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Jinton et al.

(54) **COUPLING APPARATUS FOR A BONE ANCHORED HEARING DEVICE**

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(52) **U.S. Cl.** **606/301**; 606/305; 606/308

(57) **ABSTRACT**

A coupling apparatus for a bone anchored hearing device for anchoring hearing aid devices or extra-oral prostheses in the form of ear and orbital prostheses in the skull bone. The apparatus comprises a screw-shaped anchoring fixture configured to be inserted into the skull bone and a skin-penetrating abutment coupled to the fixture by a screw connection. The fixture comprises a main body with an external screw thread and a flange having a substantially planar bottom surface. The flange is configured to stop the anchoring element from penetrating through the skull bone. The skin-penetrating abutment comprises a substantially conical outer surface. The upper end surface of the fixture is designed with an open cavity with a tapered inner contour forming a seat for the bottom part of the abutment. The bottom part of the abutment is configured to create a good connecting fit between the fixture and abutment.

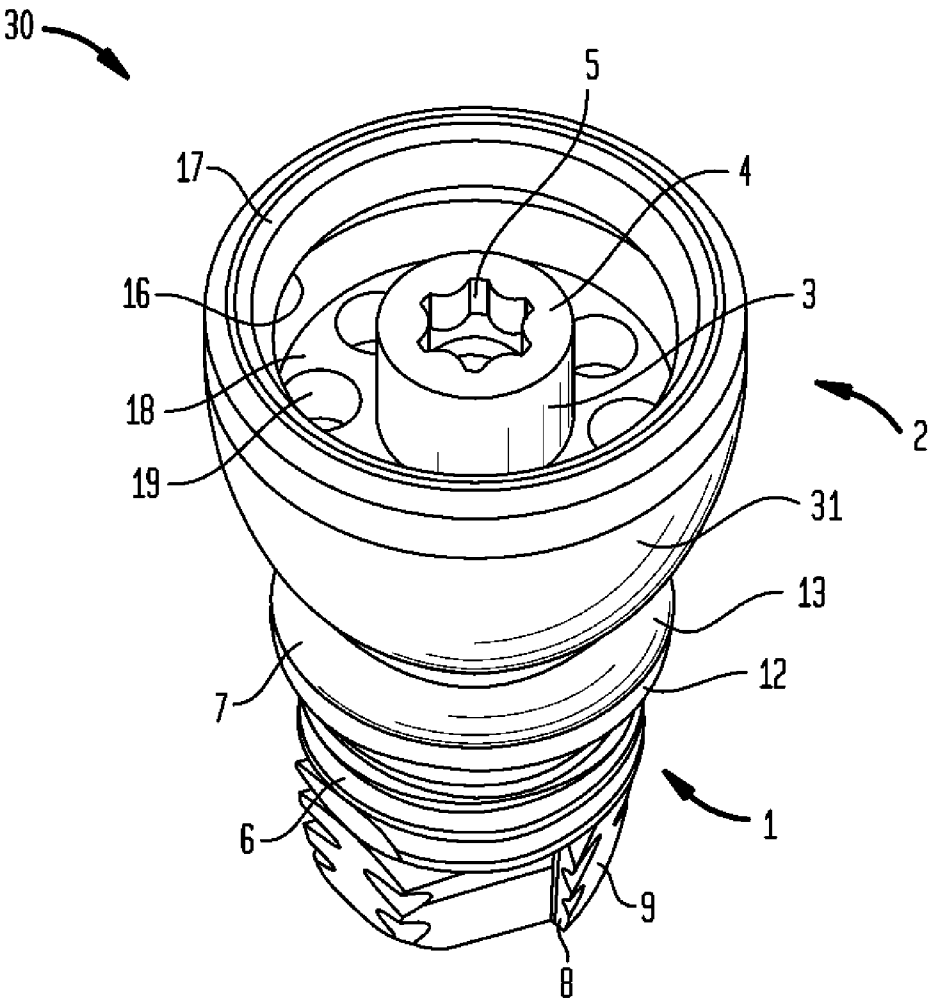


FIG. 1

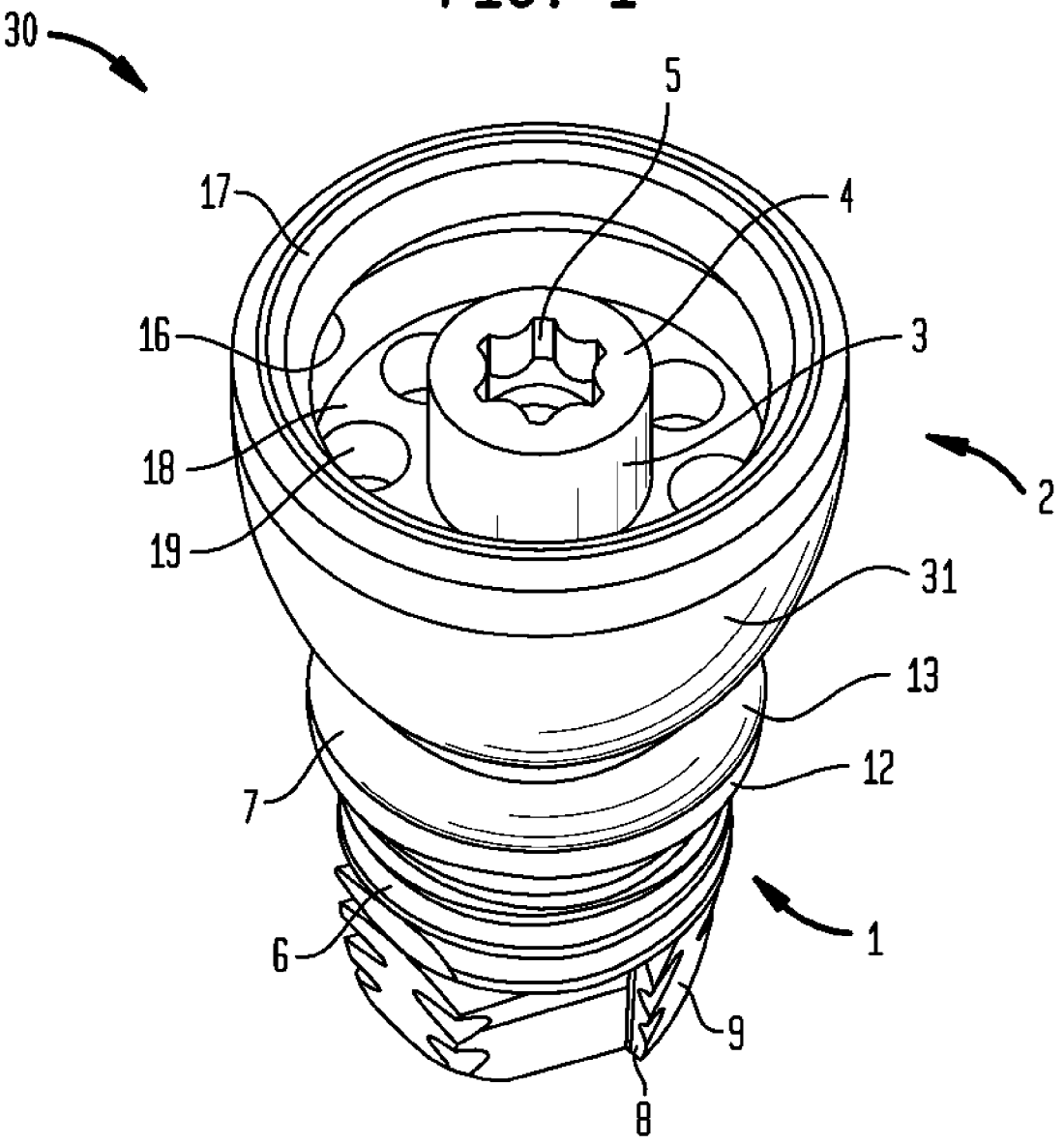


FIG. 2

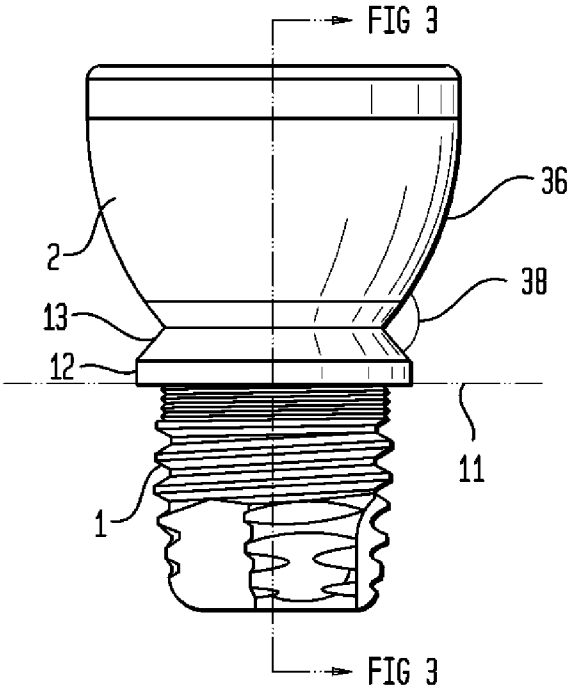

FIG 3
36
2
38
13
12
11
1
FIG 3

FIG. 3

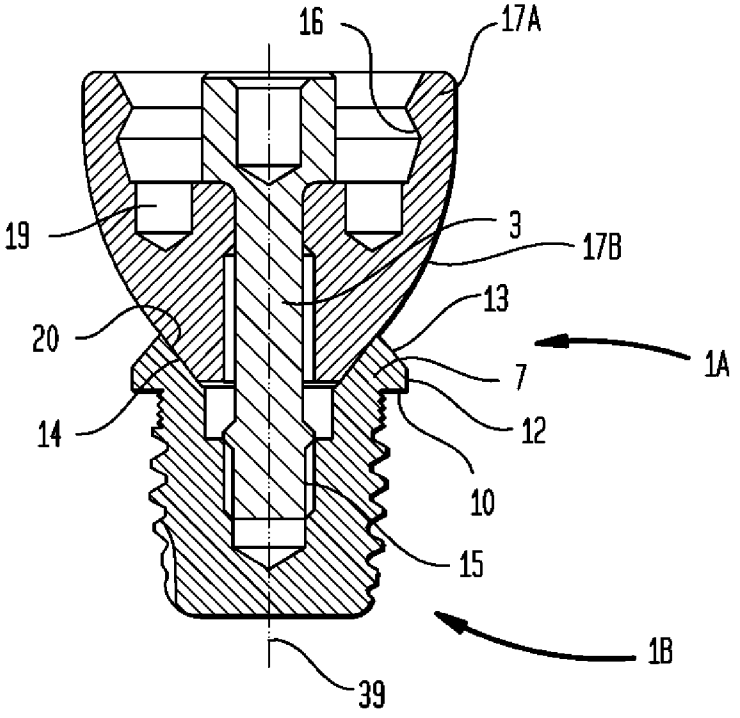

16
17A
19
3
17B
13
20
1A
7
12
14
10
15
1B
39

FIG. 4

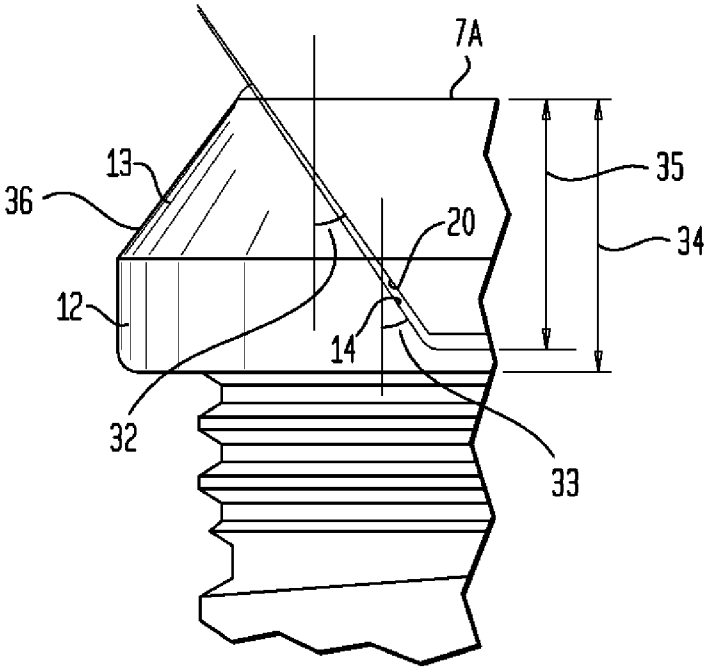


FIG. 5

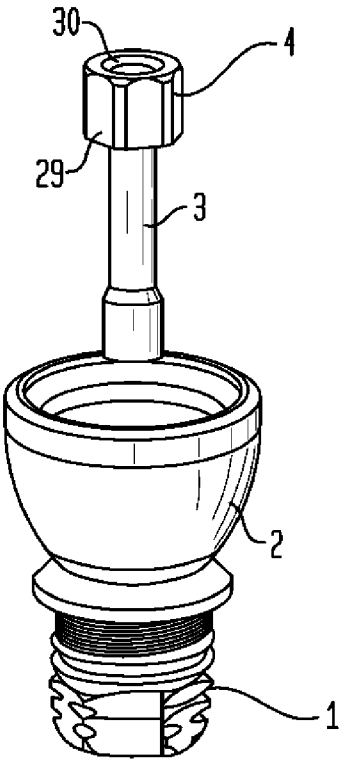


FIG. 6A

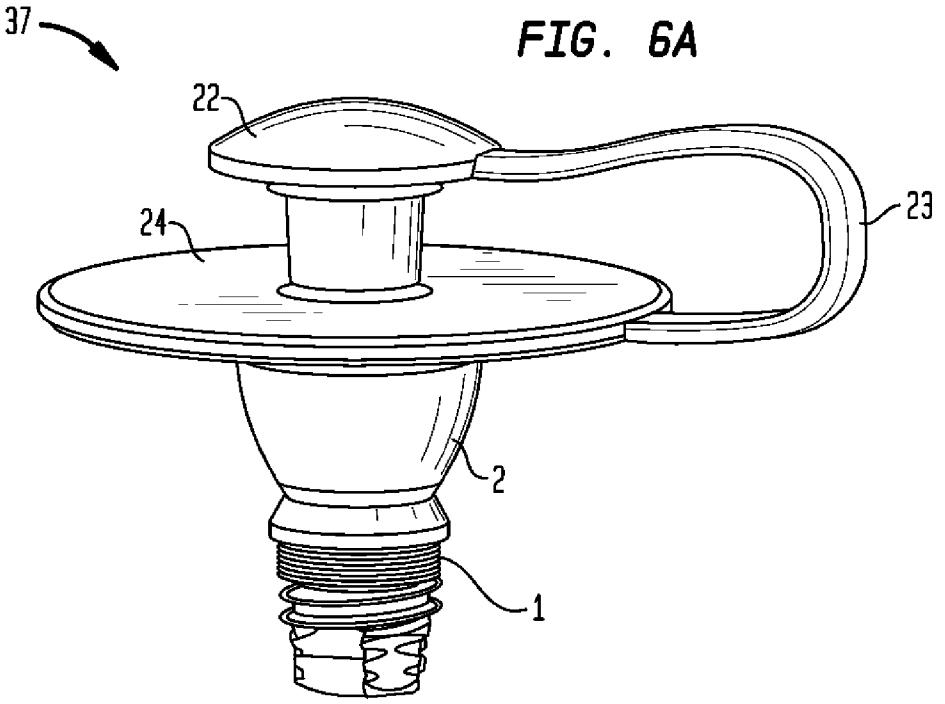


FIG. 6B

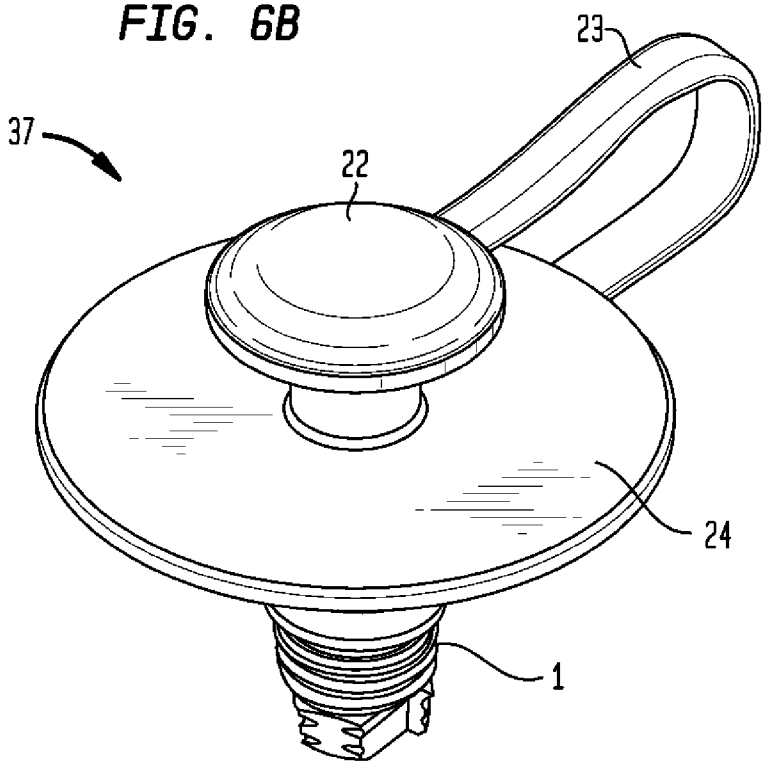


FIG. 7A

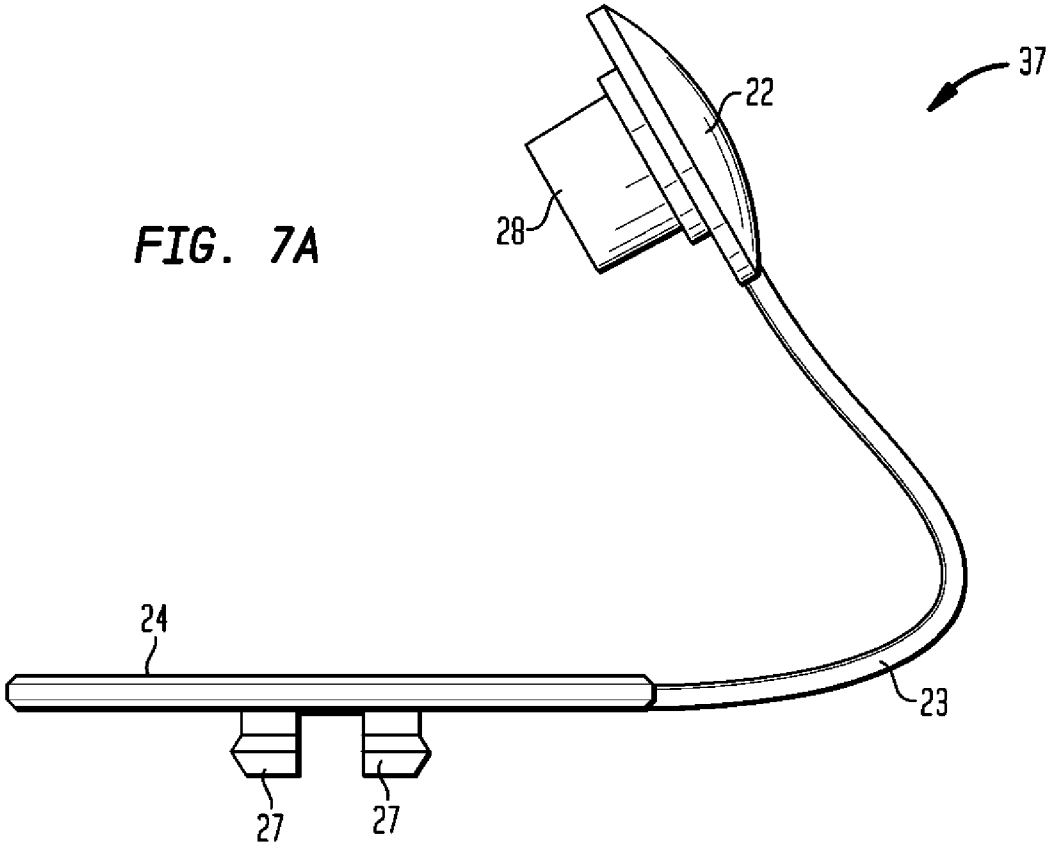
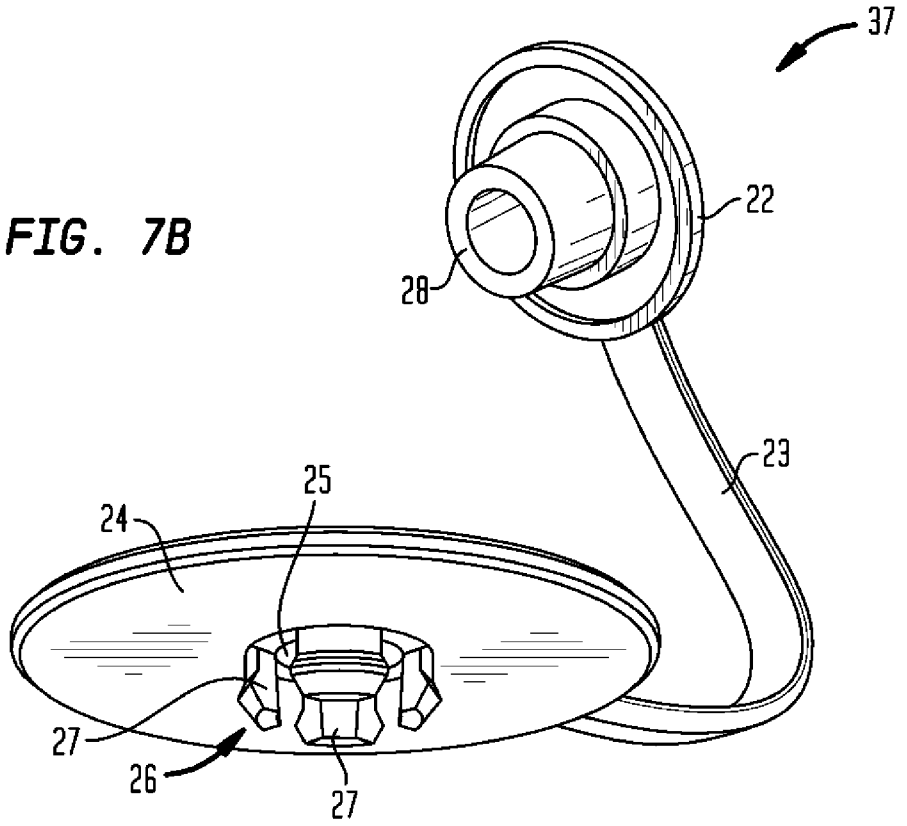


FIG. 7B



COUPLING APPARATUS FOR A BONE ANCHORED HEARING DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/951,169, entitled "Coupling Apparatus for a Bone Anchored Hearing Device," filed Jul. 20, 2007 and U.S. Provisional Application No. 60/951,163, entitled "Bone Anchor Fixture for a Medical Prosthesis," filed Jul. 20, 2007. These applications are hereby incorporated by reference herein.

BACKGROUND

[0002] 1. Field of the Invention

[0003] The present invention relates generally to hearing devices and, more particularly, to a coupling apparatus for bone anchored hearing devices.

[0004] 2. Related Art

[0005] For persons who cannot benefit from traditional, air conduction hearing aids there are other types of hearing aids on the market commonly referred to as bone anchored hearing aids. Bone anchored hearing aids mechanically transmit sound information to a person's inner ear via the skull bone by means of a vibrator. Such hearing aid devices are typically connected to a percutaneous implant in the form of a titanium screw implanted in the skull bone behind the external ear so that sound is transmitted via the skull bone to the cochlea (inner ear). This enables the hearing aid to be effective regardless of whether there is disease or damage in the middle ear. Moreover, penetration of the skin makes the vibratory transmission very efficient.

[0006] Bone anchored hearing aids were initially developed to rehabilitate certain types of hearing-impaired patients. They may also be utilized for other indications such as stuttering and for certain non-medical applications. A bone anchored hearing aid may be connected to an implant by means of a bayonet coupling, a snap-in coupling, a magnetic coupling or the like. One example of this type of hearing aid device is the BAHA® bone anchored hearing aid, described in U.S. Pat. No. 4,498,461 and commercially available from Cochlear Bone Anchored Solutions AB (previously Entific Medical Systems AB) in Göteborg, Sweden.

[0007] Typically, the implant connecting the hearing aid to the skull generally comprises two components: a bone attachment piece that is attached or implanted directly into the skull bone and a skin penetrating piece coupled to the bone attachment piece. This two-piece design facilitates the installation of the implant in two sequential steps. In the first step, the bone attachment piece is installed into the skull and the surrounding tissue is allowed to heal for a period of time that may last up to a few months. In the second step, the skin penetrating piece is coupled to the bone attachment piece. In the event that the skin penetrating piece becomes damaged, it may be replaced without removing the anchoring fixture from the skull. Moreover, this permits the hearing aid to be changed or upgraded, if necessary, without removing the bone attachment piece from the skull.

[0008] A well-known problem with many of these conventional percutaneous implants is the increased risk of infections and inflammation that results from bacterial colonization in the area surrounding the skin-implant interface. Oftentimes, unwanted pockets and gaps are formed between the skin and the implant. In conventional implants such gaps are dimensioned so as to provide an ideal environment for bacterial growth, inflammation and infection in the tissue surrounding the implant.

[0009] Another problem with these conventional percutaneous implants is the risk of micro-leakage and bacterial colonization from gaps formed between the two components. Such gaps result from insufficient connection between bone attachment piece and the skin penetrating piece, imperfections in the contact surfaces of the two components, incorrect tightening torque, or a combination of the foregoing factors.

SUMMARY

[0010] In one embodiment, a coupling apparatus for anchorage of a prosthesis to a patient's skull bone is disclosed. The coupling apparatus comprises an elongate anchoring fixture comprising an external screw thread for penetrating the bone, and a flange that abuts the bone when the fixture is implanted. The fixture has a proximate end having an open cavity with a tapered interior contour. The skin-penetrating abutment is detachably connectable to the fixture and comprises a substantially conical exterior surface with a wider proximate region and a narrower distal region having a tapered exterior contour that fits within said tapered interior contour of the open cavity.

[0011] In another embodiment, a coupling apparatus for a bone anchored prosthesis is disclosed. The coupling apparatus comprises a bone anchor fixture and an abutment sleeve coupled to the bone anchor fixture. The bone anchor fixture comprising an outer screw thread and a flange. The flange has a flared outer top surface and a bottom portion configured to prevent the bone anchor fixture from penetrating through the bone. The abutment sleeve is coupled to the bone anchor fixture and comprises a tapered outer surface adjacent to the flared outer top surface of the flange. The flared outer top surface of the bone anchor fixture and the tapered outer surface of the abutment sleeve define an outer contour having a substantially hourglass shape having a waist and a waist angle.

[0012] In yet another embodiment, a coupling apparatus for a bone anchored prosthesis is disclosed. The coupling apparatus comprises a bone anchor fixture comprising an outer screw thread and a flange having an open cavity and tapered inner side walls disposed within the open cavity. The coupling apparatus further comprises an abutment sleeve comprising a tapered outer surface configured to be seated within the tapered inner side walls of the bone anchor fixture.

[0013] In a further embodiment, a healing cap for use with a coupling apparatus for a bone anchored prosthesis is disclosed. The healing cap comprises a platform having a central opening and one or more protruding members configured to removably attach the healing cap to coupling apparatus. A cap is provided for the central opening of the platform and a flexible band connects the platform and the cap.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Embodiments of the present invention are described herein with reference to the attached drawing sheets in which:

[0015] FIG. **1** is a perspective view of the coupling apparatus in accordance with one embodiment of the coupling apparatus;

[0016] FIG. **2** is a side view of the embodiment of the coupling apparatus illustrated in FIG. **1**;

[0017] FIG. **3** is a cross-sectional side view of the embodiment of the coupling apparatus illustrated in FIG. **1**;

[0018] FIG. **4** is a partial view of a proximate end of the fixture illustrating the tapered connection between the fixture and the abutment components of the coupling apparatus illustrated in FIG. **1**, in accordance with one embodiment of the coupling apparatus;

[0019] FIG. **5** is a perspective view of one embodiment of an elongate coupling shaft having a screw head with an external hex and a bore with an internal screw thread;

[0020] FIG. **6**A is a side view of a healing cap with the coupling apparatus illustrated in FIG. **1**, with the healing cap in a closed orientation;

[0021] FIG. **6**B is a perspective view of the healing cap illustrated in FIG. **6**A;

[0022] FIG. **7**A is a side view of the healing cap illustrated in FIGS. **6**A and **6**B, with the healing cap in an open orientation; and

[0023] FIG. **7**B is a perspective view of the healing cap illustrated in FIG. **7**A.

DETAILED DESCRIPTION

[0024] Aspects and exemplary embodiments of the invention disclosed herein are generally directed to a bone anchored coupling apparatus in which the surfaces of an implanted fixture component and an associated abutment component are configured so as to reduce gaps thereby minimizing undesirable micro-leakage, preferably regardless of any imperfections in the mating surfaces and a range of tightening torques.

[0025] In certain embodiments, the coupling apparatus has a smooth outer contour facing the surrounding soft tissue to minimize unwanted pockets or gaps in the tissue-device interface. In particular embodiments, the regions of the fixture and the abutment components which mate with each other have inverse conically-shaped regions such that, when mated, the fixture forms the bottom of an hourglass shape while the abutment forms the top of the hourglass shape. Preferably, the dimensions of the hourglass configuration are such that the patient's skin abuts the narrow region of the hourglass configuration.

[0026] In certain embodiments, the upper end surface of the fixture has an open cavity with a tapered interior surface forming a seat for the tapered exterior side wall of the abutment. This preferably creates a good connecting fit between the fixture and abutment so as to reduce the risk of micro-leakage.

[0027] A well known problem with percutaneous implants is infection and inflammation at the skin-implant interface resulting from bacterial colonization in the area around the interface. The coupling apparatus disclosed herein increases the integration of the skin to the coupling apparatus thereby decreasing the likelihood that a gap will form between the two. Such gaps are, unfortunately, an ideal environment for the bacteria. By creating an integration of the skin to the coupling apparatus the adverse skin reactions associated with bone anchored percutaneous implants may be reduced.

[0028] Integration between the skin and the implant occurs when the soft tissue encapsulates the implant in fibrous tissue and does not readily dissociate itself from the implant. U.S. Provisional Patent Application No. 60/951,163, entitled "Bone Anchor Fixture for a Medical Prosthesis", filed Jul. 20, 2007, discloses a surface modification which reduces certain adverse skin reactions, and which may be implemented in embodiments of the present invention. In other embodiments the abutment sleeve is coated to reduce the shear modulus, as described in greater detail below.

[0029] Embodiments of the coupling apparatus may be used in connection with hearing aid devices of the bone conduction type, that is, hearing aid devices by which the sound is transmitted via the skull bone directly to the inner ear of a person with impaired hearing. However, embodiments of the coupling apparatus may also be configured for use in connection with other types of hearing aid devices anchored in the skull bone and for ear or orbital prostheses which are also anchored in the skull bone. Other applications of the coupling apparatus are also contemplated.

[0030] Embodiments of the bone anchored coupling apparatus will be described below with reference to the accompanying drawings. FIG. **1** is a perspective view of a bone anchored coupling apparatus **30** according to one embodiment. Coupling apparatus **30** is illustrated in FIG. **1** with a screw-shaped bone anchor fixture **1** and a skin-penetrating abutment sleeve **2**. The two components are connected by an elongate coupling shaft or an abutment screw **3** having, in one embodiment, a cylindrical screw head **4**. Screw head **4** has an internal hex or multi-lobular configuration **5** for a cooperating insertion tool, which is not part of the invention and therefore not illustrated here.

[0031] In an alternate embodiment depicted in FIG. **5**, a coupling shaft **3** is illustrated as having a screw head **4** with an external hex geometry **29**A and a bore with an internal screw thread **30**. The external hex geometry **29**A may be used for the screw tightening and the internal screw thread **30** may be used for connecting measuring probes or the like for controlling purposes, such as a Resonance Frequency Analyzer (RFA) probe for measuring implant stability and osseointegration. In one embodiment, an M **1.6** screw is used. In combination with the conical fit between the fixture **1** and the abutment sleeve **2**, the M **1.6** screw provides sufficient torque to secure the assembly and improved elastic deformation of the screw. This reduces the likelihood of the coupling assembly **30** become disassembled or unscrewed.

[0032] In the alternative embodiments, rather than external hex geometry **29**A, screw head **4** has outer threads and an internal ungrip. Such an embodiment may be suitable for connecting certain RFA probes.

[0033] Fixture **1** may be made of any material that has a known ability to integrate into surrounding bone tissue, a phenomenon commonly referred to as osseointegration. In one embodiment, fixture **1** is made of titanium. Fixture **1** has a main body with an outer screw thread **6** which is intended to be installed into the skull bone. Fixture **1** also comprises a flange **7** configured to function as a stop when fixture **1** is installed into the skull bone. Flange **7** prevents the screw thread **6** from completely penetrating through the skull bone. Fixture **1** may further comprise a tool-engaging socket having an internal grip section (now shown) for easy lifting and handling of fixture **1**. Tool-engaging socket and the internal grip section are described and illustrated in co-pending U.S. Provisional Application No. 60/951,163, entitled "Bone Anchor Fixture for a Medical Prosthesis," filed Jul. 20, 2007, which is hereby incorporated by reference herein.

[0034] The main body of fixture **1** has a length sufficient to securely anchor the fixture **1** into, without penetrating entirely through, the skull bone. The length of the main body may therefore depend on the thickness of the skull bone at the implantation site. In one embodiment the main body has a

length that is no greater than 5 mm, measured from the planar bottom surface **10** of the flange **7** to the end of the distal region **1**B. In another embodiment, the length of the main body is from about 3.0 mm to about 5.0 mm.

[0035] In the embodiment depicted in FIGS. **1-3**, the main body has a tapered apical proximate end **1**A, a straight, generally cylindrical body, and a screw thread **6**. The distal region **1**B of fixture **1** is fitted with three self-tapping cutting edges **8** formed into the exterior surface of the fixture. Further details of the self-tapping features are described in International Patent Application WO 02/09622, which is hereby incorporated by reference herein.

[0036] A clearance or relief surface **9** may be provided adjacent to the self-tapping cutting edges **8**. This design is advantageous because it reduces the squeezing effect between the fixture **1** and the bone during installation of the screw by creating more volume for the cut-off bone chips.

[0037] As more clearly illustrated in FIGS. **2** and **3**, flange **7** has a planar bottom surface **10** for resting against the outer bone surface, indicated by **11** in FIG. **2**, when anchoring fixture **1** has been screwed down into the skull bone. Again, flange **7** prevents the fixture **1** from completely penetrating through the skull bone. Preferably, flange **7** has a diameter which exceeds the peak diameter of the screw threads **6**. In one embodiment, the diameter of the flange **7** exceeds the peak diameter of the screw threads **6** by approximately 10-20%. Although flange **7** is illustrated in FIGS. **1-5** as being circumferential, flange **7** may be configured in a variety of shapes so long as flange **7** has a diameter or width that is greater than the peak diameter of the screw threads **6**. Also, the size of flange **7** may vary depending on the particular application for which the coupling apparatus **30** is intended.

[0038] The outer peripheral surface **36** of flange **7** has a cylindrical part **12** and a flared top portion **13**. Upper end **7**A of flange **7** is designed with an open cavity **14**A having a tapered inner side wall **14**. The tapered inner side wall **14** is adjacent to the grip section (not shown). The interior of the flange **7** further includes an inner bottom bore **15** having internal screw threads for securing a coupling shaft **3**.

[0039] In one embodiment, increased stability to the coupling between fixture **1** and abutment sleeve **2** is provided by having the length of the open cavity **14**A extends from flange **7** to the distal region **1**B of fixture **1**. Tapered inner side wall **14** forms a seat for abutment sleeve **2** to create a good connecting fit between the fixture **1** and abutment sleeve **2**. As shown in FIG. **4**, a cone angle **33** is defined by the tapered interior contour **14** relative to a vertical axis. In one embodiment, the cone angle **33** may be in the range of approximately 30-40 degrees.

[0040] In the embodiments illustrated in the figures, the flange **7** has a smooth, open upper end **7**A and does not have a protruding hex. The smooth upper end **7**A of the flange **7** and the absence of any sharp corners provides for improved soft tissue adaptation. Flange **7** also comprises a cylindrical part **12** which, together with the flared upper part **13**, provides sufficient height **34** in the longitudinal direction for internal connection with the abutment sleeve **2**. FIG. **4** illustrates the tapered seat **14** seated within the height **34** of flange **7**.

[0041] The skin penetrating part of the implant includes the abutment sleeve **2**. In one embodiment, abutment sleeve **2** has an inner annular flange **16** at its upper edge **17**A configured to cooperate with other components (not shown) by means of snap-in connection or the like. Abutment sleeve **2** has an internal shoulder **18** with a central opening for a connecting shaft or coupling shaft **3** and a number of peripherally arranged through holes or recesses **19** used for a tool such as that illustrated in WO 2004/105650, which is hereby incorporated by reference herein.

[0042] It should be appreciated that the fixture **1**, abutment sleeve **2** and coupling shaft **3**, may be delivered separately or they may be delivered in the form of a pre-mounted device as illustrated in WO 2004/105650. In accordance with one embodiment, the coupling apparatus **30** is delivered to the surgeon pre-mounted in its package to facilitate installation of the entire device in a single step. Abutment sleeve **2** may be pre-mounted to the fixture **1** at the manufacturing site with the correct tightening torque to obviate the need for the surgeon to know the correct tightening torque or to handle the separate pieces of the coupling apparatus **30**.

[0043] In contrast to traditional implants which require an outer fixture hex for tool engagement, the coupling apparatus **30** may be installed by using the recesses **19** in the abutment sleeve **2**. These recesses **19** are located on the upper part of the coupling apparatus **30** and are more visible than a traditional outer hex.

[0044] According to the embodiment shown in FIG. **3**, the abutment sleeve **2** has a substantially curved, conical outer surface with an upper edge **17**A and a bottom, fixture-connecting part **17**B. The upper edge **17**A may have a width or diameter that is larger than that of the bottom, fixture connecting part **17**B. The bottom part **17**B of the outer surface has a contour **20** adapted to be seated with the tapered inner contour **14** of the fixture to create a good connecting fit between the fixture **1** and abutment sleeve **2**. The two conical shaped surfaces not only provides an axially well-defined fit when assembled together, they also provides for easy disassembly.

[0045] It would be desirable to reduce the risk for micro-leakage from the coupling apparatus **30**. Designing the upper part of the fixture **1** and the lower part of the abutment sleeve **2** with a conical fit reduces the risk for gaps and unwanted micro-leakage, regardless of any imperfections in the contact surfaces or incorrect tightening torques.

[0046] As shown in FIG. **4**, the tapered portion **20** of the abutment sleeve **2** is characterized by a cone angle **32**. The cone angle **32** is configured so as to securely couple the fixture **1** and the abutment sleeve **2** without significant gaps. Preferably, the cone angles **32** and **33** are in the range of about 30° to about 40°, with little or no difference between the cone angles **32** and **33**. In one embodiment, the cone angles **32** and **33** are substantially the same. In another embodiment, the difference between the cone angles **32** and **33** is about 1° to about 5°, and more preferably about 1°.

[0047] It would also be desirable to reduce the risk of infections and inflammation that results from bacterial colonization in the unwanted pockets and gaps that are formed between the skin and the implant. As illustrated in FIG. **2**, an hourglass waist angle **38** is generally defined between the exterior peripheral surface **36** of flared portion **13** of flange **7** and the tapered lower portion **20** of abutment sleeve **2**. The hourglass waist angle **38** provides a smooth outer contour to the facing soft tissue such that unwanted pockets and gaps are not formed between the surrounding tissue and the coupling apparatus **30**. This smooth contour facilitates integration between the coupling apparatus **30** and the surrounding tissue to substantially eliminate gaps and unwanted pockets where bacteria might grow. This is in contrast to many traditional implant devices in which a comparatively sharp interface is

formed with the contacting tissue. The embodiment depicted in FIG. **2** show an hourglass waist angle is greater than 90°.

[0048] In certain embodiments, the skin-contacting surface of abutment sleeve **2** may be modified in such a way that the shear modulus of the skin-contacting part of abutment sleeve **2** is reduced to less than 35 GPa. The surface of the skin-contacting part of the percutaneous implant abutment sleeve **2** may be coated with a biocompatible polymer or a ceramic material. In accordance with one aspect of the embodiments, the coating has a thickness of approximately 0.001-50.0 μm. A surface increasing treatment may be provided resulting in a roughness value S_a of 0.5-10 μm in place of or in addition to the coating. These modifications to the skin-contact surface generally reduce the shear modulus and certain adverse skin reactions. Surface modifications of this type are discussed in more detail in the co-pending patent application incorporated by reference elsewhere herein.

[0049] In certain embodiments, the abutment sleeve is coated with a material to reduce the shear modulus. Such a material may be, for example, a biocompatible polymer, a ceramic material, and/or a combination thereof. In one specific embodiment, the material has a thickness of about 0.001 μm to about 50.0 μm. In the same or other embodiments, the shear modulus is reduced to less than 35 GPa. In the same or other embodiments, the abutment sleeve is coated with a surface increasing material. Such a material may be such that it provides a roughness value of about 0.5 μm to about 10 μm. Further details of the above and other features may be found in Swedish Patent Application No. 0701244-6, which is hereby incorporated by reference herein.

[0050] The coupling apparatus **30** may also be designed in such a way that it is easy to handle together with instruments and components used for installation and control of the implant device. As noted, surgical techniques normally used for installing the implants have been carried out as a two-step procedure. In the first step the implant is inserted and maintained unloaded during a healing period of about a couple of months. During this healing period it is important to avoid micro-leakage from the coupling apparatus and bacteria colonization.

[0051] FIGS. **6-7** depict a healing cap **37** that may be used in connection with the coupling apparatus **30**. As illustrated in FIGS. **6-7**, the healing cap **37** comprises a snap-in platform **24**, a cap **22**, and a flexible band **23** connecting the snap-in platform **24** and the cap **22**. This design makes it easy and safe for the surgeon to handle.

[0052] Snap-in platform **24** includes a central through opening **25** and a lower, central protruding portion **26** with a number of protruding, flexible members **27** arranged to cooperate with said inner annular flange **16** on the abutment sleeve **2**. Cap **22** comprises a lower, cylindrical sleeve-shaped portion **28** arranged to be inserted into the annular spacing formed between the flexible members **27** and the protruding screw head **4** of the coupling shaft **3**. Cap **22** provides a closure for the through hole in the abutment sleeve **2** as well as a locking member for snap-in platform **24**. Healing cap **37** is preferably made of a plastic material.

[0053] FIGS. **6-7** depict the sleeve-shaped portion **28** having a cylindrical shape. It is understood, however, that the sleeve-shaped portion **28** may have any other shape, such as a squared, rectangular, rounded or polygonal shape, depending on the connecting parts.

[0054] The entire implant device—including fixture **1**, abutment sleeve **2**, abutment screw **3** and healing cap **37** (discussed below)—may be installed in a single session followed by a healing period, instead of the traditional multi-step procedure in which the fixture is separately installed and followed by a healing period before the remaining parts, the abutment sleeve, abutment screw and healing cap, are installed.

[0055] Further features and advantages of the present invention may be found in U.S. Provisional Application No. 60/951,169, entitled "Coupling Apparatus For a Bone Anchored Hearing Device," and filed Jul. 20, 2007, and U.S. Provisional Application No. 60/951,163, entitled "Bone Anchor Fixture for a Medical Prosthesis," and filed Jul. 20, 2007, which are hereby incorporated by reference herein.

[0056] The invention described and claimed herein is not to be limited in scope by the specific preferred embodiments herein disclosed, since these embodiments are intended as illustrations, and not limitations, of several aspects of the invention. Any equivalent embodiments are intended to be within the scope of this invention. Indeed, various modifications of the invention in addition to those shown and described herein will become apparent to those skilled in the art from the foregoing description. Such modifications are also intended to fall within the scope of the appended claims.

What is claimed is:

1. A coupling apparatus for anchorage of a prosthesis to a patient's skull bone, comprising:

an elongate anchoring fixture comprising an external screw thread for penetrating the bone, and a flange that abuts the bone when the fixture is implanted, wherein a proximate end of the fixture has an open cavity with a tapered interior contour; and

a skin-penetrating abutment detachably connectable to said fixture comprising a substantially conical exterior surface having a tapered exterior contour that fits within the tapered interior contour of the open cavity.

2. The coupling apparatus of claim **1**, wherein said prosthesis is a hearing prosthesis.

3. The coupling apparatus of claim **1**, wherein the flange has a width that is greater than a peak diameter of the external screw threads.

4. The coupling apparatus of claim **3**, wherein the width of the flange exceeds the peak diameter of the external screw threads by about 10-20%.

5. The coupling apparatus of claim **1**, wherein the flange comprises a flared external top portion and a cylindrical portion adjacent to the flared external top portion.

6. The coupling apparatus of claim **1**, wherein the abutment sleeve further comprises an upper end and an inner annular flange disposed within the upper end.

7. The coupling apparatus of claim **1**, wherein the elongate anchoring fixture further comprises an elongate coupling shaft to securely couple the elongate anchoring fixture and the skin-penetrating abutment.

8. The coupling apparatus of claim **7**, wherein the elongate coupling shaft comprises a screw head.

9. The coupling apparatus of claim **8**, wherein the screw head comprises an internal hex or multi-lobular configuration for a cooperating insertion tool.

10. The coupling apparatus of claim **9**, wherein the screw head has an external hex geometry and a bore with an internal screw head.

11. The coupling apparatus of claim **9**, wherein the screw head has an external thread and a bore with an internal unigrip configuration.

12. The coupling apparatus of claim **8**, wherein the abutment sleeve further comprises an internal shoulder having a central opening for the elongate coupling shaft.

13. A coupling apparatus for a bone anchored prosthesis comprising:

a bone anchor fixture comprising an outer screw thread and a flange having a flared outer top surface and a bottom portion configured to prevent the bone anchor fixture from penetrating through the bone; and

an abutment sleeve coupled to the bone anchor fixture comprising a tapered outer surface adjacent to the flared outer top surface of the flange;

wherein the flared outer top surface of the bone anchor fixture and the tapered outer surface of the abutment sleeve define an outer contour having a substantially hourglass shape having a waist and a waist angle.

14. The coupling apparatus of claim **13**, wherein the outer contour is substantially smooth.

15. The coupling apparatus of claim **13**, wherein the waist angle is greater than 90°.

16. The coupling apparatus of claim **13**, wherein the abutment sleeve is coated with a material to reduce the shear modulus.

17. The coupling apparatus of claim **16**, wherein the material is selected from the group consisting of: a biocompatible polymer, a ceramic material, and a combination thereof.

18. The coupling apparatus of claim **17**, wherein the material has a thickness of about 0.001 μm to about 50.0 μm.

19. The coupling apparatus of claim **17**, wherein the shear modulus is reduced to less than 35 GPa.

20. The coupling apparatus of claim **13**, wherein the abutment sleeve is coated with a surface increasing material.

21. The coupling apparatus of claim **20**, wherein the surface increasing material provides a roughness value of about 0.5 μm to about 10 μm.

22. A coupling apparatus for a bone anchored prosthesis comprising:

a bone anchor fixture comprising an outer screw thread and a flange having an open cavity and tapered inner side walls disposed within the open cavity; and

an abutment sleeve comprising a tapered outer surface configured to be seated within the tapered inner side walls of the bone anchor fixture.

23. The coupling apparatus of claim **22**, wherein the tapered inner side walls of the bone anchor fixture and the tapered outer surface of the abutment sleeve have first and second cone angles, respectively.

24. The coupling apparatus of claim **23**, wherein the first and second cone angles are identical.

25. The coupling apparatus of claim **23**, wherein the first and cone angles have a difference of about 1° to about 5°.

26. The coupling apparatus of claim **23**, wherein the first and second cone angles are in the range of about 30° to about 40° relative to a vertical axis.

27. A healing cap for use with a coupling apparatus for a bone anchored prosthesis comprising:

a platform comprising a central opening and one or more protruding members configured to removably attach the healing cap to coupling apparatus;

a cap for the central opening; and

a flexible band connecting the platform and the cap.

28. The healing cap of claim **27**, wherein the one or more protruding members are provided around the central opening to define an annular space.

29. The healing cap of claim **28**, wherein the cap further comprises a lower, cylindrical sleeve-shaped portion configured to be inserted into the annular space.

30. A coupling apparatus for a bone anchored prosthesis comprising:

bone anchor means comprising a screw means configured to be installed into the bone and a flange means configured to prevent the screw means from penetrating through the bone;

abutment means coupled to the bone anchor means for penetrating the skin; and

coupling means for securely and removably coupling the bone anchor means and the abutment means.

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