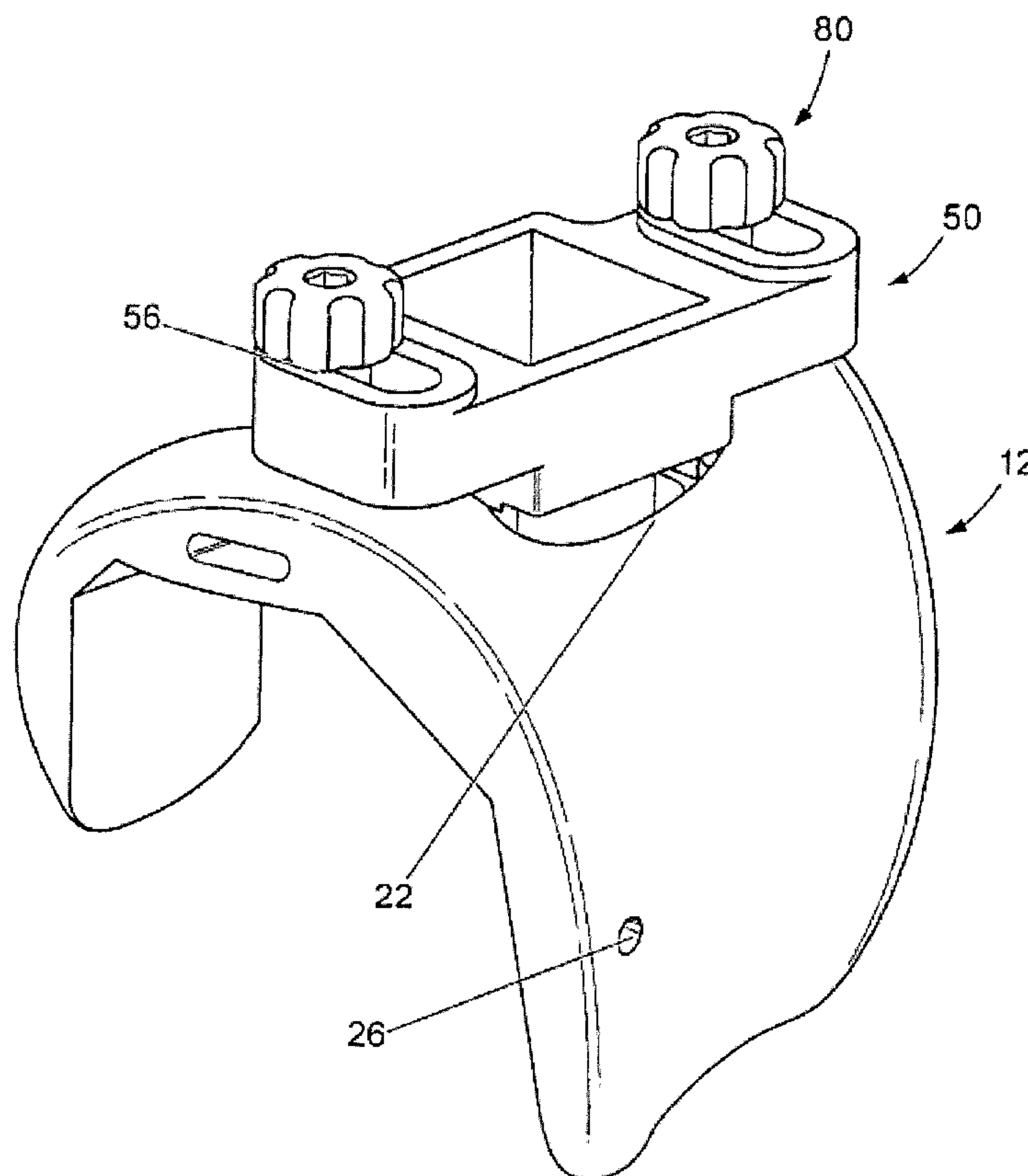




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(72) Inventeur/Inventor:
DEES, ROGER RYAN, JR., US
(73) Propriétaire/Owner:
SMITH & NEPHEW, INC., US
(74) Agent: BORDEN LADNER GERVAIS LLP

(54) Titre : DISPOSITIF D'ESSAI DE FEMUR DISTAL AVEC GUIDE DE DECOUPAGE AMOVIBLE
(54) Title: DISTAL FEMORAL TRIAL WITH REMOVABLE CUTTING GUIDE



(57) Abrégé/Abstract:

Various embodiment of the present invention provide a distal femoral trial that allows a surgeon to cut the central box geometry of a distal femur using an implant-shaped trial. The trial includes a cutting guide that is removable from the trial and adjustable with respect to the trial. The guide is intended to control the depth and direction of the cutting instruments used to prepare the femur for the a posterior stabilized implant.

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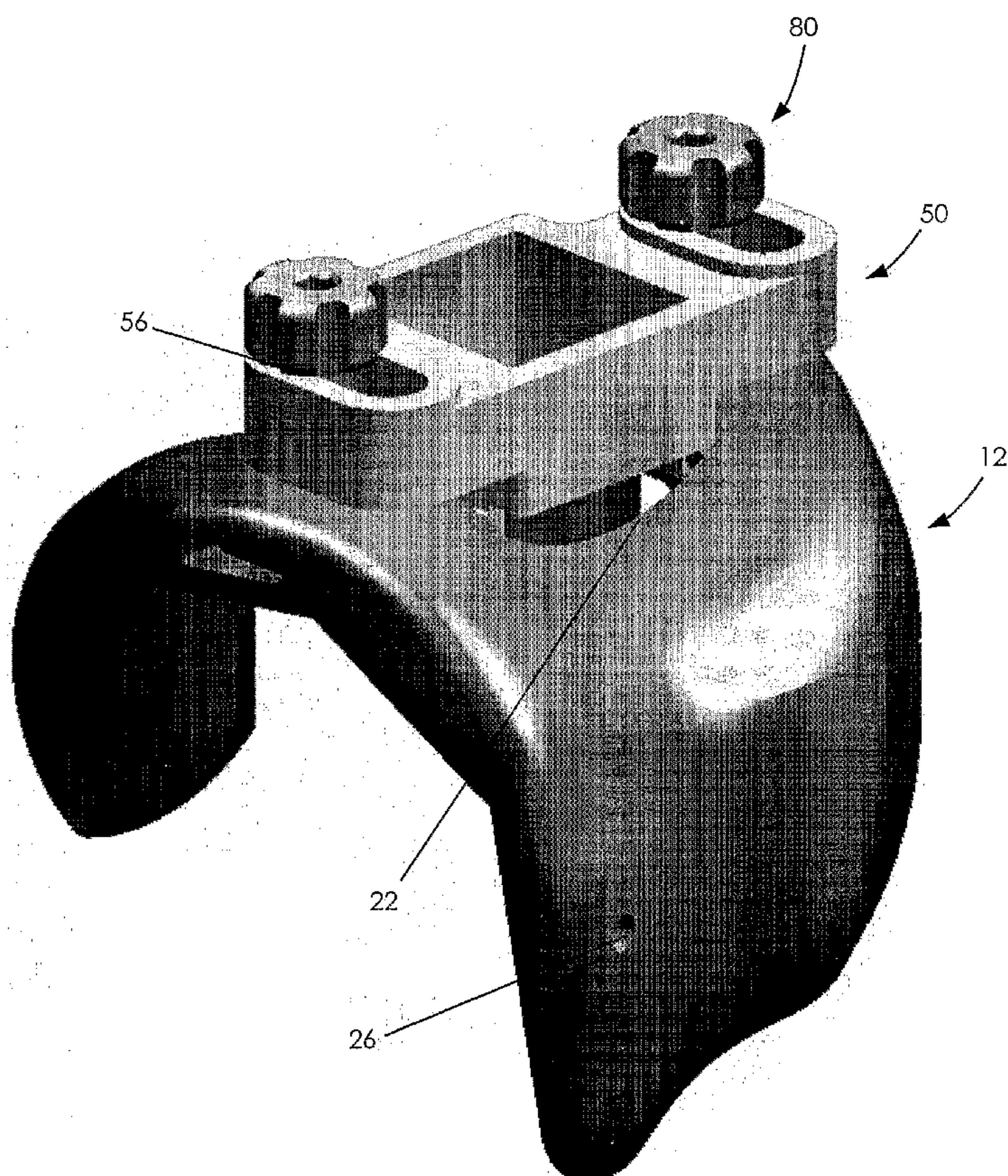
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(72) Inventor; and

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DISTAL FEMORAL TRIAL WITH REMOVABLE CUTTING GUIDE

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FIELD OF THE INVENTION

The present invention relates generally to surgical orthopaedic trials and methods, particularly to trials and methods for preparing the distal femur of a patient
10 to receive a femoral prosthesis.

BACKGROUND

Patients suffering from unstable, painful knee joints where the instability is caused by the lack or insufficiency of the posterior cruciate ligament may be
15 candidates for a total knee arthroplasty using a posterior-stabilized knee prosthesis. Such an implant or prosthesis includes a tibial component, a femoral component, and typically, a mobile bearing insert (a patella component).

The tibial component is secured to a resected portion of the patient's tibia. This component has a post that receives a bearing or patella component. The
20 femoral component typically has inner intersecting flat surfaces that interface with a surgically prepared distal femoral surface, and an outer surface with a curvature that faces the corresponding tibial component attached to the patient's tibia. The femoral component has two condylar regions with an intercondylar stabilizing housing that accepts the tibial post. These posterior stabilized and constrained femoral implant
25 components have a cam housing in between the condyles of the femur (or the condylar regions).

Bone from the distal femur must be removed from this area to accommodate for this type of cam housing. This may be referred to as cutting the central box geometry. The housing sizes may differ for posterior stabilized and constrained type
30 femoral components. The sizes may also differ from patient to patient and implant to implant. Therefore, a different amount of bone depth may need to be removed, depending upon the patient and the type of femoral implant that will be used.

For optimum results, range of motion, and patient comfort, it is important that the tibial and femoral components are properly aligned relative to the tibia and femur during implantation of the components. There are many accompanying instruments that are used to prepare the femur, e.g., cutting blocks, reamers, saws, chisels, and trial components.

Typically, the posterior bone removed from the distal femur to accommodate the cam housing discussed above is removed using a cutting block and collet configuration. One example is shown and described by U.S. Patent 5,819,829. The cutting block is placed on the patient's femur with bone spikes and used to make anterior/posterior chamfer cuts. A rotary reamer is then inserted through a collet in the block to prepare the femur for the cam housing (to cut the central box geometry). A box chisel can then be used to complete the preparation. All of this preparation is done using the cutting block as the reference guide.

Some problems encountered with the use of such a system are that once the surgeon has prepared the desired cuts in the femur, s/he will need to remove the cutting block and secure a femoral trial to the prepared distal femur in order to check the fit and sizing. This trialing step is important to ensure that the ultimate component that is implanted fits the area that has been prepared. If additional preparation for the area where the cam housing will fit needs to be done, the trial is removed, the cutting block is re-positioned (which often requires insertion of additional bone spikes) and the cuts are further perfected. It is possible that this procedure may need to be repeated more than once, causing undesired and additional bone removal or degradation during each repositioning step.

Moreover, when the bone is removed to receive the posterior stabilized and constrained femoral implant components through the cutting block, the surgeon does not have a "feel" for how the cuts relate to the actual implant because the cutting block is not shaped like the implant. It is essentially a square block.

Other systems have attempted to cut central box geometry through a femoral trial, but they have not used a constrained box geometry, which can be important to control the reaming instruments and to prevent damage to tissues that are not to be removed. If the trial being used a cutting guide does not have a posterior ledge or stopping portion, it is not always clear where the posterior cutting should stop.

Moreover, such systems also fail to provide the desired adjustability that is needed in many cases. If the cutting guide is attached at only a single position with respect to the trial, the surgeon is limited to preparing the box geometry only where the cutting guide sits. See e.g., U.S. Patent 4,721,104.

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Accordingly, there is a need in the art to provide a distal femoral trial that allows a surgeon to cut the central box geometry of a distal femur using an implant-shaped trial, while also providing removability and adjustability of the guide that controls the depth and direction of the cutting instruments. There is also a need for
10 such systems that provide constrained box geometry. There is a further need for surgical methods and kits that use such a trial.

SUMMARY

Various embodiment of the present invention provide a distal femoral trial that
15 allows a surgeon to cut the central box geometry of a distal femur using an implant-shaped trial. The trial includes a cutting guide that is removable from the trial and adjustable with respect to the trial. The guide is intended to control the depth and direction of the cutting instruments used to prepare the femur for a posterior stabilized implant.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an exploded perspective view of an assembly according to one embodiment of the invention.

FIG. 2 shows the embodiment of FIG. 1 in an assembled position.

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FIGS 3A and 3B show an example of an implant that is to be received by the bone prepared using various embodiments of this invention.

FIG. 4 shows an example of a reamer that may be used to prepare a patient's bone in connection with various embodiments of the assemblies described herein.

FIG. 5A shows a side perspective view of an alternate embodiment of a trial
30 that may be used according to various embodiments of the invention.

FIG. 5B shows a top plan view of an alternate embodiment of a trial.

FIG. 6 shows a side perspective view of an alternate cutting block that may be used according to various embodiments of the invention.

FIG. 7 shows the trial of FIG. 5 in combination with the cutting block of FIG. 6.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a femoral trial component 12, a cutting guide 50, and retaining bolts 80, collectively referred to as assembly 10. FIG. 7 shows an alternate femoral trial component 112 and cutting guide 150, collectively referred to as assembly 100. In both embodiments, the trial 12, 112 is made with the same or similar proximal and anterior/posterior box geometry as the prosthesis that will be used so that it fits the geometry of the surface of the femur that has already been resected. It also has the same articulating surface as the prosthesis except that there is an opening to accommodate a cutting guide to prepare the central stabilizing/constraining box geometry. As shown in FIG. 7, the trial may also include various cutting slots 114, allowing the trial to also be used to prepare various resections on the femur. This feature is optional and although only shown with response to the embodiment shown in FIG. 8, may be used on any trial made according to various aspects of this invention.

In a specific embodiment, the trial 12 has two condylar regions 14 and an anterior patellar region 34 with an articulating surface 36. The condylar regions 14 define an opening 16. This opening 16 is where the distal femur is prepared to receive an implant having a cam that cooperates with a tibial post. An example of the cam portion 202 of an actual implant 200 is shown in FIGS. 3A and 3B. The bone of the femur must be prepared to make room to receive this cam 202, and the opening 16 in trial 12 allows the space for instruments to pass during preparation.

The opening 16 defines a central portion 18 of the implant 12 that has an anterior-most portion 22 and opening side edges 24. In the particular embodiment shown, in FIGS. 1 and 2, the opening side edges 24 define orientation slots 20. Orientation slots 20 are adapted to receive base 52 of cutting guide 50. In the particular embodiment shown, cutting guide base 52 is defined by an outer flange 58. Edges of flange 52 may slide into orientation slots 20 to secure trial 12 and cutting guide 50 together.

The trial 12 also features one or more fixation holes 26, an example of which is shown in FIG. 2. Fixation holes 26 are adapted to receive pins, screws, pegs, or another securing mechanism to secure trial 12 in place on the patient's bone.

In a particular embodiment, the trial 12 has receiving portions 28, which are
5 adapted to receive bolts 80. Bolts 80 are intended to secure cutting guide 50 in place, explained in more detail below. Receiving portions 28 may or may not feature threads 30.

Another embodiment of trial 12 may have one or more slight indentations at the posterior end of the trial the provide stopping points to allow a post of cutting
10 block to sit into as it is moved into position. For example, the indentation could receive a movable securing pin of the cutting guide that secures cutting guide in place with respect to trial 12 without the need to use bolts 80, the use of which are described in more detail below. Further connection mechanisms may be used also; the general concept is to provide a trial and a cutting block that are securable in a
15 fixed position, but where that fixed position is adjustable before being secured.

A further embodiment of trial 112 is shown in FIGS. 5A and 5B. This trial 112 may be similar to trial 12 in that it has condylar regions and other similar features. In the particular embodiment shown, however, the trial 112 has an opening 16 with an anterior abutment portion 116 at its anterior-most portion. The anterior abutment
20 portion 116 is intended to receive a corresponding anterior abutment pin 152 of cutting block 150, shown in FIG. 6. In use, member 154 is pulled up (in the direction of arrow "A"), which causes pin 152 to be pulled up in the same direction. This may be accomplished through the use of a spring and spring pin assembly or any other feature. If a spring and spring pin is used, the upward movement of member 154
25 compresses a spring 156 that rests on top of member 154 and is retained in the guide 150. When member 154 is released, spring 156 forces pin 152 to extend out of guide 150 to the extended position shown in FIG. 6.

In use, while member 154 is activated and pin 152 is retracted, the cutting block 150 is slid into place in the opening of trial 112 along orientation slots 20.
30 When the proper position has been reached, the user releases member 154, causing pin 152 to extend from block 150. In some embodiments, pin 152 interfaces with abutment portion 116 of trial 112, as shown in FIG. 7. In even further and preferred embodiments shown in FIG. 5B, pin 152 may be received by pin receiving portion

118 to secure pin 152 (and cutting guide 150) in place. To remove guide 150 from trial 112, the member 154 is lifted back up and the guide can slide out of orientation slots 20. In a particularly preferred embodiment, the trial 112 may have a pin receiving portion 118, as shown in FIG. 5B. In a particular embodiment, pin receiving portion 118 captures the anterior portion of the pin, retaining the guide assembly from anterior dislocation while allowing posterior freedom to the posterior stop (or wall capture).

The reamer used typically is side cutting, so anterior/posterior resection is carried out until the cutter reaches both A/P stops. If the stops are positioned so that A/P freedom is not allowed, then side cutting or resecting in an A/P direction is not needed. This depends on the size and design of the trial.

The directional limits are controlled by the length L of the block 150, as shown by "L" in FIG. 6. The shorter the length of block 150, the more anterior/posterior movement will be allowed in orientation slots 20.

It is not required that the block 50, 150 cooperate with the trial with orientation slots 20. It should be understood that the block 50 may snap into place or otherwise be attached to trial through other means.

The cutting guide 50, 150 is preferably a box-shaped component that is intended to guide instruments during the preparation of the femur. The box is preferably formed by four complete vertical sides, but it is possible for the box to have fewer sides and sides that are of different heights and lengths. (The term "box" is used for convenience only, and is intended to refer to a cutting guide configuration.) In a particularly preferred embodiment, guide has a posterior wall or capture 62 that acts to constrain posterior cutting.

Cutting guide 50, 150 is intended to be attached to (and removable from) the trial 12, 112 during the preparation of the internal box geometry phase of the surgery. The guide 50, 150 has an internal box 54 that accepts a reamer, as example of which is shown in FIG. 4. The height H of internal box may vary. In addition, the width and other dimensions may be varied as well to allow the guide 50 to be fitted and femoral size specific, accommodating various box geometry depths and anterior/posterior lengths.

In preferred embodiments, more than one guide 50, 150 is provided to accommodate various implant and patient sizes. The box geometry depths are

controlled by the height of the guide 50. As shown in FIG. 4, an example of a reamer 210 that may be used with guide 50 has a collar 212 that determines how deep the reamer can extend into bone. The collar 112 is stopped by the top surface 60 of guide 50. Thus, providing variously-sized guides 50 with different heights
5 allows the surgeon to prepare cavities of different depths, while using the same reamer 110.

In the embodiment shown in FIG. 7, the A/P direction is controlled by the length of guide 150. In the alternate embodiment shown in FIGS. 1 and 2, the A/P direction is controlled by directional limit slots 56. These slots 56 are adapted to
10 receive bolts 80, if used. The medial/lateral location of slots 56 is such that the slots 56 fit the prosthetic lug punch hole locations 104 (shown in FIG. 3B). The slots 56 also allow guide 50 to be positioned in any desirable anterior/posterior position on the trial 12 so that it correlates with the position and length of the stabilizing/constraining box geometry needed for the desired prosthetic size. Slots
15 56 are adapted to receive bolts, as shown in FIG. 2, in order to secure guide 50 in place.

This feature allows the surgeon to position the trial 12 as needed in the medial/lateral position, and the position guide as needed in the anterior/posterior direction, giving the surgeon a clear view of the cuts to be made with respect to the
20 shape and position of the ultimate implant to be used. The bolts 80 limit the anterior/posterior movement once the guide 50 is properly placed.

The retaining bolts 80, shown in FIGS. 1 and 2 have posts 86 with heads 88 at one end and optional threads 82 at the other end. In a preferred embodiment, the bolts 80 are cannulated 84 to allow additional fixation pins to be used to further
25 secure to the guide 50 and bolts 80 to the patient's distal femur. If threads 82 are provided, they may cooperate with threads 30 of receiving portions 28. In a particularly preferred embodiment, bolt heads 88 are broached to allow for the use of a hex driver.

Another way that the A/P distance that block is allowed to travel with respect
30 to trial can be controlled is to insert bone spikes or screws directly into the distal bone, through the directional limit slots without the use of bolts 80 or through any other area of trial, which would secure the assembly and eliminate the need to use

bolts as A/P translation stops. An alternate embodiment would be to insert bone spikes or screw through cannulated bolts 80.

During surgery, the trial 12, 112 is placed on the distal femur after preparatory resections have been made to accommodate a distal-femoral prosthesis without a stabilizing/constraining, median box. Such cuts and methods for preparing the distal femur are known in the art. The trial 12, 112 is then positioned (via bone coverage and/or trialing with the tibia and/or patella) in the desired medial/lateral position and pinned in place through one or more fixation holes 26. In a preferred embodiment, at least one fixation hole 26 is located on the patellar region 34 (or anterior flange).

The cutting guide 50, 150 is then placed in the orientation slots 20 on opening side edges 24 of trial 12. If necessary, retaining bolts 80 are then threaded into receiving portions 28 in the trial 12. Bolts 80 can be tightened by a knob-style head or with a hex driver to the desired resistance. The cutting guide 50 can be tightened in any given place along the orientation slots 20 and along the directional-limit slots 56 with the retaining bolts 80, if desired. If additional fixation is desired, bone spikes or other securing mechanisms can be placed through the cannulation area 84 of bolts 80 and into the distal femur. Once the bone resections through the cutting guide 50, 150 are preformed using known methods, the cutting guide 50, 150 is then removed from the trial 12, while the trial 12 stays in place on the patient's femur. Any necessary trial verification may be performed before removing the trial 12. If additional box geometry preparation is needed, the cutting guide 50, 150 can be replaced into position, without having to re-secure it to bone, which helps prevent any bone degradation and deterioration caused by the surgery and the need to re-cut or re-position.

Changes and modifications, additions and deletions may be made to the structures and methods recited above and shown in the drawings. The scope of the claims should not be limited by the embodiments set out herein but should be given the broadest interpretation consistent with the description as a whole.

CLAIMS:

1. A femoral trial and cutting guide assembly, comprising:
 - (a) a femoral trial component comprising condylar regions separated by an opening, the opening defining a central portion with an anterior-most portion and opening side edges; and
 - (b) a removable cutting guide adapted to be received by the opening and secured in the opening in adjustable relation to the anterior-most portion of the opening.
2. The assembly of claim 1, wherein the cutting guide has a posterior capture.
3. The assembly of claim 1, wherein the opening side edges comprise orientation slots that receive a base portion of the cutting guide.
4. The assembly of claim 1, wherein the cutting guide has directional limit slots.
5. The assembly of claim 4, wherein the directional limit slots allow the cutting guide to be adjusted with respect to the femoral trial.
6. The assembly of claim 4 or 5, further comprising retaining bolts that are received by the directional limit slots to secure the cutting guide to the femoral trial.
7. The assembly of claim 6, wherein the bolts are cannulated.
8. The assembly of claim 1, wherein the femoral trial comprises one or more receiving portions that are adapted to receive ends of retaining bolts.
9. The assembly of claim 1, wherein the cutting guide has a movable securing pin that slides into an indent in the femoral trial to retain the cutting guide within directional limits of the femoral trial.
10. The assembly of claim 1, wherein the femoral trial has one or more fixation holes that allow it to be secured to a prepared distal femur.

11. The assembly of claim 1, wherein the cutting guide has an internal capture adapted to receive and stop a cutting instrument.
12. The assembly of claim 1, wherein the assembly is provided with a plurality of cutting guides in different sizes to provide different depth and anterior/posterior length options.
13. The assembly of claim 1, wherein the trial has an anterior abutment portion and the cutting guide has a pin adapted to be received by the anterior abutment portion to secure the cutting guide in place with respect to the trial.
14. The assembly of claim 13, wherein the cutting guide has a retractable member that activates a spring to allow the pin to be raised and lowered with respect to the cutting block and to be secured in place with respect to the trial.
15. A use of the femoral trial and cutting guide assembly defined in any one of claims 1 to 14 for preparing a distal femur to receive a posterior stabilized prosthesis.

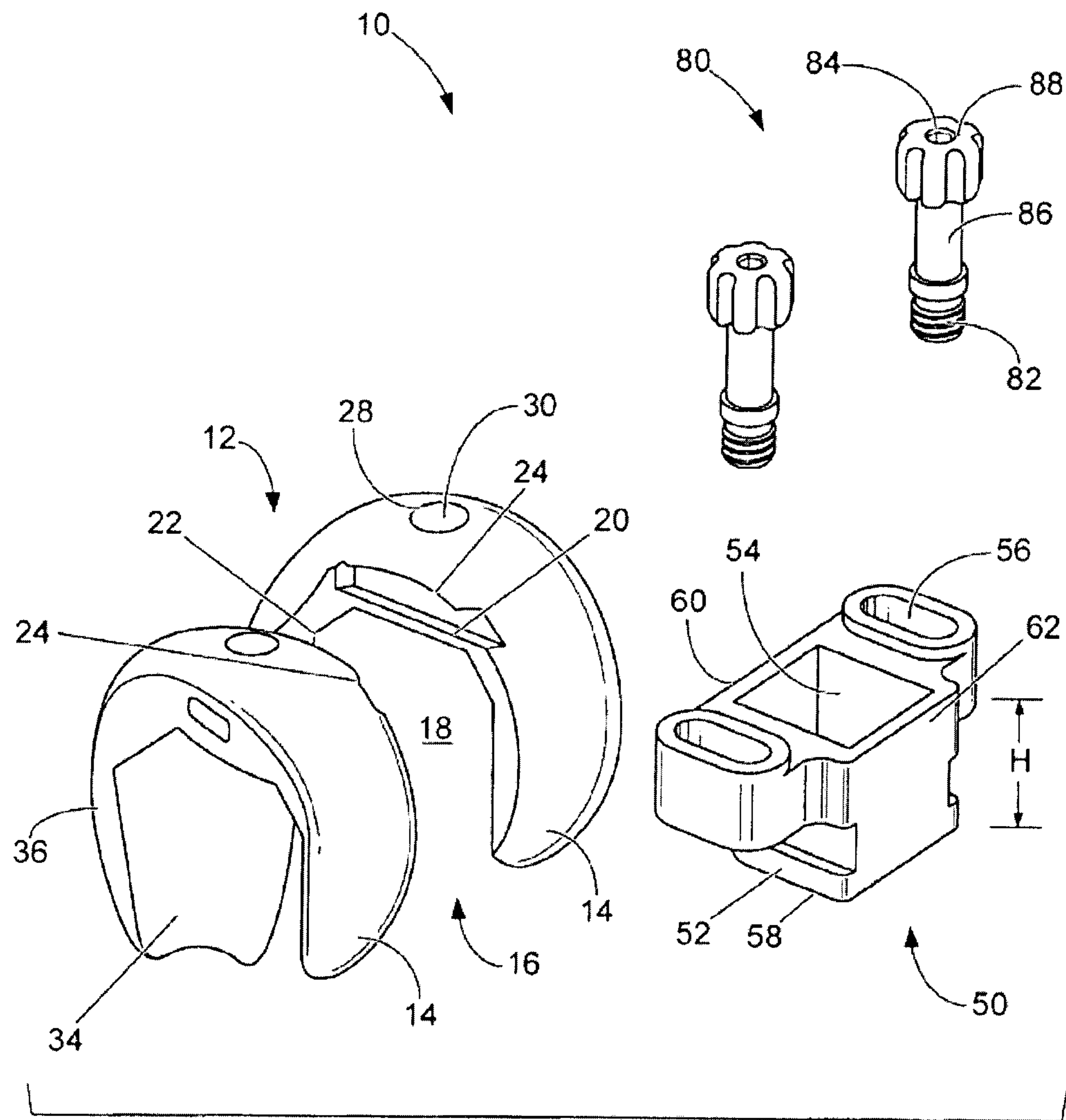


FIG. 1

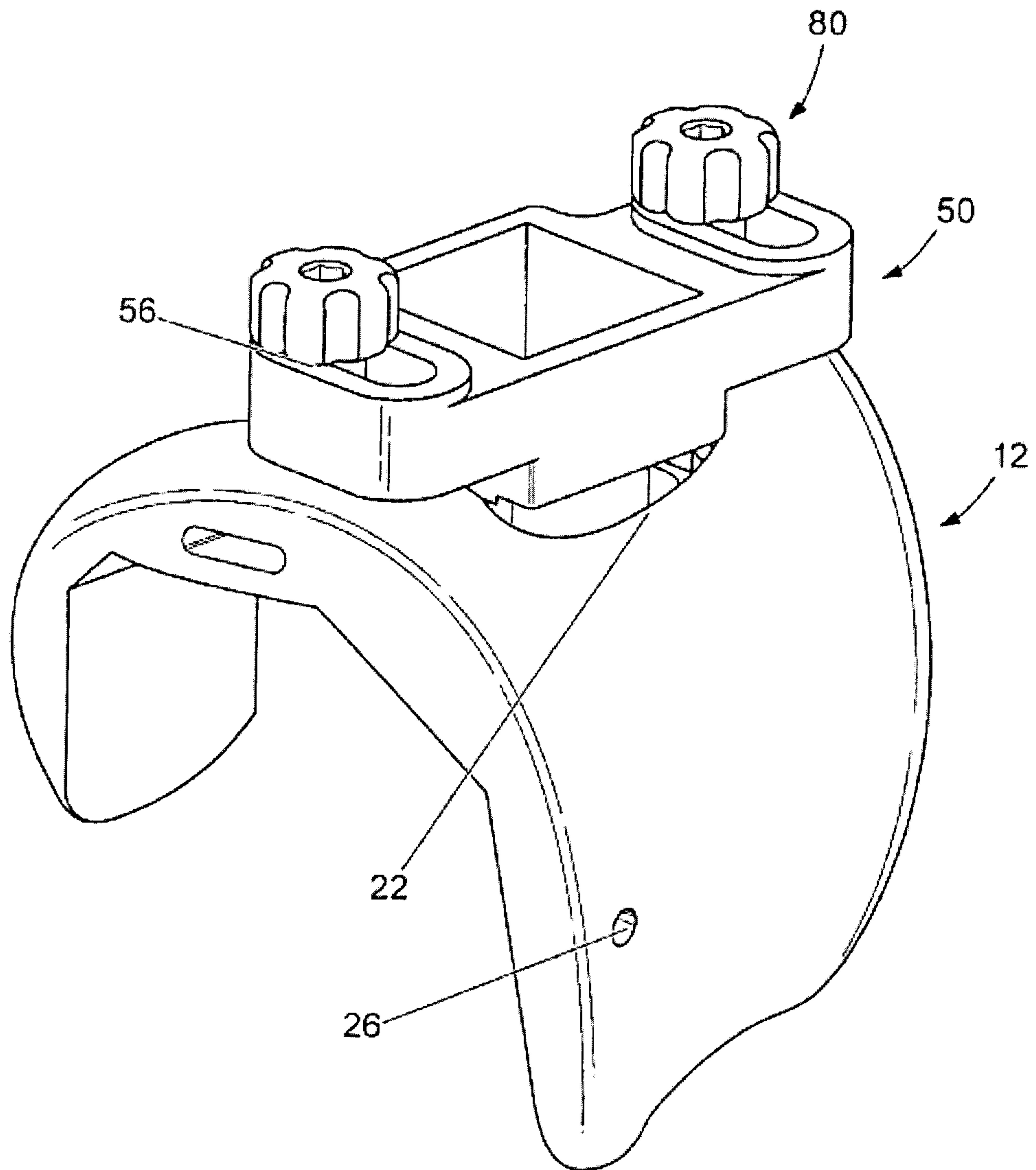


FIG. 2

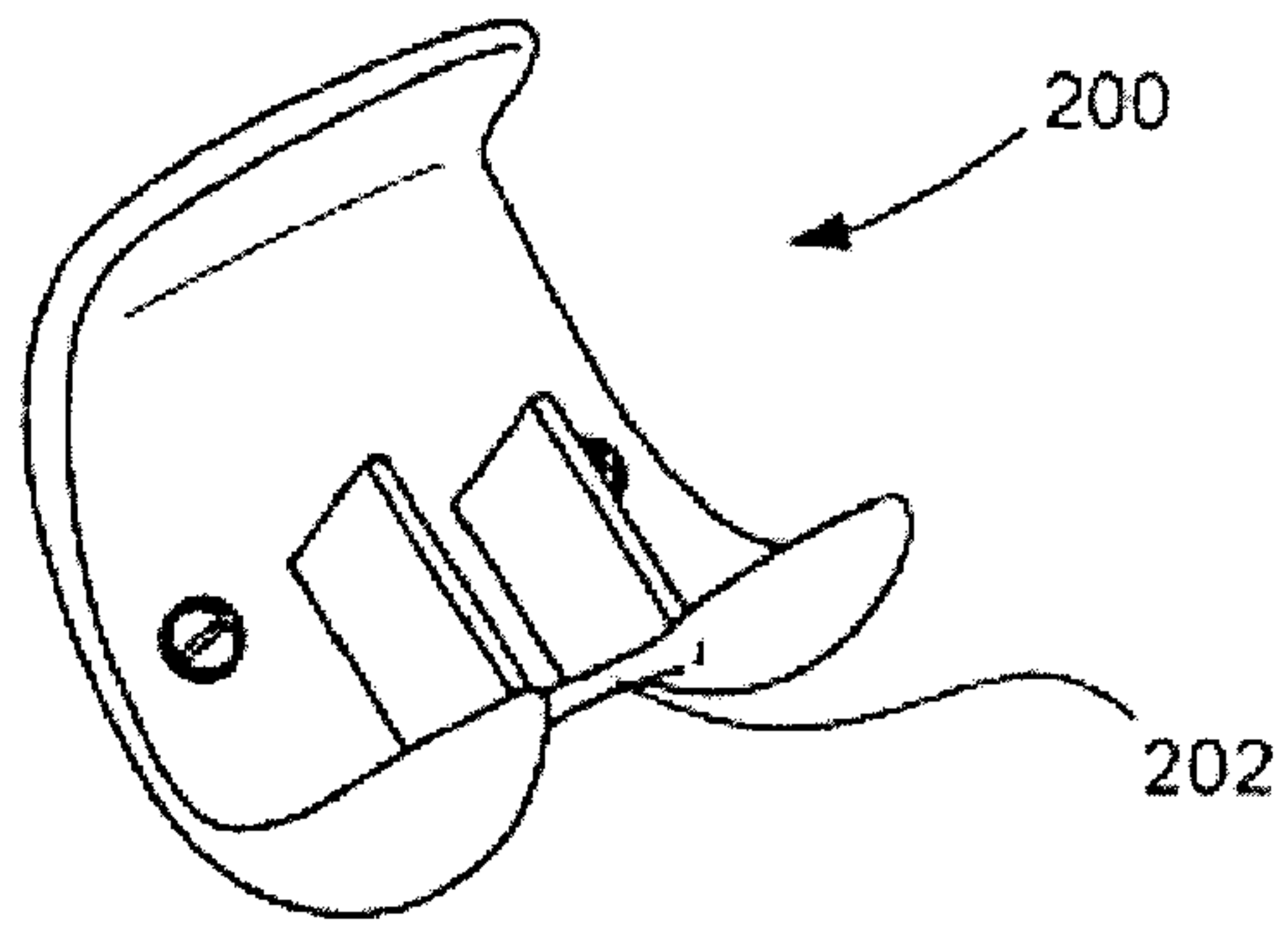


FIG. 3A

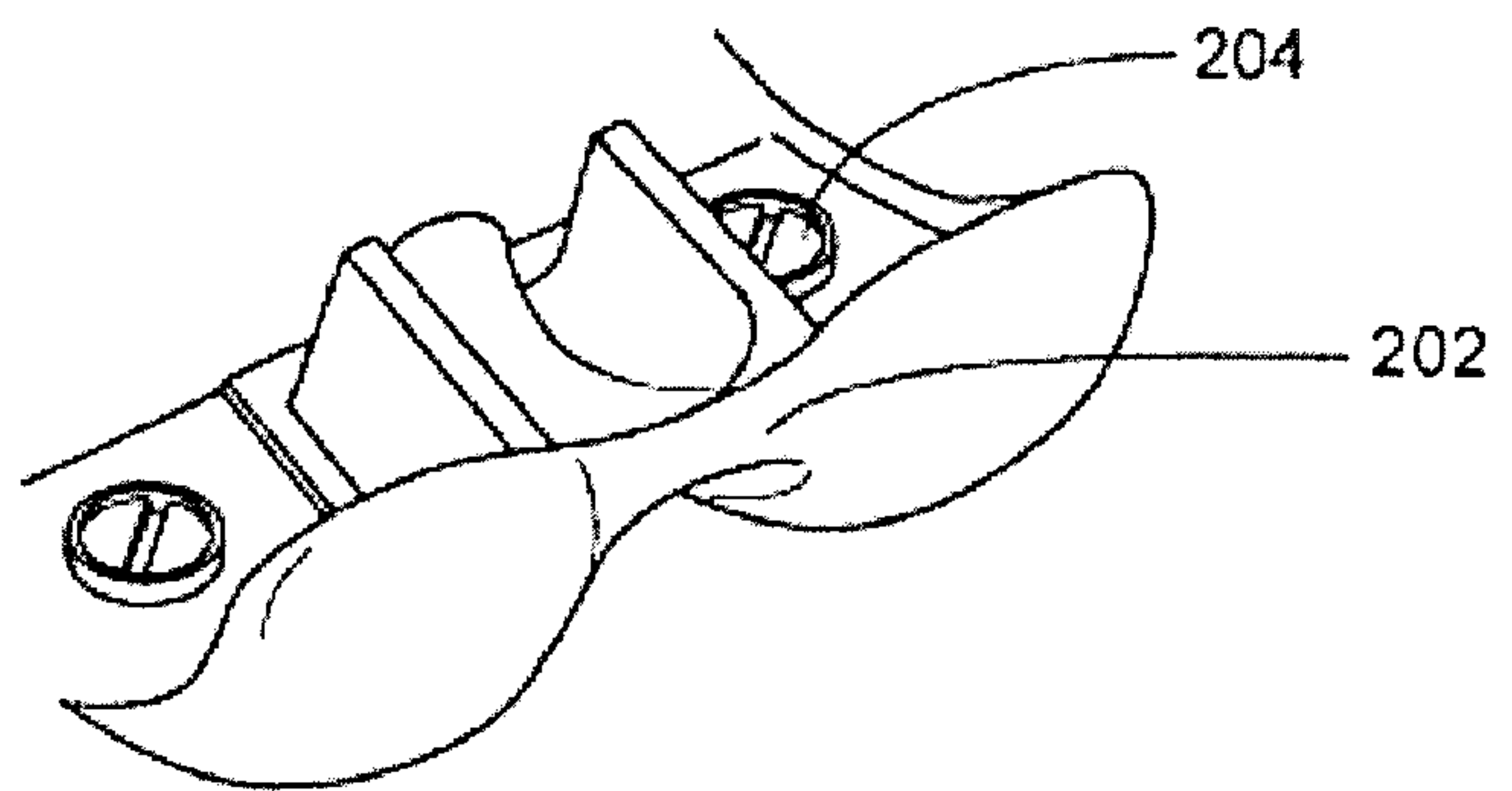


FIG. 3B

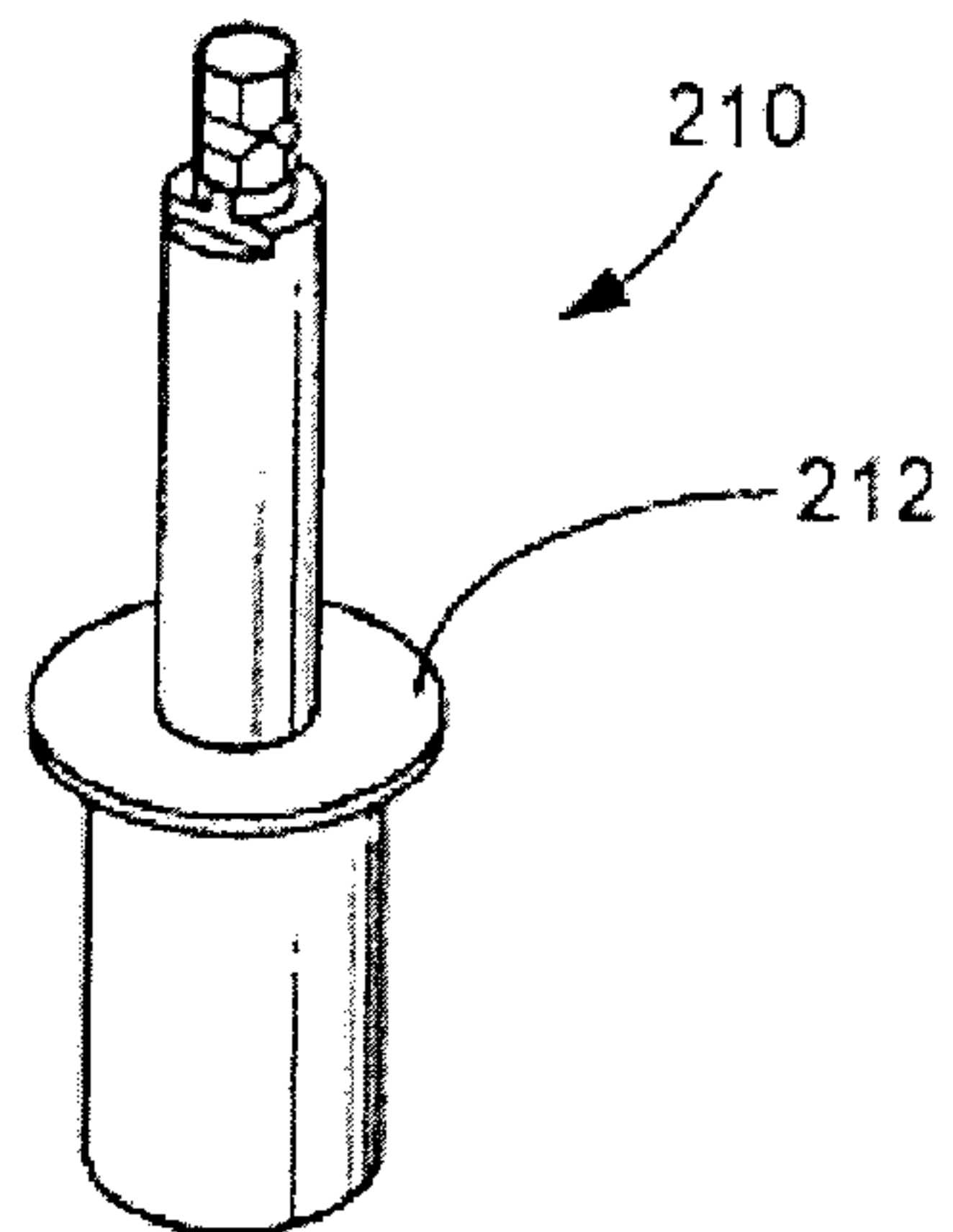


FIG. 4

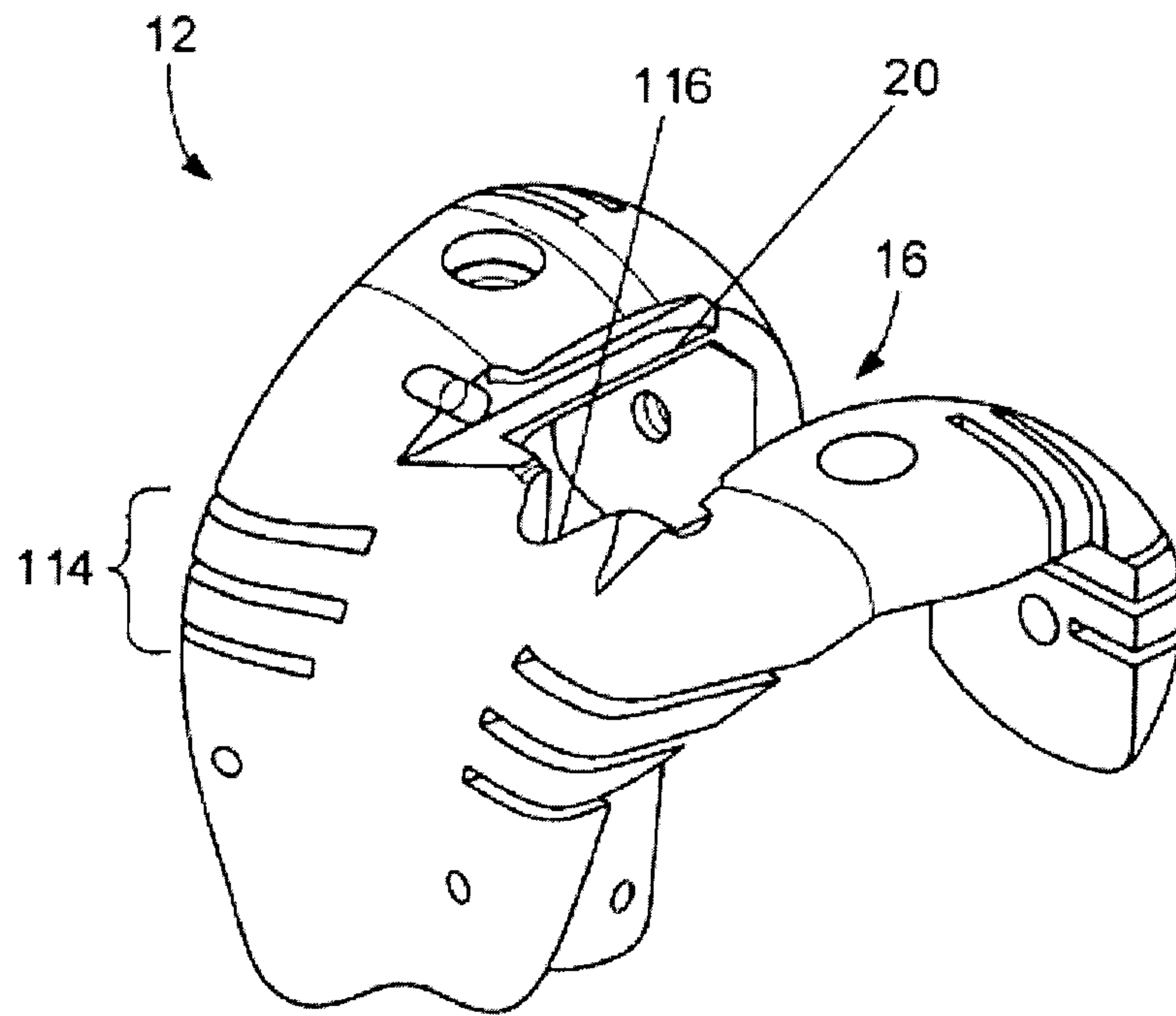


FIG. 5A

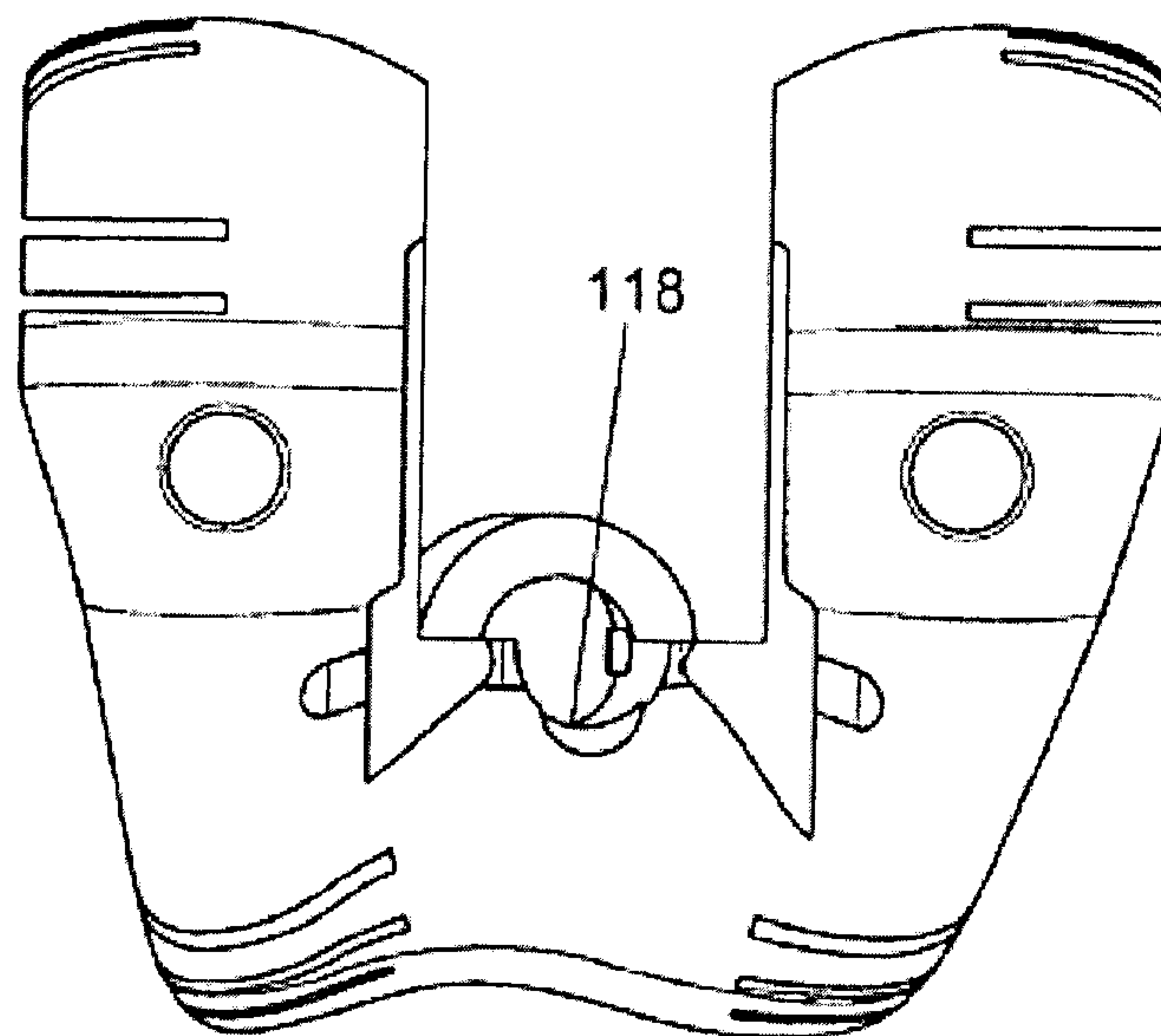


FIG. 5B

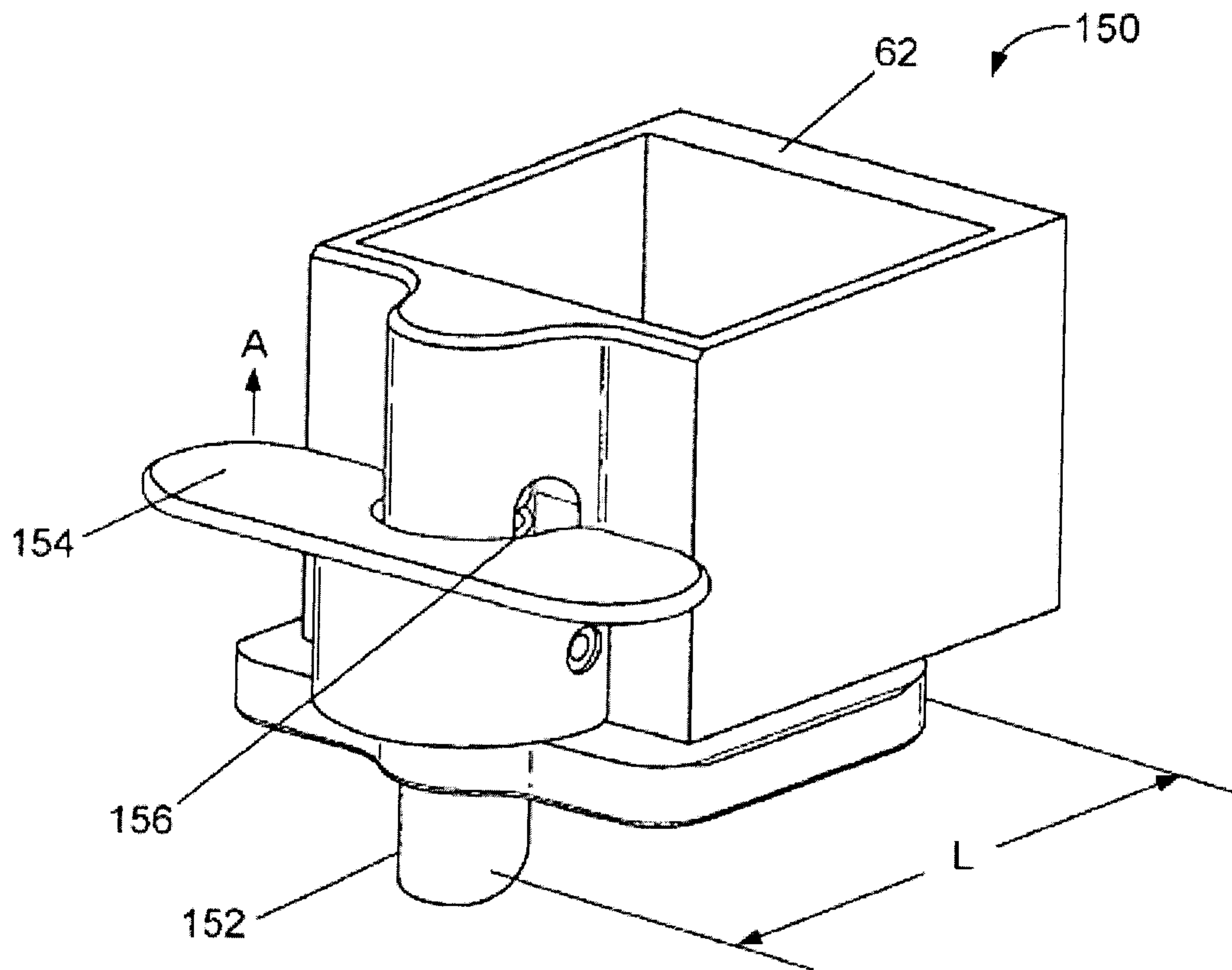


FIG. 6

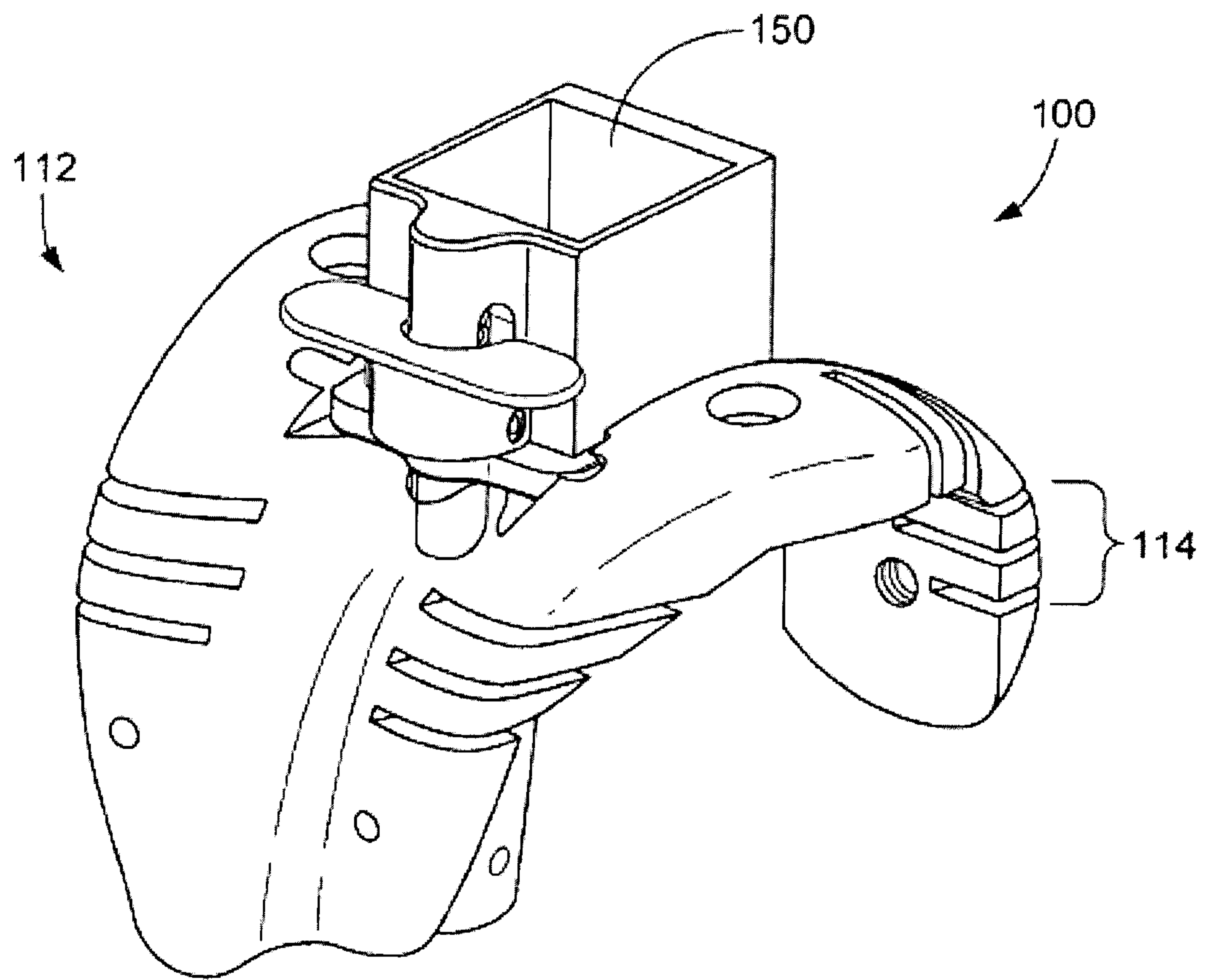


FIG. 7

