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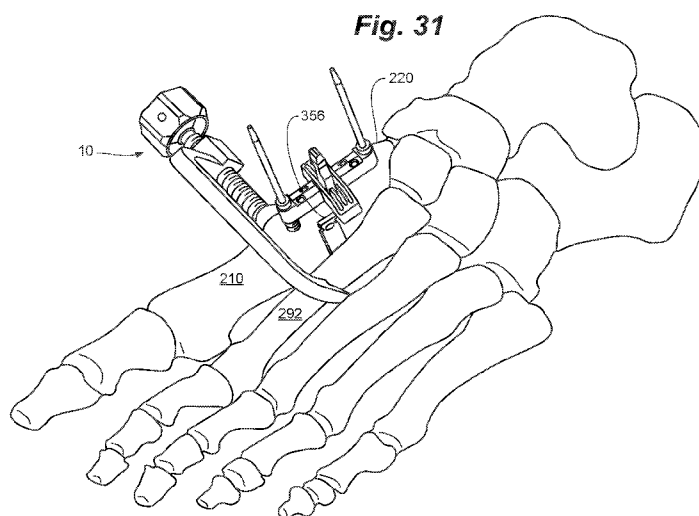
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[Continued on next page]

(54) Title: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM



(57) Abstract: A technique for correcting a bone deformity, such as a bunion, may be performed using a fulcrum. In some examples, the technique involves inserting a fulcrum between a first metatarsal that is anatomically misaligned with respect to a second metatarsal. The technique further includes preparing an end of the first metatarsal and preparing an end of a medial cuneiform opposing the end of the first metatarsal. In addition, a distal portion of the first metatarsal is moved toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.



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TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

RELATED APPLICATIONS

[0001] This application claims the benefit of US Provisional Application No. 62/293,189, filed February 9, 2016. This application is also a continuation-in-part of US Patent Application No. 14/981,335, filed December 28, 2015, which claims the benefit of US Provisional Application No. 62/205,338, filed August 14, 2015. The entire contents of all these applications are incorporated herein by reference.

TECHNICAL FIELD

[0002] This disclosure relates generally to devices and methods for positioning and/or preparing bones.

BACKGROUND

[0003] Bones, such as the bones of a foot, may be anatomically misaligned. In certain circumstances, surgical intervention is required to correctly align the bones to reduce patient discomfort and improve patient quality of life.

SUMMARY

[0004] Embodiments of the present invention include methods for fixing an orientation of a bone or bones. In general, the method of positioning a bone includes the steps of moving a bone from an anatomically misaligned position to an anatomically aligned position with respect to another bone and preparing an end of the bone and a facing end of another bone. In some embodiments, at least one bone end is prepared after the bone is moved into the aligned position. In some embodiments, the bone is anatomically aligned in more than one plane such that the bone both translates and rotates in response to a moving force.

[0005] One embodiment includes a method of correcting a bunion deformity. The method includes inserting a fulcrum between a first metatarsal and a second metatarsal, where the first metatarsal is anatomically misaligned with respect to the second metatarsal. The method further includes preparing an end of the first metatarsal and preparing an end of a medial cuneiform opposing the end of the first metatarsal. In addition, the method involves moving a distal portion of the first metatarsal toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing the intermetatarsal angle between the first metatarsal and the second metatarsal.

[0006] In one example, a fulcrum is described for use in a bone realignment procedure. The fulcrum includes a body and a handle. The body is configured to be inserted in an intermetatarsal space between adjacent metatarsals. The handle is operatively connected to the body. The example specifies that the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

[0007] In another example, a multidimensional fulcrum is described that includes a fulcrum body having a length extending from a first end to a second end, a width, and a thickness. The first end of the fulcrum has a first thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a first size. The second end of the fulcrum has a second thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a second size. The example specifies that the second thickness is greater than the first thickness.

[0008] The details of one or more examples are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The following drawings are illustrative of particular embodiments of the present invention and, therefore, in no way limit the scope of the invention. The drawings are not necessarily to scale (unless otherwise stated) and are intended for use in conjunction with the explanations in the following detailed description. Embodiments of the invention will hereinafter be described with respect to the appended drawings, wherein like numerals denote like elements.

[0010] FIG. 1 is a side perspective view of a bone positioning guide in accordance with an embodiment of the invention.

[0011] FIG. 2 is a side perspective view of a bone engagement member of a bone positioning guide in accordance with an embodiment of the invention.

[0012] FIG. 3A is a side perspective view of a tip of a bone positioning guide in accordance with an embodiment of the invention.

[0013] FIG. 3B is a side view of a bone positioning guide with a straight tip in accordance with an embodiment of the invention.

[0014] FIG. 3C is a side view of a bone positioning guide with a nonlinear tip in accordance with an embodiment of the invention.

[0015] FIG. 4 is an end view of an actuator of a bone positioning guide in accordance with an embodiment of the invention.

[0016] FIG. 5 is a top plan view of a bone preparing guide in accordance with an embodiment of the invention.

[0017] FIG. 6A is a perspective view of a bone preparing guide, a spacer, and a tissue removing instrument location check member in accordance with an embodiment of the invention.

[0018] FIG. 6B is a perspective view of another embodiment of a tissue removing instrument check location member engaged with a bone preparing guide.

[0019] FIG. 7 is a perspective view of a bone preparing guide engaged with a spacer in accordance with an embodiment of the invention.

[0020] FIG. 8 is a perspective view of a bone preparing guide engaged with a tissue removal instrument location check member in accordance with an embodiment of the invention.

[0021] FIG. 9A is a front view of a bone positioning guide on a deformed foot in accordance with an embodiment of the invention.

[0022] FIG. 9B is a front view of a bone positioning guide on a foot with a corrected alignment in accordance with an embodiment of the invention.

[0023] FIG. 10A is a top view of a bone positioning guide on a deformed foot in accordance with an embodiment of the invention.

[0024] FIG. 10B is a top view of a bone positioning guide on a foot with a corrected alignment in accordance with an embodiment of the invention.

[0025] FIGS. 11A-C depict a sequence of a bone positioning operation using a bone positioning guide on a foot at first, second, and third positions in accordance with an embodiment of the invention.

[0026] FIG. 12A is a front view of a foot with a normal first metatarsal position.

[0027] FIG. 12B is a front view of a foot with an isolated first metatarsal rotation bunion deformity.

[0028] FIG. 13A is a top view of a foot with a normal first metatarsal position.

[0029] FIG. 13B is a top view of a foot with an isolated first metatarsal transverse plane bunion deformity.

[0030] FIG. 14A is a side view of a foot with a normal first metatarsal position.

[0031] FIG. 14B is a side view of a foot with an isolated first metatarsal sagittal plane bunion deformity.

[0032] FIG. 15A is a perspective view and an enlarged view of a foot.

[0033] FIG. 15B is a perspective view of a first metatarsal.

[0034] FIG. 16 is a side perspective view of a foot depicting a bone preparation instrument inserted into a joint.

[0035] FIG. 17 is a perspective view of a foot depicting a bone positioning guide on the foot prior to an alignment of a first metatarsal.

[0036] FIG. 18 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal.

[0037] FIG. 19 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and an insertion of a spacer into a joint space.

[0038] FIG. 20 is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide.

[0039] FIG. 21A is a perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide with pins.

[0040] FIG. 21B is another perspective view of a foot depicting a bone positioning guide on the foot after an alignment of a first metatarsal and a positioning of a bone preparation guide with pins.

[0041] FIG. 22 is a perspective view of a foot depicting a bone preparation instrument preparing a bone of the foot guided by a guide surface of a bone preparation guide.

[0042] FIG. 23 is a perspective view of a foot depicting a bone positioning guide on the foot and a removal of a bone preparation guide.

[0043] FIG. 24 is a perspective view of a foot depicting a bone positioning guide on the foot and pins.

[0044] FIG. 25 is a perspective view of a foot depicting a bone positioning guide on the foot and a compression pin.

[0045] FIG. 26A is a side perspective view of a foot depicting bone plates across a joint between first and second bones and a compression pin in accordance with an embodiment of the invention.

[0046] FIG. 26B is a side perspective view of a foot depicting bone plates across a joint between first and second bones and a compression pin in accordance with an embodiment of the invention.

[0047] FIG. 27 is a side perspective view of a foot depicting bone plates across a joint between first and second bones in accordance with an embodiment of the invention.

[0048] FIG. 28A and FIG. 28B depict examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention.

[0049] FIG. 29A and FIG. 29B depict examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention.

[0050] FIG. 30A illustrates a portion of a foot having a bunion caused by a misaligned first metatarsal relative to a second metatarsal.

[0051] FIG. 30B shows an example base compression that can be caused after the foot of FIG. 30A is anatomically aligned.

[0052] FIG. 31 illustrates an example bone positioning operation in which a fulcrum is positioned at an intersection between a first bone and a second bone.

[0053] FIG. 32 is a perspective view of one example fulcrum.

[0054] FIG. 33 illustrates an example system of different sized fulcrums.

[0055] FIG. 34 is a perspective view of another bone positioning guide according to an embodiment of the invention.

[0056] FIG. 35 illustrates an example configuration of a joint spacer that can allow a bone preparation guide to rotate around the spacer.

[0057] FIG. 36A is a perspective view of an example configuration of a bone positioning guide having an opening with circular cross-sectional shape.

[0058] FIG. 36B is a perspective view of the example bone positioning guide of FIG. 36A shown with the joint spacer from FIG. 35 inserted into the guide.

[0059] FIG. 37 is a block flow diagram of an example bone correction technique utilizing a fulcrum.

[0060] FIG. 38 is a perspective view of a foot showing an example position of a fulcrum during a bone correction procedure according to the method of FIG. 37.

[0061] FIGS. 39A and 39B are different perspective views of another example fulcrum that can be used during a bone correction procedure.

[0062] FIG. 40 is an image of the example fulcrum of FIGS. 39A and 39B inserted between a first metatarsal and a second metatarsal.

[0063] FIG. 41 illustrates an alternative arrangement of surface features that may be used on the example fulcrum of FIGS. 39A and 39B.

[0064] FIGS. 42A and 42B are perspective and side views, respectively, of an example fulcrum having two fulcrum bodies.

[0065] FIGS. 43A and 43B are perspective and side views, respectively, of an example multidimensional fulcrum having ends of different dimensions and a unitary body.

DETAILED DESCRIPTION

[0066] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention. Rather, the following description provides practical illustrations for implementing exemplary embodiments of the disclosure. Examples of constructions, materials, and dimensions are provided for selected elements, and all other elements employ that which is known to those of ordinary skill in the field of the invention. Those skilled in the art will recognize that many of the noted examples have a variety of suitable alternatives.

[0067] Embodiments of the invention include a bone positioning guide and method of positioning bones in a medical procedure. In an exemplary application, embodiments of the bone positioning guide can be useful during a surgical procedure, such as a bone alignment, osteotomy, fusion procedure, and/or other procedures where one or more bones are to be prepared (e.g., cartilage or bone removal and/or cut). Such a procedure can be performed, for example, on bones (e.g., adjacent bones separated by a joint or different portions of a single bone) in the foot or hand, where bones are relatively smaller compared to bones in other parts of the human anatomy. In one example, a procedure utilizing an embodiment of the bone positioning guide can be performed to correct an alignment between a metatarsal (e.g., a first metatarsal) and a second metatarsal and/or a cuneiform (e.g., a medial, or first, cuneiform), such as in a bunion correction surgery. An example of such a procedure is a Lapidus procedure (also known as a first tarsal-metatarsal fusion). In another example, the procedure can be performed by modifying an alignment of a metatarsal (e.g., a first metatarsal). An example of such a procedure is a basilar metatarsal osteotomy procedure.

[0068] FIG. 1 shows a side perspective view of a bone positioning guide 10 in accordance with an embodiment of the invention. The bone positioning guide 10 can be useful for positioning a bone (e.g., orientating and/or translating) during a medical procedure. In some embodiments, the bone positioning guide includes a bone engagement member, a tip, a mechanism to urge the bone engagement member and the tip towards each other (e.g. moving the bone engagement member towards the tip, moving the tip towards the bone engagement member, or moving both simultaneously), and an actuator to actuate the mechanism. When the mechanism is actuated it causes a first bone engaged with the bone engagement member to move to correct an alignment in more than one plane with respect to a second bone in

contact with the tip. In some embodiments, the correction in more than one plane includes a correction about an axis in a frontal plane.

[0069] In the embodiment of FIG. 1, bone positioning guide 10 includes a main body member 20 and a shaft 30, and the bone engagement member 40 is connected to the shaft and the tip 50 is connected to the main body member. In general, the main body member 20 can be sized and shaped to clear anatomy or other instrumentation (e.g., pins and guides) while positioned on a patient. In the embodiment of FIG. 1, the main body member 20 includes a generally C-shaped configuration with a first end 60 and a second end 70. In some embodiments, the main body is sized and configured to engage bones of a human foot. In addition, although bone positioning guide 10 is illustrated as being formed of two components, main body member 20 and shaft 30, the guide can be fabricated from more components (e.g., 3, 4, or more) that are joined together to form the guide.

[0070] A shaft 30 can be movably connected to the main body member 20 proximate its first end 60. In some embodiments, the shaft 30 includes threads 80 that engage with the main body member 20 such that rotation of the shaft translates the shaft with respect to the main body member. In other embodiments, the shaft can slide within the main body member and can be secured thereto at a desired location with a set screw. In yet other embodiments, the shaft can be moved with respect to the main body by a ratchet mechanism. In the embodiment shown, the shaft moves along an axis that intersects the tip 50. In other embodiments, such as that described with respect to FIG. 34, the shaft 30 and/or bone engagement member 40 is offset from tip 50.

[0071] As shown in FIG. 2, embodiments of the bone positioning device can have a bone engagement member 40. In some embodiments, the bone engagement member includes a surface 90 configured to contact a bone, such as a metatarsal or a cuneiform. In the embodiment shown, the surface 90 is concave. Such a surface is adapted to promote surface contact with a generally cylindrical bone, such as a metatarsal. Other embodiments of surface shapes include planar surfaces and V-shaped surfaces. When using a concave or V-shaped bone engagement member 40, the sidewalls of the concavity or V-shaped groove may be symmetrical or asymmetrical. In a symmetrical configuration, the bottom of the concavity or groove can be centered between upwardly extending sidewalls configured to receive a bone. Each sidewall can extend upwardly to the same height and/or at the same slope. In the asymmetrical configuration, one sidewall can have a different configuration than the opposing sidewall. For example, one of the sidewalls may extend upwardly from the bottom of the concavity or groove to a lower height than the opposing sidewall. As another example,

one sidewall may extend upwardly at a different angle than the opposing sidewall. The asymmetrical configuration can be useful for applying a force that is biased laterally instead of only being linear toward tip 50.

[0072] In some embodiments, bone engagement member 40 includes a pin or a clamp. Independent of whether bone engagement member 40 includes such pin or clamp, the bone engagement member can engage an anatomical feature of a bone, such as a ridge (e.g., a medial ridge of a first metatarsal). In such embodiments, the engagement generally prohibits rotational movement of the bone with respect to the bone engagement member. In other embodiments, bone may be allowed to rotate with respect to the bone engagement member.

[0073] In the embodiment shown, the bone engagement member 40 is provided on an end of the shaft 30. In the embodiment of the shaft shown having threads 80, the bone engagement member 40 can be rotatably coupled to the shaft 30. In such embodiments, as the shaft is rotated relative to the main body member the bone engagement member 40 may or may not rotate with respect to the main body member even as it translates with respect to the main body member along with the shaft 30 and rotates with respect to the shaft. The bone engagement member may oscillate about the shaft 30, but generally does not rotate with respect to bone after contact with the bone.

[0074] FIGS. 3A-C depict a tip 50 of bone positioning guide 10, which can be at a second end 70 of the main body member opposite the first end. The tip 50 can be useful for contacting a bone, generally a bone distinct from a bone contacting the bone engagement member. For example, if the bone engagement member is in contact with a first metatarsal, the tip can be in contact with a metatarsal other than the first metatarsal (e.g., the second, third, fourth, or fifth metatarsal). In some embodiments, the tip is tapered to facilitate percutaneous insertion and contact with bone. The tip can also include a textured surface 100, such as serrated, roughened, cross-hatched, knurled, etc., to reduce slippage between the tip and bone. In the embodiment shown, the tip further includes a stop 110 to limit a depth of insertion. The shape of the tip can be configured to stably contact bone. For example, FIG. 3B shows a side view of the bone positioning guide with a generally straight tip 50, while FIG. 3C shows a side view of the bone positioning guide with a nonlinear tip 50 (e.g., a tip that is angled or curved). In some embodiments, the tip is configured to restrict translational movement between it and a bone, but to allow rotational movement between it and the bone.

[0075] As shown in FIG. 4, bone positioning guide 10 can also include an actuator (e.g., a knob or a handle) 120 to actuate the mechanism, in this embodiment associated with the shaft. In the embodiment shown, the actuator can be useful for allowing a user to rotate the

shaft with respect to the main body member 20. Also as shown in FIG. 4, the actuator, shaft, and bone engagement member may include a cannulation 130 to allow the placement of a fixation wire (e.g., K-wire) through these components and into contact with or through a bone engaged with the bone engagement member. For example, the fixation wire can be placed into the bone engaged with bone engagement member 40 to fix the position of the bone engagement member with respect to the bone. In another example, the fixation wire can be placed through the bone in contact with the bone engagement member and into an adjacent bone to maintain a bone position of the bone in contact with the bone engagement member and the adjacent bone.

[0076] In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a tenaculum or tong structure. In such embodiments, the guide can include a first shaft pivotably connected to a second shaft. A first end of each shaft can include an actuator, such as a handle. A second end of the first shaft can include a bone engagement member, as described above. And a second end of the second shaft can include a tip, as described above. In use, the actuator can be actuated (e.g., squeezed together) to move the bone engagement member and the tip closer together to position bone. Other embodiments of this type may include another set of shafts and another pivoting connection such that the bone engagement member and tip translate towards each other when the actuator is actuated.

[0077] In other embodiments, the mechanism to urge the bone engagement member and the tip towards each other can include a rack and pinion structure. In such embodiments, the rack can include a tip, as described above. And the pinion can include a bone engagement member, as described above, and an actuator (e.g., a knob). In use, the actuator can be actuated (e.g., turned about an axis generally perpendicular to a direction of travel) to move the bone engagement member and the tip closer together to position bone.

[0078] Embodiments of the bone positioning guide may include any suitable materials. In certain embodiments, the bone positioning guide is fabricated from a radiolucent material such that it is relatively penetrable by X-rays and other forms of radiation, such as thermoplastics and carbon-fiber materials. Such materials are useful for not obstructing visualization of bones using an imaging device when the bone positioning guide is positioned on bones.

[0079] Embodiments of the bone positioning guide can be useful in operation for positioning a bone or bones during a medical procedure. Bone positioning can be useful, for instance, to correct an anatomical misalignment of bones and maintain an anatomically aligned position,

such as in a bone alignment and/or fusion procedure. In some embodiments, the bone positioning guide is capable of reducing an angle between the first metatarsal and the second metatarsal from over 10 degrees (e.g., up to about 35 degrees) to about 10 degrees or less (e.g., to about 1-5 degrees), including to negative angles of about -5 degrees. In some embodiments, the bone positioning guide is also capable of rotating the first metatarsal about its long axis with respect to the medial cuneiform from a rotational angle of over 4 degrees to a rotational angle of less than 4 degrees (e.g., to about 0 to 2 degrees).

[0080] In some embodiments, a bone preparation guide may be provided to facilitate the preparation of a bone. The bone preparation guide can be provided with a bone positioning guide, or either device can be provided or used independently. An example of a bone preparation guide 150 is shown in FIG. 5. In some embodiments, the bone preparation guide 150 includes a body 154 defining a first guide surface 160 to define a first preparing plane and a second guide surface 164 to define a second preparing plane. A tissue removing instrument (e.g., a saw, rotary bur, osteotome, etc., not shown) can be aligned with the surfaces to remove tissue (e.g., remove cartilage or bone and/or make cuts to bone). The first and second guide surfaces 160, 164 can be spaced from each other by a distance, (e.g., between about 2 millimeters and about 10 millimeters, such as between about 4 and about 7 millimeters). In the embodiment shown, the first and second guide surfaces are parallel, such that cuts to adjacent bones using the guide surfaces will be generally parallel.

[0081] In some embodiments, as shown in FIG. 5, a first facing surface 166 is positioned adjacent the first guide surface 160 and/or a second facing surface 168 is positioned adjacent the second guide surface 164. In such embodiments, the distance between the first guide surface and the first facing surface defines a first guide slot, and the distance between the second guide surface and the second facing surface defines a second guide slot. Each slot can be sized to receive a tissue removing instrument to prepare the bone ends. The first and second slots may be parallel or skewed. In the illustrated embodiment, the facing surfaces each contain a gap, such that the surface is not a single, continuous surface. In other embodiments, the facing surfaces can be a single, continuous surface lacking any such gap.

[0082] An opening 170 can be defined by the body 154 between the first and second guide surfaces. The opening can be an area between the guide surfaces useful for allowing a practitioner to have a visual path to bones during bone preparation and/or to receive instruments. In the embodiment shown, the opening extends across the body and a distance from a surface 172 opposite of the first facing surface 166 to a surface 174 opposite of the second facing surface 168.

[0083] The embodiment shown also includes a first end 176 extending from the body 154 in a first direction and a second end 178 extending from the body in a second direction. The second direction can be different than the first direction (e.g., an opposite direction). As shown, each of the first end and the second end can include at least one fixation aperture 180 configured to receive a fixation pin (not shown in FIG. 5) to secure the guide to a bone. As shown, such apertures may extend through the end at a vertical or skewed angle relative to a top surface of the guide.

[0084] The bone preparation guide 150 can also include a first adjustable stabilization member 182 engaged with the first end 176. In some embodiments, the bone preparation guide can include a second adjustable stabilization member 184 engaged with the second end 178. Each of the members can be threaded and engage a threaded aperture defined by the ends. The elevation of each end can be adjusted with respect to a bone by adjusting the stabilization member. In some embodiments, as shown, the stabilization members are cannulated such that they can receive a fixation pin.

[0085] As shown in FIGS. 6A and 7, the bone preparation guide can also include a spacer 188 extending downward from the body 154 and configured to be placed into a joint. In some embodiments, the spacer 188 is selectively engageable with the body. The spacer can have a first portion 190 configured to extend into a joint space and a second portion 192 engageable with the body 154. In the embodiment shown, the spacer can be received within opening 170, such that the spacer extends from the body in between the first and second guide surfaces. Such a spacer can be useful for positioning the body at a desired position with respect to a joint and for properly positioning the guide with respect to bones to be cut in more than one plane (e.g., three planes selected from more than one of a frontal plane, a transverse plane, and a sagittal plane). The distance between the spacer and the first guide surface can define a length of tissue removal (e.g., bone or cartilage to be cut) from a first bone, and the distance between the spacer and the second guide surface can define a length of tissue removal (e.g., bone or cartilage to be cut) from a second bone.

[0086] As shown in FIGS. 6A/B and 8, the bone preparation guide can also include a tissue removal location check member 194 engageable with the body 154 and configured to extend to a first bone and a second bone. The tissue removal location check member can have a first portion 196 configured to extend into contact with first and second bones and a second portion 198 engageable with the body. In the embodiments shown in FIGS. 6A and 8, the tissue removal location check member extends from the body at both the first and second guiding surfaces. In other embodiments, such as the embodiment shown in FIG. 6B, separate

tissue removal location check members are provided for independent insertion into respective slots of the guide. Accordingly, embodiments of tissue removal location check members are useful for allowing a practitioner to see where a tissue removing instrument guided by the surfaces will contact the bone to be prepared.

[0087] Embodiments of the bone preparation guide can be useful in operation for guiding a preparation of a bone or bones at a targeted anatomy. Bone preparation can be useful, for instance, to facilitate contact between leading edges of adjacent bones, separated by a joint, or different portions of a single bone, separated by a fracture, such as in a bone alignment and/or fusion procedure. A bone may be prepared using one or more bone preparation techniques. In some applications, a bone is prepared by cutting the bone. The bone may be cut transversely to establish a new bone end facing an opposing bone portion. Additionally or alternatively, the bone may be prepared by morselizing an end of the bone. The bone end can be morselized using any suitable tool, such as a rotary bur, osteotome, or drill. The bone end may be morselized by masticating, fenestrating, crushing, pulping, and/or breaking the bone end into smaller bits to facilitate deformable contact with an opposing bone portion.

[0088] Embodiments of the present invention also include methods for temporarily fixing an orientation of a bone or bones, for example, prior to or in conjunction with permanently fixing the orientation of the bone or bones. In general, the method of positioning a bone includes the steps of moving a bone from an anatomically misaligned position to an anatomically aligned position with respect to another bone and preparing an end of the moved bone and a facing end of another bone. In some embodiments, the end of at least one of the moved bone and the other bone is prepared after moving the bone into the aligned position. In certain embodiments, the bone is anatomically aligned in more than one plane with respect to another bone by applying a force to one bone at a single location, such that the bone both translates and rotates in response to the force. In certain embodiments, the moving step can be accomplished with a bone positioning device and/or the preparing step can be accomplished with a bone preparation guide, as described herein. In other embodiments, the moving step can be accomplished by a clinician physically grasping a bone, either through direct contact with the bone or indirectly (e.g., by inserting a K-wire, grasping with a tenaculum, or the like), and moving his hand to move the bone. In these applications, a fulcrum may be used to control movement of the bone, as also described herein.

[0089] FIGS. 9A-B depict frontal views of a bone positioning guide 10 on a foot 200 having a first metatarsal 210, a medial cuneiform 220, a second metatarsal 292, and a third metatarsal 294. FIG. 9A depicts a foot 200 with an uncorrected bunion deformity, while FIG. 9B

depicts the foot 200 with an alignment corrected by the bone positioning guide 10. Solid line L1 represents the starting location of the bone positioning guide 10 and dotted line L2 represents the finishing location of the bone positioning guide. As shown, as the bone positioning guide 10 is actuated it rotates with the first metatarsal 210 about an axis extending through the frontal plane as it pushes the first metatarsal 210 laterally in the transverse plane and plantarly in the sagittal plane. Accordingly, in this example, the position of the first metatarsal 210 is corrected with respect to the second metatarsal 292 generally in three planes by actuating a single bone positioning guide 10 to urge a bone engagement member 40 toward a tip 50. FIG. 10A shows a top view of a foot 200 with an uncorrected bunion deformity, while FIG. 10B shows a top view of the foot 200 with an alignment corrected by the bone positioning guide 10, emphasizing the rotational correction in the frontal plane and the lateral correction in the transverse plane.

[0090] FIGS. 11A-C show three sequential images of a bone positioning guide 10 on a foot 200 positioning a first metatarsal 210 with respect to a second metatarsal 292. FIG. 11A represents the beginning of the procedure, FIG. 11B the middle, and FIG. 11C the end. The orientation of the pins 270 is useful for visualizing the amount of rotation of the first metatarsal 210 in each image. With respect to FIGS. 11A-C, it can be seen the bone positioning guide 10 and the first metatarsal 210 are rotating in the frontal plane in response to actuation of bone positioning guide 10. Further, the angle between the first metatarsal 210 and second metatarsal 292 is reduced, as the space that can be seen between the first and second metatarsals in FIG. 11A is eliminated in FIG. 11C.

[0091] Each of the three potential planes of deformity will now be described in isolation. FIGS. 12A and 12B show frontal plane views of a foot 200. In FIG. 12A, the foot 200 is normal, while in FIG. 12B the foot is depicted with an uncorrected bunion deformity showing an isolated axial rotation of the first metatarsal 210. Solid line L3 indicates the alignment of the first metatarsal 210 relative to ground, while dotted line L4 in FIG. 12B indicates the extent of axial rotation in the frontal plane.

[0092] FIGS. 13A and 13B show transverse plane views of a foot 200. In FIG. 13A, the foot 200 is normal, while in FIG. 13B the foot is depicted with an uncorrected bunion deformity showing an isolated transverse plane first metatarsal 210 deviation. Solid line L5 indicates the alignment of the second metatarsal 292 and solid line L6 indicates the proper alignment of the first metatarsal 210 relative to the second metatarsal 292. The angle between these two lines forms the intermetatarsal angle (IMA). Dotted line L7 in FIG. 13B indicates the extent of transverse deviation.

[0093] FIGS. 14A and 14B show sagittal plane views of a foot 200. In FIG. 14A, the foot 200 is normal, while in FIG. 14B the foot is depicted with an uncorrected bunion deformity showing an isolated sagittal deviation of the first metatarsal 210. Solid line L8 indicates the proper alignment of the first metatarsal 210, while dotted line L9 in FIG. 14B indicates the extent of sagittal deviation.

[0094] A specific embodiment of a method in accordance with an embodiment of the invention includes the steps of engaging a bone engagement member with a first bone, placing a tip of the bone positioning guide in apposition to a second bone, the second bone being different from the first bone, and moving the bone engagement member with respect to the tip to change the position of the first bone with respect to the second bone in more than one plane. In some embodiments, after alignment, at least one of an end of the first bone and a facing end of a third bone are prepared (e.g., only the end of the first bone or both the end of the first bone and the end of the second bone), optionally using a preparation guide.

[0095] In some embodiments, the method includes the step of mobilizing a joint for a corrective procedure. For example, after creating surgical access to the joint and before moving the bones into an aligned position, tissue can be released to allow a bone, such as a metatarsal, to rotate freely. In some embodiments, obstructing bone may be excised (e.g., a dorsolateral flare of the metatarsal base, a plantar flare of the metatarsal base (sometimes referred to as a plantar condyle), part of an end of a metatarsal facing a cuneiform, or osteophyte) to further promote free rotation by creating relatively flat surfaces with respect to a frontal plane. An example of a dorsolateral flare F on a first metatarsal 210 of a foot 200 is shown in FIG. 15A. An example of a plantar flare PF on a first metatarsal 210 is shown in FIG. 15B. FIG. 15B also depicts a medial ridge MR, which, in some embodiments, can be engaged by the bone engaging member of a bone positioning guide.

[0096] Embodiments of methods in accordance with the invention can also include steps performed after preparing the ends of the bones. For example, the ends of the bones may be placed in apposition and optionally compressed together and the position of the bones can be fixed with one or more bone fixation devices (e.g., compressing bone screw, bone plate, bone staple, external fixator, intramedullary implant or nail) prior to a closing of the surgical access to the joint.

[0097] An exemplary method will now be described with respect to FIGS. 16-27 depicting a foot 200 having a first metatarsal 210, a medial cuneiform 220, and a second metatarsal 292. Note, unless otherwise indicated, the steps described need not be carried out in the order described.

[0098] After customary surgical preparation and access, a bone preparation instrument 296 can be inserted into the joint (e.g., first tarsal-metatarsal joint) to release soft tissues and/or excise the plantar flare from the base of the first metatarsal 210, as shown in FIG. 16.

Excising the plantar flare may involve cutting plantar flare off the first metatarsal 210 so the face of the first metatarsal is generally planar. This step helps to mobilize the joint to facilitate a deformity correction. In some embodiments, the dorsal-lateral flare of the first metatarsal may also be excised to create space for the deformity correction (e.g., with respect to rotation of the first metatarsal). In certain embodiments, a portion of the metatarsal base facing the medial cuneiform can be removed during this mobilizing step.

[0099] An incision can be made and a tip 50 of a bone positioning guide 10 can be inserted on the lateral side of a metatarsal other than the first metatarsal 210, such as the second metatarsal 292. As shown in FIG. 17, the tip can be positioned proximally at a base of the second metatarsal 292 and a third metatarsal 294 interface. A surface of a bone engagement member 40 can be placed on the proximal portion of the first metatarsal 210. In some embodiments, the bone engagement member engages a medial ridge of the first metatarsal 210. As shown, the body 20 of the positioning guide can be generally perpendicular to the long axis of the second metatarsal 292.

[0100] As depicted in FIG. 18, the actuator 120 can be actuated to extend the shaft 30 to reduce the angle (transverse plane angle between the first metatarsal and the second metatarsal) and rotate the first metatarsal about its axis (frontal plane axial rotation). The first metatarsal 210 can be properly positioned with respect to the medial cuneiform 220 by moving the bone engagement member 40 with respect to the tip 50. In some embodiments, such movement simultaneously pivots the first metatarsal with respect to the cuneiform and rotates the first metatarsal about its longitudinal axis into an anatomically correct position to correct a transverse plane deformity and a frontal plane deformity. In certain embodiments, body 20 rotates in a generally lateral direction during this step. In some embodiments, fixation pins (not shown in FIG. 18) can be inserted into the bones prior to the positioning step (e.g., freehand or using apertures in the guide as a template), and can be used to impart additional force (transverse, sagittal, and/or frontal plane rotational) to the first metatarsal 210, if desired. The bone positioning guide 10 can hold the desired position of the first metatarsal 210 with respect to the second metatarsal 292. After the desired correction is achieved, a fixation wire 298 can be inserted through a cannulation in the shaft 30 and driven into the first metatarsal 210 and the second metatarsal 292 to hold the corrected position.

[0101] As depicted in FIG. 19, a joint spacer 188 can be positioned within the joint between the first metatarsal and the medial cuneiform.

[0102] As shown in FIG. 20, a bone preparation guide 150 can be placed over the joint spacer 188 and engaged with the joint spacer to set a position and orientation of the bone preparation guide relative to the joint. As shown, the bone preparation guide 150 can be positioned proximal to the bone positioning guide 10 in longitudinal alignment with the long axis of the first metatarsal 210 and the medial cuneiform 220, generally on the dorsal or dorsal-medial surface. In other embodiments, the spacer 188 is positioned after the guide 150 is provisionally placed on the bones. In yet other embodiments, bone preparation guide 150 and joint spacer 188 are placed simultaneously. In still other embodiments, bone preparation guide 150 is placed on the bones without using joint spacer 188 to aid with positioning.

[0103] As depicted in FIGS. 21A and 21B, one or more fixation pins 270 can be inserted into apertures of the bone preparation guide 150 to secure the guide to the first metatarsal 210 and the medial cuneiform 220. As shown, some pins 270 can be inserted at an angle or in a converging orientation to help prevent movement of the bone preparation guide 150 during a tissue removing step. As shown, two of the pins 270, one on the first metatarsal and one on the medial cuneiform, are parallel to allow the bone preparation guide 150 to be removed from the foot without removing all the pins. After insertion of the pins 270, the spacer 188 can optionally be removed in embodiments having a selectively engageable spacer (e.g., a joint spacer 188 that is physically removable from bone preparation guide 150).

[0104] In some embodiments, the location of the intersection of the tissue removing instrument and the bone to be prepared is confirmed before bone preparation. In one embodiment, a tissue removing instrument location check member can be engaged with the preparation guide to visually confirm where a tissue removal instrument will contact the bone. In another embodiment, a tissue removal instrument is engaged with the preparation guide to visually confirm where the instrument will contact the bone. In either embodiment, such visual confirmation can include the use of an imaging device, such as an X-ray. If the position of the preparation guide is correct, additional fixation pins may be inserted through the apertures (e.g., angled apertures) to further fix the position of the preparation guide with respect to the first metatarsal and the medial cuneiform. In some embodiments, the spacer is reattached prior to further bone preparation steps.

[0105] In some embodiments, the end of the first metatarsal 210 facing the medial cuneiform 220 can be prepared with a tissue removing instrument 296 guided by a guide surface of bone preparation guide 150 (e.g., inserted through a slot defined by a first guide surface and a first

facing surface). Additionally or alternatively, the end of the first metatarsal 210 facing the medial cuneiform 220 can be prepared by morselizing the end of the first metatarsal. In some embodiments, the first metatarsal 210 end preparation is done after the alignment of the bones, e.g., by actuating bone positioning guide 10 before preparing the end of first metatarsal 210. In other embodiments, the first metatarsal 210 end preparation is done before the alignment of the bones, e.g., by preparing the end of the first metatarsal 210 before actuating bone positioning guide 10.

[0106] In addition, as shown in FIG. 22, the end of the medial cuneiform 220 facing the first metatarsal 210 can be prepared with the tissue removing instrument 296 guided by a guide surface of bone preparation guide 150 (e.g., inserted through a slot defined by a second guide surface and a second facing surface). Additionally or alternatively, the end of the medial cuneiform 220 facing the first metatarsal 210 can be prepared by morselizing the end of the medial cuneiform. In some embodiments, the medial cuneiform 220 end preparation is done after the alignment of the bones. In yet other embodiments, the medial cuneiform 220 end preparation is done before the alignment of the bones. In embodiments that include cutting bone or cartilage, the cuneiform cut and the metatarsal cut can be parallel, conforming cuts. In the specific embodiment shown in FIG. 22, a saw blade can be inserted through a first slot to cut a portion of the medial cuneiform and the saw blade can be inserted through a second slot to cut a portion of the first metatarsal (e.g., in some embodiments the medial cuneiform can be cut before the first metatarsal). Accordingly, in the embodiment shown, the cuts to both the first metatarsal and the medial cuneiform were preformed after the first metatarsal was positioned.

[0107] Any angled/converging pins can be removed and the bone preparation guide 150 can be lifted off the parallel pins 270, as shown in FIG. 23. The parallel pins can be referred to as “reference pins” which can serve as a reference in later steps to ensure that the corrected alignment of the first metatarsal 210 has been maintained. The joint spacer can also be removed before, after, or simultaneously with the bone preparation guide. In some embodiments, the bone positioning guide 10 is also removed from the foot.

[0108] The tissue (e.g., bone or cartilage slices) from the first metatarsal and the medial cuneiform can be removed from the joint site and the joint surfaces can be fenestrated, if desired. If the bone positioning guide was taken off the foot, it can be put back on, as shown in FIG. 24, before the additional steps discussed below.

[0109] After preparation, the ends of the two bones can be placed in apposition and optionally compressed together by provisionally fixating the joint. For example, the two

bones may be placed in apposition by placing the cut and/or morselized end of the first metatarsal 210 in abutment with the cut and/or morselized end of the medial cuneiform 220. In some examples, the cut and/or morselized end of the first metatarsal 210 is placed adjacent to, and optionally in contact with, the cut and/or morselized end of the medial cuneiform 220.

[0110] As shown in FIG. 25, a compression pin, such as a threaded olive pin 300 can be inserted through the first metatarsal 210 and into the medial cuneiform 220 to provide compression and provisional fixation between the first metatarsal and the medial cuneiform. Additional compression pins can be inserted to provide additional stability. As shown, the parallel reference pins should be aligned during this step. In some embodiments, a practitioner checks for alignment of the parallel reference pins prior to insertion of the compression pin, and, if they are not aligned, adjusts the position of the first metatarsal until desired alignment is achieved.

[0111] Although they can be left in place, in some embodiments the parallel reference pins and bone positioning guide can be removed and a bone fixation device (e.g., two bone plates positioned in different planes, as shown) can be applied to stabilize the joint for fusion. FIG. 26A shows a first bone plate 310 positioned on a dorsal-medial side of the first metatarsal and medial cuneiform and a second bone plate 320 positioned on a medial-plantar side of the first metatarsal and the medial cuneiform. In other embodiments, such as the embodiment shown in FIG. 26B, the second bone plate 320 can be a helical bone plate positioned from a medial side of the cuneiform to a plantar side of the first metatarsal across the joint space. The plates can be applied with the insertion of bone screws. Example bone plates that can be used as first bone plate 310 and/or second bone plate 320 are described in US Patent Publication No. US2016/0192970, titled “Bone Plating System and Method” and filed January 7, 2016, which is incorporated herein by reference.

[0112] As shown in FIG. 27, the compression pin can be removed and the incision can be closed.

[0113] FIGS. 28 A/B and 29A/B include examples of anatomically misaligned metatarsals and metatarsals that have been anatomically aligned using methods and/or instruments in accordance with the invention. FIG. 28A shows a left foot pre-operation and post-operation, while FIG. 28B shows a right foot pre-operation and post-operation. As can be seen from a comparison of the pre-operative images to the post-operative images, the patients’ intermetatarsal angle (IMA) was significantly reduced. FIGS. 29A and 29B show the correction of an axial rotation in a frontal rotational plane. FIG. 29A shows a pre-operative image and a post-operative image of a right foot. Drawings of a metatarsal 210 are also

provided to illustrate the rotation. The rotation of the metatarsal can be seen by the position of sesamoid bones 400, which are depicted as having been rotated under the first metatarsal 210 in the post-operative drawing. FIG. 29B shows pre-operative views of a left foot 200 and a right foot 200. Again, by comparing the location of the sesamoid bones 400 with respect to a reference location, such as ground, the planter surface of the foot, and/or a cuneiform, it can be seen this patient's metatarsal is rotated out of alignment.

[0114] Methods in accordance with embodiments of the invention can be useful for positioning a bone or bones. Bone positioning can be useful, for instance, to correct an anatomical misalignment of bones and maintain an anatomically aligned position, such as in a bone alignment and/or fusion procedure. In some embodiments, an "anatomically aligned position" means that an angle of a long axis of a first metatarsal relative to a long axis of a second metatarsal is about 10 degrees or less in the transverse plane or sagittal plane. In certain embodiments, anatomical misalignment can be corrected in both the transverse plane and the frontal plane. In the transverse plane, a normal intermetatarsal angle ("IMA") between a first metatarsal and a second metatarsal may be less than about 9 degrees (e.g., less than 6 degrees). An IMA of between about 6 degrees and about 13 degrees (e.g., between about 9 degrees and about 13 degrees) may be considered a mild or moderate misalignment of the first metatarsal relative to the second metatarsal. An IMA of greater than about 16 degrees may be considered a severe misalignment of the first metatarsal relative to the second metatarsal. In some embodiments, methods in accordance with the invention are capable of anatomically aligning the bone(s) by reducing the IMA from over 10 degrees to about 10 degrees or less (e.g., to an IMA of less than 6 degrees, such as to an IMA of about 1-5 degrees), including to negative angles of about -5 degrees or until interference with the second metatarsal, by positioning the first metatarsal at a different angle with respect to the second metatarsal.

[0115] With respect to the frontal plane, a normal first metatarsal will be positioned such that its crista prominence is generally perpendicular to the ground and/or its sesamoid bones are generally parallel to the ground and positioned under the metatarsal. This position can be defined as a metatarsal rotation of 0 degrees. In a misaligned first metatarsal, the metatarsal is axially rotated between about 4 degrees to about 30 degrees or more. In some embodiments, methods in accordance with the invention are capable of anatomically aligning the metatarsal by reducing the metatarsal rotation from about 4 degrees or more to less than 4 degrees (e.g., to about 0 to 2 degrees) by rotating the metatarsal with respect to the medial cuneiform.

[0116] While various embodiments of bone positioning and preparing guide systems and methods have been described, it should be appreciated that the concepts of the disclosure can be altered in practice, e.g., based on the needs of the clinician, the patient undergoing the bone repositioning procedure, the specific anatomy being treated, and/or the target clinical outcome. As one example, the described systems and techniques may be modified to utilize a fulcrum about which rotation and/or pivoting of one bone relative to another bone occurs, e.g., with or without use of bone positioning guide 10. The fulcrum can establish and/or maintain space between adjacent bones being moved, e.g., compressed between bone engagement member 40 and tip 50 when using bone positioning guide 10, preventing lateral translation or base shift of the bones during rotation and/or pivoting.

[0117] FIG. 30A illustrates a portion of a foot having a bunion caused by a misaligned first metatarsal 210 relative to second metatarsal 292. FIG. 30B shows the foot of FIG. 30A after being anatomically aligned to correct the misalignment using bone positioning guide 10. As shown, first metatarsal 210 has been rotated counterclockwise in the frontal plane (from the perspective of a patient, clockwise from the perspective of a frontal observer) and also pivoted in the transverse plane (e.g., such that the angle 350 between the first metatarsal 210 and second metatarsal 292 is reduced). Rotation and pivoting of first metatarsal 210 can cause the base 352 of first metatarsal 210 to shift relative to medial cuneiform 220. In general, it is desirable that the offset 354A between first metatarsal 210 and medial cuneiform 220 be reduced to zero (e.g., such that there is substantially no offset) after rotation and pivoting. As shown in the illustrated application of FIG. 30B, however, the base 352 of first metatarsal 210 abutting medial cuneiform 220 has shifted toward second metatarsal 292. This results in a transverse offset 354B of first metatarsal 210 toward second metatarsal 292, causing base compression between first metatarsal 210 and second metatarsal 292.

[0118] To help avoid the base shift and offset 354B observed in FIG. 30B, a clinician can insert a fulcrum in the notch between first metatarsal 210 and second metatarsal 292 at the base of the metatarsals (e.g., adjacent respective cuneiform) before actuating bone positioning guide 10. The fulcrum can provide a point about which first metatarsal 210 can rotate and/or pivot while helping minimize or avoid base compression between the first metatarsal and the second metatarsal. In addition, use of the fulcrum may cause first metatarsal 210 and medial cuneiform 220 to be better angled relative to the guide slots of bone preparation guide 150 (once installed), providing a better cut angle through the guide slots than without use of the fulcrum. This can help reduce or eliminate unwanted spring-back, or return positioning, of

first metatarsal 210 after removing bone positioning guide 10 (in instances in which bone positioning guide 10 is used with the fulcrum).

[0119] FIG. 31 illustrates a bone positioning operation in which a fulcrum 356 is positioned at an intersection between a first bone and a second bone, where the first bone is being realigned relative to the second bone. In particular, FIG. 31 illustrates fulcrum 356 being positioned between first metatarsal 210 and second metatarsal 292. Fulcrum 356 may be positioned distally of bone preparation guide 150 between first metatarsal 210 and second metatarsal 292 as shown in FIG. 31 or, in other applications, proximally of the guide (e.g., at the ends of the first and second metatarsals abutting the medial and intermediate cuneiform bones, respectively). In still other examples, fulcrum 356 can be positioned in the intermetatarsal space between first metatarsal 210 and second metatarsal 292 without using bone preparation guide 150.

[0120] When used, the clinician can insert fulcrum 356 between first metatarsal 210 and second metatarsal 292 (or other adjacent bones, when not performing a metatarsal realignment) at any time prior to moving the first metatarsal (e.g., by actuating bone positioning guide 10 or other means of manipulating the bone). In different embodiments, fulcrum 356 can be inserted between first metatarsal 210 and second metatarsal 292 before or after inserting joint spacer 188 and/or placing bone preparation guide 150 over the joint being operated upon. In one embodiment, the clinician prepares the joint being operated upon to release soft tissues and/or excise the plantar flare from the base of the first metatarsal 210, as discussed above. Either before or after installing bone positioning guide 10 over adjacent bones, for example with bone engagement member 40 positioned in contact with the medial ridge of the first metatarsal 210 and tip 50 positioned in contact with second metatarsal 292, the clinician inserts fulcrum 356 at the joint between the first metatarsal and the second metatarsal. The clinician can subsequently actuate bone positioning guide 10 (e.g., rotate knob 120). In the case of a left foot as shown in FIG. 31, actuation of bone positioning guide 10 causes the first metatarsal 210 to rotate counterclockwise in the frontal plane (from the perspective of a patient) and also pivot in the transverse plane about the fulcrum. In the case of a right foot (not shown), actuation causes the first metatarsal to rotate clockwise in the frontal plane (from the perspective of a patient) and also pivot in the transverse plane about the fulcrum. Thus, for both feet, actuation of bone positioning guide 10 can supinate the first metatarsal in the frontal plane and pivot the first metatarsal in the transverse plane about fulcrum 356. While use of fulcrum 356 can minimize or eliminate base compression between

adjacent bones being operated upon, in other embodiments as discussed above, the described systems and techniques can be implemented without using the fulcrum.

[0121] In instances in which fulcrum 356 is used, any suitable mechanical instrument that maintains a spacing between adjacent bones can be used for the fulcrum. FIG. 32 is a perspective view of one example instrument that can be used as fulcrum 356. In this embodiment, fulcrum 356 has a generally rectangular shape and tapers in thickness along at least a portion of the length from the trailing end 358 to the leading end 360. Fulcrum 356 may be sized sufficiently small so that it does not interfere with placement of bone preparation guide 150 on the joint being worked upon. In some embodiments, the clinician is provided a system containing multiple different size and/or shape fulcrums and allowed to choose the specific size and/or shape fulcrum desired for the specific procedure being performed. FIG. 33 illustrates an example kit or system of different sized fulcrums, labeled with exemplary “width x thickness” sizes, that may be provided to a clinician in such an embodiment. In some examples, fulcrum 356 has a width ranging from 5 millimeters to 15 millimeters (e.g., about 6 millimeters to about 10 millimeters) and a thickness ranging 1 millimeter to 12 millimeters (e.g., about 2 millimeters to about 3 millimeters), although fulcrums with different dimensions can be used.

[0122] While FIGS. 32 and 33 illustrate one example style of fulcrum, other mechanical instruments providing a fulcrum functionality can be used without departing from the scope of the disclosure. For instance, as alternative examples, a surgical pin or rod, a screw driver head/shaft, an osteotome, or a retractor may be used as fulcrum 356. Depending on the instrument used as a fulcrum, the fulcrum may have a variety of cross-sectional shapes, such as a generally polygonal shape (e.g., square, hexagonal), a generally arcuate shape (e.g., circular, elliptical), or combinations of polygonal and arcuate shapes.

[0123] As discussed above, bone positioning guide 10 can have a variety of different configurations, including a configuration in which bone engagement member 40 is laterally offset from tip 50. FIG. 34 is a perspective view of bone positioning guide 10 showing an example arrangement in which bone engagement member 40 is laterally offset from tip 50. In this embodiment, the first end 60 of main body member 20 is laterally offset from an axis 362 extending through shaft 30 and a geometric center of bone engagement member 40. In particular, in the illustrated configuration, tip 50 is offset laterally in the direction of the cuneiform relative to bone engagement member 40. As a result, when bone positioning guide 10 is actuated, e.g., by rotating knob 120, a moment can be created by the offset tip. This can cause the end of the first metatarsal 210 adjacent the proximal phalange to pivot toward the

second metatarsal 292 and close angle 350, e.g., while the opposite end of the first metatarsal adjacent the medial cuneiform pivots away from the second metatarsal. This can also help avoid base compression between the first and second metatarsals.

[0124] As discussed above with respect to FIGS. 19 and 20, a joint spacer 188 can be positioned in a joint between a first metatarsal and a medial cuneiform before placing bone preparation guide 150 over the joint spacer. Bone preparation guide 150 can have an opening 170 (FIG. 5) sized to receive joint spacer 188. In some examples, opening 170 of bone preparation guide 150 is size and/or shaped indexed to joint spacer 188 such that there is substantially no, or no, relative movement between the guide and spacer (once bone preparation guide 150 is placed over joint spacer 188). This arrangement can ensure that bone preparation guide 150 is positioned precisely at the location where guided by joint spacer 188.

[0125] In practice, once bone preparation guide 150 is placed over joint spacer 188, the guide slots of the bone positioning guide may not be perfectly aligned with the ends of the bones (e.g., first metatarsal 210 and medial cuneiform 220) to be cut through the guide slots. Accordingly, in other configurations, opening 170 of bone preparation guide 150 may not be sized and/or shaped and/or indexed to joint spacer 188. In other words, opening 170 of bone preparation guide 150 may have a different cross-sectional size and/or shape than the cross-sectional size and/or shape of joint spacer 188. In these configurations, bone preparation guide 150 may actuate or rotate about an axis extending through the length of joint spacer 188. As a result, after the clinician places bone preparation guide 150 over joint spacer 188, the clinician may rotate bone preparation guide 150 around joint spacer 188 until the guide slots of the bone preparation guide are better aligned with the ends of the bones to be cut (e.g., first metatarsal 210 and medial cuneiform 220). Depending on the configuration of opening 170 of bone preparation guide 150 and the configuration of joint spacer 188, the guide may rotate freely (e.g., 360 degrees) around the joint spacer (e.g., seeker) or within a bounded angular range (e.g., from plus 20 degrees to minus 20 degrees from a normal position).

[0126] FIG. 35 illustrates one example configuration of a joint spacer 188 that can allow bone preparation guide 150 to rotate around the spacer (e.g., seeker). As shown in the illustrated example, joint spacer 188 has a proximal portion 370 having a cylindrical cross-section and a distal portion 372 having a rectangular cross-section. A leading edge of the distal portion 372 is insertable into the joint between the first metatarsal 210 and the medial cuneiform 220. Once bone preparation guide 150 is inserted over joint spacer 188, body 154

of the guide (FIG. 5) may be positioned about the proximal portion 370. This can allow the guide to be rotated around the proximal portion.

[0127] In other configurations, opening 170 of bone preparation guide 150 may be size and/or shape indexed to the cross-sectional size and/or shape of joint spacer 188 but still provide relative rotation between the two components. For example, opening 170 may have a circular cross-section sized and shaped to receive proximal portion 370 of joint spacer 188 from FIG. 35. Because both opening 170 of bone preparation guide 150 and proximal portion 370 of joint spacer 188 have circular cross-sections in such an embodiment, the two components may rotate relative to each other. FIG. 36A is a perspective view of an example configuration of bone preparation guide 150 having an opening 170 with circular cross-sectional shape. FIG. 36B is a perspective view of the example bone positioning guide of FIG. 36A shown with joint spacer 188 from FIG. 35 inserted into the guide.

[0128] In embodiments where bone preparation guide 150 can rotate relative to joint spacer 188, the bone positioning guide and/or joint spacer may include a locking mechanism that is engageable to lock the rotational angle of the bone positioning guide relative to the joint spacer. For example, bone preparation guide 150 may include a set screw with thumb wheel that can be rotated, causing a distal end of the set screw to bear against or retract away from joint spacer 188. In use, a clinician can rotate bone preparation guide 150 around joint spacer 188 until the guide slots of the bone preparation guide are best aligned with the ends of the bones to be cut (e.g., first metatarsal 210 and medial cuneiform 220). The clinician can then engage the locking mechanism to prevent further rotation of bone preparation guide 150 relative to joint spacer 188 before performing further steps of the procedure.

[0129] A bone correction procedure can be accomplished using one or more instruments according to the disclosure. In some applications, a bone correction procedure, such as a tarsal-metatarsal joint fusion procedure to correct a bunion deformity, is performed utilizing a fulcrum as a pivot point. The first metatarsal is moved relative to a second metatarsal about the fulcrum without utilizing bone positioning guide 10. In these applications, the clinician can insert the fulcrum into an intermetatarsal space between the first and second metatarsals and physically grasp the first metatarsal and move the metatarsal about the fulcrum. For example, the clinician may directly grasp the first metatarsal with his hand or indirectly grasp the first metatarsal through an intermediate tool, such as a K-wire or pin inserted into the first metatarsal, a tenaculum or tongs, or other grasping instrument. Thereafter, the clinician may translate his hand relative to the foot of the patient being operated upon to move the first

metatarsal about the fulcrum and relative to the second metatarsal, e.g., to anatomically align the first metatarsal with respect to the second metatarsal.

[0130] FIG. 37 is a block flow diagram of an example bone correction technique utilizing a fulcrum. Specific steps of the technique of FIG. 37 can be performed utilizing techniques and/or instruments discussed above. As shown, the example technique of FIG. 37 includes mobilizing a tarsal-metatarsal joint by releasing soft tissue and/or obstructing bone (500). After customary surgical preparation and access, the clinician may mobilize the tarsal-metatarsal joint by inserting a cutting instrument (e.g., saw, rotary bur, osteotome) at least partially between the first metatarsal and medial cuneiform. The clinician may use the cutting instrument to release soft tissues and/or excise the plantar flare from the base of the first metatarsal. Excising the plantar flare may involve cutting plantar flare off the first metatarsal so the face of the first metatarsal is generally planar. In some applications, the dorsal-lateral flare of the first metatarsal may also be excised to create space for the correction procedure.

[0131] The technique of FIG. 37 further involves inserting a fulcrum between the first metatarsal and the second metatarsal (502). The fulcrum may be inserted from the dorsal side of the foot toward the plantar side of the foot in the intermetatarsal space between the first metatarsal and the second metatarsal. Although the fulcrum may be positioned at any desired location in the intermetatarsal space, in some applications, the fulcrum is positioned adjacent to, and optionally in contact with, a proximal portion of the first metatarsal and/or the second metatarsal. For example, the fulcrum may be positioned adjacent to, and optionally in contact with, a proximal-most half of the first metatarsal and/or proximal-most half of the second metatarsal, such as the proximal-most third or proximal-most quarter of the first metatarsal and/or the second metatarsal. In one application, the fulcrum is positioned in the intermetatarsal space adjacent to, and optionally in contact with, the base of the first metatarsal facing the medial cuneiform and the base of the second metatarsal facing the intermediate cuneiform. This positioning can help prevent or minimize lateral translation of the base of the first metatarsal toward the base of the second metatarsal during alignment of the first metatarsal. In some applications, the clinician inserts the fulcrum from the dorsal toward the plantar side of the foot in the intermetatarsal space and then translates the fulcrum proximally in the intermetatarsal space.

[0132] The technique of FIG. 37 also involves preparing the end of the first metatarsal and/or the opposed end of the medial cuneiform (504). Typically, bone preparation is performed after inserting the fulcrum in the intermetatarsal space (502), although bone preparation can

be performed prior to inserting the fulcrum. To prepare the end of the first metatarsal and the end of the medial cuneiform, a tissue removing instrument can be applied to the ends of the bones. In one example, a cutting instrument is applied to transect each bone and thereby form a new end surface, e.g., by inserting the cutting instrument through a slot defined bone preparation guide 150. Additionally or alternatively, the tissue removing instrument can be applied to the end face of each bone to morselize at least a portion of the end face.

[0133] Independent of the specific technique used to prepare the end of the first metatarsal and/or the opposed end of the medial cuneiform (504), the technique of FIG. 37 includes moving the first metatarsal to help correct the anatomical misalignment (506). The first metatarsal can be moved relative to the second metatarsal before and/or after preparing the end of the first metatarsal and/or the opposed end of the medial cuneiform. To move the first metatarsal relative to the second metatarsal, the clinician may directly or indirectly grasp the first metatarsal and translate a distal portion of the first metatarsal toward the second metatarsal (e.g., a distal portion of the second metatarsal) in the transverse plane. As the distal end of the first metatarsal moves toward the second metatarsal in the transverse plane, the proximal portion of the first metatarsal can pivot about the fulcrum. For example, the fulcrum can function as a central point around which the proximal portion of the first metatarsal turns as the distal portion of the first metatarsal translates laterally. Accordingly, moving the distal portion of the first metatarsal toward the second metatarsal can reduce the intermetatarsal space, and hence intermetatarsal angle, between the first metatarsal and the second metatarsal.

[0134] As the first metatarsal pivots in the transverse plane toward the second metatarsal, closing the intermetatarsal space, a proximal portion of the first metatarsal may contact and press against the fulcrum, thereby causing the fulcrum to contact and press against a proximal portion of the second metatarsal. The fulcrum may function to maintain spacing between the proximal portion of the first metatarsal and proximal portion of the second metatarsal, e.g., such a spacing equal to the width of the fulcrum. This may help reduce or eliminate shifting or translation of the base of the first metatarsal toward the base of the second metatarsal during pivoting.

[0135] In some applications of the technique of FIG. 37, the clinician may rotate the first metatarsal in the frontal plane in addition to or in lieu of translating the first metatarsal in the transverse plane. For example, either before, after, or concurrent with moving the distal portion of the first metatarsal toward the second metatarsal in the frontal plane, the clinician can directly or indirectly grasp the first metatarsal and rotate the metatarsal in the frontal

plane. The clinician may rotate the first metatarsal about its longitudinal axis into an anatomically correct frontal plane position to correct a frontal plane deformity. Rotating the first metatarsal in the frontal plane may further rotate the sesamoid bones (e.g., tibial sesamoid bone and fibular sesamoid bone) from a misaligned position to an aligned position under the first metatarsal. In some examples, the clinician additionally or alternatively moves the first metatarsal in the sagittal plane to correct a misalignment in the sagittal plane.

[0136] In some applications of the technique of FIG. 37, the clinician moves the first metatarsal in at least one plane from an anatomically misaligned position with respect to the second metatarsal to an anatomically aligned position. The at least one plane may be one or more planes selected from the frontal plane, the transverse plane, and the sagittal plane. For example, the clinician may move the first metatarsal in any two of the three planes or even in all three of the planes to adjust the first metatarsal from an anatomically misaligned position to an anatomically aligned position.

[0137] After suitably moving the first metatarsal relative to the second metatarsal, the joint between the first metatarsal and medial cuneiform may be provisionally fixated (508). In one example, a fixation wire is driven into the first metatarsal and the medial cuneiform to provisionally fixate the joint. In another example, a compression pin, such as a threaded olive pin, is inserted through the first metatarsal and into the medial cuneiform to provide compression and provisional fixation between the first metatarsal and the medial cuneiform. The fulcrum can be removed from the intermetatarsal space before or after provisionally fixating the joint.

[0138] Following optional provisional fixation, the corrected position of the first metatarsal can be permanently fixated by fixing the position of the first metatarsal with respect to the medial cuneiform (510). One or more bone plates can be applied across the tarsal-metatarsal joint and the provisional fixation hardware removed. For example, a first bone plate may be positioned on a dorsal-medial region of the first metatarsal and on the medial cuneiform while a second bone plate is positioned on a medial-plantar region of the first metatarsal and on the medial cuneiform. In these applications, the second bone plate may or may not be a helical-shaped bone plate extending from a medial region of the medial cuneiform to a plantar region of the first metatarsal across the joint.

[0139] FIG. 38 is a perspective view of a foot showing an example position of a fulcrum during a bone correction procedure according to the method of FIG. 37. As shown, fulcrum 356 is positioned in the intermetatarsal space between the first metatarsal 210 and the second metatarsal 292. In particular, fulcrum 356 is illustrated as being positioned between a

proximal portion of first metatarsal 210 adjacent base 352 and an opposed proximal portion of second metatarsal 292. An optional pin 512 is inserted into the first metatarsal 210, providing a structure that a clinician can grab to move and manipulate the first metatarsal relative to the second metatarsal. As discussed with respect to FIG. 37, the clinician may pivot the first metatarsal 210 about fulcrum 356 toward the second metatarsal 292, reducing the intermetatarsal angle 350 between the first and second metatarsals. The clinician may also rotate the first metatarsal 210 in the frontal plane. The use of fulcrum 356 can provide a pivot surface that also maintains a defined spacing between first metatarsal 210 and second metatarsal 292, potentially leading to a more anatomically correct realignment than when moving first metatarsal 210 without using the fulcrum.

[0140] As discussed above with respect to FIGS. 32 and 33, fulcrum 356 can have a variety of different configurations that provide a fulcrum functionality. FIGS. 39A and 39B illustrate another example configuration of fulcrum 356 that can be used according to the disclosure. FIG. 39A is a perspective view of one side of fulcrum 356, while FIG. 39B is a perspective view of the fulcrum from the opposite side. In the illustrated configuration, fulcrum 356 includes a body 380 and a handle 382 operatively connected to the body. Typically, body 380 and handle 382 will be formed as a unitary structure, e.g., by milling, casting, or molding the components to be permanently and structurally integrated together. However, body 380 and handle 382 may be fabricated as separate components that are subsequently joined together.

[0141] Body 380 can be configured (e.g., sized and shaped) to be inserted into an intermetatarsal space between adjacent metatarsals. For example, body 380 may be configured to be inserted between a first metatarsal and a second metatarsal. Body 380 is illustrated as having a rectangular shape with a length 383 greater than its width 384 and thickness 386. Moreover, in this configuration, body 380 has a constant width 384 across its length but has a thickness 386 that tapers along at least a portion of the length from the leading end 388 to the trailing end 390. For example, body 380 may have a tapered leading end 388 to facilitate insertion of fulcrum 356 in a space between adjacent metatarsals. In other configurations, body 380 may have a constant thickness across its length or may define a different generally polygonal shape (e.g., square, hexagonal) and/or generally arcuate shape (e.g., circular, elliptical).

[0142] Fulcrum 356 in FIGS. 39A and 39B includes handle 382. Handle 382 can project angularly away from body 380 to define a tissue retraction space 392. Tissue retraction space 392 may be a region bounded on one side by body 380 and one or more other sides by handle

382. In use, fulcrum 356 may be inserted into an intermetatarsal space with handle 382 extending out of the surgical incision and over an epidermal layer with tissue captured in tissue retraction space 392. For example, fulcrum 356 may be inserted into an intermetatarsal space with handle 382 projecting toward the lateral side of the foot being operated upon. Tissue retraction space 392 may help retract tissue and push the tissue laterally away from a first metatarsal and/or medial cuneiform being operated upon. FIG. 40 illustrates fulcrum 356 in such an application with the fulcrum inserted between a first metatarsal and a second metatarsal and handle 382 extending toward the lateral side of the foot being operated upon. As shown, handle 382 pushes the skin of the foot away from the surgical incision line, helping to provide access to the surgical site in addition to providing fulcrum functionality.

[0143] With further reference to FIGS. 39A and 39B, handle 382 is illustrated as projecting laterally at a non-zero degree angle away from body 380. The specific angular orientation of the handle 382 relative to the body 380 may vary. However, in some examples, handle 382 is oriented relative to the body 380 so a handle axis 393 intersects an axis 394 extending along the length of the body at an acute angle 396 ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees. Moreover, handle 382 may be composed of a single linear portion that intersects body 380 at a specific angular orientation or may be composed of multiple linear portions oriented at different angles relative to each other.

[0144] In the illustrated example, handle 382 includes a grip portion 398 and a handle body 402. The grip portion 398 can provide a surface that a clinician physically grips to insert fulcrum 356 into an intermetatarsal space. For example, grip portion 398 may contain knurling or other anti-friction surfacing texturing to allow the clinician to help grip the fulcrum. Handle body 402 may be positioned between the body 380 of fulcrum 356 and grip portion 398. Handle body 402 may or may not have a reduced cross-sectional width compared to body 380 and/or grip portion 398, as illustrated.

[0145] When configured with grip portion 398, the grip portion can be co-linear with handle body 402 or may be offset relative to the handle body. When grip portion 398 is offset from handle body 402, a grip axis 404 extending along the length of the grip portion may intersect the handle axis 393 at an acute ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees, although other angular arrangements can also be used. In the illustrated configuration, grip axis 404 is perpendicular to the axis 394 defined by body 380.

Accordingly, when inserted into an intermetatarsal space, retracted tissue may be bounded by a laterally-facing side of body 380, by the lower surface of grip portion 393, and in the dorsal-lateral direction by handle portion 392.

[0146] In some examples, the bone-contacting faces of body 380 are configured to inhibit and/or facilitate relative motion between a bone and the respective bone-contacting face. With reference to FIG. 39A, body 380 of fulcrum 356 has a first face 410, which may be positioned in contact with a first metatarsal. First face 410 may have surface features which allow the contacting metatarsal (e.g., first metatarsal) to rotate in the frontal plane while contacting the face but inhibit movement of the metatarsal in the proximal to distal direction. The surface features may be implemented as directionally-oriented ribs and/or grooves, which are illustrated in FIG. 39A as being multiple grooves extending lengthwise across body 380. By orienting the grooves lengthwise, the edges of the grooves may have a tendency to engage or bite into the metatarsal if the metatarsal is moved proximally or distally, thereby inhibiting such movement. However, the grooves can allow the metatarsal to rotate in the frontal plane against first face 410 without inhibiting such rotation.

[0147] Additionally or alternatively, the body 380 may have different surface features on the opposite face from first face 410. With reference to FIG. 39B, for example, body 380 of fulcrum 356 has a second face 412 that is opposite first face 410. Second face 412 may have surface features that inhibit movement between fulcrum 356 and the contacting metatarsal (e.g., second metatarsal) in the dorsal-to-plantar direction. The surface features may be implemented as directionally-oriented ribs and/or grooves. For example, in FIG. 39B, second face 412 is illustrated as having knurling, or a series of intersecting and overlapping ridges. FIG. 41 is perspective view of the second face 412 of fulcrum 356 showing an alternative arrangement of surface features that may be used. In this alternative configuration, the surface features on second face 412 are illustrated as being multiple grooves extending widthwise across body 380. By orienting the grooves widthwise, the edges of the grooves may have a tendency to engage or bite into the metatarsal if the metatarsal is moved plantarly or dorsally, thereby inhibiting such movement. The knurling illustrated on FIG. 39B can also achieve this functionality.

[0148] In the configuration of FIGS. 39A and 39B, handle 382 includes grip portion 398 that can provide a surface a clinician physically grips to insert fulcrum 356. In other configurations, handle 382 may be implemented using a second fulcrum body that is a different size and/or shape than body 380. This arrangement can provide a clinician with a single instrument having two functional ends, either one of which can be selected and used by the clinician, e.g., depending on the characteristics of the patient undergoing a surgical procedure.

[0149] FIGS. 42A and 42B are perspective and side views, respectively, of such an example fulcrum 356 having two fulcrum bodies. As shown in this example, fulcrum 356 includes the body 380 and the handle 382 projecting at a non-zero degree angle away from the body. The body 380 provides a first fulcrum body configured (e.g., sized and/or shaped) to be inserted into an intermetatarsal space. In addition, handle 382 in this example is defined at least in part by a second fulcrum body 420. The second fulcrum body 420 may also be configured (e.g., sized and/or shaped) to be inserted into an intermetatarsal space. The first fulcrum body 380 can differ from the second fulcrum 420 body by having a different size and/or shape.

[0150] In FIGS. 42A and 42B, the first fulcrum body 380 and the second fulcrum body 420 are shown as having the same shape but different sizes. In particular, first fulcrum body 380 has a length 383, a thickness 386, and a width orthogonal to the length and thickness. Further, the second fulcrum body 420 has a length 422, a thickness 424, and a width orthogonal to the length and thickness. The thickness 422 of the second fulcrum body 420 is illustrated as being greater than the thickness 386 of the first fulcrum body 380. The length and width of the first and second fulcrum bodies 380, 420 are illustrated as being the same but may be different in other examples (e.g., different width with same length, different length but same width, or different length and width).

[0151] In general, configuring the first fulcrum body 380 and second fulcrum body 420 with different thicknesses can be useful to facilitate use in different sized intermetatarsal spaces. For example, the clinician may select one sized fulcrum body over the other sized fulcrum body based on the anatomy (e.g., intermetatarsal space sizing) of the patient undergoing a surgical procedure. If the clinician determines upon beginning to insert the selected fulcrum that the selected fulcrum is inappropriately sized, the clinician may retract the fulcrum, flip the instrument, and insert the fulcrum on the opposite side of the instrument.

[0152] While the first fulcrum body 380 and second fulcrum body 420 can be configured with a variety of different sizes, in some examples, each fulcrum body has a thickness ranging from 0.5 millimeters to 12 millimeters, such as from 1 millimeter to 10 millimeters, or from 1 millimeter to 5 millimeters. The thickness 424 of the second fulcrum body 420 may be at least 0.2 millimeters thicker than the thickness 386 of the first fulcrum body, such as at least 0.5 millimeters thicker, at least 1 millimeter thicker, or at least 2 millimeters thicker. In some examples, first fulcrum body 380 and second fulcrum body 420 each have a width within a range from 5 millimeters to 15 millimeters (e.g., about 6 millimeters to about

10 millimeters) and a length ranging from 10 millimeters to 30 millimeters, although other dimensions can be used.

[0153] In the illustrated example of FIGS. 42A and 42B, the first fulcrum body 380 has a leading end 388 and a trailing end 390 and the second fulcrum body 420 has a leading end 426 and a trailing end 428. In some examples as shown, the leading end 388 of the first fulcrum body 380 and/or the leading end 426 of the second fulcrum body 420 has a thickness that tapers adjacent the leading end. This configuration can be useful to facilitate insertion of a fulcrum body into an intermetatarsal space. When configured with a tapered leading end, the exemplary thickness ranges discussed above may be measured as the maximum thickness of the fulcrum body at any location along the length of the body.

[0154] When fulcrum 356 is implemented with first fulcrum body 380 and second fulcrum body 420, the bone-contacting faces of one or both of the fulcrum bodies may be configured to inhibit and/or facilitate relative motion between a bone and the respective bone-contacting face, as discussed with respect to FIGS. 39A, 39B, and 41. For example, a first face 410 of first fulcrum body 380 and/or a first face 430 of second fulcrum body 420 may have surface features which allow a contacting metatarsal (e.g., first metatarsal) to rotate in the frontal plane while contacting the face but inhibit movement of the metatarsal in the proximal to distal direction, as discussed above. Similarly, a second face 412 of first fulcrum body 380 and/or a second face 432 of second fulcrum body 420 may have surface features that inhibit movement between fulcrum 356 and a contacting metatarsal (e.g., second metatarsal) in the dorsal-to-plantar direction, as also discussed above.

[0155] In the illustrated example, first fulcrum body 380 and second fulcrum body 420 are oriented at a non-zero degree relative to each other and separated by a handle body 402, e.g., of lesser cross-sectional width. For example, as discussed with respect to FIGS. 39A and 39B, handle 382 may be oriented relative to first fulcrum body 380 such that handle axis 393 intersects an axis 394 extending along the length of the body at an acute angle 396. When handle 382 includes the handle body 402 and the second fulcrum body 420, the second fulcrum body can be co-linear with handle body 402 or may be offset relative to the handle body. For example, an axis 404 extending along the length of the second fulcrum body may intersect the handle axis 393 at an acute angle 406 ranging from 20 degrees to 75 degrees, such as 35 degrees to 55 degrees, as discussed above.

[0156] In yet other configurations where fulcrum 356 is configured with multiple ends of different dimensions, the ends may or may not be separated by a separate handle body 402.

For example, first fulcrum body 380 and second fulcrum body 420 may be formed as a unitary structure (e.g., as opposed ends of a linear or curved unitary body).

[0157] FIGS. 43A and 43B are perspective and side views, respectively, of an example multidimensional fulcrum having ends of different dimensions. As shown, fulcrum 356 is composed of first fulcrum body 380 and second fulcrum body 420 as discussed above with respect to FIGS. 42A and 42B. In the configuration illustrated in FIGS. 43A and 43B, however, the first fulcrum body 380 and the second fulcrum body 420 are integrated together to form a unitary fulcrum body having two opposed ends of different dimensions. As illustrated, the unitary fulcrum body has a generally rectangular shape such that opposed ends of the fulcrum are separated by a linear length of the body. However, the body may be curved or non-linear in alternative configurations. As discussed above, the first fulcrum body 380 and the second fulcrum body 420 forming the respective portions of the unitary body can have a variety of different dimensions, and may or may not have surface features, to provide a clinician with a variety of fulcrum options in a single instrument.

[0158] Embodiments of the invention also include a disposable, sterile kit that includes an embodiment of a bone positioning guide and/or bone preparation guide and/or fulcrum described herein. Other components that may be included within the sterile kit include bone fixation devices.

[0159] Thus, embodiments of the invention are disclosed. Although the present invention has been described with reference to certain disclosed embodiments, the disclosed embodiments are presented for purposes of illustration, and not limitation, and other embodiments of the invention are possible. One skilled in the art will appreciate that various changes, adaptations, and modifications may be made without departing from the spirit of the invention.

CLAIMS:

1. A method of correcting a bunion deformity comprising:
inserting a fulcrum between a first metatarsal and a second metatarsal, wherein the first metatarsal is anatomically misaligned with respect to the second metatarsal;
preparing an end of the first metatarsal;
preparing an end of a medial cuneiform opposing the end of the first metatarsal; and
moving a distal portion of the first metatarsal toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing an intermetatarsal angle between the first metatarsal and the second metatarsal.
2. The method of claim 1, further comprising rotating the first metatarsal in a frontal plane.
3. The method of any one of the preceding claims, wherein rotating the first metatarsal further comprises rotating a tibial sesamoid bone and a fibular sesamoid bone within the frontal plane.
4. The method of any one of the preceding claims, further comprising moving the first metatarsal in a sagittal plane while rotating the first metatarsal in the frontal plane and moving the distal portion of the first metatarsal toward the second metatarsal in the transverse plane.
5. The method of any one of the preceding claims, wherein inserting the fulcrum between the first metatarsal and the second metatarsal comprises positioning the fulcrum in contact with both first metatarsal and the second metatarsal within an intermetatarsal space between the first metatarsal and the second metatarsal.
6. The method of any one of the preceding claims, wherein positioning the fulcrum within the intermetatarsal space between the first metatarsal and the second metatarsal comprises positioning the fulcrum between the proximal portion of the first metatarsal and a proximal portion of the second metatarsal.

7. The method of any one of the preceding claims, wherein moving the distal portion of the first metatarsal toward the second metatarsal comprises moving the distal portion of the first metatarsal without causing the proximal portion of the first metatarsal to directly contact a proximal portion of the second metatarsal.
8. The method of any one of the preceding claims, wherein, when the first metatarsal is anatomically misaligned, the intermetatarsal angle is greater than 9 degrees, and reducing the intermetatarsal angle comprises reducing to an angle less than or equal to 9 degrees.
9. The method of any one of the preceding claims, wherein the fulcrum has a length extending from a leading end to a trailing end and tapers in thickness along at least a portion of the length from the trailing end to the leading end.
10. The method of any one of the preceding claims, wherein the fulcrum has a generally rectangular cross-sectional shape or a generally circular cross-sectional shape.
11. The method of any one of the preceding claims, wherein the fulcrum has a body and a handle operatively connected to the body, and the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.
12. The method of any one of the preceding claims, wherein
the body has a first face on a side that the handle projects away from and a second face on an opposite side that the handle projects towards,
inserting the fulcrum between the first metatarsal and the second metatarsal comprises positioning the first metatarsal in contact with the first face and the second metatarsal in contact with the second face,
the first face has surface features configured to inhibit proximal to distal movement of the first face relative to the first metatarsal, and
the second face has surface features configured to inhibit dorsal to plantar movement of the second face relative to the second metatarsal.
13. The method of any one of the preceding claims, further comprising, prior to inserting the fulcrum between the first metatarsal and the second metatarsal, selecting the fulcrum from a kit containing a plurality of different fulcrums varying in at least one of size and shape.

14. The method of any one of the preceding claims, wherein preparing the end of the first metatarsal and preparing the end of the medial cuneiform occurs after moving the distal portion of the first metatarsal toward the second metatarsal.

15. The method of any one of the preceding claims, wherein preparing the end of the first metatarsal and preparing the end of the medial cuneiform occurs after inserting the fulcrum.

16. The method of any one of the preceding claims, wherein preparing the end of the first metatarsal comprises at least one of cutting the end of the first metatarsal and morselizing the end of the first metatarsal, and preparing the end of the medial cuneiform comprises at least one of cutting the end of the medial cuneiform and morselizing the end of the medial cuneiform.

17. The method of any one of the preceding claims, further comprising mobilizing a tarsal-metatarsal joint site between the first metatarsal and medial cuneiform by releasing soft tissue or obstructing bone.

18. The method of any one of the preceding claims, further comprising, subsequent to moving the distal portion of the first metatarsal toward the second metatarsal, fixing a position of the medial cuneiform with respect to the first metatarsal by applying at least one bone fixation device across or through a joint between the end of the first metatarsal and the end of a medial cuneiform.

19. The method of any one of the preceding claims, wherein moving the distal portion of the first metatarsal toward the second metatarsal comprises moving the distal portion of the first metatarsal with a clinician's hand without using an instrument.

20. A method comprising:
mobilizing a tarsal-metatarsal joint site by releasing soft tissue or obstructing bone;
inserting a fulcrum between a first metatarsal and a second metatarsal, wherein the first metatarsal is anatomically misaligned with respect to the second metatarsal;
preparing an end of the first metatarsal;
preparing an end of a medial cuneiform opposing the end of the first metatarsal;

moving a distal portion of the first metatarsal toward the second metatarsal in a transverse plane, thereby pivoting a proximal portion of the first metatarsal about the fulcrum and reducing an intermetatarsal angle between the first metatarsal and the second metatarsal;

provisionally fixating a joint between the end of the first metatarsal and the end of the medial cuneiform; and

fixing the position of the first metatarsal with respect to the medial cuneiform by applying at least one bone fixation device across or through the joint between the end of the first metatarsal and the end of the medial cuneiform.

21. The method of claim 20, further comprising rotating the first metatarsal in a frontal plane.

22. The method of claim 21, wherein rotating the first metatarsal further comprises rotating a tibial sesamoid bone and a fibular sesamoid bone within the frontal plane.

23. The method of any one of claims 20–22, wherein moving the distal portion of the first metatarsal toward the second metatarsal comprises moving the distal portion of the first metatarsal without causing the proximal portion of the first metatarsal to directly contact a proximal portion of the second metatarsal.

24. The method of any one of claims 20–23, wherein the fulcrum has a body and a handle operatively connected to the body, and the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

25. The method of claim 24, wherein

the body has a first face on a side that the handle projects away from and a second face on an opposite side that the handle projects towards,

inserting the fulcrum between the first metatarsal and the second metatarsal comprises positioning the first metatarsal in contact with the first face and the second metatarsal in contact with the second face,

the first face has surface features configured to inhibit proximal to distal movement of the first face relative to the first metatarsal, and

the second face has surface features configured to inhibit dorsal to plantar movement of the second face relative to the second metatarsal.

26. The method of any one of claims 20–25, further comprising, prior to inserting the fulcrum between the first metatarsal and the second metatarsal, selecting the fulcrum from a kit containing a plurality of different fulcrums varying in at least one of size and shape.
27. A fulcrum for use in a bone realignment procedure comprising:
a body configured to be inserted in an intermetatarsal space between adjacent metatarsals, and
a handle operatively connected to the body,
wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.
28. The fulcrum of claim 27, wherein the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion.
29. The fulcrum of either of claims 27 or 28, wherein the body defines an axis extending along the length of the body, the handle defines a handle axis projecting at the non-zero degree angle from the body, and an angle between the axis of the body and the handle axis ranges from 20 degrees to 75 degrees.
30. The fulcrum of claim 29, wherein the angle ranges from 35 degrees to 55 degrees.
31. The fulcrum of any one of claims 27–30, wherein
the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion;
the handle axis is defined by the handle body;
the grip portion defines a grip axis, and
an angle between the grip axis and the handle axis ranges from 20 degrees to 75 degrees.
32. The fulcrum of claim 31, wherein the grip axis is perpendicular to the axis defined by the body of the fulcrum.

33. The fulcrum of any one of claims 27–32, wherein the body and the handle are formed as a unitary structure.

34. The fulcrum of any one of claims 27–33, wherein the body is configured to be inserted between a first metatarsal and a second metatarsal.

35. The fulcrum of any one of claims 27–34, wherein the body configured to be inserted in the intermetatarsal space is a first body, and the handle defines a second body also configured to be inserted in the intermetatarsal space, the first body and the second body varying in size.

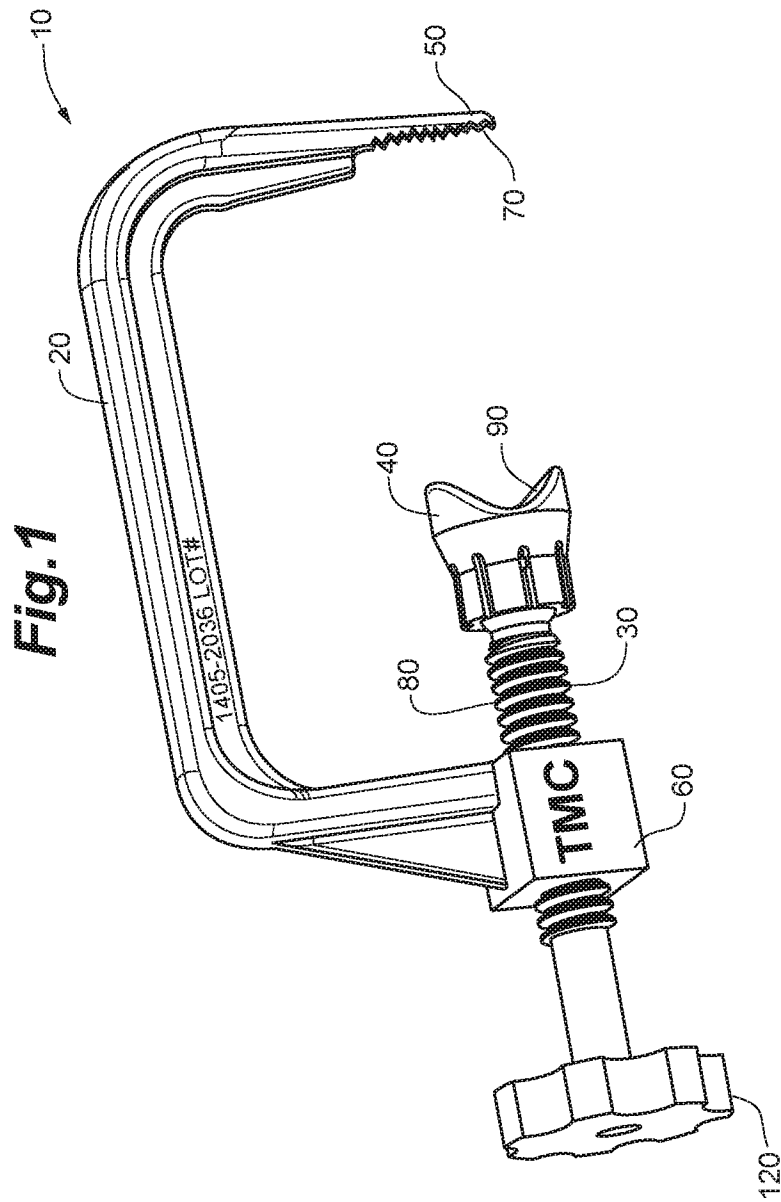
36. The fulcrum of claim 35, wherein the first body has a maximum thickness, the second body has a maximum thickness, and the maximum thickness of the first body is less than the maximum thickness of the second body.

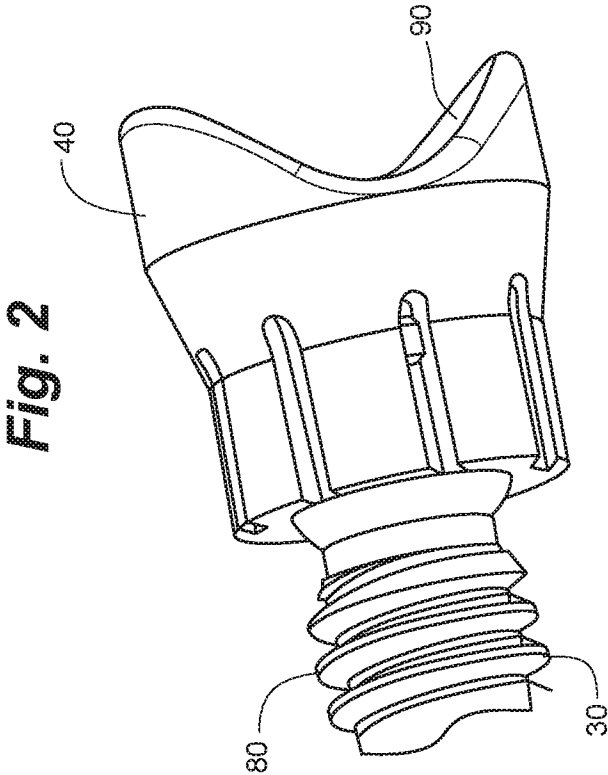
37. The fulcrum of either of claims 35 or 36, wherein
the first body extends from a leading end to a trailing end and the leading end of the first body is tapered, and
the second body extends from a leading end to a trailing end and the leading end of the second body is tapered.

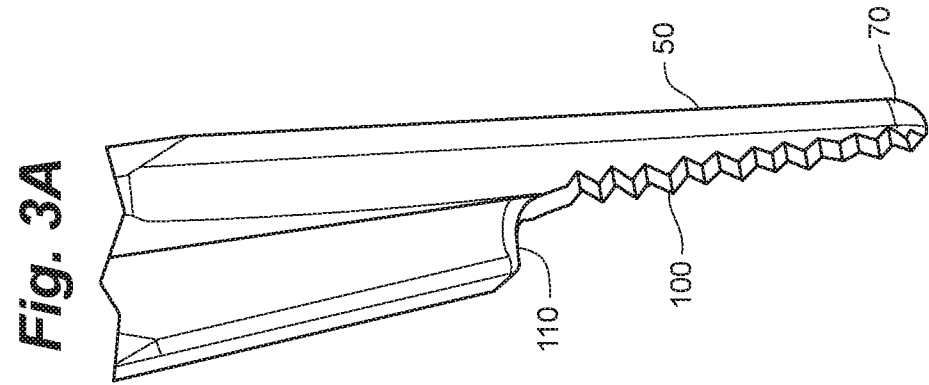
38. The fulcrum of any one of claims 27–37, wherein
the body has a first face on a side that the handle projects away from and a second face on an opposite side that the handle projects towards,
the first face has surface features configured to inhibit proximal to distal movement of the first face along a metatarsal against which the first face is positioned, and
the second face has surface features configured to inhibit dorsal to plantar movement of the second face along a metatarsal against which the second face is positioned.

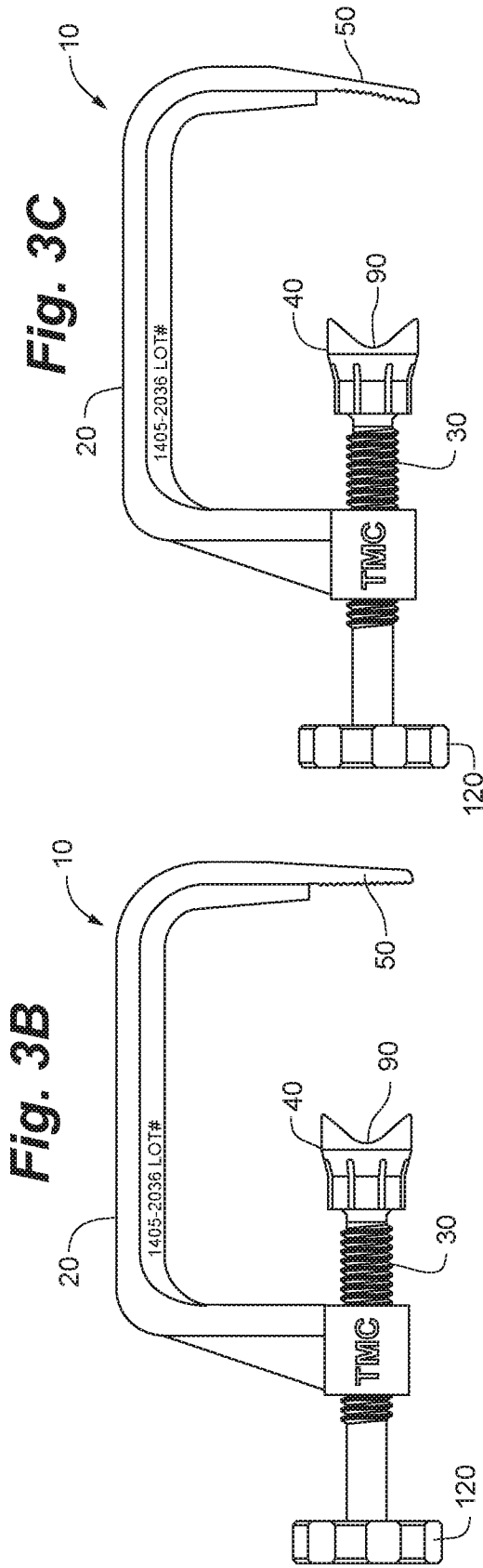
39. The fulcrum of claim 38, wherein
the first face has multiple grooves extending lengthwise across the body, and
the second face has at least one of knurling and multiple grooves extending widthwise across the body.

40. The fulcrum of any one of claims 27–39, wherein the body is rectangular shaped.
41. The fulcrum of any one of claims 27–40, wherein the body extends from a leading end to a trailing end, the handle projects off the trailing end, and the leading end is tapered.
42. A multidimensional fulcrum comprising:
a fulcrum body having a length extending from a first end to a second end, a width, and a thickness,
wherein the first end of the fulcrum has a first thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a first size,
the second end of the fulcrum has a second thickness and is configured to be inserted into an intermetatarsal space between adjacent metatarsals of a second size, and
the second thickness is greater than the first thickness.
43. The fulcrum of claim 42, wherein the first thickness and the second thickness each fall within a range from 1 millimeter to 10 millimeters, and the second thickness is at least 1 millimeter greater than the first thickness.
44. The fulcrum of either of claims 42 or 43, wherein the first end is tapered and the second end is tapered.
45. The fulcrum of any one of claims 42–44, wherein the fulcrum body has a rectangular shape.









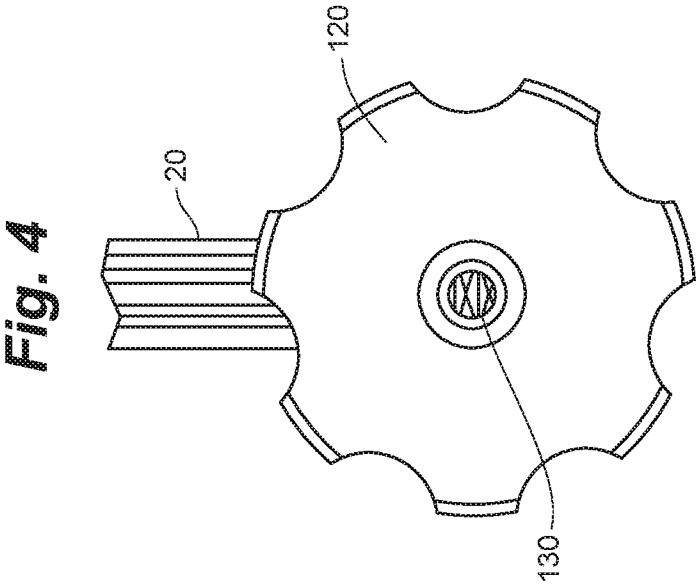


Fig. 5

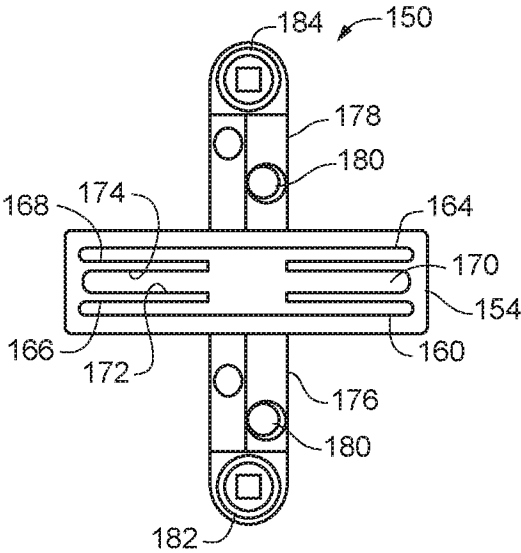
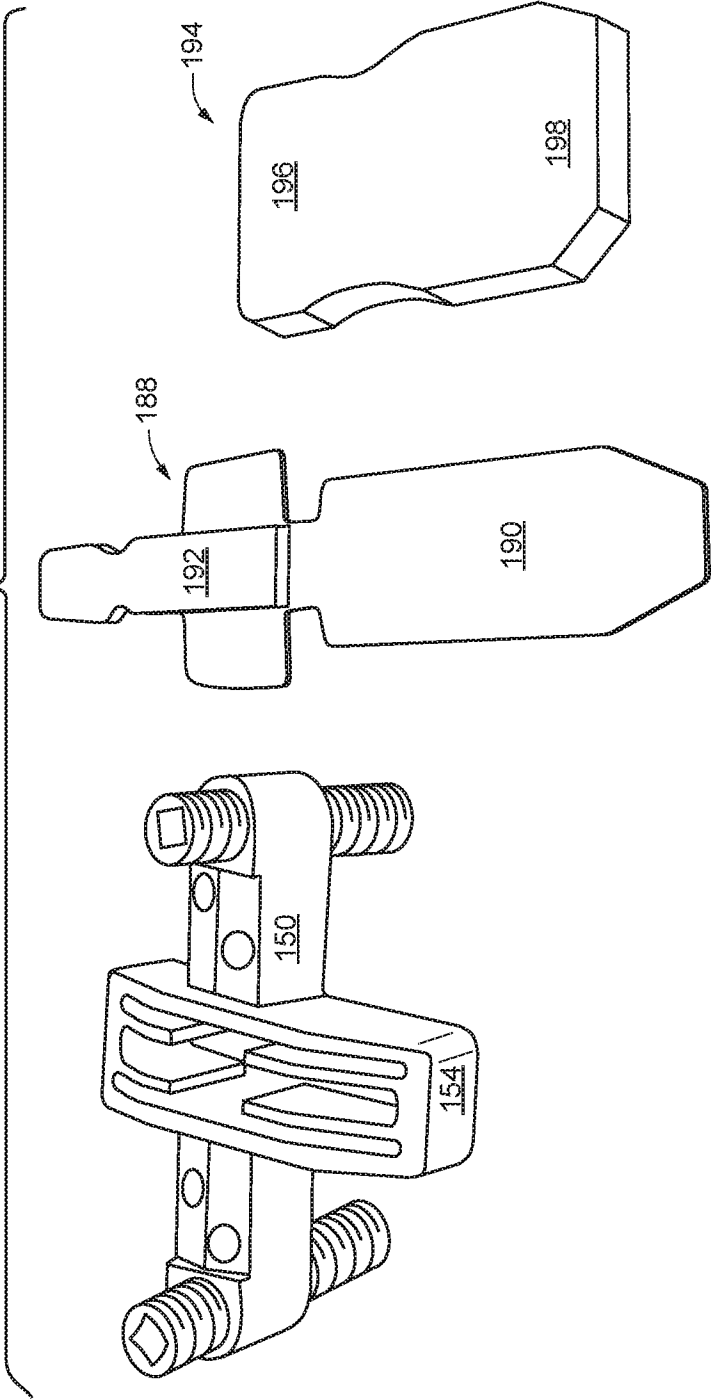


Fig. 6A



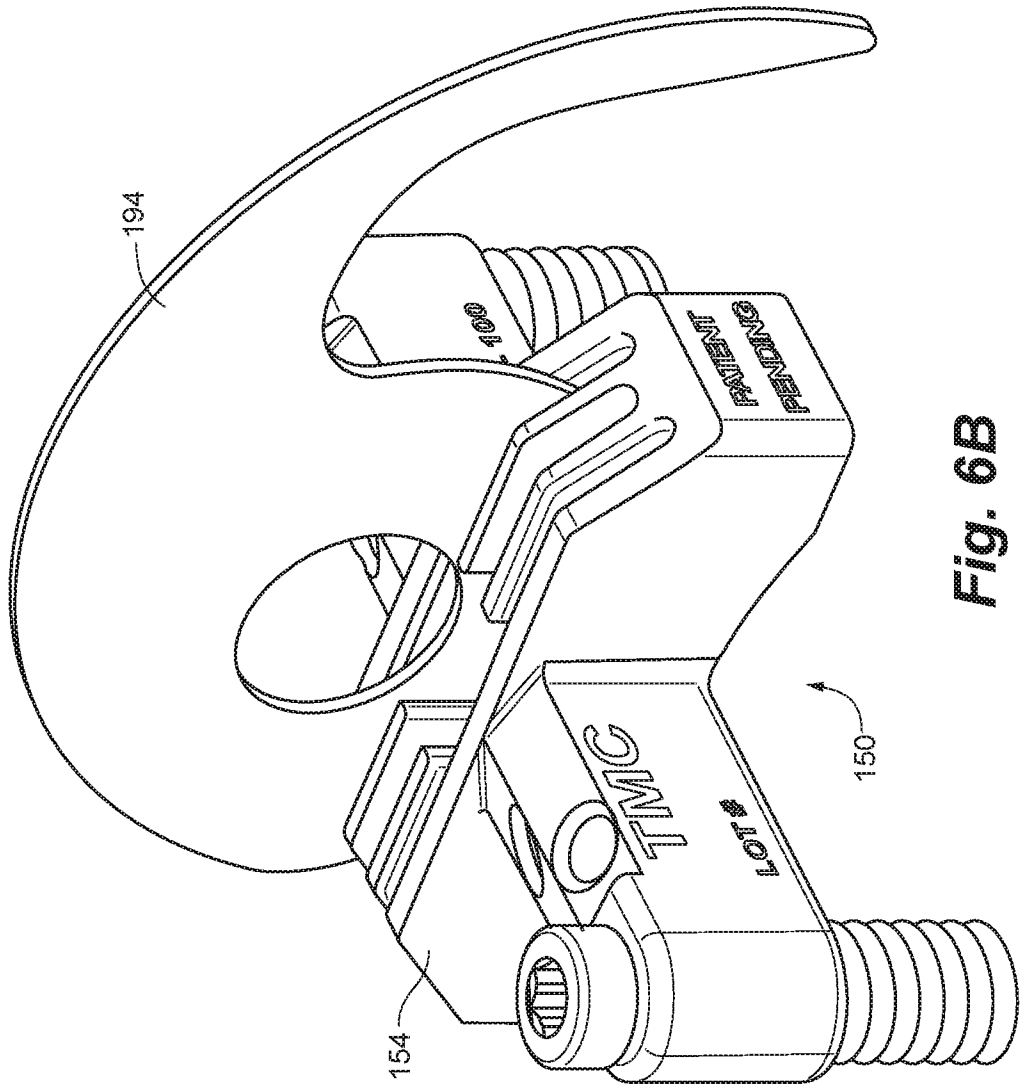


Fig. 6B

Fig. 7

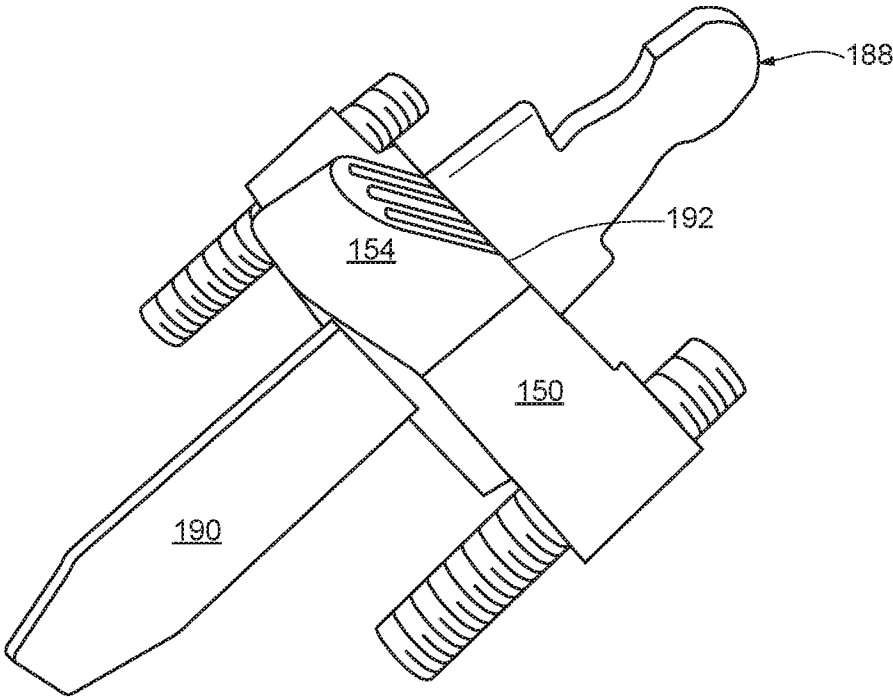


Fig. 8

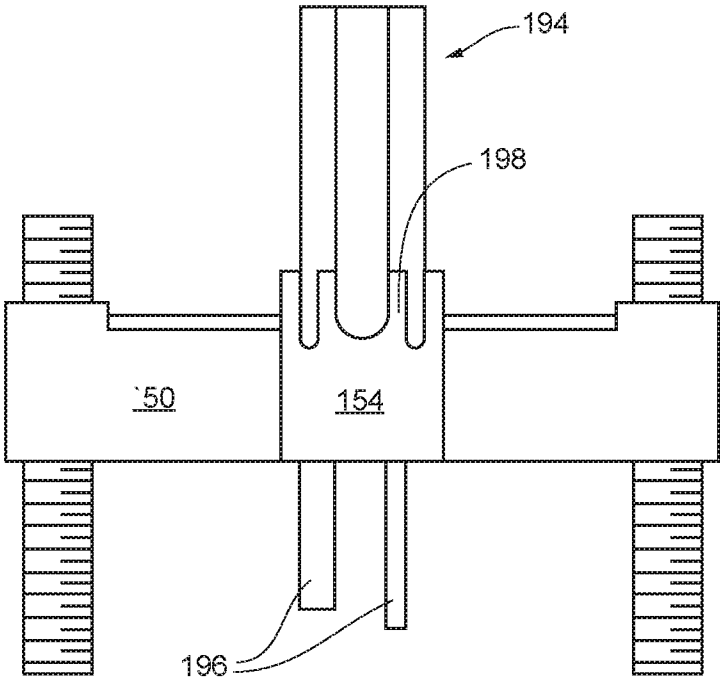


Fig. 9A

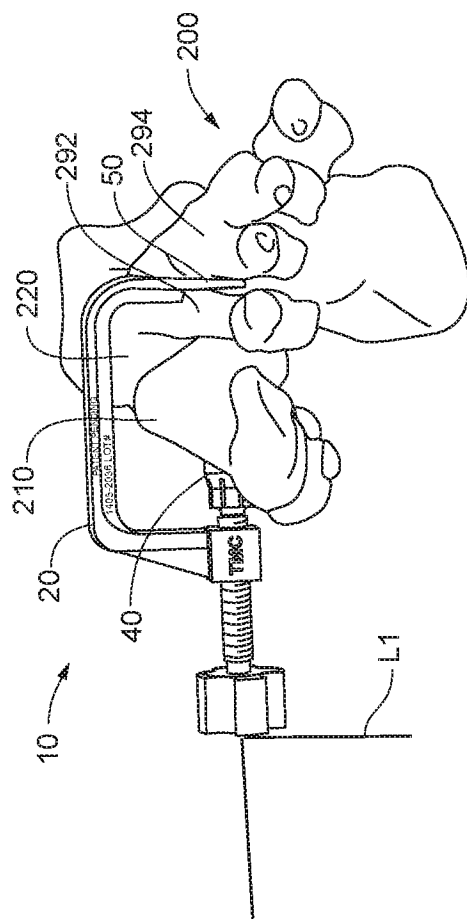
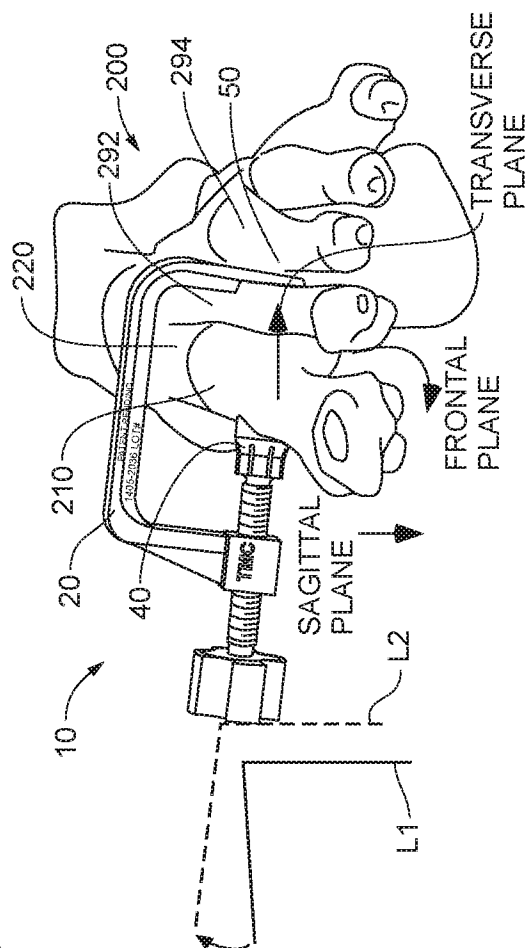
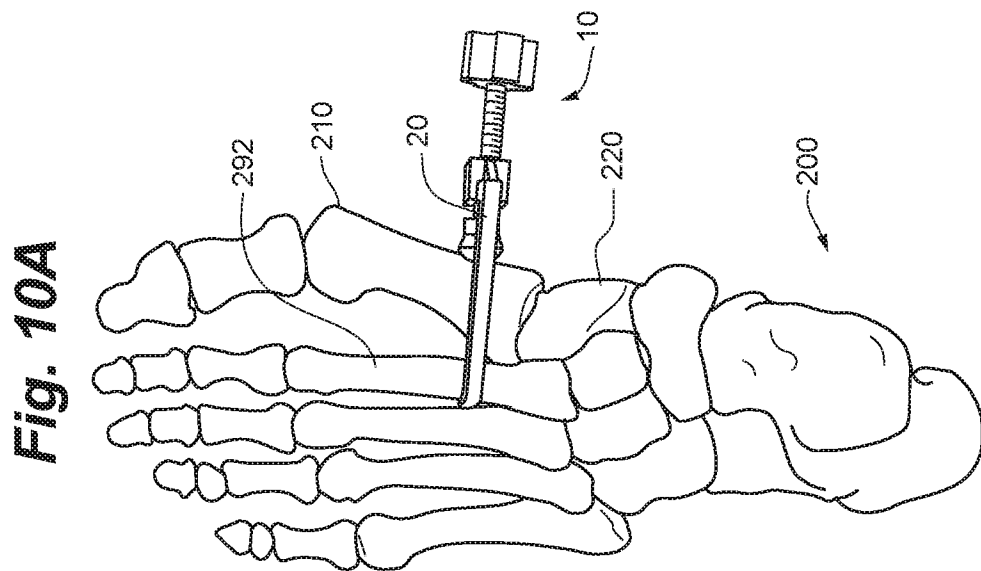
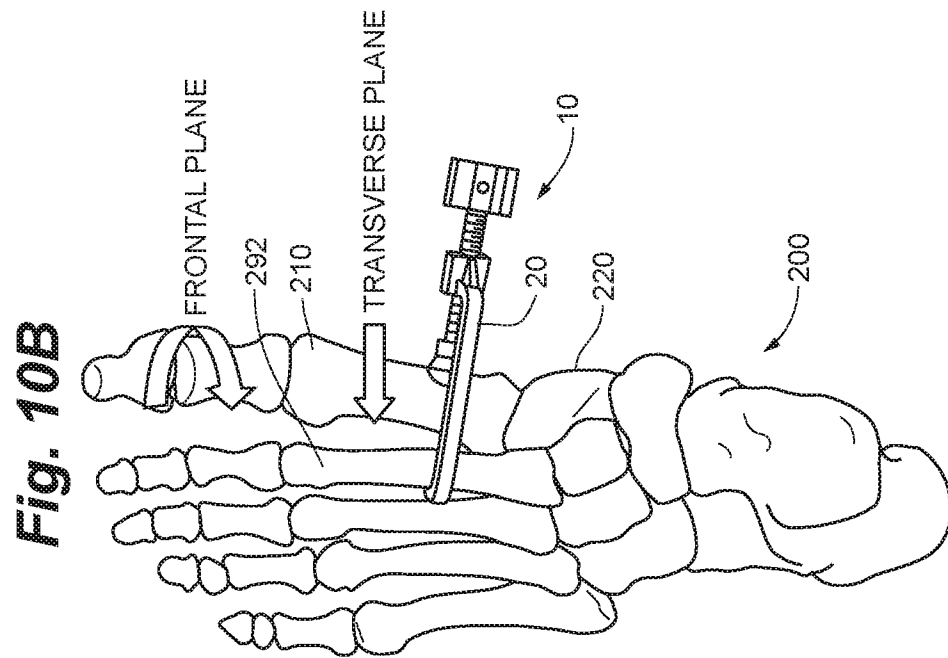
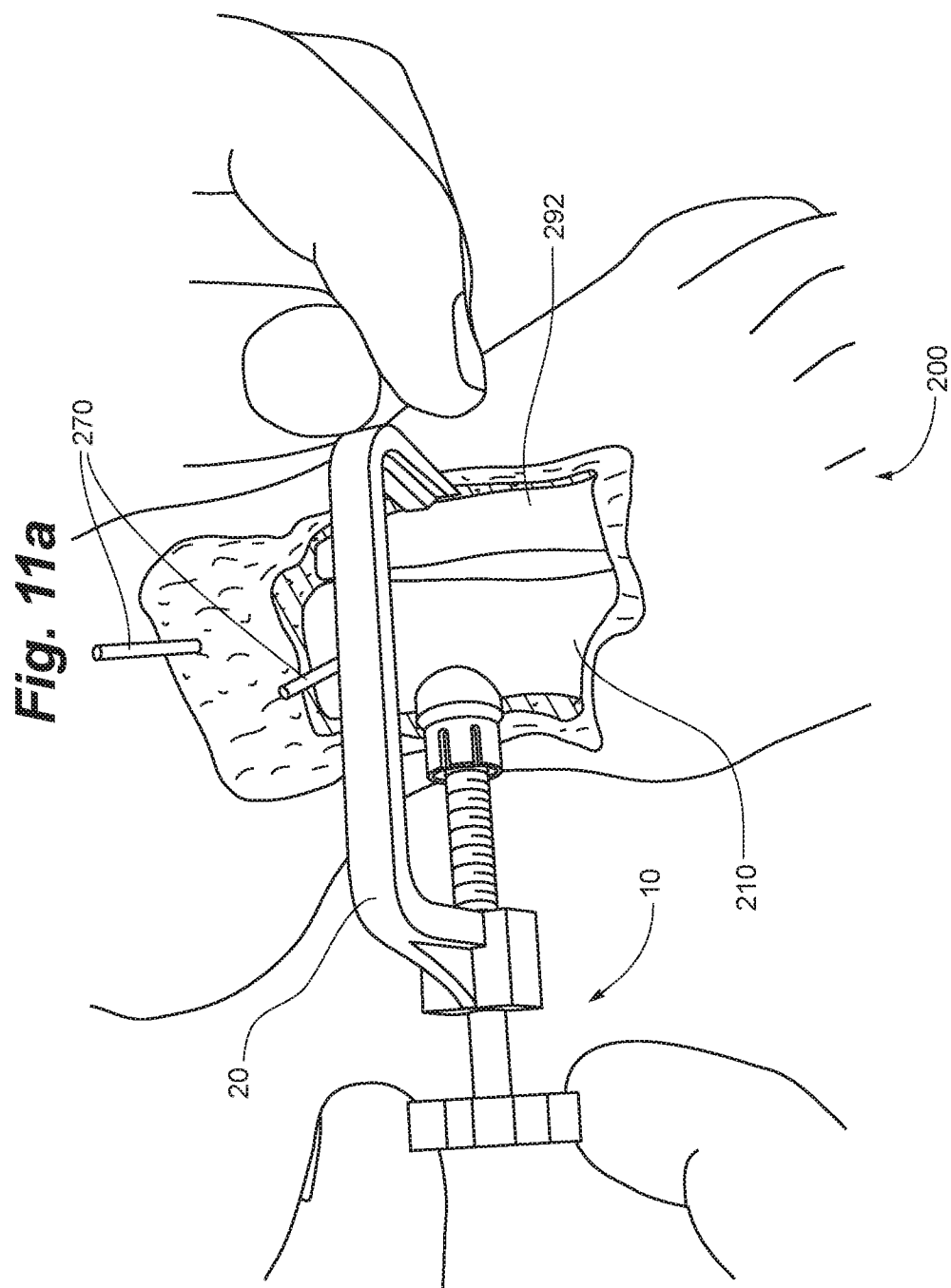


Fig. 9B







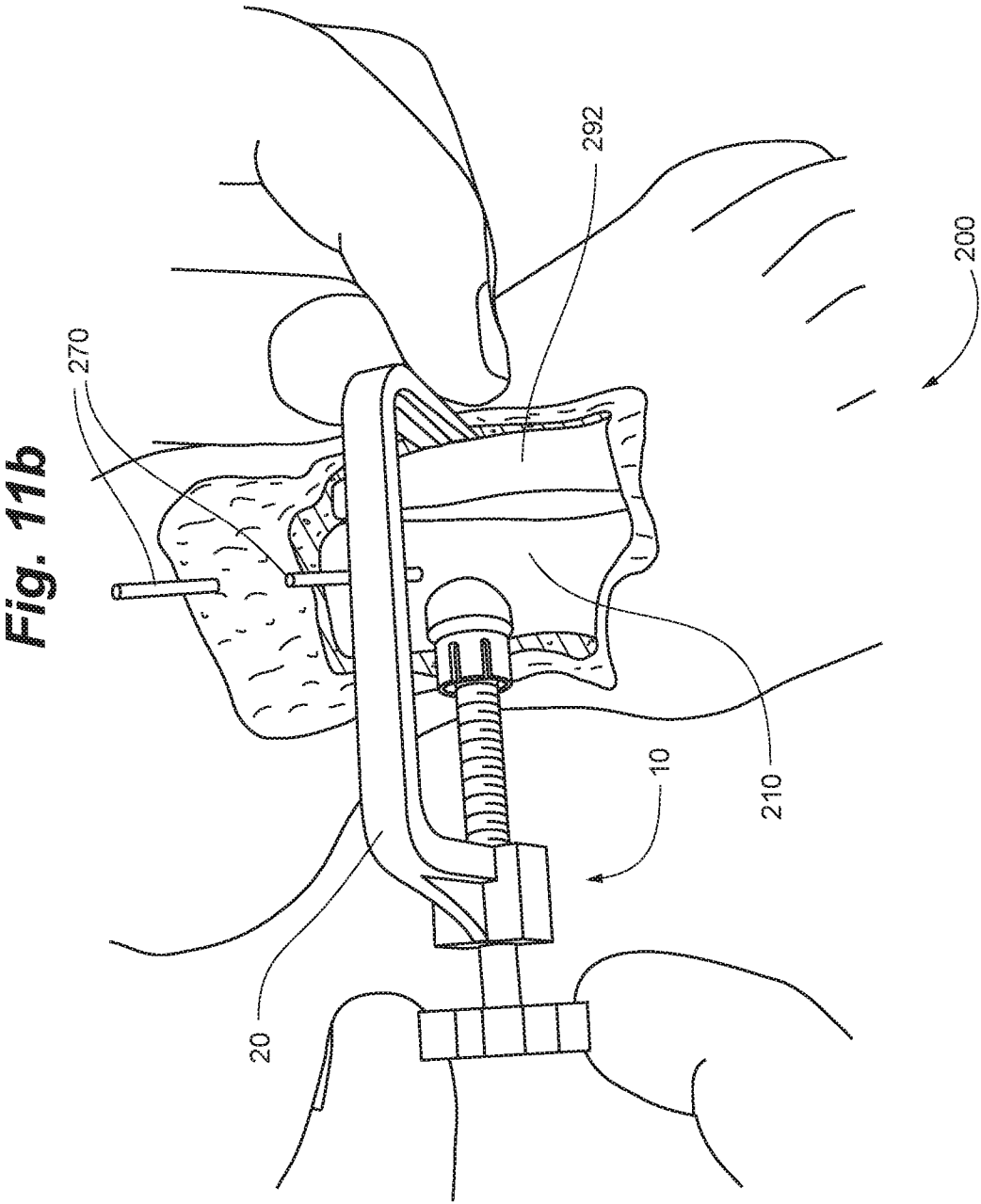
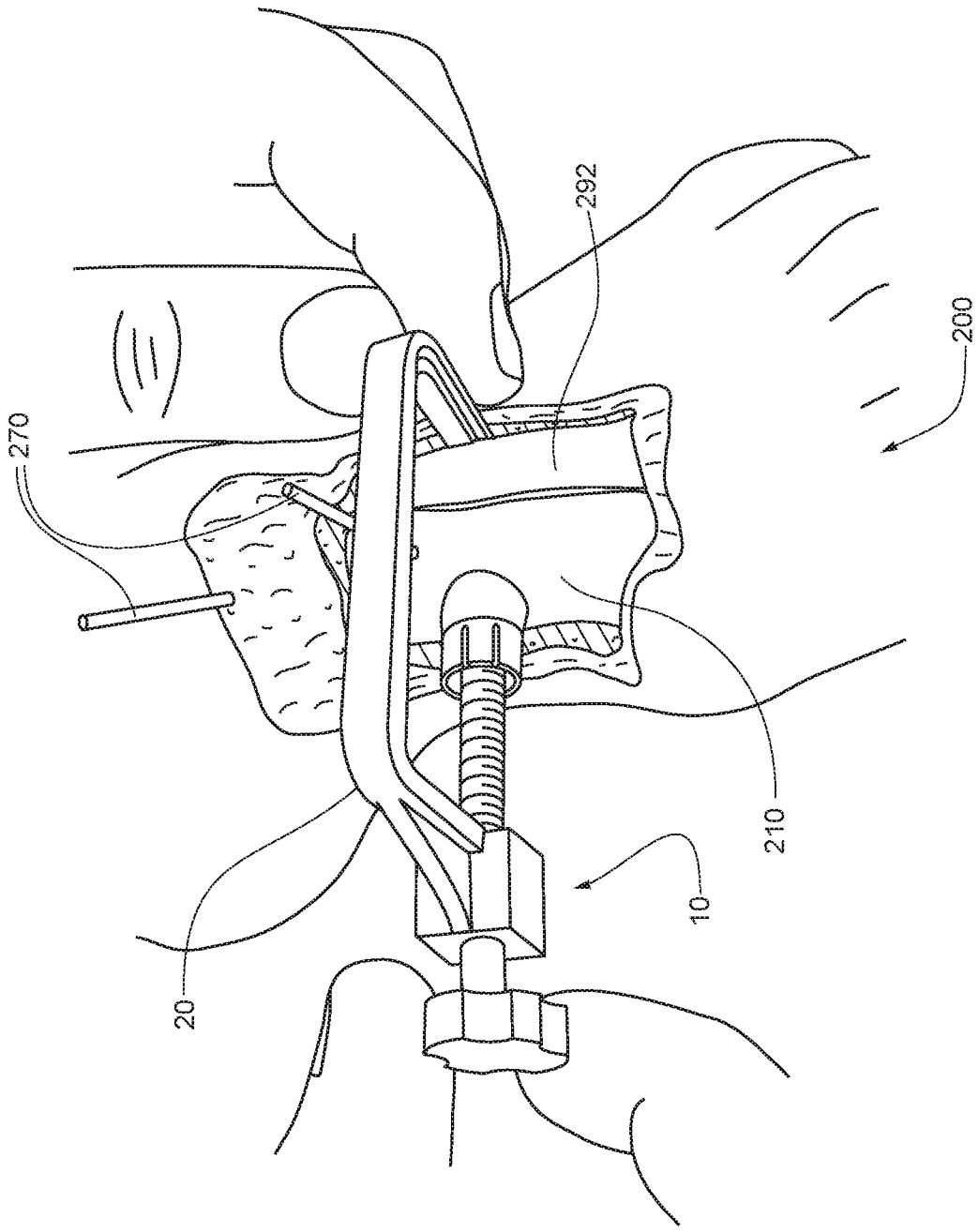
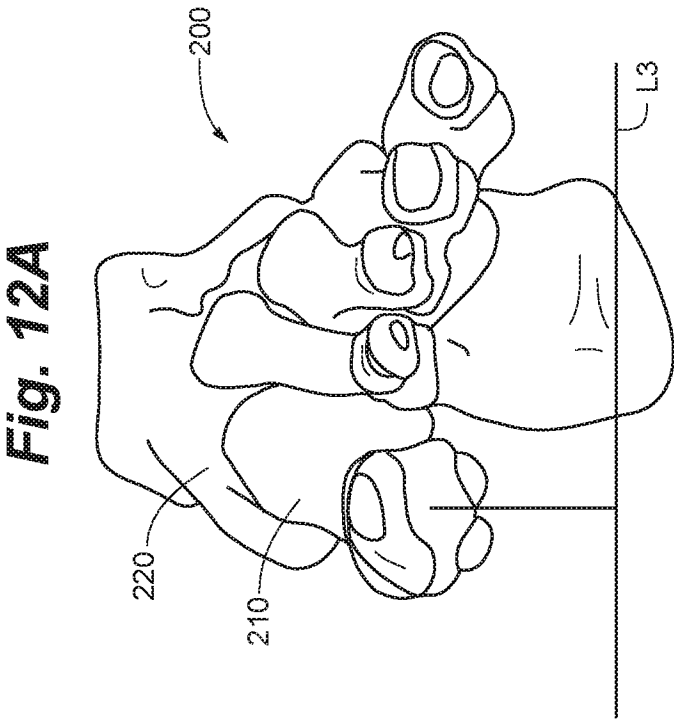
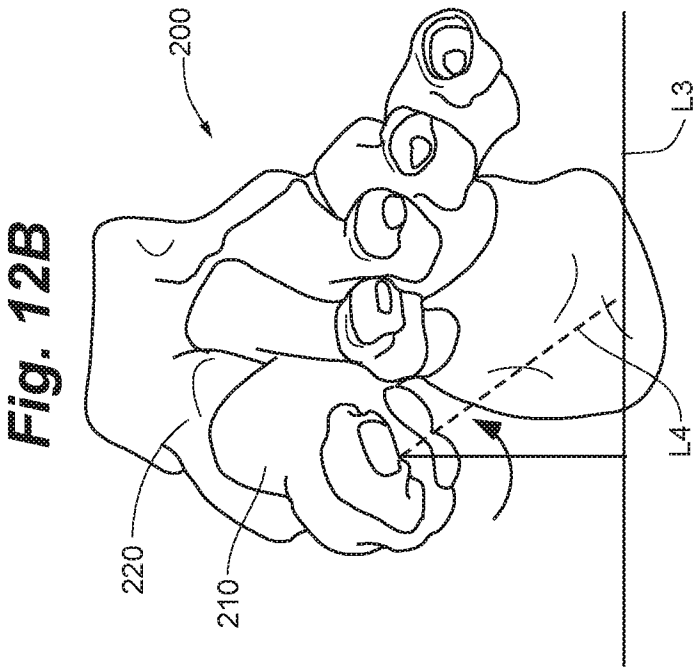


Fig. 11c





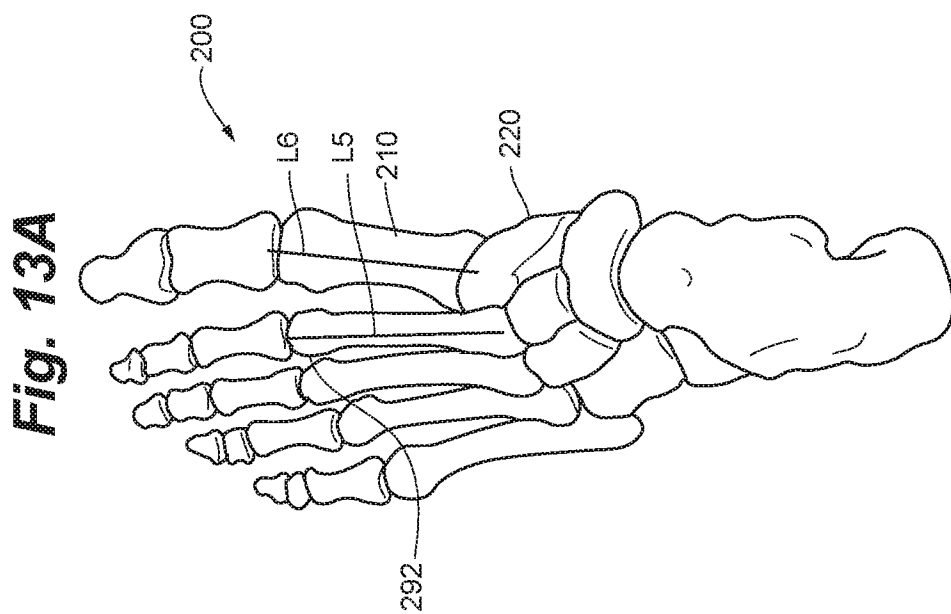
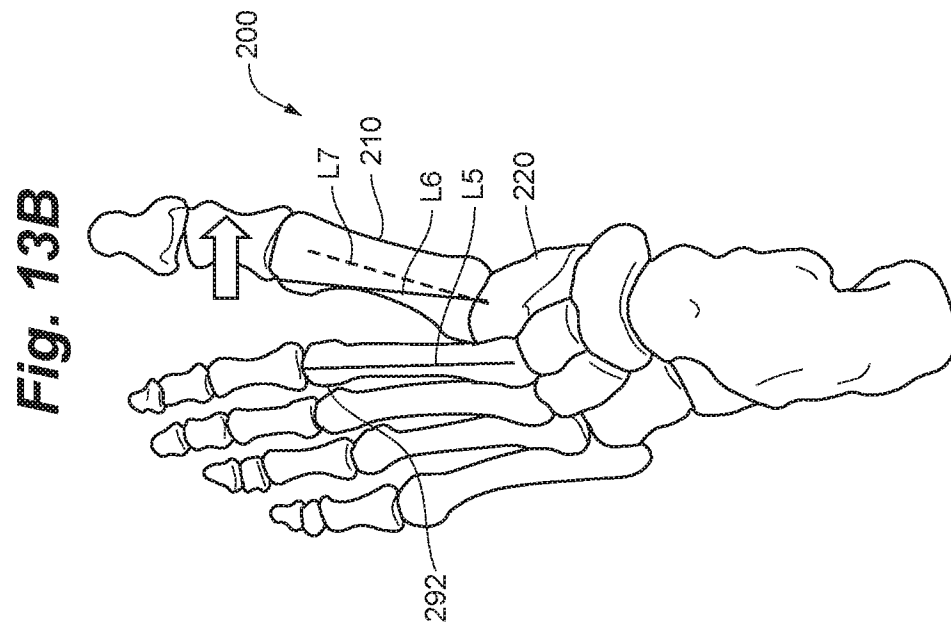


Fig. 14A

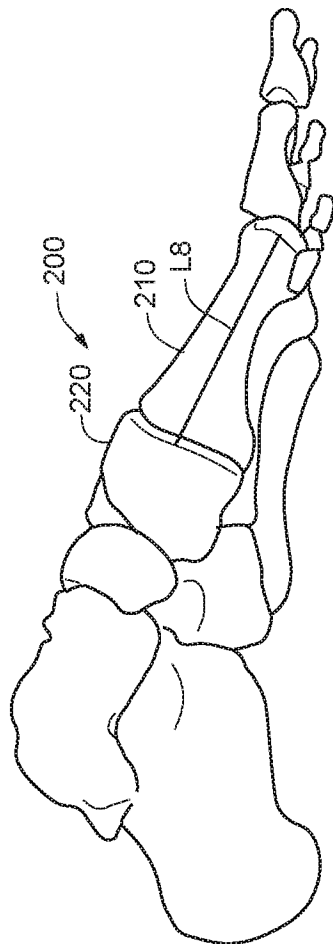


Fig. 14B

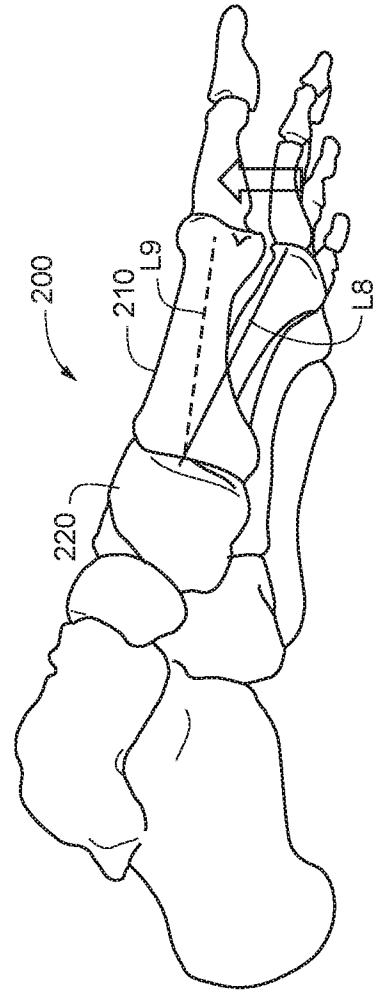


Fig. 15A

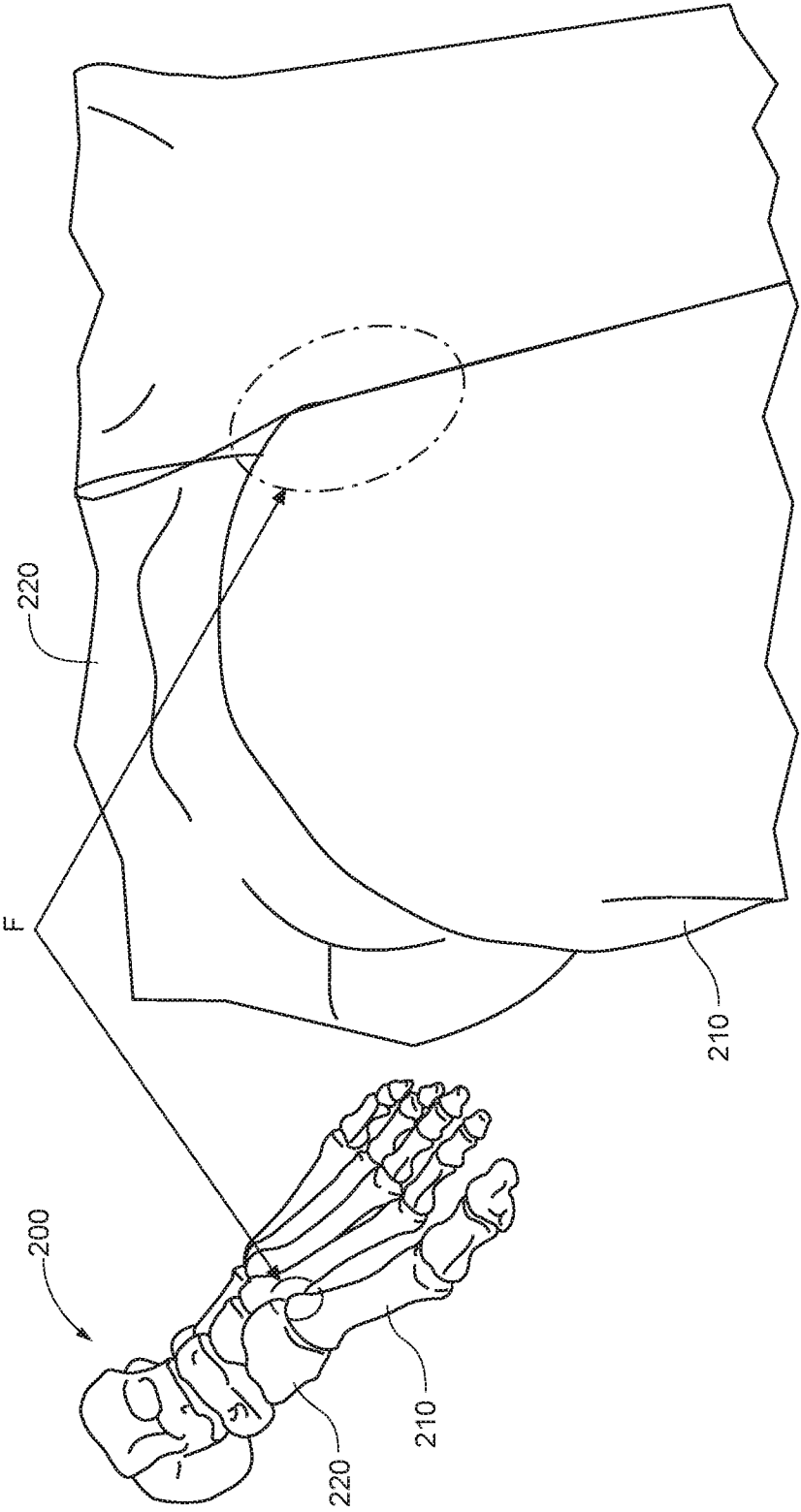
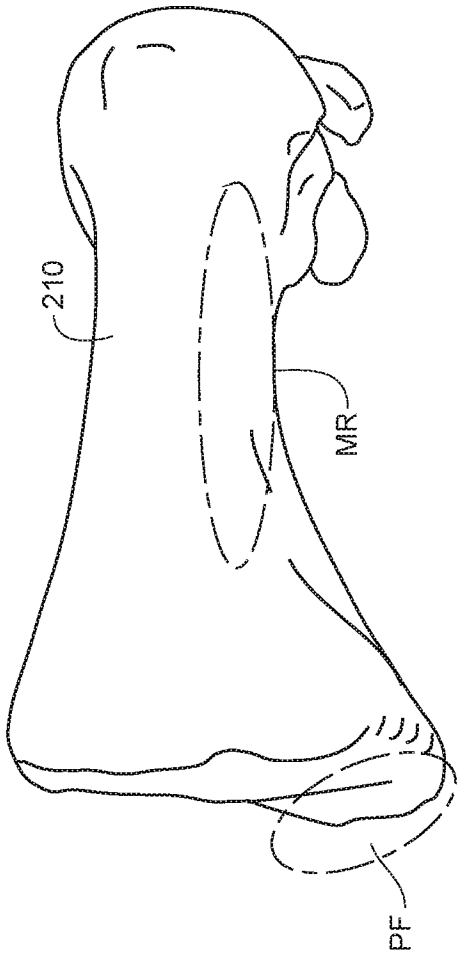
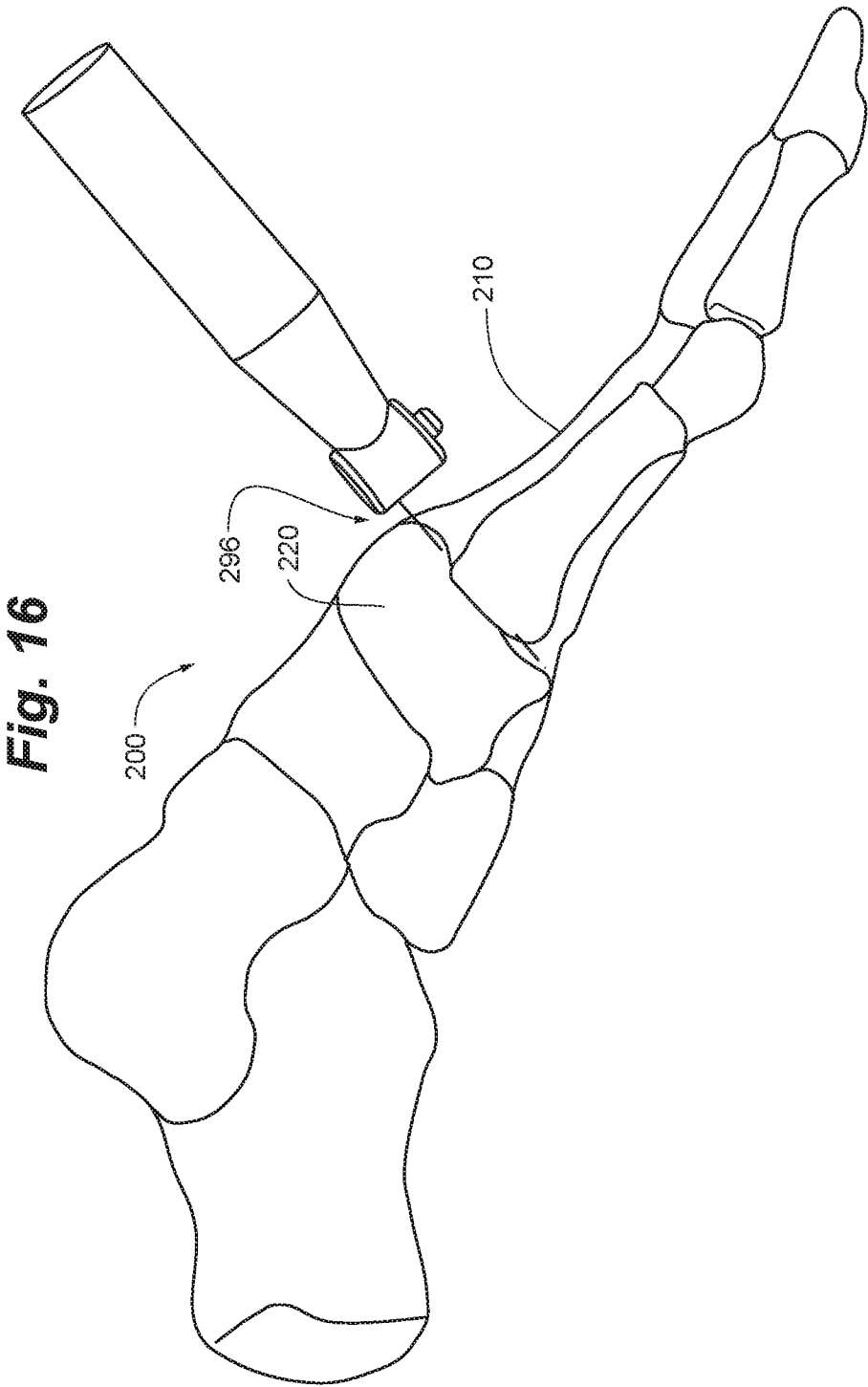
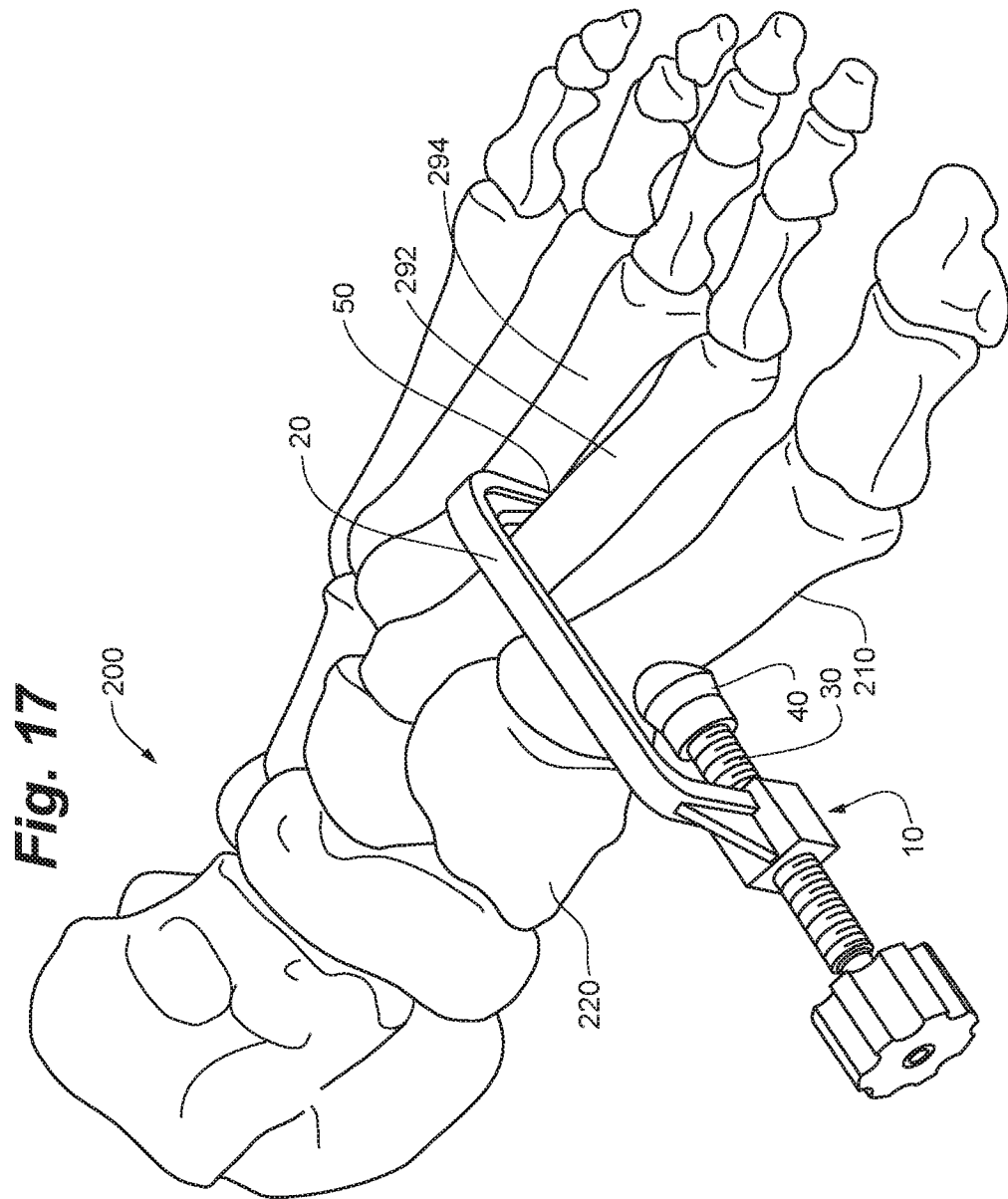
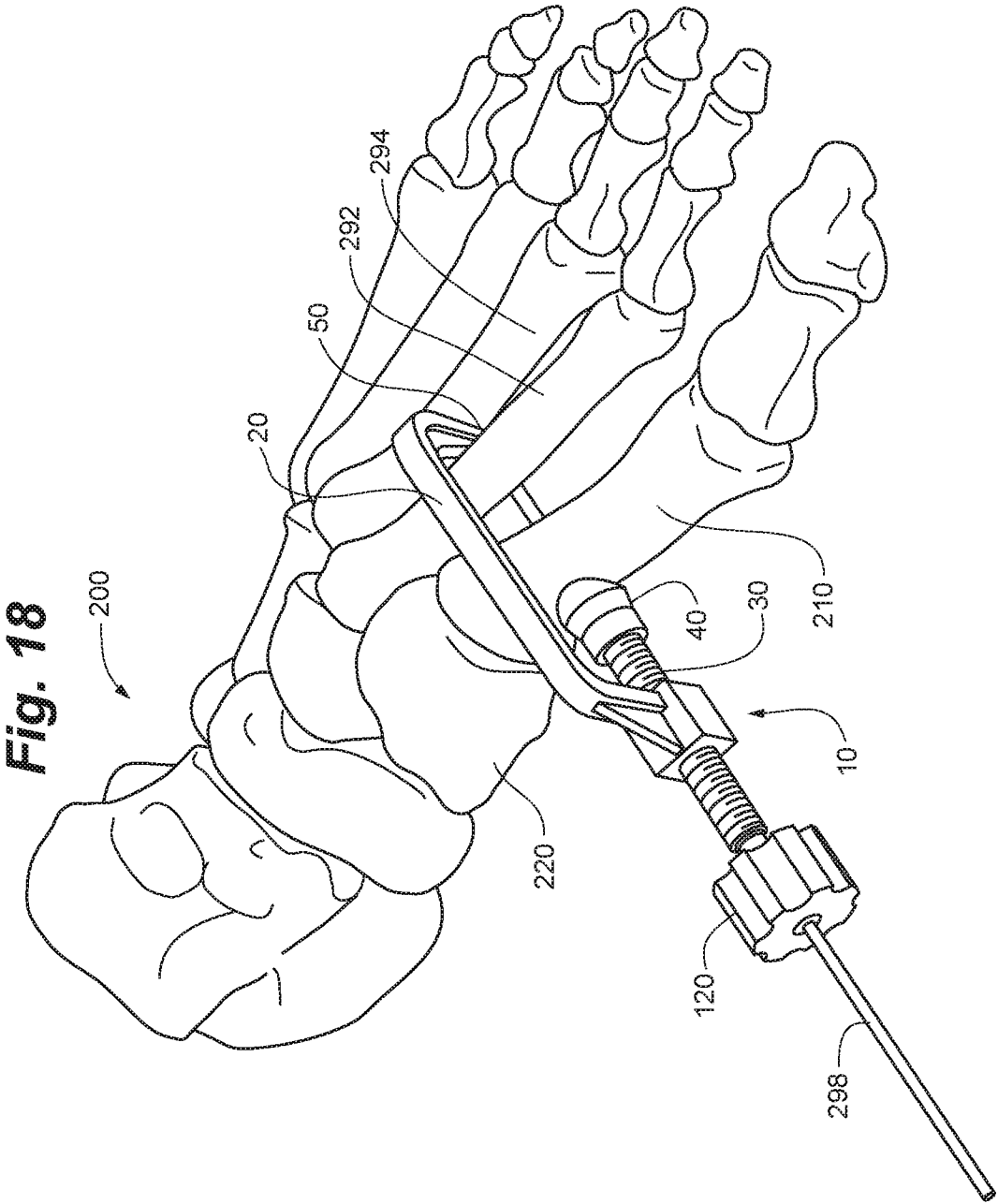


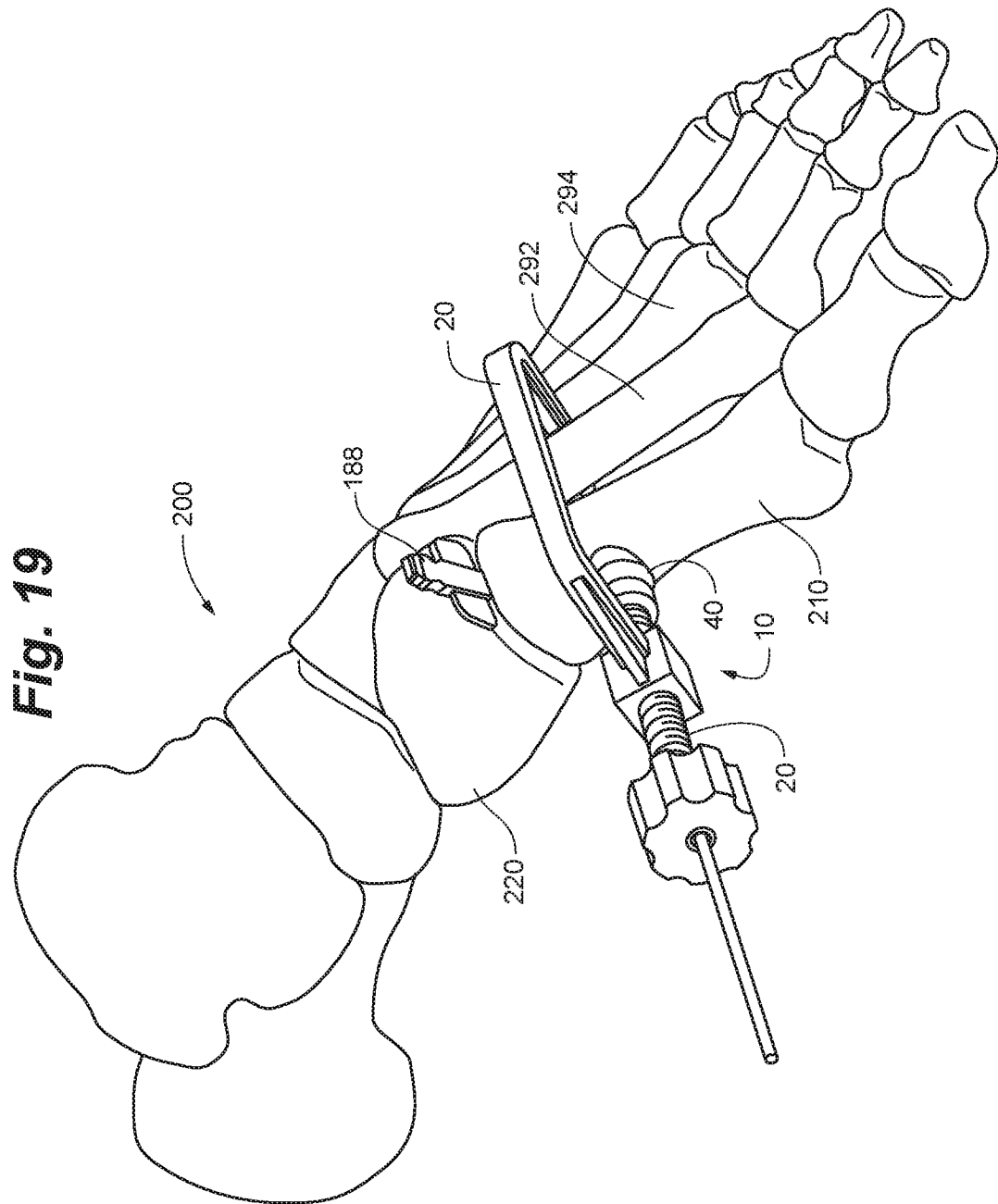
Fig. 15B











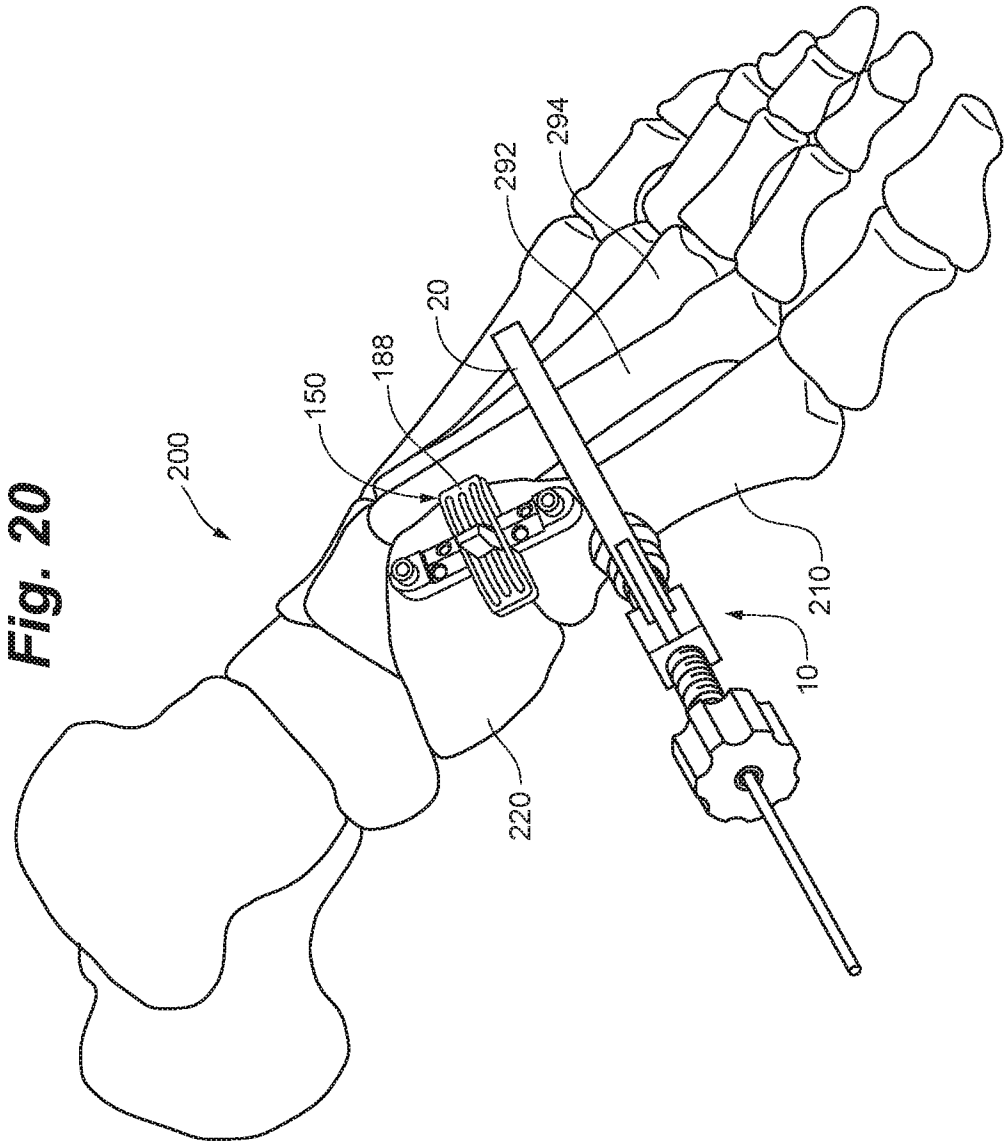
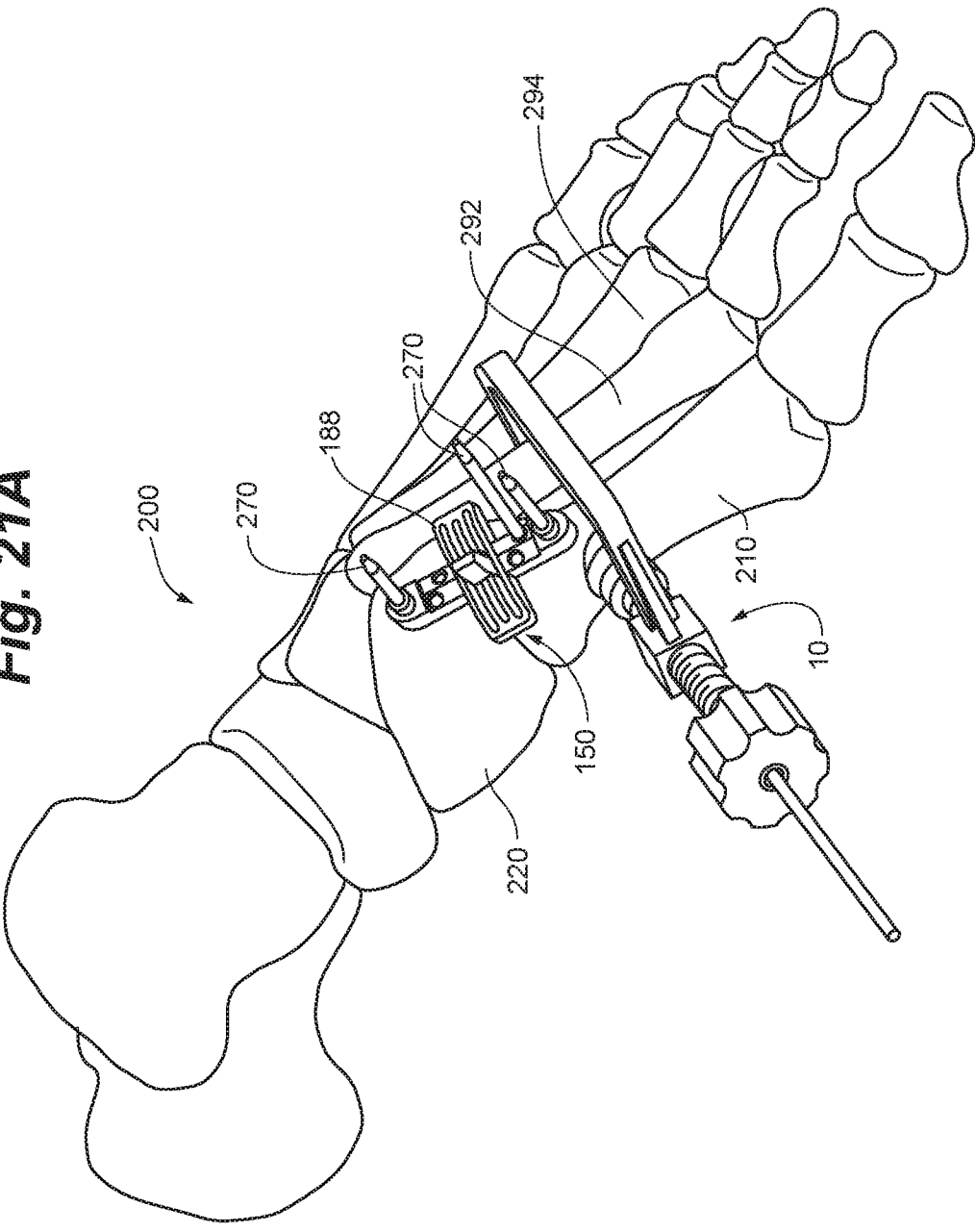


Fig. 21A



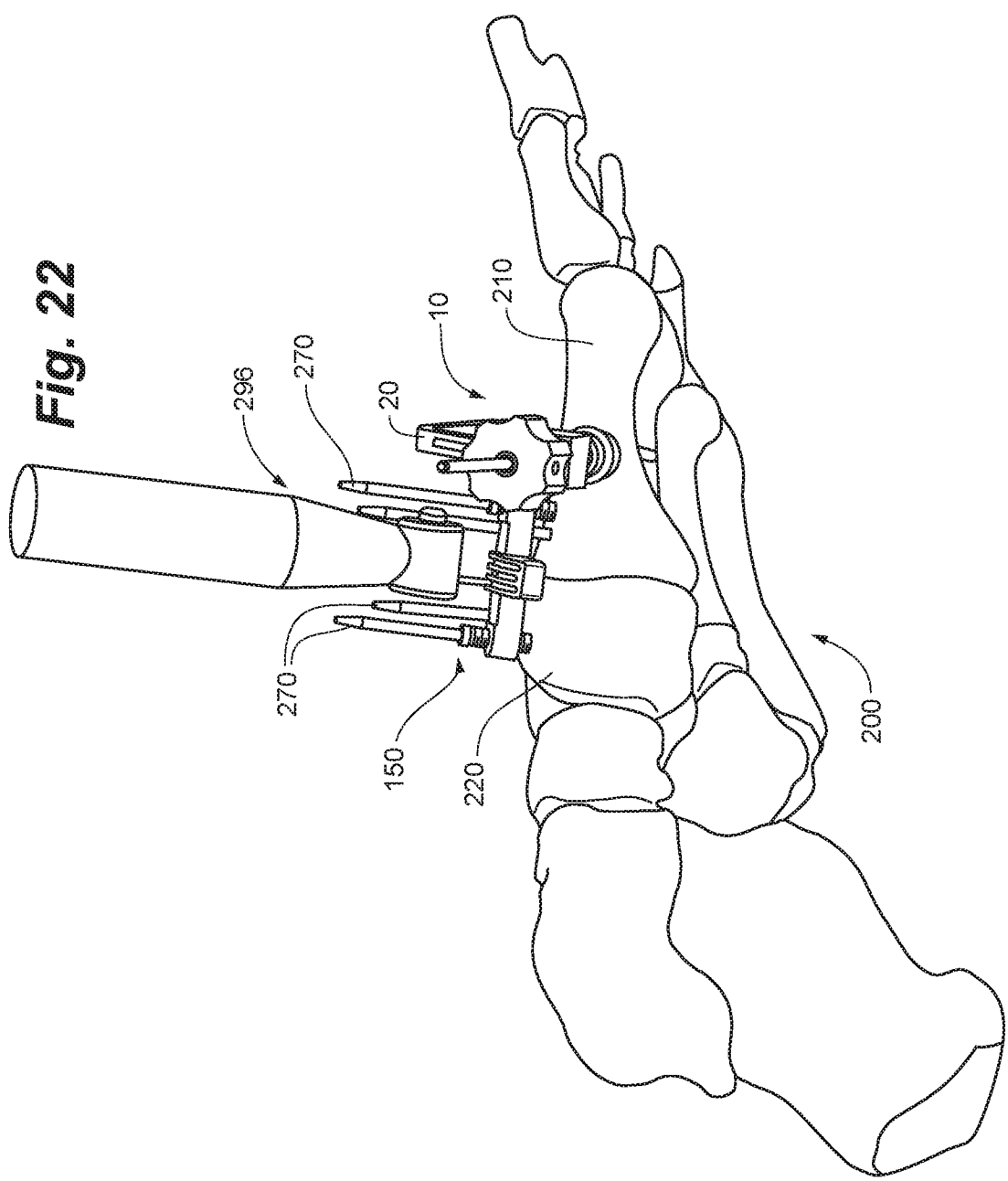
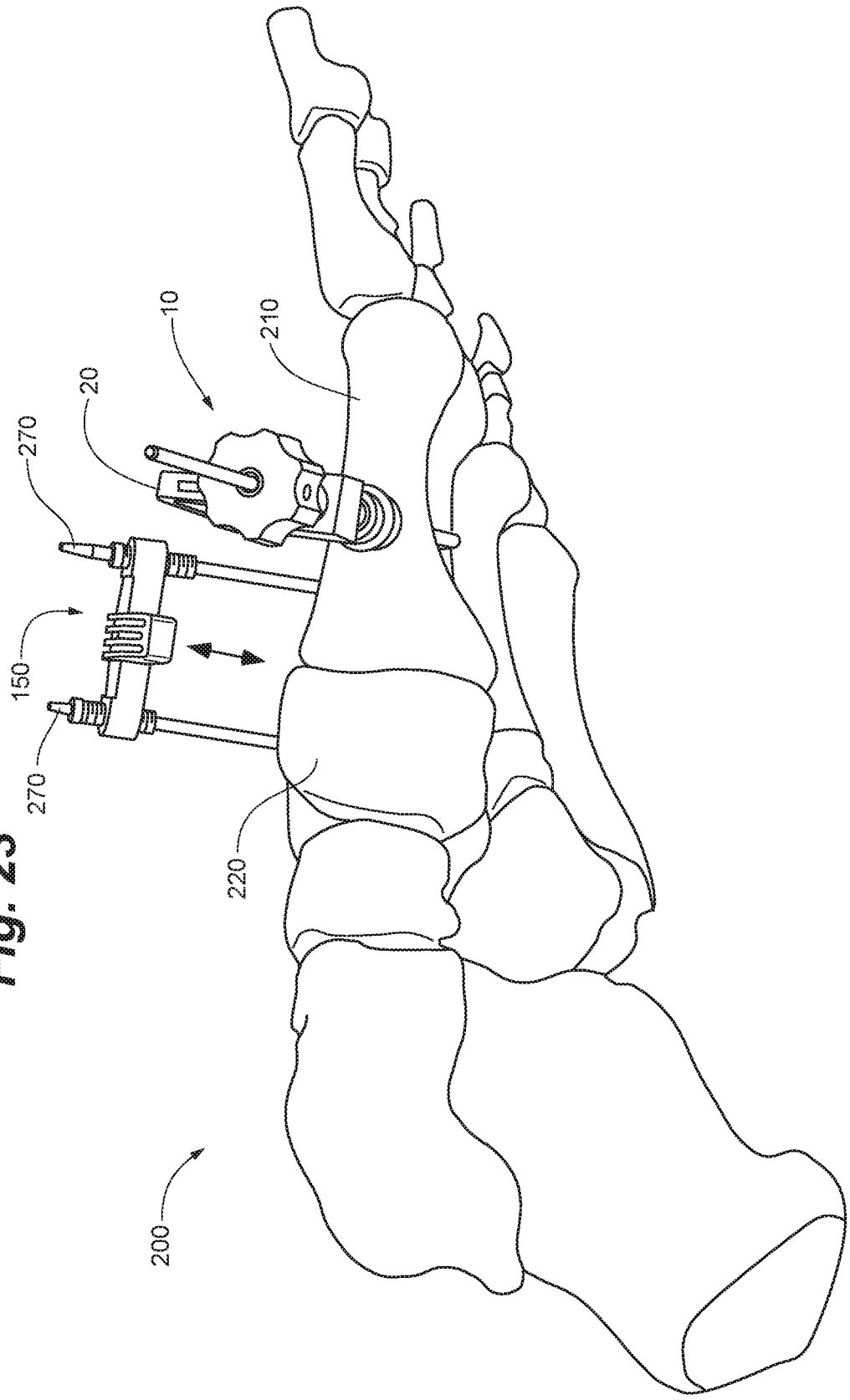


Fig. 23



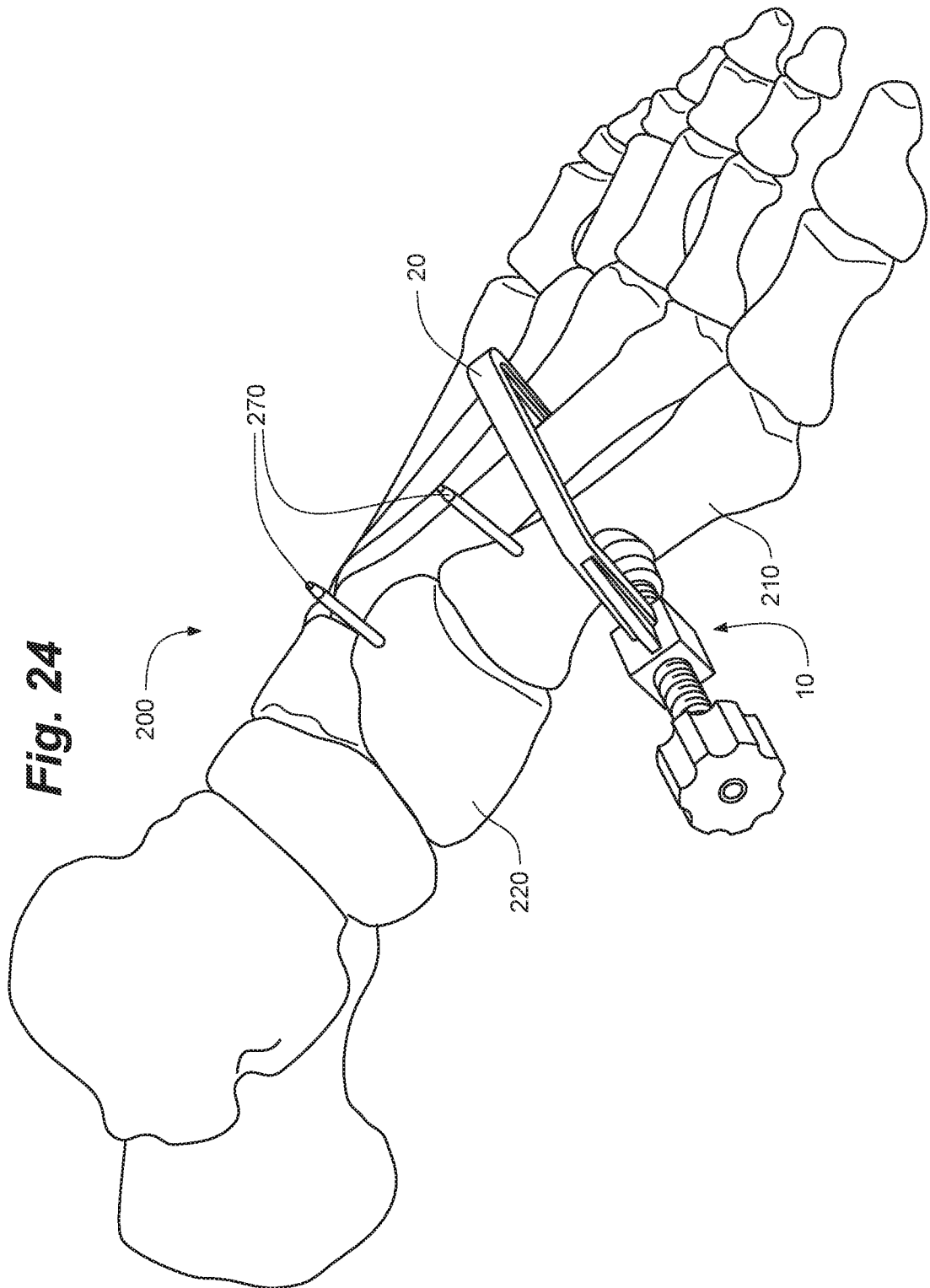


Fig. 24

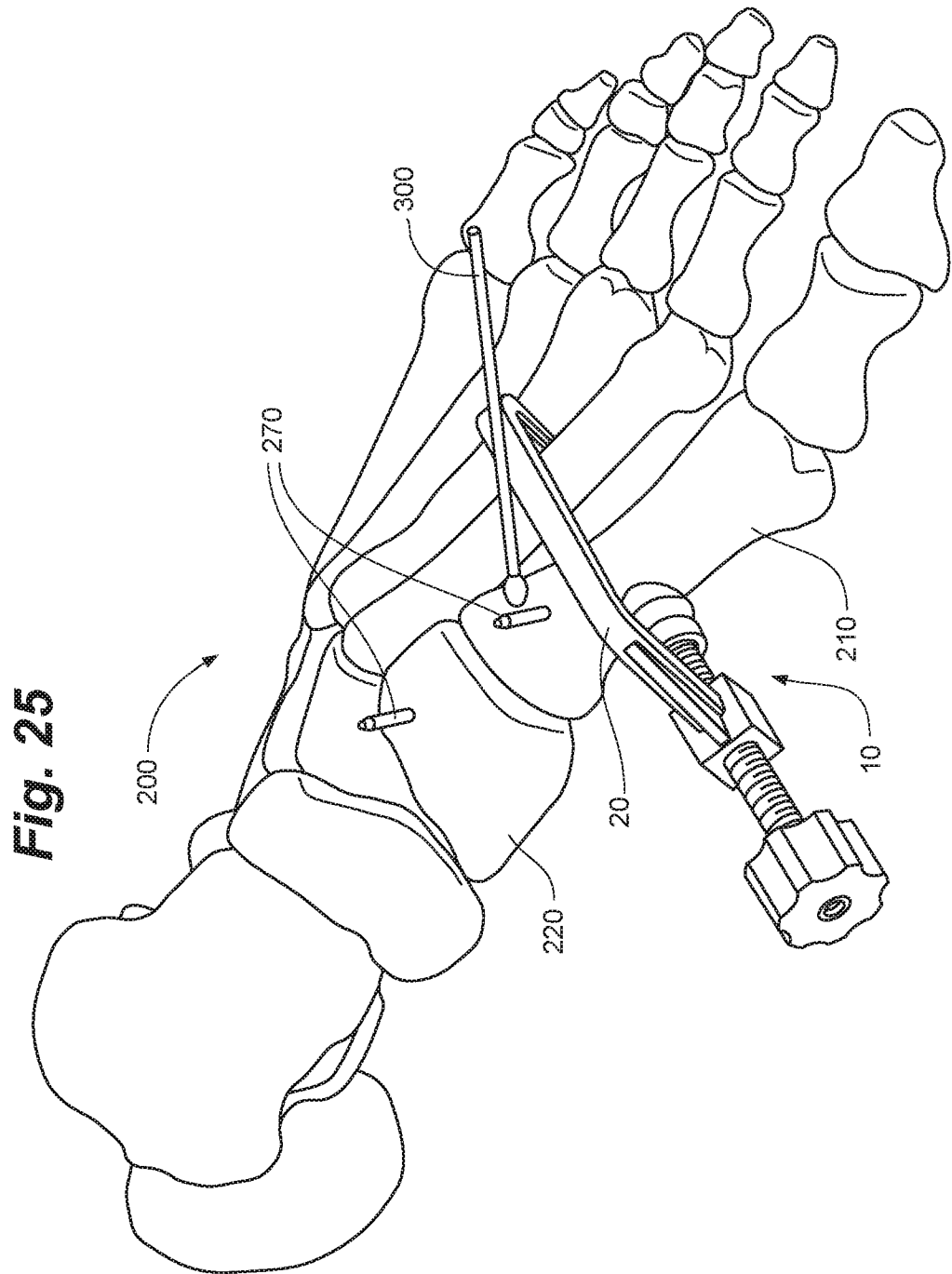
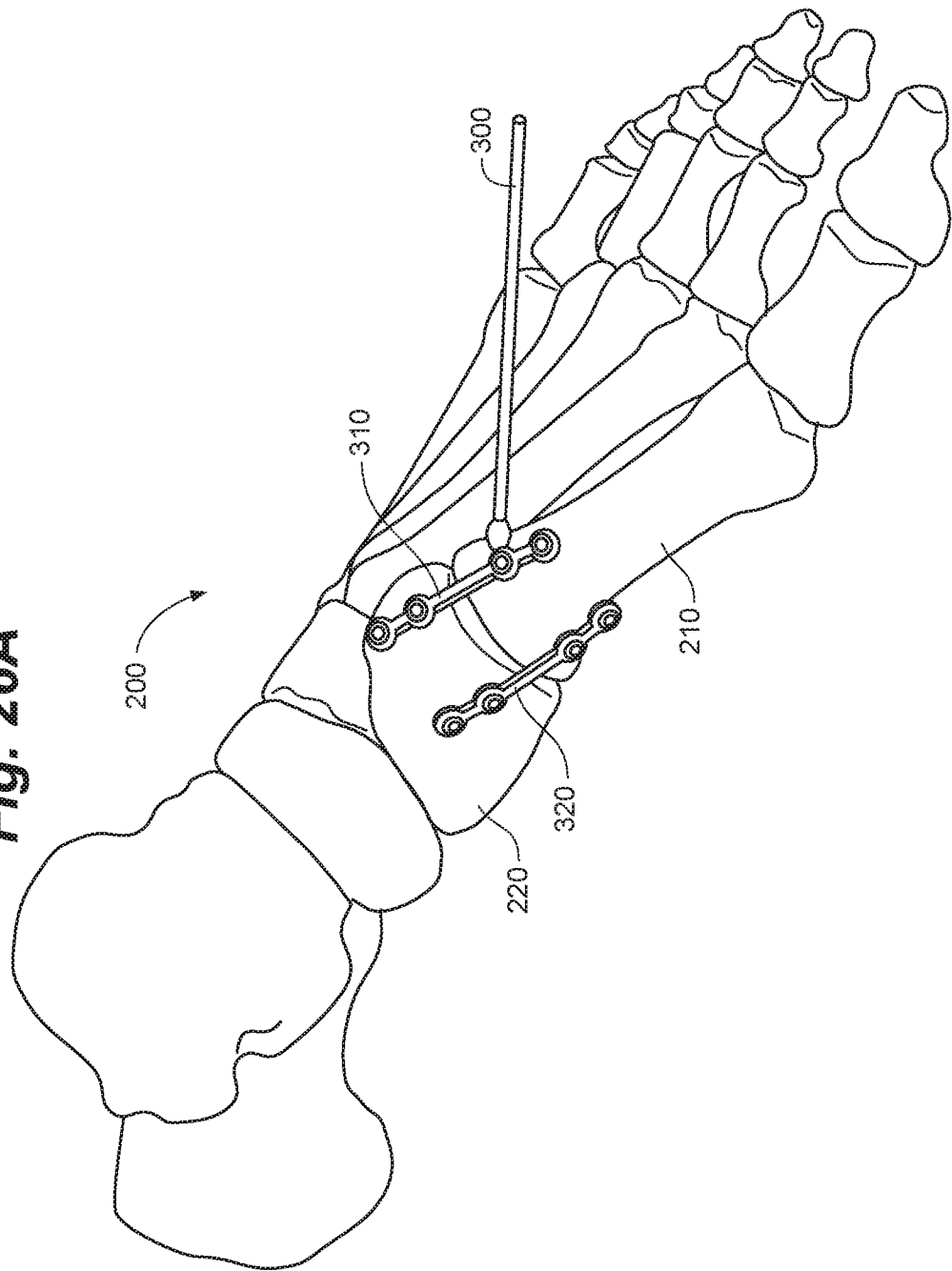


Fig. 26A



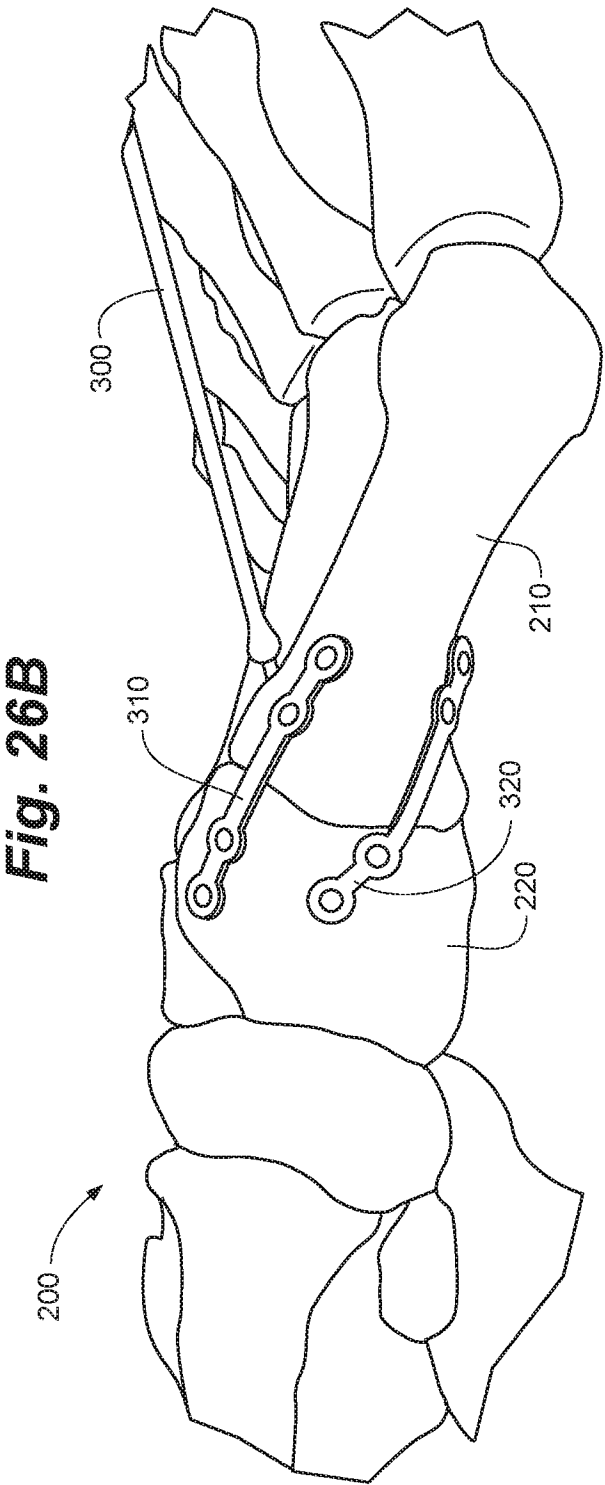
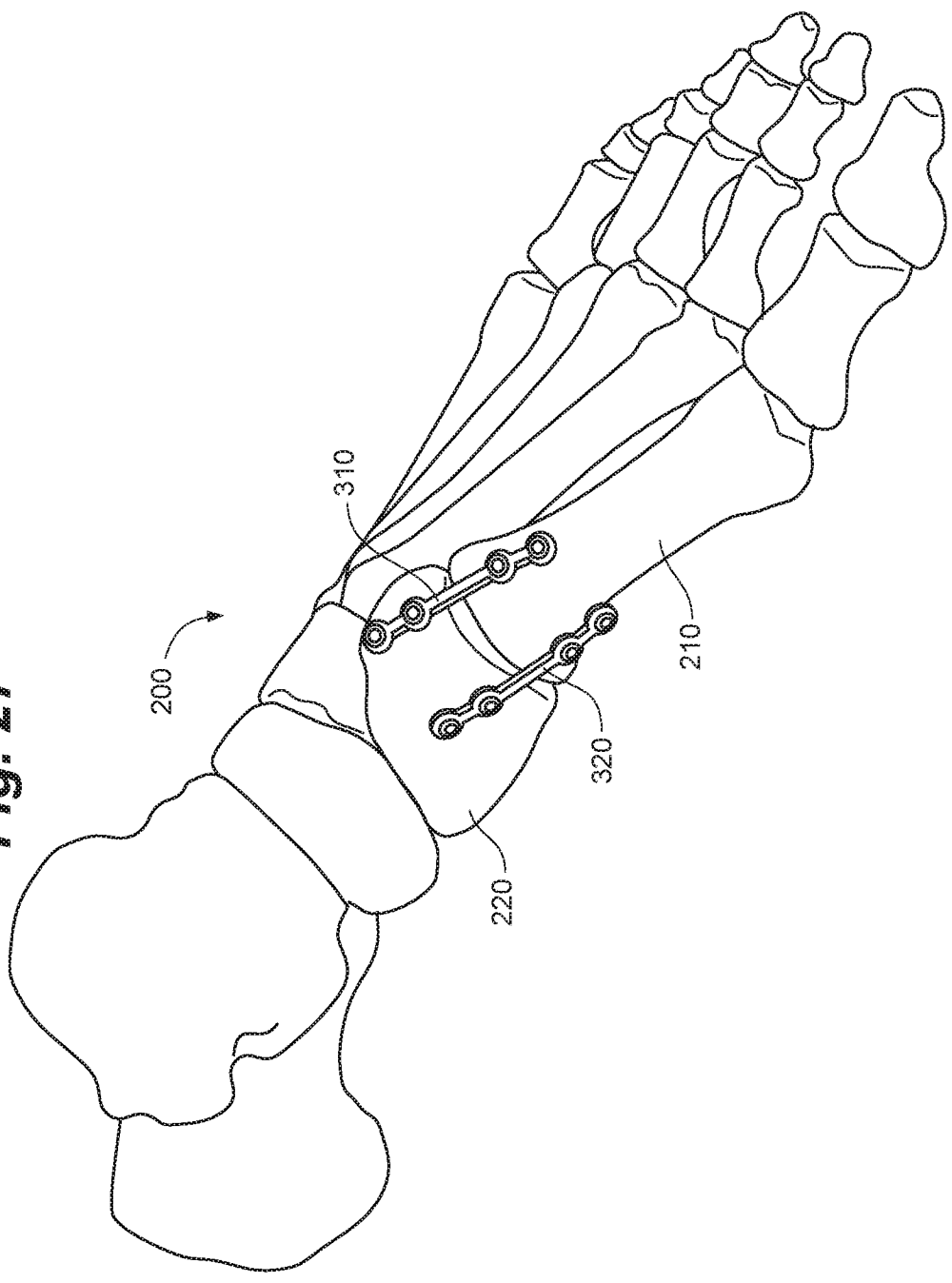
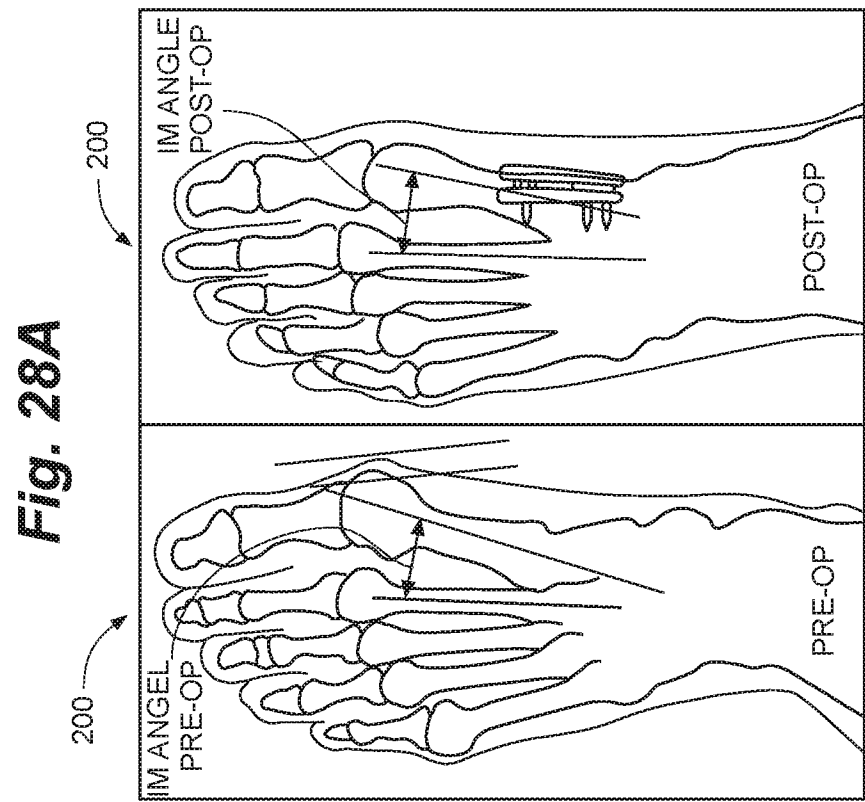
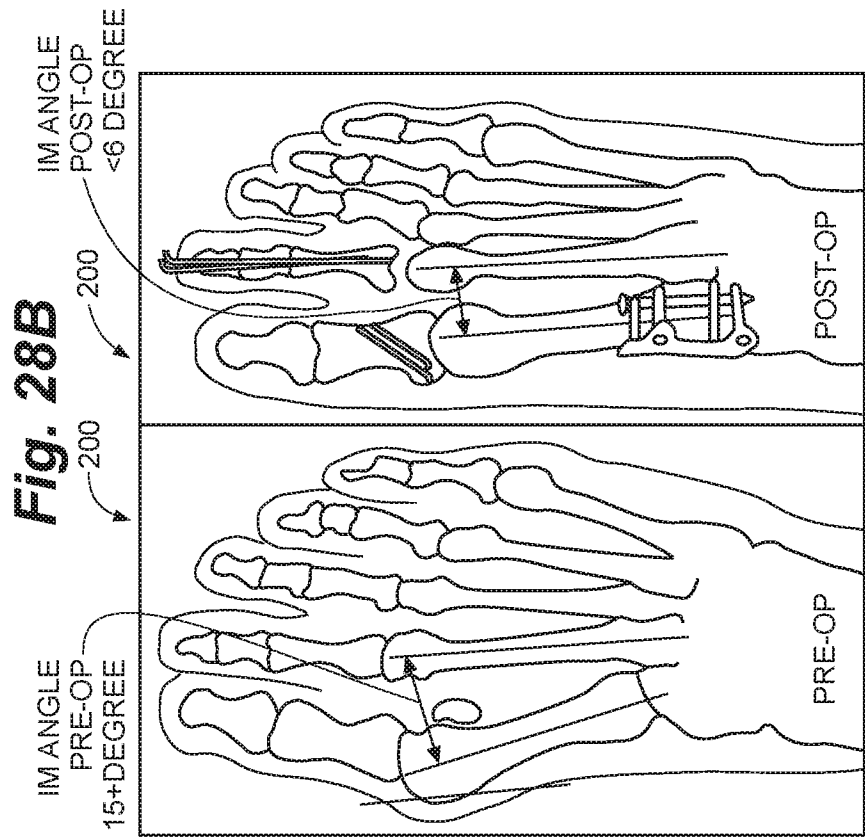


Fig. 27





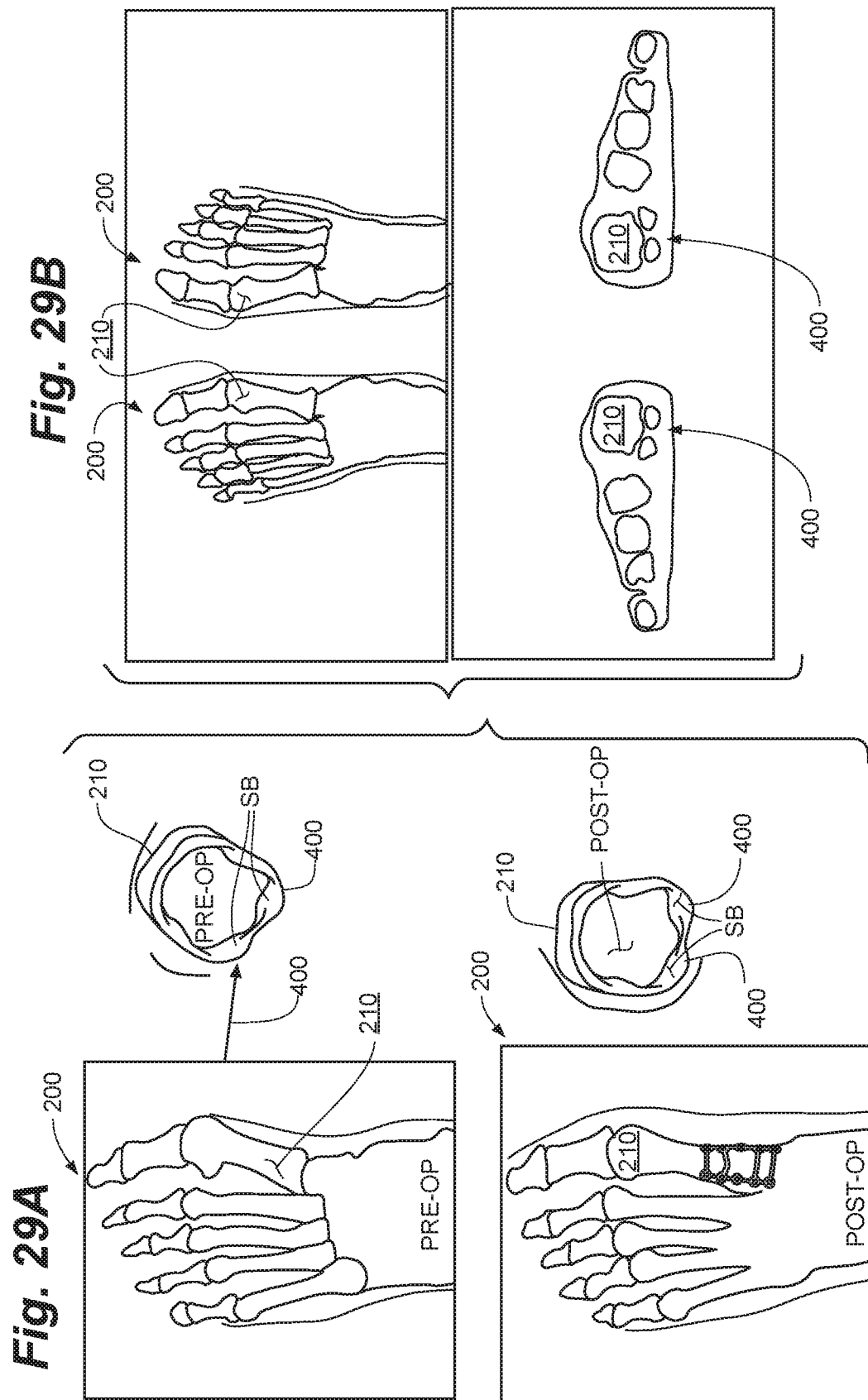


Fig. 30B

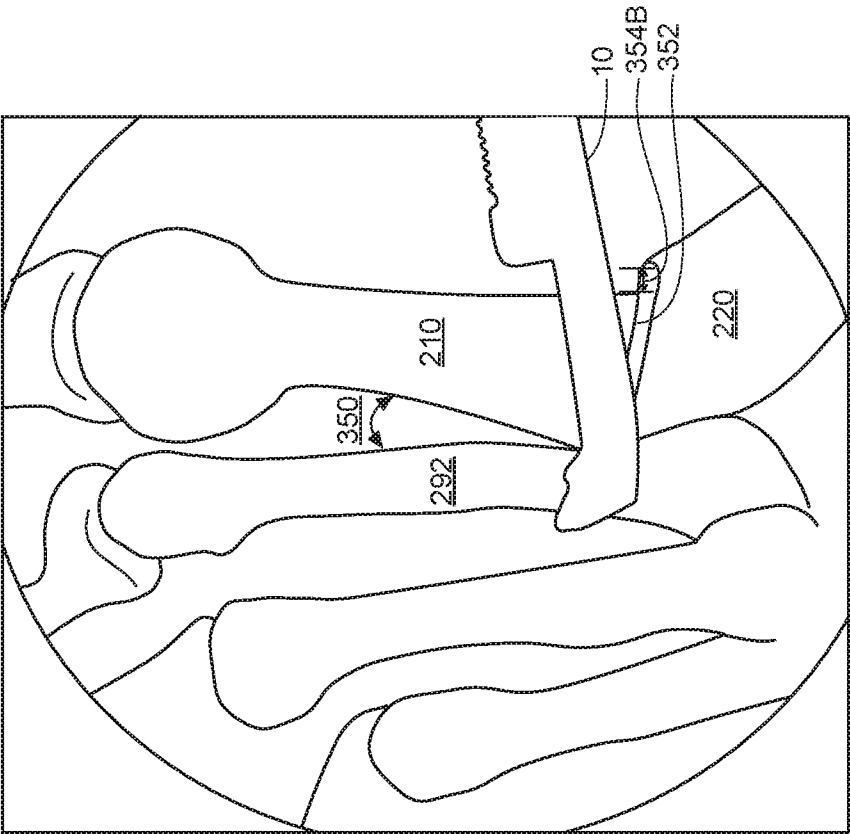
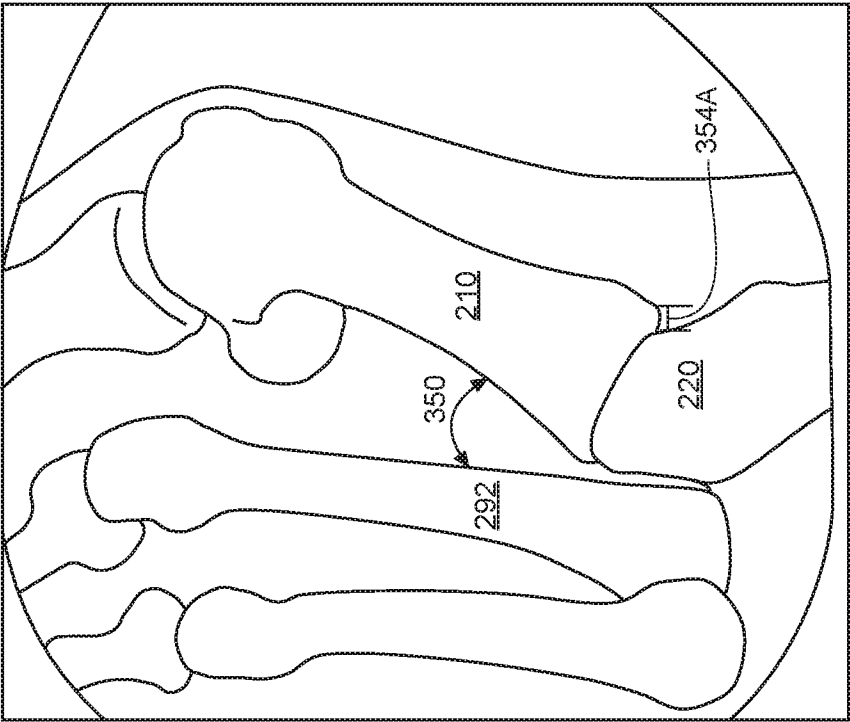


Fig. 30A



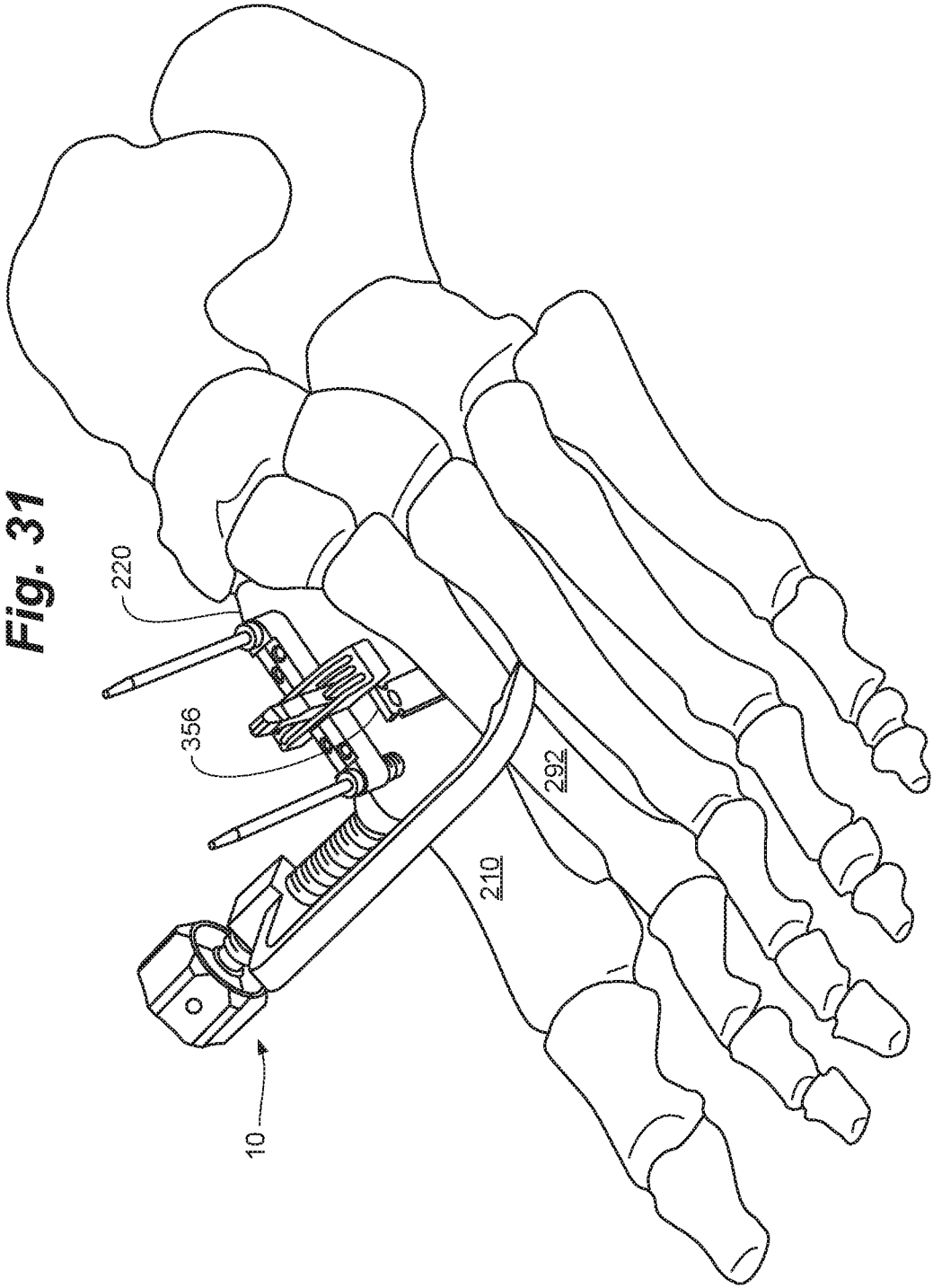


Fig. 32

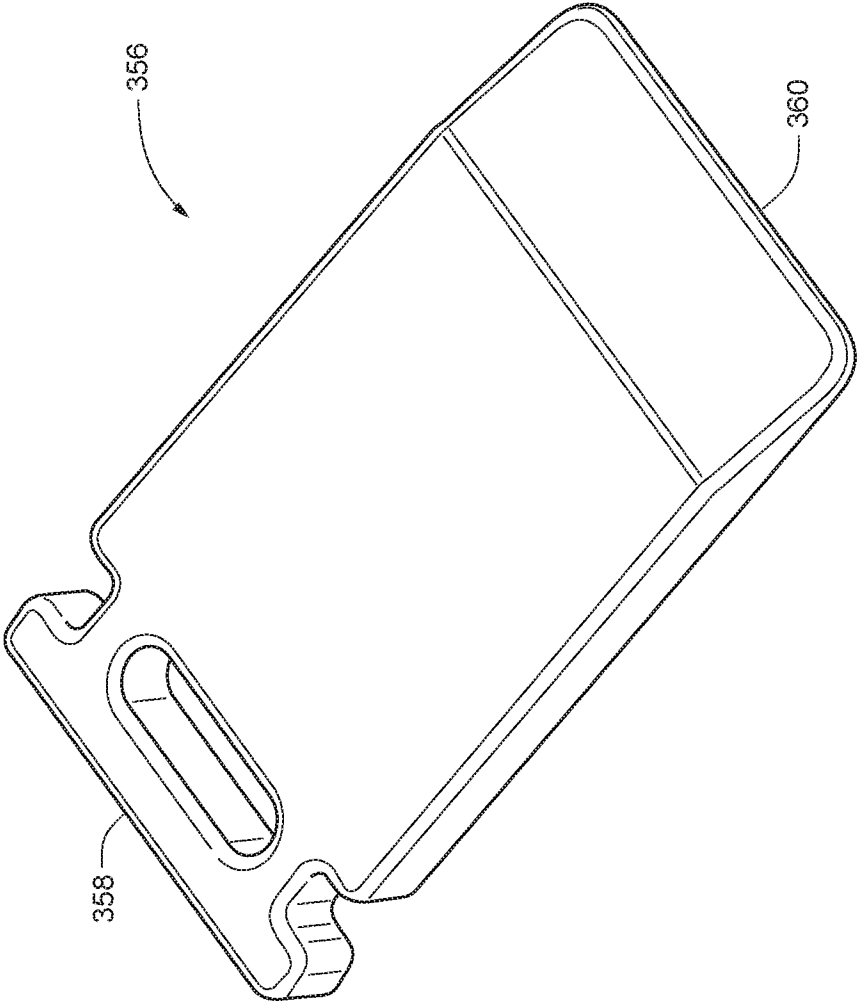
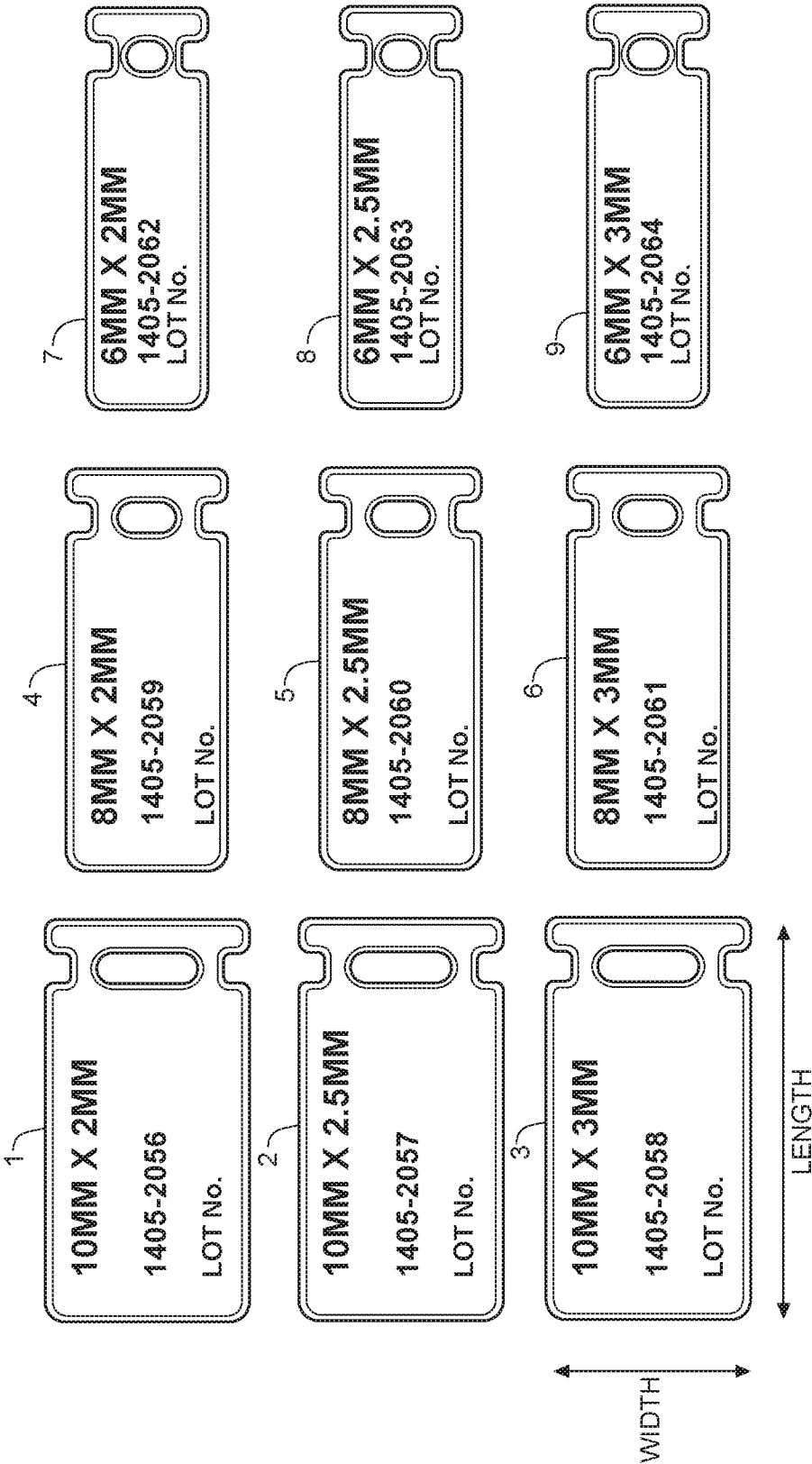
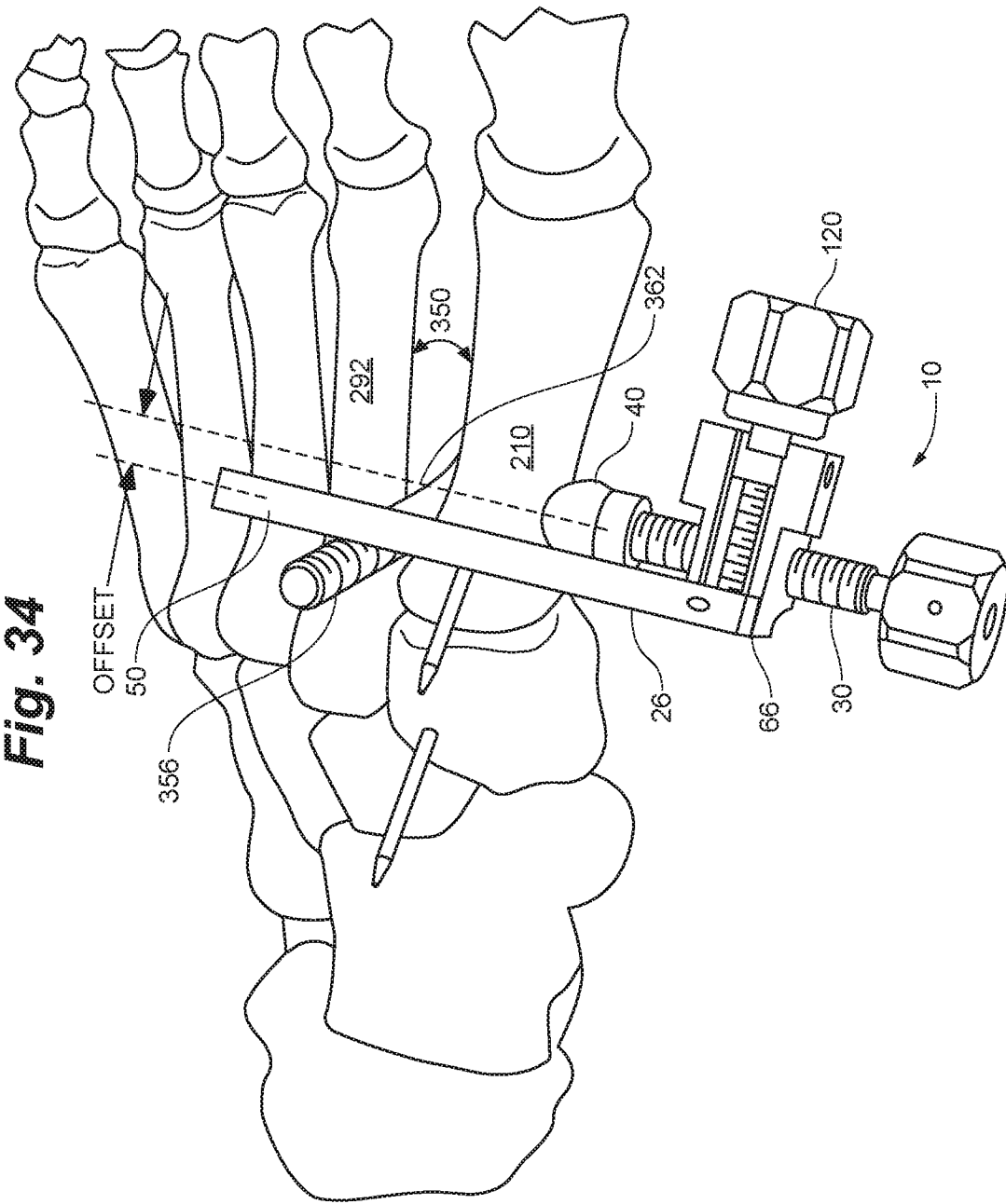
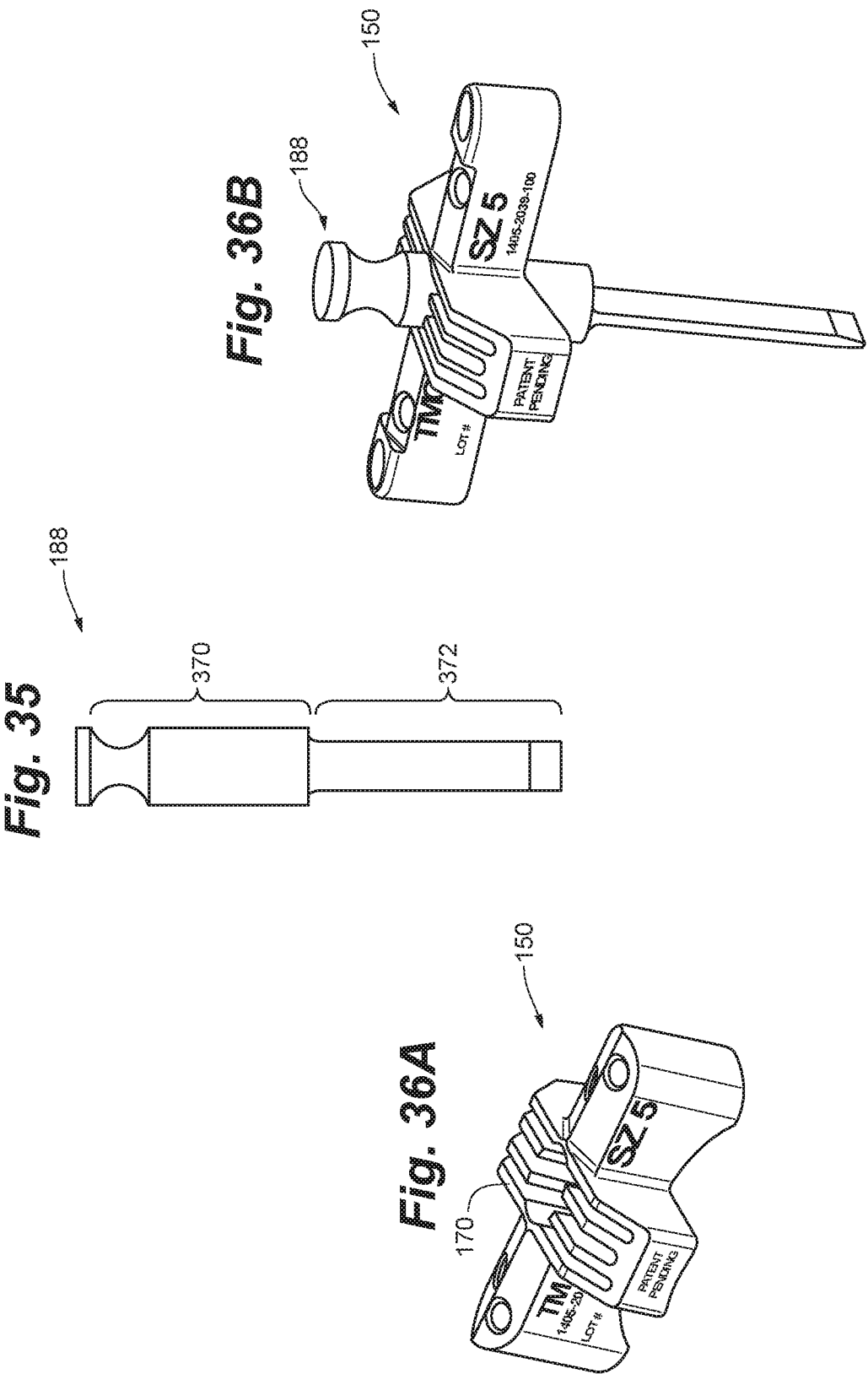


Fig. 33







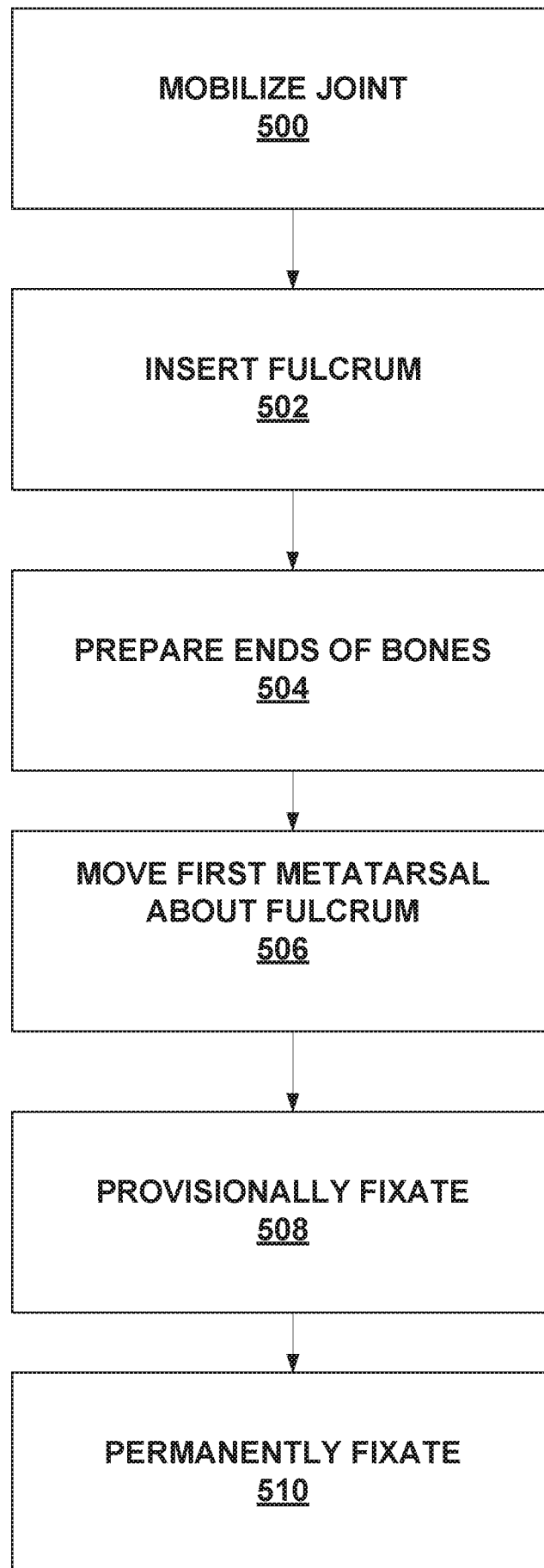


FIG. 37

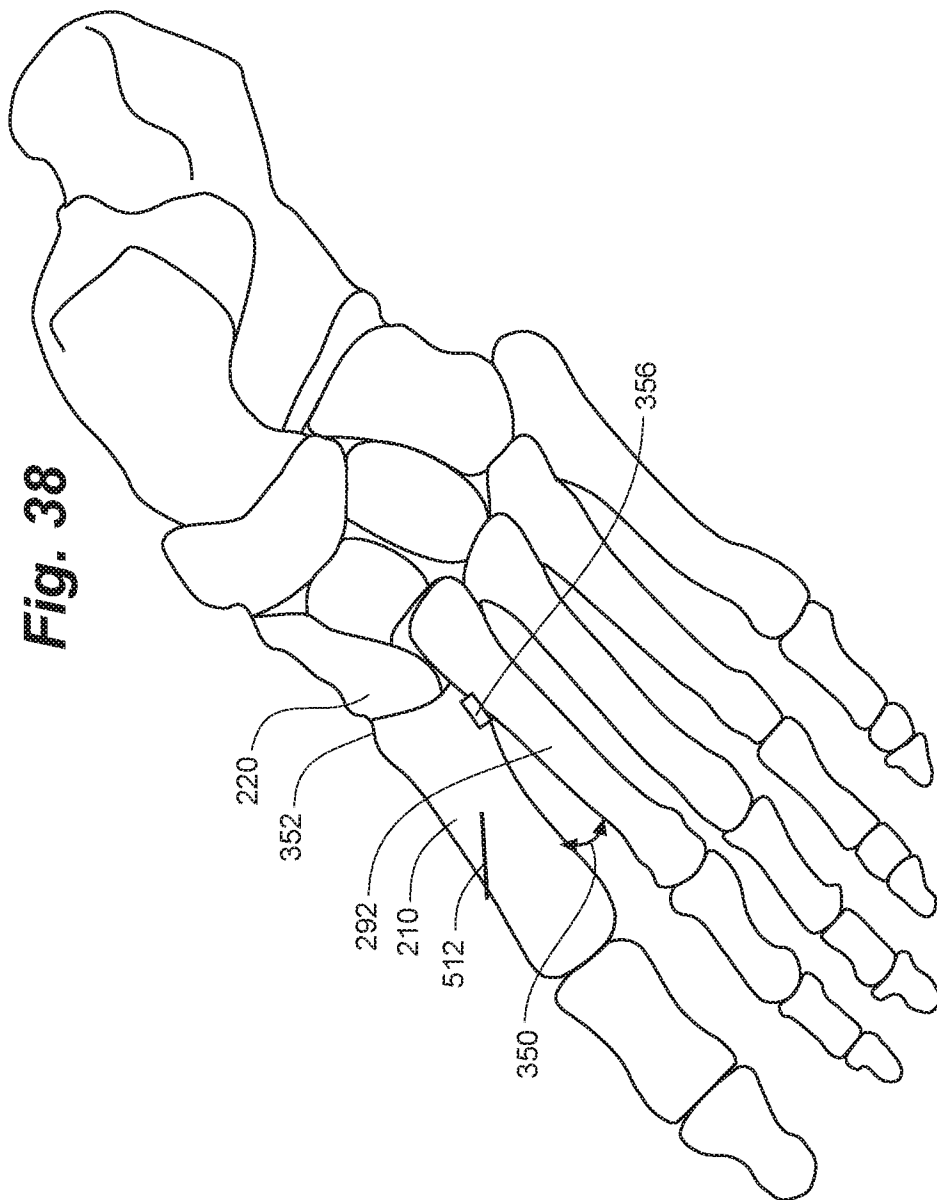


Fig. 39A

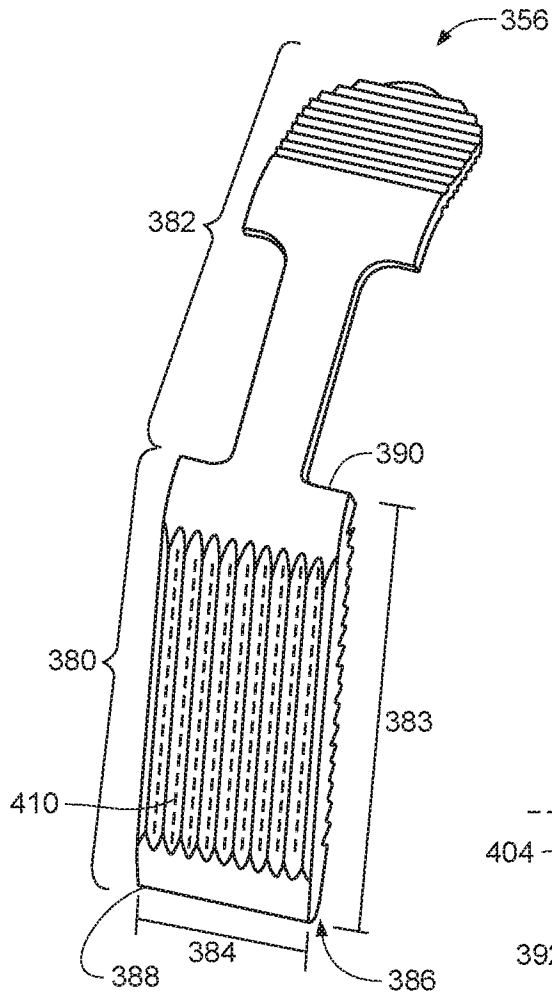


Fig. 39B

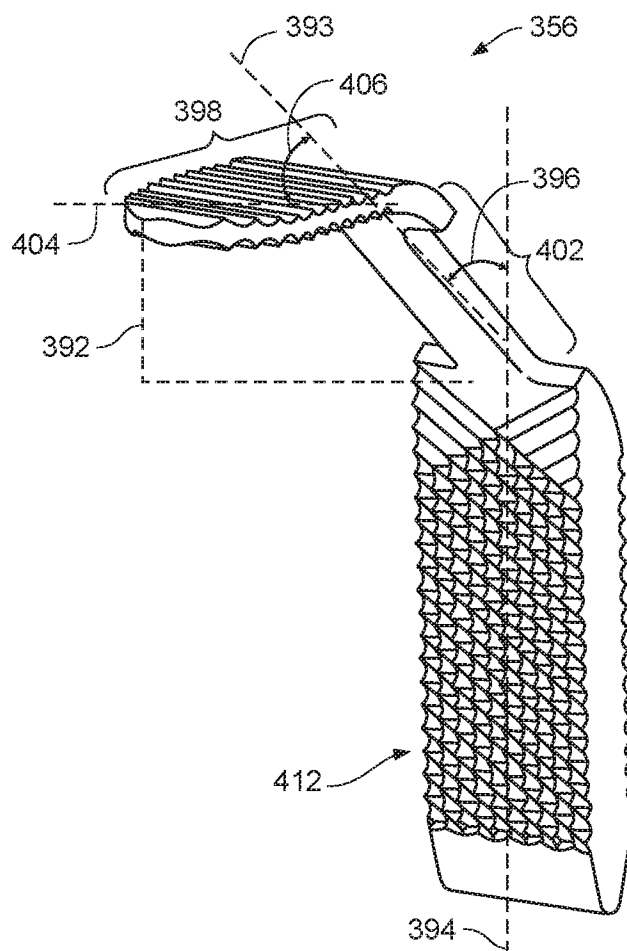
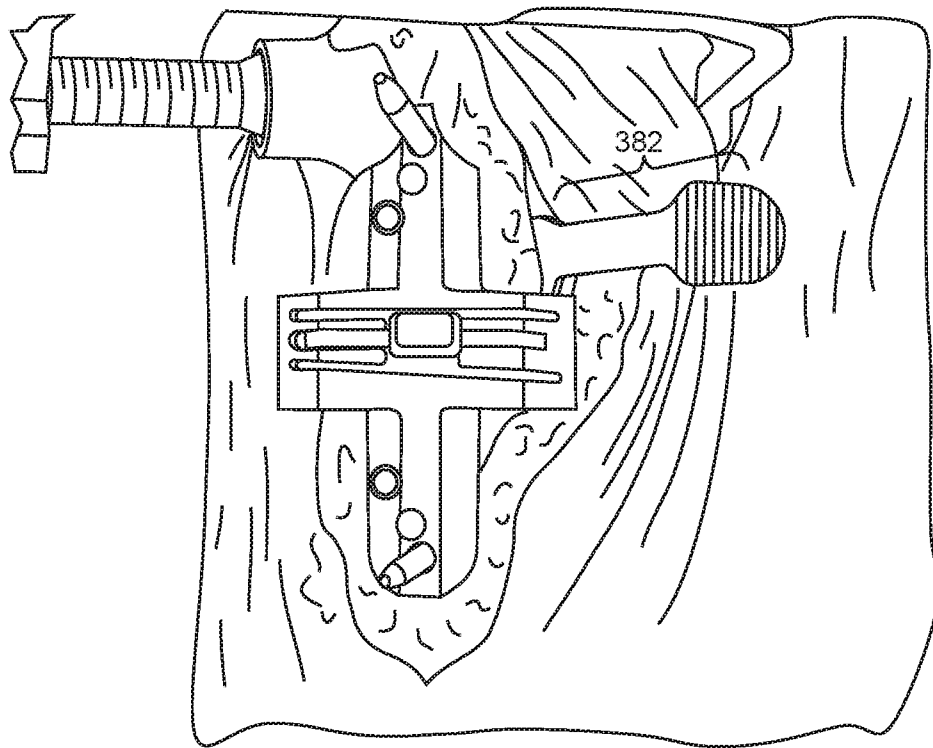


Fig. 40



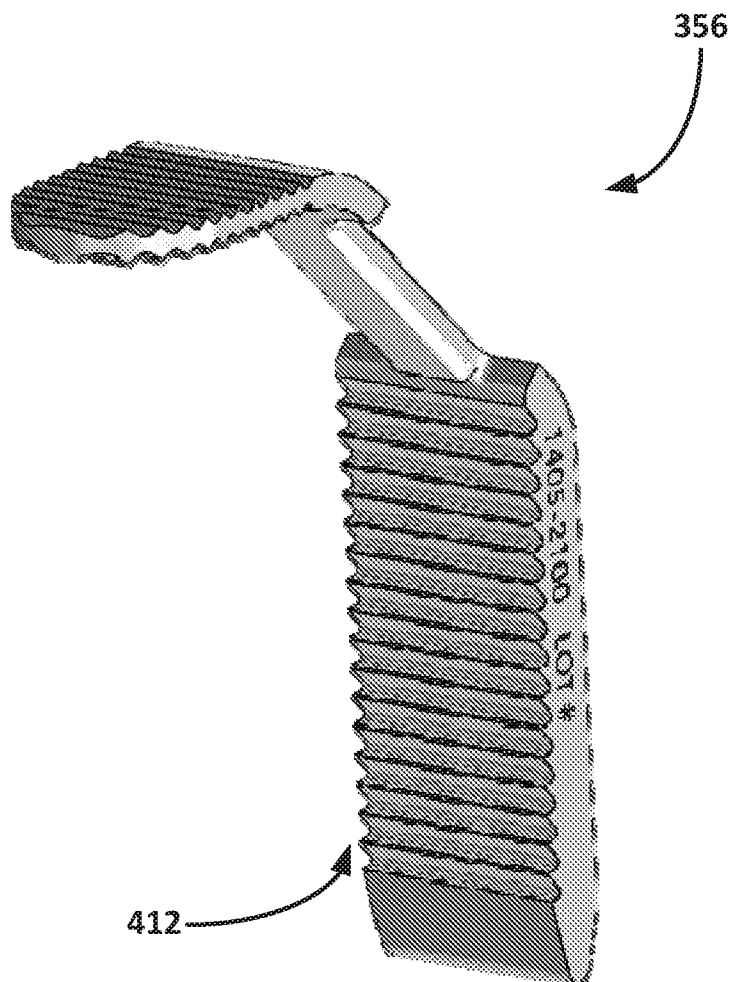


FIG. 41

Fig. 42A

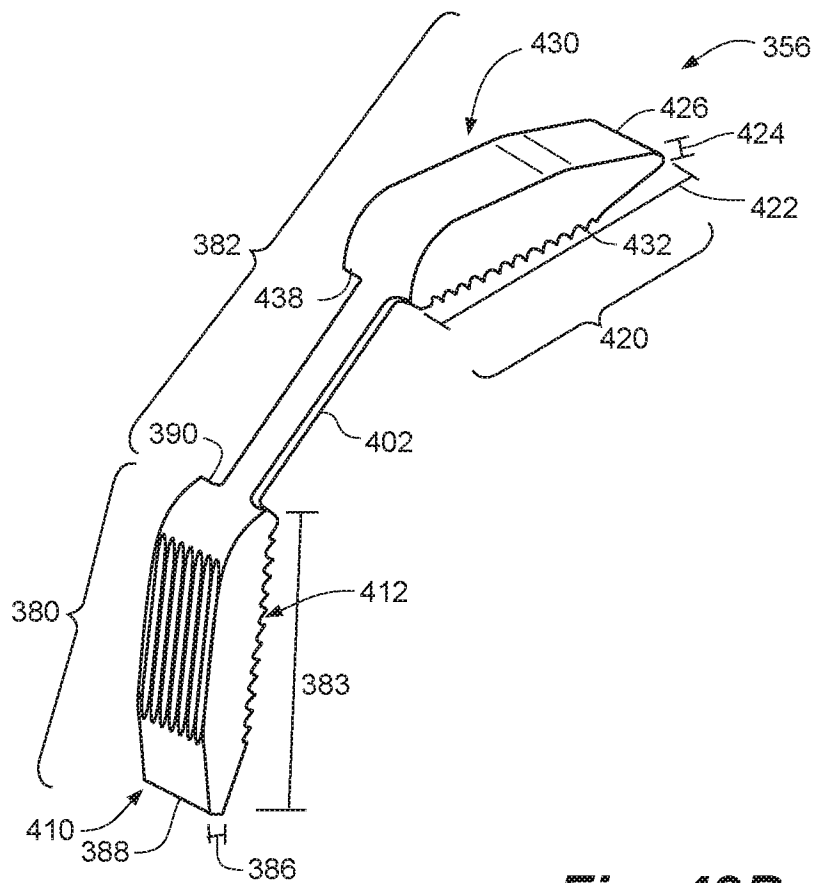
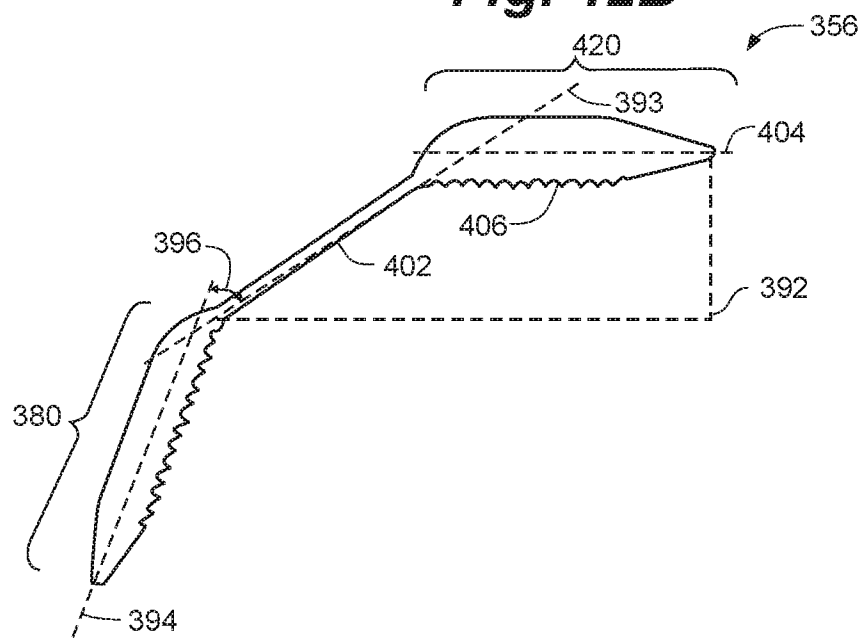


Fig. 42B



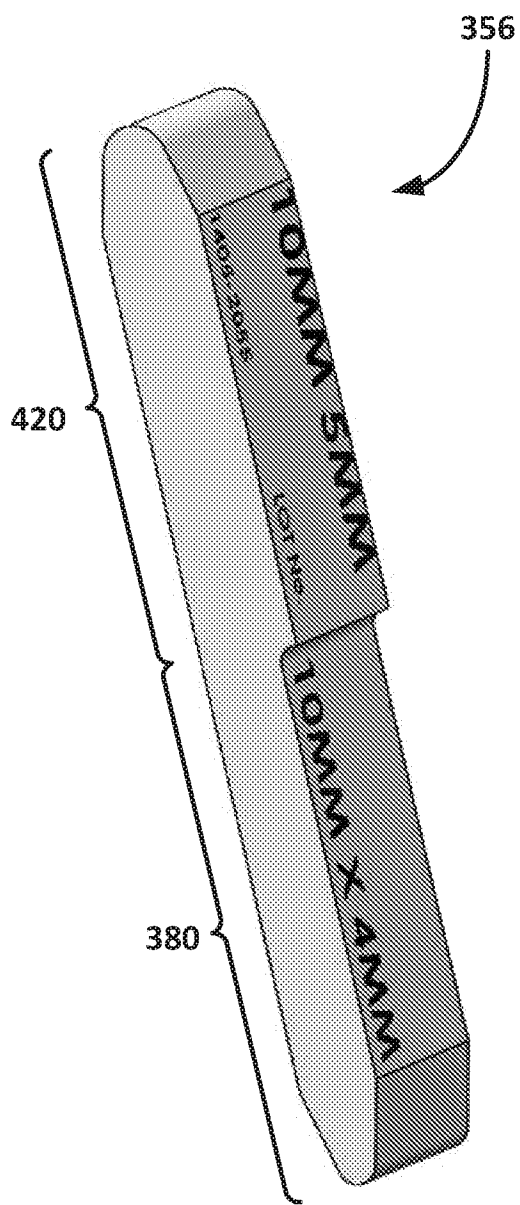


FIG. 43A

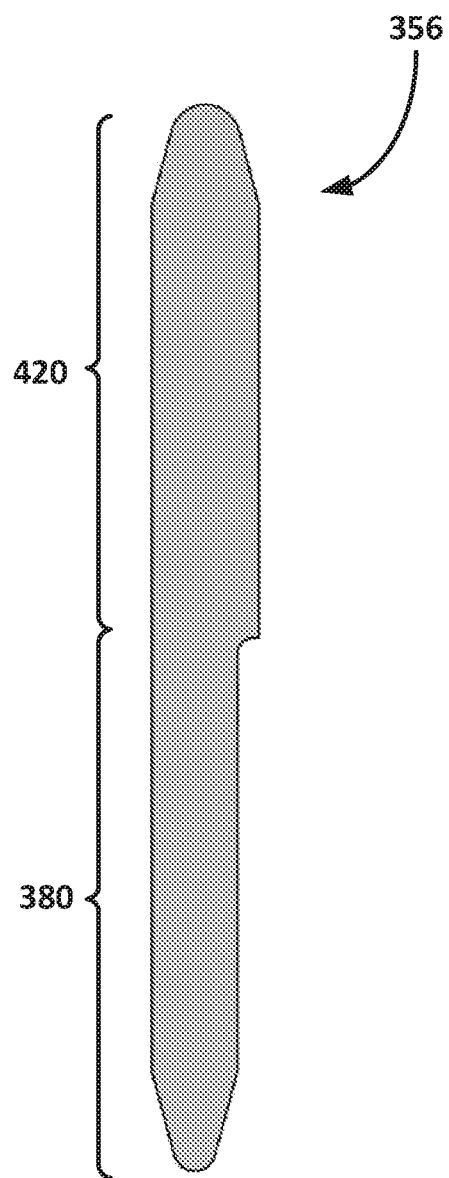


FIG. 43B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/46953

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/88 (2016.01)

CPC - A61B 2017/681, 17/88

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)

IPC(8) : A61B 17/88 (2016.01)

CPC : A61B 2017/681, 17/88

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

IPC(8) : A61B 17/00, 17/14, 17/15, 17/16, 17/17, 17/56, 17/58, 17/68, 17/90 (2016.01); CPC: A61B 17/00, 17/14, 17/15, 17/151, 17/152, 17/16, 17/1662, 17/1682, 17/17, 17/1739, 17/1775, 17/56, 17/58, 17/66, 17/68, 17/8866, 17/90

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Patbase, Google Patent, Google Scholar: bunion, hallux valgus, metatarsal, intermetatarsal, fulcrum, shim, pivot, lever, align, rotate, realign, correct, prep, cut, shave, shape, medial cuneiform, osteotomy, first, second, distract, bone, joint, toe, space, saw

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No. -
X --- A	US 2011/0077656 A1 (SAND et al) 31 March 2011 (31.03.2011) see especially para [0047], fig 6, 7	27-30 ----- 1-3, 20-23
X	US 2013/0035694 A1 (GRIMM et al) 07 February 2013 (07.02.2013) see especially para [0030], [0031], fig 9, 10	42-44
A	US 2009/0222047 A1 (GRAHAM) 03 September 2009 (03.09.2009) se especially para [0019, [0020], [0029], [0030], [0032], [0034], [0035], fig 1	1-3, 20-23
A,E	US 2016/0235414 A1 (HATCH et al) 18 August 2016 (18.08.2016) see whole document	1-3, 20-23, 27-30, 42-44
A	US 2015/0119944 A1 (GELDWERT) 30 April 2015 (30.04.2015) see whole document	1-3, 20-23, 27-30, 42-44
A	US 2011/0178524 A1 (LAWRENCE et al) 21 July 2011 (21.07.2011) see whole document	1-3, 20-23, 27-30, 42-44
A,P	FR 3,030,221 A1 (NOVASTEP) 24 June 2016 (24.06.2016) see whole document and machine translation	1-3, 20-23, 27-30, 42-44

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

22 November 2016

Date of mailing of the international search report

27 DEC 2016

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/46953

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 4-19, 24-26, 31-41, 45
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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