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Kennedy et al.(10) **Pub. No.: US 2015/0245844 A1**(43) **Pub. Date: Sep. 3, 2015**(54) **PATIENT MATCHED INSTRUMENT**(71) Applicant: **Smith & Nephew, Inc.**, Memphis, TN (US)(72) Inventors: **Eric S. Kennedy**, Memphis, TN (US);
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Zachary C. Wilkinson, Germantown, TN (US); **Randy C. Winebarger**, Southaven, MS (US)(73) Assignee: **Smith & Nephew, Inc.**, Memphis, TN (US)(21) Appl. No.: **14/420,453**(22) PCT Filed: **Aug. 9, 2013**(86) PCT No.: **PCT/US2013/054278**

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CPC **A61B 17/157** (2013.01); **A61B 17/15** (2013.01); **A61B 2017/568** (2013.01)(57) **ABSTRACT**

A patient matched instrument is disclosed. The patient matched instrument includes a body having an interior patient matched surface; a cutting slot extending through at least a portion of the body; a first paddle extending from the body; and a second paddle spaced apart from the first paddle and extending from the body; and wherein at least one of the first paddle and the second paddle further comprises a hook.

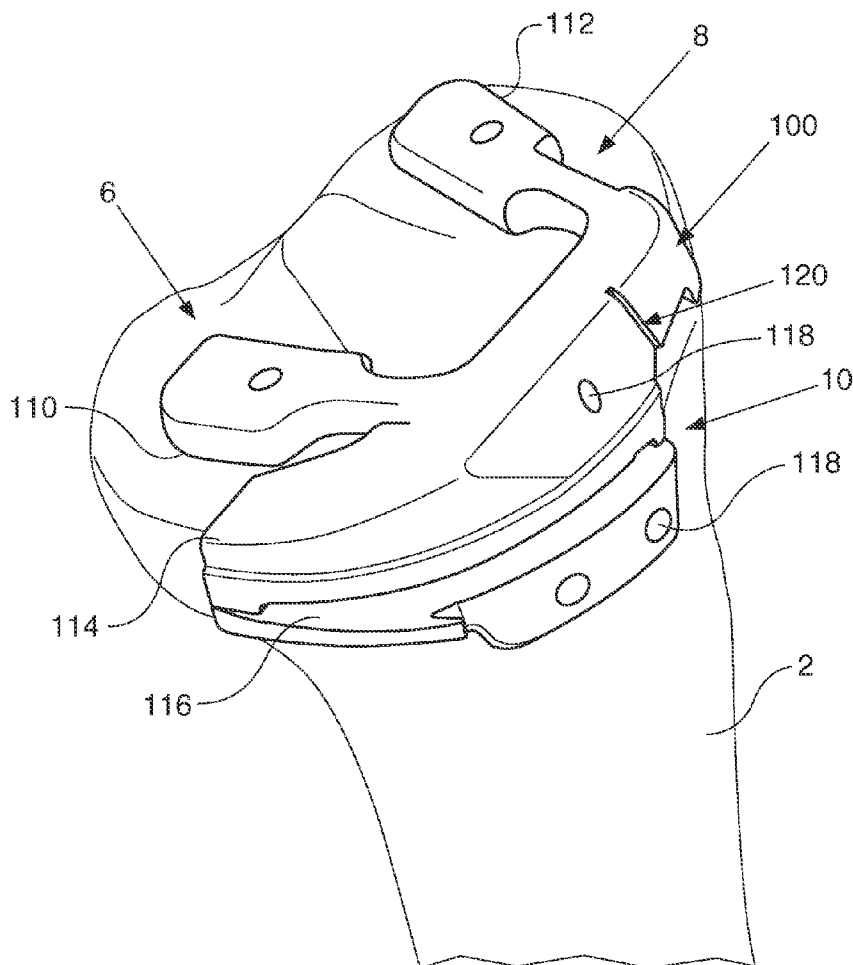


Fig. 1

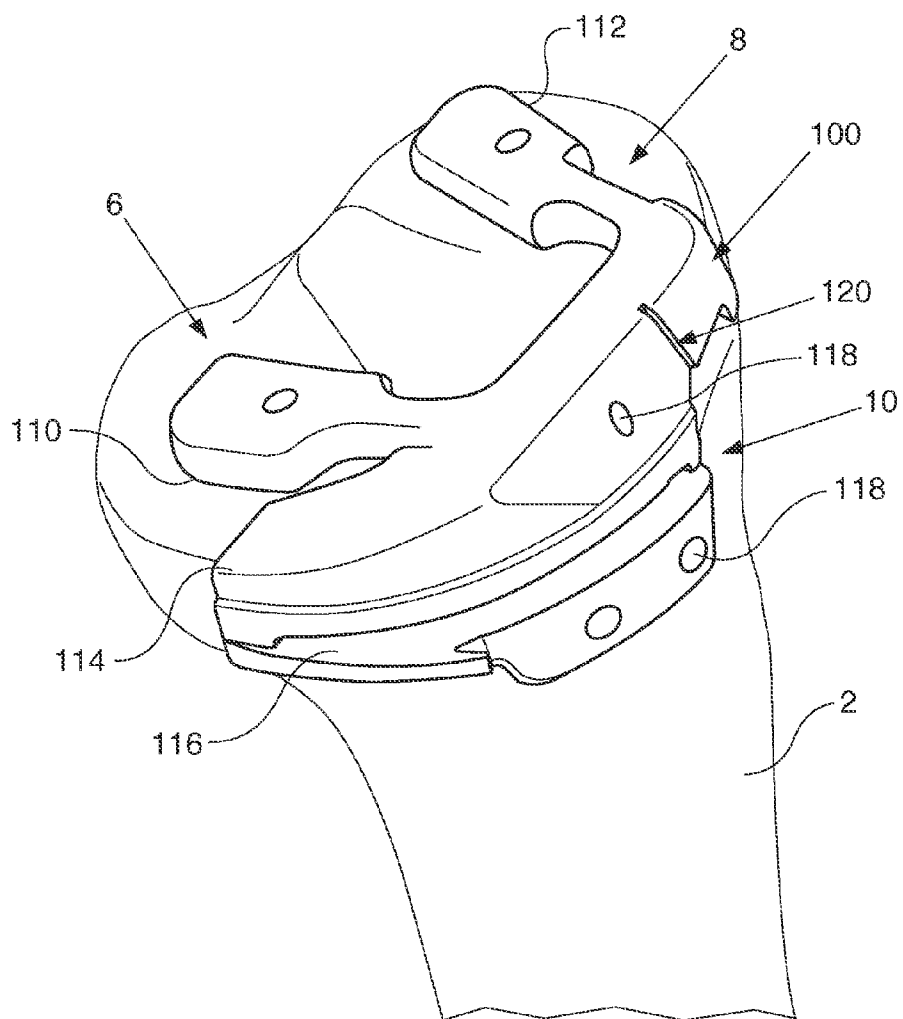


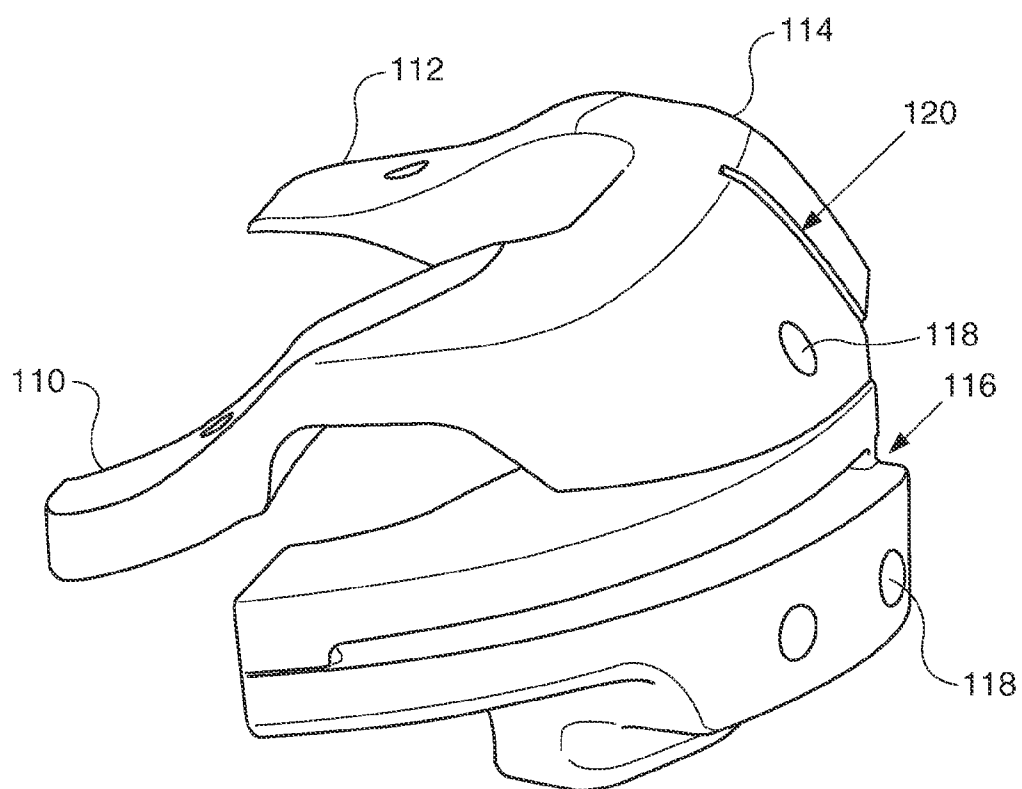
Fig. 2

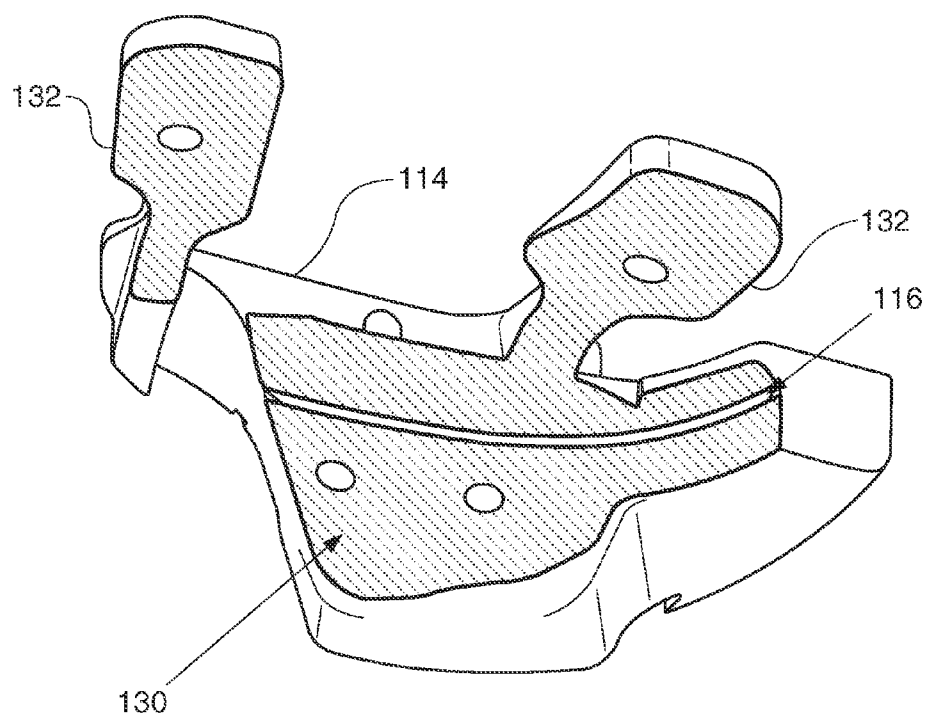
Fig. 3

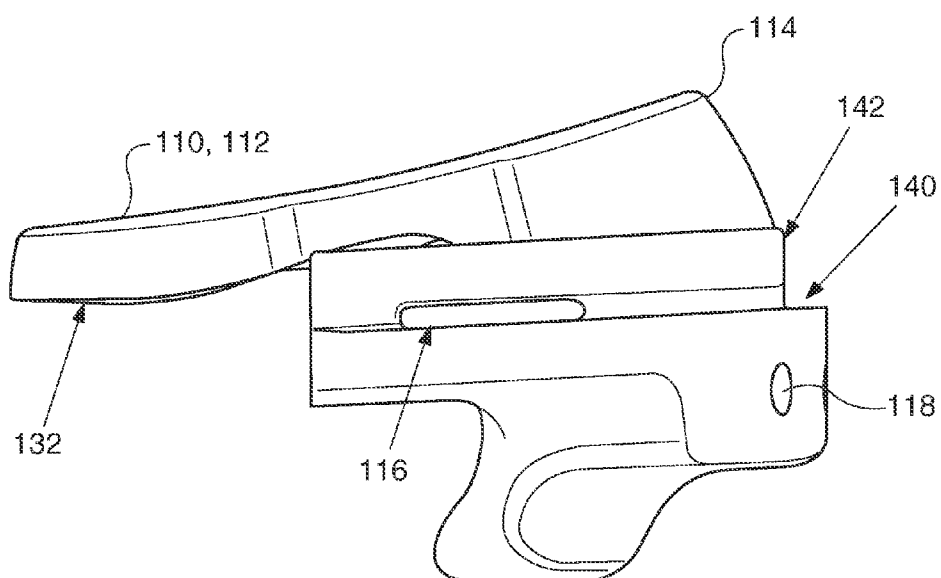
Fig. 4

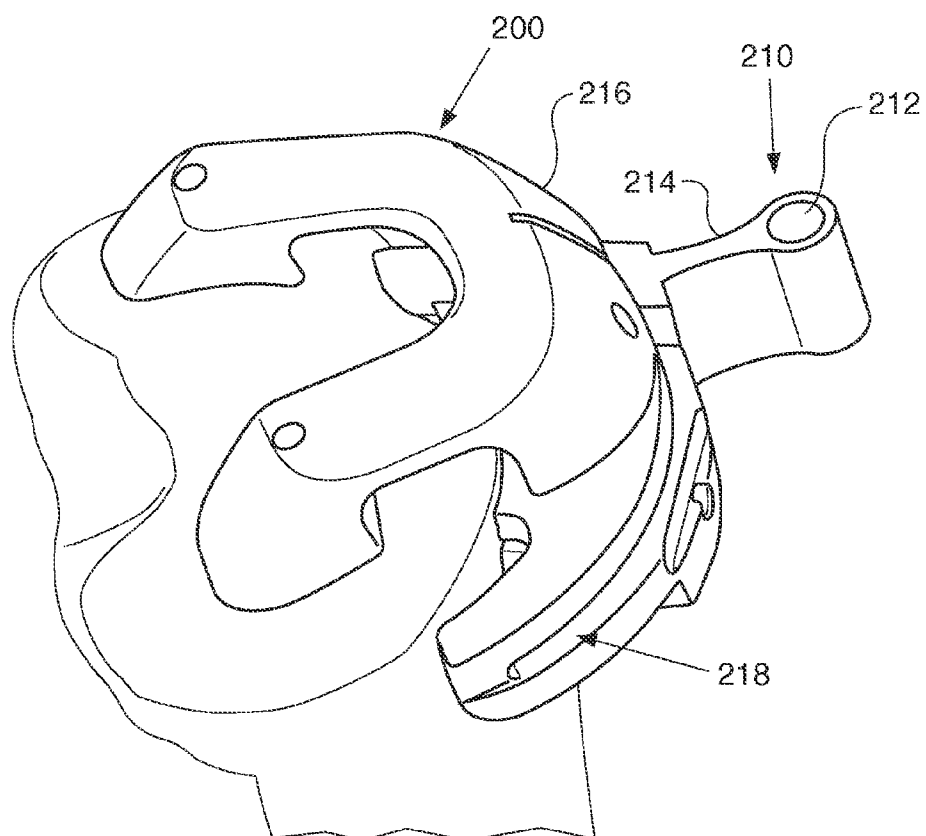
Fig. 5

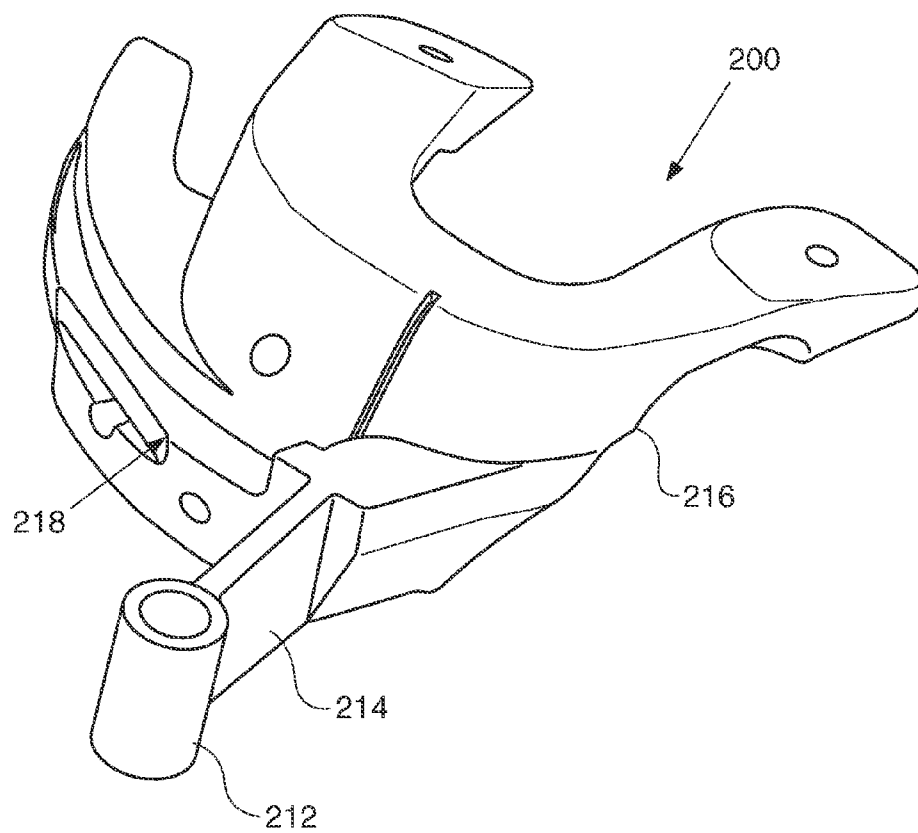
Fig. 6

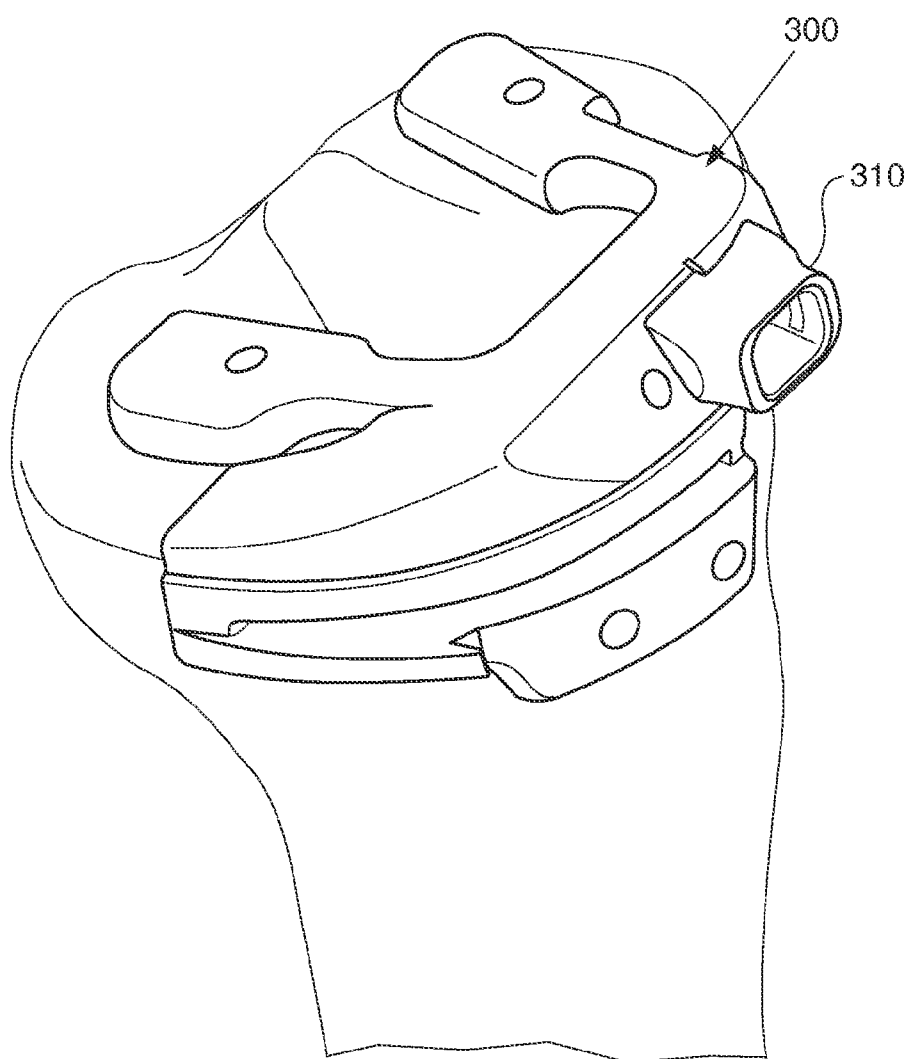
Fig. 7

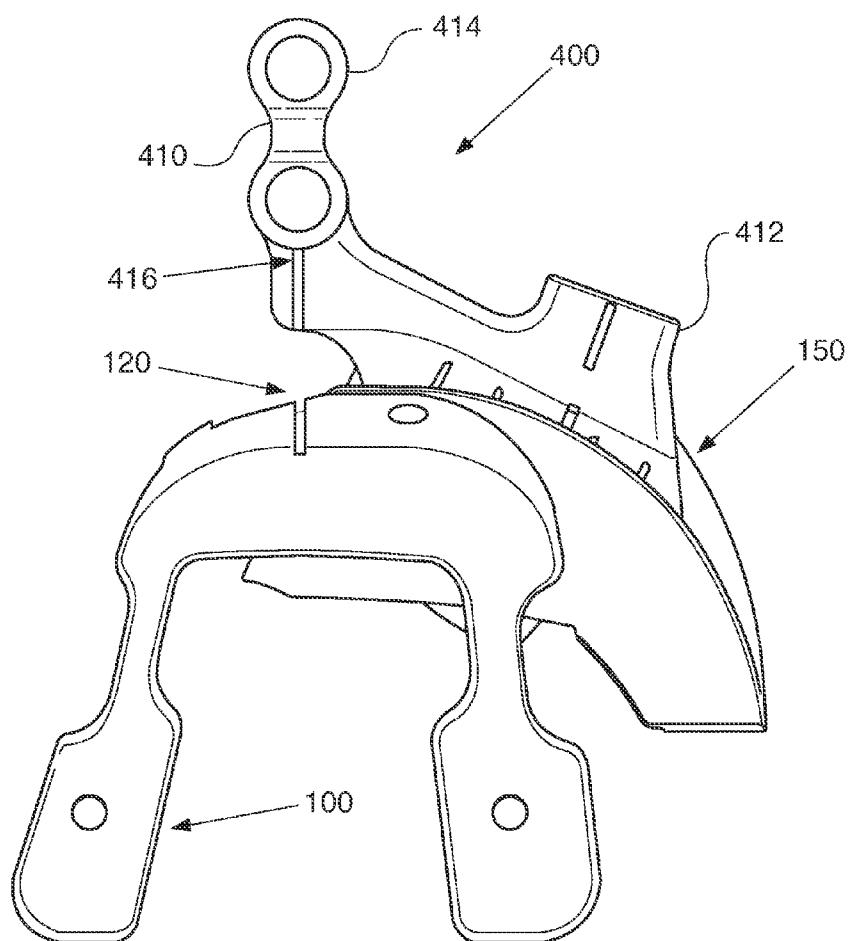
Fig. 8

Fig. 9

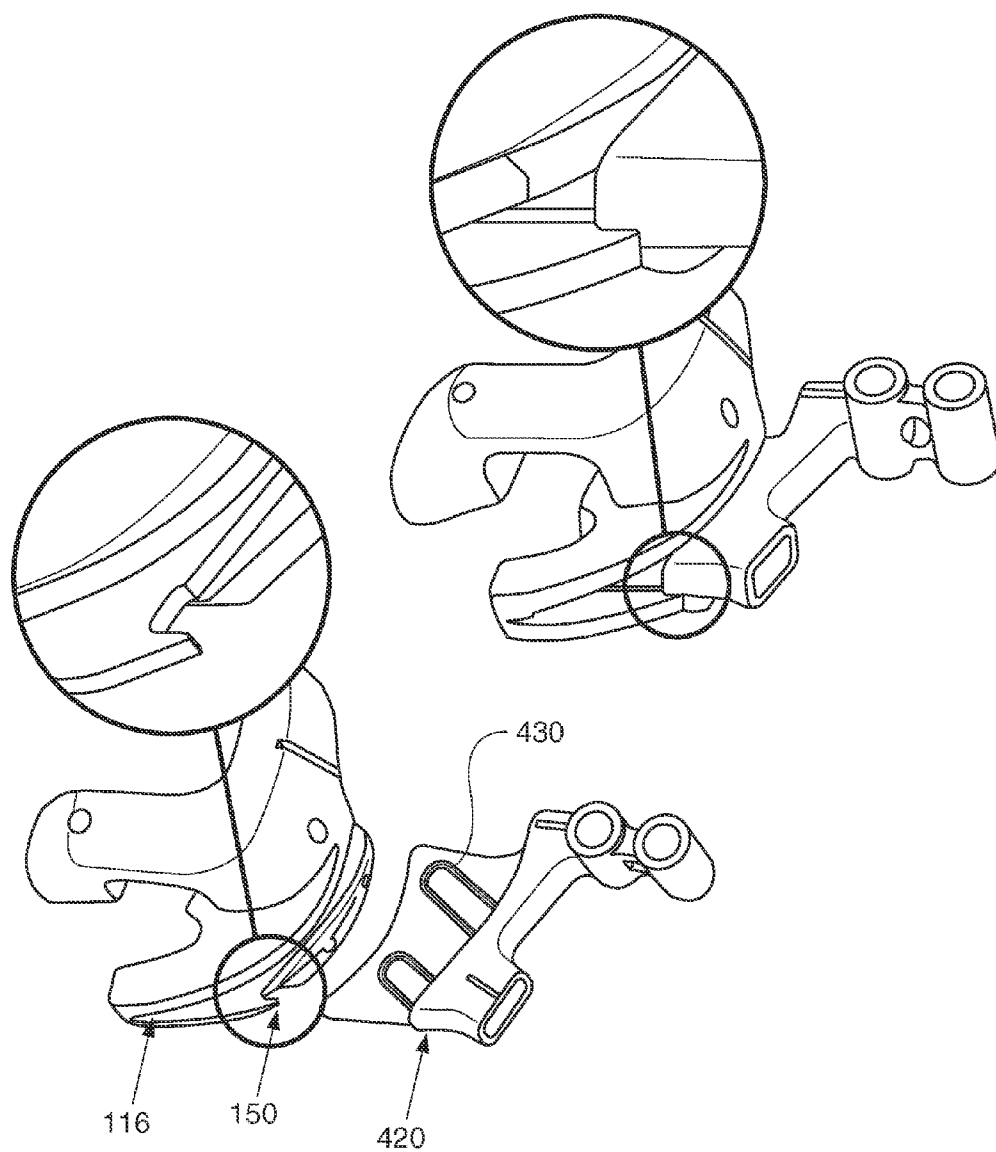


Fig. 10

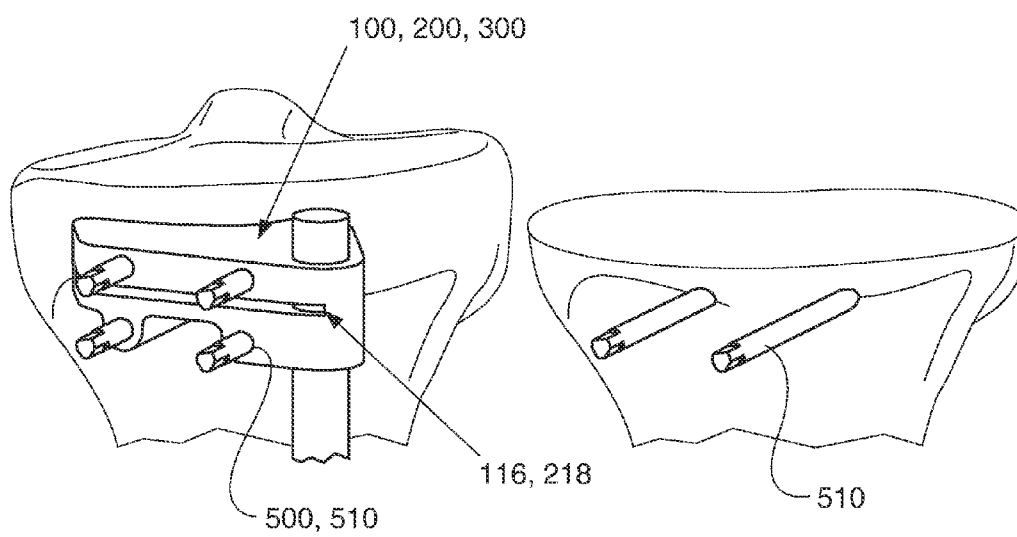


Fig. 11

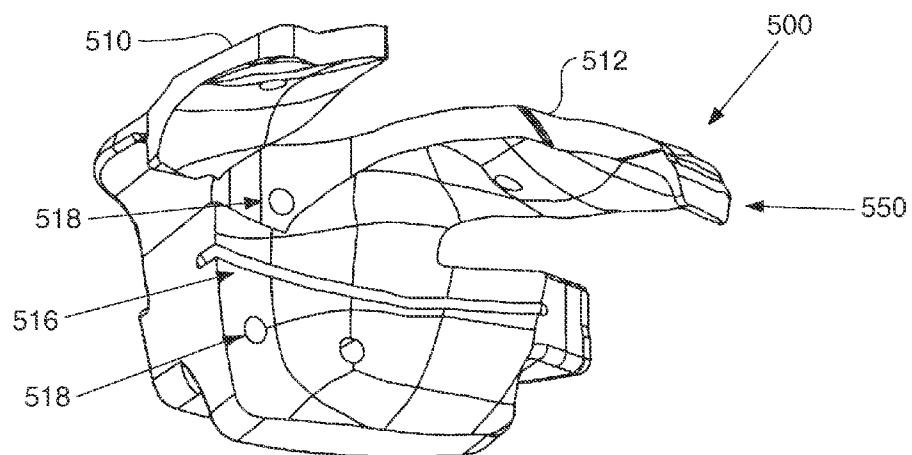


Fig. 12

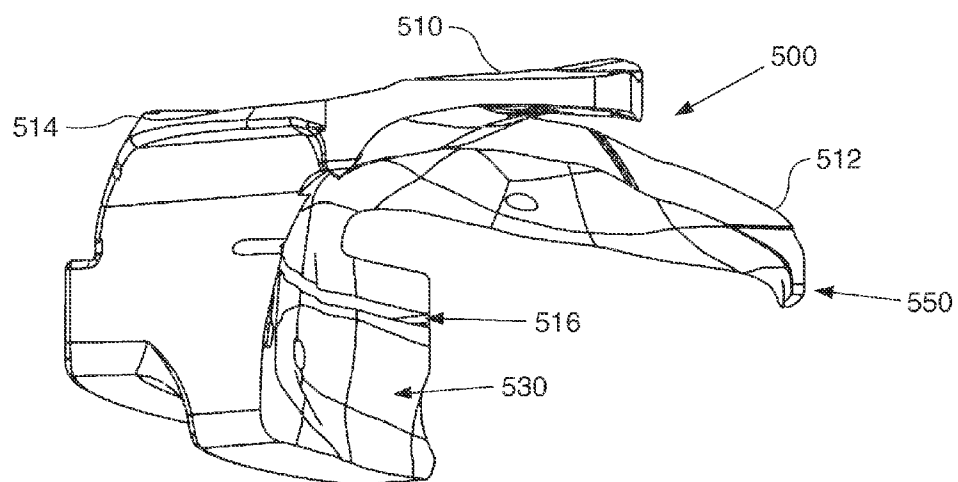


Fig. 13

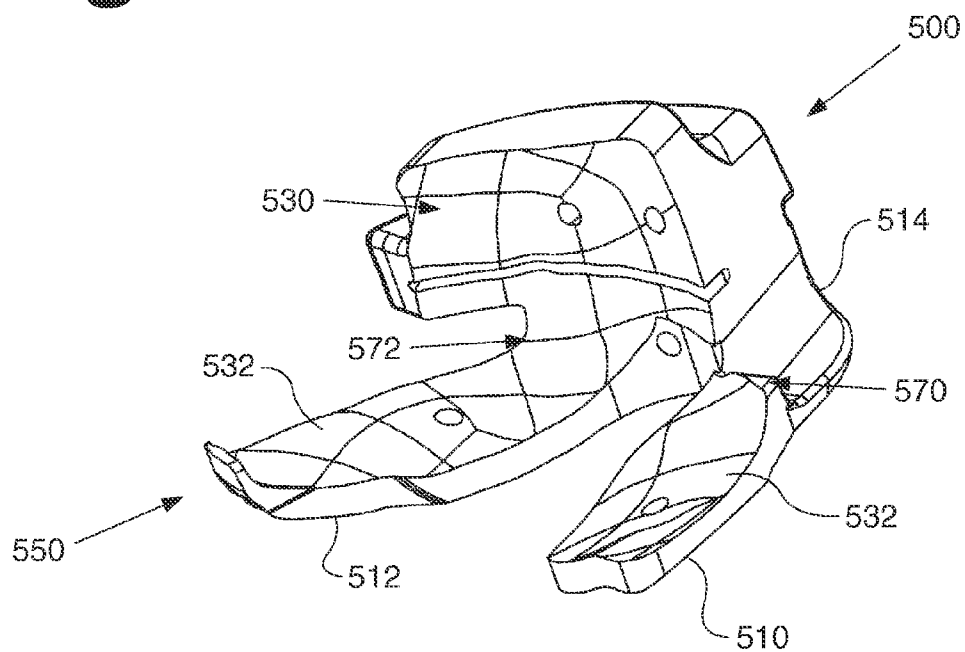


Fig. 14

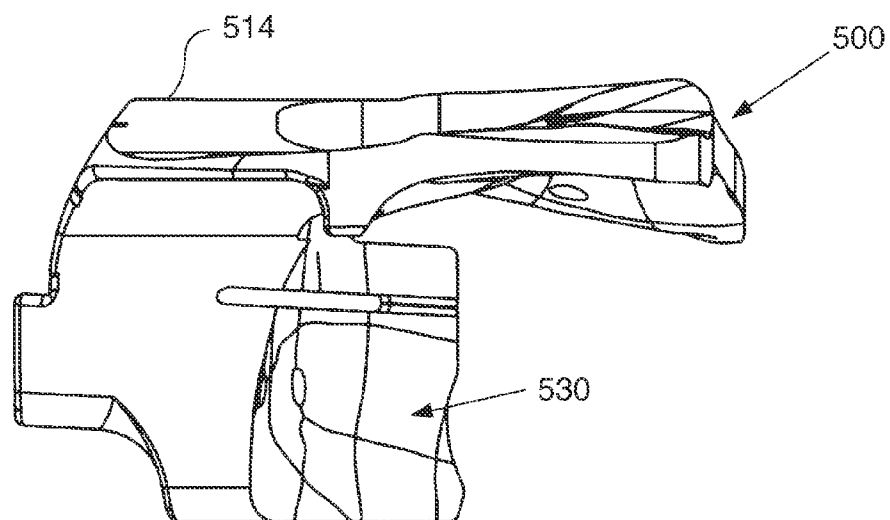


Fig. 15

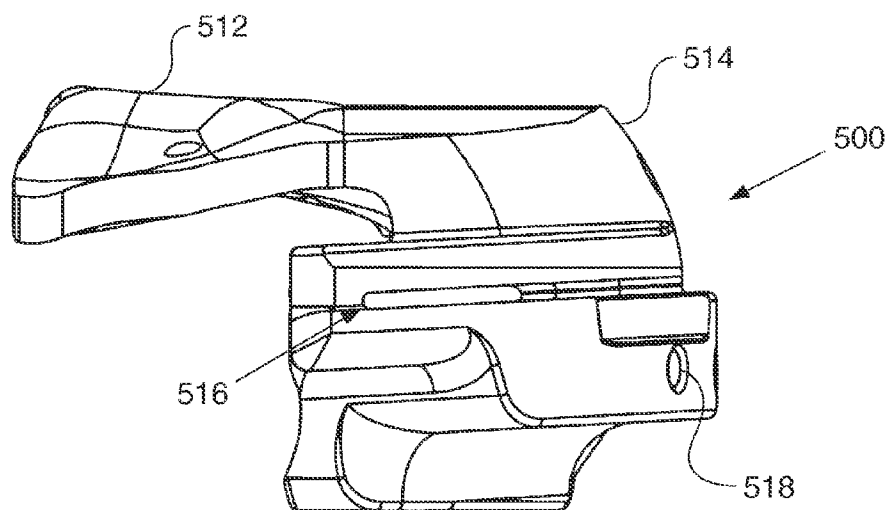


Fig. 16

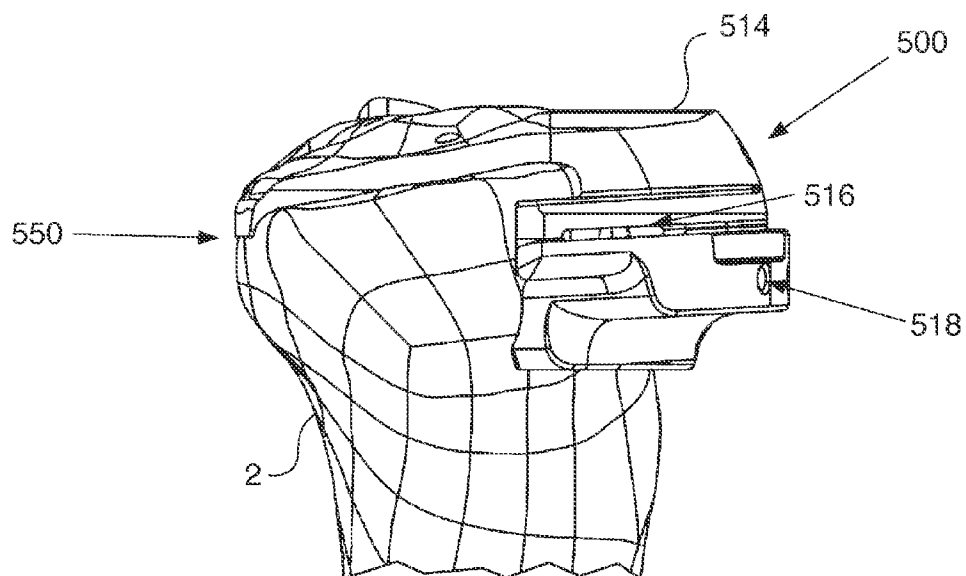


Fig. 17

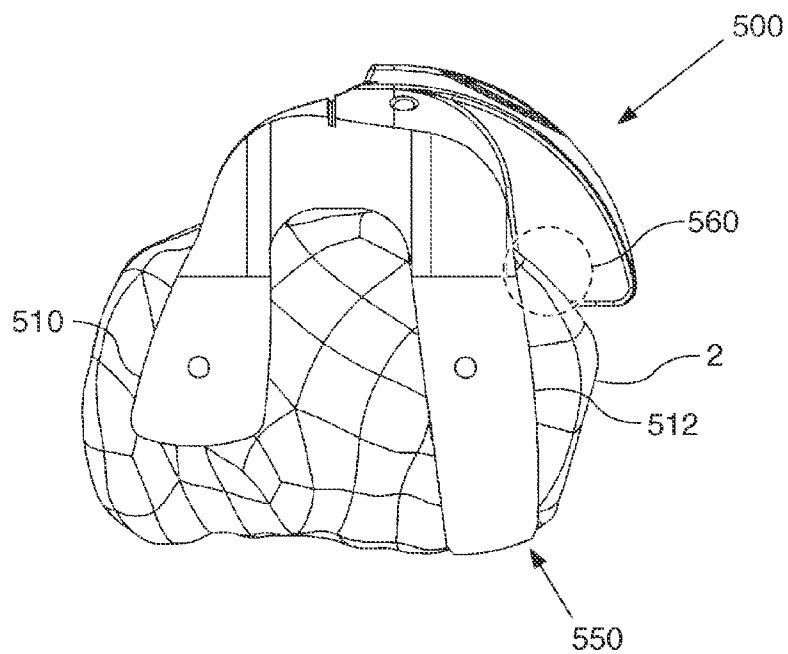


Fig. 18

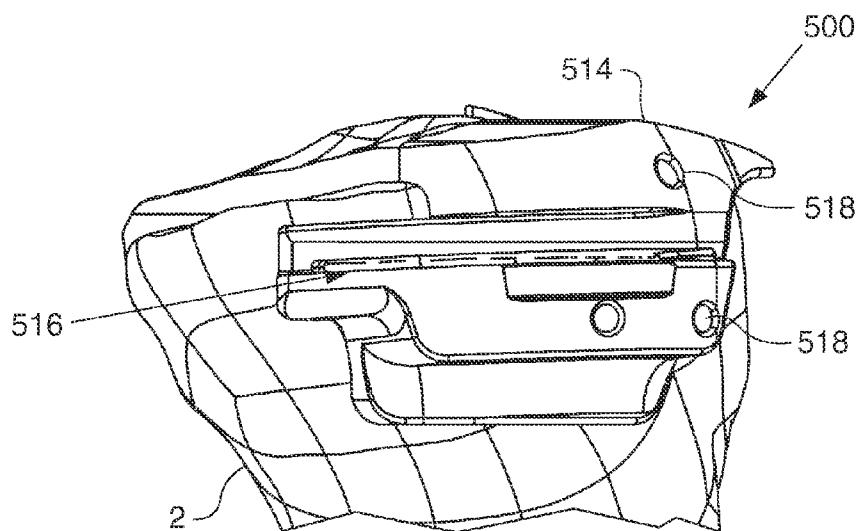


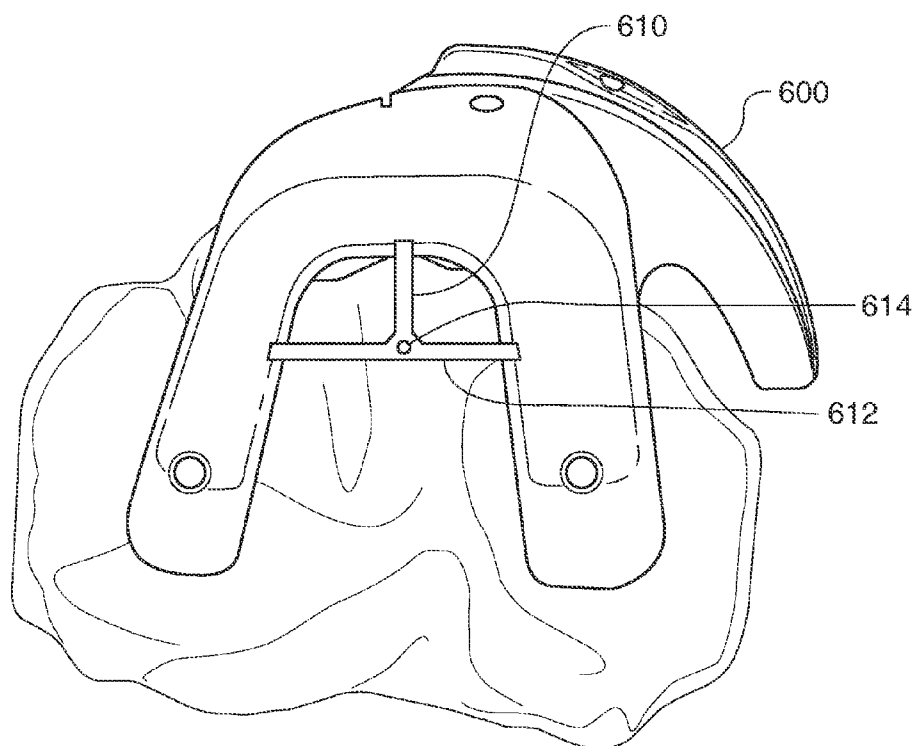
Fig. 19

Fig. 16

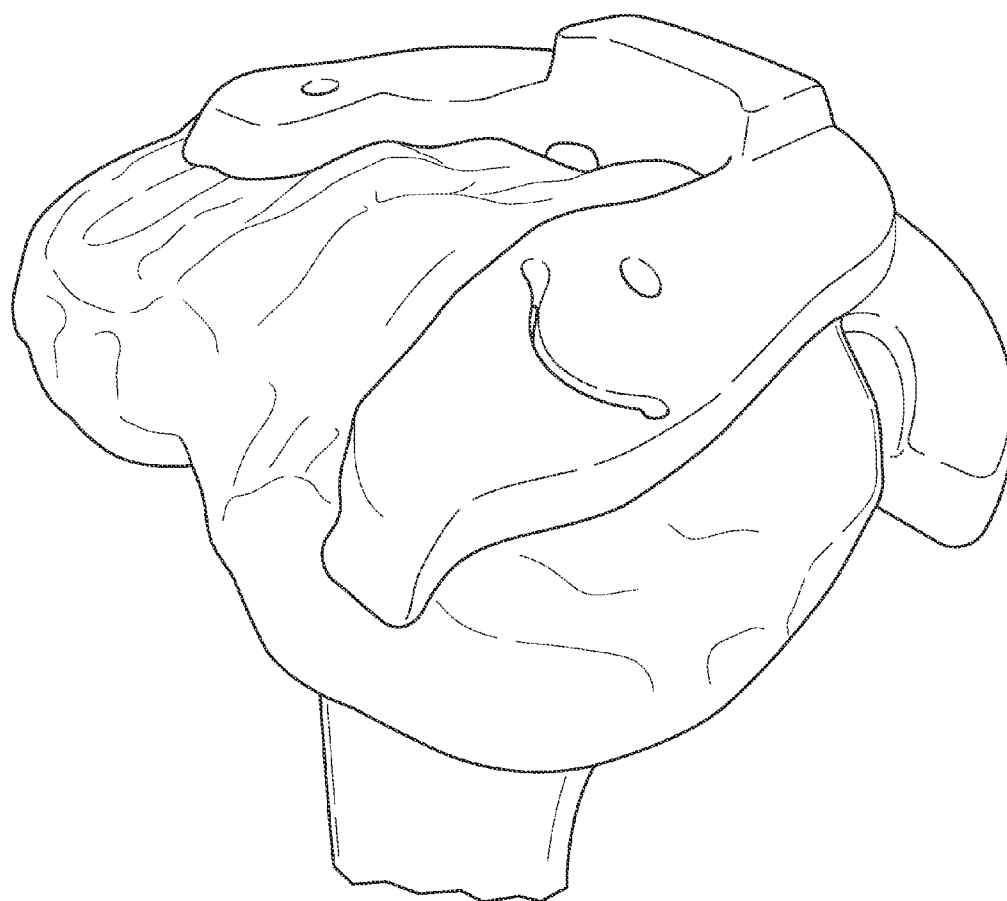
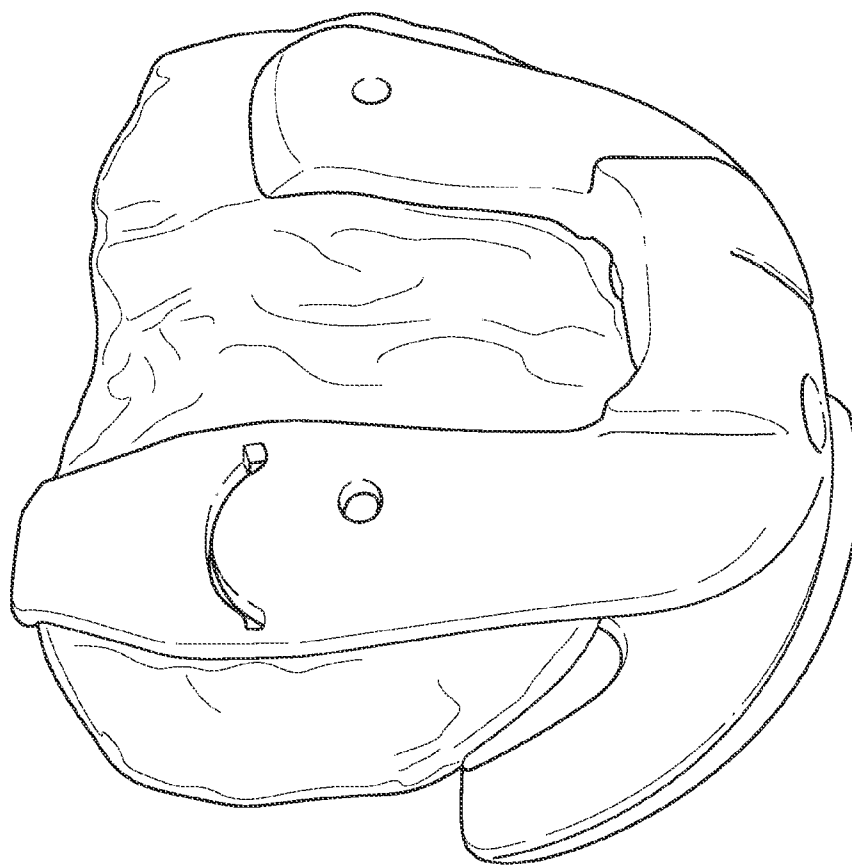


Fig. 17



PATIENT MATCHED INSTRUMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a PCT International Application of U.S. Patent Application No. 61/681,455 filed on Aug. 9, 2012, and U.S. Patent Application No. 61/715,565, filed on Oct. 18, 2012. The disclosure of each application is incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] Embodiments of the present invention generally relate to surgical instruments and methods for the treatment of bones or joints, in some instances surgical instruments that are matched to a particular patient's anatomy, are described herein. Also described are methods of designing and using such surgical instruments.

[0004] 2. Related Art

[0005] Conventional patient-matched instruments are provided with large surfaces that are configured to conform to a patient's unique anatomy. Successful surgical outcomes depend on the ability of patient-matched instruments to provide a reproducible, "confident" 3D-fit between the patient-matched instrument and the anatomy that they are designed to rest against. If there is any doubt by an end user that a patient-matched instrument fits well upon repeated engagement with a patient's unique anatomy, or if the instrument appears to fit well with the patient's anatomy in multiple spatial orientations with respect to the anatomy, the instrument is typically discarded, and the surgery is carried out with the use of conventional, non-patient specific instruments.

[0006] To date, at least some patient-matched surgical instruments for use in total knee arthroplasty have employed anatomy-contacting surfaces that are substantially "negatives" of distal femoral and proximal tibial articular joint surfaces. The anatomy-contacting surfaces are generally large surface areas that conform in a continuous manner to substantial areas of a patient's anatomy. In some instances, the custom surgical instruments are provided by obtaining 3D image data of the patient's anatomy (e.g., via an MRI scan), segmenting the 3D image data to clearly delineate surfaces of the bony and/or cartilagenous anatomy from surrounding tissues, converting the segmented data to a computer model via CAD or other software, performing one or more optional secondary processes (e.g., smoothing functions), using a computer model to customize one or more surfaces of an instrument to the patient's anatomy, and manufacturing the custom instrument such that it is adapted to conform to the patient's anatomy in a single spatial orientation.

[0007] In at least some current practices, substantially all portions of the joint anatomy shown in each 3D image data slice are segmented and conventional patient-matched instruments are provided with anatomy-contacting portions that contact substantially continuous areas of the patient's anatomy. Such anatomy-contacting portions have large continuous surface areas of contact with the patient's bone and cartilage, and therefore, it is critical that the engineers or automated programs creating the patient-matched instruments maintain a high level of accuracy and precision throughout each step of the entire segmentation process. Even if only one or two points on anatomy-contacting surfaces of a patient-matched instrument are inaccurate, misaligned, or

otherwise misrepresent the true unique anatomy of the patient, the patient-matched instrument may not fit well, sit proud, teeter, wobble, or may not fit at all. In such instances, an end user is less likely to use the instrument. In many cases, poor patient-matched instrument fit may be attributed to even a few minor errors in the segmentation process.

SUMMARY OF THE INVENTION

[0008] The various embodiments of the present invention described below and shown in the Figures provide a patient matched instrument that is designed to provide improved repeatability and reproducibility over the prior art. The patient matched instrument incorporates design features that encourage consistent placement and accurate placement.

[0009] Further areas of applicability of the invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the particular embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate embodiments of the present invention and together with the description, serve to explain the principles of the invention. In the drawings:

[0011] The accompanying drawings which in this case is a group of sketches prepared by the inventor and, which are incorporated in and form a part of the specification, illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

[0012] FIG. 1 shows a side perspective view of a patient matched instrument mounted on a left tibia.

[0013] FIG. 2 illustrates a perspective view of the patient matched instrument shown in FIG. 1.

[0014] FIG. 3 illustrates a posterior-anterior perspective view of the patient matched instrument shown in FIG. 1.

[0015] FIG. 4 illustrates a medial-lateral view of the patient matched instrument shown in FIG. 1.

[0016] FIG. 5 shows a side perspective view of a patient matched instrument mounted on a left tibia in a second embodiment.

[0017] FIG. 6 illustrates a perspective view of the patient matched instrument shown in FIG. 5.

[0018] FIG. 7 shows a side perspective view of a patient matched instrument mounted on a left tibia in a third embodiment.

[0019] FIG. 8 illustrates a superior-inferior view of a patient matched instrument in a fourth embodiment.

[0020] FIG. 9 illustrates detailed views of the patient matched instrument shown in FIG. 8.

[0021] FIG. 10 illustrates pin mounting locations that may be used with any of the above listed embodiments.

[0022] FIG. 11 shows a side perspective view of a patient matched instrument in a fifth embodiment.

[0023] FIGS. 12-15 illustrate a perspective view of the patient matched instrument shown in FIG. 11.

[0024] FIGS. 16-18 show the patient matched instrument of FIG. 11 as mounted on a tibia.

[0025] FIG. 19 shows a superior-inferior view of a patient matched instrument in a sixth embodiment.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0026] Referring to the accompanying drawings in which like reference numbers indicate like elements, FIG. 1 illustrates a patient matched instrument that is designed to provide improved repeatability and reproducibility over the prior art. FIG. 1 illustrates a patient matched (PM) instrument 100 placed on a tibia 2. The patient matched instrument 100 has a first paddle 110, a second paddle 112, a body 114, and a cutting slot 116. The paddles 110, 112 extend from the body 114 and are spaced apart from one another such that the paddles 110, 112 generally contact the medial 6 and lateral 8 tibial condyles. The body 114 may include one or more fixation holes 118. In the depicted embodiment, the body has three fixation holes but any number of holes may be used. The fixation holes 118 are dimensioned to receive pins (not shown) to temporarily fix the patient matched instrument 100 to the tibia 2. The cutting slot 116 is dimensioned to receive a cutting instrument, such as a reciprocating blade (not shown). The body 114 has sufficient depth to provide adequate strength to the cutting slot 116 such that bending of the body and skiving of the cutting instrument may be reduced. In some embodiments, the body 114 includes a groove 120 that may be used for gaging alignment.

[0027] In use, the tibia 2 is exposed via surgical incision. The patient matched cutting block 100 is placed on the tibia 2 and located in a home position. Pins (not shown) are inserted into the fixation holes 118. The cutting instrument is reciprocated in the cutting slot 116 to remove bone from a proximal end of the tibia 2.

[0028] As best seen in FIG. 2, one of the paddles 110, 112 may be thinner or thicker than the other paddle. In the depicted embodiment, the medial paddle has a thickness of about 5 mm. The thickness of the paddles may range from about 2 mm to about 15 mm, and more preferably from about 3 mm to about 5 mm. It is beneficial to the consistent and accurate placement of the PM instrument to minimize unintended potential contact with anatomic structures. For instance, some PM tibia instruments utilize tall or thick proximal paddles with the intent of stiffening the instrument to resist deformation errors, however, the thicker paddles may actually lead to an inability to properly place the PM instrument due to unintended contact between the paddles and one or both femoral condyles. Also, an operator, in attempting to avoid this unintentional contact may alter his or her surgical technique in order to make all femur resections prior to placing the PM tibial instrument. This is a limiting disadvantage because in doing so excludes many techniques that rely on alternating resections on the femur and tibia for the purpose of making resections based on joint balance rather than strictly based on measured resection. By designing the proximal paddles of the PM tibial instrument shorter and by limiting the posterior extent of the paddles, an operator is much more likely to place the instrument with greater accuracy as well as incorporate soft tissue balance techniques into his or her surgical technique. These benefits far outweigh the very small errors associated with deflection of the PM instrument's thinner paddles during placement.

[0029] FIG. 3 illustrates an interior, patient matched surface of the body 130. The patient matched surface 130 contacts an anterior surface 10 of the tibia 2. In the depicted

embodiment, the patient matched surface 130 is illustrated using a cross-hatch pattern. This is merely to highlight the area and does not indicate a texture or other surface modification; although, the patient matched area 130 could have a surface roughness different than that of the body 114. In some embodiments, the patient matched surface 130 also contacts the anterior-proximal ridge of the tibia such that the patient matched surface contacts the tibia both superior and inferior of the cutting slot 116. This is significant as the dual contact provides greater repeatability and reproducibility. In addition to the patient matched surface 130, each paddle 110, 112 has a contact surface 132. The patient matched surface 130 and the contact surfaces 132 are used to locate the cutting slot 116 relative to the tibia.

[0030] As best seen in FIG. 4, the cutting slot 116 may include a ledge 140. A user may place the cutting instrument on the ledge 140 and use it as a planar guide for cutting. The ledge 140 may extend beyond an exterior surface 142 of the body 114.

[0031] FIGS. 5 and 6 illustrate a second embodiment of the patient matched instrument 200. In this second embodiment, the patient matched instrument 200 includes a built-in alignment checker 210. The built-in alignment checker has a receiver 212 and a bridge 214. The bridge 214 spaces the receiver 212 away from a body 216 of the patient matched instrument 200. A user places a drop rod (not shown) in the receiver 212 to physically check the alignment of a cutting slot 218 before making a cut. Due to the material properties of some PM instruments, the shape of the bridge has a significant functional effect which can be advantageous. In the embodiment shown, the bridge is designed to rigidly constrain the alignment rod (not shown) to the PM instrument in the sagittal plane but to flexibly constrain in the coronal plane. The intent of this particular embodiment is to allow the operator to alter the sagittal alignment (posterior slope) of the PM tibial instrument while greatly reducing the operator's unintentional alteration of the coronal alignment (varus/valgus) of the PM tibial instrument. It has been found that the coronal alignment of the PM block is more consistent than the sagittal alignment. By allowing users to more accurately alter the sagittal alignment with the use of the alignment rod one but minimizing the effect of the alignment rod on the coronal alignment, the bridge shape preserves the inherent consistency of the PM instrument and allows operators to correct for any inconsistency in the sagittal plane. Other embodiments may also be beneficial to other users or with other PM instrument designs, such as a bridge which is shaped to constrain in both sagittal and coronal alignment or a bridge which is shaped to constrain coronal rather than sagittal alignment.

[0032] FIG. 7 illustrates a third embodiment of the patient matched instrument 300. In this third embodiment, the patient matched instrument 300 includes a quick connect handle 310. Any number of instruments may be connected to the quick connect handle 310. For example, an alignment checker may be connected to the quick connect handle.

[0033] FIG. 8 illustrates an alignment checker guidance tab 400. The alignment checker guidance tab 400 includes a drop rod holder 410 and a quick connect handle 412. The drop rod holder 410 has one or more locations 414 to receive a drop rod (not shown). The alignment checker guidance tab 400 conveniently mates with the patient matched instrument 100 via the cutting slot 116. In some embodiments, the alignment checker guidance tab 400 may include an indentation 416 such that a user can align the groove 120 of the patient

matched instrument **100** with the indentation **416** of the alignment checker guidance tab **400**.

[0034] As best seen in FIG. 9, the patient matched instrument **100** may include a positive stop **150** for locating the alignment checker guidance tab **400**. In the depicted embodiment, the positive stop **150** is a hook-feature that engages a corner **420** of the alignment checker guidance tab **400**. The alignment checker guidance tab **400** may include cantilevered tabs or flaps **430**. The flaps **430** may engage the cutting slot **116**. The flaps **430** may act as a locking mechanism to temporarily lock the alignment checker guidance tab **400** to the patient matched instrument **100** or they may simply frictionally engage the cutting slot **116** to make movement less likely.

[0035] FIG. 10 illustrates pin fixation holes **500** and pins **510** for use in conjunction with a patient matched instrument **100**, **200**, **300**. The pin fixation holes **500** may be located both superior and inferior of the cutting slot **116**, **218**. In the depicted embodiment, four pins are used in four holes but any number of holes and/or pins may be used. Fixation above and below the cutting guide has the effect of reducing resection error due to deformation of the PM instrument when making the resection than a PM instrument without pin fixation above and below the cutting guide.

[0036] FIG. 11 illustrates a patient matched instrument **500**. The patient matched instrument **500** has a first paddle **510**, a second paddle **512**, a body **514**, and a cutting slot **516**. The paddles **510**, **512** extend from the body **514** and are spaced apart from one another such that the paddles **510**, **512** generally contact the medial **6** and lateral **8** tibial condyles. The body **514** may include one or more fixation holes **518**. In the depicted embodiment, the body has five fixation holes but any number of holes may be used. The fixation holes **518** are dimensioned to receive pins (not shown) to temporarily fix the patient matched instrument **500** to the tibia **2**. The cutting slot **516** is dimensioned to receive a cutting instrument, such as a reciprocating blade (not shown). The body **514** has sufficient depth to provide adequate strength to the cutting slot **516** such that bending of the body and skiving of the cutting instrument may be reduced.

[0037] One of the paddles **510**, **512** may be thinner or thicker than the other paddle. In the depicted embodiment, both paddles have a thickness of about 4 mm. The thickness of the paddles may range from about 2 mm to about 15 mm, and more preferably from about 3 mm to about 5 mm. Moreover, the paddles **510**, **512** may be trimmed at different angles to achieve an overall desired height. The overall height of the paddles **510**, **512** may be determined by an offset function relative to the proximal tibia bone surface. Paddles with a sufficient minimum thickness may provide an advantage of allowing for tibial placement prior to making posterior femoral resections.

[0038] As best seen in FIG. 13, the body has an interior, patient matched surface **530**. The patient matched surface **530** contacts the anterior surface **10** of the tibia **2**. In the depicted embodiment, the patient matched surface **530** is illustrated using a cross-hatch pattern. This is merely to highlight the area and does not indicate a texture or other surface modification; although, the patient matched area **530** could have a surface roughness different than that of the remainder of the body **514**. In some embodiments, the patient matched surface **530** also contacts the anterior-proximal ridge of the tibia such that the patient matched surface contacts the tibia both superior and inferior of the cutting slot **516**. This is significant as the dual contact provides greater repeatability and reproduc-

ibility. In addition to the patient matched surface **530**, each paddle **510**, **512** has a contact surface **532**. The patient matched surface **530** and the contact surfaces **532** are used to locate the cutting slot **516** relative to the tibia **2**.

[0039] FIG. 13 also illustrates an anterior-proximal-lateral tibia body contact portion **570** and an anterior medial contact portion **572**.

[0040] The patient matched instrument **500** also includes a hook **550**. The hook **550** is adapted to contact a posterior surface of the tibia **2**. The height and width of the hook **550** may a set size for all patient matched instruments or may be sized based upon a particular patient's anatomy. Although the hook **550** is depicted as being upon the medial paddle, it could also be formed as part of lateral paddle, or both paddles.

[0041] As best seen in FIG. 17, the patient matched instrument **500** includes an area **560** wherein the body **514** is configured to contact a portion of the anterior of the tibia **2** and provides support for the cutting slot **516**. The area **560** is matched to the particular patient's anatomy.

[0042] In use, the tibia **2** is exposed via surgical incision. The patient matched cutting block **500** is placed on the tibia **2** and located in a home position. Pins (not shown) are inserted into the fixation holes **518**. The cutting instrument is reciprocated in the cutting slot **516** to remove bone from a proximal end of the tibia **2**.

[0043] FIG. 19 yet another embodiment of the patient matched instrument **600**. The patient matched instrument **600** includes a confidence point **614**, which is formed by the intersection of first member **610** and second member **612**. The confidence point may be placed over the ACL attachment point or some other anatomical landmark. Confidence point **614** may be just a visual aid provided by the intersection of members **610**, **612** or a hole location. For example, a pin (not shown) may be inserted into the confidence point **614**. A user, such as a surgeon, may view the anatomical landmark (e.g., ACL attachment) relative to the confidence point **614**.

[0044] In some embodiments, in order to give a user more confidence in placing a patient matched instrument and/or to minimize the chance of false placement, the patient matched instrument may be provided with certain combined features that act in synergy to enhance the patient matched instrument's fit, stability, and/or constraint. As examples, such features may be larger paddles, anterior medial contact, slot contact, and/or the posterior hook. The location, dimensions, and combinations of particular features may be worked into an algorithm based upon the patient's anatomy and/or user preference. For example, to improve varus/valgus constraint, the features may focus on constraint provided by the medial and lateral paddles. Alternatively, to enhance flexion and extension, the features may focus on constraint provided by the hook and the body along the anterior portion. Otherwise, to enhance rotation, the features may focus on constraint provided by the slot contact and the anterior-proximal-lateral tibia body contact.

[0045] Any of the features of the embodiments disclosed herein may be combined in various combinations to form alternative embodiments.

[0046] As various modifications could be made to the exemplary embodiments, as described above with reference to the corresponding illustrations, without departing from the scope of the invention, it is intended that all matter contained in the foregoing description and shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the invention should not

be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the claims and their equivalents.

[0047] In view of the foregoing, it will be seen that the several advantages of the invention are achieved and attained.

[0048] The embodiments were chosen and described in order to best explain the principles of the invention and its practical application to thereby enable others skilled in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

[0049] As various modifications could be made in the constructions and methods herein described and illustrated without departing from the scope of the invention, it is intended that all matter contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. For example, while FIG. 5 illustrates built-in alignment checker, other structure and/or methods may be used to check the alignment of the patient matched instrument. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims appended hereto and their equivalents.

What is claimed is:

1. A patient matched instrument comprising:
 - a. a body having an interior patient matched surface;
 - b. a cutting slot extending through at least a portion of the body;

- c. a first paddle extending from the body; and
- d. a second paddle spaced apart from the first paddle and extending from the body; and wherein at least one of the first paddle and the second paddle further comprises a hook.

2. The patient matched instrument of claim 1, wherein the body includes at least one fixation hole.

3. The patient matched instrument of claim 1, wherein one of the first paddle and the second paddle is thinner or thicker than the other paddle.

4. The patient matched instrument of claim 1, wherein the interior patient matched surface has a surface roughness different than the remainder of the body.

5. The patient matched instrument of claim 1, wherein the cutting slot comprises a ledge.

6. The patient matched instrument of claim 1, further comprising an area of the body configured to contact a portion of an anterior of a particular patient's tibia and is matched to the particular patient's anatomy.

7. The patient matched instrument of claim 1, further comprising a first member and a second member, and wherein the first member and the second member intersect to provide a confidence point.

8. The patient matched instrument of claim 1, further comprising a built-in alignment checker.

9. The patient matched instrument of claim 8, wherein the built-in alignment checker has a receiver and a bridge.

10. The patient matched instrument of claim 1, wherein each paddle has a contact surface.

11. The patient matched instrument of claim 10, wherein the interior patient matched surface and the contact surfaces are used to locate the cutting slot.

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