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(54) Title: SYSTEM AND METHOD FOR HIGH TIBIAL OSTEOTOMY

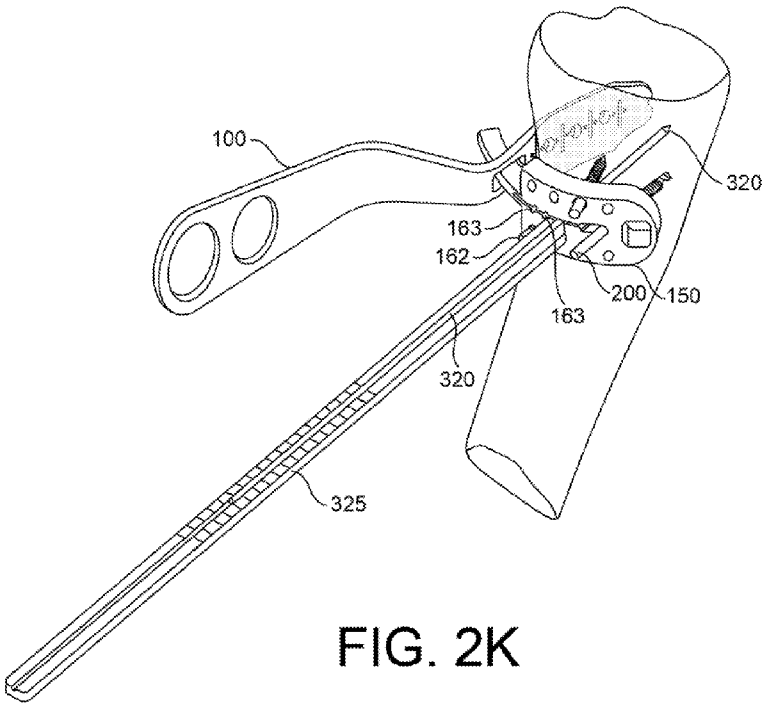


FIG. 2K

(57) Abstract: Apparatus and methods for a high tibial osteotomy (HTO) are disclosed, including system and methods for guiding a medial cut, system and methods for guiding an anterior cut, and also system and methods for providing fixation and compression to a lateral hinge during an HTO. Each of the apparatus may stand-alone. The system for creating a medial cut may include a retractor, a linkable cutting guide and a pin. The system for guiding an anterior cut may include a guide for sliding over a pin and an alignment surface and a fixation means. The apparatus for fixing and compressing a lateral hinge may include a plate, an adjustable drill guide for adjusting an offset of the plate from a bone surface and a bi-angle drill guide.

[Continued on next page]

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SYSTEM AND METHOD FOR HIGH TIBIAL OSTEOTOMY

FIELD OF THE INVENTION

This invention is related to surgical apparatus and methods in general, and more particularly to apparatus and methods for a high tibial osteotomy (HTO), including apparatus and methods for creating a medial cut, apparatus and methods for creating an anterior cut, and also apparatus and methods for providing fixation and compression to a lateral hinge during a HTO.

BACKGROUND

Osteotomies of the knee are an important technique for treating knee osteoarthritis. In essence, knee osteotomies may be used to adjust the geometry of the knee joint so as to transfer weight bearing load from arthritic portions of the joint to relatively unaffected portions of the joint. Knee osteotomies are also an important technique for addressing abnormal knee geometries, e.g., due to birth defect, injury, etc. Most knee osteotomies are designed to modify the geometry of the tibia, so as to adjust the manner in which the load is transferred across the knee joint. One of the ways to adjust the orientation of the tibia is an open wedge technique wherein a cut is made into the upper portion of the tibia, the tibia is manipulated so as to open a wedge-like opening in the bone, and then the bone is secured in this position (e.g., by screwing metal plates to the bone or by inserting a wedge-shaped implant into the opening in the bone), whereby to reorient the lower portion of the tibia relative to the tibial plateau and hence adjust the manner in which load is transferred from the femur to the tibia. Creating a consistent wedge-like opening in the bone with the necessary precision, at the correct angle and with a minimum of trauma to the surrounding tissue (e.g., the neurological and vascular structures at the back of the knee) is procedurally challenging. Furthermore, with open wedge osteotomies, it can be difficult to stabilize the upper and lower portions of the tibia relative to one another and to maintain them in this position while healing occurs. Some attempted solutions have tried to provide a system, but this has not sufficiently addressed the needs of the industry owing to its complexity. The present invention is directed to as medial open wedge, high tibial osteotomy of the knee, that may be and is intended to provide increased precision with a streamlined system when creating the wedge-shaped opening in the bone, and to provide stability to the upper and lower portions of the tibia while healing occurs.

BRIEF DESCRIPTION OF THE DRAWINGS

For a detailed description of example embodiments, reference will now be made to the accompanying drawings in which:

FIG. 1A-1B shows a tibia with a vertical anatomical marker line for marking a boundary of a lateral hinge;

FIG. 2A shows a retractor disposed on a posterior portion of a tibia, in accordance with the present disclosure;

FIG. 2B shows a retractor and cutting guide disposed around a tibia, in accordance with the present disclosure;

FIG. 2C shows a cutting datum plane defined by the retractor and cutting guide, in accordance with the present disclosure;

FIG. 2D shows the cutting datum plane defined by the retractor and cutting guide oriented through the tibia, in accordance with the present disclosure;

FIG. 2E shows a retractor, cutting guide and anterior pin oriented relative to the tibia, in accordance with the present disclosure;

FIG. 2F shows a view of datum plane, in accordance with the present disclosure;

FIG. 2G shows a cutting datum plane and boundaries defined by the retractor and cutting guide and pin, in accordance with the present disclosure;

FIG. 2H shows a linking guide system aligned with a tibia, in accordance with the present disclosure;

FIG. 2I shows an alternative view of a linking guide system aligned with a tibia, in accordance with the present disclosure;

FIG. 2J shows a method of aligning the anterior pin, in accordance with the present disclosure;

FIG. 2K shows a K-wire and depth gauge extending through the cutting guide, in accordance with the present disclosure;

FIG. 2L shows a view of a linking guide system with a saw therethrough, in accordance with the present disclosure;

FIG. 2M shows an anterior view of a system relative to the tibia, in accordance with the present disclosure;

FIG. 3A illustrates a medial-anterior view of the tibia with a pin inserted and an anterior cutting guide, in accordance with the present disclosure;

FIGS. 3B, 3C and 3D show the method of aligning an anterior cutting guide, in accordance with the present disclosure;

FIG. 4A and 4B show an alternative embodiment and method of use of an anterior cutting guide, in accordance with the present disclosure;

FIGS. 5A illustrates an exploded view of a laminar spreader in accordance with the present disclosure;

FIGS. 5B illustrates an side view of a laminar spreader in accordance with the present disclosure;

FIGS. 5C illustrates tips of a laminar spreader placed within a cut (10) in accordance with the present disclosure;

FIGS. 6A illustrates a plurality of wedges in accordance with the present disclosure;

FIGS. 6B illustrates a method of using wedges of FIGS. 6A in accordance with the present disclosure;

FIGS. 7A-7G show a method of compressing a lateral hinge using a plate and drill system, in accordance with the present disclosure;

FIGS. 8A and 8B show a top view and cross-section view respectively, of a bi-modal drill guide in accordance with the present disclosure;

FIGS. 9A and 9B show an exploded view and cross-section view respectively, of an adjustable drill guide in accordance with the present disclosure;

FIG. 10 illustrates a the mechanics of compressing a lateral hinge, in accordance with the present disclosure;

FIGS. 11 shows an isometric view of a plate embodiment, contoured and aligned with a tibia, in accordance with the present disclosure;

FIG. 12A schematically illustrates a contoured plate embodiment in accordance with the present disclosure; and

FIG. 12B schematically illustrates a contoured plate embodiment relative to a tibial diaphysis axis in accordance with the present disclosure.

SUMMARY

Various terms are used to refer to particular system components. Different companies may refer to a component by different names – this document does not intend to distinguish between components that differ in name but not function. In the following discussion and in the claims, the terms "including" and "comprising" are used an open-ended fashion, and thus should be interpreted to mean "including, but not limited to... ." Also, the term "couple" or "couples" is intended to mean either an indirect or direct connection. Thus, if a first device couples to a second device, that connection may be through a direct connection or through an indirect connection via other devices and connections.

Generally this disclosure describes a plurality of systems that may each be used together, serially, or may alternatively be used independently of each other. Each of the systems is configured to perform part of a procedure to form and stabilize an open wedge osteotomy. More specifically these systems may include a first system that aids in guiding a cutting tool along a preferred datum plane through a medial portion of the tibia; a second system that aids in guiding a cutting tool along a preferred anterior portion of the tibia, a third system that distracts the bony hinge and a fourth system that provides compression on a lateral hinge of an open wedge. Various embodiments are therefore directed to a variety of systems and methods for guiding the medial and anterior cuts through a tibia distracting and compressing a lateral hinge. The specification now turns to an example system.

Various embodiments are directed to a system for stabilizing and compressing a lateral hinge for an HTO procedure system including a plate have a plurality of holes therethrough and a tool such as a drill guide configured to extend through at least one of the plurality of holes and adjust an offset or standoff between the plate and a bone surface and thereby adjust flexion on the plate. Adjustment may be through rotating a portion of the drill guide. In some embodiments this tool is separate from the drill guide. The distal tip of the drill guide may be threadingly engaged with at least one of the holes and rotating the distal tip may translate the distal tip further through the corresponding hole, for example.

Another embodiment bone fixation system for stabilizing and compressing a lateral hinge for an HTO may include a bone plate with an interior surface, an exterior surface and a plurality of holes therethrough. The system also includes a drill guide configured to adjustably extend through at least one of the plurality of holes and adjust an offset between the plate interior surface and a bone surface and thereby adjust flexion on the bone plate. In some example embodiments the drill guide may include an outer shaft and an axially moveable inner shaft, the outer shaft configured to operatively couple to the at least one of the plurality of holes and the inner shaft configured to extend through the same hole,

engage the bone surface and push the bone plate away from the bone surface and thereby adjust flexion on the bone plate. In some example embodiments the bone plate may include a head portion that is shaped to conform to a metaphysis of the bone and the head portion may include one of more polyaxial openings. The system may further include fixation means such as a locking screw configured to cooperate with the polyaxial opening, thereby defining a polyaxial locking system that lockingly fixes the bone plate with the bone. The polyaxial locking system may be configured to direct the fixation means at an angle that avoids an anatomical structure within the metaphysis of the bone, such as a ligament or ligament tunnel. Some example embodiments may also include a dual angle drill guide, that may operatively couple with a polyaxial opening though the bone plate. A stem portion of the bone plate may also include a polyaxial opening. The dual angle drill guide may have a first guide axis for directing a first provisional fixation means at a first angle into the bone. The first angle is configured to move a median portion of the bone plate onto the bone surface, resulting in a rotation of a diasphysis bone segment of bone centered at the provisional screw and thereby compress the lateral bony hinge. The dual angle drill guide may also include a second guide axis that may be oriented at a non-zero angle relative the first axis, for guiding a drill to form a pilot hole in the bone at a second angle, different to the first angle. In some embodiments the bone plate comprises a head portion and a stem portion extending therefrom, wherein the stem portion comprises at least two openings of the plurality of openings, and wherein a first of the at least two openings is a polyaxial opening, configured to operatively couple to the dual angle drill guide and a second of the at least two openings is configured to operatively couple to the adjustable drill guide. In some embodiments at least one of the openings of the plurality of openings is a polyaxial opening configured to receive a first fixation means at a first angle therethrough, and also upon removal of the first fixation means the polyaxial opening is configured to a second fixation means at a second angle therethrough.

A method of compressing a lateral hinge of an open wedge osteotomy is also disclosed including the steps of placing a bone plate over an open wedge osteotomy; fixing a superior portion of the plate to a first side of the open wedge osteotomy; moving an inferior end-portion of the bone plate away from a bone surface on a second side of the open wedge osteotomy so as to form a standoff that bows the bone plate; adjusting the standoff; and while maintaining the adjusted standoff provisionally fixing a median portion of the bone plate against the bone so as to compress the lateral hinge of the open wedge osteotomy, the median portion disposed on the second side of the open wedge osteotomy, between the superior portion and inferior end-portion. In some example methods, the superior portion of the plate may comprise at least one variable angle opening, and fixing the superior portion of the plate comprises directing a fixation means through the variable angle opening at an angle away from a structure within the bone. The structure may include an Anterior Cruciate Ligament (ACL), an ACL reconstructed tunnel or a meniscal root repair

tunnel. In some example methods, moving an inferior end-portion of the bone plate away from a bone surface and adjusting the standoff comprises engaging an end of an adjustment guide handle with an opening at the inferior end-portion of the plate and axially moving a shaft coaxial with, and operatively coupled to, the adjustment guide handle through the opening so as to engage a surface of the bone. In some example methods, shaft may be threadingly coupled to the adjustment guide handle, and rotation of the shaft axially moves the shaft along the adjustment guide handle. In some example methods, the median portion may include a variable angle opening and fixing the median portion comprises placing a provisional fixation means through the variable angle opening at an angle that places a rotation load on the second side of the open wedge osteotomy and thereby compresses the lateral hinge. In some example methods after the median portion is provisionally fixed, other portions of the bone plate may be permanently fixed to the bone; and then the provisional fixation means may be replaced with a permanent fixation means at a different insertion angle through the variable angle opening. In some example embodiments the provisional fixation means may be placed using a dual angle guide, and wherein the dual angle guide also comprises an axis oriented to direct a drill along the different insertion angle so as to form a pilot hole.

Another embodiment system may include a linking cutting guide system for preparing a medial cut during an HTO procedure, including a retractor for inserting in the posterior aspect of the tibia to protect neurovascular structures and provide a visual indication under fluoroscopy of a medial-lateral inclination vector. The system also includes a cutting guide pivotally coupled to the retractor, the cutting guide configured to wrap around a medial aspect of the tibia and includes an elongate cutting slot for receiving and controlling a cutting tool, such as a saw to create the medial cut. The cutting slot defines a posterior slope cutting vector. The linking cutting guide system also includes an anterior pin configured to be inserted through an opening in the cutting guide at a location that defines a boundary of a preferred datum plane and also lies on the datum plane, the preferred datum plane defined by the media-lateral inclination vector and the posterior slope cutting vector.

The cutting guide system may also include a pin locating guide that selectively couples to the cutting guide for guiding insertion of the anterior pin. The cutting guide pin locating guide may include a pin guide that couples to the cutting guide and an adjustable flag having a linear edge that may be aligned with the posterior slope cutting vector. The retractor may include a slot for receiving an arm of the cutting guide. The linking cutting guide system may also include an anterior cutting guide system for guiding an anterior cut during an HTO procedure. The anterior cutting guide having a lumen for sliding over the anterior pin and a cutting surface for guiding the trajectory of a bone cutter and a fixation means for coupling to the anterior cutting guide and stabilizing an orientation of the

anterior cutting guide. Fixation means may include a pin or screw that is inserted through a portion of the anterior cutting guide.

Another further embodiment system may include a cutting guide system for guiding an anterior cut during an HTO procedure. This cutting guide system may include a pin for inserting partially into a bone so that a portion of the pin is inserted into the bone and a portion is not inserted and exposed. The cutting guide system also includes a cutting guide having a lumen for sliding over the exposed portion of the pin, a cutting surface for guiding the trajectory of a bone cutting tool and fin configured to be inserted into an open wedge osteotomy and define an orientation for the cutting surface. The cutting guide also includes a fixation means for coupling to the cutting guide and stabilizing an orientation of the cutting guide.

DETAILED DESCRIPTION

The following discussion is directed to various embodiments of the invention. Although one or more of these embodiments may be preferred, the embodiments disclosed should not be interpreted, or otherwise used, as limiting the scope of the disclosure, including the claims. In addition, one skilled in the art will understand that the following description has broad application, and the discussion of any embodiment is meant only to be exemplary of that embodiment, and not intended to intimate that the scope of the disclosure, including the claims, is limited to that embodiment.

The disclosure may generally include four systems; a first system for precisely creating a cut extending from a medial side of the tibia, a second system for creating an anterior cut in the tibia, the anterior cut extending from the medial cut, a third system for distracting the two bone segments to a desired wedge angle and also a fourth system for stabilizing the open wedge formed by opening up the medial and anterior cut. T These systems may be used together but may also be used independently of each other. Stated otherwise as an example, the first system may be used to create a medial cut in the tibia and an anterior cut may either not be required, or be created using a different system not disclosed. As a further example the entire open wedge may be prepared using a system not disclosed herein, and the fourth system only may be applied to fix and compress the lateral hinge.

The first system is a linking guide system 90, best seen in its entirety in FIG. 2J and 2L, configured to define and control a datum plane for a medial cut or osteotomy line in the tibia. Linking guide system 90 generally includes a posterior retractor 100, cutting guide 150, anterior pin 200 and means to align the anterior pin 250. Linking guide system 90 provides a method to align the retractor 100 and a cutting guide 150 to define a medial cutting plane and retract and protect neurovascular structures during the medial opening wedge osteotomy. FIGS. 1A and 1B show a tibia 5 upon which an exemplary open wedge osteotomy is to be performed. In accordance with the present invention, the open wedge osteotomy is effected by first making a cut 10 into the upper tibia, and then manipulating the lower portion of the tibia 5 so as to open a wedge-like opening (shown in FIG. 6B) in the bone, with the wedge-like opening being configured so as to adjust the manner in which load is transferred from the femur to the tibia. If a vertical (anterior cut) is to be made in a later step, a line 15 is preferably marked along the medial side of the tibial tuberosity 20, the line 15 parallel to the anterior face 25 of the tibial plateau. This line 15 may be used later as the intersect of the medial cut with the anterior cut.

The cutting plane and advancement of a cutting tool may be visualised directly or under fluoroscopy. The linking guide system 90 may include a posterior retractor 100 that may be curved to aid placement over a posterior portion of the tibia 5, and a cutting guide 150 that links to the retractor 100. Seen in FIG. 2A posterior retractor 100 includes a handle 105, opening 110 and retracting portion 120 (retracting portion is shaded as it is behind

the tibia in FIG. 2A). Handle 105 is generally sized and shaped to be held by the user and place posterior retractor 100 at correct angle. Slot 110 may be disposed between the handle 105 and retracting portion 120 and may be sized to link with a cutting guide 150 (see in later figures). Shown in FIG. 2A retractor 100 is inserted in the posterior aspect of the tibia 5 to protect neurovascular structures and provide a visual indication under fluoroscopy of the medial-lateral inclination vector 130 (MLI Vector). This posterior retractor 100 can be inserted to retract and elevate the MCL, or behind the MCL to allow the medial cutting guide (described later) to provide retraction. Retracting portion 120 may comprise markings, such as a series of holes 122 aligned along a longitudinal axis (X-X) of retractor 100, so as to align the retractor 100 with the desired vector 130. Retracting portion 120 may also include a series of slots 124, oriented perpendicularly to the longitudinal axis (X-X) to provide measurements when visualized under fluoroscopy. Slots 124 may be spaced a set and equal distance from each other to aid the surgeon in gauging a saw depth through the tibia, and therefore slots 124 are openings, sufficiently wide to view a saw blade therethrough. Slots 124 may be spaced apart 10 mm for example. In addition, slots 124 are sufficiently long, or extend both sides of the longitudinal axis X-X so as to observe deviation of the saw blade away from the longitudinal axis X-X (explained in more detail in later figures). Retractor 100 preferably is made from a metal, so that it is easily sterilized and therefore reusable. Retractor is preferably visible under fluoroscopy. In alternative embodiments, retractor 100 may at least partially comprise a translucent or clear polymer, such as PEEK in order to better observe the saw blade path. Metal ribs, in locations approximately equivalent to the slot 124 locations may be added to improve rigidity of the retractor 100 and also protect the PEEK from the saw blade and formation of PEEK shavings within the patient. Metal ribs are also preferably visible under fluoroscopy.

Retracting portion 120 may have a shape that is contoured and resembles the curvature of the posterior upper portion of the tibia 5, to use as a physical and visual reference during placement. For example retracting portion 120 may include a curved rim 126 around a portion of the periphery of the retracting portion 120 to engage a corresponding curved portion of the tibia 5 and better maintain the medial-lateral inclination vector 130 and position of retractor 100. Slot 110 may be disposed between the retracting portion 120 and handle 105, so as to be located adjacent the medial outer edge surface of tibia 5 when the retracting portion is placed on posterior portion of tibia 5. A kit may be provided with a plurality of retractors 100 that may have differing configurations from each other, such as differing contours, curvatures and longer retracting portions 120 to accommodate variations in tibia sizes.

Seen in FIG. 2B and FIG. 2F, retractor handle 105 may be offset relative to the retractor portion 120 so as to better circumvent patient anatomy and retract tissue and also visualize placement of retracting portion. The jog/offset allows for access to the posterior side by either elevating the MCL and placing the MCL at an outer surface side of retracting

portion 120, indicated by M on the retractor 100, or minimally elevating the MCL and placing the retractor on the outside of MCL, wherein the MCL would be in location M'.

Cutting guide 150 is configured to be placed substantially on medial side of tibia 5. Cutting guide 150 may define a curve, configured to wrap around the medial side of upper tibia. Cutting guide 150 includes a linking end 155 and a free end 175, linking end 155 configured to link with slot 110 of retractor 100. Once retractor 100 is in a preferred location, cutting guide 150 may be linked to retractor 100. A kit including a plurality of cutting guides may be provided, the plurality of cutting guides configured to accommodate a variety of tibia anatomy sizes. Shown in FIG. 2C, linking end 155 comprises an elongate arm 157 sized to fit through slot 110 and may be substantially rectangular in cross section. Elongate arm 157 and slot 110 are configured to cooperate with each other to allow some pivoting motion along the plane 170, and also some limited sliding motion of the cutting guide 150 along a plane 170. However the elongate arm 157 and slot 110 are configured to cooperate to maintain a saw slot 160 on plane 170. The saw slot 160 in the medial cutting guide 150 helps define the Posterior Slope Cutting vector (PSC Vector) 180. The MLI 130 and PSC 180 vectors define a datum plane 170 for the saw (described in later figures) to follow while forming the medial cut or osteotomy. The retractor 100 and cutting guide 150 are linked so that the two vectors MLI 130 and PSC 180 will maintain this cutting plane 170 even when they "hinge" open and closed. FIG. 2D shows the retractor 100 and cutting guide 150, vectors MLI 130 and PSC 180 so as to define cutting plane 170 through tibia. Cutting guide 150 may first be coupled to handle 260 (described in more detail later) and then linked to slot 110 of retractor using the handle 260.

Seen best in FIGS. 2E, 2F and 2G, the system may also include an anterior pin 200 that extends through a thickness of cutting guide 150 and into tibia 5. Cutting guide 150 includes opening 165 configured to receive pin 200, opening 165 disposed at an end of the saw slot 160, and may be continuous with saw slot 160. Opening 165 may define a lateral end of saw slot, and may also define a larger opening than saw slot 160. Opening 165 may be oblong such that anterior pin 200 may be limited so as to be aligned with saw slot 160 but may move laterally to be closer or further away from free end 175. Stated otherwise, opening 165 restricts pin location so that it's central axis lies on plane 170, but the relative location of pin 200 to retractor 100 may be adjustable depending on size of tibia 5. Shown best in FIG. 2F, distance D is selectable, up to boundaries defined by the opening 165. Anterior pin 200 is shown with a threaded end 201 and a coupling end 203. In some embodiments, the anterior pin may be entirely smooth, similar to a K-wire. Coupling end 203 may be configured to engage with an insertion tool (not shown) and may have a non-circular cross section, such as a hexagonal or square cross section so as to better transfer a rotational motion from an insertion tool to screw in the anterior pin 200. Of note, curved rim 126 of retracting portion 120 is easily observed in FIG. 2F and 2G. Shown in later

figures, cutting guide 150 may be fixed in position with speed pins or fixation means that extend through holes 162 and into the tibia 5.

Anterior pin 200 may be precisely placed using a pin guide 250 with a flag 300 that may selectively couple to the cutting guide 150. The anterior pin 200, cutting guide slot 160 and a line through the retractor 122 may all define a cutting plane 170 and its boundaries. Anterior pin 200 may be preferably placed in a position collinear with the intersection axis of the medial cut and anterior cut (described later). This anterior pin 200 serves at least 2 functions; it provides protection to the tibial tuberosity from the saw during the medial cut (described in later figures) and also provides stabilization means for the cutting guide 150 which will aid the anterior cut in a later step. Shown in FIG. 2B the line 15 may be seen through the medial cutting guide 150 (seen through the opening 165 in the view). Due to the thickness of the medial cutting guide 150, the anterior pin 200 will be placed parallel and in alignment with the medial cut datum plane. Therefore, the remaining degree of freedom for the pin placement is the angle at which it is drilled relative to the PSC vector.

The preferable pin placement trajectory is a vector that originates at the intersection of the medial cut and the scribed line 15 on the medial tibia and is parallel to the joint line. A visual guide 250 may be coupled to the medial cutting guide 150, the medial cutting guide 150 having sufficient thickness to align visual guide 250 on the correct trajectory. Visual guide 250 may comprise a handle end 260 and a distal tip 255 sized to be selectively insert in a guide opening 185 so as to selectively align visual guide 250 with cutting guide 150. Handle 260 and distal tip 255 may lie along, and be concentrically disposed on a longitudinal axis of visual guide 250. The visual guide 250 is configured to be aligned, pointing anteriorly with the reference being the anterior tibia, seen in FIGS. 2H, 2I and 2J. A flag element 300 may be coupled to the visual guide 250, and is selectively moved so as to align a linear edge 310 of the flag 300 with the anterior tibia. Handle 260 may include a hole configured to receive a pin or threaded shaft 265. As shown in FIG. 2H, flag may be slidingly coupled to a portion of visual guide 250, via threaded shaft 265. Flag element may be locking in place using a set screw. Flag 300 may terminate in a linear edge 310 for pin alignment. The tip of the anterior pin 200 may be place in the slot 165 in the medial guide 150 and preferably inserted up to the scribed line 15. It may be advanced through the tibial tuberosity parallel to the bottom, linear edge 310 of the alignment flag 300. Linear edge 310 may be aligned with vector 180.

A K wire 320 may also be placed though cutting guide 150 to the depth of the hinge point as shown in FIG. 2K and the depth measured using a depth gauge 325. Cutting guide saw slot 160 may include a series of notches 163 along the length of the saw slot 160, to receive K wire that may have a diameter larger than saw slot 160. The K-wire provides depth information as to how deep the saw should extend into the tibia 5.

Once the anterior pin 200 is placed, visual guide 250 and flag 300 may be removed. The medial cut 10 can be made safely and contained between the posterior retractor and anterior pin with depth information from the K-wire. Exemplary saw 350 is shown extending through saw slot 160 in FIG. 2L, so as to make the medial cut along plane 170. Exemplary saw 350 may be an oscillating saw or osteotome that fits through the medial cutting guide 150. The saw 350 will be coplanar and controlled so as to extend along the datum 170 created with the linking guide system 90. The saw and osteotome can be advanced laterally until it reaches the desired "lateral hinge" point, guided by the K-wire and as determined by the surgeon during pre-op planning.

Second System – Anterior Cutting Guide

The disclosure now turns to a second system, configured to guide an optional anterior cut, should the surgeon wish. The anterior cut may be preferably for forming a bi-planar High Tibial Osteotomy (HTO). The second system is an anterior cut guide 500 which may utilize the anterior pin 200 already placed in previous figures to create a vertical anterior cut, shown in FIG. 3A. Anterior cut guide 500 may be configured to a left or right leg, and therefore a kit may include two mirror image anterior cut guide 500 to accommodate the targeted side of patient. If used independently of the first system, a standalone anterior pin may be added. Using the placement of an anterior pin 200 from a previous step in the procedure, an adjustable cutting guide can be fitted over the pin 200 and used to guide the anterior cut. The pin 200 may define the intersection point of the medial and anterior cuts. Once the medial cut is complete (possible as described in Figures 2A-2L), pin 200 may remain in situ while the retractor 100 and cutting guide 150 may be removed. The anterior cut guide 550 is configured to slide over the headless pin 200. Anterior cut guide 550 may include an elongate lumen 560 or opening configured to slide over pin 200, and aid in guide alignment. Lumen 560 is sized so that guide may rotate around pin 200. Medical cut 10 may be seen in FIG. 3B with pin 200 through end of medal cut. Guide 550 may also include an elongate cutting slot 570 defined between a first vertical linear edge 575 and second parallel linear edge 580 of the guide 550. Cutting slot 570 is wide enough to receive a sagittal saw or osteotome for example. Shown in FIG. 3C, guide 560 may fit over pin 200 and rotate so as to align cutting slot 570 with marked line 15. The cutting slot 570 may be aligned visually to the line 15 made at the beginning of the procedure and then fixed in place with a provisional pin. For example a second pin or screw or fixation means 590 may be inserted through hole 585 and into the tibia 5 so as to fix alignment with marking 15. In alternative embodiments a fixation means may is inserted to as to abut an outer edge surface of the guide 550 to fix the guide 550 is its orientation, reducing the need for hole therethough. Anterior cutting guide 550 may include lip 552 so as to hold guide 550 and aligning cutting slot 570 with marking 15.

An alternative embodiment of cutting guide system 650 is shown in FIGS. 4A and 4B, the guide including a lip 652 or handle to hold and align the guide 650 and a fin 654 for

sliding into the medical cut 30. Similar to the previously described embodiment, this guide 650 includes an opening 660 for sliding over pin 200 and may include a hole 680 for receiving a screw of pin for fixing the guide 650 once aligned. Surface 690 may provide the cutting surface for guiding a saw in the correct orientation. Fin 654 may be tapered (not shown) so as to ease insertion into the medial cut 30. Shown in FIG. 4B, surface 690 does not line up with mark 15. The inventor envisions a series of guides, with differing orientations for surface 690 so that the surgeon may chose the closest one.

The main advantage with system 500 is that it uses one guide to compensate for variability instead of several fixed angle guides. Using one guide pin 200 at the intersection of the cutting planes allows for better control and management of the cuts. A sagittal saw can now be used to make the anterior cut safely with guidance.

Third system – Lateral Hinge Distraction System

The disclosure now turns to a third system, for initiating distraction of the two bony segments either side of cut 10, followed by wedging the two boney segments apart according to a determined open wedge angle. The osteotome or saw 350 used with guide 200 may have a thickness resulting in a narrow opening at tibia medial surface, therefore a laminar spreader 700 with thin tines may preferably first initiate distraction of the two bone segments. Laminar spreader 700, shown in FIGS. 5A, 5B and 5C therefore may include a "L" shaped end with a pair of thin, blade-like tines 710 that are moveable relative to each other, the tines configured for wedging into this narrow opening formed by the cut 10 and therefore between the opposing bone surfaces of cut 10. Tines 710 may be tapered 715 to further ease insertion into medial boundary of the cut 10. Spreader 700 also includes a means to control the rate of relative motion between the tines 720 and thereby bone segment distraction, the means including a pair of lever arms 720 and a set screw mechanism 725 there between. Distracting too fast may crack the lateral hinge, and so a means of limiting the rate of tine separation and thereby distraction is preferable to mitigate lateral hinge injury. Lever arms 720 may be hingedly attached 712, such that relative movement between lever arms move tines 710. Threaded knob 722 may be operably coupled to a set screw that is operable coupled to at least one lever arm 720 such that rotating knob 722 may draw the lever arms 720 towards each other and slowly separate the tines 710. In addition portions of the spreader 700 may be formed of a flexible material, such as spring steel or a polymer, to further limit the rate of distraction. FIG. 5C shows tines 710 placed within narrow opening formed by cut 10, and initiating distraction along arrows 701.

Once the laminar spreader has distracted the opening at least a few millimeters, the laminar spreader may be removed and further distraction performed with a wedge system 750, shown in FIGS 6A and 6B. A plurality of wedges 760 may be provided as part of a kit packaged with a tray for example, the plurality of wedges 760 configured to accommodate a variety of wedge opening angles, depending on the patient anatomy and desired correction geometry. Each wedge 760 may have a different wedge angle and may include a series of markings 755 with indications of corresponding thickness of wedge at that marking, for example from 1-10mm in thickness. Alternatively, each marking 755 may indicate an opening angle. Opening angle and/or opening width is preferable calculated as part of a preplanning procedure based on a series of images such as X-rays along a variety of orthogonal planes to the targeted bone.

Two wedges 760a and 760b may be selectively inserted and pounded into the opening 30 until the markings 755 align with the tibia outer surface at the values determined as part of the pre-procedure planning. In some cases a biplanar correction may be preferable wherein the anterior wedge opening is different from the posterior side. As such, wedge 760a may have a different wedge slope to wedge 760b. Each wedge may be

selectively attached to a handle system 765 that may operably couple to at least one wedge 760, and the end 766 may be pounded to insert wedges 760a and 760b. Two separate handles, one for each wedge may be an alternative configuration. In the embodiment shown, both wedges 706a and 760b are coupled to a single handle such that the anterior and posterior wedge openings are formed approximately simultaneously. This may help form a more consistent opening angle according to the determined opening angle values.

Fourth System – Lateral Hinge Compression System.

The disclosure now turns to a fourth system, including a fixation plate and drill system for providing compression to a lateral hinge of and HTO to facilitate faster bone healing during an HTO procedure. FIG. 7A shows a plate 1100 with a plurality of holes 1200 therethough. Holes 1200 are generally configured to receive a series of fixation means such as non-locking/locking screws for attaching plate 1100 to a portion of bone 5 including over a distracted portion of bone (open wedge 30). Plate 1100 is an exemplary shape and the number of holes 1200 and location may differ. Plate 110 may be contoured to approximate the tibia outer surface so as to provide for a better match with the tibia, reducing irritation between the adjacent soft tissues and the plate 1100. A plurality of plates may be provided, not only to accommodate the left or right patient leg, but also to accommodate different tibia sizes. Lateral Hinge Compression System is configured to avoid dual-holes (figure-of-8 or snowman shaped holes) while still providing compression to the distracted lateral hinge during a HTO procedure. Shown in FIG. 7A, three fixation means such as locking screws have been inserted through superior most holes 1200a to fix plate 1100 with proximal portion of tibia, superior to open wedge 30.

An adjustable drill guide 1300 may then be inserted though the inferior-most hole 1200d, adjustable drill guide 1300 including an adjustable distal tip 1310 configured to set and adjust an offset X of that portion of the plate 1100 near the inferior-most hole to the bone 5. Adjusting the offset X allows the user to choose how much offset X the inferior end of plate 1100 has and thereby adjust the amount of bow in the plate 1100 and thereby compression on the wedged opening 30 and bony hinge 35.

Turning to FIG. 10, a brief description of the mechanics of bony hinge compression is disclosed. Compression on the lateral hinge may decrease a chance of non-union should the bony lateral hinge crack during the procedure. Compression may also allow for earlier weight bearing on the osteotomy as it preloads the osteotomy, which decreases the chance of a loss of correction during the healing process. In FIG. 10 example plate 1100 is shown, fixedly coupled at point A, possibly using holes such as 1200a. Using the adjustable drill guide such as guide 1300, distal end may be pushed away to form a standoff value X from the bone surface at point B. This standoff X may be adjustable so that the surgeon may chose the level of compression to be placed on the lateral hinge. In some embodiments distance markers may be disposed on the drill guide to indicate the distance of the standoff. In other embodiments a force gauge such as a spring plunger may be operatively coupled

to the adjustable drill guide such that the surgeon may adjust the offset to a targeted force value. With the drill guide maintaining the standoff X, a temporary compression screw may then be placed through plate, and into the bone at point C. This brings the middle portion of the plate 1100 to the bone surface at point C and creates a rotation D on the inferior segment of the tibia 5 and a resultant compression force E on the lateral hinge 35.

Returning to FIGS 7A-7G, and best seen in FIG. 7B and 9A adjustable drill tip 1310 may include a handle 1320 which may include a passageway 1322 therethough (best seen in FIG. 9A and 9B) to allow passage of a tool. Passage 1322 continues through distal tip 1310. Adjustable drill guide 1300 also includes an outer shaft 1330 for receiving handle 1320 including threads 1312 that engage corresponding threads or surfaces on at least the inferior-most hole 1200d. Outer shaft 1330 and handle 1320 may also threadingly couple with each other between an outer surface of the handle 1320 and in inner surface of shaft 1330, configured so as to advance distal tip 1310 axially along shaft 1330. With the threads 1312 coupled to the inferior-most hole 1200d, rotating handle 1320 relative to shaft 1330 will therefore advance or withdraw the distal tip 1310 into and out of inferior opening 1200d and move inferior portion of the plate 1100 away from or closer to outer surface of tibia. Advancing the distal tip 1310 increases the plate offset or standoff, indicated as X on FIG. 7B and thereby the flexion of the plate 1100. Threaded portion 1312 may be tapered so as to adjust for varying sizes or diameters of hole 1200d. In alternative embodiments, distal tip may have a constant outer diameter along its length. In alternative adjustable drill guides, handle 1320 may be slidingly advanced relative to outer shaft 1330, and may include a series of teeth or engagement elements that engage with corresponding teeth or engagement elements on the outer shaft 1330. An axial spring may be coaxial with the outer shaft and handle to maintain engagement in this embodiment.

Shown in FIG. 7C, with the adjustable drill guide 1300 still inserted and standoff X maintained, a bi-modal drill guide 1400 may then be inserted in the hole 1200c which is preferably close to the middle of the plate 110 and adjacent and distal to the wedge opening 30. Bi-modal drill guide 1400 may include a threaded distal tip 1410 for engaging hole 1200c. The bi-modal drill guide 1400 may have two fixed trajectories, including a standard trajectory for the final locking screw A, and an angled trajectory B for inserting a provisional compression screw at an inferior-lateral angle. Provisional screw may include any non-locking screw such as a cortex, compression or osteopenic screw. In alternative embodiments, a cone shaped guide may be provided to set limits on the insertion angles rather than fixed valued of insertion angles of the fixation means. As described earlier, compressing the plate 1100 in this manner causes the middle third of the plate to flex inwards towards the bone 5 and the resulting rotational force creates a compression of the lateral hinge 35. Both screws or fixation means extend through the same hole 1200c in the plate, and the angled trajectory B and inferior-lateral angle may be fixed. Hole 1200c is preferably approximately circular shape, with a single central axis therethough, as opposed

to a figure-of eight hole. Hole 1200c may define a variable angled opening such as those disclosed in US patent 8888824, commonly owned and herein incorporated by reference, in its entirely. Openings such as opening 1200C may be a variable angled openings including fins or projections that extend radially inward from an inner surface of the opening 1200C and into an interior region of the opening 1200C, and which are configured to engage or cooperate with the head portion of a bone fastener. In use, the fins engage the head portion of the bone fastener in order to secure the bone fastener at a desired position and at a desired angular orientation within the variable angled opening 1200C. Additional information on the operation and configuration of the fins can be found in U.S. Patent Application No. 15/706,877, with an earliest filing date of July 25, 2005, now U.S. Patent No. 10,092,337 entitled "Systems and Methods for Using Polyaxial Plates"; U.S. Patent Application No. 13/524,506, filed on June 15, 2012, entitled "Variable Angle Locking Implant", and U.S. Patent Application No. 62/858,727, filed on June 7, entitled "Orthopedic Implant with Improved Variable Angle Locking Mechanism", the entire contents of which are hereby incorporated by reference.

Bi-modal drill guide 1400 therefore includes a first hollow shaft 1420 providing passage for a drill therethrough and into bone along trajectory A, so as to form a pilot hole along trajectory A. Bi-modal drill guide 1400 may also include a second shaft 1430 providing passage for a screw therethrough and into bone along trajectory B. Bi-modal drill guide can best be seen in FIGS. 8A and 8B. The second shaft 1430 may be smaller in diameter and screw head 1450 may remain external to and spaced away from hole 1200c, as can be seen in FIG. 7D. This allows easy access to remove the provisional screw. As explained earlier, provisional screw 1450 may draw the plate onto the bone outer surface and place the lateral hinge 35 in compression. The first hollow shaft may be configured to allow complete passage of a drill, to form a pilot hole for later placing a locking screw. First hollow shaft 1420 may be longer than second hollow shaft 1430, first hollow shaft 1420 also serving as a means of manipulating/holding bi-modal drill guide, or stated otherwise serve as a handle. Once provisional fixation means are inserted at the angled trajectory B, the two remaining locking screw holes 1200e that are inferior to the osteotomy can now be drilled and implanted, shown in FIG. 7D.

The offset drill guide may then be used to drill a pilot hole through opening 1200d, and then removed to allows a fixation means such as a locking screw to further fix the plate 1100 with the bone. The provisional screw 1450 inserted at the angled trajectory may then be removed, since the locking screws placed inferiorly are angle-stable and the flexion in the plate 1100 will remain. The bimodal drill guide 140 may be removed and a locking screw may be placed into the bone along the pilot hole formed earlier. The provisional screw 1450 may be re-used in a remaining hole 1200b immediately superior to the open wedge.

FIG. 11 shows an alternative embodiment of a plate 1500 including a plurality of openings 1550, and contoured to mate with the tibia 5. Plate may comprise a 2-3mm thick plate, formed of titanium and may include a plurality of openings 1550 some of which are variable angle locking holes, as described herein. Plate 1500 may include a first variable angle locking opening 1550a and a second variable angle locking opening 1550d. Similar to the previously described embodiment, the plate 1500 will first be attached at the superior portion of the tibia, via fixation means through 1550a and 1550b. The anterior-most hole 1550a is a variable angle opening to allow placement of a fixation means and avoid certain structure associated with the tibia 5. For example an ACL reconstruction or meniscal root repair tunnel may have been concomitantly performed as part of the procedure. A variable angle opening at the superior end of the tibia allows the fixation means to be placed at an angle that avoids the area around or on the ACL or meniscal root. Similar to the previously described plate system embodiment, an adjustable offset drill guide such as drill guide 1300 may then be operatively coupled to opening 1550c and a standoff X may be formed as described earlier. A provisional compression screw may then be placed in opening 1550d, at an angle configured to compress the lateral hinge 35. Fixation means may then be placed in opening 1550e, followed by 1550c after removal of the adjustable guide 1300. Provisional screw may be removed from opening 1550d before placing a permanent locking screw therethrough, at a different angle. Plate 1500 may include a distal curved axis 1560 to better align with tibia diaphysis Non-curved axis is labelled 1565 for reference.

The above discussion is meant to be illustrative of the principles and various embodiments of the present invention. Numerous variations and modifications will become apparent to those skilled in the art once the above disclosure is fully appreciated. It is intended that the following claims be interpreted to embrace all such variations and modifications.

CLAIMS

What is claimed is:

1. A bone fixation system for stabilizing a lateral hinge for an HTO procedure comprising:

a bone plate having an interior surface, an exterior surface and a plurality of holes therethrough; and

a drill guide configured to adjustably extend through at least one of the plurality of openings and adjust an offset between the plate interior surface and a bone surface and thereby adjust flexion on the bone plate.

2. The bone fixation system of claim 1 wherein the drill guide comprises an outer shaft and an axially moveable inner shaft, the outer shaft configured to operatively couple to the at least one of the plurality of openings and the inner shaft configured to extend through the at least one of the plurality of openings, engage the bone surface and push the bone plate away from the bone surface and thereby adjust flexion on the bone plate.

3. The bone fixation system of claim 1 wherein the plate comprises a head portion configured to conform to a metaphysis of the bone, the head portion having one or more variable angle openings such that a fixation means extending through the one or more variable angle openings may be directed away from a structure within the metaphysis of the bone.

4. The bone fixation system of claim 1 further comprising a dual angle drill guide, configured to operatively couple with a variable angle opening though the bone plate, the dual angle drill guide having a first guide axis for directing a first fixation means at a first angle into the bone configured to compress a lateral hinge, and a second guide axis for forming a pilot hole in the bone at a second angle, different to the first angle.

5. The bone fixation system of claim 4 wherein the bone plate comprises a head portion and a stem portion extending therefrom, wherein the stem portion comprises at least two openings of the plurality of openings, and wherein a first of the at least two openings is a variable angle opening, configured to operatively couple to the dual angle drill guide and a second of the at least two openings is configured to operatively couple to the adjustable drill guide.

6. The bone fixation system wherein at least one of the openings of the plurality of openings is a variable angle opening configures to receive a first fixation means at a first angle therethrough, and also upon removal of the first fixation means a second fixation means at a second angle therethrough.

7. A method of compressing a lateral hinge of an open wedge osteotomy comprising:

placing a bone plate over an open wedge osteotomy;

fixing a superior portion of the plate to a first side of the open wedge osteotomy; and

with the superior portion fixed, moving an inferior end-portion of the bone plate away from a bone surface on a second side of the open wedge osteotomy so as to form a standoff that bows the bone plate;

adjusting the standoff; and

while maintaining the standoff provisionally fixing a median portion of the bone plate against the bone so as to compress the lateral hinge of the open wedge osteotomy, the median portion disposed on the second side of the open wedge osteotomy, between the superior portion and inferior end-portion.

8. The method of claim 7 wherein fixing a superior portion of the plate further comprises directing a fixation means through a variable angle opening through the plate at an angle away from a structure within the bone.

9. The method of claim 8 wherein the structure may include an Anterior Cruciate Ligament (ACL), an ACL reconstructed tunnel or a meniscal root repair tunnel.

10. The method of claim 7 wherein moving an inferior end-portion of the bone plate away from a bone surface and adjusting the standoff comprises engaging an end of an adjustment guide handle to an opening at the inferior end portion of the plate and axially moving a shaft coaxial with and operatively coupled to the adjustment guide handle, through the opening so as to engage a surface of the bone.

11. The method of claims 10 wherein the shaft is threadingly coupled to the adjustment guide handle, and wherein moving the shaft through the opening comprises rotating the shaft relative to the handle.

12. The method of claim 10 wherein fixing the median portion comprises placing a provisional fixation means through a variable angle opening through a median portion of the plate at an angle that compressed the lateral hinge.

13. The method of claim 12 wherein after the median portion is provisionally fixed, fixing other portions of the bone plate to the bone; and then replacing the provisional fixation means with a permanent fixation means at a different insertion angle through the variable angle opening.

14. The method of claim 12 wherein fixing the median portion with a provisional fixation means comprises operatively coupling a dual angle guide with the variable angle opening and directing the provisional fixation means using a first angle of the dual angle guide.

15. A linking cutting guide system for preparing a medial cut in an HTO procedure comprising:

a retractor for inserting in the posterior aspect of the tibia to protect neurovascular structures and provide a visual indication under fluoroscopy of a medial-lateral inclination vector;

a cutting guide pivotally coupled to the retractor, the cutting guide configured to wrap around a medial aspect of the tibia and comprising a cutting slot for receiving and controlling a cutting tool that creates the medial cut the cutting slot defining a posterior slope cutting vector;

an anterior pin configured to be inserted through an opening in the cutting guide at a location that defines an anterior boundary of a preferred datum plane and also lies on the datum plane, the preferred datum plane defined by the media-lateral inclination vector and the posterior slope cutting vector.

16. The cutting guide system of claim 15 further comprising a pin locating guide that selectively couples to the cutting guide for guiding insertion of the anterior pin.

17. The cutting guide system of claim 16 wherein the pin locating guide comprises a pin guide that coupled to the cutting guide and an adjustable flag having a linear edge configured to align with the posterior slope cutting vector.

18. The linking cutting guide system of claim 15 wherein the retractor comprises a slot for receiving an arm of the cutting guide.

19. The linking cutting guide system of claim 11 further comprising an anterior cutting guide system for guiding an anterior cut during an HTO procedure comprising:

an anterior cutting guide having a lumen for sliding over the anterior pin and a cutting surface for guiding the trajectory of a bone cuttier; and

a fixation means for coupling to the cutting guide and stabilizing an orientation of the cutting guide.

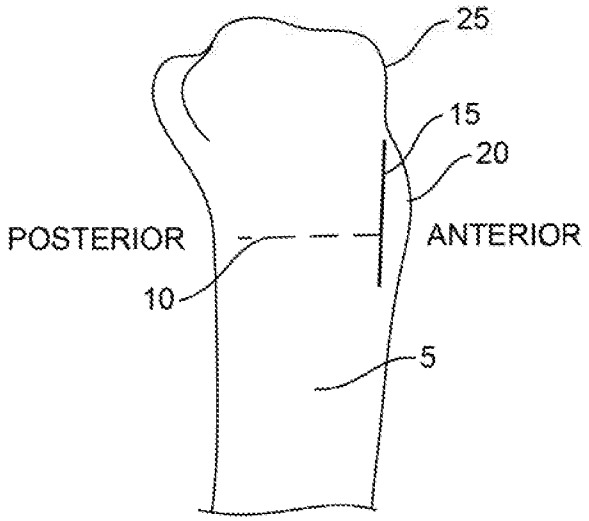


FIG. 1A

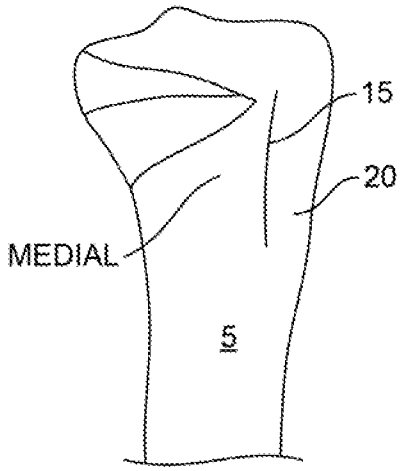


FIG. 1B

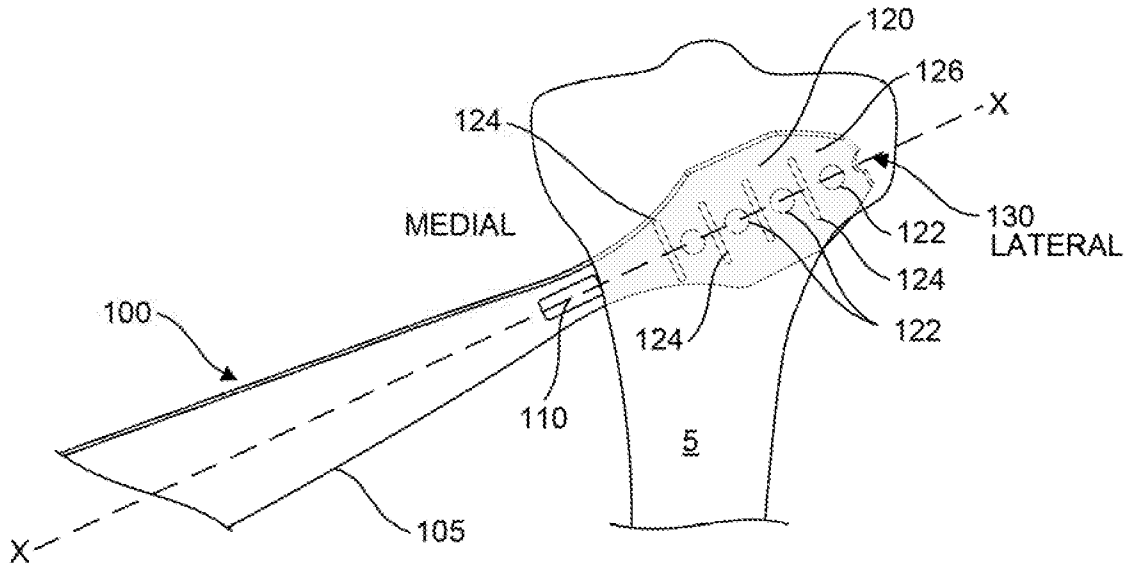


FIG. 2A

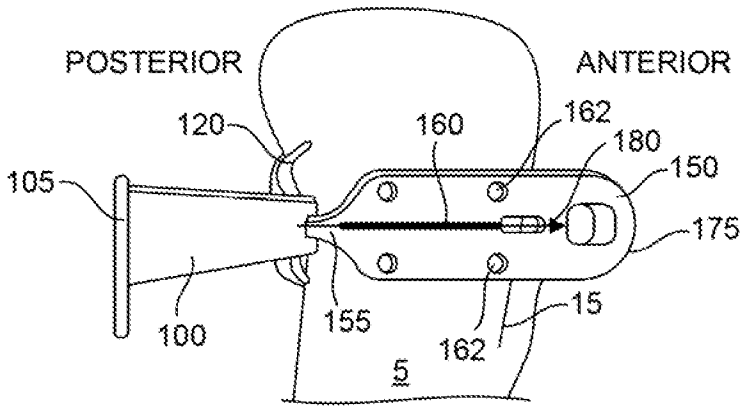


FIG. 2B

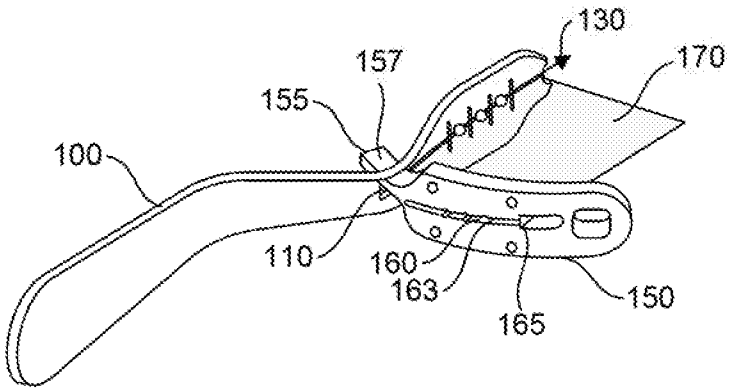


FIG. 2C

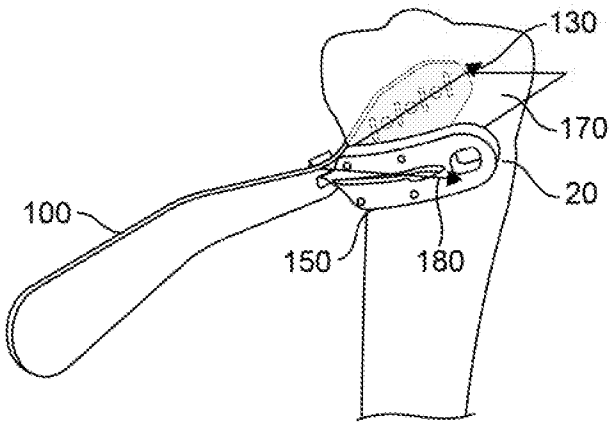


FIG. 2D

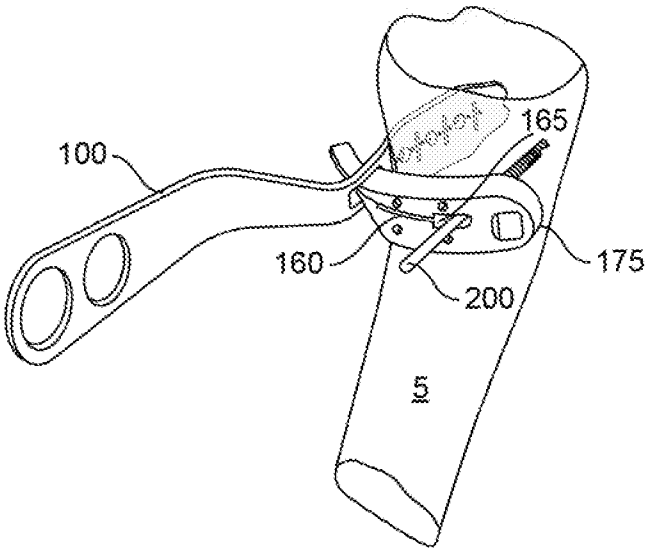


FIG. 2E

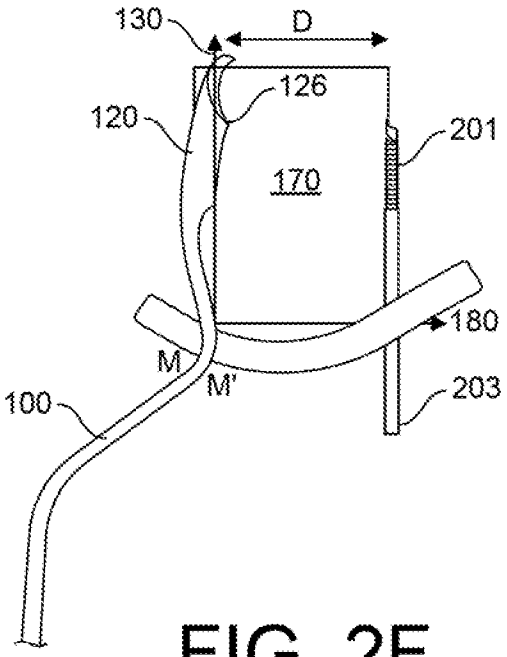


FIG. 2F

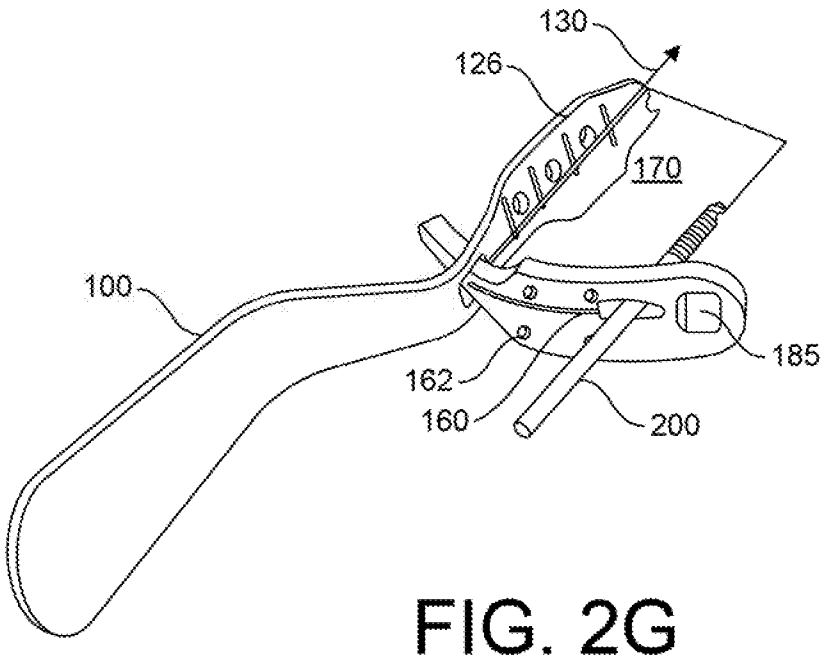


FIG. 2G

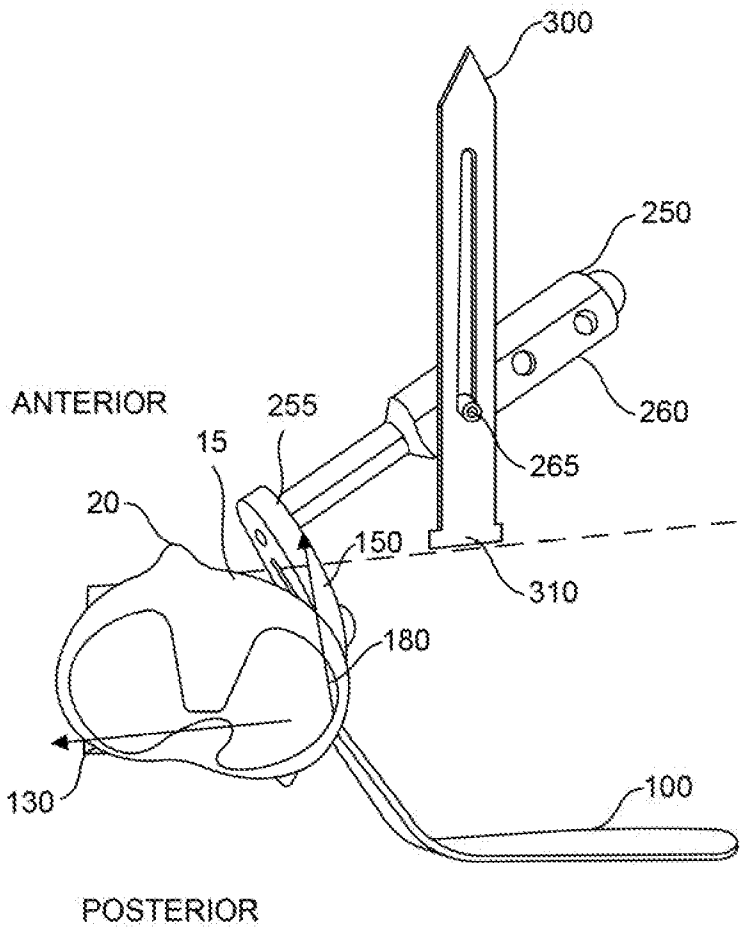

300
250
260
265
ANTERIOR
255
15
20
150
310
180
130
100
POSTERIOR

FIG. 2H

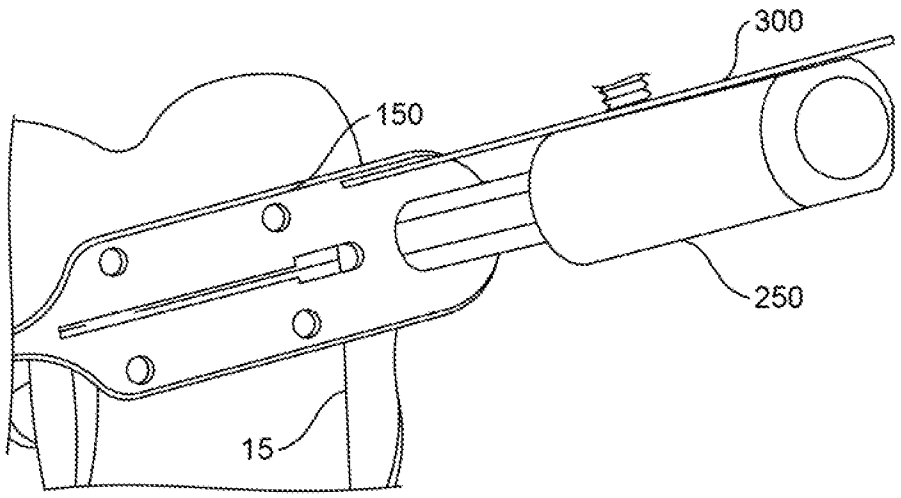

300
150
250
15

FIG. 2I

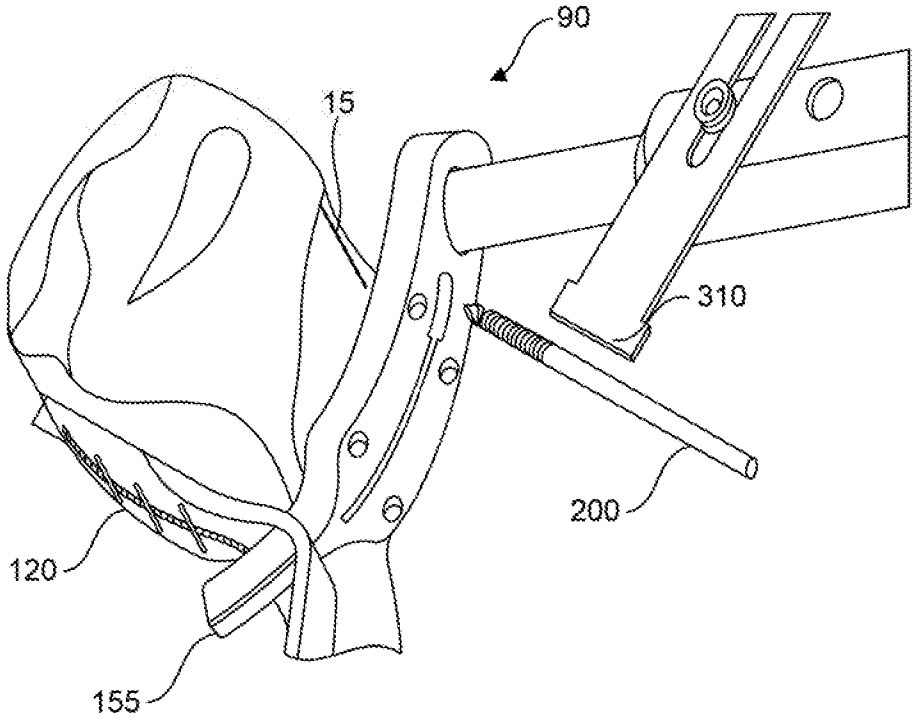


FIG. 2J

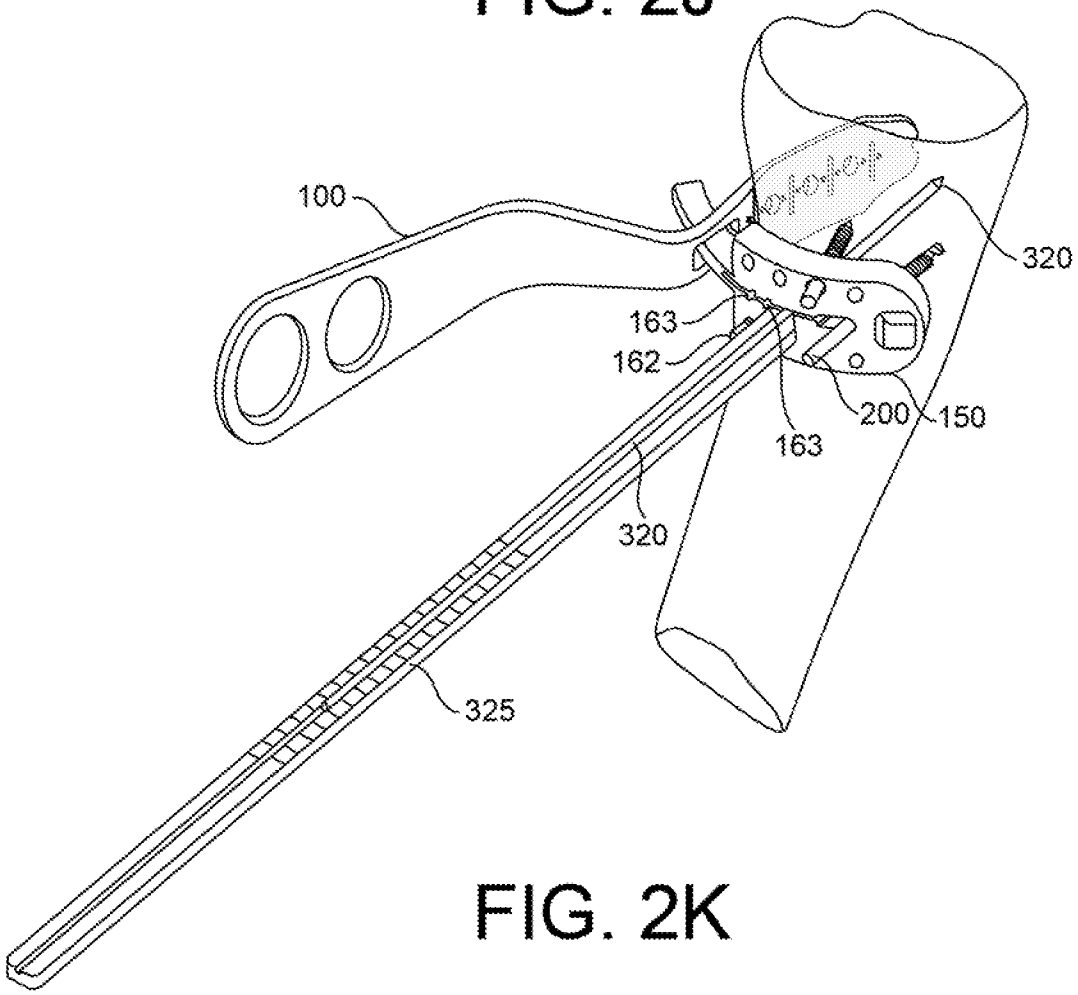


FIG. 2K

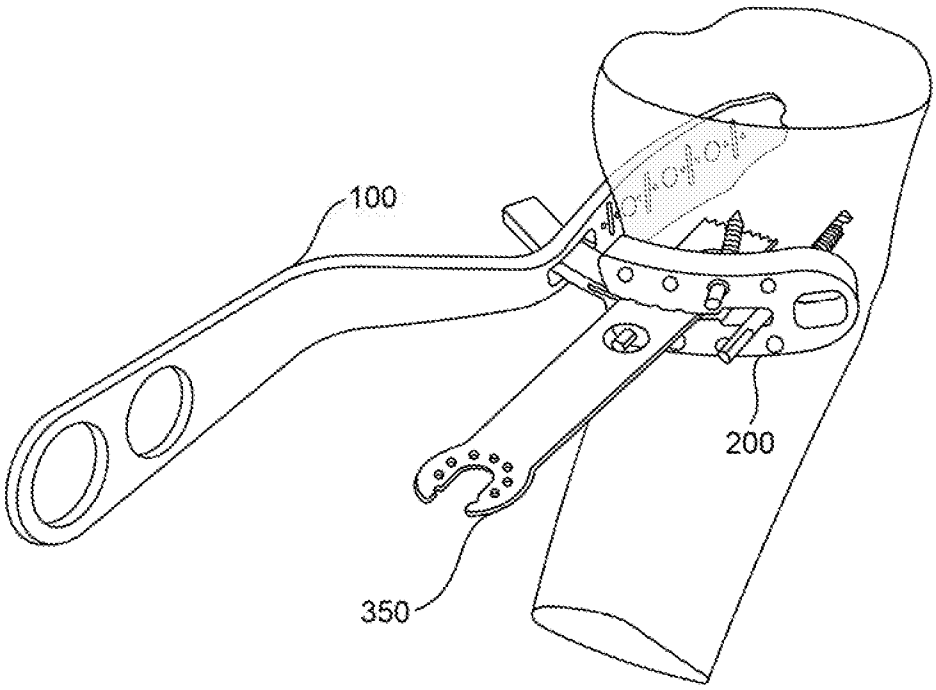


FIG. 2L

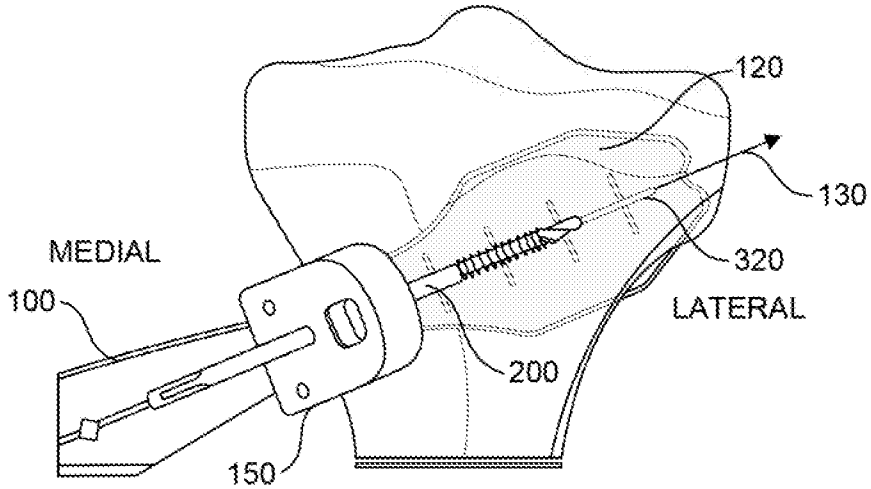


FIG. 2M

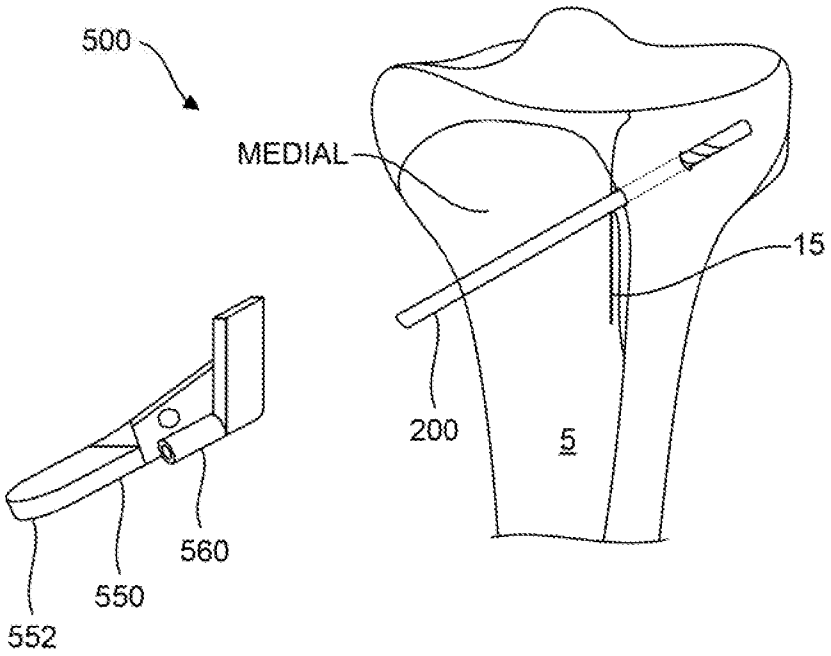

500
MEDIAL
15
200
5
560
550
552

FIG. 3A

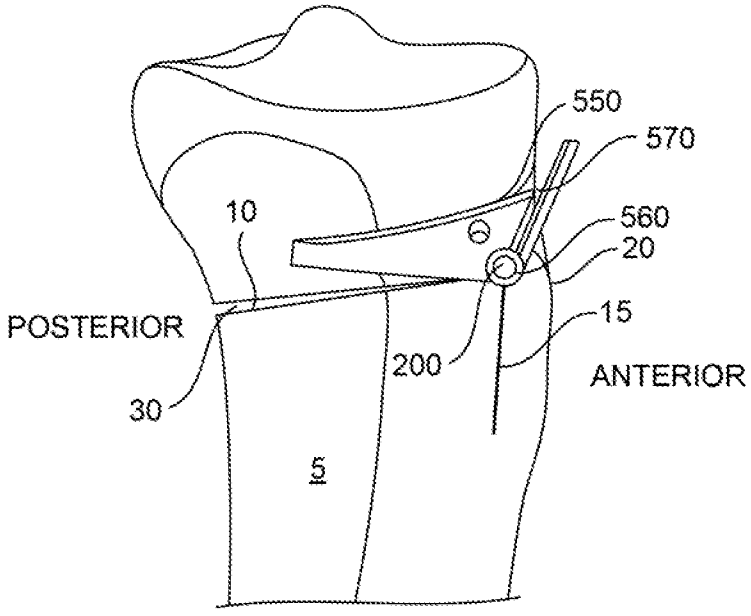

550
570
10
560
20
POSTERIOR
15
200
ANTERIOR
30
5

FIG. 3B

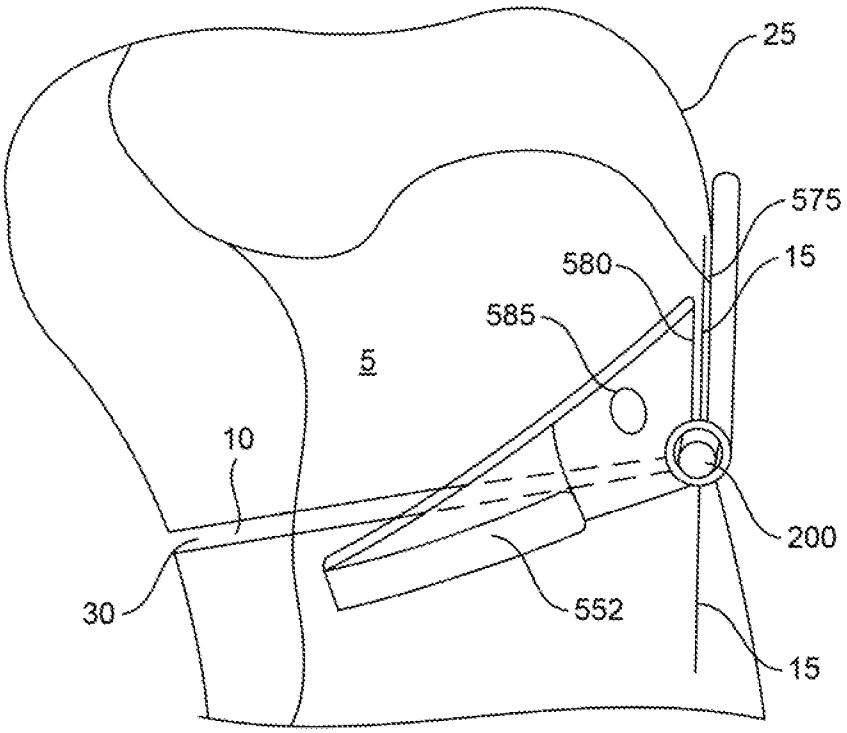


FIG. 3C

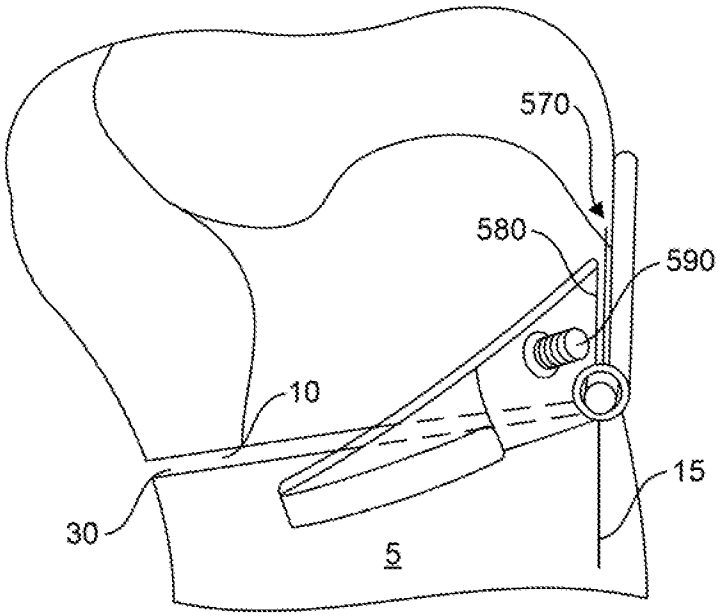


FIG. 3D

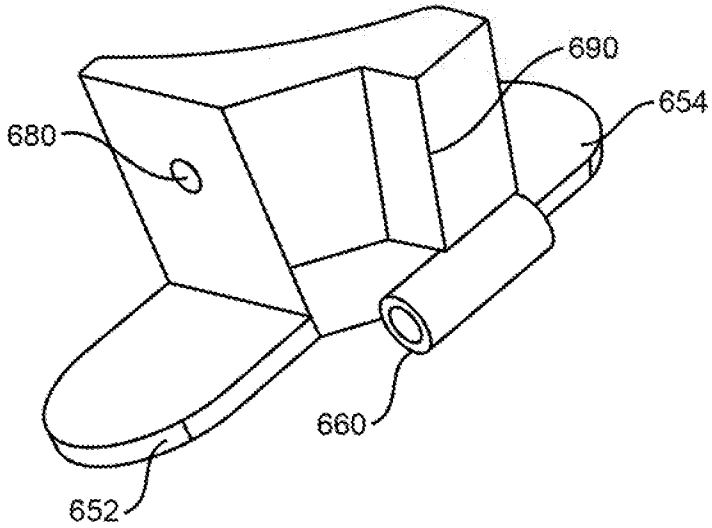


FIG. 4A

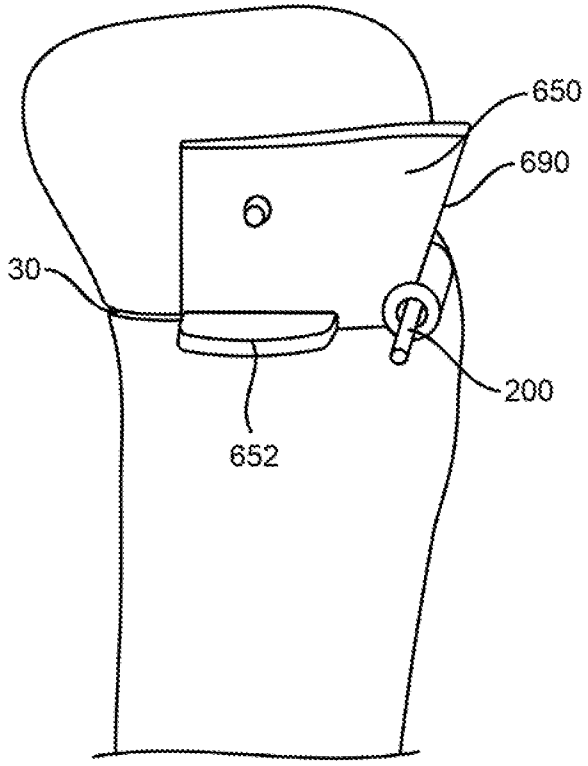


FIG. 4B

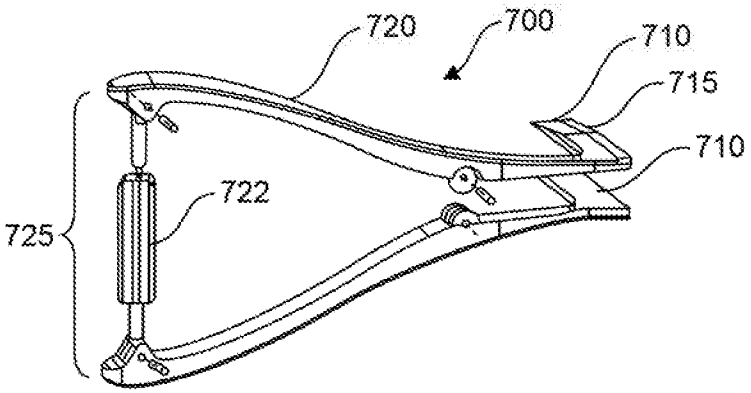


FIG. 5A

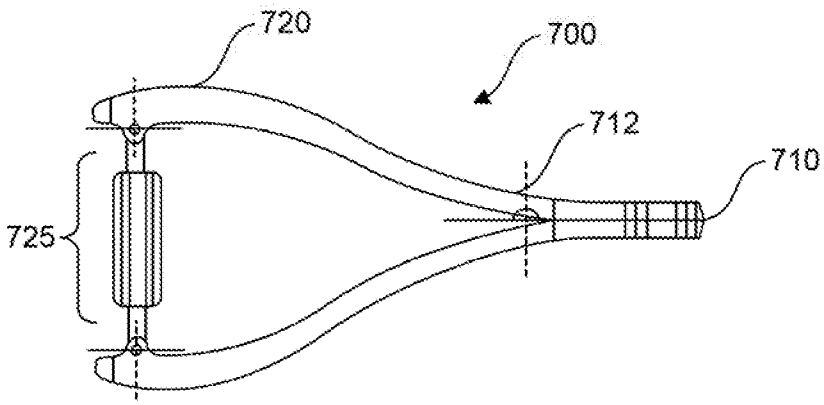


FIG. 5B

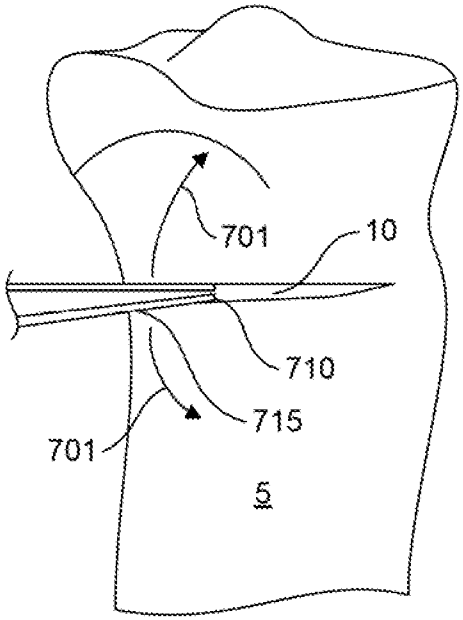


FIG. 5C

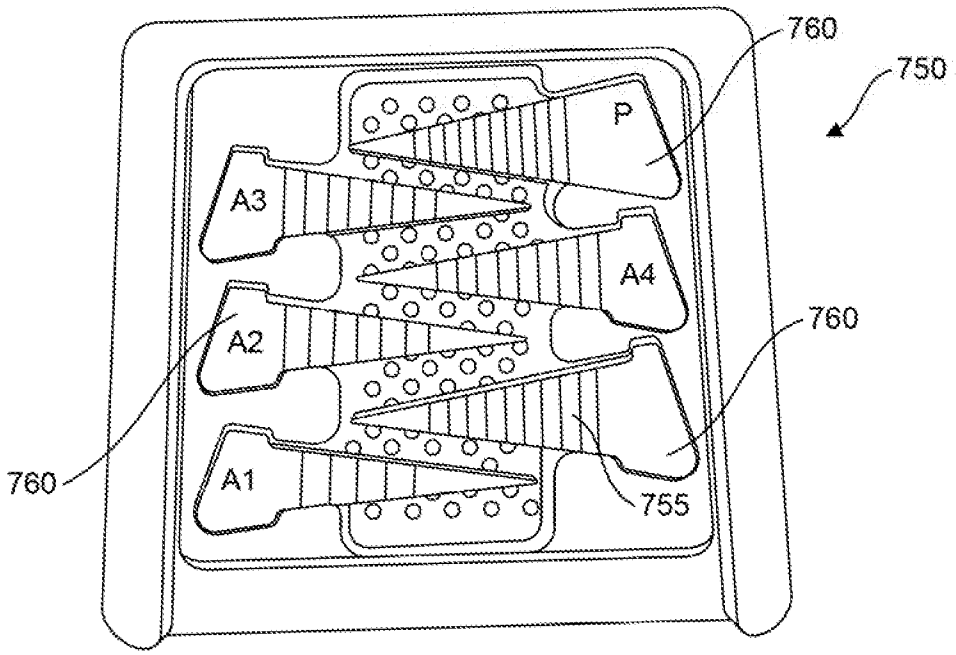


FIG. 6A

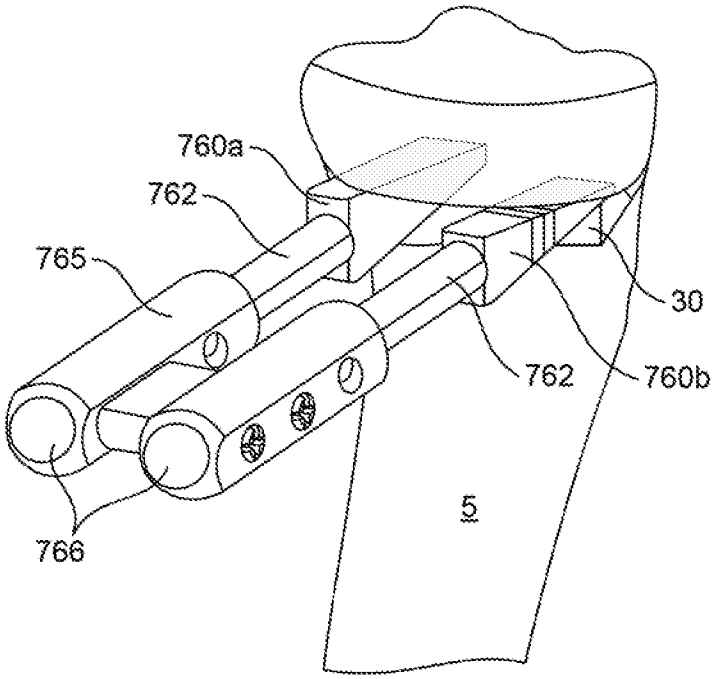


FIG. 6B

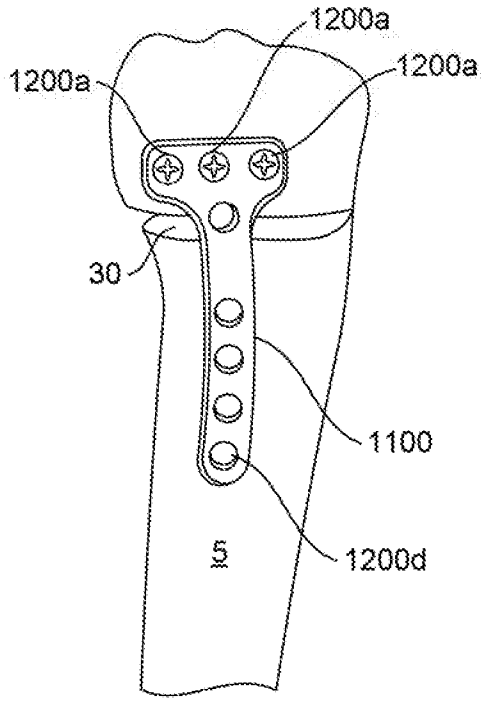

1200a
1200a
1200a
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1200d

FIG. 7A

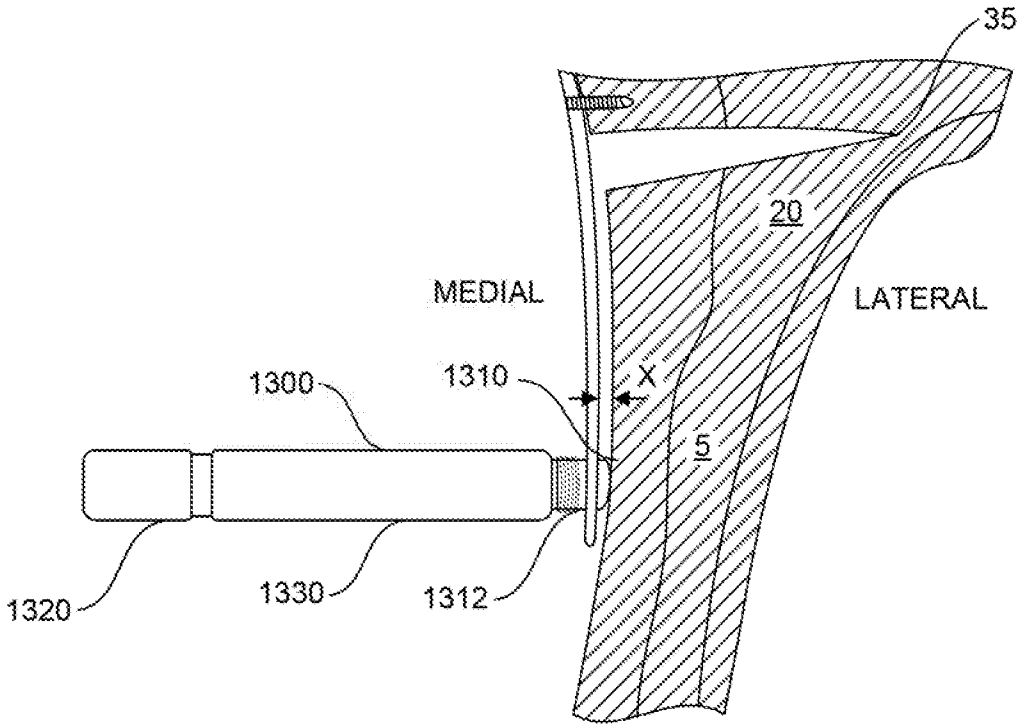

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LATERAL
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1310
X
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1330
1312

FIG. 7B

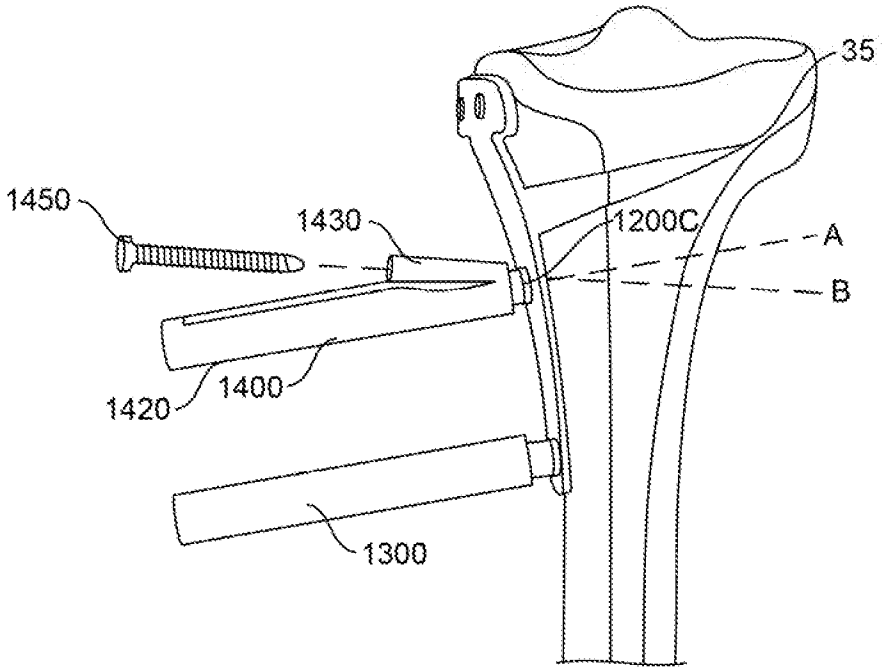


FIG. 7C

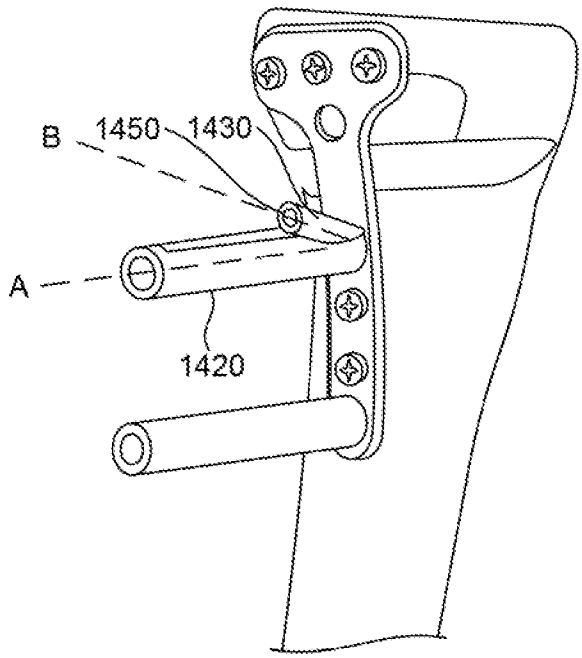


FIG. 7D

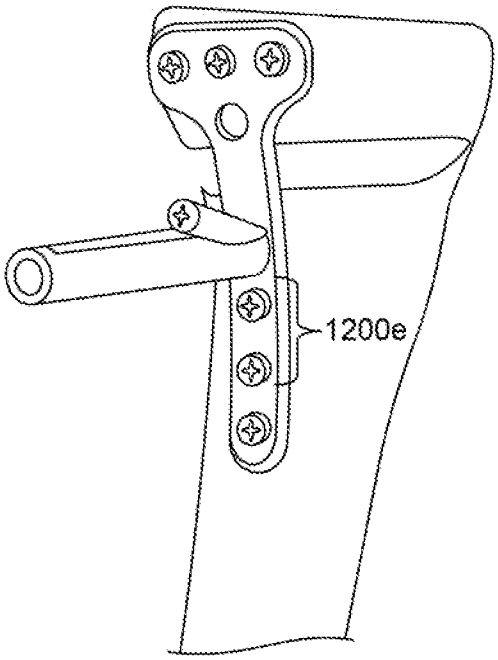


FIG. 7E

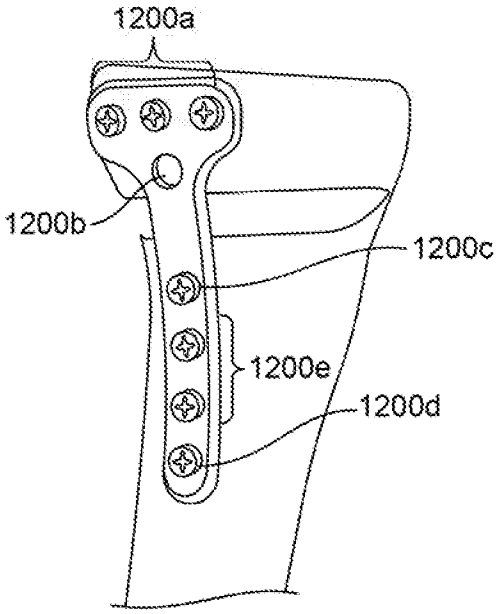


FIG. 7F

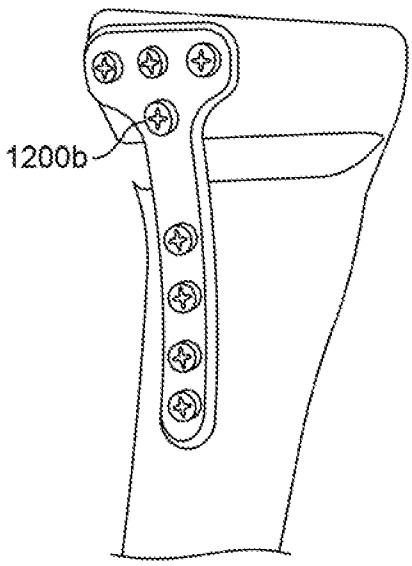


FIG. 7G

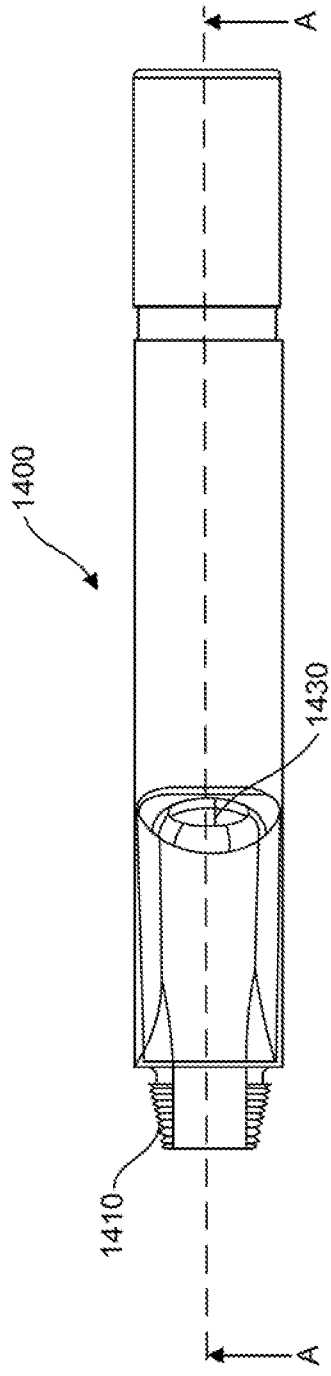


FIG. 8A

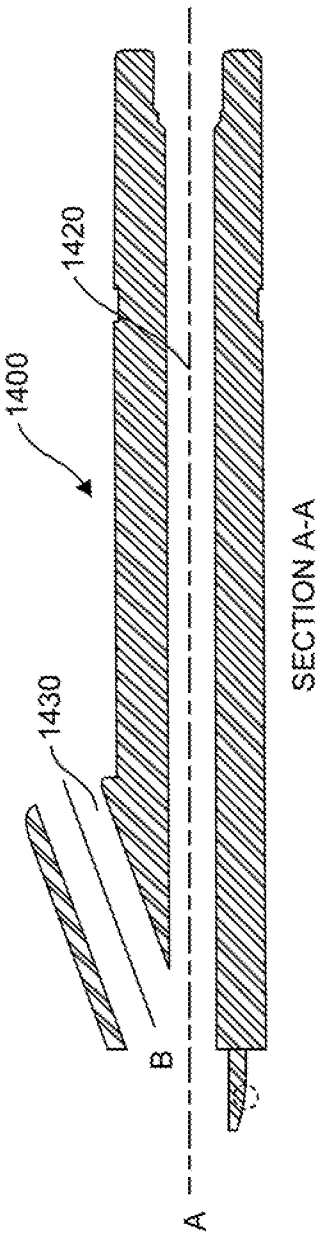


FIG. 8B

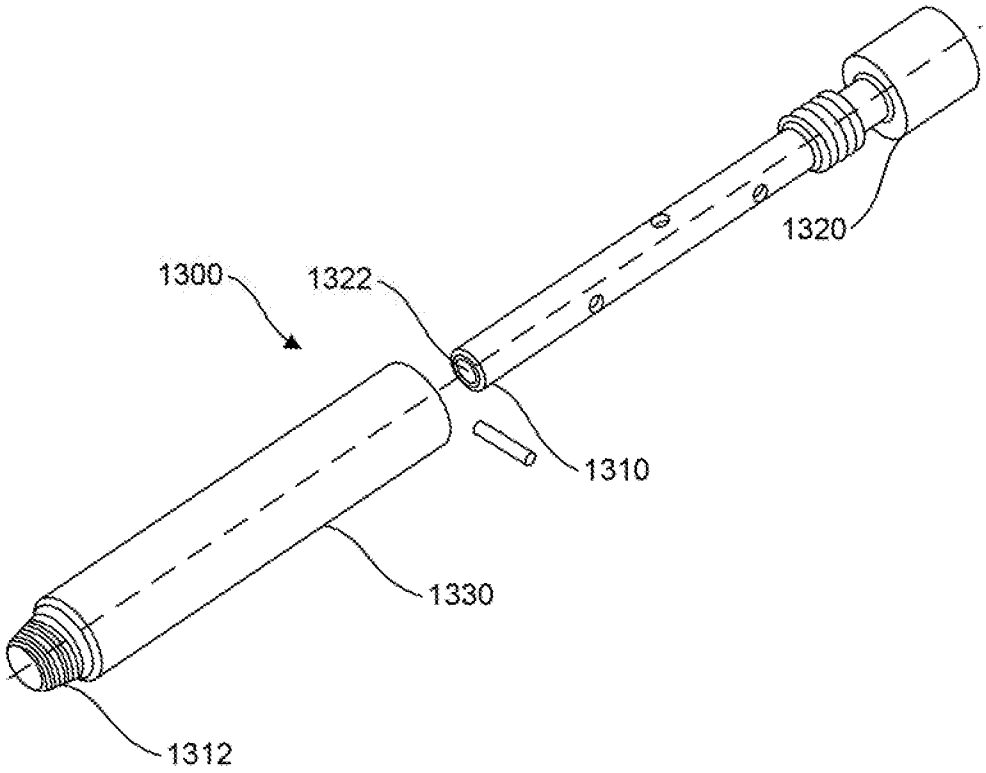


FIG. 9A

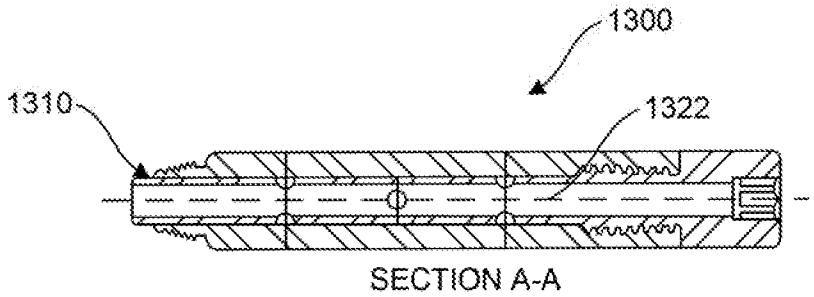


FIG. 9B

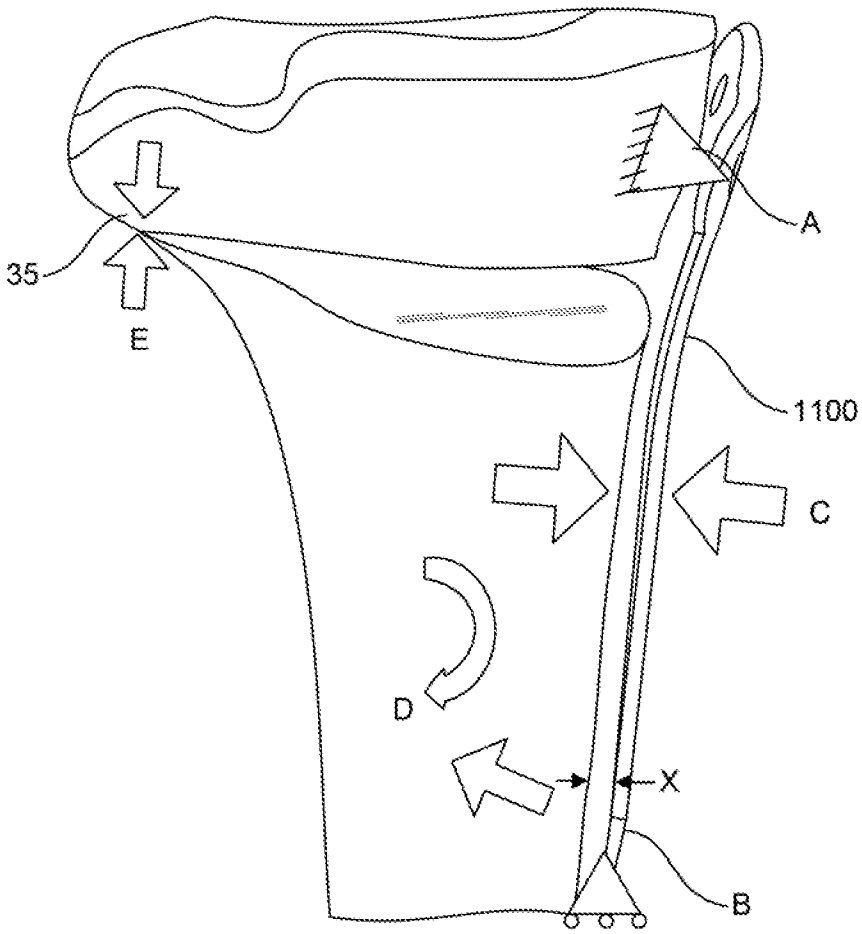


FIG. 10

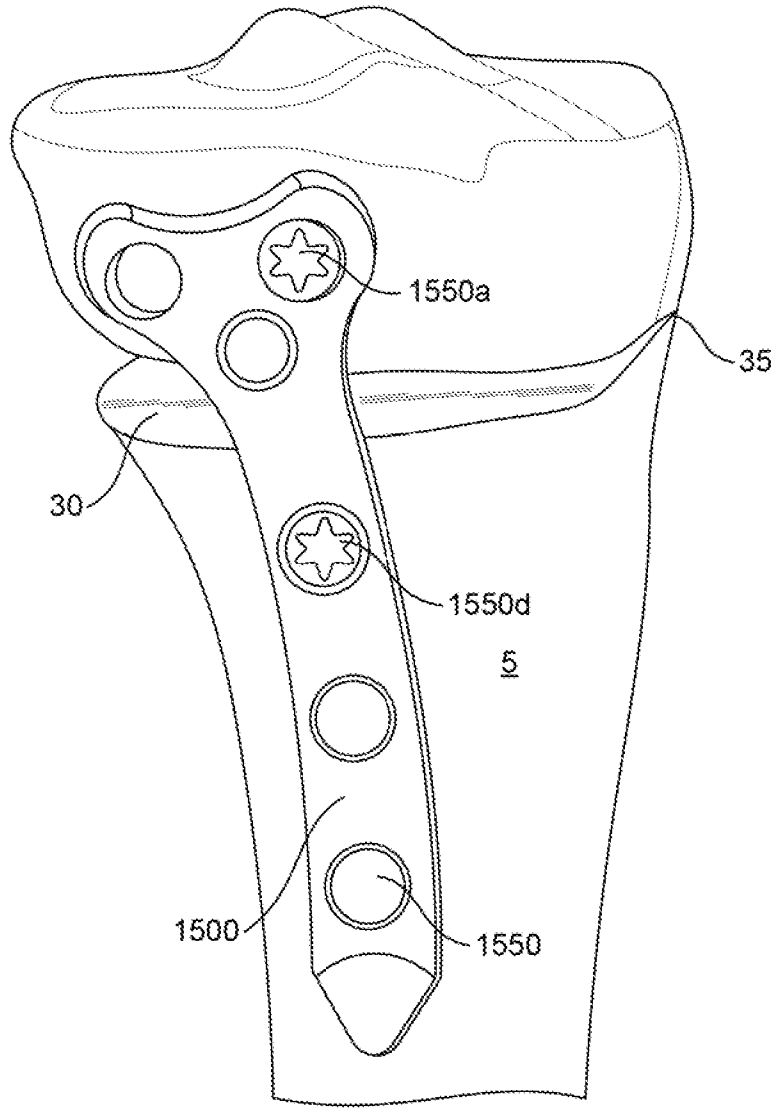


FIG. 11

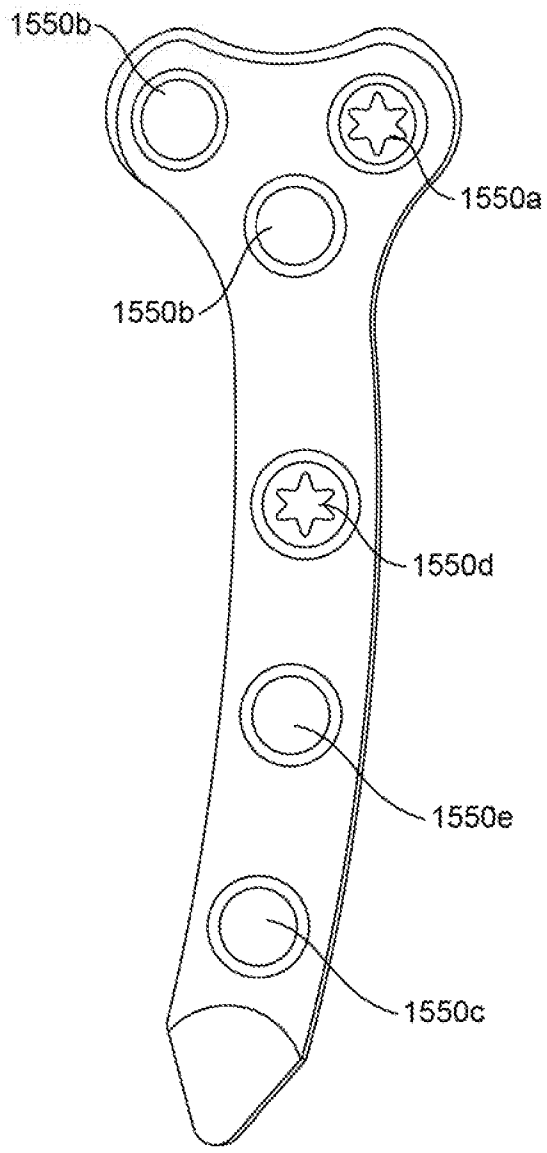


FIG. 12A

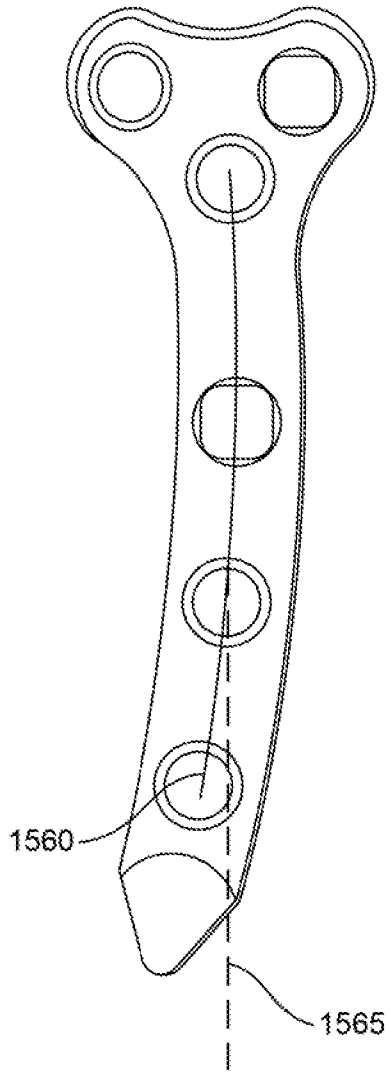


FIG. 12B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/019094

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/80 A61B17/15 A61B17/17
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)
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.
A	US 2016/192968 A1 (CHAN JASON S [US] ET AL) 7 July 2016 (2016-07-07) paragraphs [0073] - [0077] paragraphs [0087] - [0089] paragraph [0094] figures 13-14B, 25A-26C, 31	1,3-6
A	US 2014/243907 A1 (CAVALLAZZI CESARE [US] ET AL) 28 August 2014 (2014-08-28) paragraphs [0112] - [0115] figures 44-49	1-3,5,6

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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	Date of mailing of the international search report
30 April 2020	07/07/2020

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kakoullis, Marios

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2020/019094

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/039498 A1 (CHATAIN FREDERIC [FR] ET AL) 6 February 2014 (2014-02-06) paragraphs [0005] - [0011] paragraphs [0108] - [0116] pages 145-146 paragraphs [0150] - [0159] figures 1-10 -----	1,3,5,6
A	WO 2018/098086 A1 (ECA MEDICAL INSTR [US]) 31 May 2018 (2018-05-31) paragraphs [0026] - [0027] paragraphs [0031] - [0033] figures 8C-8E -----	1-3,5,6

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/019094

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. [X] Claims Nos.: 7-14
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:

see additional sheet

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. [X] 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.:

1-6

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

   A drill guide for adjusting an offset between a plate interior surface and a bone surface and thereby for adjusting flexion on the bone plate.

   ---

2. claims: 15-19

   A linking cutting guide system comprising a retractor, a cutting guide and an anterior pin.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2020/019094

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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