

ELECTRODE LEAD WITH CONTINUOUSLY VARIABLE FIXATION LENGTH

TECHNICAL FIELD

The invention relates to an electrode lead that is connectable with a pulse generator and that has electrodes to make contact with body tissue for cardiac resynchronization therapy (CRT).

BACKGROUND

An especially simple fixation technique to avoid dislocations of such electrode leads in the coronary sinus area is to wedge the distal end of the lead body in a vessel. This involves pushing the electrode lead forward, for example in the vein branches of the coronary sinus, until the distal end of the lead body gets stuck in the tapering vein and assumes a “wedge position”. In this position, the vein is occluded by the electrode lead.

However, the possibility of secure fixation of the electrode lead by means of such a wedge position is strongly dependent on the geometry (e.g., the course, length, and diameter, etc.) of the target vein in the coronary sinus. Therefore, the final position of the stimulation and/or sensing electrode(s) is determined for the most part by the geometry of the target vein, and does not necessarily correspond to the best place for the therapy.

For the printed prior art, please refer, for example, to WO 98/42403 A1 or US 5,170,802 A. These publications disclose a fixation device with a so-called “stent”, which is expanded if the electrode lead is located at the desired position in the vessel. Expansion of the stent structure clamps the lead body in the position. The disadvantage of this solution is that the fixation is not reversible, which makes it difficult to detach the electrode lead and move it to a different place after a first fixation, which is sometimes necessary, and also makes it difficult to remove the electrode lead.

WO 94/07564 A1 discloses a solution to the problem of moving the electrode lead to a different place, which involves fixing the electrode lead by an expandable or self-expanding

wire basket. The disadvantage of this design is that the wires cut into the vascular wall, and thus can be very traumatic.

Finally, US 5,411,546 A1 shows various solutions for fixation in a vessel, for example wire helices that are reversibly extendable out of the catheter sheath and that can be withdrawn back into it. However, the small diameter of the wires and the resulting small contact surface between helices and vascular wall, and the only limited tension force with which the helices may press against the vascular wall in order not to damage the latter makes the fixation not very reliable. The wire constructions further disclosed in the publication are – as was already mentioned above – highly traumatic. This published prior art also shows a so-called “sail design”, which once again is not reversible.

Please also refer to US 2006/0036307 A1. These disclose implantable cardiovascular pacemaker or defibrillator electrode devices, which comprise a long, stretched-out tubular electrode body and a fixation zone in the distal end area of the electrode body. The fixation zone has an outwardly closed peripheral sleeve and serves for detachable fixation of the electrode device in a body lumen, by being reversibly expandable. The expansion and contraction are controlled by expansion means arranged in the fixation zone.

In addition to these features, EP 0 546 414 A1 shows an electrode device in which the expansion means are formed by pneumatic or hydraulic pressurization, with the help of which the flexible wall of the electrode body in the fixation zone is reversibly expandable. However, it is difficult to produce a wall that is permanently sealed, so that it has been found that over time the mentioned solutions lose their expanded form, and thus the fixation. Furthermore, the expansion force of the flexible wall is limited.

SUMMARY

An aspect of the invention is defined in the independent claim. Some optional features of the invention are defined in the dependent claims. Thus, an improved electrode lead may be provided.

In one exemplary arrangement, there is an electrode lead for the coronary sinus with:

- a lead body that is preferably long and stretched-out, in particular one that extends along a longitudinal axis, the lead body having a distal section for insertion into the coronary sinus, and
- at least one electrode to make contact with body tissue, the at least one electrode being arranged on the distal section of the lead body.

The electrode lead may have a fixation device to fix the electrode lead in a blood vessel, this fixation device being extendable out of the lead body, in particular extendable in the direction of the longitudinal axis.

This fixation device is preferably variably extendable out of the lead body, so that a section that is extended out of the lead body has an adjustable length (in particular, in the direction of the longitudinal axis).

In at least one exemplary arrangement, the proximal end or the proximal section of the lead body is, in particular, that end or that area through which the lead body will be or has been connected with a pulse generator. Accordingly, the distal end or the distal section of the lead body is, in particular, that end or that section of the lead body that is farther away from the pulse generator.

The electrode lead can optionally comprise two or more electrodes to make contact with body tissue, the at least two electrodes being arranged on the distal section of the lead body, in particular being arranged spaced apart from one another along the longitudinal axis. A second electrode also allows a bipolar stimulation of the tissue, along with the unipolar stimulation.

Given the (optimal) position of the at least one electrode, the current techniques may advantageously simultaneously allow, by the distally extendable fixation device, secure fixation of the electrode conductor in a target vein of the coronary sinus.

This makes it possible to select, in each case, an optimal electrode position and simultaneously an optimal fixation position of the electrode conductor or the fixation device.

This also means that the current techniques may make it possible to eliminate the otherwise necessary selection of the fixation variant and, in the case of bipolar stimulation, the separations of the electrodes from one another. In particular, the variability of the fixation device may make it possible to eliminate the frequent use of leads with 4 electrodes, which offers a larger selection of electrode positions when non-variable fixation is used, however is less economical due to the larger number of electrodes.

Furthermore, the current techniques may advantageously offer the possibility of using the same electrode conductor if it is necessary to select another target vein during implantation (e.g., a longer vein).

One exemplary arrangement provides that the fixation device be movably arranged in a receptacle formed by the lead body, allowing the fixation device to be extended out of the lead body (in particular in the direction of the longitudinal axis of the lead body) through an opening of the receptacle, this opening being arranged on a distal end of the lead body.

One exemplary arrangement further provides that the respective electrode be connected with an electrical conductor that is arranged in an interior of the lead body. This electrical conductor can be in the form of a cable, for example. If there are multiple electrical conductors, it is possible to use multiple cables which are routed essentially parallel to one another, for example. A separate channel can be provided for each electrical conductor in the form of a cable, or a common channel can be provided for multiple or all electrical conductors in the form of cables. If multiple electrical conductors in the form of a cable are routed in a common channel, it is expedient if the individual conductors are insulated from one another.

One exemplary arrangement further provides that the respective electrical conductor extends helically around the said receptacle, i.e., the respective conductor helically

surrounds the fixation device if the latter is in a retracted state or at least sections of it are arranged in the said receptacle.

One exemplary arrangement further provides that if there are two or more electrical conductors, these electrical conductors are arranged coradial to one another. In particular, this may involve the individual electrical conductors being insulated from one another and wound into a multiply wound helix, in which the two electrical conductors form congruent helices that have the same diameter and pitch and that intertwine with one another.

One exemplary arrangement further provides that the lead body has a proximal end, in particular one that lies opposite the distal section in the direction of the longitudinal axis of the lead body, and that there be arranged at this proximal end of the lead body a connection device to connect the electrode lead to an implantable pulse generator, the respective electrical conductor being connected with an associated contact of the connection device. The connection device can be a plug. It is preferable to use IS-1 plugs or IS4 plugs.

One exemplary arrangement further provides that a section of fixation device extended out of the lead body be designed to be deformed into a defined shape, in particular, this section being designed to be deformed out of a linear or stretched-out shape into a shape deviating from the linear shape, the defined shape of the section causing, in particular, the fixation device and, along with it, the electrode lead to be fixed in the blood vessel.

One exemplary arrangement further provides that the defined shape correspond to one of the following shapes: a helix, an S-curve, a meandering structure, or a J-curve.

One exemplary arrangement further provides that the fixation device has a preformed helix to deform the said section. The helix can be a helical element made of a metal, the metal preferably being MP35N, stainless steel, tantalum, platinum, palladium, or silver (individually or in combination, e.g., MP35N with a silver core).

One exemplary arrangement further provides that the said helix be soft-annealed in a proximal area, so that it can be drawn for arrangement in the receptacle of the lead body.

Furthermore, a distal area of the helix can be annealed into a plastically less easily deformable area, which forms the said defined shape.

One exemplary arrangement provides that the helix extend along the longitudinal axis over an entire length of the fixation device or only over a distal area of the fixation device.

One exemplary arrangement provides that the helix of the fixation device has, on an inner surface of the helix, insulation, in particular in the form of a polymer tube, and/or that the helix of the fixation device has, on an outer surface of the helix, insulation, in particular in the form of a polymer tube.

One exemplary electrode lead further provides that the fixation device be extendable by means of a screwing motion.

One exemplary arrangement further provides that the fixation device has an external thread that engages with an internal thread of the lead body, allowing the fixation device to be screwed out of the lead body and thereby extended.

One exemplary arrangement further provides that the electrode lead has a rotatable plug, so that rotating the plug allows the fixation device to be screwed out of the lead body and thereby extended. The plug is preferably a IS-1 plug or IS4 plug that has a rotatable plug pin (pin), so that rotation on the pin allows the fixation device to be screwed out of the lead body and thereby extended.

One exemplary arrangement further provides that the fixation device has a lumen for insertion of a mandrel into the fixation device, the fixation device being designed to be extended or screwed out of the lead body by means of a mandrel inserted into the lumen, in particular the helix of the fixation device extending around the lumen of the fixation device. In particular, the lumen may be aligned with a passage on the connection device (e.g., a drill hole on the pin of the IS-1 or IS4 plug), so that the mandrel can be inserted into the lumen through the passage from the proximal end of the lead body.

One exemplary arrangement further provides that the fixation device has a sleeve on a distal end of the fixation device that forms a stop for a mandrel, so that the fixation device can be extended out of the lead body by the mandrel being inserted into the lumen of the fixation device and this mandrel being pressed against the stop, or the fixation device being able to engage with the mandrel in such a way that the mandrel can screw the fixation device out of the lead body and thereby extend it.

In both cases, the sleeve can further be configured to engage with a mandrel so that the fixation device can be retracted again by means of the mandrel, e.g., by pulling on the mandrel, so that the fixation device is retracted back into the lead body or by screwing the fixation device into the lead body so that the fixation device is retracted back into the lead body.

One exemplary arrangement further provides that the fixation device be designed to be locked in place with respect to the blood vessel and the lead body if a mandrel arranged in the lumen is pulled out of the lumen.

One exemplary arrangement further provides that the lead body has, at the distal end of the lead body, a clamping device to lock the fixation device in place (and to seal the lead body), the clamping device being able to form the said opening, and the clamping device being designed to clamp the fixation device, if a mandrel arranged in the lumen is pulled out of the lumen.

In particular, the clamping device can be a clamping sleeve provided at the distal end of the lead body, this clamping sleeve having or forming, in particular, the said opening to extend the fixation device.

One exemplary arrangement further provides that the fixation device has at least one X-ray marker to measure a length of the extended section of the fixation device, this X-ray marker being fixed on the fixation device, in particular on the helix of the fixation device, and at least one X-ray marker that is fixed on the lead body, in particular on one of the coradial electrical conductors.

DESCRIPTION OF THE DRAWINGS

The discussion below is intended to describe other features, advantages, and embodiments of this invention on the basis of the figures. The figures are as follows

- Fig. 1 an electrode lead with fixation devices that have been extended different distances in the distal section, (A) through (D);
- Fig. 2 a sectional view of a distal section of an electrode lead with a partly retracted fixation device;
- Fig. 3 an enlarged detail of Fig. 2;
- Fig. 4 a distal end of the electrode lead shown in Figures 1 through 3, in extended state;
- Fig. 5 a distal end of the fixation device of the electrode lead shown in Figures 1 through 4, with a stop for a mandrel;
- Fig. 6 the distal end according to Fig. 5 in a retracted fixation device; and
- Fig. 7 a distal end of one electrode lead in the extended state, with thread.

DETAILED DESCRIPTION

An exemplary arrangement is described below using electrode leads 1, which are suitable for use in the coronary sinus and which comprise two electrodes 12, 13 to make contact with body tissue. Such electrode leads 1 are also referred to as bipolar electrode leads. However, the current techniques are also feasible with electrode leads with only one electrode (unipolar electrode leads) or with more than two electrodes (multipolar electrode leads).

Figure 1, in connection with Figures 2 through 7, shows an electrode lead 1 for use in the coronary sinus. The electrode lead 1 has a preferably long, stretched out lead body 10, that extends along a longitudinal axis L and that has a distal section 11 for insertion into the coronary sinus. Furthermore, the electrode lead has two or even more (e.g., 3 or 4) electrodes 12, 13 to make contact with body tissue, each of which can be configured as a stimulation electrode or as a sensing electrode. The at least two electrodes 12, 13 are, in particular, ring-shaped and are arranged spaced apart from one another in the direction of the longitudinal axis L of the lead body 10 on the distal section 11 of the lead body 10.

The electrode lead 1 has a fixation device 20 to fix the electrode lead 1 in a blood vessel, in this case in a target vein of the coronary sinus, this fixation device 20 being extendable out of the lead body 10, in particular extendable in the direction of the longitudinal axis L. This fixation device 20 is variably extendable out of the lead body 10, so that when the fixation device 20 is extended out of the lead body 10, the section 21 that is extended has an adjustable length in the direction of the longitudinal axis L, as is shown in Figures 1(A) through 1(D).

Figure 1(A) shows a fixation device 20 that has been completely extended out of the lead body 10, a section 21 of the extended fixation device 20 assuming, after being extended, a defined shape, which fixes it in the blood vessel. Figures 1(B) and 1(C) show fixation devices 20 that are extended less far out. Finally, Figure 1(D) shows an essentially retracted fixation device 20, which can represent a normal state of the electrode lead 1; starting from this normal state, the section 21 to be extended can be brought to a necessary length (in the direction of the longitudinal axis L), which on the one hand securely anchors the electrode lead in the selected blood vessel of the coronary sinus and, on the other hand, allows correct positioning of the electrodes 12, 13 once the electrode lead 1 has been fixed.

As is shown especially in Figures 2 through 4 and 6, the fixation device 20 is preferably movably arranged in a receptacle 14 provided in the lead body 10, so that the fixation device 20 can be extended out of the lead body 10 in the direction of the longitudinal axis L through an opening 15 in the lead body 10, the opening 15 being arranged on a distal end 16 of the lead body 10 (see especially Figures 4 and 6).

As is also indicated, e.g., in Figure 2, it is preferably provided that the respective electrode 12, 13 be connected with an electrical conductor 120, 130 that is arranged in an interior 17 of the lead body 10, the respective electrical conductor 120, 130 extending helically around the said receptacle 14 for the fixation device 20 or around the fixation device 20 itself, if the latter is in an retracted state or if at least sections of it are arranged in the said receptacle 14 (see especially Figures 2, 3, and 6). The conductors 120, 130 are preferably in the form of coradial helices, i.e., the individual electrical conductors 120, 130 are insulated from one another and wound into a multiply wound helix.

According to Figure 1(A), the lead body 10 also has a proximal end 18, in particular a proximal end 18 that lies opposite the distal section 11 of the lead body in the direction of the longitudinal axis L, the proximal end 18 having a connection device 19 arranged on it to connect the electrode lead 1 to an implantable pulse generator, and the respective electrical conductor 120, 130 being connected with an associated contact 192, 191 of the connection device 19, so that the electrodes 12, 13 are connectable in an electrically conductive manner with the pulse generator. If the electrode lead is optionally equipped with more than two electrodes, the connection device 19 can also be equipped with more than two contacts. The contact 191 can be in the form of an annular contact and the contact 192 can be in the form of a plug pin (pin).

To deform the respectively extended section 21 of the fixation device 20, the electrode lead has, in particular, a preformed helix 22, as is shown in Figures 2 through 7. This can involve a proximal area 23 (see Figure 2) of the helix 22 being soft-annealed, so that it can be drawn (e.g., by means of a mandrel 27) for arrangement in the receptacle 14 of the lead body 10, while a distal area 24 of the helix 22 (see Figure 2) can be annealed into a plastically less easily deformable area, which can form the said defined shape that anchors the fixation device 20 (see also Figures 1(A) through 1(D)).

The fixation device 20 can also have, on an outer surface 22a of the helix 22, an insulation 25, e.g., in the form of a polymer tube that surrounds the helix 22, as is shown, e.g., in Figures 4 through 6.

One embodiment can provide that the helix 22 of the fixation device 20 has, on an inner surface of the helix, an insulation, in particular in the form of a polymer tube, and/or that the helix of the fixation device has, on an outer surface 22a of the helix 22, an insulation 25, in particular in the form of a polymer tube.

To extend the fixation device 20 out of the lead body 10, to produce, e.g., the configurations shown in Figure 1(A) through Figure 1(C), it can be provided that the fixation device 20 has a lumen 26 for insertion of a mandrel 27 into the fixation device 20, the fixation device 20 preferably being designed to be extended out of the lead body 10 by means of a mandrel 27 inserted into the lumen 26, the helix 22 of the fixation device 20 extending, in particular, around the lumen 26 of the fixation device 20. In particular, the lumen 26 is aligned with a passage 193 on the connection device 19, so that the mandrel 27 can be inserted into the lumen 26 from the proximal end 18 of the lead body 10 through the passage 193.

Furthermore, the fixation device 20 has, on a distal end 28 of the fixation device 20, a sleeve 200, preferably according to Figure 5, that forms a stop 34 for a mandrel 27, so that the fixation device 20 can be extended out of the lead body 10 by means of the mandrel 27, which is inserted into the lumen 26 of the fixation device 20 and is pressed against the stop 34, or by means of the fixation device, which is able to engage with the mandrel 27 in such a way that the mandrel 27 can screw the fixation device 20 out of the lead body and thereby extend it. In another embodiment, the fixation device 20 can have, for this purpose, an external thread 40 that engages with an internal thread 41 of the lead body 10, as is shown in Figure 7. In both cases, the sleeve 200 can further be configured to engage with a mandrel 27 so that the fixation device 20 can also be retracted again by means of the mandrel 27, e.g., by pulling on the mandrel, so that the fixation device 20 is retracted back into the lead body 10, or by screwing the fixation device 20 into the lead body 10 so that the fixation device 20 is retracted back into the lead body 10.

The sleeve 200 and the stop 34 can further have a passage, so that the electrode lead 1 can be inserted over a guide wire (not shown) (OTW = over the wire). Furthermore, there can be, in the sleeve 200 or proximal to the stop 34, a gasket or a lock system that seals the lumen

26 of the electrode lead 1 at the distal end 28 of the fixation device 20. The lock system or the gasket prevents the penetration of body fluid into the lumen 26 of the electrode lead 1.

Furthermore, the fixation device 20 is preferably designed to be locked in place with respect to the lead body 10 (e.g., in an extended state of the type shown in Figures 1(A) through 1(C)), if a mandrel 27 arranged in the lumen 26 is pulled out of the lumen 26.

In particular, to lock the fixation device 20 in place, the lead body 10 can have, at the distal end 16 of the lead body 10, a clamping device 30 that is preferably in the form of a clamping sleeve 30 and that defines the said opening 15 through which the fixation device 20 can be extended out of the lead body 10. The clamping sleeve 30 is preferably designed to clamp the fixation device 20 if a mandrel 27 arranged in the lumen 26 of the fixation device 20 is pulled out of the lumen 26 (at the proximal end of the lead body).

According to another exemplary arrangement, the electrode lead 1 can have, to measure the length of the extended section 21 of the fixation device 20, one X-ray marker on the lead body 10 and at least one other X-ray marker 32 on the fixation device 20. The function of the X-ray marker on the lead body 10 can be performed, e.g., by the clamping sleeve 30, if the latter is made of a radiopaque material. The distance between the clamping sleeve 30, which is functioning as an X-ray marker, and the X-ray marker 32 is visible in the X-ray picture and makes it possible to estimate how far the fixation device 20 is extended.

Current CRT electrodes do not always allow optimal CRT therapy under all anatomical relationships. The continuously variable length of the fixation device offered by the current techniques provide an optimal implantation site and simultaneously secure fixation of the electrode lead 1 under all anatomical vein constellations. In particular, this allows the use of economical one-electrode or two-electrode electrode leads. Furthermore, the doctor can, in particular during the implantation, adjust the fixation length as needed.

It will be apparent to those skilled in the art that numerous modifications and variations of the described examples and embodiments are possible in light of the above teaching. The disclosed examples and embodiments may include some or all of the features disclosed

herein. Therefore, it is the intent to cover all such modifications and alternate embodiments as may come within the true scope of this invention.

CLAIMS

What is claimed is

1. An electrode lead (1) for the coronary sinus, with:
 - a lead body (10) that has a distal section (11) for insertion into the coronary sinus;
 - at least one electrode (12) to make contact with body tissue, the at least one electrode (12, 13) being arranged on the distal section (11) of the lead body (10).

characterized in that

the electrode lead (1) has a fixation device (20) that can be extended out of the lead body (10) to fix the electrode lead (1) in a blood vessel.

2. An electrode lead according to claim 1, **characterized in that** the fixation device (20) is movably arranged in a receptacle (14) arranged in the lead body (10), so that the fixation device (20) can be extended out of the lead body (10) through an opening (15) in the lead body (10), the opening (15) being arranged on a distal end (16) of the lead body (10).
3. An electrode lead according to claim 2, **characterized in that** the electrode (12) is connected with an electrical conductor (120) that is arranged in an interior (17) of the lead body (10), the electrical conductor (120) extending helically around the said receptacle (14).
4. An electrode lead according to claim 3, **characterized in that** the electrode lead (1) comprises two electrodes (12, 13) to make contact with body tissue, the at least two electrodes (12, 13) being arranged on the distal section (11) of the lead body (10), the respective electrode (12, 13) being connected with an electrical conductor (120, 130) that is arranged in an interior (17) of the lead body (10), the respective electrical conductor (120, 130) extending helically around the said receptacle (14) and the electrical conductors (120, 130) being arranged coradial to one another.

5. An electrode lead according to claim 3 or 4, **characterized in that** the lead body (10) has a proximal end (18), the proximal end (18) having a connection device (19) arranged on it to connect the electrode lead (1) to an implantable pulse generator, and the respective electrical conductor (120, 130) being connected with an associated contact (191, 192) of the connection device (19).
6. An electrode lead according to any one of the preceding claims, **characterized in that** a section (21) of the fixation device (20) extended out of the lead body (10) is designed to be deformed into a defined shape.
7. An electrode lead according to claim 6, **characterized in that** the defined shape corresponds to one of the following shapes: a helix, an S-curve, a meandering structure, or a J-curve.
8. An electrode lead according to claim 6 or 7, **characterized in that** the fixation device (20) has a preformed helix (22) to deform the said section (21).
9. An electrode lead according to any one of the preceding claims, **characterized in that** the fixation device (20) has a external thread (40) that engages with an internal thread (41) of the lead body (10), allowing the fixation device (20) to be screwed out of the lead body (10) and thereby extended.
10. An electrode lead according to any one of the preceding claims, **characterized in that** the electrode lead (1) has a rotatable plug (19), so that rotating the plug (19) allows the fixation device (20) to be screwed out of the lead body and thereby extended.
11. An electrode lead according to any one of the preceding claims, **characterized in that** the fixation device (20) has a lumen (26) for insertion of a mandrel (27) into the fixation device (20), the fixation device (20) being designed to be extended out of the lead body (10) by means of a mandrel (27) inserted into the lumen (26).

12. An electrode lead according to any one of the preceding claims, **characterized in that** the fixation device (20) has a sleeve (200) on a distal end (28) of the fixation device (20), that forms a stop 34 for a mandrel (27).
13. An electrode lead according to any one of the preceding claims, **characterized in that** the fixation device (20) is designed to be locked in place with respect to the lead body (10), if a mandrel (27) arranged in the lumen (26) is pulled out of the lumen (26).
14. An electrode lead according to claim 2 or one of claims 3 through 13, to the extent that they refer back to claim 2, **characterized in that** the lead body (10) has, on the distal end of the lead body (10), a clamping device (30) to lock the fixation device (20) in place, the clamping device (30) forming the said opening (15), and the clamping device (30) being designed to clamp the fixation device (20), if a mandrel (27) arranged in the lumen (26) is pulled out of the lumen.
15. An electrode lead according to any one of the preceding claims, **characterized in that** the fixation device (20) has at least one X-ray marker (32) to measure a length of the extended section (21) of the fixation device (20), this X-ray marker being fixed on the fixation device (20), and at least one X-ray marker that is fixed on the lead body (10).