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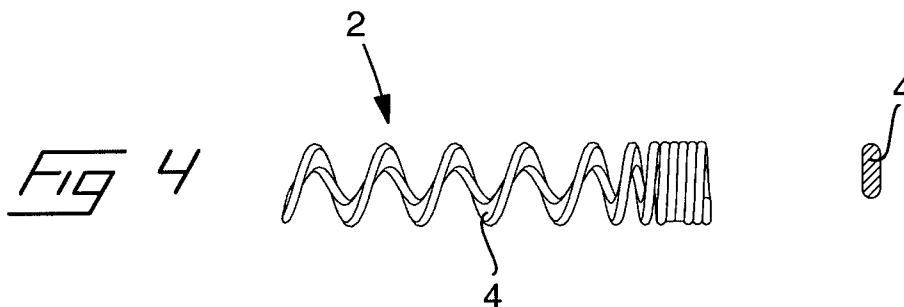
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(54) Title: AN ACTIVE FIXATION HELIX AND A MEDICAL IMPLANTABLE LEAD



(57) Abstract: The invention relates to an active fixation helix (2) for use as a tissue attaching element of a medical implantable lead and which is formed of a he- Nx wire (4), defining an inner diameter space confined by helix windings. The cross sectional dimension of the helix wire (4) is smaller in a direction in parallel to the longitudinal axis of the lead than in a direction transverse of the longitudinal axis of the lead. The invention also relates to a medical implantable lead comprising such an active fixation helix.

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AN ACTIVE FIXATION HELIX AND A MEDICAL IMPLANTABLE LEAD

The present invention relates to an active fixation helix for use as a tissue attaching element of a medical implantable lead and which is formed of a helix wire, defining an inner diameter space confined by helix windings.

5 The invention also relates to a medical implantable lead being adapted to be inserted into a human or animal body and attached to an organ inside the body for monitoring and/or controlling the function of the organ, comprising an active fixation helix in its distal end which is adapted to function as an attachment by being screwed into the tissue of the organ and which is formed of a helix wire, defining an inner diameter space confined by helix windings.

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Background of the invention

Helixes and medical implantable leads containing such helixes according to the introductory part, are well known in the art and are used to monitor and/or control the function of an organ inside a human or animal body, e.g. to monitor and pace the activity of a heart by means of a pacemaker. The helix is used to actively fixate the lead to the organ by being screwed into the tissue. The helix can be stationary attached to the lead, in which case the entire lead is rotated when attaching to the organ. The helix can also be rotatably but unextendably attached to the lead, in which case the helix is rotated in relation to the lead by means of an inner coil or a stylet inside the lead. Finally, the helix can be rotatably as well as extendably attached to the lead and in an initial stage accommodated inside a header sleeve in a distal end of the lead, in which case the helix is rotated and at the same time extended out from the header sleeve, likewise by means of an inner coil or a stylet inside the lead.

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The development in the art goes towards decreasing dimensions of the equipment used and accordingly also of the leads, which are becoming thinner. This has to effect that also the helix, which besides being utilized as an active fixation member also can function as an electrode in the organ, will become diminished with deteriorated mechanical and electrical function as a result. The helix is manufactured of a thin wire, which is formed in a helical

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shape such that the helix presents an outer diameter and an inner diameter defining a free inner space inside the helix.

As the dimensions of the medical implantable leads are decreasing, also the outer diameter of the helix has to be decreased in order to adapt the helix to the lead or to find room for it inside a header sleeve in the lead. The free inner space inside the inner diameter of the helix is often used to accommodate a steroid plug in order to prevent inflammation in the wound caused by penetration of the helix into the organ. Accordingly, it is not advisable to decrease the free inner space to much, which will lead to that also the dimension of the helix wire will be decreased as the outer diameter of the helix is decreased.

Normally, in prior art, the helix is formed of a helix wire having a circular cross section. A smaller wire diameter will generally lead to a better penetration ability, which is advantageous since in this way it will be easier to penetrate the organ.

From US 7162310 is known a cardiac stimulation lead having a helix wire profile, which in cross section has a larger dimension in a direction in parallel to the longitudinal axis of the helix than in the radial direction of the helix. I.e. the helix is constructed of a flat wire instead of one having a circular cross section. This is done to improve the helix visibility when monitoring the lead tip by means of x-ray examination when positioning and attaching the lead to a heart. However, a helix wire profiled in this way will have a larger coring tendency than a wire of a circular cross section, since the spacing between each coil of the helix will be smaller, which will reduce the amount of tissue remaining between each coil, and the surfaces facing in a direction in parallel to the longitudinal axis of the helix will be smaller, i.e. sharper, and will therefore easier cut through the tissue when a pulling force is applied to the lead.

When attaching a medical implantable lead to an organ by screwing a helix into the tissue, it will give rise to bleeding in the tissue. If, when utilizing the helix as an electrode, the blood from the wound can not escape from the tissue, it will cause a high acute electrical threshold, which will remain as long

as coagulated or liquid blood is present around the helix and which will deteriorate the performance of the lead.

Summary of the invention

5 The object of the invention is to improve prior art active fixation helixes for medical implantable leads. More precisely, it is an object to provide a helix for a medical implantable lead, which provides improved properties for attachment to the tissue. At least this object is achieved by an active fixation helix according to claim 1.

10 The invention also relates to a medical implantable lead having essentially the same object as above. At least this object is achieved by a medical implantable lead according to claim 6.

 Accordingly, the basis of the invention is the insight that the above object may be achieved by an active fixation helix, which is formed of a helix
15 wire whose cross sectional dimension in a direction in parallel to the longitudinal axis of the helix is smaller than the cross sectional dimension in a direction transverse of the longitudinal axis.

 Within this general idea, the invention may be modified in many different ways. For example, the cross sectional shape of the helix wire may be
20 generally flat, oval, triangular, C-shaped, D-shaped or any other suitable shape, as long as the helix wire has a smaller cross sectional dimension in a direction in parallel to the longitudinal axis of the helix than in a direction perpendicular thereto.

 By forming the helix according to the invention, several advantages
25 may be achieved. For example, the fixating characteristics may be enhanced since the distance between each winding, at maintained winding pitch, will become larger having to effect that more tissue will be accommodated between each winding and the area of the helix wire facing in a direction in parallel to the longitudinal axis of the helix will be enlarged, which will reduce the
30 risk of tearing the tissue when applying a pulling force in the lead. The helix wire will also be more rigid against deflection in a plane transverse to the longitudinal axis of the helix in comparison to a helix wire of circular cross sec-

tion and having the same cross sectional area. This is advantageous when screwing and penetrating the helix into the tissue.

Moreover, when using the helix as an active electrode, since the cross sectional dimension facing outwards from the helix will be reduced, the current density from the helix will be enhanced, which will improve the capability to overcome high current thresholds in the tissue and/or to reduce energy consumption. The current density can be enhanced further by providing the helix wire with a cross sectional shape having a sharp edge facing outwards from the helix, e.g. as a triangular shape having one apex facing outwards.

By providing the helix wire with a groove having a concavely formed surface in cross section, e.g. as with a C-formed helix wire, the ability for the helix wire to drain blood from the wound, caused by screwing the helix into the tissue, will be enhanced. Such a feature may be important to prevent or reduce high acute electrical threshold during the days or weeks immediately after mounting of the helix into the tissue.

A fixation helix of a helix wire having a smaller dimension in parallel to the longitudinal axis of the helix, will also give a higher flexibility along the longitudinal direction of the helix, i.e. more flexible for deflection in a plane being parallel to the longitudinal axis of the helix. This is advantageous when the helix is attached in an essentially horizontal direction, since then the lead may hang downwards from the helix by deflection in the helix, which will relief strains from the attachment in the tissue since the lead will not stand rigidly straight out from the tissue.

One further advantage with a helix wire having a more "flat" cross sectional shape, according to the invention, is that the tip of the helix can be more easily grinded, in order to facilitate penetration into the tissue. When grinding a helix wire having a circular cross sectional shape it is often necessary to perform the grinding in three different planes. However, when grinding a more flat shaped helix wire, it is often sufficient to grind the tip in only one or two planes. This will reduce the number of machining steps and machining time for each helix.

Brief description of the drawings

Hereinafter, exemplary embodiments of the invention will be described with reference to the accompanying drawings, in which:

- Fig 1 is a perspective view of a distal portion of a medical implantable lead having a helix retracted and accommodated inside a header sleeve;
- Fig 2 is a perspective view according to fig 1 but with the helix projecting from the header sleeve;
- Fig 3-6 plan views as well as cross sections of different embodiments of helixes formed of helix wires having different cross sectional shapes; and
- Fig 7 graphs showing the resulting current density around a prior art helix having a circular cross section in comparison to helixes designed according to the invention having a triangular and an oval cross sectional form, respectively.

Detailed description of embodiments of the invention

Reference is first made to figs 1 and 2 in which are illustrated, in perspective views, the distal portion of a medical implantable lead 1. The illustrated lead is of the kind having an active fixation helix 2, which in an initial stage is retracted and accommodated in a hollow header sleeve 3, as is illustrated in fig 1. The lead is highly flexible except for the distal header sleeve 3 which is rigid. When the medical implantable lead is inserted into a human or animal body and the distal end is positioned against the tissue of an organ inside the body, the helix can be projected by being screwed out from the header sleeve, as is illustrated in fig 2, by rotating the helix by means of e.g. a not shown inner coil or a stylet from the proximal end of the lead. At the same time as the helix 2 is screwed out from the distal end of the lead, it will also be screwed into the tissue and thereby attach the distal end of the medical implantable lead to the organ.

Reference is then made to figs 3 to 6, in which are illustrated helixes 2 having different profiled helix wires 4 in plan views as well as cross sectional views. One common feature of all these helix wires is that the cross sectional

dimension of the helix wire 4 is smaller in a direction x in parallel to the longitudinal axis of each helix than in a direction y transverse to the axis of the helix. The x- and y-directions are indicated by the coordinate axis above the figs 3-6.

5 In fig 3 the helix wire 4 has an oval shape in cross section and has its largest cross sectional dimension oriented in the direction y transverse to the longitudinal axis of the helix 2, whereas the smallest cross sectional dimension of the oval is oriented in the direction x in parallel to the longitudinal axis.

Fig 4 illustrates a helix 2 having an essentially flat shape in cross section. More precisely, the helix wire is formed with opposite plan surfaces facing in the direction x in parallel to the longitudinal axis of the helix and rounded edges facing in the direction y transverse to the longitudinal axis of the helix.

The helix illustrated in fig 5 is somewhat C-shaped in cross section having a convex surface and an opposed concave surface, which are facing in the direction x in parallel to the longitudinal axis of the helix. The concave surface forms a groove 5 along the helix wire which is beneficial in so far as it facilitates draining of blood from the tissue caused by screwing in of the helix 2 when attaching the medical implantable lead.

20 Finally, fig 6 illustrates a helix wire being triangular in cross section. The triangle is not an equilateral triangle but instead the triangle has a larger height in the direction y transverse of the longitudinal axis of the helix, whereas the smaller base is in the direction x in parallel to the longitudinal axis of the helix. Accordingly, the triangle forms an apex 6 directed outwards from the helix. As mentioned before, the shape of the helix wire according to the invention is advantageous when using the helix as an active electrode inside the tissue.

In order to determine the efficiency of the suggested shape of the helix, the current density surrounding the helix has been simulated, with a predetermined current delivered to the helix electrode, for three different cross sectional shapes of the helix. The result of the simulation is presented in the graphs of fig 7. The cross sectional shapes of the helix which have been simulated, is a prior art standard helix having a circular cross sectional

shape 7, a helix according to the invention having an oval cross sectional shape 8 and a helix according to the invention having a triangular cross sectional shape 9. As apparent from the graphs in fig 7, the helixes having a cross sectional shape according to the invention, have a higher current density in a region from the surface of the helix to distance about 200 μm from the helix surface. At a distance of 25 μm from the helix surface, the helixes according to the invention have about 65%, at 50 μm about 37% and at 100 μm about 23% higher current density than the prior art helix having a circular cross sectional shape. This is advantageous since it means that the capability to overcome high current thresholds in the tissue and/or to reduce energy consumption will be improved.

When implanting a helix into tissue, a layer of fibrous tissue will in the course of time be formed around the helix. However, such fibrous tissue is not excitable by means of electric current and, accordingly, the electric current has to reach beyond the fibrous tissue in order to excite the organ. Experiments performed by the present applicant, in which were measured the thickness of the fibrous tissue layer around helixes, having a surface layer of titanium nitride and being implanted into heart tissue of animals, revealed that the thickness of fibrous tissue typically is between about 12 to 30 μm , i.e. well within the distance from the helix surface where the current density is increased by means of a helix designed according to the present invention. Moreover, in the future it is not unlikely that the thickness of the fibrous tissue around implanted helixes can be further reduced by improved technology, such as new materials in surface layers and the like, in which case the improvement of the current density achieved by the present invention will be further increased.

For a skilled man in the art it is obvious that the cross sectional shape of the helix wire can be modified in many different ways within the scope of the associated claims and that the embodiments above are only exemplary.

CLAIMS

1. An active fixation helix for use as a tissue attaching element of a medical implantable lead (1) and which is formed of a helix wire (4), defining
5 an inner diameter space confined by helix windings, c h a r a c t e r i z e d in that the cross sectional dimension of the helix wire (4) is smaller in a direction (x) in parallel to the longitudinal axis of the lead than in a direction (y) transverse of the longitudinal axis of the lead.
- 10 2. An active fixation helix according to claim 1, c h a r a c t e r i z e d in that the cross sectional shape of the helix wire (4) includes at least one distinct edge (6) along the longitudinal extension of the wire.
- 15 3. An active fixation helix according to claim 2, c h a r a c t e r i z e d in that at least one distinct edge (6) is directed outwards in relation to the inner diameter space.
- 20 4. An active fixation helix according to any of the preceding claims, c h a r a c t e r i z e d in that the cross sectional shape of the helix wire (4) includes at least one groove formation (5) having a concavely shaped surface.
- 25 5. An active fixation helix according to any of the preceding claims, c h a r a c t e r i z e d in that the active fixation helix (2) is adapted to function as an electrode inside the tissue.
- 30 6. A medical implantable lead being adapted to be inserted into a human or animal body and attached to an organ inside the body for monitoring and/or controlling the function of the organ, comprising an active fixation helix (2) in its distal end which is adapted to function as an attachment by being screwed into the tissue of the organ and which is formed of a helix wire (4), defining an inner diameter space confined by helix windings, c h a r a c t e r i z e d in that the cross sectional dimension of the helix wire (4) is smaller in a

direction (x) in parallel to the longitudinal axis of the active fixation helix than in a direction (y) transverse of the longitudinal axis of the active fixation helix (2).

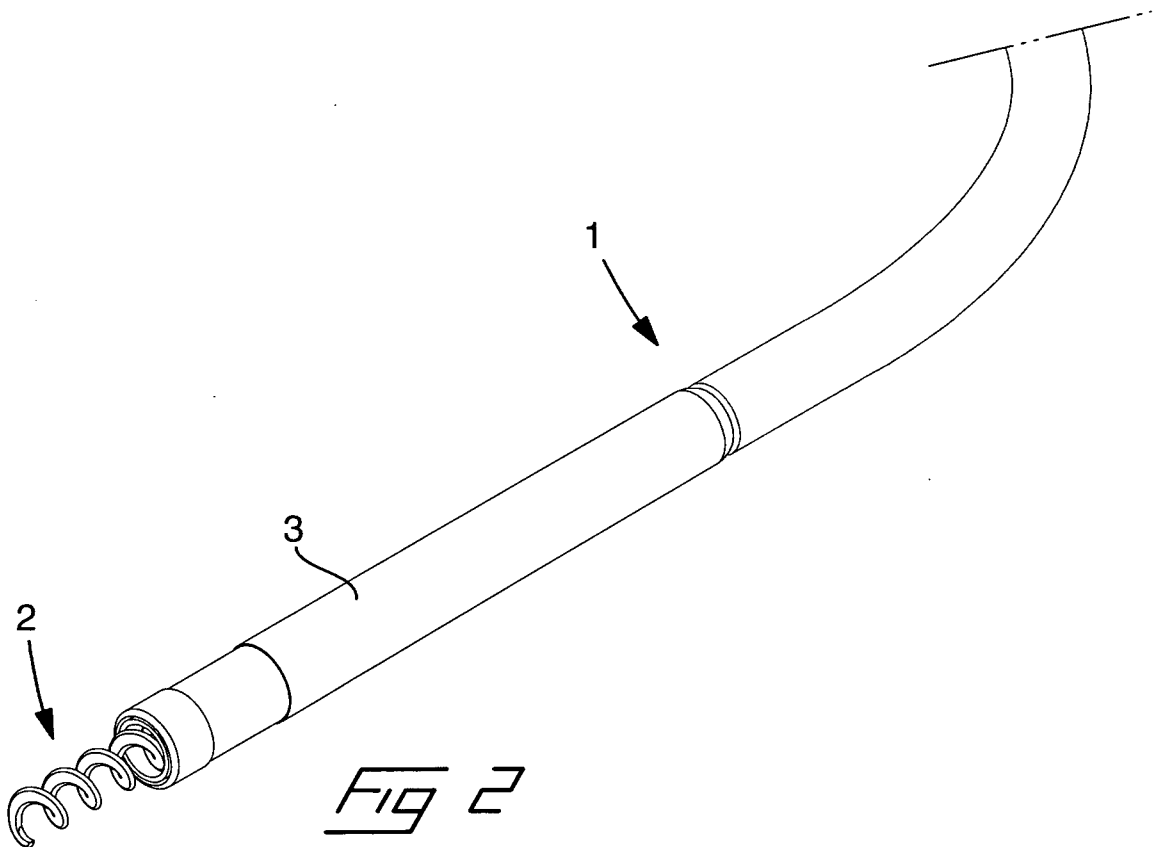
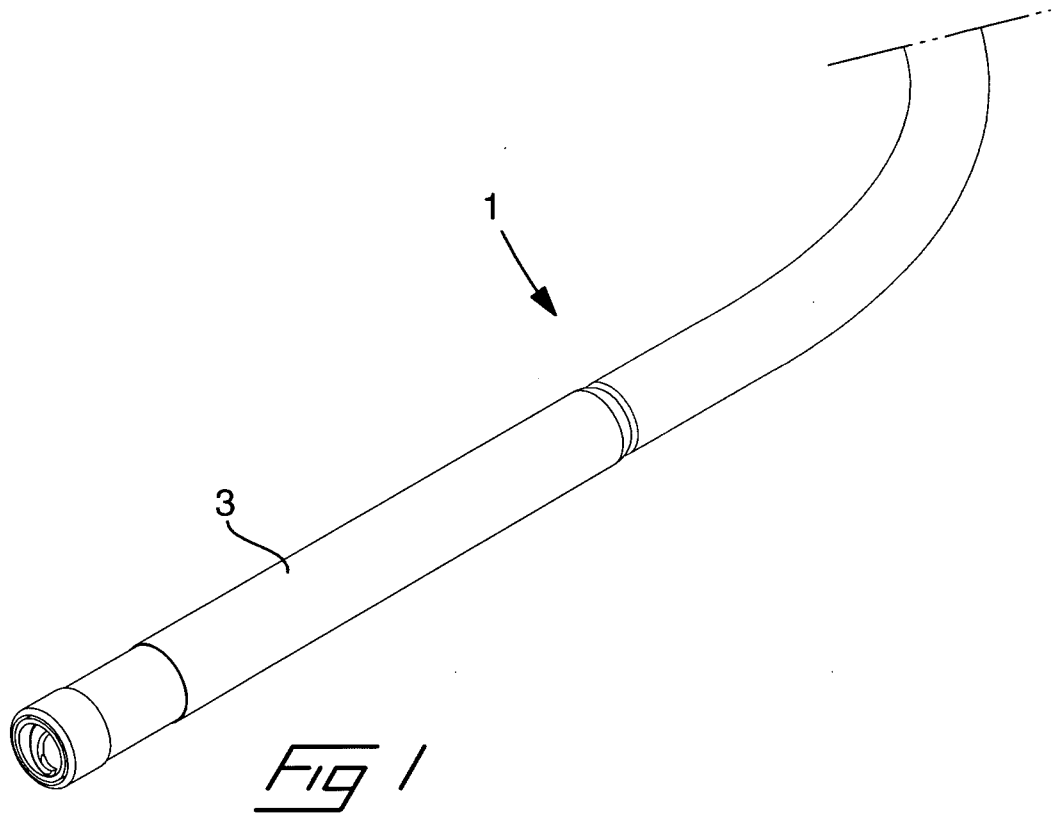
5 7. A medical implantable lead according to claim 6, c h a r a c t e r i -
z e d in that the cross sectional shape of the helix wire (4) includes at least
one distinct edge (6) along the longitudinal extension of the helix wire.

8. A medical implantable lead according to claim 7, c h a r a c t e r i -
10 z e d in that at least one distinct edge (6) is directed outwards in relation to
the inner diameter space.

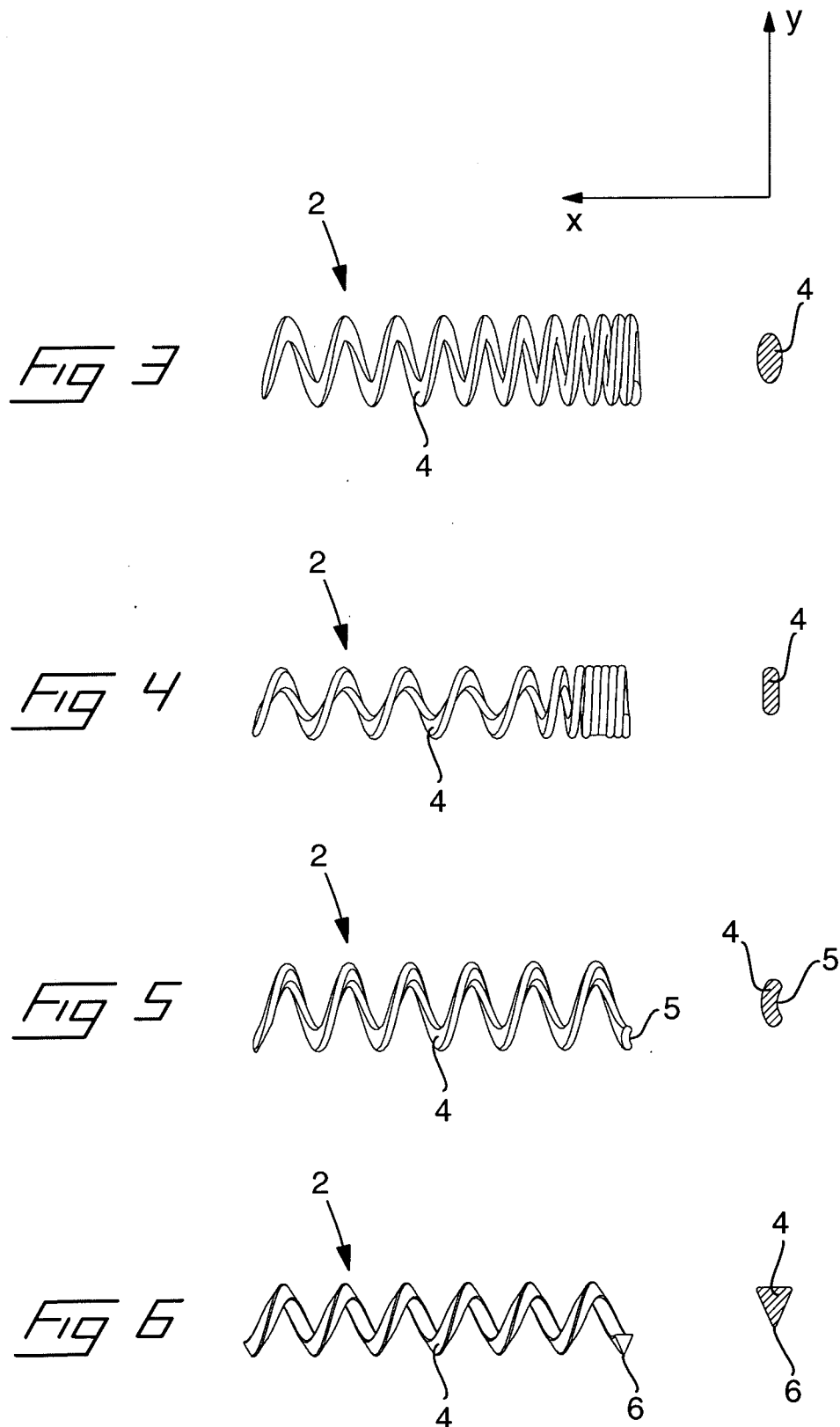
9. A medical implantable lead according to any of the claims 6-8,
c h a r a c t e r i z e d in that the cross sectional shape of the helix wire (4)
15 includes at least one groove formation (5) having a concavely shaped sur-
face.

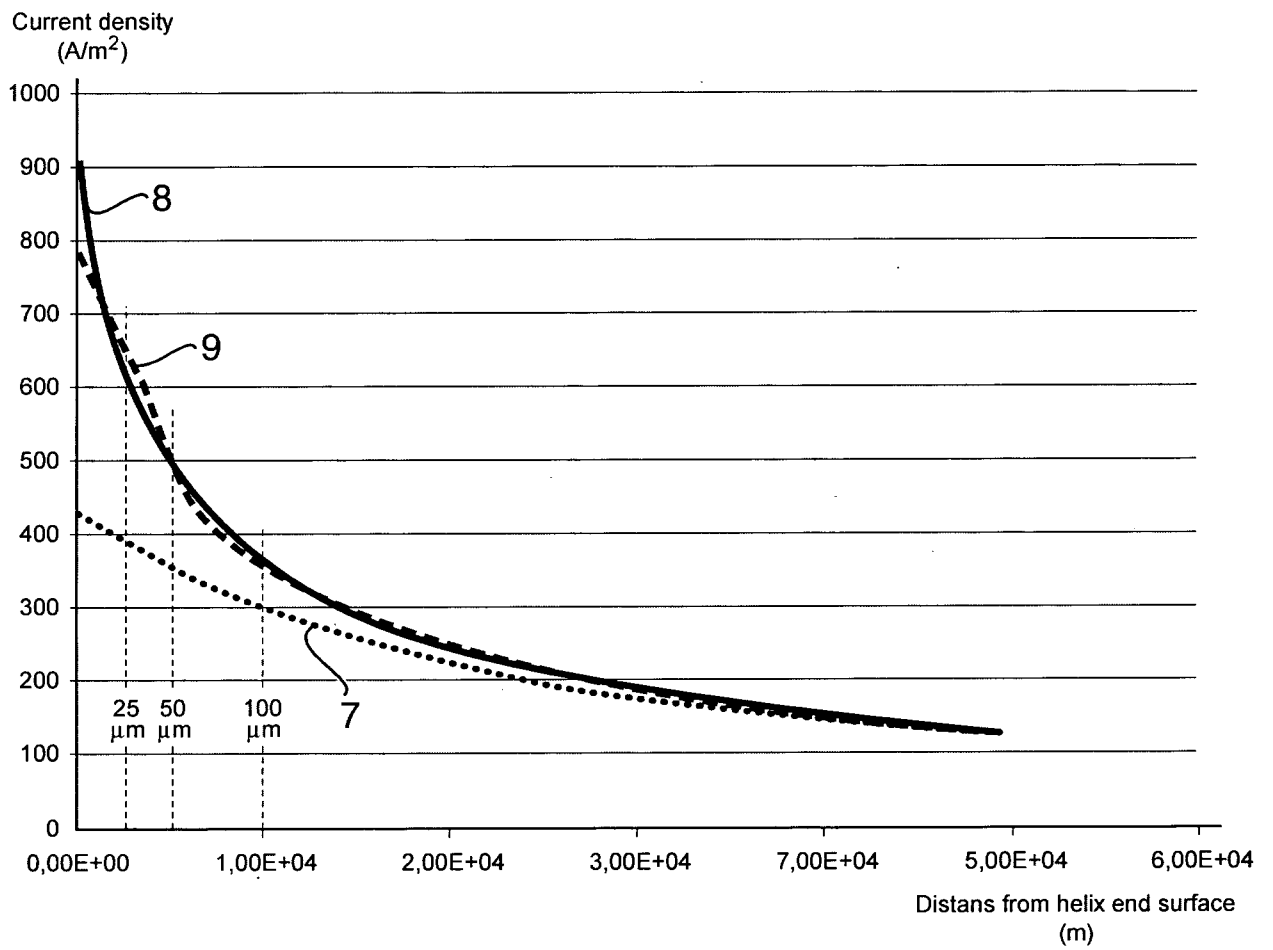
10. A medical implantable lead according to any of the claims 6-9,
c h a r a c t e r i z e d in that the active fixation helix (2) is adapted to function
20 as an electrode inside the tissue.

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2/3



*Fig 7*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2008/000639

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet

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)

IPC: A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 7204847 B1 (GAMBALE), 17 April 2007 (17.04.2007), column 1, line 1 - line 41; column 2, line 26 - line 67; column 3, line 10 - line 35, column 5, lines 6-31; figures 1-3; abstract	1-3,5-8,10
Y	--	4,9
Y	US 5002067 A (BERTHELSEN ET AL), 26 March 1991 (26.03.1991), column 1, line 45 - line 60, figure 1, abstract	4,9
A	US 5354327 A (SMITS), 11 October 1994 (11.10.1994), figures 2a-6b, abstract	1-10

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20060247751 A1 (SEIFERT), 2 November 2006 (02.11.2006), paragraph (0005); abstract --	1-10
A	US 20060052770 A1 (MULIER ET AL), 9 March 2006 (09.03.2006), figures 12-14, abstract -- -----	1-10

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Cited literature, if any, will be enclosed in paper form.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/SE2008/000639

US	7204847	B1	17/04/2007	NONE
US	5002067	A	26/03/1991	NONE
US	5354327	A	11/10/1994	WO 9422525 A 13/10/1994
US	20060247751	A1	02/11/2006	NONE
US	20060052770	A1	09/03/2006	NONE