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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
62/108,936	01/28/2015		130	IPP-0050-US05		

CONFIRMATION NO. 7184

126243
Surgical Frontiers, LLC
124 South 600 West, Suite 100
Logan, UT 84321

FILING RECEIPT



Date Mailed: 02/06/2015

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Applicant(s)

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Power of Attorney:

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/108,936**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

page 1 of 3

Paragon 28 v. Treace Medical Concepts
PGR2026-00020
Paragon Ex. 1021

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05
		Application Number	
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

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☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor 1					Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	T.	Wade	Fallin			
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
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Inventor 2					Remove	
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Prefix	Given Name	Middle Name	Family Name	Suffix		
	Robert	W.	Hoy			
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05
		Application Number	
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		

☐ An Address is being provided for the correspondence information of this application.

Customer Number	126243		
Email Address	cary@surgicalfrontiers.com	<input type="button" value="Add Email"/>	<input type="button" value="Remove Email"/>

Application Information:

Title of the Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		
Attorney Docket Number	IPP-0050-US05	Small Entity Status Claimed	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	21	Suggested Figure for Publication (if any)	

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Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05
		Application Number	
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		

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- ☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05
		Application Number	
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		

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If the Applicant is an Organization check here. ☒		
Organization Name	First Ray, LLC	

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05
		Application Number	
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		

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Country i	US	Postal Code	84321
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Signature	/Cary Reeves/	Date (YYYY-MM-DD)	2015-01-28
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	IPP-0050-US05		
		Application Number			
Title of Invention	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD				
First Name	Cary	Last Name	Reeves	Registration Number	35334
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U.S. PROVISIONAL PATENT APPLICATION

of

T. Wade Fallin of Hyde Park, UT

Robert W. Hoy, Essex Junction, VT

For

FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD

FIELD OF THE INVENTION

[0001] The invention relates to methods, implants, and instruments for performing an osteotomy.

BACKGROUND

[0002] Various conditions may affect skeletal joints such as the deterioration, elongation, shortening, or rupture of soft tissues, cartilage, and/or bone associated with the joint and consequent laxity, pain, and/or deformity. It is often desirable to change the angular alignment of a bone or a portion of a bone to restore function and/or reduce pain. To this end, various osteotomy procedures and instruments have been proposed. For example, osteotomies have been performed throughout the body to make various angular adjustments such as in a tibia, fibula, femur, pelvis, humerus, ulna, radius, metacarpal, metatarsal, and other bones. In some cases it is desirable to induce the fusion a skeletal joint, i.e. an arthrodesis, in a predetermined position. The present invention provides improved osteotomy and arthrodesis methods, implants, and instruments.

SUMMARY

[0003] The present invention provides methods, implants, and instruments for performing an osteotomy.

[0004] In one aspect of the invention, a method of performing an osteotomy between a first bone portion and a second bone portion includes cutting the first bone portion; after cutting the first bone portion, moving the first bone portion and second bone portion relative to one another to a second relative position different from the first relative position; and after moving the first bone portion and second bone portion to the second relative position, cutting the second bone portion to create a gap between the first bone portion and the second bone portion.

[0005] In another aspect of the invention, a method of performing an osteotomy to fuse a metatarsocuneiform joint of a human foot includes cutting one of the metatarsus and cuneiform to remove a first portion of bone adjacent the joint; after cutting one of the metatarsus and cuneiform, moving the metatarsus relative to the cuneiform to a second relative position different from the first relative position; and after moving the metatarsus to the second relative position, cutting the other of the metatarsus and cuneiform to remove a second portion of bone adjacent the joint to create a gap between the metatarsus and cuneiform.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Various examples of the present invention will be discussed with reference to the appended drawings. These drawings depict only illustrative examples of the invention and are not to be considered limiting of its scope.

[0007] FIG. 1 is medial view of a foot illustrating anatomic reference planes and relative directions;

[0008] FIG. 2 is a lateral view of a foot illustrating dorsiflexion and plantar flexion;

[0009] FIG. 3 is a coronal view of a foot illustrating inversion and eversion;

[0010] FIG. 4 is a dorsal view illustrating bones, tendons, and ligaments of the foot;

[0011] FIG. 5 is a plantar view illustrating bones, tendons, and ligaments of the foot;

[0012] FIG. 6 is a perspective view illustrating bones, tendons, and ligaments of the foot;

[0013] FIG. 7 is a medial view of the MTP joint of the first ray of the foot;

[0014] FIG. 8 is a sectional view taken along line 8-8 of FIG. 7;

[0015] FIG. 9 is a dorsal view of the MTC joint of the first ray of the foot;

[0016] FIG. 10 is a medial view of the MTC joint of the first ray of the foot;

[0017] FIG. 11 is a dorsal view illustrating deformity of the foot;

[0018] FIG. 12 is a plantar view illustrating deformity of the foot;

[0019] FIG. 13 is a sectional view similar to that of FIG. 8 but illustrating deformity of the foot;

[0020] FIG. 14 is a perspective view of an osteotomy guide according to the present invention;

[0021] FIG. 15 is a another perspective view of the osteotomy guide of FIG. 14;

[0022] FIG. 16 is a front elevation view of the osteotomy guide of FIG. 14;

[0023] FIG. 17 is a side elevation view of the osteotomy guide of FIG. 14;

[0024] FIG. 18 is a top plan view of the osteotomy guide of FIG. 14;

[0025] FIG. 19 is a side elevation view of the osteotomy guide of FIG. 14;

[0026] FIG. 20 is a rear elevation view of the osteotomy guide of FIG. 14;

[0027] FIGS. 21-25 illustrate the use of the osteotomy guide of FIG. 14 to perform an osteotomy;

[0028] FIG. 26 is a top plan view of an osteotomy guide like that of FIG. 14 having a two-piece construction;

[0029] FIG. 27 is a side elevation view of the osteotomy guide of FIG. 26; and

[0030] FIGS. 28-32 illustrated the use of the osteotomy guide of FIG. 26 to perform an osteotomy.

DESCRIPTION OF THE ILLUSTRATIVE EXAMPLES

[0031] The following illustrative examples describe implants, instruments and techniques for performing an osteotomy. The present invention may be used to perform osteotomies on any bone including but not limited to a tibia, fibula, femur, pelvis, humerus, ulna, radius, metacarpal, and metatarsal. The invention may be used to perform an osteotomy between two portions of the same bone or between two different bones at a joint to e.g. perform an arthrodesis. For example, the present invention may be used to perform an arthrodesis at any joint such as at the hip, knee, ankle, wrist, elbow, between adjacent bones in the hands and feet, between spinal vertebrae, or between any other bones. However, for convenience, the invention will be illustrated with reference to a metatarsus and cuneiform at a metatarsocuneiform joint of the first ray of a human foot.

[0032] FIG. 1 illustrates the orientation of anatomic planes and relative directional terms that are used for reference in this application. The coronal plane 10 extends from medial 12 (toward the midline of the body) to lateral (away from the midline of the body) and from dorsal 14 (toward the top of the foot) to plantar 16 (toward the sole of the foot). The sagittal plane 18 extends from anterior 20 (toward the front of the body) to posterior 22 (toward the back of the body) and from dorsal 14 to plantar 16. The transverse plane 24 extends anterior 20 to posterior 22 and medial to lateral parallel to the floor 26. Relative positions are also described as being proximal or distal where proximal is along the lower extremity toward the knee and distal is along the lower extremity toward the toes. The following examples serve to demonstrate the relative directions. The great toe is medial of the lesser toes and the fifth toe is lateral of the great toe. The toes are

distal to the heel and the ankle is proximal to the toes. The instep is dorsal and the arch is plantar. The toenails are dorsal and distal on the toes.

[0033] FIG. 2 illustrates dorsiflexion 23 in which the toes are moved dorsally, or closer to the shin, by decreasing the angle between the dorsum of the foot and the leg and plantar flexion 25 in which the toes are moved plantar, or further away from the shin, by increasing the angle between the dorsum of the foot and the leg. For example when one walks on their heels, the ankle is dorsiflexed and when one walks on their toes, the ankle is plantar flexed.

[0034] FIG. 3 illustrates inversion 27 in which the sole of the foot is tilted toward the sagittal plane or midline of the body and eversion 29 in which the sole of the foot is tilted away from the sagittal plane.

[0035] FIGS. 4-10 illustrate the arrangement of the bones within the foot 30. A right foot is illustrated. Beginning at the proximal aspect of the foot, the heel bone or calcaneus 32 projects plantar. The talus 34 is dorsal to the calcaneus 32 and articulates with it at the talocalcaneal or subtalar joint. Dorsally, the talus articulates medially with the tibia 36 and laterally with the fibula 38 at the ankle joint. Distal to the ankle are the navicular bone 40 medially and the cuboid bone 42 laterally which articulate with the talus and calcaneus respectively. The navicular bone 40 and cuboid bone 42 may also articulate with one another at the lateral side of the navicular bone and the medial side of the cuboid bone. Three cuneiform bones lie distal to the navicular bone and articulate with the navicular bone and one another. The first, or medial, cuneiform 44 is located on the medial side of the foot 30. The second, or intermediate, cuneiform 46 is located lateral of the first cuneiform 44. The third, or lateral, cuneiform 48 is located lateral of the second cuneiform 46. The third cuneiform 48 also articulates with the cuboid bone 42. Five metatarsals 50, 52, 54, 56, 58 extend distally from and articulate with the cuneiform and cuboid

bones. The metatarsals are numbered from 1 to 5 starting with the first metatarsal 50 on the medial side of the foot and ending with the fifth metatarsal 58 on the lateral side of the foot 30. The first metatarsal 50 articulates with the first cuneiform 44 at a metatarsocuneiform (MTC) joint 51. The second metatarsal 52 articulates with the first, second and third cuneiforms 44, 46, 48 and may articulate with the first metatarsal as well. Five proximal phalanges 60, 62, 64, 66, 68 extend distally from and articulate with the five metatarsals respectively. The first proximal phalanx 60 articulates with the first metatarsal 50 at a metatarsophalangeal (MTP) joint 61. One or more distal phalanges 70, 72, 74, 76, 78, 80 extend distally from the proximal phalanges. The first metatarsal 50, first proximal phalanx 60, and, first distal phalanx 70 together are referred to as the first ray of the foot. Similarly, the metatarsal, proximal phalanx, and distal phalanges corresponding to the lesser digits are referred to as the second through fifth rays respectively.

[0036] FIG. 4 is a dorsal view illustrating bones, tendons and ligaments of the foot. Plantar structures illustrated in FIG. 5 are omitted from FIG. 4 for clarity. The extensor hallucis longus muscle originates in the anterior portion of the leg, the extensor hallucis longus tendon 80 extends distally across the ankle and along the first ray to insert into the base of the distal phalanx 70. The tibialis anterior muscle originates in the lateral portion of the leg and the tibialis anterior tendon 82 extends distally across the ankle and inserts into the first cuneiform 44 and first metatarsus 50 at the first MTC joint 51 where it contributes to the MTC capsular structure 84 (FIGS. 9 and 10). A transverse intermetatarsal ligament 83 inserts into the capsule of the MTP joint such that it connects the heads of the first through fifth metatarsal bones. In FIG. 4, only the connection between the first and second metatarsal bones 50, 52 is shown.

[0037] FIG. 5 is a plantar view illustrating bones, tendons, and ligaments of the foot. Dorsal structures shown in FIG. 4 are omitted from FIG. 5 for clarity. The peroneus longus muscle

originates at the head of the fibula and its tendon 86 passes posteriorly around the lateral malleolus 88 of the ankle, around the cuboid notch 90 on the lateral side of the cuboid bone 42, along the peroneal sulcus 92 on the plantar surface of the cuboid bone 42, and inserts into the first metatarsal 50. The flexor hallucis brevis muscle 94 originates from the cuboid 42 and third cuneiform 48 and divides distally where it inserts into the base of the proximal phalanx 60. Medial and lateral sesamoid bones 96, 98 are present in each portion of the divided tendon at the MTP joint 61. The sesamoids 96, 98 articulate with the planar surface of the metatarsal head in two grooves 100, 102 separated by a rounded ridge, or crista 104 (FIG. 8). The flexor hallucis longus muscle originates from the posterior portion of the fibula 38. The flexor hallucis longus tendon 106 crosses the posterior surface of the lower end of the tibia, the posterior surface of the talus, runs forward between the two heads of the flexor hallucis brevis 94, and is inserted into the base of the distal phalanx 70 of the great toe.

[0038] FIG. 7 is a medial view of tendons at the MTP joint 61 of the first ray. A medial collateral ligament 108 originates from the head of the first metatarsus 50 and inserts into the proximal phalanx 60. A medial metatarsosesamoid ligament 110 originates from the head of the first metatarsus 50 and inserts into the medial sesamoid bone 96. Similar collateral and metatarsosesamoid ligaments are found on the lateral side of the first MTP joint. The flexor hallucis brevis 94 is shown inserting into the sesamoids 96, 98. Ligamentous fibers extend further distally in the form of a phalangealsesamoid ligament 112 from the sesamoids to the proximal phalanx 60.

[0039] FIG. 8 is a sectional view taken along line 8-8 of FIG. 7 showing the metatarsal head 50, the tendon of the extensor hallucis longus 80, the medial and lateral sesamoid bones 96, 98, the

grooves 100, 102 in which the sesamoids articulate, the crista 104 separating the grooves, the flexor hallucis longus 106, the abductor hallucis 114, and the adductor hallucis 116.

[0040] FIG. 9 is a dorsal view showing the dorsal capsular structure 84 of the MTC joint 51 of the first ray including the insertion of the tibialis anterior tendon 82.

[0041] FIG. 10 is a medial view of the MTC joint 51 of the first ray showing the medial capsular structure 118.

[0042] FIGS. 11-13 illustrate deformities of the first ray. In a dorsal view, as shown in FIG. 11, an intermetatarsal angle (IMA) 120 may be measured between the longitudinal axes of the first and second metatarsal bones 50, 52. The angle is considered abnormal when it is 9 degrees or greater and the condition is known as metatarsus primus varus (MPV) deformity. A mild deformity is less than 12 degrees, a moderate deformity is 12-15 degrees, and a severe deformity is greater than 15 degrees. Similarly, a hallux valgus angle (HVA) 122 may be measured between the longitudinal axes of the first metatarsus 50 and the first proximal phalanx 60 at the MTP joint 61. The angle is considered abnormal when it is 15 degrees or greater and the condition is known as a hallux valgus (HV) deformity. A mild deformity is less than 20 degrees, a moderate deformity is 20 to 40 degrees, and a severe deformity is greater than 40 degrees.

[0043] MPV and HV often occur together as shown in FIGS. 11-12. As the deformities progress several changes may occur in and around the MTC and MTP joints. Referring to FIG. 13, as the IMA and HVA increase, the extensors 80, flexors 106, abductors 114, and adductors 116 of the first ray (along with the sesamoids 96, 98) are shifted laterally relative to the MTP joint. The laterally shifted tendons exert tension lateral to the MTP joint creating a bow string effect (as best seen in FIGS. 11 and 12) that tends to cause the deformities to increase. The lateral shift of the sesamoids 96, 98 is often accompanied by erosion of the crista. The abnormal muscle forces

cause the metatarsus 50 to pronate, or in other words, rotate so that the dorsal aspect of the bone moves medially and the plantar aspect moves laterally. Rotation in the opposite direction is referred to as supination. Soft tissues on the medial side of the MTP joint and lateral side of the MTC joint attenuate, through lengthening and thinning, thus weakening the capsule and permitting the deformities to progress. Soft tissues on the opposite sides of the capsule tend to shorten, thicken and form contractures making it difficult to reduce the joints to their normal angular alignment.

[0044] More generally, deformities of the first ray may include metatarsus primus varus, hallux valgus, abnormal pronation, abnormal supination, abnormal dorsiflexion, and/or abnormal plantar flexion. These deformities correspond to three different planar rotations. Metatarsus primus varus and hallux valgus result from rotations in the transverse plane 24. Pronation and supination are rotation in the coronal plane 10. Dorsiflexion and plantar flexion are rotation in the sagittal plane.

[0045] The terms “suture” and “suture strand” are used herein to mean any strand or flexible member, natural or synthetic, able to be passed through material and useful in a surgical procedure. The term “transverse” is used herein to mean crossing as in non-parallel.

[0046] The present invention provides methods and devices for performing an osteotomy. FIGS. 14-20 depict an illustrative osteotomy guide 200 according to the present invention. The guide 200 includes a guide body 202 having a proximal end 204, a distal end 206, a first side 208, a second side 210 opposite the first side 208, an upper surface 212, and a lower surface 214.

[0047] The guide body 202 includes first and second guide features operable to guide a cutter to cut a bone. In the illustrative example of FIGS. 14-20, the guide features include a first slot 216 and a second slot 218 for receiving a cutter, such as a saw blade, to constrain the cutter to cutting

in a plane. In the illustrative example of FIGS. 14-20, the slots 216, 218 are narrow and constrain a saw blade from both sides. Alternatively, a guide feature configured for a saw blade may include a single surface against which the saw blade is pressed to guide it in a plane. Additional guide features, such as slots 220, 222, may be provided to, e.g., provide alternative spacing of cuts or the option to recut if additional bone removal is desired. The guide features may guide a cutter in parallel planes or they may be angled relative to one another to produce cuts in non-parallel planes. In the illustrative example of FIGS. 14-20, the slots 216, 218, 220, 222 are parallel.

[0048] The guide body 202 includes fixation elements for attaching the guide 200 to underlying bone. Fixation elements may include spikes, slots, holes, bands or other suitable fixation elements. The fixation elements may act alone, as with a spike or band, or they may work with additional fixation members such as pins or screws. In the illustrative example of FIGS. 14-20, the guide body 202 includes fixation elements in the form of holes operable to receive pins or screws to attach the guide 200 to bone. In the illustrative example of FIGS. 14-20, two sets of holes 224, 226 are provided distal to the guide slots 216, 218, 220, 222 and another set 228 is provide proximal to the guide slots. The distal sets of holes 224, 226 may, e.g., may be used to attach the guide to a first bone portion prior to a first bone cut and the proximal set of holes 228, e.g., may be used to attach the guide to a second bone portion prior to a second bone cut as will be described in further detail below.

[0049] In the illustrative example of FIGS. 14-20, the guide body includes first and second indexing features engageable with a bone to align the guide relative to the bone. For example, a first indexing feature 230 in the form of a planar surface and a second indexing feature 232 in the form of a planar surface may be angled relative to one another so that the first and second

indexing features may engage different sides of a bone to provide bi-planar orientation of the guide relative to a bone.

[0050] The guide 200 may be used to cut portions of the same bone or portions of different bones where they meet at a joint. The guide body 202 may include a joint alignment feature to aid in positioning the guide body 202 relative to a joint. The joint alignment feature allows a user to position the guide relative to a joint. For example, the joint alignment feature may be an opening for visualizing the alignment, a projection from the guide body 202 engageable with the joint, an opening for receiving a member engageable with the joint, or other suitable joint alignment feature. In the illustrative example of FIGS. 14-20, the guide body includes a joint alignment feature in the form of a slot 234 able to receive a feeler gauge, or shim, for positioning the joint alignment feature over the joint. The joint alignment slot 234 is positioned in a predetermined relationship to the guide slots 216, 218, 220, 222 so that a cutter guided by the guide slots will remove a predetermined amount of bone from the bones forming the joint.

[0051] The guide 200 may be configured for use on any bone any single bone or on any bones forming a joint. The particular shape and size of the guide and its various features as described above may be varied to suit the particular bone or joint. For example, the illustrative guide of FIGS. 14-20, is configured for use at the metatarsocuneiform joint of the first ray of a right human foot. The guide body 202 has a generally trapezoidal shape when viewed from the side (FIGS. 17 and 19). The distal sets of holes 224, 226 are positioned to allow at least one pin to be inserted through each set of holes and into the medial side of a first metatarsus. The proximal end 204 flairs outwardly to clear the medial cuneiform. The proximal set of holes 228 is positioned to allow pins to be inserted through them and into the medial cuneiform. The first and second indexing features 230, 232 are sized to engage the diaphysis of the metatarsus to align the guide

200 generally parallel to the metatarsal axis. The first and second indexing features 230, 232 are offset a distance 236 (FIG. 20) from the second side 210 of the guide body 202 to space the second side 210 from the metatarsus sufficiently to provide clearance for the metaphyseal flair at the ends of the metatarsus to insure that the guide is indexed to the relatively consistent geometry of the diaphysis rather than the more variable geometry of the metaphysis. The joint alignment slot 234 and guide slots 216, 218 are positioned so that with the joint alignment slot 234 aligned with the metatarsocuneiform joint, a cutter guided by the guide slots 216, 218 will remove a predetermined, and relative thin, portion of bone from the articulating ends of the metatarsus and cuneiform. The additional guide slots 220, 222 are positioned relative to the joint alignment slot 234 to permit additional bone to be removed if desired.

[0052] An illustrative method according to the present invention produces an osteotomy between a first bone portion and a second bone. The bones define a first relative position between them. The method includes cutting the first bone portion, moving the bone portions to a second relative position different from the first relative position, and cutting the second bone portion. For example, to realign first and second bone portions to correct an angular deformity, the first bone portion may be cut to form a cut surface on the first bone portion and allow the first bone portion to be freely mobilized relative to the second bone portion. The bone portions may be positioned in a new relative orientation that reduces the angular deformity between them. The second bone portion may then be cut to form a cut surface on the second bone. The cut surfaces may be brought together to promote fusion of the bone portions in the new relative orientation. Alternatively, a graft may be positioned between the cut surfaces to prevent a change in length of the bone construct. The bone portions may be portions of the same bone in the case of an osteotomy to change the shape of a bone. The bone portions may be portions of different bones

forming a joint in the case of an osteotomy to change the angular relationship between the bones and fuse the joint in the new angular relationship.

[0053] For example, in a deformity of a human foot, the relative position of the metatarsus and cuneiform at the metatarsocuneiform joint may be changed. For example, a first cut may be made on one of the metatarsus and cuneiform to remove a portion of bone creating a first cut surface and a space resulting in increased mobility between the metatarsus and cuneiform to allow them to be freely repositioned. The bones may be repositioned in one or more planes. For example, the metatarsus may be rotated laterally in the transverse plane to correct an MPV deformity, rotated in the coronal plane to correct abnormal pronation/supination, and rotated in the sagittal plane to adjust plantar/dorsal flexion. Once the new position is established, the cuneiform may be cut to create a second cut surface in predetermined relationship (as determined by the cut guide features) to the first cut surface. The first and second cut surfaces may be brought together and fixed so that they heal together fusing the joint in the new position.

[0054] To avoid shortening of the bone construct, a graft or other spacer may be placed in the gap between the bones to maintain their separation in the new position. For example, the spacer may be autograft, allograft, xenograft, synthetic graft, metal, plastic, ceramic, solid filler, particulate filler or other suitable spacer.

[0055] The bone portions may be fixed relative to one another to promote healing with fixation elements such as pins, plates, screws, rods or other suitable fixation elements.

[0056] In some cases it is advantageous for the first and second cut surfaces to be parallel planar surfaces, e.g., to facilitate abutting them together or with a solid parallel faced spacer to easily maintain the new position of the bones. In other cases, it may be desirable to angle the surfaces, e.g., to accommodate a wedge shaped spacer that may be easier to insert or to produce an

additional amount of angular correction, e.g., to produce a few degrees of additional plantarflexion to account for bone shortening where a graft is not used.

[0057] A method according to the invention may be performed freehand or with the use of an osteotomy guide. The use of an osteotomy guide, such as that shown in FIGS. 14-20, results in more precision and repeatability in the relative orientation of the cuts. Being able to produce a predefined gap facilitates providing preformed spacers that will fit the gap and lock in the new position of the bones.

[0058] FIGS. 21-25, depict an illustrative method of performing an osteotomy. In the illustrative example of FIGS. 21-25, the optional osteotomy guide of FIGS. 14-20 is used to perform an osteotomy at the metatarsocuneiform joint of the first ray of a foot for fusing the joint in a new position.

[0059] In FIG. 21, the first and second indexing features 230, 232 are abutted against the diaphysis 240 of the metatarsus 242. In the illustrative example of FIGS. 21-25, the indexing features are shown engaging the dorsal and medial aspects of the diaphysis 240. However, the guide can be positioned in other orientations around the joint. For example, the indexing features 230, 232 may be engaged with the lateral and dorsal aspects of the diaphysis 240 or some other position to facilitate surgical access. Downward and lateral pressure may be exerted on the guide such as by pressing on upper surface 212 to keep the guide 200 engaged with the bone. A feeler gauge 243, or shim, is inserted through the joint alignment slot 234 and used to align the guide 200 with the metatarsocuneiform joint 244. Pins 246, 248 are placed through the fixation holes 224, 226 to fix the guide 200 to the metatarsus 242.

[0060] In FIG. 22, a saw blade 250 in a powered handpiece (not shown) is guided in one of the distal guide slots 216 to remove bone from the proximal end of the metatarsus 242. This creates

a first planar cut surface 260 and a gap 262 and increases the mobility between the metatarsus 242 and cuneiform 252.

[0061] In FIG. 23, the metatarsus 242 is repositioned relative to the cuneiform 252 to change their relative position in one or more planes. Because the guide 200 is fixed to the metatarsus 242, the guide 200 moves with the metatarsus 242 and the position of the guide 200 relative to the metatarsus does not change insuring that the relationship of the guide slots 216, 218, 220, 222 to the cut surface of the metatarsus also remains unchanged.

[0062] In FIGS. 24 and 25, once the bones are oriented in a desired new position, pins 254, 256 are placed in the proximal fixation holes 228 to fix the metatarsus 242, and guide 200, in the new position relative to the cuneiform 252. A saw blade 250 is guided in one of the proximal guide slots 218 to remove bone from the distal end of the cuneiform 252. This creates a second planar cut surface 264 on the cuneiform 252 in predetermined relationship to the first planar cut surface 260 on the metatarsus 242 and a gap 266 between the bones having a predetermined shape. In the illustrative example of FIGS. 21-25, the cut surfaces 260 and 264 are parallel.

[0063] The guide 200 may be removed and the bones brought together with their cut surfaces in planar contact so that the bones fuse together in the new angular orientation. Alternatively, a spacer may be placed in the gap 266 in engagement with the cut surfaces 260, 264 to maintain the bone construct length while the bones fuse together in the new angular orientation. As seen in FIG. 25, the guide 200 may be used to hold the bones in the desired orientation while a spacer is inserted and any additional fixation in the forms of pins, plates, screws, rods or other suitable fixation is applied.

[0064] FIGS. 26 and 27 depict an illustrative osteotomy guide 300 according to the present invention. The guide 300 is similar to that of FIGS. 14-20. However, the guide 300 includes a

guide body 302 having a separate proximal member 304 and distal member 306 that are engaged in linear sliding relationship. In the illustrative example of FIGS. 26 and 27, the distal member 306 includes a dovetail slot 308 formed in the first side 310 and extending from the proximal end 312 of the distal member 306 toward the distal end 314. The slot 308 defines a linear motion axis 316. The proximal member 304 includes a dovetail arm 318. The slot 308 and arm 318 have complementary cross sectional shapes so that the arm fits closely within the slot and the proximal and distal members 304, 306 are constrained to linear sliding motion along the motion axis 316. The proximal member 304 is offset relative to the distal member 306 so that the proximal member may slide over the distal member. In the illustrative example of FIGS. 26 and 27, the guide 300 is shown configured for a right first metatarsus and the proximal member 304 is offset medially relative to the distal member 306.

[0065] Indicia 334, including tic marks and associated reference numbers, are formed adjacent to the slot 308. As the arm 318 slides within the slot 308, the end 336 of the arm may be aligned with the indicia to indicate the relative position of the proximal and distal members 304, 306. For example, in the illustrative example of FIGS. 26 and 27, the indicia indicate the spacing, in millimeters, between the saw slots 324, 330. A locking mechanism is provided to lock out motion between the proximal and distal members 304, 306. In the illustrative example of FIGS. 26 and 27, the locking mechanism is a locking screw 340 threaded through the arm and engageable with the wall of the slot. Tightening the screw 340 into contact with the slot wall locks the mechanism and loosening the screw 340 out of contact with the slot wall unlocks the mechanism.

[0066] The distal member 306 includes proximal and distal fixation holes 320, 322 and a saw slot 324. A window 326 allows access to a bone while the guide 300 is positioned on the bone.

The proximal member 304 includes proximal fixation holes 328 and a saw slot 330. A window 332 allows access to a bone while the guide 300 is positioned on the bone.

[0067] FIGS. 28-32 depict an illustrative method of performing an osteotomy using the guide 300 of FIG. 26. The proximal and distal members 304, 306 are positioned in a desired relative position, e.g. to set a desired cut spacing, and locked with the locking screw 340. In FIG. 28, the distal member is indexed to the metatarsus 242 as described above relative to the guide 200 of FIG. 14. A feeler gauge 243 is inserted between the proximal and distal members 304, 306 and used to align the guide 300 with the metatarsocuneiform joint 244. It may be necessary to loosen the locking screw 340 and adjust the relative position of the proximal and distal members to allow the gauge 243 to fit between the members. In addition, the motion axis 316 is aligned parallel to the floor as if the patient was standing. This will ensure that the relative loading of the rays of the foot is maintained after the first metatarsus is shortened as will be explained below. Pins 246, 248 are placed through the fixation holes 320, 322 to fix the distal member 306 to the metatarsus.

[0068] In FIG. 29, a saw blade 250 in a powered handpiece (not shown) is guided in the saw slot 324 of the distal member 306 to remove bone from the proximal end of the metatarsus. This creates the first planar cut surface 260 and gap 262 and increases the mobility between the metatarsus 242 and cuneiform 252 as described above relative to FIGS. 21-25.

[0069] In FIG. 30, once the bones are oriented in a desired position and the proximal and distal members 304, 306 are locked in a desired relative position, pins 254, 256 are placed in the fixation holes 328 of the proximal member 304 to fix guide 300 to the cuneiform 252. A saw blade 250 is guided in the saw slot 330 of the proximal member 304 to remove bone from the distal end of the cuneiform 252. This creates the second planar cut surface 264 on the cuneiform

252 in predetermined relationship to the first planar cut surface 260 on the metatarsus 242 and the gap 266 as described above relative to FIGS. 21-25.

[0070] In FIG. 31, a controlled reduction of the metatarsus and cuneiform may be performed by loosening the locking screw 340 and translating the metatarsus 242 toward the cuneiform 252. Since the bones are fixed to the distal and proximal members 306, 304 of the guide 300 respectively, the metatarsus 242 is constrained to translate along a path parallel to the motion axis 316. As best seen in FIG. 32, the metatarsal heads are arranged in the standing foot to distribute body weight among the rays of the foot. If the vertical alignment of the metatarsal heads is altered, the weight distribution on the foot can change from the anatomic distribution and cause abnormal wear and pain. By translating the cut metatarsus 242 along the motion axis 316 that has been positioned parallel to the floor relative to the standing foot, the vertical alignment of the head 350 of the cut metatarsal 242 is maintained. The metatarsus 242 is translated until the cut surface of the metatarsus abuts the cut surface of the cuneiform. In the illustrative example of FIGS. 26-32, this will correspond to a reading of "0" on the guide 300. Further translation will result in compression of the bone surfaces together and negative readings on the guide 300. Reduction and/or compression may be facilitated by using a forceps or clamp, e.g. a towel clamp, to press the bone portions together. For example, a towel clamp may be engaged with the edges of the proximal and distal members 304, 306, inside the windows 326, 332, in unused fixation holes, on the fixation pins, or in features specifically added for that purpose. The locking screw 340 may be tightened to hold the bones in the reduced position while fixation such as one or more pins, plates, screws, rods or other suitable fixation is applied. The windows 326, 332 in the members 306, 304 permits access through the guide 300 to facilitate placing such fixation.

What is claimed is:

1. A method of performing an osteotomy between a first bone portion and a second bone portion, the first bone portion and the second bone portion defining a first relative position between them, the method comprising:
 - fixing an osteotomy guide to the first bone portion;
 - guiding a cutter with the osteotomy guide to cut the first bone portion to remove part of the first bone portion to increase mobility between the first bone portion and the second bone portion;
 - after guiding a cutter with the osteotomy guide to cut the first bone portion, moving the first bone portion and second bone portion relative to one another to a second relative position different from the first relative position while maintaining the osteotomy guide in fixed relationship to the first bone portion, the osteotomy guide moving with the first bone portion in fixed relationship to the first bone portion; and
 - after moving the first bone portion and second bone portion relative to one another to a second relative position, guiding a cutter with the osteotomy guide to cut the second bone portion to remove part of the second bone portion to create a gap between the first bone portion and the second bone portion.
2. The method of claim 1 further comprising fixing the first bone portion and second bone portion in the second relative position.
3. The method of claim 2 further comprising reducing the gap so that the first bone portion and second bone portion abut before fixing the first bone portion and second bone portion.

4. The method of claim 2 further comprising filling the gap between the first and second bone portions.
5. The method of claim 4 wherein cutting the second bone portion comprises forming a gap of a predetermined shape and filling the gap comprises inserting an implant having a corresponding predetermined shape.
6. The method of claim 1 wherein the first bone portion and the second bone portion are different portions of the same bone.
7. The method of claim 6 wherein the bone is metapodial bone.
8. The method of claim 7 wherein the bone is a first metatarsal bone.
9. The method of claim 1 wherein the first bone portion and the second bone portion are portions of two different bones adjacent a bone joint.
10. The method of claim 9 wherein the bone joint is a joint of a hand or foot.
11. The method of claim 10 wherein the bone joint is a metatarsocuneiform joint.
12. The method of claim 1 further comprising fixing the osteotomy guide to the second bone portion after moving the first bone portion and second bone portion relative to one another and prior to cutting the second bone portion.
13. The method of claim 1 wherein moving the first bone portion and second bone portion relative to one another comprises changing the relative position between the first bone portion and the second bone portion in more than one plane.
14. A method of performing an osteotomy to fuse a metatarsocuneiform joint of a human foot, the metatarsocuneiform joint comprising a metatarsus and a cuneiform, the metatarsus and cuneiform having a first relative position between them, the method comprising:

fixing an osteotomy guide to the metatarsus;

guiding a cutter with the osteotomy guide to cut the metatarsus at a predetermined angle relative to the osteotomy guide to produce a first cut surface and remove a first portion of bone adjacent the joint to increase mobility between the metatarsus and cuneiform;

after guiding a cutter with the osteotomy guide to cut the metatarsus, moving the metatarsus relative to the cuneiform to a second relative position different from the first relative position while maintaining the osteotomy guide in fixed relationship to the first cut surface; and

after moving the metatarsus relative to the cuneiform to a second relative position, guiding a cutter with the osteotomy guide to cut the cuneiform at a predetermined angle relative to the osteotomy guide to produce a second cut surface and remove a second portion of bone adjacent the joint to create a gap between the metatarsus and cuneiform.

15. The method of claim 14 wherein the first cut surface is a planar surface and the second cut surface is a planar surface parallel to the first planar surface, the method further comprising:

reducing the gap between the metatarsus and cuneiform so that the first cut surface abuts the second cut surface; and

fixing the metatarsus and cuneiform together.
16. The method of claim 14 wherein cutting the cuneiform comprises forming a gap of a predetermined shape between the metatarsus and cuneiform, the method further comprising inserting an implant having a corresponding predetermined shape.

17. The method of claim 14 wherein moving the metatarsus relative to the cuneiform comprises changing the relative position between the metatarsus and cuneiform in more than one plane.
18. The method of claim 16 further comprising fixing the osteotomy guide to the cuneiform after moving the metatarsus relative to the cuneiform and then cutting the cuneiform.
19. The method of claim 16 wherein fixing an osteotomy guide to the metatarsus comprises abutting a first indexing feature of the osteotomy guide with the metatarsus in a first indexing plane and abutting a second indexing feature of the osteotomy guide with the metatarsus in a second indexing plane.
20. The method of claim 19 wherein the first and second indexing planes are normal to one another.
21. The method of claim 16 wherein fixing an osteotomy guide to the metatarsus comprises aligning the guide at a predetermined proximal-distal location relative to the joint line between the metatarsus and cuneiform.
22. The method of claim 21 wherein the osteotomy guide includes a projection extending outwardly from the osteotomy guide, the method further comprising engaging the projection with the metatarsocuneiform joint.
23. The method of claim 22 wherein the osteotomy guide includes a slot and the projection is a feeler gauge removably engageable with the slot.
24. The method of claim 16 wherein the osteotomy guide includes a first guide feature operable to guide a cutter to cut the metatarsus and a second guide feature operable to guide a cutter to cut the cuneiform, the first cut surface and second cut surface having a fixed angular relationship between them determined by the first and second guide features.

25. The method of claim 24 wherein cutting the metatarsus and cuneiform produces a gap between the metatarsus and cuneiform, the method further comprising filling the gap between the metatarsus and cuneiform.
26. The method of claim 25 wherein filling the gap with one or more materials selected from the group consisting of autograft, allograft, xenograft, synthetic graft, metal, plastic, ceramic, a solid filler, and particulate filler.
27. The method of claim 25 wherein filling the gap comprises inserting an implant having a predetermined shape corresponding to the angular relationship between the first and second cut surfaces.
28. The method of claim 24 wherein the first planar surface and second planar surface are parallel.
29. The method of claim 15 wherein the osteotomy guide comprises a proximal member and a distal member engaged with the proximal member in linear translating relationship, the proximal and distal members being constrained to linear translation along a motion axis, wherein reducing the gap between the metatarsus and cuneiform comprises translating the metatarsus parallel to the motion axis while the metatarsus is fixed to the distal member and the cuneiform is fixed to the proximal member.

ABSTRACT

Methods and devices for performing an osteotomy are presented.

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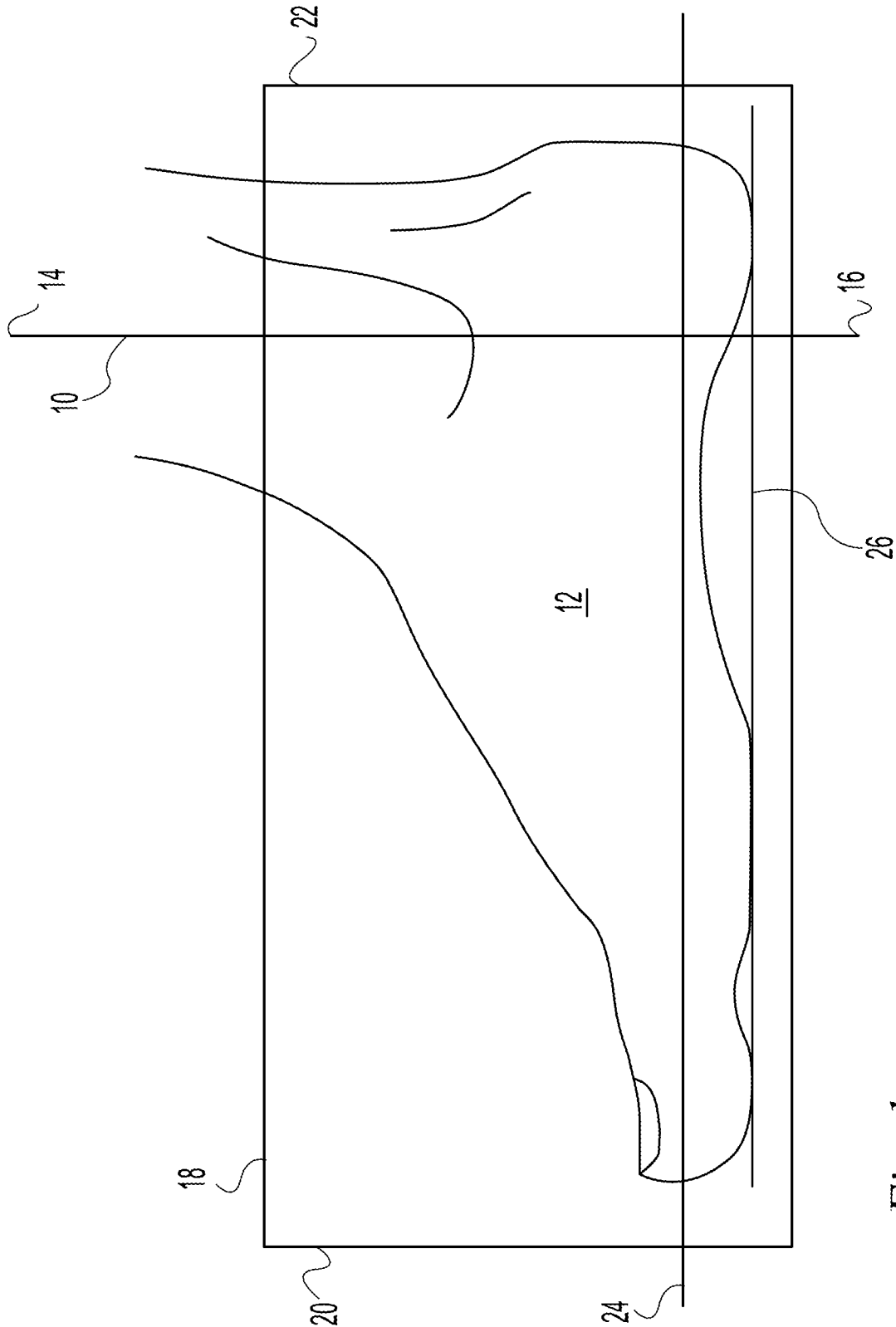
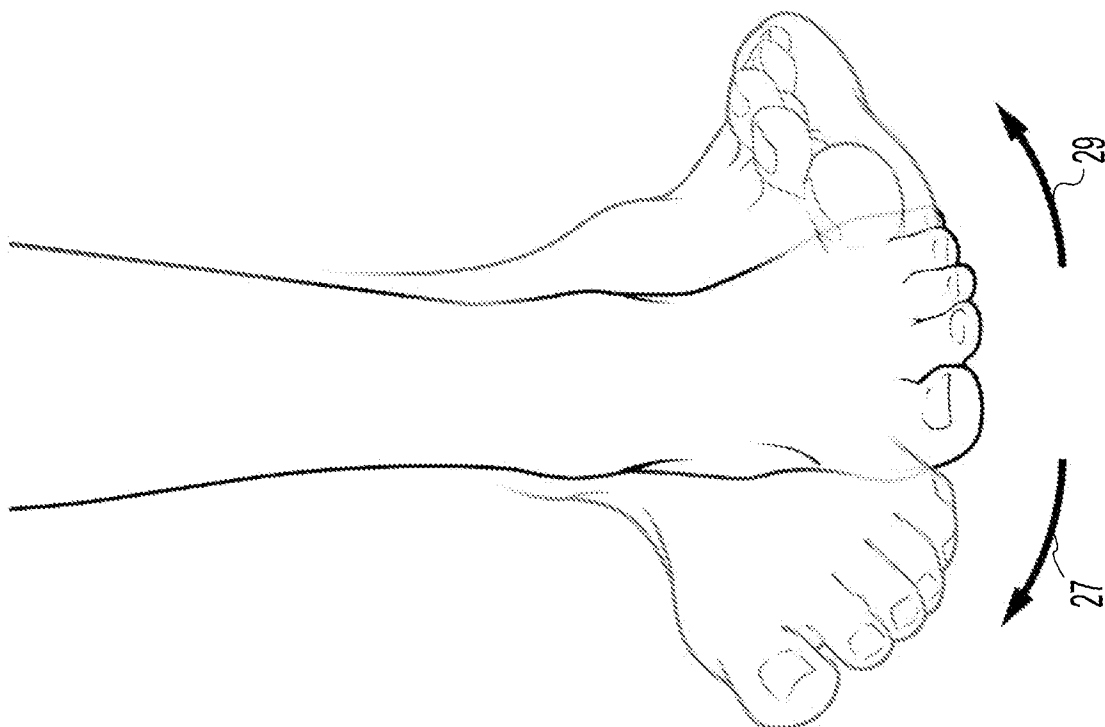
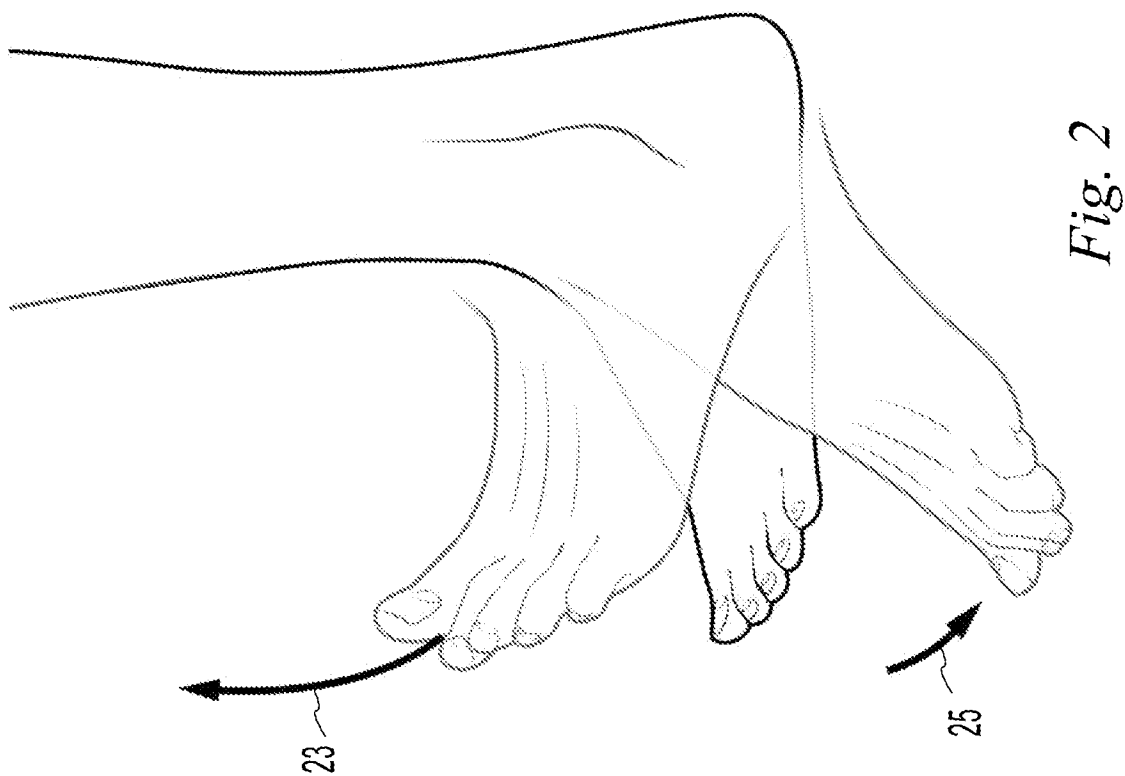


Fig. 1

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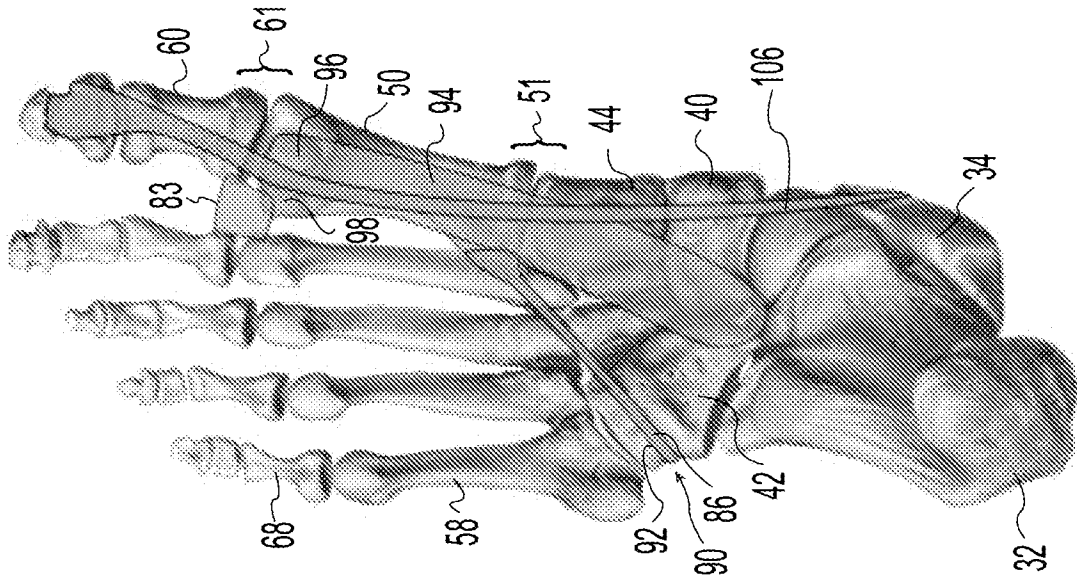


Fig. 5

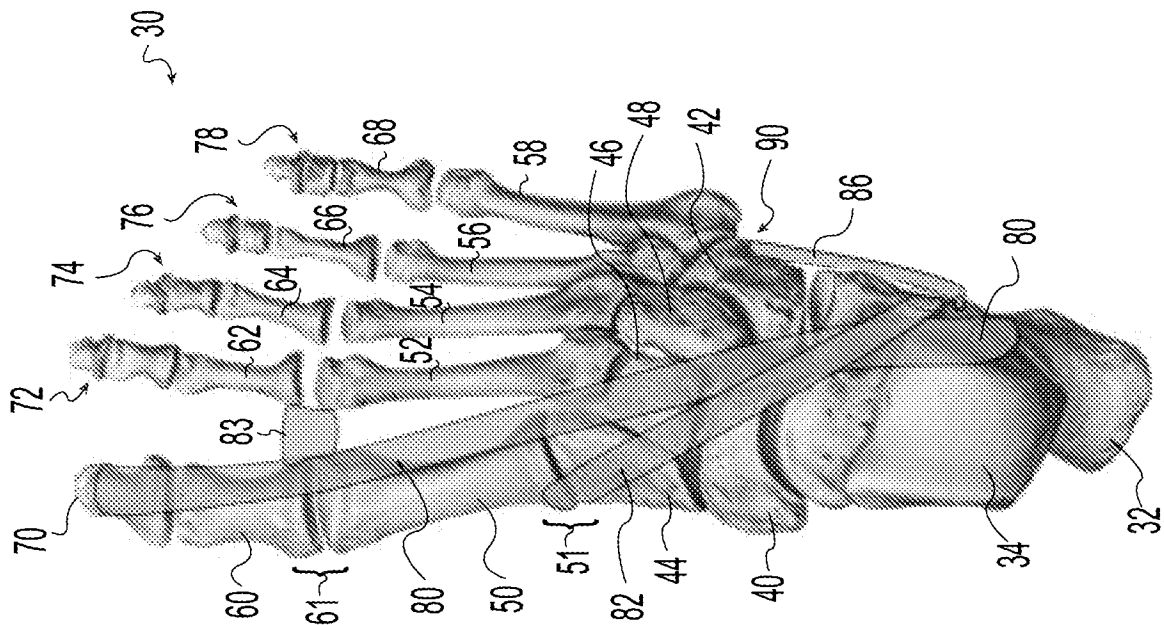
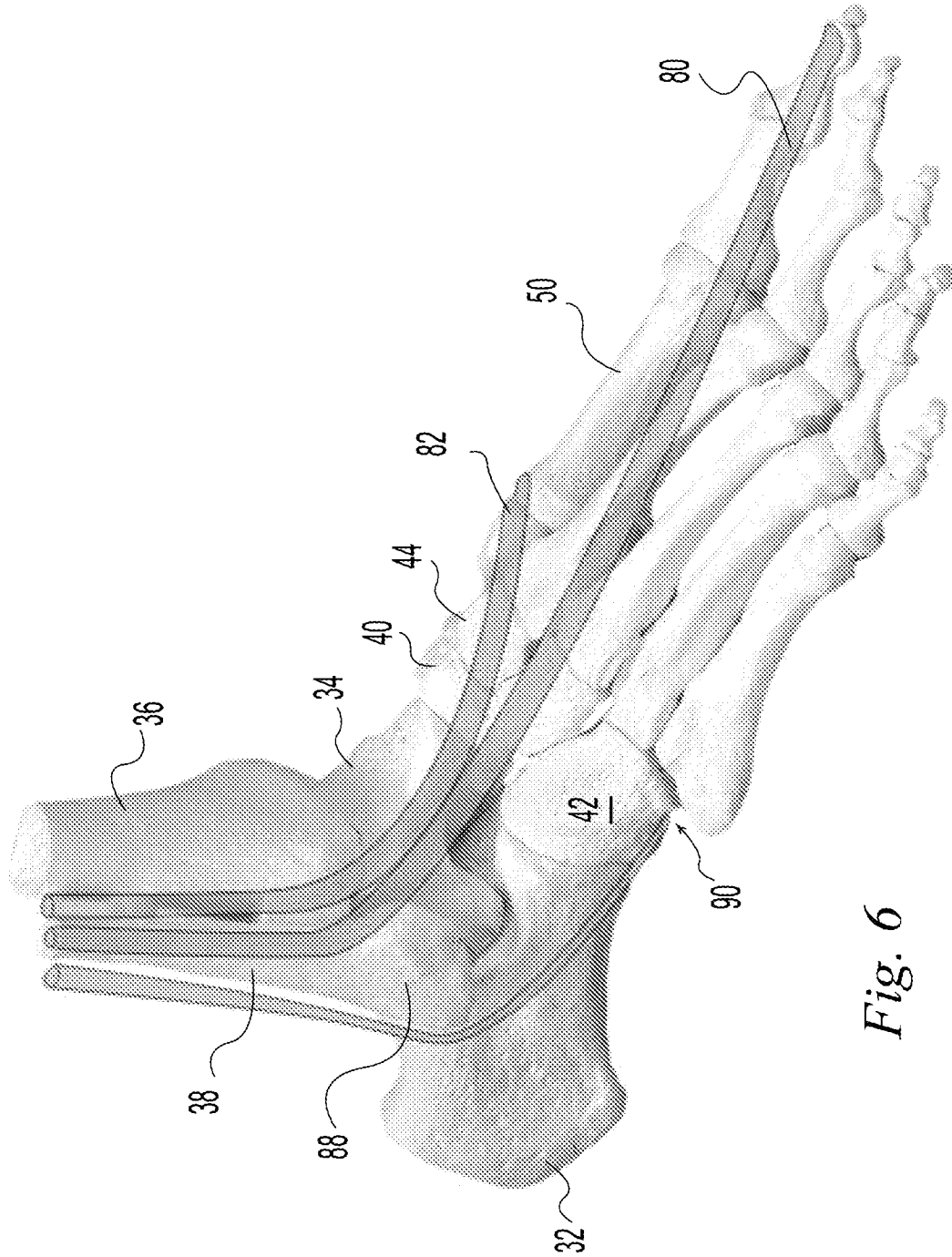


Fig. 4

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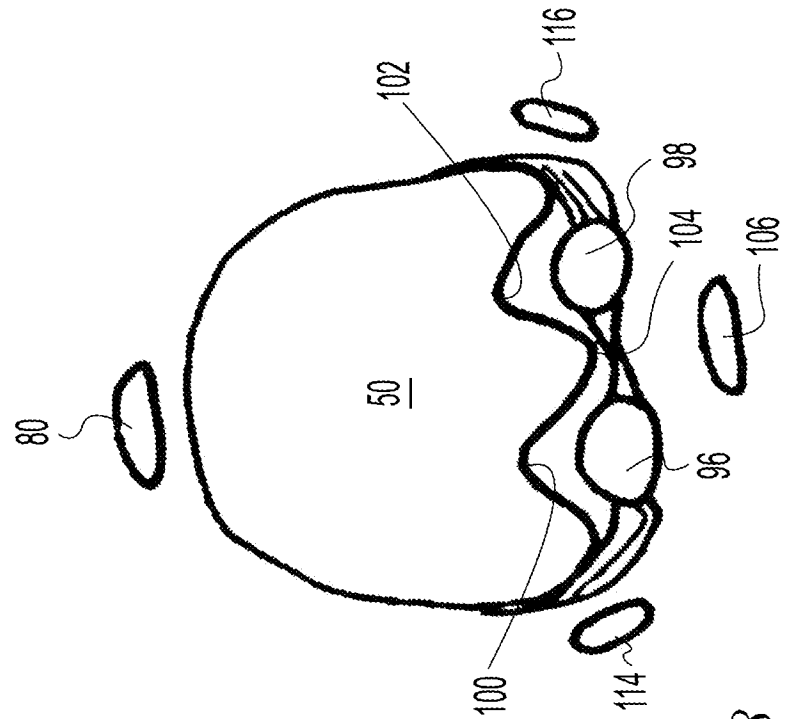


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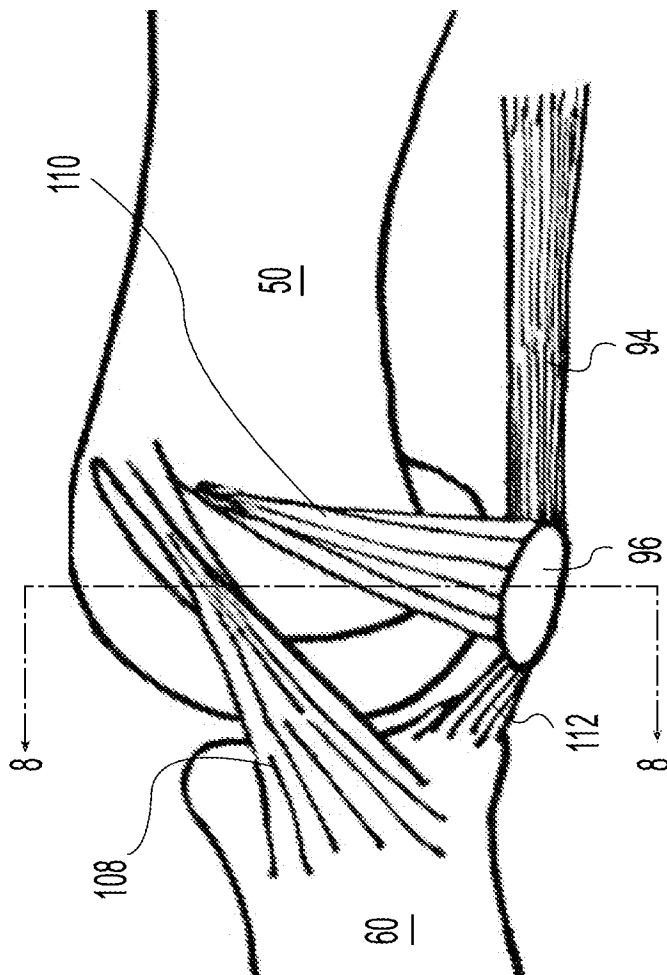


Fig. 7

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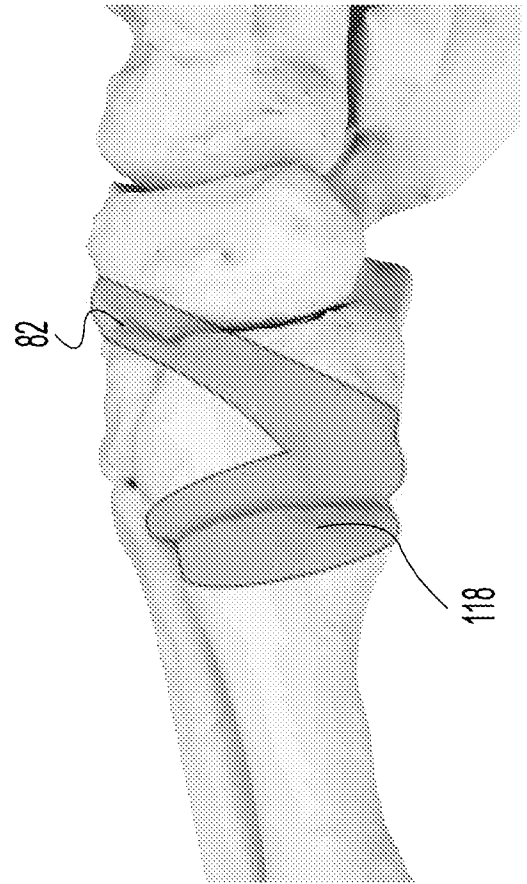


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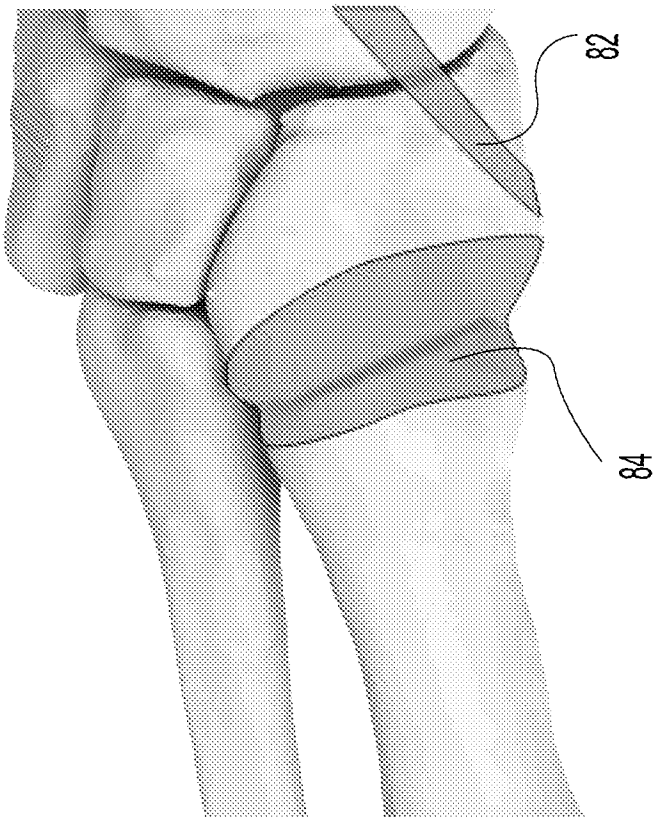


Fig. 9

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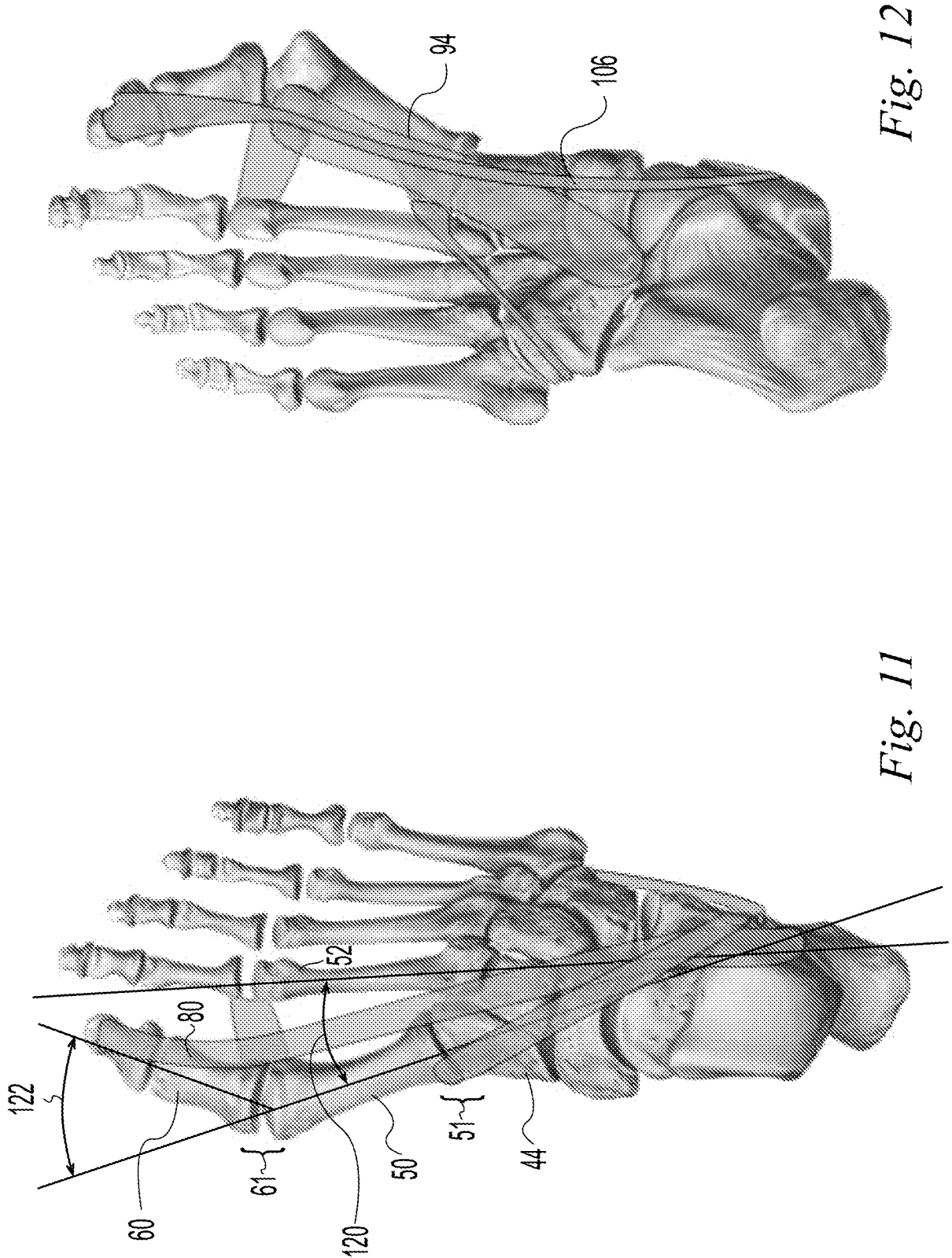


Fig. 12

Fig. 11

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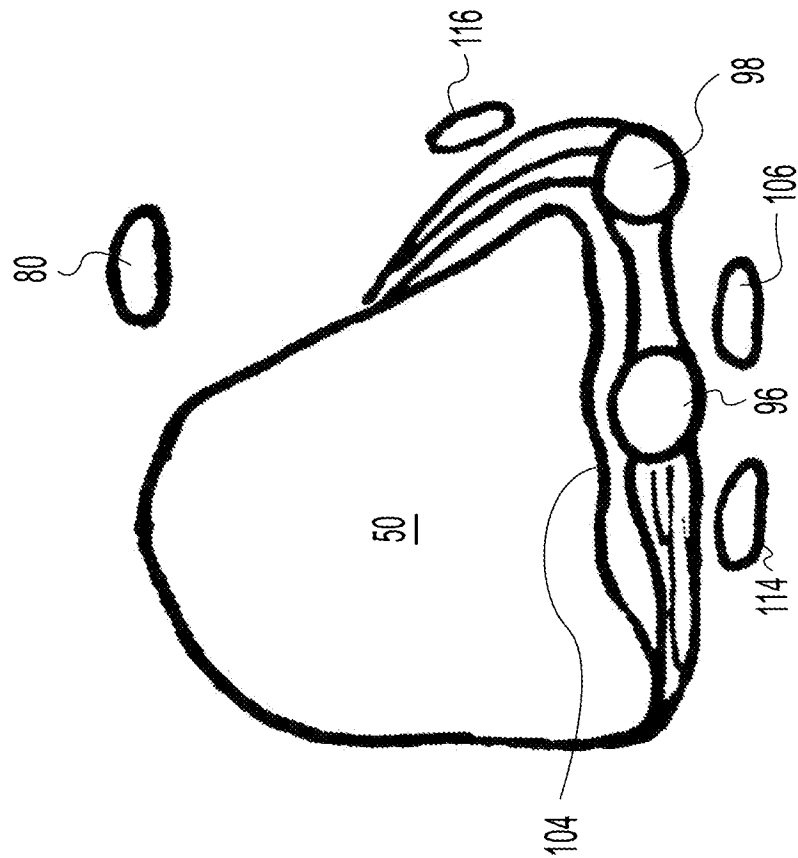


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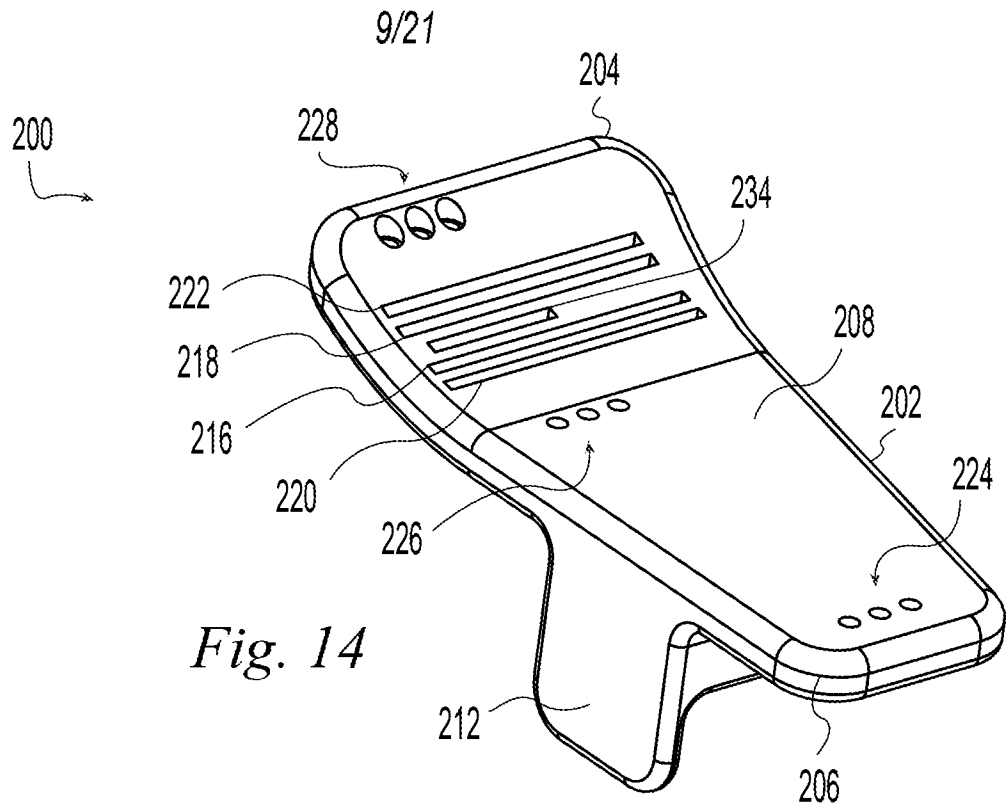


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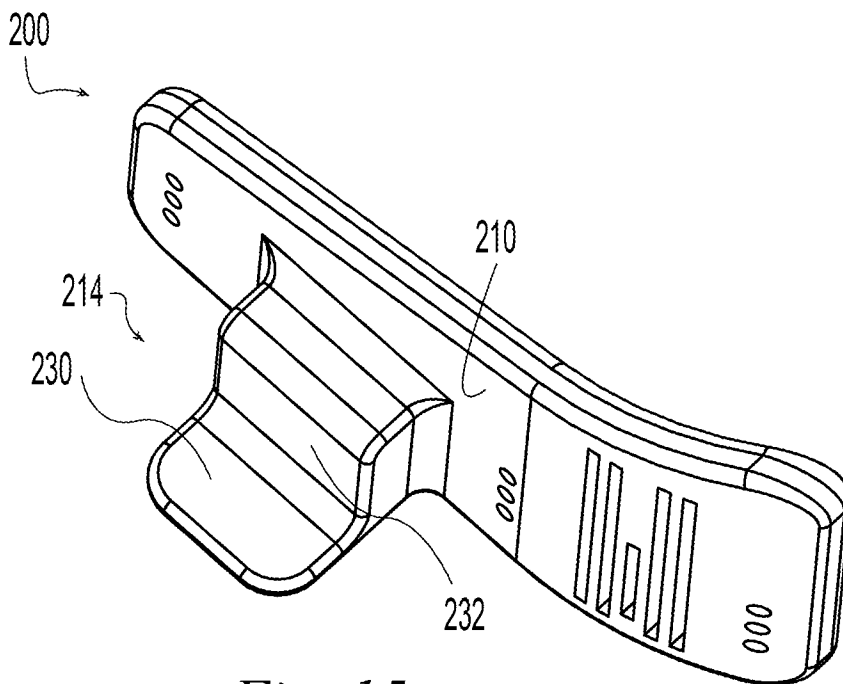


Fig. 15

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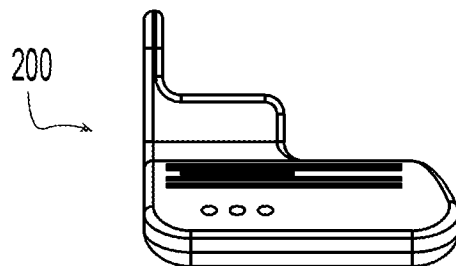


Fig. 16

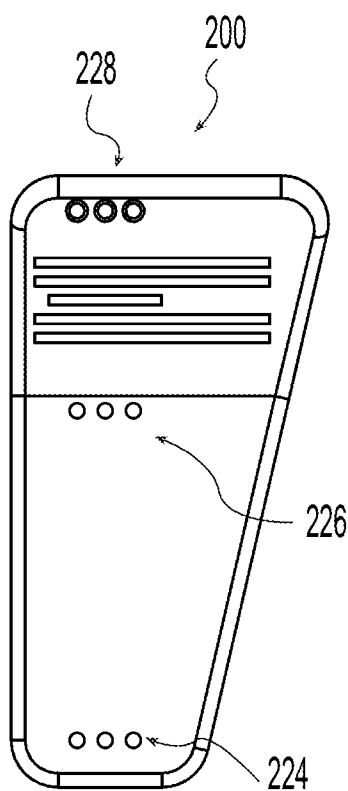


Fig. 17

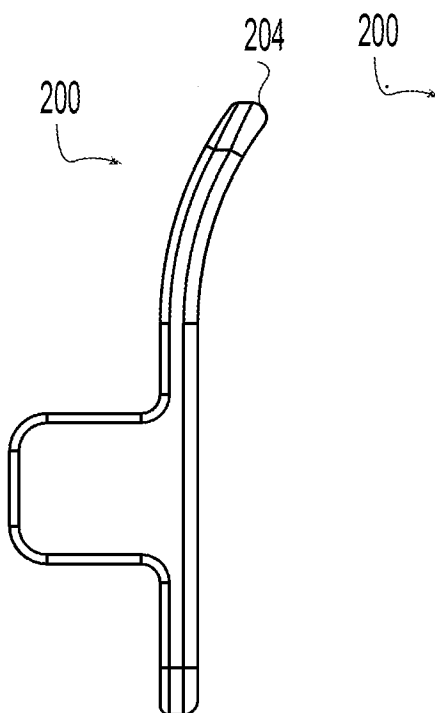


Fig. 18

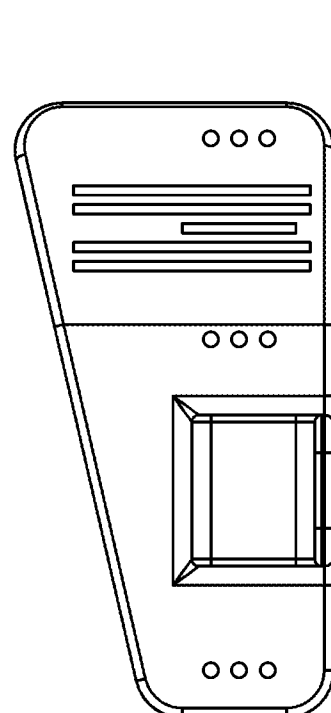


Fig. 19

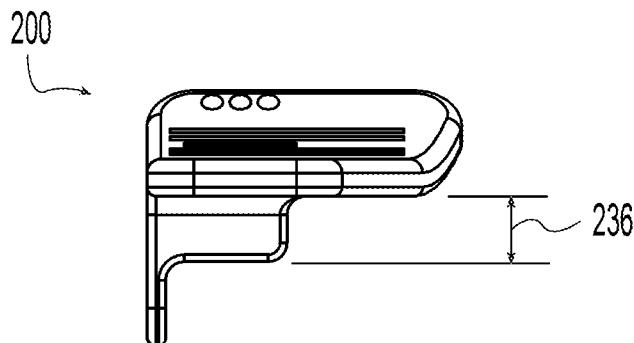


Fig. 20

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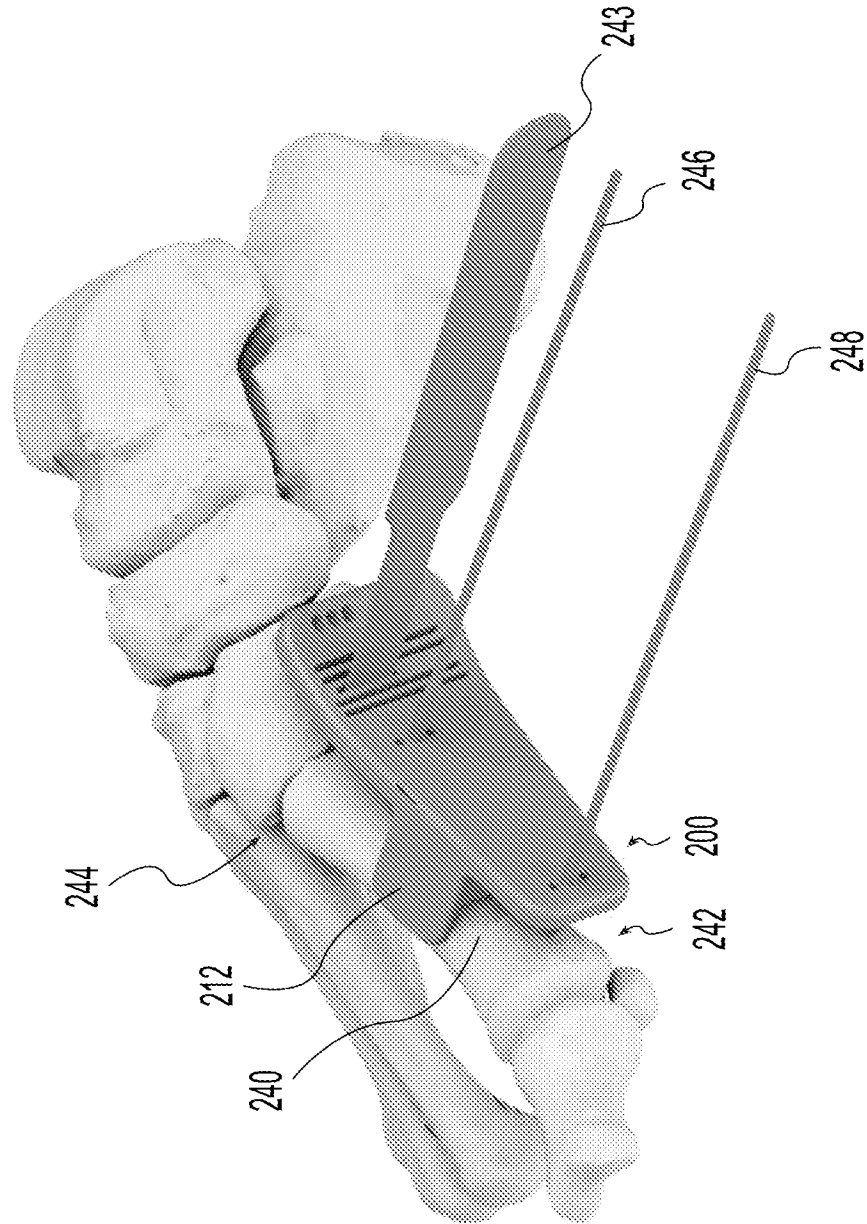


Fig. 21

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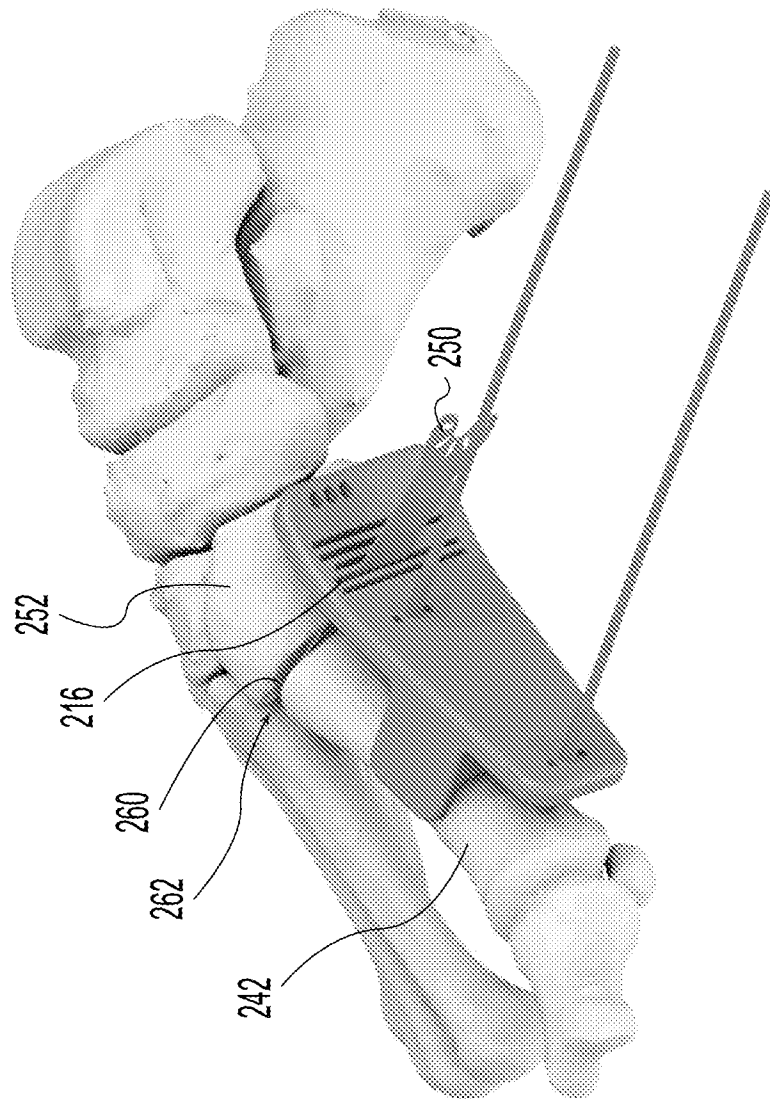


Fig. 22

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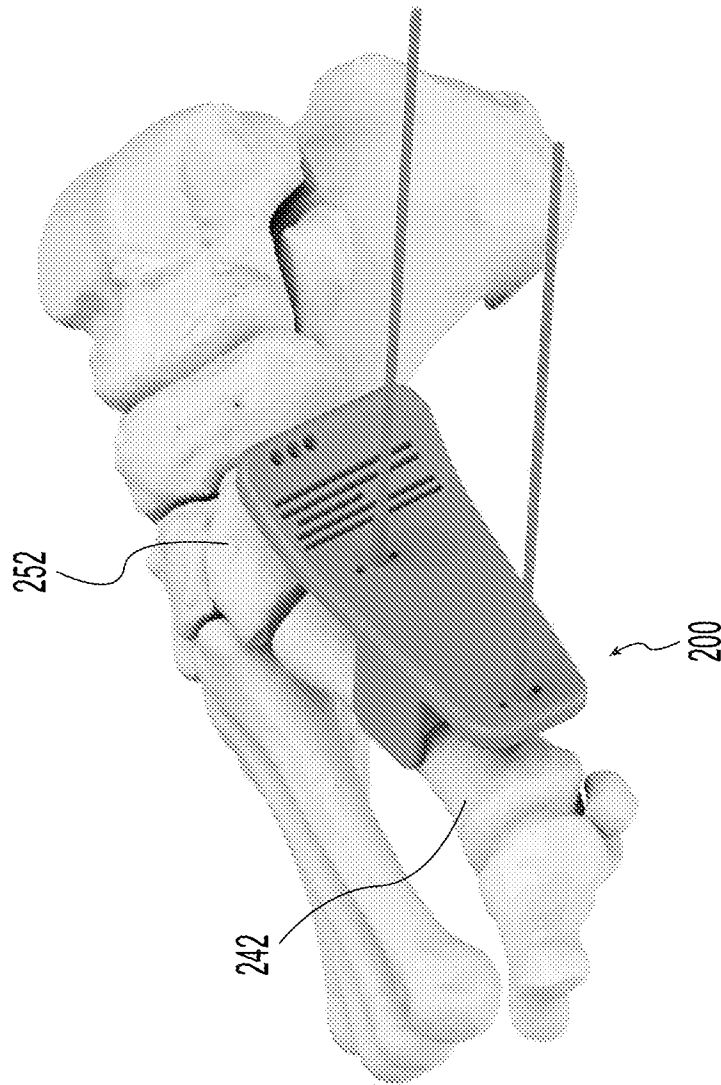


Fig. 23

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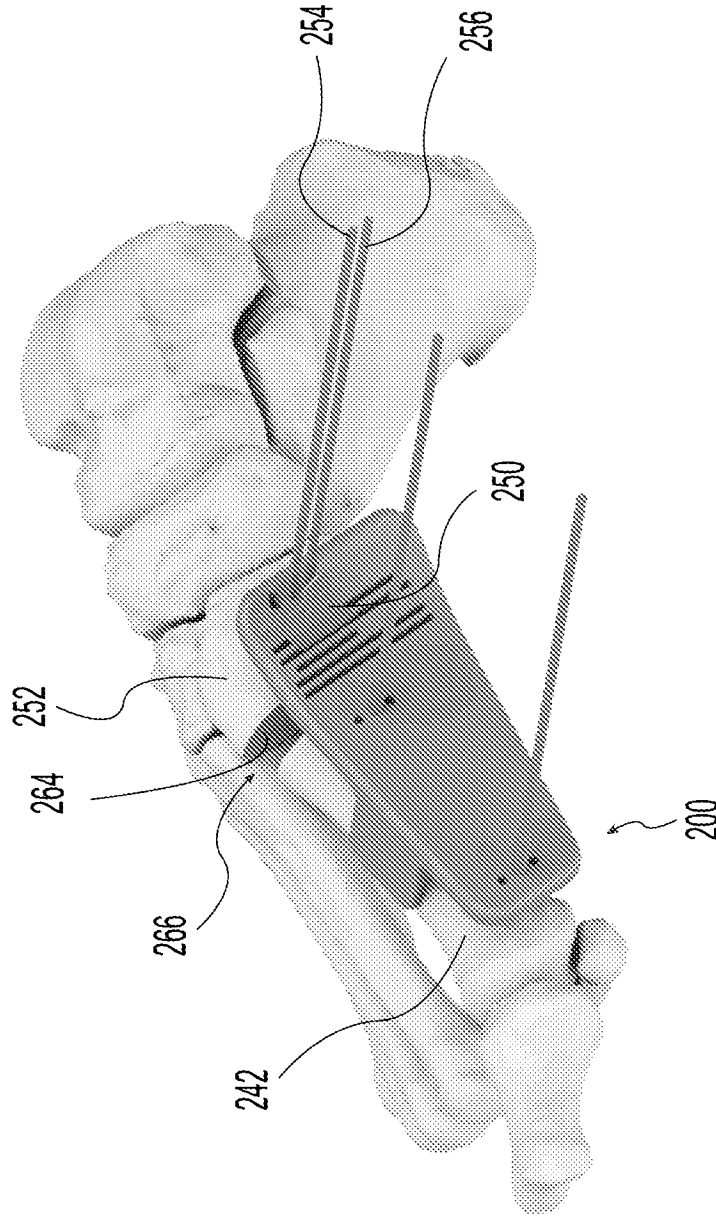


Fig. 24

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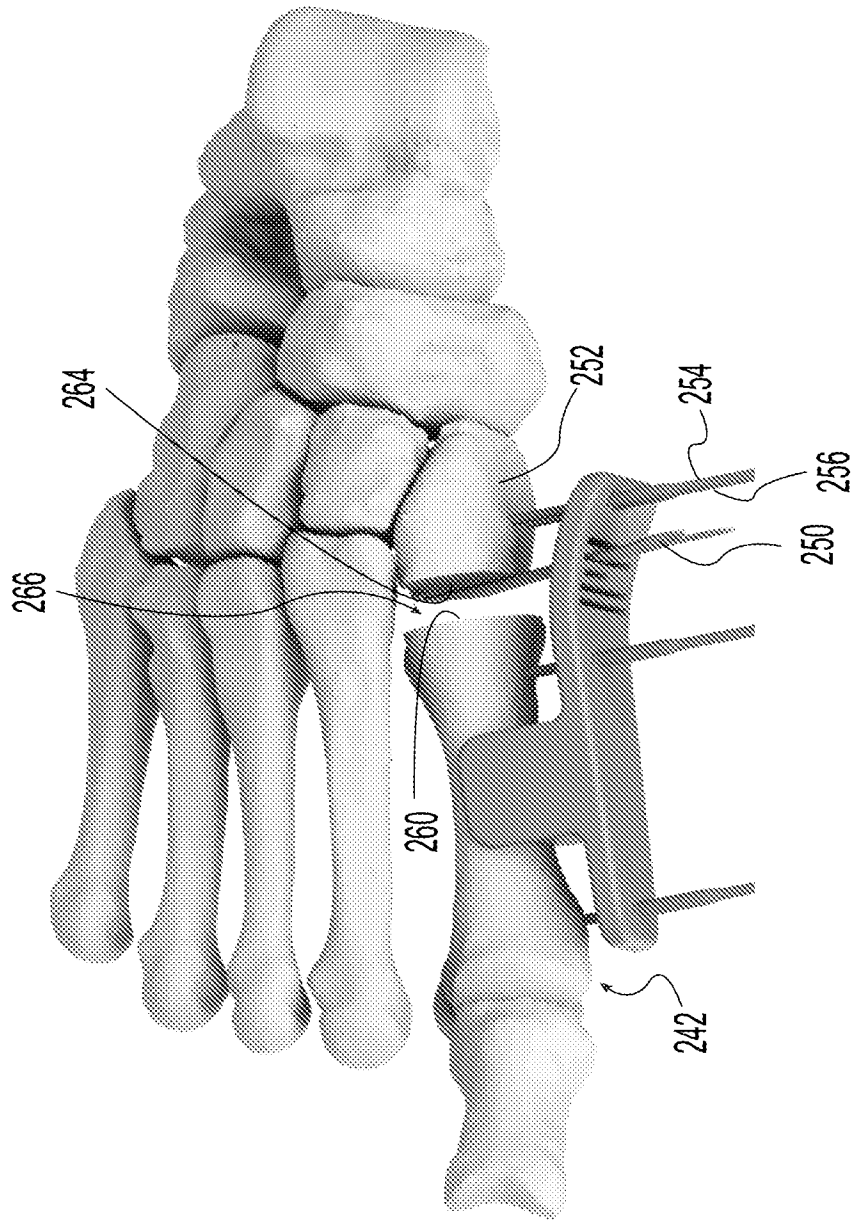
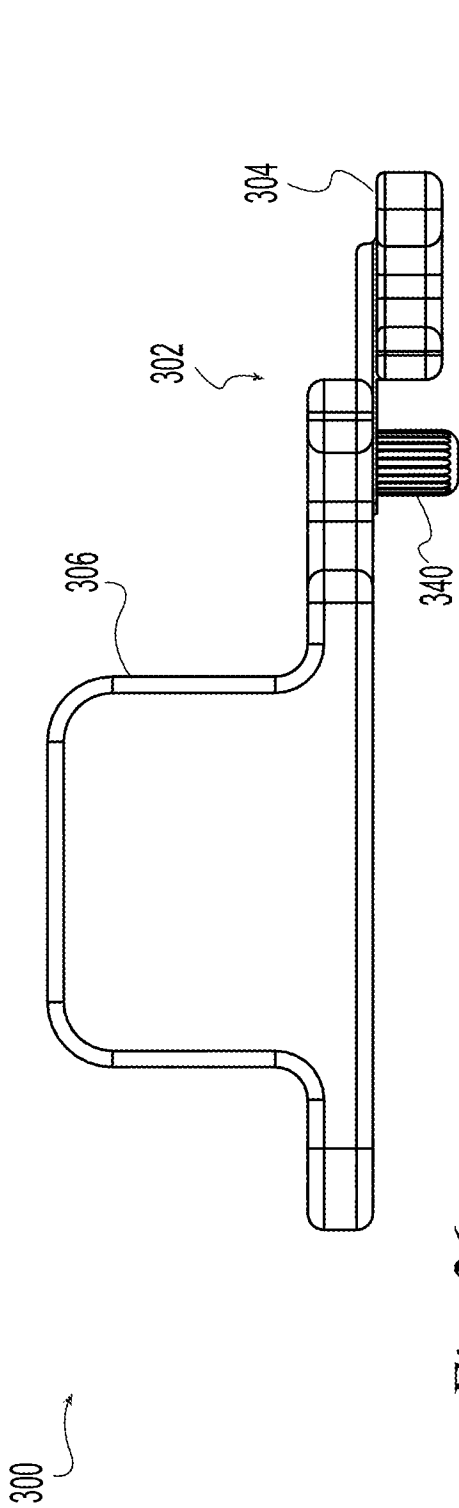
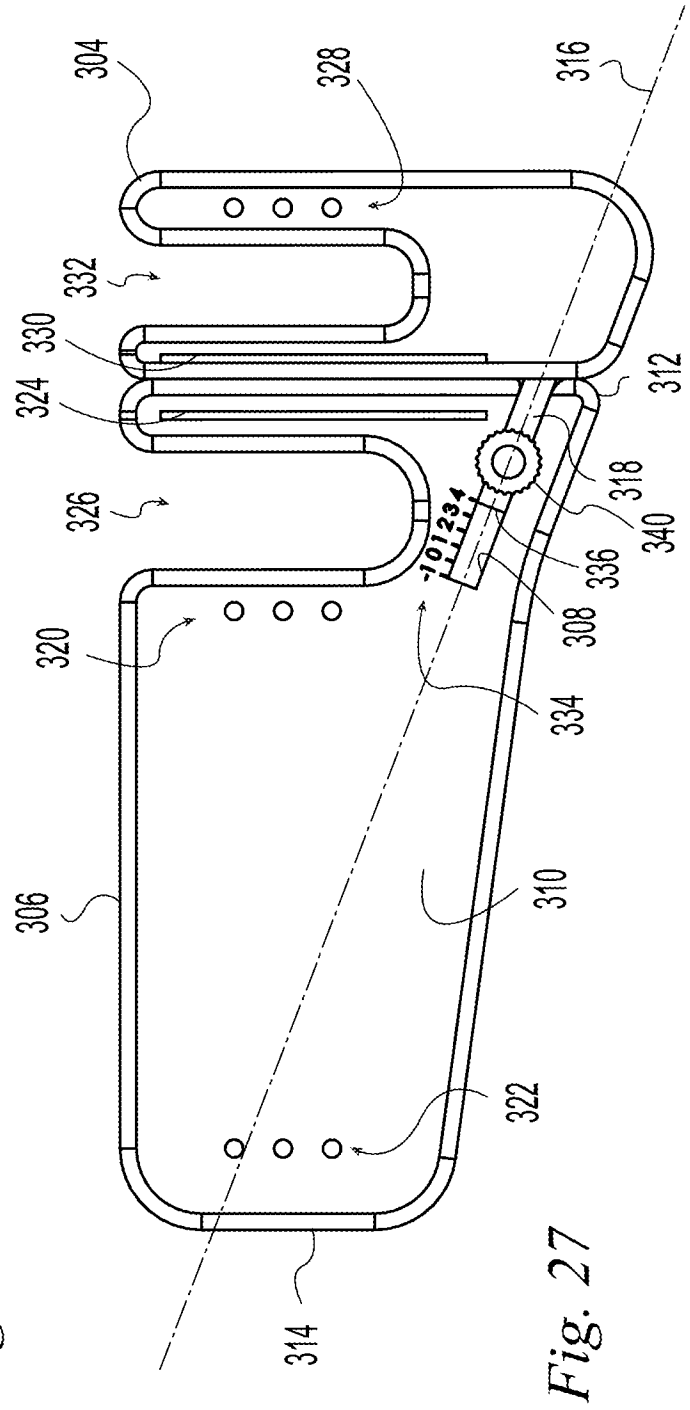


Fig. 25

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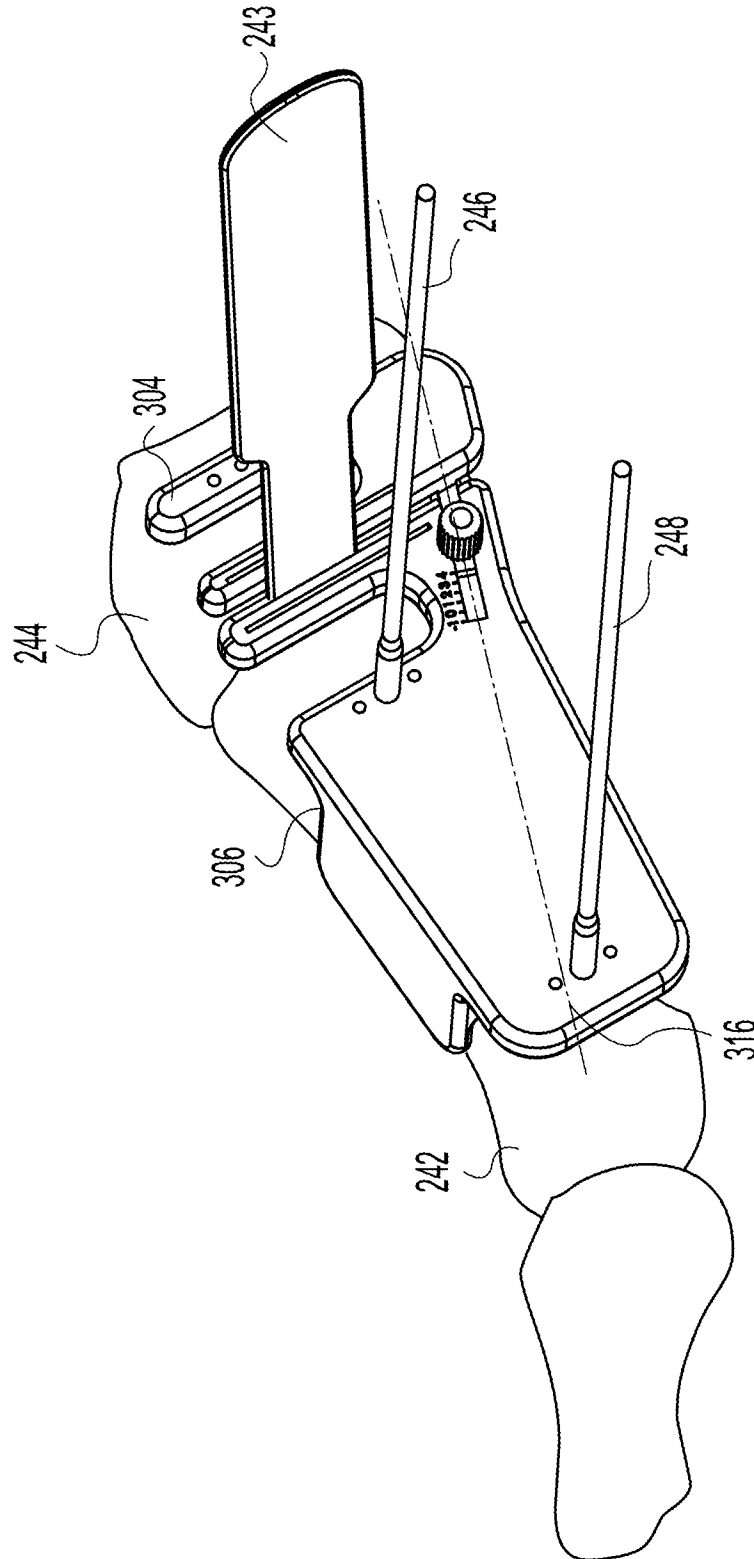


Fig. 28

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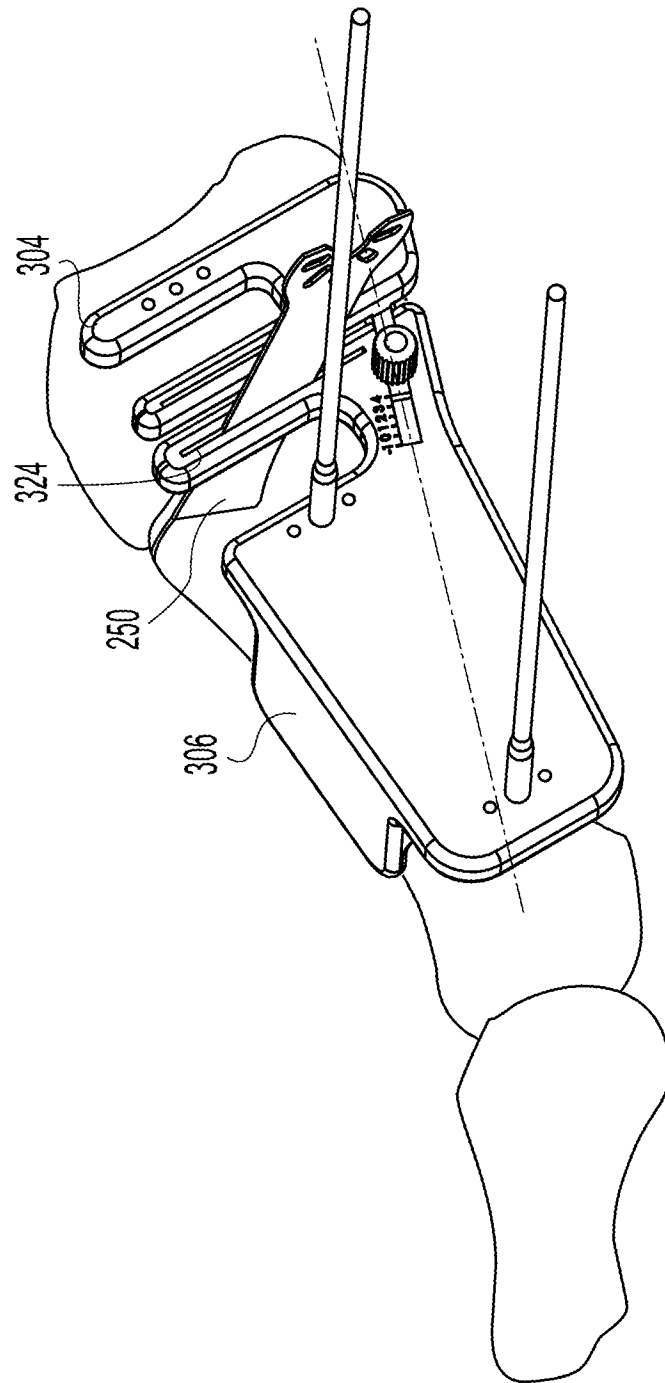


Fig. 29

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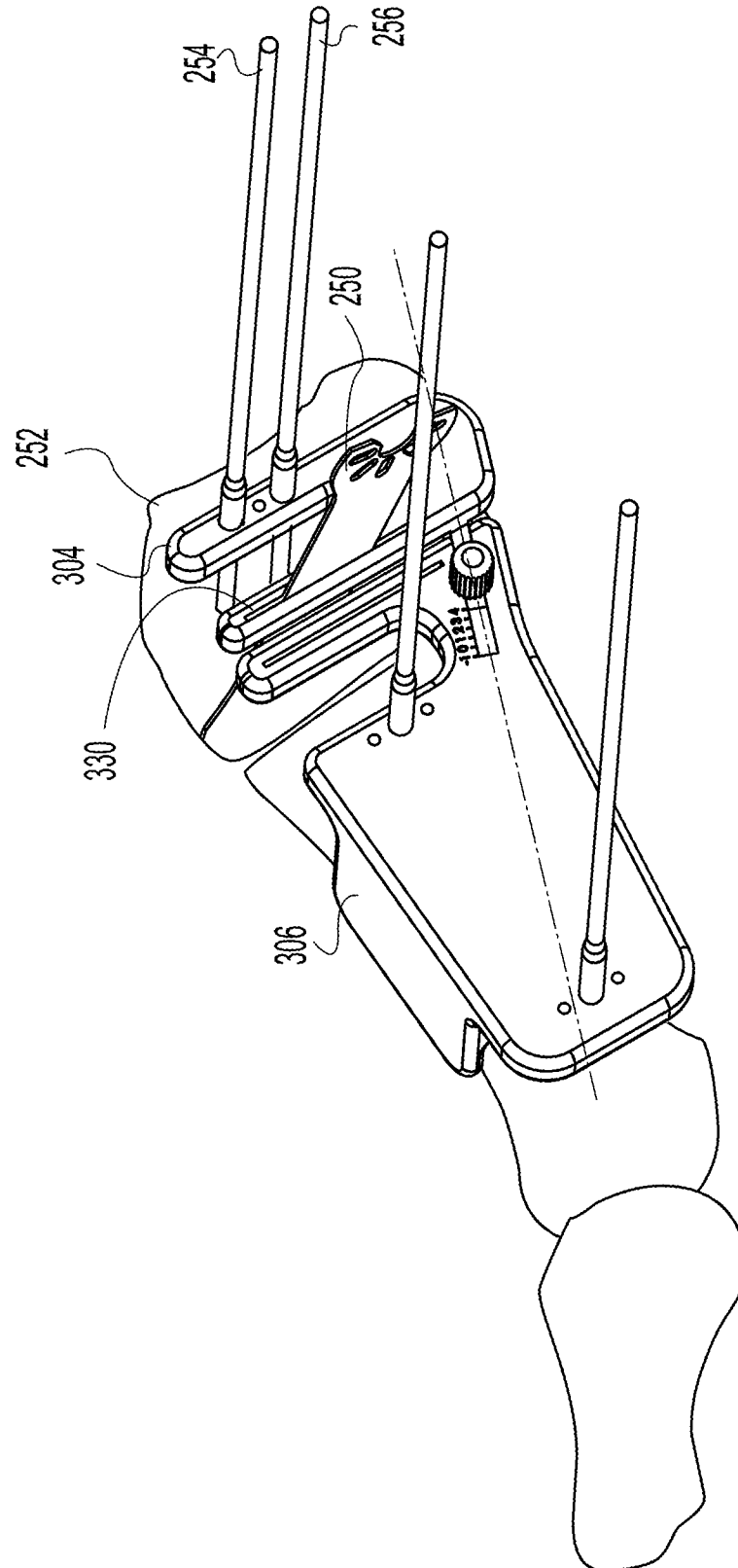


Fig. 30

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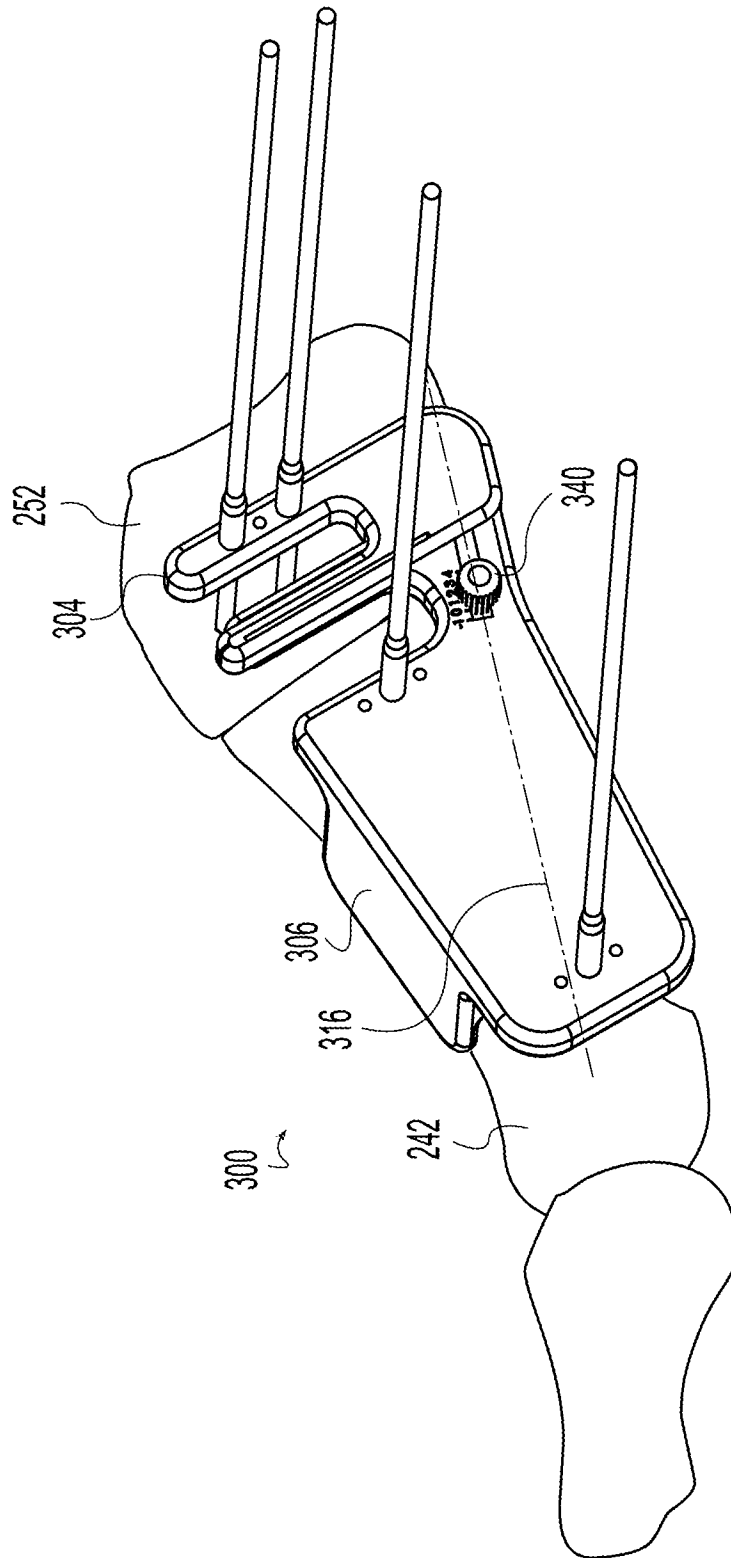


Fig. 31

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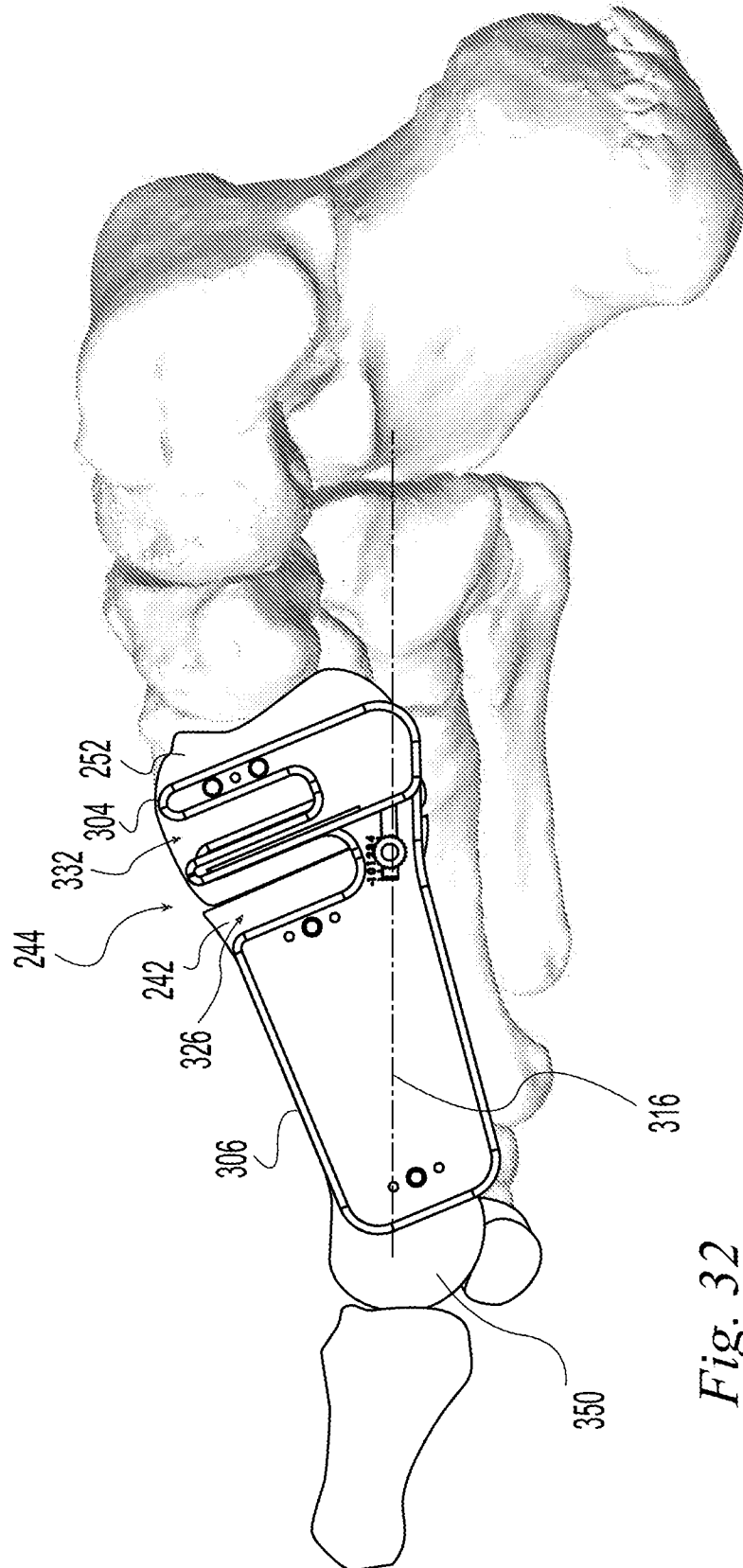


Fig. 32

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD		
First Named Inventor/Applicant Name:		T. Wade Fallin		
Filer:		Cary Randal Reeves/Denise Magee		
Attorney Docket Number:		IPP-0050-US05		
Filed as Small Entity				
Filing Fees for Provisional				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Provisional Application Filing Fee	2005	1	130	130
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				130

Electronic Acknowledgement Receipt

EFS ID:	21336051
Application Number:	62108936
International Application Number:	
Confirmation Number:	7184
Title of Invention:	FREEFORM TRI-PLANAR OSTEOTOMY GUIDE AND METHOD
First Named Inventor/Applicant Name:	T. Wade Fallin
Customer Number:	126243
Filer:	Cary Randal Reeves/Denise Magee
Filer Authorized By:	Cary Randal Reeves
Attorney Docket Number:	IPP-0050-US05
Receipt Date:	28-JAN-2015
Filing Date:	
Time Stamp:	18:27:02
Application Type:	Provisional

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Payment Type	Credit Card
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	IPP-0050-US05_ADS.pdf	1864463	no	7
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Warnings:					
Information:					
2		IPP-0050-US05_Specification.pdf	207212	yes	26
			8ea00e61bfaf574aa66f2aabf0c4d1a318def75e		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	20	
	Claims		21	25	
	Abstract		26	26	
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3	Drawings-other than black and white line drawings	IPP-0050-US05_Drawings.pdf	8012744	no	21
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4	Fee Worksheet (SB06)	fee-info.pdf	29636	no	2
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