(12) STANDARD PATENT (11) Application No. AU 2018282424 B2
(19) AUSTRALIAN PATENT OFFICE

(54) Title
GUIDE ASSEMBLY FOR GUIDING CUTS TO A FEMUR AND TIBIA DURING A KNEE ARTHROPLASTY

(51) International Patent Classification(s)
A61B 17/58 (2006.01)

(21) Application No: **2018282424** (22) Date of Filing: **2018.12.20**

(43) Publication Date: **2019.01.17**
(43) Publication Journal Date: **2019.01.17**
(44) Accepted Journal Date: **2021.01.21**

(62) Divisional of:
2016203260

(71) Applicant(s)
G Lynn Rasmussen

(72) Inventor(s)
Rasmussen, G Lynn

(74) Agent / Attorney
Griffith Hack, L 22 Allendale Square 77 St Georges Terrace, Perth, WA, 6000, AU

(56) Related Art
US 5597379 A
US 5649929 A
EP 1348382 B1

2018282424 20 Dec 2018

ABSTRACT

An assembly for guiding resection of a femur and tibia of a knee joint in preparation for installing a femoral and tibial knee components. For example, the assembly can include tibial and femoral IM rods to which are connected through a torque bolt that allows controlled adjustment of the distraction of the tibia and femur during cut positioning in a range of flexion angles. Also, the assembly is usable with relatively small, noninvasive approaches to the knee joint by way of relatively narrow, low profile components that attach to tibial and femoral IM rods. Further, the assembly includes several quick-release components to allow fast assembly and disassembly in a surgical setting. Each of these aspects, along with the ability of the assembly to accurately guide initial reference cuts to the tibia and femur, promotes an improved outcome for the patient.

GUIDE ASSEMBLY FOR GUIDING CUTS TO A FEMUR AND TIBIA DURING A KNEE ARTHROPLASTY

The present application is a divisional child of AU2016203260 and AU2013221945 the entire contents of which are hereby incorporated herein by reference in their entirety.

Background

The present disclosure is related to the use of instruments for guiding preparation of a knee for installation of an implant during an arthroplasty, and in particular, to the use of ligaments around the knee and other anatomical features to position the guide instruments and making reference cuts to the tibia and the femur.

Description of Related Art

During a knee arthroplasty, a surgeon typically must gain access to the knee joint in order to perform resections of existing bone and cartilage so as to shape the tibia and femur to fit mating surfaces of the implant. Some arthroplasty procedures seek to minimize the invasiveness of the approach to the knee joint by minimizing the size of the incision in the surrounding soft tissue structure of the knee and the patella. Preserving the soft tissue structure also preserves some of the support provided by these tissues. However, preserving the soft tissues surrounding the knee can be difficult at times due to the need to firmly support the resection guides relative to the bone of the tibia and the femur.

Preservation of the ligamentous and other soft tissue structures around the knee can provide a reference point for positioning the tibial and femoral components of the knee implant, in particular when said structure is in tensed or otherwise loaded condition. For example, ligament tensions can be used to guide placement of resection guides. Conversely, preservation of the soft tissue structures requires balancing of the forces exerted by the soft tissues to promote normal kinematics in the knee and normal patellar tracking. Therefore, ligament forces can play a significant role in restoring normal function to a knee. Generally, therefore, reductions in the invasiveness of the knee arthroplasty procedure combined with improvements in the positioning and installation of knee components can result in a better overall surgical outcome for the patient.

2018282424 16 Dec 2020

It would therefore be advantageous to have instrumentation for guiding resection of the femur, tibia and other structures in the knee during a knee arthroplasty that works well with minimally invasive approaches to the tibia and femur. It would be further advantageous if the instrumentation assisted the balancing of forces between the knee implant components and the preserved ligamentous and soft tissue structures for improved function of the knee implant. Also, it would be advantageous to have instrumentation for guiding resection that uses the ligamentous structure of the knee to guide placement of the instrumentation and the resulting placement of the knee components.

BRIEF SUMMARY OF THE DISCLOSURE

One or more embodiments of the present disclosure may meet the above needs, and achieves other advantages, by providing an assembly for guiding resection of a femur and tibia of a knee joint in preparation for installing a femoral and tibial knee component. For example, the assembly can include tibial and femoral IM rods which are connected through a torque bolt that allows controlled adjustment of the distraction of the tibia and femur during cut positioning in a range of flexion angles. Also, the assembly may be usable with relatively small, noninvasive approaches to the knee joint by way of relatively narrow, low profile components that attach to tibial and femoral IM rods. Further, the assembly may include several quick-release components to allow fast assembly and disassembly in a surgical setting. Each of these aspects, along with the ability of the assembly to accurately guide initial reference cuts to the tibia and femur, may promote an improved outcome for the patient.

The disclosure provide an apparatus for adjusting at least one of: (i) tension and (ii) an alignment of a knee joint, the apparatus comprising: a first member configured to extend into a femur when the apparatus is seated in the knee joint; a second member that is configured to contact a proximal portion of a tibia when the apparatus is seated in the knee joint; and an adjustable component that is configured to couple the first member with the second member such that the second member is rotatable with respect to a longitudinal axis of the first member when a position of the first member is constant with respect to the femur to allow for adjustment of an angle between the tibia and the femur when the apparatus is seated in the knee joint.

In an embodiment, the adjustable component may comprise a threaded object that is configured to be rotated to vary a distance between the first member and the second member when the apparatus is seated in the knee joint, and wherein the

2018282424 16 Dec 2020

apparatus may be configured to be seated in the knee joint with the first member extended into the femur and the second member contacting the proximal portion of the tibia when the knee joint is disposed in a flexed position.

In an embodiment, the first member may comprise a rod and wherein the adjustable component is configured to couple the second member to the rod such that the second member is rotatable about a longitudinal axis of the rod when the apparatus is seated in the knee joint.

The disclosure also provides an apparatus for adjusting at least one of: (i) tension and (ii) an alignment of a knee joint, the apparatus comprising: an elongated member that is configured to extend into a distal end of a femur; a tibial contact member that is configured to contact a proximal end of a tibia; and an adjustable component that connects the elongated member with the tibial contact member such that the tibial contact member is rotatable about a longitudinal axis of the elongated member when the apparatus is seated in the knee joint, when the elongated member is fixed in position with respect to the femur, and when the knee joint is in a flexed position.

In an embodiment, the adjustable component may comprise a threaded element that is configured to be rotated to vary a distance between the elongated member and the tibial contact member when the elongated member extends into the distal end of the femur and the tibial contact member contacts the proximal end of the tibia.

An assembly of one embodiment of the present disclosure includes femoral and tibial IM rods, a flexion cutting guide, an extension cutting guide and a selection of selectively lockable components. Each of the IM rods may include a shaft portion that is configured to extend within the IM canal of the femur or tibia. The femoral IM rod may also include a femoral mount on an end of the shaft that is configured to extend away from the femur when the shaft is in the femoral IM canal. Similarly, the tibial IM rod may include a tibial mount on an end of the shaft that is configured to extend away from the tibia when the shaft is in the tibial IM canal. Each of the mounts may be configured to attach to one or more of the selectively lockable components. The flexion and extension cutting guides may define one or more slots wherein the slots may be configured to guide the use of cutting and other instruments to make preparatory cuts to the femur and/or the tibia with the knee in flexion and extension. Each of the cutting guides may be configured to attach to one or more of the selectively lockable components so as to be supported by the femoral and tibial IM rods. The selectively lockable components may be configured to attach to the femoral and tibial IM rods, to have at least one portion with a relatively small cross section extending anteriorly or anterior-medial out of the knee joint compartment and to attach to the flexion and extension cutting guides and support and limit the motion thereof.

In one aspect, the femoral mount may have a cylindrical shape that extends in an anterior-posterior direction between the femoral condyles and includes a central opening and a plurality of gauge marks extending along its outside surface. The central opening may also include an anterior anti-rotation portion (e.g., a hexagonal shaped portion) and a larger diameter cylindrical portion. The tibial mount can include or support a flexion bolt with a threaded shaft at one end configured to extend into an opening in the tibial IM shaft, a bushing at the other end and an exterior hexagonal flange in between the ends. The bushing may be configured to extend into the cylindrical portion and also contains an interior hexagonal bore. The hexagonal flange may be configured to allow gripping by an external torque wrench or internal torque driver to urge the femoral mount away from the tibial mount (by turning of the threaded shaft) and distract the tibia and femur to a desired torque reading. This may allow the surgeon to apply the appropriate amount of tension to the ligamentous structure as defined by said surgeon and recorded for comparison later in the technique.

Included in an exemplary embodiment of the selectively lockable components is a first locking mechanism that has an arm, a plunger assembly and an anti-rotation extension, defined in this instance as a hex. The arm may have an elongate portion extending away from a head portion. Also extending from the head portion may be the hex-shaped anti-rotation extension. Defined through the head portion and hex extension may be an opening that is configured to receive a shaft of the plunger assembly. The plunger assembly may include a thumb press at one end of the shaft and an anti-rotation feature similar to anti-rotation extension, defined in this instance as a hexagonal tip at the other end of the shaft that extends out of the hex extension. Also, the shaft may include a peg that extends into a helically shaped slot defined in the head portion. A spring may extend between the head portion and the thumb press. Depression of the thumb press may advance the shaft, while the peg and helical slot may cause the shaft to rotate, and the flats of the hexagonal tip to align with the hex extension. This may allow the hexagonal tip and hex extension to become concentric and to be inserted into the anterior hex portion of the central opening of the femoral mount. In addition, the hexagonal tip may be configured to extend out of the hex portion of the opening and into the cylindrical portion, and to rotate (due to the helical slot and peg) into an eccentric position upon release of the thumb press, thereby locking the locking mechanism into the femoral mount. When attached, the head portion of the arm may extend proximally out of the knee joint compartment and the elongate portion extends anteriorly (with respect to the tibia) through the surgical incision.

A flexion guide support member of the assembly of an embodiment of the present disclosure may include a slider member and a ratchet bar. The slider member may be configured to attach to, and slide along, the elongate portion of the arm of the first locking mechanism, such as by having an opening defined therein matching the cross-section of the elongate portion. The ratchet bar may be configured to extend toward a plane defined by the tibial plateau. Preferably, when assembled, the femoral mount, first locking mechanism and flexion guide support member may roughly form a U-shape that is relatively narrow in the medial-lateral direction to allow its use with narrow incisions.

Also included in the selectively lockable components in some embodiments may be a quick release mechanism that is configured to slide along and lock to the ratchet bar of the flexion guide support member. For example, the quick release mechanism may define an opening configured to extend and slide along the ratchet bar, and a locking pin that is spring loaded to extend into a portion of the ratchet to stop the sliding motion. The locking pin may be spring biased, but can be overcome with a manual draw pull (for example) to allow further sliding or repositioning of the quick release mechanism. The quick release mechanism may also include a spring-biased locking lever that, along with an engagement member of the quick release mechanism, can extend into an opening and lock to the flexion cutting guide. Depressing the locking lever again may easily release the flexion cutting guide after k-wire or other fasteners have been used to secure the flexion cutting guide in place to the tibia or femur. This may allow the resection guide to translate toward the proximal tibia and away from the tensioning assembly with the knee in flexion.

Once the flexion resection guide is fixed to the proximal tibia, the resection guide may have a plurality of slots for which to resect multiple components of the femur and tibia, most notably a measured proximal tibial resection and a posterior condylar resection. Making these resections with the knee in tension at 90 degrees may allow the user to theoretically make a tensed flexion gap resection.

The selectively lockable components may also include components configured to attach to the femoral and tibial IM rods when the knee is in extension. For example, the components may include a cannulated extension bolt, a tibial angulation guide, an extension guide support member and a second locking mechanism. The tibial angulation guide may be configured to attach to the tibial IM rod through the cannulated extension bolt which may be, in turn, coupled to the tibial IM rod and extend around the femoral mount, such as by having a block defining an arc-shaped channel that may be configured to receive the cylindrical outer surface of the femoral mount. Included on the tibial angulation guide may be a plurality of gauge marks that, when correlated to gauge marks on the outer surface of the femoral mount, register an amount of valgus angulation of the tibia with respect to the femur. The tibial angulation guide may be configured to extend into the bushing of the bolt described above, or to have its own threaded shaft and hexagonal flange allowing it to be used to distract the tibia and femur in extension to a torque value corresponding to the torque value previously measured with the knee in flexion.

The extension guide support member may be configured to have a relatively narrow profile and extend anteriorly out of the joint compartment through the incision providing access thereto. For example, the extension guide support member may include a mounting portion that is cylindrical and defines a cylindrical opening and a support arm that is configured to extend proximally from the mounting portion. The second locking mechanism may be generally configured similar to the first, except it lacks the fixed elongate portion of the arm. Rather, it may include a cylindrical head portion that is configured to extend through the cylindrical opening of the mounting portion of the extension guide support member so as to connect the extension guide support member to the femoral mount while allowing said support member to rotate in a desired position independent of the previously selected valgus angle.

The extension guide support member may also include a support arm that is configured to extend proximally from the mounting portion when the mounting portion is attached to the femoral mount using the second locking member. The extension cutting guide may be configured to slidably attach over the support arm, such as via a channel defined in its body. Also, the extension cutting guide may preferably include a swivel arm that can be swung into an abutting relationship with the tibial plateau and the plateau flange of the tibial mount to provide an additional reference point for making a femoral resection with the knee in extension. The extension cutting guide, similar to the flexion cutting guide, may also define a plurality of fixation openings allowing fasteners to extend there-through and attach the extension cutting guide to the tibia or femur. This may allow removal of the selectively lockable components to provide room for the cuts to the tibia and/or the femur.

The swivel arm, once referenced off the proximal tibial resection, may allow the extension cutting guide to make a pre-determined resection of the distal femur. Resecting with the knee tensed in the extended position may allow the user to make a balanced extension gap resection when compared with the tensed resections made with the knee previously positioned in flexion.

The assembly of an embodiment of the present disclosure has many advantages. For example, it may provide a relatively narrow and low profile collection of locking components that securely attach cutting guides to tibial and/or femoral IM rods. This may provide a robust guide to reference cuts being made to the tibia and the femur with an approach to the joint that minimizes invasiveness. Further, many of the components, such as the first and second locking mechanisms and the quick release mechanism, may facilitate quick assembly, easy adjustment and quick disassembly for improved efficiency. The use of the flexion bolt in flexion, and the extension bolt and tibial angulation guide in extension, may allow the tibia and femur to be distracted under a matching amount of tension in flexion and extension to ensure a better fit for the tibial and femoral knee replacement components throughout a range of flexion. Also, the tibial angulation guide may allow the surgeon to adjust the amount of valgus angulation of the tibia as desired to match the anatomy of the patient.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

Having thus described the disclosure in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

Figure 1 is a plan view of a tibial intramedullary (IM) rod and femoral IM rod of an assembly of one embodiment of the present disclosure;

Figure 2 is a perspective view of the femoral IM rod of Figure 1 inserted into a femur;

Figure 3 is a cross-section of a femoral mount of the femoral IM rod shown in Figure 2;

Figure 4 is a perspective view of a femoral and tibial IM rods of Figure 1 inserted in the femur and tibia of a knee, respectively;

Figure 5 is a perspective view of a bushing extending from an extension bolt of the assembly of the present disclosure wherein the extension bolt is coupled to the tibial IM rod of Figure 1;

Figure 6 is a plan view of the extension bolt of Figure 5 and of a tibial angulation guide and flexed knee cutting guide of the assembly of the present disclosure;

Figure 7 is a perspective view of the bushing and IM rods of Figure 5, wherein the bushing of the extension bolt is advanced to connect the IM rods;

Figure 8 is a side elevation view of a first locking mechanism of the assembly of the present disclosure;

Figure 9 is a perspective view of the first locking mechanism being connected to the assembled IM rods and bolt of Figure 7, torqued to a desired load;

Figure 10 is another perspective view of the first locking mechanism in the unlocked position, assembled IM rods and bolt of Figure 9, torqued to a desired load; Figure 11 is yet another perspective view of the first locking mechanism assembled and locked to the IM rods and extension bolt of Figure 9, torqued to a desired load;

Figure 12 is a perspective view of a flexion guide support member of the assembly of the present disclosure connected to the first locking mechanism of Figure 11;

Figure 13 is a perspective view of a flexed knee cutting guide assembly of the assembly of the present disclosure connected to the flexion guide support member of Figure 12;

Figure 14 is a side elevation view of the assembly of Figure 13;

Figure 15 is a rear elevation view of the assembly of Figure 13;

Figure 16 is a bottom elevation view of a quick release mechanism of the flexed knee cutting guide assembly of Figure 13;

Figure 17 is a perspective view of the quick release mechanism of Figure 16 and the flexion guide support member of Figure 12;

Figure 18 is a perspective view of a flexed knee cutting guide of the flexed knee cutting guide assembly of Figure 13;

Figure 19 is a front elevation view of a tibial angulation guide of the assembly of the present disclosure extending between the femoral and tibial IM rods of Figure 1, coupled with an extension bolt;

Figure 20 is an enlarged view of the IM rods and tibial angulation guide of Figure 19;

Figure 21 is another enlarged view of the IM rods and tibial angulation guide of Figure 19;

Figure 22 is a perspective view of a second locking mechanism and extension guide support member of the assembly of the present disclosure being assembled to the femoral IM rod of Figure 1;

Figure 23 is an enlarged perspective view of the assembly of the extension guide support member of the present disclosure to the second locking mechanism of Figure 22;

Figure 24-26 are various a perspective views of an extended knee cutting guide of the assembly of the present disclosure attached to the extension guide support member and second locking mechanism of Figure 22, and the femoral IM rod of Figure 1;

Figure 27 is a perspective view illustrating disassembly of the second locking mechanism of Figure 22, from the femoral IM rod of Figure 1, once the extended knee cutting guide is fixed in position to the distal femur;

Figure 28 is a front elevation view of the extended knee cutting guide of Figure 24;

Figure 29 is a side elevation view of the extended knee cutting guide of Figure 24;

Figure 30 is a plan view of an L-shaped cutting block of the assembly the present disclosure;

Figure 31 is a side elevation view of the L-shaped cutting block of Figure 30 being used to cut an anterior condyle of a femur;

Figures 32-40 show various modular options of the present disclosure that promote quick assembly and facilitate minimally invasive intra-operative use;

Figure 41 shows a hinged retractor as used in one embodiment of the present disclosure; and

Figure 42 shows an embodiment of the present disclosure that implements mini-trials.

DETAILED DESCRIPTION

The present disclosure now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the disclosure are shown. Tndeed, this disclosure may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

An assembly 10 of the present disclosure for facilitating preparation of a knee joint, including guiding positioning of cuts to a femur 11 and tibia 12 of the knee joint, for later mating with femoral and tibial knee replacement components, is shown in the accompanying figures. Generally, the assembly 10 includes various components selected and arranged to attach to a reference point inside the knee joint compartment (such as one or more intramedullary (IM) rods), extend through a relatively narrow, small or noninvasive approach defined in the soft-tissues of the knee and attach outside the knee to a selection of resection guides.

Anatomical directions as used herein are in reference to the knee during the preparatory surgery and correspond to the illustrated embodiment of the assembly 10. However, depending upon the handedness of the knee, or variations in individual morphology and ligamentous structure, these directions could vary and should not typically be considered limiting.

The assembly 10 can be configured to be applied at different knee flexion angles to facilitate positioning of the components throughout the range of flexion or extension. Illustrated herein are components of the assembly 10 for guiding cuts and preparation of the knee at two different flexion angles, namely 90° and full extension. However, the components can be adjusted or configured, or other components employed within the spirit and scope of the present disclosure, to extend through relatively non-invasive approaches to the knee joint at any range of flexion be it hyper-extension, 30°, 45°, 60°, etc., through to hyper-flexion.

In the illustrated embodiment, the assembly 10 includes two IM rods, a femoral IM rod 13 and a tibial IM rod 14 that provide a reference point for supporting the remainder of the assembly 10 with the knee in flexion, in this case 90° of flexion. The femoral IM rod 13 includes a femoral mount 15 and a main shaft 16, as shown in Figure 1. The main shaft 16 of the femoral IM rod 13 is preferably an elongate, relatively rigid shaft that, when installed, extends within the IM canal of the femur 11 in a proximal-distal direction, as shown in Figure 2. The main shaft 16 can include structure that facilitates its insertion into the femur 11, such as a tapered end 17. Preferably, the main shaft 16 is constructed of a relatively rigid material, such as a hard plastic, stainless steel, titanium or other metal or material that is capable of insertion into bone without damage and of stably supporting the femoral mount 15.

Attached to the distal end of the main shaft 16, opposite the tapered end 17, is the femoral mount 15. Generally, the femoral mount has a cylindrical shape with an axis extending perpendicular to a long axis of the main shaft 16. Defined along the axis of the femoral mount 15 is a central opening 18, as shown by the cross-sectional view of the femoral mount in Figure 3. The central opening includes two portions, an anti-rotation portion, in this instance a hex portion, 19 and a cylindrical portion 20 which allow locking of other components of the assembly 10 to the femoral mount 15, as will be described in greater detail below. Regardless, once the femoral IM rod 13 is installed, the femoral mount 15 and its central opening 18 preferably extend in an anterior-posterior direction along the femoral notch between the femoral condyles. Defined on the outer cylindrical surface of the femoral mount 15 are a plurality of longitudinally extending gauge marks 21 that aid in positioning of the tibial and femoral components, as will be described in more detail below.

As shown in Figures 1 and 4, the tibial IM rod 14 includes a main shaft 22 supporting a tibial mount 23. Similar to the main shaft 16 of the femoral IM rod 13, the main shaft 22 has an elongate structure with a tapered distal end 24 to facilitate its insertion into the IM canal of the tibia. However, the main shaft 22 preferably includes one or more flutes 25 extending along its length in order to further facilitate insertion and to resist rotation within the IM canal of the tibia. These flutes may also, optionally, be included on the main shaft 16. Defined in the main shaft 22 at its proximal end is an opening 27 that extends into the flutes 25. These openings further facilitate insertion into the IM canal of the tibia. As with the main shaft 16 of the femoral IM rod 13, the main shaft 22 may be constructed of a range of relatively rigid materials to provide firm support for the tibial mount 23.

Included in the tibial mount 23 are a thickened cylindrical portion 26 and a plateau flange 28, as shown in Figure 4. The cylindrical portion 26 is preferably sized to fit the IM canal of the tibia 12. The cylindrical portion is connected at its distal end to the main shaft 22 and at its proximal end supports the plateau flange 28. The plateau flange extends outward at right angles from the cylindrical portion 26 and has

2018282424 16 Dec 2020

three flat sides and one crescent-shaped side. The crescent shaped side is a cutout to provide room for the anterior cruciate ligament prior to resection of the proximal tibia. The flat sides can further aid in guide positioning and cutting, such as during a tibial compartmental resection in a unicondylar arthroplasty procedure wherein only a single condyle and a portion of the tibial plateau are reconstructed.

A threaded opening 29 extends into the tibial mount 23 and provides a coupling attachment for the flexion bolt 30, which includes a threaded shaft 31, a hex flange 32 and a bushing 33, as shown in Figures 5 and 6. The threaded shaft 31 has a plurality of threads and extends away from the hex flange 32, while the bushing 33 is a smooth, cylindrical shaft that extends opposite the threaded shaft from the other side of the hex flange 32. The hex flange 32 is shaped to allow gripping by a torque or other wrench to provide motivation for advancement of the threaded shaft 32.

The threaded shaft 31 is configured to be advanced into the threaded opening 29 of the tibial mount 23 until it is flush with the plateau flange 28 thereby positioning the bushing 33 at its lowest profile position, as shown in Figure 5. This position allows the femur 11 and femoral mount 15 extending therefrom to be slipped into position above the bushing 33. Then, the torque wrench is used to reverse the advancement of the threaded shaft 31 until the bushing 33 engages the cylindrical portion 20 of the central opening 18 in the femoral mount 15, as shown in Figure 7. Advancement is reversed until a pre-selected torque measurement is reached on the torque wrench, or adequate tension of the ligamentous structure is obtained. Once the appropriate ligament tension is obtained, this torque value is recorded for comparison later in the technique. The resulting assembly emulates a static linkage of the femur and tibia with the knee in flexion (e.g., at 30°, 60°, or 90° of flexion or increments therebetween) from which the surgeon can reference subsequent resection instruments as described below.

Also included in the assembly 10 is a quick connect locking mechanism 34 that connects into the hex portion 19 of the central opening 18, as shown in Figures 8 and 9. Included in this embodiment of the locking mechanism are a static outrigger arm 35, a spring-biased plunger 36 and a static clocking extension 37 which emulates the anti-rotation feature 19, and in this instance has a hexagonal shape. The arm 35 has an elongate portion 38 and a rounded head portion 39. The elongate portion 38 of the arm 35 has a square cross-section and extends from the rounded head portion 39 which has a partially cylindrical shape with a pair of opposing flats at its ends.

Extending from one of the flats of the rounded head portion is the hex extension 37. The hex extension 37 has a hexagonal cross-section configured to snugly fit within the hex portion 19 of the central opening 18 defined in the femoral mount 15. As shown in Figure 8, defined in one rounded surface of the head portion 39 is a helically extending slot 43 which, as will be described below, guides motion of the plunger 36.

Defined through the rounded head portion 39 and the hex extension 37 is a cylindrical opening 40 through which the plunger 36 extends. In particular, the plunger 36 includes a thumb press 41, a shaft 42, a spring 45 and rotating extension 44 which emulates the anti-rotation feature 37, in this instance is a hex, but could be any non-cylindrical shape, such as square, triangle or ellipse, capable of limiting rotation. The thumb press 41 is positioned at one end of the plunger 36 and has the shape of a circular disk with ridges to promote pressing with a thumb. Subjacent the thumb press 41 is the spring 45 which is preferably in the shape of a coil and extends around the shaft 42 and between the thumb press and head portion 39 so as to bias them apart.

The shaft 42 includes a peg 46 that extends perpendicular to the shaft and into the helical slot 43 defined in the head portion 39, as shown in Figure 8. Thus, depression of the thumb press 41 advances the shaft 42 within the opening 40 in the head portion 39, and also results in rotation of the shaft as the peg 46 fixed thereto helically travels in the helical slot 43. The hexagonal end 44 of the plunger 36 is fixed to the end of the shaft 42 opposite the thumb press 41, extends along a free end of the hex extension 37 and has a hexagonal shape and size matching that of the hex extension 37.

Due to its connection to the shaft 42, depression of the thumb press 41 also causes rotation of the hexagonal end 44 of the plunger 36 until the flats of the hexagonal end match the orientation of the flats of the hex extension 37, as shown in Figure 10. Matching of this orientation allows insertion of the hex extension 37 and the hexagonal end 44 into the hex portion 19 of the central opening 18 of the femoral mount 15, as shown in Figure 11. Once the thumb press 41 is released, the spring 45 biases the thumb press, shaft 42 and hexagonal end 44 upwards, causing the flats of the hexagonal end to return to their non-matching, out-of-phase position (shown in Figure 9) with respect to the flats of the hexagonal extension 37.

At this point, the hexagonal end 44 of the plunger 36 resides in the cylindrical portion 20 of the central opening 18 and, due to its non-matching position, cannot be withdrawn through the hex portion 19 of the central opening. As a result, the locking mechanism 34 becomes rotationally and translationally locked with respect to the femoral mount 15 and the femoral IM rod 13. Once locked in place, the arm 35 of the locking mechanism 34 extends anteriorly outward from the femoral mount 15 and the condyles of the femur 11. Notably, the combination of the relatively narrow femoral mount 15 and narrow, elongate structure of the arm 35 allows passage through relatively small surgical approach openings, facilitating use of the assembly 10 with less invasive procedures. For example, a modified mid-vastus, medial mid-vastus or subvastus approach could be used with a small 8-10 cm cut which allows avoidance of a release of the quadriceps from the anterior tibia.

Also included in the assembly 10 of the illustrated embodiment of the disclosure is a flexion guide support member 47 which is supported by the locking mechanism 34. Included in the flexion guide support member is a slider member 48 and a ratchet bar 49. The slider member defines a rectangular opening 50 which is sized and shaped to allow the slider member to be supported by, and slide along, the rectangular cross-section of the arm 35 of the locking mechanism 34. This motion allows the ratchet bar 49, which is attached to the slider member 48, to move toward and away from the knee joint. The slider member 48 is preferably shaped to have finger grips (e.g., the tapered portion of the illustrated slider member) and may also include some type of a pin or locking assembly to resist, but not prohibit its sliding relative to the arm 35. The ratchet bar 49 itself is also rectangular shaped in cross-section and, when assembled, extends distally from the arm 35 of the locking mechanism 34, as shown in Figure 12. The ratchet bar 49 also includes a pair of chamfered corners supporting a plurality of adjacent ratchet grooves 51 extending along the length of the ratchet bar.

The assembly 10 also includes a flexed knee cutting guide assembly 52 that attaches to the flexion guide support member 47, as shown in Figures 13, 14 and 15. The flexed knee cutting guide assembly 52 includes a quick release mechanism 53 and a cutting guide 54. The quick release mechanism 53 includes a body 55, a draw pin 56, first and second springs 57, 58, a locking lever 59 and a locking pin 60. As shown in Figure 16, the body 55 defines a rectangular opening 61 which allows the body to be slid over the rectangular cross-section of the ratchet bar 49. In addition, the body 55 includes a side opening into which the draw pin 56 extends so that its end engages the ratchet grooves 51. In particular, the first spring 57 biases the draw pin into a position normally engaging the ratchet grooves so as to lock the draw pin, and hence the body

55, into a particular position on the slider member 48. The locking pin 60 extends through the body and through the draw pin 56 to secure the draw pin 56 and prevent it from disassembly.

The body 55 additionally includes a clevis 62 that extends outwards from the opposite side of the body from the draw pin 56 and which supports rotation of the locking lever 59 about its middle portion. As well shown in Figure 17, the locking lever has a curved finger grip biased outward from the body 55 by the second spring 58 and the opposite end of the locking lever includes a tapered tongue 63 which, as will be described below, engages the cutting guide 54 so as to lock the quick release mechanism 53 thereto. Extending away from the clevis 62, opposite the locking lever, is an engagement member 64 of the body 55. The engagement member 64 has a rectangular cross-section and, in the assembled condition shown in Figure 13, extends into a connection with the cutting guide 54.

As shown in Figure 13, the cutting guide 54 extends posteriorly (when assembled) from the quick release mechanism 53 and includes a mounting portion 65, a k-wire guide or fixation pin portion 66, a crosspin portion 71, a proximal tibial cut guide portion 67 and a posterior condylar femoral cut guide portion 68. The mounting portion 65 defines a rectangular opening 69 that is sized and shaped to slidably receive the engagement member 64 of the body 55 of the quick release mechanism 53. The mounting portion 65 also defines a notch 70 in one of the sidewalls of the rectangular opening 69, as shown in Figure 18. The notch 70 is sized, shaped and positioned to receive the tapered tongue 63 of the locking lever 59 when the locking lever is under the bias of the second spring 58, as shown in Figure 15. Release of the cutting guide 54 is easily accomplished by depressing the free end of the locking lever 59, overcoming the bias of the second spring 58 and disengaging the tapered tongue from the notch 70 of the mounting portion 65."

The fixation pin (or k-wire) guide portion 66, the tibial cut guide portion 67 and the femoral cut guide portion 68 each have a crescent shape that extends in a medial-lateral direction around the anatomical curvature of the anterior-medial or anterior-lateral tibia (depending upon which cut is being made), as shown in Figure 13. The fixation pin guide portion 66 is adjacent the mounting portion 65 and defines a plurality of fixation pin holes 72 that extend in a posterior direction at an angle so as to guide fixation pins (used to fix the cutting guide 54 before release of the other components of the assembly 10) into the thickest anterior portions of cortical bone on

2018282424 16 Dec 2020

the tibia 12. Although less preferred, the number and orientation of the fixation pin holes could be varied depending upon the firmness of the connection desired, size and morphology of the tibia 12, etc.

The tibial cut guide portion 67 is positioned adjacent the fixation pin guide portion 66 and defines a slot for guiding the tibial cut. The slot extends along the length of the crescent shape of the guide portion 67 and generally has a parallel orientation with respect to the tibial plateau. However, the resection plane defined by guide portion 67 may vary in posterior slope (sagittal plane angularity) and varus/valgus (coronal plane angularity), depending on the desired position and preference of the surgeon for the cutting guide 54. An example of such a cut is illustrated in Figure 19, wherein the tibia has a flat planar cut extending in the anterior-posterior and medial-lateral planes on the proximal end of the tibia 12. The femoral cut guide portion 68 is proximally spaced from the tibial cut guide portion 67 by a pair of connection flanges 73 so as to bridge the knee joint compartment. Similar to the tibial cut guide portion 67, the femoral cut guide portion 68 defines a slot that extends along the length of the crescent shape. However, because the knee is in flexion, the cut is guided through the posterior of the condyles of the femur 11.

An advantage of the components of the assembly 10 for positioning cuts with the knee in flexion, including the femoral mount 15, the tibial mount 23, the flexion bolt 30, the locking mechanism 34, the flexion guide support member 47 and the flexed knee cutting guide assembly 52, is their usability with relatively non-invasive, narrow cuts in the anterior soft tissues of the knee (and with a retracted patella). Generally, as can be seen in Figures 14 and 15, the assembled components for making the cuts in knee flexion are relatively narrow as they extend out of the joint space in a U-shape, while at the same time providing a firm connection for supporting the cutting guide 54, a quick assembly and release of the components and accurate positioning of the flexed knee cutting guide. Considering the cutting guide 54 by itself (which can be positioned inside of the capsular incision), the width of this component is small compared to conventional cutting guides, for example, within a range of up to 4 to 5 cm thereby allowing their use with minimally invasive approaches to the knee joint.

The assembly 10 also includes instrumentation configured to guide cuts with the knee in extension (i.e., with the tibia and femur generally aligned, or at 0° of flexion), as shown in Figures 19-29. For knee extension, both the femoral IM rod 13 and the tibial IM rod 14 remain in place, as shown in Figure 19. However, instead of

2018282424 16 Dec 2020

attachment of the tibial mount 23 to the tibial IM rod 14, a tibial angulation guide 74 is attached to the tibial IM rod. The tibial angulation guide 74 includes a gauge block 76 and a post 97 which fits into an extension bolt 96 (similar to the flexion bolt 30, but without the bushing 33). The extension bolt 96 also has a hex flange 75. Alternatively, a separate gauge block 76 may be employed with a shaft (as shown in Figure 6) that extends into an opening in the bushing 33, allowing removal of the bolt 30 to be avoided.

Regardless, gauge block 76 extends upward from the plateau flange 28 of the tibial mount 23 when the threaded shaft of the extension bolt 96 extends into the threaded opening 29 and defines an arc surface 77 and a plurality of gauge marks 78 defined on its anterior surface, as shown in Figures 19-21. The arc surface 77 is shaped and sized to receive the outer surface of the cylindrically shaped femoral mount 15 and allow the femoral mount 15 to rotate in the varus-valgus direction and slide in the anterior-posterior direction therein. These motions are left free so as to not over-constrain the femur 11 and tibia 12, but still promote anterior-posterior alignment of the instruments and rotational position selection, for better positioning of the tibial and femoral cuts. Other variations and combinations of shapes of the femoral mount 15 and tibial angulation guide 74 could be employed to allow these ranges of motion, such as by reversing the shapes of the gauge block 76 (it having a cylindrical shape) and the femoral mount 15 (it having the arc shape), by having a rounded shape between two plates, extending the angulation readings away from the instrument assembly, etc., and still be within the purview of the present disclosure.

Adjustment of the relative proximal-distal positioning of the femur 1 1 and the tibia 12 is accomplished, similar to the technique in the flexion position, by adjusting the rotation of the hex flange 75 of the extension bolt 96 with a torque wrench. This motion advances or retracts the threaded shaft of the tibial extension bolt 96 into and out of the threaded opening 29 in the tibial mount 23 and advances the tibial angulation guide 74 toward the femoral mount 15. Preferably, the femur 11 and tibia 12 are distracted until the torque wrench has a reading similar to that for the knee in flexion to ensure that the joint is not overly tight in knee extension. With respect to the torque wrench and the amount of joint space, the torque wrench may be equipped with an extender that extends the length of the wrench, has hex-shaped jaws at its end and is relatively thin or low profile. If this is the case, the torque measurements may be adjusted to compensate for the additional length of the extender. In either case, the

2018282424 16 Dec 2020

objective is to match the torque value obtained when the instrument construct constrained the knee in some degree of flexion, in this instance 90° of flexion or increments therebetween, and torque the bolt to a similar torque measurement that was reached on the torque wrench in the previous step, or until adequate tension of the ligamentous structure is obtained.

Referring again to Figures 20 and 21, the gauge marks 78 of the gauge block 76 radiate outward from the center of rotation of the femoral mount 15, starting at the outer surface of the femoral mount, and are positioned on the anterior surface of the gauge block. The gauge marks 78 of the gauge block 76 are configured to match up with gauge marks 21 of the femoral mount 15 (as shown by the arrow) to indicate a valgus angle of the tibia 12 with respect to the femur 11. Generally, the valgus angle should be within a range of 3 to 7 degrees, or even 2 to 9 degrees, depending upon the knee's morphology, surgeon preference, etc.

Once the angulation and proximal-distal positioning of the tibia 12 with respect to the femur 11 has been adjusted, an extension guide support member 79 is attached to the femoral mount 15 using a second locking mechanism 84, as shown in Figures 22 and 23. Generally, the second locking mechanism 84 includes the plunger 36 (and its components including hexagonal end 44), hex extension 37 and helical slot 43 which are similarly numbered as they share a similar function with the same components of the first locking mechanism 34. The second locking mechanism 84 differs in that the head portion 39 is somewhat longer, is cylindrical and lacks the elongate portion 38 of the arm 35. Also, the second locking mechanism 84 includes a grip flange 86 positioned adjacent the plunger 36 to facilitate a finger grip when depressing the plunger. Regardless, the hexagonal end 44 has the same rotating motion that facilitates quick attachment of the end of the second locking mechanism 84 to the femoral mount 15.

The extension guide support member 79 includes a mounting portion 80, a support arm 81 and a fixation flange 82. The mounting portion 80 has a cylindrical shape with a cylindrical opening 83 extending therethrough that is configured to slidably receive the second locking mechanism 84, but is not rotationally constrained by said second locking mechanism 84. Extending away from one side of the mounting portion 80 is the support arm 81 which is an elongate structure with a T-shaped cross section. Extending away from the other side of the mounting portion 80 is an additional flange 82 that acts as a housing for a mechanism, in this case a ball and spring 85, to provide some resistance to rotation of the extension guide support member 79 with respect to the second locking mechanism 84.

Also included in the illustrated embodiment of the assembly 10, is an extended knee cutting guide 87 that is supported by the extension guide support member 79 during positioning, as shown in Figures 24-29. The extended knee cutting guide 87 includes a mounting portion 88, a fixation pin (or k-wire) guide portion 89, a femoral cut guide portion 90 and a reference lever 91. The mounting portion 88 is generally centered in a body portion of the extended knee cutting guide 87 and defines a channel 92 that has a cross-sectional shape matched to the T-shaped cross-section of the support arm 81. The matching shapes allow the extended knee cutting guide 87 to slide in the proximal-distal direction along the support arm 81.

The fixation pin guide portion 89 defines a plurality of k-wire (or other type of fastener, e.g., screws, nails, etc.) holes 93 that allow fixation using fixation pins after positioning of the extended knee cutting guide 87. The holes 93 are positioned on medial and lateral sides of the anterior femur when positioned so as to allow fixation to relatively thick cortical bone, as shown in Figure 25. As with the k-wire holes 72, the k-wire holes 93 can be oriented at various angles or selectively positioned to guide fasteners into and through larger lengths of denser bone on the femur 11.

The femoral cut guide portion 90 extends either laterally or medially for a uni-compartmental reconstruction (as with the illustrated embodiment), or in both directions for a full resection of the femoral condyles. Notably, the guide portion 90 extends distally in the shape of a U that fits around the second locking mechanism 84 when the extended knee cutting guide 87 is in place, as well shown in Figure 29. Regardless, the guide portion 90 extends distally from the k-wire guide portion 89 and then laterally or medially to define a guide slot 94. The guide slot 94 is of sufficient width to allow passage of cutting instruments or blades but still promote a relatively straight or planar resection. Notably, extension medially allows the laterally shifted patella to be avoided in a medially oriented approach to the knee joint compartment.

Extending further distally from the femoral cut guide portion 90 is a portion of the extended knee cutting guide 87 that defines a clevis 95 that rotationally supports the reference lever 91. The reference lever extends laterally or medially and rotates in an anterior-posterior direction to allow positioning in the joint compartment, as shown in Figures 24 and 25. The reference lever 91 has a broad, flat distal surface that is configured to rest against the flat tibial cut and a flat lateral surface is configured to abut the side surface of the plateau flange 28. These surfaces provide a stop for the distal movement of the extended knee cutting guide 87 along the support arm 81 of the extension guide support member 79. With the reference lever 91 and the second locking mechanism 84 in place, fixation pins can be inserted through the pin holes 93 in the guide portion 89 to fix the femoral cut guide portion 90 to the femur 11. This allows removal of the extension guide support member 79, as shown in Figures 27, 28 and 29.

Advantageously, the components for positioning the cuts with the knee in extension, including the extension bolt 96, tibial angulation guide 74, the extension guide support member 79 and the extended knee cutting guide 87 are configured for passage through an anterior and medial approach to the knee compartment due to the narrow width and profile of the components. For example, as shown in Figure 25, the posterior portion of the second locking mechanism 84 and the reference lever 91 would pass through the incision and exhibit the aforementioned narrowness and low-profile. Preferably, the width of this component is small compared to conventional cutting guides, for example, within a range of up to 4 to 5 cm thereby allowing their use with minimally invasive approaches to the knee joint.

After these initial cuts, further cuts can then be made using the initial cuts as a reference. As shown in Figures 30 and 31, an L-plate 99 is employed to abut the posterior and distal flat surface of the femur 11 to guide an anterior cut. Chamfer cuts (anterior and posterior) can be made using a chamfer cut block and other finishing cuts can be references from the initial cuts made using the assembly 10 of the present disclosure. Additional description of these finishing cuts can be found in U.S. patent application no. 10/794,188 filed on March 5, 2004, entitled "Reference Mark Adjustment Mechanism for a Femoral Caliper and Method of Using the Same," which is hereby incorporated herein by reference.

In another embodiment of the present disclosure, as shown by Figures 32 through 40, the assembly 10 includes additional modular options to promote quick assembly. As shown in Figure 32, the femoral IM rod 13 includes a secondary femoral mount 100. The secondary femoral mount 100 has a saddle or crescent shape that extends laterally and distally from a central attachment to the distal end of the main shaft 16 of the femoral IM rod 13. Defined in the inner, convexly curved surface of the saddle is an opening 101 that is configured to receive a femoral mount rod 102 that supports the femoral mount 15, as shown in Figure 33.

Referring again to Figure 32, the tibial IM rod 14 includes a modified version of tibial mount 23 supported by the shaft 22. In particular, the plateau flange 28 of the tibial mount 23 has a widened rectangular shape that extends laterally outward from the threaded opening 29. Defined at the anterior side of the plateau flange 28 are a pair of guide mount openings 103 that extend posteriorly into the plateau flange. As shown in Figure 34, the flexion bolt 30 may also be further modularized by providing a post 104 for mounting the bushing 33 and hex flange 32 within a central opening defined in a hex-head bolt 105 that includes the threaded shaft 31 extending from its head 105. Figures 35 and 36 show the assembly of the femoral mount 15 and tibial mount 32, along with tightening adjustment by elevation of the hex head bolt 105.

As shown in Figure 37, the assembly 10 also includes a flexed knee cutting guide assembly 52 that includes a flexed knee cutting guide 54 and a direct mount 106. The direct mount includes a pair of posts 107 that are spaced apart and extend from a mounting block 108. The spacing and size of the posts 107 are configured to extend into the guide mount openings 103 defined in the plateau flange 28. Mounting block 108 can be coupled to tibial mount 32, such as by hermetically sealed magnets 111. The flexed knee cutting guide 54 is attached to and extends distally from the mounting block 108. The flexed knee cutting guide defines a selection of slots 109 for guiding tibial and femoral cuts.

The posterior femoral cut can be accomplished by turning the flexed knee cutting guide assembly 52 upside down or by using another block which would be a modification of the upside down cutting guide assembly 52 where the cutting guide 54 and selection of slots 109 is moved toward the posts 107 and therefore, closer to the posterior femoral condyles of the knee. The selection of slots 109 of cutting guide assembly 52 can be as shown with the slots attached centrally or could be open centrally and attached along both sides of the cutting guide 54.

As shown in Figures 38 and 39, the tibial IM rod 14 may also include a valgus adapter member 110 or a modified version of femoral mount 15 that has its own post that is configured to insert into the central opening of the hex head bolt 105. As shown in Figure 40, the valgus adapter member 110 has a convex shape that is configured to extend into the concave shape of the secondary femoral mount 100. This mating allows varus-valgus angulation to position the cuts when the knee is in extension, similar to the first embodiment disclosed above. Extended knee cutting guides can be mounted similar to the flexed knee cutting guide via posts 107.

2018282424 16 Dec 2020

The assembly 10 of the present disclosure has many advantages. It provides a relatively narrow and low profile collection of locking components that securely attach cutting guides to tibial and/or femoral IM rods. This provides a robust guide to reference cuts being made to the tibia and the femur with an approach to the joint that minimizes invasiveness. Further, many of the components, such as the first and second locking mechanisms 34, 84 and the quick release mechanism 53, facilitate quick assembly, easy adjustment and quick disassembly for improved efficiency. The use of the bolts 30 and 96 or 105 and the tibial angulation guide 74 or valgus adapter member 110 allow the tibia and femur to be distracted under a matching amount of torque in flexion and extension to ensure a better fit for the tibial and femoral knee replacement components throughout a range of flexion. Also, the tibial angulation guide allows the surgeon to adjust the amount of valgus angulation of the tibia as desired to match the anatomy of the patient.

As shown in Figure 41, in another embodiment of the present disclosure a modified femoral mount rod 102 and femoral mount 15 with a hinge mechanism attaching mount 15 to the femoral mount rod 102 could be used with a retractor rod placed thru the hole 18 in the femoral mount 15 and guided posterior to the tibia thus providing a fulcrum and lever arm for the retractor to displace the tibia forward or anterior to allow exposure for placement of the tibial component of the total knee arthroplasty after the bone cuts have been made. Since the IM rods fix rigidly to the bone, other retractors could also be attached to the Guide Assembly to facilitate knee exposure during the knee surgery.

As shown in Figure 42, in another embodiment of the present disclosure mini-trial components or trial components which are smaller but shaped with identical thickness and radii to the actual knee arthroplasty implants, designed to fit in holes 101 of femoral IM rod 13 and 29 of tibial IM rod 14 and articulate in the center portion of the knee could be used to check alignment and ligament stability prior to placement of the actual final knee arthroplasty implants. This design of a centrally placed mini-knee arthroplasty implant system could become a stand alone total knee arthroplasty. One advantage of this embodiment of the present disclosure is that the smaller instruments take up less space. The mini-trial femoral component could be designed with cutting surfaces or slots for making the chamfer cuts and other finishing cuts, thus eliminating the need for a chamfer cut block and L-plate 99 shown in Figures 30 and 31.

2018282424 16 Dec 2020

In another embodiment, since the Guide Assembly is fixed rigidly to the bone and left in place during the essential steps of the knee preparation, computer assisted guides are attached to the Guide Assembly Instruments thus facilitating computer assisted total knee replacement.

In some embodiments, the Guide Assembly Instruments can be modified for use with short IM rods or a tibial platform instead of an IM rod for extramedullary knee preparation.

In some embodiments, the Guide Assembly holds a patient's leg in place.

This decreases the need for medical assistants to hold the patient's leg.

Many modifications and other embodiments of the disclosure set forth herein will come to mind to one skilled in the art to which these disclosures pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the disclosure is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

Many modifications and other embodiments of the disclosures set forth herein will come to mind to one skilled in the art to which these embodiments pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the disclosure are not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

It is to be understood that, if any prior art publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

In the claims which follow and in the preceding description, except where the context requires otherwise due to express language or necessary implication, the word “comprise” or variations such as “comprises” or “comprising” is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments.

2018282424 16 Dec 2020

Claims

1. An apparatus for adjusting at least one of: (i) tension and (ii) an alignment of a knee joint, the apparatus comprising:

a first member configured to extend into a femur when the apparatus is seated in the knee joint;

a second member that is configured to contact a proximal portion of a tibia when the apparatus is seated in the knee joint; and

an adjustable component that is configured to couple the first member with the second member such that the second member is rotatable with respect to a longitudinal axis of the first member when a position of the first member is constant with respect to the femur to allow for adjustment of an angle between the tibia and the femur when the apparatus is seated in the knee joint.

2. The apparatus of claim 1, wherein the adjustable component comprises a threaded object that is configured to be rotated to vary a distance between the first member and the second member when the apparatus is seated in the knee joint, and wherein the apparatus is configured to be seated in the knee joint with the first member extended into the femur and the second member contacting the proximal portion of the tibia when the knee joint is disposed in a flexed position.

3. The apparatus of claim 1, wherein the first member comprises a rod and wherein the adjustable component is configured to couple the second member to the rod such that the second member is rotatable about a longitudinal axis of the rod when the apparatus is seated in the knee joint.

4. An apparatus for adjusting at least one of: (i) tension and (ii) an alignment of a knee joint, the apparatus comprising:

an elongated member that is configured to extend into a distal end of a femur;

a tibial contact member that is configured to contact a proximal end of a tibia; and

an adjustable component that connects the elongated member with the tibial contact member such that the tibial contact member is rotatable about a longitudinal axis of the elongated member when the apparatus is seated in the knee joint, when the elongated member is fixed in position with respect to the femur, and when the knee joint is in a flexed position.

5. The apparatus of claim 4, wherein the adjustable component comprises a threaded element that is configured to be rotated to vary a distance between the elongated member and the tibial contact member when the elongated member extends into the distal end of the femur and the tibial contact member contacts the proximal end of the tibia.

20182824242 20 Dec 2018

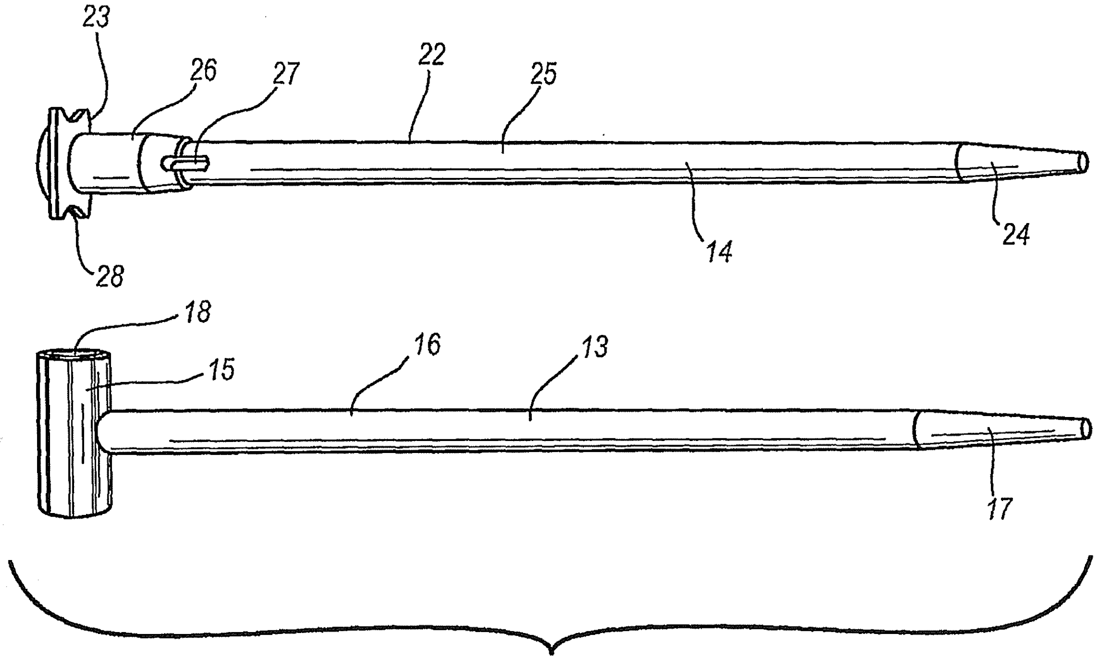

FIGURE 1

2018282424 20 Dec 2018

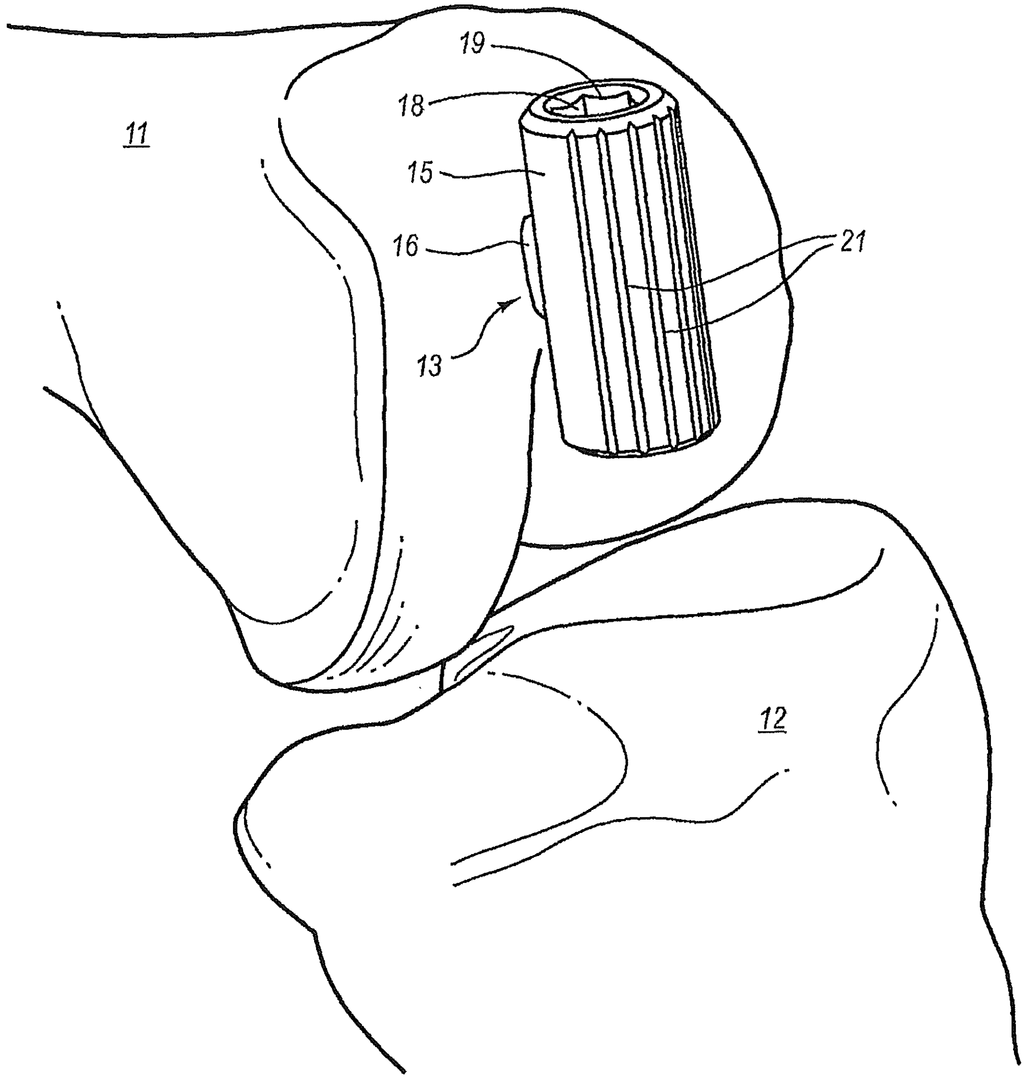

FIGURE 2

20 Dec 2018 2018282424

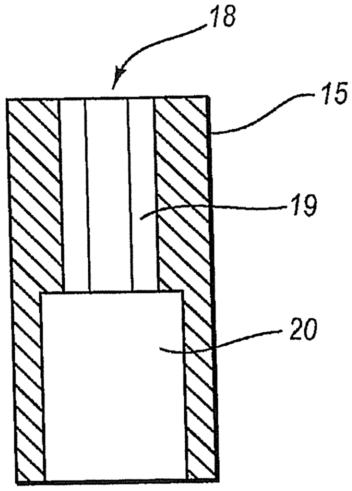

FIGURE 3

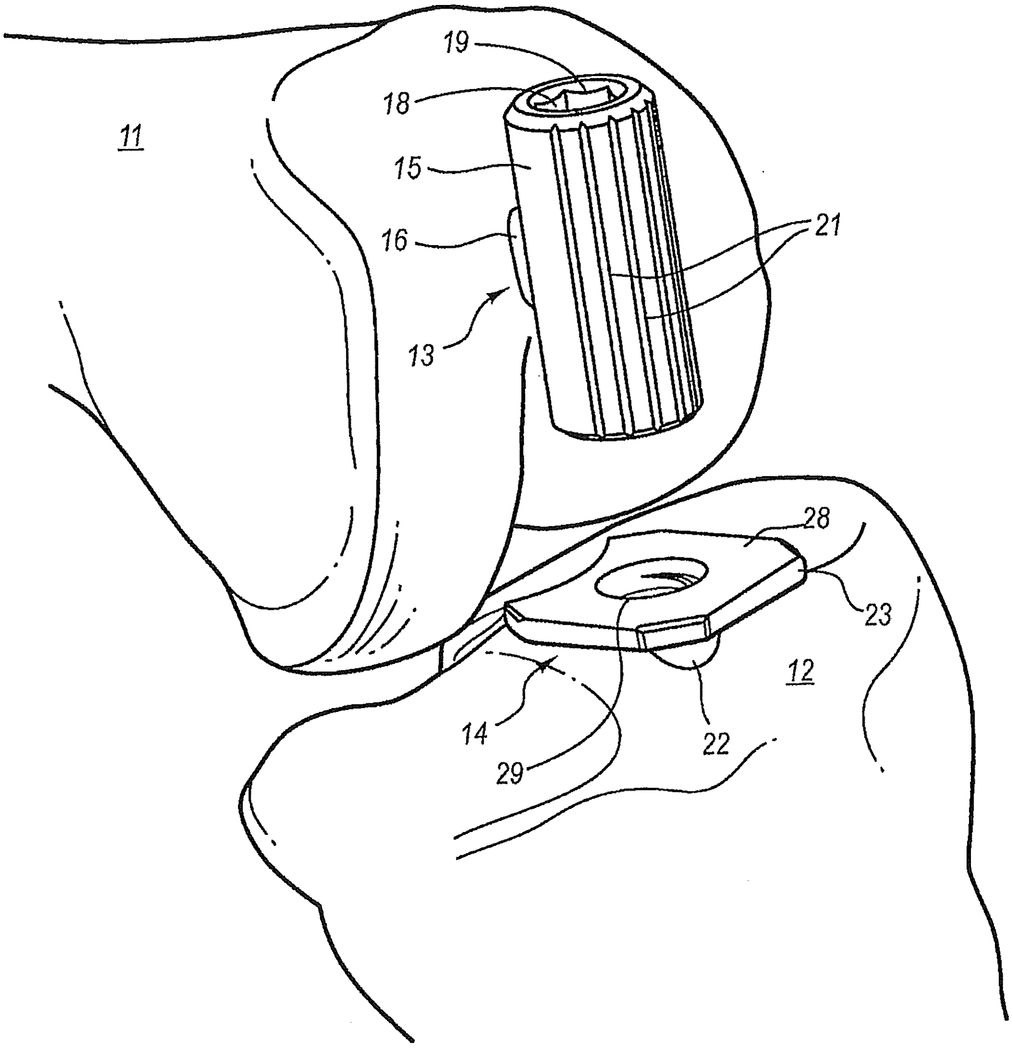

FIGURE 4

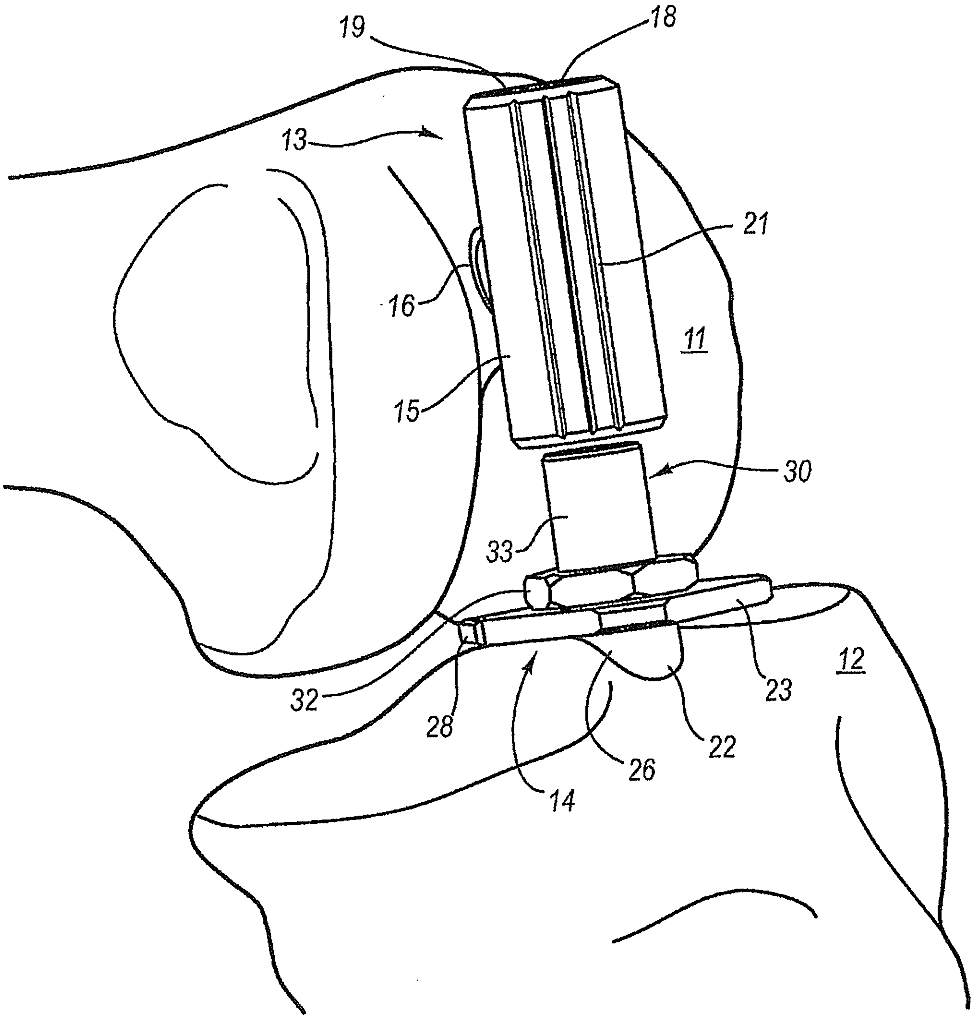

FIGURE 5

2018282424 20 Dec 2018

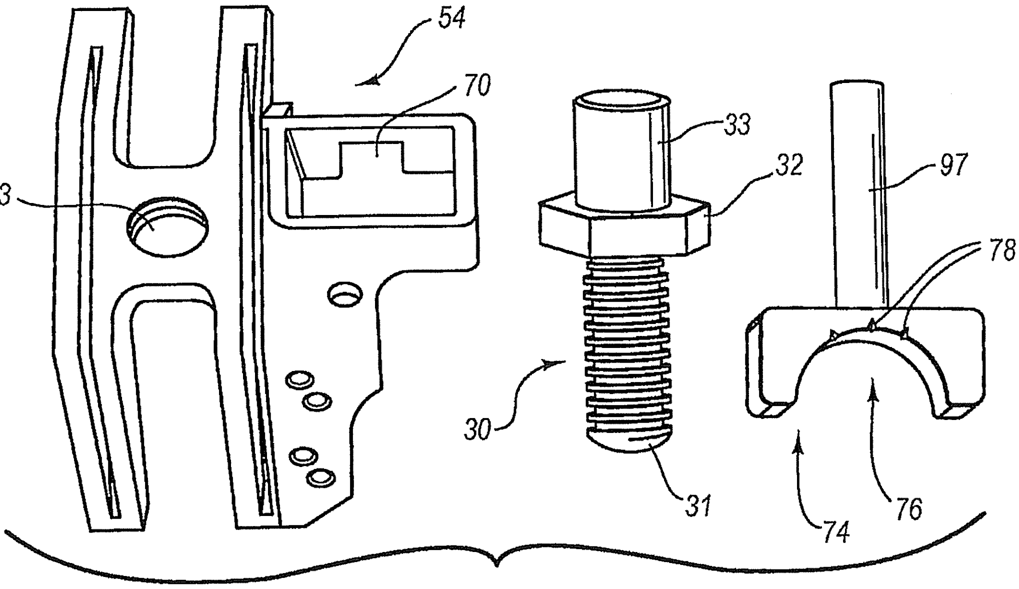

FIGURE 6

20182824242 20 Dec 2018

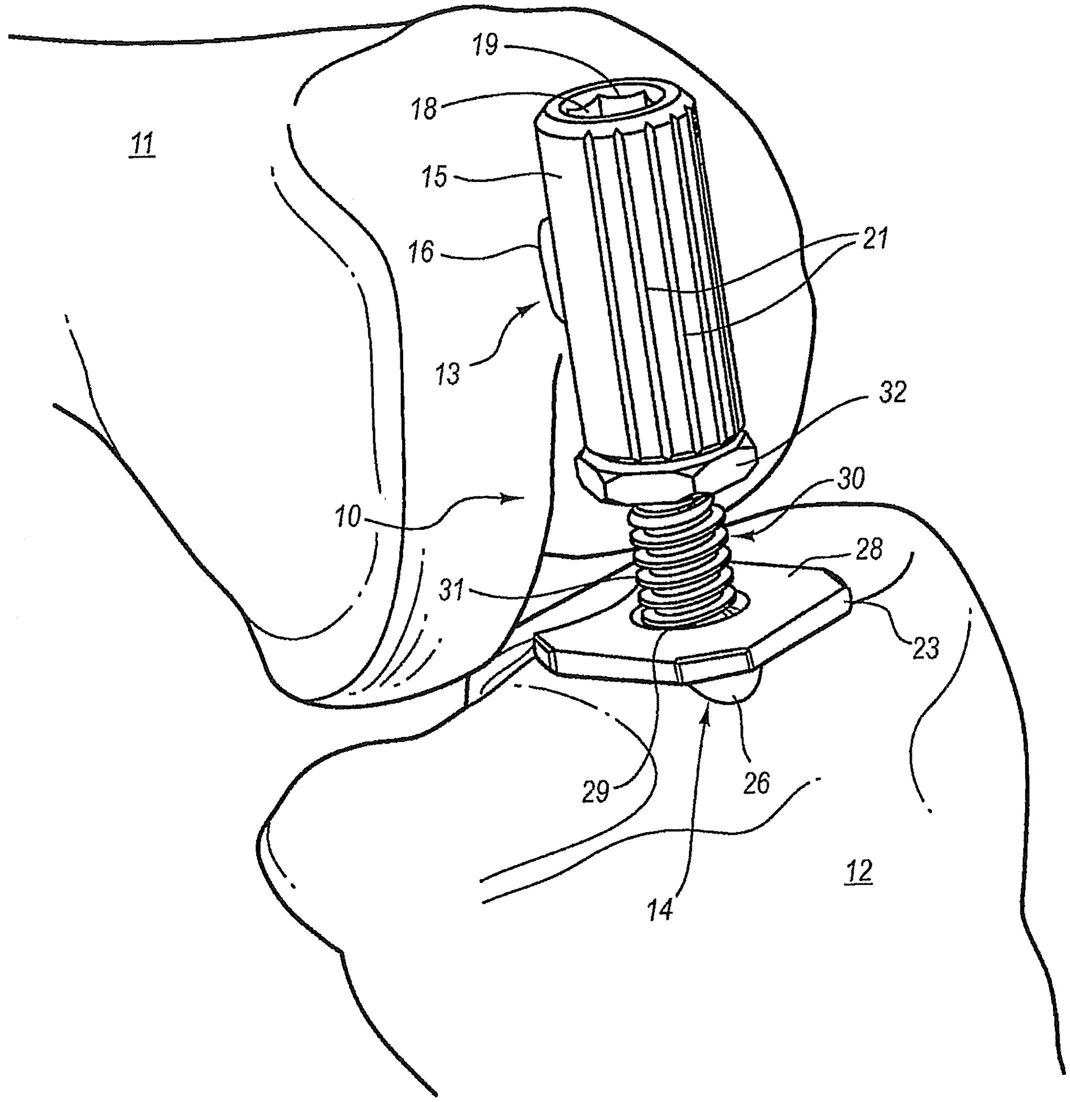

FIGURE 7

20 Dec 2018
2018282424

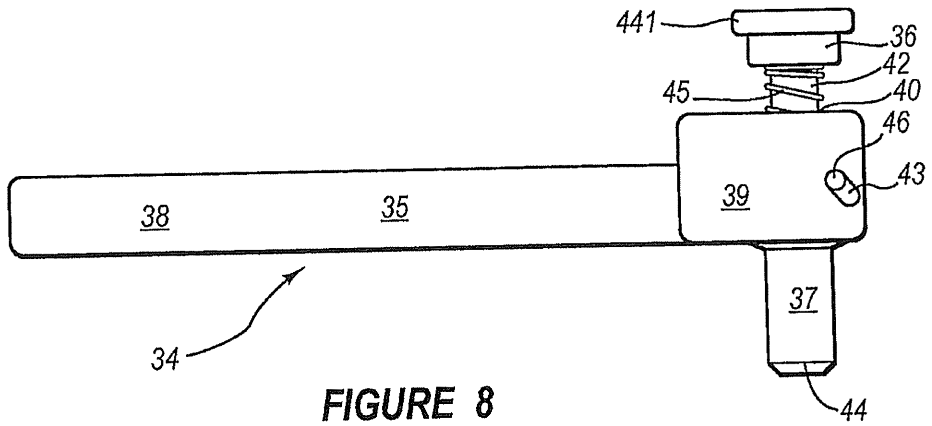

FIGURE 8

20182824242 20 Dec 2018

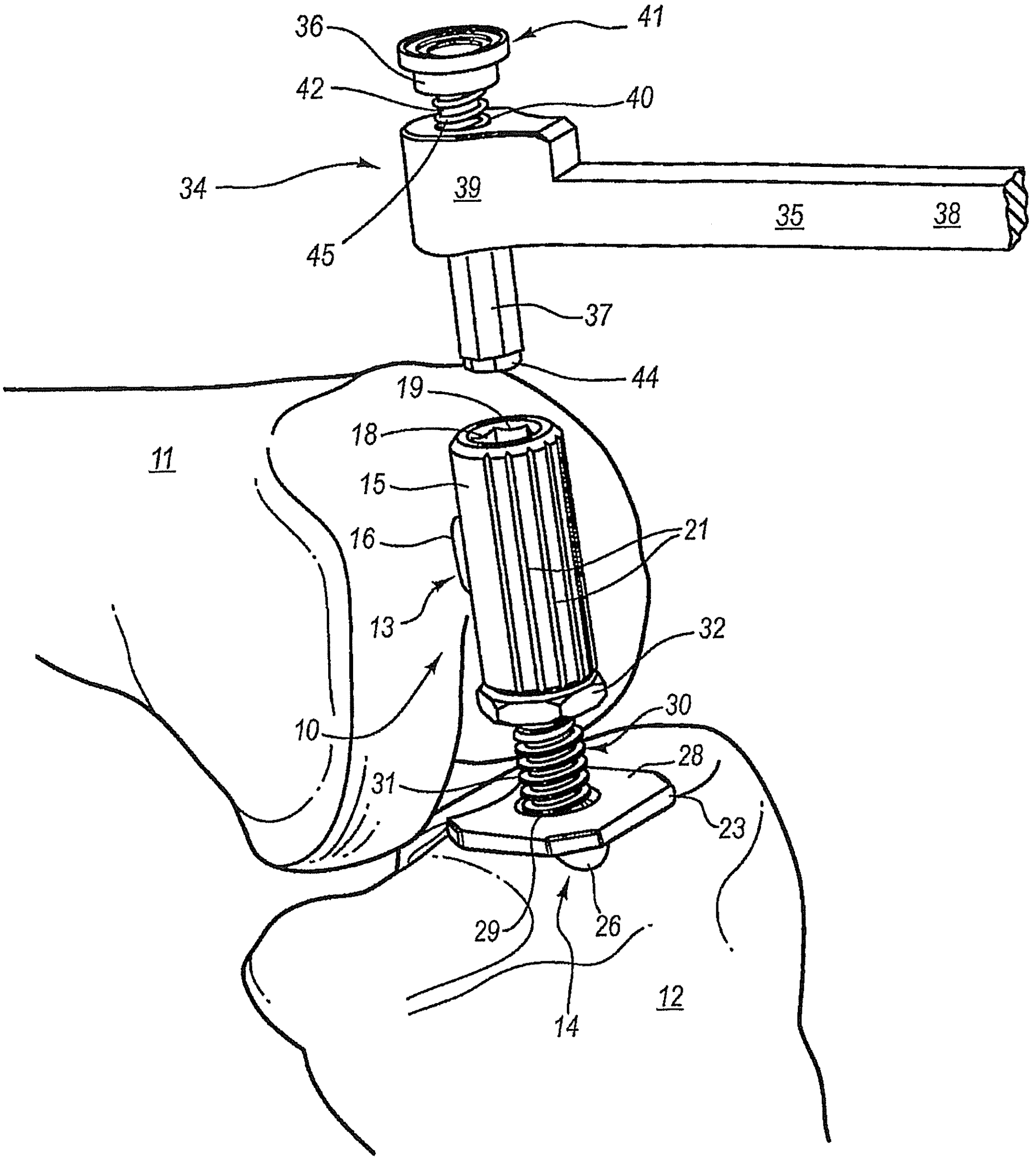

FIGURE 9

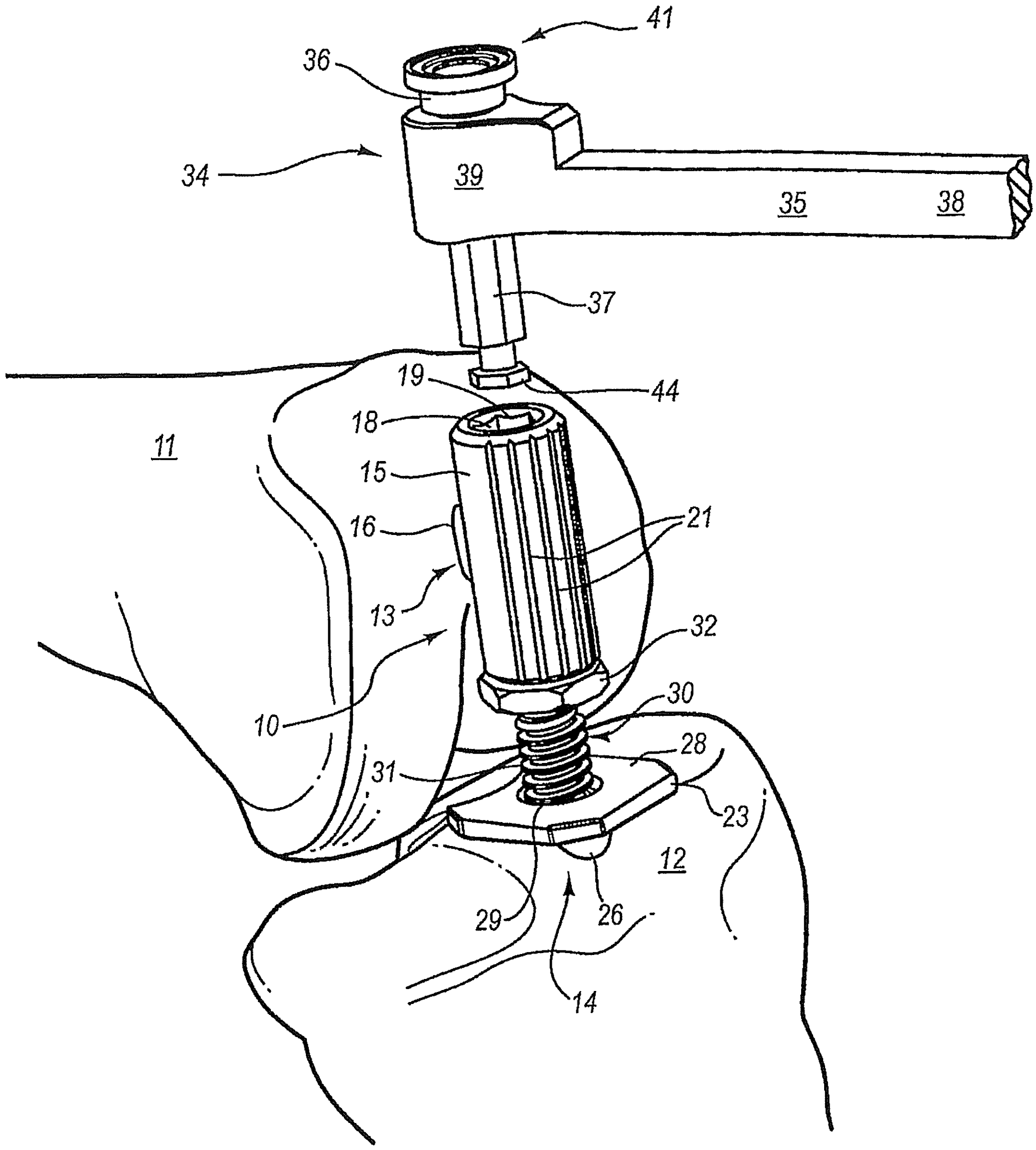
41
36
34
39
35
38
37
19
44
18
11
15
16
21
13
32
10
30
28
31
23
12
29
26
14

FIGURE 10

2018282424 20 Dec 2018

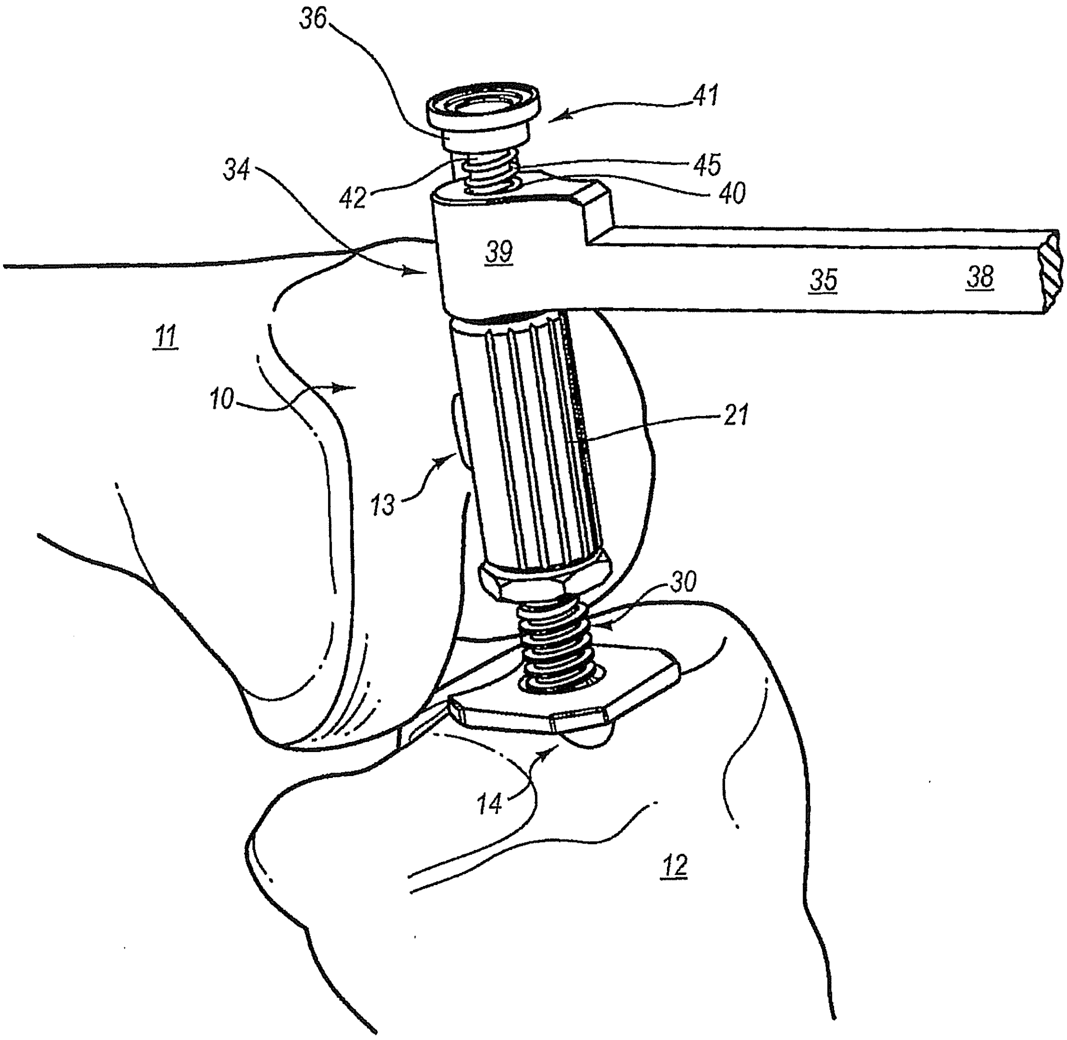

FIGURE 11

2018282424 20 Dec 2018

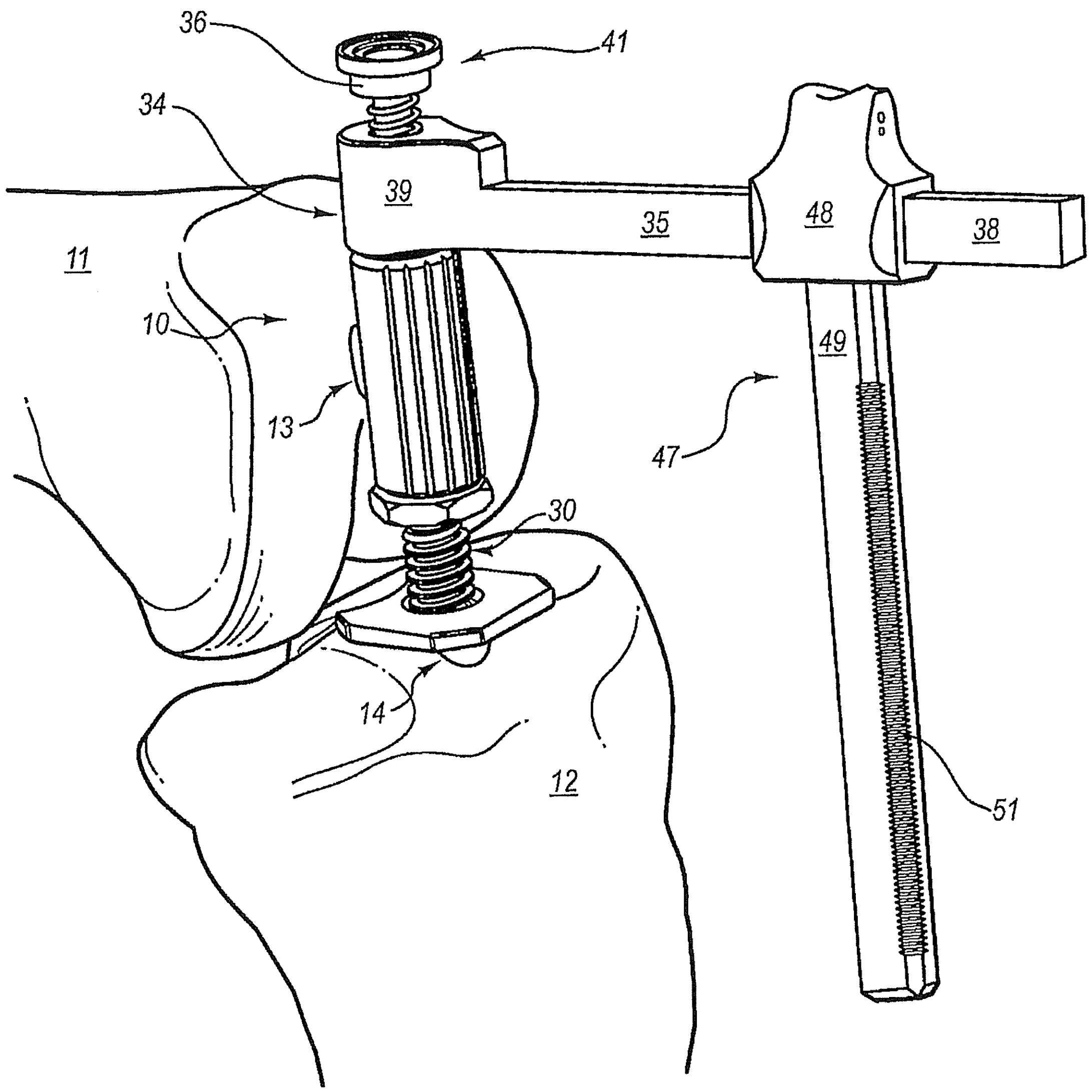

FIGURE 12

20182824 24 20 Dec 2018

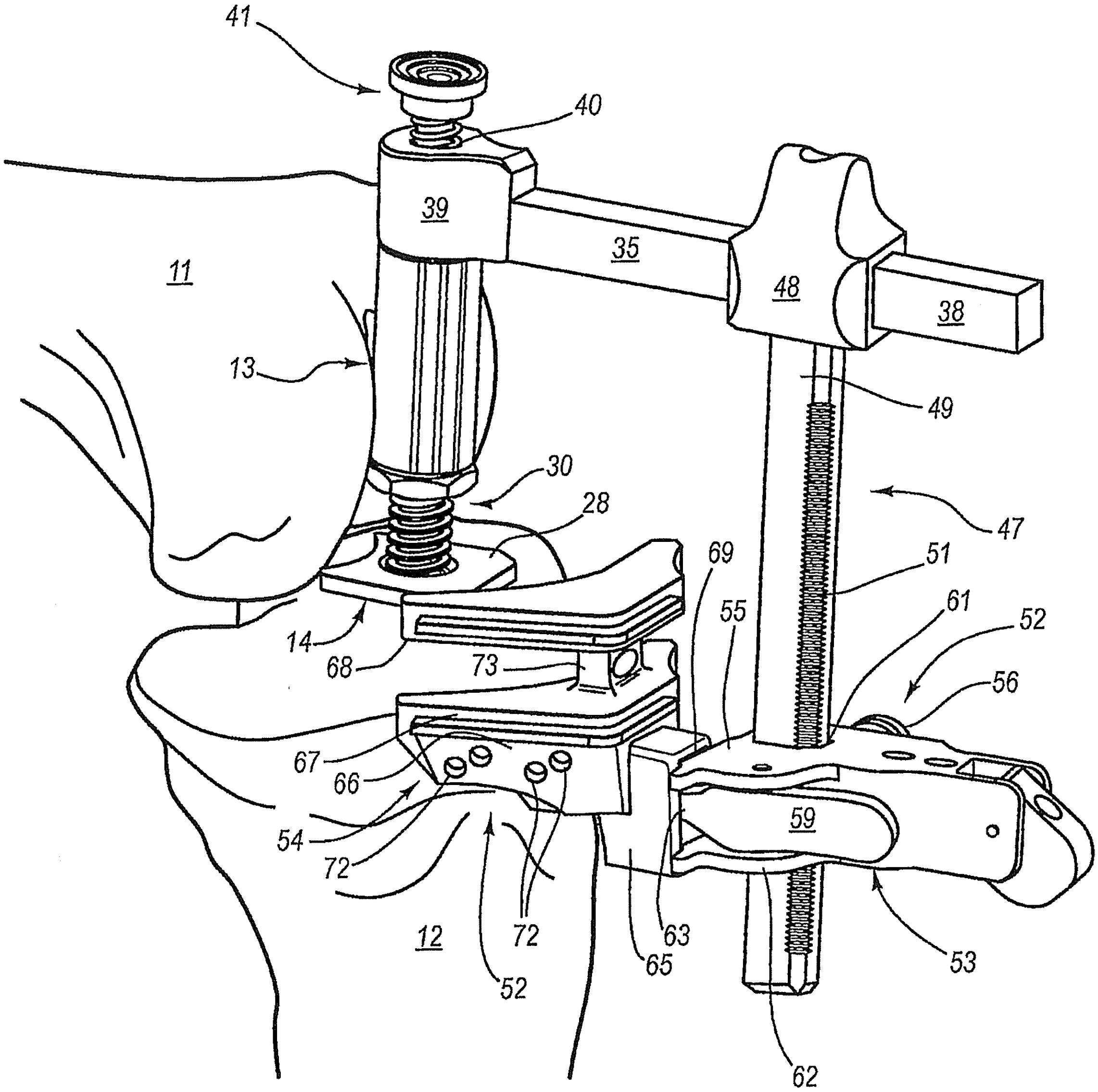

FIGURE 13

20182824224 20 Dec 2018

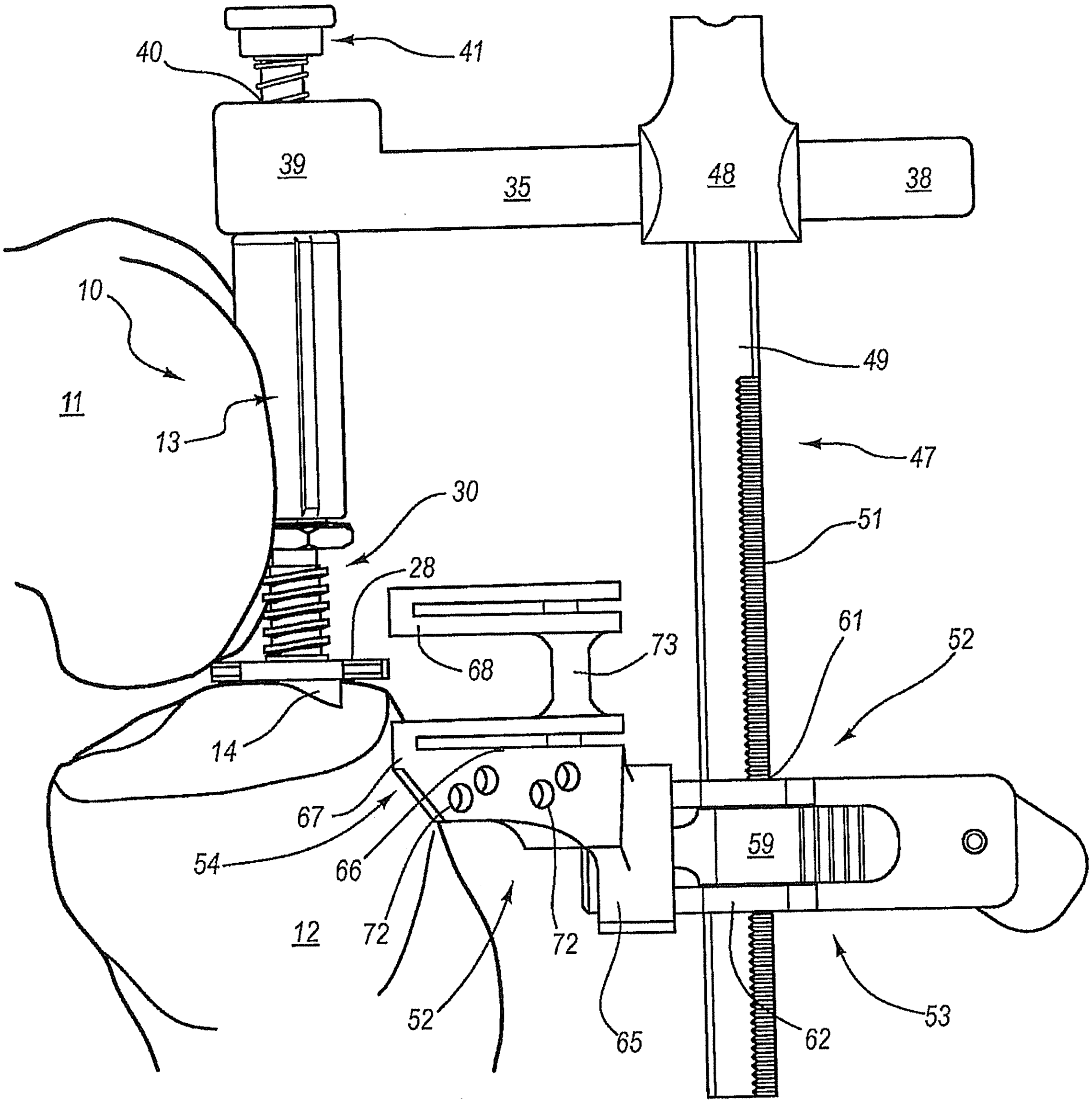

FIGURE 14

20182824242 20 Dec 2018

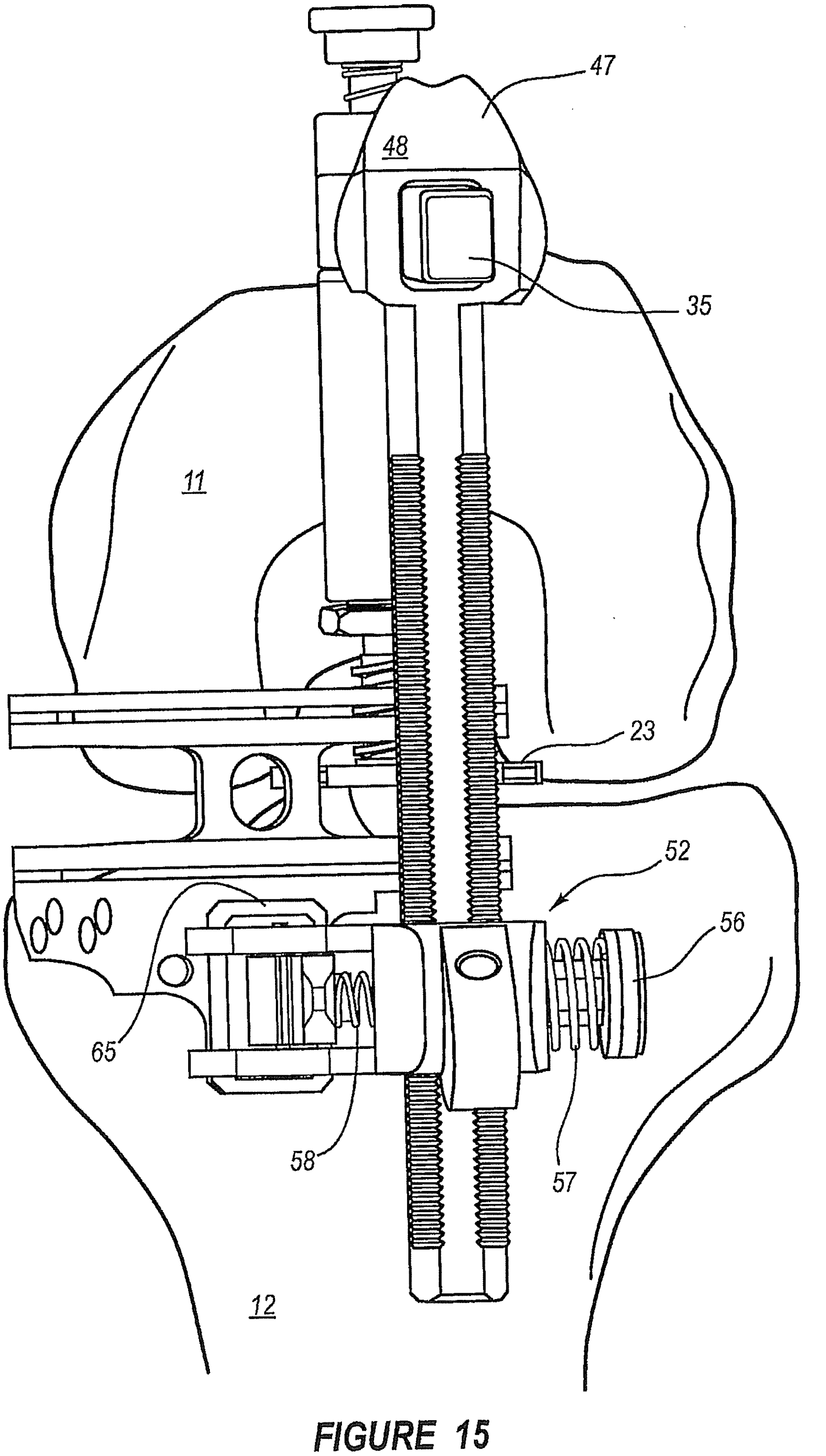

FIGURE 15

20182824242 20 Dec 2018

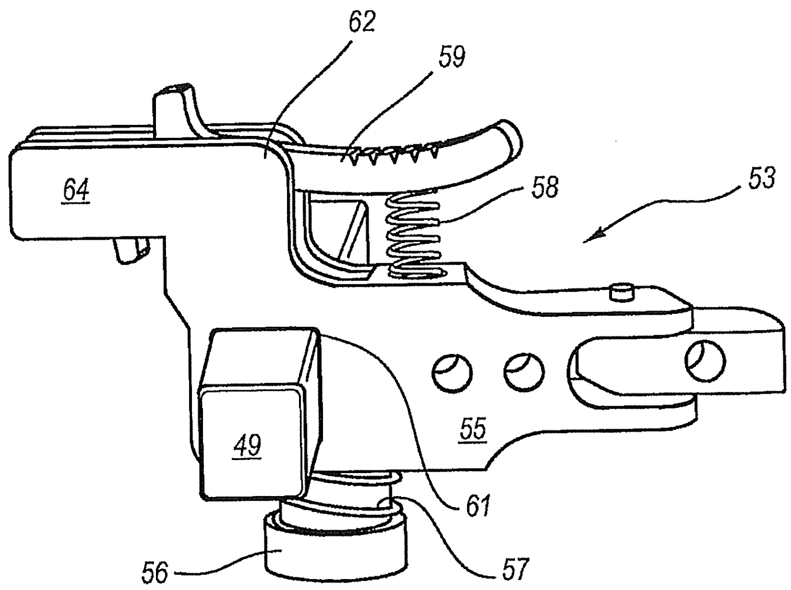

FIGURE 16

2018282424 20 Dec 2018

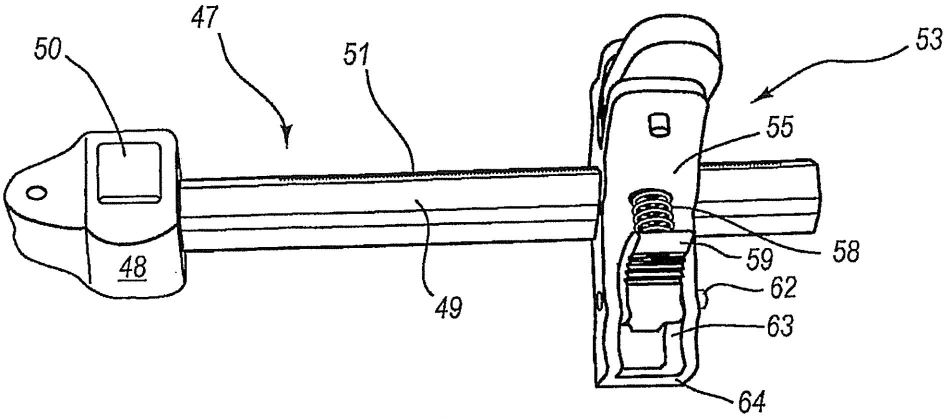

FIGURE 17

20182824424 20 Dec 2018

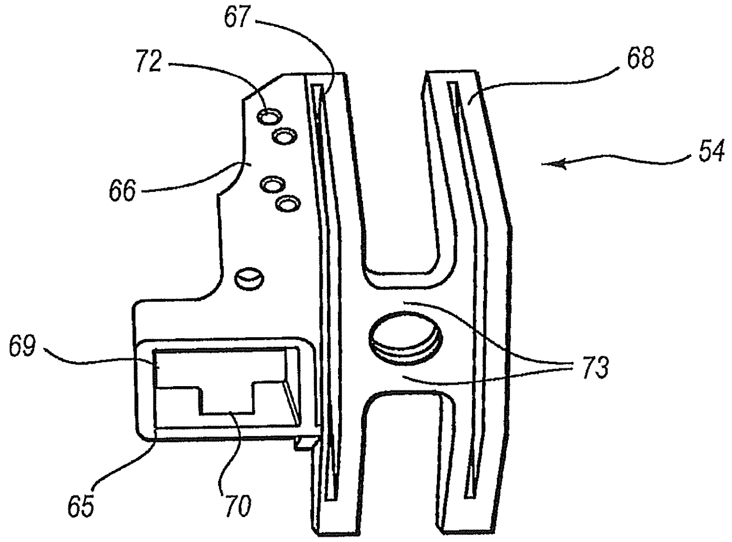

FIGURE 18

2018282424 20 Dec 2018

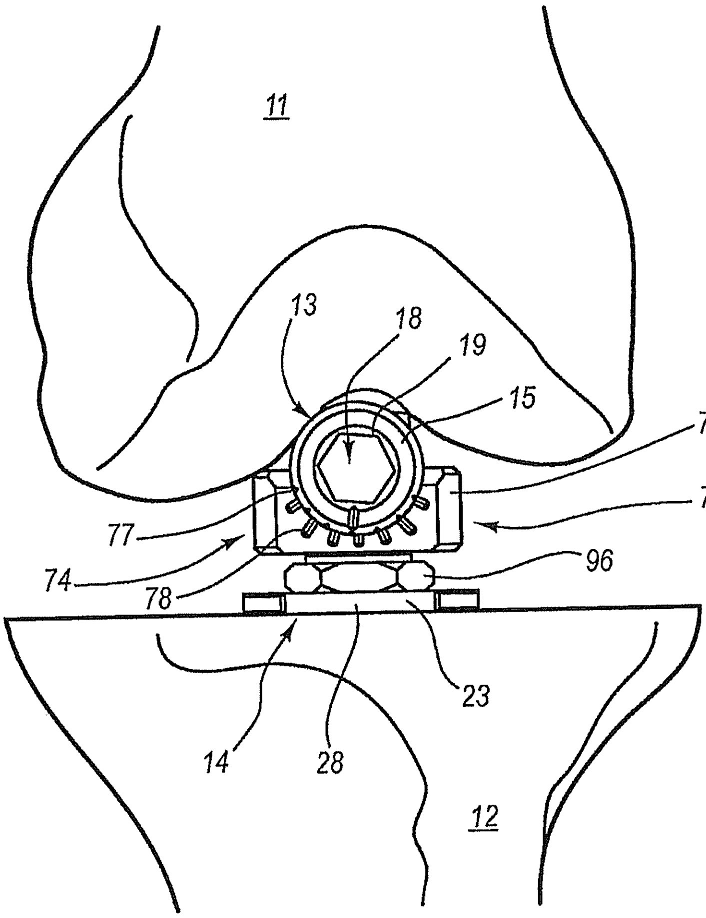

FIGURE 19

20182824 24 20 Dec 2018

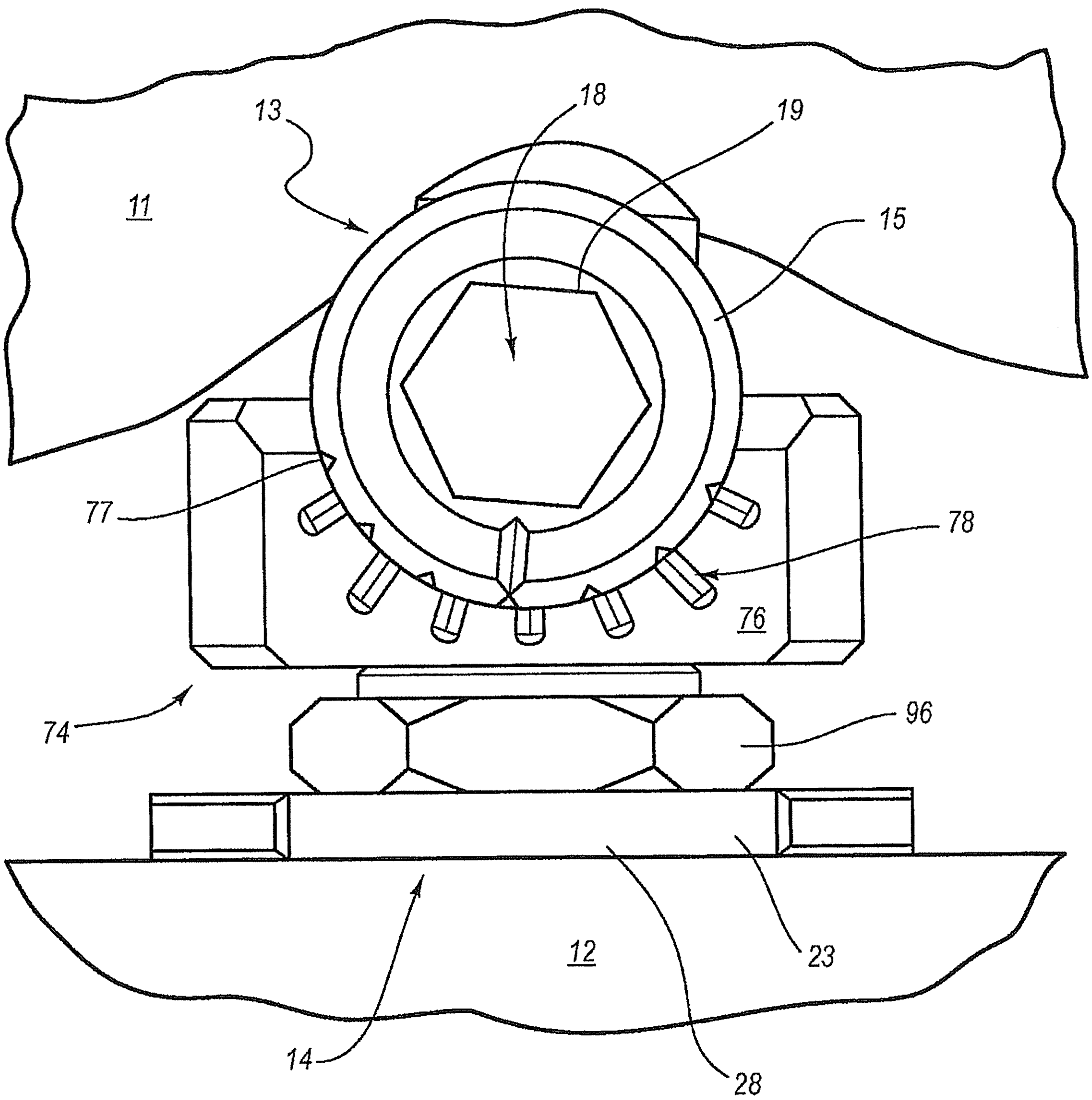

FIGURE 20

20182824242 20 Dec 2018

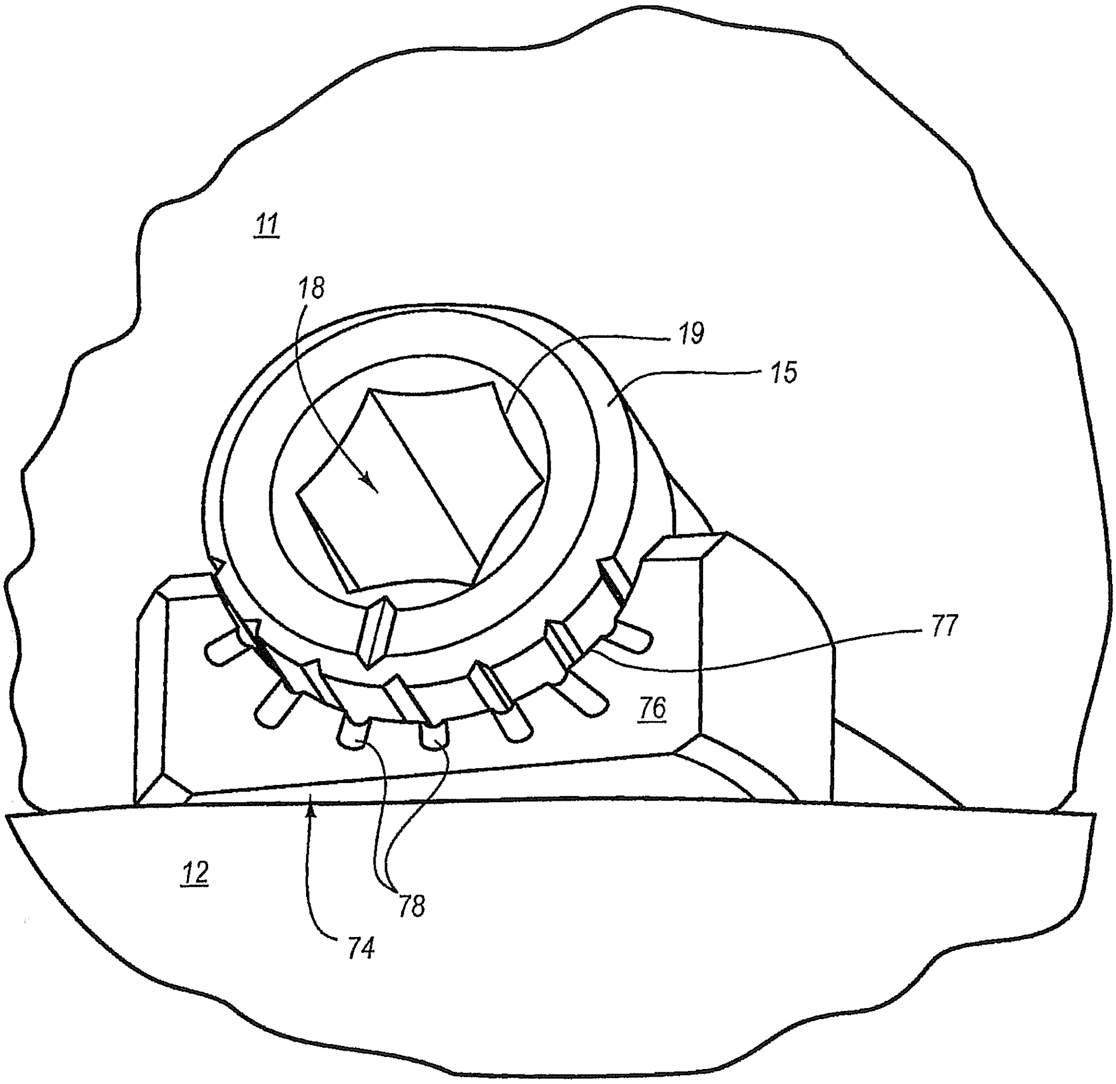

FIGURE 21

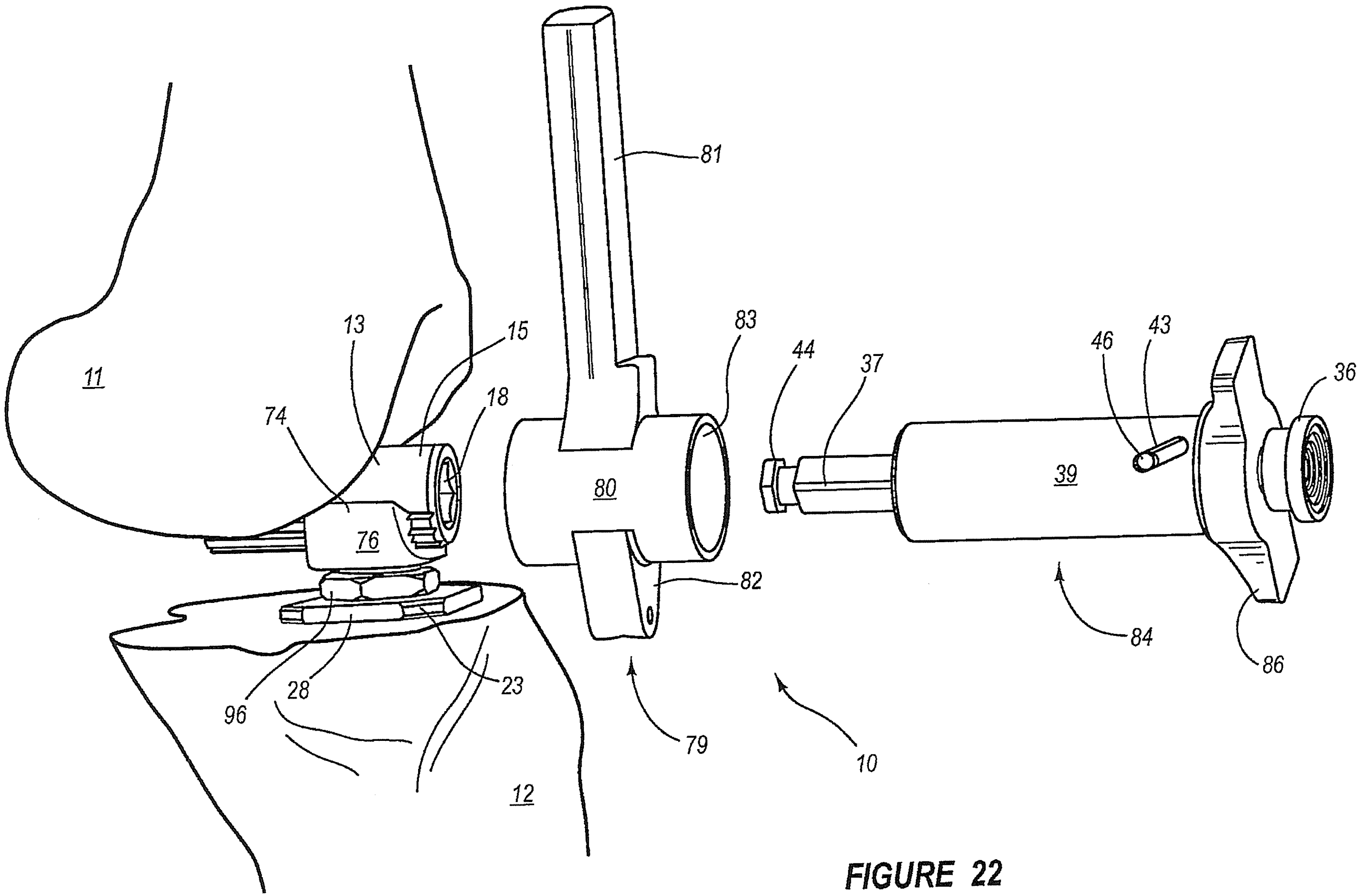

FIGURE 22

20182824242 20 Dec 2018

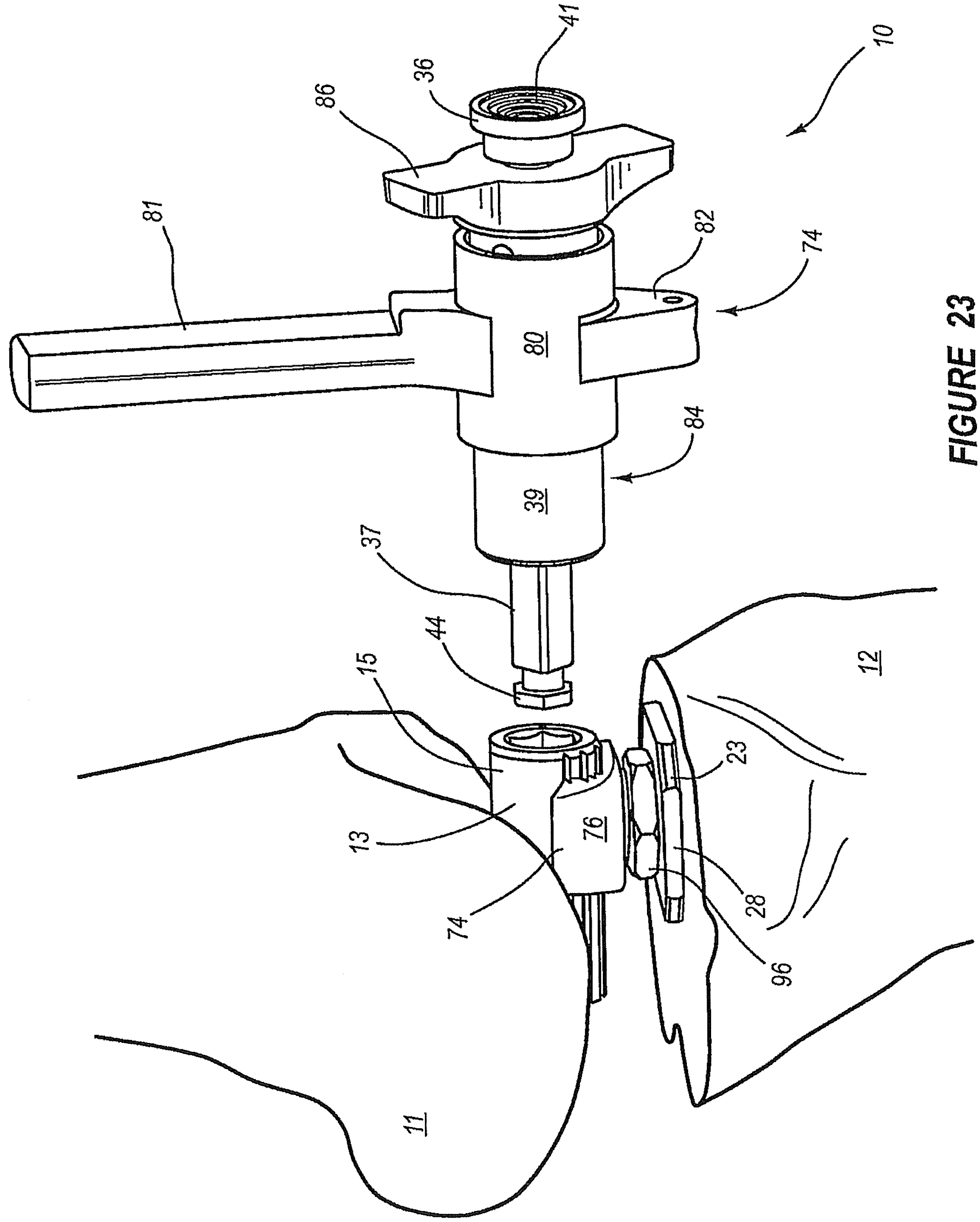

FIGURE 23

2018282424 20 Dec 2018

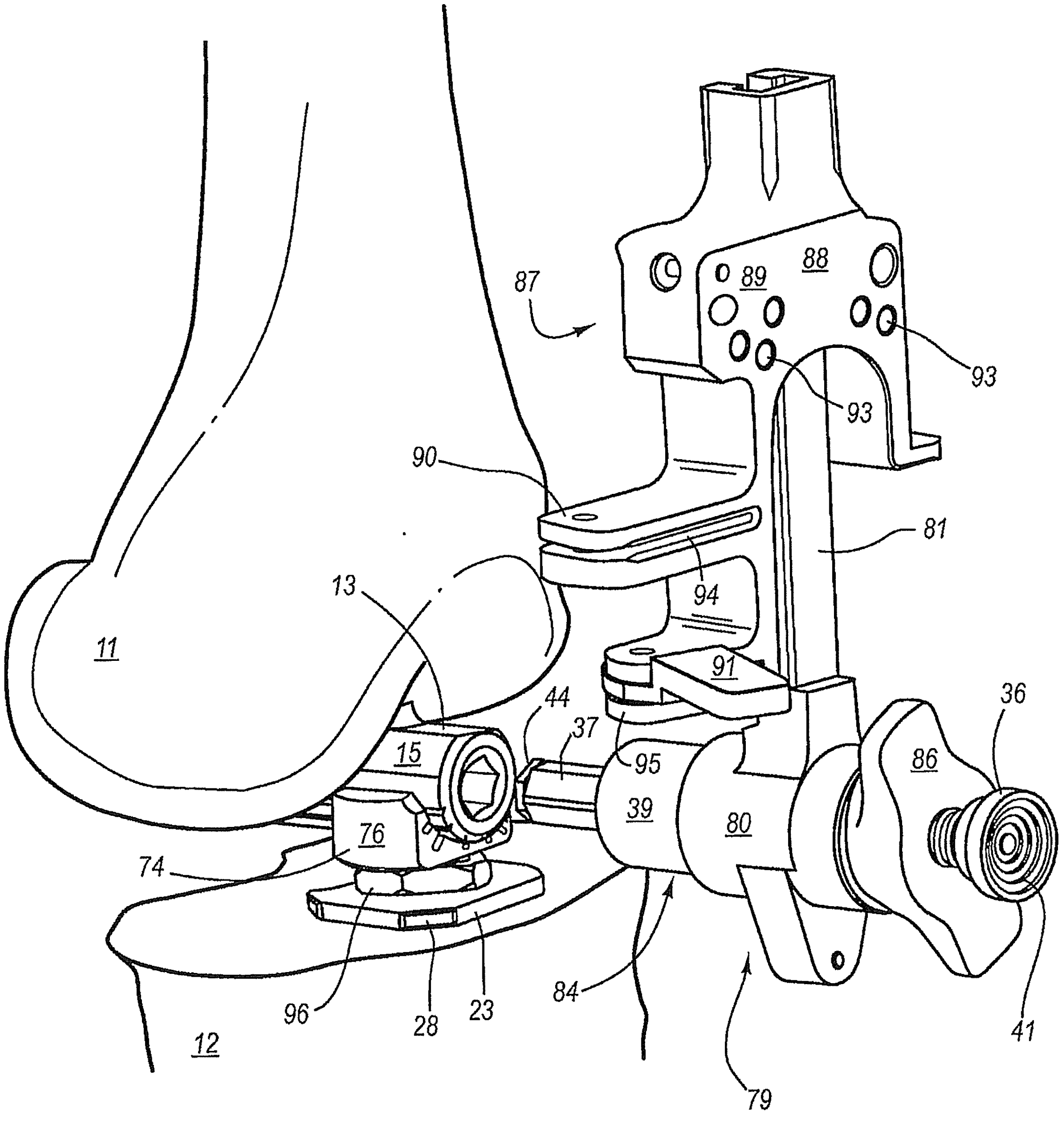

FIGURE 24

2018282424 20 Dec 2018

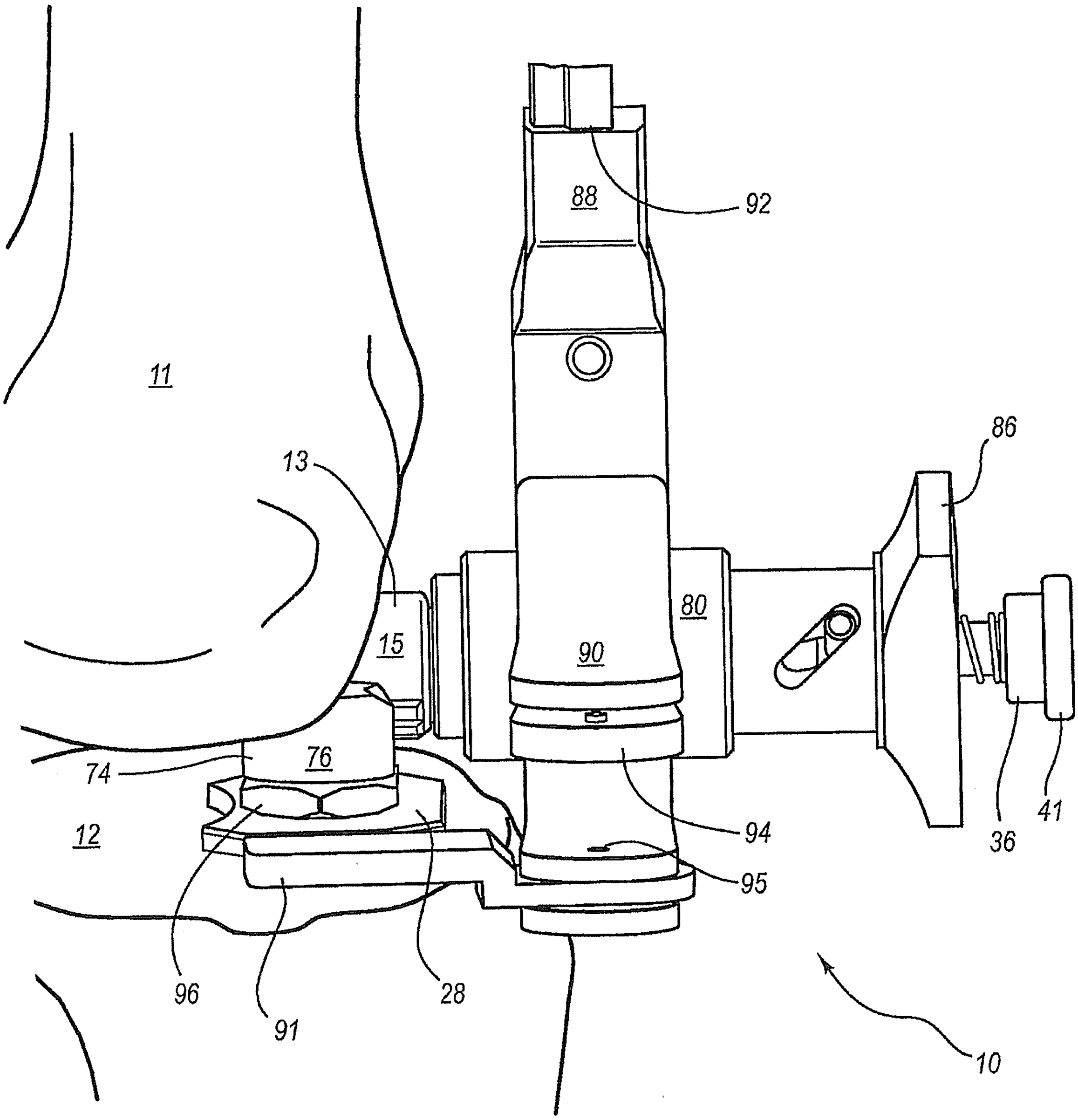

FIGURE 25

20182824 24 20 Dec 2018

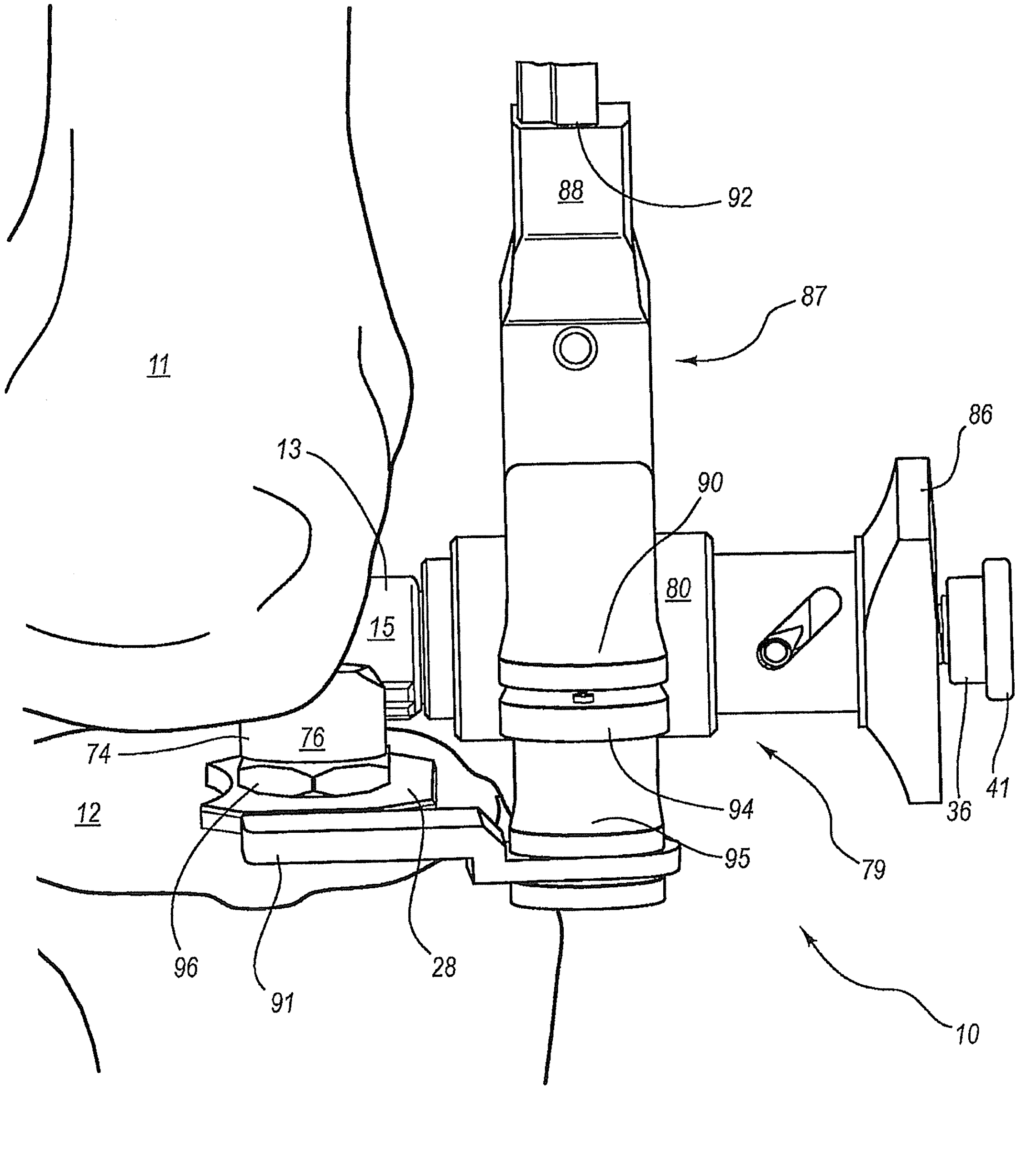

FIGURE 26

2018282424 20 Dec 2018

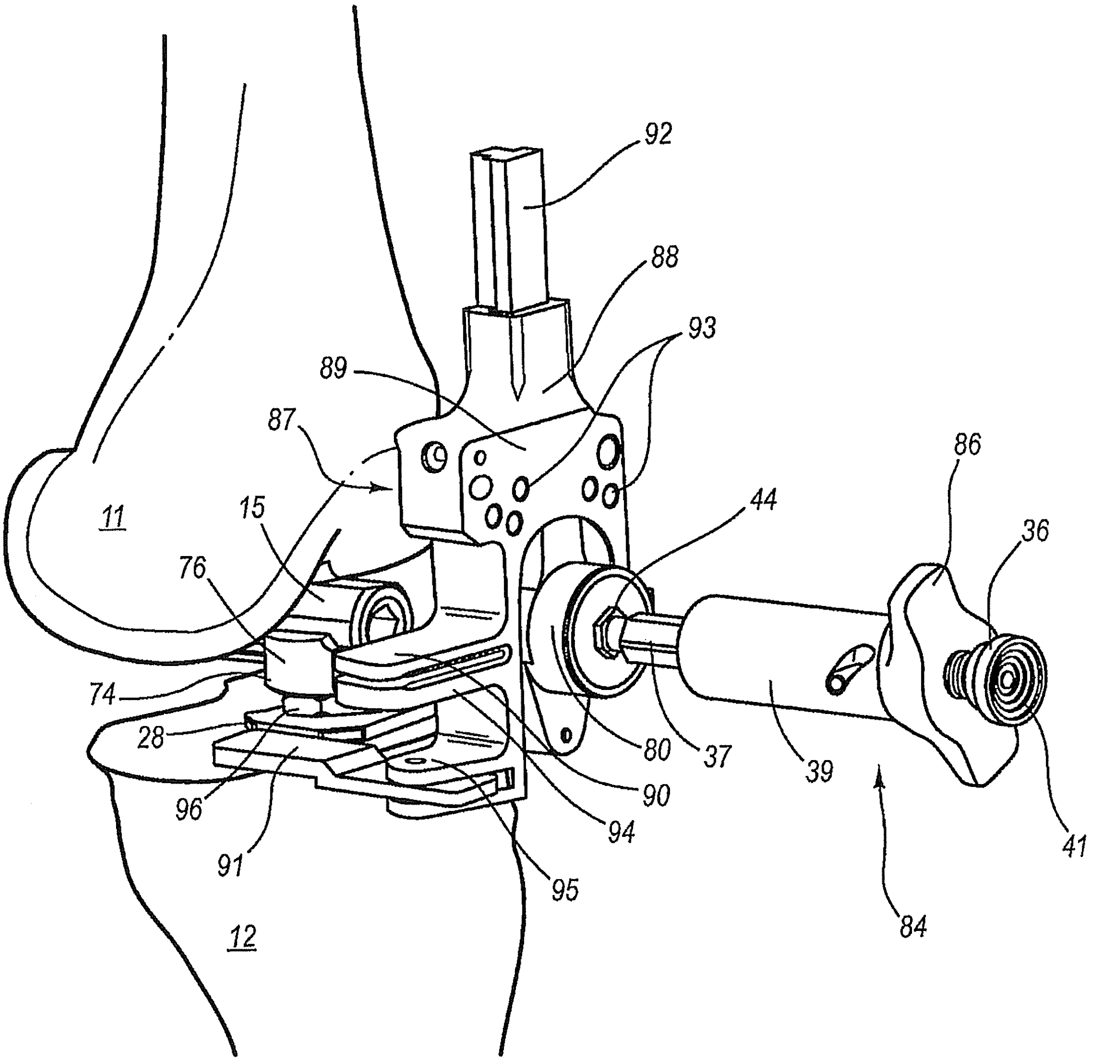

FIGURE 27

20182824424   20 Dec 2018

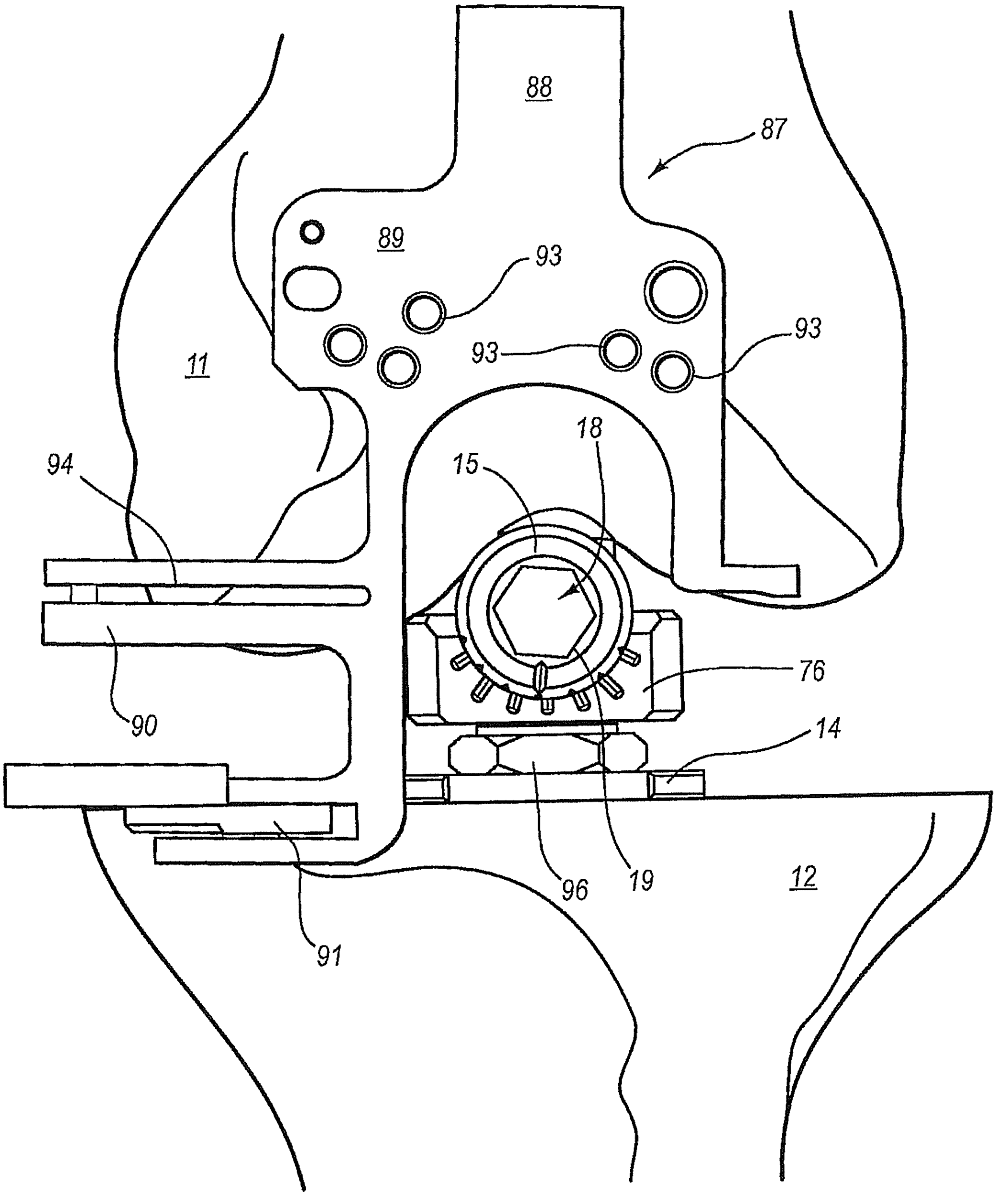

FIGURE 28

2018282424 20 Dec 2018

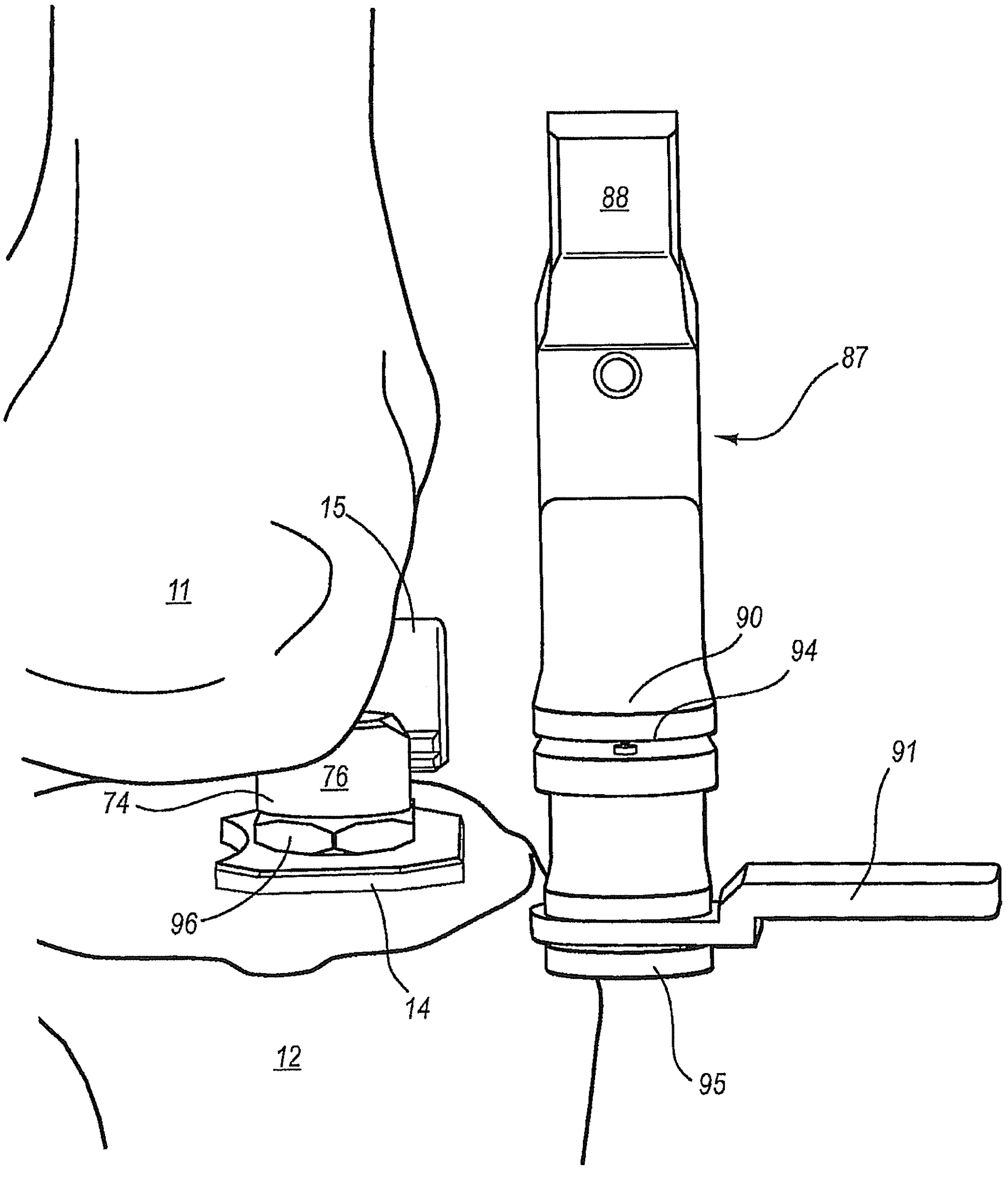

FIGURE 29

2018282424 20 Dec 2018

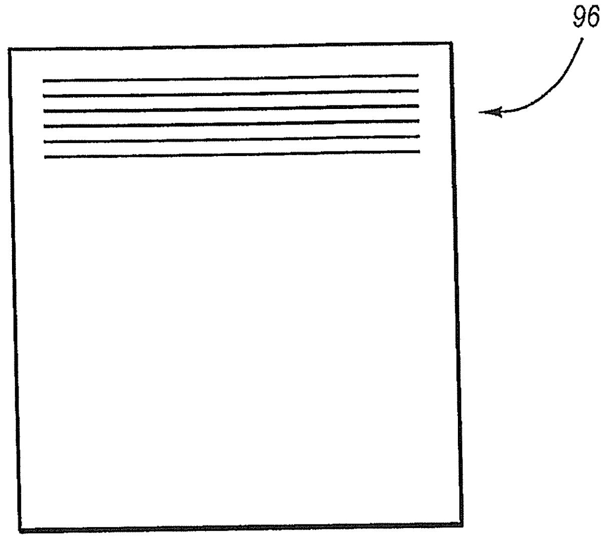

FIGURE 30

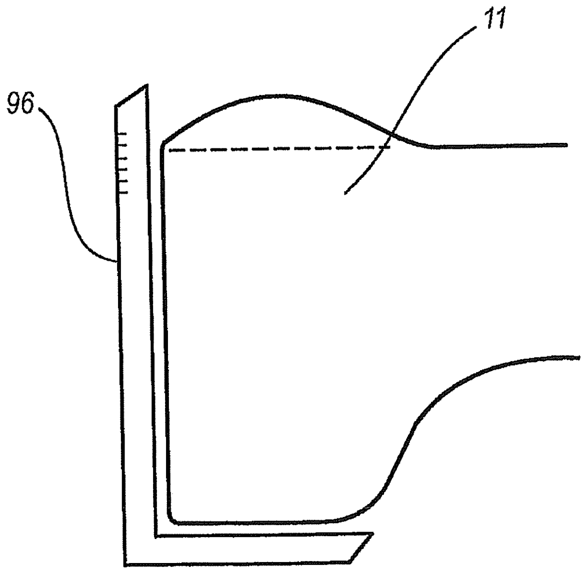

FIGURE 31

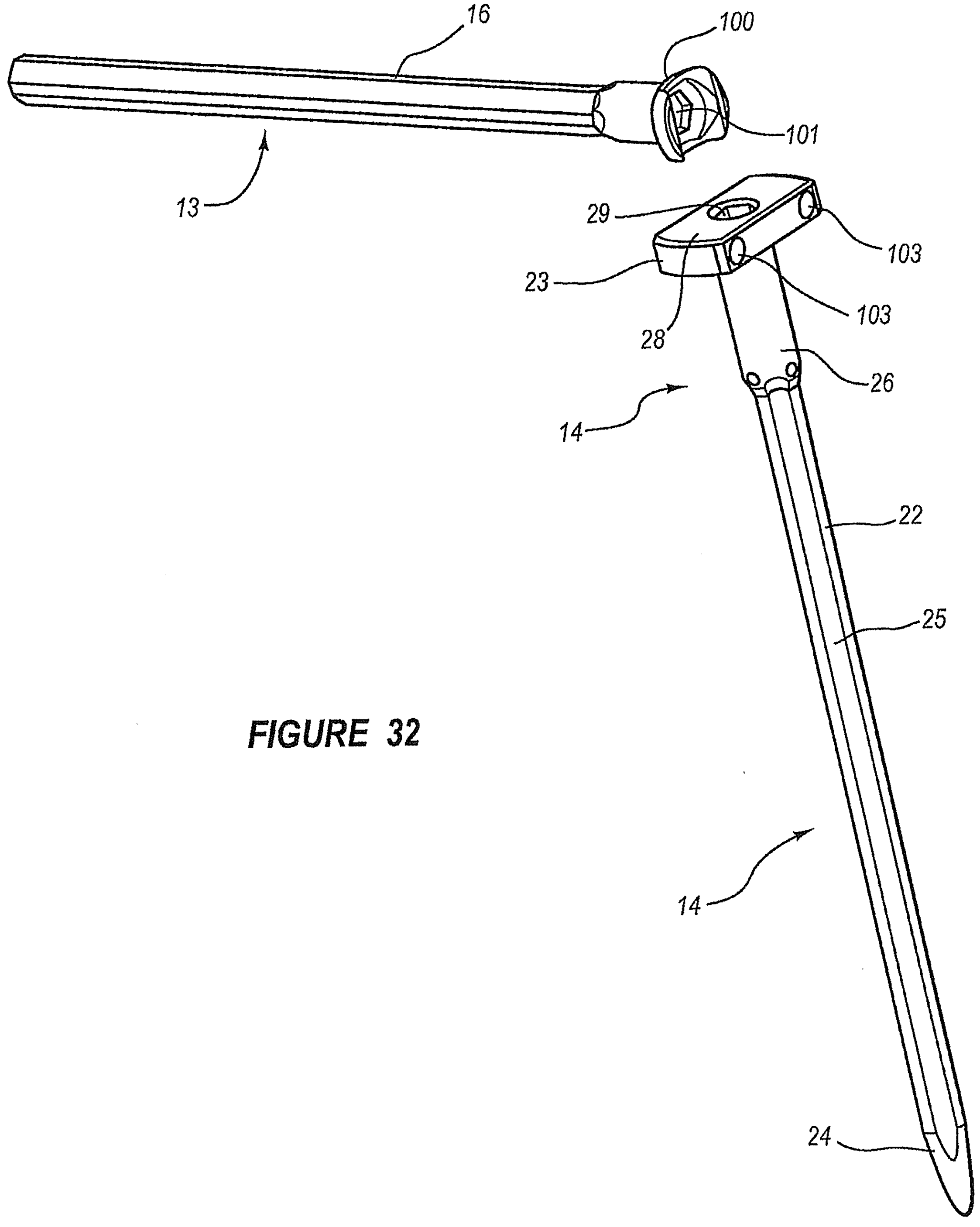

FIGURE 32

2018282424 20 Dec 2018

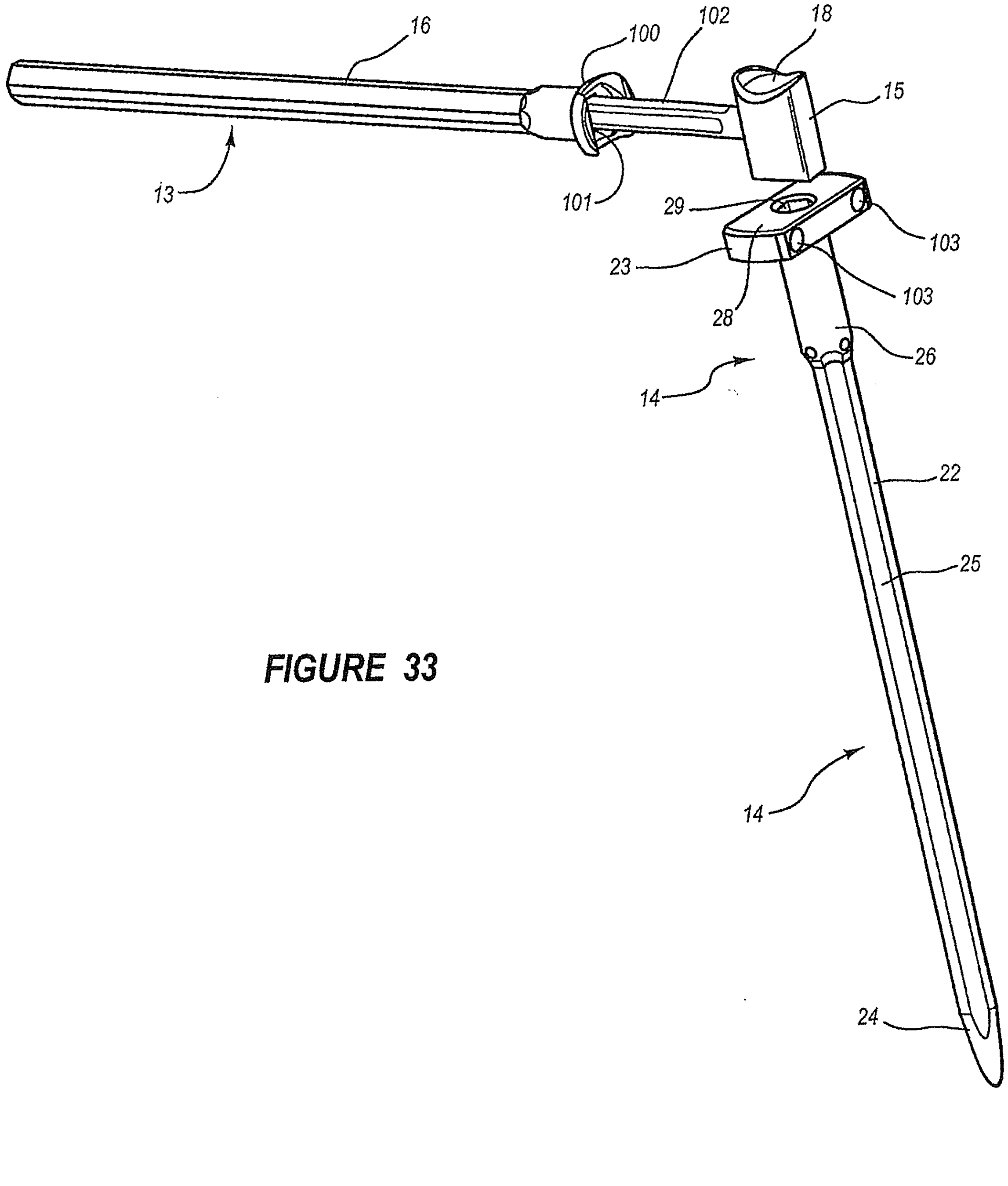

FIGURE 33

20 Dec 2018 2018282424

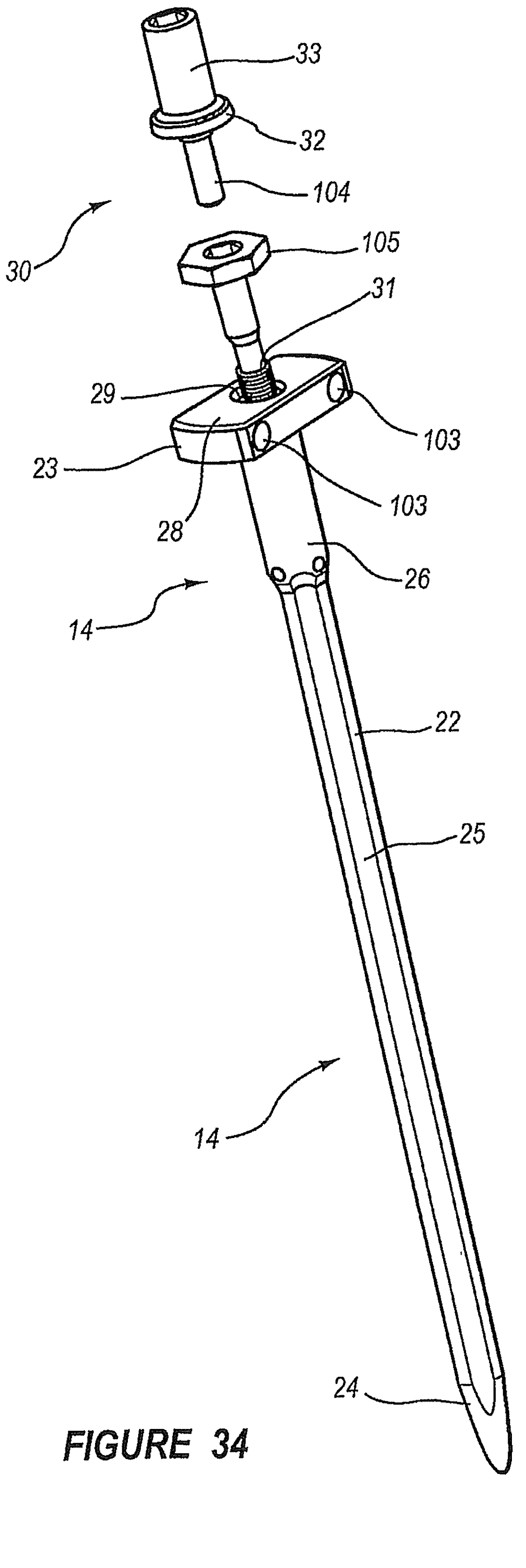

FIGURE 34

2018282424 20 Dec 2018

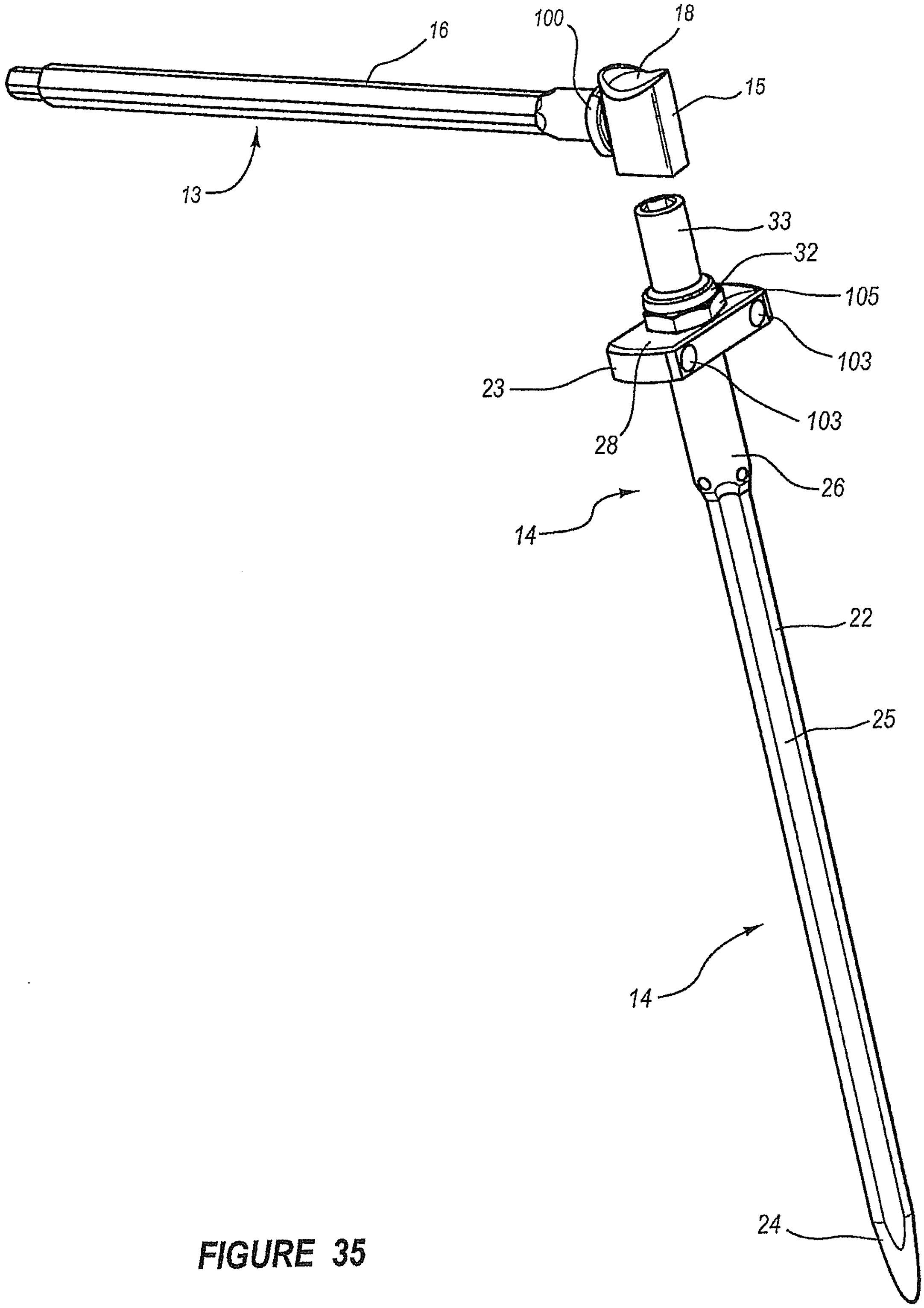

FIGURE 35

2018282424 20 Dec 2018

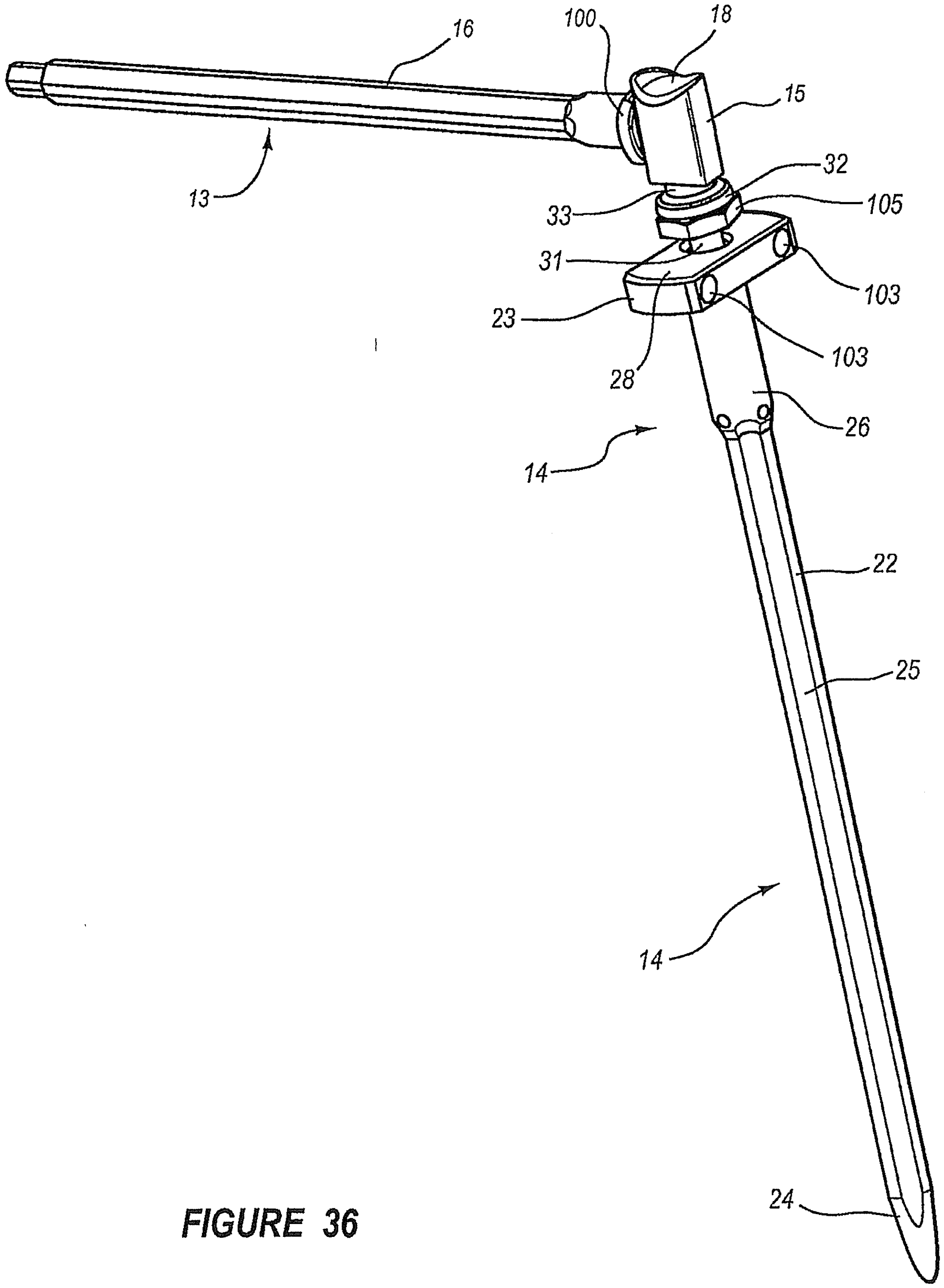

FIGURE 36

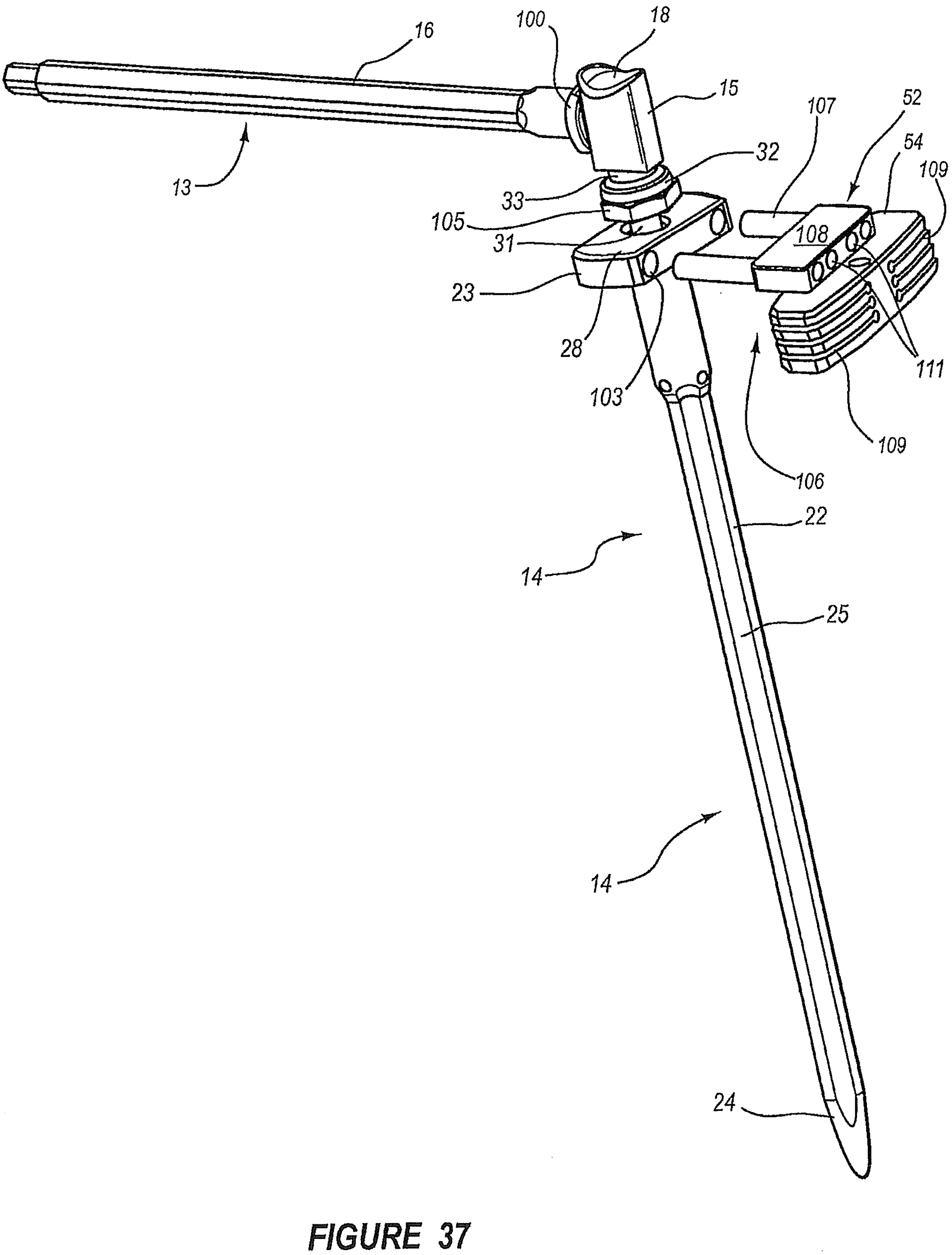
16
100
18
15
13
107
52
54
109
32
33
105
31
108
23
28
103
111
109
106
22
14
25
14
24

FIGURE 37

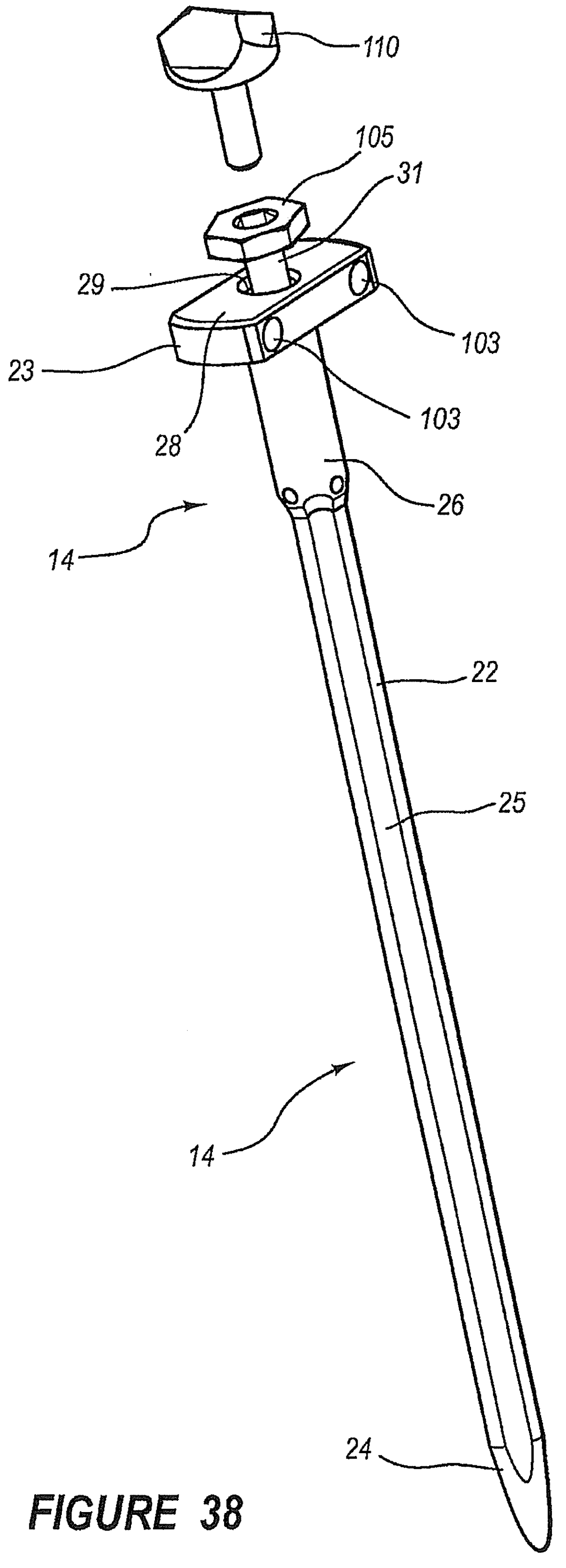

FIGURE 38

20182824244 20 Dec 2018

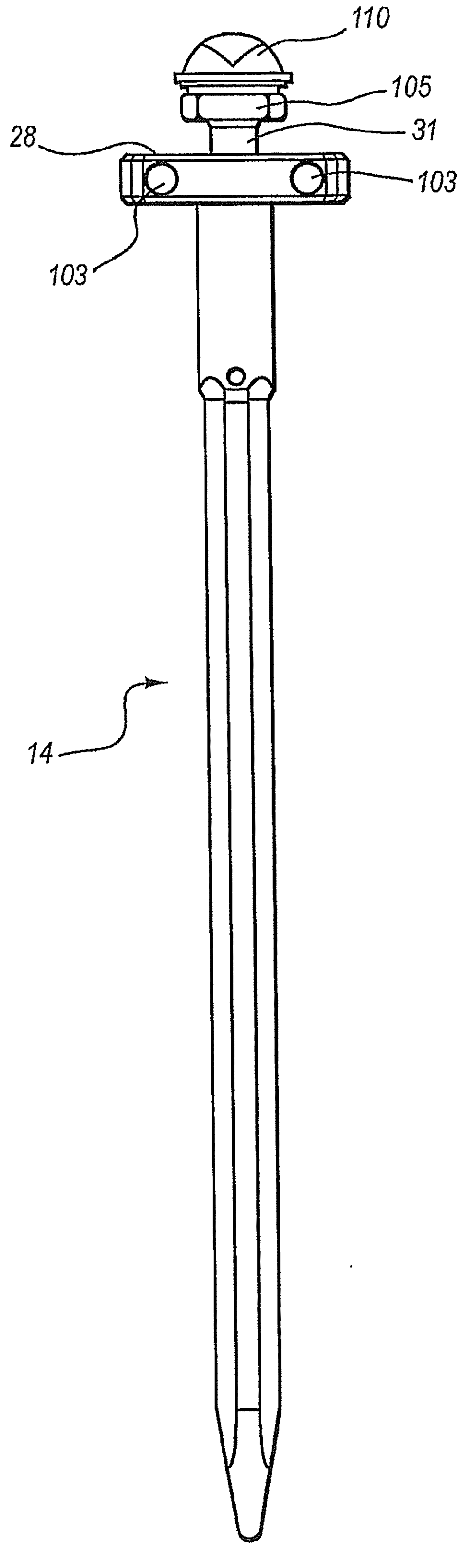

FIGURE 39

2018282424 20 Dec 2018

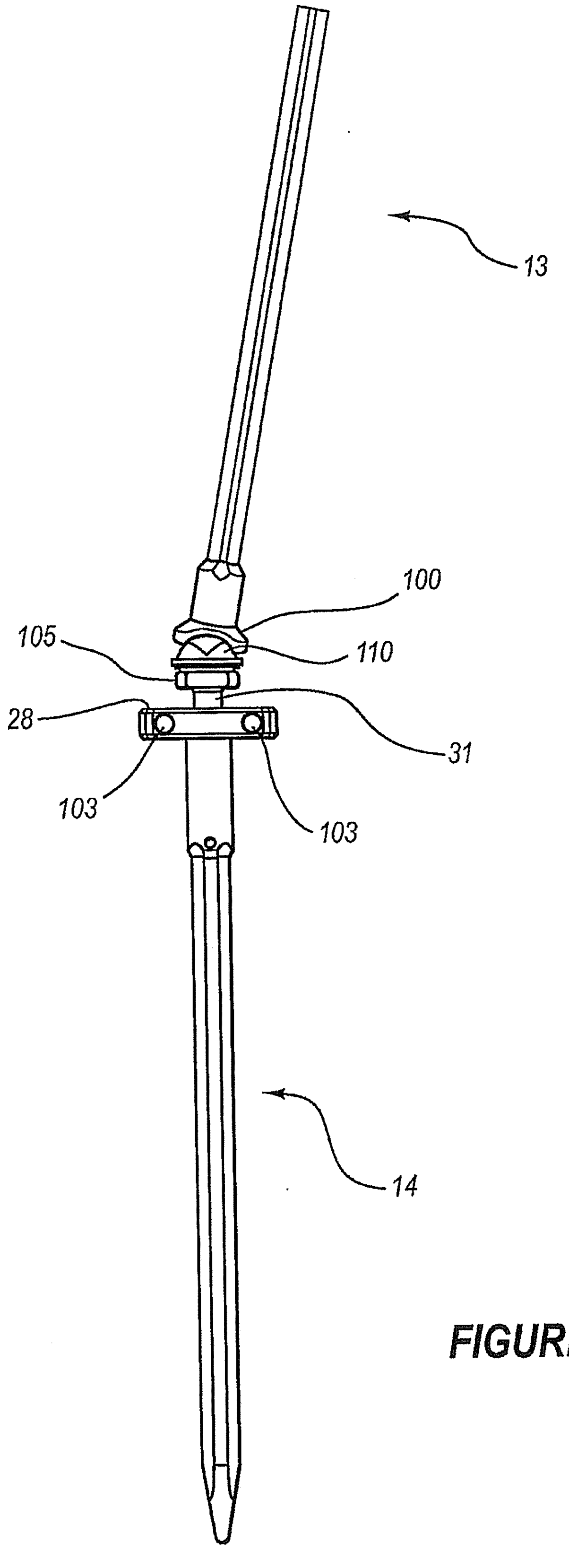

FIGURE 40

2018282424 20 Dec 2018

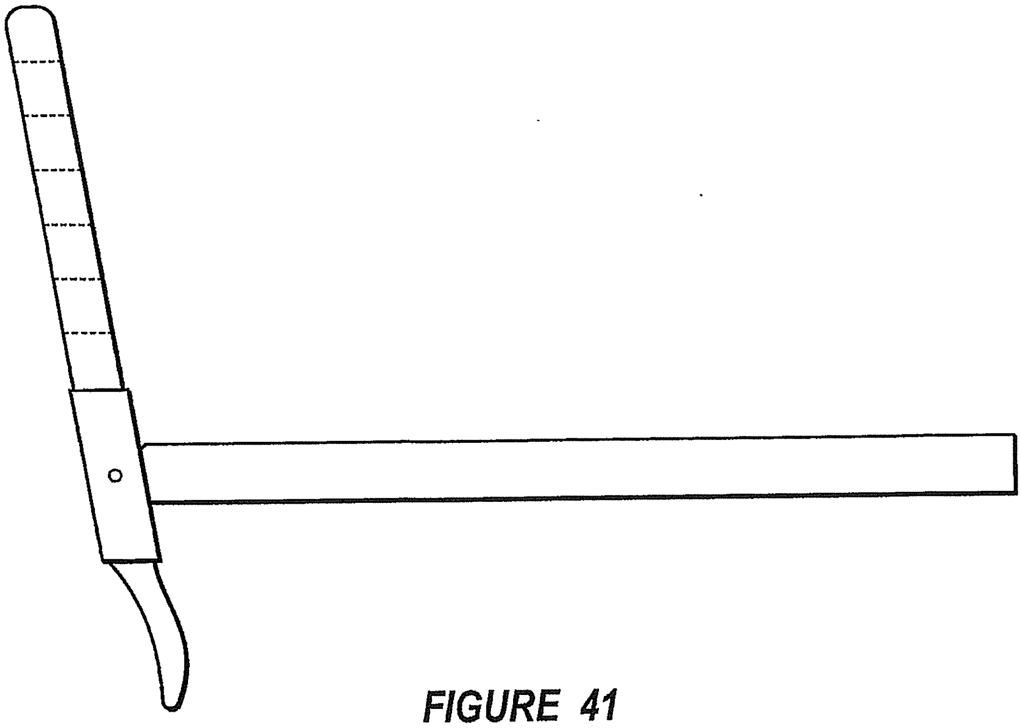

FIGURE 41

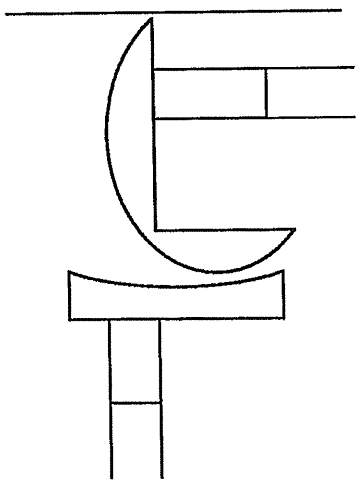

FIGURE 42