(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 June 2017 (29.06.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/108774 A1

(51) International Patent Classification:
A61F 2/46 (2006.01)

(21) International Application Number:
PCT/EP2016/081899

(22) International Filing Date:
20 December 2016 (20.12.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1522527.9 21 December 2015 (21.12.2015) GB

(71) Applicant: **SMITH & NEPHEW ORTHOPAEDICS AG** [CH/CH]; Oberneuhofstrasse 10d, 6340 Baar (CH).

(72) Inventors: **KILCHENMANN, Thomas**; c/o Smith & Nephew Orthopaedics AG, Oberneuhofstrasse 10d, 6340 Baar (CH). **MATHIEU, Claude**; c/o Smith & Nephew Orthopaedics AG, Oberneuhofstrasse 10d, 6340 Baar (CH). **LAURENT, Marc Patrick Michel**; c/o Smith & Nephew Orthopaedics AG, Oberneuhofstrasse 10d, 6340 Baar (CH). **BLASER, Karin Franziska**; c/o Smith & Nephew Orthopaedics AG, Oberneuhofstrasse 10d, 6340 Baar (CH).

(74) Agent: **SECERNA LLP**; The Catalyst, Baird Lane, Heslington East, York North Yorkshire YO10 5GA (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ,

[Continued on next page]

(54) Title: FEMORAL SIZING APPARATUS

(57) Abstract: Embodiments of the present invention relate to apparatus (1) for determining a desired femoral component for implantation on a distal end of a patient's femur. Particularly, although not exclusively, embodiments of the present invention relate to an apparatus comprising a size guide body (10) which provides more than one size guideline which is representative of a size of a femoral component. Further embodiments of the present invention provide *inter alia* a kit comprising an apparatus as described herein and a plurality of femoral components.

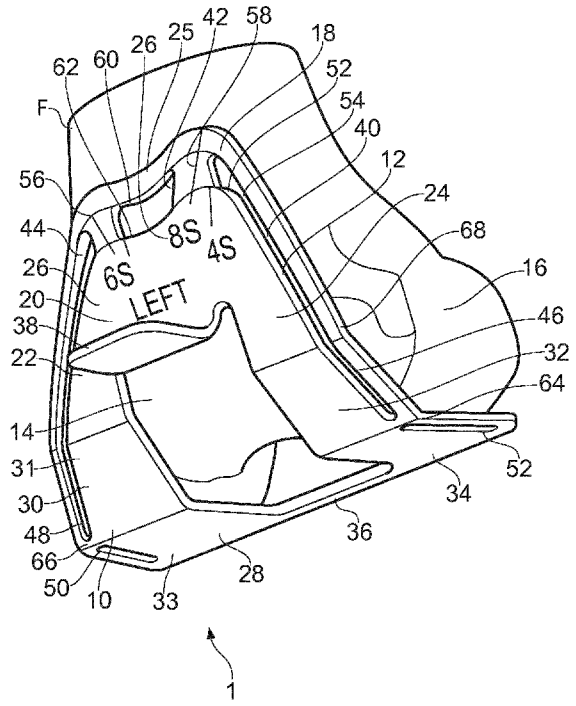


FIG. 1

WO 2017/108774 A1

TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

Femoral Sizing Apparatus

Field of the Invention

Embodiments of the present invention relate to apparatus for determining a desired femoral component for implantation on a distal end of a patient's femur. Particularly, although not exclusively, embodiments of the present invention relate to an apparatus comprising a size guide body which provides more than one size guideline which is representative of a size of a femoral component. Further embodiments of the present invention provide *inter alia* a kit comprising an apparatus as described herein and a plurality of femoral components.

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 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 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 and a trial prosthesis fitted to the femur. A box preparation procedure is then carried out. The surgeon then has an opportunity to consider whether the femoral component is the correct size or whether an alternative would be a better fit. The selected femoral component is then fitted to the distal end of the femur by the surgeon. If the size of femoral component is incorrect, it has to be removed and a different femoral component selected and implanted.

Provisional components (also 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 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 referred to as a trial reduction.

It is an aim of aspects of the present invention to at least partially mitigate the problems associated with the prior art.

It is an aim of certain embodiments of the present invention to provide a template component which indicates different sizes of a femoral component to aid in the selection of a femoral component.

Summary of Certain Embodiments of the Invention

In a first aspect of the present invention, there is provided apparatus for determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur, the apparatus comprising:

a sizing guide body comprising: at least one abutment surface locatable against an anterior surface of a distal end of a femur and one inset region, each inset region providing a plurality of size indicating guide lines, each size indicating guide line being associated with a respective one of the plurality of possible femoral components.

In certain embodiments, the at least one inset region is a through opening, the through opening providing a plurality of size indicating guide lines.

In certain embodiments, the sizing guide body further comprises an edge region extending around the sizing guide body. Aptly, each of the through openings is spaced apart from the edge region.

In certain embodiments, the edge region proximal to each through opening provides a further size indicating guide line which is associated with a respective one of the plurality of possible femoral components.

In certain embodiments, the at least one inset region, e.g. a through opening, comprise one or more stepped portions, each stepped portion providing a size indicating guide line. Aptly, the at least one inset region comprises two stepped portions. Aptly, each stepped portion comprises an edge region which provides a size indicating guide line.

In certain embodiments, the sizing guide body comprises:

a first planar body region;

a further planar body region which is substantially orthogonal to or obtuse to the first planar body region; and

a planar connecting region connecting the first planar body region to the further planar body region.

In certain embodiments, the first planar body region comprises the abutment surface which is locatable against the anterior surface of the distal end of the femur. Aptly, the abutment surface comprises a first abutment surface and a further abutment surface, and wherein the first abutment surface and the further abutment surface are connected by an abutment spanning portion.

In certain embodiments, the first planar body region is generally U-shaped. In certain embodiments, the further planar body region comprises at least one bone-contacting surface locatable against at least one of a distal surface of a medial condyle and a distal surface of a lateral condyle of the femur.

In certain embodiments, the further planar body region comprises a first bone-contacting surface locatable against the distal surface of a medial condyle and a further bone-contacting surface locatable against the distal surface of a lateral condyle. Aptly, the first bone-contacting surface and the further bone-contact surface are connected by a spanning portion, and wherein the further planar body region is generally U-shaped.

In certain embodiments, the distal surface of the medial condyle and/ or the distal surface of lateral condyle of the femur is resected. In certain embodiments, each through opening comprises a through slot in the sizing guide body.

Aptly, the sizing guide body comprises a plurality of through slots.

In certain embodiments, the sizing guide body is composed of a material selected from a metal and a plastic and combinations thereof. In certain embodiments, the sizing guide body is composed of stainless steel.

In certain embodiments, the sizing guide body further comprises a holding element configured to enable a user to hold the sizing guide body in an abutting relationship with the distal end of the femur.

In certain embodiments, the holding element is a tab portion connected to an outwardly-facing surface which opposes the abutment surface, said tab portion extending substantially orthogonal to the outwardly-facing surface.

In certain embodiments, the sizing guide body comprises at least one indicia, each indicia representing a respective one of the plurality of possible femoral components and/or a location marker for positioning of a femoral component.

Aptly, at least one femoral component of the plurality of possible femoral components differs in a dimension from at least one other femoral component of the plurality of possible femoral components.

In certain embodiments, the dimension is selected from one or more of:

a) a medial dimension;

b) a lateral dimension;

c) an anterior dimension; and

d) a distal dimension.

In a further aspect of the present invention, there is provided a system for use in knee surgery, the system comprising:

a plurality of femoral components, wherein at least one of the plurality of femoral components differs in a predetermined dimension to at least one other of the plurality of femoral components in the kit; and

an apparatus according to a first aspect of the present invention.

In certain embodiments, the plurality of femoral components comprises at least two femoral prostheses for implantation on a distal end of a femur, wherein each femoral prosthesis differs in a predetermined profile when compared to each other femoral prosthesis.

In certain embodiments, the plurality of femoral components comprises at least two femoral trial components, each femoral trial component differing in a predetermined dimension when compared to each other femoral trial component.

In a third aspect of the present invention, there is provided a method of determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur, the method comprising:

a) providing a system according to a second aspect of the present invention; and

b) selecting a femoral component from the plurality of femoral components based on a size indicating guide line of the apparatus, said size indicating guideline being associated with a respective one of the plurality of possible femoral components.

In certain embodiments, the method further comprises a step of positioning the apparatus in an abutting relationship with an anterior surface of a distal end of a femur.

In a fourth aspect of the present invention, there is provided a method for preparing a distal end of a femur to receive a femoral component, the method comprising:

(a) preparing a distal end of a patient's femur;

(b) positioning an apparatus in an abutting relationship against the distal end of the femur, wherein the apparatus is for determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur, and further wherein the apparatus comprises a sizing guide body comprising: at least one abutment surface locatable against an anterior surface of a distal end of a femur and at least one through opening, each through opening providing a plurality of size indicating guide lines, each size indicating guide line being associated with a respective one of the plurality of possible femoral components;

(c) removing the apparatus from the abutting relationship against the distal end of the femur; and

(d) positioning a femoral trial component against the distal end of the femur in a fixed relationship.

In certain embodiments, the step of preparing the distal end of the patient's femur comprises inserting an intramedullary rod into the patient's femur to assist in determination of alignment of the femur.

In certain embodiments, the step of preparing the distal end of the patient's femur comprises securing a cutting block to the distal end of the femur. Aptly, the method further comprises cutting the distal end of the patient's femur. Thus, in certain embodiments, a distal femur cut is performed, together with an anterior/posterior femur cut and anterior and posterior chamfer cuts. In certain embodiments, a tibial cut is performed prior to the distal femoral cut. Following the initial femoral cut, distal femoral resection may take place.

In certain embodiments, the method comprises (e) removing the femoral trial component and securing a femoral implant to the distal end of the patient's femur.

Detailed Description of Embodiments of the Invention

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

Figure 1 is a perspective view of an apparatus according to certain embodiments of the present invention;

Figure 2 is a perspective view of an apparatus according to certain embodiments of the present invention;

Figure 3 is a side view of the apparatus of Figure 2;

Figure 4 is a front view of the apparatus of Figure 2;

Figure 5 is a rear perspective view of the apparatus of Figure 2;

Figure 6 is a front view of an apparatus according to certain embodiments of the present invention;

Figure 7 is a back view of an apparatus according to certain embodiments of the present invention;

Figure 8 is a front view of the apparatus of Figure 7; and

Figures 9A to C are further representations of the apparatus of Figure 7 and 8.

Where appropriate, like numerals refer to like parts.

As used herein, the terms "proximal" refers to a direction generally toward the heart of a patient, and "distal" refers to the opposite direction of proximal, i.e., away from the heart of a patient. Additionally, as used herein the term "anterior" refers to a direction generally toward the front of a patient, and "posterior" refers to the opposite direction of anterior, i.e., toward the back of a patient. In addition, as used herein, "medial" refers to a direction generally toward the middle of a patient, and "lateral" refers to the opposite direction of medial, i.e., toward the side of a patient. The term "cutting" has been used herein to include any process or procedure where bone is removed, such as drilling, milling, grinding, sanding, chiseling, or the like.

In one embodiment, there is provided is an apparatus 1 for determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur. Referring generally to Figure 1, there is illustrated an apparatus 1 which comprises a sizing guide body 10. The sizing guide body 10 is configured to be placed in an abutting relationship with an anterior surface of a distal end of a patient's femur (F).

The sizing guide body 10 includes an abutment surface 12 locatable against an anterior surface 14 of a distal end 16 of a patient's femur. Thus, the abutment surface 12 is a bone-contacting surface. The abutment surface is configured to position and locate the sizing guide body relative to one or more resected surfaces of a distal end of the femur.

The sizing guide body also comprises an outwardly facing surface 18 which opposes the abutment surface 12.

The sizing guide body 10 comprises a first planar body region 20 which is configured to abut the anterior surface 14 of the distal femur in use. The sizing guide body is sized such that the first planar surface extends between a medial side of the femur to the lateral side of the patient's femur if placed against the femur. The extent to which the sizing guide body extends across the width of the femur will depend at least in part on the size of the patient's femur. It is also envisaged that the apparatus may be provided in a variety of sizes to accommodate a variety of different knee physiologies.

The first planar body region 20 comprises a first medial arm portion 22 and a first lateral arm portion 24. The first medial arm portion and the first lateral arm portion are connected by an

upper spanning portion 26 such that the first medial arm portion and the first lateral arm portion are in a spaced apart relationship. The upper spanning portion may comprise a generally symmetrical upper edge region 25. The first planar body region 20 is generally U-shaped. In alternative embodiments, the first planar body region 20 is an alternative shape.

The upper spanning portion 26 is provided with a tab portion 38 which is connected to and extends from the outwardly facing surface 18. The tab portion is configured to provide a user e.g. a surgeon with a handle for manoeuvring the apparatus during surgery. Thus, the tab portion can be gripped between the surgeon's thumb and forefinger and positioned against the patient's femur during a surgical procedure. The tab portion 38 extends generally orthogonally to the upper spanning portion 26.

The sizing guide body further comprises a second planar body region 28 which is provided generally orthogonal to the first planar body region. In some embodiments, the second planar body region is provided at an obtuse angle with respect to the first planar body region. For example, the second planar body region is provided at an angle of about 90 to about 130 degrees with respect to the first planar body region. For example, the first and second planar body regions are provided at an angle of e.g. 95, 100, 105, 110, 115, 120, 125 or 130 degrees with respect to each other.

The second planar body region comprises a second medial arm portion 33 and a second lateral arm portion 34.

The second medial arm portion 33 and the second lateral arm portion 34 are connected by a planar lower spanning portion 36 such that the second medial arm portion and the second lateral arm portion are spaced apart.

The second planar body region is configured to abut at least one of a medial and a lateral condyle of the distal femur. In the embodiment illustrated in Figure 1, the second medial arm portion is configured such that at least a portion thereof abuts the medial condyle and the second lateral arm portion is configured such that at least a portion thereof abuts the lateral condyle. Aptly, the medial and/or lateral condyles have been resected. It will be appreciated that in certain embodiments, the second medial arm portion and the second lateral arm portion are planar and not curved and therefore do not directly follow the contours of un-resected medial and lateral condyles. In the embodiments in which the apparatus is for use with an

unresected condylar region, the second medial arm portion and the second lateral arm portions may only abut the condyle at a point tangential to the curvature of the condyle.

In an alternative embodiment, the second planar body region may comprise a unitary plate portion (not shown) in place of the second medial arm portion and second lateral arm portion.

The first planar body region is connected to the second planar body region by a planar spanning body region 30. The planar spanning body region comprises a medial spanning portion 31 and a lateral spanning portion 32 which are spaced apart from each other.

Each of the first planar body region, the second planar body region and the planar spanning body region 30 comprise a bone-contacting surface which together provide the abutment surface.

The sizing guide body further comprises at least one through opening, each through opening providing a plurality of size indicating guide lines, each size indicating guide line being associated with a respective one of the plurality of possible femoral components.

In the embodiment illustrated in Figure 1, the sizing guide body comprises a plurality of through openings. Each through opening comprises edge portions which each provide a size indicating guide line. Thus, each through opening may provide at least two size indicating guide lines. Each size indicating guide line is associated with a predefined profile of a femoral component. Thus, certain embodiments of the present invention provide a simultaneous visual representation of at least two femoral prosthesis profiles.

The first planar body portion comprises a first through opening 40, a second through opening 42 and a third through opening 44 which each take the form of through slits. The first through opening 40 is provided in the first lateral arm portion and is continuous with a first through opening 46 provided in the planar spanning body region 30. The third through opening 44 is provided in the first medial arm portion of the first planar body region and is continuous with a second through opening 48 of the planar spanning body portion. The first through opening 46 of the planar spanning body region may be referred to herein as the first spanning through opening. The second through opening 48 of the planar spanning body portion may be referred to herein as the second spanning through opening.

The second planar body region also comprises a plurality of through openings. A medial opening 50 is provided in the second medial arm portion 33 and a lateral opening 52 is provided in the second lateral arm portion 34.

As shown in Figure 1, the first through opening 40 may be a slit which comprises an inner edge region 52 and an outer edge region 54, each of which provides a size indicating guide line. Similarly, the second through opening 42 provided in the upper spanning portion comprises an inner edge region 62 and an outer edge region 60. The inner edge region 62 of the second through opening provides a size indicating guide line which is associated with the predefined profile of the same femoral component as the size indicating guide line provided by the inner edge region 52 of the first through opening. Similarly, the outer edge region 60 of the second through opening provides a size indicating guide line which is associated with the same femoral component as the outer edge region of the outer edge region of the first through opening.

The first, second and third through openings of the first planar body portion may form a continuous through opening. Alternatively, and as provided in the embodiment illustrated in Figure 1, the first, second and third through openings may be separated by one or more struts such as the struts 56 and 58.

The first spanning through opening 46 may be continuous with the second lateral through opening 52 of the second planar body region. Alternatively, and as illustrated in Figure 1, the first spanning through opening 46 is separated from the second lateral opening 52 by a strut 64 which is provided at a junction between the lateral arm and the lateral portion 32 planar spanning body region 30 and the second planar body region 28. A further strut 66 is provided between medial opening 50 and the second spanning through opening 48.

Figures 2 to 5 illustrate an alternative embodiment of an apparatus 100. The sizing guide body of the apparatus generally comprises the same features as the embodiment illustrated in Figure 1. For example, the sizing guide body comprises a plurality of through openings. Each through opening comprises edge portions which each provide a size indicating guide line. The apparatus 100 comprises a first planar body region 200 and a planar spanning region 280. In the embodiment illustrated in Figure 2, the apparatus comprises a tab portion 380 which extends from a central region 300 of the planar spanning region 280. The tab portion can be used to hold and position the apparatus against the femur during surgery. The apparatus 100 comprises a generally asymmetrical upper edge region 250.

Figure 6 illustrates a further embodiment. The apparatus 1000 comprises a first planar body region which comprises one or more recessed regions 2100. Each recessed region comprises one or more stepped portions. The apparatus of Figure 6 shows a first stepped portion 2200 and a second stepped portion 2300, each of which provides a size indicating guide line. Each size indicating guide line is associated with a predefined profile of a femoral component. Thus, certain embodiments of the present invention provide a simultaneous visual representation of at least two femoral prosthesis profiles. In addition, the apparatus comprises a further size indicating guide line provided by an outer edge region 2400 of the first recessed region. The apparatus may comprise several recessed regions which are aptly provided in the first planar body region. The apparatus 1000 comprises a generally asymmetrical upper edge region 2500.

A further embodiment is shown in Figures 7 to 9. The apparatus 3000 illustrated in these figures comprises a first planar region 3020 which comprises an upper spanning portion 3260. The first planar region comprises a plurality of stepped regions as described above, for example an upper stepped recessed region 3250 each edge region of each step providing a size indicating guide line. The first planar region may also comprise medial 3350 and lateral stepped 3450 recessed regions

Additionally, the apparatus comprises a second planar body region 3280 which includes a medial arm portion 3330 and a lateral arm portion 3340 intended for abutment to the resected medial and lateral condyle respectively. Each of the medial arm portion 3330 and the lateral arm portion 3340 comprises a stepped recessed region e.g. the lateral stepped region 3300 each of which provide a plurality of size indicating guide lines as described above.

Additionally, the embodiment illustrated in Figures 7 to 9 comprises a planar spanning body region 3200 which comprises a medial recessed region 3700 which comprises a plurality of steps each comprising an edge region which provides a size indicating guide. The spanning portion further comprises a lateral recessed region 3600 each recessed region provide an edge which provides a size indicating guide line. The apparatus 3000 further comprises a tab portion 3038 as described above.

In certain embodiments, the apparatus further comprises a visual indica for enabling a surgeon to mark an optimum location of the femoral trial component on the patient's femur. As shown in Figure 8, the visual indicia is a marking line 3900.

During a knee arthroplasty procedure, the surgeon resects the distal portion of the femur. Thus, a distal femur cut is performed, together with an anterior/posterior femur cut and anterior and posterior chamfer cuts. In certain embodiments, a tibial cut is performed prior to the distal femoral cut. Following the initial femoral cut, distal femoral resection may take place. The resection may be performed using a distal femoral cutting block to guide a sawblade. The resection is typically performed using techniques and apparatus known in the art, for example the methods and apparatus associated with Smith & Nephew's TC-PLUS™ Total Knee system.

Prior to mounting a femoral trial component onto the resected distal end of the femur, a surgeon holds the apparatus in an abutting relationship to the distal end of the femur. Aptly, the apparatus is held in a medial-lateral position which provides the best bone coverage.

The surgeon may use one or more of the size indicating guide lines simultaneously to visually determine which guide line(s) are most aligned with a perimeter of a resected distal femur surface i.e. the perimeter of each of an anterior cut, an anterior chamfer cut, a distal cut, a posterior chamfer cut, and a posterior cut. Thus, in certain embodiments, the sizing guide body can be used to determine whether a standard-sized femoral component should be implanted or whether a slim femoral component should be in used instead. A number of slim femoral components of differing widths may be available. Alternatively a single "slim" alternative may be available, e.g. in a kit. In certain embodiments, the surgeon may make additional cuts in the medial and/or lateral direction to ensure a better fit of a slim femoral component.

In certain embodiments, the sizing guide body further comprises an edge region 68, 2400 which spans the abutment surface and the outwardly-facing opposing surface. In certain embodiments, the edge region may provide a further size indicating guide line which is associated with a dimension of a further possible femoral prosthesis. Thus, in some embodiments, the apparatus may provide a simultaneous visual representation of at least three femoral component profiles. In certain embodiments, the difference in width between the femoral components is 4mm.

Thus, the surgeon can use the guide lines provided by the edge regions of the opening and/or the edge region of the sizing guide body to visually depict a femoral component which aligns with the distal femur F. Thus, the surgeon can determine whether a standard sized femoral

component or a narrow sized femoral component should be placed and/or implanted on to the patient's femur based on which of the guide lines are best aligned with the anterior lateral edge of the distal femur.

Once the surgeon has determined whether to use a standard size femoral component or a slim femoral component, the sizing apparatus is removed from the femur. Typically, a femoral trial component which corresponds to the size selected by the surgeon is then positioned against the femur.

In certain embodiments, the sizing guide body comprises a visual indicator e.g. a marking line adjacent to which the surgeon may mark the patient's femur. In certain embodiments, the femoral trial component may also comprise a visual indicator e.g. a marking line in a corresponding location. The surgeon can place the femoral trial component in the same location on the distal femur thus placing the femoral trial component in the optimal position. As a result, aptly, femoral box cuts, which are made when the femoral trial component is positioned on the patient's distal femur, can be made in the optimal position.

Once the surgeon is satisfied that the femoral trial component represents the best fit to the patient's femur and the box has been prepared, it is removed and a femoral prosthesis implanted onto the femur.

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 to any novel one, or any novel combination, of the steps of any method or process so disclosed.

5

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 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 desired one of a plurality of possible femoral components for implantation on a distal end of a femur, the apparatus comprising:

a sizing guide body comprising: at least one abutment surface locatable against an anterior surface of a distal end of a femur and at least one inset region, each inset region providing a plurality of size indicating guide lines, each size indicating guide line being associated with a respective one of the plurality of possible femoral components.

2. Apparatus according to claim 1, wherein the at least one inset region is a through opening, the through opening providing a plurality of size indicating guide lines.

3. Apparatus according to claim 1 or claim 2, wherein the sizing guide body further comprises an edge region extending around the sizing guide body.

4. Apparatus according to claim 3, wherein each of the through openings is spaced apart from the edge region.

5. Apparatus according to claim 3 or claim 4, wherein the edge region proximal to each inset region provides a further size indicating guide line which is associated with a respective one of the plurality of possible femoral components.

6. Apparatus according to any of claims 2 to 5, wherein each through opening comprises a through slot in the sizing guide body, wherein optionally the sizing guide body comprises a plurality of through slots.

7. Apparatus according to any of claims 1 to 5, wherein the at least one inset region comprise one or more stepped portions, each stepped portion providing at least one size indicating guide line.

8. Apparatus according to any preceding claim, wherein the sizing guide body comprises:

a first planar body region;

a further planar body region which is substantially orthogonal to or obtuse to the first planar body region; and

a planar connecting region connecting the first planar body region to the further planar body region.

9. Apparatus according to claim 8, wherein the first planar body region comprises the abutment surface which is locatable against the anterior surface of the distal end of the femur.

10. Apparatus according to claim 9, wherein the abutment surface comprises a first abutment surface and a further abutment surface, and wherein the first abutment surface and the further abutment surface are connected by an abutment spanning portion.

11. Apparatus according to claim 10, wherein the first planar body region is generally U-shaped.

12. Apparatus according to any of claims 8 to 11, wherein the further planar body region comprises at least one bone-contacting surface locatable against at least one of a distal surface of a medial condyle and a distal surface of a lateral condyle of the femur.

13. Apparatus according to claim 12, wherein the further planar body region comprises a first bone-contacting surface locatable against the distal surface of a medial condyle and a further bone-contacting surface locatable against the distal surface of a lateral condyle.

14. Apparatus according to claim 13, wherein the first bone-contacting surface and the further bone-contact surface are connected by a spanning portion, and wherein the further planar body region is generally U-shaped.

15. Apparatus according to any of claims 13 to 15, wherein the distal surface of the medial condyle and/ or the distal surface of lateral condyle of the femur is resected.

16. Apparatus according to any preceding claim, wherein the sizing guide body is composed of a material selected from a metal, a plastic and a combination thereof.

17. Apparatus according to any preceding claim, wherein the sizing guide body further comprises a holding element configured to enable a user to hold the sizing guide body in an abutting relationship with the distal end of the femur.

18. Apparatus according to claim 17, wherein the holding element is a tab portion connected to an outwardly-facing surface which opposes the abutment surface, said tab portion extending substantially orthogonal to the outwardly-facing surface.

19. Apparatus according to any preceding claim, wherein the sizing guide body comprises at least one indicia, wherein each indicia represents a respective one of the plurality of possible femoral components and/ or a location marker for positioning of a femoral component.

20. Apparatus according to any preceding claim, wherein at least one femoral component of the plurality of possible femoral components differs in a dimension from at least one other femoral component of the plurality of possible femoral components.

21. Apparatus according to claim 20, wherein the dimension is selected from one or more of:

a) a medial dimension;

b) a lateral dimension;

c) an anterior dimension; and

d) a distal dimension.

22. A system for use in knee surgery, the system comprising:

a plurality of femoral components, wherein at least one of the plurality of femoral components differs in a predetermined dimension to at least one other of the plurality of femoral components in the kit; and

an apparatus according to any preceding claim.

23. The system according to claim 22, wherein the plurality of femoral components comprises at least two femoral prostheses for implantation on a distal end of a femur, wherein each femoral prosthesis differs in a predetermined profile when compared to each other femoral prosthesis.

24. The system according to claim 22, wherein the plurality of femoral components comprises at least two femoral trial components, each femoral trial component differing in a predetermined dimension when compared to each other femoral trial component.

25. A method of determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur, the method comprising:

a) providing a system according to any of claims 20 to 22, which comprises a plurality of possible femoral components and an apparatus, for determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur; and

b) selecting a femoral component from the plurality of femoral components based on a size indicating guide line of the apparatus, said size indicating guideline being associated with a respective one of the plurality of possible femoral components.

26. The method according to claim 25, which further comprises a step of positioning the apparatus in an abutting relationship with an anterior surface of a distal end of a femur.

27. A method for preparing a distal end of a femur to receive a femoral component, the method comprising:

(a) preparing a distal end of a patient's femur by resection;

(b) positioning an apparatus in an abutting relationship against the distal end of the femur, wherein the apparatus is for determining a desired one of a plurality of possible femoral components for implantation on a distal end of a femur, and further wherein the apparatus comprises a sizing guide body comprising: at least one abutment surface locatable against an anterior surface of a distal end of a femur and at least one inset region, each inset region providing a plurality of size indicating guide lines, each size indicating guide line being associated with a respective one of the plurality of possible femoral components;

(c) removing the apparatus from the abutting relationship against the distal end of the femur;

(d) positioning a femoral trial component against the distal end of the femur in a fixed relationship.

28. A method according to claim 27, which further comprises removing the femoral trial component from the distal end of the femur.

29. A method according to claim 28, which further comprises positioning a femoral component against the distal end of the femur and securing it to the femur.

30. A method according to any of claims 27 to 29, wherein the apparatus is as claimed in any of claims 1 to 21.

31. Apparatus according to claim 1, substantially as hereinbefore described with reference to the accompanying figures.

32. System according to claim 22, substantially as hereinbefore described with reference to the accompanying figures.

33. Method according to claim 25, substantially as hereinbefore described with reference to the accompanying figures.

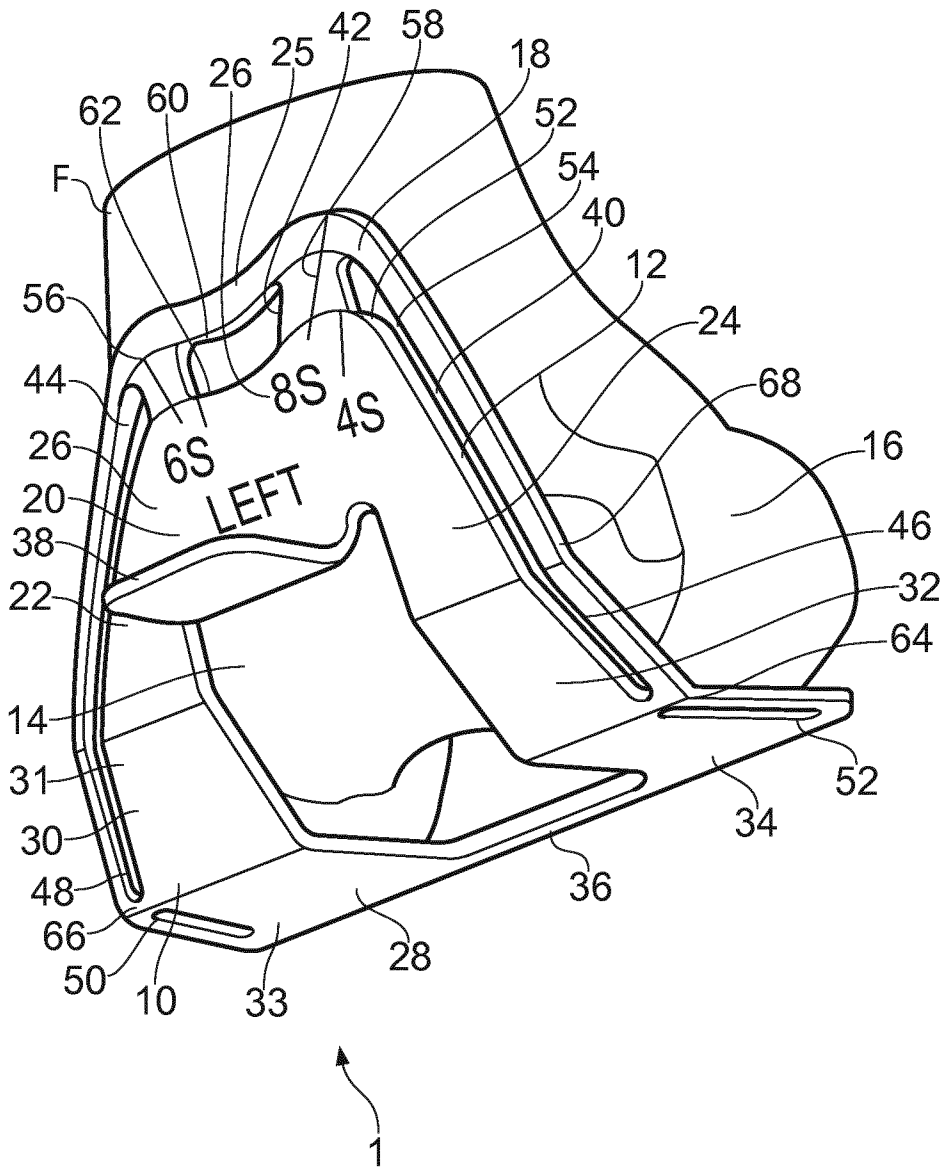

42
58
25
26
18
62
60
52
F
54
40
12
56
24
44
68
8S
4S
6S
16
26
LEFT
20
46
38
32
22
64
14
52
31
34
30
36
48
66
28
50
10
33
1

FIG. 1

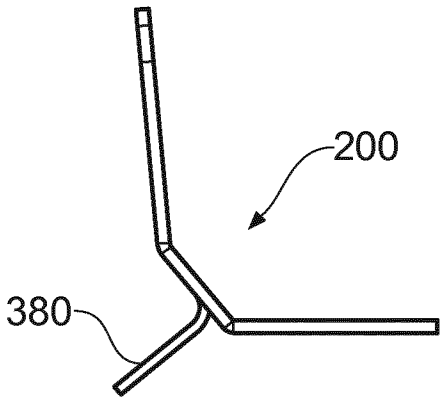


FIG. 3

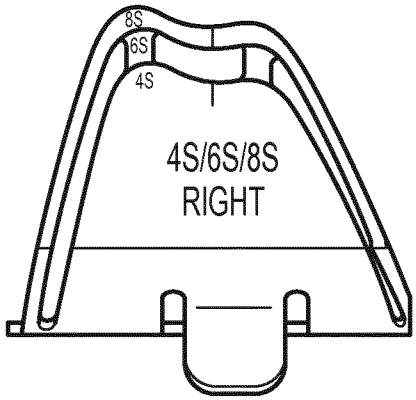


FIG. 4

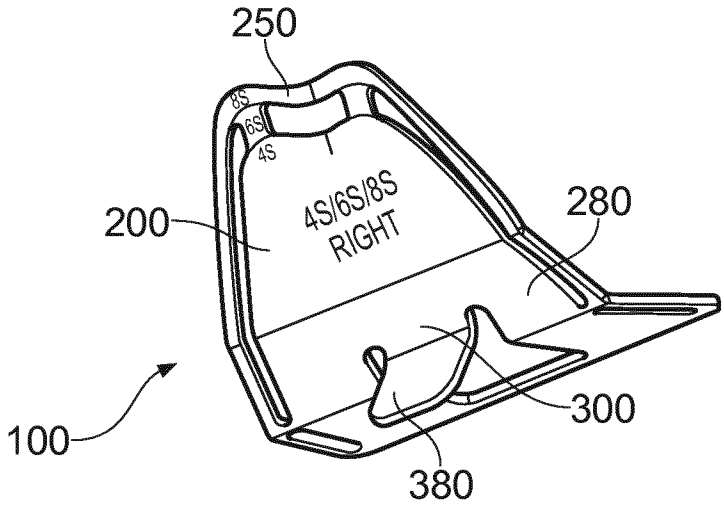


FIG. 2

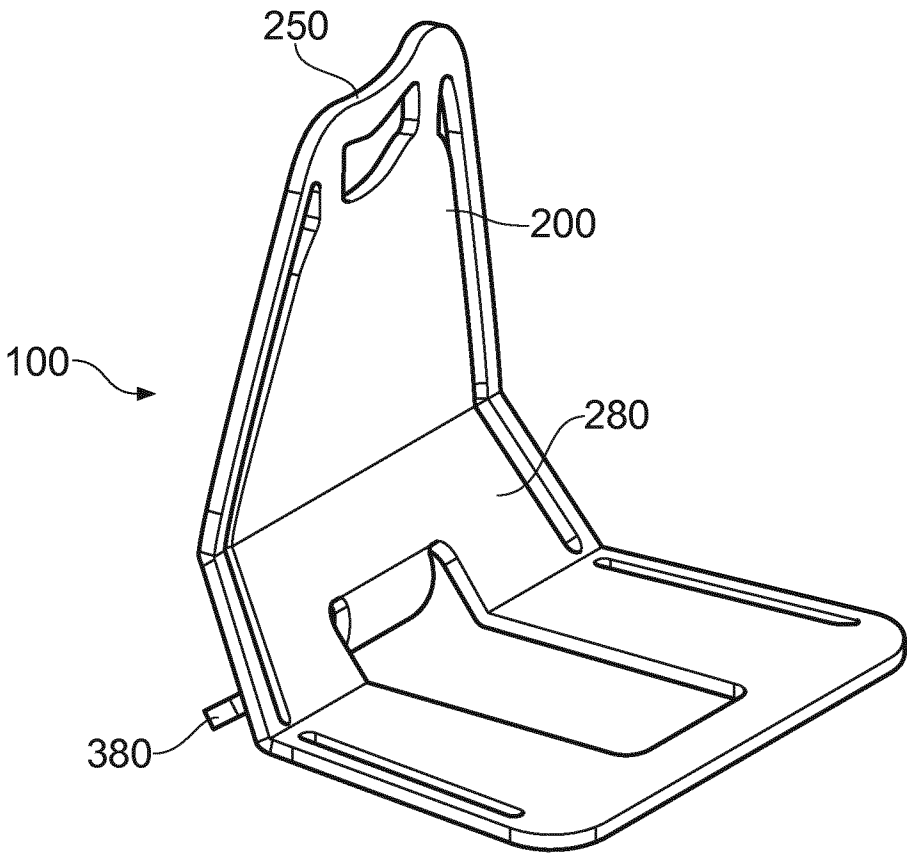


FIG. 5

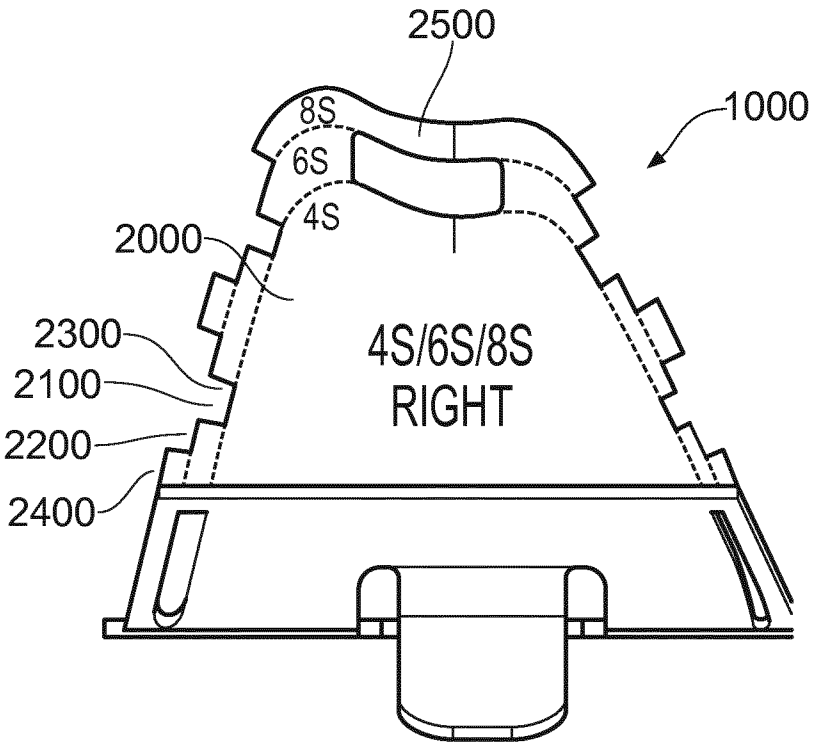


FIG. 6

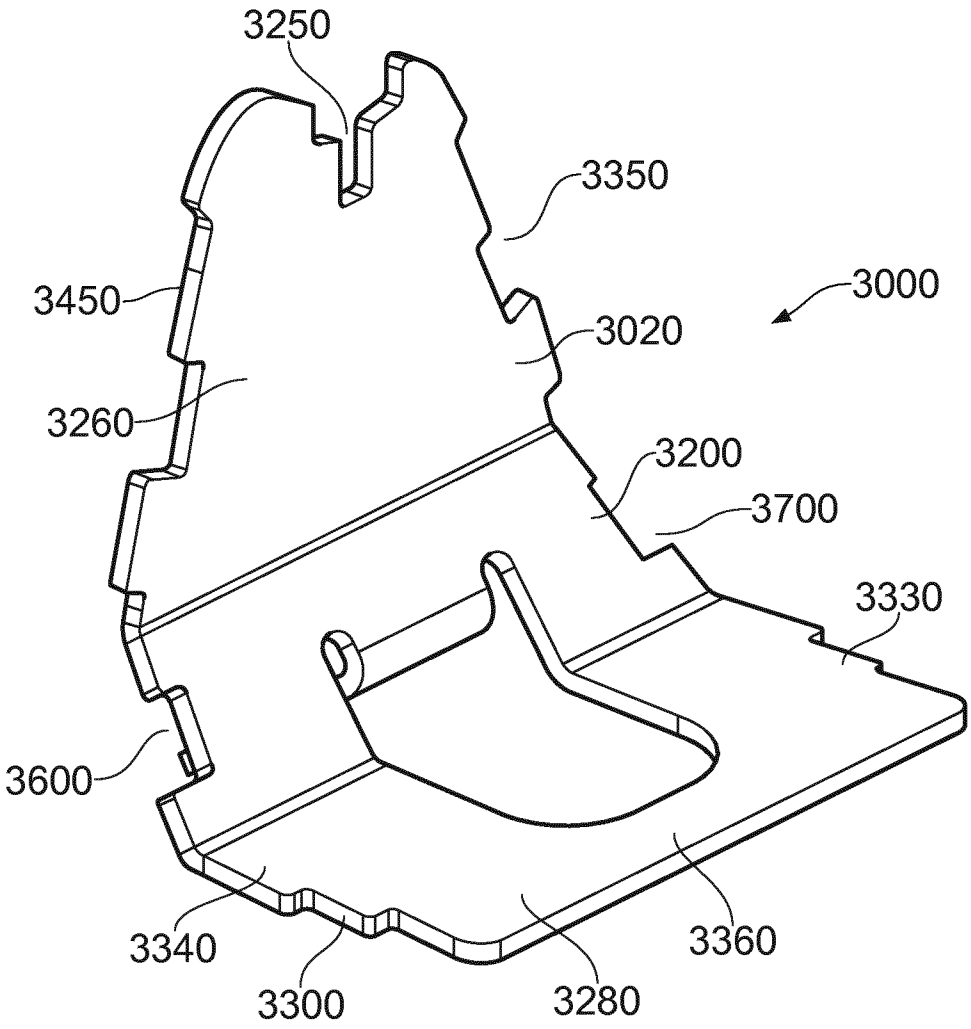

3250
3350
3000
3450
3020
3260
3200
3700
3330
3600
3340
3300
3280
3360

FIG. 7

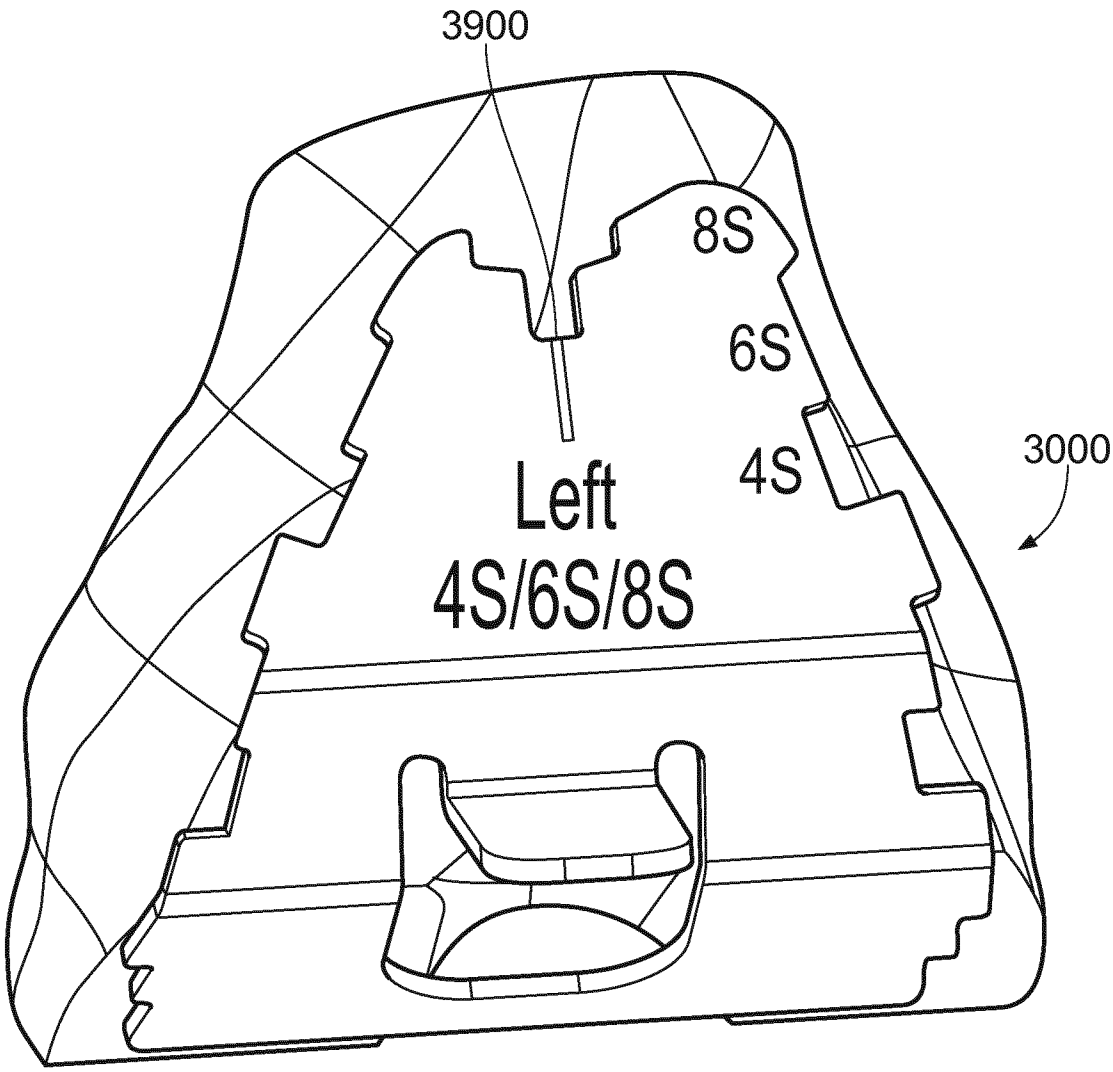


FIG. 8

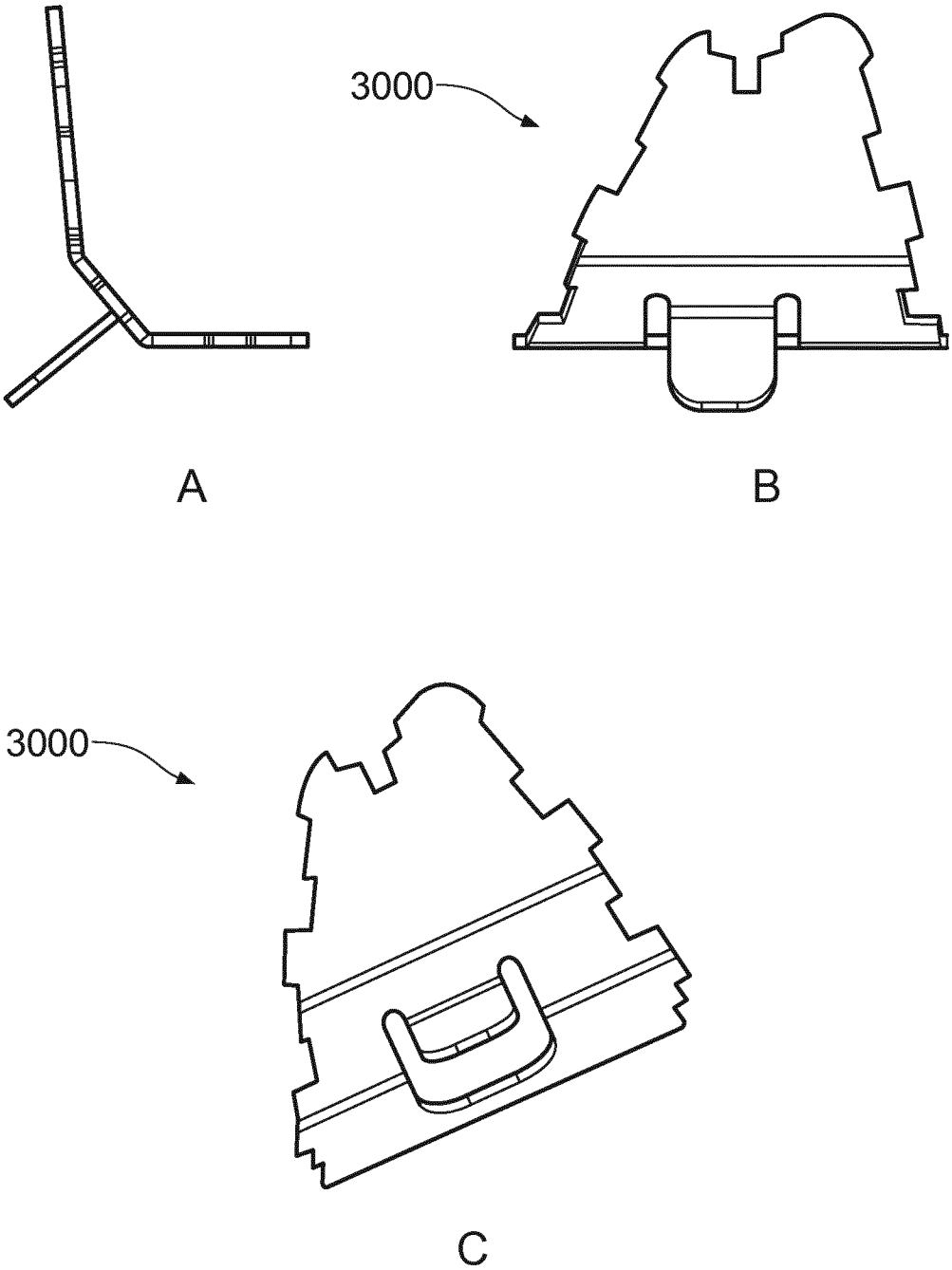


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081899

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/46
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 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)
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	US 2003/225413 A1 (SANFORD ADAM [US] ET AL) 4 December 2003 (2003-12-04)	1-4,6, 8-12,15, 19-24
Y	paragraph [0023] - paragraph [0025]	5
A	figures 2,3A,3B	7,13,14, 16,18

X	US 5 462 549 A (GLOCK STEVEN R [US]) 31 October 1995 (1995-10-31) column 3, line 33 - column 4, line 29 figures 2,3	1-3,6, 17,19-24

X	US 2010/324563 A1 (GREEN II JOHN MICHAEL [US] ET AL) 23 December 2010 (2010-12-23) paragraph [0021] - paragraph [0023] figures 1-3	1-4,17, 19-24

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
28 March 2017	10/04/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Storer, John

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/081899

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2012/323334 A1 (JONES NOLAN C [US] ET AL) 20 December 2012 (2012-12-20) paragraph [0030] - paragraph [0031] paragraph [0038] - paragraph [0039] figures 1-3,5-7 -----	5

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/081899

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. [X] Claims Nos.: 25-33
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/EP2016/081899

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003225413 A1	04-12-2003	NONE	
US 5462549 A	31-10-1995	NONE	
US 2010324563 A1	23-12-2010	AU 2010262944 A1	19-01-2012
		EP 2442736 A1	25-04-2012
		EP 2942037 A1	11-11-2015
		JP 5698227 B2	08-04-2015
		JP 5847916 B2	27-01-2016
		JP 2012530545 A	06-12-2012
		JP 2015091319 A	14-05-2015
		US 2010324563 A1	23-12-2010
		US 2012283738 A1	08-11-2012
		US 2014163572 A1	12-06-2014
		WO 2010148159 A1	23-12-2010
US 2012323334 A1	20-12-2012	AU 2012271186 A1	06-02-2014
		CA 2839349 A1	20-12-2012
		CN 103732187 A	16-04-2014
		CN 106214293 A	14-12-2016
		EP 2720649 A1	23-04-2014
		EP 2997936 A2	23-03-2016
		EP 3069693 A1	21-09-2016
		EP 3111893 A1	04-01-2017
		JP 5771745 B2	02-09-2015
		JP 2014522671 A	08-09-2014
		JP 2015164599 A	17-09-2015
		US 2012323334 A1	20-12-2012
		US 2013345821 A1	26-12-2013
		WO 2012173740 A1	20-12-2012