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#### (54) Title: ANGULATED LOCKING PLATE/SCREW INTERFACE

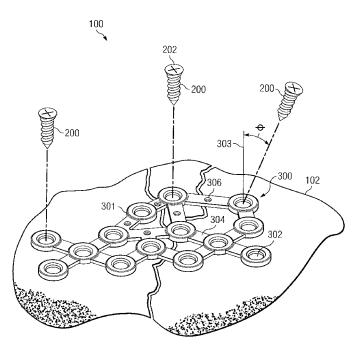


FIG. 1

(57) Abstract: A system (100) for lockably engaging bone screws into a fixation plate may include a locking fixation plate (300) including a threaded screw hole (302) defined by an inner surface surrounding the threaded screw hole, the inner surface comprising an upper countersink (310a) and a threaded portion (307), the threaded portion comprising a pair of threads arranged in a double helix configuration, and a screw (200) comprising a generally conical head (202) tapering into a generally cylindrical shaft (204) that ends at a tip (206) and a single thread (208) beginning near the tip and extending along the generally cylindrical shaft and onto the generally conical head, a thread height of the single thread being constant over a majority of the generally cylindrical shaft and tapering as the thread extends onto the head.





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#### ANGULATED LOCKING PLATE/SCREW INTERFACE

#### **TECHNICAL FIELD**

The present disclosure relates generally to repairing bone fractures, and more particularly, to an angulated locking plate/screw interface.

#### 5 BACKGROUND

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When repairing a broken, fractured, or shattered bone, a physician may often be faced with the task of affixing a fixation plate to the bone in order to align the bone, and possibly, to hold bone fragments together. In order to affix the fixation plate to the bone, a surgeon may insert a locking bone screw through one of a plurality of threaded screw holes in the fixation plate and into a predrilled hole in the bone. Alternatively, self drilling screws may be used. Since numerous threaded screw holes may be spread out across the entirety of the fixation plate, the surgeon may affix virtually any portion of the fixation plate to the bone by inserting a suitable number of locking bone screws through the plate and into the bone.

The trend in fixation for many medical practice areas such as the small bone orthopedic market and the craniofacial market is to use locking screws and plates that prevent the locking bone screws from backing out of the fixation plate once inserted. To achieve this lockable engagement, the inner surface of each threaded screw hole may be threaded to engage a corresponding set of locking threads on the head of each locking bone screw. Consequently, as a locking bone screw is screwed into one of the threaded screw holes in the fixation plate, the locking threads in the screw hole and the locking threads on the head of the locking bone screw may deform against each other to lock the locking bone screw into the fixation plate.

In certain cases, proper placement and positioning of the fixation plate may call for inserting a locking screw into a threaded screw hole at an angle other than perpendicular to the central axis of the threaded screw hole. For example, if the underlying bone beneath a particular screw hole is weak due to its proximity to a fracture line, the surgeon may wish to angle the bone screw away from the fracture line so as to anchor the screw into a more solid bony mass. Consequently, the ability to lockably engage a bone screw into a fixation plate at

an angle off of perpendicular from the plate may be a desirable feature for a surgeon repairing a broken, fractured, or shattered bone.

#### **SUMMARY**

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The present disclosure provides for a system and method for lockably engaging bone screws into a fixation plate. In particular embodiments, the system may include a locking fixation plate including a threaded screw hole defined by an inner surface surrounding the threaded screw hole. The inner surface may include an upper countersink and a threaded portion, and the threaded portion may include a pair of threads arranged in a double helix configuration. In particular embodiments, the system may further include a screw comprising a generally conical head tapering into a generally cylindrical shaft that ends at a tip and a single thread beginning near the tip and extending along the generally cylindrical shaft and onto the generally conical head. In particular embodiments, a thread height of the single thread may be constant over a majority of the generally cylindrical shaft and taper as the thread extends onto the head.

In particular embodiments, the portion of the thread disposed on the generally conical head may be configured to interfere with the pair of threads disposed on the inner surface of the screw hole to lock the screw into the screw hole once the screw is screwed into the screw hole.

In particular embodiments, the screw may include a thread root, and the thread height of a portion of the thread disposed on the head may be shallow enough to enable the portion of the root disposed on the head to contact the pair of threads disposed on the inner surface of the screw hole when the screw is screwed into the screw hole. Depending upon design, a pitch of the single thread on the head of the screw may be different that a pitch of the single thread on the body of the screw.

Depending upon design, the inner surface may further include a lower countersink, and the threaded portion may be disposed between the upper countersink and the lower countersink.

In particular embodiments, the threaded screw hole may be surrounded by a rim. Furthermore, the upper countersink may include a non-locking portion having a first

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countersink angle and a locking portion having a second countersink angle, and the non-locking portion may be disposed between the rim and the locking portion.

In particular embodiments, each thread of the pair of threads may have an included angle, and the second countersink angle may be equal to the included angle of each thread of the pair of threads.

Depending upon design, the screw may include a first material and the plate include a second material and the first material may be harder than the second material.

In particular embodiments, a method of using a screw and a locking fixation plate may include inserting a screw into a bone through a locking fixation plate. The locking fixation plate includes a threaded screw hole defined by an inner surface surrounding the threaded screw hole and the inner surface including an upper countersink and a threaded portion. Furthermore, the threaded portion may include a pair of threads arranged in a double helix configuration. The screw may include a generally conical head tapering into a generally cylindrical shaft that ends at a tip and a single thread beginning near the tip and extending along the generally cylindrical shaft and onto the generally conical head. Furthermore, a thread height of the single thread may be constant over a majority of the generally cylindrical shaft and taper as the thread extends onto the head.

In particular embodiments, the method may further include rotating the screw in the screw hole such that the portion of the thread disposed on the generally conical head interferes with the helical pair of threads disposed on the inner surface of the screw hole to lock the screw into the screw hole.

In particular embodiments, the method may further include locking the screw into the screw hole at an angle other than parallel to a central axis of the screw hole.

Technical advantages of particular embodiments of the present disclosure may include a double lead thread formed on the inside of the screw holes in the locking fixation plate that, as compared to a single lead thread, may enable a locking screw to engage the plate in half as many turns and engage the plate at an angle other than parallel to the central axis of the screw hole. Furthermore, each screw hole may include upper and lower countersinks that facilitate angled insertion of the bone screw through the plate by preventing the threading inside the screw hole from dictating the angle of insertion, and by providing clearance for the screw to tilt within the screw hole, yet another technical advantage. Also, the upper countersink may include both a locking portion and a non-locking portion. This feature may enable the

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threaded screw hole to accommodate either a locking screw or a non-locking screw, yet another technical advantage. Other technical advantages of the present disclosure will be readily apparent to one skilled in the art from the following figures, descriptions, and claims. Moreover, while specific advantages have been enumerated above, various embodiments may include all, some, or none of the enumerated advantages.

#### BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present disclosure and its advantages, reference is now made to the following descriptions, taken in conjunction with the accompanying drawings, in which:

FIGURE 1 illustrates an example embodiment of a system for attaching bone segments together including a locking plate and a plurality of locking screws according to the present disclosure;

FIGURES 2A and 2B illustrate enlarged views of one of the locking screws of FIGURE 1; and

FIGURES 3A and 3B illustrate enlarged views of a locking screw hole that may be included in the locking plate of FIGURE 1 according to the present disclosure.

#### **DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS**

20 FIGURE 1 illustrates an example system 100 for attaching together bone segments according to an example embodiment of the present disclosure. In the pictured embodiment, system 100 is being used relative to a single fractured bone 102. However, particular embodiments of system 100 may be applied equally as well to virtually any bone or group of bones in the body. For example, system 100 may be used to attach bone 102 and another bone, or bone 102 and a synthetic element such as a surgical implant.

In particular embodiments, system 100 may include one or more locking screws 200 that may be used to secure a fixation plate 300 to bone 102. For reference purposes, fixation plate 300 and other components of system 100 may be referred to as having a top or upper or side intended to face away from bone 102 and a lower or bottom side intended to face toward bone 102 (e.g., to be placed upon bone 102). Though particular features of those components may be explained using such intended placement as a point of reference, this method of

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explanation is not meant to limit the scope of the present disclosure to any particular configuration of fixation plate 300, its features, or any other components, or to any particular placement or orientation of fixation plate 300 relative to bone 102.

Fixation plate 300 may generally include a body 301 comprising a plurality of threaded screw holes 302 connected to each other in a web-like distribution by a plurality of ribs 304, although any suitable geometry of plate 301 is contemplated. In particular embodiments, ribs 304 may be thinned down relative to threaded screw holes 302 to facilitate bending of ribs 304 rather than threaded screw holes 302 when fixation plate 300 is contoured, for example to match the contour of bone 102.

Depending upon design, one or more ribs 304 may comprise one or more positioning holes 306 that may be used to position fixation plate 300 relative to bone 102. As an example, to position fixation plate 300 relative to bone 102 using a positioning hole 306, a surgeon may insert one end of a Kirschner wire ("K-wire") into bone 102 near the desired location for fixation plate 300. The surgeon may then insert the free end of the K-wire through one of positioning holes 306 and slide fixation plate 300 down onto bone 102 using the K-wire as a guide. Additionally, the surgeon may rotate fixation plate 300 about the K-wire to achieve a desired orientation of fixation plate 300 relative to bone 102. Once fixation plate 300 has been properly positioned on bone 102, the surgeon may secure fixation plate 300 to bone 102 using, for example, one or more locking screws 200. The surgeon may then remove the K-wire from bone 102.

To secure fixation plate 300 to bone 102 using a locking screw 200, the surgeon may insert locking screw 200 through one of threaded screw holes 302 and into bone 102. Locking screw 200 may be inserted either parallel to the central axis 303 of screw hole 302, or at an angle  $\theta$  relative to central axis 303. In certain procedures, the surgeon may pre-drill a pilot hole in bone 102 to establish the trajectory for locking screw 200, or, depending on design, locking screw 200 may be self-drilling in nature, making the pre-drilled hole in bone 102 unnecessary. In either case, once the tip 206 of locking screw 200 is contact with bone 102, the surgeon may use a screw driver or other suitable instrument to screw locking screw 200 into bone 102 until the head 202 of locking screw 200 comes to bear on the inner surface of screw hole 302. In particular embodiments, both the underside of head 202 and the inside of screw hole 302 may be threaded to permit locking screw 200 to lockably engage screw hole 302. In that case, further rotation of locking screw 200 at this point may cause the

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threaded portion of head 202 to interfere with the threading inside screw hole 302 and lock screw 200 into screw hole 302. The above-described process may be repeated for any suitable number of locking screw until locking plate 300 is firmly attached to bone 102. Once bone plate 300 has been secured to bone 102, the incision above bone 102 may be closed, leaving the patient to heal.

One of ordinary skill in the art will appreciate that the above-described embodiment and use of system 100 was presented for the sake of explanatory simplicity and will further appreciate that the present disclosure contemplates using any suitable number of locking screws 200 in combination with any suitable configuration of bone plate 300 to repair bone 102.

FIGURES 2A and 2B illustrate a more detailed view of one of the locking screws 200 of FIGURE 1. In particular, FIGURE 2A illustrates a side view of locking screw 200 taken perpendicular to the length of shaft 204, and FIGURE 2B illustrates a top view of locking screw 200, looking down at the top side of head 202.

As illustrated in FIGURE 2A, locking screw 200 generally includes a body 201 having a generally conical head 202 that tapers into a generally cylindrical shaft 204 ending at a tip 206. Screw 200 may further include a single generally continuous thread 208 formed around body 201 extending over a majority of locking screw 200 from tip 206 along the length of shaft 204 and onto head 202. In particular embodiments, screw 200 may be formed by carving thread 208 out of a blank. This may enable head 202 to be low profile so as to minimize the profile thickness of the plate/screw interface when screw 200 is engaged with fixation plate 300.

Thread 208 may generally be defined by a leading flank 210, a trailing flank 212, a crest 214 connecting the outer edge of leading flank 210 to the outer edge of trailing flank 212, and a root 216 connecting the inner edge of leading flank 210 to the inner edge of trailing flank 212. The dimensions of thread 208 may generally be described by one or more of a thread height 218, a leading flank thread angle 220, a trailing flank thread angle 222, a pitch 224, a crest width 226, and a thread diameter 236. The dimensions of body 201 may generally be described by one or more of a length 228, a head taper angle 230, a head diameter 232, and a shaft diameter 234. Although screw 200 may be configured to any suitable size or shape, in particular embodiments, length 228 may range, for example, from 18 millimeters to 55 millimeters, thread height 218 may be about .030 in. along the length of

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shaft 204 and may decrease from .030 in to about 0.000 in. according to taper angle 230 over the length of head 202, taper angle 230 may be about 26 degrees, leading thread flank angle 220 may be about 30 degrees, trailing thread flank angle 222 may be about 10 degrees, pitch 224 may be about .054 in. along the length of shaft 204 and about .048 in. along the length of head 202, crest width 226 may be about .001 in. to .004 in. flat (e.g., wide), thread diameter 236 may be about .138 in., head taper angle 130 may be about .26 degrees, head diameter 232 may be about .176 in., and shaft diameter 234 may be about .078 in.

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In particular embodiments, different portions of thread 208 may be configured to perform different functions. For example, the thread height 218 of the portion of thread 208 disposed on shaft 204 may be relatively large to enable thread 208 to bite into bone 102 along the length of shaft 204 while the thread height 218 of the portion of thread 208 disposed on head 202 may be relatively small along the length of head 202 to enable thread 208 and root 216 to interact with the threading inside screw hole 302 to lock screw 200 into plate 300. Depending upon design of screw 200, the pitch 224 of the portion of thread 208 disposed on shaft 204 may be the same as or different from the pitch 224 of the portion of thread 208 disposed on shaft 204 in order to enable screw 200 to lockably engage the threading on the inside of screw hole 302. As an example, pitch 224 may be constant along the entire length of screw 200.

As mentioned above, thread height 218 may taper as thread 208 extends onto head 202. This tapering may ensure that root 216 is brought into contact with the crest of the threading inside screw hole 302 when the threaded portion of head 202 comes to bear on the inner surface of screw hole 302. In particular, thread height 218 may be shallow enough on head 202 to enable the threading inside screw hole 302 to interact with (e.g., deform against or bite into) root 216 as well as thread 208. This dual interaction may increase the contact surface area between head 202 and the inner surface of screw hole 302 and provide a stable point of connection between plate 300 and screw 200, for example, when screw 200 is screwed into screw hole 302 at an angle other than perpendicular to the surface of screw hole 302. The desired locking effect may be caused by the threading inside screw hole 302 digging into thread 208 and root 216. If thread height 218 was not tapered on head 202 to enable root 216 to interact with the threading on the inner surface of screw hole 302, the threading inside screw hole 302 might only dig into thread 208, providing for a relatively weak point of connection.

The deformation process described above may be aided by forming screw 200 and plate 300 out of two materials having unequal hardness. For example, screw 200 may be formed of a material that is relatively softer than plate 300 to enable the threading inside screw hole 302 to dig into thread 208 and root 216. Alternatively, screw 200 may be formed of a material that is relatively harder than plate 300, in which case, the threading inside screw hole 302 may deform against thread 208 and root 216. In any case, the desired locking effect may be caused by threadable interference between the threading on head 202 and the threading in screw hole 302.

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Depending upon design, screw 200 and plate 300 may be formed from any one or more materials suitable for forming medical implants, such as materials that have high strength-to-weight ratios and that are inert to human body fluids. In certain embodiments, screw 200 or plate 300 may be formed from one or more titanium alloys, which provide several benefits. For example, titanium alloys are relatively lightweight, provide adequate strength for withstanding forces typically experienced by a medical implant, are inert to human body fluids, and are visible in radiographs of the implant region. In a particular embodiment, screw 200 may be formed from the titanium based alloy Ti6Al4V ELI (per ASTM F136), and plate 300 may be formed from grade 2 or grade 3 titanium (per ASTM F67). In certain other embodiments, screw 200 or plate 300 may be formed from one or more resorbable polymers, such as polylactides, polyglycolide, glycolide/lactide copolymers or other copolymers, or one or more implantable plastics, such as polyethylene or acetal copolymers for example.

Since the desired locking effect described above between plate 300 and screw 200 may depend primarily upon the interface between the threading inside screw hole 302 and the threading on head 202, head 202 may lockably engage screw hole 302 independent of the size of shaft 204. Thus, shaft 204 may have virtually any configuration (e.g., fully threaded, partially threaded, self-threaded, unthreaded, long, or short) while still maintaining the ability to lockably engage plate 300 by virtue of its connection to head 202.

As shown in FIGURE 2B, an engagement 238 is formed in head 202. In particular embodiments, engagement 238 may be adapted to receive an implantation tool such as a driver that may be used to rotate screw 200 about a longitudinal axis 240 in order to screw locking screw 200 into bone 102 and to lock locking screw 200 into screw hole 302. As an example, engagement 238 may comprises a cruciform-shaped recess adapted to mate with the

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screw driver; however, in other embodiments, engagement 238 may comprise any other suitable type of recess or engagement adapted to receive or mate with any suitable driver tool. For example, engagement 238 may comprise a recess having a hexagonal, rectangular, octagonal, or other shape. One of ordinary skill in the art will appreciate that the above-described embodiments of locking screw 200 were presented for the sake of explanatory simplicity and will further appreciate that the present disclosure contemplates locking screw 200 having any suitable dimensions and configuration, being formed from any suitable materials, and being used for any suitable purpose.

FIGURES 3A and 3B illustrate enlarged views of an example embodiment of a threaded screw hole 302 that may be included in locking plate 300 in accordance with the present disclosure. In particular, FIGURE 3A depicts an isometric view of threaded screw hole 302 and FIGURE 3B depicts a cross-sectional view of threaded screw hole 302 taken along line A of FIGURE 3A.

Referring to FIGURE 3A, threaded screw hole 302 may generally be defined by one or more of an upper countersink 310a, a lower countersink 310b, and a threaded portion 307 disposed between countersinks 310. Threaded screw hole 302 may further be surrounded by a rim 314 that comprises a generally flat surface encircling threaded screw hole 302.

Depending upon design, threaded portion 307 may include double lead threads 308 comprising a first thread 308a arranged with a second thread 308b in a double helix configuration. As an example and not by way of limitation, threads 308a and 308b may be identical to one another in all respects (e.g., size, length, and included thread angle  $\alpha$ ), except that thread 308a may be opposed from thread 308b by 180 degrees. As compared to a single lead thread, double lead threads 308 may enable screw 200 to lockably engage plate 300 in half as many rotations, enable screw 200 to engage screw hole 302 at an angle other than parallel to the central axis 303 of threaded screw hole 302, and provide a greater amount of surface area to engage the threading on head 202, thereby increasing the force needed to disengage screw 200 from locking fixation plate 300.

Referring to FIGURE 3B, in particular embodiments, upper counter sink 310a may include two portions, a locking portion 312 configured to lockably engage locking screw 200, and a non-locking portion 313 configured to seat a traditional screw having a non-locking (e.g., unthreaded) head. Locking portion 312 may be distinguished from non-locking portion 313 by the fact that threads 308 do not extend into non-locking portion 313. Including non-

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locking portion 313 on top of locking portion 312 may enable threaded screw hole 302 to accommodate either locking screw 200 or a traditional non-locking screw having a smooth under surface configured to bear against non-locking portion 313 when screwed into a bone 102.

Depending upon design, locking portion 312 may be defined by a locking countersink angle  $\phi$  while, non-locking portion may 313 may be defined by a non-locking countersink angle  $\gamma$ . Lower counter sink 310b may also be defined by a lower countersink angle  $\psi$ . Though countersinks 310 may have any suitable configuration, in particular embodiments, locking countersink angle  $\phi$  may be about 60 degrees, non-locking countersink angle  $\gamma$  may be about 90 degrees, and lower countersink angle  $\psi$  may be about 60 degrees. In particular embodiments, the included angle  $\alpha$  of threads 308a and 308b may be equal to locking countersink angle  $\phi$ .

Countersinks 310 may facilitate the ability of screw 200 to be inserted through screw hole 302 at an angle other than co-axial with central axis 303. For example, lower countersink 310b may provide clearance on the underside of plate 300 which enables shaft 204 to tilt within screw hole 302 up to a predefined angle before thread 208 (e.g., the threading on shaft 204) contacts the bottom surface of plate 300. Upper countersink 310a may enable screw 200 to lock into screw hole 302 at an angle other than perpendicular to the surface of screw hole 302 by preventing the threaded portion 307 from dictating the angle of insertion. When locking screw 200 is engaged with threaded screw hole 302, the portion of head 202 that is not engaged with threaded portion 307 may bear against upper countersink 310a to provide additional support for screw 200. In particular embodiments, upper countersink 310a may be deep enough to take in the entirety of head 202, even when head 202 is screwed into screw hole 302 at an angle other than parallel to the central axis 303 of threaded screw hole 302.

Referring back to threaded portion 307, threaded portion 307 may further be defined by one or more of a minor diameter 316, a major diameter 318, and a thread pitch 320. Although threaded portion 307 may be configured to any suitable size or shape, in particular embodiments, threaded portion 307 may include a double lead thread having a minor diameter 316 of 0.161 +/- .001 in., a major diameter 318 of .192 +/- .001 in. and a thread pitch 320 of .028 in.

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Furthermore, in particular embodiments, the outer edges of head 202 may be beveled to enable the edges of head 202 to remain below the plane of rim 314, even when inserted into screw hole 302 at an angle. Thus, the low profile of head 202 in combination with the custom size of countersinks 310 may provide a low plate/screw profile and reduce patient palpation of the implant (e.g., plate 300 and screw 200) by enabling head 202 to sink below the plane of rim 314 while still maintaining the desired angular locking interface.

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One of ordinary skill in the art will appreciate that the above-described embodiments of fixation plate 300 and threaded screw hole 302 were presented for the sake of explanatory simplicity and will further appreciate that the present disclosure contemplates any suitable configuration and number of screw holes 302, ribs 304, and positioning holes 306 in fixation plate 300. Although the present disclosure has been described in several embodiments, a myriad of changes, substitutions, and modifications may be suggested to one skilled in the art, and it is intended that the present disclosure encompass such changes, substitutions, and modifications as fall within the scope of the present appended claims.

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#### WHAT IS CLAIMED IS:

1. A system for lockably engaging bone screws into a fixation plate, comprising: a locking fixation plate including a threaded screw hole defined by an inner surface surrounding the threaded screw hole, the inner surface comprising an upper countersink and a threaded portion, the threaded portion comprising a pair of threads arranged in a double helix configuration; and

a screw comprising a generally conical head tapering into a generally cylindrical shaft that ends at a tip and a single thread beginning near the tip and extending along the generally cylindrical shaft and onto the generally conical head, a thread height of the single thread being constant over a majority of the generally cylindrical shaft and tapering as the thread extends onto the head.

- 2. The system of Claim 1, wherein the portion of the thread disposed on the generally conical head is configured to interfere with the pair of threads disposed on the inner surface of the screw hole once the screw is screwed into the screw hole to lock the screw into the screw hole.
  - 3. The system of Claim 1, wherein:

the screw comprises a thread root; and

the thread height of a portion of the thread disposed on the head is shallow enough to enable the portion of the root disposed on the head to contact the pair of threads disposed on the inner surface of the screw hole when the screw is screwed into the screw hole.

- 4. The system of Claim 1, wherein a pitch of the single thread on the head of the screw is different than a pitch of the single thread on the body of the screw.
  - 5. The system of Claim 1, wherein:

the inner surface further comprises a lower countersink; and

the threaded portion is disposed between the upper countersink and the lower countersink.

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6. The system of Claim 1, wherein:

the threaded screw hole is surrounded by a rim;

the upper countersink comprises a non-locking portion having a first countersink angle and a locking portion having a second countersink angle; and

the non-locking portion is disposed between the rim and the locking portion.

- 7. The system of Claim 6, wherein the first countersink angle is different from the second countersink angle.
- 10 8. The system of Claim 6, wherein each thread of the pair of threads comprises an included angle; and

the second countersink angle is equal to the included angle of each thread of the pair of threads.

15 9. The system of Claim 1, wherein the screw comprises a first material and the plate comprises a second material; and

the first material is harder than the second material.

- 10. A locking fixation plate, comprising a threaded screw hole defined by an inner surface surrounding the threaded screw hole, the inner surface comprising an upper countersink and a threaded portion, the threaded portion comprising a pair of threads arranged in a double helix configuration.
  - 11. The locking fixation plate of Claim 10, wherein:

the inner surface further comprises a lower countersink; and

the threaded portion is disposed between the upper countersink and the lower countersink.

- 12. The locking fixation plate of Claim 10, wherein:
- 30 the threaded screw hole is surrounded by a rim;

the upper countersink comprises a non-locking portion having a first countersink angle and a locking portion having a second countersink angle; and

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the non-locking portion disposed between the rim and the locking portion.

13. The locking fixation plate of Claim 12, wherein the first countersink angle is different from the second countersink angle.

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14. The locking fixation plate of Claim 12, wherein each thread of the helical pair of threads comprises an included angle; and

the second countersink angle is equal to the included angle of each thread of the helical pair of threads.

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15. A method of using a screw and a locking fixation plate, comprising: inserting a screw into a bone through a locking fixation plate wherein:

the locking fixation plate includes a threaded screw hole defined by an inner surface surrounding the threaded screw hole, the inner surface comprising an upper countersink and a threaded portion, the threaded portion comprising a pair of threads arranged in a double helix configuration; and

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the screw comprises a generally conical head tapering into a generally cylindrical shaft that ends at a tip and a single thread beginning near the tip and extending along the generally cylindrical shaft and onto the generally conical head, a thread height of the single thread being constant over a majority of the generally cylindrical shaft and tapering as the thread extends onto the head.

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16. The method of Claim 15, further comprising rotating the screw in the screw hole such that the portion of the thread disposed on the generally conical head interferes with the helical pair of threads disposed on the inner surface of the screw hole to lock the screw into the screw hole.

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17. The method of Claim 16, further comprising locking the screw into the screw hole at an angle other than parallel to a central axis of the screw hole.

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18. The method of Claim 15, wherein the inner surface further comprises a lower countersink; and

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the threaded portion is disposed between the upper countersink and the lower countersink.

### 19. The method of Claim 15, wherein:

5 the threaded screw hole is surrounded by a rim;

the upper countersink comprises a non-locking portion having a first countersink angle and a locking portion having a second countersink angle; and

the non-locking portion disposed between the rim and the locking portion.

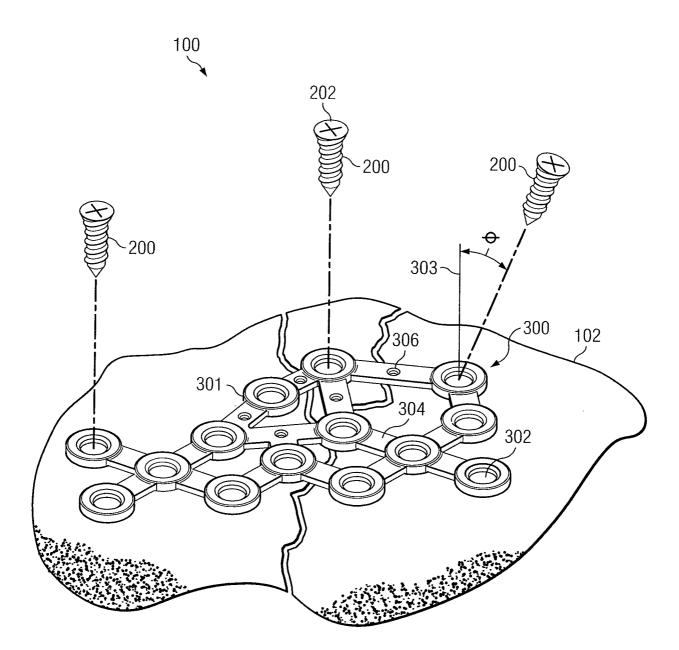
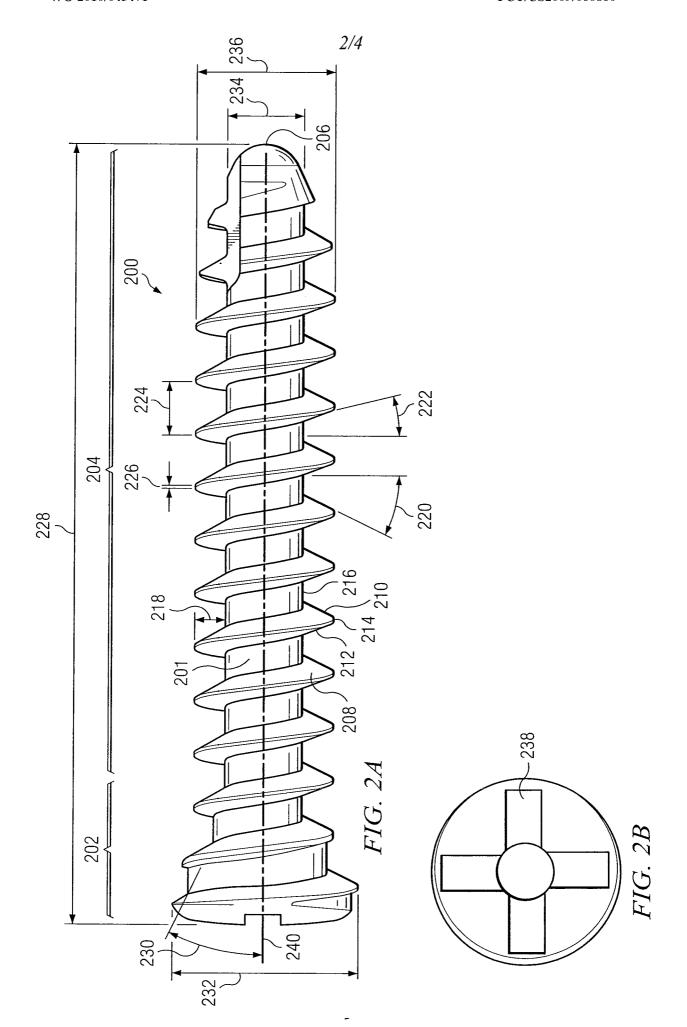
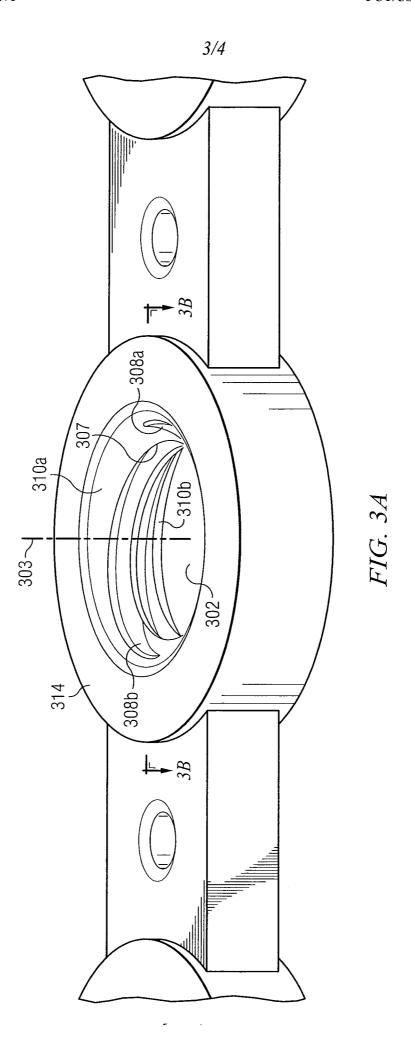
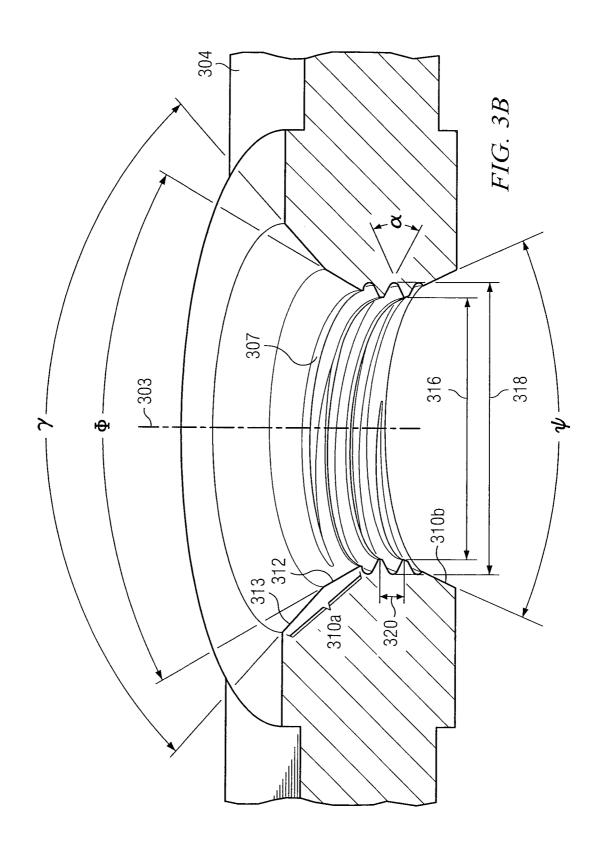


FIG. 1







#### **INTERNATIONAL SEARCH REPORT**

International application No PCT/US2009/060860

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B17/80 A61B17/86

According to International Patent Classification (IPC) or to both national classification and IPC

#### **B. FIELDS SEARCHED**

 $\begin{tabular}{ll} Minimum documentation searched & (classification system followed by classification symbols) \\ A61B & \end{tabular}$ 

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

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

#### EPO-Internal

Category*	ENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
v	HO 00/CC010 A1 (MEDADTIC AC FOUR	
X	WO 00/66012 A1 (MEDARTIS AG [CH]; PFEFFERLE JOACHIM [DE]; ROTH MICHAEL [DE]; SCHEUBLE) 9 November 2000 (2000-11-09)	1-4,10
Y	figures 3g,6b,6d page 12, line 12 page 14, lines 10-13 page 15, line 30 - page 16, line 7	5-9, 11-14
Y	WO 2005/018472 A1 (MATHYS MEDIZINALTECHNIK AG [CH]; SCHNEIDER ROLF [CH]) 3 March 2005 (2005-03-03) claim 27; figures 8,9	5-9, 11-14
<b>Y</b>	WO 2005/055842 A1 (HAND INNOVATIONS LLC [US]) 23 June 2005 (2005-06-23) figure 14 page 12, last line - page 13, line four page 7, paragraph third	
	-/	_

Further documents are listed in the continuation of Box C.	See patent family annex.
<ul> <li>Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier document but published on or after the international filling date</li> <li>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul>	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  "Y"-document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  "8" document member of the same patent family
Date of the actual completion of the international search  21 December 2009	Date of mailing of the international search report $13/01/2010$
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Authorized officer Louka, Maria

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## INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/060860

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 440 135 B2 (ORBAY JORGE L [US] ET AL) 27 August 2002 (2002-08-27) paragraphs [0016] - [0020] column 6, line 41 - line 51	1
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# International application No. PCT/US2009/060860

### INTERNATIONAL SEARCH REPORT

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 15–19 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest  The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
No protest accompanied the payment of additional search fees.

### **INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No
PCT/US2009/060860

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 0066012	A1	09-11-2000	AT AU DE EP JP US	286678 T 3954200 A 50009225 D1 1175181 A1 2002542875 T 6730091 B1	15-01-2005 17-11-2000 17-02-2005 30-01-2002 17-12-2002 04-05-2004
WO 2005018472	A1	03-03-2005	AU BR CA CN DE DE DE DE EP EP EP US	2003254686 A1 0318428 A 2536960 A1 1819799 A 20321151 U1 20321244 U1 20321245 U1 20321551 U1 20321552 U1 1658015 A1 1731107 A2 1741397 A2 2007506450 T 2006235400 A1	10-03-2005 01-08-2006 03-03-2005 16-08-2006 07-09-2006 14-06-2006 14-06-2007 27-12-2007 27-12-2007 24-05-2006 13-12-2006 10-01-2007 22-03-2007 19-10-2006
WO 2005055842	A1	23-06-2005	NONE		
US 6440135	 В2	27-08-2002	us Us	2001011172 A1	02-08-2001