



- (51) International Patent Classification:  
A61F 2/38 (2006.01)
- (21) International Application Number:  
PCT/US2016/052173
- (22) International Filing Date:  
16 September 2016 (16.09.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
62/234,141 29 September 2015 (29.09.2015) US
- (71) Applicant: ZIMMER, INC. [US/US]; 1800 W. Center Street, Warsaw, Indiana 46580 (US).
- (72) Inventor: YAGER, Edward R.; 12215 Glen Lake Dr., Fort Wayne, Indiana 46814 (US).
- (74) Agents: ARORA, Suneel et al.; Schwegman, Lundberg & Woessner P.A., P.O. Box 2938, Minneapolis, Minnesota 55402 (US).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: TIBIAL PROSTHESIS FOR TIBIA WITH VARUS RESECTION

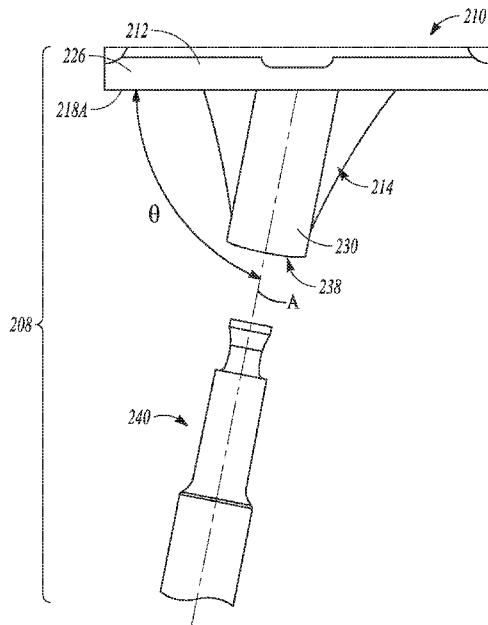


FIG. 4

(57) Abstract: Methods, systems and apparatuses are disclosed including apparatuses that can be used in a total knee replacement procedure. According to one example, a tibial implant (210) is disclosed. The tibial implant can be configured for attachment to a tibia in a knee arthroplasty and can include a baseplate (212) having a lateral portion (228) and a medial portion (226) oriented relative to an anteroposterior axis and a fixation member (214). Each of the lateral portion and the medial portion can have a distal surface configured to interface with a resected proximal surface of a tibia. The fixation member can be coupled to and extend both distally and medially from the baseplate such that the fixation member is oriented at an acute angle relative to the distal surface of the medial portion.

WO 2017/058535 A1

**Published:**

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

## TIBIAL PROSTHESIS FOR TIBIA WITH VARUS RESECTION

### CLAIM OF PRIORITY

[0001] This application claims the benefit of U.S. Provisional Patent Application  
5 Serial No. 62/234,141, filed on September 29, 2015, the benefit of priority of which  
is claimed hereby, and which is incorporated by reference herein in its entirety.

### FIELD

[0002] The present subject matter relates to orthopedic procedures and, more  
10 particularly, to tibial implants used in some knee arthroplasties where a varus  
resection of a tibia is utilized.

### BACKGROUND

[0003] Orthopedic procedures and prostheses are commonly utilized to repair  
15 and/or replace damaged bone and tissue in the human body. For example, a knee  
arthroplasty can be used to restore natural knee function by repairing damaged or  
diseased articular surfaces of the femur and/or tibia. An incision is made into the  
knee joint to expose the bones comprising the joint. Cut guides are used to guide  
the removal of the articular surfaces that are to be replaced. Prostheses are used to  
20 replicate the articular surfaces. Knee prostheses can include a femoral component  
implanted on the distal end of the femur, which articulates with a tibial component  
implanted on the proximal end of a tibia to replicate the function of a healthy natural  
knee. Various types of arthroplasties are known including a total knee arthroplasty  
(TKA), where all of the articulating compartments of the joint are repaired with  
25 prosthetic components.

### OVERVIEW

[0004] The present inventor recognizes, among other things, an opportunity for  
reducing trauma to the lateral tibial metaphysis and/or lateral tibial diaphysis during  
30 a TKA. More particularly, the present inventor has recognized that traditional

fixation members for the tibial component such as a stem, keel, and/or fins may not be appropriately referenced to a central axis of the intramedullary canal. A result of such misalignment is that the fixation member does not reference down the center of the intramedullary canal. This misalignment can result in the fixation member

5 perforating the lateral metaphysis or lateral diaphysis when the tibial component is seated down into a position on top of the resected proximal end of the tibia. The present inventor proposes a tibial implant, methods, and systems where the fixation member is appropriately referenced to substantially align with the central axis of the intramedullary canal. Achieving this orientation can include having the fixation

10 member(s) extend both distally and medially from a baseplate of the tibial implant such that the fixation member is oriented at an acute angle (i.e. be oriented in valgus) relative to the resected proximal surface (corresponding to a distal surface of a medial portion of the baseplate).

**[0005]** To further illustrate the apparatuses, systems and methods disclosed

15 herein, the following non-limiting examples are provided:

**[0006]** In Example 1, a tibial implant configured for attachment to a tibia in a knee arthroplasty is disclosed. The tibial implant can be configured for attachment to a tibia in a knee arthroplasty and can include a baseplate having a lateral portion and a medial portion oriented relative to an anteroposterior axis and a fixation

20 member. Each of the lateral portion and the medial portion can have a distal surface configured to interface with a resected proximal surface of a tibia. The fixation member can be coupled to and extend both distally and medially from the baseplate such that the fixation member is oriented at an acute angle relative to the distal surface of the medial portion.

25 **[0007]** In Example 2, the tibial implant of Example 1, wherein the fixation member can comprise one or both of a keel and a stem that are configured for insertion into a metaphysis and/or diaphysis of the tibia.

**[0008]** In Example 3, the tibial implant of Example 2, wherein one or both of the keel and stem can be configured to be removably attached to the baseplate.

- [0009]** In Example 4, the tibial implant of Example 3, wherein one or both of the keel and stem can be configured to be adjustable 180° relative to the baseplate such that the tibial implant can be configured for use with both a left tibia and a right tibia.
- 5 **[0010]** In Example 5, the tibial implant of Example 2, wherein the stem and keel can be configured to couple together, and wherein the stem can be configured to couple to the baseplate at the acute angle and coupling of the keel with the stem orients the keel at substantially a same acute angle relative to the distal surface of the medial portion as the acute angle.
- 10 **[0011]** In Example 6, the tibial implant of Example 2, wherein the stem and keel can be configured to couple together, and wherein the keel can be configured to couple to the baseplate at the acute angle and coupling of the stem with the keel orients the stem at substantially a same acute angle relative to the distal surface of the medial portion as the acute angle.
- 15 **[0012]** In Example 7, the tibial implant of any one or any combination of Examples 1-6, wherein the fixation member can include a symmetric feature having an axis of symmetry, and wherein the acute angle can be measured between the axis of symmetry and the distal surface of the medial portion.
- [0013]** In Example 8, the tibial implant of any one or any combination of
- 20 Examples 1-7, wherein the fixation member can include a lateral portion and a medial portion, and wherein the medial portion has a greater surface area than the lateral portion.
- [0014]** In Example 9, the tibial implant of any one or any combination of Examples 1-8, wherein the baseplate and fixation member can be configured such
- 25 that the fixation member is adjustable 180° relative to the baseplate such that the tibial implant is configured for use with both a left tibia and a right tibia.
- [0015]** In Example 10, a system for forming a tibial implant configured for attachment to a tibia in a knee arthroplasty is disclosed. The system can include one or more baseplates and a plurality of fixation members. The one or more baseplates
- 30 can have a lateral portion and a medial portion oriented relative to an

anteroposterior axis. Each of the lateral portion and the medial portion can have a distal surface configured to interface with a resected proximal surface of a tibia. Each of the plurality of fixation members can be configured to couple to the baseplate and can extend both distally and medially from the baseplate such that  
5 each fixation member of the plurality of fixation members is oriented at an acute angle relative to the distal surface of the medial portion. Each of the plurality of fixation members can be configured to differ from others of the plurality of fixation members such that the acute angle formed by each of the plurality of fixation members, when mounted to the baseplate, differs in degree.

10 **[0016]** In Example 11, the system of Example 10, wherein the plurality of fixation members can comprise a plurality of keels each having a different configuration and a single stem having a single configuration, wherein the single stem is configured to universally couple with any of the plurality of keels.

15 **[0017]** In Example 12, the system of Example 10, wherein the plurality of fixation members can comprise a plurality of stems each having a different configuration and a single keel having a single shape, wherein the single keel can be configured to universally couple with any of the plurality of stems.

20 **[0018]** In Example 13, the system of any one or any combination of Examples 10-12, wherein the baseplate and fixation member can be configured such that the fixation member can be coupled to the baseplate in at least two orientations including to create a first configuration for a right knee and a second configuration for a left knee.

25 **[0019]** In Example 14, a method of performing a knee arthroplasty is disclosed. The method can include resecting a proximal surface of a tibia to expose a tibial metaphysis, and attaching a tibial implant to the resected surface at a distal surface of a baseplate of the tibial implant, the tibial implant having a fixation member that is configured to generally align with a central axis of the tibial diaphysis when coupled to the distal surface of the baseplate.

30 **[0020]** In Example 15, the method of Example 14, can further comprise determining a desired angle based on degree of varus between the distal surface of

the baseplate and the central axis of the tibial diaphysis, selecting from a plurality of fixation members that are configured to achieve the desired angle when coupled to the baseplate, and coupling the selected fixation member to the tibial baseplate.

5 [0021] In Example 16, the method of any one or any combination of Examples 14 and 15, wherein the plurality of fixation members can comprise a plurality of keels and a single stem configured to universally couple with all of the plurality of keels.

10 [0022] In Example 17, the method of any one or any combination of Examples 14 and 15, wherein the plurality of fixation members can comprise a plurality of stems and a single keel configured to universally couple with all of the plurality of stems.

15 [0023] In Example 18, a tibial implant configured for attachment to a tibia in a knee arthroplasty is disclosed. The tibial implant can include a baseplate, a keel, and a stem. The baseplate can have a lateral portion and a medial portion oriented relative to an anteroposterior axis, each of the lateral portion and the medial portion having a distal surface configured to interface with a resected proximal surface of a tibia. The keel can be coupled to and extending both distally and medially from the baseplate such that the keel creates an acute angle between the keel and the distal surface of the medial portion. The stem can be configured to couple with one or  
20 both of the keel and the baseplate and configured to removably insert within a receptacle of the keel to be oriented at the acute angle relative to the distal surface of the medial portion.

25 [0024] In Example 19, the tibial implant of Example 18, wherein the keel can comprise one of a plurality of keels each keel configured to form a different degree of acute angle when coupled to the baseplate.

[0025] In Example 20, the tibial implant of Example 18, wherein the stem can comprise one of a plurality of stems each stem configured to form a different degree of acute angle when coupled to the baseplate.

30 [0026] In Example 21, the tibial implant of any one or any combination of Examples 18-20, wherein the baseplate, keel, and stem are each configured such

that at least one of the keel and stem is adjustable 180° relative to the baseplate such that the tibial implant is configured for use with both a left tibia and a right tibia.

[0027] In Example 22, the apparatuses or method of any one or any combination of Examples 1 – 21 can optionally be configured such that all elements or options  
5 recited are available to use or select from.

[0028] These and other examples and features of the present apparatuses, systems and methods will be set forth in part in the following Detailed Description. This Overview is intended to provide non-limiting examples of the present subject matter – it is not intended to provide an exclusive or exhaustive explanation. The  
10 Detailed Description below is included to provide further information about the present apparatuses and methods.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0029] In the drawings, which are not necessarily drawn to scale, like numerals  
15 can describe similar components in different views. Like numerals having different letter suffixes can represent different instances of similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various examples discussed in the present document.

[0030] FIG. 1A is a frontal or coronal plane view of a knee joint with an  
20 implanted knee prosthesis according to an example of the present application.

[0031] FIG. 1B is a coronal view of the knee joint and knee prosthesis of FIG. 1A in 90 degrees flexion according to an example of the present application.

[0032] FIG. 1C is a side or sagittal plane view of the knee joint and knee  
25 prosthesis of FIGS. 1A and 1B in full extension according to an example of the present application.

[0033] FIG. 2 is a coronal plane view of a tibia and a femur for a right knee having implants thereon and showing orientations of the implants relative to axes of the knee according to an example of the present application.

[0034] FIG. 3A is a plan view of a proximal side of a tibial implant for a left  
30 knee according to an example of the present application.



[0035] FIG. 3B is a perspective view of a distal portion of the tibial implant of FIG. 3A illustrating a fixation member canted relative to a distal surface of a baseplate according to an example of the present application.

5 [0036] FIG. 4 is a view of an assembly in a coronal plane including the tibial implant of FIGS. 3A and 3B and a stem according to an example of the present application.

[0037] FIG. 5 is a view of two assemblies including tibial implants and other components according to an example of the present application.

10 [0038] FIG. 6 is a view of two assemblies including tibial implants and other components according to another example of the present application.

[0039] FIG. 7A is a plan view of a distal side of a tibial implant according to yet another example of the present application.

[0040] FIG. 7B is a plan view of a fixation member in two orientations according to example of the present application.

15 [0041] FIG. 7C is a coronal plan view of the tibial implant of FIG. 7A coupled to the fixation member of FIG. 7B with the fixation member in a first orientation such as is shown in FIG. 7B and with the fixation member in a second orientation such as is shown in FIG. 7B according to an example of the present application.

20

#### DETAILED DESCRIPTION

[0042] It has been established that a kinematically aligned TKA can improve the results of the TKA, including overall patient satisfaction and mobility. Primary goals of kinematically aligned TKA are (1) positioning the femoral and tibial components of a knee prosthesis such that the angles and levels of the distal and posterior femoral and tibial joint lines are restored to the patient's natural joint line, (2) restoration of the patient's natural or constitutional alignment prior to the patient having developed osteoarthritis, and (3) restoration of the patient's natural soft tissue laxity and envelope. The kinematically aligned TKA can include a determination of three kinematic axes.

25

**[0043]** FIGS. 1A-1C show various views of a knee prosthesis 10 implanted on a knee joint and illustrate the three kinematic axes of the knee joint in a kinematically aligned TKA. In particular, FIG. 1A provides a view of the knee prosthesis 10 in a coronal plane as viewed from the anterior with a femoral component 12 in extension. FIG. 1B is a view of the knee prosthesis 10 in the coronal plane with the femoral component 12 in flexion. FIG. 1C is a view of the 10 in the sagittal plane with the femoral component in extension. The femoral component 12 is implanted on a femur 14 while a tibial component 16 implanted on a tibia 18. A polyethylene surface is inserted between the femur and tibia. A first kinematic axis 20 can be a transverse axis in the femur 14 about which the tibia 18 flexes and extends. The first kinematic axis 20 can be determined by projecting the lateral and medial femoral condyles of the femur 14 onto one another and fitting circles of equal radii over each other. The first kinematic axis 20 passes through a center of the circles. A second kinematic axis 22 can be a second transverse axis, parallel to the first kinematic axis 20, about which a patella of the knee joint flexes and extends. The second kinematic axis 22 can be located anterior and proximal to the first kinematic axis 20. A third kinematic axis 24 is an axis perpendicular to the first 20 and second 22 axes about which the tibia 18 internally and externally rotates on the femur 14.

**[0044]** The present application does not include a description of the surgical procedure for performing a kinematically aligned TKA. Such procedures are discussed, for example, in relation to Application Serial Numbers 14/809,810, entitled "INSTRUMENTS AND METHODS IN PERFORMING KINEMATICALLY-ALIGNED TOTAL KNEE ARTHROPLASTY" filed July 27, 2015, and 13/819,528, entitled "FEMORAL PROTHESIS WITH MEDIALIZED PATELLAR GROOVE", filed September 9, 2011, the entire disclosures of which are incorporated herein by reference and are co-owned by the Applicant. Rather, FIGS. 2-7C provide examples of surgical instruments, systems, methods and techniques that can be used to aid and improve on the kinematically aligned TKA.

**[0045]** FIG. 2 shows an example of a TKA knee prosthesis 110 in a right knee of a patient as viewed in the coronal plane. As was generally discussed with respect to

FIGS. 1A-1C, the knee prosthesis 110 can include a femoral component 112 mounted to the femur 14 and a tibial component 116 mounted to the tibia 18. FIG. 2 shows the knee prosthesis 110 alignment relative to the anatomical axes of the femur 14 and the tibia 18. In particular, FIG. 2 shows a femoral anatomical axis 120 and a tibial anatomical axis 122.

**[0046]** Disposition of the femoral component 112 relative to the femoral anatomical axis 120 is indicated by  $\alpha$  as measured between a line 124 across the bottom of the femoral condyles 113A and 113B the femoral shaft axis (superimposed with the femoral anatomical axis 120). Disposition of the tibial component 116 relative to the tibial anatomical axis 122 is indicated by  $\beta$  as measured between a line 126 across a base of a tibial plate 128 of the tibial component 116 and a tibial shaft axis (superimposed with the tibial anatomical axis 122). An angle  $\Delta$  (a tibiofemoral axis) is also indicated and comprises a measure between the femoral shaft axis and the tibial shaft axis.

**[0047]** An  $\alpha$  of  $90^\circ$  comprises a neutral placement of the femoral component 112,  $\alpha < 90^\circ$  corresponds to varus placement of the femoral component 112, and  $\alpha > 90^\circ$  corresponds to valgus placement of the femoral component 112. Similarly, if  $\beta = 90^\circ$  corresponds to a neutral placement of the tibial component 116,  $\beta < 90^\circ$  corresponds to varus placement of placement of the tibial component 116, and  $\beta > 90^\circ$  corresponds to valgus placement of the tibial component 116. If  $\Delta = 180^\circ$  this corresponds to a neutral alignment,  $\Delta < 180^\circ$  corresponds to varus alignment, and  $\Delta > 180^\circ$  corresponds to valgus alignment.

**[0048]** With regard to coronal alignment of the femoral component 112, it has generally been shown that an optimal distal femoral cut is typically 2-7° of valgus. With regard to coronal alignment of the tibial component 116, a certain degree of varus tibial alignment with a varus cut is generally desirable. With the kinematically aligned TKA it has generally been found that tibial component 116 placement of a few more degrees varus (e.g., about 0.1 degrees to about 5 degrees) and the femoral component 112 placed in a few more degrees valgus (e.g., about 0.1

degrees to about 5 degrees) than traditional mechanically aligned TKA results in improved patient outcomes.

**[0049]** The present inventor has recognized that especially with the additional varus disposition of the tibial component 116 in the kinematically aligned TKA, traditional fixation members for the tibial component 116 such as a stem, keel, or fins (e.g., a keel and stem 130 as shown in FIG. 2) may not be appropriately referenced to the intramedullary canal which generally aligns with the tibial anatomical axis 122. Indeed, an example of such misalignment is shown in FIG. 2 where the keel 130 is not substantially aligned with the tibial anatomical axis 122. A result of such misalignment is that the keel 130 does not reference down the center of the tibial diaphysis/ intramedullary canal. This misalignment can result in the keel 130 perforating the lateral metaphysis or lateral diaphysis when the tibial component 116 is seated down into a position on top of the resected proximal end surface 132 of the tibia 18.

**[0050]** FIGS. 3A and 3B show an example tibial implant 210 configured for a left knee (note difference from the configuration of FIG. 2 which is configured for the right knee). According to further examples the example of FIGS. 3A and 3B can be mirrored for use with the right knee. The tibial implant 210 includes a baseplate 212 and a fixation member 214 (FIG. 3B). The baseplate 212 includes a proximal surface 216 (FIG. 3A), a distal surface 218 (FIG. 3B), an anterior edge 220, a posterior edge 222, an anteroposterior axis 224, a lateral portion 226, and a medial portion 228. The fixation member 214 shown in FIG. 3B comprises a keel 230 and fins 232A and 232B. The keel 230 includes a medial portion 234, a lateral portion 236, and a receptacle 238.

**[0051]** In the example provided, the baseplate 212 and fixation member 214 are coupled together. As shown in FIG. 3A, the baseplate 212 can be configured at the proximal surface 216 to receive a tibial bearing component, for example. The distal surface 218 is disposed on an opposing side of the baseplate 212 from the proximal surface 216 and can be configured to interface with a resected proximal surface of a tibia. The distal surface 218 can include a medial portion 218A (corresponding to

that of the medial portion 226) and a lateral portion 218B (corresponding to that of the lateral portion 228). Both the proximal surface 216 and the distal surface 218 extend from the anterior edge 220 to the posterior edge 222 of the baseplate 212.

**[0052]** As shown in FIG. 3A the anteroposterior axis 224 can divide the baseplate 212 into the medial portion 226 and the lateral portion 228. Thus, the medial portion 226 and the lateral portion 228 can be oriented relative to the anteroposterior axis 218. Although shown with an asymmetrically shaped medial portion 226 relative to the lateral portion 228, in some examples the medial portion 226 and the lateral portion 228 can be substantially symmetric relative to one another.

**[0053]** As shown in the example of FIG. 3B, the fixation member 214 can be coupled to and can extend both distally and medially from the distal surface 218 such that the fixation member 214 is oriented at an acute angle  $\theta$  (FIG. 4) relative to the distal surface 218A of the medial portion 226 when viewed in the frontal or coronal plane. Put another way with reference to FIG. 2 for terminology and points of reference, the fixation member 214 can be provided with an angle ( $\beta > 90^\circ$  in reference to the tibial anatomical axis 122) to compensate for the varus orientation of the baseplate 212 on the resected proximal end surface 132 of the tibia 18. Thus, the fixation member 214 can be configured to substantially align with a central axis (indicated by tibial anatomical axis 122 of FIG. 2) of the tibial diaphysis when the fixation member 214 is coupled to the distal surface 218 of the baseplate 212. This orientation of the fixation member reduces the risk that the fixation member 214 will perforate the lateral metaphysis or lateral diaphysis when the tibial component 210 is seated down into a position on top of the resected proximal end surface 132 of the tibia 18.

**[0054]** As shown in the example of FIG. 3B, the fixation member 214 is configured as a keel 230, however in other examples the fixation member 214 can comprise some other type of projection (e.g., a stem, a peg, or the like) that is configured for insertion into the metaphysis or diaphysis of the tibia. According to the example of FIG. 3B, the keel 230 can have fins 232A and 232B extending to the

medial portion 226 and lateral portion 228, respectively. Additionally, the keel 230 can have the medial portion 234 be differently configured than the lateral portion 236. For example, the lateral portion 236 can have a greater surface area than the medial portion 234 as shown in the illustrated example of FIG. 3B due to the  
5 angling of the fixation member 214 relative to the distal surface 318 of the baseplate 212. Such angling can provide the lateral portion 236 with a greater distal extent than a distal extent of the medial portion 234.

**[0055]** As shown in FIG. 3B, the keel 230 can form the receptacle 238 which extends through a substantial portion of the keel 230. The receptacle 238 can  
10 receive a stem such as a stem 240 of FIGS. 4 and 5, for example. Further disclosure of various examples of keels with stems including coupling mechanisms between these two components and/or the baseplate are provided in United States Patent Application Publication 2013/0024001, entitled "ASYMMETRIC TIBIAL COMPONENTS FOR A KNEE PROSTHESIS", filed January 23, 2013 and by  
15 United States Patent Number 7,691,150, entitled "MODULAR PLATE AND KEEL PROVISIONALS", filed December 14, 2006, the entire disclosures of both of which are incorporated herein by reference.

**[0056]** FIG. 4 shows an assembly 208 of the tibial implant 210 from FIGS. 2A and 2B with the stem 240 that can be configured to be received in the receptacle  
20 238. Thus, the stem 240 is configured to be insertable into the keel 230 to couple together the stem 240 and the keel 230. One or both of the keel 230 and the stem 240 are configured to be removably attached to the baseplate 212. In the example of FIG. 4, the keel 230 has a female mating option (receptacle 238) where the stem 240 can be selected as a male counterpart. However, other configurations will be  
25 discussed subsequently. Thus, the keel 230 can be configured to couple to the baseplate 212 at the acute angle  $\theta$  and coupling of the stem 240 with the keel 230 orients the stem 240 at substantially a same acute angle relative to the distal surface 218A of the medial portion 226 as the acute angle  $\theta$  of the keel 230. In FIG. 4, the fixation member 214 includes a symmetric feature (e.g. the receptacle 238 and the  
30 stem 240) each having an axis of symmetry A. The acute angle  $\theta$  can extend

between the axis of symmetry A and the distal surface 218A of the medial portion 226.

**[0057]** Furthermore, FIGS. 3A to 4 illustrate an example where the keel 230 can be integrally formed with the baseplate 212 such that the two components comprise a single component. However, in other examples the keel 230 can be affixed by other mechanisms (weld, thread, interference fit, or the like) some of which allow the keel to be removable from the baseplate.

**[0058]** FIG. 5 shows components that can comprise assemblies 308 and 408. In particular, when assembled together the components can comprise a tibial implant similar to those previously shown and discussed herein. As shown in the example of FIG. 5, the assemblies 308, 408 can include at least one baseplate (e.g., baseplate 312 and baseplate 412). As with prior discussed embodiments, each baseplate 312, 412 can have a medial portion 326, 426 and a lateral portion 328, 428. Furthermore, each of the medial portion 326, 426 and the lateral portion 328, 428 can have a distal surface 318, 418 configured to interface with a resected proximal surface of a tibia.

**[0059]** The assemblies 308, 408 also can include at least one of a plurality of fixation members 314, 414. Each of the plurality of fixation members 314, 414 can be configured to attach to and extend both distally and medially from the distal surface 318, 418 such that each fixation member 314, 414 of the plurality of fixation members 314, 414 is oriented at an acute angle  $\theta_1$ ,  $\theta_2$  relative to the distal surface 318A, 418A of the medial portion 326, 426 when viewed in the frontal or coronal plane. Each of the plurality of fixation members 314, 414 can be configured to differ from others of the plurality of fixation members 314, 414 such that the acute angle  $\theta_2$ ,  $\theta_1$  formed by each of the plurality of fixation members 314, 414 when coupled to the baseplate 312, 412 would differ in degree.

**[0060]** More particular, a keel 330, 430 can be coupled to and extend both distally and medially relative to the distal surface 318, 412 such that the keel 330, 430 creates the acute angle  $\theta_1$ ,  $\theta_2$  between the keel 330, 430 and the distal surface 318A, 418A of the medial portion 326, 426 when viewed in the frontal or coronal

plane. A stem 340 can be configured to couple with one or both of the keel 330, 430 and the baseplate 312, 412 and can be configured to removably insert within a receptacle 338, 438 of the keel 330, 430.

**[0061]** It should be noted that although illustrated as assemblies 308, 408 that  
5 include almost entirely separate components, in some examples a component such as one or more of the baseplates 312, 412, keels 330, 430, and/or stem 340 can be configured to universally couple with others of the components. For example, in FIG. 5 the plurality of fixation members 314, 414 can comprise a plurality of keels 330, 430 (each keel 330, 430 can have a different configuration) and a single stem  
10 340. The single stem 340 can have only a single configuration and can be configured to universally couple with any of the plurality of keels 330, 430. As shown in FIG. 5, the keels 330, 430 can comprise one of a plurality of keels (e.g., 330, 430, and so on) each keel 330, 430 can be configured to form a different acute angle (e.g.,  $\theta_1$ ,  $\theta_2$ , and so on) when coupled to the baseplate 312, 412. Although a  
15 plurality of baseplates 312, 412 are shown in FIG. 5, in some examples a single baseplate can be utilized with the assemblies and can be configured to couple to any of the plurality of keels (e.g., 330, 430).

**[0062]** FIG. 6 shows assemblies 508, 608 according to further examples. According to the examples of FIG. 6, the assemblies 508, 608 can include at least  
20 one baseplate (e.g., baseplate 512 and baseplate 612). As with prior discussed embodiments, each baseplate 512, 612 can have a medial portion 526, 626 and a lateral portion 528, 628 oriented relative to an anteroposterior axis (not shown). Furthermore, each baseplate 512, 612 can have a distal surface 518, 618 configured to interface with a resected proximal end surface 132 (FIG. 2) of a tibia.

**[0063]** The assemblies 508, 608 also can include at least one of a plurality of  
25 fixation members 514, 614. Each of the plurality of fixation members 514, 614 can be configured to attach to and extend both distally and medially from the distal surface 518, 618 such that each fixation member 514, 614 of the plurality of fixation members 514, 614 is oriented at an acute angle  $\delta_1$ ,  $\delta_2$  relative to the distal surface  
30 518A, 618A of the medial portion 526, 626 when viewed in the frontal or coronal



plane. Each of the plurality of fixation members 514, 614 can be configured to differ from others of the plurality of fixation members 514, 614 such that the acute angle  $\delta_1$ ,  $\delta_2$  formed by each of the plurality of fixation members 514, 614 when mounted to the baseplate 512, 612 would differ in degree. The examples of FIG. 6 utilize a plurality of stems 540, 640 and a single keel 530. Each stem 540, 640 can be configured to couple to the baseplate 512 and/or 612 at the acute angle  $\delta_1$ ,  $\delta_2$ . Coupling of the keel 530 with the stem 540 can orient the keel 530 at substantially a same acute angle relative to the distal surface 518A, 618A of the medial portion 526, 626 as the acute angle  $\delta_1$ ,  $\delta_2$ .

10 **[0064]** It should be noted similar to assemblies 308, 408 the assemblies 508, 608 can be have one or more components configured to universally couple with others of the components of the assemblies 508, 608. For example, in FIG. 6 the plurality of fixation members 514, 614 can comprise the plurality of stems 540, 640 (each keel 330, 430 can have a different configuration) and a single keel 530. Thus, according to some examples the keel 530 can have only a single configuration and can be configured to universally couple with any of the plurality of stems 540, 640. As shown in FIG. 6, the stems 540, 640 can comprise one of a plurality of stems (e.g., 540, 640, and so on) each keel 540, 640 can be configured to form a different acute angle (e.g.,  $\delta_1$ ,  $\delta_2$ , and so on) when coupled to the baseplate 512, 612.

15 **[0065]** An example method of performing a knee arthroplasty using a tibial implant such as those discussed herein can include resecting a proximal surface of a tibia to expose a tibial metaphysis, and attaching a tibial implant to the resected surface at a distal surface of a baseplate of the tibial implant. The tibial implant can have a fixation member which is configured to generally align with a central axis of the tibial diaphysis (e.g., indicated by tibial anatomical axis 122 of FIG. 2) when coupled to the distal surface of the baseplate. According to further examples the method can include determining a desired angle based on degree of varus between the distal surface of the baseplate and the central axis of the tibial diaphysis, selecting from a plurality of fixation members that are configured to achieve the

desired angle when coupled to the baseplate, and coupling the selected fixation member to the tibial baseplate.

**[0066]** FIGS. 7A to 7C show another example of a tibial implant 710 where a baseplate 712 and fixation member 714 are configured such that the fixation member 714 is adjustable relative to the baseplate 712. The tibial implant 710 can include the baseplate 712 and the fixation member 714 similar to those previously described. Thus, the baseplate 712 can include a distal surface 718 and the fixation member 714 can comprise a stem 740 (FIGS. 7B and 7C) configured to mate with one or more keels (not shown). However, the baseplate 712 can also include a coupling feature 720 (FIG. 7A) disposed at the distal surface 718.

**[0067]** The coupling feature 720 can be configured to couple with a base 722 (FIG. 7B) of the stem 740 with the base 722 and the stem 740 assembly in multiple orientations. As illustrated and described according to the example of FIGS. 7A to 7C, the stem 740 can be configured to be adjustable 180° relative to the baseplate 712 by simply reversing the orientation of the base 722 (shown in FIG. 7B) and then recoupling the base 722 and the stem 740 to the baseplate 712. Therefore, FIGS. 7A to 7C show an example where the baseplate 712 and fixation member 714 that are configured such that the fixation member 714 can be coupled to the baseplate 712 in at least two orientations including to create a first configuration for a right knee and a second configuration for a left knee. According to other examples, rather than being configured to be adjustable 180° relative to the baseplate, the fixation member can be clocked to be incrementally adjustable both in the medial-lateral direction but also in the anterior-posterior direction. Thus, in some examples the fixation member can be re-orientable relative to the baseplate to form a plurality of different configurations.

**[0068]** More particularly, the coupling feature 720 can comprise fixation mechanisms known in the art such as those that use a slot, groove, flange, male/female connection, interference, tab, fastener, pin, or other mechanisms to couple the base 722 to the baseplate 712. According to the example of FIG. 7A, the coupling feature 720 comprises grooves 724 adapted to receive corresponding

features of the base 722 which is inserted from a posterior toward an anterior of the baseplate 712. A fastener (not shown) can be received in hole 726 in the baseplate 712 and can insert into or abut the base 722 once the base 722 is moved into the desired position. This can further lock the base 722 relative to the baseplate 712.

5 FIG. 7A provides only one example of a coupling feature others including those that utilize a different insertion direction and/or coupling mechanism(s) are contemplated.

#### Additional Notes

10 **[0069]** The above detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the invention can be practiced. These embodiments are also referred to herein as “examples.” Such examples can include elements in addition to those shown or described. However, the present  
15 inventors also contemplate examples in which only those elements shown or described are provided. Moreover, the present inventors also contemplate examples using any combination or permutation of those elements shown or described (or one or more aspects thereof), either with respect to a particular example (or one or more aspects thereof), or with respect to other examples (or one or more aspects thereof)  
20 shown or described herein.

**[0070]** In this document, the terms “a” or “an” are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of “at least one” or “one or more.” In this document, the term “or” is used to refer to a nonexclusive or, such that “A or B” includes “A but not B,” “B but not  
25 A,” and “A and B,” unless otherwise indicated. In this document, the terms “including” and “in which” are used as the plain-English equivalents of the respective terms “comprising” and “wherein.” Also, in the following claims, the terms “including” and “comprising” are open-ended, that is, a system, device, article, composition, formulation, or process that includes elements in addition to  
30 those listed after such a term in a claim are still deemed to fall within the scope of

that claim. Moreover, in the following claims, the terms “first,” “second,” and “third,” etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

**[0071]** The above description is intended to be illustrative, and not restrictive.

5 For example, the above-described examples (or one or more aspects thereof) can be used in combination with each other. Other examples can be used, such as by one of ordinary skill in the art upon reviewing the above description. The Abstract is provided to comply with 37 C.F.R. §1.72(b), to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it  
10 will not be used to interpret or limit the scope or meaning of the claims. Also, in the above detailed description, various features can be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter can lie in less than all features of a particular disclosed example. Thus, the following  
15 claims are hereby incorporated into the detailed description as examples or embodiments, with each claim standing on its own as a separate example, and it is contemplated that such examples can be combined with each other in various combinations or permutations. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to  
20 which such claims are entitled.

## THE CLAIMED INVENTION IS:

1. A tibial implant configured for attachment to a tibia in a knee arthroplasty, the tibial implant comprising:
  - 5 a baseplate having a lateral portion and a medial portion oriented relative to an anteroposterior axis, each of the lateral portion and the medial portion having a distal surface configured to interface with a resected proximal surface of a tibia; and  
a fixation member coupled to and extending both distally and medially from the baseplate such that the fixation member is oriented at an acute angle relative to  
10 the distal surface of the medial portion.
2. The tibial implant of claim 1, wherein the fixation member comprises one or both of a keel and a stem that are configured for insertion into a metaphysis and/or diaphysis of the tibia.  
15
3. The tibial implant of claim 2, wherein one or both of the keel and stem are configured to be removably attached to the baseplate.
4. The tibial implant of claim 3, wherein one or both of the keel and stem are  
20 configured to be adjustable 180° relative to the baseplate such that the tibial implant is configured for use with both a left tibia and a right tibia.
5. The tibial implant of claim 2, wherein the stem and keel are configured to couple together, and wherein the stem is configured to couple to the baseplate at the  
25 acute angle and coupling of the keel with the stem orients the keel at substantially a same acute angle relative to the distal surface of the medial portion as the acute angle.
6. The tibial implant of claim 2, wherein the stem and keel are configured to  
30 couple together, and wherein the keel is configured to couple to the baseplate at the

acute angle and coupling of the stem with the keel orients the stem at substantially a same acute angle relative to the distal surface of the medial portion as the acute angle.

- 5 7. The tibial implant of any one or any combination of claims 1-6, wherein the fixation member includes a symmetric feature having an axis of symmetry, and wherein the acute angle is measured between the axis of symmetry and the distal surface of the medial portion.
- 10 8. The tibial implant of any one or any combination of claims 1-7, wherein the fixation member includes a lateral portion and a medial portion, and wherein the medial portion has a greater surface area than the lateral portion.
- 15 9. The tibial implant of any one or any combination of claims 1-8, wherein the baseplate and fixation member are configured such that the fixation member is adjustable 180° relative to the baseplate such that the tibial implant is configured for use with both a left tibia and a right tibia.
- 20 10. A system for forming a tibial implant configured for attachment to a tibia in a knee arthroplasty, the system comprising:  
one or more baseplates having a lateral portion and a medial portion oriented relative to an anteroposterior axis, each of the lateral portion and the medial portion having a distal surface configured to interface with a resected proximal surface of a tibia;
- 25 a plurality of fixation members each of the plurality of fixation members being configured to couple to the baseplate and extend both distally and medially from the baseplate such that each fixation member of the plurality of fixation members is oriented at an acute angle relative to the distal surface of the medial portion, and wherein each of the plurality of fixation members is configured to  
30 differ from others of the plurality of fixation members such that the acute angle

formed by each of the plurality of fixation members, when mounted to the baseplate, differs in degree.

11. The system of claim 10, wherein the plurality of fixation members comprises  
5 a plurality of keels each having a different configuration and a single stem having a single configuration, wherein the single stem is configured to universally couple with any of the plurality of keels.

12. The system of claim 10, wherein the plurality of fixation members comprises  
10 a plurality of stems each having a different configuration and a single keel having a single shape, wherein the single keel is configured to universally couple with any of the plurality of stems.

13. The system of any one or any combination of claims 10-12, wherein the  
15 baseplate and fixation member are configured such that the fixation member can be coupled to the baseplate in at least two orientations including to create a first configuration for a right knee and a second configuration for a left knee.

14. A method of performing a knee arthroplasty, the method comprising:  
20 resecting a proximal surface of a tibia to expose a tibial metaphysis; and attaching a tibial implant to the resected surface at a distal surface of a baseplate of the tibial implant, the tibial implant having a fixation member that is configured to generally align with a central axis of the tibial diaphysis when coupled to the distal surface of the baseplate.

25

15. The method of claim 14, further comprising:  
determining a desired angle based on degree of varus between the distal  
surface of the baseplate and the central axis of the tibial diaphysis;  
selecting from a plurality of fixation members that are configured to achieve  
30 the desired angle when coupled to the baseplate; and

coupling the selected fixation member to the tibial baseplate.

16. The method of any one or any combination of claims 14 and 15, wherein the plurality of fixation members comprise a plurality of keels and a single stem  
5 configured to universally couple with all of the plurality of keels.

17. The method of any one or any combination of claims 14 and 15, wherein the plurality of fixation members comprise a plurality of stems and a single keel  
10 configured to universally couple with all of the plurality of stems.

10

18. A tibial implant configured for attachment to a tibia in a knee arthroplasty, the tibial implant comprising:  
a baseplate having a lateral portion and a medial portion oriented relative to an anteroposterior axis, each of the lateral portion and the medial portion having a  
15 distal surface configured to interface with a resected proximal surface of a tibia;  
a keel coupled to and extending both distally and medially from the baseplate such that the keel creates an acute angle between the keel and the distal surface of the medial portion; and  
a stem configured to couple with one or both of the keel and the baseplate  
20 and configured to removably insert within a receptacle of the keel to be oriented at the acute angle relative to the distal surface of the medial portion.

19. The tibial implant of claim 18, wherein the keel comprises one of a plurality of keels each keel configured to form a different degree of acute angle when  
25 coupled to the baseplate.

20. The tibial implant of claim 18, wherein the stem comprises one of a plurality of stems each stem configured to form a different degree of acute angle when  
30 coupled to the baseplate.

30



21. The tibial implant of any one or any combination of claims 18-20, wherein the baseplate, keel, and stem are each configured such that at least one of the keel and stem is adjustable 180° relative to the baseplate such that the tibial implant is configured for use with both a left tibia and a right tibia.

5

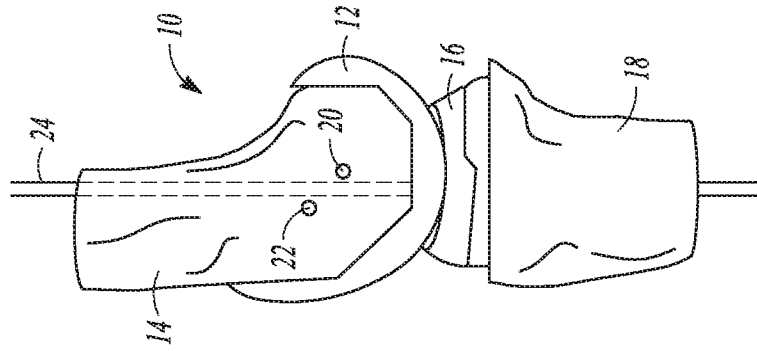


FIG. 1C

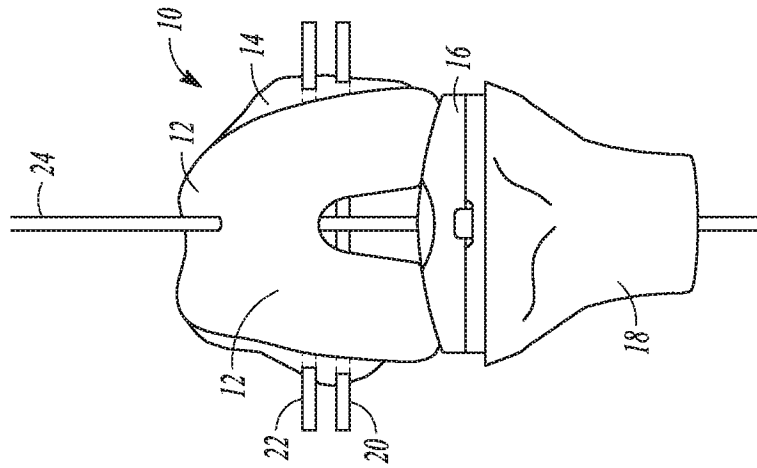


FIG. 1B

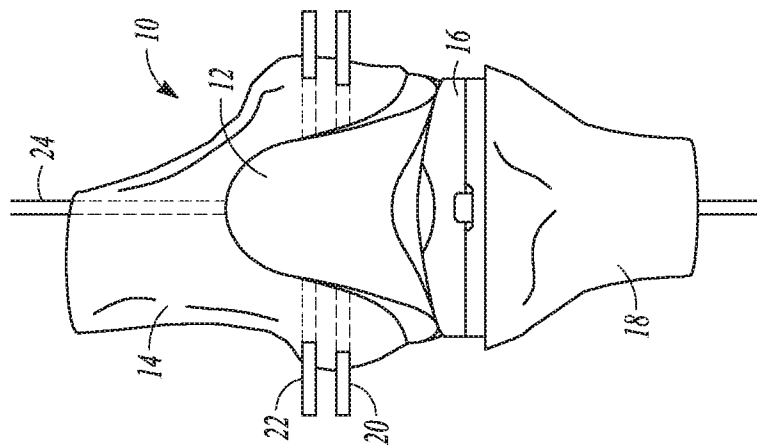


FIG. 1A

2/8

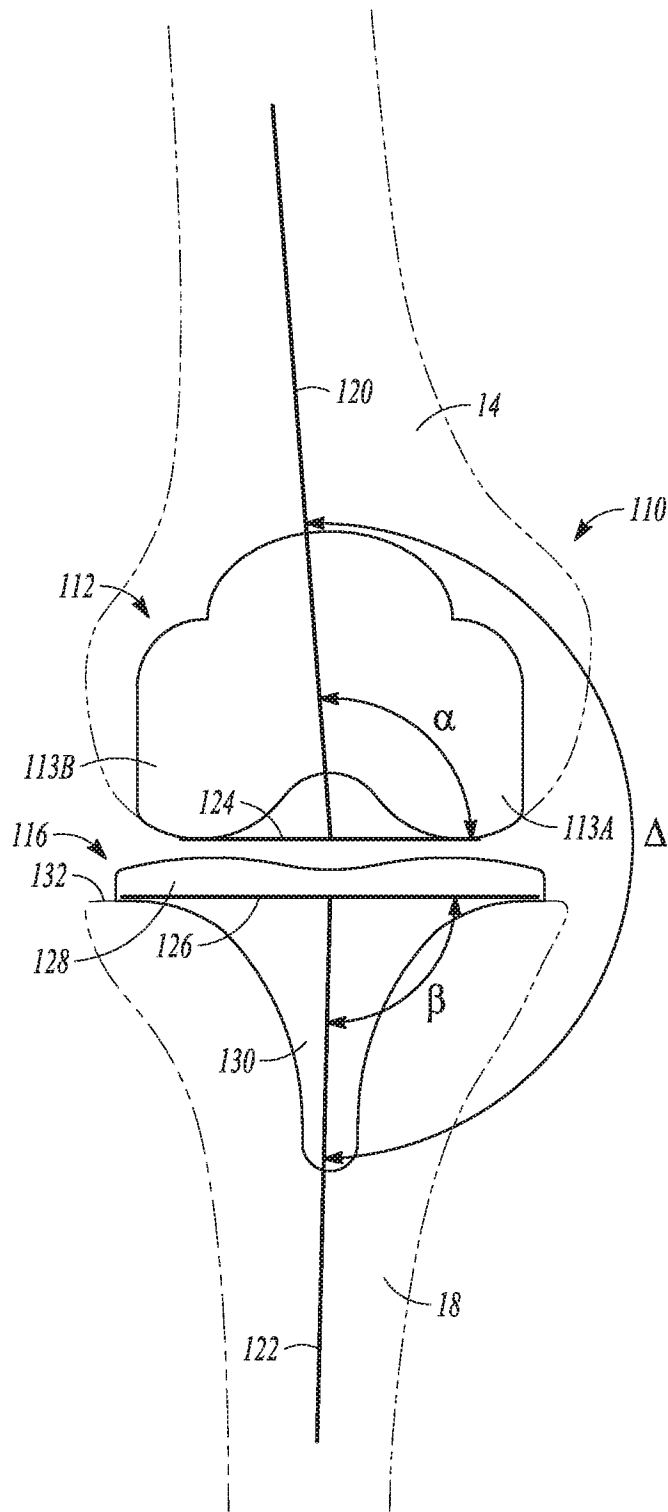


FIG. 2

3/8

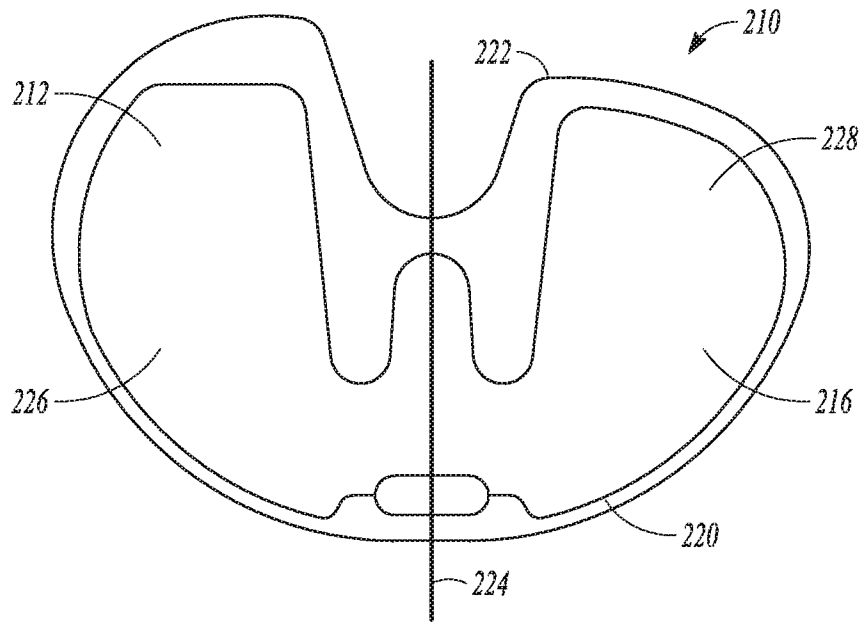


FIG. 3A

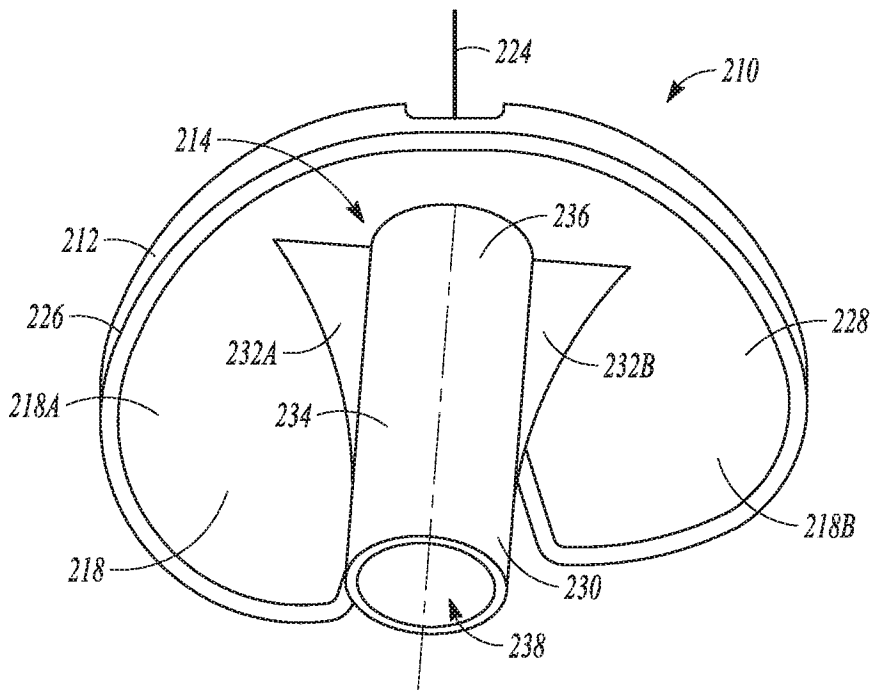


FIG. 3B

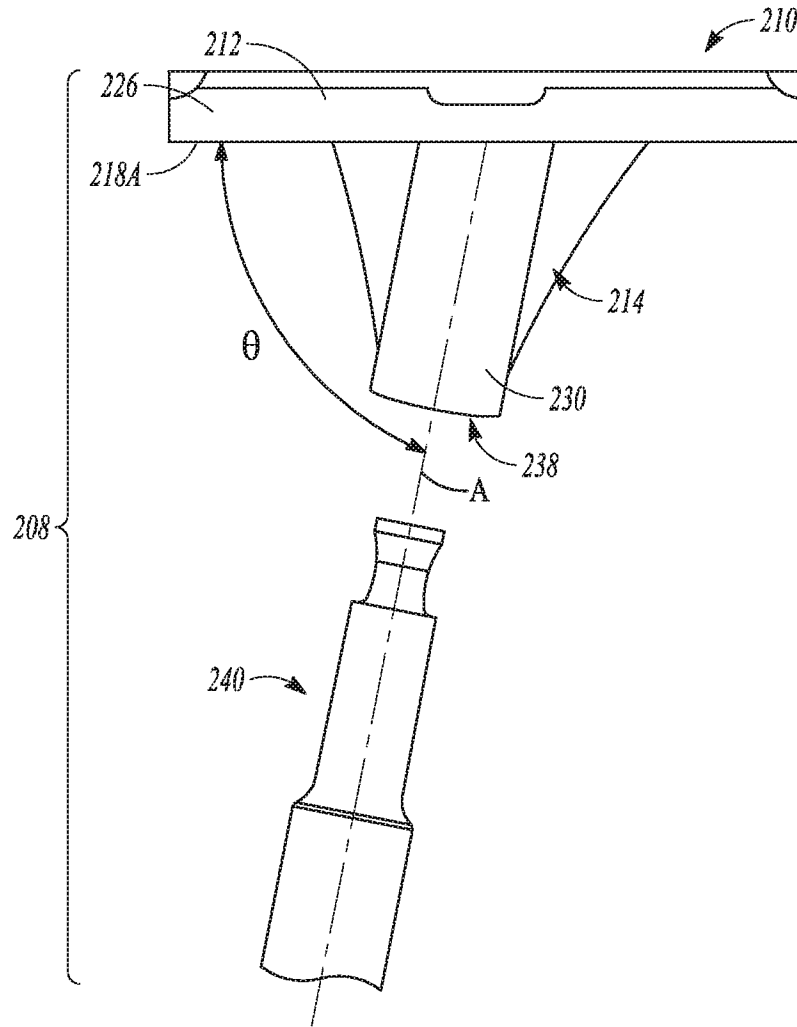


FIG. 4

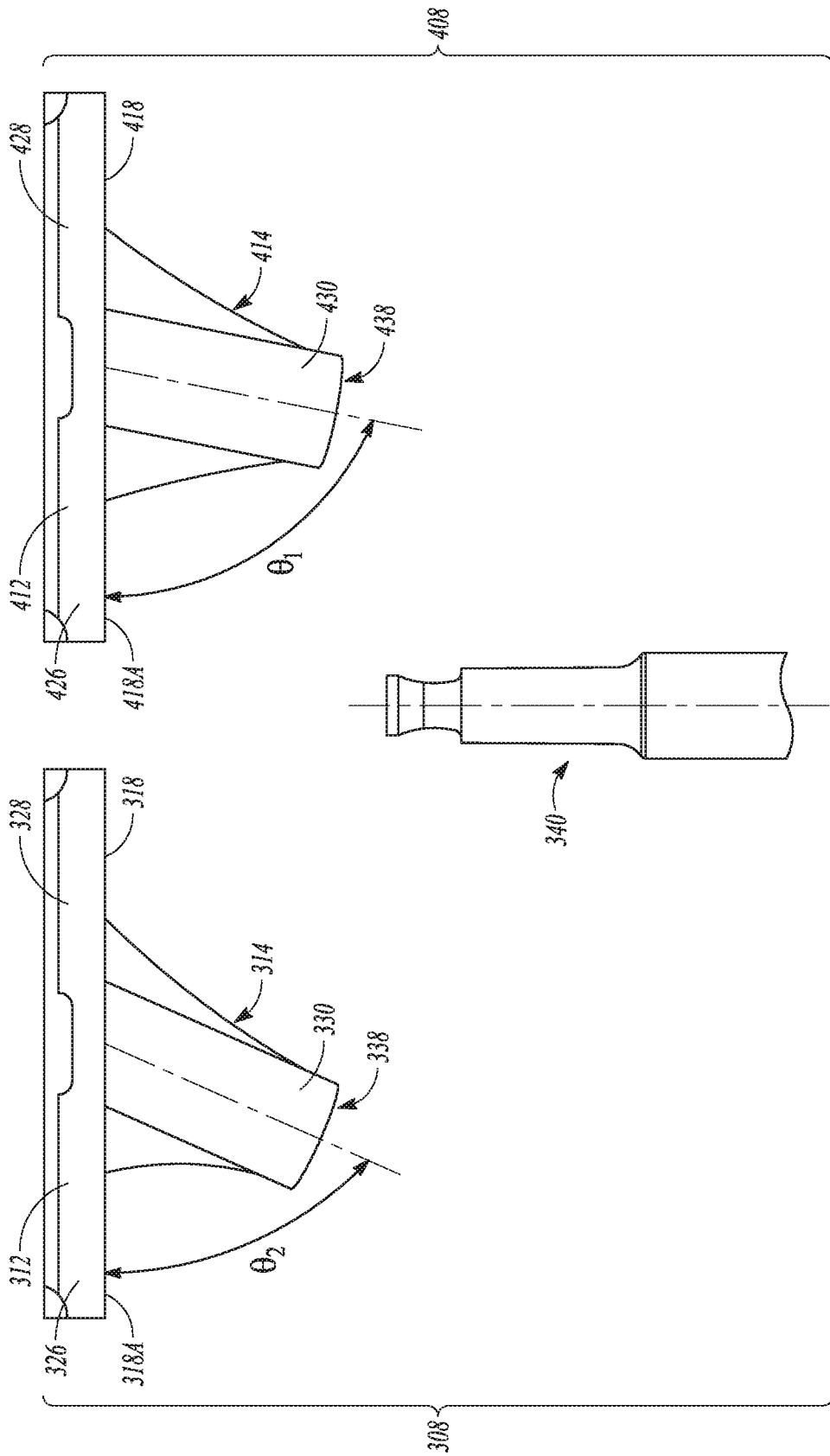


FIG. 5

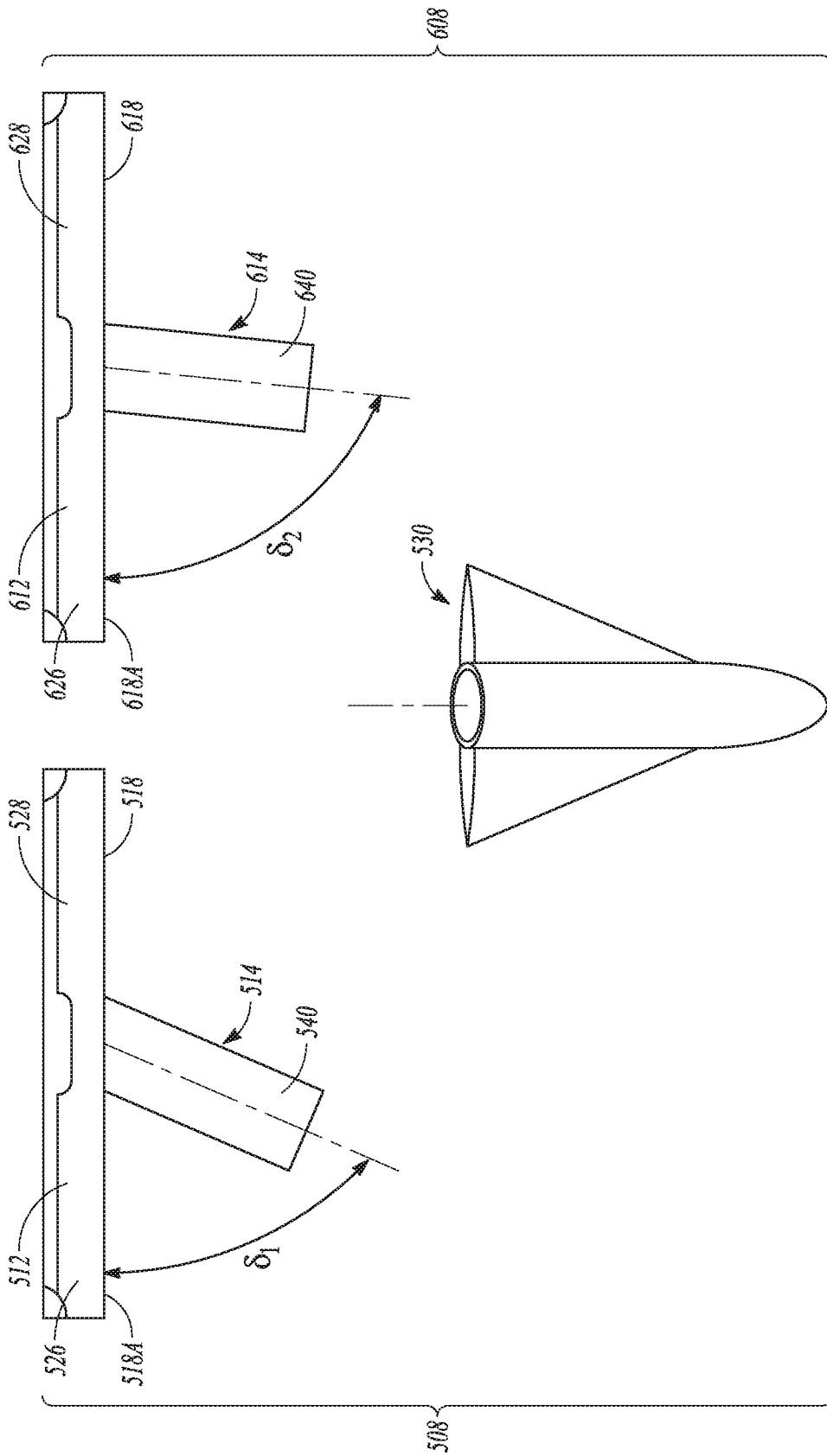


FIG. 6

7/8

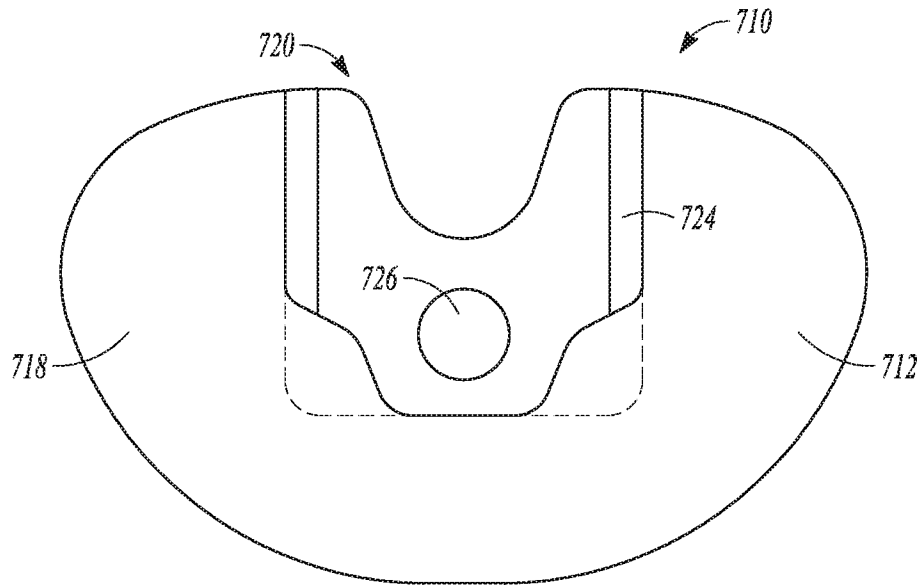


FIG. 7A

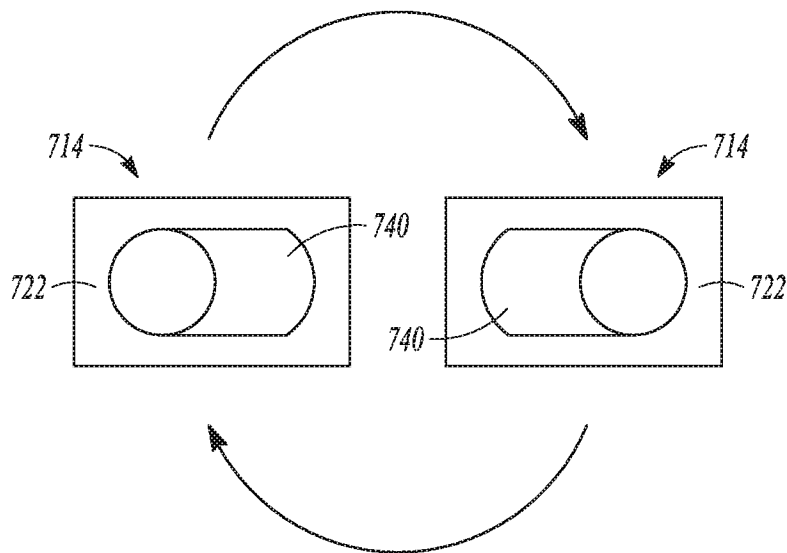


FIG. 7B



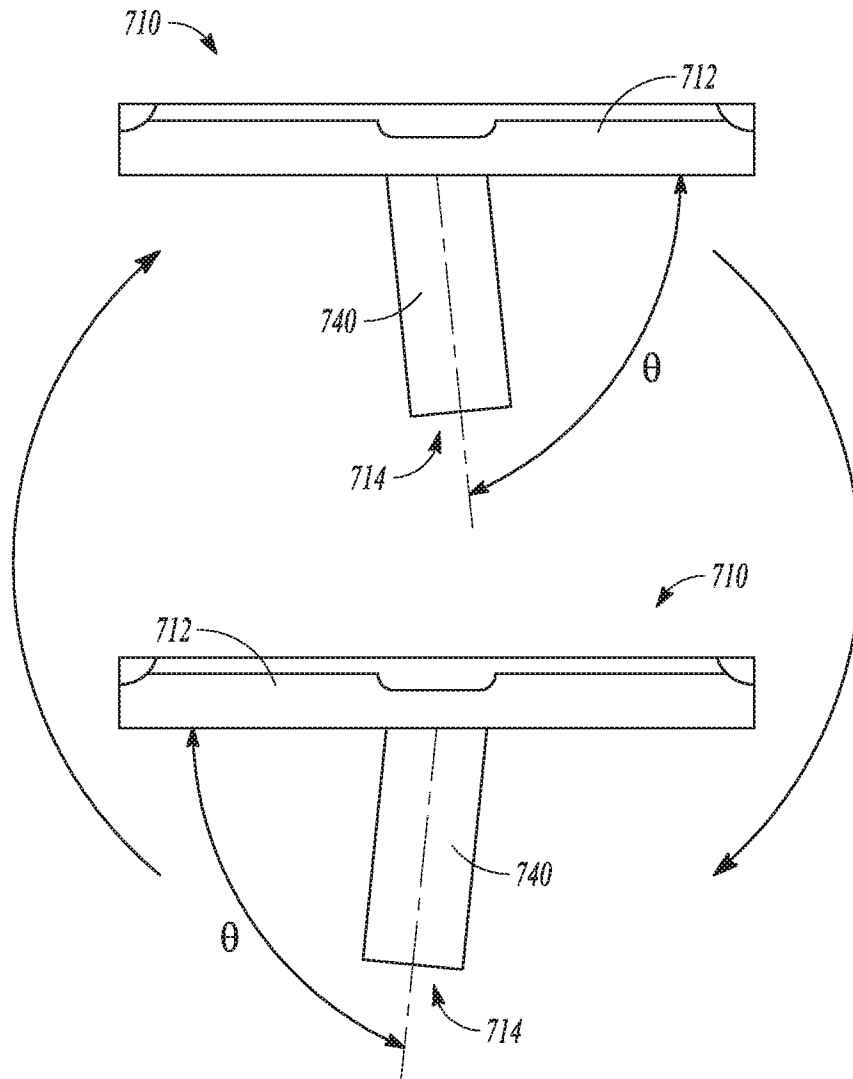


FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2016/052173

A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61F2/38  
ADD.  
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED  
Minimum documentation searched (classification system followed by classification symbols)  
A61F  
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2007/053905 A1 (PORTLAND ORTHOPAEDICS LTD [AU]; SEKEL RONALD [AU]) 18 May 2007 (2007-05-18) page 18, line 9 - page 19, line 34; figure 2 -----	1-13, 18-21
X	US 2013/218284 A1 (EICKMANN THOMAS [US] ET AL) 22 August 2013 (2013-08-22) paragraph [0064] - paragraph [0068] -----	1-13, 18-21
X	US 2011/029091 A1 (BOJARSKI RAYMOND A [US] ET AL) 3 February 2011 (2011-02-03) figures 21A-21C -----	1,2
X	FR 3 008 605 A1 (MEDACTA INT SA [CH]) 23 January 2015 (2015-01-23) -----	1-3, 5-12, 18-21
A	page 2, line 23 - page 3, line 36 ----- -/--	4,13

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  18 November 2016	Date of mailing of the international search report  10/01/2017
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Mingrino, Alessandra

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2016/052173

## 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.: 14-17  
because they relate to subject matter not required to be searched by this Authority, namely:  
The subject-matter of claims 14-17 is directed to a method of performing a knee arthroplasty, which is a method for treatment of the human body by surgery. Pursuant to Article 17(2)(a)(i)PCT and Rule 39.1(iv) PCT, the subject-matter of claims 14-17 will not be searched.
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/US2016/052173

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>Anonymous: "Natural-Knee® Modular Cemented Baseplate", Zimmer 2004, XP002764385, Retrieved from the Internet: URL:<a href="http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/medical-professionals/knee/natural-knee-modular-cemented-baseplate-brochure.pdf">http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/medical-professionals/knee/natural-knee-modular-cemented-baseplate-brochure.pdf</a> [retrieved on 2016-11-16] figure 4 -----</p>	1-13, 18-21

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2016/052173

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007053905	A1	18-05-2007	
		AU 2006313010 A1	18-05-2007
		EP 1991172 A1	19-11-2008
		JP 2009515610 A	16-04-2009
		US 2009149963 A1	11-06-2009
		WO 2007053905 A1	18-05-2007
-----			
US 2013218284	A1	22-08-2013	
		US 2013218284 A1	22-08-2013
		WO 2013123515 A1	22-08-2013
-----			
US 2011029091	A1	03-02-2011	
		US 2011029091 A1	03-02-2011
		US 2015032217 A1	29-01-2015
-----			
FR 3008605	A1	23-01-2015	NONE
-----			