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(54) Title: PATIENT-SPECIFIC HIGH TIBIA OSTEOTOMY

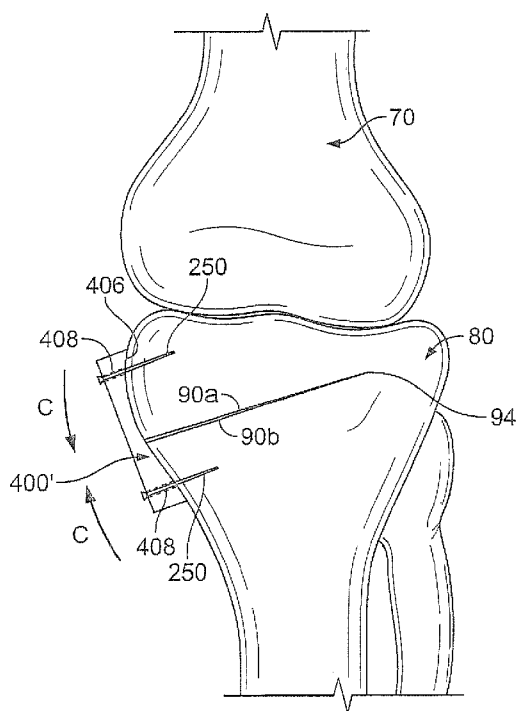


FIG. 5

(57) Abstract: A surgical kit includes a patient-specific alignment guide having a three-dimensional engagement surface custom-made by computer imaging to conform to a corresponding portion of a patient's tibial bone. The patient-specific alignment guide defines an elongated planar slot for guiding a blade. The planar slot is oriented at a selected angle and at a selected position relative to an anatomic axis of the patient when the engagement surface engages the corresponding portion of the tibial bone. The selected angle and selected position are determined during a pre-operative planning stage.

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PATIENT-SPECIFIC HIGH TIBIA OSTEOTOMY

CROSS-REFERENCE TO RELATED APPLICATIONS

5 **[0001]** This application claims the benefit and priority of U.S. Application No. 12/714,023, filed February 26, 2010.

[0002] The disclosure of the above application is incorporated herein by reference.

INTRODUCTION

10 **[0003]** Various knee osteotomies are performed to adjust or change the orientation of the tibia to correct various abnormalities caused by birth defects, trauma, or disease. High tibial osteotomies include open-wedge and closed-wedge osteotomies. Various cutting instruments and tools are used to perform such high tibial osteotomies.

15 **[0004]** The present teachings provide patient patient-specific surgical kits and methods for open-wedge or closed-wedge tibial osteotomies.

SUMMARY

20 **[0005]** The present teachings provide a surgical kit that includes a patient-specific alignment guide having a three-dimensional engagement surface custom-made by computer imaging to conform to a corresponding portion of a patient's tibial bone. The patient-specific alignment guide defines an elongated planar slot for guiding a blade. The planar slot is oriented at a selected angle and at a selected position relative to an anatomic axis of the patient when the engagement surface engages the corresponding portion of the tibial bone. The
25 selected angle and selected position are determined during a pre-operative planning stage.

30 **[0006]** The present teaching also provide a surgical kit that includes a patient-specific implantable wedge for an open-wedge osteotomy, a patient-specific fixation plate and a patient-specific alignment guide. The implantable wedge includes first and second planar surfaces defining a patient-specific wedge angle, and a patient-specific outer surface opposite to the straight edge.

The patient-specific fixation plate has a three-dimensional patient specific engagement surface for engaging the tibia and a surface engageable with the implantable wedge. The patient-specific alignment guide includes an engagement surface custom-made by computer imaging to conform to a corresponding portion of a patient's tibial bone. The patient-specific alignment guide defines an elongated planar slot for guiding a blade. The planar slot is oriented at a selected angle and at a selected position relative to an anatomic axis of the patient when the engagement surface engages the corresponding portion of the tibial bone. The selected angle and selected position are determined during a pre-operative planning stage.

[0007] The present teaching provide a surgical method including attaching a patient-specific alignment guide to a corresponding surface of a tibia of a patient for whom the alignment guide is customized during a pre-operative planning stage and making a partial bone cut in the tibia through a planar slot of the alignment guide. The planar slot is oriented at a patient-specific angle relative to an anatomic axis of the patient and the angle is customized during the pre-operative planning stage. The method includes opening the bone cut to form an opening wedge, and inserting a patient-specific implantable wedge into the opening wedge.

[0008] The present teaching provide a surgical method including attaching a patient-specific alignment guide to a corresponding surface of a tibia of a patient for whom the alignment guide is customized during pre-operative planning and making a first partial planar cut in the tibia through a first planar slot of the alignment guide. The first planar slot is oriented at a first patient-specific angle relative to an anatomic axis of the patient and the first angle customized during a pre-operative planning stage. A second partial planar cut is made in the tibia through a second planar slot of the alignment guide. The second planar slot is oriented at a second patient-specific angle relative to an anatomic axis of the patient and the second angle is customized during the pre-operative planning stage. The first and second planar cuts meet at an angle to define a bone wedge having a third patient-specific angle. The method includes removing the bone wedge to form a wedge opening and closing the wedge opening.

[0009] Further areas of applicability of the present teachings will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present
5 teachings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The present teachings will become more fully understood from the detailed description and the accompanying drawings, wherein:

10 **[0011]** FIG. 1 is a schematic illustration of a cut for open-wedge high tibial osteotomy in relation to the present teachings;

[0012] FIG. 1A is a schematic illustration of the geometry of an exemplary cut plane in relation to anatomic sagittal and transverse planes according to the present teachings;

15 **[0013]** FIG. 2 is a schematic illustration of opening the cut of FIG. 1 to form an wedge opening;

[0014] FIG. 3A is an environmental sectional view of a patient-specific wedge for the wedge opening of FIG. 2 according to the present teachings;

[0015] FIG. 3B is an environmental sectional view of a patient-specific
20 plate and a patient-specific wedge of open-wedge high tibial osteotomy according to the present teachings;

[0016] FIG. 4 is a schematic illustration of removing a bone wedge for closed-wedge high tibial osteotomy in relation to the present teachings;

[0017] FIG. 5 is a schematic illustration of closing the wedge opening
25 of FIG. 4 and attaching one fixation plate;

[0018] FIG. 5A is a schematic illustration of closing the wedge opening of FIG. 4 and attaching two fixation plates;

[0019] FIG. 6 is an environmental view of a patient-specific guide for an open-wedge high tibial osteotomy in relation to the present teachings;

30 **[0020]** FIG. 7 is an environmental view of a patient-specific guide for closed-wedge high tibial osteotomy in relation to the present teachings;

[0021] FIG. 8 is an environmental view of a patient-specific guide for an open-wedge high tibial osteotomy in relation to the present teachings;

[0022] FIG. 9 is an environmental view of a patient-specific guide for closed-wedge high tibial osteotomy in relation to the present teachings;

5 [0023] FIG. 10 is an isometric view of a patient-specific guide according to present teachings;

[0024] FIG. 11 is an environmental view of the patient-specific guide of FIG. 10 according to present teachings;

10 [0025] FIG. 12 is an isometric view of an exemplary implantable wedge according to present teachings;

[0026] FIG. 13 is an environmental view of the patient-specific wedge implant of FIG. 11 according to present teachings; and

[0027] FIGS. 14A and 14B are plan views of exemplary implantable wedges according to present teachings.

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DESCRIPTION OF VARIOUS ASPECTS

[0028] The following description is merely exemplary in nature and is in no way intended to limit the present teachings, applications, or uses. For example, although the present teachings are illustrated for patient-specific instruments and implants for high tibial osteotomy, the present teachings can be
20 used for other types of osteotomy procedures.

[0029] The present teachings generally provide patient-specific surgical kits that include alignment guides and associated implant components for use in osteotomy, such as high tibial osteotomy, for example. The patient-specific alignment guides can be used either with conventional or patient-specific implant components prepared with computer-assisted image methods. Computer modeling for obtaining three dimensional images of the patient's anatomy using MRI or CT scans of the patient's anatomy, the patient specific prosthesis components, and the patient-specific guides and templates can be
25 provided by various CAD programs and/or software available, for example, by
30 Materialise USA, Ann Arbor, Michigan.

[0030] The patient-specific alignment guides and associated patient-specific implants disclosed herein can be generally formed using computer modeling based on the patient's 3-D anatomic image generated from image scans. The patient-specific alignment guides can have a three-dimensional engagement surface that is made to conformingly contact and match a three-dimensional image of the patient's bone surface (selectively with or without soft tissue), by the computer methods discussed above. The patient-specific alignment guides can include custom-made guiding formations, such as, for example, guiding bores or cannulated guiding posts or cannulated guiding extensions or receptacles that can be used for supporting or guiding other instruments, such as drill guides, reamers, cutters, cutting guides and cutting blocks or for inserting pins or other fasteners according to a surgeon-approved pre-operative plan.

[0031] In various embodiments, the patient-specific alignment guide can include one or more patient-specific cutting guides for receiving and guiding a cutting blade at corresponding patient-specific cutting plane orientations relative to a selected anatomic axis for the specific patient. The patient-specific alignment guides can also include guiding formations for guiding the implantation of patient-specific or off-the-shelf implants associated with the osteotomy procedure, such as implantable wedges and implantable fixation plates. The geometry, shape and orientation of the various features of the patient-specific alignment guide, as well as various patient-specific implants and other patient-specific tools can be determined during the pre-operative planning stage of the procedure in connection with the computer-assisted modeling of the patient's anatomy. During the pre-operative planning stage, patient-specific alignment guides, implants and other tools, can be selected and manufactured for a specific-patient with input from a surgeon or other professional associated with the surgical procedure, as described in the commonly assigned and co-pending patent applications listed in the cross reference section and incorporated herein by reference.

[0032] In the following discussion, the terms "patient-specific", "custom-made" or "customized" are defined to apply to components, including

tools, implants, portions or combinations thereof, which include certain geometric features, including surfaces, curves, or other lines, and which are made to closely conform as mirror-images or negatives of corresponding geometric features of a patient's anatomy during a pre-operative planning stage based on
5 3-D computer images of the corresponding anatomy reconstructed from image scans of the patient by computer imaging methods. Further, patient specific guiding features, such as, guiding apertures and guiding slots, or other holes or openings that are included in alignment guides or in implants are defined as features that are made to have positions, orientations, dimensions, shapes and
10 and/or define cutting planes specific to the particular patient's anatomy based on the computer-assisted pre-operative plan associated with the patient.

[0033] A patient-specific osteotomy kit for an open-wedge osteotomy can include, according to the present teachings, a patient-specific alignment guide 200, as shown in FIG. 6, for example, a patient-specific implantable wedge
15 (or wedge implant) 300, as shown in FIGS. 3A-3B, for example, and a patient-specific implantable fixation plate 400, as shown in FIG. 5, for example. The implantable wedge 300 and a patient-specific implantable fixation plate 400 can be modularly connected, or alternatively formed monolithically as a single integral structure. An off-the-shelf, i.e. non patient-specific implantable wedge or
20 an off-the-shelf, i.e. non patient-specific implantable fixation plate can also be used optionally with the patient-specific alignment guide 200. For closed-wedge osteotomies, the implantable wedge 300 is omitted. It will be appreciated that the patient-specific alignment guides for open-wedge and closed-wedge osteotomies can include different features, as discussed below.

[0034] The patient-specific osteotomy kit can also include custom-made saw blades 500a, 500b having a predetermined cutting length
25 corresponding to a patient-specific cutting depth. The cutting depth can be determined at the pre-operative planning stage. In various embodiments, the predetermined cutting length can be an actual dimension of the cutting edge of the blade 500b (see FIG. 9). In various other embodiments, the cutting depth
30 can be adjustable and the blade 500a can include markings 502 indicating a patient-specific cutting depth. The cutting depth can also be constrained by a

depth stop engaging the patient-specific alignment guide 200 at a patient-specific depth and preventing insertion of the cutting blade beyond the pre-determined length. A separate, commercially available depth gauge can also be used to mark and restrict cutting to a pre-determined patient-specific cutting depth.

[0035] Referring to FIGS. 1 and 2, an exemplary open-wedge high tibial osteotomy is illustrated in association with a knee joint 75 between a femur 70 and a tibia 80. A planar cut 90 at a selected angle β relative to a first reference axis A of the knee joint 75 can be made using the patient-specific kit of the present teachings. The first reference axis A can be a selected anatomic axis, such as, for example a mechanical axis of the joint or leg, a mechanical axis of the femoral bone, or a mechanical axis of the tibial bone, when different from the mechanical axis of the leg. Other anatomic axes, such as axes having significantly different orientations than the orientation of axis A illustrated in FIG. 1, can be used as reference axes, including, for example, an epicondylar axis, which can be substantially transverse to the axis A of FIG. 1. The angle β of the planar cut 90 relative to the reference axis A can be determined during the pre-operative planning stage of the osteotomy and in relation to the corresponding alignment guide 200.

[0036] The planar cut 90 can also be oriented at a patient-specific angle relative to second and third reference axes B_1 and B_2 . A representative geometry illustrating the orientation of an exemplary cut plane P in relation to a sagittal plane S and a transverse plane T of the patient's anatomy is shown in FIG. 1A. In FIG. 1A, a first angle ϕ_1 is defined between an axis N perpendicular to the cut plane P and an axis z parallel to the first reference axis A, which extend superiorly-inferiorly on the sagittal plane. The first angle ϕ_1 and angle β have a sum of 90 degrees. A second angle ϕ_2 is defined between the axis N and an axis x parallel to the second reference axis B_1 , which extends medially-laterally on the transverse plane T. A third angle ϕ_3 is defined between the axis N and an axis y parallel to the third reference axis B_2 , which extends anteriorly-posteriorly on the transverse plane T. Medial-lateral, anterior-posterior and superior-inferior orientations of the cut plane P can be specified by selecting

patient specific values for these angles, keeping in mind that only two of the three angles can be specified independently, while the third can be calculated from the relation that the sum of the squares of the cosines of the angles is equal to 1. In the following discussion, although patient-specific orientations of planar cuts and corresponding planar slots relative to the axis A will be described in detail, it will be understood that the planar cuts and planar slots can be additionally or alternatively be oriented at patient-specific angles about the axes B_1 and B_2 .

[0037] Referring to FIGS. 1-3, the planar cut 90 is a partial cut, i.e., not a through cut, and can extend from a first boundary 92 at the intersection of the planar cut 90 with the outer surface of the tibia 80 to a second boundary 94 at the selected patient-specific cutting depth illustrated as distance L in FIG. 1. The first boundary 92 can be generally a curved line reflecting the curvature of the outer surface of the tibia 80. The second boundary 94 can be substantially a straight line as formed by the saw blade. The second boundary 94 can function as a hinge line (also referenced with numeral 94) for opening a wedge angle γ between first and second opposing faces 96, 98 of the cut 90, as illustrated by arrows C in FIG. 2. The wedge angle γ is patient-specific and can be selected during the pre-operative planning stage. The location of the first and second boundaries 92, 94, the angle β of the planar cut 90 relative to the reference axis A and the wedge angle γ can be determined during the pre-operative planning stage for correcting a condition of the particular patient, including conditions resulting from idiopathic bone misalignment, joint or bone disease, trauma, cancer or other therapeutic or corrective surgery. Similarly, the planar cut 90 can be oriented at a corresponding patient-specific angle ϕ_2 relative to the medial-lateral axis B_1 , as illustrated in FIG. 1A.

[0038] Referring to FIGS. 1-3A, a patient-specific implantable wedge 300 having a corresponding wedge angle γ defined between first and second planar surfaces 302, 304 can be inserted and/or pushed between the first and second faces 96, 98 of the cut 90, while the cut 90 is partially open, i.e., while the first and second faces 96, 98 form an angle smaller than the angle γ , for guiding and facilitating the correct wedge opening to form the pre-selected angle

γ . It will be appreciated, however, the cut 90 can be opened to an angle γ , using any other tool, such as trial wedge having the same angle γ .

[0039] With continued reference to FIGS. 1-3A, the first and second first and second planar surfaces 302, 304 of the implantable wedge 300 can
5 meet at a straight edge or truncated plane surface 306. Upon insertion of the implantable wedge 300, the cut 90 is opened and secured to the selected angle γ by the implantable wedge 300. The first and second planar surfaces 302, 304 of the implantable wedge 300 can abut against the first and second surfaces 96, 98 of the planar cut 90, and the edge 306 of the implantable wedge 300 can abut
10 the second boundary 94 of the planar cut 90. The implantable wedge 300 can have a patient-specific boundary surface 308 opposite to the edge/surface 306. The boundary surface 308 is designed during the pre-operative planning stage as a continuous and smooth surface that provides a continuous contour relative to the contour of the tibia 80 on either side of the cut 90. The implantable
15 wedge 300 can also be secured directly in the bone with sutures, pins, anchors or other fasteners.

[0040] Alternatively, and referring to FIGS. 3A and 3B, a patient-specific implantable fixation plate 400 can be used in combination with the patient-specific implantable wedge 300. The patient-specific implantable wedge
20 300 and the patient-specific fixation plate 400 can be modularly connected, as illustrated in FIG. 3B, or can be provided as a single monolithic and integrally formed component. A modular connection can include a dovetail connection illustrated at reference numerals 402 and 310 corresponding to opposing connection formations of the fixation plate 400 and implantable wedge 300.
25 Other connection formations can include a taper lock connection, various groove and tongue connections, or connections with threadable fasteners or other biocompatible fasteners. The modular connection can be formed at a common boundary 404 between the fixation plate 400 and the implantable wedge 300.

[0041] The fixation plate 400 can include patient-specific surfaces
30 406a, 406b on either side the implantable wedge 300 and can be anchored to the tibia 80 using bone pins or other bone fasteners 450 that pass through corresponding apertures 408 of the fixation plate 400. The location and

orientation of the apertures can also be patient-specific and determined during the pre-operative planning stage for the particular patient.

[0042] In various embodiments, and referring to FIG. 6, a patient-specific alignment guide 200 for an open-wedge osteotomy is illustrated. The alignment guide 200 can include a three-dimensional patient-specific engagement surface 202 made to conform to a corresponding outer surface of the tibia 80 by a computer-assisted method utilizing a 3-D image of the patient's tibia 80 during the pre-operative planning stage, as discussed above. The alignment guide 200 can include one or more guiding receptacles, the precise location of which is determined on the basis of a pre-operative surgical plan for locating alignment pins or other fasteners or for assisting in locating cutting blades or other cutting instruments for resecting the bone and/or shaping the bone for receiving an implant, as described in commonly-owned, co-pending in U.S. Patent Application No. 11/756057, filed on May 31, 2007, incorporated herein by reference. The alignment guide can be placed on and conform with the anterior/lateral surface of the tibia, for example.

[0043] Referring to FIG. 6, the alignment guide 200 can include a guiding receptacle in the form of a planar slot 206 oriented to define a patient-specific angle β relative to the anatomic axis A for guiding a blade 500a to form the planar cut 90. The blade 500a can include depth-control indicia 502 corresponding to the hinge line 94. The alignment guide 200 can also define one or more fixation apertures 204 for receiving bone fixation fasteners 250. Additional guiding receptacles, such as guiding apertures 208, can be provided for preparing fastener holes in the tibia 80 to receive the bone fixation fasteners 250 through the apertures 408 of the fixation plate 400. The location and orientation of the planar slot 206, the apertures 204 for the fasteners 250 and the guiding apertures 208 relative to alignment guide 200 can be determined during the pre-operative planning stage on a patient-specific (patient customized) basis. Similarly, the planar slot 206 can be oriented at a corresponding patient-specific angle ϕ_2 relative to the medial-lateral axis B₁, as illustrated in FIG. 1A.

[0044] Referring to FIG. 8, another alignment guide 200 for open-wedge osteotomy is illustrated. The alignment guide 200 can be placed on the

anterior and/or lateral side of the proximal tibia 80, such that the three-dimensional patient-specific engagement surface 202 of the alignment guide 200 closely conforms to the corresponding portion of the tibia 80. The plane defined by the planar slot 206 is shown in phantom at a corresponding angle $\beta=90-\phi_1$ relative to the reference/anatomic axis A, as discussed above in connection with FIG. 6. A blade 500b can be used for the plane cut through the planar slot 206 having size that provides automatic control of the length of the cut.

[0045] Referring to FIGS. 4 and 5, an exemplary closed-wedge high tibial osteotomy is illustrated in association with a knee joint 75 between a femur 70 and a tibia 80. First and second partial planar cuts 90a, 90b at corresponding selected first and second angles β_1 and β_2 relative to a reference/anatomic axis A of the knee joint 75 can be made using a patient-specific kit of the present teachings. The first and second planar cuts 90a, 90b can intersect at a hinge line 94. The first and second angles β_1 and β_2 of the planar cuts 90a, 90b relative to the reference axis A can be determined during the pre-operative planning stage of the osteotomy and in relation to the corresponding alignment guide 200. Each of the first and second angles β_1 and β_2 is complementary of a corresponding angle ϕ_1 shown in FIG. 1A ($90-\beta_1$ and $90-\beta_2$). Similarly, the first and second cuts 90a, 90b can be oriented at corresponding and different angles ϕ_2 relative to the medial-lateral axis B_1 , as illustrated in FIG. 1A. The first and second angles β_1 and β_2 of the planar cuts 90a, 90b define a bone wedge 91 of predetermined wedge angle $\gamma = \beta_1 - \beta_2$. The bone wedge 91 can be removed and the corresponding wedge opening can be closed by bringing the surfaces of the first and second cuts 90a, 90b in contact by rotating about the hinge line 94. A first (or osteotomy-side) patient-specific fixation plate 400' can be attached to the tibia 80 to secure the first and second cuts 90a, 90b in contact after the bone wedge 91 is removed. The first and second cuts 90a, 90b can also be secured by pins, sutures or other fasteners to the bone. In the fixation plate 400' the same reference numerals are used to indicate features having the same functions as in the fixation plate 400. The fixation plate 400' can include a patient-specific engagement surface 406 and apertures 408 at patient-specific

positions and orientations for guiding bone fixation fasteners 250 through the apertures 408 and into the tibia 80.

[0046] Referring to FIGS. 5 and 5A, a second (or hinge-side) fixation plate 400'a can be used opposite the first or osteotomy-side fixation plate 400' on the side of the osteotomy hinge. The second fixation plate 400'a can be a patient-specific fixation plate or an off-the shelf commercially available fixation plate. The second plate 400'a can be attached to the tibia with separate fasteners. Alternatively, the same fixation fasteners 250 can extend between both the first and second plates 400' and 400'a. In such case, the guiding apertures 208 of the alignment guide 200' can be used to drill guiding holes through the entire width of the tibia 80 for guiding the location of the first and second plates 400' and 400'a and the common fixation fasteners 250 through the tibia and through the first and second plates 400' and 400'.

[0047] Referring to FIG. 7, a patient-specific alignment guide 200' for a closed-wedge osteotomy is illustrated. In alignment guide 200' the same reference numerals are used to indicate features having the same functions as in alignment guide 200. The alignment guide 200' can include a three-dimensional patient-specific engagement surface 202 made to conform to a corresponding outer surface of the tibia 80 by a computer-assisted method utilizing a 3-D image of the patient's tibia 80 during the pre-operative planning stage, as discussed above. The alignment guide 200' can define first and second guiding receptacles in the form of first and second planar slots 206a, 206b oriented at selected first and second angles β_1 and β_2 relative to a reference/anatomic axis A for guiding a blade to form the planar cuts 90a, 90b of the removable bone wedge 91. The alignment guide 200' can also define one or more apertures 204 receiving bone fixation fasteners 250. Additional guiding receptacles, such as guiding apertures 208 can be provided for drilling or otherwise preparing fastener holes in the tibia 80 corresponding to the apertures 408 of the fixation plate 400 for securing the fixation plate 400 to the tibia 80. The location and orientation of the first and second planar slots 206a, 206b, the apertures 204 and the guiding apertures 208 relative to alignment guide 200' can be determined during the pre-

operative planning stage on a patient-specific base. The alignment guide 200' can be used with a blade 500a having depth indicia 502.

[0048] Referring to FIG. 9, another alignment guide 200' for closed-wedge osteotomy is illustrated. The alignment guide 200' can be placed on the
5 anterior and/or lateral side of the proximal tibia 80, such that the patient-specific engagement surface 202 of the alignment guide 200' closely conforms to the corresponding portion of the tibia 80. The planes defined by the first and second planar slots 206a, 206b are shown in phantom at corresponding first and second angles β_1 and β_2 (not shown) relative to the reference/anatomic axis A, as
10 discussed above in connection with FIG. 7 and FIG. 1A. Additionally and optionally, each of the first and second angles β_1 and β_2 is complementary of a corresponding angle ϕ_1 shown in FIG. 1A ($90-\beta_1$ and $90-\beta_2$). Similarly, the planes defined by the first and second planar slots 206a, 206b can be oriented at corresponding and different angles ϕ_2 relative to the medial-lateral axis B₁, as
15 illustrated in FIG. 1A.

[0049] Referring to FIGS. 10-13, another embodiment of a patient-specific alignment guide is illustrated at 600. As in the embodiments discussed above, the patient-specific alignment guide includes a three-dimensional patient-specific engagement surface 602, fixation apertures 604 for bone fixation
20 fasteners 650 and guiding apertures 608 for drilling holes in the bone. In this embodiment, the alignment guide 600 includes a central cylindrical through-hole 611 passing through the center of a planar slot 606. The central hole 611, which has a diameter greater than the opening of the slot 611, can facilitate cutting with a blade along the slot 606 through either side of the central hole 611. Referring
25 to FIG. 11, the central hole 611 of the alignment guide 600 can be used to drill a hole 93 in the bone 80 before the planar osteotomy cut 90 is performed at a selected patient-specific angle β , as shown in FIG. 11. The patient-specific guide 600 can include radiolucent markers 620, which are visible in radiographic images and can provide directional guidance during the surgical procedure.
30 Similar markers in the form of lines or points/spots can also be provided on the patient-specific alignment guides 200, 200' discussed above.

[0050] Referring to FIGS. 12 and 13, a patient-specific implantable wedge 700 can be inserted through the osteotomy cut to keep the osteotomy open. Similarly to the embodiments described above, the implantable wedge 700 can include a three-dimensional patient-specific surface 708 (best shown in FIG. 13), an elongated curved central portion 712 conforming to shape of the drilled hole 93 on the opposite surfaces of the planar cut 90. The elongated central portion 712 can be cylindrical or tapered (truncated cone or conical segment). A pair of planar portions 702, 704 extend radially from opposite sides of the central portion 712 from the patient specific surface 708 to an end surface 706 and define a wedge of angle γ . The central portion 712 can be aligned with the hole 93 and provide a guide for centering and inserting the implantable wedge 700 into the osteotomy cut 90. The central portion 712 can have greater thickness than and protrude away from and outside the planar portions 702, 704.

[0051] The various patient-specific implantable wedges 300, 700 for the open-wedge osteotomy can be made of various biocompatible materials including, for example, various metals or alloys, porous metal and porous metal alloys and bone-growth inducing materials, including Pro Osteon[®], commercially available from Biomet, Inc., Warsaw, IN, with or without a resorbable filler material. The implantable wedges 300, 700 can also be in the form of multiple-component wedges with or without interlocking connecting features. An exemplary illustration of a multiple-piece implantable wedge 800 is shown in FIGS. 14A and 14B. The implantable wedge 800 can extend from a first surface 808 to a second surface 807. The first surface 808 can be optionally patient-specific. The implantable wedge 800 can include a plurality of separate components 802. Two adjacent components 802 can be in contact at a common boundary 804. The adjacent components 802 can also be optionally interlocked with a connecting feature 806. The connecting feature 806 can be a single structural connector or a plurality of structural connectors, including tongue and groove, interdigitation, dovetail, threaded fasteners, etc.

[0052] The various fixation plates 400, 400', 400'a can be made of similar materials. For open-wedge osteotomies, the fixation plate 400 can be integral to the implantable wedge 300, modularly coupled to the implantable

wedge 300 via a connecting joint or fasteners, or directly coupled to the bone outside the implantable wedge 300. The various alignment guides 200, 200', 600 can be made of any biocompatible material, including, polymer, ceramic, metal or combinations thereof.

5 **[0053]** As discussed above, a surgical kit for an open-wedge or a closed-wedge high tibial osteotomy can be provided on a patient-specific basis. The surgical kit can include a patient-specific alignment guide and, optionally, a patient-specific or an off-the-self fixation plate. For an open-wedge osteotomy, the surgical kit can include a patient-specific or an off-the-shelf implantable
10 wedge. The patient-specific tools and implants are customized and prepared for the specific patient during a computer-assisted pre-operative planning stage in which the patient's anatomy is modeled in three dimensions from two-dimensional image scans. Patient-specific or customized blades can be included to provide adjustable depth control or automatic length. Other, non-
15 customized blades can also be included.

[0054] The foregoing discussion discloses and describes merely exemplary arrangements of the present teachings. Furthermore, the mixing and matching of features, elements and/or functions between various embodiments is expressly contemplated herein, so that one of ordinary skill in the art would
20 appreciate from this disclosure that features, elements and/or functions of one embodiment may be incorporated into another embodiment as appropriate, unless described otherwise above. Moreover, many modifications may be made to adapt a particular situation or material to the present teachings without departing from the essential scope thereof. One skilled in the art will readily recognize from such
25 discussion, and from the accompanying drawings and claims, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the present teachings as defined in the following claims.

CLAIMS

What is claimed is:

1. A surgical kit comprising:
5 a patient-specific alignment guide including a three-dimensional engagement surface custom-made by computer imaging to conform to a corresponding portion of a patient's tibial bone, the patient-specific alignment guide defining a first elongated planar slot for guiding a blade, the first planar slot oriented at a selected angle and at a selected position relative to an anatomic
10 axis of the patient when the engagement surface engages the corresponding portion of the tibial bone, the selected angle and selected position determined during a pre-operative planning stage.
2. The surgical kit of claim 1, wherein the alignment guide defines a
15 plurality of openings receiving bone fasteners for supporting the alignment guide on the tibial bone at a patient specific position and orientation.
3. The surgical kit of claim 1, wherein the alignment guide defines a
20 plurality of guide apertures, the guide apertures oriented and positioned at locations selected during a pre-operative planning stage for attaching a patient-specific implant.
4. The surgical kit of claim 3, further comprising a patient-specific
25 implantable fixation plate having a patient-specific surface engageable with the tibia.
5. The surgical kit of claim 1, further comprising a patient-specific
implantable wedge, the implantable wedge including first and second planar
surfaces defining a wedge angle therebetween, the wedge angle selected during
30 pre-operative planning for correcting the patient's anatomy.

6. The surgical kit of claim 5, wherein the implantable wedge includes a patient-specific curved surface opposite to the wedge angle, the curved surface continuing a contour of the tibial bone between each side of an open-wedge osteotomy.

5

7. The surgical kit of claim 5, further comprising a patient-specific implantable fixation plate connected with the implantable wedge.

8. The surgical kit of claim 7, wherein the fixation plate and the
10 implantable wedge comprise a single monolithic implant.

9. The surgical kit of claim 7, wherein the fixation plate and the implantable wedge are removably coupled to one another.

10. The surgical kit of claim 7, wherein the fixation plate and the
15 implantable wedge are removably coupled to one another with a dovetail connection.

11. The surgical kit of claim 1, further comprising a blade.
20

12. The surgical kit of claim 11, wherein the blade is customized for the patient.

13. The surgical kit of claim 1, further comprising a second elongated
25 planar slot for guiding a blade, the second planar slot at an angle with the first planar slot for closed osteotomy.

14. The surgical kit of claim 1, wherein the patient-specific alignment
30 guide includes a central guiding aperture through the planar slot.

15. The surgical kit of claim 14, further comprising a patient-specific implantable wedge, the implantable wedge including an elongated curved central portion and pairs planar surfaces extending radially from the central portion and defining a wedge angle therebetween, the wedge angle selected during pre-operative planning for correcting the patient's anatomy.

16. The surgical kit of claim 1, further comprising an implantable wedge including a plurality of separate components.

17. A surgical kit comprising:

a patient-specific implantable wedge for an open-wedge osteotomy, the implantable wedge including first and second planar surfaces forming a patient-specific wedge angle, the implantable wedge including a patient-specific outer surface opposite to the straight edge;

a patient-specific fixation plate, the fixation plate having a patient-specific engagement surface for engaging the tibia and a surface engageable with the implantable wedge; and

a patient-specific alignment guide including a three-dimensional engagement surface custom-made by computer imaging to conform to a corresponding portion of a patient's tibial bone, the patient-specific alignment guide defining an elongated planar slot for guiding a blade, the planar slot oriented at a selected angle and at a selected position relative to an anatomic axis of the patient when the engagement surface engages the corresponding portion of the tibial bone, the selected angle and selected position determined during a pre-operative planning stage

18. The surgical kit of claim 17, wherein the patient-specific alignment guide defines apertures at patient-specific orientations and positions for guiding bone fasteners for the fixation plate.

19. The surgical kit of claim 17, wherein the implantable wedge and the fixation plate comprise a single monolithically formed component.

20. The surgical kit of claim 17, wherein the implantable wedge and the fixation plate are removably connected.

21. The surgical kit of claim 17, wherein the implantable wedge and the
5 fixation plate are removably connected with a dovetail connection.

22. The surgical kit of claim 17, further comprising a blade with depth control.

10 23. The surgical kit of claim 17, wherein the implantable wedge includes a plurality of separate components.

24. A surgical method comprising:
attaching a patient-specific alignment guide to a corresponding
15 surface of a tibia of a patient for whom the alignment guide is customized during a pre-operative planning stage;
making a partial bone cut in the tibia through a planar slot of the alignment guide, the planar slot oriented at a patient-specific angle relative to an anatomic axis of the patient, the angle customized during the pre-operative
20 planning stage;
opening the bone cut to form an opening wedge; and
inserting a patient-specific implantable wedge into the opening wedge.

25 25. The surgical method of claim 24, further comprising removably attaching a patient-specific fixation plate to the implantable wedge.

26. The surgical method of claim 24, wherein inserting a patient-specific implantable wedge into the opening wedge includes attaching a patient-specific fixation plate monolithically formed with the implantable wedge.
30

27. The surgical method of claim 24, further comprising drilling bone apertures for bone fasteners through patient-specific apertures of the alignment guide.

5 28. The surgical method of claim 24, wherein the planar slot defines a depth or length dimension of the cut.

29. The surgical method of claim 24, further comprising drilling a hole in the tibia through a central aperture intersecting the planar slot of the patient-specific alignment guide before making a bone cut through the planar slot.
10

30. A surgical method comprising:
attaching a patient-specific alignment guide to a corresponding surface of a tibia of a patient for whom the alignment guide is customized during a pre-operative planning stage;
15

making a first partial planar cut in the tibia through a first planar slot of the alignment guide, the first planar slot oriented at a first patient-specific angle relative to an anatomic axis of the patient, the first angle customized during a pre-operative planning stage;

20 making a second partial planar cut in the tibia through a second planar slot of the alignment guide, the second planar slot oriented at a second patient-specific angle relative to an anatomic axis of the patient, the second angle customized during a pre-operative planning stage, the first and second planar cuts meeting at an angle to define a bone wedge having a third patient-specific angle;
25

removing the bone wedge to form a wedge opening; and
closing the wedge opening.

31. The surgical method of claim 30, further comprising attaching a patient-specific fixation plate to the tibia, the patient-specific fixation plate having a three-dimensional patient-specific engagement surface attachable over the tibia to secure the tibia after closing the wedge opening.
30

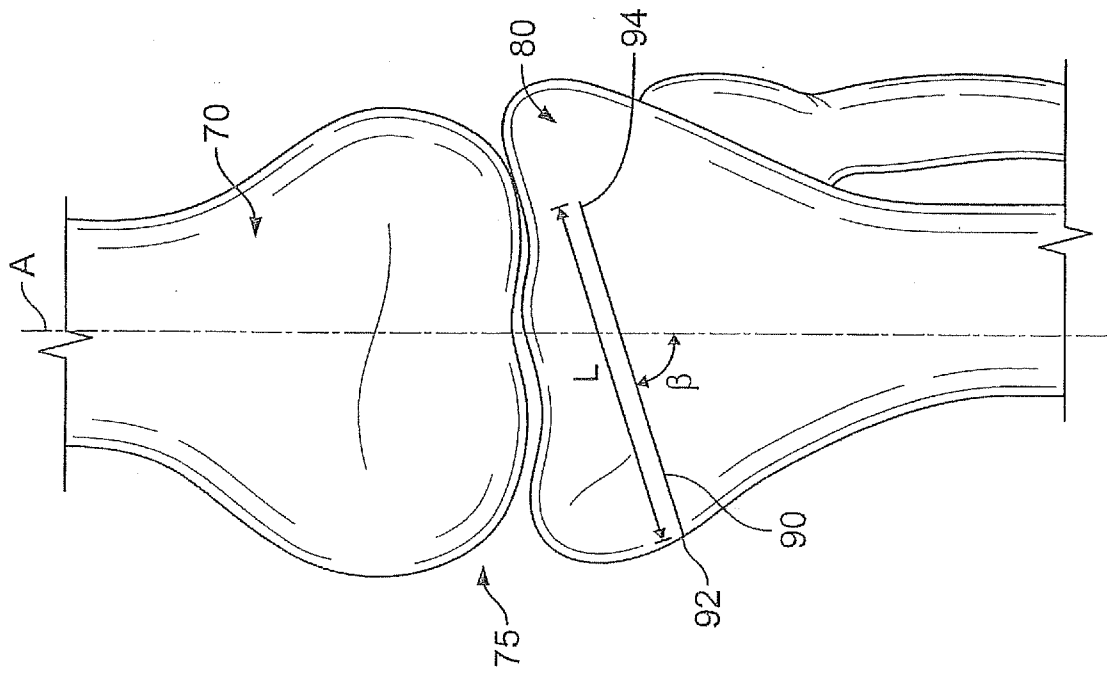


FIG. 1

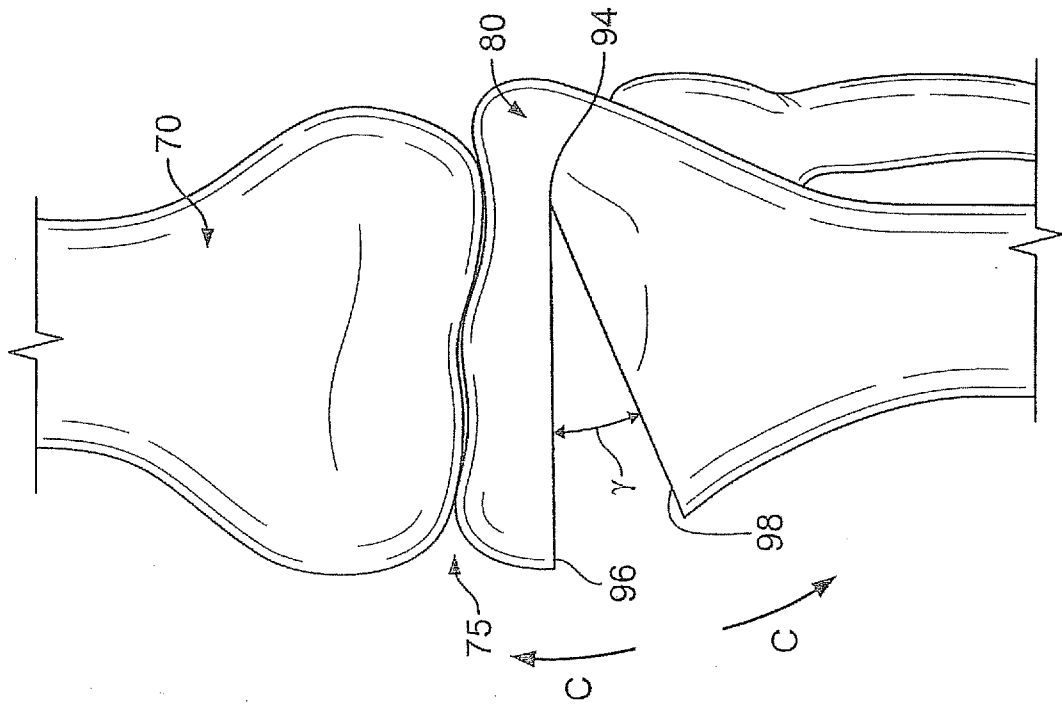


FIG. 2

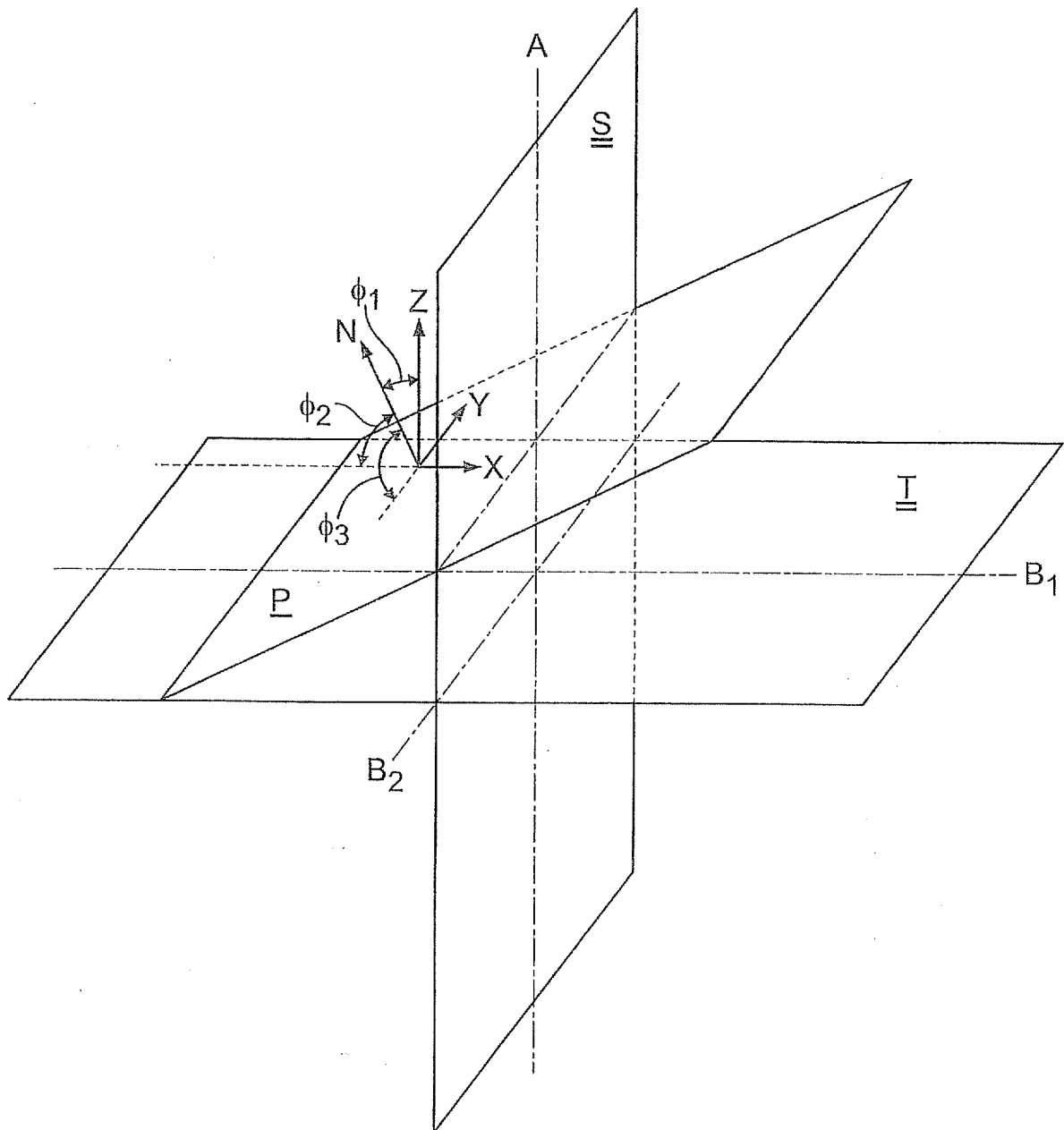


FIG. 1A

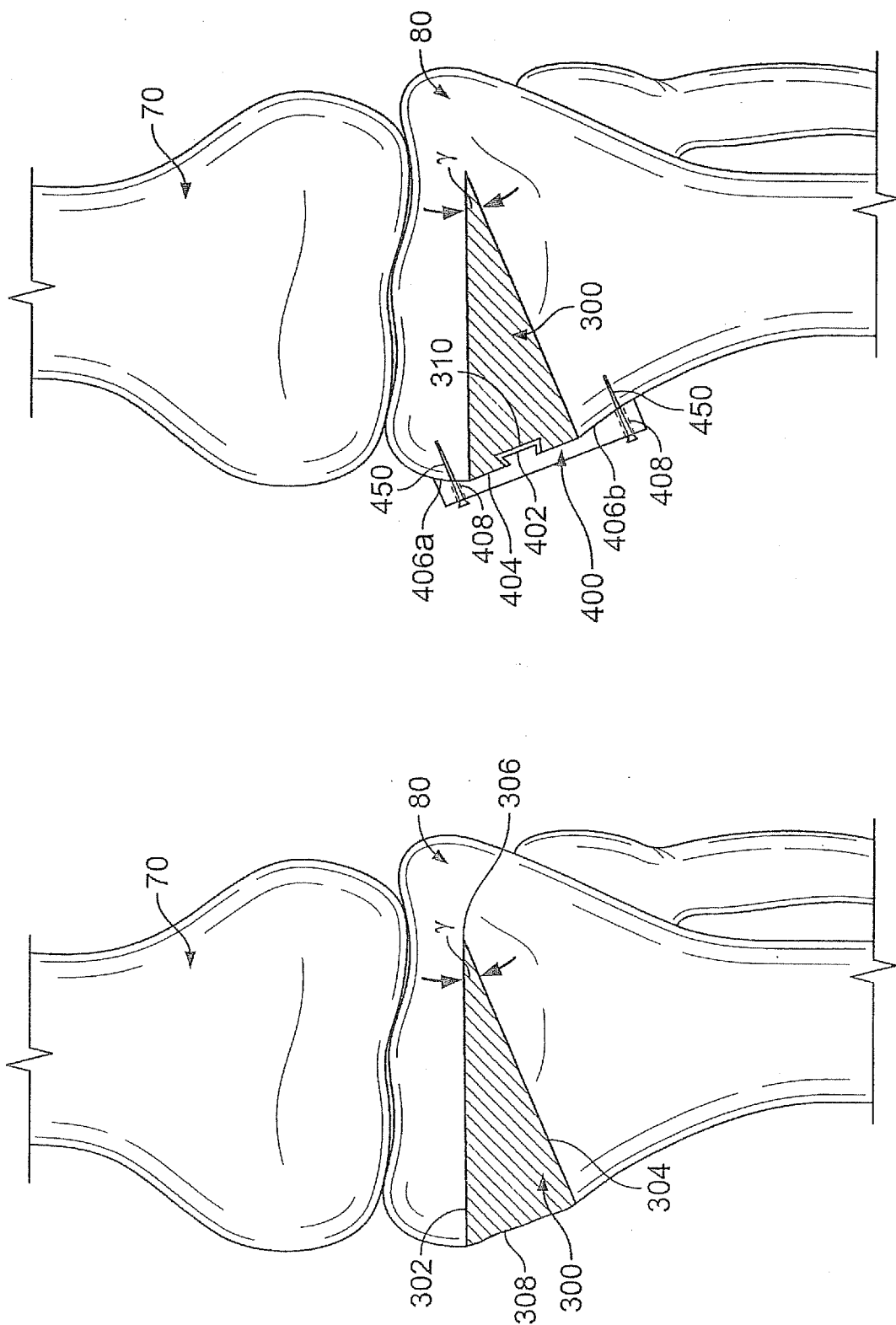


FIG. 3B

FIG. 3A

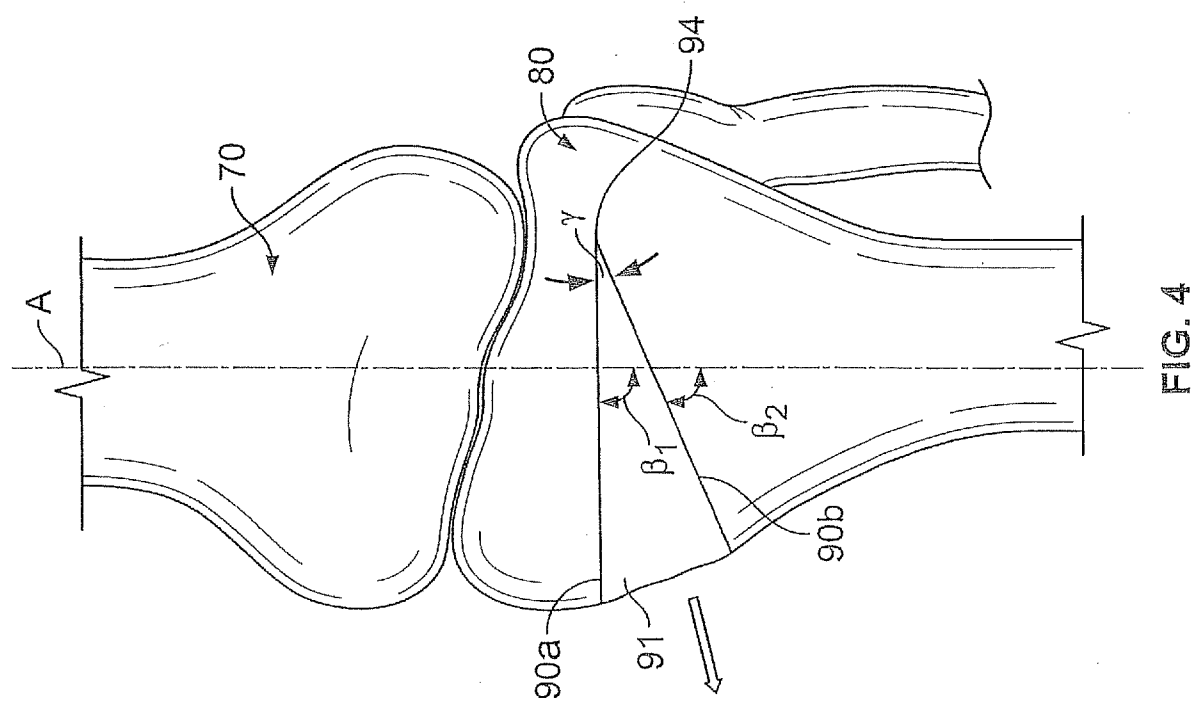


FIG. 4

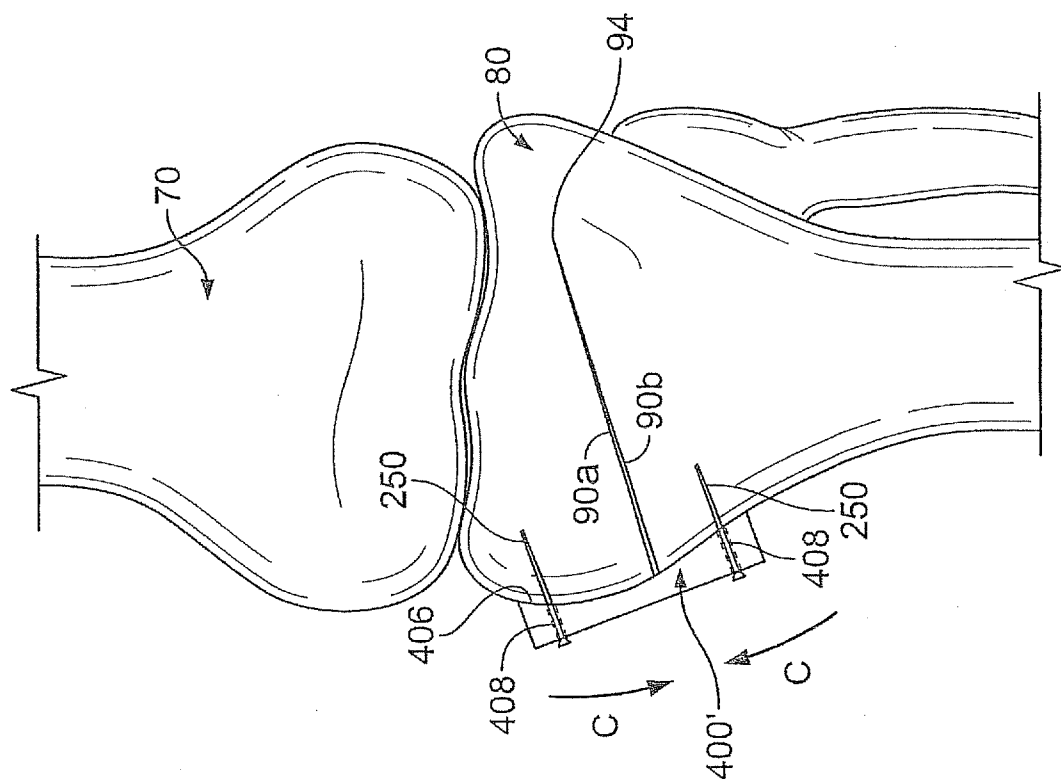


FIG. 5

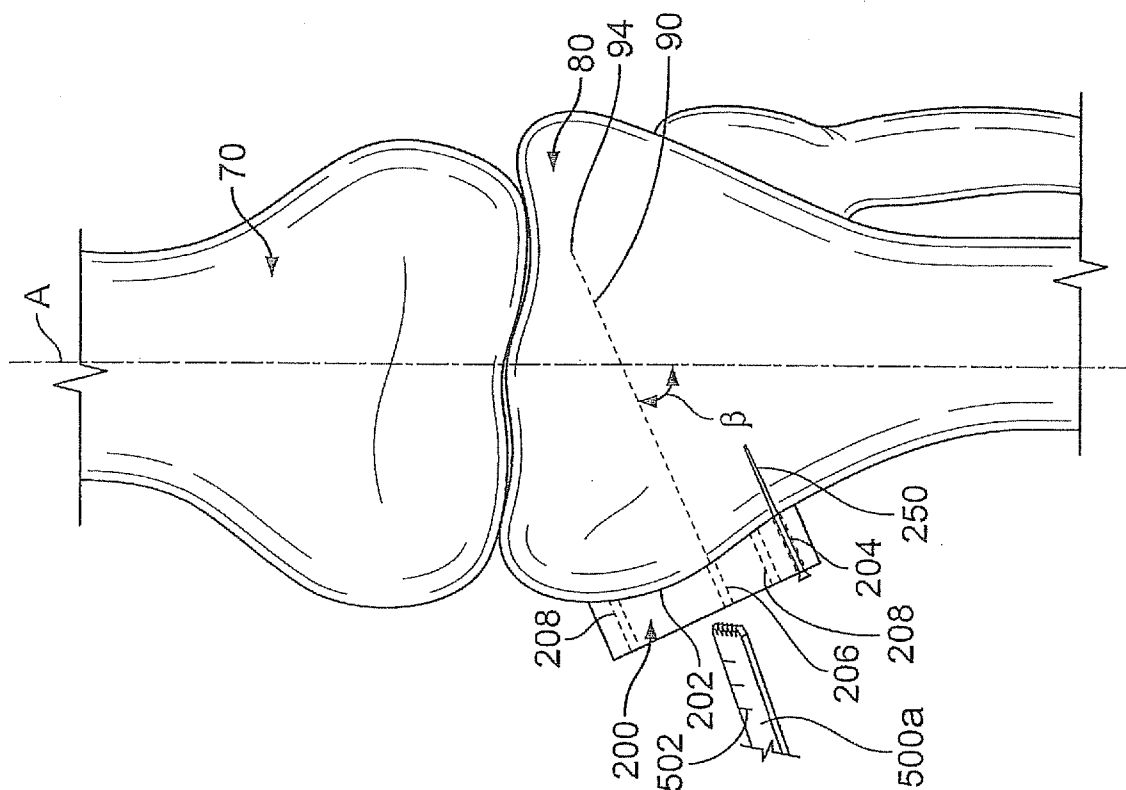


FIG. 6

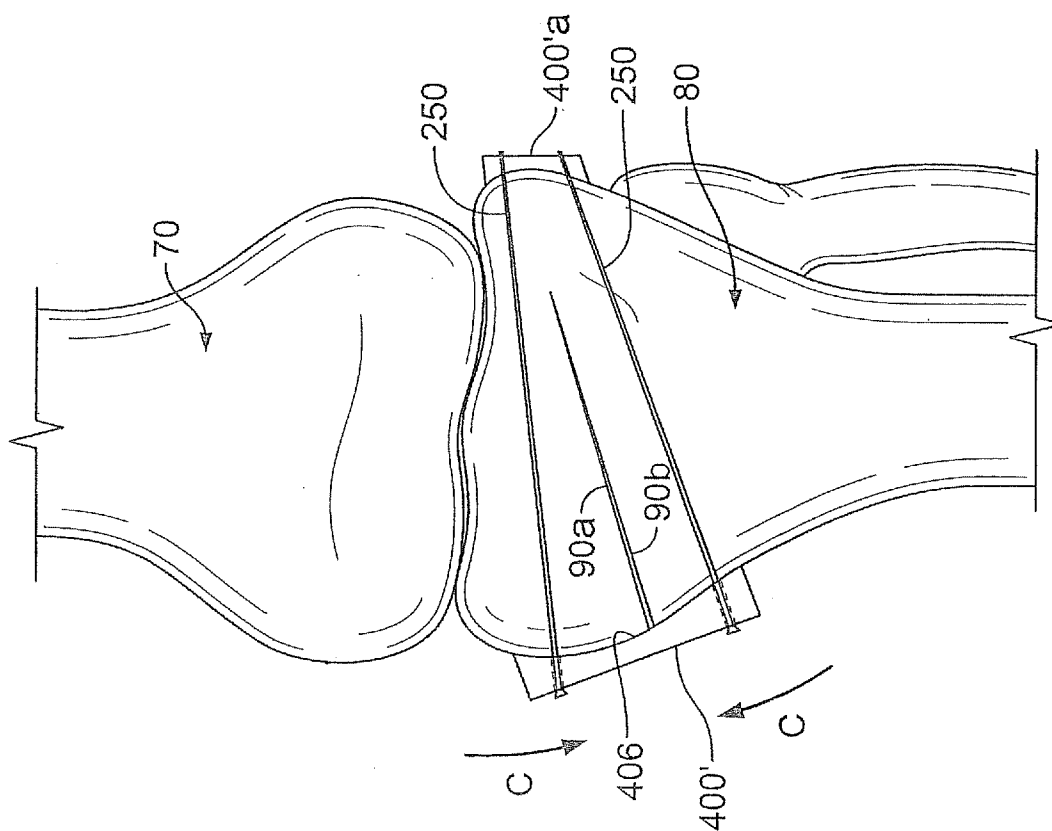


FIG. 5A

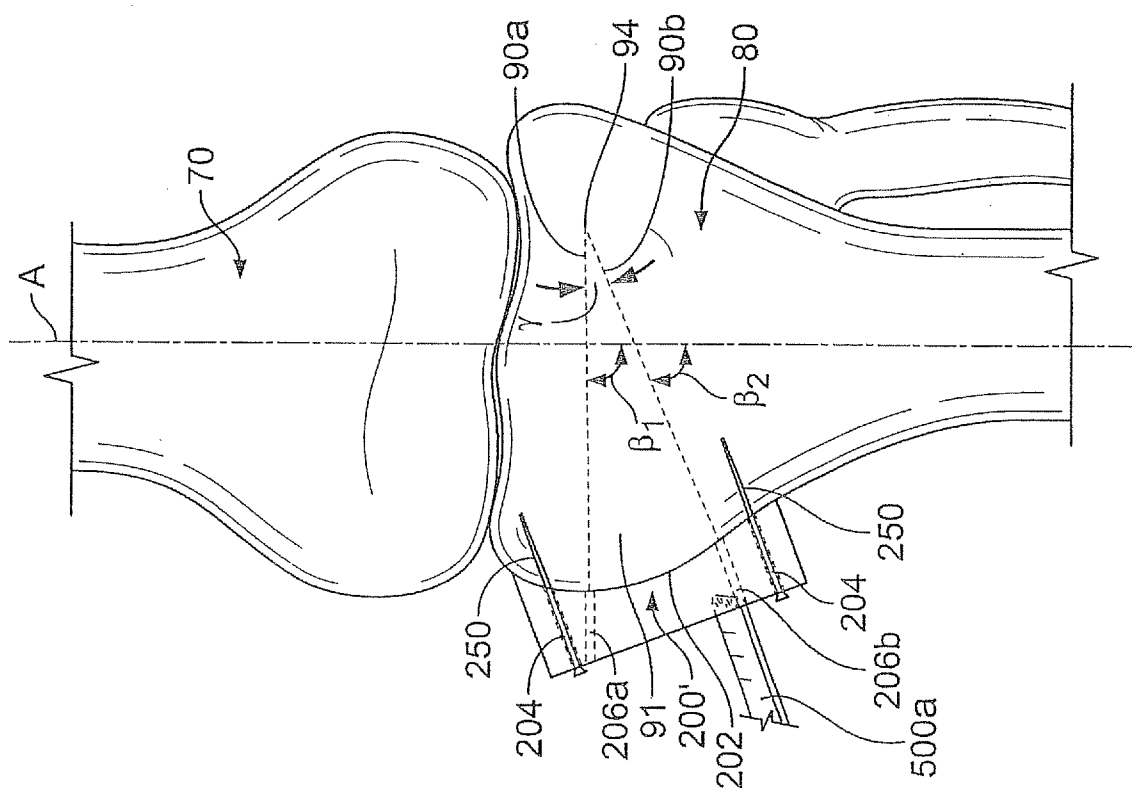


FIG. 7

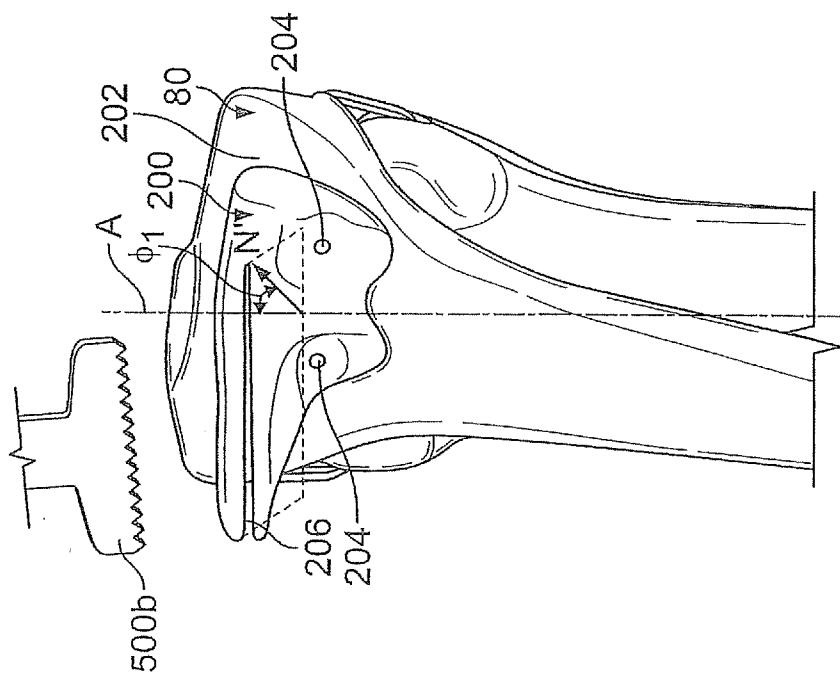
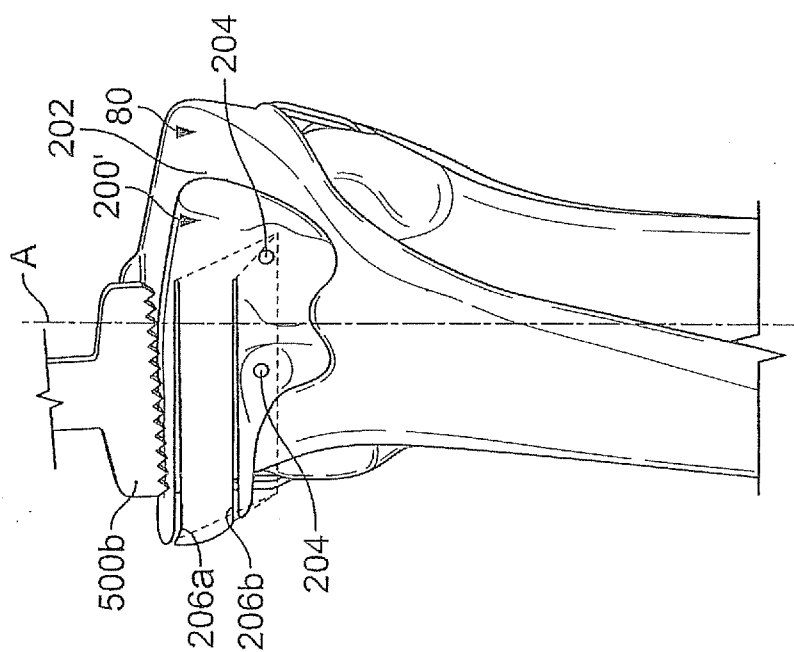
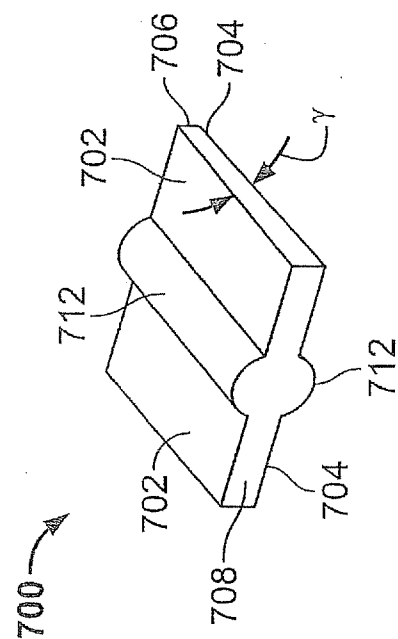
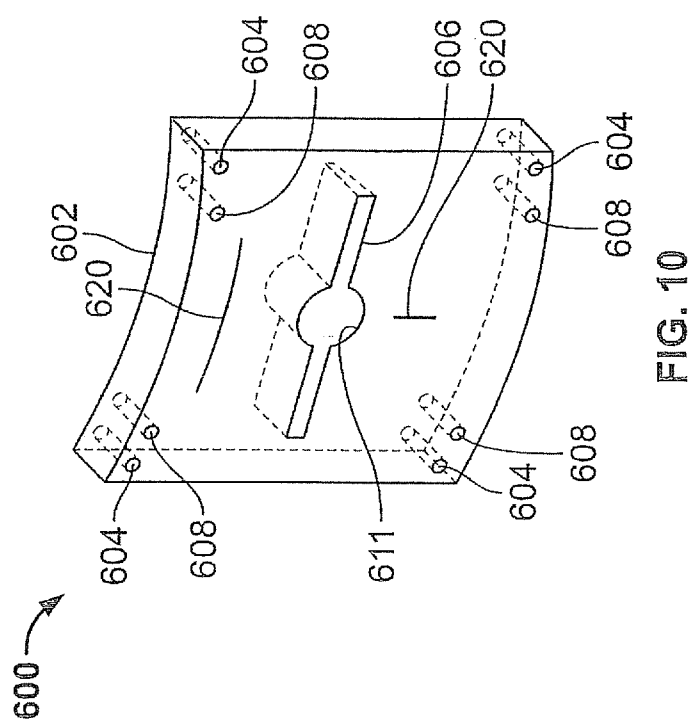
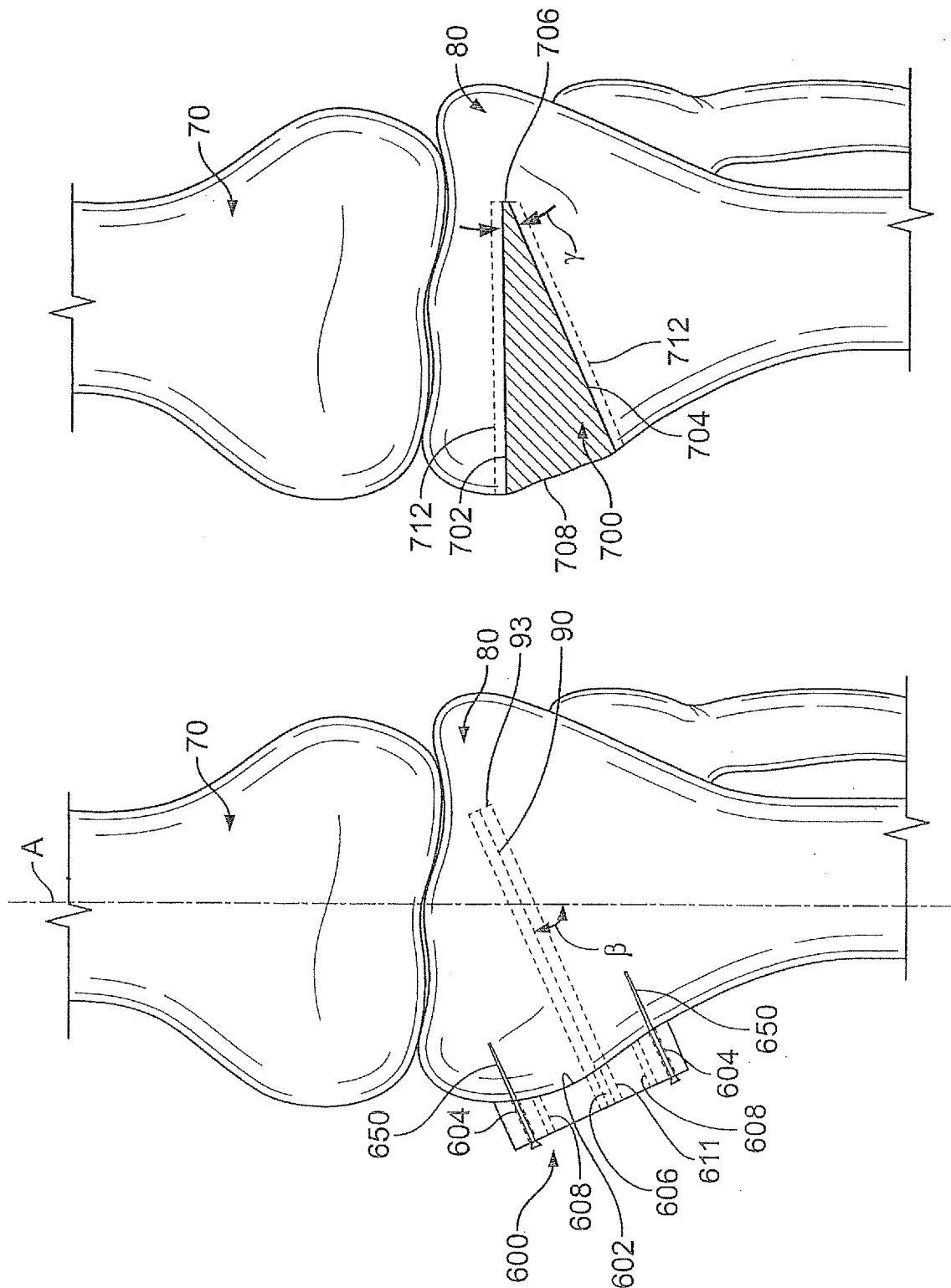


FIG. 8





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FILE

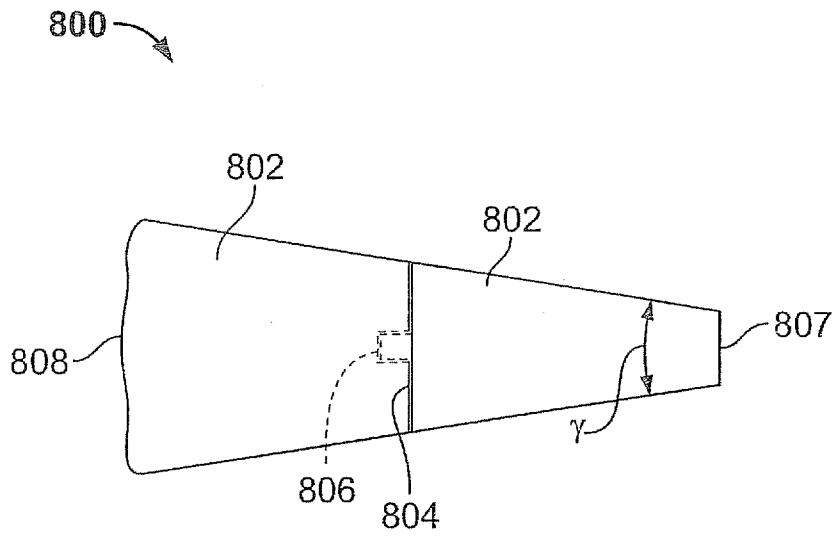


FIG. 14A

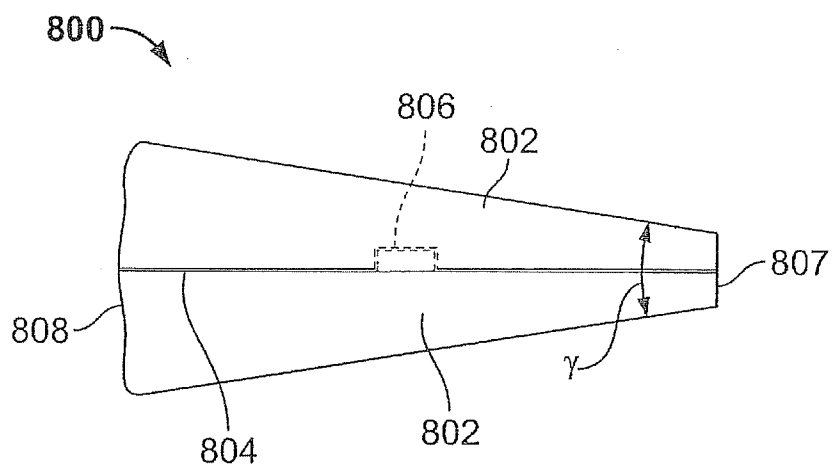


FIG. 14B

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2011/026333

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/15 A61B17/80
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 practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 721 195 A1 (AFRIAT JACQUES [FR]) 22 December 1995 (1995-12-22) figure 1	1-4, 11-13
X	----- US 5 722 978 A (JENKINS JR JOSEPH ROBERT [US]) 3 March 1998 (1998-03-03) figure 11	1-4, 11-13
X	----- FR 2 768 916 A1 (TRANSSYSTEME SA [FR]) 2 April 1999 (1999-04-02) figure 3	1-4, 11-13
X	----- US 2008/195099 A1 (MINAS TOM [US]) 14 August 2008 (2008-08-14) figures 5a, 11a-11c ----- -/-	1-5,7, 9-13,17, 18,20-22



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 document 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 April 2011

Date of mailing of the international search report

09/08/2011

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Fernández Arillo, J

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2011/026333

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/075641 A1 (SINGHATAT WAMIS [US] ET AL) 7 April 2005 (2005-04-07) figure 9 -----	1-8, 11-13, 17,19
X	WO 2005/077039 A2 (OSTEOBIOLOGICS INC [US]) 25 August 2005 (2005-08-25) figures 1A-1C -----	1-5, 11-13, 16,17,23
X	US 2009/082770 A1 (WORNER ROLAND [DE] ET AL) 26 March 2009 (2009-03-26) figure 9A -----	1-5, 11-13,17
X	WO 99/52473 A1 (STONE KEVIN R [US]) 21 October 1999 (1999-10-21) figure 2B -----	1-5, 11-13,17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/026333

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.: 24-31
because they relate to subject matter not required to be searched by this Authority, namely:
Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 24-31 has not been searched, since it is directed to a method for treatment of the human 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:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 16-23

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-13, 16-23

A surgical kit according to claim 1, further comprising a patient-specific implantable wedge (claims 5 and 17), for solving the problem of improving the efficiency of an open-wedge osteotomy.

2. claims: 14, 15

A surgical kit according to claim 1, wherein the alignment guide includes a central guiding aperture through the planar slot, thereby solving the problem of allowing a hole to be drilled in the bone before the planar osteotomy cut, said hole being able to guide a corresponding osteotomy wedge during its implantation.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/026333

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2721195	A1	22-12-1995	NONE
US 5722978	A	03-03-1998	NONE
FR 2768916	A1	02-04-1999	NONE
US 2008195099	A1	14-08-2008	WO 2008100509 A2 21-08-2008
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US 2009082770	A1	26-03-2009	DE 102007045885 A1 16-04-2009
WO 9952473	A1	21-10-1999	AU 3558999 A 01-11-1999 US 6008433 A 28-12-1999