

**(19) AUSTRALIAN PATENT OFFICE**

(54) Title  
Acetabular implant and method for the production of said implant

(51)<sup>6</sup> International Patent Classification(s)  
**A61F** 2/00 (2006.01) 20060101ALI2005100  
**A61F** 2/30 (2006.01) 8BMEP **A61F**  
**A61F** 2/34 (2006.01) 2/34  
**A61F** 2/46 (2006.01) 20060101ALI2005100  
A61F 2/00 8BMEP **A61F**  
20060101AFN200510 2/46  
08BMEP **A61F** 20060101ALN200510  
2/30 08BMEP  
PCT/FR2004/002045

(21) Application No: 2004260856 (22) Application Date: 2004 .07 .29

(87) WIPO No: W005/011537

(30) Priority Data

(31) Number	(32) Date	(33) Country
0309405	2003 .07 .30	FR

(43) Publication Date : 2005 .02 .10

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(56) Related Art  
US 5505736  
US 4883491  
WO 1995/017140

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION  
EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété  
Intellectuelle  
Bureau international



(43) Date de la publication internationale  
10 février 2005 (10.02.2005)

PCT

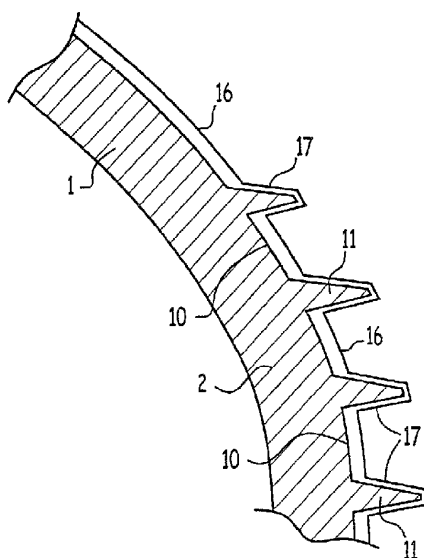
(10) Numéro de publication internationale  
WO 2005/011537 A3

- (51) Classification Internationale des brevets<sup>7</sup> : A61F 2/34, 2/30 (26) Langue de publication : français
- (21) Numéro de la demande internationale : PCT/FR2004/002045 (30) Données relatives à la priorité : 0309405 30 juillet 2003 (30.07.2003) FR
- (22) Date de dépôt international : 29 juillet 2004 (29.07.2004) (71) Déposant (pour tous les États désignés sauf US) : DEPUY (IRELAND) LIMITED [IE/IE]; Loughbeg, County Cork, Ringaskiddy (IE).
- (25) Langue de dépôt : français

[Suite sur la page suivante]

(54) Title: ACETABULAR IMPLANT AND METHOD FOR THE PRODUCTION OF SAID IMPLANT

(54) Titre : IMPLANT ACETABULAIRE ET PROCÉDE DE FABRICATION DE CET IMPLANT



(57) Abstract: A cotyloid implant comprising a screwable cup receiving an articular insert. The cup is provided with screwing means (11) on the periphery thereof and more particularly in the equatorial area (2) thereof, said means being used to penetrate the bone material of the acetabular cup during screwing. The cup includes an osteointegration-facilitating coating such as a selective calcium hydroxyapatite coating. The invention is characterized in that the coating (16) is a thick coating on the convex parts of the outer surface of the cup, including areas or valleys or hollow thread elements which are left free in the screwing means. The coating is not as thick (17) or is even absent on raised areas or screw thread areas.

(57) Abrégé : Implant cotyloïdien du type comprenant une cupule à visser recevant un insert articulaire, ladite cupule présente à sa périphérie, et notamment dans sa zone équatoriale (2) des moyens de vissage (11) destinés à pénétrer dans la matière osseuse du cotyle lors du vissage, ladite cupule porte un revêtement facilitant l'ostéointégration, tel que, notamment, un revêtement d'hydroxyapatite de calcium sélectif, caractérisé en ce que le revêtement (16) est de type épais sur les parties convexes de la surface externe de la cupule, y compris dans les zones ou vallées ou creux de filets laissés libres dans les moyens de vissage, tandis que ce revêtement présente une épaisseur inférieure

(17), ou est même absent, sur les reliefs ou filets de vissage.

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**(81) États désignés (sauf indication contraire, pour tout titre de protection nationale disponible) :** AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB,

GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

**(84) États désignés (sauf indication contraire, pour tout titre de protection régionale disponible) :** ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Publiée :**

- avec rapport de recherche internationale
- avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues

**(88) Date de publication du rapport de recherche internationale:** 14 juillet 2005

*En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.*

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Acetabular implant and method for the production of said  
implant

The present invention relates to an acetabular implant, that is to say, the component intended to be implanted in the acetabulum, within the context of a hip prosthesis. The invention also relates to a method for producing that implant.

Acetabular implants generally comprise a small cup which is intended to be introduced and secured in the acetabulum of the hip joint and an insert, in a fixed or movable state in the cup, which forms the seat of the joint of the prosthetic femoral head. The cups which are generally composed of a biocompatible metal, such as titanium, can be secured in the cotyloid cavity using cements. When securing without any cement is selected, it is necessary to bring about primary securing of the cup in the cotyloid cavity, that securing optionally being supplemented, in particular in the case of replacement of the prosthesis, by auxiliary means, such as screws, hooks or closing tabs.

However, there must then be obtained secondary securing by osteointegration, by means of healing osteogenesis, which will prolong the stability of the implant in the bone site of the acetabulum, with remodelling under permanent stress.

The primary mechanical securing can be brought about either by impaction, using, as necessary, cups having a surface effect in order to obtain adjustment by means of pressure, or by a screwing action, the cups then being provided with means, such as threads, allowing a screwing action in the acetabular bone. Efforts are made to facilitate that osteointegration either by roughening the surface of the

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cup, for example, with the action of sand or corundum, or by covering the cup with a compatible coating with an osteointegrating effect which is generally a calcium hydroxyapatite ceramic material.

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According to a first aspect of the present invention, there is provided acetabular implant comprising a screw-type cup which receives an articular insert, the cup having, in a tropical/equatorial zone of a periphery thereof, screwing  
10 means which are configured to be introduced into the bone material of the acetabulum during the screwing action, the cup carrying a coating which facilitates osteointegration, the coating being of the thick type on convex portions of the outer surface of the cup, including in the zones or  
15 troughs or recesses of threads that are left free in the screwing means, and having a lesser thickness, or even being absent, on the screw reliefs or threads.

Coating of a thick type is intended to refer to a  
20 conventional coating thickness, as is generally known on coated cups or other prostheses which are coated with a layer of an osteointegrating coating. In the case of calcium hydroxyapatite, that thickness of a coating of a thick type is preferably in the order of from 100 to 200  
25 micrometres, in particular advantageously in the order of  $150 \pm 35$  micrometres, those indications not being limiting and being dependent on the type and quality of the osteointegrating coating.

30 It will be understood that this thickness may be as high as the entire value allowed in a stable intra-osseous implantation position, which is mainly subjected to

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compression loads.

The screw reliefs, such as threads, may then either have no coating at all or, preferably, have a thinner coating which  
5 may advantageously, in the case of hydroxyapatite, be in the order of  $50 \pm 30$  micrometres.

There can thus be provided important osteointegration characteristics in the region of the thick coating layer on  
10 the convex portions of the cup, including between the threads, with the coating layer scarcely being subjected to any shearing forces during the screwing of the cup and contact being brought about without any traumatism at the end of the screwing action, when locking is brought about in  
15 the cotyloid cavity.

On the sides of threads or reliefs, the lesser thickness of the coating can improve the shearing strength of that coating and therefore reduce the risks of delamination  
20 during the screwing action, whilst at the same time bringing about excellent mechanical engagement and also allowing improved osteointegration owing to the presence of the coating.

25 Should hydroxyapatite not be provided on the threads, the sides of threads are advantageously roughened with the action of sand or corundum, also improving contact osteogenesis.

30 In a particularly preferred embodiment of the invention, the screwing means, such as threads, is arranged in order to traumatize as little as possible the acetabular zone in

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which the threads are introduced, and in order to have a maximum convex surface-area, that is to say, troughs between the sides of threads in order to facilitate, in this region, osteointegration by contact osteogenesis and remodelling  
5 under stress.

In accordance with that embodiment, the screw relief may be arranged in order to apply a self-tapping cutting effect during the screwing action and an effect involving  
10 compression of the sponge-like bone.

In a particularly preferred embodiment, threads which are arranged on the tropical/equatorial zone of the cup, have a narrow cross-section in order to leave a maximum surface-  
15 area between two crests of consecutive threads, the proportion of the thickness of a thread relative to the corresponding pitch preferably being from 0.2 to 0.5.

Preferably, the cross-section of the threads is asymmetrical  
20 in a diametral plane, with a smaller angle, for example, in the order of from 5 to 10° at the polar side of the thread, that is to say, a thread near the horizontal, in order to act counter to the introduction, and a greater angle, for example, in the order of from 15 to 20° at the equatorial  
25 side, in order to bring about a good compression effect when the bone which receives the threading is placed under stress.

Also in an advantageous embodiment, the crests of threads  
30 are relieved, with a leading edge which is radially higher than the remainder of the crest, whose radial height preferably decreases in a progressive manner towards the

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rear of the thread.

Preferably, the leading edge is itself inclined, by being formed by a milling pass which is strongly inclined in a biased manner relative to the inclination of the threading itself, the leading edge itself preferably being orientated aggressively forwards relative to the radial.

The pitch of the threading may, advantageously, be regular in order to bring about a single bone groove, in which successive threads are introduced during the screwing rotation.

Preferably, the height of the threads, or more precisely the orientation of the crests, in the entirety of the zone, is constant, it being understood that, when a replacement cup is involved, that height will be greater in order to allow screwing into a more irregular cotyloid cavity, with bone of lesser quality.

Preferably, the cup also has completely spherical convexity, including between the successive reliefs, thereby allowing excellent adaptation against the bottom of a cotyloid cavity obtained after milling, when the cup arrives at the end of the screwing action.

In a very advantageous embodiment of the invention, it is possible to use, for example, a form of threading such as that described in patent applications EP-A-0887052 and DE-A-19727846, in particular in Figures 9 to 14 of EP 98250211, the drawings and the description of that application being incorporated herein by reference.



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According to a second aspect of the present invention, there is provided a method for producing the implant cups as described above, wherein a cup is produced having a threading in an equatorial zone thereof, the outer surface of the cup is processed in order to roughen it and a coating of osteointegrating material is positioned on that cup surface, wherein the step for coating with osteointegrating material is carried out so as to bring about a thick deposit on the convex surfaces of the cup, including the troughs which separate the adjacent threads and with the coating with that material on the sides and edges of the threads being reduced or omitted.

Preferably, the roughening is effected with the action of sand or corundum.

In the conventional case, in which a plasma-type torch is used in order to project and secure, on the rough surface of the cup, the material which is intended to form that coating, it is advantageously possible to reduce the thickness of the deposit forming the coating on the threads by temporarily modifying the angle of inclination of the torch and/or by modifying the relative travel speed between the torch and the cup.

According to a third aspect of the present invention, there is provided a method for producing implant cups, comprising the following steps:

- the number of cups which are or are not coated with a coating of osteointegrating material to be produced is established beforehand;
- the non-coated cups are produced and they are subjected to

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a processing operation which is intended to roughen the surface thereof;

- in the overall production established in this manner, the proportion of cups which are intended to receive the coating is established;
- the coating of that cup is carried out in accordance with either claim 14 or claim 15;
- all the cups are packaged and sterilized in order to be contained in individual sterile packagings, the packagings having different markings in order to distinguish the coated cups from the non-coated cups.

The total number of cups to be produced may be established in conventional manner, either by forecasting or by centralizing the orders, or both.

Preferably, establishing the proportion of cups to be coated in relation to the cups which are not coated is carried out during the production operation and, if necessary, modified in accordance with the progress of events.

Those operations can be carried out using data-processing means which may optionally intervene in the control of the production means.

Preferred embodiments of the present invention provide improved screw-type cups which are coated with an osteointegrating material, such as a hydroxyapatite ceramic material.

In particular, preferred embodiments of the invention facilitate the primary securing by means of screwing and

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adjustment of those cups and improves, after initial stabilisation, the secondary securing by means of osteointegration, involving true healing osteogenesis which will prolong the stability of the implant in a bone site,  
5 with permanent remodelling.

Preferred embodiments of the present invention also reduce the degree of bone traumatism during securing by means of screwing.

10

Finally, preferred embodiments of the present invention reduce or obviate the risks of splinters being formed from the coating.

15 Other advantages and features of the invention will be appreciated from a reading of the following description which is given by way of non-limiting example with reference to the appended drawings, in which:

Figure 1 is a perspective view of an implant cup according  
20 to a preferred embodiment of the invention,

Figure 2 is an elevation of that cup,

Figure 3 is a bottom view of that cup,

Figure 4 is a top view of the cup,

Figure 5 is an axially sectioned view of the cup,

25 Figure 6 is a section taken along line B-B of Figure 2,

Figure 7 is a radially sectioned view, from Figure 5, of a detail, drawn to an enlarged scale in the region of the threading,

Figure 8 is a schematic view illustrating the zones having a  
30 thick coating and the zones having a thin coating of calcium hydroxyapatite.

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The cup illustrated is generally in the form of a hemispherical member having a polar outer surface 1 without any relief and an outer inter-tropical/equatorial zone 2 having the threading. A polar hole 3, which is generally  
5 used for the auxiliary positioning members, is provided at the very pole of the cup.

With reference most particularly to Figure 2, it is apparent that the equatorial zone carrying the screwing means extends  
10 with little spacing from the base 4 of the cup and that that equatorial zone is itself divided into a plurality of zone segments 5 by helical millings 6 over the sphere, which are

intended to form the self-tapping leading edges of the threads of the threading of the zone 2.

In the majority of the Figures, the individual threads are not illustrated, but they can clearly be seen in Figures 1, 5, 7 as can the most equatorial threads in Figure 6.

In the example illustrated, the threading forms a single spherical helix, that is to say, a helix which is formed at the surface of the sphere of the cup and which has a constant pitch  $P$  which is defined at the axis of revolution and which extends through the pole of the cup. The threads themselves have a constant inclination relative to that axis. More precisely, as can be seen in Figure 7, the polar sides 7 have an inclination which is less than that of the equatorial sides 8, the inclination of the polar sides being from 5 to 10° and that of the equatorial sides being from 15 to 20°, relative to the radial plane which is perpendicular to the polar axis. The thread tops or crests are slightly chamfered. Finally, it is apparent that the grooves or thread bottoms 10 have a width which is greater than that of the base of the threads, in order to provide a maximum spherical convex surface-area between the threads.

The form of the individual threads 11 is more clearly visible in Figure 6. Each thread 11 extends between two successive millings 6 and has in particular the following features.

The leading tooth is defined by the milled groove 6, the milling being such that the edge of the tooth extends inwards and towards the rear in order to form a cutting edge that is inclined with an aggressive tip 13, the edge forming, with the tangent relative to the tip 13, an angle

of less than 90°. It will further be appreciated that, since the milling pass 6 is inclined, as is visible in Figures 1 and 2, the cutting face of the tooth, which extends upwards in a polar direction from the edge 12, is directed in a polar direction in order to form a cutting face located in a plane which is not perpendicular to the plane of Figure 6.

The radial height of the crest 14 of the thread 11 diminishes progressively from the tip 13 towards the end 15 of the edge, as is clearly visible in Figure 6, so that the crest 14 forms a relief which is progressively recessed relative to the groove bottom which is tapped by the tip 13 in the acetabular bone.

By means of those features, it is possible both to obtain an excellent clean cut which defines the grooves and to reduce the friction forces during the self-tapping screwing action, whilst the continuation of the screwing action, owing to the inclinations of the sides of threads, brings about the desirable compression effort on the bone which is received between the threads.

Once the cup has been produced and the threads machined in accordance with the above-mentioned feature, the cup is subjected to surface processing by the action of corundum, the whole of the surface of the cup, including the threads, thus receiving the desired degree of roughness which can be defined as follows: RT 25 micrometres minimum.

Subsequently, there is carried out, by means of a plasma torch, the projection of powdered calcium hydroxyapatite onto the outer surface of the cup. The formation of a calcium hydroxyapatite coating by this means is well known in the art and does not need to be described in greater

detail. For example, a torch of the plasma torch type will be used at a distance of 100 mm from the surface, with a projection flow rate for calcium hydroxyapatite of 10g/min and a relative displacement speed of the torch relative to the surface of 30 mm/s. For example, the torch follows a variable and optimized inclination.

In accordance with the invention, a thick coating of hydroxyapatite having a substantially constant thickness which is advantageously 150 micrometres is produced over the entire spherical surface of the cup, that is to say, not only the polar zone 1, but also the threaded equatorial zone 2, that is to say, the troughs or thread bottoms 10. Figure 8 schematically illustrates, by means of the line 16, this coating, that indication being, in its spherical portion, displaced in a homothetic manner relative to the surface of the spherical portion of the cup. The hydroxyapatite projection operation is, however, carried out in the region of the threads 11 so as to produce only a thin coating of 50 micrometres, represented by the line 17, which is also displaced relative to the actual surface of the cup. It is apparent in particular that that thin coating covers both the equatorial and polar faces and the crests of the threads 11.

For example, that thinner coating may be brought about by modifying the above-described parameters.

It is optionally possible, owing to the inclination of the torches, to bring about only a very thin coating, or even a practically non-existent coating, of the thread cutting face which extends from the front cutting edge 12.

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In this manner, it is possible to bring about very thick calcium hydroxyapatite coatings over the spherical convex zones which interact mechanically with the sponge-like subchondral bone, which is exposed completely by the hemispherical milling of the cotyloid cavity only towards the end of the screwing action, whereas, owing to the small thickness of hydroxyapatite on the threads themselves, the screwing torque is particularly reduced and, as a result, the damage to the subchondral bone is also reduced in direct contact with the threads, that conservation action being further increased by the provided shape of the threads which are thin and which have an upper relieved edge and an extremely sharp cutting edge.

The risk of the hydroxyapatite coating becoming detached or delaminating is also reduced, in particular in the region of the teeth, where the layer is subjected to the greatest effort, the thin layer being far more coherent, adhesively bonding better to the subjacent metal surface which has been acted upon with corundum.

The cup, once in position, can receive any type of articular insert, for example, composed of polyethylene, aluminium or metal.

During the operation for producing a plurality of cups in accordance with a preferred embodiment of the invention, it is advantageously possible to make provision for simultaneous production of the cups which are intended to receive the coating according to the invention and non-coated cups, as required, and to adjust, permanently, if desirable, the proportion between coated cups and non-coated



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cups, by directing towards the hydroxyapatite coating station a larger or smaller number of cups, the sterile packaging operations then being controlled in accordance with that proportion.

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Many modifications will be apparent to those skilled in the art without departing from the scope of the present invention.

10 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of  
15 any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment  
20 or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

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CLAIMS

1. Acetabular implant comprising a screw-type cup which receives an articular insert, the cup having, in a tropical/equatorial zone of a periphery thereof, screwing means configured to be introduced into the bone material of the acetabulum during the screwing action, the cup carrying a coating which facilitates osteointegration, the coating being of the thick type on convex portions of the outer surface of the cup, including in the zones or troughs or recesses of threads that are left free in the screwing means, and having a lesser thickness, or even being absent, on the screw reliefs or threads.
2. Implant according to claim 1, wherein the thickness of the coating of the thick type is from 100 to 200 micrometres.
3. Implant according to claim 2, wherein the coating thickness is in the order of  $150 \pm 35$  micrometres.
4. Implant according to any one of claims 1 to 3, wherein the screw reliefs have a coating in the order of  $50 \pm 30$  micrometres.
5. Implant according to any one of claims 1 to 3, wherein the screw reliefs do not have any coating and have a rough surface.
6. Implant according to any one of claims 1 to 5, wherein the screwing means is arranged in order to traumatize as little as possible the acetabular bone site, in which the

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threads are introduced, and in order to have a maximum convex surface-area, that is to say, troughs between the sides of threads in order to facilitate, in this region, osteointegration by contact osteogenesis and remodelling  
5 under stress, the screw relief being arranged in order to apply a self-tapping cutting effect during the screwing action and an effect involving compression of the sponge-like bone.

10 7. Implant according to claim 6, wherein, in a thread pitch, the proportion of the thread width, in the region of the trough, relative to the pitch, is from 0.2 to 0.5.

8. Implant according to any one of claims 1 to 7, wherein  
15 the cross-section of the threads is asymmetrical in a diametral plane, with a smaller angle in the order of from 5 to 10° at the polar side of the thread, and a greater angle in the order of from 15 to 20° at the equatorial side, in order to bring about a good compression effect when the bone  
20 which receives the threading is placed under stress.

9. Implant according to any one of claims 1 to 8, wherein the crests of threads are relieved, with a leading edge which is radially higher than the remainder of the crest,  
25 whose radial height decreases towards the rear of the thread.

10. Implant according to any one of claims 1 to 99, wherein the leading edge is itself inclined, by being formed by a  
30 milling pass which is strongly inclined in a biased manner relative to the inclination of the threading itself, the leading edge itself being orientated aggressively forwards

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relative to the radial.

11. Implant according to any one of claims 1 to 10, wherein the threading pitch is regular in order to bring about a  
5 single bone groove, in which successive threads are introduced during the screwing rotation.

12. Implant according to any one of claims 1 to 11, wherein the screwing means has a threading formed by zones of  
10 threads which are separated by inclined grooves defining the cutting edges.

13. Implant according to any one of claims 1 to 12, wherein the screwing means has a spherical threading of constant  
15 pitch.

14. Method for producing the implant cups according to any one of claims 1 to 13, wherein a cup is produced having a  
20 threading in an equatorial zone thereof, the outer surface of the cup is processed in order to roughen it and a coating of osteointegrating material is positioned on that cup surface, wherein the step for coating with osteointegrating  
25 material is carried out so as to bring about a thick deposit on the convex surfaces of the cup, including the troughs which separate the adjacent threads and with the coating with that material on the sides and edges of the threads being reduced or omitted.

15. Method according to claim 14, wherein a torch of the  
30 plasma type is used in order to project and secure, on the rough surface of the cup, the material which is intended to form that coating and the thickness of the deposit which

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forms the coating on the threads is reduced by temporarily modifying the angle of inclination of the torch and/or by modifying the relative travel speed between the torch and the cup, and/or by temporarily modifying the flow-rate of powdered calcium hydroxyapatite.

16. Method for producing implant cups, comprising the following steps:

- the number of cups which are or are not coated with a coating of osteointegrating material to be produced is established beforehand;
- the non-coated cups are produced and they are subjected to a processing operation which is intended to roughen the surface thereof;
- in the overall production established in this manner, the proportion of cups which are intended to receive the coating is established;
- the coating of that cup is carried out in accordance with either claim 14 or claim 15;
- all the cups are packaged and sterilized in order to be contained in individual sterile packagings, the packagings having different markings in order to distinguish the coated cups from the non-coated cups.

17. Implant according to any one of claims 1 to 13 or method according to any one of claims 14 to 16, wherein the coating comprises a selective calcium hydroxyapatite coating.

18. Implant according to any one of claims 1 to 13 or method according to any one of claims 14 to 17, wherein the cup is produced from titanium alloy.

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19. Acetabular implant substantially as hereinbefore described with reference to the drawings and/or Examples.

20. Method for producing implant cups substantially as  
5 hereinbefore described with reference to the drawings and/or Examples.

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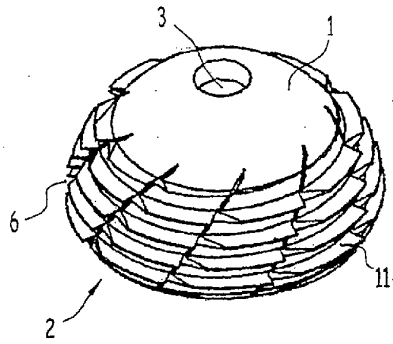


FIG.1

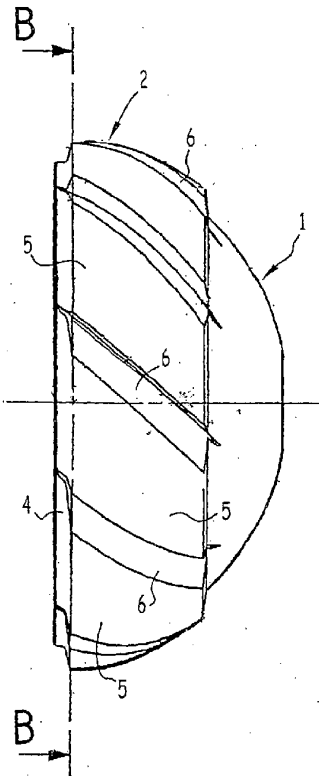


FIG.2

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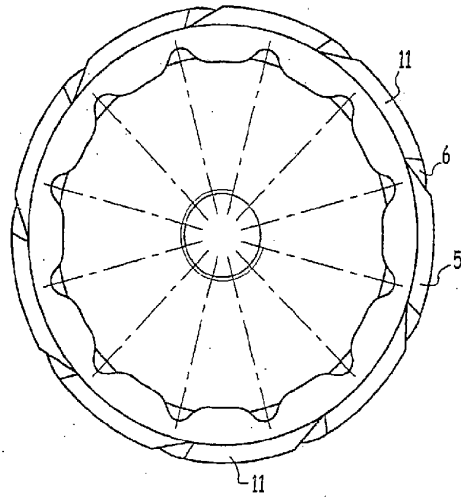


FIG. 3

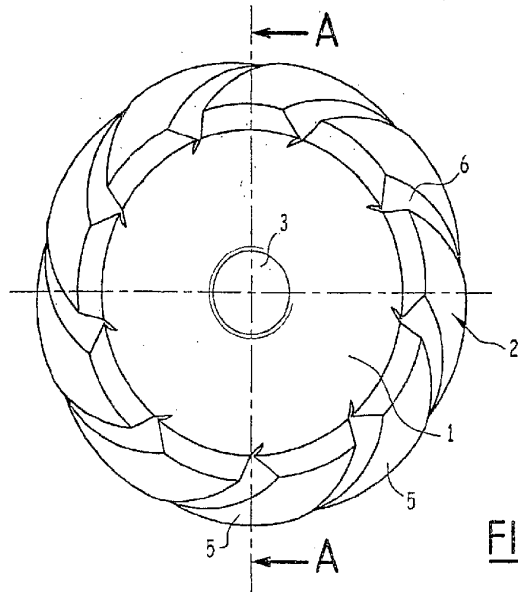


FIG. 4



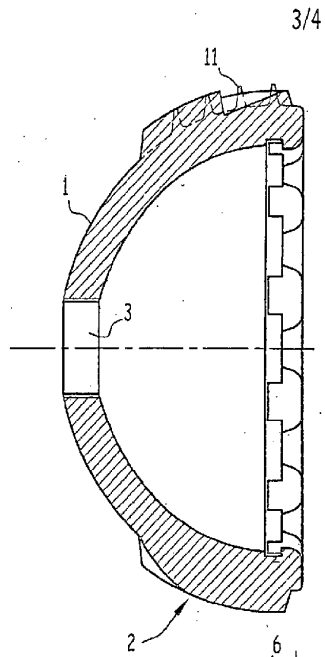


FIG.5

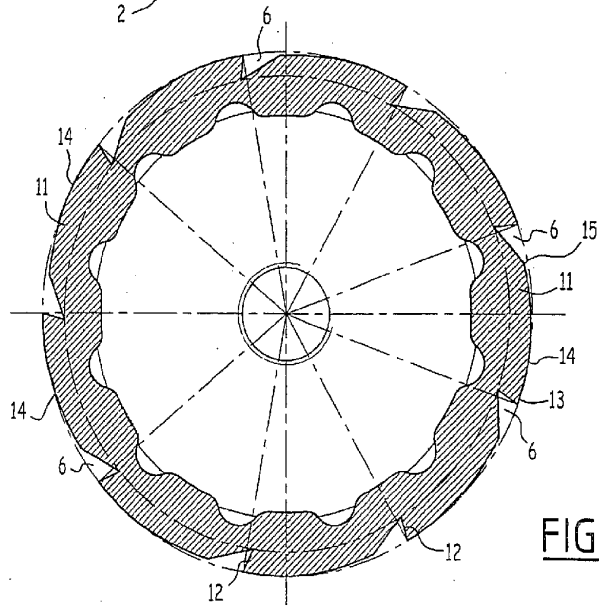


FIG.6

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FIG.7

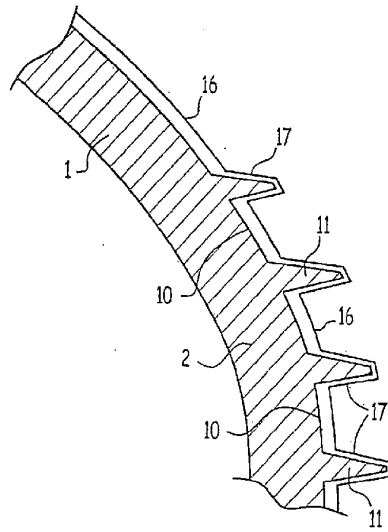
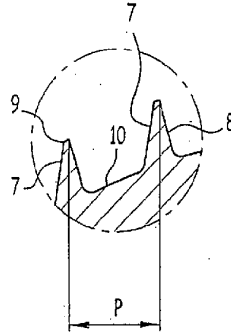


FIG.8