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(54) **Title:** IMPLANTABLE ELECTRODE ASSEMBLY

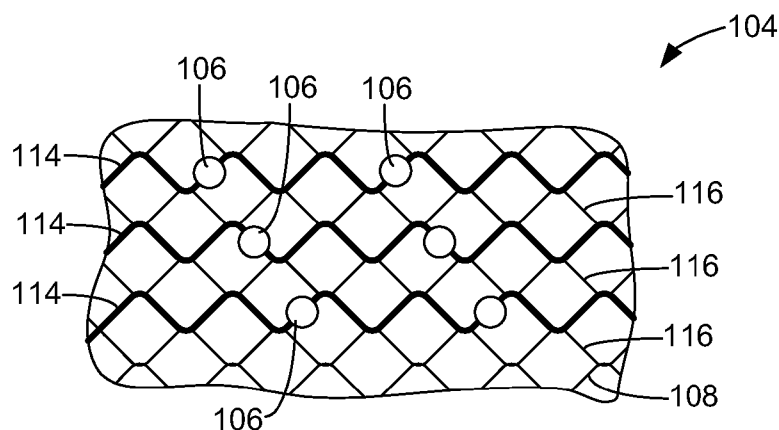


FIG. 3

(57) **Abstract:** An implantable electrode assembly (104) configured to deliver electrical stimulation signals to tissue of a patient includes an implantable mesh (108) comprising a plurality of electrically conductive wires (114). A plurality of electrodes (106) are fastened to the electrically conductive wires. The electrodes include a stimulation surface (134) and an electrically conductive path between the stimulation surface and the wire, to which the electrode is attached. In one embodiment, the plurality of electrodes each comprise first and second members (130, 132) that are fastened together around one of the electrically conductive wires.



IMPLANTABLE ELECTRODE ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is based on and claims the benefit of U.S. provisional patent application Serial No. 61/532,277, filed September 8, 2011, the content of which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] Implantable electronic stimulator devices, such as neuromuscular stimulation devices, have been disclosed for use in the treatment of various pelvic conditions, such as urinary incontinence, fecal incontinence and sexual dysfunction. Such devices generally include one or more electrodes that are coupled to a control unit by electrode leads. A stimulation therapy is applied to the tissue through the electrode leads to treat the condition of the patient. Exemplary implantable electronic stimulator devices and uses of the devices are disclosed in U.S. Patent Nos. 6,354,991, 6,652,449, 6,712,772 and 6,862,480, each of which is hereby incorporated by reference in its entirety.

[0003] The electrode leads typically include a tissue anchor, such as a helical coil or mesh. The primary objective of the tissue anchor is to prevent migration of the electrode lead within the tissue of the patient, as such movement may adversely affect the stimulation therapy.

SUMMARY

[0004] Embodiments of the invention are directed to an implantable electrode assembly that is configured to deliver electrical stimulation signals to tissue of a patient. In one embodiment, the implantable electrode assembly includes an implantable mesh comprising a plurality of electrically conductive wires. A plurality of electrodes are fastened to the electrically conductive wires. In one embodiment, the electrodes include a stimulation surface and an electrically conductive path between the stimulation surface and the wire, to which the electrode is attached. In one embodiment, the plurality of electrodes each comprise first and second members that are fastened together around one of the electrically conductive wires.

[0005] In accordance with another embodiment, the implantable electrode assembly comprises an implantable mesh including a plurality of tabs and a plurality of electrodes each fastened to one of the tabs.

[0006] Yet another embodiment of the invention is directed to a method, in which an implantable mesh comprising a plurality of electrically conductive wires is provided. A plurality of electrodes are fastened to the electrically conductive wires. In one embodiment, the electrodes are fastened to the electrically conductive wires by mechanically fastening first and second members of each of the electrodes to one of the wires. A conductive path is formed between stimulation surfaces of the electrodes and the conductive wires responsive to the fastening of the electrodes to the wires.

[0007] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter. The claimed subject matter is not limited to implementations that solve any or all disadvantages noted in the Background.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a schematic illustration of an exemplary electronic stimulator device having an electrode assembly formed in accordance with embodiments of the invention implanted around a urethra of a patient.

[0009] FIG. 2 is a schematic illustration of an electronic stimulator device including an electrode assembly formed in accordance with embodiments of the invention.

[0010] FIG. 3 is schematic illustration of a portion of an electrode assembly in accordance with embodiments of the invention.

[0011] FIGS. 4 and 5 are schematic illustrations of an electrode assembly in accordance with embodiments of the invention.

[0012] FIG. 6 is a simplified isometric view of an electrode fastened to an electrically conductive wire in accordance with embodiments of the invention.

[0013] FIGS. 7 and 8 respectively are cross-sectional exploded and assembled views of the electrode of FIG. 6 taken generally along line 6-6, in accordance with embodiments of the invention.

[0014] FIGS. 9 and 10 respectively are cross-sectional exploded and assembled views of the electrode of FIG. 6 taken generally along line 6-6, in accordance with embodiments of the invention.

[0015] FIG. 11 is a flowchart illustrating a method in accordance with embodiments of the invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0016] Embodiments of the invention are described more fully hereinafter with reference to the accompanying drawings. The various embodiments of the invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Elements that are identified using the same or similar reference characters refer to the same or similar elements.

[0017] It will be understood that when an element is referred to as being "connected" or "coupled" to another element, it can be directly connected or coupled to the other element or intervening elements may be present. In contrast, if an element is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present. As used herein, the term "mechanically coupled" or "mechanically fastened" is a technique of coupling elements without welding or soldering that utilizes cooperating members of the elements to physically join the elements together.

[0018] It will be understood that, although the terms first, second, etc. may be used herein to describe various elements, these elements should not be limited by these terms. These terms are only used to distinguish one element from another. Thus, a first element could be termed a second element without departing from the teachings of the present invention.

[0019] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to

which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art, and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0020] FIG. 1 is a schematic illustration of an exemplary electronic stimulator device 100 in accordance with embodiments of the invention. In one embodiment, the device 100 comprises a control unit 102, and an electrode assembly 104 formed in accordance with one or more embodiments described herein. The control unit 102 may be in the form of an implantable device powered by a battery, or an external device.

[0021] In one embodiment, the control unit 102 is a conventional device that generates current pulses for stimulation therapies that treat a condition of a patient. In one embodiment, the electrode assembly 104 is configured for implantation into a pelvic region of a patient and delivers current pulses generated by the control unit 102 to muscle tissue and/or nerves to control and/or treat a pelvic condition of the patient, such as pelvic pain, urinary incontinence, fecal incontinence, erectile dysfunction or other pelvic condition that may be treated through electrical stimulation. For instance, the electrode assembly 104 may be implanted adjacent the urethra 105 of a patient, such as illustrated in FIG. 1, to treat urinary incontinence. The assembly 104 may be implanted in other areas of the pelvic region to treat other conditions of the patient.

[0022] FIG. 2 is a schematic illustration of an electronic stimulator device 100 including an electrode assembly 104 formed in accordance with embodiments of the invention. In one embodiment, the electrode assembly 104 includes one or more electrodes 106 attached to mesh 108, which may be electrically coupled to the control unit 102 through an implantable lead 110. In one embodiment, the assembly 104 includes a connector (not shown) that attaches to a distal end 112 of the lead 110 and forms an electrical connection between one or more electrically conductive wires 114 of the assembly 104 that are coupled to the electrodes 106 and wires within the lead 110 that are coupled to the control unit 102. Thus, current pulses generated by the control unit 102 may be delivered to target tissue of the patient through the lead 110 and the electrodes 106.

[0023] In one embodiment, each of the electrodes 106 is coupled to the control unit 102 through a single conductive path. As a result, current pulses generated by the control unit 102 are delivered simultaneously to each of the electrodes 106 of the assembly 104.

[0024] In one embodiment, each of the electrodes 106, or subsets of the electrodes 106, are electrically coupled to the control unit 102 through different conductive paths. This allows the control unit 102 to apply different current pulses to different electrodes 106 or groups of electrodes 106, and apply the current pulses at different times. This feature can simplify the placement of the assembly 104 near the target site, as the electrodes 106 may be tested to determine which of the electrodes 106 is in the best position to apply the electrical stimulation therapy to the patient.

[0025] In one embodiment, the control unit 102 includes memory and a processor configured to execute a stimulation program stored in the memory. The stimulation program defines the current pulses to be applied to the electrodes 106, identifies the electrodes 106 that are to receive the current pulses, and defines a timing schedule that determines when the electrodes 106 receive the current pulses. The execution of the stimulation program by the processor causes the control unit 102 to deliver stimulation pulses to the electrodes in accordance with the stimulation program to treat a condition of the patient.

[0026] In one embodiment, the mesh 108 is flexible and configured to bend around the target site, such as around the urethra 105 of the patient, as shown in FIG. 1. Tissue ingrowth through the mesh 108 operates to anchor the electrodes 106 relative to the tissue, in which the mesh 108 is implanted. This prevents undesirable migration of the electrodes 106 relative to the tissue.

[0027] FIG. 3 is a schematic illustration of a portion of the electrode assembly 104 in accordance with embodiments of the invention. In one embodiment, the mesh 108 comprises one or more of the electrically conductive wires 114. In one embodiment, the wires 114 are woven together to form the mesh. In one embodiment, the mesh 108 also includes electrically insulative or non-conducting fibers 116, such as fibers formed of polypropylene or other suitable biocompatible material. In one embodiment, the wires 114 are woven through the insulative fibers 116, as shown in FIG. 3. While the electrically conductive wires 114 are illustrated in FIG. 3 as generally extending in a single direction, electrically conductive wires 114 can be included in the mesh 108 that extend transversely to those illustrated in FIG. 3.

[0028] In one embodiment, the electrodes 106 are arranged in a desired pattern on the mesh 108. Thus, the electrodes 106 may be arranged in a line, an array, or other desired pattern.

[0029] FIGS. 4 and 5 are schematic illustrations of the electrode assembly 104 in accordance with embodiments of the invention. Details of the mesh 108 are not shown in order to simplify the illustrations. In one embodiment, the mesh 108 includes tabs 118 that extend from an edge or side of the mesh 108. In one embodiment, the tabs 118 extend along opposing side edges 120 and 122 of the mesh 108, as shown in FIG. 4. In one embodiment, the tabs 118 extend from a single edge 122 of the mesh 108, as shown in FIG. 5.

[0030] In one embodiment, each of the plurality of tabs 118 are each separated from adjacent tabs 118 by a gap 124, as shown in FIG. 4. In one embodiment, at least some of the tabs 118 are separated from other portions of the mesh 108 on three sides, as shown in FIG. 4. This allows the tabs 118 to flex relative to other portions of the mesh 108 and provides a wide range of movement of the individual electrodes 106 that are attached to each of the tabs 118, and allows for additional adjustments to be made to the relative positions of the electrodes 106 to optimize the location of electrodes 106 within the target site.

[0031] In one embodiment, some of the tabs 118 adjoin adjacent tabs, as shown in FIG. 5. In one embodiment, the separation between adjacent tabs 118 is formed by a cut 126 in the mesh 108.

[0032] In one embodiment, the electrodes 106 are attached to the mesh 108 using a suitable adhesive or over-molding process. In one embodiment, each of the electrodes 106 is electrically coupled to one of the wires 114 using a conventional process, such as welding or soldering.

[0033] In accordance with one embodiment, the electrodes 106 are each mechanically coupled to one of the wires 114 of the mesh 108. FIG. 6 is a simplified isometric view of an exemplary electrode 106 that is mechanically fastened to an electrically conductive wire 114 in accordance with embodiments of the invention. In one embodiment, the electrode 106 includes members 130 and 132, and a stimulation surface 134, which is electrically coupled to the wire 114 responsive to the mechanical fastening of the members 130 and 132 together around the wire 114.

[0034] The mechanically fastened feature of the electrodes 106 allows for customized placement of the electrodes 106 on the mesh 108. For instance, the electrodes 106 can be coupled

to a selection of the available tabs 118 of the mesh 108 (FIGS. 4 and 5), or the electrodes 106 may be arranged in a desired pattern over the mesh 108.

[0035] FIG. 7 is a cross-sectional exploded view of the exemplary electrode 106 depicted in FIG. 6 taken along line 6-6 that is positioned around an electrically conductive wire 114. FIG. 8 is a cross-sectional view of the electrode of FIG. 7 with the first and second members 130 and 132 mechanically fastened around the wire 114.

[0036] In one embodiment, the wire 114 comprises an electrically insulative jacket 136 surrounding an electrically conductive core 138. In one embodiment, the member 130 includes a piercing member 140 that is configured to pierce the insulative jacket 136 of the wire 114 when the members 130 and 132 are mechanically fastened together, as shown in FIG. 8. The piercing of the insulative member 136 by the piercing member 140 creates a conductive path between the electrically conductive core 138 of the wire 114 and the stimulation surface 134. As a result, current pulses generated by the control unit 102 that are transmitted through the wire 114 are delivered to the stimulation surface 134 through the conductive path formed by the piercing member 140.

[0037] In one embodiment, the piercing member 140 comprises an electrically conductive protrusion 142. As illustrated in FIGS. 7 and 8, one embodiment of the protrusion 142 is a conical member, a point of which is used to pierce the insulative jacket 136 and engage the electrically conductive core 138.

[0038] FIGS. 9 and 10 respectively are cross-sectional exploded and assembled views of the electrode of FIG. 6 taken generally along lines 6-6, in accordance with embodiments of the invention. In accordance with another embodiment, the protrusion 142 is in the form of a blade member, as shown in FIGS. 9 and 10. In one embodiment, the blade member form of the protrusion 142 slices through the insulative jacket 136 to contact the conductive core 138 and form the electrical connection between the conductive core 138 and the stimulation surface 134.

[0039] In one embodiment, the members 130 and 132 are mechanically fastened together around the wire using mechanical coupling. In one embodiment, the members 130 and 132 are fastened together by hand using the mechanical coupling.

[0040] In one embodiment, the mechanical coupling comprises cooperating portions of the members 130 and 132 that interface to fasten the members 130 and 132 together. In one

exemplary embodiment, the member 132 includes arms 146 and 148 that define a recess 150 that is configured to receive the member 130, as shown in FIGS. 7 and 8. In one embodiment, the arms 146 and 148 flex to allow for the insertion of the member 130 within the recess 150. In one embodiment, the arms 146 extend over a top surface 152 of the member 130 to secure the member 130 within the recess 150, and provide a snap-fit connection. Other cooperating features of the members 130 and 132 may be used to provide a similar snap-fit connection and mechanically fasten the members 130 and 132 together.

[0041] In accordance with another embodiment, the mechanical coupling provides a press-fit connection (i.e., friction fit) between the first and second members 130 and 132. In one exemplary embodiment, the recess 150 of the member 132 is sized such that the sides 154 of the recess 150 interfere with the sides 156 of the member 130, as shown in FIGS. 9 and 10. When the member 130 is forced into the recess 150, the friction between the sides 154 and 156 fastens the members 130 and 132 together.

[0042] In one embodiment, at least one of the members 130 and 132 includes a wire guide that is configured to position the wire 114 in a predetermined location. In one embodiment, the wire guide is configured to promote the piercing of the insulative jacket 136 by the piercing member 140 when the members 130 and 132 are fastened together.

[0043] In one exemplary embodiment, the wire guide comprises a recess 158 that is formed in the member 132. The recess 158 is configured to position the wire in alignment with the piercing member 140, such that the piercing member 140 pierces the insulative jacket 136 of the wire 114 when the members 130 and 132 are mechanically fastened together, as shown in FIG. 8. In one embodiment, the member 130 includes a wire guide in the form of a recess 159, which operates to center the piercing member 140 over the wire 114 when the members 130 and 132 are fastened together.

[0044] FIG. 11 is a flowchart illustrating a method in accordance with embodiments of the invention. At 160 of the method, an implantable mesh 108 is provided comprising a plurality of electrically conductive wires 114 and electrically insulative fibers 116, such as shown in FIG. 3.

[0045] At 162, a plurality of electrodes 106 are fastened to the electrically conductive wires 114. In one embodiment, the electrodes 106 are mechanically fastened to the electrically conductive wires through a mechanical coupling between members 130 and 132 of the electrodes

106. Exemplary embodiments of the mechanical coupling are discussed above with reference to FIGS. 6-10.

[0046] In one embodiment of step 162, portions of the members 130 and 132 are snap-fit together, as exemplified in FIGS. 7 and 8. In accordance with another embodiment, portions of the members 130 and 132 are press-fit together to fasten electrode 106 to the conductive wire 114, as exemplified in FIGS. 9 and 10.

[0047] At 164 of the method, a conductive path is formed between the stimulation surfaces 134 of the electrodes 106 and the conductive wires 114, to which they are attached. In one embodiment, the conductive path is formed responsive to the fastening step 162. In accordance with exemplary embodiments, one or both of the members 130 and 132 includes a piercing member 140 that pierces an insulative jacket 136 of the wire 114 and engages an electrically conductive core 138 of the wire 114, as shown in FIGS. 8 and 10. The engagement of the piercing member 140 with the electrically conductive core 138 provides a conductive path between the conductive core 138 and the stimulation surface 134 of the electrode 106.

[0048] In accordance with another embodiment of the method, the electrode assembly 104 formed of the mesh 108 and the fastened electrodes 106 is implanted in tissue of a patient. In one embodiment, the electrode assembly 104 is implanted within a pelvic region of a patient, such as around the urethra 105 (FIG. 1), or other location. In one embodiment, electrical stimulation signals are delivered to the tissue of the patient through the conductive wires 114 and one or more of the attached electrodes 106 to treat a condition of the patient, such as, for example, urinary incontinence, fecal incontinence, sexual dysfunction, pelvic pain due to interstitial cystitis, or other pelvic condition.

[0049] Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An implantable electrode assembly (104) for delivering electrical stimulation signals to tissue of a patient, the assembly comprising:
 - an implantable mesh (108) comprising a plurality of electrically conductive wires (114);
 - and
 - a plurality of electrodes (106) each comprising first and second members (130, 132) fastened together around one of the electrically conductive wires, and a stimulation surface (134), wherein an electrically conductive path is formed between the stimulation surface and the wire.
2. The assembly of claim 1, wherein:
 - the electrically conductive wires each comprise an electrically insulative jacket (136) surrounding an electrically conductive core (138);
 - at least one of the first and second members comprises a piercing member (140) that pierces the insulative jacket and contacts the conductive core of the wire, to which the first and second members are fastened; and
 - the piercing member forms a portion of the electrically conductive path.
3. The assembly of claim 2, wherein the piercing member comprises an electrically conductive protrusion (142).
4. The assembly of claim 3, wherein the protrusion comprises a conical member.
5. The assembly of claim 3, wherein the protrusion comprises a blade member.
6. The assembly of claim 2, wherein at least one of the first and second members comprises a wire guide configured to position the wire, around which the first and second members are fastened, in a predetermined location.
7. The assembly of claim 6, wherein the wire guide comprises a recess (158, 159) in at least one of the first and second members.
8. The assembly of claim 2, wherein each of the electrodes comprises a mechanical coupling that fastens the first and second members together.

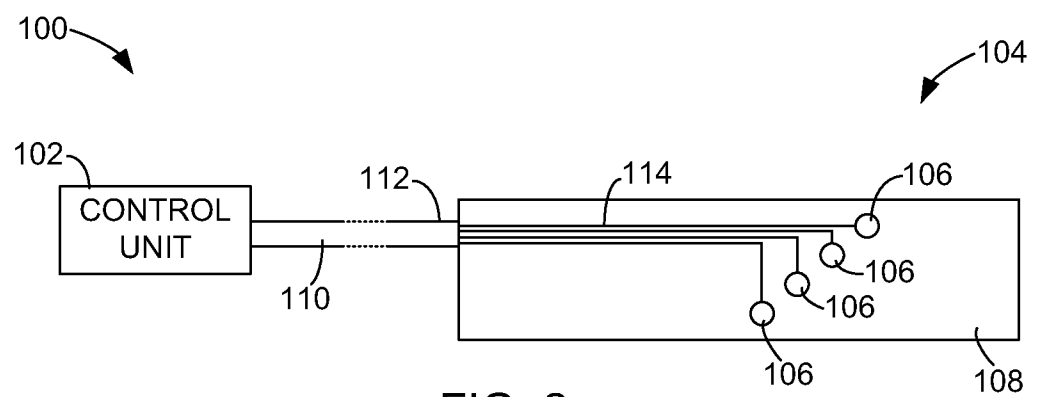
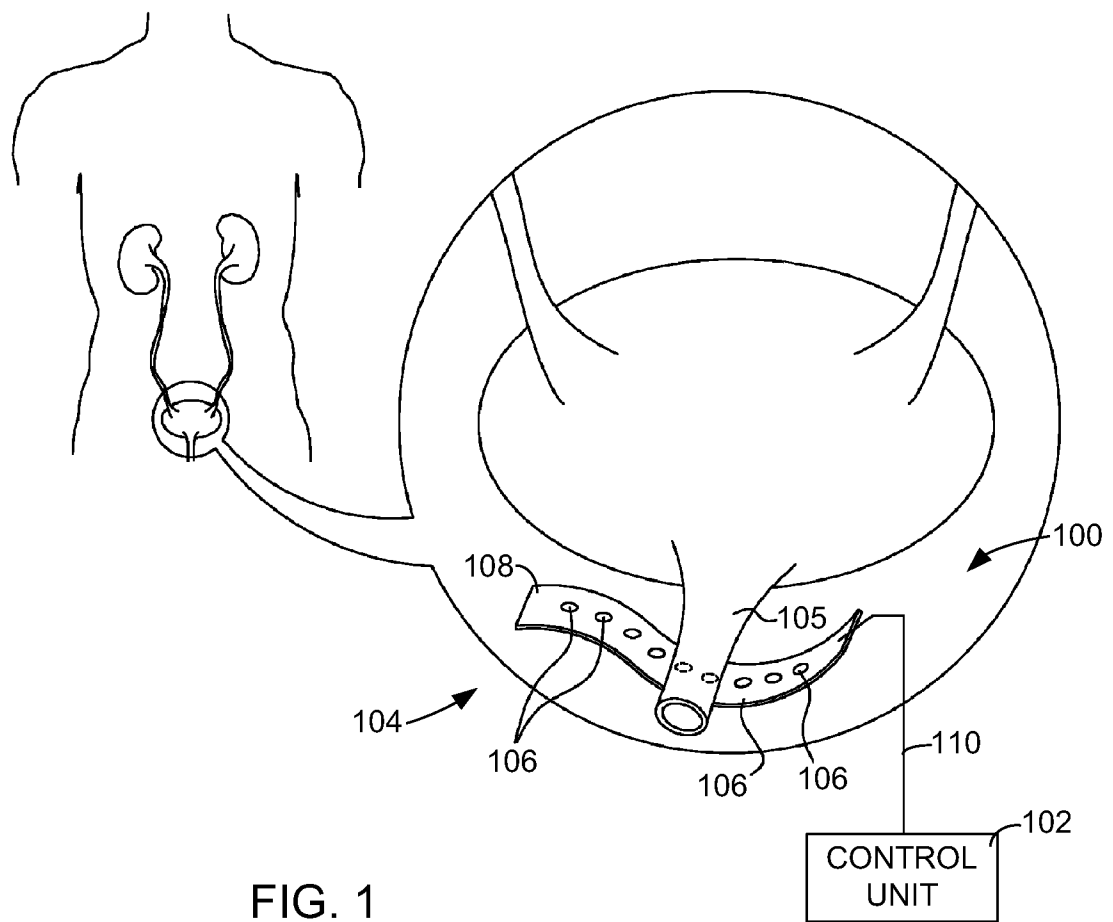
9. The assembly of claim 8, wherein the mechanical coupling comprises cooperating portions of the first and second members that interface to fasten the first and second members together.
10. The assembly of claim 9, wherein the cooperating portions form a snap-fit connection between the first and second members.
11. The assembly of claim 9, wherein the cooperating portions form a press-fit connection between the first and second members.
12. The assembly of claim 1, wherein the implantable mesh comprises a plurality of tabs (118) and each of the plurality of electrodes is fastened to one of the tabs.
13. The assembly of claim 12, wherein the tabs are formed along an edge (120, 122) of the mesh.
14. An implantable electrode assembly (104) for delivering electrical stimulation signals to tissue of a patient, the assembly comprising:
 - an implantable mesh (108) including a plurality of tabs (118); and
 - a plurality of electrodes (106), wherein each electrode is fastened to one of the tabs.
15. The assembly of claim 14, wherein the tabs extend along one of an edge (120, 122) of the mesh, and opposing edges (120, 122) of the mesh.
16. A method comprising:
 - providing an implantable mesh (108) comprising a plurality of electrically conductive wires (114); and
 - fastening a plurality of electrodes (106) to the electrically conductive wires comprising mechanically fastening first and second members (130, 132) of each of the electrodes to one of the wires; and
 - forming a conductive path between stimulation surfaces (134) of the electrodes and the conductive wires responsive to fastening a plurality of electrodes to the electrically conductive wires.
17. The method of claim 16, wherein fastening a plurality of electrodes to the electrically conductive wires comprises piercing an insulative jacket (136) of the wire with a piercing member (140) of the electrode.

18. The method of claim 17, wherein mechanically fastening first and second members of each of the plurality of electrodes to one of the wires comprises press-fitting portions of the first and second members together around the wire.

19. The method of claim 17, wherein mechanically fastening first and second members of each of the plurality of electrodes to one of the wires comprises snap-fitting portions of the first and second members together around the wire.

20. The method of claim 16, further comprising:
implanting the mesh and the fastened electrodes in tissue of a patient; and
delivering electrical stimulation signals to the tissue of the patient through the conductive wires and the electrodes.

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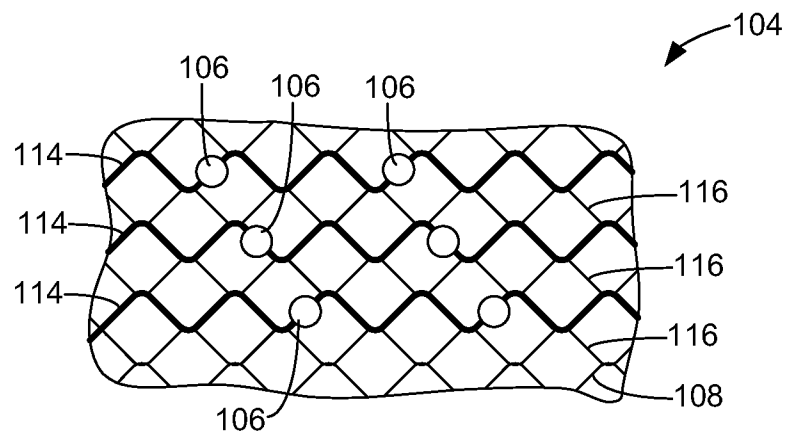


FIG. 3

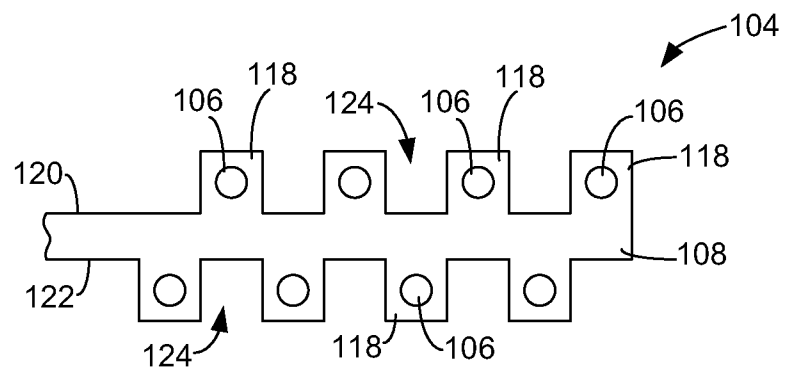


FIG. 4

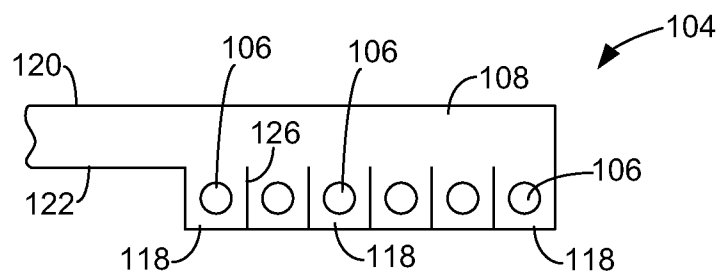


FIG. 5

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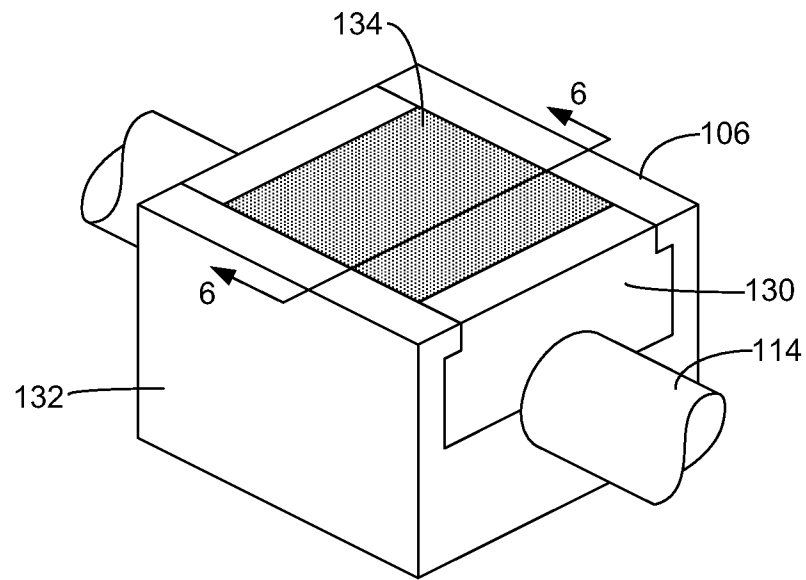


FIG. 6

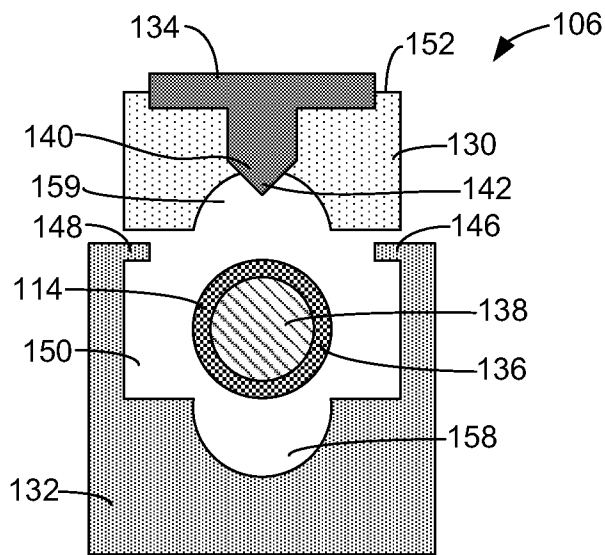


FIG. 7

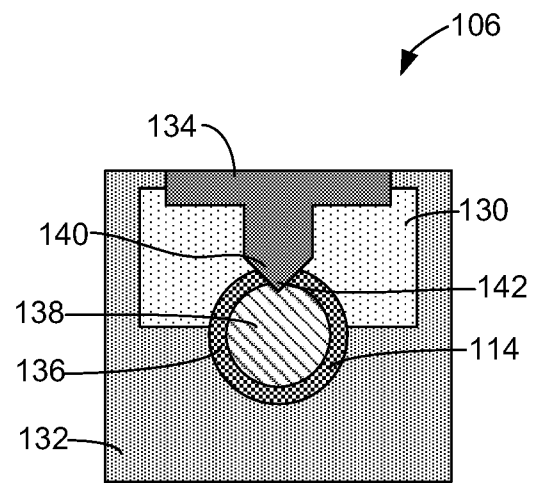


FIG. 8

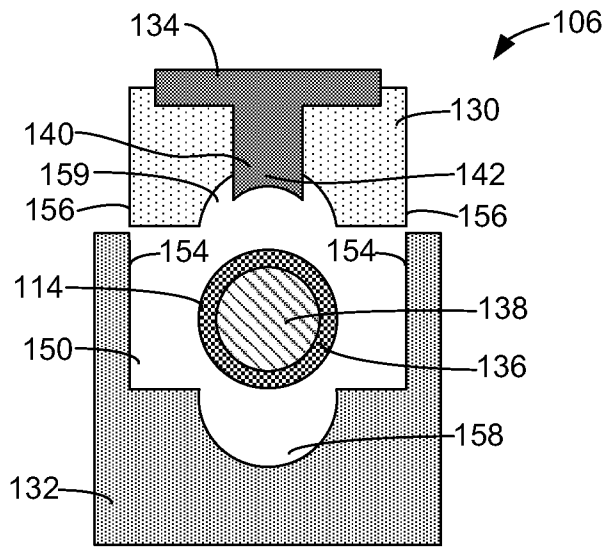


FIG. 9

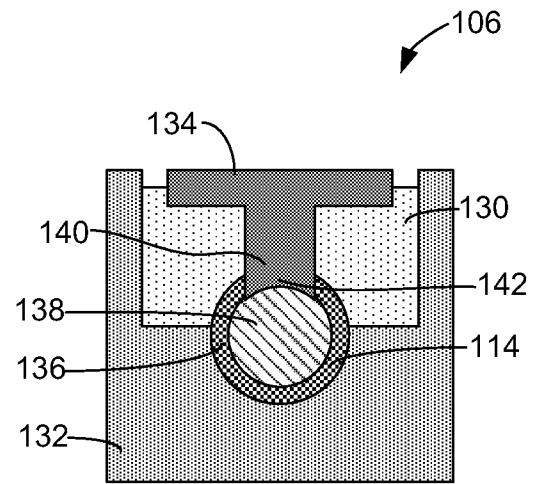


FIG. 10

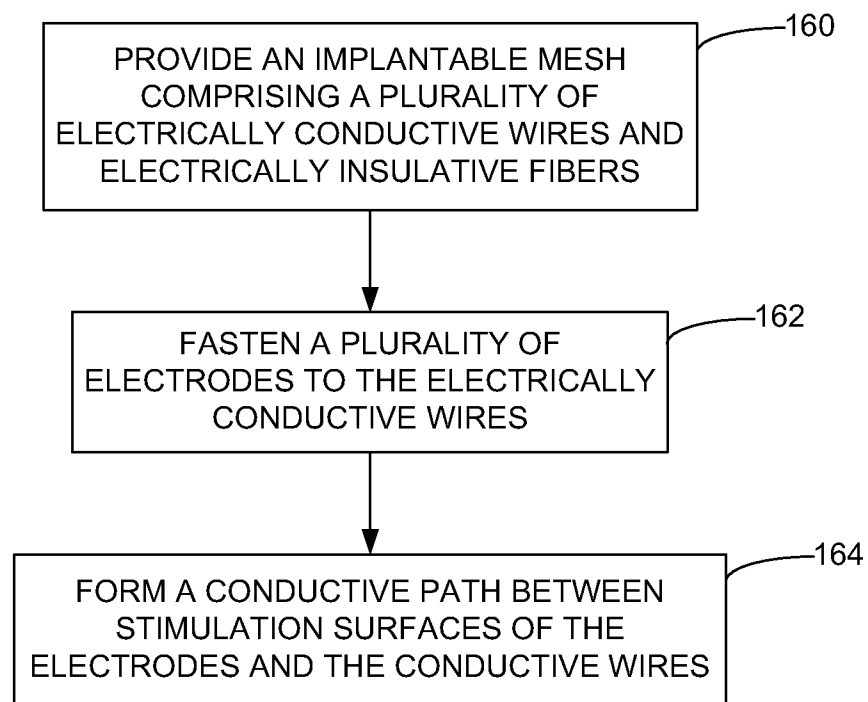


FIG. 11