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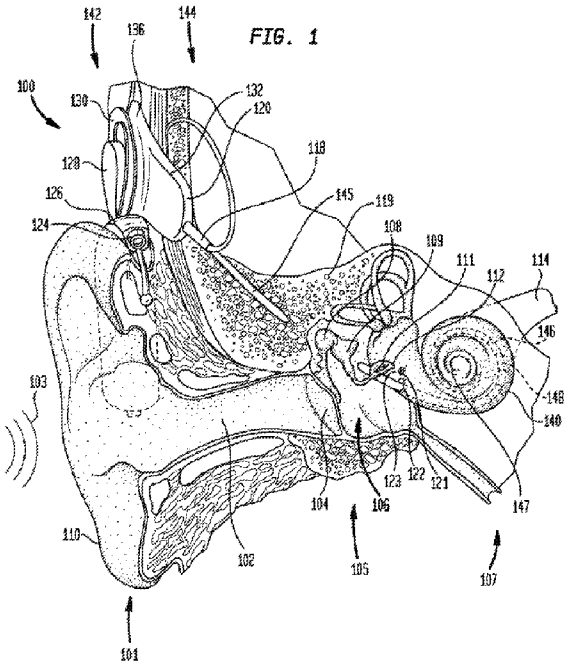
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FIG. 1



(57) Abstract: An electrode array insertion tool, including an assembly configured to provide direct array insertion functionality and ancillary array insertion functionality to a user thereof. In an exemplary embodiment, the tool includes an extra-cochlea bone conduction actuator system, and the ancillary array insertion functionality is output of vibrations directly to the cochlea by the system.

[Continued on next page]

WO 2017/221193 A1

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ELECTRODE INSERTION TOOL WITH ADDITIONAL FUNCTIONALITY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Patent Application No. 15/189,412, entitled ELECTRODE INSERTION TOOL WITH ADDITIONAL FUNCTIONALITY, filed on June 22, 2016, naming Richard Bruce MURPHY of Macquarie University, Australia as an inventor, the entire contents of that application being incorporated herein by reference in its entirety.

BACKGROUND

[0002] Hearing loss, which may be due to many different causes, is generally of two types: conductive and sensorineural. Sensorineural hearing loss is due to the absence or destruction of the hair cells in the cochlea that transduce sound signals into nerve impulses. Various hearing prostheses are commercially available to provide individuals suffering from sensorineural hearing loss with the ability to perceive sound. One example of a hearing prosthesis is a cochlear implant.

[0003] Conductive hearing loss occurs when the normal mechanical pathways that provide sound to hair cells in the cochlea are impeded, for example, by damage to the ossicular chain or the ear canal. Individuals suffering from conductive hearing loss may retain some form of residual hearing because the hair cells in the cochlea may remain undamaged.

[0004] Individuals suffering from hearing loss typically receive an acoustic hearing aid. Conventional hearing aids rely on principles of air conduction to transmit acoustic signals to the cochlea. In particular, a hearing aid typically uses an arrangement positioned in the recipient's ear canal or on the outer ear to amplify a sound received by the outer ear of the recipient. This amplified sound reaches the cochlea causing motion of the perilymph and stimulation of the auditory nerve. Cases of conductive hearing loss typically are treated by means of bone conduction hearing aids. In contrast to conventional hearing aids, these devices use a mechanical actuator that is coupled to the skull bone to apply the amplified sound.

[0005] In contrast to hearing aids, which rely primarily on the principles of air conduction, certain types of hearing prostheses commonly referred to as cochlear implants convert a received sound into electrical stimulation. The electrical stimulation is applied to the cochlea, which results in the perception of the received sound.

[0006] It is noted that in at least some instances, there is utilitarian value to fitting a hearing prosthesis to a particular recipient. In some examples of some fitting regimes, there are methods which entail a clinician or some other professional presenting sounds to a recipient of the hearing prosthesis such that the hearing prosthesis evokes a hearing percept. Information can be obtained from the recipient regarding the character of the resulting hearing percept. Based on this information, the clinician can adjust or otherwise establish settings of the hearing prosthesis such that the hearing prosthesis operates according to these settings during normal use.

[0007] It is also noted that the electrode array of the cochlear implant generally shows utilitarian results if it is inserted in a cochlea.

SUMMARY

[0008] In accordance with an exemplary embodiment, there is a cochlear electrode array insertion tool, comprising an array guide and an active functional component.

[0009] In accordance with another exemplary embodiment, there is an electrode array insertion tool, comprising an electrode array insertion guide, and an electrode.

[0010] In accordance with another exemplary embodiment, there is an exemplary method, comprising applying an acoustic source to a cochlea, and inserting an electrode array during the application of the acoustic source.

[0011] In accordance with another exemplary embodiment, there is a device comprising a cochlear implant electrode array insertion tool having a plurality of functional capabilities, at least one functional capability being different in kind than another functional capability.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Embodiments are described below with reference to the attached drawings, in which:

[0013] FIG. 1 is a perspective view of an exemplary hearing prosthesis in which at least some of the teachings detailed herein are applicable;

[0014] FIG. 2 is a side view of an embodiment of an insertion tool for implanting a cochlear implant electrode assembly such as the electrode assembly illustrated in FIG. 1;

[0015] FIGS. 3A and 3B are side and perspective views of an electrode assembly extended out of an embodiment of an insertion sheath of the insertion tool illustrated in FIG. 2;

[0016] FIGS. 4A-4E are simplified side views depicting the position and orientation of a cochlear implant electrode assembly insertion guide tube relative to the cochlea at each of a series of successive moments during an exemplary implantation of the electrode assembly into the cochlea;

[0017] FIG. 5A is a side view of a perimodiolar electrode assembly partially extended out of a conventional insertion guide tube showing how the assembly may twist while in the guide tube;

[0018] FIGS. 5B-5I are cross-sectional views of the electrode assembly illustrated in FIG. 5A;

[0019] FIG. 6A is a cross-sectional view of an embodiment of the insertion guide tube;

[0020] FIG. 6B is a perspective view of the portion of the guide tube illustrated in FIG. 6A;

[0021] FIG. 6C is a cross-sectional view of a conventional electrode assembly;

[0022] FIG. 6D is a cross-sectional view of the conventional electrode assembly of FIG. 6C positioned in the insertion guide tube illustrated in FIGS. 6A and 6B;

[0023] FIGs. 7 and 8 depict side views of respective exemplary embodiments of exemplary electrode array insertion tools;

[0024] FIGs. 9-10B depicts side views of various exemplary embodiments of various insertion tools in use;

[0025] FIGs. 11-18 depict cross-sectional views of portions of the insertion guide tube of exemplary embodiments of the electrode array insertion tool;

[0026] FIGs. 19-27 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0027] FIG. 28 depicts an exemplary use of an exemplary electrode array insertion tool;

[0028] FIGs. 29-35 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0029] FIGs. 36-37 depict exemplary functional block diagrams associated with the exemplary electrode array insertion tools;

[0030] FIGs. 38-39 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0031] FIG. 40 depicts an exemplary functional block diagram associated with the exemplary electrode array insertion tools;

[0032] FIGs. 41-44 depict cross-sectional views of portions of the insertion guide tube of exemplary embodiments of the electrode array insertion tool;

[0033] FIG. 45 is a quasi-functional schematic of an electrode array according to an exemplary embodiment;

[0034] FIG. 46 is a schematic of a conductive apparatus according to an exemplary embodiment;

[0035] FIG. 47 is another view of the conductive apparatus of FIG. 46;

[0036] FIG. 48A depicts the view of FIG. 7, along with a cross-sectional view of an electrode array located in the conductive apparatus;

[0037] FIG. 48B depicts a cross-sectional view of a portion of the insertion guide tube of exemplary embodiments of the electrode array insertion tool;

[0038] FIG. 49 depicts an exemplary scenario associated with testing an electrode array for an open circuit utilizing a component of an insertion tool;

[0039] FIG. 50A depicts a conceptual diagram depicting a test for an open circuit;

[0040] FIG. 50B depicts a conceptual diagram depicting an open circuit that can be detected utilizing the test for an open circuit;

[0041] FIGs. 51A-51C depict exemplary conductive apparatus is that can be utilized to test for open circuit according to some exemplary embodiments;

[0042] FIG. 52 depicts an exemplary cross-sectional view of an exemplary embodiment of an exemplary insertion tool;

[0043] FIGs. 53-54 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0044] FIGs. 55-56 depict exemplary cross-sectional views of an exemplary embodiment of an exemplary insertion tool;

[0045] FIG. 57 depicts an exemplary side view of an exemplary embodiment of an exemplary insertion tool;

[0046] FIG. 58 depicts an exemplary cross-sectional view of an exemplary portion of an exemplary insertion tool;

[0047] FIG. 59 depicts an exemplary side view of an exemplary embodiment of an exemplary insertion tool;

[0048] FIG. 60 depicts an exemplary cross-sectional view of an exemplary portion of an exemplary insertion tool;

[0049] FIGs. 61-63 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0050] FIG. 64 depicts an exemplary flowchart for an exemplary method according to an exemplary embodiment;

[0051] FIGs. 65-67 depict side views of exemplary embodiments of exemplary electrode array insertion tools;

[0052] FIGs. 68-70 depict exemplary flowcharts for exemplary methods according to some exemplary embodiments;

[0053] FIG. 71 depicts an exemplary thin-film that is usable for an exemplary embodiment;

[0054] FIG. 72 depicts the results of the utilization of the thin film of FIG. 71;

[0055] FIG. 73 depicts a side view of an exemplary embodiment of an exemplary insertion tool; and

[0056] FIG. 74 depicts an exemplary insertion tool – inductance coil combination enabling the insertion tool to communicate with a receiver-stimulator of a cochlear implant.

DETAILED DESCRIPTION

[0057] FIG. 1 is a perspective view of an exemplary cochlear implant 100 implanted in a recipient having an outer ear 101, a middle ear 105, and an inner ear 107. In a fully functional ear, outer ear 101 comprises an auricle 110 and an ear canal 102. Acoustic pressure or sound waves 103 are collected by auricle 110 and channeled into and through ear canal 102. Disposed across the distal end of ear canal 102 is a tympanic membrane 104 that vibrates in response to sound waves 103. This vibration is coupled to oval window or fenestra ovalis 112 through the three bones of the middle ear 105, collectively referred to as the ossicles 106, and comprising the malleus 108, the incus 109, and the stapes 111. Ossicles 106 filter and amplify the vibrations delivered by tympanic membrane 104, causing oval window 112 to articulate, or vibrate. This vibration sets up waves of fluid motion of the perilymph within cochlea 140. Such fluid motion, in turn, activates hair cells (not shown) inside the cochlea which in turn causes nerve impulses to be generated which are transferred through spiral ganglion cells (not shown) and auditory nerve 114 to the brain (also not shown) where they are perceived as sound.

[0058] The exemplary cochlear implant illustrated in FIG. 1 is a partially implanted stimulating medical device. Specifically, cochlear implant 100 comprises external components 142 attached to the body of the recipient, and internal or implantable components 144 implanted in the recipient. External components 142 typically comprise one or more sound input elements for detecting sound, such as microphone 124, a sound processor (not shown), and a power source (not shown). Collectively, these components are housed in a behind-the-ear (BTE) device 126 in the example depicted in FIG. 1. External components 142 also include a transmitter unit 128 comprising an external coil 130 of a transcutaneous energy transfer (TET) system. Sound processor 126 processes the output of microphone 124 and generates encoded stimulation data signals which are provided to external coil 130.

[0059] Internal components 144 comprise an internal receiver unit 132 including a coil 136 of the TET system, a stimulator unit 120, and an elongate stimulating lead assembly 118. Internal receiver unit 132 and stimulator unit 120 are hermetically sealed within a biocompatible housing commonly referred to as a stimulator/receiver unit. Internal coil 136 of receiver unit 132 receives power and stimulation data from external coil 130. Stimulating lead assembly 118 has a proximal end connected to stimulator unit 120, and extends through mastoid bone 119. Lead assembly 118 has a distal region, referred to as electrode assembly 145, a portion of which is implanted in cochlea 140.

[0060] Electrode assembly 145 can be inserted into cochlea 140 via a cochleostomy 122, or through round window 121, oval window 112, promontory 123, or an opening in an apical turn 147 of cochlea 140. Integrated in electrode assembly 145 is an array 146 of longitudinally-aligned and distally extending electrode contacts 148 for stimulating the cochlea by delivering electrical, optical, or some other form of energy. Stimulator unit 120 generates stimulation signals each of which is delivered by a specific electrode contact 148 to cochlea 140, thereby stimulating auditory nerve 114.

[0061] Electrode assembly 145 may be inserted into cochlea 140 with the use of an insertion tool. FIG. 2 is a side view of an embodiment of an insertion tool for implanting an elongate electrode assembly generally represented by electrode assembly 145 into a mammalian cochlea, represented by cochlea 140. The illustrative insertion tool, referred to herein as insertion tool 200, includes an elongate insertion guide tube 210 configured to be inserted into cochlea 140 and having a distal end 212 from which an electrode assembly is deployed. Insertion guide tube 210 has a radially-extending stop 204 that may be utilized to determine or otherwise control the depth to which insertion guide tube 210 is inserted into cochlea 140.

[0062] Insertion guide tube 210 is mounted on a distal region of an elongate staging section 208 on which the electrode assembly is positioned prior to implantation. A handle 202 is mounted to a proximal end of staging section 208 to facilitate implantation. During use, electrode assembly 145 is advanced from staging section 208 to insertion guide tube 210 via ramp 206. After insertion guide tube 210 is inserted to the appropriate depth in cochlea 140, electrode assembly 145 is advanced through the guide tube to exit distal end 212 as described further below.

[0063] FIGS. 3A and 3B are side and perspective views, respectively, of representative electrode assembly 145. As noted, electrode assembly 145 comprises an electrode array 146 of electrode contacts 148. Electrode assembly 145 is configured to place electrode contacts 148 in close proximity to the ganglion cells in the modiolus. Such an electrode assembly, commonly referred to as a perimodiolar electrode assembly, is manufactured in a curved configuration as depicted in FIGS. 3A and 3B. When free of the restraint of a stylet or insertion guide tube, electrode assembly 145 takes on a curved configuration due to it being manufactured with a bias to curve, so that it is able to conform to the curved interior of cochlea 140. As shown in FIG. 3B, when not in cochlea 140, electrode assembly 145 generally resides in a plane 350 as it returns to its curved configuration. That said, it is noted that embodiments of the insertion tools detailed herein and/or variations thereof can be

applicable to a so-called straight electrode array, which electrode array does not curl after being free of a stylet or insertion guide tube etc., but instead remains straight

[0064] FIGS. 4A-4E are a series of side-views showing consecutive exemplary events that occur in an exemplary implantation of electrode assembly 145 into cochlea 140. Initially, electrode assembly 145 and insertion guide tube 310 are assembled. For example, electrode assembly 145 is inserted (slidingly or otherwise) into a lumen of insertion guide tube 300. The combined arrangement is then inserted to a predetermined depth into cochlea 140, as illustrated in FIG. 4A. Typically, such an introduction to cochlea 140 is achieved via cochleostomy 122 (FIG. 1) or through round window 121 or oval window 112. In the exemplary implantation shown in FIG. 4A, the combined arrangement of electrode assembly 145 and insertion guide tube 300 is inserted to approximately the first turn of cochlea 140.

[0065] As shown in FIG. 4A, the combined arrangement of insertion guide tube 300 and electrode assembly 145 is substantially straight. This is due in part to the rigidity of insertion guide tube 300 relative to the bias force applied to the interior wall of the guide tube by pre-curved electrode assembly 145. This prevents insertion guide tube 300 from bending or curving in response to forces applied by electrode assembly 145, thus enabling the electrode assembly to be held straight, as will be detailed below.

[0066] As noted, electrode assembly 145 is biased to curl and will do so in the absence of forces applied thereto to maintain the straightness. That is, electrode assembly 145 has a memory that causes it to adopt a curved configuration in the absence of external forces. As a result, when electrode assembly 145 is retained in a straight orientation in guide tube 300, the guide tube prevents the electrode assembly from returning to its pre-curved configuration. This induces stress in electrode assembly 145. Pre-curved electrode assembly 145 will tend to twist in insertion guide tube 300 to reduce the induced stress. In the embodiment configured to be implanted in scala tympani of the cochlea, electrode assembly 145 is pre-curved to have a radius of curvature that approximates the curvature of medial side of the scala tympani of the cochlea. Such embodiments of the electrode assembly are referred to as a perimodiolar electrode assembly, and this position within cochlea 140 is commonly referred to as the perimodiolar position. In some embodiments, placing electrode contacts in the perimodiolar position provides utility with respect to the specificity of electrical stimulation, and can reduce the requisite current levels thereby reducing power consumption.

[0067] As shown in FIGS. 4B-4D, electrode assembly 145 may be continually advanced through insertion guide tube 300 while the insertion sheath is maintained in a substantially stationary position. This causes the distal end of electrode assembly 145 to extend from the distal end of insertion guide tube 300. As it does so, the illustrative embodiment of electrode assembly 145 bends or curves to attain a perimodiolar position, as shown in FIGS. 4B-4D, owing to its bias (memory) to curve. Once electrode assembly 145 is located at the desired depth in the scala tympani, insertion guide tube 300 is removed from cochlea 140 while electrode assembly 145 is maintained in a stationary position. This is illustrated in FIG. 4E.

[0068] Conventional insertion guide tubes typically have a lumen dimensioned to allow the entire tapered electrode assembly to travel through the guide tube. Because the guide tube is able to receive the relatively larger proximal region of the electrode assembly, there will be a gap between the relatively smaller distal region of the electrode assembly and the guide tube lumen wall. Such a gap allows the distal region of the electrode assembly to curve slightly until the assembly can no longer curve due to the lumen wall.

[0069] Returning to FIGS. 3A-3B, perimodiolar electrode assembly 145 is pre-curved in a direction that results in electrode contacts 148 being located on the interior of the curved assembly, as this causes the electrode contacts to face the modiolus when the electrode assembly is implanted in or adjacent to cochlea 140. Insertion guide tube 500 retains electrode assembly 145 in a substantially straight configuration, thereby preventing the assembly from taking on the configuration shown in FIG. 3B. The inability of electrode assembly 145 to curve to accommodate the bias force induces stress in the assembly. Pre-curved electrode assembly 145 will tend to twist while exiting insertion guide tube 510 to reduce this stress. With the distal end of the electrode assembly curved to abut the lumen wall, the assembly twists proximally.

[0070] This is illustrated in FIGS. 5A-5I. FIG. 5A is a side view of perimodiolar electrode assembly 145 partially extended out of a conventional insertion guide tube 500, showing how the assembly may twist while in the guide tube. FIGS. 5B-5F are cross-sectional views taken through respective sections 5B-5B, 5C-5C, 5D-5D, 5E-5E, and 5F-5F of electrode assembly 145 in FIG. 5A.

[0071] As shown in FIGS. 5A-5F, the portion of electrode assembly 145 in insertion guide tube 510 is twisted about its longitudinal axis, resulting in electrode contacts 148 in the twisted region to have a different radial position relative to insertion guide tube 510. As

shown in FIGS. 5A and 5G-I, as electrode assembly 145 exists insertion guide tube 500, the assembly is free to curve in accordance with its bias force. However, the orientation of electrode contacts in the deployed region of the assembly is adversely affected by the twisted region of the assembly remaining in guide tube 510.

[0072] Accordingly, some embodiments detailed herein and/or variations thereof are directed towards an insertion tool having an insertion guide tube that maintains a perimodiolar or other pre-curved electrode assembly in a substantially straight configuration while preventing the electrode assembly from twisting in response to stresses induced by the bias force which urges the assembly to return to its pre-curved configuration. This generally ensures that when the electrode assembly is deployed from the distal end of the insertion guide tube, the electrode assembly and insertion guide tube have a known relative orientation.

[0073] FIGS. 6A-6D are different views of but some exemplary embodiments of insertion guide tube 210, referred to herein at insertion guide tube 610. For ease of description, features of the guide tube will be described with reference to the orientation of the guide tube illustrated in the figures. FIG. 6A is a partial cross-sectional view of an embodiment of insertion guide tube 210, referred to herein at insertion guide tube 610. As can be seen, insertion guide tube 610 includes an anti-twist section 620 formed at the distal end of the guide tube. Anti-twist section 320 is contiguous with the remaining part of guide tube 610. Guide tube 610 has a lumen 640 which, in proximal section 624 has a vertical dimension 626, and an distal anti-twist section 620 has a smaller vertical dimension 634 described below. The vertical dimension of lumen 640 decreases from dimension 626 to dimension 634 due to a ramp 648 at the proximal end of anti-twist section 642.

[0074] Anti-twist section 620 causes a twisted electrode assembly traveling through guide tube 610 to return to its un-twisted state, and retains the electrode assembly in a straight configuration such that the orientation of the electrode assembly relative to the insertion guide tube 610 does not change.

[0075] As shown in FIG. 6C, electrode assembly 145 has a rectangular cross-sectional shape, with the surface formed in part by the surface of the electrode contact, referred to herein as top surface 650, and the opposing surface, referred to herein as bottom surface 652, are substantially planar. These substantially planar surfaces are utilized in embodiments of the insertion guide tube described herein.

[0076] Tube wall 658 in anti-twist section 620 has surfaces 644 and 646 which extend radially inward to form an anti-twist guide channel 680. Specifically, a superior flat 644 provides a substantially planar lumen surface along the length of section 620. As shown best in FIGS. 6A, 6B, and 6D, superior flat 644 has a surface that is substantially planar and which therefore conforms with the substantially planar top surface 650 of electrode assembly 145. Similarly, inferior flat 646 has a surface that is substantially planar which conforms with the substantially planar bottom surface 652 of electrode assembly 145. As shown in FIG. 6D, when a distal region of electrode assembly 145 is located in anti-twist section 620, the surfaces of superior flat 644 and inferior flat 646 are in physical contact with top surface 650 and bottom surface 652, respectively, of the electrode assembly. This prevents the electrode assembly from curving, as described above.

[0077] FIG. 7 depicts an exemplary embodiment of a cochlear electrode array insertion tool 700. In an exemplary embodiment, the insertion tool 700 corresponds to that of the insertion tool 200 detailed above, with the exception of the addition of acoustic stimulation generator 704, and the modifications to the tool so as to support the generator and the associated components thereof (e.g., electrical leads 706 (only the "distal" portion of the lead (distal relative to the tool 800) is depicted, the "break' being conceptual), etc. - more on this below). Accordingly, FIG. 7 depicts a cochlear electrode array insertion tool comprising an array guide (e.g., the insertion guide tube (210 of fig. 2)) and an active functional component (e.g., generator 704). Some additional details of some exemplary functional components, including some exemplary active functional components, will be described in greater detail below. However, it is briefly noted at this time that not all embodiments of the cochlear electrode array insertion tool include an intracochlear portion. In this regard, FIG. 7 depicts a tool 700 that includes an intracochlear portion 710. This is the portion to the right of stop 204 / the portion on the distal side of stop 204 (distal relative to the entire insertion tool). Conversely, FIG. 8 depicts a tool 800 that does not include an intracochlear portion. Instead, stop 204 is configured to be placed against the outside of the cochlea such that the passageway through the tool through which the electrode array is passed is aligned with the pertinent window and/or cochleostomy such that no parts of the tool 800 enters the cochlea. In an exemplary embodiment, the tool is configured such that the generator 704 abuts the outside of the cochlea in the middle ear / the wall of the cochlea dividing the inner ear from the middle ear. The generator 704 thus is in physical direct contact with the wall of the cochlea in some embodiments of use.

[0078] It is noted that while the teachings detailed herein with respect to extra functionality of the insertion tool are based on the insertion tool detailed above with respect to FIGs. 5A-6D, these teachings can be applicable to other types of insertion tools. Indeed, as will be detailed below, some embodiments of the insertion tools do not have an intracochlear portion at all. Accordingly, the teachings above with respect to FIGs. 5A-6D serve as but one example of an insertion tool that the following teachings can be utilized in conjunction therewith.

[0079] With reference back to FIG. 7, the exemplary active functional component can be an acoustic stimulation generator, as noted above. In an exemplary embodiment, the embodiment of FIG. 7 (or FIG. 8) enables the middle ear to be bypassed so as to provide a source of acoustic stimulation in an intraoperative ECoG measurement. In this regard, the stimulation generator 704 can be an extra-cochlea bone conduction actuator positioned such that, when the insertion tool is utilized when inserting the electrode array into the cochlea, the acoustic signal generator 704 is pressed against the cochlear promontory, round window, or cochleostomy during insertion. In an exemplary embodiment, the proximity of the acoustic stimulation generator 704 to the cochlea enables such to be utilized as an acoustic stimulation source during intraoperative ECoG measuring. In an exemplary embodiment, the acoustic stimulation generator 704 is a bone conduction device as detailed above. In an exemplary embodiment, the acoustic stimulation generator 704 is an electromagnetic actuator that is configured to vibrate when subjected to a current via the electrode lead 706. Alternatively, in an exemplary embodiment, the acoustic stimulation generator is a piezoelectric actuator that is configured to vibrate when subjected to a current via the electrode lead 706. In these embodiments, these actuators can be actuated for a bone conduction device, as noted above. That said, in some alternate embodiments, the acoustic stimulation generator can be a speaker. Element 704 can be any device that can enable stimulation having utilitarian value for an ECoG measurement.

[0080] The embodiments of FIGs. 7 and 8 are such that the generator 704 abuts the outside of the cochlea during use so as to establish physical contact with the outside of the cochlea. FIG. 9 depicts an exemplary scenario of use, where element 910 is the wall of the cochlea that separates the middle ear cavity from the inner cavity. In an exemplary embodiment, generator 704 abuts the cochlear promontory. In an exemplary embodiment, generator 704 abuts the round window and/or oval window. With respect to the "and/or" it is noted that while the embodiments depicted herein indicate a single generator, in alternative

embodiments, two or more generators can be utilized in an array such that one contacts the oval window and the other contacts the round window. In an exemplary embodiment, these generators can operate out of phase such that a first generator depresses the round window while a second generator provides no force against the oval window, and then the second generator depresses the oval window while the first generator provides no force against the round window. An exemplary embodiment of a structure configured to operate in such a manner or a variation thereof is detailed in U.S. Patent Application No. 15/159,335, entitled "Implantable Hearing Prosthesis With Dual Actuation" filed on May 19, 2016, to the inventor Joris Walraevens. Any force generator / vibration generator that can establish stimulation to enable ECoG measurement can be utilized in at least some exemplary embodiments.

[0081] In any event, it is again noted that the generator can be located anywhere on the tool that the generator can have utilitarian value with respect to establishing stimulation to enable ECoG measurements. In an exemplary embodiment, the generator can be located such that, during use, the generator is not necessarily in direct contact with the cochlea providing that such has the aforementioned utilitarian value with respect to generating stimulation enabling ECoG measurement.

[0082] While the embodiments detailed above have focused on the generator being located entirely outside the cochlea (e.g., entirely inside the middle ear), in an alternative embodiment, the generator is located inside the cochlea during use. FIG. 10A depicts an exemplary insertion regime utilizing exemplary electrode array insertion tool 1000 where the generator 704 is located entirely in the inner cavity (in the cochlea) when the insertion tool is fully inserted into the inner ear cavity. Still further, FIG. 10B depicts an exemplary insertion regime utilizing exemplary electrode array insertion tool 1100 where the generator is located in the wall that separates the middle ear cavity from the inner ear cavity when the insertion tool is fully inserted into the inner ear cavity. In an exemplary embodiment, a portion of the generator 704 is located in the middle ear cavity, and another portion of the generator 704 is located in the wall 910 and/or in the inner cavity when the insertion tool 1100 is fully inserted into the cochlea. In an exemplary embodiment, the tool is such that the entire generator 704 is located in the wall 910 (i.e., in the hole through the wall) when the insertion tool 1100 is fully inserted into the inner ear cavity. That is, no part of the generator is located in the middle ear cavity where the inner ear cavity (where, for the purposes of this paragraph only, the volume corresponding to the hole that is formed in the cochlea so that the array can pass from the middle ear cavity to the inner ear cavity is neither in the middle ear cavity nor in the

inner ear cavity). In an exemplary embodiment, the tool is such that a portion of the generator 704 is located in the wall 910 when the insertion tool 1100 is fully inserted into the inner ear cavity, and a portion of the generator is located in the inner ear cavity when the insertion tool is fully inserted into the inner ear cavity.

[0083] Figure 11 depicts an exemplary cross-section of an exemplary insertion tool where the frame of reference is seen relative to the stop 204, and the distance between the closest service of the stop 204 and the generator 704 is greater than the thickness of the wall of the cochlea between the middle ear cavity in the inner ear cavity. Thus, in this exemplary embodiment, the entire generator 704 is located entirely within the inner ear cavity when the insertion tool is fully inserted into the inner ear cavity.

[0084] As can be seen in this exemplary embodiment, the generator 704 is located or otherwise embedded in the tube wall 658 of the insertion tool. In the end exemplary embodiment depicted in the figure, the generator 704 is located in the proximal section 624 of the insertion guide tube 610. That said, in an alternative embodiment, the generator 704 can be located in the anti-twist section 620. The generator can be embedded anywhere within the insertion tool that can enable the teachings detailed herein and/or variations thereof. While the embodiment depicted in FIG. 11 shows only one generator 704, in an alternate embodiment, two or more generators can be located in the wall 658 or otherwise embedded in the wall 658 such that two or more generators are located inside the cochlea when the tool is fully inserted in the cochlea.

[0085] Figure 12A depicts an alternate embodiment where the generator 1204, which can correspond to any of the generators detailed herein or any other generator for that matter that can have utilitarian value with respect to enabling the teachings detailed herein, is located on the outside of tube wall 658. As can be seen, lead 706 leads from the outside of the inner ear cavity / from the tool handle section into the inner ear cavity to the actuator 1204. In the embodiment depicted in FIG. 12A the actuator is streamlined so as to not interfere or otherwise enable relative ease of insertion of the proximal section 624 of the tool into the cochlea.

[0086] While the embodiment of FIG. 12A depicts the generator located entirely on the outside surface of tube wall 658, in an alternate embodiment, a portion of the generator can be located or otherwise embedded in the tube 658, and another portion of the generator can be proud of the tube wall 658, as can be seen with respect to generator 12104 in FIG. 12B.

Still further, FIG. 12C depicts an exemplary embodiment where a cavity is located in tube wall 658, and a generator 122104 is located within that cavity. In some embodiments, the generator is not proud of the outer tube wall surface, and in some embodiments, the generator is proud of the outer tube wall surface. In an exemplary embodiment, the area around the generator can be filled with another material so as to establish a smooth outer wall.

[0087] Figure 13 depicts another exemplary embodiment, where the generator 1304 is embedded in the tube wall 658, but is in vibratory communication with a band 1305 that extends about the tube wall 658. In an exemplary embodiment, the generator 1304 vibrates when subjected to an electric signal via the leads 706, and there are vibrations conducted via a conductor, such as a piece of metal or the like, to the band 1305. In an exemplary embodiment, the band 1305 can be a titanium band. When the vibrations are conducted to band 1305, the band will vibrate.

[0088] While the embodiments detailed above have been directed towards the scenario where the generator is located within the cochlea when the insertion tool is fully inserted in the cochlea, in an alternate embodiment, the generator 1404 is located entirely outside the cochlea when the tool is fully inserted in the cochlea, and a conductive path leads to a component that is located inside the cochlea when the tool is fully inserted in the cochlea that vibrates upon actuation or otherwise energize men of the generator. This can be seen in FIG. 14, where element 1404 is the generator, element 1320 is a vibratory conductive component (e.g., a piece of metal, such as a wire or a tube embedded in the tube wall 658) that conducts vibrations to the band 1305. In an exemplary embodiment of such a conductive element is disclosed in US patent application number 12/957,085, entitled "Hearing Prosthesis Having A Flexible Elongate Energy Transfer Mechanism," to inventor Peter B.J. Van Gerwen, filed on November 30, 2010.

[0089] FIGs. 15 and 16 present an alternate embodiment where the generator 1504 is located entirely outside the cochlea when the tool is fully inserted in the cochlea. Here, generator 1504 is in fluid communication with a diaphragm 1505 via conduit 1520. The generator pulses so as to variably increase and/or decrease the pressure within the conduit 1520, which corresponds to an expansion and/or contraction of diaphragm 1505. FIG. 15 depicts the diaphragm 1505 in the contracted state, and FIG. 16 depicts the diaphragm 1505 in the expanded state. As will be understood, expansion and/or contraction of the diaphragm at a sufficient frequency with a sufficient magnitude will cause waves of fluid motion within the cochlea, and thus will provide the stimulus for an ECoG measurement.

[0090] Figure 17 depicts an exemplary embodiment of the insertion tool where the generator 704 can be located such that it is in the hole in the wall 910 of the cochlea when the tool is fully inserted into the cochlea. It is noted that while the embodiment of FIG. 17 depicts the generator embedded in the wall 658, any of the other embodiments detailed herein with respect to the location of the generator can be applicable to the embodiment of FIG. 17. It is noted that while the embodiment of FIG. 17 presents the location of the generator 704, in an alternative embodiment, the location of the output component (e.g., band 1305, diaphragm 1505, etc.) alone or in combination with the generator can be located in hole in the wall 910 of the cochlea through which the tool is inserted when the tool is fully inserted into the cochlea.

[0091] Figure 18 depicts another exemplary embodiment where the generator 704 is located on the outside of the insertion guide tube on the proximal side of the stop 204. In an exemplary embodiment, a vibrationally conductive path of material different than that made up of the tube can extend from the generator 704 to a location inside the cochlea (e.g., concomitant taunts with the embodiment of FIG. 14, etc.). Still further, the embodiments of FIGs. 15 and 16 can be practiced except where the generator is located outside the insertion guide tube. Note also that while the embodiments depicted in FIGS. 14, 15, and 16 utilize a component that establishes a vibrational path from the generator to the output component that is of a different material than that of the insertion guide tube (e.g., a wire or the like made of metal, the fluid filled tube, etc.), in an alternate embodiment, the material of the insertion guide tube itself provides the medium for the vibrations to be transferred from outside the cochlea to inside the cochlea. This embodiment is depicted in FIG. 18.

[0092] It is noted that the embodiments detailed above can enable intraoperative ECoG measurements without a functioning middle-ear, such as a functioning middle ear that is utilized to relay acoustic stimulation from an in-the-ear receiver to the cochlea. In an exemplary embodiment, this can have utility with respect to recipients with middle ear infections and/or pediatric cochlear insertions or combined conductive/ sensorineural hearing loss.

[0093] In an exemplary embodiment, the generators detailed herein are configured to output stimulation no more than 50 dBs, no more than 55 dBs, no more than 60 dB, no more than 65 dB, no more than 70 dB, no more than 75 dB, no more than 80 dB, no more than 85 dBs, or no more than 90 dB, or any value or range of values therebetween in 1 dB increments (no more than 82dBs, no more than 84dBs, a range from 50 dBs to 87 dBs). In an exemplary

embodiment, the output of the generator cannot output anymore output than the aforementioned values.

[0094] In view of the above, it is to be understood that in an exemplary embodiment, there is an electrode array insertion tool, such as by way of example only and not by way of limitation, those detailed above, wherein the insertion tool comprises an assembly configured to provide direct array insertion functionality and ancillary array insertion functionality to a user thereof. The direct array insertion functionality is just that, the functionality of inserting an electrode array into the cochlea. The ancillary array insertion functionality is a functionality having utilitarian value related to the insertion of the array in the cochlea. In view of the above, an exemplary ancillary array insertion functionality of the tool enables ECOG measurement. As will be understood from the above, in an exemplary embodiment, exemplary tools include an extra-cochlea bone conduction actuator system, and the ancillary array insertion functionality is output of vibrations directly to the cochlea by the system. By "output of vibrations directly to the cochlea," it is meant that the output is provided to the wall of the cochlea separating the inner cavity from the middle ear cavity (e.g., output directly to the cochlear promontory), that the output is provided in the hole in the wall of the cochlea/passageway from the middle ear to the inner ear, and/or inside the cochlea.

[0095] Still further, in view of the above, it can be seen that in an exemplary embodiment, there is a device, comprising a cochlear implant electrode array insertion tool having a plurality of functional capabilities. While two of the functionalities detailed correspond to that of an electrode array support and providing an acoustic stimulation for an ECoG measurement, another exemplary functionality is that of an ECoG electrode. In this regard, in an exemplary embodiment, there is an electrode array insertion tool comprising an ECoG electrode. Along these lines, FIG. 7 depicts an exemplary embodiment of a cochlear electrode array insertion tool 1900. In an exemplary embodiment, the insertion tool 1900 corresponds to that of the insertion tool 200 detailed above, with the exception of the addition of electrode 1904, and the modifications to the tool so as to support the electrode and the associated components thereof (e.g., electrical leads, etc. - more on this below). Accordingly, FIG. 19 depicts a cochlear electrode array insertion tool comprising a first functionality (the array guide - the insertion guide tube (210 of fig. 2)) and a second functionality functional (an ECoG electrode – the electrode 1904).

[0096] Again, not all embodiments of the cochlear electrode array insertion tool include an intracochlear portion. In this regard, FIG. 19 depicts a tool 1900 that includes an

intracochlear portion 710. This is the portion to the right of stop 204 / the portion on the distal side of stop 204 (distal relative to the entire insertion tool). Conversely, FIG. 20 depicts a tool 2000 that does not include an intracochlear portion. Instead, stop 204 is configured to be placed against the outside of the cochlea such that the passageway through the tool through which the electrode array is passed is aligned with the pertinent window and/or cochleostomy such that no parts of the tool 2000 enters the cochlea.

[0097] Figure 21 depicts another exemplary embodiment of an insertion tool 2100, where the electrode 1904 is mounted in the intracochlear portion / on the intracochlear portion. It is briefly noted that while the embodiments depicted in the FIGs. depict the electrode 1904 as being partially embedded in the body of the insertion tool, in some alternate embodiments, the electrode can be fully embedded in the body of the insertion tool while in other embodiments, the electrode can be fully proud of the body of the insertion tool. Any arrangement of the electrode that can enable the teachings detailed herein can be utilized in at least some exemplary embodiments.

[0098] Figure 22 depicts another exemplary embodiment of an insertion tool 2200, where there is an electrode 1904 located on the stop 204, and thus representing an extra cochlear electrode when the tool 2200 is fully inserted, and an electrode 1905 located on the intracochlear portion of the tool. Thus, exemplary embodiments can include two or more electrodes that are part of the insertion tool.

[0099] Note also that while the embodiments depicted above have been described in terms of utilizing a ball electrode, in some alternate embodiments, other types of electrodes can be utilized. To this end, FIG. 23 depicts an exemplary insertion tool 2300 that includes a band electrode 2304 in the intracochlear portion of the tool (which can be slit in embodiments where the insertion tube is split, which split facilitates removal of the insertion tool after insertion of the electrode array into the cochlea. Any type of electrode that can enable the ECoG measurements can be utilized in at least some exemplary embodiments.

[00100] As will be described in much greater detail below, the electrodes 1904 and 1905 and 2304 are so-called measurement electrodes that are utilized in an ECoG system. Corollary to this is that at least some exemplary embodiments of insertion tools include so-called reference electrodes or return electrodes. To this end, FIG. 24 depicts an exemplary insertion tool 2400, which includes a measurement electrode 1904 mounted on the stop 204, and a reference electrode 2404 mounted on a flexible support 577. In an exemplary embodiment,

when the insertion tool is fully inserted into the cochlea (i.e., the stop 204 hits the outer wall of the cochlea at the cochleostomy), and positioned at the proper angular orientation (about the longitudinal axis of the tool), the reference electrode 2404 is applied against tissue of the recipient at a proper location (e.g., in the middle ear cavity) underneath the skin of the recipient owing to the fact that the anatomy of the human being is generally the same from one human being to the other. While the exemplary embodiment depicted in FIG. 24 depicts the reference electrode 2404 being located at the "bottom" of the insertion tool, the reference electrode 2404 can be located at other places. Note also that while the embodiment depicted in FIG. 24 depicts the support 577 position at about the midway portion of the tool, in other embodiments, the support 577, and thus the reference electrode 2404, can be positioned closer to the distal end or closer to the proximal end. Note also that while the embodiment depicted in FIG. 24 depicts only a single reference electrode, in an alternate embodiment, two or more reference electrodes can be utilized. Any arrangement of reference electrodes that can have utilitarian value can be utilized in at least some exemplary embodiments.

[00101] FIG. 25 depicts an alternate embodiment of an insertion tool 2500 where a support structure 577 extends from the top portion of the tool 2500 and supports a ball electrode 1904 (or some other type of electrode) away from the stop 204. In an exemplary embodiment, this can have utilitarian value with respect to positioning the ball electrode 1904 against an outside of the cochlea at a location in direct contact to the round window and/or the oval window when the insertion tool is fully inserted in the cochlea. In an alternative embodiment, this can have utilitarian value with respect positioning the ball electrode such that the ball electrode is not in direct contact with the round window and/or the oval window when the insertion tool is fully inserted into the cochlea. Such can also have utilitarian value with respect to placing the electrode 1904 against the outer wall of the cochlea at a location away from the cochleostomy.

[00102] In this exemplary embodiment, structure 577 is a flexible structure that is configured to flex so as to accommodate the fact that the insertion tool 2500 can be utilized differently in some scenarios and/or to accommodate the fact that human physiological structure can slightly vary from recipient to recipient. In an alternate embodiment, structure 577 is a structure that is configured to press the electrode 574 against the outside of the cochlea so as to hold the electrode 574 against the tissue as a result of spring forces or the like. Indeed, in an exemplary embodiment, structure 577 can be a spring.

[00103] FIG. 26 depicts another exemplary embodiment where a support structure 578 supports a spring-loaded plunger 579 that supports the electrode 1904 at the end of a spring-loaded cylinder. In this embodiment, plunger 579 is configured to accommodate the movements of the tool 2600 relative to the cochlea, such that the ball electrode 1904 is positioned against the outer wall of the cochlea prior to full insertion of the tool 2600 into the cochlea (i.e., prior to the stop 204 contacting the outside wall the cochlea). In this regard, the configuration of the plunger 579 is such that the force applied to the electrode 1904 against the tissue of the recipient is always greater than any force that would pull the electrode 574 away from the tissue resulting from the movement of the tool slightly away from the cochlea during use of the tool. Indeed, in an exemplary embodiment, there can be utilitarian value with respect to practicing ECoG measurements without the tool 2600 fully inserted into the cochlea, if only so as to provide relief to the surgeon (if the surgeon is not constantly applying a force against the cochlea, his or her hands will not be as stressed relative to that which would be the case if the surgeon had to constantly apply force against the cochlea).

[00104] Indeed, corollary to the scenario where ECoG measurements are taken in a regime where the insertion tool is not fully inserted into the cochlea, an exemplary embodiment entails taking ECoG measurements utilizing electrodes of the insertion tool where the insertion tool is completely outside the cochlea. FIG. 27 depicts an exemplary embodiment of such an insertion tool, where the tip of the insertion tool includes a reference electrode 2704. In an exemplary scenario of use, the insertion tool 2700 is completely withdrawn from the cochlea, and the tip is placed against the outer wall of the cochlea, such as on the cochlear promontory, and then ECOG measurements are taken utilizing the reference electrode 2704 as the reference electrode. FIG. 28 depicts an exemplary scenario of utilization of the embodiment of FIG. 27, where the electrode 2704 is placed against the outer wall 910 of the cochlea, subsequent to full implantation of the electrode array 2720. Is also noted that an exemplary scenario of use can be such that the insertion tool 2700 is utilized for ECoG measurements before the electrode array 2720 is inserted into the cochlea, as well as after the electrode array 2720 is inserted into the cochlea.

[00105] It is noted that embodiments of the insertion tool having the acoustic stimulation generator can be combined with embodiments of the insertion tool having the measurement electrode. To be clear, any feature of any embodiment detailed herein can be combined with any other feature of any embodiment detailed herein, unless otherwise noted. To this end, FIG. 29 depicts an exemplary insertion tool that has a plurality of functionalities beyond the

functionality of inserting the electrode array into the cochlea. In particular, as can be seen, the insertion tool 2900 includes an acoustic stimulation generator 704 and a reference electrode 1904. In this exemplary embodiment, lead 706 from the generator 704 and lead 2406 from the electrode 1904 lead to a junction box in the hand tool, and then a lead / a plurality of leads extends to a connector 2410. The connector 2410 can be connected to a ECoG system as will be described below.

[00106] Figure 30 depicts an alternate embodiment of an insertion tool 3000 where the generator 704 is located closer to the distal end. This can have utilitarian value with respect to providing vibrations to the cochlea while the insertion tool is positioned as seen in FIG. 28 in that the generator is located closely to the tip of the insertion tool. In an exemplary embodiment, a material that is conducive to vibrations can extend from the generator 704 to the tip, or to the electrode 2704. That said, in an alternate embodiment, the housing of the generator 704 can abut or otherwise be in contact with the backside of the electrode 2704. In an exemplary embodiment, the vibrations are transferred from the generator 704 directly or indirectly to the electrode 2704, and then to the wall of the cochlea 910 so as to provide stimulation for an ECoG measurement.

[00107] That said, while the embodiment depicted in FIG. 30 has the generator 704 located in the intracochlear portion, consistent with the embodiments detailed above, an exemplary embodiment, the generator 704 can be located in the portion of the tool outside the cochlea when the tool is fully inserted into the cochlea, and the tool itself or additional material conducive to establishing a path for vibrations/conducive to conducting vibrations can extend from the generator to the electrode 2704. Thus, an exemplary scenario of use entails placing the tip of the tool 3000 on the outside wall of the cochlea, such as the cochlear promontory, such as that depicted in the scenario of use of FIG. 28, and activating the generator 704 so as to provide acoustic stimulation to the cochlea, and utilizing the electrode 2704 is part of a measurement electrode of an ECoG system.

[00108] Consistent with the teachings detailed above that embodiments can include two or more generators 704 and two or more electrodes, FIG. 31 depicts an exemplary insertion tool 3100 that includes such dual components. In an exemplary scenario of use, the generator 704 mounted on the stop and the electrode 1904 can be utilized during a first ECoG measurement where the insertion tool is fully inserted into the cochlea. In another exemplary scenario of use, the generator 704 mounted on the intracochlear portion of the tool and the electrode 2704 on the tip of the tool can be utilized during a second ECoG measurement where the tool is

completely out of the cochlea. To be clear, some embodiments can utilize one generator for both scenarios, and some embodiments can utilize one electrode for both scenarios. For example, in at least some exemplary embodiments, the electrode 2704 can be utilized for both scenarios. Still further, an exemplary scenario could utilize the generator 704 mounted on the stop for both scenarios, such as in an embodiment where a sufficiently conductive path is present for vibrations to travel between the generator 704 to the electrode 2704.

[00109] While the embodiments detailed above have depicted the generator and the electrodes as static components relative to the rest of the tool (static in the sense that the overall positions thereof do not change relative to the tool / changes in the position of the tool change the positions of the electrodes and generators), FIG. 32 depicts an alternate embodiment where a stimulation generator 7704 is mounted or otherwise adjustable in a manner somewhat analogous to a switchblade. In this regard, generator 704 is mounted on a beam 3205 that is hingedly supported/connected to the tool 3200. In an exemplary scenario of use, the insertion tool 3200 is utilized to insert the electrode array in the configuration depicted in FIG. 32. In an exemplary scenario of use, ECoG measurements are taken utilizing the tool 3200 in the configuration of FIG. 32 while the tool is fully inserted into the cochlea. For example, generator 704 can be utilized in conjunction with electrode 1904. Still further, providing there is sufficient vibratory conduction between the generator 704 and the electrode 2704, tool 32 is utilized in the scenario of use detailed above with respect to FIG. 28. That said, in another exemplary scenario of use, the generator 7704 is moved by articulating the beam 3205 about the hinge so that the generator 7704 is positioned as seen in FIG. 33. In an exemplary scenario of use, the electrode 2704 is positioned against the outer wall of the cochlea, and the generator 7704 is also positioned against the outer wall of the cochlea, and ECoG measurements are taken utilizing the generator 7704 as the source of acoustic stimulation.

[00110] Thus, embodiments of the electrode array insertion tools can include embodiments where the additional functional components can be moved in and out of position on an as-needed basis.

[00111] Note that the embodiment of FIG. 32 is but exemplary. In an alternate embodiment, such as that seen in FIG. 34, the generator 7704, supported by telescoping boom 3405, telescopes out of the tool 3300 (FIG. 35 depicts the generator 7704 telescoped out of the tool).

[00112] Note that in an alternate embodiment, the boom 3405 and the generator 7704 can be fixed to the tool in a manner analogous to fixing a bayonet to a rifle. In an exemplary scenario use, the various actions detailed herein are executed, and then subsequent withdrawal of the tool from the cochlea, boom 3405 is attached to the tool, and then ECoG measurements are commenced utilizing the generator 7704. In an exemplary embodiment, a connector can be provided at the base or another location of the boom 3405 so as to place the generator 7704 into electrical communication with a lead assembly in the body of the tool so that upon connection of the boom 3405 to the tool, electrical signal can be provided to the generator 7704 so as to actuate the actuator therein so as to cause the generator 7704 to vibrate or otherwise output stimulation so that in ECoG test can be executed.

[00113] In an exemplary embodiment, utilization of the tool of FIG. 29 is such that the electrode can be positioned adjacent the round window niche / cochleostomy so as to function as a sense electrode for an extra cochlear ECoG system. To this end, FIG. 36 depicts a functional block diagram of a system 544, at least part of which can be included in the insertion tool. More specifically, FIG. 36 depicts a functional block diagram of a system 544 usable with the insertion tools detailed herein and/or variations thereof, system 544 includes a communications unit 532 that receives and/or transmits signals to communicate with a remote component, such as a data recorder. In an exemplary embodiment, the output of unit 532 is transferred to connector 2410 of FIG. 29. In an exemplary embodiment, receiver/transmitter unit 532 is configured to receive signals from a remote unit so that the system 544 can utilize those signals so that the system 544 can utilize those signals to implement the telemetric operations / the ECoG and methods detailed herein and/or variations thereof as will be described in greater detail below. The unit 532 is also configured to transmit signals to the remote unit so as to transmit the telemetric information gathered by the system 544 as will be detailed below. As can be seen from FIG. 36, communications unit 532 is in two-way communication with stimulation arrangement 704, which corresponds to any of the generators detailed herein and/or variations thereof. FIG. 36 depicts two-way communication between units 532 and 704. That said, in an alternate embodiment, there is only one-way communication between these two components. (It is noted at this time that any disclosure herein of one-way communication corresponds to an alternate disclosure of two-way communication, and vice versa providing that the art enables such, unless otherwise specifically noted.) The communication between unit 532 and unit 704 permits the stimulation arrangement 704 to output energy to evoke a hearing percept based on received

signals by the communications unit 532 to evoke a hearing percept according to the teachings detailed above.

[00114] Still with reference to FIG. 36, system 544 includes a test unit 560 that can correspond to a processor or the like configured to implement testing according to the teachings detailed herein and/or variations thereof. It is noted that while the test unit 560 is depicted as being separate from the tool 2900 (the portions inside the dashed line), in some alternate embodiments, the units are integral with one another. Any arrangement that can enable the teachings detailed herein and/or variations thereof to be practiced can be utilized in at least some exemplary embodiments. As can be seen, test unit 560 is in two-way communication with the communications unit 532 via signal line 636.

[00115] Test unit 560 is also in communication with one or more of measurement electrodes 1904 and, optionally, 1904X (and others not shown, in some embodiments) via communication with unit 532 which is in turn in signal communication with those electrodes via signal line 570, and is also in communication with one or more reference electrodes 580 via signal line 680, where reference electrode 580. (While the embodiment of FIG. 36 depicts the reference electrode as not being part of the insertion tool, in an alternate embodiment, reference electrode can be part of the insertion tool as detailed above, and, in an exemplary embodiment, signal line 680 thus can extend to unit 532 in a manner analogous to signal line 570.

[00116] It is noted that while some embodiments depict the reference electrode 580 as being separate from the implant, in an alternate embodiment, the reference electrode is part of the implant or otherwise supported by the housing that houses, for example, the receiver/stimulator unit of the cochlear implant. In this regard, in an exemplary embodiment, the inductance coil of the cochlear implant can be utilized to communicate with the reference electrode. Accordingly, in an exemplary embodiment, signal line 680 entails an inductance coil communication system located between electrode 580 and unit 560. Any placement of the return electrode 580 that can enable the teachings detailed herein and/or variations thereof can be utilized in at least some exemplary embodiments.

[00117] It is briefly noted that some embodiments according to the teachings detailed herein are practiced without any electrodes located in the cochlea. That is, all electrodes are located outside the cochlea and are thus extra cochlear electrodes. Thus, an exemplary embodiment entails executing some or all of the teachings detailed herein and/or variations thereof in a

noninvasive manner with respect to the cochlea (although embodiments will include an invasive process or device associated with the recipient in general). In an exemplary embodiment, the electrodes are arrayed or otherwise positioned so as to measure or otherwise detect signals indicative of the cochlear function.

[00118] FIG. 37 presents additional details of test unit 560. It is again noted that the teachings associated with the test unit 560 are exemplary in nature, and can be implemented in any manner that will enable the teachings detailed herein. Indeed, the teachings detailed herein are presented for purposes of compactness and ease of understanding by referring to a "test unit." It is noted that one or more or all of the functionalities detailed herein associated with the test unit can be distributed through other portions of the prosthesis. In this regard, any prosthesis that enables the functionality detailed herein can be utilized in at least some exemplary embodiments. With this in mind, an exemplary embodiment includes a measurement system having test unit 560 that includes an electrophysiology measurement (EP) device 604, such as an electrocochleography (EC) measurement device, interconnected thereto. The electrophysiology measurement device 604 is configured to measure the electrical potential(s) associated with the cochlea and/or auditory nerve in response to test signals that are generated by the test unit 560 and supplied to the stimulation arrangement 704 (either indirectly through unit 532, or, in some other embodiments, where the test unit 560 is actually a part of the tool as well, directly to stimulation arrangement 704), where a component of the system generates stimulation signals based on that output that is utilized to actuate the stimulator arrangement 704. It is noted that while the embodiments detailed herein concentrate on the electrical potential, alternate embodiments can be utilized to measure other features associated with the cochlea and/or auditory nerve. Any measurement of any physiological feature that can enable the teachings detailed herein and/or variations thereof to be practiced can be utilized in at least some exemplary embodiments. Herein, any disclosure of the measurement of electrical potentials with the sensation of electrical potentials corresponds to a disclosure of the measurement and/or sensation of any electrical phenomenon associated with electrophysiology (e.g., electrocochleography) and/or the disclosure of a measurement and/or sensation of any electrical phenomenon associated with electrophysiological signals that can enable the teachings detailed herein and/or variations thereof (e.g., measurement of higher evoked potentials (e.g., higher than ECOG)).

[00119] In an exemplary embodiment, the measured electrical potential(s) may be output as measurement signals by the electrophysiology measurement device 604 to the test unit 560

and processed/output to a user to assess various features associated with the recipient pre- and/or post-implantation of the electrode array. The electrophysiology measurement device 604 may be provided to measure or otherwise detect/sense cochlear microphonic, summating potential and/or compound action potential of the auditory nerve and the auditory nerve neurophonic in response to the noted test signals. The cochlear microphonic, summating potential is the electrical potential generated at the hair cell level in the cochlea. In some exemplary embodiments, such summating potential has a predeterminable latency range following stimulation. Further, the summating potential can have, in some exemplary embodiments, a predeterminable durational range (e.g., directly related to the test signal duration) and predeterminable absolute amplitude range. Such predeterminable ranges are employed by test unit 560 in at least some exemplary embodiments to facilitate processing of the measured potential values output by electrophysiology measurement device 604.

[00120] The action potential of the auditory nerve is an electrical response that is generated by the cochlear end of the VIII cranial nerve and is typically viewed as representing the summed response of the synchronous firing of thousands of auditory nerve fibers. That is, the size of the action potential reflects the number of nerve fibers which are firing simultaneously. In the absence of adverse pathology, the action potential can have a predeterminable latency range (e.g., about 1.30 milliseconds to 1.70 milliseconds). Its duration can also have a predeterminable range (e.g., about 0.80 milliseconds to 1.25 milliseconds), with a predeterminable absolute amplitude range (e.g., between about 0.60 millivolts and 3.00 millivolts). Such predeterminable ranges can be employed in some exemplary embodiments by test unit 560 to facilitate processing of the measured potential output from electrocochleography measurement device 604. It is noted that measurement signal values corresponding with the measured magnitude of the summating potential and/or action potential and/or a ratio thereof can be extracted and processed by the test unit 560 in at least some exemplary embodiments to assess the interface between the implantable transducer and middle ear component or inner ear of the recipient, e.g., the actuator of stimulation arrangement 550. As will be described in greater detail below, this assessment of the interface is utilized in some exemplary methods to determine whether or not adjustments to the prosthesis can have utilitarian value relative to not making adjustments to the prosthesis, etc.

[00121] In some embodiments, to enable measurement of the summating potential and/or action potential, the test unit 560 comprises one or more measurement electrodes 1904 /

1904X. To be clear, an electrocochleography measurement electrode can be positioned as part of the insertion tool at a variety of locations, thus permitting that electrode to be positioned at a variety of locations inside the recipient (as is also the case with other types of electrography measurement electrodes).

[00122] Referring again to FIG. 37, the test unit 560 can comprise a signal generator 606, a reference transmitter 608, a signal processing unit 610, a test control processor 612, and a communication unit interface 614 that communicates with the communication unit 532 via signal line 632. By way of example, the test control processor 612 may provide signals for setting signal generator 606 to output reference signals at a predetermined frequency, or plurality of frequencies across a predetermined range, or a broadband reference signal, e.g., a click. The output reference signals may be provided to the reference transmitter 608, which in turn outputs test signals to the particular stimulation arrangement 704 (either directly or indirectly) and the signal processing unit 610. The signal processing unit 610 can analyze and/or store data based on the signals so as to enable an evaluation of the performance and positioning of the hearing prosthesis and/or a physiological aspect of the recipient. In an exemplary embodiment, the unit 610 is in communication with a non-transitory computer-readable medium having recorded thereon, a computer program for executing one or more or any of the method actions detailed herein associated with the unit 610. In certain applications, it is utilitarian for the test control processor 612 to provide signals to the signal generator 606 to output reference signals that are swept across or inherently broadband to encompass a predetermined frequency range (e.g., a frequency range that encompasses a predetermined or determinable resonant frequency of an implantable stimulation arrangement 704). Any arrangement of test signals and control regimes that will enable the teachings detailed herein and/or variations thereof to be practiced can be utilized in at least some exemplary embodiments.

[00123] It is briefly noted that while the embodiment of FIG. 36 is presented in terms of the test unit 560 being separate from the tool 2900, in some other embodiments, test unit 560 is located in the tool, the test unit 560 being in signal communication with the communication unit via an electrical connector therein and/or via hard wiring between the components. That said, in other embodiments, the test unit 560 can include its own communication unit so as to enable communication with the various components utilized in the system. Note further that in some other exemplary embodiments, wireless communication between one or more of the components can be utilized. FIG. 38 depicts an exemplary embodiment where a wireless

transmitter / receiver 3810, corresponding to the communication unit 532, is in wireless communication via a wireless link with the test unit 560. Any arrangement that can enable the teachings detailed herein and/or variations thereof to be practiced can be utilized in at least some exemplary embodiments.

[00124] It is briefly noted that while the embodiments presented above have been described in terms of the utilization of the signal generator 606 generating a signal, in an alternative embodiment, a signal upon which the basis of the telemetric teachings detailed herein are implemented can be based on a sound that is captured by the sound capture device of the hearing prosthesis, whether that be located outside of the recipient in the case of a partially implantable hearing prosthesis or within the recipient in the case of a fully implantable hearing prosthesis.

[00125] As noted above, the electrophysiology measurement device 604 provides, in some exemplary embodiments, measured electrical potential values to test unit 560 and/or another device of the prosthesis. More particularly, the measured potential values are provided to the signal processing unit 610 in the exemplary embodiment presented in FIG. 37. In turn, the signal processing unit 610 can process the measured potential values in accordance with preset algorithms. For example, utilizing the stored reference signal information and stored algorithms corresponding with one or more of the above noted predeterminable ranges, the signal processing unit 610 is configured in some embodiments to selectively extract the summating potential and/or action potential from the measured potential values. Still further, the processing unit 610 is further configured to process the extracted values (e.g., average the values and/or otherwise successively compared these values to determine whether and/or when a predetermined threshold or maximum value is reached (e.g.,, thereby indicating a desired interface).

[00126] As briefly noted above, in at least some exemplary embodiments, some exemplary insertion tools can include a self-contained ECoG system. FIG. 39 depicts such an exemplary embodiment of an insertion tool 3900. Insertion tool 3900 contains a complete ECoG system. As can be seen, the insertion tool 3900 further includes a reference electrode 2404, which is in signal communication with the electrical leads of the system via lead 2416. Lead 39061 extends from the connector to test unit 3960, which can correspond to test unit 560 detailed above. Test unit 3960 is in signal communication with communication unit 3810 via lead 39062. Communications unit 3810 can be in wireless communications with remote device 3960. In an exemplary embodiment, the remote device 3960 is a data storage

device/data recording device that records the data transmitted via the communications unit 3810. For example, 3960 can be a desktop and/or a laptop computer having memory therein to record the data. In an alternate embodiment, device 3960 can be a control unit or the like, again such as a computer, that can control the ECoG system of the tool 3900. That said, in an exemplary embodiment, the tool 3900 includes an activation switch or the like so that the ECOG system can be activated and/or deactivated by the surgeon or other healthcare professional.

[00127] Figure 40 depicts an exemplary schematic of the ECOG system 4044 of the tool 3900, or system 4044 is entirely integrated into the tool 3900 (e.g., the communication unit 532 and the test unit 3960 are integrated into the handle of the tool (either in or on the handle)) and the electrodes and the generator are supported by the tool in accordance with the teachings detailed herein and/or variations thereof. As can be seen, test unit 3960 is in signal communication with communication unit 532 via signal line 636. Through communication unit 532, the test unit 3960 can indirectly communicate with the generator 704 and the electrodes 1904 and 1904X. That said, alternatively and/or in addition to this, test unit 3960 can be in communication with the electrodes via signal line 570A and with the generator via signal line 636A. Further, the reference electrode 580 can be in communication with the communication unit 632 instead of and/or in addition to direct communication with the test unit 3960. Note also that in an exemplary embodiment, the reference electrode 580 can be a remote unit that is not part of the insertion tool. Any arrangement that can enable the teachings detailed herein can be utilized in at least some exemplary embodiments.

[00128] FIG. 41 depicts another exemplary embodiment of an insertion tool that has a functionality beyond that of an electrode array support / an electrode array insertion device. Particularly, the embodiment of FIG. 41 depicts a portion of the insertion guide tube at the stop 202 where a sensor 4101 is located in the wall 658 of the tube, although in other embodiments, the sensor 4101 is located on the inside wall of the tube and in other embodiments, the sensor 4101 is located on the outside wall of the tube. In this exemplary embodiment, the sensor is configured to sense or otherwise detect individual electrodes in the array as they pass by the sensor as the electrode array is inserted through the lumen 640 into the cochlea, and output a signal via lead 1410 indicative of at least one of an electrode passing the sensor 4101 or, in a more sophisticated embodiment, the speed of the electrode / electrode array passing by sensor 4101. In an exemplary embodiment, the sensor 4101 can be a sensor that utilizes capacitive sensing. In an exemplary embodiment, it could be a Hall

effect sensor. In some embodiments, the sensor could be a sensor that comes into direct contact with the electrodes of the electrode array. In an exemplary embodiment, there is a system that receives the signal from lead 1410 and outputs data indicative of the insertion speed of the electrode. In an exemplary embodiment, the system can be a personal computer with an algorithm that analyzes the signal 4110, and outputs data to the surgeon. Exemplary output can be output by a speaker or the like indicating the speed of the insertion of the electrode array. Exemplary output can be output by a visual device indicating the speed of insertion of the electrode array. Exemplary output can correspond to the speed of insertion, a go/no go data package (e.g., insertion too fast / insertion speed fine). Such can be done via audio and/or visual devices. For example, a green light can indicate acceptable speed and a red light can indicate an unacceptable speed. Moreover, the system can be binary. The activation of the light will indicate that the speed is too fast / the audio indication (which could be a buzzer or a tone, etc.) activates when the insertion speed is too fast. The alternative could also be the case. The tone and/or light can be activated while the insertion speed is acceptable, and the tone or light is deactivated when the insertion speed is unacceptable.

[00129] Figure 42 depicts an alternate embodiment, wherein the sensor 4201 is a visual sensor. For example, optics 4202 view the inside of the insertion guide tube 610 / view the lumen. Indicia on the array, such as markings provided especially for this purpose, or, in an alternative embodiment, the electrodes themselves, can be counted or otherwise detected via the sensor 4201 and thus the speed determined or otherwise deduced. In an exemplary embodiment, the sensor 4201 is a photosensor. In an exemplary embodiment, the sensor is a CCD. Any arrangement that can be utilized to visually sense the passage of the array can be utilized in at least some exemplary embodiments.

[00130] In an alternate embodiment, sensor 4201 utilizes a sound or a radio wave or the like to detect the passage of the array and deduce the speed thereof. In an exemplary embodiment, a Doppler shift or the like can be utilized. Thus, in an exemplary embodiment, sensor 4201 can generate a sound wave and/or a radio wave, and receive the soundwave and/or radio wave. Thus, the sensor can be akin to a sonar sensor and/or a radar sensor.

[00131] In an exemplary embodiment, lead 4110 is connected to a processor that can determine the speed and/or can utilize the information from sensor 4201 or 4101 or any other sensor to determine the insertion depth of the electrode array. In an exemplary embodiment, the processor can be part of the tool. Indeed, concomitant taunts with the teachings detailed

above with respect to the integrated ECoG system, the tool can include a processor or other device that receives the input from the lead 4110 and analyzes that input to output data to the user. Thus, in an exemplary embodiment, the tool can have an output device (e.g., a light (LED, etc.), located on the stop as seen in FIG. 43) that provides the user with data. A plurality of output devices can be utilized (e.g., two lights, one red/ one green, although it is noted that in some alternate embodiments, an LED that can change colors is utilized). In this regard, FIG. 43 depicts an exemplary insertion tool that includes a light 4120. The light is in signal communication with a processor (not shown) via lead 4210. In an exemplary embodiment, the sensor 4201 provides a signal to the processor via lead 4110, and that processor analyzes the signal, and provides output via lead 42102 activate light 4130 to indicate information regarding the insertion speed and/or the distance. In an exemplary embodiment, an array of lights is arrayed about the outer periphery of the stop. In an exemplary embodiment, these lights are variously activated and/or deactivated to indicate the speed and/or the location of the array in an analog and/or a digital manner. Note also that while the embodiment presented in FIG. 43 relies on a remote processor remote from the sensor 4102, in an alternate embodiment, the sensor can include processing capabilities and/or can be such that it can output a signal directly to the lights 4130 and/or a plurality of lights and/or other output devices (speakers – the output could be clicks like a Geiger counter or some other sound that indicates distance and/or speed, etc.). Indeed, in an exemplary embodiment, the remote processor is not needed.

[00132] In an exemplary embodiment, the sensors utilized to monitor the speed and/or location of the array within the lumen 640 utilize or otherwise implement capacitive coupling between the electrodes and the array and the sensor.

[00133] While the embodiments depicted in FIGS. 41 and 42 depict a single sensor, in alternate embodiments, a plurality of sensors are utilized. Indeed, the sensors can be arrayed such that the sensors are located "out of phase" with respect to each other and the electrodes of the array such that the sensors can be "tripped" more frequently than that which would be the case utilizing one sensor or a sensor having spacing the same as or greater than the distance between electrodes. This can have utilitarian value with respect to not having to wait for feedback from only one sensor to determine the speed and/or location of the array. For example, in an insertion tool having a plurality of sensors located out of phase with each other relative to the electrode spacing, an electrode or other indicia on the array can pass the first sensor, and then pass a second sensor, and/or a third sensor, and/or a fourth sensor, etc.

prior to another electrode passing the first sensor. Thus, this provides additional data points to deduce the speed and/or location of the array. Note also that while the embodiments depicted in the FIGs. depict the sensor located at the top of the insertion guide tube, in an alternate embodiment, the sensors can be located on the bottom. Such can have utilitarian value in embodiments where the electrodes are located on the bottom of the array as opposed to on the top of the array.

[00134] Note also that while the sensors are depicted as being proximate the stop, in alternative embodiments, the sensors can be located elsewhere. Indeed, in an exemplary embodiment, the sensor can be located at the tip or proximate to the tip of the insertion tool. In this regard, the sensor can provide an indication to the surgeon or the like when the array first leaves the tube. Again, sensors can be arrayed at a number of locations. Any arrangement of sensors that can enable the teachings detailed herein can be utilized in at least some exemplary embodiments.

[00135] It is noted that at least some embodiments that utilize the electrode or other devices to measure or otherwise monitor insertion speed and/or insertion depth do so without measurements of the impedance of individual electrodes as the array is inserted into the conductive perilymph. That is, in an exemplary embodiment, the insertion tool is configured so as to monitor insertion speed and/or insertion depth without the presence of perilymph between the sensor of the tool (e.g., electrode) and the electrode array. However, in some alternate embodiments, measurement of either voltage induced in the Paralympic due to stimulation current being passed from one intro cochlear electrode contact to another, with the impedance and passing current from a stimulating contact on the array to a return contact on the sheath, could be used to infer the proximity of a contact passing through the sheath, and thus can be utilized to monitor insertion speed and/or insertion depth based on the inference the proximity of the contact.

[00136] FIG. 44 depicts a portion of an exemplary insertion tool that is configured to enable testing for an open circuit between two or more electrodes of the electrode array as the array passes through the lumen 640. Briefly, component 4401 is made of a conductive material that essentially "shorts" two electrodes of the electrode array as they pass by in contact with the component 4401. As will be detailed below, component 4401 can be a flexible component so as to provide a compressive force on the outside of the electrode array so as to establish sufficient electrical conductivity between an electrode, component 4401, and another electrode. In general terms, FIG. 45 depicts a quasi-functional diagram of a portion

of electrode array 145, depicting electrodes 1, 2, and 3, which are respectively connected to leads 11, 12, and 13, which leads extend from the respective electrodes to the proximal end of the electrode array assembly, and then to a receiver/stimulator thereof. While only three electrodes and three leads are depicted in FIG. 45, it is to be understood that in at least some embodiments, more electrodes and more leads are present in electrode array 145. Only three electrodes and only three leads are depicted in FIG. 45 for clarity.

[00137] In isolation, without any contact with any outer material other than air, to test for a short, a source of current is applied to any one of the leads 11, 12, or 13. If current is detected (this phenomenon is described generally - in at least some exemplary embodiments, the "detection" corresponds to a given functionality of the receiver/stimulator that can be telemetrically transmitted and analyzed – more on this below) at any one of the other leads 11, 12, and/or 13, a determination can be made that a short exists. This is because the impedance between the electrodes 11, 12, and 13 should be relatively high (the material connecting the electrodes 148 is typically made of silicone). The leads 11, 12, and 13 are insulated from one another and from the electrodes other than the respective electrodes associated with the respective leads.

[00138] Conversely, to detect for an open, in the absence of contact with any other material other than air, because of the high impedance between the respective electrodes, and the aforementioned electrical insulation, there is nothing to close the circuit between a source of electrical current applied to one lead, and a detector (again, this is used generally – more on this below) located at any of the other leads.

[00139] Accordingly, in an exemplary embodiment, the apparatus 4401 is configured to enable testing for an open circuit between two electrodes by utilizing conductive material that is sufficiently conductive to test for an open circuit when placed into contact with two or more electrodes of the electrode array 144. In use, component 4401 extends a sufficient distance into the lumen 640 and has sufficient length such that it can contact two electrodes as the electrode array passes by component 4401. In an exemplary embodiment, the entire component 4401 is made of a requisite conductive material. In an exemplary embodiment, only a portion thereof is made of the requisite conductive material. By way of example only and not by way of limitation, at least the bottom surface (the surface that faces the electrodes / the surface that comes into contact with the electrodes) can be made of the requisite conductive material, or at least coated with the requisite material or otherwise the requisite material is attached to the interior thereof. In an exemplary embodiment, only a portion of

the component 4401 is made of the requisite conductive material. Any arrangement that can enable the testing of an open circuit while electrode array assembly is being passed can be utilized in at least some embodiments.

[00140] In an exemplary embodiment, the material of the component 4401 and/or other material forming a portion of the component 4401 and/or any other material that enables testing for an open circuit has a "midrange" impedance, or at least enables the establishment of a midrange impedance between two or more electrodes, such that both testing for an open circuit and testing for a short circuit can be implemented. In other exemplary embodiments, the component 4401 has a relatively high range impedance.

[00141] In an exemplary embodiment, the component 4401 is configured to provide a controlled impedance between two or more electrodes that will enable at least testing for an open circuit between two electrodes, if not both testing for an open circuit and testing for a short circuit between two electrodes.

[00142] Thus, in an exemplary embodiment, the component 4401 is configured to enable two types of conductivity testing of the electrode array (e.g., testing for an open circuit and testing for a short circuit) in some embodiments.

[00143] FIG. 46 depicts an exemplary conductive apparatus 4622 in the form of an elongate cylinder having a passage 4624 therethrough, wherein the passage 4624 is sized and dimensioned to receive the electrode array 145 therein such that at least two electrodes of the electrode array 145 contact the interior walls of the passage 4624 to establish electrical conductivity between the electrodes. In an exemplary embodiment, the conductive apparatus 4622 is configured such that an impedance between any two locations on the interior surface of the passage 4624 within a distance corresponding to the distance between two electrodes of the electrode array 145 that will be inserted or otherwise located within passage 4624 is less than about 500 ohms (or any other value that will enable testing for an open circuit between two electrodes – more on this below). In this regard, it is noted that all disclosures of impedance and related phenomenon detailed herein both correspond to the structure being described, and how the structure is arranged or otherwise used. That is, because impedance varies both with respect to distance and with respect to material type (along with some other features) and it is the resulting impedance that imparts utilitarian value on to the teachings detailed herein, as opposed to the specific impedance of a given material or the like, any disclosure herein regarding material properties also corresponds to the functionality of the

resulting apparatuses when utilized according to the teachings detailed herein and/or variations thereof.

[00144] FIG. 48A depicts the conductive apparatus 4622 located in the insertion guide tube 610 of the insertion tool. In an exemplary embodiment, the interior of the conductive apparatus at the ends thereof is rounded so as to provide a smooth interface between the interior wall of the tube wall 658 and the "bump up" that is the interior of conductive apparatus 4622. That is, because the interior of conductive apparatus 4622 is proud of the interior wall of the tube wall 658, ramping can be used so as to avoid binding or otherwise catching the electrode array one the edges of the conductive apparatus 4622.

[00145] Briefly, the embodiments utilizing apparatus 4622 and variations thereof to "short" two electrodes rely on, in some embodiments, the ability of the receiver/stimulator of the cochlear implant to provide an electrical signal to one of the electrodes and sense a voltage and/or current at the other of the electrodes. In an exemplary embodiment, a device is in inductance communication (or any other applicable communication format that will enable the teachings detailed herein and/or variations thereof to be practiced) with the receiver/stimulator of the cochlear implant so as to communicate data therefrom indicating whether or not an open circuit is present. Indeed, in an exemplary embodiment, the device that is in inductance communication with the receiver/stimulator is the device that initiates the current to one of the electrodes and the first instance. In an exemplary embodiment, the communication can correspond to the communication that transcutaneously takes place between the external component 142 and the implantable component 144 vis-à-vis the system of FIG. 1. That is, in an exemplary embodiment, the communication from the receiver/stimulator and/or to the receiver/stimulator can be executed utilizing techniques that are the same as, or at least analogous to, the transcutaneous communication that takes place while the cochlear implant 100 is implanted in a recipient fully and completely beneath the skin.

[00146] FIG. 47 depicts a view looking down the longitudinal axis of the conductive apparatus 4622 (i.e., looking from the left or the right with respect to the frame of reference of FIG. 46). It is noted that the geometric shapes presented in these FIGs. are but exemplary. Any configuration that will enable the teachings detailed herein and/or variations thereof to be practiced can be utilized.

[00147] It is further noted that while the embodiment depicted in FIG. 46 and FIG. 47 is depicted as a monolithic component (in an exemplary embodiment, the entire body 4622 is made from a conductive material, and thus conductive apparatus 4622 is a tube or cylinder of conductive material), in an alternative embodiment, the conductive apparatus 4622 can be a multilithic component. Indeed, in an exemplary embodiment, the walls of the passageway 4624 can be coated with a conductive material (e.g., gold), and the remainder of the conductive apparatus 4622 is made of a relatively nonconductive material (e.g., rubber, silicone, etc.). In this regard, for embodiments where the conductor used to test for the open circuit is movable in and out of position, the impedance range of the conductor can be very low.

[00148] It is noted that in an exemplary embodiment, the entire body 4622 and/or a portion thereof (e.g., the portion making up the walls of the passageway 4624) is a conductive foam or conductive polymer. Typically, this is foam or polymer containing conductive elements (e.g., loaded with silver, gold, carbon, etc.). This can have utilitarian value with respect to deforming around the electrode array as the electrode array passes through body 4622. Accordingly, such can have utilitarian value with respect to contracting as the localized width of the electrode array relative to body 4622 becomes wider as the electrode array is passed therethrough during insertion of the electrode array. In an alternative embodiment, electrically conductive silicone pad(s) are located on the inside of the sheath that make contact with the electrodes on the array and operate in a similar / the same manner as the conductive foam. In an exemplary embodiment, biocompatible silicone is used.

[00149] FIG. 48A depicts the view of FIG. 47, with the addition of the electrode array 145 being located in the passage 4624 (the array is shown in cross-section). More particularly, the view of FIG. 48 depicts a cross-sectional view of an electrode array 145 taken at a location where electrode 1 is located. FIG. 49 presents FIG. 48A in greater context, which depicts a side view of a cross-section through the conductive apparatus 4622 with the electrode array 145 located therein.

[00150] As can be seen, the electrodes are in contact with the inner surface of the passageway 4624. In this embodiment, the contact is sufficient to provide electrical conductivity from electrode 1 to electrode 2 and/or electrode 3 such that testing for an open circuit between one of these electrodes can be implemented. Corollary to this is that the conductive apparatus 4622 is configured to maintain the requisite contact to enable testing for an open circuit between two or more of the electrodes and/or be placed and held in that configuration for

such testing to be executed. In an exemplary embodiment, conductive apparatus 4622 is made of a conductive foam material, wherein an interference fit is established between the electrode array 145, and thus the electrodes 148, and the inner surface of the passage 4624. In an exemplary embodiment, the interference fit ensures that sufficient contact will be made between the inner surface of the passage 4624 and the respective surfaces of the electrodes 148. In an exemplary embodiment, the use of foam ensures or otherwise substantially lessens the chance that the array 145 will be damaged due to contact between the array and the conductive apparatus 4622. This will be described in greater detail below.

[00151] FIG. 50A presents a functional representation of the functionality of the conductive apparatus 622, where hypothetical leads 1010 and 1020 are located between electrodes 1 and 2 and between electrodes 1 and 3, respectively. Also shown is hypothetical lead 1030, which is located between electrodes 2 and 3. These leads place the various electrodes into electrical conductivity with one another so that testing for an open circuit can be executed. Also depicted by way of black box format is a current generator/detector 1040, which is configured to apply current to one or more of the leads 11, 12, 13, and detect a current (if there is no open circuit) at one or more of the other of leads 11, 12, 13. The current generator/detector 1040 is but a functional representation of the operation of the receiver/stimulator 180 and/or a test device. That said, in some alternate embodiments, current generator/detector 1040 can be an ohmmeter and/or a multimeter, albeit one adapted for the types of voltage and current suitable for testing of a cochlear electrode array or other array to which the teachings detailed herein are applicable.

[00152] Briefly, in an exemplary embodiment, a current is applied by current generator/detector 1040 to lead 12. Current generator/detector 1040 "looks" for a current at either or both of leads 11 and 13. (In an exemplary embodiment, the insertion tool includes a generator configured to generate current at a programmed amount through lead 12 and return it through one or all of the remaining electrodes. In an exemplary embodiment, the tool provides an output indicative of voltage required to drive this amount of current. In an exemplary embodiment, if the voltage is above a certain threshold, it is deemed an open circuit. Otherwise, it is assumed the current is flowing and thus this circuit is closed.) Because the conductive apparatus 622 has placed electrode 2 into electrical conductivity with electrodes 1 and 3 via hypothetical leads 1010 and 1030, a current should register at one or both of leads 11 and 13 (or only one of the leads if only one of the hypothetical leads 1010

and 1030 or present) thus indicating that there is no open circuit between current generator detector 1040 and electrode 2.

[00153] Note that by "looking" for a current at two or more leads, the scenario where an open circuit exists with respect to one of the other leads, which open circuit could give a "false-negative" with respect to the lead under test can be accounted for in an exemplary embodiment. For example, if lead 12 is being tested (or, more precisely, testing for an open circuit is being performed between current generator/detector 1040 and electrode 2), and if only one lead, such as lead 11, was being utilized for the test, failure to detect a current by current generator/detector 1040 at lead 11 would not necessarily indicate a break for an open circuit associated with lead 12. This is because lead 11 could have failed. However, if a current is detected at lead 13 but not lead 11, it can be surmised that lead 12 is in proper working order, and lead 11 has experienced a failure mode. That is, it can be extrapolated or otherwise inferred that lead 11 has failed in some manner (i.e., the open circuit is between current generator/detector 1040 and electrode 1). In this regard, exemplary embodiments include algorithms to more quickly test a plurality of circuits in view of the fact that deductive logic can be utilized when more than two electrodes are placed into electrical conductivity with one another via conductive apparatus 622.

[00154] Note further that to test for a short circuit, the hypothetical leads are removed from the electrodes (e.g., the electrode array is moved away from conductive apparatus 4622). A current is applied to one or more of the leads, and current is looked for at one or more of the other leads. No current (or only specific current – more on this below) should be detected because the hypothetical leads have been removed.

[00155] FIG. 50B presents a hypothetical open circuit scenario, where lead 12 has experienced a break at the location indicated by the "X." In an exemplary method, a current is applied by current generator/detector 1040 to lead 12. Current generator/detector 1040 "looks" for a current at either or both of leads 11 and 13. Because the conductive apparatus 4622 has placed electrode 2 into electrical conductivity with electrodes 1 and 3 via hypothetical leads 1010 and 1030, a current will not register at either of leads 11 and 13 (or only one of the leads if only one of the hypothetical leads 1010 and 1030 or present) thus indicating that there is an open circuit, most likely between current generator detector 1040 and electrode 2.

[00156] Note that by "looking" for a current at two or more leads, it can be immediately deduced that there is a fault between current generator/detector 1040 and electrode 2 (or a

simultaneous fault in electrodes 1 and 3, which can be addressed by running the test by applying current at lead 11 and/or lead 13 and looking at lead 12).

[00157] In an exemplary embodiment, a common ground impedance (voltage required to drive a current between a chosen electrode and all the other electrodes shorted together) is measured for each electrode in turn many times a second (1, 2, 3 . . . 22, 1, 2, 3 . . . 22, 1, 2, 3 . . . 22, etc.). In this way, whatever electrodes are in contact with the contacts in the sheath, such will show up as low impedance. As the electrode array advances through the sheath, the low impedance point will travel down the array from electrode 22 to electrode 1. An open circuit will be evident as the electrodes that never go to low impedance.

[00158] Note further that in at least some exemplary methods, the methods are not executed to detect which lead or which connection is open or otherwise has experienced a failure mode. A determination that there is some failure anywhere will typically be utilitarian in that a determination can be made in view of the single failure detection that the cochlear implant 100 should not be implanted in the recipient at that time. In an exemplary embodiment, a new cochlear implant 100, such as a cochlear implant 100, will be obtained, and a new round of testing for an open circuit will be executed. Such is also the case with respect to detecting which particular electrodes are associated with a short circuit.

[00159] Note that by way of example only and not by way of limitation, in an exemplary embodiment, a failure mode can correspond to a break in a lead and/or a disconnect between a lead and an electrode, which failure mode can typically result in an open circuit. In an exemplary embodiment, this can occur during shipping of the cochlear implant.

[00160] It is further noted that in an exemplary embodiment, instead of a solid or contiguous conductive component that contacts the various electrodes, separate contacts 2262 supported by conductive body that extends between the contacts can be configured to be compressible, at least with respect to the portions on the tip, as can be seen in FIGs. 51A and 51B. In an exemplary embodiment, element 4622 is replaced by conductive apparatus 2223. Alternatively, and/or in addition to this, the contacts 2262 can be supported on a flexible material that flexes to provide space. The contact can also be spring loaded in another exemplary embodiment (more on this below). FIG. 51C depicts another exemplary embodiment of a conductive apparatus 2224 that can be utilized in place of element 4622. Also, in this exemplary embodiment, the conductors 2262 can be located only at the top of

the conductive apparatus 2223, instead of all the way around, as is the case with the embodiment of FIG. 50C.

[00161] It is further noted that variations of the concepts depicted herein can be implemented to enable the teachings detailed herein. Instead of utilizing triangular contacts as seen, square contacts can be utilized. Still further, undulating contact surfaces can be utilized such that the crests of each undulation are in phase with the respective electrodes (e.g., aligned with the centers of the electrodes) of the electrode array. FIG. 50C depicts an exemplary embodiment of a conductive apparatus 2224 utilizing a "wavy" contact surface, where contact apparatus 2264 can be seen to have crests that are in phase with the electrodes of the electrode array 145.

[00162] In an exemplary embodiment, any of the teachings of US Patent Application Number 15/164,789, filed on May 26, 2016, to Inventor Grahame Walling, for testing for an open circuit can be incorporated into an insertion tool with the requisite modifications to enable open circuit testing.

[00163] While the embodiments detailed above have been directed towards a device that shorts two electrodes, an alternate embodiment utilizes an electrode in the insertion tool to establish a capacitive coupling with the electrodes of the electrode array as the electrodes of the electrode array pass by the electrode of the insertion tool. FIG. 52 depicts an alternate embodiment of an electrode array insertion tube having another functionality beyond that associated with supporting and/or guiding the electrode array into the cochlea. In this regard, element 5201 is an electrode that is utilized as part of an open circuit testing system. Here, electrode 5201 can establish a capacitive coupling between the electrodes in the array and the insertion tool in general, and the electrode 5201 in particular.

[00164] As can be seen, electrode 5201 is connected to a lead 5210. In an exemplary embodiment, this lead energizes the electrode with an electrical current. In an alternate embodiment, this lead provides a return path in a scenario where the electrodes of the electrode array are energized. FIG. 53 depicts an exemplary embodiment of an insertion tool 5300 having the electrode 5301 to establish the capacitive coupling with the electrodes of the electrode array. Here, electrode 5301 is located to the left (proximally) of the stop 202. FIG. 53 depicts a cutout view of the tube of the insertion tool showing electrode 5301 extending into the lumen. Lead 5210 can be seen extending from electrode 5301 to a coupling, to which is connected a lead 53061, which in turn extends to test unit 5360. Test unit 5360 is

configured to energize the electrode 5301 in at least some exemplary embodiments. In some alternate embodiments, test unit 5360 is configured to receive current from electrode 5301 in the case where the electrodes of the array are energized. At a minimum, test unit 5360 can be a voltage/energy source, such as an assembly having circuitry to provide a controlled current at a control voltage to electrode 5301. In an exemplary embodiment, test unit 5360 includes a battery to provide the source of the current. In an alternate embodiment, test unit 5360 is an assembly having circuitry configured to receive an electrical current from lead 53061 and analyze the current or at least determine whether a current is present. Indeed, in an exemplary embodiment, in view of the binary nature of an open circuit, unit 5360 can be a simple circuit that energizes an indicator upon the absence of a received current. By way of example, test unit 5360 can include a transistor or the like or some form of relay that is activated and/or deactivated upon the reception of a current through lead 53061. The activation and/or deactivation of this transistor or the relay activates an indicator, such as an LED, or disables the indicator (e.g., turns off the LED) indicating an open circuit. In an exemplary scenario, upon failure of current from lead 53061 reaching test unit 5360, a relay is closed and a circuit is accordingly closed to illuminate an LED, providing an indication to the surgeon that an open circuit is present in the electrode array. In an exemplary embodiment, this can be combined with the teachings detailed herein regarding the utilization of the insertion tool to provide an indication or otherwise determine the position of the electrode array and/or the speed of insertion. For example, such teachings can be correlated to the embodiment to test for the open circuit, so that an indication to the surgeon of an open circuit is not provided simply because electrode 5301 is not in capacitive coupling with an electrode of the electrode array, because the electrode 5301 is in between electrodes of the electrode array. Still further, in an exemplary embodiment, the system of FIG. 53 can be combined with or otherwise used in conjunction with devices that can indicate whether or not an electrode of the electrode array is proximate the electrode 5301 or otherwise at a location where capacitive coupling between the electrode can be established. The system of FIG. 53 is configured so as to only provide an indication of an open circuit when a determination has been made that the electrode of the electrode array is proximate the electrode 5301 or otherwise at a location where capacitive coupling between the electrode can be established.

[00165] The embodiment seen in FIG. 53 includes communication unit 3810 in signal communication with the test unit 5360 via lead 39062. In an exemplary embodiment, communication unit 3810 can be the communication unit detailed above. As can be seen,

communication unit 3810 can be in wireless communication with a remote device 5360. That said, in some alternate embodiments, this communication can be wired. In an exemplary embodiment, the remote device 5360 can be a laptop and/or a desktop computer that is also in signal communication with the receiver/stimulator of the cochlear implant. In an embodiment where test unit 5360 outputs a current to electrode 5301, the receiver/stimulator of the cochlear implant can detect this current via the electrodes (providing there is no open circuit – if there is, no detection will occur, thus indicating the open circuit) of the electrode array, and communicate such to device 5360, whereby device 5360 can provide an indication that there is a reason not an open circuit. Indeed, it is noted that in such an exemplary embodiment, the insertion tool 5300, in some embodiments, need not be in signal communication with remote device 5360. In this regard, it is sufficient that test unit 5360 simply provide a controlled current to the electrode 5301. FIG. 54 provides such an exemplary embodiment of an insertion tool 5400, where test unit 5460 is a current generator apparatus, such as an apparatus that includes a battery with or without circuitry to provide a controlled output current to electrode 5301. In this embodiment, providing that the receiver/stimulator of the cochlear implant is in telemetric communication via the inductance coil with a component that can indicate whether or not the electrodes of the electrode array have received a current, a remote device in signal communication with the receiver/stimulator can provide the indication to the surgeon of an open circuit. That is, the tool 5400 simply provides the electrical signal for testing of the open circuit.

[00166] That said, in an alternate embodiment where electrode 5301 receives or otherwise detects current/voltage (such as would be the case if there is no open circuit and the given electrodes of the electrode array are energized at least as they pass electrode 5301), the test unit 5460 can analyze the received signal (which can be a binary analysis that the signal is present or is not present) and provide an indication to the user that an open circuit exists and/or that no open circuit exists, or at least provide an indication to the user of the required voltage to push the current or some other indicia that will indicate the presence of an open circuit. In an exemplary embodiment, an LED or the like can be mounted on the tool at a location visible to the surgeon while inserting the electrode array. The LED can be activated (it can be a red LED, for example) to indicate an open circuit. As will be understood, this embodiment can also be practiced without being in communication with another component, such as the computer 5360. Still, in some alternate embodiments, there can be utilitarian value with respect to communicating to another device that could have additional logic

circuitry so as to perform a more sophisticated analysis or so as to provide a better indication or more informative indication.

[00167] Embodiments include an insertion tool by itself or an insertion tool that is used in conjunction with other components that can provide an indication to the surgeon or other healthcare professional that an open circuit is present. Any type of indication that can be provided to the surgeon or healthcare professional that will indicate the presence of an open circuit can be utilized in at least some exemplary embodiments.

[00168] It is briefly noted that while the embodiments depicted herein utilize one electrode located at the top of the tube for open circuit testing, in other embodiments, a plurality of electrodes can be utilized. Still further, while the embodiments depicted in the FIGs. depict a box electrode for open circuit testing, alternate embodiments can utilize other types of electrodes, such as by way of example, ball electrodes. Indeed, in an exemplary embodiment, the electrode is a band electrode that extends completely about the axis of the lumen 360°. Any number of electrodes at any spacing and any configuration that can enable open circuit testing can be utilized in at least some exemplary embodiments.

[00169] It is briefly noted that in an exemplary embodiment, the electrode 5301 utilized to test for open circuit can also be utilized as the insertion speed and/or insertion depth measurement electrode detailed above and vis-a-versa. This is also the case in embodiments where a plurality of electrodes are utilized to test for an open circuit.

[00170] In view of the above, it can be seen that in an exemplary embodiment, there is an insertion tool for an electrode array that includes an active functional component, wherein the active functional component enables the measurement of the insertion speed and/or insertion depth of the electrode array. In an exemplary embodiment, the active functional component is an electrode of an open circuit monitor configured to establish a capacitive coupling between the electrodes of the electrode array in the electrode of the insertion tool. In an exemplary embodiment, the active functional component of the electrode array insertion tool enables at least one of array insertion speed monitoring or array insertion depth monitoring. Note that this is distinguished from utilizing indicia on the insertion tool in a passive manner to determine speed and/or insertion depth.

[00171] Note also that with respect to the embodiments where the tool includes lights and/or speakers and/or other data conveyance devices (e.g., a vibrator that vibrates in the user's hand to provide indication of a phenomenon associated with the electrode array, etc.), the active

functional component can be thus an indicator to a user of the insertion tool of a phenomenon associated with insertion of the array. As detailed above, such phenomena can include insertion speed and/or insertion depth. As will be described in greater detail below, such phenomena can also include array orientation, etc. in an exemplary embodiment, any phenomenon associated with the insertion of the electrode array can be used as a basis to provide an indicator to the user of such phenomenon.

[00172] In view of the above, it can be seen that the tool can have a first functionality corresponding to an electrode array support, and a second functionality corresponding to an electrode array open circuit protection functionality for detecting an open circuit in the electrode array.

[00173] Figure 55 depicts an alternate embodiment of a portion of an electrode array insertion tool. As can be seen, a fluidic passage 5510 is located in the wall 658 of the insertion guide tube 610. A plurality of passageways 5512 extend downward from the fluidic passage 55102 orifices 5514 that open into the lumen 640. In an exemplary embodiment, the fluidic passage 5510 is utilized to conduct fluids from outside the cochlea into the lumen 640. In an exemplary embodiment, these fluids can be drugs that have utilitarian value vis-à-vis insertion into the cochlea. In an exemplary embodiment, the electrode array insertion tool is configured to connect to a reservoir of such drug(s), which can be provided to the fluidic passage 5510 under pressure, so as to be "injected" or otherwise transferred into the lumen 640. In an exemplary embodiment, the drugs are injected or otherwise transferred into the lumen 640 as the electrode array is being inserted. In an exemplary embodiment, this can coat at least a portion of the electrode array, and the drugs are transferred into the cochlea as the electrode array moves into the cochlea out of the insertion tool.

[00174] Note also that in an exemplary embodiment, a back pressure can be established in the lumen 640 so as to "push" the fluid injected or otherwise transferred into lumen 640 out of the end of the insertion sheath so that the drugs can be delivered to the cochlea irrespective of whether or not the drugs become coated onto the electrode array.

[00175] In an exemplary embodiment, the drugs perform a lubrication function between the electrode array and the interior walls of the tube wall 658. In an exemplary embodiment, the drugs are anti-inflammatory drugs, and these anti-inflammatory drugs exhibit lubrication properties that can be utilized to implement the embodiment of FIG. 55.

[00176] Thus, it is to be understood that in an exemplary embodiment, there is a device, such as the tool of FIG. 55, that provides a functionality of an electrode array guide, and drug delivery functionality in a manner that lubricates the insertion tool with respect to the array.

[00177] Figure 56 depicts an alternate embodiment of an insertion tool having drug delivery functionality. As can be seen, fluidic passage 5510 also has passageways 5512 and outlet ports 5514 to the outside of the insertion guide tube 610. In an exemplary embodiment, this can enable the injection or otherwise transfer of the fluid in passageway 5510 into the cochlea in directions normal to the longitudinal axis of the insertion tool. It is noted that in alternate embodiments, the tool only has orifices located on the outside of the tube wall 658. This is the opposite of the embodiment depicted in FIG. 55, which has orifices located only on the inside of the tube wall 658.

[00178] In an exemplary embodiment, the insertion tool enables the administration of drugs into the cochlea concurrently with insertion of the electrode array. By way of example only and not by way of limitation, the drugs are injected or otherwise transferred into the cochlea at the same time that the electrode array is being inserted into the cochlea. In an exemplary embodiment, the rate of drug delivery relative to the total amount of drugs delivered via the insertion tool or in total is at least about 1 to 1 with the length rate of insertion of the electrode array relative to the total length of the electrode array. For example, if the total amount of drugs to be delivered is A and the length of the electrode array is X, and the rate of insertion of the electrode array is $1/30^{th}$ the length of the electrode array every second, about $1/30^{th}$ of A will be delivered every second. That said, in an alternate embodiment, the tool can be utilized to administer a first quantity of drug first, followed by insertion of the electrode array, followed by the administration of a second quantity of drug. Still further, in an exemplary embodiment, the tool can be utilized to administer a first quantity of drug first, and a second quantity of drug while the electrode array is being inserted into the cochlea, and then a third quantity of drug. Still further, in an exemplary embodiment, the tool can be utilized to administer a first quality of drug first, and then a second quality of drug while the electrode array is being inserted in the cochlea, where the second quantity and the first quantity constitutes the total quantity of the drug administered, at least with respect to the utilization of the insertion tool.

[00179] It is noted that while the above ratios are provided in exact terms, it is to be understood that there can be considerable tolerance with respect to variations of a drug delivery regime relative to an electrode array insertion regime. In this regard, it is noted that

at least some embodiments of the insertion tool provide drug delivery functionality that enables drug delivery to be correlated with insertion depth of the electrode array. This correlation can be relatively loose, and need not be exact.

[00180] While the embodiments of FIGs. 55 and 56 concentrate on delivering the drug along the axial length of the insertion tool, in an alternate embodiment, the drug is delivered at the tip of the insertion tool. FIG. 57 depicts an exemplary embodiment of an insertion tool 5700, where a drug delivery device 5701 is located at the tip. In an exemplary embodiment, drug delivery device 5701 constitutes a fluidic passage 5812 (with reference to FIG. 58, which depicts the tip of the tool) that extends about the axis of the lumen (or anti-twist guide-channel 680, if such is utilized). Orifices 5814 are in fluidic communication with this fluidic passage 5812. The fluidic passage 5812 is in fluid communication with a fluidic passage 5810, corresponding to fluidic passage 5710 of FIG. 57. In an exemplary embodiment, a fluid substance, such as a liquid drug, is transported through fluidic passage 5812, and then injected or otherwise transferred out of orifices 5814. In an exemplary embodiment, this coats the electrode array with the drug about the entire circumference thereof as the electrode array is pushed through the tip of the insertion tool into the cochlea, the electrode array transporting the drug into the cochlea as the electrode array is transferred into the cochlea. In an alternate embodiment, the orifices extend outward instead of inward. In an exemplary embodiment, the orifices extend both outward and inward.

[00181] Figure 57 depicts an exemplary embodiment where a drug reservoir 5760 is located in the handle. The drug reservoir 5760 is in fluid communication with fluid passage 5710 via fluidic conduit 57061. In an exemplary embodiment, tool 5700 is configured to transport the drug contained in the reservoir 5760 to the drug delivery device 5701 (or any other drug delivery device – the embodiment of FIG. 57 is not mutually exclusive to that configuration and/or the configuration of FIG. 58 - again, any feature of any embodiment detailed herein can be combined with any feature of any other embodiment detailed herein unless otherwise noted). In an exemplary embodiment, the tool includes an actuation device that enables the surgeon or the like to activate drug delivery. In an exemplary embodiment, a plunger device can be located in the handle that pressurizes the drug in reservoir 5760 so as to reject the drug from the tool 5700. In an exemplary embodiment, the tool 5700 is configured to be "charged" with the drug. In an exemplary embodiment, a connection between reservoir 5760 and the outside of the tool is present, where a surgeon or other healthcare professional can insert the drug into the reservoir 5760. Indeed, in an exemplary embodiment, the reservoir

5760 can include a self-sealing diaphragm or the like that enables a surgeon or other healthcare professional to insert a needle of a syringe therethrough, and inject the drug from the syringe into the reservoir 5760 so as to "charge" the tool with the drug. (This is analogous to the device that vaccines, etc., are stored in, where a healthcare professional inserts a needle into the diaphragm and withdraws the drug prior to giving an injection, except here, the drug is injected into the container as opposed to withdrawn from the container.) This can have utilitarian value with respect to managing the drugs. In this regard, in at least some exemplary embodiments, the drug need only be inserted into the tool right before the use of that drug, thus avoiding a scenario where the drug becomes unstable due to age or temperature or the like.

[00182] That said, in an alternate embodiment, a fluidic connection to a reservoir of the drug located remote from the tool 5700 can be utilized. Indeed, in an exemplary embodiment, a conduit can extend from the tool 5700 to a remote syringe, where a healthcare professional other than the person handling the tool 5700 operates the drug delivery. To this end, FIG. 59 depicts an exemplary embodiment of an insertion tool 5900, that includes a flexible fluid conduit 59061 extending from a connector 5955 to fluidic passage 5710. In an exemplary embodiment, coupling 5955 is configured to be connected to a reservoir of a drug or the like, and the drug can be transferred through conduit 59061 under pressure. In an exemplary embodiment, coupling 5955 can be snapped coupled or otherwise screwed onto the reservoir the drug. In an exemplary embodiment, connector coupling 5955 has a diaphragm or the like that can be pierced by a syringe. In an exemplary embodiment, a healthcare professional inserts the needle of the syringe through the diaphragm in connector 5955, and then injects the drug by depressing the handle of the syringe, thus delivering the drug to the tool 5900, and ultimately to the recipient. This structure of the connector 5955 can be analogous to the structure of an IV tube where a healthcare professional can interact a drug into the IV without having to pierce the skin again because the skin is already pierced.

[00183] In view of the above, it is to be understood that in an exemplary embodiment, there is an electrode array insertion tool comprising an assembly configured to provide direct array insertion functionality and ancillary array insertion functionality to a user of the tool where the ancillary functionality can be drug delivery functionality.

[00184] It is noted that while the embodiments depicted above focused on the orifices of the drug delivery system of the tool being located in the intracochlear portion of the tool, the orifices can be located elsewhere, such as in the portions of the tool that are not inserted into

the cochlea. The orifices of the drug delivery system can be located anywhere within the tool that has utilitarian value. Also, it is noted that the teachings associated with the drug delivery systems detailed herein are not limited to an insertion tool that is inserted into the cochlea. In this regard, FIG. 60 depicts an exemplary portion of an exemplary insertion tool that does not have a component that is configured to be inserted into the cochlea, where the orifices 5814 are arrayed on the inside of the tube at the location of the stop 202.

[00185] Figure 61 depicts another alternate embodiment of an insertion tool 6100 for a cochlear array. Here, an ultrasonic transducer 6104 is located on the stop 204. Ultrasonic transducer 6 104 is connected to lead 6106, which is in signal communication with a device, not shown, that enables reception and/or analysis of the signal received by transducer 6104. In this regard, tool 6100 includes an ultrasonic transducer positioned on the extra cochlea section of the tool (with respect to the tool when it is fully inserted into the cochlea) such that the working end of the ultrasonic transducer directly abuts the round window and/or the oval window and/or tissue around the cochlea promise and/or the tissue around the round window and/or the oval window. The transducer 6104 can serve as an acoustic source for ultrasonic imaging. This can enable a surgeon or other healthcare professional to verify the array is positioned within the correct scala and check the final position of the array. In an exemplary embodiment, the transducer 6104 is the transducer that enables the teachings of US patent application number 13/965,348. In an exemplary embodiment, the transducer is utilized per the teachings of the '348 application.

[00186] Consistent with the other embodiments detailed herein, while the embodiment of FIG. 61 is depicted as being utilized with a tool that has an intracochlear portion, the teachings associated with this embodiment can be utilized with insertion tools that do not have a component that is inserted into the cochlea.

[00187] In an exemplary embodiment, the tool 6100 includes a connection that is in signal communication with lead 6106. This connection can enable tool 6100 to be connected to an ultrasonic imaging device that can utilize the signals from the ultrasonic transducer 6104 to create an image. In this regard, it is noted that an exemplary embodiment includes the tool 6100 connected to this ultrasonic imaging device. In this regard, FIG. 62 depicts an ultrasonic imaging system, where a connector 6205 in electrical communication with lead 6106 is connected to connector 6207 which is an electrical communication with an ultrasonic imaging unit 6250, such as that which can be obtained from the General Electric Company or the like. The ultrasonic imaging unit 6250 receives input from the transducer 6104 and

generates an image on an LCD screen and/or a cathode ray tube based on the input from transducer 6104.

[00188] Thus, in an exemplary embodiment, there is an insertion tool for an electrode array, having an ancillary array functionality in the form of an ultrasonic transmitter and/or receiver.

[00189] It is briefly noted that while the embodiment depicted in FIG. 62 represents communication of the insertion tool with an ultrasonic imaging unit, FIG. 62 can be representative of other types of devices in signal communication or otherwise connected to the insertion array tool (e.g., an ECoG analysis program on a laptop or a desktop computer, an open circuit test unit, etc.).

[00190] As noted above with respect to the embodiments utilizing the electrode in capacitive coupling with an electrode of the electrode array, the electrodes of the insertion tool can be utilized to deduce certain features associated with the electrode array. While the embodiments detailed above have been directed towards features associated with the state of the electrical system of the electrode array, electrodes can be utilized to deduce a state in which the electrode array is currently in and/or a position of the electrode array. FIG. 63 depicts an exemplary embodiment of an insertion tool 6300 that includes a plurality of electrodes that are located on the exterior of the insertion sheath. As can be seen, there is a tip electrode 6302, an electrode 6304 located on the outer surface of the anti-twist section, and electrode 6305 located at the ramp portion between the anti-twist section in the proximal section, and electrode 6306 located on the proximal section, and another electrode 6307 located on the proximal section. These electrodes are utilized to monitor voltage and/or impedance characteristics between a given electrode of the tool, and one or more electrodes of the electrode array during insertion and/or after insertion into the cochlea. It is briefly noted that while the embodiment depicted in FIG. 63 presents a plurality of electrodes on the insertion tool, it is to be understood that some embodiments can be practiced utilizing only one electrode on the insertion tool. That said, in an alternate embodiment, additional electrodes can be utilized. Note further that while the electrodes are depicted as being present on the top portion of the insertion tool, in an alternate embodiment, the electrodes can be located elsewhere such as on the bottom and/or on the lateral sides of the insertion tool. Indeed, a spread of electrodes can be located on the top, the bottom, and the sides.

[00191] In an exemplary embodiment, the electrodes of the insertion tool are utilized to monitor the voltage and/or impedance profile between the given electrodes of the tool and the

given electrodes of the electrode array as the electrode array is inserted into the cochlea. In an exemplary embodiment, this can have utilitarian value with respect to providing an indication as to the occurrence of a tip fold over. In an exemplary embodiment, one or more of the electrodes can serve the function as one or more of the electrodes of the teachings of U.S. patent application 14/843,255, filed on September 2, 2015, naming Benjamin Johnston as an inventor. In an exemplary embodiment, these electrodes can have utilitarian value with respect to providing an indication as to the occurrence of buckling of the electrode array. In an exemplary embodiment, one or more the electrodes conserve the functions as one or more of the electrodes of the teachings of US patent application number 14/843,259, filed on September 2, 2015, naming Frank Risi as an inventor. In this regard, the electrodes of the insertion tool can be utilized as part of a system that monitors the impedance and/or voltage between the electrodes and the electrodes of the electrode array to determine angular insertion depth.

[00192] In an exemplary embodiment, the electrodes of the insertion tool provide an absolute reference for monitoring the voltage and/or impedance between the electrodes of the insertion tool and the electrodes of the electrode array. In this regard, this can have utilitarian value with respect to providing more accuracy than that which results from utilizing the electrodes of the electrode array alone as is done in the aforementioned patent applications described in the prior paragraph.

[00193] Figure 66 depicts electrode 6307 in signal communication with a lead that leads to connector 6320. In an exemplary embodiment, connector 6320 is connected to a device that analyzes the output of the lead.

[00194] FIG. 64 is a flowchart of a first method 300 for monitoring the physical state of the electrode array through the use of localized stimulation. The method 300 of FIG. 64 is sometimes referred to herein as a localized monitoring method as the method uses the delivery of localized stimulation (i.e., current signals) to induce voltages at a plurality of other contacts. For ease of illustration, method 6400 will be described with reference to the cochlear implant 100 of FIG. 1.

[00195] Method 300 begins at 302 where stimulation (i.e., one or more current signals) is delivered/sourced at a selected intra-cochlear electrode of the electrode array. In one specific example, the stimulation is delivered at the most distal/apical electrode of the electrode array and is sunk at one or more of the electrodes of the electrode array insertion tool 6300. The

electrode that delivers the current signals, sometimes referred to herein as the "stimulating" or "source" contact (or source electrode) and the electrode that sinks the current signals, namely one or more of electrodes of the tool 6300, is sometimes referred to herein as the "return" contact (or return electrode). Additionally, the two electrodes between which the stimulation is delivered are collectively referred to herein as a "stimulating pair." The remaining electrodes that are not part of the stimulating pair are disconnected from the system ground (i.e., are electrically "floating").

[00196] In general, two intra-cochlear contacts are selected for delivery of the stimulation. However, alternative embodiments may use an extra-cochlear contact to source/sink current. Additionally, it is to be that the use of the most distal contacts for sourcing/sinking the current is illustrative and other contacts could be used in alternative embodiments.

[00197] While the embodiment described above and herein utilizes the electrodes of the electrode array insertion tool 6300 as sinks, it is to be understood that in an exemplary embodiment, the electrodes of the electrode array insertion tool can be utilized as sources. Thus, any disclosure herein with respect to utilizing the electrodes of the electrode array insertion tool as sinks corresponds to a disclosure of utilizing the electrodes of the electrode array insertion tool as sources.

[00198] While this embodiment details utilizing one single electrode of the electrode array insertion tool as a sink (or source), it is to be understood that in alternate embodiments, the electrodes of the electrode array can be utilized as sinks and/or sources sequentially. In this regard, in an exemplary embodiment, during a first temporal period, electrode 6307 can be utilized as a source, and then during a second temporal period, electrode 6306 can be utilized as a source, and then during a third temporal period, electrode 6305 can be utilized as a source, etc. In this regard, because the positions of the electrodes of the electrode array insertion tool are known, it can be possible to triangulate the position of the electrodes of the electrode array.

[00199] The electrode array is inserted into the recipient's scala tympani. The scala tympani is substantially filled with a conductive fluid known as perilymph. As such, when current signals are delivered at one of the electrodes of the electrode array insertion tool, at least a portion of the current will spread through the perilymph. For example, the conductive nature of the perilymph will cause at least some current to flow away from the contact. The flow of the current through the perilymph will cause the generation of voltages at the other intra-

cochlear stimulating contacts. That is, although the stimulus is localized, due to the conductive perilymph the electric field spreads and induces voltage at the other contacts.

[00200] At action 304, following the delivery of the current signals at the apical electrode of the electrode array, measurements are performed at a selected number of other intra-cochlear electrodes of the electrode array utilizing the same electrode of the electrode array insertion tool or different electrodes of the electrode array insertion tool. That is, the voltage induced at the selected other electrodes as a result of the delivery of the current signals at the apical electrode is measured. The electrodes at which the voltages are measured are sometimes referred to herein as "measurement" contacts. In the embodiment of FIG. 64, the measurement contacts may include any of the electrodes of the electrode array insertion tool. Corollary to this, the measurement contacts can include any of the electrodes of the electrode array.

[00201] In certain circumstances, the cochlear implant 100 associated with the electrode array is configured to make a plurality of voltage measurements at substantially the same time in response to the delivery of stimulation. In such embodiments, a single set of localized current signals is applied and the voltage induced at a selected number of the measurement contacts is measured substantially simultaneously at the measurement contacts. In other embodiments, the cochlear implant 100 is configured to measure the voltage at a single contact in response to the delivery of a set of current signals. In such embodiments, a plurality of sets of localized current signals are applied in sequence at the most apical electrode of the electrode array and a voltage is measured at a different contact after each sequential stimulation. As such, in the context of FIG. 64, the delivery of single stimulation pattern may refer to the delivery of one set of current signals (with subsequent, substantially simultaneous measurement at each of the selected measurement contacts) or the sequential delivery of a plurality of sets of current signals (with subsequent measurement at one of the selected measurement contacts after each set of current signals are delivered).

[00202] As noted above, stimulation delivered at an electrode will have an effect on the other electrodes, and the effect may depend on a number of factors. However, a primary factor that controls the effects of stimulation is the distance between the stimulating electrode and the measurement electrode. For example, in the embodiment of FIG. 64, when stimulation is delivered at the most apical electrode of the electrode array, the voltage measured electrodes other than electrode 6307 should be increasingly larger for electrodes along the insertion tool and should increase the closer that the electrode is to the tip of the electrode array insertion

tool. Therefore, at 306 of FIG. 64, the induced voltages measured at each of the measurement electrodes in response to the single stimulation pattern are evaluated relative to one another to determine the relative distance between the stimulating electrode of the electrode array and each of the measurement contacts (i.e., the contacts at which voltages are measured - where the electrodes of the electrode array insertion tool are utilized as the sinks, the contacts at which the voltages are measured are those electrodes). Evaluation of the voltages relative to one another enables the determination of the physical state of the electrode array based on the evaluation of measurements relative to one another, the cochlear implant 100 or a connected device may generate feedback to a surgeon or other user that provides information about the physical state of the electrode array and/or the occurrence of an adverse event. In this regard, the insertion tools detailed herein can be utilized in conjunction with the electrode array to evaluate or otherwise determine the status of an electrode array as detailed in the '255 patent application.

[00203] In view of the above, it is to be understood that in an exemplary embodiment, one or more of the electrodes of the electrode array insertion tool when utilized as a current sink "replace" one or more of the electrodes of the electrode array that are utilized as a current sink when implementing the teachings of US patent application number 14/843,255. In view of the above, it is to be understood that in an exemplary embodiment, one or more of the electrodes of the electrode array insertion tool when utilized as a current source "replace" one or more of the electrodes of the electrode array that are utilized as a current source when implementing the teachings of US patent application number 14/843,255.

[00204] In an exemplary embodiment, the electrode array insertion tool provides source currents from the electrodes thereof. In an exemplary embodiment, the electrode array insertion tool is configured with a current generator that provides a specific current at a specific voltage from the electrode(s) of the tool. In this regard, the electrodes of the electrode array insertion tool operate as a source with respect to the teachings of US patent application number 14/843,255. To this end, FIG. 65 depicts an exemplary insertion tool 6500, that provides a current and voltage generator 6520, which is in communication with electrode 6307 via an electrical lead extending therefrom. In an exemplary embodiment, the generator 6520 can also be in communication with the other electrodes of the electrode array insertion tool. In an exemplary embodiment, the generator 6520 includes relays and/or transistors and/or switching components that enable the generator to alternately switch delivery of current from one electrode to the other electrode. In this regard, in an exemplary

embodiment, the generator 6520 can have the functionality and/or the structure of the components of the receiver/stimulator of the cochlear implant of US patent application number 14/843,255 with respect to generating a source current from the electrodes of the electrode array, when implementing the teachings of that patent application. In an exemplary embodiment, the generator 6520 can be a battery that is connected to circuitry that outputs a stable current at a stable voltage. In an exemplary embodiment, the generator 6520 can be adjustable so as to output different currents at different voltages. Consistent with the teachings detailed herein, the tool 6500 can have a switch or the like to allow the surgeon to activate and/or deactivate the current generator 6520. Alternatively, and/or in addition to this, the tool 6500 can be configured so as to allow selective energizement and/or deenergizement of the electrodes of the tool. While some embodiments permit such as part of the handheld tool, in some alternate embodiments, the tool is configured to be placed into communication with a control unit. For example, as seen in FIG. 66, tool 6500 can be equipped with a connector 6320 in signal communication with the voltage/current generator 6520. The connector can be connected to a connector 6207 that is connected to a control unit 6650, which can be a personal computer or the like. In an exemplary embodiment, the control unit 6650 can control the output of the current generator 6520 with respect to the current, the voltage, and which electrodes are operated as the source. Note further that in some exemplary embodiments, the voltage/current generator 6520 is not part of the tool 6500, but instead is part of the control unit 6650. Indeed, in such an exemplary embodiment, there can be separate leads from each electrode that extend to the connector 6320.

[00205] It is noted that in an exemplary embodiment, the control unit 6650 is the implant itself. In an exemplary embodiment, it is the receiver-stimulator unit of a cochlear implant, alone in some embodiments, or when placed into inductance communication with an external component or a component that replicates the functionality of the external component, etc. By way of example only and not by way of limitation, a lead from the tool, such as the lead leading from connector 6207, could clip onto the existing extra cochlear electrode (sometimes referred to as the hardball) of the implant, allowing the implant to look for open circuits, measure voltages, etc., through the electrode on the tool. In this regard, in an exemplary embodiment, the electrodes of the insertion tool can become an extension of the extra cochlear electrode. Accordingly, an embodiment exists where any functionality of the cochlear implant that relies on the extra cochlear electrode can thus also rely on the electrodes of the insertion tool to achieve such functionality. Corollary to this is that in an

exemplary embodiment, any of the functions detailed herein that utilize the electrodes of the insertion tool can be executed by the implants in at least some exemplary embodiments when the implant is in signal communication with the implant,, or at least when the insertion tool is connected to the extra cochlear electrode of the electrode array.

[00206] Still, in at least some exemplary embodiments, the tool 6500 can be configured so that the surgeon or the like can toggle from one electrode to another. For example, the tool can be provided with a switch or a button that the surgeon depresses to selectively energize a given electrode. The electrodes can be energized in sequence by repeatedly pressing the button. In an exemplary embodiment, an indicator on the tool can be provided so as to convey information to the surgeon as to which electrode is being operated as the source. By way of example only and not by way of limitation, an array of LEDs can be arrayed about the insertion stop 204. As a given electrode is energized, the LEDs can light. The LED at the 9 o'clock position could indicate that the closest electrode to the stop has been energized (e.g., electrode 6307). The LED at the 3 o'clock position (when viewing the stop 204 from the surgeon point of view) could indicate that the furthest electrode to the stop has been energized (e.g., electrode 6302). The electrodes in between can correspond to LEDs in between the 9 o'clock position in the 3 o'clock position. Alternatively, LEDs having different colors can be utilized to indicate to the surgeon which electrode is being utilized as a source.

[00207] Figure 67 depicts an alternate embodiment of the electrode array insertion tool, insertion tool 6700, that is utilized as a sink. Here, a lead extends from electrode 6307 to a connector 6320. Other leads also extend in a similar manner, but are not shown. In an exemplary embodiment, connector 6320 can be hooked up to or otherwise connected to a unit that will receive the signal from the electrodes when used as a sink, and analyze that signal in a manner corresponding to how such would be analyzed were that electrode to be part of the electrode array as utilized in US patent application number 14/843,255. By way of example only and not by way of limitation, in an exemplary embodiment, a test unit can be a personal computer in signal communication with connector 6320. The personal computer can analyze the output from connector 6320 indicative of the current/voltage at electrode 6307 or any other electrode of the electrode array insertion tool, and analyze the properties of the electrode array in the same manner as that which is done in the '255 patent application. That said, in an exemplary embodiment, the tool 6700 can be placed into signal communication with the receiver/stimulator of the cochlear implant, and the cochlear implant can be

configured to utilize the electrodes of the insertion tool as the sink electrode when implementing the teachings of the '255 application. Note also that this is the case with respect to embodiments where the electrodes of the electrode array insertion tool are utilized as the source. That is, connector 6320 can allow the insertion tool to be placed into signal communication with the receiver/stimulator of the cochlear implant, and the cochlear implant can be configured to utilize the electrodes of the insertion tool as the source electrode when implement the teachings of the '255 application.

[00208] Note also that in an exemplary embodiment, whether the tool is utilized as a source or a sink for the current, the insertion tool 6700 can be configured to be placed into signal communication with any ancillary equipment utilized in the teachings of the '255 application so as to implement the teachings thereof where the electrodes of the insertion tool are the source or the sink.

[00209] Any arrangement of the insertion tool that can enable electrodes thereof to operate as a source or a sink instead of utilizing the electrodes of the electrode array as the respective source or a sink when implementing the teachings of the '255 patent application can be utilized in at least some exemplary embodiments. Thus, in an exemplary embodiment, the tool is configured to interface with any of the components detailed in the '255 patent application to enable such.

[00210] The teachings detailed above have utilitarian value with respect to determining or otherwise detecting electrode array tip fold over. The teachings detailed above also have utilitarian value with respect to determining angular insertion depth.

[00211] FIG. 68 depicts a flowchart of a first intra-operative method 1300 for setting the angular insertion depth of the electrode array utilizing an electrode of the electrode array insertion tool. FIG. 68 illustrates a real-time method that enables the determination of the current/present (i.e., actual) angular insertion depth of the electrode array within the cochlea.

[00212] Method 1300 begins at 1302 where the electrode array is at least partially inserted into cochlea. At 1304, during insertion of the stimulating assembly into the cochlea, the impedance between different pairs of intra-cochlear contacts is measured, one contact being an electrode of the electrode array and another contact being electrode of the electrode array insertion tool and used to determine the angular insertion depth of the stimulating assembly.

[00213] In one embodiment, to measure the impedance between two intra-cochlear contacts, bipolar electrical stimulation (i.e., one or more bipolar current signals) is repeatedly delivered

between a first intra-cochlear contact (e.g., one of the electrodes the electrode array insertion tool) and a second intra-cochlear contact (e.g., one of the electrodes of the electrode array). After the delivery of each set of bipolar stimulation between the first and second intra-cochlear contacts, the impedance between the first and second contacts is measured (e.g., at the second intra-cochlear contact). As with the embodiment detailed above with respect to FIG. 64, the contact that delivers the current signals is sometimes referred to herein as the "stimulating" or "source" contact and the contact that sinks the current is sometimes referred to herein as the "return" contact. Additionally, the two contacts between which the stimulation is delivered are sometimes collectively referred to herein as a "stimulating pair." The remaining contacts that are not part of the stimulating pair are disconnected from the system ground (i.e., are electrically "floating").

[00214] It is to be appreciated that impedance measurements are made between two points, thus the impedance may be "measured" at either of the two points (i.e., it is a relative measurement between those two points). However, merely for ease of illustration of certain embodiments presented herein, the return contact of the stimulating pair is sometimes referred to herein as a "measurement" contact.

[00215] In general, the impedance between two intra-cochlear contacts in a stimulating pair can be correlated to their physical proximity with one another and their location in the cochlea. Because one of the electrodes is mounted at a known location on the insertion tool, and the insertion tool is inserted into the cochlea by a known amount at a generally known angle, utilizing the electrodes of the electrode array insertion tool can have utilitarian value. The physically closer the contacts of the stimulating pair are to one another, the lower the impedance that will be measured between the contacts. At 1306, again while inserting the electrode array, the impedance-to-proximity relationship is used to evaluate the plurality of impedance measurements relative to one another to determine the relative proximity between the two or more intra-cochlear contacts and thus determine the real-time (current/present) angular insertion depth of the electrode array. As described further below, the method includes the selection of one or more sets/pairs of intra-cochlear contacts for impedance measurement that enables the angular insertion depth of the electrode array to be determined from the relative proximity of the one or more pairs of intra-cochlear contacts.

[00216] In an exemplary embodiment, a given electrode of the electrode array will move relative to the electrode of the electrode array insertion tool as the electrode array is inserted in the cochlea. As it travels through the cochlea and curves therein, a given electrode of the

electrode array will have a distance from the electrode of the electrode array insertion tool that changes. The distance will grow larger and then grow smaller as the electrode array snakes its way through the cochlea in a manner analogous to how distance between planets expands and contracts. Because the distance is changed, the current and/or voltage measured at a given sink contact will change. This can be utilized to determine the angular orientation according to the teachings of US patent application number 14/843,259. Thus, in an exemplary embodiment, whether the tool is utilized as a source or a sink for the current, the insertion tool 6700 can be configured to be placed into signal communication with any ancillary equipment utilized in the teachings of the '259 application so as to implement the teachings thereof where the electrodes of the insertion tool are the source or the sink.

[00217] Any arrangement of the insertion tool that can enable electrodes thereof to operate as a source or a sink instead of utilizing the electrodes of the electrode array as the respective source or a sink when implementing the teachings of the '259 patent application can be utilized in at least some exemplary embodiments. Thus, in an exemplary embodiment, the tool is configured to interface with any of the components detailed in the '259 patent application to enable such. To be clear, in an exemplary embodiment, electrode array insertion tool is configured to serve as a source and/or a sink contact in the teachings of the 259 patent application.

[00218] To summarize, any of the features detailed above that enable an insertion tool with electrodes to be utilized as source or sink to enable the teachings of US patent application number 14/843,255 can be utilized to enable an insertion tool with electrodes to be utilized as source or sink to enable the teachings of US patent application number 14/843,259. Thus, the embodiments of FIGs. 63, 65, 66 (with possible modifications to the unit 6650 for angular insertion), and 67 can be utilized to implement the teachings of the '259 application as well.

[00219] In view of the above, in an exemplary embodiment, there is an electrode array insertion tool, wherein the tool includes an intracochlear portion configured to be inserted into the cochlea. In this exemplary embodiment, the insertion tool has ancillary functionality of a voltage and/or impedance monitoring of the electrode array via an electrode mounted on the intracochlear portion thereof. It is to be understood that in an exemplary embodiment, the electrode array insertion tool has a functionality of a reference for a measurement system. In view of the above, in an exemplary embodiment, there is a cochlear electrode array insertion tool, comprising an array guide, and an active functional component. In an exemplary embodiment, the active functional component is an indicator to a user of the insertion tool of

a phenomenon associated with insertion of the electrode array. In an exemplary embodiment, the phenomenon associated with insertion of the array is an array orientation within the cochlea. In an exemplary embodiment, there is an insertion tool having a functionality voltage and/or impedance monitoring characteristics between two electrodes of the electrode array.

[00220] In view of the above, it is to be understood that the insertion tools detailed herein provided utilitarian value with respect to methods. In this regard, FIG. 69 depicts an exemplary flowchart for a method 6900. Method 6900 includes method action 6910, which entails applying an acoustic source to a cochlea. In the exemplary embodiment, this is achieved via the use of the acoustic signal generator mounted on the tool as noted above. Method 6900 further includes method action 6920, which entails inserting an electrode array during the application of the acoustic source. Consistent with the teachings detailed above, the acoustic source could be a bone conduction actuator. In an exemplary embodiment, the acoustic source is operated at a gain of less than about 80 dBs.

[00221] Figure 70 depicts another exemplary flowchart for an exemplary method, method 7000. Method 7000 includes method action 7010, which entails executing method 6900. Method 7000 further includes method action 7020, which entails executing an ECoG measurement based on the acoustic source. In an exemplary embodiment, this is executed utilizing the devices and systems detailed above. In view of the above, where the insertion tool having the acoustic source signal generator is utilized, in an exemplary embodiment, the acoustic source bypasses the middle ear to provide auditory stimuli for the ECoG measurements. Corollary to method 7000 is that the acoustic source evokes and auditory nerve action potential via bone conduction in at least some exemplary embodiments.

[00222] In at least some exemplary embodiments, the execution of the ECoG measurement can have utilitarian value with respect to determining whether or not electrode array is being properly inserted into the cochlea. Accordingly, in an exemplary embodiment, method 7000 can further include the action of temporarily halting the insertion of the electrode array based on the ECoG measurement prior to full insertion of the electrode array. Indeed, in an exemplary embodiment, method 7000 can further include the action of withdrawing a portion of the electrode array from the cochlea based on the ECoG measurement prior to the final insertion of the electrode array into the cochlea.

[00223] Still with reference to method 7000, in an exemplary embodiment, the action of inserting the electrode array is executed during a first temporal period and a second temporal period, wherein during the first temporal period, the electrode array is inserted into the cochlea along a first trajectory relative to the very beginning of the cochlea and during the second temporal period, the electrode array is inserted into the cochlea along a second trajectory relative to the very beginning of the cochlea. In this regard, by way of example only and not by way of limitation, the first trajectory can be established by the insertion tool when held at a first angle relative to the outside of the cochlea, or more specifically, relative to the tangent surface at the cochleostomy. In an exemplary embodiment, this angle could be 10°. Because of the nature of the insertion tool, the electrode array would be inserted into the cochlea along a first trajectory controlled by this angle. The second trajectory can also be that established by the insertion tool when held at a second angle relative to the outside of the cochlea, or more specifically, relative to the tangent surface of the cochleostomy. In an exemplary embodiment, this angle can be 15°. Again, because of the nature of the insertion tool, the electrode array would be inserted into the cochlea along a second trajectory controlled by this angle. It is to be understood that the method 7000 further comprises at least one of during the first temporal period or subsequent to the first temporal period, evaluating the ECoG measurement determining that the second trajectory should be adopted for insertion based on the ECoG measurement. In this regard, in an exemplary embodiment, the ECoG measurement could indicate that the electrode array is piercing a wall of the cochlea that it should not be piercing. Thus, there is utilitarian value with respect to changing the angle of orientation of insertion of electrode array into the cochlea. Still further, in an exemplary embodiment, the ECoG measurement could indicate that the electrode array is inserted into the wrong portion of the cochlea. Any data that is conveyed by the ECoG measurement that can have utilitarian value indicating that a different trajectory of electrode array insertion should be utilized, can be used in at least some exemplary embodiments as a basis for which to determine that the trajectory of insertion should be adjusted or otherwise changed.

[00224] Still referring back to method 6900, in an exemplary embodiment, the acoustic source is an ultrasonic imaging signal consistent with the utilization of an ultrasonic transducer mounted on the tool as detailed above.

[00225] It is noted that in an exemplary embodiment, the insertion tool in general, and the insertion sheath in particular, can be partially formed from or otherwise include layers of thin

film circuits with the active components (electrodes, circuits for transducers, MEMS electronics, etc.) needed to produce the added functionality. By way of example only and not by way of limitation, the tube through which the electrode array is inserted could be formed by taking a thin film and laying such flat. Electrical components can be located on the film according to a specific pattern. The film can then be rolled around the mandrel or the like so that the layer stack upon themselves as the film is rolled about the layer. The electronics will thus be located between and/or in the layers and position in the resulting tube accordingly, this tube could be utilized as part of the insertion tool in general, and the lumen through which the electrode array travels during insertion thereof in particular.

[00226] For purposes of concept illustration, FIG. 71 depicts an exemplary thin-film 7120 having located thereon circuit traces. A first circuit trace includes a lead 7130 and an electrode 7132. A second circuit trace includes a lead 7140 and an electrode 7142. The circuit traces are located on the film 7120 such that, when rolled, the first circuit trace is located closer to the inside of the resulting lumen and the second circuit trace is located close to the outside of the lumen. This is seen in FIG. 72, which depicts a view of the insertion tube showing the positions of the respective circuit traces, and the layers established by the rolling of the film. To be clear, the layers of the film form the tube wall 658 and thus the electrical circuits are embedded in the wall owing to the rolling.

[00227] As noted above, the insertion tool can incorporate visual indicators to provide intraoperative feedback to the surgeon. As detailed above, exemplary embodiments have LEDs or the like arrayed about the stop. Still further, in an exemplary embodiment, a liquid crystal display or the like can be incorporated in or on the insertion tool. In this regard, FIG. 73 depicts an exemplary embodiment of an insertion tool 7300 which includes LCD 7410 mounted on the insertion guide tube. LCD 7410 is in electrical communication with other components of the tool and/or other systems remote from the tool via electrical lead 7406. In an exemplary embodiment, the LCD can provide text and/or numerical data to the surgeon during implantation/insertion of the electrode array. The LCD or the other visual indicators can be located anywhere on the tool that will be within the surgeon's immediate field-of-view, but also where the indicator will not obstruct the surgeon's field-of-view of the pertinent portions of the anatomy of the recipient and/or the pertinent portions of the tool 7300 during insertion of the electrode array. In an exemplary embodiment, the indicators provide information pertaining to insertion depth, which can include the absolute depth and/or an indication that the electrode array has reached the intended or programmed stopped

depth. Indication can be an insertion speed, which can be absolute speed of insertion or can be an indication that the insertion speed limit has been exceeded. The indication can be an adverse measurement indication. This measurement can be a general indication, such as an indicator that something has gone wrong whatever that is, or specific indication, such as an indication explicitly relating to tip fold-over, basilar membrane contact, scala dislocation,, etc.

[00228] As noted above, embodiments include an insertion tool configured to communicate with a receiver/stimulator of a cochlear implant. In this regard, FIG. 74 depicts an exemplary insertion tool 7400 which is presented by way of concept. Insertion tool 7400 is a functional component FC mounted thereon. This functional component is representative of any of the additional functionalities of the insertion tool detailed herein and/or variations thereof. For example, element FC could be an electrode, it could be the acoustic stimulation generator, or it could be the ultrasonic transducer. FC could also be any of the indicators detailed herein (e.g., the LCD screen). As can be seen, insertion tool 7400 includes connector 64705 in electrical communication with the the functional component FC via electrical lead 746. Connector 64705 is connected to connector 7407 of inductance coil 7444. In an exemplary embodiment, inductance coil 7444 includes coil 7410 configured to establish a magnetic inductance field so as to communicate with the corresponding coil of the receiver-stimulator of the cochlear implant. Inductance coil 7444 includes a magnet 7474 so as to hold the inductance coil 7474 against the coil of the receiver/stimulator of the cochlear implant in a manner analogous to how the external component of the cochlear implant is held against the implanted component, and how the coils of those respective components are aligned with one another. While the embodiment depicted in FIG. 74 depicts no other functional component between the functional component FC and the inductance coil 7444, in an alternate embodiment, one or more of the units detailed herein can be located there between. By way of example, generator 6520 with respect to the insertion tool 6500 detailed above can be located there between or otherwise be in signal communication with the leads so as to establish communication with that element with the cochlear implant. In an exemplary embodiment, a communications unit or the like is located between or otherwise is in signal communication with the leads so as to establish communication with the cochlear implant receiver-stimulator. In an exemplary embodiment, the insertion tool includes logic or a processor or other type of control unit that enables the insertion tool to work in conjunction with the cochlear implant so as to execute any of the methods detailed herein, including the

methods associated with the '255 and the '259 applications where one or more electrodes of the electrode array insertion tool are utilized in a state of one or more electrodes of the electrode array as taught in those applications.

[00229] An exemplary embodiment includes a kit that includes an implantable component of a cochlear implant, such as that depicted in FIG. 1, and any of the insertion guide tools detailed herein. In an exemplary embodiment, the implantable component and the insertion guide tool are sealed in a hermetically sealed package, which can be a sterile package. In an exemplary embodiment, the insertion guide tool is at least partially loaded with the electrode array of the implantable component. For example, at least a portion of the electrode array is located in the tube of the insertion sheath.

[00230] It is noted that any of the method actions detailed herein and/or the functionalities of the given tools and/or systems detailed herein exists or can exist while the surgeon is inserting the electrode array into the recipient. This means that the surgeon is actually moving the electrode array into the recipient, not just during the procedure spanning a first temporal period where only a subset of that first temporal period involves actually moving the electrode array into the cochlea.

[00231] Any disclosure of any method action detailed herein corresponds to a disclosure of a device and/or a system for executing that method action. Any disclosure of any method of making an apparatus detailed herein corresponds to a resulting apparatus made by that method. Any functionality of any apparatus detailed herein corresponds to a method having a method action associated with that functionality. Any disclosure of any apparatus and/or system detailed herein corresponds to a method of utilizing that apparatus and/or system. Any feature of any embodiment detailed herein can be combined with any other feature of any other embodiment detailed herein providing that the art enables such, and it is not otherwise noted that such is not the case.

[00232] While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail can be made therein without departing from the scope of the invention.

CLAIMS

What is claimed is:

1. A cochlear electrode array insertion tool, comprising:
an array guide; and
an active functional component.

2. The tool of claim 1, wherein:
the active functional component is an acoustic stimulation generator.

3. The tool of claim 1, wherein:
the active functional component enables the measurement of insertion speed and/or insertion depth of the electrode array.

4. The tool of claim 1, wherein:
the active functional component is an electrode of an open circuit monitor configured establish a capacitive coupling between the electrodes of the electrode array and the electrode of the tool.

5. The tool of claim 1, wherein:
the active functional component is an indicator to a user of the insertion tool of a phenomenon associated with insertion of the array.

6. The tool of claim 5, wherein:
the phenomenon associated with insertion of the array is insertion depth of the electrode array.

7. The tool of claim 6, wherein:
the phenomenon associated with insertion of the array is insertion speed of the electrode array.

8. The tool of claim 6, wherein:
the phenomenon associated with insertion of the array is array orientation within the cochlea.

9. An electrode array insertion tool, comprising:
an electrode array insertion guide; and
an electrode.

10. The electrode array insertion tool of claim 9, wherein:
the electrode is mounted on an intra-cochlear portion of the insertion tool.

11. The electrode array insertion tool of claim 9, wherein:
the electrode is mounted on an extra-cochlear portion of the insertion tool.

12. The electrode array insertion tool of claim 9, wherein:
the electrode is mounted on the insertion tool such that when the insertion tool is placed fully against an outer wall of a cochlea, the electrode abuts the outer wall of the cochlea.

13. The electrode array insertion tool of claim 9, wherein:
the electrode is mounted in the tool such that the electrode is in a lumen of the electrode array insertion guide.

14. The electrode array insertion tool of claim 9, wherein:
the electrode enables ECoG measurement.

15. The electrode array insertion tool of claim 9, wherein:
the electrode enables open circuit testing of the electrode array while the electrode array travels through the guide.

16. The electrode array insertion tool of claim 9, wherein:
the electrode enables at least one of electrode array insertion speed or electrode array insertion depth to be monitored.

17. A method, comprising:
applying an acoustic source to a cochlea; and
inserting an electrode array during the application of the acoustic source.

18. The method of claim 17, wherein:

the acoustic source is a bone conduction actuator, wherein the acoustic source is held against an outer wall of the cochlea.

19. The method of claim 17, wherein:

the acoustic source is operated at a gain of less than about 80 dBs.

20. The method of claim 17, further comprising:

executing an ECoG measurement based on the acoustic source.

21. The method of claim 20, further comprising:

temporarily halting the insertion of the electrode array based on the ECoG measurement prior to full insertion of the electrode array.

22. The method of claim 20, wherein:

the action of inserting the electrode array is executed during a first temporal period and a second temporal period, wherein during the first temporal period, the electrode array is inserted into the cochlea along a first trajectory relative to the very beginning of the cochlea and during the second temporal period, the electrode array is inserted into the cochlea along a second trajectory relative to the very beginning of the cochlea; and

the method further comprises, at least one of during the first temporal period or subsequent to the first temporal period, evaluating the ECoG measurement and determining that the second trajectory should be adopted for insertion based on the ECoG measurement.

23. The method of claim 20, wherein:

the acoustic source is an ultrasonic imaging signal, the method further including imaging a position of the electrode array based on the ultrasonic imaging signal.

24. A device, comprising:

a cochlear implant electrode array insertion tool having a plurality of functional capabilities, at least one functional capability being different in kind than another functional capability.

25. The device of claim 24, wherein:

a first functionality of the tool is an electrode array support; and

a second functionality of the tool is that of an ECoG electrode.

26. The device of claim 24, wherein:

a first functionality of the tool is an electrode array support; and

a second functionality of the tool is a reference for a measurement system, the reference being established by an electrode of the tool.

27. The device of claim 24, wherein:

a first functionality of the tool is an electrode array support; and

a second functionality of the tool is an electrode array open circuit detection functionality for detecting an open circuit in the electrode array.

28. The device of claim 24, wherein:

a first functionality of the tool is an electrode array guide; and

a second functionality of the tool is a drug delivery functionality that also lubricates the insertion tool with respect to the array.

29. The device of claim 24, wherein:

a first functionality of the tool is an electrode array support; and

a second functionality is an ability to communicate with a receiver-stimulator of a cochlear implant.

30. The device of claim 24, wherein:

the first functionality of the tool is an electrode array guide; and

the secondary functionality is a drug delivery functionality that enables drug delivery to be correlated with insertion depth of the electrode array.

31. A kit, comprising:

the device of claim 24; and

an implantable component of a cochlear implant.

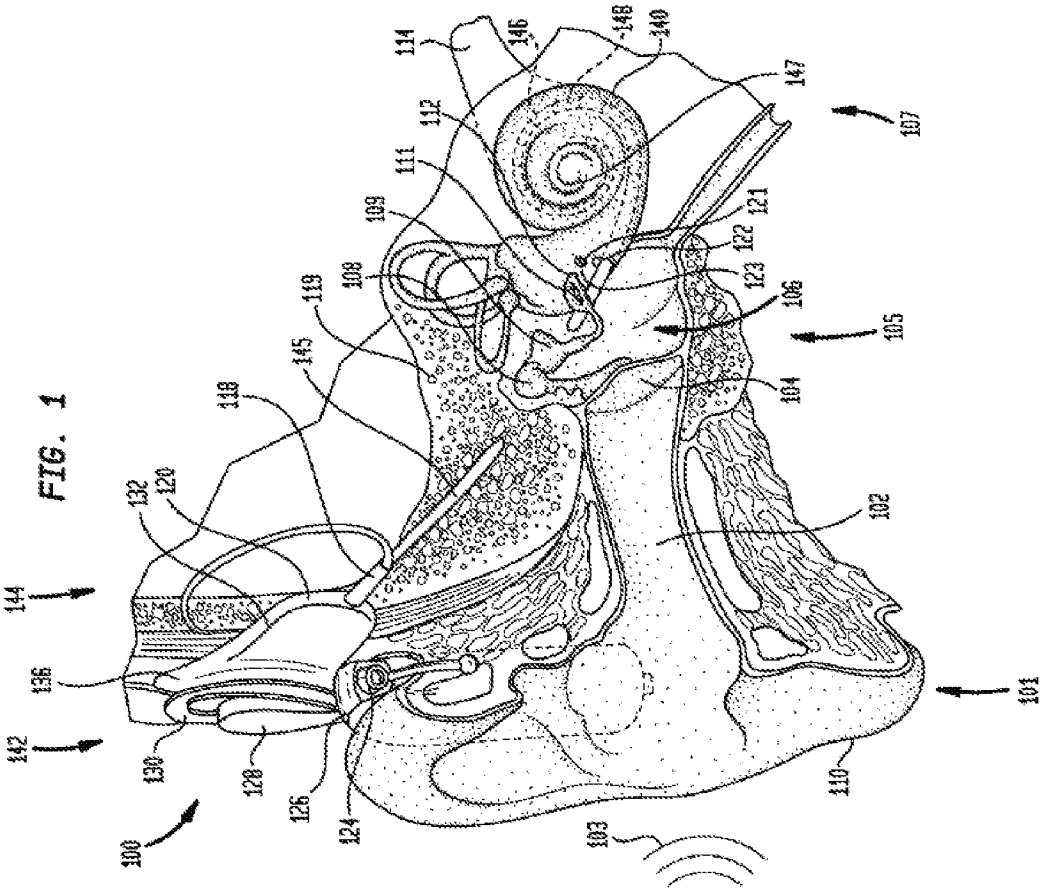

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FIG. 1

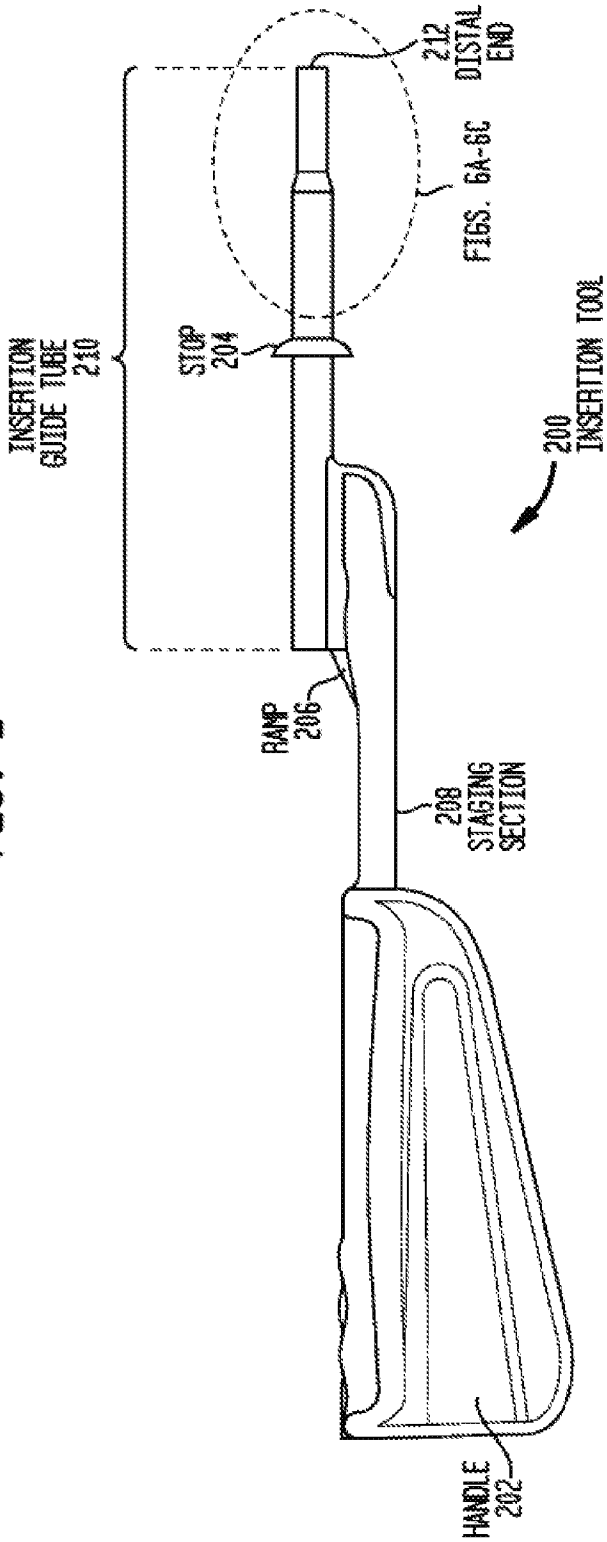

212
DISTAL
END
FIGS. 6A-6C
200
INSERTION TOOL
INSERTION
GUIDE TUBE
210
STOP
204
RAMP
206
208
STAGING
SECTION
HANDLE
202

FIG. 2

FIG. 3A

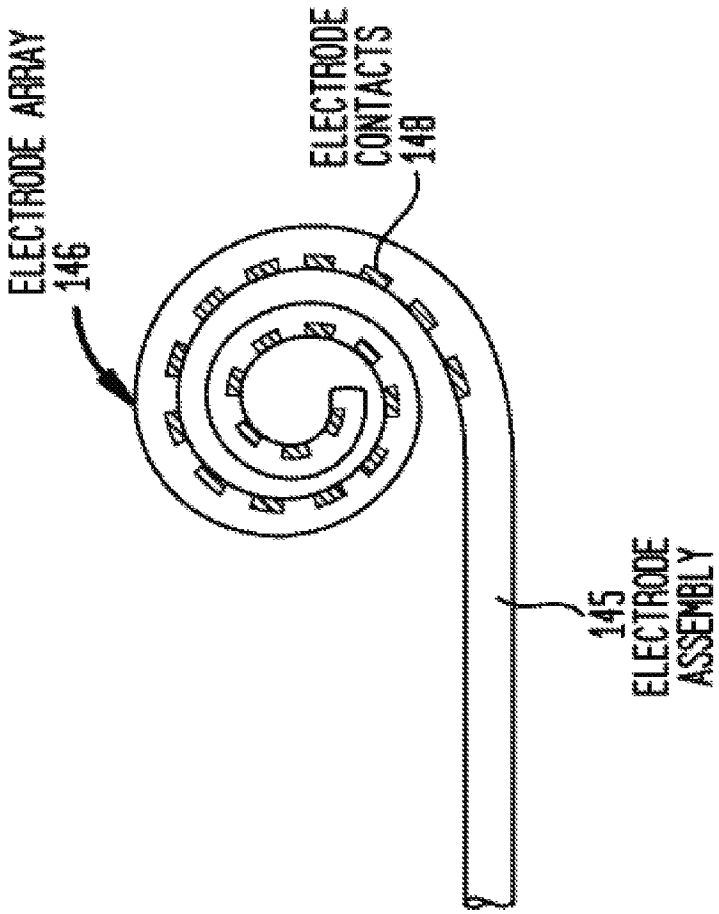
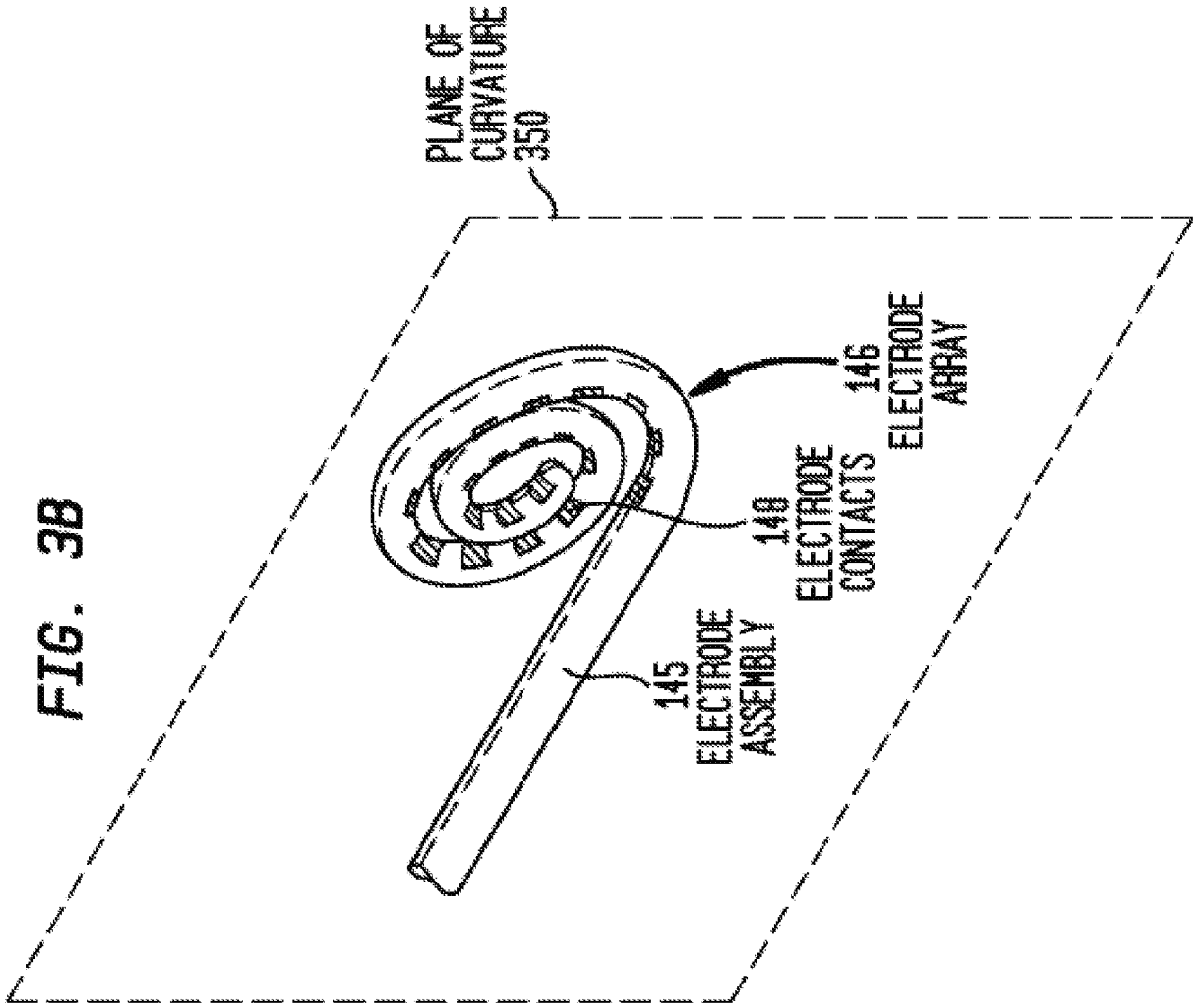
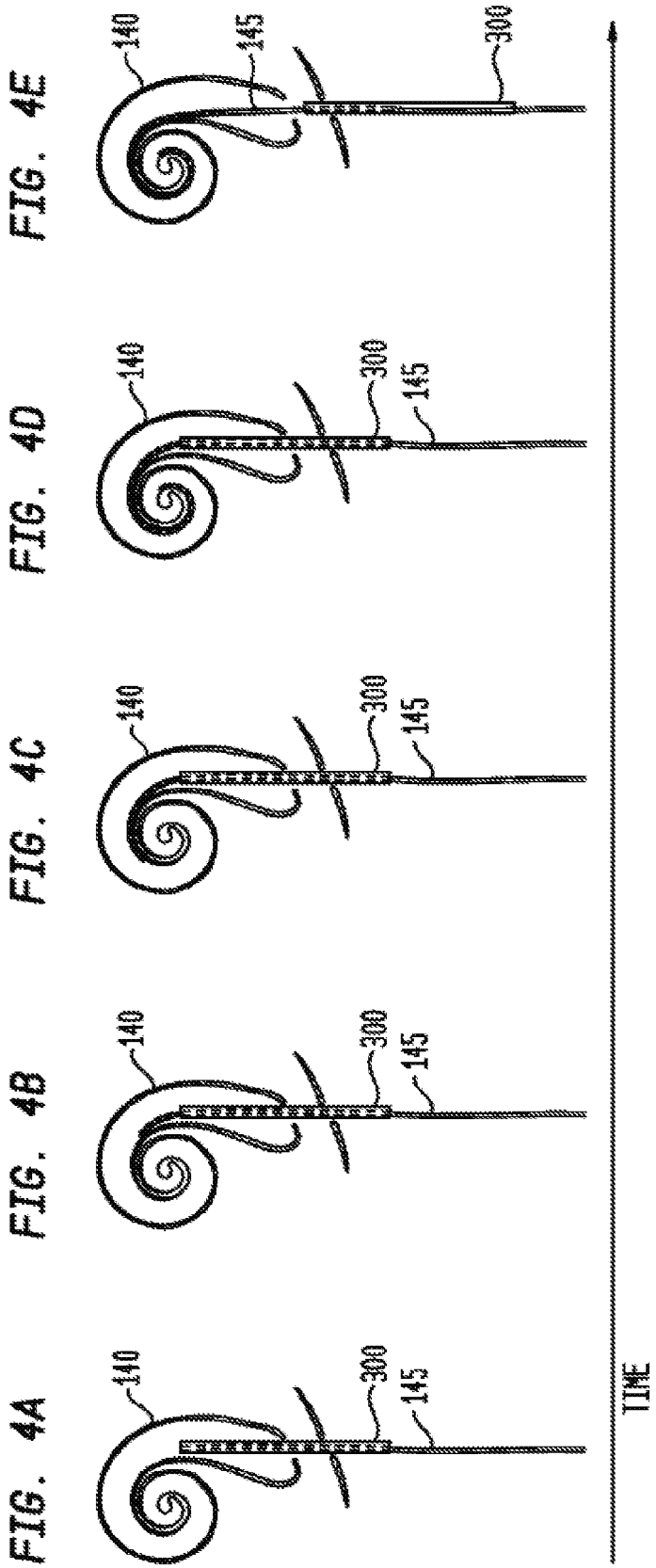

ELECTRODE ARRAY
146
ELECTRODE CONTACTS
148
145
ELECTRODE ASSEMBLY

FIG. 3B


PLANE OF CURVATURE 350
146 ELECTRODE ARRAY
148 ELECTRODE CONTACTS
145 ELECTRODE ASSEMBLY


FIG. 4A
140
300
145
FIG. 4B
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FIG. 4C
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FIG. 4D
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FIG. 4E
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TIME

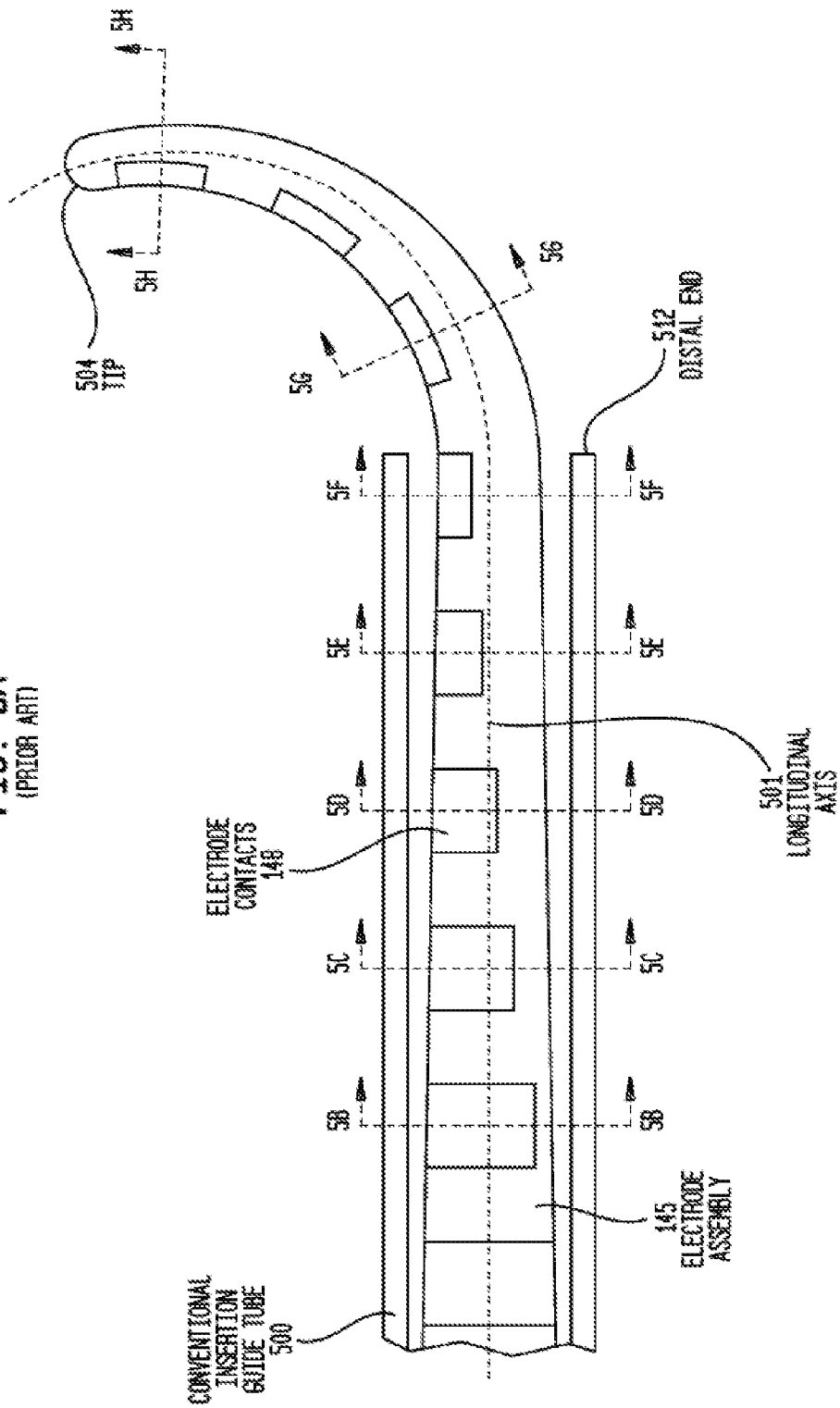


FIG. 5A
(PRIOR ART)

FIG. 5E

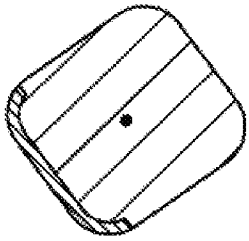


FIG. 5D

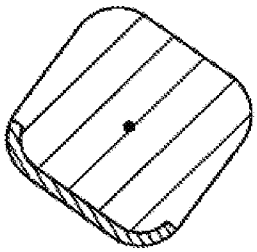


FIG. 5C

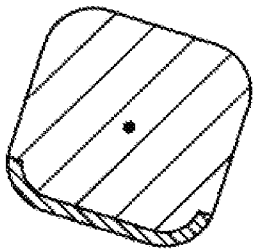


FIG. 5B

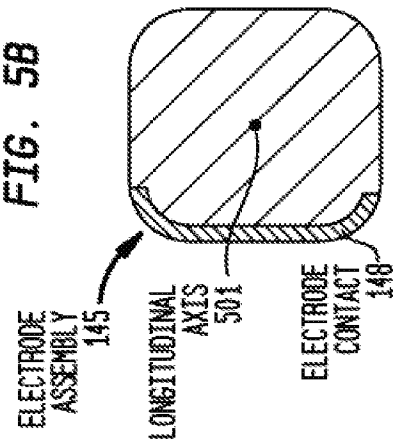


FIG. 5I

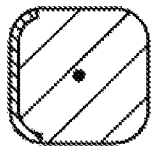


FIG. 5H

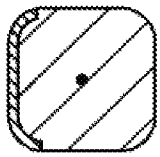


FIG. 5G

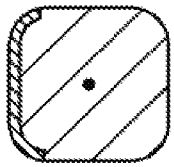


FIG. 5F

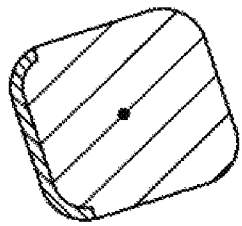


FIG. 6A

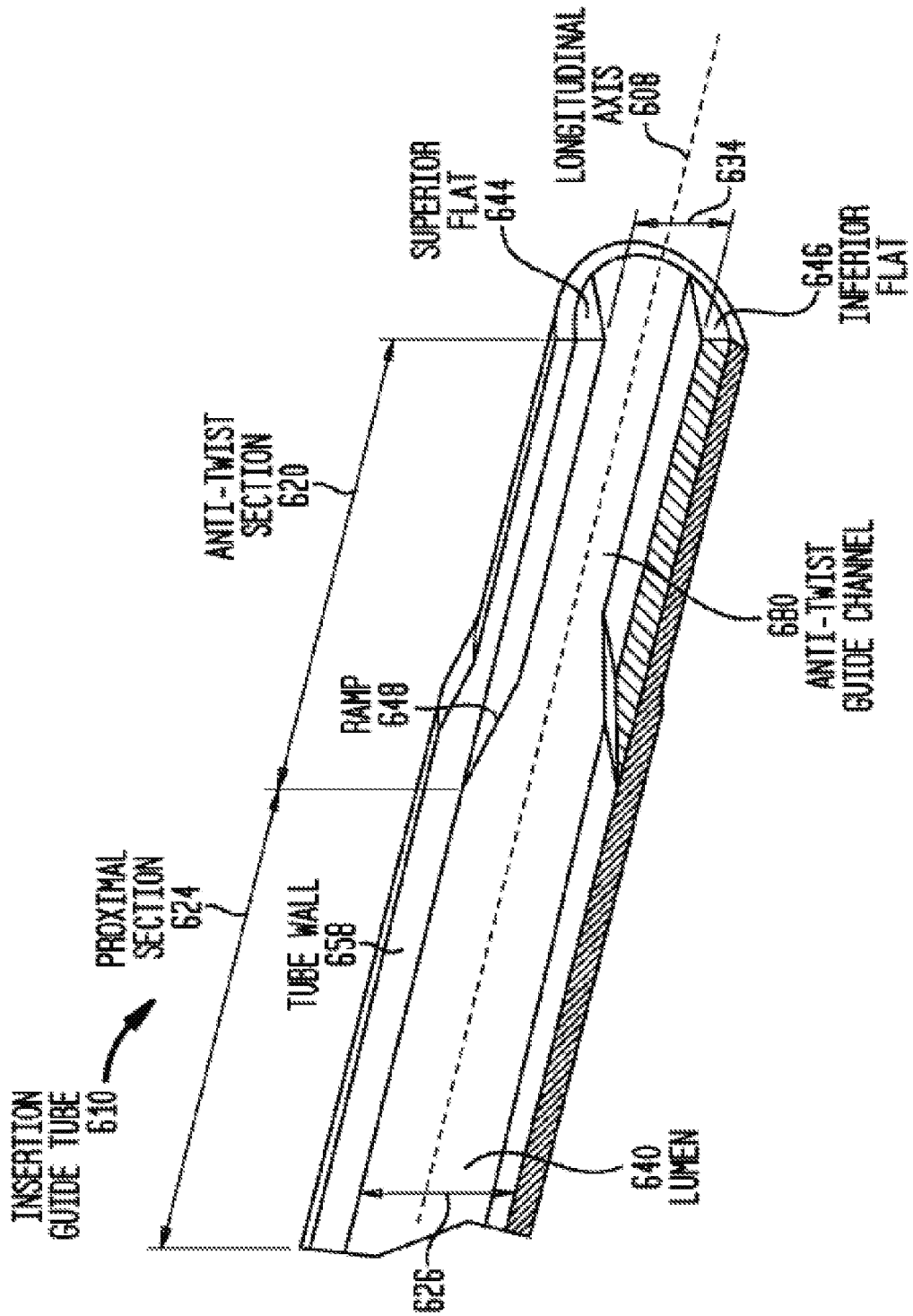

INSERTION GUIDE TUBE 610
PROXIMAL SECTION 624
TUBE WALL 658
ANTI-TWIST SECTION 620
RAMP 648
SUPERIOR FLAT 644
LONGITUDINAL AXIS 608
634
646 INFERIOR FLAT
680 ANTI-TWIST GUIDE CHANNEL
640 LUMEN
626

FIG. 6B

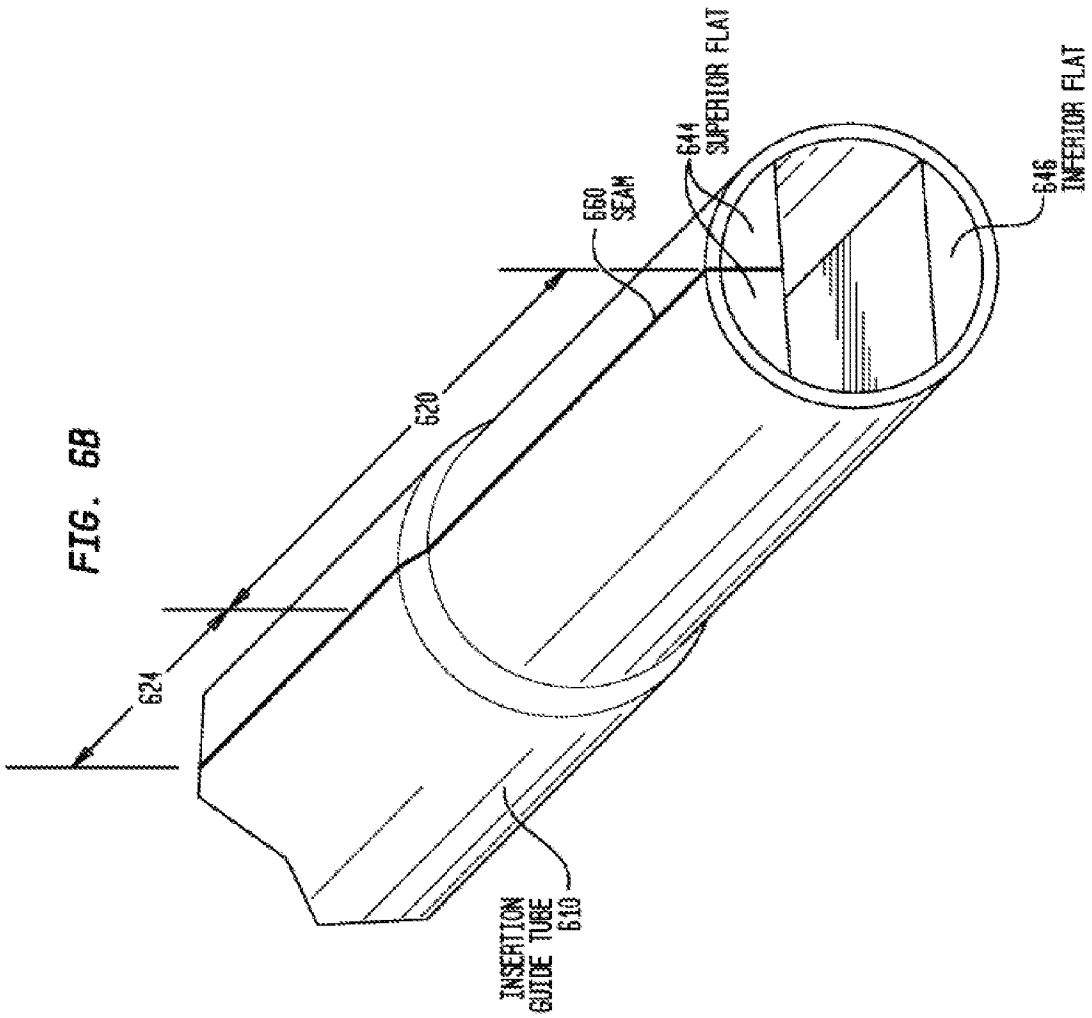

644
SUPERIOR FLAT
646
INFERIOR FLAT
660
SEAM
620
624
INSERTION
GUIDE TUBE
610

FIG. 6C

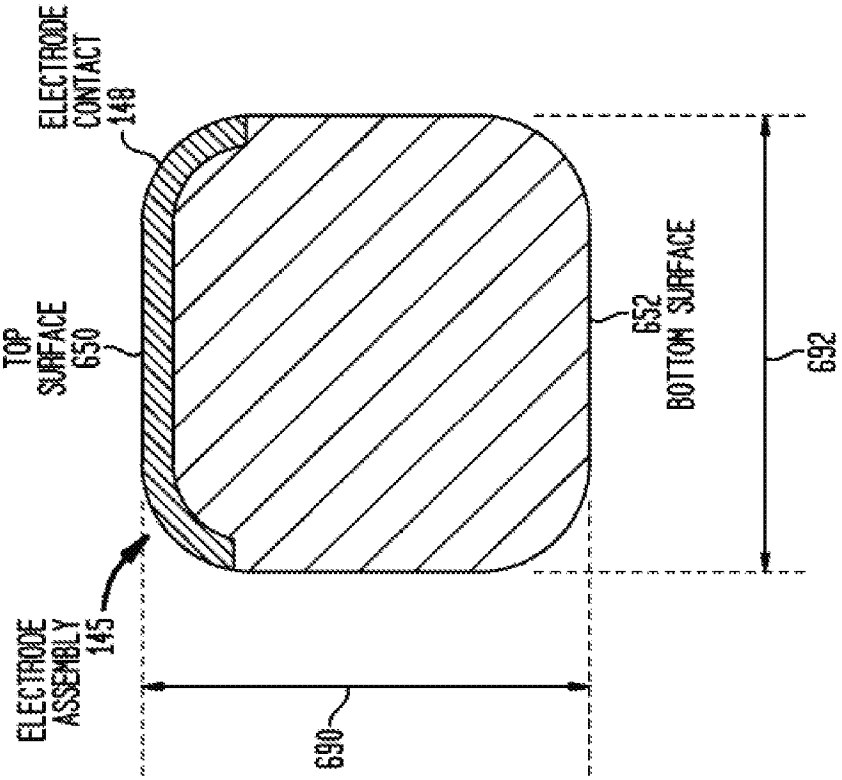

ELECTRODE CONTACT 148
TOP SURFACE 650
652 BOTTOM SURFACE
692
ELECTRODE ASSEMBLY 145
690

FIG. 6D

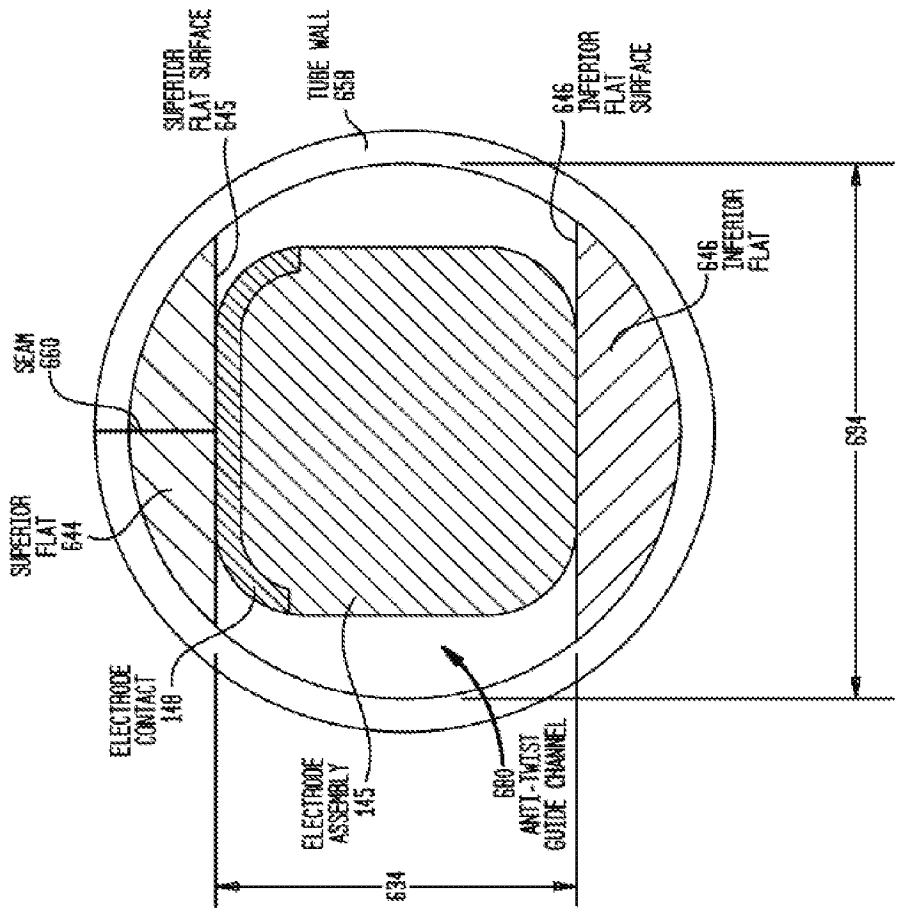

SUPERIOR FLAT SURFACE 645
TUBE WALL 650
646 INFERIOR FLAT SURFACE
646 INFERIOR FLAT
SEAM 660
SUPERIOR FLAT 644
ELECTRODE CONTACT 140
ELECTRODE ASSEMBLY 145
680 ANTI-TWIST GUIDE CHANNEL
634
634

FIG. 7

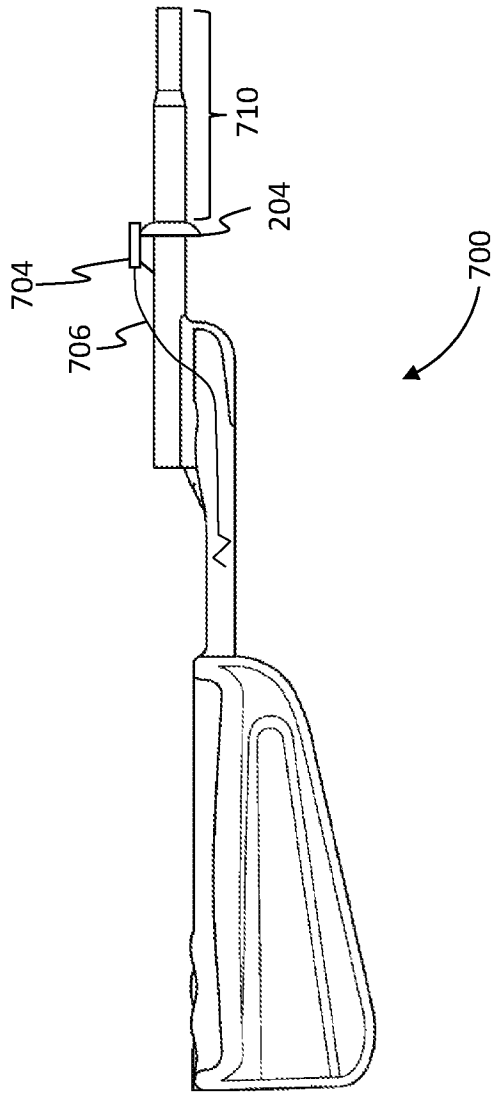


FIG. 8

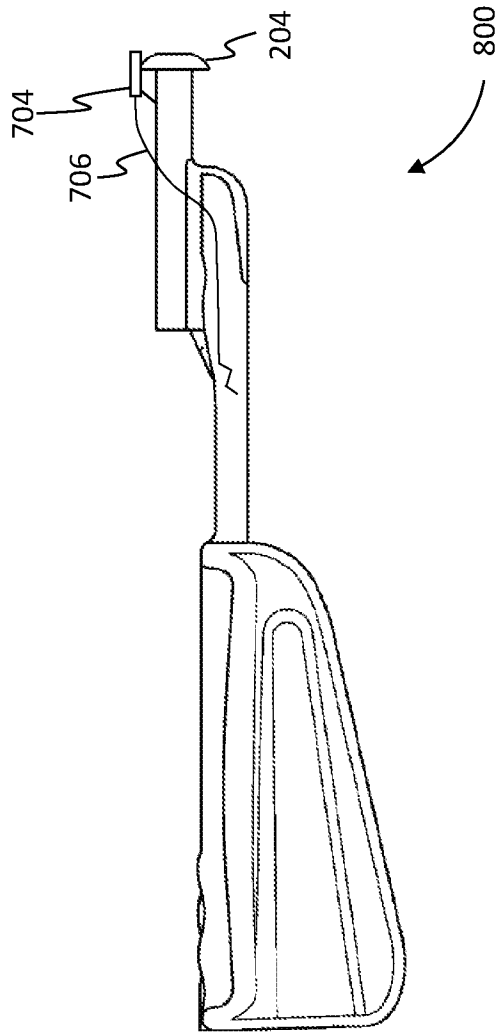


FIG. 9

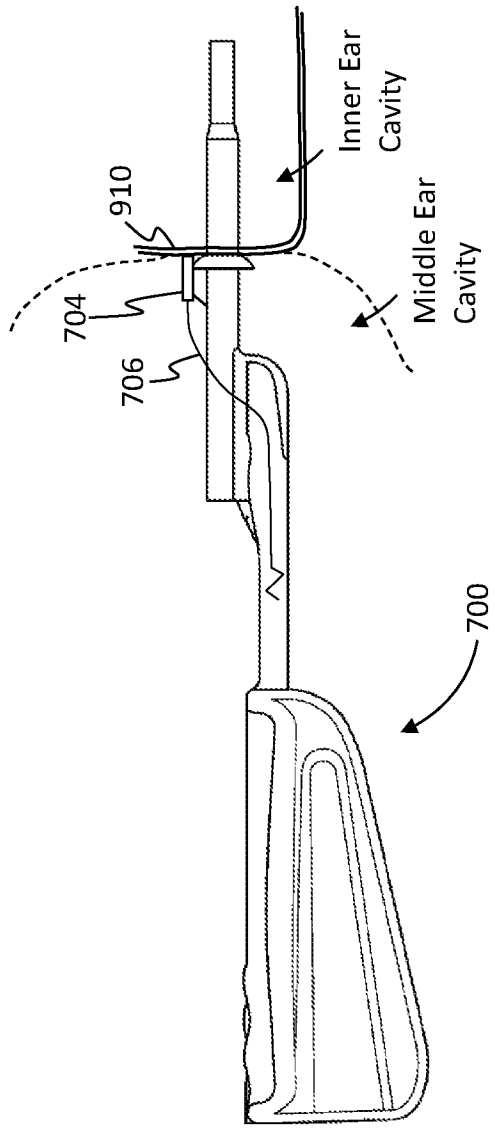


FIG. 10A

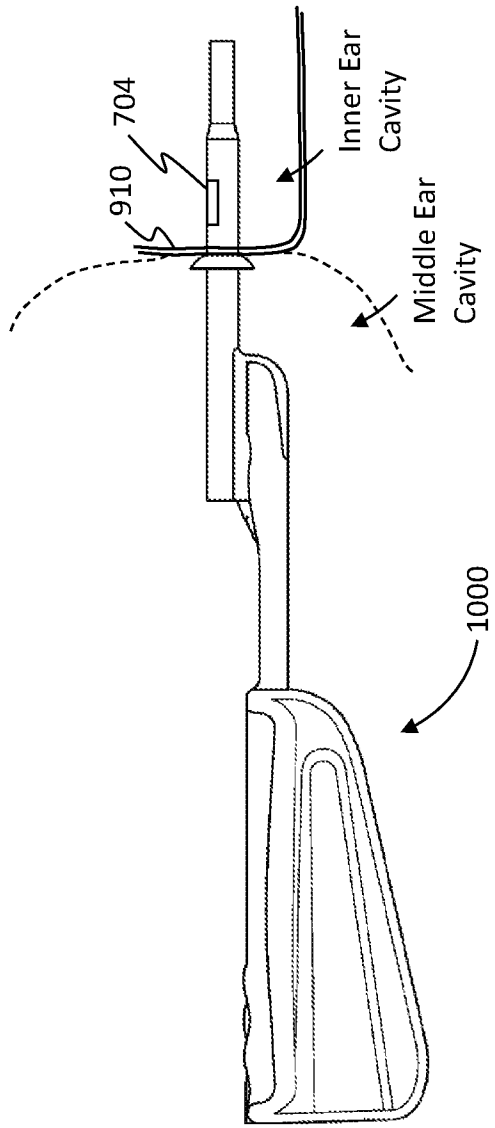


FIG. 10B

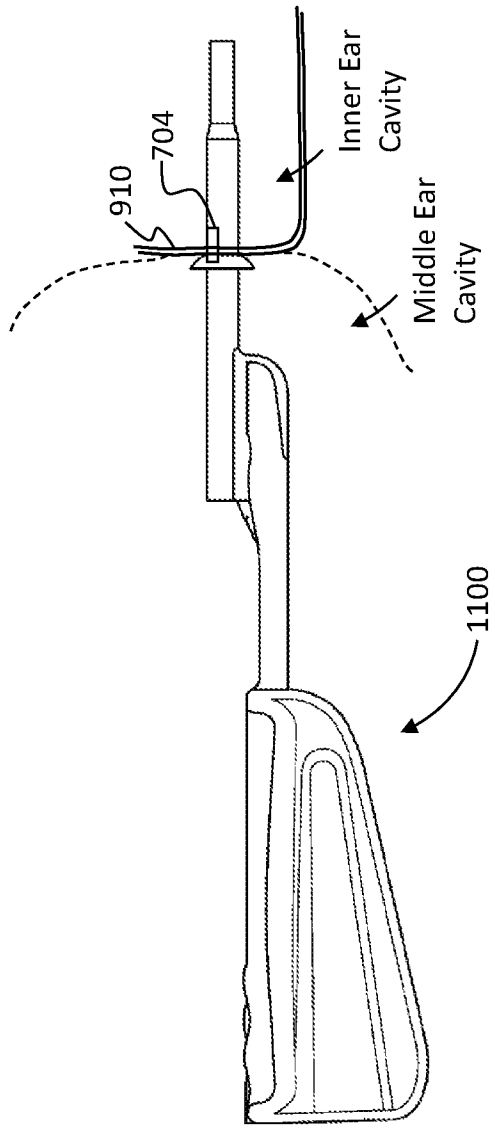


FIG. 11

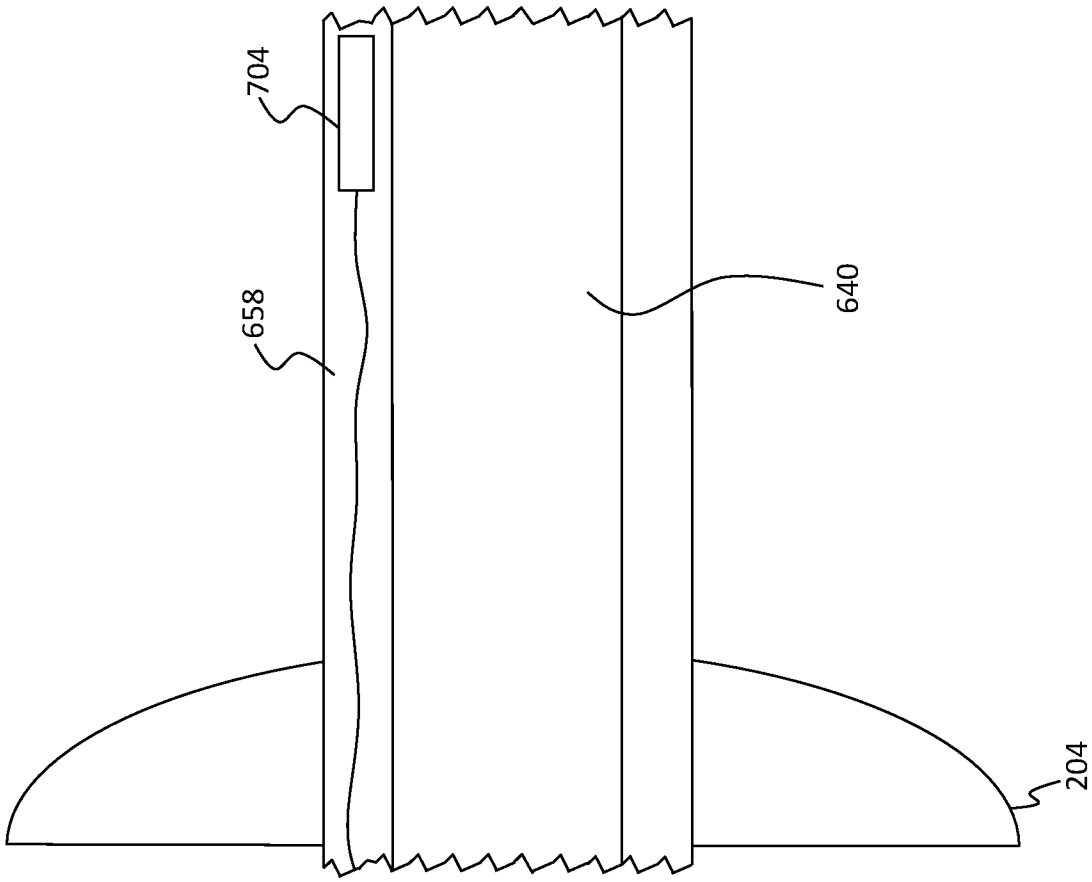


FIG. 12A

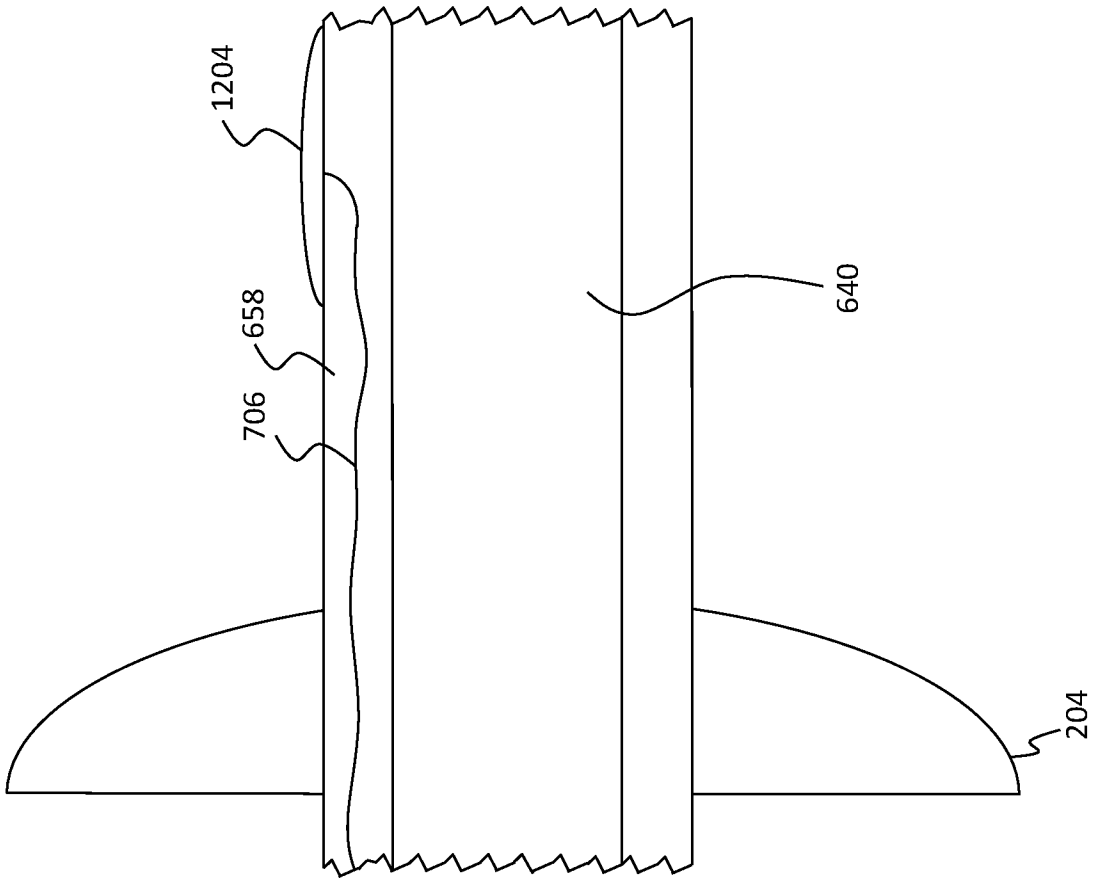


FIG. 12B

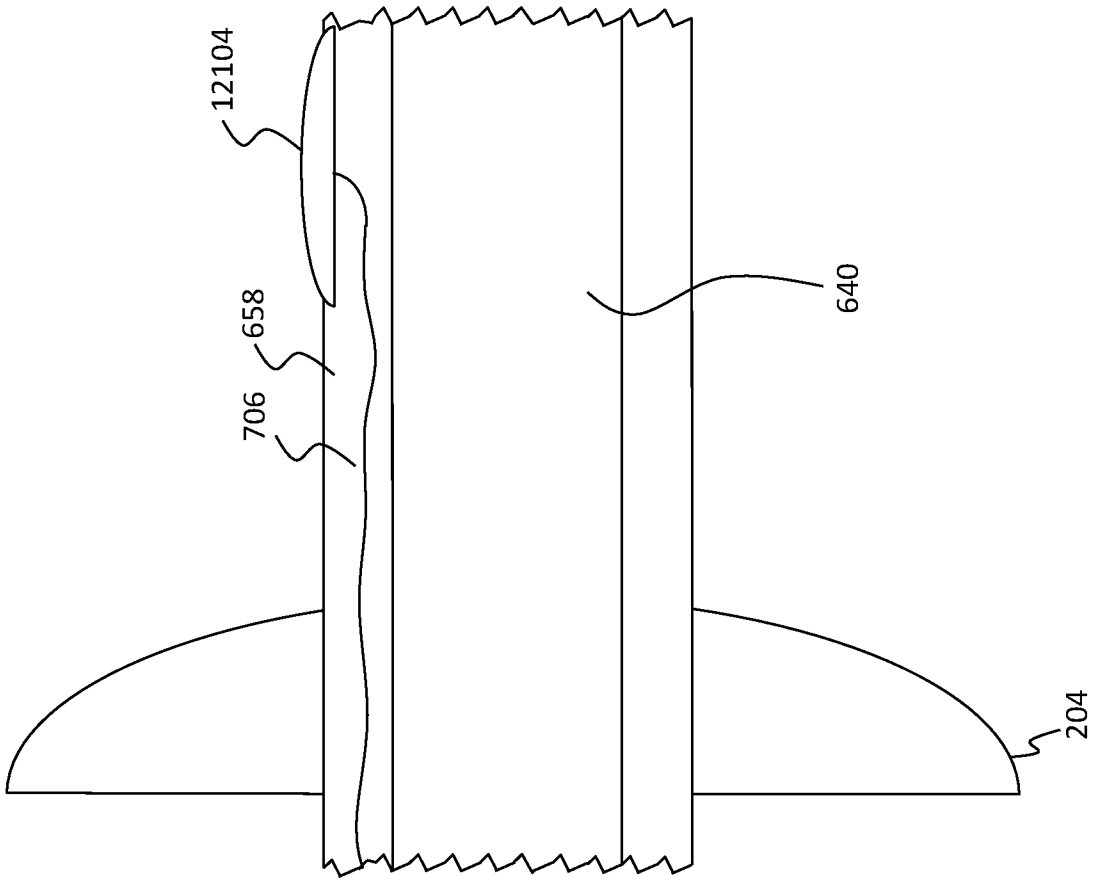


FIG. 12C

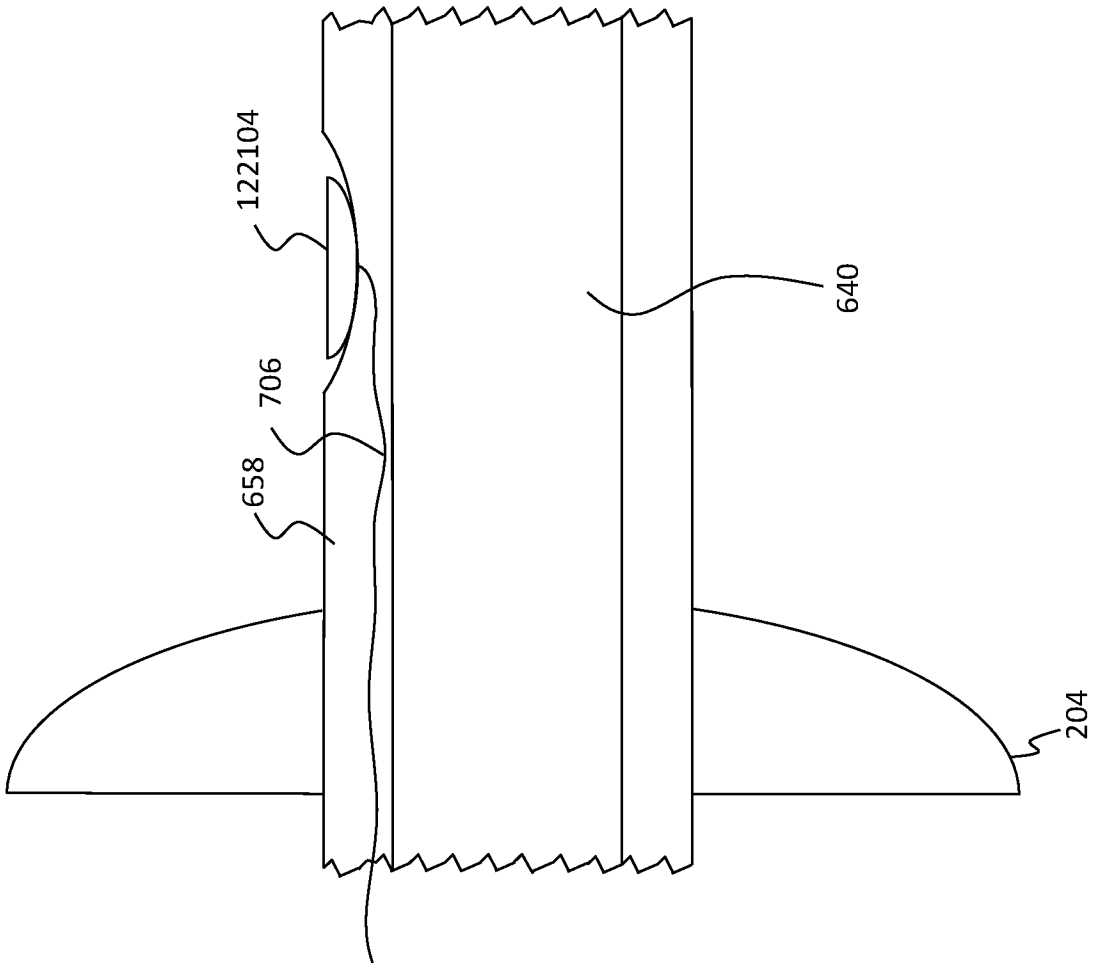


FIG. 13

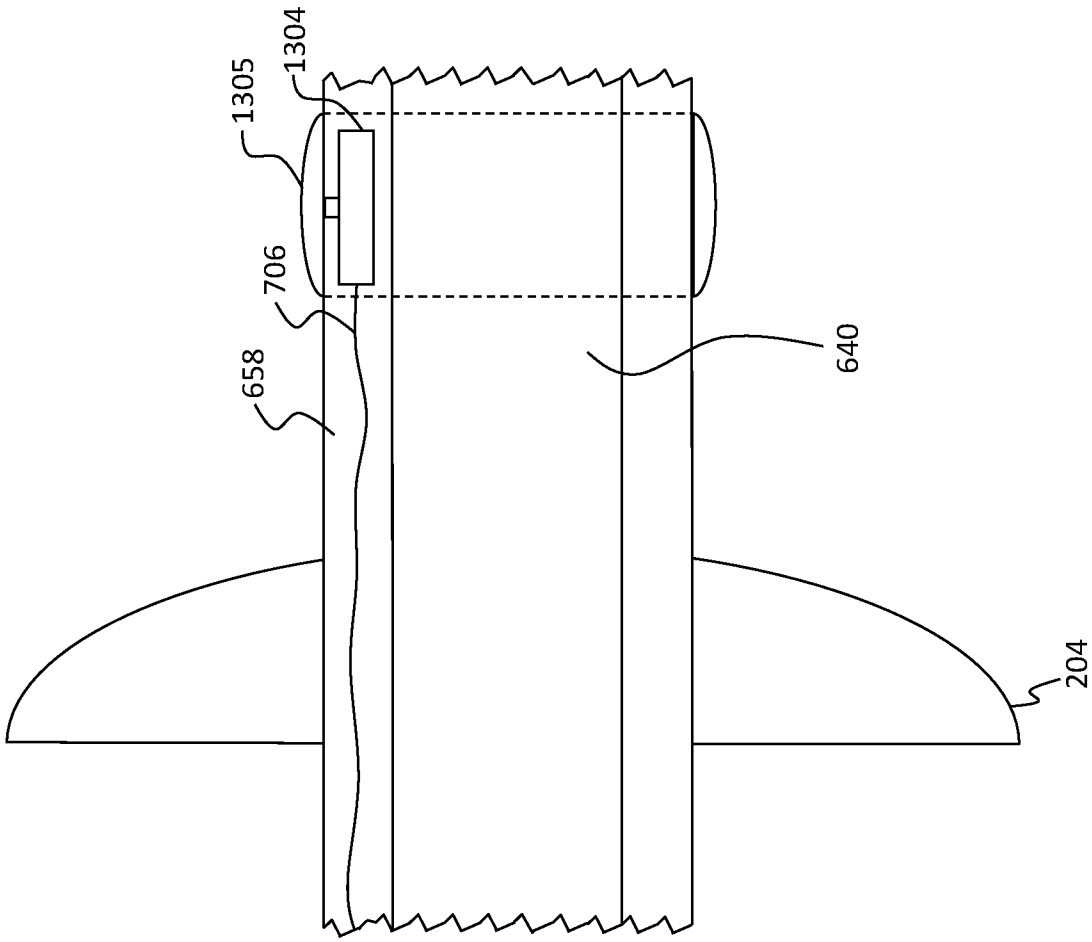


FIG. 14

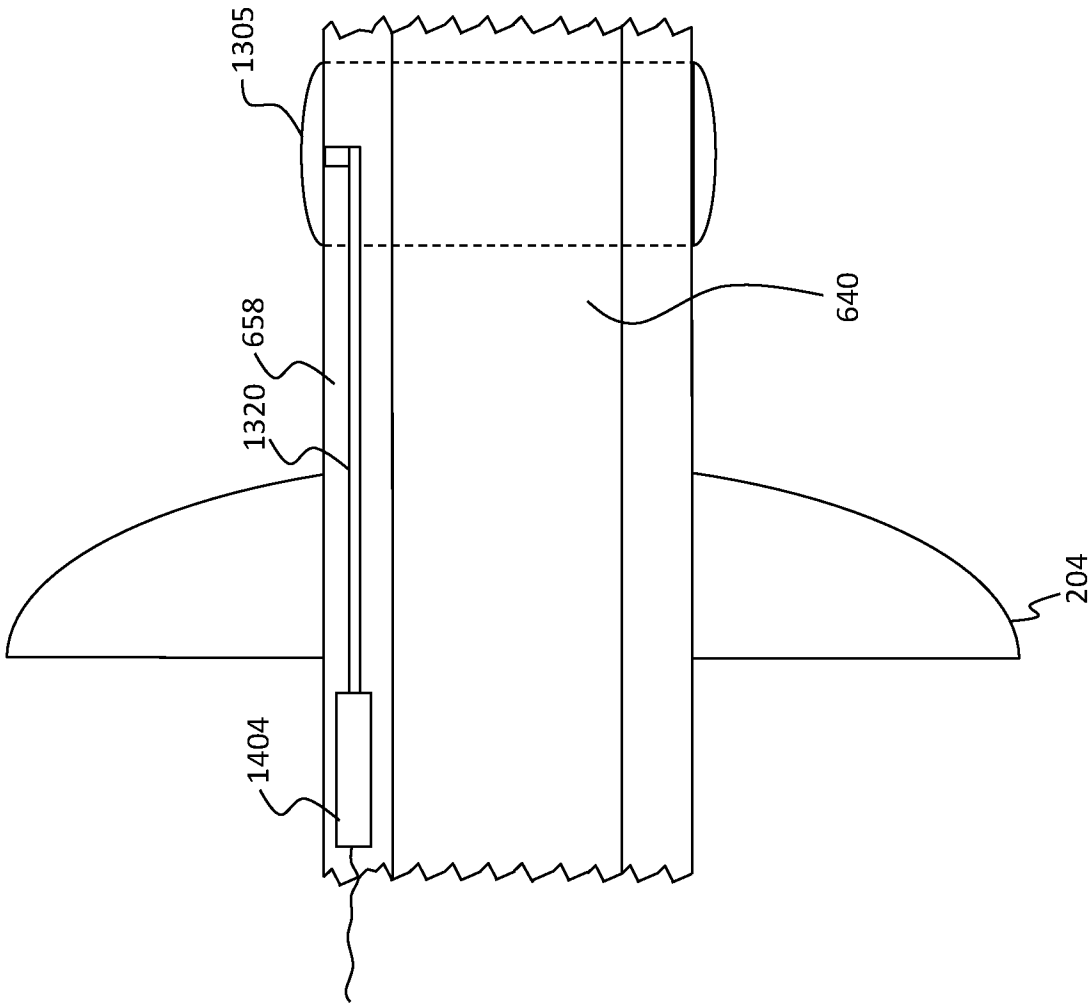


FIG. 15

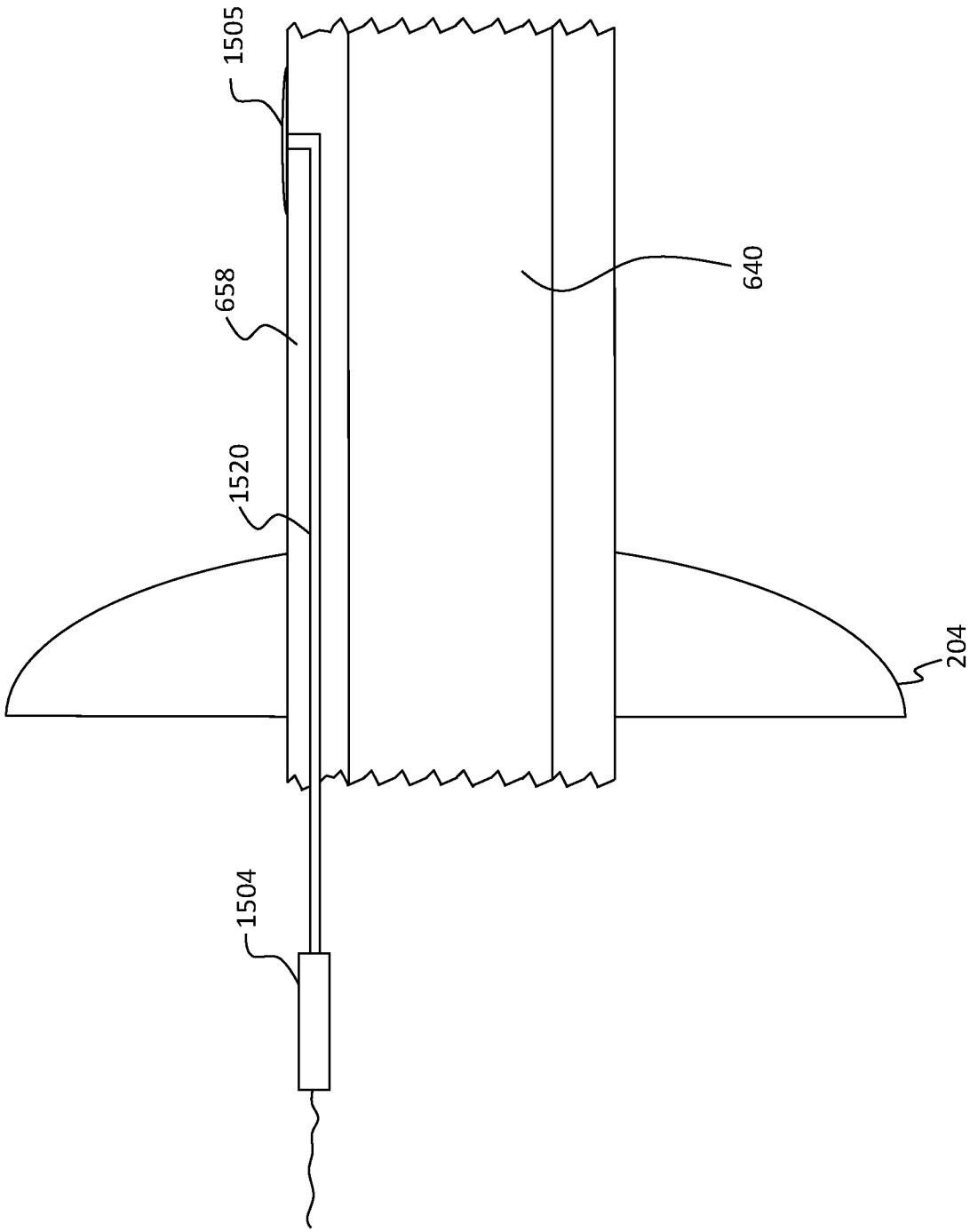
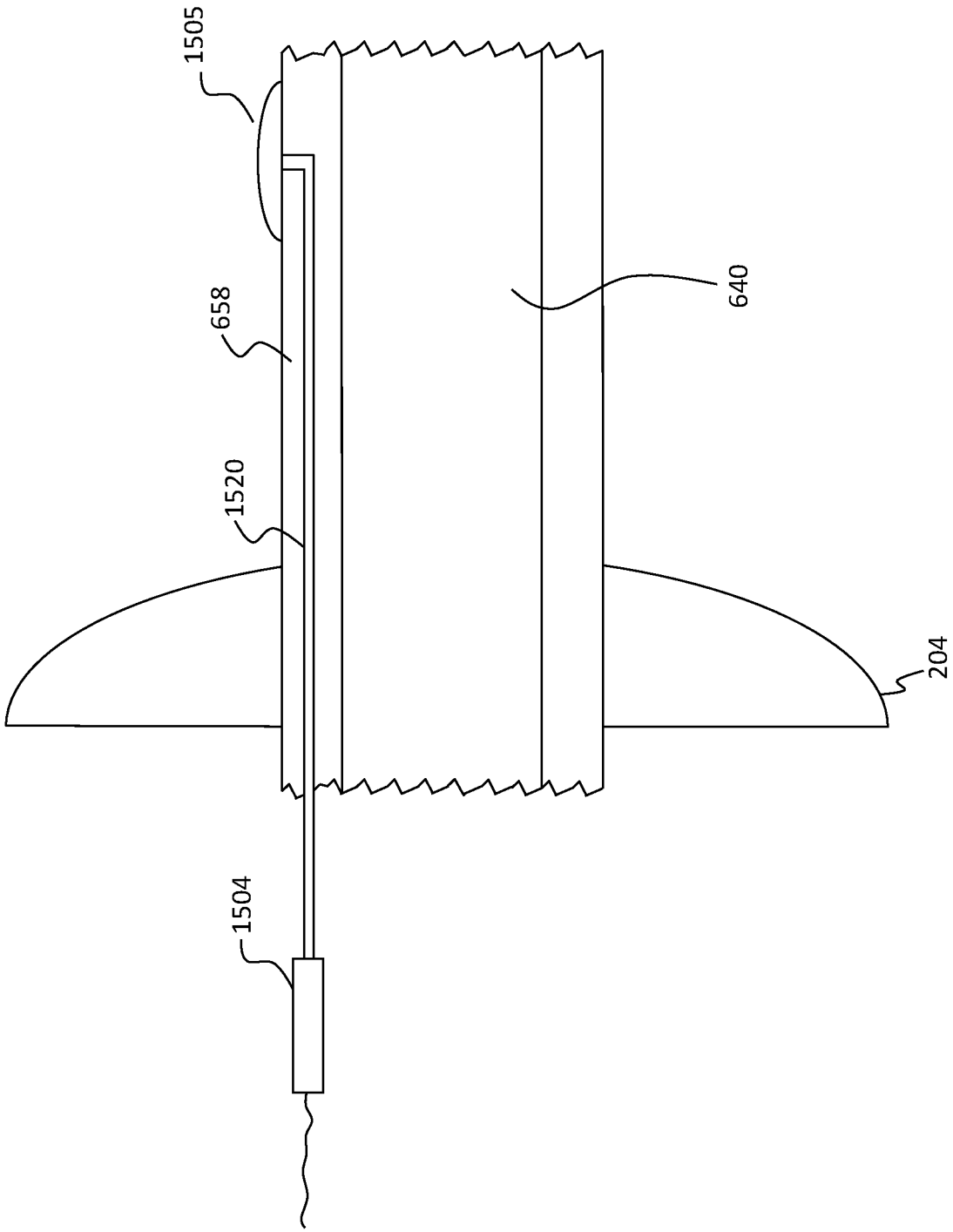


FIG. 16



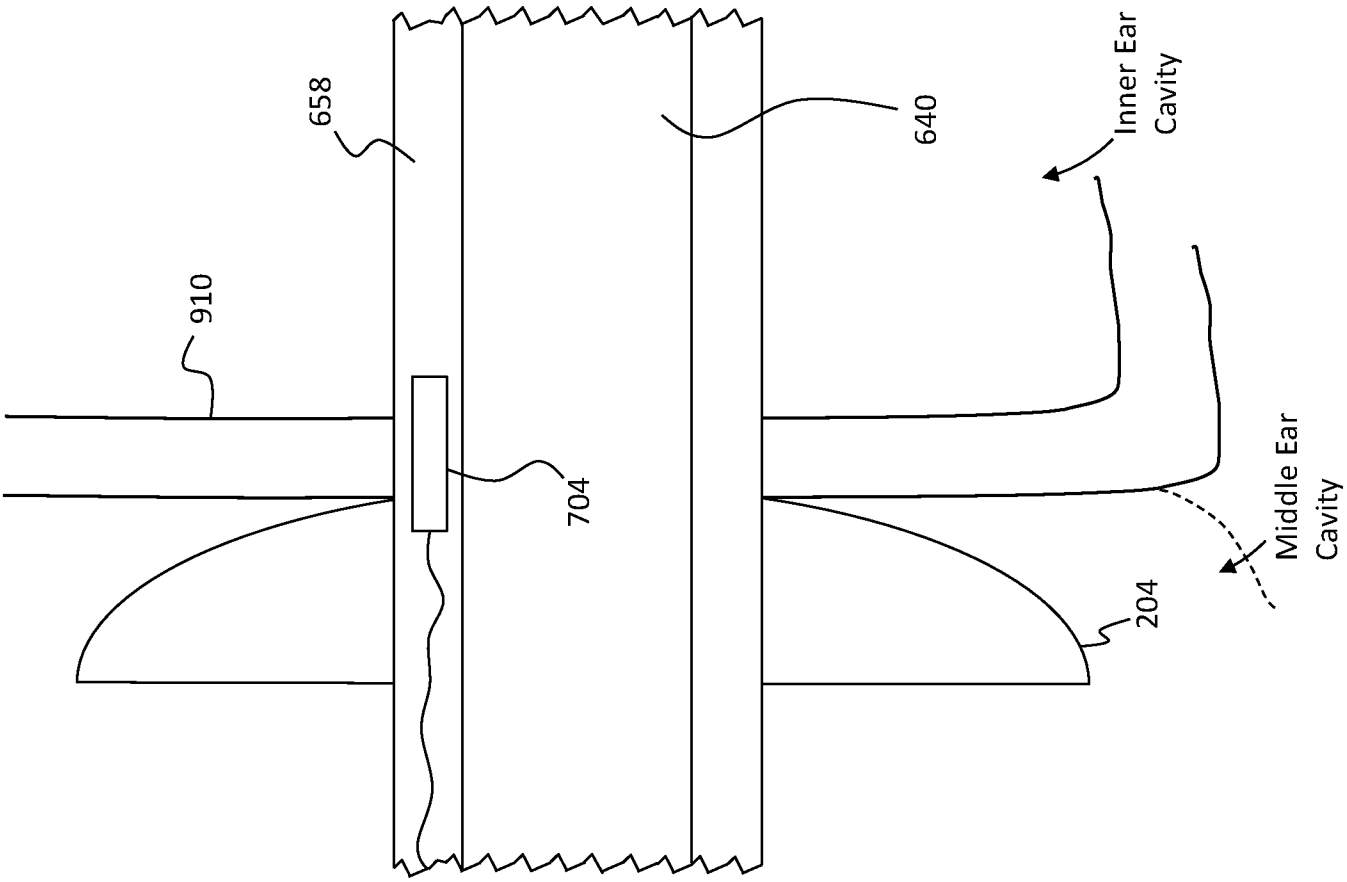


FIG. 17

FIG. 18

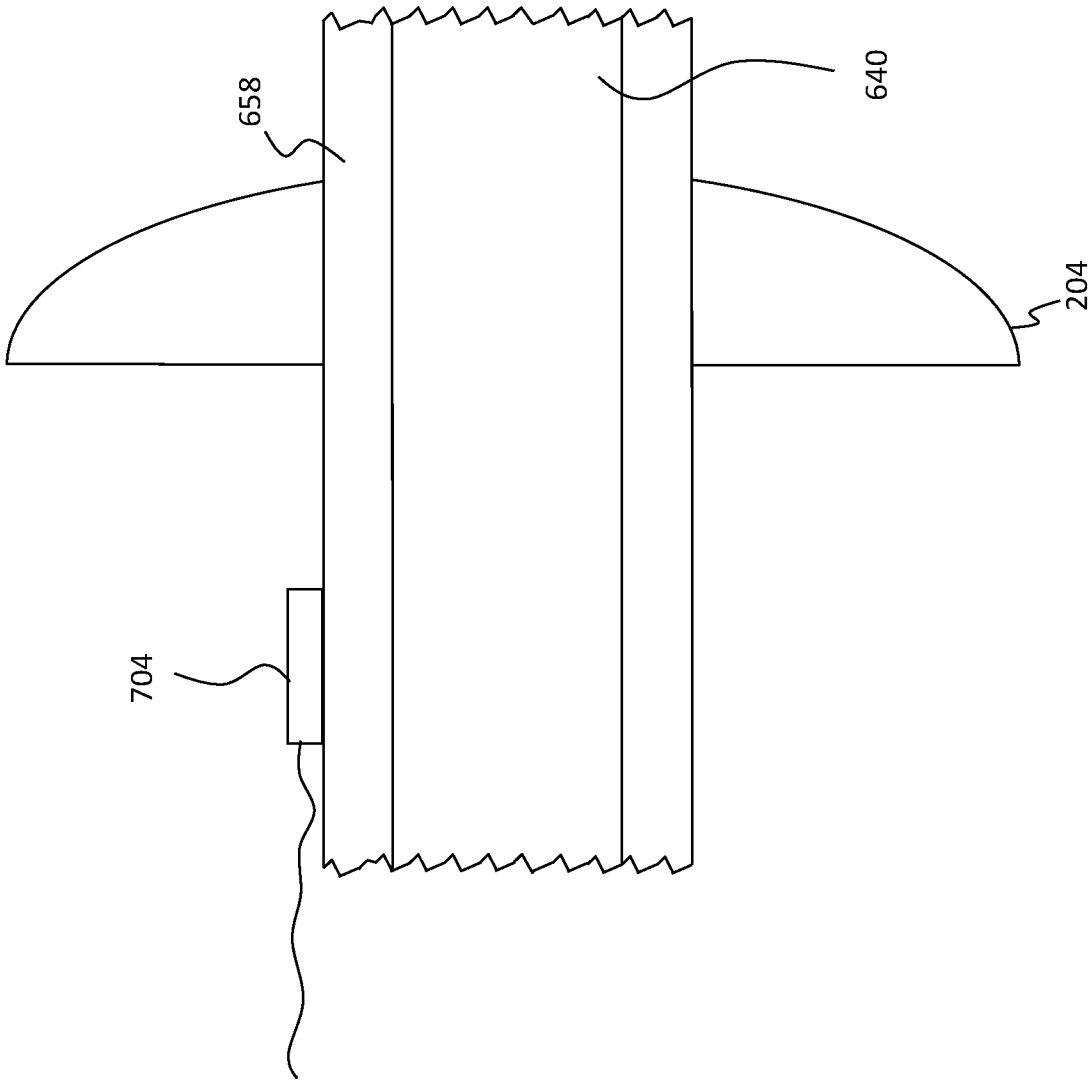


FIG. 19

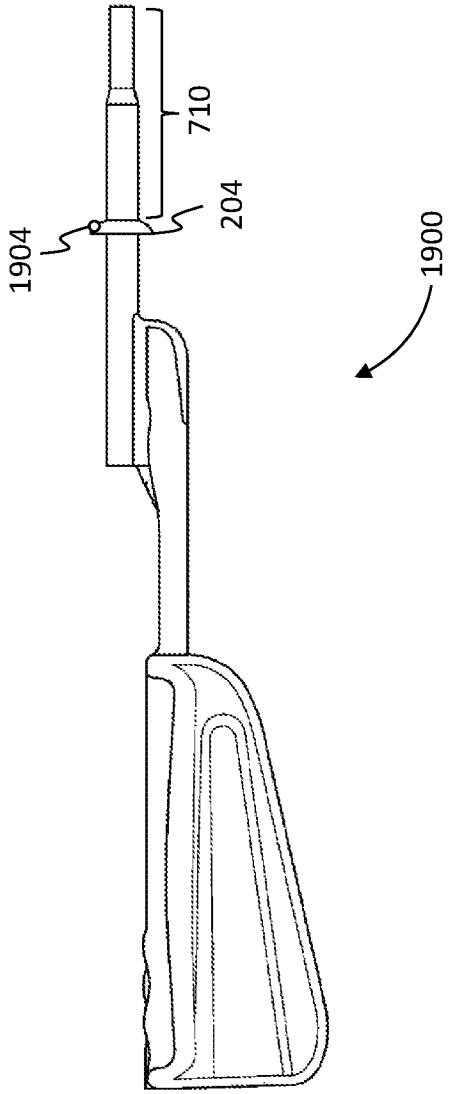
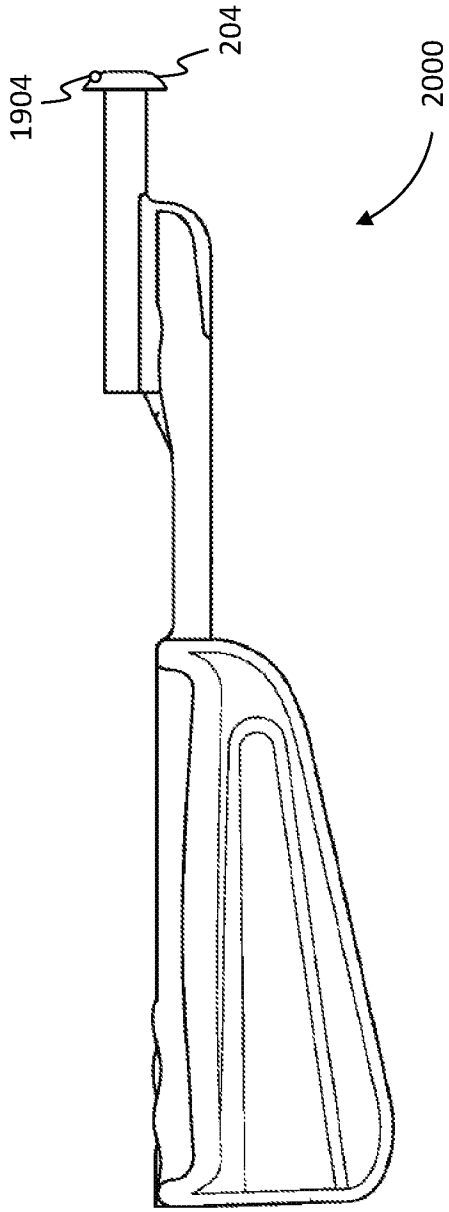


FIG. 20



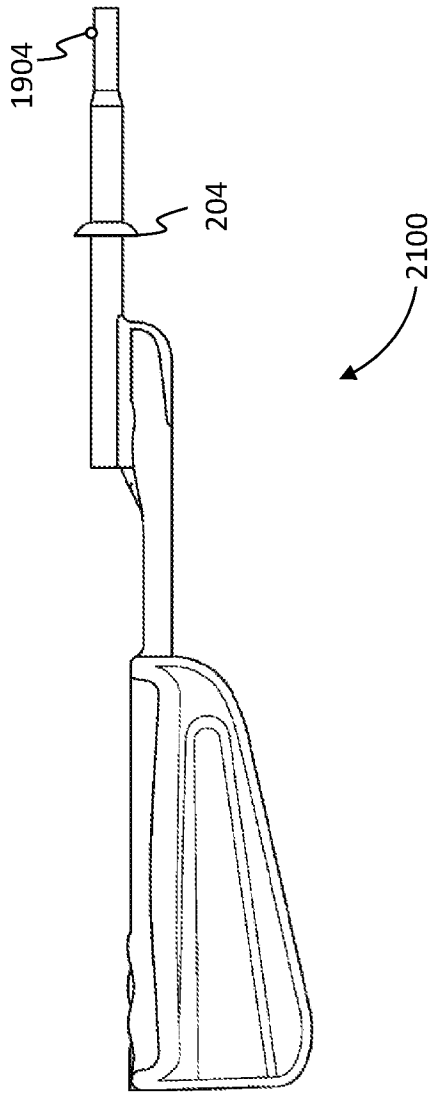


FIG. 21

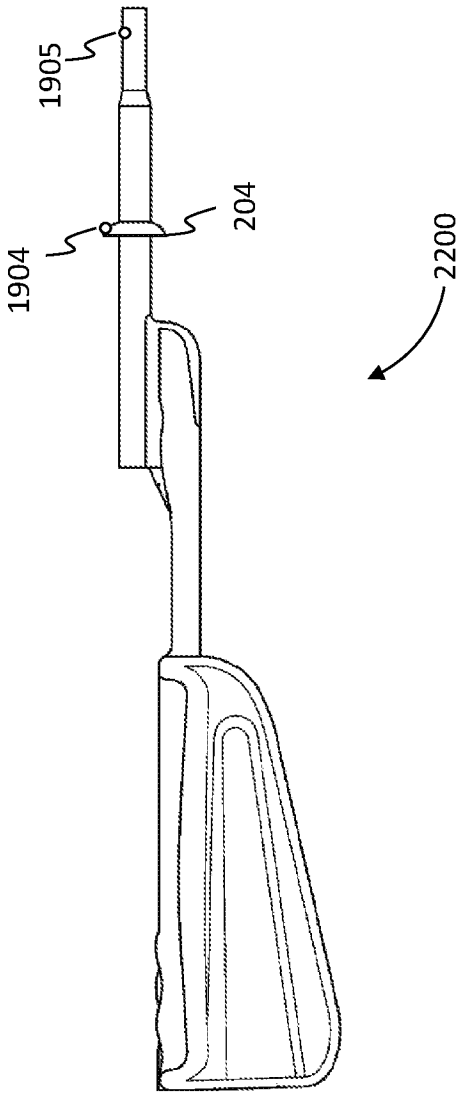


FIG. 22

FIG. 23

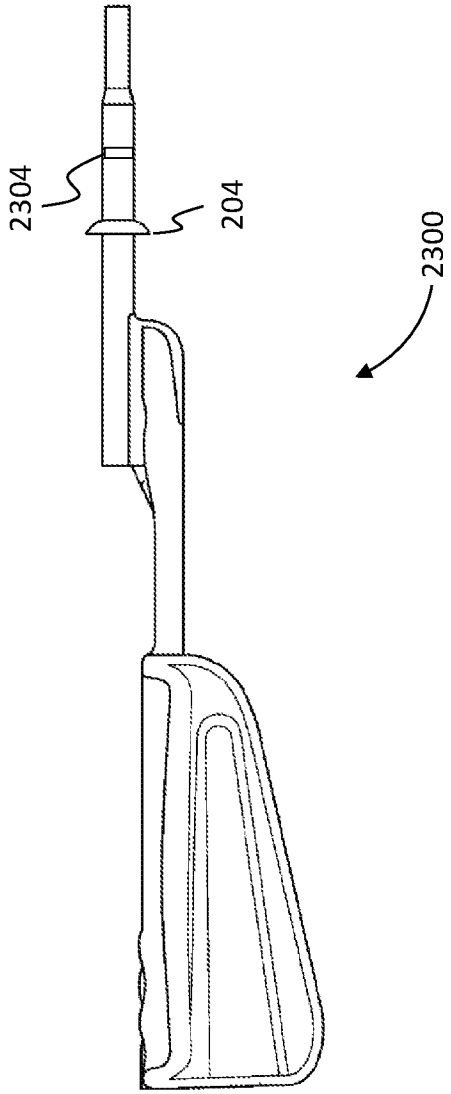
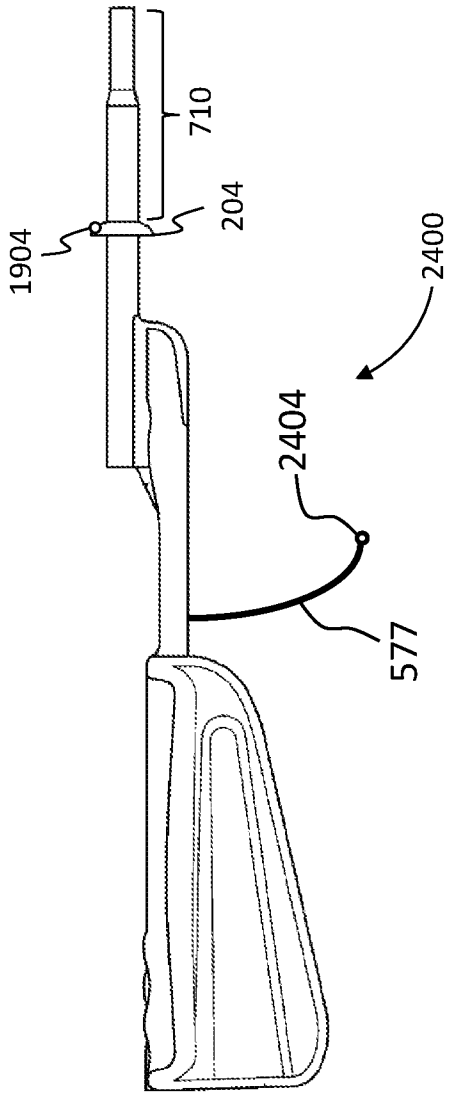


FIG. 24



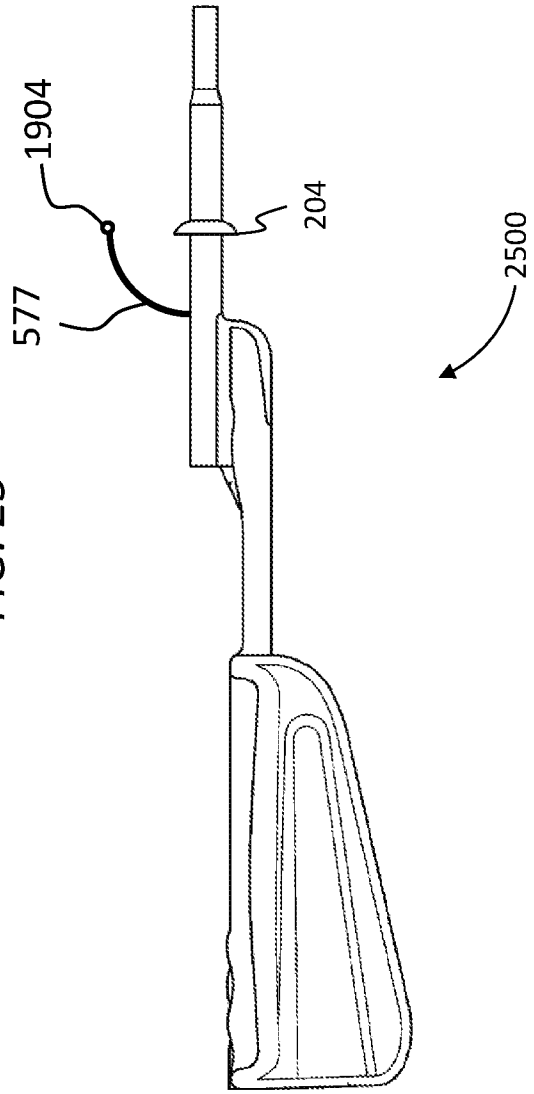


FIG. 25

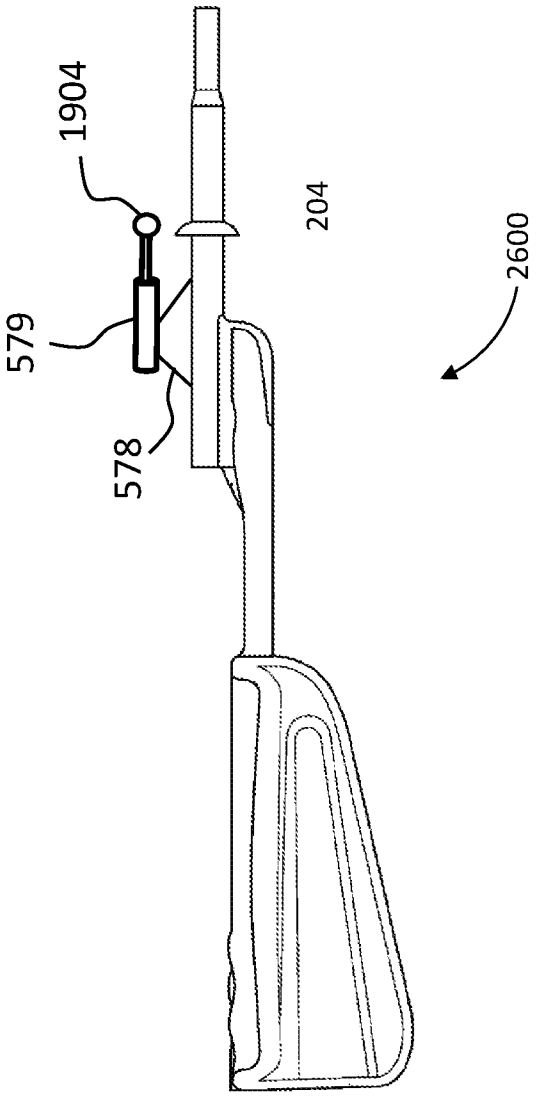


FIG. 26

FIG. 27

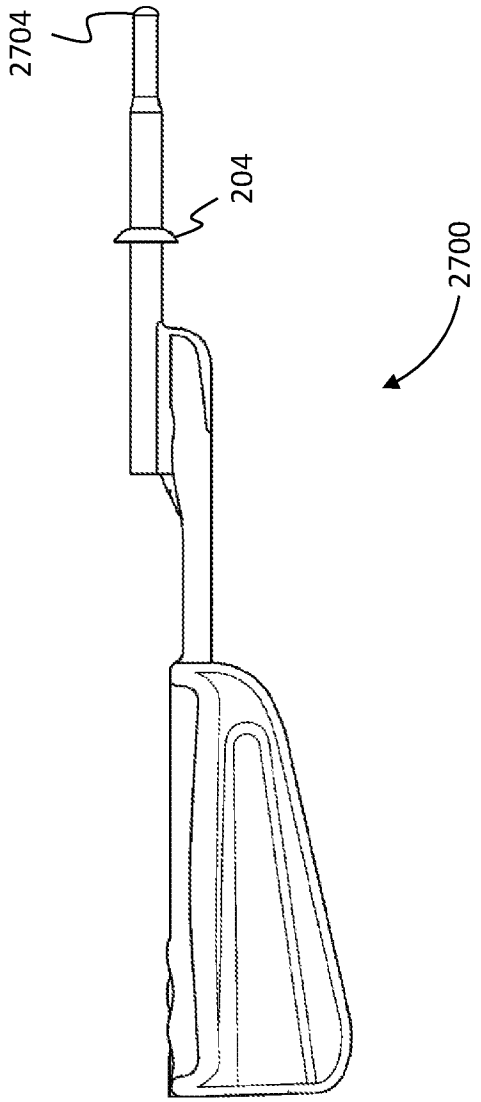

2704
204
2700

FIG. 28

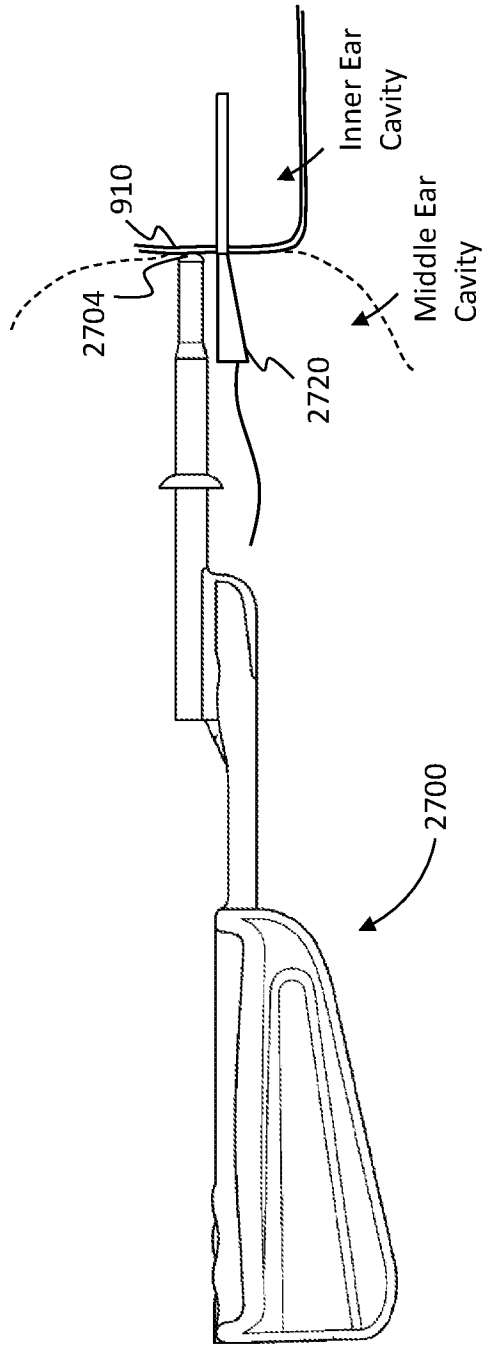

Inner Ear Cavity
910
Middle Ear Cavity
2704
2720
2700

FIG. 29

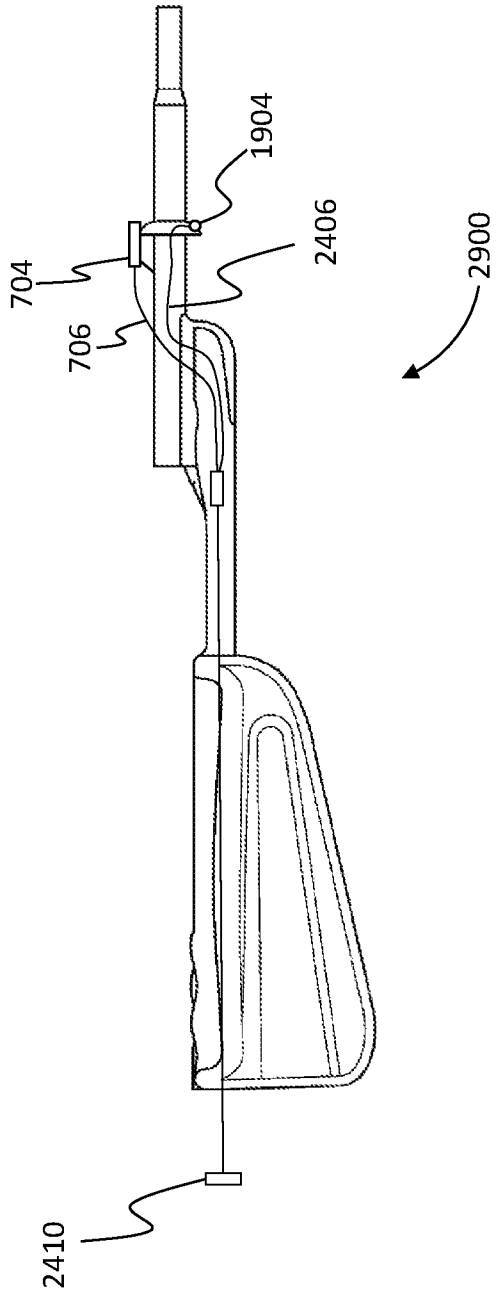


FIG. 30

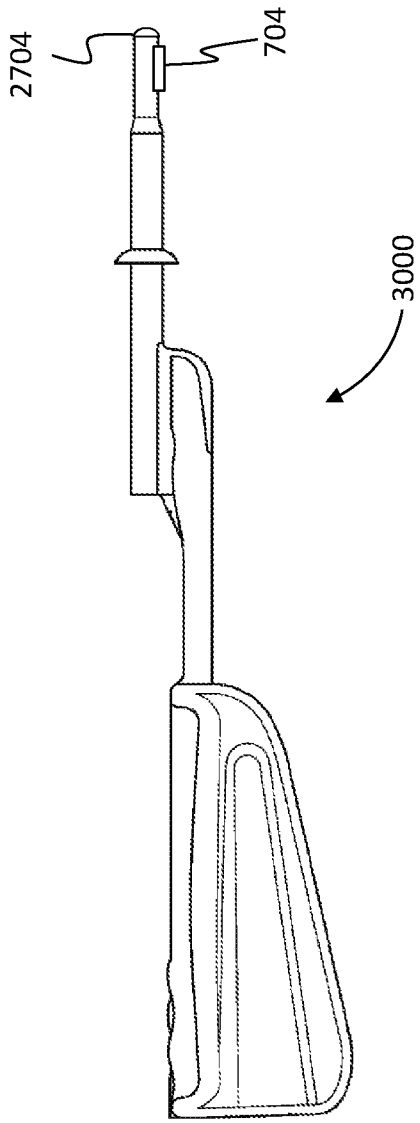


FIG. 31

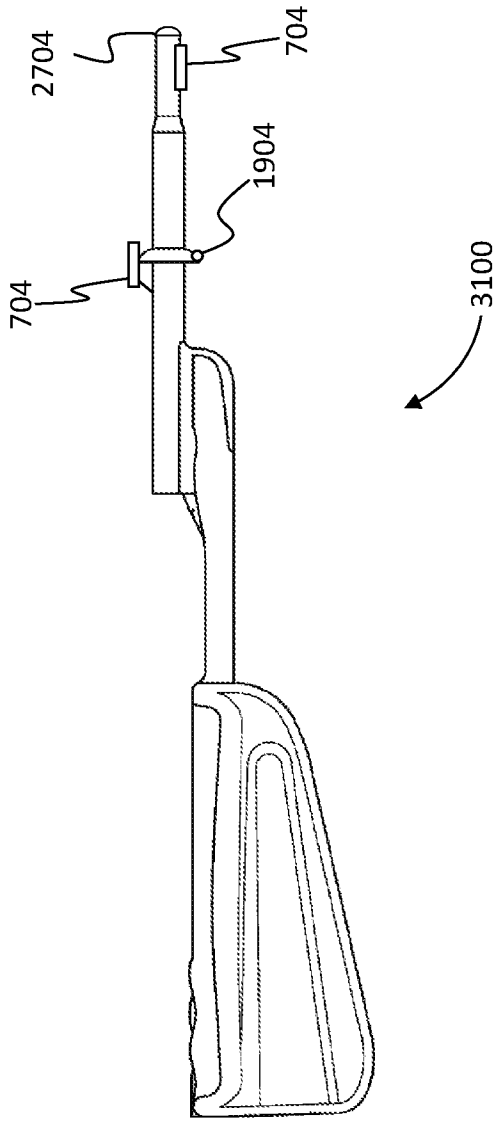
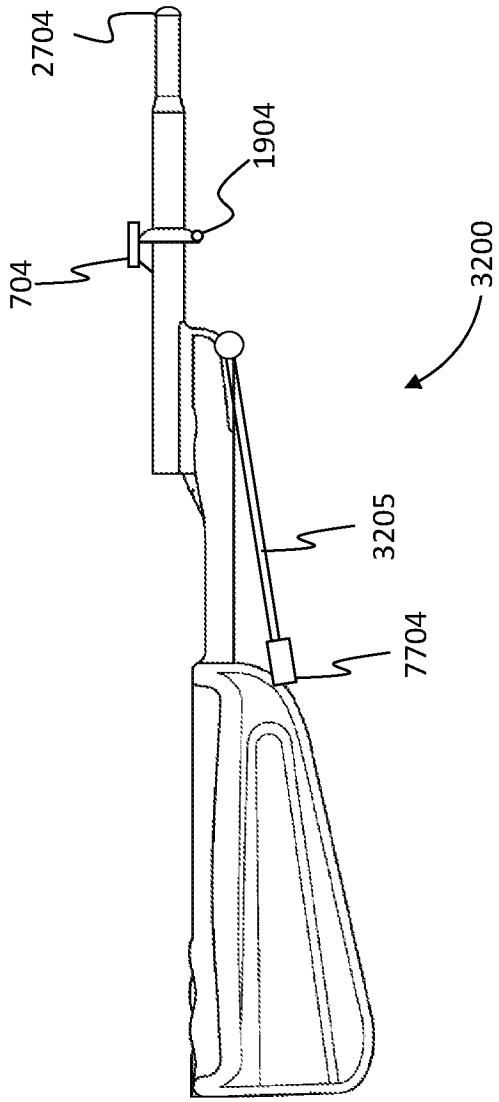


FIG. 32



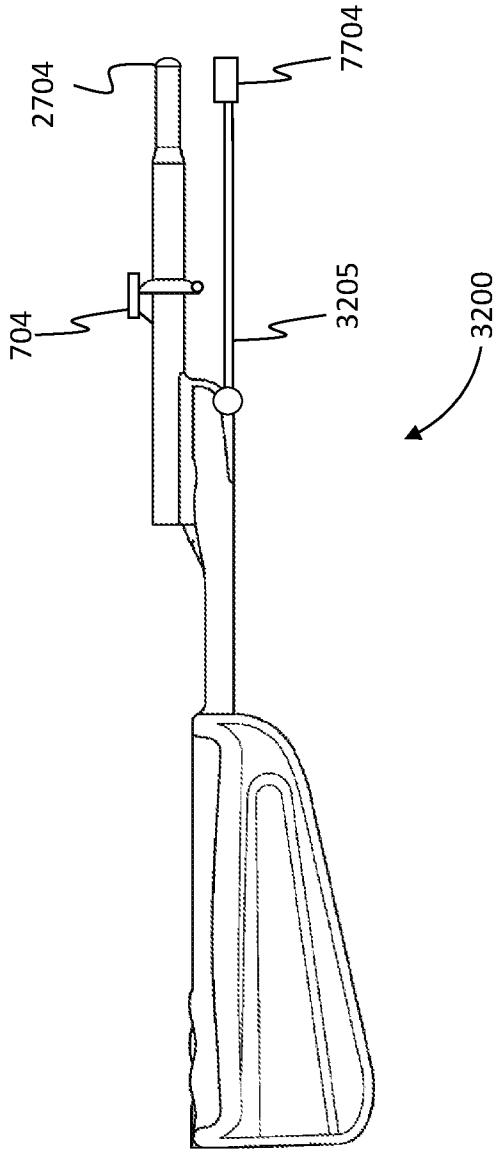
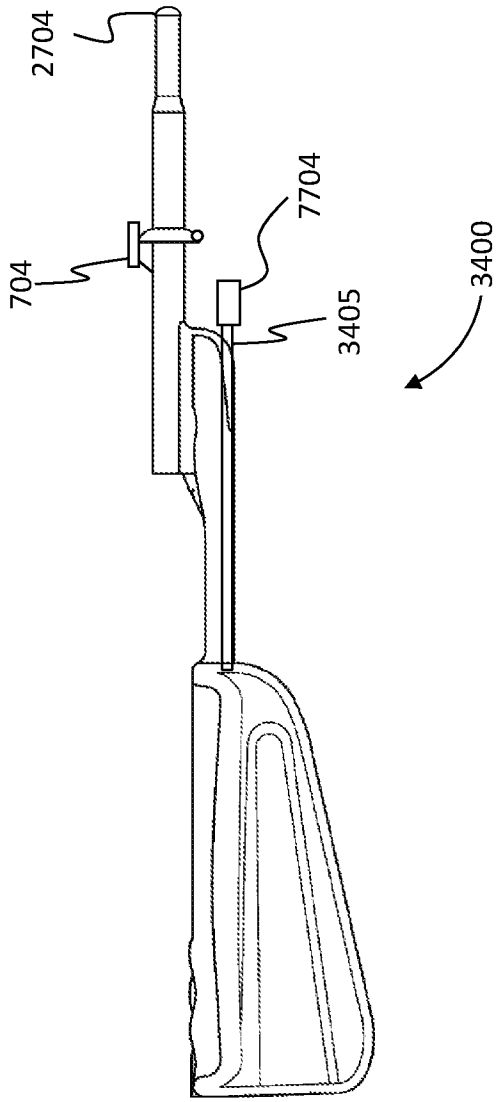


FIG. 33

FIG. 34



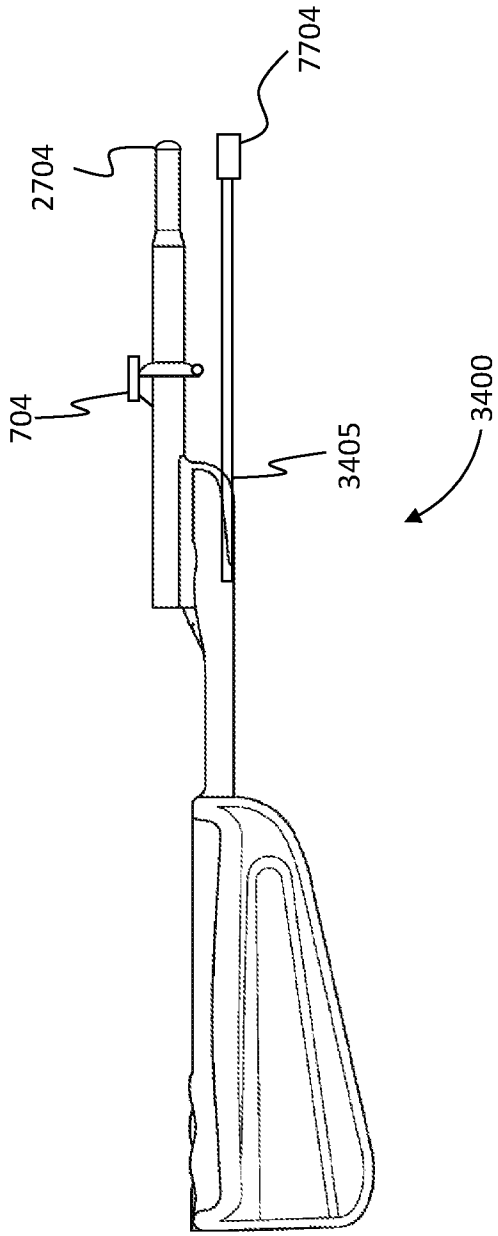


FIG. 35

FIG. 36

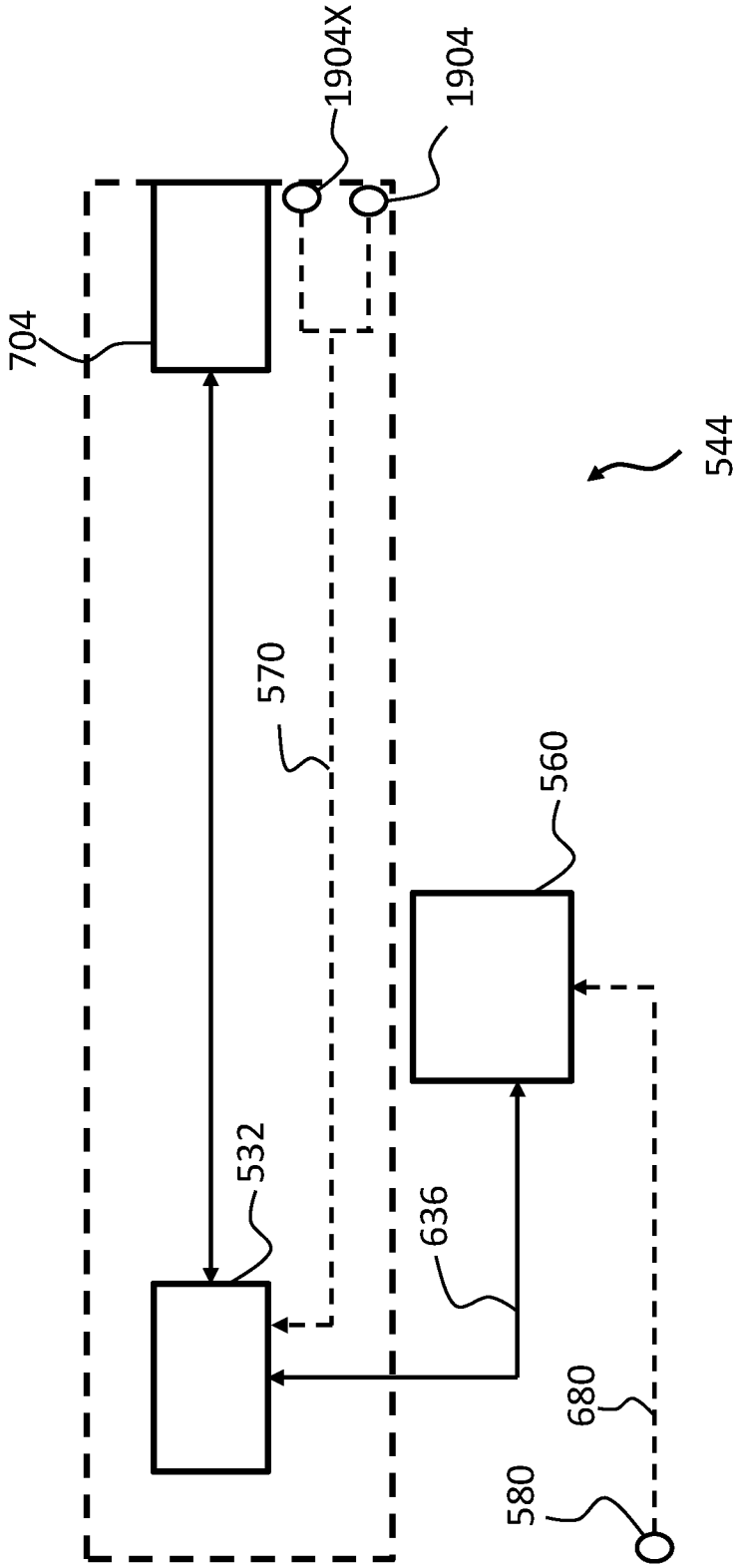


FIG. 37

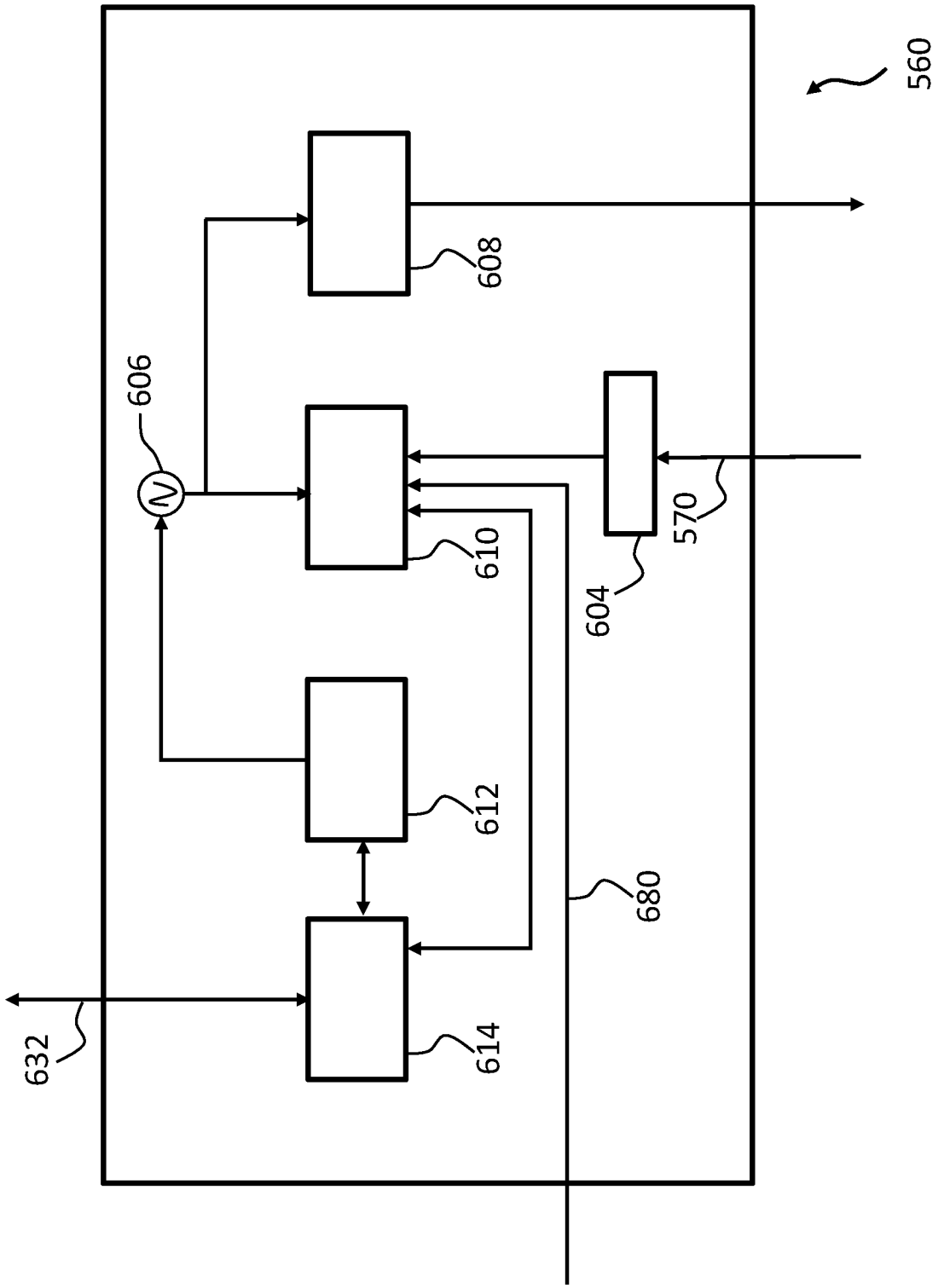


FIG. 38

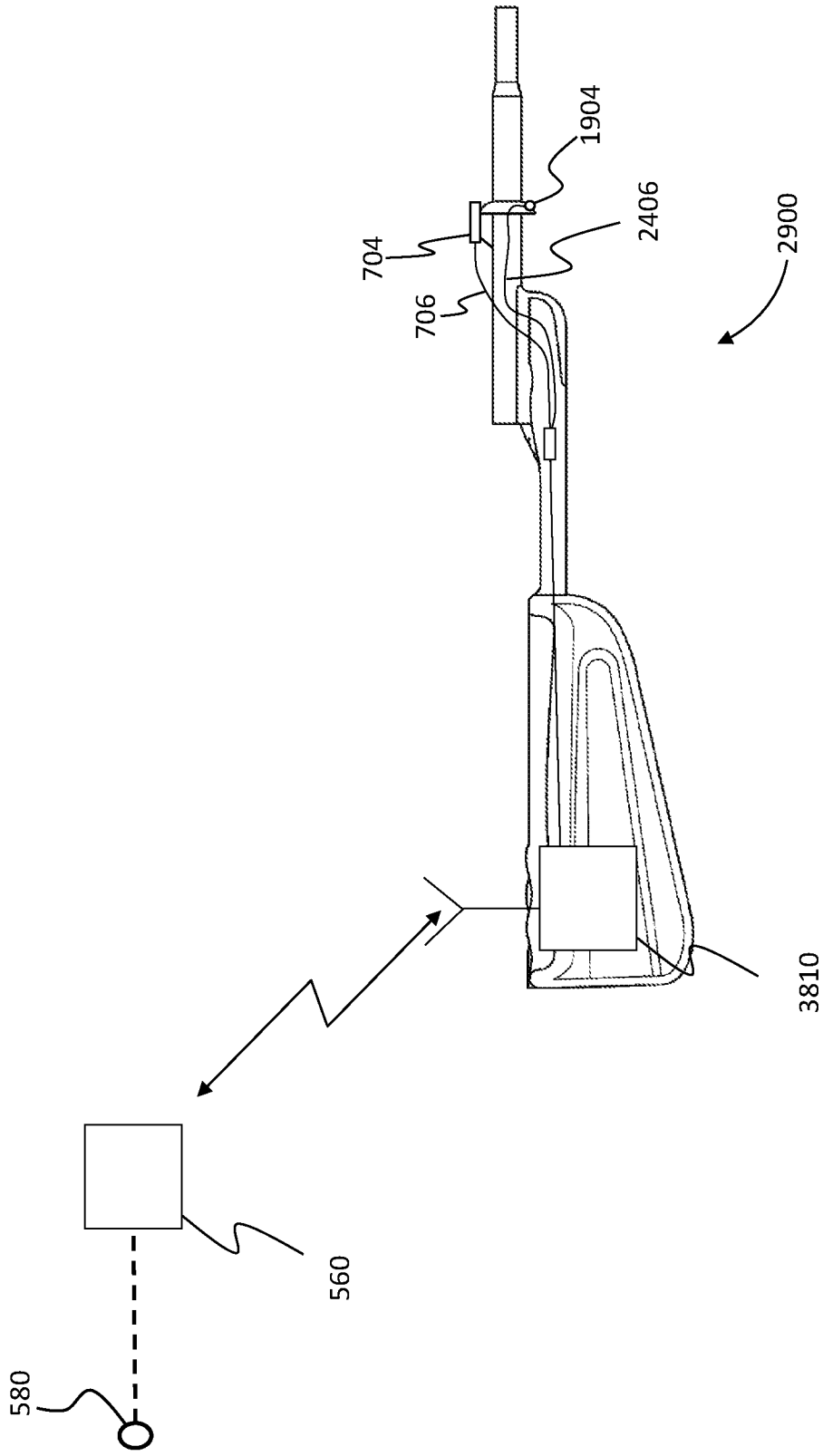


FIG. 39

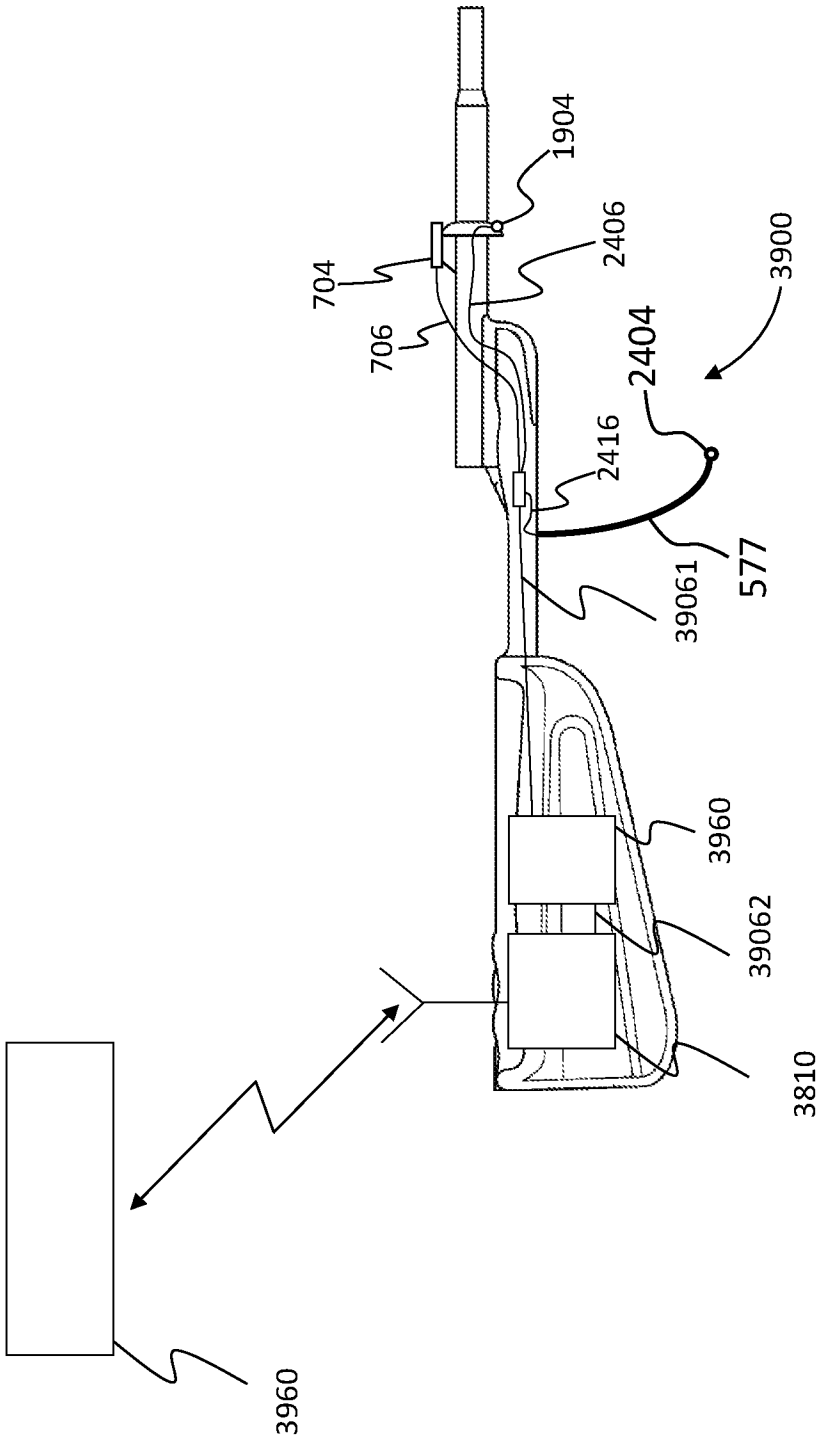

1904
2406
3900
704
706
2404
2416
39061
577
3960
39062
3810
3960

FIG. 40

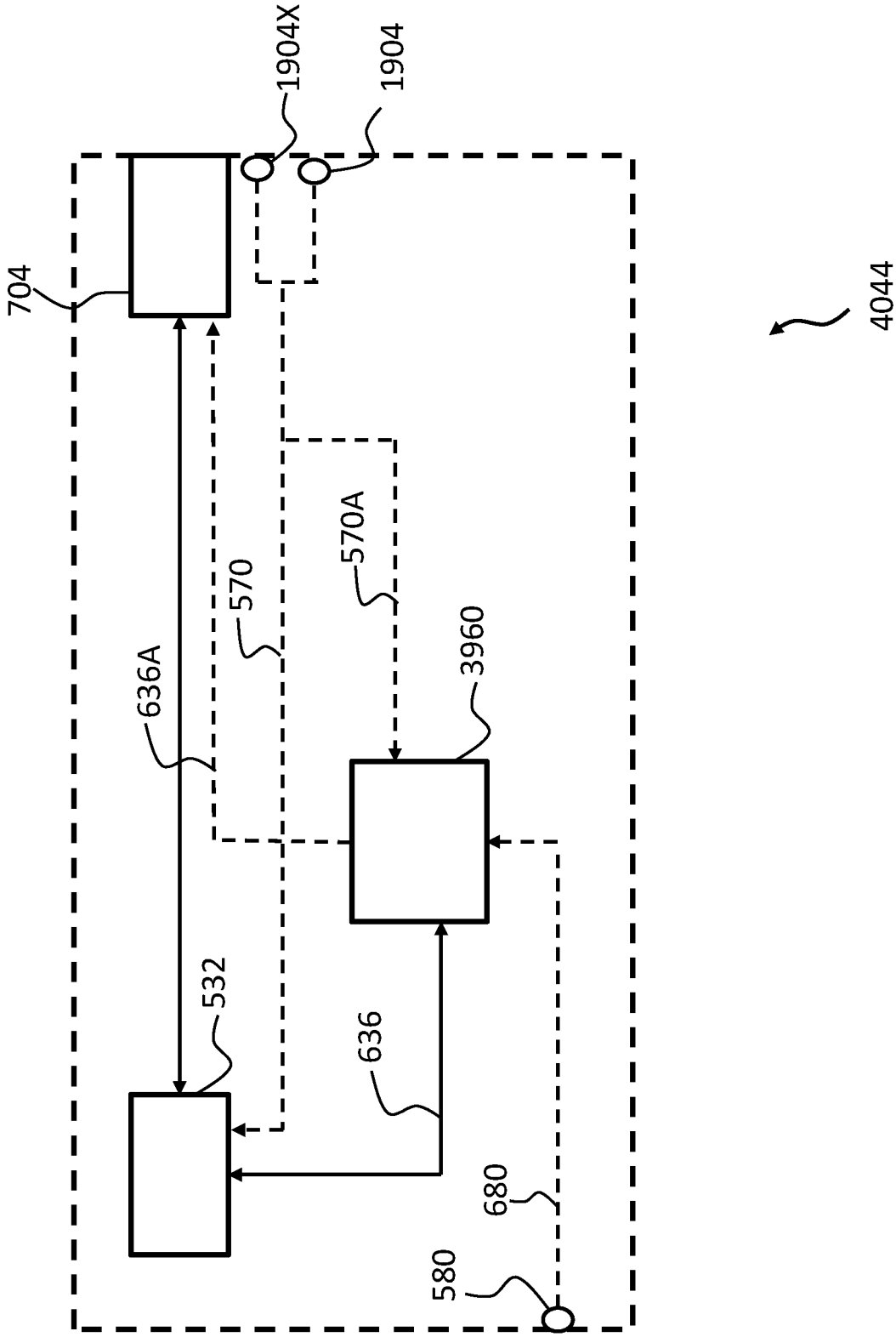


FIG. 41

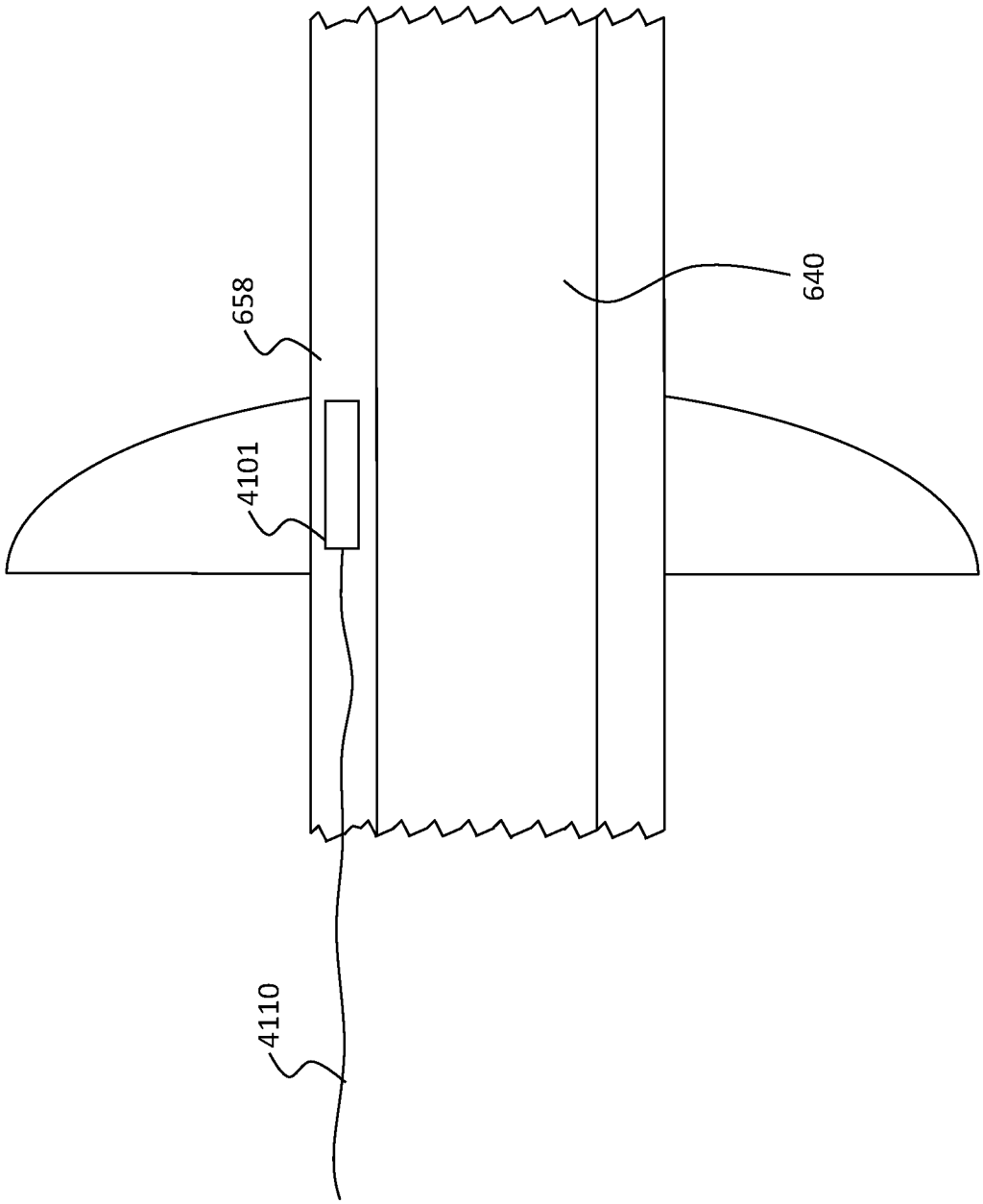


FIG. 42

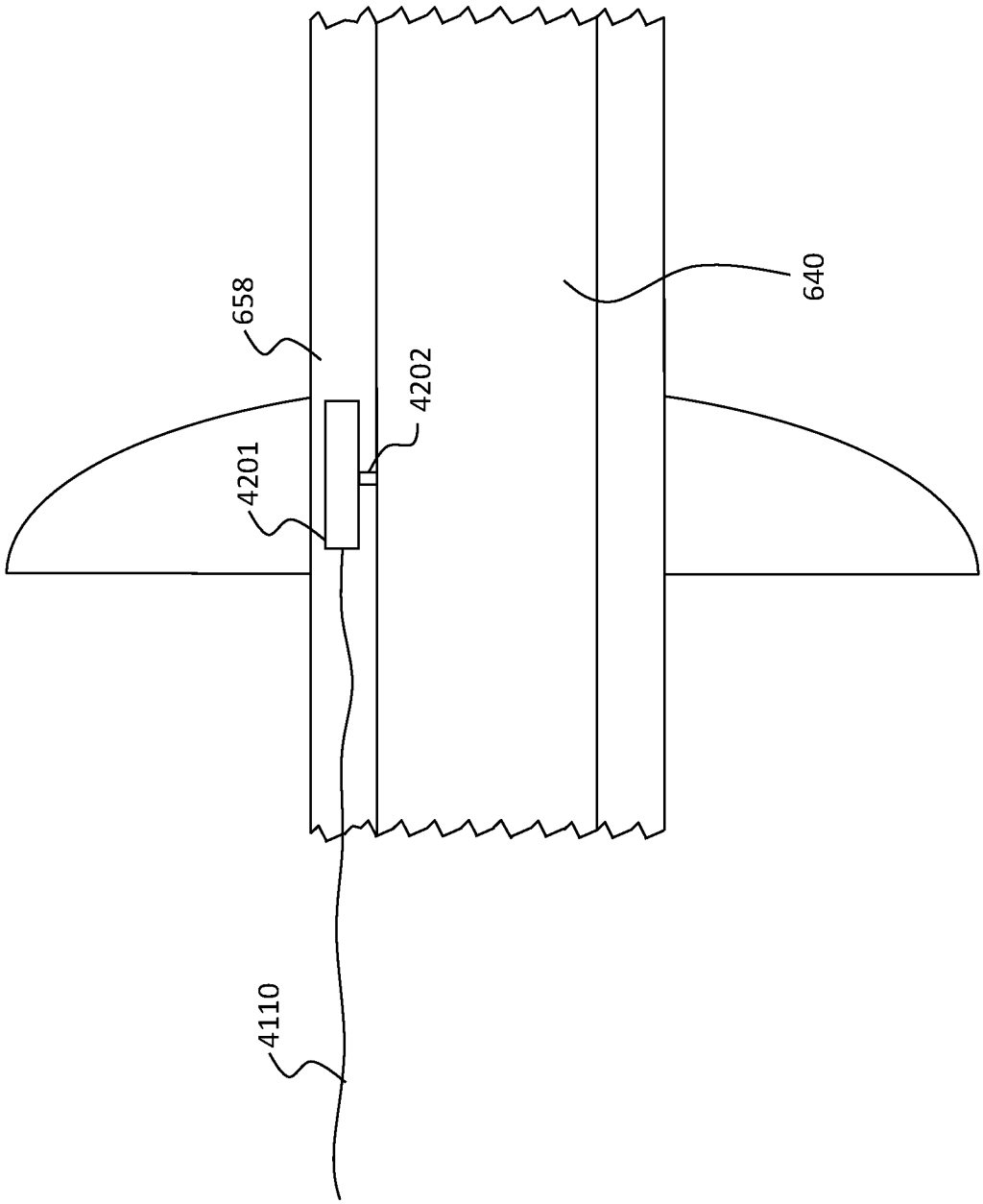


FIG. 43

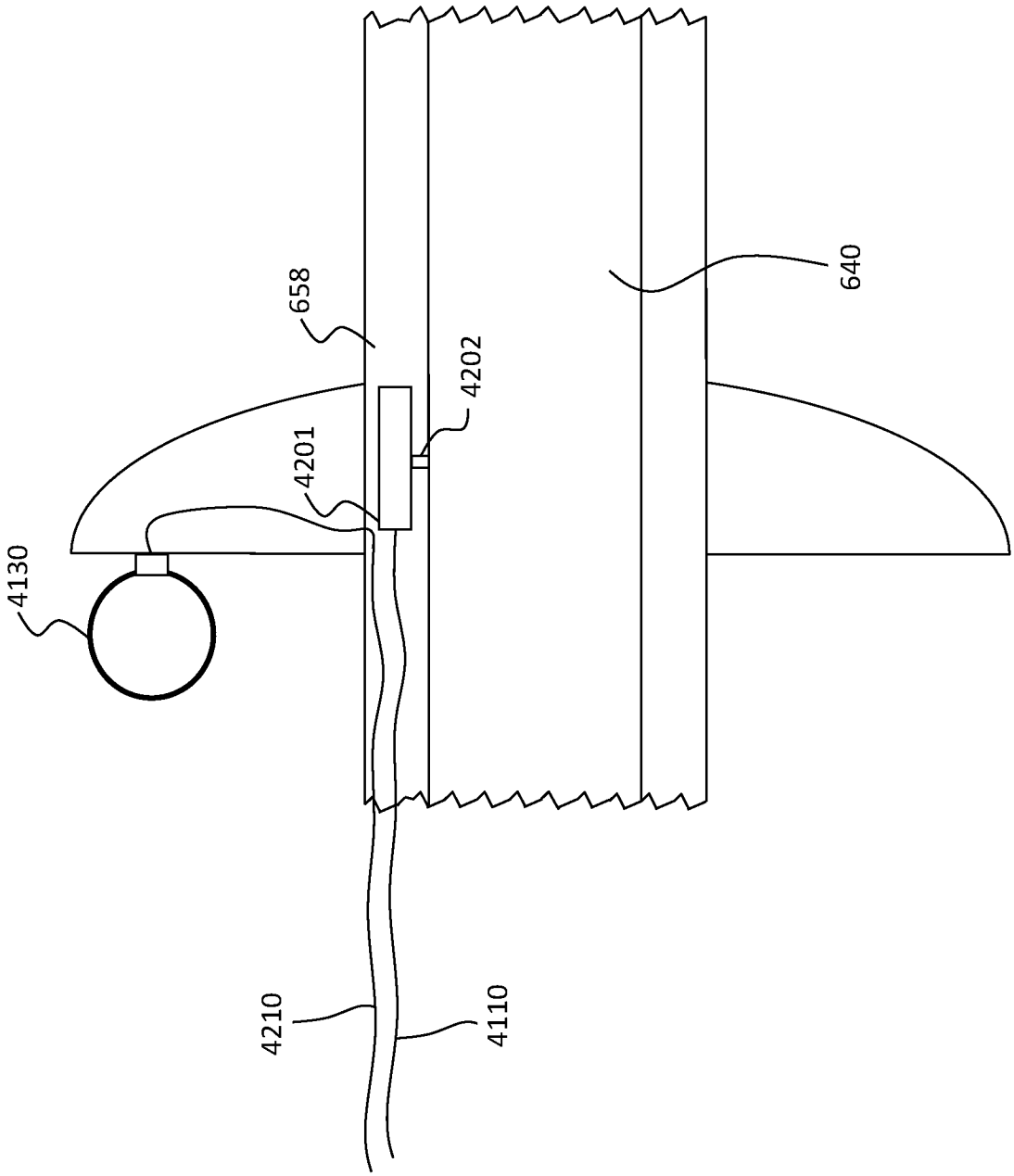


FIG. 44

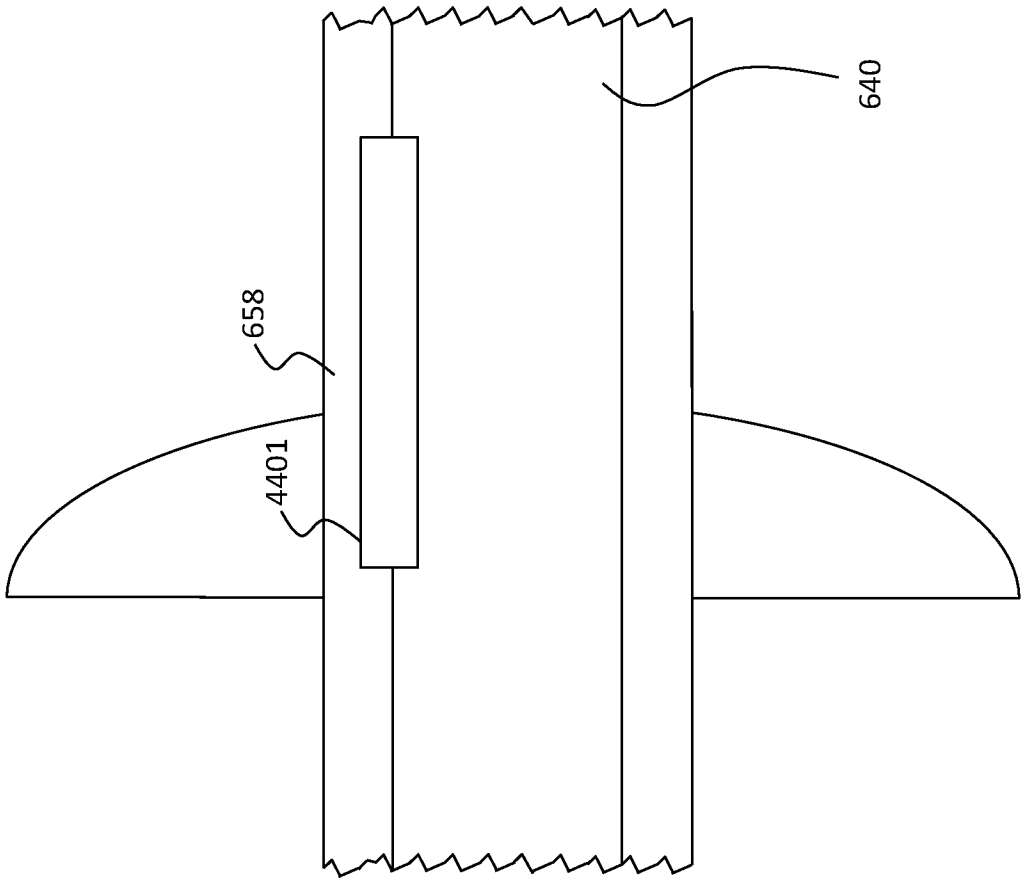


FIG. 45

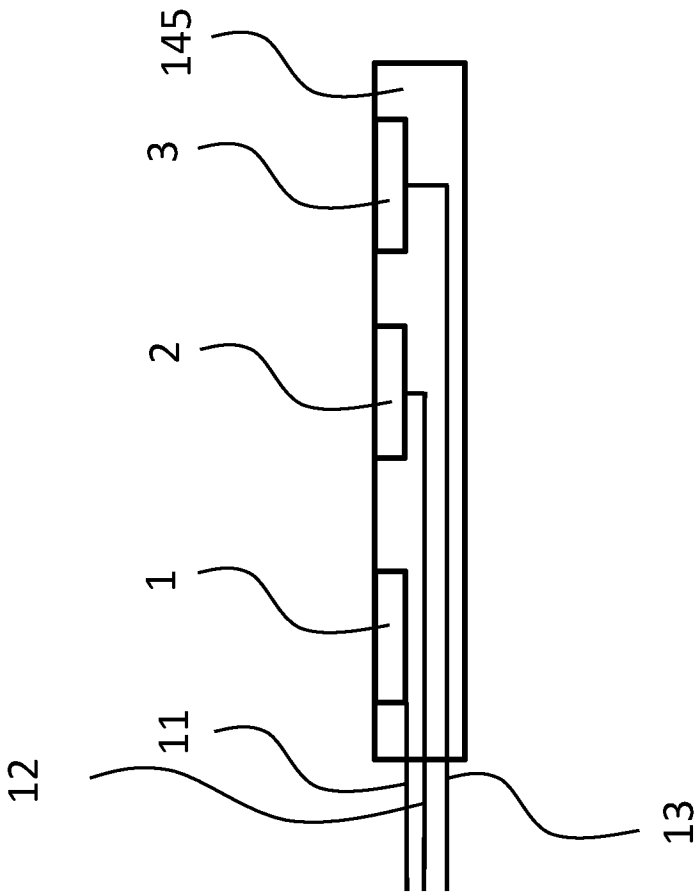
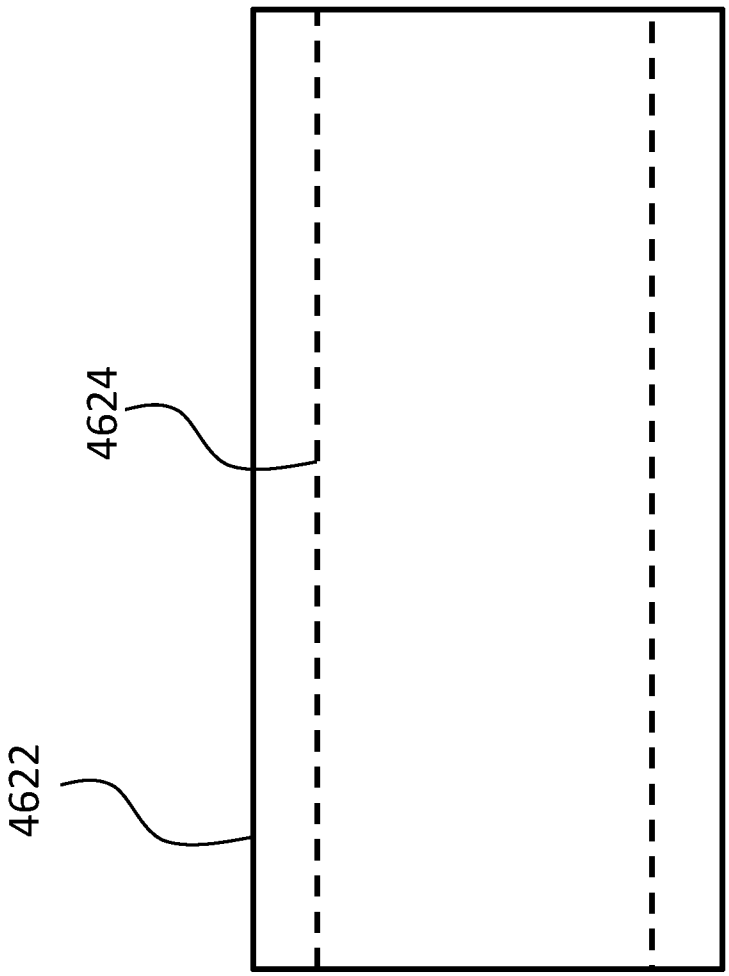


FIG. 46



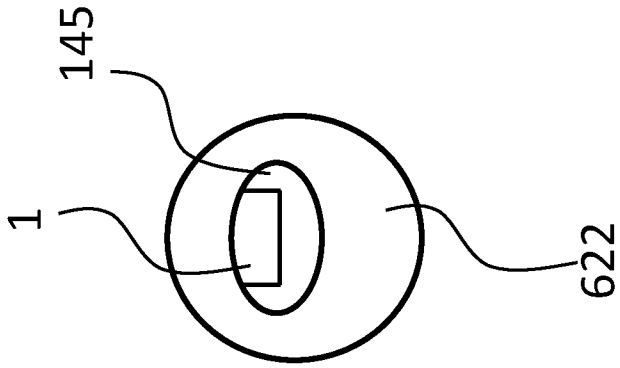


FIG. 48A

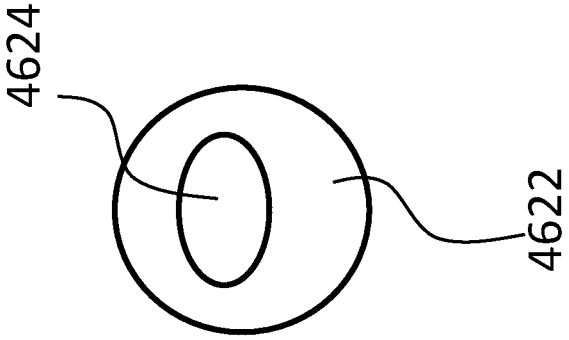
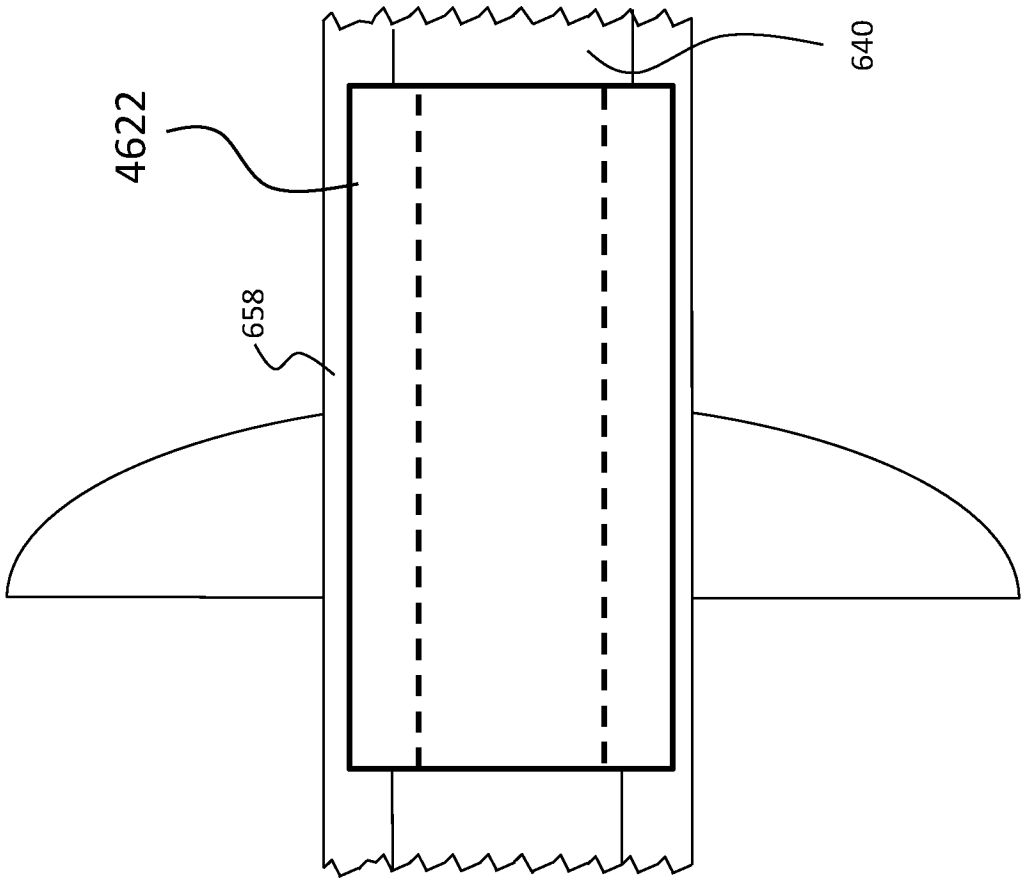


FIG. 47

FIG. 48B



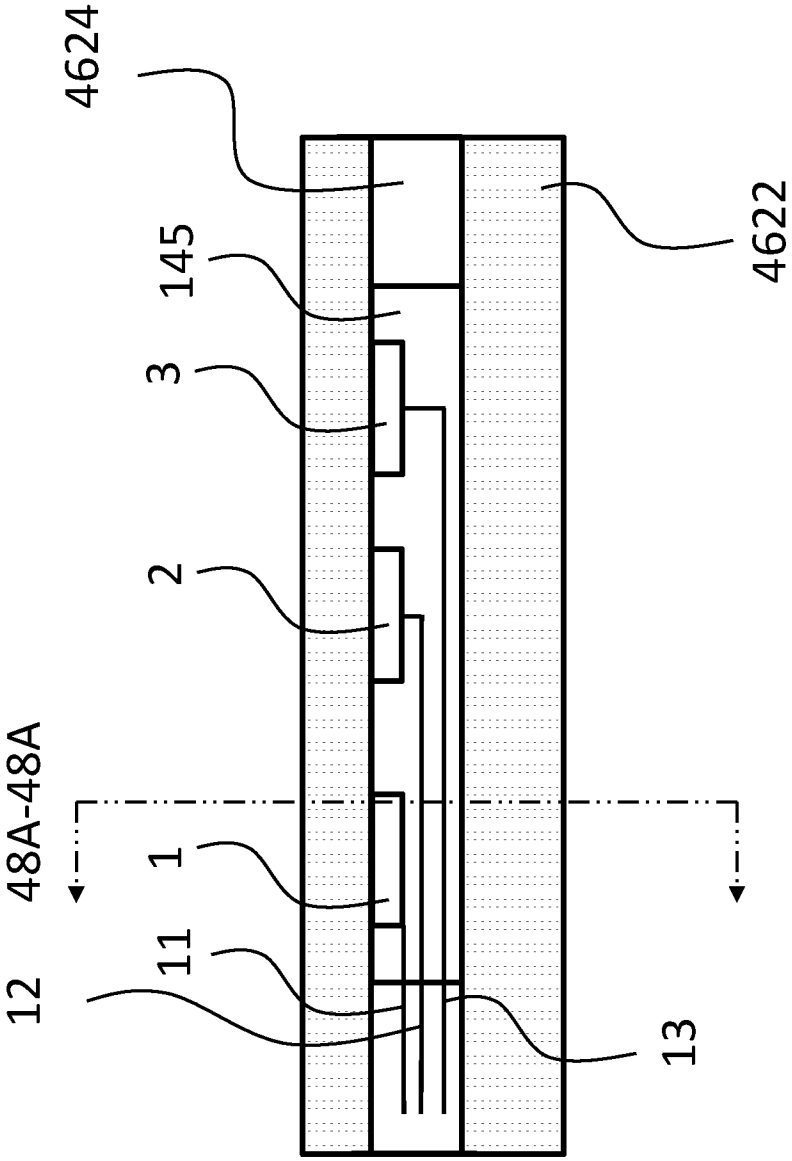


FIG. 49

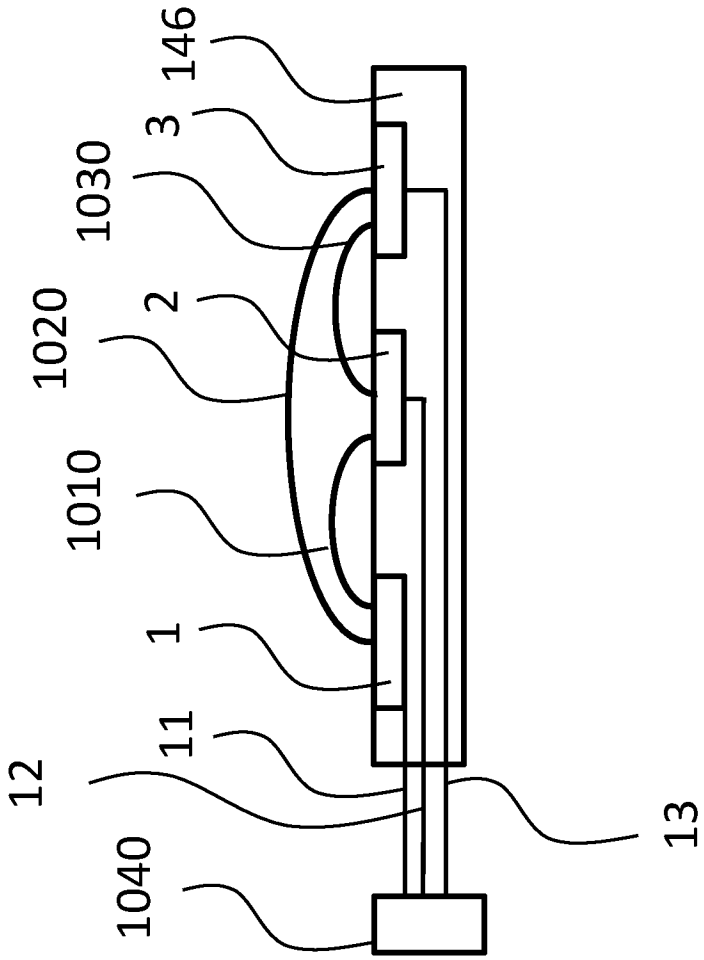


FIG. 50A

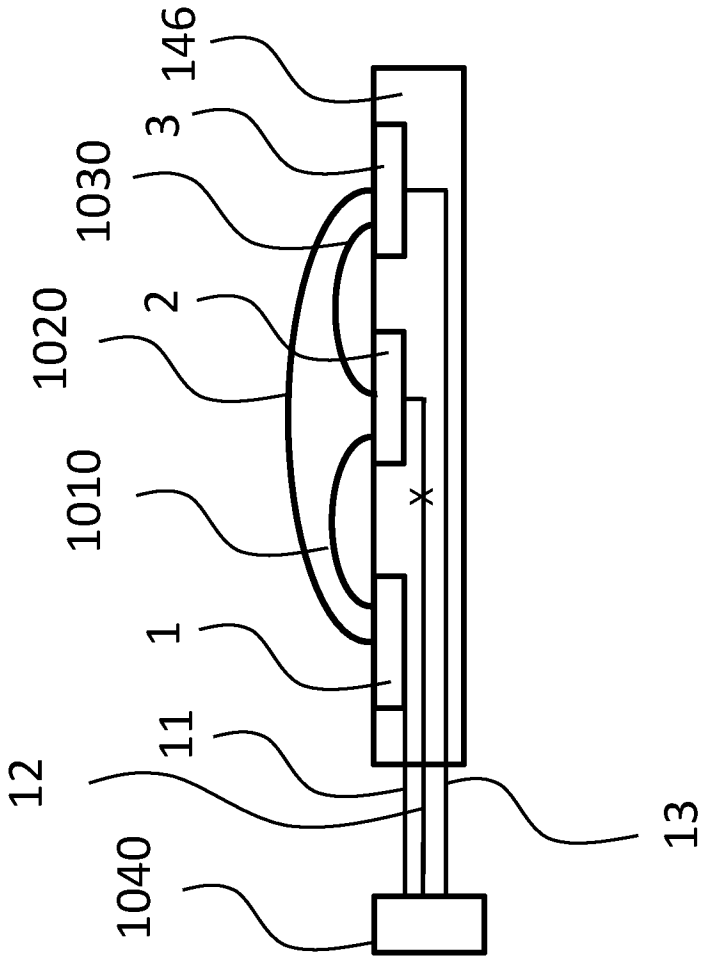


FIG. 50B

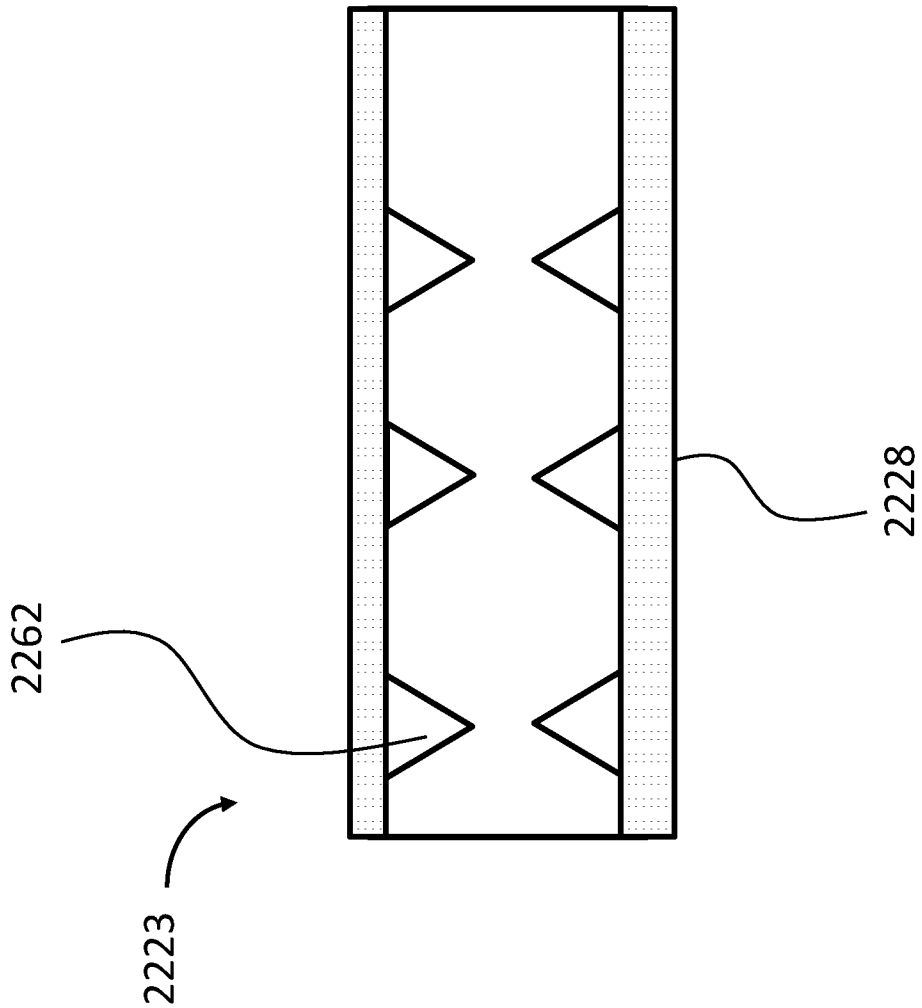


FIG. 51A

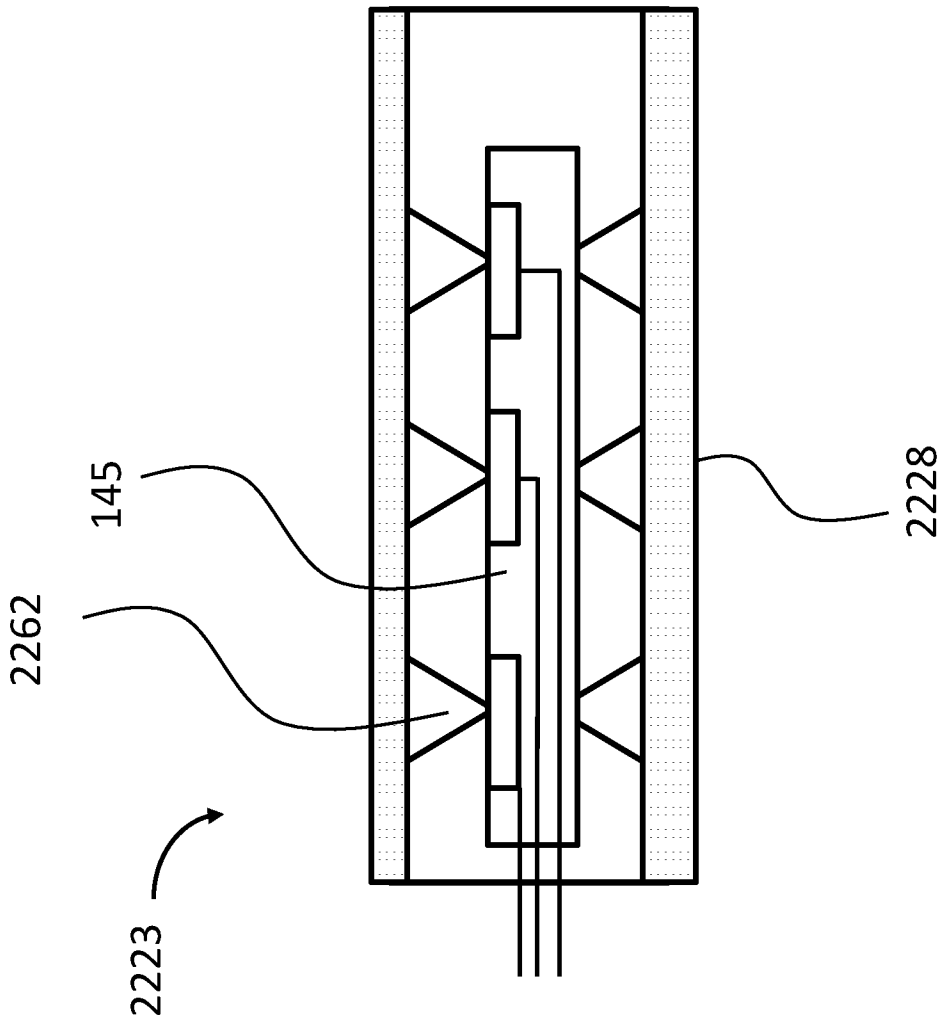


FIG. 51B

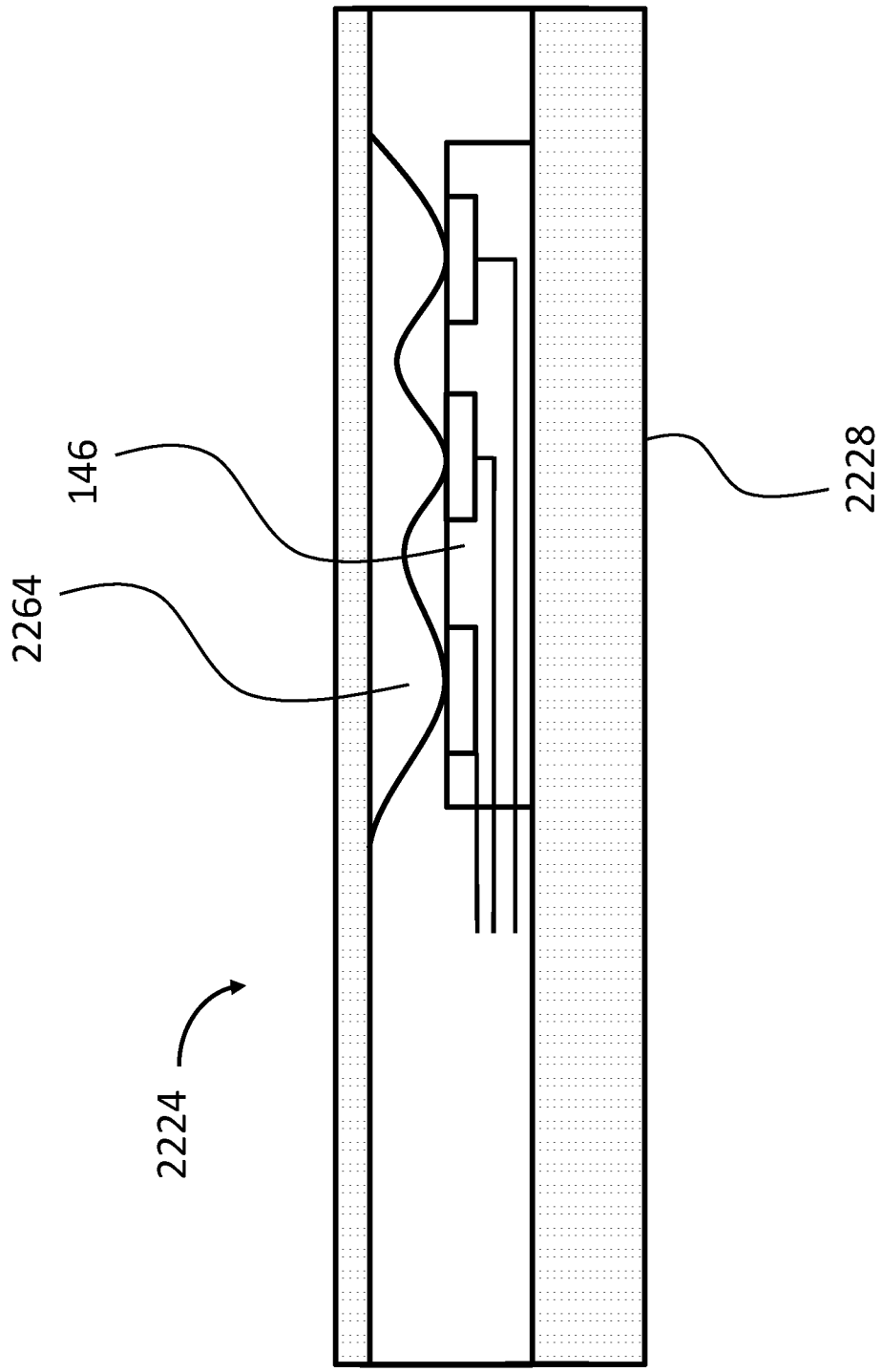


FIG. 51C

FIG. 52

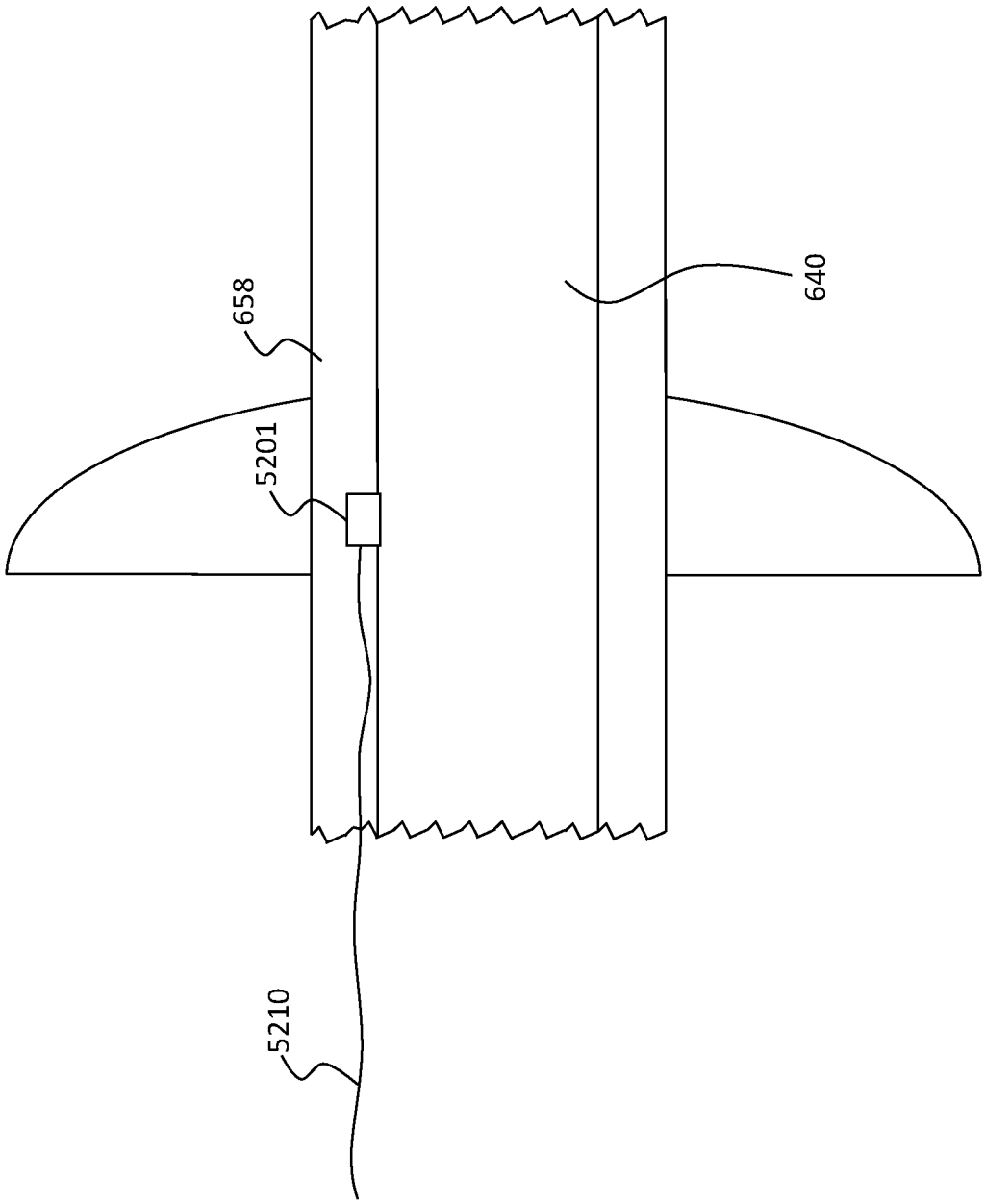


FIG. 53

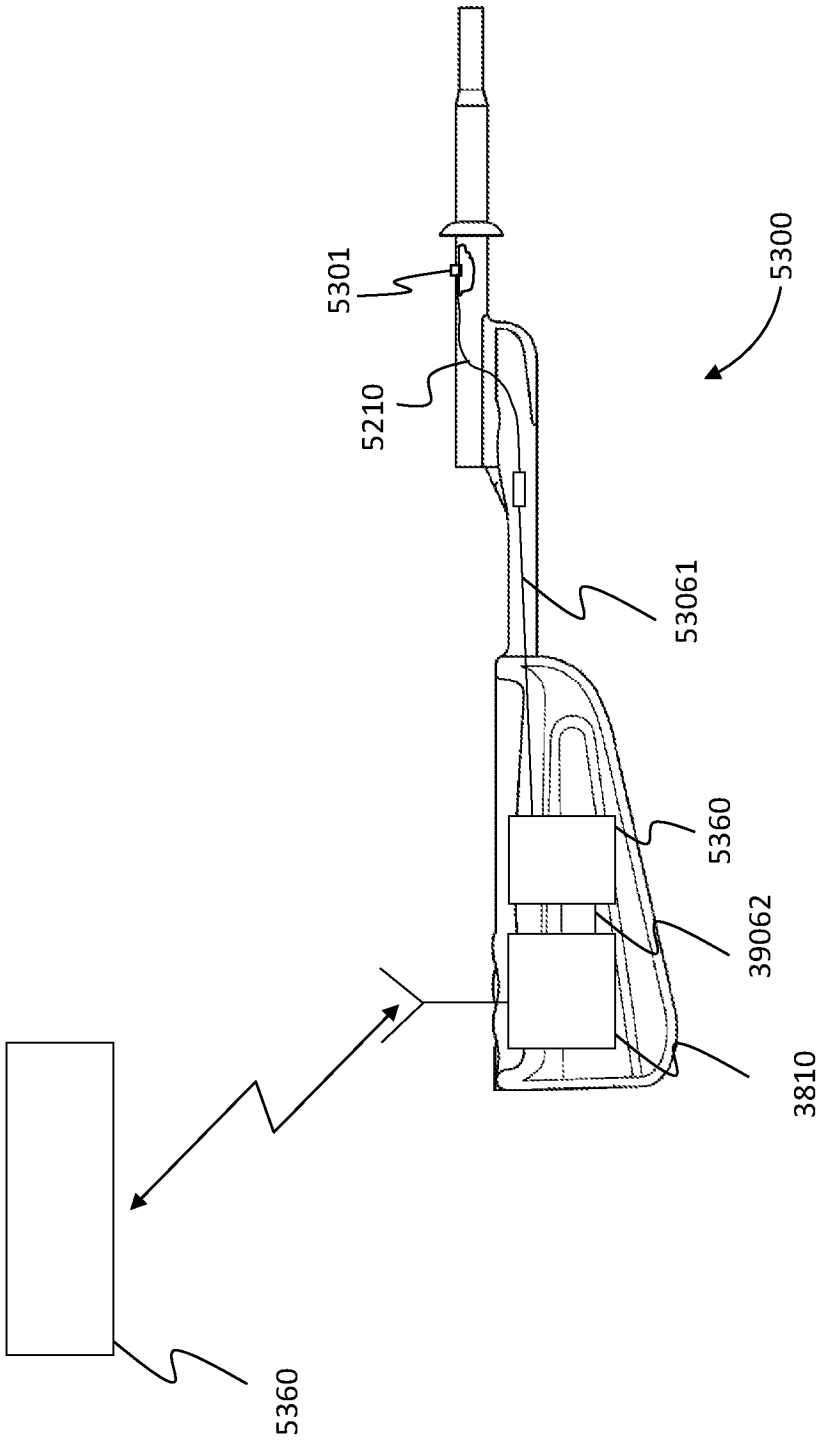


FIG. 54

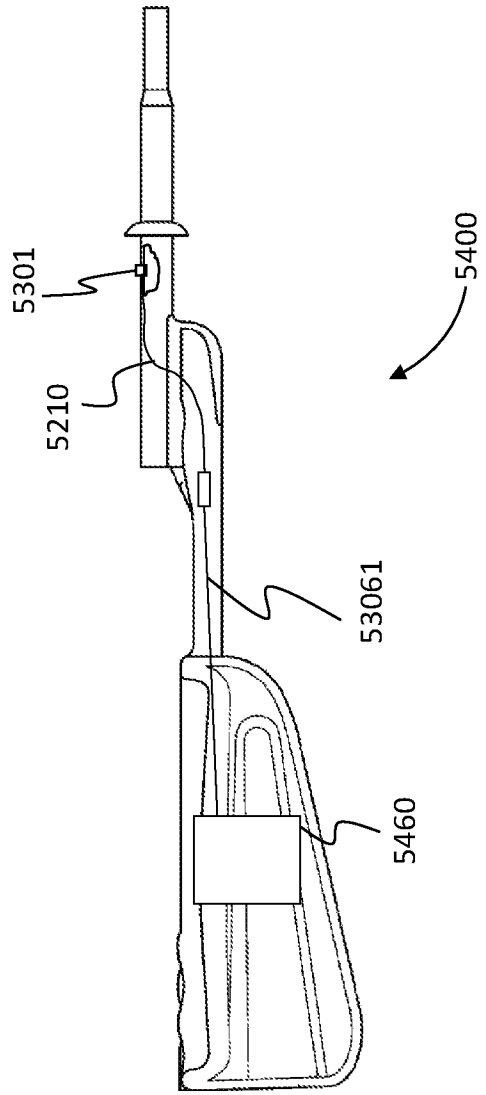


FIG. 55

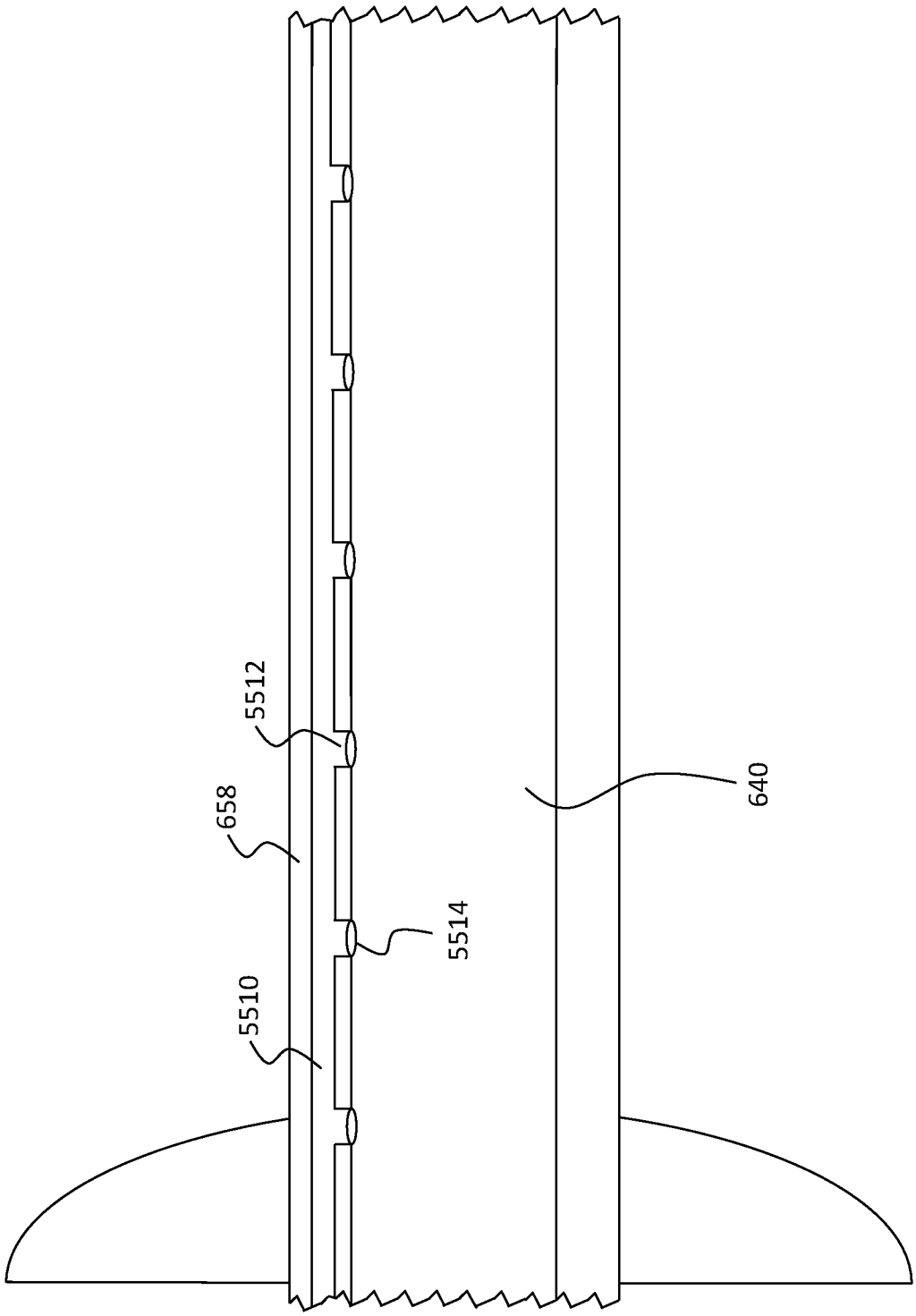


FIG. 56

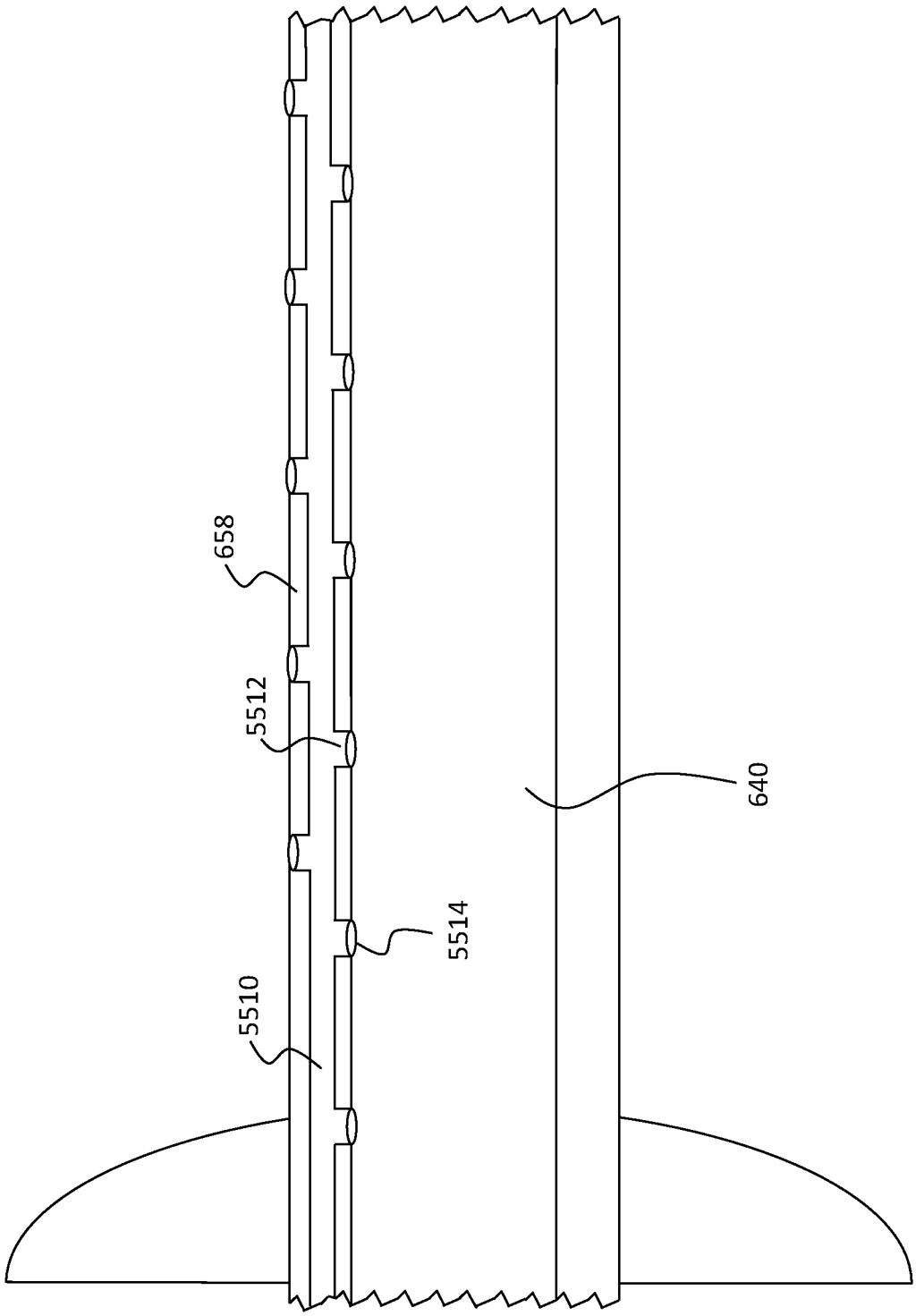


FIG. 57

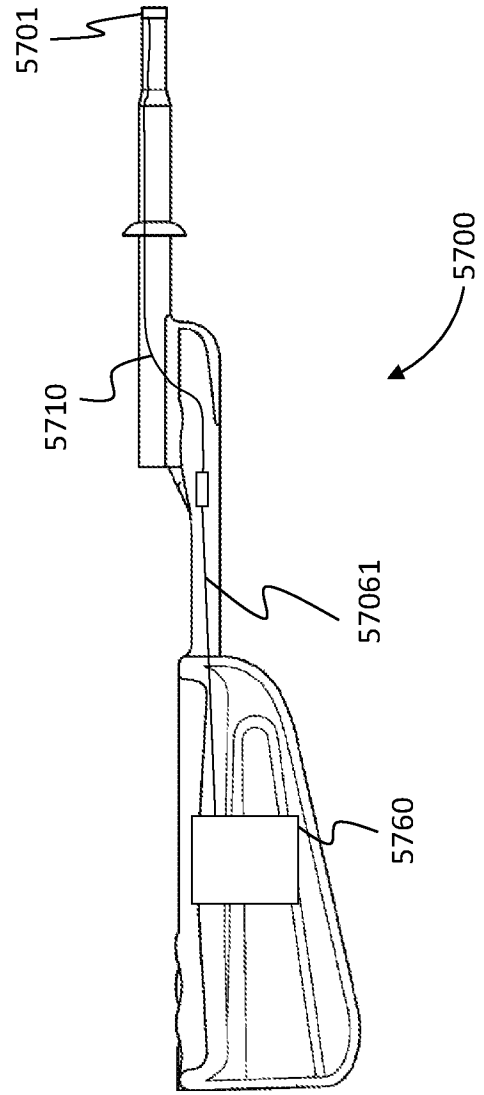


FIG. 58

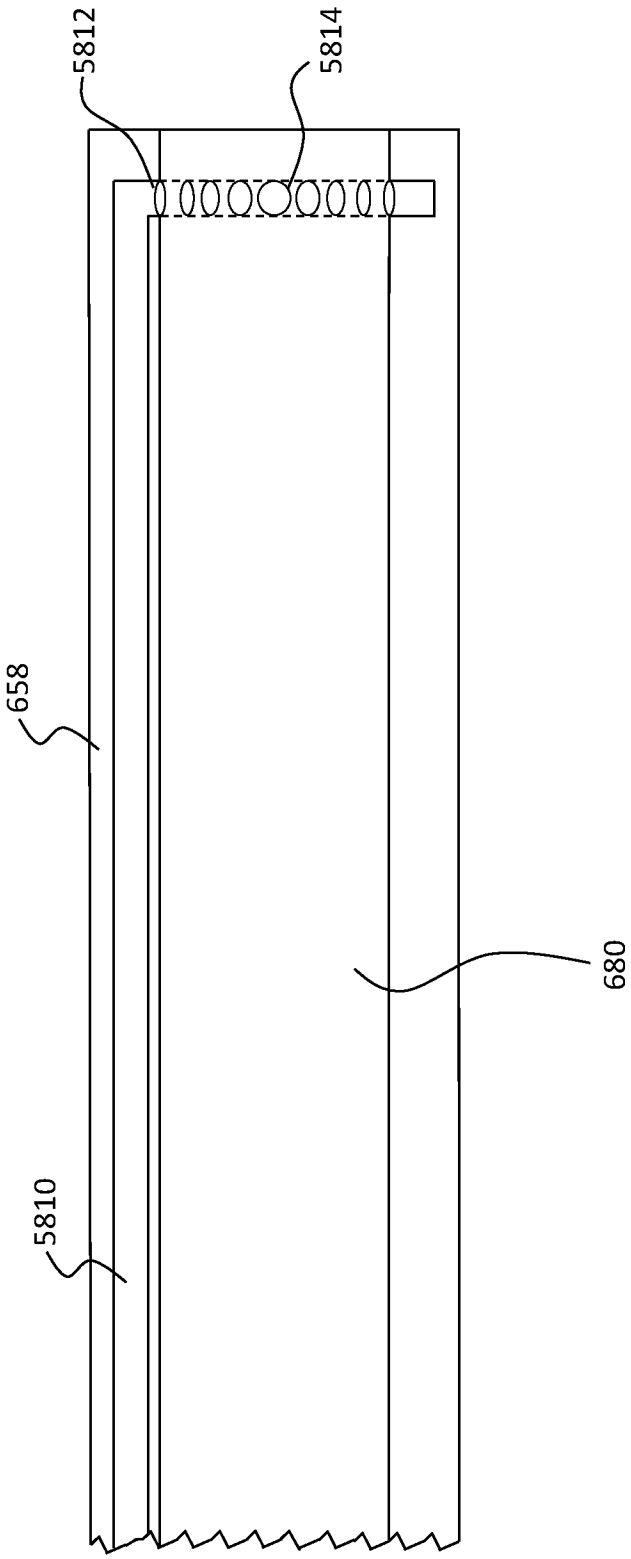
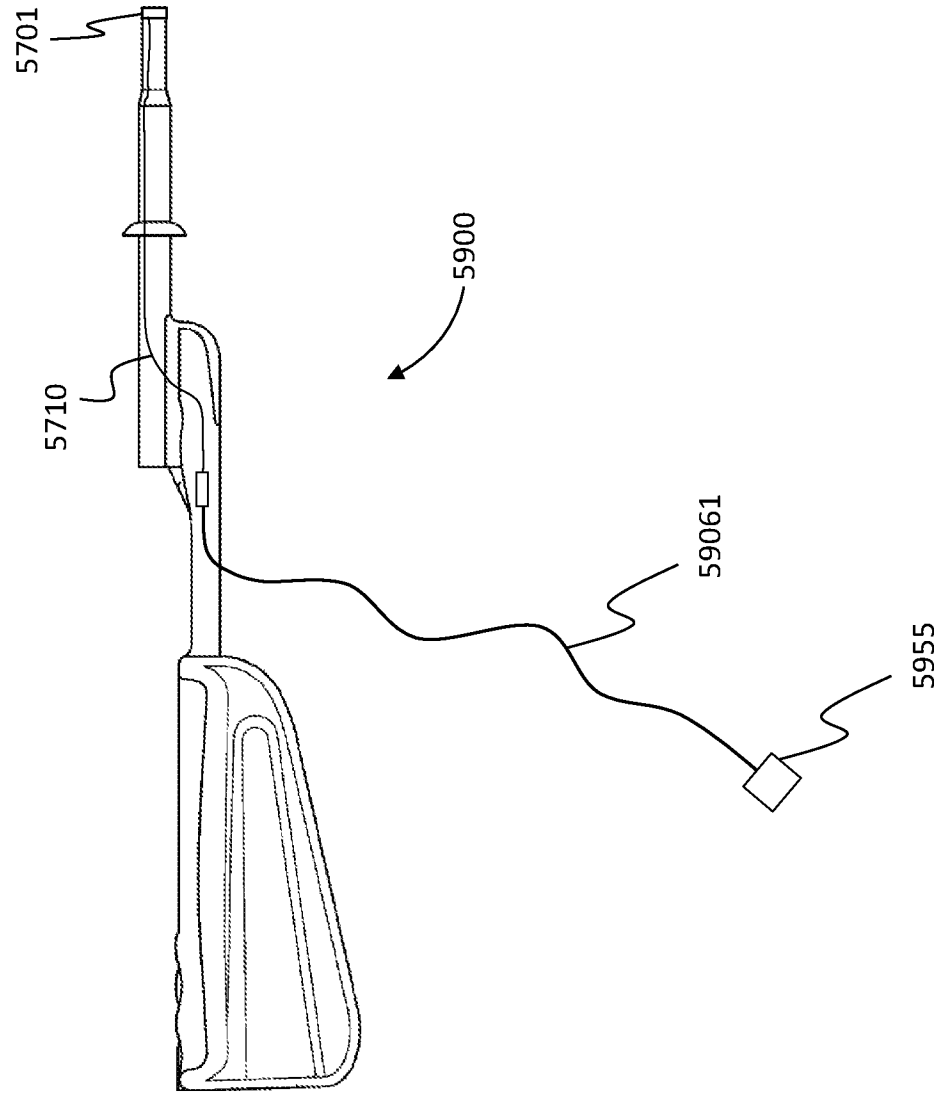


FIG. 59



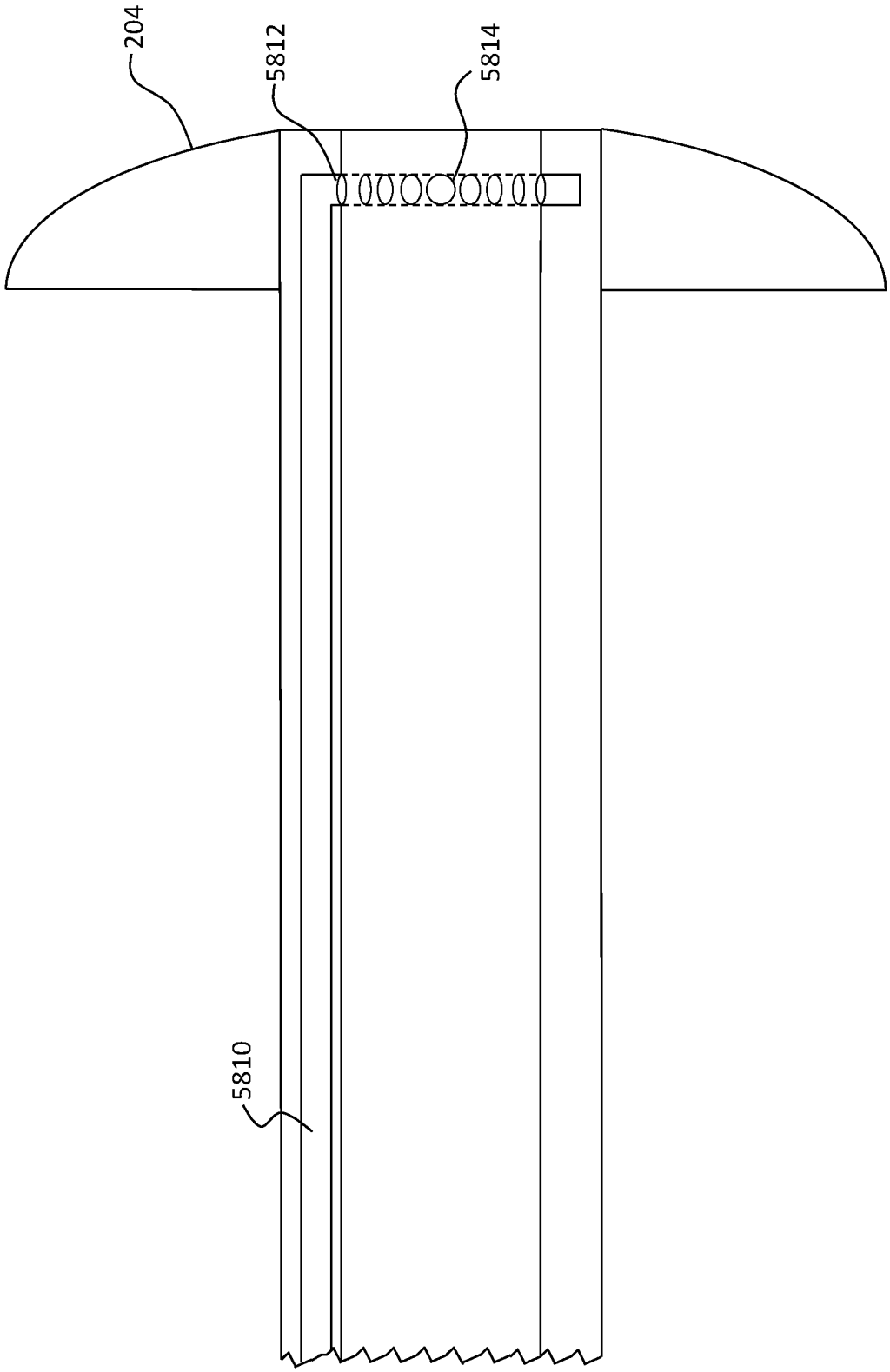


FIG. 60

FIG. 61

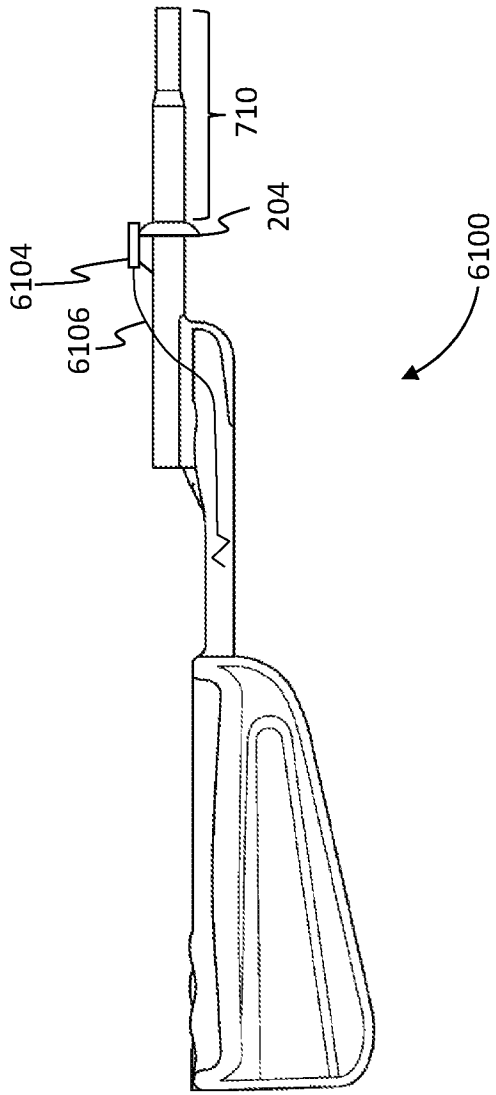
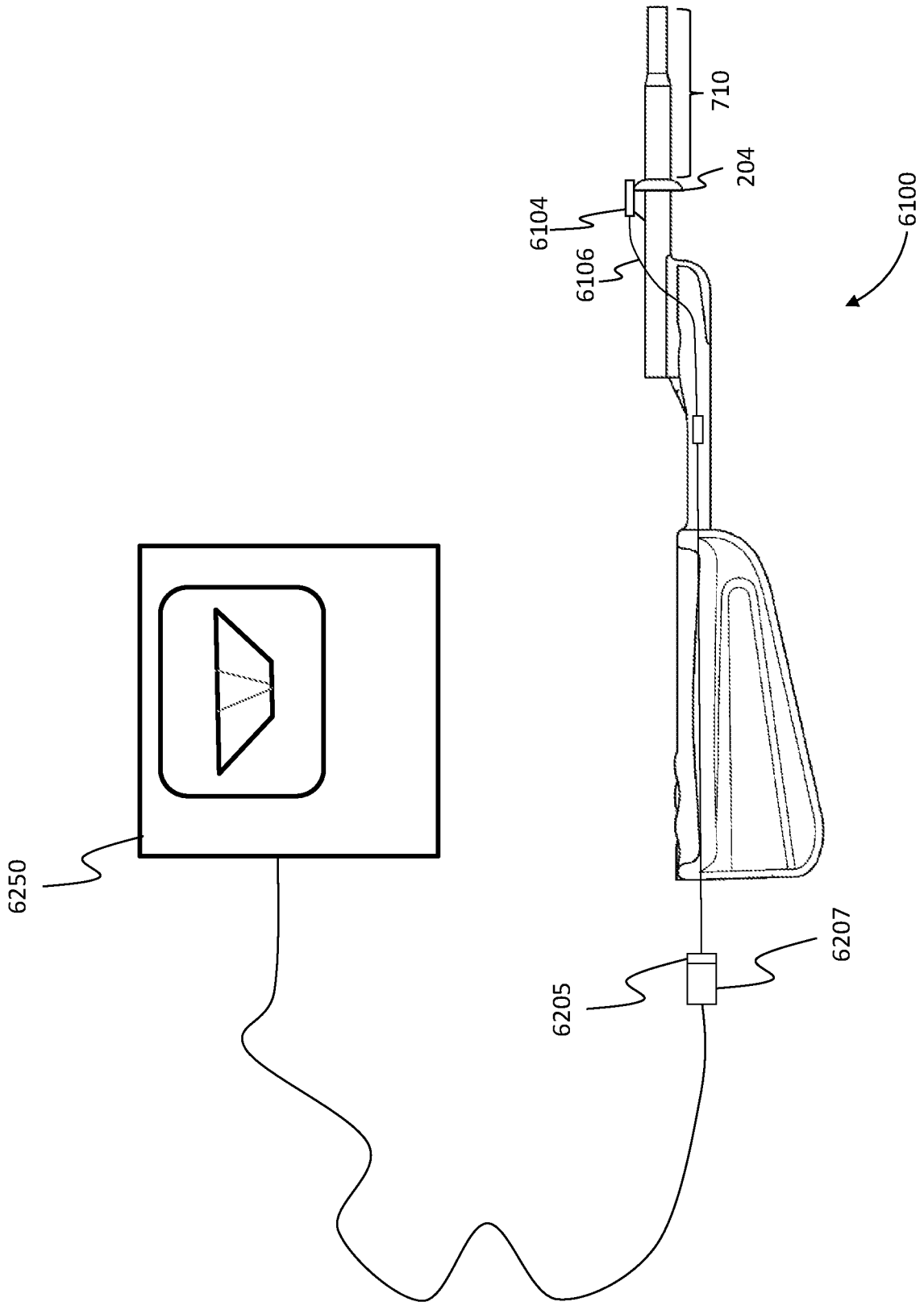


FIG. 62



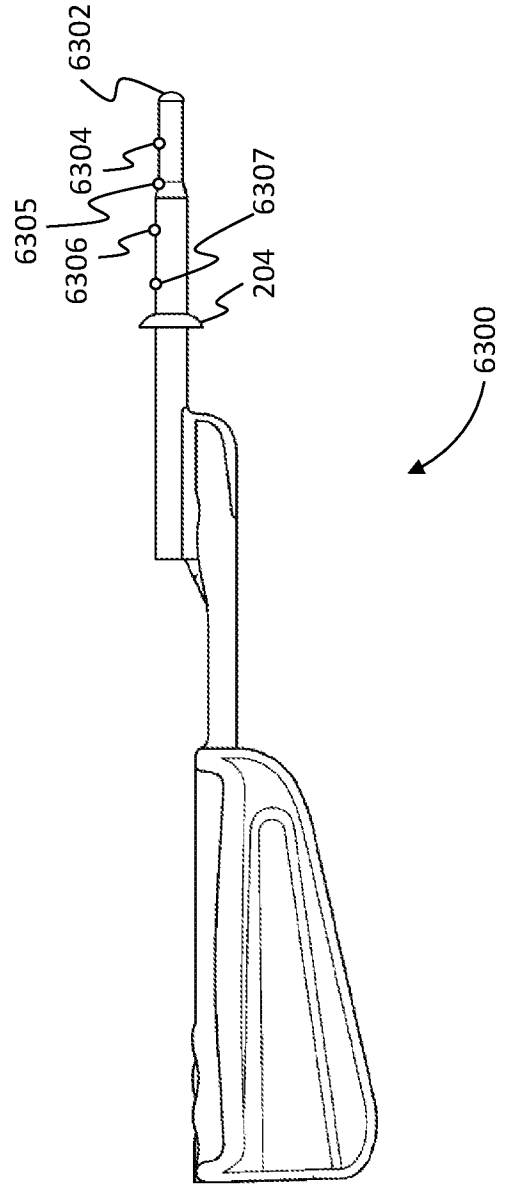
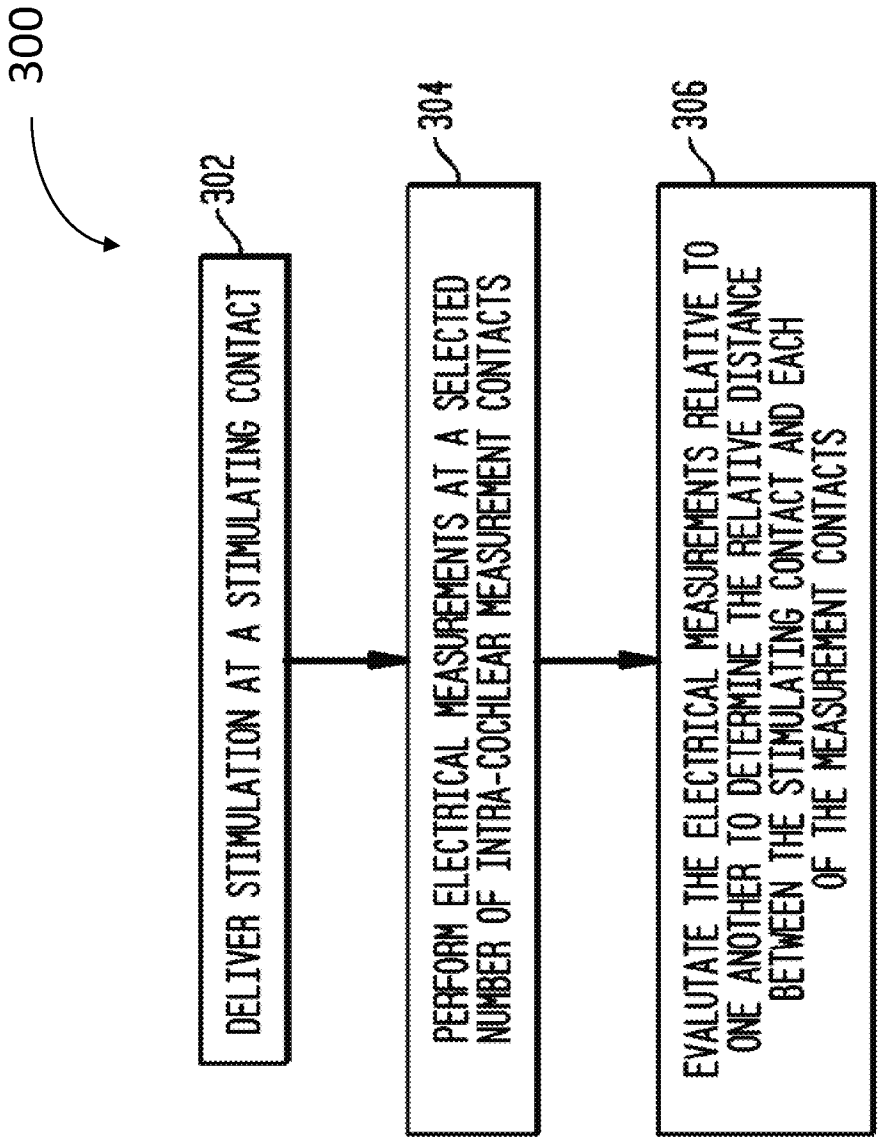


FIG. 63

FIG. 64


300
302
DELIVER STIMULATION AT A STIMULATING CONTACT
304
PERFORM ELECTRICAL MEASUREMENTS AT A SELECTED NUMBER OF INTRA-COCHLEAR MEASUREMENT CONTACTS
306
EVALUTATE THE ELECTRICAL MEASUREMENTS RELATIVE TO ONE ANOTHER TO DETERMINE THE RELATIVE DISTANCE BETWEEN THE STIMULATING CONTACT AND EACH OF THE MEASUREMENT CONTACTS

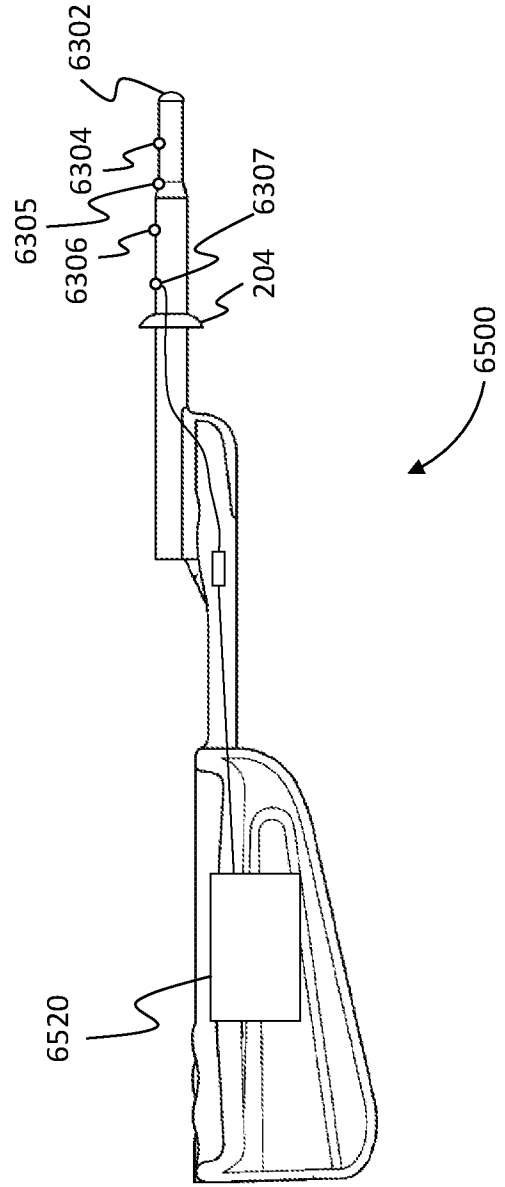


FIG. 65

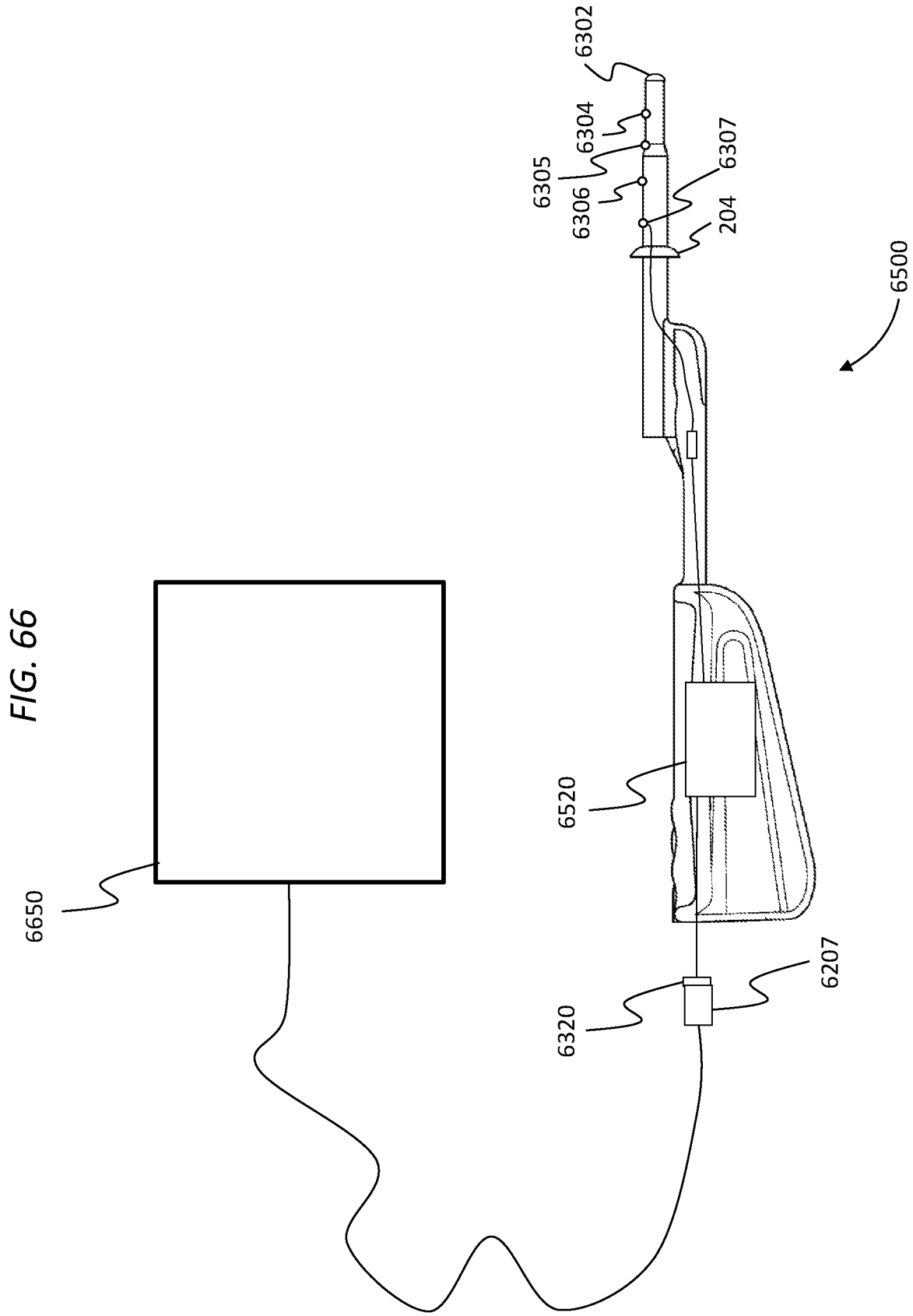


FIG. 66

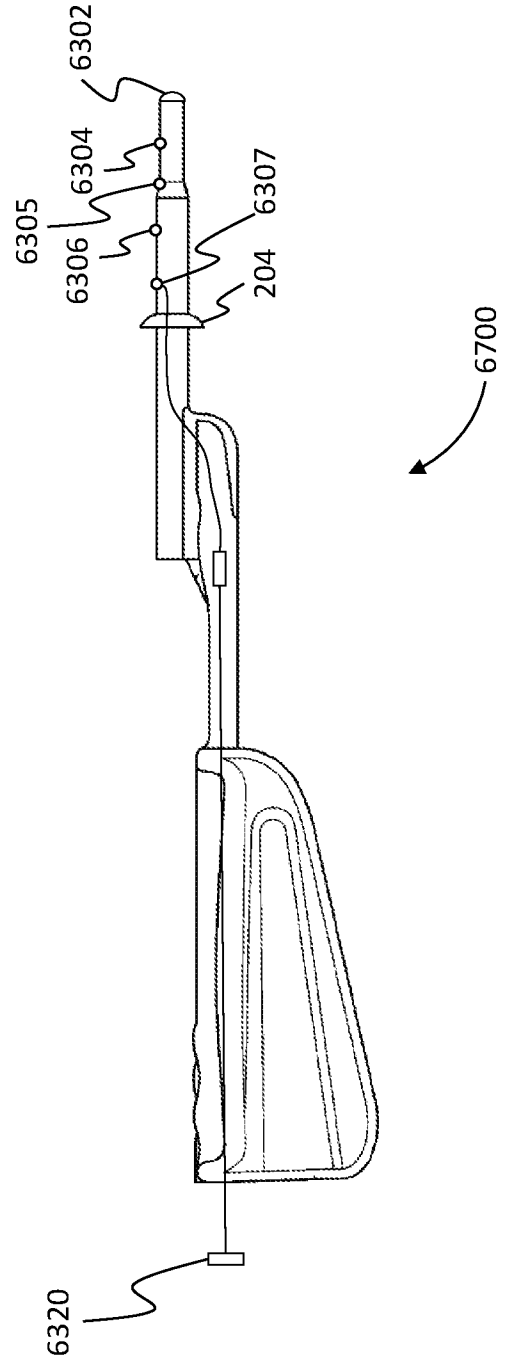
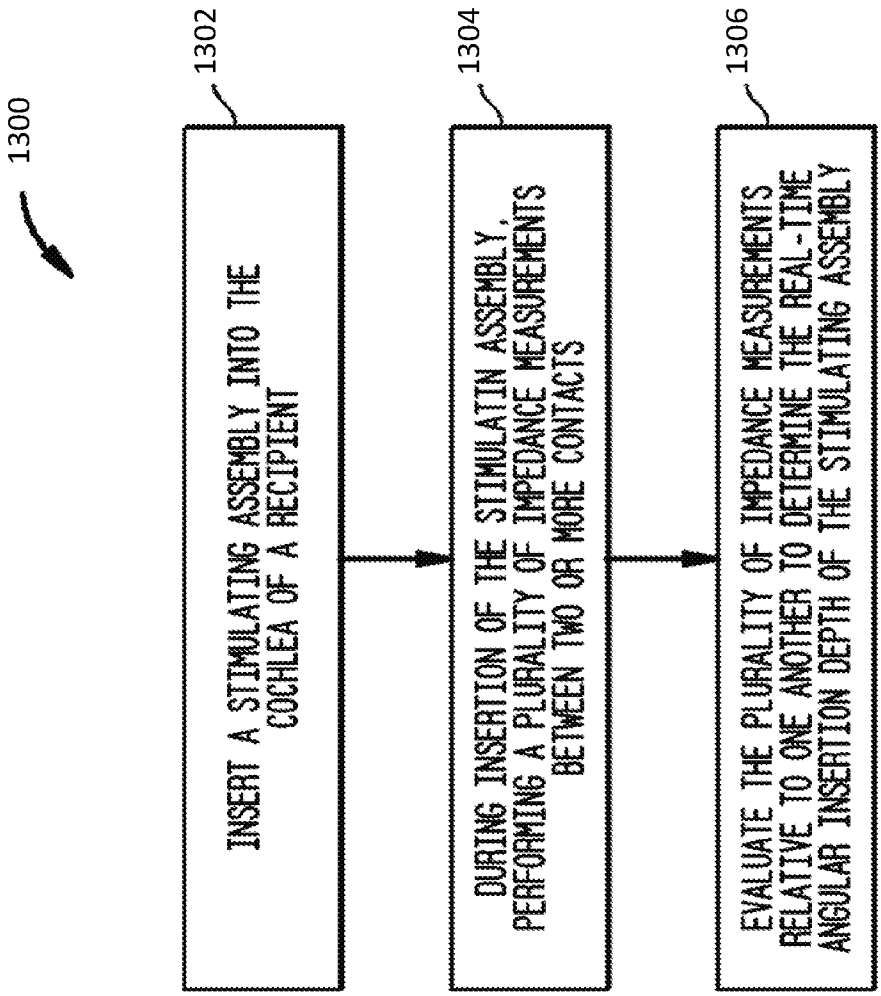


FIG. 67

FIG. 68


1300
1302
INSERT A STIMULATING ASSEMBLY INTO THE COCHLEA OF A RECIPIENT
1304
DURING INSERTION OF THE STIMULATIN ASSEMBLY, PERFORMING A PLURALITY OF IMPEDANCE MEASUREMENTS BETWEEN TWO OR MORE CONTACTS
1306
EVALUATE THE PLURALITY OF IMPEDANCE MEASUREMENTS RELATIVE TO ONE ANOTHER TO DETERMINE THE REAL-TIME ANGULAR INSERTION DEPTH OF THE STIMULATING ASSEMBLY

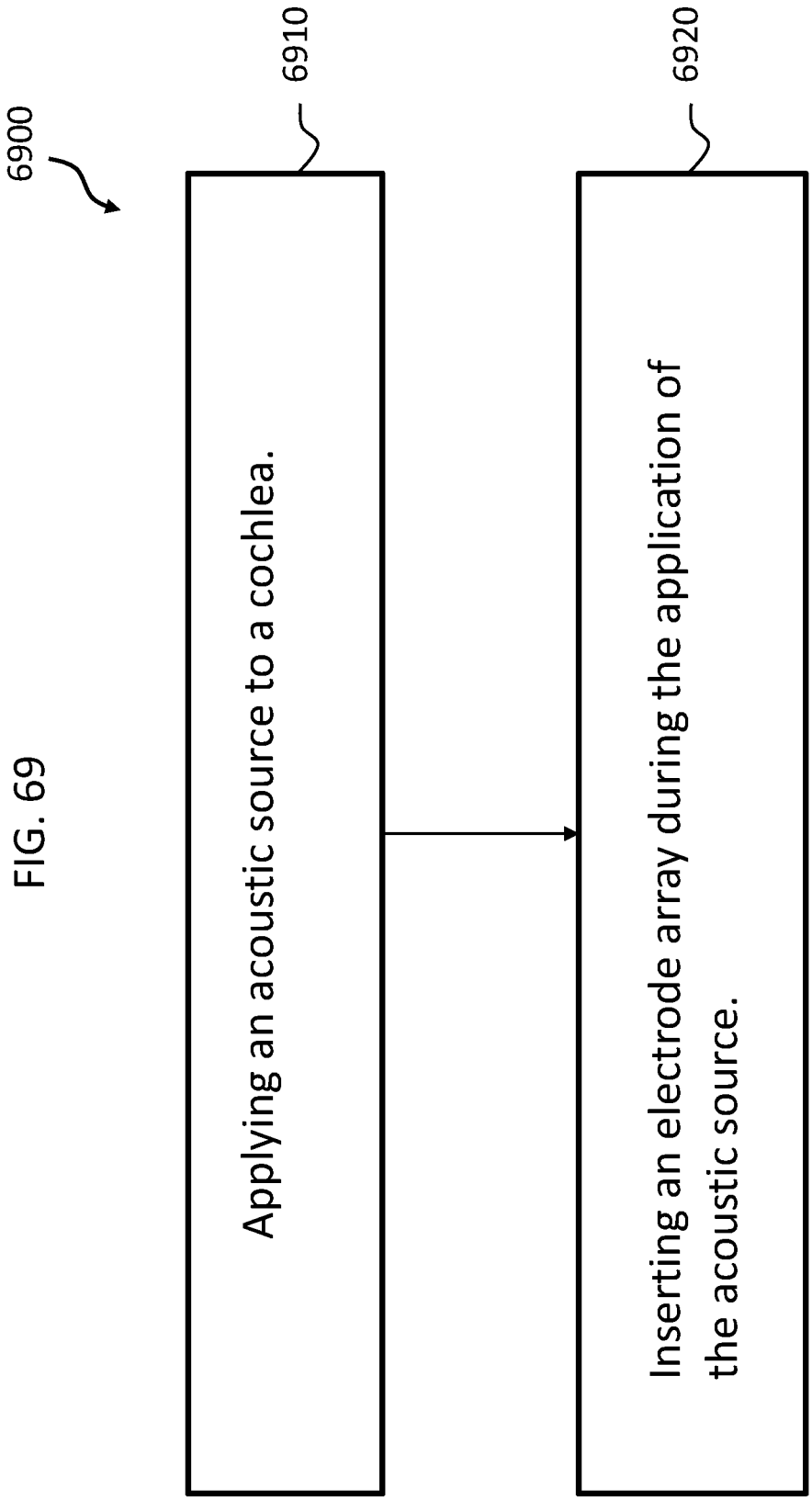

6900
6910
Applying an acoustic source to a cochlea.
6920
Inserting an electrode array during the application of the acoustic source.

FIG. 69

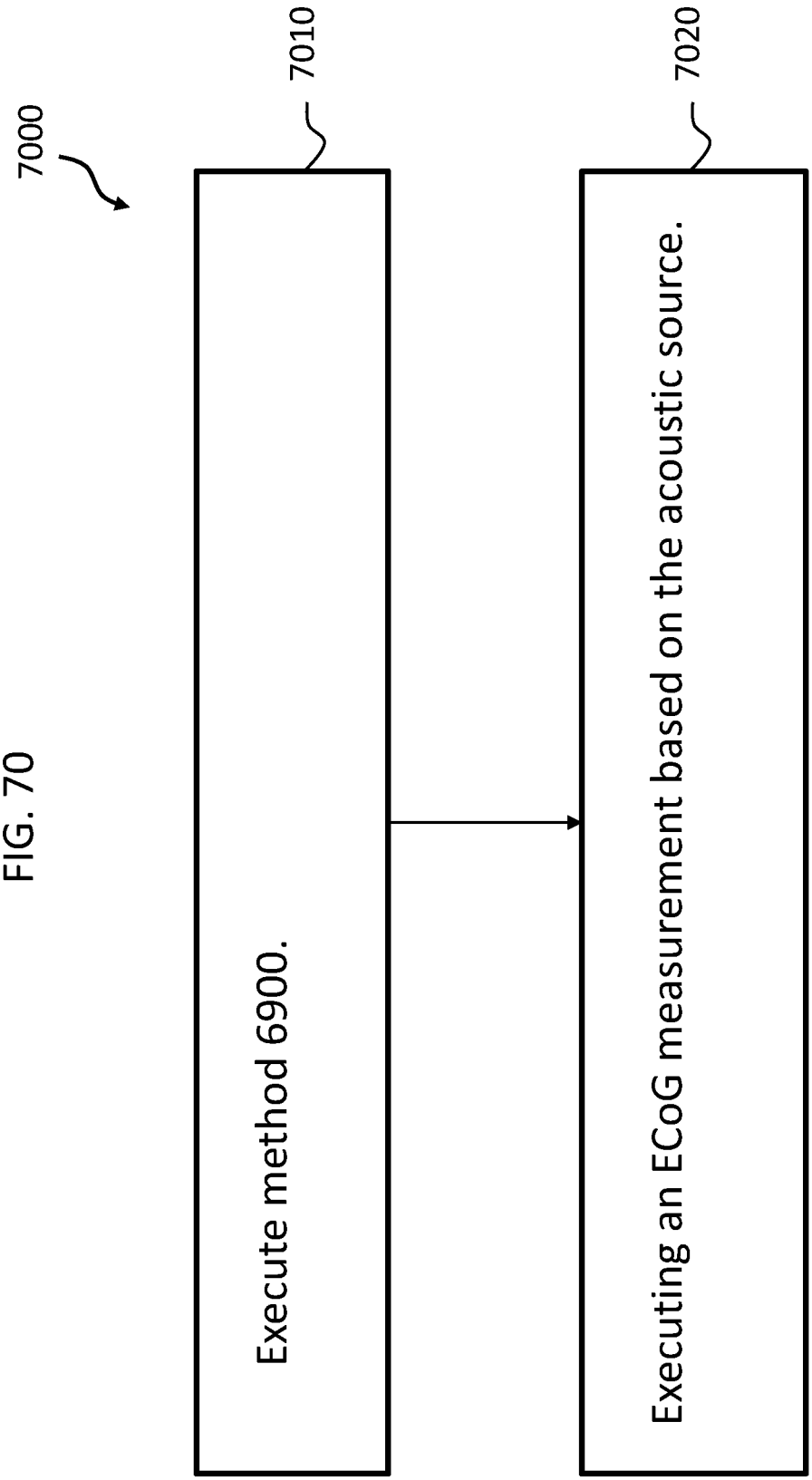

7000
7010
7020
Execute method 6900.
Executing an ECoG measurement based on the acoustic source.

FIG. 70

FIG. 71

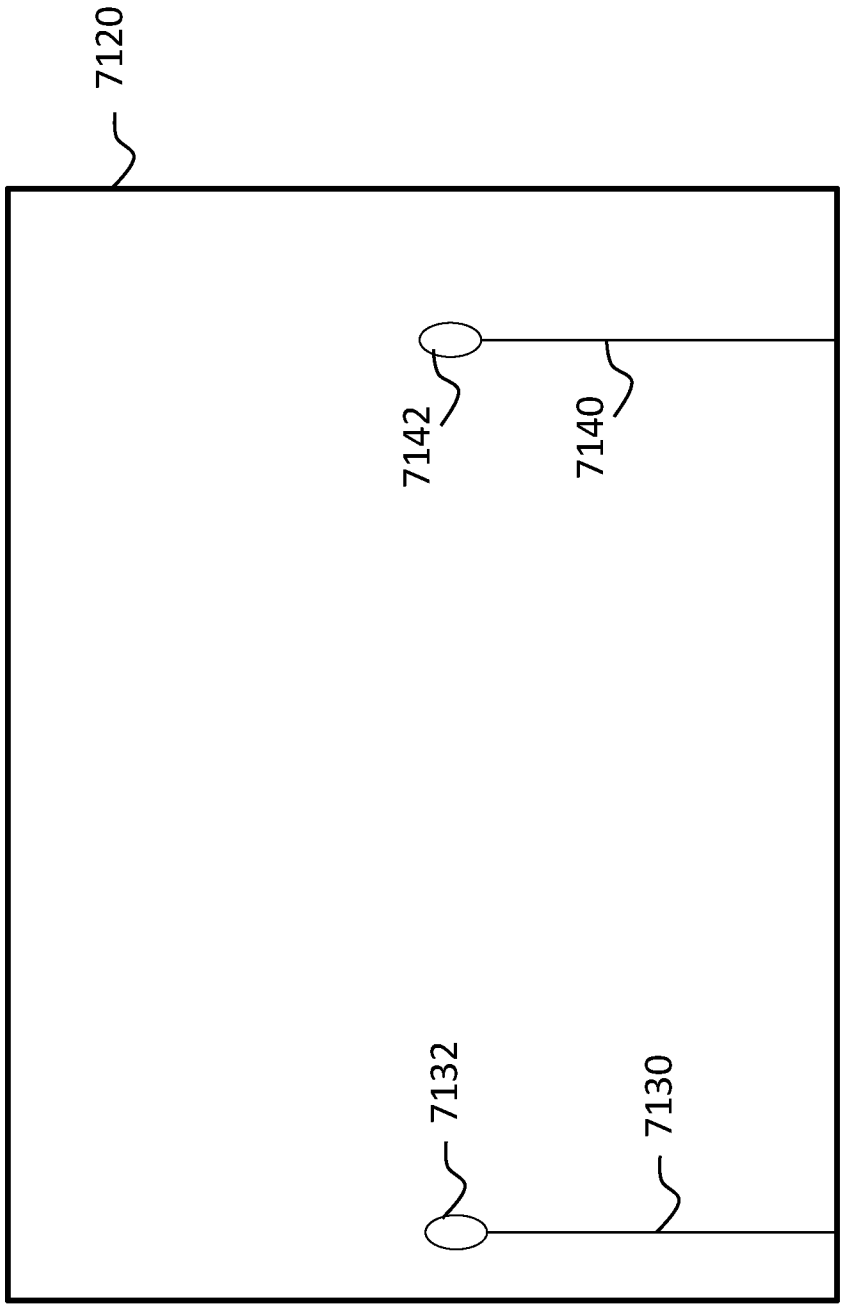


FIG. 72

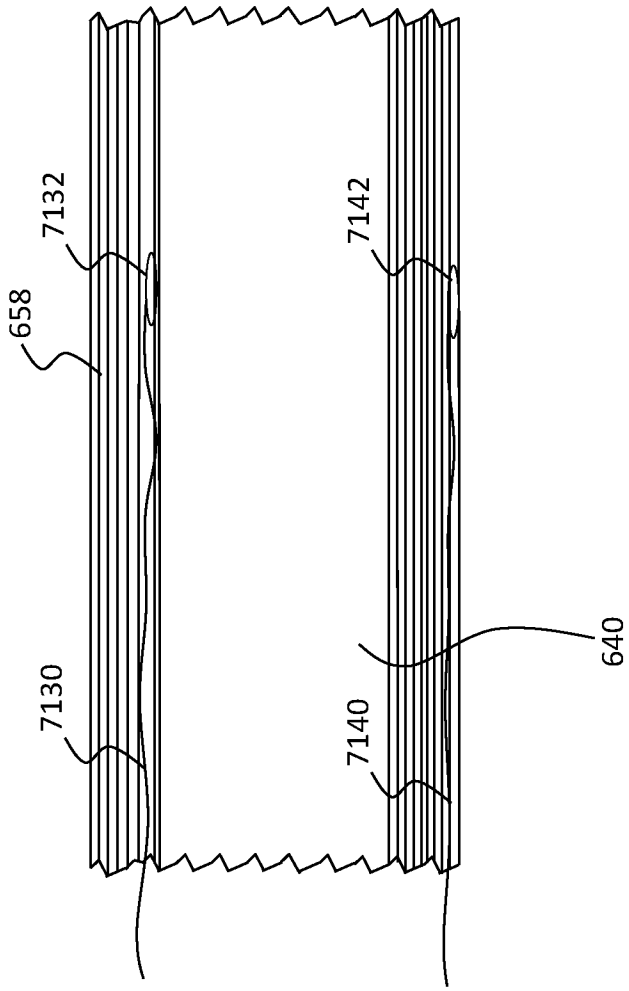


FIG. 73

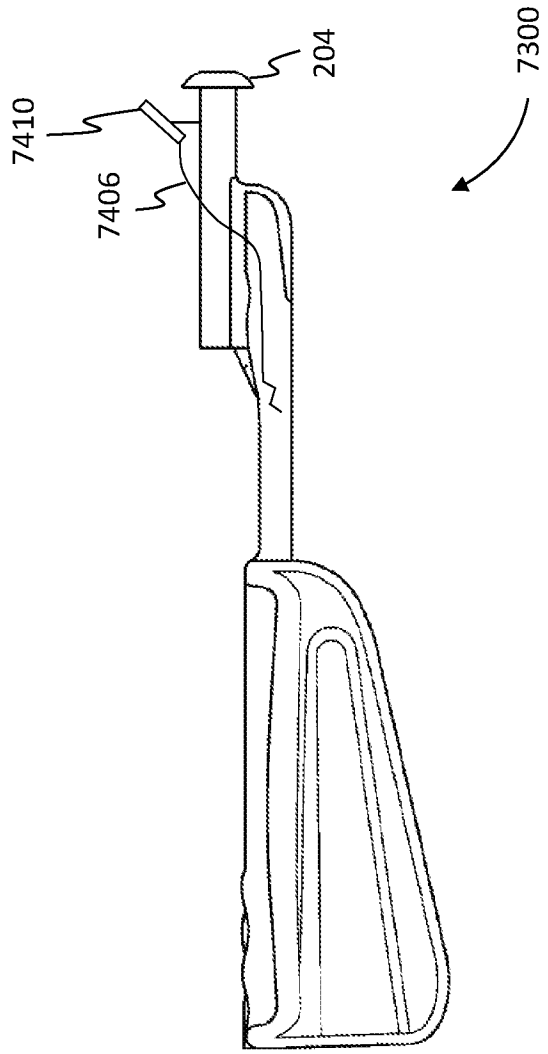
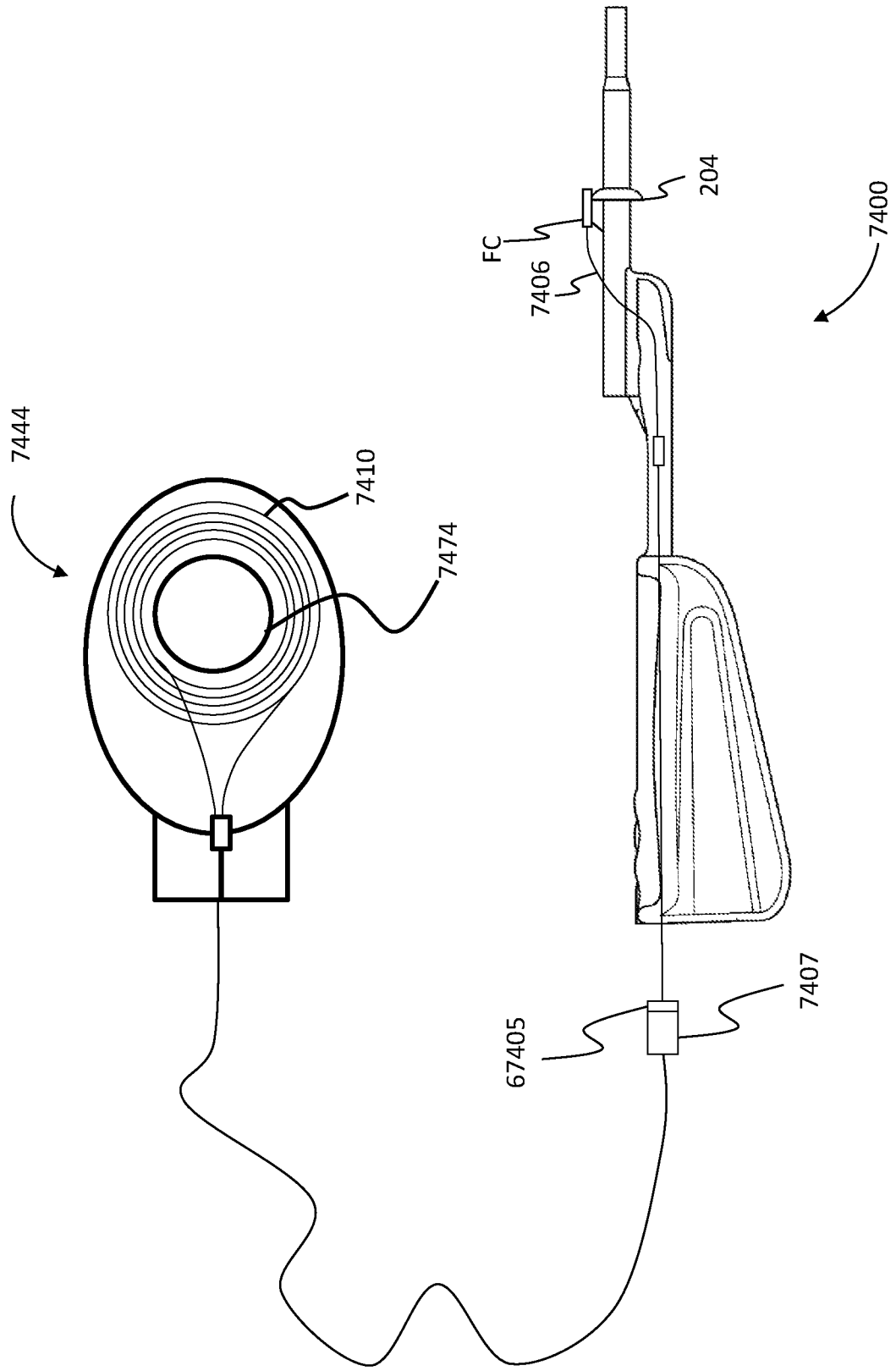


FIG. 74



A. CLASSIFICATION OF SUBJECT MATTER

A61N 1/372(2006.01)i, A61N 1/36(2006.01)i, A61N 1/05(2006.01)i, A61F 11/00(2006.01)i, A61F 2/18(2006.01)i

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 1/372; A61B 5/12; A61N 1/05; A61B 19/00; A61N 1/00; A61B 5/00; A61N 1/36; A61F 11/00; A61F 2/18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & keywords: cochlear, electrode, insertion tool, guide, insertion speed, insertion depth, indicator, eletrocorticography, ECoG, drug deliver

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 2014-0052148 A1 (VANCAILLIE, P. et al.) 20 February 2014 See claim 1; paragraphs [0019], [0020]; figures 1-2, 4A-4E.	1,2,4,9,10,12,14,15 3,5-8,11,13,16,24-31
Y	US 2011-0066160 A1 (SIMAAN, N. et al.) 17 March 2011 See claims 1, 18; paragraph [0111]; figure 12.	3,5-8,11,13,16,24-31
A	US 8594799 B2 (HALLER, M. I. et al.) 26 November 2013 See the entire document.	1-16,24-31
A	US 6968238 B1 (KUZMA, J. A.) 22 November 2005 See the entire document.	1-16,24-31
A	US 9072468 B2 (THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL) 07 July 2015 See the entire document.	1-16,24-31

☐ 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	Date of mailing of the international search report
09 November 2017 (09.11.2017)	**09 November 2017 (09.11.2017)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea
Facsimile No. +82-42-481-8578

Authorized officer
LEE, Dong Wook
Telephone No. +82-42-481-8163

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.: 17-23
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 17-23 pertain to methods for treatment of the human body and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).

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 addtional 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 any 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.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2014-0052148 A1	20/02/2014	EP 2884952 A2	24/06/2015
		US 9713713 B2	25/07/2017
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		WO 2014-027337 A3	24/04/2014
US 2011-0066160 A1	17/03/2011	WO 2009-124287 A1	08/10/2009
US 8594799 B2	26/11/2013	US 2010-0114288 A1	06/05/2010
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		US 6163729 A	19/12/2000
		US 6195586 B1	27/02/2001
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