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(54) **PATIENT-MODIFIED IMPLANT**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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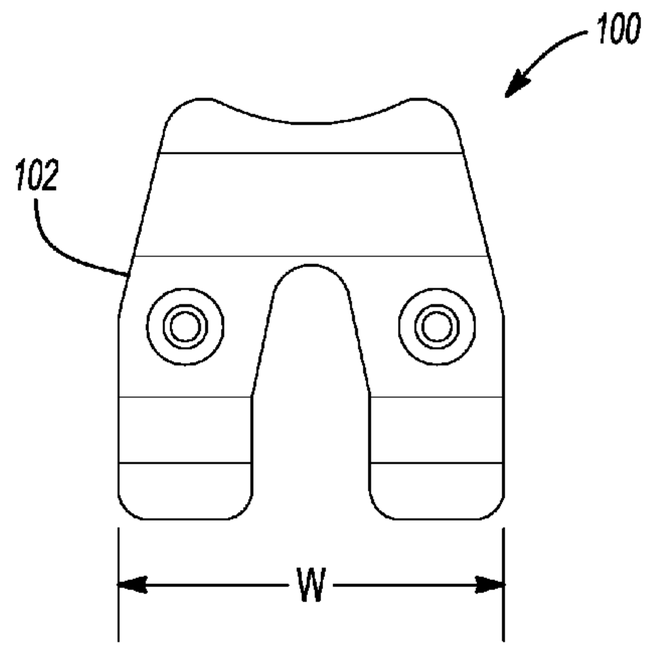
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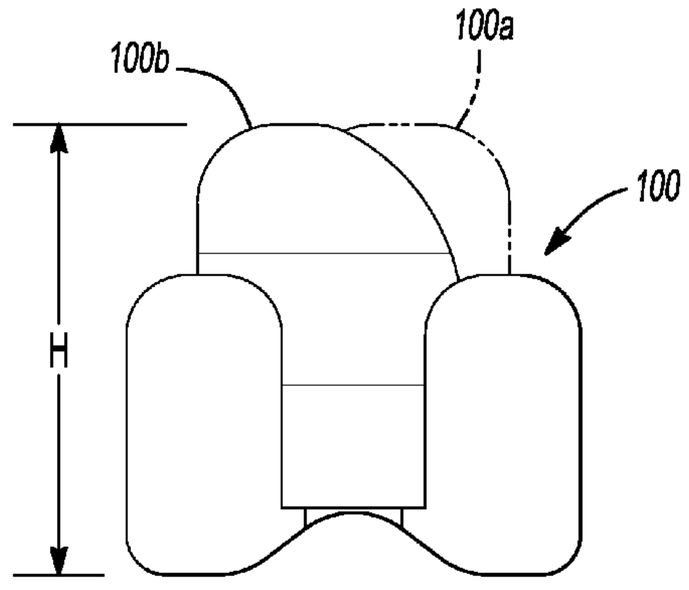
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(57) **ABSTRACT**

An orthopedic implant includes a first portion including at least one feature modified to be patient-specific and match the anatomy of a specific patient from a three-dimensional digital image of a patient's joint using computer modeling. The orthopedic implant includes a non-custom inner bone-engaging surface including a plurality of planar surfaces configured for engagement with non-custom bone cuts.

16 Claims, 4 Drawing Sheets





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continuation of application No. 13/081,618, filed on Apr. 7, 2011, now Pat. No. 8,486,150, which is a division of application No. 12/103,834, filed on Apr. 16, 2008, now Pat. No. 7,967,868.

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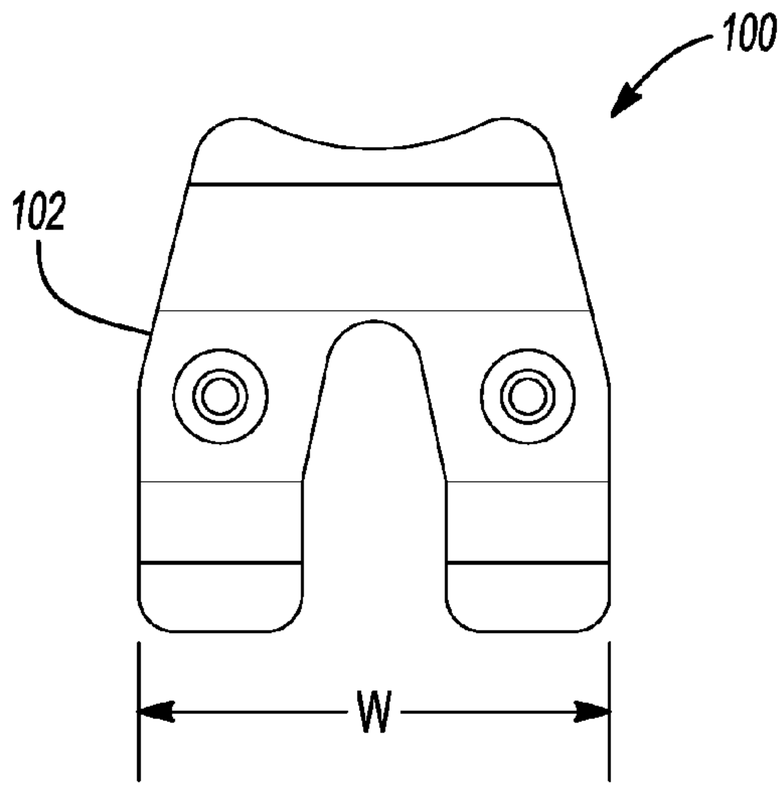


Fig-1

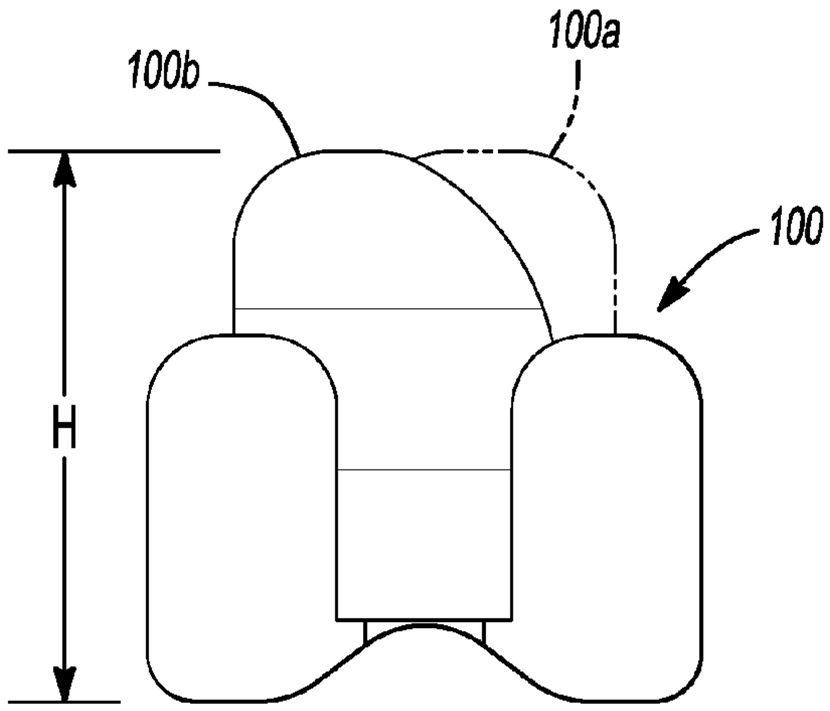


Fig-2

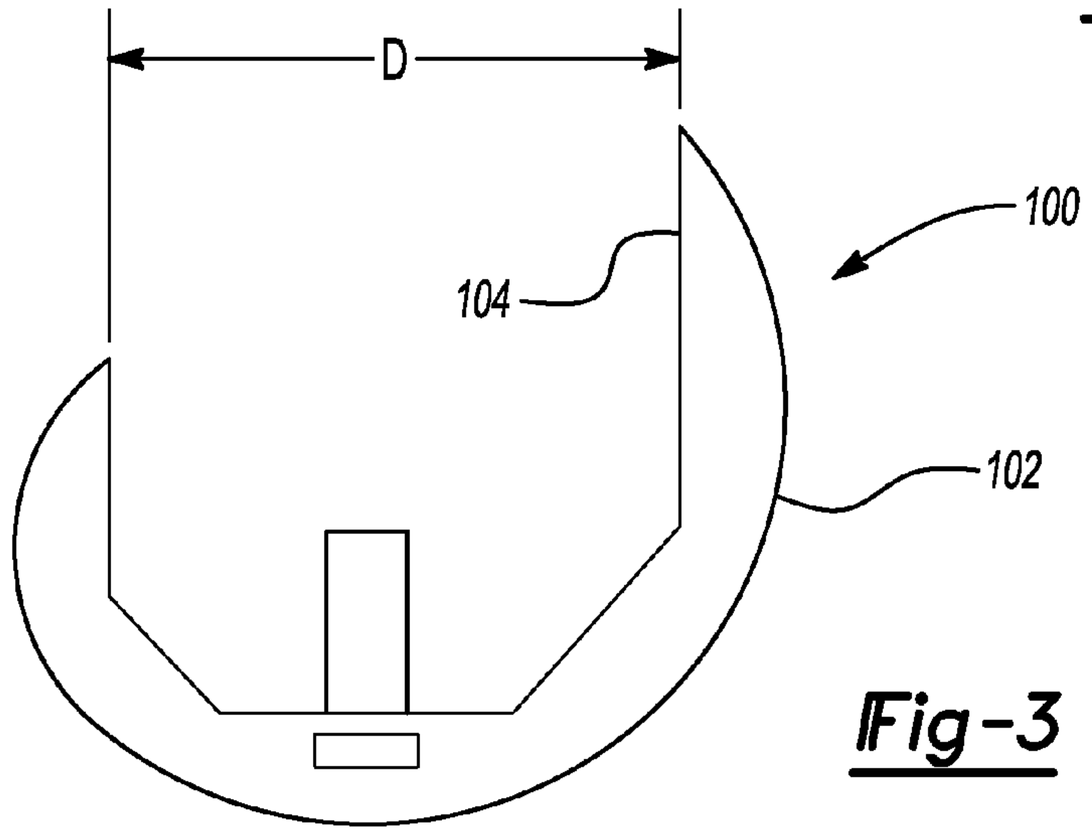


Fig-3

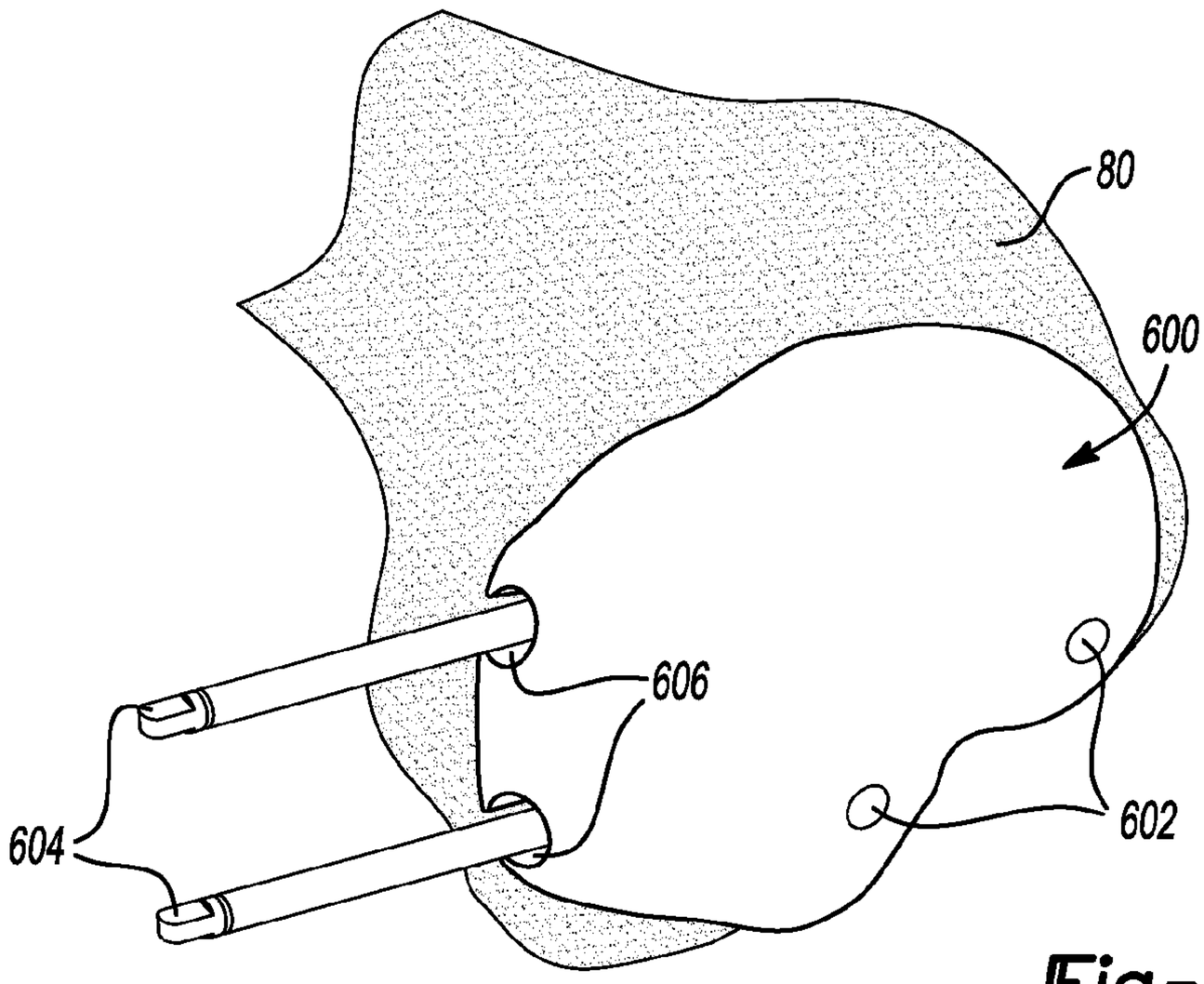


Fig-4

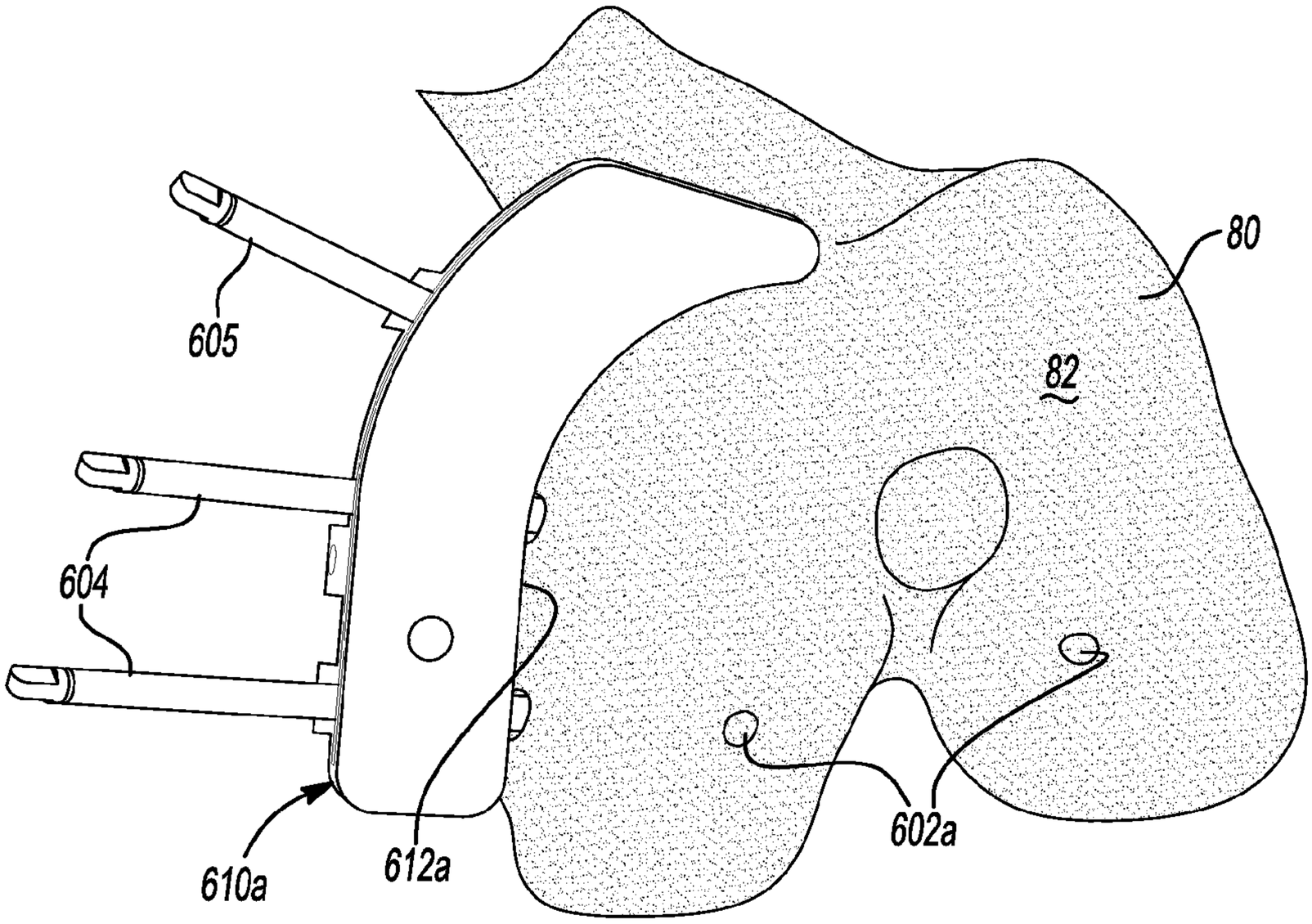


Fig-5

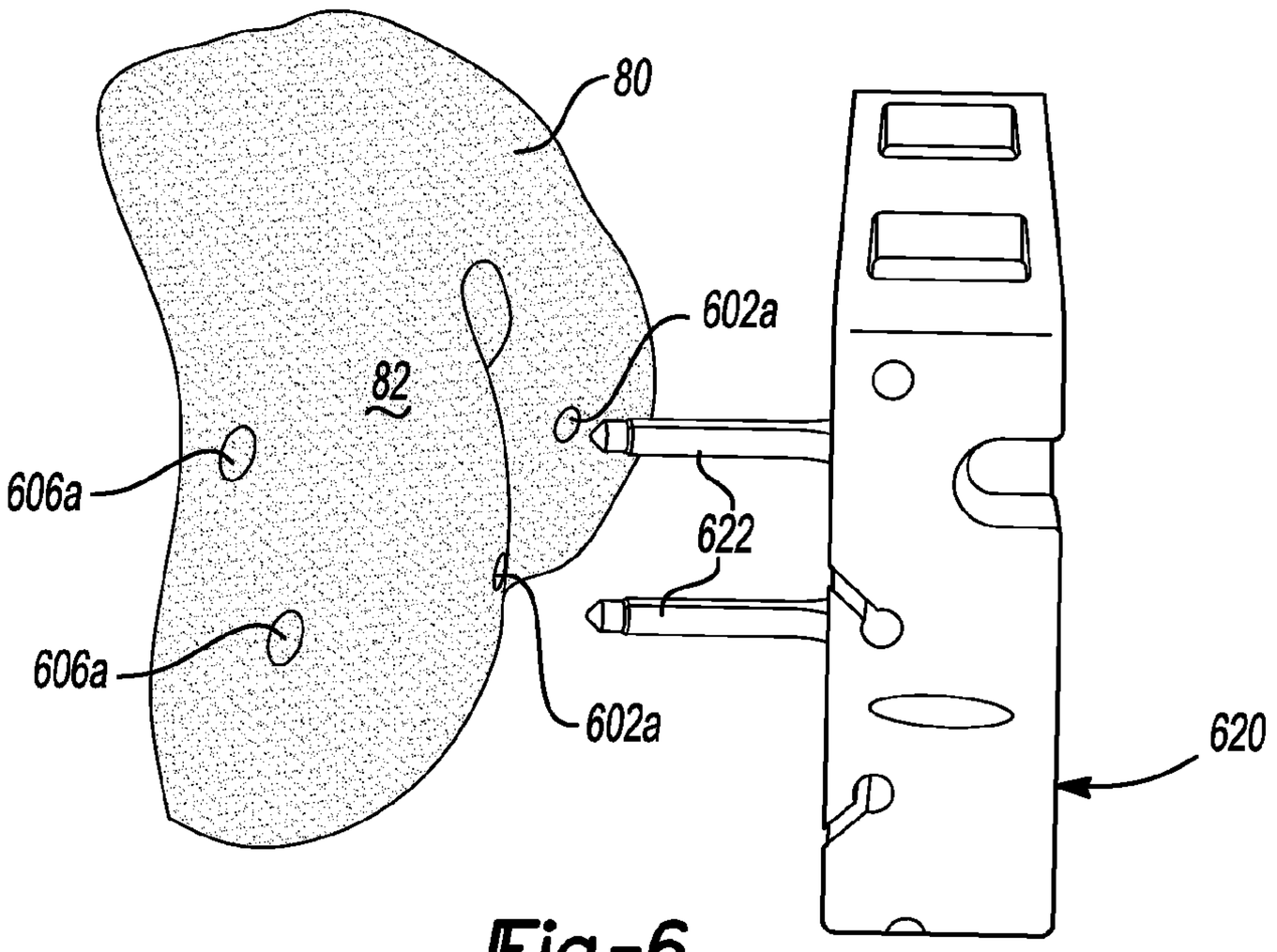

80
602a
82
606a
622
606a
602a
620

Fig-6

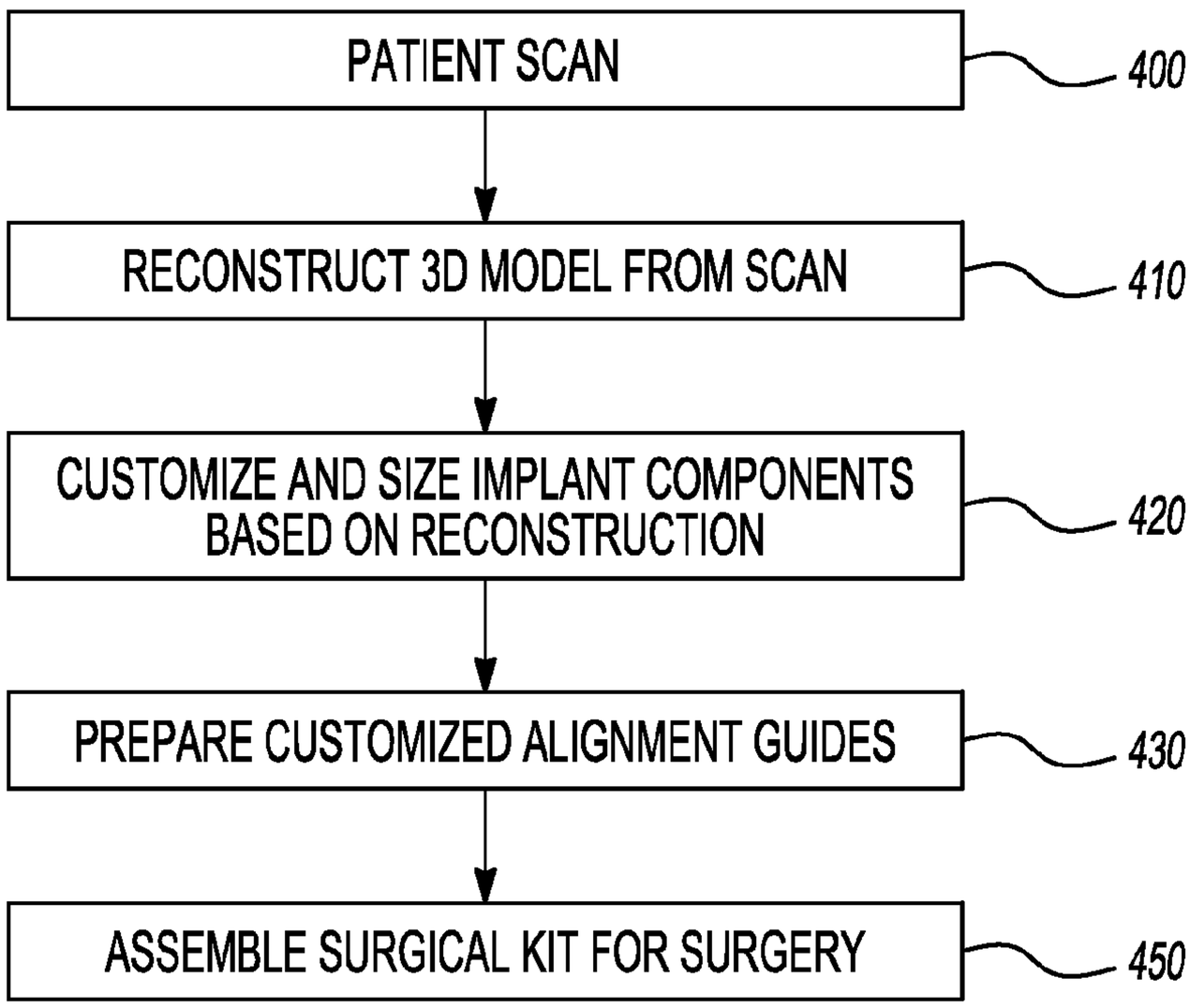

PATIENT SCAN
400
RECONSTRUCT 3D MODEL FROM SCAN
410
CUSTOMIZE AND SIZE IMPLANT COMPONENTS BASED ON RECONSTRUCTION
420
PREPARE CUSTOMIZED ALIGNMENT GUIDES
430
ASSEMBLE SURGICAL KIT FOR SURGERY
450

Fig-7

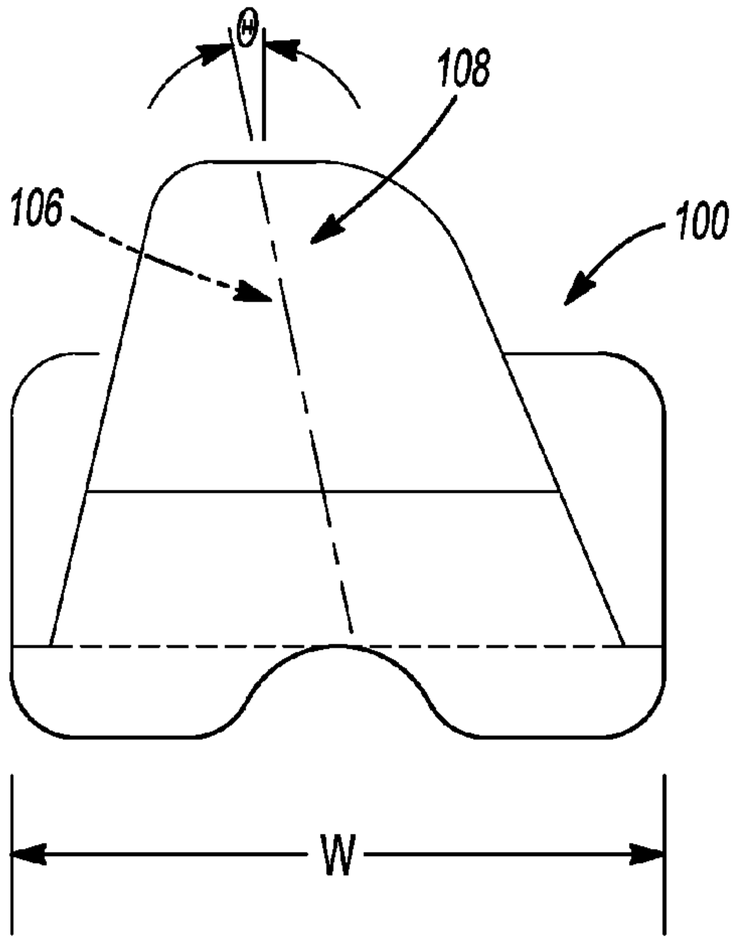


Fig-8

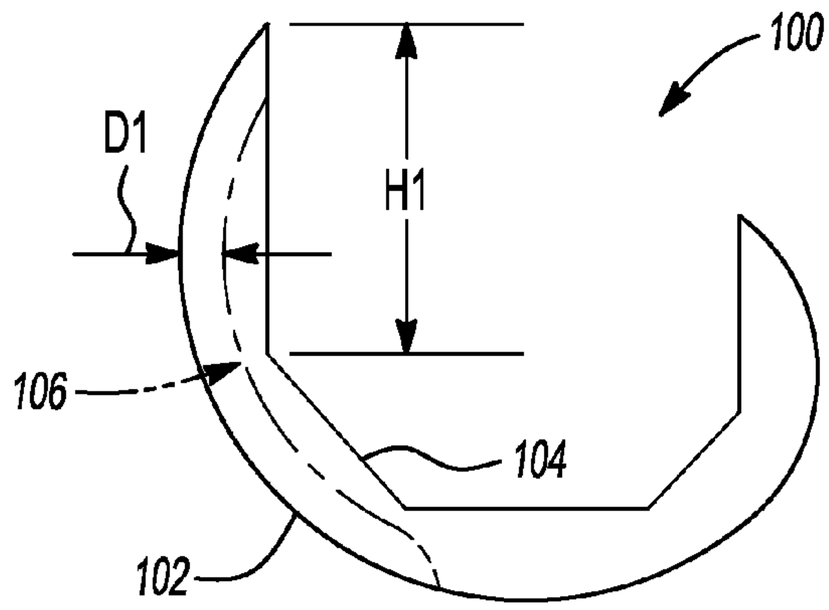


Fig-9

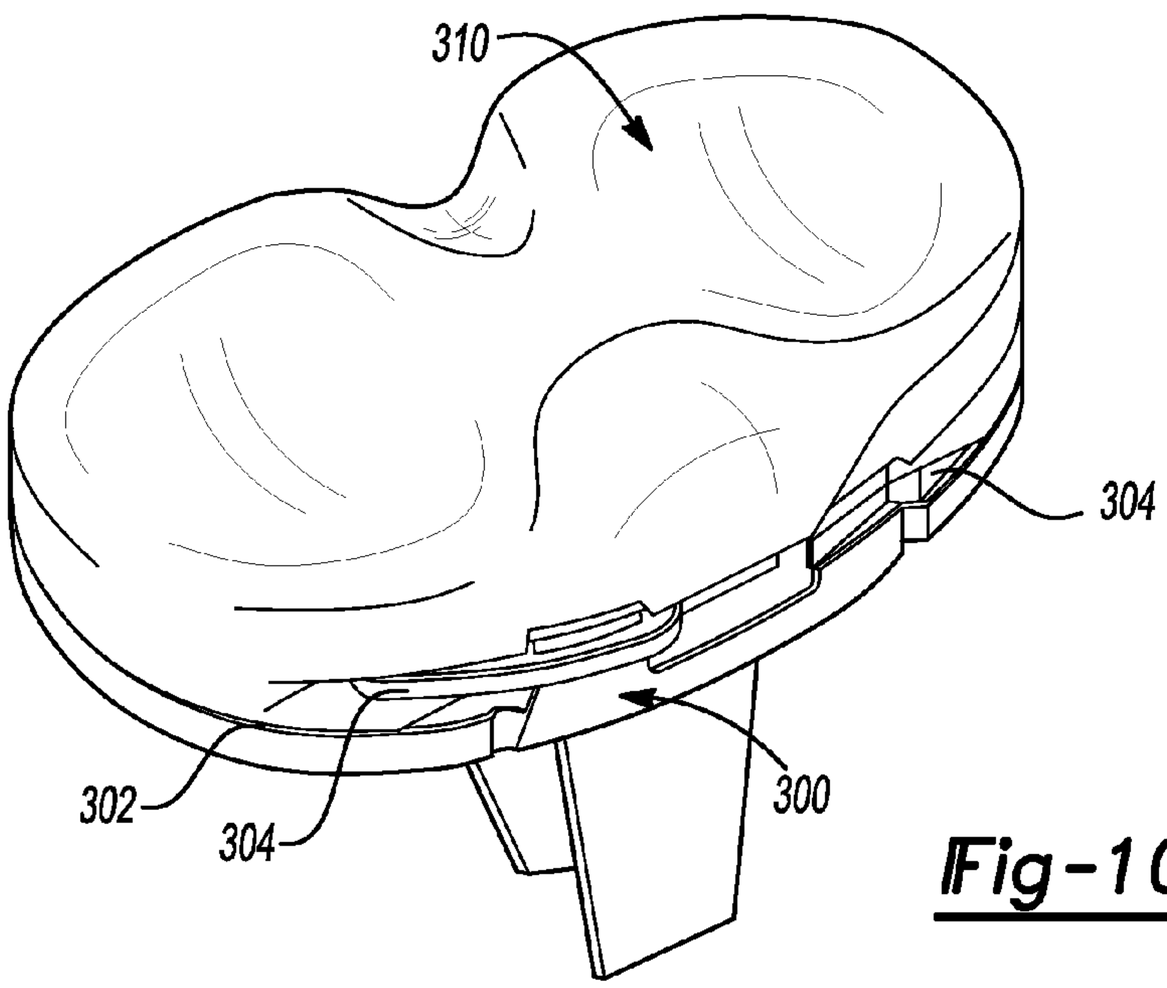


Fig-10

PATIENT-MODIFIED IMPLANT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/923,827 filed on Jun. 21, 2013, which is a continuation of U.S. application Ser. No. 13/081,618 filed on Apr. 7, 2011, now U.S. Pat. No. 8,486,150 issued on Jul. 16, 2013, which is a divisional of U.S. application Ser. No. 12/103,834 filed on Apr. 16, 2008, now U.S. Pat. No. 7,967,868 issued Jun. 28, 2011, which claims the benefit of U.S. Provisional Application No. 60/912,178 filed on Apr. 17, 2007.

This application is related to U.S. application Ser. No. 11/756,057 filed on May 31, 2007, now U.S. Pat. No. 8,092,465 issued Jan. 10, 2012, which claims the benefit of U.S. Provisional Application No. 60/812,694 filed on Jun. 9, 2006.

The disclosures of the above applications are incorporated herein by reference.

INTRODUCTION

Various custom made, patient-specific orthopedic implants and associated templates and guides are known in the art. Such implants and guides can be developed using commercially available software. Custom guides are used to accurately place pins, guide bone cuts, and insert implants during orthopedic procedures. The guides are made from a pre-operative plan formed from an MRI or CT scan of the patient and rely on matching an anatomic feature for correct positioning.

The present teachings provide semi-custom implants that can reduce inventory and allow more accurate placement and additional flexibility in addressing diverse patient-specific requirements.

SUMMARY

The present teachings provide an orthopedic implant. The implant has a first portion including at least one patient-adjustable feature, and a second portion including at least one standard feature.

The present teachings also provide an orthopedic implant manufacturing method. The method includes preparing a three-dimensional image of a patient's joint, selecting a standard size implant closely matching the joint, and modifying at least one feature of the implant to be patient-specific.

In another aspect, the implant is a femoral implant, and the method includes modifying a plurality of features of the femoral implant to be patient-specific.

The present teachings also provide an orthopedic implant that includes a first portion including at least one feature modified to be patient-specific and match the anatomy of a specific patient from a three-dimensional digital image of a patient's joint using computer modeling. The orthopedic implant includes a non-custom inner bone-engaging surface including a plurality of planar surfaces configured for engagement with non-custom bone cuts.

The present teachings provide an orthopedic implant that includes a non-custom inner bone-engaging surface including a plurality of planar surfaces configured for engagement with standard size femoral bone cuts prepared for a non-custom femoral implant. In some embodiments, the orthopedic implant includes a patient-specific feature, such as an anterior femoral flange of the orthopedic implant configured during a preoperative plan to have a patient-specific shape and closely match a corresponding portion of a femur of a specific patient from a three-dimensional digital image of a patient's joint using computer modeling. The patient-specific shape of the anterior femoral flange of the orthopedic implant is obtained by modifying a digital image of the non-custom femoral implant without modifying the plurality of planar surfaces of the inner bone-engaging surface. In some embodiments, the patient-specific feature is the orientation or the depth of a patella track.

The present teachings provide an orthopedic implant that includes a non-custom tibial bearing component, and a tibial tray including a non-custom locking mechanism couplable with the non-custom tibial bearing. The tibial tray has a patient-specific profile configured during a preoperative plan to be patient-specific and closely match a corresponding profile of a tibia of a specific patient from a three-dimensional digital image of a patient's joint using computer modeling, wherein the patient-specific profile of the tibial tray is obtained by modifying a digital image of a non-custom tibial implant without modifying the non-custom locking mechanism.

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 teachings.

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. **1** is a plan view of an exemplary femoral implant according to the present teachings;

FIG. **2** is a posterior elevated view of the femoral implant of FIG. **1**;

FIG. **3** is an anterior-posterior sectional view of the femoral implant of FIG. **1**;

FIG. **4** is an environmental view illustrating an exemplary femoral alignment guide according to the present teachings;

FIG. **5** is an environmental view illustrating an exemplary distal cutting block according to the present teachings;

FIG. **6** is an environmental view illustrating an exemplary four-in-one cutting block according to the present teachings;

FIG. **7** is a flowchart of an exemplary method according to the present teachings;

FIG. **8** is an anterior elevated view of a femoral implant according to the present teachings;

FIG. **9** is an anterior-posterior sectional view of the femoral implant of FIG. **8**; and

FIG. **10** is a perspective view of a tibial component according to the present teachings.

DESCRIPTION OF VARIOUS EMBODIMENTS

The following description is merely exemplary in nature and is in no way intended to limit the teachings, its application, or uses. For example, although the present teachings are illustrated for specific implants and alignment guides in hip or knee surgery, the present teachings can be used with other implants and guides, templates, jigs, drills, rasps or other instruments used in various orthopedic procedures.

The present teachings generally provide a surgery system for use in orthopedic surgery for the knee, hip, or shoulder, for example. The surgery system can include various

implant components **100**, patient-specific alignment guides or templates **600**, and cutting blocks or other conventional instruments **610**, **620** that can be used in the specific orthopedic procedure. At least one implant component **100** can be semi-custom made. The semi-custom implant components are standard size components that have at least one feature modified to match a specific patient, as discussed below.

The alignment guides **600** can be used either with conventional (standard size) or patient-specific femoral and tibial prosthesis components prepared with computer-assisted image methods. The implant components **100** can be patient-specific (custom made) or semi-custom. Computer modeling for obtaining three dimensional images of the patient's anatomy using MRI or CT scans of the patient's anatomy, the semi-custom and/or custom made implant components **100**, and the patient-specific alignment guides **600** can be provided by various CAD programs and/or software available, for example, by Materialise USA, Ann Arbor, Mich.

The alignment guides **600** can be generally formed using computer modeling for matching a three-dimensional image of the patient's bone surface (with or without the cartilage) by known methods. Further details of patient-specific alignment guides and associated methods are disclosed in U.S. application Ser. No. 11/756,057, filed on May 31, 2007, the disclosure of which is incorporated herein by reference.

Similarly, the implant components can be selected and modified to include patient-specific features by using computer modeling of the joint, as described above. A set of conventional femoral knee implants can be modeled and overlaid over the CAD image data to first determine the closest fit based on standard sizes. These standard sized overlays or templates can be based on commercially available implant systems, such as, for example, the Vanguard Knee System, commercially available from Biomet, Inc., of Warsaw, Ind., in size increments of 2.5 mm. Using standard sized implants as a base for semi-custom implant components can allow standard instrument sets to be used depending on the specific size selected. After the overlay is positioned on the digital representation of the femur, various adjustments can be made to this femoral implant.

Referring to FIGS. **1-3**, various views of an exemplary semi-custom implant component **100** in the form of a femoral component for a knee replacement surgery system are illustrated. The semi-custom implant component **100** can include certain portions that are custom-made to match a particular patient using imaging techniques, and other portions that are provided in a series of standardized size increments to ensure a good fit. For example, the outside geometry of the femoral component **100** can be patient-specific or patient-matched. As an illustration, the width W and height H, and/or optionally the shape and dimensions of the entire articulating or outer surface **102**, or portions thereof, can match/conform with that of the patient's corresponding joint surface. The inside geometry of the femoral component **100**, such as the bone-engaging inner surface **104**, can be selected from a standardized series of sizes, thereby allowing the use of standard instruments, such as cutting guides and resection instruments, to be used with the semi-custom implant components **100**, and avoiding the need for specialized instruments and associated manufacturing and training costs.

With continued reference to FIGS. **1-3**, to obtain a good match, the difference between consecutive sizes in the inner anterior-posterior distance D can be 3 mm or less to allow for as good a fit between the implant component **100** and the joint surface without the need to match or conform the inner surface **104** to the patient. In other words, the semi-custom implant component **100** is an implant component that can include certain portions, including shapes, dimensions, and/or sizes that are custom-made for a particular patient, while other portions including shapes and/or dimensions of the component are provided in a series of standardized sizes in increments that can provide a good fit without being fully custom-made to a particular patient.

In another aspect, and referring to the exemplary illustrations of FIGS. **8** and **9**, five adjustments can be made to a standard size femoral component to obtain a semi-custom femoral implant component **100**. These five adjustments can include the medial/lateral width W, the angle θ of the patella track **106**, the depth D**1** of the patella track, the shape of the anterior flange **108**, such as right or left-sided and a height of the anterior flange, such as the height H**1** shown in FIG. **9**, or overall height H, shown in FIG. **2**. These five features or parameters can be adjusted to more closely match the knee of the patient without requiring changes in the standard cuts for the selected standard knee implant, because the bone engaging inner surface **104** does not substantially change allowing standard cutting guides and resections instruments corresponding to standard sizes to be used. This modified or patient matched digital model of the semi-custom implant can then be provided to the surgeon along with the image data for review. The surgeon can confirm whether the proposed design is acceptable, and the specific patient matched implant can be manufactured from the digital model.

The surgery system can include patient-specific and/or conventional (standard size) implants for the remaining components of the knee replacement system, such as the tibial component, bearing component and patella component. For example, and referring to FIG. **10**, a tibial component **300** can be designed with a profile **302** that matches and conforms to the patient's anatomy based on the 3-D image data of the patient's bone. The resulting tibial component **300** can still have standard features, including a standard locking mechanism for bearings, such as, for example, slots **304** for coupling with a standard bearing component **310**. The standard locking mechanism allows existing inventory of bearings to be used. In another aspect, the bearing components **310** can be similarly customized.

In another aspect, the tibial component **300** can also be designed in closely packed tibial sizes that very in increments of less that 2 mm in width and are available for manufacture on an as-needed basis. When used with patient-specific alignment guides made from digital images of the joint, the closely packed sizes need not be stocked in inventory, but manufactured only in the size determined from the digital image from planned molds or other just-in-time manufacturing methods.

In another aspect, disease-specific off-the shelf implants can be provided and included in a surgery kit. Each disease-specific implant can be designed to address a specific deformity, by making angle or size adjustment related to the deformity, such as different lengths or thickness or angles of certain portions of the implant component, such as the size and shape of femoral condyles, the patella track angle, etc. Each disease-specific implant can be used for multiple patients with the same deformity/disease, such as valgus, varus or flexion deformities. In this regard, for each patient with the same deformity, one or more off-the-shelf disease-specific implants can be selected to address the patient's needs without using patient-specific implants.

The surgery system can also include patient-specific alignment guides **600**, as illustrated in FIG. **4**, for a joint surface **82** of the distal femur **80**. The patient specific alignment guide **600** can define openings **606** for guide elements **604** that pass through corresponding holes **606***a* drilled in the femur, and openings **602** for drilling holes **602***a* on the femur **80**, as shown in FIGS. **4**, and **6**. The surgery system can also include a set of cutting blocks for the femoral joint surface **82**, such as the distal cutting block **610** illustrated in FIG. **5** and mounted on the femur **80** with various guide or fixation elements **604**, **605**, and the four-in-one cutting block **620** illustrated in FIG. **6**. The four-in-one cutting block **620** can be supported on the femur with pins **622** received in openings **602***a*. Other cutting blocks, drill guides or other instruments can also be used. The joint surface **82** can be a bone surface with or without soft tissue, such as articular cartilage for the knee or other joint soft tissue. It will be appreciated that other instruments, such as drill guides, guide pins, attachment pins or pegs or others can be included in the surgery system.

The surgery system can be used for surgical pre-planning as illustrated in FIG. **7**. The patient's knee, or other joint, can be scanned using an imaging technique, such as MRI or CT, at **400**. A three-dimensional (3D) model of the joint surfaces can be reconstructed at **410** using known computer imaging methods. The implant components **100** can be designed, sized and positioned using the 3D reconstruction, at **420**. As discussed above, the implant components **100** can include conventional, custom made, or semi-custom implant components **100**. The semi-custom implant components can include some portions that are of standard sizes, such as a bone-engaging inner surface **104** (shown with five planar surfaces in FIG. **9**), and other portions that are customized for the patient, including portions of the articulating surface or other outer dimensions and orientations of the articulating surface **102** of the implant **100**. Customized alignment guides **600** for the joint surfaces, such as femoral and tibial alignment guides **600** for a total knee replacement, can be designed and prepared based on the 3D reconstruction and the implants **100**, at **430**. A surgery system or kit can be assembled for the surgeon at the time of surgery, at **450**. The surgery system can include at least one semi-custom implant component **100**, at least one patient specific alignment guide **600**, and at least one cutting block **610**.

It will be appreciated that surgery kits as described above can be constructed for various joints, including the knee, the hip, the shoulder, etc. The present teachings provide the ability to customize implant and alignment guide components and their position using patient-specific data. Further, the amount of inventory required in the operating room can be reduced because the sizes of the various semi-custom implant components **100** are known prior to surgery and only the required size is sent to the surgeon for the surgical procedure. In another aspect, when close-packed sizes are planned, the small difference between individual sizes of the implant components **100**, such as 3 mm or 2.5 mm or less, can allow optimal anterior-posterior fit to the joint surface **80** without adverse impact on inventory requirements, because only the required size can be manufactured and shipped for a specific patient based on the patient's image data. Additionally, the use of semi-custom implant components based on anterior-posterior sizing, as contrasted to fully patient-specific components, allows use and re-use of standard cutting blocks. Disposable cutting blocks can also be mass produced in high volumes at less cost because of the standardization.

The foregoing discussion discloses and describes merely exemplary arrangements of the present teachings. One skilled in the art will readily recognize from such discussion, and from the accompanying drawings, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the teachings as described herein.

What is claimed is:

1. An orthopedic implant system comprising:

a plurality of orthopedic implants comprising:

an inner bone-engaging surface having a length in an anterior-posterior direction that is standardized so as to be independent of an anatomy of a specific patient's joint but is rather one of a series of predetermined size increments for the orthopedic implant system with the length in the anterior-posterior direction of each of the plurality of orthopedic implants differing, each size increment varying by a set amount of the length in the anterior-posterior direction relative to others, wherein the inner bone-engaging surface includes a plurality of planar surfaces configured for engagement with bone cuts to a femur, the bone cuts having an overall length when combined in the anterior-posterior direction that is configured to correspond to that of the inner bone-engaging surface of the orthopedic implant; and

at least one of the plurality of orthopedic implants having a joint facing portion opposing the inner bone-engaging surface including at least one feature configured to be patient-specific based on an image of the specific patient's joint, wherein the at least one feature is designed using computer modeling to have a shape dependent upon an anatomy of the specific patient.

2. The orthopedic implant system of claim **1**, wherein the series of size increments are in increments of 3 mm or less.

3. The orthopedic implant system of claim **1**, wherein the at least one feature is a medial/lateral width of the at least one of the plurality of orthopedic implants.

4. The orthopedic implant system of claim **1**, wherein the orthopedic implant is a femoral knee implant and the at least one feature includes an orientation of a patella track of the femoral knee implant.

5. The orthopedic implant system of claim **1**, wherein the orthopedic implant is a femoral knee implant and the at least one feature includes a depth of a patella track of the femoral knee implant.

6. The orthopedic implant system of claim **1**, wherein the orthopedic implant is a femoral knee implant and the at least one feature includes a shape of an anterior flange of the femoral knee implant.

7. The orthopedic implant system of claim **1**, wherein the orthopedic implant is a femoral knee implant and the at least one feature includes a height of an anterior flange of the femoral knee implant.

8. An orthopedic implant system comprising:

a plurality of orthopedic implants comprising:

an inner bone-engaging surface including a plurality of planar surfaces configured for engagement with corresponding femoral bone cuts, wherein the plurality of orthopedic implants are standardized so as to be independent of the anatomy of a specific patient's joint but each of the plurality of orthopedic implants has a different length in an anterior-posterior direction that is one of a series of predetermined size increments for the implant system, wherein each size increment varies by a set amount of length in the anterior-posterior direction relative to others, and wherein selection of which one of the plurality of orthopedic implants is utilized is

made by ascertaining a closest fit from the plurality of orthopedic implants by overlaying the plurality of orthopedic implants on an image of the specific patient's joint using computer modeling; and

at least one of the plurality of implants having a joint facing portion opposing the inner bone-engaging surface configured during a preoperative plan to have a patient-specific feature based on the image of the specific patient's joint, wherein the patient-specific feature is designed using computer modeling to have a shape dependent upon the anatomy of the specific patient by modifying a computer model of the one of the plurality of orthopedic implants selected to provide for the patient specific feature, wherein the computer model includes a plurality of planar surfaces corresponding to the plurality of planar surfaces of the inner bone-engaging surface of the one of the plurality of orthopedic implants selected that remain unmodified.

9. The orthopedic implant system of claim **8**, wherein the patient-specific feature includes a medial/lateral width.

10. The orthopedic implant system of claim **8**, wherein the joint facing portion includes an anterior flange and the patient-specific feature includes a shape of the anterior flange.

11. The orthopedic implant system of claim **8**, wherein the joint facing portion includes an anterior flange and the patient-specific feature includes a height of the anterior flange.

12. The orthopedic implant system of claim **8**, wherein the joint facing portion includes a patella track and the patient-specific feature includes an orientation of the patella track.

13. The orthopedic implant system of claim **8**, wherein the joint facing portion includes a patella track and the patient-specific feature includes a depth of the patella track.

14. The orthopedic implant system of claim **8**, wherein the joint facing portion includes an anterior flange and the patient-specific feature includes a medial/lateral width of the first portion, a shape of the anterior flange, and a height of the anterior flange.

15. The orthopedic implant system of claim **14**, wherein the joint facing portion includes a patella track and the patient-specific feature includes an orientation of the patella track and a depth of the patella track.

16. An orthopedic implant system comprising:

a plurality of orthopedic implants comprising:

an inner bone-engaging surface having a length in an anterior-posterior direction that is standardized so as to be independent of an anatomy of a specific patient's joint but is rather one of a series of predetermined size increments for the orthopedic implant system with the length in the anterior-posterior direction of each of the plurality of orthopedic implants differing, each size increment varying by a set amount of the length in the anterior-posterior direction relative to others, wherein the inner bone-engaging surface includes a plurality of planar surfaces configured for engagement with bone cuts, the bone cuts having an overall length when combined in the anterior-posterior direction that is configured to correspond to that of the inner bone-engaging surface of the orthopedic implant; and

at least one of the plurality of orthopedic implants having one or more of an orientation of a patella track, a depth of the patella track, a height of an anterior flange, a shape of the anterior flange, and a medial/lateral width that is configured to be patient-specific based on an image of the specific patient's joint, wherein the at least one feature is designed using computer modeling to have a shape dependent upon an anatomy of the specific patient.

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