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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 July 2013 (04.07.20 13)

WIPO | PCT

(10) International Publication Number
WO 2013/098644 A2

(51) **International Patent Classification:**
A61N 1/375 (2006.01)

(21) **International Application Number:**
PCT/IB20 12/003007

(22) **International Filing Date:**
2 1 December 2012 (21 .12.2012)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
61/581,685 30 December 201 1 (30. 12.201 1) US

(71) **Applicant: SIRIUS IMPLANTABLE SYSTEMS LTD.** [IL/IL]; Adar Str. 3/3, 71723 Modiin (IL).

(72) **Inventor; and**
(71) **Applicant** *(for US only):* **GELVAN, Dan** [IL/IL]; Adar Str. 3/3, 71723 Modiin (IL).

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available):* AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2013/098644 A2

(54) **Title:** IMPLANTABLE MEDICAL DEVICE HOUSING AND ANCHORING

(57) **Abstract:** Various anchoring approaches and structures can be used to secure an implantable medical device to any of variety of locations within the body of a patient. And the housing of such a device can take a variety of shapes and configurations depending on the desired implant site within the body and other factors.

IMPLANTABLE MEDICAL DEVICE HOUSING AND ANCHORING

Cross-Reference to Related Applications

This application claims priority to and the benefit of Provisional U.S. Patent Application Serial No. 61/581,685, filed on December 30, 2011, the entire contents of which are incorporated herein by reference.

This application also incorporates by reference the entirety of International patent application number PCT/US2012/066830 filed on November 28, 2012, which is titled "Implantable Medical Device Communications" and which claims priority to Provisional U.S. Patent Application Serial No. 61/563,930 filed on November 28, 2011.

Technical Field

The invention generally relates to housing, anchoring, and electrode features of implantable medical devices for placement within the body of a patient such as a human or other mammal.

Background Information

A wide variety of implantable medical systems are known and available for monitoring physiological conditions and/or delivering therapies. Such systems may include sensors for monitoring physiological signals for diagnostic purposes, monitoring disease progression, or controlling and optimizing therapy delivery. Examples of implantable monitoring systems include hemodynamic monitors, ECG monitors, and glucose monitors. Examples of therapy delivery systems include devices enabled to deliver electrical stimulation pulses such as cardiac pacemakers, implantable cardioverter-defibrillators (ICDs), neurostimulators, neuromuscular stimulators, brain stimulators, gastrointestinal system stimulators, diaphragm stimulators, and lung stimulators. Implantable therapy delivery

devices also include drug delivery devices such as insulin pumps and morphine pumps. Implantable therapy delivery systems also are referred to as active implantable medical systems.

Electrical devices, characterized by the need for a power source, are typically implanted under the skin and have one or more leads (electrically conducting wires) that connect the device with the site of stimulation and/or the site where the information is collected. Thus, for example, deep brain stimulators are implanted subcutaneously in the upper pectoral region and have leads that connect them to the region of the brain where stimulation is performed. Similarly, gastric stimulators are implanted subcutaneously in the abdominal region and have leads connecting them to the stomach.

A cardiac stimulation device (such as a cardiac pacemaker, an ICD, and a CRT device, where CRT stands for cardiac resynchronization therapy) is one kind of active implantable medical system. Any cardiac stimulation device can be referred to as a pacing device or a pulse generator (PG). When leads and electrodes are included with a pacing device, the combination generally is referred to as a pacing system. The leads of a pacing system are used to span the distance between the implant site and the site of action. For example, if a cardiac pacemaker is implanted subcutaneously in the pectoral region of a human patient, electricity-transmitting leads connected to the pacemaker are typically run through the patient' s veins to the target site in the patient' s heart to provide electrical stimulation pulses from the pacemaker to the target site. Each of the leads will have at least one electrode, typically mounted at or near the distal end of the lead, and it is the electrode that is placed at the target site in the heart that provides the electrical stimulation pulses to the target site in the heart. The electrode also can be used to pick up the heart's electrical signals from the target site, and those received heart signals are transmitted back to the pacemaker via the lead. A lead generally speaking is an electrical conductor covered by an insulator, such as a copper or silver or metal alloy wire with a silicone or polyurethane coating or jacket on it. A lead sometimes is referred to as a pacing lead.

Most current cardiac pacing leads are endocardial and are positioned by passive fixation, meaning that the position of the lead is stabilized by mechanical forces such as the resistance created by tines caught in the trabeculae of the right ventricle of the patient' s heart or the wedging of a left-ventricle lead against the inner wall of the patient's cardiac veins. In

contrast, epicardial leads typically have active fixation to secure them to the outer surface of the heart. Some known leads are myocardial screw-in leads by Medtronic, Inc.

Wireless pacing systems have been developed to address perceived shortcomings of conventional pacing systems that use leads. Leads can physically fail by, for example, breaking of the conductive wire, insulation break or erosion, or dislodgement. Transvenous leads can be difficult to place into certain locations such as the left ventricle of the heart of a human patient, whereas epicardial leads are associated with a high rate of breakage and infection.

One kind of wireless pacing system uses one or more so-called leadless electrodes and also a controlling pulse generator device. A leadless electrode is a small wireless device designed to be attached directly to the heart (such as the left ventricle), and it delivers pacing pulses to the heart under the wireless control of a cardiac pacemaker, ICD, CRT device, or other pulse generator that is located elsewhere in the body.

Leadless pacing also can be achieved with a leadless pacemaker which is a very small autonomous pacing device that is attached directly to the heart and that both generates and delivers pacing pulses to the heart. A leadless pacemaker essentially is a miniature pacemaker without any leads. The leadless pacemaker is mounted directly in or on the heart. Whereas a system with leadless electrodes has a parent device to which the leadless electrodes are subordinate, a leadless pacemaker is designed to be an independent device with independent logical and technical capacity like that of a conventional pacemaker. Medtronic, Inc. introduced a leadless pacemaker at the annual meeting of the Heart Rhythm Society (HRS) in 2010.

Summary of the Invention

The invention generally relates to implantable medical devices with housing and anchoring structures or mechanisms that allow the devices to be placed at some location or area within the body of a patient such as a human or other mammal. For example, a leadless pacing device can be anchored to cardiac muscle of a patient' s heart such as the heart' s myocardium. The leadless pacing device can be a leadless electrode or a leadless pacemaker. In accordance with the invention, an implantable medical device has multiple anchoring

mechanisms or points for anchoring the device to the certain location or area within the patient's body. There can be, for example, three or more anchors.

Each of anchors can be, for example, a substantially straight member which is also referred to herein as a prong or strut. An anchor also could be a bent prong which is also referred to herein as a hook. The bent prong can be provided in the shape of a "J" hook. An anchor could be a coil that gets screwed into the certain location or area within the patient' s body. An anchor could be a suturing-receiving opening that allows a suture to be used to secure the device to the certain location or area within the patient' s body. The anchors could be active such as a ring member with multiple extending prongs, where the ring is movable relative to the housing to insert the anchors into the certain location or area within the patient's body. Regardless of the particular form of the anchors, they can cause one or more electrodes of the device to come into contact and stay in contact with the certain location or area within the patient' s body. Depending on the type of anchors used, one or more of the anchors of the device could be or contain the device's electrode(s), and this or these anchor electrodes could be in addition to any bottom surface electrode(s) or in place of any bottom surface electrode(s).

The housing or outer shell of an implantable medical device according to the invention must allow the device to be installed properly within the patient's body given whatever implant procedure is to be used to place the device. The device's housing also must be configured such that at least a portion of it contacts a desired surface within the patient' s body such as the outer or inner cardiac tissue of the patient. If the device has one or more electrodes that need to contact tissue within the patient's body directly, the device's housing must accommodate and position the electrode(s) accordingly. A top surface of the housing of the device can be curved, and the curve can be defined by an equation. The shape of the top surface can be a portion of a superellipse or a superegg, for example. A bottom, tissue-contacting surface of the housing of the device can be flat, substantially flat, or moderately curved, and the electrode(s) of the device can be in or on the device housing's bottom surface. The housing of the device preferably is configured to have a narrow longitudinal profile that allows implantation of the device within the body of the patient and to have an internal volume that accommodates all of the internal components of device.

The inner contents and components of the implantable medical devices described herein can be the inner contents and components of any of the implantable medical devices

disclosed in International patent application number PCT/US2012/066830 filed on November 28, 2012, which is titled "Implantable Medical Device Communications" and which claims priority to Provisional U.S. Patent Application Serial No. 61/563,930 filed on November 28, 2011. The entirety of International patent application number PCT/US2012/066830 is incorporated herein by reference. Those internal components of the implantable medical devices described herein can include electronics, and more particularly can include an energy source, a micro-electronic circuit, a transducer, and an amplifier, for example.

These and other aspects, features, advantages, and objects of the invention(s) will become clearer with reference to the drawings and the description that follows.

Brief Description of the Drawings

Figure 1 shows an implantable medical device such as a leadless electrode, a leadless pacemaker, or other leadless pacing device, with the device anchored to the myocardium of the heart of a human (or other mammal) patient.

Figures 2A (side view) and 2B (bottom view) show a leadless pacing device with four substantially straight struts as the device's four anchors, and with a single electrode shown (Figure 2B) centered on the bottom flat surface of the device.

Figure 3A shows a leadless pacing device with three hooks as the device's three anchors with each of the hooks pointed in a certain direction, and Figures 3B (side view) and 3C (bottom view) show the device with three hooks pointed in the same direction. A single electrode can be seen (Figures 3A and 3C) on the bottom flat surface of the device.

Figures 4A, 4B, and 4C show a leadless pacing device with three pigtail-type coils or screws as the device's three anchors, with Figure 4A being a first embodiment of a housing of the device and Figures 4B (bottom view) and 4C (side view) being a second embodiment of the device's housing. A single electrode can be seen (Figures 4A and 4B) on the bottom flat surface of the device.

Figure 5 shows a leadless pacing device with three flanges or tabs having suture-receiving holes, where this device is similar to the one shown in Figures 4B and 4C but without the pigtail screw-in coils of the device shown in Figures 4B and 4C. A single electrode can be seen on the bottom flat surface of the device.

Figures 6A, 6B, and 6C show an active-anchor pacing system with a ring-like holding structure that is used in cooperation with a body or housing of a leadless pacing device, where the device's body is somewhat similar to that of the device shown in Figure 4A but without the pigtail screw-in coils of the device shown in Figures 4A. A single electrode can be seen (Figure 6B) on the bottom flat surface of the device.

Figures 7A, 7B, and 7C show some different electrode configurations of a leadless pacing device, with Figure 7A showing a single electrode on the bottom flat surface of the device (as is also shown in Figure 2B), Figure 7B showing three electrodes on that bottom surface of the device, and Figure 7C showing an electrode as the distal tip end of each of the device's four anchoring struts and without any button-type electrodes at all on the bottom flat surface of the device.

Figures 8A and 8B show shapes that could be used for the housing or outer shell of an implantable leadless medical device and that are defined by one or more disclosed equations.

Figures 9A and 9B also show shapes that could be used for the housing or outer shell of an implantable leadless medical device and that are defined by one or more disclosed equations.

Figures 10A and 10B show more shapes that could be used for the housing or outer shell of an implantable leadless medical device and that are defined by one or more disclosed equations.

Figure 11 shows another shape that could be used for the housing or outer shell of an implantable leadless medical device and that is defined by one or more disclosed equations.

Figure 12 shows yet another shape that could be used for the housing or outer shell of an implantable leadless medical device and that is defined by one or more disclosed equations.

Description

An implantable medical device can be anchored within the body of a patient in a number of different ways. And the housing or outer shell of such a device also can be configured in a number of different ways. Anchoring is addressed first below, and thereafter housing or outer shell configurations of the device are addressed.

A leadless pacing device 100 (such as a leadless electrode or a leadless pacemaker) can be anchored to, for example, the myocardium of the heart 102 of the patient, as depicted in Figure 1. Other types of implantable medical devices also can be anchored to the myocardium or to different areas within the patient' s body. Other implantable medical devices include, for example, neurostimulators, stimulators of the gastrointestinal system, and stimulators of other organs. Also, instead of active implantable medical devices, other implantable medical devices include passive implantable medical devices such as implantable monitoring devices.

As opposed to a lead, which is light-weight and causes little strain at the site of implant, a leadless device may have considerable weight - in the range of several grams such as, for example, up to about 10 grams or 15 grams. The weight and size of the implanted leadless device may cause considerable strain at the implant site within the patient's body, particularly during vigorous movement such as that of the heart. In order to properly anchor with a patient's body an implantable medical device, such as the leadless pacing device 100, an anchoring mechanism of the leadless pacing device 100 must create a tight association between the device 100 and the selected tissue within the patient which could be the cardiac muscle of the heart 102. The tight association is required to eliminate any movement or "wobble" of the device 100 that could cause strain on the myocardium because such strain could lead to tissue injury and dislodgement of the device 100 from the myocardium. The tight junction also is beneficial and desirable for optimal transfer of energy into the implanted device 100 from a separate transmitting source and/or for efficient energy generation without undue loss of inertial energy for the generator if the device 100 contains a self-powering generator unit such as a high efficiency piezoelectric micro-generator and energy storage system as described in US Patent Application Publication No. US 2011/0304240 Al, the entirety of which is incorporated herein by reference.

In accordance with the invention, the anchoring mechanism of the leadless pacing device 100 (or of any implantable medical device) can take a variety of different forms. Several embodiments of the anchoring mechanism are possible including ones involving hooks, struts, pigtail-shaped screws or coils, and/or sutures. Each embodiment of the anchoring mechanism facilitates and provides the necessary tight association or junction. While a single hook, coil, or suture may have been used in the past to anchor an epicardial

electrode, a plurality of anchoring mechanisms have not been used together to adequately anchor within the body of a patient a single implantable medical device. The use of multiple anchoring mechanisms on a single device allows the device to be anchored securely within the patient' s body due to the combined forces or contributions of all of the plurality of anchoring mechanisms. An implantable medical device according to the invention that has multiple anchoring mechanisms or anchoring points will prevent movement or any wobble of the implanted device. There can be two, three, four, or more anchoring mechanisms or points for the device. Each of the device's anchoring mechanisms or points can be the same or of the same type, but all of them do not have to be the same or of the same type. One or more of the device's plurality of anchoring mechanisms or points can be different than one or more of the device's other anchoring mechanisms or points. Options for the type of anchoring mechanism or point include, for example, a strut, a hook, a coil, and a hole or other opening or projection for receiving a suture.

Referring to Figures 2A and 2B, a substantially straight prong or strut positioned substantially perpendicular to a housing 120 of the device 100 is one possible type of anchor. Four such struts are shown for the device 100, although two, three, or more than four are possible. Each strut has and initial portion 110 and a small counter-hook or barb 111 extending therefrom as its distal end to prevent dislodgement once inserted into the desired location within the patient's body, such as in the myocardium of the patient's heart 102. The counter-hook 111 is a structure similar to that which is used on traditional fishhooks to prevent dislodgement after the fishhook penetrates into some portion of a fish such as tissue inside of the mouth of the fish. The counter-hook 111 however has a less prominent profile than found on a traditional fishhook. The counter-hook 111 provides sufficient resistance to reverse movement and unintended dissociation of the strut (or hook) from the patient's internal body tissue, but the counter-hook 111 will not cause extensive tissue damage when intentionally retracted by a physician. The total length, and thus the penetration depth, of each of the struts can be 1 millimeters to 8 millimeters, and more preferably 2 millimeters to 4 millimeters.

Instead of being as shown in Figures 2A and 2B, one or more of the struts of the device 100 could be slightly bent or could be straight but positioned at an angle in relation to the bottom flat surface 121 of the housing 120 of the device 100 (that is, not substantially perpendicular to the bottom flat surface 121 of the housing 120) such as an angle of up to 45

degrees from the perpendicular, and more preferably up to 30 degrees from perpendicular. Regardless of how each of the struts is configured, the device with the plurality of struts is inserted into the desired location within the patient's body by pressing the device into that location (such as into the myocardium) in a direction perpendicular to the surface of the myocardium to implant the device as shown in Figure 1.

In Figure 2B, a single button-shaped electrode 130 is shown centered on or in the bottom flat surface 121 of the device 100. This electrode 130 can be used to deliver electrical pulses to any tissue within the patient's body that the bottom flat surface 121 of the device 100 is contacting and thus the tissue that the electrode 130 is contacting. One or more other electrodes (of the same button-type as the electrode 130 and/or of some other shape or type) could be provided on or in the bottom surface of the device and/or on or in other locations of the device. And it is noted that the device's bottom surface does not have to be flat, as it could be substantially flat or it could be shaped or contoured or otherwise configured to mate with and match any surface within the body of the patient.

Referring to Figures 3A-3C, a bent prong or hook is another possible type of anchor. The hook can be considered a bent or hooked version of the previously-described strut (Figures 2A and 2B). The bend in the previously-described strut can be continuous, such that the hook has the same basic shape as a fishhook which is to say a "J" shape. Or the bend in the previously-described strut could result in a more angular configuration of the hook and not a smooth, continuous curve as with a J-shaped hook anchor. Whatever the particular configuration of the hook anchor, it is noted that it preferably is a single piece or component and not separate pieces welded or otherwise joined or fastened together because such a joint in an anchor could be a point of failure. In Figures 3A-3C, three hooks are shown for the device 100, although two, four, or more are possible. The hooks prevent dislodgement of the device 100 when the hooks are inserted into the desired location within the patient's body, such as the myocardium of the patient's heart 102. A first portion 202 of each of the hooks extends substantially perpendicular to the bottom flat surface 121 of the housing 120 of the device 100, and a second portion 204 of each of the hooks extends from the first portion 202 in a direction that is substantially parallel to the bottom flat surface 121 of the housing 120. A counter-hook or barb 206 also is provided as part of each of the hooks, and this counter-hook 206 has the same purpose and function as the counter-hook 111 described above with respect to the struts shown in Figures 2A and 2B. The first portion 202, second portion 204,

and counter-hook 206 of a hook preferably are not individual components that are somehow joined together but instead preferably are sections of a monolithic or single hook anchor. They are only identified herein as portions of a hook for completeness and to provide as much detail as possible about a hook's construction and possible shape.

Instead of being as shown in Figures 3A-3C, one or more of the first portions 202 of the hooks of the device 100 could be positioned at an angle in relation to the bottom flat surface 121 of the housing 120 of the device 100 (that is, not substantially perpendicular to the bottom flat surface 121 of the housing 120) such as an angle of up to 30 degrees from perpendicular. And, instead of being as shown in Figures 3A-3C, one or more of the second portions 204 of the hooks of the device 100 could extend from its first portion 202 in a direction that is other than substantially parallel to the bottom flat surface 121 of the housing 120. For example, one or more of the second portions 204 could be angled between 60 degrees to 150 degrees off of a longitudinal axis running through the length of its first portion 202, and more preferably between 90 degrees to 135 degrees. The direction of each of the hooks can be aligned with the circumference of the device 100 as shown in Figure 3A. The length of the first portion 202 of each of the hooks of Figures 3A-3C can be from 1 millimeters to 6 millimeters and more preferably 2 millimeters to 4 millimeters, and the length of the second portion 204 of each of the hooks can be 2 millimeters to 8 millimeters and more preferably 2 millimeters to 4 millimeters.

Regardless of how each of the hooks is particularly configured, the device with the plurality of hooks is inserted into the desired location within the patient' s body by rotating the device 100 in the direction that the second portion 204 of each of the hooks is pointing while also pressing the device 100 into that location, such as into the myocardium, to implant the device 100 as shown in Figure 1. Alternatively, hooks can face in the same or in substantially the same direction as shown in Figures 3B and 3C, or with a slight angle to each other such as up to 10 degrees so as to create a tighter fixation with the tissue. In this alternative configuration shown in Figures 3B and 3C, the device is inserted into the desired location within the patient's body by pushing the device in the direction that the second part 204 of the hooks are pointing.

Also, as can be seen in Figures 2A, 2B, 3A, 3B, and 3C, but perhaps best in Figures 2B, 3A, and 3C, the struts and the hooks can be disposed out at the edge of the bottom surface 121 of the device 100 and also equidistant, or approximately equidistant, from each

other. This placement of the anchors is preferred. It can provide sufficient room to allow one or multiple electrodes 130 to be incorporated into or onto the bottom surface 121 of the device 100.

In Figures 3A and 3C, a single button-shaped electrode 130 is shown centered on or in the bottom flat surface 121 of the device 100. As indicated previously with respect to Figure 2B, the electrode 130 can be used to deliver electrical pulses to any tissue within the patient's body that the bottom flat surface 121 of the device 100 is contacting and thus the tissue that the electrode 130 is contacting. And it is also noted again that one or more other electrodes (of the same button-type as the electrode 130 and/or of some other shape or type) could be provided on or in the bottom surface of the device and/or on or in other locations of the device. And it is noted again that the device's bottom surface does not have to be flat, as it could be substantially flat or it could be shaped or contoured or otherwise configured to mate with and match any surface within the body of the patient.

Referring to Figures 4A-4C, a pigtail screw-in coil member 300 is another possible type of anchor. This member 300 is configured to be advanced into tissue by turning or screwing it. Three coils 300 are shown for the embodiment of the leadless pacing device's housing shown in Figure 4A, and three coils also are shown for the other embodiment of the leadless pacing device's housing in Figures 4B and 4C. It is noted that however that, instead of three coils, two, four, or more coils are possible. And other housing configurations are possible. The device's housing shown in Figure 4A has an indent 302 associated with each of the coils 300, whereas the device's housing shown in Figures 4B and 4C has a tab or flange 304 for each of the coils 300. In each of these two depicted possible embodiments of the device's housing, a hole is associated with each of the coils 300 to allow each of the coils 300 to extend down below the bottom flat surface 305 of the device's housing. Each of the holes can be formed such that each of the coils 300 extends through it and substantially perpendicular to a plane defined by the bottom flat surface 305 of the housing. Instead of being substantially perpendicular, each of the coils 300 could be oriented at a different angle to that plane such as between 60 degrees to 90 degrees. Each of the coils 300 can have two to three turns or curls to it, as shown in Figures 4A-4C, and each of the coils can extend away from the bottom-surface plane of the device's housing by a length of 2 millimeters to 6 millimeters. Each of the coils 300 also typically will have some type of head configuration 306 to allow the coil to be rotated and thus inserted, and that head configuration 306 could be

such that it receives and can be turned by a Phillips-head screwdriver or a ratchet-driven socket wrench. Other head configurations of the coils 300 are possible. Furthermore, each of the coils 300 and/or flanges 304 may be constructed such that the coil 300 cannot accidentally or otherwise dislodge from the pacing device without damaging the structure of the device or its coils. Regardless of the configuration of each of the coils, insertion is performed by pressing or placing the device against the cardiac surface or other desired location within the patient's body and then screwing each of the coils 300 individually (or simultaneously) into the myocardium or other desired location within the patient's body.

In Figures 4A and 4B, a single button-shaped electrode 130 is shown centered on or in the bottom flat surface 305 of the device. As indicated previously, the electrode 130 can be used to deliver electrical pulses to any tissue within the patient's body that the bottom flat surface 305 is contacting and thus the tissue that the electrode 130 is contacting. And it is also noted again that one or more other electrodes (of the same button-type as the electrode 130 and/or of some other shape or type) could be provided on or in the bottom surface of the device and/or on or in other locations of the device. And it is noted again that the device's bottom surface does not have to be flat, as it could be substantially flat or it could be shaped or contoured or otherwise configured to mate with and match any surface within the body of the patient.

Referring to Figure 5, a tab or flange 400 with a suture-receiving opening 402 is another type of anchoring configuration that can be used. Three such flanges 400 are shown in Figure 5, although two, four, or more are possible. These flanges 400 may be similar to the flanges 304 of Figures 4B and 4C, except that these flanges 400 do not have coils 300 extending therethrough. Insertion can be performed by pressing the device against the myocardial surface and threading a suture through each of the holes 402 of each of the flanges 400 and into the myocardium, penetrating 1 millimeters to 6 millimeters and more preferably 2 millimeters to 4 millimeters, and then pulling the suture back out to tie it to the first end of the suture in a surgical knot.

In Figure 5, a single button-shaped electrode 130 again is shown centered on or in the bottom flat surface 121 of the device 120. As indicated previously, the electrode 130 can be used to deliver electrical pulses to any tissue within the patient's body that the bottom flat surface 121 is contacting and thus the tissue that the electrode 130 is contacting. And it is also noted again that one or more other electrodes (of the same button-type as the electrode

130 and/or of some other shape or type) could be provided on or in the bottom surface of the device and/or on or in other locations of the device. And it is noted again that the device's bottom surface does not have to be flat, as it could be substantially flat or it could be shaped or contoured or otherwise configured to mate with and match any surface within the body of the patient.

In addition to the different forms or types of anchors that can be used, such as the four examples described in the preceding four paragraphs, it is possible to deploy a given type of anchor in different ways. For example, the anchors could be preset or of a fixed configuration, or the anchors could have an active mechanism.

With preset or fixed anchors, the anchors are arranged on the implantable device in a permanent, rigid, prearranged position such that the anchors and the device will move together as one unit. One example of preset anchors can be seen in Figures 2A and 2B, and another example is shown in Figures 3A-3C. For implantation of a preset-anchor or fixed-anchor implantable leadless pacing device, an implantation tool with the pacing device attached thereto in some manner will be advanced along the myocardial surface until the desired implant position is attained, for example. If the anchor type is the previously-described strut type, for example, the pacing device will be pressed against the myocardial surface in a direction perpendicular to the myocardial surface until the struts are fully embedded in the myocardium and the entire bottom surface of the pacing device is in firm contact with the myocardium, including any electrode(s) on or in the bottom surface of the device. The implant tool then will be released from the pacing device and retracted out of the body of the patient. To reposition the implanted device, if repositioning is required, the reverse procedure is performed. That is, to reposition the implanted device, the implant tool is inserted into the patient' s body to the location of the implanted device, and the implant tool is attached to the implanted device, and the tool is then pulled back or out to remove the device from the myocardium. The removed device can then be re-implanted within the patient's body at a new location within the patient's body such as at a slightly different spot on the patient's heart, for example. If the anchor type used is not the strut type but instead the previously-described hook type, the pacing device will be pressed against the myocardial surface and rotated in the direction the hooks are facing or pointed until the hooks are fully embedded in the myocardium and the entire bottom surface of the pacing device and any bottom-located electrode(s) are in firm and direct contact with the myocardium. The implant

tool then will be released from the pacing device and retracted. Repositioning, if required, will be performed by the reverse procedure.

With active anchors, the anchors are associated with the implantable leadless device but are operated separately by movement relative to the housing of the device. For example, as shown in Figures 6A-6C, the pacing device 100 can have a fixed, permanently, and rigidly associated holding structure around its rim, such as a lip 501, and one or more moving parts 500 that move relative to the holding structure when activated. The fixed component can be a housing 502 that includes a ring, flanges, indents in the device's housing, holes through the housing, and/or any other holding structure that will allow the advancement of the moving component 500 into the myocardium such that part of the fixed structure 502 is trapped between the moving structure 500 and the myocardium. Indents, indentations, or gratings that act to guide the movement of the movable structure 500 may be straight and perpendicular to a plane of a bottom surface of the device, as depicted in Figure 6A, and this is the preferred structure for strut type anchors, or the indents, indentations, or gratings of the housing 502 could be tilted at an angle relative to the device's bottom surface plane, or even curved, to optimize the introduction of the anchors into the myocardium, and this is the preferred structure for hook type anchors. Figure 6A shows the fixed structure 502 and the movable structure 500 apart from each other. Figure 6B shows these structures 502, 500 together with the movable structure 500 fully engaged with and pushed down into or onto the fixed structure 502. Figure 6C shows these structures 502, 500 together but with the movable structure 500 not yet fully pushed down into or onto the fixed structure 502. Figure 6C shows the preferred arrangement of the structures 502, 500 prior to and ready for introduction into the body of a patient. And the arrangement shown in Figure 6C also is the form the structures 502, 500 maintain during introduction into the patient' s body. "Introduction" here means the movement of the device through an incision or other opening in the patient's skin (or through some natural body opening or orifice) and to the intended implant site within the patient' s body. A low profile is important for introduction, and Figure 6C shows a low-profile arrangement. As can be seen in Figure 6C, the anchors are not protruding or exposed, and thus implantation into the patient' s body will not result in any tissue within the body being punctured or torn. Only when the movable structure 500 is moved relative to the fixed structure 502 will the anchors be exposed. When fully engaged, as shown in Figure 6B, the forces exerted by the ring 500 on the device's flange or lip 501 causes the device's bottom

surface 503 into direct contact with the myocardium, and this holds the device there in place. In one embodiment, after full engagement or deployment of the moving structure 500, that structure 500 can be locked into place. The ring 500 and housing 502 may be structured such that the ring cannot disengage accidentally or otherwise from the housing during handling or after implantation. This may be achieved by sloping of the sides of the housing, shaping the ring to engage the sides of the housing or using an upper flange or protrusions on the housing that will physically obstruct disengagement of the parts.

With further regard to active anchors, it is noted that a suture-receiving embodiment of the device, as shown and described with respect to Figure 5, may not have a moving part as an integral component of the implantable leadless device but rather could have a separate suturing mechanism as part of the delivery or implant system. That separate suturing mechanism would be used during an implantation procedure to throw the sutures needed to secure the device to the desired location within the patient's body.

In Figure 6B, a single button-shaped electrode 130 is shown centered on or in the bottom flat surface 503 of the device 502. As indicated previously, the electrode 130 can be used to deliver electrical pulses to any tissue within the patient's body that the bottom flat surface 503 is contacting and thus the tissue that the electrode 130 is contacting. And it also is noted again that one or more other electrodes (of the same button-type as the electrode 130 and/or of some other shape or type) could be provided on or in the bottom surface of the device and/or on or in other locations of the device. And it is noted again that the device's bottom surface does not have to be flat, as it could be substantially flat or it could be shaped or contoured or otherwise configured to mate with and match any surface within the body of the patient.

At least some of the advantages of using active anchors include the following. The electrical (threshold and sensing) and functional (myocardial function, such as, but not limited to pressure-volume curves) measurements may be performed before the fixation is activated and the myocardium is pierced, such that the need for repositioning may be drastically reduced as compared to using an implantable device with a preset anchoring configuration. Also, the profile of the implantable device can be smaller and therefore better suited to navigation within the constricted pericardial space within the patient' s body. And the risk of damaging the myocardium during navigation with exposed tips of the struts or hooks is eliminated.

For implantation of an active-anchoring pacing device, the implantation tool with the pacing device attached will be advanced along the myocardial surface until the desired implant position is attained. For a pacing device with strut type anchors, the pacing device will be pressed against the myocardial surface in a direction perpendicular to the surface, and at this point threshold and/or functional measurements may be made and, once satisfactory measurements are obtained, the appropriate force can be applied to the moving part 500 of the fixation mechanism until the struts are fully embedded in the myocardium and the entire bottom surface of the pacing device is in firm contact with the myocardium. The moving part 500 then can be locked in place, and the implant tool will be released from the pacing device and retracted. Removal, if required, may be performed by a reverse procedure - attachment of the implant tool, release of the locking mechanism (if applicable), perpendicular retraction of the moving part of the fixation mechanism, and release of the device. Repositioning may be performed by repetition of the implant procedure in a new location. For a pacing device with hook type anchors, the pacing device will be pressed against the myocardial surface and threshold and/or functional measurements may be performed. Once satisfactory measurements are obtained, the moving part 500 of the fixation mechanism will be rotated in the direction the hooks are facing until the hooks are fully embedded in the myocardium and the entire bottom surface of the pacing device is in firm contact with the myocardium. The moving part 500 then can be locked and the implant tool will be released from the pacing device and retracted. The rotational movement of the moving part 500 may be optimized to the shape of the hooks by indents, indentations, or gratings in the housing that will guide the rotational movement when pressure is applied to the ring. Removal, if required, may be performed by a reverse procedure - attachment of the implant tool, rotation of the moving part of the fixation mechanism in the reverse direction until completely released and removal of the pacing device. Repositioning may be performed by repetition of the implant procedure in a new location. For a pacing device with coil type anchors, the pacing device will be pressed against the myocardial surface and the coils will be turned individually in their holders until fully engaged in the myocardium such that the entire bottom surface of the pacing device is in firm contact with the myocardium. The coils then can be locked in position and the implant tool will be released from the pacing device and retracted. Removal, if required, may be performed by a reverse procedure - attachment of the implant tool, release of the screws and removal of the pacing device. Repositioning may be performed by

repetition of the implant procedure in a new location. For a pacing device with flanges having suture-receiving holes, the pacing device will be pressed against the myocardial surface and the suture with an associated leading needle will be passed through the suture holes into the myocardium and back out, and tied to the proximal end of the suture with a surgical knot. Removal, if required, may be performed by a reverse procedure - attachment of the implant tool, cutting the sutures and removing them safely by attaching them to the delivery tool and removal of the pacing device. Repositioning may be performed by repetition of the implant procedure in a new location.

One or more electrodes can be affixed to, in, or on the pacing device in such a way that, when the device is properly implanted within the body of a patient, the electrode(s) will be in contact with the myocardium. Various different embodiments of electrodes and electrode configurations are possible, such as single or multiple electrodes and arranged in unipolar or bipolar configurations with one or more active electrodes and one or more passive electrodes. Furthermore, one or more of the electrodes can be discrete electrodes attached to the bottom surface of the device for contact with the myocardium, as depicted in Figures 7A and 7B and also as can be seen in other figures such as Figures 2B, 3A, 3C, 4A, 4B, 5, and 6B. In some embodiments, one or more electrodes can additionally or instead be incorporated into and be an integral part of the anchor such as all or a portion (such as an end) of a strut anchor, a hook anchor, or a coil anchor. If an electrode is part of an anchor, it preferably is a tip or distal end portion of the anchor that constitutes the electrode. See Figure 7C. In comparing Figure 2B to Figure 7C, it can be seen that the counter-hook 111 part of the strut in the embodiment of Figure 7C is the electrode, such that the electrode gets inserted and embedded into the tissue within the patient's body once the device is inserted into that tissue within the patient's body. This is unlike and contrasted with the bottom-located electrodes shown in the embodiments of Figures 7A and 7B where, once implanted, the electrode(s) of the implanted device contact the surface of the patient's tissue but do not extend into that tissue. Various combinations of types and placements of electrodes can be used with any given device and are to be considered as disclosed herein even if not all possible combinations are expressly described or shown.

One way to achieve an anchor electrode is to form the entirety of one or more of the device's anchors out of a suitable electrically-conductive material and then to coat one or

more portions of the anchor with an insulating material such that just the exposed, non-coated portion of the anchor emits energy.

In general, for any given electrode type, it can have a small surface area in order to keep impedance low, and the surface area of any given electrode preferably will be in the range between 0.3 square millimeters to 14 square millimeters, and more preferably 0.5 square millimeters and 2.5 square millimeters. Regarding electrode material(s), it is noted that any given electrode can be formed of a porous or filamentous material or structure to keep capacitance low. One or more of the electrodes, and/or the insulating coating of the anchor or device described below, can be drug-eluting or not, and if drug-eluting then the drug eluted from the electrode can be a steroid such as dexamethasone, cortisone, or Cortisol or some other type of anti-inflammatory drug(s).

A single electrode may provide adequate pacing and proper safety margins when complying with the instructions to perform a stimulation threshold test at the time of implant. The electrode will preferably function as the anode (active electrode) and will be insulated from the housing 120 of the pacing device 100 by a coating of a biocompatible insulating material such as, but not limited to, a poly-para-xylylene (sometimes referred to as parylene) or silicon. The housing 120 of the device 100 will function as cathode (passive electrode) in such a fashion that the electrical current will flow from the anode through the myocardium and back to the device housing (unipolar configuration). The insulating coating can cover all or part of the device surface that is in contact with the myocardium. It may also cover the sides and/or the upper surface of the housing or part thereof. The shape of the insulating layer and the configuration of stimulation electrodes will determine the shape of the stimulating electrical field to provide optimal stimulation and lowest current drain. An example of such configuration, designed to optimize the area of stimulation in the cardiac tissue, can include an active electrode on the bottom surface of the pacing device and a housing coated with an insulating material such that only a narrow ring at or near the perimeter of the device is left uncovered and will serve as the passive electrode, effectively maximizing both the area of the cardiac tissue that will be stimulated by the pacing pulses and the amplitude of the sensed electrical activity of the myocardium.

An alternative configuration involves a plurality of electrodes, including up to eight electrodes but more preferably three or four electrodes. These electrodes may be used as alternative stimulation points to provide the lowest current drain from the pacemaker over its

lifetime. Multiple electrodes allow several variations of stimulation patterns. Stimulation may be unipolar, taking place from any of the electrodes, closing a circuit between a given electrode and the device housing through the myocardium as described above. Alternatively, two or more electrodes may be used simultaneously as anodes in the unipolar configuration (closing a circuit with the housing) to stimulate the myocardium. Furthermore, one or more of the electrodes may function as anode while one or more of the electrodes function as cathode (bipolar configuration). Programming of the electrode configuration and the stimulation pattern may be manual or automatic or both: the configuration may be chosen by the attending professional through a programmer that will instruct the pacemaker how to configure the stimulation circuit. Alternatively, the pacemaker could test its own stimulation thresholds and choose the most advantageous configuration, using an embedded algorithm. The two methods may coexist and preferences set at the discretion of the operator.

In some embodiments, the electrodes are incorporated into the anchors by, for example, constructing the tip of the anchor (such as the tip of a hook, strut, or coil) of the electrode material. The electrode material can be, for example, carbon, carbon fibers, platinum, a platinum alloy, or gold (active part). The electrode material should be firmly attached to the structural material of the anchor. See Figure 7C. And the electrode material should be connected electrically to the pacing device by, for example, a wire running along or inside the anchor. Or, the entire anchor could be constructed of the electrode material and then part of the anchor would be covered with insulating material such that a small part of the anchor, at the tip or at another location along the anchor, will be left uncovered and electrically active. When the pacing device 100 is implanted, the active or uncovered part of the anchor will be in electrical contact with the myocardium and stimulation and sensing will take place through these active or uncovered parts. Pacing and sensing may be configured by programming and/or by automatic algorithms to make one or more electrodes active and to set unipolar or bipolar configuration as described above.

The position of the electrodes at the tips of the anchors (Figure 7C) will allow the performance of stimulation and sensing thresholds and functional tests during implantation before the anchors are fully engaged in the myocardium. For example, the pacing device can be placed at a location to be tested such that the tips of all anchors are in touch with and slightly embedded in the myocardium. Sensing and threshold tests and, if desired, functional tests, are performed, allowing the implanting physician to make a decision whether to implant

the device at that site or move to another before the myocardium is fully penetrated. This mode of operation is applicable to both the preset-anchor configurations (in which anchors are attached to the device housing in a fixed position) and also the active-anchor configurations (in which anchors are movable relative to the device housing) that are described herein.

Having now described the anchoring of implantable medical devices within the body of a patient, the housing or outer shell configuration of such devices will now be addressed.

A leadless pacing device 100 (such as a leadless electrode or a leadless pacemaker) can have a housing or outer shell configured to contact and fit against or in the heart of a patient. Other types of implantable medical devices that are for implanting in or on other areas within the patient' s body can have housings or shells configured different than that of leadless pacing devices. Those other implantable medical devices could be, for example, neurostimulators, stimulators of the gastrointestinal system, and stimulators of other organs, or they could be passive implantable medical devices such as implantable monitoring devices.

Any implantable leadless medical devices will be subject to a set of constraints and considerations that is different than the set that applies to a subcutaneous device. A subcutaneous device does not, for example, need to have its overall size minimized or suited for introduction deep into the body of a patient. Implantable devices according to the invention will use a housing that is the smallest possible and typically that has a rounded shape to minimize friction with adjacent tissue and/or to minimize interference with flowing fluids like the blood stream, and the housing also typically will have smooth, non-abrasive surfaces (particularly important for inside-the-body locations that involve frequent movement such as the beating heart) and some means to reduce inflammatory and other tissue responses to the presence and movement of the device. The housing of implantable leadless devices also should contain additional design features that minimize the need for corrective procedures.

The size and shape of the device are intricately associated, reflecting both the technological needs and the need for adaptations as required by the surgical procedure and implant site. The volume of the device is dictated by the need to accommodate all of the

internal components of the device such as its power source, electronics, and sensors, considering both their size and shape, whereas space-constraints at the implant site place strict limitations on the allowable dimensions of the device. (For some examples and detail on the number and type of the device's internal components, see International patent application number PCT/US2012/066830 filed on November 28, 2012, which is titled "Implantable Medical Device Communications" and which claims priority to Provisional U.S. Patent Application Serial No. 61/563,930 filed on November 28, 2011. The entirety of International patent application number PCT/US2012/066830 is incorporated herein by reference.) The most volume-efficient shape is a cube but that is typically not allowable for an implantable leadless device due at least to its pointed corners which are not suited or acceptable for implantation into and being left within the body of a patient. For some devices, such as leadless pacing devices, specific considerations apply, such as hemodynamic interference for an endocardial device and tissue-friction for an epicardial device. Disclosed herein are considerations that apply to both (endocardial and epicardial) and some that are specific to an epicardial device.

An efficient accommodation of all considerations and constraints is achieved by the Lame curve, also known as the superellipse, which has the following mathematical description where $n > 0$, or else by an approximation of such a shape.

$$\left|\frac{x}{a}\right|^n + \left|\frac{y}{b}\right|^n = 1$$

Further, values "a" and "b" may be set such that $a = b$ to create a shape approaching a circle or such that $a \neq b$ to create an oblong shape approaching an ellipse when "n" approaches 2. A spatial structure may be constructed as a superellipsoid or it may be defined by rotation of the superellipse around its long axis to define a volume with the same surface characteristics as the flat curve, which are respectively described by

Superellipsoid: $$\left|\frac{x}{a}\right|^n + \left|\frac{y}{b}\right|^n + \left|\frac{z}{c}\right|^n = 1$$

Superegg: $$\left|\frac{x}{a}\right|^n + \left|\frac{\sqrt{y^2+z^2}}{b}\right|^n = 1$$

For the housing of an implantable medical device with rounded surfaces and even more rounded corners, n should be > 1, preferably between 2 to 10 and most preferably between 2.5 to 4, as in examples presented in Figures 8A and 8B in which n = 5/2 and 4, respectively, and in which a = b, for both. As a preferred embodiment, $a \neq b$ so as to create an elongated device that has a smaller diameter in the longitudinal direction, to facilitate introduction by a low-profile introducer and to be accommodated in elongated spaces such as a blood vessel, a cardiac chamber, or substantially along the long axis of the heart on the cardiac surface. The flat and spatial structures are presented in Figures 9A and 9B for n =5/2, a = 3, and b = 2 as used by Piet Hein for the "superegg" and described in Martin Gardner's "Piet Hein's Superellipse" (Mathematical Carnival. A New Round-Up of Tantalizers and Puzzles from Scientific American. New York: Vintage, 1977, pp. 240-254).

The three-dimensional superegg shape may be used in its entirety, for example, for use within a blood vessel, a cardiac chamber, an intestine, or other space that is characterized by a relatively open space or a longitudinal architecture. Alternatively, a slice of the three-dimensional superegg shape may be used when close association with a tissue surface is required. Thus, an epicardial leadless pacing device can be served by a device that has an overall three-dimensional shape based on the above considerations applied to a Lame curve but cut along the longitudinal plane such that, for example, half the shape remains as illustrated in Figures 10A and 10B. Cutting along the mid-longitudinal plane is the most space-efficient, but any other single or multiple plane(s) may be used for adaptation to specific attachment sites within the body of a patient. For other applications, such as endocardial fixation, the shape may be cut across the long axis at a desired angle to create a flat or near flat attachment surface as desired. Alternatively, the shape may be adjusted to the desired design by altering parameter "c" in the superellipsoid equation.

Additional shapes with specific characteristics may be created using the following more generalized form of the Lame equation where n and m > 0 and all other considerations above apply.

$$\left|\frac{x}{a}\right|^m + \left|\frac{y}{b}\right|^n = 1$$

When $m \neq n$, the curvature of a pair of opposing surfaces may be controlled independently of the other two as illustrated in Figure 11, in which m = 4, n=2, and a = b = 1. Furthermore, hybrid shapes may be used, where sections of the device's housing are constructed with different equations, joined along a plane where the circumferences meet. Thus, for example, the housing of an implantable leadless device may be constructed with one half constructed using m = n = 2, a = 2, and b = 1, and the other half using m = n = 4, a = 1, and b = 1, as illustrated in Figure 12. A hybrid shape may be beneficial for specially shaped spaces such as the surface of the left ventricle of the heart of a patient, where the space between arteries is narrow near the base of the ventricle but wider towards the apex. Thus, a device housing with a narrow end may be positioned to point towards the base and the broader end towards the ventricle's apex. A broader range of device shapes may be based on Gielis equations, thus providing a broader versatility of spatial fits to the implant-site architecture. For Gielis equations, see the following published paper from 2003 by Johan Gielis —"A generic geometric transformation that unifies a wide range of natural and abstract shapes" in the American Journal of Botany, 90 (3): 333-338.

The spatial constructs described above, and also constructs of similar or approximate structure which are to be considered part of this disclosure and included herein, provide solutions to a number of general problems associated with small autonomous medical devices and also address specific problems associated with leadless epicardial devices. These constructs have a softly rounded curvature while optimizing the largest possible volume with the smallest, site-adapted footprint and minimal thickness, all adjustable at the design level, and thus providing space for accommodating both the general components of the implantable medical device and a better fit for a three-dimensional energy-harvesting generator in a space that cannot fully utilize the "thickness". The curved or rounded shapes disclosed herein also provide the benefits of minimizing friction with adjacent tissue and minimizing interference with flowing fluids within the patient' s body such as the flow of blood within the patient' s heart and within the patient's vasculature generally. Furthermore, its dimensions may be tailored to have the shortest possible width within the limits of spatial efficiency to facilitate

easy insertion into the pericardial space, and its softly curved shape can minimize friction with the pericard or any other nearby structure.

In additions to the spatial considerations, other means to reduce interaction with the surrounding tissue may be employed. For example, the housing may be constructed of various non-abrasive materials, including highly polished titanium or titanium alloys, silicone, polyurethane, or other bio-compatible structural or coating material in present use or developed in the future. The surface may be treated with plasma or other methods for smoothness and the housing or its outer coating may contain a gradually eluting drug, such as a steroid (such as dexamethasone or cortisone, as just two examples), a non-steroid anti-inflammatory drug (such as aspirin as just one example), or any inflammation-reducing drug developed in the future - as commonly practiced at the tissue interface of pacing electrodes.

If references and citations to other documents (such as patents, patent applications, patent publications, journals, books, papers, and web contents) have been made anywhere herein, all such documents are hereby incorporated herein by reference in their entirety for all purposes.

While certain types of anchors, fixation approaches, electrode configurations, and housing configurations have been described herein in conjunction with implantable cardiac stimulation devices such as a leadless pacing device, this disclosure also relates to any of a variety of implantable medical devices including, for example, neurostimulators, stimulators of the gastrointestinal system, stimulators of other organs, and/or passive devices, although it is noted that passive devices typically will not have any electrodes.

Various modifications and combinations of what is described herein are considered to be included herein even if not specifically called out. The description is meant to be illustrative and not limiting.

Claims

1. A leadless medical device for implantation within a body of a patient, the device comprising:

a housing defining a top surface and bottom surface; and

at least three anchors, each of the anchors extending from the bottom surface of the housing and configured for attachment to a location within the body of the patient to secure the device to that location and to maintain the bottom surface of the housing in contact with tissue within the body of the patient.

2. The implantable leadless medical device of claim 1 wherein the top surface of the housing is curved.

3. The implantable leadless medical device of claim 2 wherein the curved top surface of the housing is defined by an equation.

4. The implantable leadless medical device of claim 3 wherein the equation defines a superellipse.

5. The implantable leadless medical device of claim 3 wherein the equation defines a superegg.

6. The implantable leadless medical device of claim 1 wherein the bottom surface of the housing is substantially flat.

7. The implantable leadless medical device of claim 1 wherein the housing is configured to have a narrow longitudinal profile that allows implantation of the device within the body of the patient and also is configured to have an internal volume that accommodates internal components of device.

8. The implantable leadless medical device of claim 1 wherein the bottom surface of the housing comprises one or more electrodes, each of the electrodes for delivering one or more electrical pulses to the tissue within the patient's body.

9. The implantable leadless medical device of claim 1 wherein at least one of the at least three anchors comprises at least one electrode for delivering one or more electrical pulses to the tissue within the patient's body.

10. The implantable leadless medical device of claim 1 wherein the bottom surface of the housing comprises one or more first electrodes, each of the first electrodes for delivering one or more electrical pulses to the tissue within the patient's body, and wherein at least one of the at least three anchors comprises at least one electrode for delivering one or more electrical pulses to the tissue within the patient's body.

11. The implantable leadless medical device of claim 1 wherein at least one of the at least three anchors comprises a substantially straight member.

12. The implantable leadless medical device of claim 11 wherein the substantially straight member includes a distal counter-hook.

13. The implantable leadless medical device of claim 11 wherein the substantially straight member is configured to be inserted into the tissue within the patient's body.

14. The implantable leadless medical device of claim 11 wherein at least a portion of the member comprises an electrode.

15. The implantable leadless medical device of claim 1 wherein at least one of the at least three anchors comprises a bent prong.

16. The implantable leadless medical device of claim 15 wherein the bent prong includes a distal counter-hook.

17. The implantable leadless medical device of claim 15 wherein the bent prong comprises a J-shaped hook.

18. The implantable leadless medical device of claim 15 wherein the bent prong is configured to be inserted into the tissue within the patient' s body.

19. The implantable leadless medical device of claim 1 wherein the at least three anchors comprise bent prongs, each of the bent prongs being pointed in substantially the same direction.

20. The implantable leadless medical device of claim 15 wherein at least a portion of the bent prong comprises an electrode.

21. The implantable leadless medical device of claim 1 wherein at least one of the at least three anchors comprises a coil.

22. The implantable leadless medical device of claim 21 wherein the coil is configured to be screwed into the tissue within the patient' s body.

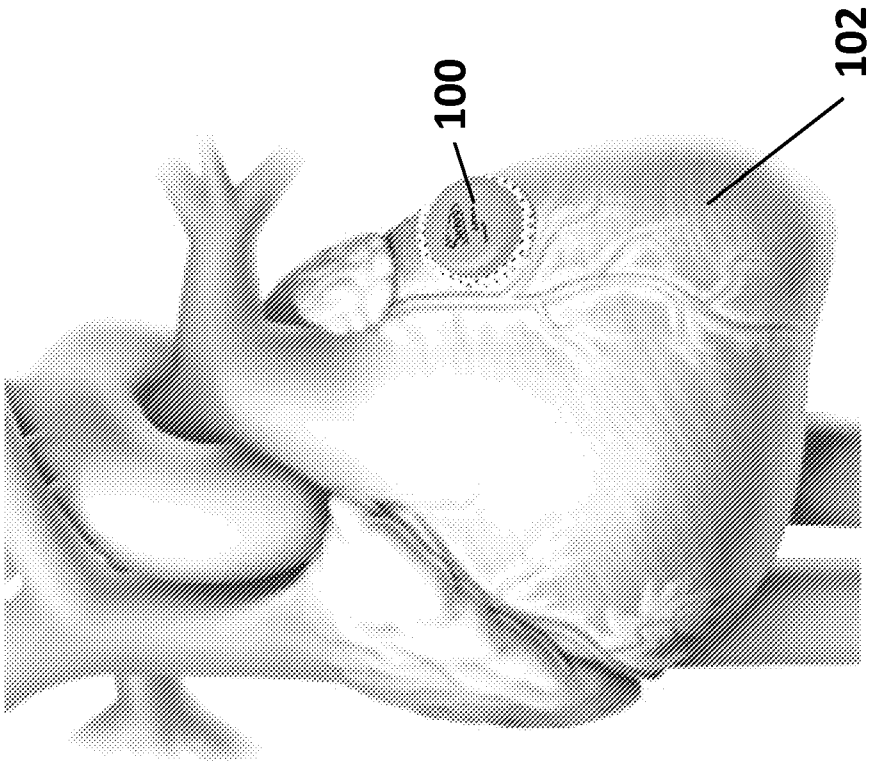
23. The implantable leadless medical device of claim 21 wherein at least a portion of the coil comprises an electrode.

24. The implantable leadless medical device of claim 1 wherein each of the least three anchors is disposed on an outer edge portion of the bottom surface of the housing.

25. The implantable leadless medical device of claim 1 wherein at least one of the at least three anchors comprises a suturing-receiving opening.

26. The implantable leadless medical device of claim 1 wherein the at least three anchors are part of a ring member that is movable relative to the housing to allow insertion simultaneously of the anchors into the tissue within the patient' s body when the ring member is moved relative to the housing.

27. The implantable leadless medical device of claim 26 wherein the housing comprises indentations that receive and cooperate with the anchors to allow and guide movement of the ring member and the anchors when the ring member is moved relative to the housing.



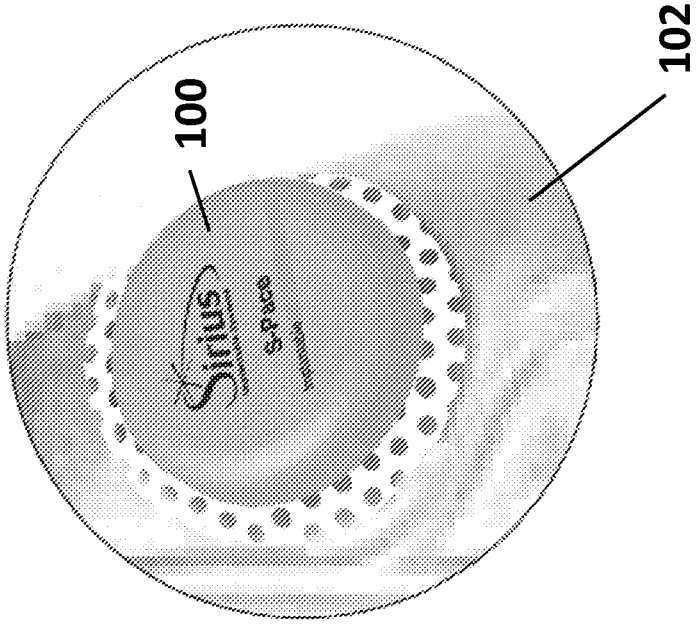


Fig. 1

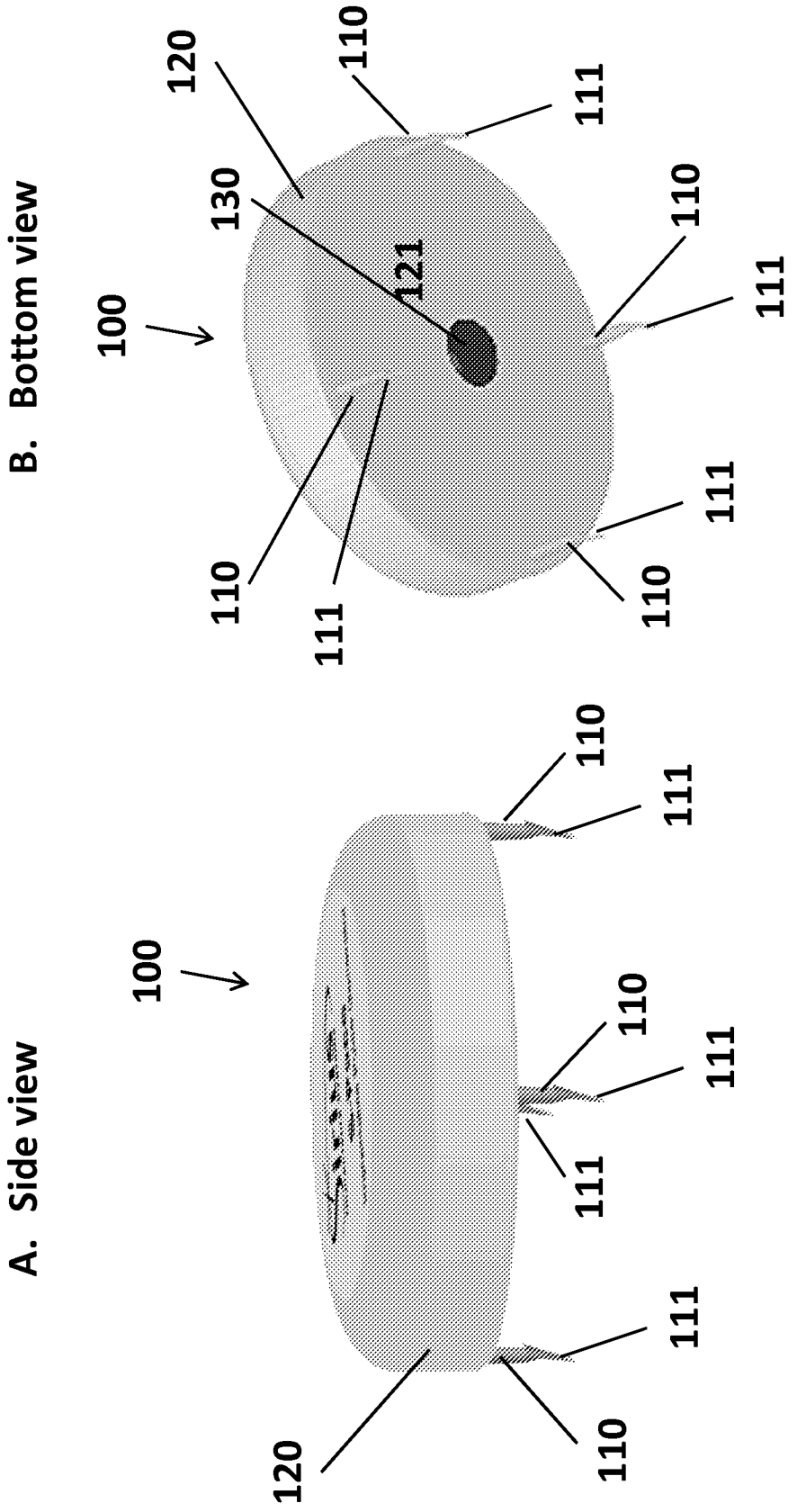

A. Side view
100
110
111
110
111
110
111
111
120
110
B. Bottom view
120
110
111
130
121
100
110
111
110
111
110
111
111

Fig. 2

Fig. 3

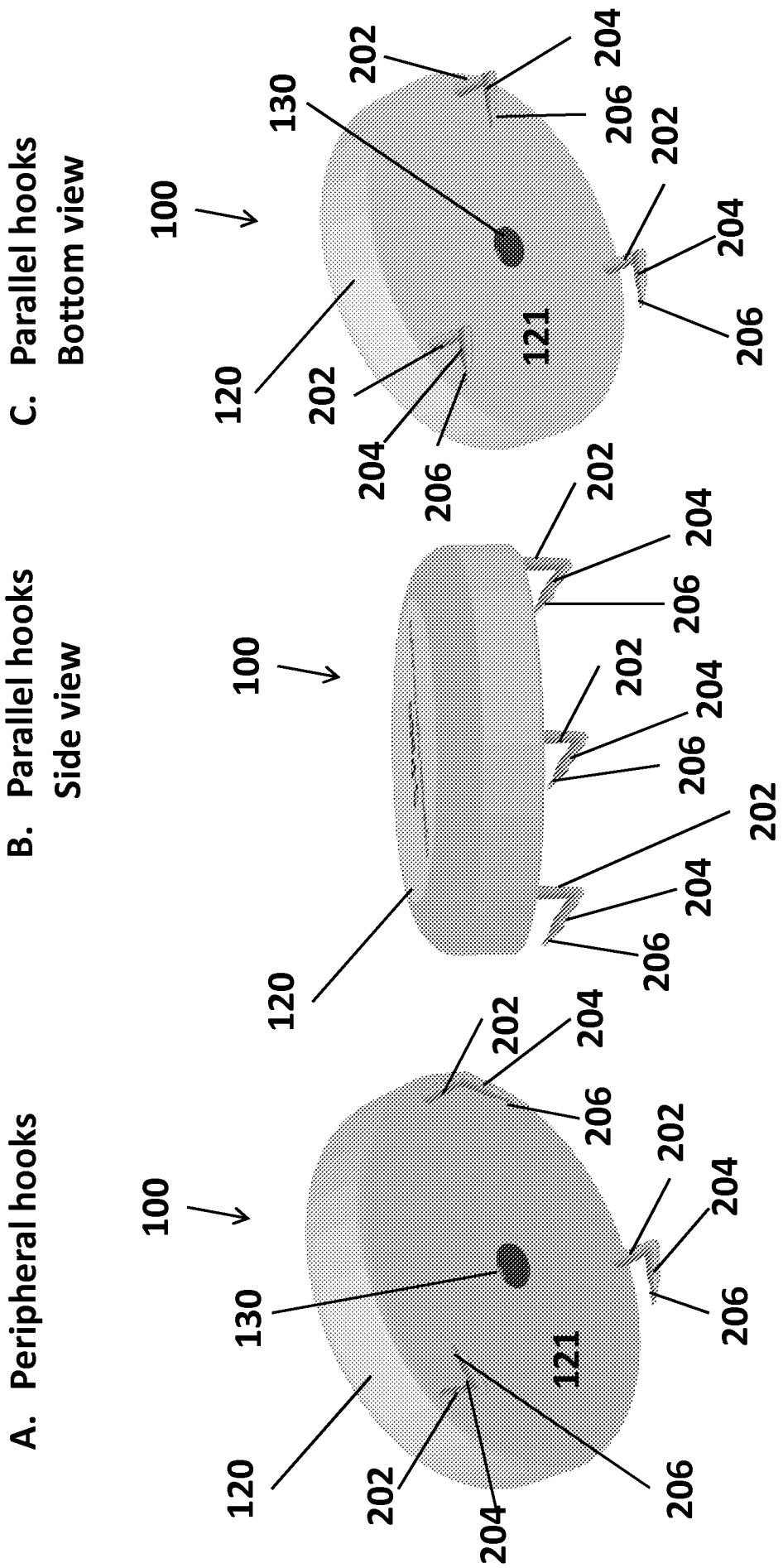
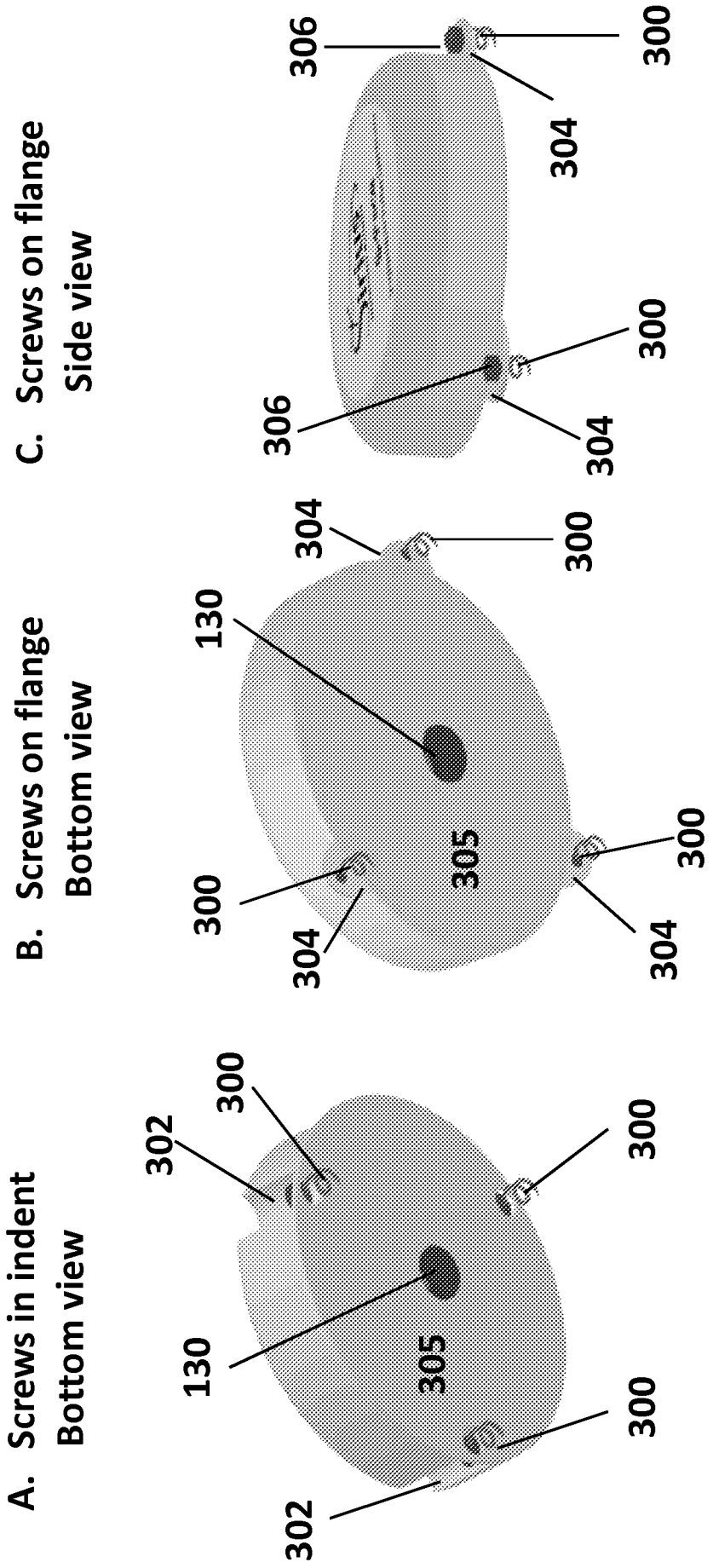

A. Peripheral hooks
B. Parallel hooks
Side view
C. Parallel hooks
Bottom view
100
120
130
121
202
204
206

Fig. 4


A. Screws in indent
Bottom view
302
300
130
305
300
302
300
B. Screws on flange
Bottom view
304
300
130
305
300
304
304
300
C. Screws on flange
Side view
306
304
300
306
304
300

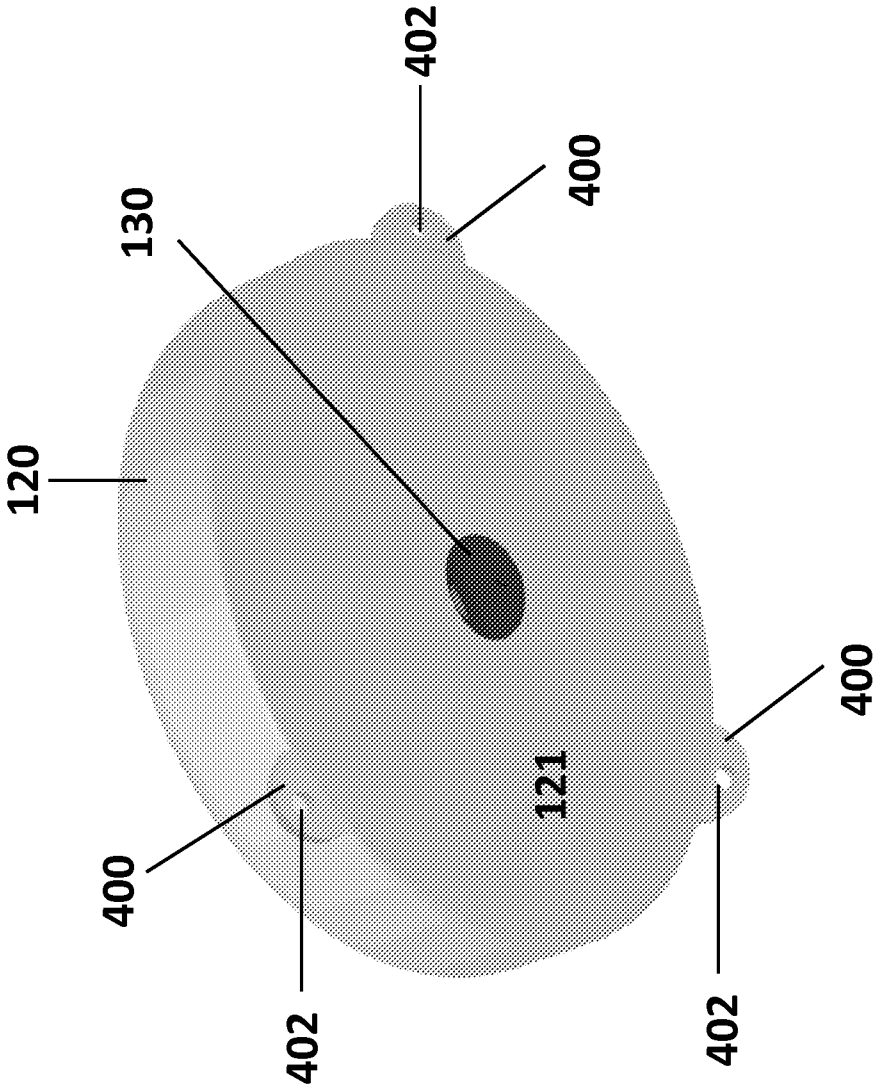


Fig. 5

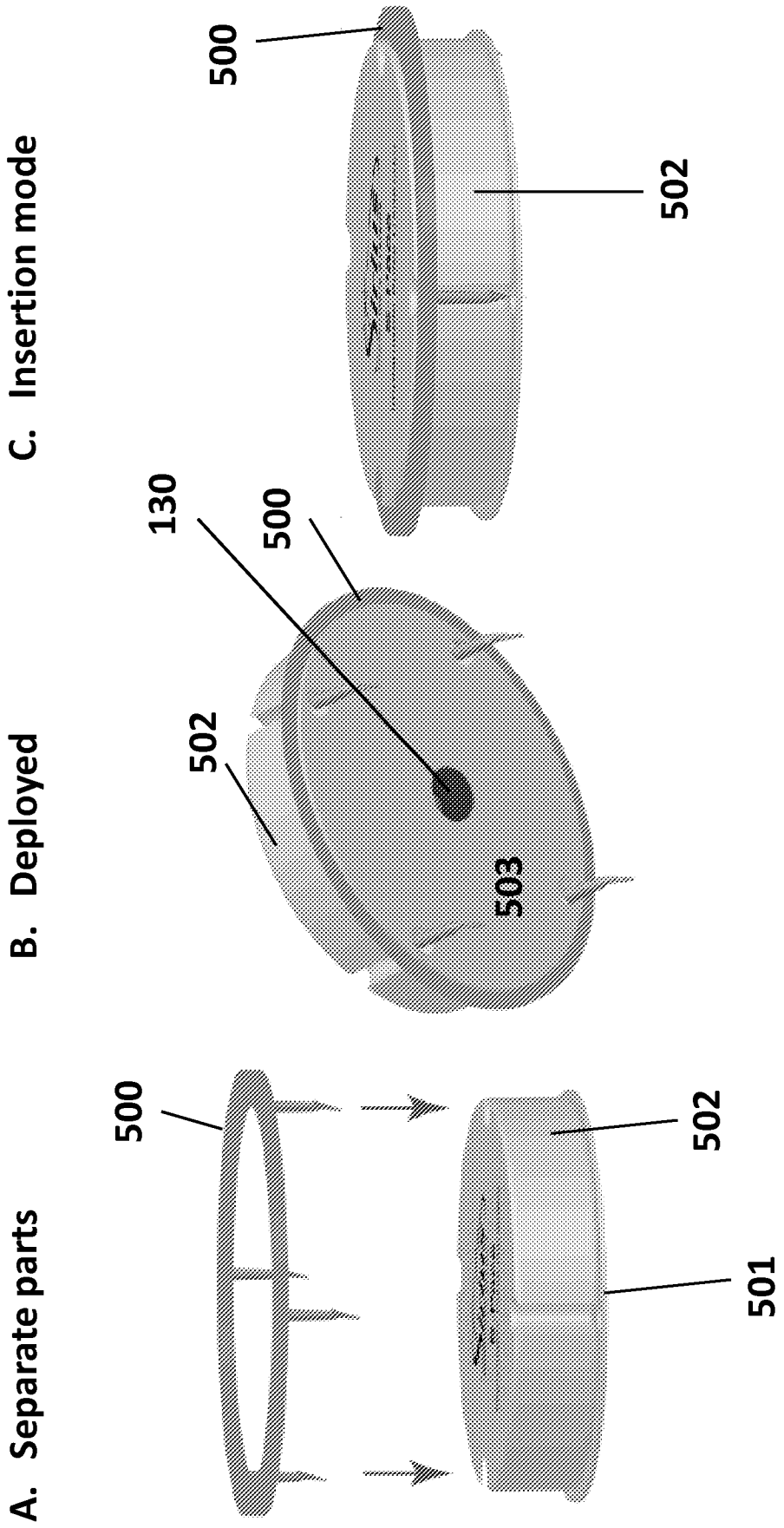
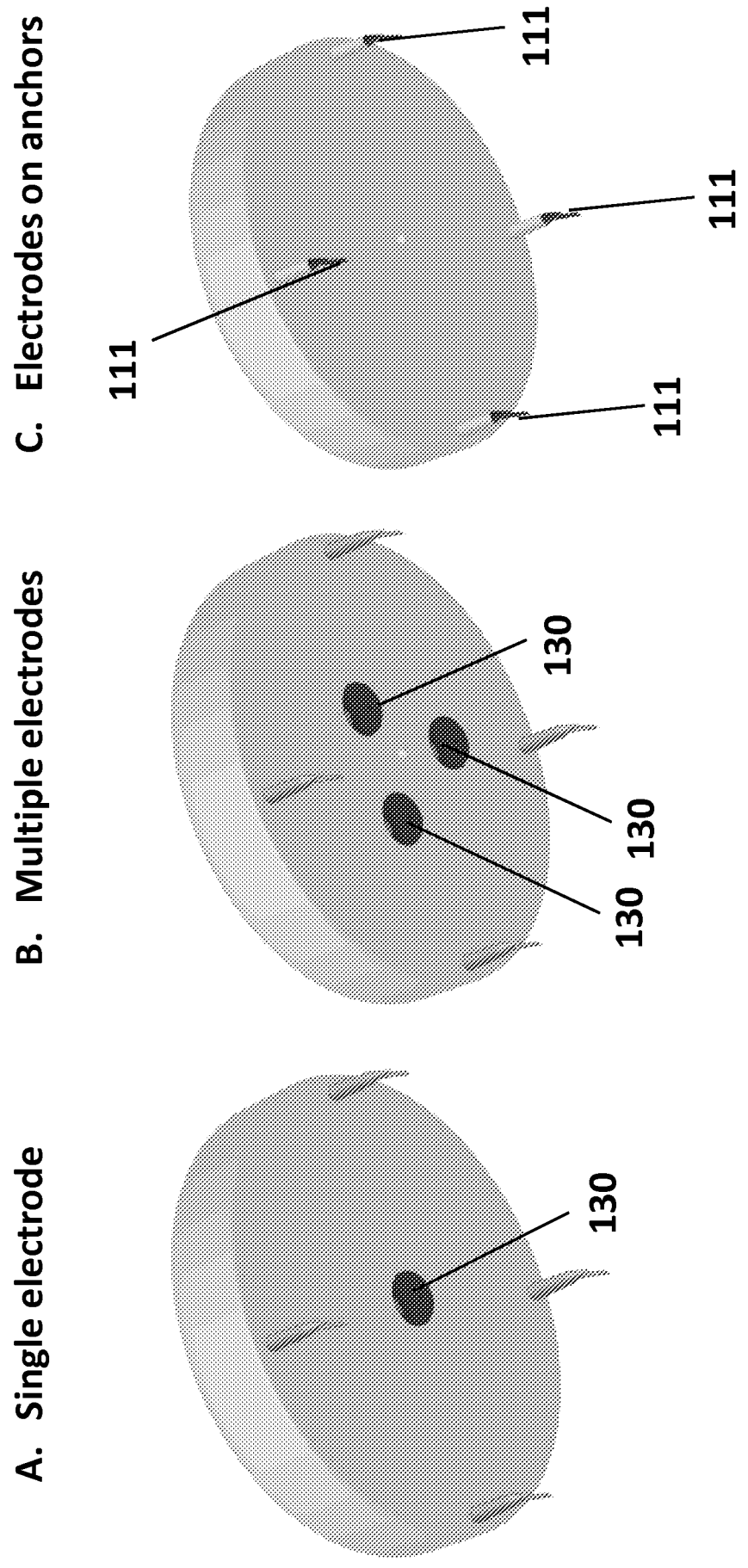
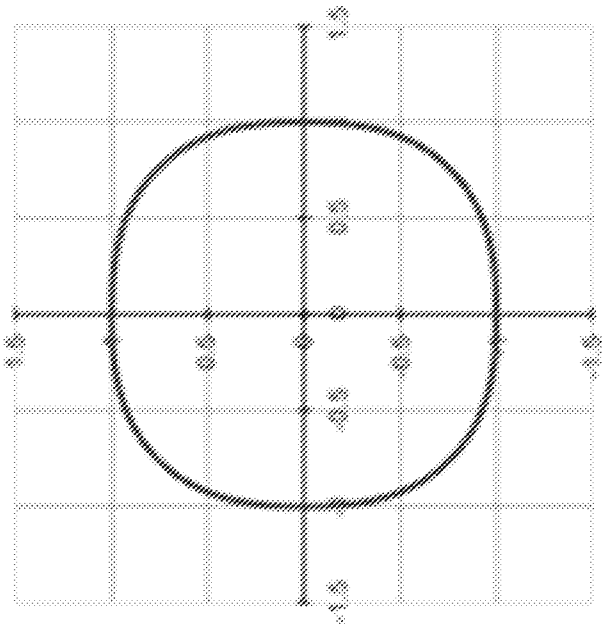

A. Separate parts
500
502
501
B. Deployed
130
500
502
503
C. Insertion mode
500
502

Fig. 6

Fig. 7


A. Single electrode
130
B. Multiple electrodes
130
130
130
C. Electrodes on anchors
111
111
111
111

A. Supercircle
n = 2.5; a = b = 1



B. Supercircle (squircle)
n = 4; a = b = 1

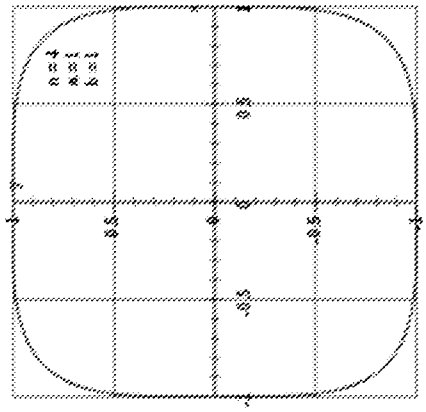
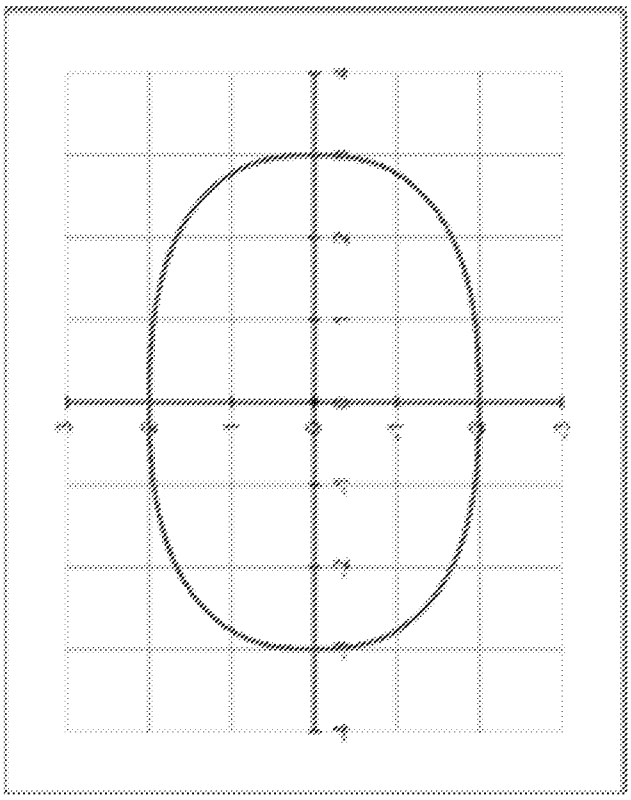


Fig. 8

Fig. 9

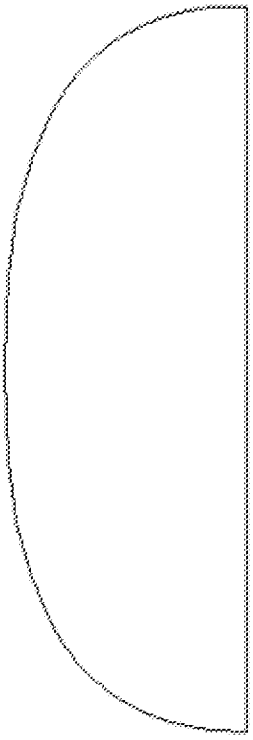


A. Superellipse
n = 2.5; a = 3; b = 2

B. Super-egg
n = 2.5; a = 3; b = 2

Fig. 10

A. Half Super-egg
Cross section



B. Half Super-egg
3 dimensional presentation

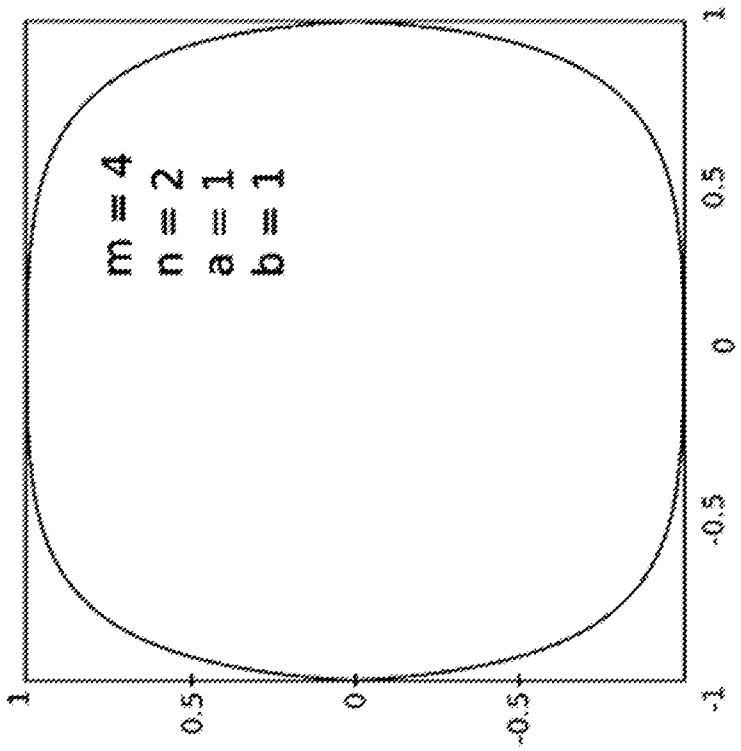


Fig. 11

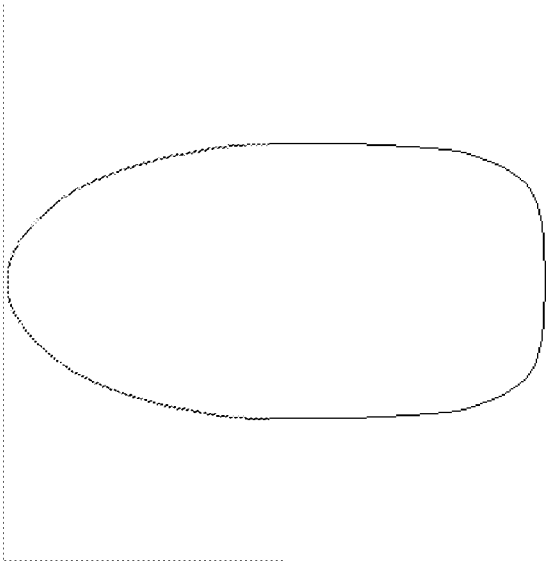


Fig. 12