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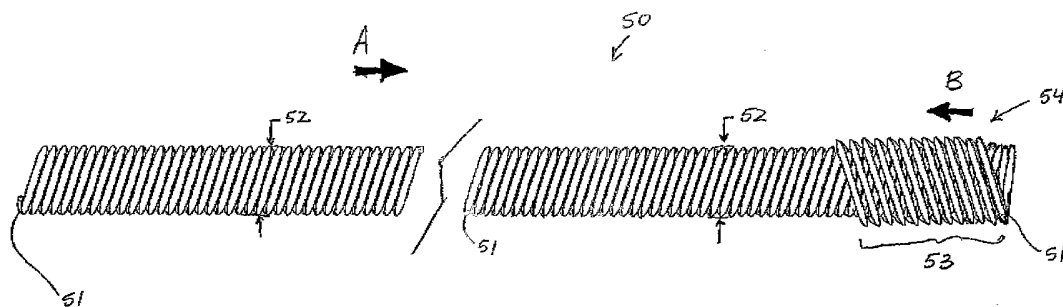
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(54) Title: REVERSE WOUND ELECTRODES



(57) Abstract: An implantable lead includes an insulative sheath and a coil member (50); the coil member including a conductor (51) wound from a proximal end of the coil member to a distal end (54) and reverse wound back toward the proximal end to form an electrode (53) on an outer diameter (52) of the coil member adjacent and distal to the insulative sheath.



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REVERSE WOUND ELECTRODES

This invention relates to implantable devices and more particularly relates to the design and manufacture of implantable leads.

In the traditional forming of implantable medical electrical leads, one or more wires are wound on a mandrel so as to form a coil. The wires are wrapped with enough tension to cause the wires to exceed their yield point and thus to hold a coiled shape. The pitch of a coil may range from close wound, that approaching the wire diameter or the sum of the wire diameters, for multi-wire coils, to space wound, that exceeding the wire diameter or sum of the wire diameters. The coil may be one of several conductors included in an implantable lead body and the coil may be formed from multiple insulated wires as a multi-conductor coil. The lead body is usually constructed having an outer polymeric sheath encasing the conductors, which may be arranged coaxially or co-linearly and are insulated from one another. A distal end of each conductor is coupled to one or more electrodes while a proximal end of each conductor is coupled to a contact of a connector that is in turn coupled to an implantable pulse generator (IPG) or an implantable cardioverter-defibrillator (ICD). The distal end of the lead is implanted to be positioned within the heart so that the electrodes may deliver pacing and or defibrillation therapy by both sensing electrical activity of the heart muscle and stimulating the heart muscle.

Each conductor is typically coupled to a corresponding electrode, which has been formed as a separate component, such as a ring electrode, a coil electrode or a tip electrode. In designing and constructing joints between the conductors and the electrodes care must be taken to form reliable mechanical and electrical coupling; it is also desirable that the joints do not increase the profile of the lead body. Eliminating as many joints as is practical in the construction of a lead may improve the reliability of the lead and increase the ease of manufacturing.

FIG. 1A is a plan view of a coil according to one embodiment of the present invention.

FIG. 1B is a plan view of a multi-conductor coil according on one embodiment of the present invention.

FIG. 1C is a plan view of a multi-conductor coil according to another embodiment of the present invention.

FIG. 1D is a partial section plan view of the multi-conductor coil of FIG. 1C.

FIG. 2A is a partial section plan view of an implantable lead incorporating the coil from FIG. 1A.

FIG. 2B is a cross-sectional plan view of a distal end of an alternate embodiment of a lead incorporating the coil from FIG. 1A

FIG. 3 is a cross-sectional plan view of a distal end of an alternate embodiment of a lead incorporating the coil from FIG. 1B

FIG. 4 is a partial section plan view of a lead incorporating the coil from FIG. 1C-D

FIGS. 5-8 are schematics depicting several embodiments of implantable leads according to the present invention joined to an implantable medical device and implanted in exemplary locations within a heart.

The following detailed description is to be read with reference to the figures, in which like elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Embodiments of the present invention may be employed in many various types of devices, such as pacemakers, cardioverter defibrillators, and neurostimulators, for treating patient medical conditions. Skilled artisans will recognize that the examples provided herein have many useful alternatives that fall within the scope of the invention.

FIG. 1A is a plan view of a coil 50 according to one embodiment of the present invention. Coil 50 is incorporated into embodiments of medical electrical leads according to the present invention as illustrated in FIG.'s 2A and 2B. As illustrated in FIG. 1A, coil 50 includes a wound conductor 51 and an electrode 53 at a distal end 54; wound conductor 51 forming an outer diameter 52 of coil 50 and a reverse wound portion of conductor 51, over outer diameter 52, forming electrode 53. Coil 50 may be formed using a programmable coil winder, known to those skilled in the art, winding in a first direction "A" and then reverse winding in a second direction "B" to form electrode 53 over outer diameter 52. Conductor 51

and all other conductors presented herein for alternate embodiments are formed from any material capable of reliably conducting electrical current after having been subjected to numerous repetitive bending and torsional stresses, examples of such materials include tantalum, MP35-N alloy, platinum, Elgiloy, and stainless steel. Conductor 51 and all other conductors illustrated herein in various embodiments include a single wire, however, in alternate embodiments, a conductor includes a plurality of common wires; anywhere from two to six wires, depending on the application, per conductor are contemplated. Furthermore, alternate embodiments include composite wires formed of any of the preceding metals and including a silver or gold core. Because the reverse wound portion of conductor 51 serves as electrode 53, an outer surface of the reverse wound portion of conductor 51, as well as outer surfaces of all reverse wound portions of conductors forming electrodes in various embodiments presented herein, must be suitable for this purpose; a platinum or platinum iridium surface is one example of a suitable electrode surface known to those skilled in the art. In one embodiment, a platinum clad wire is used for conductor 51, in another embodiment a platinum-iridium wire is used and, in yet another embodiment, a platinum surface is formed, for example, by sputtering platinum over reverse wound portion of conductor 51 forming electrode 53.

FIG. 1B is a plan view of a multi-conductor coil 60 according to one embodiment of the present invention. Coil 60 is incorporated into an embodiment of a medical electrical lead according to the present invention as illustrated in FIG. 3. As illustrated in FIG. 1B coil 60 includes a first wound conductor 61, a second wound conductor 62, forming an outer diameter 63 of coil, and an electrode 64 at a first distal end 65; first conductor 61 includes a reverse wound portion forming electrode 64, over outer diameter 63, and second conductor 62 extends beyond electrode 64 to a second distal end 66. Coil 60 may be formed using a programmable coil winder, known to those skilled in the art, winding conductors 61 and 62 in first direction "A" and then reverse winding first conductor 61 in second direction "B" to form electrode 64, while continuing to wind second conductor 62 in direction "A" to second distal end 66. It should be noted that an outer diameter and pitch of coil 60 between first distal end 65 and second distal end 66 need not be the same as a pitch or outer diameter 63 of coil 60 indicated proximal to electrode 64. According to one embodiment of the present invention, second conductor 62 is joined to an electrode tip at second distal end 66, such as tip electrode 37, illustrated in FIG. 3, therefore second conductor 62 must be electrically

isolated from first conductor 61. Either first conductor 61 or second conductor 62, or both, include an outer insulative layer according to embodiments of the present invention, such insulative layers being described in conjunction with FIG. 1D.

FIG. 1C is a plan view of a multi-conductor coil 70 according to another embodiment of the present invention. Coil 70 is incorporated into an embodiment of a medical electrical lead according to one embodiment of the present invention as illustrated in FIG. 4. As illustrated in FIG. 1C, coil 70 includes a first wound conductor 71, a second wound conductor 72, a third wound conductor 73, and a fourth wound conductor 74, all forming an outer diameter 75; coil 70 further includes a first electrode 76, a first intermediate electrode 77, and a second intermediate electrode 78. First electrode 76 is formed by reverse winding first conductor 71 over outer diameter 75 at a first distal end 79 and fourth conductor extends to a second distal end 80. In between first distal end 79 and second distal end 80 second and third conductors 72 and 73 are reverse wound to form first and second intermediate electrodes 77 and 78 over outer diameters 75' and 75'', respectively, as illustrated in FIG. 1C. In one embodiment diameters 75' and 75'' are approximately equal to diameter 75, however in an alternate embodiment diameter 75' is smaller than diameter 75 and diameter 75'' is smaller than diameter 75'. Coil 70 may be formed in generally the same manner described for coil 60 illustrated in FIG. 1B. According to one embodiment of the present invention, fourth conductor 62 is joined to an electrode tip at second distal end 80, such as tip electrode 37 illustrated in FIG. 3 or tip electrode 95 illustrated in FIG. 4. Each conductor 71-74, corresponding with different electrodes must be electrically isolated from one another; according to one embodiment of the present invention, as illustrated in FIG. 1D, each conductor 71-74 includes an outer insulative layer 101-104.

FIG. 1D is a partial section plan view of the multi-conductor coil illustrated in FIG. 1C. A section through each conductor 71-74 in a segment 100 of coil 70, proximal to first electrode 76, is illustrated in FIG. 1D, shows insulative layers 101, 102, 103, and 104. According to embodiments of the present invention, insulative layers 101-104 are formed from a biocompatible, biostable, and durable insulative material, one example of which is a polyamide. Although all four conductors are illustrated in FIG. 1D as having an insulative layer, in an alternate embodiment, one of the four may be without an insulative layer. Surfaces of reverse wound portions of conductors 71, 72, and 73, are freed of insulative layers 101, 102, and 103 in order to form electrodes 76, 77, and 78 respectively. According

to one embodiment of the present invention, a laser is used to remove the layers 101-103 away from the outer surfaces of conductors 71 - 73 according to methods well know to those skilled in the art.

FIG. 2A is a partial section plan view of an implantable lead 10 incorporating coil 50 from FIG. 1A, according to one embodiment of the present invention. As illustrated in FIG. 2A, lead 10 further includes a proximal end 30, a distal end 26, an outer insulative sheath 22, an inner tubing 23 forming a lumen 25. As illustrated in FIG. 2A, coil 50 extends around inner tubing and within outer insulative sheath 22 from a connector contact 31 at proximal end 30 to distal end 26 where electrode 53 is formed by reverse winding of conductor 51, as previously described, is disposed. In one embodiment, a fiber core 21, indicated by a dashed line, extends within lumen 25 from proximal end 30 to distal end 26 to strengthen lead 10; Williams and Chivers disclose embodiments of leads having a fiber core construction in U.S. Patent No. 6,516,230, which is incorporated herein in its entirety. In an alternate embodiment, a stylet (not shown) is used to guide lead 10 via lumen 25 to an implant site and, in yet another embodiment, as illustrated in FIG. 2B, lumen 25 surrounds another conductor attached to a tip electrode. FIG. 2B is a cross-sectional plan view of a distal end of an alternate embodiment of a lead incorporating coil 50 from FIG. 1A. As illustrated in FIG. 2B, lead 15 further includes a cable conductor 32 extending from a proximal end (not shown), where it is joined to a second connector contact (not shown), through lumen 25 past distal end 26 of coil 50, where electrode 53 is formed, to a second distal end 16 where it is joined to a helical tip electrode 24. According to embodiments of the present invention, cable conductor 32 is joined to helical tip electrode 24 by means of welding, crimping, bonding with a conductive adhesive, or a combination thereof according to methods well known to those skilled in the art. As further illustrated in FIG. 2B, lead 15 includes an insulative spacer 27 electrically isolating tip electrode 24 from reverse wound electrode 53. Although tip electrode 24 is illustrated as a helix in FIG. 2B, various geometries of tip electrodes well known to those skilled in the art are contemplated for alternate embodiments of the present invention.

FIG. 3 is a cross-sectional plan view of a distal end of an alternate embodiment of a lead incorporating coil 60 from FIG. 1B. As illustrated in FIG. 3, a lead 35 includes coil 60 extending around inner tubing 23 and within outer insulative sheath 22 from a proximal end (not shown), where conductors 61 and 62 are each joined to a connector contact (not shown),

to first distal end 65, where reverse wound electrode 64 is formed by conductor 61, and to second distal end 66, where conductor 62 is joined to a tip electrode 37. Lead 35 further includes an insulative spacer 38 including a set of tines 39 as a fixation means to hold tip electrode 37 at the implant site according to one embodiment of the present invention. In an alternate embodiment a helical electrode, such as electrode 24 illustrated in FIG. 2B, not requiring tines 39 since a helical construction provides fixation, is joined to conductor 62 at second distal end 66. Furthermore, an embodiment according to the present invention includes a tip electrode, such as tip electrode 37, without tines 39 or another fixation means. According to embodiments of the present invention, conductor 62 is joined to tip electrode 37 by means of welding, crimping, bonding with a conductive adhesive, or a combination thereof according to methods well known to those skilled in the art. According to one embodiment, lead 35 further includes fiber core 21 shown as a dashed line; fiber core 21 serves to strength lead 35 as previously described in conjunction with FIG. 2A

FIG. 4 is a partial section plan view of a lead incorporating coil 70 from FIG. 1C-D according to one embodiment of the present invention. As illustrated in FIG. 4, a lead 45 includes coil 70 extending around inner tubing 23 and within outer insulative sheath 22 from a proximal end 90, where conductors 71, 72, 73, and 74 are joined to connector contacts 91, 92, 93, and 94, respectively, to first distal end 79, where reverse wound electrode 76 is formed by conductor 71, and to a second distal end 80, where conductor 74 is joined to a helical tip electrode 95. In between first distal end 79 and second distal end 80, as further illustrated in FIG. 4, first intermediate electrode 77 and second intermediate electrode 78 are formed by reverse wound conductors 72 and 73, respectively, and insulative spacers 115, 116, and 117 are positioned between electrodes 76 and 77, 77 and 78, and 78 and 79, respectively. According to embodiments of the present invention, conductor 74 is joined to helical tip electrode 95 by means of welding, crimping, bonding with a conductive adhesive, or a combination thereof according to methods well known to those skilled in the art. Although tip electrode 95 is illustrated as a helix in FIG. 4, various geometries of tip electrodes well known to those skilled in the art are contemplated for alternate embodiments of the present invention.

In various embodiments of the leads presented in FIGS. 2A-4, outer insulative sheath 22, inner tube 23, and insulative spacers 27, 38, 115, 116, and 117 are formed from biocompatible and biostable insulative materials, examples of which are polyurethane and

silicone. Fabrication and assembly methods for such sheaths, tubes, and spacers are well known to those skilled in the art of electrical lead construction. Lengths of electrodes and spacers depicted herein vary according to different embodiments of leads, examples of which will be schematically presented in FIGS. 5-8. A maximum outer diameter of embodiments range from approximately .025 inch to approximately .120 inch depending upon an inner diameter required for lumen 25 and a diameter of the wound conductor wires. It is contemplated that various lead constructions according to the present invention will include conductors including wires having diameters ranging between approximately 0.001 inch and approximately 0.010 inch, dependent upon electrical resistance requirements. Furthermore, in one embodiment a cross-section of conductor wires is substantially round while in an alternate embodiment a cross-section of conductor wires is substantially rectangular.

An inner diameter of lumen 25, for various embodiments according to the present invention, will range between approximately 0.005 inch and 0.050 inch; the inner diameter dependent upon the incorporation within lumen 25 of additional conductors or an elongated delivery tool, for example, a stylet, guide wire, or pull wire, or upon pressure requirements for delivery of agents, for example a drug or a contrast agent, through lumen 25. In the latter case, if lumen 25 is used to deliver an agent an opening in lumen is included in proximity to a distal end of the lead.

FIGS. 5-8 are schematics depicting several embodiments of implantable leads according to the present invention joined to an implantable medical device 200 and implanted in exemplary locations within a heart 300. As illustrated in FIG. 5, a lead 400 includes a tip electrode 401 and a reverse wound electrode 402 including a length 406 and spaced at a distance 405 from tip electrode 401. In one embodiment lead 400 incorporates coil 50 of FIG. 1A and in an alternate embodiment lead 400 incorporates coil 60 from FIG. 1B. According to embodiments of the present invention, length 406 is between approximately 2 millimeters and approximately 6 centimeters and distance 405 is between 4 millimeters and approximately 15 millimeters. According to one embodiment of the present invention, length 406 of reverse wound electrode 402 and spacing 405 are appropriate for electrode 402 to serve as a pace/sense anode in conjunction with tip electrode 401 (cathode), and, according to another embodiment length 406 and spacing 405 are appropriate for reverse wound electrode 402 to serve as a defibrillation electrode.

As illustrated in FIG. 6, a lead 500 includes a tip electrode 501, a first reverse wound electrode 502, including a length 506 and spaced at a distance 505 from tip electrode 501, and a second reverse wound electrode 503, including a length 508 and space at a distance 507 from first reverse wound electrode. In one embodiment, lead 500 includes a coil including a first and second conductor wherein both conductors are reverse wound, having a configuration similar to lead 15 shown in Figure 2B in that tip electrode 501 is joined to a cable conductor; in another embodiment lead 500 includes a coil including a first, second and third conductor, having a configuration similar to lead 45 shown in FIG. 4 in that first and second conductors form reverse wound electrodes 503 and 502 while third conductor is joined to tip electrode 501. According to embodiments of the present invention, electrodes 502 and 503 have lengths 506 and 508 between approximately 2 millimeters and approximately 6 centimeters; distance 505 is between approximately 4 millimeters and approximately 10 millimeters; and distance 507 is between approximately 1 millimeter and 5 millimeters. According to one embodiment of the present invention, length 506 of electrode 502 is and distance 505 are appropriate for electrode 502 to serve as a pace/sense anode in conjunction with tip electrode 501 (cathode) and length 508 of electrode 503 and distance 507 are appropriate for electrode 503 to function as a defibrillation electrode. According to another embodiment, as illustrated in FIG. 7, distance 507 is increased so that reverse wound electrode 503 may be positioned in another chamber of heart 300 or proximal to heart.

As illustrated in FIG. 8, a lead 700 includes all the elements of lead 500 from FIGS. 6 and 7 and further includes a third reverse wound electrode 704 spaced at a distance 705 from second reverse wound electrode 503 according to one embodiment of the present invention. In one embodiment lead 700 incorporates coil 70 of FIG. 1C. Distance 705 is such that reverse wound electrode may be positioned in an area of heart 300 separate from an area in which tip electrode 501 is positioned.

Finally, it will be appreciated by those skilled in the art of lead construction and implantation that the present invention can take many forms and embodiments and be applied in many more implant sites than those represented in FIGS. 5-8, such as epicardial sites and neuro-stimulation sites. The true essence and spirit of this invention are defined in the appended claims, and it is not intended that any embodiment of the invention presented herein should limit the scope thereof.

What is claimed is:

1. An implantable lead comprising:
an insulative sheath; and
a coil member extending through the insulative sheath and including a wound conductor, a proximal end, a first distal end, a reverse wound electrode, and a first outer diameter;
wherein the conductor winds from the proximal end to the first distal end forming the first outer diameter of the coil member, and reverse winds back toward the proximal end to form the electrode on the first outer diameter, the electrode disposed adjacent and distal to the insulative sheath.
2. The implantable lead of claim 1, wherein the wound conductor includes a plurality of common wires, the plurality including from two to six wires.
3. The implantable lead of claim 1, wherein a length of the electrode is between approximately 2mm and 3 cm.
4. The implantable lead of claim 1, wherein a length of the electrode is between approximately 3 cm and 6 cm.
5. The implantable lead of claim 1, wherein the electrode serves as a pacing and sensing anode.
6. The implantable lead of claim 1, wherein the electrode serves as a defibrillation electrode.
7. The implantable lead of claim 1, wherein the insulative sheath includes an outer diameter and the electrode forms a second outer diameter of the coil member, the second outer diameter substantially equivalent to the outer diameter of the insulative sheath.
8. The implantable lead of claim 1, further comprising an electrode tip positioned at a second distal end, the second distal end disposed distal to the first distal end;
wherein the coil member further includes a second wound conductor winding from the proximal end to the second distal end further forming, proximal to the first distal end, the first outer diameter of the coil;

the second conductor including an outer insulative layer and coupled to the electrode tip.

9. The implantable lead of claim 8, wherein the wound conductor and the second wound conductor each include a plurality of wires, the plurality including a pair of wires.
10. The implantable lead of claim 8, further comprising
an inner tubing forming a lumen and extending within the coil from the proximal end to the second distal end; and
a fiber core extending within the lumen from the proximal end to the second distal end where it is joined to the electrode tip.
11. The implantable lead of claim 8, wherein the coil member further includes a third wound conductor and a first reverse wound intermediate electrode; the third conductor including an outer insulative layer and winding from the proximal end to a position in between the first distal end and the second distal end further forming the first outer diameter of the coil, and reverse winding back toward the proximal end to form the intermediate electrode on the first outer diameter of the coil.
12. The implantable lead of claim 11, wherein the coil member further includes a fourth conductor and a second reverse wound intermediate electrode; the fourth conductor including an outer insulative layer and winding from the proximal end to a position in between the first intermediate electrode and the second distal end further forming the first outer diameter of the coil and reverse winding back toward the proximal end to form the second intermediate electrode on the first outer diameter of the coil.
13. The implantable lead of claim 1, wherein the coil member further includes a second wound conductor, a second distal end, disposed distal to the first distal end, and a second reverse wound electrode; the second conductor including an outer insulative layer and winding from the proximal end to the second distal end further forming the first outer diameter of the coil and reverse winding back toward the proximal end to form the second electrode on the first outer diameter of the coil.

14. The implantable lead of claim 1, further comprising an insulated cable conductor and an electrode tip positioned at a second distal end, the second distal end disposed distal to the first distal end; wherein the cable conductor is disposed within the coil member extending from the proximal end to the second distal end and coupled to the electrode tip.
15. The implantable lead of claim 14, wherein a length of the electrode is between approximately 2mm and 3 cm.
16. The implantable lead of claim 14, wherein a length of the electrode is between approximately 3 cm and 6 cm.
17. The implantable lead of claim 14, wherein the electrode serves as a pacing and sensing anode.
18. The implantable lead of claim 14, wherein the electrode serves as a defibrillation electrode.
19. The implantable lead of claim 14, wherein the insulative sheath includes an outer diameter and the electrode forms a second outer diameter of the coil member, the second outer diameter substantially equivalent to the outer diameter of the insulative sheath.
20. The implantable lead of claim 14, wherein the coil member further includes a second wound conductor and a first reverse wound intermediate electrode; the second conductor including an outer insulative layer and winding from the proximal end to a position in between the first distal end and the second distal end further forming the first outer diameter of the coil and reverse winding back toward the proximal end forming the first intermediate electrode on the first outer diameter of the coil.
21. The implantable lead of claim 20, wherein the coil member further includes a third wound conductor and a second reverse wound intermediate electrode; the third conductor including an outer insulative layer and winding from the proximal end to a position in between the first intermediate electrode and the second distal end further forming the first outer diameter of the coil and reverse winding back toward the proximal end forming the second intermediate electrode on the first outer diameter of the coil.

22. An implantable lead comprising,
an insulative sheath including an outer diameter;
an electrode tip;
a coil member extending through the insulative sheath including a first wound conductor, a second wound conductor, a proximal end, a first distal end, a second distal end, an reverse wound electrode, a first outer diameter and a second outer diameter;
an inner tubing forming a lumen and extending within the coil from the proximal end to the second distal end; and
a fiber core extending within the lumen from the proximal end to the second distal end where it is joined to the electrode tip;
wherein the first conductor winds from the proximal end to the first distal end forming the first outer diameter of the coil and reverse winds back toward the proximal end forming the electrode on the outer diameter of the coil, the electrode disposed adjacent and distal to the insulative sheath and forming the second outer diameter of the coil substantially equal to the outer diameter of the sheath;
the second conductor includes an outer insulative layer and winds from the proximal end to the second distal end, the second distal end disposed distal to the first distal end, further forming, proximal to the first distal end, the outer diameter of the coil; and
the second conductor coupled to the electrode tip at the second distal end.
23. A method of manufacturing an implantable lead comprising the steps of:
winding a conductor to form a coil member, the coil member including a proximal end, a distal end, and an outer diameter; and
reverse winding the conductor from the distal end back toward the proximal end over the outer diameter of the coil member.

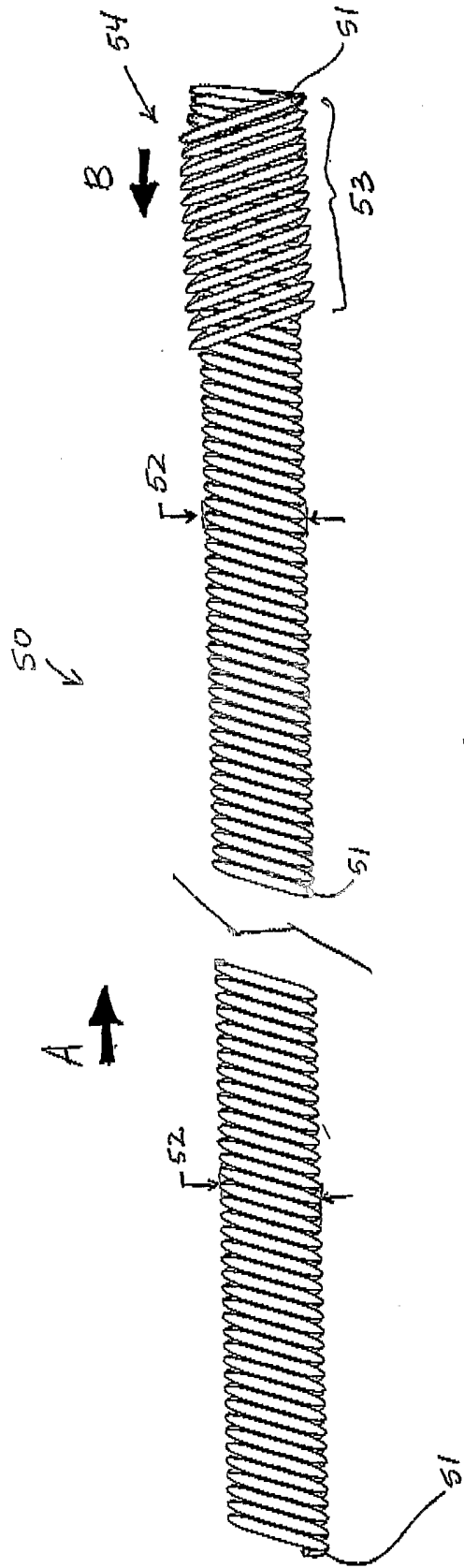


FIGURE 1A

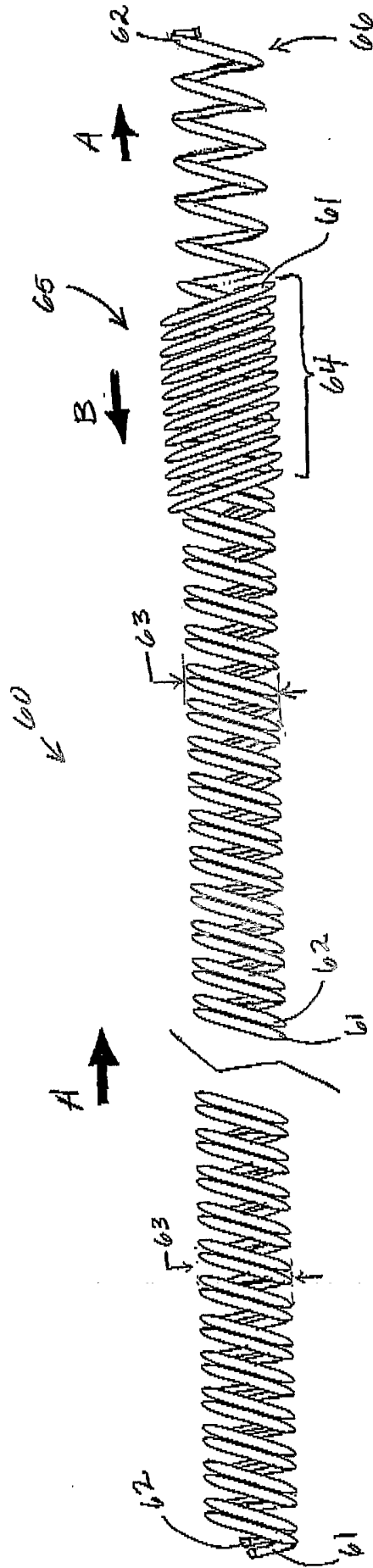


FIGURE 1B

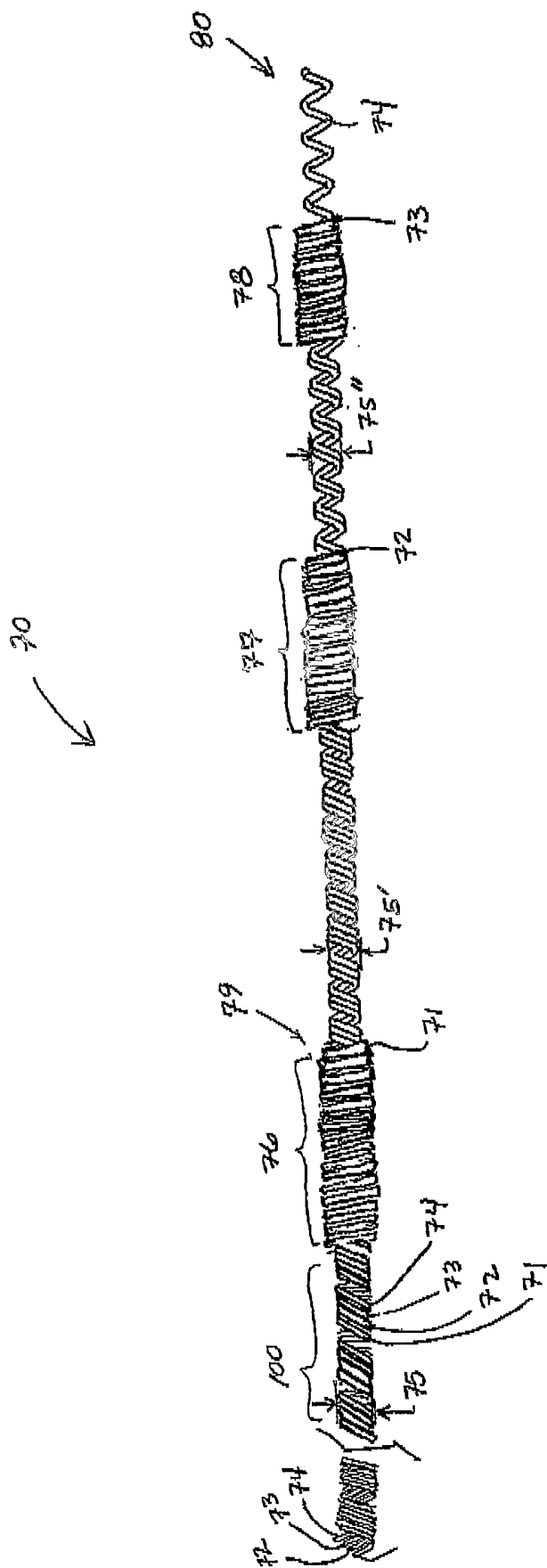


FIGURE 1C

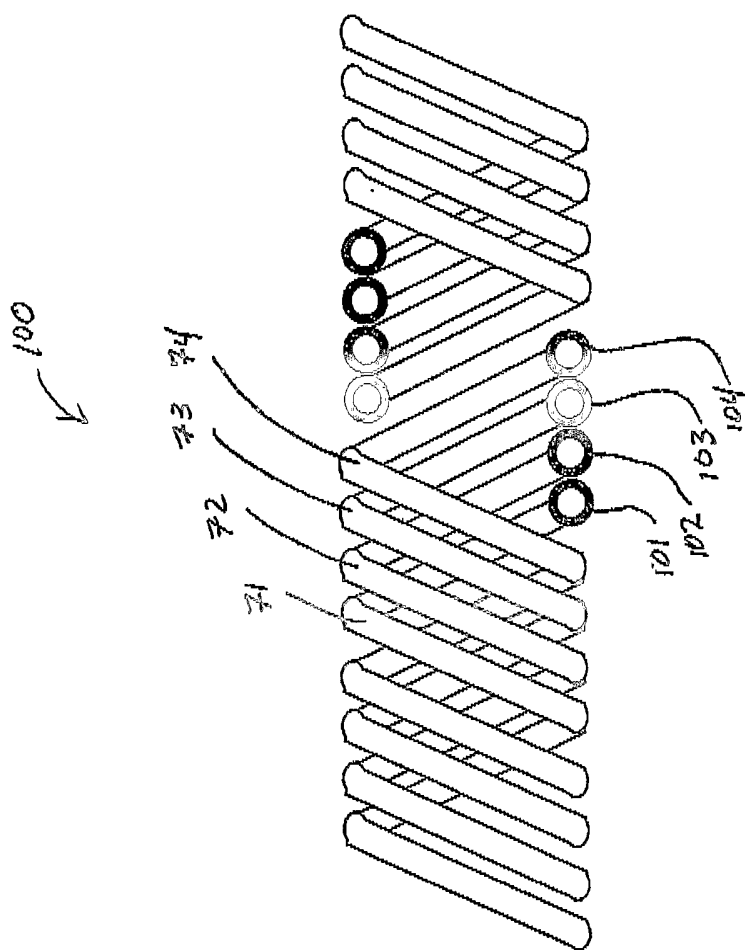
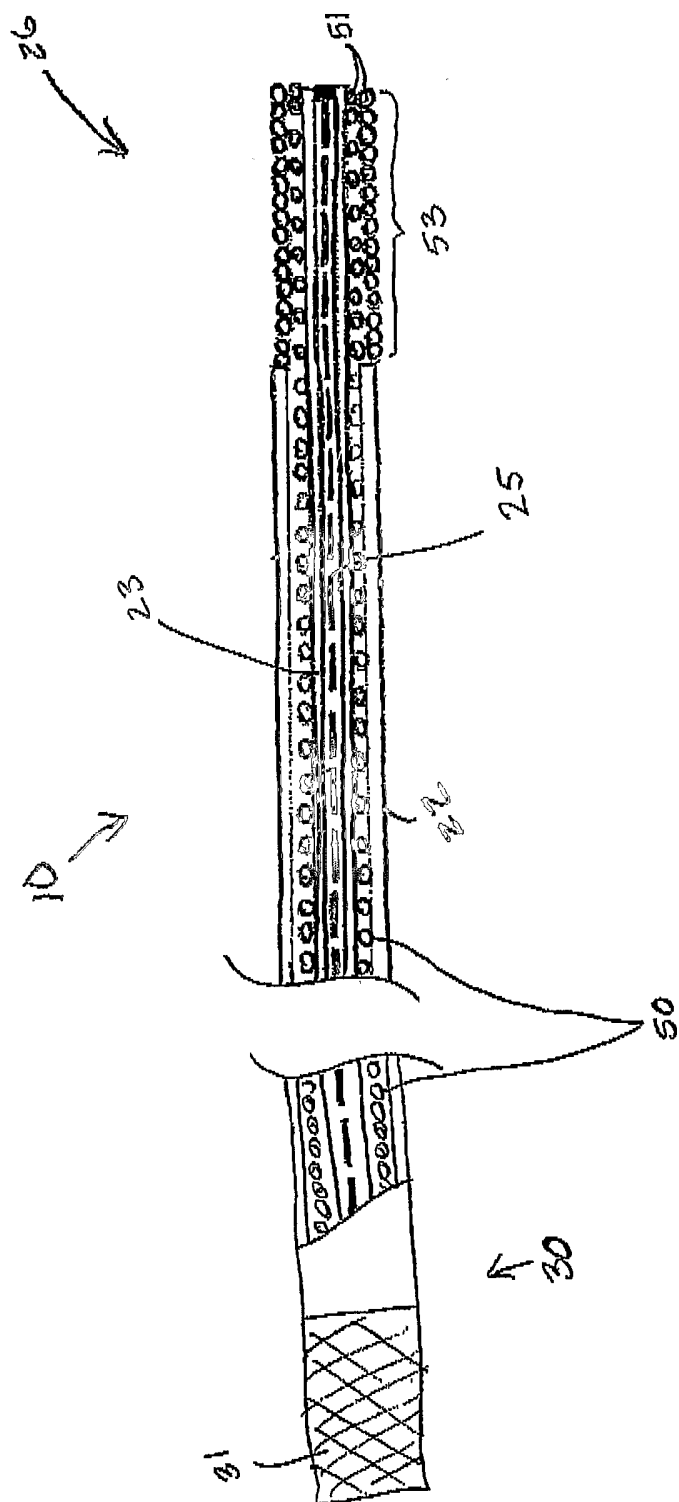


FIGURE 1D



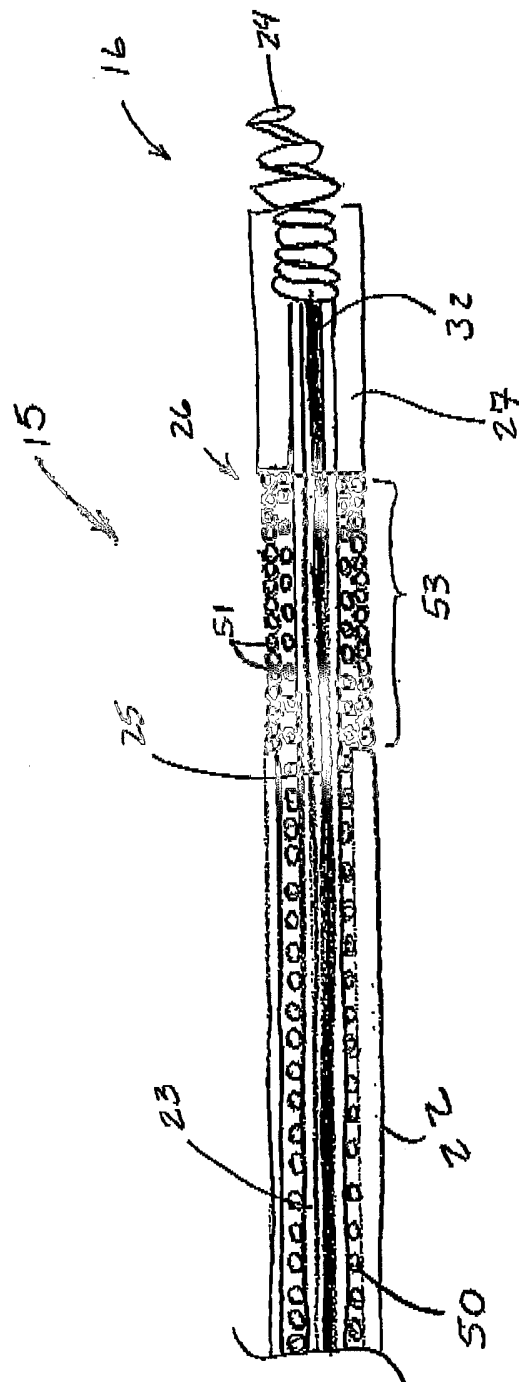


FIGURE 2B

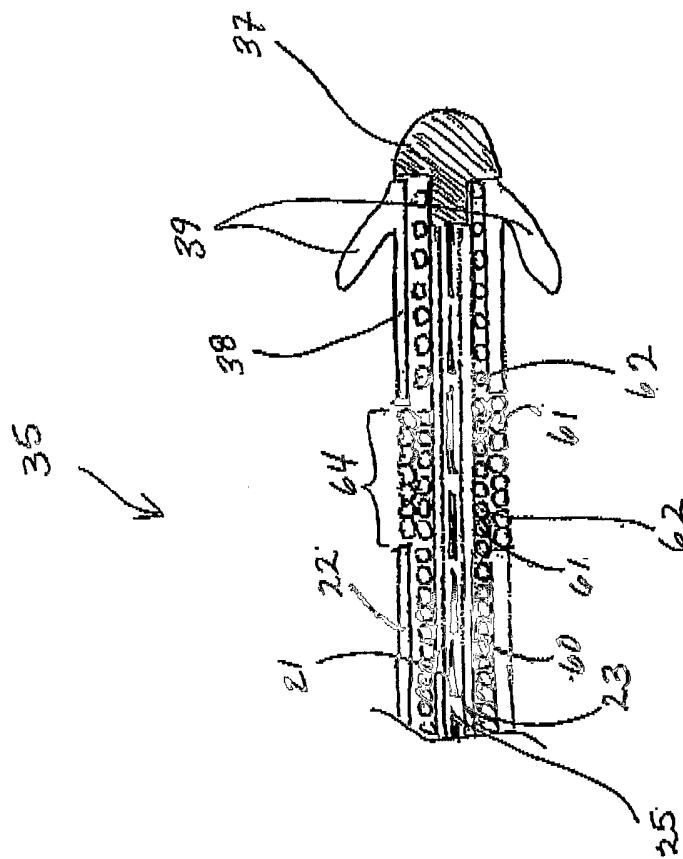


FIGURE 3

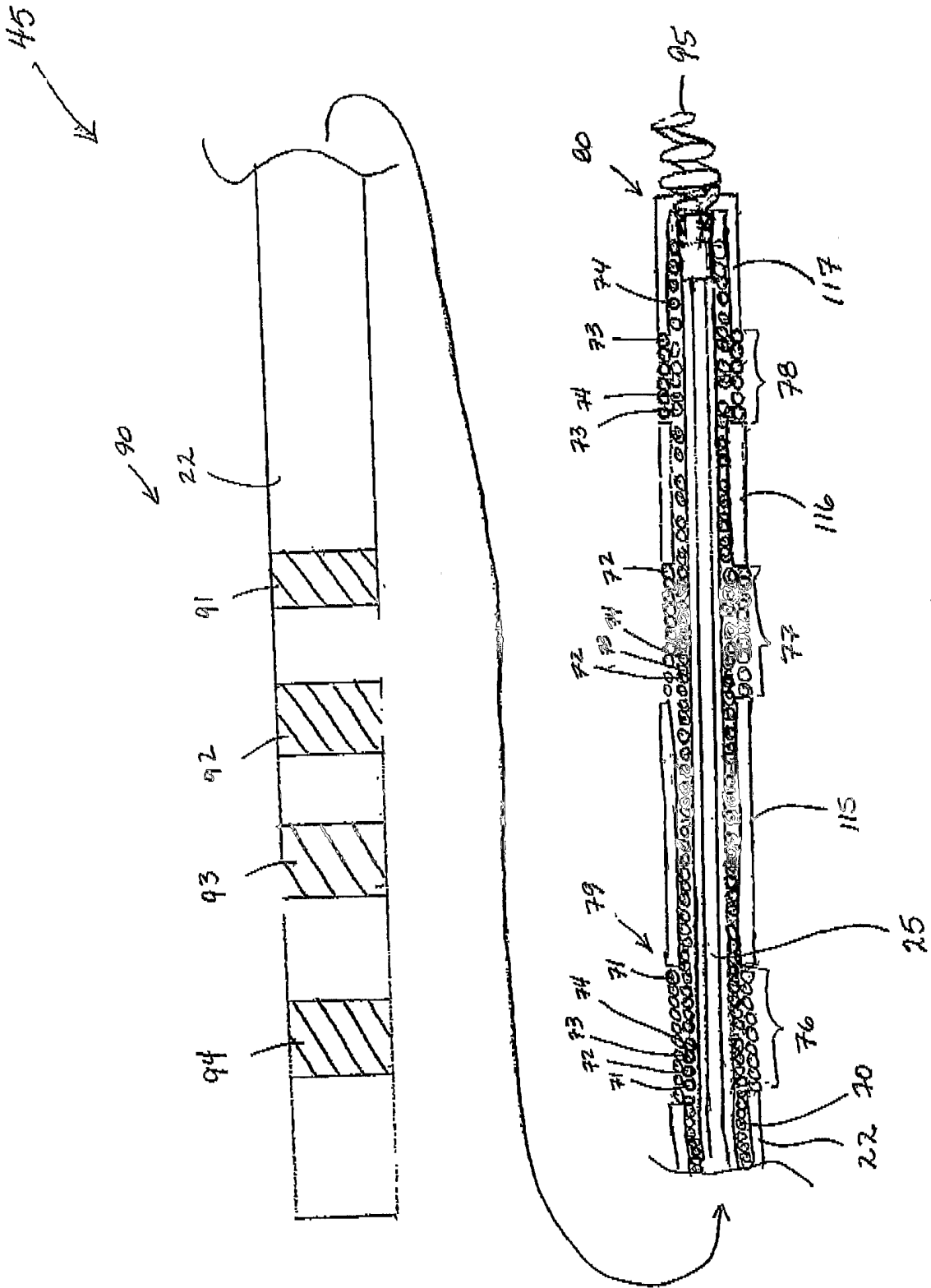


FIGURE 4

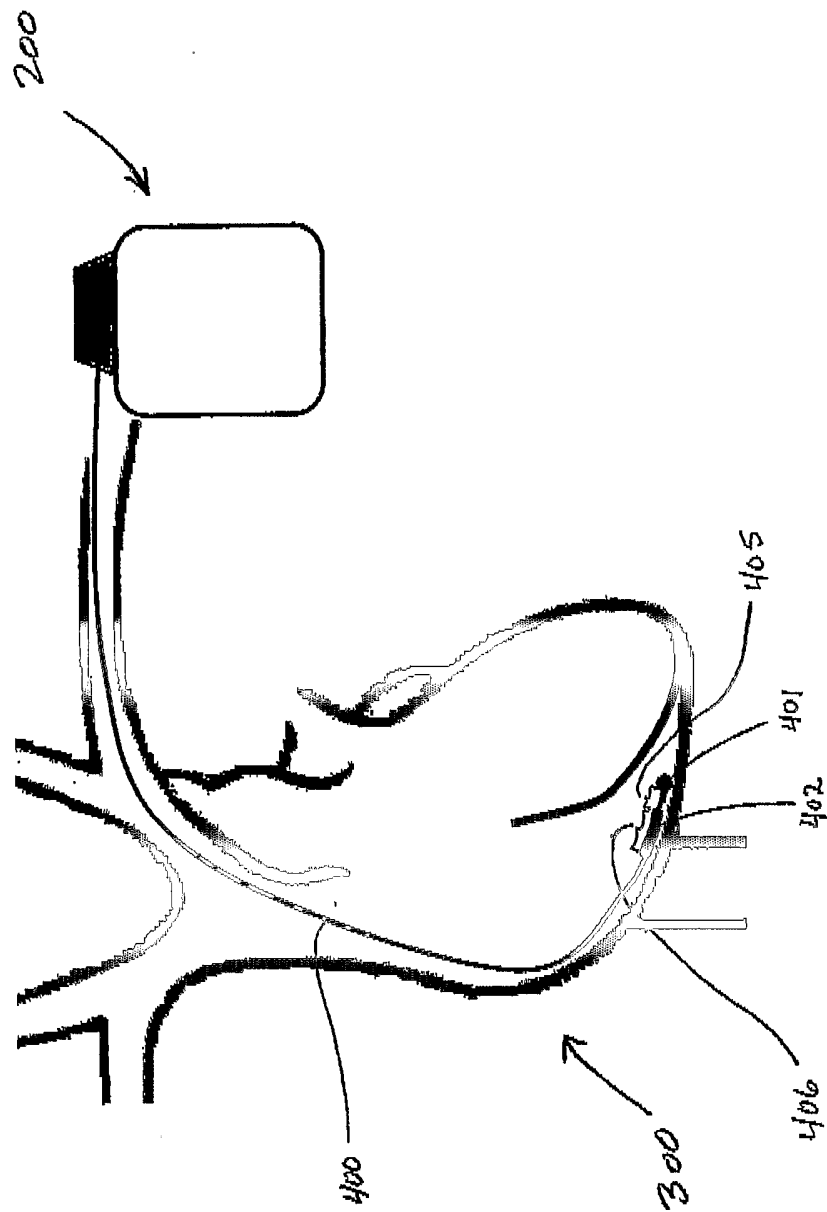


FIGURE 5

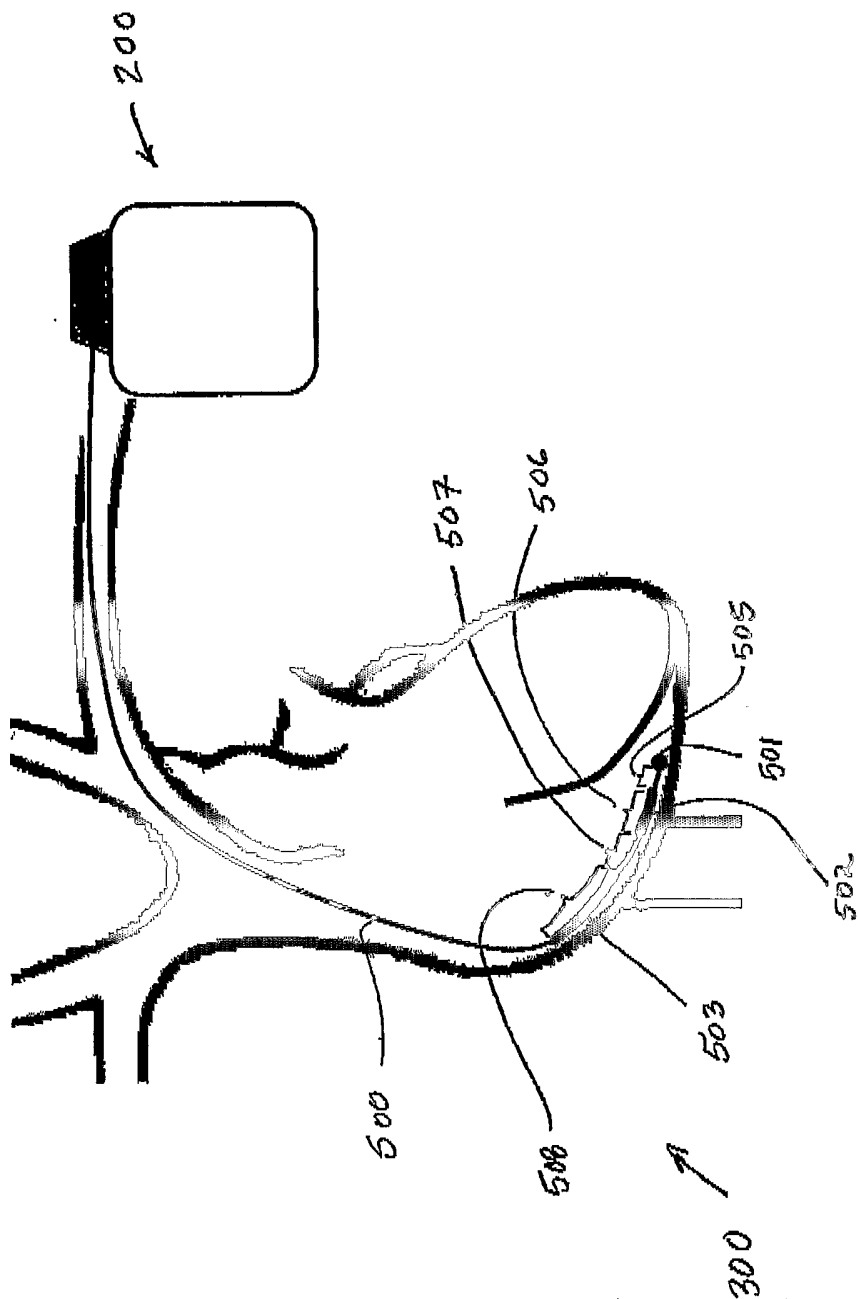


FIGURE 6

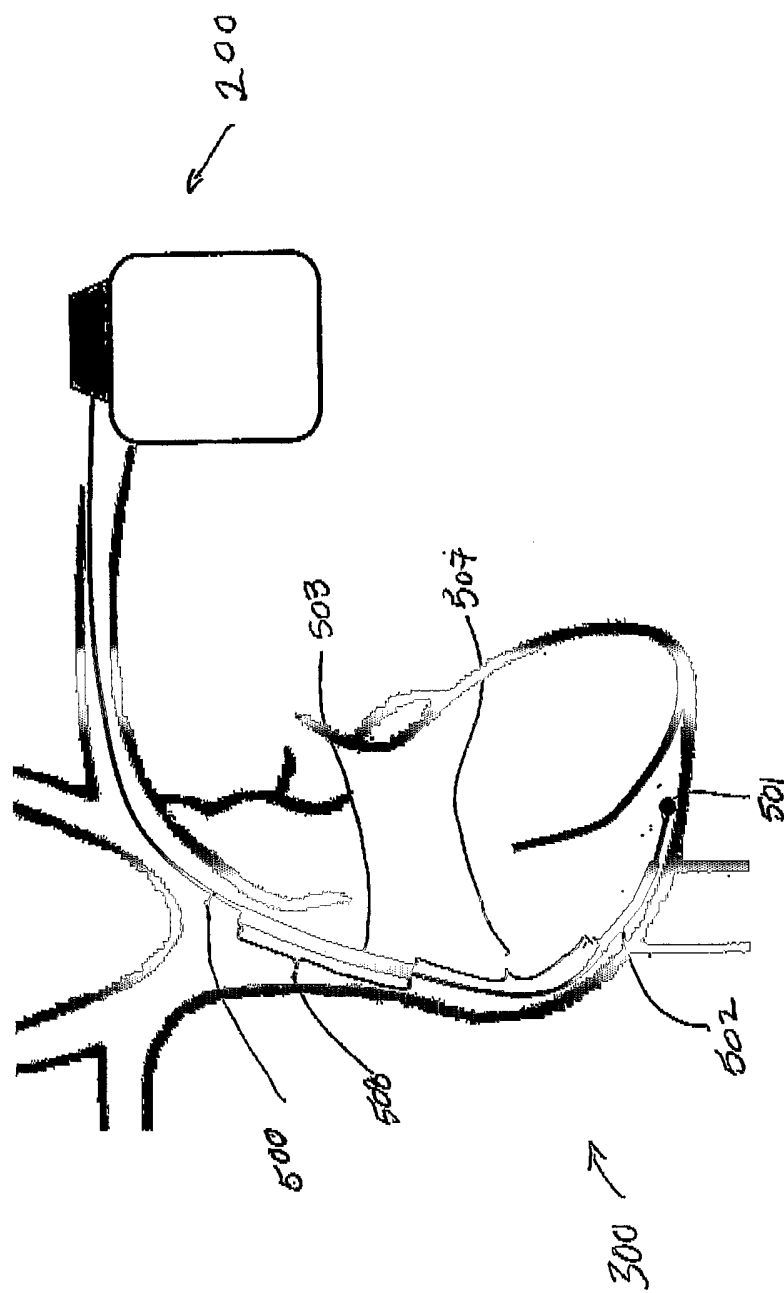


FIGURE 7

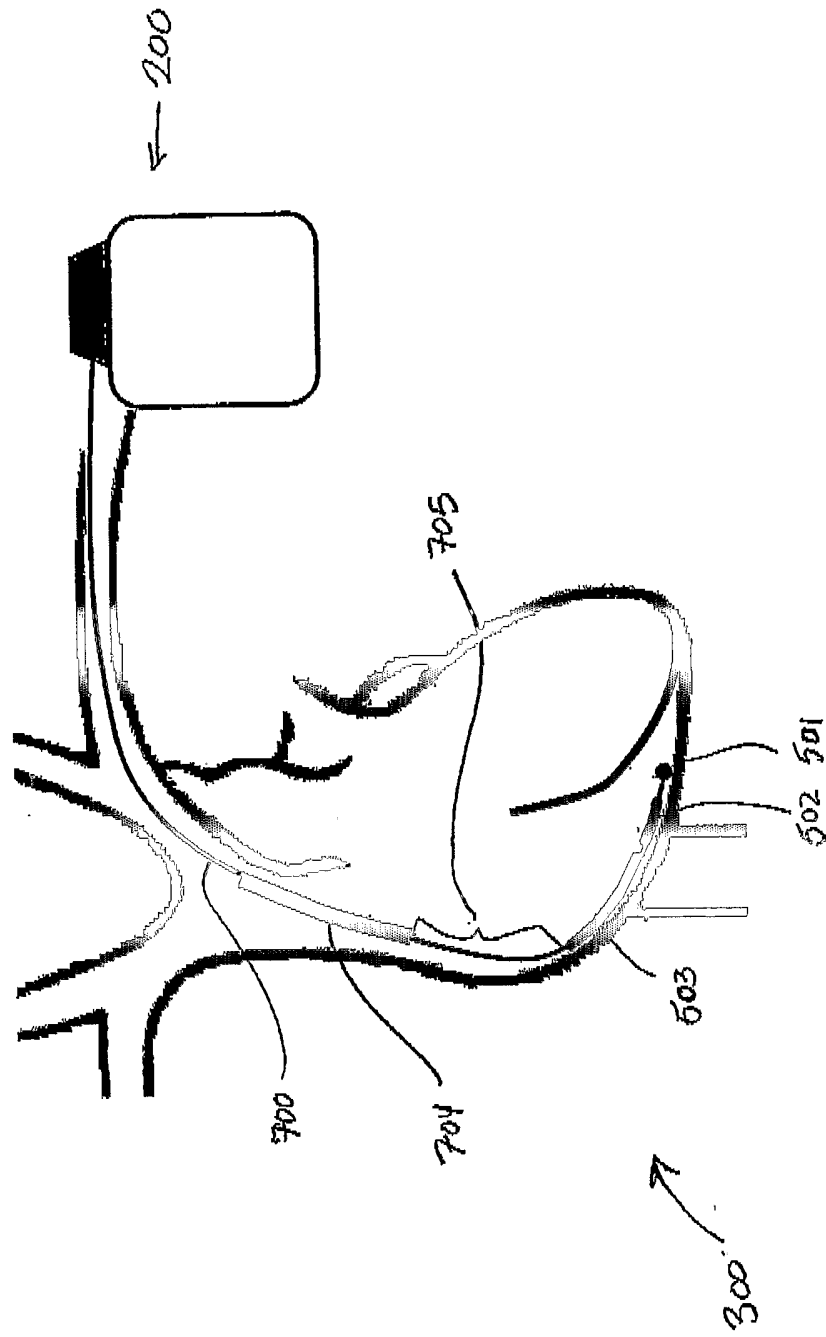


FIGURE 8

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/004114

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61N1/05 A61B5/042

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 7 A61N A61B

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 649 974 A (KROLL MARK W ET AL) 22 July 1997 (1997-07-22)	1-7, 13
Y	column 2; figures 6,8 column 6	8-12, 14, 19-22
Y	US 6 212 434 B1 (BOOKER III ROBERT S ET AL) 3 April 2001 (2001-04-03) figure 38	8, 9, 11, 12
Y	WO 00/27470 A (INTERMEDICS INC) 18 May 2000 (2000-05-18) page 8; figure 2	10, 22
Y	US 5 951 471 A (DE LA RAMA ALAN ET AL) 14 September 1999 (1999-09-14) column 4; figure 4	14, 19-21

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search 27 July 2004	Date of mailing of the international search report 03/08/2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Edward, V

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/004114

Patent document cited in search report	Publication date	Patent family member(s)~	Publication date	
US 5649974	A	22-07-1997	US 5454839 A	03-10-1995
			AU 3625295 A	22-03-1996
			WO 9606655 A1	07-03-1996
US 6212434	B1	03-04-2001	CA 2313174 A1	24-06-1999
			CA 2328867 A1	28-10-1999
			EP 1037690 A2	27-09-2000
			EP 1071492 A1	31-01-2001
			JP 2002512096 T	23-04-2002
			WO 9930772 A2	24-06-1999
			WO 9953993 A1	28-10-1999
			US 2003069625 A1	10-04-2003
			US 2003163184 A1	28-08-2003
			US 6505082 B1	07-01-2003
WO 0027470	A	18-05-2000	US 6035239 A	07-03-2000
			US 6141593 A	31-10-2000
			AU 1474500 A	29-05-2000
			AU 3788900 A	29-05-2000
			WO 0027470 A1	18-05-2000
			WO 0027471 A1	18-05-2000
US 5951471	A	14-09-1999	US 6308090 B1	23-10-2001