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(54) **PATIENT-SPECIFIC FEMORAL GUIDE**

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(71) Applicant: **Biomet Manufacturing, LLC**, Warsaw, IN (US)

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(72) Inventors: **Jason D. Meridew**, Warsaw, IN (US);  
**Tony Siebeneck**, Mentone, IN (US);  
**Robert Metzger**, Wakarusa, IN (US)

(57) **ABSTRACT**

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A medical device for preparing an elongated bone, such as a proximal femoral bone, for receiving an implant includes a patient-specific femoral guide and an elongated alignment element. The femoral guide has a patient-specific three-dimensional bone-engaging surface configured according to a preoperative plan based on a three-dimensional image model of the femoral bone to mate complementarily with the surface of the proximal femoral bone extending between the greater trochanter, the femoral neck and the femoral shaft of the proximal femur. The femoral guide includes a first guide end forming a planar guide configured for guiding a neck resection. The alignment member can be removably attached to the femoral guide and defines a reference axis for guiding a cutting tool into the femoral bone through a resected surface of the femoral neck.

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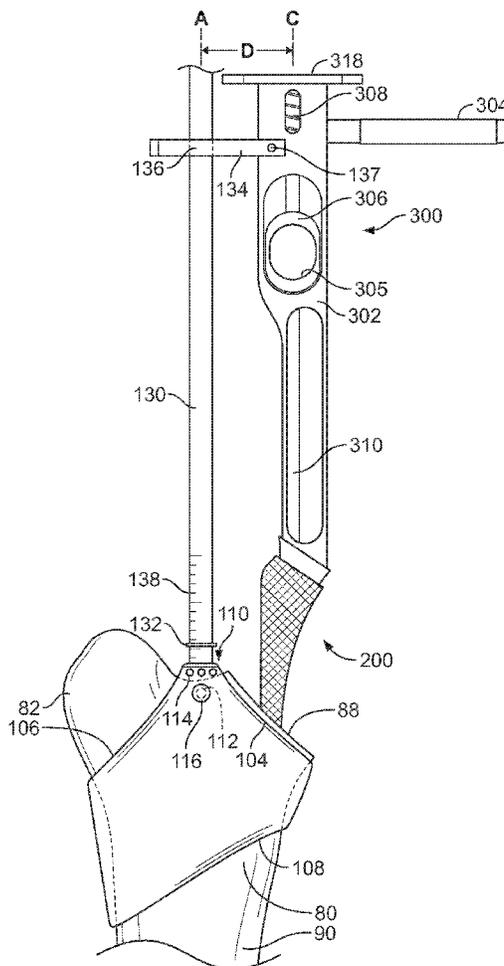
**Related U.S. Application Data**

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**Publication Classification**

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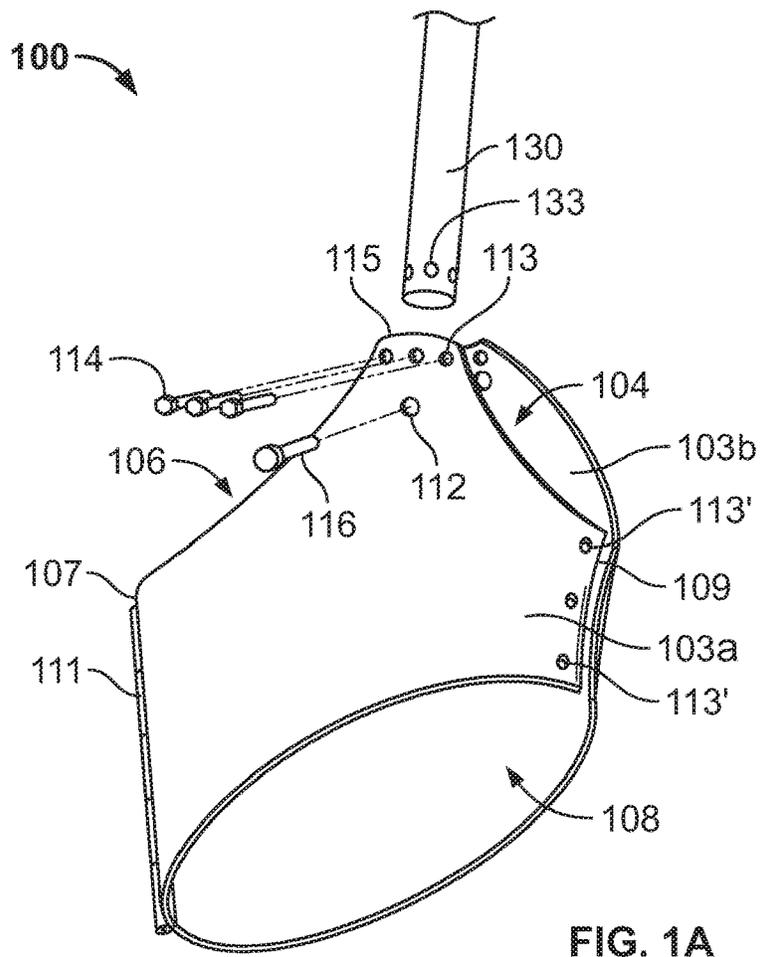


FIG. 1A

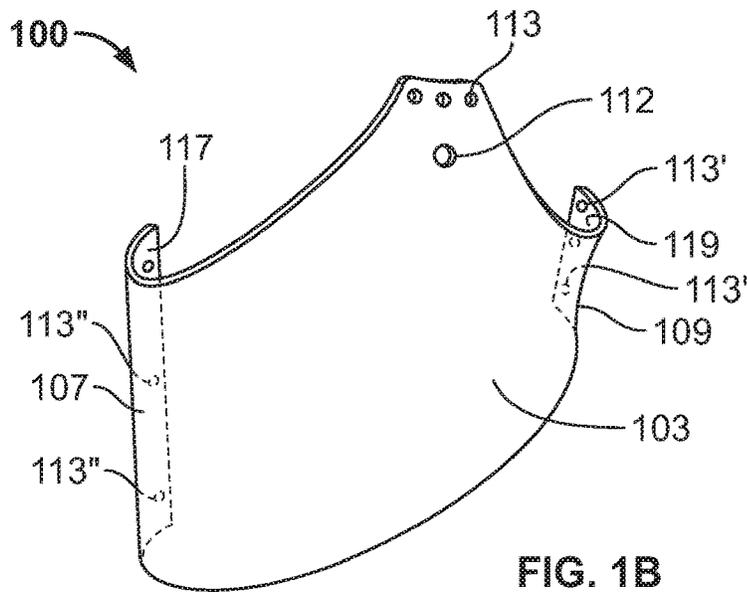


FIG. 1B



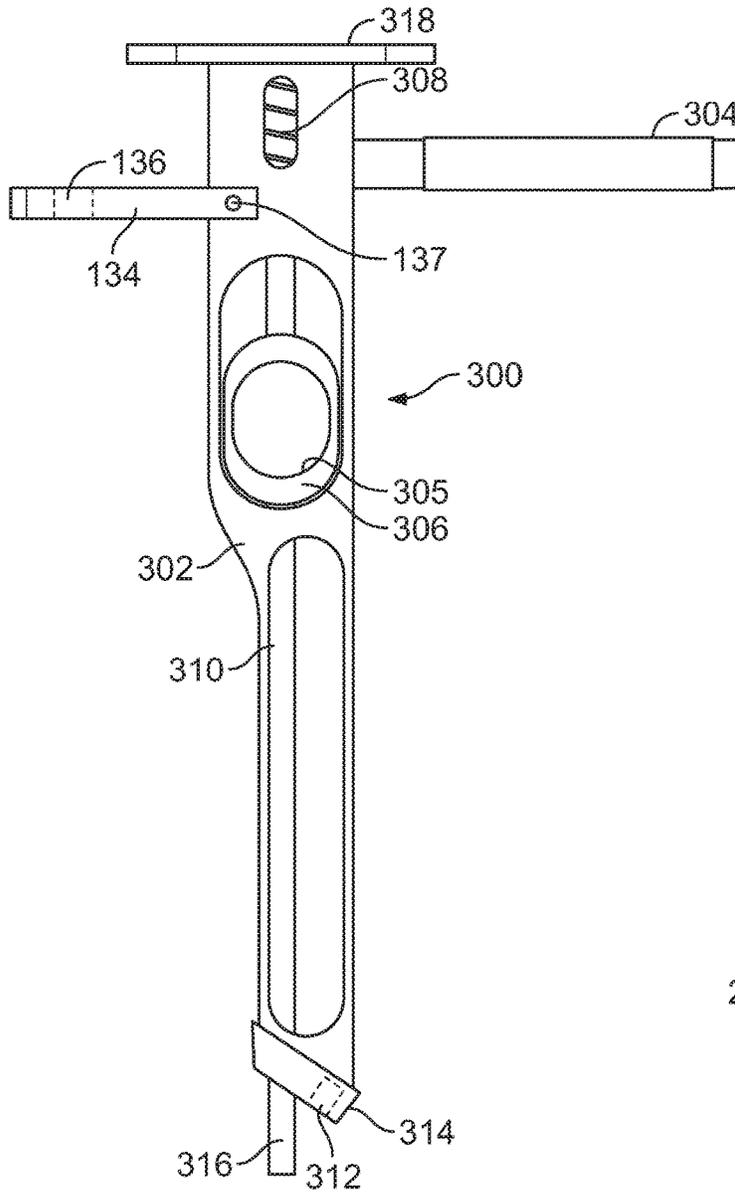


FIG. 3

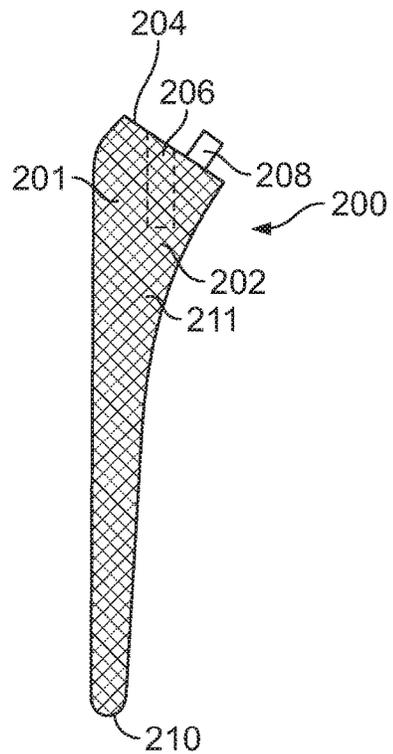


FIG. 4

## PATIENT-SPECIFIC FEMORAL GUIDE

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Application No. 61/446,660, filed on Feb. 25, 2011.

**[0002]** This application is a continuation-in-part of U.S. application Ser. No. 12/978,069 filed Dec. 23, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/973,214, filed Dec. 20, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/955,361 filed Nov. 29, 2010, which is a continuation-in-part of U.S. application Ser. Nos. 12/938,905 and 12/938,913, both filed Nov. 3, 2010, and which are continuation-in-part of U.S. application Ser. No. 12/893,306, filed Sep. 29, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/888,005, filed Sep. 22, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/714,023, filed Feb. 26, 2010, which is a continuation-in-part of U.S. application Ser. No. 12/571,969, filed Oct. 1, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/486,992, filed Jun. 18, 2009, and a continuation-in-part of U.S. application Ser. No. 12/389,901, filed Feb. 20, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/211,407, filed Sep. 16, 2008, which is a continuation-in-part of U.S. application Ser. No. 12/039,849, filed Feb. 29, 2008, which: (1) claims the benefit of U.S. Provisional Application No. 60/953,620, filed on Aug. 2, 2007, U.S. Provisional Application No. 60/947,813, filed on Jul. 3, 2007, U.S. Provisional Application No. 60/911,297, filed on Apr. 12, 2007, and U.S. Provisional Application No. 60/892,349, filed on Mar. 1, 2007; (2) is a continuation-in-part U.S. application Ser. No. 11/756,057, filed on May 31, 2007, which claims the benefit of U.S. Provisional Application No. 60/812,694, filed on Jun. 9, 2006; (3) is a continuation-in-part of U.S. application Ser. No. 11/971,390, filed on Jan. 9, 2008, which is a continuation-in-part of U.S. application Ser. No. 11/363,548, filed on Feb. 27, 2006, now U.S. Pat. No. 7,780,672 issued Aug. 24, 2010; and (4) is a continuation-in-part of U.S. application Ser. No. 12/025,414, filed on Feb. 4, 2008, which claims the benefit of U.S. Provisional Application No. 60/953,637, filed on Aug. 2, 2007.

**[0003]** This application is continuation-in-part of U.S. application Ser. No. 12/872,663, filed on Aug. 31, 2010, which claims the benefit of U.S. Provisional Application No. 61/310,752 filed on Mar. 5, 2010.

**[0004]** This application is a continuation-in-part of U.S. application Ser. No. 12/483,807, filed on Jun. 12, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/371,096, filed on Feb. 13, 2009, which is a continuation-in-part of U.S. application Ser. No. 12/103,824, filed on Apr. 16, 2008, which claims the benefit of U.S. Provisional Application No. 60/912,178, filed on Apr. 17, 2007.

**[0005]** This application is also a continuation-in-part of U.S. application Ser. No. 12/103,834, filed on Apr. 16, 2008, which claims the benefit of U.S. Provisional Application No. 60/912,178, filed on Apr. 17, 2007.

**[0006]** The disclosures of the above applications are incorporated herein by reference.

### INTRODUCTION

**[0007]** The present teachings provide a patient-specific alignment and resection guide and associated tools for guiding a resection of the femoral neck and aligning a

broach or other cutting instrument or tool along the proximal femur in preparation for a femoral implant.

### SUMMARY

**[0008]** The present teachings provide a medical device for preparing an elongated bone, such as a femoral bone, for receiving an implant. The medical device includes a patient-specific femoral guide and an elongated alignment element. The femoral guide has a patient-specific three-dimensional bone-engaging surface configured according to a preoperative plan based on a three-dimensional image model of a proximal femoral bone to mate complementarily with the surface of the proximal femoral bone extending between the greater trochanter, the femoral neck and the femoral shaft of the proximal femur. The femoral guide includes a first guide end forming a planar guide configured for guiding a neck resection. The alignment member can be removably attached to the femoral guide. The alignment member defines a reference axis for guiding a cutting tool into the femoral bone through a resected surface of the femoral neck.

**[0009]** In some embodiments, the medical device includes a cutting tool, such as a broach or reamer, for example, for preparing the proximal femoral bone after the neck resection, a driver tool for holding and driving the cutting tool into the femoral bone along a first axis, and a connector. The connector can be slidably coupled to the alignment member and to the driver tool. The connector has a patient-specific distance between the first axis and reference axis for guiding the cutting tool into the femoral bone through a resected surface of the femoral neck at a position determined during a preoperative plan based on the three-dimensional image model of the femoral bone.

**[0010]** The present teachings provide a method for preparing a proximal femoral bone for an implant. The method includes attaching a patient-specific femoral guide to the proximal femoral bone, guiding a cutting instrument along a planar cutting guide of the femoral guide, and cutting the femoral neck along a patient-specific plane using the cutting guide. The method also includes coupling a cutting tool to a driver tool, and slidably connecting the driver tool to an alignment member extending from the patient-specific guide along a reference axis such that the cutting tool is automatically positioned at a preselected distance from the reference axis and at a preselected location relative to the resected femoral neck. The method includes preparing the femoral bone for receiving an implant using the cutting tool.

**[0011]** 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

**[0012]** The present teachings will become more fully understood from the detailed description and the accompanying drawings, wherein:

**[0013]** FIG. 1 is an environmental view of a patient-specific femoral guide according to the present teachings;

**[0014]** FIG. 1A is a perspective view of an exemplary femoral guide according to the present teachings;

**[0015]** FIG. 1B is a perspective view of another exemplary femoral guide according to the present teachings;

**[0016]** FIG. 2 is an environmental view of the patient-specific femoral guide of FIG. 1 shown with a driver holder and a cutting tool;

**[0017]** FIG. 3 is a side view of the driver holder for the cutting tool of FIG. 2; and

**[0018]** FIG. 4 is a side view of the cutting tool of FIG. 2.

#### DESCRIPTION OF VARIOUS ASPECTS

**[0019]** The following description is merely exemplary in nature and is in no way intended to limit the present teachings, applications, or uses.

**[0020]** The present teachings provide a patient-specific alignment and resection guide and associated tools for guiding a resection of the femoral neck and aligning a broach or other cutting tool along the proximal femur in preparation for receipt of a femoral implant.

**[0021]** As described in commonly assigned U.S. application Ser. No. 11/756,057, filed on May 31, 2007, during a preoperative planning stage, imaging data of the relevant anatomy of a patient can be obtained at a medical facility or doctor's office. The imaging data can include, for example, a detailed scan of a pelvis, hip, knee, ankle or other joint or relevant portion of the patient's anatomy. The imaging data can be obtained using MRI, CT, X-Ray, ultrasound or any other imaging system. The imaging data obtained can be used to construct a three-dimensional computer image of the joint and prepare an initial pre-operative plan that can include bone or joint preparation, including planning for resections, milling, reaming, broaching, cutting, implant selection and fitting, design of patient-specific guides, templates, tools and alignment protocol for the surgical procedure.

**[0022]** Computer modeling for obtaining three-dimensional computer images of the relevant patient's anatomy can be provided by various CAD programs and/or software available from various vendors or developers, such as, for example, from Materialise USA, Ann Arbor, Mich. The computer modeling program can be used to plan a preoperative surgical plan, including planning various bone preparation procedures, selecting or designing/modifying implants and designing patient-specific guides and tools including patient-specific prosthesis components, and patient-specific tools, including reaming, broaching, milling, drilling or other cutting tools, alignment guides, templates and other patient-specific instruments.

**[0023]** The pre-operative plan can be stored in any computer storage medium, in a computer file form or any other computer or digital representation. The pre-operative plan, in a digital form associated with interactive software, can be made available via a hard medium, a web-based or mobile or cloud service, or a cellular portable device to the surgeon or other medical practitioner, for review. Using the interactive software, the surgeon can review the plan, and manipulate the position of images of various implant components relative to an image of the anatomy. The surgeon can modify the plan and send it to the manufacturer with recommendations or changes. The interactive review process can be repeated until a final, approved plan, is sent to a manufacturing facility for preparing the actual physical components.

**[0024]** After the surgical plan is approved by the surgeon, patient-specific implants and associated tools, including, for example, alignment guides, cutting/milling/reaming/broaching or other tools for the surgical preparation of the joint or other anatomy portion of the specific patient can be designed

using a CAD program or other three-dimensional modeling software, such as the software provided by Materialise, for example, according to the surgical plan. Patient-specific guides and other instruments can be manufactured by various stereolithography methods, selective laser sintering, fused deposition modeling or other rapid prototyping methods. In some embodiments, computer instructions of tool paths for machining the patient-specific guides and/or implants can be generated and stored in a tool path data file. The tool path data can be provided as input to a CNC mill or other automated machining system, and the tools and implants can be machined from polymer, ceramic, metal or other suitable material depending on the use, and sterilized. The sterilized tools and implants can be shipped to the surgeon or medical facility for use during the surgical procedure.

**[0025]** Patient-specific implants, guides, templates, tools or portions thereof are defined as those constructed by a surgical plan approved by the surgeon using three-dimensional images of the specific patient's anatomy. These patient-specific components have a three-dimensional engagement surface that is made to closely conform, contact and mate substantially as a negative mold of corresponding complementary portions of the patient's anatomy. The complementary anatomy can include bone surfaces with or without associated soft tissue, such as articular cartilage, for example, and inner surfaces of different bone density, such as cancellous and cortical bone.

**[0026]** Referring to FIGS. 1 and 2, an exemplary patient-specific femoral guide 100 for a proximal femur 80 is illustrated. The femoral guide 100 is designed to have a three-dimensional patient-specific bone engagement surface 102 designed during the pre-operative plan from the three-dimensional image of the specific patient's hip joint with or without associated cartilage or other soft tissue. The femoral guide 100 can be in the form of a thin curved shell 101 having a first guide end 104 or guide side 104 (in the form of a slot or an edge, as discussed below) forming a planar resection guide for resecting the femoral neck 84 at a location and orientation relative to first and second reference axes A and B along a resection plane R and creating a resected surface 88. The location and orientation of the resection plane R is determined in the pre-operative plan using the three-dimensional image of the patient's joint to conserve bone, remove abnormalities, conform to or correct anteversion angle or other orientation of the femoral neck.

**[0027]** Referring to FIGS. 1 and 1A, the shell 101 can be in the form of a two-piece clamshell with couplable anterior and posterior components 103a, 103b that can engage the anterior and posterior surfaces of the proximal femur 80 with corresponding patient-specific engagement surfaces 102 to nestingly and securedly engage the bone. The shell 101 can include a second end side 106 defining an opening for a greater trochanter 82 and a third end side 108 defining an opening for a femoral bone shaft 90. Similarly, the first guide end 104 can be in the form of an opening defining an annular resection plane or guide R. The edge of the first guide end 104 can be made thicker or reinforced or with an added flange for additional stability during resection. The shell 101 can be additionally secured to the proximal femur 80 with one or more bone screws or pins 116 passing through a hole 112. The anterior and posterior components 103a, 103b can be movably connected, for example, along a lateral side 107 with a hinge or other connector 111

permitting pivoting, clamping, snap-on or other connection. The anterior and posterior components **103a**, **103b** can be connected to one another or to the bone with fasteners or pins passing through holes **113'** along the opposite or medial side **109**, or with a snap-on or other connection to one another.

[0028] Alternatively, the shell **101** can include a single one-piece component **103**, which can be attached to only the anterior (or only the posterior) surface of the proximal femur **80** with bone fasteners or pins inserted through hole **112** and other corresponding holes, as discussed above. In the embodiment in which the shell **101** includes a single component **103**, as shown in FIG. 1B, the single component **103** can partially wrap around from the lateral and medial sides **107**, **107** toward the posterior (or anterior) surface of the proximal femur **80** along curved lateral and medial flanges **117** and **119**. In the single-component embodiment, the first guide end **104**, second end side **106** and third end side **108** can be in the form of edges or partial openings or slots, rather than openings with a closed periphery. Additional holes **113'** and **113''** can be used for fastening the alignment guide **100** to the lateral and medial sides **107**, **109**.

[0029] With the femoral guide **100** secured on the proximal femur **80**, a cutting blade or saw or other surgical instrument can be guided by the first guide end **104** to cut the femoral neck **84** along a resection plane R, thereby removing the femoral head **86** and exposing the resected surface **88** of the femoral neck **84**, as shown in FIGS. 1 and 2. After resection, the femoral guide **100** can be used to guide instruments for preparing the proximal femur **80** for a femoral implant, as discussed below. As discussed above, the resection plane R is selected during pre-operative planning to conserve healthy bone, adjust or conform to patient-specific anteversion or other angles and in conformance with the planned implants for the femoral joint. When the femoral guide **100** is attached to the femur intra-operatively, the resection plane R is automatically determined by the first guide end side **104**.

[0030] The femoral guide **100** can include an elongated alignment member **130**, such as a rod or bar, which can be attached to the shell **101** with bolts, screws, clamps or other fasteners **114** at a portion **115** of the shell **101** between the first and second end sides **104**, **106** of the shell **101** and through holes **133** of the alignment member **130**. The attachment position of the alignment member **130** at portion **115** is determined during the pre-operative plan and such that the alignment member **130** defines a reference axis A, when the shell **101** is attached to the proximal femur **80**. The reference axis A can coincide or be parallel to the intramedullary axis of the femoral shaft **90**, as shown in FIGS. 1 and 2 and can be used to reference the position for a cutting tool or broach **200** for preparing the proximal femur **80** to receive a femoral and intramedullary implant, as discussed below. In this regard, the alignment member **130** can include a scale **138** for showing the advance or position and insertion level of the broach **200** relative to the bone, and a stop element **132** indicating when a full seated position of the broach **200** is reached and broaching is completed. The alignment member **130** can be either permanently or removably attached to the femoral guide **100**, such that the alignment member **130** can be optionally attached to the femoral guide **100** after the femoral head **86** is resected using the femoral guide **100**. The alignment member can have a round cross-

section, or alternatively, a rectangular or otherwise keyed cross-section, as discussed below.

[0031] Referring to FIG. 2, a driver tool **300** for holding a broach or reamer or other cutting tool **200** can be slidably coupled to the alignment member **130** using a connector **134**. The connector **134** is designed during the pre-operative plan to locate the driver tool **300** and the broach **200** at a preselected distance and orientation relative to the reference axis A, such that the broach **200** can automatically engage the resected surface **88** of the femoral neck **84** at a location and orientation determined during the pre-operative plan. For example, when the connector **134** is coupled between the alignment member **130** and the driver tool **300**, a distance D between the reference axis A and a longitudinal axis C of the driver tool **300** equals a value determined during the pre-operative plan for positioning the broach **200** in a pre-planned position and orientation for preparing the proximal femur **80** to receive an implant. When the connector **134** reaches the stop **132**, the sliding motion of the connector **134**, the driver tool **300** and the broach **200** is arrested and depth is limited to the desired depth to accommodate a pre-determined positioning of an implant according to the pre-operative plan. The alignment member **130** can be rotationally keyed to the connector **134** to allow motion only along the reference axis A, i.e., to prevent or reduce any rotational instabilities during use. For rotational stability, other than circular cross-sections for the alignment member **130** can be used, such as, oval, triangular or polygonal, for example.

[0032] The connector **134** can be an elongated element, such as a bar, having an opening **136** for receiving the alignment member **130** therethrough. The connector **134** can be coupled to the driver tool **300** with a clamp, bolt, screw, snap fit, forked end connector or other coupling device **137**.

[0033] Referring to FIG. 4, the broach **200** can include have a body **201** with an outer peripheral three-dimensional cutting surface **202** extending from a proximal end surface **204** to a distal end surface **210** of the body **201**. The cutting surface **202** is provided with cutting teeth and channels or grooves **211** for moving bone chips away from the cavity created by the broach **200**.

[0034] Referring to FIGS. 2-4, the broach **200** can be coupled to the driver tool **300** by providing a coupling interface between the proximal end surface **204** of the broach and a distal surface **314** of the driver tool **300**. The coupling interface can include, for example, a finger or rod or other protrusion **208** extending from the proximal end surface **204** of the broach **200** to be received in a corresponding bore or other opening **312** defined through the distal surface **314** of the driver tool **300**. The coupling interface can also include an opening or bore **206** defined through the proximal end surface **204** of the broach **200** for receiving a distal portion **316** of a retractable bar or rod **310** of the driver tool **300**. The driver tool **300** can include a body **302**, a handle bar **304**, and a proximal flange **318** for impaction. The retractable rod **310** can extend along the body **302** and is biased by a proximal spring **308**. The retractable rod **310** can be deployed for engaging the broach **200** by using a trigger **306** which can be operated by holding with one hand the handle bar **304** and squeezing the trigger opening **305** with an index finger and move the broach **200** from a first to a second position along the axis C. The broach **200** can be held securely with the driver tool **300**, as shown in FIG. 2 and inserted through the resected surface **88** the

femoral neck **84** to prepare the femoral bone **80** for receiving a femoral implant. The depth of insertion of the broach **200** can be monitored by the scale **138** and the broach **200** can be removed after the connector **134** reaches the stop **132**. In some embodiments, the broach **200** can be patient-specific and designed during the pre-operative plan to conform to an inner boundary surface of the femur, which is imaged and selected during the pre-operative plan.

**[0035]** The patient-specific femoral guide **100** can be manufactured from biocompatible materials using machining, rapid manufacturing by stereolithography, laser welding, or computer-assisted manufacturing using numerical machining or robotic controllers.

**[0036]** 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 present teachings 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.

**1.-20.** (canceled)

**21.** A guide for preparing a proximal portion of an elongated bone for receiving an implant comprising:

a body having a patient-specific three-dimensional bone-engaging surface configured according to a preoperative plan based on a three-dimensional image model of the proximal portion of the elongated bone to mate complementarily with a surface thereof;

a resection surface formed by an edge of the body and positioned thereby, wherein the resection surface is configured for guiding a resection of a neck of the elongated bone; and

one or more holes defined by the body and configured to receive one or more pins that mount the guide to the proximal portion of the elongated bone in a patient-specific position such that the patient-specific three-dimensional bone-engaging surface of the body mates complimentary with the surface of the proximal portion of the elongated bone.

**22.** The guide of claim **21**, wherein the body is configured to extend around less than an entirety of the proximal portion of the elongated bone such that the body is configured to engage with one of an anterior of the surface or a posterior of the surface of the proximal portion of the elongated bone.

**23.** The guide of claim **22**, wherein at least one of the one or more holes are positioned adjacent a medial edge of the body.

**24.** The guide of claim **22**, wherein the body is formed as a single one-piece component.

**25.** The guide of claim **22**, wherein the body is configured to partially wrap a lateral side and a medial side of the proximal portion of the elongated bone.

**26.** The guide of claim **25**, wherein the body has a curved medial flange and a curved lateral flange configured to partially wrap the medial side and the lateral side, respectively.

**27.** The guide of claim **21**, wherein the body is configured for viewing of at least a part of the proximal portion of the elongated bone.

**28.** The guide of claim **21**, wherein the elongated bone comprises a femur, and wherein the body is configured to extending between a greater trochanter, a femoral neck and a femoral shaft of the femoral bone.

**29.** The guide of claim **21**, wherein the elongated bone comprises a femur, and wherein the resection surface is configured to guide the resection of a femoral neck along a resection plane, thereby removing a femoral head and exposing a resected surface of the femoral neck, wherein the resection plane is selected during pre-operative planning to conserve healthy bone, adjust or conform to patient-specific anteversion or other angles and in conformance with the planned implant for the femoral joint.

**30.** A method for preparing a proximal femoral bone for an implant comprising:

attaching a femoral guide to the proximal femoral bone, wherein the femoral guide has a body with a patient-specific three-dimensional bone-engaging surface configured according to a preoperative plan based on a three-dimensional image model of the proximal femoral bone to mate complementarily with a surface thereof; and

guiding a cutting instrument along a resection surface of the femoral guide to cut a femoral neck of the proximal femoral bone along a patient-specific plane, wherein the resection surface is formed by an edge of the femoral guide.

**31.** The method of claim **30**, wherein attaching the femoral guide includes positioning the body to extend around less than an entirety of the proximal femoral bone such that the body is configured to engage with one of an anterior of the surface or a posterior of the surface of the proximal portion of the elongated bone.

**32.** The method of claim **31**, wherein the body is configured to partially wrap a lateral side and a medial side of the proximal femoral bone.

**33.** The method of claim **32**, wherein the body has a curved medial flange and a curved lateral flange configured to partially wrap the medial side and the lateral side, respectively.

**34.** A guide for preparing a proximal femoral bone for receiving an implant comprising:

a body having a patient-specific three-dimensional bone-engaging surface configured according to a preoperative plan based on a three-dimensional image model of the proximal femoral bone to mate complementarily with a surface thereof, wherein the body is configured to extend around less than an entirety of the proximal femoral bone such that the body is configured to engage with one of an anterior of the surface or a posterior of the surface of the proximal femoral bone;

one or more holes defined by the body and configured to receive one or more pins that mount the guide to the proximal femoral bone in a patient-specific position such that the patient-specific three-dimensional bone-engaging surface of the body mates complimentary with the surface of the proximal femoral bone;

a resection surface formed by an edged of the body and positioned thereby, wherein the resection surface is configured for guiding a resection of a neck of the proximal femoral bone along a resection plane, thereby removing a femoral head and exposing a resected surface of the femoral neck, and wherein the resection plane is selected during pre-operative planning to conserve healthy bone, adjust or conform to patient-specific anteversion or other angles and in conformance with the planned implant for the femoral joint.

**35.** The guide of claim **34**, wherein at least one of the one or more holes are positioned adjacent a medial edge of the body.

**36.** The guide of claim **34**, wherein the body is formed as a single one-piece component.

**37.** The guide of claim **34**, wherein the body is configured to partially wrap a lateral side and a medial side of the proximal femoral bone.

**38.** The guide of claim **37**, wherein the body has a curved medial flange and a curved lateral flange configured to partially wrap the medial side and the lateral side, respectively.

**39.** The guide of claim **34**, wherein the body is configured for viewing of at least a part of the proximal femoral bone.

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