECAPTURE IMD 508
REPOSTION OR REPLACE IMD 510
RELEASE IMD FROM TETHER 512
WITHDRAW CATHETER 514
END

FIG. 10

IMPLANTABLE MEDICAL DEVICE FIXATION

This application claims the benefit of U.S. Provisional Application No. 61/428,067, entitled, "IMPLANTABLE MEDICAL DEVICE FIXATION," and filed on Dec. 29, 2010, the entire content of which is incorporated herein by reference.

TECHNICAL FIELD

This disclosure relates to fixation techniques for implantable medical devices.

BACKGROUND

Medical devices such as electrical stimulators, leads, and electrodes are implanted to deliver therapy to one or more target sites within the body of a patient. To ensure reliable electrical contact between the electrodes and the target site, fixation of the device, lead, or electrodes is desirable.

A variety of medical devices for delivering a therapy and/or monitoring a physiological condition have been used clinically or proposed for clinical use in patients. Examples include medical devices that deliver therapy to and/or monitor conditions associated with the heart, muscle, nerve, brain, stomach or other organs or tissue. Some therapies include the delivery of electrical signals, e.g., stimulation, to such organs or tissues. Some medical devices may employ one or more elongated electrical leads carrying electrodes for the delivery of therapeutic electrical signals to such organs or tissues, electrodes for sensing intrinsic electrical signals within the patient, which may be generated by such organs or tissue, and/or other sensors for sensing physiological parameters of a patient.

Medical leads may be configured to allow electrodes or other sensors to be positioned at desired locations for delivery of therapeutic electrical signals or sensing. For example, electrodes or sensors may be carried at a distal portion of a lead. A proximal portion of the lead may be coupled to a medical device housing, which may contain circuitry such as signal generation and/or sensing circuitry. In some cases, the medical leads and the medical device housing are implantable within the patient. Medical devices with a housing configured for implantation within the patient may be referred to as implantable medical devices (IMDs).

Implantable cardiac pacemakers or cardioverter-defibrillators, for example, provide therapeutic electrical signals to the heart, e.g., via electrodes carried by one or more implantable medical leads. The therapeutic electrical signals may include pulses for pacing, or shocks for cardioversion or defibrillation. In some cases, a medical device may sense intrinsic depolarizations of the heart, and control delivery of therapeutic signals to the heart based on the sensed depolarizations. Upon detection of an abnormal rhythm, such as bradycardia, tachycardia or fibrillation, an appropriate therapeutic electrical signal or signals may be delivered to restore or maintain a more normal rhythm. For example, in some cases, an IMD may deliver pacing stimulation to the heart of the patient upon detecting tachycardia or bradycardia, and deliver cardioversion or defibrillation shocks to the heart upon detecting fibrillation.

Leadless IMDs may also be used to deliver therapy to a patient, and/or sense physiological parameters of a patient. In some examples, a leadless IMD may include one or more electrodes on its outer housing to deliver therapeutic electrical signals to patient, and/or sense intrinsic electrical signals of patient. For example, leadless cardiac devices, such as leadless pacemakers, may also be used to sense intrinsic depolarizations and/or other physiological parameters of the heart and/or deliver therapeutic electrical signals to the heart. A leadless cardiac device may include one or more electrodes on its outer housing to deliver therapeutic electrical signals and/or sense intrinsic depolarizations of the heart. Leadless cardiac devices may be positioned within or outside of the heart and, in some examples, may be anchored to a wall of the heart via a fixation mechanism.

SUMMARY

In general, this disclosure describes remotely-deployable active fixation tines for fixating IMDs or their components, such as leads, to patient tissues. As referred to herein an "IMD component," may be an entire IMD or an individual component thereof. Examples of IMDs that may be fixated to patient tissues with remotely-deployable active fixation tines according to this disclosure include leadless pacemakers and leadless sensing devices.

Active fixation tines disclosed herein may be deployed from the distal end of a catheter located at a desired implantation location for the IMD or its component. As further disclosed herein, active fixation tines provide a deployment energy sufficient to permeate a desired patient tissue and secure an IMD or its component to the patient tissue without tearing the patient tissue. This disclosure includes active fixation tines that allow for removal from a patient tissue followed by redeployment, e.g., to adjust the position of the IMD relative to the patient tissue. As different patient tissues have different physical and mechanical characteristics, the design of active fixation tines may be coordinated with patient tissue located at a selected fixation site within a patient. Multiple designs may be used to optimize fixation for a variety of patient tissues.

In one example, the disclosure is directed to an assembly comprising: an implantable medical device; and a set of active fixation tines attached to the implantable medical device. The active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device. The active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue.

In another example, the disclosure is directed to a kit for implanting an implantable medical device within a patient, the kit comprising: the implantable medical device; a set of active fixation tines attached to the implantable medical device. The active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device. The active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue. The kit further comprises a catheter forming a lumen sized to receive the implantable medical device and hold the active fixation tines in the spring-loaded position, wherein the lumen includes an aperture that is adjacent to the distal end of the catheter; and a deployment element configured to initiate deployment of the active fixation tines while the implantable medical device is posi-

tioned within the lumen of the catheter. Deployment of the active fixation tines while the implantable medical device is positioned within the lumen of the catheter causes the active fixation tines to pull the implantable medical device out of the lumen via the aperture that is adjacent to the distal end of the catheter.

In another example, the disclosure is directed to a method comprising: obtaining an assembly comprising an implantable medical device and a set of active fixation tines attached to the implantable medical device; positioning the distal ends of the active fixation tines adjacent to a patient tissue; and deploying the active fixation tines from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device to secure the implantable medical device to the patient tissue.

The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the disclosure will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** is a conceptual diagram illustrating an example therapy system comprising a leadless IMD that may be used to monitor one or more physiological parameters of a patient and/or provide therapy to the heart of a patient.

FIG. **2** is a conceptual diagram illustrating another example therapy system comprising an IMD coupled to a plurality of leads that may be used to monitor one or more physiological parameters of a patient and/or provide therapy to the heart of a patient.

FIGS. **3**A-**3**B illustrate the leadless IMD of FIG. **1** in further detail.

FIGS. **4**A-**4**B illustrate an assembly including the leadless IMD of FIG. **1** and a catheter configured to deploy the leadless IMD of FIG. **1**

FIGS. **5**A-**5**H illustrate techniques for securing the leadless IMD of FIG. **1** to a patient tissue using the catheter of FIG. **4**A-**4**B.

FIGS. **6**A-**6**B illustrate an active fixation tine showing measurements used to calculate performance characteristics of the active fixation tine.

FIGS. **7**A-**7**D illustrate exemplary tine profiles.

FIG. **8** is a functional block diagram illustrating an example configuration of an IMD.

FIG. **9** is a block diagram of an example external programmer that facilitates user communication with an IMD.

FIG. **10** is a flowchart illustrating techniques for implanting an implantable medical device within a patient.

DETAILED DESCRIPTION

Active fixation tines disclosed herein may be useful to secure an implantable medical device (IMD) including any components thereof, such as a medical lead, to a patient tissue during minimally invasive surgery. Minimally invasive surgery, such as percutaneous surgery, permits IMD implantation with less pain and recovery time than open surgery. However, minimally invasive surgery tends to be more complicated than open surgery. For example, forming device fixation requires a surgeon to manipulate instruments remotely, e.g., within the confines of an intravascular catheter. With techniques for remote deployment and fixation of IMDs it can be difficult to ensure adequate fixation while minimizing tissue damage. The active fixation tines disclosed are suitable for securing an IMD to a patient tissue. In addition, active fixation tines disclosed herein also allow for simple removal from a patient tissue without tearing the patient tissue followed by redeployment, e.g., to adjust the position of the IMD after first securing the IMD to the patient tissue.

In one example, active fixation tines disclosed herein may be deployed from the distal end of a catheter positioned by a clinician at a desired implantation location for the IMD. As further disclosed herein, active fixation tines provide a deployment energy sufficient to permeate a desired patient tissue and secure an IMD to the patient tissue without tearing the patient tissue. As different patient tissues have different physical and mechanical characteristics, the design of active fixation tines may be configured according to the properties of the patient tissue located at a selected fixation site within a patient. Multiple designs may be made for a variety of patient tissues, and available for selection based on the patient tissue at the fixation site.

Although various examples are described with respect to cardiac leads and leadless IMD, the disclosed active fixation tines may be useful for fixation of a variety of implantable medical devices in a variety of anatomical locations, and fixation of cardiac leads and leadless IMD is described for purposes of illustration. The described techniques can be readily applied securing catheters and other medical leads, e.g., for neurostimulation. As examples, medical leads with active fixation tines may be used for cardiac stimulation, gastric stimulation, functional electrical stimulation, peripheral nerve stimulation, spinal cord stimulation, pelvic nerve stimulation, deep brain stimulation, or subcutaneous neurological stimulation as well as other forms of stimulation. In addition, described techniques can be readily applied to IMDs including sensors, including leadless IMDs and IMDs with medical leads. As examples, IMDs including sensors and active fixation tines may include one or more of the following sensors: a pressure sensor, an electrocardiogram sensor, an oxygen sensor (for tissue oxygen or blood oxygen sensing), an accelerometer, a glucose sensor, a potassium sensor, a thermometer and/or other sensors.

FIG. **1** is a conceptual diagram illustrating an example therapy system **10**A that may be used to monitor one or more physiological parameters of patient **14** and/or to provide therapy to heart **12** of patient **14**. Therapy system **10**A includes IMD **16**A, which is coupled to programmer **24**. IMD **16**A may be an implantable leadless pacemaker that provides electrical signals to heart **12** via one or more electrodes (not shown in FIG. **1**) on its outer housing. Additionally or alternatively, IMD **16**A may sense electrical signals attendant to the depolarization and repolarization of heart **12** via electrodes on its outer housing. In some examples, IMD **16**A provides pacing pulses to heart **12** based on the electrical signals sensed within heart **12**.

IMD **16**A includes a set of active fixation tines to secure IMD **16**A to a patient tissue. In the example of FIG. **1**, IMD **16**A is positioned wholly within heart **12** proximate to an inner wall of right ventricle **28** to provide right ventricular (RV) pacing. Although IMD **16**A is shown within heart **12** and proximate to an inner wall of right ventricle **28** in the example of FIG. **1**, IMD **16**A may be positioned at any other location outside or within heart **12**. For example, IMD **16**A may be positioned outside or within right atrium **26**, left atrium **36**, and/or left ventricle **32**, e.g., to provide right atrial, left atrial, and left ventricular pacing, respectively.

Depending on the location of implant, IMD **16**A may include other stimulation functionalities. For example, IMD

16A may provide atrioventricular nodal stimulation, fat pad stimulation, vagal stimulation, or other types of neurostimulation. In other examples, IMD 16A may be a monitor that senses one or more parameters of heart 12 and may not provide any stimulation functionality. In some examples, system 10A may include a plurality of leadless IMDs 16A, e.g., to provide stimulation and/or sensing at a variety of locations.

As discussed in greater detail with respect to FIGS. 3A-5H, IMD 16A includes a set of active fixation tines. The active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the IMD to a hooked position in which the active fixation tines bend back towards the IMD. The active fixation tines allow IMD 16A to be removed from a patient tissue followed by redeployment, e.g., to adjust the position of IMD 16A relative to the patient tissue. For example, a clinician implanting IMD 16A may reposition IMD 16A during an implantation procedure if testing of IMD 16A indicates a poor electrode-tissue connection.

FIG. 1 further depicts programmer 24 in wireless communication with IMD 16A. In some examples, programmer 24 comprises a handheld computing device, computer workstation, or networked computing device. Programmer 24, shown and described in more detail below with respect to FIG. 9, includes a user interface that presents information to and receives input from a user. It should be noted that the user may also interact with programmer 24 remotely via a networked computing device.

A user, such as a physician, technician, surgeon, electrophysiologist, other clinician, or patient, interacts with programmer 24 to communicate with IMD 16A. For example, the user may interact with programmer 24 to retrieve physiological or diagnostic information from IMD 16A. A user may also interact with programmer 24 to program IMD 16A, e.g., select values for operational parameters of the IMD 16A. For example, the user may use programmer 24 to retrieve information from IMD 16A regarding the rhythm of heart 12, trends therein over time, or arrhythmic episodes.

As an example, the user may use programmer 24 to retrieve information from IMD 16A regarding other sensed physiological parameters of patient 14 or information derived from sensed physiological parameters, such as intracardiac or intravascular pressure, activity, posture, tissue oxygen levels, blood oxygen levels, respiration, tissue perfusion, heart sounds, cardiac electrogram (EGM), intracardiac impedance, or thoracic impedance. In some examples, the user may use programmer 24 to retrieve information from IMD 16A regarding the performance or integrity of IMD 16A or other components of system 10A, or a power source of IMD 16A. As another example, the user may interact with programmer 24 to program, e.g., select parameters for, therapies provided by IMD 16A, such as pacing and, optionally, neurostimulation.

IMD 16A and programmer 24 may communicate via wireless communication using any techniques known in the art. Examples of communication techniques may include, for example, low frequency or radiofrequency (RF) telemetry, but other techniques are also contemplated. In some examples, programmer 24 may include a programming head that may be placed proximate to the patient's body near the IMD 16A implant site in order to improve the quality or security of communication between IMD 16A and programmer 24.

FIG. 2 is a conceptual diagram illustrating another example therapy system 10B that may be used to monitor one or more physiological parameters of patient 14 and/or to provide therapy to heart 12 of patient 14. Therapy system 10B includes IMD 16B, which is coupled to medical leads 18, 20, and 22, and programmer 24. As referred to herein, each of IMD 16B and medical leads 18, 20 and 22 may be referred to generally as an IMD. In one example, IMD 16B may be an implantable pacemaker that provides electrical signals to heart 12 via electrodes coupled to one or more of leads 18, 20, and 22. IMD 16B is one example of an electrical stimulation generator, and is configured attached to the proximal end of medical leads 18, 20, and 22. In other examples, in addition to or alternatively to pacing therapy, IMD 16B may deliver neurostimulation signals. In some examples, IMD 16B may also include cardioversion and/or defibrillation functionalities. In other examples, IMD 16B may not provide any stimulation functionalities and, instead, may be a dedicated monitoring device. Patient 14 is ordinarily, but not necessarily, a human patient.

Medical leads 18, 20, 22 extend into the heart 12 of patient 14 to sense electrical activity of heart 12 and/or deliver electrical stimulation to heart 12. In the example shown in FIG. 2, right ventricular (RV) lead 18 extends through one or more veins (not shown), the superior vena cava (not shown), right atrium 26, and into right ventricle 28. RV lead 18 may be used to deliver RV pacing to heart 12. Left ventricular (LV) lead 20 extends through one or more veins, the vena cava, right atrium 26, and into the coronary sinus 30 to a region adjacent to the free wall of left ventricle 32 of heart 12. LV lead 20 may be used to deliver LV pacing to heart 12. Right atrial (RA) lead 22 extends through one or more veins and the vena cava, and into the right atrium 26 of heart 12. RA lead 22 may be used to deliver RA pacing to heart 12.

In some examples, system 10B may additionally or alternatively include one or more leads or lead segments (not shown in FIG. 2) that deploy one or more electrodes within the vena cava or other vein, or within or near the aorta. Furthermore, in another example, system 10B may additionally or alternatively include one or more additional intravenous or extravascular leads or lead segments that deploy one or more electrodes epicardially, e.g., near an epicardial fat pad, or proximate to the vagus nerve. In other examples, system 10B need not include one of ventricular leads 18 and 20.

One or more of medical leads 18, 20, 22 may include a set of active fixation tines to secure a distal end of the medical lead to a patient tissue. The inclusion of active fixation tines for each medical leads 18, 20, 22 is merely exemplary. One or more of medical leads 18, 20, 22 could be secured by alternative techniques. For example, even though each of medical leads 18, 20 and 22 is shown with a set of active fixation tines to secure a distal end of the medical lead, LV lead 20, which extends through one or more veins and the vena cava and into the right atrium 26 of heart 12, may instead be fixed using passive fixation.

The active fixation tines in set active fixation tines attached to a medical lead are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the IMD to a hooked position in which the active fixation tines bend back towards the IMD. The active fixation tines allow the distal end of the medical lead be removed from a patient tissue followed by redeployment, e.g., to adjust the position of the distal end of the medical lead relative to the patient tissue. For example, a clinician implanting IMD 16B may reposition the distal end of a medical lead during an implantation procedure if testing of IMD 16B indicates a poor electrode-tissue connection.

IMD **16**B may sense electrical signals attendant to the depolarization and repolarization of heart **12** via electrodes (described in further detail with respect to FIG. **4**) coupled to at least one of the leads **18**, **20**, **22**. In some examples, IMD **16**B provides pacing pulses to heart **12** based on the electrical signals sensed within heart **12**. The configurations of electrodes used by IMD **16**B for sensing and pacing may be unipolar or bipolar.

IMD **16**B may also provide neurostimulation therapy, defibrillation therapy and/or cardioversion therapy via electrodes located on at least one of the leads **18**, **20**, **22**. For example, IMD **16**B may deliver defibrillation therapy to heart **12** in the form of electrical pulses upon detecting ventricular fibrillation of ventricles **28** and **32**. In some examples, IMD **16**B may be programmed to deliver a progression of therapies, e.g., pulses with increasing energy levels, until a fibrillation of heart **12** is stopped. As another example, IMD **16**B may deliver cardioversion or anti-tachycardia pacing (ATP) in response to detecting ventricular tachycardia, such as tachycardia of ventricles **28** and **32**.

As described above with respect to IMD **16**A of FIG. **1**, programmer **24** may also be used to communicate with IMD **16**B. In addition to the functions described with respect to IMD **16**A of FIG. **1**, a user may use programmer **24** to retrieve information from IMD **16**B regarding the performance or integrity of leads **18**, **20** and **22** and may interact with programmer **24** to program, e.g., select parameters for, any additional therapies provided by IMD **16**B, such as cardioversion and/or defibrillation.

Leads **18**, **20**, **22** may be electrically coupled to a signal generator and a sensing module of IMD **16**B via connector block **34**. In some examples, proximal ends of leads **18**, **20**, **22** may include electrical contacts that electrically couple to respective electrical contacts within connector block **34** of IMD **16**B. In some examples, a single connector, e.g., an IS-4 or DF-4 connector, may connect multiple electrical contacts to connector block **34**. In addition, in some examples, leads **18**, **20**, **22** may be mechanically coupled to connector block **34** with the aid of set screws, connection pins, snap connectors, or another suitable mechanical coupling mechanism.

The configuration of system **10**B illustrated in FIG. **2** is merely one example. In other examples, a system may include epicardial leads and/or patch electrodes instead of or in addition to the transvenous leads **18**, **20**, **22** illustrated in FIG. **2**. Further, IMD **16**B need not be implanted within patient **14**. In examples in which IMD **16**B is not implanted in patient **14**, IMD **16**B may deliver defibrillation pulses and other therapies to heart **12** via percutaneous leads that extend through the skin of patient **14** to a variety of positions within or outside of heart **12**. For each of these examples, any number of the medical leads may include a set of active fixation tines on a distal end of the medical lead in accordance with the techniques described herein.

In addition, in other examples, a system may include any suitable number of leads coupled to IMD **16**B, and each of the leads may extend to any location within or proximate to heart **12**. For example, other examples of systems may include three transvenous leads located as illustrated in FIG. **2**, and an additional lead located within or proximate to left atrium **36**. Other examples of systems may include a single lead that extends from IMD **16**B into right atrium **26** or right ventricle **28**, or two leads that extend into a respective one of the right ventricle **28** and right atrium **26**. Any electrodes located on these additional leads may be used in sensing and/or stimulation configurations. In each of these examples, any number of the medical leads may include a set of active fixation tines on a distal end of the medical lead in accordance with the techniques described herein.

FIGS. **3**A-**3**B illustrate leadless IMD **16**A of FIG. **1** in further detail. In the example of FIGS. **3**A and **3**B, leadless IMD **16**A includes tine fixation subassembly **100** and electronic subassembly **150**. Tine fixation subassembly **100** is configured to anchor leadless IMD **16**A to a patient tissue, such as a wall of heart **12**.

Electronic subassembly **150** includes control electronics **152**, which controls the sensing and/or therapy functions of IMD **16**A, and battery **160**, which powers control electronics **152**. As one example, control electronics **152** may include sensing circuitry, a stimulation generator and a telemetry module. As one example, battery **160** may comprise features of the batteries disclosed in U.S. patent application Ser. No. 12/696,890, titled IMPLANTABLE MEDICAL DEVICE BATTERY and filed Jan. 29, 2010, the entire contents of which are incorporated by reference herein.

The housings of control electronics **152** and battery **160** are formed from a biocompatible material, such as a stainless steel or titanium alloy. In some examples, the housings of control electronics **152** and battery **160** may include an insulating coating. Examples of insulating coatings include parylene, urethane, PEEK, or polyimide among others. Electronic subassembly **150** further includes anode **162**, which may include a low polarizing coating, such as titanium nitride, iridium oxide, ruthenium oxide among others. The entirety of the housings of control electronics **152** and battery **160** are electrically connected to one another, but only anode **162** is uninsulated. In other examples, the entirety of the housing of battery **160** or the entirety of the housing of electronic subassembly **150** may function as an anode instead of providing a localized anode such as anode **162**. Alternatively, anode **162** may be electrically isolated from the other portions of the housings of control electronics **152** and battery **160**.

Delivery tool interface **158** is located at the proximal end of electronic subassembly **150**. Delivery tool interface **158** is configured to connect to a delivery device, such as catheter **200** (FIG. **5**A) used to position IMD **16**A during an implantation procedure. Tine fixation subassembly interface **153** and feedthrough pin **154** are located at the distal end of electronic subassembly **150**. Tine fixation subassembly interface **153** includes three tabs that interlock with tine fixation subassembly **100**.

As best illustrated in FIG. **3**B, tine fixation subassembly **100** includes fixation element **102**, header body **112**, header cap **114**, locking tab **120**, electrode **122**, monolithic controlled release device (MCRD) **124** and filler cap **126**. Fixation element **102** includes a set of four active fixation tines **103** that are deployable from a spring-loaded position in which distal ends of active fixation tines **103** point away from electronic subassembly **150** to a hooked position in which active fixation tines **103** bend back towards electronic subassembly **150**. For example, active fixation tines **103** are shown in the hooked position in FIG. **3**A. As discussed in further detail with respect to FIGS. **4**A-**5**H, active fixation tines **103** are configured to secure IMD **16**A to a patient tissue, e.g., a tissue inside the heart or outside the heart, when deployed while the distal ends of active fixation tines **103** are positioned adjacent to the patient tissue. In different examples, active fixation tines **103** may be positioned adjacent to patient tissue such that distal ends **109** penetrate the patient tissue prior to deployment, positioned adjacent to patient tissue such that distal ends **109** contact but do not penetrate the patient tissue prior to deployment or positioned

adjacent to patient tissue such that distal ends **109** are near to but do not contact or penetrate the patient tissue prior to deployment.

Fixation element **102** may be fabricated of a shape memory material, which allows active fixation tines **103** to bend elastically from the hooked position to the spring-loaded position. As an example, the shape memory material may be shape memory alloy such as Nitinol. In one example, fixation element **102** including active fixation tines **103** and base **111**, may be manufactured by cutting fixation element **102** as a unitary component from a hollow tube of Nitinol, bending the cut tube to form the hooked position shape of active fixation tines **103** and heat-treating fixation element **102** while holding active fixation tines **103** in the hooked position. Sharp edges of fixation element **102** may be rounded off to improve fatigue loading and reduce tearing of patient tissue during deployment and retraction of active fixation tines **103**.

In some examples, all or a portion of fixation element **102**, such as active fixation tines **103**, may include one or more coatings. For example, fixation element **102** may include a radiopaque coating to provide visibility during fluoroscopy. In one such example, fixation element **102** may include one or more radiopaque markers. As another example, fixation element **102** may be coated with a tissue growth promoter or a tissue growth inhibitor. A tissue growth promoter may be useful to increase the holding force of active fixation tines **103**, whereas a tissue growth inhibitor may be useful to facilitate removal of IMD **16**A during an explantation procedure, which may occur many years after the implantation of IMD **16**A.

During assembly of IMD **16**A, prior to being mounted to electronic subassembly **150**, fixation element **102** may be mounted in a header including header body **112** and header cap **114**. For example, fixation element **102** may be mounted such that one tine extends though each of holes **113** in header body **112**. Then header cap **114** is positioned over base **111** of fixation element **102** and secured to header body **112**. As an example, header body **112** and header cap **114** may be fabricated of a biocompatible polymer such as polyether ether ketone (PEEK). Header body **112** and header cap **114** may function to electrically isolate fixation element **102** from electronic subassembly **150** and feedthrough pin **154**. In other examples, fixation element **102** itself may be used as an electrode for stimulation and/or sensing a physiological condition of a patient and may electrically connect to control electronics **152**.

During assembly of IMD **16**A, once fixation element **102** is assembled with header body **112** and header cap **114**, fixation element **102**, header body **112** and header cap **114** are mounted to the tabs of tine fixation subassembly interface **153** on electronic subassembly **150** by positioning header body **112** over the tabs of tine fixation subassembly interface **153** and rotating header body **112** to interlock header body **112** with the tabs of tine fixation subassembly interface **153**. Feedthrough pin **154** extends through the center of header body **112** once header body **112** is secured to tine fixation subassembly interface **153**.

During assembly of IMD **16**A, after header body **112** is secured to tine fixation subassembly interface **153**, locking tab **120** is positioned over feedthrough pin **154**. As an example, locking tab **120** may be fabricated of a silicone material. Next, electrode **122** is positioned over locking tab **120** and feedthrough pin **154**, and then mechanically and electrically connected to feedthrough pin **154**, e.g., using a laser weld. As an example, electrode **122** may comprise a biocompatible metal, such as an iridium alloy or a platinum alloy.

MCRD **124** is located within recess **123** of electrode **122**. In the illustrated example, MCRD **124** takes the form of a cylindrical plug. In other examples, an MCRD band may positioned around the outside of the electrode rather than configured as a cylindrical plug. MCRD **124** may be fabricated of a silicone based polymer, or other polymers. MCRD **124** may incorporate an anti-inflammatory drug, which may be, for example, the sodium salt of dexamethasone phosphate. Because MCRD **124** is retained within recess **123** of electrode **122**, migration of the drug contained in MCRD **124** is limited to the tissue in contact with the distal end of electrode **122**. Filler cap **126** is positioned over electrode **122**. As an example, filler cap **126** may be fabricated of a silicone material and positioned over both electrode **122** and locking tab **120** during assembly of IMD **16**A.

As different patient tissues have different physical and mechanical characteristics, active fixation tines **103** may be specifically designed to perform with patient tissues having specific characteristics. For example, active fixation tines **103** may be designed to provide a selected fixation force, designed to penetrate to a particular depth of a patient tissue, designed to penetrate to a particular layer of patient tissue (as different tissue layers may have different mechanical properties) and/or designed to facilitate removal and redeployment from the patient tissue without tearing the patient tissue, either on deployment or removal. Multiple designs of active fixation tine **103** may be used to optimize fixation for a variety of patient tissues. The design of active fixation tine **103** is discussed in further detail with respect to FIGS. **6**A-**6**B. In addition, the specific design of tine fixation subassembly **100** is not germane to the operation of active fixation tines **103**, and a variety of techniques may be used to attach a set of active fixation tines to an IMD.

FIG. **4**A illustrates assembly **180**, which includes leadless IMD **16**A and catheter **200**, which is configured to remotely deploy IMD **16**A. Catheter **200** may be a steerable catheter or be configured to traverse a guidewire. In any case, catheter **200** may be directed within a body lumen, such as a vascular structure to a target site in order to facilitate remote positioning and deployment of IMD **16**A. In particular, catheter **200** forms lumen **201**, which is sized to receive IMD **16**A at the distal end of catheter **200**. For example, the inner diameter of lumen **201** at the distal end of catheter **200** may be about the same size as the outer diameter of IMD **16**A. When IMD **16**A is positioned within lumen **201** at the distal end of catheter **200**, lumen **201** holds active fixation tines **103** in the spring-loaded position shown in FIG. **4**A. In the spring-loaded position, active fixation tines **103** store enough potential energy to secure IMD **16**A to a patient tissue upon deployment.

Lumen **201** includes aperture **221**, which is positioned at the distal end of catheter **200**. Aperture **221** facilitates deployment of IMD **16**A. Deployment element **210** is positioned proximate to IMD **16**A in lumen **201**. Deployment element **210** configured to initiate deployment of active fixation tines **103**. More particularly, a clinician may remotely deploy IMD **16**A by pressing plunger **212**, which is located at the proximal end of catheter **200**. Plunger **212** connects directly to deployment element **210**, e.g., with a wire or other stiff element running through catheter **200**, such that pressing on plunger **212** moves deployment element **210** distally within lumen **201**. As deployment element **210** moves distally within lumen **201**, deployment element **210** pushes IMD **16**A distally within lumen **201** and towards

aperture **221**. Once the distal ends **109** of active fixation tines **103** reach aperture **221**, active fixation tines **103** pull IMD **16**A out of lumen **201** via aperture **221** as active fixation tines **103** move from a spring-loaded position to a hooked position to deploy IMD **16**A. The potential energy released by active fixation tines **103** is sufficient to penetrate a patient tissue and secure IMD **16**A to the patient tissue.

Tether **220** is attached to delivery tool interface **158** (not shown in FIG. **4**A) of IMD **16**A and extends through catheter **200**. Following deployment of IMD **16**A, a clinician may remotely pull IMD **16**A back into lumen **201** by pulling on tether **220** at the proximal end of catheter **200**. Pulling IMD **16**A back into lumen **201** returns active fixation tines **103** to the spring-loaded position from the hooked position. The proximal ends of active fixation tines **103** remain fixed to the housing of IMD **16**A as active fixation tines **103** move from the spring-loaded position to the hooked position and vice-versa. Active fixation tines **103** are configured to facilitate releasing IMD **16**A from patient tissue without tearing the tissue when IMD **16**A is pulled back into lumen **201** by tether **220**. A clinician may redeploy IMD **16**A with deployment element **210** by operating plunger **212**.

FIG. **4**B is a sectional view of the distal end of assembly **180** in which IMD **16**A is positioned within lumen **201**. Lumen **201** holds active fixation tines **103** in a spring-loaded position. Distal ends **109** of active fixation tines **103** are indicated in FIG. **4**B. As shown in FIG. **4**B, the four active fixation tines **103** are positioned substantially equidistant from each other in a circular arrangement. As best seen in FIG. **3**A, active fixation tines **103** are oriented outwardly relative to the circular arrangement.

Positioning active fixation tines **103** substantially equidistant from each other in a circular arrangement creates opposing radial forces **222** when active fixation tines **103** are deployed in unison. This allows the combined forces of active fixation tines **103** acting on the distal end of catheter **200** to pull IMD **16**A about perpendicularly out of aperture **221**. When the active fixation tines are deployed while aperture **221** and distal ends **109** of active fixation tines **103** are positioned adjacent to a patient tissue, the forces of active fixation tines **103** acting on the distal end of catheter **200** combine to pull IMD **16**A straight out from aperture **221** and directly towards the patient tissue. While IMD **16**A includes a set of four active fixation tines, a set of more or less than four active fixation tines may be used. For example, as few as two active fixation tines may provide opposing radial forces **222**; however, a set of at least three active fixation tines may provide better directional consistency in the deployment of an IMD such as IMD **16**A.

Distal ends **109** of active fixation tines **103** include substantially flat outer surfaces to register active fixation tines **103** on the inner surface of lumen **201**. The flat outer surfaces of active fixation tines **103** help ensure that the interaction between active fixation tines **103** and the inner surface of lumen **201** during deployment of IMD **16**A provides opposing radial forces **222**.

FIGS. **5**A-**5**H illustrate example techniques for securing IMD **16**A to patient tissue **300** using catheter **200**. As an example, patient tissue **300** may be a heart tissue, such as the inner wall of the right ventricle. For simplicity, a set of only two active fixation tines **103** are shown in each of FIGS. **5**A-**5**H; however, the described techniques for securing IMD **16**A to patient tissue **300** are equally applicable to IMDs including a set of more than two active fixation tines **103**.

FIG. **5**A illustrates IMD **16**A within lumen **201** of catheter **200**. Lumen **201** holds active fixation tines **103** in a spring-loaded position in which distal ends **109** of active fixation tines **103** point away from IMD **16**A. Aperture **221** is positioned adjacent patient tissue **300**. The distal end **202** of catheter **200** may not pressed forcefully into patient tissue **300**, as pressing patient tissue **300** would alter the mechanical characteristics of patient tissue **300**. As active fixation tines **103** may be designed accordingly to the mechanical characteristics of patient tissue **300**, altering the mechanical characteristics of patient tissue **300** may undesirably alter the interaction of active fixation tines **103** and patient tissue **300** during deployment of active fixation tines **103**. In other examples, it may be desirable to alter the mechanical characteristics of patient tissue **300** for deployment, by significantly pressing on patient tissue **300** during deployment or by otherwise altering the mechanical characteristics of patient tissue **300**, to achieve a desired interaction (e.g., tissue permeation, fixation depth, etc.) between patient tissue **300** and active fixation tines **103** during deployment of active fixation tines **103**.

FIG. **5**B illustrates IMD **16**A shortly after a clinician remotely activated active fixation tines **103** using deployment element **210** by pressing on plunger **212** (FIG. **4**A). As the clinician pressed plunger **212**, deployment element **210** pushed IMD **16**A distally within lumen **201**. Once the distal ends **109** of active fixation tines **103** reached aperture **221**, active fixation tines **103** began to pull IMD **16**A out of lumen **201** via aperture **221**. Distal ends **109** of active fixation tines **103** then penetrated patient tissue **300**. FIG. **5**B illustrates active fixation tines **103** in a position after distal ends **109** of active fixation tines **103** penetrated patient tissue **300** and shortly after beginning the transition from a spring-loaded position to a hooked position.

FIGS. **5**B-**5**F illustrates active fixation tines **103** as they move from a spring-loaded position in which distal ends **109** of active fixation tines **103** point away from IMD **16**A to a hooked position in which distal ends **109** of active fixation tines **103** bend back towards IMD **16**A. FIGS. **5**D-**5**F illustrate active fixation tines **103** in hooked positions. In FIG. **5**D, distal ends **109** of active fixation tines **103** remain embedded in patient tissue **300**, whereas FIGS. **5**E-**5**F illustrate distal ends **109** of active fixation tines **103** penetrating out of patient tissue **300**.

As active fixation tines **103** move from a spring-loaded position to a hooked position, potential energy stored in active fixation tines **103** is released as IMD **16**A is pulled from lumen **201** via aperture **221**. In addition, active fixation tines **103** penetrate patient tissue **300** to secure IMD **16**A to patient tissue **300** such that electrode **123** (FIG. **5**E) contacts patient tissue **300** within the center of the circular arrangement of active fixation tines **103**. Active fixation tines **103** provide a forward pressure of electrode **123** onto tissue **300** to assure good electrode-tissue contact.

As active fixation tines **103** pull IMD **16**A from lumen **201**, tether **220**, which is attached to delivery tool interface **158** of IMD **16**A is exposed, e.g., as shown in FIG. **5**E. Following deployment of IMD **16**A, a clinician may remotely pull IMD **16**A back into lumen **201** by pulling on tether **220** at the proximal end of catheter **200**. For example, the clinician may perform a test of IMD **16**A to evaluate a performance characteristic of electrode **123** while the IMD **16**A is secured to patient tissue **300** as shown in FIG. **5**E. If the test of IMD **16**A indicates inadequate performance, the clinician may decide to redeploy IMD **16**A. Pulling IMD **16**A back into lumen **201** releases IMD **16**A from patient tissue **300** and returns IMD **16**A to the position shown in FIG. **5**A. From this position a clinician may reposition IMD **16**A as desired and redeploy IMD **16**A.

As shown in FIG. **5**F, once IMD **16**A is secured to patient tissue **300** in the desired position, the clinician may release IMD **16**A from tether **220**. For example, the clinician may sever tether **220** at the proximal end of catheter **200** and remove tether **220** from delivery tool interface **158** by pulling on one of the severed ends of tether **220**. As shown in FIG. **5**G, once IMD **16**A is released from tether **220**, the clinician may remove catheter **200**, leaving IMD **16**A secured to patient tissue **300**. As shown in FIG. **5**H, active fixation tines **103** may continue to migrate to a lower-potential energy hooked position over time. However, any of the hooked positions of active fixation tines **103** as shown in FIGS. **5**D-**5**G may be sufficient to adequately secure IMD **16**A to patient tissue **300**.

While the techniques of FIGS. **5**A-**5**H are illustrated with respect to IMD **16**A, the techniques may also be applied to a different IMD, such as a medical lead including a set of active fixation tines like medical leads **18**, **20**, **22** of IMD **16**B (FIG. **2**). For example, such a medical lead may extend through a catheter during an implantation procedure. As such, deploying a medical lead may not require a separate deployment element within the catheter. Instead, simply pushing on the medical lead at the proximal end of the catheter may initiate deployment of a set of active fixation tines at the distal end of the medical lead by pushing the active fixation tines attached to the distal end of the medical lead out of the distal end of the catheter. Similarly retracting a medical lead for redeployment may not require a tether, but may instead simply involve pulling on the medical lead at the proximal end of the catheter.

FIGS. **6**A-**6**B illustrate one active fixation tine **103** and further illustrate measurements used to calculate performance characteristics of active fixation tine **103**. In particular, FIG. **6**A illustrates a cross-section of active fixation tine **103** with width **104** and thickness (T) **105**. FIG. **6**B illustrates a side-view of active fixation tine **103** with tine length (L) **106**, tine radius (r) **107** and tine angle **108**.

The design of active fixation tine **103** is based on many criteria. As one example, an active fixation tine must penetrate a patient tissue when extended in the spring-loaded position. To meet this criteria, length **106** must be large enough to overcome the elasticity of the patient tissue such that distal end **109** of active fixation tine **103** permeates the patient tissue before active fixation tine **103** starts to bend significantly when deployed. For example, active fixation tine **103** will start to bend significantly when deployed once the curved portion of active fixation tine **103** reaches aperture **221** in distal end **202** of catheter **200** (FIG. **4**A).

If distal end **109** of active fixation tine **103** were pointed, this would reduce the insertion force; however, adding a sharp point to active fixation tine **103** may cause tearing of patient tissue during deployment and removal of active fixation tine **103**. For this reason, distal end **109** of active fixation tine **103** may be rounded. As one example, tine thickness **105** may be between about 0.005 inches and about 0.010 inches. In a further example, tine thickness **105** may be between about 0.006 inches and about 0.009 inches. In some examples, a tine may include a ball on its distal end to further resist tearing of patient tissue. One such example is shown in FIG. **7**C.

As another example, the straight section providing length **106** of active fixation tine **103** must provide a column strength great enough to resist buckling from the force of the patient tissue before distal end **109** of active fixation tine **103** permeates the patient tissue. Column strength is dependent on length **106**, width **104** and thickness **105**, whereas the force required to permeate a patient tissue is dependent on mechanical properties of the tissue and the cross-sectional area of distal end **109** of active fixation tine **103**. In addition, active fixation tine **103** may be designed to buckle before penetrating a particular tissue layer deeper than a targeted tissue layer. For example, when attaching to endocardial tissue, a tine may be designed to buckle before penetrating an epicardial layer of heart tissue to prevent penetrating an epicardial layer of heart tissue during deployment.

As another example, a set of active fixation tines may be designed to provide a selected holding force, which may also be referred to as the pull force required to remove a deployed set of active fixation tines from patient tissue (or other material). As one example, a holding force of between 1 and 5 newtons (N) or between 2 and 3 N may be suitable for securing IMD **16**A within heart **12** (FIG. **1**), while facilitating removal of the set of active fixation tines without tearing patient tissue.

Releasing an IMD from the tissue without tearing the tissue by pulling the implantable medical device away from the tissue includes, pulling on the implantable medical device to stretch the tissue until the tissue stiffness matches the tine straightening force, further pulling on the implantable medical device until the tines straighten without tearing the tissue, and continued pulling on the implantable medical device once the tines have straightened sufficiently to remove the tines from the patient tissue. The pulling distance required to release the tines from the tissue is longer than the length of the tines because of the elasticity of the tissue. For an example, in an example wherein the tines 7 mm long, removing the tines from the tissue may require pulling the IMD 12-20 mm away from the tissue.

Tine holding force may be considered the sum of tine straightening forces (to move the active fixation tines from the hooked position to the spring-loaded position) plus forces between the tine and the patient tissue, including frictional forces and forces that resist straightening of the tine in the patient tissue. Using finite element analysis, validated by actual testing, the following transfer function of the pull force required to remove a set of four active fixation tines deployed in cardiac tissue was determined, wherein C_1:C_8 each represents a constant greater than zero:

$$\text{Pull Force} = -C_1 + C2*T - C_3*L + C_4*r - C_5*T*L - C_6*T*r - C_7*L*r + C_8*T*L*r \quad \text{(Equation 1)}$$

A sensitivity analysis using a Pareto Chart of Effects on the importance of the different factors of Equation 1 indicated that pull force is most sensitive to tine thickness (59%), followed by tine radius (38%). Pull force showed the least sensitivity to tine length (3%). In addition, the interaction between thickness and radius was also important, whereas the other interactions were less significant.

In some examples, thickness greater than 0.009 inches or less than 0.003 inches may not be able to produce a pull forces suitable for securing IMD **16**A within heart **12** (FIG. **1**). Of course, in other examples, e.g., using a different selected holding forces, or assuming different material properties of active fixation tines **103** and/or of patient tissue tine thickness of greater than 0.009 inches or less than 0.003 inches may be suitable.

One additional design factor is fatigue loading, e.g., fatigue loading resulting from movement of a patient. For example, active fixation tines **103** may be designed to secure IMD **16**A to patient heart **12** for a period of eighteen or more years. During that time, active fixation tines **103** may experience about 600 million heart beats from heart **12**. In addition, sharp corners are detrimental to withstanding

fatigue loading; for this reason, corners of active fixation tines **103** may be rounded, e.g., as best shown in FIG. **6**A.

FIGS. **7**A-**7**D illustrate exemplary profiles of the distal ends of different active fixation tine designs. In particular, FIG. **7**A, illustrates rectangular profile **410** that provides a consistent width through its distal end **412**. A tine providing rectangular profile **410** may also provide a generally consistent thickness. As an example, rectangular profile **410** is consistent with the profile of active fixation tines **103**.

FIG. **7**B illustrates profile **420**, which includes an increased width at its distal end **422**. A tine providing profile **420** may also provide a generally consistent thickness. Profile **420** may provide an increased insertion force and reduced column strength relative to tine profile **410**. In addition, a tine providing profile **420** may reduce tearing of patient tissue during insertion and removal relative to a tine providing tine profile **410**.

FIG. **7**C illustrates profile **430**, with includes an enlarged distal tip **432**. Enlarged distal tip **432** is wider and thicker than the rest of a tine providing profile **430**. A tine including enlarged distal tip **432** may reduce tearing of patient tissue during insertion and removal relative to a tine providing tine profile **410**.

FIG. **7**D illustrates profile **440**, which includes an increased width at its distal end **442**. A tine providing profile **440** may also provide a generally consistent thickness. Profile **440** also includes a series of apertures **444**. After implantation, a tine including apertures **444** may provide a significant increase in holding strength relative to tine providing profile **410** as patient tissue grows around apertures **444**. In addition, tine profile **440** may provide an increased insertion force and reduced column strength relative to tine profile **410**.

FIG. **8** is a functional block diagram illustrating one example configuration of IMD **16**A of FIGS. **1** and **3** or IMD **16**B of FIG. **2** (referred to generally as IMD **16**). In the example illustrated by FIG. **8**, IMD **16** includes a processor **80**, memory **82**, signal generator **84**, electrical sensing module **86**, telemetry module **88**, and power source **89**. Memory **82** may include computer-readable instructions that, when executed by processor **80**, cause IMD **16** and processor **80** to perform various functions attributed to IMD **16** and processor **80** herein. Memory **82** may be a computer-readable storage medium, including any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital or analog media.

Processor **80** may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), or equivalent discrete or integrated logic circuitry. In some examples, processor **80** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processor **80** in this disclosure may be embodied as software, firmware, hardware or any combination thereof. Processor **80** controls signal generator **84** to deliver stimulation therapy to heart **12** according to operational parameters or programs, which may be stored in memory **82**. For example, processor **80** may control signal generator **84** to deliver electrical pulses with the amplitudes, pulse widths, frequency, or electrode polarities specified by the selected one or more therapy programs.

Signal generator **84**, as well as electrical sensing module **86**, is electrically coupled to electrodes of IMD **16** and/or leads coupled to IMD **16**. In the example illustrated in FIG. **8**, signal generator **84** is configured to generate and deliver electrical stimulation therapy to heart **12**. For example, signal generator **84** may deliver pacing, cardioversion, defibrillation, and/or neurostimulation therapy via at least a subset of the available electrodes. In some examples, signal generator **84** delivers one or more of these types of stimulation in the form of electrical pulses. In other examples, signal generator **84** may deliver one or more of these types of stimulation in the form of other signals, such as sine waves, square waves, or other substantially continuous time signals.

Signal generator **84** may include a switch module and processor **80** may use the switch module to select, e.g., via a data/address bus, which of the available electrodes are used to deliver stimulation signals, e.g., pacing, cardioversion, defibrillation, and/or neurostimulation signals. The switch module may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple a signal to selected electrodes.

Electrical sensing module **86** monitors signals from at least a subset of the available electrodes, e.g., to monitor electrical activity of heart **12**. Electrical sensing module **86** may also include a switch module to select which of the available electrodes are used to sense the heart activity. In some examples, processor **80** may select the electrodes that function as sense electrodes, i.e., select the sensing configuration, via the switch module within electrical sensing module **86**, e.g., by providing signals via a data/address bus.

In some examples, electrical sensing module **86** includes multiple detection channels, each of which may comprise an amplifier. Each sensing channel may detect electrical activity in respective chambers of heart **12**, and may be configured to detect either R-waves or P-waves. In some examples, electrical sensing module **86** or processor **80** may include an analog-to-digital converter for digitizing the signal received from a sensing channel for electrogram (EGM) signal processing by processor **80**. In response to the signals from processor **80**, the switch module within electrical sensing module **86** may couple the outputs from the selected electrodes to one of the detection channels or the analog-to-digital converter.

During pacing, escape interval counters maintained by processor **80** may be reset upon sensing of R-waves and P-waves with respective detection channels of electrical sensing module **86**. Signal generator **84** may include pacer output circuits that are coupled, e.g., selectively by a switching module, to any combination of the available electrodes appropriate for delivery of a bipolar or unipolar pacing pulse to one or more of the chambers of heart **12**. Processor **80** may control signal generator **84** to deliver a pacing pulse to a chamber upon expiration of an escape interval. Processor **80** may reset the escape interval counters upon the generation of pacing pulses by signal generator **84**, or detection of an intrinsic depolarization in a chamber, and thereby control the basic timing of cardiac pacing functions. The escape interval counters may include P-P, V-V, RV-LV, A-V, A-RV, or A-LV interval counters, as examples. The value of the count present in the escape interval counters when reset by sensed R-waves and P-waves may be used by processor **80** to measure the durations of R-R intervals, P-P intervals, P-R intervals and R-P intervals. Processor **80** may use the count in the interval counters to detect heart rate, such as an atrial rate or ventricular rate. In some examples, a leadless IMD with a set of active fixation tines may include one or more

sensors in addition to electrical sensing module **86**. For example, a leadless IMD may include a pressure sensor and/or an oxygen sensor (for tissue oxygen or blood oxygen sensing).

Telemetry module **88** includes any suitable hardware, firmware, software or any combination thereof for communicating with another device, such as programmer **24** (FIGS. **1** and **2**). Under the control of processor **80**, telemetry module **88** may receive downlink telemetry from and send uplink telemetry to programmer **24** with the aid of an antenna, which may be internal and/or external. Processor **80** may provide the data to be uplinked to programmer **24** and receive downlinked data from programmer **24** via an address/data bus. In some examples, telemetry module **88** may provide received data to processor **80** via a multiplexer.

In some examples, processor **80** may transmit an alert that a mechanical sensing channel has been activated to identify cardiac contractions to programmer **24** or another computing device via telemetry module **88** in response to a detected failure of an electrical sensing channel. The alert may include an indication of the type of failure and/or confirmation that the mechanical sensing channel is detecting cardiac contractions. The alert may include a visual indication on a user interface of programmer **24**. Additionally or alternatively, the alert may include vibration and/or audible notification. Processor **80** may also transmit data associated with the detected failure of the electrical sensing channel, e.g., the time that the failure occurred, impedance data, and/or the inappropriate signal indicative of the detected failure.

FIG. **9** is a functional block diagram of an example configuration of programmer **24**. As shown in FIG. **9**, programmer **24** includes processor **90**, memory **92**, user interface **94**, telemetry module **96**, and power source **98**. Programmer **24** may be a dedicated hardware device with dedicated software for programming of IMD **16**. Alternatively, programmer **24** may be an off-the-shelf computing device running an application that enables programmer **24** to program IMD **16**.

A user may use programmer **24** to select therapy programs (e.g., sets of stimulation parameters), generate new therapy programs, or modify therapy programs for IMD **16**. The clinician may interact with programmer **24** via user interface **94**, which may include a display to present a graphical user interface to a user, and a keypad or another mechanism for receiving input from a user.

Processor **90** can take the form of one or more microprocessors, DSPs, ASICs, FPGAs, programmable logic circuitry, or the like, and the functions attributed to processor **90** in this disclosure may be embodied as hardware, firmware, software or any combination thereof. Memory **92** may store instructions and information that cause processor **90** to provide the functionality ascribed to programmer **24** in this disclosure. Memory **92** may include any fixed or removable magnetic, optical, or electrical media, such as RAM, ROM, CD-ROM, hard or floppy magnetic disks, EEPROM, or the like. Memory **92** may also include a removable memory portion that may be used to provide memory updates or increases in memory capacities. A removable memory may also allow patient data to be easily transferred to another computing device, or to be removed before programmer **24** is used to program therapy for another patient. Memory **92** may also store information that controls therapy delivery by IMD **16**, such as stimulation parameter values.

Programmer **24** may communicate wirelessly with IMD **16**, such as using RF communication or proximal inductive interaction. This wireless communication is possible through the use of telemetry module **96**, which may be coupled to an internal antenna or an external antenna. An external antenna that is coupled to programmer **24** may correspond to the programming head that may be placed over heart **12**, as described above with reference to FIG. **1**. Telemetry module **96** may be similar to telemetry module **88** of IMD **16** (FIG. **8**).

Telemetry module **96** may also be configured to communicate with another computing device via wireless communication techniques, or direct communication through a wired connection. Examples of local wireless communication techniques that may be employed to facilitate communication between programmer **24** and another computing device include RF communication according to the 802.11 or Bluetooth® specification sets, infrared communication, e.g., according to the IrDA standard, or other standard or proprietary telemetry protocols. In this manner, other external devices may be capable of communicating with programmer **24** without needing to establish a secure wireless connection. An additional computing device in communication with programmer **24** may be a networked device such as a server capable of processing information retrieved from IMD **16**.

In some examples, processor **90** of programmer **24** and/or one or more processors of one or more networked computers may perform all or a portion of the techniques described in this disclosure with respect to processor **80** and IMD **16**. For example, processor **90** or another processor may receive one or more signals from electrical sensing module **86**, or information regarding sensed parameters from IMD **16** via telemetry module **96**. In some examples, processor **90** may process or analyze sensed signals, as described in this disclosure with respect to IMD **16** and processor **80**.

FIG. **10** is a flowchart illustrating techniques for implanting an implantable medical device within a patient. The techniques of FIG. **10** are described with respect to IMD **16**A, but are also applicable to other IMDs, such as deployment of leads associated with IMD **16**B. First, assembly **180**, which includes leadless IMD **16**A and catheter **200**, is positioned to a location within the patient, such as right ventricle **28** or a vasculature of the patient (**502**). Next, IMD **16**A is deployed from catheter **200** to the location within the patient, such as right ventricle **28** or a vasculature of the patient (**504**). For example, the clinician may push on plunger **212** to deploy IMD **16**A.

The clinician evaluates whether IMD **16**A is adequately fixated and positioned within the patient (**506**). For example, the clinician may use fluoroscopy to evaluate whether IMD **16**A is adequately fixated and positioned within the patient. If the clinician determines IMD **16**A is inadequately positioned within the patient, the clinician operates catheter **200** to recapture IMD **16**A by pulling on tether **220** (**508**). Then, the clinician either repositions distal end of catheter **200** or replaces IMD **16**A with another IMD better suited for the implantation location (**510**). Then step **502** (see above) is repeated.

Once the clinician determines IMD **16**A is adequately fixated within the patient (**506**), the clinician operates catheter **200** to fully release IMD **16**A within the patient, e.g., by cutting tether **220** (**512**). Then, the clinician withdraws catheter **200**, leaving IMD **16**A secured within the patient (**514**).

Various examples of the disclosure have been described. These and other examples are within the scope of the following claims.

The invention claimed is:

1. An assembly comprising:
an implantable medical device; and
a set of active fixation tines attached to the implantable medical device,
wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,
wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue;
wherein the active fixation tines are configured to deploy from the springloaded position to the hooked position by releasing the active fixation tines in unison from the spring loaded position and allowing the active fixation tines to assume the hooked position;
wherein the active fixation tines are positioned substantially equidistant from each other in a circular arrangement; and
wherein the active fixation tines are configured to create opposing radial forces when deployed in unison such that the active fixation tines pull the implantable medical device towards the patient tissue when the active fixation tines are deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue.

2. An assembly comprising:
an implantable medical device; and
a set of active fixation tines attached to the implantable medical device,
wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,
wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue;
wherein the active fixation tines are configured to deploy from the springloaded position to the hooked position by releasing the active fixation tines in unison from the spring loaded position and allowing the active fixation tines to assume the hooked position;
wherein the implantable medical device includes an electrode for at least one of sensing a physiological condition of the patient and delivering a therapy to the patient,
wherein the electrode located within the circular arrangement, wherein the implantable medical device is configured such that the electrode contacts the patient tissue when the implantable medical device is secured to the patient tissue by the set of active fixation tines; and
wherein the active fixation tines are configured to provide a forward pressure of the electrode on the patient tissue to assure good electrode-tissue contact.

3. An assembly comprising:
an implantable medical device; and
a set of active fixation tines attached to the implantable medical device,
wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,
wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue; and
wherein the set of the active fixation tines is configured to be remotely deployable to facilitate securing the implantable medical device to the tissue during an implantation procedure,
wherein, after the set of the active fixation tines is deployed to secure the implantable medical device to a patient tissue, the assembly is configured to facilitate releasing the implantable medical device from the tissue without tearing the tissue by pulling the implantable medical device away from the tissue.

4. The assembly of claim 3, wherein the implantable medical device is configured to be released from the tissue without tearing the tissue by pulling the implantable medical device away from the tissue and:
first, pulling on the implantable medical device to stretch the tissue until the tissue stiffness matches the tine straightening force;
second, further pulling on the implantable medical device until the tines straighten without tearing the tissue; and
third, continue pulling on the implantable medical device once the tines have straightened sufficiently to remove the tines from the tissue without tearing the tissue.

5. The assembly of claim 3, wherein the assembly is further configured to facilitate the redeployment of the set of the active fixation tines after releasing the implantable medical device from the tissue by pulling the implantable medical device away from the tissue and back into the delivery system.

6. A kit for implanting an implantable medical device within a patient, the kit comprising:
the implantable medical device;
a set of active fixation tines attached to the implantable medical device,
wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,
wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue;
a catheter forming a lumen sized to receive the implantable medical device and hold the active fixation tines in the spring-loaded position, wherein the lumen includes an aperture that is adjacent to the distal end of the catheter; and
a deployment element configured to initiate deployment of the active fixation tines while the implantable medical device is positioned within the lumen of the catheter,
wherein deployment of the active fixation tines while the implantable medical device is positioned within the lumen of the catheter causes the active fixation tines to

pull the implantable medical device out of the lumen via the aperture that is adjacent to the distal end of the catheter.

7. The kit of claim **6**,

wherein, after the set of the active fixation tines is deployed to secure the implantable medical device to the patient tissue, the active fixation tines are configured to facilitate releasing the implantable medical device from the tissue without tearing the tissue by pulling the implantable medical device away from the tissue using the tether.

8. The kit of claim **6**, wherein the deployment element is configured to be remotely activated by a clinician from a proximal end of the catheter.

9. The kit of claim **6**, the active fixation tines are configured to be deployed by pushing the implantable medical device towards the distal end of the catheter until the distal ends of the active fixation tines extend out of the aperture.

10. The kit of claim **6**, wherein the active fixation tines are positioned substantially equidistant from each other in a circular arrangement.

11. The kit of claim **6**,

wherein the active fixation tines are in a circular arrangement,

wherein the active fixation tines are oriented outwardly relative to the circular arrangement.

12. The kit of claim **6**,

wherein the active fixation tines in the set are positioned in a circular arrangement,

wherein the implantable medical device includes an electrode for at least one of sensing a physiological condition of the patient and delivering a therapy to the patient,

wherein the electrode located within the circular arrangement, wherein the implantable medical device is configured such that the electrode contacts the patient tissue when the implantable medical device is secured to the patient tissue by the set of active fixation tines.

13. The kit of claim **6**, wherein the implantable medical device is a leadless pacemaker.

14. The kit of claim **6**, wherein the implantable medical device is a medical lead and the set of active fixation tines are attached to the distal end of the medical lead, the kit further comprising an electrical stimulation generator configured to attach to the proximal end of the medical lead.

15. The kit of claim **6**, wherein at least one of the active fixation tines functions as an electrode of the implantable medical device for at least one of sensing a physiological condition of the patient and delivering a therapy to the patient.

16. The kit of claim **6**, wherein the set of active fixation tines are formed from a shape memory alloy material.

17. A kit for implanting an implantable medical device within a patient, the kit comprising:

the implantable medical device;

a set of active fixation tines attached to the implantable medical device,

wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,

wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue;

a catheter forming a lumen sized to receive the implantable medical device and hold the active fixation tines in the spring-loaded position, wherein the lumen includes an aperture that is adjacent to the distal end of the catheter; and

a deployment element configured to initiate deployment of the active fixation tines while the implantable medical device is positioned within the lumen of the catheter,

wherein deployment of the active fixation tines while the implantable medical device is positioned within the lumen of the catheter causes the active fixation tines to pull the implantable medical device out of the lumen via the aperture that is adjacent to the distal end of the catheter; and

further comprising a tether attached to the implantable medical device, the tether being configured to facilitate pulling the implantable medical device back into the lumen from the proximal end of the catheter after the active fixation tines pull the implantable medical device out of the lumen, wherein pulling the implantable medical device back into the lumen with the tether returns the active fixation tines to the spring-loaded position from the hooked position such that the active fixation tines can be redeployed with the deployment element.

18. An assembly comprising:

an implantable medical device; and

a set of active fixation tines attached to the implantable medical device,

wherein the active fixation tines in the set are deployable from a spring-loaded position in which distal ends of the active fixation tines point away from the implantable medical device to a hooked position in which the active fixation tines bend back towards the implantable medical device,

wherein the active fixation tines are configured to secure the implantable medical device to a patient tissue when deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue,

wherein the active fixation tines are positioned substantially equidistant from each other in a circular arrangement, and

wherein the active fixation tines are configured to create opposing radial forces when deployed in unison such that the active fixation tines pull the implantable medical device towards the patient tissue when the active fixation tines are deployed while the distal ends of the active fixation tines are positioned adjacent to the patient tissue.

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