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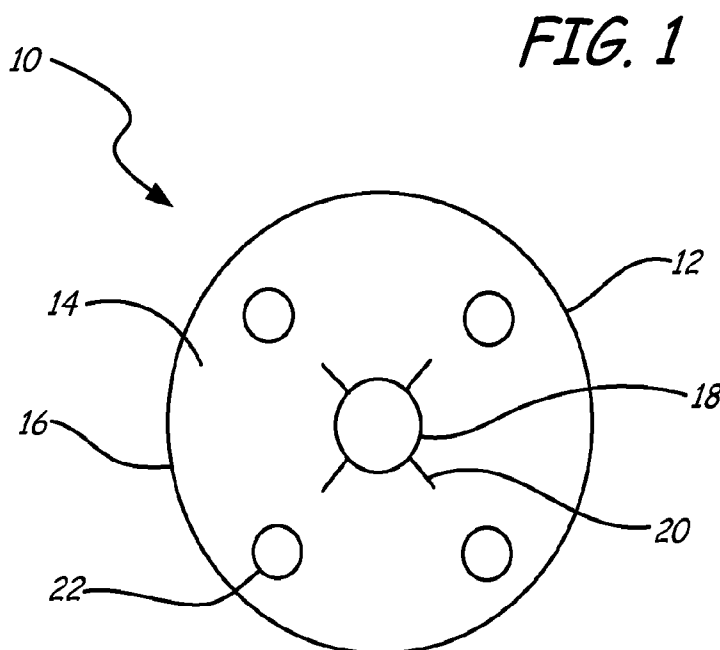
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[Continued on next page]

(54) Title: IMPLANT SHIELD FOR BONE ANCHORED HEARING AIDS



(57) Abstract: An implant shield can be placed against the user's scalp to protect a bone anchored hearing aid from hair growth and other interference. Adhesives can be used to secure the implant shield to the scalp. One embodiment of the implant shield is a barrier of a flexible polymeric material having an implant opening through which an implanted or other portion of the hearing aid can extend.



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IMPLANT SHIELD FOR BONE ANCHORED HEARING AIDS

TECHNICAL FIELD

[0001] The present invention relates to devices and methods for use with bone anchored devices including bone anchored hearing aids. More particularly, the present invention relates to a device and method for shielding a bone anchored hearing aid from hair growth or other interference.

BACKGROUND

[0002] A bone anchored hearing aid is a type of hearing aid based on bone conduction. It is primarily suited to people who have conductive hearing losses, unilateral hearing loss and people with mixed hearing losses who cannot otherwise wear “in the ear” or “behind the ear” hearing aids.

[0003] Bone anchored hearing aids transmit sound by direct conduction through bone to the inner ear, bypassing the external auditory canal and middle ear. Bone anchored hearing aids include three main components: 1) an implanted portion or post; 2) an external abutment which couples to the implanted post; and 3) a sound processor. The implanted portion or post, as it is also referred to, is surgically embedded into the skull. The abutment is then attached to the post. During the first few weeks after implantation, a healing cap is used to protect the abutment. Over a period of a few months, the post bonds with the surrounding tissue in a process called osseointegration. After osseointegration is complete, the sound processor is coupled to the abutment.

[0004] There remains a continuing need for improved devices and methods for use in connection with bone anchored hearing aids.

SUMMARY

[0005] According to various embodiments, the present invention is an implant shield for a bone anchored hearing aid including a flexible barrier configured to engage a scalp of a bone anchored hearing aid user. The flexible barrier includes an implant opening through which an implant or other component of the bone anchored hearing aid can extend to enable an abutment and/or processor of the bone anchored hearing aid to be attached to the implant.

[0006] According to other embodiments, the present invention is a method for shielding a bone anchored hearing aid on a user from hair growth and/or other interference including the

step of applying an implant shield to the scalp of the user around the portion of the hearing aid extending from the scalp.

[0007] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention.

Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a plan view of an implant shield in accordance with an embodiment of the present invention.

[0009] FIG. 2 is a schematic view of an implant shield in accordance with another embodiment of the present invention including a partially removed release liner.

[0010] FIG. 3 is a schematic view of an implant shield in use with a bone anchored hearing aid implanted within a user's skull in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION

[0011] FIG. 1 shows an implant shield 10 according to an embodiment of the present invention. The implant shield 10 can be used to facilitate a decrease in potential interference with an implanted device. According to various embodiments, the implant shield 10 can be used with a bone anchored hearing aid to protect the hearing aid from hair growth and other interference. For example, the implant shield 10 may be used to prevent hair from being wrapped around external portions of the hearing aid and in some cases, may prevent hair or other debris from working its way down to a patient's skull. Exemplary bone anchored hearing aids are sold and manufactured by Cochlear Limited of Sydney, Australia.

[0012] According to various embodiments, the implant shield 10 includes a flexible barrier 12. The flexible barrier 12 has sufficient flexibility so as to be able to conform to and engage a scalp of a bone anchored hearing aid user. The flexible barrier 12 includes an upper surface 14 and a lower surface 16 defining a thickness. In one embodiment, the thickness of the flexible barrier 12 ranges from about 0.020 to about 0.030 inches, although it can be formed from a variety of materials of varying thicknesses. Additionally, the flexible barrier 12 can have a variety of shapes. In some embodiments, as shown in FIG. 1, the flexible barrier 12

has a circular shape. In one embodiment, the flexible barrier 12 has a circular shape having a diameter of about 20-50 mm.

[0013] The flexible barrier 12 serves as a barrier between the user's scalp and external portions of an implanted device such as, for example, a bone anchored hearing aid. According to various embodiments, the flexible barrier 12 includes an implant opening 18 extending through the upper and lower surfaces 14 and 16. The post or other implantable portion of a bone anchored hearing aid can extend through the implant opening 18 to enable the abutment or other external portion of the bone anchored hearing aid to be attached to the post or other implantable portion. The implant opening 18 can be located anywhere on the flexible barrier 12. In the illustrated embodiment, the implant opening 18 is at a center of the flexible barrier 12. For example, FIG. 1 shows an embodiment in which the flexible barrier 12 is circular and the implant opening 18 is at the center of the circular flexible barrier 12. The implant opening 18 is sized and shaped so as to facilitate extension of the abutment or other external component of a bone anchored hearing aid through the opening 18. For example, in one embodiment, the implant opening 18 has a circular shape and a diameter ranging from about 3 to about 5 mm. In some embodiments, the flexible barrier 12 has sufficient pliability such that it can be stretched so as to enlarge the implant opening 18. The implant opening 18 is enlarged such that it can be slipped over the lateral most part of an implant such as for example, the abutment of a bone anchored hearing aid. In some embodiments the implant opening 18 can include one or more slits 20 in the material surrounding the opening 18 to facilitate placement of the shield 10 over the abutment of a bone anchored hearing aid. In one example, as shown in FIG. 1, the opening 18 includes four slits 20. The flexible barrier 12 can then be placed against the user's scalp.

[0014] In some embodiments, the flexible barrier 12 can also include one or more ventilation openings 22 surrounding the implant opening 18. The ventilation openings 22 are for ventilation and may facilitate the escape of any bodily secretions. In one embodiment, the flexible barrier 12 includes four ventilation openings 22 surrounding the implant opening 18. The ventilation openings 22 can have any size and shape. In some embodiments, the ventilation openings 22 are generally smaller in size than the implant opening 18. In one embodiment, the ventilation openings 22 have a circular shape with a diameter of about 1 mm.

[0015] In some embodiments, the implant shield 10 merely rests against a surface of a user's scalp. In other embodiments, a variety of attachment devices and/or methods can be used to attach the implant shield 10 to a user's scalp. For example, in one embodiment,

adhesive can be used to attach the implant shield 10 to the user's scalp. The adhesive can be applied to the user's scalp and/or the lower surface 16 of the flexible barrier 12. In another embodiment, sutures can be used to secure the implant shield to the user's scalp. In still other embodiments, a combination of attachment devices and/or methods can be used.

[0016] FIG. 2 shows an implant shield 110 according to another embodiment of the present invention. Like the implant shield 10, discussed above, the implant shield 110 includes a flexible barrier 112 including an upper surface 114 and a lower surface 116. Additionally, the flexible barrier 112 includes an implant opening (not visible) and one or more ventilation openings 122. In the embodiment shown, the lower surface 116 of the flexible barrier 112 includes an adhesive 124 for securing the implant shield 110 to a user's scalp. As shown in FIG. 2, the implant shield 110 can also include a release liner 126 disposed over the lower surface 116 including the adhesive 124 to protect the adhesive 124 prior to use of the implant shield 110. The release liner 126 can be peeled away from the lower surface 116 of the implant shield 110 to expose the adhesive such that the implant shield 110 can be adhered to the user's scalp.

[0017] The implant shields 10 and 110, discussed above with reference to FIGS. 1 and 2, can be fabricated from a wide variety of materials. The material used to fabricate the implant shields 10 and 110, should be selected for its flexibility (i.e. its ability to conform to the user's scalp), pliability and biocompatibility. According to various embodiments, the implant shields 10 and 110 can be fabricated from a biocompatible polymeric material. In one embodiment, the implant shields 10 and 110 can be fabricated from silicone sheeting. In another embodiment, the implant shields 10 and 110 can be fabricated from SILASTIC®. The thickness of the material used to fabricate the implant shield may also impact its flexibility as well as its pliability.

[0018] FIG. 3 shows an implant shield 10 as described above with reference to FIG. 1, in use. As described above, a bone anchored hearing aid includes a surgically implanted post that is integrated into the user's skull 134, an external abutment that attaches to the post and extends away from the user's skull 134, and a sound processor that couples to the external abutment. As shown in FIG. 3, the implant shield 10 is positioned against a user's scalp 136 such that it is situated between the user's scalp 136 and an abutment 130 of a bone anchored hearing aid. In one embodiment, the implant shield 10 is installed after implantation of the post and the abutment 130 of a bone anchored hearing aid is complete and the area surrounding the bone anchored hearing aid is sufficiently healed. The implant shield 10 is stretched such that the implant opening (not visible) is enlarged so as to fit over the widest

portion of the abutment 130. The implant shield 10 is placed around the abutment 130 and then slipped down on the abutment 130 until it rests on the user's scalp 136. In some embodiments, an adhesive can be applied to the user's scalp and/or to the lower surface of the flexible barrier prior to placing the implant shield 10 against the user's scalp 163 to promote adherence of the implant shield 10 to the user's scalp 136. In other embodiments, an antibiotic or other treatment may be applied to the user's scalp and/or to the lower surface of the implant shield 10 prior to placing the implant shield 10 against the user's scalp 136. The implant shield 10 may hold the treatment in place against the user's scalp 136 and may protect the treatment from any interference. In another embodiment, the implant shield 10 can be applied to the patient's scalp 136 after implantation of the post so that it is present during the healing process. The abutment 130 can then be attached to the surgically implanted post through the implantation opening provided in the implant shield 10.

[0019] It will be generally understood that the implant shield, as described herein according to the various embodiments, can be used with any implanted device having an implanted portion and an external portion.

[0020] Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the above described features. For example, although described above as an implant shield for behind the ear hearing aids, the implant shield can also be used around portions of implantable devices of other types extending from the skin of a patient in an area prone to hair growth.

CLAIMS

The following is claimed:

1. An implant shield for a bone anchored hearing aid, comprising a flexible barrier configured to engage a scalp of a bone anchored hearing aid user, the barrier having an implant opening through which an implant or other component of the bone anchored hearing aid can extend to enable an abutment and/or processor of the bone anchored hearing aid to be attached to the implant.
2. The implant shield of claim 1 and further including adhesive for attaching the barrier to the scalp of the user.
3. The implant shield of claim 2, wherein the adhesive is disposed on a surface of the barrier and the shield further includes a release liner over the adhesive for protecting the adhesive prior to use of the shield.
4. The implant shield of claim 1 and further including one or more ventilation openings surrounding the implant opening.
5. The implant shield of claim 1, wherein the barrier is fabricated from a biocompatible polymeric material.
6. The implant shield of claim 5, wherein the barrier is fabricated from silicone sheeting.
7. The implant shield of claim 1, wherein the barrier is circular and the implant opening is at a center of the barrier.
8. A method for shielding a bone anchored hearing aid on a user from hair growth and/or other interference, including applying an implant shield of the type recited in claim 1 to the scalp of the user around the portion of the hearing aid extending away from the scalp.

9. A method for shielding a bone anchored hearing aid on a user from hair growth and/or other interference, including placing on a scalp of the user, around a portion of the hearing aid extending away from the scalp, a flexible barrier.

10. The method of claim 9, further comprising enlarging an implant opening provided in the flexible barrier to place the flexible barrier around the portion of the hearing aid extending away from the scalp.

11. The method of any of claim 9 and further including adhesively attaching the flexible barrier to the scalp of the user.

12. The method of claim 9 and further including applying antibiotics or other medicines to the scalp of the user under the flexible barrier.

13. The method of claim 9 and further shielding the hearing aid from hair growth.

14. An implant shield for a bone anchored implantable device of a type having a portion extending from a surface of a user's body, comprising: a flexible barrier configured to engage a surface of a user's body, the barrier having an implant opening through which an implantable portion of the bone anchored implantable device can extend to enable an external portion of the bone anchored implantable device to be attached to the implantable portion

15. The implant shield of claim 14 and further including adhesive for attaching the barrier to the surface of the user's body.

16. The implant shield of claim 15, wherein the adhesive is disposed on a surface of the barrier and the implant shield further includes a release liner disposed over the adhesive for protecting the adhesive prior to use of the implant shield.

17. The implant shield of claim 14 and further including one or more ventilation openings surrounding the implant opening.

18. The implant shield of claim 14, wherein the barrier is fabricated from a polymeric material.
19. The implant shield of claim 14, wherein the flexible barrier is circular and the implant opening is at a center of the flexible barrier.
20. A method for shielding a bone anchored device extending away from a patient's skin from hair growth and/or other interference, including applying a flexible barrier to the patient's skin around at least a portion of the bone anchored device.

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FIG. 1

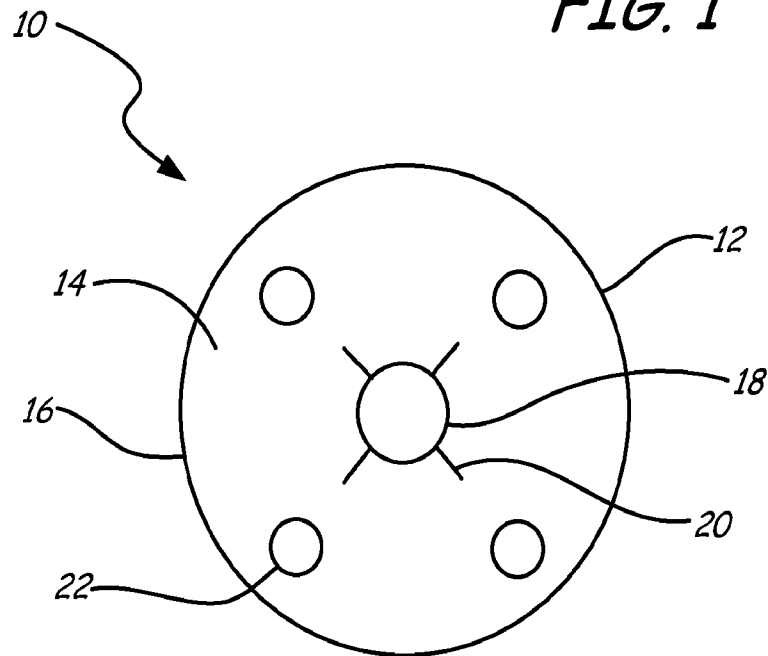
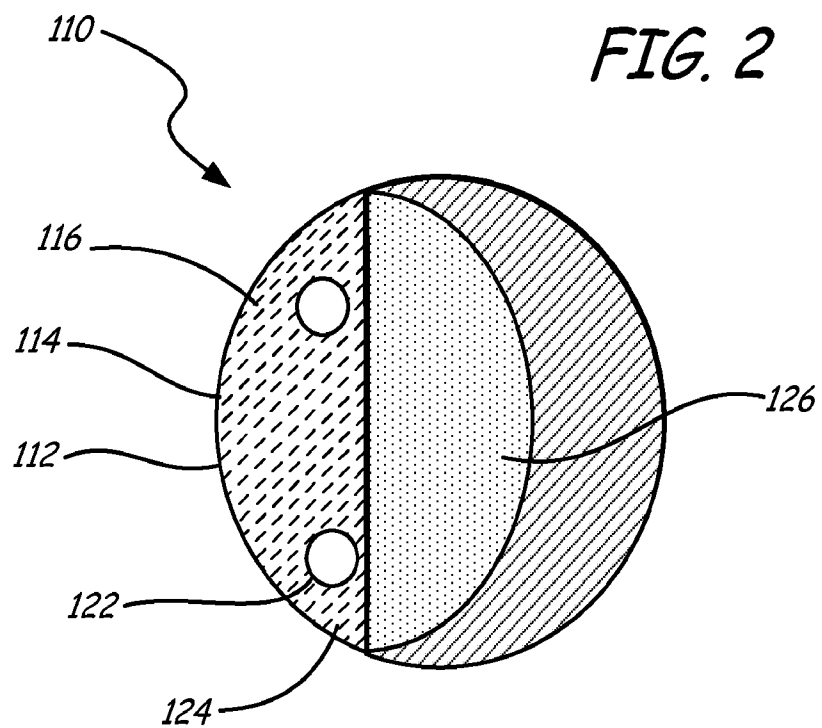


FIG. 2



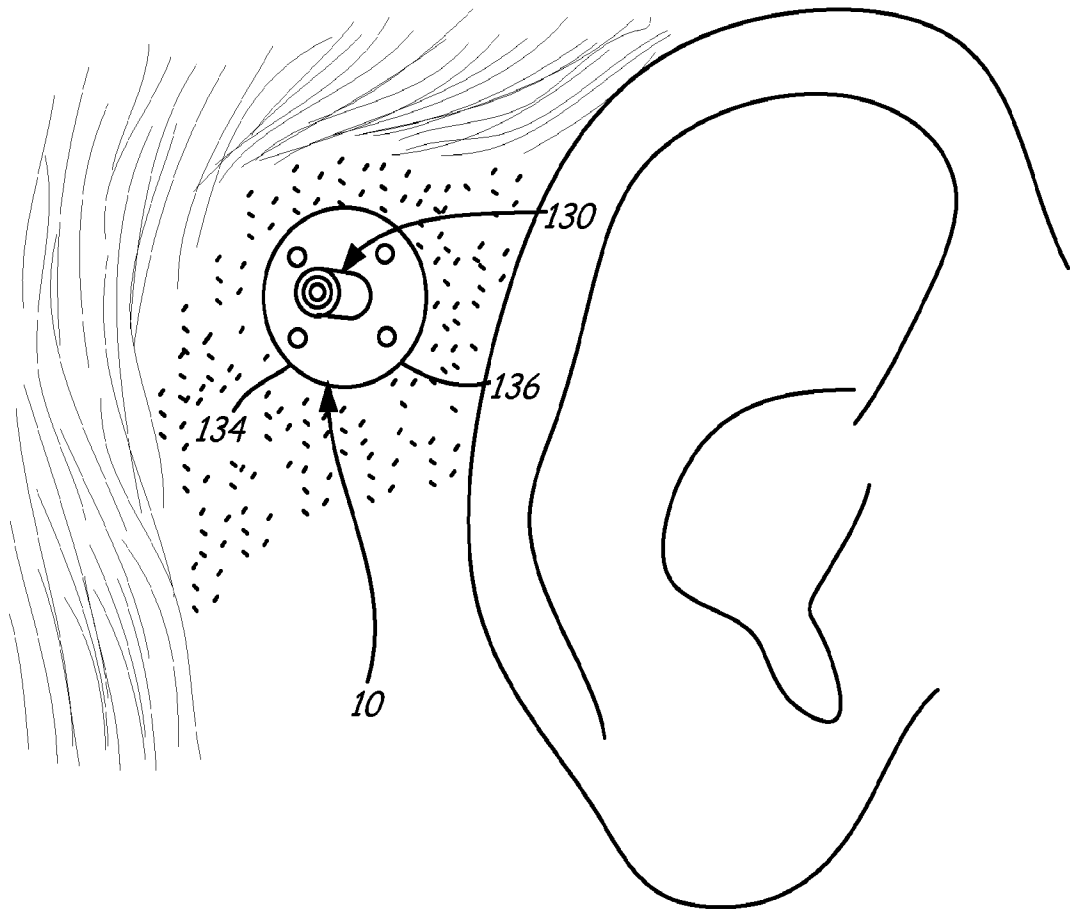


FIG. 3