

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 August 2008 (07.08.2008)

PCT

(10) International Publication Number
WO 2008/094350 A1

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

[US/US]; 1367 California Avenue West, Falcon Heights,
Minnesota 55108 (US).

(21) International Application Number:
PCT/US2007/086130

(74) Agents: **SPOLAR, Catherine D.** et al.; Faegre & Benson
LLP, 2200 Wells Fargo Center, 90 South Seventh Street,
Minneapolis, Minnesota 55402-3901 (US).

(22) International Filing Date:
30 November 2007 (30.11.2007)

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
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, SV, SY,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,
ZM, ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/669,047 30 January 2007 (30.01.2007) US

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

(72) Inventor; and

(75) Inventor/Applicant (*for US only*): **BLY, Mark J.**

(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,

[Continued on next page]

(54) Title: DIRECT DELIVERY SYSTEM FOR TRANSVASCULAR LEAD

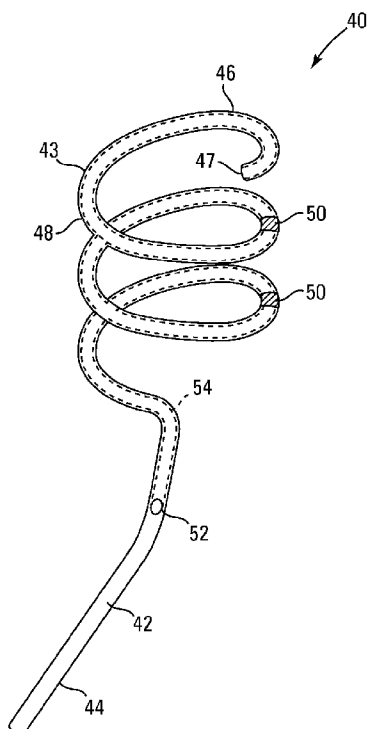


Fig. 2

(57) Abstract: A lead delivery system is described for delivering a neurostimulation lead to a patient's internal jugular vein using a percutaneous stick. The system includes a neurostimulation lead adapted to stimulate a vagus nerve from the internal jugular vein. The lead includes a side port interposed between a retaining structure and a proximal end of the lead. The side port provides access to a lumen extending from a distal end to the side port. A guidewire is sized to fit within the side port and lumen and reduce a force exerted by the retaining structure against the internal jugular vein, thereby allowing rotation of the lead and orientation of the electrode by applying a torque to the lead.

WO 2008/094350 A1



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, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, 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*

DIRECT DELIVERY SYSTEM FOR TRANSVASCULAR LEAD

TECHNICAL FIELD

[001] The present invention relates to medical electrical leads for nerve or muscle stimulation. The present invention more particularly relates to a system for direct delivery of a neurostimulation lead into an internal jugular vein and adjacent to a vagus nerve.

BACKGROUND

[002] A significant amount of research has been directed both to the direct and indirect stimulation of nerves including the left and right vagus nerves, the sympathetic and parasympathetic nerves, the phrenic nerve, the sacral nerve, and the cavernous nerve to treat a wide variety of medical, psychiatric, and neurological disorders or conditions. More recently, stimulation of the vagus nerve has been proposed as a method for treating various heart conditions, including heart failure. Heart failure is a cardiac condition characterized by a deficiency in the ability of the heart to pump blood throughout the body and high filling pressure causing pulmonary fluid to build up in the lungs.

[003] Typically, nerve stimulating electrodes are cuff- or impalement-type electrodes placed in direct contact with the nerve to be stimulated. These electrodes require surgical implantation and can cause irreversible nerve damage due to swelling or direct mechanical damage to the nerve. A less invasive approach is to stimulate the nerve through an adjacent vessel using an intravascular lead. A lead including one or more electrodes is inserted into a patient's vasculature and delivered to a site within a vessel adjacent a nerve to be stimulated.

[004] Intravascular leads can be implanted using an over-the-wire technique where the lead includes a lumen extending the length of the lead and the lead is advanced over a guidewire to the desired location in the vein. Current over-the-wire leads, however, have lumens extending the length of the lead. This requires threading of the entire lead over the wire and results in a larger than desirable lead diameter. Furthermore, the lead generally travels an

extensive distance through the vasculature, which requires navigability and flexibility of the lead. Thus, there is a need in the art for an intravascular medical electrical lead that can be implanted using an over-the-wire technique, yet does not require a lumen extending the length of the lead. There is also a need in the art for a lead that can be delivered directly to a desired location in the vasculature.

SUMMARY

[005] In one embodiment, the invention is a lead delivery system for delivering a neurostimulation lead to a patient's internal jugular vein using a percutaneous stick. The system comprises a neurostimulation lead adapted to stimulate a vagus nerve from the internal jugular vein. The lead includes a proximal end, a distal end, a generally spiral shaped retaining structure interposed between the proximal and distal ends and configured to retain the lead in the internal jugular vein, an electrode coupled to the retaining structure, and a side port interposed between the retaining structure and the proximal end. The side port provides access to a lumen extending from the distal end to the side port. A guidewire is sized to fit within the side port and lumen and reduce a force exerted by the retaining structure against the internal jugular vein, thereby allowing rotation of the lead and orientation of the electrode by applying a torque to the lead. A catheter has a lumen sized to slideably receive the medical electrical lead and is configured to provide access to the internal jugular vein from the percutaneous stick site.

[006] In another embodiment, the present invention is a lead delivery system for delivering a neurostimulation lead to a patient's internal jugular vein using a percutaneous stick. The system comprises a neurostimulation lead adapted to stimulate a vagus nerve from the internal jugular vein, the lead including a proximal end, a distal end, a retaining structure configured to retain the lead in the internal jugular vein interposed between the proximal and distal ends, and a side port interposed between the retaining structure and the proximal end. The side port provides access to a lumen extending from the distal end to the side port. A guidewire is sized to fit within the side port and lumen and reduce a force exerted by the retaining structure against a surface external to the retaining structure, thereby facilitating advancement and

orientation of the lead. A catheter has a lumen sized to slideably receive the medical electrical lead and is configured to provide access to the internal jugular vein from the percutaneous stick site.

[007] In another embodiment, the present invention is a method of directly delivering a neurostimulation lead to a patient's internal jugular vein. The method comprises inserting a catheter into the internal jugular vein using a percutaneous stick. A guidewire is inserted into a side port and through a lumen of a neurostimulation lead. The neurostimulation lead includes a proximal end, a distal end, a retaining structure interposed between the proximal and distal ends, and an electrode coupled to the retaining structure. The side port is interposed between the retaining structure and the proximal end and the lumen extends from the distal end to the side port. A portion of the neurostimulation lead is advanced through the catheter and the lead is oriented to a desired position in the internal jugular vein. The catheter and guidewire are removed.

[008] 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

[009] FIG. 1 is a schematic view of a patient's upper torso.

[010] FIG. 2 is a schematic view of a medical electrical lead according to one embodiment of the present invention.

[011] FIG. 3 is a schematic view of a catheter according to one embodiment of the present invention.

[012] FIG. 4 is a schematic view of a guidewire according to one embodiment of the present invention.

[013] FIG. 5 is a schematic view of a guidewire inserted into a medical electrical lead according to one embodiment of the present invention.

[014] FIG. 6 is a schematic view of a catheter after insertion into an internal jugular vein according to one embodiment of the present invention.

[015] FIG. 7 is a schematic view of a medical electrical lead and guidewire inserted into a catheter according to one embodiment of the present invention.

[016] FIG. 8 is a schematic view of a medical electrical lead located in a patient's internal jugular vein after removal of the catheter and guidewire according to one embodiment of the present invention.

[017] FIG. 9 is a flowchart illustrating an exemplary method of implanting a medical electrical lead into an internal jugular vein according to one embodiment of the present invention.

[018] 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

[019] FIG. 1 shows a schematic view of a patient's upper torso, including a heart 10 and the veins of the neck 12 and thorax 14. The subclavian veins 16 drain blood from the arms 18. The internal jugular veins 20 drain blood from the head 22 and join the subclavian veins 16 to form the brachiocephalic or innominate veins 24. The union of the brachiocephalic veins 24 forms the superior vena cava 26, which returns blood from the head 22, neck 12, arms 18, and thorax 14 to the right atrium 28. A vagus nerve 30 is shown adjacent to the right internal jugular vein 20. Another vagus nerve (not shown) is adjacent to the left internal jugular vein 20. A stimulating device 32 is located in a subcutaneous pocket near the patient's subclavian vein. The stimulating device 32 is connected to a medical electrical lead 40. A portion of the medical electrical lead 40 extends through the internal jugular vein 20 and the remainder is subcutaneously tunneled to the stimulating device 32. In one embodiment, the stimulating device 32 provides electrical stimulation to a nerve.

[020] FIG. 2 is a schematic view of the medical electrical lead 40 of FIG. 1. The medical electrical lead 40 includes a lead body 42 comprised of an

electrically insulative material 43 extending from a proximal end 44 to a distal end 46. The proximal end 44 is adapted for connection to the stimulating device 32 using connectors or any other means known in the art. A retaining structure 48 adapted to exert a force against a surface external to the retaining structure 48 is located at the distal end 46. In one embodiment, the retaining structure 48 exerts a force against the internal jugular vein 20. In another embodiment, the retaining structure 48 exerts a force against the catheter 60. In yet another embodiment, the retaining structure 48 exerts a force against both the catheter 60 and the internal jugular vein 20. The force exerted by the retaining structure 48 against the internal jugular vein 20 helps retain the electrodes 50 against the internal jugular vein 20 and adjacent to the vagus nerve 30. The retaining structure 48 also stabilizes the lead 40 within the internal jugular vein 20.

[021] In the illustrated embodiment, the retaining structure 48 has a generally spiral shape. In one embodiment, the retaining structure 48 has a spiral shape as disclosed in U.S. Patent Application Ser. No. 11/668,926 filed January 30, 2007, entitled SPIRAL CONFIGURATIONS FOR INTRAVASCULAR LEAD STABILITY, above-incorporated by reference in its entirety. In an alternative embodiment, the retaining structure 48 has the form of a dual spiral as disclosed in U.S. Patent Application Ser. No. 11/668,887, filed January 30, 2007, entitled DUAL SPIRAL LEAD CONFIGURATIONS, above-incorporated by reference in its entirety. In another embodiment, the retaining structure 48 has the stent-like structure disclosed in U.S. Patent Application Ser. No. 11/668,834, filed January 30, 2007, entitled NEUROSTIMULATING LEAD HAVING A STENT-LIKE ANCHOR, above-incorporated by reference in its entirety. In other embodiments, the retaining structure 48 has any shape that retains an electrode against a vessel.

[022] The retaining structure 48 can be formed using molded silicone parts, metal conductor coils, heat formed polyurethane tubing, or any other method known in the art. The retaining structure 48 can have a variety of cross-sectional shapes, including circular or oval. In one embodiment, the retaining structure 48 is a spiral having a pitch of between approximately 0 and approximately 5 centimeters. In an alternative embodiment, the retaining structure 48 is a spiral having a diameter of between approximately 5 and

approximately 50 millimeters. In another alternative embodiment, the retaining structure 48 has a length of between approximately 30 and approximately 200 millimeters.

[023] Electrodes 50 are located at the distal end 46. In the embodiment shown in FIG. 2, the electrodes 50 are coupled to the retaining structure 48. The electrodes 50 can provide electrical stimulation, sense electrical activity, or both. The lead 40 includes conductive members (not shown) coupling electrodes 50 to the stimulating device 32. Although two electrodes 50 are shown in FIG. 2, the medical electrical lead 40 can include any number of electrodes 50. In the embodiment illustrated in FIG. 2, the electrodes 50 are ring electrodes. In other embodiments, the electrodes have any other configuration known in the art. In one embodiment, the electrodes 50 are configured according to commonly assigned U.S. Patent Application Ser. No. 11/668,957, filed January 30, 2007, entitled ELECTRODE CONFIGURATIONS FOR TRANSVASCULAR NERVE STIMULATION, above-incorporated by reference in its entirety.

[024] A side port 52 communicates with and provides access to a lumen 54 extending from the distal end 46 to the side port 52. As shown in FIG. 2, the lumen 54 extends out of the tip 47 of the medical electrical lead 40 and terminates at the side port 52. In another embodiment, the lumen 54 extends beyond the side port 52. In another embodiment, the lumen 54 extends substantially the length of the medical electrical lead 40. In yet another embodiment, the lumen 54 extends the length of the medical electrical lead 40. In one embodiment, the lumen 54 is separate from a lumen formed by a conductive coil member. In another embodiment, all or a portion of the lumen 54 is formed by a conductive coil member lumen. In yet another embodiment, the lumen 54 is formed from multiple serial lumens. The lumen 54 can extend through the lead body 42 or through silicone or polyurethane molded parts in the lead 40. In one embodiment, the electrodes 50 are ring electrodes having insulated lumens and the lumen 54 is at least partially formed from the insulated electrode lumens. In another embodiment, the electrodes 50 are only partially exposed and the lumen 54 passes through the electrodes 50.

[025] The side port 52 is interposed between the retaining structure 48 and the proximal end 44. In one embodiment, the side port 52 is located a

maximum of approximately 5 centimeters from the retaining structure 48. In one embodiment, the lead 40 has a length of between about 40 and about 100 centimeters and a diameter of between about 3 and about 8 French. In one embodiment, the lumen 54 has a diameter of between about 0.014 and about 0.042 inch.

[026] FIG. 3 depicts an introducer or catheter 60 used to provide access to the internal jugular vein 20. The catheter 60 has a proximal end 62, a distal end 64, and a lumen 66. The catheter 60 is sized to slideably receive the medical electrical lead 40 in the lumen 66 after insertion of the guidewire 70 into the lead 40 (as shown in FIG. 7). In one embodiment, the catheter 60 is configured to provide access to the internal jugular vein 20 via percutaneous stick. The catheter 60 can be made of a polytetrafluoroethylene (PTFE) or fluoronated ethylene propylene (FEP) inner lining, a 304 V stainless steel braiding, and an outer jacket of Pebax and/or Nylon. Tungsten wire can optionally be added to the stainless steel braiding to improve radiopacity of the catheter. In other embodiments, the catheter 60 is made out of any other material known in the art. In one embodiment, the catheter 60 has a length of between about 10 and about 20 centimeters, an outer diameter of between about 6 and about 14 French, and an inner diameter that is slightly smaller than the outer diameter. In one embodiment, the inner diameter is about 0.020 inch smaller than the outer diameter.

[027] FIG. 4 depicts a guidewire 70 according to one embodiment of the present invention. In the illustrated embodiment, the guidewire 70 has a proximal end 74, a distal end 76, and a distal tip 78. The guidewire 70 allows a clinician to introduce and position a medical electrical lead 40 in a patient. In one embodiment, the guidewire 70 has a core (not shown), and includes a coating, for example, a hydrophilic coating. In one embodiment, the wire core is made from nickel/titanium. In an alternative embodiment, the wire core is made from stainless steel. In yet another alternative embodiment, the wire core is made from any other metal known in the art. The guidewire 70 has an outer diameter that allows it to slide into the side port 52 and through the lumen 54 of the medical electrical lead 40. In one embodiment, the guidewire 70 has a diameter of between approximately 0.012 and approximately 0.040 inch. In one embodiment, the guidewire 70 includes a grind profile. In one embodiment, the

grind profile is parabolic. In another embodiment, the guidewire 70 has a length of between about 10 and about 40 centimeters.

[028] FIG. 5 illustrates the medical electrical lead 40 after insertion of the guidewire 70 into the side port 52 and lumen 54. In one embodiment, the lead 40 is advanced over the guidewire 70 during implantation. In another embodiment, the guidewire 70 straightens the retaining structure 48 enough to reduce the force exerted on the internal jugular vein 20 by the retaining structure 48, thereby facilitating implantation of the lead 40. Although the medical electrical lead 40 is shown as straight after the insertion of the guidewire 70 in the illustrated embodiment, in another embodiment, the guidewire 70 does not completely straighten the retaining structure 48. The guidewire 70 is used to advance the medical electrical lead 40 through the catheter 60 and to a desired location in the internal jugular vein 20.

[029] FIG. 6 is a schematic view showing the catheter 60 inserted into the internal jugular vein 20. The catheter 60 provides access to the internal jugular vein 20 for the lead 40. FIG. 7 is a cutaway view showing the medical electrical lead 40 and guidewire 70 after advancement through the catheter 60 and into the internal jugular vein 20. As shown in FIG. 8, after the catheter 60 and guidewire 70 are removed, the retaining structure 48 retains the distal end 46 of the lead 40 in the internal jugular vein 20. In one embodiment, the retaining structure 48 retains the electrodes 50 in a location adjacent to the vagus nerve 30. In one embodiment, the remainder of the medical electrical lead 40 is subcutaneously tunneled to the stimulating device 32.

[030] In one embodiment, a suture 80 secures the distal end 46 of the medical electrical lead 40 at the site of the percutaneous stick. In another embodiment, a suture sleeve (not shown) can be used to protect the lead body 42 when using a suture 80 to secure the distal end 46. In yet another embodiment, an anchor or any other securing means known in the art is used to secure the proximal end 46 of the medical electrical lead 40.

[031] FIG. 9 depicts an exemplary method 900 for implanting a medical electrical lead 40. A catheter 60 is inserted into the internal jugular vein 20 using a percutaneous stick (block 910). A guidewire 70 (or stylet) is inserted into the side port 52 and through the lumen 54 of the medical electrical lead 40 (block 920). The lead 40 is advanced through the catheter 60 into the internal

jugular vein 20 and oriented to a desired position (block 930). The guidewire 70 and catheter 60 are then removed (block 940). In one embodiment, the lead 40 is advanced over the guidewire 70 and through the catheter 60. In another embodiment, the lead 40 and the guidewire 70 are advanced through the catheter 60 together.

[032] The lead 40 can be advanced and oriented to a desired position in a number of ways. For example, in one embodiment, a portion of the retaining structure 48 is retained in the catheter 60 and the retaining structure 48 exerts a force against the catheter 60. The lead 40 can be oriented by applying a torque to the catheter 40 or to the lead body 42. In another embodiment, the entire retaining structure 48 is retained in the catheter 60 and the lead 40 is oriented by applying a torque to the catheter 40 or to the lead body 42. In yet another embodiment, a guidewire 70 inserted into the side port 52 and lumen 54 of the lead 40 straightens the retaining structure 48 to reduce the force exerted by the retaining structure 48 on the catheter 60. This force reduction facilitates advancement of the lead 40 through the catheter 60 and the internal jugular vein 20. The force reduction also facilitates orientation of the lead 40 in the internal jugular vein 20. In one embodiment, the lead 40 is advanced and oriented so that the electrodes 50 are adjacent to the vagus nerve 30.

[033] In another embodiment, the retaining structure 48 extends beyond the distal end 64 of the catheter. The lead 40 is oriented by applying a torque to the lead body 42. In one embodiment, the guidewire 70 is used to reduce the force exerted by the retaining structure 48 on the internal jugular vein 20 during implantation of the lead 40. In another embodiment, the guidewire 70 is retracted from the retaining structure 48, yet remains in a portion of the lumen 54, thereby allowing for additional manipulation of the lead 40 using the guidewire 70.

[034] In one embodiment, removal of the catheter 60 allows the retaining structure 48 to further expand, causing the retaining structure 48 to exert a greater force against the internal jugular vein 20. In one embodiment, the catheter 60 is split or peeled apart for removal. In another embodiment, the catheter 60 is slid over the medical electrical lead 40. In one embodiment, a stylet is inserted into the lumen 54 instead of a guidewire 70. In another embodiment, the lumen 54 does not extend out of the tip 47 of the medical

electrical lead 40 and a stylet (not shown) is used to push the lead 40 to the desired position in the internal jugular vein 20. In yet another embodiment, the method 900 includes securing the distal end 46 of the lead 40 at the stick site using a suture 80. In another embodiment, the remainder of the lead 40 is subcutaneously tunneled to a stimulating device 32.

[035] The invention allows for direct delivery of the medical electrical lead 40 into the internal jugular vein 20 without threading the guidewire 70 through the entire length of the lead 40. It is easier to exchange guidewires 70, if necessary, because the guidewire 70 is not threaded through the entire length of the lead 40. Additionally, the lead 40 is more easily turned because instead of turning the entire length of the lead 40, a shorter length may be turned. In one embodiment, the lead 40 is turned by applying a torque to the lead body 42 at a region near the side port 52.

[036] Although the present invention has been described in reference to an internal jugular vein, the invention could also be used to implant a lead 40 in any vessel, such as a vein, artery, lymphatic duct, bile duct, for the purposes of nerve or muscle stimulation. The medical electrical lead 40 can include any number of conductors, electrodes, terminal connectors, and insulators, and can be used with any combination of catheters, introducers, guidewires, and stylets.

[037] 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

We claim:

1. A lead delivery system for delivering a neurostimulation lead to a patient's internal jugular vein using a percutaneous stick, the system comprising:
 - a neurostimulation lead adapted to stimulate a vagus nerve from the internal jugular vein, the lead including a proximal end, a distal end, a generally spiral shaped retaining structure interposed between the proximal and distal ends and configured to retain the lead in the internal jugular vein, an electrode coupled to the retaining structure, and a side port interposed between the retaining structure and the proximal end, the side port providing access to a lumen extending from the distal end to the side port;
 - a guidewire sized to fit within the side port and lumen and reduce a force exerted by the retaining structure against the internal jugular vein, thereby allowing rotation of the lead and orientation of the electrode by applying a torque to the lead; and
 - a catheter having a lumen sized to slideably receive the medical electrical lead and configured to provide access to the internal jugular vein from the percutaneous stick site.
2. The lead delivery system of claim 1 wherein the distance between the side port and the generally spiral shaped retaining structure is a maximum of approximately 5 centimeters.
3. The lead delivery system of claim 1 wherein the lumen extends beyond the side port.

4. The lead of claim 1 wherein the generally spiral shaped retaining structure has a diameter of between approximately 5 and approximately 50 millimeters.
5. The lead of claim 1 wherein the generally spiral shaped retaining structure has a length of between approximately 30 and approximately 200 millimeters.
6. The lead of claim 1 wherein the generally spiral shaped retaining structure has a pitch of between approximately 0 centimeters and approximately 5 centimeters.
7. The lead delivery system of claim 1 wherein the neurostimulation lead has a diameter of between approximately 3 and approximately 8 French.
8. The lead delivery system of claim 1 wherein the lumen has a diameter of between approximately 0.014 and approximately 0.042 inch.
9. The lead delivery system of claim 1 wherein the catheter has a length of between approximately 10 and approximately 20 centimeters.
10. The lead delivery system of claim 1 wherein the guidewire has a diameter of between approximately 0.012 and approximately 0.040 inch and a length of between approximately 10 and approximately 40 centimeters.
11. A lead delivery system for delivering a neurostimulation lead to a patient's internal jugular vein using a percutaneous stick, the system comprising:
 - a neurostimulation lead adapted to stimulate a vagus nerve from the internal jugular vein, the lead including a proximal end, a distal end, a retaining structure configured to retain the lead in the internal jugular vein interposed between the proximal and distal ends, and a side port interposed between the retaining

structure and the proximal end, the side port providing access to a lumen extending from the distal end to the side port;

a guidewire sized to fit within the side port and lumen and reduce a force exerted by the retaining structure against a surface external to the retaining structure, thereby facilitating advancement and orientation of the lead; and

a catheter having a lumen sized to slideably receive the medical electrical lead and configured to provide access to the internal jugular vein from the percutaneous stick site.

12. The lead delivery system of claim 11 wherein the surface external to the retaining structure is the catheter.

13. The lead delivery system of claim 11 wherein the surface external to the retaining structure is the internal jugular vein.

14. The lead delivery system of claim 11 wherein the retaining structure has a spiral, dual spiral, or stent-like structure.

15. A method of directly delivering a neurostimulation lead to a patient's internal jugular vein, the method comprising:

inserting a catheter into the internal jugular vein using a percutaneous stick;

inserting a guidewire into a side port and through a lumen of a neurostimulation lead, the neurostimulation lead including a proximal end, a distal end, a retaining structure interposed between the proximal and distal ends, and an electrode coupled to the retaining structure, wherein the side port is interposed between the retaining structure and the proximal end and the lumen extends from the distal end to the side port;

advancing a portion of the neurostimulation lead through the catheter and orienting the lead to a desired position in the internal jugular vein; and

removing the catheter and the guidewire.

16. The method of claim 15 wherein advancing a portion of the neurostimulation lead comprises retaining a portion of the retaining structure in the catheter and orienting the lead comprises turning the catheter.

17. The method of claim 15 wherein advancing a portion of the neurostimulation lead comprises retaining all of the retaining structure in the catheter and orienting the lead comprises turning the catheter.

18. The method of claim 15 wherein advancing a portion of the neurostimulation lead comprises advancing the retaining structure beyond a distal end of the catheter and orienting the lead comprises turning the lead.

19. The method of claim 15 further comprising reducing a force exerted by the retaining structure against a surface external to the retaining structure by inserting the guidewire through the lumen.

20. The method of claim 15 wherein orienting the lead comprises orienting the electrode so the electrode is adjacent to a vagus nerve.

1/8

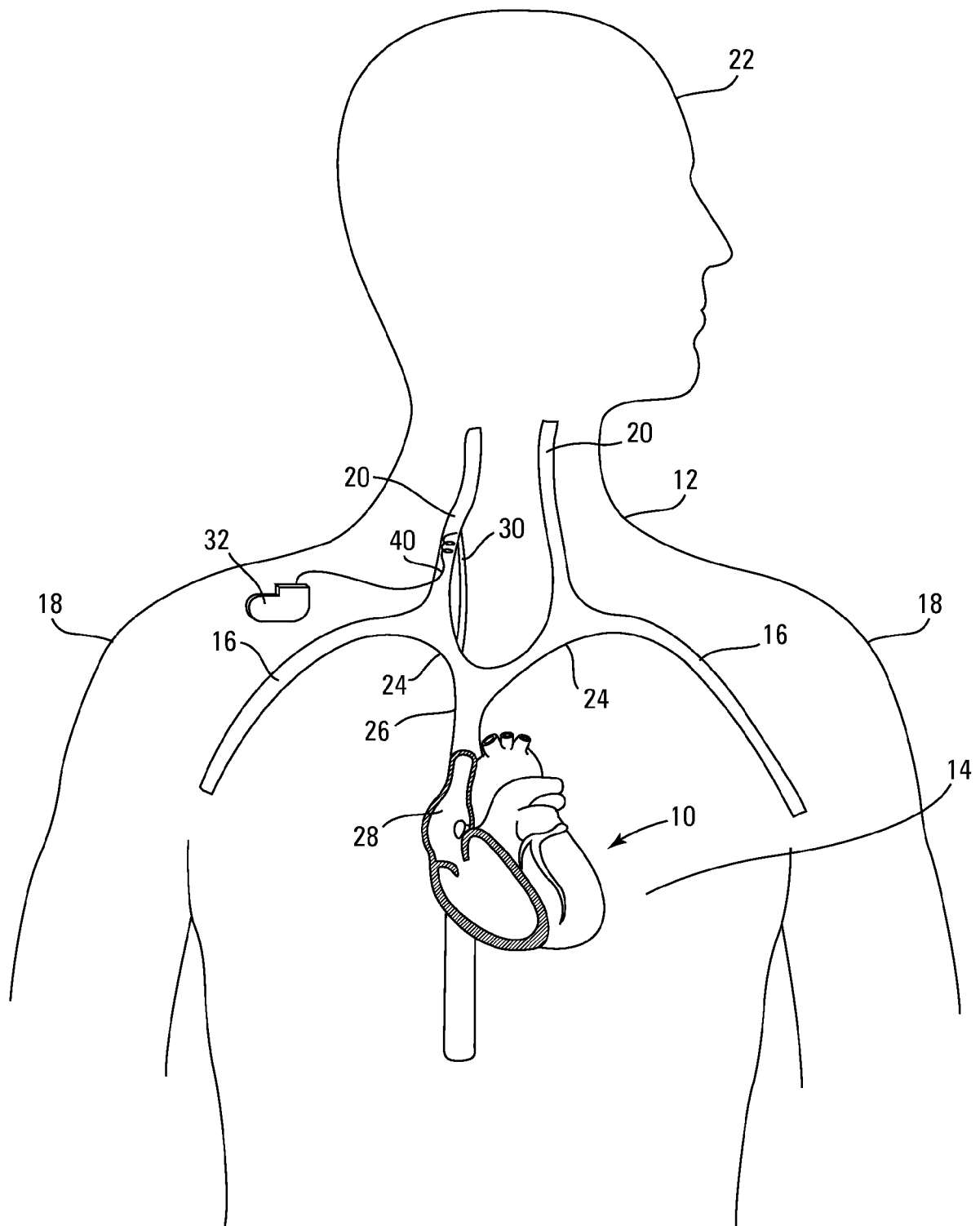
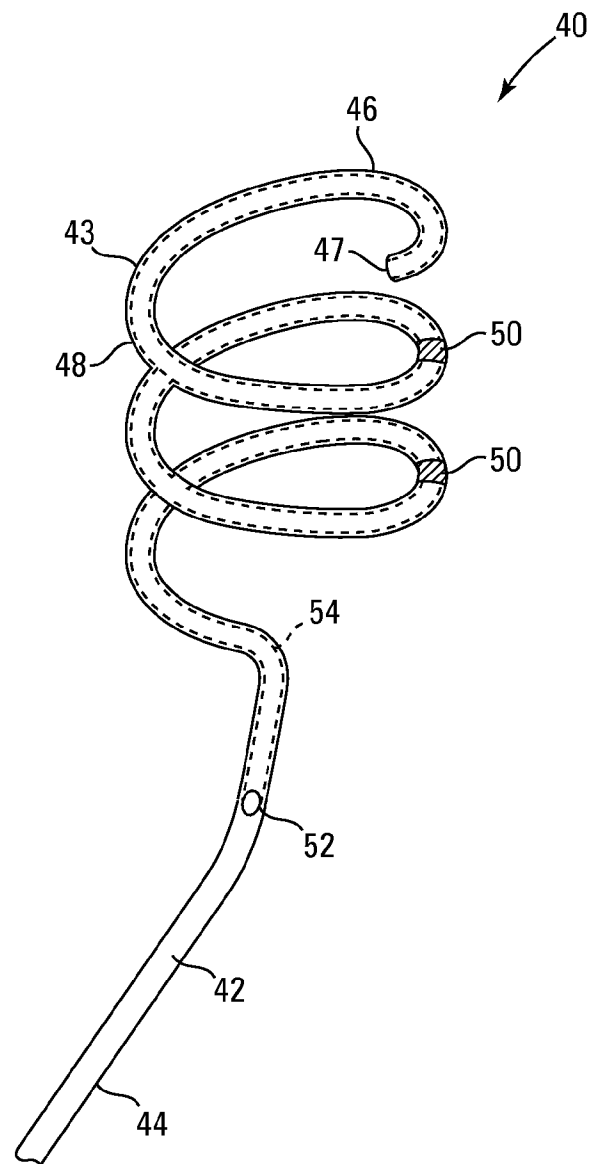


Fig. 1

2/8

*Fig. 2*

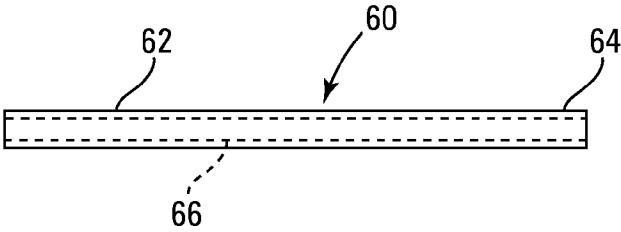


Fig. 3

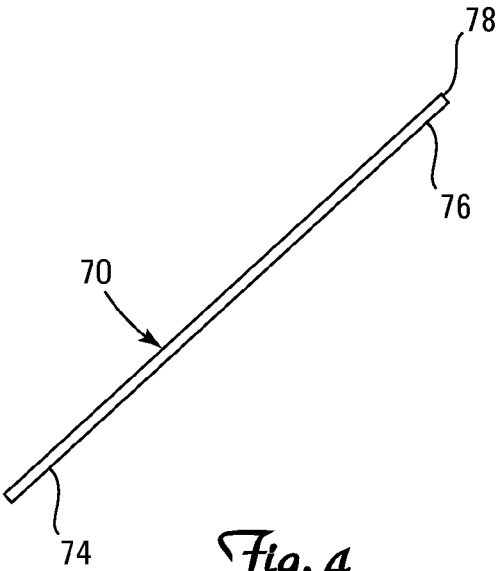
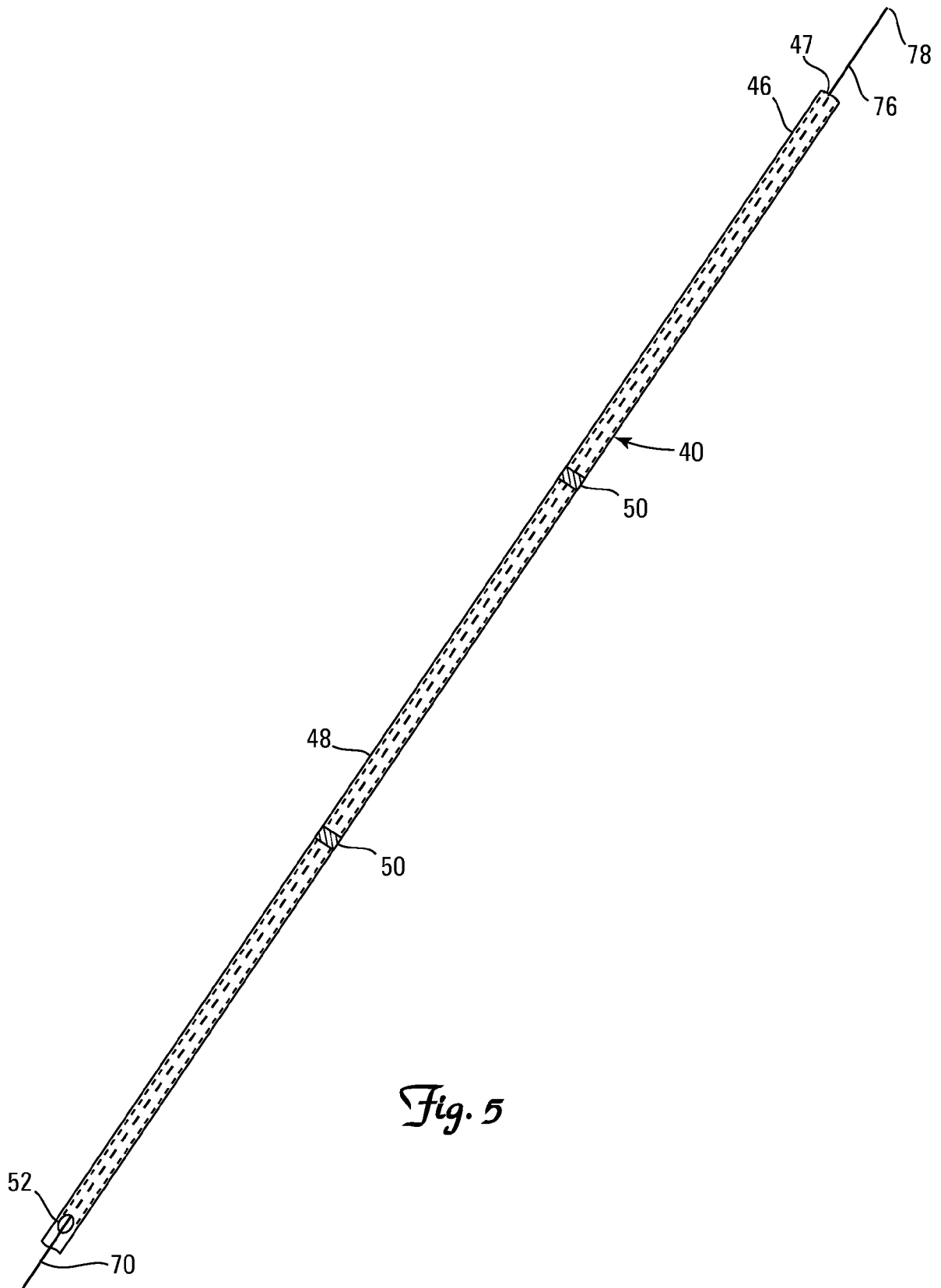


Fig. 4

4/8

*Fig. 5*

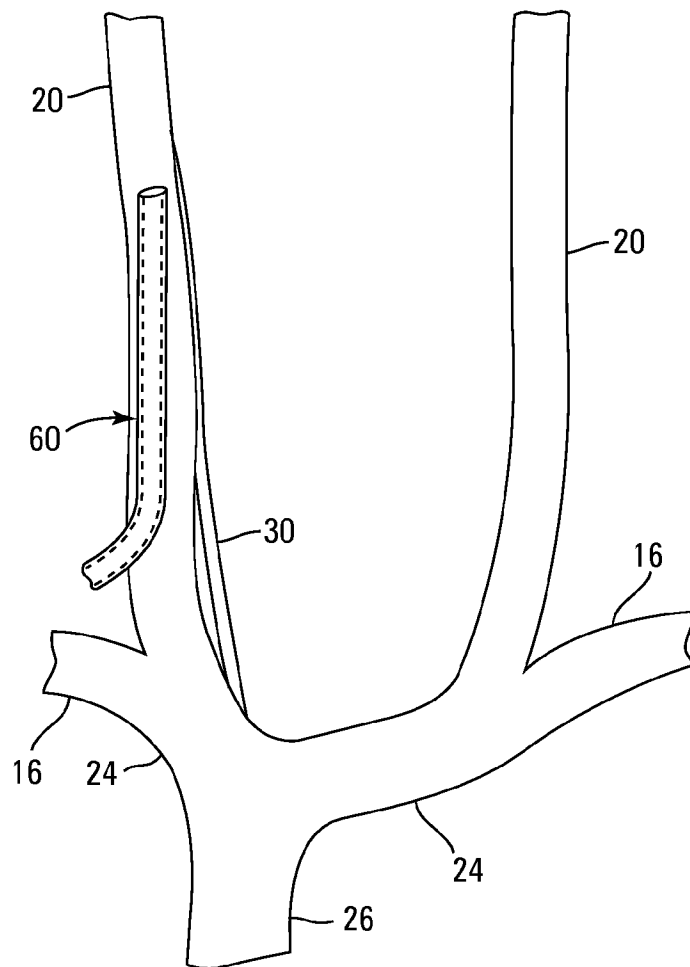


Fig. 6

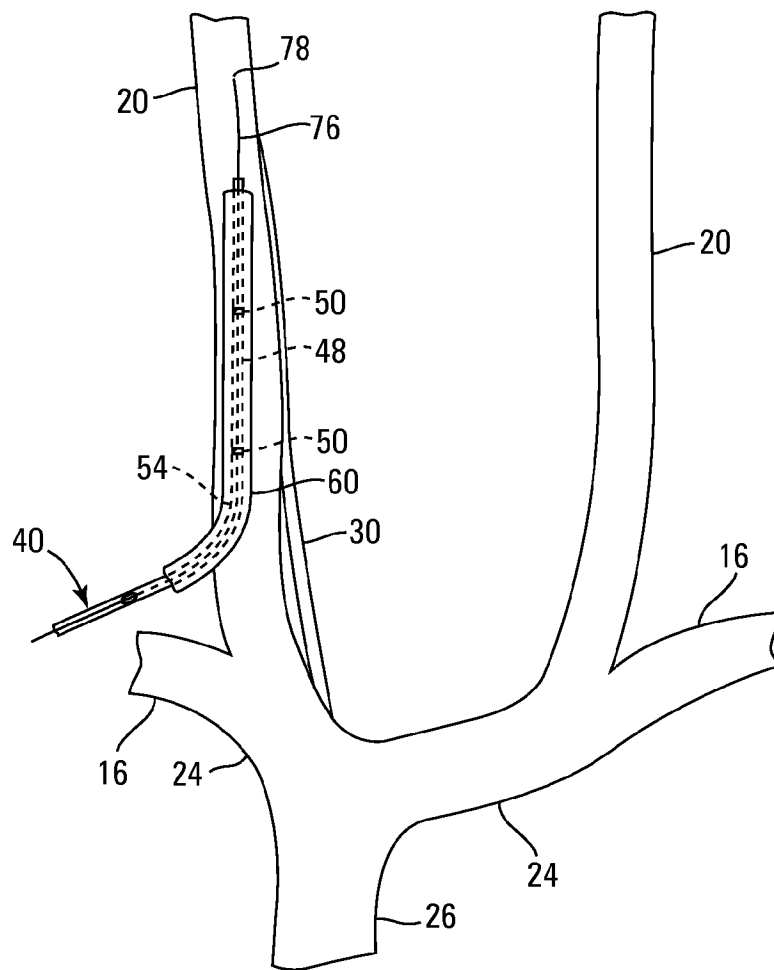


Fig. 7

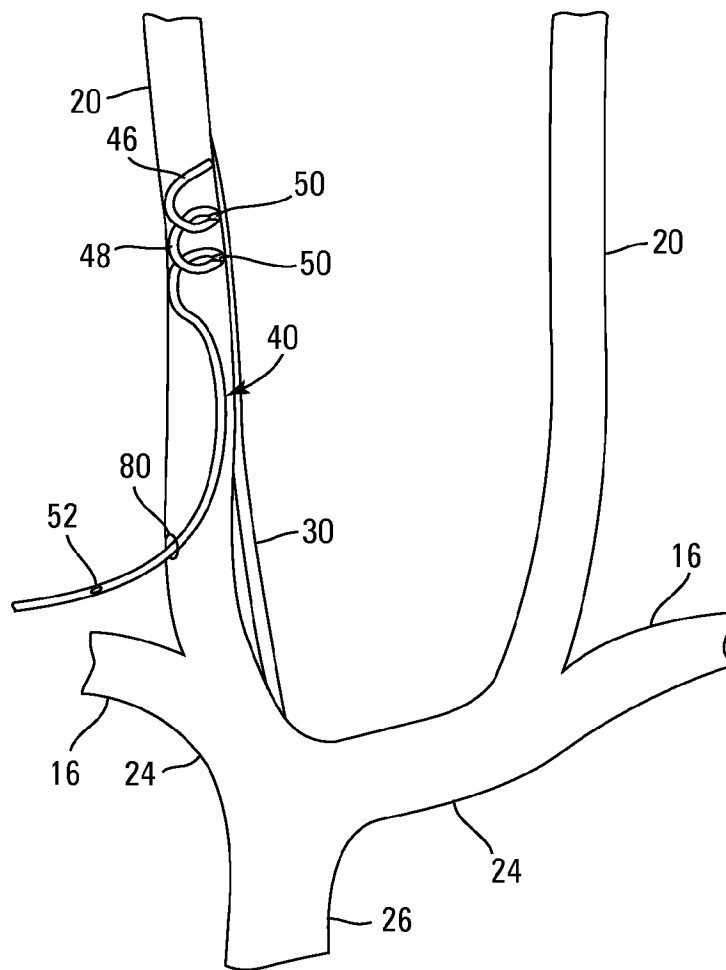
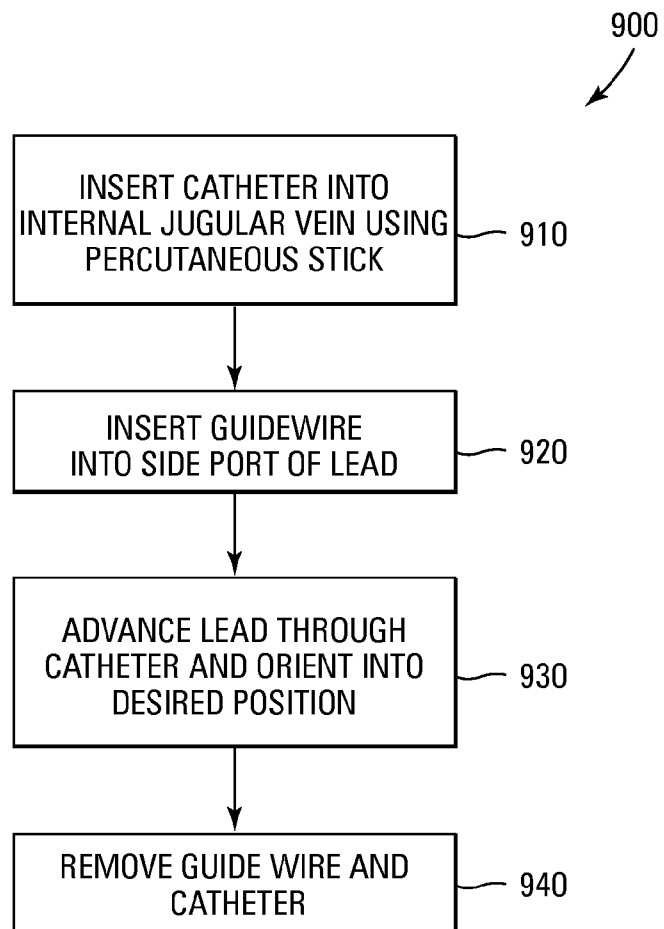


Fig. 8

8/8

*Fig. 9*

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/086130

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/05
ADD. A61N1/36

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)

A61N

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 304 135 A (PACESETTER INC [US]) 23 April 2003 (2003-04-23) paragraph [0030] paragraphs [0092], [0093]; figures 9,10 paragraphs [0098] - [0101]; figure 15 -----	1-14
Y	WO 82/04181 A (JIMLAW NOMINEES PTY LTD [AU]; LAWRIE JAMES MALCOLM [AU]) 9 December 1982 (1982-12-09) the whole document -----	1-14
A	WO 02/18006 A (CARDIAC PACEMAKERS INC [US]; WESTLUND RANDY [US]; TOCKMAN BRUCE [US];) 7 March 2002 (2002-03-07) page 10, lines 21-28; figures 1,3 page 15, line 5 - page 16, line 29 ----- -/--	2,4-10



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.

G document member of the same patent family

Date of the actual completion of the international search

28 March 2008

Date of mailing of the international search report

09/04/2008

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

Loveniers, Kris

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/086130

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/206153 A1 (LIBBUS IMAD [US] ET AL) 14 September 2006 (2006-09-14) paragraphs [0058] - [0072]; figures 1-3 paragraphs [0092] - [0096]; claims 10-12; figure 8 paragraphs [0079] - [0088]; figures 4-6 paragraphs [0104] - [0108]; figure 11	1-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/086130

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/086130

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 1304135	A	23-04-2003	US 2003078623 A1	24-04-2003
WO 8204181	A	09-12-1982	EP 0080465 A1	08-06-1983
WO 0218006	A	07-03-2002	AU 8853801 A	13-03-2002
			EP 1363697 A2	26-11-2003
			US 2003109914 A1	12-06-2003
			US 2003195603 A1	16-10-2003
			US 6584362 B1	24-06-2003
US 2006206153	A1	14-09-2006	NONE	