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(54) Title: EXPANDABLE SYSTEMS FOR MEDICAL ELECTRICAL STIMULATION

(57) Abstract: A medical system for electrical stimulation includes a first column of electrodes, a second column of electrodes, an expandable member disposed between first and second columns, and an expansion mechanism adapted to transmit an externally applied pressure to the expandable member. The pressure expands the expandable member in order to force the first column of electrodes apart from the second column of electrodes. The first and second columns, disposed side-by-side, may be inserted through a percutaneous needle and into a epidural space, alongside a spinal cord; after insertion, the first column may be forced apart from the second column by applying the pressure to the expandable member.

EXPANDABLE SYSTEMS FOR MEDICAL ELECTRICAL STIMULATION

RELATED APPLICATIONS

[01] This application claims priority to US Patent Application No. 11/622,538, filed January 12, 2007, the teachings of which are incorporated herein by reference.

TECHNICAL FIELD

[02] The present invention pertains to systems for medical electrical stimulation and more particularly to stimulation systems that include a expandable member.

BACKGROUND

[03] Medical electrical stimulation systems typically include one or more conductors that extend within an elongate insulative lead body and are coupled to one or more electrodes supported by the body. The one or more electrodes are typically coupled to a distal portion of the lead body so that, when the distal portion is implanted in a patient's body, the one or more electrodes are positioned to provide electrical stimulation therapy, for example, pain-relieving spinal stimulation from electrodes implanted along a spinal cord within an epidural space.

104] One type of spinal cord stimulation system includes a single column of electrodes, which is coupled along a distal portion of a lead body and has a profile that facilitates percutaneous delivery through a needle to an implant site along the spinal cord within the epidural space. Another type of spinal cord stimulation system includes at least two columns of electrodes coupled to a distal portion of a lead body; the at least two columns are spaced apart from one another so that a profile of the distal portion is often paddle-like and requires surgical implantation, because the size of the distal portion is too large to fit through a needle for percutaneous delivery. These paddle-type electrode assemblies, having more than one column of electrodes, provide flexibility for selection from a variety of stimulation patterns upon implantation without having to physically reposition the assemblies within the epidural space.

[05] Some spinal cord stimulation systems, which include more than one column of electrodes and which collapse into a smaller profile for percutaneous implantation, are known in the art. Yet, there is still a need for spinal cord stimulation systems that include more than one column of electrodes and are designed to further facilitate operator control over the systems during an implant procedure thereby increasing an ease of implanting the electrode columns at desired locations.

BRIEF DESCRIPTION OF THE DRAWINGS

[06] The following drawings are illustrative of particular embodiments of the present invention and therefore do not limit the scope of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements.

[07] Figure 1A is a plan view of a stimulation system and a percutaneous delivery needle, according to some embodiments of the present invention.

[08] Figure 1B is an end view of the system shown in Figure 1A disposed within the needle.

[09] Figures 1C-D are an end view and a plan view, respectively, of a distal portion of the system of Figure 1A in an expanded state or condition.

[10] Figure 2 is a plan view of an expanded distal portion, according to some alternate embodiments of the present invention.

[11] Figure 3A is a plan view of a stimulation system, according to some additional embodiments of the present invention.

[12] Figure 3B is an end view of the system of Figure 3A disposed within a needle, according to some embodiments of the present invention.

[13] Figure 3C is a plan view of a distal portion of the system of Figure 3A in an expanded condition.

[14] Figure 4 is a plan view of an expanded distal portion, according to an alternate embodiment of the present invention.

[15] Figure 5A is a plan view of a stimulation system, according to some additional embodiments of the present invention.

[16] Figure 5B is a section view through section-line X-X of Figure 5A, according to some embodiments.

[17] Figure 5C is a plan view of an expanded distal portion of the system shown in Figure 5A.

[18] Figure 5D is a schematic end view of the distal portion of Figure 5C implanted along a spinal cord in an epidural space.

[19] Figure 5E is a schematic end view of an expanded distal portion implanted in the epidural space and having electrodes configured according to some alternate embodiments of the present invention.

[20] Figure 6A is a plan view of a stimulation system, according to further additional embodiments of the present invention.

[21] Figure 6B is a section view through section line Y-Y of Figure 6A, according to some embodiments.

[22] Figure 6C is a plan view of an expansion element, according to some embodiments of the present invention.

[23] Figure 6D is another plan view of the system of Figure 6A, wherein a distal portion thereof is expanded, according to some embodiments of the present invention.

[24] Figure 6E is a section view through section line Z-Z of Figure 6D, according to some embodiments.

[25] Figure 7A is a plan view including a partial cut-away section of a stimulation system, according to yet further additional embodiments of the present invention.

[26] Figure 7B is a plan view of the system shown in Figure 7A wherein a distal portion thereof is expanded, according to some embodiments of the present invention.

DETAILED DESCRIPTION

[27] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in

any way. Rather, the following description provides practical illustrations for implementing exemplary embodiments of the present invention. Examples of constructions, materials, dimensions, and manufacturing processes are provided for selected elements, and all other elements employ that which is known to those of skill in the field of the invention. Those skilled in the art will recognize that many of the examples provided have suitable alternatives that can be utilized.

[28] Figure 1A is a plan view of a stimulation system 1200 and a percutaneous delivery needle 13, according to some embodiments of the present invention. Figure 1A shows system 1200 configured for insertion into needle 13 (according to the dashed line arrow) for percutaneous implantation, for example, in an epidural space along a spinal cord, according to general implantation techniques which are known to those skilled in the art. Figure 1A illustrates system 1200 including a first lead body 10 and a second lead body 20, wherein each body 10, 20 extends from a corresponding proximal connector assembly C1, C2 to a corresponding distal column of electrodes 11, 12; electrodes E1 of column 11 are separated from one another by insulative spacers S1, and each electrode E1 is coupled by a lead, or elongate conductor (not shown), which extends within body 10, to a corresponding connector contact of connector assembly C1; likewise electrodes E2 of column 12 are separated from one another by insulative spacers S2, and each electrode E2 of column 12 is coupled by a lead (not shown), which extends within body 20, to a corresponding connector contact of connector assembly C2. Those skilled in the art will appreciate that connector assemblies C1, C2 (and C3, introduced below) are adapted for coupling with a pulse generator, which is the electrical stimulation source for electrodes, and is typically implanted within a subcutaneous space apart from the stimulation site.

[29] According to an exemplary embodiment, a length of spacers S1, S2 is between approximately 0.06 inch and approximately 0.24 inch, and a length of electrodes E1, E2 is approximately 0.12 inch. Column of electrodes 11 is shown disposed in proximity to a distal tip D1 of lead body

10, and column of electrodes 12 is shown disposed in proximity to a distal tip D2 of lead body 20. Although columns of electrodes 11, 12 are shown aligned with one another, so that each electrode E1 is adjacent a corresponding electrode E2, the scope of the invention is not so limited, and, according to other embodiments, one of columns 11, 12 is shifted proximally or distally so that electrodes E1 are not aligned with electrodes E2 as shown. Furthermore, a number of electrodes E1, E2 in each column 11, 12 is not limited to that illustrated herein, and may range from two to eight, or even more, for some embodiments.

[30] Figure 1A further illustrates system 1200 including an elongate tube or sidewall 105, through which a lumen (shown with dashed lines) extends, and an expandable member 100, shown in a collapsed, or unexpanded, state, disposed between columns of electrodes 11, 12. According to the illustrated embodiment, the lumen that extends within sidewall 105 provides a passageway for transmission of externally applied pressure to expandable member 100 in order to expand expandable member 100 to force apart columns 11, 12, after columns of electrodes 11, 12 have been passed through needle 13 and positioned against the spinal cord. Arrow A indicates a proximal opening of the lumen which provides access for an expansion mechanism to deliver the externally applied pressure through the lumen. It may be appreciated that an initial position of columns of electrodes 11,12, achieved by passing the columns out from the needle, may be adjusted prior to delivering the externally applied pressure to expandable member 100. According to some preferred embodiments, the expansion mechanism comprises an inflation medium, which may be delivered via a syringe-type tool to inflate expandable member 100. Although expansion member 100 is preferably coupled to each lead body 10, 20, for example, either all along columns of electrodes 11, 12, or to one or all of spacers S1, S2, or just proximal to columns 11, 12 and/or just distal to columns 11, 12, sidewall 105 is, preferably, not coupled to lead bodies 10, 20, since sidewall 105 is preferably rigid and will not expand when columns 11, 12 are forced apart by expandable member 100.

[31] Figure 1A further illustrates needle 13 including a sidewall 130 extending about a lumen 132 and longitudinally between a piercing distal tip 137 and a proximal hub 135; sidewall 130 includes a slot 134 extending along a length thereof. Figure 1B is an end view of system 1200 disposed within needle 13, for example, for percutaneous implantation. Figure 1B illustrates a fit of collapsed system 1200 within a lumen 132 of needle 13 wherein sidewall 105 protrudes into slot 134. With reference to Figure 1B, it will be appreciated that expansion element 100, being in a collapsed state, allows both lead bodies 10, 20 to fit side-by-side within needle lumen 132. According to some alternate embodiments, sidewall 105 may be collapsible so that a needle lumen without a sidewall slot, such as slot 134, can accommodate both lead bodies 10, 20 and sidewall 105. According to some methods of the present invention, once needle 13, via piercing tip 137, has been inserted into an epidural space, distal tips D1, D2 of bodies 10, 20 are inserted into needle lumen 132, and bodies 10, 20 are pushed through lumen 132 to advance columns of electrodes 11, 12 into the epidural space; after columns 11, 12 have been pushed out from needle 13, and positioned at target implant site along the spinal cord, a pressure is applied to expandable member 100 causing member 100 to expand and force columns 11, 12, apart from one another for example, as illustrated in Figures 1C-D. Expandable member 100 may be inflated, as previously described, to force columns 11, 12 apart, or member 100 may be comprised of a cellular sponge-like material that swells when a fluid is injected though the lumen of sidewall 105; additional embodiments of expandable members will be described below.

[32] Figures 1C-D are an end view and a plan view, respectively, of the system of Figure 1A in an expanded state or condition. Figures 1C-D illustrate expandable member 100 having been expanded to force columns of electrodes 11, 12 into a position in which the columns are spaced apart from one another by a distance F; columns 11, 12 are preferably approximately parallel to one another in the illustrated position. Distance F may range from approximately 1.5 mm to approximately 4 mm, and,

according to some embodiments of the present invention, expandable member 100, or any of the other embodiments of expandable members described herein, may be expanded to different degrees for multiple separations, or distances F, between columns of electrodes 11, 12 in order to provide a flexibility, at the time of implant, in spacing columns 11,12 apart at a distance which is most suitable for stimulation therapy.

[33] Figure 1D further illustrates expandable member 100 extending alongside and over a length of columns of electrodes 11, 12, however, expandable member can vary in location and extent with respect to columns 11, 12 to form alternate embodiments. Figure 2 is a plan view of an expanded distal lead portion, according to some such alternate embodiments. Figure 2 illustrates an expandable member 100' disposed just proximal to columns of electrodes 11, 12, and, with dashed lines, an alternate or additional location for member 100'. According to the illustrated embodiment, columns 11, 12 have sufficient stiffness to be displaced by the relatively limited extent illustrated for member 100'.

[34] Figure 3A is a plan view of a stimulation system 1300, according to some additional embodiments of the present invention. Figure 3A illustrates system 1300 including a lead body 30 extending distally from a connector assembly C3 to a bifurcation from which first and second distal lead bodies 301 , 302 extend; first column of electrodes 11 is coupled to first distal lead body 301 and second column of electrodes 12 is coupled to second distal lead body 302. Each electrode E1 of column 301 and each electrode E2 of column 302 is coupled to a corresponding connector contact of connector assembly C3, for example, by a corresponding filar of a multi-conductor coil 39, each filar of coil 39 being a conductive wire, for example MP35N wire, isolated from the others via a coating of electrical insulation, for example, comprised of polyimide, PTFE, and/or ETFE. Figure 3A further illustrates a lumen 35 extending within body 30 and being surrounded by a sidewall 305 just proximal to expandable member 100; a proximal opening of lumen 35 is preferably located in proximity to connector assembly C2 for the introduction of an expansion mechanism.

[35] Figure 3B is an end view of system 1300 assembled within a needle 13' for a percutaneous implantation; a plan view of needle 13' would be similar to that of needle 13 as shown in Figure 1A, with the exception of the absence of a slot in a sidewall 130' of needle 13'. As previously described for system 1200, distal ends D1, D2 may be inserted through needle 13', which has been inserted into the epidural space, and body 30 pushed to pass columns of electrodes 11, 12 out from needle 13' into the epidural space alongside the spinal cord. After columns 11, 12 have been positioned at a target stimulation site, expandable member 100 may be expanded by the expansion mechanism, for example, a pressurized inflation fluid introduced through lumen 35, in order to force columns 11, 12 apart, for example, as illustrated in Figure 3C. Figure 3C is a plan view showing first and second columns 11, 12 spaced apart from one another by expanded member 100 and, preferably, approximately parallel with one another. As previously described for system 1200, expandable member 100 may be expanded to different degrees for multiple separations between columns of electrodes 11, 12 in order to provide a flexibility, at the time of implant, in spacing columns 11,12 apart at a distance that is most suitable for stimulation therapy.

[36] Figure 3C further illustrates expandable member 100 extending alongside and over a length of columns of electrodes 11, 12, but, according to alternate embodiments, expandable member varies in location and extent with respect to columns 11, 12. Figure 4 is a plan view of an expanded distal lead portion, according to some such alternate embodiments. Similar to Figure 2, Figure 4 illustrates expandable member 100' disposed just proximal to columns of electrodes 11, 12. According to the illustrated embodiment, columns 11, 12 have sufficient stiffness to be displaced by the relatively limited extent illustrated for member 100'. Although sidewall 305 through which lumen 35 extends is shown, in both Figure 3C and Figure 4, as extending beyond the bifurcation of body 30, alternate embodiments of the present invention include an expandable member

extending proximally to an opening of lumen 35 in bifurcation, such that lumen 35 need not extend distally beyond bifurcation.

[37] Figure 5A is a plan view of a stimulation system 1500, according to some additional embodiments of the present invention; and Figure 5B is a section view through section line X-X of Figure 5A, according to some embodiments. Figures 5A-B illustrate system 1500 including a first lead body 510 and a second lead body 520, wherein each body 510, 520 extends from a corresponding proximal connector assembly C1, C2 to the corresponding distal column of electrodes 11, 12; each electrode E1 of column 11 is coupled by a corresponding filar of a multi-conductor coil 58 to a corresponding connector contact of connector assembly C1; likewise, each electrode E2 of column 12 is coupled by a corresponding filar of a multi-conductor coil 59 to a corresponding connector contact of connector assembly C2. (Filars of coils 58, 59 may be similar in construction to those described above for coil 39.) Figure 5B shows each body 510, 520 including a lumen 56, 57, respectively, and optional inner sheaths 508, 509 extending around respective coiis 58, 59 and within respective lumens 56, 57.

[38] Figures 5A-B further illustrate an expandable member 500 disposed between columns of electrodes 11, 12 and formed by walls 515 which are coupled to bodies 510, 520, for example, via adhesive and/or thermal bonding, and an inflation device 570 coupled to a proximal end of body 520; a tubular member 578 of inflation device 570 is in fluid communication with lumen 57. According to the illustrated embodiment, inflation device 570 includes a chamber 507 holding an inflation medium, or fluid, which acts as an expansion mechanism for transmitting a pressure applied by a plunger 575 of inflation device 570; the inflation fluid, being transmitted, through lumen 57 and into expandable member 500, via a port 550 of lumen 57, and pressurized by plunger 575, inflates expandable member 500 by spreading walls 515, for example as illustrated in Figure 5C. After member 500 has been inflated, device 570 may be detached from lumen 57 and replaced with a plug 52 to seal off the proximal end of lumen 57 in

order to maintain inflation pressure within member 500. However, it should be noted that, according to alternate embodiments, it is not necessary to hold the inflation pressure within member 500 in order to maintain a desired separation between columns 11, 12, after the initial inflation.

[39] According to preferred embodiments of the present invention, walls 515 of expandable member 500 are relatively thin, for example, ranging from approximately 0.0002 inch to approximately 0.004 inch, and are formed from a relatively compliant material, for example, silicone, low to medium durometer urethane, or polyolefin copolymer (POC); according to other embodiments, walls 515 are formed from a relatively non-compliant material, for example, polyethylene terephthalate (PET). In some embodiments of the present invention, expandable member 500 may initially be formed, according to methods known to those skilled in the art, as a balloon whose outer surface may subsequently be bonded to bodies 510, 520.

[40] Figure 5C is a plan view of the expanded distal lead portion of system 1500; and Figure 5D is a schematic end view of the expanded distal lead portion implanted along a spinal cord in an epidural space. With reference to Figures 5C-D, it may be appreciated that expanded member 500 forces columns of electrodes 11, 12 to be spaced apart from one another, for example, in a configuration mimicking that of a paddle-type surgical lead, and that a flexibility of expanded member 500 facilitates conformance within the epidural space, such that electrodes E1, E2 of columns 11, 12 make good contact with the dura mater enclosing the spinal cord. Figures 5B-D further illustrate with dashed lines additional expandable members and corresponding ports (Figure 5B) extending from corresponding lumens 56, 57 for inflation thereof; according to some embodiments of the present invention, these additional members may be added to enlarge the distal lead portion of system 1500, for a snug fit within the epidural space. Alternately, expandable member 500 may expand to a larger size for the snug fit, without compromising electrode contact with the dura mater, for

example as illustrated in Figure 5E, which is another schematic end view of the expanded distal lead portion implanted in the epidural space.

[41] Electrodes E1, E2 have heretofore been illustrated as rings extending about respective lead bodies, but Figure 5E illustrates an alternate embodiment: electrodes E1', E2', which each have a relatively flat surface for stimulating contact. Each electrode E1', E2' may be formed, for example, as a plate mounted on the respective lead bodies 510, 512, being either coupled directly with the corresponding conductive filar of respective coil 58, 59 (Figure 5B), or coupled to a conductive ring, which is, in turn coupled to the corresponding conductive filar; an example of the latter construction is described for a surgical-type lead in co-pending and commonly assigned patent application serial number 11/413,582, salient portions of which are hereby incorporated by reference. According to other contemplated embodiments, columns of electrodes 11, 12 are incorporated into an expandable element, for example, element 100 or 500, wherein the electrodes are coupled to a surface of the expandable element; such electrodes may be rigid or formed from a flexible material, for example, from a foil.

[42] Figure 6A is a plan view of a stimulation system 1600, according to further additional embodiments of the present invention; and Figure 6B is a section view through section line Y-Y of Figure 6A, according to some embodiments. Figures 6A-B illustrate system 1600 including a lead body 60 extending distally from connector assembly C3 to a bifurcation from which a first distal lead body 601, to which column of electrodes 11 is coupled, and a second distal lead body 602, to which column of electrodes12 is coupled, each extend; each electrode E1 of column 11 is coupled by a corresponding conductor 691 to a corresponding connector contact of connector assembly C3, and each electrode E2 of column 12 is coupled by a corresponding conductor 692 to a corresponding connector contact of connector assembly C3. Figure 6A further illustrates a single distal tip D3 terminating distal bodies 601, 602. According to the illustrated embodiment, a lumen 675 extends through lead body 60 from a proximal

opening 65, in proximity to connector assembly C3, to a distal opening at the bifurcation, the distal opening providing fluid communication between lumen 675 and an expandable area 600, which is enclosed by sidewalls 615.

[43] Figure 6C is a plan view of an expansion element 670, according to some embodiments of the present invention, which is adapted for insertion into expandable area 600, via lumen 675. Figure 6C illustrates expansion element 670 including a first elongate member 674 extending within a second elongate member 676, and an expandable member 607. Figure 6C further illustrates a distal end of second elongate member 676 coupled to a proximal end 617 of expandable member 607, and a distal end of first elongate member 674 coupled to a distal end 627 of expandable member 607, so that elongate member 674 forms an expansion mechanism for expandable member 607. According to the illustrated embodiment, when first elongate member 674 is pulled in a direction corresponding to arrow B, distal end 627 of expandable member 607 is brought closer to proximal end 617 thereby expanding expandable member 607 per arrows C, for example, as illustrated with dashed lines in Figure 6C, and as illustrated, for some embodiments, in Figure 6E.

[44] Figure 6D is another plan view of system 1600, according to some embodiments of the present invention, wherein a distal portion thereof is expanded by insertion and subsequent expansion of expansion element 670 within walls 615 of expandable area 600. Figure 6E is a section view through section line Z-Z of Figure 6D, according to some embodiments, wherein expandable member 607 is formed by a plurality of flexible slats 650, which are coupled together at proximal and distal ends 617, 627, and thus bent outward when first elongate member 674 pulls distal end 627 toward proximal end 617. According to the illustrated embodiment, after system 1600, in an unexpanded state (Figure 6A), has been inserted into the epidural space alongside the spinal cord, for example, via a percutaneous needle, expansion element 670 may be inserted into proximal opening 65 of lumen 675 and advanced therein until expandable

element 607 resides in expandable area 600. (Alternately, element 670 may be inserted into area 600 prior to insertion of system 1600 into the epidural space.) When system 1600 is within the epidural space, and expandable element 607 resides within expandable area 600, first elongate member 674 of element 607 may be pulled with respect to second elongate element 676 to expand expandable member 607 thereby expanding expandable area 600 and forcing first column of electrodes 11 apart from second column of electrodes 12, for example, as illustrated in Figures 6D-E. According to preferred embodiments, after expansion element 670 has expanded expandable area 600, expandable member 607 of element 670 may be collapsed, by pushing first elongate member 674 back into the position shown in Figure 6C, and element 670 withdrawn from system 1600 to leave the system in the expanded state, as is illustrated in Figure 6D.

[45] It should be noted that, although body 60 of system 1600 has been described to include lumen 675 for passage of expansion element, alternate embodiments of the present invention need not include such a lumen. According to some such alternate embodiments, an entry for passage of expansion mechanism 670 into expandable area 600 may be formed in body 60 in close proximity to bifurcation and expandable area 600, or through one of walls 615 of expandable area 600. According to some other alternate embodiments, a lumen for passage of expansion element 670 may be provided by a sidewall external to body 60, wherein the sidewall extends alongside body 60 to join with expandable area 600 being either attached to, or detached from body 60.

[46] Figure 7A is a plan view including a partial cut-away section of a stimulation system 1700, according to yet further additional embodiments of the present invention. Figure 7A illustrates system 1700 including a lead body 70 extending distally from connector assembly C3 to a bifurcation from which distal lead bodies 701, 702 extend to corresponding distal tips D1, D2; column of electrodes 11 is coupled to lead body 701 and column of electrodes 12 to lead body 702, wherein each of electrodes E1 is coupled to a corresponding connector contact of connector assembly C3 via the

corresponding conductor 691, and each of electrodes E2 is coupled to a corresponding connector contact of connector assembly C3 via the corresponding conductor 692. Figure 7A further illustrates expansion element 670 having been inserted into a proximal port 75 of a lumen 775 of body 70, and advanced within lumen 775 so that expandable member 607 has exited lumen 775 at a distal port 71. According to the illustrated embodiment, expandable member 607 is disposed in an area between electrode columns 11, 12, which is not enclosed by expandable walls, for example walls 615 of system 1600, and may be expanded, as previously described in conjunction with Figures 6C-E, to force columns of electrodes 11, 12 apart, for example, as is illustrated in Figure 7B.

[47] Figure 7B is a plan view of the system 1700 wherein a distal portion thereof is expanded, according to some embodiments of the present invention. Figure 7B illustrates distal end 627 of expandable member 607 having been pulled, via first elongate member 674, per arrow B, to expand slats 650, thereby spacing apart columns of electrodes 11, 12. According to preferred embodiments, after columns of electrodes 11, 12 have been forced into the spaced apart position, expansion element 670 is collapsed and withdrawn through lumen 775.

[48] It should be noted that an alternate embodiment of expansion element 670 includes a balloon, in place of slats 650, as expandable member 607, and second elongate member 676, rather than being disposed about first elongate member 674, is disposed about an inflation lumen. According to this embodiment, second elongate member 676 is adapted to couple with an inflation device, for example device 570 shown in Figure 5A, that will apply a pressure via an inflation medium to expand member 607.

[49] In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention. as set forth in the appended claims. Furthermore, the embodiments of the invention described herein have been described in the context of spinal cord stimulation, yet those skilled in the art should

appreciate that embodiments of the present invention rriay be applied in other contexts, for example, cardiac sensing and stimulation, either endocardial or epicardial.

WE CLAIM:

1. A medical system for electrical stimulation, the system comprising:

a first column of electrodes, and a second column of electrodes extending alongside the first column of electrodes, each of the first and second columns of electrodes including at least a first electrode separated from a second electrode by an insulative spacer;

an expandable member disposed between the first and second columns of electrodes; and

an expansion mechanism adapted to transmit externally applied pressure to expand the expandable member, the expansion of the expandable member forcing the first column of electrodes and the second column of electrodes into a position in which the first and second columns of electrodes are spaced apart from one another being approximately parallel with one another.

2. The system of claim 1, wherein:

each of the first and second columns of electrodes further includes a length defined from a proximal end of the first electrode to a distal end of the second electrode; and

the expandable member extends along the length of the first and second columns.

3. The system of claim 1, wherein:

the first column of electrodes is coupled to a first body, the first body including a distal tip; and

the second column of electrodes is coupled to a second body, the second body including a distal tip unattached to the first body distal tip, such that, when the first and second columns of electrodes are in the spaced apart position, the first body distal tip is spaced apart from the second body distal tip.

4. The system of claim 1, wherein the expandable member comprises a sidewal! attached to each of the first and second columns of electrodes; and further comprising an expansion element adapted for insertion within the sidewall of the expandable member; the expansion element receiving the externally applied pressure from the expansion mechanism to expand the expandable member, via expansion of the expansion element, when the expansion element is inserted within the sidewall.

5. The system of claim 4, wherein the expansion element comprises an inflatable member, and the expansion mechanism comprises an inflation medium.

6. The system of claim 4, wherein:

the expansion element includes a first end and a second end, and extends between the first end and the second end; and

the expansion mechanism comprises an elongate member adapted to bring the first end of the expansion element closer to the second end of the expansion element in order to expand the expansion element.

7. The system of claim 4, 5, or 6 further comprising another sidewall surrounding a lumen, the lumen extending proximaliy from the expandable member and providing a passageway for the expansion element.

8. The system of claim 4, 5, or 6 further comprising a body extending proximaliy from one of the first and second columns of electrodes, the body including a lumen extending proximaliy from the expandable member and providing a passageway for the expansion element.

9. The system of claim 4, 5, or 6 further comprising:

a body extending proximally from one of the first and second columns of electrodes; and

another sidewall surrounding a lumen, the sidewall extending alongside the body and proximally from the expandable member, and the lumen providing a passageway for the expansion element.

10. The system of claim 4, 5, or 6 further comprising a body extending proximally from both of the first and second columns of electrodes, the body including a lumen extending proximally from the expandable member and providing a passageway for the expansion element.

11. The system of claim 1, 2 or 3, wherein the expandable member comprises an inflatable chamber; and the expansion mechanism comprises an inflation medium.

12. The system of claim 1, 2, or 3, wherein:

the expandable member includes a first end and a second end and extends between the first end and the second end; and

the expansion mechanism comprises an elongate member adapted to bring the first end of the expandable member closer to the second end of the expandable member to expand the member.

13. The system of claim 1, 2 or 3, further comprising a sidewall surrounding a lumen, the lumen extending proximally from the expandable member and providing a passageway for the transmission of externally applied pressure.

14. The system of claim 1, 2 or 3, further comprising a body extending proximally from one of the first and second columns of electrodes, the body including a lumen extending proximally from the expandable member and providing a passageway for the transmission of externally applied pressure.

15. The system of claim 1, 2 or 3, further comprising:

a body extending proximally from one of the first and second columns of electrodes; and

a sidewall surrounding a lumen, the sidewall extending alongside the body and proximally from the expandable member, and the lumen providing a passageway for the transmission of externally applied pressure.

16. The system of claim 1, 2 or 3, further comprising a body extending proximally from both the first and second columns of electrodes, the body including a lumen extending proximaliy from the expandable member and providing a passageway for the transmission of externally applied pressure.

17. The system of claim 1, 2, 3, 4, 5 or 6, further comprising:

another expandable member extending alongside at least one of the first and second columns of electrodes; and

wherein the expansion mechanism is further adapted to transmit externally applied pressure to expand the other expandable member.

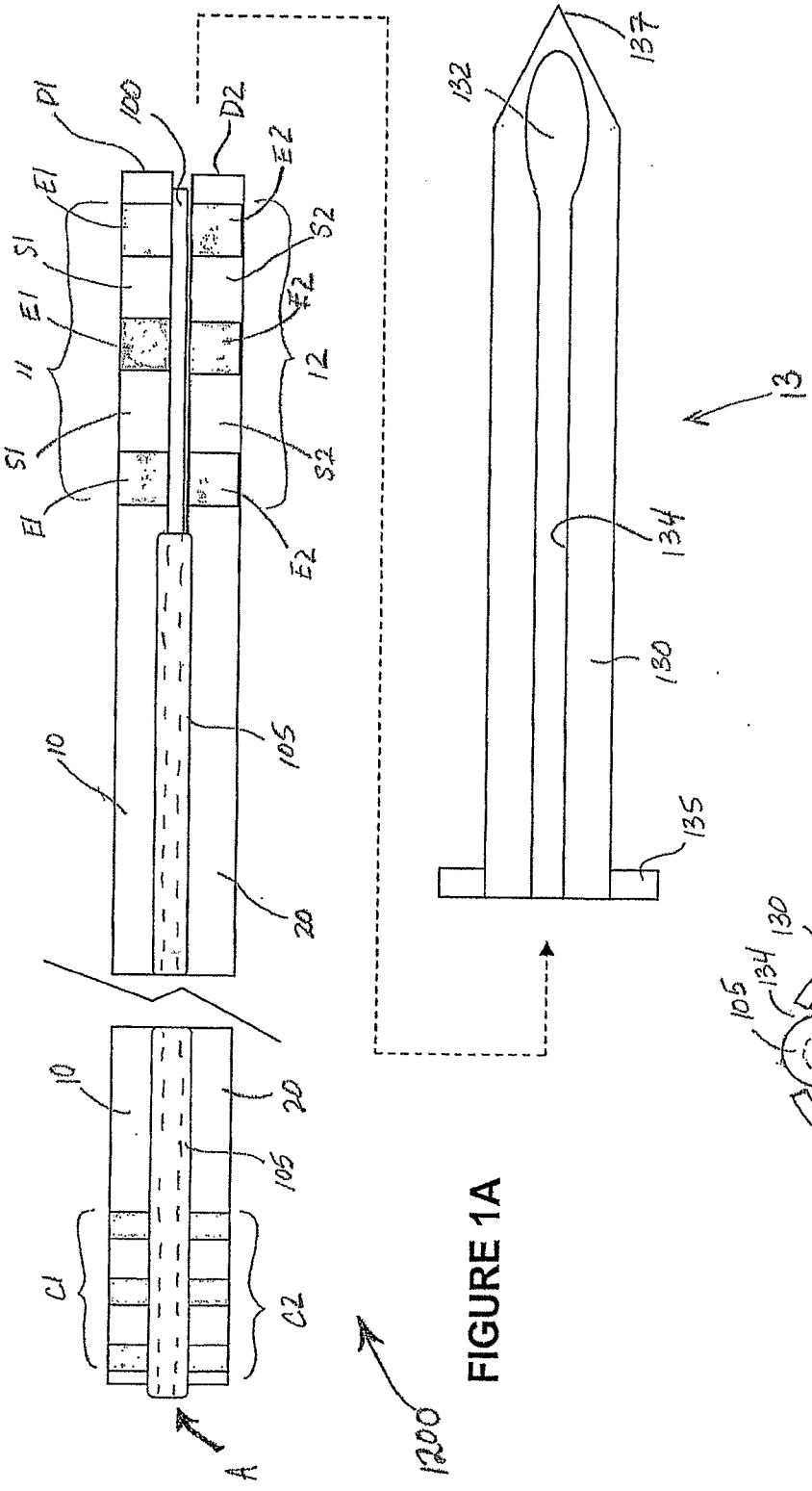


FIGURE 1A

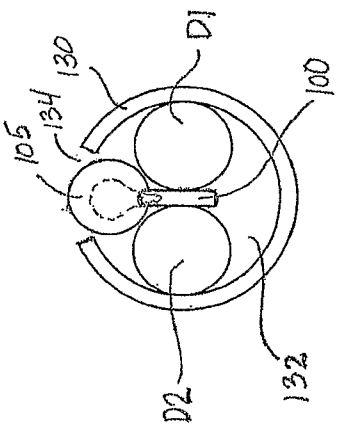


FIGURE 1B

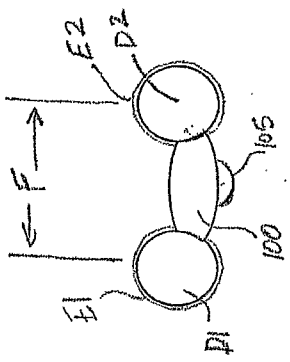


FIGURE 1C

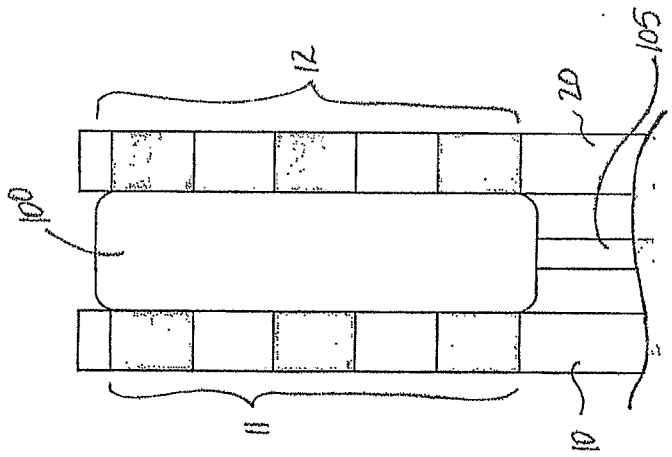


FIGURE 1D

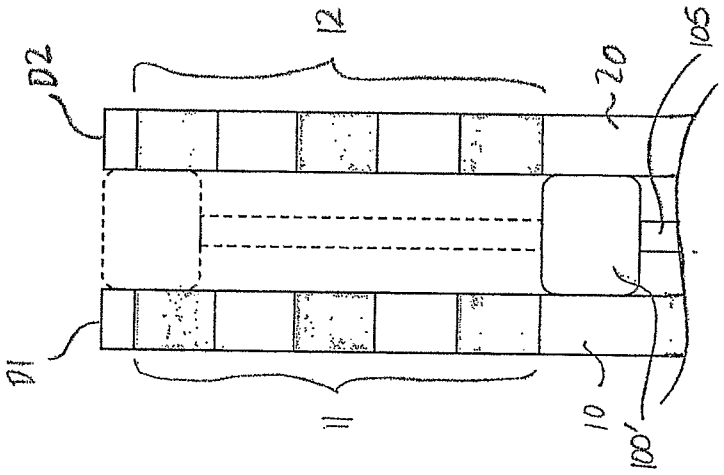
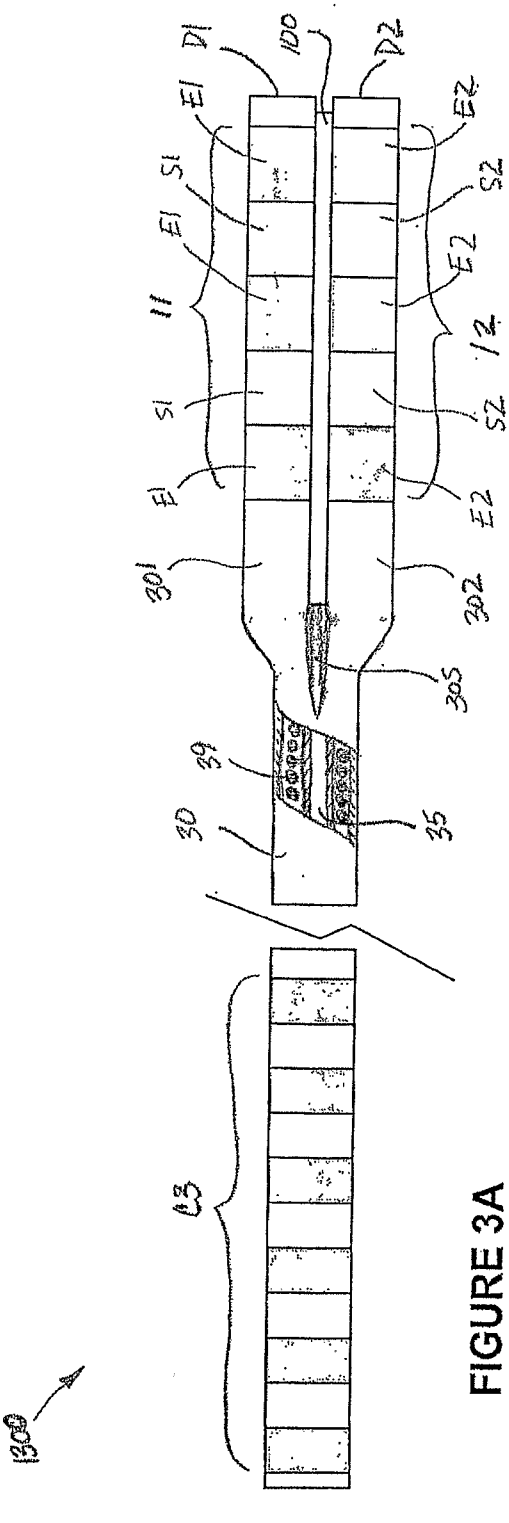
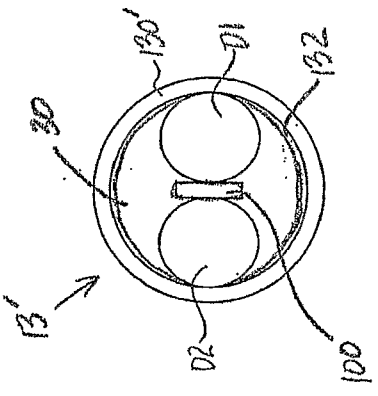
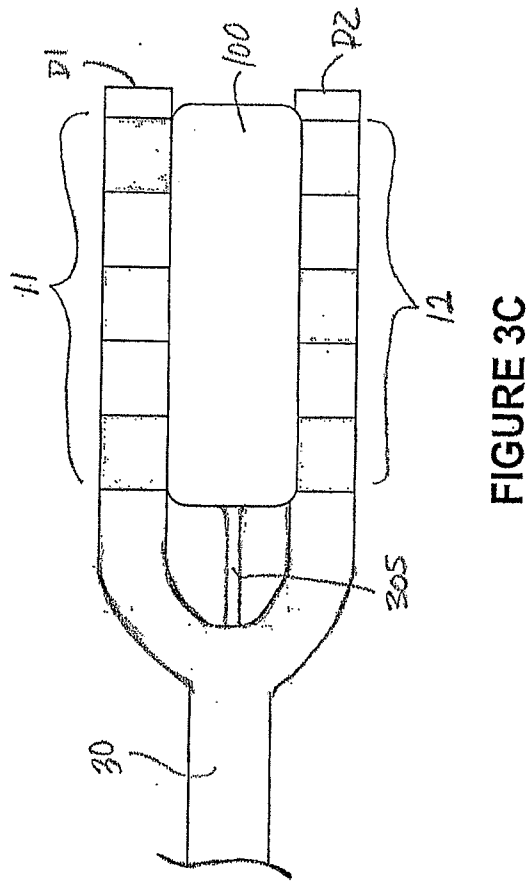


FIGURE 2


1300
13
FIGURE 3A


13'
30
130'
D1
132
D2
100
FIGURE 3B


D1
100
D2
11
12
30
305
FIGURE 3C

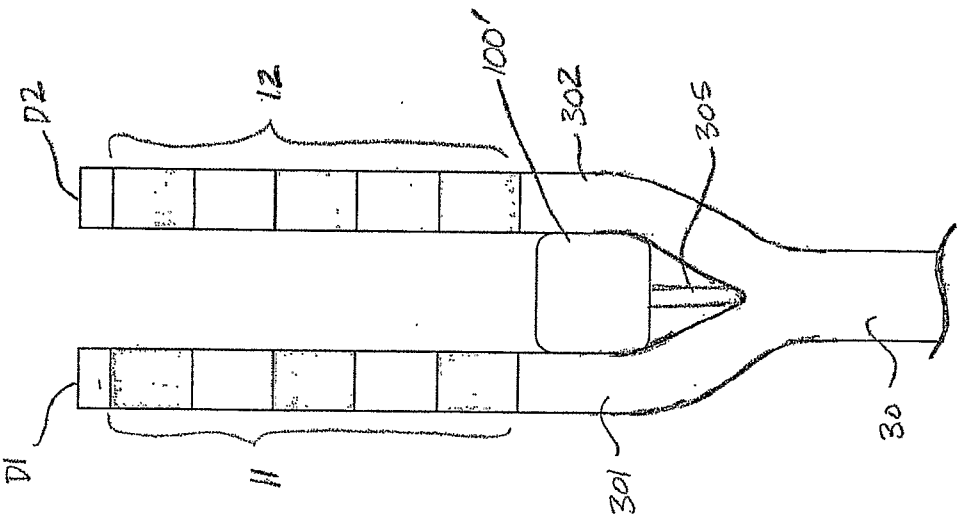


FIGURE 4

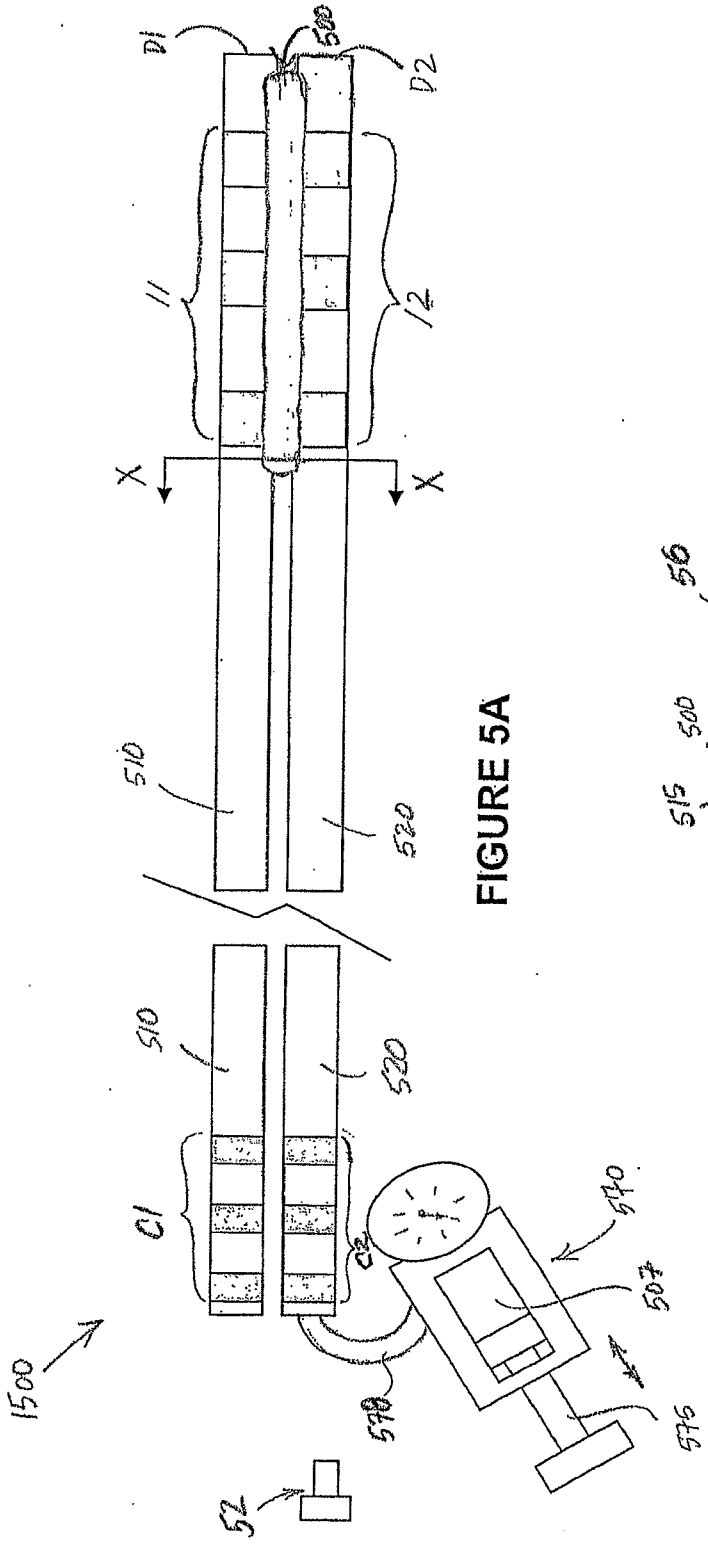


FIGURE 5A

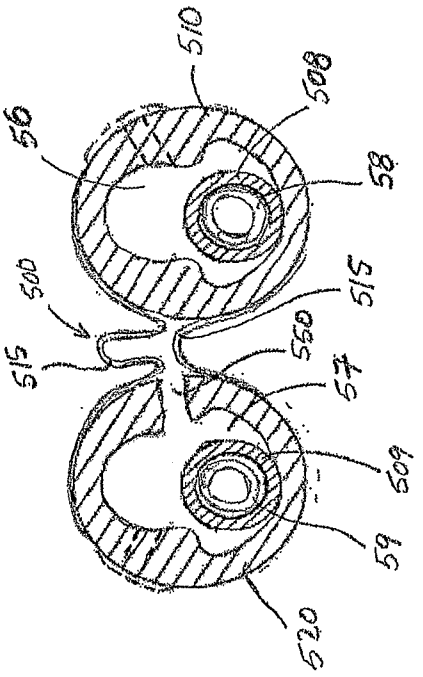


FIGURE 5B

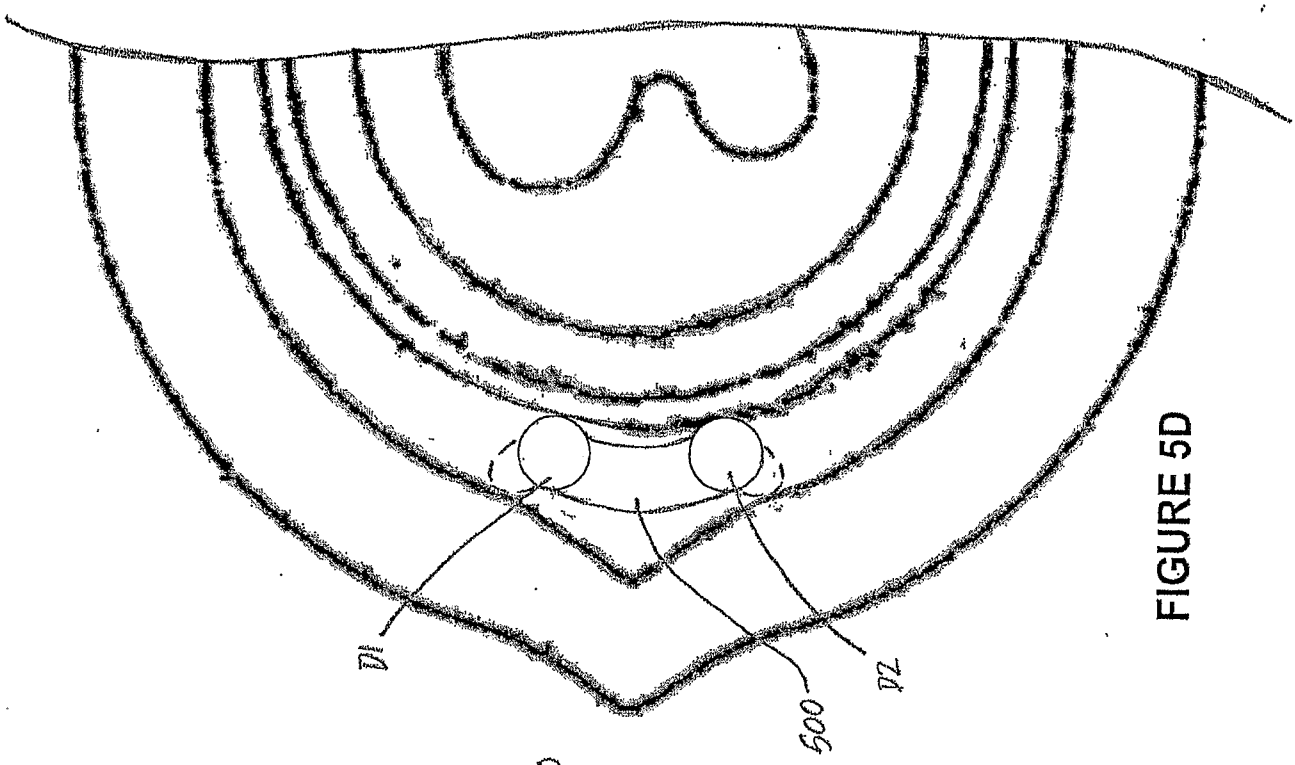


FIGURE 5D

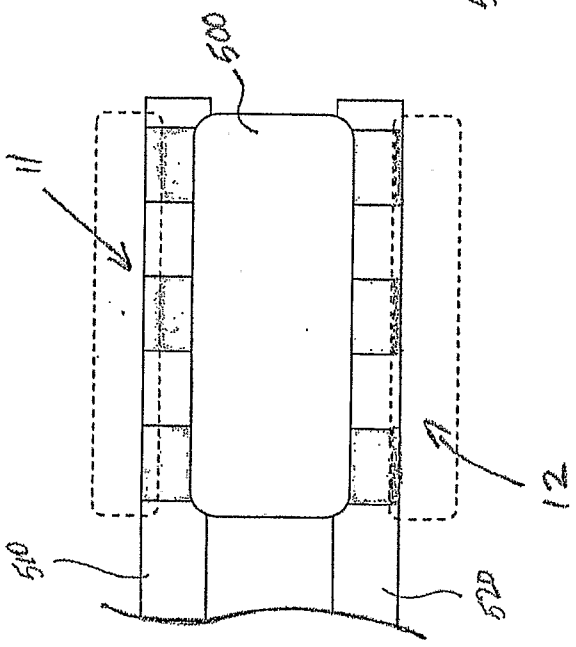


FIGURE 5C

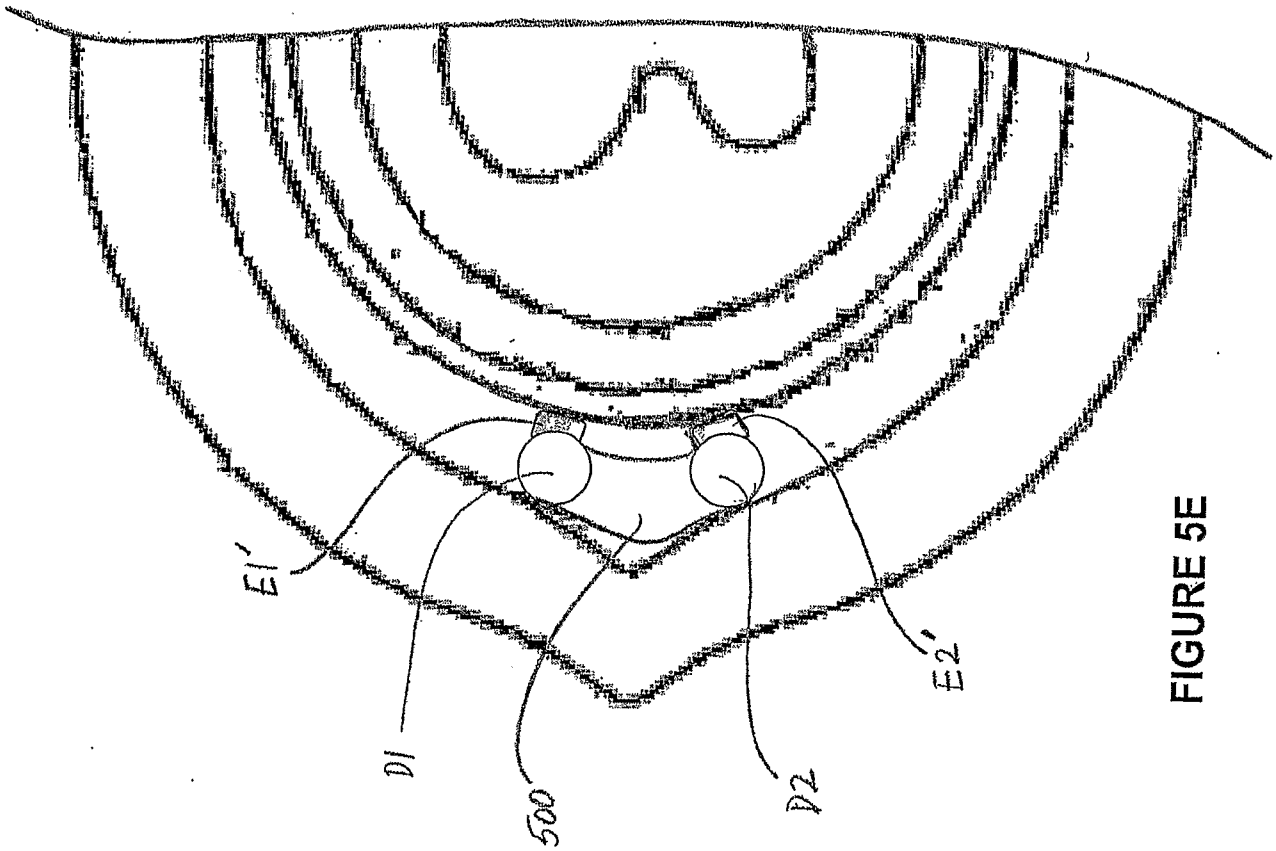


FIGURE 5E

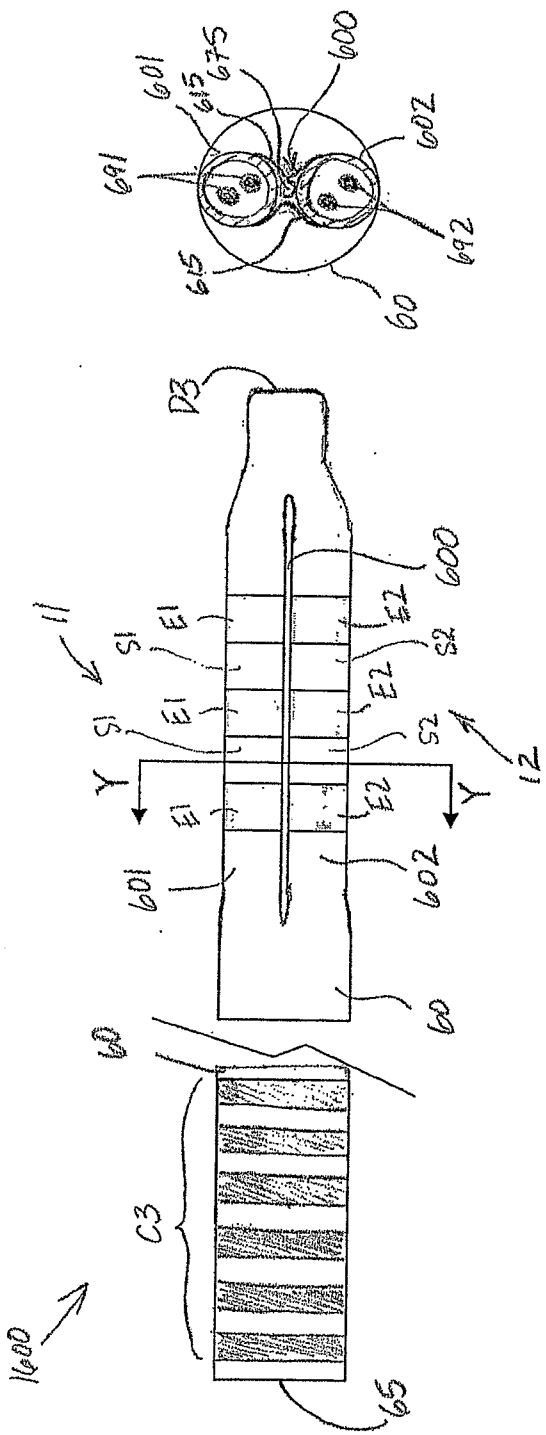


FIGURE 6A

FIGURE 6B

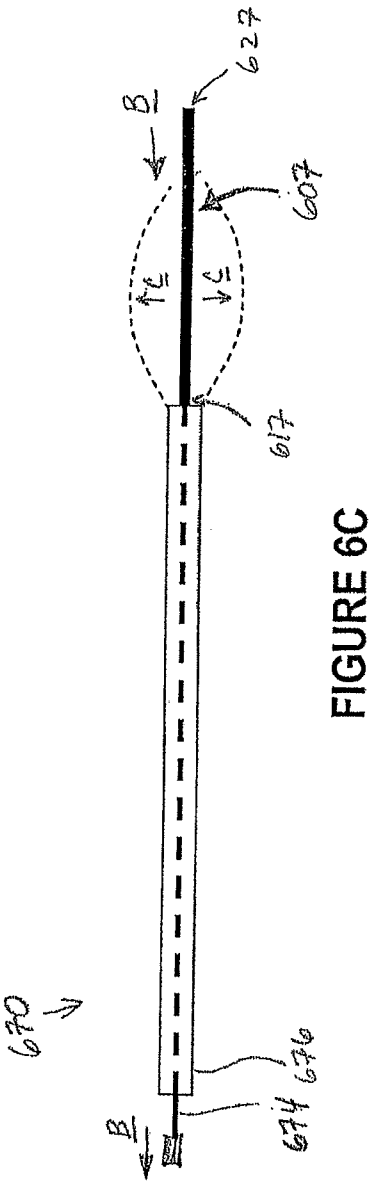


FIGURE 6C

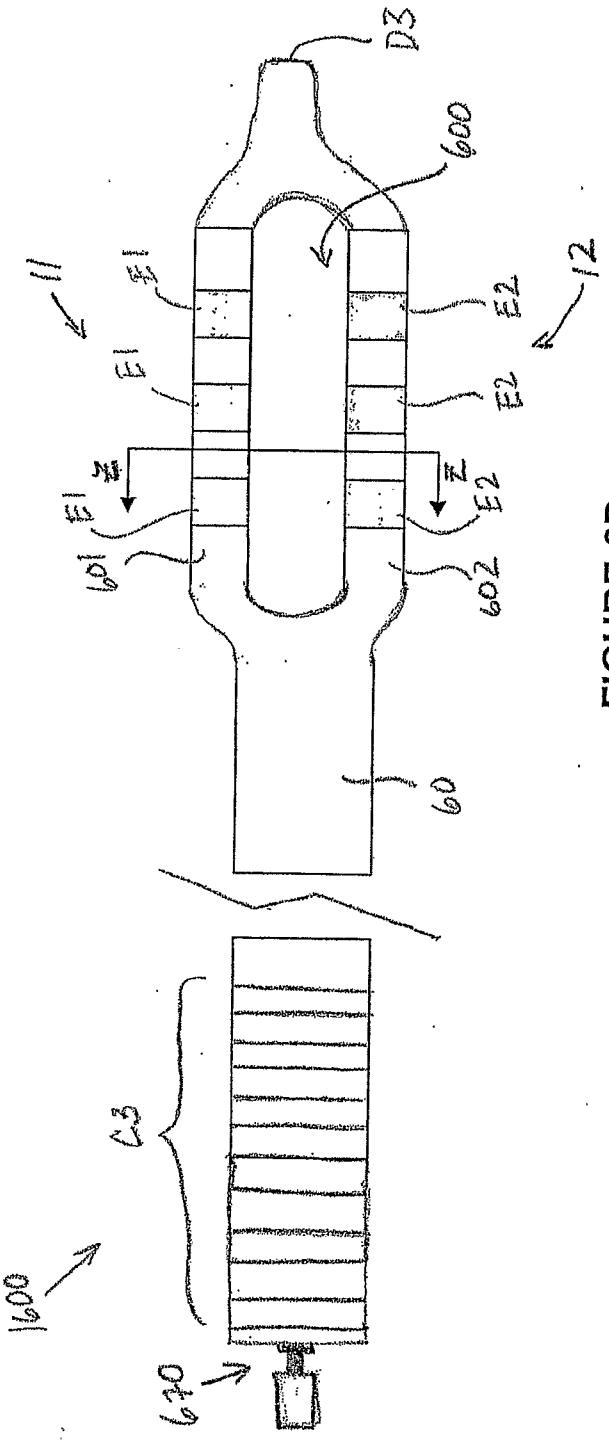


FIGURE 6D

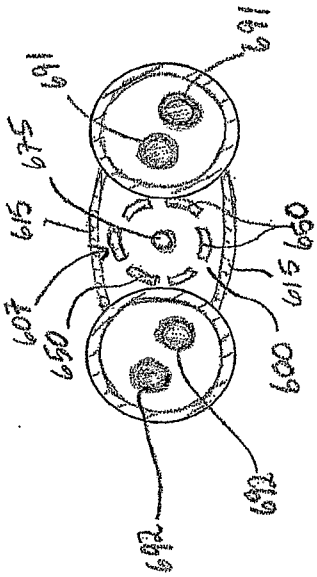


FIGURE 6E

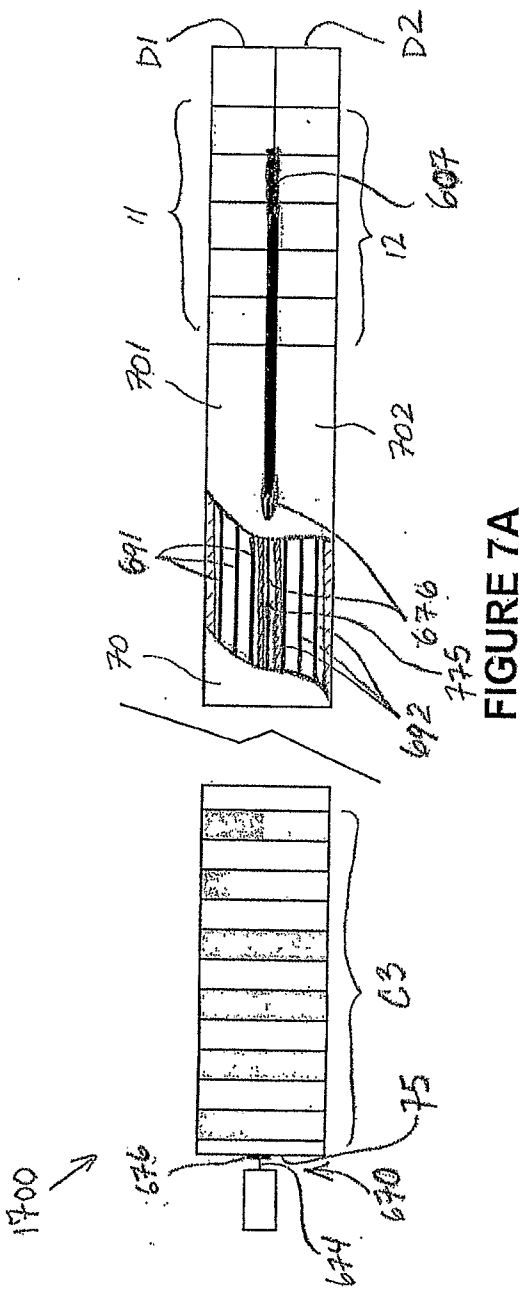


FIGURE 7A

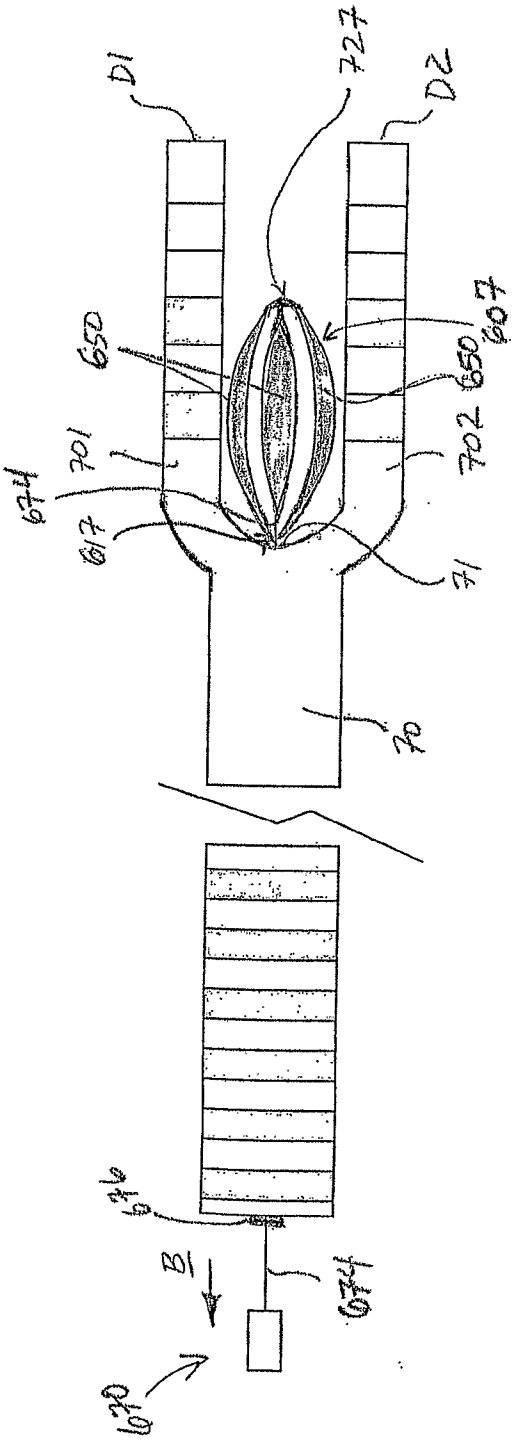


FIGURE 7B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/060943

A. CLASSIFICATION OF SUBJECT MATTER
INV . A61N1/00

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)
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
Y	**US 6 415 187 Bl (KUZMA JANUSZ A [US] ET AL) 2 July 2002 (2002-07-02)** **abstract; figures 1,3,3A** **column 1, line 14 - line 17** column **1, line 56 - line 64** column **2,** line **8 -** line **27** **column 3,** line **28 - line 48** column **3,** line **59 - column 4 , line 4** **column 4 , line 27 - line 64**	**1-17**
Y	**WO 01/76495 A (CURON MEDICAL INC [US]; EDWARDS STUART D [US]; GAISER JOHN W [US]; UTL) 18 October 2001 (2001-10-18)** **abstract; figures 2d,2e,4** **page 10, line 7 - line 18** **page 12, line 1 - line 8** **page 16, line 14 -** line **24** **page 22, line 4 -** line **10**	**1-17**

-/--

[X] **Further documents are listed in the continuation of Box C**

[X] **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[1] document which may throw doubts on pnonty d aim(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[1] 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

[1]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 docu- ments, 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
3 December 2007	**10/12/2007**

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, Tx 31 651 epo nl, Fax (+31-70) 340-3016	Pereda Cubi án, David

Form **PCT/ISA/210 (second sheet) (April 2005)**

C(ContInuatIon). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 6 254 598 Bl (EDWARDS STUART D [US] ET AL) 3 July 2001 (2001-07-03) the whole document	1-17
A	EP 0 590 431 Al (CARDIAC PACEMAKERS [US]) 6 April 1994 (1994-04-06) the whole document	1-17
A	US 2005/203599 Al (GARABEDIAN ROBERT J [US] ET AL) 15 September 2005 (2005-09-15) the whole document	1-17
A	US 2001/053885 Al (GIELEN FRANS [NL] ET AL) 20 December 2001 (2001-12-20) the whole document	1-17
A	EP 1 048 317 A (MEDTRONIC INC [US]) 2 November 2000 (2000-11-02) the whole document	1-17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/060943

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