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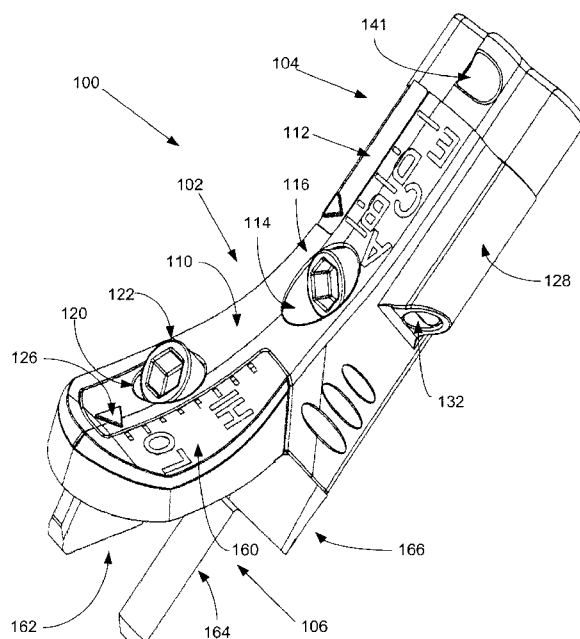
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(54) Title: ADJUSTABLE TRIAL NECK

Fig. 1



(57) Abstract: An adjustable trial neck (100) and method of use are described. The adjustable trial neck includes a body (102), a first part (104), and a second part (106). A first adjustment mechanism is actuable by a first drive (118) which presents a first external interface (116) for a tool and which is operable by a user using the tool to translate the first part relative to the body to adjust the neck length. A second adjustment mechanism is actuable by a second drive (124) which presents a second external interface (122) for a tool and which is operable by a user using the tool to translate the second part relative to the body to adjust the neck offset.

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Adjustable Trial Neck

The present invention relates to trialling for orthopaedic surgical procedures and in particular to trialling apparatus and methods for use in surgical procedures for ball and
5 socket joints.

Orthopaedic surgical procedures relating to joint replacement or arthroplasty often involve replacing the patient's natural body parts with one or more prosthetic components. Part of the original bony body part is at least partially or wholly removed
10 and replaced with a prosthetic implant. An important part of this can be in ensuring that the disposition, in terms of the position and/or orientation, of the prosthetic implant or implants, is appropriate to try and achieve a desired surgical outcome. It is preferable not to use the actual prosthetic components themselves in order to avoid any damage to them, for example to their articulating surfaces which are often highly polished.

15

Hence, instead of using the prosthetic components, trial components, having the same geometry and/or size as the prosthetic components are often provided so that the surgeon can construct some or all of the joint using the trial components during a process known generally as trialling. For, example, the surgeon may try using different positions and/or
20 orientations of a component and/or may try different sizes of components until they arrive at a configuration of components for the actual joint that he is happy with, The surgeon then replaces the trial components with the actual prosthetic ones.

One type of joint in which trial components are sometimes used are ball and socket type
25 joints, such as the shoulder joint or the hip joint. A hip joint typically includes an acetabular component and also a femoral component. For the acetabular component, typically an acetabular cup, its position, orientation and size may all be varied. For the femoral component, typically in the form of a stem with a neck and a femoral head, the size of the head may be varied, but should match the size of the cup, the neck angle may
30 be varied and also the neck length may be varied. In some instances, this is achieved by using a large number of single piece trial femoral components, across which all these properties vary. In other instances, more modular systems can be used in which different

necks, stems, or trial heads can be interchangeably attached to each other to provide the variations in size and geometry.

US 7,425,214 describes a trial proximal femoral part including a trial femoral head which
5 is coupled for selective movement relative to a femoral stem to vary the neck length.

However, these approaches require either a large number of different trial parts to be provided, many of which may be redundant, or do not permit sufficient trialling flexibility. Hence, a more efficient approach to trialling for ball and socket type joints
10 would be beneficial.

According to a first aspect of the invention, there is provided an adjustable trial neck, comprising: a body; a first part; a second part; a first adjustment mechanism actuatable by a first drive which presents a first external interface for a tool to translate the first part
15 relative to the body to adjust the neck length; and a second adjustment mechanism actuatable by a second drive which presents a second external interface for a tool to translate the second part relative to the body to adjust the neck offset.

Hence, the adjustable trial neck permits adjustment of the head and neck geometry of a
20 trial ball and socket joint while the trial joint is still reduced.

The first external interface and the second external interface may be for the same tool or for different tools.

25 The first external interface and the second external interface may be for the same tool so that the neck offset and/or the neck length are each adjustable by the user using the same tool.

The first part may include an attachment formation at a free end for receiving a trial head.
30 The position of the attachment formation relative to the body may be adjustable by the first adjustment mechanism.

The first part may include a trial head attached toward an end of the adjustable neck trial. The position of the trial head relative to the body may be adjustable by the first adjustment mechanism.

- 5 The second part may include a base for releasably attaching the adjustable trial neck to a long bone component or part. The position of the base relative to the body may be adjustable by the second adjustment mechanism.

The second part may include a base attaching the adjustable trial neck to a long bone
10 component or part. The position of the long bone component or part relative to the body may be adjustable by the second adjustment mechanism.

The first adjustment mechanism and second adjustment mechanism may be operable independently of each other.

15

The first adjustment mechanism may be operable to translate the first part continuously along a first axis. The second adjustment mechanism may be operable to translate the second part continuously along a second axis.

- 20 The first adjustment mechanism may be operable to translate the first part along a first axis. The second adjustment mechanism may be operable to translate the second part along a second axis. The first axis and second axis may subtend an obtuse angle to a superior side. The obtuse angle may be in the range of 120° to 150°. The obtuse angle may be in the range of 130° to 140°. The obtuse angle may be greater than 130°. The
25 obtuse angle may be substantially 130° or 135°.

The first external interface and/or the second external interface may each comprise a female formation. The femoral formation may be in the form of a polygonal socket. The polygonal socket may be hexagonal.

30

The first adjustment mechanism may include a first rack and /or the second adjustment mechanism may include a second rack.

The first drive mechanism may include a first worm gear which meshes with the first rack and /or the second drive mechanism may include a second worm gear which meshes with the second rack.

- 5 The first drive mechanism may include a first pinion including a first gear which meshes with the first rack and /or the second drive mechanism may include a second pinion including a second gear which meshes with the second rack.

The first drive mechanism may include a first releasable lock and/or the second drive
10 mechanisms may include a second releasable lock.

The first releasable lock may be arranged to be disengaged when the tool is introduced into the first external interface and/or the second releasable lock may be arranged to be disengaged when the tool is introduced into the second external interface. The first
15 releasable lock may be pivotable and/or the second releasable lock may be pivotable. The first releasable lock may include a pawl arranged to interact with a first rack and/or the second releasable lock may include a pawl arranged to interact with a second rack.

The adjustable trial may further comprise a first set of indicia associated with the first
20 adjustment mechanism and providing a first scale.

The first scale may indicate an amount of neck length or head offset.

The adjustable trial may further comprise a second set of indicia associated with the
25 second adjustment mechanism and providing a second scale.

The second scale may indicate an amount of neck offset.

The first set of indicia may be provided on the body. The second set of indicia may be
30 provided on the second part.

A first datum associated with the first scale may be provided on the first part.

A second datum associated with the second scale may be provided on the body.

The adjustable trial neck may further comprise a first guide mechanism arranged to guide translation of the first part relative to the body.

5

The first guide mechanism may comprise at least one or a pair of rods attached to the first part. The rod or the pair of rods may be slidably received within one or a pair of cavities formed within one or more housings attached to the body.

- 10 The first guide mechanism may comprise one or more ribs respectively slidably received in one or more slots.

The adjustable trial neck may further comprise a second guide mechanism arranged to guide translation of the second part relative to the body.

15

The second guide mechanism may comprise a tongue and groove arrangement. One of the tongue and groove may be provided by the second part and the other of the tongue and groove may be provided by the body. The tongue may be slidably received within the groove.

20

The second guide mechanism may comprise one or more ribs respectively slidably received in one or more slots.

- 25 The attachment formation mechanism may comprise a taper. The attachment mechanism may have a groove extending at least partially around the attachment mechanism.

The attachment mechanism may include an anti-rotation device or formation arranged to interact with the trial head to allow the trial head to be mounted on the attachment formation with at a pre-selected angular orientation.

30

The base may include a releasable attachment mechanism comprising a first formation and a second formation.

The first formation and the second formation may have different shapes.

The first formation may be a male formation and/or the second formation may be a male formation.

5

The first formation may be a peg and/or the second formation may be a keel or tab.

The first formation and the second formation may be positioned along a centre line of the base.

10

The long bone component or part may be selected from: a broach; a trial stem; and a prosthetic stem.

The adjustable trial neck may be an adjustable trial femoral neck, the trial head may be a
15 trial femoral head and the long bone component or part may be a femoral component or part.

The adjustable trial neck may be an adjustable trial humeral neck, the trial head may be a
20 trial glenoid head and the long bone component or part may be a humeral component or part.

According to a second aspect of the invention there is provided a kit of parts comprising:
the adjustable trial neck of the first aspect; a trial head attachable to the first part; and a
long bone component or part attachable to, or attached to, the second part.

25

Preferred features of the first aspect may also be preferred features of the second aspect.

According to a third aspect of the invention there is provided a trialling assembly
comprising: the adjustable trial neck according to the first aspect, a trial head attached to
30 the first part; and a long bone component or part attached to the second part.

Preferred features of the first aspect may also be preferred features of the third aspect.

According to a fourth aspect of the invention, there is provided a method for trialling a trial ball and socket joint of a patient including at least a trial head on an adjustable trial neck, comprising: adjusting the neck offset and neck length using a tool while the trial ball and socket joint is reduced; and assessing the trial ball and socket joint of the patient.

5

The method may comprise using the same tool to adjust the neck offset and the neck length.

The method may further comprising using a tool to operate the adjustable trial neck to
10 reduce the size of the adjustable trial neck while the trial ball and socket joint is reduced and after assessing the trial ball and socket joint to facilitate removal of the trial head from the socket joint

The method may further comprise iteratively adjusting and assessing the trial ball and
15 socket joint to determine a preferred geometry for a neck and head.

The method may further comprise obtaining a prosthetic implant having a neck and head geometry matching the preferred geometry. The prosthetic implant may then be implanted in a long bone of the patient.

20

The method may be part of a hip arthroplasty procedure and the trial head may be a femoral trial and the neck may be a femoral neck.

The method may be part of a shoulder arthroplasty procedure and the trial head may be a
25 humeral head trial and the neck may be a humeral neck.

Preferred features of the first, second or third aspects may also give rise to counterpart preferred features of the fourth aspect.

30 Embodiments of the invention will now be described in detail, by way of example only, and with reference to the accompanying drawings, in which:

Figure 1 shows a perspective view from the front and side of an adjustable trial neck according to a first embodiment of the invention;

Figure 2 shows a side view of the adjustable trial neck shown in Figure 1 in use as part of an assembly also according to the invention;

Figure 3 shows a front view of the adjustable trial neck shown in Figure 1;

Figure 4 shows a plan view of the adjustable trial neck shown in Figure 1;

5 Figure 5 shows a perspective view of the adjustable trial neck of Figure 1 with the main body omitted and showing the adjustment mechanism;

Figure 6 shows a flow chart illustrating a surgical method according to the invention in which the adjustable trial neck can be used;

10 Figure 7 shows a perspective exploded view of an adjustable neck trial according to a second embodiment of the invention;

Figure 8 shows a side view of the adjustable neck trial shown in Figure 7;

Figure 9 shows an end view of the adjustable neck trial shown in Figure 7;

Figure 10 shows a cross sectional view of the adjustable neck trial shown in Figure 7 along line A-A' of Figure 9;

15 Figure 11 shows a perspective exploded view of an adjustable neck trial according to a third embodiment of the invention;

Figure 12 shows a side view of the adjustable neck trial shown in Figure 11;

Figure 13 shows an end view of the adjustable neck trial shown in Figure 11;

20 Figure 14 shows a cross sectional view of the adjustable neck trial shown in Figure 11 along line B-B' of Figure 13;

Figure 15 shows a perspective exploded view of an adjustable neck trial according to a fourth embodiment of the invention;

Figure 16 shows a side view of the adjustable neck trial shown in Figure 15;

Figure 17 shows an end view of the adjustable neck trial shown in Figure 15;

25 Figure 18 shows a cross sectional view of the adjustable neck trial shown in Figure 15 along line C-C' of Figure 17; and

Figure 19 shows a perspective view of an assembly of the adjustable trial neck of Figures 15 to 18 and a broach.

30 Similar items in the different Figures share common reference signs unless indicated otherwise.

With reference to Figure 1 there is shown a perspective view of a first embodiment of an adjustable trial neck 100 according to the invention. The adjustable trial neck will be described below in the context of a femoral adjustable trial neck, but the invention is not limited to that. Rather, the adjustable trial neck can also be used for trialling of other ball and socket joints. Hence, the adjustable trial neck may also be adapted for use during trialling of shoulder joint, in which case it may be referred to as a humeral adjustable trial neck.

The adjustable trial neck 100 includes a main body 102, an upper part 104 and a lower part 106. The upper part 104 may be referred to as a head engaging part as in use a trial head may be attached to it. The lower part 106 may be referred to as a stem engaging part as in use the lower part may engage a stem, such as a broach, a trial stem or a prosthetic stem. The upper part 104 and lower part 106 individually are best shown in Figure 5. The upper part 104 and lower part 106 each slidingly engage the main body 102 and include a respective drive mechanism actuatable to cause them each to translate linearly with respect to the main body.

The main body 102 may be made from any suitable biocompatible material such as a metal, alloy or plastic. For example, the main body may be made from stainless steel, such as 17-4 PH stainless steel. The upper part 104 and lower part 106 may be made from any suitable biocompatible material such as a metal, alloy or plastic, or high performance polymer. For example, the upper part and lower part may be made from a polymer such as PAEK (polyaryletherketone), PEEK (Polyetheretherketone) or 30% glass filled PAEK.

25

The main body 102 has a generally curved upper surface. Toward an upper end, a first set of indicia 112 provide a first scale providing a visual indication of an amount of neck length adjustment and which corresponds generally to head offset. A first circular aperture 114 housing a first external interface 116 for actuating the first drive mechanism is provided below the first scale. The first external interface 116 is in the form of a hexagonal head of a first worm screw 118. A second circular aperture 120 housing a second external interface 122 for actuating the second drive mechanism is provided below the first aperture 114. The second external interface 122 is also in the form of a hexagonal

head of a second worm screw 124. The hex headed worm screws 118, 124 are each retained within the main body by a retaining ring (not shown). A lower end of the main body 102 includes a second datum 126, in the form of an arrow head, which can be used to read a second scale on the lower part indicating an amount of neck offset. A shoulder 5 128, 130 is provided on each side of the main body 102 toward its upper end. Each shoulder 128, 130 defines a respective interior circular cavity 132, 134 extending along the length of its longitudinal axis.

The upper part 104 has a free mounting end 140 having a generally cross shape or X- 10 shape in plan view and which is configured to be received within a trial head to allow a trial head 202 to be releasably attached to the adjustable trial neck, as best illustrated in Figure 2. The mounting end 140 has a generally cross shape to provide an anti-rotation feature so that a trial head can be more reliably mounted with a preferred orientation of the trial head relative to the trial neck. This can be helpful when the trial head 202 has 15 any markings on its surface which should be visible to the user during use, such as size or alignment markings or similar. The mounting end 140 also has at least one recess 141, 142 therein which can interact with at least one corresponding resilient or biased proud or male member (not shown) of the cavity of the trial head 202 to provide tactile feedback to a user to signify proper seating of the trial head 202 on the trial neck 100.

20

First 150 and second 152 circular rods or pins extend downwardly from the mounting end 140 and are arranged to be received within the circular cavities of the shoulders 128, 130 of the main body. A further member 154 extends downwardly from the mounting end 140 and bears a first datum 156 in the form of an arrow on an upper surface and which is 25 positioned adjacent the first set of indicia 112 to allow a current value to be read from the first scale. A first rack 158 having a plurality of teeth inclined to its longitudinal axis also extends downwardly from the mounting end 140. The longitudinal axis of the first rack 158 is generally parallel to the longitudinal axes of the circular rods 150, 152.

30 As best illustrated in Figure 5, the first worm gear 118 meshes with the teeth of the first rack and provide the first adjustment mechanism. As the first worm gear is retained by the main body, rotation of the worm gear drives the rack along its longitudinal axis and therefore causes the upper part 104 to translate in that direction and with the circular rods

150, 152 sliding within the shoulders 128, 130. Hence, a surgeon can adjust the position of the mounting end 140 relative to the main body 102 by using a tool with a hexagonal end part engage the externally accessible hex head 116 to rotate the worm screw 118.

5 The lower part 106 has a second plurality of indicia 160 on an upper curved surface and which provides a second scale indicating the amount of neck offset. The second datum 126 on the main body is positioned adjacent the second scale to allow a current value to be from the second scale. The lower part 106 generally has the form of a foot and includes a plurality of member extending from its lower or under surface. A relatively
10 narrow keel 162 extends downwardly and also along a central longitudinal axis of the lower part. A base 166 extends from the rear of the lower part 106 and the main body sits on an upper surface of the base in the Figures. A circular shaft or peg 164 extends from a lower or under side of the base 166 and its central axis is generally parallel to the longitudinal axis of the main body 102 and upper part 104. Keel, 162, base, 166 and peg
15 164, allow the adjustable trial neck to be releasably attached to a stem part during trialling as best illustrated in Figure 2.

Figure 2 shows a schematic partial cross-sectional diagram of the side of an assembly 200 according to the invention which includes the adjustable trial neck 100, a trial head 202
20 and a long bone component 204. For a hip joint, the long bone component will be a femoral component, whereas for a shoulder, the long bone component will be a humeral component. The long bone component may be a rasp, broach, trial component or prosthetic component. As can be seen, a trial head 202 having a central circular cavity is mounted on the mounting end 140 of the upper part 104. As noted above, the long bone
25 component 204 may be of different types. For example, the long bone component 204 may be a broach which has been used to broach a cavity in the femur for receiving the actual stem implant. Instead, the long bone part 204 may be a trial stem which is used specifically for trialling. Instead, the long bone part 204 may be the actual prosthetic stem which has been implanted in the femur, although trialling from stem implants is less
30 common.

Irrespective of the nature of the long bone component 204, an upper or proximal portion 206 includes female features arranged to receive the male features 162, 164 of the trial

neck. In particular the long bone component 204 includes a generally slot shaped cavity for receiving the keel 162 and a circular cavity for receiving peg 164. The base 166 of the lower part then rests on and supports the trial neck on an upper surface of the long bone component 202. The use of the keel 162 and peg 164 helps to resist torque about all three
5 axes. The pin alone prevents rotation about two axes and the keel prevents rotation about the third, although a further pin could be used instead of the keel. However, using a keel can be preferred to using a further pin as the keel can be made narrower and so a narrower slot can be used in the long bone component 204, thereby preserving its material and maintaining its strength so as to be able to stand up to the loads that would be applied
10 during use.

Also, the use of a pin and keel helps to avoid a user trying to accidentally attach the trial neck incorrectly, if two pins and two circular holes were used instead.

15 It will also be noted that the pin 164 and keel 162 are provided on the lateral axis of the trial neck and aligned along the lateral axis of the trial neck. Hence, the keel 162 and pin 164 are symmetric about the lateral axis of the trial neck and therefore can be used for a right hand joint or a left hand joint.

20 Also, providing male attachment features 162, 164 on the trial neck 100 and female attachment features on the long bone component 204, helps to preserve space within the trial neck so that the first and second drive mechanism can be accommodated within the trial neck.

25 Returning to Figure 5 in particular, the lower part 106 also includes a second rack 168 having a plurality of teeth inclined to its longitudinal axis and which extends outwardly from the foot end 106. The longitudinal axis of the second rack 168 subtends a generally obtuse angle with the longitudinal axis of the first rack 158.

30 As best illustrated in Figure 5, the second worm gear 124 meshes with the teeth of the second rack and provides the second adjustment mechanism. As the second worm gear is retained by the main body, rotation of the worm gear drives the rack along its longitudinal axis and therefore causes the lower part 106 to translate in that direction. As can be seen

in Figures 1 and 5, the main body 102 ends in a generally tongue like shape which is received in a generally groove like structure of the lower part 106 and which guides the relative movement of the lower part and main body as the tongue slides within the groove. As illustrated in Figure 2, the lower part 106 is mounted on the stem and so can
5 be considered the generally more immobile part. Hence, a surgeon can adjust the position of the mounting end 140 relative to lower part 106, and hence, the stem 204, using a tool with a hexagonal end part to engage the externally accessible hex head 122 to rotate the worm screw 124.

10 Conventionally, neck trials have allowed a surgeon to trial different neck positions, and corresponding neck angles, sometimes referred to as neck offset, but not neck length, sometimes referred to as head offset. Neck length or head offset is generally the position of the centre of rotation of the head along the neck axis. Trialling different head offsets is conventionally done using a set of trial heads, each with a different depth of taper hole.
15 Hence, how far the head sits down onto the taper or trunnion of the stem neck can be changed by mounting trial heads with different head off sets on the neck.

In this invention, the neck trial is an adjustable assembly in which the position of the head relative to the broach or stem body can be altered continuously to mimic any available
20 combination of neck length and neck offset. The adjustment is achieved using an external handheld driver, meaning that the surgeon does not need to reach his fingers into the joint to operate the adjustment.

As illustrated in Figure 2, the trial neck 100 is mounted on broach 204 such that the
25 second adjustment mechanism extends substantially entirely parallel to the later-medial axis as indicated by first double headed arrow 210. Also, the first adjustment mechanism extends substantially along the neck axis as indicated by second double headed arrow 212. The centre of rotation of the trial head 202 is indicated by cross 214. Hence, as configured in Figure 2, by operating the second adjustment mechanism along the centre of
30 rotation of the trial head 214 moves entirely in the medial-lateral direction 210 and therefore changes the neck offset but does not change the leg-length. By operating the first adjustment mechanism along the centre of rotation of the trial head 214 moves along the neck axis direction 212 and hence changes both in the medial-lateral direction 210 and

also in the superior-inferior direction 216 and therefore changes both the neck offset but and also the leg-length. Changing the neck length alone is generally the same as changing the head off set. Operating both the first and second adjustment mechanisms therefore adjust the position of the trial head in both the medial-lateral direction 210 and
5 also in the super-inferior direction 216 in a continuous manner thereby allowing any combination of neck off set and neck length to be arrived at. Also, by operating the first and/or second adjustment mechanisms the overall effective size of the neck, for example defined by the distance between the centre of rotation of the trial head 214 to some arbitrary point on the long bone component 204, may be continuously adjusted.

10

As will be appreciated, in other embodiments in which the trial neck is mounted on the femoral part so that the second adjustment mechanism is not parallel to the medial-lateral direction, then operating the second adjustment mechanism will adjust the medial-lateral position of the head, i.e. adjust neck offset, and also the inferior-superior position of the
15 head and therefore also affect leg length. However, generally speaking the adjustable neck will be mounted on the long bone component so that the second adjustment mechanism can cause movement of the centre of the femoral head at least partially in the media-lateral direction to allow the neck offset to be adjusted.

20 As described above, the embodiment uses two threaded hex screws, each retained in place using a retaining ring. When turned, the screws acts as a worm-rack gear, translating the neck assembly parts along two linear axes. Two external high-contrast indicator scales show the current positions and corresponding different amounts of neck offset (second scale, LO to HIGH) and neck length or head offset (first scale, A to E).

25

The conventional approach is typically to provide a range of solid modular neck trials which allow surgeons to evaluate which range of stem-neck options will best suit a patient's anatomy. The surgeon uses the neck trial to check for range-of-motion (ROM) and impingement but also to evaluate soft tissue tension, leg length, stability or likelihood
30 of dislocation (force to dislocate at various angles, jump height). In theory the surgeon can combine the neck trials with different head trials and different liner trials to achieve the ideal or optimum result.

In practice, due to time constraints, manual difficulty and the inherently inaccurate, qualitative and subjective nature of the evaluation, most surgeons are likely to trial only one or perhaps two combinations before finalising their choice. Surgeons tend not to iterate with trials multiple times to achieve the best result. Rather they work up to
5 "good enough". In the conventional approach, every time a surgeon wants to evaluate a different combination of neck, head and liner, they must dislocate the joint, remove the trial components (all three or a subset of them) and then reassemble and reduce the joint. This takes time and effort, the components are slippery and hard to hold. For example heads are often dropped by surgeons.

10

With reference to Figure 6, there is shown a flow chart illustrating a surgical method 300 according to the invention in which the adjustable neck trial 100 can be used. The method 300 will be described below with reference to a hip replacement surgical procedure. However, it can also be applied with suitable modifications to a shoulder
15 replacement surgical procedure. As will be understood by a person of ordinary skill in the art, for a hip joint, the long bone having the ball of the ball and socket joint is the femur and the socket is the acetabulum, whereas for the shoulder, the long bone is the humerus and the socket is the glenoid.

20 At 302 the long bone and socket are prepared. In a total joint arthroplasty procedure both the ball and socket are replaced with prosthetic components. However, the method 300 is also applicable to a partial joint arthroplasty in which the socket is not replaced by a prosthetic component, but only the ball is replaced. In that case, various steps of the method relating to the socket will be omitted or modified accordingly. For a hip joint,
25 step 302 can include removing soft tissues from around the acetabulum and using an acetabular reamer to ream the acetabular cavity. The femur may be prepared by resecting the proximal part of the femur to remove the femoral head and neck and using a mill or planer to provide a flat resected bone surface. A drill and/or various sized rasps and broaches may then be used to prepare a cavity in the intramedullary canal of the femur for
30 receiving the femoral component and generally aligned with the local anatomical axis of the femur.

At 304, a trial cup may be inserted in the acetabular cavity. In other embodiments, the final prosthetic cup may be inserted instead if a trial cup is not used. Any trial or final liner may also be inserted at this stage if used. A long bone part 204 is positioned in the femur. The long bone part 204 may be a final broach used to prepare the femoral cavity
5 and may simply be left in the femur at the end of broaching. In other embodiments, a trial stem or a final prosthetic stem may be inserted at 304. At 306, the trial head 202 is attached to the mounting end 104 of the adjustable trial neck 100 and the adjustable trial neck is attached to the long bone part 204. As noted above, the shape of the free end of the trial neck 140 can be used to help to control the orientation of the trial head relative to
10 the trial neck. In other embodiments, in which the adjustable trial neck is provided as an integral part of a trial long bone part, then the adjustable trial neck is already present and the trial head may be attached before or after inserting the trial femoral component into the femur at 304.

15 At 308, the joint is reduced by locating the trial head in the cup component. At 310 the surgeon may visually inspect and articulate the trial hip joint to assess it. For example this may include a Range of Motion (ROM) assessment and other assessments and evaluations of the hip joint which are generally known in the art, including, for example, impingement, soft tissue tension, leg length, leg offset, stability or likelihood of joint
20 dislocation. In some embodiments, the surgeon may carry out an initial adjustment of the neck offset and/or neck length/head offset by using a manual tool to rotate hex heads 116 or 122 before any initial assessment. After the initial assessment at 310, at 312 the surgeon may adjust the neck offset and/or neck length.

25 The first adjustment mechanism operated by screw 116 causes the head to move along the neck axis direction 212, which may subtend a stem-neck angle of approximately 135° relative to the stem axis and allows for different neck lengths and hence head offsets to be trialled. For example, a stem with a long neck and a trial head with a negative offset would be the same as using a short neck and a trial head with a high positive offset. Both
30 arrangements would each correspond to the same indication by the adjustable trial neck 100.

Operation of the second adjustment mechanism allows for a high/low offset of the neck, which is sometimes called base offset. This adjustment corresponds to movement of the neck and head at least partially in the medial-lateral direction, sometimes referred to as medialisation/lateralisation of the neck and head. In some embodiments, as illustrated in

5 Figure 2, the second adjustment mechanism can be arranged to adjust truly in the medial-lateral axis 210, and in other embodiments to adjust along the top of the stem, depending on the implant design and the range of offerings, in which case at least some adjustment in the medial-lateral direction is provided by the second adjustment mechanism.

10 As illustrated by process flow line, 314, the surgeon may then carry out a further assessment and evaluation of the trial joint at 310, with this new joint geometry, however without having to dislocate the joint. Hence, using the manual tool, the surgeon can repeatedly adjust the neck offset and/or neck length/head offset and assess the resulting trial joint in an iterative manner until satisfied with the trial joint. The surgeon can then

15 read of the information from the first and second scales to determine the preferred neck offset and neck length/head offset from the trialling stage.

At 316, the trial components can be removed. A benefit of the invention is that the surgeon can operate the first and/or second adjustment mechanism to reduce the overall

20 effective size of the neck thereby making it easier to dislocate the trial joint assembly. This may help to reduce damage or injury to soft tissues associated with the joint.

At 318, the prosthetic cup component is obtained, together with any liner. Also a femoral component is obtained at 318 having a geometry corresponding as close as practicable to

25 the neck with the neck offset and neck length/head offset determined during the trialling stage. This may include simply selecting a single femoral component, from a range of femoral components, having a neck length, neck angle and head position as close as practicable to the preferred geometry. In other embodiments, a modular femoral component may be provided in which different length and/or angle necks may be attached

30 to a stem. Hence, a customised femoral component is assembled from these modular parts having a geometry close to the preferred geometry determined during the trialling. In other embodiments, an adjustable femoral component may be provided in which the length and angle of the neck attached to a stem may be adjusted and locked.

Irrespective of how the prosthetic femoral component is obtained at 318, at 320, the cup prosthetic component and femoral prosthetic component are implanted at 320 and the joint is reduced at 322. An immediate ROM assessment may optionally then be carried out before the joint is closed and the surgical method is generally finished.

Hence, the invention may make the process of iterative trialling quicker, makes trial constructs easier to assembled and/or disassemble, more informative and more useful to the surgeon. In addition, it reduces the number of modular components provided in the surgical kit for trialling, making the scrub nurse's job simpler and reducing the size, weight and complexity of trays.

Further embodiments of the adjustable trial neck, similar to the first embodiment and which can also be used in the illustrated method, will now be described.

15

Figure 7 shows a perspective exploded view of a second embodiment of an adjustable trial neck 400 generally similar to the first embodiment 100. The adjustable trial neck 400 has a main body 402, an upper part 404 and a lower part 406. The upper part 404 includes a free end 440 including a taper 442 with an annular groove 444 extending there around and on which a trial head can be releasably attached in use. The annular groove 444 is for receiving a corresponding resiliently biased or sprung male part located within the trial head bore to provide a push fit attachment. The upper part is generally hollow and has a slot extending along its longitudinal axis 446 as best illustrated in Figure 10. Figure 8 shows a side view of the adjustable trial neck 400, Figure 9 shows an end view and Figure 10 shows a cross sectional view along the line A-A' of Figure 9.

The main body 402 includes a post having a slot 450 extending along its longitudinal axis and bearing a plurality of formations 452 on an outer side. A screw member 410 includes a head 418 with a hexagonal external interface 416 for receiving a tool at a first end. Screw member 410 includes a neck portion 412 dimensioned to be received in and to slide along slot 450, and also includes a free end 414 arranged to be received in and journaled within a circular aperture 446 in the upper part 404. An under surface of head 418 bears a portion of a screw thread 420 which is arranged to co-operate and interact

with formations 452. Rotation of screw member 410 causes thread portion 420 to sequentially interact with formations 452 which act like a rack to cause neck 412 to travel up and down slot 450. Hence, screw member 410 provides a first drive mechanism for a first adjustment mechanism by which the upper part 404 can be caused to translate
5 relative to the main body 402 to adjust the neck length. Screw member 410 is like a scroll thread but only makes partial contact with the rack and may be described as a canted scroll driving against the rack. The canted scroll drive is effectively self-locking, in a similar way to a worm drive. The main force in the trial assembly acts to compress the neck so the self-locking adjustment mechanism removes the need for any additional lock
10 to act as a brake.

Lower part 406 includes a keel 472 and peg 474 for releasably attaching the adjustable trial neck to a long bone component, such as a broach, trial or stem, via corresponding female formations therein. The lower part 406 is generally in the form of an open
15 channel 430 with a guide slot 432, 434 on each side. A base part 460 of the main body 402 from which post 450 extends, defines a central threaded aperture 462. Base part 460 includes a rib 464, 466 on each side arranged to slidably engage in respective ones of the guide slots 432, 434. A worm screw 470 includes a second external interface 422 in the form of a hex socket at one end and is rotatably captured within the lower part 406 with
20 its thread engaging the central threaded aperture of the main body as best illustrated in Figure 10. Hence, worm screw 470 provides a second drive mechanism for a second adjustment mechanism which is operable to cause the lower part 406 to translate relative to the main body 402 to adjust the neck offset.

25 Hence, the second embodiment of the adjustable trial neck 400 can be used similarly to the first embodiment to allow independent and continuous adjustment of the trial neck assembly in two directions so that the neck length and/or neck offset can be adjusted continuously during trialling and/or to make it easier to remove the trial head from the cup at the end of trialling.

30

Figure 11 shows a perspective exploded view of a third embodiment of an adjustable trial neck 500 generally similar to the first and second embodiments. The adjustable trial neck 500 has a main body 502, an upper part 504 and a lower part 506. The upper part 504

includes a free end 540 including a taper 542 with an annular groove 544 extending there around and on which a trial head can be releasably attached in use. Annular groove 544 can retain a spring clip within the trial head which releasably attaches the trial head to the neck in use. The upper part is generally hollow and has a slot 545 extending along its longitudinal axis 546 as best illustrated in Figure 14. A portion 547 of the slot extends toward a front surface 549 of the upper part 502 for the inclusion of a stop pin (not shown) to prevent the upper part from being removed from the main body. Figure 12 shows a side view of the adjustable trial neck 500, Figure 13 shows an end view and Figure 14 shows a cross sectional view along the line B-B' of Figure 13.

10

The main body 502 includes a post 550 having a plurality of teeth 552 on an outer surface and extending along its longitudinal axis to provide a rack 554. Rack 554 may be offset to one side to allow space for the stop pin (not shown) mentioned above. A pinion member 510 includes a head 518 with a hexagonal external interface 516 for receiving a tool at a first end. Pinion member 510 includes a neck portion 512 towards head 518 and a plurality of teeth 520 extending around its rotation axis and forming a circular gear or cog arranged to mesh with rack 554. A far free end 514 and the head 518 are arranged to be received in and journaled within respective circular apertures 546, 548 in the upper part 504. Rotation of pinion member 510 causes teeth 520 to sequentially mesh with teeth 552 of rack 554 forming a rack and pinion arrangement to cause the upper part 504 to travel up and down post 550. Hence, pinion member 510 provides a first drive mechanism for a first adjustment mechanism by which the upper part 504 can be caused to translate relative to the main body 502 to allow the neck length to be adjusted.

25 Lower part 506 includes a keel 572 and peg 574 for releasably attaching the adjustable trial neck to a long bone component, such as a broach, trial or stem, via corresponding female formations therein. The lower part 506 is generally in the form of a flat base 530 with a respective rib 532, 534 extending from each side. An upper side of the base 530 has a plurality of teeth extending along its longitudinal axis to provide a further rack 536 off set to one side of the base. A generally triangular member 538, to mimic the shape of the prosthetic neck, extends from a front end of the lower part 506 and acts as a stop to limit travel between 506 and 502.

30

A base part 560 of the main body 502 from which post 550 extends has first and second side walls 562, 564 which defines central aperture 566. A lower part of each side wall 562, 564 has a respective slot 568, 570 therein arranged to slidingly engage respective ones of the ribs 532, 534. A further pinion member 570, having a similar construction to the first pinion member 510, includes a second external interface 522 in the form of a hex socket at one end and is rotatably captured within the lower part 406 with its gear or cog 572 meshed with the further rack 536. Hence, further pinion 570 provides a second drive mechanism for a second adjustment mechanism, also in the form of a rack and pinion arrangement, which is operable to cause the lower part 506 to translate relative to the main body 502 to adjust neck off set.

Hence, the third embodiment of the adjustable trial neck 500 can be used similarly to the first and second embodiments to allow independent and continuous adjustment of the trial neck assembly in two directions so that the neck length and/or neck offset can be adjusted during trialling and/or to make it easier to remove the trial head from the cup at the end of trialling.

Figure 15 shows a perspective exploded view of a fourth embodiment of an adjustable trial neck 600 generally similar to the first and second embodiments and more similar to the third embodiment. The adjustable trial neck 600 has a main body 602, an upper part 604 and a lower part 606. The upper part 604 includes a free end 640 including a taper 642 with an annular groove 644 extending there around and on which a trial head can be releasably attached in use. The upper part is generally hollow and has a slot 645 extending along its longitudinal axis 646 as best illustrated in Figure 18. Respective channels 647, 649 are provided to either side of slot 645 for receiving corresponding ribs 651, 653 of post 650. Figure 16 shows a side view of the adjustable trial neck 600, Figure 17 shows an end view and Figure 18 shows a cross sectional view along the line C-C' of Figure 17.

The main body 602 includes a post 650 having a plurality of teeth 652 on an outer surface and extending along its longitudinal axis to provide a rack 654 extending along the post 650 and positioned centrally. A pinion member 610 includes a head 618 with a hexagonal external interface 616 for receiving a tool at a first end. Pinion member 610

includes a plurality of teeth 620 extending around its rotation axis and forming a circular gear or cog arranged to mesh with rack 654. A far free end 614 and the head 518 are arranged to be received in and journaled within respective circular apertures, e.g. 646, in the upper part 604. Rotation of pinion member 610 causes teeth 620 to sequentially mesh
5 with teeth 652 of rack 654 forming a rack and pinion arrangement to cause the upper part 604 to travel up and down post 650. Hence, pinion member 610 provides a first drive mechanism for a first adjustment mechanism by which the upper part 604 can be caused to translate relative to the main body 602 to adjust the neck length.

10 Lower part 606 includes a keel 672 and peg 674 for releasably attaching the adjustable trial neck to a long bone component, such as a broach, trial or stem, via corresponding female formations therein. The lower part 506 is generally in the form of a flat base 630 with a respective rib 632, 634 extending from each side. An upper side of the base 630 has a plurality of teeth extending along its longitudinal axis to provide a further rack 636
15 extending along the base and positioned centrally.

A base part 660 of the main body 602 from which post 650 extends has first and second side walls 662, 664 and upper wall 665 which defines a central cavity 666. A lower part of each side wall 662, 664 has a respective slot 668, 670 therein arranged to slidingly
20 engage respective ones of the ribs 632, 634. A further pinion member 670, having a similar construction to the first pinion member 610, includes a second external interface 622 in the form of a hex socket at one end and is rotatably captured within the lower part 606 with its gear or cog 672 meshed with the further rack 636. Hence, further pinion 670 provides a second drive mechanism for a second adjustment mechanism, also in the form
25 of a rack and pinion arrangement, which is operable to cause the lower part 606 to translate relative to the main body 602 to adjust the neck offset.

Upper part 604 and bases 602 each include a respective locking mechanism 680, 690 made from metal. Each locking mechanism includes a pivot 682, 692 and a locking part
30 684, 694 arranged to interact with the teeth of the associated rack. The locking mechanisms 680, 690 act like pivoted locking pawls which drop into position on the rack (which has a deepened rectangular tooth root) to stop any back-driving when the adjustment tool 720 is not inserted. Each of the pawls 684, 694 is biased to interfere with

the respective rack, so that they are only lifted up and out of the way when the driver is inserted in place. The tooth 684, 694 on the end of the pawl is what takes the load in neck offset and in neck length when load is applied. Without the pawls, the pinions would just freewheel under load.

5

Hence, the fourth embodiment of the adjustable trial neck 600 can be used similarly to the first, second and third embodiments to allow independent and continuous adjustment of the trial neck assembly in two directions so that the neck length and/or neck offset can be adjusted during trialling and/or to make it easier to remove the trial head from the cup at

10 the end of trialling.

Figure 19 shows an assembly 700 of the fourth embodiment of the trial neck 600 when mounted on a broach 710. Figure 19 also shows a hex headed screw driver 720 which can be used to adjust the neck length and/or neck offset. As illustrated in Figure 19, when
15 mounted on the broach 710, the second drive mechanism will not extend parallel to the medial-lateral axis but will extend at least partially along the medial-lateral axis. Hence operation of the second drive mechanism will vary the position of the trial neck at least partially in the medial-lateral direction but also in the inferior-superior direction. Hence, the second drive mechanism can vary both the neck off set and also the leg-length. The
20 first drive mechanism is directed along the neck axis of the trial neck and hence allows the neck length to be adjusted. Hence, the neck length may be adjusted to compensate for any unwanted changes in the leg length arising from operating the second drive mechanism.

25 In this specification, an example embodiment has been presented as a particular combination of features. However, a person of ordinary skill in the art would understand that many other embodiments may be practiced which include a different combination of features, including fewer features or a greater number of features. It is intended that the following claims cover all possible embodiments.

30

Any instructions and/or flowchart steps may be carried out in any order, unless a specific order is explicitly stated or would be understood to be required from the context of the description. Also, those skilled in the art will recognize that while one example method

has been discussed, a variety of other differing methods are possible based on other combinations and/or orders of method steps, and are to be understood within a context provided by this detailed description.

- 5 While the inventions are amenable to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and described in detail. It should be understood, however, that other embodiments, beyond the specific embodiments described, are possible as well. All modifications, equivalents, and alternative embodiments falling within the scope of the appended claims are covered as
- 10 well.

CLAIMS:

1. An adjustable trial neck, comprising:
a body;
5 a first part;
a second part;
a first adjustment mechanism actuatable by a first drive which presents a first external interface for a tool and which is operable by a user using the tool to translate the first part relative to the body to adjust the neck length; and
10 a second adjustment mechanism actuatable by a second drive which presents a second external interface for a tool and which is operable by a user using the tool to translate the second part relative to the body to adjust the neck offset.
2. The adjustable trial neck as claimed in claim 1, where the first part includes an
15 attachment formation at a free end for receiving a trial head, and wherein the position of the attachment formation relative to the body is adjustable by the first adjustment mechanism.
3. The adjustable trial neck as claimed in claim 1, where the first part includes a trial
20 head attached toward an end of the adjustable trial neck, and wherein the position of the trial head relative to the body is adjustable by the first adjustment mechanism.
4. The adjustable trial neck as claimed in any of claims 1 to 3, wherein the second
part includes a base for releasably attaching the adjustable trial neck to a long bone
25 component and wherein the position of the base relative to the body is adjustable by the second adjustment mechanism.
5. The adjustable trial neck as claimed in any of claims 1 to 3, wherein the second
part includes a base attaching the adjustable trial neck to a long bone component and
30 wherein the position of the stem part relative to the body is adjustable by the second adjustment mechanism.

6. The adjustable trial neck as claimed in any preceding claim wherein the first adjustment mechanism is operable to translate the first part along a first axis and the second adjustment mechanism is operable to translate the second part along a second axis, and wherein the first axis and second axis subtend an obtuse angle to a superior side.

5

7. The adjustable trial neck of any preceding claim, wherein the first external interface and the second external interface each comprise a female formation.

8. The adjustable trial neck of any preceding claim wherein the first adjustment
10 mechanism and the second adjustment mechanism are independently operable.

9. The adjustable trial neck of any preceding claim wherein the first adjustment mechanism is continuously adjustable and/or the second adjustment mechanism is continuously adjustable.

15

10. The adjustable trial neck as claimed in any of claims 1 to 9, wherein the first adjustment mechanism includes a first rack and /or the second adjustment mechanism includes a second rack.

20 11. The adjustable trial neck as claimed in claim 9, wherein the first drive mechanism includes a first worm gear which meshes with the first rack and /or the second drive mechanism includes a second worm gear which meshes with the second rack.

12. The adjustable trial neck as claimed in claim 10 or 11, wherein the first drive
25 mechanism includes a first pinion including a first gear which meshes with the first rack and /or the second drive mechanism includes a second pinion including a second gear which meshes with the second rack.

13. The adjustable trial neck as claimed in any preceding claim, wherein the first drive
30 mechanism includes a first releasable lock and/or wherein the second drive mechanisms includes a second releasable lock.

14. The adjustable trial neck as claimed in claim 13, wherein the first releasable lock is arranged to be disengaged when the tool is introduced into the first external interface and/or the second releasable lock is arranged to be disengaged when the tool is introduced into the second external interface.

5

15. The adjustable trial neck as claimed in any of claims 1 to 14, and further comprising:

a first set of indicia associated with the first adjustment mechanism and providing a first scale; and/or

10 a second set of indicia associated with the second adjustment mechanism and providing a second scale.

16. The adjustable trial neck as claimed in claim 15, wherein the first scale indicates an amount of neck length or head offset and the second scale indicates an amount of neck
15 offset.

17. The adjustable trial neck as claimed in claim 15 or 16, wherein the first set of indicia are provided on the body and the second set of indicia are provided on the second
20 part.

20

18. The adjustable trial neck as claimed in any preceding claim, and further comprising a first guide mechanism arranged to guide translation of the first part relative to the body.

25 19. The adjustable trial neck as claimed in claim 18, wherein the first guide mechanism comprises a pair of rods attached to the first part and slidably received within a pair of cavities formed within housings attached to the body.

20. The adjustable trial neck as claimed in claim 18 wherein the first guide
30 mechanism comprises one or more ribs respectively slidably received in one or more slots.

21. The adjustable trial neck as claimed in any preceding claim, and further comprising a second guide mechanism arranged to guide translation of the second part relative to the body.
- 5 22. The adjustable trial neck as claimed in claim 21, wherein the second guide mechanism comprises a tongue and groove arrangement in which one of the tongue and groove is provided by the second part and the other of the tongue and groove is provided by the body, and the tongue is slidingly received within the groove.
- 10 23. The adjustable trial neck as claimed in claim 21 wherein the second guide mechanism comprises one or more ribs respectively slidingly received in one or more slots.
24. The adjustable trial neck as claimed in claim 2, wherein the attachment formation
15 mechanism comprises a taper having a groove extending at least partially around the taper.
25. The adjustable trial neck as claimed in claim 4, wherein the base includes a releasable attachment mechanism comprising a first formation and a second formation.
20
26. The adjustable trial neck as claimed in claim 25, wherein the first formation and the second formation have different shapes.
27. The adjustable trial neck as claimed in claim 26, wherein the first formation is a
25 male formation and the second formation is a male formation.
28. The adjustable trial neck as claimed in claim 27, wherein the first formation is a peg and the second formation is a keel.
- 30 29. The adjustable trial neck as claimed in any of claims 25 to 28, wherein the first formation and the second formation are positioned along a centre line of the base.

30. The adjustable trial neck as claimed in claim 4 or 5, wherein the long bone component is selected from: a broach; a trial stem; and a prosthetic stem.
31. The adjustable trial neck as claimed in any preceding claim, wherein the
5 adjustable trial neck is an adjustable trial femoral neck, the trial head is a trial femoral head and the long bone component is femoral component.
32. The adjustable trial neck as claimed in any of claims 1 to 30, wherein the
10 adjustable trial neck is an adjustable trial humeral neck, the trial head is a trial glenoid head and the long bone component is a humeral component.
33. A kit of parts comprising:
the adjustable trial neck as claimed in any of claims 1 to 29;
a trial head attachable to the first part; and
15 a long bone component attachable to, or attached to, the second part.
34. A trialling assembly comprising:
the adjustable trial neck as claimed in any of claims 1 to 29;
a trial head attached to the first part; and
20 a long bone component attached to the second part.
35. A method for trialling a trial ball and socket joint of a patient including at least a trial head on an adjustable trial neck, comprising:
adjusting the neck length and the neck offset while the trial ball and socket joint is
25 reduced by operating the adjustable trial neck using a tool; and
assessing the trial ball and socket joint of the patient.
36. The method of claim 35, further comprising using the tool to operate the adjustable trial neck to reduce the overall size of the adjustable trial neck while the trial
30 ball and socket joint is reduced and after assessing the trial ball and socket joint to facilitate removal of the trial head from the socket joint

37. The method of claim 35 or 36, and further comprising iteratively adjusting and assessing the trial ball and socket joint to determine a preferred geometry for a neck and head.
- 5 38. The method of claim 37, further comprising obtaining a prosthetic implant having a neck and head geometry matching the preferred geometry and implanting the prosthetic implant in a long bone of the patient.

Fig. 1

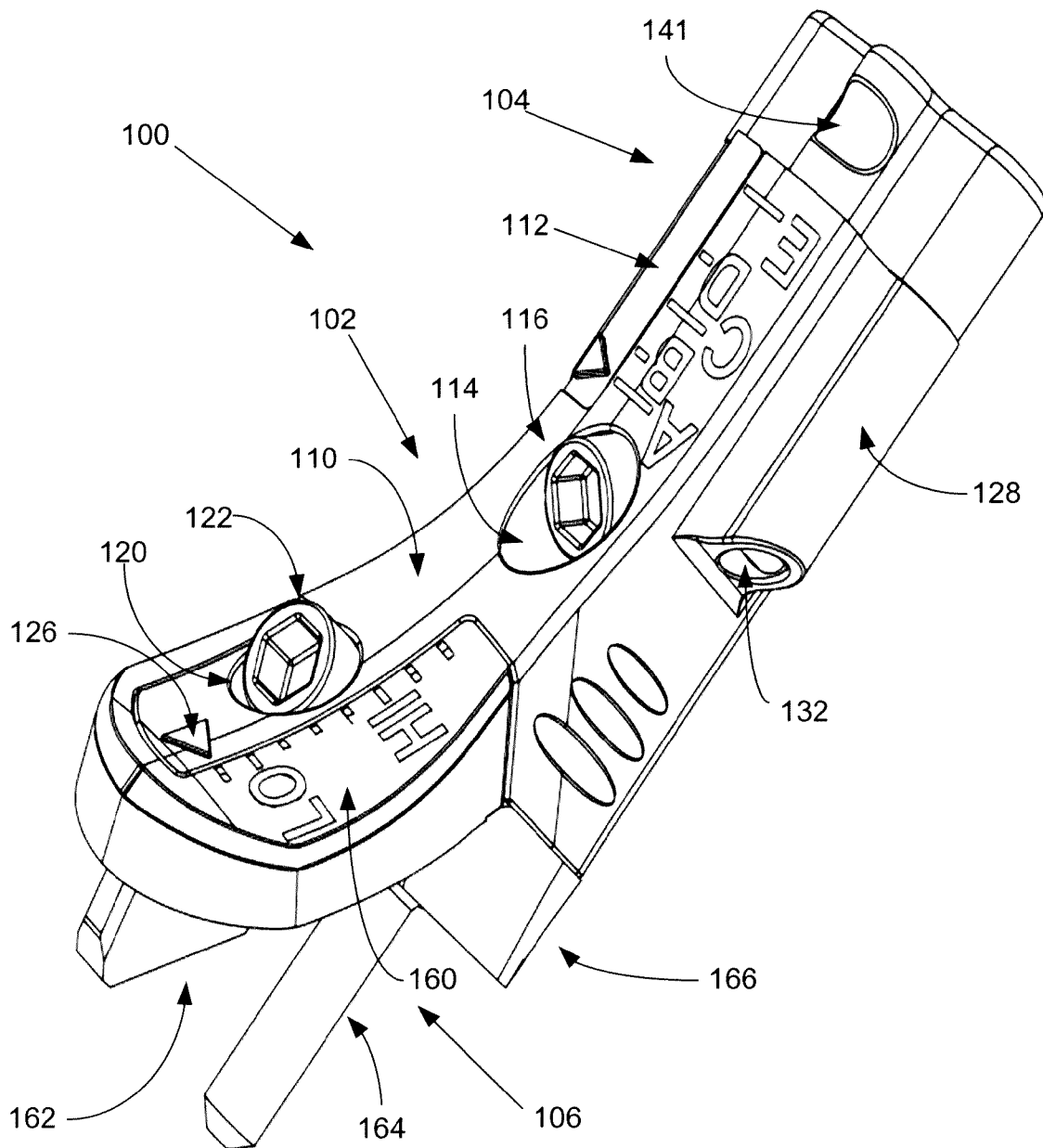


Fig. 2

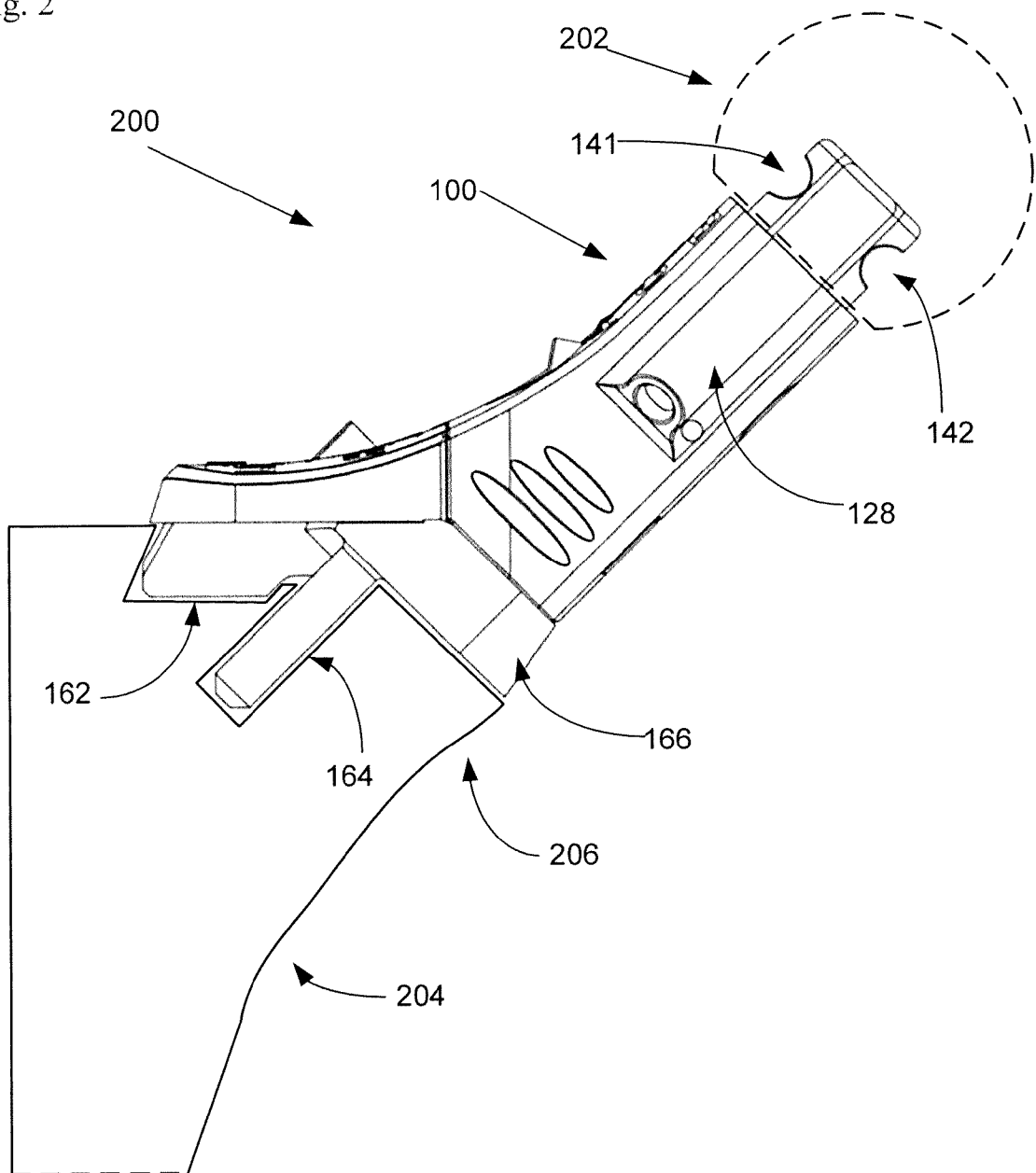


Fig. 3

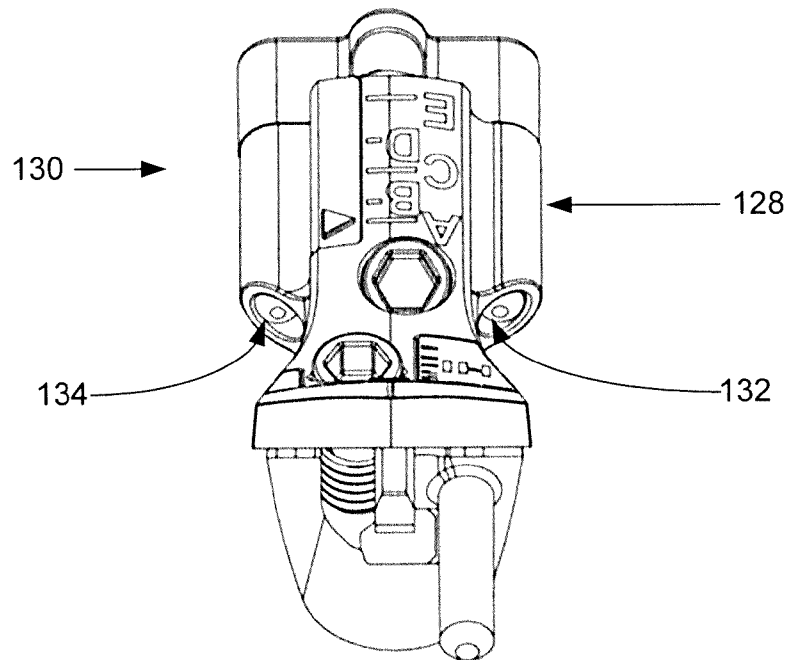


Fig. 4

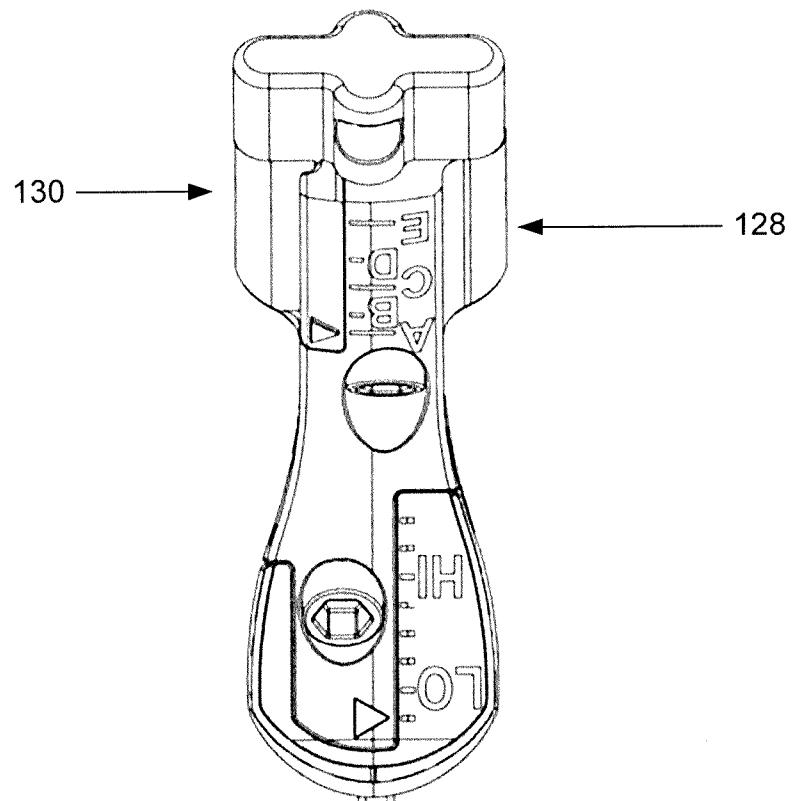


Fig. 5

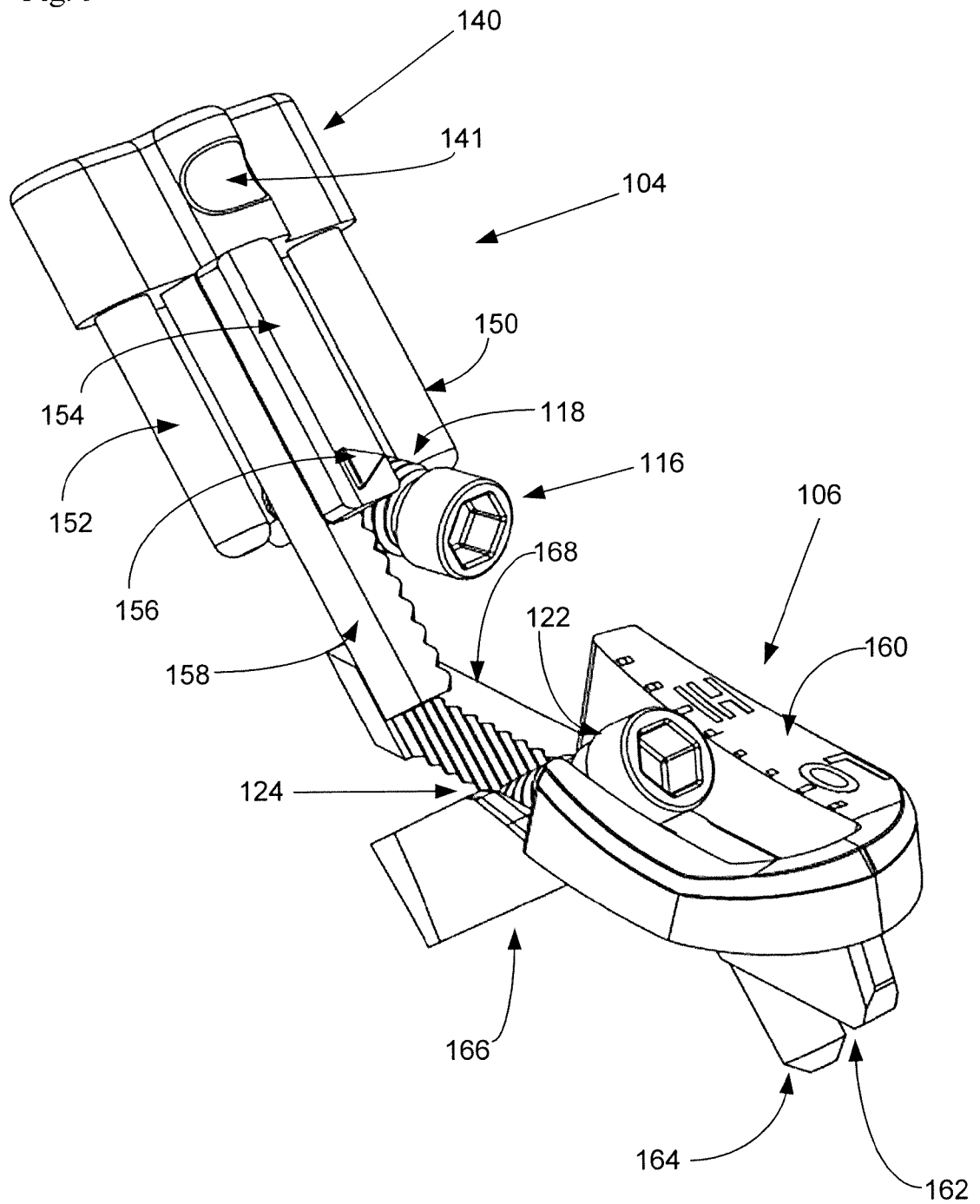
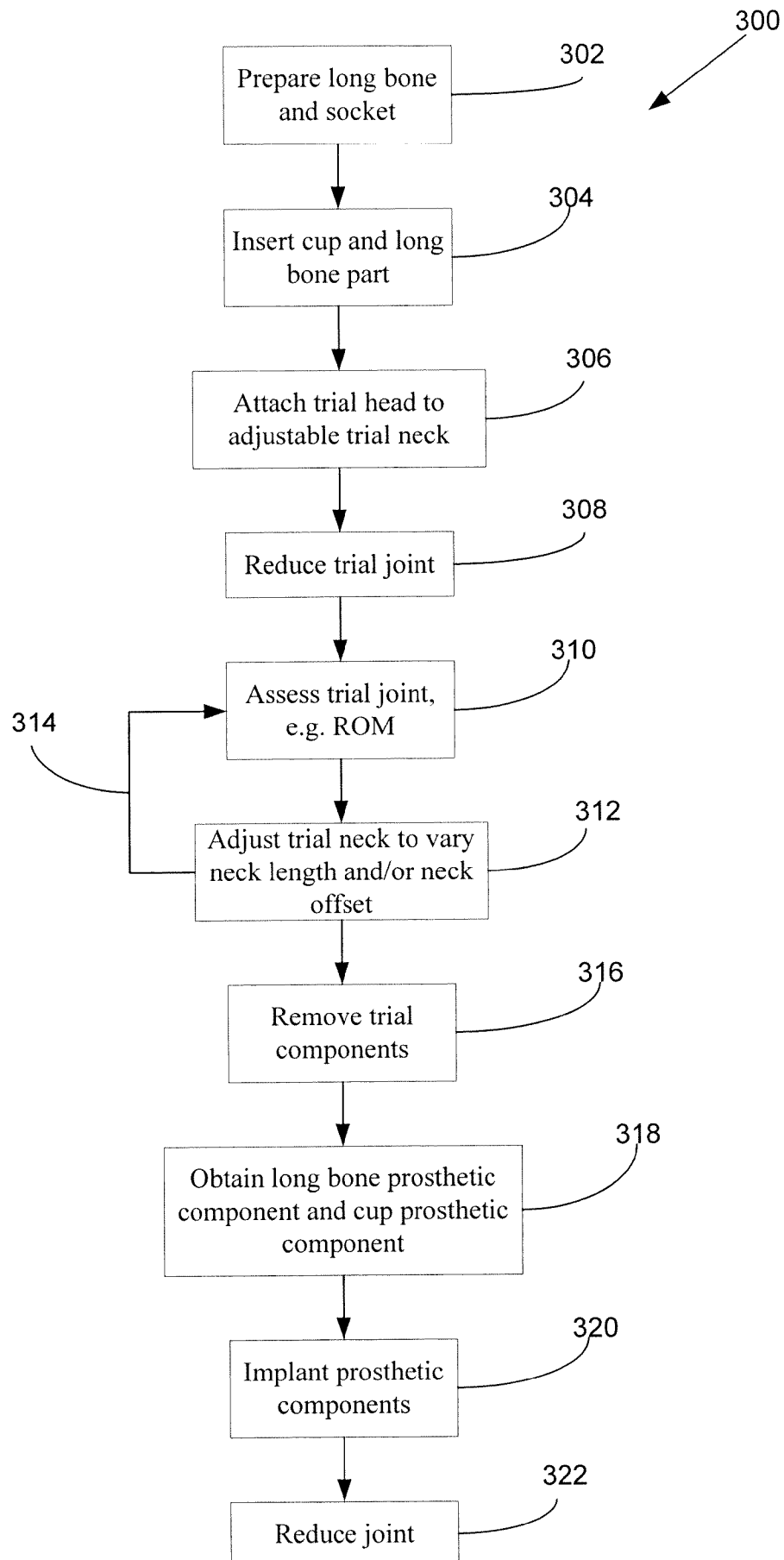


Fig. 6



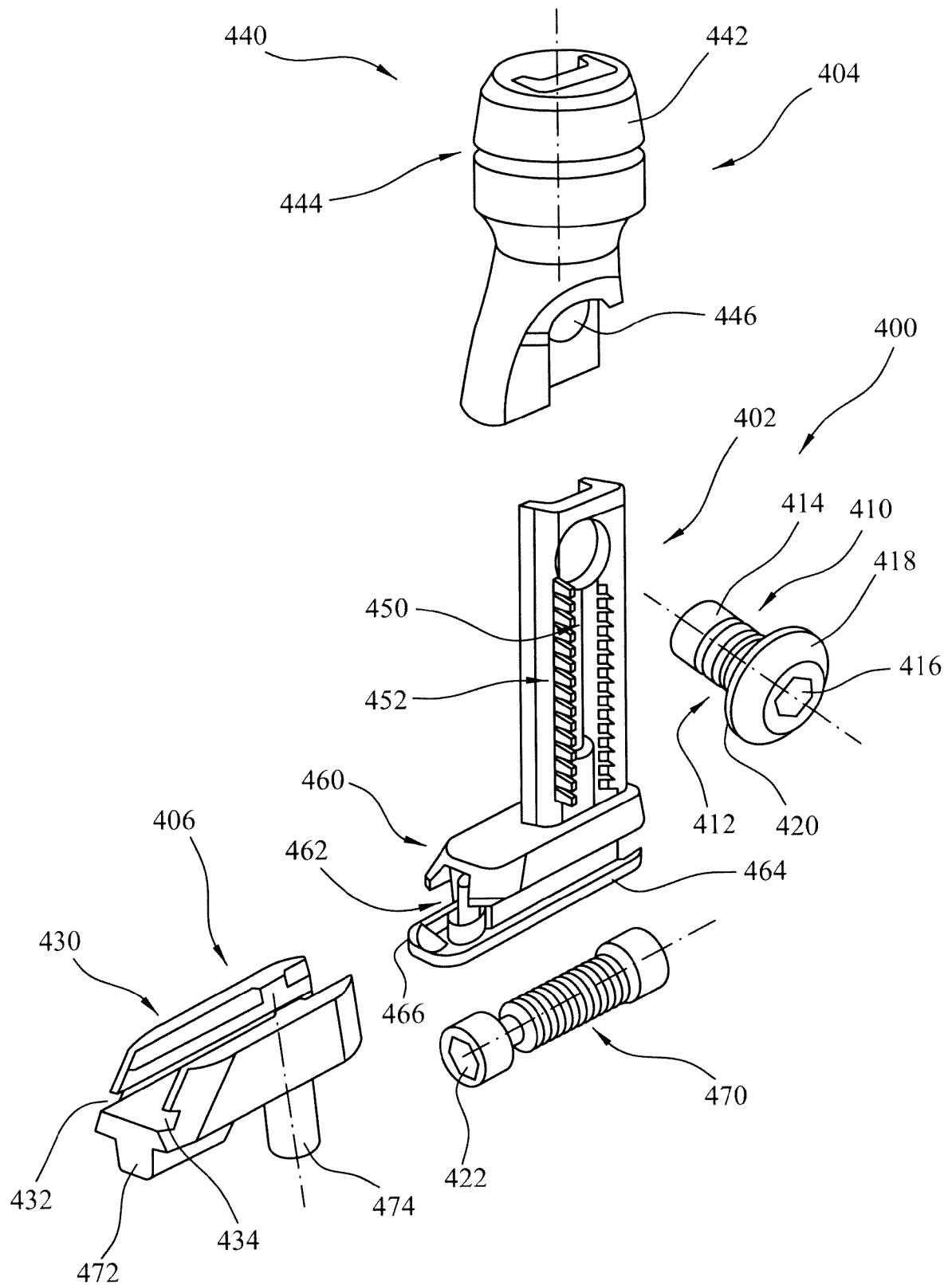
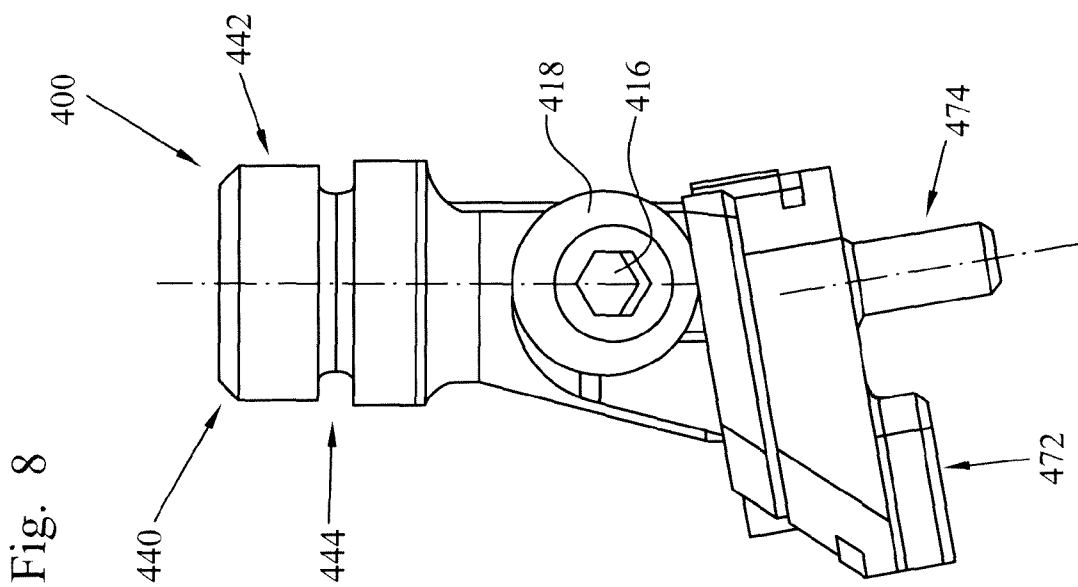
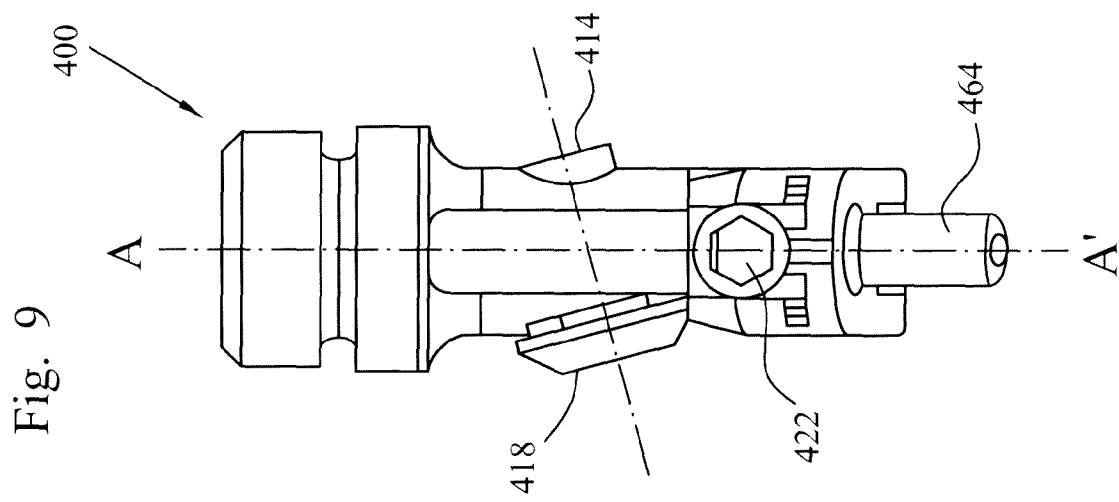
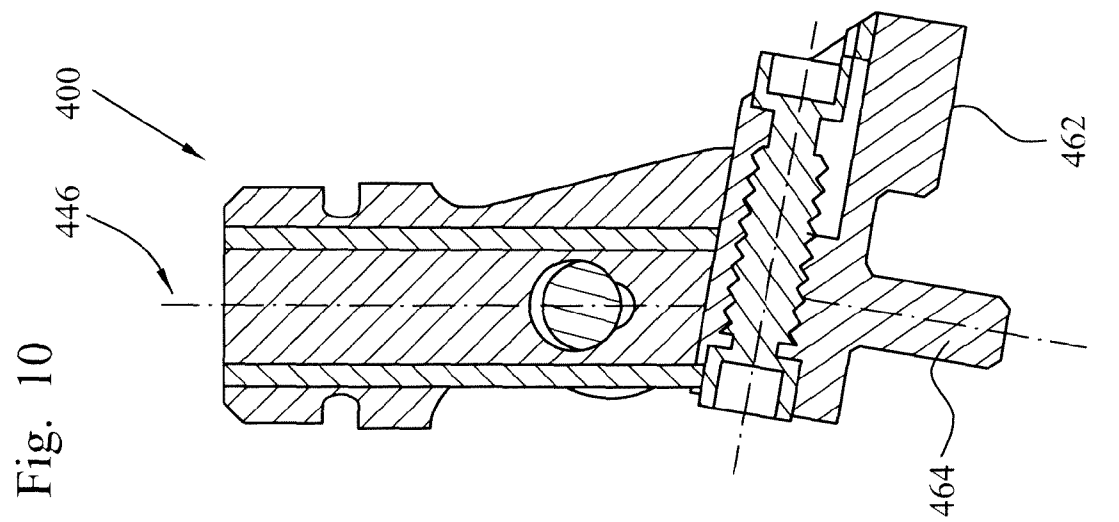


Fig. 7



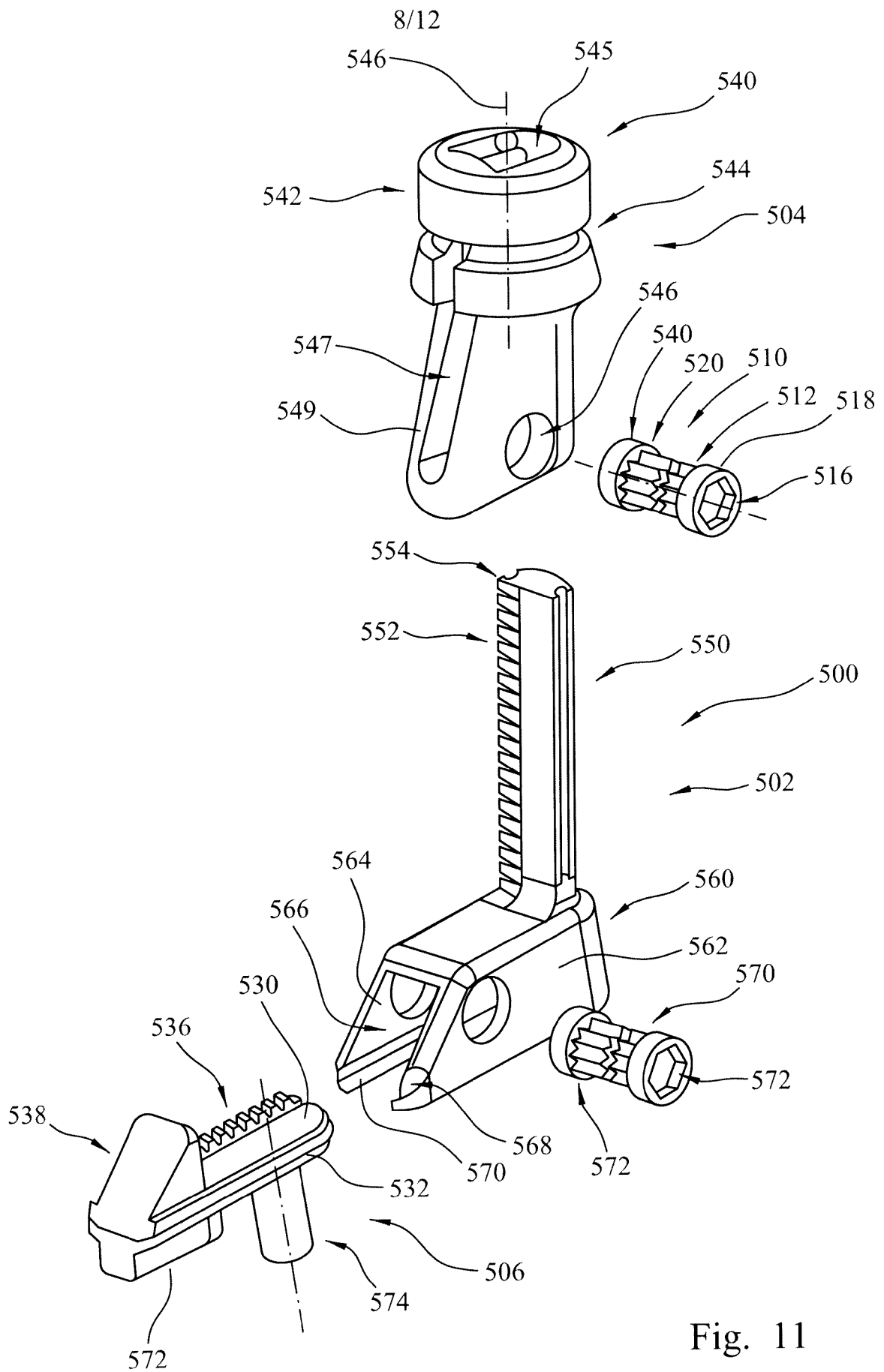


Fig. 11

Fig. 14

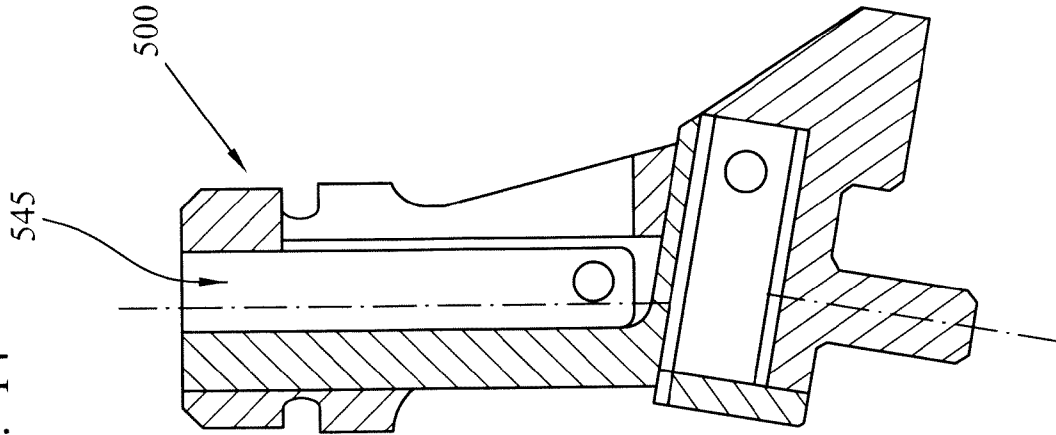


Fig. 13

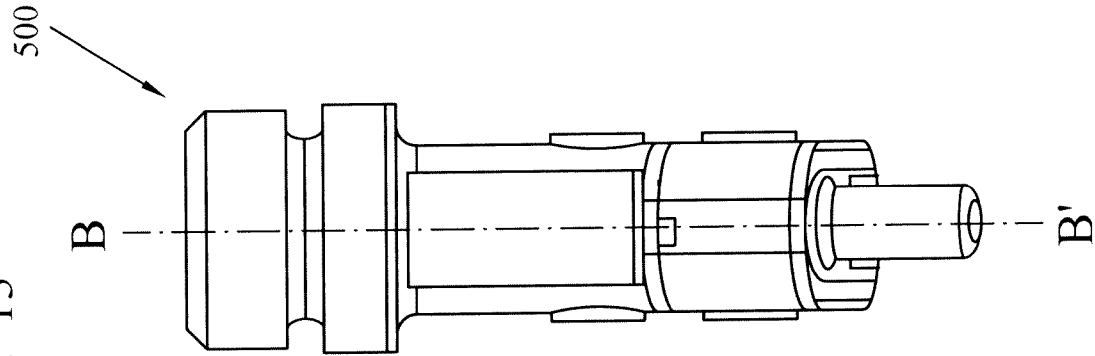
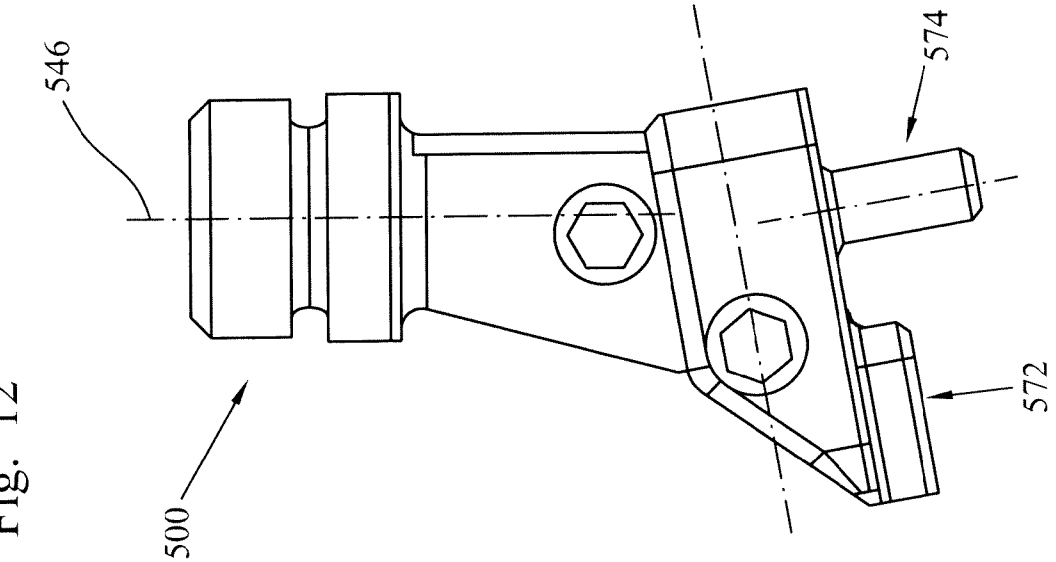


Fig. 12



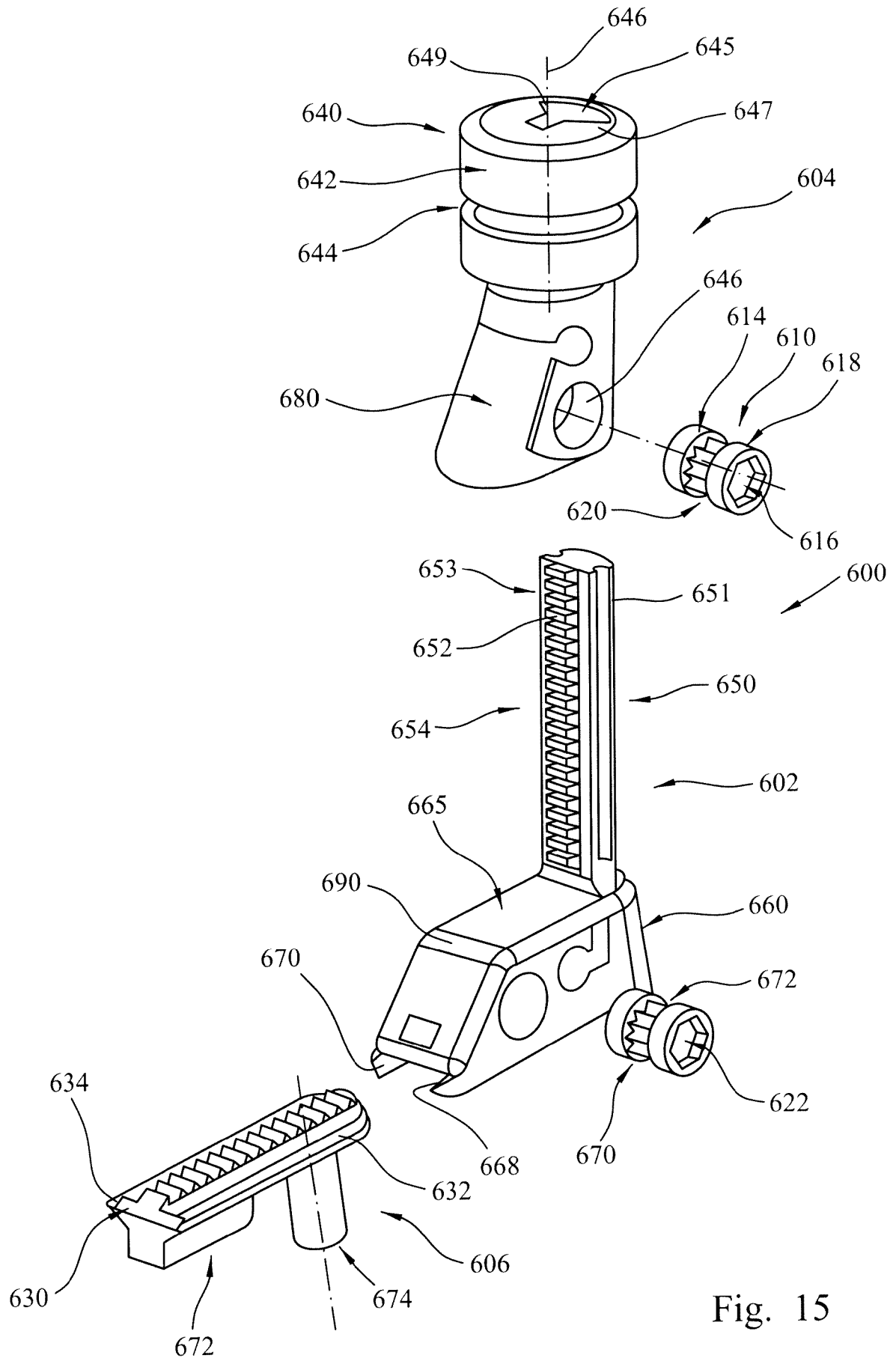


Fig. 15

Fig. 18

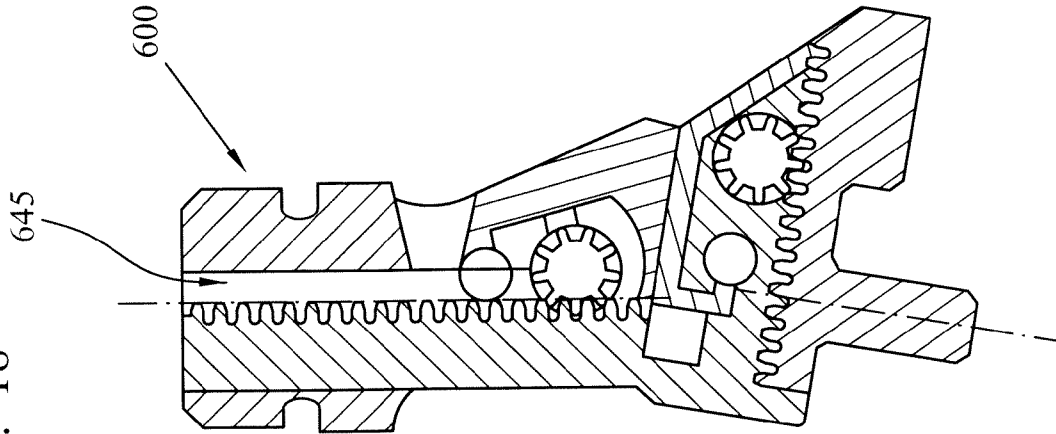


Fig. 17

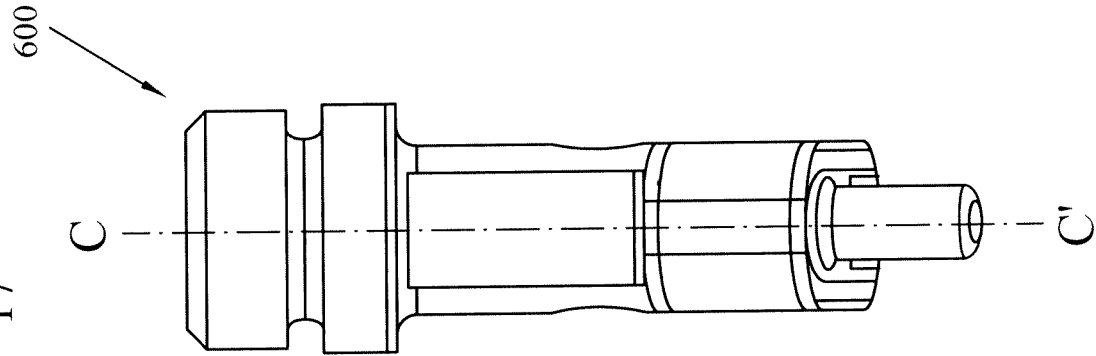
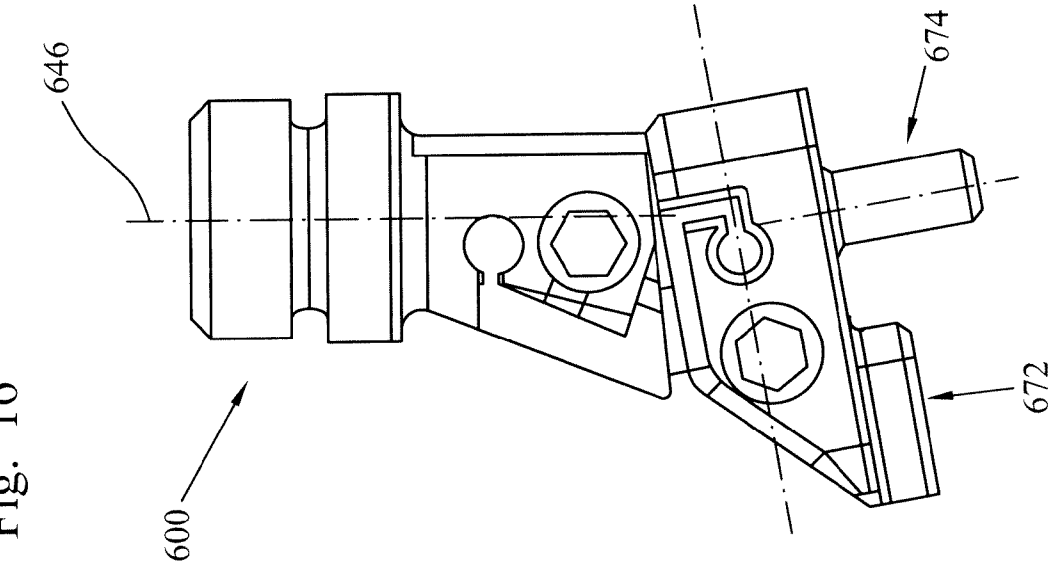


Fig. 16



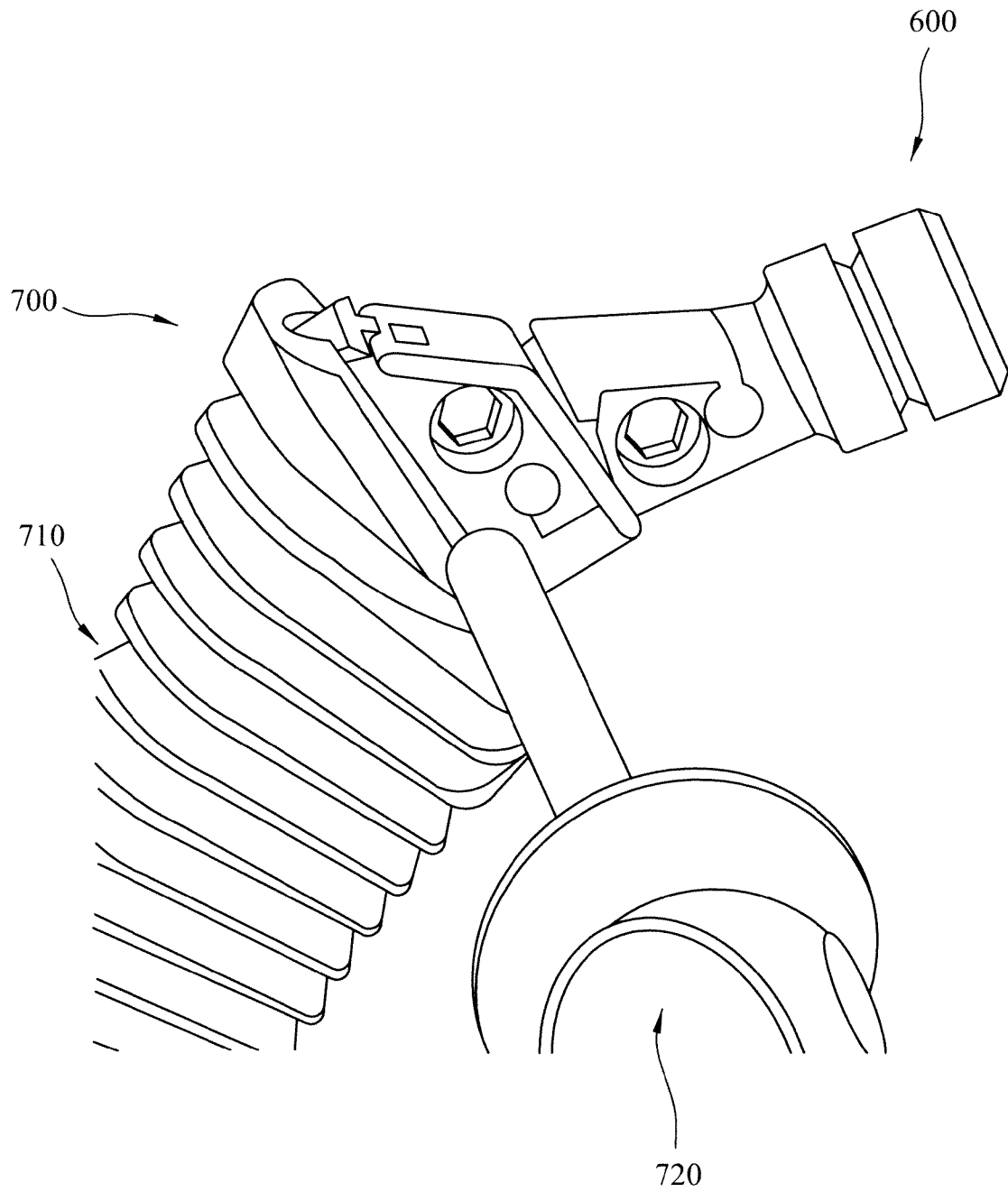


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/072310

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/46
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/083116 A1 (QUANTUM TECHNOLOGY S R L [IT]) 11 June 2015 (2015-06-11)	1-10,12,18,20-23,25,26,29-31,33,34
Y	abstract	11,13,
A	page 12, line 27 - page 16, line 31	15,16,24
	figures 23-32	14,17,19,27,28,32
Y	----- US 2016/262912 A1 (BURNIKEL BRIAN G [US] ET AL) 15 September 2016 (2016-09-15) paragraph [0042] - paragraph [0049] claims 1,6 figures 2A,2B,2D ----- -/-	11,13



Further documents are listed in the continuation of Box C.



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 application or patent 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

22 October 2018

Date of mailing of the international search report

31/10/2018

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Storer, John

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/072310

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 35-38
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2018/072310

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/267372 A1 (VANASSE THOMAS M [US] ET AL) 30 December 2004 (2004-12-30) abstract paragraph [0023] figure 1 -----	24
Y	US 2004/122439 A1 (DWYER KIMBERLY A [US] ET AL) 24 June 2004 (2004-06-24) abstract paragraph [0071] - paragraph [0072] paragraph [0080] figure 8 -----	15,16

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2018/072310

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2015083116 A1	11-06-2015	EP 3076904 A1	12-10-2016
		EP 3076905 A1	12-10-2016
		WO 2015083116 A1	11-06-2015
		WO 2015083132 A1	11-06-2015

US 2016262912 A1	15-09-2016	NONE	

US 2004267372 A1	30-12-2004	NONE	

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		AU 2003268842 A1	08-07-2004
		DE 60309419 T2	30-08-2007
		EP 1430859 A1	23-06-2004
		JP 2004202230 A	22-07-2004
		US 2004122439 A1	24-06-2004
