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(54) Title: COCHLEAR IMPLANT ELECTRODE INSERTION SUPPORT DEVICE

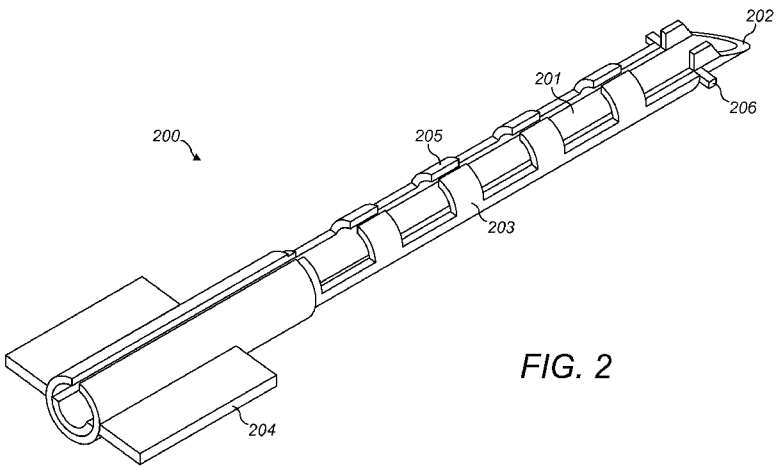

FIG. 2

(57) Abstract: An electrode insertion support device is used for inserting a cochlear implant electrode into a cochlea scala of a patient cochlea. A stiff electrode holder encloses at least a portion of a cochlear implant electrode while allowing the electrode within to slide freely. A pointed distal tip of the electrode holder is adapted to pierce an electrode opening through an outer surface of the patient cochlea into the cochlea scala. The insertion support device prevents an apical tip of the enclosed electrode from contacting tissues around the electrode opening during the insertion surgery.

WO 2015/013120 A1

TITLE

Cochlear Implant Electrode Insertion Support Device

[0001] This application claims priority from U.S. Provisional Patent Application 61/858,659, filed July 26, 2013, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to an insertion device for cochlear implant electrodes.

BACKGROUND ART

[0003] A normal ear transmits sounds as shown in Figure 1 through the outer ear **101** to the tympanic membrane **102** which moves the bones of the middle ear **103** that 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. It 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 cochlea **104** 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 which 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**. To improve impaired hearing, auditory prostheses have been developed. For example, when the impairment is related to operation of the middle ear **103,** a conventional hearing aid may be used to provide acoustic-mechanical stimulation to the auditory system in the form of amplified sound. Or when the impairment is associated with the cochlea **104**, a cochlear implant with an implanted electrode can electrically stimulate auditory nerve tissue with small currents delivered by multiple electrode contacts distributed along the electrode.

[0005] Figure 1 also shows some components of a typical cochlear implant system

where an external microphone provides an audio signal input to an external signal processor **111** in which various signal processing schemes can be implemented. The processed signal is then converted into a digital data format for transmission by external transmitter coil **107** into the implant **108**. Besides receiving the processed audio information, the implant **108** also performs 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 **110**. Typically, this electrode array **110** includes multiple stimulation contacts **112** on its surface that provide selective stimulation of the cochlea **104**.

[0006] The electrode array **110** contains multiple electrode wires embedded in a soft silicone body referred to as the electrode carrier. The electrode array **110** needs to be mechanically robust, and yet flexible and of small size to be inserted into the cochlea **104**. The material of the electrode array **110** needs to be soft and flexible in order to minimize trauma to neural structures of the cochlea **104**. But an electrode array **110** that is too floppy tends to buckle too easily so that the electrode array **110** cannot be inserted into the cochlea **104** up to the desired insertion depth. A trade-off needs to be made between a certain stiffness of the electrode array **110** which allows insertion into the cochlea **104** up to the desired insertion depth without the array buckling, and certain flexibility of the electrode array **110** which keeps mechanical forces on the structures of the scala tympani of the cochlea **104** low enough.

[0007] One of the important steps in cochlear implant surgery is the insertion of the electrode array into the scala tympani of the cochlea. Starting from the opening of the electrode opening in the round window membrane until complete full insertion of the electrode array **110**, the insertion surgery should be as atraumatic as possible in order to preserve residual hearing. To achieve that goal, the surgical opening of the round window membrane and the electrode insertion technique should be a uniform reproducible procedure. But the reality is that some surgeons cut a slit in the round window membrane, while others create a flap opening.

[0008] In some cases, the electrode insertion process can be disrupted when the flexible

tip of the electrode array **110** slips and sticks to the wet tissues around the electrode opening into the cochlea **104** rather than entering through the electrode opening as desired. This is frustrating and time consuming for the surgeon who often has to make repeated efforts to thread the tip of the electrode array **110** through the electrode opening. In addition, the contact with the wet tissues can deposit blood and other fluids onto the tip of the electrode array **110** which then contaminate the interior of the cochlea **104**. Surgeons also try to insert the electrode array **110** as slowly as possible by step-wise advancing it into the scala tympani which also is time consuming.

SUMMARY OF THE INVENTION

[0009] Embodiments of the present invention are directed to an electrode insertion support device and corresponding surgical method for inserting a cochlear implant electrode into a cochlea scala of a patient cochlea. A stiff electrode holder encloses at least a portion of a cochlear implant electrode while allowing the electrode within to slide freely. A pointed distal tip of the electrode holder is adapted to pierce an electrode opening through an outer surface of the patient cochlea into the cochlea scala. The insertion support device prevents an apical tip of the enclosed electrode from contacting tissues around the electrode opening during the insertion surgery.

[0010] There may be a flexible electrode cover around at least a portion of the electrode holder adapted to allow placement of the electrode into the electrode holder. There may also be a device handling feature at a proximal end of the electrode holder for surgical manipulation of the insertion support device and the enclosed electrode during the insertion surgery. And there may be an insertion stopper near the distal tip adapted to limit penetration distance of the distal tip into the cochlea scala. An electrode projection mechanism may allow pushing the enclosed electrode through the electrode opening into the cochlea scala.

[0011] In specific embodiments, the electrode holder may be cylindrical and may form an open tubular section enclosing the at least a portion of the cochlear implant electrode, and/or a perforated tubular section enclosing the at least a portion of the cochlear implant electrode. The electrode holder includes an inner surface coated with a reduced friction

material that promotes free sliding of the enclosed portion of the cochlear implant electrode.

[0012] The electrode holder may be sized to fit within a mastoidectomy passage during the insertion surgery; for example, there may be a mastoidectomy section sized to fit within a mastoidectomy passage and tympanotomy section sized to fit within a posterior tympanotomy, wherein the two sections meet at a connecting angle that changes the direction of the enclosed electrode.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 shows the anatomy of the human ear with a cochlear implant system.

[0014] Figure 2 shows an example of an electrode insertion support device according to one embodiment of the present invention.

[0015] Figure 3 shows structural details of the distal tip of an electrode insertion support device.

[0016] Figure 4 highlights the sharpness of the distal tip.

[0017] Figure 5 shows an alternative embodiment of an electrode cover having a handling feature.

[0018] Figure 6 shows an alternative embodiment having a mastoidectomy section sized to fit within a mastoidectomy passage and tympanotomy section sized to fit within a posterior tympanotomy with a connecting angle that changes the direction of the enclosed electrode.

[0019] Figure 7 shows an alternative embodiment having a perforated tubular section.

[0020] Figure 8 A-D shows details of cochlear implant electrodes having electrode projection features that allow pushing the electrode through the electrode opening into the

cochlea scala.

[0021] Figure 9 shows an electrode insertion support device with a cochlear implant electrode enclosed within for insertion into a patient cochlea.

[0022] Figure 10 shows an example of a surgical insertion tool incorporating a an electrode insertion support device according to an embodiment of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0023] Embodiments of the present invention are based on using an electrode insertion support device that promotes a uniform incision of the electrode opening (e.g., in the round window membrane) and a uniform electrode insertion procedure which avoids the electrode array contacting and being contaminated by the surrounding tissue.

[0024] Figure 2 shows an electrode insertion support device **200** which includes a stiff electrode holder **201** made of any structurally appropriate biocompatible material (e.g., made of metal or stiff plastic) that encloses at least a portion of a cochlear implant electrode while allowing the enclosed electrode to slide freely within. The electrode holder **201** may include an inner surface **207** coated with a reduced friction material that promotes free sliding of the enclosed portion of the cochlear implant electrode; for example, a highly hydrophilic material such as a hydrogel. In addition or alternatively, the inner surface **207** may be coated with a special coating that generally absorbs liquids (again, e.g., a hydrogel) so that even if some blood is present in the middle ear during insertion surgery and enters within the electrode holder **201**, that blood will absorbed by the coating material on the inner surface **207** and will not enter the cochlea together with the electrode.

[0025] A pointed distal tip **202** of the electrode holder **201** is adapted to pierce an electrode opening through an outer surface of the patient cochlea into the cochlea scala. The insertion support device **200** prevents an apical tip of the enclosed electrode from contacting tissues around the electrode opening during the insertion surgery.

[0026] The embodiment depicted in Fig. 2 includes a flexible electrode cover **203** around at least a portion of the electrode holder **201** which adapted to allow placement of the electrode into the electrode holder **201**. In this example, the electrode cover **203** includes multiple flexible slit ribs **205** that easily deflect aside for insertion of the implant electrode into the open tubular section (i.e., half-pipe) of the electrode holder **201**. At the proximal end of the electrode holder **201** is a device handling feature, in this case a wing projection **204**, for surgical manipulation and orientation of the insertion support device **200** and the enclosed electrode during the insertion surgery.

[0027] Figure 3 shows structural details of the distal tip **202** of the electrode insertion support device **200** and Figure 4 highlights the sharpness of the distal tip **202**. An insertion stopper **206** is located near the distal tip **202** to limit penetration distance of the distal tip **202** into the cochlea scala. Specifically, the distal tip **202** typically has a length of not more than about one millimeter which is the desired insertion depth of the electrode insertion support device **200** inside the scala tympani. The height **302** of the distal tip **202** is important in controlling a proper incision of the electrode opening. In particular, the height **302** should be about the same as or slightly greater than the thickness of the electrode array **110** at its basal end. The distal tip **202** has a sharp edge (see Fig. 4) all the way along its cutting length **303** which enables a rotational movement of the distal end **202** to open/incise the electrode opening.

[0028] Immediately after the cutting edge of the distal tip **202** is a short flat section **301** without a cutting edge before reaching an insertion stopper **206** that prevents over-insertion of the distal tip **202** into the scala tympani. The dimensions of the flat section **301** (e.g. 50 μm) and the insertion stopper **206** allow the distal tip **202** to be inserted far enough to overcome the elastic character of the round window membrane to promote an optimal incision of the electrode opening, preferably creating a flap from a portion of the round window membrane rather than a relatively large hole as would be the case with the tip of a standard syringe.

[0029] Figure 5 shows an alternative embodiment of an electrode cover **203** with slit ribs **205** and handling wing **501** located in the middle of the electrode cover **203** for surgical

handling and orientation of an electrode insertion support device **200.** Locating the handling wing **501** in the middle of the electrode cover **203** as shown allows the handling wing **501** to conveniently be positioned in the facial recess of the posterior tympanotomy after insertion of the electrode array **110** into the cochlea so that the electrode insertion support device **200** can easily be removed.

[0030] The relative geometries of the mastoidectomy and the tympanotomy are such that it may be useful to have an angle between the relative sections of the electrode insertion support device **200** that are intended to fit into those spaces. For example, Figure 6 shows an embodiment of an electrode insertion support device **200** having a mastoidectomy section **601** sized to fit within a mastoidectomy passage and tympanotomy section **602** sized to fit within a posterior tympanotomy with a connecting angle θ that changes the direction of the enclosed electrode array **110**. The electrode insertion support device **200** and the electrode array **110** enclosed within are gently introduced into the posterior tympanotomy where the sharp tip **202** of the electrode insertion support device **200** can incise the electrode opening in the round window membrane.

[0031] Figure 7 shows an alternative embodiment of an electrode insertion support device **200** wherein the electrode holder **201** includes a perforated tubular section **701**. With a fully enclosed tubular section **701** it may not be possible to remove the electrode insertion support device **200** after surgical insertion of the electrode array **110** into the cochlea. So such an embodiment would need to be suitable for permanent implantation inside the skull.

[0032] For ease in inserting the electrode array **110** into the cochlea, it may be useful for the combination of the electrode insertion support device **200** and the electrode array **110** to include one or more electrode projection mechanisms. Figure 8 A-D shows details of electrode arrays **110** having electrode projection mechanisms that allow pushing the electrode array **110** through the electrode opening into the cochlea scala. Fig. 8A shows an example of a pushing wing **801** that allows the electrode array **110** to be pushed into the scala tympani during insertion surgery. Fig. 8B an electrode array **110** having a projection disk **802** at its base that coordinates with a groove in the electrode insertion support device

200 to allow pushing of the electrode array **110**. In Fig. 8C, the base of the electrode array **110** includes one or more handling rings **803** that allow pushing of the electrode array **110** into the scala tympani. And as shown in Fig. 8D, an electrode projection mechanism may be based on a temporary handling clip **804** that fits onto the electrode array **110** for use during the insertion surgery, and then be removed when the electrode insertion support device **200** is removed.

[0033] Figure 9 shows an electrode insertion support device **200** with an electrode array **110** enclosed within for insertion into a patient cochlea **104**. The sharp distal tip **202** pierces the round window membrane and just barely enters into the scala tympani. The electrode array **110** within the electrode insertion support device **200** can then be pushed into the cochlea **104** without contacting the surrounding tissues.

[0034] Figure 10 shows an example of a surgical insertion tool **1001** incorporating an electrode holder **201** according to an embodiment of the present invention. The tool base **1002** may include one or more sliding grooves **1003** on which the surgical insertion tool **1001** is mounted. The electrode holder **201** is also mounted on the tool base **1002**. The insertion tool **1001** has handles **1004** that allow the insertion tool **1001** to control the electrode array **110** enclosed within the electrode holder **201** to push it into the cochlea.

[0035] 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 electrode insertion support device for inserting a cochlear implant electrode into a cochlea scala of a patient cochlea, the insertion support device comprising:

a stiff electrode holder enclosing at least a portion of a cochlear implant electrode while allowing the electrode within to slide freely; and

a pointed distal tip of the electrode holder adapted to pierce an electrode opening through an outer surface of the patient cochlea into the cochlea scala;

wherein the insertion support device prevents an apical tip of the enclosed electrode from contacting tissues around the electrode opening during the insertion surgery.

2. An electrode insertion support device according to claim 1, further comprising:

a flexible electrode cover around at least a portion of the electrode holder adapted to allow placement of the electrode into the electrode holder.

3. An electrode insertion support device according to claim 1, further comprising:

a device handling feature at a proximal end of the electrode holder for surgical manipulation of the insertion support device and the enclosed electrode during the insertion surgery.

4. An electrode insertion support device according to claim 1, further comprising:

an insertion stopper near the distal tip adapted to limit penetration distance of the distal tip into the cochlea scala.

5. An electrode insertion support device according to claim 1, wherein the implant electrode includes an electrode projection mechanism for pushing the electrode through the electrode opening into the cochlea scala.

6. An electrode insertion support device according to claim 1, wherein the electrode holder forms an open tubular section enclosing the at least a portion of the cochlear

implant electrode.

7. An electrode insertion support device according to claim 1, wherein the electrode holder forms a perforated tubular section enclosing the at least a portion of the cochlear implant electrode.

8. An electrode insertion support device according to claim 1, wherein the electrode holder includes a mastoidectomy section sized to fit within a mastoidectomy passage and tympanotomy section sized to fit within a posterior tympanotomy, wherein the two sections meet at a connecting angle that changes the direction of the enclosed electrode.

9. An electrode insertion support device according to claim 1, wherein the electrode holder is sized to fit within a mastoidectomy passage during the insertion surgery.

10. An electrode insertion support device according to claim 1, wherein the electrode holder includes an inner surface coated with a reduced friction material that promotes free sliding of the enclosed portion of the cochlear implant electrode.

11. A method for inserting a cochlear implant electrode into a cochlea scala of a patient cochlea, the method comprising:

enclosing at least a portion of a cochlear implant electrode within a stiff electrode holder while allowing the electrode within to slide freely while preventing an apical tip of the enclosed electrode from contacting tissues around the electrode opening during the insertion surgery;

piercing an electrode opening through an outer surface of the patient cochlea into the cochlea scala with a pointed distal tip of the electrode holder; and

inserting the electrode over the apical tip and into the cochlea scala.

12. A method according to claim 11, further comprising:

providing a flexible electrode cover around at least a portion of the electrode holder which is adapted to allow placement of the electrode into the electrode holder.

13. A method according to claim 11, a device handling feature at a proximal end of the electrode holder is used for surgical manipulation of the insertion support device and the enclosed electrode when inserting the electrode.

14. A method according to claim 11, wherein an insertion stopper near the distal tip limits penetration distance of the distal tip into the cochlea scala when piercing an electrode opening.

15. A method according to claim 11, wherein the implant electrode includes an electrode projection mechanism for pushing the electrode through the electrode opening into the cochlea scala.

16. A method according to claim 11, wherein the electrode holder forms an open tubular section enclosing the at least a portion of the cochlear implant electrode.

17. A method according to claim 11, wherein the electrode holder forms a perforated tubular section enclosing the at least a portion of the cochlear implant electrode.

18. A method according to claim 11, wherein the electrode holder includes a mastoidectomy section sized to fit within a mastoidectomy passage and tympanotomy section sized to fit within a posterior tympanotomy, wherein the two sections meet at a connecting angle that changes the direction of the enclosed electrode.

19. A method according to claim 11, wherein the electrode holder is sized to fit within a mastoidectomy passage during the insertion surgery.

20. A method according to claim 11, wherein the electrode holder wherein the electrode holder includes an inner surface coated with a reduced friction material that promotes free sliding of the enclosed portion of the cochlear implant electrode.

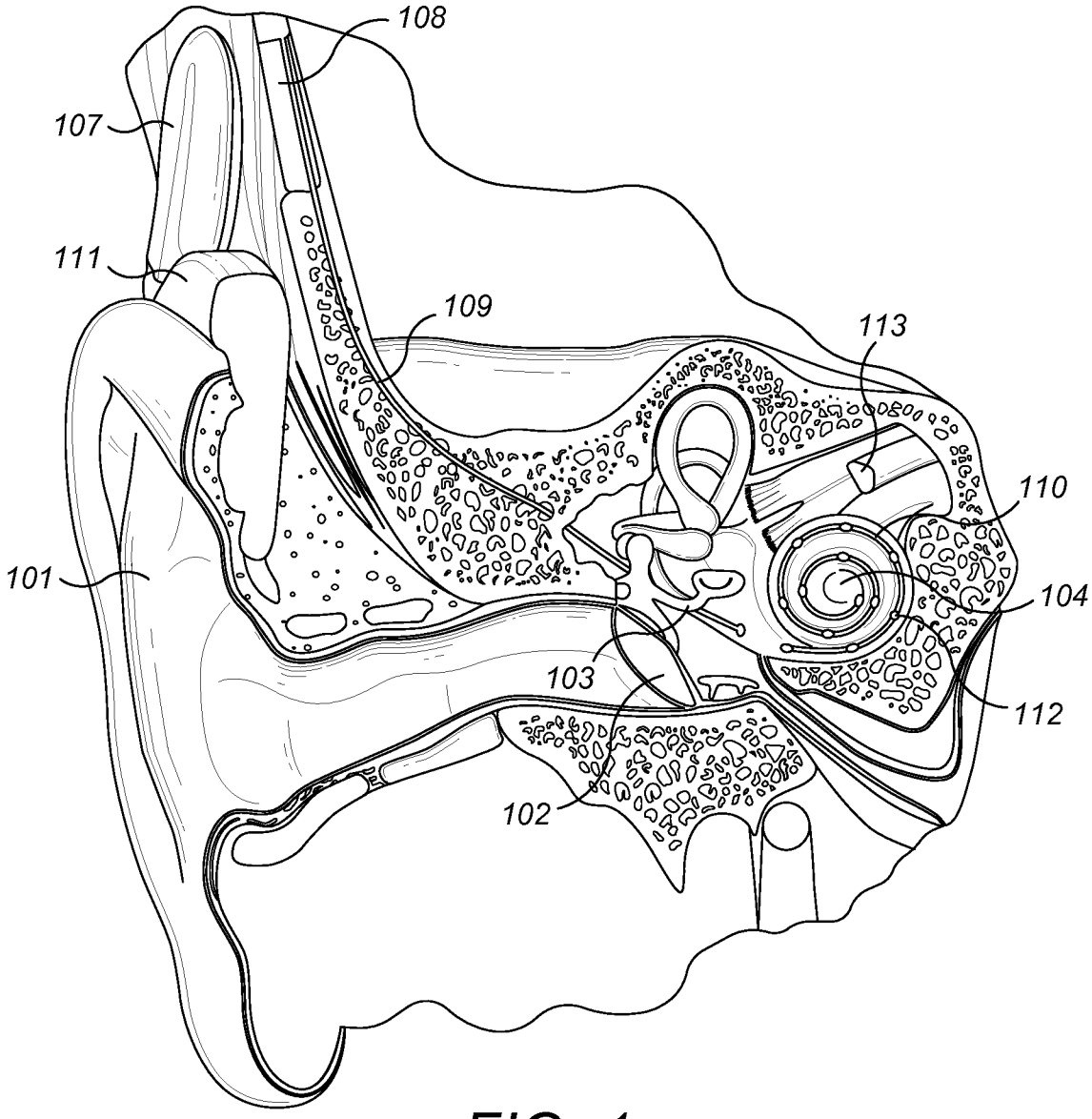

FIG. 1

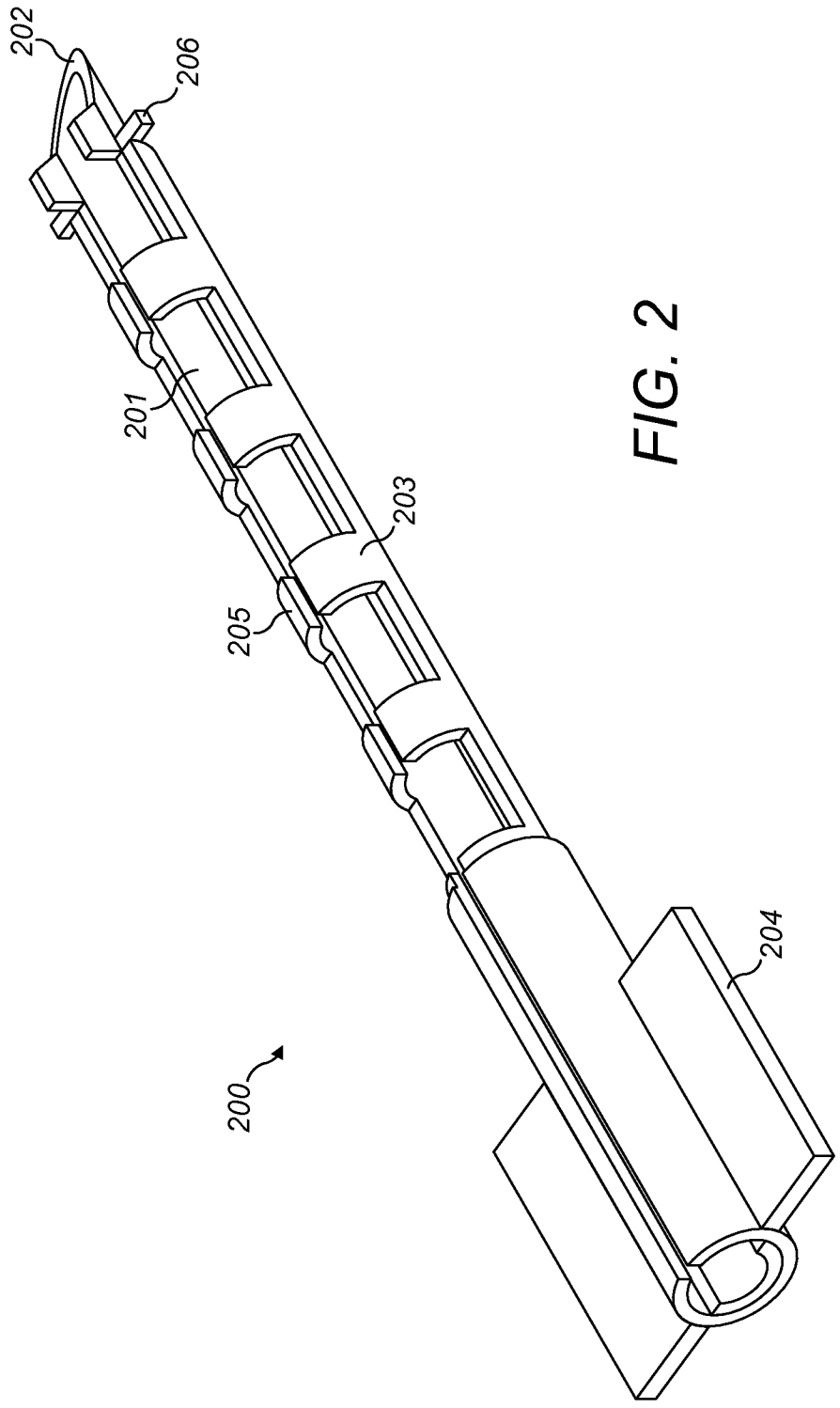

FIG. 2

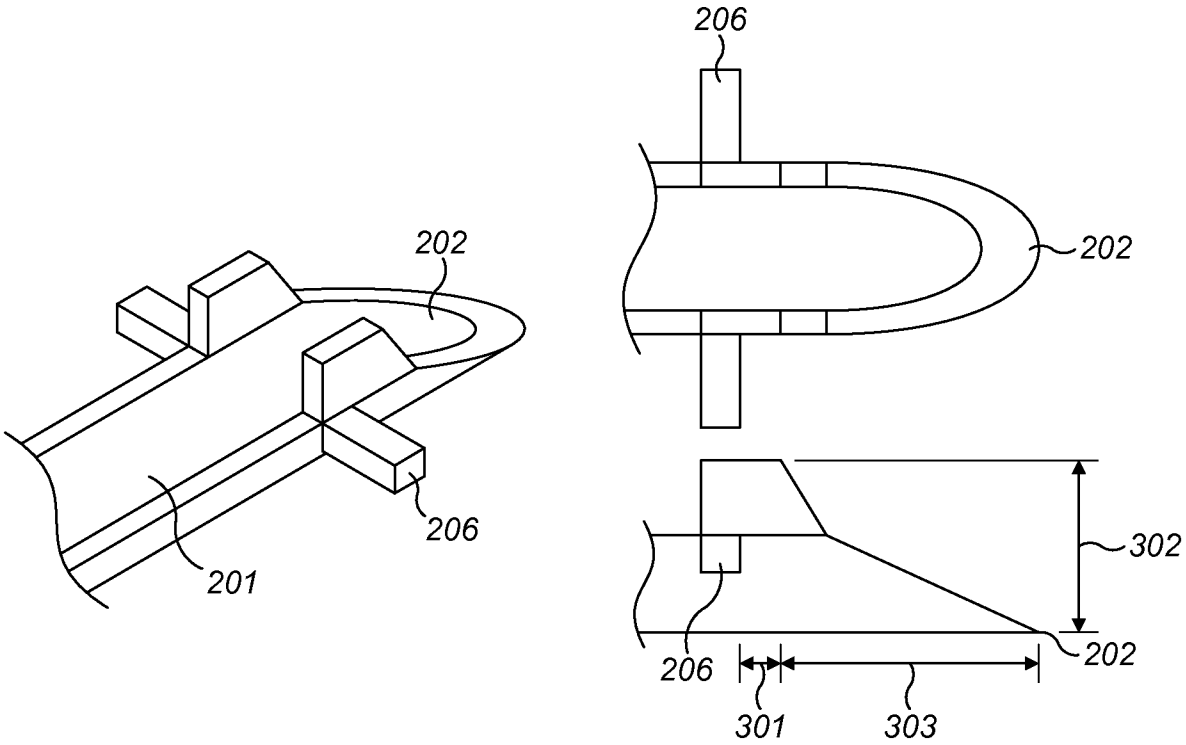

FIG. 3

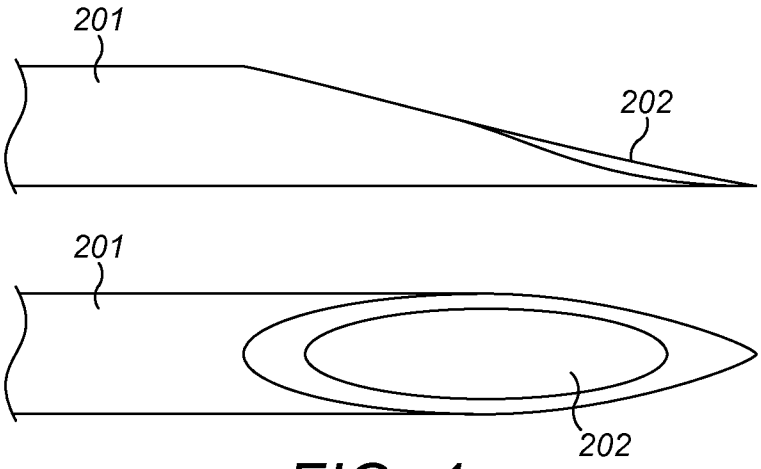

FIG. 4

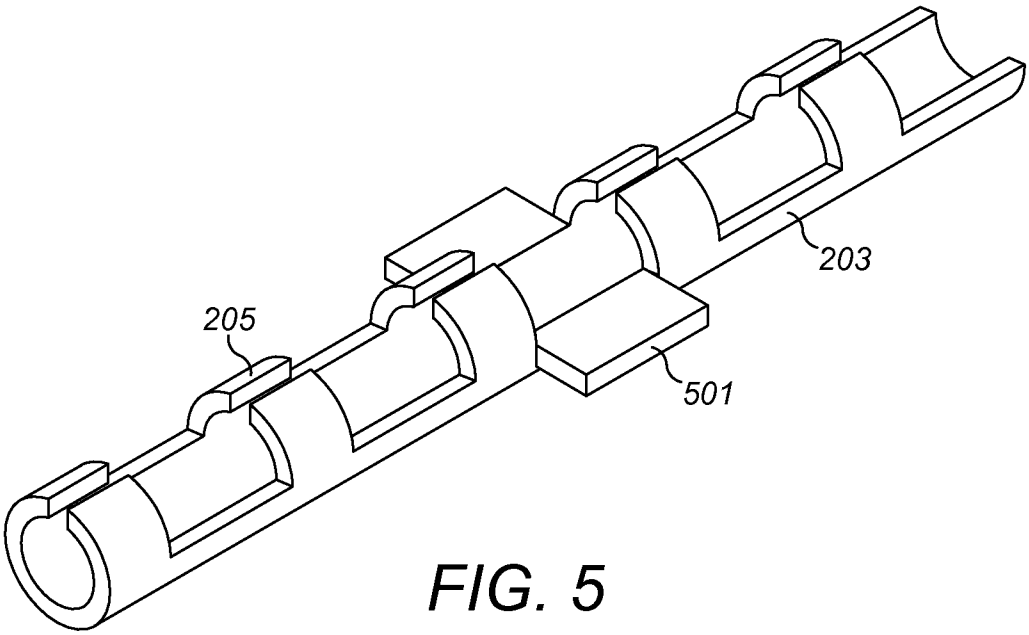

FIG. 5

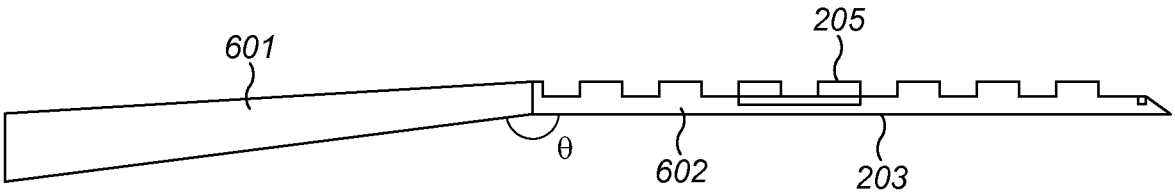

FIG. 6

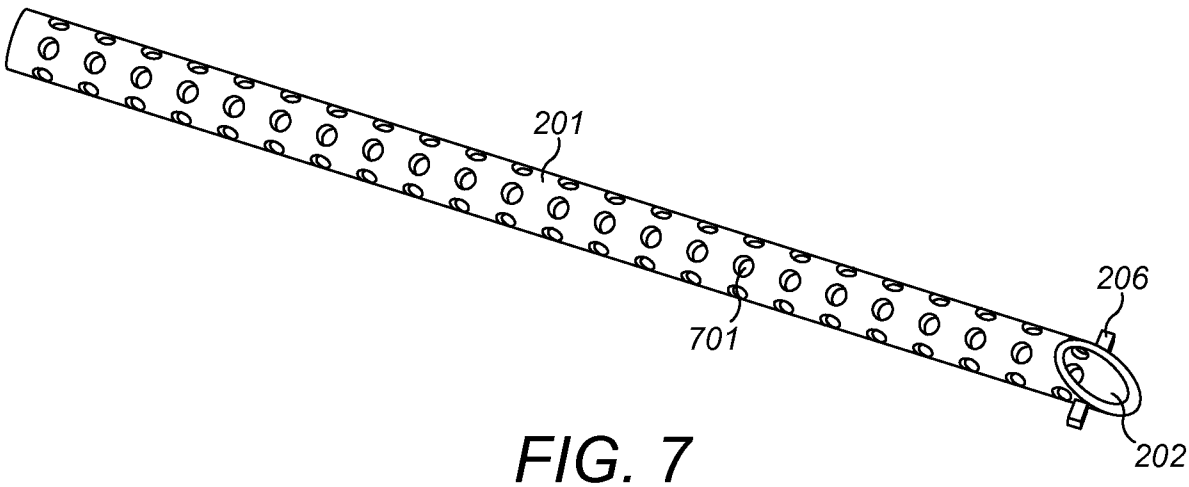

FIG. 7

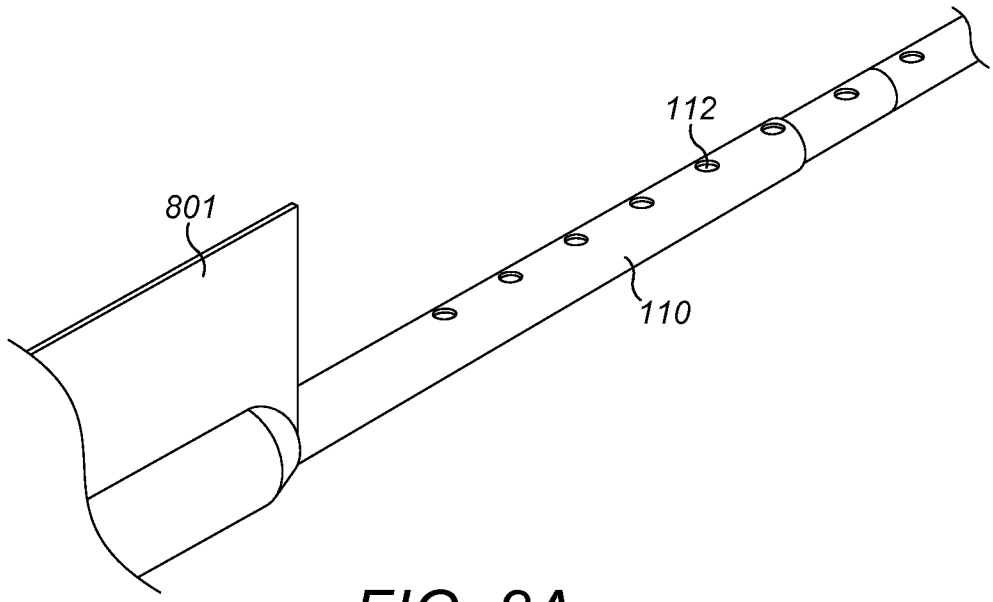

FIG. 8A

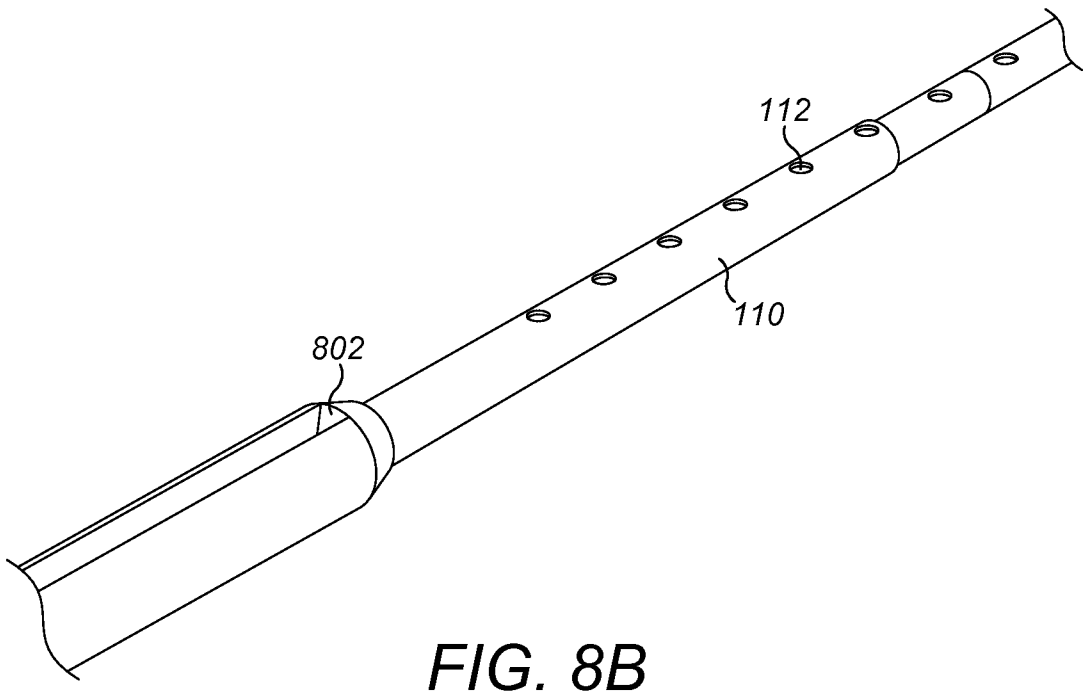

FIG. 8B

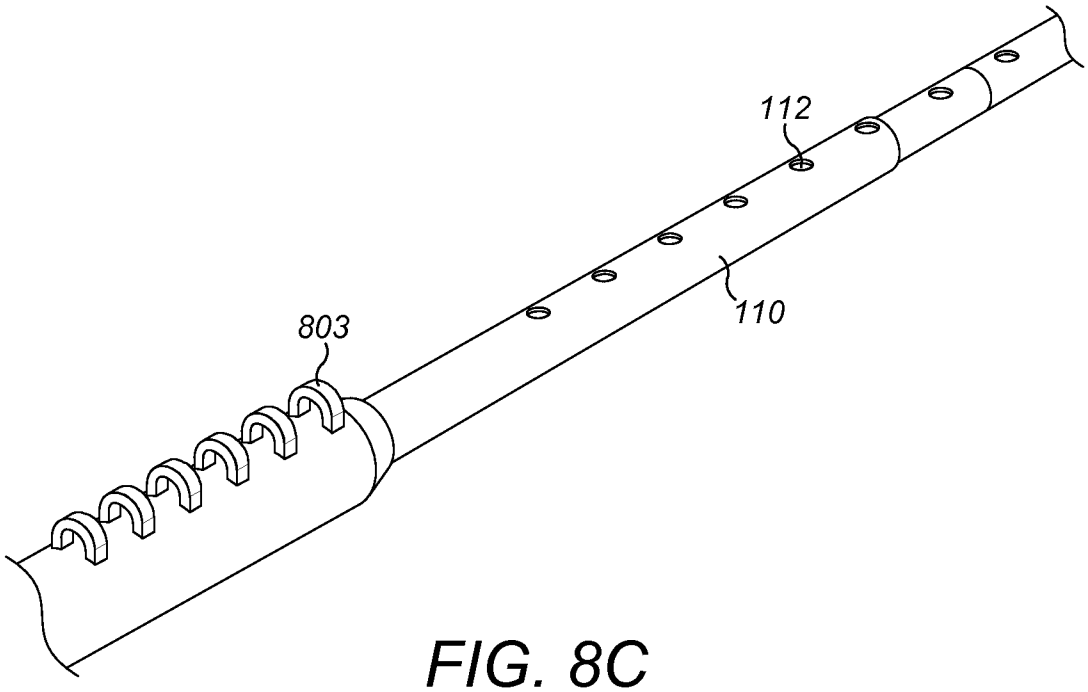

FIG. 8C

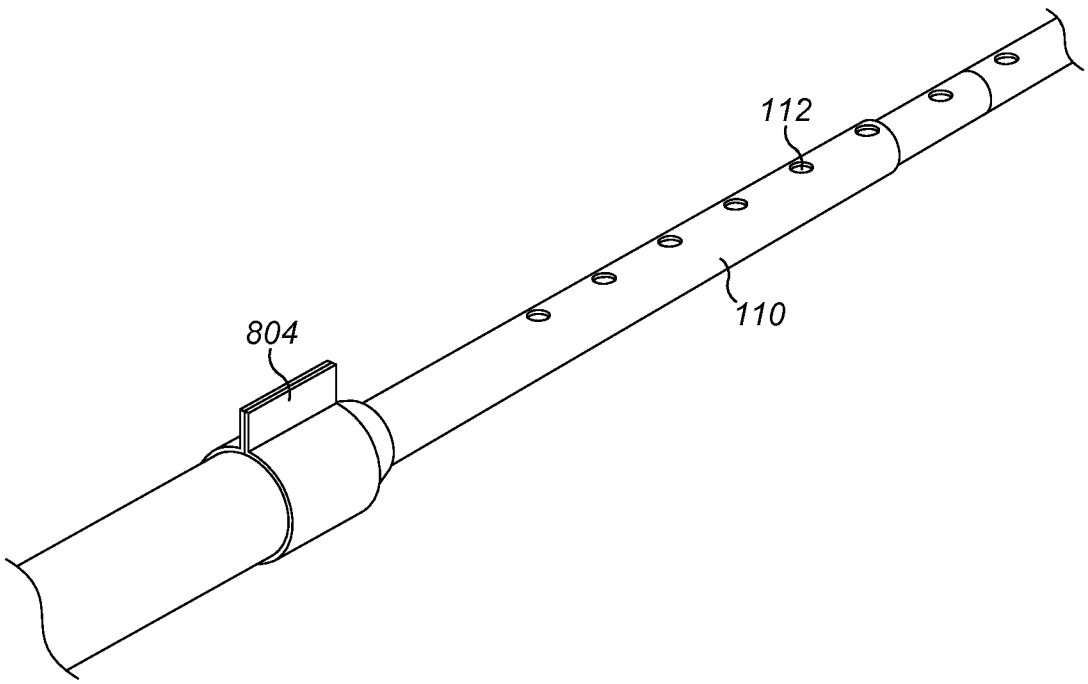

FIG. 8D

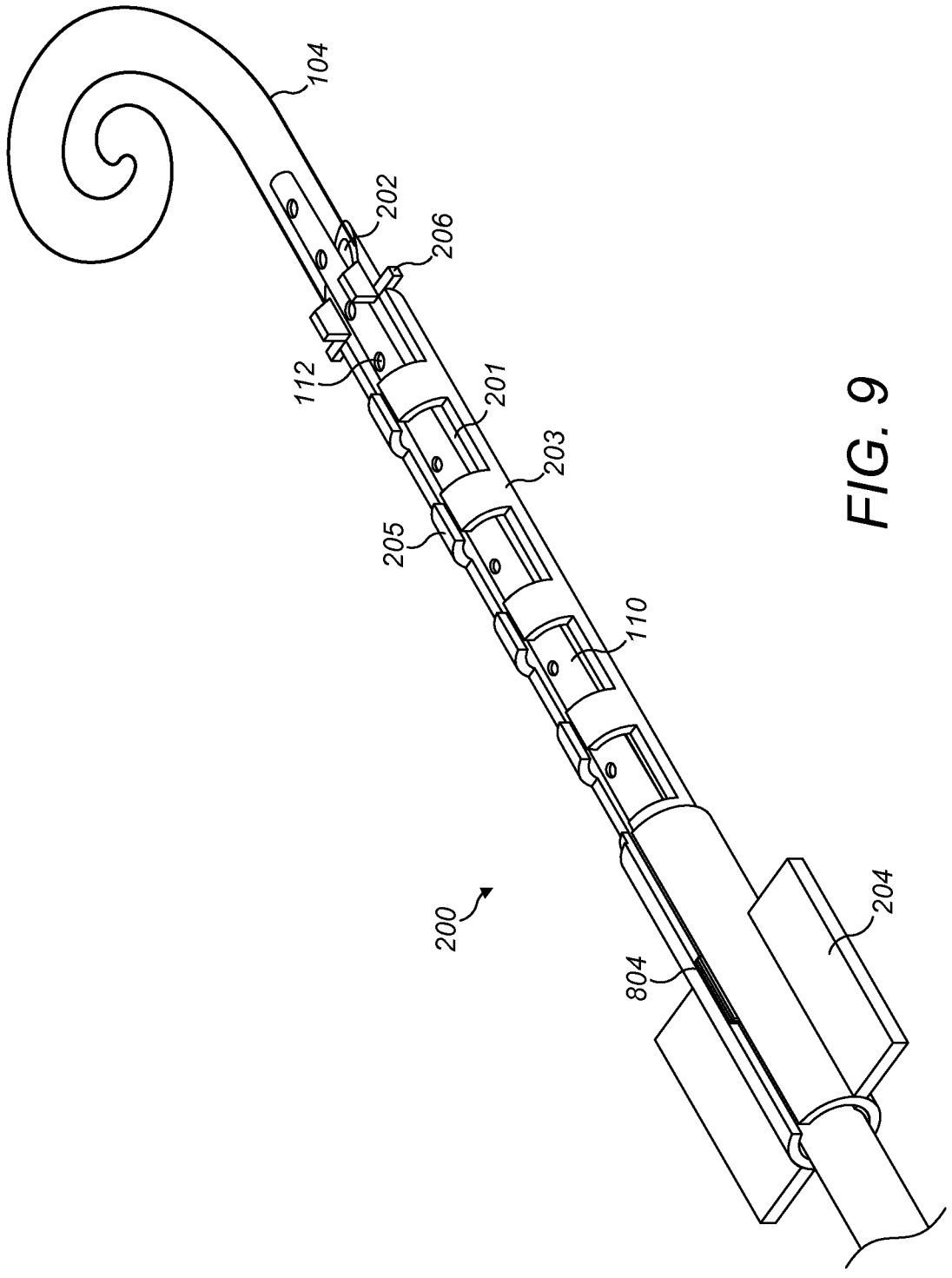

FIG. 9

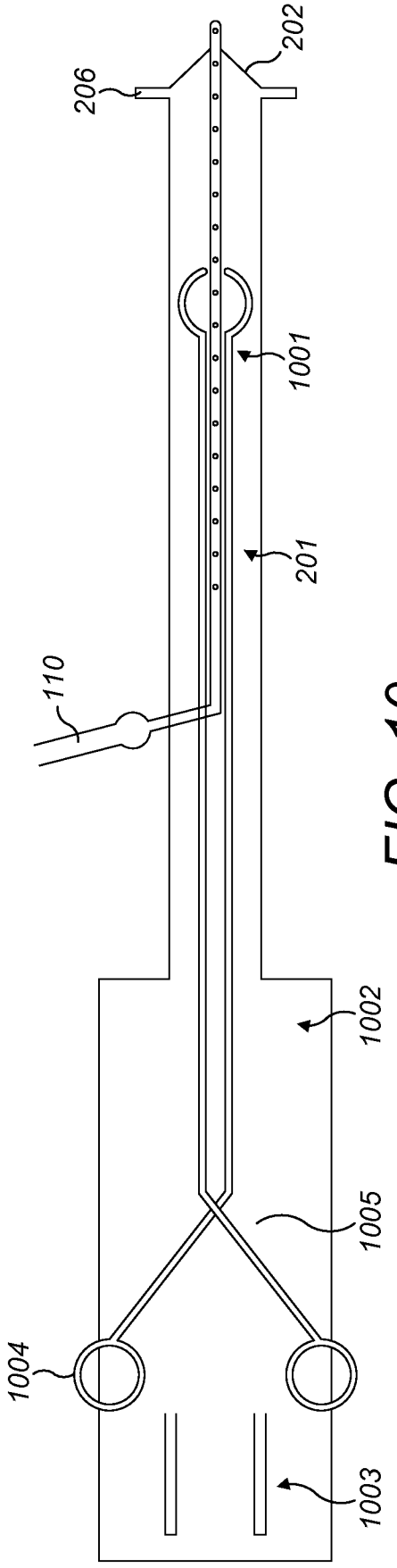

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/47133

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/05 (2014.01)
CPC - A61B 17/3468; A61N 1/0541; A61N 1/36032
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)
IPC(8) - A61N 1/05 (2014.01)
CPC - A61B 17/3468; A61N 1/0541; A61N 1/36032

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 607/57,137; CPC - A61B 2017/00787
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: cochlea*, auditory, acoustic, vestibulocochlear, eighth cranial, nerv*, neur*, implant, lead, electrode, stimulat*, insert*, deliver*, introduc*, placement, placing, emplac*, install*, deploy*, implanting, implantation, guide, sheath, cannula, tube, tubular, aid, aidin

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/0069613 A1 (KUZMA et al.) 10 April 2003 (10.04.2003) Entire document, especially Abstract, para[0041], para[0047]- para[0049] and FIGS. 205.	1-2, 5-6, 11-12, 15-16
Y	US 6,397,110 B1 (KUZMA) 28 May 2002 (28.05.2002) Entire document, especially Abstract and FIGS. 8-9.	1-2, 5-6, 11-12, 15-16
Y	US 2009/0306744 A1 (PARKER et al.) 10 December 2009 (10.12.2009) Entire document, especially Abstract, para[0036], para[0041], para[0092]- para[0100] and FIGS. 1-7.	1, 3-4, 7-11, 13-14, 17-20
Y	US 2010/0179626 A1 (PILARSKI et al.) 15 July 2010 (15.07.2010) Entire document, especially Abstract para[0037], para[0045] and FIGS. 5.	1, 3-4, 7-11, 13-14, 17-20
Y	US 2010/0087905 A1 (JOLLY) 08 April 2010 (08.04.2010) Entire document, especially Abstract, para[0018] and FIGS. 2.	7, 17
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Y	US 2011/0319908 A1 (THENUWARA et al.) 29 December 2011 (29.12.2011) Entire document, especially Abstract and para[0065].	10, 20
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A	US 2009/0209972 A1 (LOUSHIN et al.) 20 August 2009 (20.08.2009) Entire document.	1-20

☒ Further documents are listed in the continuation of Box C. ☐

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28 October 2014 (28.10.2014)	05DEC 2014
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

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/0241723 A1 (DADD et al.) 26 October 2006 (26.10.2006) Entire document.	1-20
A	US 7,050,858 B1 (KUZMA et al.) 23 May 2006 (23.05.2006) Entire document.	1-20