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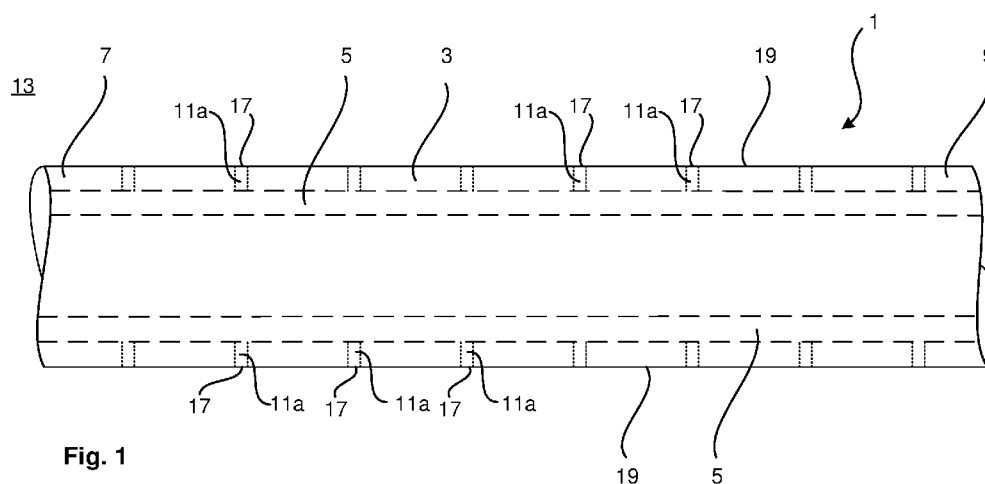


Fig. 1

(57) Abstract: An electrode assembly (1) for an active implantable medical device comprising: an elongated, biocompatible, electrically non-conductive body (3) having a first portion (7) and a second portion (9); one or more biocompatible, electrically conductive filaments (5) inside the elongated non-conductive body (3) between the first portion (7) and the second portion (9); and one or more fluid passages (11) along the elongated electrically non-conductive body (3) between the first portion (7) and second portion (9), wherein the one or more fluid passages (11) allow a surrounding fluid (13) of a patient to be in electrical contact with the one or more conductive filaments (5). There is also disclosed a method of manufacturing an electrode assembly.

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"Electrode assembly"

Technical Field

[1] The present disclosure relates to an electrode assembly for an active implantable medical device (AIMD) for implanting into tissue of a patient.

Background

[2] Medical devices having one or more active implantable components, generally referred to herein as active implantable medical devices (AIMDs), have provided a wide range of therapeutic benefits to patients over recent decades. AIMDs often include an implantable, hermetically sealed electronics module, and a device that interfaces with a patient's tissue, sometimes referred to as a tissue interface. The tissue interface may include, for example, one or more instruments, apparatus, sensors or other functional components that are permanently or temporarily implanted in a patient. The tissue interface is used to, for example, diagnose, monitor, and/or treat a disease or injury, or to modify a patient's anatomy or physiological process.

[3] In particular applications, an AIMD tissue interface includes one or more conductive electrical contacts, referred to as electrodes, which deliver electrical stimulation signals to, or receive signals from, a patient's tissue. The electrodes are typically disposed in a biocompatible electrically non-conductive member, and are electrically connected to the electronics module. The electrodes and the non-conductive member are collectively referred to herein as an electrode assembly.

[4] For neuro-stimulators, the tissue interface is a stimulating lead 1000 which delivers electrical pulse to a specific nerve or tissue. This lead 1000 may consist of a long thin non-conductive (and insulating) body 1004 and a number of conductive rings 1006, 1008 at both ends 1007, 1009 of the body 1004. Referring to Fig. 22 and 23, the rings 1008 at a therapeutic end 1009 are known as electrodes and the rings 1006 at the connector end 1007 are known as contacts, where the electrodes are connected to the contacts along the long thin non-conductive body 1004. An example of the long thin non-conductive body 1004 is shown

in the cross-section in Fig. 23 that shows conductive wires 1005 surrounded by a non-conductive body 1003.

[5] Patients with an implanted neuro-stimulator and associated lead may have issues undergoing magnetic resonance imaging (MRI). The MRI uses three types of fields to create an image: a static magnetic field; a radiofrequency (RF) magnetic field; and a gradient magnetic field. Exposure to these fields may cause heating to the leads. This heating may result in tissue burns and damage (which may not be immediately felt by the patient). Another potentially damaging effect is damage to the implant due to radiofrequency energy being transmitted from the lead. This can lead to reprogramming, damage to the implant or explant of the implant. Additionally, the MRI could cause a temporary unintended stimulation due to induced voltage through the assembly and system.

[6] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

[7] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

Summary

[8] There have been attempts to provide designs for MRI safe leads. US patent publication US 8798767 B2 illustrates a method of reducing the heat caused by MRI conditions. This document suggests coiling conductors in a multi-layer structure, with each coil layer electrically connected to the next to provide parallel conductive paths. However, this method may result in high inductance when exposed to MRI radiation. US patent publication US 9050457 B2 uses a similar approach with a lead body and multi-layer coil conductor within the length of the lead body. The stiffness of the multi-layer coil conductor is similar to the lead body, ensuring consistent mechanical properties of the lead. US patent

publication US 9302101 B2 uses a different approach with the lead body providing an additional path for containing conductive material. This path spans at least a section of the length of the lead for conducting the induced RF energy away from the conductive wire of the lead.

[9] In light of the above mentioned issues, it would be advantageous to have an electrode assembly, such as one used in an implantable medical device, that may be implanted in a patient whilst the patient is undergoing magnetic resonance imaging. This may include providing an implantable electrode assembly which, when exposed to an MRI environment, does not generate significant heat in the leads due to electromagnetic currents. It may be further advantageous for an implantable medical device that can operate during magnetic resonance imaging without, or with reduced, side effects described above.

[10] An electrode assembly for an active-implantable medical device comprising: an elongated, biocompatible, electrically non-conductive body having a first portion and a second portion; one or more biocompatible, electrically conductive filaments inside the elongated non-conductive body between the first portion and the second portion; and one or more fluid passages along the elongated electrically non-conductive body between the first portion and second portion. The one or more fluid passages allow a surrounding fluid of a patient to be in electrical contact with the one or more conductive filaments.

[11] When implanted in the tissue of a patient, the surrounding fluid of a patient is in electrical contact with the electrically conductive filaments. This fluid, such as saline, is electrically conductive and therefore reduces (or eliminates) the high capacitive coupling due to exposure of electromagnetic fields in the MRI environment. In particular, the RF frequency that induces an alternating current at a surface of the electrically conductive filaments will be electrically shorted by the fluid. On the other hand, lower frequency or direct current used for stimulation (i.e. when used with the AIMD), will take the lowest resistance such as at the core of the electrically conductive filaments (in contrast with the through the surrounding fluid).

[12] Therefore the electrode assembly, when implanted in a patient, may allow the patient to undergo MRI without, or with reduced, adverse effects as noted above. In some examples,

the electrically conductive filaments may have a very thin insulating coating that is in contact with the surrounding fluid.

[13] The electrode assembly may further comprise a plurality of apertures along the elongated electrically non-conductive body, wherein the plurality of apertures provide the fluid passages from an outer surface of the electrically non-conductive body to the one or more conductive filaments.

[14] The electrode assembly may also comprise one or more conductive filament lumens to receive respective conductive filaments passing through the elongated electrically non-conductive body, wherein the one or more conductive filament lumens has a diameter greater than the respective conductive filament lumens to provide at least part of the one or fluid passages.

[15] The electrode assembly may further comprise one or more channels along the elongated electrically non-conductive body, wherein the one or more channels provide the one or more fluid passages from an outer surface of the electrically non-conductive body to the one or more conductive filaments.

[16] In the electrode assembly, the elongated electrically non-conductive body may comprise a biocompatible non-biodegradable polymer.

[17] The electrode assembly may further comprise one or more plugs in the one or more fluid passages, wherein the plugs comprise a biocompatible biodegradable material and wherein the one or more plugs biodegrade in a body of the patient after implantation.

[18] The electrode assembly may further comprise a biocompatible biodegradable sheath to surround the elongated electrically non-conductive body, wherein the biodegradable sheath biodegrades in a body of the patient after implantation.

[19] In the electrode assembly, the biocompatible biodegradable material may include polyvinyl alcohol.

[20] The electrode assembly may further comprise a central lumen in the elongated electrically non-conductive body to receive a stylet.

In the electrode assembly, the biocompatible, elongated electrically non-conductive body may comprise: an outer wall; and a cavity within the outer wall, the cavity containing the one or more conductive filaments disposed within a biocompatible biodegradable material, wherein the biodegradable material biodegrades in a body of a patient after implantation.

[21] The electrode assembly may further comprise a core disposed in the cavity, wherein the one or more filaments are helically disposed around the core.

[22] The electrode assembly may further comprise a biocompatible, electrically non-conductive and needle-piercable base, wherein the elongated electrically non-conductive body, having the one or more conductive filaments, is stitched to the needle-piercable base.

[23] In the electrode assembly, the elongated electrically non-conductive body may be stitched to the needle-piercable base with a biocompatible, electrically non-conductive filament sewn into the base.

[24] An electrode assembly for an active implantable medical device comprising: a biocompatible porous support body; and one or more biocompatible electrically conductive filaments inside the porous support body from a first portion to a second portion, wherein the porous support body provide fluid passages to allow a surrounding fluid of a patient to be in electrical contact with the one or more conductive filaments.

[25] The electrode assembly may further comprise a core disposed in the porous support body, wherein the one or more filaments are helically disposed around the core.

[26] In the electrode assembly, the core may include a central lumen to receive a stylet.

[27] In the electrode assembly, the at least one or more conductive filaments may comprise a plurality of the conductive filaments arranged in a matrix in the porous support body.

[28] In the electrode assembly, the plurality of conductive filaments may be substantially parallel to one another in the matrix to prevent the conductive filaments from directly contacting one another.

[29] An electrode assembly for an active implantable medical device, the electrode assembly comprising a textile assembly, having a textile structure. The textile assembly comprises: one or more biocompatible, electrically non-conductive filaments; and one or more biocompatible, electrically conductive filaments. The electrode assembly also comprises a bio-compatible, electrically non-conductive and non-woven base that surrounds at least one section of the textile assembly. The textile structure is porous to allow a surrounding fluid of the patient to be in electrical contact with the one or more conductive filaments.

[30] In the electrode assembly, the textile assembly may be a knitted assembly, and the textile structure is an intermeshed loop structure.

[31] In the electrode assembly, the textile assembly may be a braided assembly and the textile structure is a braided structure comprising braiding of the one or more non-conductive filaments and the one or more conductive filaments.

[32] In the electrode assembly, the base may be applied to surround the textile assembly by electrospinning.

[33] The implanted electrode assembly may be coupled with the active implantable medical device and in contact with the surrounding fluid so that it has a capacitance in the range of 0.25 nanofarads to 3.30 nanofarads per metre.

[34] The capacitance per unit length of the lead depends on the permittivity and the thickness of the non-conductive body (which acts as an insulator). A capacitor is formed between the conductive filament and the surrounding tissue to form an impediment to current flow between the conductive filament and the tissue. Therefore it is desirable to have the capacitance to be high enough so that the current is not impeded. The capacitance value increases with higher filament diameter and higher permittivity of the non-conductive body. Furthermore, the capacitance value decreases with decreasing thickness of the non-conductive body.

[35] A method of manufacturing an electrode assembly for an active implantable medical device, comprising:

- providing an elongated biocompatible, electrically non-conductive body;

- locating one or more biocompatible, electrically conductive filaments through the elongated non-conductive body from a first portion to a second portion; and

- forming one or more fluid passages along the elongated electrically non-conductive body between the first portion and the second portion,

wherein the one or more fluid passages allow a surrounding fluid of a patient to be in contact with the one or more conductive filaments.

[36] The method of manufacturing an electrode assembly, wherein the method may further comprise forming a plurality of apertures along the elongated electrically non-conductive body to provide the fluid passages from an outer surface of the electrically non-conductive body to the one or more conductive filaments.

[37] The method of manufacturing an electrode assembly, wherein the method may further comprise forming one or more conductive filament lumens inside the elongated electrically non-conductive body to receive respective electrically conductive filaments, wherein the one or more conductive filament lumens has a diameter greater than the respective conductive filament lumens to form at least part of the one or fluid passages.

[38] The method of manufacturing an electrode assembly, wherein the method may further comprise forming one or more channels along the elongated electrically non-conductive body, wherein the one or more channels provide the one or more fluid passages from an outer surface of the electrically non-conductive body to the one or more conductive filaments.

[39] The method of manufacturing an electrode assembly, wherein the method may further comprise filling one or more fluid passages with one or more plugs, wherein the plugs comprise a biocompatible biodegradable material, wherein the one or more plugs biodegrade in a body of the patient after implantation.

[40] The method of manufacturing an electrode assembly, wherein the method may further comprise surrounding the elongated biocompatible, electrically non-conductive body with a biocompatible biodegradable sheath, wherein the biodegradable sheath biodegrades in a body of the patient after implantation.

[41] The method of manufacturing an electrode assembly, wherein the method may further comprise forming a central lumen in the elongated electrically non-conductive body, wherein the central lumen is configured to receive a stylet.

[42] In the method of manufacturing an electrode assembly, the elongated electrically non-conductive body may comprise an outer wall that defines a cavity within, and the method may further comprise surrounding the one or more conductive filaments with a biodegradable material, wherein the biodegradable material and conductive filaments are provided inside a cavity, and wherein the biodegradable material biodegrades in a body of a patient after implantation.

[43] The method of manufacturing an electrode assembly may further comprise helically disposing the one or more conductive filaments around a core.

[44] The method of manufacturing an electrode assembly may further comprise stitching the elongated, biocompatible, electrically non-conductive body to a biocompatible, electrically non-conductive and needle-piercable base.

[45] A method of manufacturing an electrode assembly for an active implantable medical device, comprising:

- providing one or more biocompatible, electrically conductive filaments; and
- forming a biocompatible, porous support body around the one or more biocompatible electrically conductive filaments;

wherein the porous support body provide fluid passages to allow a surrounding fluid of a patient to be in electrical contact with the one or more conductive filaments.

[46] The method of manufacturing an electrode assembly may further comprise: providing a core; and helically disposing the one or more conductive filaments around the core.

[47] The method of manufacturing an electrode assembly may further comprise forming a central lumen in the core.

[48] In the method of manufacturing an electrode assembly, the one or more biocompatible electrically conductive filaments may comprise a plurality of conductive filaments, and the method may further comprise arranging the plurality of conductive filaments in a matrix in the porous support body.

[49] A method of manufacturing an electrode assembly for an active implantable medical device, comprising:

- providing a textile assembly, having a textile structure, comprising:

- one or more biocompatible, electrically non-conductive filaments; and

- one or more biocompatible, electrically conductive filaments; and

- surrounding at least one section of the textile assembly with a biocompatible, electrically non-conductive and non-woven base,

wherein the textile structure is porous to allow a surrounding fluid of the patient to be in electrical contact with the one or more conductive filaments.

[50] In the method of manufacturing an electrode assembly, the textile assembly may be a knitted assembly, and the textile structure is an intermeshed loop structure, and wherein the step of providing a textile assembly comprises knitting the one or more non-conductive filaments with the one or more conductive filaments.

[51] In the method of manufacturing an electrode assembly, wherein the textile assembly may be a braided assembly and the textile structure is a braided structure, and wherein the step of providing a textile assembly comprises braiding the one or more non-conductive filaments with the one or more conductive filaments.

[52] In the method of manufacturing an electrode assembly, surrounding the at least one section of the textile assembly with a biocompatible electrically non-conductive and non-woven base may comprise applying the base by electrospinning.

[53] An electrode assembly for an active implantable medical device comprising: an elongated, biocompatible, electrically non-conductive body having a first portion and a second portion; one or more biocompatible, electrically conductive filaments inside the elongated non-conductive body between the first portion and the second portion; wherein the electrode assembly is configured to be coupled with the active implantable medical device and in contact with the surrounding fluid to have a capacitance in the range of 0.25 nanofarads to 3.30 nanofarads per metre.

[54] A method of manufacturing an electrode assembly for an active implantable medical device, comprising: providing an elongated biocompatible, electrically non-conductive body; locating one or more biocompatible, electrically conductive filaments through the elongated non-conductive body from a first portion to a second portion; and coupling the electrode assembly with the active implantable medical device and locating the electrode assembly to be in contact with the surrounding fluid to have a capacitance in the range of 0.25 nanofarads to 3.3 nanofarads per metre.

Brief Description of Drawings

[55] Fig. 1 illustrates an electrode assembly for an active implantable medical device having a plurality of apertures;

[56] Fig. 2 is a cross-section of the electrode assembly of Fig. 1;

[57] Fig. 3 is a flow diagram of a method to manufacture an electrode assembly;

[58] Fig. 4 illustrate another example of an electrode assembly for an active implantable medical device having a conductive filament lumen with a greater diameter than the conductive filament ;

[59] Fig. 5 is a cross-section of the electrode assembly of Fig. 4;

[60] Fig. 6 illustrates yet another example of an electrode assembly for an active implantable medical device having channels;

[61] Fig. 7 is a cross-section of the electrode assembly of Fig. 6;

[62] Fig. 8 illustrates another example of an electrode assembly for an active implantable medical device having biodegradable plugs;

[63] Fig. 9 illustrates another example of an electrode assembly for an active implantable medical device having a biodegradable sheath;

[64] Fig. 10 illustrates a cross-section of an example of an electrode assembly having a central lumen to receive a stylet;

[65] Fig. 11 illustrates another example of an electrode assembly for an active implantable medical device having an outer wall and biodegradable material within;

[66] Fig. 12a is a cross-section of the electrode assembly of Fig. 11 with the biodegradable material;

[67] Fig. 12b is a cross-section of the electrode assembly of Fig. 11 without the biodegradable material after implantation;

[68] Fig. 13 illustrates another example of an electrode assembly that includes a non-conductive body, having the conductive filaments passing through, stitched to a non-conductive base;

[69] Fig. 14 illustrates another example of an electrode assembly for an active implantable medical device that includes a porous support body;

[70] Fig. 15 is a cross-section of the electrode assembly of Fig. 14;

[71] Fig. 16 is another flow diagram of a method to manufacture an electrode assembly;

[72] Fig. 17 illustrates another example of an electrode assembly for an active implantable medical device that has a porous support body and a plurality of conductive filaments arranged in a matrix pattern;

[73] Figs. 18a and 18b illustrates another example of an electrode assembly for an active implantable medical device having a textile assembly that includes a knitted assembly;

[74] Fig. 19 is yet another flow diagram of a method to manufacture an electrode assembly.

[75] Figs. 20a and 20b illustrates another example of an electrode assembly for an active implantable medical device having a braided assembly;

[76] Fig. 21 illustrates an example of electrospinning a material to the electrode assembly;

[77] Fig. 22 is a side view of an example of an electrode assembly for an active implantable medical device including a connector end and a therapeutic end; and

[78] Fig. 23 is a cross-section of an example of the electrode assembly having a central lumen and lumens to receive conductive wires.

Description of Embodiments

[79] Aspects of the present disclosure are generally directed to an electrode assembly for an active implantable medical device (AIMD). An AIMD may include an implantable electronics module and a tissue interface. The electrode assembly that, at least in part, forms the tissue interface.

[80] The electrode assembly may be used with one type of AIMD, a neuro stimulator, and more specifically a deep brain stimulator or spinal cord stimulator. Deep brain stimulators are a particular type of AIMD that deliver electrical stimulation to a patient's brain, while spinal cord stimulators deliver electrical stimulation to a patient's spinal column. As used herein, deep brain stimulators and spinal cord stimulators refer to devices that deliver electrical stimulation alone or in combination with other types of stimulation. It should be appreciated that embodiments of the present disclosure may be implemented in any brain stimulator (deep brain stimulators, cortical stimulators, etc.), spinal cord stimulator or other neuro stimulator now known or later developed, such as cardiac pacemakers/defibrillators, functional electrical stimulators (FES), pain stimulators, etc. Embodiments of the present disclosure may also be implemented in AIMDs that are implanted for a relatively short period of time to address acute conditions, as well in AIMDs that are implanted for a relatively long period of time to address chronic conditions.

[81] The electrode assembly in accordance with embodiments of the present disclosure are not limited to devices that deliver electrical stimulation signals to a patient. For instance, in certain embodiments, the electrode assembly may be used to receive, record or monitor the physiological response of a patient's tissue to, for example, a therapy. In such embodiments, the electrodes receive a signal from the patient's tissue representing the physiological response. An electrode assembly of the present disclosure that delivers electrical stimulation signals to, or receives signals from, a patient's tissue may also include one or more other components, such as therapeutic agent delivery systems, sensors, etc., that interface with the patient's tissue.

[82] The present disclosure relates to an electrode assembly 1 for an active implantable medical device and a method 100 for manufacturing the electrode assembly 1. Referring to Figs. 1 and 2, the electrode assembly 1 includes an elongated, biocompatible, electrically non-conductive body 3 having a first portion 7 and a second portion 9 (which in this example are proximal to respective opposite first and second ends). One or more biocompatible, electrically conductive filaments 5 are inside the non-conductive body 3 between the first portion 7 and the second portion 9. The electrode assembly 1 may further include one or more fluid passages 11 along the elongated electrically non-conductive body between the first portion 7 and the second portion 9, wherein the one or more fluid passages 11 allow a surrounding fluid 13 of a patient to be in electrical contact with the one or more conductive filaments 5.

[83] The fluid passages 11 allow the surrounding fluid in the patient, which may include a saline solution (i.e. ionic solution that is at least partially electrically conductive) to provide additional electrical paths. As described above, it is noted that an MRI generates three types of fields that can cause heating of in conventional electrodes. This may include RF frequencies that induce an alternating current at the surface of wire filaments of the electrode. This alternating current may be sufficiently high so as to heat the wire and so any means to reduce the current flow in the wire reduces the heating. In a conventional lead design the wires are imbedded in an insulator. The wire itself is capacitively coupled to the ionic solution in which it resides. The current would flow from the wire to solution and back to the wire thus reducing the current flow in the wire and reducing the heating. By providing an additional electrical path (via the surrounding fluid) this reduces (or eliminates) the induced current due to exposure of the electromagnetic fields in the MRI environment. Any step which

increases the capacitance to the fluid reduces the resistance for the current to flow into the solution and hence reduces the heating effect. Increasing the capacitance will reduce resistivity to the solution and further reduce the heating effect. One form is to have the insulator as thin as possible to have the highest capacitance as possible and reduce the resistance to the solution. Unfortunately this may be in conflict with the other goal that needs to be met by implanted leads, such as having a lead that is robust inside the body. This goal necessitates the addition of insulating materials (for support). One way to overcome the competing aims is to provide polymeric support that is porous such that fluid can completely surround the wire. The wires may be insulated with thin insulation such as vapour deposited polymers (such as polymers known as PARYLENE) as a coating or Teflon coating.

[84] Effectively increasing the capacitance with respect to the solution in this manner may not affect the conduction of the lower frequency pulse trains used for stimulation (such as when used with the AIMD), as these will take the lower resistance path such as the core of the electrically conductive filaments 5. This allows examples of the electrode assembly 1 to function as intended whilst being safe when exposed to an MRI.

[85] Furthermore, the elongated electrically non-conductive body 3 may function to provide structural support to the conductive filaments 5 which may be thin wire(s). This is in contrast to using bare wire filaments as electrode assemblies.

[86] In some examples the capacitance of the electrode assembly 1 is in the range of 0.25 nanofarads to 3.30 nanofarads per metre. This may include designing the electrode assembly 1 to have a capacitance in this range when surrounded with the surrounding fluid 13 and/or when coupled with the active implantable medical device. In another example, the specified capacitance range may be between 0.5 nanofarads to 1 nanofarads per metre. In further examples, the capacitance range may be between 1 nanofarads and 3 nanofarads per metre. In yet further examples, the specified capacitance range may be between 1.5 nanofarads and 2.5 nanofarads per metre. Achieving the desired capacitance range may include configuring the electrode assembly with combinations of one or more of: the thickness of the elongated, biocompatible, electrically non-conductive body 3; selection of material for the non-conductive body 3; forming fluid passages 11 along the non-conductive body to the conductive filaments; the size, number and location of the fluid passages 11; porosity of the

porous support body 43, 73; the size, number and dimensions of the electrically conductive filaments 5; and selection of material for the electrically conductive filaments 5.

[87] There is also described a method 100 of manufacturing an electrode assembly 1 for an implantable medical device. This includes manufacturing the electrode assembly 1 to include an elongated biocompatible non-conductive body 3 and locating one or more biocompatible electrically conductive filaments 5 inside the non-conductive body 3. The method also includes forming one or more fluid passages 11 in the non-conductive body 3 so that the surrounding fluid in the patient may be in electrical contact with the one or more conductive filaments when implanted for the reasons described above.

[88] Various examples of the electrode assembly 1 will now be described in detail. In these examples, the elongated length portions and cross-section of the electrode assembly 1 are described. It is to be appreciated that the therapeutic ends and connector ends of these example electrode assemblies 1 may be similar to those described above.

Example 1

[89] Figs. 1 and 2 illustrate an example of the electrode assembly 1. In this example the elongated biocompatible, electrically non-conductive body 3 has a plurality of apertures 17 along the length between the first portion 7 and the second portion 9. The plurality of apertures 17 provide the fluid passages 11a from an outer surface 19 of the electrically non-conductive body 3 to the one or more conductive filaments 5 therein. Therefore when implanted, the surrounding fluid 13 may flow into the fluid passages 11a and be in electrical contact with the filaments 5.

[90] Referring to the cross-section in Fig. 2, the fluid passages 11a may extend radially outward from the conductive filaments 5 inside the non-conductive body 3.

[91] The elongated biocompatible electrically non-conductive body 3 may comprise of a biocompatible non-biodegradable polymer. Examples of such polymers may include thermoplastic polyurethanes (such as those under the trade name PELLETHANE offered by Lubrizol Corporation) and silicon rubbers.

[92] The biocompatible, electrically conductive filaments 5 may include a metal or metallic alloy. An example of such conductive filaments 5 may include platinum, platinum iridium alloys, MP35N stainless steel. In some examples, the electrically conductive filaments 5, as noted above, may have a thin insulation such as a vapour deposited polymer coating or Teflon coating.

[93] A method 400 of manufacturing the electrode assembly 1 is shown in the flow diagram in Fig. 3. This includes providing 410 the elongated biocompatible, electrically non-conductive body 3 having a first portion 7 and a second portion 9. In some examples, the electrically non-conductive body may be extruded through a die.

[94] The method 400 also includes locating one or more biocompatible, electrically conductive filaments 5 inside the elongated non-conductive body 3. This may include inserting the conductive filaments 5 through lumens in the electrically non-conductive body 3. In other examples, this may include feeding the conductive filaments 5 through an extruder as the electrically non-conductive body 3 is formed.

[95] The method also includes forming one or more fluid passages 11 along the electrically non-conductive body 3 so that when the electrode assembly 1 is implanted, the surrounding fluid 13 in a patient is in electrical contact with the conductive filaments 5. In some examples, the fluid passages 11 are formed by laser cutting the non-conductive body 3. In other examples, the fluid passages 11 are formed during extrusion of the non-conductive body 3, where the die creates the fluid passages 11.

[96] It is to be appreciated that examples of the method 400 may have steps performed in different orders than that shown in Fig. 3.

Example 2

[97] Figs. 4 and 5 illustrate another example of the electrode assembly 1. In this example the electrode assembly 1 may be the main lead of a percutaneous lead. Accordingly, the electrode assembly 1 may incorporate features of known percutaneous leads with the exception of the features discussed below.

[98] The elongated non-conductive body 3 may include one or more conductive filament lumens 15 that extend lengthwise inside the elongated body. These conductive filament lumens 15 may receive respective conductive filaments 5. The conductive filament lumens 15 may have a greater diameter than the conductive filaments 5 so that there is space between the walls of the conductive filament lumens 15 and the conductive filaments 5 for fluid to permeate through. That is, the conductive filament lumens 15 would be larger than conventionally provided for a given filament 5 size. Thus the conductive filament lumens 15 provide at least part of the one or more fluid passages 11b for the surrounding fluid to be in electrical contact with the filament.

[99] Referring to Figs. 4 the one or more fluid passages may also include additional fluid passages 11a that fluidly connects the conductive filament lumens 15 towards the outer surface 19 and the surrounding fluid 13. These additional fluid passages 11a may be provided along the length of the elongated non-conductive body 3.

[100] It is to be appreciated that the lumens 15 may be formed by providing a corresponding shape to the die during extrusion.

Example 3

[101] Figs. 6 and 7 illustrate another example of the electrode assembly 1. In this example, one or more channels 21 may be provided along the elongated electrically non-conductive body 3. The one or more channels 21 provides the one or more fluid passages 11c from an outer surface 19 of the non-conductive body 3 to the one or more conductive filaments 5.

[102] In some examples, the filaments 5 may be inserted into the channels 21 and held in place therein. For example, the channels 21 may include widened bottom and a narrower mouth such that a filament 5 may be pressed into place at the widened bottom. The resilience of the non-conductive body 3 may provide compression force or otherwise hold the filament 5 in place.

[103] It is to be appreciated that these channels 21 may be formed by having a die with a corresponding shape to form channels 21 during extrusion of the non-conductive body 3.

Example 4

[104] In the examples described herein, the one or more fluid passages 11 may be provided with respective one or more plugs 23. Referring to Fig. 8, a plug 23 made of a biocompatible biodegradable material is provided in the fluid passages 11 so that the fluid passages 11 are plugged during implantation into a patient. This may assist implantation as open fluid passages 11 may cause catch points or otherwise impede insertion. This may also assist by allowing existing implantation devices, surgical tools and techniques to be used.

[105] After implantation, the plugs 23 may biodegrade in the body of the patient thereby allowing the surrounding fluid to flow into the fluid passages 11.

[106] The biocompatible biodegradable material may include polyvinyl alcohol (PVA), polylactic acid (PLA), polyglycolic acid (PGA), and poly(lactic-co-glycolic) acid (PLGA).

[107] Thus in some examples of manufacturing the electrode assembly 1, the method 400 may include filling the one or more fluid passages 11 with the one or more plugs 23.

Example 5

[108] Fig. 9 illustrates another example of the electrode assembly 1 that further includes a biocompatible biodegradable material to cover the fluid passages 11. In this example, a biocompatible biodegradable sheath 25 is provided to surround the elongated non-conductive body 3. This sheath may be a tube-like sheath provided around the outer surface (19) of the non-conductive body 3. The biodegradable sheath 25 may provide a smooth outer surface to assist in implantation of the electrode assembly 1. The sheath 25 (as well as plugs 23 described above) may also function to protect the fluid passages 11 from contamination until they have been implanted. For example, preventing dust, other foreign objects, blood, etc. from entering into the fluid passages 11 and preventing the surrounding fluid 13 flowing into the fluid passages 11.

[109] Once the electrode assembly 1 is implanted, the biodegradable sheath 25 may then biodegrade into the body of the patient and allow the fluid passages 11 to operate as discussed herein.

[110] It is to be appreciated that the biodegradable plugs 23 and biodegradable sheaths 25 in examples 4 and 5 may be used with other electrode assemblies described in the other examples.

[111] Thus in some examples of manufacturing the electrode assembly 1, this includes surrounding the non-conductive body 5 with the biodegradable sheath 25. In some examples, this may include dipping or spraying the non-conductive body 5 with the biodegradable material. In other examples, this may include sliding the sheath 25, in the form of a tube, over the non-conductive body 5.

Example 6

[112] Fig. 10 illustrates an example of an electrode assembly 1 further comprising a central lumen 35 in the elongated electrically non-conductive body 3. The central lumen 35 may receive a stylet to assist implantation. It is to be appreciated that a central lumen 35 may be applied to some of the other examples of the electrode assembly described herein.

Example 7

[113] Figs. 11, 12a and 12b illustrate another example of the electrode assembly 1, wherein the elongated non-conductive body 3 comprises an outer wall 29 that defines a cavity 27 within the outer wall 29. The cavity 27 contains the one or more conductive filaments 5 along the elongated cavity 27. In one example, the conductive filaments 5 are surrounded with a biodegradable material 31 that is also inside the cavity 27 as shown in Fig. 12a.

[114] After implantation, the biodegradable material 31 biodegrades into the body of the patient, and the cavity 27 then forms at least part of the one or more fluid passages 11d to allow surrounding fluid 13 to be in electrical contact with the filaments as shown in Fig. 12b. It is to be appreciated that additional apertures could be provided in the outer wall 29 or elsewhere (such as end portions) of the non-conductive body 3 to provide further fluid passages 11.

[115] Furthermore, as illustrated in Figs. 11, 12a and 12b, the electrode assembly 1 may also include a core 33 disposed in the cavity 27. The one or more conductive filaments 5 may

be helically disposed around the core 33. The core 33 is preferably made of a biocompatible and non-biodegradable material.

[116] In one variation (not shown), the core 33 of the electrode assembly may further include a central lumen 35 to receive a stylet to aid implantation.

Example 8

[117] Fig. 13 illustrates another example of an electrode assembly 81. In this example, the electrode assembly further comprises a biocompatible, electrically non-conductive needle-piercable base 83. The elongated electrically non-conductive body 3, that has the one or more conductive filaments 5 passing inside, is stitched to the electrically non-conductive needle-piercable base 83. The electrically non-conductive body 3, and the conductive filaments 5, may configured as described in the other examples of the electrode assembly 81 described herein. As used herein, stitching a conductive filament to a base refers to sewing, embroidering or otherwise securing the filament to the base through the use of hand or machine needlework.

[118] The electrically non-conductive needle piercable base 83 may provide additional support and structure to the electrode assembly 81. This may assist in implantation and/or retention of the electrode assembly 81 in the patient.

[119] The non-conductive needle-piercable base 83 may comprise, for example, woven or continuous fabric, a solid sheet or film of synthetic material, etc. In some examples, the non-conductive needle-piercable base 83 is a solid sheet or film of thermoplastic material. In such examples, a heated needle is used to stitch a thread to secure the electrically non-conductive body 3 to the needle-piercable base 83 so that the material around each perforation will melt and re-seal after the stitch is formed. The re-sealing of the needle-piercable base 83 secures the thread to the base 83 thereby increasing reliability. In some examples, having a thermoplastic base 83 may be advantageously as it can be molded into a desired shape before or after stitching with the thread.

[120] The stitch may be formed with a thread, such as a biocompatible, electrically non-conductive filament 85 sewn into the base 83. However depending on application, the thread may include an electrically conductive filament to conduct electrical current.

Example 9

[121] Figs. 14 and 15 illustrate yet another example of an electrode assembly 41. In this example, the electrode assembly 41 comprises a biocompatible porous support body 43. One or more biocompatible electrically conductive filaments 5 are provided to inside the porous support body 43 from a first portion 7 to a second portion 9. The porous support body 43 provides fluid passages 11d through the pores to allow the surrounding fluid 13 in a patient to be in electrical contact with the one or more electrically conductive filaments 5.

[122] Examples of porous material include porous films of ultra-high molecular weight polyethylene (HDPE).

[123] Fig. 16 illustrates an example of a method 500 of manufacturing the electrode assembly 41 including providing 510 one or more biocompatible, electrically conductive filaments 5; and forming a biocompatible, porous support body 43, 73 around the one or more electrically conductive filaments 5. In some examples, forming the porous support body 43, 73 may include moulding the porous support body 43 with the electrically conductive filaments in the mould. In other examples, this may include dipping or spraying the electrically conductive filaments 5 with a porous material.

[124] In one example, the electrode assembly 41 further comprises a core 33 disposed in the porous support body 43. One or more of the electrically conductive filaments 5 may be helically disposed around the core 33.

[125] In yet a further variation, the core 33 may include a central lumen 35 to receive a stylet.

Example 10

[126] Fig. 17 illustrates yet another embodiment of the electrode assembly 71. In this example there is a biocompatible porous support body 73 that has a plurality of biocompatible

electrically conductive filaments 5 passing inside. The plurality of conductive filaments 5 are arranged in a matrix 74 in the porous support body 73.

[127] It is to be appreciated that the arrangement of the conductive filaments 5 may include other patterns (when viewed in a cross section).

[128] In some examples, the plurality of conductive filaments 5 are substantially parallel to one another between the first portion 7 and second portion 9 of the porous support body 73. Having the conductive filaments 5 extending parallel to one another may prevent, or reduce the likelihood, of the conductive filaments 5 from directly contacting one another. For example, if the electrode assembly 71 is twisted or bent.

Example 11

[129] Figs. 18a and 18b illustrate another example of an electrode assembly 51 for an AIMD. The electrode assembly 51 is manufactured by a method shown in Fig. 19 that includes providing 610 a textile assembly 53 having a textile structure 55 and surrounding 620 at least a section of the textile assembly 53 with a bio-compatible, electrically non-conductive and non-woven base 59

[130] The textile assembly 53 comprises one or more biocompatible electrically non-conductive filaments 57 and one or more biocompatible, electrically conductive filaments 5. The textile structure 55 is porous to allow a surrounding fluid 14 in a patient to pass into the pores and be in electrical contact with the one or more conductive filaments 5. It is to be appreciated that additional passages and aperture may be provided to allow the surrounding fluid a passage from outside the electrode assembly 51 to the textile structure 57.

[131] Exemplary textile manufacturing methods include, but are not limited to, weaving, knitting, braiding, crocheting, etc. For ease of illustration, the examples below will be primarily discussed herein with reference to knitting or braiding. It would be appreciated that other textile manufacturing methods are also within the scope of the present disclosure.

[132] In some examples, the textile assembly 53 is a knitted assembly 53 and the textile structure 55 is an intermeshed loop structure 55 as illustrated in Fig. 18a. In some examples, the one or more biocompatible, electrically non-conductive filaments 57 are arranged in

substantially parallel rows each stitched to an adjacent row with one or more loops. The one or more biocompatible, electrically conductive filaments 5 are intertwined with the one or more row of non-conductive filaments 57. The intermeshed loop structure 55 may also include a central lumen 303 to receive a stylet.

[133] Fig. 18b illustrates the electrode assembly 51 with the knitted assembly surrounded by the non-conductive and non-woven base 59.

Example 12

[134] Fig. 20a and 20b illustrate another example of an electrode assembly 61 with a textile assembly 63 comprising of a textile structure 65 that is braided. Referring to Fig. 20a, the braided structure 65 comprises braiding of the one or more non-conductive filaments 67 and the one or more conductive filaments 5. The textile structure 65 may have a central lumen 303 to allow a stylet to pass through. Fig. 20b illustrates the electrode assembly 61 with the braided structure 65, as shown in Fig. 20a, that is surrounded by the non-conductive and non-woven base 69.

Example 13

[135] In some examples, the bio-compatible, electrically non-conductive and non-woven base 59, 69 is applied to surround a section of the textile assembly 53, 63 by electrospinning. Fig. 21 illustrates how an electrospinning process may be applied to create a cover (the non-conductive and non-woven base 59, 69) of an electrode assembly 51, 61. The electrode assembly 51, 61 includes an electrically non-conductive support member and electrically conductive filaments for stimulation. A conductive stylet 304 is inserted in a lumen 303 in of the electrode assembly 51, 61. Then, a suitable polymer material, such as PET, is loaded into a syringe delivery system 306. A high voltage source 308 is connected to the syringe nozzle 310 and the conductive stylet 304. The non-woven coating 312 is formed around the electrode assembly 51, 61 by suitably moving the lead / stylet assembly 302/304 beneath the syringe. As a result, the electrode assembly 51, 61 is provided with a cover made of an electrically non-conductive and non-woven base 59, 69. The base 59, 69 may include openings between the strand that is formed by the electrospinning process, which may in turn provide the one or more fluid passages 11 for the surrounding fluid in a patient to be in

electrical contact with the conductive filaments 5. The movement of the lead / stylet assembly 302/304 beneath the syringe is such that the openings formed by the strand are dimensioned such that the openings allow stimulation of tissue by the electrodes while preventing tissue ingrowth.

[136] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the above-described embodiments, without departing from the broad general scope of the present disclosure. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. An electrode assembly (1) for an active implantable medical device comprising:
 - an elongated, biocompatible, electrically non-conductive body (3) having a first portion (7) and a second portion (9);
 - one or more biocompatible, electrically conductive filaments (5) inside the elongated non-conductive body (3) between the first portion (7) and the second portion (9); and
 - one or more fluid passages (11) along the elongated electrically non-conductive body (3) between the first portion (7) and second portion (9), wherein the one or more fluid passages (11) allow a surrounding fluid (13) of a patient to be in electrical contact with the one or more conductive filaments (5).
2. An electrode assembly according to claim 1 comprising:
 - a plurality of apertures (17) along the elongated electrically non-conductive body (3), wherein the plurality of apertures (17) provide the fluid passages (11a) from an outer surface (19) of the electrically non-conductive body (3) to the one or more conductive filaments (5).
3. An electrode assembly according to either claim 1 or 2 comprising:
 - one or more conductive filament lumens (15) to receive respective conductive filaments (5) passing through the elongated electrically non-conductive body (3), wherein the one or more conductive filament lumens (15) has a diameter greater than the respective conductive filament lumens (15) to provide at least part of the one or fluid passages (11b).
4. An electrode assembly according to any one of the preceding claims comprising:
 - one or more channels (21) along the elongated electrically non-conductive body (3), wherein the one or more channels (21) provide the one or more fluid passages (11c) from an

outer surface (19) of the electrically non-conductive body (3) to the one or more conductive filaments (5).

5. An electrode assembly according to any one of the preceding claims wherein the elongated electrically non-conductive body (3) comprises a biocompatible non-biodegradable polymer.

6. An electrode assembly according to any one of the preceding claims further comprising:

- one or more plugs (23) in the one or more fluid passages (11), wherein the plugs comprise a biocompatible biodegradable material and wherein the one or more plugs (23) biodegrade in a body of the patient after implantation.

7. An electrode assembly according to any one of the preceding claims further comprising:

- a biocompatible biodegradable sheath (25) to surround the elongated electrically non-conductive body (3), wherein the biodegradable sheath (25) biodegrades in a body of the patient after implantation.

8. An electrode assembly according to claim 6 or 7 wherein the biocompatible biodegradable material includes polyvinyl alcohol.

9. An electrode assembly according to any one of the preceding claims further comprising a central lumen 35 in the elongated electrically non-conductive body (3) to receive a stylet.

10. An electrode assembly according to claim 1, wherein the biocompatible, elongated electrically non-conductive body (3) comprises:

- an outer wall (29); and

- a cavity (27) within the outer wall (29), the cavity (27) containing the one or more conductive filaments (5) disposed within a biocompatible biodegradable material (31),

wherein the biodegradable material (31) biodegrades in a body of a patient after implantation.

11. An electrode assembly according to claim 10, further comprising a core (33) disposed in the cavity (27), wherein the one or more filaments (5) are helically disposed around the core (33).

12. An electrode assembly (81) according to any one of claims 1 to 11 further comprising:

- a biocompatible, electrically non-conductive and needle-piercable base (83);

wherein the elongated electrically non-conductive body (3), having the one or more conductive filaments (5), is stitched to the needle-piercable base (83).

13. An electrode assembly (81) according to claim 12, wherein the elongated electrically non-conductive body (3) is stitched to the needle-piercable base (83) with a biocompatible, electrically non-conductive filament (85) sewn into the base (83).

14. An electrode assembly (41, 71) for an active implantable medical device (41, 71) comprising:

- a biocompatible porous support body (43, 73); and

- one or more biocompatible electrically conductive filaments (5) inside the porous support body (43) from a first portion (7) to a second portion (9);

wherein the porous support body (43) provides fluid passages (11d) to allow a surrounding fluid (13) of a patient to be in electrical contact with the one or more conductive filaments (5).

15. An electrode assembly (41) according to claim 14, further comprising:

- a core (33) disposed in the porous support body (43), wherein the one or more filaments (5) are helically disposed around the core (33).

16. An electrode assembly (41) according to claim 15 wherein the core (33) includes a central lumen (35) to receive a stylet.

17. An electrode assembly (71) according to claim 14 wherein the at least one or more conductive filaments (5) comprise a plurality of the conductive filaments (5) arranged in a matrix (74) in the porous support body (73).

18. An electrode assembly (71) according to claim 17 wherein the plurality of conductive filaments (5) are substantially parallel to one another in the matrix (74) to prevent the conductive filaments (5) from directly contacting one another.

19. An electrode assembly (51, 61) for an active implantable medical device comprising:

- a textile assembly (53, 63), having a textile structure (55, 65), comprising:

- one or more biocompatible, electrically non-conductive filaments (57, 67);

and

- one or more biocompatible, electrically conductive filaments (5); and

- a bio-compatible, electrically non-conductive and non-woven base (59, 69) that surrounds at least one section of the textile assembly (53, 63),

wherein the textile structure (55, 65) is porous to allow a surrounding fluid (13) of the patient to be in electrical contact with the one or more conductive filaments (5).

20. An electrode assembly (51) according to claim 19, wherein the textile assembly (53) is a knitted assembly (53), and the textile structure (55) is an intermeshed loop structure (55).

21. An electrode assembly (61) according to claim 19, wherein the textile assembly (63) is a braided assembly (63) and the textile structure (55, 65) is a braided structure (65) comprising braiding of the one or more non-conductive filaments (67) and the one or more conductive filaments (5).

22. An electrode assembly (51, 61) according to any one of claims 19 to 21 wherein the base (59, 69) is applied to surround the textile assembly (53) by electrospinning.

23. An electrode assembly according to any one of the preceding claims wherein the implanted electrode assembly coupled with the active implantable medical device and in contact with the surrounding fluid (13) has a capacitance in the range of 0.25 nanofarads to 3.30 nanofarads per metre.

24. A method of manufacturing an electrode assembly (1) for an active implantable medical device, comprising:

- providing an elongated biocompatible, electrically non-conductive body (3);
- locating one or more biocompatible, electrically conductive filaments (5) through the elongated non-conductive body (3) from a first portion (7) to a second portion (9); and
- forming one or more fluid passages (11) along the elongated electrically non-conductive body (3) between the first portion (7) and the second portion (9),

wherein the one or more fluid passages (11) allow a surrounding fluid (13) of a patient to be in contact with the one or more conductive filaments (5).

25. A method of manufacturing an electrode assembly (1) according to claim 24 further comprising:

- forming a plurality of apertures (18) along the elongated electrically non-conductive body (3) to provide the fluid passages (11a) from an outer surface (19) of the electrically non-conductive body (3) to the one or more conductive filaments (5).

26. A method of manufacturing an electrode assembly (1) according to either claim 24 or 25, further comprising:

- forming one or more conductive filament lumens (15) inside the elongated electrically non-conductive body (3) to receive respective electrically conductive filaments (5), wherein the one or more conductive filament lumens (15) has a diameter greater than the

respective conductive filament lumens (15) to form at least part of the one or fluid passages (11b).

27. A method of manufacturing an electrode assembly (1) according to any one of claims 24 to 26, further comprising:

- forming one or more channels (21) along the elongated electrically non-conductive body (3), wherein the one or more channels (21) provide the one or more fluid passages (11c) from an outer surface (19) of the electrically non-conductive body (3) to the one or more conductive filaments (5).

28. A method of manufacturing an electrode assembly (1) according to any one of claims 24 to 27, further comprising:

- filling one or more fluid passages (11) with one or more plugs (23), wherein the plugs comprise a biocompatible biodegradable material, wherein the one or more plugs (23) biodegrade in a body of the patient after implantation.

29. A method of manufacturing an electrode assembly (1) according to any one of claims 24 to 28, further comprising:

- surrounding the elongated biocompatible, electrically non-conductive body (3) with a biocompatible biodegradable sheath (25), wherein the biodegradable sheath (25) biodegrades in a body of the patient after implantation.

30. A method of manufacturing an electrode assembly (1) according to any one of claims 24 to 29, further comprising:

- forming a central lumen in the elongated electrically non-conductive body (3), wherein the central lumen is configured to receive a stylet.

31. A method of manufacturing an electrode assembly (1) according to claim 24, wherein the elongated electrically non-conductive body (3) comprises an outer wall (29) that defines a cavity (27) within, the method further comprising:

- surrounding the one or more conductive filaments (5) with a biodegradable material, wherein the biodegradable material (31) and conductive filaments are provided inside a cavity (27),

wherein the biodegradable material (31) biodegrades in a body of a patient after implantation.

32. A method according to claim 31 further comprising:

- helically disposing the one or more conductive filaments (5) around a core (33).

33. A method according to any one of claims 24 to 32 further comprising:

- stitching the elongated, biocompatible, electrically non-conductive body (3) to a biocompatible, electrically non-conductive and needle-piercable base (83).

34. A method of manufacturing an electrode assembly (41, 71) for an active implantable medical device, comprising:

- providing one or more biocompatible, electrically conductive filaments (5); and

- forming a biocompatible, porous support body (43, 73) around the one or more biocompatible electrically conductive filaments (5);

wherein the porous support body (43) provide fluid passages (11d) to allow a surrounding fluid (13) of a patient to be in electrical contact with the one or more conductive filaments (5).

35. A method of manufacturing an electrode assembly according to claim 34 further comprising:

- providing a core (33); and

- helically disposing the one or more conductive filaments (5) around the core (33).

36. A method of manufacturing an electrode assembly according to claim 35 further comprising:

- forming a central lumen (35) in the core (33).

37. A method of manufacturing an electrode assembly according to claim 34, wherein the one or more biocompatible electrically conductive filaments (5) comprise a plurality of conductive filaments (5), the method further comprising:

- arranging the plurality of conductive filaments (5) in a matrix (74) in the porous support body (43, 73).

38. A method of manufacturing an electrode assembly (51, 61) for an active implantable medical device, comprising:

- providing a textile assembly (53, 63), having a textile structure (55, 65), comprising:

- one or more biocompatible, electrically non-conductive filaments (57, 67);

and

- one or more biocompatible, electrically conductive filaments (5); and

- surrounding at least one section of the textile assembly (53, 63) with a biocompatible, electrically non-conductive and non-woven base (59, 69),

wherein the textile structure (55, 65) is porous to allow a surrounding fluid (13) of the patient to be in electrical contact with the one or more conductive filaments (5).

39. A method of manufacturing an electrode assembly according to claim 38, wherein the textile assembly (53) is a knitted assembly (53), and the textile structure (55) is an intermeshed loop structure (55), and wherein providing a textile assembly (53, 63) comprises:

-knitting the one or more non-conductive filaments (57) with the one or more conductive filaments (5).

40. A method of manufacturing an electrode assembly according to claim 38, wherein the textile assembly (63) is a braided assembly (63) and the textile structure (65) is a braided structure (65), and wherein providing a textile assembly (53, 63) comprises:

- braiding the one or more non-conductive filaments (57) with the one or more conductive filaments (5).

41. A method of manufacturing an electrode assembly according to any one of claims 38 to 40, wherein surrounding the at least one section of the textile assembly (53, 63) with a biocompatible electrically non-conductive and non-woven base (59, 69) comprises applying the base (59, 69) by electrospinning.

42. An electrode assembly (1) for an active implantable medical device comprising:

- an elongated, biocompatible, electrically non-conductive body (3) having a first portion (7) and a second portion (9);

- one or more biocompatible, electrically conductive filaments (5) inside the elongated non-conductive body (3) between the first portion (7) and the second portion (9);

wherein the electrode assembly (1) is configured to be coupled with the active implantable medical device and in contact with the surrounding fluid (13) to have a capacitance in the range of 0.25 nanofarads to 3.30 nanofarads per metre.

43. A method of manufacturing an electrode assembly (1) for an active implantable medical device, comprising:

- providing an elongated biocompatible, electrically non-conductive body (3);

- locating one or more biocompatible, electrically conductive filaments (5) through the elongated non-conductive body (3) from a first portion (7) to a second portion (9); and

- coupling the electrode assembly (1) with the active implantable medical device and locating the electrode assembly (1) to be in contact with the surrounding fluid (13) to have a capacitance in the range of 0.25 nanofarads to 3.3 nanofarads per metre.

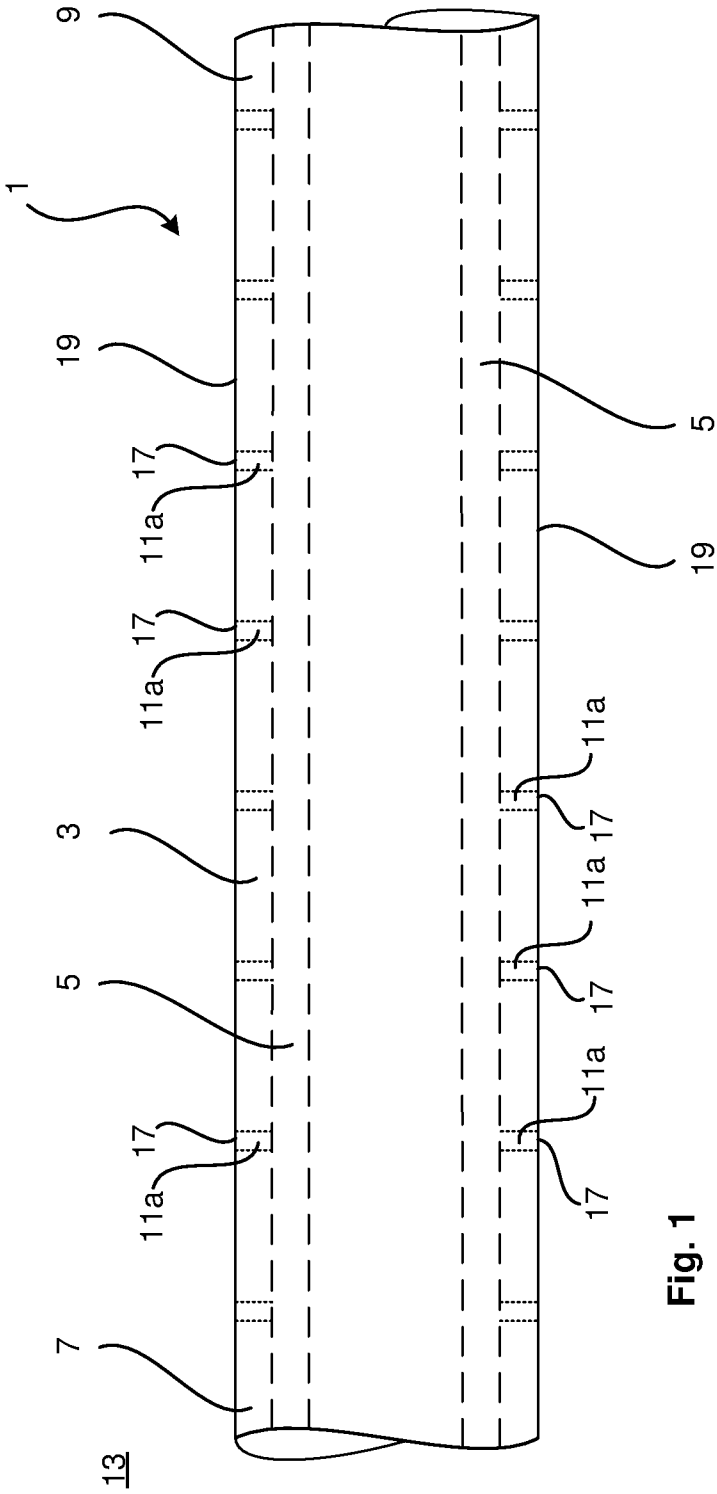


Fig. 1

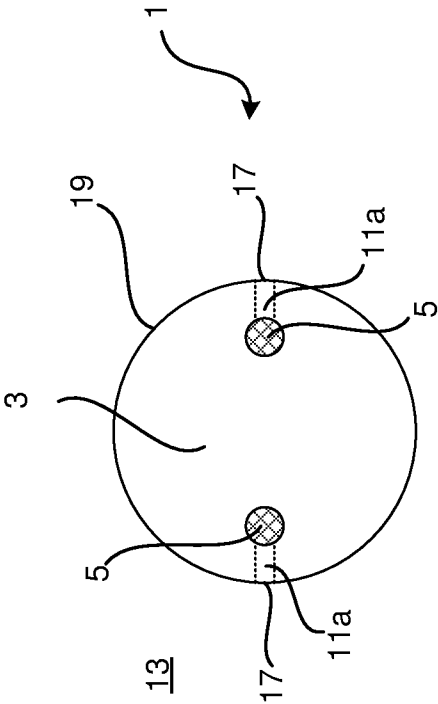


Fig. 2

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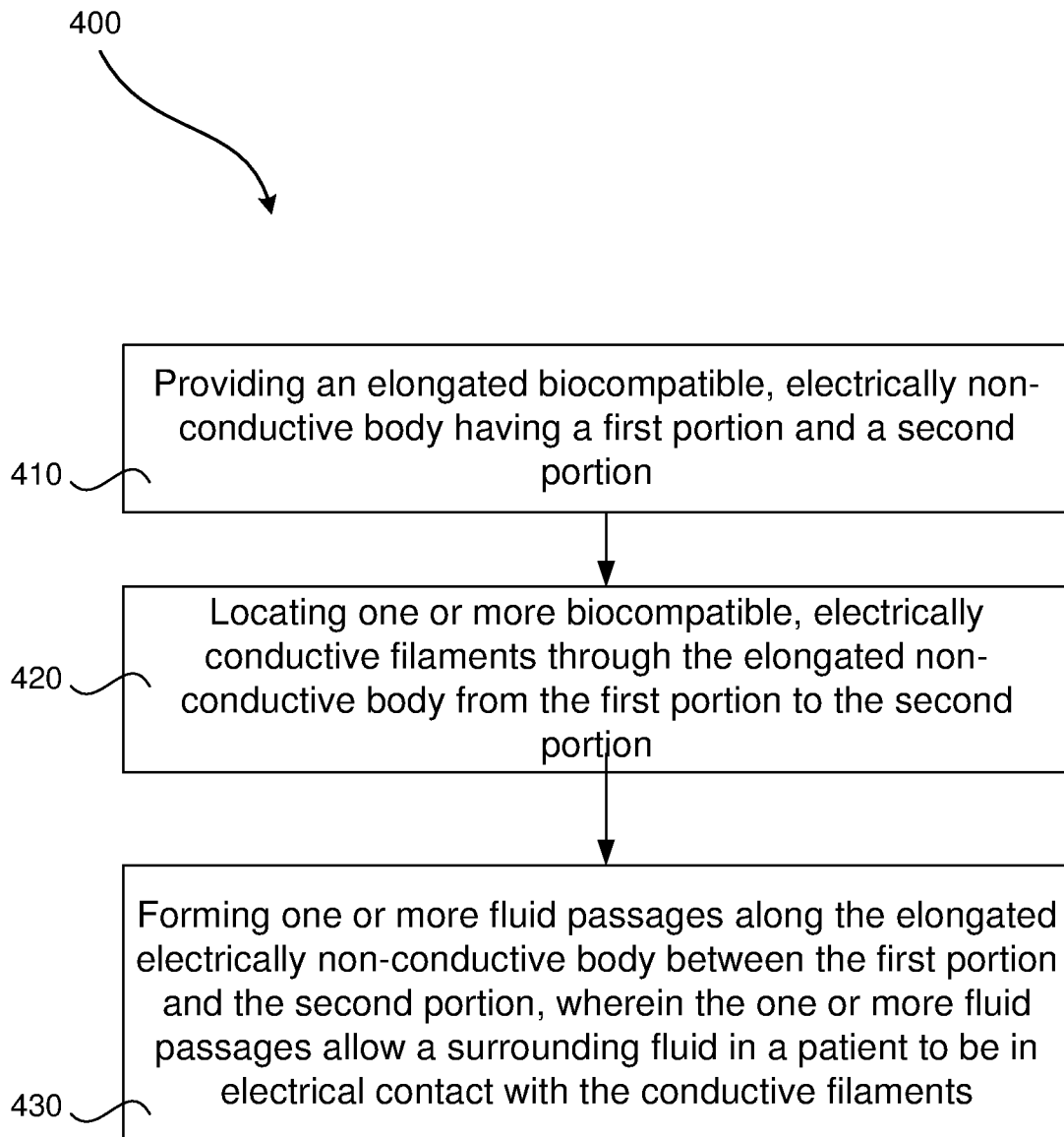


Fig. 3

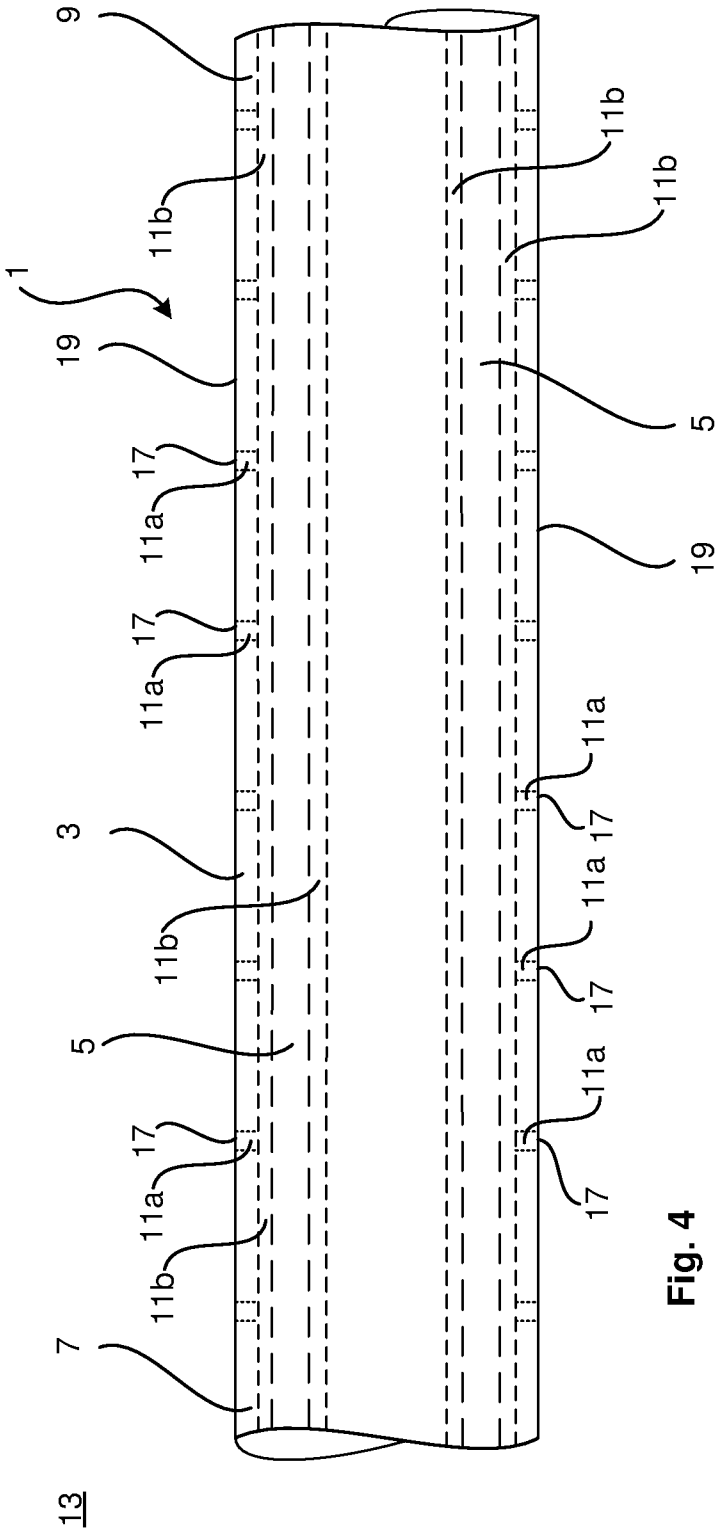


Fig. 4

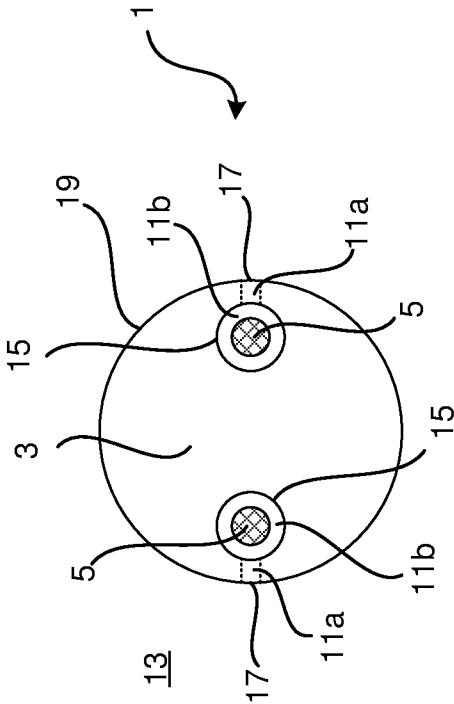


Fig. 5

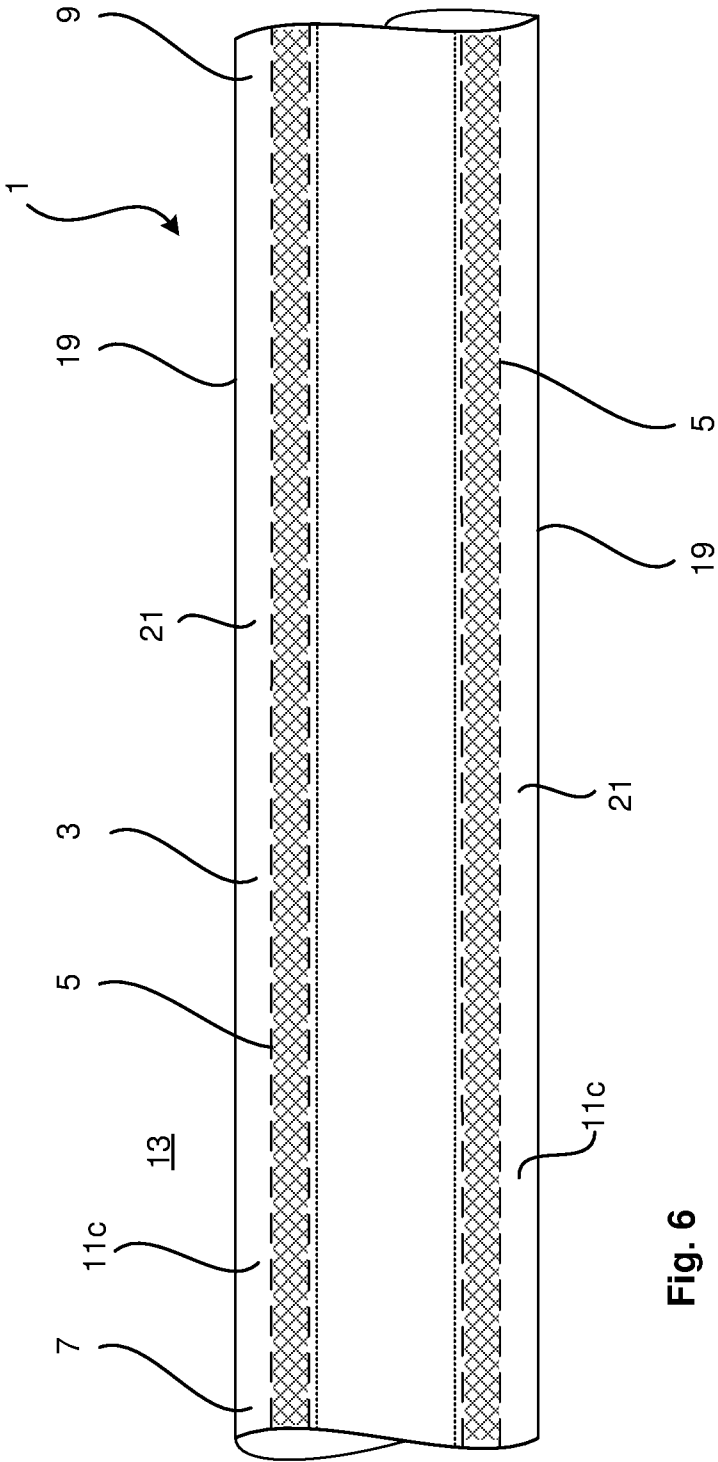


Fig. 6

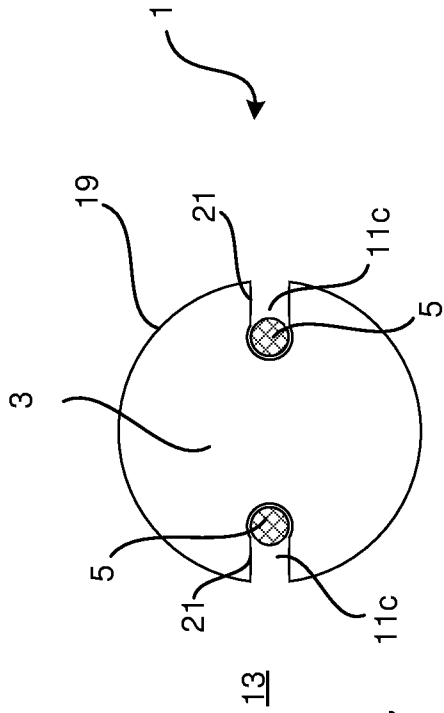


Fig. 7

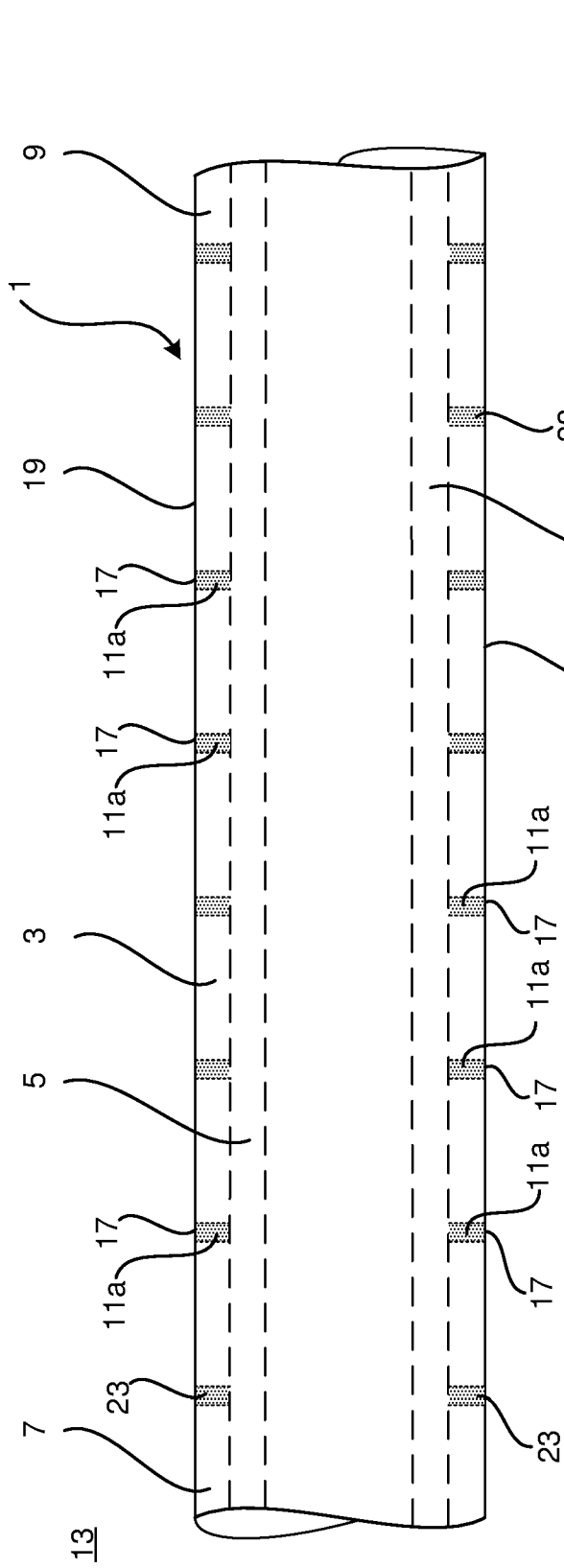


Fig. 8

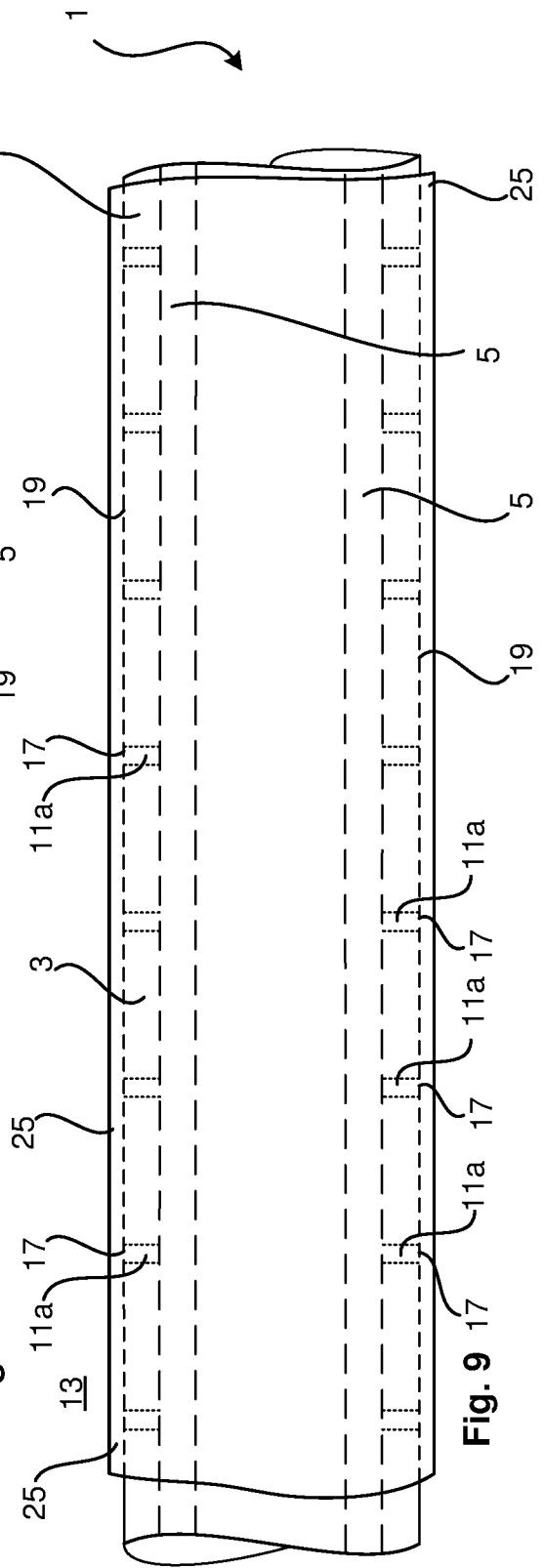


Fig. 9

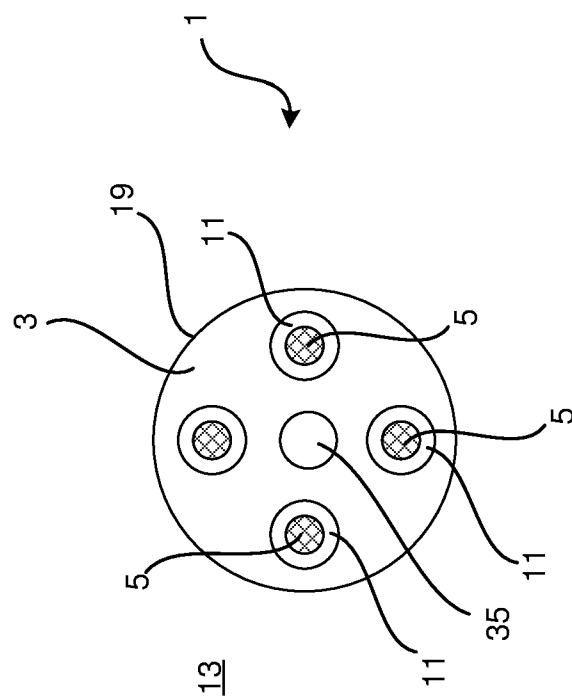


Fig. 10

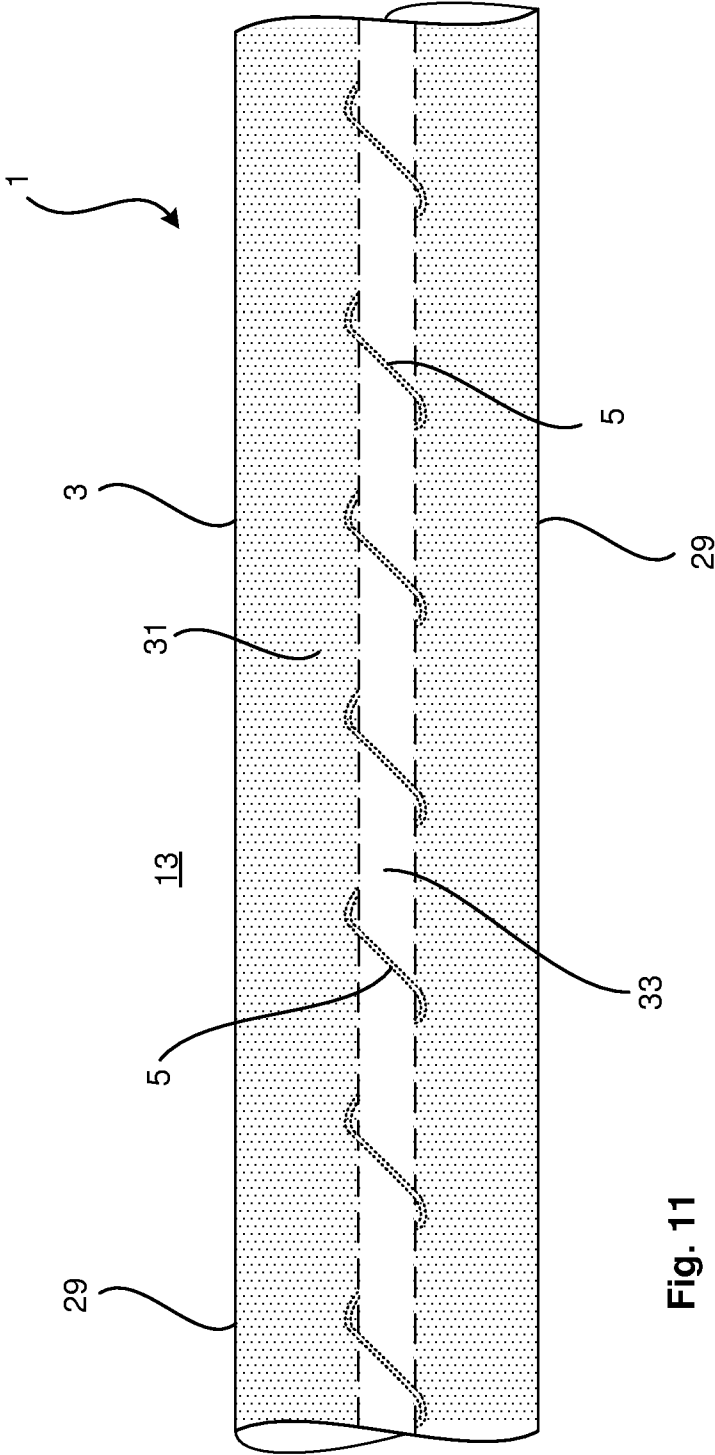


Fig. 11

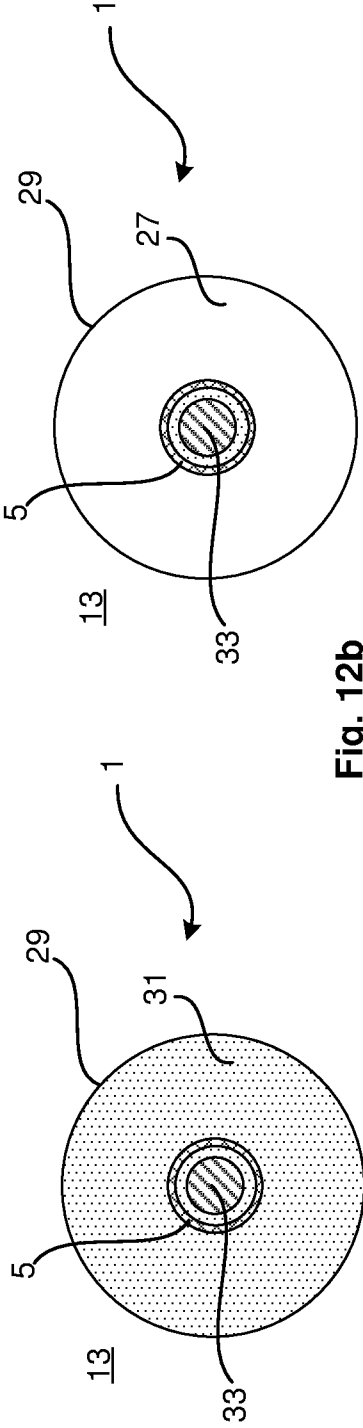


Fig. 12a

Fig. 12b

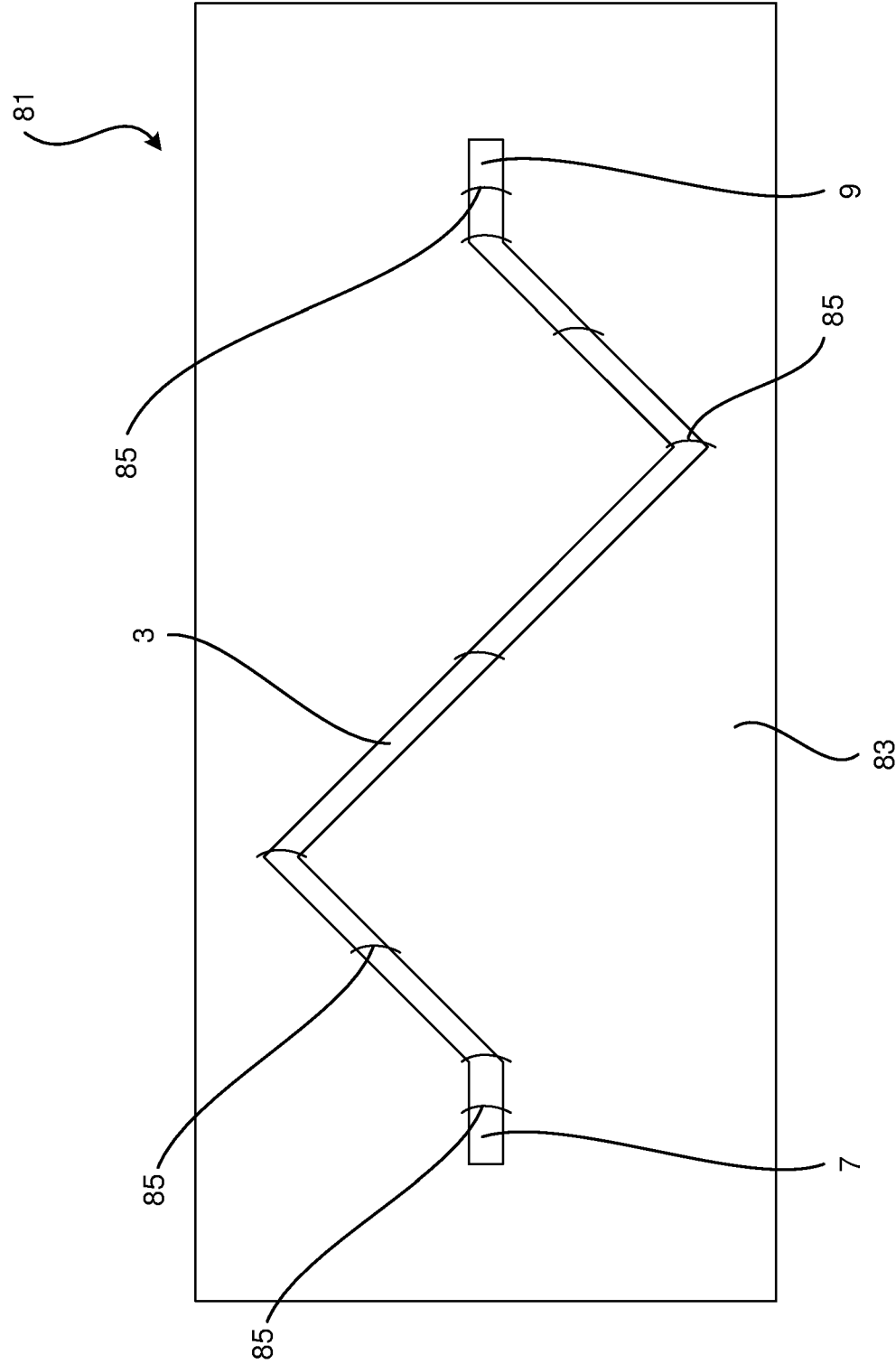


Fig. 13

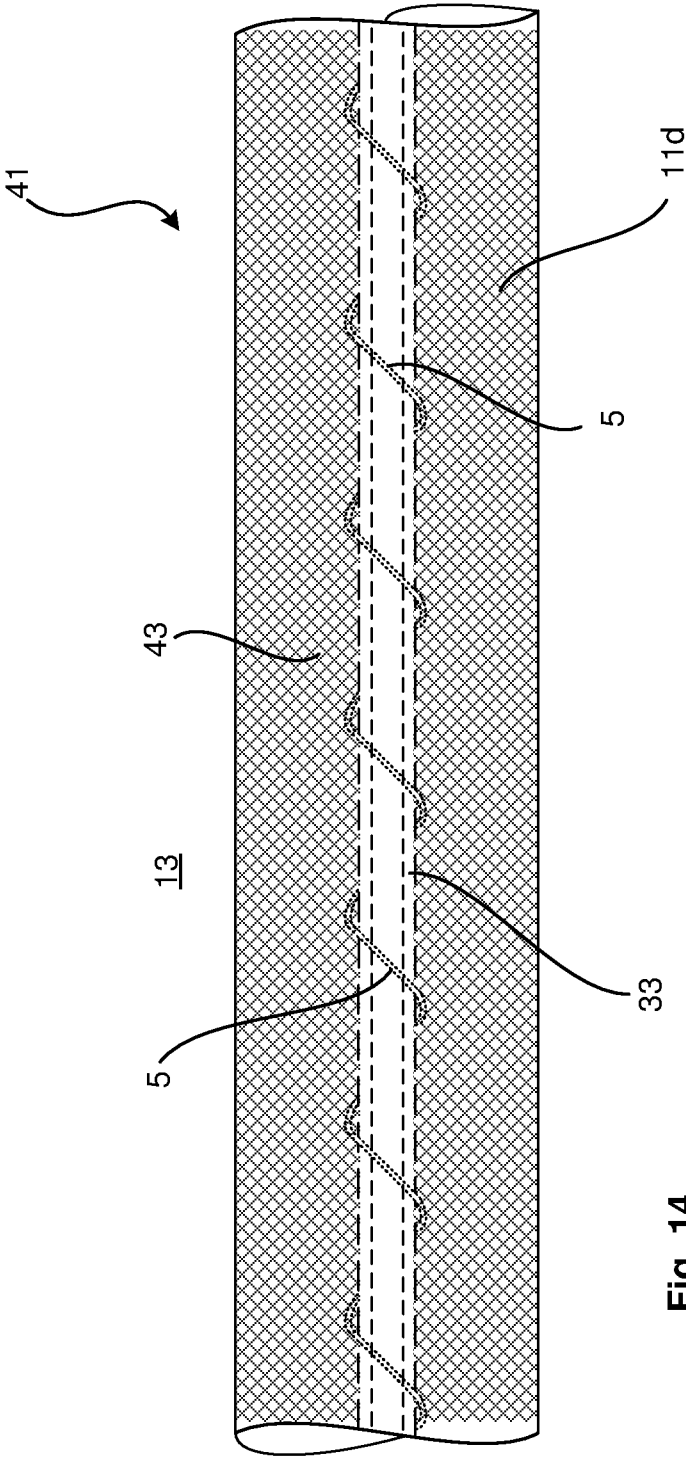


Fig. 14

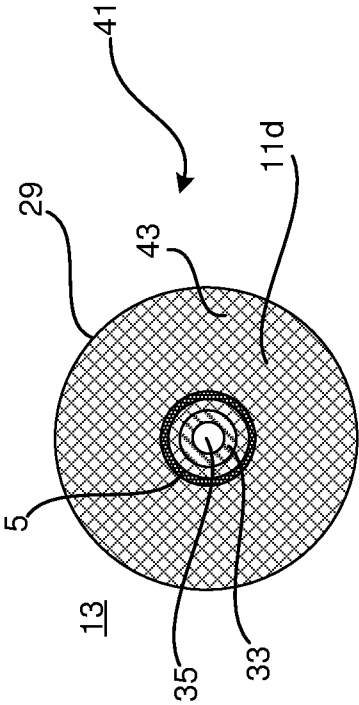


Fig. 15

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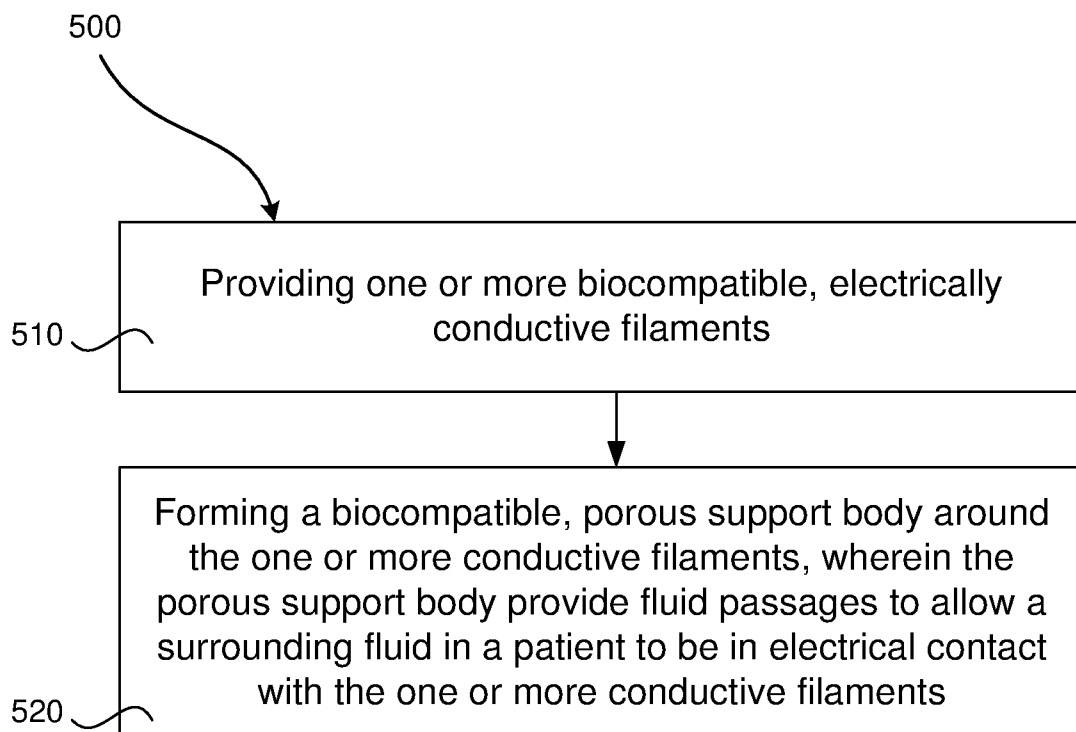


Fig. 16

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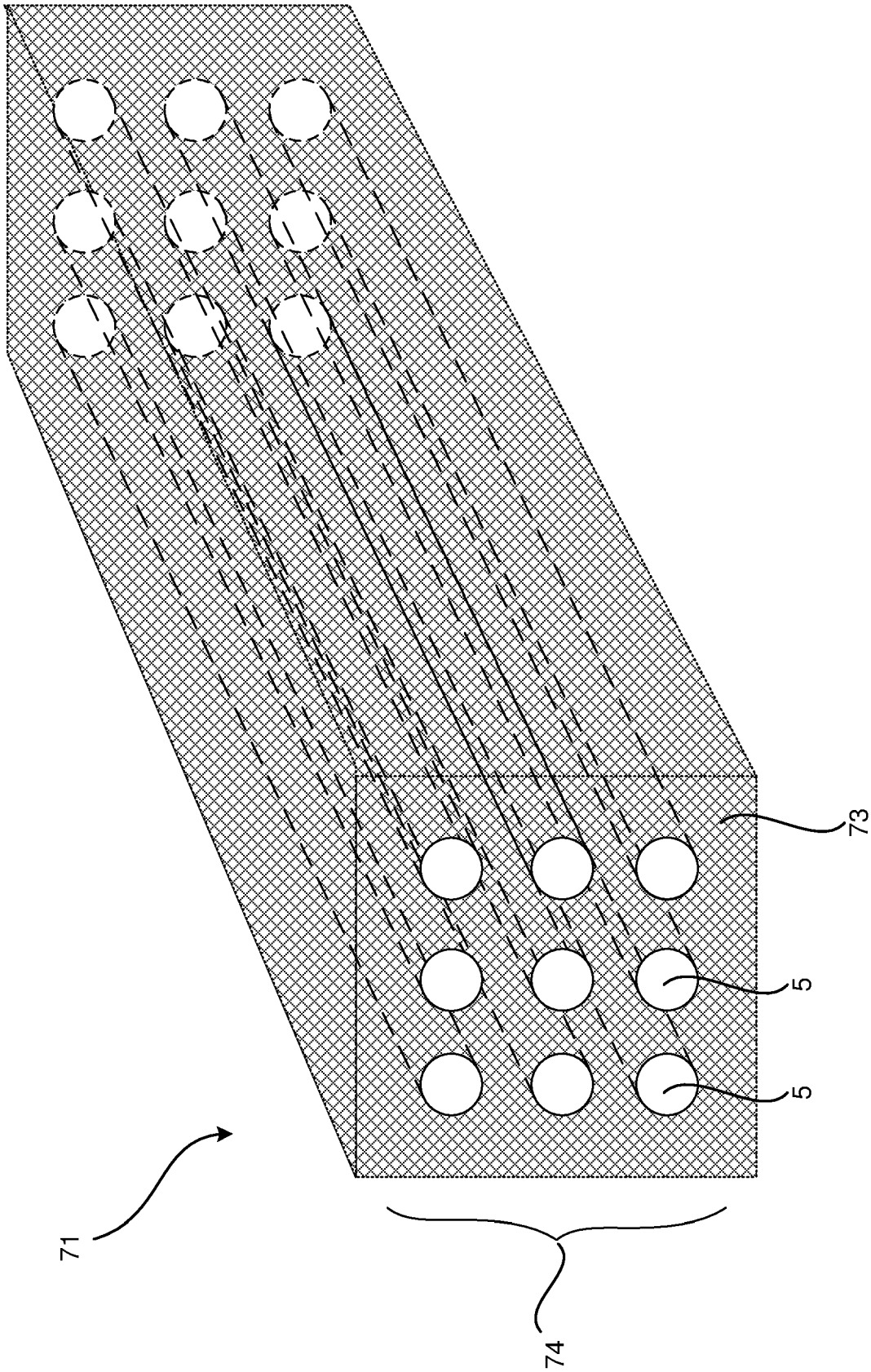
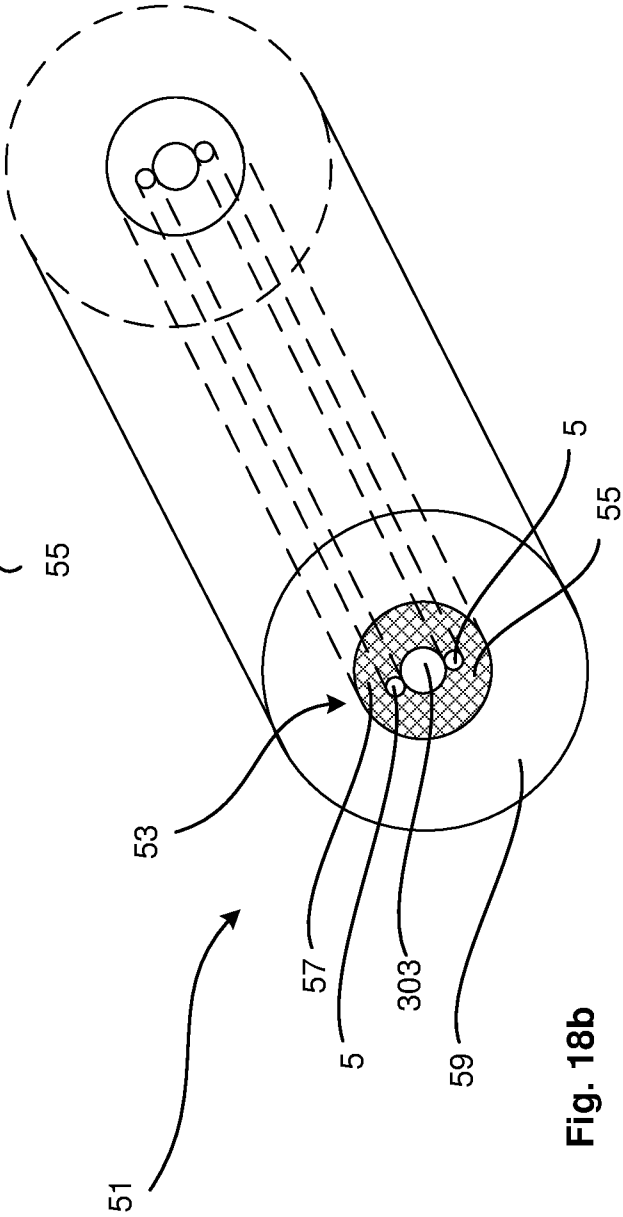
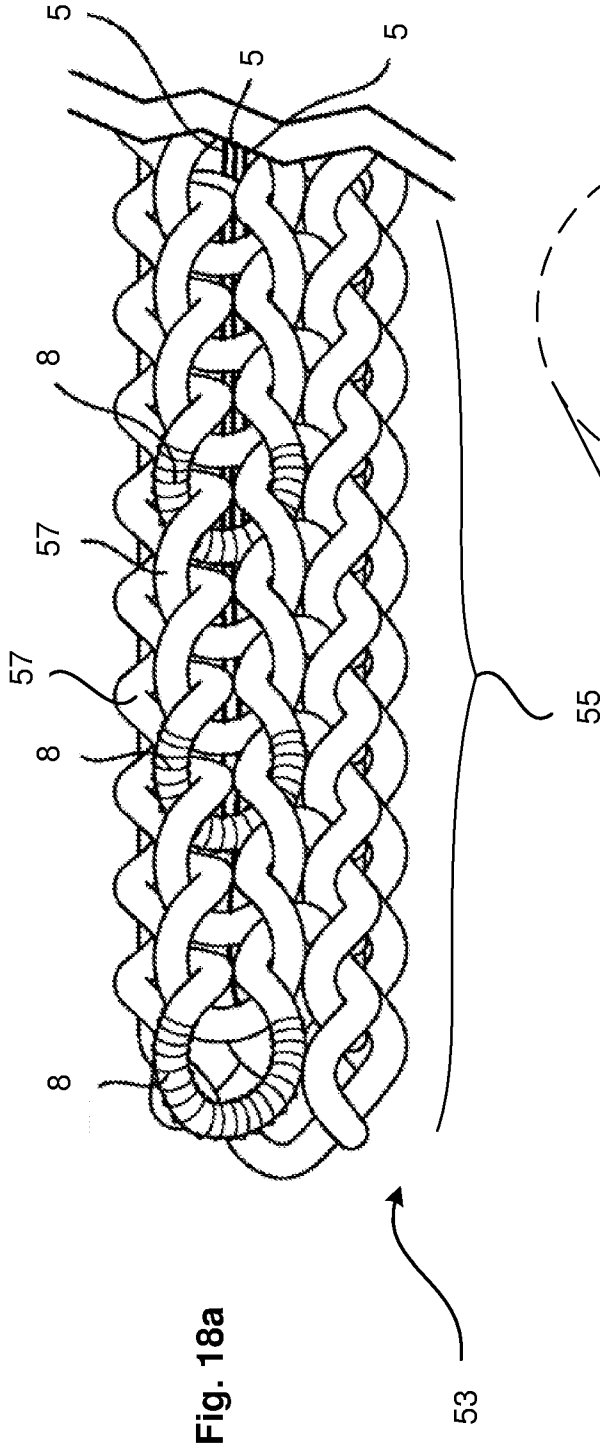


Fig. 17



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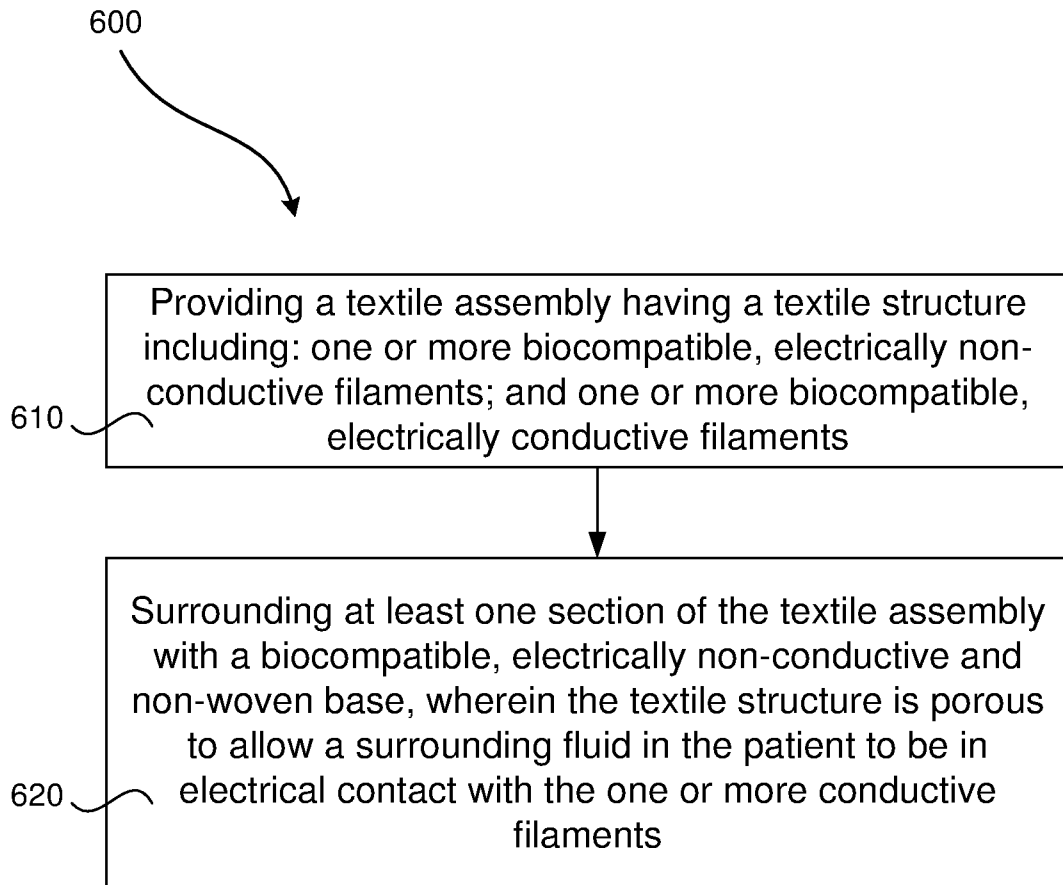


Fig. 19

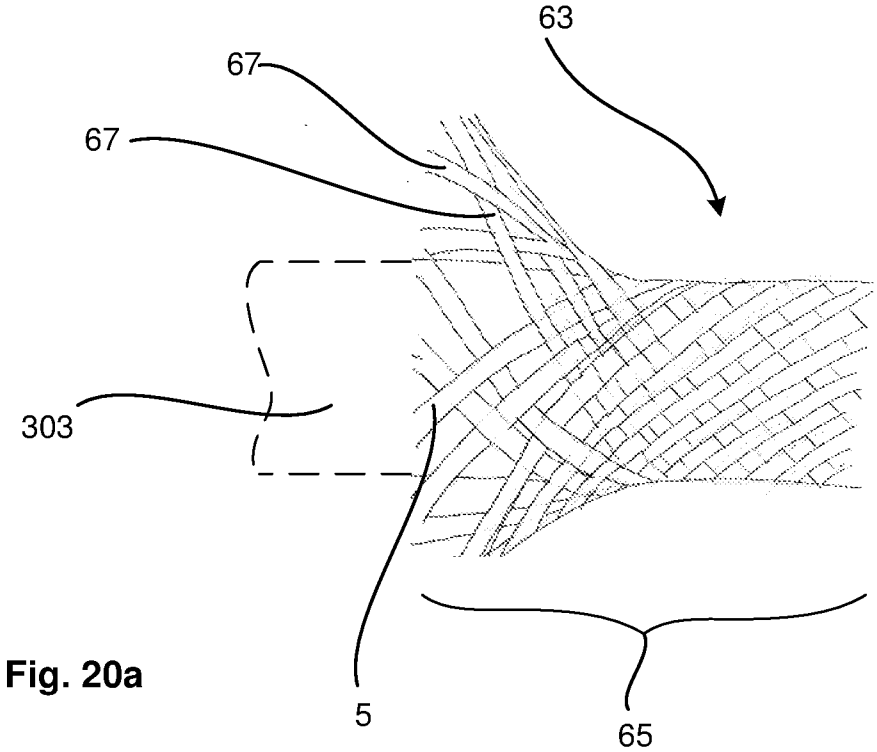


Fig. 20a

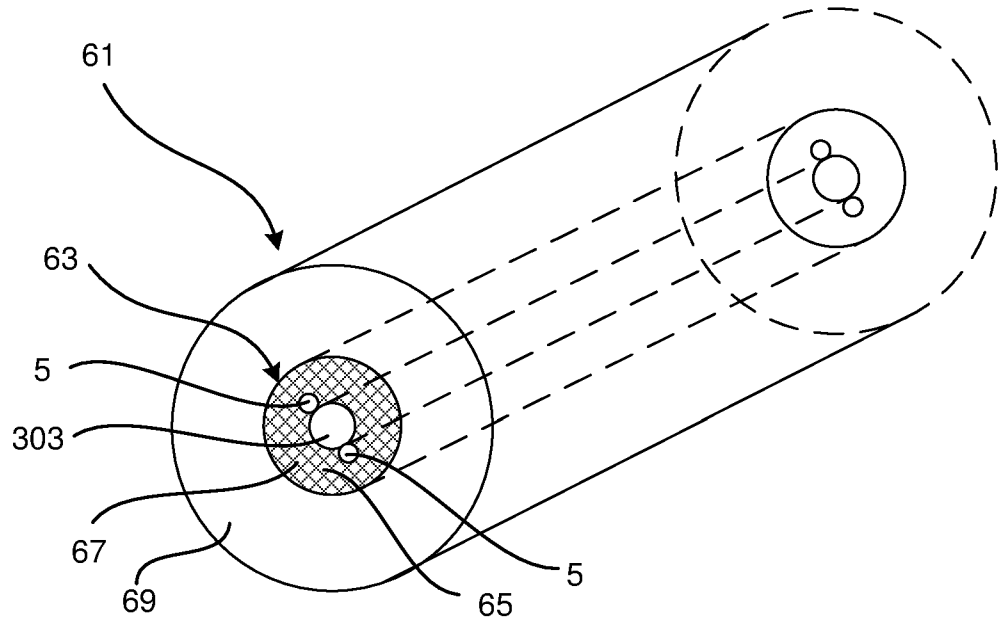


Fig. 20b

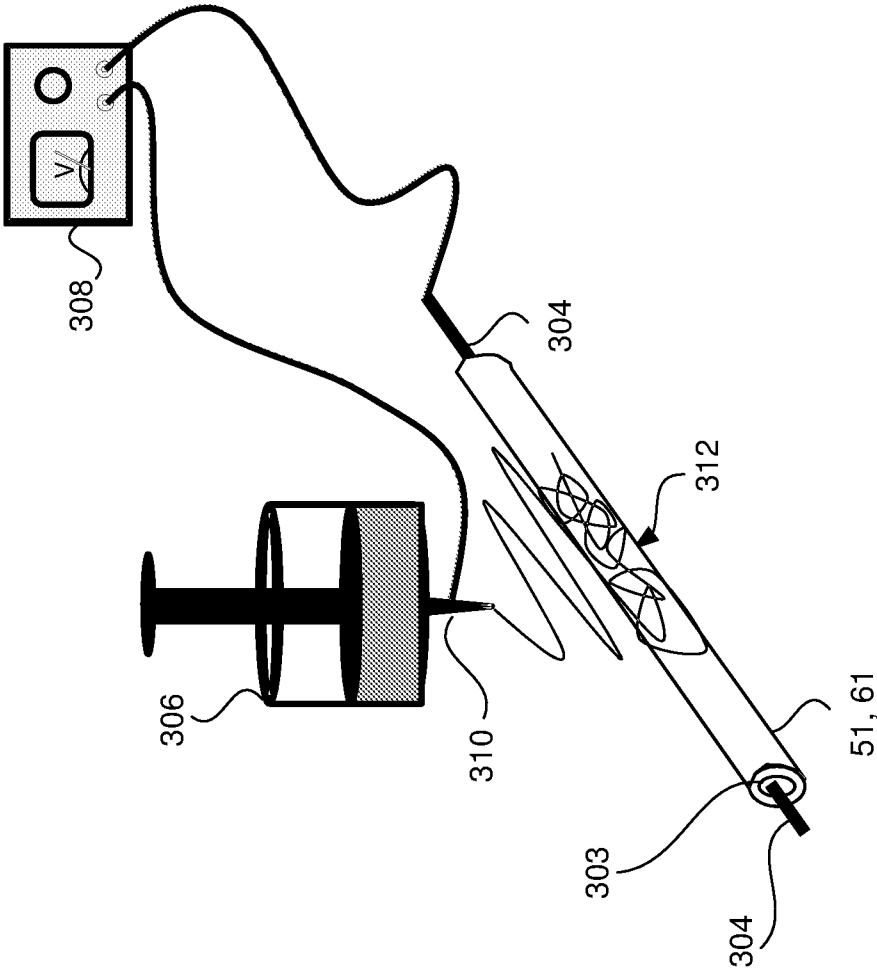


Fig. 21

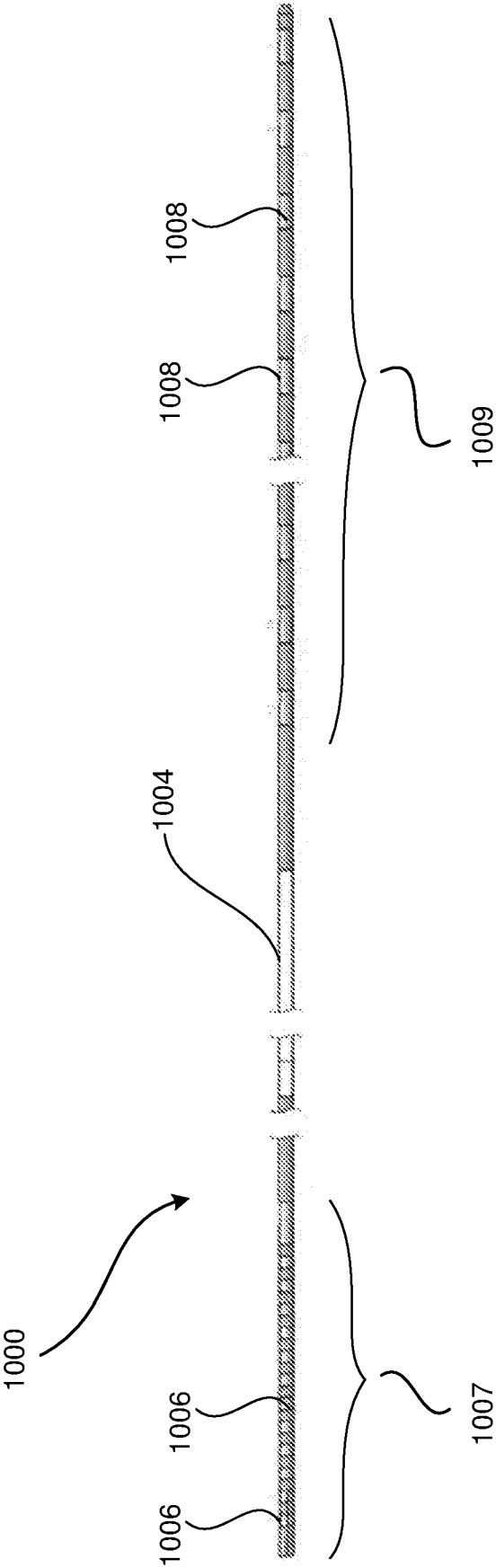


Fig. 22

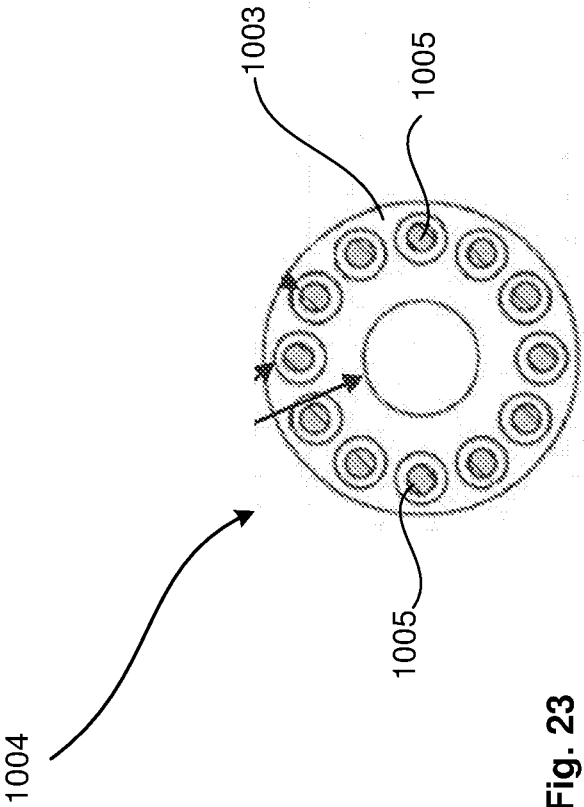


Fig. 23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2018/050191

A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/05 (2006.01)

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)

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)

PATENW and A61N1/05/low, A61N1/086 and keywords: conduct, filament, fluid, permeable, aperture, body, electrode, contact, fabric, capacitance, biodegrade, sleeve and similar terms. PATENW and SALUDA as applicant.

Espacenet: Applicant and inventor name searches.

Google and Google Patents: Electrode, implant, fluid, coupling, capacitive, capacitance, contact. Selected documents viewed. Electrode, electrolyte, interface, capacitance. Selected documents viewed. Electrode, implant, matrix, conductor, parallel. Selected documents viewed.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

☒ Further documents are listed in the continuation of Box C ☒ See patent family annex

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"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 1 May 2018		Date of mailing of the international search report 01 May 2018	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustalia.gov.au		Authorised officer David Melhuish AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61262832426	

INTERNATIONAL SEARCH REPORT		International application No.
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		PCT/AU2018/050191
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/0144189 A1 (MEDTRONIC BAKKEN RESEARCH CENTER B.V.) 26 May 2016 paragraphs 3, 79, 82, 97, figure 12	1 - 3, 5, 14, 15, 23 - 26, 34 - 36, 42, 43
Y	paragraphs 3, 79, 82, 97, figure 12	7, 12, 13, 17, 18, 29, 33, 37
X	US 2015/0151107 A1 (NEURONANO AB) 04 June 2015 paragraph 80, figures 1b to 1e, 5b, 12a	1 - 3, 5 - 8, 10, 11, 23 - 26, 28, 29, 31, 32, 42, 43
Y	paragraph 80, figures 1b to 1e, 5b, 12a	7, 12, 13, 29, 33
X	US 2014/0324143 A1 (SALUDA MEDICAL PTY LTD) 30 October 2014 figures 4a and 4b, paragraphs 4, 68 to 70	1 - 3, 5, 6, 9, 14 - 16, 19 - 26, 28, 30, 34 - 36, 38 - 43
Y	figures 4a and 4b, paragraphs 4, 68 to 70	7, 12, 13, 17, 18, 29, 33, 37
X	US 2016/0235967 A1 (SORIN CRM SAS) 18 August 2016 figures 2a and 6, paragraph 55	1, 2, 4, 5, 9, 23 - 25, 27, 30, 42, 43
Y	figures 2a and 6, paragraph 55	7, 12, 13, 29, 33
X	US 2006/0282146 A1 (ARON et al.) 14 December 2006 figures 3A and 5, paragraph 34	1, 2, 5, 14, 15, 23 - 25, 34 - 36, 42, 43
Y	figures 3A and 5, paragraph 34	7, 12, 13, 17, 18, 29, 33, 37
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
Form PCT/ISA/210 (Family Annex)(July 2009)			

INTERNATIONAL SEARCH REPORT Information on patent family members		International application No. PCT/AU2018/050191	
This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.			
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