



US009271092B2

(12) **United States Patent**
Bjorn et al.

(10) **Patent No.:** **US 9,271,092 B2**
(45) **Date of Patent:** **Feb. 23, 2016**

(54) **MEDICAL IMPLANT SYSTEM**
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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 338 days.

(21) Appl. No.: **13/371,763**
(22) Filed: **Feb. 13, 2012**

(65) **Prior Publication Data**
US 2012/0172658 A1 Jul. 5, 2012

Related U.S. Application Data
(63) Continuation of application No. PCT/AU2010/000401, filed on Apr. 9, 2010.

(30) **Foreign Application Priority Data**
Aug. 13, 2009 (AU) 2009903789
Oct. 14, 2009 (AU) 2009905020

(51) **Int. Cl.**
H04R 25/00 (2006.01)
(52) **U.S. Cl.**
CPC **H04R 25/606** (2013.01)
(58) **Field of Classification Search**
CPC A61B 17/70-17/7059
USPC 433/172-176; 411/369, 186, 399; 600/25; 381/312, 326
See application file for complete search history.

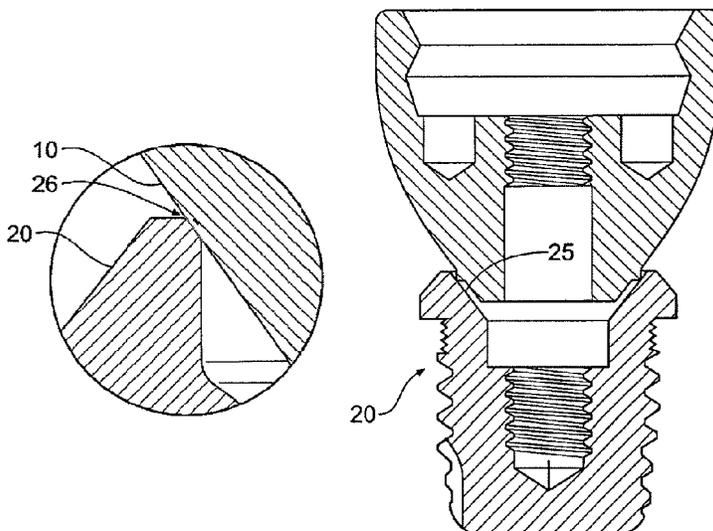
(56) **References Cited**
U.S. PATENT DOCUMENTS
4,498,461 A 2/1985 Hakansson
5,702,342 A 12/1997 Metzler et al.
6,447,295 B1 9/2002 Kumar et al.
7,065,223 B2 6/2006 Westerkull
2003/0124491 A1* 7/2003 Honkura et al. 433/189
2005/0014108 A1* 1/2005 Wohrle et al. 433/173
2009/0082817 A1* 3/2009 Jinton et al. 606/301

FOREIGN PATENT DOCUMENTS
WO 98/55049 12/1998
OTHER PUBLICATIONS
International Search Report of PCT/AU2010/000401, mailed Jun. 3, 2010, 8 pages.
Written Opinion of PCT/AU2010/000401, mailed Jun. 3, 2010, 7 pages.
European Search Report and Search Opinion for European Application No. 10807771.0 mailed Feb. 25, 2013 (6 pages).

* cited by examiner
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(57) **ABSTRACT**
An implant including a bone fixture configured to anchor to bone of a recipient, and a structural component configured to be connected to the bone fixture and connect a functional component of the implant to the bone fixture, wherein at least one of the bone fixture or the structural component includes a deformable element configured to deform to form an anti-microbial seal between the bone fixture and the structural component, and the at least one deformable element and the respective at least one bone fixture or structural component form a monolithic structure.

13 Claims, 21 Drawing Sheets



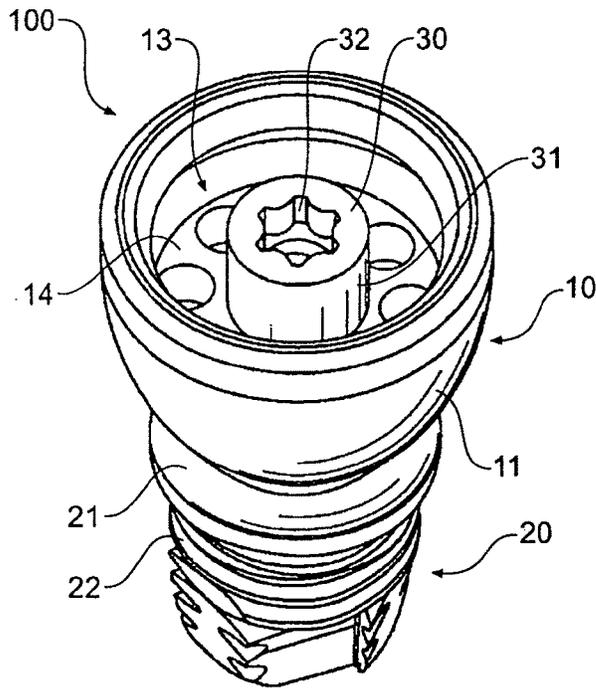


Figure 3

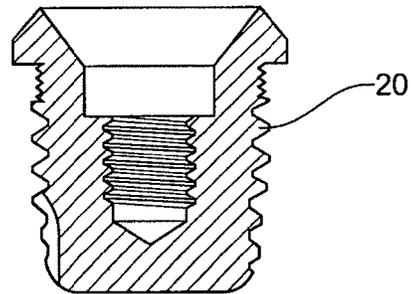
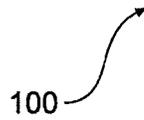
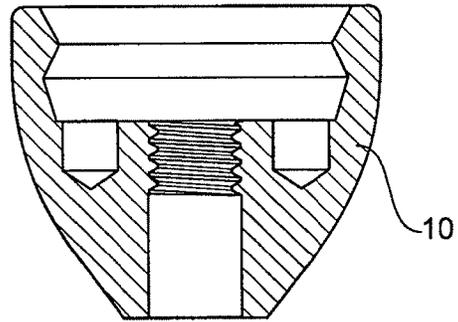
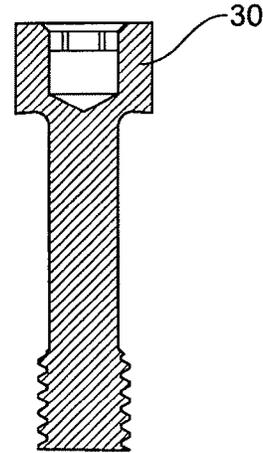


Figure 4

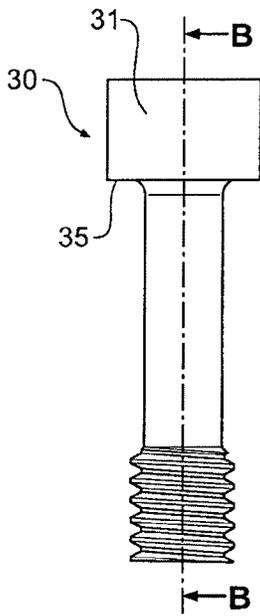


Figure 5a

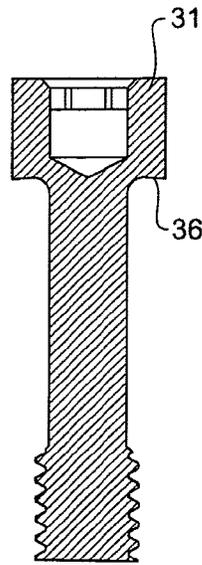


Figure 5b

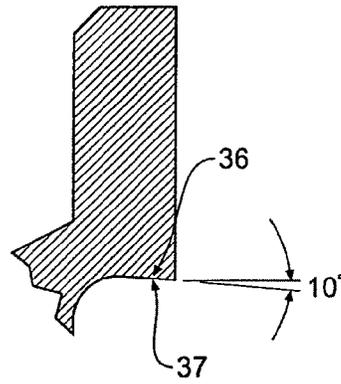


Figure 5c

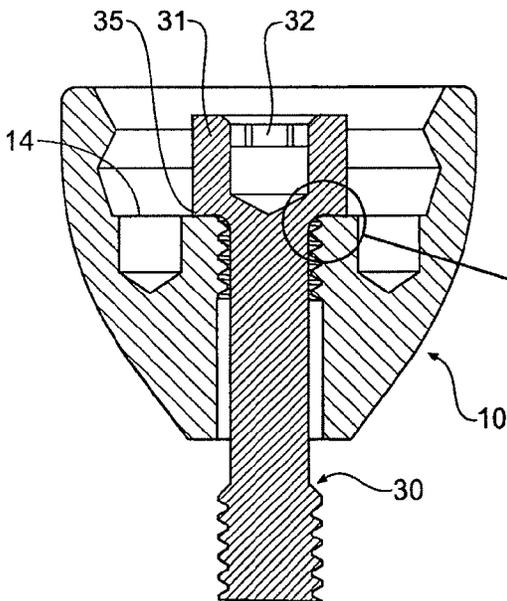


Figure 6

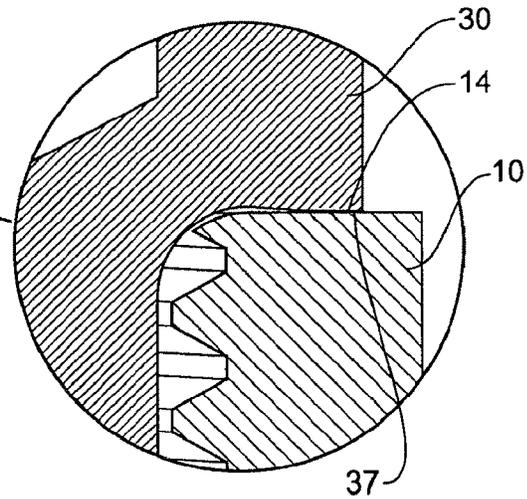


Figure 7

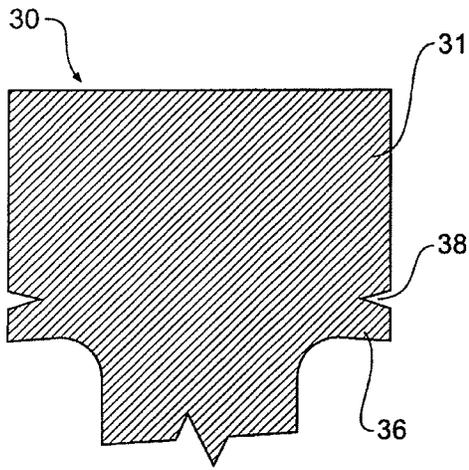


Figure 8

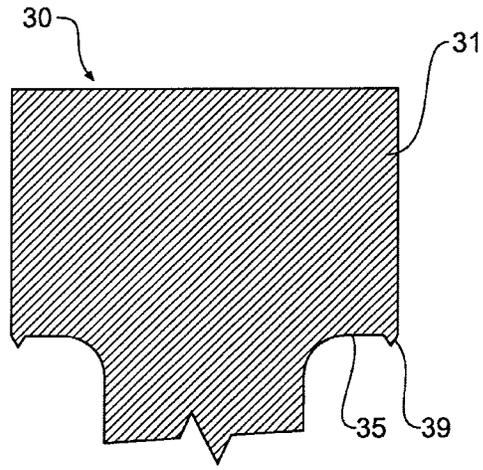


Figure 9a

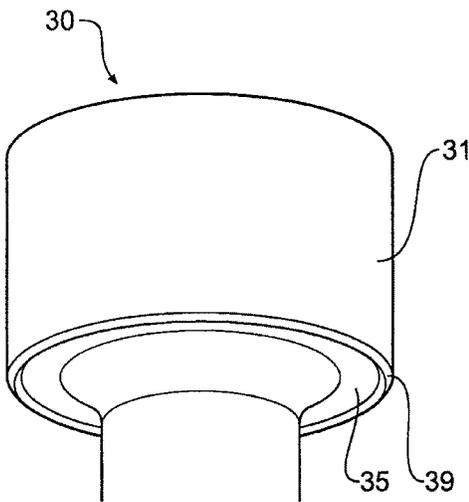


Figure 9b

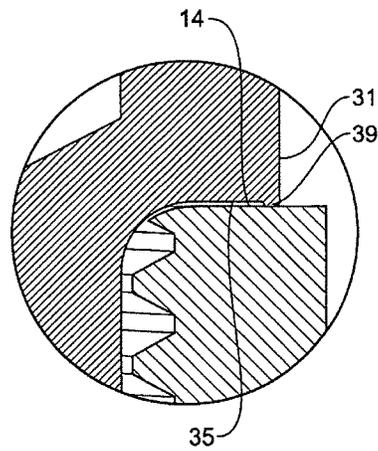


Figure 10

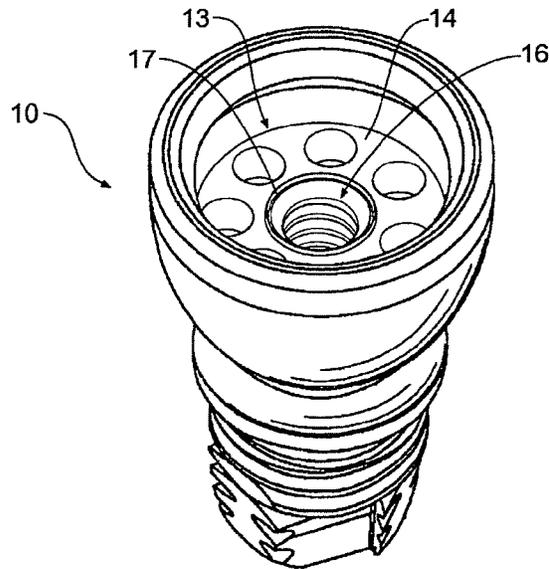


Figure 11

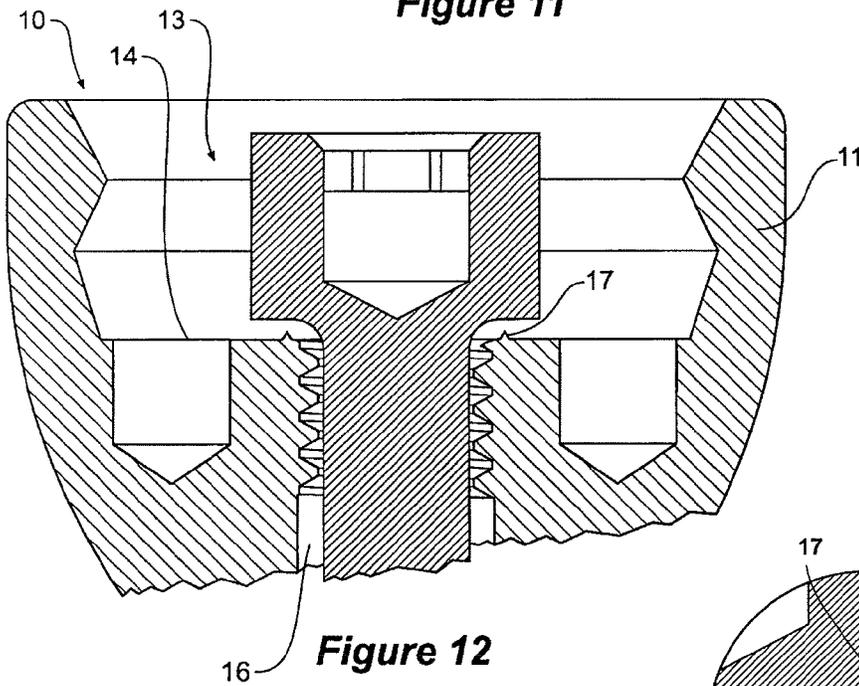


Figure 12

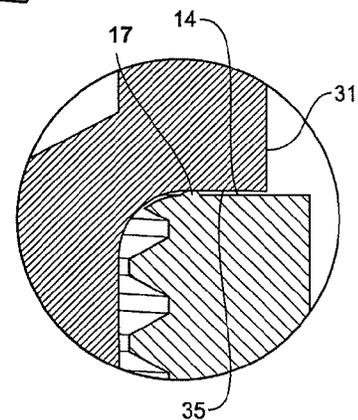


Figure 13

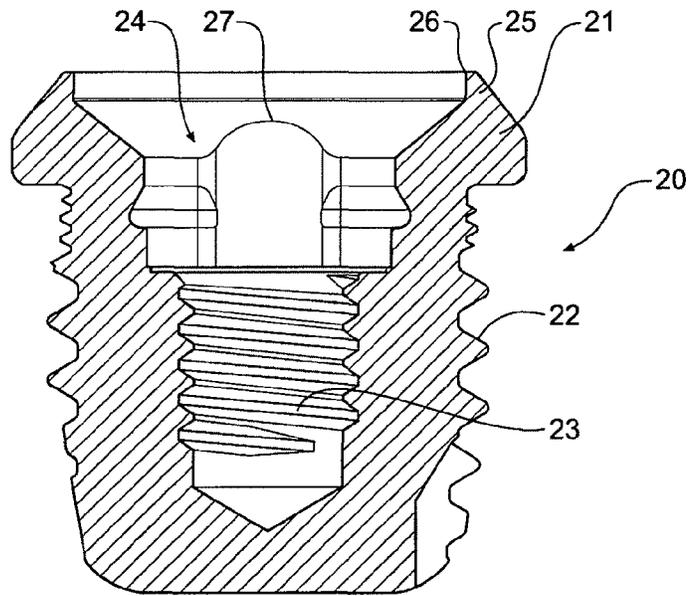


Figure 14

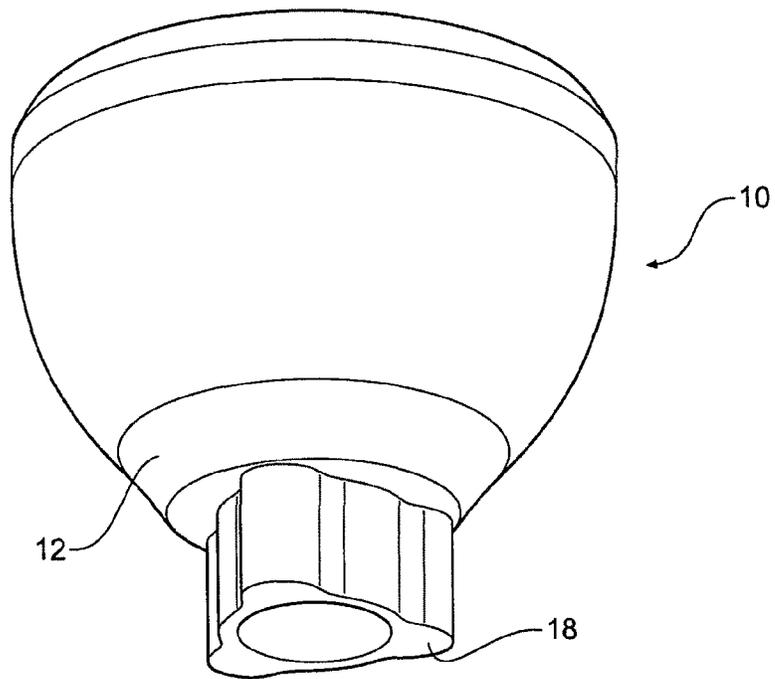


Figure 15

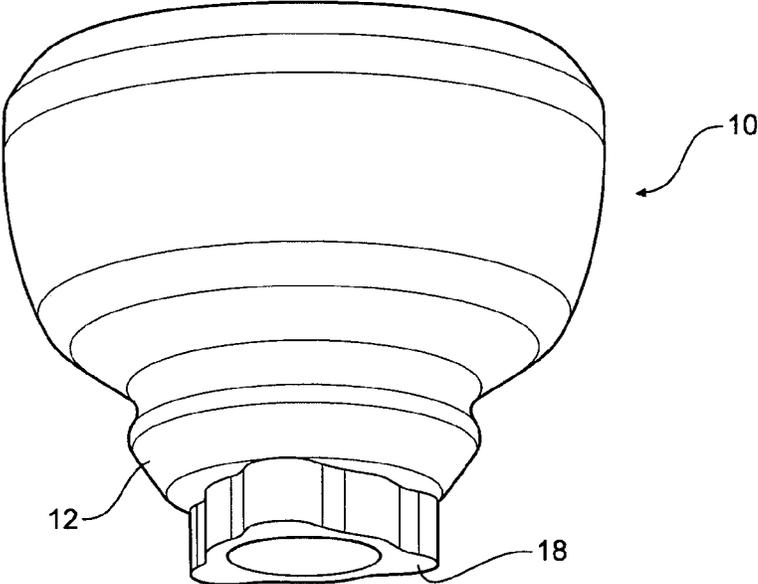


Figure 16

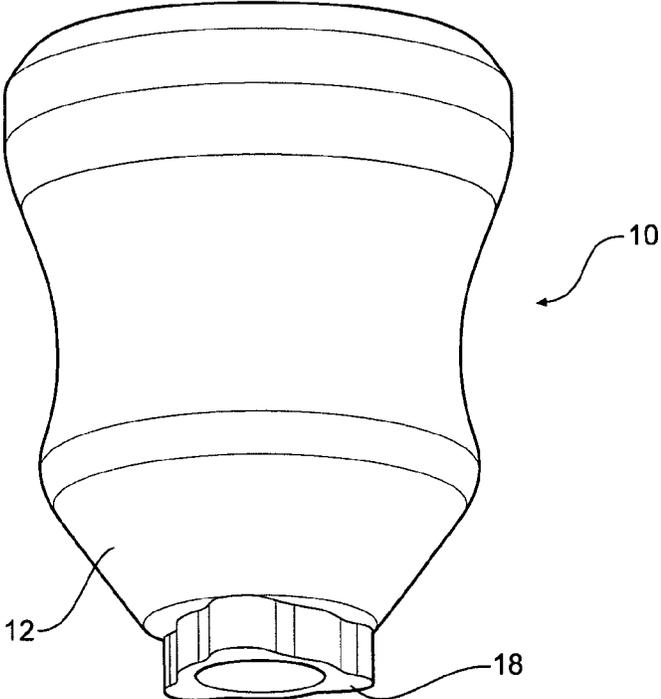


Figure 17

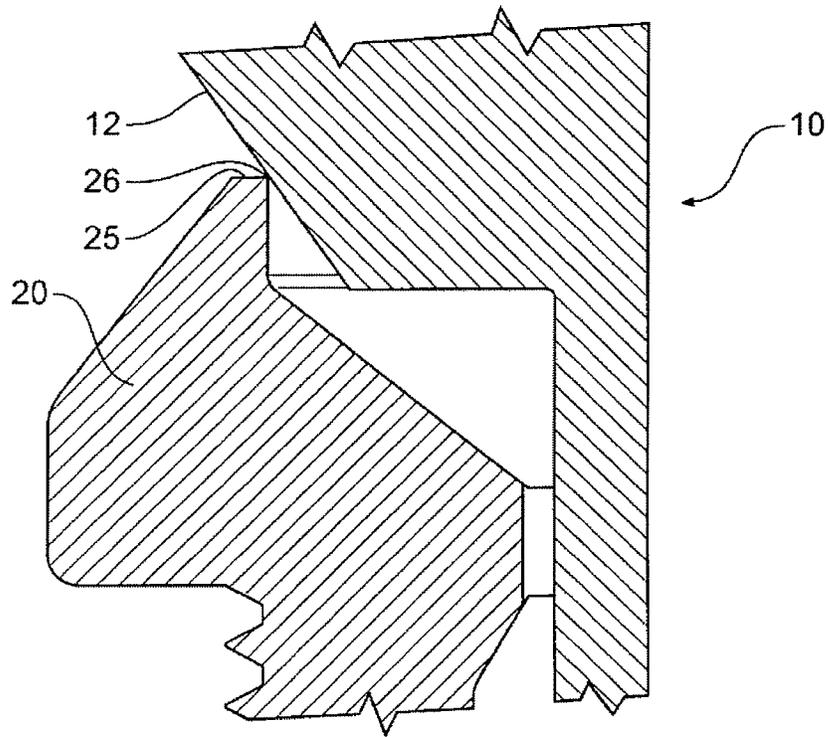


Figure 18

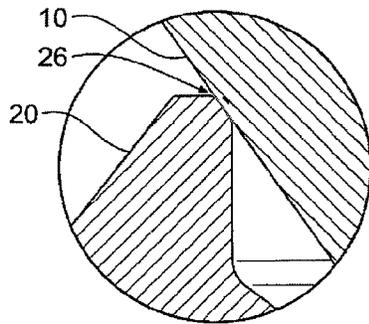


Figure 19

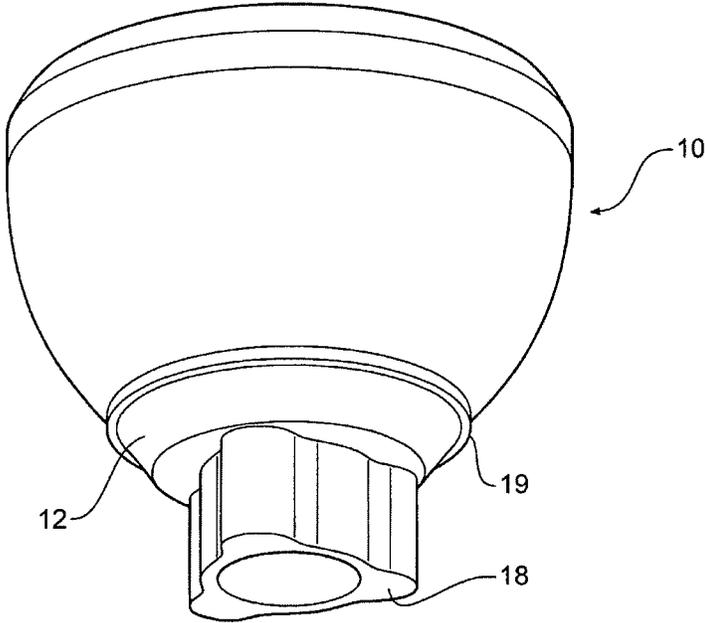


Figure 20

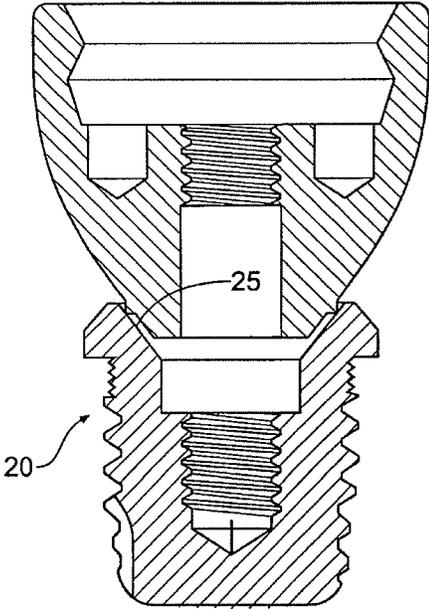


Figure 21

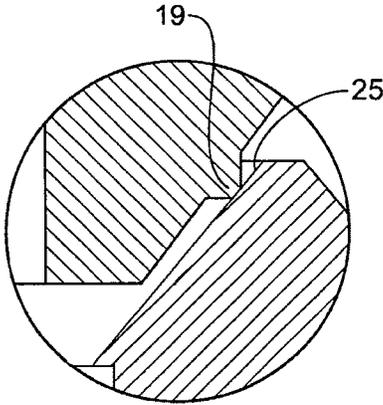


Figure 22

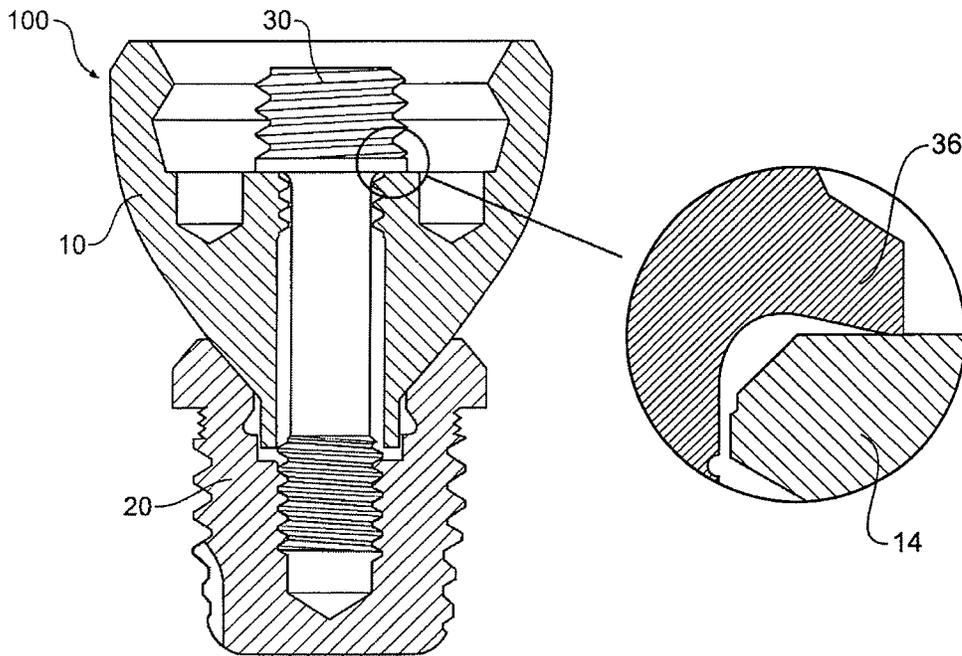


Figure 23

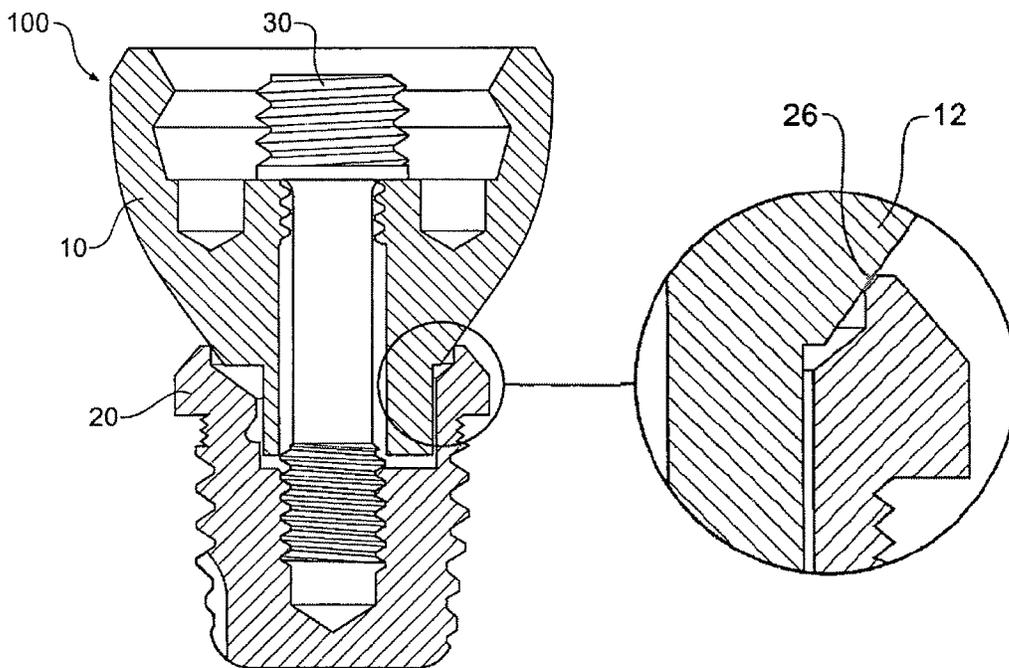


Figure 24

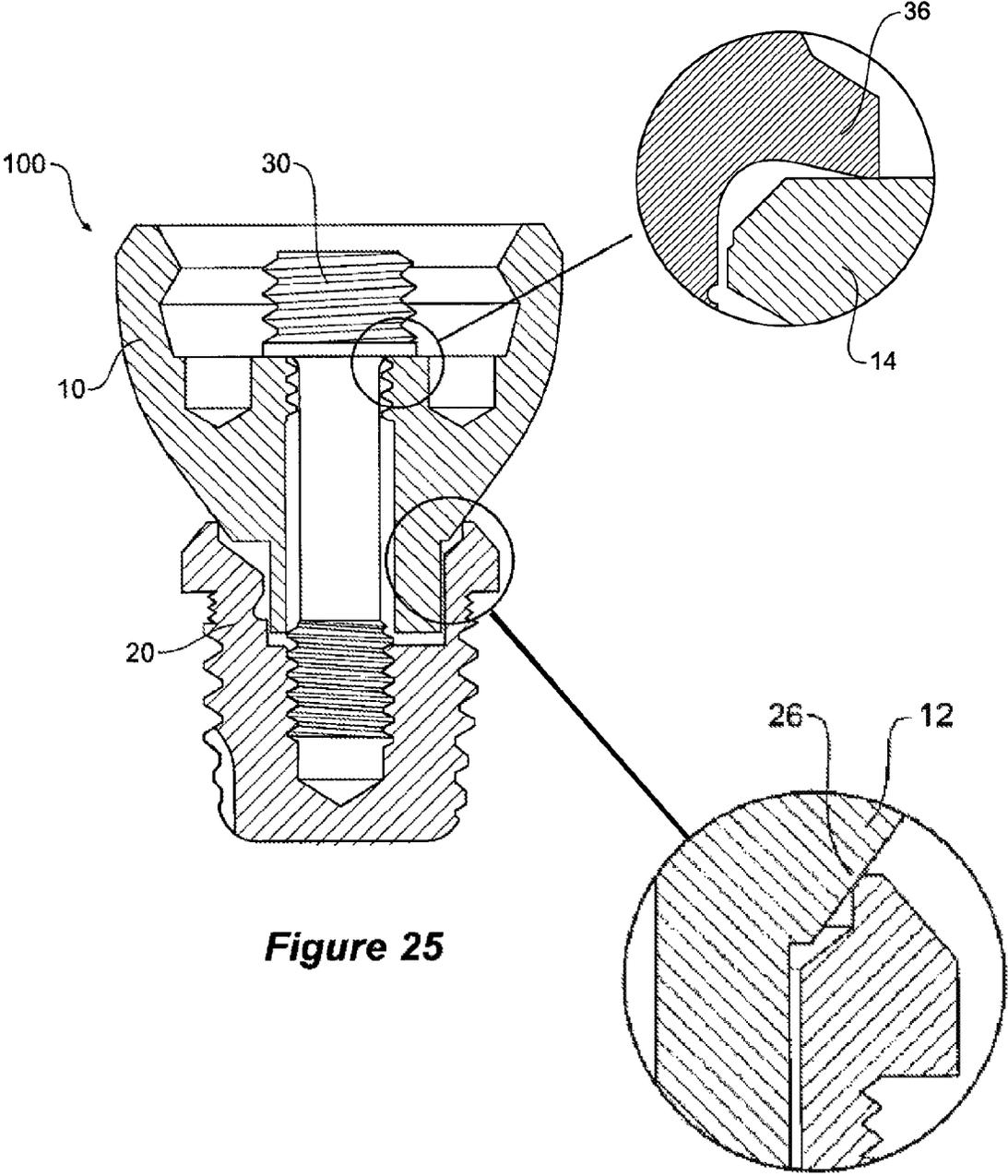


Figure 25

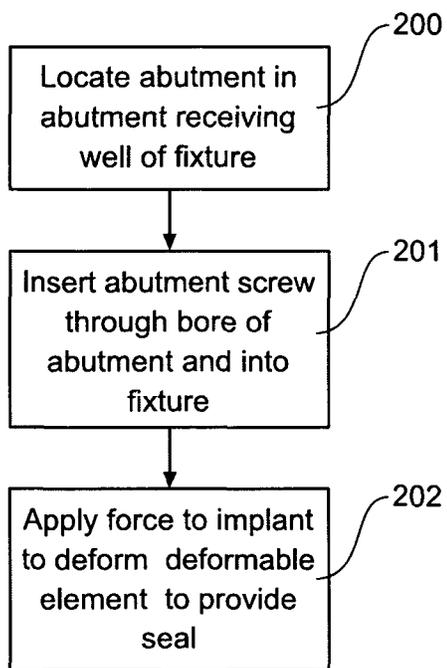


Figure 26a

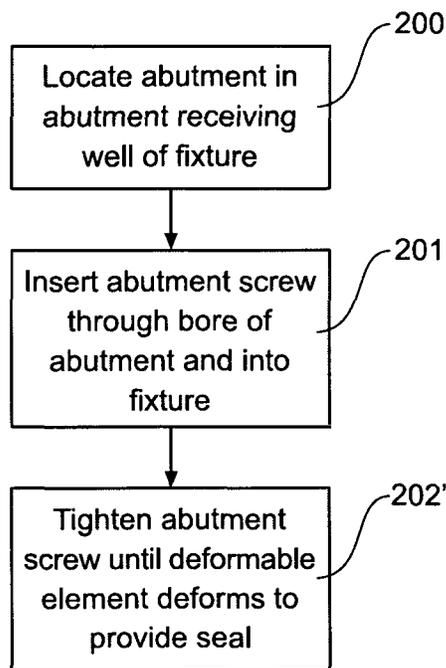


Figure 26b

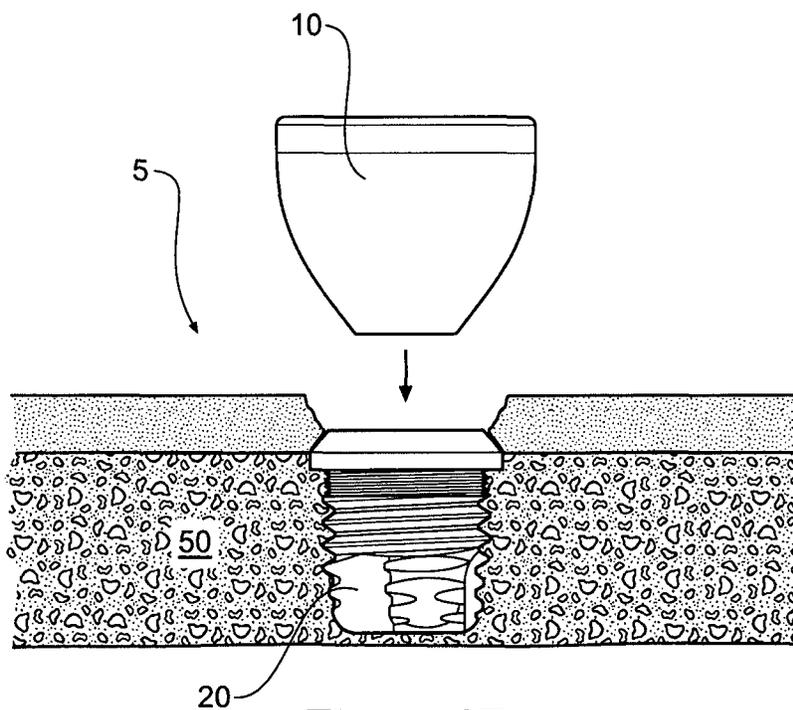


Figure 27a

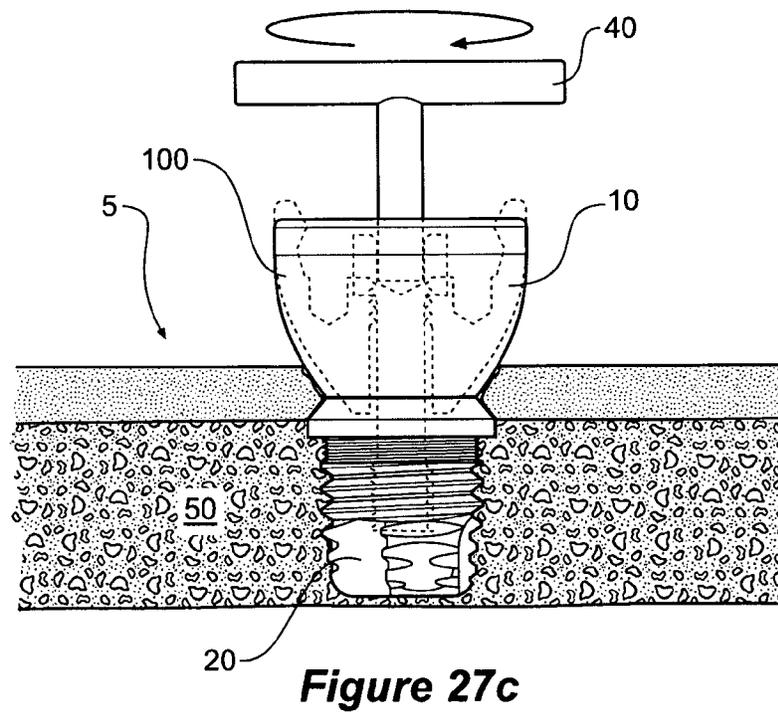
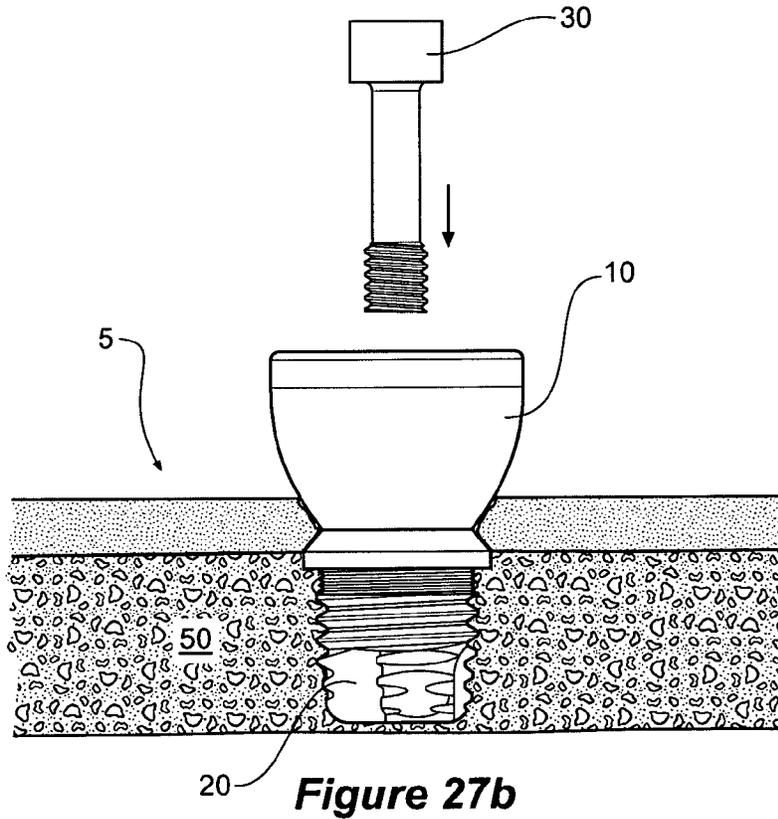
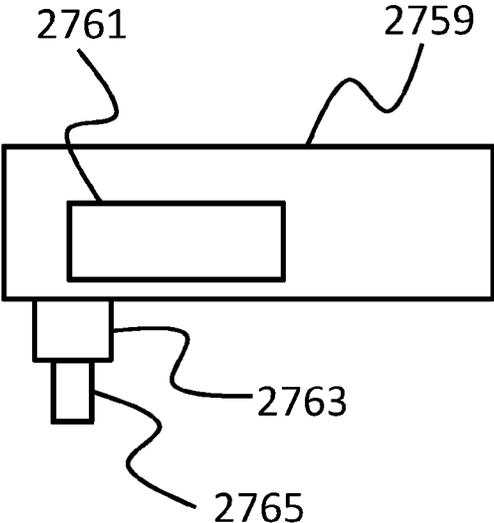


Figure 27d



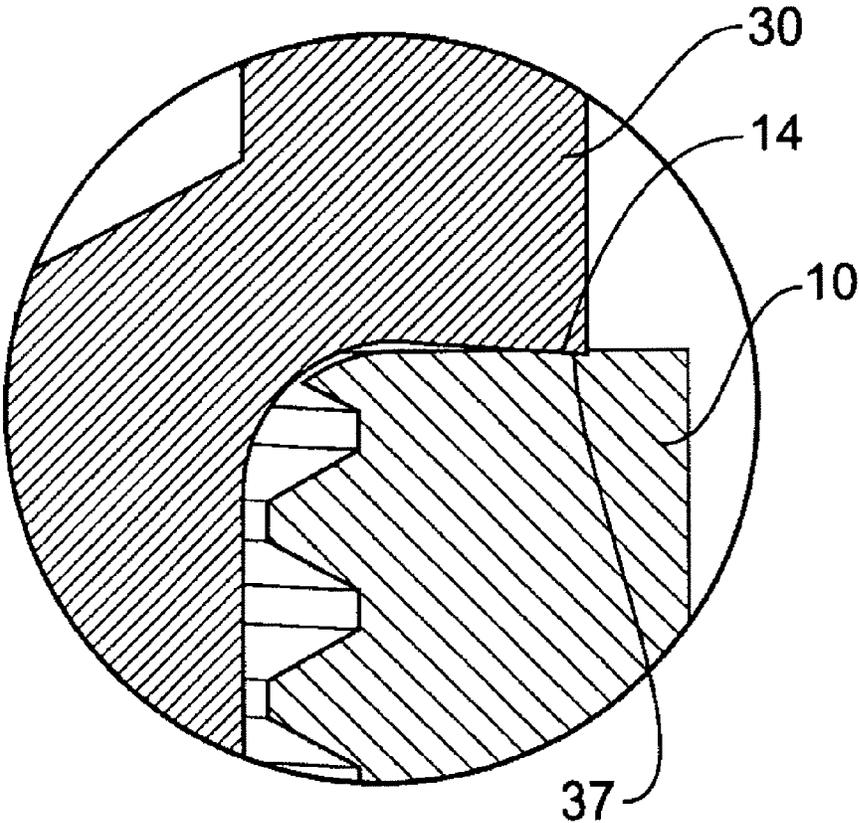


Figure 28

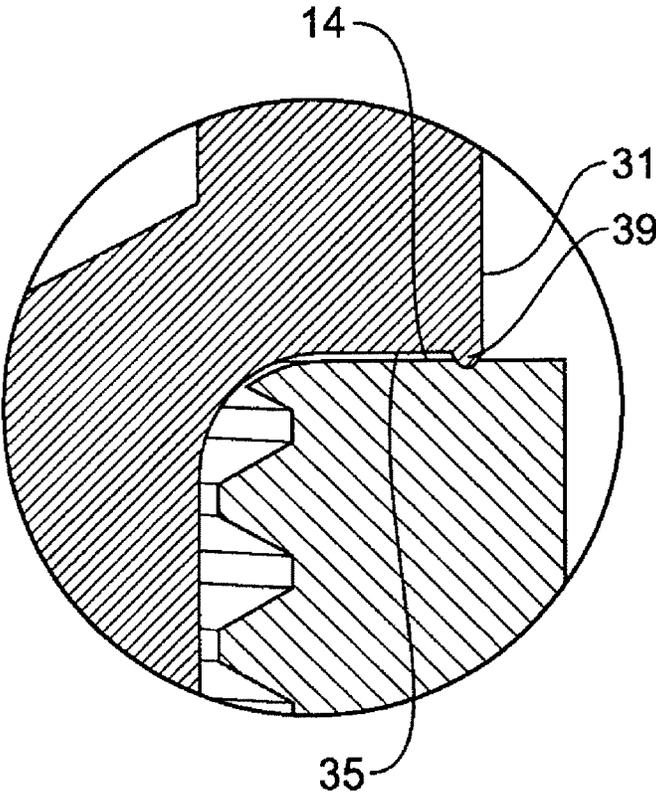


Figure 29

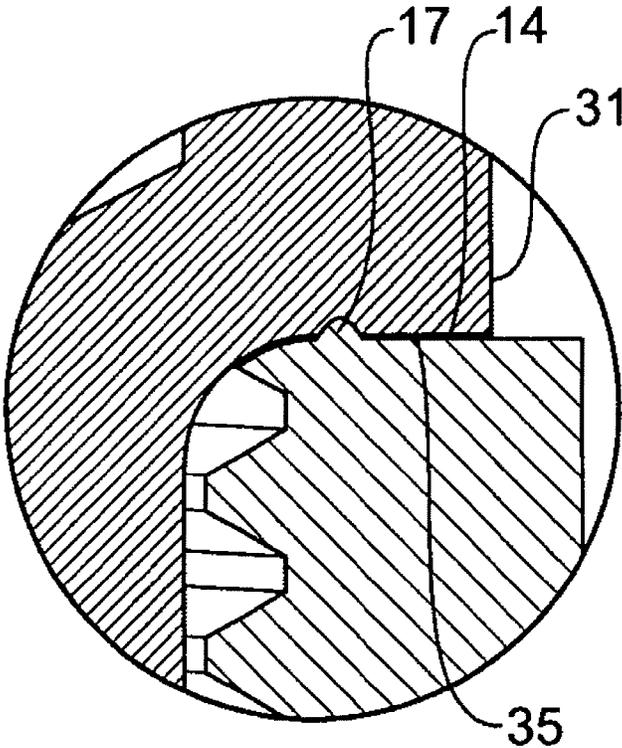


Figure 30a

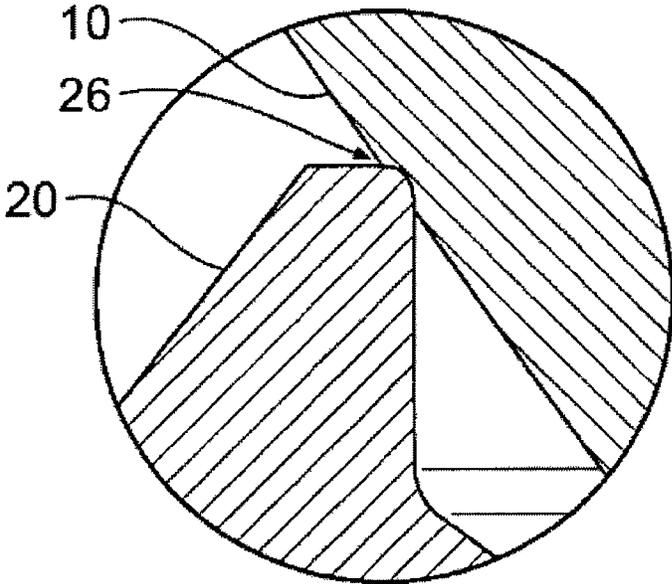


Figure 30b

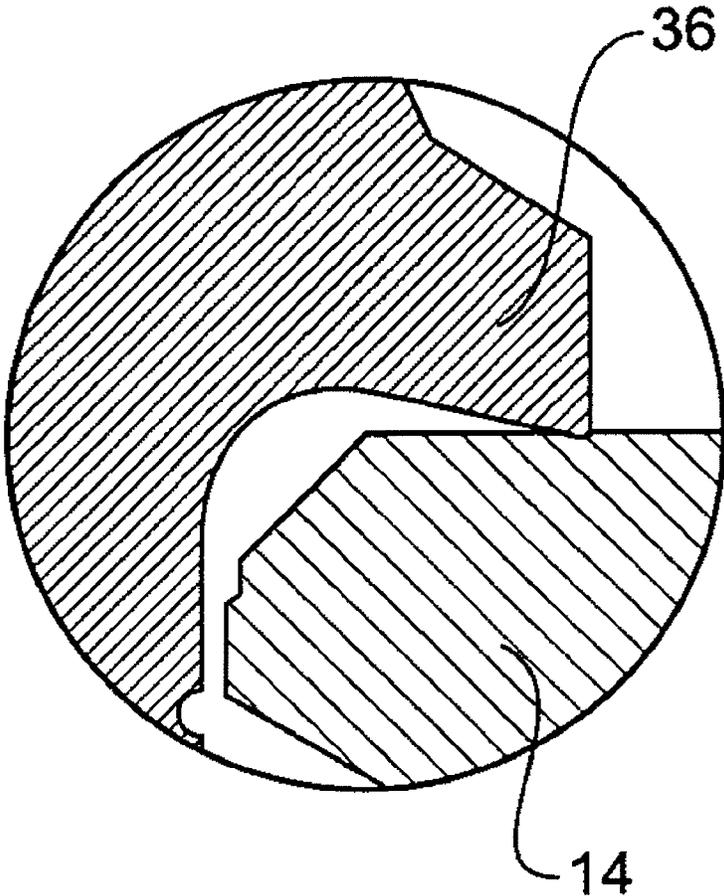


Figure 31

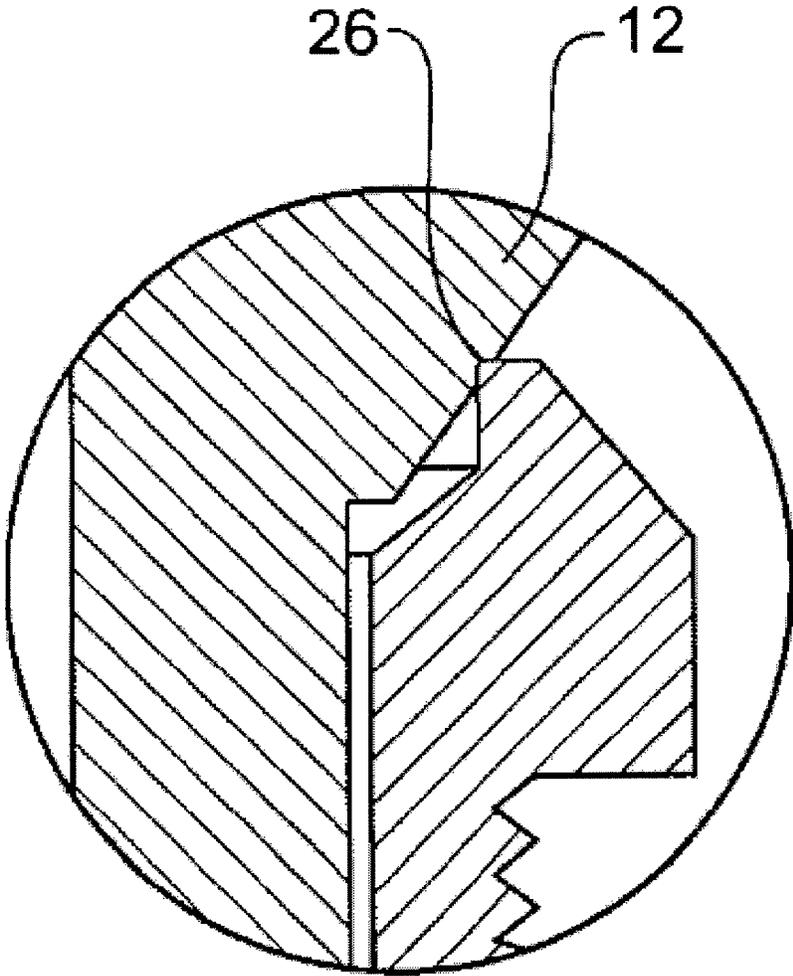


Figure 32

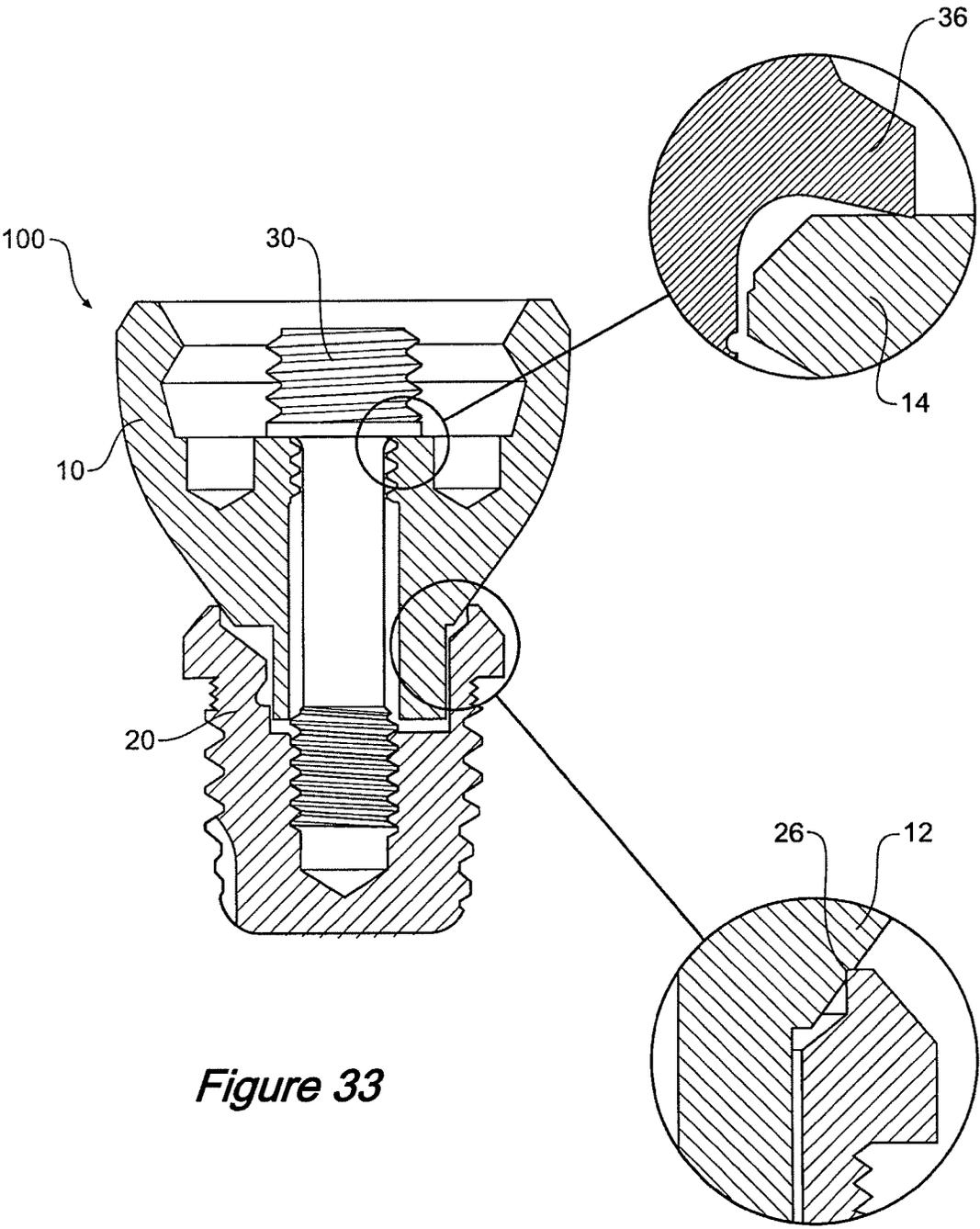


Figure 33

MEDICAL IMPLANT SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation application of International Patent Application No. PCT/AU2010/000401, filed on Apr. 9, 2010, designating Goran Bjorn of Sweden and Dr. Marcus Andersson, also of Sweden, as inventors, which claims priority to Australian Provisional Patent Application No. 2009903789 entitled "Implant Device" filed on 13 Aug. 2009, and Australian Provisional Patent Application No. 2009905020 entitled "Implant Device" filed on 14 Oct. 2009, the entire content of each of these applications being hereby incorporated by reference herein in their entirety.

BACKGROUND

1. Field of the Invention

The present invention relates generally to bone conduction devices, and more particularly, to infection prevention measures associated with percutaneous bone conduction devices.

2. Related Art

Bone-anchored medical implant systems are used to connect or fixate hearing devices to a recipient, directly to the bone or skull of the recipient. Some applications include hearing implants such as bone conduction devices marketed by Cochlear Bone Anchored Solutions AB in Sweden. Such bone conduction devices sometimes comprise, in the case of percutaneous bone conduction devices as is shown by way of example in FIG. 27*d* in black-box format, an external, removable unit 2759 including a vibrator 2761 which transforms sound into mechanical vibrations. Percutaneous bone conduction devices conduct those mechanical vibrations via an abutment 2763 and a bone fixture 2765 of the implant, into the bone of the skull. Passive transcutaneous bone conduction devices conduct those mechanical vibrations through skin of the recipient to an implantable component which includes a bone fixture. The vibrations are transmitted mechanically via the skull bone and thereafter to the inner ear of a person with impaired hearing and allows for the hearing organ to register the sound. A hearing device of the bone conduction device type typically includes an anchoring element or fixture, in the form of, for example, an implanted titanium screw, corresponding to the bone fixture, installed in the bone behind the external ear and the sound is transmitted via the skull bone to the cochlea (inner ear), irrespective of any disease, injury or other dysfunction of the middle ear. In percutaneous bone conduction or anchoring arrangements, the skin is penetrated, which makes the vibratory transmission very efficient. This arrangement can also be used in connection with facial prostheses, such as, for example, some of those marketed by Cochlear Limited, Australia.

The implants which are used with percutaneous bone conduction devices are sometimes provided in two pieces. One piece comprises the screw-shaped anchoring element (fixture or anchor) and the other piece comprises the abutment, which penetrates the skin. This two-piece design, in many exemplary embodiments, allows the surgical implantation to be carried out as a two-step procedure. In the first step of implanting such a two-pieced design, the fixture is inserted and maintained unloaded during a healing period of some months or so. After this healing period the second step of the surgical procedure, i.e. the connection of the abutment by means of an abutment screw, is executed. The two-part design may allow for the implants to be up-graded, if desirable, without removing the fixture or anchor. Furthermore, if the

abutment is damaged, it can then be replaced without need of removal of the bone anchored screw or fixture.

A situation sometimes experienced with bone conduction devices in general, and percutaneous implant devices in particular, is the risk of infections and inflammation. This exists sometimes at the tissue-implant interface. The infections are a result of bacterial colonization at the area around the interface between the bone fixture and the abutment. This problem can be persistent and cause infections. Cleaning of the interface has utility, but even regular cleaning and disinfection is not always entirely successful. The risk of infections may also exist at the interface between separate components of totally implantable prostheses.

With respect to a percutaneous bone conduction device, the bacteria may enter the implant-tissue interface by two different routes—an external route on the external surface of the abutment, and an internal route which starts at the top of the abutment and travels via internal parts (screw connection) of the implant system and may exit at the abutment-fixture-soft tissue junction or interface. The external route is the most open route, but the bacteria may also reach the implant-tissue interface from the internal route, known as the internal micro-leakage pathway.

SUMMARY

Some aspects of the present invention are generally directed to an implant including a bone fixture configured to anchor to bone of a recipient, and a structural component configured to be connected to the bone fixture and connect a functional component of the implant to the bone fixture, wherein at least one of the bone fixture or the structural component includes a deformable element configured to deform to form an anti-microbial seal between the bone fixture and the structural component, and the at least one deformable element and the respective at least one bone fixture or structural component form a monolithic structure.

Some other aspects of the present invention are generally directed to an implant, comprising a bone fixture configured to anchor to bone of a recipient, a structural component configured to be connected to the bone fixture and connect a functional component of the implant to the bone fixture, and a screw configured to bolt the structural component to the bone fixture, wherein the implant includes an anti-microbial seal between the structural component and the screw.

Some other aspects of the present invention are generally directed to an implant, comprising, a bone fixture configured to anchor to bone of a recipient, and a structural component configured to be connected to the bone fixture and connect a functional component of the implant to the bone fixture, wherein at least one of the bone fixture or the structural component includes a deformable element configured to plastically deform to form an anti-microbial seal between the bone fixture and the structural component.

Some other aspects of the present invention are generally directed to a method of attaching an abutment to an implanted bone fixture to form a percutaneous implant, comprising positioning the abutment in contact with the implanted bone fixture, and applying a torque of about 15 Ncm or more to a component of the percutaneous implant threadably engaged with the implanted bone fixture, thereby driving the abutment towards the bone fixture via reaction against the implanted bone fixture, wherein the applied torque is sufficient to at least one of deform material of at least one of the bone fixture and the abutment to form an anti-microbial seal between the bone fixture and the abutment, or deform material of at least one of

an abutment screw and the abutment to form an anti-microbial seal between the abutment screw and the abutment.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention are described below with reference to the attached drawings, in which:

FIG. 1—shows an example of a medical implant system to which various aspects of the present disclosure may be applied;

FIG. 2—shows a cross section of the medical implant system of FIG. 1;

FIG. 3—shows a perspective view of the medical implant system of FIG. 1;

FIG. 4—shows a cross section exploded view of the components of the medical implant system of FIG. 1;

FIG. 5a—shows one embodiment of an abutment screw of one aspect of the disclosure;

FIG. 5b—shows a cross section of the abutment screw of FIG. 5A;

FIG. 5c—shows a close up view of the deformable element of FIG. 5B;

FIG. 6—shows a cross section of the abutment screw of FIG. 5A in an abutment;

FIG. 7—shows a close-up cross section view of a seal provided between the abutment screw of FIG. 5A and the abutment;

FIG. 8—shows a cross section of an alternative embodiment of the abutment screw of FIG. 5A;

FIG. 9a—shows a cross section of yet a further alternative of the abutment screw of FIG. 5A;

FIG. 9b—shows a perspective view of the abutment screw of FIG. 9A;

FIG. 10—shows a close-up cross section view of a seal provided between the abutment screw of FIG. 9a and the abutment;

FIG. 11—shows a perspective view of one embodiment of an abutment;

FIG. 12—shows a cross section of the abutment of FIG. 11;

FIG. 13—shows a close-up view of a seal provided between the abutment screw and the abutment of FIG. 11;

FIG. 14—shows a cross section of one embodiment of a fixture;

FIG. 15—shows a perspective view of one embodiment of an abutment for use with the fixture of FIG. 14;

FIG. 16—shows a perspective view of another embodiment of an abutment for use with the fixture of FIG. 14;

FIG. 17—shows a perspective view of yet another embodiment of an abutment for use with the fixture of FIG. 14;

FIG. 18—shows the abutment of any one of FIGS. 15 to 17 in place in the fixture of FIG. 14;

FIG. 19—shows a close-up view of the seal provided by the arrangement of FIG. 18;

FIG. 20—shows a different embodiment of an abutment;

FIG. 21—shows the abutment of FIG. 20 engaging with a fixture;

FIG. 22—shows a close-up of a seal provided by the arrangement of FIG. 21;

FIG. 23—shows an embodiment of a medical implant system with a seal provided between the abutment and the abutment screw;

FIG. 24—shows another embodiment of a medical implant system with a seal provided between the abutment and the fixture;

FIG. 25—shows another embodiment of a medical implant system with a seal provided between the abutment and the abutment screw as well as between the abutment and the fixture;

FIG. 26a—shows a flow chart of a method of implanting a medical implant system;

FIG. 26b—shows a specific example of the method of FIG. 26a;

FIG. 27a—shows a cross section of the arrangement of the first step of the method of FIG. 26b;

FIG. 27b—shows a cross section of the arrangement of the second step of the method of FIG. 26b; and

FIG. 27c—shows a cross section of the arrangement of the third step of the method of FIG. 26b;

FIG. 27d—shows in black-box format a functional conceptual external removable unit of a percutaneous bone conduction device including a vibrator, along with an implant;

FIG. 28—shows a close-up cross section view of a seal provided between the abutment screw of FIG. 5a and the abutment in an alternate embodiment;

FIG. 29—shows a close-up cross section view of a seal provided between the abutment screw of FIG. 9a and the abutment in an alternate embodiment;

FIG. 30a—shows a close-up view of a seal provided between the abutment screw and the abutment of FIG. 11 in an alternate embodiment;

FIG. 30b—shows a close-up view of the seal provided by the arrangement of FIG. 18 in an alternate embodiment;

FIG. 31—shows an alternate embodiment of a medical implant system with a seal provided between the abutment and the abutment screw;

FIG. 32—shows another embodiment of a medical implant system with a seal provided between the abutment and the fixture; and

FIG. 33—shows another embodiment of a medical implant system with a seal provided between the abutment and the abutment screw as well as between the abutment and the fixture.

DETAILED DESCRIPTION

FIG. 1 shows a side view of a medical implant system 100. The implant system has an abutment 10 that enables a hearing device to be coupled through a percutaneous connection to a bone anchoring device in the form of fixture 20. Abutment 10 is connected to fixture 20. Fixture 20 has a base collar 21 and screw threads 22. In use, screw threads 22 is screwed into bone of the recipient (sometimes herein also referred to as the user) to fixate and retain fixture 20 to the user's skull.

As can be seen in FIG. 2, which shows a cross section view along the line A-A' of FIG. 1, abutment 10 is connected to and retained to fixture 20 by abutment screw 30. Abutment screw 30 has head 31, a well 32 within the head 31 to receive an insertion tool or the like, and an apical outer screw threaded section 34 on an elongate main body 33. In some examples, abutment screw 30 may be an M 1.8 titanium screw and the well 32 in head 31 may be a tubular hex configuration for receiving and cooperating with the insertion tool (not shown). The apical outer screw threaded section 34 engages with inner screw thread 23 of the fixture 20 upon turning of the insertion tool.

FIG. 3 shows a perspective view of the medical implant system 100. In this view, the abutment interior 13 is visible, showing the abutment interior base 14. Also visible in this view is abutment screw 30 with head 31 and hexagonal well 32. The fixture 20 with base collar 21 and outer screw thread 22 is also visible.

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FIG. 4 shows a cross section view of three constituent parts of the medical implant system 100, with those parts separated from one another for clarity. There shown are abutment screw 30, abutment 10 and fixture 20.

FIG. 5A shows an exemplary embodiment of abutment screw 30. In particular, abutment screw head includes a base 35 which includes a deformable element in the form of a flange 36, which is angled downwards and outwards away from the head at a flange angle of about 10 degrees (in one example), as is more clearly seen in FIG. 5C. FIGS. 5B and 5C show a cross section view of the abutment screw 30 of FIG. 5A. In these views, the deformable element in the form of the flange 36 is more clearly visible.

In one embodiment, the outer portion of the flange 36, corresponding to at least part of the deformable element of the abutment screw 30, has a flat portion 37 (see FIG. 5C) which, in use, rests on a corresponding contact surface, in this case, the abutment interior base 14 as shown in FIG. 6. The deformable element is able to deform to form a seal. In one example, when the abutment screw 30 is screwed down into the inner screw thread 23 of fixture 20, flat portion 37 comes into contact with the corresponding contact surface or abutment interior base 14. When the abutment screw 30 is screwed further downwards, the deformable element corresponding to flange 36 with flat portion 37 is pressed downwards (which may cause the edge to move outwards) against the corresponding contact surface or abutment interior base 14 and thereby deform to provide a seal between the abutment screw 30 and the corresponding contact surface, in this case abutment interior base 14. In other words, the deformable element deforms a sufficient amount to provide a seal between the abutment screw 30 and the abutment 10, upon tightening of the abutment screw 30.

In other examples, the deformable element may deform upon application of downward pressure on the implant system or on a part thereof, such as on the screw head 31.

In the various examples detailed herein and/or variations thereof, the type of deformation may be plastic, elastic or a combination of both.

FIG. 7 shows a close up view of this engagement between the abutment screw 30 and the abutment 10, and in particular, shows how the deformation of the deformable element as flange 36 and the flat portion 37 is deformed and pressed into the surface of the abutment interior base 14, to provide a seal. In some cases, the corresponding contact surface, in this case the abutment interior base 14, may itself also deform slightly to further increase the seal formed therebetween. In the same vein, FIG. 28 shows a close up view of engagement between the abutment screw 30 and the abutment 10 in an alternate embodiment, which depicts the flange 36 being pressed into the surface of the abutment interior base 14, to provide a seal. As will be understood from FIG. 28, in this alternate embodiment, the corresponding contact surface, in this case the abutment interior base 14, may itself deform slightly to further increase the seal formed therebetween. The degree of resulting deformation of the abutment screw and/or the abutment may vary between embodiments. In some embodiments, all or substantially all of the overall deformation may occur in the abutment screw 30, while in some embodiments, all or substantially all of the deformation may occur in the abutment 10, while in some embodiments, the amount of deformation may be more evenly distributed between these two components.

As the contact surface increases by the deformation of the flange 36 and/or the abutment interior base 14, surface imperfections between the contacting surfaces might be compensated for, which reduces any gaps or holes for microbes

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(including fungi and bacteria) to pass through from the outside into the inside of the abutment.

This thereby provides a seal at the abutment and abutment screw interface, to reduce the risk of bacterial infection via the micro leakage pathway.

While the screw head 31 of abutment screw 30 may in some embodiments, have a well 32 as shown in FIGS. 5A, 5B, 5C and 6, which may assist in providing the deformable element as flange 36, in other embodiments, head 31 need not have a well. Further, the deformable element may be provided by any suitable structure, and may include the provision of an annular relief 38 above flange 36 to enhance the deformation, as shown in FIG. 8.

The screw head 31 of abutment screw 30 may in some embodiments, have a screw thread which may assist in providing the deformable element as flange 36 (not shown).

In another embodiment, as shown in a cross section view in FIG. 9A, the deformable element may be provided on the base of the head 31 by way of an annular ring 39 extending about the outer edge of the abutment screw head base 35. FIG. 9B shows a perspective view of this arrangement. As in the previous example, when abutment screw 30 is tightened into position, the deformable element in the form of annular ring 39, is deformed so as to form a seal between the abutment screw 30 and the abutment 10. FIG. 10 shows a close up view of this seal formed by the deformation of the deformable element. Again, in some cases, the abutment interior base 14 may also be slightly deformed. In the same vein, FIG. 29 shows an alternate embodiment where the deformable element is located again on the interior 14 abutment 10, and element 39 presses into the abutment 10, thereby forming a seal. In another embodiment, the deformable element in the form of the annular ring may be provided on the abutment itself. As may be seen from FIG. 10 the deformable element may be a protrusion having a triangular cross-section or semi-circular cross section extending from a generally planar surface of a component of the medical implant.

FIG. 11 shows a perspective view of abutment 10 showing abutment interior 13 providing an abutment receiving well for receiving the abutment 10, and abutment interior base 14. Without abutment screw 30, the through bore 16, into which abutment screw 30 is inserted in use, is visible. In this embodiment, the deformable element is provided by an annular ring 17 surrounding the through bore 16. FIG. 12 shows a cross section view of abutment 10 with annular ring 17 surrounding through bore 16. Again, as abutment screw 30 is inserted into through bore 16 and tightened, the base 35 (in this case providing the corresponding contact surface) of head 31 will be compressed over deformable element, in this case, annular ring 17, so as to deform it to provide a seal between abutment screw 30 and abutment 10. This again provides a barrier to bacteria entry into the micro leakage path and reduces risk of infection. In this case, the base 35 of head 31 may be planar rather than angled as in a previous example.

FIG. 13 shows a close up view of the seal so formed, showing the deformation of deformable element, in this case, annular ring 17. FIG. 30a shows an alternate embodiment where the deformable element is located on the abutment screw 30 and element 17 presses into the screw 30, thereby forming a seal.

In one example, the height of annular ring 17 is about 0.05 mm and the width of annular ring 17 is about 0.05 mm (prior to deformation). Of course, any other suitable dimensions may be used, including but not limited to about 0.01 mm to about 0.1 mm, about 0.04 mm, about 0.06 mm, about 0.03 mm and about 0.07 mm or any combination thereof.

The above embodiments have provided examples of forming the seal between the abutment screw **30** and the abutment **10**. In other embodiments and aspects, the seal may alternatively, or also, be formed between the fixture **20** and the abutment **10**, as will now be detailed.

In one embodiment of this aspect, as shown by way of example in FIG. **14**, fixture **20** is provided with an annular corner **26** on lip **25** of the abutment receiving well, which defines the fixture interior **24**. The abutment base **12** of abutment **10** is received in fixture interior **24** to be retained by tightening the abutment screw **30** as previously described. FIGS. **15**, **16** and **17** show various examples of abutment **10** configurations that may be used in this aspect.

In some exemplary embodiments of this aspect of the present invention, the fixture interior **24** of the fixture **20** has a bottom geometrical configuration, for instance a lobe shaped geometrical configuration **27**, and the protruding bottom part of the abutment **10** has a corresponding geometrical configuration **18** as illustrated in FIGS. **15**, **16** and **17**, to prevent otherwise resist against rotation between these two parts when coupled together.

The abutment **10** may have a substantially curved, conical outer surface with the upper edge having the wider diameter and the bottom, fixture-connecting part having a smaller diameter, as illustrated. A feature in these particular embodiments for the three different examples of abutments **10** illustrated in FIGS. **15**, **16** and **17** may be that the bottom tapered outer surface **12** which cooperates with the annular corner **26** of the fixture **20** when the two parts are coupled together as shown in FIG. **18**. This provides a concave outer contour of the connection between the abutment and the fixture.

In this example, the deformable element is provided by the annular corner **26**. When the abutment **10** is placed in the fixture **20** and the abutment screw **30** is tightened as previously described, the abutment base **12**, (in this case acting as the corresponding contact surface) is pressed down onto annular corner **26**, which deforms to provide a seal between abutment **10** and fixture **20**. FIG. **19** shows a close up view of the seal formed therebetween.

The deformable element may also deform upon application of other force, such as by downward pressure on abutment **10**, rather than, or in conjunction with, tightening of the abutment screw **30**.

In some embodiments, the outer surface of the abutment **10** and/or the fixture **20** might be modified in order to improve the skin tissue integration. Different types of structured or coated surfaces might be used, for instance hydroxyapatite (HA) coated surfaces. In this case it should be understood that the coating might be applied on the fixture and the abutment separately, or applied on a pre mounted implant device.

In a further embodiment of this aspect, the deformable element may be provided on the abutment **10** as shown in FIG. **30b**, which corresponds to the view of FIG. **19**, and, in some embodiments, the deformable element may be in the form of an annular ring, as depicted in FIGS. **20** and **21**. In the embodiment of FIG. **20**, the deformable element is provided by abutment annular corner **19** on the abutment base **12**. In this embodiment, the lip **25** of fixture **20** may be a more conventional rounded shape, which provides the corresponding contact surface for the deformable element, in this case, abutment annular corner **19**. As in the previous example, abutment **10** is placed in the fixture **20** and when abutment screw **30** is tightened, abutment **10** is pressed down onto fixture **20**. In this arrangement, deformable element (abutment annular corner **19**) will be deformed against the lip **25** to form a seal between the abutment **10** and the fixture **20**.

FIG. **22** is a close up view of the seal formed between the abutment **10** and the fixture **20** of FIG. **21**.

FIG. **23** shows an example of another embodiment of a medical implant system **100**, comprising abutment **10**, fixture **20** and abutment screw **30**. In this example, the system is designed so as to provide a seal between the abutment **10** and the abutment screw **30**. In this case, this seal is provided by an arrangement similar and/or the same as that described earlier with reference to FIGS. **5A**, **5B**, **5C**, **6** and **7**. With respect to the embodiment of FIG. **23**, the deformable element is provided on the abutment screw **30** in the form of an angled flange that upon tightening of abutment screw **30** (or application of other force), deforms against the corresponding contact surface (in this case abutment interior base **14**) to form the seal. FIG. **31** depicts an alternate embodiment where engagement between the abutment screw **30** and the abutment **10** is depicted, and the abutment interior base **14** of abutment **10** deforms. Specifically, flange **36** is pressed into the surface of the abutment interior base **14**, to provide a seal. As will be understood from FIG. **31**, in this alternate embodiment, the corresponding contact surface, in this case the abutment interior base **14**, may itself deform slightly to further increase the seal formed therebetween. The degree of resulting deformation of the abutment screw and/or the abutment may vary between embodiments. In some embodiments, all or substantially all of the overall deformation may occur in the abutment screw **30**, while in some embodiments, all or substantially all of the deformation may occur in the abutment **10**, while in some embodiments, the amount of deformation may be more evenly distributed between these two components.

FIG. **24** shows another embodiment of a medical implant system **100** comprising abutment **10**, fixture **20** and abutment screw **30**. In this example, the system is designed to provide a seal between abutment **10** and fixture **20**. In this case, the seal is provided by the same arrangement as described earlier with reference to FIGS. **14** to **19**. That is, that the deformable element is provided on the fixture **20** in the form of an annular corner **26** provided on the lip **25** of fixture **20**, that upon tightening of abutment screw **30** (or application of other force), deforms against the corresponding contact surface (in this case abutment base **12**) to form the seal. FIG. **32** depicts an alternate embodiment where engagement between the bone fixture **20** and the abutment **10** is depicted. The depicted deformation of the abutment **10** is a result of the annular corner **26** of lip **25** of the fixture **20** being pressed into the surface of the abutment **10**, to provide a seal. As will be understood from FIG. **32**, in this alternate embodiment, the corresponding contact surface, in this case the annular corner **26**, may itself deform slightly to further increase the seal formed therebetween. The degree of resulting deformation of the fixture **20** and/or the abutment **10** may vary between embodiments. In some embodiments, all or substantially all of the overall deformation may occur in the abutment **10**, while in some embodiments, all or substantially all of the deformation may occur in the bone fixture **20**, while in some embodiments, the amount of deformation may be more evenly distributed between these two components.

FIG. **25** shows yet another embodiment of a medical implant system **100** comprising abutment **10**, fixture **20** and abutment screw **30**. In this example, the system is designed to provide a seal between the abutment **10** and the abutment screw **30** as well as between the abutment **10** and fixture **20**. In this case, the first seal is provided by the same arrangement as described above with reference to FIG. **23**. That is, that the deformable element is provided on the abutment screw **30** in the form of an angled flange that upon tightening of abutment screw **30** (or application of other force), deforms against the

corresponding contact surface (in this case abutment interior base **14**) to form the seal. The second seal is provided by the arrangement described above with reference to FIG. **24**. That is, that the deformable element is provided on the fixture **20** in the form of an annular corner **26** provided on the lip **25** of fixture **20**, that upon tightening of abutment screw **30** (or application of other force), deforms against the corresponding contact surface (in this case abutment base **12**) to form the seal. Accordingly, the arrangement of FIG. **25** is a combination of both the arrangements of FIGS. **23** and **24**.

In yet further embodiments, any combination of any two or more of the seals previously described may be used, including two different seals provided between the abutment **10** and the abutment screw **30** as shown in FIGS. **5** to **10** as well as FIGS. **11** to **13**. By way of example, FIG. **33** depicts yet another embodiment of a medical implant system **100** comprising abutment **10**, fixture **20** and abutment screw **30**. In this example, the system is designed to provide a seal between the abutment **10** and the abutment screw **30** as well as between the abutment **10** and fixture **20**. In this case, the first seal is provided by the alternate arrangement as described above with reference to FIG. **23** and FIG. **31**. That is, that the deformable element is provided on the abutment **10** (in this case (in this case, abutment interior base **14**) such that that upon tightening of abutment screw **30** (or application of other force), the abutment **10** deforms against the corresponding contact surface of the abutment screw **30** to form the seal. The second seal is provided by the arrangement described above with reference to the alternate arrangement described above with reference to FIG. **24** and FIG. **32**. That is, that the deformable element is again provided on the abutment **10** (in this case, abutment base **12**) such that upon tightening of abutment screw **30** (or application of other force), the abutment **10** deforms against the corresponding contact surface (annular corner **26** provided on the lip **25** of fixture **20**) to form the seal. Accordingly, the arrangement of FIG. **25** is a combination of both the alternate arrangements of FIGS. **23** and **24** described above.

It will be appreciated that the various deformable elements described may be provided by any suitable means, including by turning, during or after the usual component production process.

The provision of the deformable element(s) in the various components of the medical implant system **100** provide for a unique method of implanting the medical implant system.

The steps of one possible method of implanting the medical implant system **100** are shown in FIG. **26a**. At step **200**, the abutment **10** is located in the abutment receiving well of fixture interior **24** of the already implanted fixture. At step **201**, the abutment screw **30** is inserted in the through bore **16** of the abutment **10** and into the fixture **20**. In step **202**, force is applied to the implant system until the deformable element (s) deforms to provide the seal(s) between the various components of the medical implant system, thereby reducing the risk of infection in the user or patient. In one example, the force may be applied by way of pressure on the abutment.

In another example, as shown in FIG. **26b**, the same steps **200** and **201** may be used, however, in step **202'**, the force may be applied by way of tightening the abutment screw **30**. In one example, the abutment screw is tightened using a torque of greater than about 15 Ncm, and including about 15 Ncm to about 20 Ncm, and about 20 Ncm to about 30 Ncm. In one particular example, the torque used is about 25 Ncm.

In some embodiments, the, or part of, the surfaces of one or more of the components, such as the abutment screw **30** may be coated with a friction-reducing material such as diamond

like carbon (DLC). In these embodiments, the required torque or other force will be reduced.

FIGS. **27a**, **27b** and **27c** illustrate these steps **200**, **201** and **202'**. In FIG. **27a**, the abutment **10** is located inside fixture **20**. In this example, fixture **20** has already been implanted and anchored in the bone **50** of the patient's skull, in a previous procedure and allowed to heal. This example method therefore begins with the location of the abutment **10** in fixture **20**. This is done through an opening created in the tissue **5** of the patient.

In FIG. **27b**, the abutment screw **30** is inserted into the abutment **10** and the fixture **20** and in FIG. **27c**, the abutment screw **30** is tightened using an insertion tool **40**. This tightening causes any deformable elements in the system to deform and form seals to reduce the risk of bacteria entering into the micro leakage path and thus reducing risk of infection.

The seals may be provided as previously described, between the abutment screw **30** and the abutment **10**, the abutment **10** and the fixture **20**, or both, with the locations of these discernible from the dotted lines superimposed on FIG. **27c**.

Embodiments utilizing multiple deformable elements may use different types of deformable elements/deformable elements of different geometries as detailed herein and/or variations thereof.

In view of the above, it can be seen that in at least one aspect of the invention, there is a medical implant system for attaching a hearing device to a user is provided. In one form, the medical implant system comprises a fixture, an abutment and an abutment screw for connecting the abutment to the fixture. In this aspect, there is provided on one or more of these components, a deformable element that deforms to form a seal between the one or more components of the medical implant system.

In view of the above, it can be seen that in at least one other aspect of the invention, there is an abutment for use in a medical implant system comprising a fixture, the abutment and an abutment screw. In one form, the abutment comprises a through bore for receiving the abutment screw and a deformable element that is deformed against the abutment screw when the abutment screw is inserted in the through bore and tightened.

In view of the above, it can be seen that in at least one other aspect of the invention, there is an abutment screw that comprises a head, an elongate main body and a deformable element that may be deformed between the abutment screw and an abutment to provide a seal upon inserting the abutment screw through the through bore of the abutment and tightening the abutment screw.

In view of the above, it can be seen that in at least one other aspect of the invention, there is a fixture for use in a medical implant system. The fixture comprises a main body, an abutment receiving well and a screw thread for anchoring the fixture into bone. In one form, a deformable element is provided as an annular corner of the abutment receiving well.

In view of the above, it can be seen that in at least one other aspect of the invention, there is a method of implanting a medical implant system into a user. The medical implant system comprises a fixture, an abutment and an abutment screw. The method involves locating the abutment in an abutment receiving well of the fixture, inserting the abutment screw in a through bore of the abutment and into the fixture, and applying a force to the implant. In one form, this force is provided by tightening the abutment screw until a deformable element deforms to provide a seal between one or more of the components of the implant system.

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In some embodiments, the seals formed by the embodiments detailed herein and/or variations thereof may form a hermetic seal. In some embodiments, the seal is an air tight seal.

Throughout the specification and the claims that follow, unless the context requires otherwise, the words “comprise” and “include” and variations such as “comprising” and “including” will be understood to imply the inclusion of a stated integer or group of integers, but not the exclusion of any other integer or group of integers.

It will be understood that the invention disclosed and defined in this specification extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

While various embodiments of the present technology have been described above, it should be understood that they have been presented by way of example only, and not limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the technology. For instance, features described as part of one implementation can be used on another implementation to yield a still further implementation. Thus, the breadth and scope of the present technology should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents. All patents and publications discussed herein are hereby incorporated in their entirety by reference thereto.

What is claimed is:

1. An extra-oral percutaneous prosthesis, comprising:
 - a monolithic bone fixture configured to anchor to bone of a recipient via outer threads of the bone fixture, wherein the bone fixture also includes internal threads;
 - an external removable unit of a percutaneous bone conduction device including a vibrator, wherein the external removable unit transforms sound into mechanical vibrations;
 - a monolithic abutment configured to be retainably connected to the bone fixture, wherein a distal portion of the abutment is further configured to be in direct contact with the bone fixture and a proximal portion of the abutment defines a coupling portion configured to couple with and support the external removable unit to be connected to the bone fixture, wherein the abutment comprises an inner wall and an inner bottom; and
 - a screw having a head, the screw configured be extended through the abutment, so as to bolt the abutment to the bone fixture by threading with the internal threads of the bone fixture such that the head rests on the abutment at a distance away from the bone fixture, wherein
 - at least one of the bone fixture or the abutment includes a deformable element comprising at least one of a projecting element or an annular corner configured to deform to form an anti-microbial seal between the bone fixture and the abutment establishing a seal between an interior of the prosthesis and an external environment,
 - wherein the deformable element and at least one of the bone fixture or the abutment form a monolithic structure, and is configured to deform upon threadably tightening

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of the screw, thereby pressing the abutment against the bone fixture to form the anti-microbial seal, and wherein the deformable element is configured to at least one of plastically or elastically deform against a contact surface of the other of the abutment or bone fixture.

2. The prosthesis of claim 1, wherein: the deformable element is part of the bone fixture.
3. The prosthesis of claim 2, wherein: the contact surface is a contact surface of the abutment, and the deformable element is configured to deform against the contact surface of the abutment, and the deformable element includes the annular corner and is configured such that the corner deforms against the contact surface when the contact surface is pressed against the corner while the contact surface is at an oblique angle relative to the corner.
4. The prosthesis of claim 1, wherein: the deformable element is part of the abutment.
5. The prosthesis of claim 4, wherein: the contact surface is a contact surface of the bone fixture, and the deformable element is configured to deform against the contact surface of the bone fixture, and the deformable element includes the annular corner and is configured such that the corner deforms against the contact surface when the contact surface is pressed against the corner while the contact surface is at an oblique angle relative to the corner.
6. The prosthesis of claim 1, wherein the abutment comprises an interior base surface including a plurality of openings therein spaced apart from one another.
7. The prosthesis claim 1, wherein the deformable element is configured to plastically deform to form the anti-microbial seal.
8. The prosthesis of claim 1, wherein: the deformable element deforms to compensate for surface imperfections of the contact surface to form the anti-microbial seal.
9. The prosthesis of claim 1, wherein the deformable element of the bone fixture or the abutment is configured to deform against the contact surface of the other of the bone fixture or abutment, thereby reducing at least one of gaps or holes between the deformable element and the contact surface otherwise passable therethrough by microbes to form the anti-microbial seal.
10. The prosthesis of claim 1, wherein the anti-microbial seal is an air tight seal.
11. The prosthesis of claim 1, wherein: the bone fixture includes a female portion; the abutment includes a male portion; and at least a portion of the male portion of the abutment is located in at least a portion of the female portion of the bone fixture.
12. The prosthesis of claim 1, wherein: the bone fixture includes a female portion; the abutment includes a male portion; and all portions of the bone fixture are located outside of the abutment.
13. The prosthesis of claim 1, wherein the deformable element is configured to elastically deform to form the anti-microbial seal.

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