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(54) Title: MIDDLE EAR TRANSDUCER WITH BIOCOMPATIBLE IMPLANTABLE ADHESIVE PAD

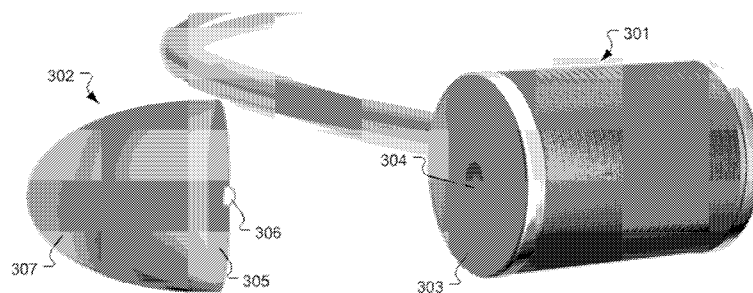


Fig. 3

(57) Abstract: An implantable transducer converts an electrical stimulation signal into a corresponding mechanical stimulation signal. The transducer has an elongated shape with a transducer end face having a transducer drive surface adapted to produce the mechanical stimulation signal, and a transducer adhesive feature adapted to intra-operatively receive adhesive material. A separate coupling cap has a coupling end face with a coupling adhesive feature adapted to engage the transducer adhesive feature with the adhesive material and a coupling drive surface adapted for distortion-free coupling of the mechanical stimulation signal from the transducer drive surface to the coupling cap. A signal delivery surface of the coupling cap delivers the mechanical stimulation signal to an adjacent cochlear surface for sensation as sound.



TITLE

Middle Ear Transducer with Biocompatible Implantable Adhesive Pad

[0001] This application claims priority from U.S. Provisional Patent Application 61/836,243, filed June 18, 2013, which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to medical implants, and more specifically to a novel clover shape attachment for securing an implantable floating mass transducer to the incus bone in the middle ear of a patient.

BACKGROUND ART

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

[0004] Hearing is impaired when there are problems in the ear's ability to transduce external sounds into meaningful action potentials along the neural substrate of the cochlea **104**. To improve impaired hearing, various types of hearing prostheses have been developed. For example, when a hearing impairment is related to the operation of the middle ear **103**, a conventional hearing aid or a middle ear implant (MEI) device may be used to provide acoustic-mechanical vibration to the auditory system.

[0005] Fig. 1 also shows some components in a typical MEI arrangement where an

external audio processor **111** processes ambient sounds to produce an implant communications signal that is transmitted through the skin by external transmitter **107** to an implanted receiver **108**. Receiver **108** includes a receiver coil that transcutaneously receives the implant communications signal which is then demodulated into transducer stimulation signals which are sent over leads **109** through a surgically created channel in the temporal bone to a floating mass transducer (FMT) **110** secured to the incus bone in the middle ear **103**. The transducer stimulation signals cause drive coils within the FMT **110** to generate varying magnetic fields which in turn vibrate a magnetic mass suspended within the FMT **110**. The vibration of the inertial mass of the magnet within the FMT **110** creates vibration of the housing of the FMT **110** relative to the magnet. This vibration of the FMT **110** is coupled to the incus in the middle ear **103** and then to the cochlea **104** and is perceived by the user as sound. *See* U.S. Patent 6,190,305, which is incorporated herein by reference.

[0006] Figure 2A shows an FMT **110** ideally implanted so that its end drive surface **203** generates a mechanical stimulation signal that optimally drives the round window membrane **202** to vibrate the fluid within the scala tympani **201**. In some patients, it may be difficult or impossible to implant the FMT **110** as shown in Fig. 2A with its cylindrical axis perpendicular to the round window membrane **202**. When the patient's anatomy does not allow placement of the FMT **110** perpendicular to the round window membrane **202**, Figure 2B shows an FMT **110** that drives the round window membrane **202** via a vibroplasty coupling cap **204** within a round drive surface that drives the round window membrane **202** at an angle to the longitudinal axis of the FMT **110**.

[0007] But implanting the FMT **110** with such a coupling cap **204** can be difficult. Because the FMT **110** and the coupling cap **204** are so small, they can be hard to handle and manipulate with standard non-custom surgical tools. It can be difficult for the surgeon to correctly place the coupling cap **204** coaxially onto the FMT **110** at a right angle. In other cases, the coupling cap **204** is initially placed correctly onto the FMT **110**, but then gets pushed askew or off during the surgery (the holding force of the clamping fingers on the coupling cap **204** is limited). Or the surgeon may accidentally damage the FMT **110** and/or the coupling cap **204**. These problems can arise due to various factors, for example,

stress or poor lighting, and they can become quite time consuming to correct.

[0008] In addition, the arrangement as shown in Fig. 2 where the coupling cap **204** has clamping fingers that fit over the FMT **110** increases the outside diameter of the resulting arrangement which undesirably increases the volume needed for implantation.

[0009] Nor is it the case that a conventional adhesive material can simply be added to increase the bonding force between the FMT **110** and the coupling cap **204**. There is no way to apply the same amount of adhesive material in the same repeatable way to bond the FMT **110** and the coupling cap **204** so as to provide a consistent and predictable effect in the operating performance of the implanted FMT **110**. The adhesive material also has elastic properties that generated undesired linear and non-linear damping in the mechanical stimulation signal that is coupled between the FMT **110** and the coupling cap **204**. In addition, evaporating the dilutant component of the adhesive material during surgery takes significant time and requires complicated sterile-safe procedures and other procedures that ensure that the toxic dilutant safely and completely evaporates. The only acceptable adhesive for use in an implantation application is fibrin glue, which is only intended for use with tissue, not mechanical components such as an FMT **110**. A further challenge is to achieve an acceptably precise alignment of the coupling cap **204** with the FMT **110**.

SUMMARY

[0010] Embodiments of the present invention are directed to an implantable transducer such as an FMT that converts an electrical stimulation signal into a corresponding mechanical stimulation signal. The transducer has an elongated shape with a transducer end surface having a transducer drive surface adapted to produce the mechanical stimulation signal, and a transducer adhesive feature adapted to intra-operatively receive adhesive material. A separate coupling cap has a coupling end face with a coupling adhesive feature adapted to engage the transducer adhesive feature with the adhesive material and a coupling drive surface adapted for distortion-free coupling of the mechanical stimulation signal from the transducer drive surface to the coupling cap. A signal delivery surface of the coupling cap delivers the mechanical stimulation signal to

an adjacent cochlear surface for sensation as sound.

[0011] At least one adhesive feature may be an adhesive recess adapted to receive the adhesive material, in which case, the other adhesive feature may be an adhesive projection adapted to engage the adhesive recess. The adhesive recess may be located at a radial center of the end faces. Or the adhesive recess may be located around a circumference of the end faces. The transducer drive surface and the coupling drive surface may be flat. The adhesive features may be rougher than the drive surfaces to promote adhesive bonding with the adhesive material.

[0012] Applying the adhesive material may include applying heat of between 60 °C and 80 °C to promote evaporation of volatile components of the adhesive material, and/or reducing air pressure around the middle ear transducer arrangement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 shows various anatomical structures in a human ear containing a middle ear implant device.

[0014] Figure 2 A-B show anatomical details of implanted FMT devices.

[0015] Figure 3 shows a middle ear transducer and coupling cap that are adapted for use with an adhesive material according to one embodiment of the present invention.

[0016] Figure 4 shows a middle ear transducer and coupling cap that are adapted for use with an adhesive material according to another embodiment of the present invention.

[0017] Figure 5 shows an assembled transducer and coupling cap according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0018] Embodiments of the present invention are directed to a middle ear transducer arrangement with a vibroplasty coupling cap that is adapted for use with an adhesive

material in a controlled consistent way that is reproducible and predictable, especially in that is distortion-free engagement between the drive surfaces of the transducer and the coupling cap to couple the mechanical stimulation signal free from damping and distortion.

[0019] Figure 3 shows a middle ear transducer **301** and coupling cap **302** that are adapted for use with an adhesive material according to one embodiment of the present invention. In this case, the transducer **301** is an FMT that converts an electrical stimulation signal into a corresponding mechanical stimulation signal. The transducer **301** may have a cylindrical or rectangular shape, or any other suitable shape. One end face of the transducer **301** acts as a transducer drive surface **303** that is adapted to produce the mechanical stimulation signal. The end face of the transducer **301** also includes a transducer adhesive feature **304** that is adapted to intra-operatively receive adhesive material.

[0020] A separate coupling cap **302** includes a signal delivery surface **307** for delivering the mechanical stimulation signal from the transducer **301** to an adjacent cochlear surface for sensation as sound. A coupling end face includes a coupling adhesive feature **306** that is adapted to engage the transducer adhesive feature **304** and the adhesive material to fixedly connect the coupling cap **302** and the transducer **301**. A coupling drive surface **305** is adapted for distortion-free engagement with the transducer drive surface **303** to couple the mechanical stimulation signal from the transducer **301** to the coupling cap **302**.

[0021] Intra-operatively during the surgery to implant the transducer arrangement, the surgeon may decide to attach a coupling cap **302** to the transducer **110**. Alternatively, it may be desirable to attach the coupling cap **302** to the transducer **301** during the manufacturing process. Rather than simply allowing the adhesive material to form a smooth bonding layer between the transducer **301** and the coupling cap **302**, it is preferred to avoid distributing adhesive material over the entire connecting area. That is, the transducer drive surface **303** and the coupling drive surface **305** preferably should contact each other directly without adhesive to allow direct coupling of the mechanical stimulation signal from the transducer **301** to the coupling cap **302** without damping or other linear or

non-linear distortion caused by the elastic properties of the adhesive material.

[0022] In the specific embodiment shown in Fig. 3, the coupling adhesive feature **306** is in the specific form of an adhesive recess at the radial center of the end face of the coupling cap **302** that is adapted to receive the adhesive material. The recess shape of the coupling adhesive feature **306** should be sufficiently large to promote control of the dispensing process of the adhesive material so as to correctly measure and reliably dispense the right amount during manufacturing. The recess may have a rough inner surface to further promote adhesive bonding with the dispensed adhesive material during manufacturing process. The transducer drive surface **303** and optionally the coupling drive surface **305** may have a smooth or rough surface, which may be flat, concave, or a hybrid concave and flat shape.

[0023] In one embodiment the transducer adhesive feature **304** may be coated with an adhesive friendly material, such as for example silicone. In Fig. 3, the transducer adhesive feature **304** is shown in the specific form of an adhesive recess at the radial center of the end face of the transducer **301** that adapted to receive the adhesive material and promoting self-alignment. For example the shape of the recess may be conical or any other suitable shape, for example, one with a trapezoidal cross-section. In general, any shape recess will be acceptable where the edge of the transducer adhesive feature **304** and the transducer drive surface **303** forms an obtuse angle suitable for self-alignment. The coupling adhesive feature **306** is formed as an adhesive projection located at the radial center of the coupling drive surface **305** that is adapted to engage the e.g. recessed shape of the transducer adhesive feature **304**. The flat outer ring transducer drive surface **303** and coupling drive surface **305** do not contain any adhesive material, which allows for an adhesive-free direct connection and distortion free propagation of the mechanical stimulation signal.

[0024] During surgery, a protective shipping sheet is removed from the coupling drive surface **305** and coupling adhesive feature **306** of the coupling cap **302**. The transducer drive surface **303** and the coupling drive surface **305** are gently pressed together by the surgeon. This brings the coupling adhesive feature **306** at least partially into contact with the transducer adhesive feature **304**. In some cases the surgeon will be able to perfectly

align the coupling cap **302** and transducer **301** perfectly so that the coupling adhesive feature **306** and transducer adhesive feature **304** are lying exactly upon one another. But in most cases the coupling cap **302** and transducer **301** will be slightly misaligned so that the most protruding point of the coupling adhesive feature **306** projection (i.e., the center) contacts the transducer adhesive feature **304**. This binds the coupling adhesive feature **306** to the adhesive friendly surface of the transducer adhesive feature **304** first and simultaneously avoids binding to the transducer drive surface **303** and promotes self-alignment. This self-alignment characteristic aids handling during surgery and provides form-locking fitting. After removal of the protective shipping sheet, the coupling adhesive feature **306** is exposed to air and a chemical curing process begins. Typically this chemical curing takes less than a minute during which the coupling cap **302** will self-align and afterwards the shrunken adhesive feature **306** exerts a compressive force, thereby fixedly connecting the transducer **301** and coupling cap **302** which are then ready for placement by the surgeon as for example shown in Figure 2B.

[0025] Figure 4 shows a middle ear transducer **301** and coupling cap **302** where the adhesive features are formed based on using an adhesive ring recess **401** formed around a circumference of the cylinder end face of the transducer **301**; i.e., around the transducer drive surface **303**. A corresponding adhesive ring projection **402** around a circumference of the coupling drive surface **302** fits into the adhesive ring recess **401** to engage the adhesive material therein. In other specific embodiments the transducer drive surface **303** and/or the coupling drive surface **305** may be convex, which improves coupling of the mechanical stimulation signal from the transducer **301** to the coupling cap **302**. Some embodiments may have both a center adhesive recess and center adhesive projection as in Fig. 3, and a circumferential adhesive ring recess and adhesive ring projection as in Fig. 4. In specific embodiments, the surfaces of the coupling drive surface **305** and the transducer drive surface **303** may be flat, convex or concave. Figure 5 shows an example of an assembled transducer **301** and coupling cap **302**.

[0026] The adhesive material may be any suitable dilutable medical grade adhesive, as for example available from Nusil Technology or Applied Silicone. Before dispensing the adhesive material onto the adhesive feature, it may be useful to dilute it with a suitable

volatile substance such as N-Heptan. Then in a further step, the coupling cap **302** with the adhesive material thereon may be heated up to 60°C to 80°C for up to 3 hours. This ensures that the toxic dilution substance entirely evaporates. It has further been found that by heating up to 80°C this evaporation process can be shortened to 20 minutes, effectively keeping the manufacturing time acceptably short. In addition or alternatively, it may be useful to reduce the air pressure around the transducer **301** and coupling cap **302** after joining them with the adhesive material in order to reduce the dilutant evaporation time and temperature further. This has the additional advantage of promoting the release of any micro air-bubbles that might be contained within the adhesive material. In one specific embodiment, an adhesive feature was formed from medical grade silicone diluted with N-Heptan in a ratio of 1:0.5 and then dispensed with 50 psi to achieve a proper fit into the tight manufacturing tolerances such as a 0.02 mm height of the adhesive feature after heating and evaporation (i.e. after the adhesive feature shrinks and obtains its final size).

[0027] A transducer and coupling cap such as those described above can be provided in a surgical kit for the surgeon to use during implantation surgery. If the surgeon decides during the surgery that a coupling cap is needed to properly couple the mechanical stimulation signal to the round window, then it is easy and reliable to attach the coupling cap to the transducer with a predictable amount of adhesive material without creating undesired damping and distortion. The arrangement is safe and convenient to handle without undesirably increasing the outside diameter of the transducer.

[0028] Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

CLAIMS

What is claimed is:

1. A middle ear transducer arrangement comprising:
 - an implantable transducer for converting an electrical stimulation signal into a corresponding mechanical stimulation signal, the transducer having an elongated shape with a transducer end face having:
 - i. a transducer drive surface adapted to produce the mechanical stimulation signal, and
 - ii. at least one transducer adhesive feature adapted to intra-operatively receive adhesive material during surgery to implant the transducer in a recipient patient; and
 - a coupling cap having:
 - i. a coupling end face including:
 - (1) at least one coupling adhesive feature adapted to engage the at least one transducer adhesive feature and the adhesive material to fixedly connect the coupling cap to the transducer end face, and
 - (2) a coupling drive surface adapted for distortion-free coupling of the mechanical stimulation signal from the transducer drive surface to the coupling cap; and
 - ii. a signal delivery surface for delivering the mechanical stimulation signal to an adjacent cochlear surface for sensation as sound.
2. A middle ear transducer arrangement according to claim 1, wherein at least one adhesive feature is an adhesive recess adapted to receive the adhesive material.
3. A middle ear transducer arrangement according to claim 2, wherein at least one adhesive feature is an adhesive projection adapted to engage the adhesive recess.
4. A middle ear transducer arrangement according to claim 1, wherein the adhesive features are located at a radial center of the end faces.

5. A middle ear transducer arrangement according to claim 1, wherein the adhesive features are located around a circumference of the end faces.
6. A middle ear transducer arrangement according to claim 1, wherein the transducer drive surface and the coupling drive surface are flat.
7. A middle ear transducer arrangement according to claim 1, wherein the adhesive features are rougher than the drive surfaces to promote adhesive bonding with the adhesive material.
8. A middle ear transducer arrangement according to claim 1, wherein the transducer drive surface and the coupling drive surface are adapted for adhesive-free engagement.
9. A middle ear transducer arrangement according to claim 1, wherein the implantable transducer has a cylindrical shape.
10. A middle ear transducer arrangement according to claim 1, wherein the implantable transducer has a rectangular shape.
11. A middle ear transducer arrangement according to claim 1, wherein the implantable transducer is a floating mass transducer.
12. A method of creating a middle ear transducer arrangement comprising:
 - providing an implantable transducer for converting an electrical stimulation signal into a corresponding mechanical stimulation signal, the transducer having an elongated shape with a transducer end face having:
 - i. a transducer drive surface adapted to produce the mechanical stimulation signal, and
 - ii. at least one transducer adhesive feature adapted to intra-operatively receive adhesive material; and
 - intra-operatively fitting onto the transducer end face a coupling cap having a signal delivery surface for delivering the mechanical stimulation signal to an adjacent

cochlear surface for sensation as sound, the fitting including:

- i. using at least one coupling adhesive feature to engage the at least one transducer adhesive feature and the adhesive material to fixedly connect the coupling cap to the transducer end face, and
- ii. fitting a coupling drive surface into engagement with the transducer drive surface for distortion-free coupling of the mechanical stimulation signal free from the transducer drive surface to the coupling cap.

13. A method according to claim 12, wherein at least one adhesive feature is an adhesive recess adapted to receive the adhesive material.

14. A method according to claim 13, wherein at least one adhesive feature is an adhesive projection adapted to engage the adhesive recess.

15. A method according to claim 12, wherein the adhesive features are located at a radial center of the end faces.

16. A method according to claim 12, wherein the adhesive features are located at around a circumference of the end faces.

17. A method according to claim 12, wherein the transducer drive surface and the coupling drive surface are flat.

18. A method according to claim 12, wherein the adhesive features are rougher than the drive surfaces to promote adhesive bonding with the adhesive material.

19. A method according to claim 12, wherein the transducer drive surface and the coupling drive surface are adapted for adhesive-free engagement.

20. A method according to claim 12, wherein the implantable transducer has a cylindrical shape.

21. A method according to claim 12, wherein the implantable transducer has a rectangular shape.

22. A method according to claim 12, wherein the implantable transducer is a floating mass transducer.

23. A method according to claim 12, wherein using at least one coupling adhesive feature to engage the adhesive material with the at least one transducer adhesive feature includes applying heat of between 60 °C and 80 °C to promote evaporation of volatile components of the adhesive material.

24. A method according to claim 12, wherein using at least one coupling adhesive feature to engage the adhesive material with the at least one transducer adhesive feature includes reducing air pressure around the middle ear transducer arrangement.

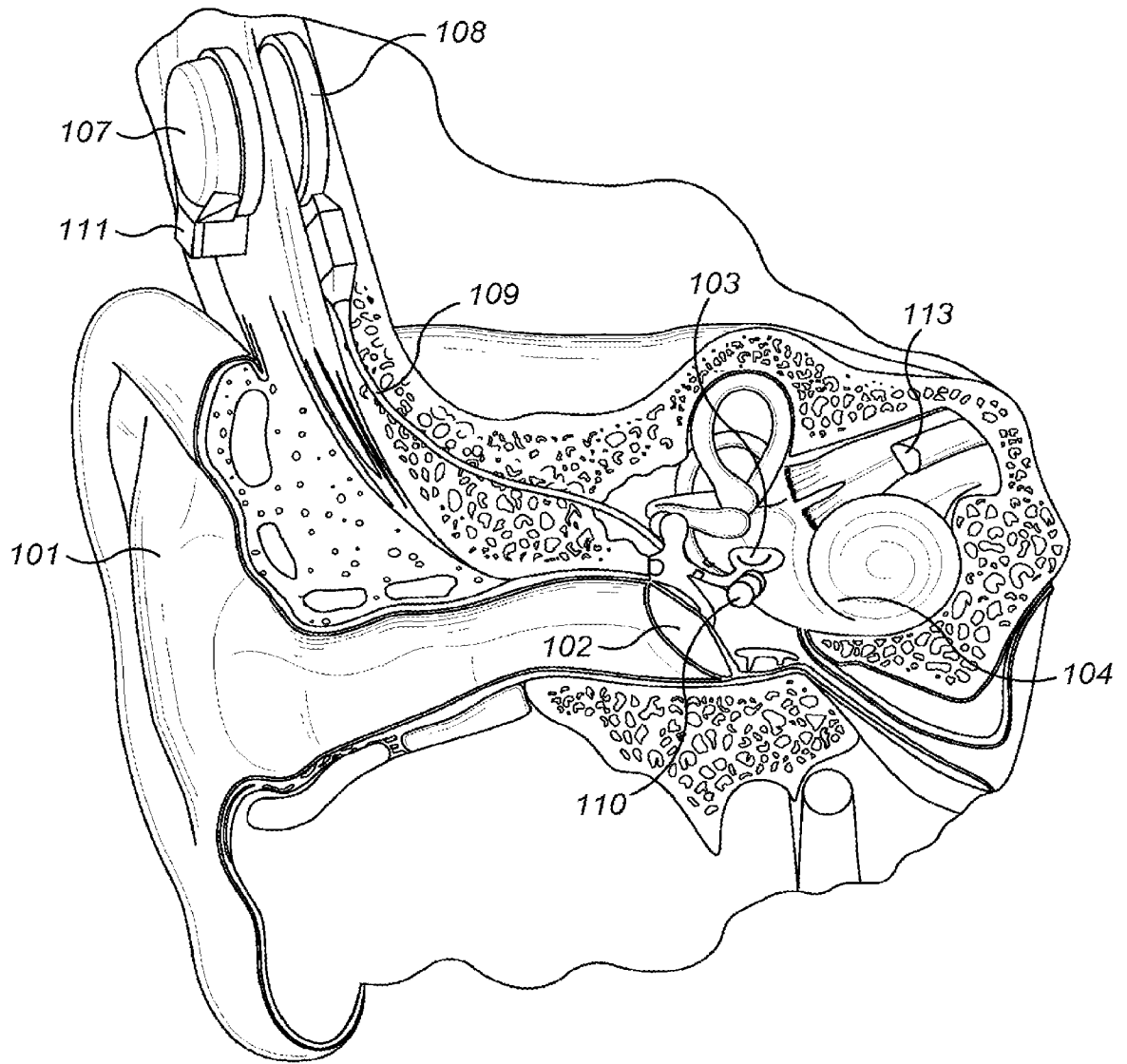


FIG. 1

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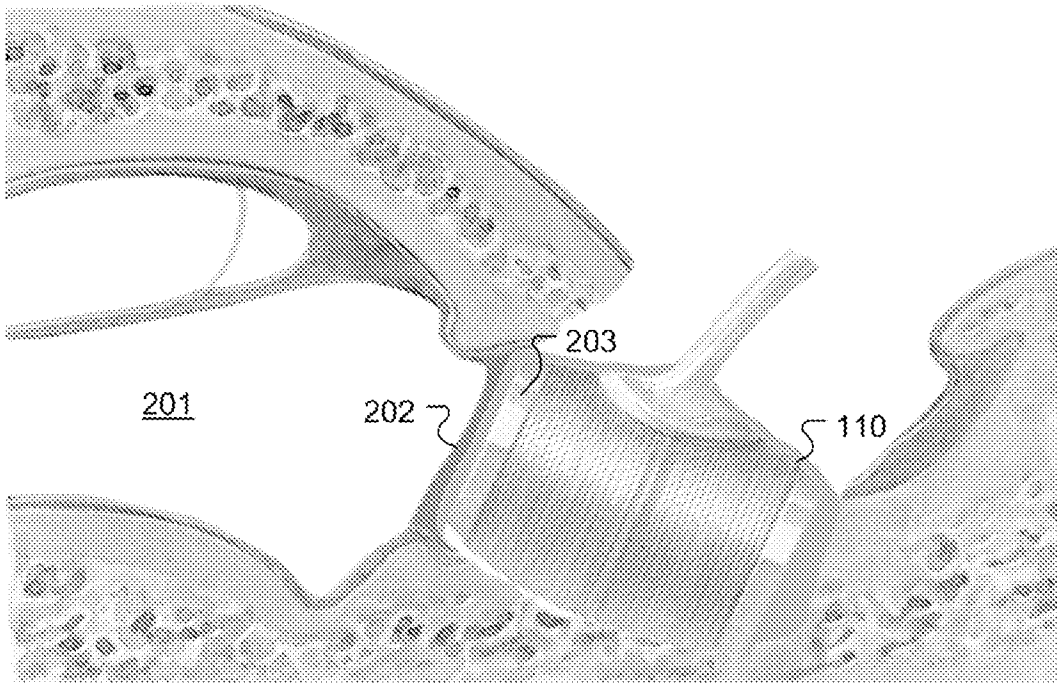


Fig. 2A

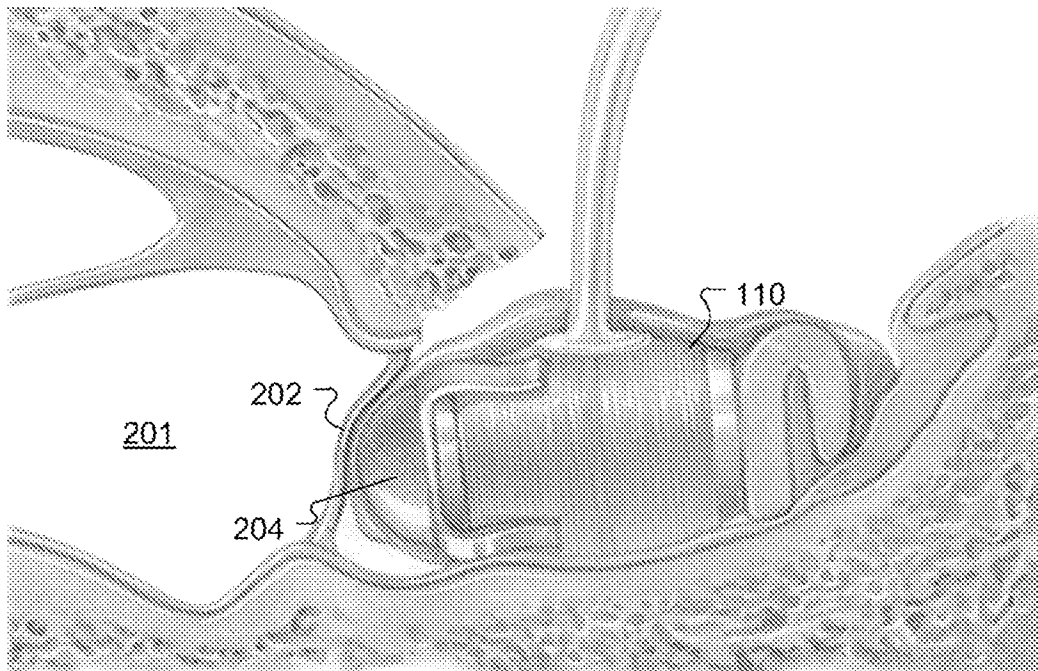


Fig. 2B

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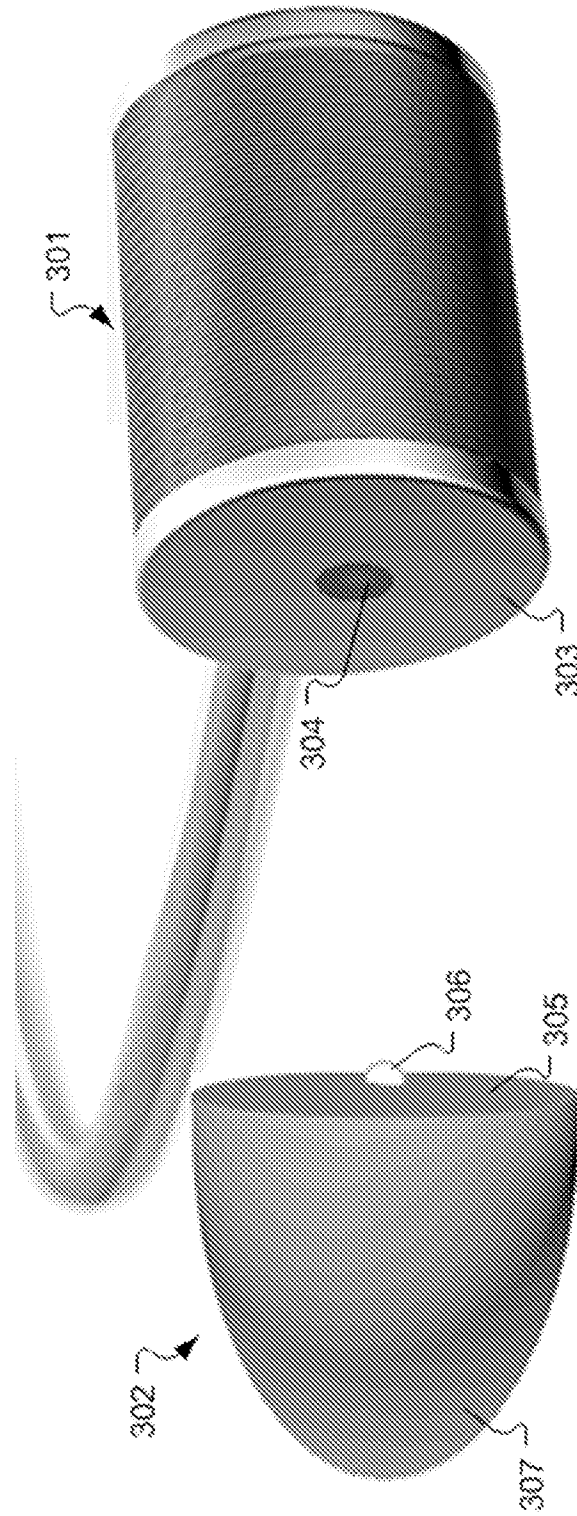


Fig. 3

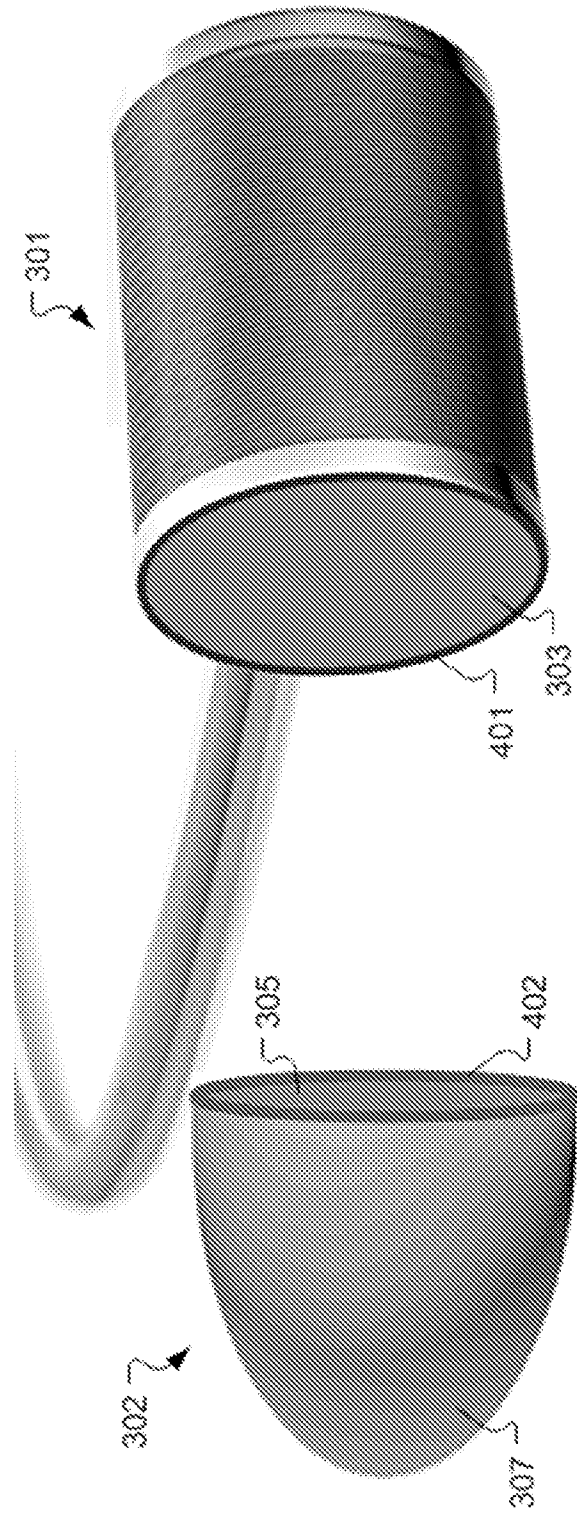


Fig. 4

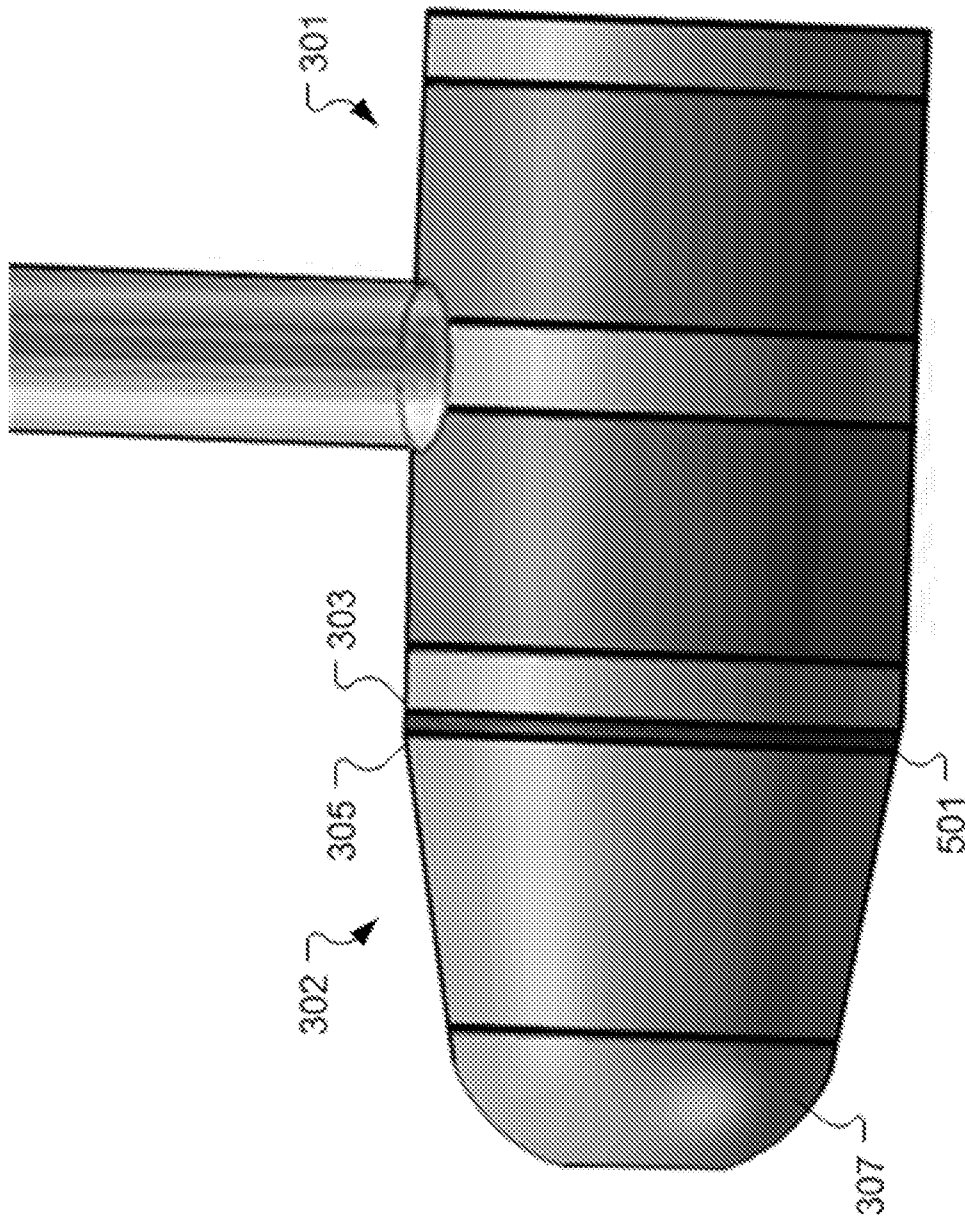


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/042606

A. CLASSIFICATION OF SUBJECT MATTER
 IPC(8) - H04R 25/00 (2014.01)
 CPC - H04R 25/00 (2014.09)
 According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC(8) - A61F 2/18, 11/00, 11/04; A61N 1/05, 1/36; H04R 25/00, 25/02, 25/65 (2014.01)
 CPC - A61F 11/00, 11/04, 2002/183; A61N 1/36032; H04R 2225/67, 2460/13, 25/00, 25/65, 25/606 (2014.09)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 USPC - 381/312, 322, 324, 328; 600/25, 559; 607/55, 56; 623/10

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2012/0245407 A1 (BALL) 27 September 2012 (27.09.2012) entire document	1-24
A	US 2002/0038072 A1 (MULLER et al) 28 March 2002 (28.03.2002) entire document	1-24
A	US 5,259,032 A (PERKINS et al) 02 November 1993 (02.11.1993) entire document	1-24
A	US 6,592,513 B1 (KROLL et al) 15 July 2003 (15.07.2003) entire document	1-24
A	US 2010/0324355 A1 (SPITAEELS et al) 23 December 2010 (23.12.2010) entire document	1-24

Further documents are listed in the continuation of Box C.

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"A" document defining the general state of the art which is not considered to be of particular relevance	"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
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 06 October 2014	Date of mailing of the international search report 28 OCT 2014
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