



- (51) **International Patent Classification:**
A61N 1/08 (2006.01) *H01B 7/04* (2006.01)
- (21) **International Application Number:**
PCT/SE2008/000678
- (22) **International Filing Date:**
2 December 2008 (02.12.2008)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
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- (81) **Designated States (unless otherwise indicated, for every kind of national protection available):** AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States (unless otherwise indicated, for every kind of regional protection available):** ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

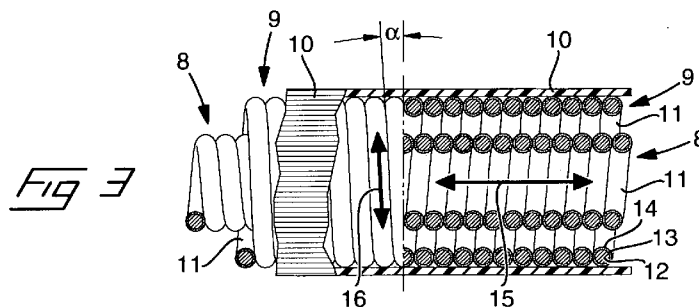
Declarations under Rule 4.17:

— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

(54) **Title:** A MEDICAL IMPLANTABLE LEAD AND A METHOD FOR MANUFACTURING THE SAME



(57) **Abstract:** The invention relates to a medical implantable lead of the kind being adapted to be implanted into a human or animal body for monitoring and/or controlling of an organ (2) inside the body. The lead (3) comprising a fixation means (6) in a distal end, which is adapted to fixate a distal end of the lead (3) to the organ, an electrode member (6) in the distal end adapted to be in contact with tissue of the organ and receive and/or transmit electrical signals from and/or to the organ, and at least one electrically conducting coil (8, 9), which includes one or more electrically conducting helical wires (11) and which is adapted to connect the electrode member in the distal end with a monitoring and/or controlling device (1) in a proximal end of the lead. The one or more individual wires (11) of the coil comprises a wire core (12) which is provided with a surrounding electrically insulating layer (13), which in its turn is provided with a surrounding electrically conducting shield layer (14), and the coil is close-lapped such that electrically conducting shield layers of adjacent loops of the coil are in electrical contact with each other.



A MEDICAL IMPLANTABLE LEAD AND A METHOD FOR
MANUFACTURING THE SAME

The present invention relates to a medical implantable lead of the kind being adapted to be implanted into a human or animal body for monitoring and/or controlling of an organ inside the body, comprising a fixation means in a distal end which is adapted to fixate the distal end of the lead to the organ,
5 an electrode member in the distal end adapted to be in contact with tissue of the organ and receive and/or transmit electrical signals from and/or to the organ, and at least one electrically conducting coil, which includes one or more electrically conducting helical wires and which is adapted to connect the electrode member in the distal end with a monitoring and/or controlling device in a
10 proximal end of the lead.

The invention also relates to a method for manufacturing of a medical implantable lead.

Background of the invention

15 It is well known in the art to use a medical implantable lead of the above kind to monitor and/or control the function of an organ inside a human or animal body, for example to monitor and/or control a heart by means of a monitoring and/or controlling device in form of a pacemaker or cardiac defibrillator connected to the proximal end of the lead. The medical implantable
20 lead is provided with at least one electrical conductor in form of a coil having one or more helically formed electrical conducting wires. The lead is, in its distal end, provided with one or more electrodes, which is adapted to be in contact with the tissue of the organ and which is connected to the one or more electrical conducting coils, for receiving and/or transmitting electrical
25 signals from and/or to the organ. The electrodes can optionally be formed as a contact electrode, abutting against a surface of the organ, as a penetrating electrode being penetrated through a surface of the organ and embedded within the tissue, or as a so called indifferent electrode which is surrounded by body fluids such as blood.

Normally, such medical implantable leads are not considered to be compatible with Magnetic Resonance Imaging (MRI), i.e. persons or animals having such a lead implanted into the body, are excluded from being examined by MRI scanning. This is due to the fact that the electromagnetic field, that is generated during the MRI scanning, will induce a current in the conductor, which connects the one or more electrodes in the distal end of the medical implantable lead with the monitoring and/or controlling device in the proximal end of the lead. This induced current may cause heating in the electrode being in contact with the tissue of the organ. If the heating is too high, there is a risk that this will cause damages to the tissue. However, the use of MRI scanning for diagnostics is growing extensively and an increasing number of the population having a lead implanted, would benefit from MRI scans. It is thus desirable to reduce any heating at or close to the lead tip to acceptable and safe levels.

It is known in the art to provide such medical implantable leads with an electrical shielding, in form of a tube of braided wires, which surrounds the coil and which in its proximal end normally is connected to the casing of the monitoring and/or controlling device. However, such shielded medical implantable leads are associated with several disadvantages. On the one hand, the braided shielding will give the medical implantable lead an increased thickness as well as increased rigidity, which normally is not desirable. On the other hand, the braided shielding will considerably increase the costs for manufacturing the lead, since it will involve the provision of one additional component, which has to be mounted when assembling the lead. Also, it has appeared that such a braided shielding can not prevent the induction of electrical current to the coiled conductor in a degree that is sufficient to, without risk, expose an individual, having an implanted lead, to a MRI scanning.

Summary of the invention

It is an object of the invention to provide a medical implantable lead having an improved shielding in relation to prior art. More specifically, it is an object to provide a shielded medical implantable lead, by which the shielding can be made with excellent shielding properties and in a cost-saving way. At

least this object is achieved by a medical implantable lead according to claim 1.

The invention also relates to a method for manufacturing a medical implantable lead comprising an electrical shielding, having essentially the same object as above. At least this object is achieved by a method according to claim 11.

Accordingly, the basis of the invention is the insight that the above object may be achieved by manufacturing the conductor coil from one or more wires, which each has an electrically conducting central wire core provided with a surrounding electrically insulating layer and also a surrounding electrically conducting shield layer on the outside of the insulating layer. One or more such composite wires, having such a structure, are thereafter helically formed to a close-lapped coil. During operation the wire core is utilized for conduction of signals, normally low frequency signals, between the electrode and the monitoring and/or controlling device, whereas the outer electrically conducting shield layer will function as a shielding for preventing or at least restricting an electromagnetic field from MRI scanning, or from some other type of source, to induce voltage/current into the wire core. At least one end of the shield layer is preferably connected to a casing of the monitoring and/or controlling device for electrical bonding of the shield.

Several advantages may be achieved by a medical implantable lead formed in this way. One advantage is that a wire coil having an electrical shielding according to the invention, may be manufactured to a cost that is not significantly higher than for manufacturing a regular coil without any shielding.

Another advantage is that the shielding properties for a wire coil according to the invention, will be improved in relation to a regular shielding in form of a tube of braided wires. This is due to the fact that, since the coil is close-lapped and adjacent loops of the coil will normally be in contact with each other, the conducting path for the induced electric current in the shield layer will be directed in the longitudinal direction of the lead, while the conducting path for the signals in the wire core will be directed in the longitudinal direction of the wires, i.e. nearly 90° in relation to each other since the wire is

close-lapped. Small spacings may sometimes be formed between adjacent loops when the lead is bent. However, the small capacitance occurring at the near lying shield layers, will act as a shortage for the high frequency signals such that electric contact and a conducting path in the longitudinal direction of the lead is nevertheless maintained. However, the possible electric current induced into the outer conducting shield layer, will in its turn have a low susceptibility of inducing its electric current into the wire core since their mutual direction of current flow, will have a large angle, of almost 90° in relation to each other. Moreover, any current induced from the electromagnetic field and from the current in the outer conducting shielding layer into the wire core of the coil will, since it usually concerns electromagnetic fields of very high frequencies, generally radio frequencies of about 30 MHz or more, experience a very high impedance in the coiled conductor which effectively will counteract any induced current in the wire coil. Also, the reactance between adjacent loops of the central wire core will be rather high due to the insulation layer around the wire core, such that the capacitive coupling between adjacent loops will be low which effectively will reduce any current flow due to capacitive coupling.

It is also an advantage that the present invention will result in a less increment of the diameter and the stiffness of the wire coil in comparison with using an ordinary shielding in form of a tube of braided wires, since the shield layer may be formed with a small thickness.

A medical implantable lead according to the invention can be modified in many different ways. A common embodiment of a medical implantable lead comprises two electrically conducting wire coils, which are concentric positioned with one inside the other and which are connected to separate electrodes in the distal end of the lead. One electrode can be in form of a helix, which is connected to the inner wire coil and which is adapted to be screwed into the tissue and accordingly also serves the double function of attaching the distal end of the lead to the organ. The rotating of the helix can optionally be performed by rotating of the inner wire coil in relation to the outer wire coil, as is common knowledge within the art. The outer wire coil, in its turn, can be

connected to an indifferent electrode, e.g. a ring formed electrode on the outer circumference of the distal end.

However, also other embodiments are conceivable. For example a medical implantable lead having only one wire coil. In most cases each wire coil forms only one single conductor which, even if it is composed of two or more individual wires, is connected to one single electrode. However, it is within the scope of the invention that a wire coil may contain two or more individual conductor wires, which are co-radially wound to form the wire coil and which are connected to different electrodes. The lead may comprise more than two electrodes and accordingly also more than two individual conductors. Moreover, the electrodes may be formed in other ways than as a rotatable helix or a ring-formed electrode. For example it can be some other type of penetrating electrode having barbes or the like, or be a contact electrode adapted to abut against a surface of the organ. Also, a fixation means does not need to be penetrating or to have the function of an electrode. Instead the fixation means may be of a type which e.g. is adapted to engage in the trabecular network inside a heart and may have only a fixating function and be combined with a separate electrode, for instance a contact electrode abutting against the surface of the tissue.

In case the medical implantable lead comprises two or more wire coils, it is within the scope of the invention that only one, all of them, or an arbitrary number of the wire coils are provided with a wire core, a surrounding insulating layer and a surrounding conducting shield layer, according to the invention. The chosen configuration may vary depending on the actual field of application, the required characteristics and the like. Normally, the most critical electrode with regard to heating problems due to induced electromagnetic radiation, is an electrode being in direct contact with the tissue, such as an electrode penetrated into the tissue or abutting against a surface, while an indifferent electrode being only in contact with body fluids, normally is not critical since it often has a rather large surface which will give low current density and the body fluids will cause sufficient cooling of the electrode. However, even if an electrode that is in direct contact with the tissue, is connected to an inner wire coil and there is provided also an outer wire coil, it may be

beneficial to arrange the outer wire coil with an insulating layer and a conducting shield layer, according to the invention, in case only one of the wire coils are to be shielded. This is due to the fact that in such case the main part of the electromagnetic field will be absorbed by a shielding being positioned on a comparatively long distance from the most critical inner wire coil, having the result that the inductive as well as the capacitive coupling to the inner wire coil will be rather poor.

Prior art medical implantable leads having two uninsulated wire coils, are normally separated by a flexible tube of an insulating material positioned between the wire coils, in order to maintain the signals in the respective wire coils separated from each other. By a medical implantable lead according to the invention, where both of the wire coils are provided with a surrounding insulating layer and a surrounding conducting shield layer, such an intermediate flexible tube may be dispensed with since the inner signal conducting wire cores are insulated from each other. In such a case the inner and outer wire coils will have a common shielding since the outer surrounding conducting shield layer of each wire coil will be in contact with each other. However, it is also conceivable that only one wire coil is provided with a surrounding conducting shield layer whereas the other is provided with only a surrounding insulating layer, as in a hereinafter described and illustrated embodiment.

In an actual embodiment of the invention, the inner conducting wire core may have of diameter of about 0,1 – 0,15 mm, the surrounding insulating layer may have a thickness of about 0,02 – 0,1 mm and the surrounding conductive shield layer may have a thickness of about 1 – 50 μ m. However, also other dimensions could be conceivable. The insulating layer could for example be an oxide layer, silicon, polyurethane, a combination of those, fluorinated hydrocarbon, e.g. ETFE, polyimide, polyamide, etc. The outer surrounding conducting shield layer may be a metal such as a noble metal, e.g. gold, but also electrical conducting non-metals could be conceivable. The insulating layer as well as the shield layer are preferably applied when the wire is in a straight condition and thereafter the wire is wounded to a coil. The shield layer may be applied by means of any suitable method, such as by

means of e.g. plasma sputtering, physical vapour deposition, physical vapour decomposition, electrochemical bath, etc.

The thickness of the shield layer will influence the shielding characteristics and is also dependant of the conductance of the material as well as the frequency of the electromagnetic field. By means of a customary braided shield, the characteristics are hard to control. However, with a shield layer according to the invention, the thickness of the shield layer can be controlled within very narrow limits, such that the shielding characteristics may be very close adapted to a specific electromagnetic field, such as from MRI scanning.

The angle between the axial direction of the lead, i.e. the direction which the induced current in the electrical conducting shield layer will have, and the direction of the inner wire core, i.e. the direction of the signals between the electrode and the monitoring and/or controlling device, is dependant of the outer diameter of the wire, the diameter of the wire coil and the number of wires in the wire coil. If, for example, the wire coil comprises two or more individual wires, the angle will be smaller than if the wire coil only comprises one single wire, since with two or more wires the pitch of the helically wound wires will increase. Generally, it is advantageous the larger the angle is and it is preferred that the angle is at least 70°.

20

Brief description of the drawings

The invention will hereinafter be described by way of example by reference to embodiments illustrated in the accompanying drawings, in which:

- Fig 1 is a schematic view illustrating connection of a pacemaker to a heart by means of two medical implantable leads;
- Fig 2 is a view of a shortened medical implantable lead;
- Fig 3 is a partly longitudinal section and partly cut view through a medical implantable lead according to a first embodiment of the invention;
- Fig 4 is a partly longitudinal section and partly cut through view through a medical implantable lead according to a second embodiment of the invention;

- Fig 5 is a partly longitudinal section and partly cut through view through a medical implantable lead according to a third embodiment of the invention;
- Fig 6 is a cross section of a wire having a wire core, an insulating layer and a shield layer; and
- 5 Fig 7 is a cross section of a wire having a wire core and an insulating layer.

Detailed description of embodiments of the invention

10 Reference is first made to fig 1, in which is disclosed, in a schematic view, the connection of a pacemaker 1 to a heart 2 by means of two medical implantable leads 3. More precisely, one lead is connected to the right atrium and the other lead is connected to the right ventricle of the heart for monitoring and pacing of the heart rate. The pacemaker is normally adapted to be

15 implanted under the skin of the patient, e.g. in the area of one of the collar bones, and the leads can preferably be inserted through a vein leading to the heart. It is to be noted that the reproduction scale of the pacemaker and the heart in the view of fig 1 are different for simplified drawing.

In fig 2 is illustrated a medical implantable lead 3, which has been

20 shortened for simplified drawing. The lead comprises a connector 4 in a proximal end for connection to the pacemaker, an intermediate flexible lead portion, and a so called header 5 in a distal end. The header is provided with a helix 6, which can be screwed out in the axial direction of the lead from a cavity in the distal end of the header. The helix has the function of attaching the

25 distal end of the lead to the heart, by being screwed into the tissue, and also functions as an electrode for receiving and/or transmitting electrical signals from and to the tissue, respectively. The header is also provided with a second electrode 7, a so called indifferent electrode, which is formed as a ring and positioned a small distance from the distal end and has the purpose of

30 forming a complete current path together with the helix.

Reference it then made to fig 3, which is a partly longitudinal section and a partly cut through view of a first embodiment of the medical implantable lead along the line A-A in fig 2. The lead comprises an inner wire coil 8, an

outer wire coil 9 and an outer protecting, fluidtight and flexible tube 10. The inner as well as the outer wire coils are each comprised of one close-lapped wire 11 which forms an inner bore and, as can be seen, the inner wire coil is concentric positioned within the inner bore of the outer wire coil.

5 With reference also to fig 6, which illustrates a cross section through the wire 11 of the inner as well as the outer wire coil 8, 9, it can be seen that the wire is composed of an electrically conducting central wire core 12, a surrounding electrically insulating layer 13 and, on the outside of the insulating layer, a surrounding electrically conducting shield layer 14. The central wire
10 core 12 of the inner wire coil 8 is electrically connected to the helix electrode 6, whereas the central wire core 12 of the outer wire coil 9 is connected to the second electrode 7. Since both of the wire coils are close-lapped, the outer electrically conducting shield layer 14 of each of the wires 11 in the inner and
15 outer wire coils 8, 9, respectively, will form a continuous conducting path along the outside as well as the inside of each wire coil. By electrically bonding of this conducting path, formed by the outer conducting shield layers of the wires, to a casing of the pacemaker 1 or the like, an effective shield is obtained for the wire core 12, which is utilized for conducting signals between the pacemaker 1 and the heart 2. The shield layers of the wire coils can both
20 be arranged with electrically bonding or only one of them according to what is most appropriate in each individual case.

 Since the shield layers each forms a continuous conducting path along the lead, any induced current from an external electromagnetic field, will induce a high frequency current moving in the axial direction of the lead illustrated by a horizontal bidirectional arrow 15 in fig 3. The signals between the
25 pacemaker and the electrodes, on the other hand, will move within the wire core 12 in the direction of the nearly vertical bidirectional arrow 16 in fig 3. This has the effect that the directions of any induced current in the shield layer and the signals inside the wire core will be nearly 90° in relation to each other. In the embodiments of fig 3 and 6, an angle α between the wire and a
30 line being perpendicular to the coil axis, is approximately 3° and consequently the angle between the coil axis and the wire is approximately 87°. This means that any current induced into the shield layer 14 will in its turn be restrained

from being induced into the signal conducting wire core 12, as discussed hereinbefore.

Reference is then made to fig 4, in which is illustrated an embodiment being similar to fig 3 except that only the outer wire coil 9 is composed of a wire 11 having a central wire core 12, an insulating layer 13 and a shield layer 14, as in the embodiment according to fig 3 and as shown in fig 6, while the inner wire coil 8 is composed of a plain electrical conducting wire 17 having neither an insulating layer nor a shield layer. Accordingly, only the outer wire coil 9 is shielded. In order to prevent the inner wire coil 8 from being short-circuited by contact with the shield layer of the outer wire coil, also an inner flexible tube 18 of an electrically insulating material is arranged in the area between the inner and outer wire coils.

In fig 5 is illustrated a third embodiment of a medical implantable lead according to the invention. This embodiment comprises an inner wire coil 8, an outer wire coil 9 and an outer protecting, fluidtight and flexible tube 10, i.e. similar to the embodiment of fig 3. As in the embodiment in fig 3, the outer wire coil 9 is formed of a wire 11 having an inner wire core 12, a surrounding insulating layer 13 and an outer surrounding shield layer 14. However, the inner wire coil 8 is in this embodiment formed of a wire 19, as illustrated in fig 7, which only has an inner wire core 12 and a surrounding electrically insulating layer 13. I.e. a surrounding shield layer is missing in this embodiment of the wire. This can be advantageous in so far as in this case the main part of the electromagnetic radiation will be absorbed by the shield layer 14 at the outer wire coil 9. The induced current in the outer wire coil will in its turn have difficulties to be induced over to the inner wire coil, since the induced current in the outer wire coil will be directed in the axial direction of the lead, i.e. in parallel to the arrow 15, while the inner wire coil 8 will only have one conducting direction along the wire core 12, i.e. in parallel to the arrow 16 and almost 90° in relation to the axial direction of the lead, due to the insulating layer 13 and the absence of any shield layer. In comparison to the embodiment according to fig 3, the embodiment of fig 5 is not formed with an inner coil having a surrounding shield layer conducting an induced current all around the wire core 12, which might further restrain current from being induced into the

wire core of the inner coil. On the other hand, in comparison to the embodiment according to fig 4, the wire of the inner coil in the embodiment of fig 5 is provided with an insulating layer such that the conducting path in the wire core¹² will be in the direction of the wires and not in the axial direction of the lead as in the embodiment of fig 4, which also may further restrain current from being induced into the wire core of the inner lead.

It is obvious for those skilled in the art that this invention is applicable for any type of medical implantable lead, e.g. for an implantable pulse generator such as ICD, neurostimulators etc.

CLAIMS

1. A medical implantable lead of the kind being adapted to be im-
planted into a human or animal body for monitoring and/or controlling of an
5 organ (2) inside the body, comprising a fixation means (6) in a distal end,
which is adapted to fixate the distal end of the lead (3) to the organ, an elec-
trode member (6) in the distal end adapted to be in contact with tissue of the
organ and receive and/or transmit electrical signals from and/or to the organ,
and at least one electrically conducting coil (8, 9), which includes one or more
10 electrically conducting helical wires (11) and which is adapted to connect the
electrode member in the distal end with a monitoring and/or controlling device
(1) in a proximal end of the lead, c h a r a c t e r i z e d in that the one or
more individual wires (11) of the coil comprises a wire core (12) which is pro-
vided with a surrounding electrically insulating layer (13), which in its turn is
15 provided with a surrounding electrically conducting shield layer (14), and that
the coil is close-lapped such that electrically conducting shield layers of adja-
cent loops of the coil are in electrical contact with each other.

2. A medical implantable lead according to claim 1, c h a r a c t e r i -
20 z e d in that it comprises two electrically conducting coils (8, 9), of which at
least one comprises a wire (11) including a central wire core (12) with a sur-
rounding electrically insulating layer (13) and an electrically conducting shield
layer (14).

25 3. A medical implantable lead according to claim 1 or 2, c h a r a c t e -
r i z e d in that the fixation means is a penetrating fixation means (6), which is
adapted to penetrate into the tissue for fixation to the same.

30 4. A medical implantable lead according to claim 3, c h a r a c t e r i -
z e d in that the fixation means is in form of a helix (6), which is adapted to be
screwed into the tissue of the organ.

5. A medical implantable lead according to any of the preceding claims, characterized in that the fixation means (6) functions as an electrode member.

5 6. A medical implantable lead according to any of the preceding claims, characterized in that the angle between the direction of the individual wires (11) and the longitudinal axis of the coil (8, 9) is at least 70°.

7. A medical implantable lead according to any of the preceding claims, 10 characterized in that the insulating layer (13) surrounding each individual wire core (12) is between 0,02 and 0,1 mm.

8. A medical implantable lead according to any of the preceding claims, 15 characterized in that the electrically conducting shield layer (14) surrounding each individual wire (11) is between 1 and 50 μm .

9. A medical implantable lead according to any of the preceding claims, 20 characterized in that the coil (8, 9) comprises two or more coradial wires (11), each having a wire core (12), an insulating layer (13) and an electrically conducting shield layer (14).

10. A medical implantable lead according to any of the preceding 25 claims, characterized in that it comprises at least one wire coil (9) being formed of a wire (11) having an inner wire core (12), a surrounding insulating layer (13) and a surrounding shield layer (14), and at least one wire coil (8) being formed of a wire (19) having an inner wire core (12) and a surrounding insulating layer (13).

11. A method for manufacturing of a medical implantable lead of the 30 kind being adapted to be implanted into a human or animal body for monitoring and/or controlling of an organ (2) inside the body, the lead (3) comprising a fixation means (6) in a distal end, which is adapted to fixate the distal end of the lead to the organ, an electrode member (6) in the distal end adapted to

receive and/or transmit electrical signals from and/or to the organ, and at least one electrically conducting coil (8, 9), which is provided with an electrically shielding (14), for restraining induction of electric current from a varying electromagnetic field, and includes one or more electrically conducting helical

5 wires (11), and which is adapted to connect the electrode member (6) in the distal end with a monitoring and/or controlling device (1) in a proximal end of the lead, comprising the steps of:

providing an electrically conducting wire core (12);

covering the electrically conducting wire core with a surrounding electrically

10 insulating layer (13);

covering the insulating layer with an electrically conducting shield layer (14);

forming the in this way formed composite wire (11) by winding to a close-lapped coil (8, 9); and

assembling the close-lapped coil into a medical implantable lead (3), wherein

15 the central wire core (12) is connected to an electrode (6) in a distal end of the lead and the outer electrically conducting shield layer (14) is adapted for electrical bonding.

1/2

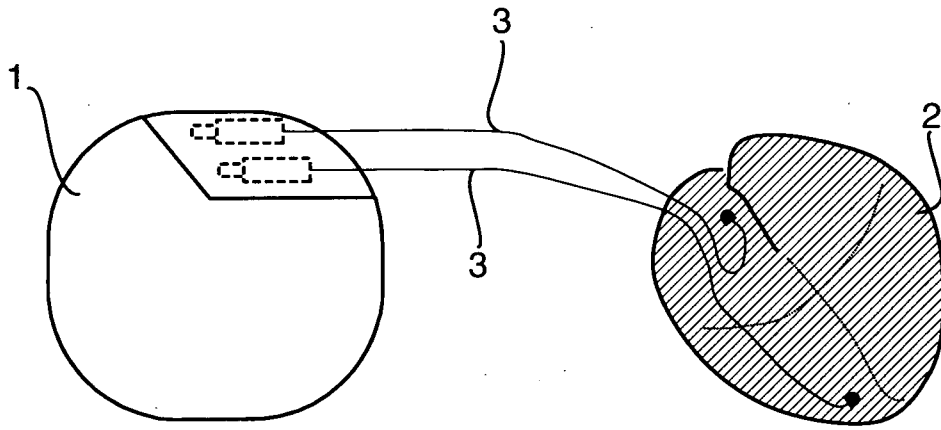


Fig 1

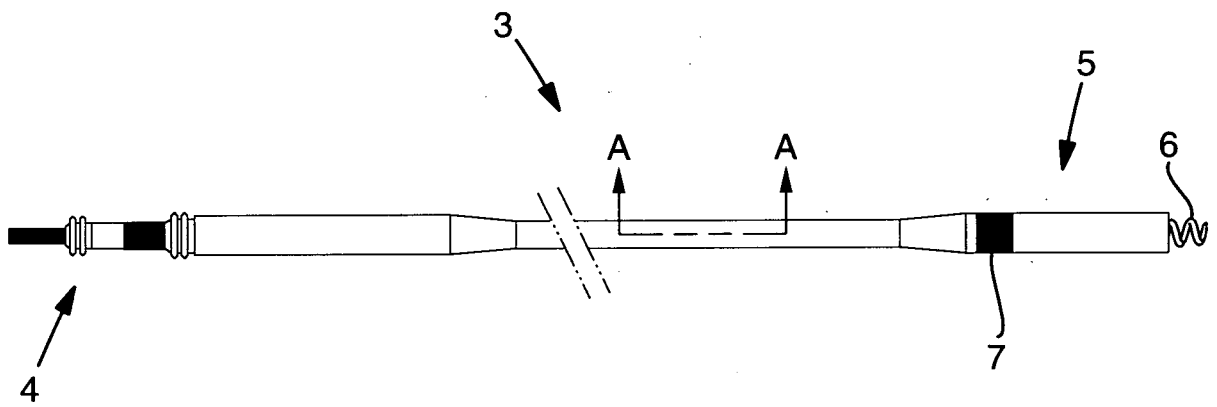


Fig 2

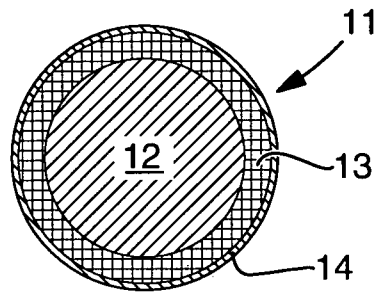
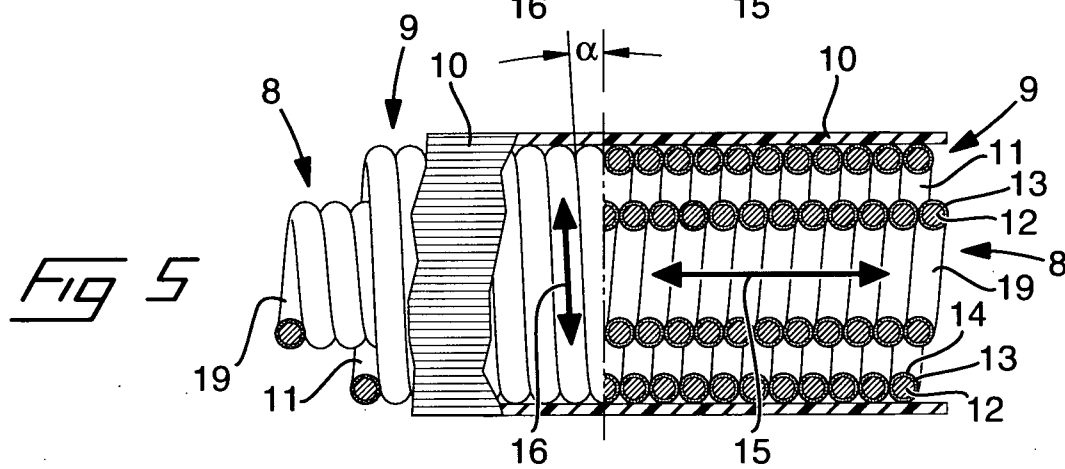
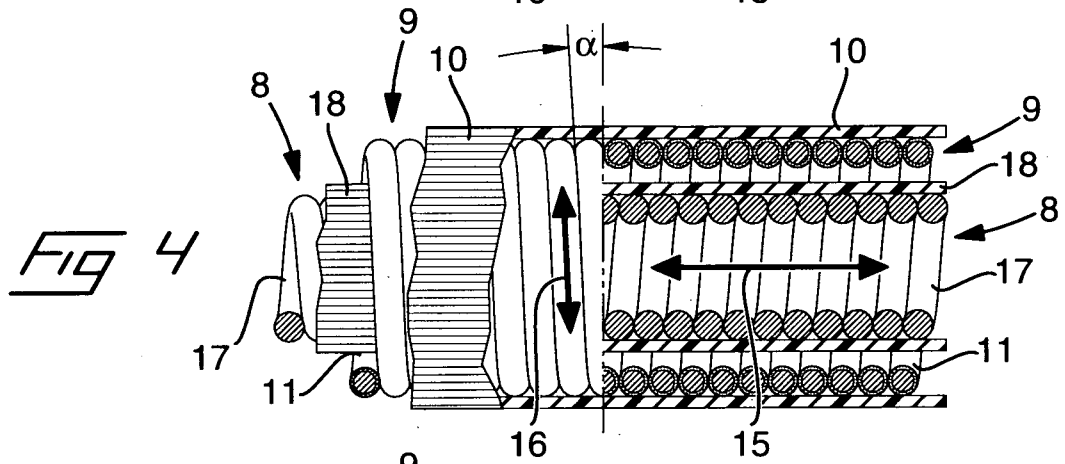
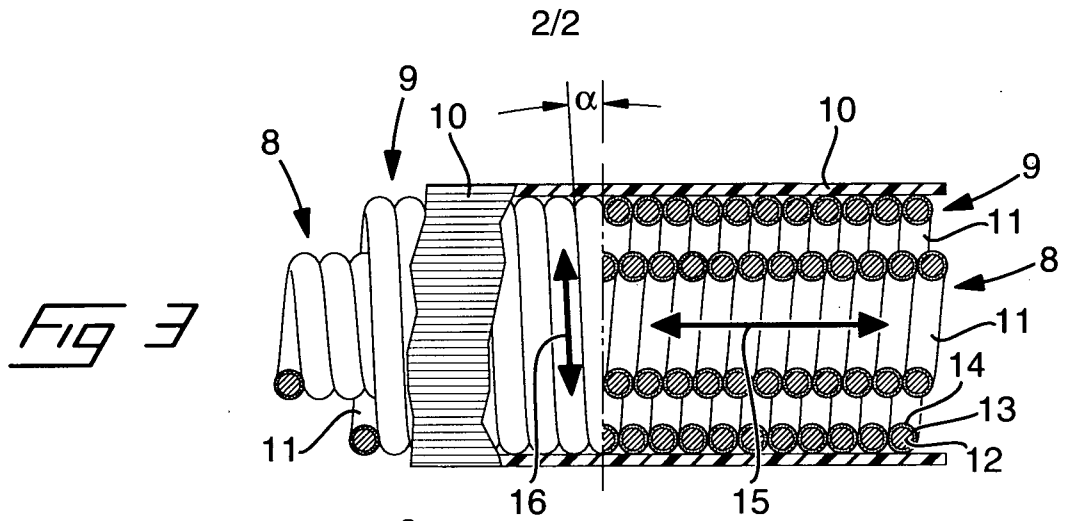


Fig 6

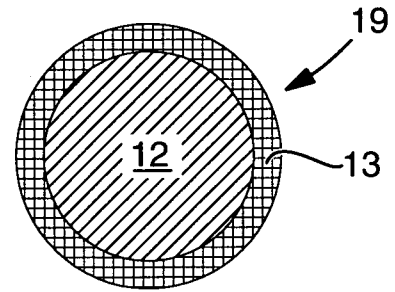


Fig 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE2008/000678

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, H01B

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.
A	US 20080132985 A1 (S.R. WEDAN ET AL), 5 June 2008 (05.06.2008), abstract, paragraph (0003) --	1-11
A	US 20040014355 A1 (T.P. OSYPKA ET AL), 22 January 2004 (22.01.2004), figure 8A, abstract --	1-11
A	WO 2007047966 A2 (SURGIVISION, INC.), 26 April 2007 (26.04.2007), figures 18A-18C, paragraph (0110) -- -----	1-11

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