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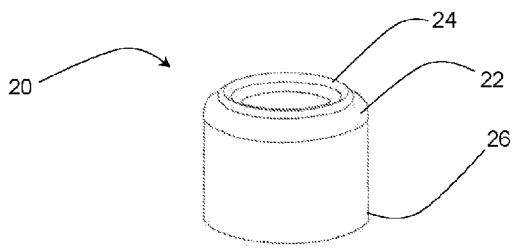

Fig. 2

(57) Abstract: The invention relates to a a multi-level tip electrode and a pacing device (e.g., a leadless or lead device) that comprises the multi-level tip electrode and a fixation helix for fixing the pacing device at a patient's tissue. A multi-level shape of the tip electrode in the axial/longitudinal direction of the pacing device stabilizes the attachment to the patient's tissue and improves electrical connection by offering more effective surface area.

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Multi-level electrode

FIELD OF THE INVENTION

The invention relates to the field of electrode structures for pacing, sensing and/or communicating devices (e.g., capsules, lead devices and/or leadless electrode devices) for cardiac or other pacing and/or sensing systems, such as but not limited to, left bundle branch (LBB) pacing, cardiac resynchronization or tachycardia (“tachy”) systems.

BACKGROUND OF THE INVENTION

The cardiac conduction system includes the sinus atrial node (SAN), the atrioventricular node (AVN), the bundle of His, bundle branches and Purkinje fibers. A heart beat is initiated in the SAN, which may be described as the natural “pacemaker” of the heart. An electrical impulse arising from the SAN causes the atrial myocardium to contract. The signal is conducted to the ventricles via the AVN which inherently delays the conduction to allow the atria to stop contracting before the ventricles begin contracting thereby providing proper AV synchrony. The electrical impulse is conducted from the AVN to the ventricular myocardium via the bundle of His, bundle branches, and Purkinje fibers.

Patients with a conduction system abnormality, such as poor AV node conduction or poor SAN function, may receive an implantable medical device (IMD), such as a pacemaker, to restore a more normal heart rhythm and AV synchrony. Some types of IMDs, such as cardiac pacemakers, implantable cardioverter defibrillators (ICDs), or cardiac resynchronization therapy (CRT) devices, provide therapeutic electrical stimulation to a heart of a patient via electrodes on one or more implantable endocardial, epicardial, or coronary venous leads that are positioned in or adjacent to the heart. The therapeutic electrical stimulation may be delivered to the heart in the form of pulses or shocks for pacing, cardioversion, or defibrillation. In some cases, an IMD may sense intrinsic depolarizations of the heart, and control the delivery of therapeutic stimulation to the heart based on the sensing.

Left bundle branch pacing (LBBP) has emerged as an alternative method for delivering physiological pacing to achieve electrical synchrony of the LV, especially in patients with infranodal atrioventricular block and/or LBBB. The proximal LBB runs through the LV septum and fans out to form a wider target for pacing, as compared to the His bundle. A technique for LBBP has been developed using a ventricular transseptal approach (i.e., pacing the LV from the RV). LBBP has been reported to offer low pacing thresholds and large R waves, and because the distal conduction system is targeted, has a lower theoretical risk for development of distal conduction block.

After an initial site for an LBBP location at the right surface of the ventricular septum is determined, a helical fixation element is screwed into the LV septum, e.g., by puncturing the tissue with the distal tip of the helical fixation element (fixation helix). The insertion depth into the LV septum may be determined by one or more of the observed changes in the notch in V1 lead, sheath angiography, fulcrum sign, and impedance monitoring. The pacing electrode is slowly progressed to a determined depth into the septum (e.g., approximately 8 to 12 mm) by the application of a torque, meanwhile avoiding the perforation of the LV side of the septum. Finally, LBB capture is confirmed based on acceptable pacing parameters. Such confirmation may be based on at least one of a paced morphology of an RBBB pattern, a recording of an LBB potential, a stimulus-peak of the LVAT that shortens abruptly with increasing output or remains shortest and constant at low and high outputs, a selective LBBP and a non-selective LBBP, and a recording of a retrograde His potential or anterograde LBB potential during pacing.

The tips of pacing or tachy leads are typically designed to avoid a risk of perforation of the septum. They may also be equipped with a soft tip (made of e.g. Silicone) to increase a stop surface. That is, when the helical fixation element or electrode (called “helix” hereinafter) is engaged with (e.g., screwed into) the (cardiac) issue, this tissue is pushed against the soft tip to stop the helix from rotation and further progression within the tissue. The length of the helix may be limited, e.g., to an active length of about 2 mm.

In a lead-based LBBP technique, common features of implantation or placement processes include transvenous access, transseptal placement of the pacing lead into the LV septal sub-endocardium in the LBB region, and confirmation of capture of the LBB as referred to above.

As an alternative, a leadless technique has been developed, wherein a leadless medical device (e.g., capsule) with e.g. a helix is implanted into the apex region, more preferably into the lower septum to limit the risk of perforation of the thin apex. The typical length of the capsule is 35 mm including the helix (2 mm). This capsule may be delivered through a vascular catheter introduced by a femoral access.

Leadless capsules may need a system of fixation and two electrodes (tip and ring), where the electrodes are a key for electric performances and low power consumption (minimal stimulation threshold).

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an improved electrode and fixation system.

This object is achieved by a tip electrode as claimed in claim 1 and a pacing device as claimed in claim 9.

Accordingly, two or more axially protruding contact areas between tip electrode (e.g., cathode) and patient's tissue improve strength and efficiency of tissue contact and minimizes tissue damage. Moreover, the improved shape factor and an optional coating of the proposed tip electrode improve electrical connection and provide a more effective contact surface, even in case of slight capsule dislodgements. Thus, attachment of the capsule to the myocardial or other patient's tissue can be stabilized in a safe manner without critical damages to the heart or other body portion.

According to a first option, the protruding tissue contact areas may be configured as closed or open circular or polygonal rings or ring sections or as protrusion patterns arranged in a closed or open circular or polygonal ring or ring section shape, that may or may not be arranged around a central axis of the pacing device.

According to a second option, the tip electrode may comprise a cylindrical body, wherein the axially protruding tissue contact areas may comprise an outer ring and an inner ring.

According to a third option, the inner ring may be formed on top of the outer ring in the distal direction.

According to a fourth option, the cylindrical body may be coated at the protruding tissue contact areas with a contact-improving coating, in particular a TiN coating.

According to a fifth option which can be combined with any of the first to fourth options, the protruding tissue contact areas may or may not be arranged around a central hole of the tip electrode.

According to a sixth option, the central hole may at least partially be filled with a steroid.

According to a seventh option, a further steroid portion may be placed around the protruding tissue contact areas.

According to an eighth option, which can be combined with any of the first to seventh options, the pacing device may comprise a conical fixation helix, wherein a diameter of helical turns of the conical helix may increase in the distal direction to obtain a conical shape.

According to a ninth option, a largest diameter of the helical turns at the distal end of the conical helix may be configured to match with a diameter of a cylindrical housing of the device.

It shall be further understood that a preferred embodiment of the invention can also be any combination of the dependent claims or above embodiments with the respective independent claim.

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following drawings:

Fig. 1 shows schematically a heart in which respective placement options for a lead device and a leadless device for ventricular transseptal LBB pacing are schematically indicated;

Fig. 2 shows schematically a perspective side view of a double-ring tip electrode according to a first embodiment;

Fig. 3 shows schematically a side view and a cross-sectional side view of the double-ring tip electrode of Fig. 2 with additional through hole and dimensional parameters ;

Fig. 4 shows schematically a perspective top view of a double-ring tip electrode with integrated steroids according to a second embodiment;

Fig. 5 shows schematically a perspective top view of a leadless capsule with double-ring tip electrode and conical helix according to a third embodiment; and

Fig. 6 shows schematically a perspective side view of a leadless pacemaker in which the double-ring tip electrode can be implemented.

DETAILED DESCRIPTION OF EMBODIMENTS

Various embodiments of the present invention are now described based on a leadless medical pacing, sensing and/or communicating device (e.g., capsule) with multi-level tip electrode. Although the present invention is particularly advantageous within the context of leadless pacing devices for transseptal pacing such as LBBP, the invention is not limited thereto and may also be used in connection with any type of pacing, sensing and/or communicating leads and/or other pacing types and/or sites for other applications that require placement of a pacing device within a body tissue.

It is noted that throughout the present disclosure only those elements, portions, components and/or devices that are relevant for the proposed pacing device and placement operation are shown in the accompanying drawings. Other elements, portions, components and/or devices may have been omitted for reasons of brevity. Furthermore, components designated by same reference signs or numbers are intended to have the same or at least a similar function, so that their function is not described again later.

Furthermore, throughout the present disclosure, “proximal” and “distal” are terms that are used to indicate distances from an operating end (reference point) of the pacing device, where the physician or other user controls the screwing process. Proximal is closer to the operating end, while distal is further away (at a greater distance) from the operating end.

As used herein, "leadless" refers to a medical device (e.g., a pacing, sensing and/or communicating device) being devoid of any lead(s) extending out from it that is/are attachable to a patient's heart. Some leadless devices may be introduced through a vein, but once implanted, such devices are free of, or may not include, any transvenous lead and may be configured to provide cardiac therapy without using any transvenous lead.

As used herein, “axial” direction or length refers to the longitudinal axis of the pacing device and/or a fixation helix for fixing the pacing device at a patient’s tissue.

Fig. 1 shows schematically a heart with an inserted lead device 200, where the pacing lead tip 20 is placed for ventricular transseptal LBBP. Additionally, for comparison reasons, a leadless device (capsule) 400 is shown prior to insertion of its helix 300 into the septum 24. Thereby, the LV can be paced from the RV by a ventricular transeptal approach. The placement of the pacing lead tip 20 may be performed based on the procedure briefly explained in the above introductory section. LBBP may be defined as capture of the LBB (i.e., left bundle trunk or its proximal fascicles), usually with septal myocardium capture at low output (e.g., <1.0 V/0.4 ms).

It is noted that, contrary to what is shown in Fig. 1, the pacing lead tip 20 and the leadless device 400 are not intended to be used together. They can be used as alternatives depending on the situation/condition of the patient.

In a normal cardiac function, as mentioned in the introductory section, the heartbeat starts in the heart itself due to the SAN which is found at the top (i.e., towards the neck/head region of the body) of the right atrium (RA) and sets the rate at which the heart contracts. It sends out electrical impulses that are carried through the muscular walls of both atria. These impulses cause atrial systole. The impulse is then passed to another node within the heart – the AVN. This node is in the lower part of the RA within the subendocardial layer of the heart wall of the interatrial septum that separates the RA from the left atrium (LA). Once the impulse from the SAN reaches the AVN, the impulse is passed to conducting fibers which travel down the central wall of the heart. The impulse then splits and travels up the LV and RV causing them to contract with a natural delay between LV and RV contraction (ventricular systole).

Important elements of the conduction system of the heart are found within the septum 24. The His bundle travels in the sub-endocardium down the right side of the septum 24 for about 1cm before dividing into the LBB and RBB. The LBB continues down the right side of the septum 24, while the LBB crosses to the left side and splits into anterior and posterior divisions.

Under normal circumstances, excitation from the SAN controls the heart rhythm. An abnormality in the sinus rhythm leads to arrhythmia, which refers to abnormalities in the rate, rhythm, site of origin, and conduction of the cardiac electrical pulse. When disorders occur in specific intraventricular conduction fibers, the repolarization wave must then travel through the slower muscle-muscle conduction to reach the ventricles. Classic disorders related to conditions that involve different conduction bundle branches include LBBB and RBBB. An electrogram (EGM), as obtained from an inserted lead device, can be used to measure and record cardiac electrical activities and thus can provide important information on cardiac functions. The ECG has been used as a standard diagnostic tool to analyze arrhythmia.

In one or more embodiments, the pacing device for bundle pacing is a leadless device that does not use a lead to operably connect to an electrode disposed proximate to the septum when a housing of the device is positioned in the RV. It is however noted that, in embodiments, the pacing device (e.g., capsule or lead) could as well be placed in the RA. The helix may be leadlessly coupled to the housing of the leadless device without using a lead between the electrode and the housing. The leadless device (i.e., an implemented medical pacing device) may sense electrical signals attendant to the depolarization and repolarization of heart via tip electrode distal end of the body of the leadless device and optionally via a tip electrode of the fixation helix. In some examples, the leadless device may provide pacing pulses to the heart based on the electrical signals sensed within heart. The configurations of electrodes for sensing and/or pacing may be unipolar (e.g., in case of a lead device) or multipolar (e.g., in case of a leadless capsule or a lead device). The lead device may be a regular lead with a single pole (unipolar) connected to a housing/case of a pacemaker/defibrillator, wherein the housing/case becomes the second pole for sensing and/or pacing.

The leadless device may also provide defibrillation therapy and/or cardioversion therapy via electrode(s), based on a detected arrhythmia of the heart, such as fibrillation of ventricles, e.g., by delivering a defibrillation therapy to the heart in the form of electrical pulses. In some examples, the leadless device may be programmed to deliver a progression of therapies, e.g., pulses with increasing energy levels, until a fibrillation of heart is stopped. To achieve this, the leadless device may detect fibrillation employing one or more fibrillation detection techniques known in the art.

The leadless device may comprise an intracardiac housing including a sensing circuit operably coupled to an electrode (i.e., the tip electrode) and configured to sense one or both of an atrial event and a ventricular event using the electrode. Further, the housing of the leadless device my include an electrical pulse generator coupled to a bundle pacing electrode (i.e., the tip electrode), the electrical pulse generator configured to generate and deliver electrical bundle-branch stimulation pulses based on one or both of atrial and ventricular events to the patient's heart using the bundle pacing electrode. The housing of the leadless device may also include a communication interface configured to receive control signals. The leadless device may further include a controller disposed in the housing and operatively coupled to the pulse generator to control delivery of bundle-branch pacing pulses to the patient's heart in response to the received control signals.

The following embodiments of the proposed tip electrode and the proposed fixation helix of the pacing device (i.e., leadless device) are configured to maximize contact surface and improve contact efficiency of the tip electrode.

In embodiments, this can be achieved by configuring the shape of the surface of the tip electrode to provide two or more axially protruding tissue contact areas with different axial (longitudinal) levels at the distal end of the tip electrode. In examples, the protruding tissue contact areas may be configured as closed or open circular or polygonal rings or ring sections or protrusion patterns arranged in a closed or open circular or polygonal ring or ring section shape. Two or more of the closed and/or open polygonal and/or circular rings and/or ring sections and/or patterns may be arranged concentrically on the tip electrode around the central axis of the pacing device. Such a multi-level tip electrode provides an enhanced tissue contact surface area for improved electrode performance.

In a first embodiment, the protruding tissue contact areas with different axial levels are configured as two concentric rings with different thickness placed on top of each other to obtain a double-ring tip electrode.

Fig. 2 shows schematically a perspective side view of the double-ring tip electrode 20 according to the first embodiment.

The proposed double-ring tip electrode 20 comprises a cylindrical body 26 which may be coated with a TiN coating on top of the cylindrical body where two axially protruding rings 22 and 24 are provided. The two axially protruding rings comprise a thicker outer (lower-level) ring 22 on which a thinner inner (upper-level) ring 24 is formed.

The double-ring tip electrode 20 has an increased distal contact surface area and ensures an improved tissue contact to keep better tissue contact at times of movements of the patient with implanted pacing device. Such an improved tissue contact provides the advantage that the tip electrode can sufficiently touch cardiac tissue without or prior to implanting the capsule with the tip electrode in order to check electrical performance of an implantation site. Thereby, the capsule can be implanted at good sites with desirable electrode performance, e.g., to ensure less tissue damage.

Fig. 3 shows schematically a side view and a cross-sectional side view from different angles shifted by 90 degrees of the double-ring tip electrode of Fig. 2 with additional through hole in the electrode body. The through hole may be provided to attach the double-ring electrode to a capsule (not shown) via a screw, a pin, a spring pin or bolt fixation mechanism. Other fixation methods (e.g., welding, gluing etc.) may be used.

In an example, the diameter of the central axial through hole within the two rings 22, 24 may be about 0.9mm and the diameter of the cylindrical body of the double-ring tip electrode 20 may be about 1.6mm, while the height H_1 of the cylindrical body may be about 1.3mm. Moreover, the radius R_1 of the outer surface of the outer ring 22 may be about 1mm, the radius R_2 of the inner surface of the outer ring 22 may be about 0.5mm and the radius R_3 of the inner ring may about 0.6 mm. The height H_2 of the inner ring 24 may be about 0.1mm. Furthermore, the diameter D of the fixation though hole may be about 0.3mm.

Other dimension may be chosen depending on the application and conditions at the implantation and/or pacing site.

The through hole at the center of the two rings 22, 24 may have at least one of several possible functions. It may be filled at least partially with a steroid or other drug, and/or it may ensure that the tip electrode has a shape of a double ring as opposed to a cup, and/or it may provide a better contact with cardiac tissue or other patient’s tissue even on the inner edges of the inner ring 24.

Fig. 4 shows schematically a perspective top view of a double-ring tip electrode with integrated steroids according to a second embodiment.

A steroid 44 at the center of the double-ring tip electrode may be used to reduce fibrosis. A steroid is a drug that attenuates the fibrosis around a wounded tissue area which may have been caused by a screwing operation of the fixation helix during the attachment of a pacing device (e.g., capsule) with the double-ring tip electrode.

A variation of design, as shown in Fig. 4, may integrate a further steroid 46 around the outer ring 22 to provide steroids 44, 46 on both sides of the double-ring tip electrode and thereby ensure a better quality of tissue and resulting electrical contact of the pacing device with the myocardial tissue or other patient’s tissue.

Fig. 5 shows schematically a perspective top view of a tip portion of a leadless capsule with double-ring tip electrode 20 and conical helix 50 according to a third embodiment.

To achieve the required quality and/or integrity of the electrical contact between output connection(s)/interface (not shown) of the leadless capsule and the double-ring tip electrode 20, a permanent firm connection (e.g., by screwing, welding, crimping etc.) may be established. Furthermore, a proximal portion of the conical helix 50 may be mechanically fixed to a housing 54 of the leadless capsule and may then optionally be connected to internal electronic circuitry (e.g., via a feed-through technology which may also ensure hermetical sealing of the housing), if the conical helix 50 comprises a tip electrode as well.

The diameter of the helical turns of the conical helix 50 increases in the distal direction to obtain a conical shape. The conical shape with widening diameter of the helical turns towards the distal end enables better attachment of the leadless capsule to the myocardial tissue while compressing the tissue towards the double-ring tip electrode 20. This provides a synergistic effect in combination with the improved effective surface achieved by the double-ring electrode 20 or any other type of the proposed multi-level tip electrode.

The largest diameter of the helical turns at the distal end of the conical helix 50 may be selected to (substantially) match with the diameter of the housing 54 of the capsule, to thereby facilitate smooth implantation of the capsule during perforation of the tissue. Furthermore, the helical turns of the conical helix 50 may include an insulated surface to prevent a non-desired electrode functionality. The insulated surface may be achieved by covering the helical turns by a dielectric or other insulative material.

Furthermore, a protection ring with radially protruding protection elements 52 may be provided at the proximal end of the conical helix 50 to prevent unscrewing of the conical helix 50 with the capsule from the patient’s tissue.

In addition, a non-conductive (e.g., non-metal) isolation ring 56 may be provided to insulate the tip electrode 20 from the conical helix 50.

Optionally, to provide an additional cathode function for LBBP, the helical turns of a distal section of the conical helix 50 may not be insulated by any non-conductive coverage or isolation. In an example, the surface of the helical turns of the non-isolated distal section may be coated with classic TiN (Titanium nitride) to optimize electrical performances. Furthermore, the distal section may be configured to provide X-ray visibility to help the physician to precisely locate the cathode within the width of the septum.

In such a case of two tip electrodes (one at the distal end of the helix 50 and the other at the double-ring electrode 20), the double-ring tip electrode 20 can be used as (additional) RV cathode. If the double-ring tip electrode 20 is used in combination with the helix tip electrode, independent LV/RV pacing can be implemented with a controlled delay between stimulation of both chambers.

The conical helix 50 may be made using classic coiling of one or more insulated wires (as used e.g. for inner conductors of lead devices with a coiling of 4 to 6 individual wires).

Fig. 6 shows schematically a perspective side view of a leadless capsule (as an example of a lead device or pacing device) in which a double-ring tip electrode 20 of the above embodiments is implemented.

The leadless capsule comprises a housing 130 having, or defining, an outer sidewall 135, shown as a cylindrical outer sidewall, extending from a housing distal end region 132 to a housing proximal end region 134. The housing 130 may enclose electronic circuitry configured to perform single or multiple chamber cardiac therapy, including atrial and ventricular cardiac electrical signal sensing and pacing the atrial and ventricular chambers. A delivery tool interface member 126 may be provided on the housing proximal end region 134.

Furthermore, a distal fixation and electrode assembly 136 may be coupled to the housing distal end region 132. The distal fixation and electrode assembly 136 may comprise an electrically-insulative distal member 172 coupled to the housing distal end region 132. The electrically-insulative distal member 172 comprises the double-ring tip electrode 20 and a fixation helix 112 that extends away from the housing distal end region 132. The fixation helix 112 extends in a longitudinal direction away from the housing distal end region 132 and may be coaxial with the longitudinal center axis 131 of the housing 130.

The fixation helix 112 may comprise an electrically insulated shaft 140 and functions as a fixation member. It may optionally include a distal cathode tip electrode element (not shown). A shaft proximal end region of the fixation helix 112 may be directly coupled to the insulative distal member 172. The helical shaft 140 may be coated with an electrically insulating material, e.g., parylene, to avoid sensing or stimulation of cardiac tissue along the shaft length.

The double-ring tip electrode 20 may serve as a cathode electrode for delivering ventricular pacing pulses and sensing ventricular electrical signals using a proximal housing-based electrode 124 as a return anode. The proximal housing-based electrode 124 may be a ring electrode circumscribing the housing 130 and may be defined by an uninsulated portion of the longitudinal sidewall 135. Other portions of the housing 130 not serving as an electrode may be coated with an electrically insulating material.

In embodiments, multiple cathodes (e.g., the tip electrode of the fixation helix 112 together with the dual-ring tip electrode 20) may be used for bipolar or multipolar sensing or pacing. Such multiple cathodes may comprise tissue piercing electrodes (e.g., the fixation helix 112 or a straight dart- or needle-type electrode) and non-tissue-piercing electrodes (e.g., the double-ring tip electrode 20) at the periphery of the insulative distal member 172. The insulative distal member 172 may define a distal-facing surface 138 of the capsule and a circumferential surface 139 that circumscribes the capsule adjacent to the housing longitudinal sidewall 135.

When the fixation helix 112 is advanced into cardiac tissue, the dual-ring tip electrode 20 is in intimate contact with a cardiac tissue surface for delivering pulses and/or sensing cardiac electrical signals produced by the patient's heart. The dual-tip electrode 20 may be coupled to a therapy delivery circuit and a sensing circuit enclosed by the housing 130 to function as a cathode electrode for delivering atrial pacing pulses and for sensing atrial electrical signals (e.g., P-waves) in combination with the proximal housing-based electrode 124 as a return anode. Switching circuitry included in the sensing circuit may be activated under the control of the control circuit to couple the dual-ring tip electrode 20 to the atrial sensing channel. Switching circuitry included in the therapy delivery circuit may be activated under the control of the control circuit to couple the dual-ring tip electrode 20 to the atrial pacing circuit.

In the above embodiments, the housing of the leadless device (e.g., leadless pacemaker) may be made with plastic material like polyetheretherketon (PEEK) due to its high biocompatible properties and extremely rigid mechanical structure. As another option, the housing of the leadless device 40 may be made of titanium (to achieve e.g. X-ray transparency, weldability, desired mechanical and biological properties etc.) and coated with an insulation coating like parylene or ethylene tetrafluoroethylene (ETFE). Optionally, an extra safety insulation layer may be added onto the housing to reinforce the electrical insulation and increase the abrasion resistance of the housing.

To summarize, a multi-level tip electrode and a capsule (e.g., including but not limited to a leadless pacing and/or sensing device) that comprises the multi-level tip electrode and a fixation helix for fixing the pacing device at a patient’s tissue has been described. A multi-level shape of the tip electrode in the axial/longitudinal direction of the capsule stabilizes the attachment to patient’s tissue and improves electrical connection by offering more effective surface area.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive. The invention is not limited to the disclosed embodiments of tip electrodes with double-ring configuration. Any other multi-level shape with circular or polygonal ring or ring sections or ring patterns are intended to be covered. The multi-level tip electrode can be applied to various types of pacing devices (e.g., bradycardia or tachycardia lead devices with multi-lumen, coaxial or coradial structure) and applications in the field of cardiac pacing or sensing systems to reduce the required space before and/or after insertion of the fixation helix.

More specifically, the proposed multi-level tip electrode with or without conical helix may be used in connection with various designs of lead devices that may have a multi-lumen, coaxial and coradial structure, both as tachycardia leads or bradycardia leads, and a central lumen for a stylet passage may be provided. Coaxial leads have an inner conductor that extends down the length of the lead to the tip electrode (helix), the cathode, arranged in a coil configuration that provides a central lumen e.g. to allow for passage of a stylet at implantation. The multi-lumen or coaxial or coradial leads may optionally comprise a fixed, non-retractable helix to minimize size. However, a retractable helix may also be used in connection with the described embodiments.

Furthermore, the lead system with the proposed multi-level tip electrode may be configured to provide improved torquability, i.e., an ability to transmit torque safely and accurately to the helix (e.g., full lead body torque) and stylet-driven compatibility to ease the handling (e.g., by push transmission). In an example, a coradial lead with compatible screwing stylet (screwdriver stylet) may be provided.

The capsule with the proposed multi-level tip electrode may be configured to be adapted or adaptable to IS1, IS4 (low voltage) or DF4 (high voltage) connectors.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure and the appended claims. In the claims, the word “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. The foregoing description details certain embodiments of the invention. It will be appreciated, however, that no matter how detailed the foregoing appears in the text, the invention may be practiced in many ways, and is therefore not limited to the embodiments disclosed. It should be noted that the use of particular terminology when describing certain features or aspects of the invention should not be taken to imply that the terminology is being re-defined herein to be restricted to include any specific characteristics of the features or aspects of the invention with which that terminology is associated.

CLAIMS:

1. A tip electrode (20) for a pacing, sensing and/or communicating device, the tip electrode (20) being configured to be mounted on a distal end of the device and comprising a distal surface with two or more axially protruding tissue contact areas (22, 24) with different axial levels at the distal end of the tip electrode (20).

2. The tip electrode (20) of claim 1, wherein the protruding tissue contact areas (22, 24) are configured as closed or open circular or polygonal rings or ring sections or as protrusion patterns arranged in a closed or open circular or polygonal ring or ring section shape.

3. The tip electrode (20) of claim 1 or 2, comprising a cylindrical body (26), wherein the axially protruding tissue contact areas (22, 24) comprise an outer ring (22) and an inner ring (24).

4. The tip electrode (20) of claim 3, wherein the inner ring (24) is formed on top of the outer ring (22) in the distal direction.

5. The tip electrode (20) of claim 3 or 4, wherein the cylindrical body (26) is coated at the protruding contact areas (22, 24) with a contact-improving coating, in particular a TiN coating.

6. The tip electrode (20) of any one of the preceding claims, wherein the protruding tissue contact areas (22, 24) are arranged around a central hole of the tip electrode (20).

7. The tip electrode (20) of claim 6, wherein the central hole is at least partially filled with a steroid (44).

8. The tip electrode (20) of claim 7, further comprising a further steroid portion (46) placed around the protruding contact areas (22, 24).

9. A pacing, sensing and/or communicating device comprising a tip electrode (20) of any of the preceding claims.

10. The device of claim 9, further comprising a conical fixation helix (50), wherein a diameter of helical turns of the conical helix (50) increases in the distal direction to obtain a conical shape

11. The device of claim 10, wherein a largest diameter of the helical turns at the distal end of the conical helix (50) is configured to match with a diameter of a cylindrical housing (54) of the device.

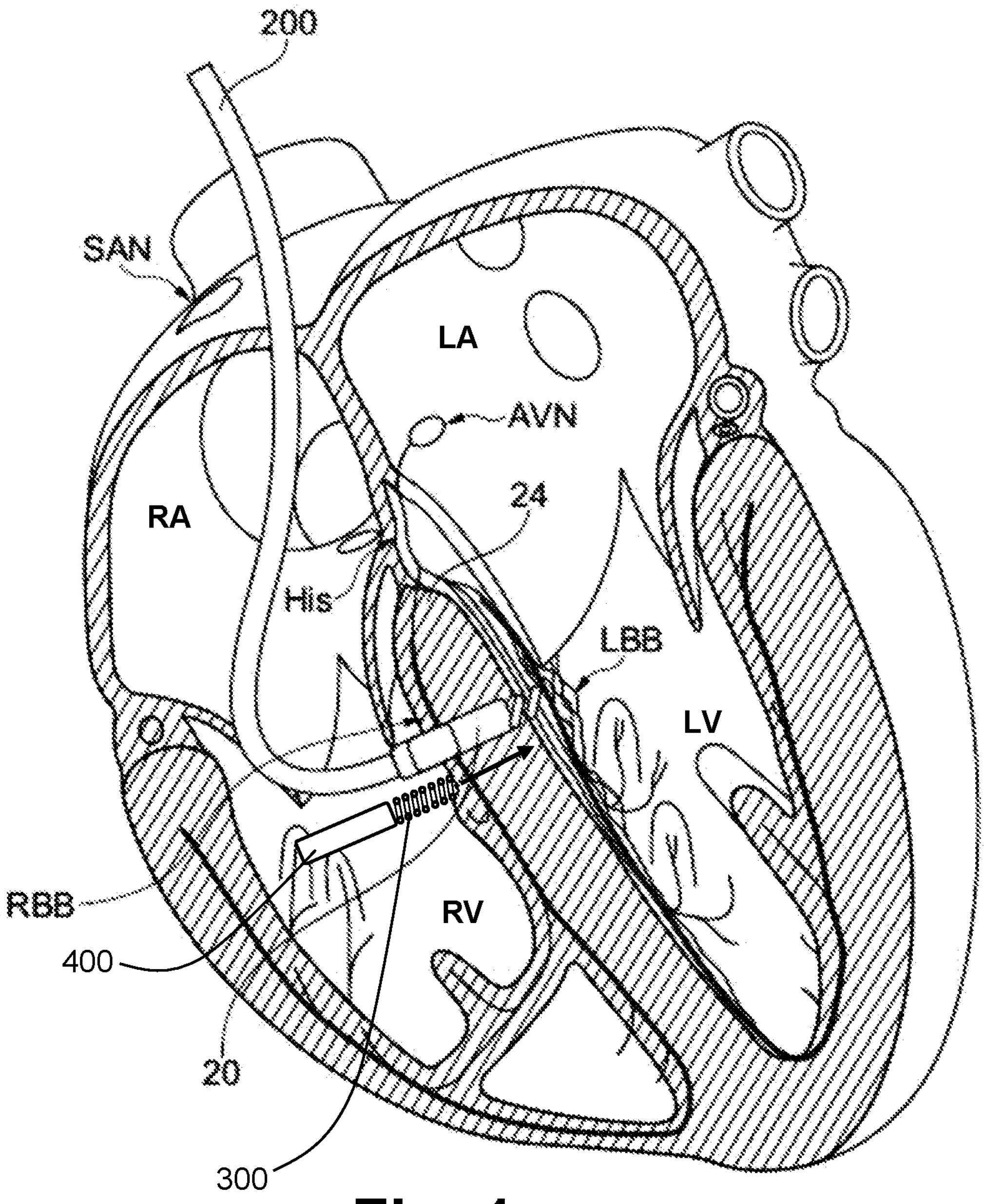

Fig. 1

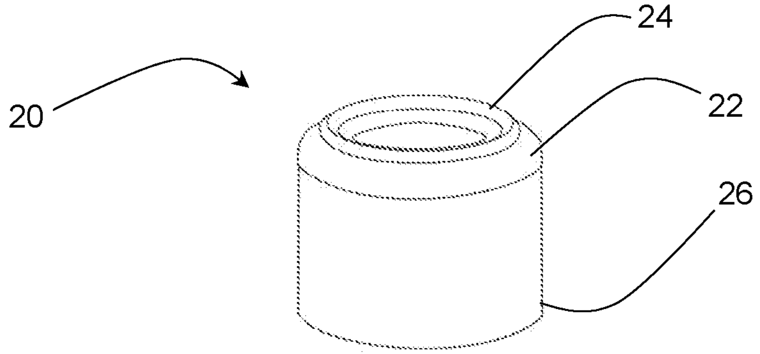

Fig. 2

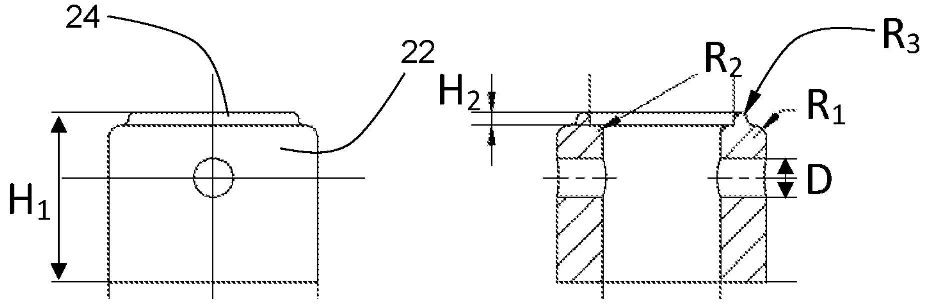

Fig. 3

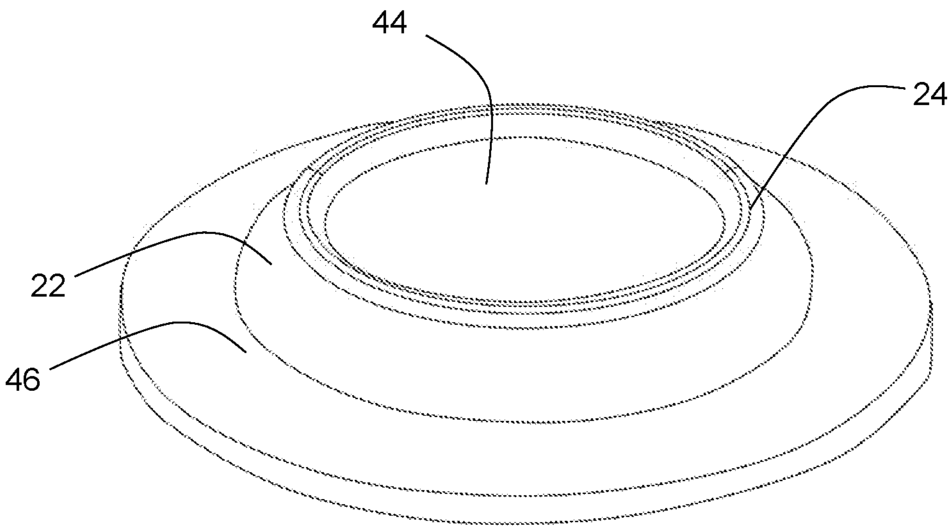

Fig. 4

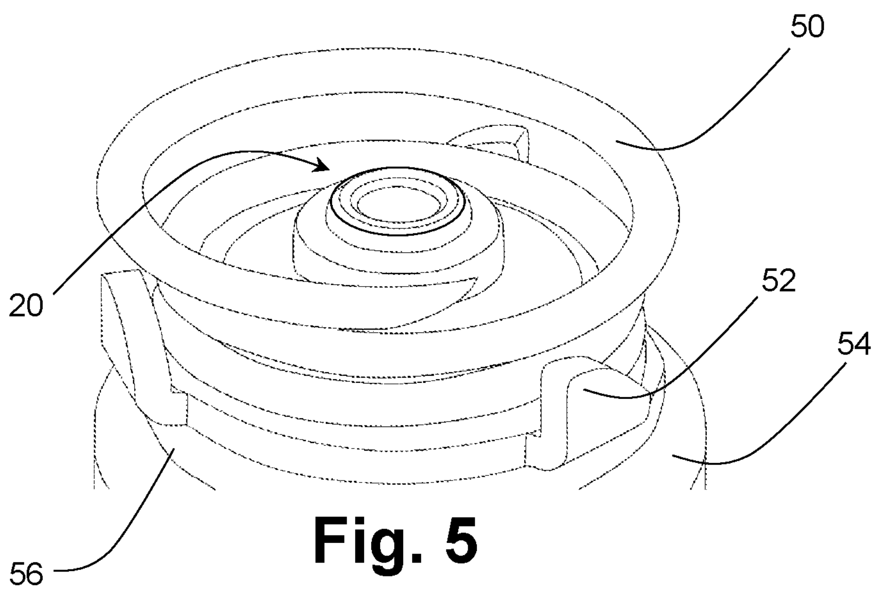

Fig. 5

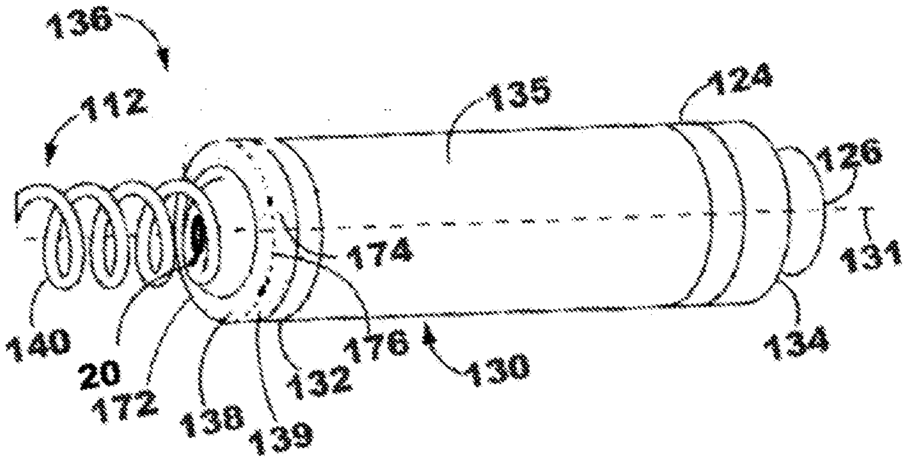

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2023/000769

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05 A61N1/375
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 2012/172892 A1 (GRUBAC VLADIMIR [US] ET AL) 5 July 2012 (2012-07-05)	1-4,6-9
Y	the whole document	5
A		10,11
Y	US 2017/136245 A1 (SCHIBLI STEFAN [DE] ET AL) 18 May 2017 (2017-05-18) abstract paragraph [0059] paragraph [0184] - paragraph [0196] figures 1-9	5
A	US 2023/201578 A1 (REGNIER WILLY [FR] ET AL) 29 June 2023 (2023-06-29) the whole document	1-11
A	US 2023/001215 A1 (YANG ZHONGPING C [US] ET AL) 5 January 2023 (2023-01-05) the whole document	1-11

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 April 2024	22/04/2024

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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