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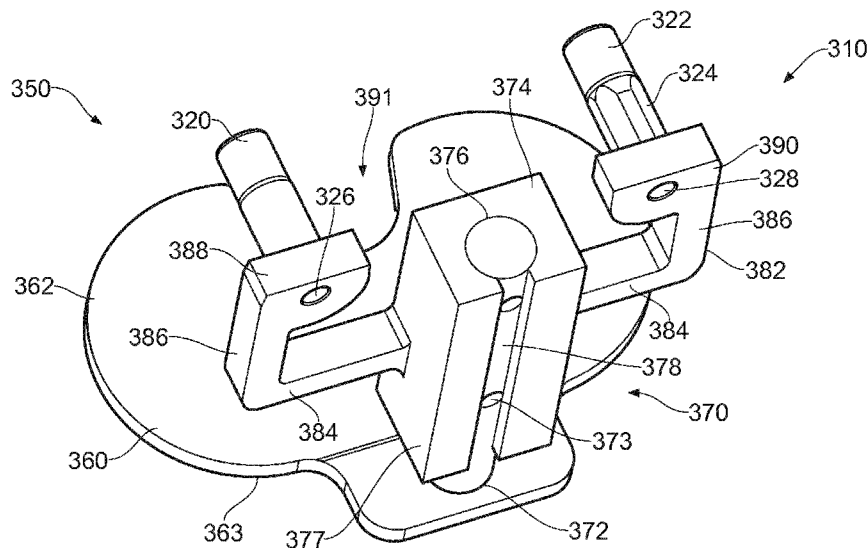


FIG. 3

(57) Abstract: The present invention relates to a method and apparatus for use during a knee arthroplasty procedure. In particular, but not exclusively, the present invention relates to a method and apparatus (350) for evaluating a gap between a proximal end of a tibia and a distal end of a femur when the knee joint is placed in flexion.

Knee Arthroplasty

Field of the Invention

- 5 The present invention relates to a method and apparatus for use during a knee arthroplasty procedure. In particular, but not exclusively, the present invention relates to a method and apparatus for evaluating a gap between a proximal end of a tibia and a distal end of a femur when the knee joint is placed in flexion.

10 Background to the Invention

- Joint arthroplasty is a surgical procedure by which a diseased and/or damaged natural joint is replaced by a prosthetic joint. During knee arthroplasty, a knee prosthesis which may include a tibial tray and a femoral component, is implanted. Femoral components are designed to be
15 attached to a surgically-prepared distal end of a patient's femur, whilst tibial trays are designed to be attached to a surgically-prepared proximal end of a patient's tibia.

- Orthopaedic surgeons typically use a variety of orthopaedic surgical instruments to facilitate the replacement of the natural joint with the knee prosthesis. The surgical instruments used
20 may be for example, prosthetic trial components, cutting blocks, drill guides and other surgical instruments.

- Currently, a femoral component of a predetermined size is selected by a surgeon following a visual determination. The distal end of the femur is then cut. Provisional components (also
25 referred to as "trial components"), e.g. a femoral trial component and a tibial bearing trial component, may be used to size and select the components of the knee prosthesis that will replace the patient's natural joint. Provisional tibial and femoral components are respectively positioned on a resected proximal end of the tibia and a resected distal end of the femur to allow a surgeon to test a range of motion and ensure that the joint kinematics and/or
30 component sizing is correct. During surgery, a surgeon may replace a first provisional femoral component with a second provisional femoral component of a different size to evaluate and compare the joint kinematics and/or sizing of the different femoral components to decide which final femoral component to use in the knee prosthesis. A procedure that utilizes provisional or 'trial' components to size and select the final components of the knee prosthesis is often
35 referred to as a trial reduction.

A key factor in determining the correct position and size of a final femoral component, and therefore the correct location and orientation of the various cuts made to the distal end of the femur, is the tension in adjacent soft tissues, such as the collateral ligaments. Correct tension the ligaments ensures the knee joint is stable, particularly in a medial/lateral direction. Such tissues also limit the amount of anterior/posterior travel of the femur with respect to the tibia. Typically, whilst the knee joint is in a fully extended state, it is distracted by a conventional tensioning device known as a 'distractor' to force the resected distal end of the femur and the resected proximal end of the tibia apart. The distance between the resected distal end of the femur and the resected proximal end of the tibia when the knee joint is in the fully extended state is known as the 'extension gap'. The extension gap and ligament tension are conventionally measured by scales on the distractor. If a medial-lateral imbalance exists when equal medial and lateral distraction forces are applied to the knee joint, the ligament tension can be adjusted by releasing soft tissue attachments such that, for example, the resected surfaces of the femur and tibia are oriented in parallel with each other.

However, this conventional approach fails to account for correct ligament tensioning when the knee joint is in a flexed state. If the final femoral component is not located properly on the distal end of the femur, particularly in the anterior/posterior direction, the flexion gap will be incorrect. This in turn may result in the ligaments being overly tight or loose, or the range of motion of the knee joint may be limited. Furthermore, poor tensioning in flexion can lead to improper femoral rotation, condylar lift-off, and/or accelerated wear of the final femoral and tibial components.

It is an aim of certain embodiments of the present invention to provide an apparatus for attaching to a conventional femoral sizer to provide a compact and lightweight combination for accurately and efficiently evaluating/measuring a flexion gap between the resected femur and a resected tibia when the knee joint is placed in flexion during a knee arthroplasty procedure.

Summary of Certain Embodiments of the Invention

According to a first aspect of the present invention there is provided apparatus for determining a flexion gap of a knee joint, comprising:

- at least one tibia engagement portion configured to engage a proximal end of a tibia;
- at least one attachment portion configured to attach the apparatus to a femoral sizing

device locatable on a distal end of a femur; and

at least one connecting portion connecting the at least one tibia engagement portion to the at least one attachment portion.

5 Aptly, the at least one connecting portion comprises a first connecting portion slidably movable with respect to a further connecting portion.

Aptly, the first connecting portion is slidably received in the further connecting portion.

10 Aptly, at least one of the first and further connecting portions is configured to retain at least one of the connecting portions in a desired location with respect to the other connecting portion.

Aptly, the at least one of the first and further connecting portions is configured to provide a frictional force component between the first and further connecting portions.

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Aptly, the at least one of the first and further connecting portions is configured to provide an interference fit between the first and further connecting portions.

20 Aptly, the apparatus further comprises a retaining element to selectively retain at least one of the first and further connecting portions in a desired location with respect to the other connecting portion.

Aptly, the retaining element is receivable in at least one corresponding recess of the first connecting portion to selectively couple the first and further connecting portions together.

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Aptly, the at least one recess comprises a plurality of spaced apart recesses disposed at least partially along an outer surface of the first connecting portion.

30 Aptly, the retaining element is slidably mounted in a through aperture disposed in the further connecting portion.

Aptly, the through aperture comprises a threaded hole configured to engage with a threaded region of the retaining element.

35 Aptly, the retaining element is biased towards the recess of the first connecting portion.

Aptly, the first connecting portion is substantially elongate and extends substantially upwardly from the engagement portion.

Aptly, the first connecting portion comprises a cross section that is at least partially circular.

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Aptly, the further connecting portion comprises a bore having a cross section that is at least partially circular to receive the first connecting portion.

10 Aptly, a one of the first and further connecting portions comprises a scale for determining flexion gap between the femur and tibia.

Aptly, the further connecting region comprises a pair of arms each outwardly extending from a respective one of opposed side regions of the further connecting region, the opposed side regions being medial and lateral side regions in use.

15

Aptly, the at least one attachment portion comprises a plurality of attachment portions, each attachment portion extending substantially posteriorly in use from a respective one of said arms.

20 Aptly, the at least one attachment portion is substantially elongate and comprises a substantially circular cross section for engaging in a correspondingly sized aperture of the femoral sizing device.

Aptly, the at least one attachment portion comprises a through hole for guiding a drill bit.

25

Aptly, the at least one tibia engagement portion comprises a substantially planar engagement surface for engaging a resected proximal end of the tibia.

30 Aptly, the at least one tibia engagement portion is substantially plate-like having substantially planar upper and lower surfaces, wherein the lower surface is engagable with a resected proximal end of the tibia.

35 Aptly, the at least one tibia engagement portion comprises a notched region in an edge which is a posterior edge in use, the notched region configured to receive an intercondylar eminence of the tibia.

According to a second aspect of the present invention there is provided a system for determining a flexion gap of a knee joint when in flexion, comprising:

an apparatus according to the first aspect of the present invention; and

5 a femoral sizing device comprising at least one support portion configured to cooperate with the at least one attachment portion of the apparatus.

Aptly, the at least one support portion of the femoral sizing device comprises a pair of spaced apart through holes each for guiding a drill bit.

10 Aptly, the femoral sizing device further comprises at least one femur engagement portion for engaging a distal end of a femur.

According to a third aspect of the present invention there is provided a method for evaluating a flexion gap of a knee joint when in flexion, comprising:

15 locating a femoral sizing device on a femur, wherein a femur engagement portion of the femoral sizing device engages a distal end of the femur;

attaching an apparatus according to the first aspect of the present invention to the femoral sizing device, wherein a tibia engagement portion of the apparatus engages a proximal end of the femur; and

20 determining a distance between the femur engagement portion and the tibia engagement portion to evaluate the flexion gap.

Aptly, the method further comprises:

25 slidably moving a first connecting portion of the apparatus with respect to a further connecting portion of the apparatus to selectively adjust the distance between the femur engagement portion and the tibia engagement portion.

Aptly, the method further comprises:

30 selectively retaining at least one of the first and further connecting portions in a desired location with respect to the other connecting portion.

According to a fourth aspect of the present invention there is provided apparatus substantially as hereinbefore described with reference to the accompanying figures.

35 According to a fifth aspect of the present invention there is provided a system substantially as hereinbefore described with reference to the accompanying figures.

According to a sixth aspect of the present invention there is provided a method substantially as hereinbefore described with reference to the accompanying figures.

5 Detailed Description of Certain Embodiments of the Invention

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

10 Figure 1 illustrates a conventional femoral sizer located on the distal end of a femur;

Figure 2 illustrates the femoral sizer of Figure 1 securely attached to the femur by pins;

15 Figure 3 illustrates apparatus according to certain embodiments of the present invention for mounting to the femoral sizer of Figures 1 and 2;

Figures 4a to 4c illustrate the femoral sizer of Figures 1 and 2 and an alternative apparatus according to certain embodiments of the present invention for mounting on the femoral sizer to provide a combination for evaluating a flexion gap between the resected femur and tibia;

20

Figure 5 illustrates the apparatus of Figure 3 mounted on the femoral sizer to provide a combination for evaluating a flexion gap according to certain embodiments of the present invention; and

25 Figure 6 illustrates an alternative view in the anterior-posterior direction of the combination and knee joint of Figure 5.

The terms “proximal” and “distal” have been used herein with reference the heart of a patient, e.g. “proximal” refers to a feature of the knee joint that is close to the heart of the patient and “distal” refers to a feature of the knee joint that is distant from the heart of a patient. Additionally, as used herein, the term “anterior” refers to the front of a patient, and the term “posterior” refers to the back of a patient. In addition, as used herein, the term “medial” refers to the middle of a patient, and the term “lateral” refers to the side of a patient.

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The term “cutting” has been used herein to include any process or procedure where bone is removed from a femur, such as by drilling, milling, grinding, sanding, chiseling, or the like. Similarly, a “cutting tool” shall include all tools that are suitable for removing bone a femur such as a drill or drill bit, a chisel, a blade, a disc, a cutter, a saw, a file, or the like.

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As illustrated in Figure 1, during a knee arthroplasty procedure, the proximal end 100 of the tibia 104 and the distal end 102 of the femur 106 are resected using suitable cutting guides and cutting tools (not shown). A femoral sizing device 150, or so-called ‘femoral sizer’, is placed on the resected planar surface of the distal femur. The femoral sizer 150 includes a set of spaced apart paddles 152 that contact a respective one of the medial and lateral femoral condyles. A sizing stylus 154 is shown attached to an upper region of the femoral sizer 150.

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As illustrated in Figure 2, the femoral sizer 150 is secured to the distal femur by pins 256. The femoral sizer 150 is used to determine certain characteristics/dimensions of the distal end of the femur in order to select a suitably sized femoral trial component for later trial reduction and ultimately a final femoral component that ensures correct kinematics, joint stability and minimal component wear etc. The femoral sizer 150 is adjustable to correctly set the orientation/position of the sizer with respect to the distal femur and/or to take measurements of the distal femur. For example, the sizing stylus 154 is used to contact the anterior surface of the femur, e.g. the lateral run-out of the patellar groove, and indicate the size of femur component to be used for the particular patient. A first screw 258 is used to adjust the anterior/posterior position of the femoral component in order to avoid overhang of the femoral shield (the anterior portion of the femoral implant) or notching of the anterior cortex. A scale 260 is used to indicate the anterior/posterior shift in millimetres of the femoral component. A suitable tool (not shown), such as a screw driver, is used to drive a second screw 262 to set the final rotation of the femoral component from, for example, about around -3 degrees to about around 10 degrees using the respective scale 264, 266 depending on which knee the sizer is located on. The measured femoral rotation is generally associated with the flexion gap between the tibia and femur when the knee joint is placed in full flexion.

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As illustrated in Figure 3, apparatus 350 according to certain embodiments of the present invention includes an attachment portion 310 for attaching the apparatus to the femoral sizer 150, and a tibia engagement portion 360 for engaging the resected tibia when the flexion gap is being evaluated/measured. The engagement portion 360 is adjustably connected to the attachment portion by a connecting portion 370 to allow the engagement portion to be selectively moved towards or away from the attachment portion.

35

The engagement portion 360 is substantially plate-like and has planar upper and lower (superior and inferior) surfaces 362,363. The planar lower surface 363 is configured to contact the planar resected surface of the proximal tibia in use. The tibia engagement portion 360 includes a notched recess 391 for accommodating the posterior cruciate ligament.

The attachment portion 310 includes a pair of spaced apart projections 320, 322 configured to be inserted in respective drill guide holes 280 of the femoral sizer 150. The drill guide holes 280 of the femoral sizer are used later on in the knee arthroplasty procedure for drilling holes in the resected distal end of the femur which are used to attach a cutting block to the femur which in turn is used to carry out the anterior, posterior and chamfer cuts when preparing the femur. As shown in Figure 3, one of the projections 320 is substantially circular in cross section along its entire length whilst the other projection 322 includes a substantially non-circular portion along its length which includes a number of flat surfaces 324 around its circumference. These flat surfaces 324 are to compensate for any tolerances and make it easier for a surgeon to attach and remove the apparatus 350 to and from the femoral sizer 150. Each projection 320, 322 comprises a through bore 326, 328 for receiving and guiding a drill bit. This allows a surgeon to drill the holes in the distal end of the femur for later attaching the cutting block to the femur whilst the apparatus 350 is mounted to the femoral sizer 150. The position where to place the femoral component is now defined and the drill holes for positioning and orienting a cutting block on the distal femur 102 can be made without having to remove the apparatus according to certain embodiments of the present invention from the femoral sizer 150.

The connecting portion 370 of the apparatus 350 includes a first substantially elongate connecting portion 372 extending upwardly from the upper surface of the tibial engagement portion 360. The first connecting portion 372 is shown as being substantially perpendicular to the planar upper surface of the tibial engagement portion but may aptly be oriented at any desired angle relative to the engagement portion. The first connecting portion 372 may be integral with or attached to the tibial engagement portion 360. For example, the first connecting portion 372 and tibial engagement portion 360 may be machined or molded from the same piece of material, such as steel or plastic, or the first connecting portion 372 may be welded or mechanically fastened by at least one bolt, rivet or the like to the tibial engagement portion 360.

The first connecting portion 372 as illustrated in Figure 3 has a substantially solid and circular cross section and is slidably received substantially within a second connecting portion 374. The second connecting portion 374 as illustrated in Figure 3 is configured to mount onto, and at least partially around, the first connecting portion 372 such that the first connecting portion 372 and tibial engagement portion 360 are movable with respect to the second connecting portion 374. The first connecting portion 372 is shown in a retracted position with respect to the second connecting portion 374. The second connecting portion 374 is similar in length to the first connecting portion 372 and is in the form of an elongate block having a centrally disposed and substantially circular through bore 376 for receiving the first connecting portion 372. The second connecting portion 374 includes a longitudinal slot 378 extending along the length of a front (anterior) surface of the second connecting portion 374 to communicate with the central bore 376. The first connecting portion 372 includes a plurality of spaced apart recesses 380 aligned with the slot 378 for selective engagement with a retaining element (not shown) for retaining/locking the first and second connecting portions 372, 374 with respect to each other.

As illustrated in Figure 3 the second connecting portion 374 further includes an integral frame 382 extending outwardly and upwardly from the block-like main body 377 and in a substantially perpendicular direction with respect to the upper planar surface of the tibial engagement portion 360. The frame 382 is at least partially rectangular in shape and includes two opposing lower arm portions 384 which extend outwardly from the main body 377, a pair of opposed side portions 386 and upper portions 388 extending inwardly from the side portions 386. Oversized corner portions 390 support the projections 320, 322. A hole in each corner portion may be threaded to receive a correspondingly threaded region of a respective one of the projections 320, 322 to attach the respective projection to the corner portion. Alternatively, each projection 320, 322 may be welded to or integrally formed with the frame 382 of the second connecting portion 374.

An alternative embodiment of the apparatus 450 is illustrated in Figure 4a to c wherein the upper portions 488 of the frame 482 connect the side portions 486 to the main body 476 of the second connecting portion 474 to form a closed rectangular frame 482 which may provide the apparatus 450 with additional strength and rigidity. The apparatus 450 further includes a retaining element 492 to retain the first and second connecting portions 472, 474 with respect to each other and prevent at least one of the connecting portions 472, 474 moving with respect to the other. The retaining element 492 is a rotatable knob including a shaft which engages a selected one of a number of incremental recesses 493 located along the edges of the slot

378. The shaft may have a cam-like outer surface that, when rotated into a locked position, engages a selected one of the recesses 493 to prevent the connecting portions 372, 474 moving relative to each other, whilst disengages the selected recess 493 when rotated into an unlocked position. Alternatively, the shaft may be translatable towards or away from the first connecting portion 372 by rotating the knob. The shaft may simply abut the outer surface of the first connecting portion 372 such that the connecting portions are locked together by friction between the shaft and the outer surface of the first connecting portion 372. Alternatively, the shaft may be received by a corresponding recess 373 or hole in the first connecting portion 372. A number of spaced apart recesses or holes 373 (as shown in Figure 3) may be provided in the first connecting portion to provide for incremental retainment/locking of the first and second connecting portions 372, 374 or 474 relative to each other. Other suitable mechanisms/arrangements for locking the connecting portions 372, 374 or 474 together in a desired position can be envisaged, such as via a frictional component provided by a material characteristic of an outer surface of at least one of the first and second connecting portions 372, 374 or 474, for example. In a further alternative embodiment, the first connecting portion 372 may comprise a substantially resilient protrusion outwardly extending into the slot 378 of the second connecting portion 374, 474 wherein the protrusion has a diameter which is slightly larger than a width of the slot 378 such that the protrusion engages in a selected one of the slot recesses 493 to retain the first connecting portion 372 relative to the second connecting portion 374, 474, whilst being substantially resilient to allow the protrusion to be moved out of a selected recess and into another recess if desired.

Figure 4b is an alternative view of the apparatus 450 which illustrates the relationship between the first connecting portion 472 and the second connecting portion 474 in more detail. As shown in Figure 4c, the first connecting portion 472 may comprise a substantially cylindrical lower portion 480 and an upper portion 482 comprising a generally planar surface 484 and a curved surface 486. The upper portion may comprise a slot 488 located between the planar surface 484 and the curved surface 486.

According to certain embodiments of the present invention, the first and second connecting portions of the apparatus may have other suitable cross sections to provide the selectively adjustable mechanism of the apparatus. For example, the first connecting portion extending upwardly from the tibial engagement portion may have substantially square, triangular, T-shape cross section, or the like, and the second connecting portion may be correspondingly shaped to slidably receive the first connecting portion. Alternatively, the first connecting portion may be configured to receive the second connecting portion. Furthermore, the first

and/or second connecting portions may be hollow to reduce the overall weight of the apparatus and combination when attached to the femoral sizer.

The combination 550 of the apparatus 350 when attached to the femoral sizer 150 is shown in Figures 5 and 6 which provides a compact and non-complex or intrusive system for measuring the flexion gap whilst the femoral sizer is attached to the femur and thus expanding the functionality of the femoral sizer. The flexion gap can be compared with the extension gap. Afterwards, the surgeon can decide to perform a ligament release in order to keep the ligaments in balance and/or to change the size of a femoral component to be finally used to adapt the flexion gap to the extension gap.

As best illustrated in Figure 6, the frame 482 of the second connecting portion 474 provides a window to allow a surgeon to easily view the scales 260, 264, 266 on the femoral sizer 150 during the femoral sizing steps in a knee arthroplasty procedure. A scale 695 is also provided on the second connecting portion 474 either side of the slot 478 thereof and a reference element 697, such as a pin or recess, is provided on the first connecting portion 372 which follows the scale 695 as the first connecting portion 372 moves relative to the second connecting portion 474. The scale 695 corresponds to the flexion gap FG measured between the resected ends of the tibia 104 and femur 106.

As best illustrated in Figure 6, the flexion gap FG can be evaluated/measured with reference to the femoral sizer 150. In view of the femoral sizer 150 being fixed to the distal end of the femur by pins 256 and the paddles 152 being securely engaged with the condyles of the femur, the tibial engagement portion 360 can be moved relative to the paddles 152 of the femoral sizer 150 until they engage with the resected tibial plateau. The scale 380 on the apparatus 350 can then be read through the apertures 378 by the surgeon to provide an indication of the flexion gap FG. The distance between the lower surface of the tibial engagement portion 360 and the upper surface of the paddles 152 of the femoral sizer 150, which corresponds to the flexion gap FG being determined, can be locked by actuating the retaining element 380. A ligament release and/or change of the femoral component size, if required, to adapt the flexion gap to the extension gap can be made before cutting and preparing the femoral bone for receipt of a femoral trial component.

Alternatively or additionally, the surgeon may pre-set the apparatus 350 by locking the connecting portions 372, 474 in a predetermined position relative to each other before the apparatus is attached to the femoral sizer 150. The predetermined position may correspond

to a theoretical tibial trial insert thickness/height. The surgeon can then use the combination 550 to determine whether the pre-set distance between the tibia engagement portion 360 and the femoral paddles 152 is too large or too small and thus if the ligament balancing is adequate.

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Certain embodiments of the present invention therefore provide an apparatus that is configured to be easily and efficiently attached to a conventional femoral sizer which is already fixed to a resected distal end of a femur to provide a compact and lightweight combination for easily and efficiently evaluating/measuring a flexion gap between the resected femur and a resected tibia. Certain embodiments of the present invention provide apparatus for attaching to a conventional femoral sizer fixed to a femur and to engage with a resected tibial plateau to thereby determine a gap between a resected femur and the resected tibia using a portion of the femoral sizer, such as a pair of femoral paddles in engagement with the resected femur, to accurately and efficiently measure the flexion gap. Certain embodiments of the present invention allow the flexion gap to be measured by mounting apparatus according to certain embodiments of the present invention to a conventional femoral sizer attached to a resected femur whilst also allowing for holes to be drilled in the femur for later mounting a cutting block to the femur without having to remove the apparatus from the femoral sizer. Certain embodiments of the present invention allow the flexion gap to be compared with the extension gap and allow a surgeon to then decide whether or not to perform a ligament release in order to keep the ligaments in balance and/or to change the size of a femoral component to adapt the flexion gap to the extension gap before cutting/preparing the femoral bone.

Throughout the description and claims of this specification, the words “comprise” and “contain” and variations of them mean “including but not limited to” and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

Features, integers, characteristics or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in

any combination, except combinations where at least some of the features and/or steps are mutually exclusive. The invention is not restricted to any details of any foregoing embodiments. The invention extends to any novel one, or novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or
5 to any novel one, or any novel combination, of the steps of any method or process so disclosed.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to
10 public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

Claims:

1. Apparatus for determining a flexion gap of a knee joint, comprising:
at least one tibia engagement portion configured to engage a proximal end of
5 a tibia;
at least one attachment portion configured to attach the apparatus to a
femoral sizing device locatable on a distal end of a femur; and
at least one connecting portion connecting the at least one tibia engagement
portion to the at least one attachment portion.
10
2. The apparatus as claimed in claim 1, wherein the at least one connecting portion
comprises a first connecting portion slidably movable with respect to a further
connecting portion.
- 15 3. The apparatus as claimed in claim 2, wherein the first connecting portion is slidably
received in the further connecting portion.
4. The apparatus as claimed in claim 2 or 3, wherein at least one of the first and further
connecting portions is configured to retain at least one of the connecting portions in a
20 desired location with respect to the other connecting portion.
5. The apparatus as claimed in claim 4, wherein the at least one of the first and further
connecting portions is configured to provide a frictional force component between the
first and further connecting portions.
25
6. The apparatus as claimed in claim 4, wherein the at least one of the first and further
connecting portions is configured to provide an interference fit between the first and
further connecting portions.
- 30 7. The apparatus as claimed in any of claims 2 to 6, further comprising a retaining
element to selectively retain at least one of the first and further connecting portions in
a desired location with respect to the other connecting portion.
8. The apparatus as claimed in claim 7, wherein the retaining element is receivable in at
35 least one corresponding recess of the first connecting portion to selectively couple
the first and further connecting portions together.

9. The apparatus as claimed in claim 8, wherein the at least one recess comprises a plurality of spaced apart recesses disposed at least partially along an outer surface of the first connecting portion.
- 5 10. The apparatus as claimed in claim 8 or 9, wherein the retaining element is slidably mounted in a through aperture disposed in the further connecting portion.
- 10 11. The apparatus as claimed in claim 10, wherein the through aperture comprises a threaded hole configured to engage with a threaded region of the retaining element.
12. The apparatus as claimed in claim 10, wherein the retaining element is biased towards the recess of the first connecting portion.
- 15 13. The apparatus as claimed in any of claims 2 to 12, wherein the first connecting portion is substantially elongate and extends substantially upwardly from the engagement portion.
- 20 14. The apparatus as claimed in claim 13, wherein the first connecting portion comprises a cross section that is at least partially circular.
- 25 15. The apparatus as claimed in claim 14, wherein the further connecting portion comprises a bore having a cross section that is at least partially circular to receive the first connecting portion.
- 30 16. The apparatus as claimed in any of claims 2 to 15, wherein a one of the first and further connecting portions comprises a scale for determining flexion gap between the femur and tibia.
- 35 17. The apparatus as claimed in any of claims 2 to 16, wherein the further connecting region comprises a pair of arms each outwardly extending from a respective one of opposed side regions of the further connecting region, the opposed side regions being medial and lateral side regions in use.
18. The apparatus as claimed in claim 17, wherein the at least one attachment portion comprises a plurality of attachment portions, each attachment portion extending substantially posteriorly in use from a respective one of said arms.

19. The apparatus as claimed in any preceding claim, wherein the at least one attachment portion is substantially elongate and comprises a substantially circular cross section for engaging in a correspondingly sized aperture of the femoral sizing device.
20. The apparatus as claimed in claim 18 or 19, wherein the at least one attachment portion comprises a through hole for guiding a drill bit.
21. The apparatus as claimed in any preceding claim, wherein the at least one tibia engagement portion comprises a substantially planar engagement surface for engaging a resected proximal end of the tibia.
22. The apparatus as claimed in any preceding claim, wherein the at least one tibia engagement portion is substantially plate-like having substantially planar upper and lower surfaces, wherein the lower surface is engagable with a resected proximal end of the tibia.
23. The apparatus as claimed in any preceding claim, wherein the at least one tibia engagement portion comprises a notched region in an edge which is a posterior edge in use, the notched region configured to receive an intercondylar eminence of the tibia.
24. A system for determining a flexion gap of a knee joint when in flexion, comprising:
an apparatus as claimed in any preceding claim; and
a femoral sizing device comprising at least one support portion configured to cooperate with the at least one attachment portion of the apparatus.
25. The system as claimed in claim 24, wherein the at least one support portion of the femoral sizing device comprises a pair of spaced apart through holes each for guiding a drill bit.
26. The system as claimed in claim 24 or 25, wherein the femoral sizing device further comprises at least one femur engagement portion for engaging a distal end of a femur.
27. A method for evaluating a flexion gap of a knee joint when in flexion, comprising:

locating a femoral sizing device on a femur, wherein a femur engagement portion of the femoral sizing device engages a distal end of the femur;

attaching an apparatus as claimed in any of claims 1 to 23 to the femoral sizing device, wherein a tibia engagement portion of the apparatus engages a proximal end of the femur; and

determining a distance between the femur engagement portion and the tibia engagement portion to evaluate the flexion gap.

28. The method as claimed in claim 27, further comprising:

slidably moving a first connecting portion of the apparatus with respect to a further connecting portion of the apparatus to selectively adjust the distance between the femur engagement portion and the tibia engagement portion.

29. The method as claimed in claim 28, further comprising:

selectively retaining at least one of the first and further connecting portions in a desired location with respect to the other connecting portion.

30. Apparatus substantially as hereinbefore described with reference to the accompanying figures.

31. A system substantially as hereinbefore described with reference to the accompanying figures.

32. A method substantially as hereinbefore described with reference to the accompanying figures.

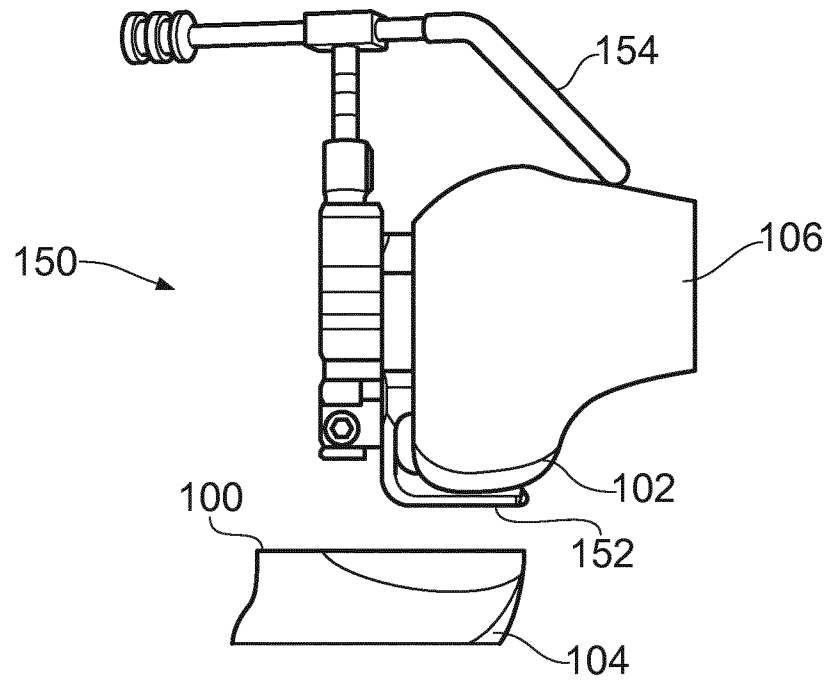


FIG. 1

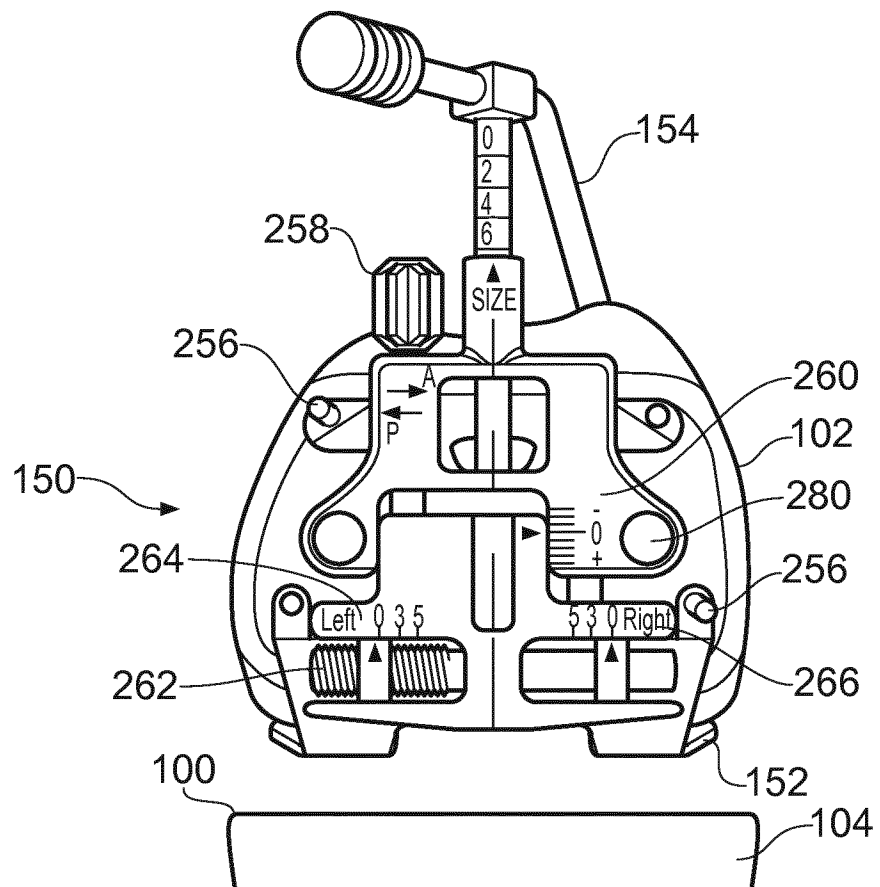


FIG. 2

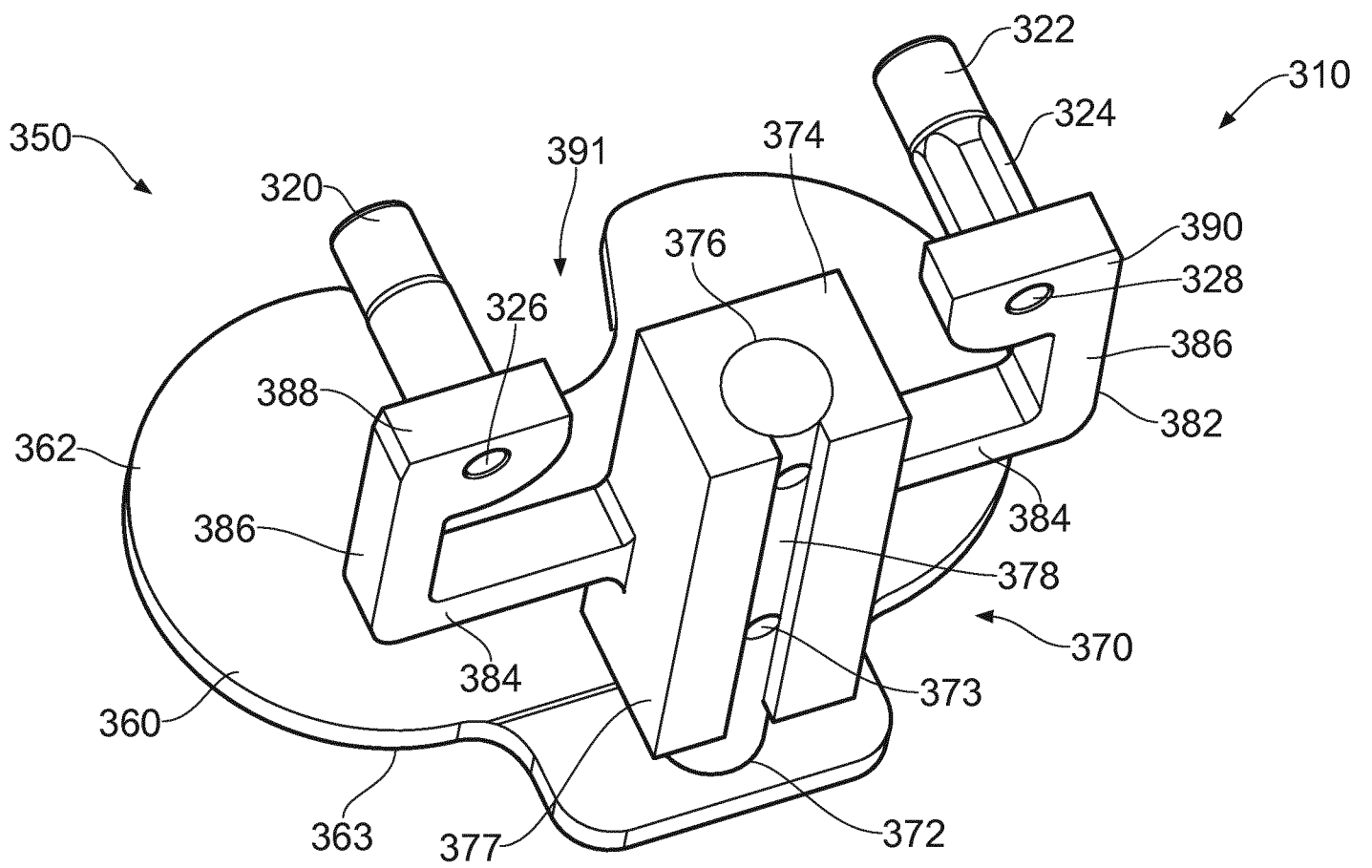


FIG. 3

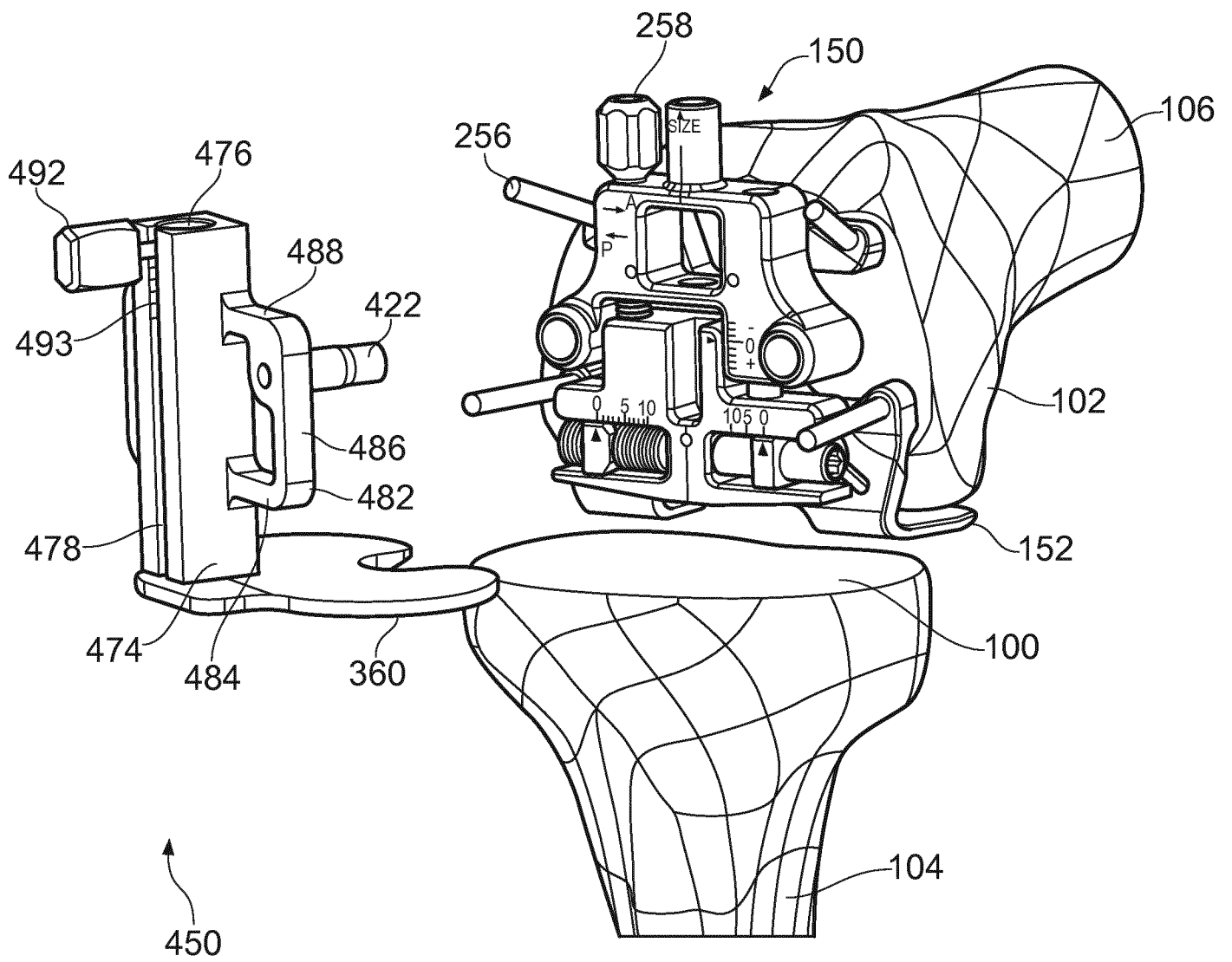


FIG. 4a

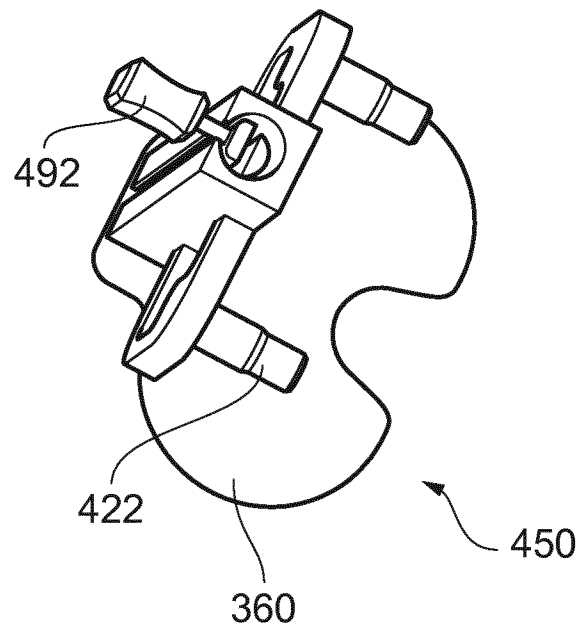


FIG. 4b

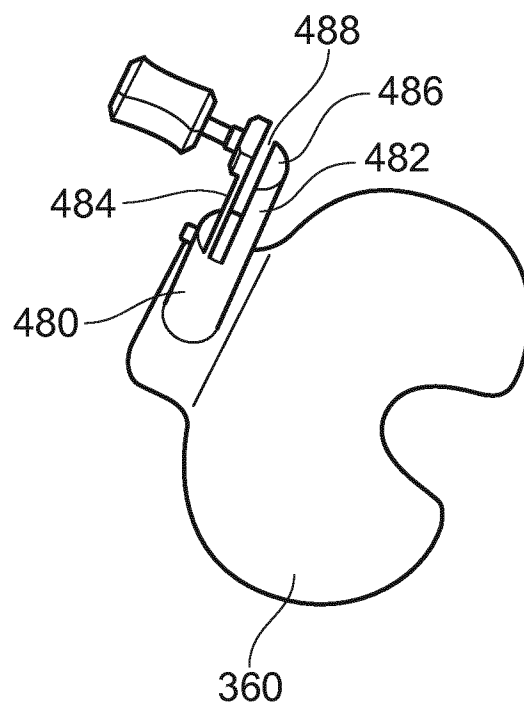


FIG. 4c

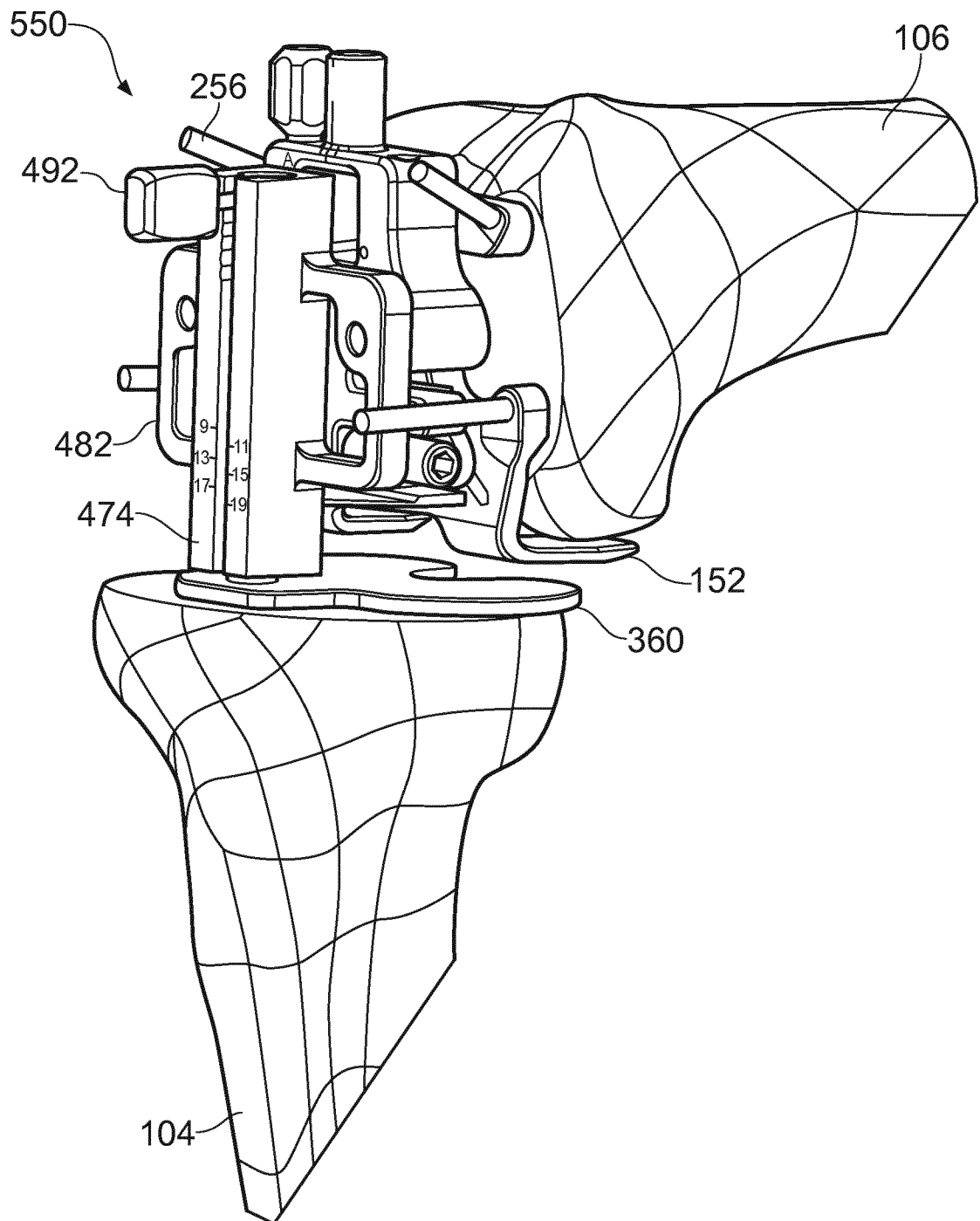


FIG. 5

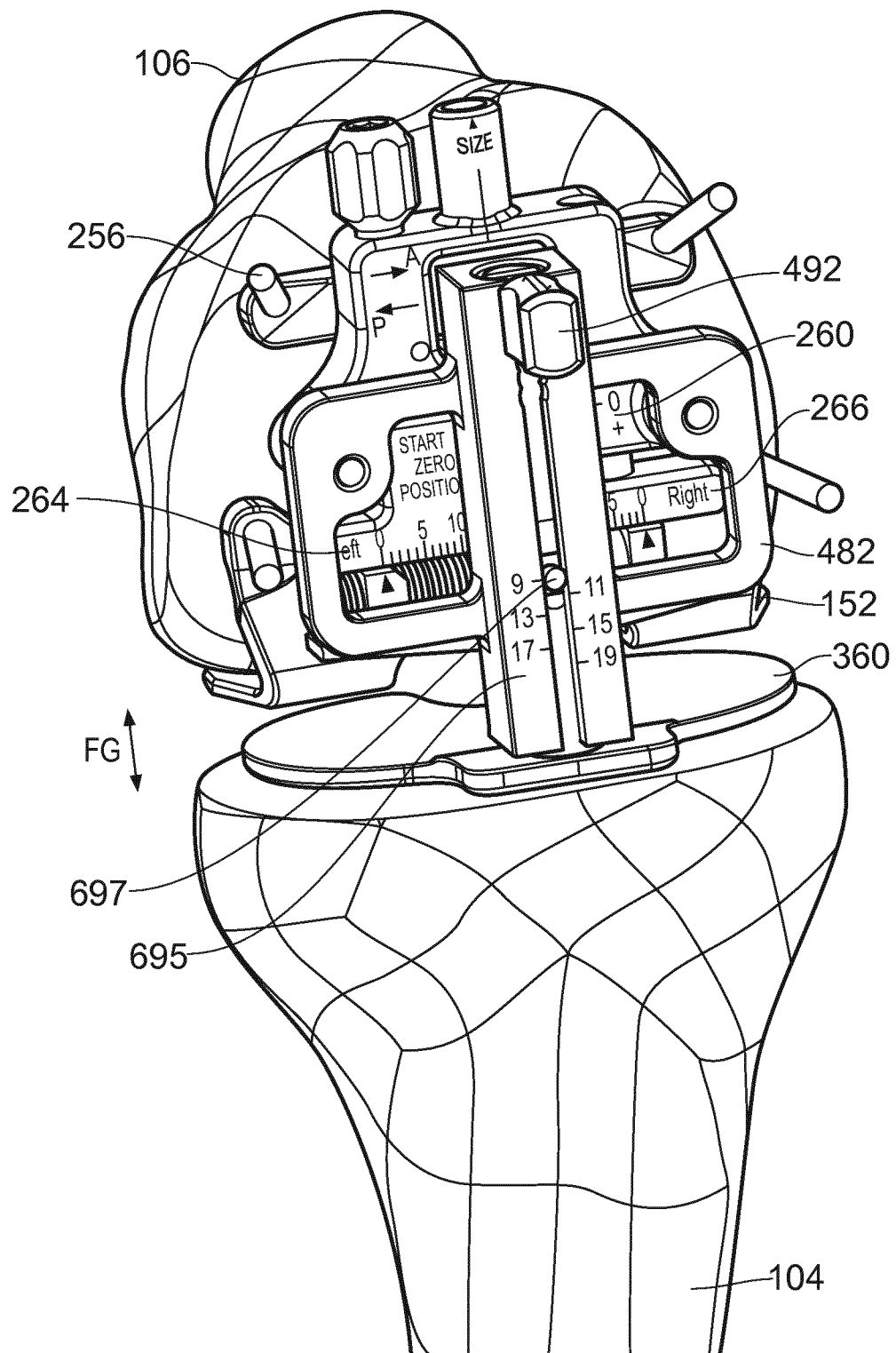


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081901

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/02 A61B17/15
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)

A61B

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)

EP0-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	US 2015/209158 A1 (REEVE MICHAEL [GB]) 30 July 2015 (2015-07-30) paragraph [0053] - paragraph [0058] paragraph [0062] - paragraph [0066] figures 1-4,6,7	1-6, 13-16, 19, 21-24,26
X	FR 2 935 092 A1 (GUILLAUME FRANCIS [FR]) 26 February 2010 (2010-02-26) page 9, line 3 - line 13 page 9, line 24 - page 11, line 14 figures 1-5B ----- -/--	1-6,13, 20-26



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

20 February 2017

Date of mailing of the international search report

01/03/2017

Name and mailing address of the ISA/

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Authorized officer

Storer, John

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081901

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/85038 A1 (FINSBURY DEV LTD) 15 November 2001 (2001-11-15) page 19, line 6 - line 22 page 21, line 23 - page 22, line 6 page 23, line 5 - page 24, line 4 page 28, line 9 - page 29, line 7 figures 1,9,23-25 -----	1,2, 4-12, 14-18, 20-26
X	US 2014/288563 A1 (CLAYPOOL JODY L [US] ET AL) 25 September 2014 (2014-09-25) paragraph [0032] - paragraph [0035] paragraph [0049] - paragraph [0052] paragraph [0073] figures 7,13 -----	1-4, 6-10,12, 14-16, 20-26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/081901

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.: 27-32
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2016/081901

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