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Régnier et al.

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(54) **IMPLANTABLE CAPSULE FOR LEADLESS CARDIAC PACING**

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A61N 1/372	(2006.01)
A61B 5/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61N 1/0575*** (2013.01); ***A61N 1/3756*** (2013.01); ***A61N 1/37205*** (2013.01); ***B23K 26/21*** (2015.10); ***B23K 26/323*** (2015.10); *A61B 5/6882* (2013.01); *A61N 1/0573* (2013.01); *B23K 2203/05* (2015.10); *B23K 2203/14* (2013.01); *B23K 2203/24* (2013.01)

(58) **Field of Classification Search**

CPC A61N 1/0575; A61N 1/3756; A61N 1/37205; B23K 26/323; B23K 26/21

USPC 607/2, 116, 119, 120, 126, 127, 131

See application file for complete search history.

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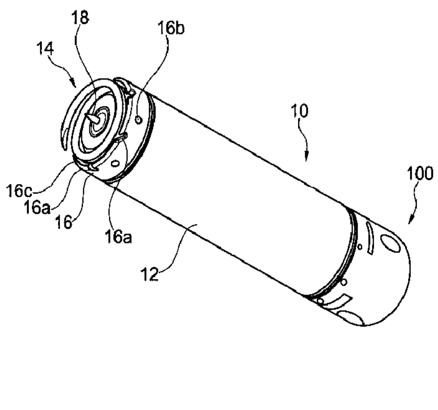
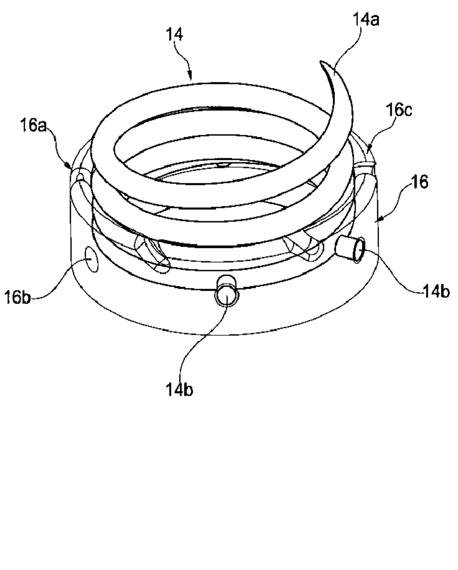
(57) **ABSTRACT**

The invention relates to an implantable capsule, particularly an autonomous capsule of cardiac stimulation, comprising a tubular body provided at the distal end of an anchoring element with a helical screw adapted to penetrate tissue a wall of an organ of a patient, the body housing a set of functional elements of the capsule. It comprises an annular support integral with the body and coaxial therewith, said support surrounding the base of the anchoring element and comprising a series of openings radially extending. The base of the anchoring element comprises a series of rods or tubes projecting in a generally radial direction, and engaged in said openings to thereby secure the anchoring element to the support.

16 Claims, 5 Drawing Sheets





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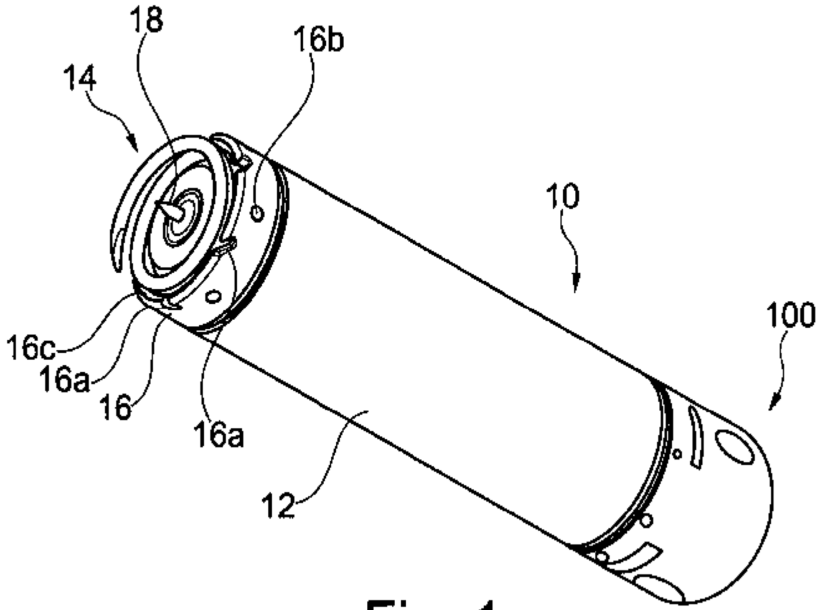
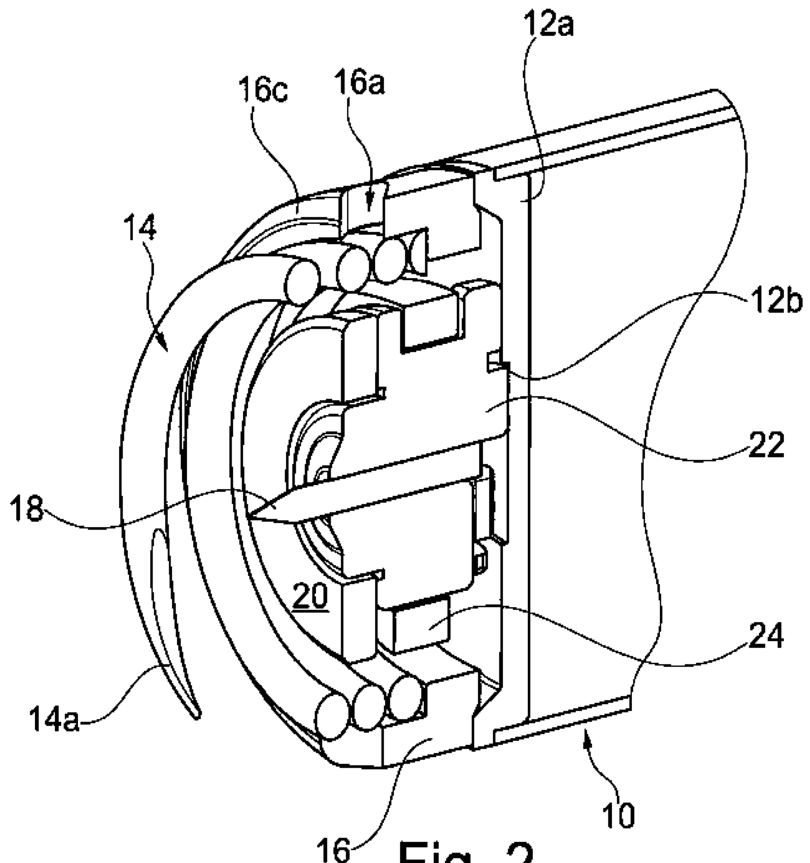

18
16b
14
10
100
16c
16a
16
16a
12

Fig. 1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16a
14
12b
22
18
20
24
14a
10
16

Fig. 2

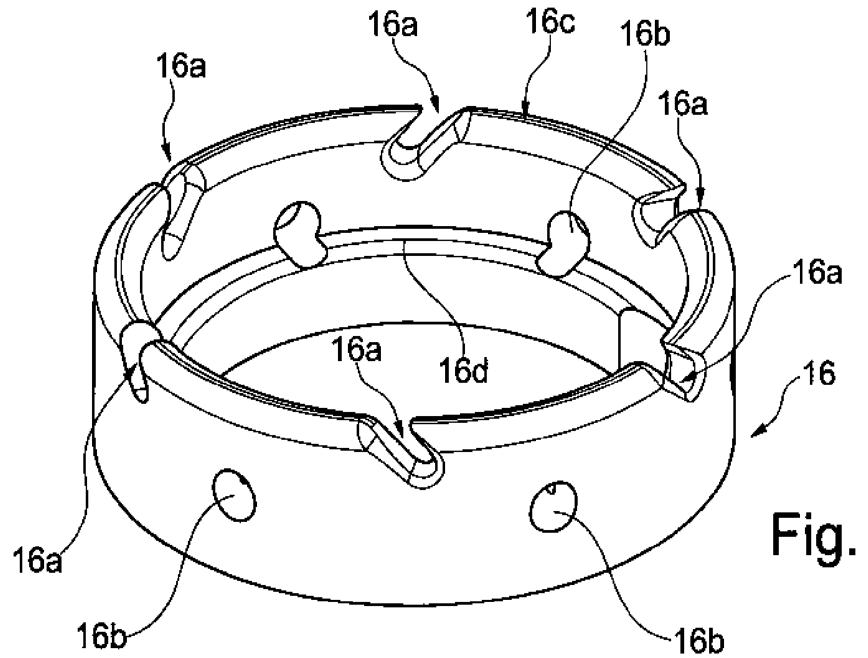

Fig. 3

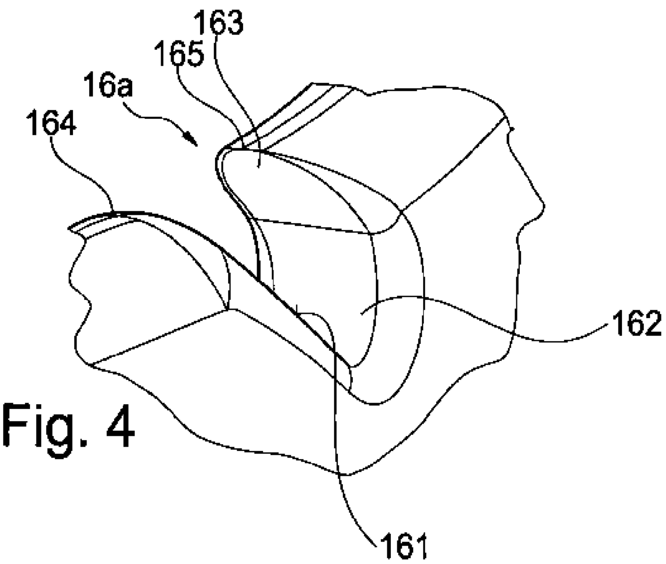

Fig. 4

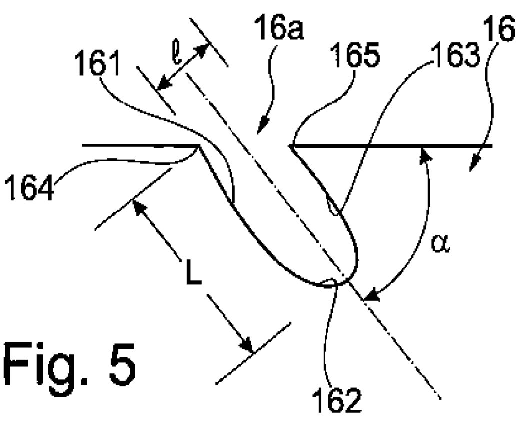

Fig. 5

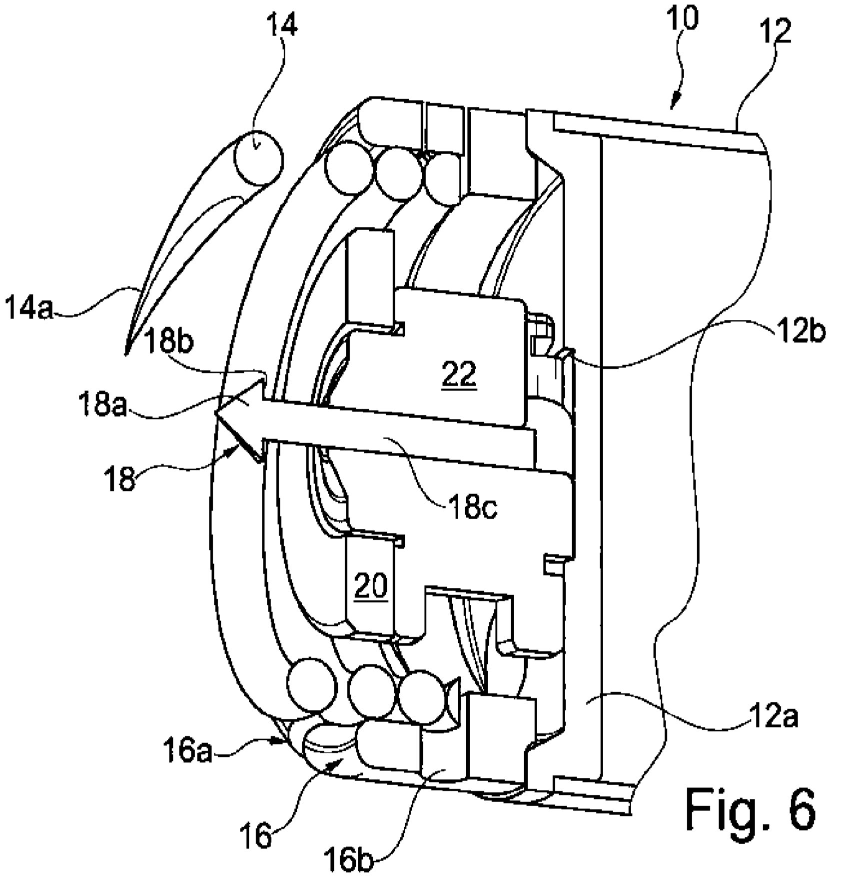
14
10
12
14a
18b
12b
22
18a
18
18c
20
12a
16a
16
16b

Fig. 6

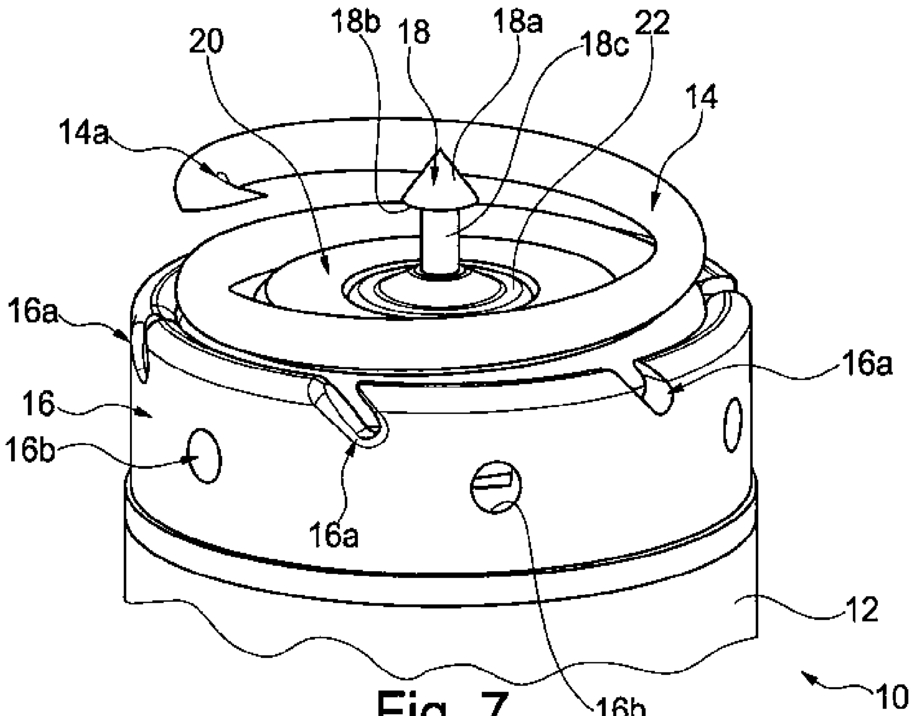
18b
18
18a
18c
22
20
14
14a
16a
16a
16
16b
16a
12
16b
10

Fig. 7

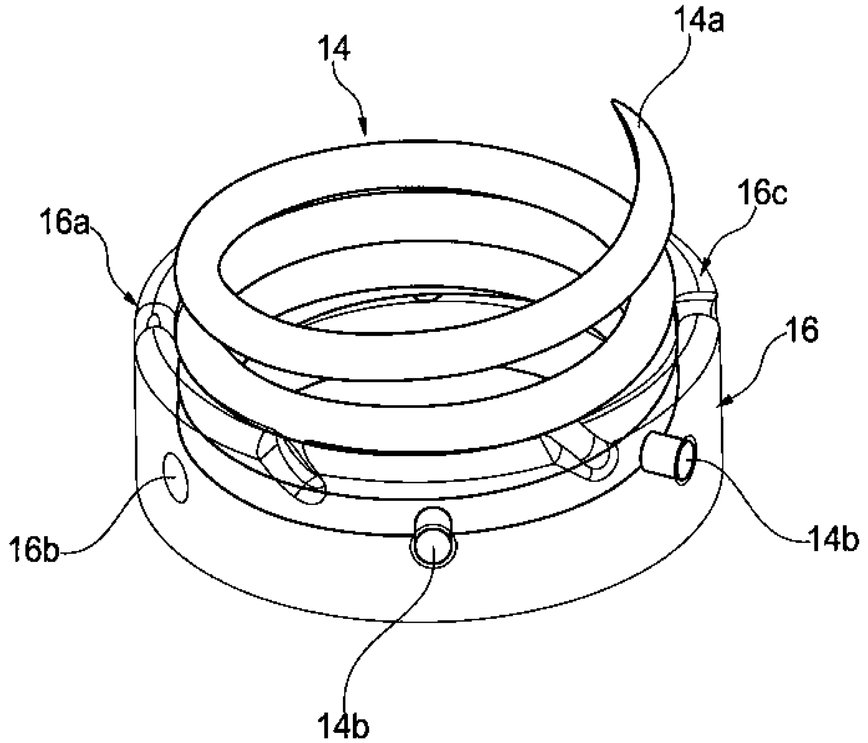

Fig. 8

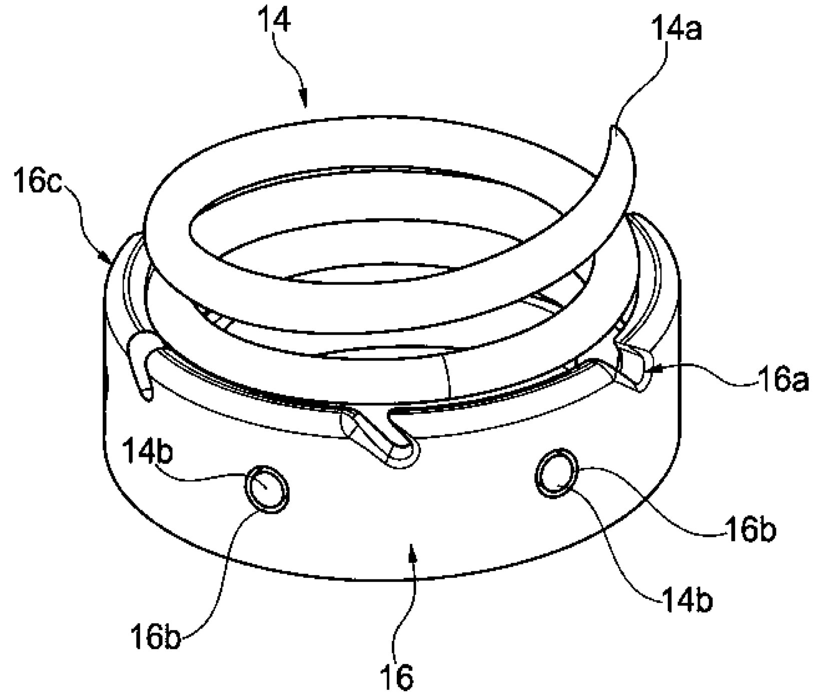

Fig. 9

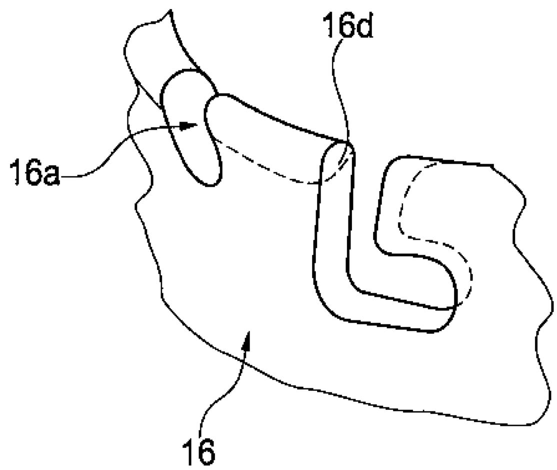

Fig. 10

IMPLANTABLE CAPSULE FOR LEADLESS CARDIAC PACING

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application claims the benefit of and priority to French Patent Application No. 1455898, filed Jun. 25, 2014, which is hereby incorporated by reference herein in its entirety.

BACKGROUND

The invention relates to "active implantable medical devices" as defined by Directive 90/385/EEC of 20 Jun. 1990 of the Council of the European Communities, specifically to devices that continuously monitor heart rhythm and deliver to the heart if necessary stimulation, resynchronization and/or defibrillation pulses in cases of arrhythmia detected by the device.

The invention relates especially, but is not limited to, those devices that are in the form of an autonomous capsule intended to be implanted in a heart chamber (atrium or ventricle, right or left). These capsules are free of any mechanical connection to an implantable (such as a housing of the stimulation pulse generator) or non-implantable (external device such as programmer or monitoring device for patient remote monitoring) main device. For this reason they are called "leadless capsules" to distinguish them from electrodes or sensors disposed at the distal end of a conventional probe (lead), which is traversed throughout its length by one or more conductors connecting the electrode or sensor to a generator connected to an opposite, proximal end of the lead.

EP 2394695 A1 (Sorin CRM) describes an autonomous intracardiac capsule, and a method to implant it to the selected detection/stimulation site and reposition it if necessary.

Note, however, as will be understood on reading the description, that the autonomous nature of the capsule is not inherently a necessary feature of the invention, and that the latter can be both applied to capsules permanently mounted at the distal end of a lead.

An implantable capsule includes a body housing the main components of the device (electronic circuits, power source, stimulation electrodes, etc.) and a base secured to the body and rigidly supporting a fixing means to the wall.

In the case of cardiac leads, two types of fasteners are known and conventionally employed: fixation with "barbs" is the oldest and is still used marginally, but the leads based on a fixing screw have supplanted barb leads and currently represent the majority of the market. They allow a generally robust and effective fixation. The screw is a projecting helical screw extending axially the capsule body and adapted to penetrate the heart tissue by screwing in the implantation site, in the same method as the conventional screw leads.

The WO 2012/088118 A1 and EP 2537555 A1 describe such structures of leadless capsules provided with a helical screw for attachment to the wall of the heart.

However, the fixing of such devices is still an important point to the extent that accidental detachment of the capsule would cause the latter to be released into the heart chamber and then transported by the blood in the venous or arterial system. Complication risk to the patient would be extremely high, as well as the risk of cardiac system injury which can be generated by the end of the fastening system or other projecting regions of the implant such as a needle electrode or a projecting ridge.

More than a lead device, an autonomous device undergoes stresses and movements generated by the heart wall, as it does not benefit from the axial holding force from the lead body.

SUMMARY

To fulfill its function of permanent anchoring, the fastening system must be particularly safely secured to the body both practically and industrially. One aspect of the present invention provides an implantable autonomous device that meets that need.

More specifically, one embodiment of the invention provides an implantable capsule, including an autonomous capsule for cardiac pacing, including, in a manner known per se a tubular body provided at its distal end with a helical screw anchoring element adapted to penetrate in the tissue of a wall of an organ of a patient, the body housing a set of functional elements of the capsule.

In one embodiment of the invention, the capsule includes a ring-shaped support secured to the body and generally coaxial therewith, this support surrounding a base of the anchoring member and including a series of holes extending radially. The base of the anchoring element includes a series of rods or tubes projecting in a radial direction and engaged in said holes to thereby secure the anchoring member to said support.

According to various advantageous embodiments:

- The capsule further includes a pharmaceutical product elution ring, arranged inside said support, and holes are provided in a number superior than the number of rods or tubes, so as to promote the flow of the product outwards the support;
- The rods or tubes are reported on the basis of the anchoring element by laser welding, or attached to the support material at the holes by laser welding;
- The capsule includes a weld fixing the support to the body;
- The body and the support are made of stainless steel, while the anchoring element and the rods or tubes are of a titanium alloy;
- The holes are angularly regularly distributed at the periphery of the support, the rods or tubes being especially possibly located in two adjacent holes, the other holes being free;
- The holes have a section corresponding to that of the rods or tubes; and
- The holes includes notches in the general shape of L extending from a free face of the support, allowing a bayonet mounting of the anchoring element provided with rods or tubes in the support.

The invention also relates to a method of assembly of an implantable capsule as above, including the steps of:

a) fixing to the body, by welding in a position coaxial with said body, an annular support having a series of holes extending radially,

b) engaging a base of the anchoring element inside the support,

c) engaging in the holes of the support a series of rods or tubes,

d) welding the rods or tubes on the basis of the anchoring element, by laser welding through the inside of the support, and

e) welding the rods or tubes to the support material in their respective holes by laser welding, externally to the support.

In a variant, the method includes the following steps:

a) fixing to the body, by welding in a position coaxial with the body, an annular support having a series of holes extending radially and formed by notches in the general shape of L,

b) welding a series of rods or tubes on the basis of the anchoring element, by laser welding, the rods or tubes extending radially,

c) pre-assembling the anchoring element, by its base, to the support, by bayonet mounting involving the rods or tubes and the notches, and

d) welding the rods or tubes to the support material in the notches, by laser welding, externally to the support.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features, characteristics and advantages of the present invention will become apparent to a person of ordinary skill in the art from the following detailed description of preferred embodiments of the present invention, made with reference to the drawings annexed, in which like reference characters refer to like elements and in which:

FIG. **1** is an overall perspective view of an implantable capsule according to one embodiment of the invention.

FIG. **2** is a perspective view and in half-section of a distal region of the capsule of FIG. **1**.

FIG. **3** is a perspective view of an anchoring screw supporting the capsule of FIGS. **1** and **2**.

FIG. **4** is a perspective view of a detail of the support of FIG. **3**.

FIG. **5** is a side view of the detail of FIG. **4**.

FIG. **6** is a perspective view and in half-section of a distal region of a capsule incorporating an alternative embodiment.

FIG. **7** is a perspective view, in another direction, of that distal region.

FIG. **8** is a perspective view of a screw-support assembly according to another aspect of an implantable capsule, the screw being visible in transparency.

FIG. **9** is a perspective view of the screw-support assembly of FIG. **8**.

FIG. **10** is a partial perspective view of an alternative arrangement of the support for the fixing of the screw on the support.

DETAILED DESCRIPTION

An exemplary embodiment of the device of the invention will now be described, along with examples of realization of an implantable capsule.

Referring firstly to FIG. **1**, an implantable capsule **10** is shown, here an autonomous capsule for cardiac stimulation, including a capsule body **12** and an anchoring member of helical screw-type **14**.

The screw **14** is formed by a helically wound wire with a right screw pitch and is mounted on a screw support **16** incorporating arrangements ensuring the irreversibility of the anchoring as will be seen hereinafter.

The screw **14** is rendered permanently secured to its support **16**, for example by laser welding according to the distributed welding points.

The assembly is then permanently secured to the body of the capsule **12** by a laser welding bead.

Note that the material of the screw **14** and of its support **16** may be different, for example a platinum/iridium **90/10** couple for the screw **14**, and titanium for the support **16**. It is indeed possible, as will be seen below with reference to the embodiment shown in FIGS. **8** and **9**, to implement an effective method of assembly of these elements even if they are made of heterogeneous materials.

The various parts are made, for example, of biocompatible metal alloys such as stainless steel or a titanium alloy, preferably a biocompatible titanium alloy for the capsule body **12** and the support **16**.

The arrangements for the irreversibility of fastening include notches or recesses **16***a* formed in the support **16**.

The fastener assembly consisting of parts **14**, **16** has a diameter preferably equal to that of the body of the implant, typically 6 to 7 mm, and a slightly lower axial length, typically between 4 and 6 mm. The screw **14** defines a space occupied by another sub-assembly of the device, here a sub-assembly of stimulation electrodes.

The fastening system is designed to secure the implant in a stable and a sustainable manner over time through the helical screw **14** forming a spring with scalable turns and ending in a point capable of puncturing the endothelium and of penetrating muscle tissue. This presses the cardiac wall on the generally annular end face of the support **16**, substantially at the same position (in the axial direction) than the inner bearing surface of the electrode system.

In more detail, the screw support **16** presents on said end face **16***c* a series of recesses **16***a* which perform the function of irreversibility once in contact with the endothelium. In this position, the fastening system is unremovable. Under the action of the screw **14** which acts as a tension spring carrying an axial retaining force, the cardiac wall is pressed against the face **16***c* of the screw support **16** and locally anchors in the recesses (here six in number, uniformly distributed) by the above-mentioned spring effect.

As will be discussed in more detail later, the six recesses may be defined as sharp, but shallow edges in their (circumferentially) area opposite the direction of screwing of the helix and then provide six punctual anchoring points distributed on the endothelium (mutual spacing of 60° in this example), which provide the irreversibility of screwing to anchor the capsule.

Now in more detail and with reference to FIG. **2**, a stimulation subassembly is observed, constituted by two electrodes **18** and **20** maintained by an electrode support **22** which also supports at its periphery a ring **24** for elution of a steroid product.

The support **22** is positioned coaxially with the screw support **16**, inside the latter, and fixed by adhesive or other suitable methods on a wall **12***a* closing the interior of the capsule body **12** at its distal, screw side, end, the support being accurately located thanks to a circular shoulder **12***b* provided on the outer face of said wall.

The central pacing tip electrode **18** is fixed (by crimping, bonding, etc.) in the center of the support **22** and electrically connected to the internal electronics of the capsule accommodated in the body **12** via a micro-feedthrough. The second electrode **20** here has the form of a washer positioned and fixed, for example by bonding, on the external face of the support **22** and is also connected through a micro-feedthrough to the internal electronics.

The ring **24** is impregnated with a steroid such as dexamethasone and is positioned under the electrode **20**. The steroid product can diffuse through the space remaining between the screw **14** and the second electrode **20** and come into contact with the cardiac wall, which reduces tissue inflammation during the first weeks after implantation.

The electronics associated with the electrodes can implement, in the case of cardiac pacing, functions of sensing and pacing, the described structure ensuring a reliable and permanent contact between the electrodes **18**, **20** and the tissues.

The helix screw **14** is constituted of a metal wire with a diameter of about 0.5 mm, with a winding diameter typically about 5 mm and preferably identical to the body **12** of the device.

The screw includes a planar base followed by two adjacent turns and a final turn extending, e.g., approximately on 1.5 turns with an inter-coil space of the same order of magnitude as the diameter of the wire.

The free end of the screw **14** is refined, in this case by machining in two mutually orthogonal planes, creating a perforating, but not sharp tip **14***a*. The purpose of this tip is to allow crossing the endothelium and then of easily penetrating into the cardiac muscle, while creating minimal tissue damage. The helix screw **14** here is made of implantable and biocompatible stainless steel 316L or of any other equivalent material, which delivers a stiffness of about 0.1 N/mm (linear spring stiffness, as measured by tensile or compression using a dynamometer on a 1 mm stroke).

This gives the screw an axial flexibility which gives it a spring effect, operating a tensile effort to maintain firm contact between the support **16** and the cardiac wall. Thus, during the penetration of the screw **14** in the muscle, the screw deforms axially until contact with the free edge **16***c* of the support **16** with the endothelium. The spring effect of the screw will then axially compress the endothelium and the muscle between the coils and create a wedging effect. In addition, the close proximity of the coils and their tensile effect on the endothelium force the input thereof in the anti-unscrewing notches. During this movement, the pacing tip electrode **18** pierces the endothelium and thus comes into contact with the excitable cells of the cardiac wall.

Other coil configurations are of course possible, but it is advantageous to provide a spacing between turns which increases from the base of the screw (wherein as we saw the spacing may be zero) and the tip **14***a* of the screw. This helps promote the axial tensile force applying the support **16** against the cardiac wall.

Furthermore it is understood that the electrode **18** contributes to the fastening of the capsule while providing reliable and continuous contact with the compressed tissues by the axial force of the screw **14** towards the support **16**.

Such a configuration is particularly suitable for low energy stimulation, with a needle length of the order of 1.2 mm and a diameter of the order of 0.4 mm, a surface area of the order of 1 mm^2.

Referring particularly to FIGS. **3**-**5**, the support **16** of the screw **14** has as stated a face or support edge **16***c*, preferably with a slightly rounded profile, from which six recesses **16***a* for performing six sharp edges **165**, highly localized and highly punctual (see in particular FIGS. **4** and **5**) ensuring the irreversibility of the screwing of the capsule made as described above, are formed in an oblique direction. Localized perforation of endothelium is achieved by the sharp edges **165**, the other edges which form the boundaries of the notch being deliberately very rounded so as not to spread or enlarge the piercing of the endothelium during unscrewing effort.

The support surface supporting unscrewing constraints being maximized, the risks of tearing of the endothelium are minimized.

Preferably, but not limited to, the relative surface area occupied by the recesses of the support surface **16***c* is from 20 to 40% of this surface, more preferably around 30%, which allows to limit the traumatic effect of the sharp edges **165** by limiting the penetration of tissues into the recesses **16***a*, while ensuring a good attachment of said edges **165** in the endothelium, and thus the effectiveness of the anti-unscrewing function.

The dimensions of the recesses may vary. For example and with reference particularly to FIG. **5**, the width l may be of the order of 0.3 to 0.8 mm, the depth or the length L can be between 0.5 and 1 mm, and their inclination α may be between 20 and 60°, and preferably close to 45°.

In an advantageous implementation variant, the recesses **16***a* defining the sharp edges **165** are made of a biodegradable insert on the support **16**. The material used to make this patch may especially be a bioabsorbable biopolymer such as polylactide (PLA), polyglycolide (PGA) and polylactide-co-glycolide (PLGA) or any other equivalent, implantable, absorbable material in body. The anti-unscrewing function is then provided for a predetermined period, for example from 3 to 12 months, during which the fibrosis progressively overlap the base of the capsule.

Then, in the long term it will become easier to remove the capsule once the anti-unscrewing function has disappeared.

Referring now to FIGS. **6** and **7**, we will describe an alternative embodiment of the tip electrode **18**. The latter in this case has an enlarged head **18***a*, preferably of conical shape, joining at its base, an annular returning shoulder **18***b*, a narrower rod **18***c*.

The shoulder **18***b* has a surface which mechanically strengthens the stability of the capsule on the cardiac wall, participating in the retention of the tissue compressed by the axial force of the screw **14**.

In this example, the shoulder **18***b* has a ring width of the order of 0.2 mm. This value can vary depending on requirements and the size of the capsule, typically between 0.05 and 1 mm.

The cone angle is in turn included between about 30 and 60°, and typically around 50°.

A permanent assembly solution of the screw **14** on its support **16** will now be described, this solution being implemented independently of the anti-unscrewing and attachment characteristics to the cardiac wall, as detailed in the foregoing.

The problem solved by this solution is to assemble a screw **14** made of stainless steel or of other not directly sealable material on the titanium housing of the capsule.

Thus, referring to FIGS. **8** and **9**, the support **16** has a configuration including a plurality of through orifices **16***b*, having a cross section approximately corresponding to that of the rods or tubes and for example circular, formed in the wall of the support **16**. These orifices receive counterpart rods or tubes **14***b* formed on the periphery of the base of the screw **14**, corresponding angular locations. In this example, two through orifices **16***b*, spaced for example by 60°, and two corresponding tubes or rods **14***b*, are provided.

Specifically, first, the screw **14** slides under slight tightening into the support **16** until the axial abutment against a shoulder formed in the central bore of the support. Several radial through holes **16***b* are arranged in the support **16**, which coincide with the part of the screw with contiguous coil. A rod or a tube **14***b* of the same material as the screw, or a laser-weldable material to the screw material, is then inserted into each of these side holes. In the (preferred) case of a tube, the bore of the tubes then leads to the turns of the screw. A laser shot through these holes then allows direct tube/screw welding ensuring the requirements of a good laser welding, namely: i) material compatibility, ii) direct contact and iii) visual access for shooting and quality control.

This welding being done, the screw is locked in translation and rotation in its support by mechanical anchoring and without direct laser welding, which leaves a lot of freedom in the combination of support/screw materials. Other significant advantages of this solution are the small footprint and very low complexity of machining.

According to an alternative embodiment illustrated in FIG. **10** of the drawings, a bayonet-type mounting may be provided between the screw **14** and its support **16**, the screw **14** then having at its base two rods or tubes such as **14**_b_, preferably diametrically opposed, and the support **16** having in two diametrically opposite regions notches **16**_d_ in the general form of a L extending from the free face of the support **16**. This allows, prior to laser welding, the mounting of the screw **14** by axial translation for engagement of the rods or tubes in the notches, followed by a rotation for the locking of the rods or tubes at the bottom of the notches. It can exist, in addition to these two notches, other notches **16**_d_ and/or other circular holes **16**_b_.

In the first case described above, the assembly method of the capsule preferably includes the steps of:

a) fixing the support **16** to the body by welding,

b) engaging the base of member **14** within said support,

c) engaging the rods or tubes **14**_b_ in the orifices **16**_b_,

d) welding the rods or tubes on the base of member **14**, by laser welding through the inside of the support, and

e) welding the rods or tubes in their respective orifices, by laser welding, externally to the support.

Note that the "welding" step d) should not be understood in the narrow sense of mechanical welding with melting of the material of two separate pieces, but as an operation to collapse the material of the rod or of the tube within the housing supporting the mechanical connections and to enhance the atraumatic function by removal of the protruding shapes.

In the case of the variant of FIG. **10**, the method preferably includes the steps of:

a) fixing the support **16** provided with notches **16**_d_ to the body by welding,

b) welding the rods or tubes on the base of member **14** by laser welding,

c) pre-assembling the anchoring element with its base in the support, by bayonet-type mounting involving said rods or tubes and the said notches, and

d) welding the rods or tubes in the notches, by laser welding, externally to the support.

Advantageously, orifices **16**_b_ or **16**_d_ in a greater number to the number of rods or tubes **14**_b_ of the screw **14** are present. In this method, the orifices **16**_b_ or **16**_d_ remaining free facilitate the diffusion of the steroid product delivered by the ring **24** radially towards the cardiac wall.

In another variant, it is planned that the notches **16**_d_ for such a bayonet type mounting are formed to participate in an anti-unscrewing function as described above.

The various components and parts described above may be made by machining or other shaping in accordance with conventional techniques.

Moreover, it is planned as described above that the support **16** surrounds the base of the anchoring element, but alternatively that the base of the anchoring member surrounds the support, in which case a skilled-in-the-art person will make necessary modifications, in particular with regard to the positioning of rods or tubes **14**_b_ for fixing between the anchoring element and support.

The capsule can be placed by the practitioner according to the method described in particular in EP 2394695 A1, and also extracted using a known technique, the proximal portion **12** of the body of the capsule being arranged in an appropriate method.

The invention is not limited to the attachment of an autonomous stimulation capsule in a cardiac wall of the human body, but can be implemented in other implantable systems, whether they are autonomous or contained in a lead tip. Depending on the nature of the attachment wall in question, the lengths of the helix and optionally of the electrode can be easily adapted by a skilled in the art person, without degrading the fixing and irreversibility performances.

What is claimed is:

1. An implantable capsule including an autonomous capsule for cardiac stimulation, comprising:

a tubular body;

an anchoring element with a helical screw (**14**) adapted to penetrate into a tissue of a wall of a body of a patient;

a support coupled to the body and generally coaxial therewith, the support surrounding a base of the anchoring element and comprising a series of openings extending radially through the support,

a series of rods or tubes extending from a base of the anchoring element, the series of rods or tubes projecting in a radial direction and engaged in the openings to thereby secure the anchoring element to said support.

2. The capsule of claim **1**, further comprising a drug diffusion ring disposed within the support and wherein the number of openings is greater than the number of rods, so as to promote the movement of a drug towards the outside of the support.

3. The capsule of claim **1**, wherein the rods are welded to the anchoring element.

4. The capsule of claim **1**, wherein the rods are welded within the openings.

5. The capsule of claim **1**, wherein the support is welded to the body.

6. The capsule of claim **1**, wherein the body and the support are made of stainless steel, while the anchoring element and the rods are made of titanium alloy.

7. The capsule of claim **1**, wherein the openings are evenly distributed around the periphery of the support.

8. The capsule of claim **7**, wherein the rods are located in two adjacent openings, the other openings being free.

9. The capsule of claim **1**, wherein the openings have a cross section corresponding to the outer perimeter of the rods.

10. The capsule of claim **1**, wherein the openings comprise notches in the general form of a L extending from a free face of the support, allowing a bayonet mounting of the anchoring element in the support.

11. The capsule of claim **1**, wherein rods are hollow such that the rods are tubes.

12. The capsule of claim **1**, wherein the support is annular.

13. A method of assembling an implantable capsule such as a pacemaker autonomous capsule, the capsule comprising a tubular body provided at the distal end of an anchoring element with a helical screw adapted to penetrate into a tissue of a wall of an organ of a patient, the body housing a set of functional elements of the capsule, the method comprising the steps of:

a) fixing to the body, by welding in a position coaxial with said body, an annular support having a series of openings radially extending therein;

b) engaging a base of the anchoring element within said support;

c) engaging in the openings of the support a series of rods or tubes;

d) welding the rods or tubes on the base of the anchoring element, by laser welding through the inside of the support; and

e) welding the rods or tubes to the support material in their respective openings by laser welding externally to the support.

14. The method of claim **13**, wherein the body and the support are made of stainless steel, while the anchoring element and the rods or tubes are made of titanium alloy.

15. A method of assembling an implantable capsule such as a pacemaker autonomous capsule, said capsule comprising a tubular body provided at the distal end of an anchoring element with a helical screw adapted to penetrate into a

tissue of a wall of an organ of a patient, the body housing a set of functional elements of the capsule, the method comprising the steps of:

a) fixing to the body by welding in a position coaxial with said body, an annular support having a series of openings extending radially and formed by L-shaped notches,

b) welding a series of rods or tubes on a base of the anchoring element by laser welding, said rods or tubes radially extending outwardly from the anchoring element;

c) pre-assembling the anchoring element, by its base, to the support, by bayonet mounting the rods or tubes into the notches; and

d) welding the rods or tubes to the support material in the slots, by laser welding externally to the support.

16. The method of claim **14**, wherein the body and the support are made of stainless steel, while the anchoring element and the rods or tubes are made of titanium alloy.

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摘要(译)

本发明涉及一种可植入的胶囊，特别是一种心脏刺激的自主胶囊，包括设置在锚固元件远端的管状体，该管状体具有螺旋形螺钉，该螺旋形螺钉适于穿透组织的患者器官的壁，该主体容纳胶囊的功能元素集。它包括与主体一体并与其同轴的环形支撑件，所述支撑件围绕锚固元件的基部并包括径向延伸的一系列开口。锚固元件的基部包括一系列沿大致径向方向突出的杆或管，并且接合在所述开口中，从而将锚固元件固定到支撑件上。