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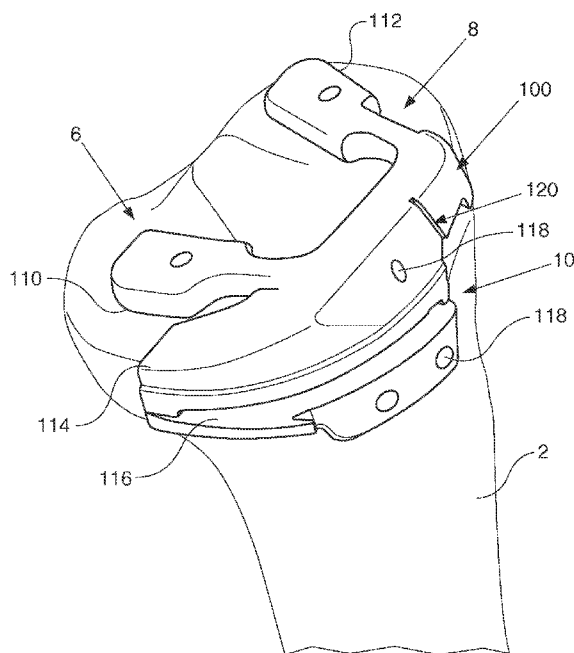
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(54) Title: PATIENT MATCHED INSTRUMENT

Fig. 1



(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.



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Patient Matched Instrument

Cross-Reference to Related Applications

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

Background of the Invention

1. Field of the Invention

[0002] Embodiments of the present invention generally relate to surgical instruments
10 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.

2. Related Art

15 [0003] 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
20 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.

[0004] To date, at least some patient-matched surgical instruments for use in total
25 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),
5 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
10 such that it is adapted to conform to the patient's anatomy in a single spatial orientation.

[0005] 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
15 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
20 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

[0006] 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
5 instrument incorporates design features that encourage consistent placement and accurate placement.

[0007] 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
10 invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

Brief Description of the Drawings

[0008] The accompanying drawings, which are incorporated in and form a part of the
15 specification, illustrate embodiments of the present invention and together with the description, serve to explain the principles of the invention. In the drawings:

[0009] 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
20 to explain the principles, characteristics, and features of the invention. In the drawings:

[0010] FIG. 1 shows a side perspective view of a patient matched instrument mounted on a left tibia.

[0011] FIG. 2 illustrates a perspective view of the patient matched instrument shown in FIG. 1.

[0012] FIG. 3 illustrates a posterior-anterior perspective view of the patient matched instrument shown in FIG. 1.

[0013] FIG. 4 illustrates a medial-lateral view of the patient matched instrument shown in FIG. 1.

5 [0014] FIG. 5 shows a side perspective view of a patient matched instrument mounted on a left tibia in a second embodiment.

[0015] FIG. 6 illustrates a perspective view of the patient matched instrument shown in FIG. 5.

[0016] FIG. 7 shows a side perspective view of a patient matched instrument
10 mounted on a left tibia in a third embodiment.

[0017] FIG. 8 illustrates a superior-inferior view of a patient matched instrument in a fourth embodiment.

[0018] FIG. 9 illustrates detailed views of the patient matched instrument shown in FIG. 8.

15 [0019] FIG. 10 illustrates pin mounting locations that may be used with any of the above listed embodiments.

[0020] FIG. 11 shows a side perspective view of a patient matched instrument in a fifth embodiment.

[0021] FIGS. 12-15 illustrate a perspective view of the patient matched instrument
20 shown in FIG. 11.

[0022] FIGS. 16-18 show the patient matched instrument of FIG. 11 as mounted on a tibia.

[0023] FIG. 19 shows a superior-inferior view of a patient matched instrument in a sixth embodiment.

25

Detailed Description of the Embodiments

[0024] Referring to the accompanying drawings in which like reference numbers indicate like elements, Figure 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.

[0025] 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.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

5 **[0031]** 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
10 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.

[0032] 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
15 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
20 cutting slot 116 to make movement less likely.

[0033] 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
25 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.

[0034] 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.

[0035] 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.

[0036] 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.

5 This is significant as the dual contact provides greater repeatability and reproducibility. 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.

[0037] FIG. 13 also illustrates an anterior-proximal-lateral tibia body contact portion
10 570 and an anterior medial contact portion 572.

[0038] 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 be 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
15 could also be formed as part of lateral paddle, or both paddles.

[0039] 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.

20 [0040] 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.

[0041] FIG. 19 yet another embodiment of the patient matched instrument 600. The
25 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
5 614. A user, such as a surgeon, may view the anatomical landmark (e.g., ACL attachment) relative to the confidence point 614.

[0042] 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
10 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
15 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.

[0043] Any of the features of the embodiments disclosed herein may be combined in
20 various combinations to form alternative embodiments.

[0044] 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
25 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.

[0045] In view of the foregoing, it will be seen that the several advantages of the invention are achieved and attained.

5 [0046] 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.

[0047] As various modifications could be made in the constructions and methods
10 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
15 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.

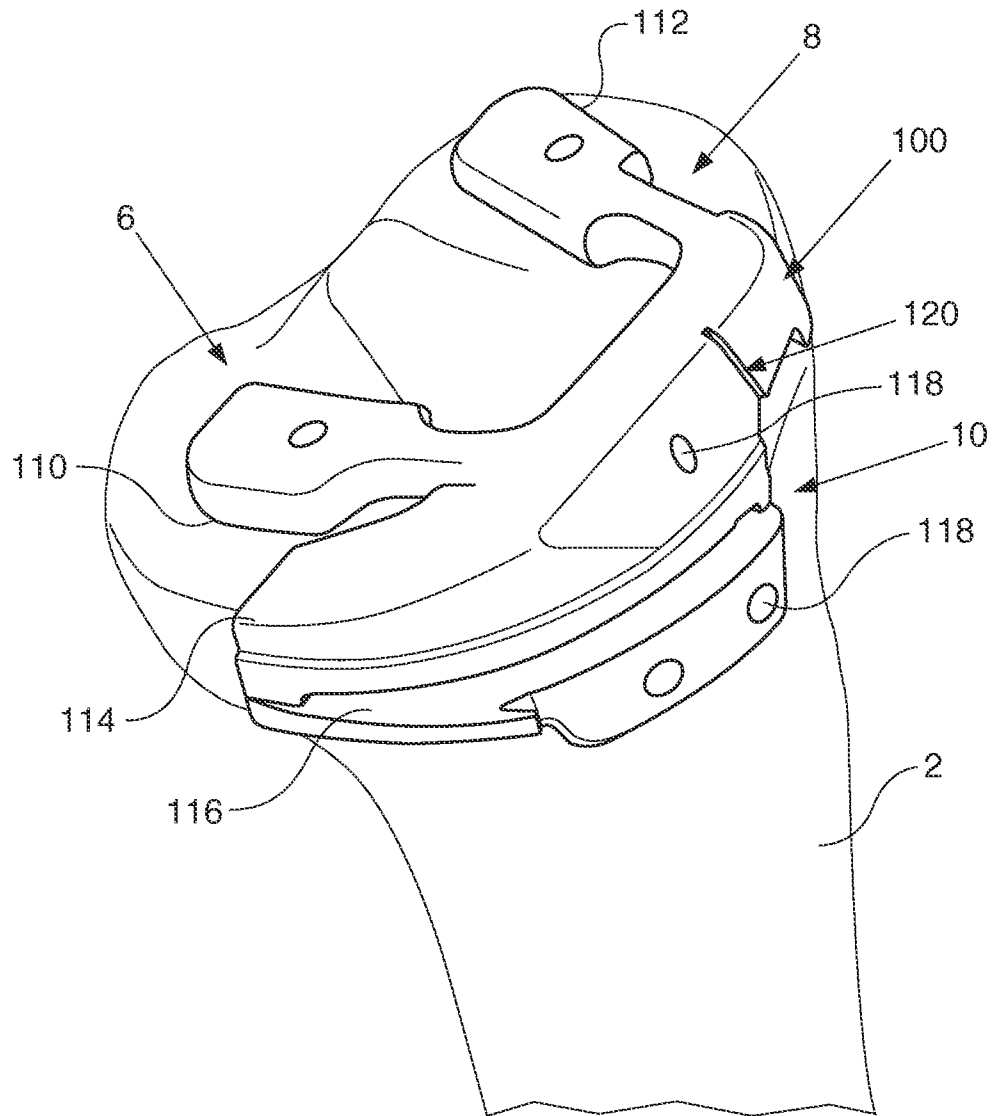
What is Claimed Is:

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;
 - 5 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.
- 10 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.
- 15 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
20 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
25 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.

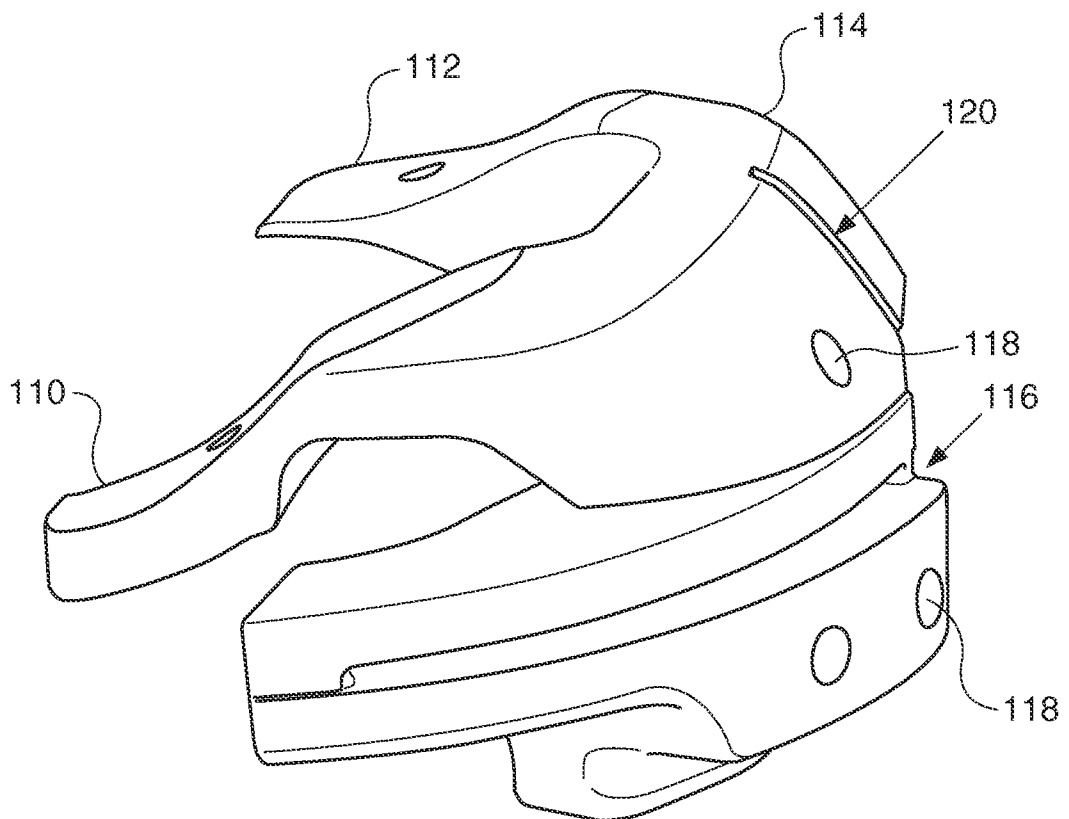
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Fig. 1



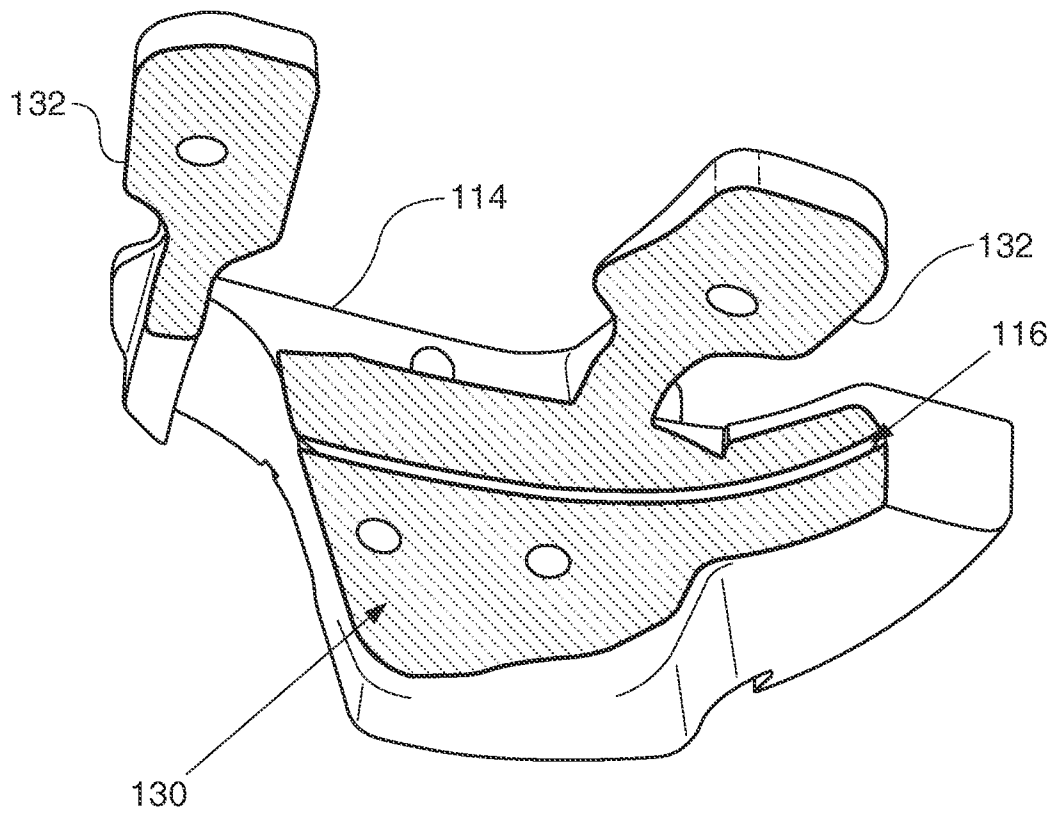
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Fig. 2



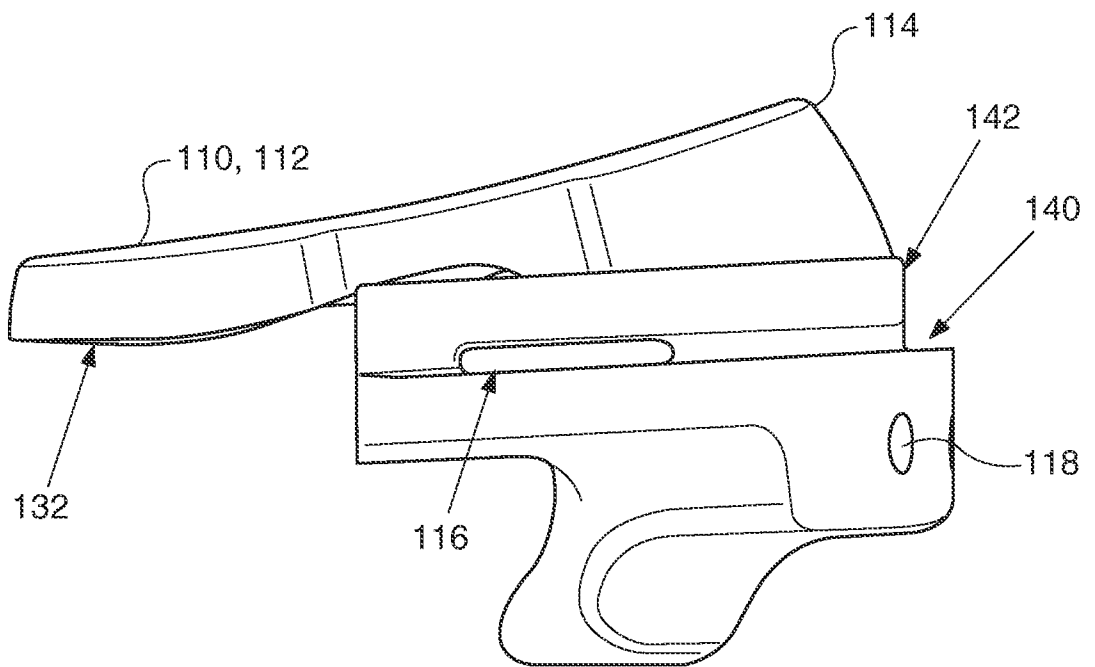
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Fig. 3



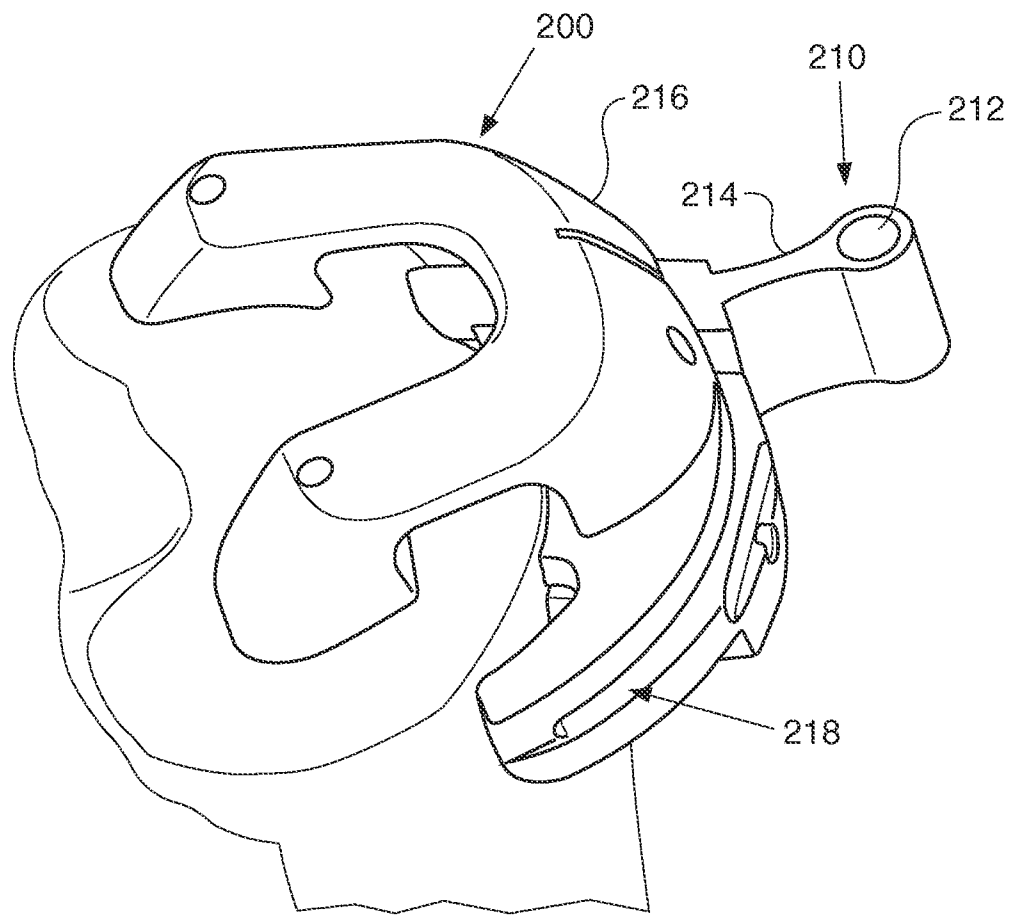
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Fig. 4



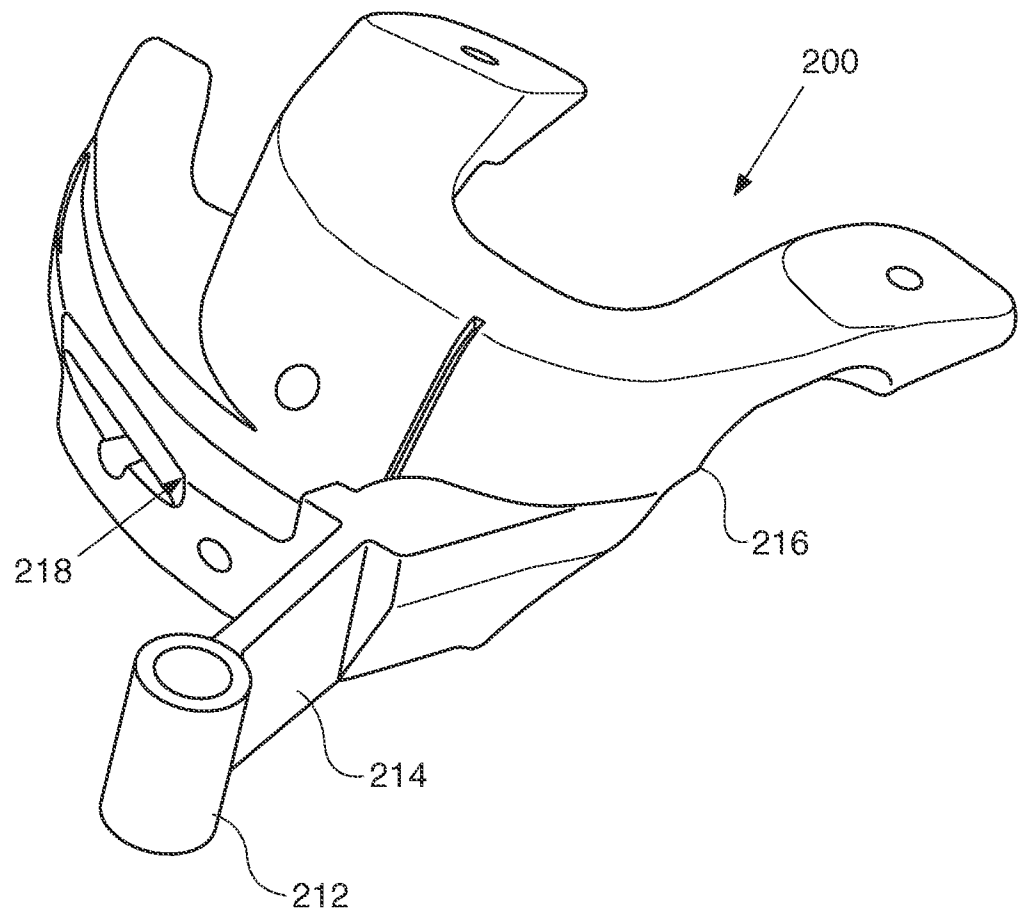
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Fig. 5



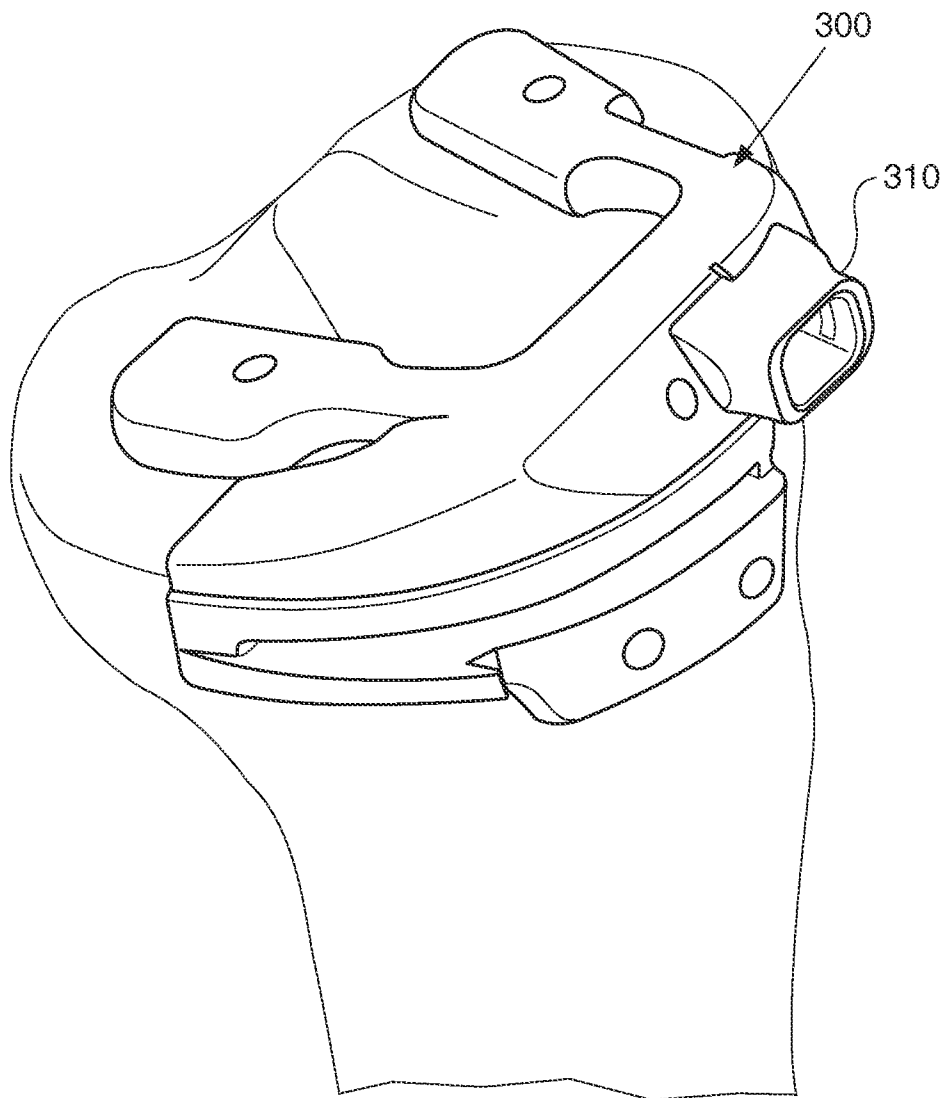
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Fig. 6

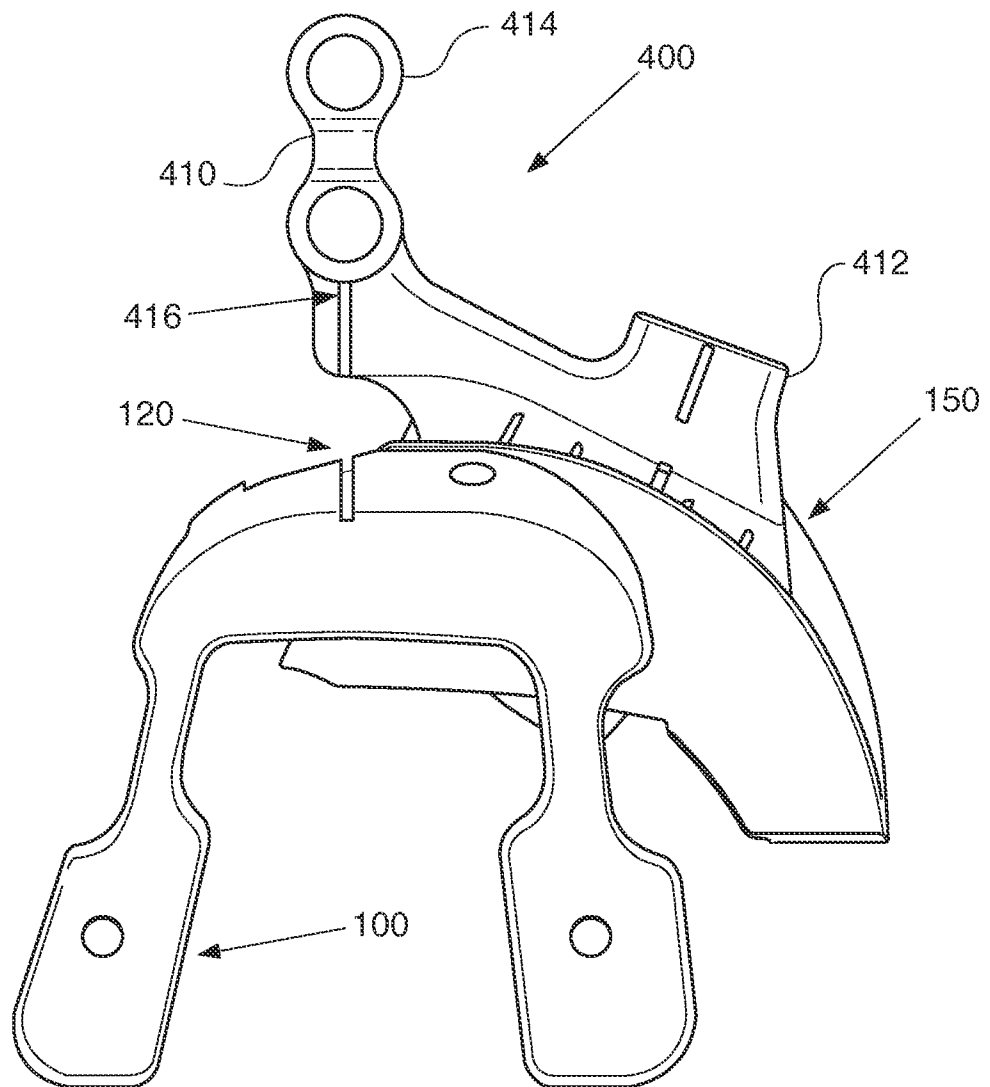


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Fig. 7

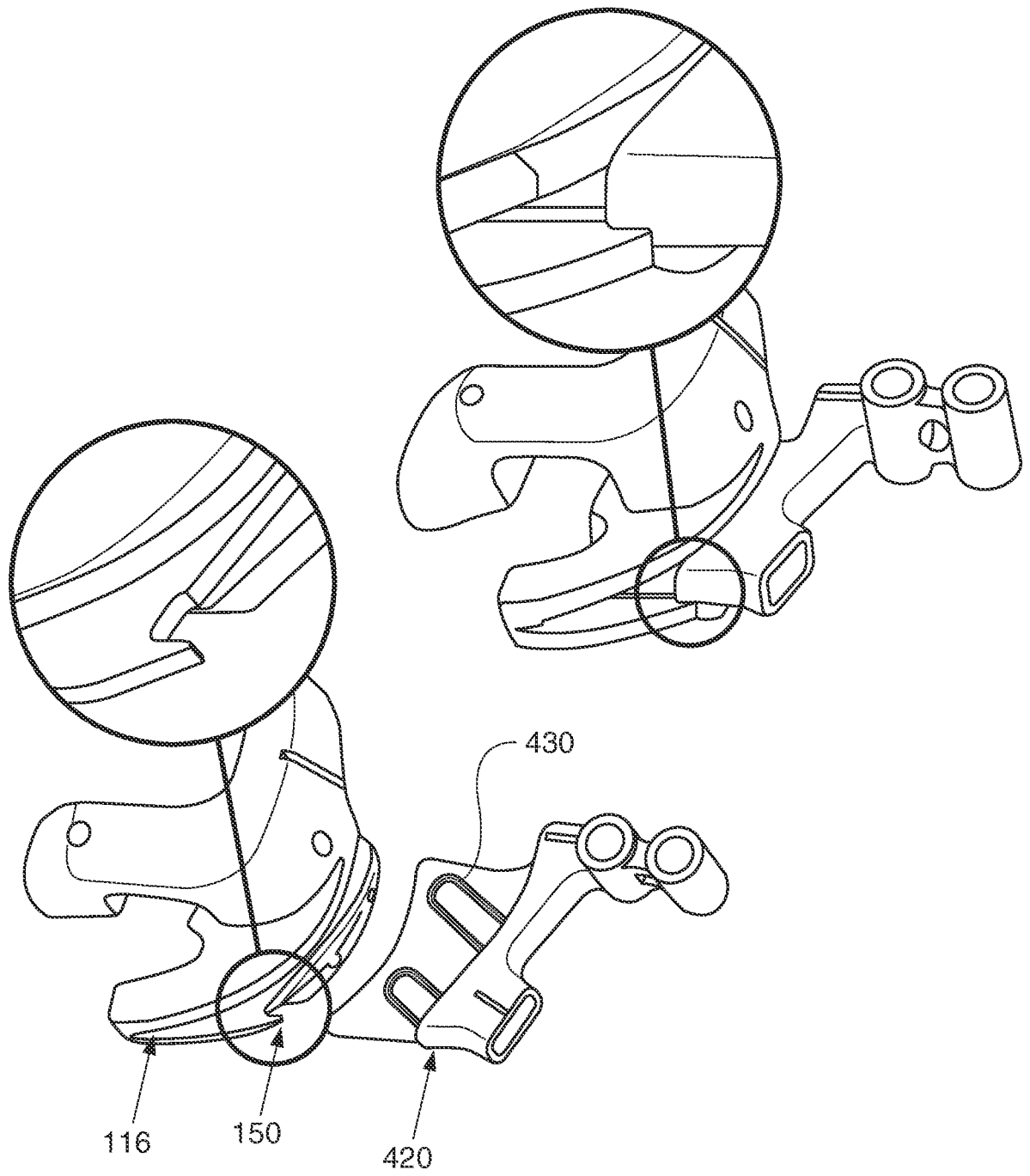


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Fig. 8

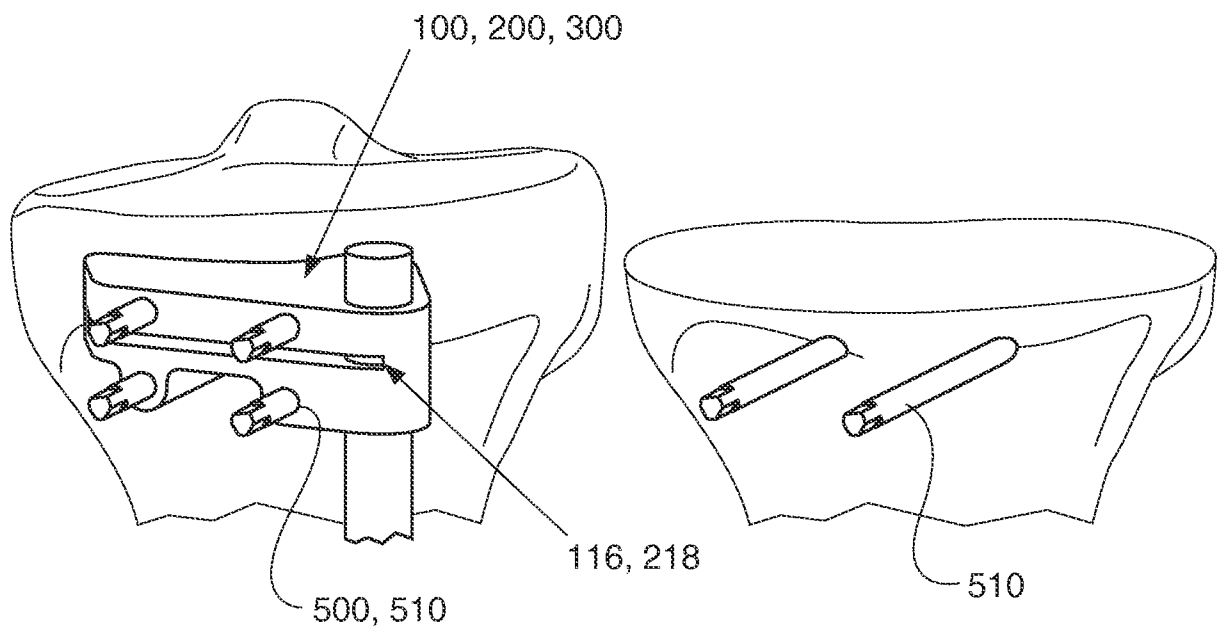
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Fig. 9

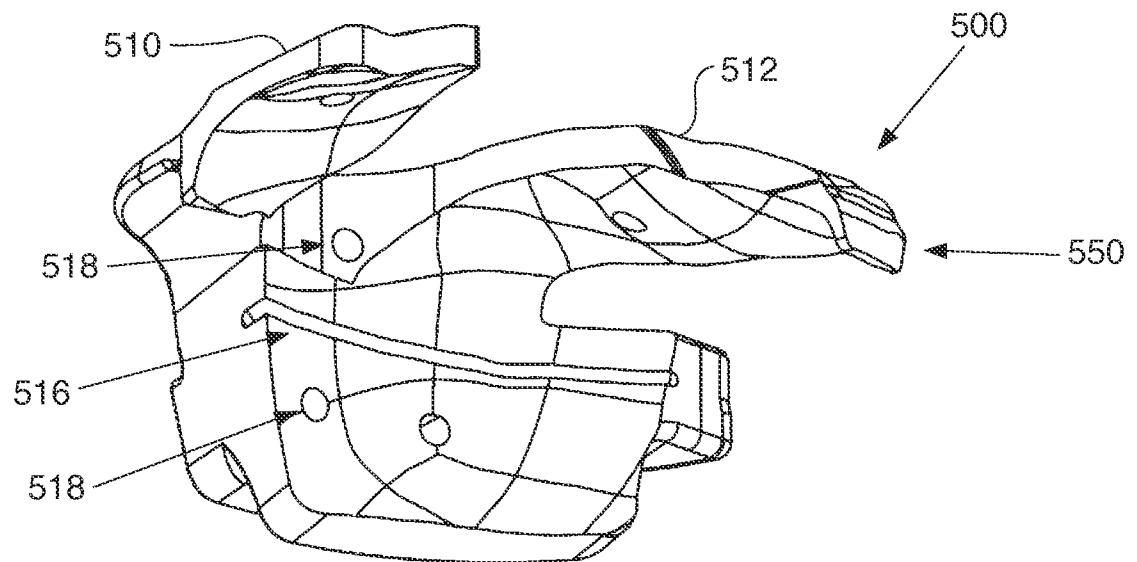
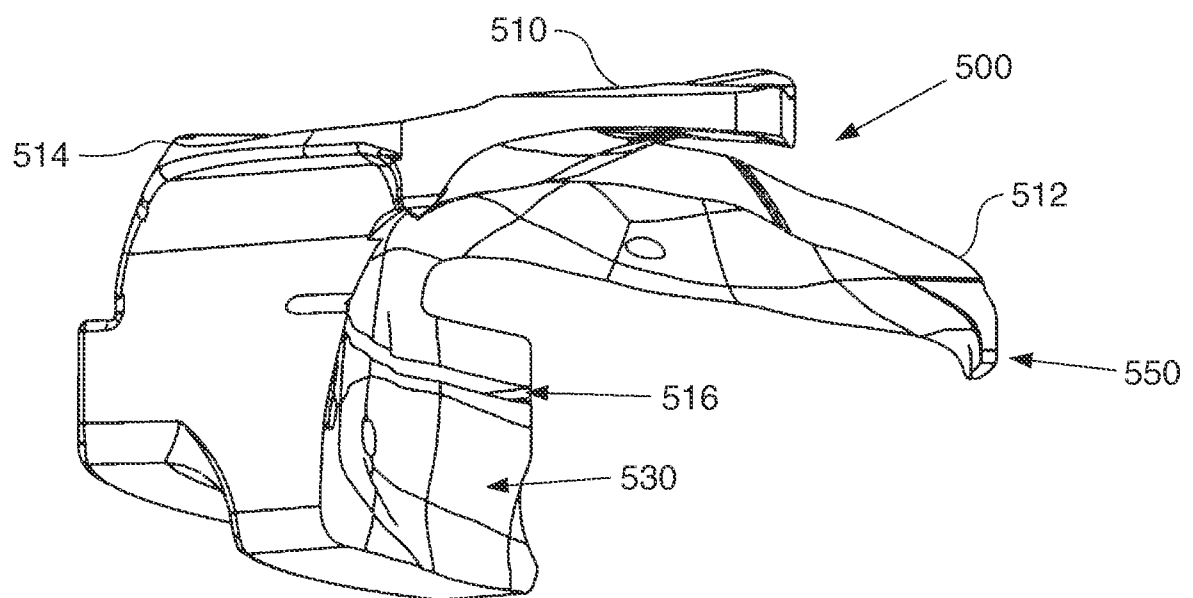


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Fig. 10



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Fig. 11**Fig. 12**

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Fig. 13

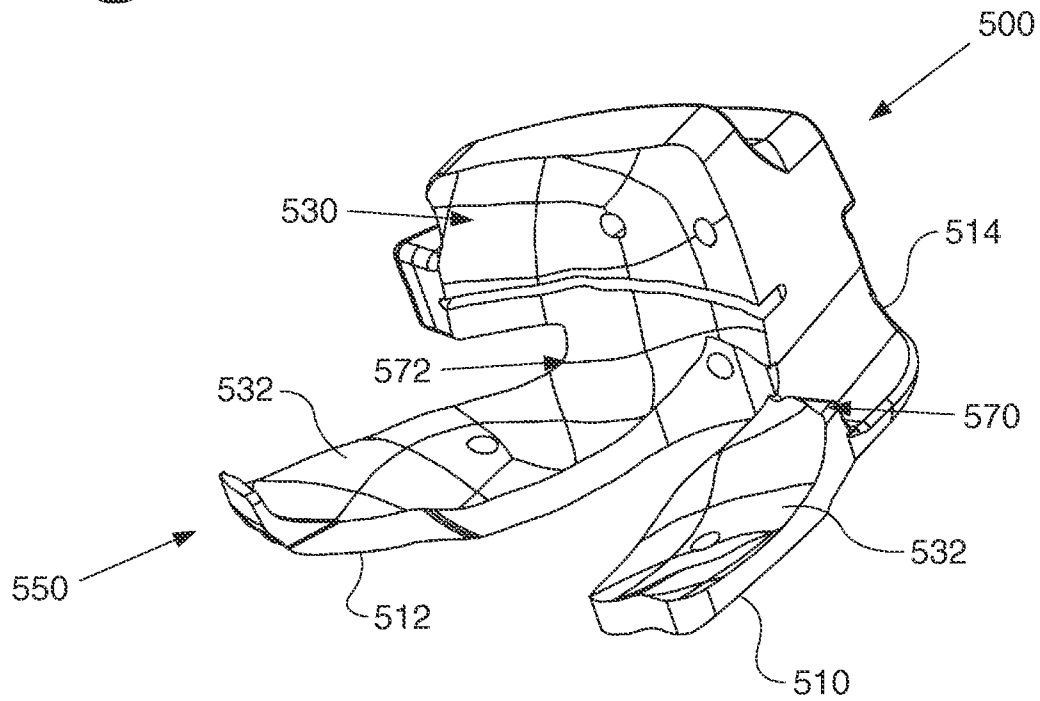
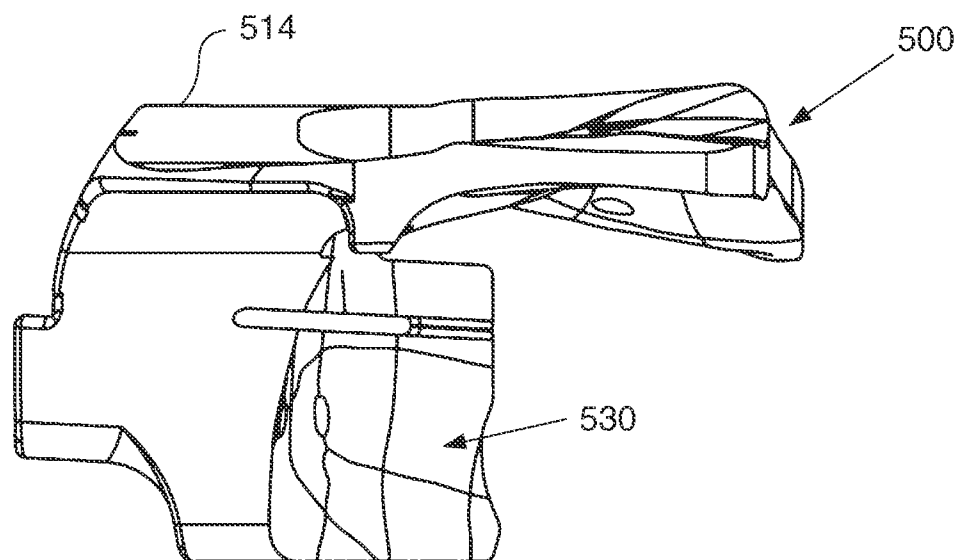
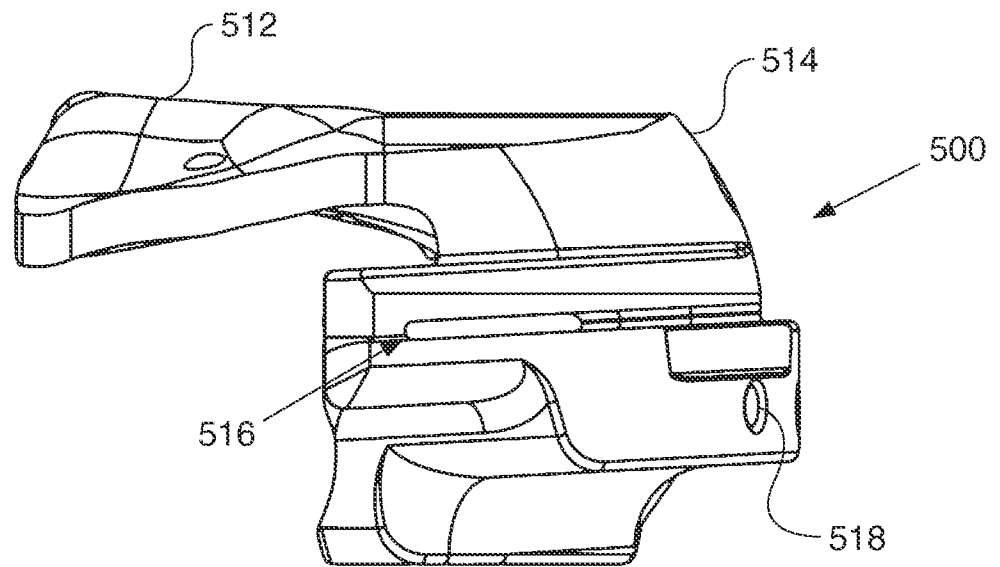
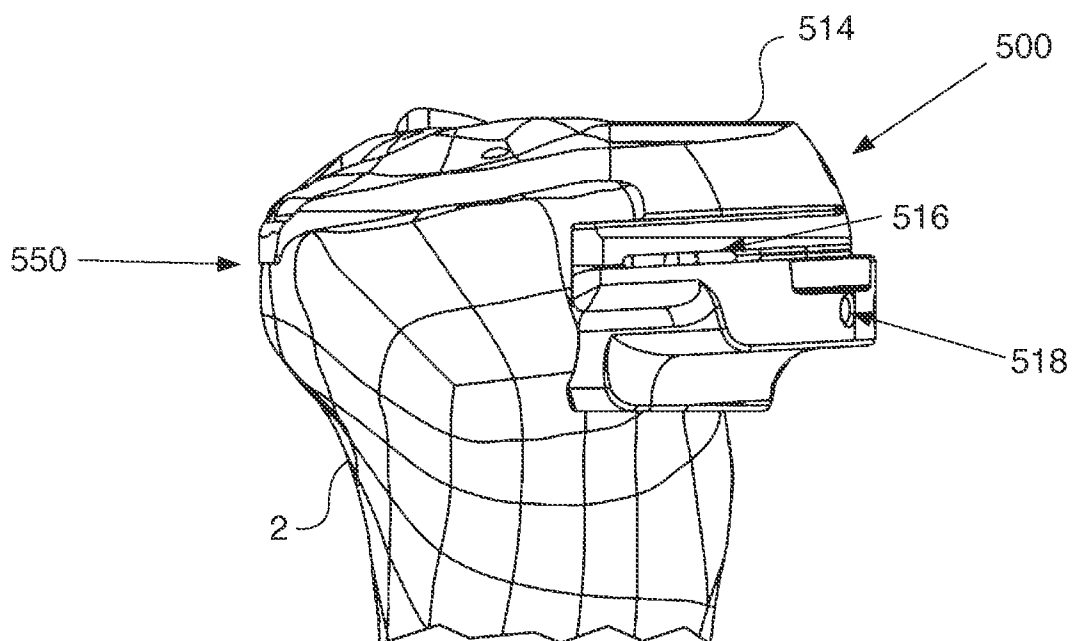


Fig. 14



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Fig. 15**Fig. 16**

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Fig. 17

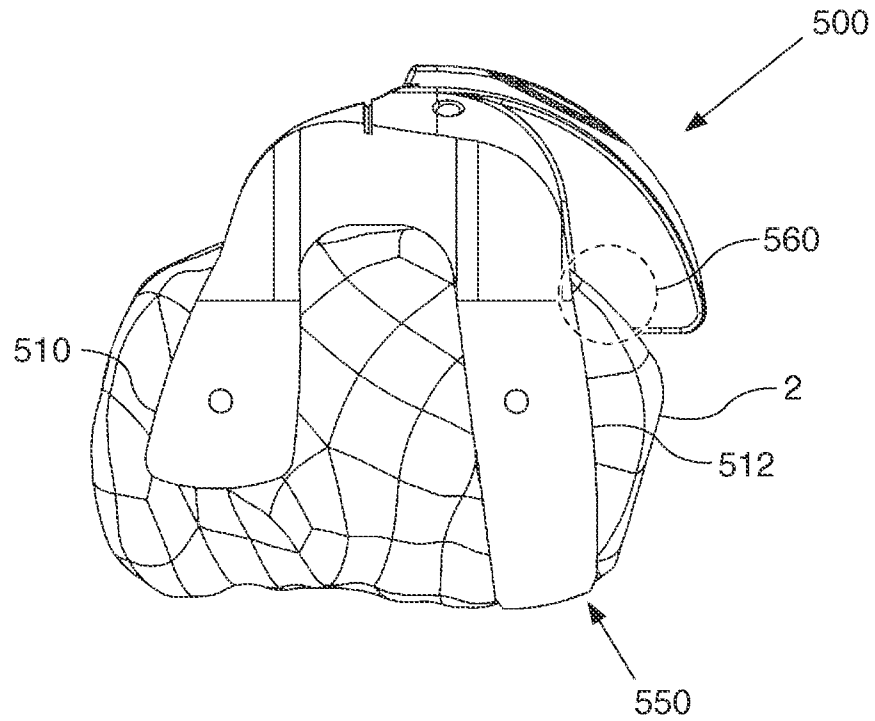
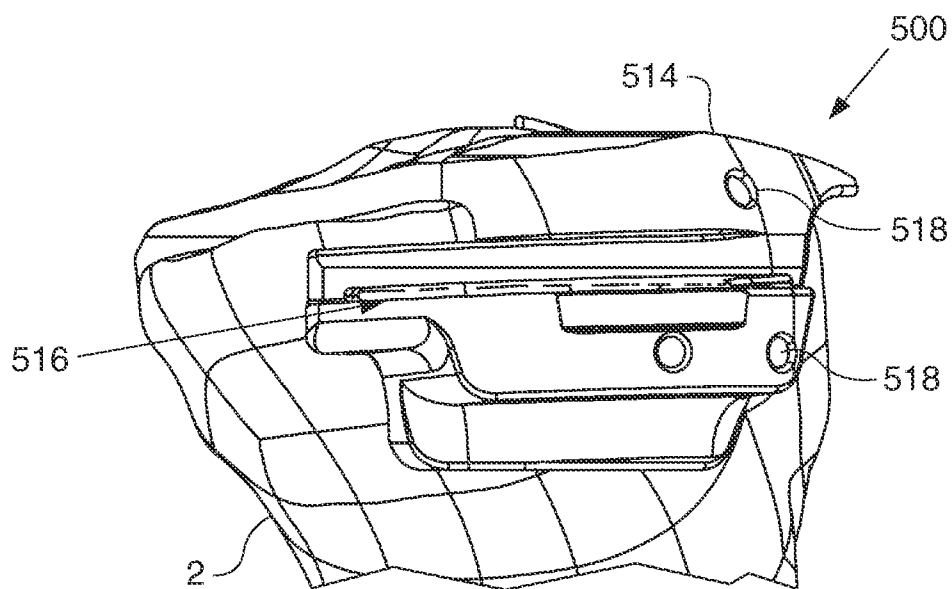
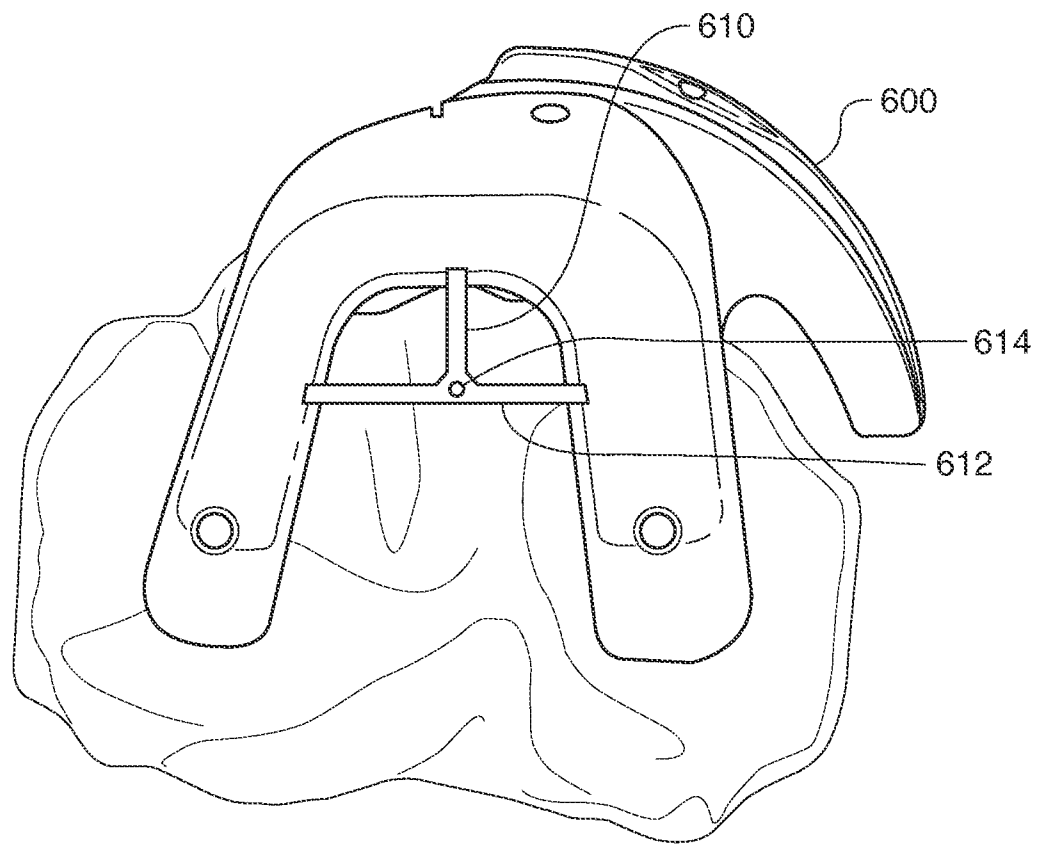


Fig. 18



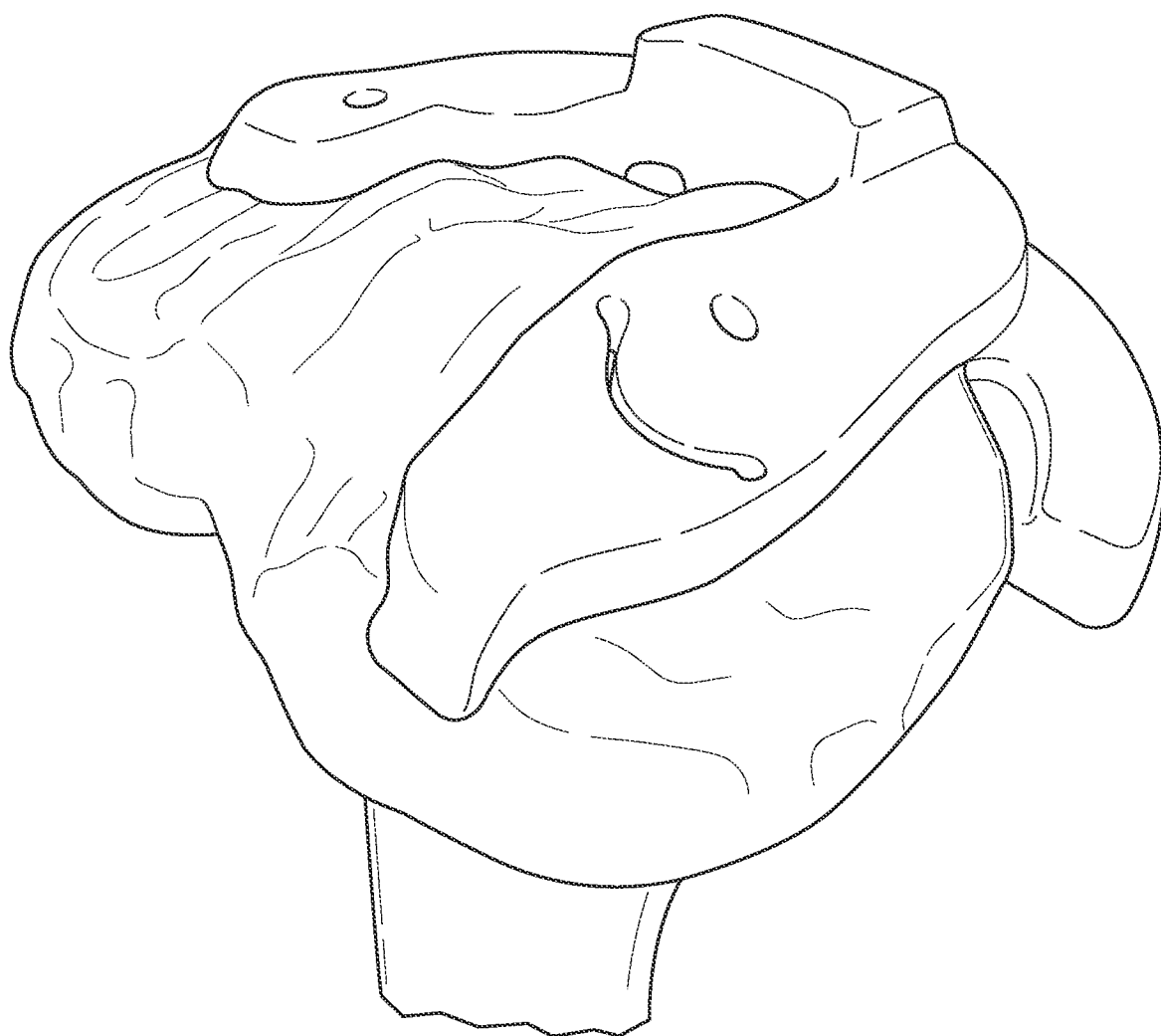
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Fig. 19



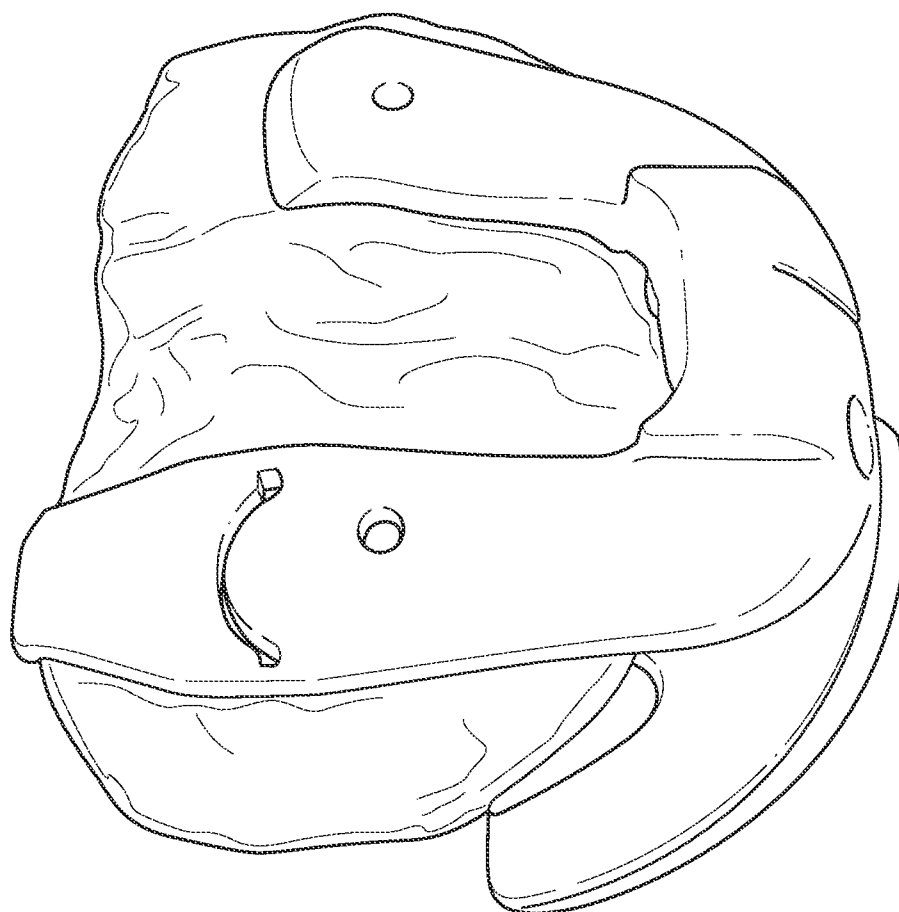
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Fig. 16



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Fig. 17



A. CLASSIFICATION OF SUBJECT MATTER**A61B 17/15(2006.01)i, A61B 17/56(2006.01)i, A61B 17/90(2006.01)i**

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 17/15; A61B 17/16; A61B 19/00; A61B 17/00; A61B 17/56; A61B 17/90

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: patent matched, tibial, cutting slot, drop rod, acl attachment, hook, paddle

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	US 2011-0092977 A1 (SALEHI, A. B. et al.) 21 April 2011 See paragraphs [0016], [0023]-[0025], [0029], [0031]; figures 1, 4, 5.	1-6, 10, 11
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Y	US 2010-0305575 A1 (WILKINSON, Z. C. et al.) 02 December 2010 See paragraph [0089]; figure 16.	1-6, 10, 11
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