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(54) Title: ACETABULAR CUP

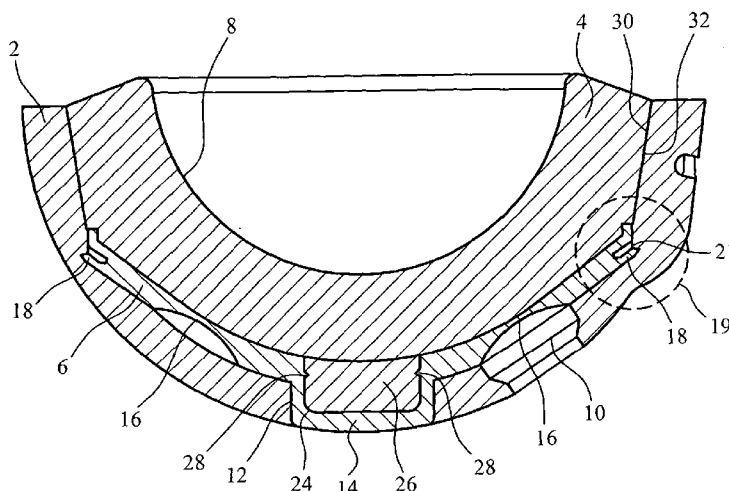


FIG. 1

(57) Abstract: A cup and method for implanting in a patient's body coupled to the surface of a bone are described. The cup comprises a shell (2) defining a recess including at least one screw hole (10) in the wall of the shell arranged to receive a screw passing into a bone to secure the shell to the surface of the bone. A plate (6) is arranged to be received in the shell recess. A liner (8) is arranged to be received within the shell recess such that the plate is positioned between the shell and the liner. The liner defines an interior concave articulating surface. The plate is arranged to separate the at least one screw hole from the liner, to prevent worn material from migrating from the inside of the shell through the screw hole into the bone.

ACETABULAR CUP

The present invention relates to a surgically implantable cup. In particular, the invention relates to a cup for implanting into a patient's body secured to the surface of a bone to form part of a prosthetic joint. An embodiment of the present invention relates to an acetabular cup for implanting into the acetabulum of a patient.

The acetabular cup component of a hip joint prosthesis typically comprises a part-spherical shell which can be implanted in a hole or recess prepared in the patient's acetabulum. Generally the shell is formed from a metal. A liner component may be fitted to the shell to provide articulating contact with a convex femoral head implant. The liner is typically formed from a polymeric material.

The cup is typically provided with at least one screw hole in the wall of the shell to receive a screw passing into the bone to secure the shell to the bone. As the cup wears due to articulating contact with a femoral head implant, small amounts of worn material may accumulate within the shell or the liner. Additionally, slight movement between the shell and the liner may also generate debris. If that debris passes through a screw hole to the interface region between the shell and the bone this can cause irritation and reduce the strength of the implant and cause bone lucency. If multiple screw holes are provided in the shell to allow flexibility for the surgeon to select screw holes according to clinical indications then it may be necessary to provide hole blanks to seal the unused holes to prevent debris passing through.

Repeated loading and unloading of a conventional implanted hip joint comprising a shell and a liner may generate a pumping pressure between the shell and the liner caused by slight movement between the shell and the liner. The liner may then move within the shell and act as a piston in a hydraulic cylinder generating a variable pressure between the shell and the liner. It is difficult to design a liner and shell system to fit together sufficiently so as to prevent this movement. The pumping pressure can exacerbate the flow of debris within the shell through screw holes to the interface between the shell and the bone. Additionally, or alternatively, fluid within the shell is in hydraulic communication with the

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tissue behind the shell through the screw holes. Cyclic pumping pressure of that fluid may be a cause of bone resorption. Further, the head of a screw within a shell screw hole typically does not form a sufficiently good seal to prevent the flow of debris through the screw hole. Shortly after implantation bone screws typically slightly loosen during settling
5 of the implant, again reducing the seal to the shell wall. Where screw-in or taper fit hole blanks are used to close off unused screw holes, these may also not provide a sufficiently good seal to prevent the flow of debris through the screw hole.

It is an object of certain embodiments of the present invention to obviate or mitigate one or
10 more of the problems associated with the prior art, whether identified herein or elsewhere.

According to a first aspect of the present invention there is provided a cup for implanting in a patient's body coupled to the surface of a bone, the cup comprising: a shell defining a recess including at least one screw hole in the wall of the shell arranged to receive a screw
15 passing into a bone to secure the shell to the surface of the bone; a plate arranged to be received in the shell recess; and a liner arranged to be received within the shell recess such that the plate is positioned between the shell and the liner, the liner defining an interior concave articulating surface; wherein the plate is arranged to separate the at least one screw hole from the liner.

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An advantage of the present invention is that because the plate seals to the shell such that the screw holes are separate from the liner, the risk of debris from the liner or a femoral head implant passing through a screw hole to the interface region between the shell and the bone is reduced. If there are unused screw holes, it is no longer necessary to provide hole
25 blanks. Additionally, a hole blank is not required to seal an apical hole within the shell used to couple to an inserter instrument when inserting the shell into a bone cavity. No longer requiring hole blanks at least partially offsets the cost of the plate. Additionally, inserting hole blanks into unused screw holes is difficult to do once the shell is implanted. Consequently, the plate may reduce the amount of time required to implant a cup. The
30 liner and the plate may be coupled together before being delivered to the surgeon so that there is no additional surgical step required.

A further advantage of the present invention is that in the event that the cup sinks into the bone the screw heads will not penetrate into the liner, which is a known cause of implanted cup failure.

- 5 In preferred embodiments of the invention the configuration of the shell, plate and liner reduces movement and fretting within the cup, thereby reducing the amount of debris at risk of working its way through to the interface region between the shell and the bone.

The plate may have a periphery and the plate may be arranged to contact the shell about at
10 least a portion of the periphery.

The plate may be arranged to seal to the shell about the periphery of the plate such that the seal extends about a portion of the wall of the shell recess surround the or each screw hole.

- 15 At least a portion of the periphery of the plate may form a deformable flange arranged to press against the wall of the shell recess to contact the shell.

The periphery of the plate may form a deformable flange arranged to press against the wall of the shell recess to seal the plate to the shell. The wall of the shell recess may further
20 comprise a groove arranged to receive the deformable flange.

The cup may further comprise a resilient band arranged to be received between the periphery of the plate and the wall of the shell recess to seal the plate to the shell.

- 25 The shell may comprise an aperture or depression arranged to receive a boss extending from the plate to align the plate to the shell recess. The shell may be generally defined by a portion of a sphere and the shell aperture or depression is positioned at the pole of the portion of a sphere.

30 The surface of the plate facing the wall of the shell recess may comprise a depression arranged to match the shape and position of a head of a screw passing through a screw hole into the bone.

Part of the exterior surface of the liner may be tapered and part of the wall of the shell recess may comprise a corresponding taper such that the liner and the shell form a taper lock when the liner is inserted into the shell.

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At least one of the plate and the shell may comprise barbs facing into the shell recess and arranged to engage the liner to secure the liner within the shell recess.

10 The interior concave articulating surface of the liner may be defined by a portion of a spherical surface.

According to a second aspect of the present invention there is provided a method of implanting a cup in a patient's body coupled to the surface of a bone, the method comprising: passing a screw through at least one screw hole in a wall of a shell into a bone
15 to secure the shell to the surface of the bone, the shell defining a recess; inserting a plate into the shell recess; and inserting a liner into the shell recess such that the plate is positioned between the shell and the liner, the liner defining an interior concave articulating surface; wherein the plate separates the at least one screw hole from the liner.

20 The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 illustrates a cup in accordance with a first embodiment of the present invention;

25 Figures 2a to 2d illustrate alternative resiliently deformable flanges which may form part of the cup of figure 1;

Figures 3 and 4 illustrate first and second steps in assembling the cup of figure 1;

30 Figure 5 illustrates a cup in accordance with a second embodiment of the invention; and

Figures 6a to 6c illustrate different options for securing the plate of figure 5 to the shell of figure 5.

Referring to figure 1, this illustrates an acetabular cup in accordance with a first

5 embodiment of the present invention. The cup comprises a shell 2, a liner 4 and a plate 6 arranged to seal to the shell 2 such that the plate 6 closes off the base of the shell 2 from the liner 4. The liner 4 has an interior articulating surface 8 that generally conforms to a portion of a sphere. The articulating surface 8 is suitable for articulation with a corresponding femoral head implant.

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The shell 2 is arranged to be secured to the surface of a bone. Specifically, the shell is arranged to be received within a prepared socket formed in the surface of a bone. The shell 2 is generally hemispherical or part spherical and is hollow to receive the plate 6 and the liner 8 as will be described below. To secure the shell 2 to the bone at least one screw hole 15 10 is formed in the shell 2, generally towards the pole of the shell 2. When the shell 2 is received within a prepared bone socket a screw (not illustrated) can be passed through the screw hole 10 until the screw head is positioned within the screw hole 10.

As noted above, it is desirable to prevent debris generated during articulating contact 20 between the liner 4 and the femoral head from passing through the or each screw hole 10 to the interface between the shell 2 and the bone. To reduce this risk, the plate 6 seals to the shell 2 to separate the or each screw hole 10 from the liner 4. The plate 6 generally matches the shape of the base of the shell 2. Shell 2 is further provided with a socket 12 at or close to the pole defined by the part spherical shell. Socket 12 may extend partially or 25 fully through the wall of the shell 2. The plate 6 comprises a corresponding boss 14 which is arranged to press fit into the socket 12 to ensure the plate 6 is correctly aligned with the shell 2. Boss 14 may be secured within socket 12 with an impaction force. Plate 6 further comprises a domed groove 16 extending annularly about the boss 14. The dome groove 16 is shaped to fit the screw head received in the or each screw hole 10 and to apply pressure 30 to the screw head to prevent the screw head from backing out of the bone through the screw hole 10 as the screws loosen after implantation.

Around the rim of the plate 6 is a resiliently deformable flange 18. Flange 18 is arranged to deform as the plate 6 is inserted into the shell 2 to engage an annular groove 20 extending about the shell 2. This engagement serves to prevent the plate 6 from pulling out of the shell 2 and also seals the plate 6 to the shell 2 to prevent debris from passing
5 from the liner recess defined by the shell 2 and the plate 6 to the or each screw hole 10. The snap in solid plate 6 is designed to not move as a piston within the shell recess, as may occur with the liner. The plate 6 compartmentalises the screws and screw holes from the liner such that the pumping pressure generated by movement of the liner within the shell does not pass to the screw holes.

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Referring to figures 2a to 2d these illustrate alternative flanges 18 that may be combined with the plate 6 of figure 1. Figures 2a to 2d are enlargements of the region of the cup shown in circle 19. Figure 2c is an enlargement of the form of flange 18 shown in figure 1. For each of figures 2a to 2d, flange 18 is arranged to be bent upwards and inwards as the
15 plate 6 is inserted into the shell 2 before reverting towards its unstressed position to engage groove 20. To ensure a tight seal to the shell it may be desirable for the flange 18 to remain stressed when engaged in groove 20 to ensure that it presses against the shell wall. Figure 2c illustrates in phantom the stressed position of the flange 18 during insertion of the plate 6 into the shell 2 before the flange 18 engages the groove 20. Figure 2c illustrates
20 the rim of the plate 2 further comprising an upwards extending second flange 22 to provide a further seal to the shell 2. Figures 2a and 2b show different shapes of flange 18 that are engage the groove 20 in generally the same way as for figure 2c. The flange 18 of figure 2d comprises two prongs forming a U or V shape arranged to seat on the edge of groove 20 with one prong within the groove and one prong outside of the groove. In alternative
25 embodiments of the present invention there may be no flange at all. The periphery of the plate 6 may have a straight edge arranged to contact the wall of the shell 2 such that the plate 6 is generally dish shaped with a raised rim. Strain within the dished plate causes the rim to bear against the wall of the shell 2 to effect a seal separating the liner 4 from the or each screw hole 10.

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Boss 14 of plate 6 is hollow as illustrated in figure 1 to form a further socket 24 to receive a boss 26 at the pole of liner 4. Boss 26 serves to ensure that the shell is correctly aligned

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to the shell 2 and the plate 6 as it is inserted into a liner recess defined by the shell 2 and the plate 6. Alternatively, as described in connection with figures 3 and 4 below, the liner 4 may be coupled to the plate 6 before they are inserted together into the shell. To secure the liner 4 in position the boss 26 forms a press fit in socket 24. Additionally, the boss 26 is engaged by barbs 28 within socket 24 to prevent the liner 4 from separating from the plate 6. The upper part of liner 4 forms a taper 30 and the upper part of the inside edge of the shell 2 has a tapered part 32 such that when the liner 4 is inserted into the shell 2 it locks to the shell 2. An impaction force may be applied to the liner 4 to achieve the taper lock.

10 Referring now to figures 3 and 4, the process of assembling the cup of figure 1 will be described. The first step illustrated in figure 3 is to insert the liner 4 into the plate 6 such that barbs 28 (not visible in figure 3) engage boss 26. The liner 4 and the plate 6 may be assembled at a factory (or at least before being passed to the surgeon) under pressure to ensure a tight coupling. Figure 4 shows the combined liner 4 and plate 6 being inserted into the shell 2 after the shell 2 has been coupled to a bone 34 by at least one bone screw 36 (the bone 34 is illustrated cut away to reveal hidden detail). Figure 4 further illustrates the outside of the shell 2 comprising ribs 38 to grip the bone 34 to prevent the shell 2 rotating.

20 Referring now to figure 5, this illustrates a cup in accordance with a second embodiment of the invention. The second embodiment of the invention is generally similar to the first embodiment, and so corresponding features are identified by reference numbers incremented by 100. Plate 106 is arranged to seal to cup 102 by bearing against a polymeric band 150 which has a square cross section. The arrangement of plate 106, shell 25 102 and O-ring 150 is shown enlarged in figure 6b. Figure 6a shows an alternative arrangement with an O-ring 152 having a circular cross section. Figure 6c shows a further option with a resiliently deformable flange 154 similar to the arrangement of figures 2a to 2d. It will be appreciated that in alternative embodiments the polymeric band or O-ring of figure 5 may be used in combination with the deformable flanges 18 of figures 2a to 2d to provide additional sealing. Plate 106 comprises a boss 114 arranged to be received within a socket 112 within the shell 102. As for the embodiment of figure 1, boss 114 may be a

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press fit within the socket 112. Alternatively, boss 114 may be a screw fit driven by a screwdriver which engages slot 156.

5 Unlike the liner 4 shown in figure 1, liner 104 does not include a boss to be received within a socket formed in the plate 106. Liner 104 includes a tapered section 130, and shell 132 comprises a corresponding tapered section 132 to lock the liner 104 to the shell 102. Additionally, tapered section 132 further comprises barbs 158 to engage the liner 104 to lock the liner in place. Barbs 158 are broken, for instance in three places, to prevent the liner 104 from rotating within the liner socket. It will be understood that similar barbs may
10 be provided within tapered portion 32 of the shell 2 of figure 1.

As for the first embodiment, the boss 114 of plate 106 may be impacted into the socket 112. However, unlike for the first embodiment the liner 104 cannot be coupled to the plate 106 before the two components are inserted into the shell 102.

15

As illustrated in figures 1 and 5 the liner 4, 104 protrudes above the rim of the shell 2, 102 and is chamfered about its outer edge to slope down to the rim of the shell. As noted above, the plate 6, 106 serves to seal the screw holes 10, 110 from the liner 4, 104. However, movement of the liner within the shell may still be causing a pumping effect
20 generating pressure in any fluid trapped between the liner and the shell. Additionally, during insertion of the liner into the shell, if there is any fluid present, which is generally unavoidable during surgery, there is no possibility of the fluid escaping through the screw holes, which could make inserting the liner difficult. Consequently there is a need to provide a relief route for this fluid pressure. An exhaust groove may be formed to reduce
25 the pressure difference between the articulating surface and the reverse side of the liner. The groove may run around the edge of the liner adjacent to the shell. Alternatively, a hole through the liner to the articulating surface would achieve the same pressure relief.

A range of appropriate materials will be readily apparent to the skilled person. In
30 particular, the shell is preferably formed from a biocompatible and high strength material capable of resisting deformation under the forces typically experienced for implanted acetabular cups. Suitable materials include metals, plastic materials such as polymers

including ultra high molecular weight polyethylene (UHMWPE), polyetheretherketone (PEEK) or carbon reinforced PEEK or ceramics. In particular the shell may be formed from titanium alloy coated with a material on the outside to encourage bone growth to assist in securing the cup to the bone. The plate may be formed from a metal such as

5 titanium, titanium alloy, stainless steel or a cobalt chrome alloy with a resiliently deformable rim. Advantageously, the liner may be formed from a plastic material to provide a smooth articulating surface. In particular, cross linked polyethylene (XLPE) or highly cross linked polyethylene (HXLPE) may be used. Preferably the liner is at least 6mm thick. Alternatively, the liner may be metallic or ceramic.

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Although the invention has been primarily described above in connection with an acetabular cup, the invention is not limited to this application. For instance, the cup may form part of a shoulder joint.

15 Further modifications to the present invention will be readily apparent to the appropriately skilled person from the teaching herein without departing from the scope of the appended claims.

CLAIMS:

1. A cup for implanting in a patient's body coupled to the surface of a bone, the cup comprising:
 - 5 a shell defining a recess including at least one screw hole in the wall of the shell arranged to receive a screw passing into a bone to secure the shell to the surface of the bone;
 - a plate arranged to be received in the shell recess; and
 - a liner arranged to be received within the shell recess such that the plate is
 - 10 positioned between the shell and the liner, the liner defining an interior concave articulating surface;
 - wherein the plate is arranged to separate the at least one screw hole from the liner.
2. A cup according to claim 1, wherein the plate has a periphery and the plate is
- 15 arranged to contact the shell about at least a portion of the periphery.
3. A cup according to claim 2, wherein the plate is arranged to seal to the shell about the periphery of the plate such that the seal extends about a portion of the wall of the shell recess surround the or each screw hole.
- 20 4. A cup according to claim 2 or claim 3, wherein at least a portion of the periphery of the plate forms a deformable flange arranged to press against the wall of the shell recess to contact the shell.
- 25 5. A cup according to claim 4, wherein the wall of the shell recess further comprises a groove arranged to receive the deformable flange.
6. A cup according to any one of claims 2 to 5, further comprising a resilient band arranged to be received between the periphery of the plate and the wall of the shell recess.

7. A cup according to any one of the preceding claims wherein the shell comprises an aperture or depression arranged to receive a boss extending from the plate to align the plate to the shell recess.
- 5 8. A cup according to claim 7, wherein the shell is generally defined by a portion of a sphere and the shell aperture or depression is positioned at the pole of the portion of a sphere.
9. A cup according to any one of the preceding claims, wherein the surface of the
10 plate facing the wall of the shell recess comprises a depression arranged to match the shape and position of a head of a screw passing through a screw hole into the bone.
10. A cup according to any one of the preceding claims, wherein part of the exterior
15 surface of the liner is tapered and part of the wall of the shell recess comprises a corresponding taper such that the liner and the shell form a taper lock when the liner is inserted into the shell.
11. A cup according to any one of the preceding claims, wherein at least one of the
20 plate and the shell comprise barbs facing into the shell recess and arranged to engage the liner to secure the liner within the shell recess.
12. A cup according to any one of the preceding claims, wherein the interior concave articulating surface of the liner is defined by a portion of a spherical surface.
- 25 13. A method of implanting a cup in a patient's body coupled to the surface of a bone, the method comprising:
- passing a screw through at least one screw hole in a wall of a shell into a bone to secure the shell to the surface of the bone, the shell defining a recess;
 - inserting a plate into the shell recess; and
 - 30 inserting a liner into the shell recess such that the plate is positioned between the shell and the liner, the liner defining an interior concave articulating surface;
- wherein the plate separates the at least one screw hole from the liner.

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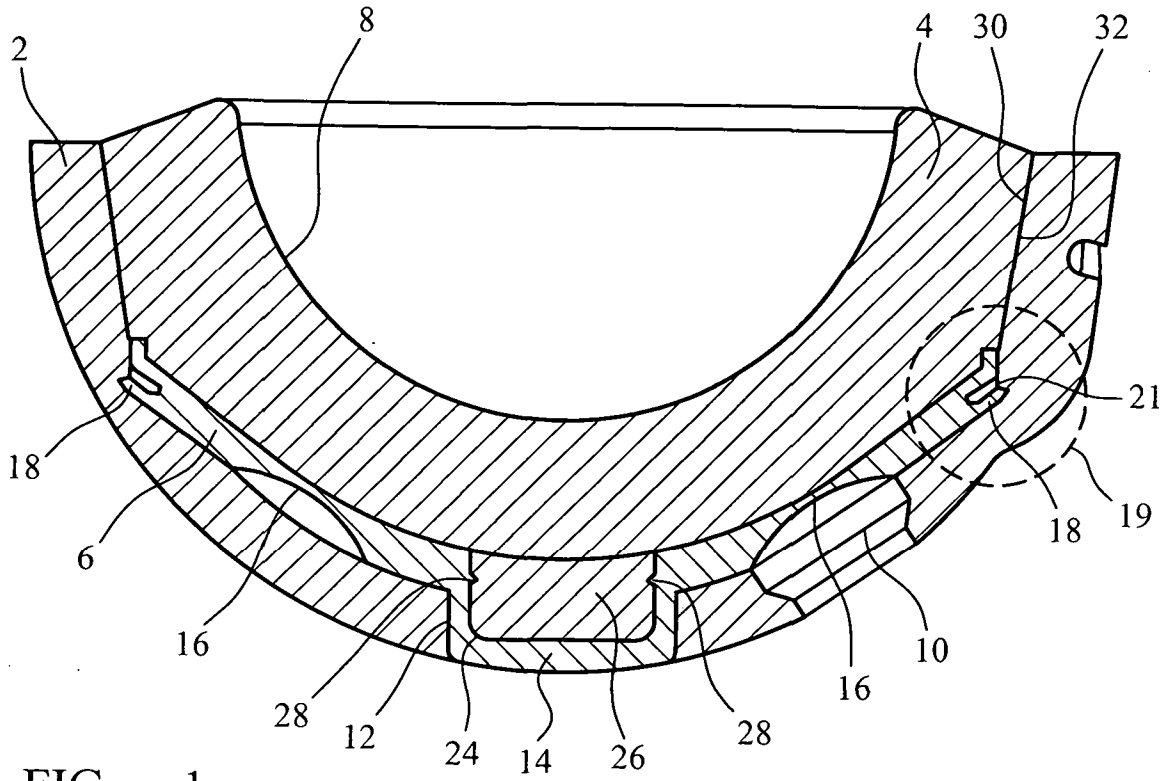


FIG. 1

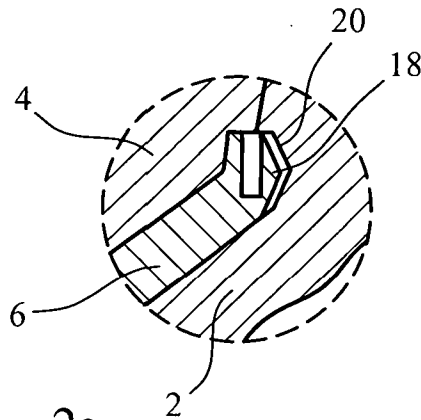


FIG. 2a

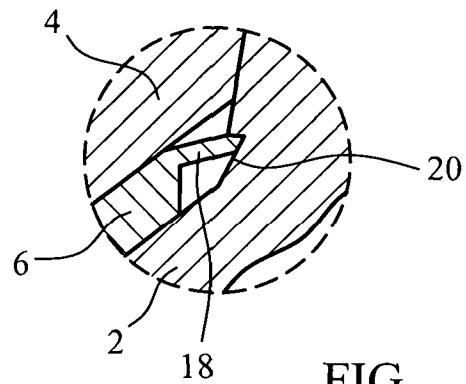


FIG. 2b

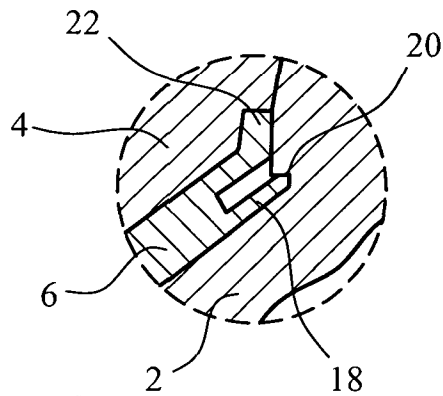


FIG. 2c

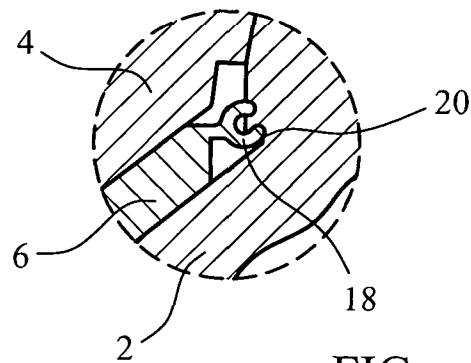


FIG. 2d

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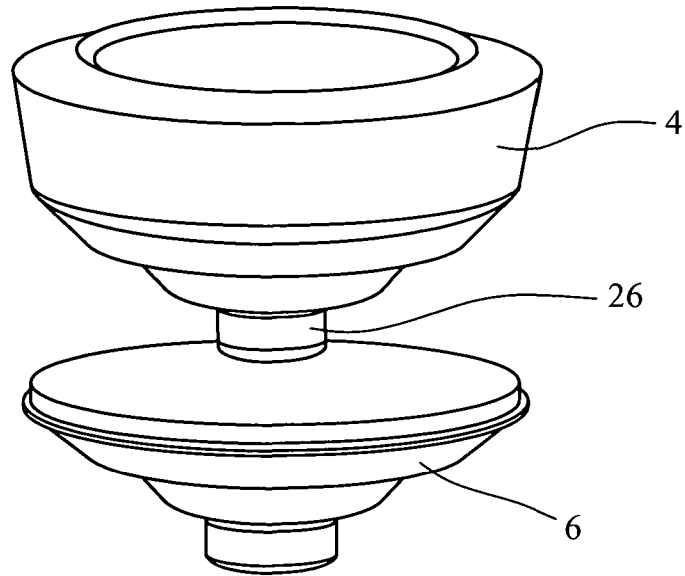


FIG. 3

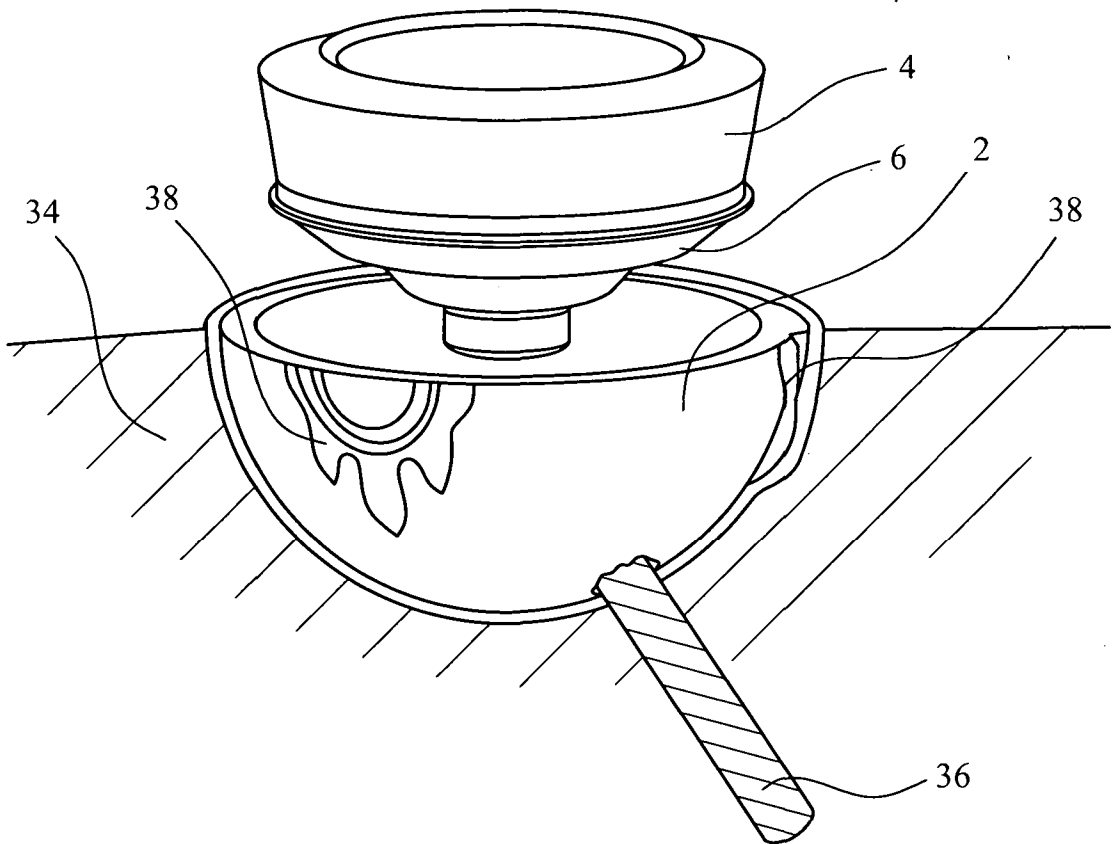


FIG. 4

-3/3-

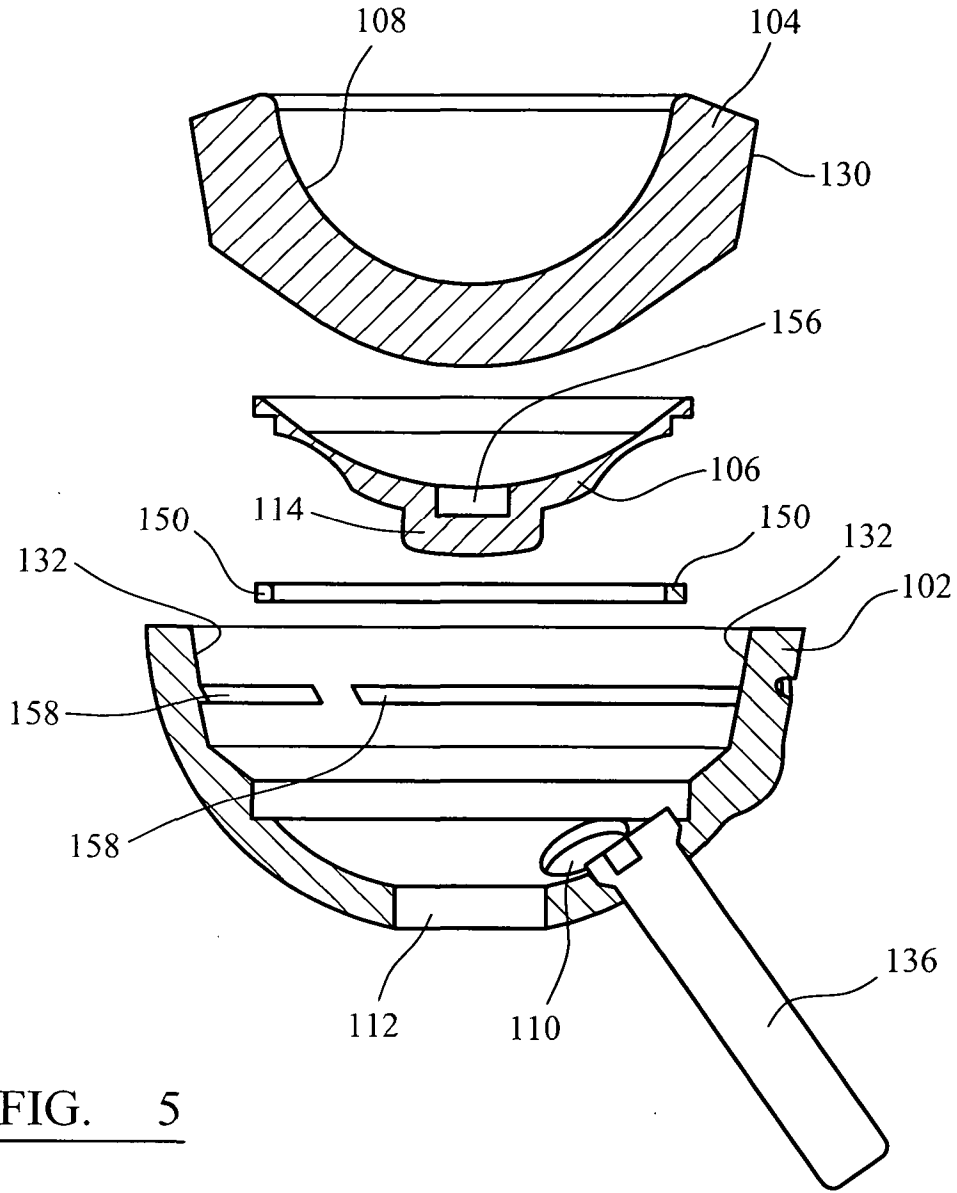


FIG. 5

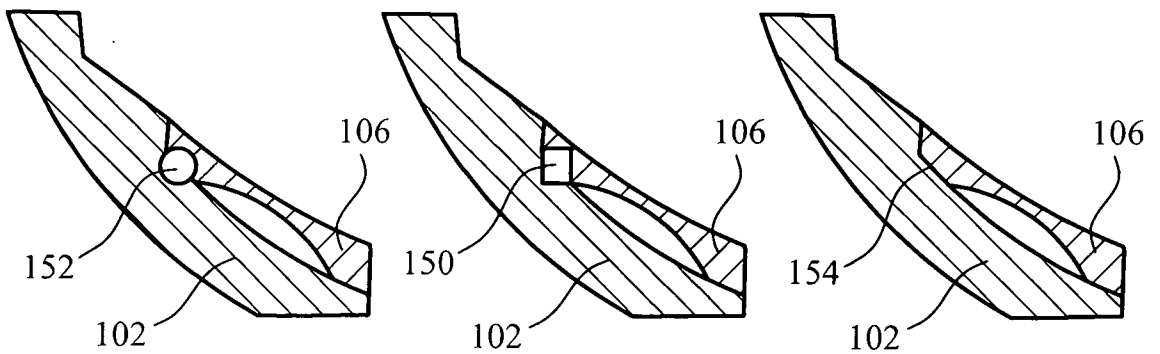


FIG. 6a

FIG. 6b

FIG. 6c

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/050850

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/34
ADD.
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)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/255672 A1 (GIL CARLOS E [US]) 16 October 2008 (2008-10-16) paragraphs [0029] - [0053] -----	1-12
X	EP 1 163 891 A1 (BIOMET MERCK DEUTSCHLAND GMBH [DE]) 19 December 2001 (2001-12-19) paragraph [0021] -----	1-5
X	EP 0 341 199 A1 (SULZER AG [CH]; PROTEK AG [CH]) 8 November 1989 (1989-11-08) column 1, line 20 - column 2, line 58 -----	1,10
X	DE 195 20 495 C1 (SCHOLZ WERNER [DE]) 14 November 1996 (1996-11-14) column 1, lines 60-68 column 3, lines 9-30 -----	1

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

11 July 2012

Date of mailing of the international search report

18/07/2012

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Authorized officer

Buchmann, Gerhard

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2012/050850

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 13
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2012/050850

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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