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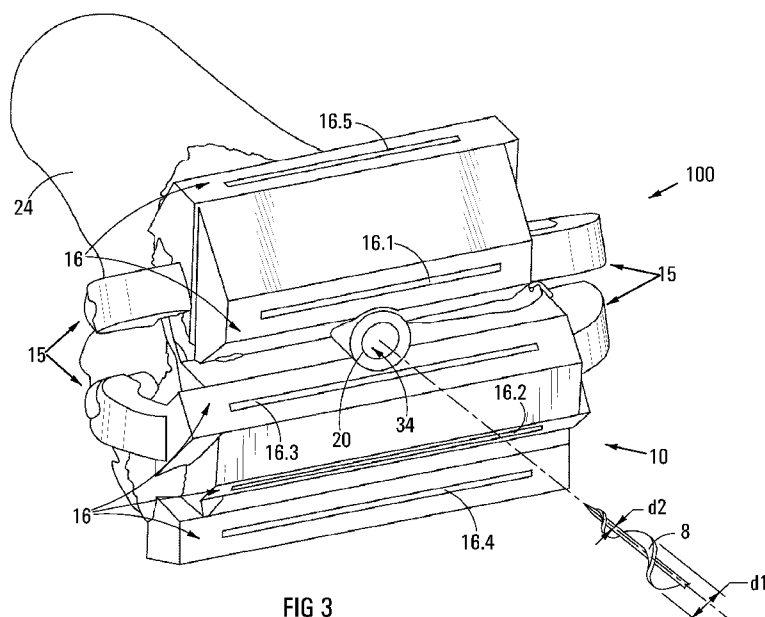
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(54) Title: A BONE CUTTING GUIDE AND A BONE CUTTING GUIDE SYSTEM



(57) Abstract: A bone cutting guide 10 comprising a moulding; mounting formations 15; five cutting tool guides 16; and a guide formation 20. The moulding is constructed from anatomical data obtained from a radiographic scan of a femur 24 before surgery. Each guide 16 has a predetermined spatial relationship relative to the moulding which is obtained from anatomical data of the femur 24. After secure fitment of the moulding to the femur 24, guides 16 are located for guiding cutting tools for cutting the femur in order to locate and fit a prosthetic joint thereto. The formation 20 defines a guide passage 34 having a predetermined orientation and spatial relationship to the moulding, for guiding insertion of a pin 8 into the femur 24 along a longitudinal axis thereof. The pin 8 provides for mounting of a bone cutting guide assembly to the femur 24. The guide 16 and the passage 34 permits a surgeon to make an election intra-operatively between utilizing the guide 16 or the passage 34.

A BONE CUTTING GUIDE AND A BONE CUTTING GUIDE SYSTEM

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FIELD OF INVENTION

This invention relates to a bone cutting guide and to a bone cutting guide system for use in guiding the cutting of a patient's joint bone during joint bone replacement surgery. In this specification the terms "replacement surgery" and "replacement surgical procedure" must be interpreted sufficiently broadly to include a reference to bone resurfacing and bone resurfacing surgical procedure, respectively. In this specification the term "bone" must be interpreted to mean any elongate bone having a medullary canal, such as, for example, a femur, a tibia, a humerus, a radius, a finger bone or a toe bone.

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BACKGROUND TO THE INVENTION

A patient's joint bones may require replacement due to injury or deterioration caused by aging, or certain debilitating conditions, such as, for example, arthritis.

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During bone replacement surgery, at least one prosthetic joint locating face must be cut in an end region of a joint bone by removing a portion of bone, so as to allow for the secure fitment of a prosthetic joint to the end region of the joint bone in a predetermined orientation which approximates the anatomical normality of the patient's joint bone.

In the case of knee replacement surgery, prosthetic joint locating faces are cut into a lower extremity of the femur and into an upper extremity of the tibia. More specifically, a number of flat femoral prosthetic joint locating faces are cut into the lower extremity of the femur along planes which are offset at predefined angles relative to one another.

A single flat tibial prosthetic joint locating face is typically cut into the upper extremity of the tibia. The flat tibial prosthetic joint locating face is typically, but not necessarily, cut perpendicular with respect to the longitudinal axis of the tibia.

A prosthetic knee joint which is fitted to the patient during surgery comprises a femoral component and a tibial component. The femoral and tibial components each comprise a generally cup-shaped receiving formation for receiving cut ends of the patient's femur and tibia, respectively.

The femoral component has a number of flat faces defined on inner sides of the receiving formation which are angularly offset with respect to one another, for abutting against corresponding flat prosthetic joint locating faces cut into the lower extremity of the femur. More particularly, when the femoral component is fitted to the cut femur of the patient such that the cut femur is received within the receiving formation of the femoral component, the angled faces of the femoral component abut corresponding angled joint locating faces cut on the lower extremity of the patient's femur, thereby to orientate the femoral component with respect to the femur in a predetermined orientation which approximates the anatomical normality of the patient's joint bone.

The tibial component has a flat locating face defined on an inner side of the receiving formation for abutting against the cut flat joint locating face cut into the upper

extremity of the tibia. More particularly, when the tibial component is fitted to the cut tibia of the patient such that the cut tibia is received within the receiving formation of the tibial component, the flat prosthetic joint locating face of the tibial component abuts against the flat prosthetic joint locating face which was cut during surgery into the upper extremity of the tibia so as to orientate the tibial component with respect to the tibia in a predetermined orientation which approximates the anatomical normality of the patient's knee joint.

Surgeons are divided in their approach taken towards bone replacement surgery and, in particular towards knee replacement surgery. One group of surgeons follow a so-called "bony-cut approach" wherein these surgeons believe that knee surgery can be planned pre-operatively based solely on a particular patient's bone anatomy which is obtained pre-operatively by means of bone scan data obtained by means of, for example, x-rays, ultrasounds, or the like. More particularly, these surgeons believe that in order to approximate anatomical normality of a patient's knee joint, the correct location and configuration of the cuts to be made to the lower extremity of the femur can be predetermined pre-operatively, so as to plan the fitment of the prosthetic joint for optimal alignment with respect to a mechanical axis of the patient's leg, which extends through the centre of a head of the femur and through the centres of the knee and ankle joints of the leg. Furthermore, the size of the prosthetic joint and the position and orientation of joint locating faces to accommodate the selected size of prosthetic joint is planned pre-operatively. Also a so-called "external rotation" of the prosthetic joint is planned pre-operatively. The external rotation of the prosthetic joint is the particular rotation of the femoral component of the prosthetic joint about a central axis of rotation of the prosthetic joint which is parallel with the mechanical axis of the patient's leg. It is believed that the soft tissue around the knee, including muscles, tendons and cartilage must adapt after surgery to accommodate the particular size and alignment of the prosthetic joint.

Another group of surgeons having an opposing view, advocate a so-called "soft tissue approach" to bone replacement surgery and in particular to knee replacement surgery. These surgeons believe that in order to approximate anatomical normality of a patient's knee joint, the fitment of the prosthesis for optimal alignment with respect to the mechanical axis of the patient's leg is not the only important

consideration. This group of surgeons believes that the soft tissue anatomy of the knee must also, under certain circumstances, be taken into consideration when determining the location and configuration of the cuts that are to be made to the patient's bones to orientate the prosthetic joint, so as to ensure that after surgery the knee joint is properly balanced and supported by the soft tissue, such that the knee joint is not too loose or too tight a fit with respect to the natural tensions of the soft tissue of the patient. These surgeons thus believe that the cutting of the bone can only be finally determined intra-operatively once the surgeon has determined the tension of soft tissue connected around the knee joint. These surgeons also believe that after surgery the patient feels that the knee joint is more natural because the surgeon followed the soft tissue approach of considering the patient's soft tissue anatomy when cutting the patient's bone. Furthermore, these surgeons believe that as a result of considering the anatomy of the patient's soft tissue and cutting prosthetic joint locating faces into the bone according to information gained from a visual inspection of the soft tissue, the soft tissue does not need to adapt to the same extent as it would if the surgeon followed the bony-cut approach, thus resulting in faster and more comfortable recovery of the patient.

Surgeons advocating the bony-cut approach often make use of so-called "custom-made bone cutting guides" which are constructed preoperatively from anatomical data of the patient obtained by means of bone scan data obtained by means of, for example, x-rays, ultrasounds, or the like. Such custom-made bone cutting guides include a femoral bone cutting guide and a tibial bone cutting guide, which each include receiving formations which conform to the shape and configuration of a particular patient's lower extremity of the femur and upper extremity of the tibia, respectively. Furthermore, the custom-made bone cutting guides each define cutting guide formations for guiding cutting tools used during surgery for guiding the cutting of the patient's lower extremity of the femur and upper extremity of the tibia, respectively.

In contrast thereto, proponents of the soft tissue approach to knee surgery do not use the custom made bone cutting guides described above, as the guides do not allow the surgeon to deviate from the pre-operative plan. For this reason, surgeons subscribing to the soft tissue approach to surgery are forced to use a so-called "bone

cutting guide assembly” during surgery for guiding the cutting of a joint bone which does not allow any flexibility in the selection of the location and configuration of the cuts.

- 5 In the case of knee surgery, the bone cutting guide assembly is configured for guiding the cutting of a lower extremity of the patient's femur and an upper extremity of a patient's tibia. More particularly, the bone cutting guide assembly is configured for guiding the cutting of joint locating faces in end regions of a patient's distal femur or upper extremity of a patient's tibia to allow for the secure fitment of a prosthetic
10 joint to the bone in a predetermined orientation which approximates the anatomical normality of the patient's knee joint.

In order to correctly orientate the bone cutting guide assembly relative to the joint bone, the bone cutting guide assembly must firstly be orientated with respect to some
15 easily established reference. Typically, the reference which is used is a longitudinal axis of the patient's femur. In order to establish a reference or datum for a longitudinal axis of a bone, it is common practice to insert an intramedullary rod into a medullary canal of the bone, sufficiently deeply so as to align the intramedullary rod with the medullary canal of the patient and such that a projecting end of the
20 intramedullary rod is aligned with the medullary canal of the patient, so as to serve as a reference which approximates the longitudinal axis of the bone and to serve as a point of attachment to which a bone cutting guide assembly can be mounted.

As a first step, the bone cutting guide assembly must thus firstly be orientated with
25 respect to the longitudinal axis of the femur, as referenced by the intramedullary rod. Once the bone cutting guide assembly is orientated with respect to the intramedullary rod, the bone cutting guide assembly must, as a second step, be orientated with respect to the mechanical axis of the femur, by adjusting the bone cutting guide assembly a predetermined degree of deviation, typically 6° from the longitudinal axis
30 of the femur, as referenced by the intramedullary rod. Thereafter, adjustment must be made to the bone cutting guide assembly, if necessary, so as to accommodate the soft tissue requirements of the patient's joint, and so as to orientate the bone cutting guide assembly for guide the cutting of joint locating faces which will align the prosthetic joint optimally, taking into account both the mechanical axis of the patient's

leg and adjustments made to accommodate the soft tissue requirements of the patient's joint.

The flat femoral prosthetic joint locating faces which are cut into the lower extremity of the femur so as to orientate and align the femoral component of the prosthetic joint typically includes an anterior cut; an anterior chamfer; a posterior chamfer; a posterior cut; and a distal cut. The distal cut establishes the mechanical axis of the patient's leg after fitment of the prosthetic joint to the patient. The anterior cut establishes the so-called "external rotation" of the prosthetic joint.

In this specification, any reference to a "bone cutting guide assembly" must be interpreted to mean an assembly configured for guiding the cutting of a patient's joint bone during joint replacement surgery and which includes a bone cutting guide having at least one cutter guide formation for guiding a cutter for cutting a prosthetic joint locating face in an end region of the joint bone; and guide mounting means to which the bone cutting guide is releasably mounted for releasably mounting the bone cutting guide to an elongate intramedullary rod, or similar elongate pin which projects from the patient's joint bone.

The applicant has identified a need for a surgical tool which can be used by a surgeon advocating a soft tissue approach, to accurately guide the cutting of at least one joint locating face in an end region of a patient's joint bone, in accordance with a pre-operative plan as advocated by the bony-cut approach if the surgeon is satisfied, after examining the soft tissue, that the soft tissue favours this pre-operative plan approach, but which will also enable, as an alternative, the surgeon to deviate from the pre-operative plan, so as to accommodate the patient's soft tissue, by enabling the surgeon to accurately and securely locate and position a bone cutting guide assembly relative to the joint bone, so as to permit the surgeon to thereafter adjust the position of the bone cutting guide of the bone cutting guide assembly, to a predetermined position, which differs from the pre-operative planned bone cutting position, so as to guide the cutting of the patient's joint bone to optimally align the prosthetic joint with respect to the patient's joint bone.

SUMMARY OF INVENTION

According to a first aspect of the invention, there is provided a bone cutting guide for use in a joint replacement surgical procedure for guiding the cutting of at least one
5 prosthetic joint locating face in an end region of a joint bone of a human patient, the bone cutting guide including:

(a) a moulding which is constructed from anatomical data obtained of the end region of the joint bone so as to define locating formations which correspond to
10 anatomical formations of said end region of the joint bone, thereby to provide for the secure fitment of the bone mounting structure to the end region of the joint bone wherein the profile of the complementary locating formations of the moulding conforms to the profile of the corresponding anatomical formations of the end region of the joint bone; and

15 (b) at least one cutting tool guide having a predetermined orientation and spatial relationship relative to the moulding which is obtained from the anatomical data of the end region of the joint bone, the cutting tool guide, after fitment of the moulding to the end region of the joint bone, being positioned and located for guiding a cutting tool for
20 cutting a prosthetic joint locating face in an end region of the joint bone, to allow for the secure fitment of a prosthetic joint to the joint bone in a predetermined orientation which approximates the anatomical normality of the patient's joint; and

25 (c) a pin-guiding formation which defines a guide passage having a predetermined orientation and spatial relationship relative to the moulding for guiding insertion of a reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, has a predetermined spatial relationship with respect to at least one of a mechanical axis of the joint bone and a longitudinal axis of the joint bone, so as to provide for mounting of guide mounting means of a
30 bone cutting guide assembly to a projecting end region of the inserted reference pin, in use, thereby to facilitate accurate location of a bone cutting guide of the bone cutting guide assembly relative to the joint bone, for guiding the cutting of the prosthetic joint locating face in the end region of the joint bone,

whereby, the cutting tool guide and the pin-guiding formation permit a surgeon to make an election intra-operatively during bone replacement surgery between utilizing at least one of the cutting tool guide and the pin-guiding formation.

- 5 The guide passage may be configured for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the longitudinal axis of the joint bone.

10 In another embodiment, the guide passage may be configured for guiding insertion of a reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the mechanical axis of the joint bone.

15 According to a second aspect of the invention, there is provided a bone cutting guide system for use in a joint replacement surgical procedure for guiding the cutting of at least one prosthetic joint locating face in an end region of a joint bone of a human patient, the bone cutting guide system including:

20 a reference pin which is configured to be at least partially inserted into an end region of a patient's joint bone; and

a bone cutting guide including:

25 (a) a moulding which is constructed from anatomical data obtained of the end region of the joint bone so as to define locating formations which correspond to anatomical formations of the end region of the joint bone, thereby to provide for the secure fitment of the bone mounting structure to the end region of the joint bone wherein the profile of the complementary locating formations of the moulding conforms to the profile of the corresponding anatomical formations of the end region
30 of the joint bone; and

(b) at least one cutting tool guide having a predetermined orientation and spatial relationship relative to the moulding which is obtained from the anatomical data of the end region of the joint bone, the cutting tool guide, after fitment of the moulding to the

end region of the joint bone, being positioned and located for guiding a cutting tool for cutting a prosthetic joint locating face in an end region of the joint bone, to allow for the secure fitment of a prosthetic joint to the joint bone in a predetermined orientation which approximates the anatomical normality of the patient's joint; and

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(c) a pin-guiding formation which defines a guide passage having a predetermined orientation and spatial relationship relative to the moulding for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, has a predetermined spatial
10 relationship with respect to at least one of a mechanical axis of the joint bone and a longitudinal axis of the joint bone, so as to provide for mounting of guide mounting means of a bone cutting guide assembly to a projecting end region of the inserted reference pin, in use, thereby to facilitate accurate location of a bone cutting guide of the bone cutting guide assembly relative to the joint bone, for guiding the cutting of
15 the prosthetic joint locating face in the end region of the joint bone,

whereby, the cutting tool guide and the pin-guiding formation permit a surgeon to make an election intra-operatively during bone replacement surgery between utilizing at least one of the cutting tool guide and the pin-guiding formation.

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The guide passage may be configured for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the longitudinal axis of the joint bone.

25 In another embodiment, the guide passage may be configured for guiding insertion of a reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the mechanical axis of the joint bone.

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BRIEF DESCRIPTION OF THE DRAWINGS

Further features of the invention are described hereinafter by way of a non-limiting example of the invention, with reference to and as illustrated in the accompanying diagrammatic drawings. In the drawings:

Figure 1 shows a perspective view of an outer side of a bone cutting guide in accordance with the invention;

5 Figure 2 shows a perspective view of an inner side of the bone cutting guide of Figure 1;

Figure 3 shows a perspective view of a bone cutting guide system in accordance with the invention which includes the bone cutting guide of Figure 1, illustrating the
10 manner in which the insertion of a reference pin is guided into a lower extremity of a patient's femur;

Figure 4 shows a perspective view of the bone cutting guide of Figure 1, shown guiding a cutting tool;
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Figure 5A shows a perspective view of the femur of Figure 4, showing prosthetic joint locating faces cut, in use, into the femur of Figure 4;

Figure 5B shows a perspective view of the femur of Figure 3, shown with the
20 reference pin inserted into the femur;

Figure 6 shows an anterior view of the femur of Figure 5B, showing a bone cutting guide assembly mounted to the reference pin; and

25 Figure 7 shows the bone cutting guide assembly of Figure 6 shown prior to being mounted to the reference pin shown in Figure 6.

DETAILED DESCRIPTION OF THE DRAWINGS

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With reference to Figure 3 of the drawings, a bone cutting guide system in accordance with the invention, is designated generally by the reference numeral 100.

The bone cutting guide system 100 includes a reference pin 8 which is configured to be partially inserted into an end region of a patient's bone; and a bone cutting guide 10.

- 5 The reference pin 8 has an overall length of between 100 mm to 120 mm. The reference pin 8 has a penetrating end of between 10mm to 40mm defining a helical screw formation having a core diameter d_2 of approximately 3.5mm and a helical screw diameter d_1 of approximately 8mm.
- 10 The bone cutting guide 10 comprises a moulding 14; mounting formations 15; five cutting tool guides 16; and a pin-guiding formation in the form of a cylindrical tubular guide formation 20.

The moulding 14 is constructed from anatomical data obtained from a lower extremity
15 22 of the femur 24 prior to surgery. The moulding 14 is constructed prior to the surgical procedure, from anatomical data obtained by means of a radiographic scan of the lower extremity 22 of the patient's femur 24, from which scan, a three-dimensional model of the lower extremity 22 is constructed (not shown).

- 20 The moulding 14 defines locating formations 26 on an inner side thereof which correspond to anatomical formations 28 defined on the lower extremity 22 of the femur 24 (shown in Figure 5B). The locating formations 26 provide for secure fitment of the moulding 14 to the lower extremity 22 of the femur 24 in a specific position. More particularly, the profiles of the locating formations 26 of the moulding 14
25 conform to the profiles of corresponding anatomical formations 28 of the lower extremity 22 of the femur 24.

The mounting formations 15 define apertures 17 therethrough for receiving bone mounting pins (not shown) for removably mounting and fixedly securing the moulding
30 14 to the femur.

Each of the cutting tool guides 16 has a predetermined orientation and spatial relationship relative to the moulding 14 which is obtained from the anatomical data of the lower extremity 22 of the femur 24. After fitment of the moulding 14 to the lower

extremity 22 of the femur 24, the cutting tool guides 16 are positioned and located relative to the femur for guiding a cutting tool 48 for cutting prosthetic joint locating faces 32 in the lower extremity 22 of the femur 24, to allow for the secure fitment of a prosthetic joint (not shown) to the lower extremity 22 of the femur 24 in a predetermined orientation which approximates the anatomical normality of the patient's knee joint.

The cutting tool guides 16 include an anterior cut cutting tool guide formation 16.1, an anterior chamfer cutting tool guide formation 16.2, a posterior chamfer cutting tool guide formation 16.3, a posterior cut cutting tool guide formation 16.4, and a distal cut cutting guide tool guide formation 16.5 for guiding the cutting, respectively, of an anterior cut which forms an anterior cut joint locating face 32.1; an anterior chamfer which forms an anterior chamfer joint locating face 32.2; a posterior chamfer which forms a posterior chamfer joint locating face 32.3; a posterior cut which forms a posterior cut joint locating face 32.4; and a distal cut which forms a distal cut joint locating face 32.5.

The guide formation 20 is configured for positioning a bone cutting guide assembly, such as, for example, the bone cutting guide assembly 36 (shown in Figure 6) relative to the lower extremity 22 of a femur 24 of a human patient's knee joint during a knee joint replacement surgical procedure, as will be explained in more detail hereinbelow.

The bone cutting guide assembly 36 is similar to the distal femoral cutting guide apparatus disclosed in US patent US 5,417,694. More particularly, the bone cutting guide assembly 36 is configured for guiding the cutting of joint locating faces in the lower extremity 22 of the femur 24 in order to allow for the secure fitment of a prosthetic joint (not shown) to the femur 24 in a predetermined orientation which approximates the anatomical normality of the patient's knee joint. The bone cutting guide assembly 36 includes a bone cutting guide 38; and guide mounting means in the form of a valgus block and stylus assembly 42 for releasably mounting the bone cutting guide 38 to the femur 24, as will be explained in more detail below.

The bone cutting guide 38 has a dove-tail like recess 43 defined on an inner side thereof and a cutter guide formation in the form of a distal femoral cutting block 40 for guiding a cutter (not shown) for cutting a prosthetic joint locating face (not shown) in the lower extremity 22 of the femur 24.

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The valgus block and stylus assembly 42 includes a valgus block 45 and a stylus 46, which are both illustrated in Figure 7 of the drawings; and a locking screw 48 illustrated in Figure 6 of the drawings.

10 The valgus block 45 has a rectangular prism shape and includes a pair of spaced apart apertures 50 extending therethrough; a central angled aperture 52 extending therethrough and a pair of lock nuts 54, each lock nut threadably engages the valgus block 45 adjacent a different one of the pair of spaced apart apertures 50, the purpose of these features will be explained in more detail hereinbelow. The central
15 angled aperture 52 is angularly offset with respect to a line that is normal to the opposite parallel faces of the rectangular prism shaped valgus block 45 through which the aperture 52 extends. The reason for this will be explained in more detail hereinbelow.

20 The stylus 46 has a T-shaped configuration and includes a first carrying arm 56 and a second carrying arm 58. The second carrying arm 58 extends perpendicularly from a middle region of the first carrying arm 56, as illustrated in Figure 7 of the drawings. The first carrying arm 56 of the stylus 46 has a pair of upstanding posts 60 projecting upwardly therefrom. The second carrying arm 58 of the stylus 46 has a pair of
25 opposite parallel sides which have a bevelled configuration such that the second carrying arm 58 forms a dove-tail type connector, the purpose of which will be explained in more detail hereinbelow.

The guide formation 20 defines a cylindrical guide passage 34 in which the reference
30 pin 8 is received for guiding insertion of the reference pin 8 into the lower extremity 22 of the femur 24, when the moulding 14 is fitted to the femur 24.

The guide formation 20 has a predetermined orientation and spatial relationship relative to the moulding 14 and is integrally formed therewith. More specifically, the

orientation and spatial relationship of the guide formation 20 relative to the moulding 14, is obtained from the anatomical data obtained from a radiographic scan of the joint bone from which scan the position and orientation of a longitudinal axis 44 of the joint bone is accurately ascertained.

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After fitment of the moulding 14 to the lower extremity 22 of the femur 24 in said specific position, as shown in Figure 3 of the drawings, such that the locating formations 26 of the moulding 14 are aligned with the corresponding anatomical formations 28 of the lower extremity 22 of the femur 24, the guide formation 20 guides insertion of the reference pin 8 along an axis accurately aligned with respect to the longitudinal axis 44 of the femur 24.

10

In use, the guide formation 20 provides for the location of the reference pin 8 relative to the femur 24 such that the reference pin 8 is accurately aligned with respect to the longitudinal axis 44 of the femur 24. More particularly, in use, the guide formation 20 provides for location of the valgus block and stylus assembly 42 of the bone cutting guide assembly 36, when the valgus block and stylus assembly 42 is releasably mounted to a projecting end region of the inserted reference pin 8, in use, thereby to provide for the accurate location of the bone cutting guide 38 with respect to the patient's femur 24 at a predetermined position relative to the longitudinal axis 44 of the femur 24, so as to facilitate the cutting of prosthetic joint locating faces in the lower extremity 22 of the femur 24, thereby to provide for the fitment of the prosthetic joint thereto in a predetermined orientation which approximates the anatomical normality of the patient's joint.

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More particularly, in use, by mounting the valgus block and stylus assembly 42 to the projecting end portion of the reference pin 8 the surgeon is able to adjust the positioning of the bone cutting guide 38 of the bone cutting guide assembly 36 such that the distal femoral cutting block 40 of the bone cutting guide 38 is located at a predetermined position, so as to guide the cutting of joint locating faces into the lower extremity 22 of the femur 24 which allow for the fitment of the prosthetic joint to the femur and furthermore for the correct orientation of the prosthetic joint with respect to a particular patient's bone and soft tissue anatomy, when the prosthetic joint is fitted thereto.

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In use, a surgeon will select a valgus block 45 from a library of valgus blocks. Each valgus block is configured to compensate for a different so-called "valgus angle" of the patient, to produce a desired orientation of cuts into the patient's distal femur. In use, the selected valgus block is releasably mounted to the reference pin 8 by receiving the projecting end portion of the reference pin 8 within the central angled aperture 52 of the valgus block 45 and sliding the valgus block 45 down the reference pin 8 to the position shown in Figure 6 of the drawings. The stylus 46 is then releasably mounted to the valgus block 45 by inserting the posts 60 projecting from the first carrying arm 56 of the stylus 46 through the pair of apertures 50 defined through the valgus block 45 and locking the lock nuts 54 such that each lock nut 54 clamps onto a different one of the pair of posts 60 for releasably mounting the stylus 46 and the valgus block 45 to one another. The bone cutting guide 38 is then releasably mounted to the valgus block and stylus assembly 42, as shown in Figure 6 of the drawings, so as to locate the distal femoral cutting block 40 relative to the lower extremity 22 of the femur 24. More particularly, as best illustrated in Figure 7 of the drawings, the second clamping arm 58 of the stylus 46 is slidingly received within the dove-tail type recess 43 defined on the inner side of the bone cutting guide 38, as illustrated in Figure 7 of the drawings. The bone cutting guide 38 is then fixedly secured to the femur by means of bone mounting pins (not shown). After the bone cutting guide 38 is fixedly secured to the femur, the reference pin 8, and the valgus block and stylus assembly 42 are then removed from the femur, leaving only the bone cutting guide 38 mounted to the patient's femur 24. The distal femoral cutting block 40 of the bone cutting guide 38 then guides surgical cutters used to cut a distal cut into the patient's distal femur to provide a first one of a series of joint locating faces cut into the femur, to provide for the fitment of the prosthetic joint thereto in a pre-determined configuration. For example, if a surgeon selects a 6° valgus block, a cut made on the anterior distal femur will be offset by 6° with reference to the longitudinal axis 44 of the patient's femur 24. This cut will also be normal to a mechanical axis of the patient's femur. The distal cut thus defines the distal joint locating face which is then used to orientate other cutting guides (not shown), for guiding the cutting of a series of second and subsequent prosthetic joint locating faces which are cut into the lower extremity of the patient's femur.

The cutting tool guides 16 and the guide formation 20 permit a surgeon, in use, to make an election intra-operatively during bone replacement surgery between utilizing the cutting tool guides 16 or the guide formation 20, or both. More specifically, after the surgeon has performed a visual inspection and an assessment of the soft tissue requirements of the patient intra-operatively during bone replacement surgery, the surgeon is then in a position to proceed with the pre-operative plan if satisfied that the soft tissue favours the pre-operative planned cutting of the patient's bone. More particularly, if entirely satisfied, the surgeon can then commence the cutting of the patient's bone, utilizing the cutting tool guides 16 to guide the cutting tool 48, as shown in Figure 4 of the drawings, to guide the cutting of the prosthetic joint locating faces 32, as shown in figure 5A of the drawings.

If, however, after the visual inspection and assessment of the patient's soft tissue, the surgeon wishes to deviate entirely from the pre-operative plan, then the guide formation 20 of the bone cutting guide 10 and the reference pin 8 of the bone cutting guide system 100 enables the surgeon to guide the insertion of the reference pin 8 into the lower extremity 22 of the patient's femur 24, thereby permitting the surgeon to mount the bone cutting guide assembly 36 to the patient's bone, as described hereinabove. This permits the surgeon to deviate entirely from the pre-operative plan and adjust the position of cuts to be made to the bone, which the surgeon deems necessary after his visual inspection and assessment of the patient's soft tissue of the patient's knee joint, so as to guide the cutting of joint locating faces which will approximate the anatomical normality of the patient's knee joint, after fitment of the prosthesis thereto.

Alternatively, if, however, after a visual inspection and assessment of the patient's soft tissue, the surgeon wishes to deviate partially from the pre-operative plan, then the surgeon may utilize a selected one or more of the cutting tool guides 16 and the guide formation 20. More specifically, if the surgeon is satisfied only with the pre-operative plan relating to the pre-planned mechanical axis of the patient's leg, the surgeon may utilize the distal cutting tool guide 16.5 to guide the cutting of the distal cut joint locating face 32.5, thereby to establish the mechanical axis of the patient's leg after fitment of the prosthetic joint to the patient. Furthermore, if the surgeon is satisfied also with the pre-operative plan relating to the pre-planned external rotation

of the prosthetic joint, then the surgeon may utilize the anterior cutting tool guide 16.1 to guide the cutting of the anterior cut joint locating face 32.1, thereby to establish the so-called "external rotation" of the femoral component of the prosthetic joint about a central axis of rotation of the prosthetic joint which is parallel to the mechanical axis

5 of the patient's leg.

The surgeon may then also utilize the guide formation 20 of the bone mounting structure 12 of the bone cutting guide 10 to guide the insertion of the reference pin 8 into the lower extremity 22 of the patient's femur 24, so as to permit the surgeon to

10 mount the bone cutting guide assembly 36 to the patient's bone, so as to permit the surgeon to execute the balance of the cuts to be made to the patient's bone using the bone cutting guide assembly 36, which particularly, as explained hereinabove, permits the surgeon to make adjustments to the location and configuration of cuts made to the patient's femur 24.

15

The invention extends to a bone cutting guide 10 as hereinabove described and defined.

It will be appreciated that the exact configuration of the bone cutting guide system

20 100 and the bone cutting guide 10 in accordance with the invention, may vary greatly while still incorporating the essential features of the invention as described hereinabove. For example, the applicant also envisages that in another embodiment (not shown) the guide passage may be configured for guiding insertion of a reference pin into the femur along an axis which, after fitment of the moulding to the end region

25 of the joint bone, is aligned with the mechanical axis of a femur.

CLAIMS:

1. A bone cutting guide for use in a joint replacement surgical procedure for guiding the cutting of at least one prosthetic joint locating face in an end region of a joint bone of a human patient, the bone cutting guide including:
 - (a) a moulding which is constructed from anatomical data obtained of the end region of the joint bone so as to define locating formations which correspond to anatomical formations of the end region of the joint bone, thereby to provide for the secure fitment of the bone mounting structure to the end region of the joint bone wherein the profile of the complementary locating formations of the moulding conforms to the profile of the corresponding anatomical formations of the end region of the joint bone; and
 - (b) at least one cutting tool guide having a predetermined orientation and spatial relationship relative to the moulding which is obtained from the anatomical data of the end region of the joint bone, the cutting tool guide, after fitment of the moulding to the end region of the joint bone, being positioned and located for guiding a cutting tool for cutting a prosthetic joint locating face in an end region of the joint bone, to allow for the secure fitment of a prosthetic joint to the joint bone in a predetermined orientation which approximates the anatomical normality of the patient's joint; and
 - (c) a pin-guiding formation which defines a guide passage having a predetermined orientation and spatial relationship relative to the moulding for guiding insertion of a reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, has a predetermined spatial relationship with respect to at least one of a mechanical axis of the joint bone and a longitudinal axis of the joint bone, so as to provide for mounting of guide mounting means of a bone cutting guide assembly to a projecting end region of the inserted reference pin, in use, thereby to facilitate accurate location of a bone cutting guide of the bone cutting guide assembly relative to the joint bone, for guiding the cutting of the prosthetic joint locating face in the end region of the joint bone,

whereby, the cutting tool guide and the pin-guiding formation permit a surgeon to make an election intra-operatively during bone replacement surgery between utilizing at least one of the cutting tool guide and the pin-guiding formation.

2. A bone cutting guide as claimed in Claim 1, wherein the guide passage is configured for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the longitudinal axis of the joint bone.
3. A bone cutting guide as claimed in Claim 1, wherein the guide passage is configured for guiding insertion of a reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the mechanical axis of the joint bone.
4. A bone cutting guide system for use in a joint replacement surgical procedure for guiding the cutting of at least one prosthetic joint locating face in an end region of a joint bone of a human patient, the bone cutting guide system including:

a reference pin which is configured to be at least partially inserted into an end region of a patient's joint bone; and

a bone cutting guide including:

- (a) a moulding which is constructed from anatomical data obtained of the end region of the joint bone so as to define locating formations which correspond to anatomical formations of the end region of the joint bone, thereby to provide for the secure fitment of the bone mounting structure to the end region of the joint bone wherein the profile of the complementary locating formations of the moulding conforms to the profile of the corresponding anatomical formations of the end region of the joint bone; and

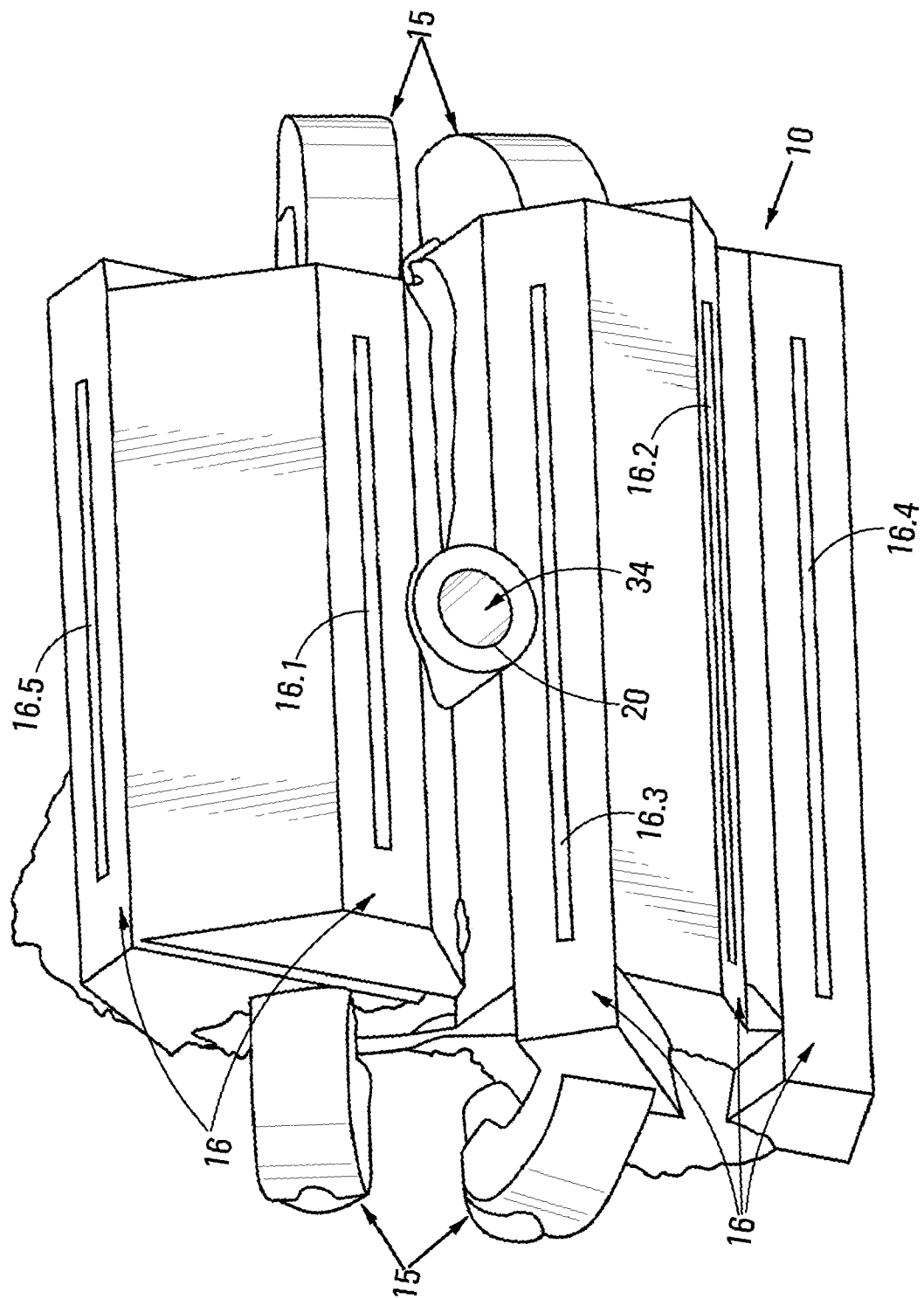
(b) at least one cutting tool guide having a predetermined orientation and spatial relationship relative to the moulding which is obtained from the anatomical data of said end region of the joint bone, the cutting tool guide, after fitment of the moulding to the end region of the joint bone, being positioned and located for guiding a cutting tool for cutting a prosthetic joint locating face in an end region of the joint bone, to allow for the secure fitment of a prosthetic joint to the joint bone in a predetermined orientation which approximates the anatomical normality of the patient's joint; and

(c) a pin-guiding formation which defines a guide passage having a predetermined orientation and spatial relationship relative to the moulding for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, has a predetermined spatial relationship with respect to at least one of a mechanical axis of the joint bone and a longitudinal axis of the joint bone, so as to provide for mounting of guide mounting means of a bone cutting guide assembly to a projecting end region of the inserted reference pin, in use, thereby to facilitate accurate location of a bone cutting guide of the bone cutting guide assembly relative to the joint bone, for guiding the cutting of the prosthetic joint locating face in the end region of the joint bone,

whereby, the cutting tool guide and the pin-guiding formation permit a surgeon to make an election intra-operatively during bone replacement surgery between utilizing at least one of the cutting tool guide and the pin-guiding formation.

5. A bone cutting guide system as claimed in Claim 4, wherein the guide passage is configured for guiding insertion of the reference pin into the joint bone along an axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the longitudinal axis of the joint bone.
6. A bone cutting guide as claimed in Claim 4, wherein the guide passage is configured for guiding insertion of a reference pin into the joint bone along an

axis which, after fitment of the moulding to the end region of the joint bone, is aligned with the mechanical axis of the joint bone.



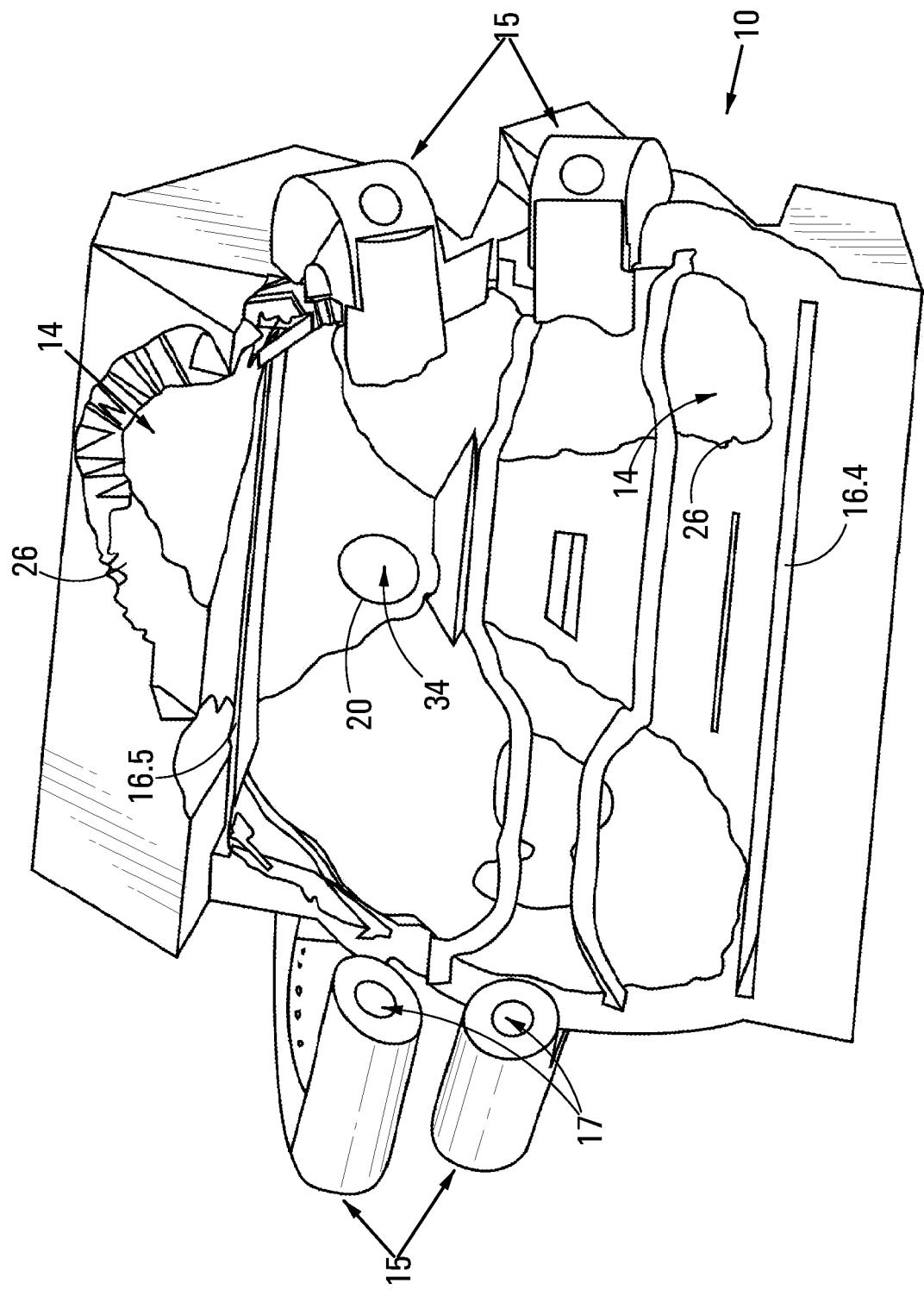
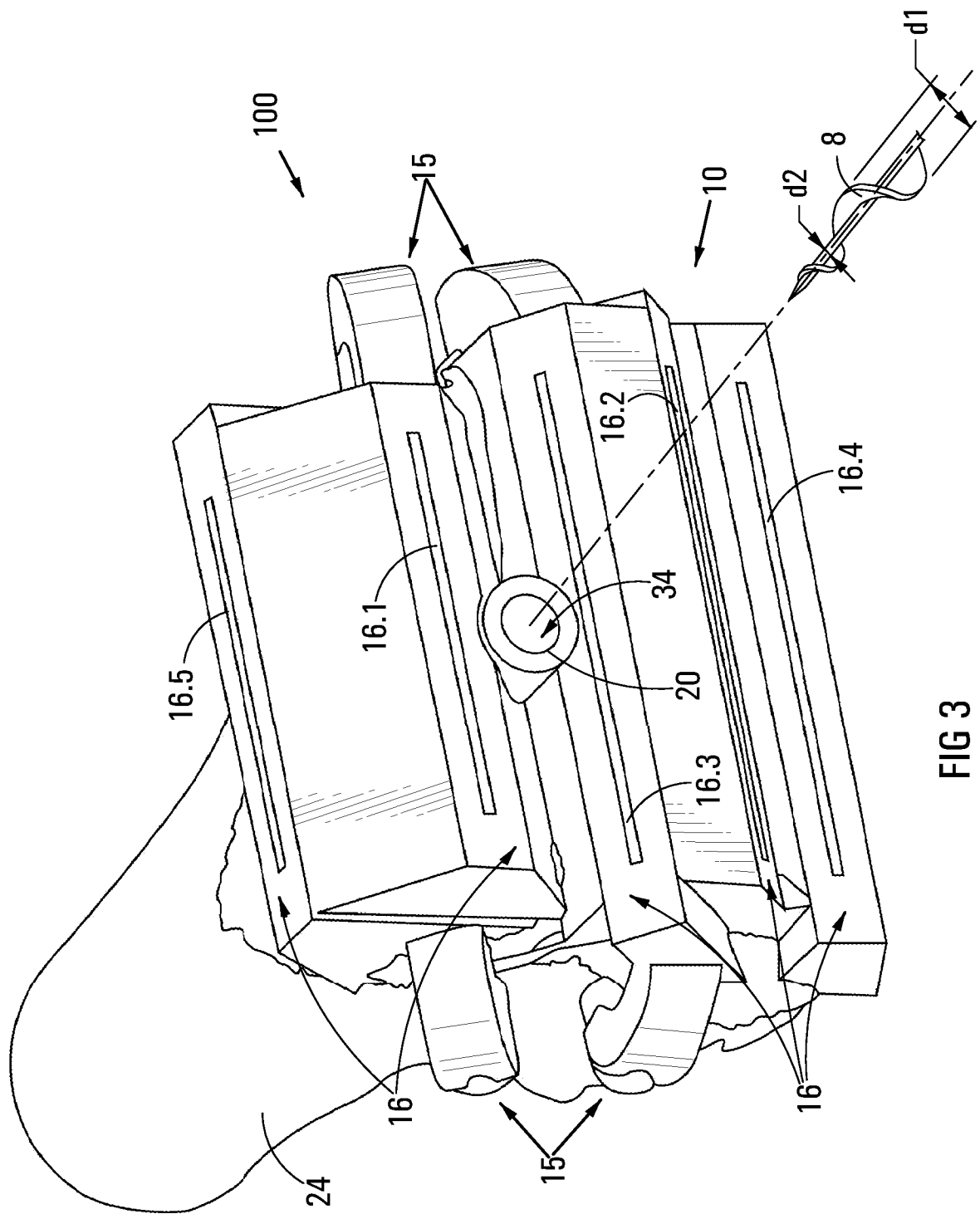


FIG 2



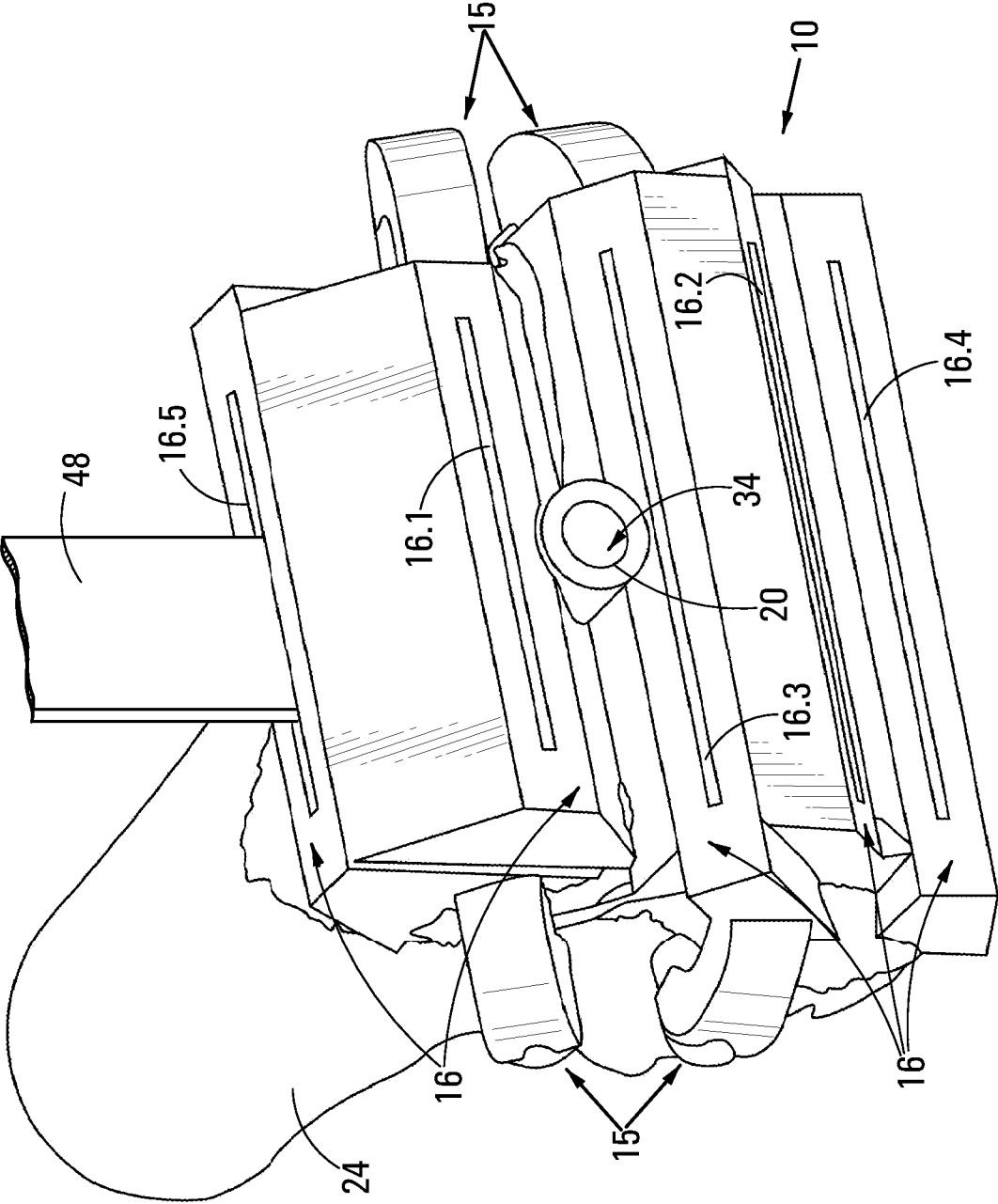


FIG 4

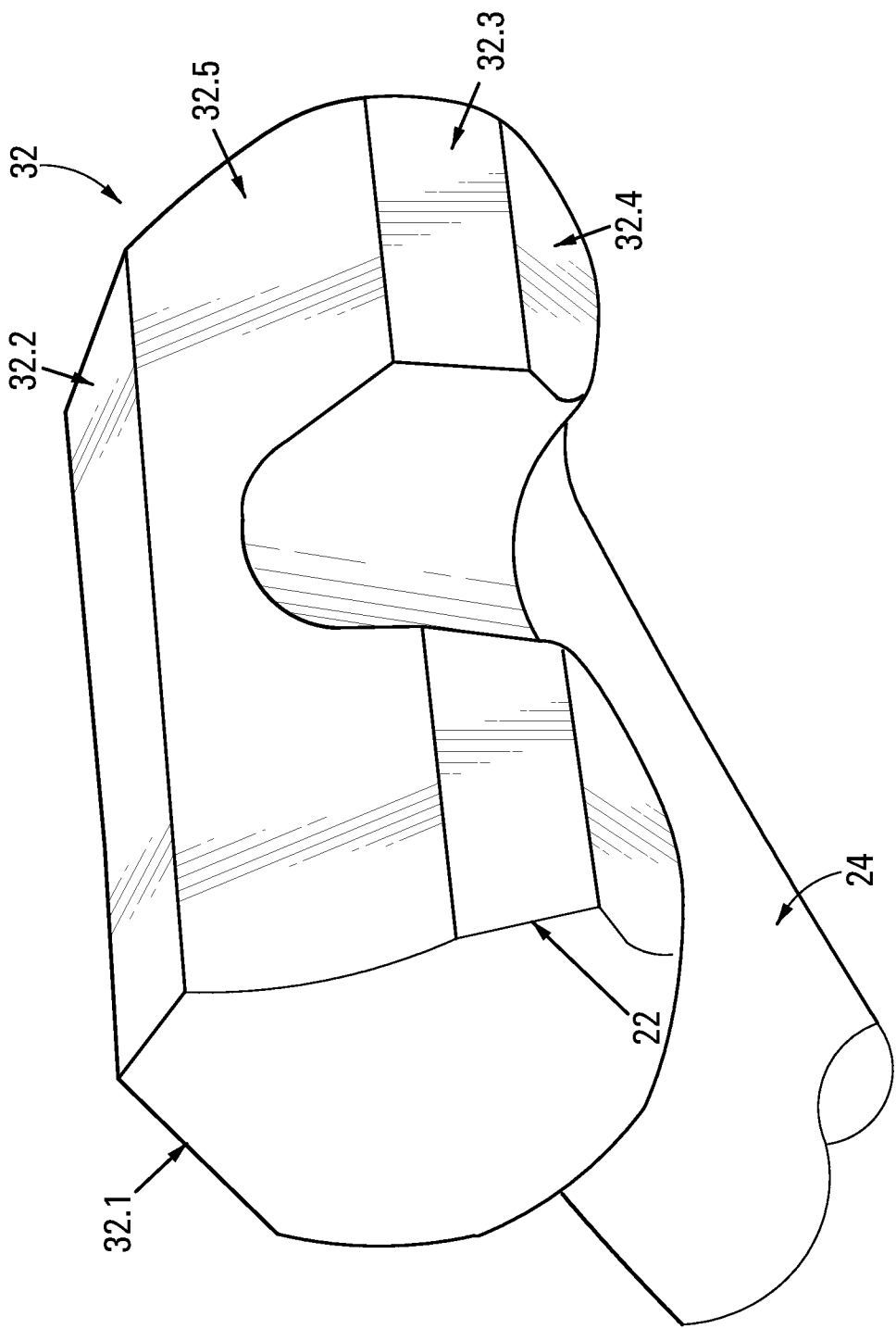


FIG 5A

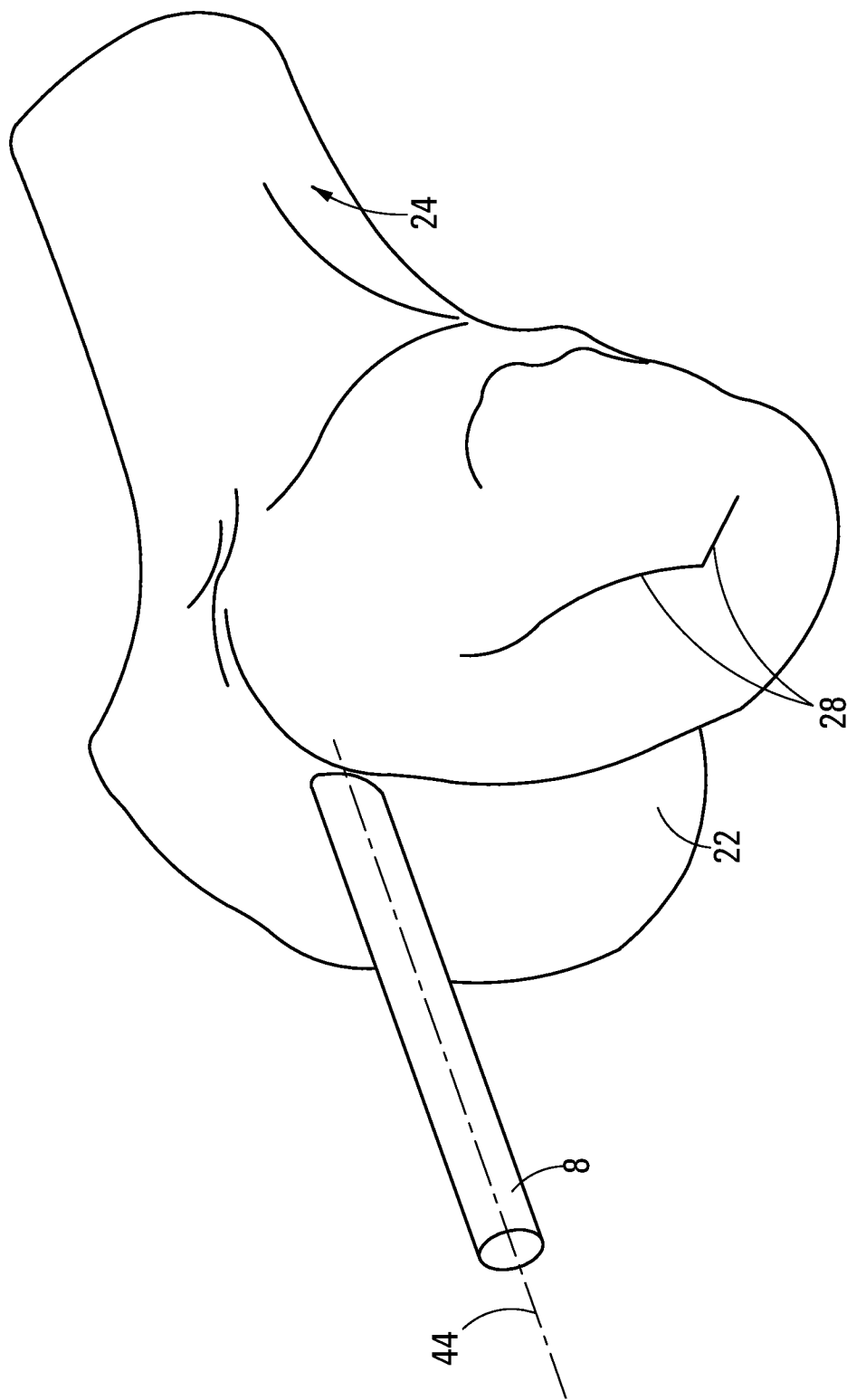


FIG 5B

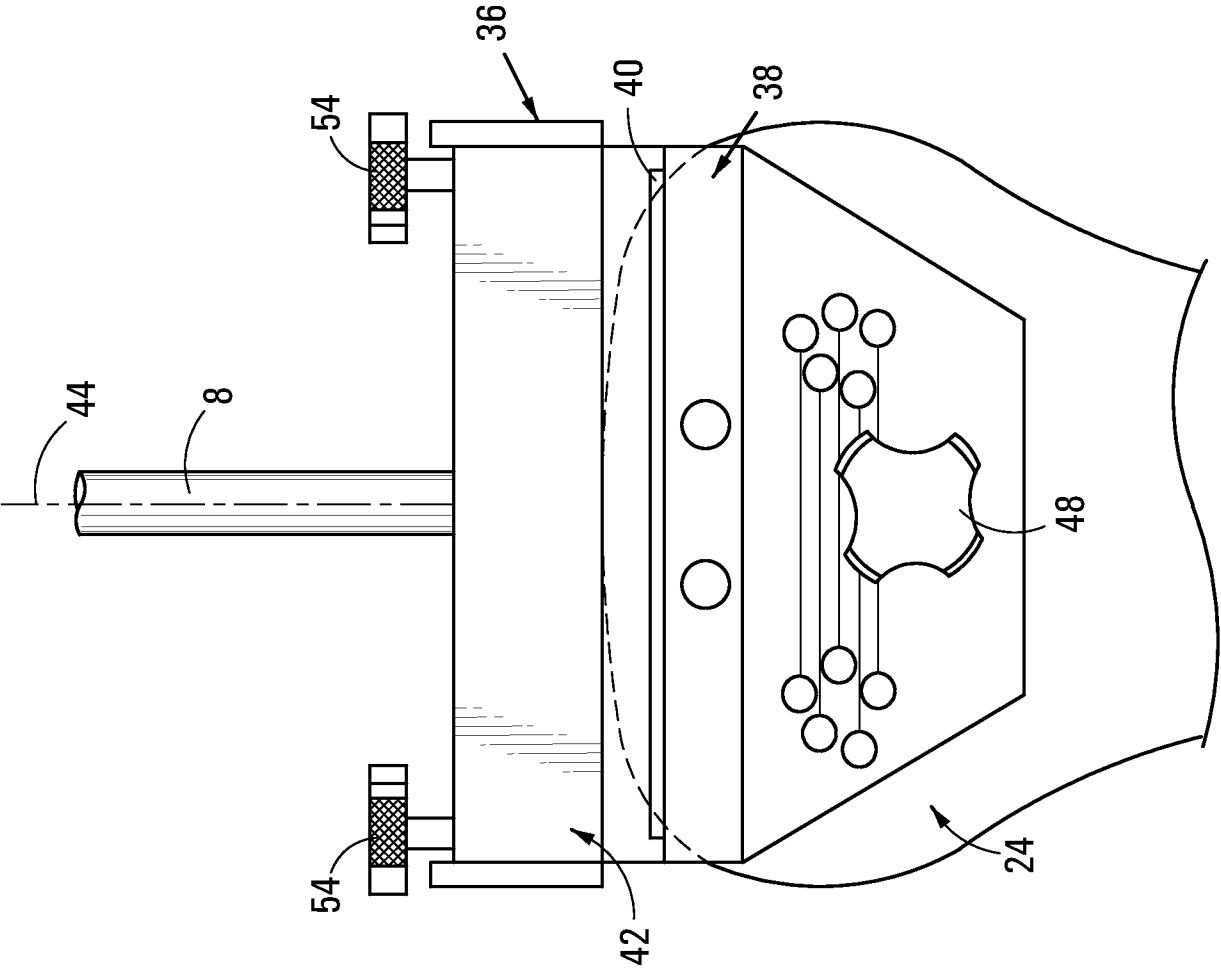


FIG 6

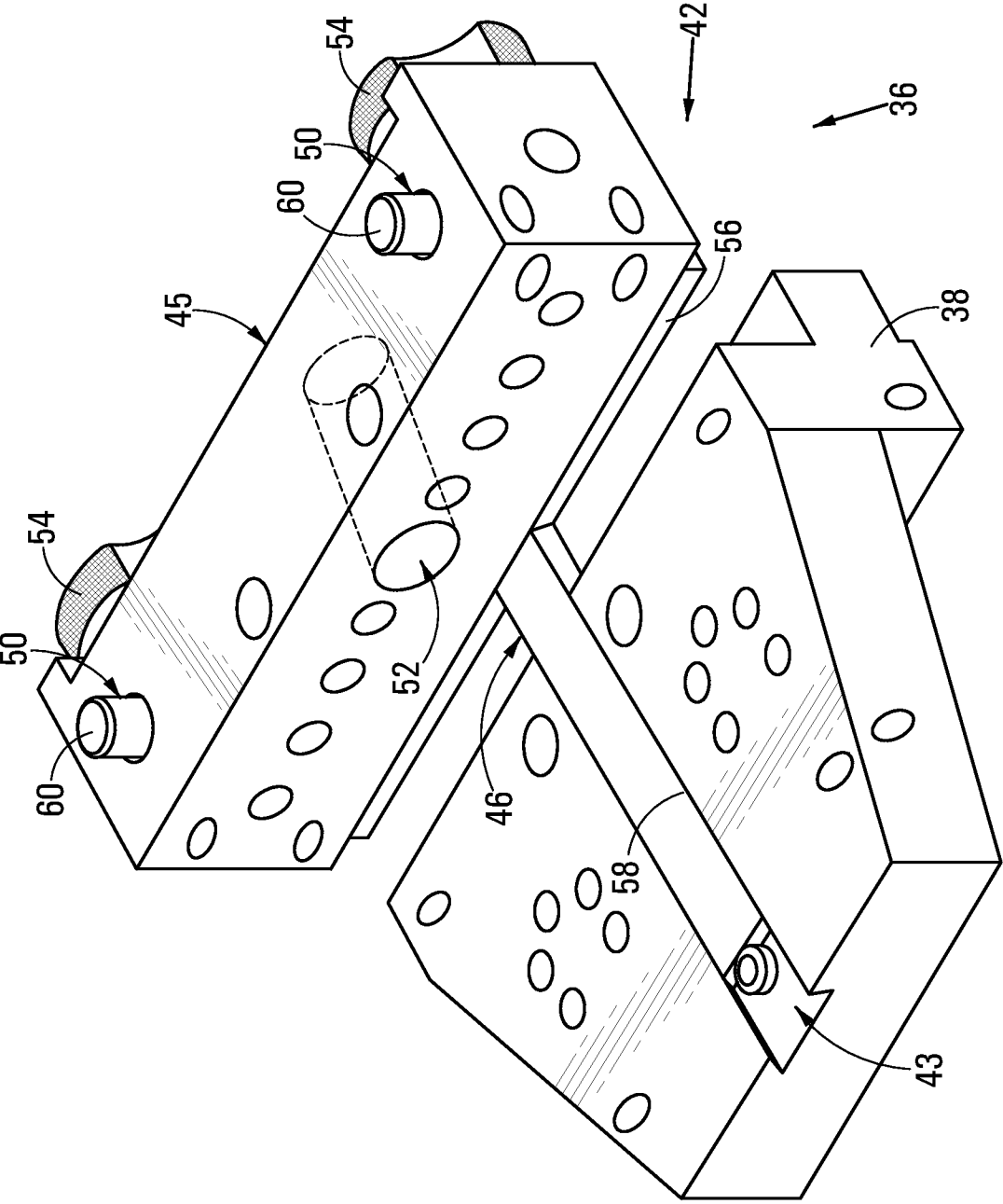


FIG 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/052068

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/15
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)
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 practicable, search terms used)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 2011/156748 A2 (SMITH & NEPHEW INC [US]; AGNIHOTRI AASHIISH [US]; CONWAY PATRICK BRIAN) 15 December 2011 (2011-12-15) page 16, line 18 - page 20, line 22 page 28, line 8 - page 29, line 5 figures 1-9	1,3,4,6



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

5 July 2013

Date of mailing of the international search report

16/07/2013

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INTERNATIONAL SEARCH REPORT

International application No
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Information on patent family members

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