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(54) Title: DRUG DELIVERY ELECTRODE WITH TEMPORARY FILL TUBE

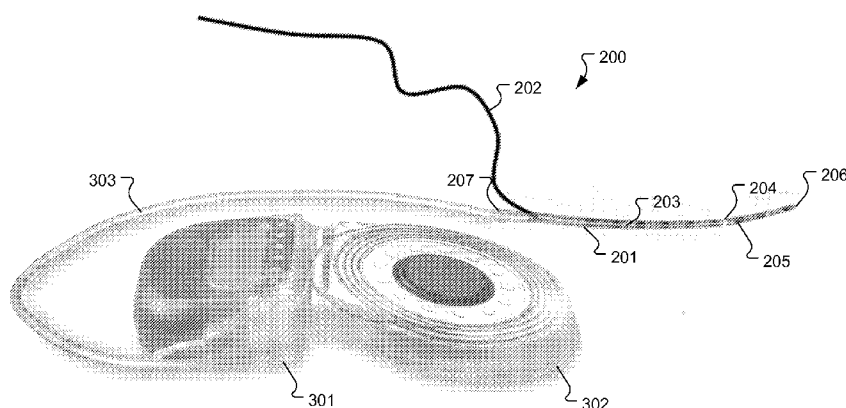


Fig. 3

(57) Abstract: An ear implant electrode device is described. An implantable electrode array has an outer surface with electrode contacts for electrically stimulating adjacent neural tissue. There is a fluid delivery channel within the electrode array for delivering a therapeutic fluid through one or more fluid delivery ports on the outer surface. A temporary fill tube is connected to the fluid delivery channel for providing the therapeutic fluid when the electrode array is partially inserted into a patient neural tissue without being functional after the electrode array is fully inserted. At least a portion of the fill tube is adapted for removal after providing the therapeutic fluid to have the fluid delivery channel and any remaining portion of the fill tube completely enclosed within the neural tissue after the electrode array has been fully inserted so as to leave no exposed fluid opening outside the neural tissue.



Drug Delivery Electrode with Temporary Fill Tube

[0001] This application claims priority from U.S. Provisional Patent 61/467,474, filed March 25, 2011, which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to an implantable electrode for auditory prostheses.

BACKGROUND ART

[0003] A normal ear transmits sounds as shown in Figure 1 through the outer ear **101** to the tympanic membrane (eardrum) **102**, which moves the bones of the middle ear **103**, which in turn vibrate the oval window and round window openings of the cochlea **104**. The cochlea **104** is a long narrow duct wound spirally about its axis for approximately two and a half turns. The cochlea **104** includes an upper channel known as the scala vestibuli and a lower channel known as the scala tympani, which are connected by the cochlear duct. The scala tympani forms an upright spiraling cone with a center called the modiolar where the spiral ganglion cells of the acoustic nerve **113** reside. In response to received sounds transmitted by the middle ear **103**, the fluid filled cochlea **104** functions as a transducer to generate electric pulses that are transmitted to the cochlear nerve **113**, and ultimately to the brain.

[0004] Hearing is impaired when there are problems in the ability to transduce external sounds into meaningful action potentials along the neural substrate of the cochlea **104**. In some cases, hearing impairment can be addressed by an auditory prosthesis system such as a cochlear implant that electrically stimulates auditory nerve tissue with small currents delivered by multiple electrode contacts distributed along an implant electrode. Figure 1 shows some components of a typical cochlear implant system where an external microphone provides an audio signal input to an external signal processing stage **111** which implements one of various known signal processing schemes. The processed signal is converted by the external signal processing stage **111** into a digital data format, such as a sequence of data frames, for transmission into a receiver processor in an implant housing

108. Besides extracting the audio information, the receiver processor in the implant housing **108** may perform additional signal processing such as error correction, pulse formation, etc., and produces a stimulation pattern (based on the extracted audio information) that is sent through an electrode lead **109** to an implanted electrode array **112** which penetrates into the cochlea **104** through a surgical opening called a cochleostomy. Typically, this electrode array **112** includes multiple electrode contacts **110** on its surface that deliver the stimulation signals to adjacent neural tissue of the cochlea **104** which the brain of the patient interprets as sound. The individual electrode contacts **110** may be activated sequentially, or simultaneously in one or more contact groups.

[0005] There are many inner ear disorders which can lead to some degree of hearing loss. Among these are sudden hearing loss, noise induced hearing loss, progressive hearing loss, aminoglycoside induced hearing loss, presbiyacusis etc., autoimmune inner ear disorder, and infections (bacterial, viral, fungal). Many of the diseases that lead to partial or total hearing loss could utilize a therapeutic pharmaceutical treatment to reach some tissue or cells within the inner ear, for example, to arrest or reverse the hearing loss and improve hearing. Examples of therapeutic pharmaceutical molecules include without limitation cortico-steroids, peptides, and other proteins.

[0006] But there are relatively few ways to deliver therapeutic drugs to the inner ear. Typical clinical practice involves either oral, veinous, or arterial drug delivery. Topical drug delivery to treat the inner ear is limited to deposition of the drug at the round window and relying on diffusion of the drug through the round window to reach targeted cells. This may be accomplished by flooding the middle ear cavity with the drug in liquid form, or by applying a soaked sponge at or near the round window, for example, through an opening in the tympanic membrane. But a diffusion process through the round window is not particularly predictable or reliable. The permeability of the round window varies greatly between patients and by other criteria such as time of day, physical conditions, application methods, drug used. Thus, the amount of drug that reaches the inner ear through such delivery methods may vary anywhere between zero and toxically too much.

[0007] U.S. Patent Publication 20090259267 describes an implantable electrode with an

enlarged fluid storage reservoir that stores a treatment volume of therapeutic fluid for an extended therapeutic treatment period. One or more fluid delivery ports connect the fluid storage reservoir to the outer surface of the electrode for delivering the therapeutic fluid from the fluid storage reservoir to the outer surface.

SUMMARY

[0008] Embodiments of the present invention are directed to an ear implant electrode device. An implantable electrode array has an outer surface with electrode contacts for electrically stimulating adjacent neural tissue. There is a fluid delivery channel within the electrode array for delivering a therapeutic fluid through one or more fluid delivery ports on the outer surface. A temporary fill tube is connected to the fluid delivery channel for providing the therapeutic fluid when the electrode array is partially inserted into patient neural tissue without being functional after the electrode array is fully inserted. At least a portion of the fill tube is adapted for removal after providing the therapeutic fluid to have the fluid delivery channel and any remaining portion of the fill tube completely enclosed within the neural tissue after the electrode array has been fully inserted so as to leave no exposed fluid opening outside the neural tissue.

[0009] The fill tube may have a free end that extends into a posterior tympanotomy or even a mastoidectomy when the electrode array is partially inserted. The at least a portion of the fill tube may be adapted for removal by cutting, for example, by cutting the fill tube flush with the outer surface of the electrode array.

[0010] Embodiments of the present invention also include a method of delivering a therapeutic fluid with an ear implant electrode. An electrode array is partially inserted into patient neural tissue, which array includes an outer surface including a plurality of electrode contacts for electrically stimulating adjacent neural tissue, a fluid delivery channel within the electrode array for delivering a therapeutic fluid through at least one fluid delivery port on the outer surface, and a temporary fill tube connected to the fluid delivery channel. The therapeutic fluid is provided to the fluid delivery channel via the fill tube to deliver the therapeutic fluid through the at least one fluid delivery port to the outer surface of electrode array. At least a portion of the fill tube is removed and the insertion of

the electrode array into the patient neural tissue is completed so that the fluid delivery channel and any remaining portion of the fill tube are completely enclosed within the neural tissue so as to leave no exposed fluid opening outside the neural tissue.

[0011] The fill tube may have a free end that extends into a posterior tympanotomy or even a mastoidectomy when the electrode array is partially inserted. And removing the at least a portion of the fill tube may include cutting the fill tube, for example, cutting the fill tube flush with the outer surface of the electrode array.

[0012] The ear implant system may include a cochlear implant system, an auditory brainstem implant system, or a vestibular implant system. And embodiments of the present invention also include an ear implant system having an electrode arrangement according to any of the above.

[0013] These objects of the invention are solved by the subject matter as claimed by the independent claims 1 and 9. Various embodiments of the invention are subject of the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Figure 1 shows anatomical structures of a human ear and some components of a typical cochlear implant system.

[0015] Figure 2 shows structural details of an implantable cochlear electrode having a temporary fill tube according to an embodiment of the present invention.

[0016] Figure 3 shows a cochlear implant system having an implantable electrode with a temporary fill tube according to an embodiment of the present invention.

[0017] Figure 4 shows various logical steps in implanting a cochlear electrode using a temporary fill tube according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0018] It would be useful to be able to safely deliver therapeutic drugs to the cochlea during implantation of cochlear electrodes. For example, corticosteroid could be useful for the treatment of cochlear inflammation after opening the scala and inserting the electrode. It would also be beneficial to bring other type of therapeutic drugs to the cochlea for acting on the spiral ganglion cells and the cochlear neurites. Some peptides in the form of nerve growth factors also could be useful. With any drug delivery to the inner ear, it is important to bring a precise and controlled dose into the scala at specific locations other than the very base of the cochlea.

[0019] In the past, this problem has been addressed by injecting a small amount of drug with a needle at the entrance point of the electrode into the cochlea during implantation. Alternatively, the electrode has been dipped in a drug solution in the hope that a coating of the drug would stay on the electrode during insertion. In another approach, the drug has been placed at the round window of the cochlea before electrode insertion in the hope that some diffusion would occur before, during, or after surgery. Other methods proposed have been a drug delivery reservoir connected to a port and septum for filling or refilling, and to load crystal-form drugs in the silicone carrier material of the electrode and rely on diffusion out of the silicone.

[0020] Embodiments of the present invention are directed to an improved ear implant electrode device. This novel approach uses a temporary fill tube that is used after the electrode has been partially inserted to deliver therapeutic drugs to the inner ear. After delivery of the drugs, the fill tube is removed and insertion of the electrode is completed. This ensures that after the implantation surgery all the fluid delivery structures are completely enclosed within the cochlea so as to leave no fluid opening outside the cochlea. This ensures that any future infection in the middle ear does not spread through the implanted electrode into the inner ear, a potentially deadly complication that could otherwise arise.

[0021] Figure 2 shows structural details of an implantable ear implant electrode arrangement for a cochlear implant system, an auditory brainstem implant system, or a

vestibular implant system. The ear implant arrangement **200** has an implantable electrode array **201** with electrode contacts **205** on its outer surface for electrically stimulating cochlear neural tissue after the device has been inserted in the cochlea. Within the electrode array **201** is a fluid delivery channel **203** for delivering a therapeutic fluid through one or more fluid delivery ports **204** on the outer surface of the array.

[0022] A temporary fill tube **202** is connected to the fluid delivery channel **203** for providing the therapeutic fluid when the electrode array **201** is partially inserted into a patient cochlea. The free end of the fill tube **202** may extend back into a posterior tympanotomy or even a mastoidectomy when the electrode array **201** is partially inserted during implantation surgery. At least a portion of the fill tube **202** is adapted for removal after providing the therapeutic fluid so that the fluid delivery channel **203** and any remaining portion of the fill tube **202** remain completely enclosed within the cochlea after the electrode array **201** has been fully inserted so as to leave no fluid opening outside the cochlea. For example, a portion of the fill tube **202** may be removable by cutting the fill tube **202** flush with the outer surface of the basal end **207** of the electrode array **201**.

[0023] Figure 3 shows a cochlear implant system having an implantable electrode arrangement **200** having a temporary fill tube **202**. That is, Fig. 3 shows how the electrode array **201** extends back as an electrode lead **303** that connects to the housing of an implantable stimulator **301** coupled to an implantable receiver coil **302**. The receiver coil **302** receives an externally transmitted implant communications signal which the stimulator **301** converts into the electrical stimulation signals for the electrode contacts **205** of the electrode array **201**.

[0024] During surgical implantation, the electrode array **201** is partially inserted into the patient cochlea, step **401** in Fig. 4. The therapeutic fluid is provided to the fluid delivery channel **203** via the fill tube **202** to deliver the therapeutic fluid through one or more fluid delivery ports **204** to the outer surface of electrode array **201**, step **402**. Then at least a portion of the fill tube **202** is removed, step **403**, for example, by cutting the fill tube **202** flush with the outer surface of the basal end **207** of the electrode array **201**. Once the fill tube **202** has been cut, the insertion of the electrode array **201** into the patient cochlea can

be completed, step **404**, so that the fluid delivery channel **203** and any remaining portion of the fill tube **202** are completely enclosed within the cochlea so as to leave no fluid opening outside the cochlea.

[0025] Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

CLAIMS

What is claimed is:

1. An ear implant electrode device comprising:
an implantable electrode array having an outer surface including a plurality of
electrode contacts for electrically stimulating adjacent neural tissue;
a fluid delivery channel within the electrode array for delivering a therapeutic fluid
through at least one fluid delivery port on the outer surface; and
a temporary fill tube connected to the fluid delivery channel for providing the
therapeutic fluid when the electrode array is partially inserted into patient
neural tissue without being functional after the electrode array is fully inserted;
wherein at least a portion of the fill tube is adapted for removal after providing the
therapeutic fluid to have the fluid delivery channel and any remaining portion
of the fill tube completely enclosed within the neural tissue after the electrode
array has been fully inserted so as to leave no exposed fluid opening outside
the neural tissue.
2. An ear implant electrode device according to claim 1, wherein the fill tube includes a
free end that extends into a posterior tympanotomy when the electrode array is partially
inserted.
3. An ear implant electrode device according to claim 1, wherein the fill tube includes a
free end that extends into a mastoidectomy when the electrode array is partially inserted.
4. An ear implant electrode device according to claim 1, wherein the at least a portion of
the fill tube is adapted for removal by cutting.
5. An ear implant electrode device according to claim 4, wherein the cutting is flush with
the outer surface of the electrode array.
6. An ear implant electrode according to any of claims 1-5, wherein the ear implant
includes a cochlear implant.

7. An ear implant electrode according to any of claims 1-5, wherein the ear implant includes an auditory brainstem (ABI) implant.
8. An ear implant electrode according to any of claims 1-5, wherein the ear implant includes a vestibular implant.
9. A method of delivering a therapeutic fluid with an ear implant electrode device, the method comprising:
- partially inserting into patient neural tissue an implantable electrode array having:
 - i. an outer surface including a plurality of electrode contacts for electrically stimulating adjacent neural tissue;
 - ii. a fluid delivery channel within the electrode array for delivering a therapeutic fluid through at least one fluid delivery port on the outer surface; and
 - iii. a temporary fill tube connected to the fluid delivery channel;
 - providing the therapeutic fluid to the fluid delivery channel via the fill tube to deliver the therapeutic fluid through the at least one fluid delivery port to the outer surface of electrode array;
 - removing at least a portion of the fill tube and completing the insertion of the electrode array into the patient neural tissue so that the fluid delivery channel and any remaining portion of the fill tube are completely enclosed within the neural tissue so as to leave no exposed fluid opening outside the neural tissue and so that the remaining portion of the fill tube is no longer functional.
10. A method according to claim 9, wherein the fill tube includes a free end that extends into a posterior tympanotomy when the electrode array is partially inserted.
11. A method according to claim 9, wherein the fill tube includes a free end that extends into a mastoidectomy when the electrode array is partially inserted.
12. A method according to claim 9, wherein removing the at least a portion of the fill tube includes cutting the fill tube.

13. A method according to claim 12, wherein the cutting is flush with the outer surface of the electrode array.

14. A method according to any of claims 9-13, wherein the electrode array includes a cochlear implant electrode array.

15. A method according to any of claims 9-13, wherein the electrode array includes an auditory brainstem (ABI) implant electrode array.

16. A method according to any of claims 9-13, wherein the electrode array includes a vestibular implant electrode array.

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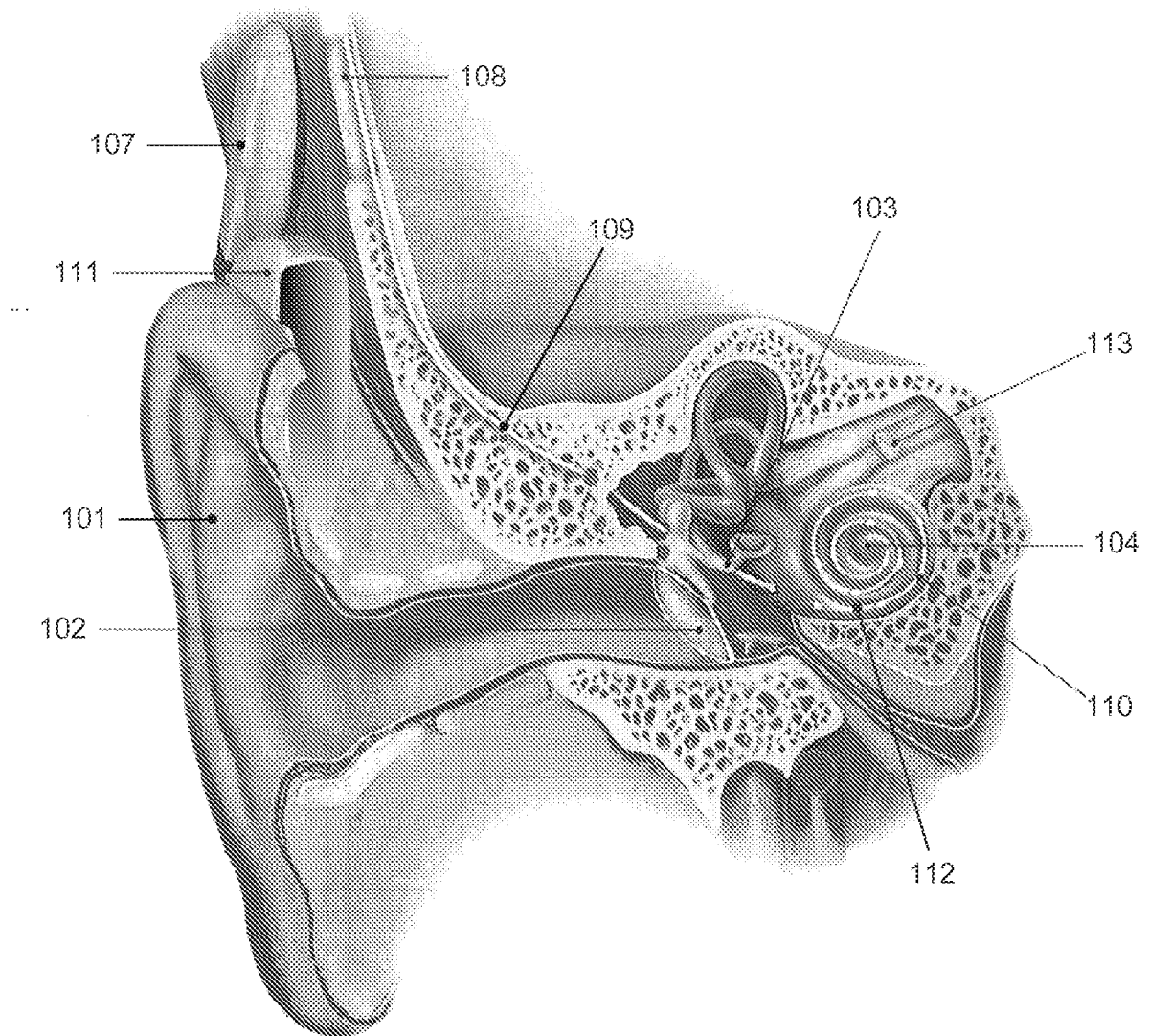


Fig. 1

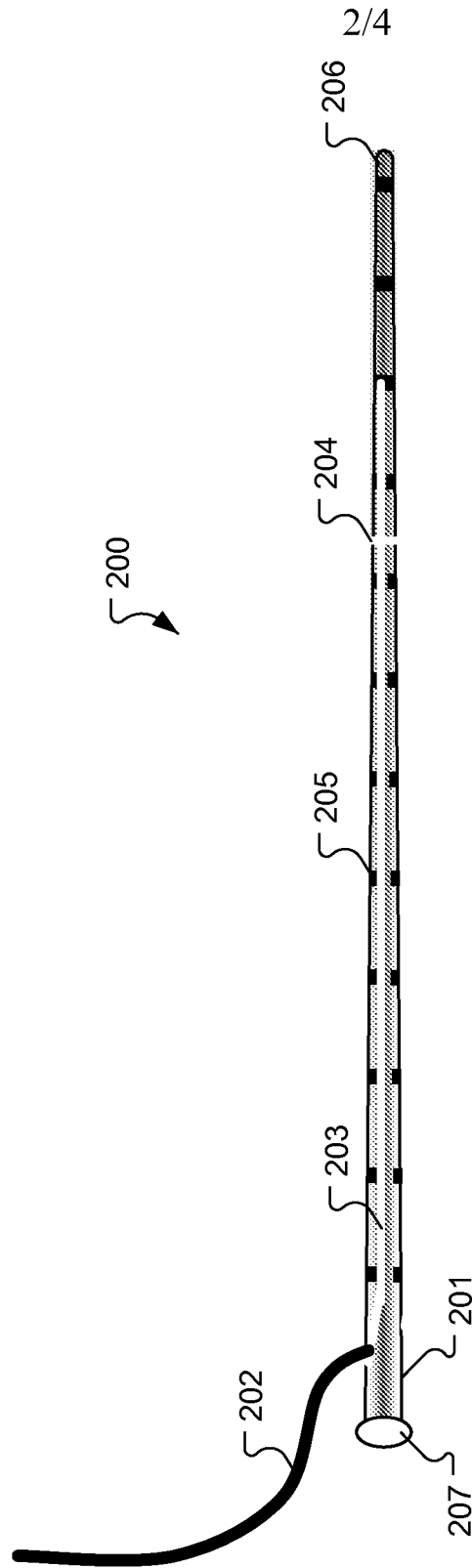


Fig. 2

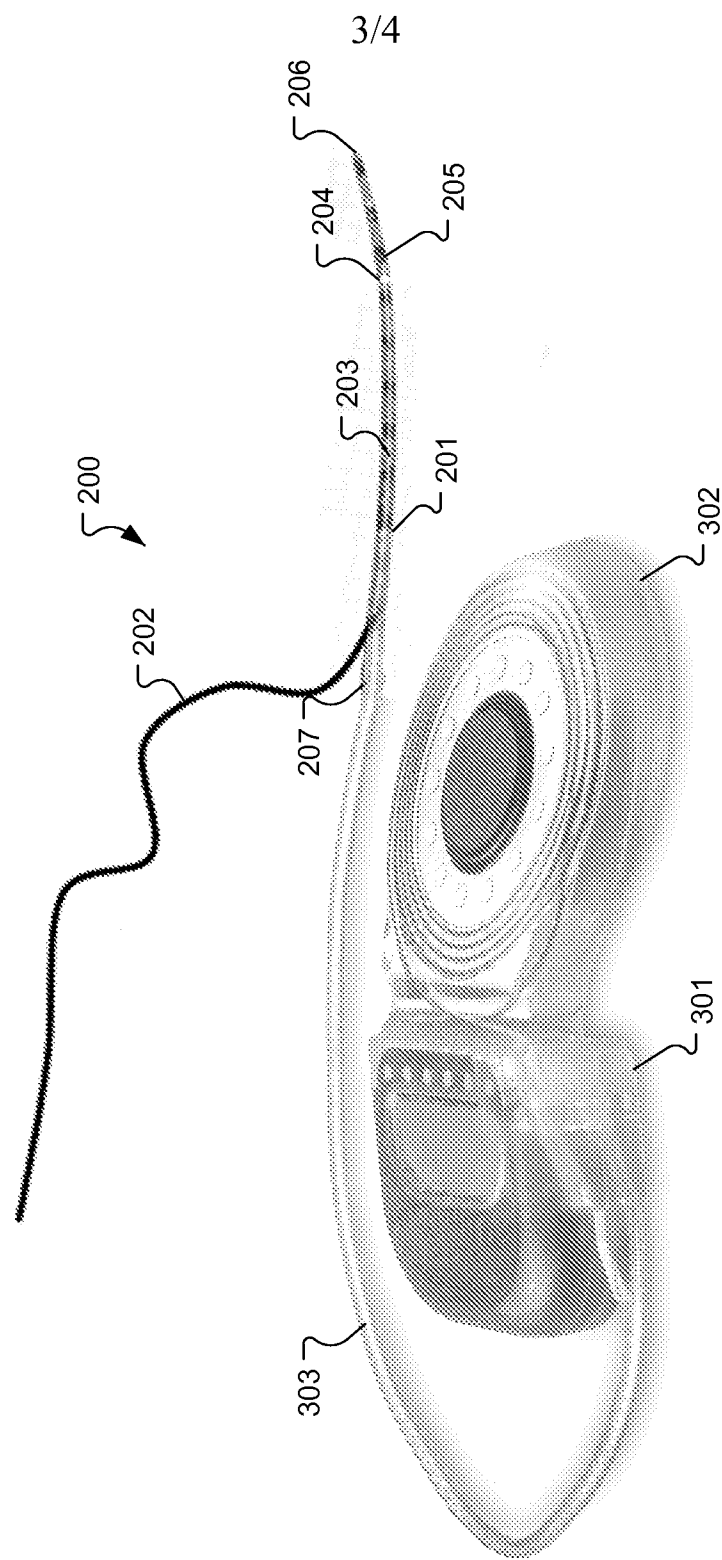
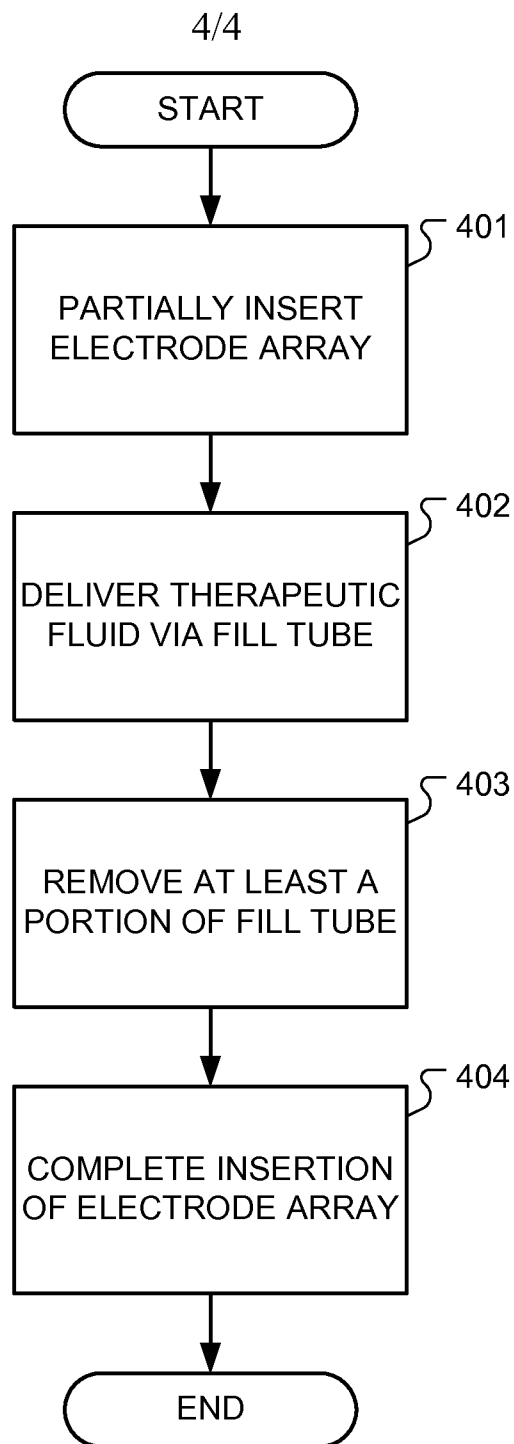


Fig. 3

**Fig. 4**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/029738

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/05
ADD. A61N1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 309 410 B1 (KUZMA JANUSZ A [US] ET AL) 30 October 2001 (2001-10-30) column 1, lines 15-24; figures 1A, 2A column 5, line 62 - column 6, line 60 column 7, lines 30-44	1-8
A	----- US 2009/292237 A1 (OVERSTREET EDWARD H [US] ET AL) 26 November 2009 (2009-11-26) paragraph [0002] paragraph [0039]	1
A	----- US 2009/259267 A1 (JOLLY CLAUDE [AT]) 15 October 2009 (2009-10-15) cited in the application paragraph [0002] paragraphs [0081] - [0086] figures 18, 27 ----- -/-	1



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

4 June 2012

Date of mailing of the international search report

19/06/2012

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/029738

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **9-16**
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 9-16

The subject-matter of 9-16 refers to a surgical treatment due to the step of inserting an electrode array into patient neural tissue, and a therapeutic treatment, due to the step of delivering a therapeutic fluid. According to the PCT neither search (Rule 39.1(iv) PCT) nor examination (Rule 67.1(iv) PCT) is required for such subject-matter.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/029738

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/43623 A1 (COCHLEAR LTD [AU]; GIBSON PETER [AU]; DADD FYSH [AU]; TREABA CLAUDIU []) 6 June 2002 (2002-06-06) page 8, line 7 - page 9, line 10 -----	1
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/029738

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