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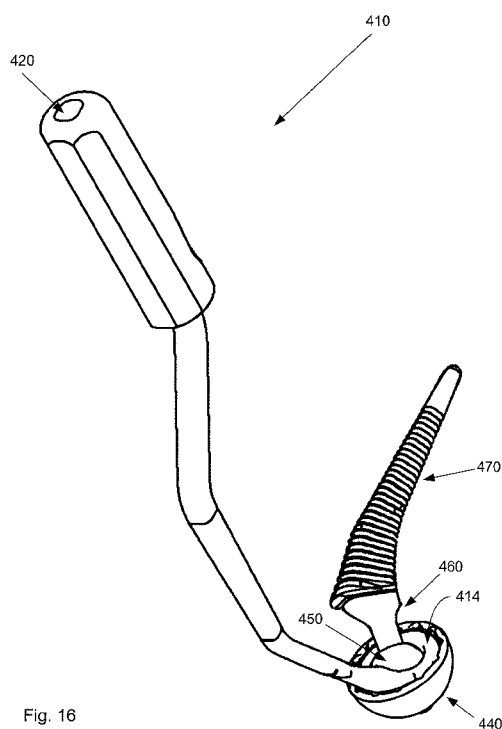


Fig. 16

(57) Abstract: Instrumentation for implanting a prosthetic acetabular cup in an acetabulum of a patient, a femoral head and methods of use are described. An inserter (410) has a handle (412) at a proximal end and an impactation head (414) at a distal end. The impactation head is configured to couple with an acetabular cup to transmit an impactation force to the acetabular cup and includes a formation to prevent the acetabular cup from pivoting relative to the impactation head. The impactation head defines a cavity and the handle and the impactation head are arranged to define an impactation axis extending along the inserter. A femoral part is attachable to a femur and includes a femoral head bearing a visual alignment guide and which is pivotably receivable within the cavity of the impactation head to permit the impactation head to pivot relative to the femoral head. In use, a change in orientation of the inserter causes a change of orientation of the acetabular cup within the acetabulum of the patient.

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PROSTHETIC ACETABULAR CUP INSERTER AND IMPACTOR

The present invention relates to apparatus and methods for hip surgery, and in particular to instrumentation for placing and/or assessing the placement of a component of a hip
5 joint and/or methods of hip surgery using such instrumentation.

A variety of methods of hip surgery are generally known. The hip joint may generally be considered a ball and socket joint in which the head of the femur articulates within the acetabular cavity of the pelvis. Some methods of hip surgery may involve the
10 replacement of one or more parts of the hip joint with one or more prosthetic components. This may be to replace damaged, worn, diseased or otherwise imperfect parts of the hip joint including the respective articulating surfaces of the acetabular cavity and/or femoral head.

15 Different surgical procedures may involve replacement of a part of the acetabulum or the femoral head or both. Some procedures, sometimes referred to as resurfacing procedures, may involve replacement of only the articulating surface of the femoral head. Other procedures may involve replacement of the entire femoral head. Such procedures often also use a stem component which is implanted in the resected femur and having a neck to
20 which the femoral head is attached. In some procedures, a prosthetic cup may be implanted in a prepared acetabular cavity to provide a cavity in which the femoral head or prosthetic femoral head may articulate when the joint is reduced. Surgical procedures in which both the acetabulum and at least a part of the femoral head are replaced with prosthetic components are generally referred to as total hip replacement procedures.

25

During hip surgery procedures, some surgeons may sometimes use one or more trial components, which have the same geometry and size as the intended prosthetic components, so that the surgeon may trial the joint before final implantation of one or both of the prosthetic components. For example, the surgeon may use trial components to
30 check that the size, position or orientation of one or more of the components is suitable. Other surgeons may opt not to use trial components or may use them occasionally based on their professional judgement.

One of the considerations in hip surgery is the angular orientation of the acetabular cavity. When the acetabulum is replaced with an acetabular cup, then it is often an aim of the surgeon to place the acetabular cup so that it is pointing generally in a preferred direction
5 or range of directions. The orientation of an acetabular cup is often defined in terms of an angle of abduction (or inclination) and an angle of anteversion.

A variety of approaches have been used to try and assess the angular orientation of an acetabular cup, either a trial or a prosthesis, after placement in the acetabular cavity.
10

Anatomical approaches may be used in which the surgeon uses either their experience and/or a piece of instrumentation, in order to gauge, by inspection or instrumentation, the angular orientation of the acetabular cup relative to one or more anatomical features of the patient's pelvis. However, there is often limited access to the surgical site,
15 particularly for minimally invasive approaches, and therefore this is often not easy nor accurate.

Other approaches may use markings or other features on the trial or prosthetic components in order to gauge the angular orientation of the acetabular cup relative to the
20 patient's pelvis.

For example "The Ranawat Sign A Specific Maneuver to Assess Component Positioning in Total Hip Arthroplasty", Lucas, David H., and Scott, Richard D., Journal of Orthopaedic Techniques, Vol. 2, No. 2, June 1994, describes a method of intraoperative
25 assessment of component orientation for total hip arthroplasty. With the patient in the true lateral decubitus position, the femur is internally rotated without hip flexion until a flat underside of the prosthetic head (generally perpendicular to the femoral neck) is co-planar with a rim of the acetabular cup. The amount of internal rotation necessary to achieve this position is known as the Ranawat sign and relates to the combined
30 anteversion of the acetabular and femoral components of the joint. For example a Ranawat sign of 45° may correspond to a cup anteversion of 30° and a femoral anteversion of 15°. However, any knee laxity or deformity can influence the

interpretation of this value. Also, there may be difficulty in assessing the actual magnitude of the angle of internal rotation. Further, different surgeons may have different approaches to manipulating the patient's leg and also any one surgeon's approach may not easily be reproducible from patient-to-patient either by that same
5 surgeon or by other surgeons.

WO 2009/108683 describes another approach in which markings are applied to a femoral head and in which the surgeon again applies an amount of internal rotation to the patient's leg, during trial reduction, so that the angle between the rim of the acetabular cup and
10 various markings on the femoral head indicates the angular position of the acetabular cup relative to the patient's pelvis. A neutral leg position is used in which the patient's leg is in full, relaxed extension at zero degrees abduction, zero degrees anteversion and approximately 15° internal rotation, or otherwise internally rotated by an amount equal to the amount of version of the natural or artificial femoral neck. Hence, this approach also
15 requires the surgeon to apply a specific amount of internal rotation to the patient's leg. Again, it may be difficult to apply the correct amount of internal rotation, there may be inaccuracies introduced by deformities of the patient's leg and the surgical technique may be difficult to reproduce and/or reliably learn. This is particularly the case for a relatively small angle, 15°, as even a relatively small error in the amount of internal rotation, for
20 example 5°, is a large proportion (33%) of the target internal rotation.

Other approaches and associated instrumentation are described in US 2005/0107799. An accessory for implanting a hip cup, includes a manipulable cup, a manipulation head having a hemispherical portion and a circular rim around it for aligning the manipulable
25 cup in the acetabulum. A device for immobilizing the aligned position of the manipulable cup is provided and allows a guide to be set for alignment of a bone bur and a drive-in instrument for reaming placing the acetabular cavity and placing the cup. In another approach, a manipulable cup is located in the acetabulum and its orientation can be adjusted by a handle until a lip of the manipulable cup is parallel with an equatorial line
30 on a femoral head or a plane on the reverse of a femoral head

Hence, apparatus and/or methods making accurate placement of an acetabular cup simpler, easier and/or more reliable would be beneficial.

A first aspect of the invention provides instrumentation for implanting a prosthetic
5 acetabular cup in an acetabulum of a patient, including: an inserter, comprising: a handle
at a proximal end of the inserter; and an impaction head at a distal end of the inserter,
wherein the impaction head is configured to couple with an acetabular cup to transmit an
impaction force to the acetabular cup when located in an acetabulum of a patient and
includes a formation to prevent the acetabular cup from pivoting relative to the impaction
10 head, wherein the impaction head defines a cavity and wherein the handle and the
impaction head are arranged to define an impaction axis of the inserter extending along
the inserter; and a femoral part attachable to a femur of the patient and including a
femoral head bearing a visual alignment guide, and wherein the femoral head is pivotably
receivable within the cavity of the impaction head to permit the impaction head to pivot
15 relative to the femoral head, and wherein, in use, a change in orientation of the inserter
causes a change of orientation of the acetabular cup within the acetabulum of the patient.

The impaction head may be releasably attachable to the acetabular cup.

20 The formation may releasably attach the impaction head and the acetabular cup.

The impaction head may have the form of a hemispherical bowl.

The formation may be positioned at a pole of the bowl so as to engage with a polar
25 feature of the acetabular cup.

The inserter may include an intermediate portion between the handle and the impaction
head and wherein the intermediate portion is offset to the impaction axis.

30 The femoral head may have a polar axis and the visual alignment guide may extend along
an alignment axis. The alignment axis and a plane perpendicular to the polar axis may
subtend an acute angle corresponding to an anteversion angle of the acetabular cup

resulting in a target combined anteversion for the hip of the patient when the hip of the patient is placed in a preselected position.

The acute angle may be the range of 30° to 40°. The acute angle may be substantially
5 35°.

The acute angle may be the range of 20° to 30°. The acute angle may be substantially
25°.

10 The visual alignment guide may comprise a first part and a second part. The first part may correspond to a first target anteversion angle of the acetabular cup for a first surgical approach. The second part may correspond to a second target anteversion angle of the acetabular cup for a second surgical approach. The first surgical approach may be a posterior approach. The second surgical approach may be an anterior approach.

15

The femoral head may be a trial femoral head.

The femoral part may include or be a femoral neck.

20 The femoral neck may have a taper and the femoral head may have a cavity configured to releasably receive the taper therein.

The femoral part may also include an insert configured to be received within a cavity within the femur of the patient. The insert may include an insert attachment formation by
25 which the femoral neck is attachable to the insert.

The insert may be selected from: a femoral broach; a femoral rasp; a trial femoral stem; and a prosthetic femoral stem.

30 The cavity may have a mouth defining an alignment plane and wherein when the femoral head is oriented with the visual alignment guide parallel to the alignment plane, the inserter is configured to orient the acetabular cup for implantation in the acetabulum of

the patient with an anteversion angle corresponding to a target combined anteversion angle for the hip of the patient joint when the hip of the patient is positioned at a preselected position.

- 5 The target combined anteversion may be in the range of 30° to 40°.

The preselected position may be an anatomical position.

- The anatomical position may corresponds substantially to 0° extension/flexion of the leg
10 of the patient and/or 0° abduction/adduction of the femur and/or 0° rotation of the femur.

- The visual alignment guide may include a feature of the femoral head which is proud of an articulating surface of the femoral head and which is enlargeable with a part of the impaction head to provide haptic feedback when the impaction head is aligned with the
15 visual alignment guide.

The feature may be a ring received in a groove in the articulating surface.

- The impaction head may include a female formation arranged to mate with the feature of
20 the femoral head.

The visual alignment guide may include or comprises an at least partially x-ray opaque material.

- 25 The femoral head may be located within the cavity of the impaction head.

- A second aspect of the invention provides a method for implanting a prosthetic acetabular cup in an acetabulum of a patient using an inserter comprising a handle at a proximal end of the inserter and an impaction head at a distal end of the inserter wherein the handle and
30 the impaction head are arranged to define an impaction axis of the inserter extending along the inserter, the method comprising: coupling the impaction head to an acetabular cup to be implanted in an acetabulum of a pelvis of the patient; moving a femur of the

patient relative to the pelvis into an anatomical position, wherein the femur has a femoral head attached thereto including a visual alignment guide and which is pivotably received within a socket of the impaction head so that the visual alignment guide corresponds to an acetabular cup orientation in the pelvis corresponding to a target combined anteversion angle for the hip joint of the patient; moving the handle of the inserter to pivot the acetabular cup in the acetabulum about the femoral head to align the acetabular cup with the visual alignment guide; and impacting the inserter to impart an impaction force to the acetabular cup along the impaction axis so as to implant the acetabular cup in the acetabulum.

10

The anatomical position may correspond substantially to 0° extension/flexion of the leg and/or 0° abduction/adduction of the femur and/or 0° rotation of the femur.

The combined anteversion angle may be in the range of 30° to 40°. The combined anteversion angle may be substantially 35°.

The femoral part may be or may include a femoral neck.

The femoral neck may include a taper at a free end and wherein the femoral head may be releasably attached to the taper.

The method may further comprise attaching the femoral neck to a femoral broach located in the femur of the patient.

The impaction head may be in the form of a liner or a trial liner.

The impaction head may be releasably attached to the acetabular cup and the method may further comprise releasing the impaction head from the acetabular cup after the impaction head has been implanted in the acetabulum.

30

The method may further comprise visually inspecting the visual alignment guide to assess the current orientation of the acetabular cup in the acetabulum before impacting the acetabular cup.

- 5 The method may further comprise using haptic feedback while moving the handle of the inserter to assess the current orientation of the acetabular cup in the acetabulum before impacting the acetabular cup.

- A third aspect of the invention provides a trial femoral head comprising: a body defining
10 a cavity therein for receiving a taper of a femoral neck; an articulating surface; and a visual alignment guide on the articulating surface, wherein the visual alignment guide is configured to define an acetabular cup orientation within a pelvis of a patient corresponding to a target combined anteversion for a hip of the patient when the femoral head is mounted on a femur of the patient and when the hip of the patient is placed in the
15 anatomical position.

The anatomical position may correspond substantially to 0° extension/flexion of the leg and/or 0° abduction/adduction of the femur and/or 0° rotation of the femur.

- 20 The target combined anteversion angle may be in the range of 30° to 40°. The target combined anteversion angle may be substantially 35°.

The visual alignment guide may be further configured to define an acetabular cup orientation within a pelvis of a patient corresponding to an inclination of 40°.

- 25 The visual alignment guide may be formed by the interface between a first part of the trial femoral head and a second part of the trial femoral head.

- The first part of the trial femoral head and the second part of the trial femoral head may
30 be different colours. The different colours may have high contrast.

The visual alignment guide may be a band. The band may have a width of between 2mm and 6mm. The band may have a width of substantially 3mm or 4mm or 5mm.

The visual alignment guide may include a first part configured to correspond to a first
5 target combined anteversion and/or a second part configured to correspond to a second target combined anteversion different to the first target combined anteversion.

The visual alignment guide may include a formation which is proud of the adjacent articulating surface and arranged to be engageable in use with a part of an acetabular cup
10 or liner to provide haptic feedback. The part may be a rim of the acetabular cup or liner.

The formation may be a ring. The formation may be a C-ring.

The ring may be received in a groove in the articulating surface of the trial femoral head.
15

The visual alignment guide may include or comprise an at least partially x-ray opaque material.

A fourth aspect of the invention provides a method for assessing the orientation of an
20 acetabular cup in an acetabulum of a patient using a trial femoral head having a visual alignment guide on an articulating surface, the method comprising: mounting the trial femoral head on a femur of the patient; locating the trial femoral head in an acetabular cup within a prepared acetabulum of the patient; moving a femur of the patient relative to the pelvis into an anatomical position to pivot the trial femoral head relative to the
25 acetabular cup so that the visual alignment guide corresponds to an acetabular cup orientation in the pelvis corresponding to a target combined anteversion angle for the hip joint of the patient; and visually inspecting the visual alignment guide and a part of the acetabular cup to assess the orientation of the acetabular cup in the acetabulum.

30 The method may further comprise further moving the femur and using haptic feedback while moving the femur to assess the orientation of the acetabular cup.

The anatomical position may correspond substantially to 0° extension/flexion of the leg and/or 0° abduction/adduction of the femur and/or 0° rotation of the femur.

The target combined anteversion angle may be in the range of 30° to 40°. The target
5 combined anteversion angle may be substantially 35°.

The visual alignment guide may be further configured to correspond to an acetabular cup orientation in the pelvis of the patient corresponding to an inclination of 40°.

10 The visual alignment guide may be at least partially x-ray opaque, and the method may further comprise: capturing an x-ray image of the hip including the acetabular cup and the visual alignment guide after moving the femur of the patient relative to the pelvis into the anatomical position.

15 Other aspects of the invention may provide kits of parts of instrumentation and/or implants.

Other aspects of the invention may provide assemblies of instrumentation and/or
implants.

20

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

Figure 1 shows a coronal view of a femur;

Figure 2 shows a sagittal view of the femur of Figure 1;

25 Figure 3 shows a transverse view of the femur of Figures 1 and 2;

Figure 4 shows a view of the femur in a plane parallel to the anatomic axis and the neck of the femur;

Figure 5 shows a coronal view of a pelvis;

Figure 6 shows a sagittal view of the pelvis of Figure 5;

30 Figure 7 shows a transverse view of the pelvis of Figures 5 and 6;

Figure 8 shows a partial cross sectional perspective view of the pelvis along line A-A of Figure 5;

Figure 9 shows a perspective view of the pelvis;

Figure 10 shows a coronal view of a hip comprising the femur of Figures 1 to 4 and the pelvis of Figures 5 to 9;

Figure 11 shows a partial cross sectional perspective view of the pelvis along line
5 C-C of Figure 10;

Figure 12 shows a perspective exploded view of an embodiment of an assembly according to a first aspect of the invention and including an embodiment of an instrument according to a second aspect of the invention and a femoral head according to a third aspect of the invention;

10 Figure 13 shows a first side elevation of the instrument shown in Figure 12;

Figure 14 shows a second side elevation of the instrument shown in Figure 13;

Figure 15 shows a cross sectional view of the instrument shown in Figures 13 and
14;

Figure 16 shows a perspective view of the assembly shown in Figure 12 when
15 assembled and in use;

Figures 17A to 17F shows various elevations and cross sectional views of a first embodiment of the femoral head part of the assembly shown in Figure 12 according to the third aspect of the invention;

Figures 18A to 18F shows various elevations and cross sectional views of a
20 second embodiment of the femoral head part of the assembly shown in Figure 12 according to the third aspect of the invention;

Figures 19A to 19F shows various elevations and cross sectional views of a third embodiment of the femoral head part of the assembly shown in Figure 12 according to the third aspect of the invention;

25 Figure 20 shows a perspective view of a fourth embodiment of the femoral head part according to the third aspect of the invention;

Figure 21 shows a cross sectional elevation of an end of a further embodiment of the instrument;

Figure 22 shows a cross sectional elevation of an assembly of the end of the
30 instrument shown in Figure 21, the femoral head shown in Figure 21 and a taper of a femoral neck; and

Figure 23 shows a flow chart illustrating an embodiment of a surgical method according to a fourth aspect of the invention in which the assembly may be used to position and implant an acetabular cup;

Figure 24 shows a flow chart illustrating an embodiment of a surgical method according to a fifth aspect of the invention in which the femoral head of the third aspect may be used assess the orientation of an implanted acetabular cup; and

Figure 25 shows an APP x-ray of a hip which may be captured during the surgical methods shown in Figures 23 or 24.

10 Similar items in the different Figures share common reference signs unless indicated otherwise.

Before describing the apparatus and/or methods of the invention, the geometry of a hip joint will be discussed generally. In the below, a right hip joint is described, but it will be appreciated that a similar discussion applies to a left hip joint. Also, the following discussion is intended to relate to both the pre-operative natural or native, hip joint, as well as to the artificial, or prosthetic, hip joint. Hence, although the magnitude of the various angles may vary between the native hip joint and the prosthetic hip joint, the definitions of those angles may be generally the same for the native and prosthetic hip and may be determined by the positions and/or orientations of the various parts making up the native hip joint and prosthetic hip joint respectively.

With reference to Figures 1 to 4, there are shown various different views of a right femur 100. In particular Figure 1 shows a coronal view in the anterior to the posterior direction (generally herein the AP direction), Figure 2 shows a sagittal view in the medial to the lateral direction (generally herein the ML direction), Figure 3 shows a transverse view in the superior to the inferior direction, and Figure 4 shows a view of the femur in a plane parallel to the anatomic axis of the femur and the neck of the femur as explained in greater detail below. Pre-operatively, the proximal part of the femur 100 includes the native femoral neck and native femoral head. Intra-operatively and post-operatively the proximal part of the femur may include various trial or prosthetic parts or components providing trial or prosthetic femoral necks and femoral heads. The following will refer

generally to femoral necks and femoral heads and is intended to include native, trial or prosthetic ones.

With particular reference to Figures 1 and 2, the proximal part 102 of femur 100 includes
5 a femoral head 104 (represented by a sphere) attached to a femoral neck 126, best illustrated in Figure 4, having a neck axis extending generally in the direction of arrow 106. The femur 100 has an epicondylar axis 108 extending between the lateral femoral epicondyle 110 and the medial femoral epicondyle 112. The femur 100 also has an anatomic axis 114 extending between, for example, the distal femur intercondylar notch
10 116 and the piriformis fossa, close to the medial face of the greater trochanter. The femur 100 also has a mechanical axis 120 extending between, for example, close to the distal femur intercondylar notch 116 and the centre of the femoral head 104. The anatomical axis 114 and mechanical axis 120 of the femur 100 may be defined by other anatomical points in other embodiments.

15

With reference to Figure 3, a femoral neck anteversion angle 124 can be defined as the angle in the transverse plane subtended by the femoral neck axis 106 and the epicondylar axis 108. In practice, the femoral neck anteversion angle for the native neck is typically in the range of about 12° to 15°, but may have other values. Neck anteversion angle 124
20 is a measure of the anteversion of the femoral neck relative to the local anatomy of the femur 100.

Figure 4 shows a view of the femur 100 in a plane parallel to line BB of Figure 3, which is parallel to the femoral neck axis 106, and the anatomical axis 114, and which more
25 clearly shows the femoral neck 126. Figure 4 also illustrates the neck angle 128 subtended between the femoral neck axis 106 and the anatomical axis 114 of the femur. The native neck angle 128 varies from patient to patient, but is typically about 130°. The neck angle 128 for a trial or prosthetic implant is usually fixed by the implant design, unless the implant is adjustable, and is often intended to approximately reproduce the
30 native geometry and so may also be about 130°. In the following a neck angle 128 of 130° may be used as an example, but it will be appreciated that in other embodiments, other neck angle values may also be used.

Hence during hip surgery in which a prosthetic femoral component is used, one of the variables is the femoral neck anteversion angle 124, which generally measures how far forward the femoral neck 126 is directed compared to the medial-lateral axis of the femur.

5

With reference to Figures 5 to 9, there are shown various different views of a pelvis 200 and right acetabulum. In particular Figure 5 shows a coronal view in the anterior to the posterior direction (generally herein the AP direction), Figure 6 shows a sagittal view in the medial to the lateral direction (generally herein the ML direction), Figure 7 shows a transverse view in the superior to the inferior direction, Figure 8 shows a partial sectional view along line A-A of Figure 5, and Figure 9 shows a perspective view of the pelvis 200 with the anterior pelvic plane (APP) vertical and the transverse axis generally horizontal. Pre-operatively, the pelvis 200 includes an acetabulum which provides a native socket in which the native femoral head is received and articulates. Intra-operatively and/or post-operatively the pelvis may include various trial or prosthetic implants, such as trial or prosthetic acetabular cups (with or without liners depending on the specific implant system being used). The following will refer generally to the acetabulum or acetabular cup and is intended to include the native acetabulum as well as trial or prosthetic components.

20

As illustrated in Figure 5, the acetabulum 202 may be represented by a hemisphere or hemispherical cup which generally has a position and an orientation. The orientation or direction of the acetabulum may generally be defined by two angles. A first angle indicates how much the acetabulum is directed forward or backward (generally referred to as anteversion when pointing anteriorly and retroversion when pointed posteriorly) relative to the pelvis. A second angle indicates how much the acetabulum is pointing downward or in an inferior direction (generally referred to as inclination or abduction) relative to the pelvis. The direction of the acetabulum may be defined by an acetabular axis 204, best illustrated in Figure 9, which generally passes through the centre of the mouth of the acetabulum and perpendicular to the plane of the mouth of the acetabulum.

30

The pelvis 200 includes a transverse axis 206 passing between the right ASIS 208 and the left ASIS 210. An anterior pelvic plane 212 (generally referred to as APP in the following) is defined by the transverse axis 206 and first and second points on the symphysis pubis 214, 216.

5

As best illustrated in Figure 5, an inclination angle for the acetabulum or acetabular cup 202 may be defined by the angle 220 subtended by the transverse axis 206 and a long axis, or inclination axis, 222 of the acetabular cup 202 within, or parallel to, the anterior pelvic plane 212. In Fig. 5, the illustrated inclination angle 220 is approximately 40° .

10 Figure 8 shows a view of a cross section of the pelvis 200 along line A-A in Figure 5 and in a direction along the long axis 222 of the acetabular cup 202. Hence, Figure 8 shows the plane generally perpendicular to the long axis 222 of the pelvic cup 202. From Figure 8, an anteversion angle 224 may be defined as the angle subtended between the plane 226 of the mouth of the acetabular cup and a plane 228 perpendicular to the anterior
15 acetabular plane 212. Hence, as illustrated in Figure 8, the acetabulum or acetabular cup 202 has an anteversion angle 224 of approximately 20° .

Hence, as illustrated in the perspective view of the pelvis 200 in Figure 9, the acetabulum or acetabular cup 202 has an orientation corresponding to an inclination of 40° and an
20 anteversion of 20° . These angles may be referred to as radiographic angles as they are based on the APP view of the pelvis illustrated in Figure 5 and which is the view of the pelvis typically radiographically imaged or X-rayed and which images are often used by surgeons pre-, intra- and/or post operatively to assess acetabular orientation.

25 With reference to Figures 10 to 11, there are shown various different views of a right hip joint 300 formed by femur 100 and pelvis 200. In particular, Figure 10 shows a coronal view in the anterior to the posterior direction (generally herein the AP direction), similar to Figures 1 and 5 combined. In Figure 10, the femur has been placed in an anatomical position as described in greater detail below. Figure 11 shows a partial section along line
30 C-C of Figure 10 and viewed in a direction along the inclination axis 222 of the acetabular cup 202. Hence, the plane of Figure 11 is generally perpendicular to the direction of the inclination axis 222 of the acetabular cup.

As illustrated in Figure 11, the acetabular cup 202 has an anteversion angle 224 of 20° in the plane perpendicular to the inclination axis 222 of the acetabulum. Figure 11 also illustrates the femoral anteversion angle 230 in the plane perpendicular to the inclination axis of the acetabulum and being defined by the angle 230 subtended in that plane by the femoral neck axis 106 and the anterior pelvic plane 212. As illustrated in Figure 11, the apparent femoral anteversion angle 230 is approximately 11° .

Hence, as can be seen the overall geometry of the hip joint arises from the orientation of the acetabulum relative to the pelvis and also the orientation of the femoral neck relative to the femur. In the illustrated example, the overall or combined anteversion of the hip joint 200 shown in Figures 10 and 11 is the combination of the acetabular anteversion, about 20° , and the amount of femoral anteversion projected into the same plane, which in this example is approximately 11° . Hence, the combined anteversion of the hip joint 300 in this plane is about 31° .

However, in practice, when surgeons talk about a combined anteversion of about 35° , this may be arrived at by adding absolute values of angles in different planes, 15° anteversion of the neck relative to the femur in a first plane and 20° anteversion of the acetabulum relative to the pelvis in a second, different plane, to give approximately 35° . In practice, the combined anteversion is assumed to be in the range of approximately 30° to 40° , as being typically greater than 30° and less than 40° , and that any measurement or assessment is likely to be accurate to plus or minus a few degrees anyway and so measurement of the angles in different, non-parallel planes is not crucial.

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Herein, combined anteversion may refer, depending on the context, to the general idea that the anteversion of a hip joint is the combined effect of the degree of anteversion of the femoral neck relative to the femur and also the degree of anteversion of the acetabulum relative to the pelvis. More specifically, for non-extreme cases, combined anteversion may also refer to a general rule of thumb that the sum of the acetabular anteversion and the femoral anteversion, measured in the same plane, should have a certain value, for example approximately 35° . Hence, if a low value of one occurs, then

the other can be increased (or vice versa) in order to bring the combined anteversion closer to this target value.

While there can be a reasonable degree of adjustment of the orientation of the acetabular cup in the reamed acetabulum, there is less freedom to vary the orientation of the femoral stem. This is because once the proximal part of the femur has been resected and the intramedullary canal reamed or otherwise prepared, there is little remaining bone stock. Hence, there is little freedom in how the surgeon can orient the stem in order to adjust the version of the neck. Hence, in some surgical approaches, a “stem first” approach may be used in which the stem component’s position and orientation are determined first. Then, based on the position and orientation of the stem component, the position and/or orientation of the cup may be adjusted particularly as there is greater flexibility in the orientation of the cup within the acetabulum.

With reference to Figure 12 there is shown a perspective exploded view of an assembly 400 including an inserter instrument 410, an acetabular cup 440, a femoral head 450, a femoral neck 460 and a femoral insert or component 470. In the illustrated embodiment, the acetabular cup is a prosthetic acetabular cup, but in other embodiments may also be a trial acetabular cup. Also, the acetabular cup 440 may be an acetabular shell and either a prosthetic acetabular shell or a trial acetabular shell. The femoral head 450 is a trial femoral head, but in other embodiments may also be a prosthetic femoral head. The femoral neck 460 is a trial femoral neck, but in other embodiments may be a prosthetic femoral neck either attached to or a part of a femoral stem implant or prosthesis. The femoral insert or component 470 is a femoral broach, but in other embodiments may be a femoral reamer or other femoral cutting tool or a femoral stem, including a trial femoral stem or a prosthetic femoral stem.

Various embodiments of the femoral head 450 are described in greater detail below. The femoral head alone is also an aspect of the invention, but its use as part of the assembly 400 as an aspect of the invention will be described first. Generally speaking the femoral head includes at least one indicia which provides a visual alignment guide which can be used to visually assess the anteversion of an acetabular cup and hence the combined

anteversion of a corresponding hip joint of a patient. The indicia 452 may also be used as a visual alignment guide to assess visually the inclination of the acetabular cup relative to the patient's pelvis.

5 As illustrated in Figure 12, the femoral head has a generally spherical outer bearing surface and the indicia may be in form of a extending around a great circle of the corresponding sphere. The femoral head 450 defines an internal cavity extending generally along the polar axis of the trial head 450 and generally perpendicular to the flat distal or rear face 454 of the femoral head 450. The cavity is configured and dimensioned
 10 to receive a taper 462 at a free end of a neck shaft 464 of the femoral neck 460. Hence, in use the femoral head may be releasably attached to the neck 460 by the interference or friction fit provided by the taper 462 when received in the femoral head cavity. When so assembled, the polar axis of the head is generally coincident with a neck axis which extends longitudinally along the shaft 464 of the neck.

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The indicium 452 is not perpendicular to the polar axis of the head or the neck axis. Rather, the indicium is tilted by an angle corresponding to an acetabular cup orientation in the pelvis corresponding to a target combined anteversion of the hip joint when the patient's hip joint is placed in a preselected position. The preselected position may be an
 20 anatomical position as described in greater detail below. For the anatomical position, and for a target combined anteversion for the hip joint of approximately 35°, then the indicium is tilted so as to subtend an acute angle of approximately 35° with the plane of the distal face 454 of the femoral head. Equivalently, the indicium subtends an acute angle of approximately 55° with the polar axis of the head. The position of the indicium
 25 about the polar axis of the trial head is also configured to correspond to a target inclination of the acetabular cup relative to the pelvis of approximately 40°.

A base or inferior part 466 of the trial neck 460 includes a male feature 466 and a female feature (not visible) and which are arranged and dimensioned to mate with corresponding
 30 female (not visible) and male 472 features on an upper or superior face of the femoral broach 470. These features allow the trial head to be releasably attached to the femoral broach and also help to ensure that the trial head is mounted on the femoral broach with

the correct orientation. The male 472 and female features of the femoral broach 470 also allow a broach handle to be releasably attached to the femoral broach so that a user can use the broach to prepare the intramedullary canal of the patient's femur.

- 5 The inserter instrument 410 generally includes a handle 412 at a proximal end, an impaction head 414 at a distal end and a body 416 extending between them. As best illustrated in Figures 13, 14 and 15, the body 416 includes a handle portion 418 which extends into the handle and which may include a handle material 420 to provide increased grip. A proximal most end surface 420 of the handle portion 418 provides a strike plate
10 against which an impaction force may be applied using a suitable tool such as a slap hammer or mallet or similar. The intermediate portion of the body 416 between the handle portion 418 and impaction head includes a first portion 422 extending at least partially transversely away from the longitudinal axis of the inserter instrument, a second portion 424 extending generally parallel to, but off set from, the longitudinal axis, and a
15 third portion 426 extending at least partially transversely back toward the longitudinal axis.

- The impaction head 414 is attached to the end of the third portion 426 and has the general form of a concave hemisphere. A threaded fastener 430 passes through a pole of the
20 impaction head 414 for releasably attaching the acetabular cup 440 using a corresponding threaded polar or apical bore (not shown) in the acetabular cup. A side wall 432 of the impaction head defines a generally hemispherical cavity 431 dimensioned to snugly receive the femoral head 450 therein in use. A rim 434 of the impaction head 414 defines a generally circular mouth of the cavity and which defines an impaction head mouth
25 plane. The impaction head is arranged such that an impaction head axis 436 passing through its pole or apex and the centre of its mouth, and hence perpendicular to the impaction head mouth plane, is coincident with a handle axis 419 extending along the centre of the handle and which between them define a longitudinal impaction axis 438 of the inserter instrument. Hence, in use, when a user imparts a force on the strike plate 420,
30 the force is transferred along the impaction axis 438 of the inserter instrument and can be transferred by the outer surface of impaction head 414 to the acetabular cup 440 when mounted on the impaction head, as illustrated in Figure 16.

Figure 16 shows a perspective view of the parts shown in Figure 12 when assembled in use. As can be seen, the acetabular cup 440 is releasably attached to the impaction head 414 of the inserter instrument 410 and such that the impaction axis of the inserter instrument also passes along the polar axis of the acetabular cup 440. The trial neck 460 is attached to the femoral broach 470 and the trial head 450 is attached to the trial neck. The trial head is received within the impaction head cavity 431 and can pivot therein.

Hence, in use, as described in greater detail below, after the patient's hip joint has been placed in a preselected position, the orientation of the trial head 450 relative to the pelvis is fixed as the femoral stem is received in the patient's femur which is held in a fixed position relative to the pelvis. The handle of the inserter instrument can then be moved by the surgeon so that the impaction head, and acetabular cup which is fixed thereon, can pivot about the trial head which acts as the ball of a ball and socket joint (the socket being provided by the impaction head cavity). The surgeon can move the handle, until the indicium 452 on the femoral head becomes visible and then continue to move the handle until the plane of the mouth of the impaction head, and the plane of the mouth of the acetabular cup, are generally parallel with the plane of the indicium, which may be visually assessed by the indicium becoming generally aligned with the rim 433 of the of the impaction head. Hence, the handle of the impaction instrument is used like a lever to adjust the orientation of the acetabular cup relative to the pelvis until the indicium indicates that the orientation of the acetabular cup corresponds to that needed for a target combined anteversion for the hip, arising from that cup orientation and the orientation that the femoral broach 470 has in the patient's femur, such as approximately 35° and also a target inclination of approximately 40°. The surgeon can then impact the insertion instrument so as to implant the cup at that orientation.

Before describing surgical methods of use of the inserter instrument 410 in greater detail, various embodiments of the femoral head 450 will be described with reference to Figures 17 to 20. As noted above the trial femoral heads 450 are themselves an aspect of the invention and can be used in in other surgical methods which are also aspects of the invention.

With reference to Figures 17A to 17F there are shown various views of a first embodiment of a trial femoral head 510 corresponding generally to femoral head 450.

Figure 17A shows a plan view from above along a trial head axis, Figure 17B shows a
5 side elevation in a generally anterior-posterior direction, Figure 17C shows a cross sectional side elevation along the line A-A' of Figure 17B, Figure 17D shows a side elevation in a generally medial-lateral direction, Figure 17E shows a cross sectional side elevation along the line B-B' of Figure 17D, and Figure 17F shows a plan view from below along the trial head axis.

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As illustrated in Figure 17A, the trial femoral head 510 has a generally truncated spherical form and inner walls define a trial femoral head cavity 512 extending along the trial head axis 514 and configured to receive a taper 462 of a femoral neck 460. A channel 516 also extends along the trial head axis 514 from an inner end face of the cavity 512 and to
15 the outer articulating surface 518 of the trial femoral head. Channel 516 prevents an air-lock forming when the head is mounted on the neck and also facilitates cleaning of the head after use.

An upper or superior part of the articulating surface may bear at least a first indicium 520
20 indicating the size or diameter of the trial femoral head, e.g. 36mm, and also at least a second indicium 522 indicating the offset of the centre of rotation of the trial femoral head, along the neck axis, e.g. +5mm, that the cavity 512 of the trial femoral head is configured to produce.

25 As best illustrated by cross sections 17C and 17E, the trial femoral head consists substantially entirely of a first part 524 and a second part 526. The second part 526 provides the majority of the body and core of the trial femoral head, defines the cavity 512 therein, and also provides a lower or inferior portion 528 of the articulating surface 518. The first part 5124 is mounted on the second part 526 and provides largely just the
30 upper or superior portion 530 of the articulating surface 518. The interface between the first part and the second part at the articulating surface provides the indicium 532 used to visually assess orientation of the acetabular cup and corresponds to indicium 452 in

Figure 12. In particular, the first part 524 and the second part 526 have different colours which are high contrast, e.g., black and white, blue and white, blue and yellow, green and white, green and yellow, black and yellow, red and white, red and yellow, for example, and hence a highly visible indicium is provided by the interface between the first and
 5 second parts.

The first and second parts may be made from any suitable biocompatible material including various plastics and polymers. Suitable materials include, for example, a polyphenylsulphone material, such as that provided under the trade mark RADEL,
 10 Polyoxymethylene (POM) or Polyacetal. The trial femoral head may also be made from PEEK/PAEK, either glass filled or otherwise. Also, single use versions could be made from Nylon, POM, Polypropylene, polyarylamide (PARA), acrylonitrilebutadienestyrene (ABS) or similar. Various biocompatible materials such as fillers or additives may be used to provide the different colours. For example Titanium Dioxide may be used for
 15 white and Vegetable Carbon Black may be used for black. The trial femoral head 510 can be made using various manufacturing techniques such as over moulding the first part on the second part in a two-step moulding process, a two-part press-fit process or a glued assembly of first and second parts using a medical grade adhesive.

20 As best illustrated in Figure 17B the indicium 532 provided by the interface between the first and second differently coloured parts is tilted and generally subtends an acute angle 534 of approximately 35° degrees with the plane of the distal face 536 of the trial femoral head. When appropriately oriented relative to the pelvis, this angle corresponds to a cup orientation giving rise to a combined hip anteversion of 35°.

25 As best illustrated in Figure 17D and 17A, the indicium also has a specific orientation relative to the polar axis of the trial femoral head. As illustrated in Figure 17F, the distal or under surface 536 of the trial femoral head bears a first orientation indicium 538, "L", and a second orientation indicium 540, "R". The "L" and the "R" are placed generally on
 30 an axis which extends generally in the inferior-superior direction in use. When used for a left hand hip joint, then the trial femoral head 510 should be placed on the neck with the "L" symbol at the superior surface of the neck. When used for a right hand hip joint,

then the trial femoral head 510 should be placed on the neck with the “R” symbol at the superior surface of the neck. The arrangement of “L” and “R” separated by 180° shown in Figure 17F is suitable for a stem-neck angle 128 of 135°.

- 5 As can be seen in the Figures the indicium 532 extends around a great-circle of the spherical articulating surface 518 and is tilted by about 35° and about an axis extending generally in the same direction as the axis of the L and R indicia and which is into and perpendicular to the plane of Figure 17B. Hence the highpoint 542 and the low point 544 of the indicium define an axis extending generally transverse to the tile axis and generally
- 10 in the anterior-posterior direction in use. This orientation of the indicium about the polar axis means that the plane defined by the indicium will be parallel to the plane of the mouth of the acetabular cup when the acetabular cup also an inclination of about 40° relative to the pelvis, as well as the target anteversion, when the trial femoral head is appropriately positioned as described above. Hence, the indicium 532 can be used to
- 15 assess both cup anteversion and cup inclination.

With reference to Figures 18A to 18F there are shown various views of a second embodiment of a trial femoral head 550 corresponding generally to femoral head 450 and generally similar to the first embodiment 510. The second embodiment differs in that the

20 indicium 552 which acts as the visual alignment guide has two parts. A first part 554 is tilted to subtend an acute angle of approximately 35 ° relative to the distal face 558 of the trial head and extends approximately half way around the polar axis of the trial femoral head. A second part 556 is tilted to subtend an acute angle of approximately 25 ° relative to the distal face 558 of the trial head and extends approximately half way around the

25 polar axis of the trial femoral head. Again, the trial femoral head is made from essential two parts of contrasting colour such that the interface between the two parts at the articulating surface provides the indicium. Similarly to the first embodiment, the first part 554 can be used to assess an acetabular cup orientation compared to a target combined anteversion of 35° and an inclination of 40°. This part is particularly suitable for use in a

30 posterior surgical approach.

However, the second part 556 of the indicium can be used to assess an acetabular cup position compared to a target combined anteversion of substantially 25° and an inclination of substantially 40° . This second part 556 of the indicium is particularly suitable for use in an anterior surgical approach.

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In a posterior approach, because the incision passes through posterior muscle groups, it is easier for the hip to dislocate towards the posterior. Hence, surgeons tend to put in plenty of anteversion so that the cup orientation can also be used to prevent posterior dislocation. With an anterior approach, the posterior muscle groups are left intact so less anteversion
10 tends to be needed. A little less anteversion may give a better range of motion without any loss of stability in the anterior approach.

With reference to Figures 18A to 18F there are shown various views of a second embodiment of a trial femoral head 550 corresponding generally to femoral head 450 and
15 generally similar to the first embodiment 510. The second embodiment differs in that the indicium 552 which acts as the visual alignment guide has two parts. A first part 554 is tilted to subtend an acute angle of approximately 35° relative to the distal face 558 of the trial head and extends approximately half way around the polar axis of the trial femoral head. A second part 556 is tilted to subtend an acute angle of approximately 25° relative
20 to the distal face 558 of the trial head and extends approximately half way around the polar axis of the trial femoral head. Again, the trial femoral head is made from essential two parts of contrasting colour such that the interface between the two parts at the articulating surface provides the indicium. Similarly to the first embodiment, the first part 554 can be used to assess an acetabular cup orientation compared to a target combined
25 anteversion of 35° and an inclination of 40° . This part is particularly suitable for use in a posterior surgical approach.

With reference to Figures 19A to 19F there are shown various views of a third embodiment of a trial femoral head 560 corresponding generally to femoral head 450 and
30 generally similar to the first embodiment 510. The third embodiment differs in that the indicium 562 which acts as the visual alignment guide has a noticeable width and is in the form of a coloured band rather than simply a line. The indicium 562 is tilted to subtend

an acute angle of approximately 35° relative to the distal face 564 of the trial head. However, the indicium has a width of approximately 4mm, for the 36mm diameter trial head 560 illustrated. Using a band of colour can improve the ease and accuracy with which a user can visually assess the orientation of the acetabular cup. If the indicium is too narrow, then it may be obscured by the rim or the liner or impaction head or material at the surgical site. However, if the indicium is too broad, then the indicium can correspond to too broad a range of angles of the acetabular cup and thereby reduce the accuracy of assessment of the cup orientation. A width of between about 2mm and 6mm has been found to provide a reasonable balance between these competing factors for a typical range of trial head diameters and a width of about 4mm has been found to be particularly suitable.

Again, the trial femoral head is made from essentially two parts of contrasting colour. The centre or core of the head may be made from a first material of a first colour and then a second material of a second colour can be over moulded to form the articulating outer surface and then a band of the second material can be removed to reveal the underlying material. Alternatively, the second material can be over moulded to provide the articulating surface everywhere other than the band so that the central core is already exposed. Hence, the interfaces between the two parts of differing colours provides the indicium. Similarly to the first embodiment, the indicium 562 can be used to assess an acetabular cup orientation compared to a target combined anteversion of 35° and an inclination of 40° , with the 4mm band providing approximately several degrees of variation away from 35° . For example, for a 40mm diameter head, a 4mm band would provide approximately $\pm 6^\circ$ and for a 28mm diameter head a 4mm band would provide approximately $\pm 8^\circ$.

In other embodiments the visual alignment guide indicium of the trial femoral heads 510, 550, 560, may additionally, or alternatively include an at least partially x-ray opaque material so that the indicium can be captured in an x-ray image. For example a metal wire, ring, film, filament or particles may also be provided extending around some or all of the same or an adjacent great circle as the indicium. Hence, an intra-operative x-ray of

the assembly and/or trial femoral head can be used to assess and/or record the corresponding acetabular cup position for that trial head orientation.

Figure 20 shows a perspective view of a fourth embodiment of a trial femoral head 570 generally similar to the first embodiment 510. However, the fourth embodiment includes a first indicium 572 providing a first visual and tactile alignment guide for a right hand hip and a second indicium 574 providing a visual and tactile alignment guide 574 for a left hand hip. Each indicium 572, 574 extends around a respective great circle of the spherical articulating surface 576 of the trial femoral head and each of which is tilted to subtend an acute angle of approximately 35° with the plane of distal end face 578 of the trial femoral head 570. Each indicium is in the form of a respective groove 580, 582 defined in the outer surface of the trial femoral head and a respective ring, 584, 586 received in a corresponding one of the grooves. The ring is not complete and has a generally C-shape. The ring is made of a compliant and resilient material, so that the ring can be received in, and compressed into, its groove in use. Each ring may be made from a suitable biocompatible material, and is preferably made from an at least partially x-ray opaque material. For example, each ring may be made from a surgical grade stainless steel.

When used with the inserter instrument 410 illustrated in Figure 12, the rings 584, 586 can provide some tactile or haptic feedback to the user, when they engage with the rim 433 of the impaction head 414. Hence, rings 584, 586 can provide both visual and haptic feedback to a user which can be beneficial when the surgical site has limited visual access.

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Trial femoral head 570 may also be used with a further embodiment of the inserter instrument. Figure 21 shows a cross sectional view of an impactor head 590 of a further embodiment of the inserter instrument and which is generally similar to impactor head 414 of the first embodiment. However, impactor head 590 differs in that its side wall 592 defines a greater than hemispherical impaction head cavity 594. An inner surface of the impaction head defines a groove 596 extending around the equator of a sphere corresponding to the cavity 594. The cavity 594 is dimensioned to snugly receive the

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trial femoral head 570 such that cavity 594 and trial femoral head 570 have generally the same diameter. Impaction head groove 592 is arranged to cooperate with either of rings 584, 586 when the trial head is received in cavity 594 in use as illustrated in Figure 22.

- 5 Also, impaction head 590 includes a clip 598 at its pole to provide a releasably attachment mechanism for releasably attaching an acetabular cup, instead of a screw fastener.

As illustrated in Figure 22, when trial head 570 is mounted on trial neck taper 462 and
10 received in the impaction head cavity 594 in use, then rings 584 and 586 (586 has been omitted from Figure 22 for the sake of clarity) are compressed into their respective groove and the impaction head can be pivoted about the trial femoral head. When the inserter instrument has been moved into the correct position, then the appropriate ring for that hip, e.g. ring 584 in Figure 22, will be parallel to the plane of the mouth of the cup,
15 and also the plane of the mouth of the impaction head cavity. Hence, the resilient ring 584 can release from its groove 580 and engage with the groove 596 in the inner surface of the impaction head cavity and provide some resistance to further movement of the handle of the inserted instrument. Hence, when a user can feel the ring 584 engaging with groove 596 thereby providing haptic feedback that the acetabular cup has now been
20 correctly oriented. By applying a greater force to the handle of the inserter, the ring 584 can be forced back into its groove 580, if required. Hence, trial head 570 can provide both haptic and visual feedback to the user for assessing cup orientation.

With reference to Figure 23 there is shown a flow chart illustrating a hip replacement
25 surgical procedure 600 in which the inserter instrument 410 and instrumentation assembly 400 may be used to implant a prosthetic acetabular cup. As will be apparent to a person of ordinary skill in the art from the following, the order of some of the steps is not relevant, but the order of some of the steps may be relevant as will become apparent from the following description. Also, some of the described steps may be optional, and may be
30 omitted, depending on a particular workflow that a surgeon may prefer. Also, some of the details of the procedure and steps are omitted for the sake of clarity or explanation of the present apparatus.

At 602, the femur is prepared in a generally conventional manner, which may include resecting the native femoral neck and head. Then, at 604, a cavity is formed generally along the intramedullary canal which will later be used to accept a femoral stem implant.

5 Preparation of the cavity typically includes the use of one or more brooches and / or rasps. When a final sized broach, e.g. broach 470, has been used, then a broach handle is removed and the broach 470 is left in the femur. At 606, the acetabulum is prepared in a generally conventional manner which may include removing soft tissues and forming a hemispherical cavity within the native acetabulum using an acetabular grater and/or

10 reamer. After the acetabulum has been prepared, then at 608, the instrumentation 400 is assembled. The acetabular cup implant 440, i.e. the final cup rather than a trial cup, is attached to the impaction head 414. The trial neck 460 is attached to the femoral broach 470 in the patient's femur and the trial femoral head 450 is attached to the neck 460 with the correct orientation for the type of hip, i.e. left or right hip. The inserter 410 is used

15 generally to place the acetabular cup 440 in the patient's prepared acetabulum and may be manually oriented in the generally appropriate orientation relative to the patient's pelvis, but not yet impacted in position. Then at 610, the trial hip joint is reduced by introducing the trial femoral head 450 into the cavity 431 of the impaction head 414.

20 Then at 612, the patient's pelvis and femur may be manipulated and positioned so as to place the patient's hip joint into a preselected position. In particular, once the patient's pelvis has been correctly aligned, the patient's femur is moved so as to place the patient's hip joint in the anatomical position. In the anatomical position, the patient's leg is placed with the femur in 0° of flexion / extension, 0° of adduction / abduction and 0° of internal /

25 external rotation. Assuming that the pelvis on the operating table has taken up an approximately neutral amount of pelvic tilt, then the anatomical position can be achieved by comparing the following factors. The long axis of the leg relative to the longitudinal axis of the patient can be adjusted by pulling lightly on the lower limb to pull the leg into full extension. If an anterior approach is being used, with the patient supine, then the leg

30 will naturally rest in full extension. Zero abduction / adduction of the legs can be achieved by placing both lower legs (tibia from knee to ankle) parallel and almost touching. An internal / external rotation angle of 0° can be checked using the epicondyle

- axis of the knee relative to the transverse axis of the pelvis. If the pelvis is level (supine) or vertical (in a lateral decubitus approach) on the table, then the epicondyle axis can be compared to the table. If a posterior approach is being used, with the patient lateral, then the tibia can be flexed 90° to provide a more discernible indication of the femoral
- 5 articular axis which would indicate any internal / external rotation of the femur. Hence, depending on the orientation of the patient on the table, the patient's legs may be placed in appropriate positions to provide 0° of flexion / extension, 0° of abduction / adduction and 0° of internal / external rotation of the femur with respect to the pelvis.
- 10 As the trial femoral head is connected to the patient's femur via the neck 460 and femoral broach 470, the trial femoral head rotates as the femur is moved until the femur has been correctly positioned at 612. The femur is then not moved relative to the pelvis and hence the orientation of the trial femoral head does not vary and the indicium 452 then provides a fixed datum against which the acetabular cup orientation can be assessed. At 614, the
- 15 surgeon can use the handle 412 of the inserter 410 to pivot the acetabular cup within the acetabulum with the trial femoral head 450 providing a fixed ball around which the socket 431 of the impaction head can pivot. The surgeon can view the trial head to see whether the rim 431 of the impaction head 414 is generally aligned with the indicium 452 on the trial head or not yet. Hence, indicium 452 provides a visual alignment guide which
- 20 provides real time visual feedback to the surgeon on how far the current acetabular cup orientation is away from a target orientation. When the fourth embodiment of the trial head 570 is used, or when a ring is also used with any of the first to third embodiments, then some haptic feedback can also be provided by the ring impinging on the rim 431 of the impaction head.
- 25
- When the surgeon determines that the current acetabular cup orientation is sufficiently close to the target orientation, or any offset or variation from the target orientation that the surgeon may decide is appropriate based on their experience, expertise or other factors, then at 616, the surgeon can implant the acetabular cup by hitting strike plate 420 with a
- 30 mallet, slap hammer or similar. The impaction axis of the instrumentation 438 will be generally perpendicular to the planes of the indicium, mouth of the impaction head and

mouth of the acetabular cup, which are all parallel in this configuration, and hence should implant the cup at or close to the intended orientation.

The assembly of instrumentation may then be disassembled. The initial trial joint is
 5 disassembled by removing the trial femoral head 450 from the impaction head 414 cavity and then the inserter instrument is detached from the acetabular cup which is left implanted in the acetabulum. Then at 618 a trial liner may optionally be added to the acetabular cup, if used. In other embodiments, no trial liner may be used. Further, at 618,
 10 in embodiments in which the femoral component does not include a trial neck, but some other attachment mechanism for attaching the femoral component to the inserter, then a trial neck may be attached to the femur. If a liner is not used, then a larger diameter trial femoral head may be attached at 618 or if a liner is used, then the same trial femoral head 450 may be used. The trial joint may then be reduced again at 620 and the trial joint may be assessed and optionally a range of motion assessment may be carried out and / or other
 15 assessments of the trial joint carried out. At 622, the trial components may be removed, and the broach 470. At 624, any trial liner may be removed and a final liner may be introduced into the implanted acetabular cup depending on the cup system being used. The femoral stem and prosthetic head may be implanted at 626 into the femur. Finally, the final joint reduction may be carried out at step 628 after which the surgical procedure
 20 is generally finished and ends in a conventional manner.

With reference to Figure 24 there is shown a flow chart illustrating a hip replacement surgical procedure 700 in which the trial femoral head is used to assess acetabular cup placement, but not to implant the acetabular cup. Hence, in this approach the inserter
 25 instrument is not used, but rather the trial femoral head is used to provide an intra-operative guide to the surgeon as to the orientation of an acetabular cup, either a trial or an implant, compared to a target orientation.

As will be apparent to a person of ordinary skill in the art from the following, the order of
 30 some of the steps is not relevant, but the order of some of the steps may be relevant as will become apparent from the following description. Also, some of the described steps may be optional, and may be omitted, depending on a particular workflow that a surgeon

may prefer. Also, some of the details of the procedure and steps are omitted for the sake of clarity or explanation of the present apparatus. Further some of the steps are similar to those described above in relation to Figure 23 and so will not be described again in detail.

- 5 Steps 702 to 706 are generally similar to steps 602 to 606. At 708, the prosthetic acetabular cup may be implanted using a conventional cup inserter and any liner, which may be a trial liner or a final liner, is inserted if used. At 710, the trial femoral head, such as any of the embodiments 450, 510, 550, 560, 570 described herein, is attached to the trial neck 460 which is attached to the femoral broach 470. The trial joint is then reduced
10 at 710 by introducing the trial femoral head into the acetabular cup and liner if present. At 712, the trial joint is placed in the anatomical position as described above. The surgeon can then visually assess the acetabular cup orientation by visually inspecting the trial joint to see how far the plane of the mouth of the cup or liner is from the plane defined by the indicium on the trial head. If they are generally parallel, then this indicates
15 to the surgeon that the acetabular cup has been placed with an orientation close to 40° of inclination and an anteversion corresponding to a combined anteversion of close to 35°. The less parallel the planes then the greater the divergence of the cup orientation from these target orientation values.
- 20 Also, optionally at 712, when the trial head includes one or more rings similar to the fourth embodiment 570, then the surgeon can move the femur away from the anatomical position until they feel impingement of the ring on the rim of the cup or liner. This can provide a further indication, via haptic feedback, as to how far from the target orientation the cup has been placed.
25 Hence, at 712, the surgeon can assess the acetabular cup orientation in a more reliable manner particularly as the anatomical position is easier to reliably and reproducibly achieve.
- 30 Optionally at 714, the surgeon may capture an x-ray or fluoroscopic image of the trial hip joint and in particular an anterior-posterior plane image of the patient's hip and including the trial femoral head. In embodiments in which the indicium includes an x-ray opaque

material, the indicium will also be displayed in the APP x-ray image as well as the acetabular cup. For example, Figure 25 shows an APP x-ray image 730 of a left hip in which the rim 734 of the cup 732 can be seen as well as an image 738 of the first ring 584 and an image 740 of the second ring 586 of the trial head. Surgeon's commonly use an

5 APP image of the cup to help assess the orientation of the cup as the variations in the shape of the rim 734 of the cup from circular in the APP image can be measured to determine the anteversion and inclination of the cup. As the indicium has been positioned with the target orientation an x-ray image of the indicium will exhibit a similar variation to that the rim of the cup should have and can facilitate further assessment of the cup

10 orientation from the x-ray image additionally or alternatively to measurements of the cup image. Hence, the surgeon can compare the shape of the rim of the cup 734 with the shape of the ring on the trial head 740 in the x-ray image to further assess how close the cup is to the target anteversion angle as indicated by the shape of the image 740 of the ring 586. In Figure 25, the cup has been placed with an abduction of approximately 43°

15 and an anteversion of approximately 25° and hence rim 734 is not parallel to ring 740 (which corresponds to an abduction of approximately 40° and an anteversion of approximately 35°).

A step similar to step 714 may optionally be included in method 600 in some

20 embodiments.

Hence, the surgeon can assess the acetabular cup orientation in a greater number of ways which may be particularly useful when visual access to the site is limited or it is otherwise difficult to inspect the trial joint visually. The surgeon may use this assessment purely for

25 information purposes or may use this assessment to determine that some further action should be considered or is required, such as removing and repositioning the cup, or changing or adjusting other parts of the implant system, if possible, if the cup orientation is too far from the target orientation.

30 At 716 the trial joint can be further assessed if required and, for example, a range of motion assessment may optionally be carried out. At 718 the trial components and broach

470 are removed and at 720 the prosthetic femoral stem and prosthetic femoral head are implanted before reducing the final joint at 722.

Hence, the invention improves the reliability with which a prosthetic acetabular cup may
5 be implanted in a patient with a target orientation relative to the pelvis and in particular with a specific anteversion.

In this specification, example embodiments have been presented as particular combinations of features. However, a person of ordinary skill in the art would understand
10 that many other embodiments may be practiced which include a different combination of features, including fewer features or a greater number of features. It is intended that the following claims cover all possible embodiments.

Any instructions and/or flowchart steps may be carried out in any order, unless a specific
15 order is explicitly stated or would be understood to be required from the context of the description. Also, those skilled in the art will recognize that while one example method has been discussed, a variety of other differing methods are possible based on other combinations and/or orders of method steps, and are to be understood within a context provided by this detailed description.

20

While the inventions are amenable to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and described in detail. It should be understood, however, that other embodiments, beyond the specific
25 alternative embodiments falling within the scope of the appended claims are covered as well.

CLAIMS:

1. Instrumentation for implanting a prosthetic acetabular cup in an acetabulum of a patient, including:
 - 5 an inserter, comprising:
 - a handle at a proximal end of the inserter; and
 - an impaction head at a distal end of the inserter, wherein the impaction head is configured to couple with an acetabular cup to transmit an impaction force to the acetabular cup when located in an acetabulum of a patient and includes a
 - 10 formation to prevent the acetabular cup from pivoting relative to the impaction head, wherein the impaction head defines a cavity and wherein the handle and the impaction head are arranged to define an impaction axis of the inserter extending along the inserter; and
 - a femoral part attachable to a femur of the patient and including a femoral head
 - 15 bearing a visual alignment guide, and wherein the femoral head is pivotably receivable within the cavity of the impaction head to permit the impaction head to pivot relative to the femoral head, and wherein, in use, a change in orientation of the inserter causes a change of orientation of the acetabular cup within the acetabulum of the patient.
- 20 2. Instrumentation as claimed in claim 1, wherein the impaction head is releasably attachable to the acetabular cup.
3. Instrumentation as claimed in claim 2, wherein the formation releasably attaches the impaction head and acetabular cup.
- 25 4. Instrumentation as claimed in any of claims 1 to 3, wherein the impaction head has the form of a hemispherical bowl.
5. Instrumentation as claimed in claim 4, wherein the formation is positioned at a
- 30 pole of the bowl so as to engage with a polar feature of the acetabular cup.

6. Instrumentation as claimed in any preceding claim, wherein the inserter includes an intermediate portion between the handle and the impaction head and wherein the intermediate portion is offset to the impaction axis.
- 5 7. Instrumentation as claimed in any preceding claim, wherein the femoral head has a polar axis and the visual alignment guide extends along an alignment axis and wherein the alignment axis and a plane perpendicular to the polar axis subtend an acute angle corresponding to an anteversion angle of the acetabular cup resulting in a target combined
10 position.
8. Instrumentation as claimed in claim 7, wherein the acute angle is the range of 30° to 40°.
- 15 9. Instrumentation as claimed in claim 8, wherein the acute angle is 35°.
10. Instrumentation as claimed in any preceding claim, wherein the visual alignment guide comprises a first part and a second part, and wherein the first part corresponds to a first target anteversion angle of the acetabular cup for a first surgical approach and the
20 second part corresponds to a second target anteversion angle of the acetabular cup for a second surgical approach.
11. Instrumentation as claimed in any preceding claim, wherein the femoral head is a trial femoral head.
25
12. Instrumentation as claimed in any preceding claim, wherein the femoral part includes a femoral neck.
13. Instrumentation as claimed in claim 12, wherein the femoral neck has a taper and
30 the femoral head has a cavity configured to releasably receive the taper therein.

14. Instrumentation as claimed in claim 12 or 13, wherein the femoral part also includes an insert configured to be received within a cavity with the femur of the patient and wherein the insert includes an insert attachment formation by which the femoral neck is attachable to the insert.
- 5
15. Instrumentation as claimed in claim 14, wherein the insert is selected from: a femoral broach; a femoral rasp; a trial femoral stem; and a prosthetic femoral stem.
16. Instrumentation as claimed in any preceding claim, wherein the cavity has a
- 10 mouth defining an alignment plane and wherein when the femoral head is oriented with the visual alignment guide parallel to the alignment plane, the inserter is configured to orient the acetabular cup for implantation in the acetabulum of the patient with an anteversion angle corresponding to a target combined anteversion angle for the hip of the patient joint when the hip of the patient is positioned at a preselected position.
- 15
17. Instrumentation as claimed in claim 16, wherein the target combined anteversion is in the range of 30° to 40°.
18. Instrumentation as claimed in claim 17, wherein, wherein the preselected position
- 20 is the anatomical position.
19. Instrumentation as claimed in claim 18, wherein the anatomical position corresponds substantially to 0° extension/flexion of the leg of the patient, 0° abduction/adduction of the femur and 0° rotation of the femur.
- 25
20. Instrumentation as claimed in any preceding claim, wherein the visual alignment guide includes a feature of the femoral head which is proud of an articulating surface of the femoral head and which is enlargeable with a part of the impaction head to provide haptic feedback when the impaction head is aligned with the visual alignment guide.
- 30
21. Instrumentation as claimed in claim 20, wherein the feature is a ring received in groove in the articulating surface.

22. Instrumentation as claimed in claim 20 or 21, wherein the impaction head includes a female formation arranged to mate with the feature of the femoral head.
- 5 23. Instrumentation as claimed in any preceding claim, wherein the visual alignment guide includes or comprises an at least partially x-ray opaque material.
24. An assembly of the instrumentation of any preceding claim, wherein the femoral head is located within the cavity of the impaction head.
- 10 25. A method for implanting a prosthetic acetabular cup in an acetabulum of a patient using an inserter comprising a handle at a proximal end of the inserter and an impaction head at a distal end of the inserter wherein the handle and the impaction head are arranged to define an impaction axis of the inserter extending along the inserter, the method
- 15 comprising:
- coupling the impaction head to an acetabular cup to be implanted in an acetabulum of a pelvis of the patient;
 - moving a femur of the patient relative to the pelvis into an anatomical position, wherein the femur has a femoral head attached thereto including a visual alignment guide

20 and which is pivotably received within a socket of the impaction head so that the visual alignment guide corresponds to an acetabular cup orientation in the pelvis corresponding to a target combined anteversion angle for the hip joint of the patient;

 - moving the handle of the inserter to pivot the acetabular cup in the acetabulum about the femoral head to align the acetabular cup with the visual alignment guide; and

25 impacting the inserter to impart an impaction force to the acetabular cup along the impaction axis so as to implant the acetabular cup in the acetabulum.
26. The method of claim 25, wherein the anatomical position corresponds substantially to 0° extension/flexion of the leg, 0° abduction/adduction of the femur and
- 30 0° rotation of the femur.

27. The method of any of claims 25 to 26, wherein the combined anteversion angle is in the range of 15° to 45°.
28. The method of claim 27, wherein the combined anteversion angle is 35°.
- 5 29. The method of any of claims 25 to 27, wherein the femoral part is or includes a femoral neck.
30. The method of claim 29, wherein the femoral neck includes a taper at a free end
10 and wherein the femoral head is releasably attached to the taper.
31. The method of any of claim 29 or 30 and further comprising attaching the femoral neck to a femoral broach located in the femur of the patient.
- 15 32. The method of any of claims 25 to 31, wherein the impaction head is in the form of a liner or a trial liner.
33. The method of any of claims 25 to 32, wherein the impaction head is releasably attached to the acetabular cup and further comprising releasing the impaction head from
20 the acetabular cup after the impaction head has been implanted in the acetabulum.
34. The method of any of claims 25 to 33, further comprising visually inspecting the visual alignment guide to assess the current orientation of the acetabular cup in the acetabulum before impacting the acetabular cup.
- 25 35. The method of any of claims 25 to 34, further comprising using haptic feedback while moving the handle of the inserter to assess the current orientation of the acetabular cup in the acetabulum before impacting the acetabular cup.
- 30 36. A trial femoral head comprising:
a body defining a cavity therein for receiving a taper of a femoral neck;
an articulating surface; and

a visual alignment guide on the articulating surface, wherein the visual alignment guide is configured to define an acetabular cup orientation within a pelvis of a patient corresponding to a target combined anteversion for a hip of the patient when the femoral head is mounted on a femur of the patient and when the hip of the patient is placed in the
5 anatomical position.

37. The trial femoral head as claimed in claim 36, wherein the anatomical position corresponds substantially to 0° extension/flexion of the leg, 0° abduction/adduction of the femur and 0° rotation of the femur.

10

38. The trial femoral head of claims 36 or 37, wherein the target combined anteversion angle is in the range of 30° to 40°.

39. The trial femoral head of claim 38, wherein the target combined anteversion angle
15 is 35°.

40. The trial femoral head of any of claims 35 to 39, wherein the visual alignment guide is further configured to define an acetabular cup orientation within a pelvis of a patient corresponding to an inclination of 40°.

20

41. The trial femoral head as claimed in any of claims 35 to 40, wherein the visual alignment guide is formed by the interface between a first part of the trial femoral head and a second part of the trial femoral head.

25 42. The trial femoral head as claimed in claim 41, wherein the first part of the trial femoral head and the second part of the trial femoral head are different colours.

43. The trial femoral head as claimed in claim 42 wherein the different colours are high contrast.

30

44. The trial femoral head as claimed in any of claims 35 to 43, wherein the visual alignment guide is a band and wherein the band has a width of between 2mm and 6mm.

45. The trial femoral head as claimed in any of claims 35 to 44, wherein the visual alignment guide includes a first part configured to correspond to a first target combined anteversion and a second part configured to correspond to a second target combined
5 anteversion different to the first target combined anteversion.

46. The trial femoral head as claimed in any of claims 35 to 45, wherein the visual alignment guide includes a formation which is proud of the adjacent articulating surface and arranged to be engageable in use with a part of an acetabular cup or liner to provide
10 haptic feedback.

47. The trial femoral head as claimed in claim 46, wherein the formation is a ring.

48. The trial femoral head as claimed in claim 47, wherein the ring is received in a
15 groove in the articulating surface of the trial femoral head.

49. The trial femoral head as claimed in any of claims 35 to 48, wherein the visual alignment guide includes or comprises an at least partially x-ray opaque material.

20 50. A method for assessing the orientation of an acetabular cup in an acetabulum of a patient using a trial femoral head having a visual alignment guide on an articulating surface, the method comprising:

mounting the trial femoral head on a femur of the patient;

locating the trial femoral head in an acetabular cup within a prepared acetabulum
25 of the patient;

moving a femur of the patient relative to the pelvis into an anatomical position to pivot the trial femoral head relative to the acetabular cup so that the visual alignment guide corresponds to an acetabular cup orientation in the pelvis corresponding to a target combined anteversion angle for the hip joint of the patient; and

30 visually inspecting the visual alignment guide and a part of the acetabular cup to assess the orientation of the acetabular cup in the acetabulum.

51. The method of claim 50, further comprising further moving the femur and using haptic feedback while moving the femur to assess the orientation of the acetabular cup.
52. The method of claim 50 or 51, wherein the anatomical position corresponds substantially to 0° extension/flexion of the leg, 0° abduction/adduction of the femur and 0° rotation of the femur.
53. The method of any of claims 50 to 52, wherein the target combined anteversion angle is in the range of 30° to 40°.
54. The method of claim 53, wherein the target combined anteversion angle is 35°.
55. The method of any of claims 50 to 54, wherein the visual alignment guide is further configured to correspond to an acetabular cup orientation in the pelvis of the patient corresponding to an inclination of 40°.
56. The method of any of claims 50 to 55, wherein the visual alignment guide is at least partially x-ray opaque, and further comprising:
capturing an x-ray image of the hip including the acetabular cup and the visual alignment guide after moving the femur of the patient relative to the pelvis into the anatomical position.

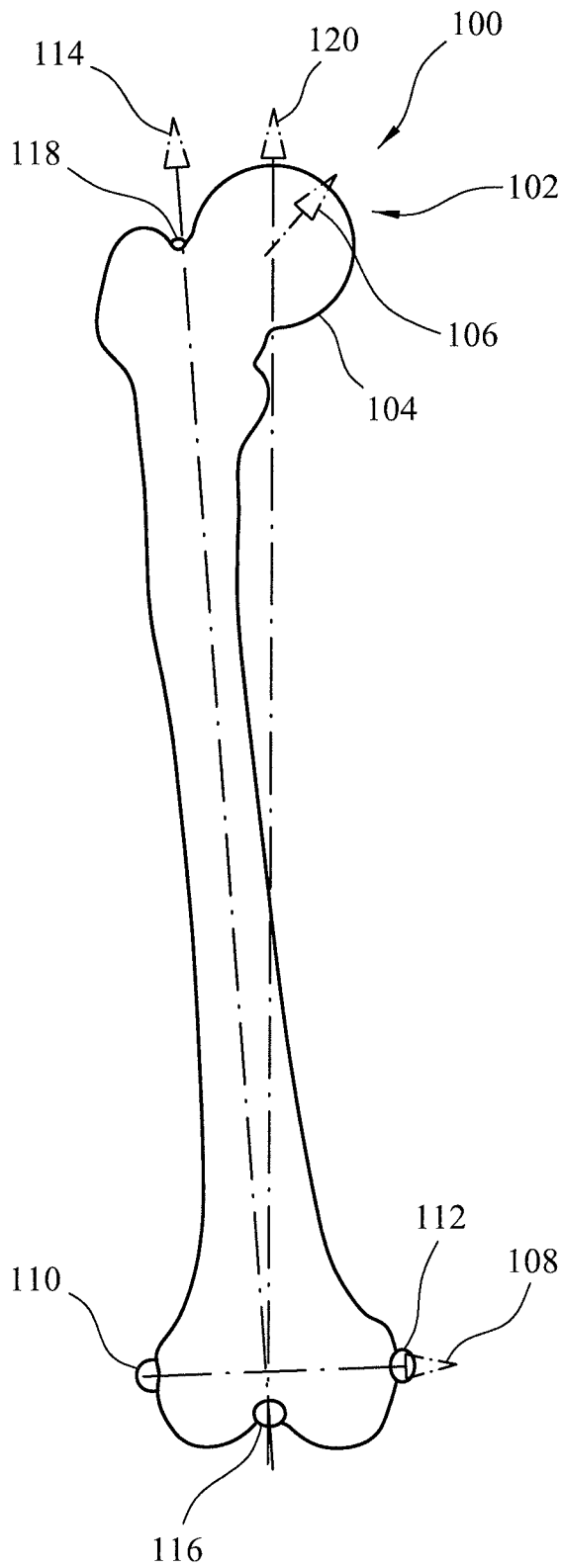


Fig. 1

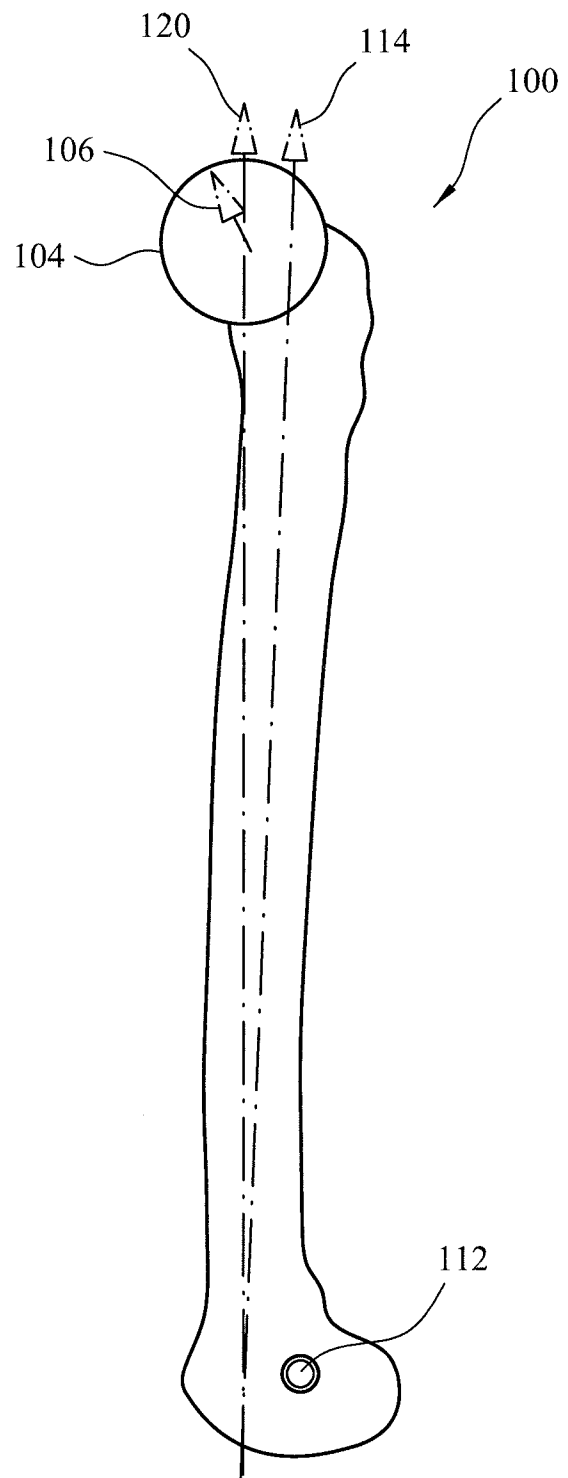


Fig. 2

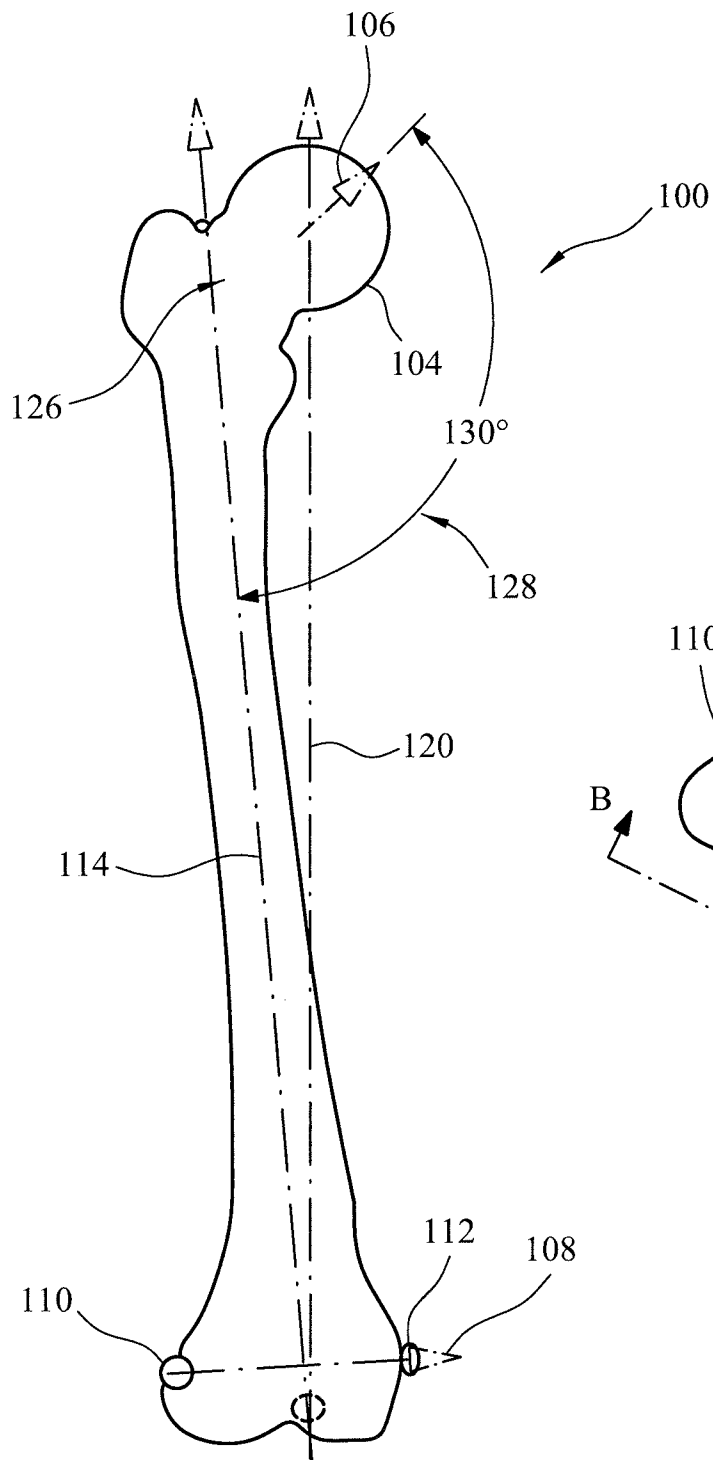


Fig. 4

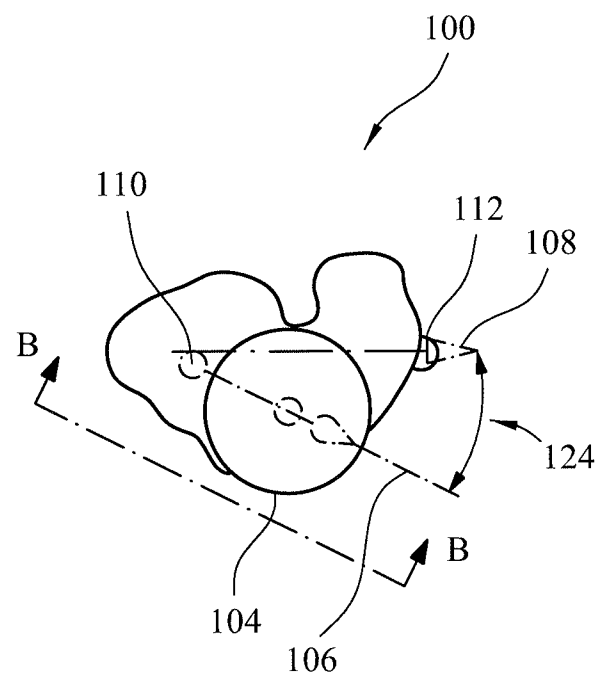


Fig. 3

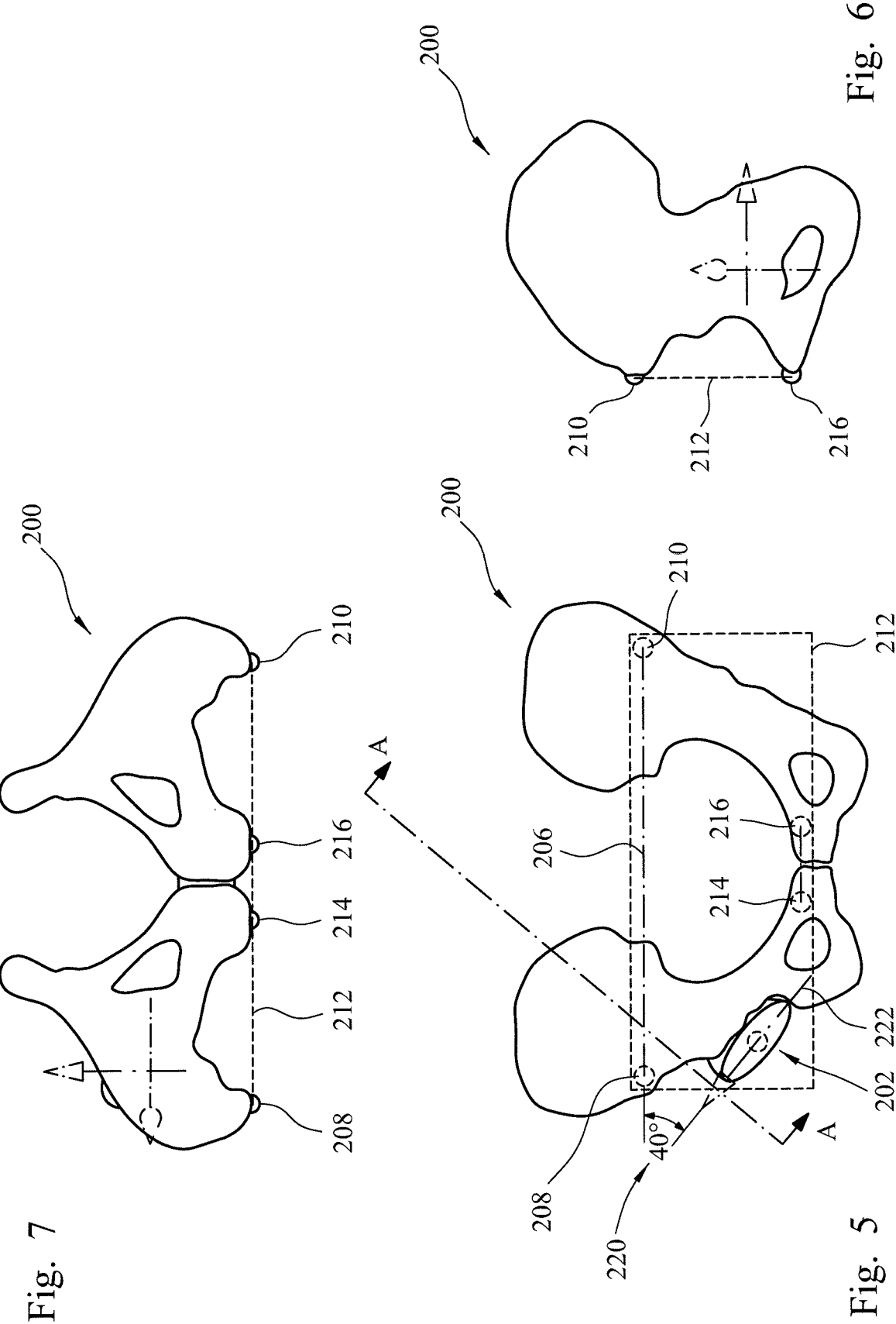


Fig. 8

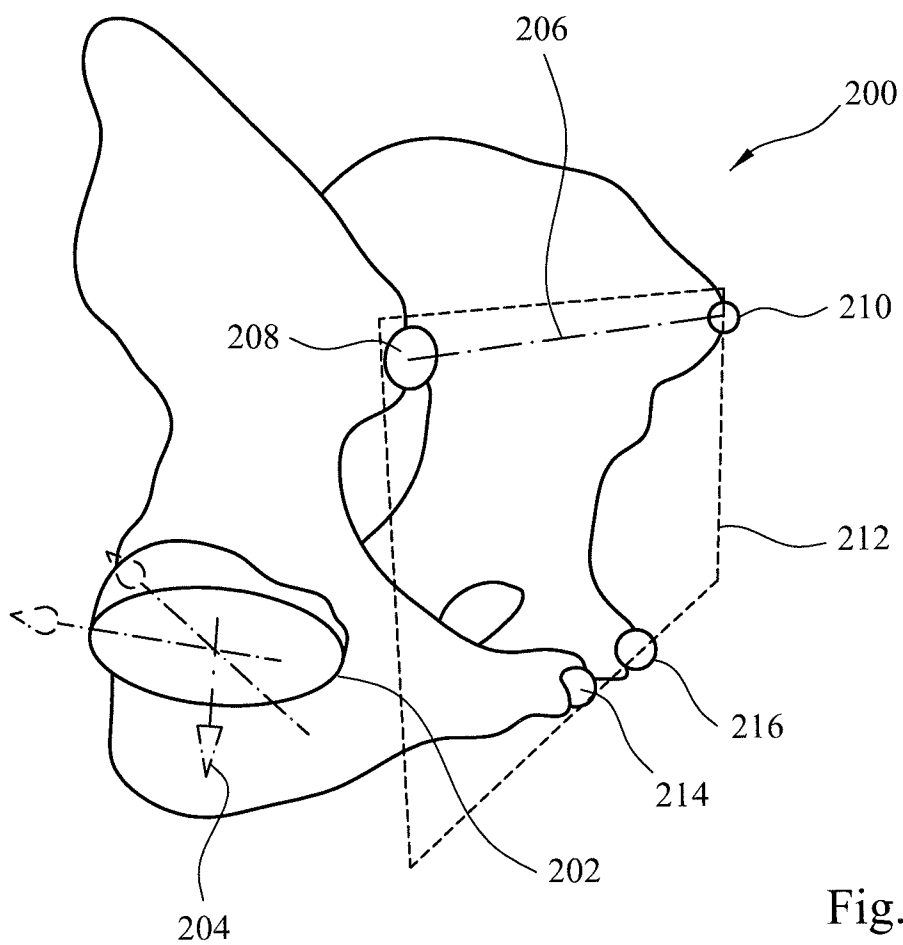
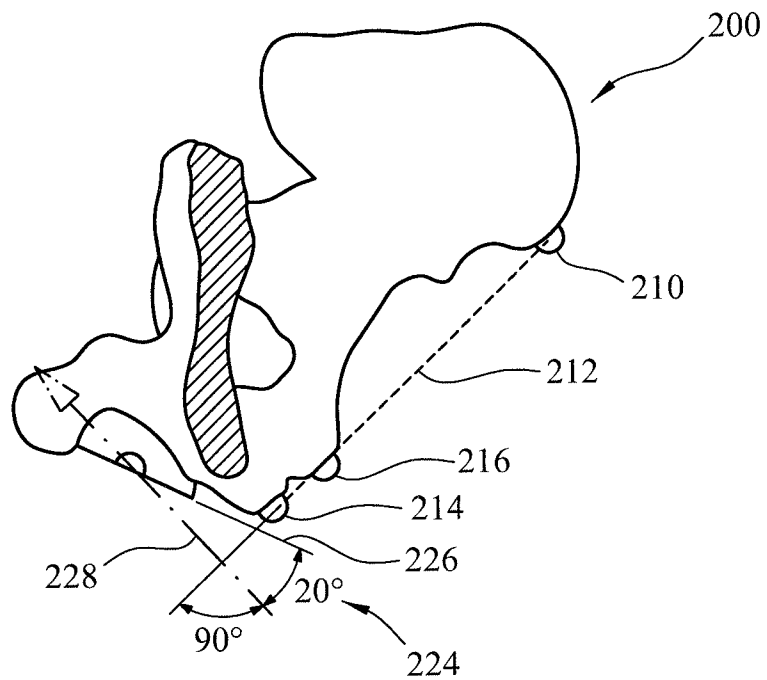


Fig. 9

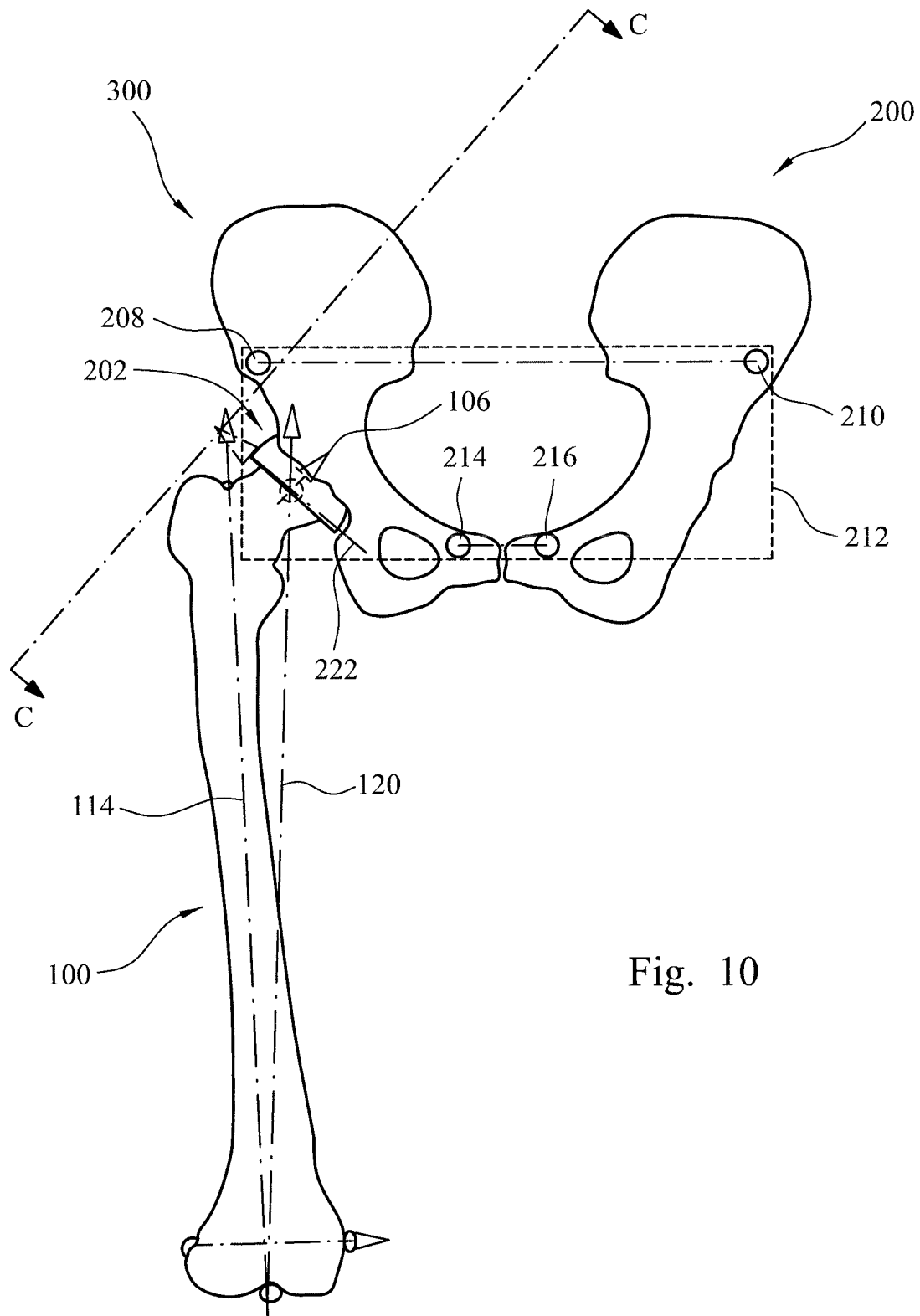


Fig. 10

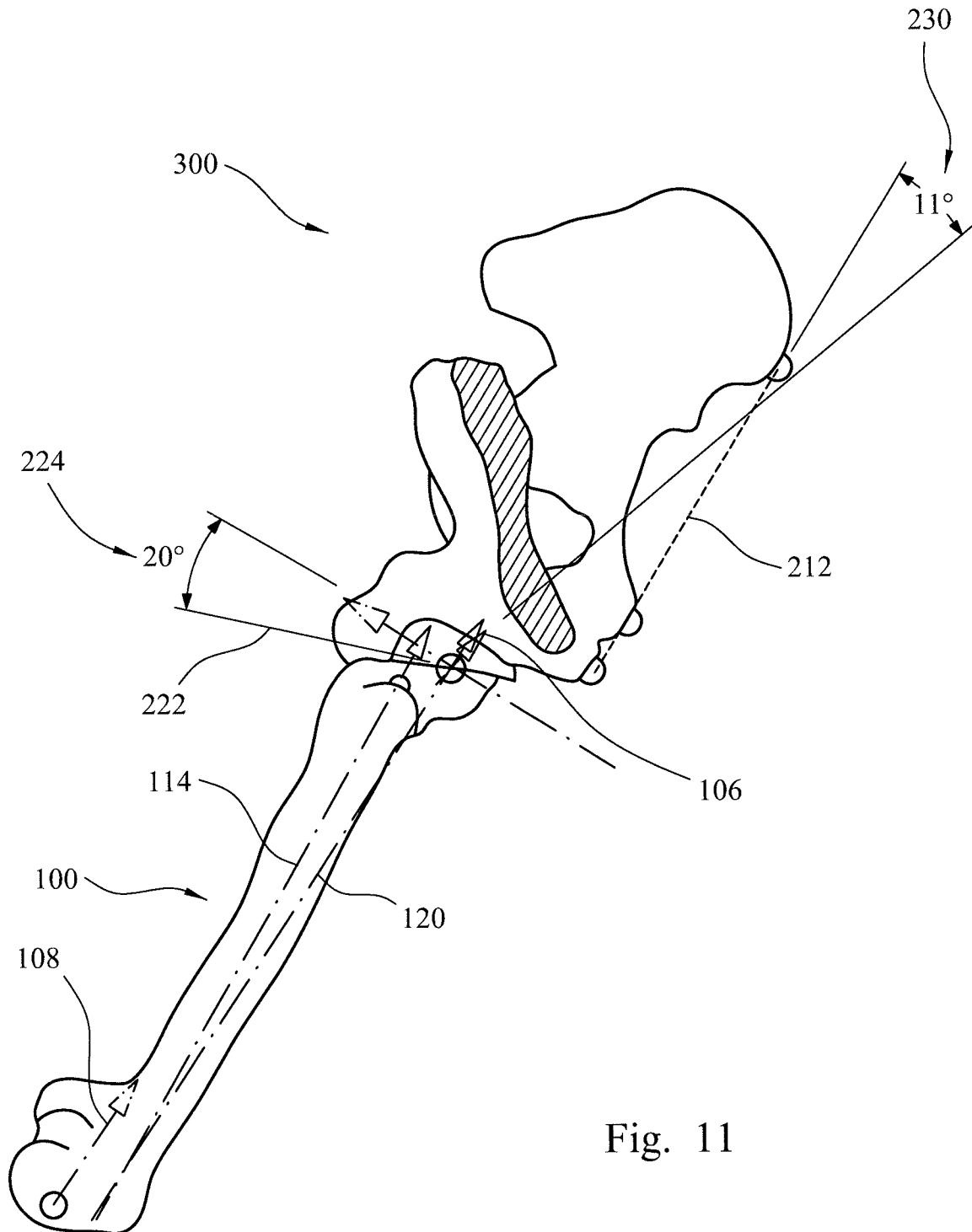


Fig. 11

Fig. 12

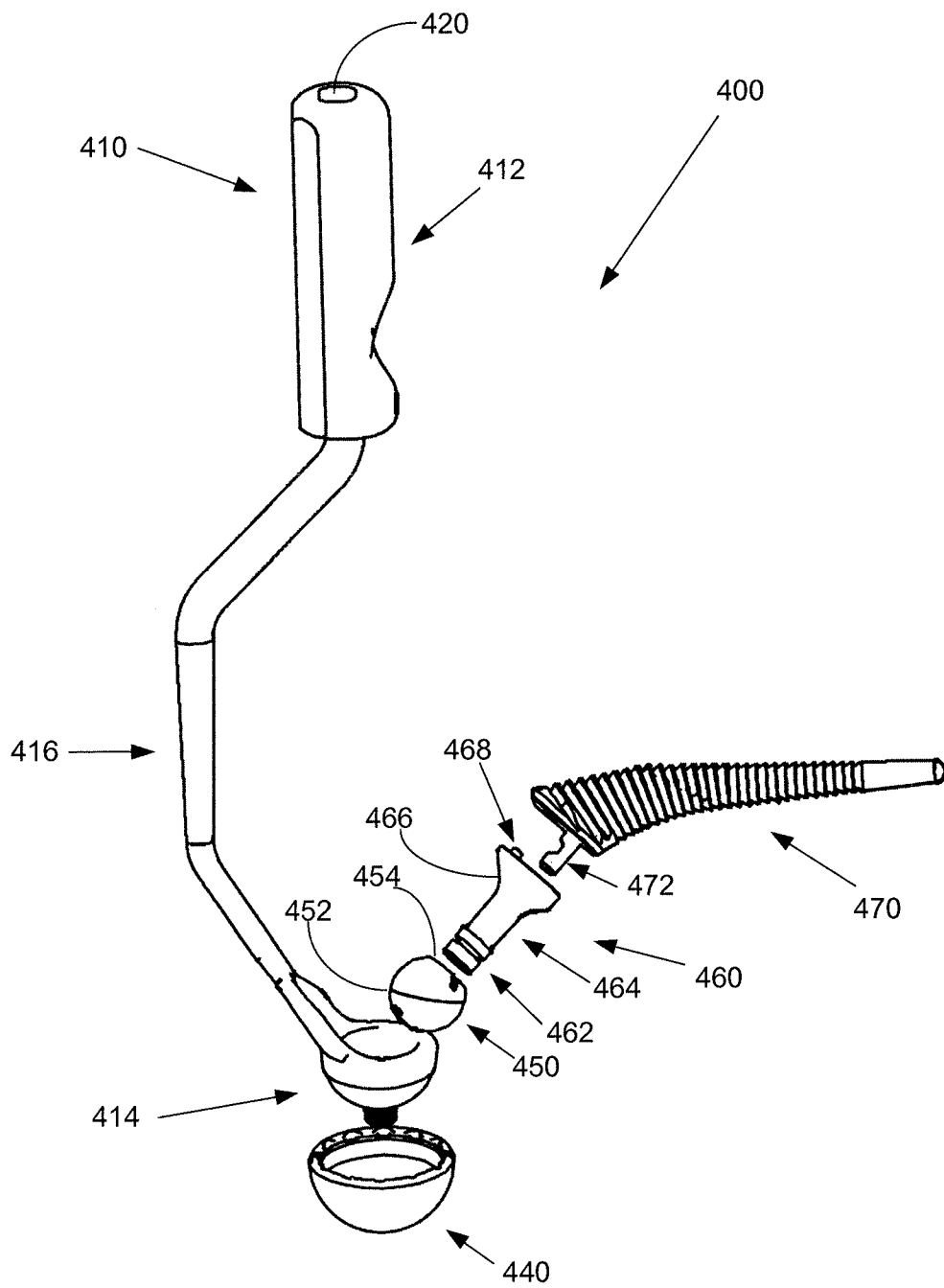


Fig. 15

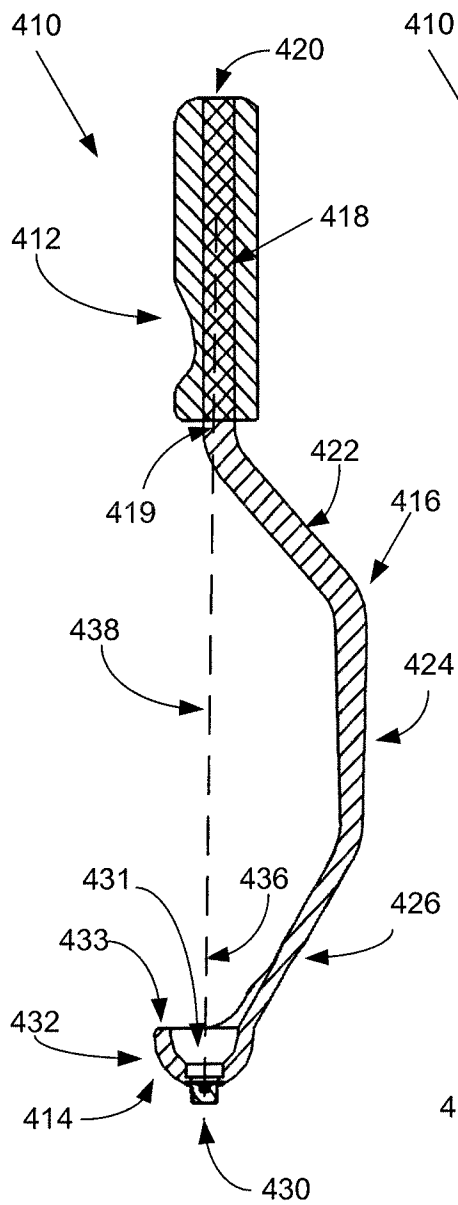


Fig. 14

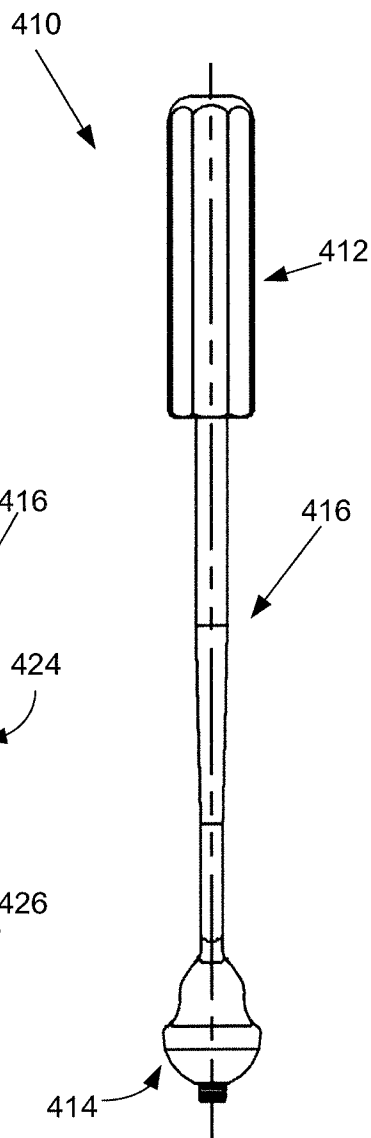


Fig. 13

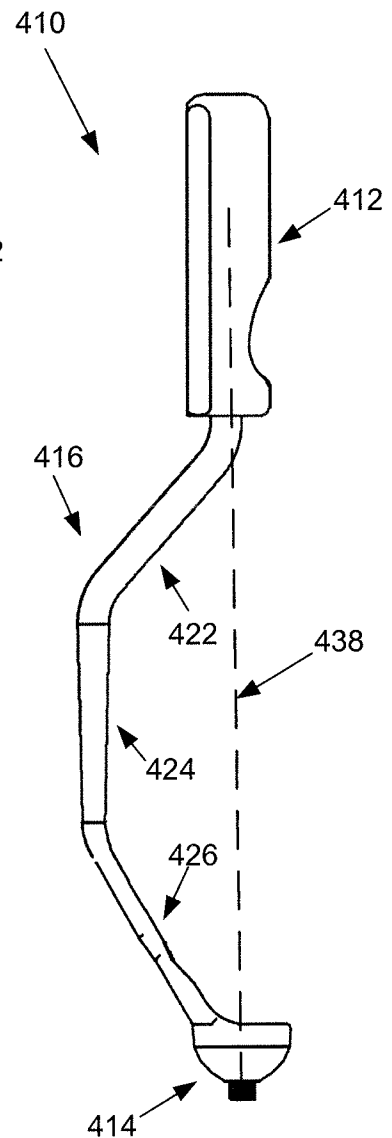


Fig. 16

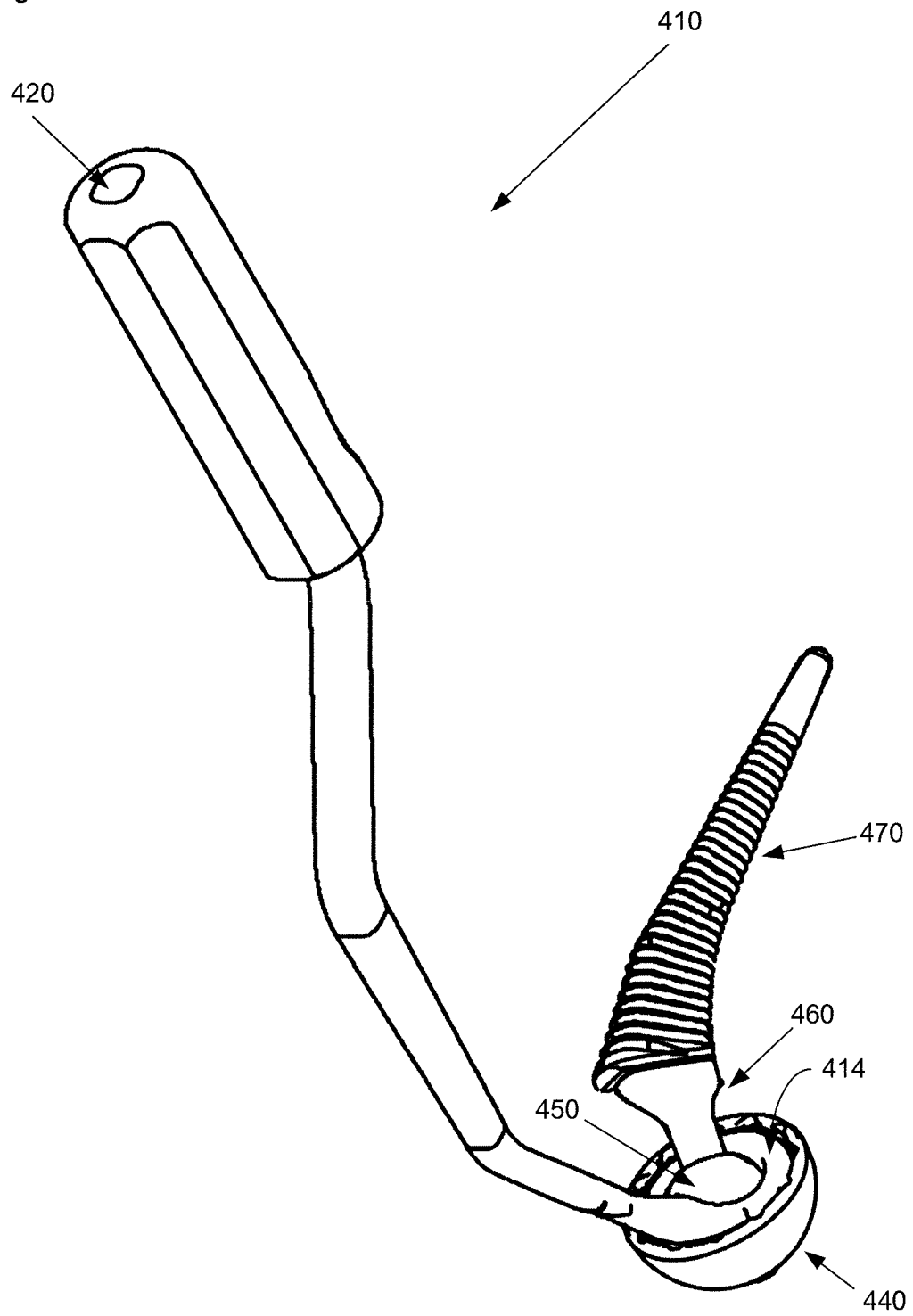


Fig. 17A

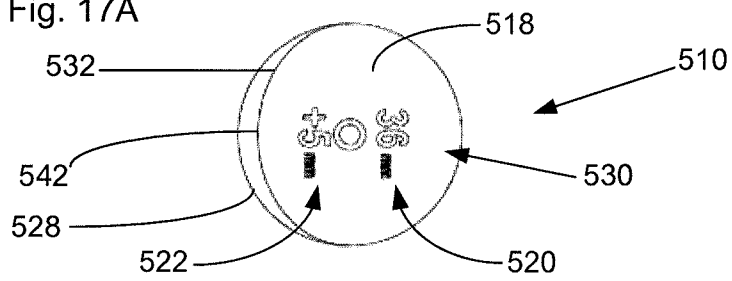


Fig. 17B

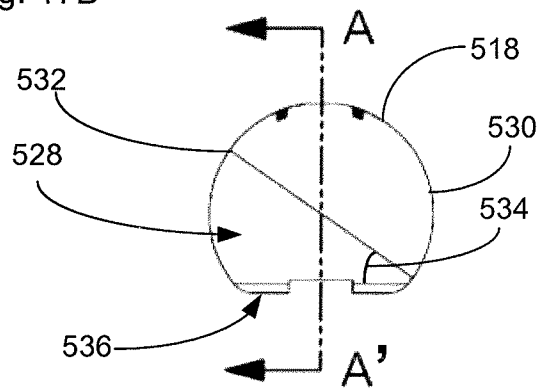


Fig. 17C

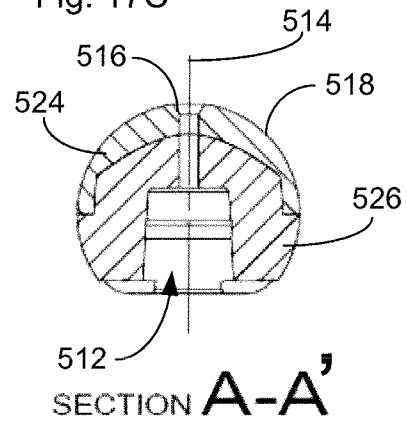


Fig. 17D

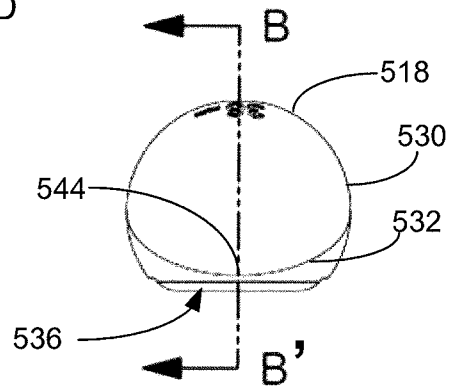


Fig. 17E

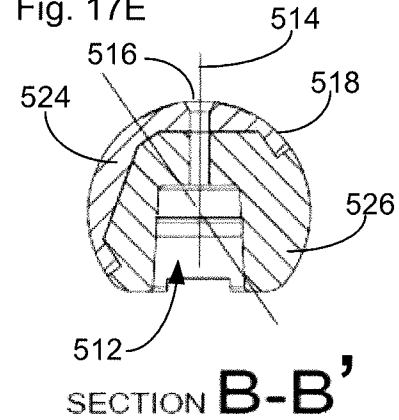


Fig. 17F

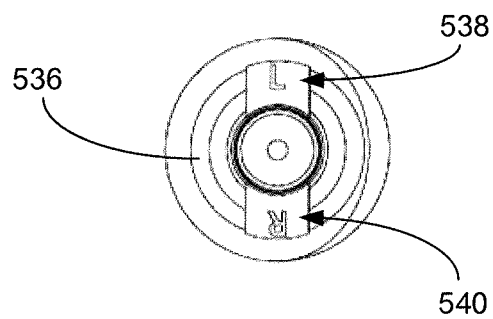


Fig. 18A

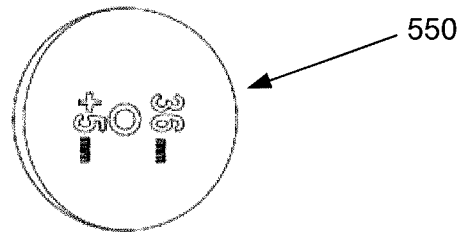


Fig. 18D

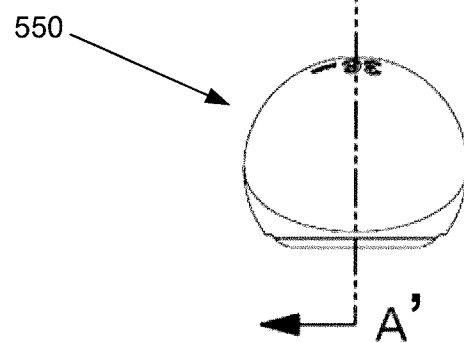


Fig. 18E

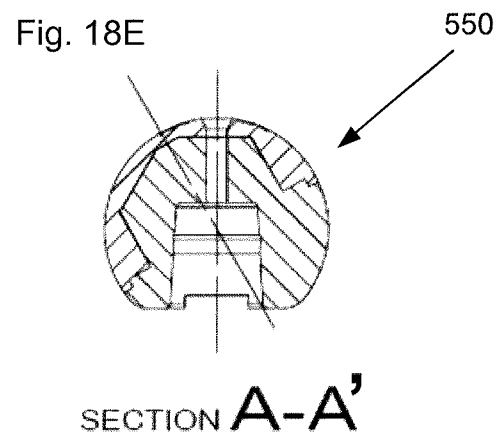


Fig. 18B

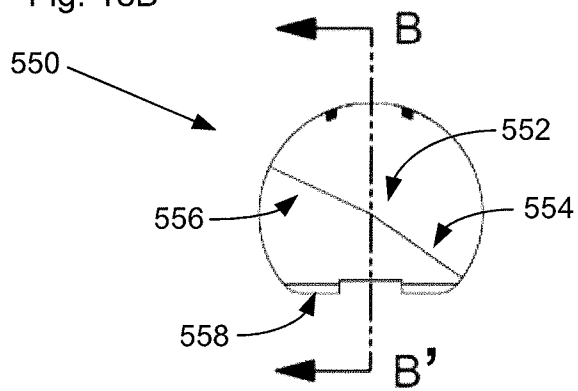


Fig. 18C

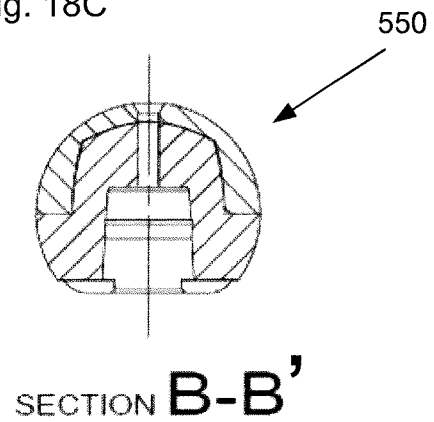


Fig. 18F

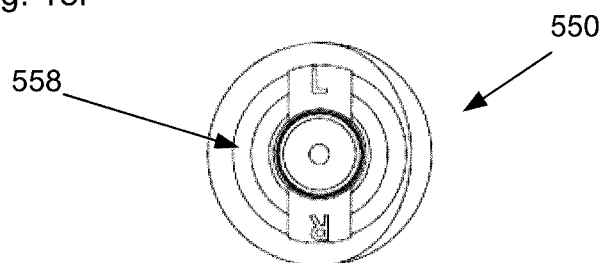


Fig. 19A

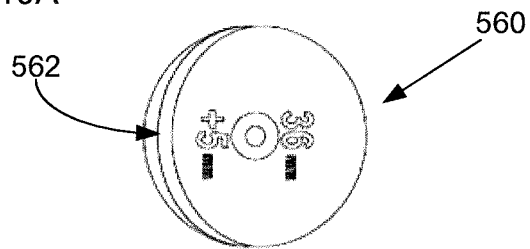


Fig. 19B

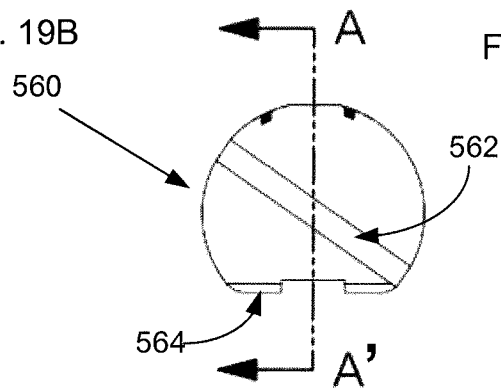


Fig. 19C

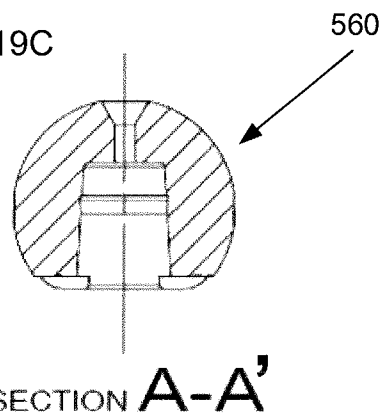


Fig. 19D

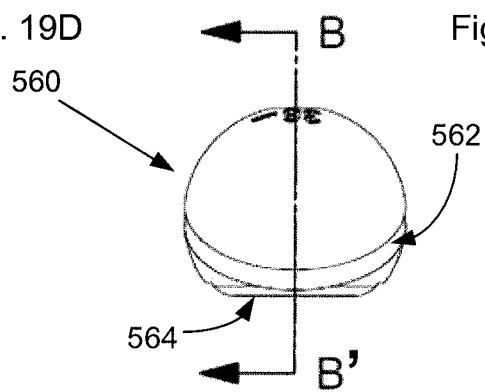


Fig. 19E

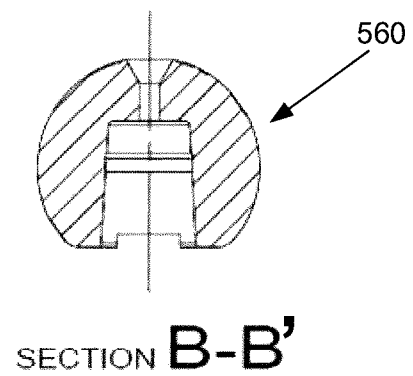
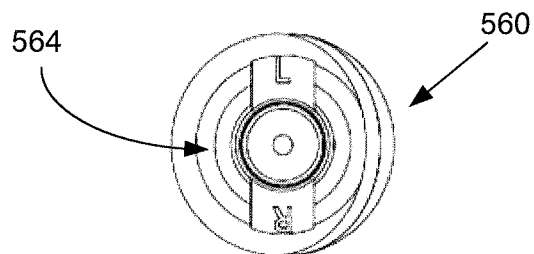


Fig. 19F



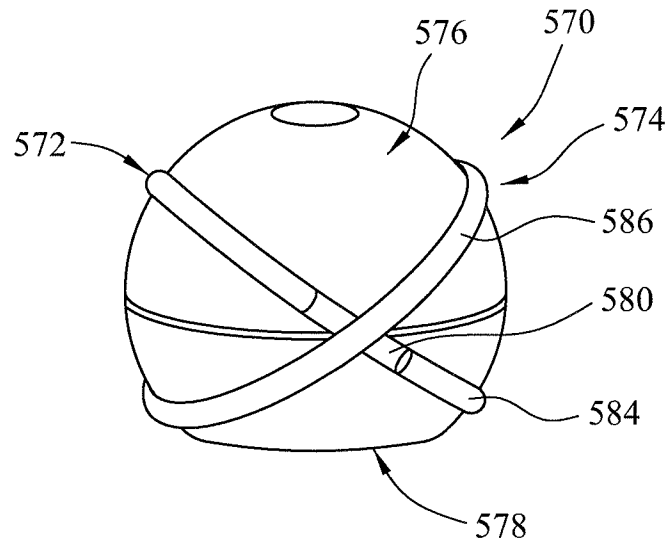


Fig. 20

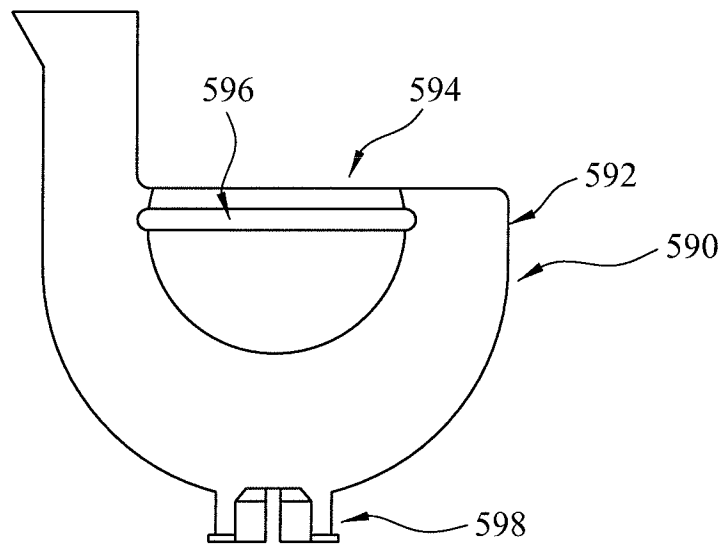


Fig. 21

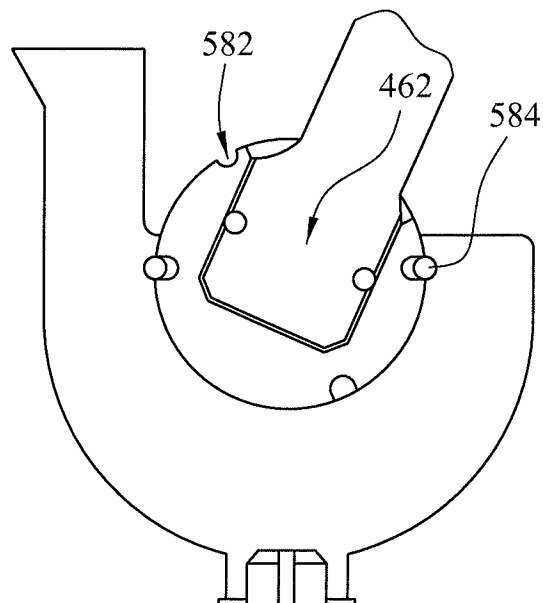
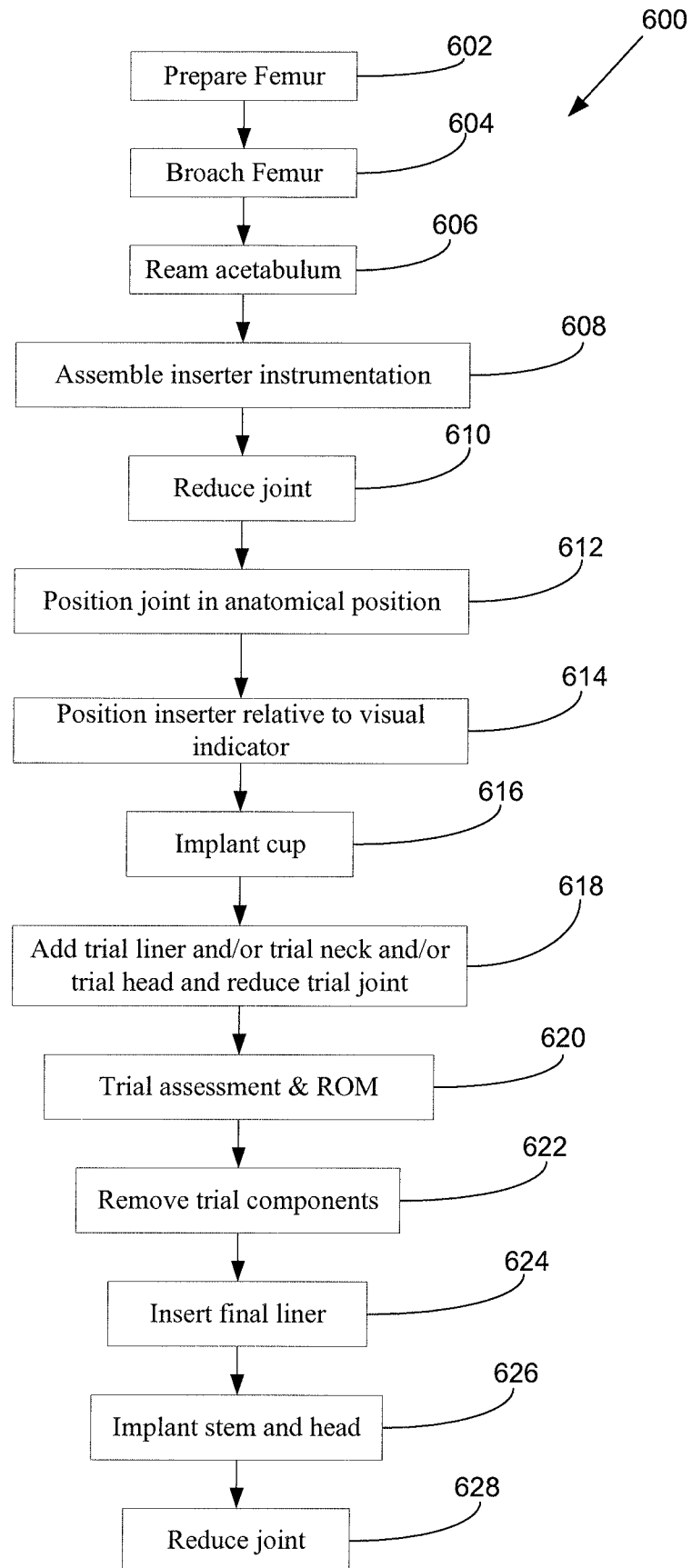


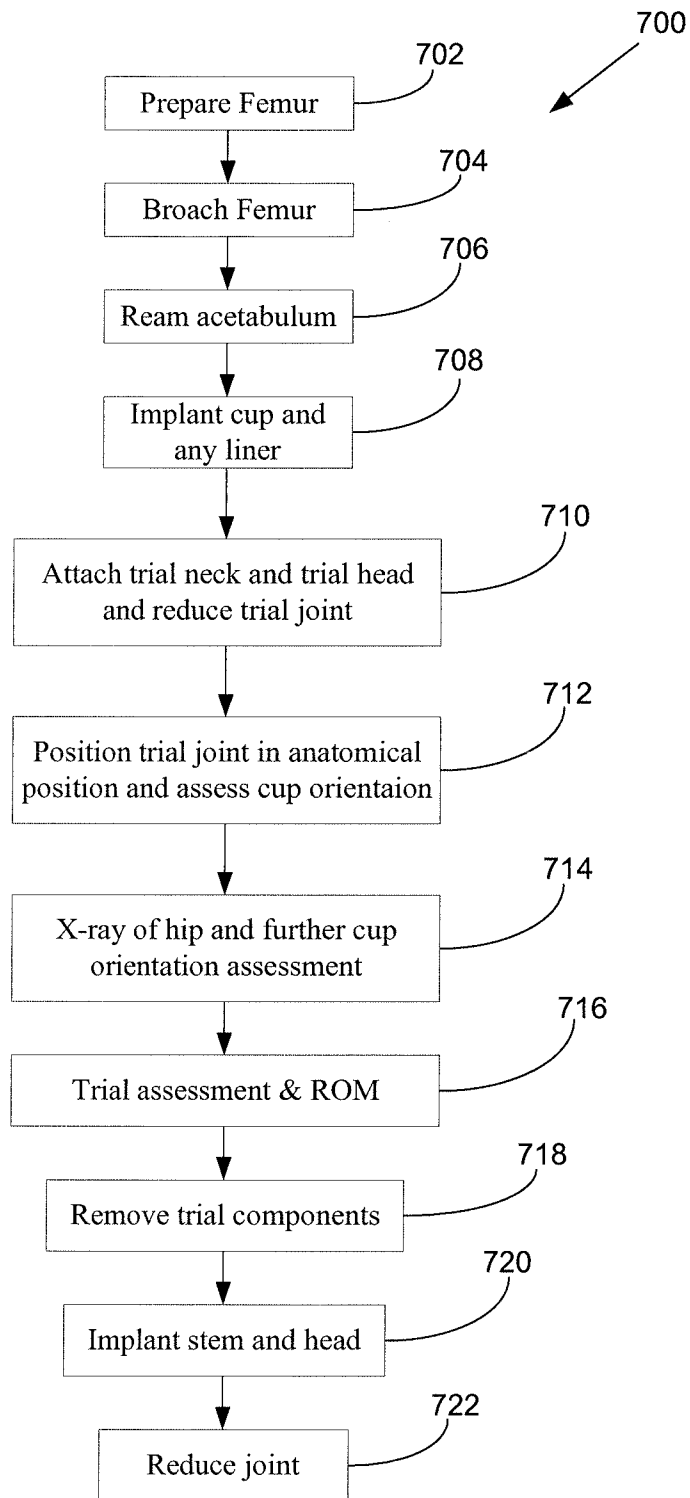
Fig. 22

Fig. 23



15/16

Fig. 24



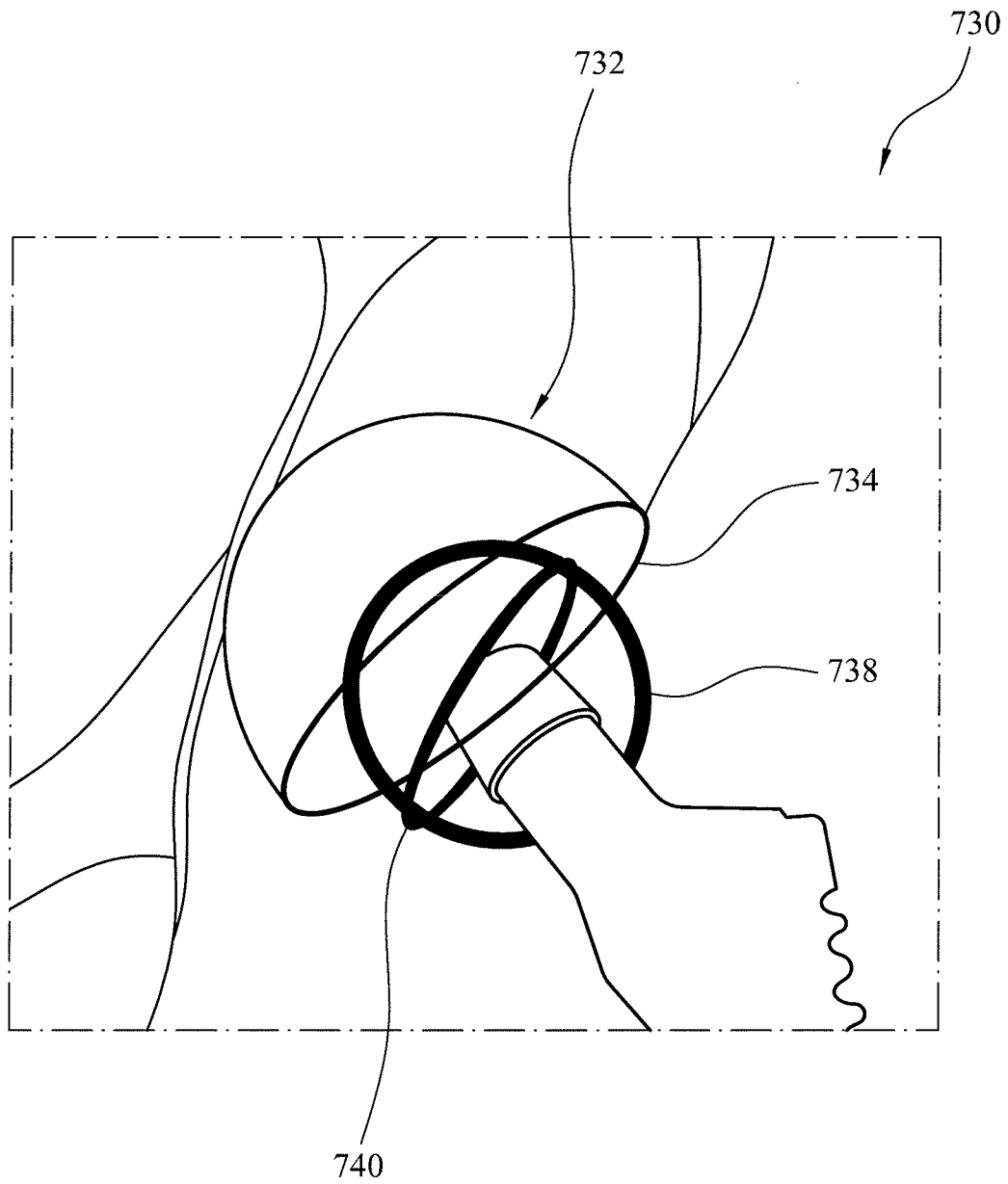


Fig. 25

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/072328

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/46 A61F2/32 A61F2/36 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, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/108683 A1 (SMITH & NEPHEW INC [US]; MCMAHON STEPHEN [AU]; ALLEN CHARLES R [US]; K) 3 September 2009 (2009-09-03) the whole document	36-48
Y	----- US 2005/107799 A1 (GRAF REINHARD [AT] ET AL) 19 May 2005 (2005-05-19) the whole document	49 1-24
A	----- WO 2013/117909 A1 (UNIV WARWICK [GB]) 15 August 2013 (2013-08-15) page 13, line 17 - page 17, line 17; figures 7i, 7ii	36-45, 49 1-24, 46-48
Y	----- US 5 658 294 A (SEDERHOLM GARY W [US]) 19 August 1997 (1997-08-19) column 4, lines 34-38 ----- -/-	49
☒ 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 29 January 2019		Date of mailing of the international search report 05/02/2019
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Mingrino, Alessandra

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2018/072328

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 991 656 B2 (MEARS DANA [US] ET AL) 31 January 2006 (2006-01-31) column 13, line 55 - column 15, line 47 -----	1-24
A	US 2014/249535 A1 (MCCARTHY THOMAS FRANCIS [US] ET AL) 4 September 2014 (2014-09-04) the whole document -----	36-49

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/072328

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.: 25-35, 50-56
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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:

see additional sheet

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-24

Instrumentation for implanting a prosthetic acetabular cup in an acetabulum of a patient, including: an inserter comprising a handle and an impaction head at a distal end of the inserter, wherein the impaction head is configured to couple with an acetabular cup to transmit an impaction force to the acetabular cup when located in an acetabulum of a patient and includes a formation to prevent the acetabular cup from pivoting relative to the impaction head, wherein the impaction head defines a cavity and wherein the handle and the impaction head are arranged to define an impaction axis of the inserter extending along the inserter; and a femoral part attachable to a femur of the patient and including a femoral head bearing a visual alignment guide, and wherein the femoral head is pivotably receivable within the cavity of the impaction head to permit the impaction head to pivot relative to the femoral head, and wherein, in use, a change in orientation of the inserter causes a change of orientation of the acetabular cup within the acetabulum of the patient.

2. claims: 36-49

A trial femoral head comprising:
a body defining a cavity therein for receiving a taper of a femoral neck;
an articulating surface; and
a visual alignment guide on the articulating surface,
wherein the visual alignment guide is configured to define an acetabular cup orientation within a pelvis of a patient corresponding to a target combined anteversion for a hip of the patient when the femoral head is mounted on a femur of the patient and when the hip of the patient is placed in the anatomical position.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 25-35, 50-56

According to Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT the International Search Authority, in the present case the EPO, is not required to carry out a search if the subject-matter of the international application relates to methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods. The method for implanting a prosthetic acetabular cup in an acetabulum of a patient using an inserter and the method for assessing the orientation of an acetabular cup in an acetabulum of a patient defined in Claims 25-35 and 50-56 comprise surgical steps (impacting the inserter to impart an impaction force to the acetabular cup so as to implant the acetabular cup and mounting the trial femoral head on a femur of the patient) and therefore are considered methods of treatment of the human or animal body by surgery. Therefore, no search is performed.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2018/072328

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