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(54) Title: PERCUTANEOUS IMPLANTATION OF AN ELECTRICAL STIMULATION LEAD FOR STIMULATING DORSAL ROOT GANGLION

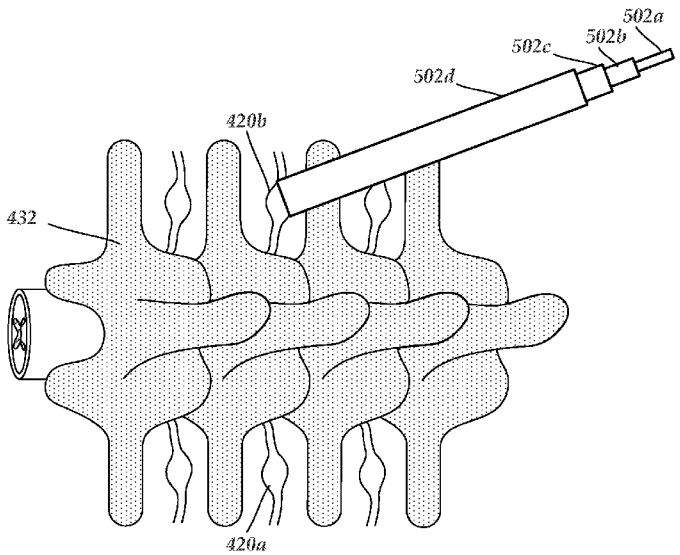

Fig. 5D

(57) Abstract: A method of implanting an electrical stimulation lead to stimulate a dorsal root ganglion includes providing an electrical stimulation lead having a distal end, a proximal end, a longitudinal length, electrodes disposed along the distal end of the lead, terminals disposed on the proximal end of the body, a plurality of conductors electrically coupling the electrodes to the terminals. The method further includes sequentially inserting a series of hollow introducers into the back of a patient to open a passage to the dorsal root ganglion. Each introducer in the series has an inner diameter larger than an inner diameter of a preceding introducer in the series. The method also includes implanting the electrical stimulation lead through the passage formed using the series of hollow introducers. Upon implantation of the electrical stimulation lead, at least one of the plurality of electrodes is adjacent the dorsal root ganglion.

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PERCUTANEOUS IMPLANTATION OF AN EL[illegible]
STIMULATION LEAD FOR STIMULATING DORSAL ROOT GANGLION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/651,815 filed on May 25, 2012, which is incorporated herein by reference.

FIELD

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to percutaneous implantation of an electrical stimulation lead for stimulation the dorsal root ganglion, as well as electrical stimulation systems containing the leads.

BACKGROUND

Implantable electrical stimulation systems have proven therapeutic in a variety of diseases and disorders. For example, spinal cord stimulation systems have been used as a therapeutic modality for the treatment of chronic pain syndromes. Peripheral nerve stimulation has been used to treat chronic pain syndrome and incontinence, with a number of other applications under investigation. Functional electrical stimulation systems have been applied to restore some functionality to paralyzed extremities in spinal cord injury patients.

Stimulators have been developed to provide therapy for a variety of treatments. A stimulator can include a control module (with a pulse generator), one or more leads, and an array of stimulator electrodes on each lead. The stimulator electrodes are in contact with or near the nerves, muscles, or other tissue to be stimulated. The pulse generator in the control module generates electrical pulses that are delivered by the electrodes to body tissue.

Dorsal root ganglia are nodules of cell bodies disposed along the dorsal roots of spinal nerves. Dorsal root ganglia are disposed external to the epidural space. Dorsal root ganglia, however, are disposed in proximity to the spinal cord and the vertebral column.

BRIEF SUMMARY

One embodiment is a method of implanting an electrical stimulation lead to stimulate a dorsal root ganglion. The method includes providing an electrical stimulation lead having a distal end, a proximal end, a longitudinal length, a plurality of electrodes disposed along the distal end of the lead, a plurality of terminals disposed on the proximal end of the body, and a plurality of conductors, each conductor electrically coupling at least one of the electrodes to at least one of the terminals. The method further includes sequentially inserting a series of hollow introducers into the back of a patient to open a passage to the dorsal root ganglion. Each introducer in the series has an inner diameter larger than an inner diameter of a preceding introducer in the series. The method also includes implanting the electrical stimulation lead through the passage formed using the series of hollow introducers. Upon implantation of the electrical stimulation lead, at least one of the plurality of electrodes is adjacent the dorsal root ganglion.

Another embodiment is an electrical stimulation lead implantation kit that includes an electrical stimulation lead having a distal end, a proximal end, a longitudinal length, a plurality of electrodes disposed along the distal end of the lead, a plurality of terminals disposed on the proximal end of the body, and a plurality of conductors, each conductor electrically coupling at least one of the electrodes to at least one of the terminals; and a series of hollow introducers configured and arranged for insertion into the back of a patient to open a passage to a dorsal root ganglion. Each introducer in the series has an inner diameter larger than an inner diameter of a preceding introducer in the series.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following drawings. In the drawings, like reference numerals refer to like parts throughout the various figures unless otherwise specified.

For a better understanding of the present invention, reference will be made to the following Detailed Description, which is to be read in association with the accompanying drawings, wherein:

FIG. 1 is a schematic view of one embodiment of an electrical stimulation system that includes a paddle body coupled to a control module via lead bodies, according to the invention;

FIG. 2 is a schematic view of another embodiment of an electrical stimulation system that includes a percutaneous lead body coupled to a control module via a lead body, according to the invention;

FIG. 3A is a schematic view of one embodiment of a plurality of connector assemblies disposed in the control module of FIG. 1, the connector assemblies configured and arranged to receive the proximal portions of the lead bodies of FIG. 1, according to the invention;

FIG. 3B is a schematic view of one embodiment of a connector assembly disposed in the control module of FIG. 2, the connector assembly configured and arranged to receive the proximal portion of one of the lead body of FIG. 2, according to the invention;

FIG. 3C is a schematic view of one embodiment of a proximal portion of the lead body of FIG. 2, a lead extension, and the control module of FIG. 2, the lead extension configured and arranged to couple the lead body to the control module, according to the invention;

FIG. 4A is a schematic transverse cross-sectional view of spinal nerves extending from a spinal cord, the spinal nerves including dorsal root ganglia;

FIG. 4B is a schematic perspective view of a portion of the spinal cord of FIG. 4A disposed in a portion of a vertebral column with the dorsal root ganglia of FIG. 4A extending outward from the vertebral column;

FIG. 4C is a schematic top view of a portion of the spinal cord of FIG. 4A disposed in a vertebral foramen defined in a vertebra of the vertebral column of FIG. 4B, the vertebra also defining intervertebral foramina extending between an outer surface of the vertebra and the vertebral foramen, the intervertebral foramina providing an opening through which the dorsal root ganglia of FIG. 4B can extend outward from the spinal cord of FIG. 4B;

FIG. 4D is a schematic side view of two vertebrae of the [illegible] FIG. 4B, the vertebrae defining an intervertebral foramen through which the dorsal root ganglia of FIG. 4B can extend outward from the spinal cord of FIG. 4B;

FIG. 5A is a schematic perspective view illustrating the insertion of a first introducer of a series of introducer to obtain access to a dorsal root ganglion for implantation of an electrical stimulation lead, according to the invention;

FIG. 5B is a schematic perspective view illustrating the insertion of a second introducer of a series of introducer to obtain access to a dorsal root ganglion for implantation of an electrical stimulation lead, according to the invention;

FIG. 5C is a schematic perspective view illustrating the insertion of a third introducer of a series of introducer to obtain access to a dorsal root ganglion for implantation of an electrical stimulation lead, according to the invention;

FIG. 5D is a schematic perspective view illustrating the insertion of a fourth introducer of a series of introducer to obtain access to a dorsal root ganglion for implantation of an electrical stimulation lead, according to the invention;

FIG. 5E is a schematic perspective view illustrating the removal of the first, second and third introducers of the series of introducer and the implantation of an electrical stimulation lead near a dorsal root ganglion, according to the invention;

FIG. 6A is a schematic perspective view of one embodiment of a lead implanted near a dorsal root ganglion, according to the invention;

FIG. 6B is a schematic perspective view of a second embodiment of a lead implanted near a dorsal root ganglion, according to the invention;

FIG. 6C is a schematic perspective view of one embodiment of a lead having distal end with paddle body implanted near a dorsal root ganglion, according to the invention;

FIG. 6D is a schematic perspective view of one embodiment of a lead having distal end with a hook shape disposed around a dorsal root ganglion, according to the invention;

FIG. 6E is a schematic perspective view of one embodiment of a lead having a distal end with a coil shape disposed around a dorsal root ganglion, according to the invention; and

FIG. 7 is a schematic overview of one embodiment of components of an electrical stimulation system, according to the invention.

DETAILED DESCRIPTION

The present invention is directed to the area of implantable electrical stimulation systems and methods of making and using the systems. The present invention is also directed to percutaneous implantation of an electrical stimulation lead for stimulation the dorsal root ganglion, as well as electrical stimulation systems containing the leads.

Suitable implantable electrical stimulation systems include, but are not limited to, an electrode lead ("lead") with one or more electrodes disposed on a distal end of the lead and one or more terminals disposed on one or more proximal ends of the lead. Leads include, for example, deep brain stimulation leads, percutaneous leads, paddle leads, and cuff leads. Examples of electrical stimulation systems with leads are found in, for example, U.S. Patents Nos. 6,181,969; 6,516,227; 6,609,029; 6,609,032; 6,741,892; 7,244,150; 7,672,734; 7,761,165; 7,949,395; 7,974,706; 8,175,710; 8,224,450; and 8,364,278; and U.S. Patent Application Publication No. 2007/0150036, all of which are incorporated by reference.

Figure 1 illustrates schematically one embodiment of an electrical stimulation system 100. The electrical stimulation system includes a control module (*e.g.,* a stimulator or pulse generator) 102 and a lead 103. The lead 103 including a paddle body 104 and one or more lead bodies 106 coupling the control module 102 to the paddle body 104. The paddle body 104 and the one or more lead bodies 106 form the lead 103. The paddle body 104 typically includes a plurality of electrodes 134 that form an array of electrodes 133. The control module 102 typically includes an electronic subassembly 110 and an optional power source 120 disposed in a sealed housing 114. In Figure 1, two lead bodies 106 are shown coupled to the control module 102.

The control module 102 typically includes one or more connector assemblies 144 into which the proximal end of the one or more lead bodies 106 can be plugged to make an electrical connection via connector contacts (*e.g.,* 316 in Figure 3A) disposed in the

connector assembly 144 and terminals (*e.g.*, 310 in Figure 3A) c... ... ... more lead bodies 106. The connector contacts are coupled to the electronic subassembly 110 and the terminals are coupled to the electrodes 134. In Figure 1, two connector assemblies 144 are shown.

The one or more connector assemblies 144 may be disposed in a header 150. The header 150 provides a protective covering over the one or more connector assemblies 144. The header 150 may be formed using any suitable process including, for example, casting, molding (including injection molding), and the like. In addition, one or more lead extensions 324 (see Figure 3C) can be disposed between the one or more lead bodies 106 and the control module 102 to extend the distance between the one or more lead bodies 106 and the control module 102.

It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different configurations including those configurations disclosed in the electrical stimulation system references cited herein. For example, instead of a paddle body 104, the electrodes 134 can be disposed in an array at or near the distal end of a lead body 106' forming a percutaneous lead 103, as illustrated in Figure 2. The percutaneous lead may be isodiametric along the length of the lead body 106'. The lead body 106' can be coupled with a control module 102' with a single connector assembly 144.

The electrical stimulation system or components of the electrical stimulation system, including one or more of the lead bodies 106, the control module 102, and, in the case of a paddle lead, the paddle body 104, are typically implanted into the body of a patient. The electrical stimulation system can be used for a variety of applications including, but not limited to, spinal cord stimulation, brain stimulation, neural stimulation, muscle activation via stimulation of nerves innervating muscle, and the like.

The electrodes 134 can be formed using any conductive, biocompatible material. Examples of suitable materials include metals, alloys, conductive polymers, conductive carbon, and the like, as well as combinations thereof. In at least some embodiments, one or more of the electrodes 134 are formed from one or more of: platinum, platinum iridium, palladium, titanium, or rhenium.

The number of electrodes 134 in the array of electrodes [illegible] example, there can be two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, or more electrodes 134. As will be recognized, other numbers of electrodes 134 may also be used. In Figure 1, sixteen electrodes 134 are shown. The electrodes 134 can be formed in any suitable shape including, for example, round, oval, triangular, rectangular, pentagonal, hexagonal, heptagonal, octagonal, or the like.

Any suitable type of electrodes can be used. For example, for lead 103 of Figure 2, each of the electrodes can be, for example, a ring electrode, a segmented electrode, or a tip electrode and the array of electrodes can include any combination of ring electrodes, segmented electrodes, or a tip electrode. Examples of leads with segmented electrodes include U.S. Patents Nos. 8,295,944; and 8,391,985; and U.S. Patent Applications Publication Nos. 2010/0268298; 2011/0005069; 2011/0078900; 2011/0130817; 2011/0130818; 2011/0238129; 2011/0313500; 2012/0016378; 2012/0046710; 2012/0165911; 2012/0197375; 2012/0203316; 2012/0203320; and 2012/0203321, and U.S. Provisional Patent Application Serial No. 61/651,822, all of which are incorporated herein by reference.

The electrodes of the paddle body 104 or one or more lead bodies 106 are typically disposed in, or separated by, a non-conductive, biocompatible material including, for example, silicone, polyurethane, and the like or combinations thereof. The paddle body 104 and one or more lead bodies 106 may be formed in the desired shape by any process including, for example, molding (including injection molding), casting, and the like. Electrodes and connecting wires can be disposed onto or within a paddle body either prior to or subsequent to a molding or casting process. The non-conductive material typically extends from the distal end of the lead 103 to the proximal end of each of the one or more lead bodies 106. The non-conductive, biocompatible material of the paddle body 104 and the one or more lead bodies 106 may be the same or different. The paddle body 104 and the one or more lead bodies 106 may be a unitary structure or can be formed as two separate structures that are permanently or detachably coupled together.

Terminals (*e.g.,* 310 in Figure 3A) are typically disposed at the proximal end of the one or more lead bodies 106 for connection to corresponding conductive contacts

(*e.g.*, 316 in Figure 3A) in connector assemblies (*e.g.*, 144 in Figure 1) disposed on, for example, the control module 102 (or to other devices, such as conductive contacts on a lead extension, an operating room cable, a splitter, an adaptor, or the like).

Conductive wires (not shown) extend from the terminals (*e.g.*, 310 in Figure 3A) to the electrodes 134. Typically, one or more electrodes 134 are electrically coupled to a terminal (*e.g.*, 310 in Figure 3A). In some embodiments, each terminal (*e.g.*, 310 in Figure 3A) is only coupled to one electrode 134.

The conductive wires may be embedded in the non-conductive material of the lead or can be disposed in one or more lumens (not shown) extending along the lead. In some embodiments, there is an individual lumen for each conductive wire. In other embodiments, two or more conductive wires may extend through a lumen. There may also be one or more lumens (not shown) that open at, or near, the proximal end of the lead, for example, for inserting a stylet rod to facilitate placement of the lead within a body of a patient. Additionally, there may also be one or more lumens (not shown) that open at, or near, the distal end of the lead, for example, for infusion of drugs or medication into the site of implantation of the paddle body 104. The one or more lumens may, optionally, be flushed continually, or on a regular basis, with saline, epidural fluid, or the like. The one or more lumens can be permanently or removably sealable at the distal end.

As discussed above, the one or more lead bodies 106 may be coupled to the one or more connector assemblies 144 disposed on the control module 102. The control module 102 can include any suitable number of connector assemblies 144 including, for example, two three, four, five, six, seven, eight, or more connector assemblies 144. It will be understood that other numbers of connector assemblies 144 may be used instead. In Figure 1, each of the two lead bodies 106 includes eight terminals that are shown coupled with eight conductive contacts disposed in a different one of two different connector assemblies 144.

Figure 3A is a schematic side view of one embodiment of a plurality of connector assemblies 144 disposed on the control module 102. In at least some embodiments, the control module 102 includes two connector assemblies 144. In at least some embodiments, the control module 102 includes four connector assemblies 144. In Figure

3A, proximal ends 306 of the plurality of lead bodies 106 are sh... ... ... arranged for insertion to the control module 102. Figure 3B is a schematic side view of one embodiment of a single connector assembly 144 disposed on the control module 102'. In Figure 3B, the proximal end 306 of the single lead body 106' is shown configured and arranged for insertion to the control module 102'.

In Figures 3A and 3B, the one or more connector assemblies 144 are disposed in the header 150. In at least some embodiments, the header 150 defines one or more ports 304 into which the proximal end(s) 306 of the one or more lead bodies 106/106' with terminals 310 can be inserted, as shown by directional arrows 312, in order to gain access to the connector contacts disposed in the one or more connector assemblies 144.

The one or more connector assemblies 144 each include a connector housing 314 and a plurality of connector contacts 316 disposed therein. Typically, the connector housing 314 defines a port (not shown) that provides access to the plurality of connector contacts 316. In at least some embodiments, one or more of the connector assemblies 144 further includes a retaining element 318 configured and arranged to fasten the corresponding lead body 106/106' to the connector assembly 144 when the lead body 106/106' is inserted into the connector assembly 144 to prevent undesired detachment of the lead body 106/106' from the connector assembly 144. For example, the retaining element 318 may include an aperture 320 through which a fastener (*e.g.*, a set screw, pin, or the like) may be inserted and secured against an inserted lead body 106/106'.

When the one or more lead bodies 106/106' are inserted into the one or more ports 304, the connector contacts 316 can be aligned with the terminals 310 disposed on the one or more lead bodies 106/106' to electrically couple the control module 102 to the electrodes (134 of Figure 1) disposed at a distal end of the one or more lead bodies 106. Examples of connector assemblies in control modules are found in, for example, U.S. Patent No. 7,244,150 and 8,224,450, which are incorporated by reference.

In at least some embodiments, the electrical stimulation system includes one or more lead extensions. The one or more lead bodies 106/106' can be coupled to one or more lead extensions which, in turn, are coupled to the control module 102/102'. In Figure 3C, a lead extension connector assembly 322 is disposed on a lead extension 324. The lead extension connector assembly 322 is shown disposed at a distal end 326 of the

lead extension 324. The lead extension connector assembly 322 includes a connector housing 328. The contact housing 328 defines at least one port 330 into which a proximal end 306 of the lead body 106' with terminals 310 can be inserted, as shown by directional arrow 338. The lead extension connector assembly 322 also includes a plurality of connector contacts 340. When the lead body 106' is inserted into the port 330, the connector contacts 340 disposed in the contact housing 328 can be aligned with the terminals 310 on the lead body 106 to electrically couple the lead extension 324 to the electrodes (134 of Figure 1) disposed at a distal end (not shown) of the lead body 106'.

The proximal end of a lead extension can be similarly configured and arranged as a proximal end of a lead body. The lead extension 324 may include a plurality of conductive wires (not shown) that electrically couple the connector contacts 340 to terminal on a proximal end 348 of the lead extension 324. The conductive wires disposed in the lead extension 324 can be electrically coupled to a plurality of terminals (not shown) disposed on the proximal end 348 of the lead extension 324. In at least some embodiments, the proximal end 348 of the lead extension 324 is configured and arranged for insertion into a lead extension connector assembly disposed in another lead extension. In other embodiments (as shown in Figure 3C), the proximal end 348 of the lead extension 324 is configured and arranged for insertion into the connector assembly 144 disposed on the control module 102'.

It will be understood that the control modules 102/102' can receive either lead bodies 106/106' or lead extensions 324. It will also be understood that the electrical stimulation system 100 can include a plurality of lead extensions 224. For example, each of the lead bodies 106 shown in Figures 1 and 3A can, alternatively, be coupled to a different lead extension 224 which, in turn, are each coupled to different ports of a two-port control module, such as the control module 102 of Figures 1 and 3A.

Turning to Figure 4A, one potential target stimulation location is the dorsal root ganglia. Figure 4A schematically illustrates a transverse cross-sectional view of a spinal cord 402 surrounded by dura 404. The spinal cord 402 includes a plurality of levels from which spinal nerves 412a and 412b extend. In at least some spinal cord levels, the spinal nerves 412a and 412b extend bilaterally from the spinal cord 402. In Figure 4A, the spinal nerves 412a and 412b attach to the spinal cord 402 via corresponding dorsal roots

414a and 414b and corresponding ventral (or anterior) roots 416[illegible], the dorsal roots 414a and 414b relay sensory information into the spinal cord 402 and the ventral roots 416a and 416b relay motor information outward from the spinal cord 402. Dorsal root ganglia ("DRG") 420a and 420b are nodules of cell bodies that are disposed along the dorsal roots 416a and 416b in proximity to the spinal cord 402.

Figure 4B schematically illustrates a perspective view of a portion of the spinal cord 402 disposed along a portion of a vertebral column 430. The vertebral column 430 includes a plurality of stacked vertebrae, such as vertebrae 432a and 432b, and a plurality of DRGs 420a and 420b extending outwardly bilaterally from the spinal cord 402.

Figure 4C schematically illustrates a top view of a portion of the spinal cord 402 and dura 404 disposed in a vertebral foramen 440 defined in the vertebra 432b. The vertebrae 432 are stacked together and the vertebral foramina 440 of the vertebrae collectively form a spinal canal through which the spinal cord 402 extends. The space within the spinal canal between the dura 404 and the walls of the vertebral foramen 440 defines the epidural space 442. Intervertebral foramina 446a and 446b defined bilaterally along sides of the vertebra 432b form openings through the vertebra 432b between the epidural space 442 and the environment external to the vertebra 432b.

Figure 4D schematically illustrates a side view of two vertebrae 432a and 432b coupled to one another by a disc 444. In Figure 4D, the intervertebral foramen 446b is shown defined between the vertebrae 432a and 432b. The intervertebral foramen 446b provides an opening for one or more of the dorsal root 414b, ventral root 416b, and DRG 420b to extend outwardly from the spinal cord 402.

Conventional electrical stimulation leads for spinal stimulation are often implanted into the epidural space and stimulate a portion of the spinal cord. In at some instances, these leads may be implanted percutaneously using an introducer or needle. In other instances, particularly for at least some paddle leads, the lead is implanted using a more invasive procedure, such as a laminectomy.

Instead of stimulating a portion of the spinal cord, an electrical stimulation lead can be used to stimulate the dorsal root ganglion which branches off from the spinal cord. The dorsal root ganglia can be accessed without entry of the lead into the epidural space. Such access, however, may pass through a relatively thick area of tissue,

including muscle tissue, to implant the lead. It is desirable to fi[illegible] for implantation of a lead.

The electrical stimulation lead can be implanted near or around the dorsal root ganglion using a set of introducers, each introducer in the set having a larger inner diameter than the preceding introducer. The introducers can be inserted into the patient sequentially starting with the introducer having the smallest inner diameter. This first introducer of the set may be inserted over a guidewire or over or through a needle that has been inserted into patient tissue. Each subsequent introducer is inserted over the preceding introducer so that the opening into the patient becomes sequentially larger. In at least some embodiments, a larger diameter introducer may be inserted deeper into the tissue than the preceding introducer, thereby increasing the depth of the opening, as well as expanding its size.

Once the set of introducers has been inserted into the patient, one or more of smaller diameter introducers (and, in at least some embodiments, all of the introducers except the one with the largest diameter) are removed to leave a passage with access to the dorsal root ganglion and sufficient space to permit a practitioner to reliably implant the distal end of the electrical stimulation lead around or near the dorsal root ganglion. The distal end of the lead is implanted through the passage formed by the introducer(s) and positioned relative to the dorsal root ganglion to be stimulated. The proximal end of the lead can be directed to the site of implantation of the control module. For example, the control module may be implanted in the abdominal cavity and the proximal end of the lead may be directed to the control module by tunneling through the intervening tissue.

Figures 5A-5E schematically illustrate one embodiment of a method of implanting an electrical stimulation lead using a series of introducers. Figure 5A illustrates the insertion of a first introducer 502a into patient tissue near the vertebra 432 and directed toward a target dorsal root ganglion 420b. This first introducer 502a may be directed into the tissue without any guiding element or the first introducer may be inserted over a guidewire, needle, or the like (not shown) that had been previously inserted into the tissue. In at least some embodiments, an obturator or trocar is provided within the first introducer to reduce or prevent coring of tissue during insertion of the first introducer.

Figure 5B illustrates the insertion of a second introducer [illegible], with a larger inner diameter than the first introducer 502a, over the first introducer 502a. Figure 5C illustrates the insertion of a third introducer 502c, with a larger inner diameter than the second introducer 502b, over the second introducer 502b. Figure 5D illustrates the insertion of a fourth introducer 502d, with a larger inner diameter than the third introducer 502c, over the third introducer 502c. In the Figures, each subsequent introducer is pushed closer to the target dorsal root ganglion 420b. In other embodiments, the introducers may be inserted to identical, or near identical, depth in the vicinity of the target DRG. Any number of introducers can be used including, but not limited to, two, three, four, five, six, eight, or more. Typically, but not necessarily, the inner diameter of an introducer is larger than the outer diameter of the preceding introducer(s). Preferably, the introducers slide over each other. In at least some embodiments, a lubricating substance may be used to facilitate sliding of an introducer over the preceding introducer in the series.

Once the introducers have been inserted, one or more of the earlier introducers are removed. As illustrated in Figure 5E, the first introducer 502a, second introducer 502b, and third introducer 502c are removed, leaving the fourth introducer 502d and a passage defined by the fourth introducer and extending from outside the body to the dorsal root ganglion. In some embodiments, one or more of the preceding introducers may be left within the final introducer to, for example, provide structural stability.

Once the passage is open, an electrical stimulation lead 506 can then be implanted through the passage defined by the introducer 502d. The practitioner may select the diameter of the introducer 502d and the resulting passage to facilitate the implantation of the lead. Factors that can affect the diameter of the passage include, but are not limited to, the size of the lead, the desired implantation site and arrangement of the lead around the dorsal root ganglion, trauma to the tissue through which the introducer passes, and the like. Similar arrangements of introducers have been developed for spinal surgery including surgery on the vertebrae and discs, as described, for example, in U.S. Patent No. 7.993,378, incorporated herein by reference, and are instructive for the series of introducers used to implant an electrical stimulation lead as described herein.

Figures 6A-6E illustrate a variety of different implantati... ...gements ... ... distal end 518 of the electrical stimulation lead 506 with respect to the dorsal root ganglion 420a. Figure 6A illustrates one embodiment of a lead 506 with a distal end 518 having a linear or curved shape that lies next to the DRG 420a. In these embodiments, the lead forms an angle of at least 45°, 50°, 60°, 70°, 80°, or 85° with the dorsal root 414a.

Figure 6B illustrates one embodiment of a lead 506 with a distal end 518 having a linear or curved shape that lies next to the DRG 420a. In these embodiments, the lead forms an angle of no more than 45°, 30°, 20°, 15°, 10°, or 5° with the dorsal root 414a.

Figure 6C illustrates one embodiment with a lead 506 with a paddle body 510 at the distal end of the lead. In at least some embodiments, the portion of the lead extending from the paddle body forms an angle of at least 45°, 50°, 60°, 70°, 80°, or 85° with the dorsal root 414a, as illustrated in Figure 6C. In other embodiments, the portion of the lead extending from the paddle body forms an angle of at least 45°, 50°, 60°, 70°, 80°, or 85° with the dorsal root 414a

Figure 6D illustrates one embodiment of a lead 506 with a distal end 508 of the lead having a hook-shaped distal end 518 to fit around the DRG 420a. In at least some embodiments, the hook-shaped distal end extends around at least 40%, 50%, 60%, 70%, 75%, 80%, 90%, 95%, or 100% of the circumference of the DRG 420a.

Figure 6E illustrates one embodiment of a lead 506 with a distal end 508 of the lead having a coil-shaped distal end 518 to fit around a portion of the DRG 420a. The coil-shaped distal end may include any number of full turns (360° turn) around the DRG 420a including, for example, at least one, two, or three full turns. The coil-shaped distal end may also include a partial turn (less than 360° turn). The turns of the coil-shaped distal end may be situated immediately adjacent to each other in a touching arrangement, as illustrated in Figure 6E, or the turns may be separated from each other or any combination thereof.

In at least some embodiments of the arrangements exemplified by Figures 6D and 6E, the portion of the lead extending from the hook-shaped or coil-shaped distal end is arranged to form an angle of at least 45°, 50°, 60°, 70°, 80°, or 85° with the dorsal root 414a. In at least some embodiments, the hook-shaped or coil-shaped distal end of the

lead body is isodiametric. In at least some embodiments, the ho[illegible] distal end of the lead body is also isodiametric with the remainder of the lead. Further description of leads with hook-shaped or coiled-shaped distal end can be found in U.S. Provisional Patent Application Serial No. 61/651,830, incorporated herein by reference.

Figure 7 is a schematic overview of one embodiment of components of an electrical stimulation system 700 including an electronic subassembly 710 disposed within a control module. It will be understood that the electrical stimulation system can include more, fewer, or different components and can have a variety of different configurations including those configurations disclosed in the stimulator references cited herein.

Some of the components (for example, power source 712, antenna 718, receiver 702, and processor 704) of the electrical stimulation system can be positioned on one or more circuit boards or similar carriers within a sealed housing of an implantable pulse generator, if desired. Any power source 712 can be used including, for example, a battery such as a primary battery or a rechargeable battery. Examples of other power sources include super capacitors, nuclear or atomic batteries, mechanical resonators, infrared collectors, thermally-powered energy sources, flexural powered energy sources, bioenergy power sources, fuel cells, bioelectric cells, osmotic pressure pumps, and the like including the power sources described in U.S. Patent No. 7,437,193, incorporated herein by reference.

As another alternative, power can be supplied by an external power source through inductive coupling via the optional antenna 718 or a secondary antenna. The external power source can be in a device that is mounted on the skin of the user or in a unit that is provided near the user on a permanent or periodic basis.

If the power source 712 is a rechargeable battery, the battery may be recharged using the optional antenna 718, if desired. Power can be provided to the battery for recharging by inductively coupling the battery through the antenna to a recharging unit 716 external to the user. Examples of such arrangements can be found in the references identified above.

In one embodiment, electrical current is emitted by the electrodes 134 on the paddle or lead body to stimulate nerve fibers, muscle fibers, or other body tissues near

the electrical stimulation system. A processor 704 is generally i... timing and electrical characteristics of the electrical stimulation system. For example, the processor 704 can, if desired, control one or more of the timing, frequency, strength, duration, and waveform of the pulses. In addition, the processor 704 can select which electrodes can be used to provide stimulation, if desired. In some embodiments, the processor 704 may select which electrode(s) are cathodes and which electrode(s) are anodes. In some embodiments, the processor 704 may be used to identify which electrodes provide the most useful stimulation of the desired tissue.

Any processor can be used and can be as simple as an electronic device that, for example, produces pulses at a regular interval or the processor can be capable of receiving and interpreting instructions from an external programming unit 708 that, for example, allows modification of pulse characteristics. In the illustrated embodiment, the processor 704 is coupled to a receiver 702 which, in turn, is coupled to the optional antenna 718. This allows the processor 704 to receive instructions from an external source to, for example, direct the pulse characteristics and the selection of electrodes, if desired.

In one embodiment, the antenna 718 is capable of receiving signals (e.g., RF signals) from an external telemetry unit 706 which is programmed by a programming unit 708. The programming unit 708 can be external to, or part of, the telemetry unit 706. The telemetry unit 706 can be a device that is worn on the skin of the user or can be carried by the user and can have a form similar to a pager, cellular phone, or remote control, if desired. As another alternative, the telemetry unit 706 may not be worn or carried by the user but may only be available at a home station or at a clinician's office. The programming unit 708 can be any unit that can provide information to the telemetry unit 706 for transmission to the electrical stimulation system 700. The programming unit 708 can be part of the telemetry unit 706 or can provide signals or information to the telemetry unit 706 via a wireless or wired connection. One example of a suitable programming unit is a computer operated by the user or clinician to send signals to the telemetry unit 706.

The signals sent to the processor 704 via the antenna 718 and receiver 702 can be used to modify or otherwise direct the operation of the electrical stimulation system. For example, the signals may be used to modify the pulses of the electrical stimulation

system such as modifying one or more of pulse duration, pulse frequency, pulse waveform, and pulse strength. The signals may also direct the electrical stimulation system 700 to cease operation, to start operation, to start charging the battery, or to stop charging the battery. In other embodiments, the stimulation system does not include an antenna 718 or receiver 702 and the processor 704 operates as programmed.

Optionally, the electrical stimulation system 700 may include a transmitter (not shown) coupled to the processor 704 and the antenna 718 for transmitting signals back to the telemetry unit 706 or another unit capable of receiving the signals. For example, the electrical stimulation system 700 may transmit signals indicating whether the electrical stimulation system 700 is operating properly or not or indicating when the battery needs to be charged or the level of charge remaining in the battery. The processor 704 may also be capable of transmitting information about the pulse characteristics so that a user or clinician can determine or verify the characteristics.

The above specification, examples and data provide a description of the manufacture and use of the composition of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention also resides in the claims hereinafter appended.

CLAIMS

What is claimed:

1. A method of implanting an electrical stimulation lead to stimulate a dorsal root ganglion, the method comprising:

providing an electrical stimulation lead having a distal end, a proximal end, a longitudinal length, a plurality of electrodes disposed along the distal end of the lead, a plurality of terminals disposed on the proximal end of the lead, and a plurality of conductors, each conductor electrically coupling at least one of the electrodes to at least one of the terminals;

sequentially inserting a series of hollow introducers into the back of a patient to open a passage to the dorsal root ganglion, each introducer in the series having an inner diameter larger than an inner diameter of a preceding introducer in the series; and

implanting the electrical stimulation lead through the passage formed using the series of hollow introducers, wherein, upon implantation of the electrical stimulation lead, at least one of the plurality of electrodes is adjacent the dorsal root ganglion.

2. The method of claim 1, wherein the series of introducers comprises a largest diameter introducer and the method further comprises, prior to implanting the electrical stimulation lead, removing a plurality of the introducers in the series leaving at least the largest diameter introducer inserted in the patient.

3. The method of claim 2, wherein removing a plurality of the introducers comprises removing all of the introducers except the largest diameter introducer.

4. The method of claim 1, wherein the electrical stimulation lead is an isodiametric lead.

5. The method of claim 1, wherein the electrical stimulation lead further comprises a paddle body disposed at the distal end of the electrical stimulation lead.

6. The method of claim 1, wherein implanting the electrical stimulation lead comprises implanting the electrical stimulation lead so that the lead forms an angle of at least 45° with respect to a dorsal root extending from the dorsal root ganglion.

7. The method of claim 1, wherein implanting the electrical stimulation lead comprises implanting the electrical stimulation lead so that the lead forms an angle of no more than 25° with respect to a dorsal root extending from the dorsal root ganglion.

8. The method of claim 1, wherein implanting the electrical stimulation lead comprises implanting the lead around at least a portion of the dorsal root ganglion with the distal end of the lead formed into a hook shape situated around the portion of the dorsal root ganglion.

9. The method of claim 1, wherein implanting the electrical stimulation lead comprises implanting the lead around at least a portion of the dorsal root ganglion with the distal end of the lead formed into a coil shape situated around the portion of the dorsal root ganglion.

10. The method of claim 1, wherein sequentially inserting a series of hollow introducers into the back of a patient comprises inserting at least one of the introducers of the series deeper into patient tissue than an immediately preceding one of the introducers was inserted.

11. The method of claim 10, wherein sequentially inserting a series of hollow introducers into the back of a patient comprises inserting each of the introducers of the series deeper into patient tissue than an immediately preceding one of the introducers was inserted.

12. The method of claim 1, wherein sequentially inserting a series of hollow introducers into the back of a patient comprises inserting each of the introducers of the series a substantially identical depth into the patient.

13. The method of claim 1, further comprising inserting a guidewire into the patient prior to sequentially inserting the series of hollow introducers into the back of the patient.

14. The method of claim 13, wherein sequentially inserting a series of hollow introducers into the back of a patient comprises inserting a first introducer of the series of hollow introducers over the guidewire.

15. An electrical stimulation lead implantation kit, comprising:

an electrical stimulation lead having a distal end, a proximal end, a longitudinal length, a plurality of electrodes disposed along the distal end of the lead, a plurality of terminals disposed on the proximal end of the body, and a plurality of conductors, each conductor electrically coupling at least one of the electrodes to at least one of the terminals; and

a series of hollow introducers configured and arranged for insertion into the back of a patient to open a passage to a dorsal root ganglion, each introducer in the series having an inner diameter larger than an inner diameter of a preceding introducer in the series.

16. The electrical stimulation lead implantation kit of claim 15, wherein the electrical stimulation lead is an isodiametric lead.

17. The electrical stimulation lead implantation kit of claim 15, wherein the electrical stimulation lead further comprises a paddle body disposed at the distal end of the electrical stimulation lead.

18. The electrical stimulation lead implantation kit of claim 15, wherein the distal end of the electrical stimulation lead is formed in a hook or coil shape.

19. The electrical stimulation lead implantation kit of claim 15, further comprising a control module coupleable to the terminals of the electrical stimulation lead.

20. The electrical stimulation lead implantation kit of claim 15, further comprising a lead extension coupleable to the electrical stimulation lead.

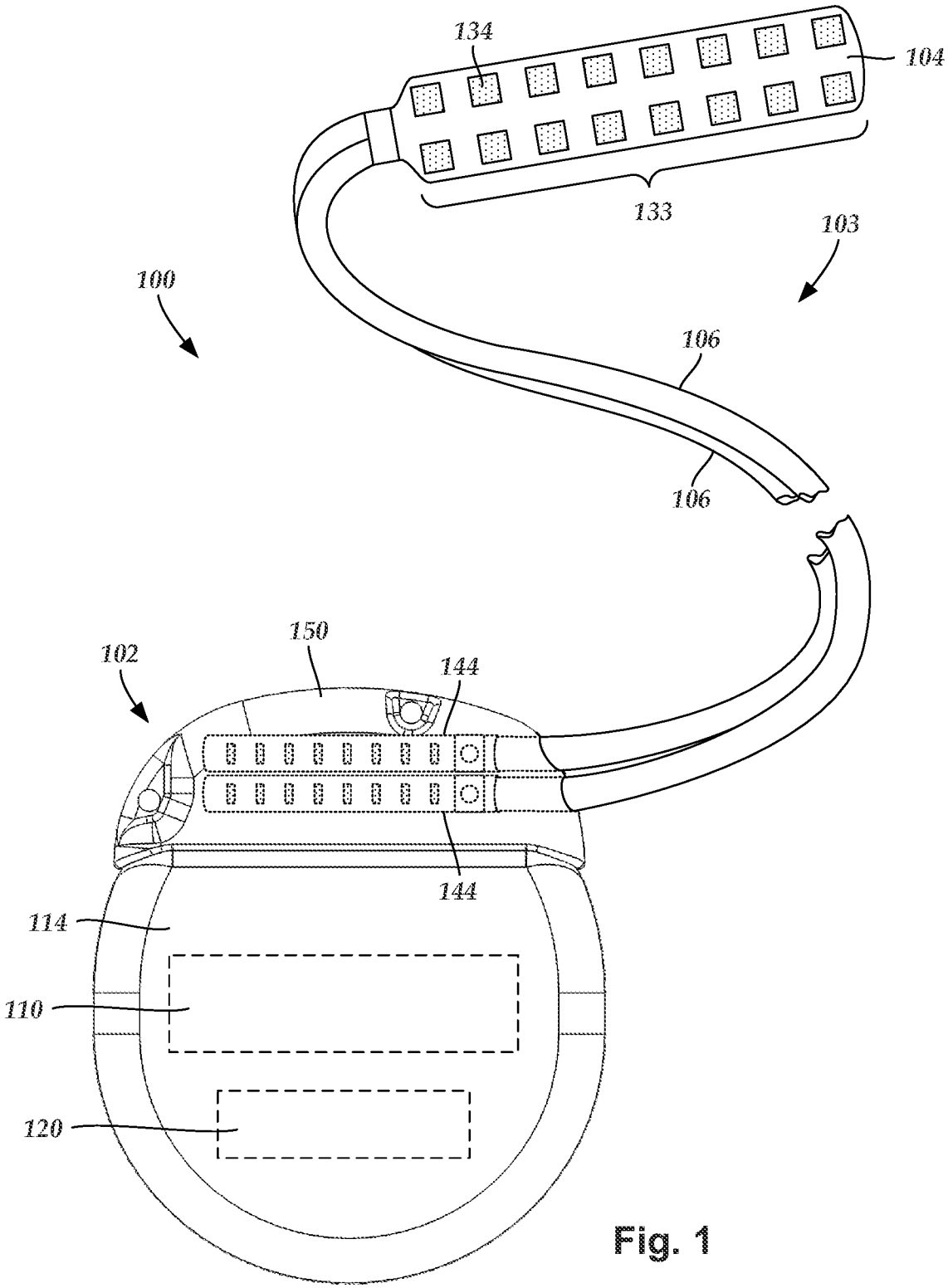

Fig. 1

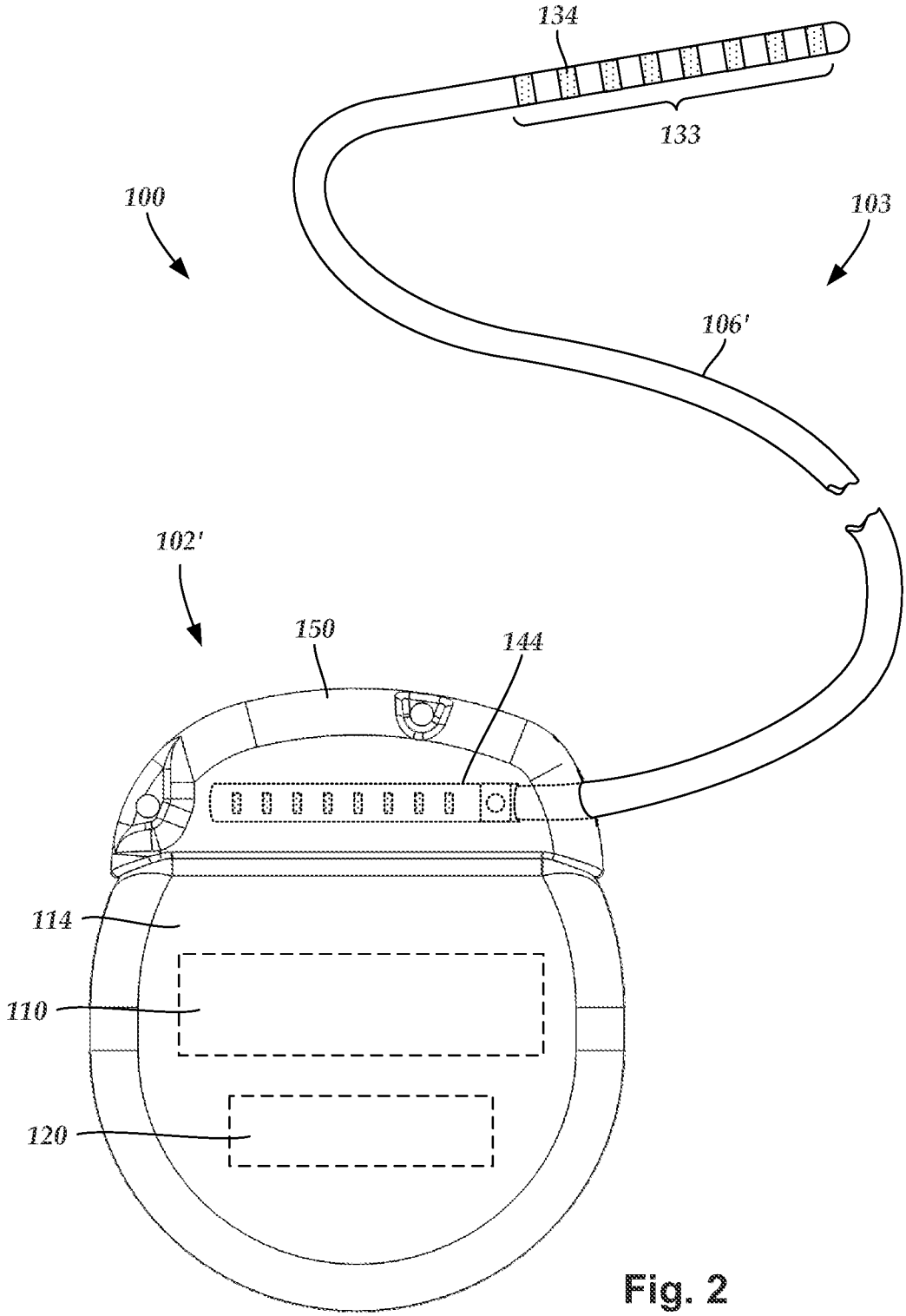

Fig. 2

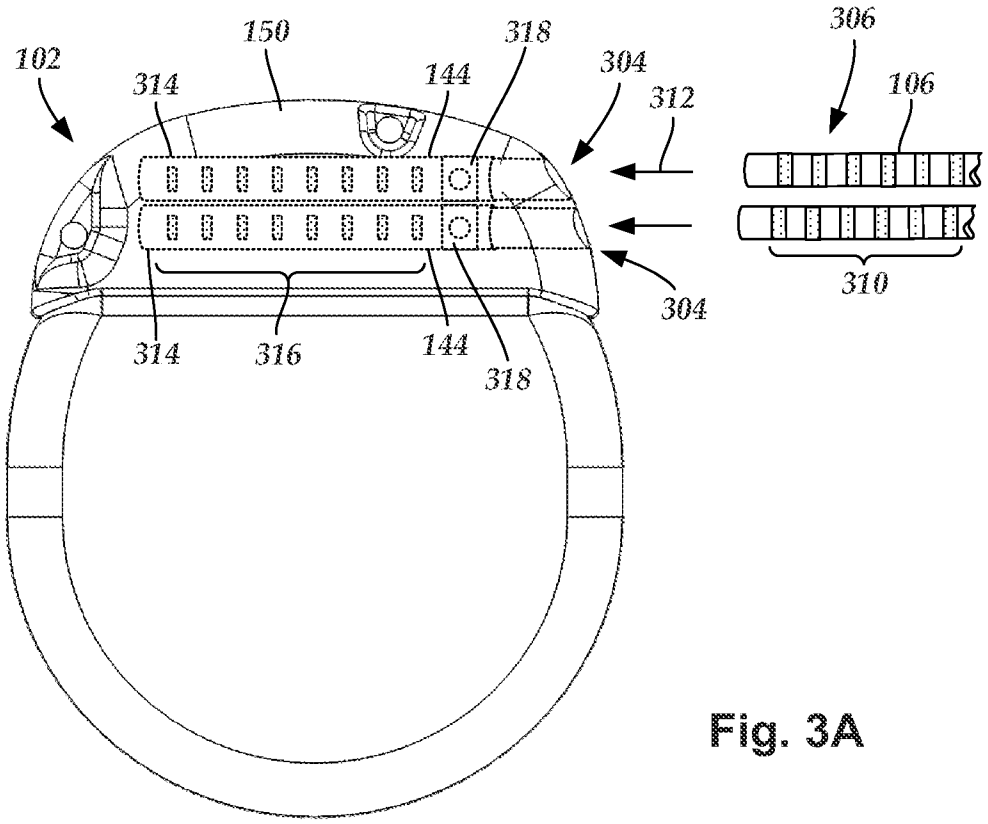
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Fig. 3A

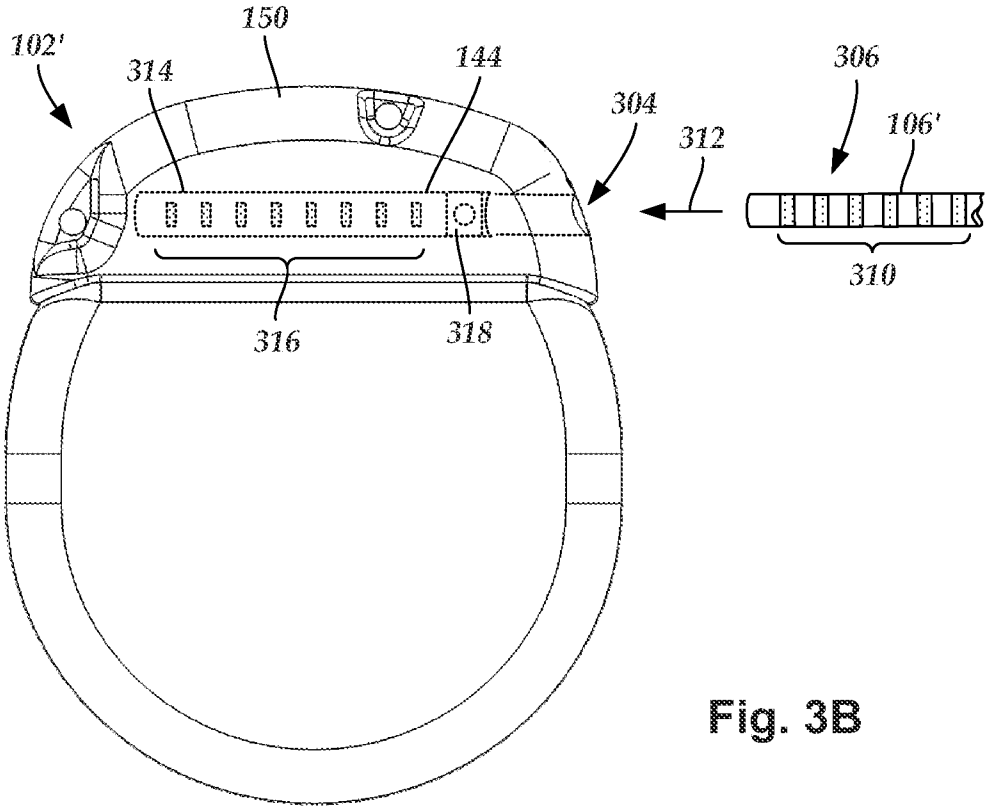
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Fig. 3B

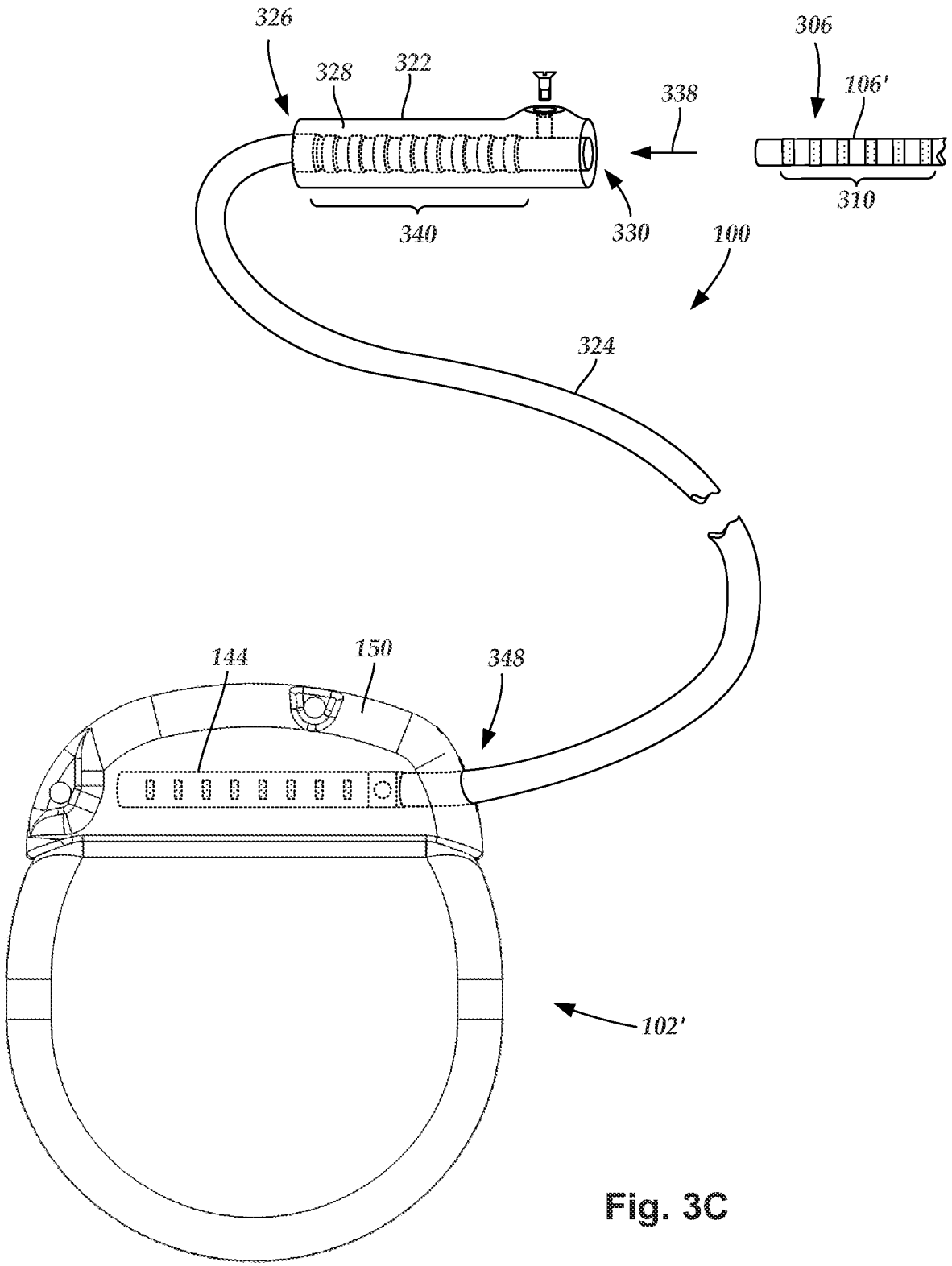

Fig. 3C

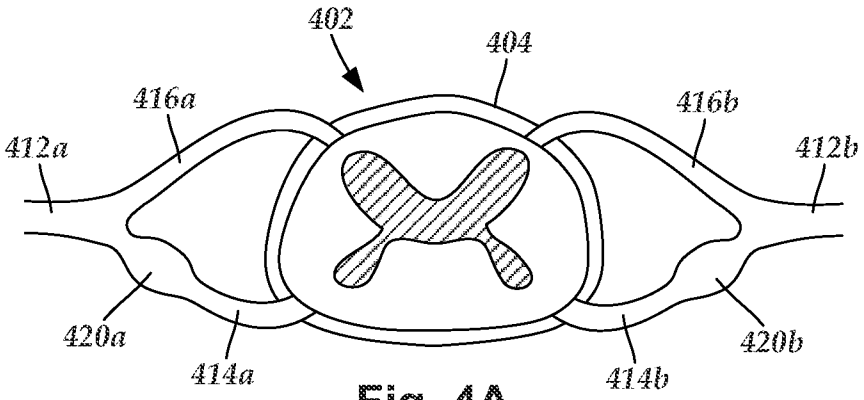
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Fig. 4A

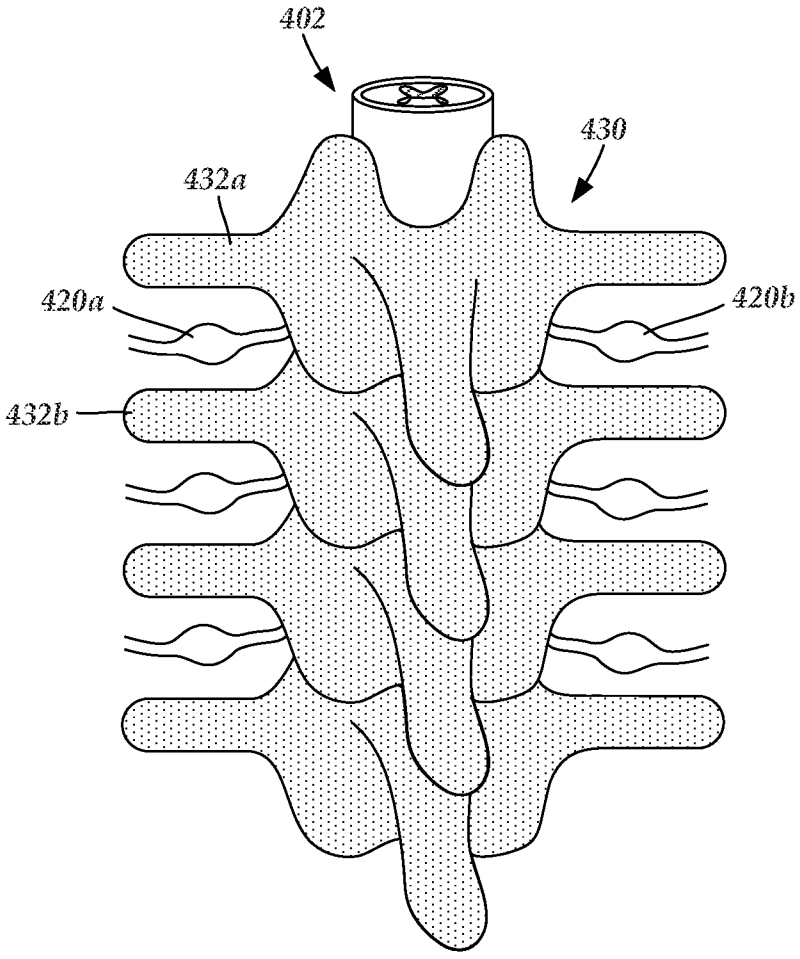
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Fig. 4B

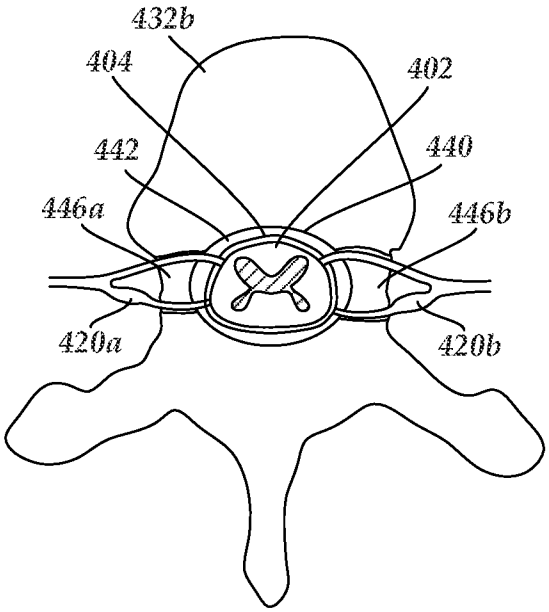

Fig. 4C

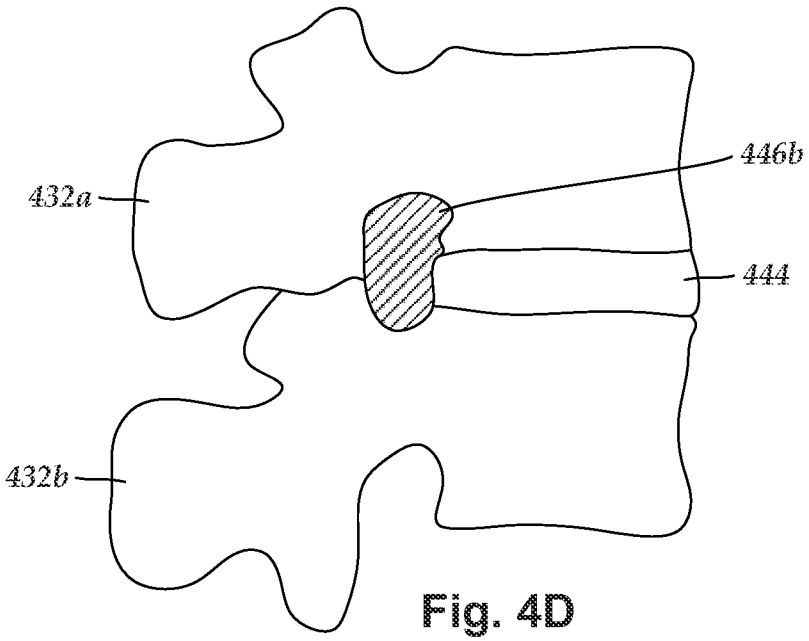

Fig. 4D

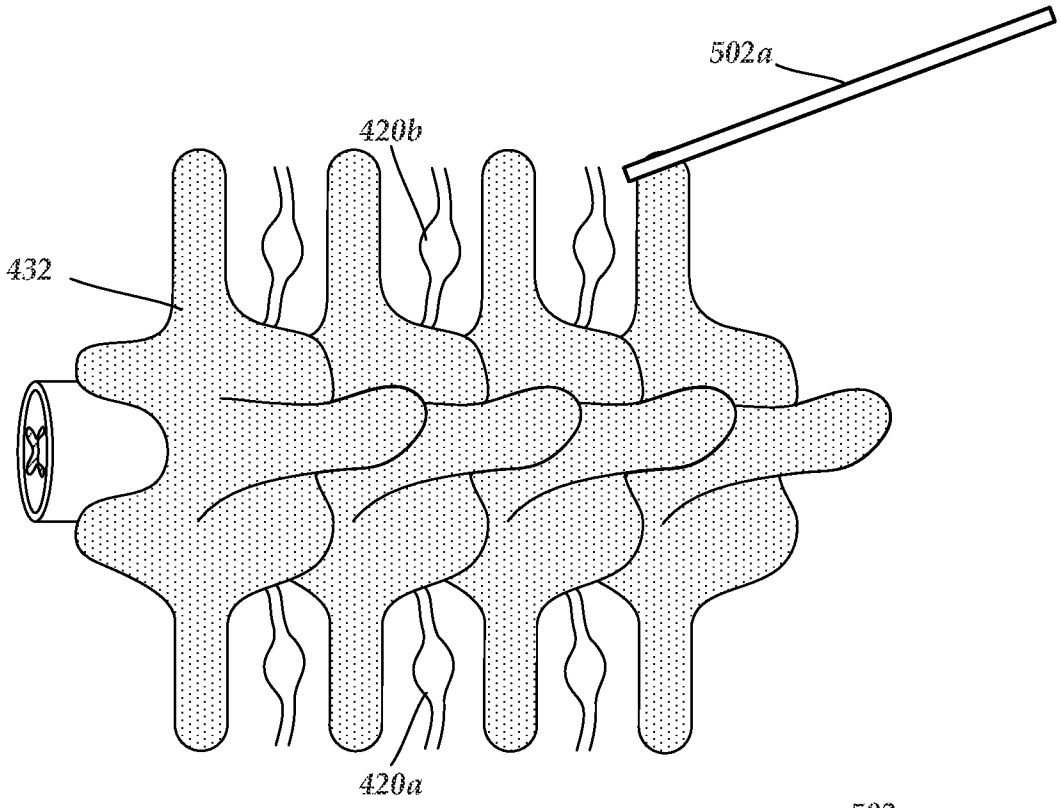

Fig. 5A

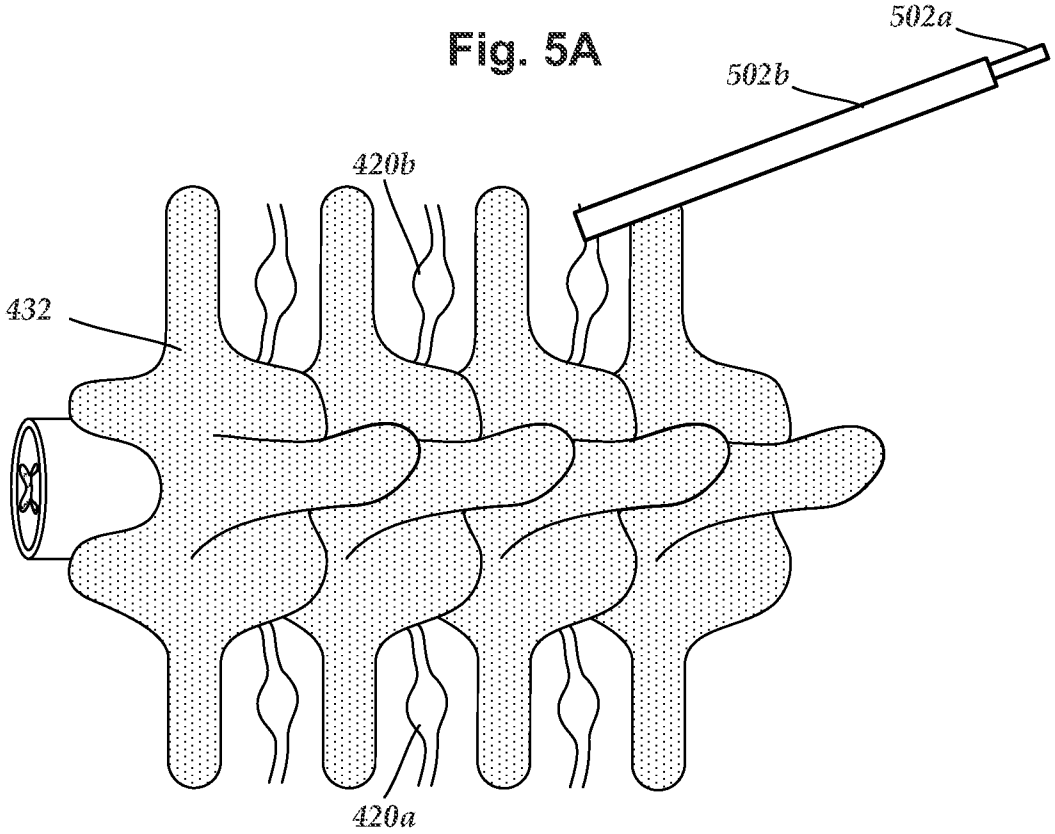

Fig. 5B

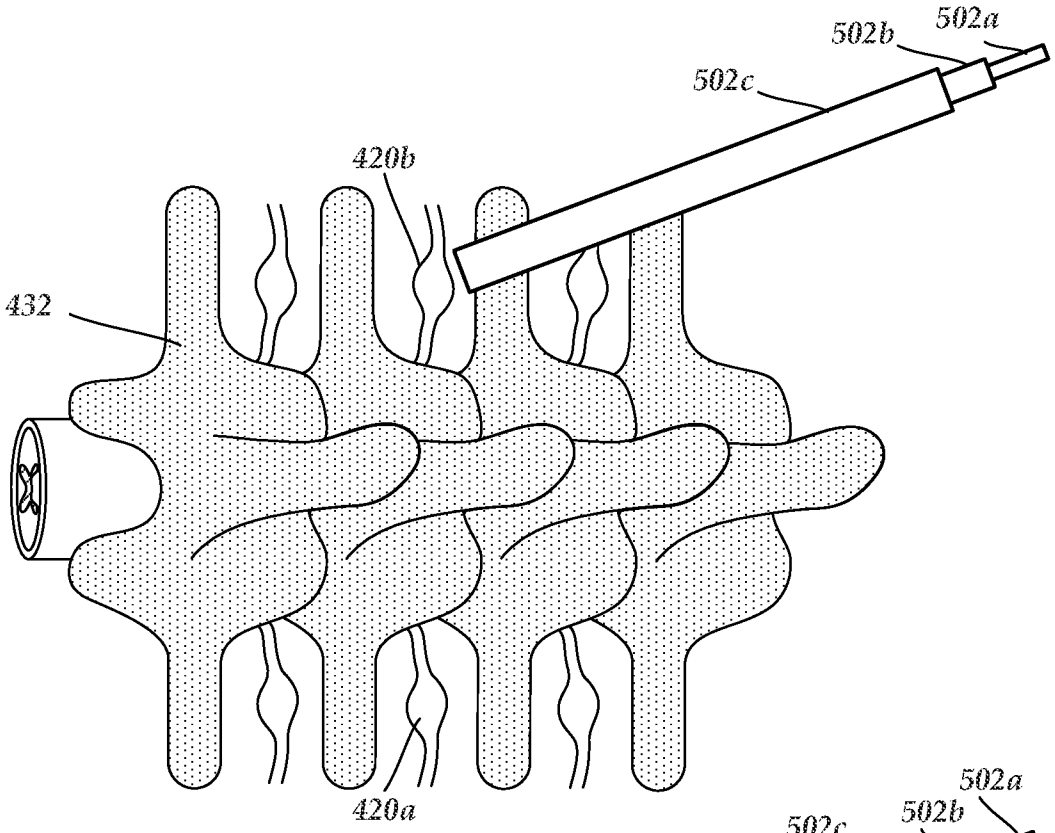
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Fig. 5C

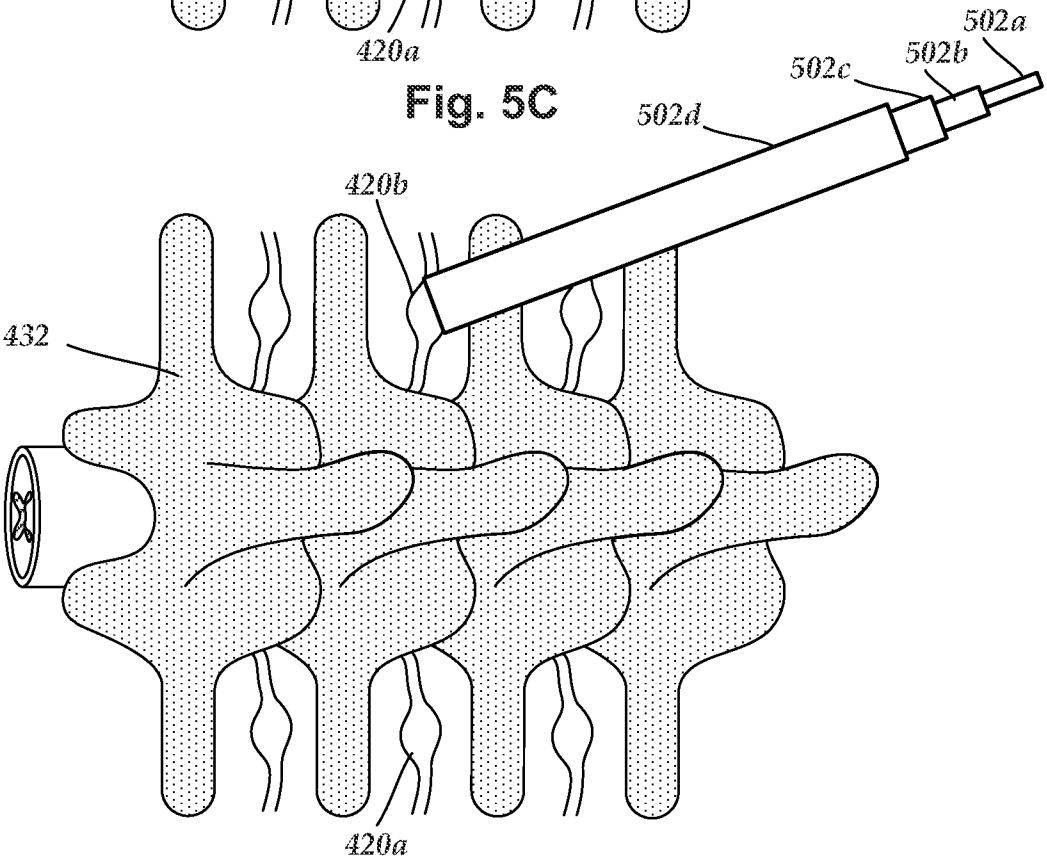
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Fig. 5D

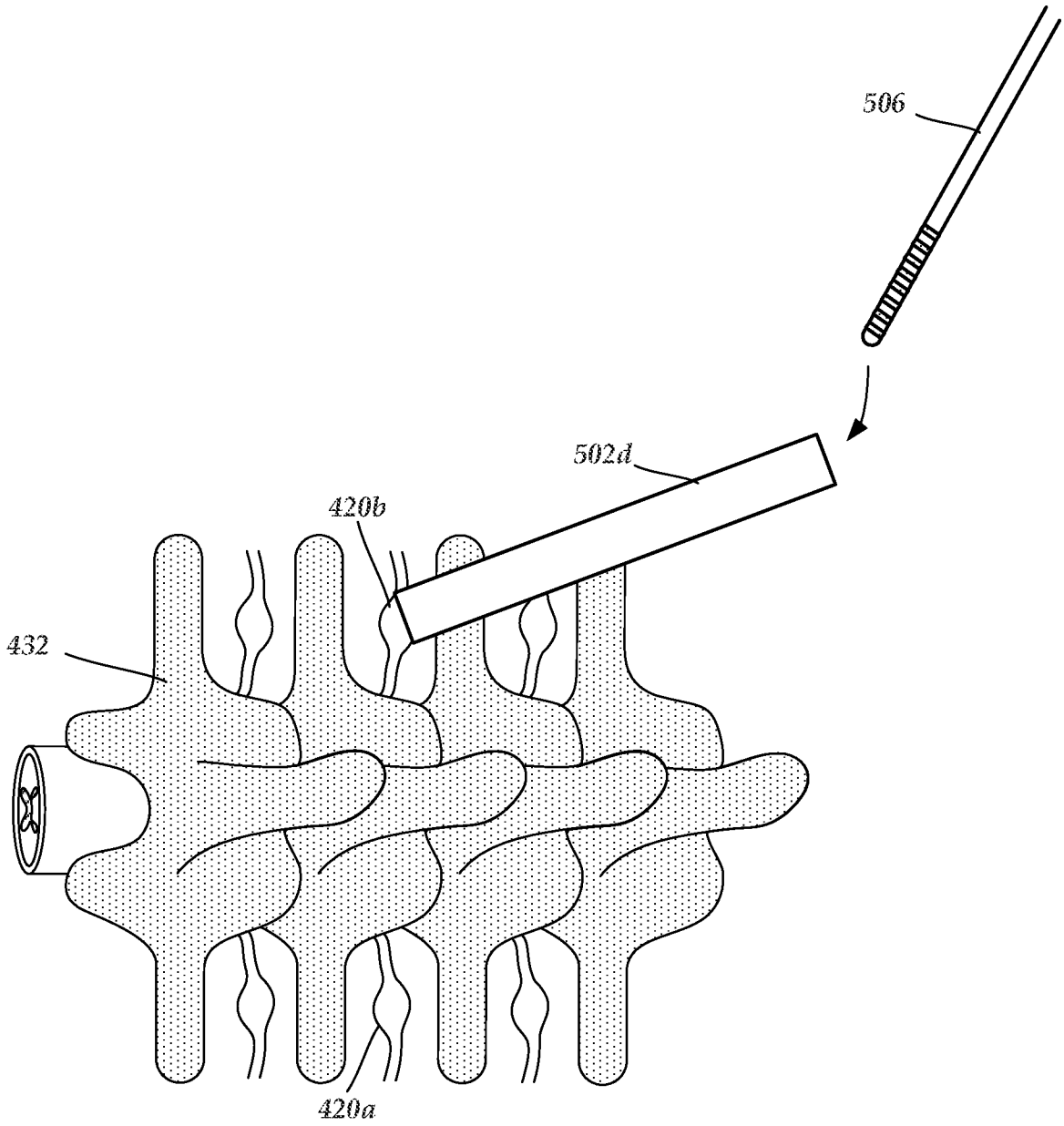

Fig. 5E

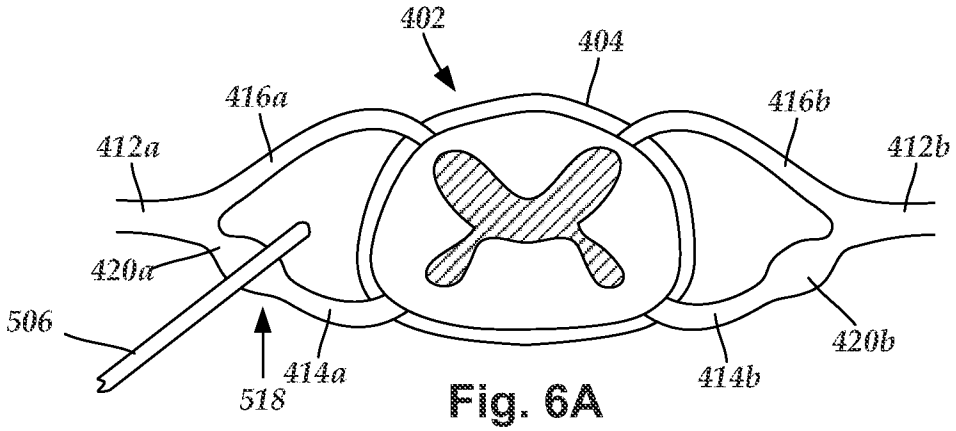

Fig. 6A

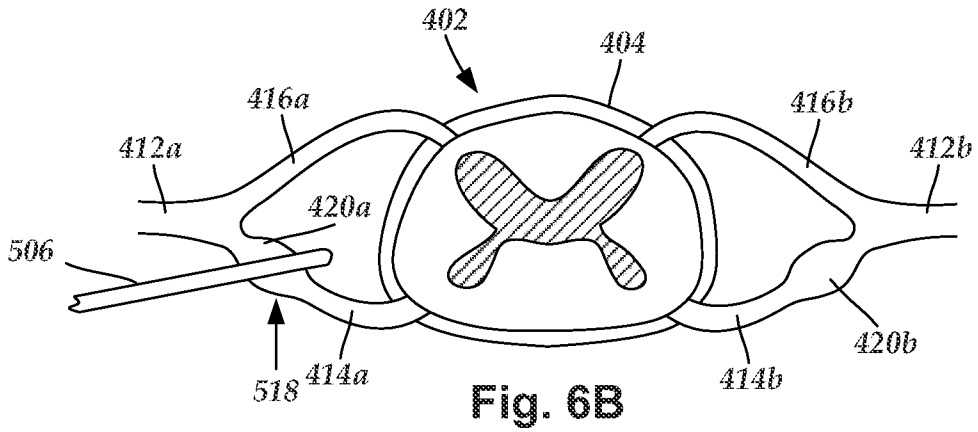

Fig. 6B

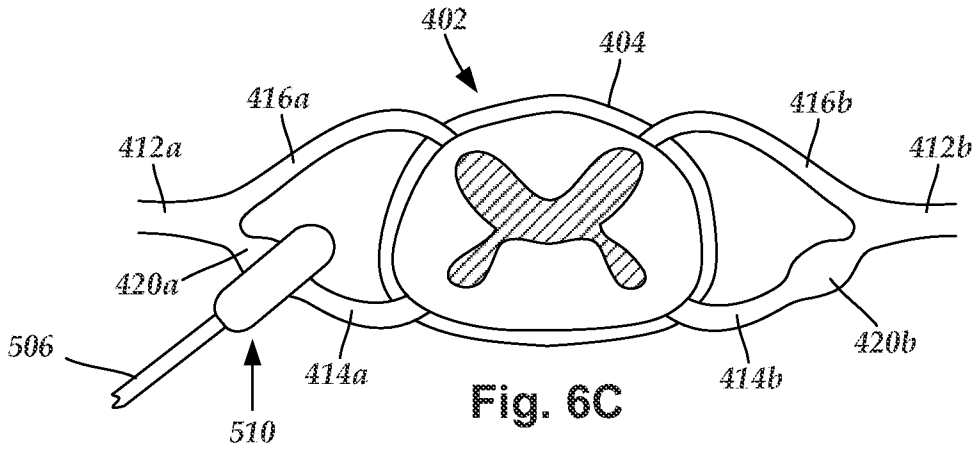

Fig. 6C

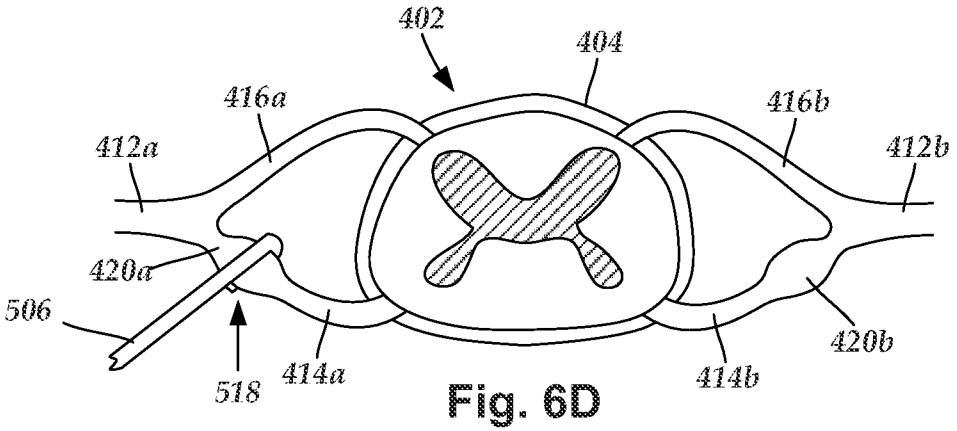
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Fig. 6D

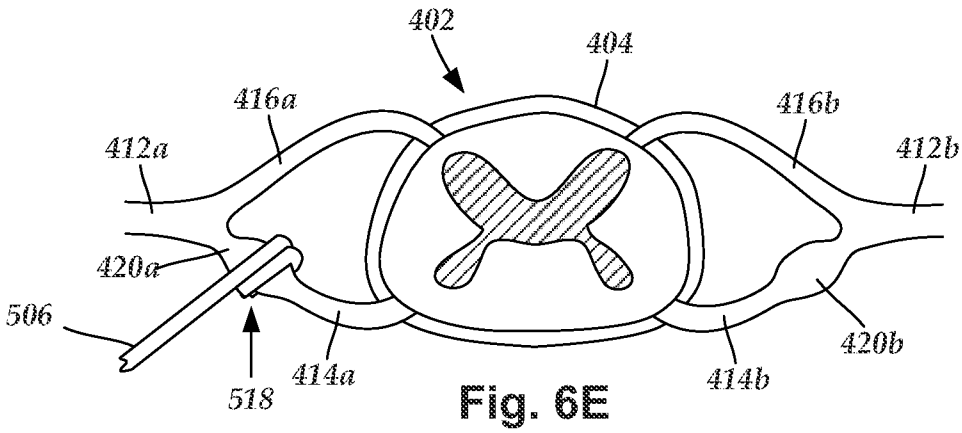
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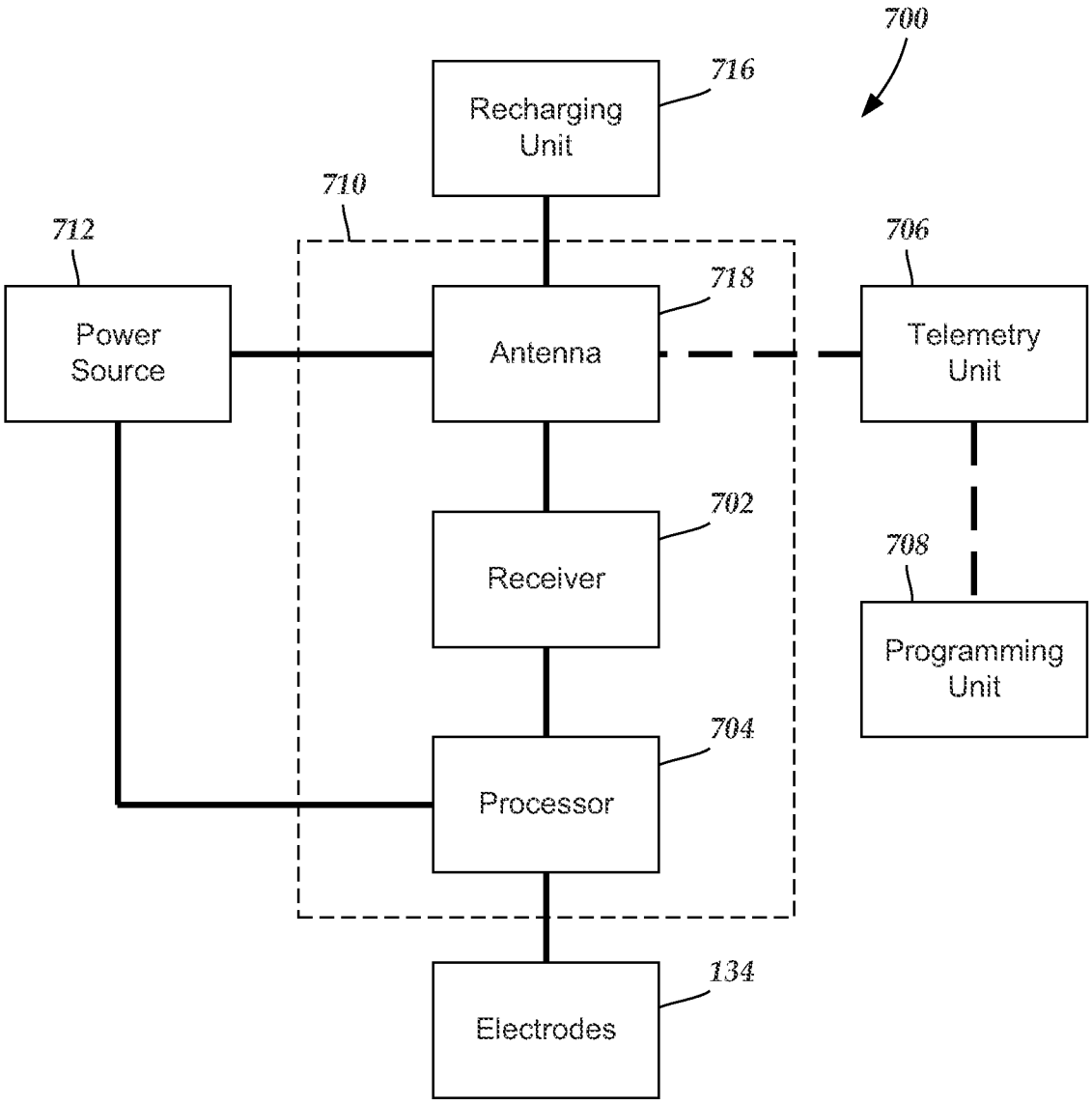
Fig. 6E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Recharging Unit
710
712
706
718
Power Source
Antenna
Telemetry Unit
702
708
Receiver
Programming Unit
704
Processor
134
Electrodes

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/042268

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34
ADD. A61N1/05

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)
A61B 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 practicable, 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	WO 2010/083308 A1 (SPINAL MODULATION INC [US]; LINKER FRED I [US]; BROUNSTEIN DANIEL M [U) 22 July 2010 (2010-07-22) figures 24A, 27, 37 paragraph [0063] paragraph [0102] - paragraph [0109] paragraph [0139] - paragraph [0143] paragraph [0158] -----	15-20
X	WO 03/084398 A1 (MANN ALFRED E FOUND SCIENT RES [US]) 16 October 2003 (2003-10-16) figures 7, 11 page 9, line 5 - page 10, line 9 page 11, line 18 - page 13, line 13 -----	15-20

-/--

[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 application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 August 2013	19/08/2013

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

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/042268

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 2005/033374 A1 (GERBER MARTIN T [US]) 10 February 2005 (2005-02-10) the whole document -----	15-20
A	WO 03/020365 A1 (MEDTRONIC INC [US]) 13 March 2003 (2003-03-13) the whole document -----	15-20

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/042268

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. [X] Claims Nos.: 1-14
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 all searchable 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 report covers 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/US2013/042268

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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