

A HYBRID INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part application of Application Serial No.

- 5 12/658,680, filed February 11, 2010, which is a continuation-in-part application of Application Serial No. 12/456,808, filed June 23, 2009, which claims the benefit of Provisional Application No. 61/132,932, filed June 24, 2008, the entire contents of the entire chain of applications are herein incorporated by reference.

10 FIELD OF THE INVENTION

This invention relates to the field of orthopedic implant devices, and more particularly, to a hybrid intramedullary fixation assembly used for fusion of the angled joints, bones and deformity correction, such as the hand and foot bones.

15 BACKGROUND OF THE INVENTION

Orthopedic implant devices, such as intramedullary nails, plates, rods and screws are often used to repair or reconstruct bones and joints affected by trauma, degeneration, deformity and disease, such as Charcot arthropathy caused by diabetes in some patients, Hallux Valgus deformities, failed Keller Bunionectomies, Rheumatoid Arthritis, and severe deformities.

- 20 Moreover, infections and wound complications are a major concern in the aforementioned procedures. Wound closure is technically demanding for the surgeon, and devices that add surface prominence, such as plates or exposed screws, add to the difficulty by requiring greater tissue tension during incision reapproximation. This increases the risk of postoperative wound infections and dehiscence that may ultimately result in limb amputation.

Various implants have been utilized for surgical treatment of these bones and joints, including bone screws. Implants have also been utilized to treat severe deformities in the metatarsal and phalangeal bones, including multiple screws and plates. These multiple screws and plate implants have been commonly used in a first metatarsal-phalangeal fusion procedure to fuse the first metatarsal to the first phalangeal bone in hallux valgus deformities, failed Keller
5 bunionectomies, rheumatoid arthritis, and other types of severe deformities in the metatarsal and phalange bones. While these devices allow fixation and promote fusion, they do not deliver restoration of the arch in a Charcot foot, they are not effective in metatarsal-phalangeal (MTP) fusion procedures, nor do they deliver uniform compression for various predetermined angles of
10 compression.

Particularly, screw implants in MTP procedures are ineffective in delivering sufficient compression to the bones in the foot, preventing screw head break out, or delivering effective bending resistance. Moreover, hard to control dorsiflexion and valgus angles as well skin irritation from proximity to the skin prevents these screw implants from being readily utilized for
15 surgical treatment. Yet further, plate implants used with bone screws too have the same drawbacks as fixed varus and valgus angles, lack of direct compression across the MTP joint, and skin irritations from proximity to the skin reduce the effectiveness of these implants.

Yet further, some screw implants are not available to be readily interchangeable from a fixed angle compression to a variable angle compression while utilizing a common bone anchor
20 and minimizing the members required by a surgeon.

There is therefore a need for an intramedullary fixation assembly and method of use that overcomes some or all of the previously delineated drawbacks of prior fixation assemblies.

SUMMARY OF THE INVENTION

An object of the invention is to overcome the drawbacks of previous inventions.

Another object of the invention is to provide a novel and useful intramedullary fixation assembly that may be utilized to treat bones in a human body.

5 Another object of the invention is to provide a system for compressing bones using an intramedullary fixation assembly.

Another object of the invention is to fuse bones through the use of an intraosseous assembly.

10 Another object of the invention is to provide a novel intramedullary fixation assembly that incorporates design characteristics of both non-locking and locking screws.

Another object of the invention is to provide a fixed acute angle intramedullary fixation assembly for bone fixation.

Another object of the invention is to provide variable acute angles of fixation.

15 Another object of the invention is to provide at least three point of compression on bone fragments through a variable angle intramedullary fixation assembly.

In a first non-limiting aspect of the invention, an intramedullary fixation assembly for bone fusion is provided and includes a hybrid screw member and a lag screw member. The hybrid screw member is aligned along a longitudinal axis, and includes a first shaft, and a head portion including a first aperture coupled to a second aperture. The first aperture has a first
20 spherical radius and the second aperture is tapered and has a second radius. The lag screw member includes a second shaft, a bulbous portion, and a threaded portion. The lag screw member is adapted to be inserted into each of the first and the second apertures.

In a second non-limiting aspect of the invention, a method for bone fusion includes several steps. In one non-limiting step, an intramedullary assembly is provided, where the intramedullary assembly includes a hybrid screw member and a lag screw member. The hybrid screw member is aligned along a longitudinal axis and includes first shaft and a head portion having a first aperture coupled to a second aperture. The first aperture has a first spherical radius and the second aperture is tapered and has a second radius. Also, a lag screw member includes a second shaft, a bulbous portion, and a threaded portion. In another non-limiting step, an incision is made to access a plurality of bones. In another non-limiting step, a first medullary canal is drilled in at least a first bone. In another non-limiting step, the hybrid screw member is inserted into the first medullary canal and is aligned in the first medullary canal. In another non-limiting step, a second medullary canal is drilled in a second bone. In another non-limiting step, the lag screw member is coupled to the hybrid screw member and inserted into the second medullary canal. In another non-limiting step, compression is applied to the lag screw member to lock the hybrid screw member to the lag screw member, thereby fusing the first bone to the second bone.

In a third non-limiting aspect of the invention, an intramedullary fixation assembly for bone fusion includes a hybrid screw member and a lag screw member. The hybrid screw member is aligned along a longitudinal axis, and includes a first shaft, a threaded portion, and a head portion having a first internal surface with a first spherical radius and a second internal surface with a second radius. The first internal surface is coupled to the second internal surface to enclose a bore extending through the head portion along a bore axis. The second internal surface is tapered. The lag screw member includes a second shaft, a bulbous portion, and a threaded portion. The lag screw member is adapted to be inserted into bore and forms an acute angle with the longitudinal axis.

BRIEF DESCRIPTION OF THE DRAWINGS

A further understanding of the invention can be obtained by reference to a preferred embodiment set forth in the illustrations of the accompanying drawings. Although the illustrated embodiment is merely exemplary of systems and methods for carrying out the invention, both
5 the organization and method of operation of the invention, in general, together with further objectives and advantages thereof, may be more easily understood by reference to the drawings and the following description. The drawings are not intended to limit the scope of this invention, which is set forth with particularity in the claims as appended or as subsequently amended, but merely to clarify and exemplify the invention.

10 For a more complete understanding of the invention, reference is now made to the following drawings in which:

Figure 1 is a perspective view of a fixation system according to a preferred embodiment of the invention;

Figure 2 is a perspective view of a proximal screw member used in the fixation system
15 shown in Figure 1 according to the preferred embodiment of the invention;

Figure 3A is a perspective view of a distal member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention;

Figure 3B is a perspective cross-sectional view of the distal member shown in Figure 3A according to the preferred embodiment of the invention;

20 Figure 4 is a perspective view of the instrument member used in the fixation system shown in Figure 1 according to the preferred embodiment of the invention;

Figure 5 is a perspective view of the assembled intramedullary fixation assembly inserted into the bones of a patient's foot according to the preferred embodiment of the invention;

Figure 6 is a side view of the assembled intramedullary fixation assembly shown in Figure 5 according to the preferred embodiment of the invention;

Figure 7 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figures 1-6 to tarsal and metatarsal bones in a patient's foot according to the preferred embodiment of the invention;

Figure 8 is a perspective view of an assembled intramedullary fixation assembly inserted into the bones of a patient's foot according to an alternate embodiment of the invention;

Figure 9 is a perspective view of the intramedullary fixation assembly shown in Figure 8 according to the alternate embodiment of the invention;

Figure 10 is a perspective view of the lag screw member used in the intramedullary fixation assembly shown in Figures 8-9 according to the alternate embodiment of the invention;

Figure 11 is a perspective view of the tapered screw member used in the intramedullary fixation assembly shown in Figures 8-9 according to the alternate embodiment of the invention;

Figure 12 is a flow chart illustrating the method of coupling the intramedullary fixation assembly shown in Figure 8-9 to bones in a patient's foot according to the alternate embodiment of the invention;

Figure 13 is a perspective view of an assembled intramedullary fixation assembly inserted into the bones of a patient's hand according to an alternate embodiment of the invention;

Figure 14 is a perspective view of the intramedullary fixation assembly shown in Figure 13 according to the alternate embodiment of the invention;

Figure 15 is a perspective view of the lag screw member used in the intramedullary fixation assembly shown in Figures 14 according to the alternate embodiment of the invention;

Figure 16 is a perspective view of the polyaxial screw member used in the intramedullary fixation assembly shown in Figure 14 according to the alternate embodiment of the invention;

Figure 17 is a perspective view of an assembled intramedullary fixation assembly according to an alternate embodiment of the invention;

5 Figure 18 is a perspective view of an assembled intramedullary fixation assembly having a plurality of lag screw members according to an alternate embodiment of the invention;

Figure 19 is an exploded perspective view of a cover member for a lag screw according to an alternate embodiment of the invention;

10 Figure 20A is a perspective view of an intramedullary fixation assembly having a polyaxial screw member according to an alternate embodiment of the invention;

Figure 20B is a cross-sectional view of the intramedullary fixation assembly shown in Figure 20A according to an alternate embodiment of the invention;

Figure 21A is a perspective view of an intramedullary fixation assembly having a tapered screw member according to an alternate embodiment of the invention;

15 Figure 21B is a cross-sectional view of the intramedullary fixation assembly shown in Figure 21A according to an alternate embodiment of the invention;

Figure 22A is a perspective view of a hybrid screw member used in the intramedullary fixation assembly shown in Figures 20A-21B according to an alternate embodiment of the invention; and

20 Figure 22B is a sectional view of the hybrid screw member shown in Figure 22A according to an alternate embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The invention may be understood more readily by reference to the following detailed description of preferred embodiment of the invention. However, techniques, systems, and operating structures in accordance with the invention may be embodied in a wide variety of forms and modes, some of which may be quite different from those in the disclosed embodiment. Consequently, the specific structural and functional details disclosed herein are merely representative, yet in that regard, they are deemed to afford the best embodiment for purposes of disclosure and to provide a basis for the claims herein, which define the scope of the invention. It must be noted that, as used in the specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly indicates otherwise.

Referring now to Figure 1, there is shown a fixation system 100 which is made in accordance with the teachings of the preferred embodiment of the invention. As shown, the fixation system 100 includes an intramedullary fixation assembly 110, comprising a proximal screw member 130 and a distal member 140. Proximal screw member 130 is provided on proximal end 135 of assembly 110 and is coupled to a distal member 140 that is provided on the distal end 145 of the fixation assembly 110. Also, proximal screw member 130 makes a fixed angle 150 with distal member 140 and this angle 150 determines the angle for arch restoration. Moreover, fixation system 100 includes instrument 120 that is utilized to couple intramedullary fixation assembly 110 to the bones in the mid-foot region (not shown). It should be appreciated that in one non-limiting embodiment, intramedullary fixation assembly 110 may be made from a Titanium material, although, in other non-limiting embodiments, intramedullary fixation assembly 110 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials.

As shown in Figure 2, proximal screw member 130 is generally cylindrical in shape and extends from first bulbous portion 202 to second tapered end 204. End 204 has a diameter that is slightly smaller than diameter 226 of bulbous portion 202. Additionally, bulbous portion 202 has a taper, such as a Morse taper, with a width that decreases from end 211 to end 212. The taper
5 allows for a locked interference fit with tapered aperture 316 when tapered bulbous portion 202 is combined with tapered aperture 316, shown and described below. Moreover, bulbous portion 202 is generally circular and has a generally hexagonal torque transmitting aperture 208 that traverses length 210 of bulbous portion 202. However, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the
10 invention. Torque transmitting aperture 208 is utilized to transmit a torque from bulbous portion 202 to tapered end 204 by rotating bulbous portion 202.

Further, proximal screw member 130 has a first smooth exterior portion 206 extending from end 212 of bulbous portion 202. Portion 206 includes an internal aperture 214 that longitudinally traverses portion 206 in direction 201. Portion 206 terminates into a second
15 generally tubular portion 216. Portion 216 may comprise internal circular aperture 220 that longitudinally traverses inside portion 216. Internal circular aperture 220 is aligned with apertures 214 and 208 along axis 203 to form a continuous opening (i.e., a cannula) from bulbous portion 202 to end 204. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening thereby
20 positioning and locating the proximal member 130. In other non-limiting embodiments, the proximal member 130 may be provided without apertures 220 and 214 (i.e., the proximal member is solid).

Furthermore, tubular portion 216 has a plurality of circular threads, such as threads 218, which are circumferentially disposed on the external surface of portion 216 and, with threads 218 having an external diameter 224. Portion 216 may also be provided with a self-tapping leading edge 222 to provide portion 216 with the ability to remove bone material during insertion of proximal screw member 130 into bone. It should be appreciated that the length of the proximal member 130 may be selected of varying lengths to allow a surgeon to fuse different joints in a foot (not shown).

As shown in Figures 3A-3B, distal member 140 of the preferred embodiment is generally tubular in shape and tapers from a first end 302 to a second end 304 (i.e. end 302 has a diameter 306 that is slightly larger than diameter 308 of end 304). However, in another non-limiting embodiment, distal member 140 has a constant width from first end 302 to second end 304. Further, first end 302 is generally semi-spherical in shape and has an internal circular aperture 316, which traverses end 302 along direction 301 (i.e. end 302 is generally “donut” shaped). Additionally, circular aperture 316 emanates from surface 322, such that portion 310 has a generally tapered aperture 316 provided in portion 310. Circular aperture 316 includes slope 320 from first end 302 to end 322 of portion 310. Further, aperture 316 is aligned along axis 303, which is offset from horizontal axis 305 of distal member 140. Axis 303 forms an angle 150 with horizontal axis 305 that determines the angle for arch restoration, as shown in figure 3A. Angle 150 may be any angle greater than 90 degrees and less than 180 degrees. Tapered aperture 316 when combined with tapered bulbous portion 202, shown in Figure 2, creates a locked interference fit between proximal member 130 and distal member 140. First end 302 has a plurality of substantially similar grooves 326 and 328, which form an “L-shape” with surface 330 of end 302. Grooves 326 and 328 are provided to receive instrument 120 of fixation system

100, which is later described. In other non-limiting embodiments, other similar instruments may be provided to be received within grooves 326 and 328.

Distal member 140 further includes a generally smooth portion 310 coupled to end 302. Portion 310 has a generally hexagonal shaped aperture 312, which opens into aperture 316 and
5 which longitudinally traverses through portion 310 in direction 301. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized. Circular aperture 316 has a diameter 314 that is slightly larger than external diameter 224 of portion 216 and 206 of proximal screw member 130, with portions 216 and 206 being
slidably received within aperture 316 of portion 310. Aperture 316 has a diameter that is smaller
10 than diameter 226 of bulbous portion 202.

Portion 310 of distal member 140 terminates into a second generally cylindrical portion 318 which has a plurality of threads 324, which are circumferentially disposed on the external surface of portion 318. Portion 318 has an internal circular aperture 326 which is longitudinally coextensive with portion 318 in direction 301. Circular aperture 326 aligns with aperture 312 to
15 form a continuous opening from end 302 to end 304.

As shown in Figure 4, instrument 120 is illustrated for coupling proximal screw member 130 to distal member 140. Particularly, instrument 120 includes a handle portion 402 coupled to a rod portion 404. Rod portion 404 emanates from handle portion 402 at end 406 and terminates into a rectangular planar portion 408 at end 410. Planar portion 408 is aligned along axis 401
20 and is fixably coupled to a generally cylindrical tubular portion 412 (i.e., an aiming device). Portion 412 traverses portion 408 from top surface 414 to bottom surface 416. Further, tubular portion 412 is aligned along dissimilar axis 403, forming an angle 405 with axis 401. Also,

tubular portion 412 has a through aperture 420 that longitudinally traverses portion 412 along axis 403.

Planar portion 408 is coupled to planar portion 422, with portion 422 having a width slightly smaller than width of portion 408. Portion 422 terminates into a generally “U-shaped” portion 424 with portion 424 being orthogonal to portion 422. Further, portion 424 has a plurality of substantially similar sides 426 and 428 which are provided to be slidably coupled to grooves 326 and 328 of distal member 140.

In operation, sides 426 and 428 of instrument 120 are received in respective grooves 326 and 328 of distal member 140, of Figures 3A-3B, thereby slidably coupling distal member 140 to instrument 120. In this position, axis 303 of aperture 316 is aligned along substantially the same axis as axis 403 of instrument 120. Proximal screw member 130 is coupled to distal member 140 by slidably coupling portions 206 and 216 through aperture 420 of tubular portion 412. Tubular portion 412 guides proximal screw member 130 through internal aperture 420 and into aperture 316 on surface 322 and may also guide a Kirschner wire (K wire) or a drill. Proximal screw member 130, of Figure 2, travels into bone as portions 216 and 206 travel further through aperture 316 at end 302 until bulbous portion 202 is restrained by surface 322 and end 302. Aperture 316, being tapered along axis 303, causes proximal screw member 130 to form an angle 150 with distal member 140, with proximal member 130 being aligned along an axis 303, which is substantially the same axis as axis 403 of tubular portion 412 of instrument 120.

In operation, and as best shown in Figures 5, 6 and 7, the fixation system 100 utilizes the intramedullary fixation assembly 110 for treating and fixating the deteriorated and damaged or fractured bones in the human foot 500. This restores the arch in a human foot 500 by coupling the intramedullary fixation assembly 110 to the human foot 500 of a left leg. In one-non limiting

example, and as shown in Figure 5, the intramedullary assembly 110 is coupled to the medullary canals of the first metatarsal 502, medial cuneiform 504, navicular 506 and talus bone 508.

Talus bone 508 makes up part of the ankle joint where the threaded portion 216 of the proximal screw member 130 of the intramedullary assembly 110 is threadably coupled. The medial

5 cuneiform 504 and navicular 506 bones are most affected by Diabetic Charcot foot disorder that causes deterioration and collapse of the arch of the foot 500. It should be appreciated that the intramedullary assembly 110 may be used within each of the five rays, with a ray representing a line drawn from each metatarsal bone to the talus. The angulation in the smaller rays will be smaller than the two rays (i.e., a line from the first and second metatarsal bones to the talus
10 bone). Also, the diameter of distal member 140 will decrease from the large ray to the small ray. In one non-limiting example, the angulation may be any angle greater than 90 degrees and less than 180 degrees. For example, the angle for the first ray may be 150-170 degrees and the angles for the other rays may be 160-175 degrees.

As shown in Figures 6 and 7, the intramedullary fixation assembly 110 may be utilized to
15 reconstruct an arch in a mid-foot region of a human foot 500. As shown, the method starts in step 700 and proceeds to step 702, whereby a Dorsal Lis Franc incision (i.e., mid-foot incision) (not shown) is made in foot 500 in order to gain access to the joint. In step 704, the joint capsule is separated by “Gunstocking” foot 500 in direction 601 (i.e., the foot 500 is bent mid-foot) to expose the articular surface 602 and the articulating cartilage is removed. Next, in step 706, the
20 intramedullary canal is reamed and the distal member 140 is inserted into the intramedullary canal (not shown) of the metatarsal 502. In other non-limiting embodiments, the distal member 140 may be inserted by impaction, by press fit, by reaming a hole in the intramedullary canal (not shown) or substantially any other similar strategy or technique.

Next, in step 708, the instrument 120 is coupled to the distal member 140 by coupling sides 426 and 428 of instrument 120 to respective grooves 326 and 328. In step 710, initial positioning of the proximal member 130 is assessed with the use of a guide wire through portion 412 (i.e., aiming device). Next, in step 712, a countersink drill is inserted through portion 412 and the proximal cortex is penetrated. In this step, a cannulated drill or guide wire is used to pre-drill the hole through the joints selected for fusion. In step 714, the proximal screw member 130 is inserted over the guide wire and into the distal member 140. Particularly, the proximal member 130 is inserted through tubular portion 412 (i.e., aiming device), causing proximal member 130 to travel through internal longitudinal aperture 420, into distal member 140 and further into bones 504, 506 and 508 until rigid connection with the tapered aperture 316 is made, thereby compressing the joint. In one non-limiting embodiment, a locking element (not shown) such as a plate or a washer is coupled to end 302 of the intramedullary fixation assembly 110 to further secure proximal threaded member 130 to distal member 140. Next, in step 716 the instrument 120 is removed and the dorsal Lis Franc (i.e., mid-foot) incision is closed. The method ends in step 718.

It should be appreciated that a plurality of intramedullary fixation assemblies, such as intramedullary fixation assembly 110, may be inserted into any of the bones of a foot 500 such as, but not limited to the metatarsal, cuneiform, calcaneus, cuboid, talus and navicular bones, in order to restore the natural anatomical shape of the arch of the foot 500. Thus, the fixation system 100, in one non-limiting embodiment, is utilized to couple the intramedullary fixation assembly 110 to the foot 500, which causes the metatarsal 504, medial cuneiform 504, navicular 506 and talus 508 bones to be aligned to the proper anatomical shape of an arch when assembled within foot 500. It should be appreciated that the intramedullary fixation assembly 110 is

delivered through a dorsal midfoot incision, thereby reducing the disruption to the plantar tissues and/or the metatarsal heads while at the same time minimizing the tension on the skin. This allows for improved wound closure, reduced operating room time, reduction in the number of incisions required and reduction in the total length of incisions. It should also be appreciated that
5 in other non-limiting embodiments, the intramedullary assembly 110 may be utilized with graft material (i.e., autograft, allograft or other biologic agent).

In an alternate embodiment, as shown in Figure 8, an intramedullary fixation assembly 800 is provided in order to apply intraosseous compression to bones. Particularly, the intramedullary fixation assembly 800 includes a tapered screw member 810 coupled to a lag
10 screw member 815 at a fixed acute angle for the internal fusion of the bones of the human foot 805, such as, for example, the calcaneus bone 820, the talus bone 825, and the cuboid bone 830. In other non-limiting embodiments, the intramedullary fixation assembly 800 may be utilized for any other appropriate use for the internal fixation of the other bones. It should be appreciated that the intramedullary fixation assembly 800 may be provided at several lengths for the internal
15 fixation of a variety of bone sizes in the human body.

Also as shown in Figure 9, the intramedullary fixation assembly 800 includes the tapered screw member 810 coupled to the lag screw member 815 at a fixed angle 905. The fixed angle 905 may be provided at various fixed angles depending on the bone segments that are being compressed. The fixed angle between the tapered screw member 810 and the lag screw member
20 815 causes the intramedullary fixation assembly 800 to “hook” into the bone segments and translates the compression applied to bone fragments across the members 810 and 815. It should be appreciated that in one non-limiting embodiment, the intramedullary fixation assembly 800 may be made from a Titanium material, although, in other non-limiting embodiments, the

intramedullary fixation assembly 800 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials. It should also be appreciated that the intramedullary fixation assembly 800 is locked at the fixed angle after insertion of the same into bone. The intramedullary fixation assembly 800 translates compression applied to bone fragments by the tapered screw member 810 and the lag screw member 815 into uniform compression through multi-point fixation.

As shown in Figure 10, lag screw member 815 is generally cylindrical in shape and has a first smooth exterior portion 1005 that extends from first bulbous portion 1010 to a second threaded portion 1015. Additionally, bulbous portion 1010 has a taper, such as a Morse taper, with a width that decreases from end 1030 in direction 1000. The Morse taper allows for a locked interference fit with tapered aperture 1130 (shown in Figure 11) when tapered bulbous portion 1010 resides within tapered aperture 1130, which will be shown and described below. Moreover, tapered bulbous portion 1010 is generally cylindrical in shape and has a generally hexagonal-shaped aperture 1035 aligned along axis 1002 traversing the longitudinal length of bulbous portion 1010. However, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Aperture 1035 is provided to transmit torque from bulbous portion 1010 to threaded portion 1015 as bulbous portion 1010 is rotated in a direction that causes a corresponding rotation of threaded portion 1015.

Further, lag screw member 815 has a first smooth exterior portion 1005 that has a uniform diameter 1025 from first end 1040 to second end 1045. Portion 1005 includes an internal aperture 1050 aligned along axis 1002 that traverses the longitudinal length of portion 1005 in direction 1000. Further, portion 1005 terminates into a threaded portion 1015. Threaded

portion 1015 includes an internal aperture 1055 aligned along axis 1002 that longitudinally traverses threaded portion 1015. Internal aperture 1055 being aligned on the same axis 1002 as apertures 1035 and 1055 cooperatively form a continuous opening (i.e., a cannula) from end 1030 of bulbous portion 1010 to end 1060 of threaded portion 1015. The continuous opening or
5 cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening to help guide and position the lag screw member 815 during insertion of the lag screw member 815. In other non-limiting embodiments, the lag screw member 815 may be provided without apertures 1050 and 1055 (i.e., the lag screw member 815 is solid).

Furthermore, threaded portion 1015 has a plurality of circular threads, such as threads
10 1065, which are circumferentially disposed on the external surface of threaded portion 1015. Threaded portion 1015 has a diameter 1020 that is substantially the same as diameter 1025 of portion 1005. Threaded portion 1015 may also be provided with a self-tapping leading edge 1070 to provide portion 1015 with the ability to remove bone material during insertion of lag screw member 815 into bone. It should be appreciated that the length of the lag screw member
15 815 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that the lag screw member 815 may be positioned at one angle inside the tapered screw member 810. Also, lag screw member 815 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

20 As shown in Figure 11, tapered screw member 810 is generally cylindrical in shape and has a smooth exterior portion 1105 that extends from a tapered portion 1110 to a threaded portion 1115. Tapered screw member 810 is aligned along longitudinal axis 1104, which is longitudinally coextensive with length of tapered screw member 810.

Further, tapered portion 1110 is generally tubular in shape and tapers from end 1120 to end 1125 (i.e. end 1120 has a diameter 1125 that decreases slightly in diameter from end 1120 in direction 1100). Further, first end 1120 has a tapered aperture 1130, which traverses tapered portion 1110 along axis 1102, which causes tapered aperture 1130 to emanate from surface 1135.

5 Axis 1102 is offset from longitudinal axis 1104 at an angle 1140. Moreover, tapered portion 1110 has a generally hexagonal-shaped aperture contained within portion 1110, which is aligned along axis 1104 and is provided to receive an instrument (not shown) for applying torque to tapered screw member 810. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope
10 of the invention. With tapered aperture 1130 being aligned along axis 1102, tapered aperture 1130 forms a fixed angle 1140 with longitudinal axis 1145. Fixed angle 1140 determines the angle for fixation of tapered screw member 810 with respect to lag screw member 815 (shown in figure 10). It should be appreciated that fixed angle 1140 may be any angle less than 90 degrees to allow a surgeon the flexibility of determining the angle for internal fixation of bones in the
15 human body. It should also be appreciated that tapered aperture 1130 when combined with tapered bulbous portion 1010, shown in Figure 10, creates a locked interference fit between tapered screw member 815 and lag screw member 815.

Further, tapered screw member 810 has a smooth exterior portion 1105 that has a uniform diameter 1145 from end 1125 to end 1150. Tapered screw member 810 is generally solid,
20 however, in other non-limiting embodiments, screw member 810 may be cannulated. Further, portion 1105 terminates into a threaded portion 1115. Threaded portion 1115 is generally solid and includes a plurality of circular threads, such as threads 1155, which are circumferentially disposed on the external surface of threaded portion 1115. Threaded portion 1115 has a diameter

1160 that is substantially the same as diameter 1145 of portion 1105. Threaded portion 1115 may also be provided with a self-tapping leading edge 1165 to provide portion 1115 with the ability to remove bone material during insertion of tapered screw member 810 into bone. It should be appreciated that the length of the tapered screw member 810 may be selected of
5 varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that tapered screw member 810 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figures 8 and 12, the intramedullary fixation assembly 800 may be utilized
10 to apply compression, for example to the bones in a human foot through an acute angle fixation of the tapered screw member 810 to the lag screw member 815. As shown, the method starts in step 1200 and proceeds to step 1205, whereby a central incision is made in the hind-foot region of foot 805. Next, in step 1210, a pilot hole is drilled into the calcaneus 820 and the cuboid 830 bones. In this step, a countersink drill is inserted a cannulated drill or guide wire is used to pre-
15 drill the hole through the joints selected for fusion. Next, in step 1215, tapered screw member 810 is inserted into the intraosseous intramedullary canal (not shown) of the calcaneus 820. In other non-limiting embodiments, the tapered screw member 810 may be inserted by impaction, by press fit, by reaming a hole in the intramedullary canal (not shown) or substantially any other similar strategy or technique.

20 Next, in step 1220, the final position of the tapered screw member 810 is aligned so that the coupling of the lag screw member 815 forms a predetermined angle with the tapered screw member 810. In step 1225, align a guide through tapered aperture 1130 at surface 1135 and pre-drill a hole through the joint substantially along axis 1102. Next, in step 1230, insert a K-wire

(not shown) into the pre-drilled hole and into the tapered screw member 810 so that the K-wire makes an acute angle with the tapered screw member 810. Next, in step 1235, the lag screw member 815 is rotated and inserted over the K-wire and into the calcaneus bone 820 so that the K-wire guides the lag screw member 815. The K-wire, in assisting the lag screw member 815, penetrates end 1060 and emanates from end 1030. In some non-limiting embodiments, the lag member 815 may be inserted by impaction, by press fit, or substantially any other similar strategy or technique. Next, in step 1240, the K-wire is removed and the incision is closed. The method ends in step 1245.

In an alternate embodiment, as shown in Figure 13, an intramedullary fixation assembly 1300 is provided for the internal fixation of bones in a human hand 1305. Particularly, the intramedullary fixation assembly 1300 is substantially the same as the intramedullary fixation assembly 800 of the embodiment shown and described in Figure 8. The intramedullary fixation assembly 1300 includes a tapered screw member 1310 forming a fixed acute angle with the lag screw member 1315. The fixed acute angle is predetermined and the angle may be selected up to 90 degrees by, in one example, a surgeon to provide for the internal fixation of the bones in the human hand 1305, such as for example the radius 1320 and ulna 1325.

In another alternate embodiment, as shown in Figure 14, an intramedullary fixation assembly 1400 may be provided to vary the acute angle between 0 and 90 degrees after insertion of the intramedullary fixation assembly 1400. Particularly, the intramedullary fixation assembly 1400 includes a polyaxial screw member 1410 coupled to a lag screw member 1415 and forming an angle 1405 between the two members 1410 and 1415. The angle 1405 between the polyaxial screw member 1410 and the lag screw member 1415 causes the intramedullary fixation assembly 1400 to “hook” into the bone segments and translates the compression applied to bone fragments

across the members 1410 and 1415. It should be appreciated that the intramedullary fixation assembly 1400 may be provided at several lengths for the internal fixation of a variety of bone sizes in the human body. It should also be appreciated that in one non-limiting embodiment, the intramedullary fixation assembly 1400 may be made from a Titanium material, although, in other non-limiting embodiments, the intramedullary fixation assembly 1400 may be made from SST, PEEK, NiTi, Cobalt chrome or other similar types of materials.

As shown in Figure 15, lag screw member 1415 is generally cylindrical in shape and has a first smooth exterior portion 1505 that extends from first bulbous portion 1510 to a second threaded portion 1515. Bulbous portion 1510 is generally semispherical in shape and has a diameter 1500 that is slightly larger than the internal diameter of aperture 1630 (shown in figure 16), which is provided to receive bulbous portion 1510. The bulbous portion 1510 resides within the internal aperture 1630 (shown in Figure 16) and provides for rotational movement of both the polyaxial screw member 1410 and the lag screw member 1415 at various angles between 0 and 90 degrees after insertion of the intramedullary fixation assembly 1400. Also, bulbous portion 1510 has a generally hexagonal-shaped aperture 1535 aligned along axis 1502 traversing the longitudinal length of bulbous portion 1510. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Aperture 1535 is provided to transmit torque from bulbous portion 1510 to threaded portion 1515 as bulbous portion 1510 is rotated in a direction that causes a corresponding rotation of threaded portion 1515. It should also be appreciated that axis 1502 is longitudinally coextensive with the length of lag screw member 1415.

Further, lag screw member 1415 has a first smooth exterior portion 1505 of a uniform diameter 1525 from first end 1540 to second end 1545. Portion 1505 includes an internal

aperture 1550 aligned along axis 1502 that traverses the longitudinal length of portion 1505 along direction 1504. Further, portion 1505 terminates into the threaded portion 1515. Threaded portion 1515 also includes an internal aperture 1555 aligned along axis 1502 that longitudinally traverses threaded portion 1515. Internal aperture 1555 being aligned along the same axis 1502 as apertures 1535 and 1555 cooperatively form a continuous opening (i.e., a cannula) from bulbous portion 1510 to end 1560 of threaded portion 1515. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the continuous opening to help guide and position the lag screw member 1415 during insertion into bone. In other non-limiting embodiments, the lag screw member 1415 may be provided without apertures 1550 and 1555 (i.e., the lag screw member 1415 is non-cannulated or solid).

Furthermore, threaded portion 1515 has a plurality of circular threads, such as threads 1565, which are circumferentially disposed on the external surface of threaded portion 1515. Threaded portion 1515 has a diameter 1520 that is substantially the same as diameter 1525 of portion 1505. Threaded portion 1515 may also be provided with a self-tapping leading edge (not shown) to provide portion 1515 with the ability to remove bone material during insertion of lag screw member 1415 into bone. It should be appreciated that the length of the lag screw member 1415 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. Also, lag screw member 1415 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figure 16, polyaxial screw member 1410 is generally cylindrical in shape and has a smooth exterior portion 1605 that extends from portion 1610 to a threaded portion

1615. Polyaxial screw member 1410 is aligned along longitudinal axis 1604, which is longitudinally coextensive with length of polyaxial screw member 1410.

Further, portion 1610 is generally tubular in shape having a uniform diameter, which is slightly larger than diameter of aperture 1630 causing portion 1610 to abut the interior surface of portion 1610 at aperture 1630. However, in other non-limiting embodiments, portion 1610 may be tapered going from a larger diameter to a smaller diameter as we traverse portion 1610 along direction of axis 1600. Further, portion 1610 has a plurality of apertures 1620 and 1630 of dissimilar diameters. Aperture 1630 is a through aperture and is tapered along axis 1602, causing aperture 1630 to emanate from surface 1635. On the other hand, aperture 1620 is longitudinally disposed along axis 1604 and has a generally hexagonal shaped aperture, although in other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shapes aperture may be utilized. Aperture 1630 is offset from axis 1604 at an angle 1640. Angle 1640 determines the angle for rotation of lag screw member 1415 when bulbous portion 1510 (shown in Figure 15) resides in aperture 1630 with lag screw member 1415 rotating angularly around axis 1602. It should be appreciated that angle 1640 may be any angle less than 90 degrees to allow a surgeon the flexibility of fixing the rotation of polyaxial screw member 1410 and lag screw member 1415.

Further, polyaxial screw member 1410 has a smooth exterior portion 1605 having a uniform diameter from end 1625 to end 1650. The diameter of exterior portion 1605 is smaller than the diameter of aperture 1630. Polyaxial screw member 1410 is generally solid, however, in other non-limiting embodiments, polyaxial screw member 1410 may be cannulated. Further, portion 1605 terminates into a threaded portion 1615. Threaded portion 1615 is generally solid and includes a plurality of circular threads, such as threads 1655, circumferentially disposed on

the external surface of threaded portion 1615. Threaded portion 1615 has a uniform diameter that is slightly larger than the diameter of portion 1605. However, in other non-limiting embodiments, the respective diameters of portions 1605 and 1615 may be substantially the same. Threaded portion 1615 may also be provided with a self-tapping leading edge (not shown) to provide portion 1615 with the ability to remove bone material during insertion of proximal screw member 1410 into bone. It should be appreciated that the length of the proximal screw member 1410 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that polyaxial screw member 1410 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

In another alternate embodiment, as shown in Figure 17, length of the polyaxial screw member 1710 may be varied in order to accommodate the intramedullary fixation assembly 1700 in bones of various sizes. Particularly, the polyaxial screw member 1710 includes a smooth end portion 1720 coupled directly to a threaded portion 1725, thereby varying the angle 1705 that is formed between the polyaxial screw member 1710 and the lag screw member 1715. In all other respects, the intramedullary fixation assembly 1700 is substantially similar to the intramedullary fixation assembly 1400 as was shown and described in Figure 14.

In another alternate embodiment, as shown in Figure 18, an intramedullary fixation assembly 1800 having a plurality of lag screw members 1805 and 1810 coupled to a tapered screw member 1815 is provided in order to apply compression at multiple points on the bone fragment surface. Particularly, the lag screw members 1805 and 1810, and the tapered screw member 1815 are substantially similar to the lag screw member 815 and tapered screw member 810 respectively shown and described in the embodiment of Figures 8-11. Each of the lag screw

members 1805 and 1810 forms an fixed acute angle with the tapered screw member 1815, with these angles being predetermined by, for example, a surgeon to fix the bones in a human body.

As shown, tapered screw member 1815 is generally cylindrical in shape and has a smooth exterior portion 1820 that extends longitudinally along axis 1806 from end 1825 to a threaded portion 1830. Further, end 1825 has a tapered aperture 1835, which is aligned on axis 1802 and forms a fixed angle 1808 with axis 1806. Fixed angle 1808 determines the angle for fixation of tapered screw member 1810 with respect to lag screw member 1805. Also, tapered screw member 1815 has a second tapered aperture 1840, aligned along axis 1804 and forms a fixed angle 1812 with axis 1804. The fixed angle 1812 determines the angle for fixation of lag screw member 1810 with tapered screw member 1815. It should be appreciated that fixed angles 1808 and 1812 may be any angle less than 90 degrees to allow a surgeon the flexibility of determining the angle for internal fixation of bones in the human body. It should also be appreciated that tapered screw member 1815 creates a locked interference fit with each of the lag screw members 1805 and 1810.

Further, tapered screw member 1815 has a smooth exterior portion 1820 having a uniform diameter from end 1825 to threaded portion 1830. Tapered screw member 1815 is generally solid, however, in other non-limiting embodiments, screw member 1815 may be cannulated. Further, threaded portion 1830 is generally solid and includes a plurality of circular threads circumferentially disposed on the external surface of threaded portion 1830. Threaded portion 1830 may also be provided with a self-tapping leading edge to provide portion 1830 with the ability to remove bone material during insertion of tapered screw member 1815 into bone. It should be appreciated that the length of the tapered screw member 1815 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be

appreciated that tapered screw member 1815 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

Also as shown in Figure 18, each of the respective lag screw members 1805 and 1810 are substantially similar to the lag screw member of the embodiment shown and described in Figure 10. Particularly, lag screw member 1805 is generally cylindrical in shape and has a first smooth exterior portion 1845 that extends from bulbous portion 1850 to a threaded portion 1855, while lag screw member 1810 has a smooth exterior portion 1860 that extends from bulbous portion 1865 to threaded portion 1870. Additionally, each of the bulbous portions 1850 and 1865 have a taper, such as a Morse taper, that provides for a locked interference fit with tapered apertures 1835 and 1840 respectively.

In an alternate embodiment, as shown in Figure 19, a lag screw member 1900 may include a cover or plug member 1905. The cover member 1905 includes a first end portion 1910 having substantially the same diameter as end portion 1915. The cover member 1905 also includes a second end portion 1920, which is smaller than the internal diameter of end portion 1915 and which is provided to be received inside aperture 1925 of lag screw member 1900.

In other alternate embodiments, as shown in Figures 20A-21B, an intramedullary fixation assembly having interconnected members is provided for intraosseous fixation and to apply an acute angle compression to bones. In particular, intramedullary fixation assembly 2000 (Figures 20A-20B) is provided for applying compression to bones at an acute angle, which is at a variable or an intramedullary fixation assembly 2100 (Figures 21A-21B) is provided for applying compression to bones at a predetermined and fixed acute angle. Further, the interconnected members of each of the intramedullary fixation assemblies 2000 or 2100 may be made from a

Titanium material, although, in other non-limiting embodiments, either of these intramedullary fixation assemblies 2000 or 2100 may be made from SST, PEEK, NiTi, Cobalt Chrome or other similar types of materials

As shown in Figures 20A-20B, intramedullary fixation assembly 2000 is provided to
5 apply compression at an acute angle that is variable between 0 and 90 degrees prior to compression, after which compression is applied to set the angle of fixation. Particularly, the intramedullary fixation assembly 2000 includes a hybrid screw member 2005 aligned along longitudinal axis 2007 and being coupled to a polyaxial screw member 2010, with the hybrid screw member 2005 forming an acute angle 2015 with the longitudinal axis 2012 of polyaxial
10 screw member 2010. The acute angle 2015 between the hybrid screw member 2005 and the polyaxial screw member 2010 causes the intramedullary fixation assembly 2000 to “hook” into bone segments and translates the compression applied to these bone segments across the members 2005 and 2010. The hybrid screw member 2005 is described in the embodiment shown in Figures 22A-22B.

15 The polyaxial screw member 2010, shown in Figures 20A-20B, is substantially similar to the lag screw member 1415 shown and described in Figure 15, and includes a generally cylindrically-shaped longitudinal body 2020 that extends from a bulbous portion 2025 to a threaded portion 2030. The threaded portion 2030 has a plurality of helical threads on the external surface of threaded portion 2030. The threaded portion 2030 may also be provided with
20 a self-tapping leading edge 2045 (Figure 20A) for removing bone material during insertion of the polyaxial screw member 2010 into bone. Polyaxial screw member 2010 has several widths as we traverse its length, with a first diameter at body 2020 for allowing the body 2020 to traverse aperture 2230 (Figure 22A-22B), while bulbous portion 2025 has a second diameter or width for

causing the portion 2025 to abut the head portion 2205 (Figures 22A-22B) and restrain the polyaxial screw member against the hybrid screw member 2005. The bulbous portion 2025 is provided for rotational movement of polyaxial screw member 2010 along its longitudinal axis at various angles less than 90 degrees with respect to the hybrid screw member 2005 after insertion of the polyaxial screw member 2010 into the hybrid screw member 2005, however prior to applying compression. Also, bulbous portion 2025 has a generally hexagonal-shaped aperture 2040 (Figure 20B) residing within the bulbous portion 2025 and being aligned along the longitudinal axis of polyaxial screw member 2010. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be provided without departing from the scope of the invention. Aperture 2040 is provided to transmit torque from bulbous portion 2025 to threaded portion 2030 as bulbous portion 2025 is rotated with a complementary shaped tool in a direction that causes a corresponding rotation of threaded portion 2030. In one embodiment, polyaxial screw member 2010 is non-cannulated or solid, although in another non-limiting embodiment, the polyaxial screw member 2010 is cannulated (i.e., screw member 2010 has a continuous internal opening longitudinally coextensive with the length of the polyaxial screw member 2010). It should be appreciated that the length of the polyaxial screw member 2010 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should also be appreciated that the polyaxial screw member 2010 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar type of porous material that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figures 21A-21B, intramedullary fixation assembly 2100 is provided to apply compression at an acute angle that is fixed at a predetermined angle between 0 and 90

degrees depending on the bone segments that are being compressed. As shown, the intramedullary fixation assembly 2100 includes a hybrid screw member 2005 aligned along axis 2107 and being coupled to a tapered screw member 2105 that is aligned along axis 2109, with the hybrid screw member 2005 forming an acute angle 2110 with the tapered screw member 2105. The acute angle 2110 is fixed at a predetermined angle, and similarly, causes the intramedullary fixation assembly 2100 to “hook” into the bone segments and translates the compression applied to bone fragments into uniform compression through multi-point fixation. As previously stated, the hybrid screw member 2005 is described in the embodiment shown in Figures 22A-22B.

The tapered screw member 2105, shown in Figures 21A-21B, is substantially similar to the lag screw member 815 shown and described in Figure 10, and includes a generally cylindrically-shaped body 2115 that longitudinally extends from a bulbous portion 2120 to a threaded portion 2125. Threaded portion 2125 has a plurality of helical threads on an external surface of the threaded portion 2125. The threaded portion 2125 may also be provided with a self-tapping leading edge 2150 (Figure 21A) for removing bone material during insertion of the tapered screw member 2105 into bone. The bulbous portion 2120 has a taper, such as a Morse taper, with a width that decreases from end 2130 to end 2135 (i.e., tapered portion has a slope in direction 2140). Additionally, body 2115 has a diameter for allowing the body 2115 to traverse the plurality of aperture 2230 (shown in Figures 22A-22B), while the Morse taper on bulbous portion 2120 allows for a locked interference with internal surface 2245 (shown in Figures 22A-22B) at a fixed angle between 0 and 90 degrees. Also, bulbous portion 2120 has a generally hexagonal-shaped aperture 2145 (Figure 21B) residing within bulbous portion 2120 and being aligned along the longitudinal axis 2109 of tapered screw member 2105. In other non-limiting

embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. Aperture 2145 is provided to transmit torque from bulbous portion 2120 to threaded portion 2125 as bulbous portion 2120 is rotated with a complementary shaped tool, received within aperture 2145, in a direction that causes a corresponding rotation of threaded portion 2125. In one embodiment, tapered screw member 2105 is non-cannulated or solid, although in another non-limiting embodiment, the tapered screw member 2105 is cannulated (i.e., screw member 2105 has a continuous internal opening longitudinally coextensive with the length of tapered screw member 2105). It should be appreciated that the length of the tapered screw member 2105 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should also be appreciated that the tapered screw member 2105 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar type of porous material that is capable of supporting or encouraging bone ingrowth into this material.

As shown in Figures 22A-22B, hybrid screw member 2005 is generally cylindrical in shape and has a head portion 2205 coupled to a threaded portion 2210. The hybrid screw member 2005 is aligned along longitudinal axis 2215, which is longitudinally coextensive with length of hybrid screw member 2005. The threaded portion 2210 has a uniform diameter and includes a plurality of helical threads on an external surface of portion 2210. Threaded portion 2210 may also be provided with a self-tapping leading edge 2270 for removing bone material during insertion of the hybrid screw member 2005 into bone.

Further, head portion 2205 is generally tubular in shape and has a generally tapered external surface from first end 2220 to second end 2225 (i.e. head portion 2205 decreases slightly in diameter from end 2220 to end 2225). Also, head portion 2205 has a central aperture

or bore 2230 that is aligned along axis 2235, with central aperture 2230 forming an acute angle 2265 with longitudinal axis 2215 (i.e., central aperture 2230 extends from a first surface 2275 (Figure 22B) to opposed surface 2280 (Figure 22B) along axis 2235). The central aperture 2230 is formed from a plurality of apertures formed on the internal surface of the head portion 2205.

- 5 Particularly, internal surface 2240 has a spherical radius that defines a first aperture within the central aperture 2230 while internal surface 2245 has a second radius that defines a second aperture 2230 within central aperture 2230. The internal surface 2240 is provided to receive the bulbous portion 2025 of polyaxial screw member 2010 (Figures 20A-20B) and surface 2245 is provided to receive bulbous portion 2120 of tapered screw member 2105 (Figures 22A-22B).
- 10 Additionally, internal surface 2245 has a taper that decreases from first surface 2275 (Figure 22B) in direction 2250. It should be appreciated that the taper on internal surface 2245 is provided to receive bulbous portion 2120 in order to cause bulbous portion 2120 to create a locked interference fit with internal surface 2245 and align the hybrid screw member 2005 and the tapered screw member 2105 (Figures 21A-21B) along this axis 2235. It should also be
- 15 appreciated that the bulbous portion 2025 (Figures 20A-20B) is restrained at internal surface 2245, while the threaded portion 2030 (Figures 20A-20B) may rotate in a circumference that is orthogonal to the axis 2235, with this polyaxial screw member 2010 maintaining its acute angle position with respect to the hybrid screw member 2005. The angle 2265 may predetermined to be any angle less than 90 degrees to allow a surgeon the flexibility of setting the angle for
- 20 compression as well the flexibility of fixing bones of various sizes.

Further, head portion 2205 has a generally hexagonal shaped aperture 2255 (Figure 22B) residing within head portion 2205 and being aligned along the longitudinal axis 2215. In other non-limiting embodiments, a star-shaped aperture, a square-shaped aperture, or any other shaped

aperture may be utilized without departing from the scope of the invention. Aperture 2255 is accessible at one end through aperture 2230 and is also coupled at a second end to longitudinal aperture 2260, which is longitudinally coextensive with threaded portion 2210 from end 2220 to end 2265 (i.e., hybrid screw member 2005 is cannulated). Aperture 2255 is provided to transmit torque from head portion 2205 to threaded portion 2210 as head portion 2205 is rotated when a complementary shaped tool is received in aperture 2255 and rotated in a direction that causes a corresponding rotation of threaded portion 2210. It should be appreciated that the length of the hybrid screw member 2005 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should also be appreciated that hybrid screw member 2005 may be coated with an osteoconductive material, such as, for example, plasma spray or other similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

In operation, and as best shown in Figures 20A-22B, each of the intramedullary fixation assemblies 2000 and 2100 may be utilized for treating and fusing the deteriorated, damaged or fractured bones in the human body (not shown). In one non-limiting example, an incision is made in the foot to access the bones in the foot, and a first medullary canal is drilled in a first bone. The hybrid screw member 2005 (Figure 22A) is inserted into the first medullary canal by coupling a complementary shaped tool into the hexagonal shaped aperture 2255 (Figure 22B) and rotating the hybrid member 2005 to cause the member 2005 to travel into bone and reside substantially within the bone. The position of the hybrid screw member 2005 is assessed and adjustments may be made with respect to the position of the aperture 2230 (Figures 22a-22B). Further, a second medullary canal is drilled in the first bone or another adjacent bone at a predetermined acute angle. In one non-limiting embodiment, a polyaxial screw member 2010

(Figures 20A-20B) is selected and inserted into the hybrid screw member 2005 at a predetermined angle selected by a surgeon, although in another embodiment, the tapered screw member 2105 (Figures 21A-21B) may be selected and inserted into the hybrid screw member 2005 (Figures 21A-21B). The polyaxial screw member 2010 is inserted into the hybrid screw member 2005 (Figures 20A-20B) by inserting the threaded portion 2030 (Figures 20A-20B) into the aperture 2230 (Figure 22B) and into the second medullary canal by coupling a complementary shaped tool in hexagonal shaped aperture 2040 (Figure 20B) and rotating polyaxial screw member 2010 to cause polyaxial screw member 2010 to travel into the second medullary canal until bulbous portion 2025 (Figure 20A) abuts internal surface 2240. The polyaxial screw member 2010 is further rotated to apply compression to the polyaxial screw member 2010 to lock the polyaxial screw member 2010 to the hybrid screw member 2005, thereby fusing the damaged or deteriorated bones.

It should be appreciated that the intramedullary fixation assembly 2000 is provided to be inserted into, for example, the joints of the human foot by incorporating either a polyaxial screw member 2010 or a tapered screw member 2105 so as to provide for acute angle compression of these joints. It should also be appreciated that the intramedullary fixation assembly 2000 is delivered through an incision and is provided to be substantially within the bone (i.e., intraosseous), thereby reducing the disruption to the plantar tissues while at the same time minimizing the tension on the skin. This allows for improved wound closure, reduced operating room time, reduction in the number of incisions required and reduction in the total length of incisions. It should also be appreciated that in other non-limiting embodiments, the intramedullary assembly 2000 may be utilized with graft material (i.e., autograft, allograft or other biologic agent).

It should also be understood that this invention is not limited to the disclosed features and other similar method and system may be utilized without departing from the spirit and the scope of the invention.

While the invention has been described with reference to the preferred embodiment and
5 alternative embodiments, which embodiments have been set forth in considerable detail for the purposes of making a complete disclosure of the invention, such embodiments are merely exemplary and are not intended to be limiting or represent an exhaustive enumeration of all aspects of the invention. The scope of the invention, therefore, shall be defined solely by the following claims. Further, it will be apparent to those of skill in the art that numerous changes
10 may be made in such details without departing from the spirit and the principles of the invention. It should be appreciated that the invention is capable of being embodied in other forms without departing from its essential characteristics.

IN THE CLAIMS:

1. An intramedullary fixation assembly for bone fusion, comprising:

a hybrid screw member aligned along a longitudinal axis, wherein the hybrid screw

5 member comprises a first shaft, and a head portion comprising a first aperture coupled to a second aperture; and

a lag screw member comprising a second shaft, a bulbous portion, and a threaded portion;

wherein the first aperture has a first spherical radius and the second aperture is tapered and has a second radius; and

10 wherein the lag screw member is adapted to be inserted into each of the first and the second apertures.

2. The intramedullary fixation assembly of claim 1, wherein the first and the second apertures cooperate to form a bore through the head portion.

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3. The intramedullary fixation assembly of claim 1, wherein the lag screw member is at a fixed angle to the hybrid screw member.

4. The intramedullary fixation assembly of claim 1, wherein the fixed angle is an acute

20 angle.

5. The intramedullary fixation assembly of claim 1, wherein the bulbous portion comprises a taper for providing an interference lock with the second aperture.

6. The intramedullary fixation assembly of claim 3, wherein the bulbous portion is spherical for coupling the lag screw member at a variable angle.

7. The intramedullary fixation assembly of claim 6, wherein compression is applied at the
5 variable angle.

8. The intramedullary fixation assembly of claim 1, wherein the hybrid screw member further comprises a first threaded portion aligned along the first shaft and opposed to the head portion.

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9. The intramedullary fixation assembly of claim 8, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

10. The intramedullary fixation assembly of claim 8, wherein the first threaded portion
15 includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the hybrid screw member.

11. The intramedullary fixation assembly of claim 1, wherein the hybrid screw member further comprises an orifice aligned along the longitudinal axis less than the entirety of the shaft.

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12. The intramedullary fixation assembly of claim 11, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

13. The intramedullary fixation assembly of claim 11, wherein the orifice is provided to receive a complementary shaped end of an instrument.

14. The intramedullary fixation assembly of claim 1, wherein the lag screw member is
5 cannulated.

15. The intramedullary fixation assembly of claim 1, wherein the lag screw member further comprises a second threaded portion aligned along the second shaft and opposed to the bulbous portion.

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16. The intramedullary fixation assembly of claim 15, wherein the second threaded portion contains a plurality of bone threads on an outer surface of the second threaded portion.

17. The intramedullary fixation assembly of claim 15, wherein the second threaded portion
15 includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the lag screw member.

18. The intramedullary fixation assembly of claim 1, wherein the lag screw member further comprises a second orifice aligned along a second longitudinal axis for less than the entirety of
20 the second shaft.

19. The intramedullary fixation assembly of claim 18, wherein the second orifice has a hexagonal shape, a star shape, or a square shape.

20. The intramedullary fixation assembly of claim 18, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

21. A method for fusing bones, comprising:

5 providing an intramedullary fixation assembly, wherein the intramedullary assembly further comprises:

a hybrid screw member aligned along a longitudinal axis, wherein the hybrid screw member further comprises a first shaft and a head portion comprising a first aperture coupled to a second aperture; and

10 a lag screw member comprising a second shaft, a bulbous portion, and a threaded portion;

wherein the first aperture has a first spherical radius and the second aperture is tapered and has a second radius;

making an incision, wherein the incision is made to access a plurality of bones;

15 drilling a first medullary canal in at least a first bone;

inserting the hybrid screw member into the first medullary canal;

aligning the hybrid screw member in the first medullary canal;

drilling a second medullary canal in a second bone;

coupling the lag screw member to the hybrid screw member;

20 inserting the lag screw member into the second medullary canal;

applying compression to the lag screw member to lock the hybrid screw member to the lag screw member, thereby fusing the first bone to the second bone.

22. The method of claim 21, wherein the lag screw member is coupled to the hybrid screw member and makes a fixed angle with the hybrid screw member.

23. The method of claim 22, wherein the fixed angle is an acute angle.

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24. The method of claim 21, wherein the lag screw member is adapted to be inserted into each of the first and the second apertures.

25. The method of claim 21, wherein the first and the second apertures cooperate to form a
10 bore through the head portion.

26. The method of claim 21, wherein the bulbous portion comprises a taper for providing an interference lock with the second aperture.

15 27. The method of claim 21, wherein the bulbous portion is spherical for coupling the lag screw member at a variable angle.

28. The method of claim 27, wherein compression is applied at the variable angle.

20 29. The method of claim 21, wherein the hybrid screw member further comprises a first threaded portion aligned along the first shaft and opposed to the head portion.

30. The method of claim 29, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

31. The method of claim 29, wherein the first threaded portion includes a self-tapping edge,
5 wherein the self-tapping edge provides for removal of bone material during insertion of the hybrid screw member.

32. The method of claim 21, wherein the hybrid screw member further comprises an orifice aligned along the longitudinal axis less than the entirety of the shaft.

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33. The method of claim 32, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

34. The method of claim 32, wherein the orifice is provided to receive a complementary
15 shaped end of an instrument.

35. The method of claim 21, wherein the lag screw member is cannulated.

36. The method of claim 21, wherein the lag screw member further comprises a second
20 threaded portion aligned along the second shaft and opposed to the bulbous portion.

37. The method of claim 36, wherein the second threaded portion contains a plurality of bone threads on an outer surface of the second threaded portion.

38. The method of claim 36, wherein the second threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the lag screw member.

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39. The method of claim 21, wherein the lag screw member further comprises a second orifice aligned along a second longitudinal axis for less than the entirety of the second shaft.

40. The method of claim 39, wherein the second orifice has a hexagonal shape, a star shape,
10 or a square shape.

41. The method of claim 39, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

15 42. An intramedullary fixation assembly for bone fusion, comprising:

a hybrid screw member aligned along a longitudinal axis, wherein the hybrid screw member comprises a first shaft, a threaded portion, and a head portion comprising a first internal surface having a first spherical radius and a second internal surface having a second radius; and

a lag screw member comprising a second shaft, a bulbous portion, and a threaded portion;
20 wherein the first internal surface is coupled to the second internal surface to enclose a bore extending through the head portion along a bore axis;

wherein the second internal surface is tapered;

wherein the lag screw member is adapted to be inserted into bore and forms an acute angle with the longitudinal axis.

43. The intramedullary fixation assembly of claim 42, wherein the bulbous portion is spherical for coupling the bulbous portion at a variable acute angle.

44. The intramedullary fixation assembly of claim 42, wherein the bulbous portion is tapered for providing an interference lock with the second internal surface.

45. The intramedullary fixation assembly of claim 42, wherein the hybrid screw member further comprises a first threaded portion aligned along the first shaft and opposed to the head portion.

46. The intramedullary fixation assembly of claim 45, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

47. The intramedullary fixation assembly of claim 45, wherein the first threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the hybrid screw member.

48. The intramedullary fixation assembly of claim 42, wherein the hybrid screw member further comprises an orifice aligned along the longitudinal axis less than the entirety of the shaft.

49. The intramedullary fixation assembly of claim 48, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

50. The intramedullary fixation assembly of claim 49, wherein the orifice is provided to
5 receive a complementary shaped end of an instrument.

51. The intramedullary fixation assembly of claim 42, wherein the lag screw member is cannulated.

10 52. The intramedullary fixation assembly of claim 42, wherein the lag screw member further comprises a second threaded portion aligned along the second shaft and opposed to the bulbous portion.

53. The intramedullary fixation assembly of claim 52, wherein the second threaded portion
15 contains a plurality of bone threads on an outer surface of the second threaded portion.

54. The intramedullary fixation assembly of claim 52, wherein the second threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the lag screw member.

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55. The intramedullary fixation assembly of claim 42, wherein the lag screw member further comprises a second orifice aligned along a second longitudinal axis for less than the entirety of the second shaft.

56. The intramedullary fixation assembly of claim 55, wherein the second orifice has a hexagonal shape, a star shape, or a square shape.

5 57. The intramedullary fixation assembly of claim 55, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

ABSTRACT

An intramedullary assembly for intraosseous bone fusion includes a hybrid screw member and a lag screw member. The hybrid screw member is aligned along a longitudinal axis, and includes a first shaft, a threaded portion, and a head portion having a first internal surface of a first spherical radius and a second tapered internal surface of a second radius. The first internal surface is coupled to the second internal surface to enclose a bore extending through the head portion along a bore axis. The lag screw member includes a second shaft, a bulbous portion, and a threaded portion. The lag screw member is adapted to be inserted into bore and forms an acute angle with the longitudinal axis.

10

FIG. 1

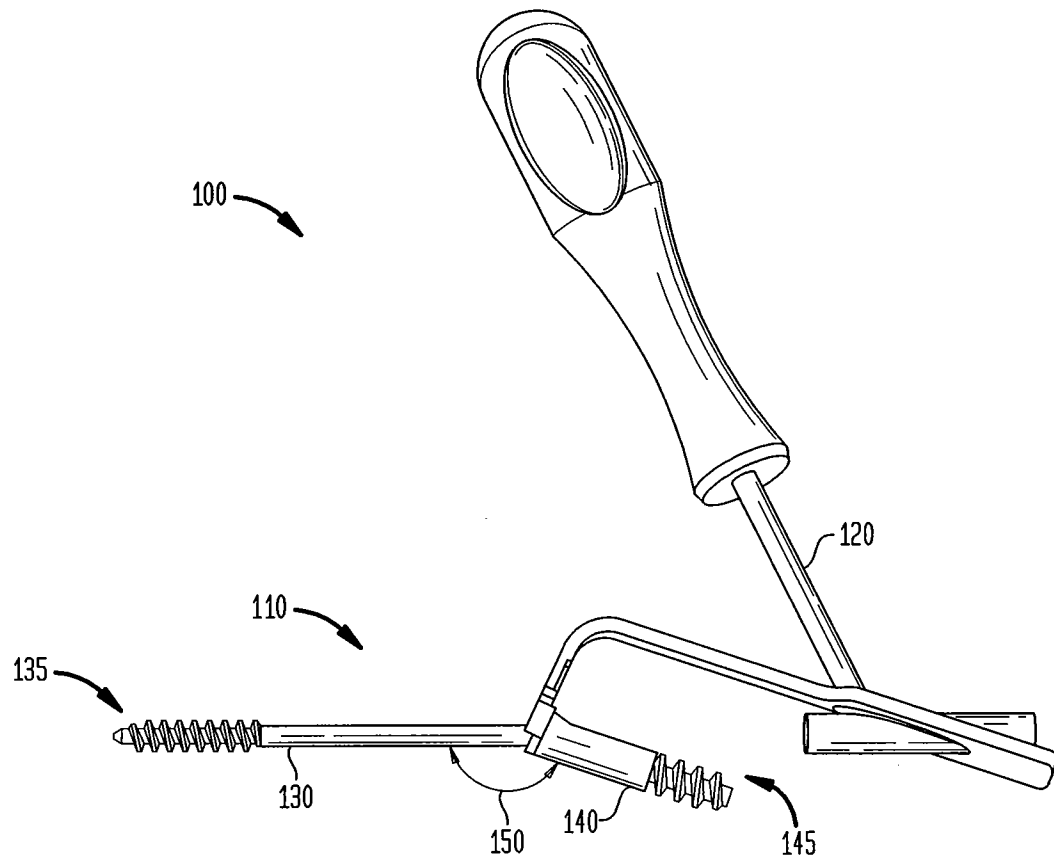


FIG. 2

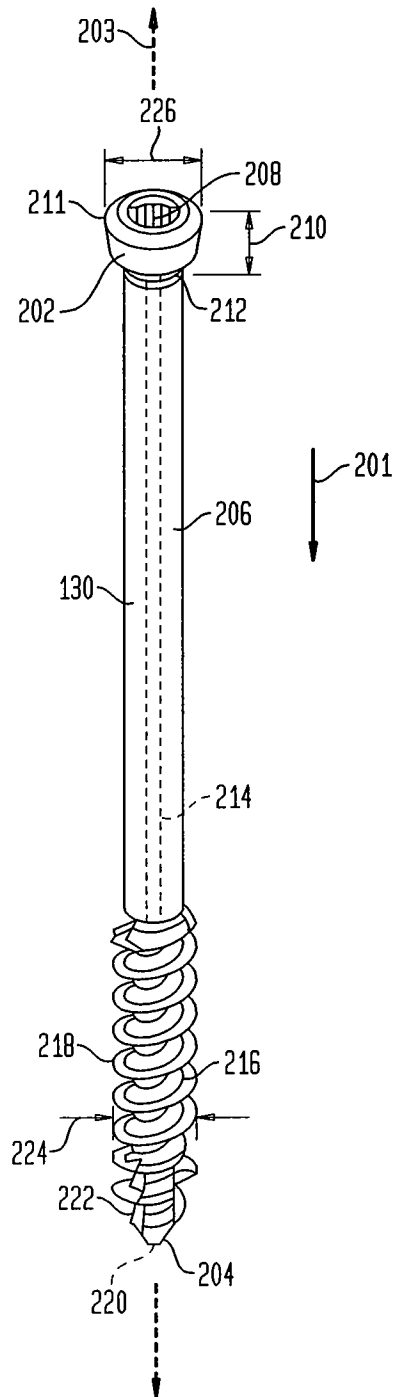


FIG. 3A

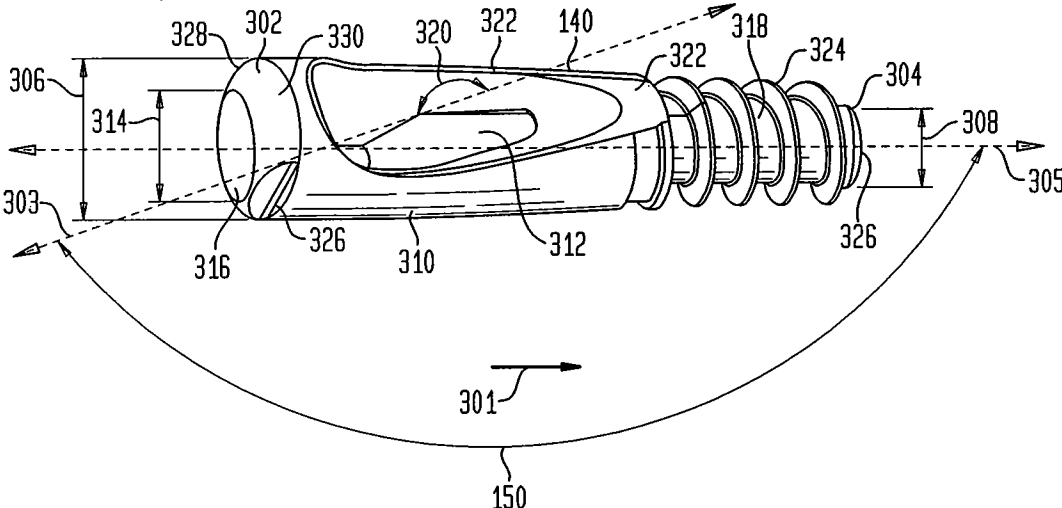


FIG. 3B

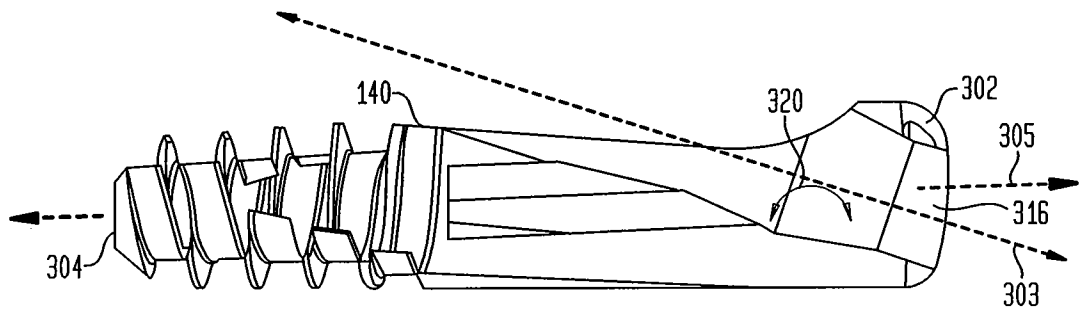
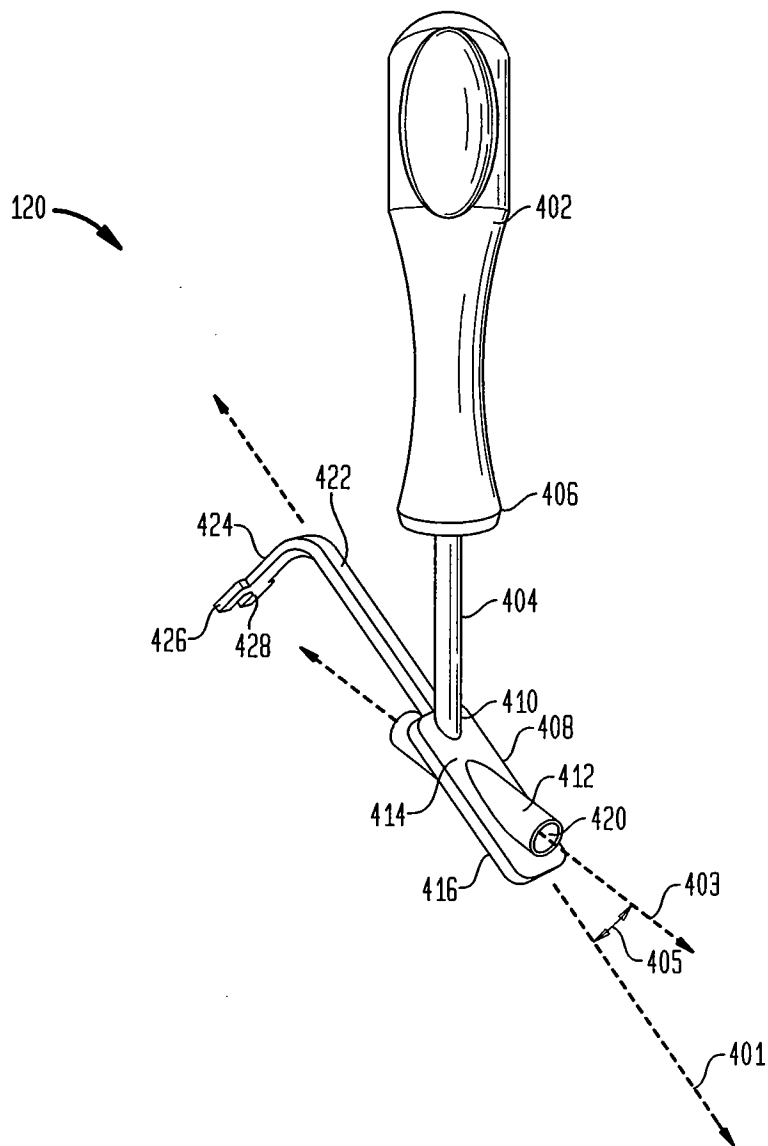
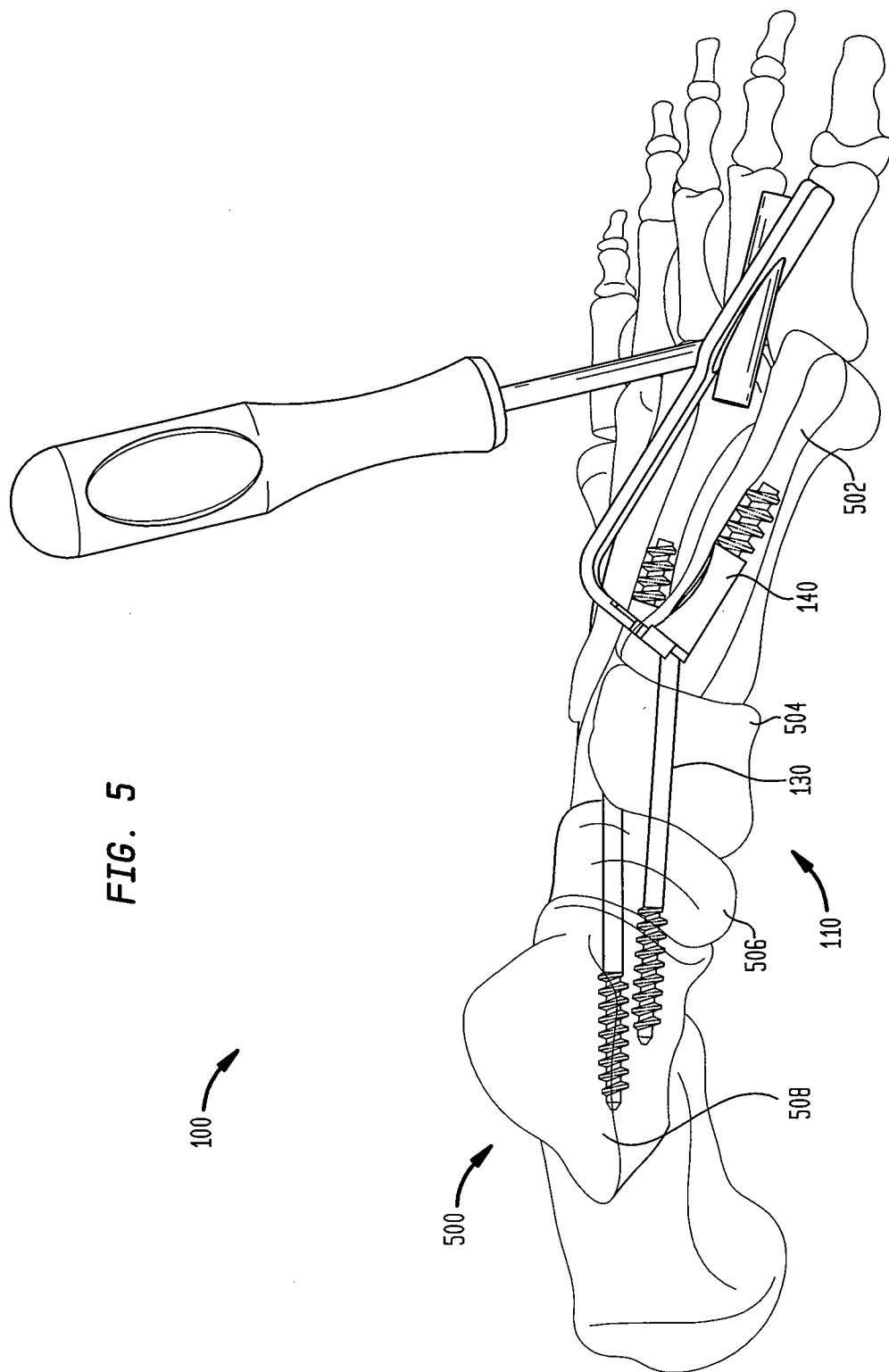


FIG. 4





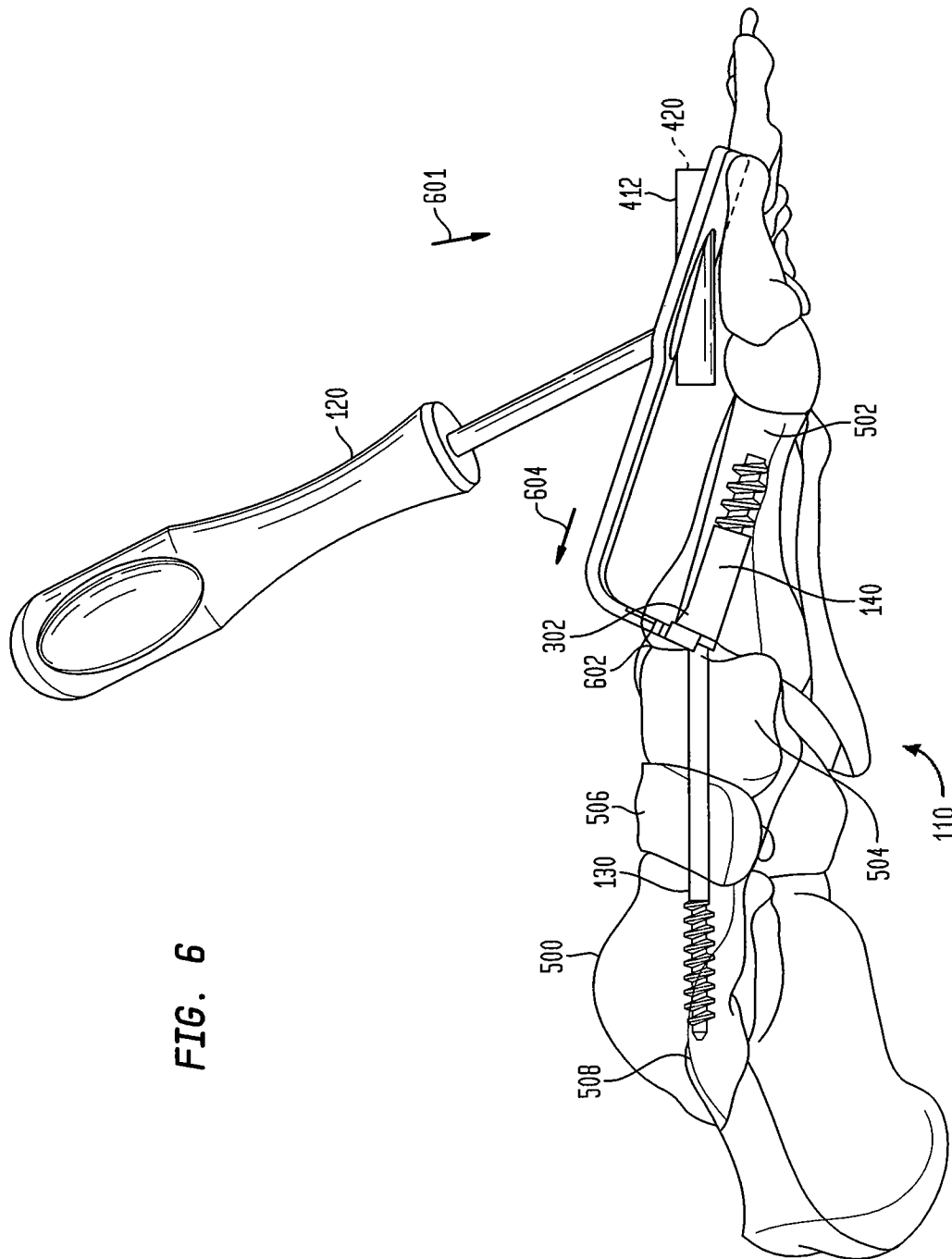


FIG. 6

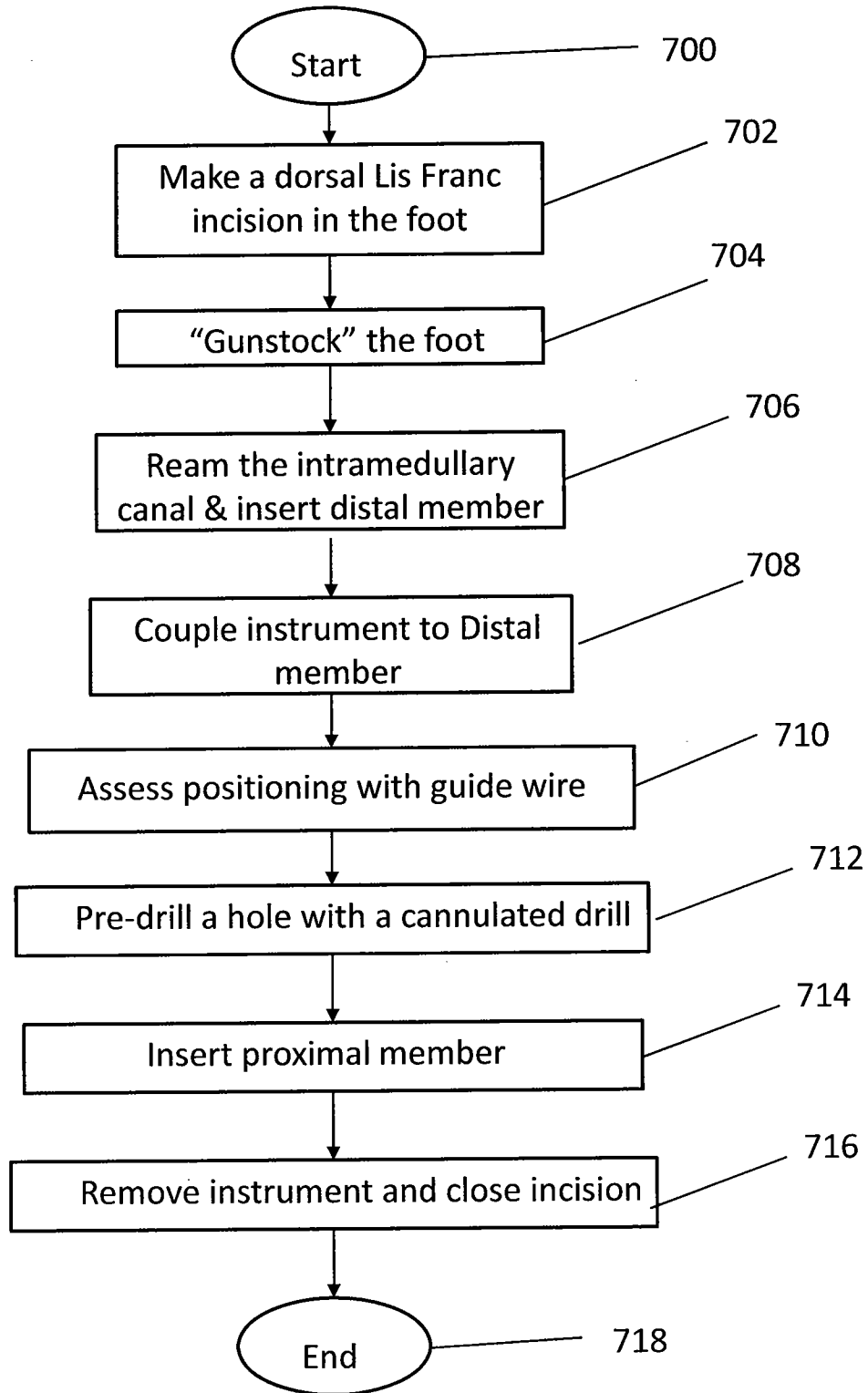


FIG. 7

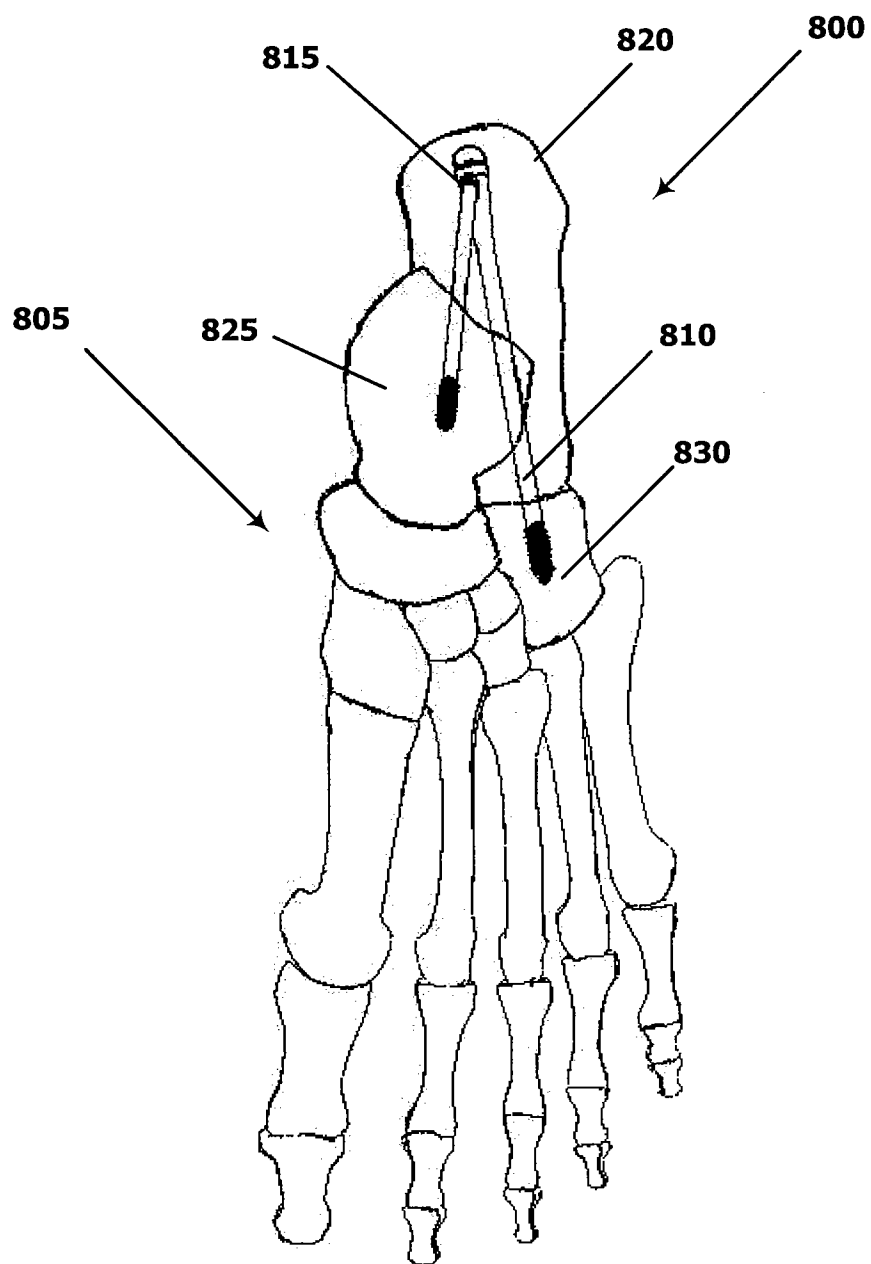


FIG. 8

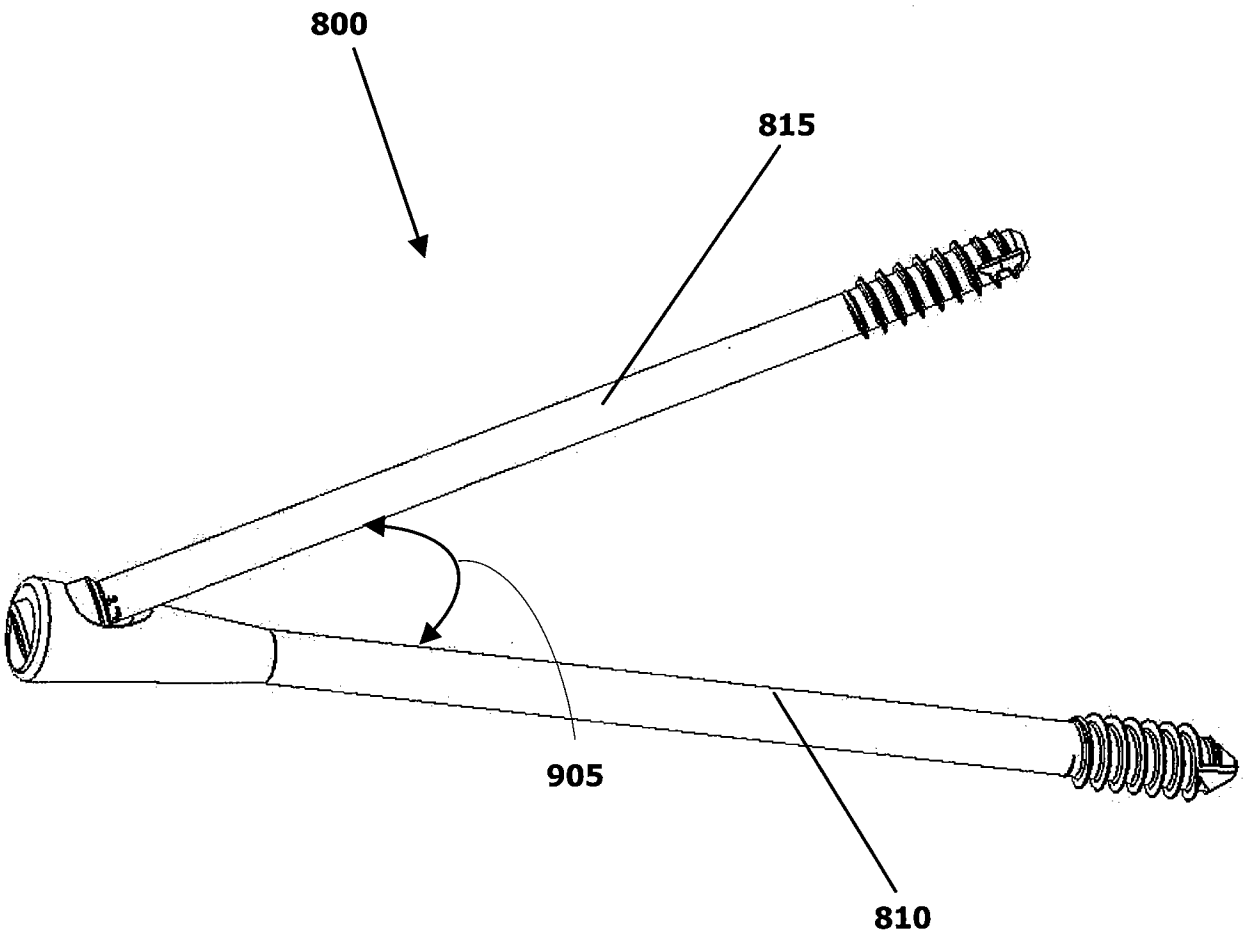


FIG. 9



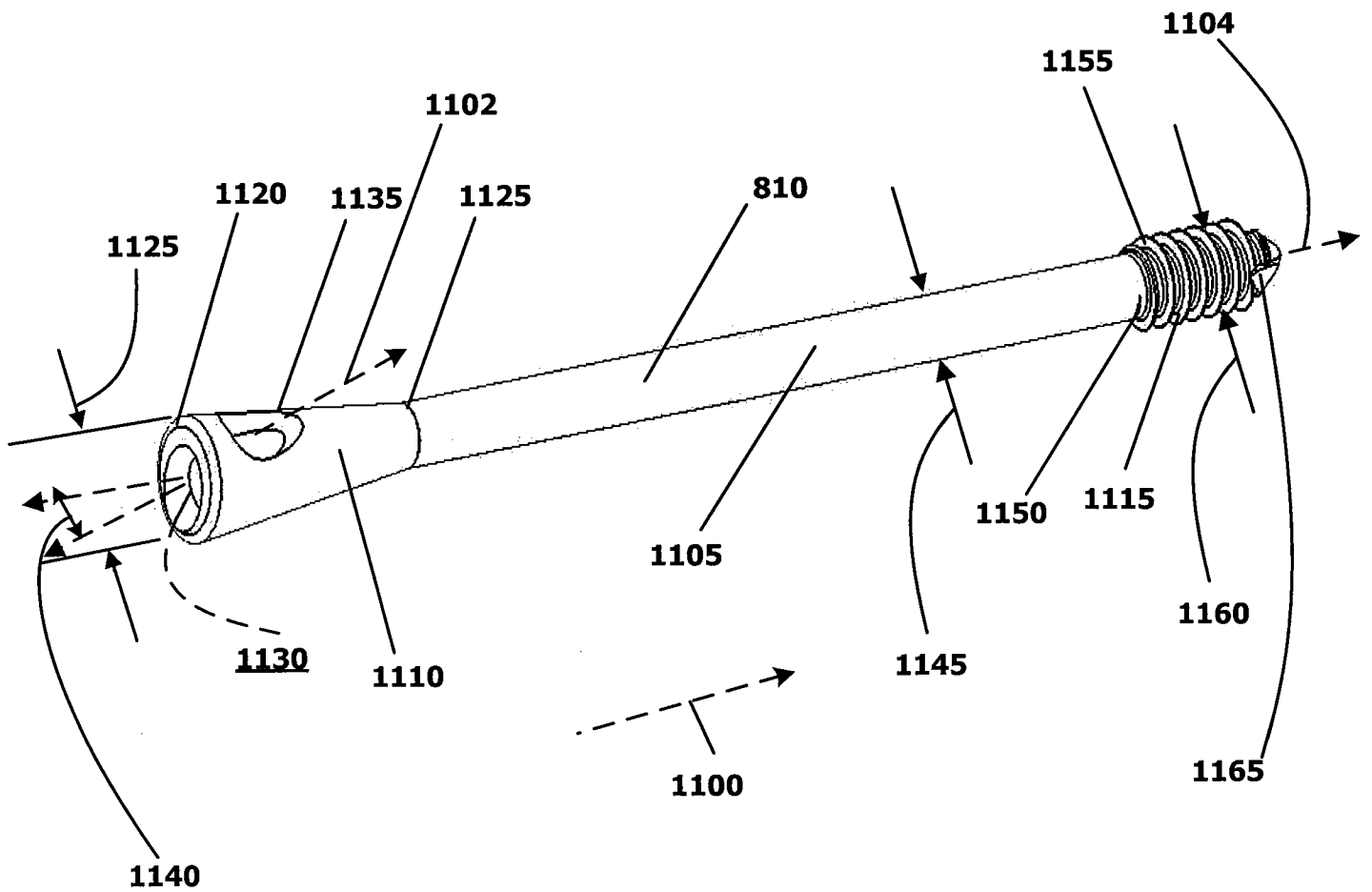


FIG. 11

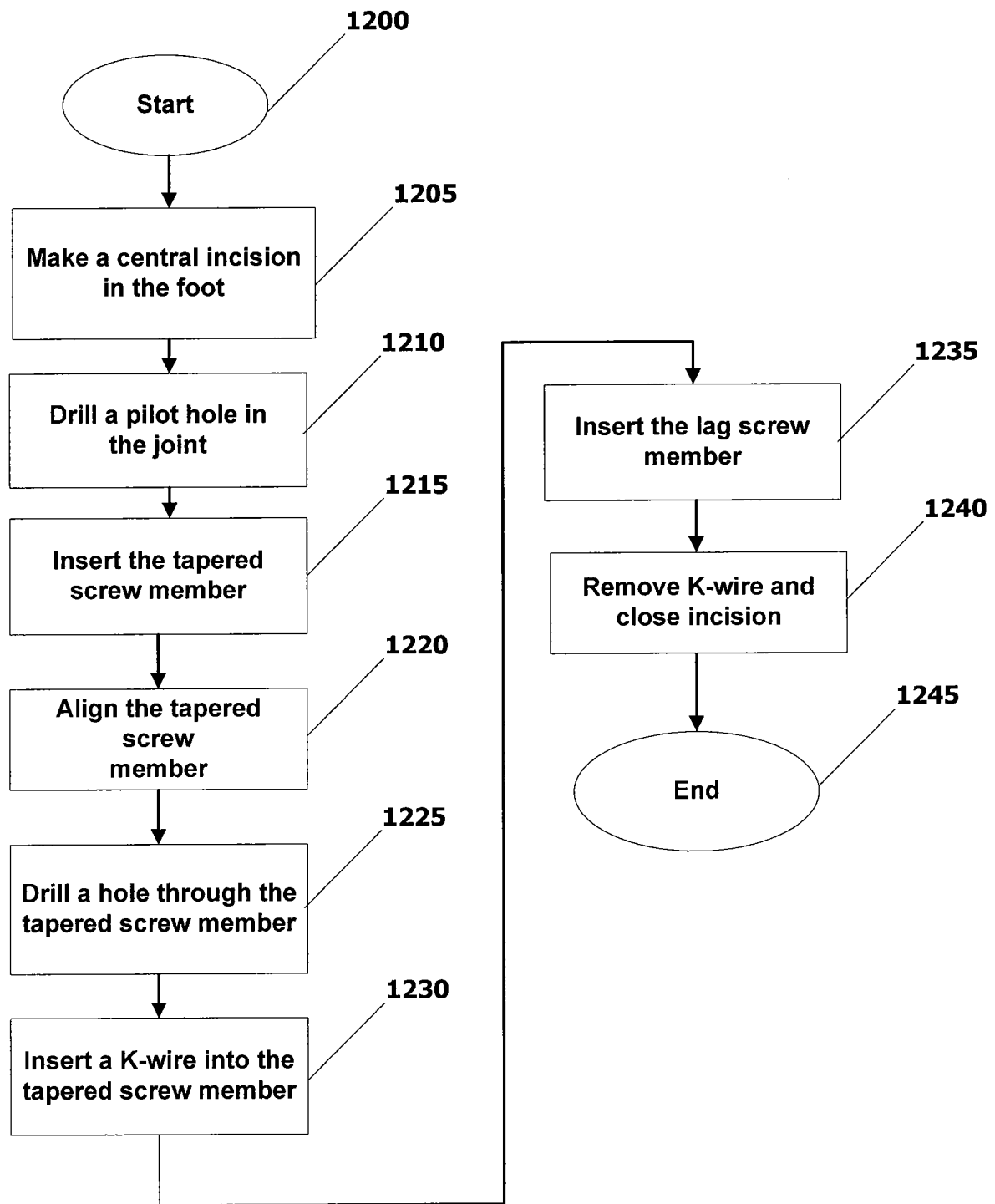


FIG. 12

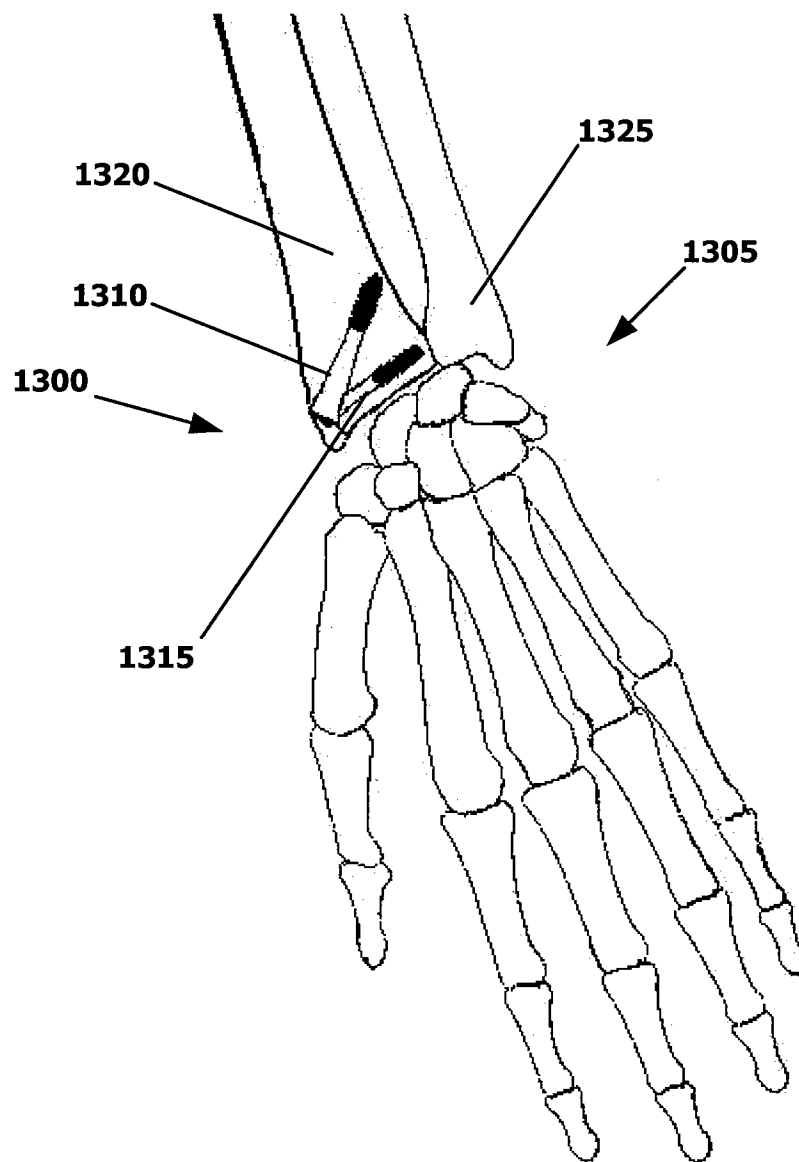


FIG. 13

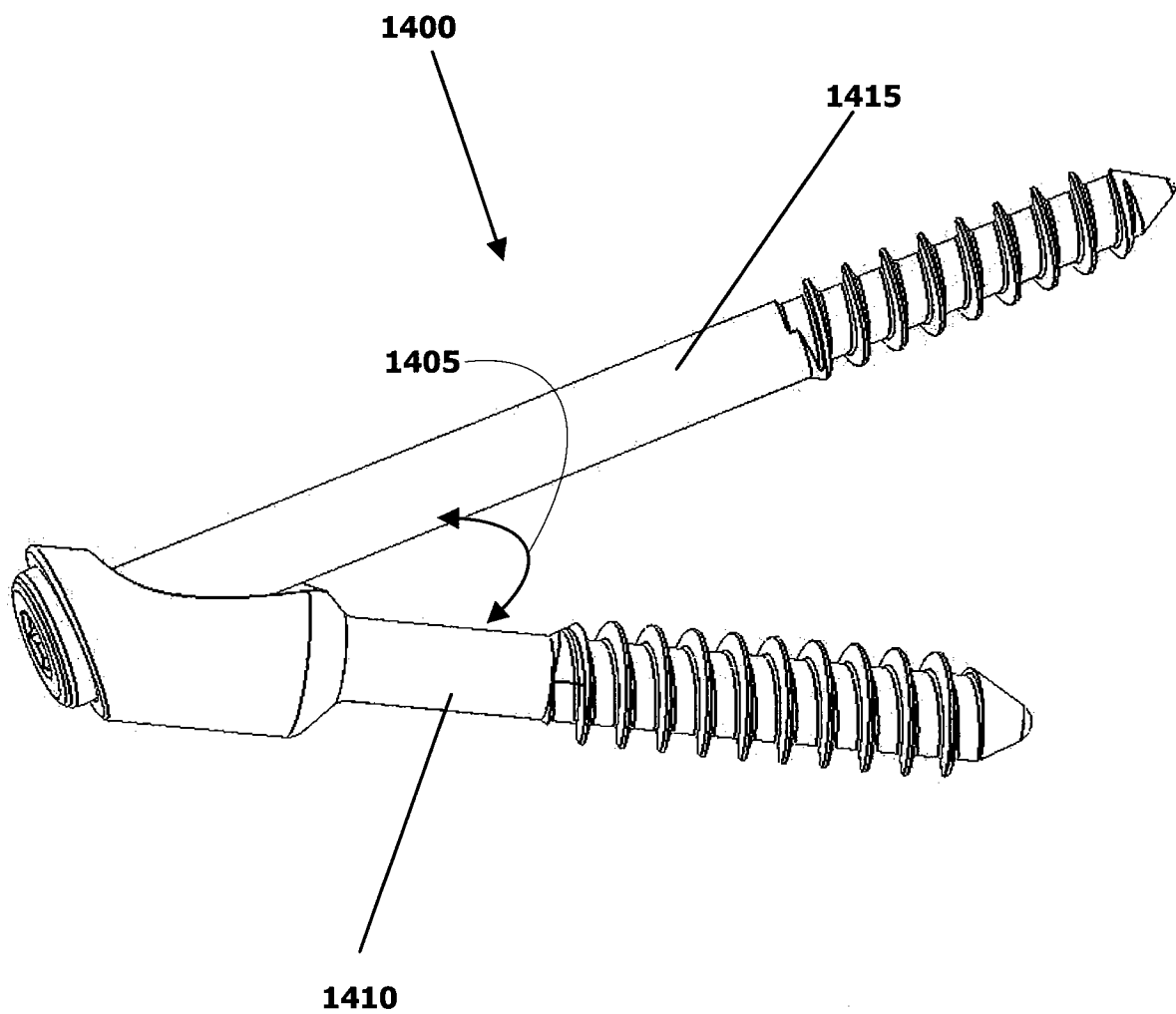


FIG. 14



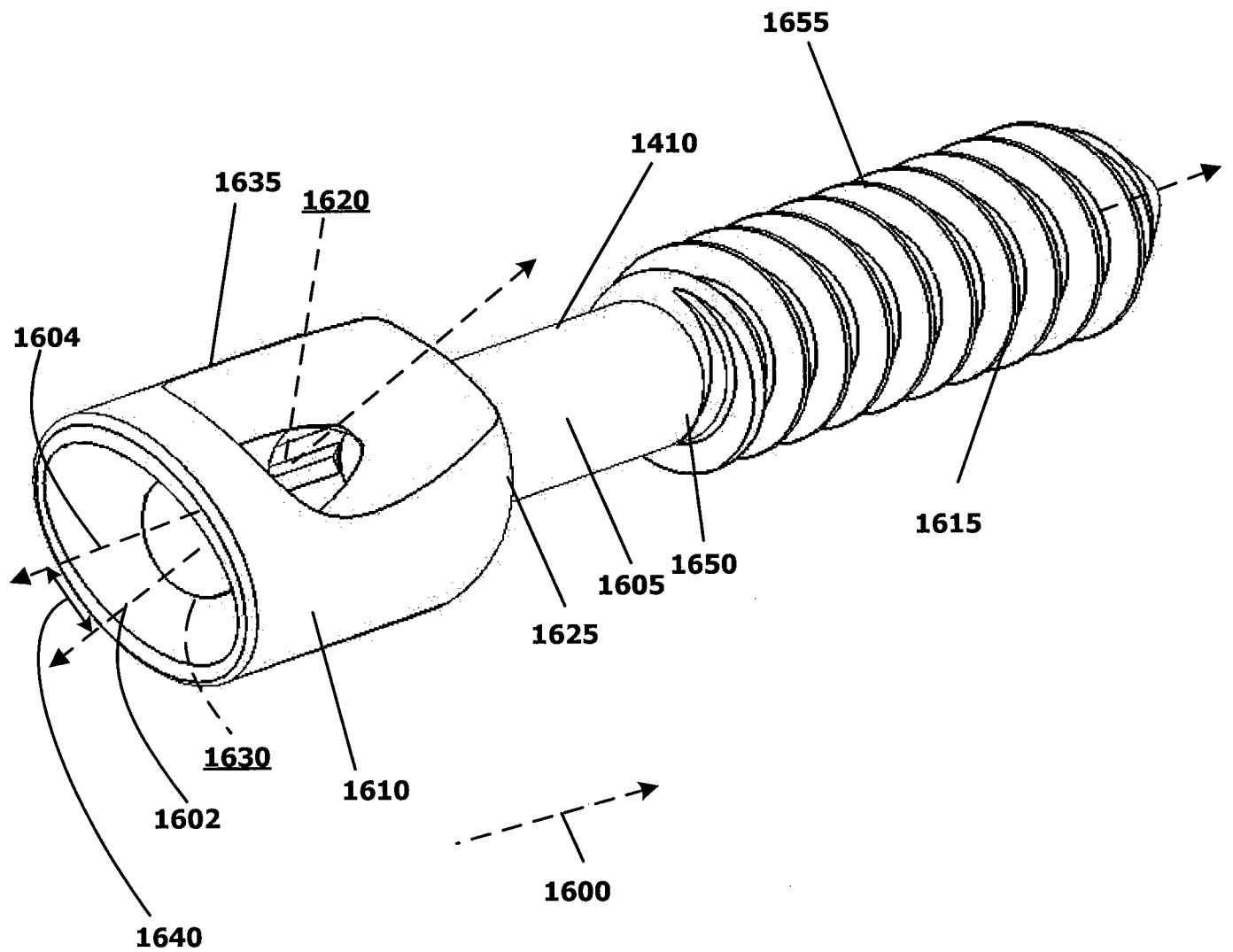


FIG. 16

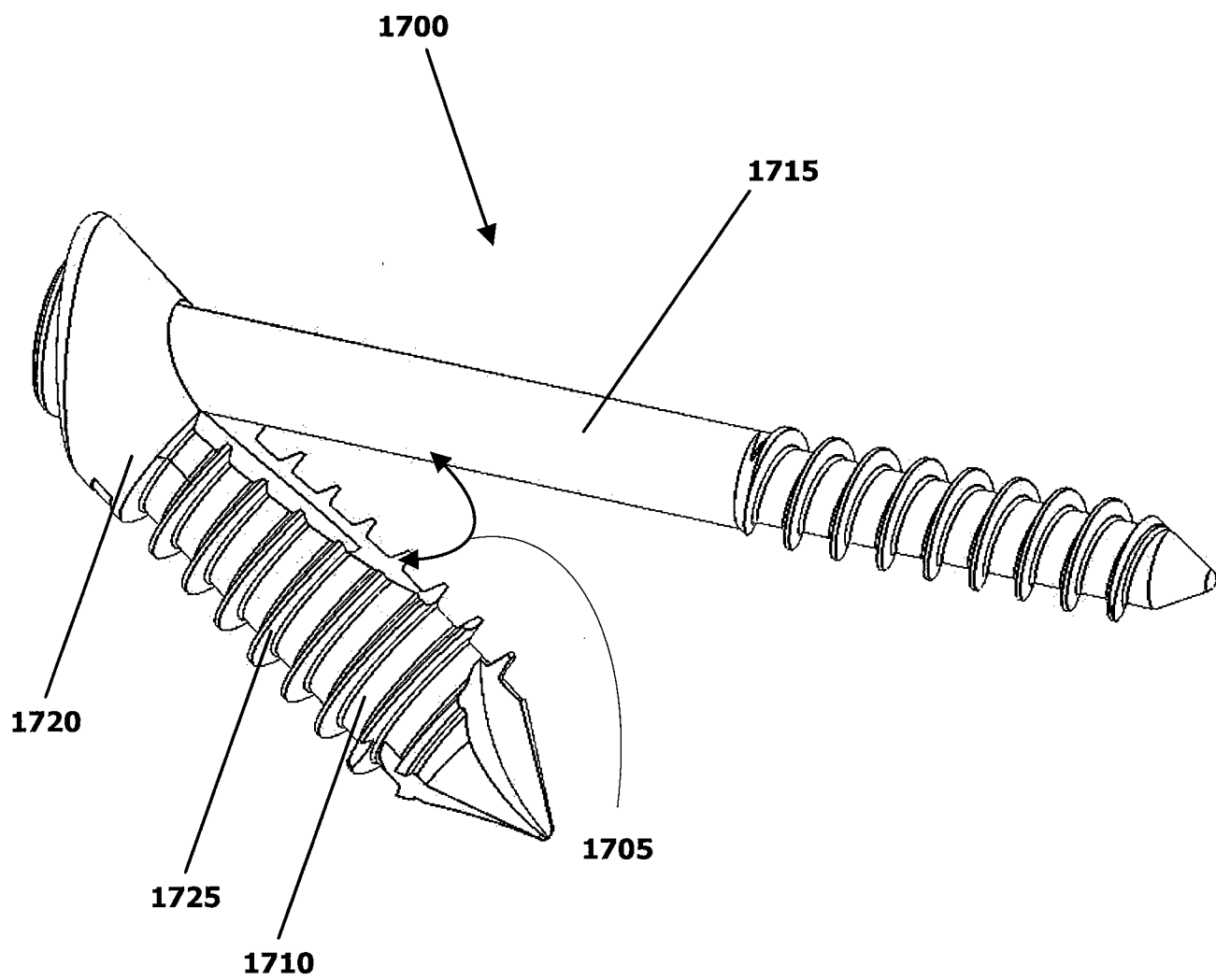


FIG. 17

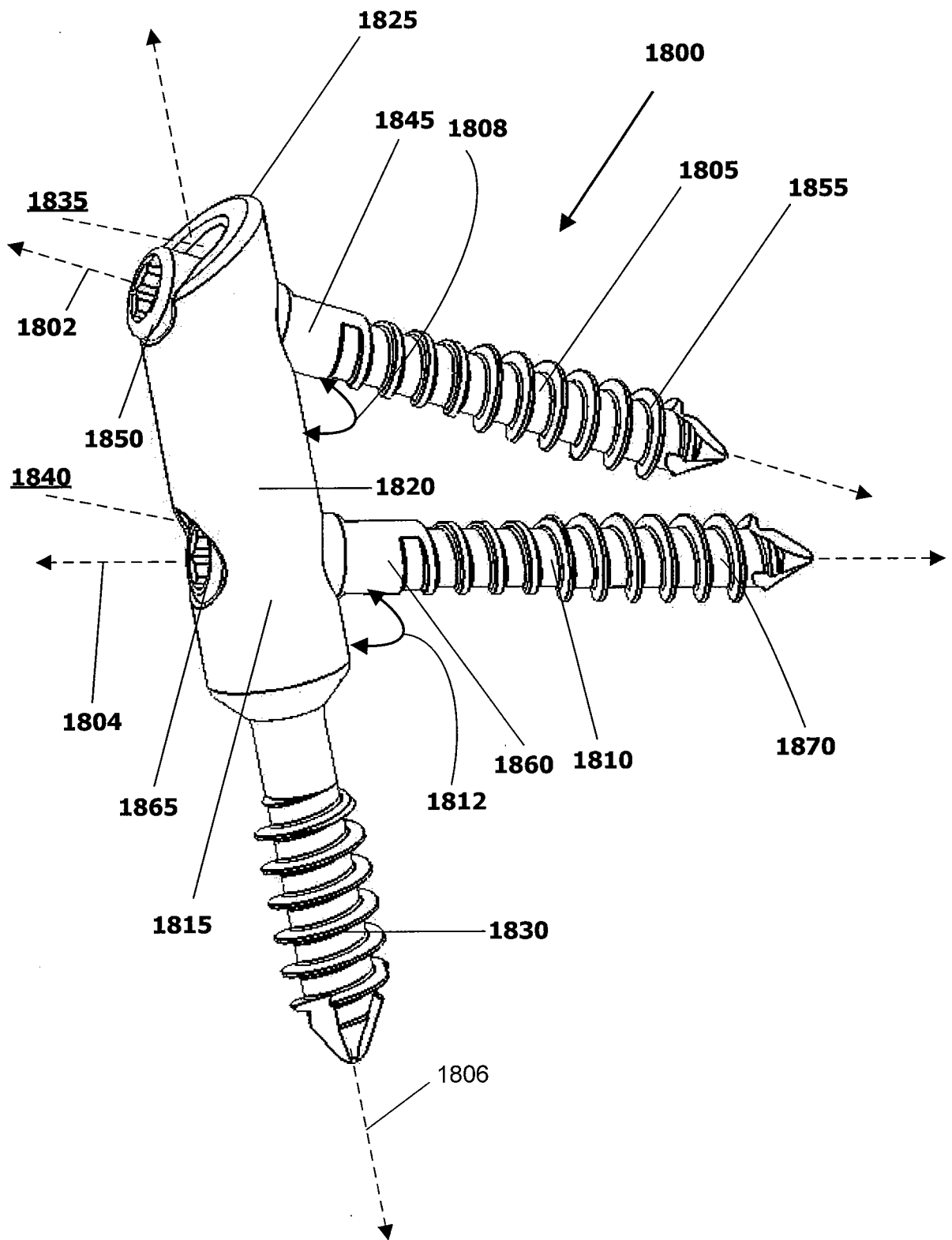


FIG. 18

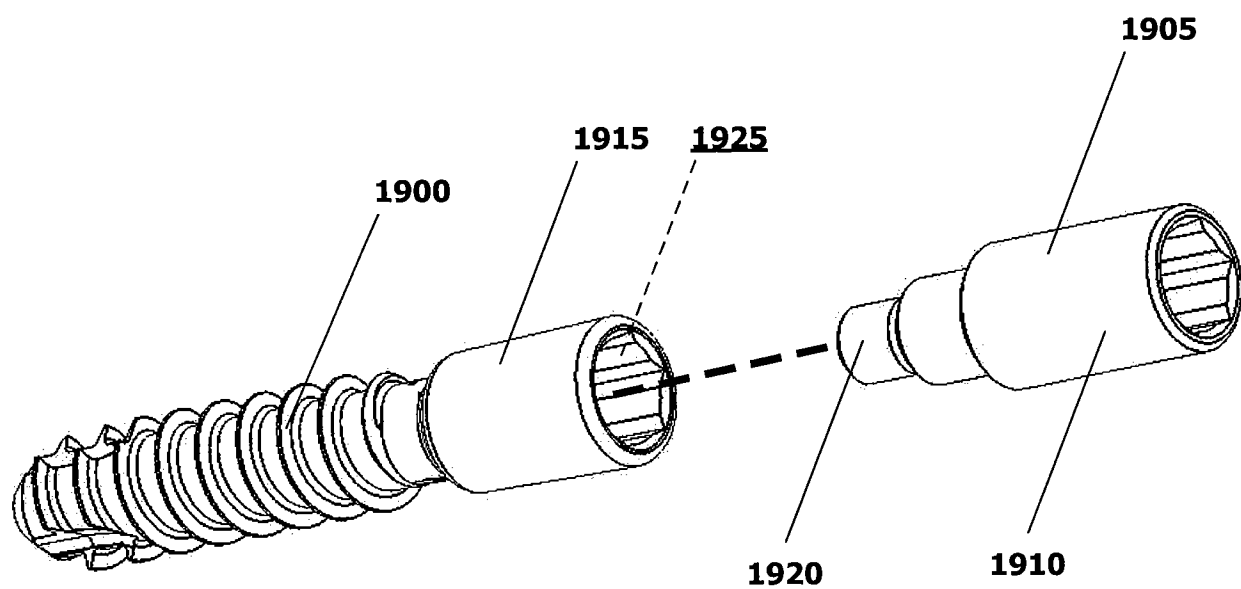


FIG. 19

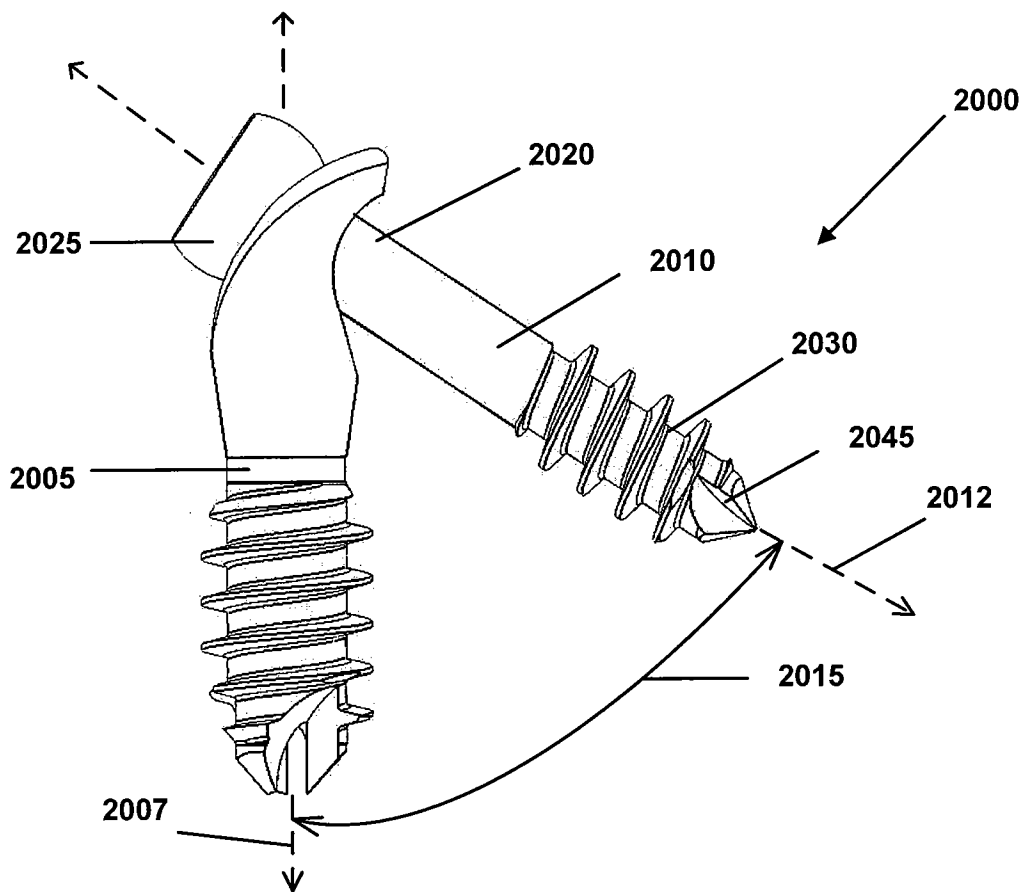


FIG. 20A

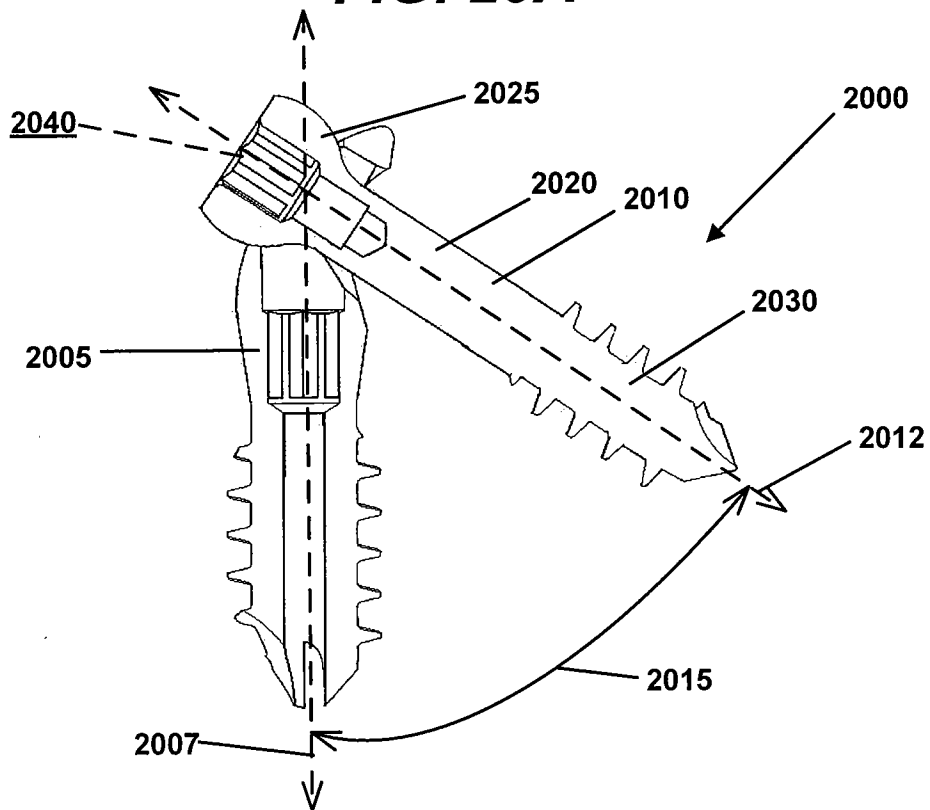


FIG. 20B

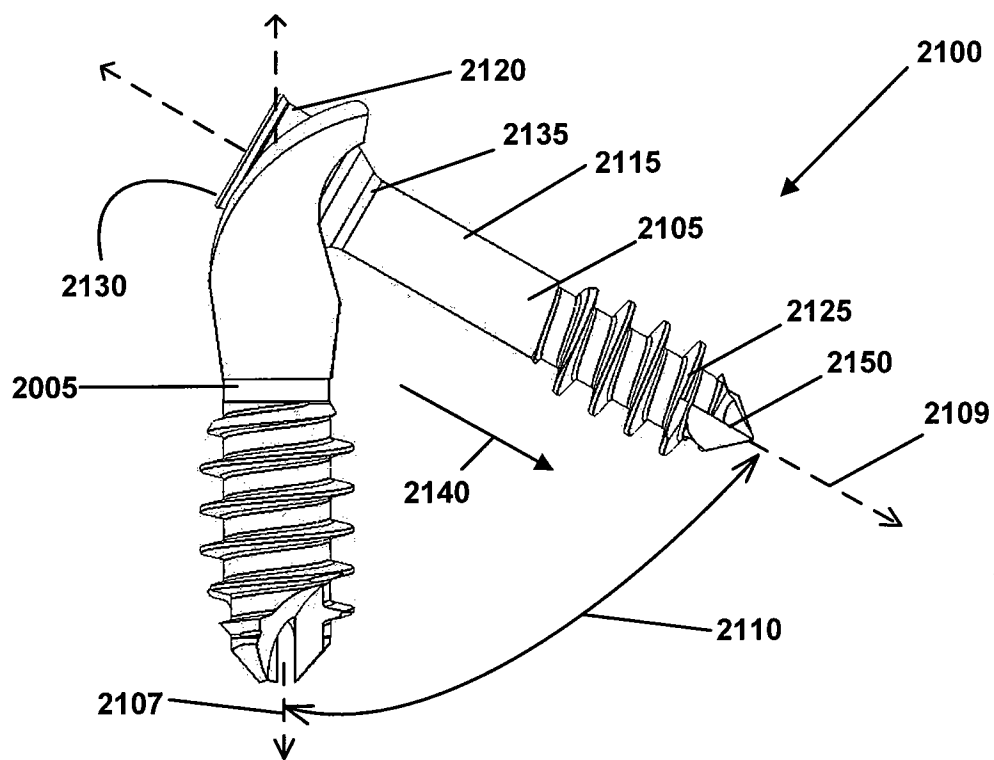


FIG. 21A

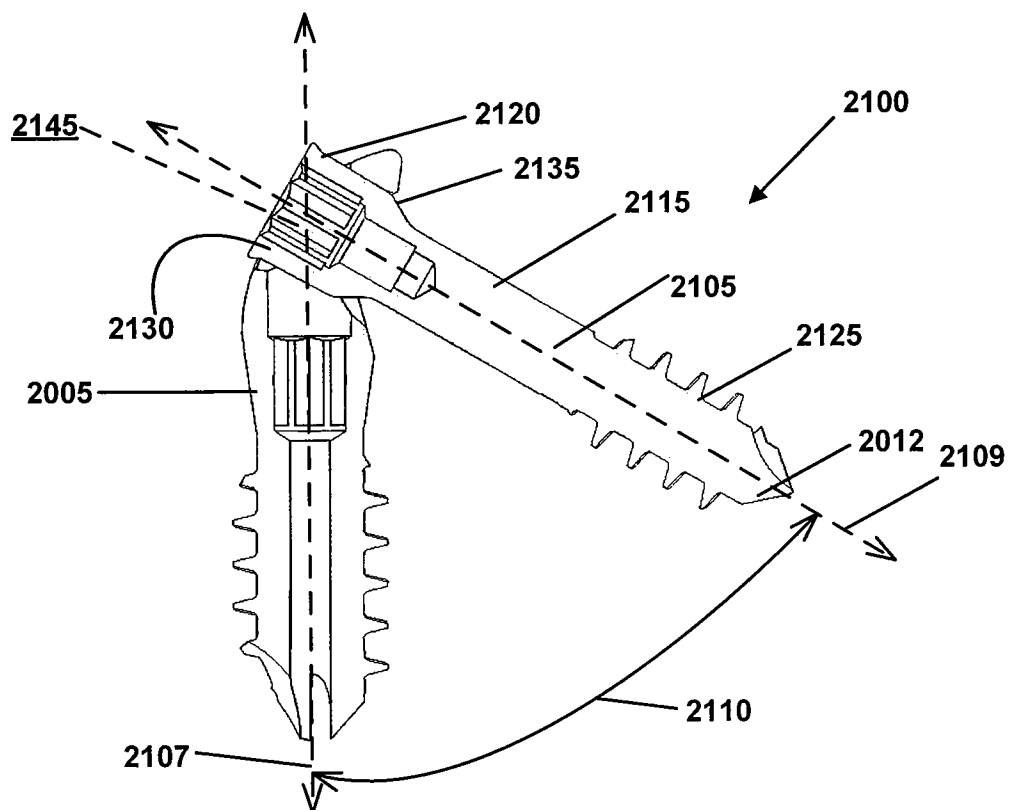


FIG. 21B

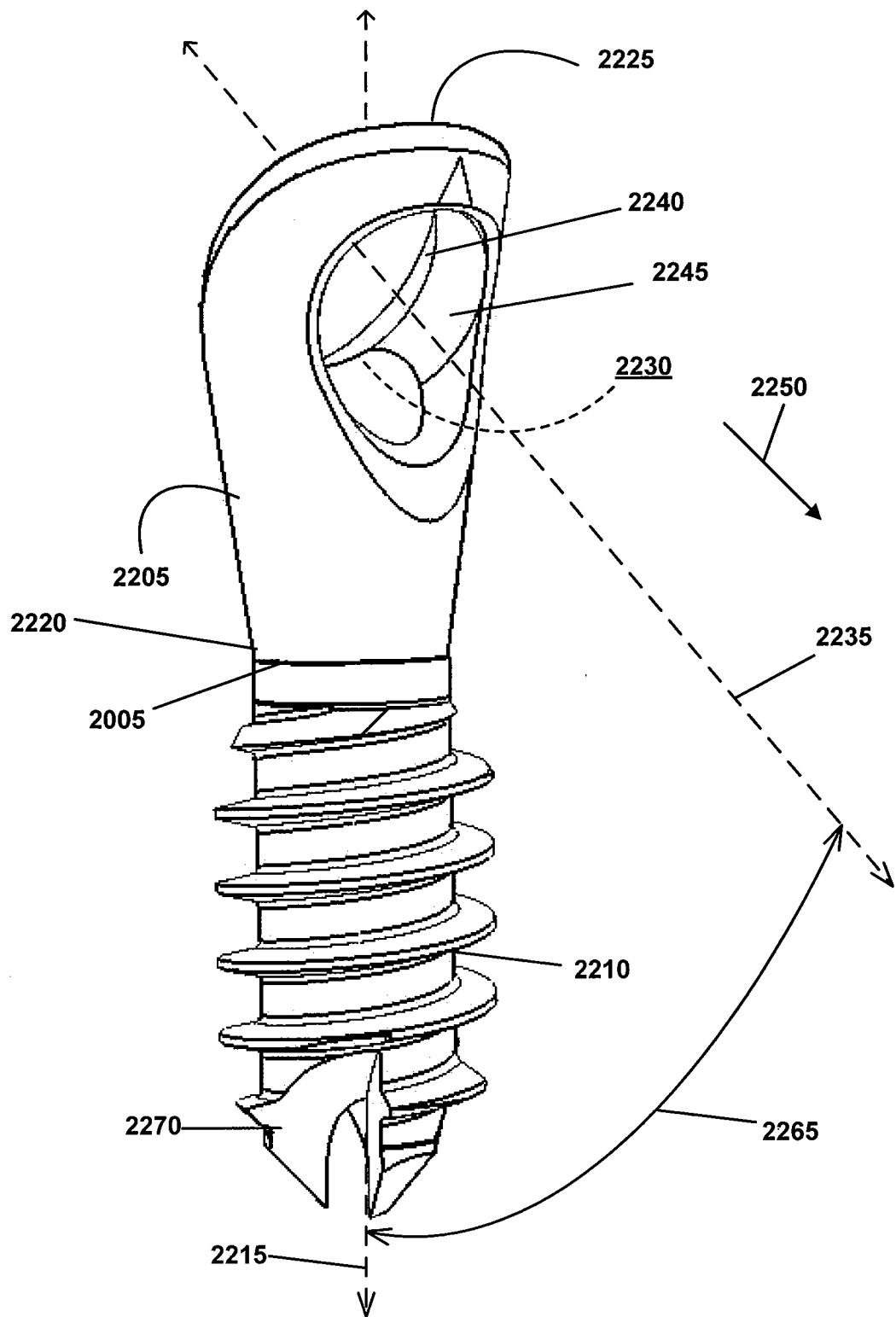


FIG. 22A





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/906,454

10/18/2010

Adam Mantzaris

277-065

1120

27776

7590

03/08/2012

Ward & Zinna, LLC

SUITE 300

382 SPRINGFIELD AVENUE

SUMMIT, NJ 07901

EXAMINER

BRAY, STUART SAMUEL

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

03/08/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	12/906,454	MANTZARIS ET AL.	
	Examiner	Art Unit	
	STUART S. BRAY	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-57 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-57 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☒ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 18 October 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) ☐ Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: on page 10, lines 14 and 16, "surface" and "end" are both referred to with reference numeral 322.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 8, 11-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2009/0240252 to Chang in view of U.S. Patent 5,456,267 to Stark.

Chang discloses a hybrid screw member (10) aligned along a longitudinal axis, including a first shaft, a head portion, and a first aperture (opposite side of 101) with a spherical radius and a second tapered aperture (101) with a second radius, a lag screw member (11) and combined with 41, as in figure 1) with a second shaft a bulbous portion and first and second threaded portions (111, which may be divided to make different portions). The lag screw can be inserted into the first and second aperture. The apertures cooperate to form a bore in the head portion. The lag screw (11) is at a fixed acute (based on Fig 4) angle to the hybrid screw member (Fig 3); yet the tapered spherical bulbous portion and the tapered aperture allow for a variable angle as well. Chang discloses that the lag screw member (11) is cannulated (para 0020). Compression can be applied at the variable angle, by the device (40). The bulbous portion has a taper (112) for providing an interference fit with the second aperture. Chang does not disclose that the hybrid screw member has a threaded portion. Stark discloses a second elongated body with a threaded portion in order to better “draw the pin into the bone” (col 6 11 19-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang with a threaded portion on the hybrid screw member. Chang discloses that the hybrid screw member has an orifice (103) aligned along the longitudinal axis less than the entirety of the shaft and received the complementary end (3131) of an instrument (31). Chang in view of Stark discloses the invention as claimed and discussed above but do not disclose that the second aperture (103) comprises a hexagonal, star, or square shaped end. However, aperture (113) has a hex shape (Fig 3) which is complementary to the end of

an instrument (40). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the aperture (103) to be a hex shape to connect with the complementary instrument (31, Figs 3 and 4) already connected to the aperture (103) in order to make a secure fit between the two. Chang also discloses that the lag screw (the combination of 11 and 41 as in Figure 1) has a second orifice (412) with a hexagonal shape (shown in Fig 4) that receives a complementary end (442) of an instrument (40).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark and in further view of U.S. Patent 6,669,700 to Farris et al ("Farris").

Chang in view of Stark do not disclose that the bulbous portion (112) is semi-spherical for providing angular rotation of the lag screw member (11). Farris teaches a variable angle bone screw (60) with a semi-spherical surface (Fig 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang and Stark with a screw with a semi-spherical head in view of Farris in order to provide a lag screw (11) that can rotate about various angles.

Claims 9-10, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al ("Culbert").

Chang in view of Stark disclose the invention as claimed and discussed above but do not disclose that the bone threads on the hybrid or lag screws are self-tapping or self-drilling. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in

order to omit a separate step of drilling into bone. (Para 0226) It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the bone threads of Chang and Stark in view of Culbert in order to eliminate a step of drilling into the bone, to remove bone material.

Claims 21-26, 29,32-36, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark and in further view of U.S. Patent Publication 2009/0099571 to Cresina et al ("Cresina").

Chang discloses a hybrid screw member (10) aligned along a longitudinal axis, including a first shaft, a head portion, and a first aperture (opposite side of 101) with a spherical radius and a second tapered aperture (101) with a second radius, a lag screw member (11) and combined with 41, as in figure 1) with a second shaft a bulbous portion and first and second threaded portions (111, which may be divided to make different portions). The lag screw can be inserted into the first and second aperture. The apertures cooperate to form a bore in the head portion. The lag screw (11) is at a fixed acute (based on Fig 4) angle to the hybrid screw member (Fig 3); yet the tapered spherical bulbous portion and the tapered aperture allow for a variable angle as well. Chang discloses that the lag screw member (11) is cannulated (para 0020). Compression can be applied at the variable angle, by the device (40). The bulbous portion has a taper (112) for providing an interference fit with the second aperture. Chang does not disclose that the hybrid screw member has a threaded portion. Stark discloses a second elongated body with a threaded portion in order to better "draw the

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pin into the bone" (col 6 11 19-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang with a threaded portion on the hybrid screw member. Chang discloses that the hybrid screw member has an orifice (103) aligned along the longitudinal axis less than the entirety of the shaft and received the complementary end (3131) of an instrument (31). Chang in view of Stark discloses the invention as claimed and discussed above but do not disclose that the second aperture (103) comprises a hexagonal, star, or square shaped end.

However, aperture (113) has a hex shape (Fig 3) which is complementary to the end of an instrument (40). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the aperture (103) to be a hex shape to connect with the complementary instrument (31, Figs 3 and 4) already connected to the aperture (103) in order to make a secure fit between the two. Chang also discloses that the lag screw (the combination of 11 and 41 as in Figure 1) has a second orifice (412) with a hexagonal shape (shown in Fig 4) that receives a complementary end (442) of an instrument (40).

Chang does not disclose making an incision to access the bones, forming a first medullary canal in a first bone and forming a second medullary canal in a second bone; inserting the hybrid member into the first canal; coupling the lag screw member to the hybrid member; inserting the lag screw member into the second canal; and applying torque to the head portion to lock the distal member to the proximal screw member, thereby compressing the first bone to the second bone.

Cresina discloses that an intramedullary fixation device can be used to secure two or more bones together (Figs 7 and 8). In this case, the lag (11) and hybrid screw (10) members can be used in a similar manner as disclosed in Cresina; whereby the two screw members can be inserted into two bones in close proximity, such as bones in the foot, as shown in Cresina Figs 7 and 8. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the device of Chang in a method disclosed by Cresina to compress two bones. It would have been obvious that in order to insert a shaft into a bone, an incision must first be made into the skin, holes must first be drilled into the bone; which may be done with a drill bit or a self-tapping screw. Using an instrument (screwdriver, 44, or 31 for the proximal member), such as disclosed in Chang would create torque on the head portion (112) and pull one bone (gripped by the threads 111 of the screw) towards a bone gripped by the distal member (10).

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark in view of Cresina and in further view of U.S. Patent 6,669,700 to Farris et al ("Farris").

Chang in view of Stark do not disclose that the bulbous portion (112) is semi-spherical for providing angular rotation of the lag screw member (11). Farris teaches a variable angle bone screw (60) with a semi-spherical surface (Fig 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang and Stark with a screw with a semi-spherical head in view of Farris in order to provide a lag screw (11) that can rotate about various angles.

Claims 30-31, 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark in view of Cresina and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al ("Culbert").

Chang in view of Stark disclose the invention as claimed and discussed above but do not disclose that the bone threads on the hybrid or lag screws are self-tapping or self- drilling. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in order to omit a separate step of drilling into bone. (Para 0226) It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the bone threads of Chang and Stark in view of Culbert in order to eliminate a step of drilling into the bone, to remove bone material.

Claims 42, 44-45, 48-52, 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark.

Chang discloses a hybrid screw member (10) aligned along a longitudinal axis, including a first shaft, a head portion, and a first internal surface with a first spherical radius coupled to a second internal surface with a second internal radius, creating a bore in the head portion. The hybrid screw (10) is tapered along its length so that the first and second internal surfaces may be at any point along the internal surface of the member (10) and the surfaces will be tapered and likely have different radii. The surfaces may be next to apertures 103 or 101 and 102 (and the opposite apertures). Furthermore, the bore axis may be at any point along the screw member (10), from 103 or along 101 or 102. Chang also has a first aperture (opposite side of 101) with a

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spherical radius and a second tapered aperture (101) with a second radius, a lag screw member (11 and combined with 41, as in figure 1) with a second shaft a bulbous portion and first and second threaded portions (111, which may be divided to make different portions). The lag screw can be inserted into the first and second aperture. The apertures cooperate to form a bore in the head portion. The lag screw (11) is at a fixed acute (based on Fig 4) angle to the hybrid screw member (Fig 3); yet the tapered spherical bulbous portion and the tapered aperture allow for a variable angle as well. Chang discloses that the lag screw member (11) is cannulated (para 0020).

Compression can be applied at the variable angle, by the device (40). The bulbous portion has a taper (112) for providing an interference fit with the second aperture. Chang does not disclose that the hybrid screw member has a threaded portion. Stark discloses a second elongated body with a threaded portion in order to better “draw the pin into the bone” (col 6 11 19-25). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang with a threaded portion on the hybrid screw member. Chang discloses that the hybrid screw member has an orifice (103) aligned along the longitudinal axis less than the entirety of the shaft and received the complementary end (3131) of an instrument (31). Chang in view of Stark discloses the invention as claimed and discussed above but do not disclose that the second aperture (103) comprises a hexagonal, star, or square shaped end.

However, aperture (113) has a hex shape (Fig 3) which is complementary to the end of an instrument (40). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the aperture (103) to be a hex shape to connect with the

complementary instrument (31, Figs 3 and 4) already connected to the aperture (103) in order to make a secure fit between the two. Chang also discloses that the lag screw (the combination of 11 and 41 as in Figure 1) has a second orifice (412) with a hexagonal shape (shown in Fig 4) that receives a complementary end (442) of an instrument (40).

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark and in further view of U.S. Patent 6,669,700 to Farris et al ("Farris").

Chang in view of Stark do not disclose that the bulbous portion (112) is semi-spherical for providing angular rotation of the lag screw member (11). Farris teaches a variable angle bone screw (60) with a semi-spherical surface (Fig 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to construct the device of Chang and Stark with a screw with a semi-spherical head in view of Farris in order to provide a lag screw (11) that can rotate about various angles.

Claims 46-47, 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Stark and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al ("Culbert").

Chang in view of Stark disclose the invention as claimed and discussed above but do not disclose that the bone threads on the hybrid or lag screws are self-tapping or self-drilling. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in order to omit a separate step of drilling into bone. (Para 0226) It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the bone

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threads of Chang and Stark in view of Culbert in order to eliminate a step of drilling into the bone, to remove bone material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART S. BRAY whose telephone number is (571)270-7648. The examiner can normally be reached on Mon-Thurs 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Eduardo C. Robert, at 571-272-4719.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/STUART S BRAY/

Examiner, Art Unit 3733

/EDUARDO C. ROBERT/

Supervisory Patent Examiner, Art Unit 3733

Electronically filed July 9, 2012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Adam Mantzaris, *et al.*

Confirmation No.: 1120

Serial No.: 12/906,454

Examiner: Bray, Stuart Samuel

Filed: 10/18/2010

Art Unit: 3733

For: HYBRID INTRAMEDULLARY
FIXATION ASSEMBLY AND
METHOD OF USE

Atty. Doc. No.: 277-065

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION OF MARCH 8, 2012

SIR:

This is an amendment and response to the office action mailed March 8, 2012. Based upon the following amendments and remarks, the application is believed to be in condition for allowance and action to that end is respectfully requested.

Prior to further substantive examination, please amend the subject application as follows:

AMENDMENTS TO THE SPECIFICATION begin on page 2 of this paper.

AMENDMENTS TO THE DRAWINGS begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS begin on page 9 of this paper.

REMARKS begin on page 22 of this paper.

Amendments to Specification and Drawings remarks begin on page 22 of this paper.

35 U.S.C. § 103 remarks begin on page 23 of this paper.

IN THE SPECIFICATION:

Please revise the specification as provided below:

1. Please revise the paragraph found on page 10, line 8 through page 11, line 2 of the specification, or paragraph [0053] of U.S. Patent Application Publication No. 2011/0230884, as follows:

As shown in Figures 3A-3B, distal member 140 of the preferred embodiment is generally tubular in shape and tapers from a first end 302 to a second end 304 (i.e. end 302 has a diameter 306 that is slightly larger than diameter 308 of end 304). However, in another non-limiting embodiment, distal member 140 has a constant width from first end 302 to second end 304. Further, first end 302 is generally semi-spherical in shape and has an internal circular aperture 316, which traverses end 302 along direction 301 (i.e. end 302 is generally “donut” shaped). Additionally, circular aperture 316 emanates from surface 322, such that portion 310 has a generally tapered aperture 316 provided in portion 310. Circular aperture 316 comprises slope 320 from first end 302 to end 323 ~~[[322]]~~ of portion 310. Further, aperture 316 is aligned along axis 303, which is offset from horizontal axis 305 of distal member 140. Axis 303 forms an angle 150 with horizontal axis 305 that determines the angle for arch restoration, as shown in figure 3A. Angle 150 may be any angle greater than 90 degrees and less than 180 degrees. Tapered aperture 316 when combined with tapered bulbous portion 202, shown in Figure 2, creates a locked interference fit between proximal member 130 and distal member 140. First end 302 has a plurality of substantially similar grooves 326 and 328, which form an “L-shape” with surface 330 of end 302. Grooves 326 and 328 are provided to receive instrument 120 of fixation

system 100, which is later described. In other non-limiting embodiments, other similar instruments may be provided to be received within grooves 326 and 328.

2. Please revise the paragraph found on page 11, lines 11-15 of the specification, or paragraph [0055] of U.S. Patent Application Publication No. 2011/0230884, as follows:

Portion 310 of distal member 140 terminates into a second generally cylindrical portion 318 which has a plurality of threads 324, which are circumferentially disposed on the external surface of portion 318. Portion 318 has an internal circular aperture 327 ~~[[326]]~~ which is longitudinally coextensive with portion 318 in direction 301. Circular aperture 327 ~~[[326]]~~ aligns with aperture 312 to form a continuous opening from end 302 to end 304.

3. Please revise the paragraph found on page 18, lines 1-17 of the specification, or paragraph [0069] of U.S. Patent Application Publication No. 2011/0230884, as follows:

Further, tapered portion 1110 is generally tubular in shape and tapers from end 1120 to end 1125 (i.e. end 1120 has a diameter ~~1125~~ 1127 that decreases slightly in diameter from end 1120 in direction 1100). Further, first end 1120 has a tapered aperture 1130, which traverses tapered portion 1110 along axis 1102, which causes tapered aperture 1130 to emanate from surface 1135. Axis 1102 is offset from longitudinal axis 1104 at an angle 1140. Moreover, tapered portion 1110 has a generally hexagonal-shaped aperture contained within portion 1110, which is aligned along axis 1104 and is provided to receive an instrument (not shown) for applying torque to tapered screw member 810. In other non-limiting embodiments, a star-shaped

aperture, a square-shaped aperture, or any other shaped aperture may be utilized without departing from the scope of the invention. With tapered aperture 1130 being aligned along axis 1102, tapered aperture 1130 forms a fixed angle 1140 with longitudinal axis 1145. Fixed angle 1140 determines the angle for fixation of tapered screw member 810 with respect to lag screw member 815 (shown in figure 10). It should be appreciated that fixed angle 1140 may be any angle less than 90 degrees to allow a surgeon the flexibility of determining the angle for internal fixation of bones in the human body. It should also be appreciated that tapered aperture 1130 when combined with tapered bulbous portion 1010, shown in Figure 10, creates a locked interference fit between tapered screw member ~~815~~ 810 and lag screw member 815.

4. Please revise the paragraph found on page 21, line 22 through page 22, line 10 of the specification, or paragraph [0076] of U.S. Patent Application Publication No. 2011/0230884, as follows:

Further, lag screw member 1415 has a first smooth exterior portion 1505 of a uniform diameter 1525 from first end 1540 to second end 1545. Portion 1505 includes an internal aperture 1550 aligned along axis 1502 that traverses the longitudinal length of portion 1505 along direction 1504. Further, portion 1505 terminates into the threaded portion 1515. Threaded portion 1515 also includes an internal aperture 1555 aligned along axis 1502 that longitudinally traverses threaded portion 1515. Internal aperture 1555 being aligned along the same axis 1502 as apertures 1535 and ~~1555~~ 1550 cooperatively form a continuous opening (i.e., a cannula) from bulbous portion 1510 to end 1560 of threaded portion 1515. The continuous opening or cannula is provided to interact with a guide wire (not shown) by receiving the guide wire within the

continuous opening to help guide and position the lag screw member 1415 during insertion into bone. In other non-limiting embodiments, the lag screw member 1415 may be provided without apertures 1550 and 1555 (i.e., the lag screw member 1415 is non-cannulated or solid).

5. Please revise the paragraph found on page 23, line 18 to page 24, line 10 of the specification, or paragraph [0080] of U.S. Patent Application Publication No. 2011/0230884, as follows:

Further, polyaxial screw member 1410 has a smooth exterior portion 1605 having a uniform diameter from end 1625 to end 1650. The diameter of exterior portion 1605 is smaller than the diameter of aperture 1630. Polyaxial screw member 1410 is generally solid, however, in other non-limiting embodiments, polyaxial screw member 1410 may be cannulated. Further, portion 1605 terminates into a threaded portion 1615. Threaded portion 1615 is generally solid and includes a plurality of circular threads, such as threads 1655, circumferentially disposed on the external surface of threaded portion 1615. Threaded portion 1615 has a uniform diameter that is slightly larger than the diameter of portion 1605. However, in other non-limiting embodiments, the respective diameters of portions 1605 and 1615 may be substantially the same. Threaded portion 1615 may also be provided with a self-tapping leading edge (not shown) to provide portion 1615 with the ability to remove bone material during insertion of ~~proximal~~ polyaxial screw member 1410 into bone. It should be appreciated that the length of the ~~proximal~~ polyaxial screw member 1410 may be selected of varying lengths to allow a surgeon to fuse different joints in the human body. It should be appreciated that polyaxial screw member 1410 may be coated with an osteoconductive material, such as, for example, plasma spray or other

similar types of porous materials that is capable of supporting or encouraging bone ingrowth into this material.

6. Please revise the paragraph found on page 30, line 21 through page 31, line 20 of the specification, or paragraph [0093] of U.S. Patent Application Publication No. 2011/0230884, as follows:

Further, head portion 2205 is generally tubular in shape and has a generally tapered external surface from first end ~~2220~~ 2225 to second end ~~2225~~ 2220 (i.e. head portion 2205 decreases slightly in diameter from end ~~2220~~ 2225 to end ~~2225~~ 2220). Also, head portion 2205 has a central aperture or bore 2230 that is aligned along axis 2235, with central aperture 2230 forming an acute angle 2265 with longitudinal axis 2215 (i.e., central aperture 2230 extends from a first surface 2275 (FIG. 22B) to opposed surface 2280 (FIG. 22B) along axis 2235). The central aperture 2230 is formed from a plurality of apertures formed on the internal surface of the head portion 2205. Particularly, internal surface 2240 has a spherical radius that defines a first aperture within the central aperture 2230 while internal surface 2245 has a second radius that defines a second aperture 2230 within central aperture 2230. The internal surface 2240 is provided to receive the bulbous portion 2025 of polyaxial screw member 2010 (FIGS. 20A-20B) and surface 2245 is provided to receive bulbous portion 2120 of tapered screw member 2105 (FIGS. 22A-22B). Additionally, internal surface 2245 has a taper that decreases from first surface 2275 (FIG. 22B) in direction 2250. It should be appreciated that the taper on internal surface 2245 is provided to receive bulbous portion 2120 in order to cause bulbous portion 2120 to create a locked interference fit with internal surface 2245 and align the hybrid screw member

2005 and the tapered screw member 2105 (FIGS. 21A-21B) along this axis 2235. It should also be appreciated that the bulbous portion 2025 (FIGS. 20A-20B) is restrained at internal surface 2245, while the threaded portion 2030 (FIGS. 20A-20B) may rotate in a circumference that is orthogonal to the axis 2235, with this polyaxial screw member 2010 maintaining its acute angle position with respect to the hybrid screw member 2005. The angle 2265 may predetermined to be any angle less than 90 degrees to allow a surgeon the flexibility of setting the angle for compression as well the flexibility of fixing bones of various sizes.

IN THE DRAWINGS:

The attached sheets are replacement drawings of Figures 3A and 11 and are each labeled REPLACEMENT SHEET.

IN THE CLAIMS:

Please revise the claims to read as follows:

1. **(Currently amended)**: ~~An intramedullary~~ fixation assembly for bone fusion, comprising:

a ~~hybrid~~ first screw member ~~aligned~~ extending along a first longitudinal axis, ~~wherein the~~
~~hybrid~~ first screw member ~~comprises~~ comprising a first shaft[,] and a head portion comprising
a bore extending therethrough, the bore including a first aperture coupled to internal surface
having a partially spherical shape and a second aperture internal surface that tapers from a first
end to a second end; and

a ~~lag~~ second screw member extending along a second longitudinal axis, the second screw
member comprising a second shaft[,] and a bulbous portion, and a threaded portion;

~~wherein the first aperture has a first spherical radius and the second aperture is tapered~~
~~and has a second radius; and~~

~~wherein the lag second screw member is adapted to be inserted into each of~~ for coupling
to at least one of the first and the second apertures internal surfaces.

2. **(Canceled)**.

3. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~lag~~
second screw member is coupled to the first screw member such that the first and the second
longitudinal axes define is at a fixed angle to the hybrid screw member.

4. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim ~~[[1]]~~ 3, wherein the fixed angle is an acute angle.

5. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the bulbous portion comprises a taper for providing an interference lock with the second ~~aperture~~ internal surface.

6. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim ~~[[3]]~~ 1, wherein the bulbous portion is partially spherical for coupling the ~~lag~~ second screw member at a variable angle.

7. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 6, wherein compression is applied at the variable angle.

8. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~hybrid~~ first screw member further comprises a first threaded portion aligned along the first shaft and opposed to the head portion.

9. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 8, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

10. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 8, wherein the first threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~hybrid~~ first screw member.

11. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~hybrid~~ first screw member further comprises an orifice aligned along the first longitudinal axis ~~less than the entirety of the shaft.~~

12. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 11, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

13. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 11, wherein the orifice is provided to receive a complementary shaped end of an instrument.

14. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~lag~~ first screw member is cannulated.

15. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~lag~~ second screw member further comprises a second threaded portion aligned along the second shaft and opposed to the bulbous portion.

16. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 15, wherein the second threaded portion contains a plurality of bone threads on an outer surface of the second threaded portion.

17. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 15, wherein the second threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~lag~~ second screw member.

18. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 1, wherein the ~~lag~~ second screw member further comprises a second orifice aligned along ~~[[a]]~~ the second longitudinal axis ~~for less than the entirety of the second shaft~~.

19. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 18, wherein the second orifice has a hexagonal shape, a star shape, or a square shape.

20. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 18, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

21. **(Currently amended)**: A method for fusing bones, comprising:

providing an ~~intramedullary~~ fixation assembly for bone fusion comprising, ~~wherein the intramedullary assembly further comprises~~:

a ~~hybrid~~ first screw member ~~aligned~~ extending along a first longitudinal axis,
~~wherein the hybrid first screw member further comprises~~ comprising a first shaft and a

head portion comprising a bore extending therethrough, the bore including a first aperture coupled to internal surface having a partially spherical shape and a second aperture internal surface that tapers from a first end to a second end; and

a lag second screw member extending along a second longitudinal axis, wherein the second screw member comprising a second shaft[[,]] and a bulbous portion, and a threaded portion;

wherein the first aperture has a first spherical radius and the second aperture is tapered and has a second radius;

making an incision, wherein the incision is made to access a plurality of bones;

drilling forming a first medullary canal bore hole in at least a first bone;

inserting the hybrid first screw member into the first medullary canal bore hole;

aligning the hybrid screw member in the first medullary canal;

drilling forming a second medullary canal bore hole in a second bone;

coupling the lag screw member to the hybrid screw member;

inserting the lag second screw member through the bore of the first screw member and into the second medullary canal bore hole;

applying compression to the lag second screw member to lock couple the hybrid second screw member to at least one of the first and second internal surfaces of the lag first screw member, thereby fusing the first bone to the second bone.

22. **(Currently amended):** The method of claim 21, wherein the ~~lag~~ second screw member is coupled to the ~~hybrid first~~ screw member ~~and makes~~ such that the first and the second longitudinal axes define a fixed angle with the hybrid screw member.

23. **(Original)**: The method of claim 22, wherein the fixed angle is an acute angle.
24. **(Canceled)**.
25. **(Canceled)**.
26. **(Currently amended)**: The method of claim 21, wherein the bulbous portion comprises a taper for providing an interference lock with the second ~~aperture~~ internal surface.
27. **(Currently amended)**: The method of claim 21, wherein the bulbous portion is partially spherical for coupling the ~~lag~~ second screw member at a variable angle.
28. **(Original)**: The method of claim 27, wherein compression is applied at the variable angle.
29. **(Currently amended)**: The method of claim 21, wherein the ~~hybrid~~ first screw member further comprises a first threaded portion aligned along the first shaft and opposed to the head portion.
30. **(Original)**: The method of claim 29, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

31. **(Currently amended)**: The method of claim 29, wherein the first threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~hybrid~~ first screw member.

32. **(Currently amended)**: The method of claim 21, wherein the ~~hybrid~~ first screw member further comprises an orifice aligned along the first longitudinal axis ~~less than the entirety of the~~ shaft.

33. **(Original)**: The method of claim 32, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

34. **(Original)**: The method of claim 32, wherein the orifice is provided to receive a complementary shaped end of an instrument.

35. **(Currently amended)**: The method of claim 21, wherein the ~~lag~~ first screw member is cannulated.

36. **(Currently amended)**: The method of claim 21, wherein the ~~lag~~ second screw member further comprises a second threaded portion aligned along the second shaft and opposed to the bulbous portion.

37. **(Original)**: The method of claim 36, wherein the second threaded portion contains a plurality of bone threads on an outer surface of the second threaded portion.

38. **(Currently amended)**: The method of claim 36, wherein the second threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~lag~~ second screw member.

39. **(Currently amended)**: The method of claim 21, wherein the ~~lag~~ second screw member further comprises a second orifice aligned along ~~[[a]]~~ the second longitudinal axis ~~for less than the entirety of the second shaft.~~

40. **(Original)**: The method of claim 39, wherein the second orifice has a hexagonal shape, a star shape, or a square shape.

41. **(Original)**: The method of claim 39, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

42. **(Currently amended)**: ~~An intramedullary~~ fixation assembly for bone fusion, comprising:
a ~~hybrid~~ first screw member ~~aligned~~ extending along a first longitudinal axis, ~~wherein the~~
~~hybrid~~ first screw member ~~comprises~~ comprising a first shaft, a first threaded portion, and a head
portion comprising a bore extending therethrough, the bore including a first internal surface
having a ~~first spherical radius~~ partially spherical shape and a second internal surface ~~having a~~
~~second radius~~ that tapers from a first end to a second end; and

a ~~lag~~ second screw member extending along a second longitudinal axis, the second screw
member comprising a second shaft, a bulbous portion, and a second threaded portion~~[[;]]~~,

~~wherein the first internal surface is coupled to the second internal surface to enclose a bore extending through the head portion along a bore axis;~~

~~wherein the second internal surface is tapered;~~

~~wherein the lag second screw member is adapted to be inserted into bore for coupling to at least one of the first and the second internal surfaces of the first screw member, and wherein the first and second longitudinal axes forms define an acute angle ~~with the longitudinal axis.~~~~

43. **(Currently amended):** The ~~intramedullary~~ fixation assembly of claim 42, wherein the bulbous portion is partially spherical for coupling the bulbous portion at a variable acute angle.

44. **(Currently amended):** The ~~intramedullary~~ fixation assembly of claim 42, wherein the bulbous portion is tapered for providing an interference lock with the second internal surface.

45. **(Currently amended):** The ~~intramedullary~~ fixation assembly of claim 42, wherein the ~~hybrid screw member further comprises a first threaded portion aligned~~ extends along the first shaft and opposed to the head portion.

46. **(Currently amended):** The ~~intramedullary~~ fixation assembly of claim ~~[[45]]~~ 42, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

47. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim ~~[[45]]~~ 42, wherein the first threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~hybrid~~ first screw member.

48. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 42, wherein the ~~hybrid~~ first screw member further comprises an orifice aligned along the first longitudinal axis ~~less than the entirety of the shaft~~.

49. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 48, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

50. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 49, wherein the orifice is provided to receive a complementary shaped end of an instrument.

51. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 42, wherein the ~~leg~~ first screw member is cannulated.

52. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 42, wherein the ~~leg screw member further comprises a~~ second threaded portion ~~aligned~~ extends along the second shaft and opposed to the bulbous portion.

53. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim ~~[[52]]~~ 42, wherein the second threaded portion contains a plurality of bone threads on an outer surface of the second threaded portion.

54. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim ~~[[52]]~~ 42, wherein the second threaded portion includes a self-tapping edge, wherein the self-tapping edge provides for removal of bone material during insertion of the ~~lag~~ second screw member.

55. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 42, wherein the ~~lag~~ second screw member further comprises a second orifice aligned along ~~[[a]]~~ the second longitudinal axis ~~for less than the entirety of the second shaft~~.

56. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 55, wherein the second orifice has a hexagonal shape, a star shape, or a square shape.

57. **(Currently amended)**: The ~~intramedullary~~ fixation assembly of claim 55, wherein the second orifice is provided to receive a complementary shaped end of an instrument.

58. **(New)**: A fixation assembly for bone fusion, comprising:

 a first screw member comprising:

 a first shaft having an external surface and extending along a first longitudinal axis from a first terminal end to a second terminal end, and

a bore extending through the first terminal end to the external surface of the first shaft, the bore including a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end; and

a second screw member comprising a bulbous portion and a second shaft extending along a second longitudinal axis;

wherein the second screw member is adapted for coupling to at least one of the first and the second internal surfaces of the first screw member such that the first and the second longitudinal axes define an acute angle.

59. **(New):** A fixation assembly for bone fusion, comprising:

a first screw member comprising:

a first shaft having an external surface and extending along a first longitudinal axis from a first terminal end to a second terminal end, and

a bore extending through the first terminal end to the external surface of the first shaft, the bore including a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end; and

a second screw member comprising a bulbous portion and a second shaft extending along a second longitudinal axis;

wherein the second screw member is adapted for coupling to at least one of the first and the second internal surfaces of the first screw member.

60. **(New):** The fixation assembly of claim 1, wherein the bulbous portion is partially spherical for providing an interference lock with the first internal surface.

61. **(New)**: The method of claim 21, wherein the bulbous portion is partially spherical for providing an interference lock with the first internal surface.

62. **(New)**: The fixation assembly of claim 42, wherein the bulbous portion is partially spherical for providing an interference lock with the first internal surface.

REMARKS

Claims 1, 3-23 and 26-62 are pending in this application. Please amend claims 1, 3-22, 26-27, 29, 31-32, 35-36, 38-39 and 42-57, cancel claims 2, 24 and 25, and add new claims 58-62. Although these claims have been amended, added, and/or canceled herein to provide clarification, correct typographical inaccuracies and/or informalities, and/or to better track practical/commercial implementations/practices (hereinafter “amendment,” “amendments,” and/or “amended”), Applicants submit that the originally filed claims are patentable and reserve the right to pursue the originally filed claims (as well as any claims dependent therefrom) at a later time and/or in one or more continuation/divisional application(s). Applicants submit that these new claims and/or claim amendments are supported throughout the originally filed specification and that no new matter has been added by way of these amendments. Applicants respectfully submit that the invention, as defined by claims 1, 3-23 and 26-62 is patentable over the prior art.

Accordingly, Applicants respectfully request reconsideration of the instant application in view of the following remarks:

I. AMENDMENTS TO THE SPECIFICATION AND DRAWINGS

The Examiner objected to the disclosure because reference numeral 322 refers to both a “surface” and an “end.” *See* Office Action dated Mar. 8, 2012, p. 2. The Examiner required appropriate correction.

In response to the Examiner’s objection, Applicants revised the specification as provided above and submit herewith replacement FIG. 3A. Specifically, the “end 322” of portion 310, as previously presented, was amended to “end 323.” Moreover, FIG. 3A was replaced to remove

the duplicate use of reference numeral 322 and to reflect the amendment to the specification. Applicants submit that no new matter has been added with this amendment to the specification and figures. In light of the amendment to the specification and replacement of FIG. 3A, Applicants submit that the Examiner's objection to the specification has been overcome and respectfully request the Examiner to withdraw the objection.

Moreover, Applicants submit herewith amendments to the specification as provided above and to FIGS. 3A and 11 as shown in attached replacement FIGS. 3A and 11. Applicants submit the above amendments to the specification and the amendments to attached replacement FIGS. 3A and 11 to correct typographical errors previously presented. Applicants submit that no new matter has been added with these amendments to the specification and figures. As such, Applicants respectfully request that the amendments to the specification and replacement FIGS. 3A and 11 be entered.

II. THE 35 U.S.C § 103 REJECTION

The Examiner rejected claims 1-57 under 35 U.S.C. § 103(a) as being unpatentable over various combinations of U.S. Patent Publication No. 2009/0240252 to Chang (hereinafter "Chang") in view of U.S. Patent No. 5,456,267 to Stark (hereinafter "Stark"), U.S. Patent No. 6,669,700 to Farris, et al. (hereinafter "Farris"), U.S. Patent Publication No. 2009/0149857 to Culbert, et al. (hereinafter "Culbert"), and U.S. Patent Publication No. 2009/0099571 to Cresina, et al. (hereinafter "Cresina"). Applicants respectfully traverse the Examiner's rejection, and submit that Chang, Stark, Farris, Culbert, and Cresina, alone or in combination, do not disclose or disclose every element of currently pending claims 1, 3-23 and 26-62.

Referring first to independent claim 1, Applicants submit that Chang and Stark alone or in combination do **not** disclose, and are in fact missing, at least the following element, *inter alia*, a first screw member comprising “a head portion comprising a bore extending therethrough, the bore including a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end,” as required by currently amended independent claim 1. Such a bore allows the coupling of different second screw members with variously shaped bulbous portions. In contrast, Chang merely discloses a nail retention member (10) with upper through hole (101) which retains locking nail (11). *See* Chang, FIGS. 1-5 and paragraphs [0017] and [0024]. As shown in Chang’s FIG. 4, the through hole (101) has only a single cylindrical internal surface to which the locking nail (11) couples. Nowhere does Chang disclose a bore with two internal surfaces, one being partially spherical and another that tapers from a first end to a second end. Likewise, Stark fails to disclose this feature.

In light of the remarks above, Applicants respectfully submit that Chang and Stark, alone or in combination, do not teach, suggest or render obvious the features of currently amended claim 1. Accordingly, Applicants respectfully submit that claim 1 is patentable over Chang and Stark. Dependent claims 3-20 and 60 are patentable by virtue of their dependency on claim 1. For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 1, 3-20 and 60.

Referring now to claim 21, Applicants submit that Chang, Stark and Cresina, alone or in combination, do **not** disclose, and are in fact missing at least the following element, *inter alia*, a first screw member comprising “a head portion comprising a bore extending therethrough, the bore including a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end,” as required by currently amended

independent claim 21. For the same reasons discussed above with respect to claim 1, Chang, Stark, and Cresina, alone or in combination, do not disclose this limitation.

In light of the remarks above, Applicants respectfully submit that Chang, Stark, and Cresina, alone or in combination, do not teach, suggest or render obvious the features of currently amended claim 21. Dependent claims 22-23, 26-41 and 61 are patentable by virtue of their dependency on claim 21. As such, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 21-23, 26-41 and 61.

Referring now to claim 42, Applicants submit that Chang and Stark, alone or in combination, do **not** disclose, and are in fact **missing** at least the following element, *inter alia*, a first screw member comprising “a head portion comprising a bore extending therethrough, the bore including a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end,” as required by currently amended independent claim 42. For the same reasons discussed above with respect to claim 1, Chang and Stark, alone or in combination, do not disclose this limitation. In addition, Applicants submit that Chang and Stark, alone or in combination, do **not** disclose, and are in fact **missing** at least the following element, *inter alia*, “wherein the second screw member is adapted for coupling to at least one of the first and the second internal surfaces of the first screw member, wherein the first and second longitudinal axes define an acute angle.” In contrast, Chang in FIG. 4 clearly shows that locking nail (11) is perpendicular to retention member (10). Nowhere does Chang disclose that locking nail (11) is at an acute angle to nail retention member (10). Likewise, Stark fails to disclose this feature.

In light of the remarks above, Applicants respectfully submit that Chang and Stark, alone or in combination, do not teach, suggest or render obvious the features of currently amended

claim 42. Accordingly, Applicants respectfully submit that claim 42 is patentable over Chang and Stark. Dependent claims 43-57 and 62 are patentable by virtue of their dependency on claim 42. As such, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 42-57 and 62.

Applicants further submit that newly added independent claims 58-59 are patentable over the references cited by the Examiner for the same reasons discussed above with respect to claim 1.

CONCLUSION

In view of the foregoing, the application is believed to be in condition for allowance and therefore Applicants respectfully request reconsideration and withdrawal of the rejections and objections and allowance of pending claims 1, 3-23 and 26-62.

Should any changes to the claims and/or specification be deemed necessary to place the application in condition for allowance, the Examiner is respectfully requested to contact the undersigned to discuss the same.

This response is being filed with a petition for a one month extension of time. If any other petitions and/or other fees are required, the Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 23-0420 in the name of Ward & Zinna, LLC.

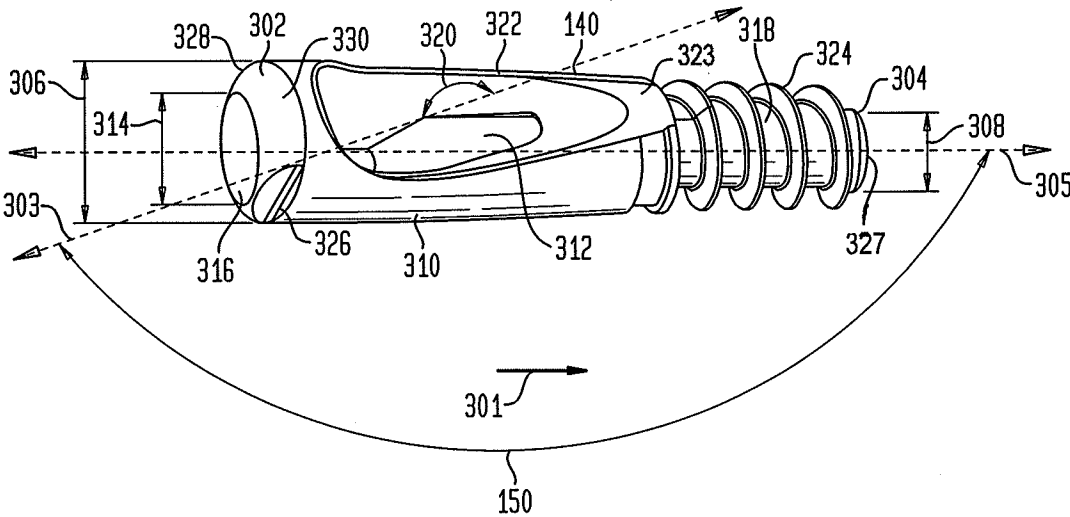
Respectfully submitted,

Date: July 9, 2012

/Francis E. Morris/

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Summit, New Jersey 07901
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FIG. 3A



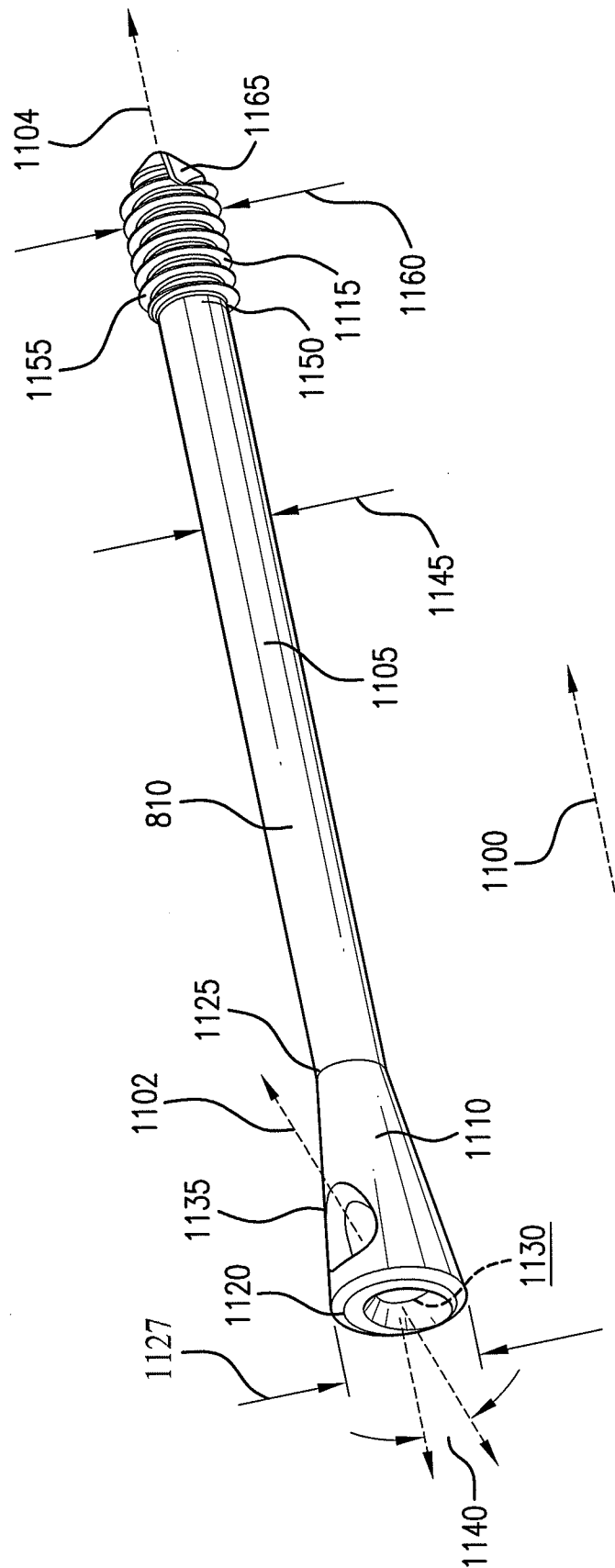


FIG. 11



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/906,454

10/18/2010

Adam Mantzaris

277-065

1120

27776

7590

08/29/2012

Ward & Zinna, LLC

SUITE 300

382 SPRINGFIELD AVENUE

SUMMIT, NJ 07901

EXAMINER

BRAY, STUART SAMUEL

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

08/29/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 12/906,454	Applicant(s) MANTZARIS ET AL.	
	Examiner STUART S. BRAY	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3-23 and 26-62 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3-23 and 26-62 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/9/2012</u> . | 6) ☐ Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 provides for the use of the second screw member and somehow applying compression, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10, 15-17, 42-47, 52-54, 60, 62 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 7,542,326 to Dierks.

Dierks discloses a first screw member (1) extending along a first longitudinal axis, with a first threaded (bone threads and self-tapping [Fig 1]) shaft, a head member with a bore extending therethrough with a first internal surface with a partially spherical shape and a second internal surface that tapers from a first end to a second end, a second screw member (41, col 7 line 40, a fastener, which is interpreted as including a screw that has threads opposite the spherical bulbous portion), along a second axis, with a second shaft and a partially spherical bulbous portion with a taper. The second screw is adapted for coupling to at least one of the internal surfaces (Fig 3a-d). The first and second screws are coupled at a fixed acute angle. Because the bulbous portion is partially spherical, the angle is variable when not locked/fixed. Because the fastener is interpreted to include a bone screw, it is interpreted that Dierks discloses the second screw to have bone threads and a self-tapping edge like the first screw. Regarding claim 7, based on the above 112 rejection, the second screw member applies compression to the first screw member when the second screw is inserted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14, 18-20, 48-51, 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dierks in view of 2009/0240252 to Chang.

Dierks discloses the invention as claimed and discussed above but does not disclose cannulation or a longitudinal orifice in the first or second screws. Chang discloses that the screw member can be cannulated, which is also a longitudinal orifice (para 0020). Chang discloses that a screw member has an orifice (103) aligned along the longitudinal axis and receives the complementary end (3131) of an instrument (31). Chang teaches an aperture (113) with a hex shape (Fig 3) which is complementary to the end of an instrument (40). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the aperture/orifices in both the first and second screws to be a hex shape to connect with a complementary instrument in order to make a secure fit between the two.

Claims 58-59 are rejected over Dierks in view of Chang.

Dierks discloses a first screw member with a first shaft with a first longitudinal axis (6) from a first terminal end to a second terminal end, a second internal surface that tapers (14) from a first end to a second end (Fig 1D), a second screw member with a bulbous portion and a second shaft along a second longitudinal axis (Fig 3a-3c), wherein the second screw is adapted for coupling to the second internal surface and define an acute angle (Fig 3C). Dierks does not disclose that the first screw has a first internal surface from the first terminal end to the second terminal end. Chang teaches cannulation in a screw member. The cannulation creates a first internal surface in the first screw. It would have been obvious to one ordinarily skilled in that art at the time of the invention to cannulate the first screw in order to pass guide wires or catheters through it.

Claims 21-23, 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dierks in view of Chang and in further view of U.S. Patent Application 2009/0099571 to Cresina et al ("Cresina").

Dierks discloses a first screw member (1) extending along a first longitudinal axis, with a first threaded (bone threads and self-tapping [Fig 1]) shaft, a head member with a bore extending therethrough with a first internal surface with a partially spherical shape and a second internal surface that tapers from a first end to a second end, a second screw member (41, col 7 line 40, a fastener, which is interpreted as including a screw that has threads opposite the spherical bulbous portion), along a second axis, with a second shaft and a partially spherical bulbous portion with a taper. The second

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screw is adapted for coupling to at least one of the internal surfaces (Fig 3a-d). The first and second screws are coupled at a fixed acute angle. Because the bulbous portion is partially spherical, the angle is variable when not locked/fixed. Because the fastener is interpreted to include a bone screw, it is interpreted that Dierks discloses the second screw to have bone threads and a self-tapping edge like the first screw.

Dierks discloses the invention as claimed and discussed above but does not disclose cannulation or a longitudinal orifice in the first or second screws. Chang discloses that the screw member can be cannulated, which is also a longitudinal orifice (para 0020). Chang discloses that a screw member has an orifice (103) aligned along the longitudinal axis and receives the complementary end (3131) of an instrument (31). Chang teaches an aperture (113) with a hex shape (Fig 3) which is complementary to the end of an instrument (40). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the aperture/orifices in both the first and second screws to be a hex shape to connect with a complementary instrument in order to make a secure fit between the two.

Dierks in view of Chang do not disclose forming a first bore hole in a first bone and forming a second bore hole in a second bone; inserting the first screw member into the first bore hole; coupling the second screw member to the hybrid member; inserting the lag screw member into the second canal; and applying torque to the head portion to lock the distal member to the proximal screw member, thereby compressing the first bone to the second bone.

Cresina discloses that an intramedullary fixation device can be used to secure two or more bones together (Figs 7 and 8). In this case, the lag (11) and hybrid screw (10) members can be used in a similar manner as disclosed in Cresina; whereby the two screw members can be inserted into two bones in close proximity, such as bones in the foot, as shown in Cresina Figs 7 and 8. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the device of Chang in a method disclosed by Cresina to compress two bones. It would have been obvious that in order to insert a shaft into a bone, an incision must first be made into the skin, holes must first be drilled into the bone; which may be done with a drill bit or a self-tapping screw. Using an instrument (screwdriver, 44, or 31 for the proximal member), such as disclosed in Chang would create torque on the head portion (112) and pull one bone (gripped by the threads 111 of the screw) towards a bone gripped by the distal member (10).

Response to Arguments

Applicant's arguments with respect to claims 1-57 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART S. BRAY whose telephone number is (571)270-7648. The examiner can normally be reached on Mon-Thurs 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Eduardo C. Robert, at 571-272-4719.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/STUART S BRAY/

Examiner, Art Unit 3733

/Alvin J Stewart/

Primary Examiner, Art Unit 3774

Electronically filed December 27, 2012
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Adam Mantzaris, *et al.*

Confirmation No.: 1120

Serial No.: 12/906,454

Examiner: Bray, Stuart Samuel

Filed: 10/18/2010

Art Unit: 3733

For: HYBRID INTRAMEDULLARY
FIXATION ASSEMBLY AND
METHOD OF USE

Atty. Doc. No.: 277-065

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

SIR:

This is to request pre-appeal brief review of the final rejection of the claims in this application except for the rejection of claim 7.

Claims 1, 3-23 and 26-62 are pending in this application. In the final office action mailed August 29, 2012, claim 7 was rejected under 35 U.S.C. 112, second paragraph. Claims 1, 3 - 10, 15 - 17, 42 - 47 , 52 - 54, 60, and 62 were rejected under 35 USC 102(b) as anticipated by Dierks (USP 7,542,326). Claims 11 - 14, 18 - 20, 48 - 51, 55 - 59 were rejected under 35 USC 103 (a) an unpatentable over Dierks in view of Chang (2009/0240252). Claims 21 - 23, 26 - 41 were rejected under 35 U.S.C. 103 (a) on Dierks in view of Chang and Cresina (2009/0099571). Except for the rejection of claim 7 which has not been appealed, these rejections are respectfully traversed.

The independent claims in this application are 1, 21, 42, 58, and 59. Each of independent claims 1, 21 and 42 was amended in the response filed on July 9, 2012 to recite a "bore including

a first internal surface having a partially spherical shape and a second internal surface that tapers from a first end to a second end." Claims 58 and 59 which were added at that time recite the same limitation.

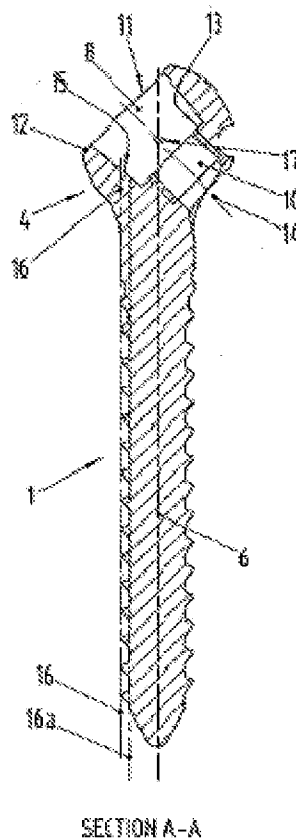
An illustrative example of the bore that is referred to in the claims is bore 2230 that is shown in FIGS. 22A and 22B and is described in paragraph 0093 of applicants' specification. With reference to the same figures, the first internal surface having a partially spherical shape is internal surface 2240 which is described in paragraph 0093 as having "a spherical radius that defines a first aperture within the central aperture 2230." And the second internal surface that tapers from a first end to a second end is internal surface 2245 which is described in paragraph 0093 as having "a taper that decreases from first surface 2275 (FIG. 22B) in direction 2250."

As is also stated in paragraph 0093, one advantage of the multiple internal surfaces is that the bore can receive different screws such as polyaxial screw member 2010 of FIGS. 20A - 20B) which have partially spherical surfaces and tapered screw member 2105 of FIGS. 21A and 21B.

The claims have all been rejected on either Dierks alone or Dierks in combination with other references. Independent claims 1 and 42 and several dependent claims have been rejected as anticipated by Dierks. Without referring to specific structure, the Examiner takes the position that Dierks discloses "a head member with a bore extending therethrough with a first internal surface with a partially spherical shape and a second internal surface that tapers from a first end to a second end."

While Dierks discloses a screw having a head with a bore that tapers, Dierks does not disclose an additional internal surface in the bore that has a partially spherical shape. The bore in Dierks is best shown in Fig. 1f, which is reproduced at the top of the following page:

Fig. 1f



As can be seen in Fig. 1f, the bore has an axis 14 and includes a recess 8 and a hole 10. Recess 8 is further described at Col.7, lines 63 - 64, as being "of conical design, tapering towards the mid-point of the screw head." Hole 10 is described at Col. 7, lines 38 - 39 as a "threaded hole." Fig. 1f is consistent with these descriptions showing a recess 8 that tapers from an opening 11 to a shoulder 13 and a hole 10 of uniform diameter. Nowhere does Dierks disclose or suggest an internal surface that has a partially spherical shape as required in each of the independent claims of the present application.

As is well known, "[a] claim is anticipated only if each and every element as set forth in the claims is found, expressly or inherently described, in a single prior are reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628 , 631, 2 USPQ2d, 1051, 1053 (Fed. Cir.

1987). Since Dierks does not disclose an internal surface in the bore that has a partially spherical shape, the rejection of independent claims 1 and 42 and the claims dependent thereon for anticipation must be withdrawn.

The remaining claims have all been rejected on various combinations of Dierks with other references. In the rejection of these claims, the Examiner relies on Dierks for the teaching of a bore having an internal surface that has a partially spherical shape. As discussed above, Dierks makes no such teaching; and Dierks also does not suggest such a structure. In the absence of any disclosure or suggestion of a bore having a second internal surface that has a partially spherical shape, independent claims 21, 58 and 59 and the claims dependent thereon are likewise patentable.

Claims 21 – 23 and 26 – 41 have been rejected under 35 U.S.C. 103(a) on Dierks in view of Chang and Cresina. These claims are method claims. The Examiner acknowledges at the bottom of page 6 of the final office action that Dierks and Chang do not disclose several steps of applicants' claimed method but relies on Cresina to make up for these deficiencies. The rejection of these method claims is traversed for the additional reason that Cresina does not disclose or suggest the specific steps recited in these claims.

Cresina discloses in FIGS. 7 and 8 the use of an intramedullary nail 214 that extends upward from the base of the heel through the ankle into the leg. Two unnumbered screws pass transversely through the mid-section of nail 214 and two stabilization screws 212 are located on either side of nail 214.

Applicants' claim 21 recites providing first and second screw members, the first screw member having a head portion with a bore having first and second internal surfaces as discussed above, and the steps of "forming a first bore hole in a first bone; inserting the first screw member

into the first bore hole; forming a second bore hole in a second bone; inserting the second screw member through the bore of the first screw member and into the second bore hole; and applying compression to the second screw member to couple the second screw member to at least one of the first and second internal surfaces of the first screw member, thereby fusing the first bone to the second bone."

Cresina fails to disclose a method of bone fixation that uses two screws to couple two bones. In particular, Cresina fails to disclose coupling a first screw that is in a first bore hole in a first bone to a second screw that eventually becomes located in a second bore hole in a second bone by "inserting the second screw through the bore of the first screw member and into the second bore hole" as recited in applicants' claim 21. The only bores disclosed in Cresina are the bores in the mid-section of nail 214. But the unnumbered screws that pass through these bores do not enter a bone that is different from the bone in which the bores are located, as required by applicants' claim 21. Nor is there any suggestion in Cresina of an arrangement in which screws that pass through the bore enter a different bone.

Accordingly independent method claim 21 and the claims dependent thereon are believed patentable over the cited art for this additional reason.

In view of the foregoing, claims 1, 3 - 6, 8 - 23, and 26 - 62 are believed to be in condition for allowance.

Respectfully submitted,

Date: December 27, 2012

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