(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 November 2009 (12.11.2009)

PCT

(10) International Publication Number
WO 2009/137186 A1

(51) International Patent Classification:
A61N 1/05 (2006.01) *A61N 1/08* (2006.01)

(21) International Application Number:
PCT/US2009/038629

(22) International Filing Date:
27 March 2009 (27.03.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/051,927 9 May 2008 (09.05.2008) US
12/411,681 26 March 2009 (26.03.2009) US

(71) Applicant *(for all designated States except US)*: **CARDIAC PACEMAKERS, INC.** [US/US]; 4100 Hamline Avenue North, St. Paul, MN 55112 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **FOSTER, Arthur, J.** [US/US]; 6926 Tourville Circle, Centerville, MN 55038 (US).

(74) Agents: **RODGERS, James** et al.; 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402-3901 (US).

(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, MK, 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).

Published:

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

(54) Title: MEDICAL LEAD COIL CONDUCTOR WITH SPACER ELEMENT

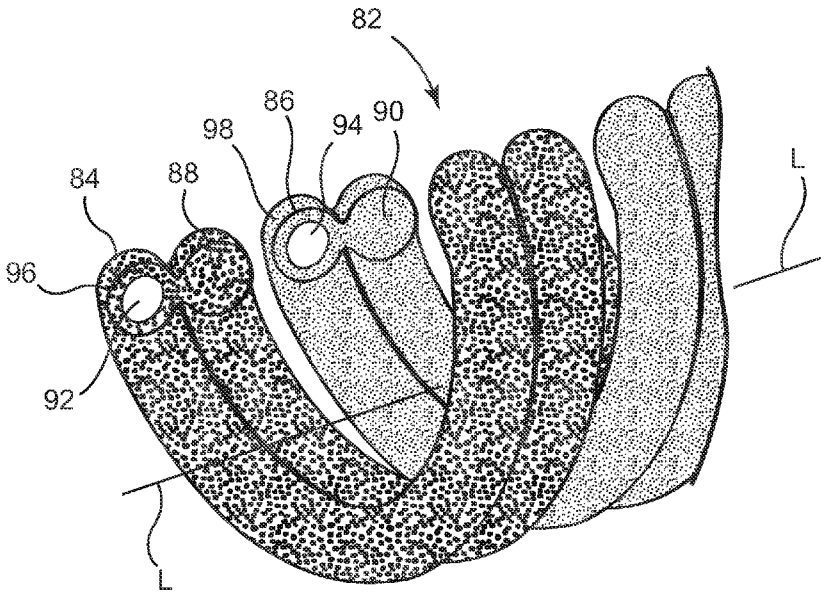

Fig. 6

(57) Abstract: Medical electrical leads equipped with spacer elements and configured for use during medical procedures such as magnetic resonance imaging (MRI) are disclosed. An illustrative medical electrical lead includes a proximal connector, an insulated lead body including at least one electrode, a helically coiled conductor wire, and a helically coiled spacer element interstitially disposed between adjacent turns of the conductor wire.

WO 2009/137186 A1

MEDICAL LEAD COIL CONDUCTOR WITH SPACER ELEMENT

TECHNICAL FIELD

[0001] The present invention relates to implantable medical devices for stimulating body tissues and/or sensing physiological attributes. More specifically, the present invention relates to medical electrical leads that dissipate and/or deflect electromagnetic energy during medical procedures such as magnetic resonance imaging (MRI).

BACKGROUND

[0002] Magnetic resonance imaging (MRI) is a non-invasive imaging method that utilizes nuclear magnetic resonance techniques to render images within a patient's body. Typically, MRI systems employ the use of a magnetic coil having a magnetic field strength of between about 0.2 to 3 Teslas. During the procedure, the body tissue is briefly exposed to RF pulses of electromagnetic energy in a plane perpendicular to the magnetic field. The resultant electromagnetic energy from these pulses can be used to image the body tissue by measuring the relaxation properties of the excited atomic nuclei in the tissue.

[0003] During imaging, the electromagnetic radiation produced by the MRI system may be picked up by implantable device leads used in implantable medical devices such as pacemakers or cardiac defibrillators. This energy may be transferred through the lead to the electrode in contact with the tissue, which may lead to elevated temperatures at the point of contact. The degree of tissue heating is typically related to factors such as the length of the lead, the conductivity or impedance of the lead, and the surface area of the lead electrodes. Exposure to a magnetic field may also induce an undesired voltage in the lead.

SUMMARY

[0004] The present invention relates to medical electrical leads configured to dissipate and/or deflect electromagnetic energy during medical procedures such as magnetic resonance imaging (MRI). An illustrative medical electrical lead includes a proximal connector configured to couple the lead to an implantable medical device, and an insulated lead body coupled to the proximal connector and including at least one electrode for use in providing therapeutic stimulus energy to the body and/or for sensing electrical activity within the body. The lead includes at least one helically coiled conductor wire electrically coupled to an electrode, and at least one non-conductive spacer element electrically isolated from the electrode. The turns of the spacer element are interstitially disposed between the turns of the conductor coil, and in some embodiments include a conductive inner core that can be used to dissipate electromagnetic energy along the length of the lead.

[0005] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 is a schematic view showing an implantable medical device including a lead implanted within the heart of a patient;

[0007] Figure 2 is a perspective view of a medical electrical lead in accordance with an illustrative embodiment;

[0008] Figure 3 is a partial cross-sectional view showing an illustrative conductor coil assembly for use with the medical electrical lead of Figure 2;

[0009] Figure 4 is a cross-sectional view of the conductor coil assembly along line 4-4 in Figure 3;

[0010] Figure 5 is a partial cross-sectional view showing another illustrative conductor coil assembly for use with a medical electrical lead;

[0011] Figure 6 is a partial cross-sectional view showing another illustrative conductor coil assembly for use with a medical electrical lead;

[0012] Figure 7 is a partial cross-sectional view showing another illustrative conductor coil assembly for use with a medical electrical lead;

[0013] Figure 8 is a partial cross-sectional view showing another illustrative conductor coil assembly for use with a medical electrical lead; and

[0014] Figure 9 is a partial cross-sectional view showing another illustrative conductor coil assembly for use with a medical electrical lead.

[0015] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION

[0016] Figure 1 is a schematic view showing an implantable medical device 12 including a lead implanted within the body of a patient. In the illustrative embodiment depicted, the implantable medical device 12 includes a pulse generator 14 implanted within the patient's body and a lead 16 (e.g., a unipolar or bipolar lead) placed at a location in or near the patient's heart 18. The heart 18 includes a right atrium 20, a right ventricle 22, a left atrium 24, and a left ventricle 26. The pulse generator 14 can be implanted subcutaneously within

the body, typically at a location such as in the patient's chest or abdomen, although other implantation locations are possible.

[0017] A proximal portion 28 of the lead 16 can be coupled to or formed integrally with the pulse generator 14. A distal tip portion 30 of the lead 16, in turn, can be implanted at a desired location in or near the heart 18 such as the right ventricle 22, as shown. Although the illustrative embodiment depicts only a single lead 16 inserted into the patient's heart 18, in other embodiments multiple leads can be utilized so as to electrically stimulate other areas of the heart 18. In some embodiments, for example, the distal portion of a second lead (not shown) may be implanted in the right atrium 20. In addition, or in lieu, another lead may be implanted in or near the left side of the heart 18 (e.g., in the coronary veins) to stimulate the left side of the heart 18. Other types of leads such as epicardial leads may also be utilized in addition to, or in lieu of, the lead 16 depicted in Figure 1.

[0018] During operation, the lead 16 can be configured to convey electrical signals from the pulse generator 14 to the heart 18. For example, in those embodiments where the pulse generator 14 is a pacemaker, the lead 16 can be used to deliver electrical therapeutic stimulus for pacing the heart 18. In those embodiments where the pulse generator 14 is an implantable cardiac defibrillator, the lead 16 can be used to deliver electric shocks to the heart 18 in response to an event such as a heart attack or ventricular tachycardia. In some embodiments, the pulse generator 14 includes both pacing and defibrillation capabilities.

[0019] When the pulse generator 14 is subjected to a gradient magnetic field, as shown generally by arrow "B" in Figure 1, a magnetically-induced voltage may be induced on the lead 16 that interferes with the therapeutic electrical signals normally delivered by the lead 16. During an MRI procedure, for example, a rapidly changing magnetic field B produced by an energized MRI coil may induce a voltage on the lead 16 that combines with the excitation voltage

normally generated by the pulse generator 14 for providing therapy. This voltage is transmitted as a current on the lead 16 along with the desired therapeutic stimulus current produced by the pulse generator 14. During operation, this voltage can result in undesirable currents on the lead 16 that are then transmitted into the surrounding cardiac tissue.

[0020] Figure 2 is a perspective view of a medical electrical lead 32 in accordance with an illustrative embodiment. As shown in Figure 2, the lead 32 includes an elongated lead body 34 having a proximal section 36 and a distal section 38. The proximal section 36 of the lead 32 has a proximal end 40, which in some embodiments is coupled to a hub connector 42 for use in connecting the lead 32 to an implantable medical device such as a pulse generator. The distal section 38 of the lead 32 terminates in a distal lead tip 44, which in some embodiments includes a distal electrode 46 for transmitting a therapeutic stimulus to the heart and/or for sensing electrical activity occurring in the heart. The lead 32 can further include one or more other electrodes in addition to, or in lieu of, the distal electrode 46. In a bipolar lead, for example, the lead 32 can include a pair of distal electrodes 46 for providing bipolar electrical energy to the heart.

[0021] The lead body 34 may be constructed of a flexible, electrically non-conductive material that permits the lead 32 to bend or flex to facilitate insertion of the lead 32 through the patient's body to a desired implantation site. In some embodiments, the lead 32 includes a means to attach the lead 32 to adjacent tissue within the body. For example, in some embodiments the lead 32 includes a number of barbs or tines 48 that facilitate attachment of the distal section 38 of the lead 32 to an inner wall of the heart or at some other desired location within the body.

[0022] As discussed further herein with respect to several embodiments, the lead 32 can be configured to dissipate and/or deflect electromagnetic or RF energy picked up by the lead 32, which can

cause tissue heating at the interface of the electrode 46 and the surrounding tissue. In some embodiments, for example, the lead 32 can be configured to dissipate and/or deflect electromagnetic energy caused by a gradient magnetic field B produced by an energized MRI coil during magnetic resonance imaging. The lead 32 can be further configured to dissipate and/or deflect electromagnetic energy or RF energy produced by other sources of magnetic interference within the patient's body.

[0023] Figure 3 is a partial cross-sectional view showing an illustrative conductor coil assembly 50 for use with the medical electrical lead 32 of Figure 2. As shown in Figure 3, the conductor coil assembly 50 includes a single filar conductor coil 52 helically disposed about the longitudinal axis L of the assembly 50. The conductor coil 52 may be coupled proximally to electrical feedthroughs or connectors on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at one or more distal electrodes. With respect to the lead 32 of Figure 2, for example, the conductor coil 52 may be electrically connected at its proximal end (not shown) to an implantable medical device (e.g., the pulse generator 14), and may extend along the length of the lead body 34 to one or more distal electrodes 46 on the lead 32.

[0024] In use, the conductor coil 52 can be configured to deliver electrical energy through the lead body 34 to the electrodes 46, which in some embodiments can be used for providing stimulus therapy to the patient and/or for sensing electrical impedance or other parameters within the patient's body. In some embodiments, for example, the conductor coil 52 may be used in conjunction with a unipolar lead to deliver electrical energy to heart tissue adjacent to the distal lead tip 44 or to other locations along the length of the lead 32.

[0025] In some embodiments, the conductor coil 52 comprises a single filar wire coil formed from an electrically conductive material such as gold or platinum. Alternatively, and in other embodiments, the

conductor coil 52 comprises a multi-filar wire coil formed from an electrically conductive material. In the embodiment depicted, the conductive coil 52 has a substantially circular transverse shape perpendicular to the length of the coil 52, which can be seen generally at a cut portion of the assembly 50 indicated by cross-hatching in Figure 3. In other embodiments, the conductive coil 52 may have an oval, rectangular, square, polygonal, or other transverse shape.

[0026] The dimensions of the conductor coil 52 will typically vary depending on the intended use of the lead 32 and the implantation location of the lead 32 within the body. For cardiac applications in which the lead 32 is implanted in or near the heart, and as further shown in Figure 4, the conductor coil 52 may have an outer diameter D_1 in the range of about 0.2 mm to 3.0 mm, although other dimensions are possible. The transverse dimension D_2 of the conductor coil 52 may be constant along the length of the coil 52, or can vary along the length of the coil 52. In some embodiments, for example, the conductor coil 52 has a constant transverse dimension D_2 in the range of about 0.05 mm to 1.0 mm. In other embodiments, the transverse dimension D_2 may vary continuously or at one or more discrete locations along the length of the lead 32. In one embodiment, for example, the transverse dimension D_2 may gradually taper from a relatively large dimension (e.g., 1 mm) at or near the proximal end 40 of the lead 32 to a relatively small dimension (e.g., 0.05 mm) at or near the distal end 44 of the lead 32.

[0027] The dimensions of the conductor coil 52 may vary depending on the intended use and/or implantation location of the lead 32 within the body. In neurological applications, for example, the conductor coil 52 may have an outer dimension D_1 in the range of about 0.2 mm to 3.0 mm, and a transverse dimension D_2 in the range of about 0.05 mm to 1.0 mm. The dimensions of the conductor coil 52 will typically vary depending on the anatomy of the patient at the implantation location and the dimensions of the lead 32. Other design

factors such as the flexibility of the lead 32, fatigue considerations, manufacturing ease, and the ability to dissipate and/or deflect electromagnetic energy along the length of the lead 32 may also affect the dimensions D_1,D_2 of the conductor coil 52.

[0028] In the embodiment of Figure 3, the coil assembly 50 further includes a non-conductive spacer filar 54 helically disposed about the longitudinal axis L of the coil assembly 50 and interstitially disposed between each adjacent turn of the conductive coil 52. In contrast to the conductor coil 52, the spacer filar 54 is formed at least in part of a non-conductive material, and is electrically isolated from the conductor coil 52, the pulse generator 14, and the lead tip electrode or electrodes 46. Examples of electrically non-conductive materials include, but are not limited to, polyurethane, silicon, and polytetrafluoroethylene (PTFE).

[0029] In some embodiments, the spacer filar 54 has an outer diameter and transverse dimension similar to that of the conductor coil 52. In certain embodiments, for example, the spacer filar 54 has an outer diameter in the range of about 0.2 mm to 3.0 mm, and a transverse dimension in the range of about 0.05 mm to 1.0 mm. In other embodiments, the outer diameter and/or transverse dimension of the spacer filar 54 may differ from the conductor coil 52. The transverse shape of the spacer filar 54 may be similar to the transverse shape of the conductor coil 52, or alternatively, can have a different transverse shape from that of the conductor coil 52.

[0030] In some embodiments, the spacer filar 54 is configured to contact each adjacent wire turn of the conductive coil 52, forming a close-wound coil assembly 50 along all or a portion of the length of the lead body 34. As used herein, the term “close-wound” indicates that there are no significant gaps or spaces between any of the turns of the conductive coil 52 or spacer filar 54. In other embodiments, a small gap or spacing may exist between one or more of the spacer filar 54 turns and adjacent conductor coil 52 turns, forming an open-wound coil

assembly 50 along all or a portion of the lead body 34. In one embodiment, for example, a first portion of the coil assembly 50 (e.g., a proximal portion) may be close-wound with each spacer filar turn 54 contacting an adjacent conductor coil 52 turn whereas a second portion of the coil assembly 50 (e.g., a distal portion) may be open-wound with each spacer filar turn 54 spaced a distance apart from an adjacent conductor coil 52 to form a small gap or space therebetween.

[0031] The coil assembly 50 can be manufactured using medical electrical lead fabrication techniques known in the art. In some embodiments, for example, the coil assembly 50 can be fabricated by drawing a conductive wire and non-conductive wire through a series of dies to impart a desired transverse shape to each wire, and then wrapping both wires together about a mandrel to impart the desired helical shape to the assembly 50. Other lead fabrication techniques are also contemplated.

[0032] In use, the presence of the spacer filar 54 between each turn of the conductor coil 52 increases the lateral distance D_3 between each of the conductor coil turns 52 while also maintaining the desired flexibility and fatigue characteristics of the coil assembly 50. As a result, the spacing provided by the spacer filar 54 acts to increase the pitch of the conductor coil 52 relative to single-filar conductor coil designs with no interstitial spacer filar, thus reducing the total length of the conductor coil 52 within the lead 32. For example, for a close-wound coil assembly employing a spacer filar 54 having a transverse dimension D_2 similar to that of the conductor coil 52, the effective pitch of the conductor coil 52 is approximately twice that of a close-wound conductor coil with no spacer filar. When subjected to electromagnetic or RF energy during an MRI or other such medical procedure, this reduced length of the conductor coil 52 may help to deflect a greater amount electromagnetic energy away from the lead 32, thus reducing the effects of tissue heating within the body.

[0033] Figure 5 is a partial cross-sectional view showing another illustrative coil assembly 56 for use with a medical electrical lead. As shown in Figure 5, the coil assembly 56 includes a pair of conductor coils 58,60 each helically disposed about the longitudinal axis L of the assembly 56. A first conductor 58 of the coil assembly 56 is coupled proximally to a first electrical feedthrough or connector on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at a first electrode on the lead 32. A second conductor 60 of the coil assembly 56, in turn, is coupled proximally to a second electrical feedthrough or connector on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at a second electrode on the lead 32. In use, and in some embodiments, the conductor coils 58,60 can be used in conjunction with a bipolar lead to deliver bipolar electrical energy through the lead body 34 for providing therapy to the patient and/or for sensing parameters such as electrical impedance within the patient's body. In some embodiments, for example, the conductor coils 58,60 may function, respectively, as anode and cathode electrodes to deliver bipolar electrical energy to body tissue adjacent to the distal lead tip 44 or to other locations along the length of the lead 32.

[0034] The configuration of the conductor coils 58,60, including the shape and/or dimensions of the conductors 58,60, may be similar to that of the conductor coil 52 of Figure 3. Alternatively, and in other embodiments, the shape and/or dimensions of the conductor coils 58,60 may vary from the conductor coil 52. In the embodiment of Figure 5, each of the conductor coils 58,60 comprises an insulated wire having an inner core 62,64 of electrically conductive material such as gold or platinum. In some embodiments, each of the conductor coils 58,60 include a layer or coating 66,68 of electrically non-conductive material disposed about the inner core 62,64. For example, the conductor coils 58,60 can include a layer or coating 66,68 of polyurethane, silicon, or polytetrafluoroethylene (PTFE) disposed about

an inner core 62,64 of gold or platinum. Other configurations, however, are possible.

[0035] The coil assembly 56 further includes a number of non-conductive spacer filars 70,72 interstitially disposed between laterally adjacent turns of the conductor coils 58,60. Each of the spacer filars 70,72 are formed at least in part of an electrically non-conductive material, and are electrically isolated from the conductor coils 58,60, the pulse generator 14, and the lead tip electrode or electrodes 46. The configuration of the spacer filars 70,72, including the shape and/or dimensions of the spacer filars 70,72 may be similar to that of the spacer filar 54 of Figure 3. Alternatively, and in other embodiments, the shape and/or dimensions of the spacer filars 70,72 may differ from the spacer filar 54 of Figure 3.

[0036] In the embodiment of Figure 5, each of the spacer filars 70,72 comprises a respective inner core 74,76 made from an electrically conductive material, and an outer layer or coating 78,80 made from an electrically non-conductive material. For example, in some embodiments each of the spacer filars 70,72 can be fabricated from a gold or platinum wire jacketed or coated with polyurethane, silicon, or polytetrafluoroethylene (PTFE) shielding.

[0037] As with the embodiment of Figure 3, the presence of the spacer filars 70,72 between the turns of the conductor coils 58,60 increases the pitch of the coils 58,60, which in turn, reduces the length of the conductor coils 58,60. This reduced length of the conductor coils 58,60 may help to deflect a greater amount of electromagnetic energy away from the lead 32, thus reducing the effects of tissue heating within the body. The presence of the inner core 74,76 of conductive material within the spacer filars 70,72 may further help to collect and dissipate electromagnetic energy received by the lead 32, further reducing the effects of tissue heating within the body.

[0038] Figure 6 is a partial cross-sectional view showing another illustrative coil assembly 82 for use with a medical electrical lead. As

shown in Figure 6, the coil assembly 82 includes a pair of conductor coils 84,86 each helically disposed about the longitudinal axis L of the assembly 82. A first conductor 84 of the assembly 82 is coupled proximally to a first electrical feedthrough or connector on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at a first electrode on the lead 32. A second conductor 86 of the assembly, in turn, is coupled proximally to a second electrical feedthrough or connector on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at a second electrode on the lead 32. In some embodiments, the conductor coils 84,86 can be configured for use in a bipolar lead to deliver bipolar electrical energy through the lead body 34 that can be used to provide therapy to the patient and/or for sensing parameters such as electrical impedance within the patient's body.

[0039] In the embodiment of Figure 6, each of the conductor coils 84,86 includes an associated spacer filar 88,90 coupled to or formed integrally with the conductor coils 84,86. In some embodiments, for example, each of the conductor coils 84,86 is formed from an inner core 92,94 of electrically conductive material (e.g., gold or platinum) and an outer layer or coating 96,98 of an electrically non-conductive material. In one embodiment, fabrication of each of the conductor coils 84,86 is accomplished via a co-extrusion process in which the outer, non-conductive layer or coating 96,98 (including the material forming the spacer filar 88,90) is co-extruded with the inner core 92,94 material, forming a non-symmetric extrusion (e.g., a dumb-bell shape) over the conductor coils 84,86. Other techniques such as over-molding the outer layer or coating 96,98 over the inner wire core 92,94 material can also be used to fabricate each of the conductor coils 84,86.

[0040] Figure 7 is a partial cross-sectional view showing another illustrative coil assembly 100 for use with a medical electrical lead. The coil assembly 100 is similar to the coil assembly 50 of Figure 3,

including a single filar conductor coil 102 helically disposed about the longitudinal axis L of the assembly 100. In the embodiment of Figure 7, however, the coil assembly 100 includes a pair of non-conductive spacer filars 104,106 interstitially disposed between each laterally adjacent turn of the conductive coil 102. The spacer filars 104,106 can be formed from a solid wire coil, or alternatively can be formed from an inner core of electrically conductive material and one or more outer layers or coatings of an electrically non-conductive material.

[0041] In use, and as with other embodiments herein, the presence of the spacer filars 104,106 between each coil turn of the conductor coil 102 functions to increase the pitch of the conductor coil 102 while also maintaining the flexibility and fatigue characteristics of the coil assembly 100. This increase in pitch reduces the total length of the conductor coil 102 along the length of the lead 32, which may help to deflect a greater amount of electromagnetic energy away from the lead 32.

[0042] The number of conductor coils and/or spacer filars can be varied to produce other coil assemblies. In one embodiment depicted in Figure 8, for example, the coil assembly 108 includes two conductor coils 110,112 and three spacer filars 114,116,118. The coil assembly 108 can include a greater or lesser number of spacer filars and/or conductor coils. For example, in some embodiments the coil assembly includes a single filar conductor coil having two or more non-conductive spacer filars interstitially disposed between each coil turn of the conductor coil. Alternatively, and in other embodiments, the coil assembly includes multiple conductor coils (e.g., two, three, four, etc.) with one or more spacer filars interstitially disposed between each conductor coil turn.

[0043] Figure 9 is a partial cross-sectional view showing another illustrative coil assembly 120 for use with a medical electrical lead. As shown in Figure 9, the coil assembly 120 includes a pair of conductor coils 122,124 and a pair of spacer filars 126,128. The conductor coils

122,124 may each be coupled proximally to electrical feedthroughs or connectors on the pulse generator 14, and may extend along all or a portion of the length of the lead body 34, terminating distally at a respective set of electrodes on the lead 32. In some embodiments, for example, the conductor coils 122,124 can be configured for use in bipolar leads to deliver bipolar electrical energy through the lead body 34 for providing therapy to the patient and/or for sensing parameters such as electrical impedance within the patient's body.

[0044] The configuration of the conductor coils 122,124, including the shape and/or dimensions of the coils 122,124 may be similar to that of the conductor coil 52 of Figure 3. Alternatively, and in other embodiments, the shape and/or dimensions of the conductor coils 122,124 may vary from the conductor coil 52. In the embodiment of Figure 9, each of the conductor coils 122,124 comprises an insulated wire having an inner core 130,132 of electrically conductive material, and an outer layer or coating of electrically non-conductive material 134,136. In other embodiments, the conductor coils 122,124 may each comprise a solid, conductive material with no insulation.

[0045] In the embodiment of Figure 9, the spacer filars 126,128 are each interstitially disposed between laterally adjacent turns of the conductor coils 122,124. The spacer filars 126,128 can be configured to contact each adjacent turn of the conductor coil 122,124, as shown, or can be spaced apart from each adjacent turn of the conductor coil 122,124 via a small gap or spacing. In some embodiments, the spacer filars 126,128 can be formed from a solid coil of electrically non-conductive material. In other embodiments, the spacer filars 126,128 can be formed from an inner core of electrically conductive material and one or more outer layers or coatings of an electrically non-conductive material.

[0046] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described

above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

CLAIMS

What is claimed is:

1. A medical electrical lead, comprising:

an insulated lead body including at least one electrode;

at least one helically coiled conductor electrically coupled to the at least one electrode, the at least one conductor including a plurality of turns disposed about a longitudinal axis of the lead body;

at least one helically coiled spacer element electrically isolated from the at least one electrode, the at least one spacer element including a plurality of turns disposed about the longitudinal axis, wherein one or more turns of the spacer element are interstitially disposed between at least one adjacent turn of the conductor; and

wherein the at least one helically coiled conductor and the at least one helically coiled spacer element form a close-wound coil assembly extending along a length of the lead body.

2. The medical electrical lead of claim 1, wherein the at least one helically coiled conductor is an insulated wire.

3. The medical electrical lead of claim 1, wherein the at least one helically coiled conductor is a non-insulated wire.

4. The medical electrical lead of claim 1, wherein the at least one helically coiled conductor comprises a single conductor filar.

5. The medical electrical lead of claim 1, wherein the at least one helically coiled conductor comprises multiple conductor filars.

6. The medical device of claim 1, wherein the at least one helically coiled conductor comprise a plurality of helically coiled conductor wires each including a plurality of wire turns.

7. The medical device of claim 1, wherein the at least one helically coiled conductor extends from the at least one electrode to a proximal connector coupled to an implantable medical device.

8. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element has a circular transverse shape.

9. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element includes a single polymeric filar.

10. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element includes a plurality of polymeric filars.

11. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element includes at least one insulated metal filar.

12. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element is integrally formed with the at least one helically coiled conductor.

13. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element includes a plurality of spacer elements interstitially disposed between adjacent turns of the at least one helically coiled conductor.

14. The medical electrical lead of claim 1, wherein the one or more turns of the spacer element are interstitially disposed adjacent to and in contact with at least one adjacent turn of the conductor.

15. The medical electrical lead of claim 1, wherein the at least one helically coiled spacer element comprises a plurality of helically coiled spacer elements.

16. The medical electrical lead of claim 15, wherein the plurality of helically coiled spacer elements includes two or more spacer elements disposed adjacent to and in contact with each other.

17. The medical electrical lead of claim 1, wherein the medical electrical lead is a unipolar lead.

18. The medical electrical lead of claim 1, wherein the medical electrical lead is a bipolar lead.

19. A medical electrical lead, comprising:

a proximal connector configured to couple the lead to an implantable medical device;

an insulated lead body extending distally from the proximal connector and including at least one electrode;

a single helically coiled conductor wire electrically coupled to the at least one electrode, the conductor

wire including a plurality of turns disposed about a longitudinal axis of the lead body;

at least one helically coiled non-conductive spacer element electrically isolated from the at least one electrode, the at least one spacer element including a plurality of turns disposed about the longitudinal axis, wherein one or more wire turns of the spacer element are interstitially disposed between adjacent turns of the conductor wire; and

wherein the helically coiled conductor wire and the at least one helically coiled non-conductive spacer element form a close-wound coil assembly extending along a length of the lead body.

20. A medical electrical lead, comprising:

a proximal connector configured to couple the lead to an implantable medical device;

an insulated lead body extending distally from the proximal connector and including a plurality of electrodes;

a pair of helically coiled conductor wires electrically coupled to the electrodes, each conductor wire including a plurality of turns disposed about a longitudinal axis of the lead body;

at least one helically coiled non-conductive spacer element electrically isolated from the electrodes, the at least one spacer element including a plurality of turns disposed about the longitudinal axis, wherein one or more turns of the spacer element are

interstitially disposed between adjacent turns of the conductor wires; and

wherein the pair of helically coiled conductor wires and the at least one helically coiled non-conductive spacer element form a close-wound coil assembly extending along a length of the lead body.

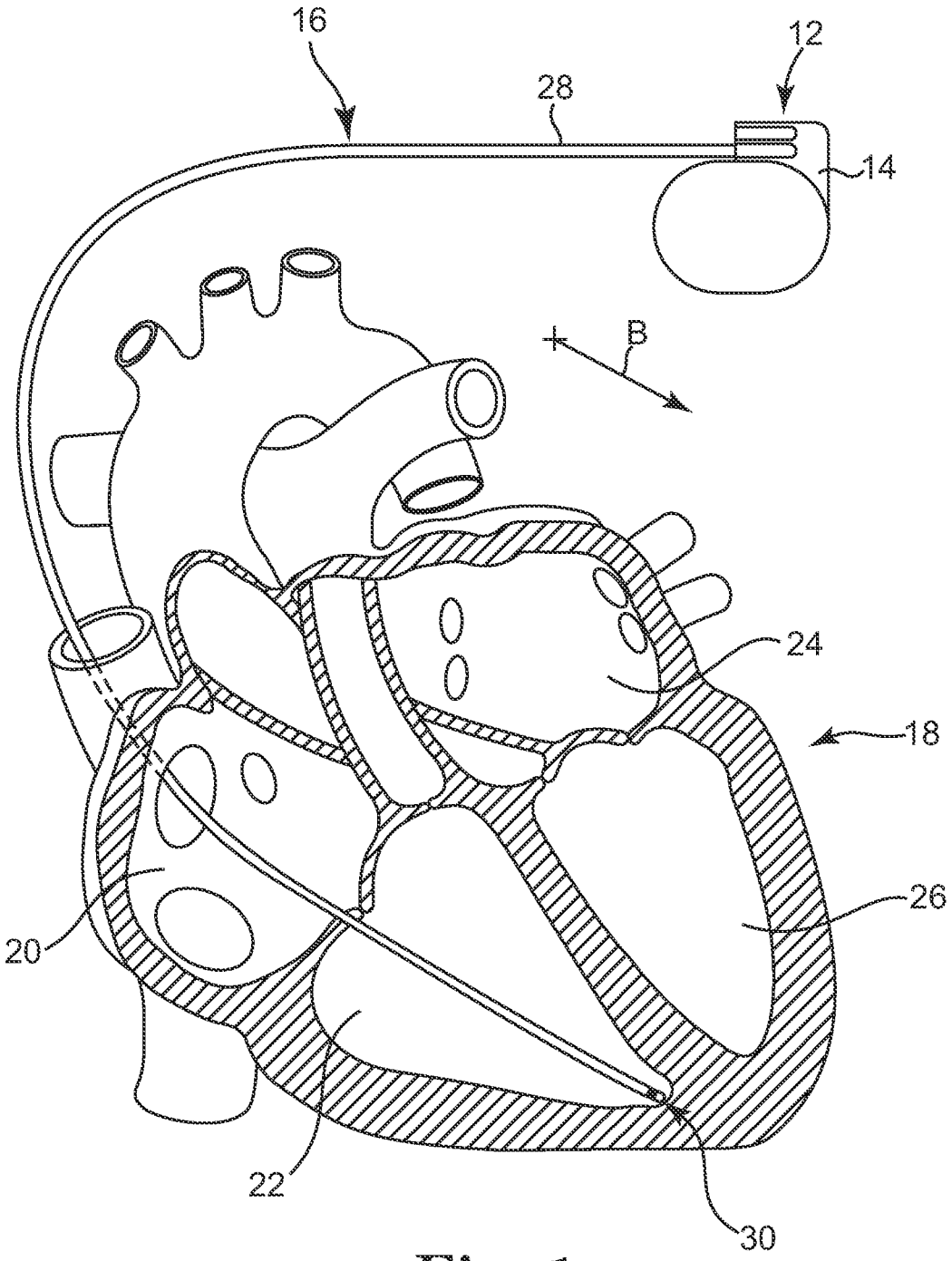

Fig. 1

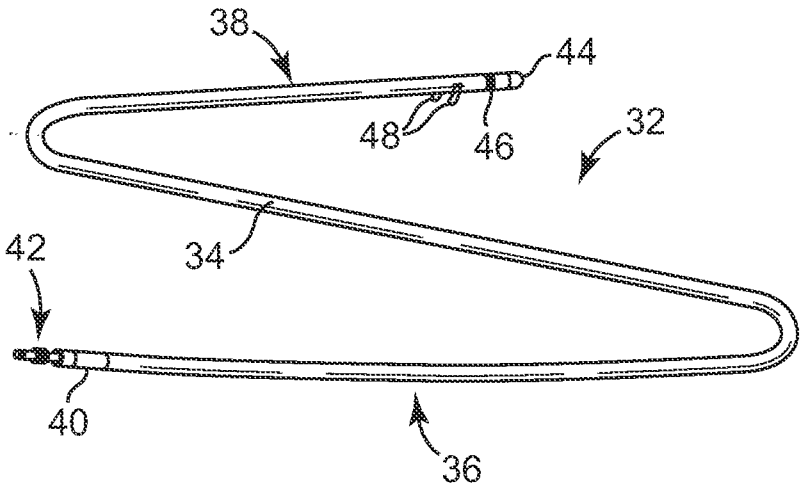

Fig. 2

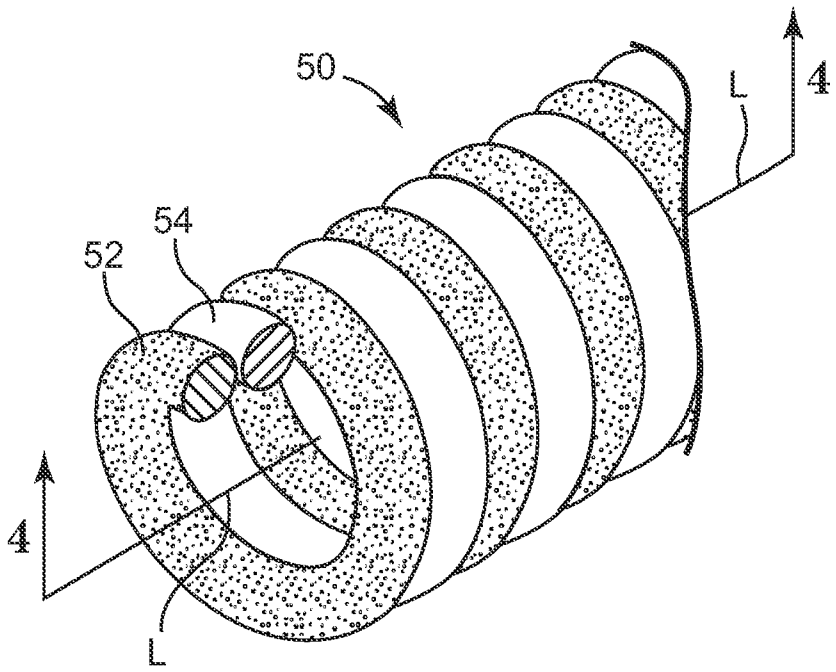

Fig. 3

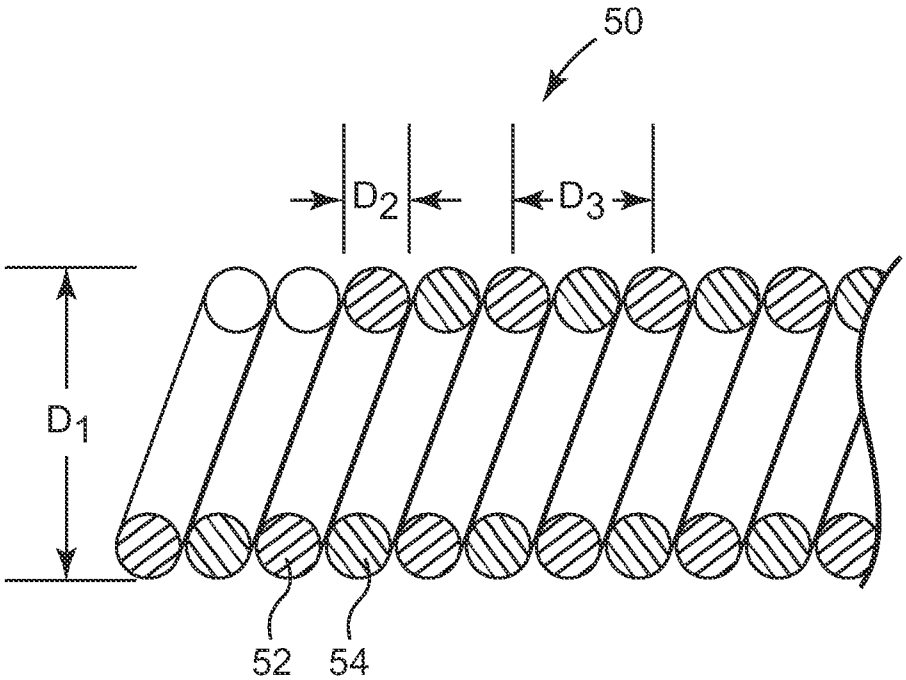

Fig. 4

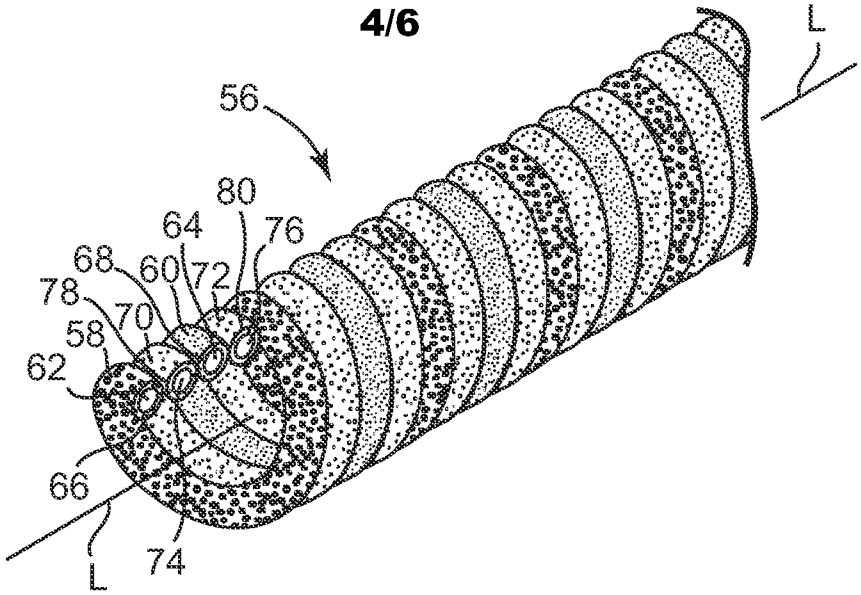

Fig. 5

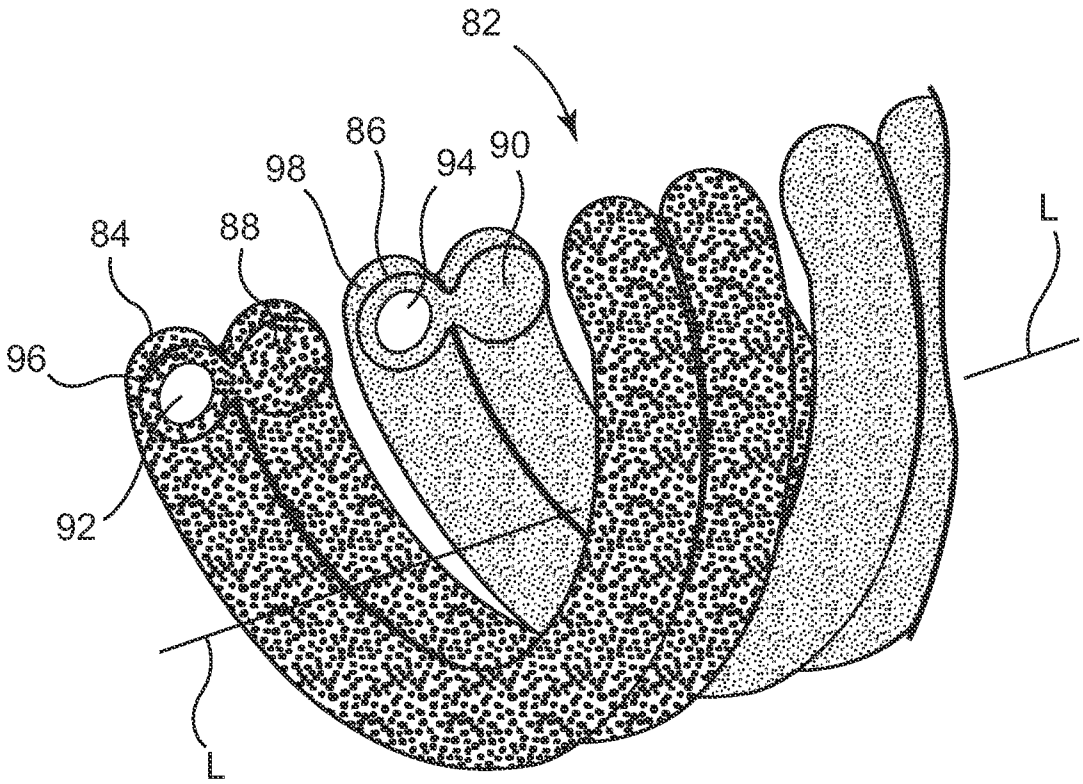

Fig. 6

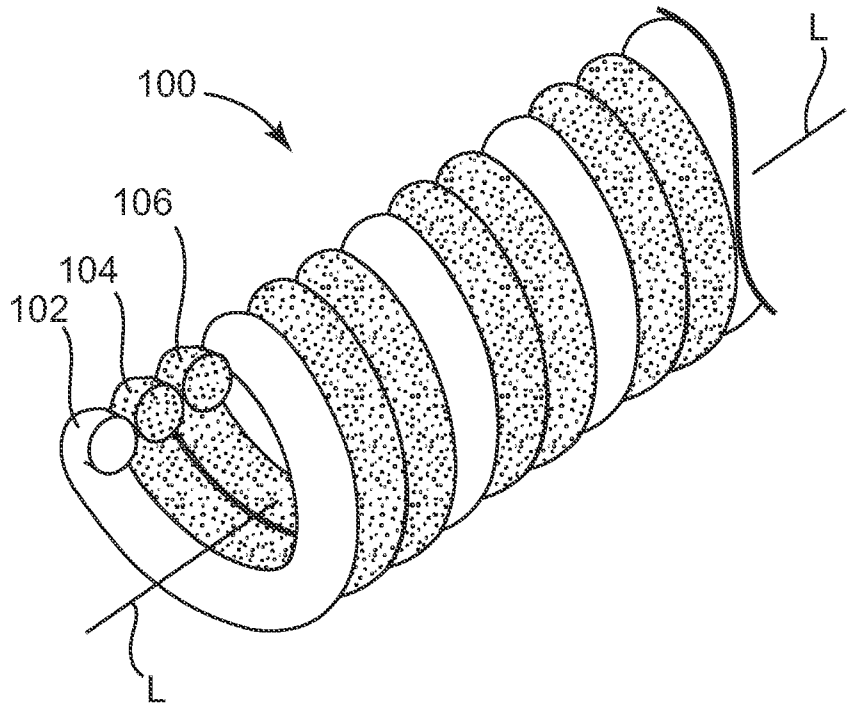

Fig. 7

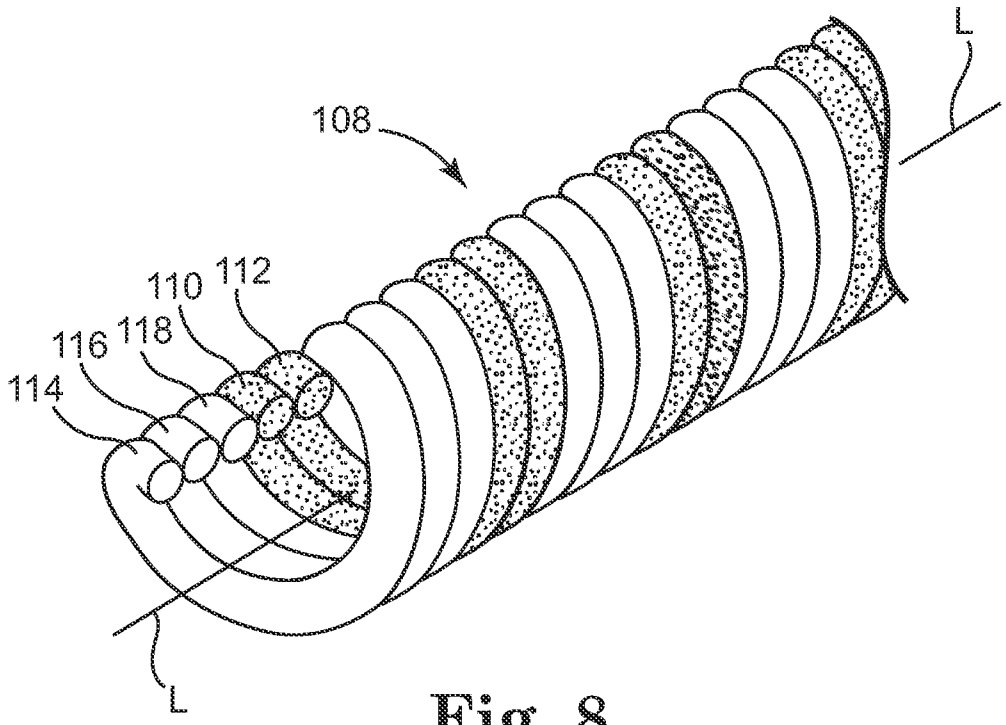

Fig. 8

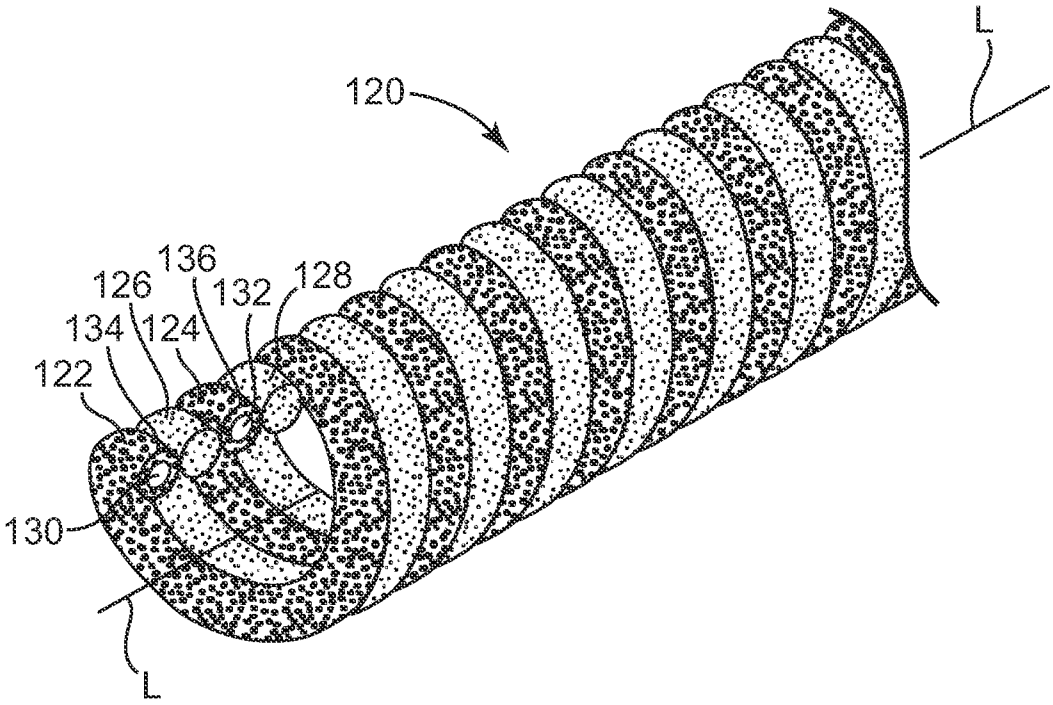

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/038629

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05
ADD. A61N1/08

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)
H03H A61N G01R

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/030774 A1 (GRAY ROBERT W [US] ET AL) 9 February 2006 (2006-02-09) figures 1,23-26 claims 1-29 paragraph [0086] paragraph [0138] - paragraph [0151] paragraph [0167] - paragraph [0198]	1-20
X	WO 2007/047966 A (SURGI VISION INC [US]; ATALAR ERGIN [TR]; ALLEN JUSTIN [US]; BOTTOMLEY) 26 April 2007 (2007-04-26) figures 17,20a paragraph [0106] - paragraph [0108] paragraph [0118] - paragraph [0119]	1,2,6,7, 11,14, 19,20
X	WO 2007/118194 A (BIOPHAN TECHNOLOGIES INC [US]; GRAY ROBERT W [US]; MACDONALD STUART G) 18 October 2007 (2007-10-18) paragraph [0333]; figure 55	1,3,7,9, 19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 June 2009	29/06/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Ließmann, Frank

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/038629

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006030774 A1	09-02-2006	EP 1804665 A2	11-07-2007
		WO 2006044550 A2	27-04-2006
WO 2007047966 A	26-04-2007	AU 2006304775 A1	26-04-2007
		CA 2623453 A1	26-04-2007
		EP 1933933 A2	25-06-2008
WO 2007118194 A	18-10-2007	EP 2010271 A2	07-01-2009
		EP 2067501 A2	10-06-2009