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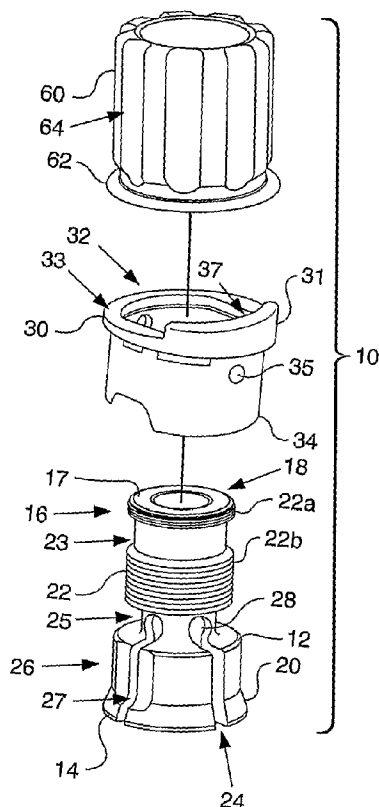
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[Continued on next page]

(54) Title: LOCKING INSTRUMENT ASSEMBLY



(57) Abstract: A locking instrument assembly (10, 200, 400, 500) for use in conjunction with an intramedullary device (100) is disclosed. The locking instrument assembly (10, 200, 400, 500) includes an inner collet (12, 70, 212, 412, 512), an outer body (30, 80, 230, 430, 530), and a knob (60, 90, 260, 460, 560). The inner collet (12, 70, 212, 412, 512) has a collar (20, 79, 220, 420, 520) and a fastener member (22, 222, 422). The knob (60, 90, 260, 460, 560) engages the fastener member (22, 222, 422) to press the outer body (30, 80, 230, 430, 530) against the collar (20, 79, 220, 420, 520). As the knob (60, 90, 260, 460, 560) mates with the fastener member (22, 222, 422), the collar (20, 79, 220, 420, 520) applies a clamping force to the intramedullary device (100).

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## LOCKING INSTRUMENT ASSEMBLY

### Cross-Reference to Related Applications

[0001] This application claims the benefit of U.S. Provisional Application No. 60/723,228, filed October 3, 2005 and U.S. Provisional Application No. 60/725,345, filed  
5 October 11, 2005. The disclosure of each application is incorporated by reference in its entirety.

### Statement Regarding Federally Sponsored Research or Development.

[0002] Not Applicable.

### Appendix.

10 [0003] Not Applicable.

### *Background of the Invention*

#### *1. Field of the Invention*

[0004] This invention relates generally to orthopaedic instrumentation and, more particularly, to orthopaedic cutting instruments.

#### *15 2. Related Art*

[0005] Most orthopedic instruments rely on bone spikes or pins for fixation. Other instruments use an intramedullary (IM) instrument with coupling configurations for the purpose of instrument correlation. However, these previous devices do not control all degrees of freedom. These previous devices are not stable nor are they relatively accessible.

20 [0006] Other instruments connect to a preset-length, intramedullary instrument through a threaded connection. This method restricts the amount of stability achieved to what is derived from the preset-length intramedullary instruments. If it were possible not to restrict the intramedullary instrument length, a surgeon could first stabilize the intramedullary instrument and then rigidly connect the correlating instrument to the  
25 intramedullary instrument.

[0007] Typically, the intramedullary or axial reference instrument(s) and/or the guide assembly are removed before resection because absent such removal the guide or instrument would interfere with the resection. Thus, the stability gained through the connection of the guide assembly and the axial reference instrument is typically lost.

5 [0008] The cutting plane and/or axis must be derived anatomically, usually through intramedullary referencing. However, in some instances, an alternative reference axis is utilized for unusual circumstances (i.e., deformities, trauma, disease, etc.). In either case, an instrument establishing a reference axis usually relative to a mechanical axis (i.e. intramedullary referencing) is rigidly fixed to/in bone. A cutting guide, with or without a  
10 guide assembly, is attached to this reference axis with a purpose of deriving a cutting plane and/or axis (i.e., posterior slope, valgus angle, etc.). The cutting guide is usually fixed to the bone using a bone spike(s), screw(s), drill(s) and/or pin(s). Normally, the reference axis and guide assembly are then removed for clearance for a cutting instrument.

[0009] There remains a need in the art for a device that can accurately establish rigid  
15 fixation of an instrument relative to an intramedullary reference axis. Further, there remains a need in the art for a modular device that allows for positioning of cutting guides and alignment guides relative to an intramedullary reference axis.

### *Summary of the Invention*

[0010] It is in view of the above problems that the present invention was developed.  
20 The invention is a locking instrument assembly for use in conjunction with an intramedullary device. The locking instrument assembly includes an inner collet, an intermediate body, and a knob. The inner collet has a first end portion, a second end portion, and a longitudinally extending inner bore. The first end portion has a collar, and the inner bore is adapted to receive the intramedullary device. The intermediate body has an inner portion and an outer  
25 portion. The inner portion is adapted to engage the collar. The knob is adapted to engage the

intermediate body. As the knob engages the intermediate body, the intermediate body engages the collar such that the inner collet applies a clamping force to the intramedullary device.

[0011] In embodiments of the invention, the intermediate body is selected from the group consisting of an outer body and an orientation base.

5 [0012] In other embodiments of the invention, the second end portion has a fastener member, and the knob engages the fastener member.

[0013] In some embodiments of the invention, the knob has a flange, the intermediate body has a shoulder with a recess, and the recess receives the flange.

[0014] In embodiments of the invention, the inner collet has at least one relief area.

10 [0015] In other embodiments of the invention, the intermediate body has at least one relief area.

[0016] In some embodiments of the invention, the inner collet and the intermediate body have complimentary planar sections.

15 [0017] In embodiments of the invention, the locking instrument assembly also includes an offset collet handle base and an offset collet inner thread.

[0018] In embodiments of the invention, an instrument is attached to the intermediate body. The intermediate body may apply a clamping force to the instrument. The instrument may be selected from the group consisting of an anterior-posterior cutting block and a valgus alignment guide.

20 [0019] In some embodiments, a portion of the intermediate body is angled in order to angle the instrument relative to the intramedullary device.

[0020] In embodiments of the invention, the intermediate body is an orientation base, and the locking instrument assembly further comprises an outer body mounted on the orientation base.

[0021] In embodiments of the invention, the locking instrument assembly also includes a translation rod connected to the outer body. A rotation lock knob may be connected to the translation rod. A down rod may be connected to the translation rod. A translation lock knob may be connected to the down rod. A cutting guide may be connected to the down rod.

5 [0022] In other embodiments of the invention, the orientation base further comprises at least one notch and the rotation lock knob selectively engages the at least one notch.

[0023] In embodiments of the invention, the inner collet includes a base portion, and the inner bore is coaxial with the base portion.

10 [0024] In other embodiments of the invention, the inner collet includes a base portion, and a central axis of the inner bore is offset from a central axis of the base portion. A handle may be operatively connected to the inner collet.

[0025] In embodiments of the invention, the intermediate body of the locking instrument assembly provides a modular connection point for various instruments.

15 [0026] In embodiments of the invention, the locking instrument assembly may be adjusted axially and/or rotationally relative to the intramedullary device.

[0027] The invention has several advantages over prior devices and techniques. For example, by adding the ability to rotate the cutting guide on either a reference axis or an established secondary axis, the surgeon is able to maneuver the resection instrumentation around obstructions or clearance issues. By the ability to rotate the cutting guide around the second cutting axis, the removal of the reference axis prior to resection is not necessary. Therefore, primary fixation can be derived from the primary axis; reducing and/or eliminating the need for secondary fixation devices, such as bone spike(s), screw(s), drill(s) and/or pin(s).

20

[0028] Further features, aspects, and advantages of the present invention, as well as the structure and operation of various embodiments of the present invention, are described in detail below with reference to the accompanying drawings.

***Brief Description of the Drawings***

5 [0029] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate embodiments of the present invention and together with the description, serve to explain the principles of the invention. In the drawings:

[0030] Figure 1 is an exploded perspective view of a locking instrument assembly in a first embodiment;

10 [0031] Figure 2 is a perspective view of the locking instrument assembly as mounted on a intramedullary device;

[0032] Figure 3 is a bottom perspective view of an inner collet in a second embodiment;

[0033] Figure 4 is a top perspective view of the inner collet shown in Figure 3;

15 [0034] Figure 5 is a front perspective view of an outer body in a second embodiment;

[0035] Figure 6 is a top perspective view of the outer body shown in Figure 5;

[0036] Figure 7 is a bottom perspective view of the outer body shown in Figure 5;

[0037] Figure 8 is a top perspective view of a knob in a second embodiment;

[0038] Figure 9 is a bottom perspective view of the knob shown in Figure 8;

20 [0039] Figure 10 is a front perspective view of a first instrument attached to the locking instrument assembly;

[0040] Figure 11 is a top view of the first instrument shown in Figure 10;

[0041] Figure 12 is a bottom view of the first instrument shown in Figure 10;

[0042] Figure 13 is an exploded perspective view of the first instrument shown in  
25 Figure 10;

[0043] Figure 14 is a front perspective view of a second instrument attached to the locking instrument assembly;

[0044] Figure 15 is an exploded perspective view of a first portion of the second instrument shown in Figure 14;

5 [0045] Figure 16 is a rear view of the first portion shown in Figure 15;

[0046] Figure 17 is a front perspective view of the first portion shown in Figure 15;

[0047] Figure 18 is a top view of a second portion of the second instrument shown in Figure 14;

[0048] Figure 19 is a bottom view of the second portion shown in Figure 18;

10 [0049] Figure 20 is an exploded perspective view of the second portion shown in Figure 18;

[0050] Figure 21 is an exploded perspective view of the locking instrument assembly in a second embodiment;

[0051] Figure 22 is a top perspective view of the inner collet in a third embodiment;

15 [0052] Figure 23 is a bottom perspective view of the inner collet shown in Figure 22;

[0053] Figure 24 is a front perspective view of the outer body in a third embodiment;

[0054] Figure 25 is a rear perspective view of the outer body shown in Figure 24;

[0055] Figure 26 is a top perspective view of the knob in a third embodiment;

[0056] Figure 27 is a bottom perspective view of the knob shown in Figure 26;

20 [0057] Figure 28 is a top perspective view of the orientation base in a second embodiment;

[0058] Figure 29 is a top perspective view of the orientation base in a third embodiment;

25 [0059] Figure 30 is a bottom perspective view of the orientation base shown in Figure 29;



[0060] Figure 31 is a front perspective view of a down rod;

[0061] Figure 32 is a side perspective view of the down rod shown in Figure 31;

[0062] Figure 33 is a front perspective view of a rotation lock knob;

[0063] Figure 34 is a rear perspective view of the rotation lock knob shown in Figure

5 33;

[0064] Figure 35 is a front perspective view of the second embodiment of the locking instrument assembly mounted on an intramedullary device;

[0065] Figure 36 is a side view of the second embodiment shown in Figure 35;

[0066] Figure 37 is an exploded view of a tibia cutting block assembly;

10 [0067] Figure 38 is a front view of the tibia cutting block assembly shown in Figure

37;

[0068] Figure 39 is a bottom view of the tibia cutting block assembly shown in Figure

37;

[0069] Figure 40 is an exploded perspective view of the locking instrument assembly

15 in a third embodiment;

[0070] Figure 41 is a side view of the locking instrument assembly shown in Figure

40;

[0071] Figure 42 is a front view of the locking instrument assembly shown in Figure

40;

20 [0072] Figure 43 is a top perspective view of the inner collet in a fourth embodiment;

[0073] Figure 44 is a bottom perspective view of the inner collet shown in Figure 43;

[0074] Figure 45 is an exploded perspective view of the locking instrument assembly

in a fourth embodiment;

[0075] Figure 46 is a side view of the locking instrument assembly shown in Figure

25 45;

[0076] Figure 47 is a side view of the locking instrument assembly shown in Figure 45;

[0077] Figure 48 is a top perspective view of an offset collet handle base;

[0078] Figure 49 is a top perspective view of the knob in a fourth embodiment;

5 [0079] Figure 50 is a top perspective view of an offset collet inner thread;

[0080] Figure 51 is a top perspective view of the inner collet in a fourth embodiment;

[0081] Figure 52 is a bottom perspective view of the inner collet shown in Figure 51;

[0082] Figure 53 is a front view of an intramedullary device and a tibia;

[0083] Figure 54 is a side perspective view of the locking instrument assembly;

10 [0084] Figure 55 is a front perspective view of the locking instrument assembly as mounted on the intramedullary device;

[0085] Figure 56 is a front perspective view of the locking instrument assembly as mounted on the intramedullary device;

15 [0086] Figure 57 is a front perspective view of the locking instrument assembly as utilized in a resection;

[0087] Figure 58 is a front view of an intramedullary device and a femur;

[0088] Figure 59 is a front perspective view of an offset indicator;

[0089] Figure 60 is a side perspective view of the offset indicator and an anterior-posterior sizing plate;

20 [0090] Figure 61 is a side perspective view of the offset indicator, the anterior-posterior sizing plate, and an epicondylar axis target;

[0091] Figure 62 is a front view of a valgus guide sizing plate;

[0092] Figure 63 is a side view of the locking instrument assembly as mounted on the intramedullary device;

[0093] Figure 64 is a side view of the locking instrument assembly as mounted on the intramedullary device;

[0094] Figure 65 is a top perspective view of the locking instrument assembly as utilized in a femoral resection;

5 [0095] Figure 66 is a top perspective view of the locking instrument assembly as utilized in a femoral resection;

[0096] Figure 67 is a front perspective view of a cutting block mounted on the locking instrument assembly;

10 [0097] Figure 68 is a front perspective view of quick connect handles connected to the cutting block;

[0098] Figure 69 is a side perspective view of the cutting block and the neutral locking instrument assembly;

[0099] Figure 70 is a side perspective view of the locking instrument assembly as utilized in a femoral resection;

15 [00100] Figure 71 is a top perspective view of an offset cutting block mounted on the locking instrument assembly;

[00101] Figure 72 is a front perspective view of quick connect handles connected to the cutting block;

20 [00102] Figure 73 is a front view of the offset femoral cutting block in a first orientation;

[00103] Figure 74 is a front view of the offset femoral cutting block in a second orientation;

[00104] Figure 75 is a front view of the offset femoral cutting block in a third orientation;

[00105] Figure 76 is a side perspective view of the offset locking instrument assembly;  
and

[00106] Figure 77 is a side perspective view of the offset locking instrument assembly.

*Detailed Description of the Embodiments*

5 [00107] Referring to the accompanying drawings in which like reference numbers indicate like elements, Figure 1 illustrates a locking instrument assembly 10. The locking instrument assembly 10 may be used in conjunction with an intramedullary device 100, such as an intramedullary nail, intramedullary reamer, or trial stem. The assembly 10 includes an inner collet 12, an outer body 30, and a knob 60.

10 [00108] The inner collet 12 has a first end portion 14, a second end portion 16, and a longitudinally extending inner bore 18. The first end portion 14 has a collar 20 and a base portion 26. The base portion 26 may include one or more planar sections 27. In the embodiment depicted in Figure 1, the inner collet has two planar sections 27 that are substantially parallel to one another. The base portion 26 may be cylindrical, oval, or  
15 cylindrical with tangent portions removed. In the depicted embodiment, the base portion 26 is generally cylindrical, and the inner bore 18 is substantially coaxial with the base portion 26.

[00109] Inner collet 12 functions as a collet or wedge. The collar 20 may include one or more relief areas 24. The relief areas 24 allow a portion of the inner bore 18 to at least  
20 partially collapse. In the embodiment depicted in Figure 1, the collar 20 has four equally spaced relief areas 24 about its circumference. In some embodiments, the relief area 24 has a rectangular shape and terminates in a hole 28. The second end portion 16 has a fastener member 22. In the embodiment depicted in Figure 1, the fastener member 22 is a helical groove or thread, but those of ordinary skill in the art would understand that other types of  
25 fastening mechanisms may be used. For example, the fastener member 22 may be a pin that

engages a cam slot of the outer body 30. The fastener member 22 may extend from the base portion 26 to an inner collet face 17, but in the depicted embodiment the inner collet 12 includes a first cylindrical portion 23 and a second cylindrical portion 25 which separate a first fastener member portion 22a and a second fastener member portion 22b from one another and from the base 26. The inner bore 18 is adapted to receive the intramedullary device 100. In other words, the inner bore 18 is shaped to fit the intramedullary device 100.

[00110] The outer body 30 has a shoulder 31, an inner portion 32, a face 33 and an outer portion 34. The outer body 30 may be cylindrical, oval, or elliptical in shape. The inner portion 32 is shaped and dimensioned to receive the inner collet 12 and particularly the base portion 26. In some embodiments, the outer body 30 includes one or more instrument mounting holes 35. The inner portion 34 is adapted to engage the collar 20 when the outer body 30 is placed over the inner collet 12. The knob 60 engages the face 33, and the shoulder 31 projects from the face 33. In some embodiments, the knob 60 has a flange 62, and the shoulder 31 has a recess that receives a portion of the flange 62. In some embodiments, the face 33 is substantially perpendicular to a central axis of the inner bore 18, but in other embodiments, the face 33 may be angled from about one to about ten degrees to adjust the valgus angle of an instrument. In the depicted embodiment, the face 33 is angled from about four to about seven degrees. The outer body 30 may include one or more base engagement portions 37. The base engagement portions 37 are adapted to mate with the planar sections 27. In the depicted embodiments, the base engagement portions 37 are substantially planar.

[00111] The knob 60 is adapted to mate with the fastener member 22 and engage the outer body 30, wherein as the knob 60 mates with the fastener member 22, the outer body 30 engages the collar 20 such that the inner collet 12 applies a clamping force to the intramedullary device 100. The knob 60 is removably attached to the outer body 30 to pull

the outer body 30 upwardly and away from the collar 20 in order to remove the clamping force. As noted above, some embodiments of the knob 60 include the flange 62 which is received by a recess of the shoulder 31. The flange 62 engages the shoulder 31 to pull the outer body 30 upwardly and away from the collar 20 in order to remove the clamping force.

5 Alternatively, the knob 60 may be pinned to the outer body 30. In some embodiments, the knob 60 includes one or more longitudinal grooves 64. The longitudinal grooves 64 aid a user in gripping the knob 60.

[00112] The locking instrument assembly 10 is assembled by inserting inner collet 12 through outer body 30 and then threading the knob 60 on to inner collet 12. If the knob 60  
10 includes the flange 62, then a first step would be to engage the flange 62 with the recess of the shoulder 31 and then insert the inner collet 12 through outer body 30.

[00113] Outer body 30 is used as a modular connector. Thus, an instrument, such as a cutting guide or an alignment block, may be attached to the outer body 30. In an alternative embodiment, an instrument may substitute directly for the outer body 30. Thus,  
15 in this alternative embodiment, an instrument that has the same characteristics as the outer body 30 is placed over the inner collet 12 and locked into place as the knob 60 tightens against the inner collet 12.

[00114] Referring now to Figure 2, the intramedullary device 100 is rigidly fixed in a bone. The locking instrument assembly 10 is assembled but without tightening the knob 60.  
20 After rigid fixation of the intramedullary device 100, the pre-assembled locking instrument assembly 10 is slid over the intramedullary device 100. The locking instrument assembly 10 is located axially in the desired position along the intramedullary device 10. The knob 60 is turned to tighten and wedge the outer body 30 against the inner collet 12. The collar 20 collapses slightly to apply a clamping force and grip the intramedullary device 100. After  
25 the outer body 30 is locked in place, any number of various instruments may be attached to

the outer body 30. Thus, outer body 30 provides a rigid connection point for connecting any number of instruments to a rigidly connected intramedullary device 100.

[00115] Figures 3 and 4 illustrate a second embodiment of the inner collet. The inner collet 70 includes a first end portion 76, a second end portion 71, and a longitudinally extending inner bore 77. The first end portion 76 has a collar 79 and a base portion 75. The base portion 75 may be cylindrical, oval, or cylindrical with tangent portions removed. In the depicted embodiment, the base portion 75 is generally cylindrical, and the inner bore 77 is substantially coaxial with the base portion 75.

[00116] Inner collet 70 functions as a collet or wedge. The collar 79 may include one or more relief areas 78. The relief areas 78 allow a portion of the inner bore 77 to at least partially collapse. In some embodiments, the relief area 24 has a keyhole shape. The second end portion 71 has a fastener member 73. In the embodiment depicted in Figure 3, the fastener member 73 is a helical groove or thread, but those of ordinary skill in the art would understand that other types of fastening mechanisms may be used. The fastener member 73 may extend from the base portion 75 to an inner collet face 69, but in the depicted embodiment the inner collet 70 includes a first cylindrical portion 72 and a second cylindrical portion 74 which separate a first fastener member portion 73a and a second fastener member portion 73b from one another and from the base 75. The inner bore 77 is adapted to receive the intramedullary device 100. In other words, the inner bore 77 is shaped to fit the intramedullary device 100.

[00117] Figures 5, 6, and 7 illustrate a second embodiment of the outer body. The outer body 80 has a shoulder 87, an inner portion 88, a face 82 and an outer portion 89. The outer body 80 may be cylindrical, oval, or elliptical in shape. The inner portion 88 is shaped and dimensioned to receive the inner collet 12, 70 and particularly the base portion 26, 75. In some embodiments, the outer body 80 includes one or more instrument mounting holes 83.

The inner portion 88 is adapted to engage the collar 20, 79 when the outer body 80 is placed over the inner collet 12, 70. The knob 60 engages the face 82, and the shoulder 87 projects from the face 82. In some embodiments, the knob 60 has a flange 62, and the shoulder 87 has a recess 81 that receives a portion of the flange 62. In some embodiments, the face 82 is substantially perpendicular to a central axis of the inner bore 18, 77, but in other 5 embodiments, the face 82 may be angled from about one to about ten degrees relative to the central axis to adjust the valgus angle of an instrument. In the depicted embodiment, the face 82 is angled from about four to about seven degrees. The outer body 80 may include one or more first relief areas 84 and one or more second relief areas 85. The relief areas 84, 10 85 allow the outer body 80 to expand as it is pressed against the collar 20, 79. In this manner, the locking instrument assembly 10 is dual locking. First, as the outer body 80 is pressed against the collar 20, 79, the inner collet 12, 70 at least partially collapses to lock the inner collet 12, 70 relative to the intramedullary device. Second, as the outer body 80 presses against the collar 12, 70, the outer portion 89 expands. As is explained in greater 15 detail below, when an instrument is connected to the outer portion 89, this expansion locks the outer body 80 to the instrument. This expansion of the outer portion 89 prevents the instrument from moving axially and/or rotationally relative to the outer body 80. The outer body 80 also may include one or cutouts 86. The cutouts 86 are used to remove sharp edges.

[00118] Figures 8 and 9 illustrate a second embodiment of the knob. The knob 90 is 20 adapted to mate with the fastener member 22, 73 and engage the outer body 30, 80, wherein as the knob 90 mates with the fastener member 22, 73, the outer body 30, 80 engages the collar 20, 79 such that the inner collet 12 applies a clamping force to the intramedullary device 100. The knob 90 is removably attached to the outer body 30, 80 to pull the outer body 30, 80 upwardly and away from the collar 20, 79 in order to remove the clamping 25 force. Some embodiments of the knob 90 include a flange 93 which is received by the



recess 81 of the shoulder 87. The flange 93 engages the shoulder 31, 87 to pull the outer body 30, 80 upwardly and away from the collar 20, 79 in order to remove the clamping force. Alternatively, the knob 90 may be pinned to the outer body 30, 80. In some embodiments, the knob 90 includes one or more longitudinal grooves 92. The longitudinal grooves 92 aid a user in gripping the knob 90. The knob 90 includes an inner bore 91. At least a portion of the inner bore 91 is threaded and includes threads 96. The inner bore 91 is sized to receive the inner collet 12, 70, and the threaded portion 96 is adapted to mate with the fastener member 22, 73. In some embodiments, the knob 90 includes a pin hole 95. In some embodiments, a spring pin (not shown) is inserted into the pin hole 95 to retain the inner collet 12, 70 to the knob 90. The knob 90 also includes the third cylindrical portion 94. The knob 90 includes a main body 97, and the third cylindrical portion 94 distally spaces the flange 93 away from the main body 97.

[00119] The locking instrument assembly 10 is assembled to any number of various instruments without tightening the knob 60, 90. Thus, outer body 30, 80 provides a rigid connection point for connecting any number of instruments to a rigidly connected intramedullary device 100. This is significant as modularity can reduce the time necessary for surgery and can reduce the costs of manufacturing. The pre-assembled locking instrument assembly 10 is slid over the intramedullary device 100. The locking instrument assembly 10 is located axially in the desired position along the intramedullary device 10. The knob 60, 90 is turned to tighten and wedge the inner collet 12, 70 against the outer body 30, 80. The collar 20 collapses slightly to apply a clamping force and grip the intramedullary device 100. In some embodiments, the knob 60, 90 continues to be tightened to wedge the outer body 80 against any of the various instruments and thereafter rigid fixation of the intramedullary device 100 is achieved. Thus, this last embodiment locks against both the intramedullary device and against the instrument.

[00120] Figures 10, 11, 12 and 13 illustrate a first instrument 110 attached to the locking instrument assembly 10. In the depicted embodiments, the first instrument 110 is an anterior-posterior cutting block assembly. The first instrument 110 includes an anterior-posterior cutting block 112 and at least one plunger 114. The anterior-posterior cutting block 112 includes at least one slot 118 and at least one plunger hole 116. The at least one plunger hole 116 receives the at least one plunger 114. In the depicted embodiments, the at least one plunger 114 is press-fit into the at least one plunger hole 116. The anterior-posterior cutting block 112 also includes an outer body hole 120. The outer body hole 120 is shaped and dimensioned to receive the outer body 30, 80. As such, the at least one plunger 114 is adapted to engage the instrument mounting hole 35, 83. As noted above, the outer body 80 is adapted to expand as the outer body 80 engages the collar 20, 79. Thus, the outer body 80 may expand to engage the outer body hole 120 of the first instrument 110. The engagement of the expanding outer body 80 with the outer body hole 120 prevents or substantially reduces the likelihood that the first instrument 110 will rotate or move axially after the inner collet 12, 70 locks against the intramedullary device 100.

[00121] Figures 14, 15, 16, 17, 18, 19, and 20 illustrate a second instrument 150 attached to the locking instrument assembly 10. In the depicted embodiments, the second instrument 150 is a valgus guide assembly. The second instrument 150 includes a first portion 152 and a second portion 156. The second portion 156 is removably attached to the first portion 152. The first portion 152 includes a valgus guide collet block 153 and an alignment guide frame sub-assembly 154. The valgus guide block 153 is removably attached to the alignment guide frame sub-assembly 154. The valgus guide block 153 includes plungers 151. The alignment guide frame sub-assembly 154 includes plungers 155. The second portion 156 includes a distal femoral cutting block assembly 157 and a block knob 158. In some embodiments, the second portion 156 includes a spring pin 159 to retain the block knob 158 to

the distal femoral cutting block assembly 157. The first portion 152 includes an outer body mounting hole 160. As noted above, the outer body 80 is adapted to expand as the outer body 80 engages the collar 20, 79. Thus, the outer body 80 may expand to engage the outer body hole 160 of the first portion 152. The engagement of the expanding outer body 80 with the outer body hole 160 prevents or substantially reduces the likelihood that the second instrument 150 will rotate or move axially after the inner collet 12, 70 locks against the intramedullary device 100.

[00122] Figure 21 illustrates a second embodiment of the locking instrument assembly. Figure 21 illustrates a locking instrument assembly 200. The locking instrument assembly 200 may be used in conjunction with the intramedullary device 100, such as an intramedullary nail, intramedullary reamer, or trial stem. The assembly 200 includes an inner collet 212, an outer body 230, an orientation base 238, and a knob 260.

[00123] A translation rod 240 is connected to the outer body 230. The translation rod receives a rotation lock knob 242. A down rod 246 is connected to the translation rod 240. A translation lock knob 248 is connected to the down rod 246. The locking instrument assembly 200 is further assembled by connecting the translation rod 240 to the outer body 230. As an example, the translation rod 240 may be welded to the outer body 230. The down rod 246 is oriented and slid over the translation rod 240. Then, the rotation lock knob 242 is threaded into the translation rod 240. The translation lock knob 248 is threaded into the down rod 246.

[00124] Figures 22 and 23 illustrate the inner collet 212. The inner collet 212 has a first end portion 214, a second end portion 216, and a longitudinally extending inner bore 218. The first end portion 214 has a collar 220 and a base portion 226. The base portion 226 may include one or more planar sections 227. In the embodiment depicted in Figure 23, the inner collet has two planar sections 27 that are substantially parallel to one another. The

base portion 226 may be cylindrical, oval, or cylindrical with tangent portions removed. In the depicted embodiment, the base portion 226 is generally cylindrical, and the inner bore 218 is substantially coaxial with the base portion 226.

[00125] Inner collet 212 functions as a collet or wedge. The collar 220 may include one or more relief areas 224. The relief areas 224 allow the collapse of a portion of the inner bore 218. In the embodiment depicted in Figure 23, the collar 220 has four equally spaced relief areas 224 about its circumference. The relief areas 224 may be rectangular, prolated, or key hole shaped. The second end portion 216 has a fastener member 222. In the embodiment depicted in Figure 22, the fastener member 222 is a helical groove or thread, but those of ordinary skill in the art would understand that other types of fastening mechanisms may be used. The fastener member 222 may extend from the base portion 226 to an inner collet face 217, but in the depicted embodiment the inner collet 212 includes a first cylindrical portion 223 and a second cylindrical portion 225 which separate a first fastener member portion 222a and a second fastener member portion 222b from one another and from the base 226. The inner bore 218 is adapted to receive the intramedullary device 100. In other words, the inner bore 218 is shaped to fit the intramedullary device 100.

[00126] Figures 24 and 25 illustrate the outer body 230. The outer body 230 has a shoulder 287, an inner portion 288, a face 282 and an outer portion 289. The outer body 230 may be cylindrical, oval, or elliptical in shape. The inner portion 288 is shaped and dimensioned to receive the inner collet 12, 70, 212 and particularly the base portion 26, 75, 226. The inner portion 288 is shaped and dimensioned to receive the orientation base 238. In some embodiments, the knob 260 has a flange 262, and the shoulder 287 has a recess 281 that receives a portion of the flange 262. In some embodiments, the face 282 is substantially perpendicular to a central axis of the inner bore 18, 77, 218, but in other embodiments, the face 282 may be angled from about one to about ten degrees relative to the central axis to

adjust the valgus angle of an instrument. In the depicted embodiment, the face 282 is substantially perpendicular to the inner bore 18, 77, 218.

[00127] The translation rod 240 is connected to the outer body 230. In the embodiment depicted in Figures 24 and 25, the translation rod 240 is threaded into a boss 239, which is welded to the outer portion 289. The translation rod 240 includes a longitudinally extending slot 241. As explained in greater detail below, the longitudinally slot 241 is used to orient the down rod 246. The translation rod 240 is tubular and is at least partially threaded on inner end portion 245. In some embodiments, the translation rod 240 includes a pin mounting hole 243.

[00128] Figures 26 and 27 illustrate the knob 260. The knob 260 is adapted to mate with the fastener member 222 and engage the orientation base 238, wherein as the knob 260 mates with the fastener member 222, the orientation base 238 engages the collar 220 such that the inner collet 212 applies a clamping force to the intramedullary device 100. The knob 260 is removably attached to the outer body 230 to pull the outer body 230 upwardly and away from the orientation base 238. Some embodiments of the knob 260 include a flange 293 which is received by the recess 281 of the shoulder 287. The flange 293 engages the shoulder 287 to pull the outer body 230 upwardly. Alternatively, the knob 90 may be pinned to the outer body 30, 80. In some embodiments, the knob 260 includes one or more longitudinal grooves 292. The longitudinal grooves 292 aid a user in gripping the knob 260. The knob 260 includes an inner bore 291. At least a portion of the inner bore 291 is threaded and includes threads 296. The inner bore 291 is sized to receive the inner collet 212, and the threaded portion 296 is adapted to mate with the fastener member 222. In some embodiments, the knob 260 includes a pin hole 295. In some embodiments, a spring pin (not shown) is inserted into the pin hole 295 to retain the inner collet 212 to the knob 260. The knob 260 also includes the third cylindrical portion 294. The knob 260 includes a

main body 297, and the third cylindrical portion 294 distally spaces the flange 293 away from the main body 297.

[00129] Referring once again to Figure 21, the orientation base 238 has an inner portion 232 and an outer portion 234. The inner portion 232 is adapted to engage the collar 220 when the orientation base 238 is placed over the inner collet 212. The knob 260 engages the orientation base, and the orientation base 238 pushes against the collar 220 to at least partially collapse the inner collet 212 such that the inner collet 212 exerts a clamping force on the intramedullary device 100. The orientation base 238 includes ears 252 and notches 254. In some embodiments, the axis of the inner diameter of the orientation base 238 is not coaxial with the outer diameter, and the ears 252 may be used to indicate an angle of the orientation base relative to the central axis of the inner bore 218. The notches 254 are spaced about the circumference of the outer portion 234. As explained in greater detail below, the notches 254 receive a tip portion 256 of the rotation lock knob 242.

[00130] Figure 28 illustrates a second embodiment of the orientation base. The orientation base 270 includes an inner portion 271, an outer portion 272, a lip 273, one or more notches 274, and a face 276. The inner portion 271 may include one or more first planar walls 275. The first planar walls 275 are adapted to mate with the planar sections 227. When the locking instrument assembly 200 is assembled, the lip 273 engages the outer body 230. The notches 274 are spaced about the circumference of the outer portion 272. As explained in greater detail below, the notches 274 receive the tip portion 256 of the rotation lock knob 242. The face 276 is selectively engaged with the knob 260. In other words, as the knob 260 threads onto the inner collet 212, the knob 260 also engages the face 276.

[00131] Figures 29 and 30 illustrate a third embodiment of the orientation base. The orientation base 280 is similar to the second embodiment except the third embodiment includes second planar walls 282. The second planar walls 282 are substantially parallel to

the first planar walls 275 and provide an indication as to orientation of the orientation base 280.

[00132] Figures 31 and 32 illustrate the down rod 246. The down rod 246 includes a block member 263 and a post 264. The post 264 is operatively connected to the block member 5 263. The block member 263 includes an opening 265. The opening 265 is shaped and dimensioned to mate with the translation rod 240. In some embodiments, the block member 263 includes key 266. The key 266 fits within the longitudinally extending slot 241 to provide an orientation to the down rod 246. The block member 263 also includes aperture 267. The aperture 267 receives the translation lock knob 248. In some embodiments, the 10 aperture 267 is threaded. The post 264 may include locators 268. The locators 268 are cylindrical depressions that provide a positive stop for an instrument, such as a cutting block. The locators 268 are evenly spaced apart. In the embodiment depicted in Figure 31, the locators 268 are spaced apart by about five millimeters. In some embodiments, the block member 263 includes pin hole 269. A spring pin (not shown) may be inserted into the 15 pin hole 269 after the translation lock knob 248 is inserted into the aperture 267 in order to retain the translation lock knob 248.

[00133] Figures 33 and 34 illustrate the rotation lock knob 242. The rotation lock knob 242 includes a knob portion 257 and a rod portion 258. The knob portion 257 may include a fastener driver receiver 259. The fastener driver receiver 259 receives a fastener driver (not 20 shown), which may be used to tighten the rotation lock knob 242. In the depicted embodiments, the fastener driver receiver 259 is hex shaped. A portion of the rod portion 257 may be threaded. The rod portion 258 also includes the tip portion 256. The tip portion 256 may be used to engage the notch 254, 274.

[00134] The locking instrument assembly 200 is assembled by inserting inner collet 25 212 through the orientation base, through the outer body 230 and then threading the knob

260 on to inner collet 212. Outer body 230 is used as a modular connector. Thus, an instrument, such as a cutting guide or an alignment block, may be attached to the outer body 230. In an alternative embodiment, an instrument may substitute directly for the outer body 230. Thus, in this alternative embodiment, an instrument that has the same characteristics as the outer body 230 is placed over the orientation base 238, 270, 280 and locked into place axially as the knob 260 tightens against the inner collet 212.

[00135] In a method of use, the locking instrument assembly 200 is slid over the intramedullary device 100, then the knob 260 is tightened onto the inner collet 212 pulling the inner collet 212 into the orientation base 238, 270, 280 causing a wedge effect between the inner collet 212 and the intramedullary device 100. Optionally, the rotation lock knob 242 is loosened or tightened to facilitate rotational freedom or constraint of the cutting guide/plane around the orientation base 238, 270, 280. The translation lock knob 248 is loosened or tightened to facilitate translational freedom or constraint of the cutting guide/plane along the translation rod 240.

[00136] In the instance shown, the knob 260 pulls the inner collet 212 with the use of threads creating a wedge effect between the intramedullary device 100 and the inner collet 212. This action locks all degrees of freedom of the orientation base with respect to the intramedullary device 100. The outer body 230 only has rotational freedom around the orientation base 238, 270, 280 because it is constrained axially by the orientation base 238, 270, 280 and the knob 260. The orientation base 238, 270, 280 dictates/determines the cutting axis that can be collinear to or at an angle to the intramedullary device 100. This cutting axis is maintained/translated through the connections of the outer body, the translation rod 240, and the down rod 246. The down rod 246 is where a cutting guide is attached.



[00137] The translation lock knob 248 is used to lock the down rod 246 from translation on the translation rod 240. The rotation lock knob 242 is used to lock rotation of the outer body 230, the translation rod 240, the down rod 246 and the cutting guide on the cutting axis or the orientation base 238, 270, 280. Notches 254, 274 around the central circumference of the orientation base 238, 270, 280 are to provide a positive stop location for the rotation lock knob 242.

[00138] Figures 35 and 36 illustrate the locking instrument assembly 200 as mounted on the intramedullary device 100. A tibia cutting block assembly 310 is mounted on the down rod 246. Figures 35 and 36 also illustrate a reference axis 106. An angle A of the down rod 246 is measured from this reference axis. The angle A may vary from zero degrees to about ten degrees. Because the tibia cutting block assembly 310 is mounted to the down rod 246, the angle A indicates a slope of the resection plane. It may be desirable in some instances to adjust the slope of the resection plane when using the tibia cutting block assembly 310. This may be accomplished in several ways. First, as noted above, the orientation base 238 may have an outside diameter that is angled relative to the inside diameter. Second, the translation rod 240 may be angled relative to the outer body 230. Third, the down rod 246 may be angled relative to the translation rod 240. However, in the embodiments depicted in Figures 35 and 36, the down rod 246 is substantially parallel to the intramedullary device 100.

[00139] Figures 37, 38, and 39 illustrate the tibia cutting block assembly 310. The tibia cutting block assembly 310 includes the tibial cutting block 312 and a knob 314. In some embodiments, the tibia cutting block assembly 310 also includes a spring pin 316 which is used to retain the knob 314 to the cutting block 312. In the depicted embodiments, the tibial cutting block 312 is left-handed, but those of ordinary skill in the art would understand that a right-handed cutting block could also be used.

[00140] Figures 40, 41, and 42 illustrate a third embodiment of the locking instrument assembly. The locking instrument assembly 400 includes an inner collet 412, an outer body 430, a handle 456, a fastener 458, a knob 460, and a washer 464. The fastener 458 and the washer 464 are used to mount the handle 456 to the inner collet 412.

5 [00141] Figures 43 and 44 illustrate the inner collet 412. The inner collet 412 has a first end portion 414, a second end portion 416, and a longitudinally extending inner bore 418. The inner bore 418 is adapted to receive the intramedullary device 100. In other words, the inner bore 418 is shaped to fit the intramedullary device 100. The first end portion 414 has a collar 420 and a base portion 426. The base portion 426 may be  
10 cylindrical, oval, or cylindrical with tangent portions removed. In the depicted embodiment, the base portion 426 is generally cylindrical. In contrast to the previous embodiments, the inner bore 418 is offset from the central axis of the base portion 426. In other words, the central axis of the inner bore 418 is radially offset a certain distance from the central axis of the base portion 426. This offset distance may be anywhere from about one millimeter to  
15 about eighteen millimeters and rather from about two millimeters to about six millimeters. The offset inner bore 418 allows the locking instrument assembly 400 to offset an instrument when the instrument is mounted to the outer body 430.

[00142] Inner collet 412 functions as a collet or wedge. The collar 420 may include one or more relief areas 424. The relief areas 424 allow a portion of the inner bore 418 to  
20 collapse. In the embodiment depicted in Figure 44, the collar 420 has five relief areas 424. The relief areas 424 may be cylindrical, rectangular, prolated, or key hole shaped. The second end portion 416 has a fastener member 422. In the embodiment depicted in Figure 44, the fastener member 422 is a helical groove or thread, but those of ordinary skill in the art would understand that other types of fastening mechanisms may be used.

[00143] The inner collet also includes a first projection 470 and a second projection 472. The projections 470, 472 are spaced apart to receive the handle 456 therebetween. The first projection 470 has a first hole 474, and the second projection 472 has a second hole 476. In the embodiments depicted in Figures 43 and 44, the first hole 474 and the second hole 476 are coaxial. The first hole 474 and/or the second hole 476 may be threaded. The holes 474, 476 receive the fastener 458, such as a screw, bolt or pin.

[00144] Figures 45, 46, and 47 illustrate a fourth embodiment of the locking instrument assembly. The fourth embodiment is similar to the third embodiment except the inner collet has at least two portions in the fourth embodiment. The locking instrument 500 includes an inner collet 512, an offset collet handle base 511, an offset collet inner thread 513, an outer body 530, a handle 556, a first fastener 558, a knob 560, a second fastener 562, a washer 564, and a spring pin 566.

[00145] The locking instrument assembly 500 is assembled as follows. First, the offset collet inner thread 513 is threaded into the knob 560 until both components are flush at the top. Second, the knob 560 is removably attached to the outer body 530. In the depicted embodiment, the knob 560 has a flange 570 that is received by a recess (not shown) of a shoulder 587 of the outer body 530. Third, the inner collet 512 is inserted through the outer body 530 and into the offset collet inner thread 513. Fourth, the second fastener 562 is installed to secure the inner collet 512 to the offset collet inner thread 513. Fifth, the offset collet handle base 511 is threaded into the offset collet inner thread 513 until both components are nearly flush at the top. Sixth, the knob 560 is tightened. Seventh, the spring pin 566 is inserted through the offset collet inner thread 513 and into the offset collet handle base 511. Eighth, the handle 556 and the washer 564 are placed on the offset collet handle base 511 and the first fastener 558 is inserted into the offset collet handle base 511.

[00146] Figure 48 illustrates the offset collet handle base 511. The offset collet handle base 511 includes a first projection 550, a second projection 552, a bottom portion 551, and an outer portion 554. The projections 550, 552 are spaced apart to receive the handle 556. The projections 550, 552 each also include a first mounting hole 555. The first mounting holes 555 receive the first fastener 558. The outer portion 554 is adapted to mate with the offset inner thread 513. In the depicted embodiments, the outer portion 554 is threaded, but those of ordinary skill in the art would understand that other methods of engagement may be used. The offset collet handle base 511 also includes the inner bore 548. The inner bore 548 is curved or arcuate. In the embodiment depicted in Figure 48, the inner bore 548 is in the shape of a semicircle. In some embodiments, the inner bore 548 is substantially circular.

[00147] Figure 49 illustrates the knob 560. The knob 560 includes the flange 570.

[00148] Figure 50 illustrates the offset collet inner thread 513. The offset collet inner thread 513 includes a barrel member 571, a column 572, and a bottom face 577. The barrel member 571 is adapted to mate with the knob 560. In the depicted embodiment, the barrel member 571 is threaded but other methods of engagement may be used. The column 572 extends upwardly from the barrel member 571. The column 572 has cutouts 573 and a vertical slot 574. An inner portion 578 of the column 572 receives the offset collet handle base 511. In the depicted embodiment, the inner portion 578 is threaded but other methods of engagement may be used. The bottom face 577 has an inner bore 575 and a through hole 576. The inner bore 575 is dimensioned and shaped to receive the intramedullary device 100. The through hole 576 is dimensioned and shaped to receive a portion of the second fastener 562. The bottom face 577 engages the inner collet 512.

[00149] Figures 51 and 52 illustrate the inner collet 512. The inner collet 512 has a first end portion 514, a second end portion 516, and a longitudinally extending inner bore 518. The inner bore 518 is curved or arcuate. In the embodiment depicted in Figure 51, the

inner bore 518 is substantially cylindrical. The inner bore 518 is adapted to receive the intramedullary device 100. In other words, the inner bore 518 is shaped to fit the intramedullary device 100. The first end portion 514 has a collar 520 and a base portion 526. The base portion 526 may be cylindrical, oval, or cylindrical with tangent portions removed. In the depicted embodiment, the base portion 526 is generally cylindrical. The inner bore 518 is offset from the central axis of the base portion 526. In other words, the central axis of the inner bore 518 is radially offset a certain distance from the central axis of the base portion 526. This offset distance may be anywhere from about one millimeter to about eighteen millimeters and rather from about two millimeters to about six millimeters. The offset inner bore 518 allows the locking instrument assembly 500 to offset an instrument when the instrument is mounted to the outer body 530.

[00150] Inner collet 512 functions as a collet or wedge. The collar 520 may include one or more relief areas 524. The relief areas 524 allow a portion of the inner bore 518 to collapse. In the embodiment depicted in Figure 52, the collar 520 has five relief areas 524. The relief areas 524 may be cylindrical, rectangular, prolated, or key hole shaped.

[00151] The inner collet 512 also includes a second mounting hole 522. The second mounting hole receives a portion of the fastener 562. In the depicted embodiment, the second mounting hole 522 is threaded but other methods of engagement may be used.

[00152] The invention also includes a surgical method. Portions of the surgical method utilize the locking instrument assembly. While the depicted embodiments illustrate a surgical method for revision knee arthroplasty, those of ordinary skill in the art would understand that the surgical method and the locking instrument assembly may be used in primary knee arthroplasty. Moreover, while the depicted embodiments illustrate bi-compartmental knee replacement, those of ordinary skill in the art would understand that the

surgical method and the locking instrument assembly are equally applicable in uni-compartmental knee replacement.

[00153] The surgical method begins with preoperative evaluation. In the case of revision knee arthroplasty, the preoperative evaluation begins with a complete patient history and physical examination. Determination of the etiology or failure may require radiographic evaluation, the use of technetium bone scans, the use of laboratory studies and/or aspiration to rule out the possibility of indolent infection.

[00154] The exposure of the total knee may be complicated by previous incisions, stiffness, or a fibrotic soft tissue envelope. In general, greater exposure is required for a revision total knee arthroplasty as compared with that of a primary procedure. Proper tissue planes medially and laterally must be elevated and fasciocutaneous flaps must be maintained in order to minimize wound healing complications. Typically, a standard medial parapatellar arthrotomy is used when feasible. An extensile exposure proximally, such as a quadriceps snip, or distally, such as a tibial tubercle osteotomy, may be required to achieve adequate exposure.

[00155] After adequate exposure of all components has been achieved, attention is turned to component removal. This is normally achieved through dissection of the interface between the prosthesis and the cement or at the prosthetic/bone interface. Many surgeons prefer to remove the femoral component first in order to improve visualization of the posterior tibial component. A thin, flexible osteotome or a thin oscillating saw may be used to disrupt the prosthetic interface in order to allow removal with minimal bone loss. Alternative techniques include the use of a Midas-Rex burr or a Gigli saw to free this interface. Angled osteotomes may be helpful in freeing the condylar portions of the femoral components. If the interfaces have been adequately freed, minimal force is typically

required to remove the femoral component. Excessive force to remove the component may lead to femoral fracture.

[00156] Removal of the tibial component is then carried out in a similar manner. Occasionally, exposure of the lateral side may be more difficult, and the use of a small capsular incision about the lateral aspect of the joint may be required to gain access to the posterolateral aspect of the tibial component. If disruption of the interface at the level of the plateau does not allow for easy implant removal, a cortical window may be made in the metadiaphysis of the tibia to allow a bone tamp access to the keel of the prosthesis. As bone cement fails most easily in tension, a controlled, well-placed blow will often dislodge the tibial component.

[00157] If the patellar button is securely fixed, well-positioned and does not show excessive wear then it may be left and protected for the remainder of the case. If the patellar button must be revised, removal is most easily performed with a sagittal saw at the cement interface. Remaining cement and polyethylene plugs from the component may then be removed with a small, high-speed burr. Great care must be taken during this stage of the procedure in order to ensure adequate patellar bone stock remains for revision component placement so that fracture is prevented. Once components have been removed, the remaining cement can then be removed with curettes, rongeurs or cement osteotomes. The wounds may be irrigated with a water pick to remove loose debris and attention can then be turned to the reconstructive portion of the surgical method.

[00158] Figure 53 is a front view of an intramedullary device 100 and a tibia 104. In an optional first step, a pilot hole may be drilled into the tibia 104 using an intramedullary drill. The intramedullary canal is reamed until cortical contact is achieved using progressively larger diameter reamers. The intramedullary device 100 is placed or left in the reamed intramedullary canal. The intramedullary device 100 may be the last reamer used to ream the

canal or it may be a trial stem connection rod assembly. In the case of the trial stem connection rod assembly, a note is made as to the depth and diameter of the last reamer, the appropriate diameter trial stem connection rod is selected, and the trial stem connection rod assembly is inserted into the tibial canal. For this purpose, the reamers may include depth  
5 indicators.

[00159] Next, the tibial alignment guide is assembled to the locking instrument assembly, and the locking instrument assembly is mounted to the intramedullary device 100. Referring now to Figure 54, a stylus 308 is connected to the tibial cutting block 310. Then, the tibial cutting block 310 is assembled to the down rod 246. Next, as best seen in Figure 55, the  
10 locking instrument assembly 200 is slid onto the intramedullary device 100. The down rod 246 is adjusted towards the anterior tibia and locked into position. The locking instrument assembly 200 is lowered until the stylus 312 touches the least affected area of the tibial plateau. The knob 60, 90, 260 is tightened to lock the locking instrument assembly in place. Thereafter, the tibial cutting block 310 may be rotated around the anterior tibia for optimum  
15 access by loosening the rotation lock knob 242.

[00160] Referring to Figures 56 and 57, the next step is resection of the tibia. An optional first step is to use a fastener driver, such as a hex screwdriver, to tighten the rotational lock knob, translation lock knob, and the cutting block lock knob. A second optional step is to pin the tibial cutting block to the tibia. Pins 313 may be used to pin the cutting block 310.  
20 The stylus 308 is removed, a saw blade is inserted into the tibial cutting block, and the tibia is resected. The locking instrument assembly is removed. Thereafter, the surgeon may perform typical steps for tibial preparation. This may include the steps of counterboring the tibia, inserting a trial into the tibia, assessing the tibial trial, and adjusting the tibia for proper trial alignment.



[00161] The surgical method also includes step for femoral preparation to receive an implant. Figure 58 illustrates an intramedullary device 100 and a femur 103. In an optional first step, a pilot hole may be drilled into the femur 102 using an intramedullary drill. The intramedullary canal is reamed until cortical contact is achieved using progressively larger diameter reamers. The intramedullary device 100 is placed or left in the reamed intramedullary canal. The intramedullary device 100 may be the last reamer used to ream the canal or it may be a trial stem connection rod assembly. In the case of the trial stem connection rod assembly, a note is made as to the depth and diameter of the last reamer, the appropriate diameter trial stem connection rod is selected, and the trial stem connection rod assembly is inserted into the femoral canal. For this purpose, the reamers may include depth indicators.

[00162] Next, the femur 102 is assessed for anterior-posterior size and stem offset position. As best seen in Figures 59 and 60, an offset indicator 320 is slid over the intramedullary device 100 and an anterior-posterior sizing plate 322 is positioned relative to the anterior cortex of the femur and adjacent to the offset indicator. The anterior-posterior size is assessed. Once the anterior-posterior size is determined, the offset indicator is used to assess the anterior-posterior position relative to the reamer position. The offset indicator 320 is rotated parallel to the epicondylar axis and a note is made of the offset indicator stylus position relative to the offset markings on the medial face of the anterior-posterior sizing plate. Thereafter, the offset indicator 320 and the anterior-posterior sizing plate 322 are removed.

[00163] Alternatively, the surgeon may assess the offset using the epicondyles. Figure 61 illustrates an epicondylar axis target 324. After the offset indicator and anterior-posterior sizing plate are installed, the surgeon aligns the center of the epicondyles along the line markings of the epicondylar axis target. It is not necessary to have the center of the epicondyles within the open space of the target axis. The surgeon varies the anterior-posterior

sizing plate and distal augment estimates until the epicondyles align with the epicondylar axis target. The goal is to restore the desired joint line positioning. Once a desired position of the anterior-posterior sizing plate is achieved relative to the femoral epicondyles, the surgeon assesses the distal and posterior wedge by referencing the wedge resection level marks on the anterior-posterior sizing plate. The surgeon retains position of the anterior-posterior sizing plate and notes the offset indicator position relative to the indicator marking on the medial face of the anterior-posterior sizing plate. This provides a rough estimate of the offset needed.

[00164] In an optional step, the surgeon may assess the medial-lateral femoral sizing. A valgus alignment guide is attached to the locking instrument assembly, and the locking instrument assembly is attached to the intramedullary device. A distal cutting block is attached to the valgus alignment guide. As best seen in Figure 62, a valgus guide sizing plate 326 is attached to the valgus alignment guide. Thereafter, the surgeon assesses the medial-lateral femoral size with the size correlating steps of the valgus guide sizing plate in relation to the femur 102.

[00165] Referring now to Figures 63 through 66, the next step is resection of the femur. The valgus guide assembly 150 is attached to the locking instrument assembly 10, and the locking instrument assembly 10 is attached to the intramedullary device 100. The locking instrument assembly 10 is slid down the intramedullary device 100 until the valgus guide assembly 150 is flush with the distal femur. Alternatively, a stylus 330 is attached to the distal cutting block 157, and a tip of the stylus 330 is positioned on the least affected side. An optional first step is to use a fastener driver, such as a hex screwdriver, to tighten the valgus collet. A second optional step is to pin the distal cutting block 157 to the femur 102. The stylus 330 is removed, a saw blade 328 is inserted into the distal cutting block 157, and the femur is resected. In some embodiments of the method, it may be necessary to resect an additional femoral wedge. The saw blade 328 is inserted into the second or third slot and the

femur is resected. Thereafter, any pins 313 are removed and the valgus guide assembly 150 is removed.

[00166] The femoral implant may be neutral or offset from the intramedullary canal. Typically, a neutral placement is selected unless this will result in poor bone by the implant.

5 In that case, an offset placement must be selected.

[00167] Figure 67 to 70 illustrate a neutral resection of the distal femur. An anterior-posterior hemi distal shim 332 is attached to the anterior-posterior cutting block 112, and the locking instrument assembly 10 is attached to the anterior-posterior cutting block 112. The locking instrument assembly 10 is slid over the intramedullary device 100 until the shim  
10 contacts the femur 102. In some embodiments, quick connect handles 334 are connected to the anterior-posterior cutting block 157. The anterior-posterior position and the medial-lateral position of the anterior-posterior cutting block 112 is checked to ensure the anterior-posterior cutting block 112 is properly located with respect to the epicondylar axis. If the anterior-posterior cutting block 112 is not in the appropriate position, an offset resection and placement  
15 may be required. The knob 60, 90 is tightened. Optionally, the anterior-posterior cutting block 112 may be pinned to the femur 10 using pins 313. The femur 102 is then resected using saw 318. Thereafter, the surgeon may perform typical steps for femoral preparation. This may include the steps of counterboring the femur, inserting a trial into the femur, assessing the femoral trial, and adjusting the femur for proper trial alignment.

20 [00168] Figures 71 through 77 illustrate an offset resection of the distal femur. The anterior-posterior hemi distal shim 332 is attached to the anterior-posterior cutting block 112, and the offset locking instrument assembly 400, 500 is attached to the anterior-posterior cutting block 112. The locking instrument assembly 400, 500 is slid over the intramedullary device 100 until the shim contacts the femur 102. In some embodiments, quick connect  
25 handles 334 are connected to the anterior-posterior cutting block 157. The handle 456, 556 is

rotated until the anterior-posterior cutting block 112 is appropriately positioned. The clock position of the handle 456, 556 references or indicates the positioning of the anterior-posterior cutting block relative to the intramedullary canal. Figure 73 illustrates an "11 O'clock" position. Figure 74 illustrates a "1 O'clock" position. Figure 75 illustrates a "7 O'clock" position. When the anterior-posterior cutting block is appropriately positioned, the knob 460, 560 is tightened. Optionally, the anterior-posterior cutting block 112 may be pinned to the femur 10 using pins 313. The femur 102 is then resected using saw 318. Thereafter, the surgeon may perform typical steps for femoral preparation. This may include the steps of counterboring the femur, inserting a trial into the femur, assessing the femoral trial, and adjusting the femur for proper trial alignment.

**[00169]** The instrument and method have several advantages over the state of the art. Most instruments use bone spikes or pins to locate and mount the instrument. Some instruments use an intramedullary device as a reference axis but do not use the intramedullary device to control movement. Still others utilize an intramedullary device that has a pre-set length configuration. In other words, the instrument cannot be adjusted axially along the intramedullary device for a particular patient.

**[00170]** The locking instrument assembly 10 allows for instrument adjustment axially along the intramedullary device 100. By not restricting the usable length portion of the intramedullary device, a surgeon can first stabilize the intramedullary device 100 independently from the correlating/desired connecting instrument and then rigidly connect the correlating instrument to the locking instrument assembly 10. For example, Figure 2 illustrates the locking instrument assembly 10 and the intramedullary device 100. In the embodiment depicted in Figure 10, an anterior-posterior cutting block 110 is operatively connected to the outer body 30. In another example, Figure 14 illustrates the locking

instrument assembly 10 and the intramedullary device 100. In the embodiment depicted in Figure 14, a valgus alignment guide 150 is operatively connected to the outer body 30.

[00171] In view of the foregoing, it will be seen that the several advantages of the invention are achieved and attained.

5 [00172] The embodiments were chosen and described in order to best explain the principles of the invention and its practical application to thereby enable others skilled in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

[00173] As various modifications could be made in the constructions and methods  
10 herein described and illustrated without departing from the scope of the invention, it is intended that all matter contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary  
embodiments, but should be defined only in accordance with the following claims appended  
15 hereto and their equivalents.

*What is Claimed Is:*

1. A locking instrument assembly for use in conjunction with an intramedullary device,  
the assembly comprising:
  - a. an inner collet, said inner collet having a first end portion, a second end  
5 portion, and a longitudinally extending inner bore, said first end portion  
having a collar, and said inner bore adapted to receive the intramedullary  
device;
  - b. an intermediate body, said intermediate body having an inner portion and an  
outer portion, said inner portion adapted to engage said collar; and
  - 10 c. a knob, said knob adapted to engage said intermediate body, wherein as said  
knob engages said intermediate body, said intermediate body engages said  
collar such that said inner collet applies a clamping force to the intramedullary  
device.
2. The locking instrument assembly of claim 1, wherein said intermediate body is  
15 selected from the group consisting of an outer body and an orientation base.
3. The locking instrument assembly of claim 1 or 2, wherein said second end portion has  
a fastener member, and said knob engages said fastener member.
4. The locking instrument assembly of any of claims 1-3, wherein said knob has a  
flange, said intermediate body has a shoulder with a recess, and said recess receives  
20 said flange.
5. The locking instrument assembly of any of claims 1-4, wherein said inner collet has at  
least one relief area.
6. The locking instrument assembly of any of claims 1-5, wherein said intermediate  
body has at least one relief area.
- 25 7. The locking instrument assembly of any of claims 1-6, wherein said inner collet and

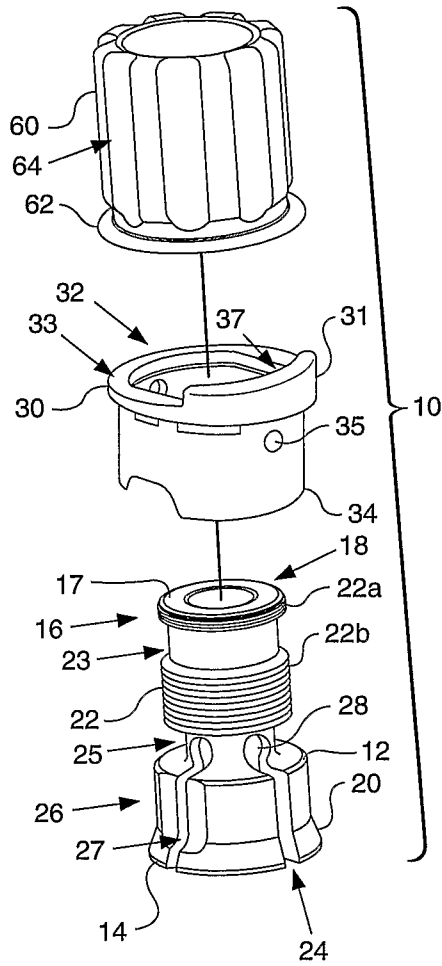
said intermediate body have complimentary planar sections.

8. The locking instrument assembly of any of claims 1-7, further comprising an offset collet handle base and an offset collet inner thread.
9. The locking instrument assembly of any of claims 1-8, further comprising an instrument attached to said intermediate body.  
5
10. The locking instrument assembly of claim 9, wherein said intermediate body applies a clamping force to said instrument.
11. The locking instrument assembly of claim 9 or 10, wherein a portion of said intermediate body is angled in order to angle said instrument relative to the intramedullary device.  
10
12. The locking instrument assembly of any of claims 9-11, wherein said instrument is selected from the group consisting of an anterior-posterior cutting block and a valgus alignment guide.
13. The locking instrument assembly of claim 1, wherein said intermediate body is an orientation base, and said locking instrument assembly further comprises an outer body mounted on said orientation base.  
15
14. The locking instrument assembly of claim 13, further comprising a translation rod connected to said outer body.
15. The locking instrument assembly of claim 14, further comprising a rotation lock knob connected to said translation rod.  
20
16. The locking instrument assembly of claim 15, wherein said orientation base further comprises at least one notch and said rotation lock knob selectively engages said at least one notch.
17. The locking instrument assembly of any of claims 14-16, further comprising a down rod connected to said translation rod.  
25

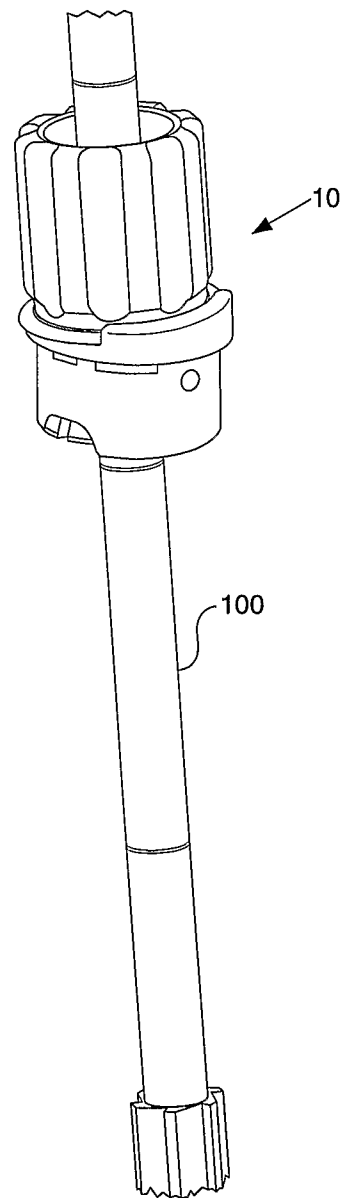
18. The locking instrument assembly of claim 17, further comprising a translation lock knob connected to said down rod.
19. The locking instrument assembly of claim 17 or 18, further comprising a cutting guide connected to said down rod.
- 5 20. The locking instrument assembly of claim 1, wherein said inner collet includes a base portion, and said inner bore is coaxial with said base portion.
21. The locking instrument assembly of claim 1, wherein said inner collet includes a base portion, and a central axis of said inner bore is offset from a central axis of said base portion.
- 10 22. The locking instrument assembly of claim 21, further comprising a handle operatively connected to said inner collet.



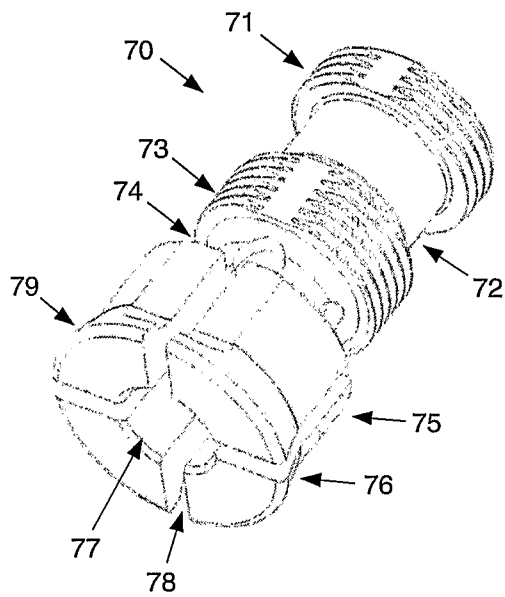
**FIG. 1**



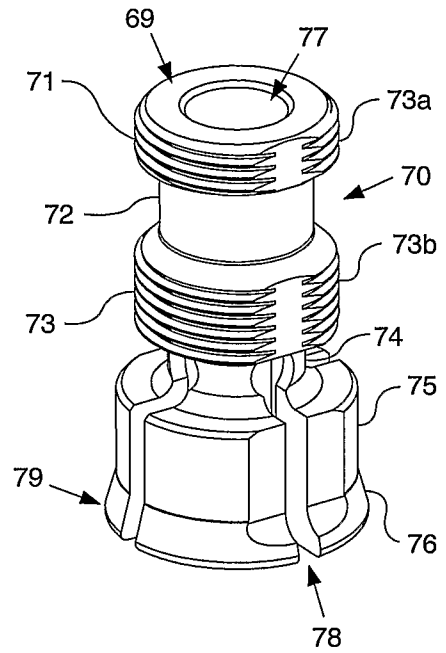
**FIG. 2**



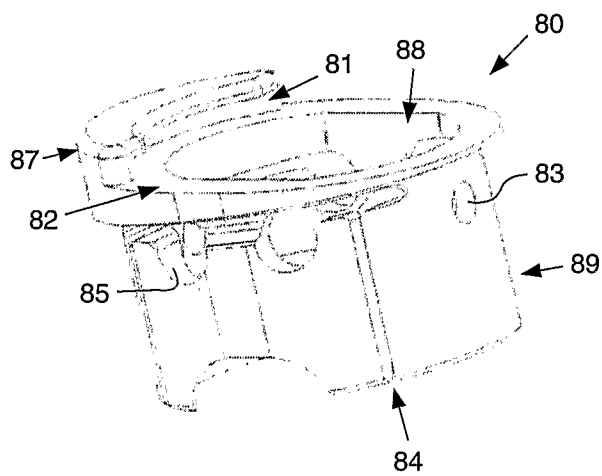
**FIG. 3**



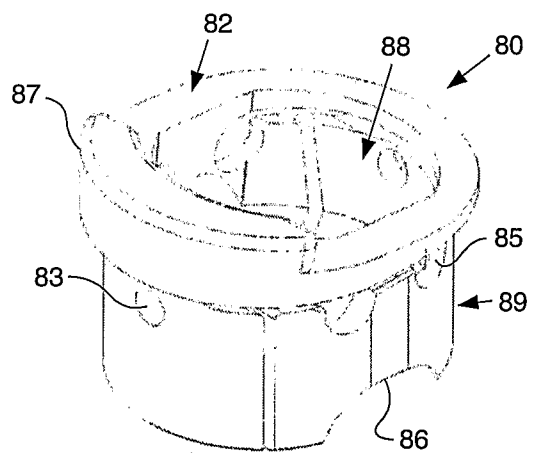
**FIG. 4**



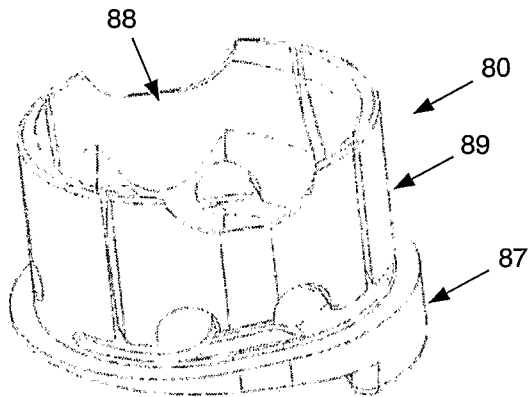
**FIG. 5**



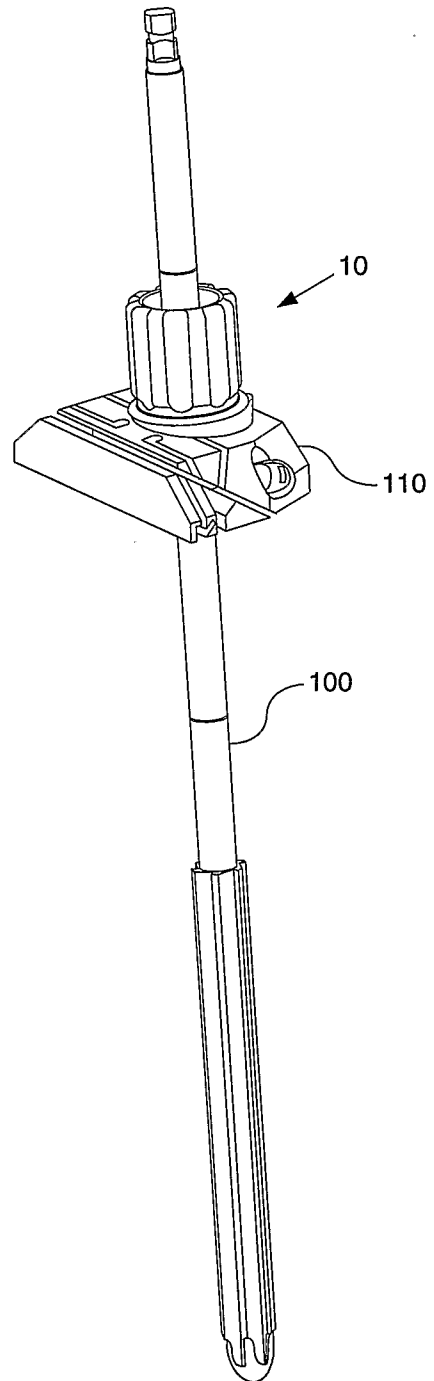
**FIG. 6**



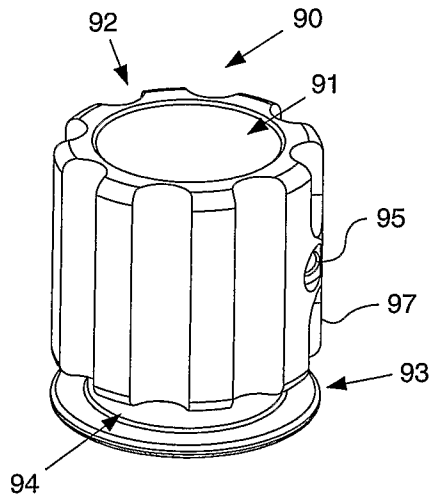
**FIG. 7**



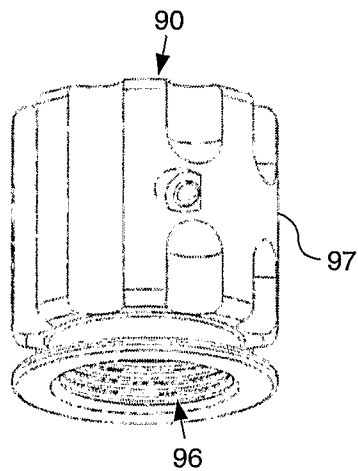
**FIG. 10**



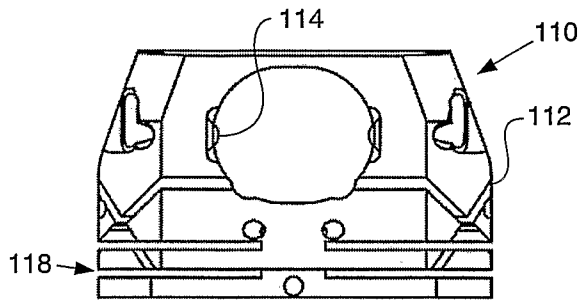
**FIG. 8**



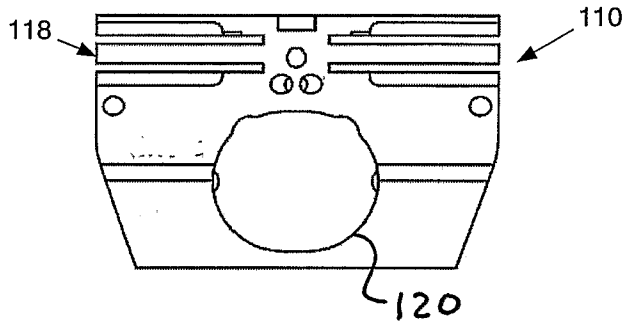
**FIG. 9**



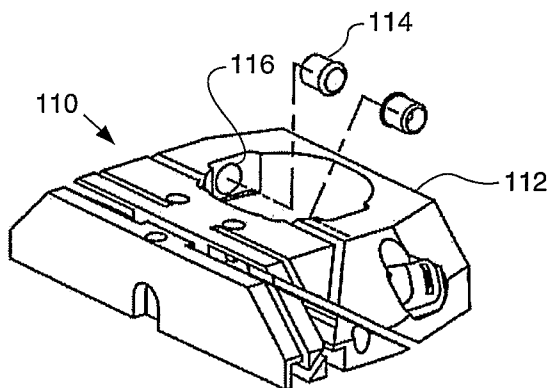
**FIG. 11**



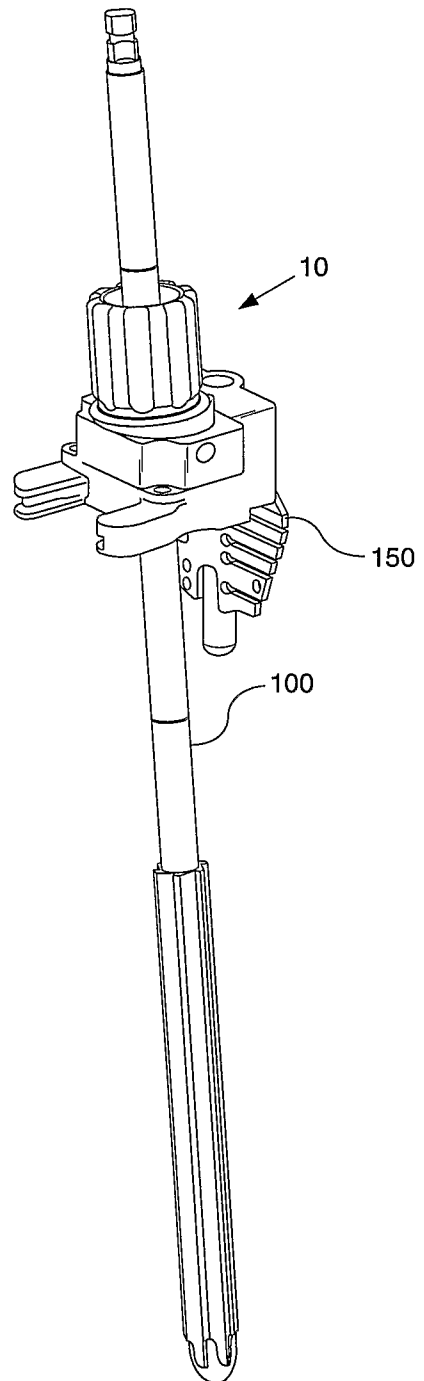
**FIG. 12**



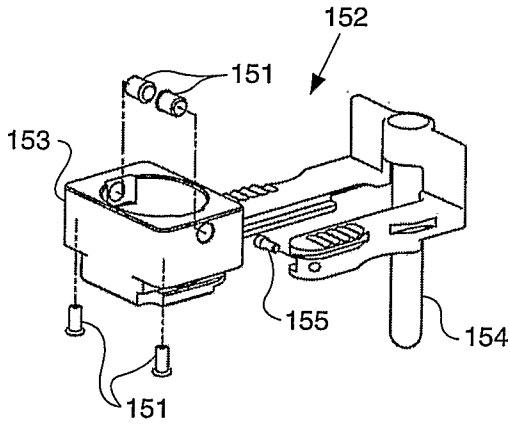
**FIG. 13**



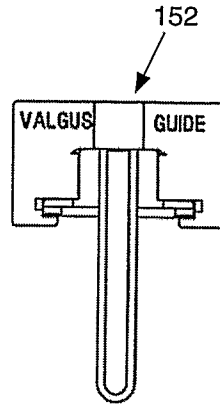
**FIG. 14**



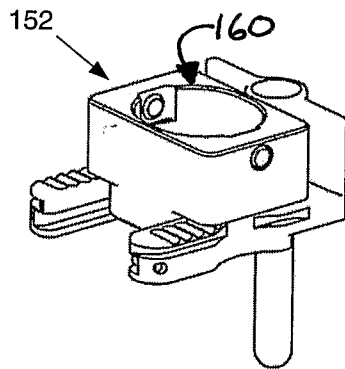
**FIG. 15**



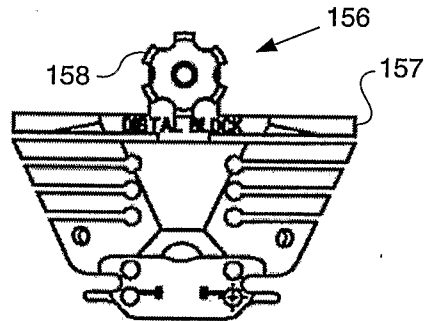
**FIG. 16**



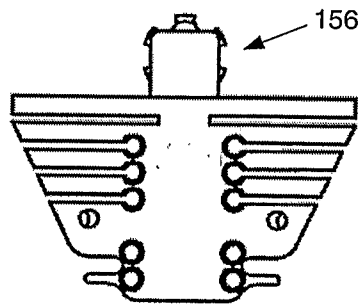
**FIG. 17**



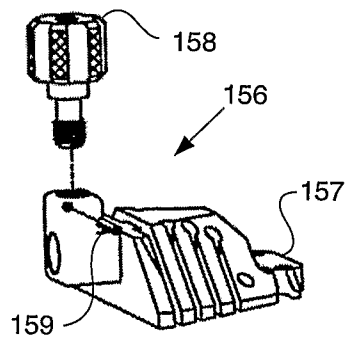
**FIG. 18**



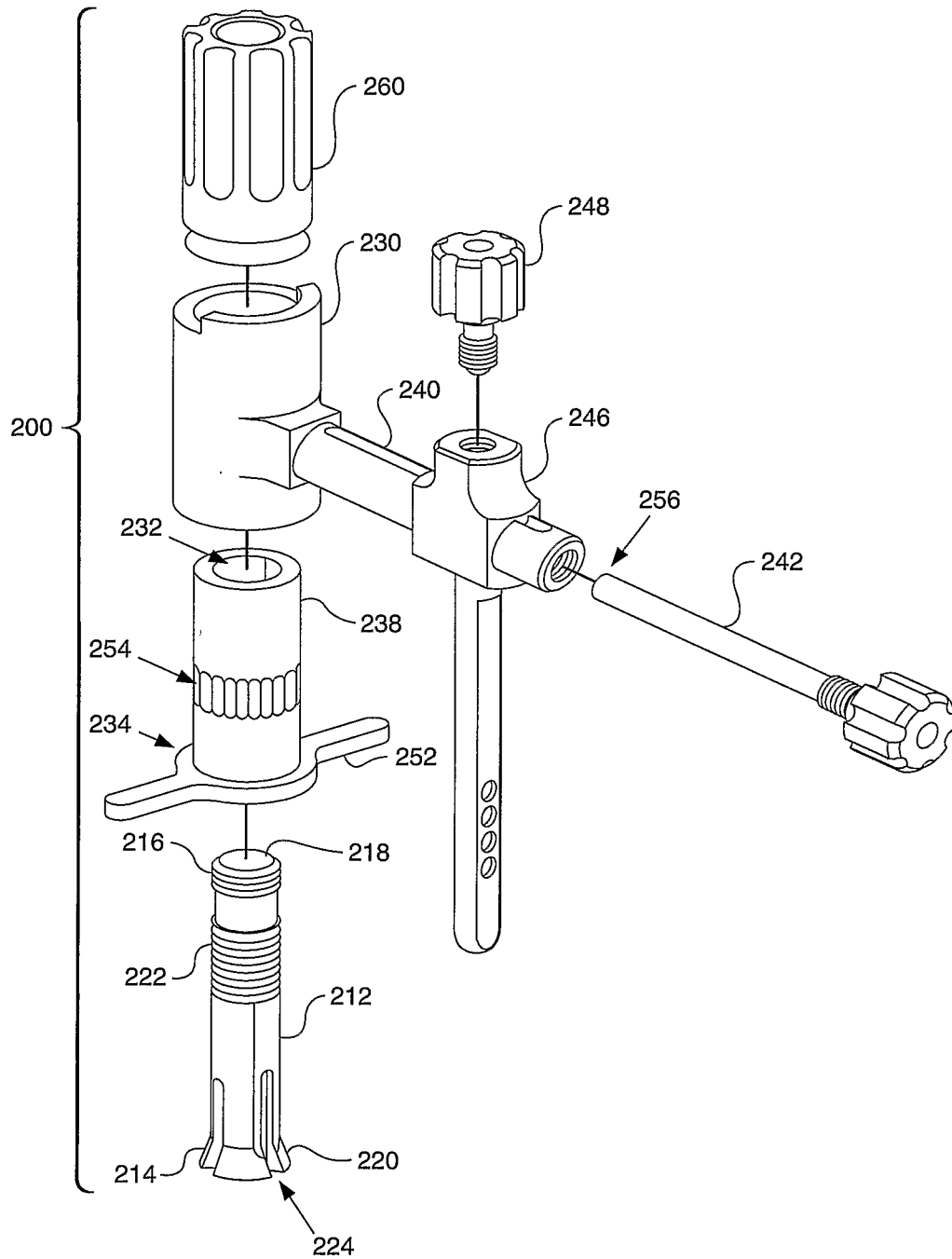
**FIG. 19**



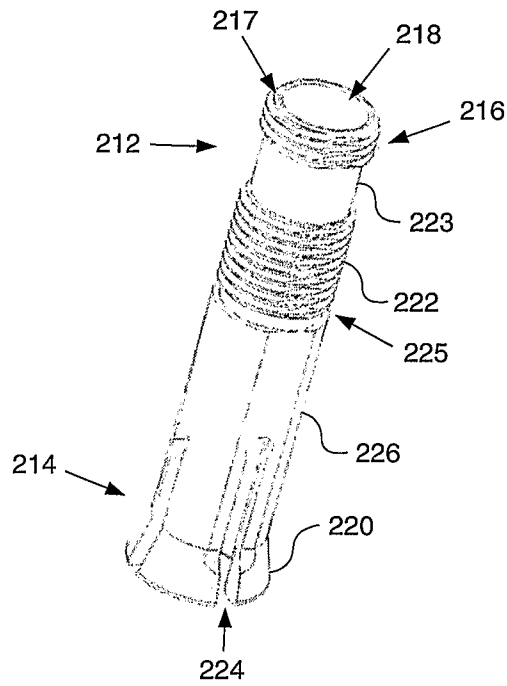
**FIG. 20**



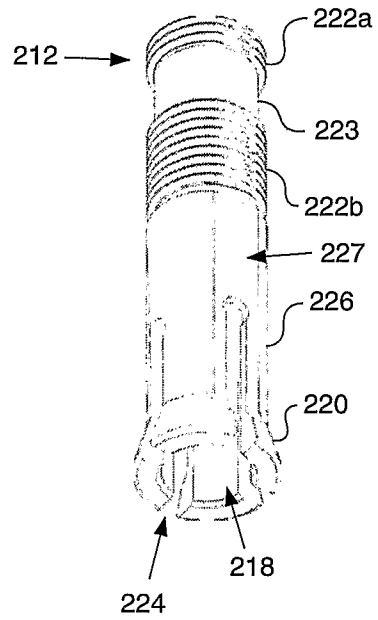
**FIG. 21**



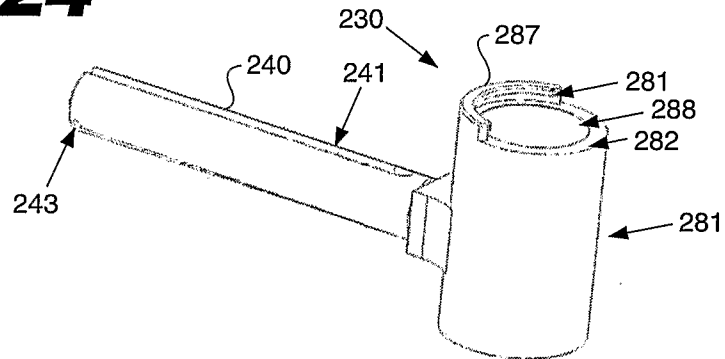
**FIG. 22**



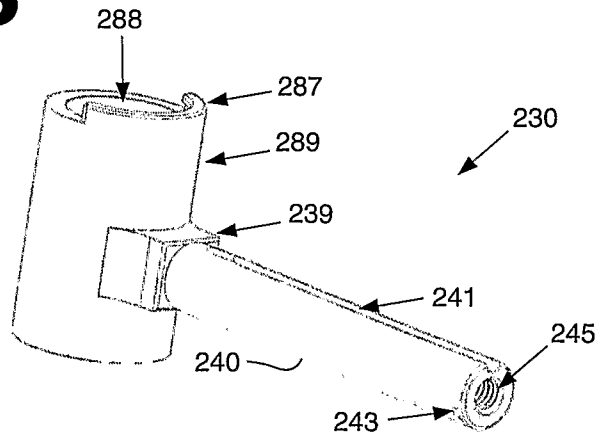
**FIG. 23**



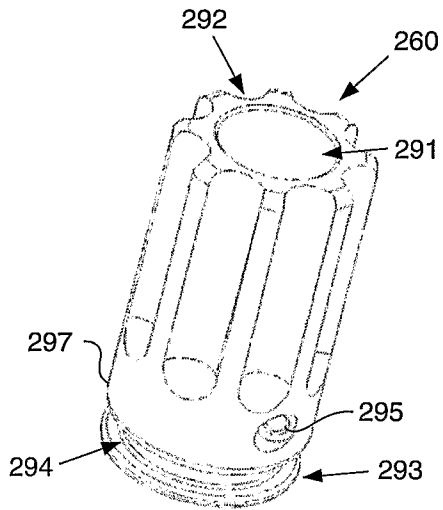
**FIG. 24**



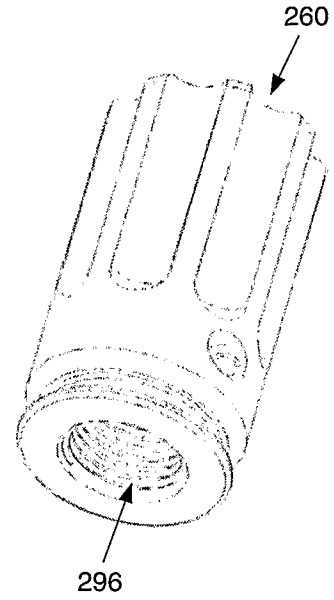
**FIG. 25**



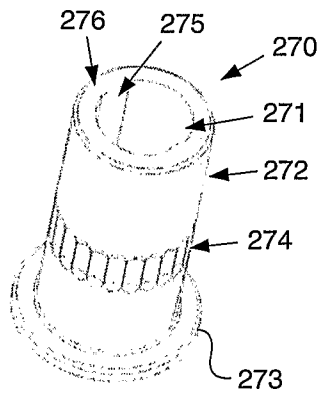
**FIG. 26**



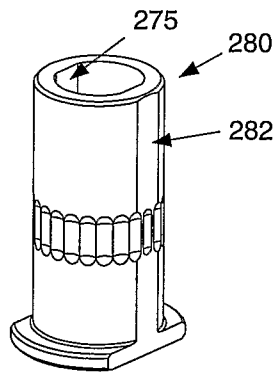
**FIG. 27**



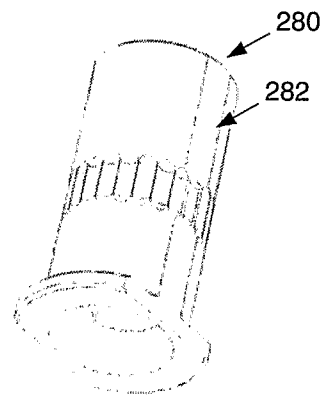
**FIG. 28**



**FIG. 29**

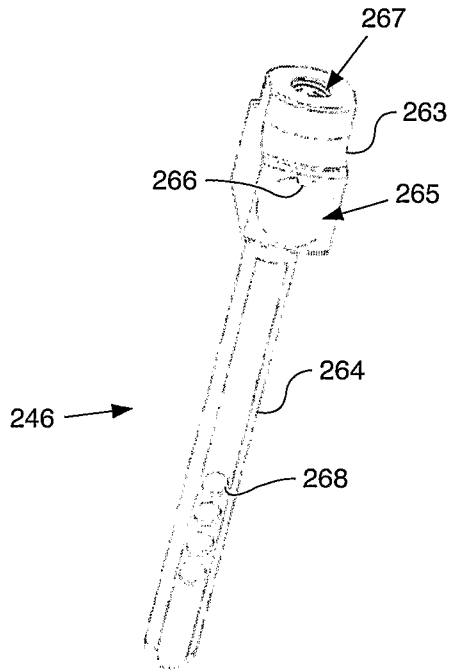


**FIG. 30**

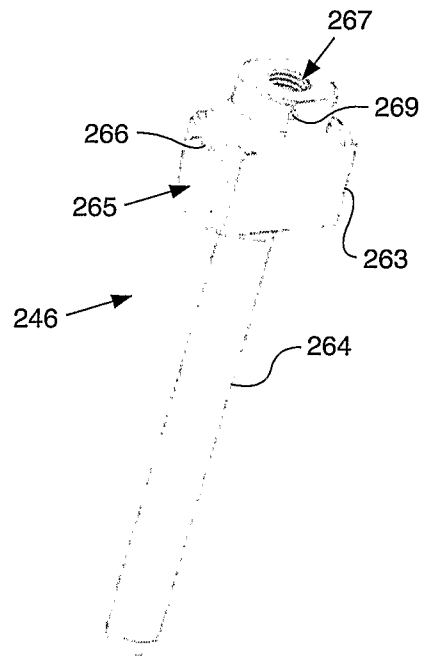




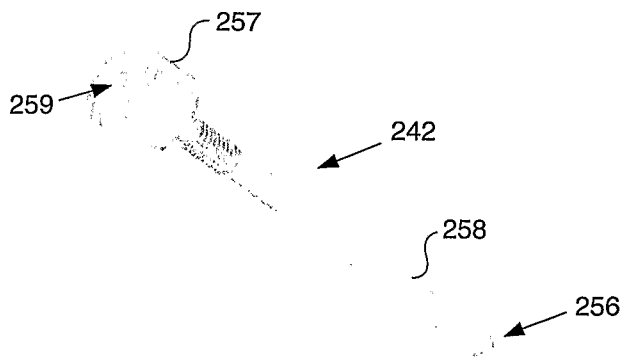
**FIG. 31**



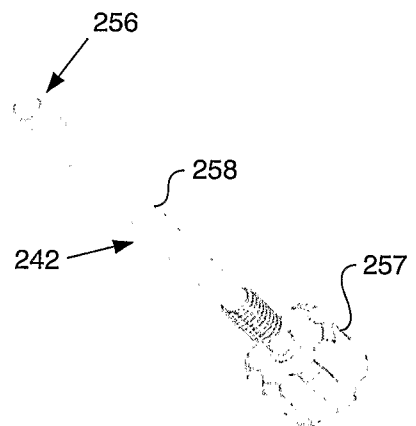
**FIG. 32**



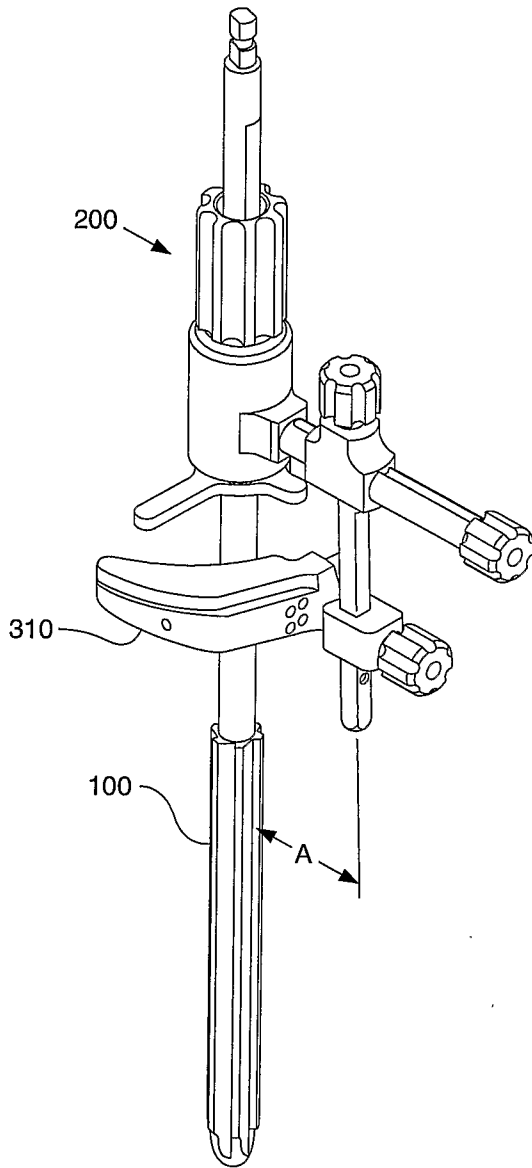
**FIG. 33**



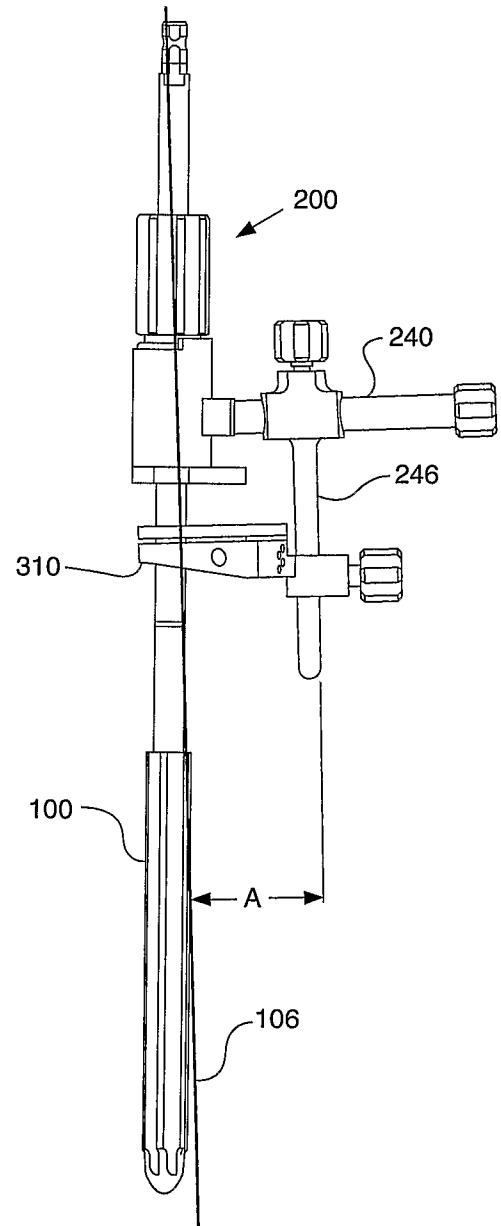
**FIG. 34**



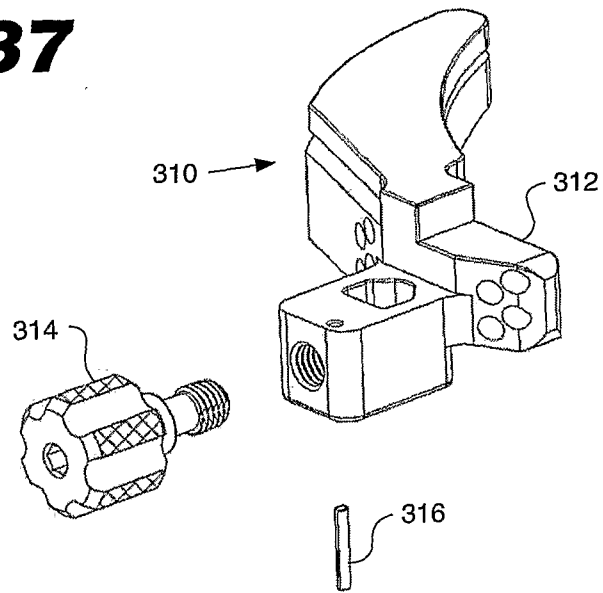
**FIG. 35**



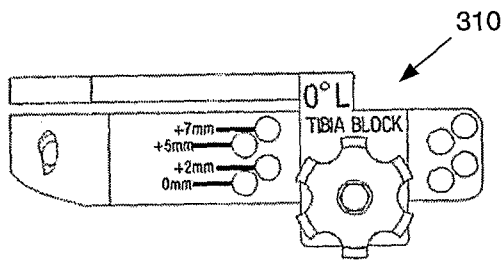
**FIG. 36**



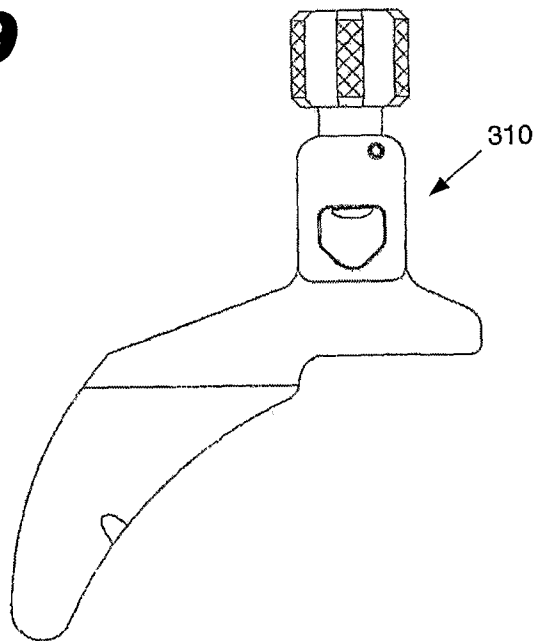
**FIG. 37**



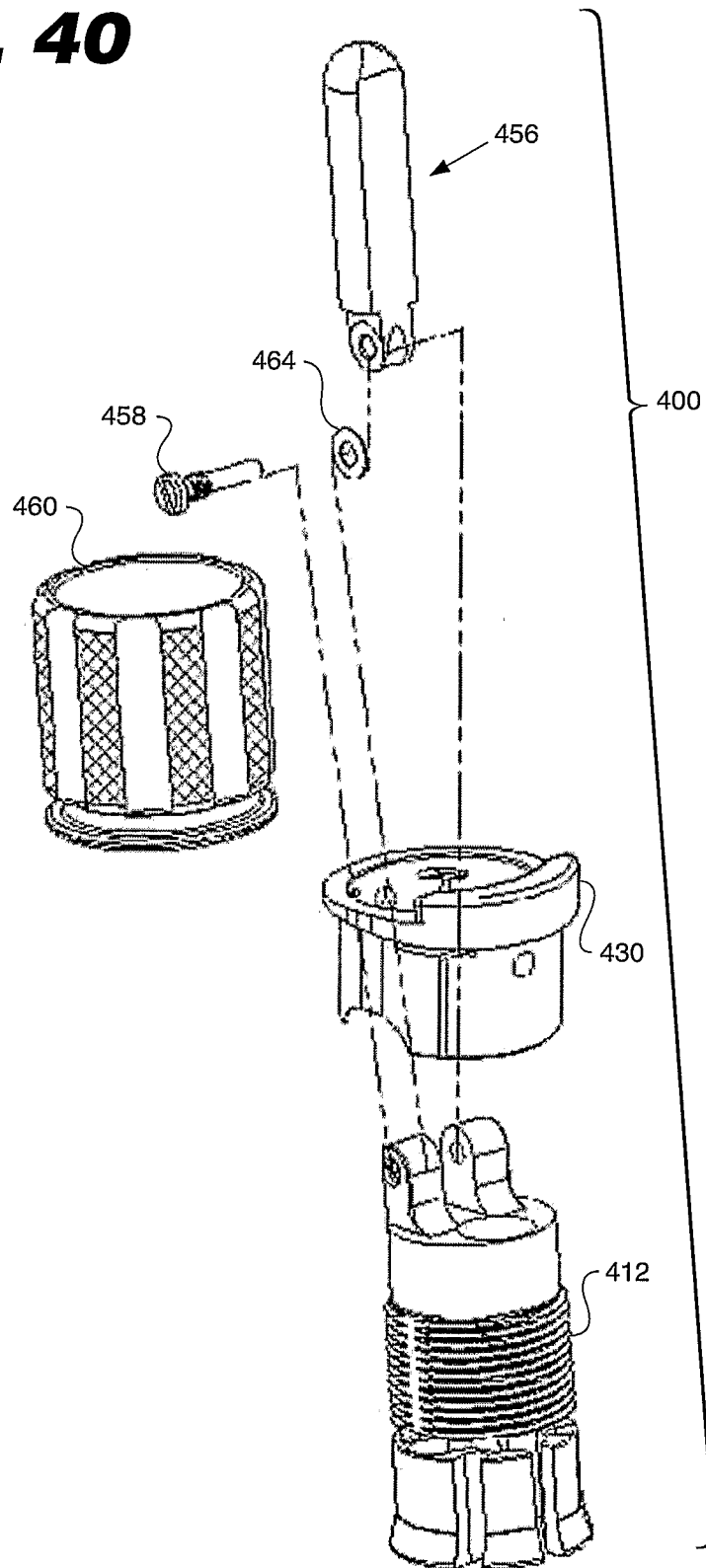
**FIG. 38**



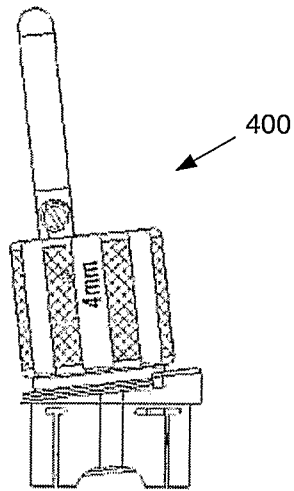
**FIG. 39**



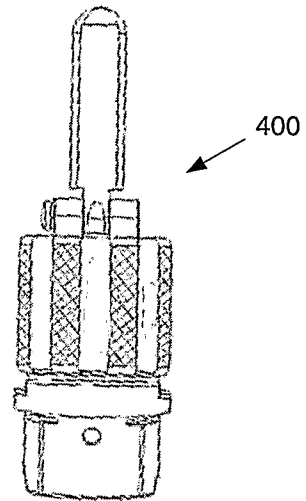
**FIG. 40**



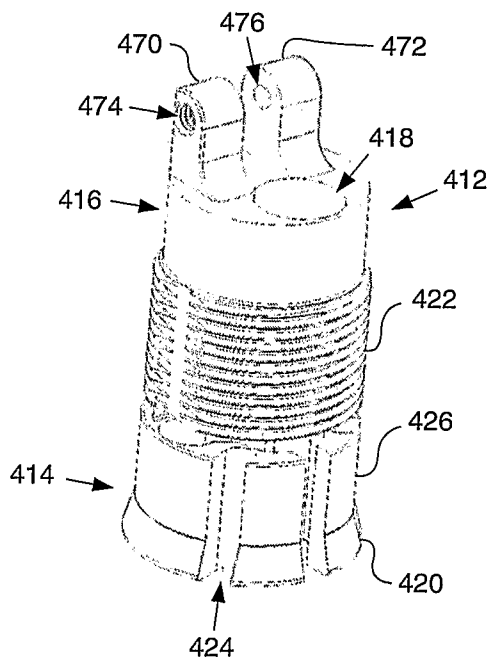
**FIG. 41**



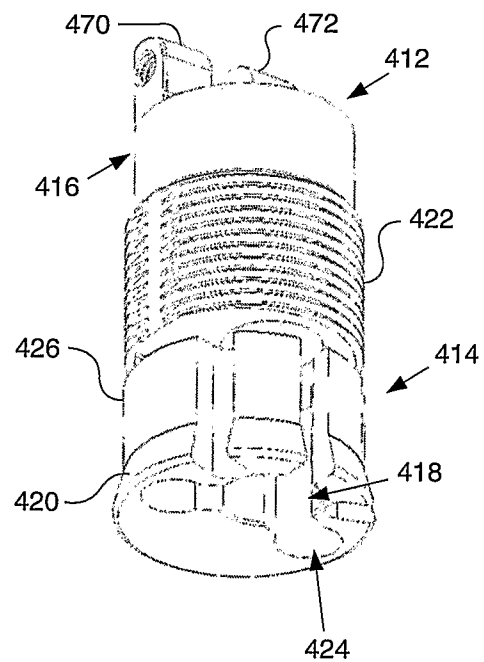
**FIG. 42**



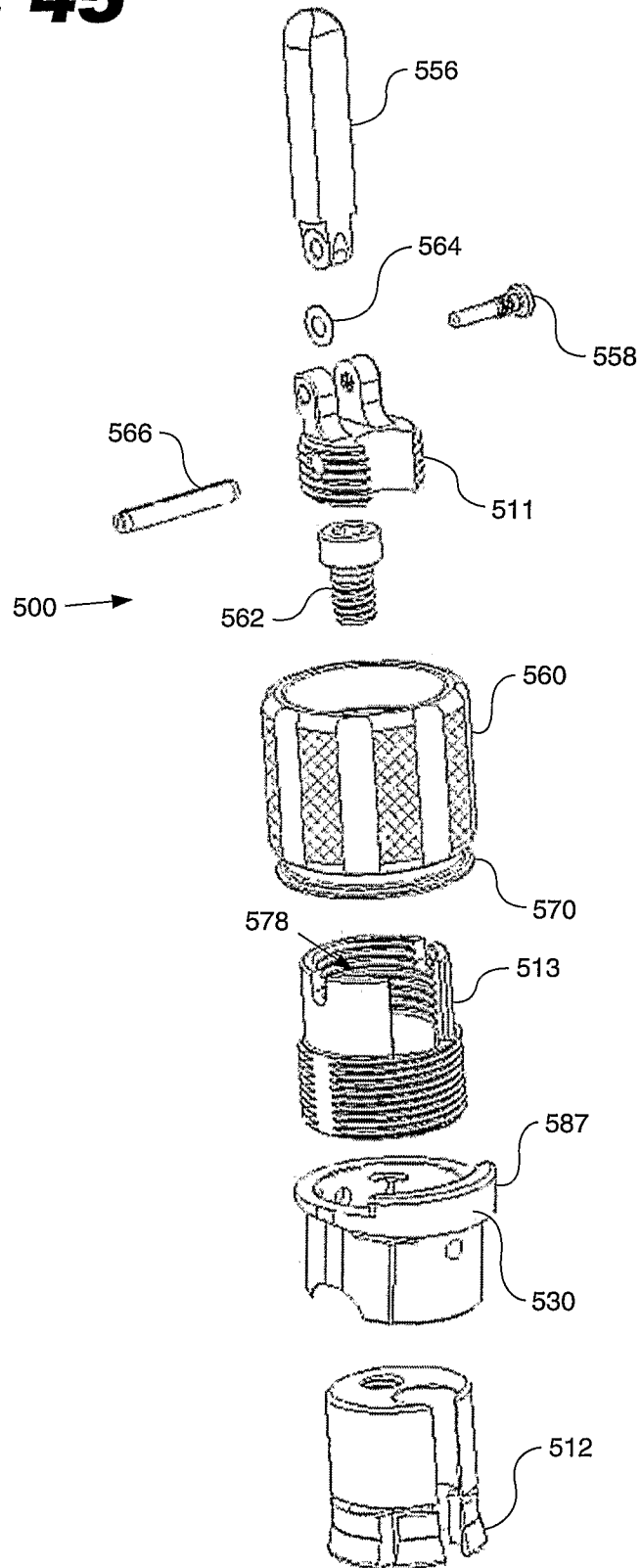
**FIG. 43**



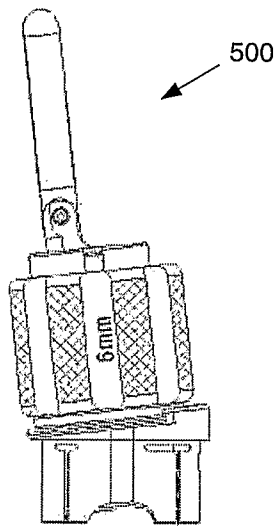
**FIG. 44**



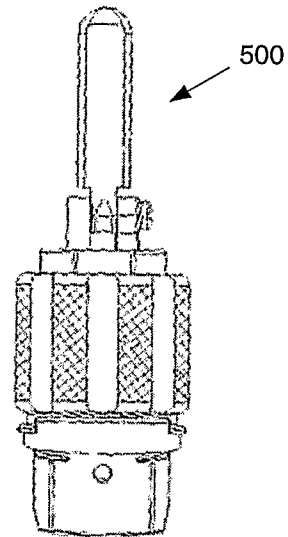
**FIG. 45**



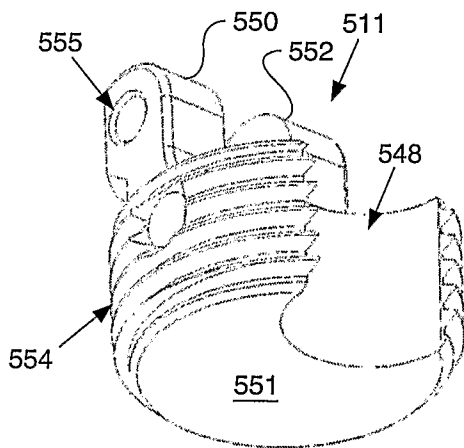
**FIG. 46**



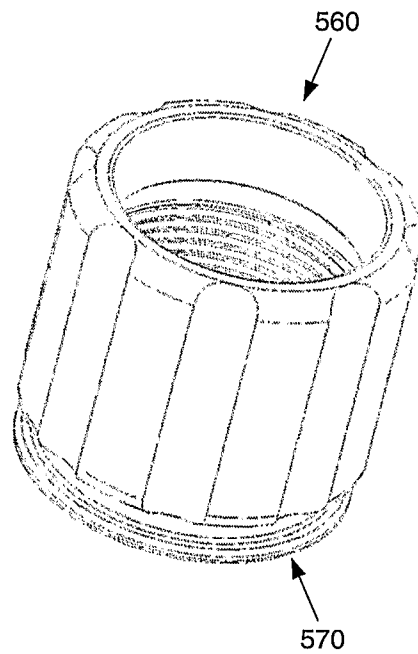
**FIG. 47**



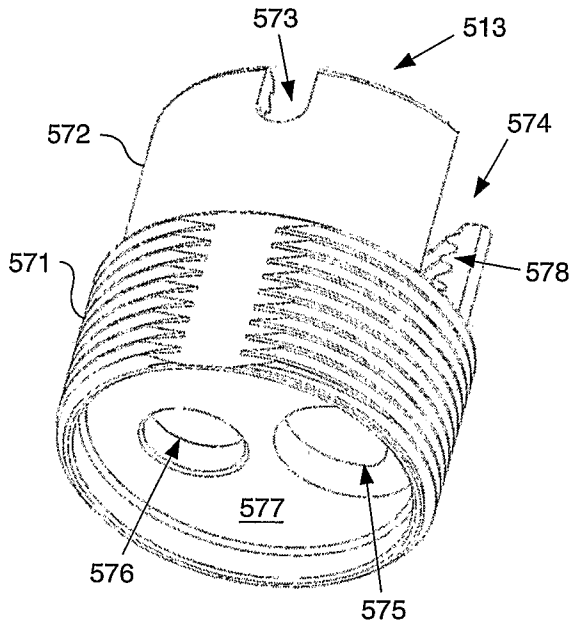
**FIG. 48**



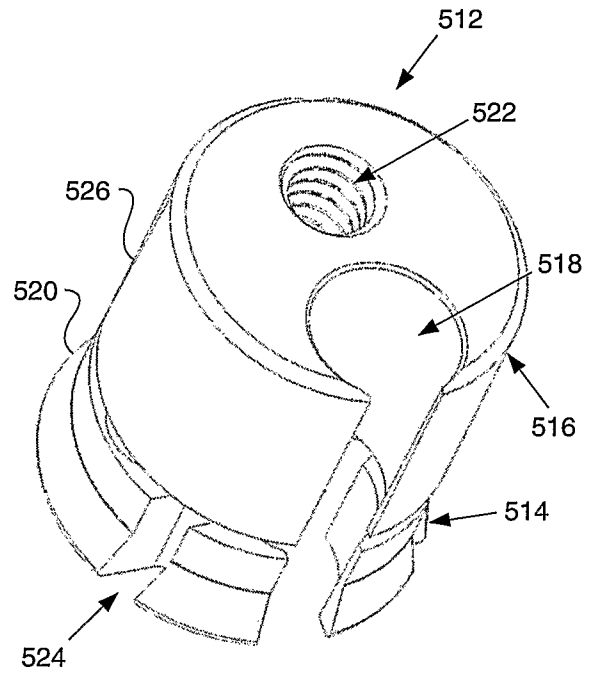
**FIG. 49**



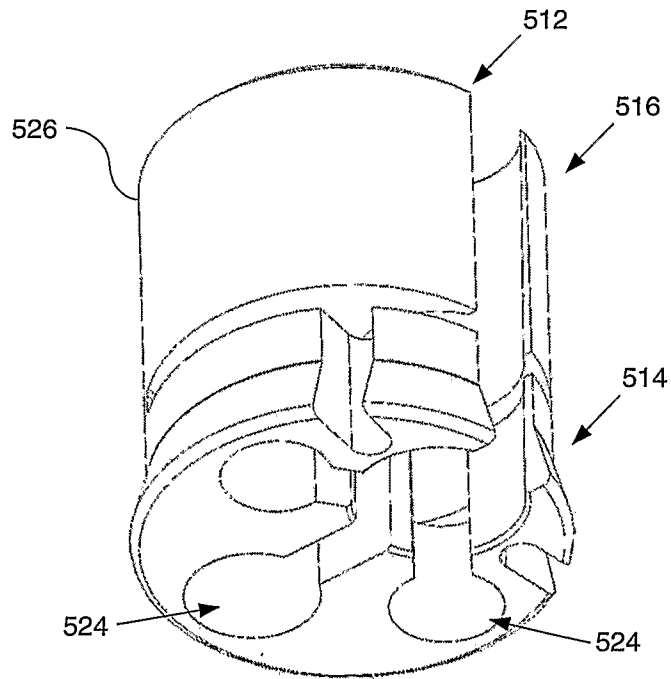
**FIG. 50**



**FIG. 51**

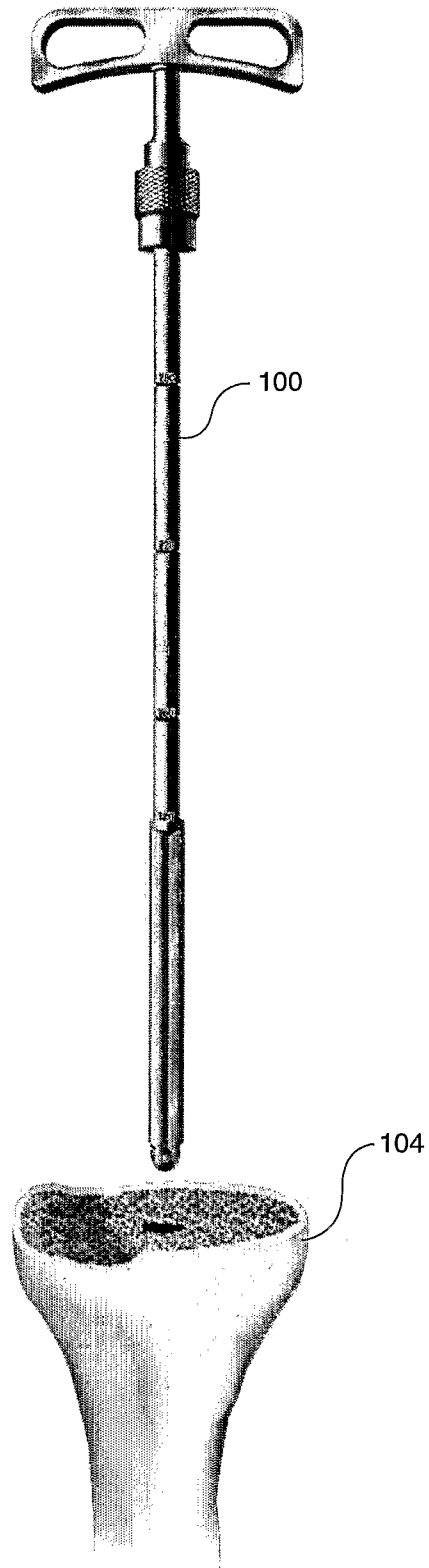


**FIG. 52**

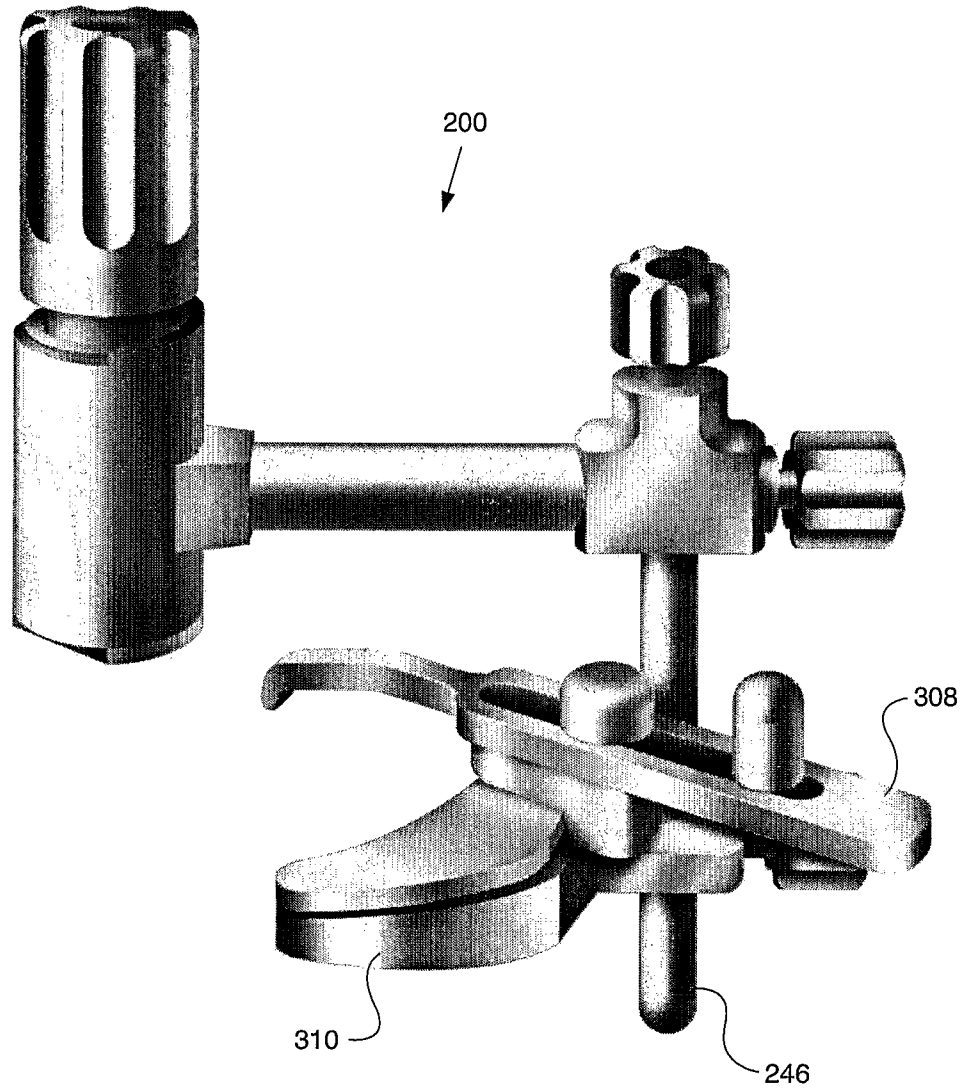




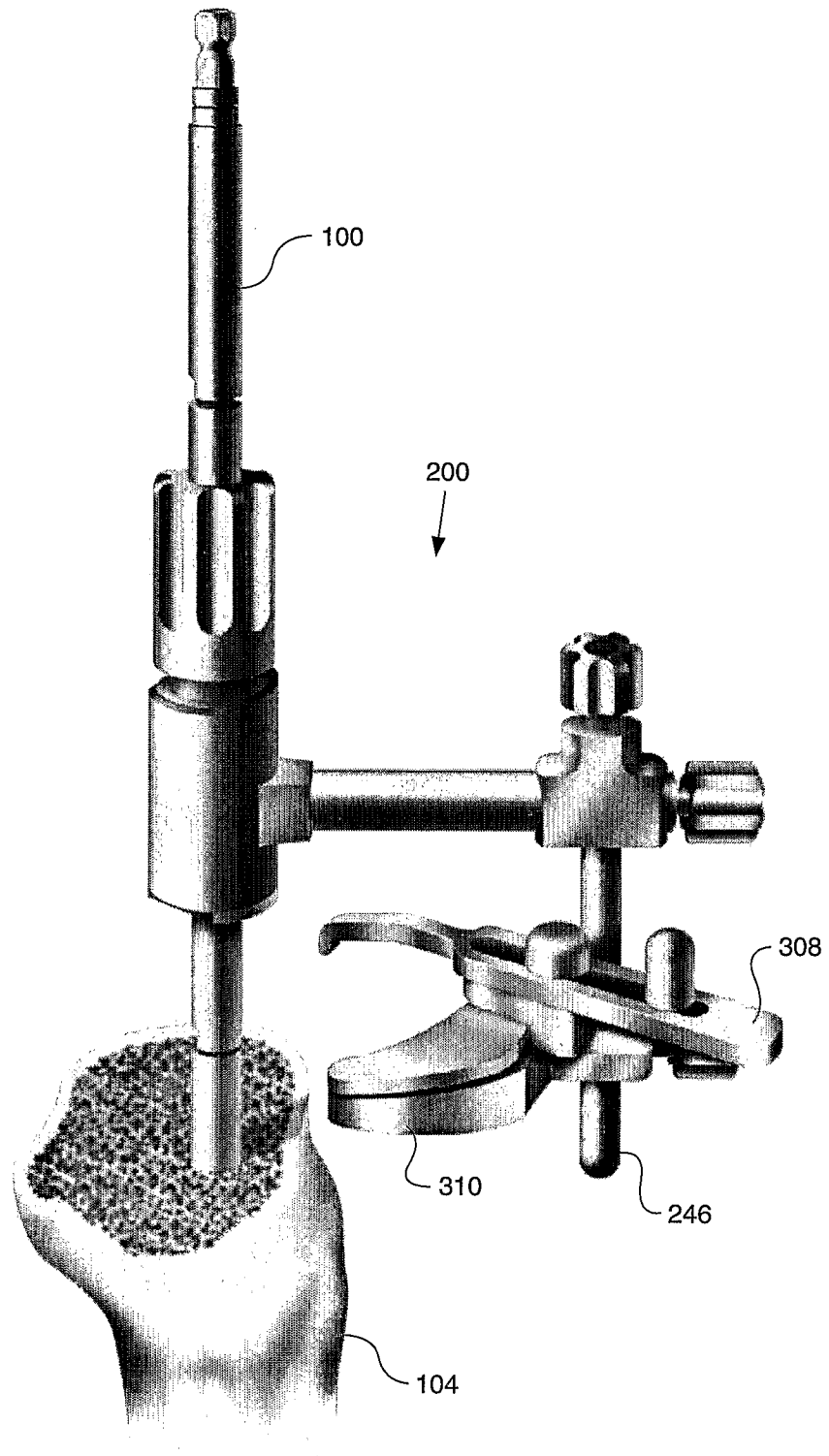
**FIG. 53**



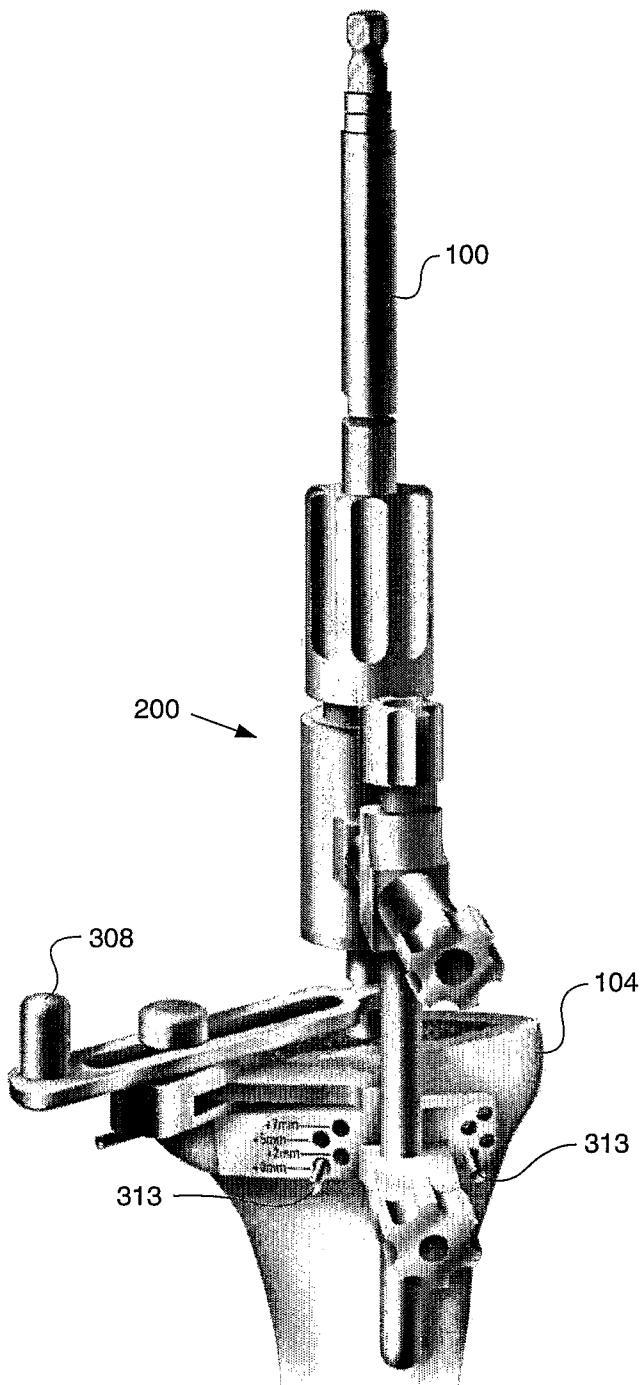
**FIG. 54**



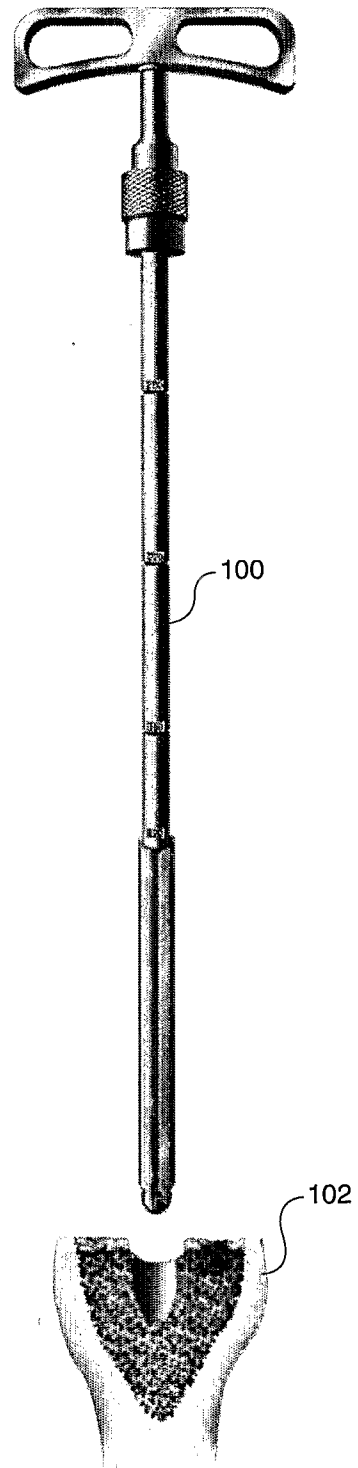
**FIG. 55**



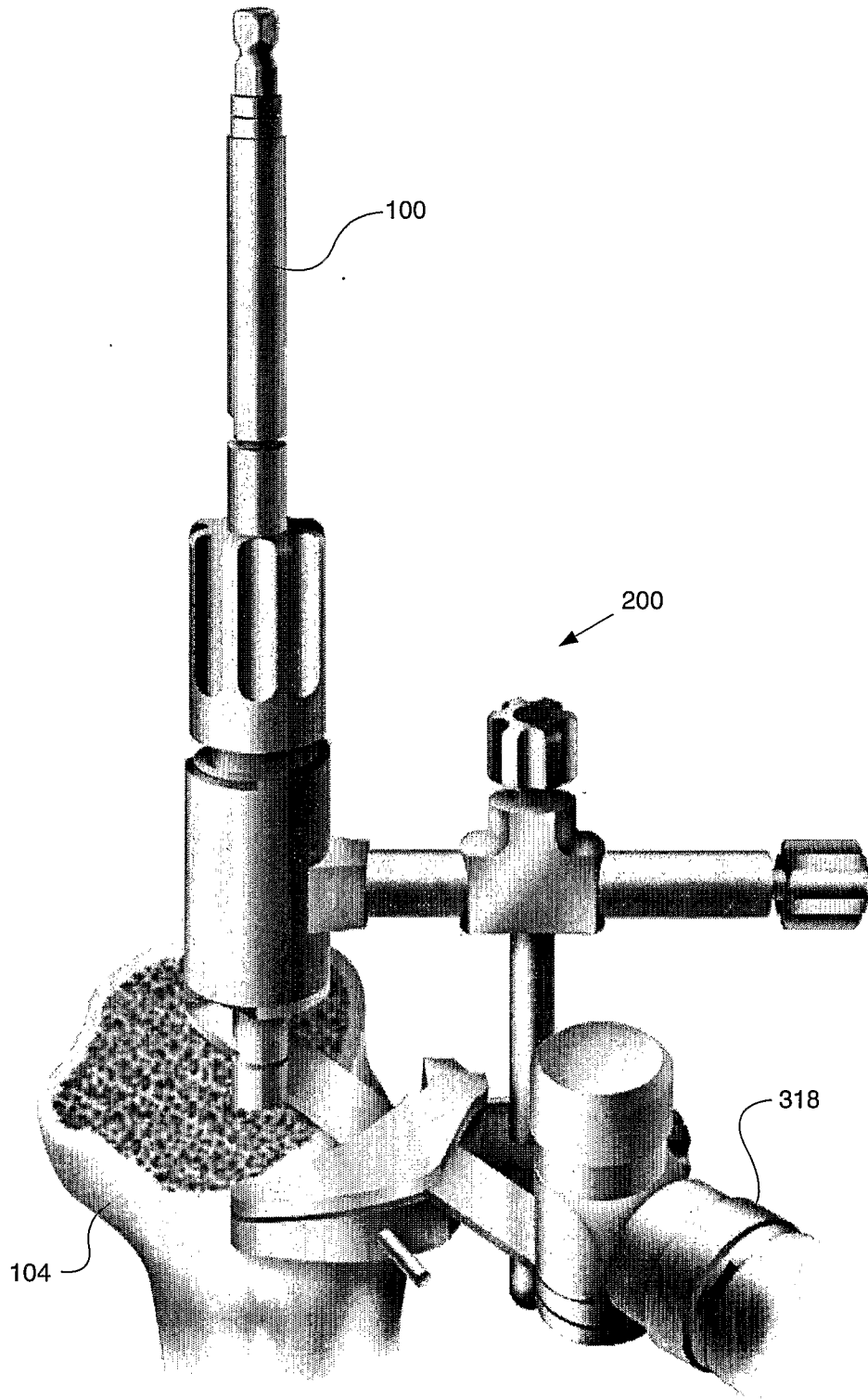
**FIG. 56**



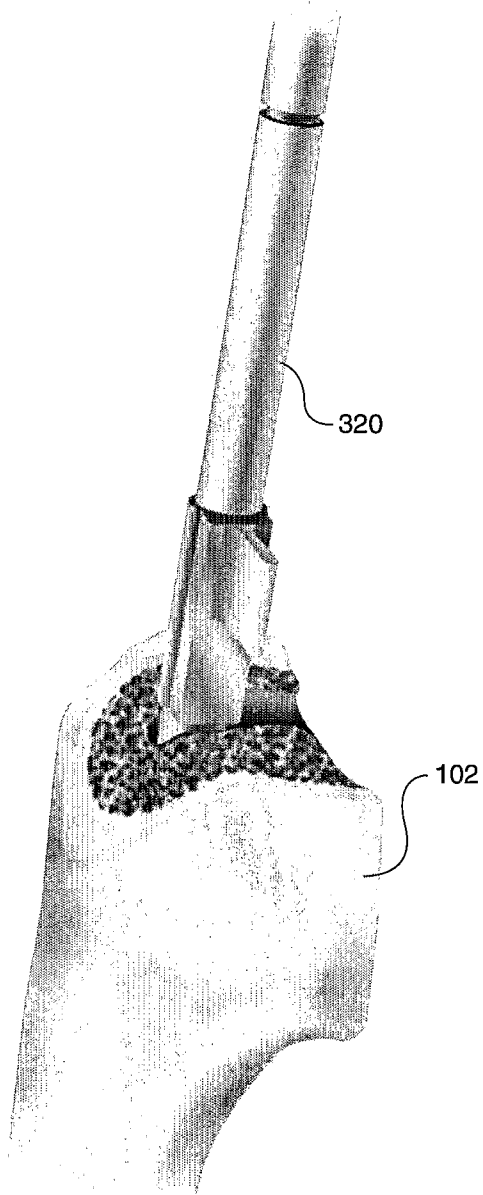
**FIG. 58**



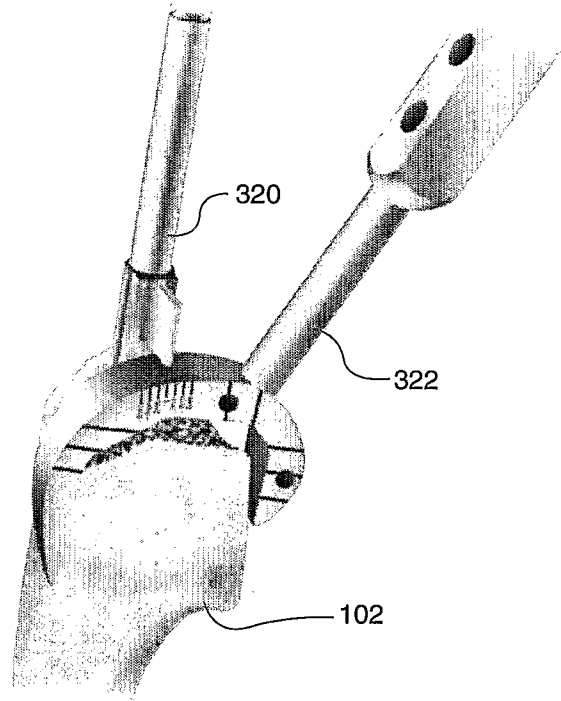
**FIG. 57**



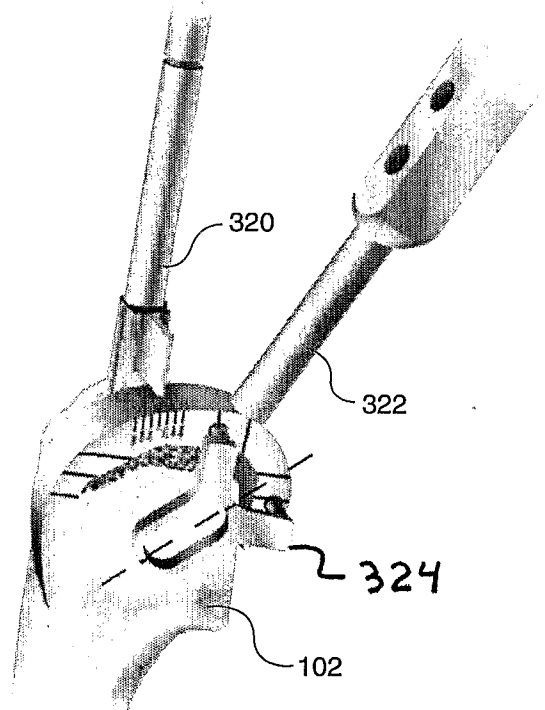
**FIG. 59**



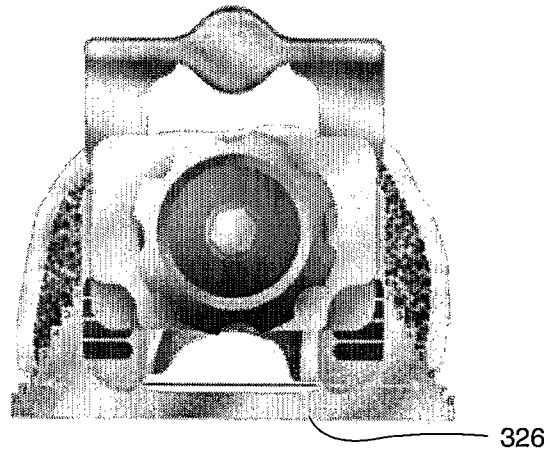
**FIG. 60**



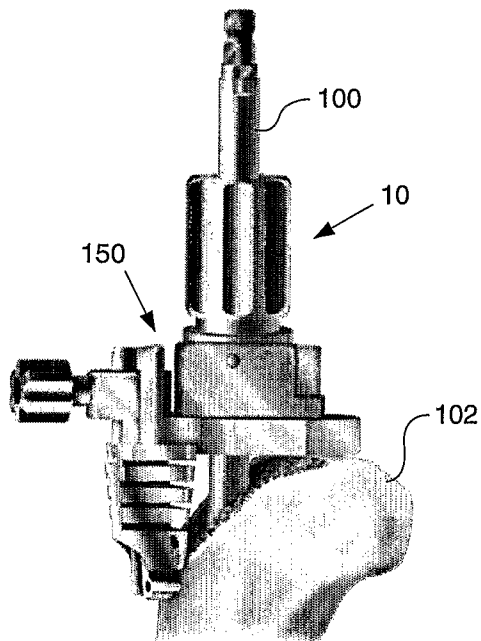
**FIG. 61**



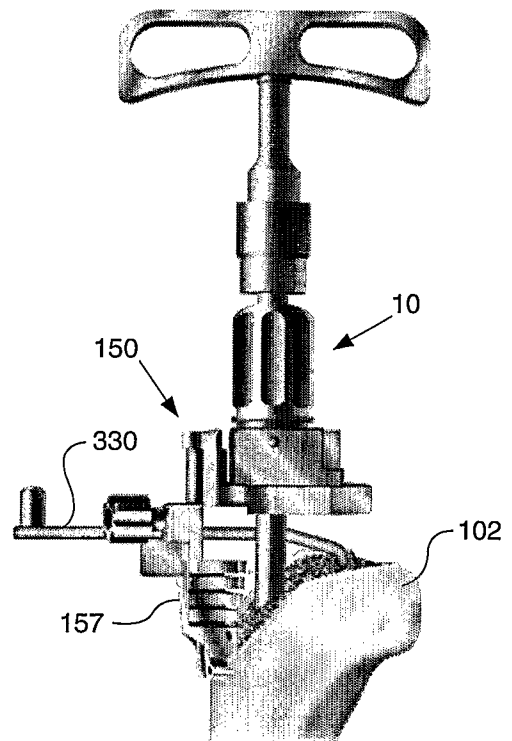
**FIG. 62**



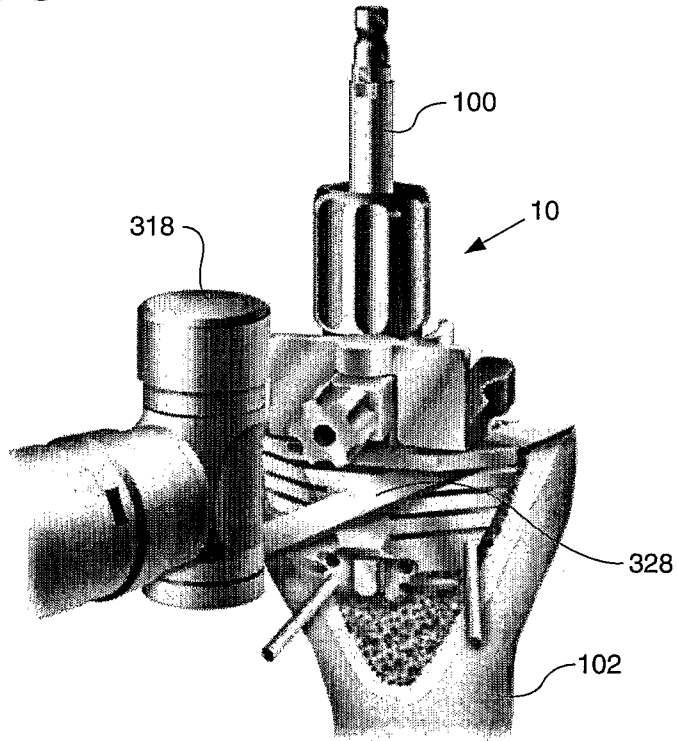
**FIG. 63**



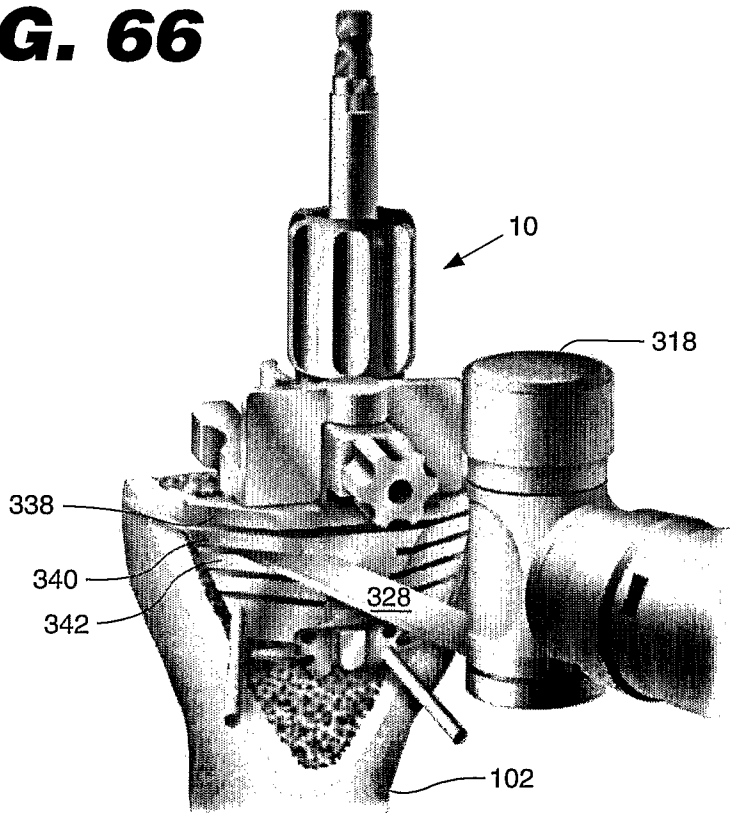
**FIG. 64**



**FIG. 65**

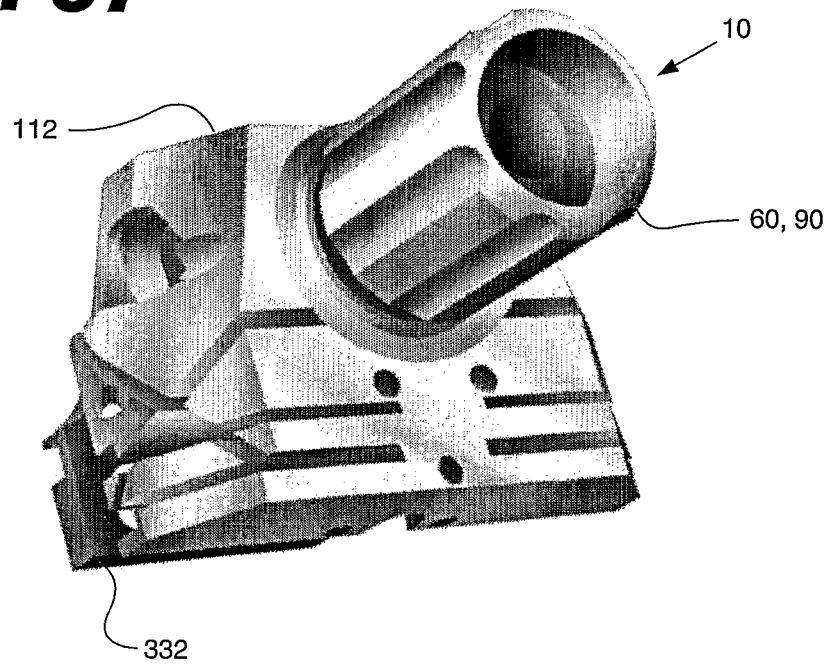


**FIG. 66**

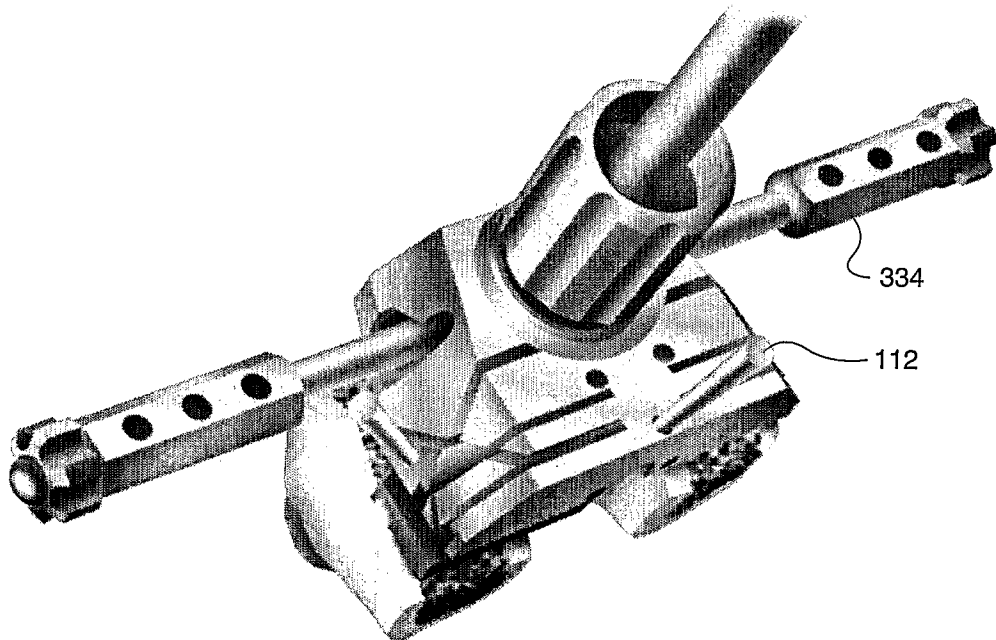




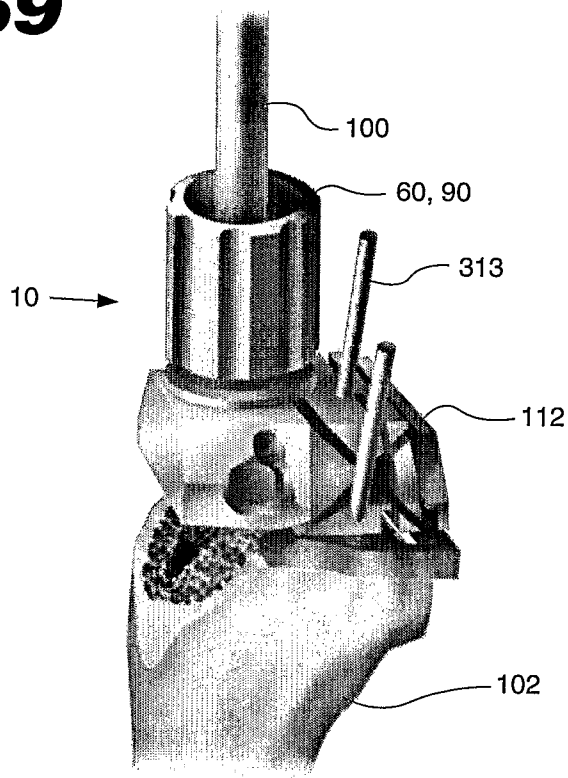
**FIG. 67**



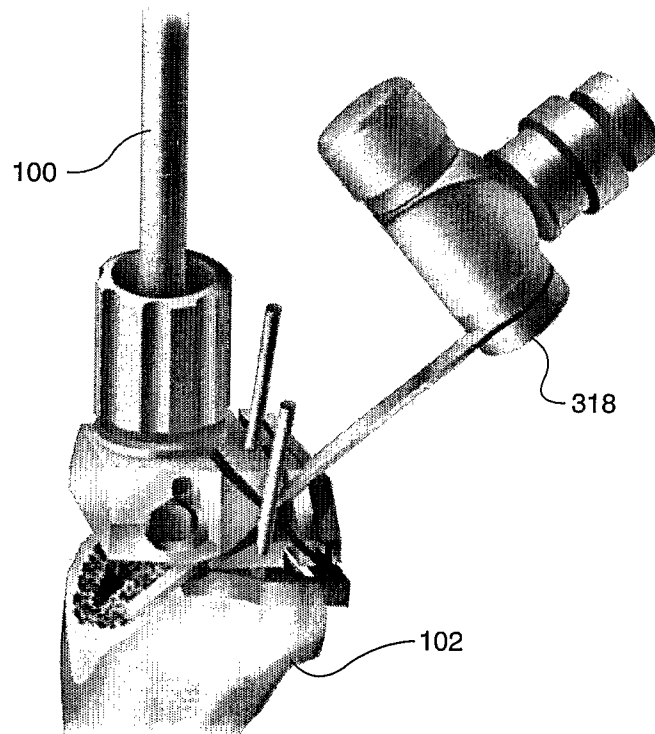
**FIG. 68**



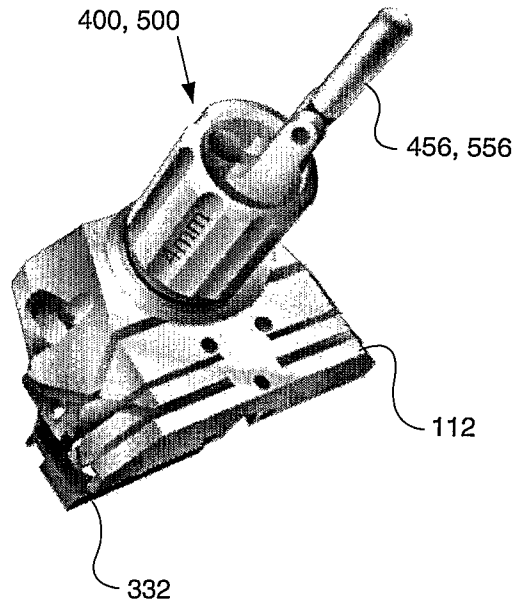
**FIG. 69**



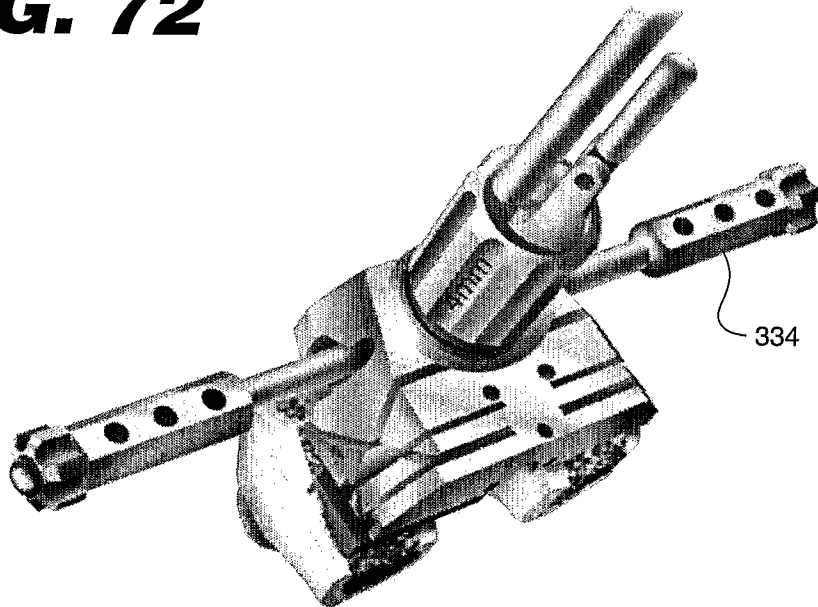
**FIG. 70**



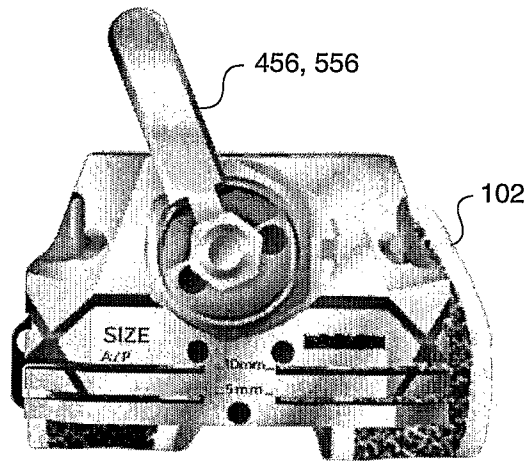
**FIG. 71**



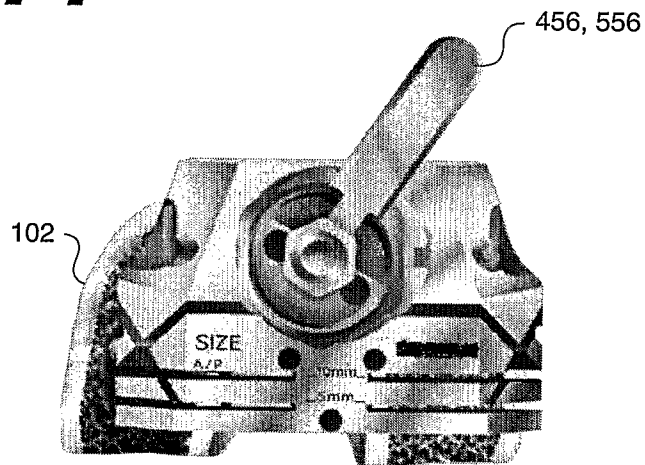
**FIG. 72**



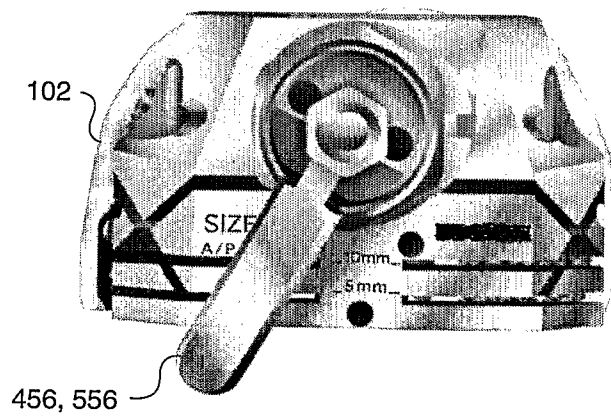
**FIG. 73**



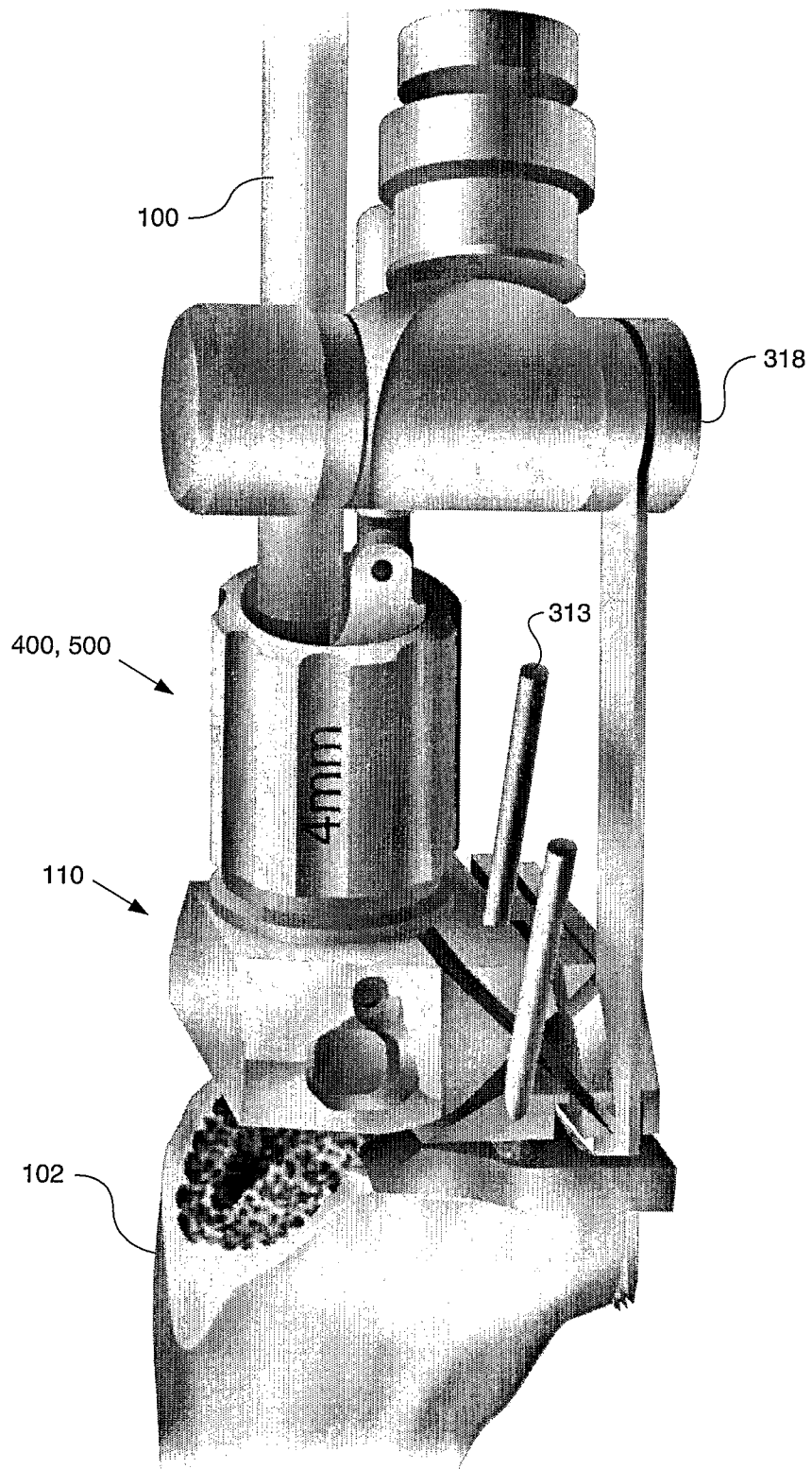
**FIG. 74**



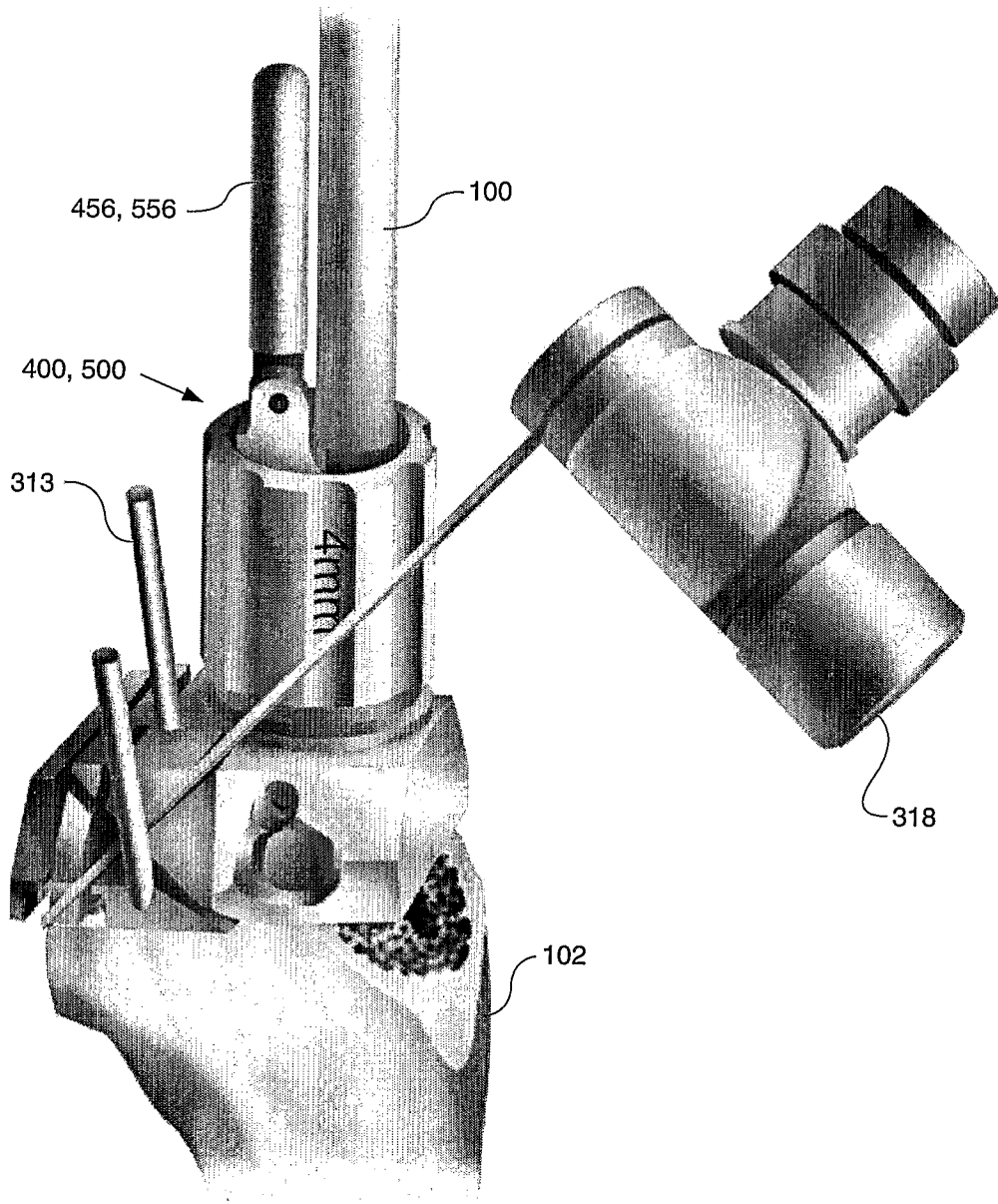
**FIG. 75**



**FIG. 76**



**FIG. 77**



INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/038859

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61B17/17 A61B17/15 ADD. A61B17/00  According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) A61B  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 168 595 B1 (DURHAM ALFRED A [US] ET AL) 2 January 2001 (2001-01-02)	1-3,5-7,9,10,13,20,22
A	column 26, line 63 - column 28, line 8	4
Y	figures 65-76	8,11,12,14-19,21
X	US 5 674 225 A (MUELLER STEPHAN [CH]) 7 October 1997 (1997-10-07) abstract; figures 1,2	1-7,9,11,20
A	DE 85 28 770 U1 (ORTOPEDIA GMBH, 2300 KIEL, DE) 5 December 1985 (1985-12-05) abstract; claim 1; figures 1-3	1-7
Y	US 5 910 143 A (CRIPE PHIL [US] ET AL) 8 June 1999 (1999-06-08) abstract; figures 2,3,5,6	8,11,12,14-19,21
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
23 January 2007		02/02/2007
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Macaire, Stéphane

INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/038859

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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A	US 6 575 980 B1 (ROBIE BRUCE [US] ET AL) 10 June 2003 (2003-06-10) abstract; figures 2,3,7a,8b -----	9-22



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