

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
23 April 2009 (23.04.2009)

PCT

(10) International Publication Number
WO 2009/052425 A1

(51) International Patent Classification:
A61N 1/00 (2006.01)

(74) Agent: **SCHOX, Jeffrey**; 730 Florida Street #2, San Francisco, CA 94110 (US).

(21) International Application Number:
PCT/US2008/080366

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(22) International Filing Date: 17 October 2008 (17.10.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/980,659 17 October 2007 (17.10.2007) US

(71) Applicant (for all designated States except US): **NEURONEXUS TECHNOLOGIES** [US/US]; 3985 Research Park Drive, Ann Arbor, MI 48108 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **HETKE, Jamille, F.** [US/US]; 10724 Hewitt Rd, Brooklyn, MI 49230 (US). **KIPKE, Daryl, R.** [US/US]; 5041 Dexter Pinckney Rd, Dexter, MI 48103 (US). **VETTER, Rio, J.** [US/US]; 7371 Copper Creek Dr., Ypsilanti, MI 48107 (US).

Published:
— with international search report

(54) Title: IMPLANTABLE DEVICE INCLUDING A RESORBABLE CARRIER

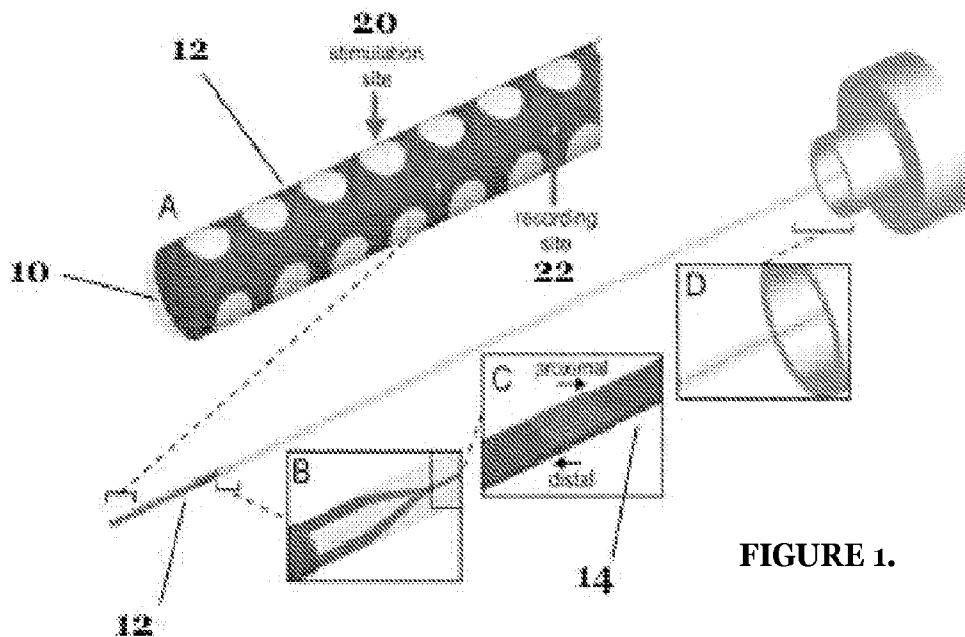


FIGURE 1.

(57) Abstract: An implantable device for body tissue, including an electrical subsystem that flexes within and interfaces with body tissue and a carrier that operates in the following two modes: provides structural support for the electrical subsystem during implantation of the device in body tissue and allows flexing of the electrical subsystem after implantation of the device in body tissue. The implantable device is preferably designed to be implanted into the brain, spinal cord, peripheral nerve, muscle, or any other suitable anatomical location. The implantable device, however, may be alternatively used in any suitable environment and for any suitable reason.

WO 2009/052425 A1

IMPLANTABLE DEVICE INCLUDING A RESORBABLE CARRIER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of US Provisional Application number 60/980,659 filed 17 OCT 2007 and entitled "Carrier for an Implantable Device System", which is hereby incorporated in its entirety by this reference.

[0002] This application is related to US Publication Number 2008/0208283 published on 28 AUG 2008 and entitled "Neural Interface System", which is incorporated in its entirety by this reference.

TECHNICAL FIELD

[0003] This invention relates generally to the implantable device field, and more specifically to an implantable device including a resorbable carrier.

BACKGROUND

[0004] Conventional microfabricated electrode arrays by themselves are often not mechanically robust enough to be inserted into body tissue. Therefore, they must be coupled to a carrier that is strong enough to resist buckling while being inserted into the tissue. Conventional carriers typically remain implanted with the microfabricated electrode arrays, potentially reducing the ability of the microfabricated electrode arrays to move freely in the tissue. Thus, there is a need for an improved carrier that increases the ability of the microfabricated electrode arrays to move freely. This invention provides such an improved and useful carrier.

BRIEF DESCRIPTION OF THE FIGURES

[0005] FIGURE 1 is a representation of the device of the preferred embodiments of the invention, shown with four detailed views.

[0006] FIGURE 2 is a representation of the device of FIGURE 1, shown with two cross-sectional views.

[0007] FIGURE 3 is a representation of the device of a second version of the preferred embodiments of the invention, shown in an exploded, pre-assembled view.

[0008] FIGURE 4 is a representation of the method of the preferred embodiments of the invention, shown with the three major steps

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0009] The following description of preferred embodiments of the invention is not intended to limit the invention to these embodiments, but rather to enable any person skilled in the art to make and use this invention.

[0010] As shown in FIGURES 1 and 2, the implantable device of the preferred embodiments includes a carrier 10 and an electrical subsystem 12 coupled to the carrier 10. The carrier 10 functions to facilitate the insertion of the electrical subsystem 12 and is adapted to allow the electrical subsystem 12 to move freely in the tissue. The implantable device is preferably designed to be implanted into the brain, spinal cord, peripheral nerve, muscle, or any other suitable anatomical location. The implantable device, however, may be alternatively used in any suitable environment and for any suitable reason.

[0011] The carrier 10 functions to facilitate the insertion of the electrical subsystem 12 and is adapted to allow the electrical subsystem 12 to move freely in the tissue or other substances. The electrical subsystem 12 is preferably attached to the carrier 10 such that the carrier functions to provide structural support. The carrier may include a sharpened end adapted to penetrate the tissue and aid in the insertion of the carrier and electrical subsystems into the tissue. The carrier 10 may also include alignment and or fixation features to facilitate positioning and stabilizing the electrical subsystem 12 in the tissue.

[0012] The carrier 10 of the preferred embodiments is resorbable into tissue after a period of time. Upon resorption of the carrier 10, the electrical subsystem 12 supported by the carrier will be left to float freely in the brain or other suitable tissue or material. The resorbable carrier is preferably made of a material that demonstrates at least one of the following characteristics: minimal foreign body reaction, biocompatibility, biodegradability, long-term mechanical and chemical stability, sterilizability, and sufficient porosity. The material is preferably adapted to undergo a controlled action and reaction to the surrounding tissue, a controlled chemical breakdown and resorption, replacement by regenerating tissue, stimulation of regeneration of living tissues, or any combination thereof. The resorbable carrier is preferably made from a bioresorbable polymer. The bioresorbable polymer is preferably polyglycolide or polylactide, but may alternatively be made from any suitable bioresorbable material such as a biodegradable magnesium alloy or a corrodible iron alloy. If the bioresorbable polymer is polyglycolide (or any other material that absorbs into the body after approximately one month), the carrier absorbs into the body at about

the same time the body heals around the implanted device, which may be advantageous in some situations. If the bioresorbable polymer is polylactide (or any other material that absorbs into the body after approximately one year), the carrier absorbs into the body much after the body heals around the implanted device, which may be advantageous in other situations.

[0013] The carrier 10 may further extend the functionality of the device by providing fluidic channels through which therapeutic drugs, drugs to inhibit biologic response to the implant, or any other suitable fluid or substance may be transmitted. The fluidic channels are preferably channels defined by the geometry of the carrier 10, but may alternatively be separate microtubes molded, inserted, woven, knitted, or otherwise disposed into the carrier 10. The channels preferably provide for the precise delivery of specific pharmaceutical compounds to localized regions of the body, such as the nervous system, and could facilitate, for example, intraoperative mapping procedures or long-term therapeutic implant devices. The fluidic channels may also provide a location through which a stiffener (or even a shape-memory alloy such as Nitinol) may be inserted to aid with the implantation or to facilitate post-implantation navigation of the device. The shape of the carrier is preferably tubular with about a 1-mm diameter, but may alternatively be solid or any other suitable shape of any suitable diameter for the desired functions.

[0014] The carrier 10 is preferably made from a material that is woven or knitted, but may alternatively be made from a material that is cast, molded, or machined. The carrier 10 is preferably flexible, but may alternatively be rigid or semi rigid. The material may be uniformly rigid, or rigid only in a particular direction (such as the axial

direction). The resorbable carrier may also be impregnated with fluids and/or deliver the fluids such as drugs and/or neurotrophins, similar to the "Stent Device and Method" of U.S. Pat. No. 7,001,680, which is incorporated in its entirety by this reference. The carrier 10 may be further adapted to act as a template for tissue regeneration and/or as a matrix for autologous or analogous cells or stem cells.

[0015] The carrier 10 may be made from a combination of materials. The layers or portions of distinct materials may have distinct absorption, degradation, or incorporation times. The distinct materials may further include distinct particles, agents, and/or cells that they deliver or release into the tissue. The carrier 10 may further include scaffolding for structural support and/or for drug or cell delivery. The scaffolding is preferably bioresorbable, but may alternatively remain implanted with the device.

[0016] The carrier 10 may be manufactured in one of several variations. In a first variation, the carrier may be manufactured such that the weave of the material is large enough to accept "weaving" of the electrical subsystem 12 directly into the fabric. In this variation, the electrical subsystem can be adapted to be woven in and out of the resorbable carrier to secure the electrical subsystem 12 to the carrier 10. A single electrical subsystem 12 could be woven into the fabric or multiple subsystems could be incorporated, resulting in a three-dimensional system of electrical subsystems. In a second variation, the electrical subsystem could be coupled directly to the surface of the carrier using a biocompatible adhesive such as epoxy or silicone. In this variation, the weave of the resorbable carrier may be tighter and/or the porosity of the carrier may be smaller as the electrical subsystem 12 is not woven into the material in this variation. In

a third variation, the resorbable carrier may be manufactured as a concentric, multi-lumen structure. In this variation, the electrical subsystem 12 may be coupled to the carrier between the inner and outer lumens of the electrical subsystem.

[0017] Although the carrier 10 is preferably one of these several variations, of several various materials, manufactured in several variations, the carrier may be any suitable element, material, manufactured in any suitable fashion to facilitate the insertion of the electrical subsystem 12 and to allow the electrical subsystem 12 to move freely in the tissue or other substances.

[0018] The electrical subsystem 12 of the preferred embodiments functions to interface with the tissue, or any other suitable substance, within which it has been implanted. The electrical subsystem 12 may include multiple different electrical subsystems or a plurality of the same subsystems. The electrical subsystem 12 is preferably at least one of several versions or any combination thereof.

[0019] The electrical subsystem 12 is preferably a neural interface electrode array. The electrode array preferably has a plurality of electrode sites, and more preferably both stimulation sites 20 and recording sites 22. The neural interface electrode array is adapted to provide dynamic tunable electrical stimulation ranging from stimulation with macroscale specificity to microscale directional patterning. The electrode array is preferably adapted to optimally sample (record) and/or selectively activate (stimulate) neural populations. The plurality of electrode sites can be tuned for recording, stimulation, or any combination thereof. Additionally, at least two electrode sites may be grouped to form a larger composite site that enables tuning the neural interface region for recording and/or stimulation.

[0020] The neural interface electrode array is preferably made from a thin-film polymer substrate, such as parylene or some combination of parylene and inorganic dielectrics, but may alternatively be made out of any suitable material including, for example, silicon. The neural interface electrode array is preferably made such that there is high density of electrode sites at a first end of the array (the distal end) and bonding regions at a second end of the array (the proximal end). The distal end of the array is preferably coupled to the carrier 10 to provide structural support. The electrode array may further include fluidic channels providing the capability to deliver therapeutic drugs, drugs to inhibit biologic response to the implant, or any other suitable fluid.

[0021] The neural interface electrode array in this variation is preferably a composite assembly that includes the neural interface electrode array and the carrier 10. The neural interface electrode array includes two pieces, a distal element and a proximal element. The distal element wraps or is woven around the circumference of the carrier 10. Ascending from the distal element, are preferably interconnects that transition from the outer surface of the carrier 10 into a single connector 14, such that the entire proximal element is imbedded in silicone. To facilitate adhesion between the carrier 10 and the neural interface electrode array, small non-homogeneous perforations are preferably micromachined in the neural interface electrode array to allow for the material of the carrier 10 to form a robust anchor with the electrode array.

[0022] In a second version of the preferred embodiments, as shown in FIGURE 3, the neural interface electrode array preferably defines series of “cut-aways” or perforations that axially extend in a discontinuous manner along the length of the neural interface electrode array. With the perforations, the neural interface electrode

array preferably has adequate flexibility to allow bending and flowing of the device within body tissue after implantation of the device. The perforations preferably extend in a radial direction completely through the neural interface electrode array, and preferably extend in a circumferential direction approximately 45-90 degrees. The neural interface electrode array preferably includes two perforation series, and thus the neural interface electrode array preferably extends 180-270 degrees in the areas with perforations. The perforation series is preferably discontinuous (i.e., the neural interface electrode array extends completely in the circumferential direction at particular points along the length of the neural interface electrode array). While the neural interface electrode array has been described as having perforations, it is also possible for the neural interface electrode array to be described as being one or more strips that are circumferentially connected by several "bridges".

[0023] In a third version of the preferred embodiments, the neural interface electrode array omits the "bridges" and is merely one or more rectangular and generally planar (i.e., either flat or slightly curved) "strips". The carrier provides structural support for these "strips" to be placed onto a stylet and implanted into body tissue. Although the electrical subsystem 12 is preferably one of these three versions, the electrical subsystem 12 may be any suitable element or combination of elements to perform the desired functions.

[0024] The device of the preferred embodiments may further include an additional electrical subsystem that functions to operate with the electrical subsystem 12. The additional electrical subsystem may include multiple different electrical subsystems or a plurality of the same subsystems. The additional electrical subsystem is

preferably at least one of several versions or any combination thereof. In a first version, the additional electrical subsystem is a suitable electronic subsystem to operate with an implantable neural interface. The additional electrical subsystem may be a printed circuit board with or without on-board integrated circuits and/or on-chip circuitry for signal conditioning and/or stimulus generation, an Application Specific Integrated Circuit (ASIC), a multiplexer chip, a buffer amplifier, an electronics interface, an implantable pulse generator, an implantable rechargeable battery, integrated electronics for either real-time signal processing of the input (recorded) or output (stimulation) signals, integrated electronics for control of the fluidic components, any other suitable electrical subsystem, or any combination thereof. Although the additional electrical subsystem is preferably one of these several subsystems, the additional electrical subsystem may be any suitable element or combination of elements to operate any suitable electrical subsystem 12.

[0025] The device of the preferred embodiments may further include a connector 14 that functions to couple the electrical subsystem 12 to the additional electrical subsystem. The connector 14 is preferably one of several versions. As shown in FIGURES 1 and 2, the cable is preferably a flexible ribbon cable. The ribbon cable is preferably polymer ribbon cable, but may alternatively be any other suitable ribbon cable. The connector 14 may alternatively be any suitable element to couple the electrical subsystem 12 to the additional electrical subsystem, such as wires, conductive interconnects, etc. The ribbon cable may be encased in silicone or any other suitable material. In some versions, the electrical subsystem may have multiple ribbon cables. Preferably, multiple ribbon cables would be physically attached along their entire

length, using a suitable adhesive such as medical grade adhesive or any other suitable connection mechanism. The cable is preferably connected to the electrical subsystems through ball bonds or any other suitable connection mechanisms. The connector 14 may alternatively be seamlessly manufactured with the first and or additional electrical subsystem. The connector 14 may further include fluidic channels adapted to deliver therapeutic drugs, drugs to inhibit biologic response to the implant, or any other suitable fluid.

[0026] As shown in FIGURE 3, the device of the preferred embodiments may further include a stylet 16. The stylet 16 of the preferred embodiments functions to penetrate the tissue or other material and/or functions to provide structural support to the device during implantation of the device. The stylet 16 is preferably inserted into a lumen of the carrier 10, but may alternatively be located and inserted into any suitable component of the device in any suitable manner. The stylet 16 may include a sharpened end adapted to penetrate the tissue and aid in the insertion of the stylet, the carrier 10, and/or the electrical subsystems into the tissue. The stylet 16 is preferably removed from the tissue following the placement of an electrical subsystem, but may alternatively be adapted to remain in the tissue while still allowing the implanted electrical subsystem 12 to float freely in the brain. This may be accomplished by the stylet being selectively flexible (through electrical stimulus or other suitable method) or by being resorbable into the tissue after a period of time. The stylet 16 is preferably made from a stiff material such as metal, but may alternatively be made from any suitable material. In one variation, the metal is an insulated metal wire. In this variation, the insulated metal wire

may not have insulation covering a sharpened tip, and thus can be used as a conventional single-channel microelectrode.

[0027] As shown in FIGURE 4, a method of implanting and using the implantable device and its corresponding electrical components preferably includes the following steps: (a) providing an electrical subsystem and a carrier that provides structural support for the electrical subsystem; (b) implanting the electrical subsystem and the carrier into the body tissue; and (c) dissolving the carrier into the body tissue and allowing the electrical subsystem to flex within and interface with the body tissue. Step (c) may include dissolving the carrier into the body tissue at a rate approximately equal to the healing process of the body tissue, or may include dissolving the carrier into the body tissue at a rate much slower than the healing process of the body tissue. The method may also include providing a stylet, placing the electrical subsystem and the carrier onto the stylet, and penetrating the body tissue with the stylet.

[0028] Although omitted for conciseness, the preferred embodiments include every combination and permutation of the various carriers 10, the various electrical subsystems, the various connectors, the various stylets, and the various methods of use.

[0029] As a person skilled in the art will recognize from the previous detailed description and from the figures and claims, modifications and changes can be made to the preferred embodiments of the invention without departing from the scope of this invention defined in the following claim.

CLAIMS

I claim:

1. An implantable device for body tissue, comprising:
 - an electrical subsystem that flexes within and interfaces with body tissue; and
 - a carrier that operates in the following two modes:
 - provides structural support for the electrical subsystem during implantation of the device in body tissue and
 - allows flexing of the electrical subsystem after implantation of the device in body tissue.
2. The implantable device of claim 1, wherein the carrier allows flexing of the electrical subsystem through absorption of the carrier into body tissue.
3. The implantable device of claim 1, wherein the carrier is resorbable into body tissue over a time period.
4. The implantable device of claim 3, wherein the carrier is made from a bioresorbable polymer selected from the group consisting of polyglycolide and polylactide.
5. The implantable device of claim 1, wherein the carrier has a tubular shape.
6. The implantable device of claim 5, wherein the carrier has a woven structure.

7. The implantable device of claim 1, wherein the electrical subsystem is an electrode array that interfaces with neural tissue.
8. The implantable device of claim 7, wherein the electrode array includes a plurality of electrode sites that electrically stimulate different portions of neural tissue.
9. The implantable device of claim 8, wherein the electrode sites are positioned both circumferentially and axially relative to the carrier.
10. The implantable device of claim 8, wherein the electrode array further includes a plurality of electrode sites that electrically record different portions of neural tissue.
11. The implantable device of claim 8, wherein the electrode array is made of a thin-film substrate.
12. The implantable device of claim 11, wherein the electrode array is made of a thin-film polymer substrate.
13. The implantable device of claim 1, wherein the electrical subsystem has a tubular shape.

14. The implantable device of claim 13, wherein the electrical subsystem defines a perforation, and wherein the carrier - when providing rigidity to the electrical subsystem - anchors in the perforation.
15. The implantable device of claim 13, wherein the electrical subsystem defines a series of perforations that axially extend in a discontinuous manner along the length of the electrical subsystem.
16. The implantable device of claim 13, wherein the electrode array is made of a thin-film substrate.
17. The implantable device of claim 16, wherein the electrode array is made of a thin-film polymer substrate.
18. The implantable device of claim 1, wherein the electrical subsystem has a elongated, substantially planar shape.
19. The implantable device of claim 1, wherein the further comprising an additional electrical subsystem that controls the electrical subsystem.
20. The implantable device of claim 19, wherein the further comprising a connector that couples the electrical subsystem to the additional electrical subsystem.

21. The implantable device of claim 20, wherein the connector is a flexible ribbon cable.
22. The implantable device of claim 1, wherein the further comprising a stylet adapted to penetrate body tissue.
23. The implantable device of claim 22, wherein the carrier defines a lumen, and wherein the stylet is located within the stylet during implantation of the device into body tissue.
24. A method of implanting and using an implantable device comprising the steps of:
- providing an electrical subsystem and a carrier that provides structural support for the electrical subsystem;
 - implanting the electrical subsystem and the carrier into the body tissue; and
 - dissolving the carrier into the body tissue and allowing the electrical subsystem to flex within and interface with the body tissue.
25. The method of claim 24, wherein the step of dissolving the carrier includes dissolving the carrier into the body tissue at a rate approximately equal to the healing process of the body tissue.

26. The method of claim 24, further comprising the step of providing a stylet, placing the electrical subsystem and the carrier onto the stylet, and penetrating the body tissue with the stylet.

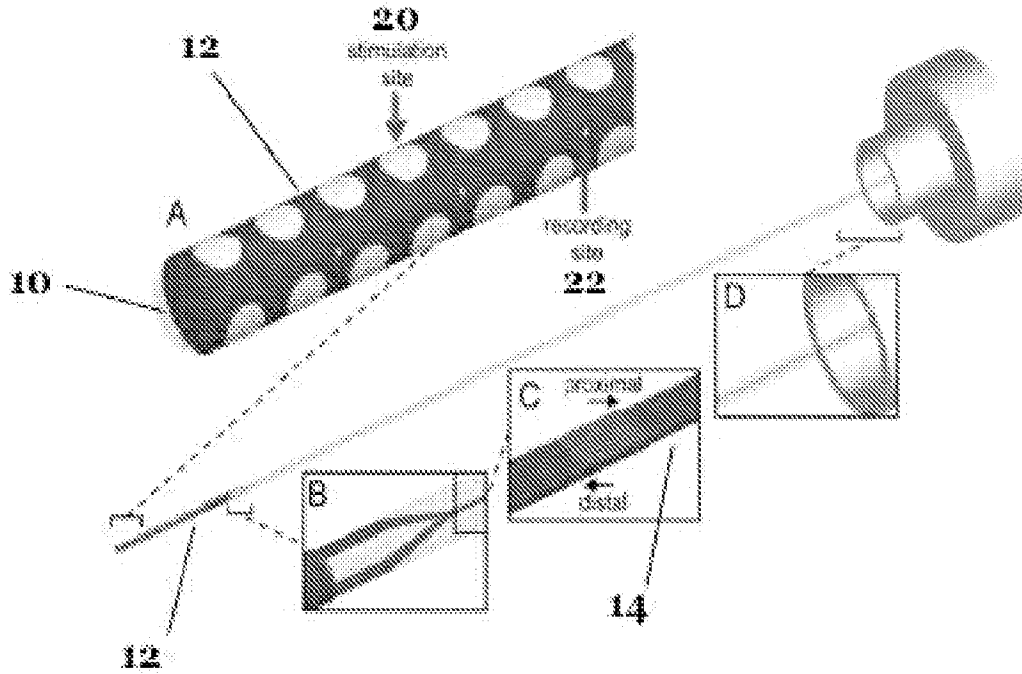


FIGURE 1.

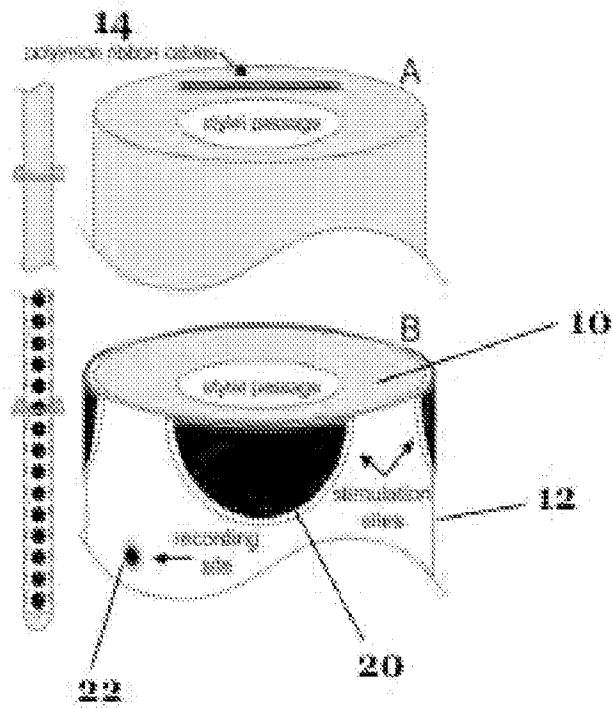


FIGURE 2.

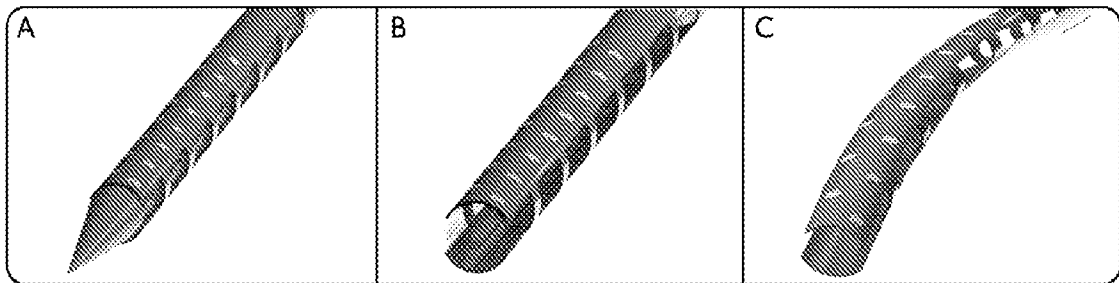
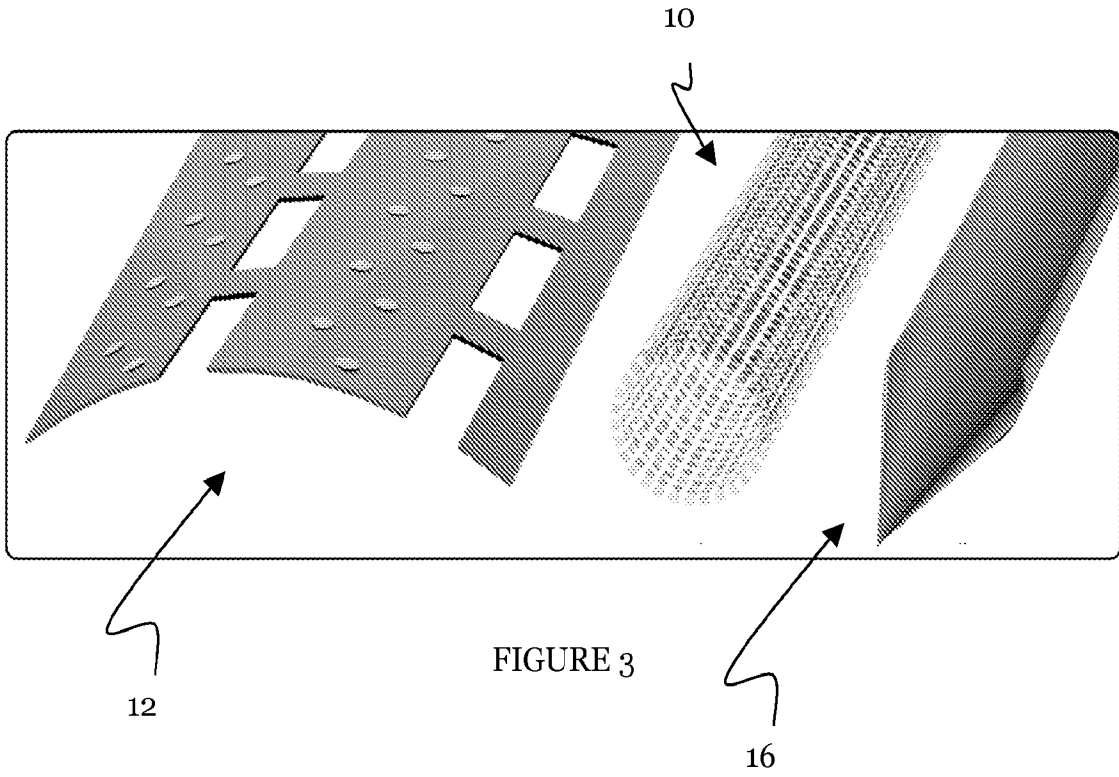


FIGURE 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 08/80366

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61N 1/00 (2008.04)

USPC - 607/116

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)
607/116

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
607/115, 116, 117, 118,

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWest, Google

Search Terms Used: Implantable, Carrier, electrode, flexible, insertion, resorbable, tubular, woven, knitted, neural, array, thin film, sharp, stylet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2007/0135885 A1 (Risi) 14 June 2007 (14.06.2007), abstract, para [0023], [0026], [0032], [0034], [0035].	1, 5, 7-9, 19 ----- 2-4, 6, 10-18, 20-26
Y	US 6,228,111 B1 (Tormala et al.) 8 May 2001 (08.05.2001), abstract; Col 12, ln 30-34.	6
Y	US 2007/0073130 A1 (Finch et al.) 29 March 2007 (29.03.2007), para [0025], [0038], [0055], [0057], [0096].	2-4, 10-18, 20-21, 24-26
Y	US 2004/0199235 A1 (Younis) 7 October 2004 (07.10.2004), abstract, para [0017], [0124], [0011], [0131]-[0133].	13-18, 20-23, 26
Y	US 6,374,143 B1 (Berrang et al.) 16 April 2002 (16.04.2002), Col 5, Ln 61-66; Col 12, ln 1-3.	14-15

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

21 November 2008 (21. 11. 2008)

Date of mailing of the international search report

10 DEC 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

