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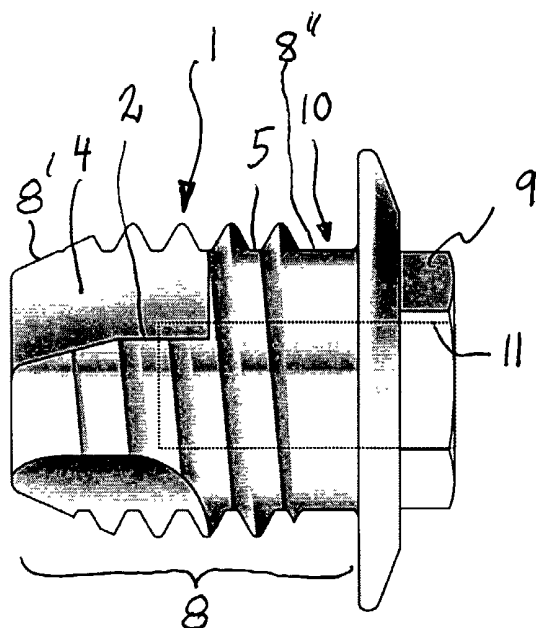
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ANCHORING ELEMENT



(57) **Abstract:** The invention relates to a screw-shaped anchoring element (fixture) (1) for permanent anchorage of hearing aid devices or ear and orbital prostheses in the skull bone. The main body (8) of the anchoring element which is intended to be inserted into the skull bone is shorter than 5 mm. The apical part of the anchoring element is self-tapping with at least one cavity (4) with a cutting edge (2). The cavity or cavities have been designed in such a way that their total volume corresponds to at least half of the bone tissue material which is cut-off by the cutting edge (2) when the anchoring element is screwed down into a hole drilled in the skull bone with a diameter corresponding to the inner diameter of the screw thread. The cavities (4) are extending along the apical, bottom half of the main body (8) of the fixture which is intended to be inserted in the skull bone and the cavities are deep enough to make room for said cut-off bone tissue material.



WO 02/09622 A1

Anchoring element

The present invention relates to a screw-shaped anchoring element (fixture) for permanent anchorage of hearing aid devices or extraoral prostheses in the form of ear and orbital prostheses in the skull bone. The invention is specifically intended to be used in connection with hearing aid devices of the bone conduction type, i.e. 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, the invention is not limited to this specific application, but can be used in connection with other types of hearing aid devices for anchorage in the skull bone and for ear or orbital prostheses which are also anchored in the skull bone.

For persons who cannot benefit from traditional, air conduction hearing aids there are other types of sound transmitting hearing aids on the market, i.e. bone anchored hearing aids which mechanically transmit the sound information to a person's inner ear via the skull bone by means of a vibrator. The hearing aid device is connected to an anchoring element in the form of an implanted titanium screw installed in the bone behind the external ear and the sound is transmitted via the skull bone to the cochlea (inner ear), i.e. the hearing aid works irrespective of a disease in the middle ear or not. The bone anchoring principle means that the skin is penetrated which makes the vibratory transmission very efficient.

This type of hearing aid device has been a revolution for the rehabilitation of patients with certain types of impaired hearing. It is very convenient for the patient and almost invisible with normal hair styles. It can easily be connected to the implanted titanium fixture by means of a bayonet coupling or a snap in coupling. One example of this type of hearing aid device is described in US Patent No. 4,498,461 and it is also referred to the BAHA® bone

anchored hearing aid marketed by Entific Medical Systems in Göteborg.

5 The fixtures which have been used so far for the bone anchored hearing aid devices of the type which have been mentioned here as well as for existing ear or orbital prostheses, have been designed in such a way that a screw tap is required to form an internal thread in the hole drilled in the skull bone. One example of such a fixture
10 is illustrated in US Des. 294,295. This fixture has an external thread with small cutting edges with only a minor scraping effect in the pre-tapped bone hole. It has also a flange which functions as a stop against the bone surface when the fixture is screwed down into the skull bone. The
15 flange is also in this case provided with through holes for bone ingrowth or the like.

It is also previously known to use so-called self-tapping fixtures for permanent anchorage of dental prostheses, dental implants, see for instance US 5,064,425 and US
20 5,269,685, which fixtures can be installed without the use of any screw taps. However, these types of fixtures which are used in the jaw-bone cannot be used for anchorage in the skull bone, which bone is much thinner than the jaw-bone. The dental implants (fixtures) are too long and they
25 have very deep, longitudinal bone cavities for collecting and retaining all the cut-off bone chips material.

One object of the present invention is to provide a screw-shaped anchoring element (fixture) adapted for anchorage
30 in the comparatively thin skull bone and which fixture is self-tapping so that no screw tapping is required and the installation can be carried out in a more simple way.

35 The invention is mainly characterized by the following features: the part of the anchoring element which is intended to be inserted in the skull bone is shorter than 5 mm, the apical portion of the anchoring element is self-tap-

ping with at least one cavity with a cutting edge and the
total volume of the cavity or cavities corresponds to at
least half of the cut-off bone tissue material when the
anchoring element is screwed down into a hole in the skull
bone with a diameter corresponding to the inner diameter
of the screw thread.

According to a preferred embodiment the cavities have a
total volume which corresponds to 50-100% of the cut-off
bone volume.

In the following the invention will be described more in
detail in connection with the accompanying drawings, in
which

figure 1 is a side view of a self-tapping anchoring ele-
ment according to the invention, and

figure 2 is an end view of the apical portion of the an-
choring element.

Figure 1 illustrates a screw-shaped anchoring element, a
so-called fixture 1, according to the invention. The fix-
ture is made of titanium which has a known ability to in-
tegrate into surrounding bone tissue, so-called osseointe-
gration. The fixture has a main body 8 which is intended
to be installed into the skull bone, a flange 7 which
functions as a stop when the fixture is installed into the
skull bone and a tool engaging socket 9 in the form of an
external hex. The main body 8 is shorter than 5 mm, in or-
der not to go completely through the thin skull bone, and
it has a tapered apical portion 8' and a straight, gene-
rally cylindrical portion 8'' with external threads. The
screw thread diameter of the main body 8 is about 3,5 -
4,0 mm.

The apical part of the main body 8 is fitted with in this
case three self-tapping cutting edges 2 with a cutting

angle 3 of 100° or less formed by cavities 4 made in the main body material.

5 The cavities are designed in such a way that the total volume of the cavities 4 corresponds to at least half of the bone chips volume which is cut-off when the anchoring element is screwed down into a bore drilled in the bone which bore has a diameter corresponding to the inner diameter 5 of the screw thread. Preferably the cavities have a total
10 volume which corresponds to 50-100% of the cut-off bone chips volume.

As illustrated in the figure the cavities 4 are not extending all the way along the cylindrical portion 8 of the
15 main body, they are only extending along the bottom or apical half of the cylindrical portion so that a couple of full screw threads are remained above the cavities which is important for the initial stability of the fixture. The cavities are made only deep enough so that there is sufficient place for the above-mentioned cut-off bone chips volume in the cavities.
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That part of the screw body which follows behind the self-tapping cutting edge 2 when the screw is installed in the
25 bone can be provided with a clearance or relief surface 6. This design has two effects. First any squeezing effect between the screw and the bone during installation of the screw is reduced. And second, more volume for the cut-off bone chips is created.

30 The flange 7 has a planar bottom surface for resting against the outer bone surface when the screw has been screwed down into the skull bone. The flange has a diameter which exceeds the peak diameter of the threads with
35 10-20 %. Extending between the flange 7 and the threaded part of the main body there is an unthreaded cylindrical part 10 having a diameter which corresponds to the inner diameter of the threads.

The fixture has an inner bore 11 with an internal screw thread for connecting an hearing aid device or any orbital or ear prosthesis. In order to achieve a stable connection
5 the inner bore is extending through the external hex 9 and all the way down into the bottom half of the cylindrical portion 8'' with the cavities.

The invention is not limited to the embodiment illustrated
10 in the drawing but can be varied within the scope of the accompanying claims. Specifically, it should be understood that the main body 8 which is intended to be inserted in the skull bone could be slightly tapered along its length. Furthermore, the screw may be designed with an internal
15 tool engaging socket instead of an external one which has been illustrated in the drawing.

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CLAIMS

1. Screw-shaped anchoring element (fixture) (1) for permanent anchorage of hearing aid devices or ear and eye prostheses in the skull bone comprising a main body (8) with external threads and intended to be inserted into the skull bone, a flange (7) which provides a stop for the anchoring element when it is screwed down into the comparatively thin skull bone and a tool engaging socket (9),
5 characterized in that said main body is shorter than 5 mm, that the apical part of the anchoring element is self-tapping with at least one cavity (4) with a cutting edge (2), that the cavity or cavities have been designed in such a way that their total volume corresponds
10 to at least half of the bone tissue material which have been cut-off by the cutting edge (2) when the anchoring element is screwed down into a hole in the skull bone with a diameter corresponding to the inner diameter of the screw thread and that the flange (7) has a substantially
15 planar bottom surface for resting against the bone when the anchoring element has reached its final screwed-down position.
2. Anchoring element according to claim 1 characterized in that the cavity or cavities (4) have a
25 total volume which corresponds to 50-100% of the cut-off bone volume.
3. Anchoring element according to claim 1 characterized in that the flange (7) has a diameter
30 which exceeds the peak diameter of the external screw thread of the main body with about 10-20 %.
4. Anchoring element according to claim 1 characterized in that the self-tapping edges (2) have a
35 maximal cutting angle of about 100°.
5. Anchoring element according to claim 1 characterized in that

terized in that the self-tapping edges (2) have a relief surface (6).

5 6. Anchoring element according to claim 1 characterized in that the main body (8) which is intended to be inserted into the skull bone has an apical, tapered portion (8') as well as a straight, substantially cylindrical portion (8'') along its length provided with said external threads.

10 7. Anchoring element according to claim 1 characterized in that the main body (8) which is intended to be inserted into the skull bone has an apical portion (8') with a first tapering as well as a second, slightly tapered portion (8'') along the rest of its length and provided with said external threads.

20 8. Anchoring element according to claim 1 characterized in that the main body (8) has a straight, cylindrical, unthreaded portion (10) next to the planar, bottom surface of the flange (7) with a diameter corresponding to the inner diameter of the screw threads.

25 9. Anchoring element according to claim 1 characterized in that the cavities (4) are arranged on the bottom half of the main body (8) intended to be inserted into the skull bone and being deep enough for said bone volume.

30 10. Anchoring element according to claim 9 characterized by an inner bore (11) extending all the way down into the bottom half of the main body (8) where the cavities (4) are arranged.

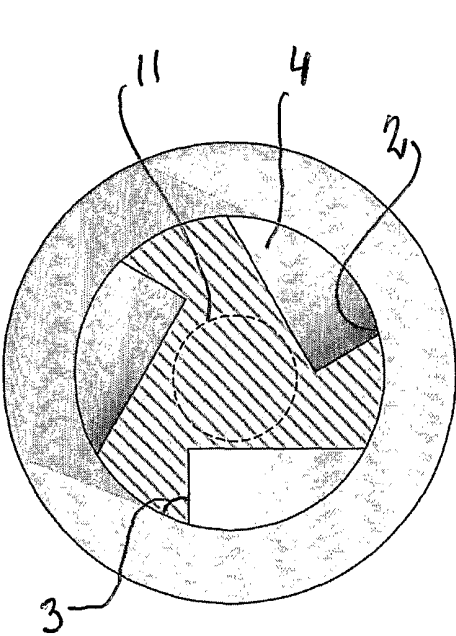


FIG. 2

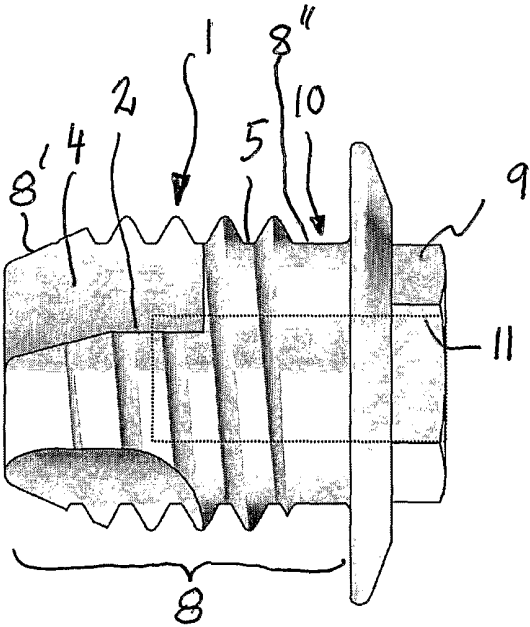


FIG. 1

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International application No.

PCT/SE 01/01506

A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

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

EPODOC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	FR 2723837 A1 (SOFAMOR DANEK GROUP INC), 1 March 1996 (01.03.96), figure 1, abstract --	1-10
A	US 5593410 A (GIUSEPPE VRESPIA), 14 January 1997 (14.01.97), figures 3-8, abstract --	1-10

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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International application No.

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