PASSIVE FIXATION OF AN IMPLANTABLE ELECTRODE LEAD BY MEANS OF COMPRESSIBLE ANCHORING ELEMENTS

TECHNICAL FIELD

The invention relates to an implantable device, comprising an end section of the implantable device, and comprising at least one or more anchoring elements for anchoring the end section of the implantable device in the tissue (such as cardiac tissue) of a patient, wherein the respective anchoring element extends in an extension direction of the respective anchoring element.

BACKGROUND

Usually, either active fixation systems, such as screws, or passive fixation systems, which may include anchoring elements (in particular barbs) made of plastic material, for example, are used to fix implantable electrode leads, for example, in the heart of a patient.

For reliably anchoring the electrode lead in the cardiac tissue, a certain minimum degree of flexural rigidity of the anchoring system is preferred. The flexural rigidity depends on the dimensions of the component in the bending direction and the stiffness (modulus of elasticity) of the material used. Less stiff materials may require larger dimensions for a predefined flexural rigidity, thereby usually taking up a larger volume. The maximum permissible volume is limited by the inside diameter of the sheath introducer used, which preferably corresponds to the diameter of the electrode lead. As a result, the selection of materials for the fixation system is accordingly limited when the electrode diameter is predefined.

The plastic materials used are usually polyurethane-based or silicone-based polymers. Polyurethanes have the advantage of comparatively high mechanical strength and stiffness,

which allows them to be reliably anchored in the cardiac tissue and positioned using a sheath introducer having a small inside diameter. The drawback of polyurethanes is the susceptibility thereof to chemical degradation (in particular oxidative processes).

Silicone-based plastic materials are comparatively inert from a chemical point of view, but compared to polyurethanes have considerably lower material stiffness, so that the geometry of the barbs has to be increased to achieve the same anchoring resistance levels as with polyurethanes. However, larger geometries cannot readily be used for passive fixation systems without increasing the inside diameter of the sheath introducer.

SUMMARY

An aspect of the invention is achieved by an implantable device having the features of claim 1. Thus it may be possible to provide an implantable device that allows passive fixation based on chemically inert plastic materials, such as silicone, in such a way that the anchoring element has or the anchoring elements have sufficient flexural rigidity and, in particular, allow the use of conventional sheath introducers.

Advantageous embodiments of the invention are provided in the dependent claims and will be described hereafter.

An exemplary implantable device is disclosed, comprising:

- an end section of the implantable device, which extends in particular along a longitudinal axis; and
- at least one anchoring element or a plurality of anchoring elements, wherein the at least one anchoring element is or the anchoring elements are connected to the end section and is or are designed to anchor the end section of the implantable device in the tissue of a patient, wherein the at least one anchoring element or the respective anchoring element extends in an extension direction.

To the extent that mention is made hereafter of the respective anchoring element, this shall also include the at least one anchoring element in the case where the implantable device comprises at least one anchoring element.

The respective anchoring element may have an elastically compressible design, wherein the respective anchoring element can be arranged in a compressed state in which the respective anchoring element is folded toward the end section, and wherein the respective anchoring element is designed to automatically move toward an expanded state in which the respective anchoring element projects from the end section of the implantable device at an angle of inclination, wherein the respective anchoring element comprises at least one first lamella and a second lamella connected (in particular in one piece) to the first lamella, and wherein the two lamellae extend along the extension direction of the respective anchoring element and include an (in particular obtuse, right or acute) first angle with one another in a plane perpendicular to the extension direction of the respective anchoring element.

In particular, a hook geometry including lamellae is thus used, which meets the requirements with regard to sufficiently high flexural rigidity of the hooks or of the anchoring elements for attachment in the body tissue, while requiring only little material volume. Due to the deformable lamellae, this hook geometry can also be guided bidirectionally through sheath introducers having a small inside diameter. In this way, it becomes possible to use chemically inert, but less stiff plastic materials, such as silicone, for the fixation component, without increasing the volume of the component.

According to one exemplary arrangement, it is provided that the respective anchoring element is or the lamellae are made of silicone.

According to one exemplary arrangement, it is provided that the respective anchoring element is or the lamellae are made of polyurethane. Anchoring elements or lamellae that are made of polyurethane have the additional advantage that the geometry of the anchoring elements can be further reduced, which opens up the option of producing electrode leads having a smaller diameter than is possible with silicone, using the described hook geometry including lamellae.

Furthermore, according to one exemplary arrangement, it is provided that the respective first angle in the compressed state of the respective anchoring element is smaller than in the expanded state of the respective anchoring element.

Furthermore, according to one exemplary arrangement, it is provided that the respective first angle in the expanded state of the respective anchoring element is 90º.

Furthermore, according to one exemplary arrangement, it is provided that the respective anchoring element comprises a third lamella and a fourth lamella, wherein the third and fourth lamellae extend along the extension direction of the respective anchoring element and enclose an (in particular obtuse, right or acute) second angle with one another in a plane perpendicular to the extension direction of the respective anchoring element.

According to one exemplary arrangement, it is provided that the respective second angle is smaller in the compressed state than in the expanded state of the respective anchoring element. According to one exemplary arrangement, it is further provided that the respective second angle in the expanded state of the respective anchoring element is 90º.

Furthermore, according to one exemplary arrangement, it is provided that the first angle and the second angle of the respective anchoring element form vertical angles.

In this regard, it is further preferably provided according to one exemplary arrangement that the third and fourth lamellae of the respective anchoring element are connected to the first and second lamellae of the respective anchoring element, in particular in one piece, so that the respective anchoring element in the expanded state has a cross-shaped design in a plane extending perpendicularly to the extension direction of the respective anchoring element.

Such a cross-shaped configuration of the respective anchoring element advantageously allows the flexural rigidity of the respective anchoring element to be increased, without the material volume of the respective component or anchoring element being increased. The material selection is thus subject to fewer limitations.

Furthermore, according to one exemplary arrangement, it is provided that the respective anchoring element is designed as a hollow profile comprising a peripheral wall, wherein the first and second lamellae of the respective anchoring element each form a portion of the wall of the respective anchoring element.

Furthermore, according to one exemplary arrangement it is provided that the wall of the respective hollow profile comprises a third lamella and a fourth lamella, wherein the wall of the respective hollow profile is designed to have a rectangular cross-section with respect to a plane extending perpendicularly to the extension direction of the respective hollow profile.

According to an alternative one exemplary arrangement, it is provided that the wall of the respective hollow profile - apart from the first and second lamellae - comprises a third, a fourth, a fifth and a sixth lamella, wherein the wall of the respective hollow profile is designed to have a hexagonal cross-section with respect to a plane extending perpendicularly to the extension direction of the respective hollow profile.

Furthermore, according to one exemplary arrangement, it is provided that the end section of the implantable device, on a peripheral outer side, has a recess for receiving the anchoring elements (or the at least one anchoring element) in the compressed state of the anchoring elements (or of the at least one anchoring element). Said recess may be formed by a taper of the end section.

Furthermore, according to one exemplary arrangement, it is provided that the respective angle of inclination at which the respective anchoring element projects from the end section of the implantable device is in a range of 30º to 85º, and in particular in a range of 50º to 70º.

According to one exemplary arrangement, it is provided that the device comprises one to eight anchoring elements, in particular two to eight anchoring elements, and in particular three to four anchoring elements.

Furthermore, according to one exemplary arrangement, it is provided that the device comprises four anchoring elements, wherein the anchoring elements are arranged equidistantly with respect to one another in the circumferential direction of the end section of the implantable device, that is two adjoining anchoring elements in each case have the same angular separation in the circumferential direction.

According to one exemplary arrangement, the implantable device comprises an electrode lead or is designed as an electrode lead, wherein the electrode lead comprises said end section, from which the anchoring elements project or from which the at least one anchoring element projects.

According to a further exemplary arrangement, it is provided that the implantable device or the electrode lead comprises an electrode, which is arranged at the end section, wherein the electrode is arranged, in particular, at one end of the electrode lead or of the end section.

DESCRIPTION OF THE DRAWINGS

Further features, advantages and embodiments of the present invention shall be described hereafter with reference to the figures. In the drawings:

FIG. 1 shows an active implant, having an implantable device connected thereto, including anchoring elements at the end section thereof;

FIG. 2 shows a perspective view of an end section of an implantable device, including anchoring elements;

FIG. 3 shows a sectional illustration of an anchoring element in the manner of FIG. 2 in the expanded state (A) and in the compressed state (B);

FIG. 4 shows a perspective view of an anchoring element in the manner of FIGS. 2 and 3 in the expanded state (A) and in the compressed state (B); and

FIG. 5 shows a sectional illustration of an anchoring element in the form of a hollow profile (A) having a rectangular cross-section and in the form of a hollow profile (B) having a hexagonal cross-section.

DETAILED DESCRIPTION

FIG. 1 shows an active implant 100, for example in the form of a cardiac pacemaker, having an implantable device 1, for example in the form of an electrode lead, connected thereto. The device 1 is connected to the implant 100, in particular, via a detachable connection.

At the distal end section 10, the implantable device 1 comprises anchoring elements 20.

FIG. 2 shows an implantable device 1, here, for example, in the form of an electrode lead 1 for a cardiac pacemaker, comprising an end section 10 of the implantable device 1, wherein an electrode 2 of the electrode lead 1 is arranged at the distal end of the end section 10 or of the electrode lead 1. The electrode lead 1 further comprises at least one anchoring element 20 connected to the end section 10. The discussion of this example is based on a plurality of anchoring elements 20 connected to the end section 10, each being used to anchor the end section 10 or the electrode 2 of the implantable device 1 in the tissue of a patient, wherein the respective anchoring element 20 extends in an extension direction E of the respective anchoring element 20.

The respective anchoring element 20 may have an elastically compressible design, wherein the respective anchoring element 20 can be arranged in a compressed state in which the respective anchoring element 20 is folded toward the end section 10, and wherein the respective anchoring element 20 is designed to automatically move out of the compressed state thereof into the expanded state in which the respective anchoring element 20 projects from the end section 10 at an angle of inclination A. Furthermore, the respective anchoring element 20 comprises a first lamella 21 and a second lamella 22 connected to the first lamella 21, wherein the two lamellae 21, 22 extend along the extension direction E of the respective anchoring element 20 and enclose a first angle W1 with one another in a plane perpendicular to the extension direction E of the respective anchoring element 20, the angle preferably

being 90º in the expanded state of the respective anchoring element. Furthermore, the respective anchoring element 20 preferably comprises a third and fourth lamellae 23, 24, wherein the four lamellae 21, 22, 23, 24 are preferably connected to one another (in particular in one piece) so that the respective anchoring element 20 has a cross-shaped cross-section. The third and fourth lamellae 23, 24 of the respective anchoring element 20 enclose a second angle W2, which is likewise preferably 90º in the expanded state of the respective anchoring element. The two angles W1, W2 form vertical angles, wherein the two angles W1, W2 in the compressed state of the respective anchoring element 20, as is apparent from FIGS. 3 and 4, can be more acute than 90º, at least in sections along the respective anchoring element 20.

The cross-shaped configuration of the lamellae 21, 22, 23, 24 ensures sufficient flexural rigidity, wherein in particular a bidirectional configuration of the anchoring system 20 is also present since the electrode lead 1 can essentially be guided in both directions through the sheath introducer (not shown). According to FIG. 2, the device 1 comprises, in particular, four anchoring elements 20, which can be made of silicone, for example, and are symmetrically distributed around the electrode lead 1. The respective angle of inclination of the silicone hooks 20 or anchoring elements 20 in relation to the end section 10 of the electrode lead 1 is preferably in the range of 30º to 85º, and in particular in the range of 50º to 70º.

According to one example, the flexural rigidity of the anchoring elements 20 can be approximately 0.07 Nmm² in the uncompressed or expanded state.

During the insertion of the sheath introducer, a radial force acts on the respective anchoring element 20, pressing this toward the end section 10 or the electrode lead 1 (see FIG. 4(B)). Since both the respective anchoring element 20 and the lamellae 21, 22, 23, 24 thereof are being bent, the maximum outside diameter of the electrode lead 1 or of the end section 10 corresponds to the inside diameter of the sheath introducer. It is also conceivable for the respective anchoring element 20 to comprise more than four lamellae.

Furthermore, it is preferably provided that the end section 10 of the electrode lead 1, on a peripheral outer side 11 of the end section 10, has a recess 12 for receiving the anchoring elements 20 in the compressed state of the anchoring elements 20.

Increased compressibility of the anchoring elements 20 can also be achieved by forming the anchoring elements into hollow bodies or hollow profiles 20, as is indicated in FIG. 5, which shows anchoring elements 20 having a rectangular or square cross-section (see FIG. 5(A)) or anchoring elements 20 having a hexagonal cross-section (see FIG. 5(B)).

According to FIG. 5(A), the respective anchoring element 20 designed as a hollow profile 20 comprises four mutually connected lamellae 21, 22, 23, 24, which form a peripheral wall 200 of the respective hollow profile 20, which has said rectangular or square cross-section in a plane extending perpendicularly to the extension direction E of the respective hollow profile 20 or anchoring element 20.

According to FIG. 5(B), the respective anchoring element 20 designed as a hollow profile 20 can also comprise six mutually connected lamellae 21, 22, 23, 24, 25, 26 which form a peripheral wall 200 of the respective hollow profile 20, which has said hexagonal cross-section in a plane extending perpendicularly to the extension direction E of the respective hollow profile 20 or anchoring element 20.

In principle, the anchoring elements 20 can have a length in the range of 2 mm to 4 mm, for example, in all embodiments in the respective extension direction.

Furthermore, the lamellae 21, 22, 23, 24 according to FIG. 3 or FIG. 5(A) can each have a width B perpendicular to the respective extension direction E which is in the range of 0.4 mm to 0.6 mm, for example.

Furthermore, the lamellae 21, 22, 23, 24, 25, 26 according to FIG. 5(B) can each have a width B perpendicular to the respective extension direction E which is in the range of 0.4 mm to 0.6 mm, for example.

Furthermore, the lamellae 21, 22, 23, 24 according to FIG. 3 or FIG. 5(A) can each have a thickness D which is in the range of 0.1 mm to 0.3 mm.

Furthermore, the lamellae 21, 22, 23, 24, 25, 26 according to FIG. 5(B) can each have a thickness D which is in the range of 0.1 mm to 0.3 mm.

Furthermore, according to one example, it may be provided that the flexural rigidity of the respective anchoring element 20 is in the range of 0.05 Nmm² to 0.10 Nmm², for example. Furthermore, the material stiffness of the material used for the anchoring elements 20 can be in the range of 2 N/mm² to 20 N/mm².

Furthermore, the lamellae 21, 22, 23, 24, 25, 26 according to FIGS. 2, 3 and 5 can have a cuboid design across the majority of the lengths thereof in the extension direction E, but may also each taper in the connecting region to the electrode lead 1 or the end section 10.

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 implantable device (1), comprising:
   - an end section (10) of the implantable device (1); and
   - at least one anchoring element (20) connected to the end section (10) for anchoring the end section (10) of the implantable device (1) in the tissue of a patient, the at least one anchoring element (20) extending in an extension direction (E) of the at least one anchoring element (20),

   characterized in that the at least one anchoring element (20) has an elastically compressible design, wherein the at least one anchoring element (20) can be arranged in a compressed state in which the at least one anchoring element (20) is folded toward the end section (10), and wherein the at least one anchoring element (20) is designed to automatically move into an expanded state in which the at least one anchoring element (20) projects from the end section (10) at an angle of inclination (A), wherein the at least one anchoring element (20) comprises at least one first lamella (21) and a second lamella (22) connected to the first lamella (21), and wherein the two lamellae (21, 22) extend along the extension direction (E) of the at least one anchoring element (20) and include a first angle (W1) with one another in a plane perpendicular to the extension direction (E) of the at least one anchoring element (20).

2. The implantable device according to claim 1, **characterized in that** the first angle (W1) is smaller in the compressed state than in the expanded state of the at least one anchoring element (20).

3. The implantable device according to claim 1 or 2, **characterized in that** the at least one anchoring element (20) comprises a third and a fourth lamella (23, 24), wherein the third and fourth lamellae (23 24) extend along the extension direction (E) of the at least one anchoring element (20) and enclose a second angle (W2) with one another in a plane perpendicular to the extension direction (E) of the at least one anchoring element (20).

4. The implantable device according to claim 3, **characterized in that** the second angle (W2) is smaller in the compressed state than in the expanded state of the at least one anchoring element (20).

5. The implantable device according to claims 1 and 4, **characterized in that** the first angle (W1) and the second angle (W2) of the at least one anchoring element (20) form vertical angles.

6. The implantable device according to any one of claims 3 to 5, **characterized in that** the third and fourth lamellae (23, 24) of the at least one anchoring element (20) are connected to the first and second lamellae (21, 22) of the at least one anchoring element (20), so that the at least one anchoring element (20) has a cross-shaped design in the expanded state in a plane extending perpendicularly to the extension direction (E) of the at least one anchoring element (20).

7. The implantable device according to claim 1, **characterized in that** the at least one anchoring element (20) is designed as a hollow profile comprising a peripheral wall (200), wherein the first and second lamellae (21, 22) of the at least one anchoring element (20) each form a portion of the wall (200) of the at least one anchoring element (20).

8. The implantable device according to claim 7, **characterized in that** the wall (200) of the hollow profile (20) comprises a third and a fourth lamella (23, 24), wherein the wall of the hollow profile (20) is designed to have a rectangular cross-section.

9. The implantable device according to claim 7, **characterized in that** the wall (200) of the hollow profile (20) comprises third, fourth, fifth and sixth lamellae (23, 24, 25, 26), wherein the wall (200) of the hollow profile (20) is designed to have a hexagonal cross-section.

10. The implantable device according to any one of the preceding claims, **characterized in that** the end section (10), on a peripheral outer side (11), has a recess (12) for

receiving the at least one anchoring element (20) in the compressed state of the at least one anchoring element (20).

11. The implantable device according to any one of the preceding claims, **characterized in that** the angle of inclination (A) is in a range of 30° to 85°.

12. The implantable device according to any one of the preceding claims, **characterized in that** the device (1) comprises one to eight anchoring elements (20), in particular two to eight anchoring elements (20), in particular three to four anchoring elements (20), and in particular four anchoring elements (20).

13. The implantable device according to any one of the preceding claims, **characterized in that** the implantable device (1) is an electrode lead (1).

14. The implantable device according to any one of the preceding claims, **characterized in that** the implantable device (1) comprises an electrode (2), which is arranged on the end section (10).