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OCCLUDENT FOR TISSUE OPENINGS****Publication Classification**

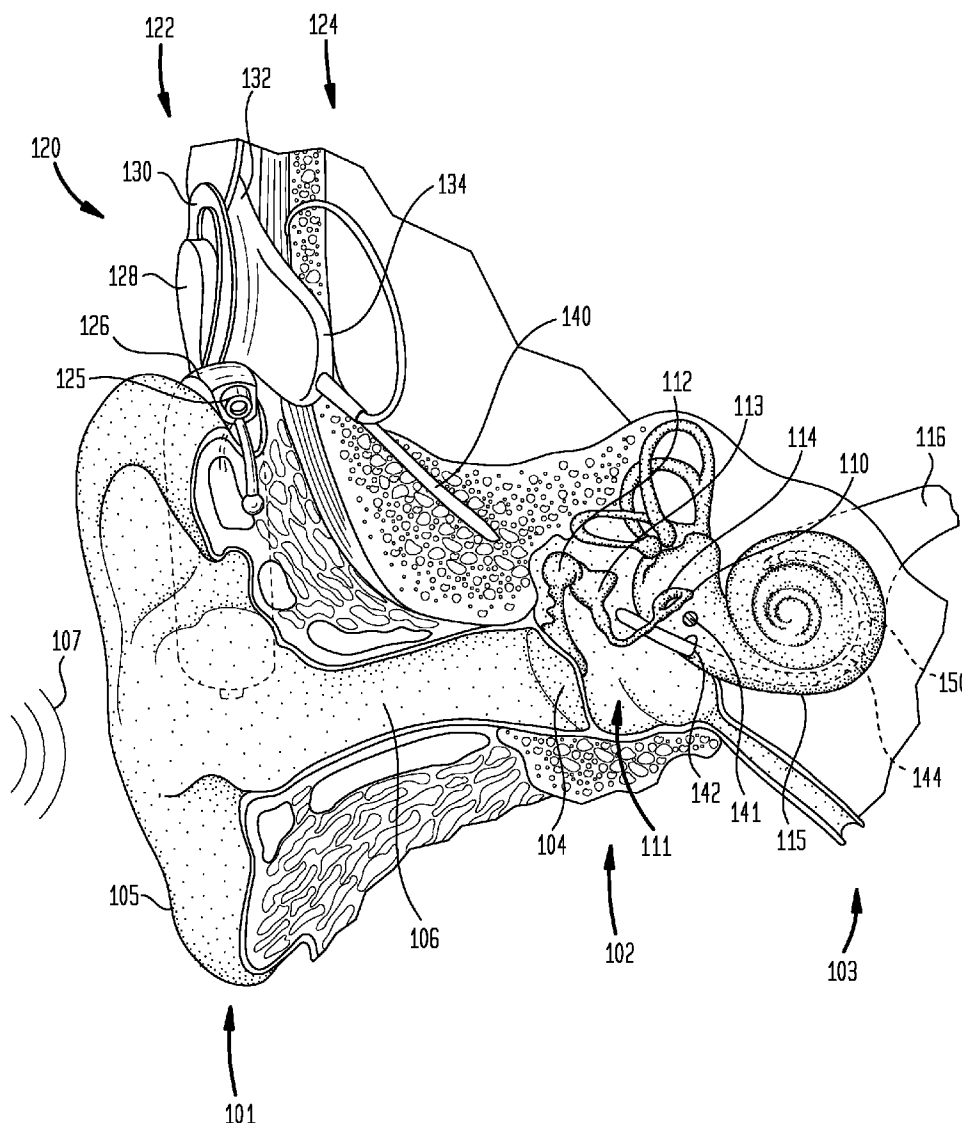
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(57) **ABSTRACT**

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An electrically nonconductive occludent constructed and arranged to forcefully infill a tissue opening so as to effectively prevent transport of electrical current, fluid and bacteria through the tissue opening. A cochlear implant comprising: an elongate electrode carrier member having at least one electrode disposed thereon, wherein the carrier member is configured to traverse a cochleostomy to position the electrodes in the cochlea; and an electrically nonconductive occludent constructed and arranged to circumferentially surround a portion of the carrier member traversing the cochleostomy, and to forcefully infill cochleostomy thereby segregating perilymphatic canals of the cochlea from extracochlear regions.



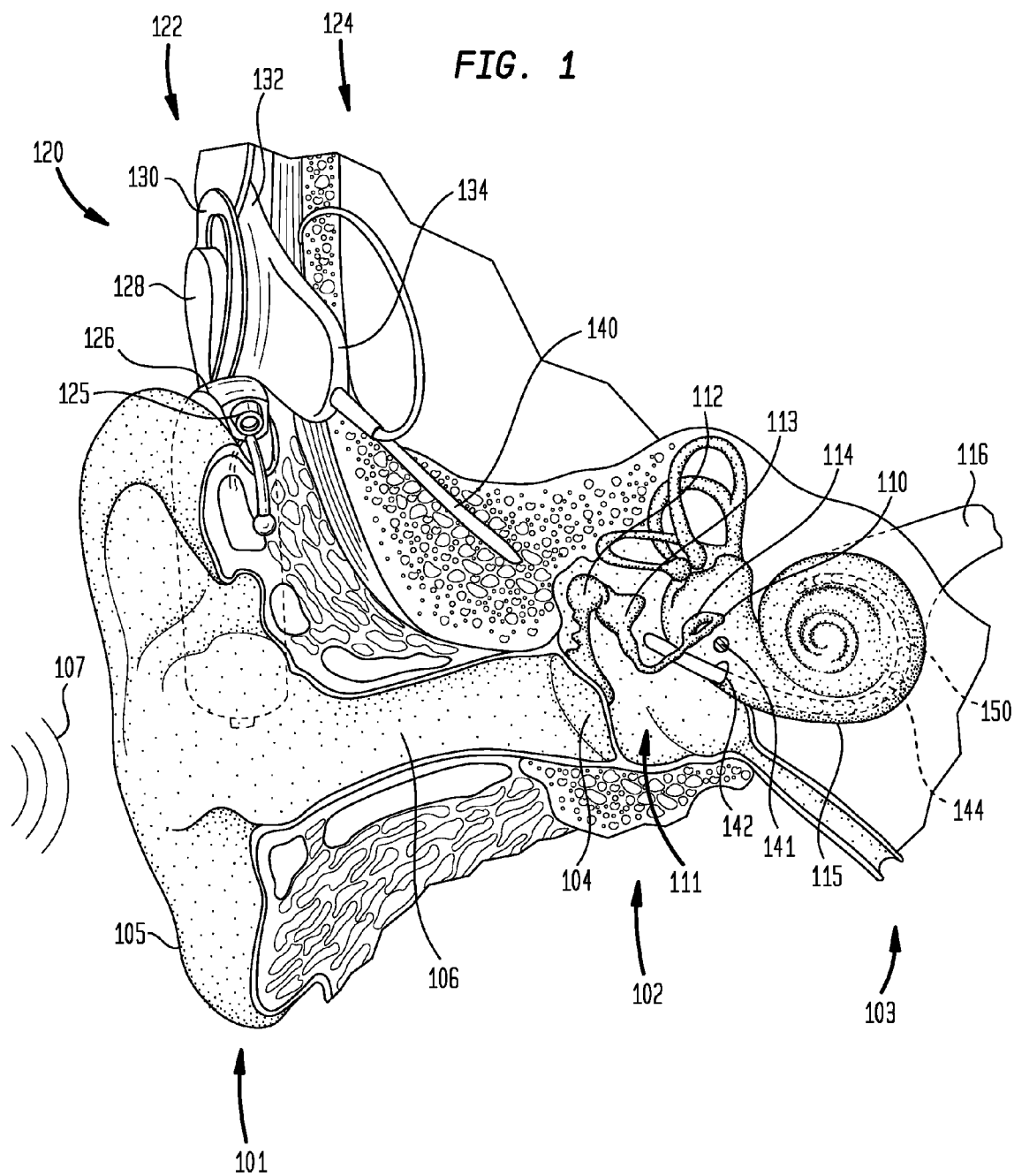


FIG. 2A

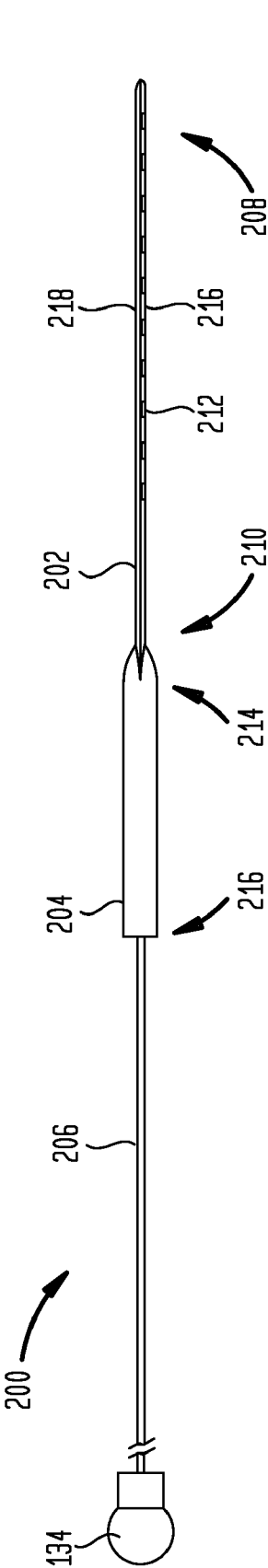


FIG. 2B

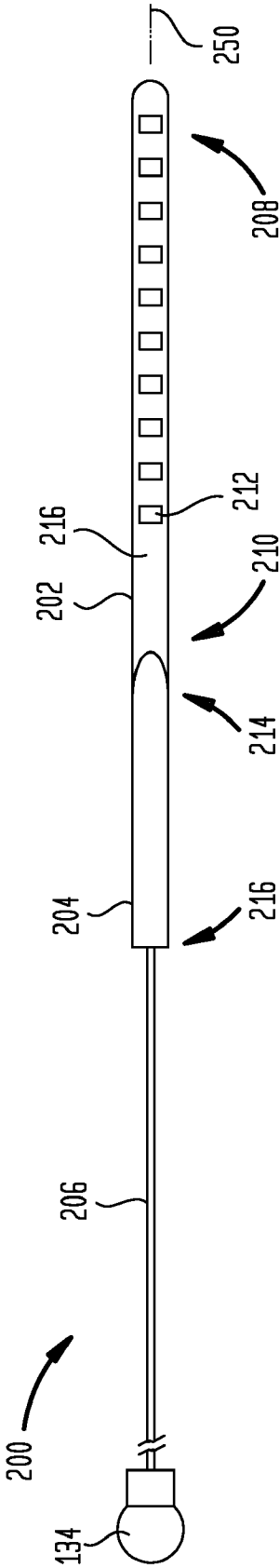


FIG. 3
(PRIOR ART)

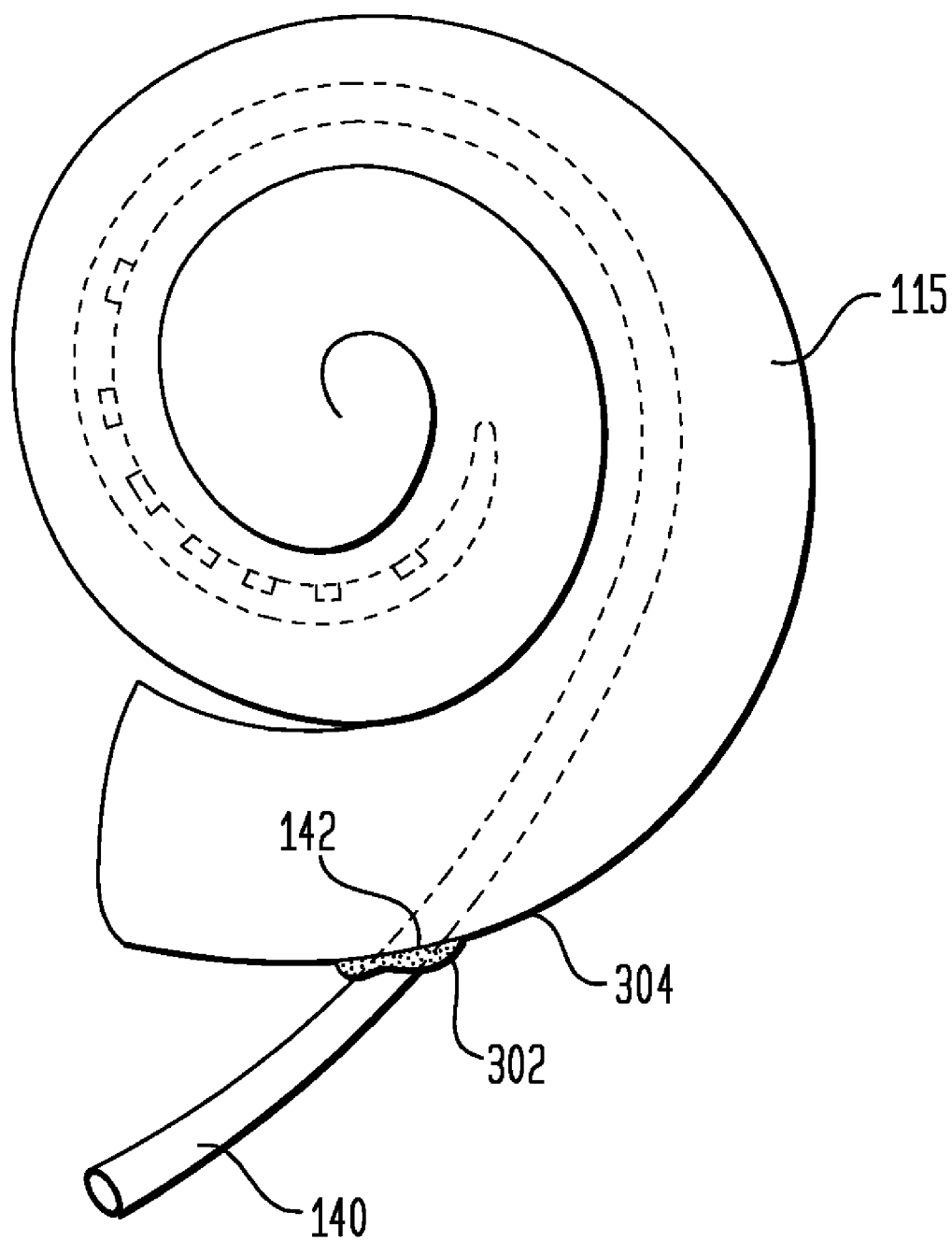


FIG. 4

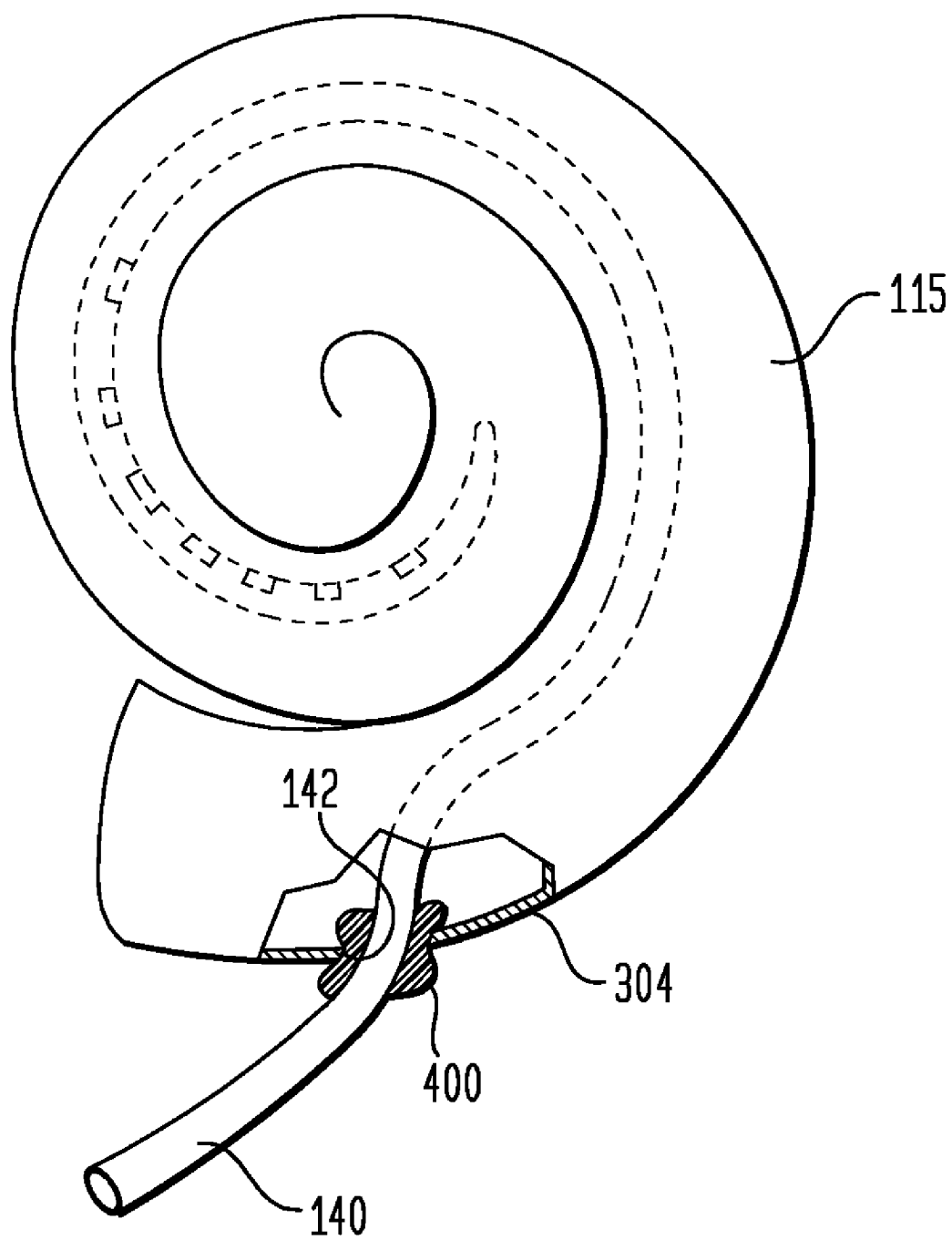


FIG. 5

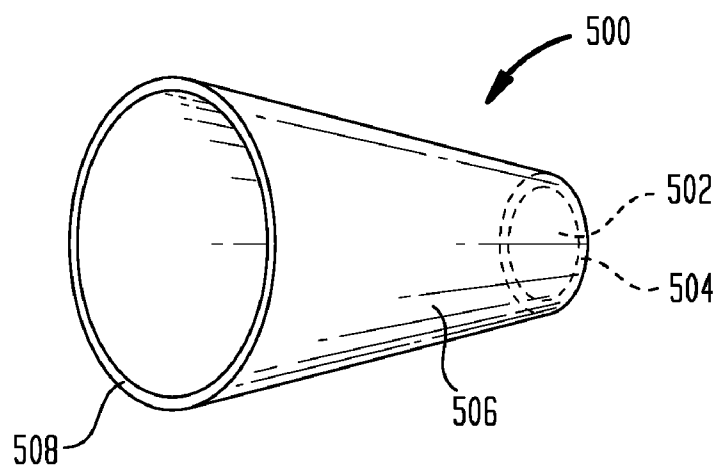


FIG. 6

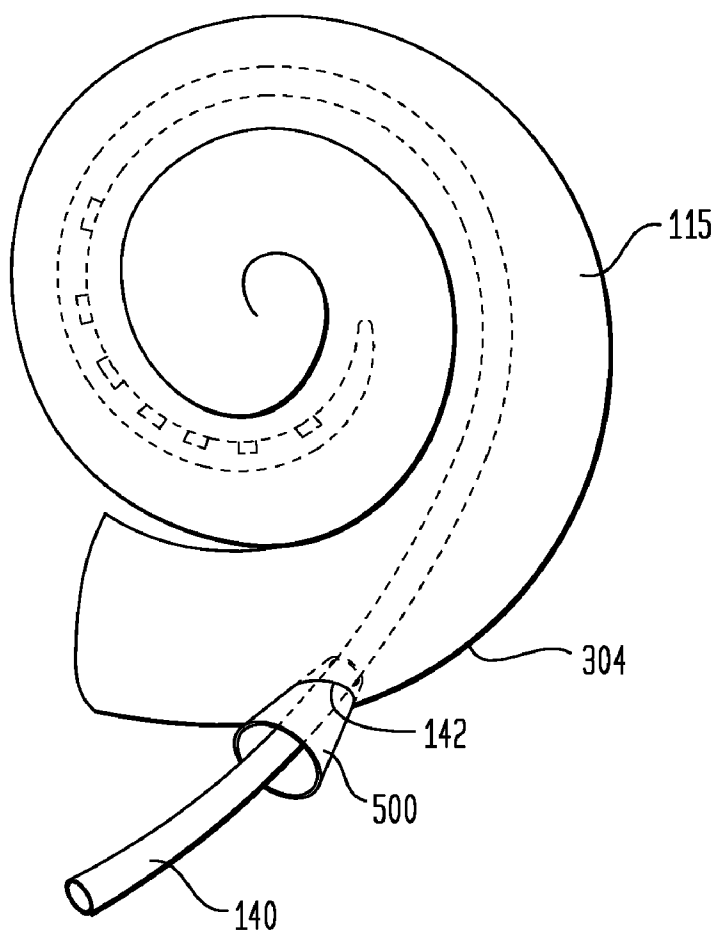
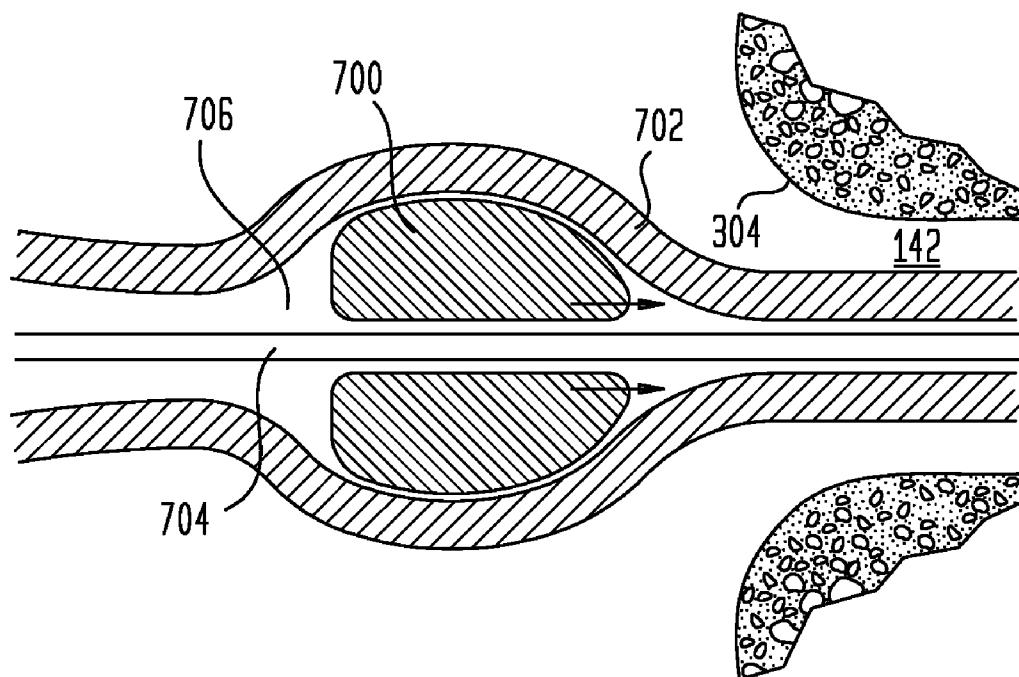


FIG. 7



ELECTRICALLY NONCONDUCTIVE OCCLUDENT FOR TISSUE OPENINGS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from Australian Provisional Patent Application No. 2005907188, entitled, "Improved Cochleostomy Sealing" which was filed on Dec. 21, 2005.

BACKGROUND

[0002] 1. Field of the Invention

[0003] The present invention relates generally to cochlear implant devices, and more particularly, to an electrically non-conductive cochleostomy occludent.

[0004] 2. Related Art

[0005] Hearing loss is generally of two types, namely conductive and sensorineural. The treatment of both of types of hearing loss has been quite different, relying on different principles to deliver sound signals to be perceived by the brain as sound. Conductive hearing loss occurs when the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. In such cases, hearing loss is often improved with the use of conventional hearing aids, which amplify the sound so that acoustic information reaches the cochlear hair cells. Such hearing aids utilize acoustic mechanical stimulation, whereby the sound is amplified according to a number of varying techniques, and delivered to the inner ear as mechanical energy. This may be through a column of air to the eardrum, or through direct delivery to the ossicles of the middle ear.

[0006] On the other hand, sensorineural hearing loss is due to the absence or destruction of the cochlear hair cells which are needed to transduce acoustic signals into auditory nerve impulses. Individuals suffering from this type of hearing loss are unable to derive any benefit from conventional hearing aid systems regardless of the volume of the acoustic stimulus. This is because the natural mechanisms for transducing sound energy into auditory nerve impulses are either absent or damaged. In such cases, cochlear™ implants (also referred to as cochlear™ devices, cochlear™ prostheses, cochlear™ implant systems, and the like; simply "cochlear implants" herein) have been developed to provide the sensation of hearing to such individuals. In cochlear implants, electrical stimulation is provided via stimulating electrodes positioned as close as possible to the nerve endings of the auditory nerve, essentially bypassing the hair cells in a normally functioning cochlea. The application of a stimulation pattern to the nerve endings causes impulses to be sent to the brain via the auditory nerve, resulting in the brain perceiving the impulses as sound.

[0007] The electrode array is inserted during an operation that usually takes between 2-3 hours depending on the device to be implanted. An incision is made behind the ear to expose the temporal bone; the temporal bone consists of the squamous, the mastoid, the tympanic, zygomatic and petrous segment. Typically, cochlear implants require the opening of the mastoid bone which leads to the middle ear. A shallow recess is then created to hold the implant package in place substantially level with the bone. Next a hole is drilled which allows the surgeon access into the cochlea. This hole is known as a cochleostomy—the opening from the middle ear to the peri-

lymphatic canals of the cochlea. A cochleostomy may be formed through the round window **141**, the oval window **110**, the promontory or through the apical turn of the cochlea. The electrode array is then gently threaded into the shell-like structure of the cochlea and the incision closed; the cochleostomy remains open and heals with scar tissue over the next few days.

[0008] More recently various alternative approaches have been proposed to cause dynamic volume displacements of the perilymph, some of which require the implantation of an actuator that breaches the cochlea. These procedures require a cochleostomy or equivalent incision to provide the requisite access to the perilymphatic canals of the cochlea.

[0009] It is conventional during surgical implantation to use a tissue graft from the patient to provide a seal at the cochleostomy, primarily to reduce the risk of meningitis resulting from communication between the inner ear and the middle ear.

SUMMARY

[0010] In one aspect of the invention, an electrically non-conductive occludent is disclosed, the occludent constructed and arranged to forcefully infill a tissue opening so as to effectively prevent transport of electrical current, fluid and bacteria through the tissue opening.

[0011] In another aspect of the invention, a cochlear implant is disclosed, the cochlear implant comprising: an elongate electrode carrier member having at least one electrode disposed thereon, wherein the carrier member is configured to traverse a cochleostomy to position the electrodes in the cochlea; and an electrically nonconductive occludent constructed and arranged to circumferentially surround a portion of the carrier member traversing the cochleostomy, and to forcefully infill cochleostomy thereby segregating perilymphatic canals of the cochlea from extracochlear regions.

[0012] In a further embodiment of the present invention, a method for implanting an elongate carrier member in a cochlea of a recipient is disclosed, the method comprising: creating a cochleostomy; implanting the carrier member into the cochlea; and positioning an electrically nonconductive occludent in the cochleostomy so as to cause the portion of the carrier member and the occludent to forcefully infill the cochleostomy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] An illustrative embodiment of the present invention will be described with reference to the accompanying figures, in which:

[0014] FIG. 1 is a perspective view of an example of an implanted cochlear implant suitable for implementing embodiments of the present invention;

[0015] FIG. 2A is a side view of an electrode assembly in accordance with one embodiment of the present invention;

[0016] FIG. 2B is a top view of the electrode assembly illustrated in FIG. 2A;

[0017] FIG. 3 is a schematic diagram of the cochlea showing a conventional intra-cochlear electrode insertion with the cochleostomy sealed using muscle/fat tissue;

[0018] FIG. 4 is a cross-sectional view of a portion of a cochlea showing an improved cochleostomy seal in accordance with one embodiment of the present invention;

[0019] FIG. 5 is a perspective view of one embodiment of the electrically nonconductive occludent of the present invention;

[0020] FIG. 6 is a perspective view of a human cochlea showing the embodiment of the occludent illustrated in FIG. 5 implanted in a cochleostomy, in accordance with embodiments of the present invention; and

[0021] FIG. 7 is a cross-sectional view of an alternative embodiment of a cochleostomy occludent of the present invention.

DETAILED DESCRIPTION

[0022] The present invention is generally directed to an electrically nonconductive occludent that forcefully infills and seals a cochleostomy or other tissue opening with or without an implantable component traversing the tissue opening. In one application described herein, an embodiment of the electrically nonconductive occludent is utilized to seal a cochleostomy having an implanted electrode assembly traversing therethrough, or other tissue opening such as the oval or round window with no such implanted component, thereby segregating the perilymphatic canals of the cochlea from extracochlear regions such as the middle ear. In certain embodiments, the occludent has a toroidal cross-sectional shape, circumferentially surrounding the implanted component such as an electrode carrier member.

[0023] The occludent may have a combination of one or more characteristics such as shape and durometer to partially enter the cochleostomy and to consume substantially all space between the carrier member and cochlea at the cochleostomy. The occludent may be permanently positioned on the carrier member, or it may be configured to slide over the carrier member to be positioned at the occluding position. In alternative embodiments, the occludent is configured to travel through the carrier member lumen to the occluding position. Such embodiments of the occludent may be configured to travel over the stylet used to implant the carrier member, or may be configured to be inserted with a tool for subsequent expansion. For example, the occludent may be a mechanical structure that is inflated mechanically or with a balloon.

[0024] Regardless of the method used to deploy the occludent, the region of the radially distensible carrier member containing the wedge dilates to consume the entire cochleostomy. Advantageously, the present invention provides a high electrical impedance blockage within the cochleostomy, thereby reducing the electric charge which may travel from the electrodes to, for example, an extracochlear reference electrode of the cochlear implant. It should be appreciated that the present invention is operable regardless of the relative size and location of the cochleostomy and carrier member regardless of whether the cochleostomy is formed through round window 141, the oval window 110, the promontory, the apical turn of the cochlea, or at any other therapeutically beneficial location to operatively reduce current flow through a tissue opening and thereby improve the electrical efficiency of the implant.

[0025] As noted, openings other than a cochleostomy may be made to accommodate the requirements of other types of prosthetic hearing implants. There are also circumstances that it is desirable to seal round window 141 and/or oval window 110 due to natural conditions, prior surgical procedure, etc. Such openings in tissue, whether they form naturally or occur due to disease, injury or surgery, are collectively and generally referred to herein as a tissue opening.

[0026] The present invention may be implemented in a variety of ways and the embodiments illustrated are to be considered only as illustrative constructions. More particularly, the present invention is potentially useful for purposes other than sealing a cochleostomy created as described herein. For example, the present invention may be applied to seal an existing orifice between the middle ear and the inner ear such as round window 141. The present invention may be used to seal any opening created between the middle ear and the perilymph, whether this is intended to be used as a conduit for a part of an implanted device, or to be sealed completely after surgery. The term cochleostomy should accordingly be understood for the purposes of this application in this expansive sense. Such sealing may have further advantages, for example reducing the chance of the recipient contracting meningitis. It may also reduce the risk of unintended explanation.

[0027] For the purpose of power reduction it is desirable to reduce the amount of electrical current required to stimulate the auditory nerve. During stimulation, as much as possible the current flowing from the electrode within the cochlea must be directed towards the auditory nerve. Any leakage of current through paths other than the auditory nerve should therefore be minimised in order to reduce the power consumption of the implant. The present invention accordingly allows current leakage via the cochleostomy of a hearing implant prosthesis to be reduced. As a consequence, the current levels used for stimulation can be decreased as the implant's energy is used more efficiently.

[0028] Although many different stimulation approaches have been proposed and used, in each scheme the energy for the stimulations is provided by the implant, and conventionally this is supplied ultimately by the batteries in the external component. Hence, the degree to which the energy supplied by the batteries is effectively delivered impacts upon battery life.

[0029] Embodiments of the present invention are described below in connection with one type of stimulating medical device having an component implantable through a tissue opening; that is, a prosthetic hearing implant and, more specifically, a cochlear implant. Cochlear implants use direct electrical stimulation of auditory nerve cells to bypass absent or defective hair cells that normally transduce acoustic vibrations into neural activity. Such devices generally use multi-contact electrodes inserted into the scala tympani of the cochlea so that the electrodes may differentially activate auditory neurons that normally encode differential pitches of sound. Such devices are also used to treat a smaller number of patients with bilateral degeneration of the auditory nerve. For such patients, the cochlear implant provides stimulation of the cochlear nucleus in the brainstem. Such devices, therefore, are commonly referred to as auditory brainstem implants (ABIs).

[0030] Exemplary embodiments of a cochlear implant include a Contour™, Freedom™, Nucleus™ or Cochlear™ implant sold by Cochlear Limited, Australia. Such devices are described in U.S. Pat. Nos. 4,532,930, 6,537,200, 6,565,503, 6,575,894, and 6,697,674, the entire contents and disclosures of which are hereby incorporated by reference herein. It should be understood to those of ordinary skill in the art that embodiments of the present invention may be used in other stimulating medical devices such as neurostimulators, cardiac pacemakers/defibrillators, etc. as well as other medical devices which utilize an elongate carrier member to tempo-

rarily or permanently implant, deliver or otherwise introduce a therapeutic agent, sensor, device, etc. into a recipient.

[0031] FIG. 1 is a cut-away view of the relevant components of outer ear 101, middle ear 102 and inner ear 103, which are described next below. In a fully functional ear, outer ear 101 comprises an auricle 105 and an ear canal 106. An acoustic pressure or sound wave 107 is collected by auricle 105 and channeled into and through ear canal 106. Disposed across the distal end of ear canal 106 is a tympanic membrane 104 which vibrates in response to acoustic wave 107. This vibration is coupled to oval window, or fenestra ovalis, 110 through three bones of middle ear 102, collectively referred to as the ossicles 111.

[0032] Ossicles 111 comprises the malleus 112, the incus 113 and the stapes 114. Bones 112, 113 and 114 of middle ear 102 serve to filter and amplify acoustic wave 107, causing oval window 110 to articulate, or vibrate. Such vibration sets up waves of fluid motion within cochlea 115. Such fluid motion, in turn, activates tiny hair cells (not shown) that line the inside of cochlea 115. Activation of the hair cells causes appropriate nerve impulses to be transferred through the spiral ganglion cells (not shown) to auditory nerve 116 and, ultimately, to the brain where they are perceived as sound. In some persons experiencing sensorineural hearing loss, there is an absence or destruction of the hair cells. Cochlear implant 120 is utilized to directly stimulate the ganglion cells to provide a hearing sensation to such persons.

[0033] FIG. 1 also shows how cochlear implant 120 is positioned in relation to outer ear 101, middle ear 102 and inner ear 103. Cochlear implant 120 comprises external component assembly 122 which is directly or indirectly attached to the body of the recipient, and an internal component assembly 124 which is temporarily or permanently implanted in the recipient. External assembly 122 comprises microphone 125 for detecting sound which is provided to a behind-the-ear (BTE) speech processing unit 126 that generates coded signals. The coded signals are provided to an external transmitter unit 128, along with power from a power source (not shown) such as a battery. External transmitter unit 128 comprises an external coil 130 and, preferably, a magnet (not shown) secured directly or indirectly in external coil 130.

[0034] Internal component assembly 124 comprises an internal receiver unit 132 having an internal coil (not shown) that transcutaneously receives power and coded signals from external assembly 122, and provides such signals to a stimulator unit 134. In response to the coded signals, stimulator 134 applies stimulation signals to cochlea 115 via an implanted electrode assembly 140. Electrode assembly 140 enters cochlea 115 via a cochleostomy 142, and has an array 144 of one or more electrodes 150 positioned to be substantially aligned with portions of tonotopically-mapped cochlea 115. The delivery of stimulation signals at various locations along cochlea 115 causes a hearing percept representative of the received sound 107.

[0035] While cochlear implant 120 is described as having external components, in another embodiment, the controller, including the microphone, speech processor and power supply, may also be implantable. In such embodiments, the controller may be contained within a hermetically sealed housing or the housing used for stimulator unit 134.

[0036] Electrode assembly 140 preferably assumes an optimal electrode position in cochlea 115 upon or immediately following implantation into the cochlea. It is also desirable that electrode assembly 140 be configured such that the inser-

tion process causes minimal trauma to the sensitive structures of cochlea 115. Usually electrode assembly 140 is pre-curved, held in a straight configuration at least during the initial stages of the implantation procedure, conforming to the natural shape of the cochlea during and subsequent to implantation.

[0037] FIG. 2A is a side view of an embodiment of electrode assembly 140, referred to herein as electrode assembly 200. FIG. 2B is a top view of electrode assembly 200. Electrode assembly 200 comprises a carrier member 202, a stop member 204 and lead 206. Carrier member 202 has a distal end 208 adapted to be implanted furthest into cochlea 115, and a proximal end 210 connected to a distal end 214 of laterally-extending stop member 204. The opposing proximal end 216 of stop member 204 is connected to lead 206. Lead 206 physically and electrically connects electrode assembly 200 with stimulator unit 134.

[0038] When implanted in a recipient, the surface of carrier member 202 which faces the interior of cochlea 115 is referred to herein as the medial surface 216 of carrier member 202. The opposing side of carrier member 202, referred to herein as lateral surface 218, faces the external wall and bony capsule (not shown) of cochlea 115. It should be understood that the terms medial surface, medial direction, and the like, are generally used herein to refer to the surfaces, features and directions toward the center of cochlea 115, while the terms lateral surface, lateral direction, and the like, are generally used herein to refer to surfaces, features and directions toward the exterior of cochlea 115. In addition, a longitudinal axis 250 is utilized herein to facilitate descriptions herein.

[0039] A plurality of spaced-apart electrodes 212 are mounted on or in carrier member 202. Electrodes 212 may be disposed in a linear or non-linear array on or in carrier member 202, and may be positioned to align with predetermined regions of tonotopically mapped cochlea 115. In alternative embodiments, electrodes 212 are implemented as described in U.S. Provisional Patent Application No. 60/748,217, 60/748,273 and 60/748,314, hereby incorporated by reference herein.

[0040] FIG. 3 is a schematic of cochlear 115 showing a conventional, intra-cochlear electrode insertion, where cochleostomy 142 is sealed using a graft 302 of the recipient's tissue, typically muscle and fat. In this illustrative example, cochleostomy 142 is shown in an exterior wall 304 of cochlea 115, and is situated in the space of middle ear 102. Graft 302 is positioned around carrier member 140 over cochleostomy 142, as shown in FIG. 3.

[0041] FIG. 4 is a cross-sectional view of a portion of a cochlea showing an improved cochleostomy seal in accordance with one embodiment of the present invention. In this exemplary embodiment, a deformable electrically nonconductive occludent 400 is inserted into cochleostomy 142 to prevent the transfer of fluids, bacteria and electrical current through cochleostomy 142. In one particular embodiment, occludent 400 is formed from a soft, deformable grade of silicone elastomer. Such combination of characteristics allows occludent 400 to elastically conform to the generally irregular shape of cochleostomy 142.

[0042] Occludent 400 may be formed around elongate electrode carrier member 140 so that it can slide along the carrier member. For example, in one embodiment, occludent 400 has an aperture suitable for slidably receiving the implantable component that is to be traversing through the tissue opening, here carrier member 140 traversing cochleostomy 142. In

practice, the surgeon would insert electrode carrier member **140** through cochleostomy **142** and into cochlea **115** in a conventional manner. This process is well understood in the art, and described in the literature, and conventional aspects of this process will not be further described in detail. A standard reference for such a process is described in "Surgical Techniques for Cochlear Implants", Noel L. Cohen, Chapter 8, p 151 in "Cochlear Implants", Waltzman, S. B. and Cohen, L. L. (1997) ISBN 0-86577-882-5, the disclosure of which is hereby incorporated by reference.

[0043] The extent of insertion will vary significantly from recipient to recipient, depending upon the peculiarities of the anatomy of the recipient, the specific surgical procedure used by the surgeon, and the precise location of cochleostomy **142**. It is expected that the most improvement in leakage reduction will be for the basal electrodes **150**, as these electrodes have the shortest leakage path. It therefore also follows that greater improvement may be seen in short or partial electrode arrays, for example as used in electro-acoustic stimulation.

[0044] After carrier member **140** has been inserted as far as desired, occludent **400** may be slid along electrode carrier member **140** to be partially inside cochlea **115** and partially outside cochlea **115**; that is, occludent **400** infills cochleostomy **142**. Because this embodiment of occludent **400** has an exterior radius that is larger than the interior radius of cochleostomy **142**, and because occludent **400** is malleable; that is, has a low durometer, it deforms to partially enter cochlea **115** thereby forcefully infilling cochleostomy **142** so as to effectively prevent transport of electrical current, fluid and bacteria through the cochleostomy. In other words, occludent **400** fills the available space between the walls of cochlea **115** defining cochleostomy **142** and the exterior of carrier member **140** which passes through the cochleostomy. Furthermore, occludent **400** sufficiently infills cochleostomy **142** so that fluids, bacteria, etc., cannot pass through an remaining apertures between cochlea **115** and occludent **400**. Thus, occludent **400** provides a seal of electrically nonconductive, or insulating, biocompatible material within cochleostomy **142**. Occludent **400** thereby increases the impedance of the undesired current path through cochleostomy **142** to the reference electrode (not shown) of cochlear implant **120** located outside the inner ear **103**. It should be appreciated to those of ordinary skill in the art that as the anatomical structures surrounding occludent **400** are partially conductive and, as such, electric current may still leak through this general region, but current leakage through cochleostomy **142** will be reduced.

[0045] The embodiment of occludent **400** shown in FIG. 4 is generally toroidal in shape, as it surrounds electrode carrier member **140** and infills cochleostomy **142** as described above. However, any other suitable shape may be used. One such suitable shape is a truncated cone **500**, as shown in FIGS. 5 and 6. FIG. 5 is a perspective view of an occludent **500** having a truncated cone configuration, while FIG. 6 is a perspective view of occludent **500** inserted into cochleostomy **142** of cochlea **115**.

[0046] The end **504** of truncated cone occludent **500** which has a smaller diameter is dimensioned to easily pass through cochleostomy **142** to enable occludent **500** to enter cochlea **115**. Conversely, the end **508** of occludent **500** which has a relatively greater diameter is dimensioned to not pass through cochleostomy **142**. As such, occludent **500** forcefully infills cochleostomy **142** as it is inserted into the cochleostomy, thereby sealing cochlea **115**. In one embodiment, body

506 of occludent **500** is also malleable to enable the occludent to deform in response to the forced insertion of the occludent, further insuring a forceful infilling sufficient to seal cochleostomy **142**. As shown in FIG. 6, when implanted, base **508** of occludent **500** remains on the outside of cochleostomy **142**, allowing for easy removal should that be necessary.

[0047] As noted above with reference to the embodiment of the electrically nonconducting occludent **400**, occludent **500** may be implemented as an integrated or unitary element of electrode carrier member **140**, or it may be a separately manufactured component that has a channel **502** dimensioned to slide over carrier member **140**. In either embodiment, once electrode carrier member **140** is in a suitable position and occludent **500** is in the occluding position; that is, partially infilling cochleostomy **142**, occludent **400** seals cochleostomy **142**.

[0048] Occludent **500** may be formed of any suitable inert biocompatible material that is operatively an electrical insulator. In one embodiment, occludent **500** is preferably formed of silicone. It should be appreciated, however, that occludent **500** may be formed of different materials or from a combination of one or more other material. It could be partly formed from a more stiff material, with the outer portions being resilient in order to provide the necessary conformable seal.

[0049] Occludent **500** may be formed from a suitable polymer putty material in situ. It could be formed, with a slit or the like, to allow it to be attached around the electrode carrier member **140** after insertion. Importantly, occludent **500** is formed of an insulating material and substantially seal cochleostomy **142** so as to increase the impedance of the leakage path. If different shapes or forms of electrode carrier member **140** are used, then the shape of the occludent **500** will need to be adapted to suit the shape of the implanted carrier member which traverses cochleostomy **142**.

[0050] Alternatively, as shown in FIG. 7, an alternative embodiment of the present invention, carrier member **140** is radially distensible and has a longitudinally-extending lumen **706**. In one embodiment, lumen **706** is configured to receive a stylet as is conventionally utilized in certain pre-curved electrode carrier members. In an alternative embodiment, lumen **706** is configured to interoperate with occludent **700** as described herein.

[0051] Occludent **700** is configured to be slidably passed through lumen **706** as shown in FIG. 7. The exterior dimensions of occludent **700** are larger than the interior dimensions of lumen **706**. As such, occludent **700** applied a force radially outward in that region of carrier member **702** in which occludent **700** is located. Because carrier member **702** is outwardly distensible, such force causes carrier member **702** to dilate or expand in the region containing occludent **700**, as shown in FIG. 7. In such embodiments, advancing occludent **700** to be partially inside cochlea **115**; that is, to infill cochleostomy **142**, causes carrier member **702** to expand to about the perimeter of cochlea **115** that defines cochleostomy **142**.

[0052] Occludent **700** may take on any form necessary. In the embodiment shown in FIG. 7, occludent **700** is solid. Alternatively occludent **700** may be hollow. In the embodiment shown in FIG. 7, occludent **700** is distally tapered and has round edges. This is to avoid damage to interior surfaces of carrier member **702** defining lumen **706**. It should be appreciated, however, that occludent **700** may take on other shapes in alternative embodiments.

[0053] In operation, occludent **700** is initially located near a proximal end of electrode carrier member **702** so that it does

not interfere with the normal insertion of the carrier member. After insertion of electrode carrier member **702**, occludent **700** is slid along lumen **706** to cochleostomy **142** where it deforms the sides of carrier member **702** sufficiently to seal the cochleostomy **142**. This embodiment has the further advantage in that two separate components do not abut to create a potential space, thereby reducing the risk of infection.

[0054] It should be appreciated that tools or guide wires may be used to facilitate the advancement of occludent **700** in lumen **706**. For example, in the example shown in FIG. 7, a guide wire **704** is provided, and occludent **700** has an aperture for sliding receiving the guide wire **704**. Alternatively, occludent **700** may be detachably secured to the distal end of a tool that may be advanced into lumen **706**.

[0055] Alternatively, occludent **700** may be formed by being moulded as part of the electrode moulding process, at an appropriate location along the length of electrode carrier member **702**. In such embodiments, implantation of electrode carrier member **702** is performed until occludent **700** is positioned in cochleostomy **142**.

[0056] Such an embodiment has the same advantage as the sliding space filling plug of FIG. 7 in that it has no separate insulator parts abutting and therefore has a reduced risk of infection. It also has the advantage of not requiring a small device to be moved, relative to the array, in the confined space and delicate structures of the inner ear during implantation.

[0057] In alternative embodiment, occludent **700** may be initially of smaller dimensions when advanced through lumen **706**, and then expanded to a larger size to effect the radial distension of carrier member **702** noted above. Such an expansion may be achieved in many ways now or later developed, such as by implementing mechanically expandable members, a material that expands in response to the pumping of air or other fluid, the mixing of materials, and the like.

[0058] It should also be appreciated that the occludent of the present invention may be specifically shaped to fit an actual aperture, for example the oval window. Alternatively, it could be formed in situ, for example by a fast curing sealant injected around the cochleostomy **142**. Any effective artificial seal which can be positioned as required may be used to implement the invention.

[0059] The efficacy of implementing embodiments of the present invention has been investigated using an animal model. Experiments on two Guinea Pigs, with a total of three ears investigated acutely have been performed. In these experiments, the bulla (middle ear cavity) was exposed, a cochleostomy was drilled over the round window and a four electrode array was inserted. Stimulation was applied between the most apical intracochlear electrode (ICE) and a monopolar ball electrode inserted in the temporalis muscle.

[0060] Monopolar Electrical Auditory Brainstem Response (EABR) thresholds and the voltage waveform between the stimulus electrodes (to deduce impedance) were measured. In the last of the three ears investigated the voltage between the two most basal ring electrodes was also measured during the stimulus pulse (to determine the current flow along the cochlea at a point near the cochleostomy).

[0061] To calibrate this measurement a known current pulse had been previously applied between the most apical ICE and another ring electrode (on a separate array) held by hand in the cochleostomy.

[0062] Four different methods of sealing the cochleostomy were used: no sealing; small piece of muscle of approx. the

volume of the cochleostomy; larger piece of muscle several times the volume of the cochleostomy (residual muscle extending out of the cochleostomy) and otoform paste (one ear only).

[0063] Otoform paste is a settable silicone material, used in hearing aid fitting and similar applications, which is initially mouldable but which then sets to a soft deformable consistency.

[0064] In every ear the EABR thresholds, the impedance and the current flow at the cochleostomy varied depending on the plug type used. The following table shows the four sealing methods and how those parameters varied:

Plug material	EABR T	Impedance (Z)	Cochleostomy current
Large muscle	Largest	lowest	Largest
Small muscle	2 nd largest	2 nd lowest	2 nd largest
No seal	3 rd largest	3 rd lowest	3 rd largest
Otoform putty	Smallest	highest	smallest

[0065] The smallest EABR threshold (otoform putty) was about 40% smaller than the largest threshold (large muscle). The impedance results varied by around 20-35% from smallest to largest. The current flow through the cochleostomy varied from 84% of total current (large muscle) to 70% (otoform putty).

[0066] The results are consistent with a significant proportion of the stimulus current flowing through the cochleostomy. Different sealing arrangements appear to change the amount of current flow through the cochleostomy and thereby change the EABR threshold. The changes in impedance and cochleostomy current flow as measured by the voltage on the basal two rings are consistent with this model. These results indicate it is possible to lower thresholds by effective sealing of the cochleostomy.

[0067] Another perspective is that any T and C decrease gained from using the plug will manifest itself as a decrease in power consumption of the implant and a subsequent increase in battery life. Power consumption of the implant can be divided into two parts—power consumed to run the implant electronics (W_E) and power consumed to deliver current to the auditory nerve (W_N). The decrease in T/C level current will manifest itself as a proportional decrease in W_N . For present implant designs the ratio of W_N to W_E is about 50:50 for high rate strategies. If, for example, it is assumed that the plug provides a 10% decrease in T/C level this would translate to about a 5% decrease in overall implant power consumption for high rate strategies, less for lower rate strategies. However, the most recent tests show that the plug yields an improvement of between 20-40% decrease in T/C level, indicating at least a 10% improvement in power consumption.

[0068] Variations and additions are possible to the structures described within the general scope of the present invention. For example, embodiments of the present invention may be employed in addition to a tissue graft type sealing approach.

[0069] Although the present invention has been principally described with reference to a cochlear implant prosthesis, it will be appreciated that embodiments of the present invention may readily be applied to provide a nonconductive seal of a tissue opening regardless of whether a carrier member **140** or other implant prosthesis or component is positioned within the tissue opening. Such applications in which there are elec-

trical losses through the tissue opening may particularly benefit from the present invention. It should also be understood that although the description has referred principally to a prosthetic hearing implant with an external receiver/stimulator unit **134**, embodiments of the present invention are equally applicable to a totally implanted device.

[0070] It will also be appreciated that although this invention has been principally used to provide sealing at the cochleostomy there are other tissue openings between cochlea **115** and middle ear **102** that may pass similar electric current and that may also provide similar benefit by being sealed with an embodiment of the electrically nonconductive occludent of the present invention. These include round window **141** and oval window **110**. Embodiments of the electrically nonconductive occludent of the present invention which are not integrated in or unitary with a carrier member may be inserted into these other tissue openings, providing a further decrease in stray electrical current. It will be understood that the present invention may also be applied to seal a cochleostomy which is not intended to remain open, for example in some form of totally implanted device which does not require a physical conduit to remain out of inner ear **103**.

[0071] All documents, patents, journal articles and other materials cited in the present application are hereby incorporated by reference.

[0072] Although the present invention has been fully described in conjunction with several embodiments thereof with reference to the accompanying drawings, it is to be understood that various changes and modifications may be apparent to those skilled in the art. Such changes and modifications are to be understood as included within the scope of the present invention as defined by the appended claims, unless they depart therefrom.

What is claimed is:

1. An electrically nonconductive occludent constructed and arranged to forcefully infill a tissue opening so as to effectively prevent transport of electrical current, fluid and bacteria through the tissue opening.

2. The occludent of claim 1, wherein a component traverses the tissue opening, and further wherein said occludent is configured to circumferentially surround a portion of the component traversing the tissue opening.

3. The occludent of claim 2, wherein the component is an electrode carrier member, and further wherein said occludent is configured to circumferentially surround said electrode carrier member thereby segregating perilymphatic canals of the cochlea from extracochlear regions.

4. The occludent of claim 3, wherein the electrode carrier member is a component of a prosthetic hearing implant.

5. The occludent of claim 3, wherein the prosthetic hearing implant comprises a cochlear implant.

6. The occludent of claim 4, wherein the tissue opening is a cochleostomy.

7. The occludent of claim 5, wherein the cochleostomy is formed through one of either the cochlea round window, the cochlea oval window, the cochlea promontory, and the cochlea apical turn.

8. The occludent of claim 2, wherein the tissue opening is an opening in a cochlea.

9. The occludent of claim 1, wherein a component traverses the tissue opening, and further wherein said occludent has an aperture formed therein to receive a portion of the component traversing the tissue opening.

10. The occludent of claim 10, wherein said occludent has a toroidal cross-sectional shape.

11. The occludent of claim 10, wherein said occludent has a combination of one or more characteristics to enable said occludent to forcefully consume substantially all space between the carrier member and cochlea at the cochleostomy.

12. The occludent of claim 10, wherein said occludent is permanently positioned on the electrode carrier member.

13. The occludent of claim 2, wherein said occludent is further configured to slidably receive the component.

14. The occludent of claim 11, wherein said characteristics comprise one or more of the group consisting of shape and durometer.

15. The occludent of claim 2, wherein said component is radially distensible and has a accessible orifice disposed therein, and further wherein said occludent is configured to be slidably adjusted within the orifice.

16. The occludent of claim 15, wherein said occludent has a surface configuration that tapers distally.

17. The occludent of claim 15, wherein said orifice is a lumen longitudinally disposed in the electrode carrier member.

18. The occludent of claim 17, wherein the lumen is configured to receive a stylet, and further wherein said occludent is configured to travel over the stylet.

19. The occludent of claim 15, wherein said occludent is expandable, such that when expanded while located in the lumen, said occludent causes the carrier member to radially dilate to seal the cochleostomy.

20. The occludent of claim 1, wherein said occludent is formed from a resilient, deformable material so that operatively it conforms substantially to the surface of the tissue opening.

21. The occludent of claim 20, wherein said resilient, deformable material comprises silicone.

22. The occludent of claim 20, wherein said resilient, deformable material comprises silicone.

23. The occludent of claim 3, wherein said occludent is a truncated cone.

24. A cochlear implant comprising:

an elongate electrode carrier member having at least one electrode disposed thereon, wherein the carrier member is configured to traverse a cochleostomy to position the electrodes in the cochlea; and

an electrically nonconductive occludent constructed and arranged to circumferentially surround a portion of the carrier member traversing the cochleostomy, and to forcefully infill cochleostomy thereby segregating perilymphatic canals of the cochlea from extracochlear regions.

25. The cochlear implant of claim 24, wherein the cochleostomy is formed through one of either the cochlea round window, the cochlea oval window, the cochlea promontory, and the cochlea apical turn.

26. The cochlear implant of claim 24, wherein said occludent has an aperture formed therein to receive a portion of the carrier member.

27. The cochlear implant of claim 24, wherein said occludent has a toroidal cross-sectional shape.

28. The cochlear implant of claim 24, wherein said occludent has a combination of one or more characteristics including shape and durometer to enable said occludent to forcefully consume substantially all space between the carrier member and cochlea at the cochleostomy.

29. The cochlear implant of claim **24**, wherein said occludent and said electrode carrier member are fixedly integrated.

30. The cochlear implant of claim **24**, wherein said occludent and said electrode carrier member are unitary.

31. The cochlear implant of claim **24**, wherein said occludent is further configured to slidably receive the component.

32. The cochlear implant of claim **27**, wherein said occludent is further configured to slidably receive the component.

33. The cochlear implant of claim **24**, wherein said carrier member is radially distensible and has a lumen longitudinally disposed in the electrode carrier member, and further wherein said occludent is configured to be slidably adjusted within the lumen.

34. The cochlear implant of claim **33**, wherein said occludent has a surface configuration that tapers distally.

35. The cochlear implant of claim **33**, wherein the lumen is configured to receive a stylet, and further wherein said occludent is configured to travel over the stylet.

36. The cochlear implant of claim **33**, wherein said occludent is expandable, such that when expanded while located in the lumen, said occludent causes the carrier member to radially dilate to seal the cochleostomy.

37. The cochlear implant of claim **24**, wherein said occludent is formed from a resilient, deformable material so that operatively it conforms substantially to the surface of the tissue opening.

38. The occludent of claim **37**, wherein said resilient, deformable material comprises silicone.

39. The occludent of claim **37**, wherein said resilient, deformable material comprises silicone.

40. The occludent of claim **24**, wherein said occludent is a truncated cone.

41. A method for implanting an elongate carrier member in a cochlea of a recipient, comprising:

creating a cochleostomy;

implanting the carrier member into the cochlea; and

positioning an electrically nonconductive occludent in the cochleostomy so as to cause the portion of the carrier member and the occludent to forcefully infill the cochleostomy.

42. The method of claim **41**, wherein said occludent is configured to circumferentially surround a portion of the carrier member traversing the cochleostomy.

43. The method of claim **41**, wherein creating the cochleostomy comprising:

forming the cochleostomy through one of either the cochlea round window, the cochlea oval window, the cochlea promontory, and the cochlea apical turn.

44. The method of claim **41**, wherein said occludent has an aperture formed therein to receive a portion of said carrier member traversing the cochleostomy, and wherein positioning the occludent in the cochleostomy comprises:

sliding said occludent over said carrier member until at least a portion of said occludent infills said cochleostomy.

45. The method of claim **41**, wherein said occludent is permanently positioned on the electrode carrier member, and wherein positioning the occludent in the cochleostomy comprises:

implanting said carrier member to a depth at which at least a portion of said occludent infills said cochleostomy.

46. The method of claim **41**, wherein said carrier member is radially distensible and has an accessible lumen longitudinally disposed therein, wherein said occludent is configured to be slidably adjusted within the orifice, and further wherein positioning the occludent in the cochleostomy comprises:

sliding said occludent through said lumen into at least a portion of said occludent infill said cochleostomy, wherein said occludent causes the carrier member to radially dilate to seal the cochleostomy.

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