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(71) Applicant: **BIOTRONIK SE & CO. KG** [DE/DE]; Woermannkehre 1, 12359 Berlin (DE).

(72) Inventor: **HUEGERICH, Burkhard**; 4011 SE 27th Ave, Portland, Oregon 97202 (US).

(74) Agent: **BIOTRONIK CORPORATE SERVICES SE / ASSOCIATION NO. 1086**; Sieversufer 7-9, 12359 Berlin (DE).

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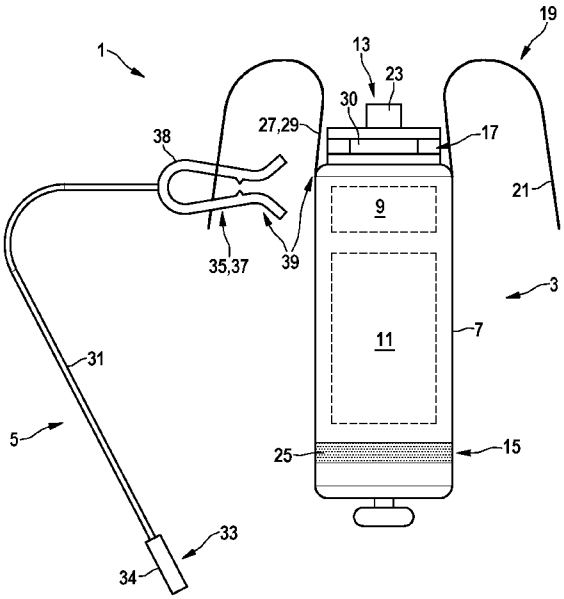


FIG. 1

(57) Abstract: An intracardiac pacemaker arrangement (1) is described to comprise an intracardiac pacemaker device (3) and a separable external lead arrangement (5). The pacemaker device comprises: a housing (7) to be implanted entirely within a ventricle of a heart, an electronic module (9) for detecting cardiac activity by sensing electric voltages within the heart and for generating pacing pulses taking into account the detected cardiac activity, an energy source (11) for supplying energy to the electronic module, a first electrode (13) at a first portion of the housing (7) for contacting cardiac tissue, a second electrode (15) at a second portion of the housing (7), a connector arrangement (17) comprising a mechanical connection structure (27) and an electrical energy transmitter (29). The mechanical connection structure is configured for releasably fixing a mechanical counterpart structure (35) to the intracardiac pacemaker device, the mechanical counterpart structure being comprised at the external lead arrangement. The electrical energy transmitter is configured for electrically releasably coupling to an electrical energy transmitter counterpart (37) for transmitting electric energy between the electrical energy transmitter and an electrical energy transmitter counterpart, the electrical energy transmitter counterpart being comprised at the external lead arrangement.

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INTRACARDIAC PACEMAKER DEVICE AND ARRANGEMENT WITH RELEASABLE EXTERNAL LEAD AND METHOD FOR IMPLANTING OR RETROFITTING SAME

The present invention relates to an intracardiac pacemaker device and an intracardiac pacemaker arrangement. Furthermore, the present invention relates to a method of implanting such intracardiac pacemaker arrangement and to a method for retrofitting an intracardiac pacemaker device of such intracardiac pacemaker arrangement.

A pacemaker is a device for controlling an abnormal heart rhythm of a patient. Generally, a pacemaker paces a cardiac activity by inducing electric voltages in the heart and thereby stimulating myocardial tissue. Implantable pacemakers may be implanted into the body of the patient.

Conventionally, a pacemaker housing may be implanted external to the heart and a lead may be implanted into the heart, one end of the lead being connected to an electronic module comprised in the pacemaker housing and an opposite end comprising a pacing electrode for applying electric pacing pulses to the myocardial tissue.

Modern miniaturized intracardiac pacemakers are configured for being implanted entirely directly within a cavity in the heart. For example, a housing of the intracardiac pacemaker may be implanted in a ventricle of the heart. Generally, such intracardiac pacemaker comprises a fixation mechanism for being fixed to myocardial tissue. Furthermore, the intracardiac pacemaker comprises an energy source such as a battery, an electronic module for generating pacing pulses and electrodes for electrically stimulating the myocardial tissue. Such intracardiac pacemaker is also referred to as implantable leadless pacemaker (iLP).

Generally, various types or modes of pacing a heart exist and are characterised with respect to a location of a cardiac stimulation, a location of sensing cardiac activity and an operation mode. The location of cardiac stimulation and the location of sensing cardiac activity may be in the atrium (A), in the ventricle or double (D), i.e. in both the atrium and the ventricle. The operation mode may be inhibition (I), triggering (T) or double (D), i.e. inhibition and triggering. Furthermore, special functions such as rate modulation (R) may be established.

Conventionally, most intracardiac pacemakers were configured for VVI operation mode, i.e. the housing was implanted into the ventricle and had electrodes for sensing electrical voltages in the ventricle and applying electrical pacing pulses to myocardial tissue at the ventricle.

However, for treating specific cardiac abnormalities, it may be beneficial to not only pace the ventricle but also pace the adjacent atrium. Therein, pacing the ventricle and pacing the atrium should be synchronised with each other and, preferably, should also take into account an intrinsic cardiac activity in each of the ventricle and the atrium. In a best case scenario, a DDD operation mode may be established.

Various approaches have been tested for fulfilling such requirements.

For example, additionally to a first intracardiac pacemaker implanted into the ventricle, a second intracardiac pacemaker may be implanted into the atrium. The first and second intracardiac pacemakers may communicate for example using wireless communication for synchronising their activities. However, the atrial heart chamber is smaller and more delicate walled than the ventricular heart chamber. Accordingly, implanting a separate pacemaker into the atrium may be difficult. Furthermore, establishing and maintaining a wireless communication between both pacemakers may be critical as such communication may for example be disturbed by external electromagnetic fields. Furthermore, implanting separate intracardiac pacemakers generally results in increased costs.

Another approach has been proposed by the present applicant in an earlier patent application US 2019/0240496 A1. Therein, an intracardiac pacemaker device is described, the device being specifically configured for VDD or VDDR pacing. Therein, the pacemaker device comprises a housing to be implanted within a ventricle and an elongated lead extension protruding from the housing. At least one electrode is arranged on the elongated lead extension. The lead extension may be arranged within the atrium adjacent to the ventricle for applying pacing pulses to myocardial tissue at such atrium. Features and characteristics described in US 2019/0240496 A1 may be applied or may be adopted in a similar manner to the approach described in the present application. Accordingly, the content of US 2019/0240496 A1 shall be incorporated herein by reference in its entirety.

However, it has been observed that an implantation procedure for implanting the intracardiac pacemaker device described in US 2019/0240496 A1 may be complex. Furthermore, it has been observed that explantation or replacement of such intracardiac pacemaker device at its end of life may be complex.

It is an object of the present invention to provide an intracardiac pacemaker device and an intracardiac pacemaker arrangement allowing reliable operation, simplifying an implantation procedure and/or reduced costs. Furthermore, it is an object of the present invention to provide a method of implanting such intracardiac pacemaker arrangement and a method for retrofitting an intracardiac pacemaker device of such intracardiac pacemaker arrangement in a simplified manner.

Such objects may be met with the subject-matter of the independent claims. Advantageous embodiments are defined in the dependent claims as well as in the corresponding specification and figures.

According to a first aspect of the present invention, an intracardiac pacemaker device is proposed. The device comprises (i) a housing being configured to be implanted entirely within a ventricle of a heart, (ii) an electronic module being configured for detecting cardiac activity by sensing electric voltages within the heart and for generating pacing pulses taking into account the detected cardiac activity, (iii) an energy source being

configured for supplying energy to the electronic module, (iv) a first electrode arranged at a first portion of the housing for contacting cardiac tissue upon the housing being implanted within the ventricle, (v) a second (additional) electrode arranged at a second portion of the housing and (vi) a connector arrangement comprising a mechanical connection structure and an electrical energy transmitter. The mechanical connection structure is configured for releasably fixing a mechanical counterpart structure to the intracardiac pacemaker device, the mechanical counterpart structure being comprised at an external lead arrangement. The electrical energy transmitter is configured for electrically releasably coupling to an electrical energy transmitter counterpart for transmitting electric energy between the electrical energy transmitter and an electrical energy transmitter counterpart, the electrical energy transmitter counterpart being comprised at the external lead arrangement.

For example, the external lead arrangement may be an atrial lead arrangement configured for an implantation into the atrium of a heart. An atrial lead arrangement configured for an implantation into the atrium of a heart would allow a synchronized pacing of the ventricle and the atrium. Preferably, it would also take into account an intrinsic cardiac activity in each of the ventricle and the atrium. In this embodiment, a DDD operation mode of the intracardiac pacemaker may be established.

According to a second aspect of the invention, an intracardiac pacemaker arrangement is described. The arrangement comprises the intracardiac pacemaker device according to an embodiment of the first aspect of the invention and an external lead arrangement, in particular an atrial lead arrangement configured for an implantation into the atrium of a heart. The external lead arrangement comprises an electrically conductive lead, the mechanical counterpart structure and the electrical energy transmitter counterpart. The mechanical counterpart structure is releasably fixed to the mechanical connection structure of the intracardiac pacemaker device. The electrical energy transmitter counterpart is releasably electrically coupled to the electrical energy transmitter of the intracardiac pacemaker device.

According to a third aspect of the invention, a method of implanting an intracardiac pacemaker arrangement according to an embodiment of the second aspect of the invention into a heart of a patient is described. The method comprises at least the following steps, preferably in the indicated order:

- implanting the housing of the intracardiac pacemaker device into a ventricle of the heart,
- arranging a portion of the external lead arrangement at another body portion such as in an atrium of the heart, and
- fixing the mechanical counterpart structure of the implanted external lead arrangement to the mechanical connection structure of the implanted intracardiac pacemaker device and electrically coupling the electrical energy transmitter counterpart of the implanted external lead arrangement to the electrical energy transmitter of the implanted intracardiac pacemaker device.

According to a fourth aspect of the invention, a method for retrofitting an intracardiac pacemaker device of an intracardiac pacemaker arrangement according to an embodiment of the second aspect of the invention is proposed, the pacemaker arrangement having its housing implanted into a ventricle of the heart and having its external lead arrangement partially arranged at another body portion such as in an atrium of the heart. The method comprises at least the following steps, preferably in the indicated order:

- disengaging the releasable mechanical fixation between the mechanical counterpart structure of the implanted external lead arrangement and the mechanical connection structure of the implanted intracardiac pacemaker device and releasing the electrically coupling between the electrical energy transmitter counterpart of the implanted the external lead arrangement and the electrical energy transmitter of the implanted intracardiac pacemaker device,
- optionally, explanting the intracardiac pacemaker device from the heart,
- implanting a replacement intracardiac pacemaker device into the ventricle of the heart, and
- fixing the mechanical counterpart structure of the implanted external lead arrangement to the mechanical connection structure of the implanted replacement intracardiac pacemaker device and electrically coupling the electrical energy transmitter counterpart of the

implanted external lead arrangement to the electrical energy transmitter of the implanted replacement intracardiac pacemaker device.

Ideas underlying embodiments of the present invention may be interpreted as being based, inter alia, on the following observations and recognitions.

Briefly summarised in a non-limiting manner, embodiments of the present invention relate to an intracardiac pacemaker arrangement in which an intracardiac pacemaker device may be implanted with its housing in a ventricle for pacing the ventricle, preferably by sensing and synchronised pacing cardiac activity at the ventricle. The pacemaker arrangement shall furthermore be configured for pacing, stimulating and/or sensing one or more other body portions such as the atrium adjacent to the ventricle, preferably by sensing and synchronised pacing cardiac activity at the atrium. For such purpose, the pacemaker arrangement shall additionally comprise an external lead arrangement with an electrically conductive lead which may be implanted such as to extend from the implanted housing of the intracardiac pacemaker device to the other body portion such as the atrium.

However, it has been found that implanting a pacemaker arrangement into a heart with a conductive lead fixedly mounted to the pacemaker housing is generally very complex. For example, a surgeon would first have to implant the housing into the ventricle, then grasp the attached external lead and finally transport an end of the external lead e.g. into the neighbouring atrium and preferably fix such end of the external lead to myocardial tissue of the atrium. The entire implantation procedure may become particularly complex upon the external lead being permanently coupled to the pacemaker housing and may disturb implantation or extraction efforts.

It is therefore suggested to provide the intracardiac pacemaker device with a connector arrangement which allows releasably attaching and detaching the external lead both in terms of mechanical fixation and in terms of electrical coupling. For such purpose, the connector arrangement comprises a mechanical connection structure which may releasably mechanically engage with a mechanical counterpart structure provided at the external lead arrangement. Furthermore, the connector arrangement comprises an electrical energy

transmitter which may releasably couple to an electrical energy transmitter counterpart provided at the external lead arrangement for transmitting electrical energy between both components. The external lead arrangement may be an atrial lead arrangement configured for an implantation into the atrium of a heart.

Having such releasable connector arrangement, an implantation procedure may be adapted such that, first, the housing of the intracardiac pacemaker is implanted into the ventricle and, independently, a portion of the external lead arrangement is arranged e.g. in the atrium of the heart. Subsequently, the external lead may be connected mechanically and electrically to the housing using the connector arrangement. Thereby, enabling implanting the pacemaker housing, on the one hand, and implanting the external lead, on the other hand, in two separate implantation steps may allow significantly simplifying the entire implantation procedure.

The above-described implantation sequence of the external lead could as well be performed with first connecting one end of the lead mechanically and electrically to the housing of the intracardiac pacemaker and subsequently establishing the location and connection of the other end of the lead to the distant location (e.g. the Atrium). The external lead may be an atrial lead configured for an implantation into the atrium of a heart.

Furthermore, due to the connector arrangement being releasable, the electrical and mechanical connection between the pacemaker housing and the external lead may be disconnected for example at an end of service of the intracardiac pacemaker device such that the pacemaker device may be explanted and replaced by a replacement pacemaker device while the external lead arrangement may remain implanted e.g. within the patient's heart, in particular in the atrium, and may then be re-used by connecting it to the replacement pacemaker device.

In the following, possible characteristics and advantages of embodiments of the present invention will be described in more detail.

The housing of the pacemaker device may have miniaturized dimensions such as to be, in an implantation procedure, transferred via vascular vessels into the ventricle of a patient's heart. The housing may be made with or may be coated with biocompatible material. For example, the housing may consist of metal such as titanium. The housing may have any geometry. For example, the housing may be cylindrical. The housing may accommodate components of the pacemaker device such as the electronic module, the energy source and other parts in a hermetically tight manner. A fixation arrangement may be provided at one end of the housing for fixing the housing to myocardial tissue. Such fixation arrangement may comprise a plurality of tines which may engage the myocardial tissue.

The electronic module may comprise a circuitry enabling sensing electric voltages resulting from cardiac activity. Furthermore, the circuitry may enable generating electric pacing pulses. Therein, the circuitry may generate the pacing pulses in a synchronised manner depending on the sensed cardiac activity. Preferably, the electronic module is electrically connected to at least three different electrodes comprised in the intracardiac pacemaker arrangement. Therein, at least one electrode may be provided at the external lead, i.e. external to the pacemaker housing, and the electronic module may be electrically connected to this external electrode via the connector arrangement of the pacemaker device. The electronic module may be energised by the energy source.

The energy source stores electrical energy. For example, the energy source may be a battery, a capacitor, a super-capacitor or a combination of such devices.

The first electrode may be provided at the pacemaker housing for example at a first position close to a first end of the housing. For example, the first electrode may be provided by a pin having a tip protruding from the pacemaker housing. The pin may extend through an opening (feedthrough) in the housing with one end of the pin being electrically connected to the electronic module and an opposing end of the pin forming the protruding tip for establishing a contact to cardiac tissue upon the housing being implanted in the ventricle. Preferably, the pin is electrically isolated with regards to the pacemaker housing.

The second electrode may be provided at the pacemaker housing for example at a second position distant to the position of the first electrode. For example, such second position may be at or close to a second end of the housing opposing the housing's first end. The second electrode may be arranged at the pacemaker housing or may be integrated into the pacemaker housing. For example, the second electrode may be a ring electrode. The second electrode may be arranged such that, when the pacemaker device is implanted in the ventricle, the second electrode floats in blood within the ventricle cavity without generally being in direct contact to any ventricle wall.

According to an embodiment of the intracardiac pacemaker arrangement, the external lead arrangement comprises an electrode for at least one of sensing electric sensing voltages and applying electric pacing voltages. The external lead arrangement may be an atrial lead arrangement configured for an implantation into the atrium of a heart and may comprise an electrode for at least one of sensing electric sensing voltages in atrium and applying electric pacing voltages to the atrium.

Such electrode may be referred to herein as third electrode. The third electrode may be a ring electrode, a plate electrode or another kind of electrode attached to the external lead. The third electrode may be arranged at or close to a free end of the external lead, such free end being opposite to an end of the external lead at the mechanical counterpart structure and the electrical energy transmitter counterpart. Upon being implanted, the external lead arrangement may be arranged with its free end and the third electrode being positioned at a location which is different from the internal volume of the ventricle. For example, the external lead arrangement may be arranged with its free end and the third electrode being positioned within the atrium. Preferably, the third electrode may be arranged at or close to myocardial tissue of the atrium. Accordingly, the third electrode may sense electric potentials at the atrium and/or may apply electric pacing voltages to atrial tissue.

According to an embodiment, the electronic module is electrically coupled to the first and second electrodes and the electronic module is configured to sense first electric sensing voltages between the first and second electrodes. Furthermore, the electronic module is electrically coupled to the electrical energy transmitter and the electronic module is

configured to sense second electric sensing voltages between the electrical energy transmitter and at least one of the first and second electrodes. Therein, the electronic module is configured for generating pacing pulses taking into account the sensed first and second electric sensing voltages.

In other words, the electronic module may electrically sense cardiac activity in the ventricle using its first and second electrodes. Furthermore, upon the external lead being electrically coupled via its energy transmitter counterpart to the electrical energy transmitter of the pacemaker device, the electronic module may electrically sense e.g. cardiac activity in the atrium using its first and/or second electrodes and additionally using an electrode provided at the external lead being positioned within the atrium. Accordingly, the pacemaker arrangement may be configured for sensing cardiac activity in a double (D) mode both with regards to the ventricle and to the atrium.

According to an embodiment, the electronic module is electrically coupled to the first and second electrodes and the electronic module is configured to apply first electric pacing voltages between the first and second electrodes. Furthermore, the electronic module is electrically coupled to the electrical energy transmitter and the electronic module is configured to apply second electric pacing voltages between the electrical energy transmitter and at least one of the first and second electrodes.

Expressed differently, the electronic module may apply first electric pacing voltages to the first and second electrodes for pacing myocardial tissue at the ventricle. Furthermore, upon the external lead being electrically coupled via its energy transmitter counterpart to the electrical energy transmitter of the pacemaker device, the electronic module may apply second electric pacing voltages between the third electrode provided at the external lead e.g. in the atrium, on the one hand, and the first or second electrode, on the other hand, thereby e.g. pacing myocardial tissue at the atrium. Accordingly, the pacemaker arrangement may be configured for pacing cardiac activity in a double (D) mode both in the ventricle and in the atrium.

Furthermore, the electronic module may be configured for operating in a double (D) operation mode including inhibition operation as well as triggering operation.

Overall, the proposed intracardiac pacemaker arrangement with the external lead arrangement being connected to the connector arrangement of the pacemaker device may therefore be configured for DDD operation.

According to an embodiment, the electrical energy transmitter comprises a contact structure being accessible from external to the housing for establishing an electric ohmic contact with the electrical energy transmitter counterpart comprised at the external lead arrangement. Accordingly, in the intracardiac pacemaker arrangement, the electrical energy transmitter counterpart may be electrically coupled to the electrical energy transmitter via the electric ohmic contact.

In other words, the electrical energy transmitter at the pacemaker device and its counterpart at the external lead arrangement may be configured for coming into an electric ohmic contact upon being engaged with each other. In such electric ohmic contact, an electrically conductive member at the energy transmitter comes into direct mechanical contact with an electrically conductive member at the energy transmitter counterpart such that an electric current may flow between the transmitter and its transmitter counterpart. Due to such ohmic contact, an electric potential sensed at the electrode at the external lead may be transmitted via the connection arrangement to the electronic module of the pacemaker device and/or electric pacing pulses may be transmitted from the electronic module via the connection arrangement to the electrode at the external lead.

According to an embodiment, the electrical energy transmitter comprises an electric inductor for establishing an electric inductive contact with the electrical energy transmitter counterpart comprised at the external lead arrangement. Accordingly, in the intracardiac pacemaker arrangement, the electrical energy transmitter counterpart may be electrically coupled to the electrical energy transmitter via the electric inductive contact.

Expressed differently, the electrical energy transmitter at the pacemaker device may comprise an inductor such as a coil which is connected to the electronic module. On the other side, the electrical energy transmitter counterpart at the external lead arrangement may comprise another inductor such as another coil which is connected to the electrode at the external lead. Upon being electrically energised, such inductor generates an electromagnetic field. Such electromagnetic field induces a voltage in the other inductor. Accordingly, an inductive contact is generated between the energy transmitter and the energy transmitter counterpart. Such inductive contact does typically not require any mechanical contact between electrical conductors, but these conductors only need to be in close proximity such that their electromagnetic fields overlap. Accordingly, the electrical conductors in the transmitter and its counterpart may be electrically isolated from each other and/or from an environment. Therein, an isolation may also protect the conductors e.g. against direct contact with blood or tissue and/ or may serve as corrosion protection.

According to an embodiment, the external lead arrangement of the intracardiac pacemaker arrangement comprises an attachment structure configured for being attached to cardiac tissue. In particular, the external lead arrangement may be an atrial lead arrangement configured for an implantation into the atrium of a heart and comprising an attachment structure configured for being attached to atrial tissue. Accordingly, an embodiment of the methods of implanting the pacemaker arrangement further comprises attaching the attachment structure to cardiac tissue, in particular to atrial tissue.

In other words, the external lead arrangement may be implemented for forming an atrial lead arrangement and thereby may be adapted such as to be fixed to cardiac tissue in the atrium. Preferably, the attachment structure is provided at or close to the third electrode such that the electrode may be attached to atrial tissue such as to be in electrical and/or mechanical contact to the myocardial tissue. The attachment structure may comprise one or more tines to be engaged with the atrial tissue. Using the attachment structure, the external lead arrangement may be implanted into the atrium and securely held at the external wall before, at a later stage, its mechanical counterpart structure and its electrical energy transmitter counterpart are connected to the connector arrangement of the pacemaker

device.

According to an embodiment of the intracardiac pacemaker arrangement, the mechanical counterpart structure is releasably fixed to the mechanical connection structure via a snap-fit connection mechanism.

Generally, a snap-fit connection mechanism enables a reliable mechanical interconnection of two counterparts while also enabling easily engaging and, potentially, disengaging the interconnection. Typically, the snap-fit connection comprises at least one counterpart being elastically deformable during a connecting procedure. Accordingly, while the two counterparts are displaced in an engagement direction with respect to each other in a connecting procedure, such elastic counterpart temporarily deforms and then again relaxes upon achieving a final connection configuration. In the final connection configuration, the counterparts are reliably engaged with each other. However, upon applying sufficient forces in a direction against the engagement direction, the engagement between the counterparts may be reversibly released.

In many snap-fit connections, the two counterparts and their mechanical characteristics are adapted such that forces required for engaging the connection between the counterparts are lower than forces required for releasing the connection. Accordingly, in the pacemaker arrangement proposed herein, the external lead may be easily mechanically connected via its mechanical counterpart structure to the mechanical connection structure at the pacemaker device in a snap-fit manner. This may simplify an assembly procedure for interconnecting the external lead to the pacemaker device upon both components having been implanted. Nevertheless, both components are reliably coupled with each other and, while disengagement may be in principle possible, significant forces may be required to reversibly release the interconnection between both components.

The snap-fit connection may be configured such that an engagement between both components may be achieved upon linearly displacing the components relative to each other. Alternatively, the snap-fit connection may be configured such that both components may engage with each other by rotating the components relative to each other. Both, the

linear engagement motion as well as the rotating engagement motion are relatively simple motions to be applied to the interconnecting counterparts during an implantation procedure.

According to embodiments of the intracardiac pacemaker device and/or of the intracardiac pacemaker arrangement, at least one of the following conditions may apply:

(i) The mechanical connection structure has a non-circular outer contour. In other words, a cross-section of the mechanical connection structure may be other than rotationally symmetric. Particularly, the mechanical connection structure may have an elongate contour. For example, the outer contour of the mechanical connection structure may be oval.

(ii) The mechanical counterpart structure has a non-circular inner contour. In other words, a cross-section of the mechanical counterpart structure may be other than rotationally symmetric. Particularly, the mechanical counterpart structure may have an elongate contour. For example, the outer contour of the mechanical counterpart structure may be oval.

(iii) The mechanical connection structure has an outer contour being complementary to an inner contour of the mechanical counterpart structure. Accordingly, when being fixed to each other, the inner contour of the mechanical counterpart structure may softly abut to the outer contour of the mechanical connection structure. Excessive mechanical stress between both structures may be prevented.

Particularly when both structures have a non-circular contour, an orientation preference may be established between both structures upon the structures being fixed to each other. In other words, due to their for example elongate contours, the mechanical connection structure and the mechanical counterpart structure may be guided into an intended position and/or orientation relative to each other upon being mechanically connected to each other, e.g. during a snap-fit procedure.

(iv) The mechanical connection structure comprises a contact portion and a non-contact portion, wherein the contact portion is electrically conductive and extends along a first portion of a circumference of the mechanical connection structure, whereas the non-contact portion is electrically isolating and extends along a second portion of the circumference of the mechanical connection structure, the second portion being distinct from first portion of a circumference of the mechanical connection structure. Expressed differently, only a partial area of an outer circumference at the mechanical connection structure may be established with an electrically conductive material, whereas adjacent portions of the outer circumference are established with an electrically isolating material. Due to limiting the exposed contact portion to a partial area of the outer circumference, an unintended electrical connection to components other than the mechanical counterpart structure or e.g. to neighbouring tissue or body fluids may be prevented or limited. As a result, for example contamination of electrical signals transmitted between the pacemaker device and the external lead arrangement may be prevented.

(v) The mechanical counterpart structure comprises a contact portion and a non-contact portion, wherein the contact portion is electrically conductive and extends along a first portion of a circumference of the mechanical counterpart structure, whereas the non-contact portion is electrically isolating and extends along a second portion of the circumference of the mechanical counterpart structure, the second portion being distinct from first portion of a circumference of the mechanical connection structure. Expressed differently, only a partial area of an inner circumference at the mechanical counterpart structure may be established with an electrically conductive material whereas adjacent portions of the inner circumference are established with an electrically isolating material. Due to limiting the exposed contact portion to a partial area of the inner circumference, an unintended electrical connection to components other than the mechanical connection structure or e.g. to neighbouring tissue or body fluids may be prevented or limited. As a result, for example contamination of electrical signals transmitted between the pacemaker device and the external lead arrangement may be prevented.

(vi) The mechanical connection structure and the mechanical counterpart structure each comprise an electrically conductive contact portion and an electrically isolating non-

contact portion, wherein the mechanical connection structure and the mechanical counterpart structure are configured such that their respective contact portions come into physical connection upon the mechanical counterpart structure being releasably fixed to the mechanical connection structure. In other words, by suitably implementing and arranging the contact portions at the mechanical connection structure, on the one side, and at the mechanical counterpart structure, on the other side, both structures may be specifically configured such that, upon being fixed to each other, they come into physical contact exclusively or mainly at their respective contact portions, thereby establishing an electrical connection between both components, whereas outside such contact portions, each of the connection structure and the counterpart structure is protected by its respective electrically isolating non-contact portion. As a result, for example contamination of electrical signals transmitted between the pacemaker device and the external lead arrangement may be prevented.

For implanting the intracardiac pacemaker arrangement described herein with a method according to an embodiment of the third aspect of the invention, first implantation steps include implanting the housing of the pacemaker device into the ventricle of the heart and arranging a portion of the external lead arrangement at another body portion such as in the atrium of the heart. Therein, the pacemaker housing may be implanted without the external lead being attached thereto, thereby simplifying the implantation procedure. Similarly and in a separate step, the external lead arrangement may be implanted in a simple manner without the pacemaker housing being attached thereto. In principle, the proposed intracardiac pacemaker device may be implanted in a similar manner as conventional intracardiac pacemaker devices by transferring the device into the ventricle heart chamber and fixing it to the ventricle wall using its fixation mechanism including e.g. several tines. Similarly, the external lead arrangement may be implanted e.g. by transferring it into the heart with its electrode being arranged in the atrial heart chamber while an opposing end of the external lead extending into the ventricle. Minimally invasive surgical procedures as well as monitoring techniques such as ultrasonic monitoring and/or X-ray monitoring may be applied in the implantation procedures. After such first implantation steps have been completed, the implanted external lead arrangement may be fixed with its mechanical counterpart structure to the mechanical connection structure of the implanted intracardiac

pacemaker device. Simultaneously, the external lead arrangement may be electrically connected to the pacemaker device by electrically coupling its electrical energy transmitter counterpart to the electrical energy transmitter of the pacemaker device. Also this procedure may be implemented using minimally invasive techniques and/or monitoring techniques.

The releasable character of the connection between the external lead arrangement and the pacemaker device may not only be beneficial during implantation of the intracardiac pacemaker arrangement. For example, such releasable connection may be used upon any defects occurring at the pacemaker device or upon the pacemaker device reaching its end of service life for example due to an empty energy source.

In such case, the pacemaker device of the implanted pacemaker arrangement may be replaced in a method according to an embodiment of the fourth aspect of the invention. Therein, the releasable mechanical and electrical interconnection between the external lead arrangement and the pacemaker device may be disengaged in a surgical step. Upon having the external lead separated from the pacemaker device, the pacemaker device may be explanted, i.e. its fixation in the ventricle may be released and the pacemaker housing may be removed from the heart in a surgical procedure. In cases where such explantation of the pacemaker may not be completed for example due to the pacemaker being excessively ingrown or incorporated into cardiac tissue, the old pacemaker may remain within the ventricle and may be deactivated. Generally, the external lead arrangement does not have to be replaced and, as it is released from the pacemaker device, may remain fixed e.g. in the atrium during the pacemaker device being replaced. Particularly, there may be no need to disengage the fixation of the external lead arrangement to the atrial wall, which may be beneficial as such disengagement procedure typically may be complex due to the limited space in the atrium and/or due to the atrial wall be delicate. Subsequently, a new pacemaker device may be implanted into the ventricle and fixed to the ventricle wall. Finally, the external lead arrangement may be connected to the newly implanted replacement pacemaker device using the releasable connector arrangement.

It shall be noted that possible features and advantages of embodiments of the invention are described herein with respect to various embodiments of an intracardiac pacemaker device or arrangement as well as with respect to methods for implanting or retrofitting same. One skilled in the art will recognize that the features may be suitably transferred from one embodiment to another and features may be modified, adapted, combined and/or replaced, etc. in order to come to further embodiments of the invention.

In the following, advantageous embodiments of the invention will be described with reference to the enclosed drawings. However, neither the drawings nor the description shall be interpreted as limiting the invention.

Fig. 1 shows an intracardiac pacemaker arrangement according to an embodiment of the present invention.

Fig. 2 shows an intracardiac pacemaker arrangement according to another embodiment of the present invention.

Fig. 3 shows details of a mechanical connection structure at an intracardiac pacemaker according to an embodiment of the present invention.

Fig. 4 shows details of a mechanical counterpart structure at an external lead arrangement of an intracardiac pacemaker arrangement according to an embodiment of the present invention.

The figures are only schematic and not to scale. Same reference signs refer to same or similar features.

Fig. 1 shows an intracardiac pacemaker arrangement 1 including an intracardiac pacemaker device 3 and a separable external lead arrangement 5.

The pacemaker device 3 comprises a housing 7, an electronic module 9, an energy source 11, a first electrode 13, a second electrode 15, a connector arrangement 17 and a fixation arrangement 19.

The housing 7 has a cylindrical shape and is made of biocompatible material such as titanium. The housing 7 is miniaturized such as to completely fit inside a ventricle. The fixation arrangement 19 comprises several deployable tines 21 located close to a front end face of the housing 7. The first electrode 13 comprises a pin 23 of electrically conductive material, the pin 23 extending through an opening in the front end face of the housing 7 such as to protrude from this front end face. Generally, the first electrode 13 is electrically isolated against the housing 7. The second electrode 15 is arranged distant to the first electrode 13 close to a rear end face of the housing 7. In the example shown, the second electrode 15 is provided with a ring electrode 25. Such ring electrode 25 extends at or close to a circumference of the cylindrical housing 7 but, in general, is electrically isolated against the housing 7.

Inside the housing 7, the electronic module 9 is electrically connected to the first and second electrodes 13, 15. The electronic module 9 is configured for sensing first electric sensing voltages between the first and second electrodes 13, 15 and for applying first electric pacing voltages between the first and second electrodes 13, 15 for pacing cardiac activity in the ventricle in a synchronized manner.

The connector arrangement 17 comprises a mechanical connection structure 27 and an electrical energy transmitter 29. The electrical energy transmitter 29 is electrically connected to the electronic module 9. In the example shown in figure 1, both, the connection structure 27 and the energy transmitter 29 are implemented with a same contact structure 30 such as a ring made of electrically conductive material such as metal. Generally, such contact structure 30 is electrically isolated against the housing 7 as well as against the pin 23 forming the first electrode 13.

The external lead arrangement 5 comprises an electrically conductive lead 31, a third electrode 33 at a distal end of the lead 31 and, at a proximal end of the lead 31, a

mechanical counterpart structure 35 as well as an electrical energy transmitter counterpart 37. The electrode 33 includes an attachment structure 34 for attachment to another body portion such as an atrial wall. In the example shown in figure 1, both, the mechanical counterpart structure 35 and the electrical energy transmitter counterpart 37 are implemented with a same physical structure such as a clipping structure 38 or clamping structure made of electrically conductive material such as metal. The lead 31 generally has a sufficient length such as to extend from the housing 7 implanted in the ventricle to the other body portion such as to the atrium such that the third electrode 33 may be arranged at or fixed to a wall of the atrium.

The mechanical connection structure 27 of the connector arrangement 17 at the pacemaker device 3 and the mechanical counterpart structure 35 at the external lead arrangement 5 are configured to cooperate and engage with each other such as to generate a loadable and reliable, but releasable, mechanical connection between the external lead arrangement 5 and the pacemaker device 3. Preferably, the clipping structure 38 of the mechanical counterpart structure 35 may form a snap-fit connection mechanism 39 when cooperating with the ring of the contact structure 30 of the mechanical connection structure 27.

Furthermore, the electrical energy transmitter 29 of the connector arrangement 17 at the pacemaker device 3 and the electrical energy transmitter counterpart 37 at the external lead arrangement 5 are configured to cooperate with each other such as to electrically couple both components in a releasable manner. Therein, upon the clipping structure 38 of the mechanical counterpart structure 35 engaging with the ring of the contact structure 30 of the mechanical connection structure 27, an electric ohmic contact may be established between the electrical energy transmitter 29 at the pacemaker device 3 and the electrical energy transmitter counterpart 37 at the external lead arrangement 5.

The electronic module 9 is also electrically connected to the electrical energy transmitter 29 at the connector arrangement 17. Accordingly, due to the electrical energy transmitter counterpart 37 being electrically connected to such electrical energy transmitter 29, the electronic module 9 is electrically connected to the third electrode upon the external lead arrangement 5 being coupled with the intracardiac pacemaker device 3. The electronic

module 9 is configured for sensing second electric sensing voltages between the third electrode 33 and at least one of the first and second electrodes 13, 15 and for applying a second pacing voltages between the third electrode 33 and at least one of the first and second electrodes 13, 15. Accordingly, using the third electrode 33 arranged in the atrium, the intracardiac pacemaker arrangement 1 may pace a cardiac activity in the atrium in a synchronized manner.

Accordingly, upon the external lead arrangement 5 being releasably connected to the pacemaker device 3 via the connector arrangement 17, the entire intracardiac pacemaker arrangement 1 may operate in a DDD operation mode.

Fig. 2 shows an alternative embodiment of an intracardiac pacemaker arrangement 1. While many components and characteristics of such alternative embodiment may be same or similar to the embodiment shown in figure 1, this alternative intracardiac pacemaker arrangement 1 is established with a different connector arrangement 17 at the pacemaker device 3 and, accordingly, different counterparts at the external lead arrangement 5.

Particularly, the connector arrangement 17 is not configured for establishing an electric ohmic contact but for establishing an electric inductive contact between the electrical energy transmitter 29 at the pacemaker device 3 and the electrical energy transmitter counterpart 37 at the external lead arrangement 5.

For such purpose, the electrical energy transmitter 29 comprises a first inductor 41 formed by a first coil 42 and the electrical energy transmitter counterpart 37 comprises a second inductor 43 formed by a second coil 44. The first coil 42 is arranged at or adjacent to the housing 7. The second coil 44 is dimensioned such that it may be slid in an axial direction (as indicated with the arrow 45) over the housing 7 such as to come into close proximity with the first coil 42. Accordingly, upon one of the first and second coils 42, 44 being electrically energised, electric energy may be transmitted to the other coil 44, 42 via electrical induction. Therein, the coils 42, 44 or wires forming such coils 42, 44 may be electrically isolated such that any ohmic contact between the coils or between a coil 42, 44

and an environment may be prevented.

In order to mechanically fix the second coil 44 of the second inductor 43 at the housing 7, a pair of protrusions 47 is provided at the housing 7. Such protrusions 47 may serve as mechanical connection structure 27. The protrusions 47 may have a ring-shape and may enclose the cylindrical housing 7. The protrusions 47 may have a slanted surface. For mechanically connecting the mechanical counterpart structure 35 formed by the cylindrical second coil 44 to the housing 7, the coil 44 me be slid in the axial direction 45 until reaching a first one of the pair of protrusions 47. Upon further pushing the coil 44 in the axial direction 45, the coil 44 and/or the protrusions 47 may temporarily slightly deform and the coil 44 may slide further in the axial direction 45 until being interposed between the pair of protrusions 47. Accordingly, the entire mechanism serves as a snap-fit connection mechanism for fixing the coil 44 at a desired position at the housing 7.

Fig. 3 shows a perspective partial view onto a top section of an intracardiac pacemaker device 3 including a specific implementation of a mechanical connection structure 27. Fig. 4 visualises an external lead arrangement 5 including a specific implementation of a mechanical counterpart structure 35. The mechanical connection structure 27 and the mechanical counterpart structure 35 are specifically configured for establishing an optimised electric and mechanic connection between the intracardiac pacemaker device 3, on the one side, and the external lead arrangement 5, on the other side.

Particularly, in the approach shown in Fig. 1, the mechanical connection structure 27 is established with a cylindrical shape, i.e. with a circular outer contour. In contrast hereto, the mechanical connection structure 27 of the embodiment shown in Fig. 3 has a non-circular outer contour such as an elongate and/or oval outer contour or shape. Furthermore, the mechanical counterpart structure 35 shown in Fig. 4 may also have a non-circular contour at its inner surface. Particularly, the inner contour of the mechanical counterpart structure 35 may be adapted to comply or to be complementary with the elongate outer contour of the mechanical connection structure 27. Due to such elongate contour, the mechanical connection structure 27 may induce a preferred connection orientation upon the mechanical counterpart structure 35 being connected thereto, for example in a snap-in

or clip-on procedure. In other words, when connecting the external lead arrangement 5 to the intracardiac pacemaker device 3 by pushing the mechanical counterpart structure 35 onto the mechanical connection structure 27, the mechanical counterpart structure 35 is guided into an intended orientation and/or position due to the non-circular interface between the respective inner and outer contours of both structures 27, 35.

Furthermore, the mechanical connection structure 27 comprises a contact portion 49 and a non-contact portion 51. At the contact portion 49, an electrically conductive material is exposed such as to be accessible, i.e. to be mechanically and electrically contacted from outside. However, the contact portion 49 does not extend along the entire circumference of the mechanical connection structure 27. Instead, an extension of this contact portion 49 is limited to a first portion 53 of such circumference. For example, such first portion 53 may extend along 70% or less, preferably 50% or less or even 30% or less of the entire circumference. Another second portion 55 of the circumference of the mechanical connection structure 27 is provided or covered with an electrically isolating material, thereby forming the non-contact portion 51.

In the example shown in Fig. 3, part of the non-contact portion 51 is formed by insulating humps 57. Such humps 57 may extend and/or protrude in areas next to the contact portion 49 while leaving the contact portion 49 exposed. Accordingly, during for example a snap-in procedure, the humps 57 may guide the mechanical counterpart structure 35 into a suitable mechanic and electric contact to the contact portion 49 of the mechanical connection structure 27. In other words, the humps 57 may be specifically shaped such as to help guiding the mechanical counterpart structure 35 into an intended location and/or orientation upon being clipped on the mechanical connection structure 27.

For example, such humps 57 may comprise or may consist of electrically insulating material such as plastics material. Due to its electrically isolating characteristics, the non-contact portion 51 formed by the humps 57 may prevent or limit unintended electrical contact between the mechanical connection structure 27 and any surrounding medium or component other than the mechanical counterpart structure 35. Accordingly, an electrical signal transmission between the connection structure 27 and the counterpart structure 35

may be protected against environmental influences such as contamination by electric fields.

Similarly, the mechanical counterpart structure 35 comprises a contact portion 59 and a non-contact portion 61. Also in this case, the contact portion 59 is made of or covered with electrically conductive material being exposed for example at an inner surface of the mechanical counterpart structure 35. Such contact portions 59 do not extend along the entire circumference of the mechanical counterpart structure 35 (wherein it is to be mentioned that this circumference does not necessarily need to be closed or ring-shaped), but extend only along a first portion 63 of such circumference. A neighbouring second portion 65 of the circumference is formed or covered by electrically isolating material, thereby implementing the non-contact portion 61. Again, by limiting the contact portion 59 to a locally limited first portion 63 of the circumference of the mechanical counterpart structure 35, unintended electrical contact to a medium or component other than the mechanical connection structure 27 may be prevented upon both structures 27, 35 being fixed to each other.

Therein, the contact portion 49 of the mechanical connection structure 27 and the contact portion 59 of the mechanical counterpart structure 35 are arranged and formed such that both connection portions 49, 59 come into physical connection upon the mechanical counterpart structure 35 being releasably fixed to the mechanical connection structure 27, whereas all or most of the neighbouring portions of both structures 27, 35 are formed by non-contact portions 51, 61.

Finally, some characteristics of embodiments of the pacemaker arrangement described herein will be explained with a slightly different wording which shall not limit the scope of the invention:

Leadless pacemakers are shown in the Figures. The devices have a cathode for pacing and sensing of ventricular signals (“Ventricular lead tip”). The devices have an anode which is formed by a high surface area ring at the opposite end of the device (“Ring electrode”). An additional cathode for atrial connectivity is added to the devices to accomplish a direct

connectivity to the atrial heart chamber ("Atrial lead connection"). The atrial cathode may be either available as a ring electrode on the elongated body of the device (as depicted in Figure 2) or as an additional electrode in the header portion of the device (as depicted in Figure 1).

The atrial lead connection can be established after the initial ventricular based ILP body was implanted. To secure the mechanical atrial lead connection/position to the ventricular side implanted ILP body, either a simple mechanical connection (friction) is established to the electrically exposed atrial cathode, by a magnetic connection or a combination of both to support the snap-in action of the electrode end.

The inventive solution allows for ILP devices to only be implanted in the ventricular heart chamber but providing additionally direct connectivity to the atrial heart chamber to implement DDD pacemaker functionality. Deploying pre-attached atrial leads to a ventricular based ILP body faces very complex requirements to the deployment tool. By providing two separate implantable items (the ventricular heart chamber located ILP body plus the additional short atrial lead) and providing a mean to connect these two devices after implantation reduces the complexity of the implantation itself as well as the complexity of the ILP based DDD solution. Additionally, connecting single leads into the atrial chamber is a known and proven technology which reduces unknown risks associated with the implantation of a full ILP device body into the atrial heart chamber.

In a simple embodiment as shown in Fig. 1, a circular device electrode may expose the ILP electrical receiver amplifier for the external signal to electrical fields close to the device body. This design may result in a contaminated external signal. Additionally, the push-on mechanical force to clip on the lead might be unnecessary high.

A further developed embodiment as shown in Figs. 3 and 4 may provide for an improved connection between the clip-on of the additional electrode and the ILP body located receptable for that external feature (e.g. an atrial lead).

To secure the mechanical external lead connection/position to the ventricular side implanted ILP body, a simple mechanical connection (direct contact) is established to the electrically exposed atrial cathode. To prevent the external electrical signal to be contaminated by the electric field close to the body of the device, the electrode connection is shaped to minimize possible electrical connections with the immediate area around the second electrode. Following properties of the proposed solution are intended to possibly provide this outcome:

1. The receiver electrode part of the device is not shaped circular but elongated (oval).
2. The receiver electrode of the device is not conductive all around the circumference but only on a limited section in the middle of the elongated side of the oval shape.
3. The clip-on part of the atrial lead is only conductive in the middle of the inside of the clip in the area where the clip will have contact with the conductive section of the related reception area of the device.
4. The elongated shape of the device area with the external connectivity electrode ensures a mechanical preference for the clip-on part of the external electrode to fit correctly alongside the elongated electrode area of the device.
5. The insulated humps surrounding the clip reception area above and below the contact patch further helps guiding the clip onto the designated place.
6. The clip-on part of the external lead is shaped so that the mechanical connection provides a close fit to the elongated shape of the device electrode area.
7. The limited conductive area of the clip-on part of the external lead as well as the related device electrode receiving area provide an electrical decoupling from the surrounding area of the device.

The oval instead of a circular shaped reception area of the ILP device for accepting the external lead clip, together with the insulated humps surrounding the clip reception area, helps to guide the external lead clip into the correct space for the direct electrical contact between the external lead and the designated contact patch of the ILP device.

Because the clamping area of the clip is shaped to perfectly match the oval shape of the reception area of the device, the close contact between the two features will allow for the electrical insulation from the surrounding electrically active medium.

Additionally, the oval shaped receiving area for the connector clip reduces the necessary force to push the narrow clip opening over the reduced diameter of the device body when compared to the diameter of a circular body shape of the same volume.

The inventive solution of such specific embodiments allows for ILP devices to improve for example the atrial signal detection in case of the external feature being an atrial lead.

Finally, it should be noted that the term “comprising” does not exclude other elements or steps and the “a” or “an” does not exclude a plurality. Also elements described in association with different embodiments may be combined. It should also be noted that reference signs in the claims should not be construed as limiting the scope of the claims.

List of Reference Numerals

1 intracardiac pacemaker arrangement
3 intracardiac pacemaker device
5 external lead arrangement
7 housing
9 electronic module
11 energy source
13 first electrode
15 second electrode
17 connector arrangement
19 fixation arrangement
21 tines
23 pin
25 ring electrode
27 mechanical connection structure
29 electrical energy transmitter
30 contact structure
31 electrically conductive lead
33 third electrode
34 attachment structure
35 mechanical counterpart structure
37 electrical energy transmitter counterpart
38 clipping structure
39 snap-fit connection mechanism
41 first inductor
42 first coil
43 second inductor
44 second coil
45 axial direction
47 protrusion
49 contact portion

51 non-contact portion

53 first portion

55 second portion

57 hump

59 contact portion

61 non-contact portion

63 first portion

65 second portion

Claims

1. An intracardiac pacemaker device (3), comprising:
a housing (7) being configured to be implanted entirely within a ventricle of a heart,
an electronic module (9) being configured for detecting cardiac activity by sensing electric voltages within the heart and for generating pacing pulses taking into account the detected cardiac activity,
an energy source (11) being configured for supplying energy to the electronic module (9),
a first electrode (13) arranged at a first portion of the housing (7) for contacting cardiac tissue upon the housing (7) being implanted within the ventricle,
a second electrode (15) arranged at a second portion of the housing (7),
a connector arrangement (17) comprising a mechanical connection structure (27) and an electrical energy transmitter (29),
wherein the mechanical connection structure (27) is configured for releasably fixing a mechanical counterpart structure (35) to the intracardiac pacemaker device (3), the mechanical counterpart structure (35) being comprised at an atrial lead arrangement (5) configured for an implantation into the atrium of a heart ,
wherein the electrical energy transmitter (29) is configured for electrically releasably coupling to an electrical energy transmitter counterpart (37) for transmitting electric energy between the electrical energy transmitter (29) and an electrical energy transmitter counterpart (37), the electrical energy transmitter counterpart (37) being comprised at the atrial lead arrangement (5).

2. The intracardiac pacemaker device according to claim 1,
wherein the electronic module (9) is electrically coupled to the first and second electrodes (13, 15) and wherein the electronic module (9) is configured to sense first electric sensing voltages between the first and second electrodes (13, 15),
wherein the electronic module (9) is electrically coupled to the electrical energy transmitter (29) and wherein the electronic module (9) is configured to sense second electric sensing voltages between the electrical energy transmitter (29) and at least one of the first and second electrodes (13, 15), and

wherein the electronic module (9) is configured for generating pacing pulses taking into account the sensed first and second electric sensing voltages.

3. The intracardiac pacemaker device according to one of the preceding claims,
wherein the electronic module (9) is electrically coupled to the first and second electrodes (13, 15) and wherein the electronic module (9) is configured to apply first electric pacing voltages between the first and second electrodes (13, 15),
wherein the electronic module (9) is electrically coupled to the electrical energy transmitter (29) and wherein the electronic module (9) is configured to apply second electric pacing voltages between the electrical energy transmitter (29) and at least one of the first and second electrodes (13, 15).

4. The intracardiac pacemaker device according to one of the preceding claims,
wherein the electrical energy transmitter (29) comprises a contact structure (30) being accessible from external to the housing (7) for establishing an electric ohmic contact with the electrical energy transmitter counterpart (37) comprised at the atrial lead arrangement (5).

5. The intracardiac pacemaker device according to one of the preceding claims,
wherein the electrical energy transmitter (29) comprises an electric inductor (41) for establishing an electric inductive contact with the electrical energy transmitter counterpart (37) comprised at the atrial lead arrangement (5).

6. An intracardiac pacemaker arrangement (1), comprising:
the intracardiac pacemaker device (3) according to one of the preceding claims, and
an atrial lead arrangement (5) configured for an implantation into the atrium of a heart,
wherein the atrial lead arrangement (5) comprises
an electrically conductive lead (31),
the mechanical counterpart structure (35), and
the electrical energy transmitter counterpart (37),
wherein the mechanical counterpart structure (35) is releasably fixed to the

mechanical connection structure (27) of the intracardiac pacemaker device (3), and wherein the electrical energy transmitter counterpart (37) is releasably electrically coupled to the electrical energy transmitter (29) of the intracardiac pacemaker device (3).

7. The intracardiac pacemaker arrangement according to claim 6, wherein the atrial lead arrangement (5) comprises an electrode (33) for at least one of sensing electric sensing voltages and applying electric pacing voltages.

8. The intracardiac pacemaker arrangement according to one of claims 6 and 7, wherein the atrial lead arrangement (5) comprises an attachment structure (34) configured for being attached to cardiac tissue.

9. The intracardiac pacemaker arrangement according to one of claims 6 to 8, wherein the electrical energy transmitter counterpart (37) is electrically coupled to the electrical energy transmitter (29) via an electric ohmic contact.

10. The intracardiac pacemaker arrangement according to one of claims 6 to 8, wherein the electrical energy transmitter counterpart (37) is electrically coupled to the electrical energy transmitter (29) via an electric inductive contact.

11. The intracardiac pacemaker arrangement according to one of claims 6 to 10, wherein the mechanical counterpart structure (35) is releasably fixed to the mechanical connection structure (27) via a snap-fit connection mechanism (39).

12. The intracardiac pacemaker arrangement according to one of claims 6 to 11, wherein at least one of the following conditions applies:
(i) the mechanical connection structure (27) has a non-circular outer contour;
(ii) the mechanical counterpart structure (35) has a non-circular inner contour;
(iii) the mechanical connection structure (27) has an outer contour being complementary to an inner contour of the mechanical counterpart structure (35);
(iv) the mechanical connection structure (27) comprises a contact portion (49) and a

non-contact portion (51), wherein the contact portion (49) is electrically conductive and extends along a first portion (53) of a circumference of the mechanical connection structure (27) whereas the non-contact portion (51) is electrically isolating and extends along a second portion (55) of the circumference of the mechanical connection structure (27), the second portion (55) being distinct from first portion (53) of the circumference of the mechanical connection structure (27);

(v) the mechanical counterpart structure (35) comprises a contact portion (59) and a non-contact portion (61), wherein the contact portion (59) is electrically conductive and extends along a first portion (63) of a circumference of the mechanical counterpart structure (35) whereas the non-contact portion (61) is electrically isolating and extends along a second portion (65) of the circumference of the mechanical counterpart structure (35), the second portion being distinct from first portion of the circumference of the mechanical connection structure (27);

(vi) the mechanical connection structure (27) and the mechanical counterpart structure (35) each comprise an electrically conductive contact portion (49, 59) and an electrically isolating non-contact portion (51, 61), wherein the mechanical connection structure (27) and the mechanical counterpart structure (35) are configured such that their respective contact portions come into physical connection upon the mechanical counterpart structure (35) being releasably fixed to the mechanical connection structure (27).

13. A method of implanting an intracardiac pacemaker arrangement (1) according to one of claims 6 to 12 into a heart of a patient, the method comprising:

- implanting the housing (7) of the intracardiac pacemaker device (3) into a ventricle of the heart,

- arranging a portion of the atrial lead arrangement (5) in an atrium of the heart, and

- fixing the mechanical counterpart structure (35) of the implanted atrial lead arrangement (5) to the mechanical connection structure (27) of the implanted intracardiac pacemaker device (3) and electrically coupling the electrical energy transmitter counterpart (37) of the implanted atrial lead arrangement (5) to the electrical energy transmitter (27) of the implanted intracardiac pacemaker device (3).

14. The method according to claim 13,
wherein the atrial lead arrangement (5) comprises an attachment structure (34), and
wherein the method further comprises attaching the attachment structure (34) to cardiac tissue.

15. A method for retrofitting an intracardiac pacemaker device (3) of an intracardiac pacemaker arrangement (1) according to one of claims 6 to 12 having its housing (7) implanted into a ventricle of the heart and having its atrial lead arrangement (5) partially arranged in an atrium of the heart,
the method comprising:
- disengaging the releasable mechanical fixation between the mechanical counterpart structure (35) of the implanted atrial lead arrangement (5) and the mechanical connection structure (27) of the implanted intracardiac pacemaker device (3) and releasing the electrically coupling between the electrical energy transmitter counterpart (37) of the implanted atrial lead arrangement (5) and the electrical energy transmitter (29) of the implanted intracardiac pacemaker device (3),
- optionally, explanting the intracardiac pacemaker device (3) from the heart,
- implanting a replacement intracardiac pacemaker device (3) into the ventricle of the heart, and
- fixing the mechanical counterpart structure (35) of the implanted atrial lead arrangement (5) to the mechanical connection structure (27) of the implanted replacement intracardiac pacemaker device (3) and electrically coupling the electrical energy transmitter counterpart (37) of the implanted atrial lead arrangement (5) to the electrical energy transmitter (29) of the implanted replacement intracardiac pacemaker device (3).

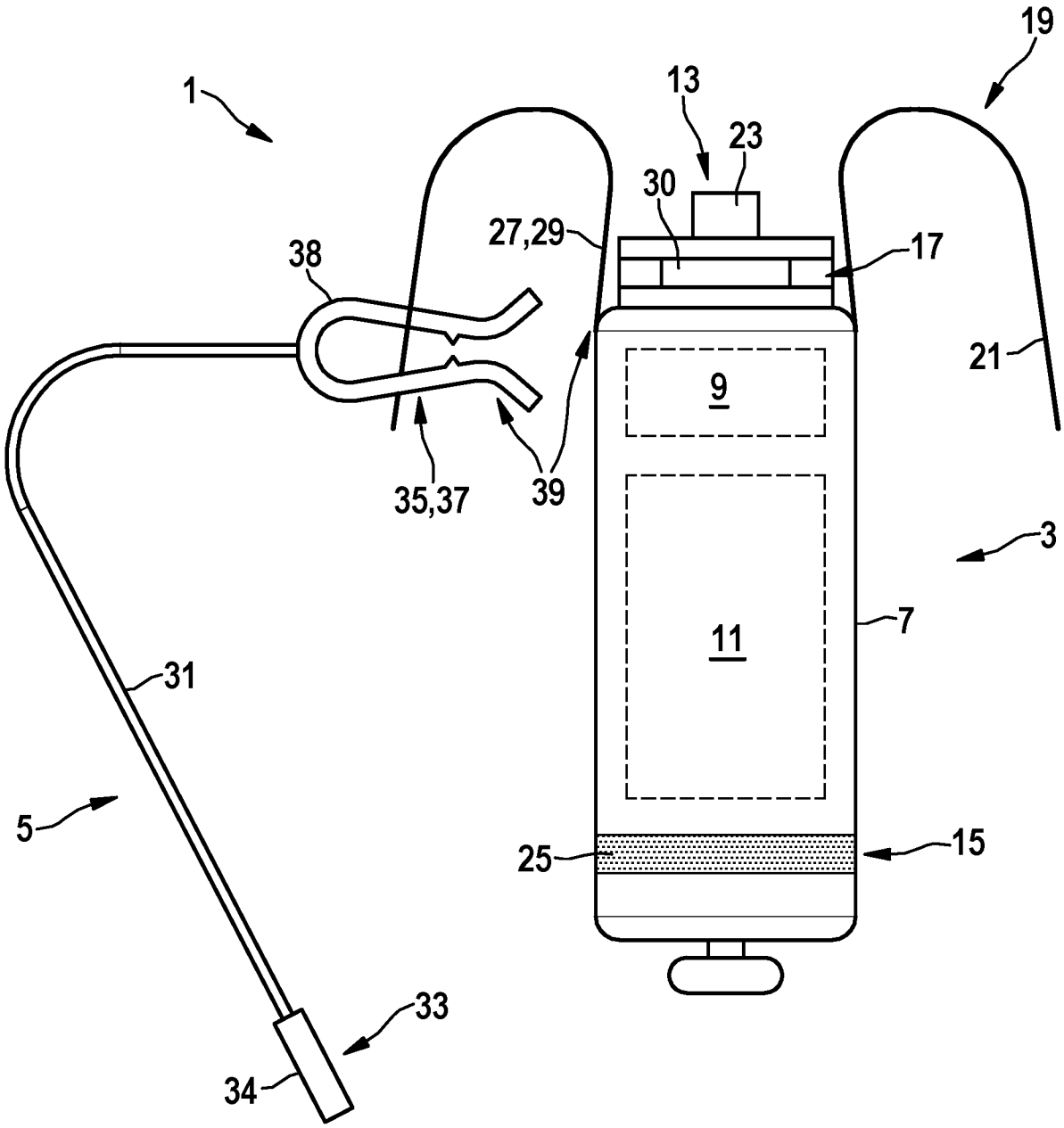


FIG. 1

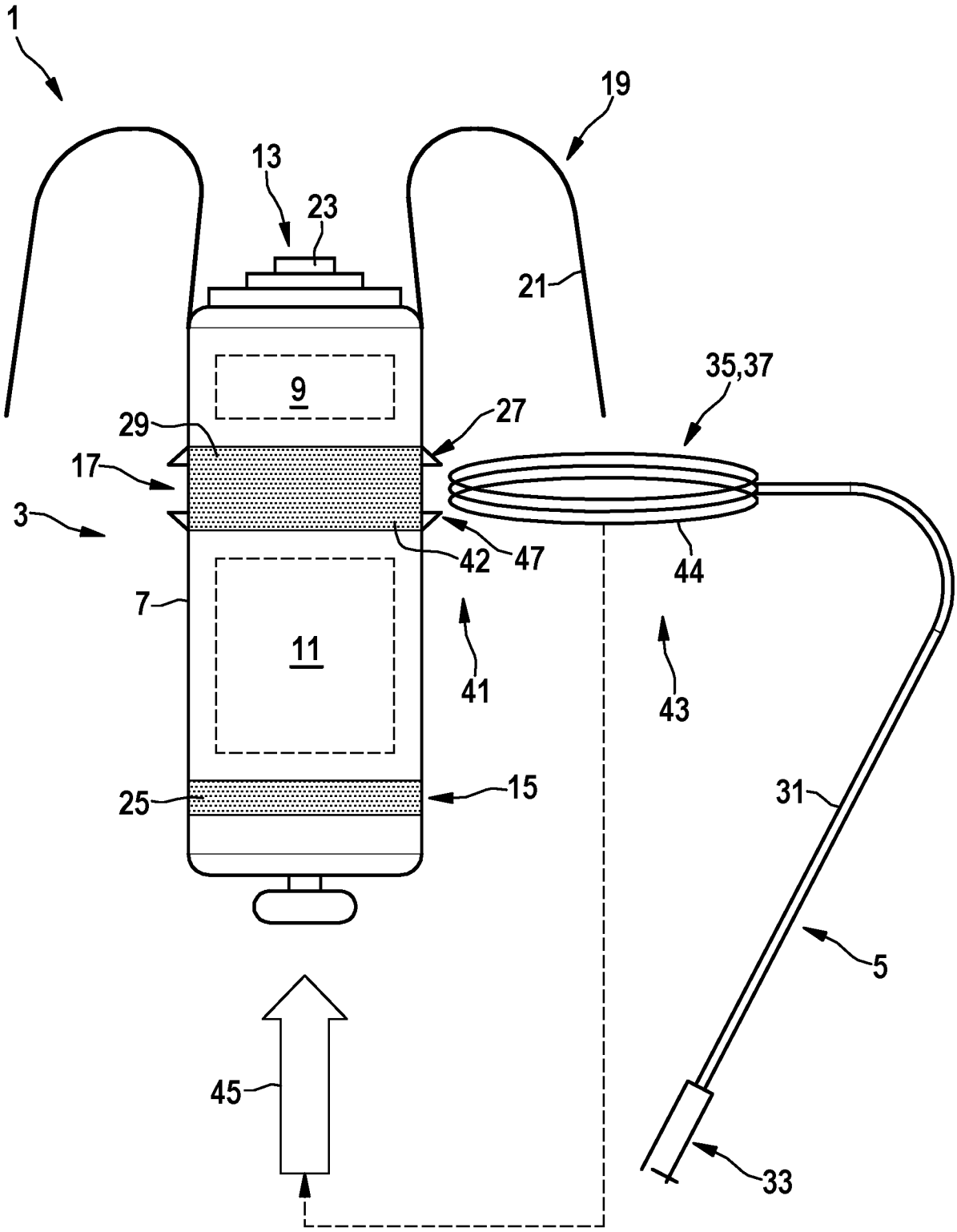


FIG. 2

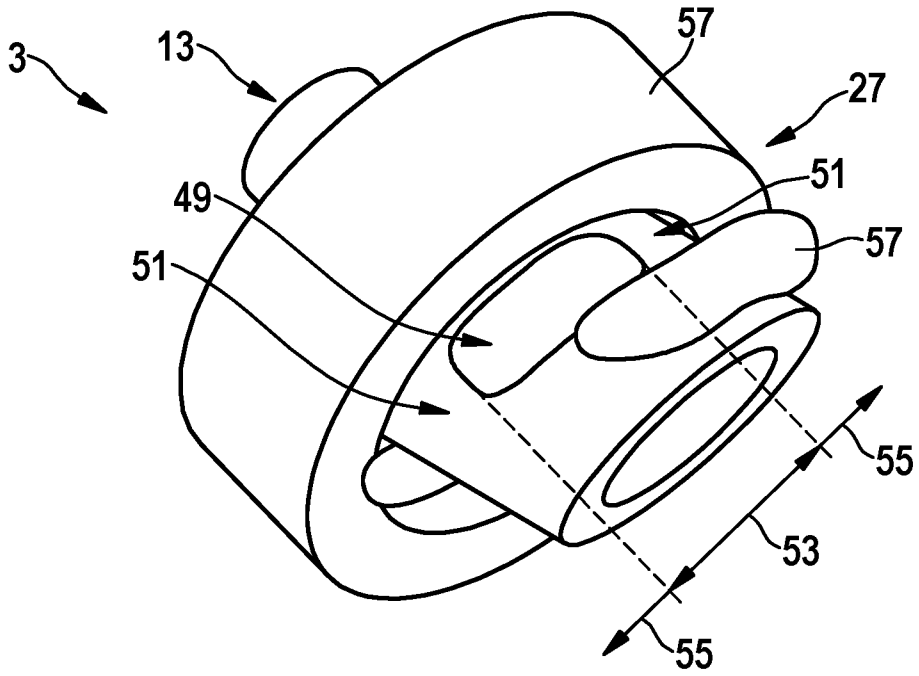


FIG. 3

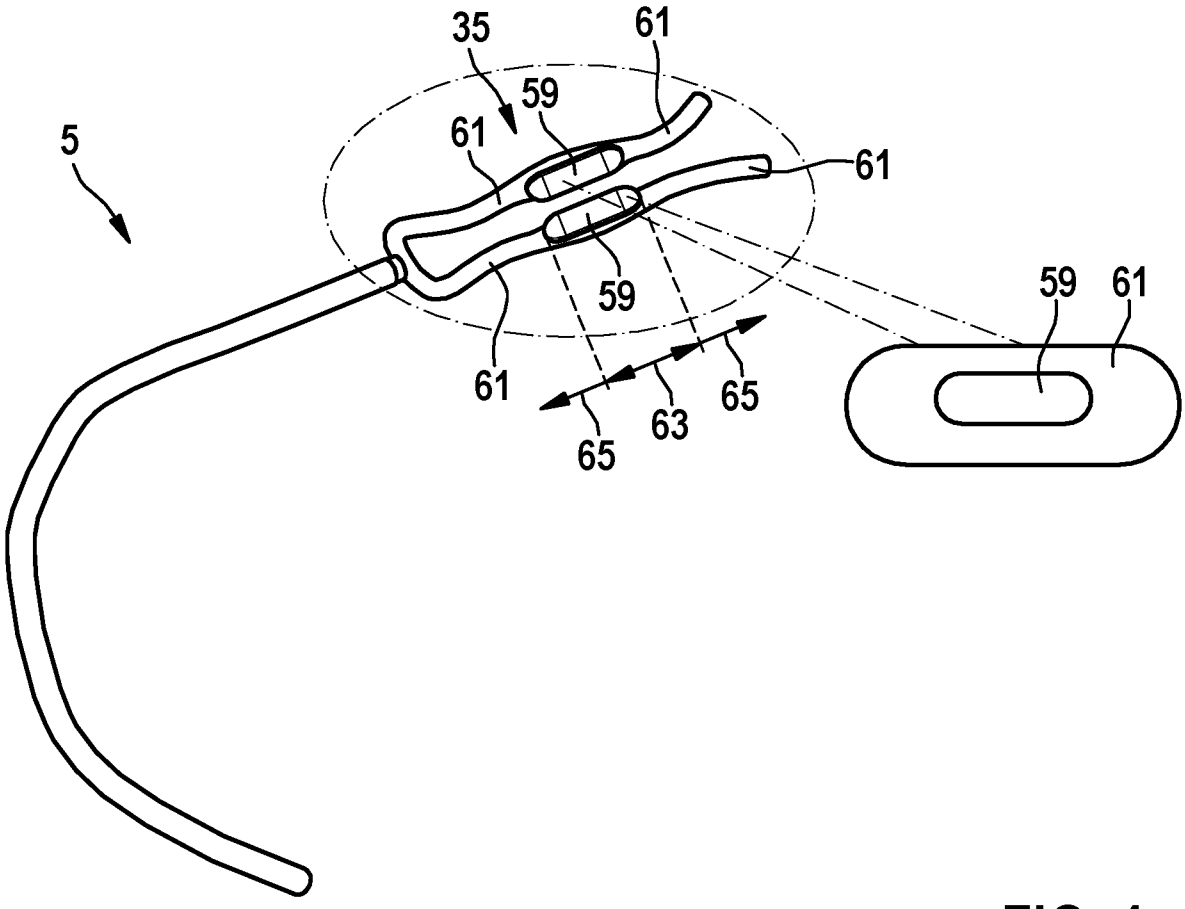


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/078648

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372 A61N1/368 A61N1/05
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 A61B

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

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 11 154 706 B1 (FISHEL ROBERT [US] ET AL) 26 October 2021 (2021-10-26) column 7, line 11 - column 8, line 37; figures 2A, 3D, 5 column 11, line 25 - column 12, line 20	1-4,6-9, 11,12 5,10
A	US 2011/160557 A1 (CINBIS CAN [US] ET AL) 30 June 2011 (2011-06-30) paragraphs [0042], [0044], [0046], [0060], [0063], [0068], [0070], [0071], [0072], [0076], [0087], [0118]; figures 18,19,23	1-12
A	US 2016/158560 A1 (MOORE DAVID F [US] ET AL) 9 June 2016 (2016-06-09) paragraphs [0002] - [0005], [0032] - [0034], [0054], [0057] - [0061]	1-12

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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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
7 December 2023	19/12/2023

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	Pfeiffer, Uwe

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2023/078648

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011/270339 A1 (MURRAY III ROBERT [US] ET AL) 3 November 2011 (2011-11-03) paragraphs [0012] - [0021]	1-12

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2023/078648

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-15
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2023/078648

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 11154706 B1	26-10-2021	NONE	
US 2011160557 A1	30-06-2011	US 2011160557 A1	30-06-2011
		US 2011160801 A1	30-06-2011
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US 2016158560 A1	09-06-2016	EP 2265166 A1	29-12-2010
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		US 2018280704 A1	04-10-2018
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		WO 2009120636 A1	01-10-2009
US 2011270339 A1	03-11-2011	NONE	