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(54) **Title**: DRILL GUIDES FOR CONFIRMING ALIGNMENT OF PATIENT-SPECIFIC ALIGNMENT GUIDES

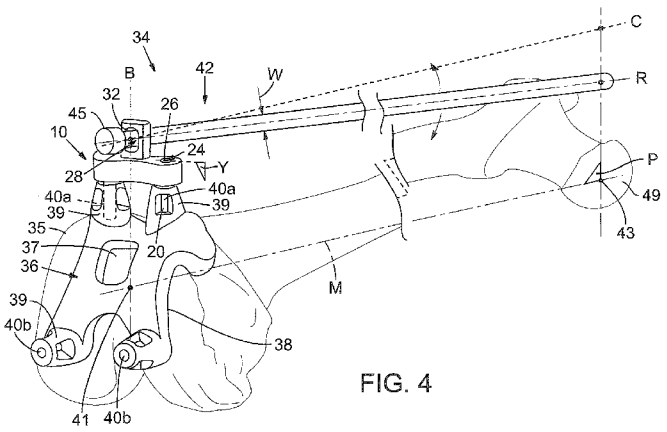

FIG. 4

(57) **Abstract**: An orthopedic device includes a drill guide configured to be mounted on a patient-specific alignment guide for intra-operatively confirming alignment of the patient-specific alignment guide relative to a bone. The patient-specific alignment guide includes first and second referencing holes. The drill guide includes a main body with a first coupling member and a second coupling member. The first and second coupling members are configured to be received within the first and second referencing holes, respectively. The first and second coupling members each include corresponding first and second drill openings configured to align with the first and second referencing holes, respectively. The drill openings each guide a drilling tool toward the bone to drill corresponding holes in the bone. The main body also includes an alignment confirmation feature configured for confirming alignment of the patient-specific alignment guide relative to the bone before drilling holes in the bone.

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DRILL GUIDES FOR CONFIRMING ALIGNMENT OF PATIENT-SPECIFIC ALIGNMENT GUIDES

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Utility Application No. 13/493,509, filed June 11, 2012 and U.S. Provisional Application No. 61/496,085, filed June 13, 2011. The disclosure of the above application is incorporated herein by reference.

FIELD

[0002] The following relates to an orthopedic device and, more particularly, relates to an orthopedic device with a drill guide used for confirming alignment of a patient-specific alignment guide relative to a bone.

INTRODUCTION

[0003] The present teachings provide various drill guides for knee arthroplasty, including femoral and tibial guides. The drill guides are configured to reference corresponding patient-specific alignment guides and confirm the alignment of the patient-specific alignment guides relative to the mechanical axis of the knee joint before drilling holes into the bone through the patient-specific guides.

SUMMARY

[0004] An orthopedic device is disclosed. The orthopedic device includes a drill guide configured to be mounted on a patient-specific alignment guide for intraoperatively confirming alignment of the patient-specific alignment guide relative to a bone. The patient-specific alignment guide includes first and second referencing holes. The drill guide includes a main body with a first coupling member and a second coupling member. The first and second coupling members are configured to be received within the first and second referencing holes, respectively. The first and second coupling members each include corresponding first and second drill openings configured to align with the first and

second referencing holes, respectively. The drill openings each guide a drilling tool toward the bone to drill corresponding holes in the bone. The main body also includes an alignment confirmation feature configured for confirming alignment of the patient-specific alignment guide relative to the bone before drilling holes in the bone.

[0005] An orthopedic method is also disclosed. The method includes intraoperatively nesting a three-dimensional patient-specific surface of a patient-specific alignment guide to a corresponding surface of the bone. The three-dimensional patient-specific surface is preoperatively configured to align the patient-specific alignment guide relative to the bone when nested to the corresponding surface in only one position. The patient-specific alignment guide includes a first referencing hole and a second referencing hole. The method also includes intraoperatively mounting a drill guide onto the patient-specific alignment guide by inserting first and second coupling members of the drill guide into the first and second referencing holes, respectively, and aligning corresponding drill openings of the first and second coupling members with the first and second referencing holes, respectively. Moreover, the method includes intraoperatively confirming that the patient-specific alignment guide is aligned relative to a mechanical axis of the bone using an alignment confirmation feature of the drill guide. Furthermore, the method includes drilling a hole into the bone through one of the drill openings after confirming that the patient-specific alignment guide is aligned relative to the mechanical axis of the bone.

[0006] Still further, an orthopedic device is disclosed. The orthopedic device includes a patient-specific alignment guide having a three-dimensional patient-specific surface that nests and closely conforms to a corresponding surface of a bone in only one position relative to the bone. The three-dimensional patient-specific surface is pre-operatively configured to align the alignment guide relative to a mechanical axis of the bone in only one position. The alignment guide includes a first referencing hole and a second referencing hole. Also, the orthopedic device includes a drill guide having a main body, a first projection, and a second projection. The first and second projections have first and second through holes, respectively, and the first and second projections are configured to

be received within the first and second referencing holes, respectively, to intra-operatively couple the drill guide to the alignment guide and to guide a drilling tool toward the bone to form corresponding holes therein. The drill guide additionally includes an alignment opening configured to orient a rod along an axis parallel to the mechanical axis to confirm the alignment of the patient-specific alignment guide relative to the mechanical axis of the bone.

[0007] 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 teachings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The present teachings will become more fully understood from the detailed description and the accompanying drawings, wherein:

[0009] FIG. 1 is an isometric view of a drill guide according to various teachings of the present disclosure;

[0010] FIG. 2 is a front view of the drill guide of FIG. 1;

[0011] FIG. 3 is a section view of the drill guide taken along the line 3-3 of FIG. 2;

[0012] FIG. 4 is an isometric view of the drill guide of FIG. 1 shown operably coupled to a patient-specific alignment guide, which is nested on a femur;

[0013] FIG. 5 is an isometric view of the femur of FIG. 4 during resection;

[0014] FIG. 6 is an isometric view of a drill guide according to additional teachings of the present disclosure;

[0015] FIG. 7 is a front view of the drill guide of FIG. 6;

[0016] FIG. 8 is a section view of the drill guide taken along the line 8-8 of FIG. 7;

[0017] FIG. 9 is an isometric view of the drill guide of FIG. 6 shown operably coupled to a patient specific alignment guide, which is nested on a tibia;

[0018] FIG. 10 is an isometric view of the tibia of FIG. 9 shown with a resection guide mounted thereon;

[0019] FIG. 11 is an isometric view of a drill guide according to additional teachings of the present disclosure;

[0020] FIG. 12 is a front view of the drill guide of FIG. 11;

[0021] FIG. 13 is a section view of the drill guide taken along the line 13-13 of FIG. 12; and

[0022] FIG. 14 is an isometric view of the drill guide of FIG. 11 shown operably coupled to a patient specific alignment guide, which is nested on a tibia.

DESCRIPTION OF VARIOUS ASPECTS

[0023] 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 discussed in association with resection guides and other instruments for performing knee surgery (e.g., knee arthroplasty), the present teachings can be used in association with other guides, templates, jigs, drills, rasps or other instruments used in various orthopedic procedures.

[0024] The present teachings are directed to various knee arthroplasty procedures that use patient-specific femoral or tibial alignment guides. The patient-specific alignment guides are configured preoperatively to register only in one position on the patient's bone and guide a drill template or drill guide to drill holes in the bone through referencing holes of the patient-specific alignment guide. The presents teachings further provide drill guides that can confirm intraoperatively the alignment and registration of the patient-specific guides relative to the mechanical axis of the bone.

[0025] Referring initially to FIGS. 1-4, an orthopedic device 34 for knee arthroplasty, such as implanting a prosthetic device (e.g., a knee joint prosthesis) in a patient's distal femur 35. The orthopedic device 34 can include a femoral drill guide 10 and a patient-specific alignment guide 36. As shown in FIG. 4, the drill guide 10 is configured to couple to the alignment guide 36 to intraoperatively confirm that the alignment guide 36 is properly aligned with respect to the femoral

bone. Also, as will be discussed, the drill guide 10 can be used for guiding a drilling tool (e.g., a drill bit) during formation of one or more holes in the distal femur 35. The drill guide 10 is illustrated in detail in FIGS. 1-3.

[0026] Moreover, as will be discussed in relation to FIGS. 9 and 14, orthopedic devices 134, 234 can be configured for preparing a tibia 155, 255 for the orthopedic procedure as well. Various exemplary embodiments of tibial drill guide 110, 210 are illustrated in detail in FIGS. 6-8 and 11-13.

[0027] In each of these embodiments, the alignment of the patient-specific alignment guides 36, 136, 236 can be confirmed with the corresponding femoral or tibial drill guides 10, 110, 210. Alignment can be confirmed before any holes are drilled in the bone, and as such, the overall surgical procedure can be performed more quickly and efficiently.

[0028] As shown in FIGS. 1-3, the femoral drill guide 10 can include a main body 12 with a top surface 14, a bottom surface 16, and a side surface 18. The top and bottom surfaces 14, 16 can be substantially flat, and the side surface 18 can be contoured. The side surface 18 can also include recessed slots 19 that improve handling of the drill guide 10.

[0029] The drill guide 10 can also include one or more coupling members 20. The coupling members 20 can be frusto-conically shaped projections that extend from the bottom surface 16. As such, the coupling members 20 can each include a tapered outer surface 22. The drill guide 10 can include any number of coupling members 20. For instance, in the embodiments illustrated, the drill guide 10 can include two coupling members 20 (i.e., first and second coupling members 20). The coupling members 20 can be spaced apart on opposite ends of the bottom surface 16.

[0030] Furthermore, as shown in FIGS. 1 and 2, the drill guide 10 can include one or more through-holes 24. The through-holes 24 can each extend continuously through the main body 12 and a respective one of the coupling members 20. A guide surface 26 can be defined by the inner diameter surface of each through-hole 24. Each guide surface 26 can have a circular cross section with a diameter that remains substantially constant along its length. The diameter of the guide surface 26 can also closely correspond to a drill bit 27 (shown in

phantom in FIG. 2) or other drilling tool. Thus, the drill bit 27 can rotate and move axially through each through-hole 24, and the guide surface 26 can support the drill bit 27 such that the drill bit 27 remains aligned with the axis of the through-hole 24 as the drill bit 27 moves toward its target (e.g., a bone). Accordingly, the drill bit 27 can be supported and guided by the drill guide 10 for forming holes in the bone as will be discussed. Then, as will be discussed, referencing pins can be inserted and fixed within the holes. Subsequently, cutting guides, resection guides, or other tools can be attached to the bone via the referencing pins.

[0031] As shown in FIG. 1, a plane Y (i.e., a guide plane) can be defined by the longitudinal axes of the through-holes 24. Specifically, the longitudinal axes of both through-holes 24 can extend along the plane Y in the embodiments of FIG. 1.

[0032] The femoral drill guide 10 can additionally include an alignment confirmation feature 28. The alignment confirmation feature 28 can include a block 30 with an opening 32 (i.e., an alignment opening) formed therethrough. The block 30 can include a plurality of substantially flat sides, and the block 30 can extend from the top surface 14 of the main body 12. The opening 32 can be a through-hole that extends through the block 30. As shown in FIG. 2, the opening 32 can be elongated in cross-section so as to include a minor axis A and a major axis B that is longer than the minor axis A. The opening 32 can also include a longitudinal axis C (i.e., a confirmation axis) that is substantially straight and that extends substantially perpendicular to the plane Y as shown in FIG. 1.

[0033] The alignment confirmation feature 28 can be used for confirming that the patient-specific alignment guide 36 (FIG. 4) is aligned as intended relative to the bone before any holes are drilled in the bone. Then, once proper alignment has been confirmed, holes can be drilled in the bone using the drill guide 10. Next, referencing pins 46, bone nails, or other similar bone fasteners can be positioned in the holes as shown in FIG. 5, and a resection guide 48 or other tools can be attached to those pins 46 to guide a resection tool 52, such as a reciprocating saw or cutting blade, after the patient-specific alignment guide 36 and the drill guide 10 are removed from the distal femur 35. Accordingly, the alignment confirmation feature 28 of the drill guide 10 can ultimately ensure that

the referencing pins 46 and resection guide 48 will be aligned as intended relative to the bone.

[0034] It will be appreciated that the drill guide 10 can be a monolithic or unitary member made out of any suitable material. More specifically, the block 30 and the coupling members 20 can be integrally attached to the main body 12 to form a monolithic structure. The drill guide 10 can be made out of a metal (e.g., stainless steel), hard polymeric material, ceramic material, composite material, or any other material. Furthermore, the drill guide 10 can be formed in any suitable fashion (e.g., casting, milling, etc.). Additionally, it will be appreciated that the drill guide 10 can have various sizes and shapes, depending on the size of the patient's anatomy, etc. Moreover, the drill guide 10 can be designed and built preoperatively as will be discussed.

[0035] Referring now to FIGS. 4 & 5, the drill guide 10 is illustrated as part of the orthopedic device 34. The orthopedic device 34 can be used in preparation for implanting a knee joint prosthesis. Specifically, as shown in FIGS. 4 and 5, the device 34 can be used in preparation for resecting the distal femur 35; however, the device 34 can be used before resecting any other bone or before performing any other suitable surgical procedure.

[0036] For purposes of clarity, only the proximal and distal ends of the femoral bone are shown in FIG. 4, and the ends are translated toward each other along the mechanical axis M of the femoral bone. Moreover, it will be appreciated that other portions of the leg (e.g., muscle tissue, connective tissue, other bones, etc.) are not shown for clarity.

[0037] As mentioned above, the orthopedic device 34 can include a patient-specific alignment guide 36. Patient-specific alignment guides 36 and their method of manufacture are disclosed and described in detail in the commonly-owned, co-pending U.S. Patent Application No. 11/756057, filed on May 31, 2007, and published as U.S. Patent Publication No. 2007/0288030, which is hereby incorporated herein by reference in its entirety. The alignment guide 36 can be configured preoperatively to include a three-dimensional patient-specific surface 38 that nests and closely conforms to a corresponding surface 37 of the distal femur 35 in only one position. For instance, the patient-specific surface 38 can be

shaped and contoured to nest and closely conform to a portion of anterior and distal (i.e., condylar) surfaces 37 of the distal femur 35 as shown in FIG. 4. Specifically, a three dimensional electronic model of the patient's knee joint or other anatomy can be generated from Magnetic Resonance Imaging (MRI) or other imaging data of the patient's anatomy, and the patient-specific alignment guide 36 can be designed such that the patient-specific surface 38 can be complementary to and nestingly mate with a corresponding surface of the distal femur 35 with or without articular cartilage. The drill guide 10 (discussed above) can also be designed preoperatively to be operably coupled to the alignment guide 36 as will be discussed. This preoperative design process can be performed, for instance, using software that is commercially available from Materialise USA of Plymouth, Michigan.

[0038] The alignment guide 36 can also include one or more frusto-conic projections 39, each with a referencing hole 40a, 40b extending therethrough. The alignment guide 36 can include any number of referencing holes 40a, 40b, and the holes 40a, 40b can be in any position/orientation relative to the distal femur 35. In the embodiments illustrated, for instance, the alignment guide 36 includes two anterior holes 40a and two distal holes 40b. When the alignment guide 36 is nested on the distal femur 35, the anterior holes 40a are directed generally toward the anterior surface of the distal femur 35, and the distal holes 40b are directed generally toward the distal surface of the distal femur 35. The alignment guide 36 can also be designed such that the holes 40a, 40b have a predetermined orientation relative to the bone. For instance, when nested against the distal femur 35, the anterior holes 40a can both be substantially perpendicular to a mechanical axis M of the femoral bone. The mechanical axis M is defined between a centerpoint 43 of the femoral head 49 and a central point 41 between the condylar surfaces of the distal femur 35.

[0039] As shown in FIG. 4, the drill guide 10 can operably couple to the alignment guide 36. Specifically, the coupling members 20 can be simultaneously received within the anterior holes 40a. The anterior holes 40a can have a female-tapered shape so as to nest with the tapered outer surfaces 22 of the coupling members 20. When coupled as such, the through holes 24 of the drill guide 10

can substantially align with the holes 40a, respectively. Also, when the drill guide 10 is mounted to the alignment guide 36, the confirmation axis C can be substantially parallel to a mechanical axis M of the femoral bone, assuming that the alignment guide 36 is aligned as intended relative to the mechanical axis M.

[0040] The device 34 can additionally include an alignment rod 42. The rod 42 can be rigid and elongate with a substantially straight axis R. The rod 42 can have a substantially circular cross section, or the rod 42 can have a different cross sectional shape. Also, the rod 42 can have a width W (i.e., diameter) that allows the rod 42 to be received (e.g., slidingly received) within the opening 32 of the drill guide 10. For instance, the width W can be substantially equal or slightly less than the minor axis A of the opening 32 (FIG. 2). However, the width W can be significantly less than the major axis B of the opening 32. The rod 42 can also include an enlarged head 45 that limits sliding movement of the rod 42 relative to the drill guide 10.

[0041] The rod 42 can be slidingly received within the opening 32 of the drill guide 10 to thereby confirm that the alignment guide 36 is, in fact, properly aligned relative to the femoral bone (i.e., in a target orientation). The target orientation can be any suitable orientation relative to the femoral bone (e.g., relative to the mechanical axis M). For instance, the target orientation can be such that the plane Y is substantially perpendicular to the mechanical axis M. If the alignment guide 36 is at this target orientation, then the axis C should be substantially parallel to the mechanical axis M. Thus, by sliding the rod 42 along the axis C, the rod axis R should likewise be parallel to the mechanical axis M. Otherwise, the rod 42 can be rotated about the axis A (FIGS. 2 and 3) of the drill guide 10 (e.g., to avoid interference with anatomical soft tissue) and the rod axis R can remain within a plane P defined by the mechanical axis M and the confirmation axis C as shown in FIG. 4. If these conditions are satisfied, then it is confirmed that the alignment guide 36 is properly aligned. Otherwise, the alignment guide 36 is misaligned.

[0042] It will be appreciated that the predetermined alignment or target orientation of the alignment guide 36 could be relative to any other anatomical feature or anatomic axis other than the mechanical axis M. Also, it will be

appreciated that the predetermined alignment or target orientation could be disposed at a predetermined offset angle relative to the mechanical axis M.

[0043] Thus, during the surgical procedure, the patient-specific alignment guide 36 can be nested against the corresponding surface 37 of the distal femur 35. Then, the coupling members 20 of the drill guide 10 can be removably inserted into the corresponding pair of referencing holes 40a of the guide 36 as shown in FIG. 4. Next, the rod 42 can be slidingly inserted into the opening 32 in the drill guide 10, and the orientation of the rod axis R can be inspected relative to the mechanical axis M and the plane P. Specifically, it can be determined if the rod axis R lies substantially within the plane P. If so, it is confirmed that the alignment guide 36 is properly aligned. If not, misalignment of the guide 36 can be recognized. Advantageously, this procedure can be performed before any holes are drilled or any resections are made on the distal femur 35.

[0044] Once proper alignment of the guide 36 has been confirmed, the rod 42 can be withdrawn. Then, the drill bit 27 (FIG. 2) can be introduced into each of the holes 24 of the drill guide 10, and anterior drill holes 44a (FIG. 5) can be formed in the distal femur 35 while being guided by the guide surfaces 26 of the drill guide 10. Specifically, holes 44a in the distal, anterior portion of the distal femur 35 can be formed first. Distal holes 44b for a cutting block can be formed through the referencing holes 40b of the alignment guide, as shown in FIG. 5.

[0045] Next, referencing pins 46 can be driven into respective ones of the drill holes 44a on the anterior surface of the distal femur 35 as shown in FIG. 5. Subsequently, a known distal resection guide 48 with a guide surface 50 can be attached to the distal femur 35 by sliding the guide 48 onto both pins 46. As shown in FIG. 5, the pins 46 are disposed on the plane Y, which was previously confirmed to be perpendicular to the mechanical axis M of the femoral bone. Thus, when a resection tool 52 (e.g., a reciprocating blade) is guided toward the distal femur 35 by the guide surface 50, the resection can be substantially perpendicular to the mechanical axis M, as desired.

[0046] Referring now to FIGS. 6-8, exemplary embodiments of a tibial drill guide 110 are illustrated. Components that correspond to those of the

embodiments of FIGS. 1-4 are indicated with corresponding reference numbers increased by 100.

[0047] As will be discussed, the tibial drill guide 110 can be used in connection with resecting a tibia 155 (FIG. 9). However, the drill guide 110 can be used for resecting another bone without departing from the scope of the present disclosure.

[0048] As shown, the opening 132 can extend directly through the main body 112 of the drill guide 110. The opening 132 can also be substantially centered between the coupling members 120 such that the axis C of the opening 132 defines a line of symmetry of the main body 112.

[0049] Furthermore, the opening 132 can have a cross section that closely conforms to that of the alignment rod 142 (FIG. 9). As such, the rod 142 can only slide in a direction substantially parallel to the axis C of the opening 132.

[0050] Thus, as shown in FIG. 9, the drill guide 110 can be used during resection of the tibia 155 to confirm that the alignment guide 136 is aligned relative to the mechanical axis M of the tibia 155. The mechanical axis M of the tibia 155 is defined by the tibial tubercle 151 and a center point of the ankle 153.

[0051] Once alignment of the alignment guide 136 has been confirmed as shown in FIG. 9, the drill guide 110 can be used to guide the drilling of holes for pins 146 (FIG. 10). Subsequently, the tibial resection guide 148 can be attached to the tibia 155 via the pins 146 as shown in FIG. 10, and the tibia 155 can be resected in a known manner.

[0052] Referring now to FIGS. 11-14, additional exemplary embodiments of the drill guide 210 are illustrated. Components that correspond to those of the embodiments of FIGS. 6-8 are indicated with corresponding reference numbers increased by 100. Like the embodiments of FIGS. 6-8, the drill guide 210 can be used in connection with resecting a tibia 255 (FIG. 14). However, the drill guide 210 can be used for resecting another bone without departing from the scope of the present disclosure.

[0053] As shown, the opening 232 can extend directly through the main body 212 of the drill guide 110. However, the opening 232 can be off-center such that the opening 232 is disposed adjacent a first end 263 and is spaced away from

a second end 265 of the main body 212. Furthermore, the opening 232 can be disposed on one side of the main body 112 relative to the coupling members 220.

[0054] Thus, as shown in FIG. 14, the drill guide 210 can be used during resection of the tibia 255 to confirm that the alignment guide 236 is properly oriented relative to the mechanical axis M of the tibia 255. Once alignment of the drill guide 210 has been confirmed as shown in FIG. 14, holes can be drilled using the drill guide 210 and the subsequent resection of the tibia 255 can be performed as discussed above with respect to FIG. 10.

[0055] Accordingly, the drill guide 210 allows the surgeon to quickly and efficiently check that the alignment guide 236 is properly aligned relative to the patient's anatomy. This check can be performed before the bone is drilled and/or resection cuts are made.

[0056] In summary, the orthopedic device 34, 134, 234 of the present teachings provide an intraoperative confirmation of the alignment of patient-specific alignment guides relative to corresponding mechanical axes of the bone prior to drilling or resection of the bone during an arthroplasty. The drill guide 10, 110, 210 is configured to intraoperatively couple to the patient-specific alignment guide 36, 136, 236, and the alignment rod 42, 142, 242 can be coupled to the drill guide 10, 110, 210 to confirm that the alignment guide 36, 136, 236 is aligned as intended relative to the bone. This confirmation step can be performed before any of the drill holes are formed in the bone. Thus, any unintended misalignment can be corrected early in the procedure. Accordingly, the procedure can be performed accurately and efficiently.

[0057] It will be appreciated that the drill guide 10, 110, 210 can vary in a number of ways without departing from the scope of the present disclosure. For instance, the alignment confirmation feature 28, 128, 228 of the drill guide 10, 110, 210 can be another feature other than an opening 32, 132, 232 that receives the rod 42, 142, 242. For instance, the alignment confirmation feature 28, 128, 228 could be a male connector, and the rod 42, 142, 242 could include a female opening that receives the male connector to thereby attach the rod 42, 142, 242 to the drill guide 10, 110, 210. It will also be appreciated that the rod 42, 142, 242 could be replaced by a laser pointer that is coupled to the alignment confirmation

feature 28, 128, 228 of the drill guide 10, 110, 210 to confirm that the alignment guide 36, 136, 236 is properly aligned.

[0058] 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 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 teachings of the invention without departing from the essential scope thereof. One skilled in the art will readily recognize from such 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. An orthopedic device comprising:

a drill guide configured to be mounted on a patient-specific alignment guide for intraoperatively confirming alignment of the patient-specific alignment guide relative to a bone, the patient-specific alignment guide including a first referencing hole and a second referencing hole, the drill guide including:

a main body with a first coupling member and a second coupling member, the first and second coupling members configured to be received within the first and second referencing holes, respectively, the first and second coupling members including corresponding first and second drill openings configured to align with the first and second referencing holes, respectively, for guiding a drilling tool toward the bone to drill corresponding holes in the bone, the main body further including an alignment confirmation feature configured for confirming alignment of the patient-specific alignment guide relative to the bone before drilling holes in the bone.

2. The orthopedic device of claim 1, wherein the alignment confirmation feature is configured for confirming that the patient-specific alignment guide is aligned relative to a mechanical axis of the bone.

3. The orthopedic device of claim 2, wherein the alignment confirmation feature includes an alignment opening configured to receive a rod and orient a longitudinal rod axis of the rod parallel to the mechanical axis to thereby confirm alignment of the patient-specific alignment guide.

4. The orthopedic device of claim 3, wherein the alignment opening is elongate in cross-section, the alignment opening having a minor axis that substantially corresponds to a cross-sectional width of the rod, the alignment opening having a major axis that is greater than the cross-sectional width of the rod.

5. The orthopedic device of claim 3, further comprising a block that extends away from a surface of the main body, the alignment opening extending through the block.

6. The orthopedic device of claim 3, wherein the alignment opening passes directly through the main body.

7. The orthopedic device of claim 3, wherein the alignment opening defines a line of symmetry of the main body.

8. The orthopedic device of claim 3, wherein the alignment opening is disposed adjacent a first end of the main body and is spaced away from a second end of the main body.

9. The orthopedic device of claim 1, further comprising a patient-specific alignment guide, the patient-specific alignment guide having a three-dimensional patient-specific surface preoperatively configured to nest and closely conform to a corresponding surface of the bone in only one position relative to the bone.

10. The orthopedic device of claim 1, wherein the main body includes a plurality of drill openings, each having a respective longitudinal axis, the longitudinal axes of the drill openings cooperating to define a guide plane, and wherein the alignment confirmation feature defines a confirmation axis that is substantially perpendicular to the guide plane.

11. The orthopedic device of claim 1, wherein at least one of the first and second coupling members has a tapered outer surface that is removably received within the corresponding one of the first and second referencing holes.

12. The orthopedic device of claim 1, wherein the bone is at least one of a tibia and a femur.

13. An orthopedic method comprising:

intraoperatively nesting a three-dimensional patient-specific surface of a patient-specific alignment guide to a corresponding surface of the bone, the three-dimensional patient-specific surface being preoperatively configured to align the patient-specific alignment guide relative to the bone when nested to the corresponding surface in only one position, the patient-specific alignment guide including a first referencing hole and a second referencing hole;

intraoperatively mounting a drill guide onto the patient-specific alignment guide by inserting first and second coupling members of the drill guide into the first and second referencing holes, respectively, and aligning corresponding drill openings of the first and second coupling members with the first and second referencing holes, respectively;

intraoperatively confirming that the patient-specific alignment guide is aligned relative to a mechanical axis of the bone using an alignment confirmation feature of the drill guide; and

drilling a hole into the bone through one of the drill openings after confirming that the patient-specific alignment guide is aligned relative to the mechanical axis of the bone.

14. The method of claim 13, wherein confirming that the patient-specific alignment guide is aligned relative to the mechanical axis includes passing a rod through an alignment opening of the alignment confirmation feature confirming that a rod axis of the rod is parallel to the mechanical axis of the bone.

15. The method of claim 14, further comprising rotating the rod relative to the mechanical axis to avoid abutment of the rod with an anatomical feature.

16. The method of claim 14, further comprising:

drilling a plurality of holes in the bone with the drilling tool;

inserting a referencing pin into each of the plurality of holes;

removing the patient-specific guide and the drill guide without removing the referencing pins;

mounting a resection guide onto the referencing pins; and

resecting the bone with a resection tool that is guided by the resection guide.

17. An orthopedic device comprising:

a patient-specific alignment guide having a three-dimensional patient-specific surface that nests and closely conforms to a corresponding surface of a bone in only one position relative to the bone, the three-dimensional patient-specific surface being pre-operatively configured to align the alignment guide relative to a mechanical axis of the bone in only one position, the alignment guide including a first referencing hole and a second referencing hole;

a drill guide including a main body, a first projection, and a second projection, the first and second projections having first and second through holes, respectively, the first and second projections configured to be received within the first and second referencing holes, respectively, to intra-operatively couple the drill guide to the alignment guide and to guide a drilling tool toward the bone to form corresponding holes therein, the drill guide additionally including an alignment opening configured to orient a rod along an axis parallel to the mechanical axis to confirm the alignment of the patient-specific alignment guide relative to the mechanical axis of the bone.

18. The orthopedic device of claim 17, wherein the first and second projections each include a tapered outer surface.

19. The orthopedic device of claim 17, wherein the alignment opening is elongate in cross section, the alignment opening having a minor axis that substantially corresponds to a width of the rod, the alignment opening having a major axis that is greater than the width of the rod.

20. The orthopedic device of claim 17, wherein the drill guide is a femoral drill guide for drilling holes in a femur, wherein the alignment opening is elongate in cross section, the alignment opening having a minor axis that

substantially corresponds to a cross-sectional width of the rod, the alignment opening having a major axis that is greater than the cross-sectional width of the rod, the alignment opening passing through a block that extends away from a surface of the main body.

21. The orthopedic device of claim 17, wherein the drill guide is a tibial drill guide for drilling holes in a tibia, wherein the alignment opening passes directly through the main body, the alignment opening defining a line of symmetry of the main body.

22. The orthopedic device of claim 17, wherein the drill guide is a tibial drill guide for drilling holes in a tibia, wherein the alignment opening passes directly through the main body, the alignment opening being disposed adjacent a first end of the main body and being spaced away from a second end of the main body.

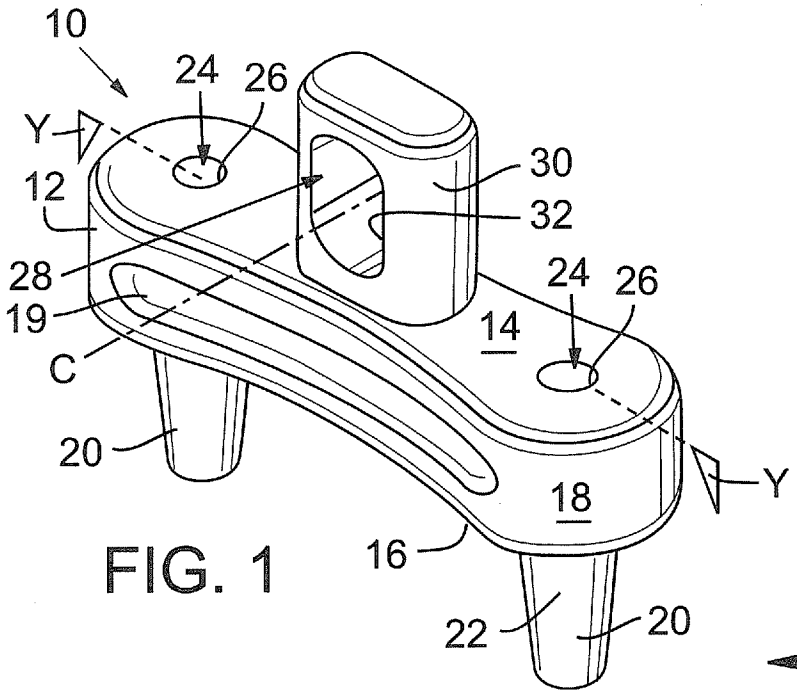

FIG. 1

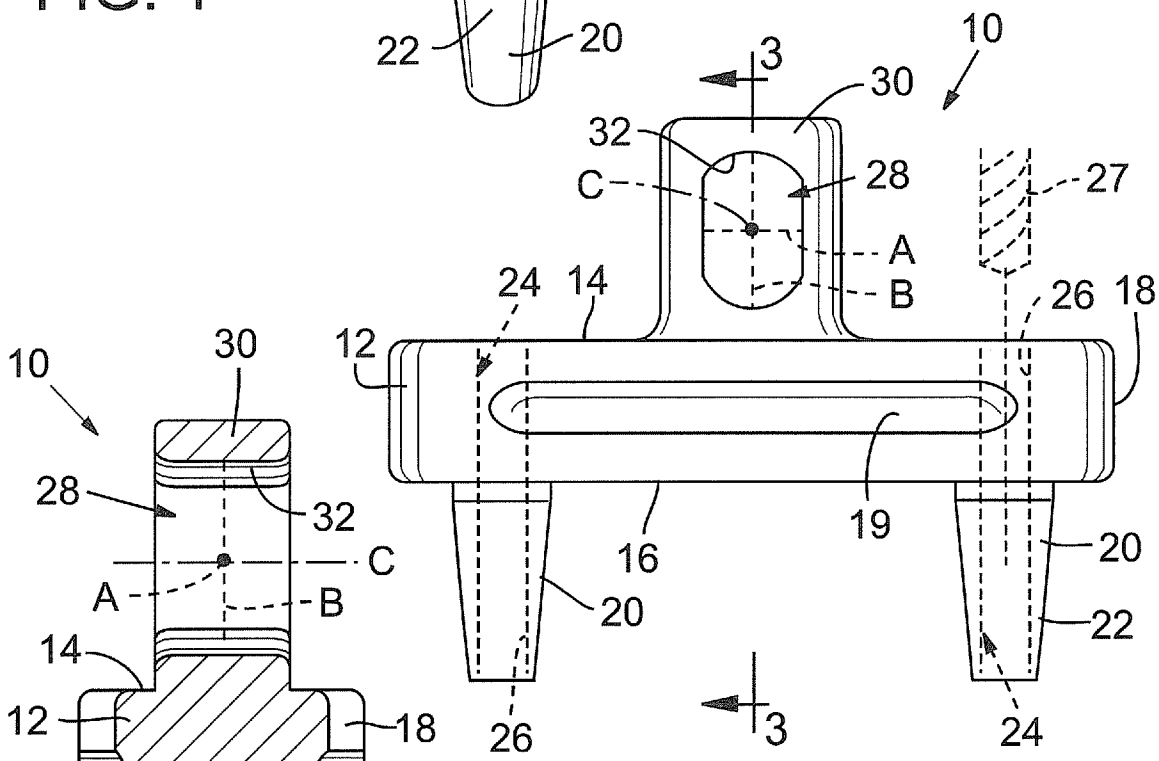

FIG. 2

FIG. 3

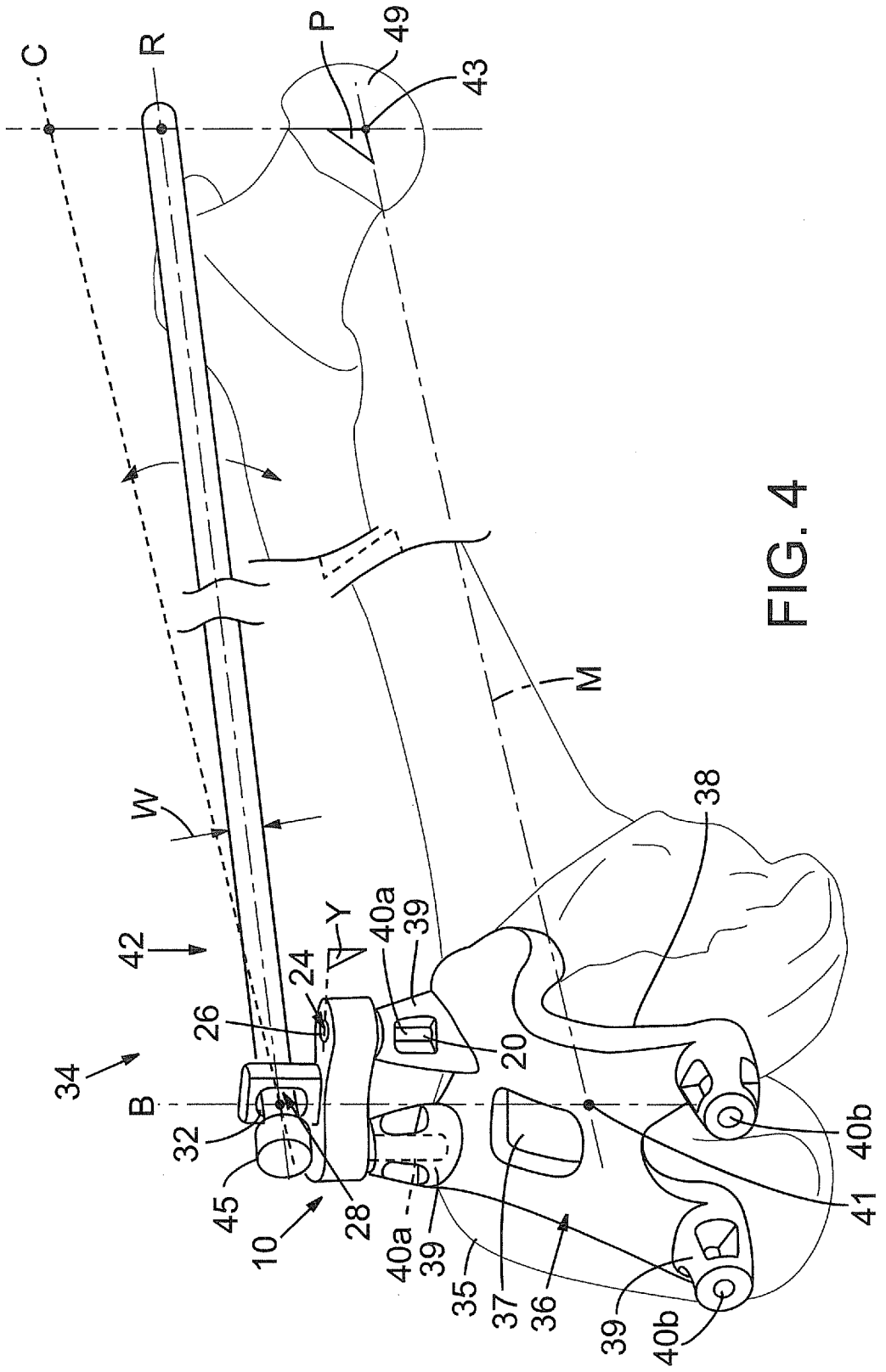
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FIG. 4

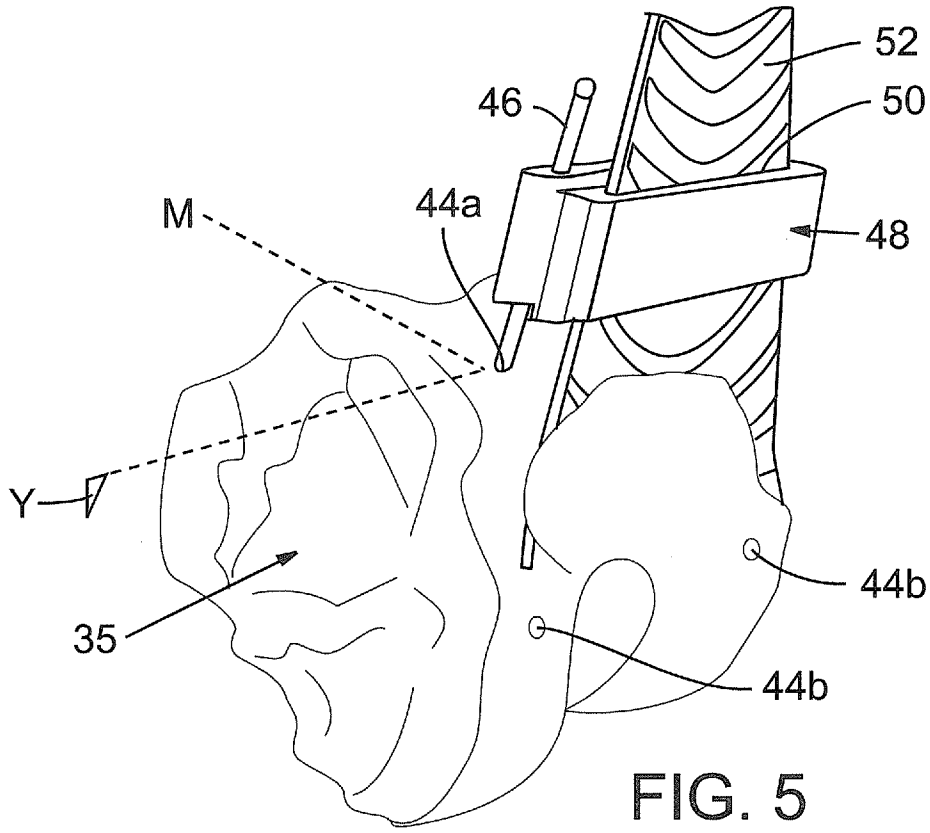

FIG. 5

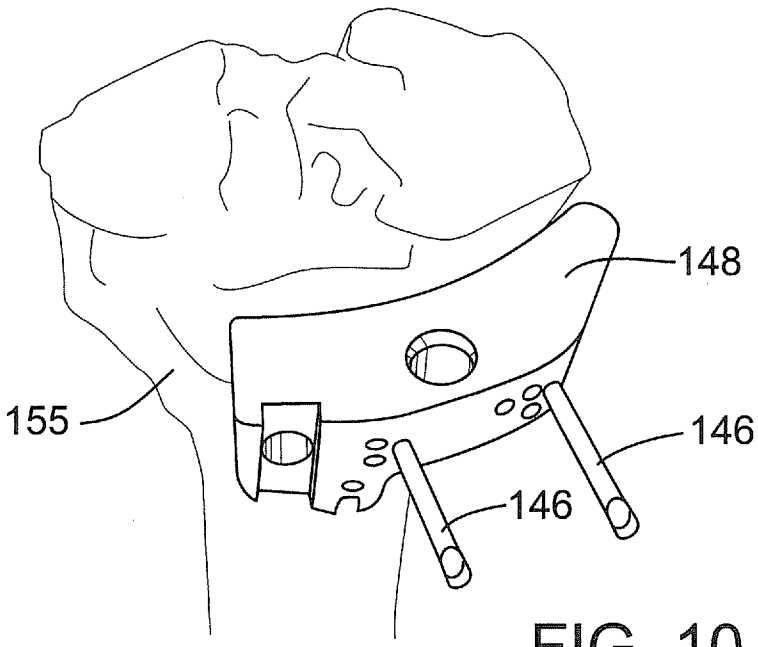

FIG. 10

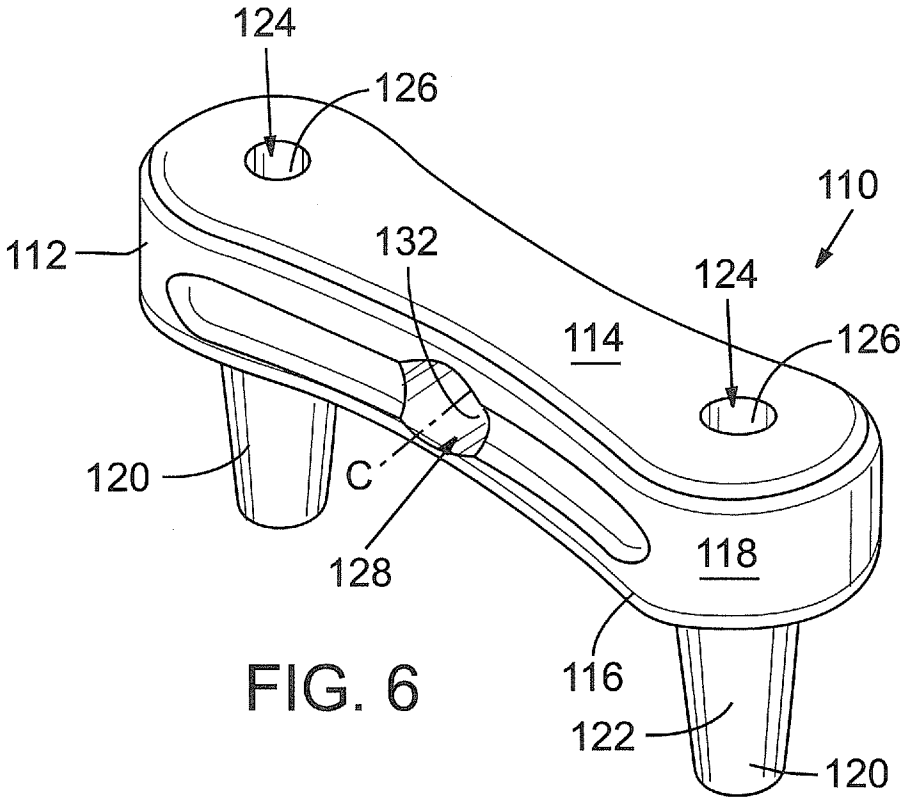

FIG. 6

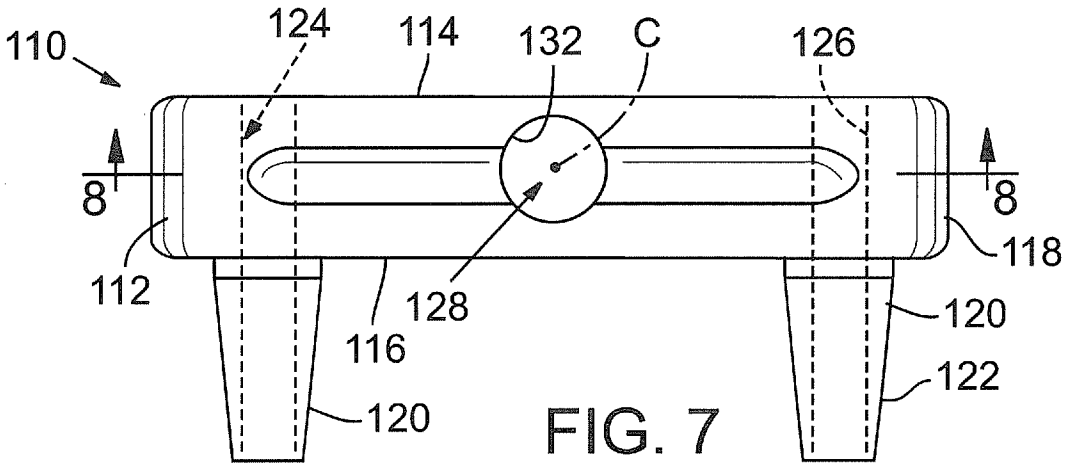

FIG. 7

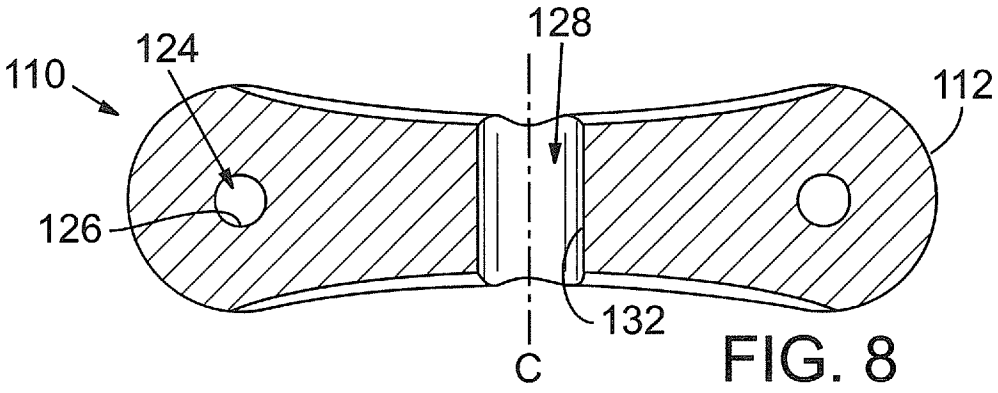

FIG. 8

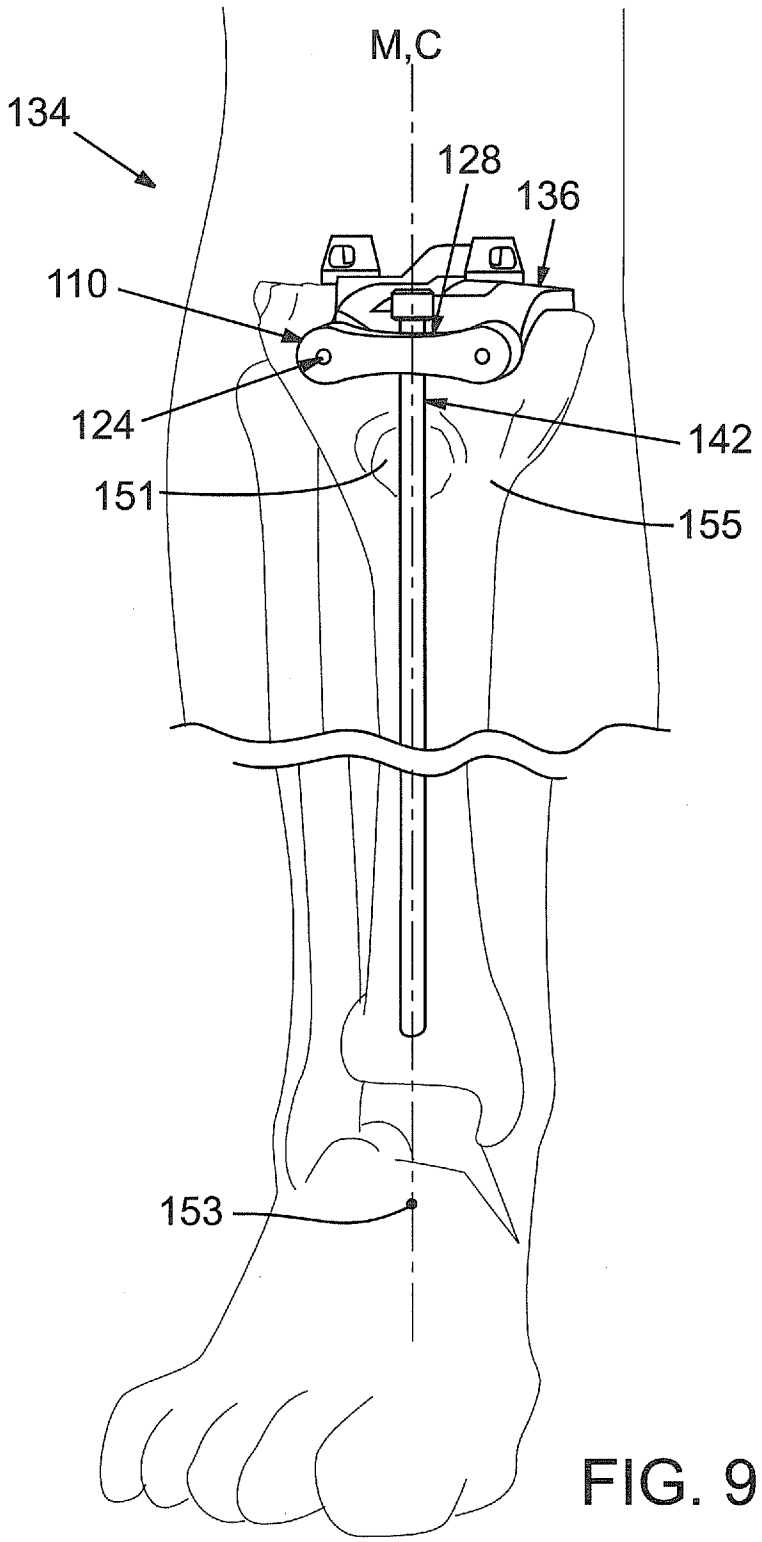

FIG. 9

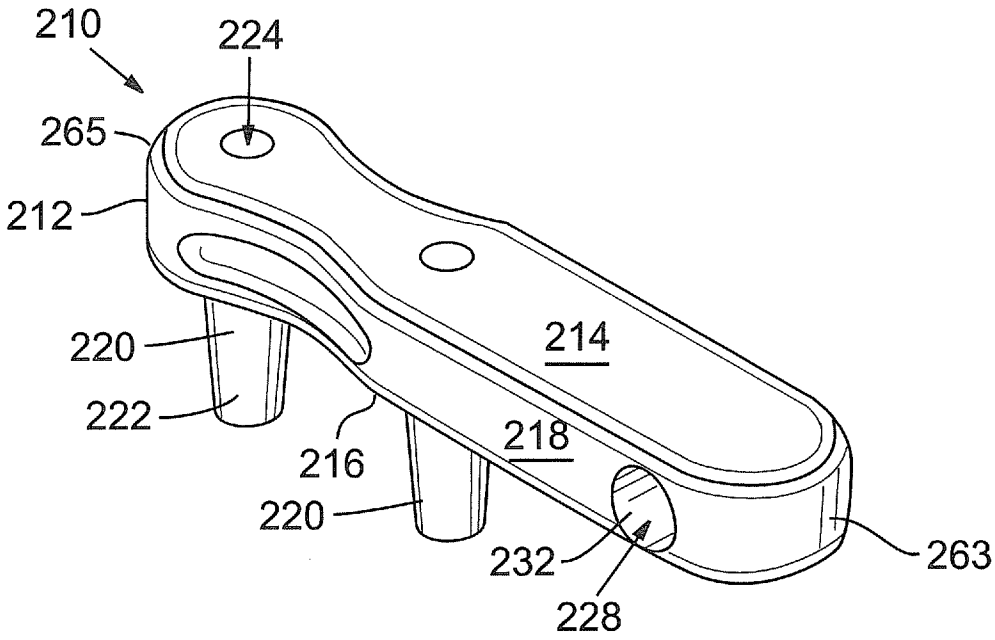

FIG. 11

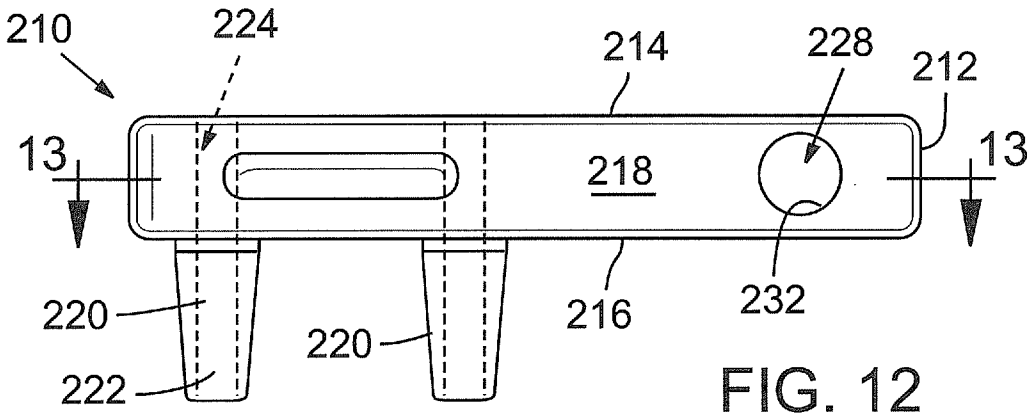

FIG. 12

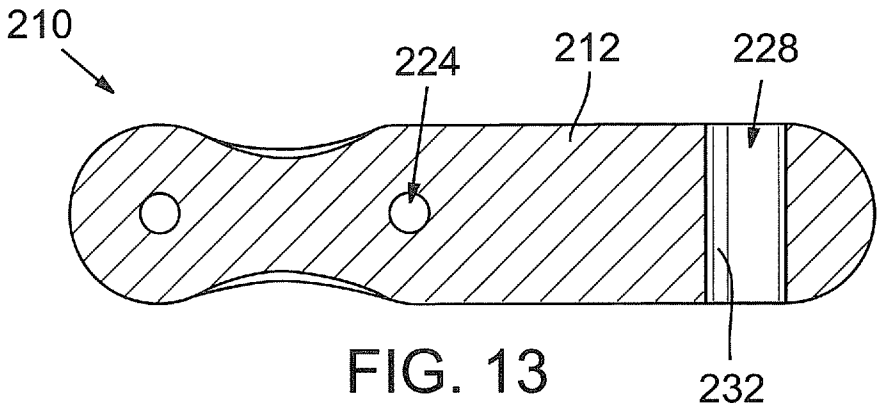

FIG. 13

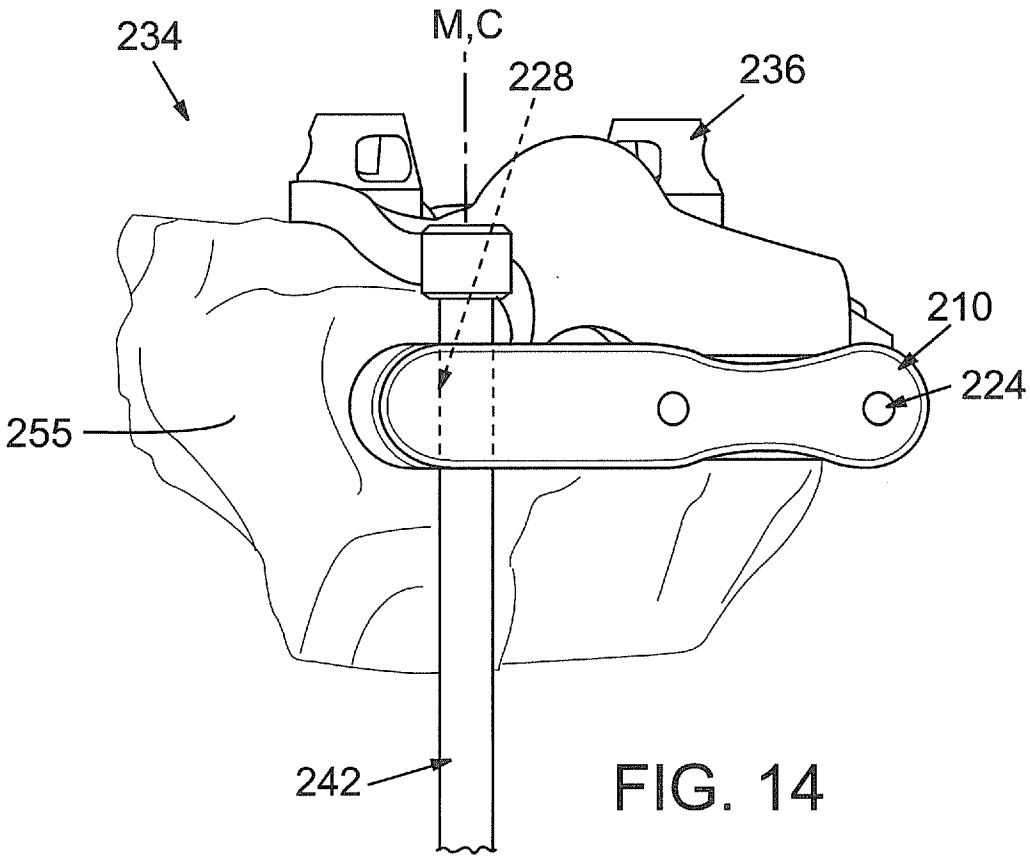

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/042081

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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 A	US 2009/024131 A1 (METZGER ROBERT [US] ET AL) 22 January 2009 (2009-01-22) figures 9-19 -----	1,2,9,12 17

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2012	05/09/2012

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	Hamann, Joachim

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/042081

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.: 13-16
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

International application No
PCT/US2012/042081

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009024131 A1	22-01-2009	EP 2352445 A1	10-08-2011
		JP 2012502740 A	02-02-2012
		US 2009024131 A1	22-01-2009
		WO 2010033431 A1	25-03-2010