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

(72) Inventors: **MAXFIELD, Michelle**; Körtestrasse 4, 10967 Berlin (DE). **FRIEDRICH, Michael**; Am Hochwald 28, 14532 Kleinmachnow (DE).

(74) Agent: **HEINZ, Benjamin**; Sieversufer 7-9, 12359 Berlin (DE).

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(54) Title: A SYSTEM FOR HOLDING AN ACTIVE IMPLANT IN AN ATRIAL APPENDAGE OF A HEART AND METHODS FOR IMPLANTING AN ACTIVE IMPLANT

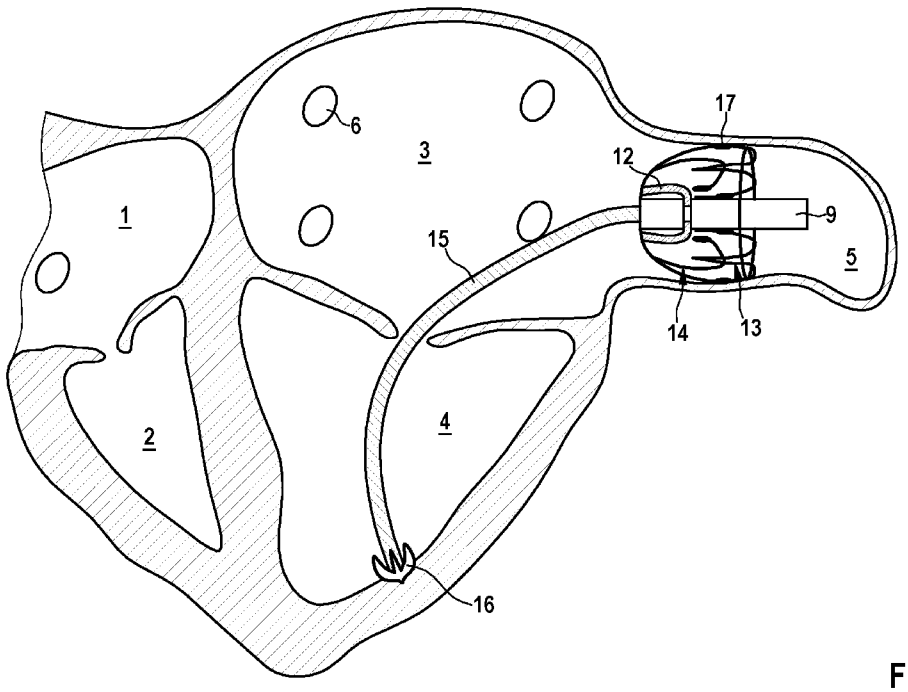


FIG. 2

(57) Abstract: The disclosure relates to a system for holding an active implant in an atrial appendage of a heart. The system comprises an anchoring device and an active implant, wherein the anchoring device is coupled to the active implant, and wherein the anchoring device comprises a fixation element which is configured to hold the anchoring device in the atrial appendage. Also, methods for implanting an active implant are disclosed.

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# A system for holding an active implant in an atrial appendage of a heart and methods for implanting an active implant

The disclosure relates to a system for holding an active implant in an atrial appendage of a heart and methods for implanting an active implant.

The human heart has four chambers, namely the right atrium, the left atrium, the right ventricle, and the left ventricle. The right atrium receives and holds deoxygenated blood from the superior vena cava, inferior vena cava, anterior cardiac veins and the coronary sinus, which it then sends down to the right ventricle (through the tricuspid valve). The right ventricle sends the blood to the pulmonary artery for pulmonary circulation. The left atrium receives the oxygenated blood from the left and right pulmonary veins and pumps the blood to the left ventricle (through the mitral valve). The left ventricle pumps the blood out through the aorta for systemic circulation.

Attached to the right atrium is the right atrial appendage – a pouch-like extension of the pectinate muscles. High in the upper part of the left atrium is a muscular ear-shaped pouch - the left atrial appendage.

It is known to close the left atrial appendage with a left atrial appendage occlusion device (LAAOD) in order to reduce the risk of left atrial appendage blood clots from entering the bloodstream and causing a stroke in patients with atrial fibrillation. Some embodiments for such LAAODs are disclosed in documents US 2014/0163605 A1 and US 2016/0008122 A1.

The space in the atrial appendage (left or right) can also be used for pacing purposes.

Document US 2017/0209690 A1 discloses a dual chamber intracardiac pacing device. A main device is implanted in the right ventricle. A lead extending from the main device is positioned in the right atrial appendage and fixed there using a screw helix.

Document US 9,526,891 B2 discloses an intracardiac pacemaker which can be implanted in an atrial appendage. Multiple fixation tines are provided on a housing of the pacemaker. The tines are passive, non-penetrating tines which are wedged between opposing tissue surfaces, e.g. endocardial walls of the right or left atrial appendage.

Document US 2018/0126179 A1 discloses an implantable medical device (IMD) which may be deployed within a patient's right atrium at a location near a right atrial appendage of the patient's heart in order to pace the patient's heart and/or to sense electrical activity within the patient's heart. In some cases, an IMD may be implanted within the right atrial appendage. The IMD may include an expandable anchoring mechanism configured to secure the IMD in place.

It is an objective to provide improved technology for arranging an active implant in an atrial appendage.

In one aspect, a system for holding an active implant in an atrial appendage of a heart is provided. The system comprises an anchoring device and an active implant, wherein the anchoring device is coupled to the active implant. The anchoring device comprises a fixation element which is configured to hold the anchoring device in the atrial appendage.

In another aspect, a method for implanting an active implant is disclosed. The method comprises steps of: providing an active implant which is coupled to an anchoring device, wherein the anchoring device comprises a fixation element which is configured to hold the anchoring device in an atrial appendage of a heart; and arranging the anchoring device and the active implant in the atrial appendage.

In yet another aspect, a further method for implanting an active implant is disclosed. The further method comprises steps of: providing an anchoring device, wherein the anchoring

device comprises a fixation element which is configured to hold the anchoring device in an atrial appendage of a heart; arranging the anchoring device in the atrial appendage; and arranging an active implant in the anchoring device.

In yet another aspect, a method for exchanging an active implant or a part thereof, comprising the steps of: providing an active implant which is coupled to an anchoring device in an atrial appendage of a heart, wherein the anchoring device comprises a fixation element which is configured to hold the anchoring device in the atrial appendage; and wherein the anchoring further comprises a planar structure, particularly a mesh, a fabric, or a membrane, which is configured to enhance tissue ingrowth and the anchoring device is configured to close or to occlude the atrial appendage; decoupling and removing the active implant or at least a part thereof, and arranging and coupling a replacement active implant or a replacement part corresponding the removed part. In one embodiment, the at least part of the active implant is an energy storage releasably attached to the active implant, the energy storage is decoupled and removed from the active implant leaving the active implant in place, and wherein a replacement energy storage in arranged and coupled to the active implant left in place.

According to the present invention, it is particularly envisioned that the anchoring device is configured to close or occlude the atrial appendage.

The anchoring device may be arranged in the right atrial appendage or in the left atrial appendage. The active implant is held by the anchoring device such that at least a part of the active implant is arranged in the (right or left) atrial appendage. The active implant may be held by the anchoring device such that the active implant is completely arranged in the atrial appendage.

An active implant (also called active implantable medical device) is an active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure. An active medical device is a medical device relying for its

functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

The active implant may comprise a housing, an electronic module which is arranged in the housing, as well as a first electrode and a second electrode which are coupled to the electronic module and optionally an energy storage which is arranged in the same housing or in another housing. Additionally or alternatively, such energy storage may be releasably attached to the active implant, which allows an exchange of the energy storage once depleted. The first electrode may be arranged at a distal end of the active implant. The second electrode may be arranged in a proximal region of the active implant apart from the first electrode. The second electrode may be formed by a part of the housing, wherein particularly the remaining part of the housing is insulated, e.g. by a coating comprising, for example. a parylene. In addition, the active implant may comprise a device for explantation, such as, for example, a hitch. The active implant may be configured to sense electrical signals from the heart and/or provide pacing pulses to the heart via the first electrode and/or the second electrode. The active implant may be an intracardiac pacing device (also called leadless pacemaker) or an implantable cardioverter-defibrillator (ICD).

The energy storage may comprise a battery and/or a capacitor. The energy storage may be configured to provide electrical energy to the electronic module, to the first electrode and/or to the second electrode.

The housing may be made of a biocompatible material, e.g. a biocompatible metal such as titanium or a titanium alloy.

The fixation element may be configured to provide an electrical shock to the surrounding tissue, for example in case the active implant is an ICD.

The anchoring device with the fixation element may be permanently fixed to the active implant. In this embodiment, the anchoring device and the active implant may be formed as an integral device.

The active implant may be releasably fixed to the anchoring device. The anchoring device may comprise a receiving element which is configured to receive and hold the active implant. In this embodiment, the anchoring device and the active implant are formed as two separate devices. The active implant may be releasably held in the receiving element of the anchoring device. Hereby, the active implant may be replaced, if needed. For example, an old implant with depleted energy storage may be removed from the receiving element and a fresh implant may be arranged in the receiving element. Since the anchoring device remains in place, trauma of the myocardial tissue is avoided. The active implant may be held in the receiving element using magnetic force. A first magnet may be arranged at or in the receiving element. A second magnet may be arranged at the housing of the active implant. Alternatively, the active implant may have one or more hooks which releasably hook in the receiving element. Also other releasable attachments between the implant and the receiving element are conceivable, particularly any mechanical interference or retention element such as, for example ball detents using spring-loaded balls, deformable flexible elements or spring elements on the active implant or the receiving element, a ratchet mechanism utilizing loops (which particularly would enable to adjust the active implant at the best position). Another alternative may be an inflatable balloon to releasably attach the active implant to the receiving element.

The fixation element may have a curved shape. The fixation element may be formed such that at least a section of the fixation element pushes against the inner surface of the atrial appendage.

The anchoring device and/or the fixation element may be made of an elastic material, for example an elastic metal or metal alloy. The anchoring device and/or the fixation element may be made of a shape memory alloy, e. g., nitinol. Nitinol is a metal alloy of nickel and titanium, where the two elements are present in roughly equal atomic percentages.

In one embodiment, a proximal end of the housing may be held in the receiving element, and the first electrode may be arranged on a distal end of the housing. The anchoring device may be arranged in the atrial appendage such the first electrode is in contact with

tissue at the inner surface of the atrial appendage when the anchoring device and the active implant are implanted.

The anchoring device may comprise a guiding element for guiding a device to the anchoring device. The guiding element may guide the active implant during an implantation procedure to the anchoring device. The guiding element may comprise one or more conductive coils which interact with magnets (e.g. permanent magnets or electromagnets). Magnets (permanent magnets or electromagnets) can be used on the anchoring device and on the retrieval system to aid docking for battery/device exchange. During implantation or device exchange, a feedback may be provided to a user indicating the approach of the (new) active implant to the anchoring device, e.g. an acoustic or optical feedback. Alternatively, the guiding element may comprise capacitive and/or inductive elements forming a capacitive-inductance guidance system that gives visual or acoustic feedback for manual alignment, e.g. a solenoid centering device with coils in which the active implant is arranged, wherein a magnetic field is created inside by a current. The guiding element may also be designed as a funnel. Also conceivable are markers on the implant and/or the anchoring device as guiding element, particularly markers visible in fluoroscopy or ultrasound imaging.

The above described guiding elements may also be arranged on an implantation or explantation tool or device, e.g. an implantation or explantation catheter. Accordingly, the system according to the invention may comprise an implantation device, e.g. an implantation catheter comprising a guiding element. The implantation/explantation device may include a tether with a magnet that is attached to the implantation/explantation device that may guide the device to the receiving element or the hitch and then guide the new active implant into place.

The fixation element may have a basket-like structure comprising one or more loops. The fixation element may form a container which comprises several fibers (basket). The fibers may be intersecting each other. Alternatively, the fixation element may have a ball-like structure comprising one or more loops and enclosing a substantially closed volume, or an umbrella-like structure. The fixation element may comprise several equally formed ribs or

struts which protrude from a center of the fixation element with equal angles between them (umbrella).

The anchoring device may comprise one or more fixation elements which extend from the receiving element. The one or more fixation elements may be configured to hold the anchoring device in the atrial appendage. The receiving element may be arranged in the center of the fixation elements. In another embodiment, the receiving element may be arranged offset from the center of the fixation elements. The fixation elements may have an equal length and/or an equal form. The fixation elements may protrude from the receiving element. The fixation elements may be equally distributed around the receiving element.

The fixation elements may be formed as spring-fingers which press against the inner surface of the atrial appendage when the anchoring device is implanted. In one embodiment, the fixation element is formed as a single spring-finger.

The system may further comprise a further device which is coupled to the anchoring device. The further device may be coupled to the active implant. The further device may be another active implant (e.g. for upgrading or replacing the active implant) or an energy storage for the active implant. Hereby, a battery backpack can be added to the active implant (e.g. intracardiac pacing device) after “End of Life” of its original battery in order to increase the lifetime of the active implant. In another embodiment, a stack of several devices may be formed, e.g. for adjusting the therapy delivered to a patient. In a first step, an intracardiac pacing system may be arranged in the anchoring device for providing bradycardia therapy. If at a later stage, cardiac resynchronization therapy (CRT) becomes necessary, a CRT device can be arranged on top of the intracardiac pacing system in the anchoring device. Several devices in the anchoring device may be coupled to each other by resistive welding.

The anchoring element and/or the fixation element may be configured as an antenna for emitting and/or receiving signals. The anchoring element and/or the fixation element may be configured to act as an antenna of the active implant for communication (e.g. two-way

communication) with an external device, e.g. a programmer or a patient device. The coupling between the antenna and the external device may be inductive or capacitive (a galvanic coupling is not necessarily needed).

The anchoring device may comprise a coating which is configured to inhibit encapsulation.

The anchoring device may comprise a planar structure which is configured to enhance tissue ingrowth. Particularly, the planar structure extends, particularly flatly, across or around the anchoring device or the fixation element, and particularly encircles or encloses the anchoring device and/or the fixation element. The planar structure may comprise a surface with a three dimensional texture, such as, for example, with grooves, protrusions or the like. The planar structure may be designed or formed as a mesh, a fabric, or a membrane. The fixation element may be formed as a mesh, a fabric, particularly a woven fabric, or a membrane. The planar structure, particularly the mesh or the fabric, may comprise several strands which intersect which each other. The strands may be connected with each other. The planar structure, particularly the mesh, the fabric or the membrane, may promote tissue ingrowth of the fixation element after implantation of the anchoring device. The planar structure, e.g. the mesh, the fabric or the membrane, may comprise a surface texture being configured to promote cell ingrowth. The planar structure may be designed in form of a two layer sealing surface, wherein one layer is configured to immediately seal the appendage and the other layer to allow endothelialization. In addition or alternatively, the planar structure may comprise a coating, particularly a fractal coating configured to promote ingrowth. The planar structure may further be made of a bioresorbable material.

The anchoring device may comprise tissue removal means which are configured to remove tissue from the active implant, e.g. when the active implant shall be replaced by another device. The tissue removal means may be mechanical (e.g. like a scalpel or a cutter) or electrical (e.g. using electrosurgery or electroporation). These removal means may utilize a catheter to provide motion or energy to perform task.

The active implant may comprise a third electrode which is connected to the electronic module by a lead. The third electrode may be configured to be arranged in a ventricle of the heart. Alternatively, the third electrode may be configured to be arranged in the coronary sinus. When the anchoring device with the active implant is implanted in the right atrial appendage, the third electrode may be arranged in the right ventricle. In case the anchoring device with the active implant is implanted in the left atrial appendage, the third electrode may be arranged in the left ventricle. The third electrode may have tines or a screw for fixation in the ventricle.

The active implant may comprise one or more electrically conductive contact elements, particularly configured to establish an electrically conductive connection to the anchoring device or the fixation element. Additionally or alternatively, the one or more conductive contact elements may be configured to establish an electrically conductive connection to an energy storage or to a further device.

In one embodiment, the anchoring device can be seen as a LAAOD-type anchor (e.g., an elastic expanding basket or umbrella) which is preloaded onto the intracardiac pacing device (e.g. by means of spring fingers or similar elements). The intracardiac pacing device is inserted into the left atrial appendage (LAA) with a transseptal sheath. A good atrial pacing contact location is found in the LAA. The anchor is deployed to hold the intracardiac pacing device in place. A pacing sequence is determined. The anchoring device grows in. Connective tissue forms on the anchor, but not on the intracardiac pacing device itself (e.g. by a coating of the intracardiac pacing device and/or by virtue of distance from the LAA ostium tissue to the intracardiac pacing device). For replacement, a tool is provided which attaches into/onto the anchor (possibly through magnetic locators) and allows proper hitching to the intracardiac pacing device and then the release of the spring fingers holding it to the anchor. A new intracardiac pacing device can be inserted in the same docking station.

In another embodiment, a LAAOD-type anchor is inserted in left atrial appendage. The anchor may be a flexible basket/umbrella-like structure which elastically presses against the opening of the left atrial appendage entrance. It is usually made of nitinol and

comprises planar structure, particularly a mesh, a fabric or a membrane, to allow it to grow in and seal off the left appendage. By means of a sheath insertion tool, an intracardiac pacing device is inserted into the space in the appendage and attaches with spring fingers to the anchor for fixation. Atrial sensing surfaces could be on the anchor which are in contact with the atrium and feed to the intracardiac pacing device. A lead (mini-lead) may extend into the ventricle or the coronary sinus. The anchor grows in and the lead grows in (or the lead can have an active fixation in the ventricle, e.g., one or more tines). Pacing and/or sensing of the left ventricle, the left atrium or the coronary sinus would be possible. If multiple sensing/pacing surfaces could be placed on the anchor, then after deployment, a user could choose (e.g. via software settings) various combinations for best results. For replacement, a tool may be provided which attaches into/onto the anchor (possibly through magnetic locators) and allows proper hitching to the intracardiac pacing device and then the release of the spring fingers holding it to the anchor. A new intracardiac pacing device can be inserted in the same docking station.

The anchoring device allows distributing the load of anchoring an intracardiac pacing device over the large area of the entrance to the atrial appendage. The left atrial appendage has been thoroughly researched for the insertion of the LAAOD which are used to block off the appendage to prevent thrombus formation in patients with atrial fibrillation. This area remains stable throughout the contraction cycle and has less movement as compared to the ventricle. In addition, by such anchoring device, also explantation is easier due to the lesser movement.

The anchoring device would also allow a known location for accessing or docking onto an intracardiac pacing device to be exchanged without the intracardiac pacing device being embedded in and inextricable from the heart wall.

The large volume of the atrial appendage will allow potentially a larger implant, e.g. with a larger battery and/or additional sensors without filling the ventricular cavity. It may even allow multiple intracardiac pacing devices to be implanted without having to remove existing ones, e.g. by means of a single or multiple docking stations in the anchoring device.

If an LAAOD-type fixation is used which seals off the LAA, then the thrombus risk due to a complex structure of the anchor or the active implant (e.g. intracardiac device) is eliminated, since the active implant will mostly sit in the sealed cavity. The patients will not need to take prophylactic anticoagulants, particularly after grow-in period, due to an additional risk of thrombus potentially caused by stagnating blood from the device creating a pocket. This applies particularly to patients who suffer from these medications, and to older people generally having a higher risk of stroke due to thrombus formation in the LAA. The anchoring may be configured as an occlusion device for the atrial appendage.

The anchoring device may have multiple electrodes so that it may be placed in the atrium and the active implant (e.g. intracardiac pacing device) can choose from the various electrodes to find the best pacing location after it is deployed or as the patient's tissue substrate changes. During implantation, it can be checked which subset of the multiple electrodes provides the best combination for pacing/sensing. The test may be performed as a trial-and-error test covering all possible combinations of the multiple electrodes to select the best configuration.

Sensing and pacing can be done directly on the housing of the intracardiac pacing device and can have multiple poles, which can be chosen or altered (polarity etc.) at a later time.

Sensing electrodes, pacing electrodes and/or defibrillation electrodes can be part of the fixation element.

Sensing electrodes and/or pacing electrodes can be hardwired into the intracardiac pacing device with spring fingers providing contact to the fixation element (with or without aiding the anchoring mechanism).

A sealed lip "phone jack" design or IS4 type jack can be provided for sealing and connecting to multiple electrodes on the anchoring device.

Variants in which the anchoring device (e.g. basket/umbrella) contains pacing/sensing electrodes allow the possibility to partially or temporarily deploy it to test electrical suitability of a location, retracting and repositioning, if necessary.

The lead distal end can be designed to interact with a ventricular placement tool (VPT) to allow good placement of a stimulating electrode in the ventricle. One example could be to have an eyelet (through hole) in the lead to accept a long sterile suture which is pre-threaded before loading in the transseptal sheath. This suture would then be loaded into the VPT (which is a steerable catheter with a lumen to accept the suture and pull the lead tip to the distal tip of VPT). Once the lead is over the valve and a good stimulation location is located, the suture is cut and removed and the lead remains in place to grow in.

In one embodiment, the system may comprise another active implant. The active implant may a first intracardiac pacing device and the other active implant may be a second intracardiac pacing device. The first intracardiac pacing device may be arranged in the atrial appendage with the anchoring device. The second intracardiac pacing device may be arranged in the corresponding ventricle. The first intracardiac pacing device and the second intracardiac pacing device may be configured for a bi-directional communication with each other, e.g. via ultrasound or a body area network communication. For example, the first intracardiac pacing device and the second intracardiac pacing device may each comprise a communication module. With such embodiment, a DDD(R) pacing system can be implemented allowing atrial-ventricular synchronization of the pacing.

In another embodiment, the system may comprise another pacemaker or another ICD, wherein the other pacemaker or the other ICD is connected to one or more other electrodes. The one or more other electrodes may be configured to be arranged in a coronary sinus of the heart. If an intracardiac pacing device is mounted in either appendage, a coronary sinus lead (coupled to the other pacemaker or the other ICD) could convey electrical activity from the other chamber for synchronization.

The features disclosed in regard with the system can also be applied to the methods in an analogue manner and vice versa.

Following, exemplary embodiments are described with reference to figures. Here show:

Fig. 1 one embodiment of the system according to the invention,

Fig. 2 another embodiment of the system according to the invention,

Fig. 3 another embodiment of the system according to the invention,

Fig. 4 a further embodiment of the system including implantation/explantation device, and

Fig. 5 another additional embodiment of the system including an implantation/explantation device

Same reference numerals are used for same components.

Fig. 1 shows a first embodiment of a system which is implanted in a heart of a patient. The heart comprises the right atrium 1, the right ventricle 2, the left atrium 3, and the left ventricle 4. In the left atrium 3, the left atrial appendage 5 is formed. Also, the pulmonary veins 6 in the left atrium 3 are shown.

An anchoring device comprising a fixation element 7and a receiving element 8 is arranged in the left atrial appendage 5. An intracardiac pacing device 9 is held by the receiving element 8 such that the intracardiac pacing device 9 is arranged completely in the left atrial appendage. An electrode 10 is arranged on a distal end of the intracardiac pacing device 9. The electrode 10 is in contact with heart tissue (inner surface of the left atrial appendage 5). The intracardiac pacing device is configured to sense electrical activity in the heart tissue with the electrode 10. Also, if needed, a stimulation pulse (pacing pulse) can be provided by the intracardiac pacing device 9 via the electrode 10. The intracardiac pacing device 9 comprises a battery for energy supply and an electronic module for implementing the functions of the device such as measuring electrical activity and stimulating the heart

(not shown). The intracardiac pacing device 9 may also comprise a hitch at its proximal end, as shown, for example in Fig. 3, which is configured to facilitate explantation of the device 9.

The fixation element 7 is formed as an umbrella-like anchor and comprises several equally formed ribs or struts which protrude from the receiving element 8. A proximal end of the intracardiac pacing device 9 is held releasably in the receiving element 8.

The receiving element 8 may be provided with a means for adjusting the axial position (and thus the distal extent) of the active implant 9 relative to the fixation element 7, for example to ensure good electrical contact of the pacing electrode 10 with the wall of the atrial appendage 5. Furthermore, the receiving element 8 and/or active implant 9 may be provided with conductive contact elements 22 (e.g. over springs, as shown in Fig. 3) in order to connect the implant's pacing and sensing electronics with electrodes 17 external to it (e.g. on the fixation element 7).

Axial adjustment and fixation of the intracardiac device 9 in the receiving element 8 may be provided by a locking means 24 such as a ratchet (e.g. hooks or loops) or threads to screw in the device 8. Alternatively, flexible elements (e.g. made of silicone or metal springs/helices) on the device 9 and/or receiving element 8 may be coupled with an interference fit, whereby during insertion or removal a flexible element may be deformed (e.g. by pressing, stretching or twisting) to temporarily cause it to contract or expand and therewith remove the interference. Also, a ball or balloon may be inflated (e.g. with saline solution) to effect the fixation, release or adjustment. Axial adjustment may also be achieved by adjusting the tension in the loops of the fixation element 7 (e.g. basket).

The intracardiac device 9 may be released by grasping the proximal end of the active implant with a tool and pushing, pulling or rotating it relative to the fixation element 7. This motion provides either direct traction to the implant 7 and/or causes certain retention mechanisms (e.g. spring-loaded balls or flexible, deformable elements) to be released or fixed.

Also shown in Fig. 1 is a sheath 11 which is used as an insertion tool for the anchoring device and the intracardiac pacing device 9. The sheath 11 is introduced through the inferior vena cava in the right atrium 1 and brought through the fossa ovalis in the left atrium 3. During implantation, the anchoring device and the intracardiac pacing device are arranged in a distal end of the sheath 11. The fixation element 7 is made of an elastic material. It is in a first, compressed state in the distal end of sheath 11. After implantation, the ribs of the fixation element 7 expand and form a second, uncompressed state of the fixation element 7. In the uncompressed state, the ribs of the fixation element 7 push against the inner surface of the left atrial appendage 5 and hold the intracardiac pacing device 9 in position.

Another embodiment is shown in Fig. 2. The anchoring device comprises a spring finger receiving element 12. At least two spring fingers are arranged opposite to each other. The spring fingers push together and hold the distal end of the intracardiac pacing device 9. The fixation element is formed by spring finger loops 13 which push against the cardiac tissue and hold the anchoring device and the intracardiac pacing device 9 in the left atrial appendage 5. Between the spring finger loops 13, a mesh 14 is formed which promotes tissue ingrowth. Several electrodes 17 are arranged in the spring finger loops 13. The electrodes 17 may be configured as pacing/sensing electrodes and may be coupled to the intracardiac pacing device 9.

The intracardiac pacing device 9 has an electrode lead which extends through the mitral valve into the left ventricle 4. A further electrode 16 is arranged at a distal end of the electrode lead 15. The further electrode 16 is fixed in the left ventricle with tines. The further electrode 16 is configured for sensing electrical activity in the left ventricle and/or for providing a pacing pulse to the left ventricle. Hereby, DDD operation of the intracardiac pacing device 9 can be provided (DDD – dual chamber pacing, dual chamber sensing, and triggered as well as inhibited response to sensing), optionally with rate adaption.

As shown in Figures 3 to 5, the system according to the invention 7 may comprise one or more guiding elements 18, 19. The guiding elements 18, 19 serve to ease positioning of the

distal tip of an implantation tool 25 (e.g. a catheter) over the proximal end of the active implant 9 in order to grasp it, for the purpose of attaching the intracardiac device 9 to, repositioning, or removing it from the fixation element 7 and/or receiving element 8.

The guiding element 18, 19 might be a simple mechanical provision such as a funnel. The guiding element 18,19 may consist of markers on the distal tip of the implantation tool 25 and the proximal end of the intracardiac device 9 to enhance their visibility in an imaging modality (such as X-ray or ultrasound) for visual guidance. Alternatively, the implantation tool 25 and the device 9 ends may be equipped with passive or powered electrical elements (such as capacitors, inductors or RF chips) to gauge proximity and the relative position of the ends, in order to provide guidance with the help of electronic circuitry.

The ends of the implantation tool 25 and the intracardiac device 9 may be provided with magnets so that they automatically join when brought in proximity to each other. These can be permanent or electromagnets. Alternatively, one of the ends need only be made of ferromagnetic material, such as ferritic stainless steel.

The implantation tool 25 with the guiding elements 18 can also be used to insert the intracardiac device 9 into an empty fixation element 4 with receiving element 8. The fixation element 7 and/or the receiving element 8 may contain one or more guiding elements 19 to allow proper orientation.

In order to simplify locating the intracardiac device 9, a guiding element 18 may be formed or designed as a magnet that is affixed to the end of a guidewire 23 inserted through the implantation tool 25, rather than on the implantation tool 25 itself, because the guidewire 23 is more flexible and thus easier to move around when searching for the implant. Similar to some available ventricularly implanted leadless pacemakers, the device 9 may be provided with a hitch 20 at the proximal end to aid in securely capturing it. Typically, the hitch 20 is entrapped by pulling a wire snare 21 or loop tight around it; this snare 21 having been previously inserted through a catheter. The snare wire 21 may be fitted with magnets to assist in properly locating it over and around the hitch before pulling the snare tight.

Also, prior to pulling the snare tight, the snare 21 may be electrically powered in order to ablate away any ingrown tissue that may have formed around the hitch 20.

The above mentioned guiding elements may facilitate not only implantation of the anchoring device of the invention, but also, e.g. exchange of a depleted intracardiac device 9 while leaving the anchoring device in place. An explantation or exchange catheter may use the guiding elements to find the hitch 20 and, if necessary, may use blades or energy (e.g. RF) to remove encapsulation growth. The catheter may attach to the hitch 20, release the lock, e.g. between the device 9 and the receiving element 8, and remove the depleted device 9. Afterwards, another implantation catheter carrying a fresh intracardiac device 9 may be introduced in the patient, wherein the fresh device 9 is guided using the guiding elements 18, 19 to the anchor device of the invention, adjusted to get a tissue contact (e.g. good electrical signals, and locked into the anchoring device.

List of reference numerals

| | |
|---|---|
| 1 | right atrium |
| 2 | right ventricle |
| 3 | left atrium |
| 4 | left ventricle |
| 5 | left atrial appendage |
| 6 | pulmonary veins (x 4) |
| 7 | fixation element |
| 8 | receiving element |
| 9 | intracardiac pacing device |
| 10 | pacing electrode |
| 11 | sheath |
| 12 | spring finger receiving element |
| 13 | spring finger loops |
| 14 | mesh |
| 15 | electrode lead |
| 16 | further electrode |
| 17 | electrodes on spring finger loops |
| 18 | guiding element (on catheter) |
| 19 | guiding element (on receiving element) |
| 20 | hitch |
| 21 | snare |
| 22 | conductive contact element |
| 23 | guidewire |
| 24 | locking means (in receiving element) |
| 25 | tool (catheter) |
| 26 | replacement energy storage |

## Claims

1. A system for holding an active implant in an atrial appendage (5) of a heart, the system comprising an anchoring device and an active implant (9), wherein the anchoring device is coupled to the active implant (9), and wherein the anchoring device comprises a fixation element (7, 13, 14) which is configured to hold the anchoring device in the atrial appendage (5), wherein the anchoring device further comprises a planar structure (14) which is configured to enhance tissue ingrowth, and wherein the anchoring device is configured to close or occlude the atrial appendage.

2. The system according to claim 1, wherein the planar structure is designed as a mesh, a fabric, or a membrane.

3. The system according to claim 1 or 2, wherein said active implant (9) comprises a coating configured to inhibit or prevent formation of tissue on the active implant.

4. The system according to any one of the preceding claims, wherein the fixation element (7, 13, 14) has a basket-like or ball-like structure comprising one or more loops.

5. The system according to any one of the preceding claims, wherein the active implant (9) comprises
   - a housing,
   - - an electronic module which is arranged in the housing,
   - a first electrode (10) and a second electrode which are coupled to the electronic module and
   - optionally an energy storage which is arranged in the housing or in another housing.

6. The system according to any one of the preceding claims, wherein the active implant (9) is releasably fixed to the anchoring device.

7. The system of claim 6, wherein the anchoring device comprises a guiding element (19) for guiding a device, particularly the active implant (9), to the anchoring device, particularly comprising one or more conductive coils, one or more capacitors, one or more inductors, one or more RF chips, a funnel, one or more markers, wherein particularly the one or more markers are visible in fluoroscopy or ultrasound imaging.

8. The system according to any one of the preceding claims, wherein the anchoring device comprises a receiving element (8) configured to receive and hold the active implant.

9. The system according to claim 8, wherein the receiving element (8) comprises a first magnet and the active implant (9) comprises a second magnet.

10. The system according to claim 8, wherein the active implant (9) comprises one or more mechanical interference or retention elements (24) configured to releasably attach the active implant (9) in the receiving element (8), particularly one or more hooks configured to releasably hook in the receiving element (8).

11. The system according to any one of the preceding claims, wherein the active implant (9) comprises one or more electrically conductive contact elements (22), particularly configured to establish an electrically conductive connection to the anchoring device or the fixation element (8).

12. The system according to any one of the preceding claims, further comprising a third electrode (16) that is connected to the electronic module by a lead (15), wherein particularly the third electrode is configured to be arranged in a ventricle of the heart or in the coronary sinus.

13. The system according to any one of the preceding claims, further comprising a further device which is coupled to the anchoring device.

14. The system according to claim 13, wherein the further device is coupled to the active implant (9).

15. The system according to claim 13 or 14, wherein the further device is another active implant or an energy storage for the active implant (9).

16. The system according to any one of the preceding claims, wherein the anchoring element is configured as an antenna for emitting and/or receiving signals.

17. The system according to any one of the preceding claims, wherein the anchoring device comprises tissue removal means which are configured to remove tissue from the active implant.

18. A method for implanting an active implant, comprising the steps of:
- providing an active implant (9) which is coupled to an anchoring device, wherein the anchoring device comprises a fixation element (7; 13, 14) which is configured to hold the anchoring device in an atrial appendage (5) of a heart; and wherein the anchoring device further comprises a planar structure which is configured to enhance tissue ingrowth, and the anchoring device is configured to close or to occlude the atrial appendage, particularly a system according to any one of claims 1 to 17;
- arranging the anchoring device and the active implant (5) in the atrial appendage (5).

19. A method for implanting an active implant, comprising the steps of:
- providing an anchoring device, wherein the anchoring device comprises a fixation element (7; 13, 14) which is configured to hold the anchoring device in an atrial appendage (5) of a heart, wherein the anchoring device further comprises a planar structure which is configured to enhance tissue ingrowth, and the anchoring device is configured to close or to occlude the atrial appendage (5), particularly a system according to any one of claims 1 to 17;

- arranging the anchoring device in the atrial appendage (5); and
- arranging an active implant (9) in the anchoring device.

20. A method for exchanging an active implant or a part thereof, comprising the steps of
- providing an active implant (9) which is coupled to an anchoring device in an atrial appendage of a heart, wherein the anchoring device comprises a fixation element (7; 13, 14) which is configured to hold the anchoring device in the atrial appendage (5); and wherein the anchoring further comprises a planar structure which is configured to enhance tissue ingrowth and the anchoring device is configured to close or to occlude the atrial appendage (5), particularly a system according to any one of claims 1 to 17;
- decoupling and removing the active implant (9) or at least a part thereof (26), and
- arranging and coupling a replacement active implant (9) or a replacement part (26) corresponding the removed part.

21. The method according to claim 20, wherein the at least part of the active implant (9) is an energy storage (26) releasably attached to the active implant (9), the energy storage (26) is decoupled and removed from the active implant (9) leaving the active implant (9) in place, and wherein a replacement energy storage (26) in arranged and coupled to the active implant (9) left in place.

FIG. 1

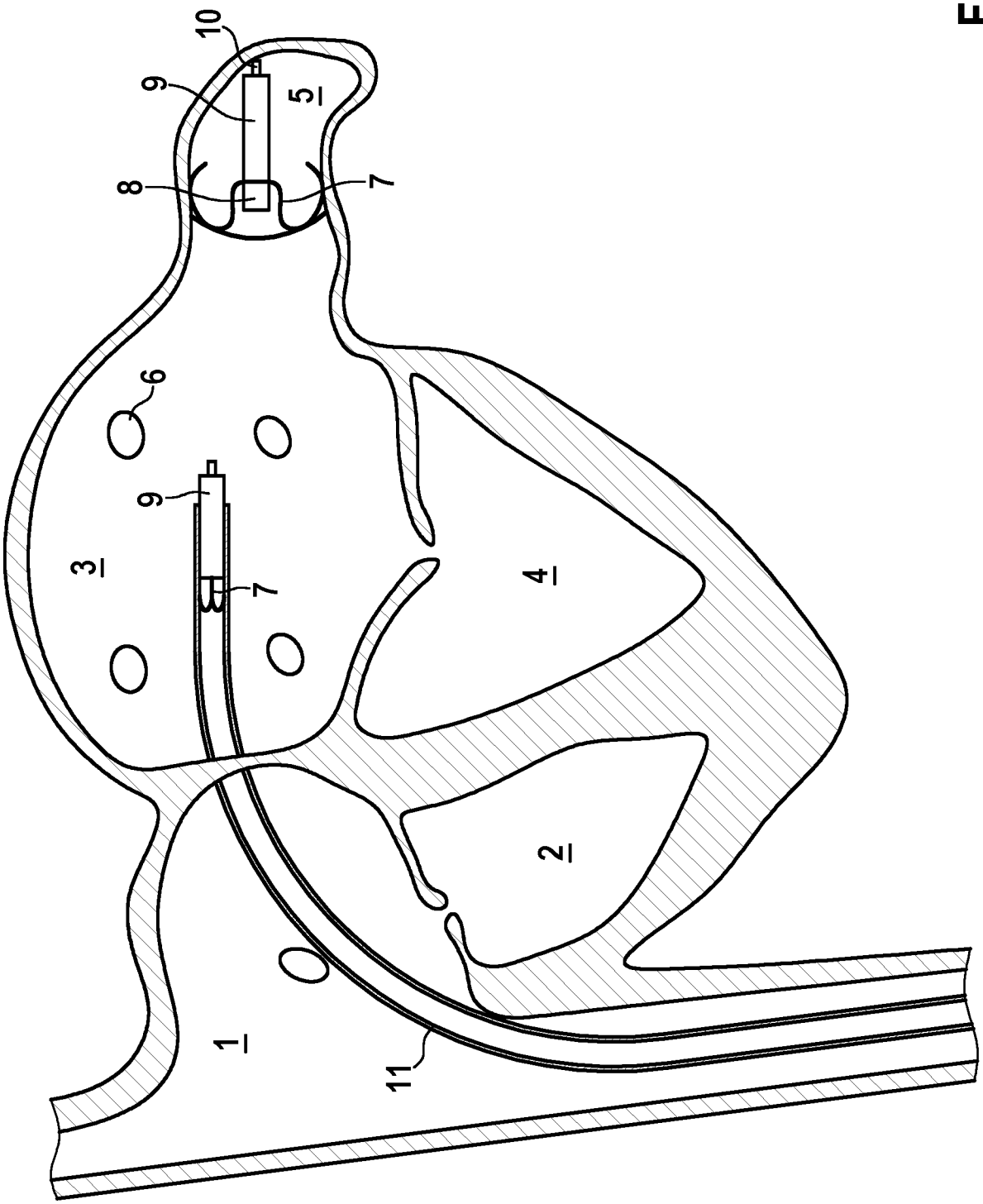
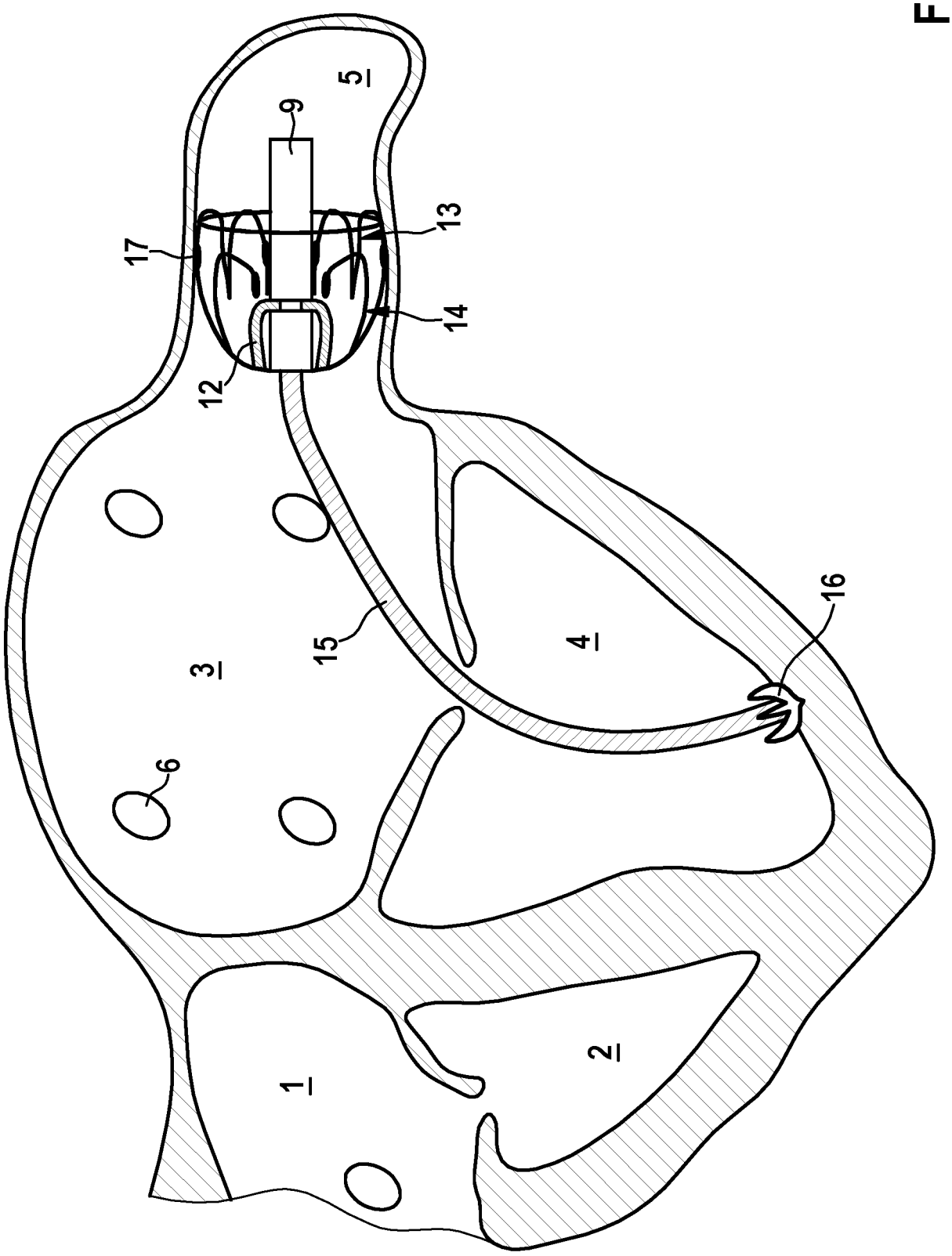


FIG. 2



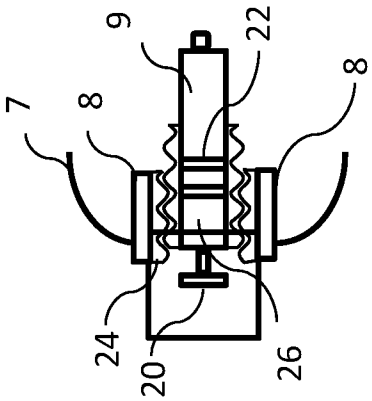



Fig. 3

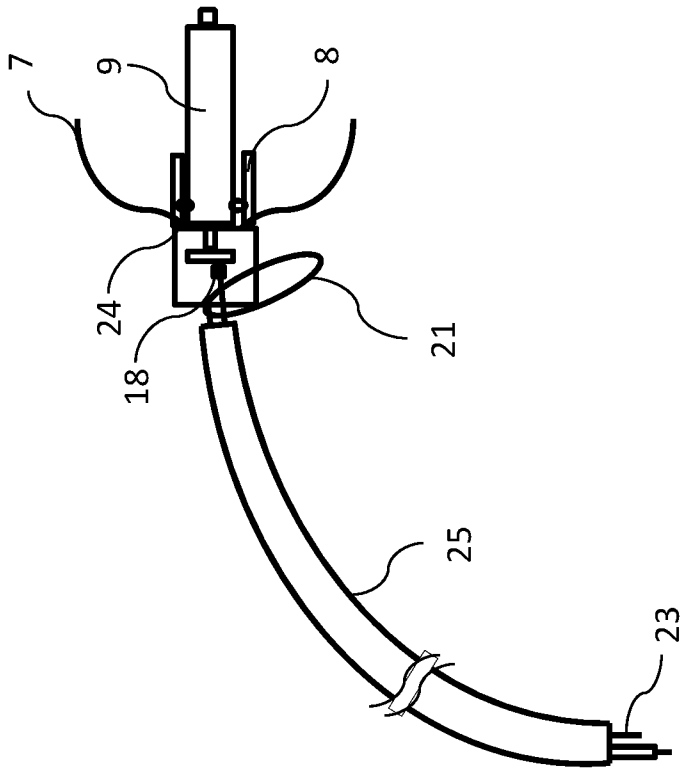



Fig. 4

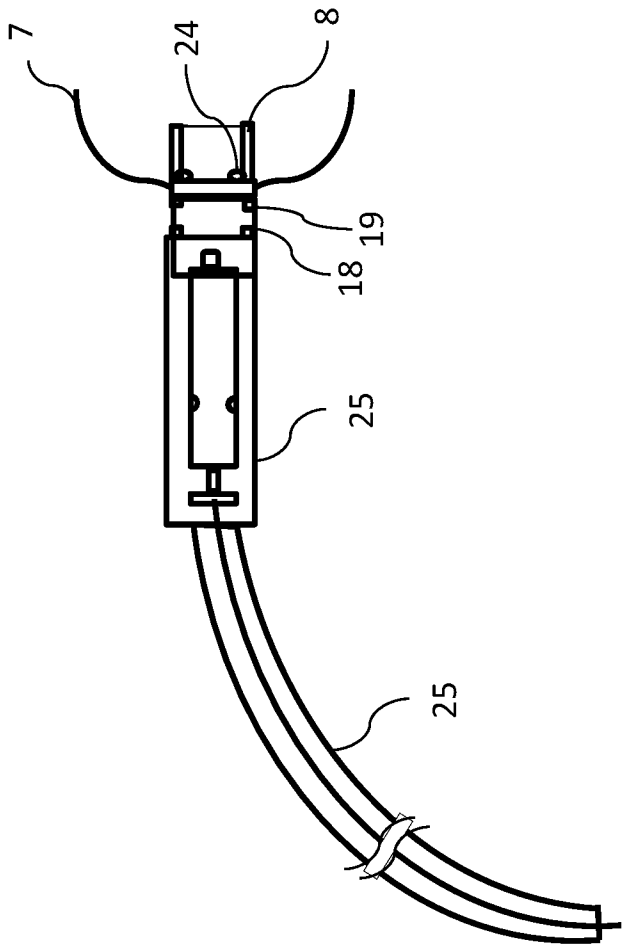



Fig. 5

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/076554

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/372 A61N1/375 A61B17/12
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. |
|---|---|---|
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| A | paragraphs [0072] - [0075] | 16 |
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| Y | abstract; figures 2A, 3A, 4A | 9,10 |
| A | paragraphs [0004], [0005], [0014], [0067] - [0073], [0078], [0089], [0104], [0112] - [0114], [0116] | 16 |
| | ----- | |
| | -/-- | |

[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 |
|---|---|
| 27 November 2020 | 09/12/2020 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>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/EP2020/076554

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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| A | US 2018/264272 A1 (HAASL BENJAMIN J [US] ET AL) 20 September 2018 (2018-09-20) paragraphs [0005] - [0019], [0068], [0075], [0116], [0117], [0122] | 1-16 |
| A | WO 2018/085545 A1 (ST JUDE MEDICAL CARDIOLOGY DIV INC [US]; BELK PAUL A [US]) 11 May 2018 (2018-05-11) the whole document | 1-16 |
| A | WO 00/27292 A1 (MV MEDICAL DEVICES INC [US]) 18 May 2000 (2000-05-18) page 3, lines 14-22; figure 1 | 1-16 |

1

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2020/076554

**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.: 18-21
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/EP2020/076554

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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