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02/11/2010

PTO/SB/05 (08-08)
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# UTILITY PATENT APPLICATION TRANSMITTAL

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

| | |
|---|---|
| *Attorney Docket No.* | 277-042 |
| *First Inventor* | Jamy Gannoe |
| *Title* | An Intraosseous Intramedullary... |
| *Express Mail Label No.* | EM 284427428 US |

## APPLICATION ELEMENTS

*See MPEP chapter 600 concerning utility patent application contents.*

1. ☑ **Fee Transmittal Form** (e.g., PTO/SB/17)
2. ☑ **Applicant claims small entity status.** See 37 CFR 1.27.
3. ☑ **Specification** [*Total Pages* 53 ]
   Both the claims and abstract must start on a new page
   *(For information on the preferred arrangement, see MPEP 608.01(a))*
4. ☑ **Drawing(s)** (*35 U.S.C. 113*) [*Total Sheets* 20 ]
5. **Oath or Declaration** [*Total Sheets* 2 ]
   a. ☐ Newly executed (original or copy)
   b. ☐ A copy from a prior application (37 CFR 1.63(d))
   *(for continuation/divisional with Box 18 completed)*
   i. ☐ DELETION OF INVENTOR(S)
   Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   ☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
   *(if applicable, items a. – c. are required)*
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Paper
   c. ☐ Statements verifying identity of above copies

*ADDRESS TO:*
**Commissioner for Patents**
**P.O. Box 1450**
**Alexandria VA 22313-1450**

## ACCOMPANYING APPLICATION PARTS

9. ☐ **Assignment Papers** (cover sheet & document(s))
   Name of Assignee_____
10. ☐ **37 CFR 3.73(b) Statement** *(when there is an assignee)* ☐ **Power of Attorney**
11. ☐ **English Translation Document** *(if applicable)*
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    ☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☑ **Return Receipt Postcard** (MPEP 503)
    (*Should be specifically itemized*)
15. ☐ **Certified Copy of Priority Document(s)**
    *(if foreign priority is claimed)*
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. ☑ Other: Check for $1,949.00

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☑ Continuation-in-part (CIP) of prior application No.: 12/456,808

*Prior application information:* Examiner TBD Art Unit: 3733

## 19. CORRESPONDENCE ADDRESS

☑ The address associated with Customer Number: 27776 *OR* ☐ Correspondence address below

| | | | | | |
|---|---|---|---|---|---|
| Name | | | | | |
| Address | | | | | |
| City | | State | | Zip Code | |
| Country | | Telephone | | Email | |

| | | | |
|---|---|---|---|
| Signature | | Date | February 11, 2010 |
| Name (Print/Type) | David M. Hill | Registration No. (Attorney/Agent) | 46,170 |

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**
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**Extremity Medical, LLC**
**EXHIBIT 2021 - Corrected**
**Fusion Orthopedics v. Extremity Medical**
**Case IPR2023-00894**

U.S. PTO
12/658680
02/11/2010

PTO/SB/17 (10-08)
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*Effective on 12/08/2004.*
*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*

# FEE TRANSMITTAL
## For FY 2009

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 1,949.00

| Complete if Known | |
|---|---|
| Application Number | TBD |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jamy Gannoe |
| Examiner Name | TBD |
| Art Unit | TBD |
| Attorney Docket No. | 277-042 |

**METHOD OF PAYMENT** (check all that apply)

☑ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 23-0420 Deposit Account Name: Ward & Olivo

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

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**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES Fee ($) | FILING FEES Small Entity Fee ($) | SEARCH FEES Fee ($) | SEARCH FEES Small Entity Fee ($) | EXAMINATION FEES Fee ($) | EXAMINATION FEES Small Entity Fee ($) | Fees Paid ($) |
|---|---|---|---|---|---|---|---|
| Utility | 330 | 165 | 540 | 270 | 220 | 110 | $545.00 |
| Design | 220 | 110 | 100 | 50 | 140 | 70 | |
| Plant | 220 | 110 | 330 | 165 | 170 | 85 | |
| Reissue | 330 | 165 | 540 | 270 | 650 | 325 | |
| Provisional | 220 | 110 | 0 | 0 | 0 | 0 | |

**2. EXCESS CLAIM FEES**

| Fee Description | Fee ($) | Small Entity Fee ($) |
|---|---|---|
| Each claim over 20 (including Reissues) | 52 | 26 |
| Each independent claim over 3 (including Reissues) | 220 | 110 |
| Multiple dependent claims | 390 | 195 |

| Total Claims | Extra Claims | Fee ($) | Fee Paid ($) |
|---|---|---|---|
| 74 - 20 or HP = | 54 | x 26 | = $1,404.00 |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | Extra Claims | Fee ($) | Fee Paid ($) |
|---|---|---|---|
| 3 - 3 or HP = | 0 | x 110 | = 0 |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims Fee ($) | Multiple Dependent Claims Fee Paid ($) |
|---|---|
| | 0 |

**3. APPLICATION SIZE FEE**

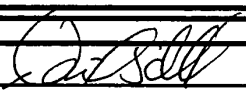
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee ($) | Fee Paid ($) |
|---|---|---|---|---|
| 73 - 100 = | 0 | / 50 = _____ (round up to a whole number) | x _____ = | 0 |

**4. OTHER FEE(S)**

| | Fees Paid ($) |
|---|---|
| Non-English Specification, $130 fee (no small entity discount) | 0 |
| Other (e.g., late filing surcharge): _____ | 0 |

**SUBMITTED BY**

| | | | |
|---|---|---|---|
| Signature |  | Registration No. (Attorney/Agent) 46,170 | Telephone 212-697-6262 |
| Name (Print/Type) | David M. Hill | | Date February 11, 2010 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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# AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

## CROSS-REFERENCE TO RELATED APPLICATIONS

This continuation-in-part application claims the benefit of Non-Provisional Application 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.

## FIELD OF THE INVENTION

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

## 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.

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 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 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 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.

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.

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 the bones in the human body through the use of an intraosseous intramedullary assembly.

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 an intramedullary fixation assembly for bone fixation having variable acute angles of fixation.

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 assembly for bone fusion is provided and includes a lag screw member and a tapered screw member. The lag screw member includes a first elongated body, where the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end. The tapered screw member is coupled to the lag screw member, and the tapered screw member includes a second elongated body, where the second elongated body includes a second threaded portion at a third end, and an opening at a fourth end.

In a second non-limiting aspect of the invention, a method for bone fusion includes eight steps. In step one, an intramedullary assembly is provided, where the intramedullary assembly includes a lag screw member having a first elongated body. The first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end.

The intramedullary assembly also includes a tapered screw member coupled to the lag screw member, where the tapered screw member includes a second elongated body having a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end. Step two includes making an incision in the foot. Step three includes drilling a first medullary canal in a first bone. Step four includes inserting the tapered screw member into the first medullary canal. Step five includes aligning the tapered screw member in the first medullary canal. Step six includes drilling a second medullary canal in the first bone. Step seven includes slideably coupling the lag screw member to the tapered screw member. Step seven includes inserting the lag screw member into the second medullary canal. Step eight includes applying compression to the lag screw member to lock the tapered screw member to the lag screw member, thereby fusing the first bone to the second bone.

**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 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.

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 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.

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.

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.

**DETAILED DESCRIPTION**

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 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 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 comprises an internal aperture 214 that longitudinally traverses portion 206 in direction 201. Portion 206 terminates into a second 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 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 comprises 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 comprises a generally smooth portion 310 coupled to end 302. Portion 310 has a generally hexagonal shaped aperture 312, which opens into aperture 316 and 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 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 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 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 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 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 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 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 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 comprises a tapered screw member 810 coupled to a lag 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 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 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 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 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 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.

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. 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 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, 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 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 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-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.

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 comprises 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 155 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.

It should be appreciated that any number of intramedullary fixation assemblies, such as intramedullary fixation assembly

800, may be inserted into the joints, for example, of the human foot in order to provide for compression of the bones of the foot. It should also be appreciated that the intramedullary fixation assembly 800 is delivered through an incision, 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 the intramedullary fixation assembly 800 may also be utilized to restore any of the other bones in the human body. It should also be appreciated that in other non-limiting embodiments, the intramedullary assembly 800 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 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 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 assembly for bone fusion, comprising:

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, wherein the tubular portion comprises an opening disposed at an end of the tubular portion.

2. The intramedullary assembly of claim 1, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

3. The intramedullary assembly of claim 1, wherein the fixed angle is in the range of 0 to 90 degrees.

4. The intramedullary assembly of claim 3, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

5. The intramedullary assembly of claim 4, wherein the taper provides for an interference lock with the tapered screw member.

6. The intramedullary assembly of claim 5, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

7. The intramedullary assembly of claim 6, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

8. The intramedullary assembly of claim 7, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

9. The intramedullary assembly of claim 8, wherein the orifice is provided to receive a complementary shaped end of an instrument.

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

11. The intramedullary assembly of claim 10, 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 lag screw member.

12. The intramedullary assembly of claim 11, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

13. The intramedullary assembly of claim 12, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

14. The intramedullary assembly of claim 13, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

15. The intramedullary assembly of claim 14, wherein the first internal aperture further includes a hexagonally shaped opening,

a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

16. The intramedullary assembly of claim 15, wherein the opening is provided to receive a complementary shaped member.

17. The intramedullary assembly of claim 16, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

18. The intramedullary assembly of claim 17, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

19. The intramedullary assembly of claim 18, wherein the tapered aperture forms a predetermined angle with the second elongated body.

20. The intramedullary assembly of claim 19, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

21. The intramedullary assembly of claim 20, 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 tapered screw member.

22. The intramedullary assembly of claim 21, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

23. The intramedullary assembly of claim 25, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

24. The intramedullary assembly of claim 23, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

25. The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped

opening, or a square-shaped opening partially disposed in the second elongated body.

26. A method for bone fusion, comprising:

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

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

drilling a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

drilling a second medullary canal in the first bone;

slideably coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

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

27. The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

28. The method of claim 27, wherein the fixed angle is in the range of 0 to 90 degrees.

29. The method of claim 28, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

30. The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

31. The method of claim 30, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

32. The method of claim 31, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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 33, further comprising receiving a complementary shaped end of an instrument in the orifice.

35. The method of claim 34, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

36. The method of claim 35, 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 lag screw member.

37. The method of claim 36, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

38. The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

39. The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

40. The method of claim 39, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

41. The method of claim 40, further comprising receiving a complementary shaped member in the opening.

42. The method of claim 41, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

43. The method of claim 42, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

44. The method of claim 43, wherein the tapered aperture forms a predetermined angle with the second elongated body.

45. The method of claim 44, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

46. The method of claim 45, 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 tapered screw member.

47. The method of claim 46, further comprising inserting the lag screw member into at least a first medullary canal of bone.

48. The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

49. The method of claim 48, wherein the intramedullary assembly comprises a cover portion coupled to the bulbous portion of the lag screw member.

50. The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

51. An intramedullary assembly for bone fusion, comprising:

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and wherein the tubular portion comprises an opening at the fourth end.

52. The intramedullary assembly of claim 51, wherein the lag screw member is slideably coupled to the tapered screw member and makes an angle with the tapered screw member.

53. The intramedullary assembly of claim 52, wherein the angle varies between 0 and 90 degrees.

54. The intramedullary assembly of claim 53, wherein the bulbous portion is semi-spherical for providing angular rotation of the lag screw member .

55. The intramedullary assembly of claim 54, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

56. The intramedullary assembly of claim 55, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

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

59. The intramedullary assembly of claim 58, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

60. The intramedullary assembly of claim 59, 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 lag screw member.

61. The intramedullary assembly of claim 60, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

62. The intramedullary assembly of claim 61, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

63. The intramedullary assembly of claim 62, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

64. The intramedullary assembly of claim 63, wherein the first internal aperture further includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

65. The intramedullary assembly of claim 64, wherein the opening is provided to receive a complementary shaped member.

66. The intramedullary assembly of claim 65, wherein the tapered aperture traverses the second elongated body from the fourth end to an exterior surface on the second elongated body.

67. The intramedullary assembly of claim 66, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the fourth end.

68 The intramedullary assembly of claim 67, wherein the tapered aperture forms a predetermined angle with the second elongated body.

69. The intramedullary assembly of claim 68, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

70. The intramedullary assembly of claim 69, 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 tapered screw member.

71. The intramedullary assembly of claim 70, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

72. The intramedullary assembly of claim 71, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

73. The intramedullary assembly of claim 72, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

74. The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**ABSTRACT**

An intramedullary assembly for intraosseous bone fusion includes a lag screw member and a tapered screw member. The lag screw member includes a first elongated body, where the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end. The tapered screw member is coupled to the lag screw member, and the tapered screw member includes a second elongated body, where the second elongated body includes a second threaded portion at a third end, and an opening at a fourth end.

FIG. 1

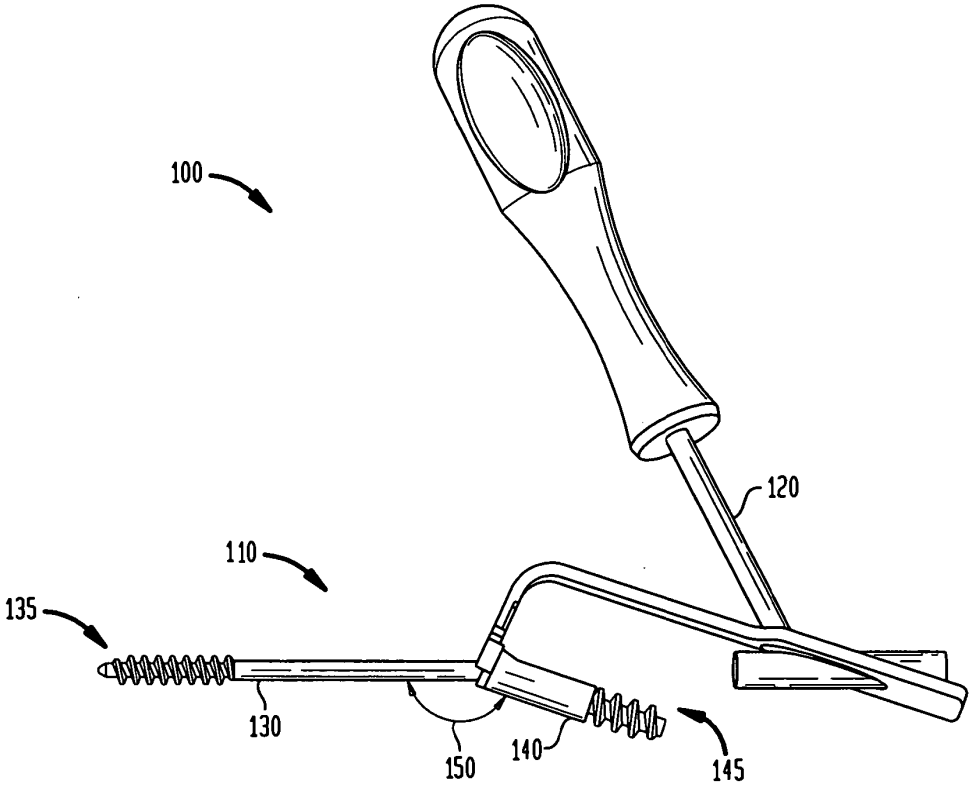


FIG. 2

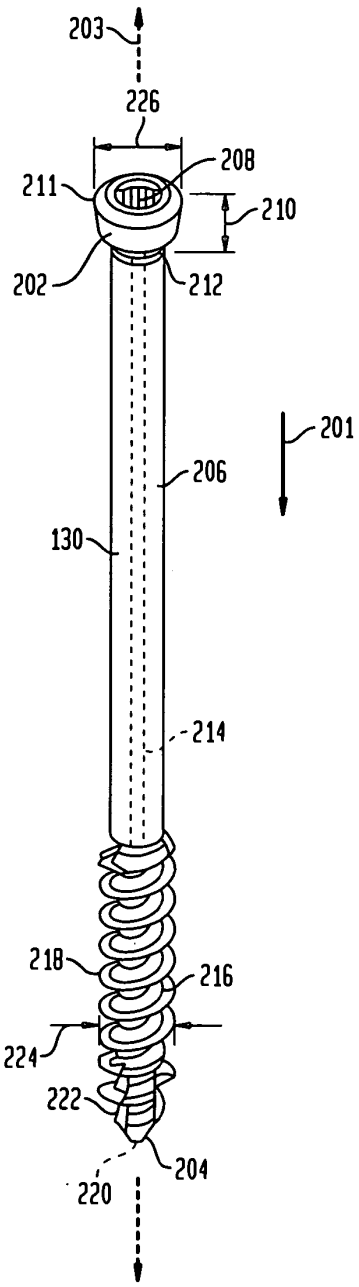

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FIG. 3A

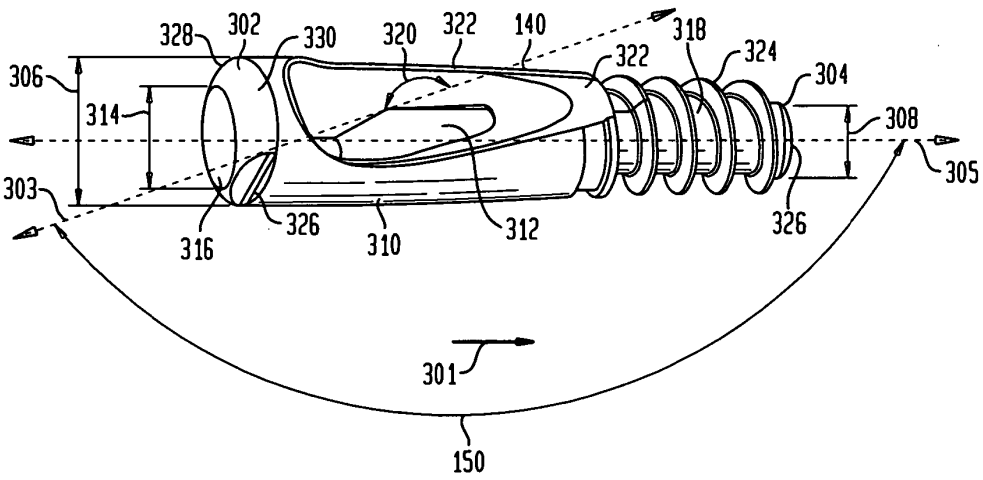

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FIG. 3B

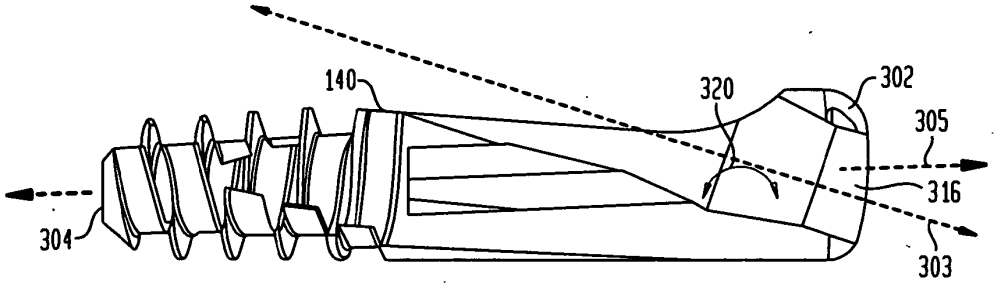
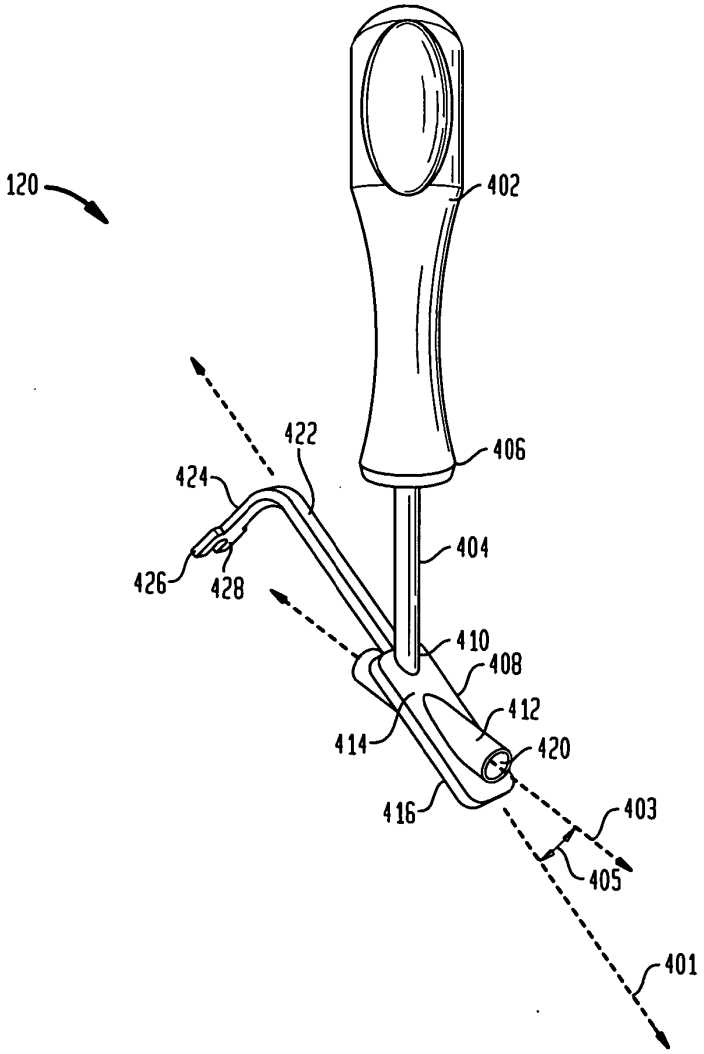


FIG. 4


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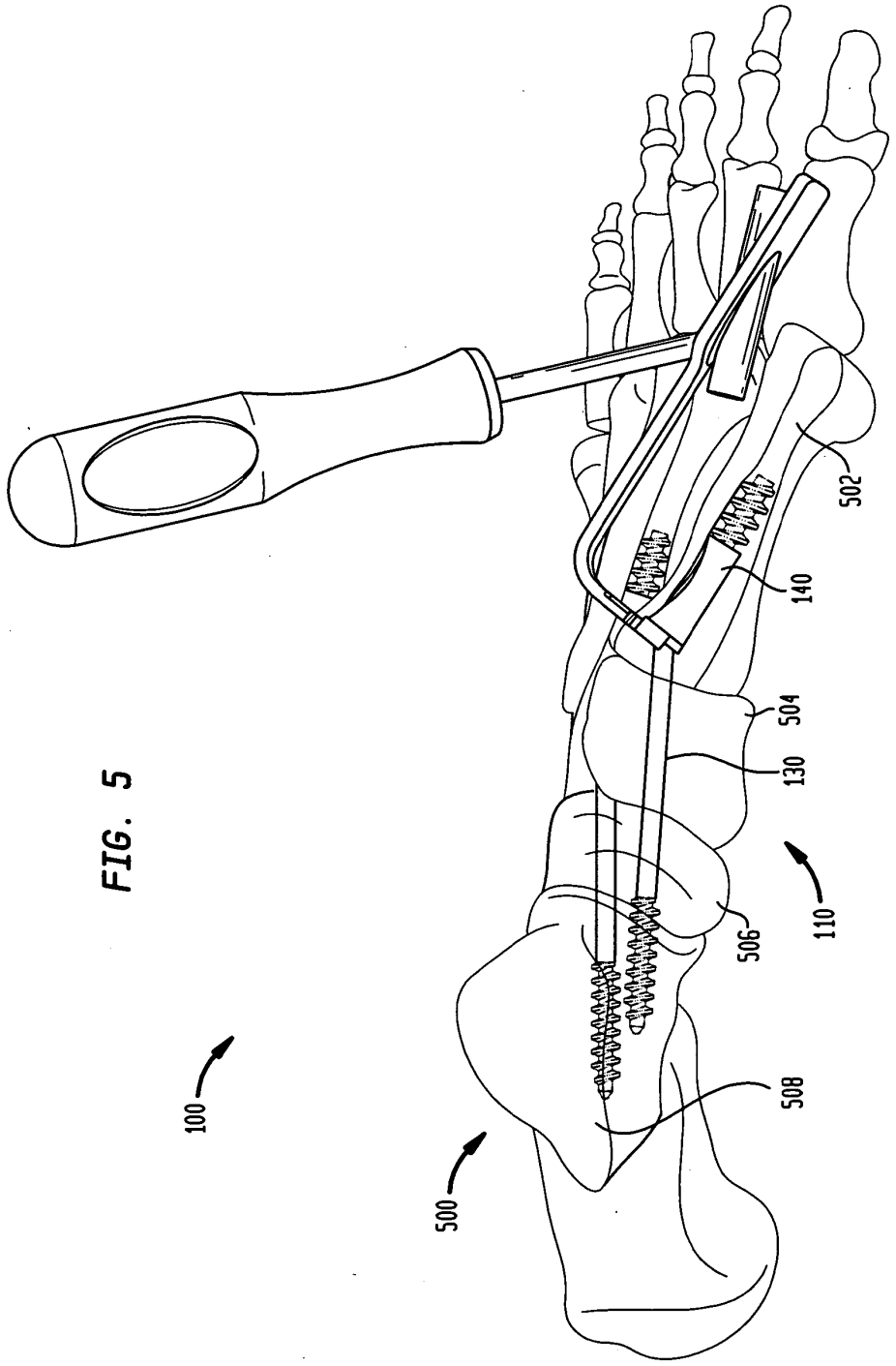



FIG. 5

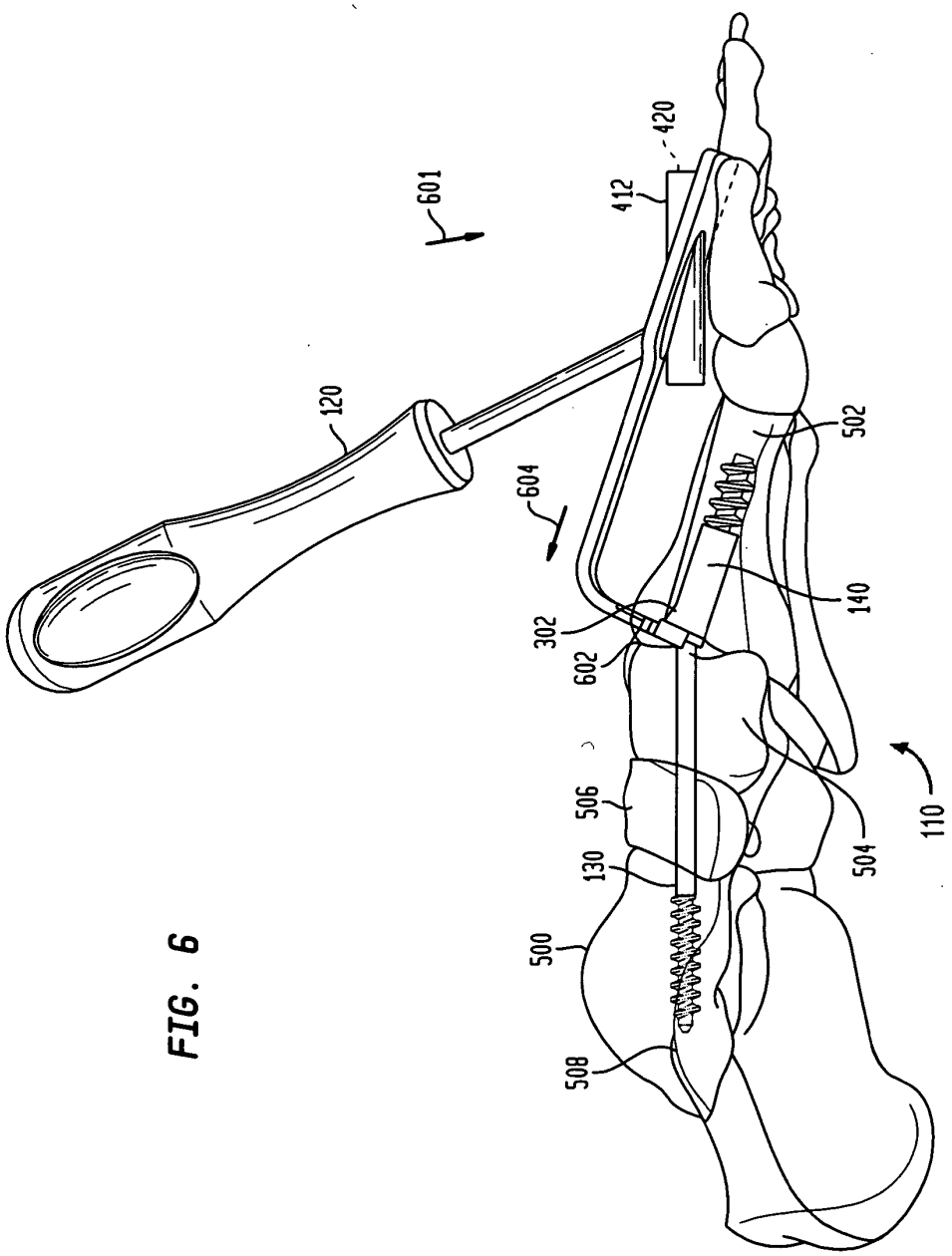



FIG. 6

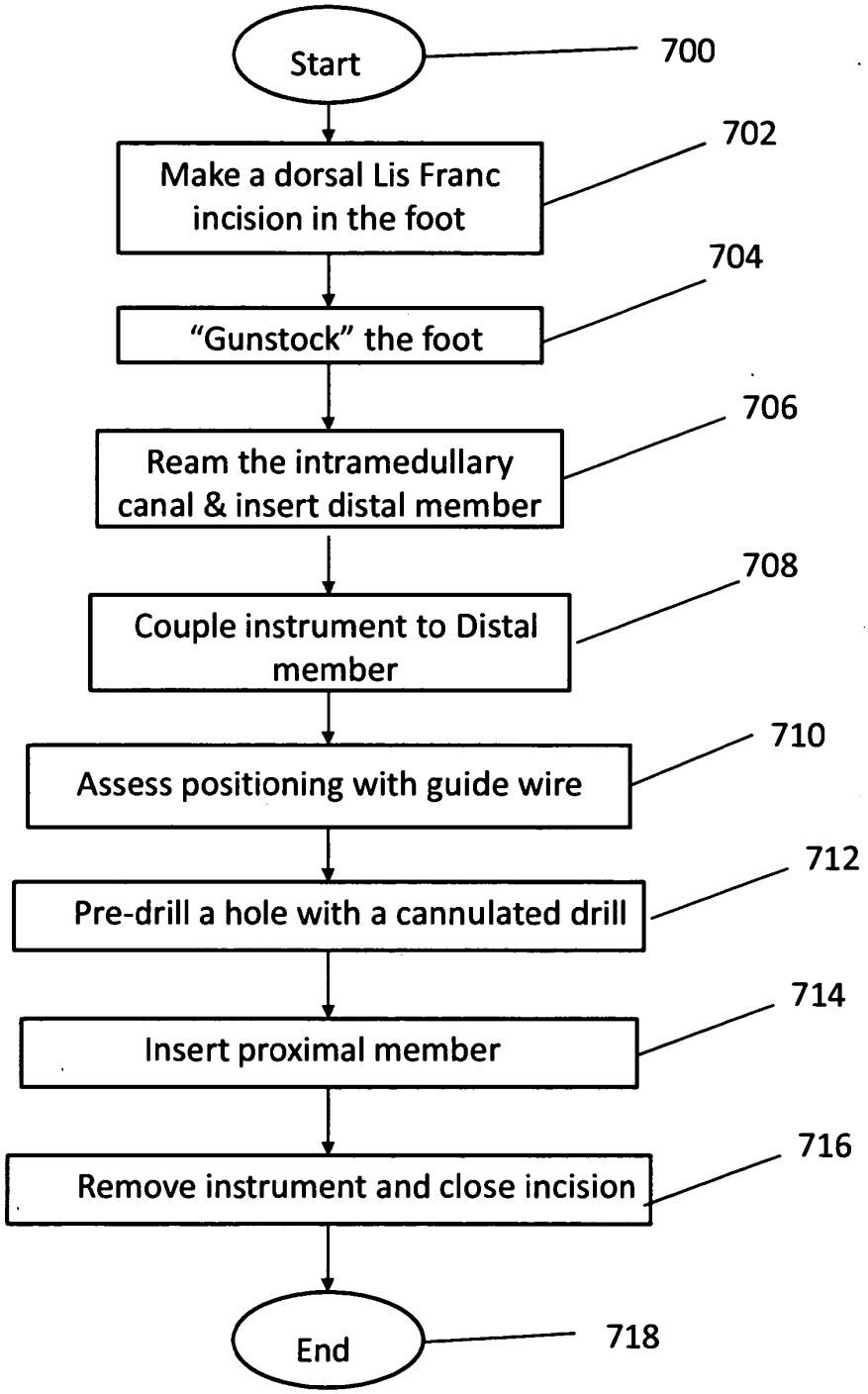

Start
700
Make a dorsal Lis Franc incision in the foot
702
"Gunstock" the foot
704
Ream the intramedullary canal & insert distal member
706
Couple instrument to Distal member
708
Assess positioning with guide wire
710
Pre-drill a hole with a cannulated drill
712
Insert proximal member
714
Remove instrument and close incision
716
End
718

*FIG. 7*

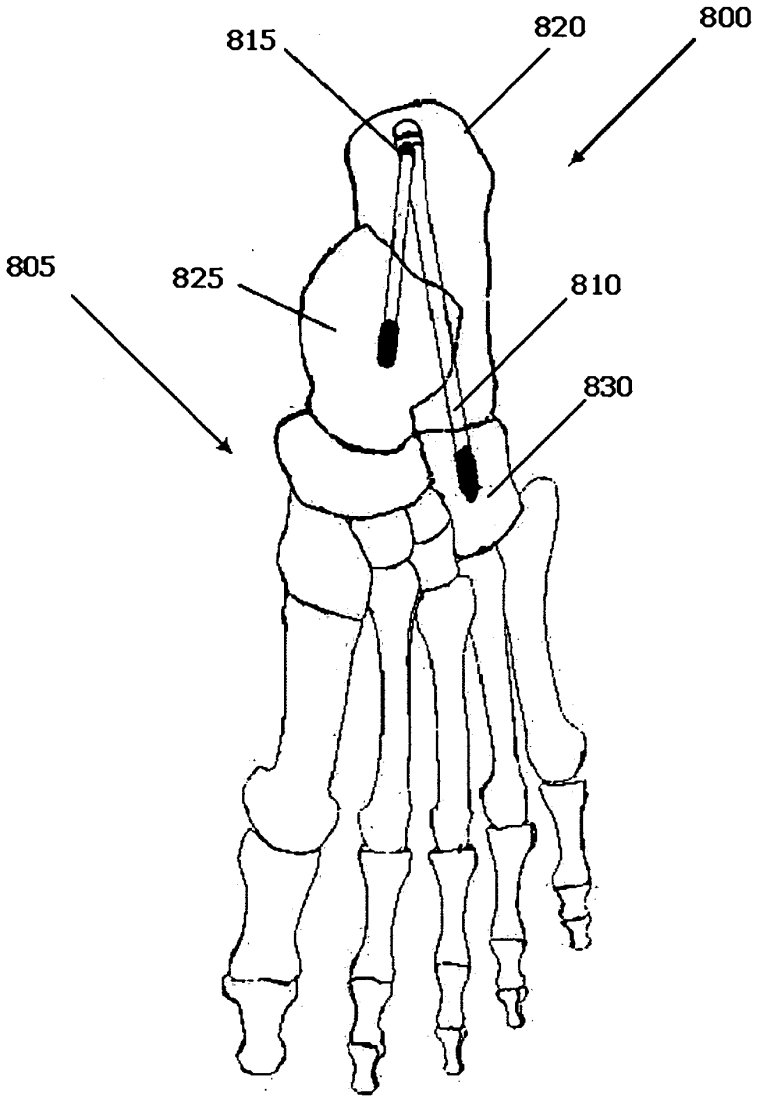



*FIG. 8*

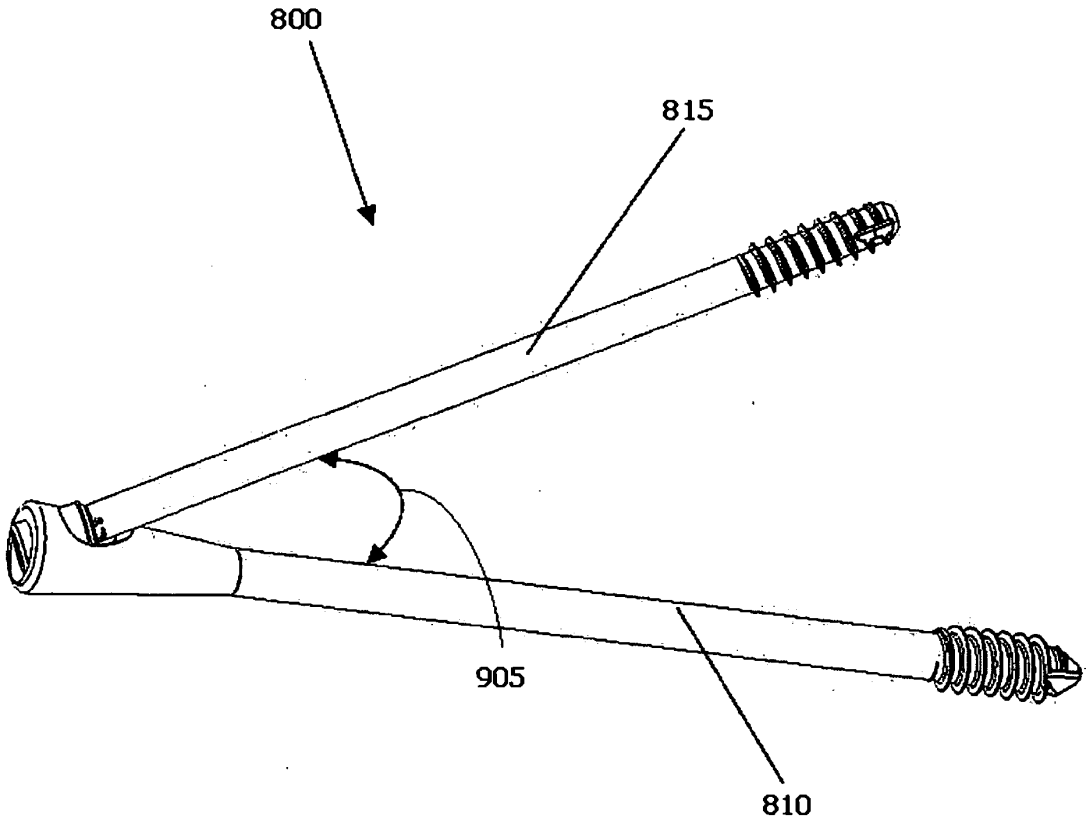



*FIG. 9*

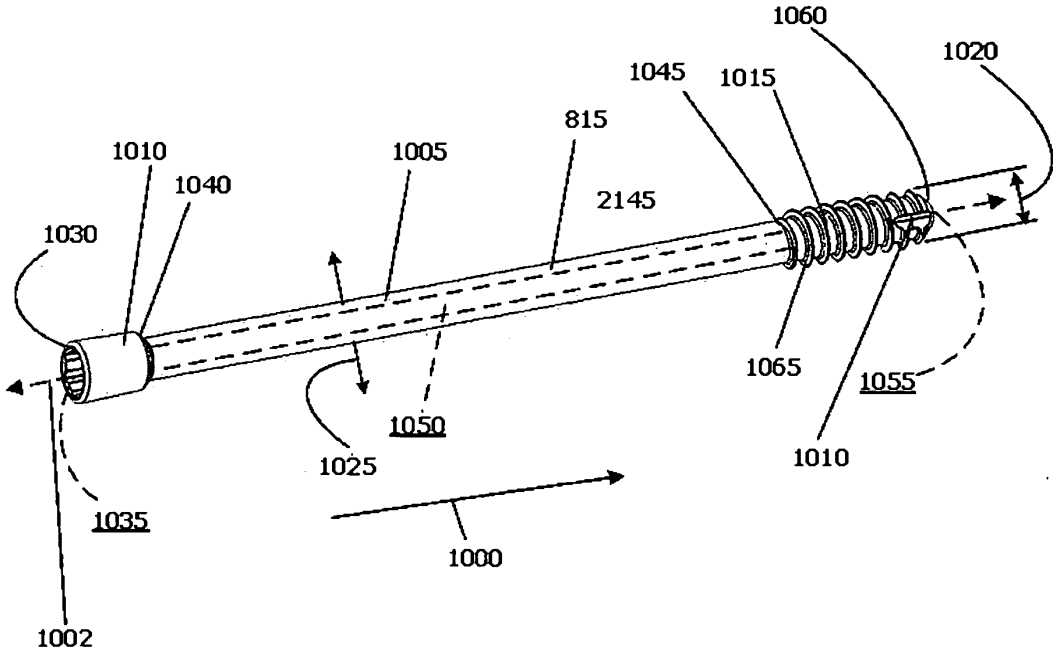

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*FIG. 10*

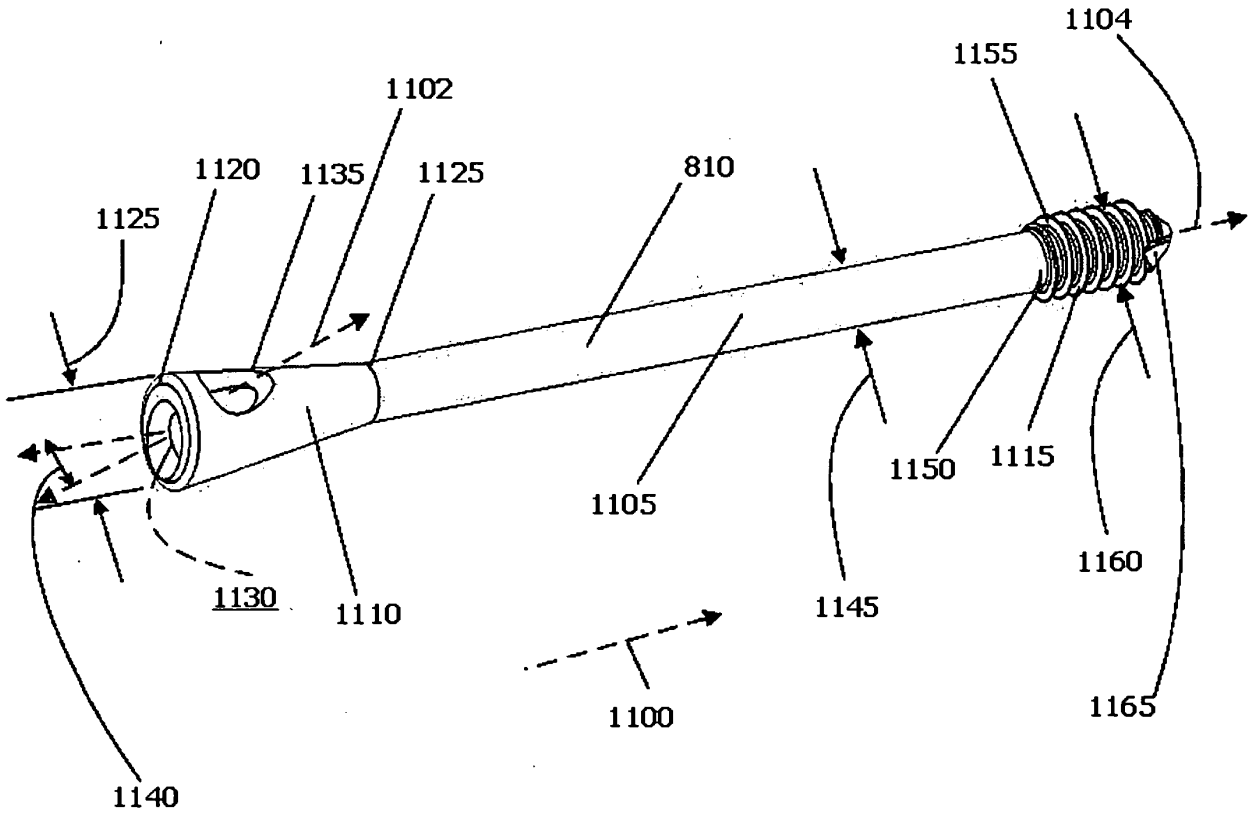

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FIG. 11

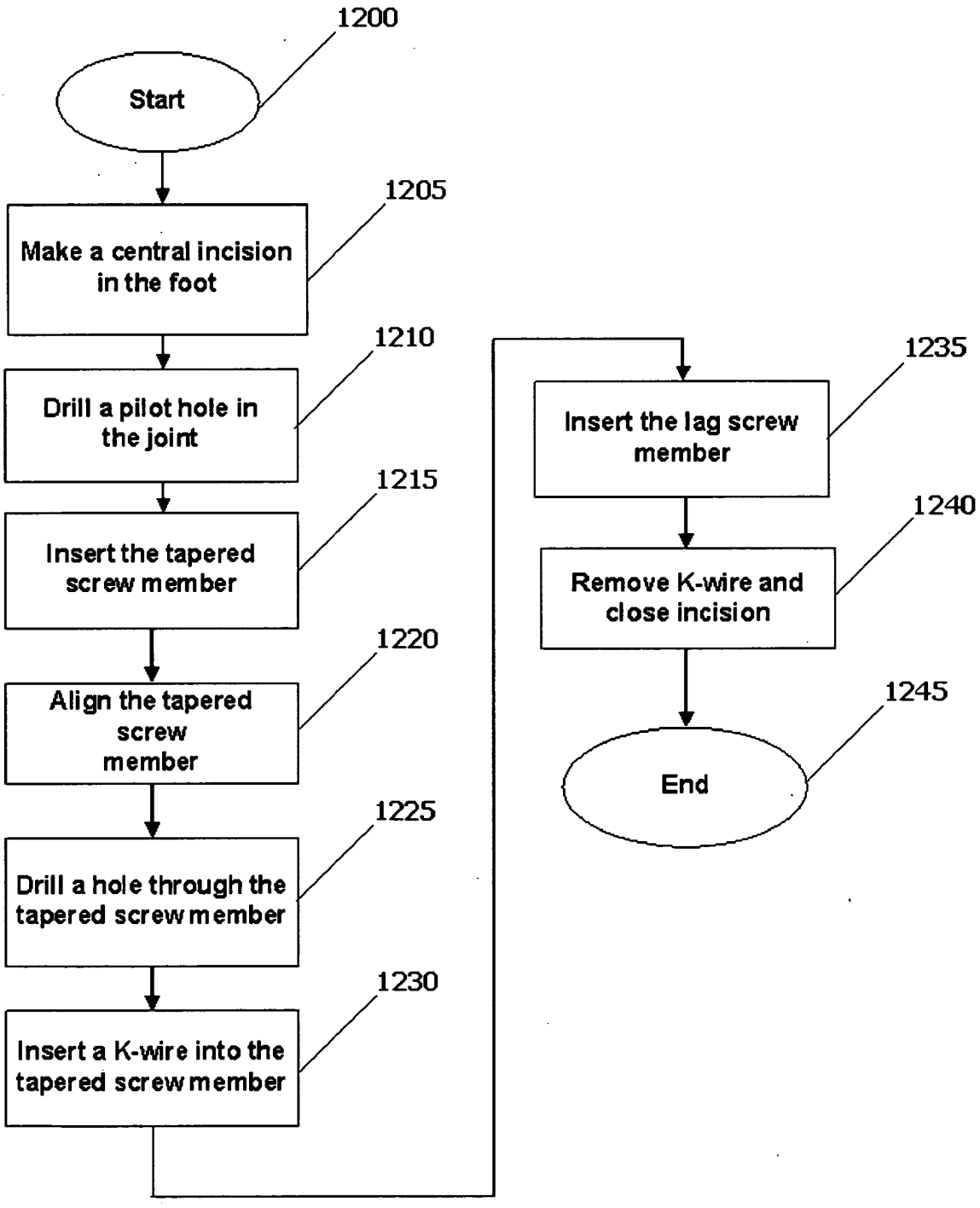

1200
Start
1205
Make a central incision in the foot
1210
Drill a pilot hole in the joint
1215
Insert the tapered screw member
1220
Align the tapered screw member
1225
Drill a hole through the tapered screw member
1230
Insert a K-wire into the tapered screw member
1235
Insert the lag screw member
1240
Remove K-wire and close incision
1245
End

FIG. 12

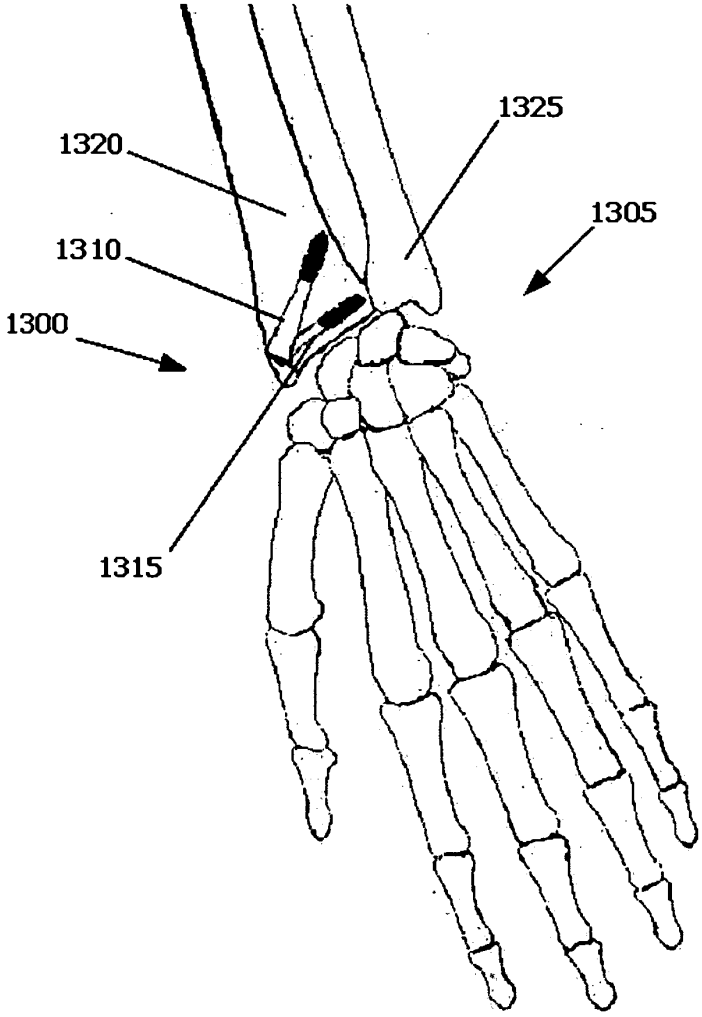



*FIG. 13*

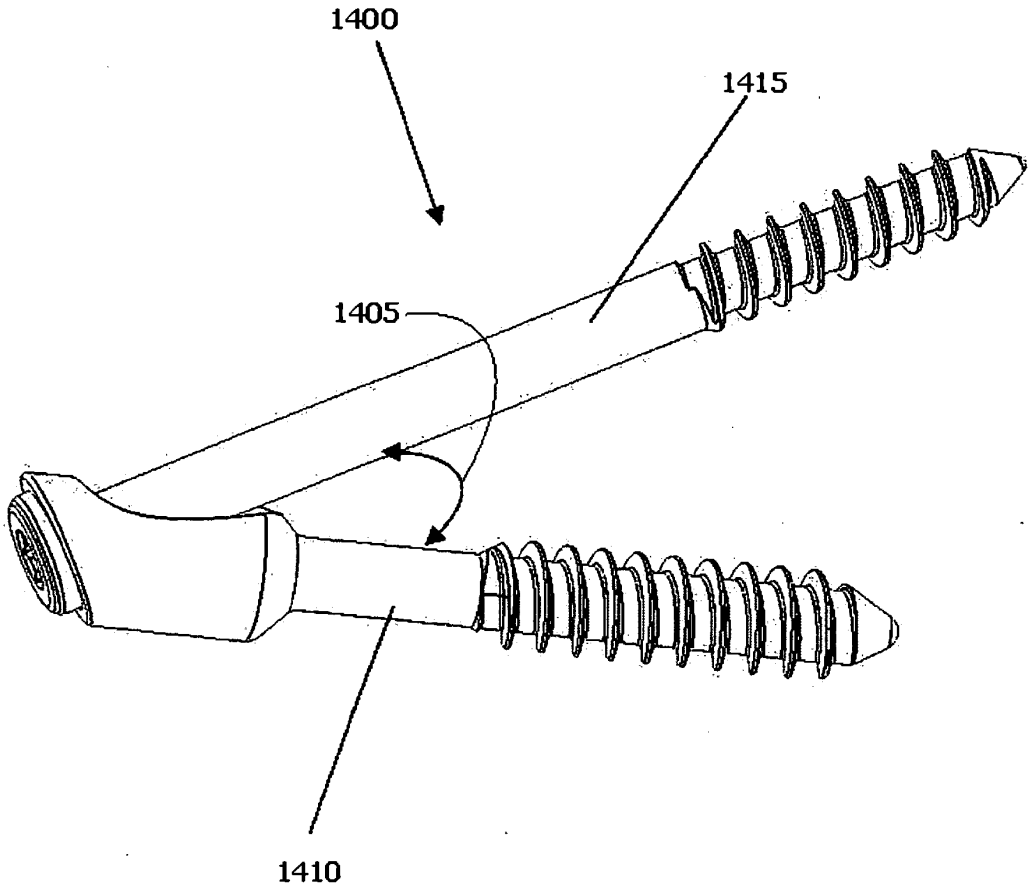



*FIG. 14*

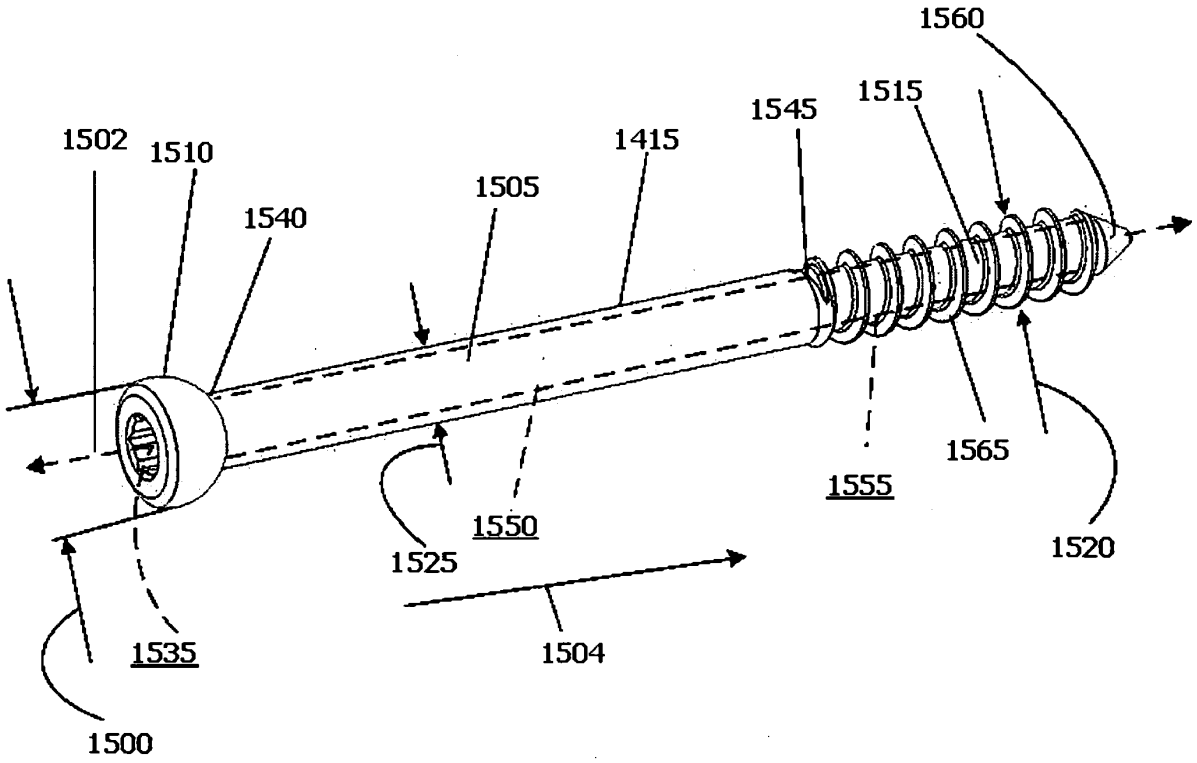

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*FIG. 15*

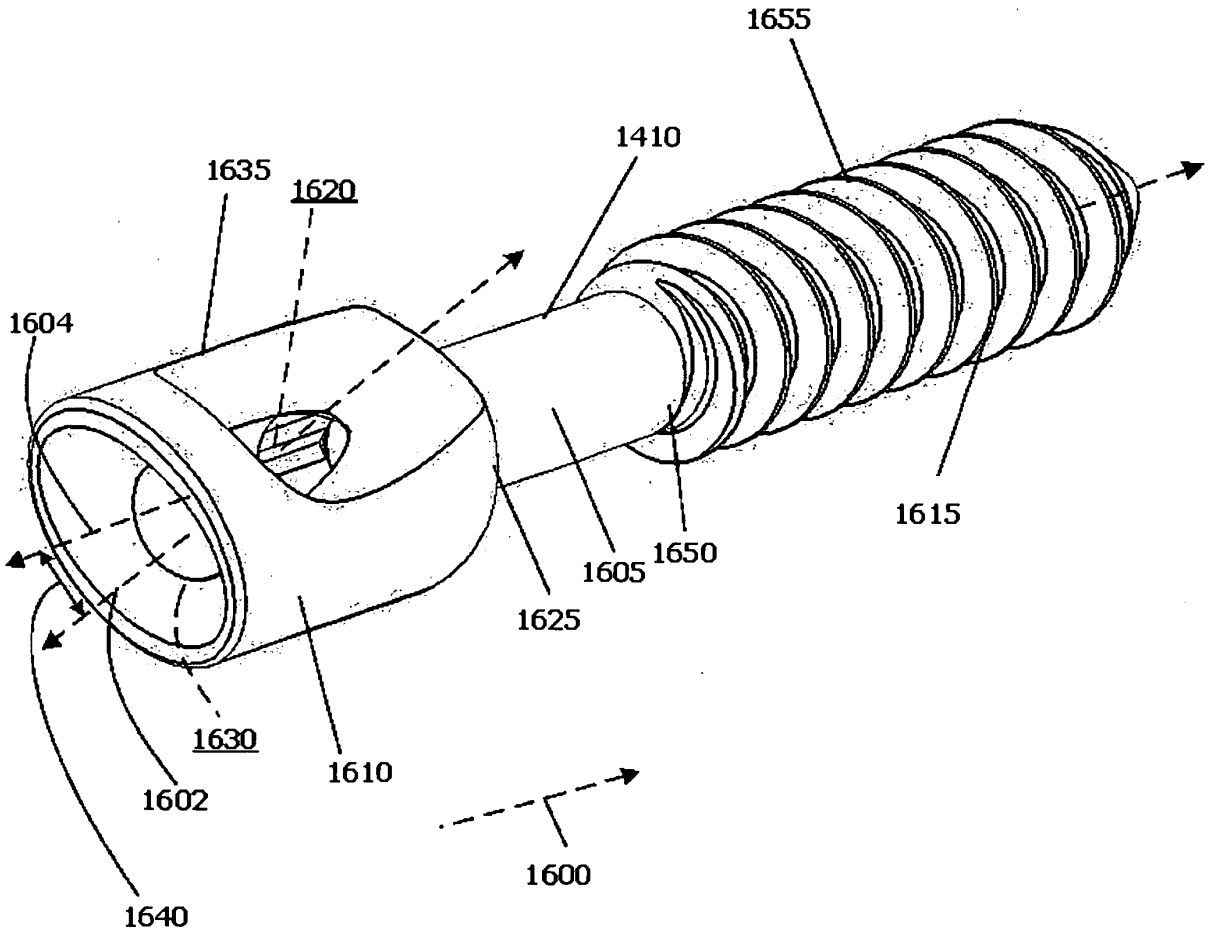

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*FIG. 16*

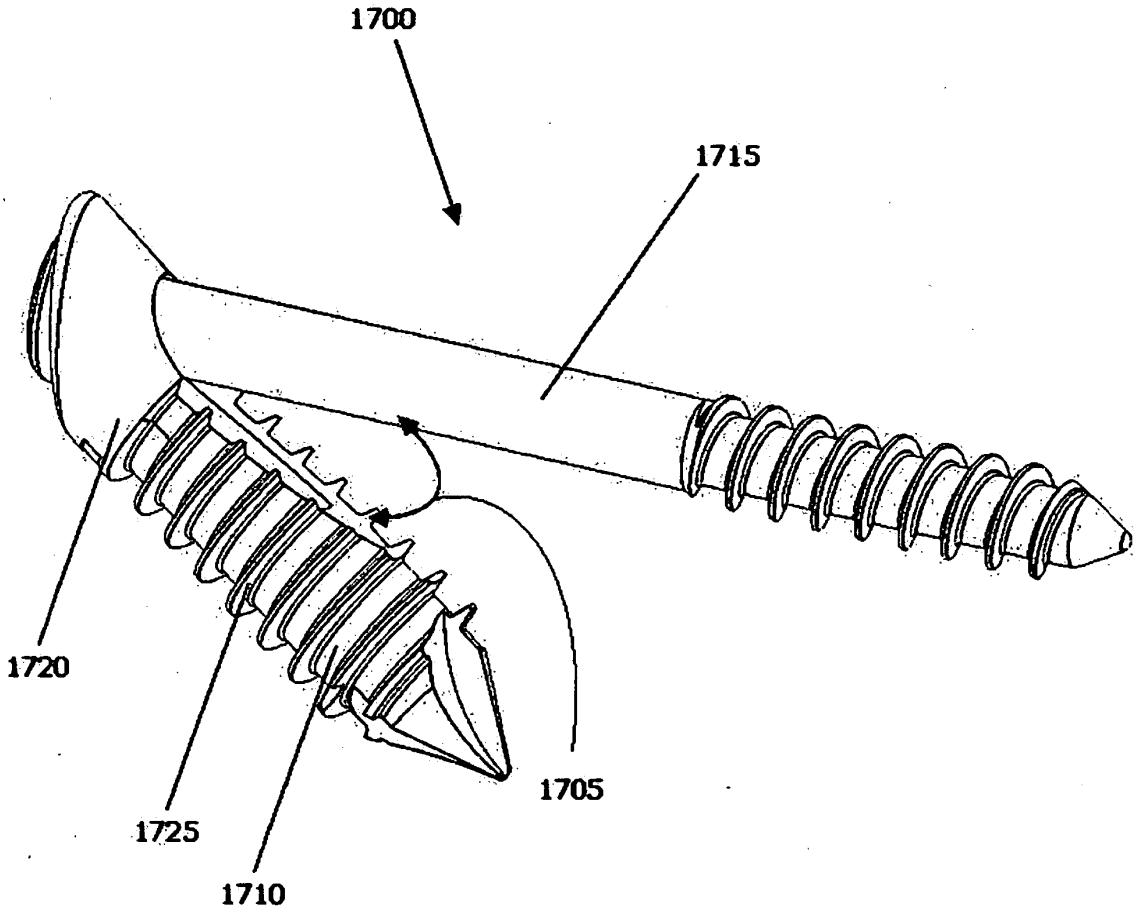



*FIG. 17*

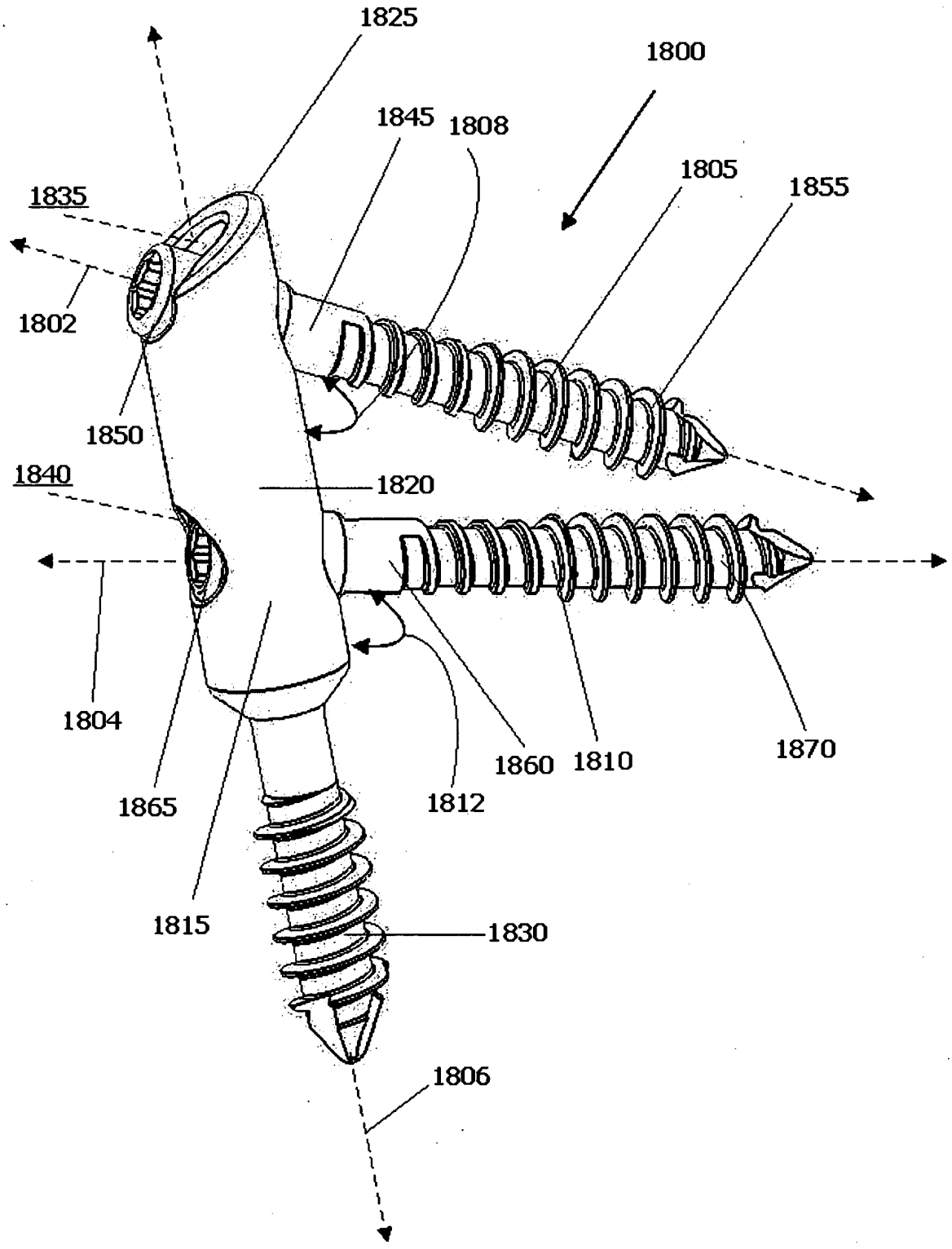

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FIG. 18

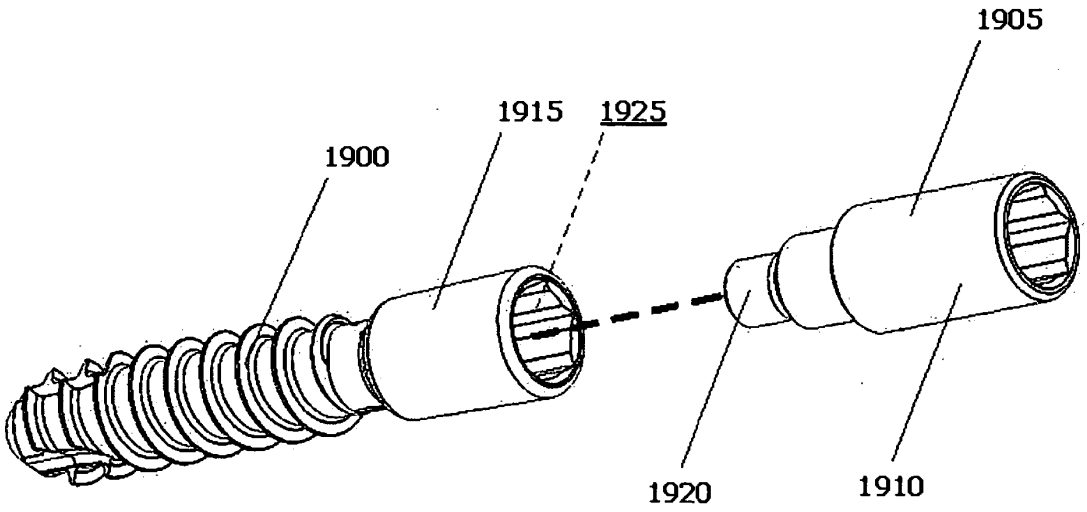



*FIG. 19*

**DECLARATION**
**AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below at 201 et seq. underneath my name.

I believe I am the original, first and sole inventor if only one name is listed at 201 below, or an original, first and joint inventor if plural names are listed at 201 et seq. below, of the subject matter which is claimed and for which a patent is sought on the invention entitled AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE, the specification of which:

■ is attached hereto ☐ was filed on , as application serial no.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119/§172 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED PRIOR TO THE FILING DATE OF THE APPLICATION | | | |
|---|---|---|---|
| APPLICATION NUMBER | COUNTRY | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 35 U.S.C. 119/172 |
| N/A | | | YES ☐ NO ☐ |
| | | | YES ☐ NO ☐ |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

| APPLICATION SERIAL NO. | FILING DATE | STATUS | | |
|---|---|---|---|---|
| | | | | |
| 12/456,808 | 06/23/2009 | | | |
| | | | | |

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

| PROVISIONAL APPLICATION NUMBER(S) | FILING DATE (day, month, year) |
|---|---|
| **61/132,932** | **06/24/2008** |
| | |

POWER OF ATTORNEY: As a named inventor, I hereby appoint Practitioners at Customer Number 27776; jointly, and each of them severally, my/our attorney(s) or agents(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent and to transact all business in the Patent and Trademark Office connected therewith.

I hereby direct that all correspondence and telephone calls in connection with this application be addressed to the Correspondence address associated with Customer Number 27776.

| | | | | | |
|---|---|---|---|---|---|
| 201 | FULL NAME OF INVENTOR | LAST NAME<br>GANNOE | FIRST NAME<br>JAMY | MIDDLE NAME | |
| | | CITY<br>WEST MILFORD | STATE OR FOREIGN COUNTRY<br>NEW JERSEY | COUNTRY OF CITIZENSHIP<br>UNITED STATES | |
| | | POST OFFICE ADDRESS<br>85 GREEN TERRACE WAY | CITY<br>WEST MILFORD | STATE OR COUNTRY<br>NEW JERSEY | ZIP CODE<br>07480 |
| 202 | FULL NAME OF INVENTOR | LAST NAME<br>TYBER | FIRST NAME<br>JEFF | MIDDLE NAME | |
| | | CITY<br>BETHLEHEM | STATE OR FOREIGN COUNTRY<br>PENNSYLVANIA | COUNTRY OF CITIZENSHIP<br>UNITED STATES | |
| | | POST OFFICE ADDRESS<br>11 WEST 2nd STREET | CITY<br>BETHLEHEM | STATE OR COUNTRY<br>PENNSYLVANIA | ZIP CODE<br>18015 |
| 203 | FULL NAME OF INVENTOR | LAST NAME<br>ARELLANO | FIRST NAME<br>LUIS | MIDDLE NAME<br>A. | |
| | | CITY<br>FAIR LAWN | STATE OR FOREIGN COUNTRY<br>NEW JERSEY | COUNTRY OF CITIZENSHIP<br>UNITED STATES | |
| | | POST OFFICE ADDRESS<br>13-49 EASTERN DRIVE | CITY<br>FAIR LAWN | STATE OR COUNTRY<br>NEW JERSEY | POST OFFICE ADDRESS<br>07410 |
| 204 | FULL NAME OF INVENTOR | LAST NAME<br>KIEFER | FIRST NAME<br>LAWRENCE | MIDDLE NAME | |
| | | CITY | STATE OR FOREIGN COUNTRY | COUNTRY OF CITIZENSHIP | |
| | | POST OFFICE ADDRESS | CITY | STATE OR COUNTRY | ZIP CODE |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| | | |
|---|---|---|
| SIGNATURE OF INVENTOR 201<br>JAMY GANNOE | SIGNATURE OF INVENTOR 202<br>JEFF TYBER | SIGNATURE OF INVENTOR 203<br>LUIS ARELLANO |
| DATE | DATE | DATE |
| SIGNATURE OF INVENTOR 204<br>LAWRENCE KIEFER | SIGNATURE OF INVENTOR 205 | SIGNATURE OF INVENTOR 206 |
| DATE | DATE | DATE |

PATENT APPLICATION SERIAL NO._____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

02/18/2010 RMEBRAHT 00000033 12658680

| | | |
|---|---|---|
| 01 FC:2011 | 165.00 | OP |
| 02 FC:2111 | 270.00 | OP |
| 03 FC:2311 | 110.00 | OP |
| 04 FC:2202 | 1404.00 | OP |

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002- 489-267/69033

PTO/SB/06 (12-04)

**Filing Date:** 021210

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

12/658,680

### APPLICATION AS FILED – PART I

| FOR | (Column 1) NUMBER FILED | (Column 2) NUMBER EXTRA | SMALL ENTITY RATE ($) | SMALL ENTITY FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | OTHER THAN SMALL ENTITY FEE ($) |
|---|---|---|---|---|---|---|---|
| BASIC FEE (37 CFR 1.16(a), (b), or (c)) | | | | 165 | | | |
| SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | | | | 270 | | | |
| EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | | | | 110 | | | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | 74 minus 20 = | 54 | X 26 = | 1404 | OR | X 52 = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | 3 minus 3 = | 7 | X 110 = | | | X 220 = | |
| APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | * | |
| MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | N/A | | | N/A | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | TOTAL | 1949 | | TOTAL | |

### APPLICATION AS AMENDED – PART II

| | | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | SMALL ENTITY RATE ($) | SMALL ENTITY ADDI-TIONAL FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | OTHER THAN SMALL ENTITY ADDI-TIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| AMENDMENT A | Total (37 CFR 1.16(i)) | * | Minus | ** | = | X = | | OR | X = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X = | | OR | X = | |
| | Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | N/A | | OR | N/A | |
| | | | | | | TOTAL ADD'T FEE | | OR | TOTAL ADD'T FEE | |

| | | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | RATE ($) | ADDI-TIONAL FEE ($) | OR | RATE ($) | ADDI-TIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| AMENDMENT B | Total (37 CFR 1.16(i)) | * | Minus | ** | = | X = | | OR | X = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X = | | OR | X = | |
| | Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | N/A | | OR | N/A | |
| | | | | | | TOTAL ADD'T FEE | | OR | TOTAL ADD'T FEE | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 12/658,680 | 02/12/2010 | Jamy Gannoe | 277-042 |

**CONFIRMATION NO. 1344**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

**FORMALITIES LETTER**

*OC000000040469377*

Date Mailed: 03/08/2010

# NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

**FILED UNDER 37 CFR 1.53(b)**

***Filing Date Granted***

**Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 9/11/14/16-18.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $**65** for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this notice.

**SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is $**65** for a small entity
- $**65** Surcharge.

**Items Required To Avoid Processing Delays:**

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A new oath or declaration, identifying this application number is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:
- does not identify the residence (e.g., city and either state or foreign country) of each inventor.
- does not identify the complete mailing or post office address of each inventor.
- does not identify the citizenship of each inventor.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/ebanaybanay/

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Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 12/658,680 | 02/12/2010 | 3733 | 1949 | 277-042 | 74 | 3 |

**CONFIRMATION NO. 1344**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

**FILING RECEIPT**




Date Mailed: 03/08/2010

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

**Applicant(s)**

Jamy Gannoe, West Milford, NJ;
Jeff Tyber, Bethlehem, PA;
Luis A. Arellano, Fair Lawn, NJ;
Lawrence Kiefer, Residence Not Provided;

**Power of Attorney:** None

**Domestic Priority data as claimed by applicant**

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**Foreign Applications**

**If Required, Foreign Filing License Granted:** 03/05/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/658,680**

**Projected Publication Date:** To Be Determined - pending completion of Missing Parts

**Non-Publication Request:** No

**Early Publication Request:** No
**** SMALL ENTITY ****

**Title**

Intraosseous intramedullary fixation assembly and method of use

**Preliminary Class**

606

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

## LICENSE FOR FOREIGN FILING UNDER

## Title 35, United States Code, Section 184

## Title 37, Code of Federal Regulations, 5.11 & 5.15

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

OPAP
JUN 14 2010
IAP6

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 12/658,680 | 02/12/2010 | Jamy Gannoe | 277-042 |

**CONFIRMATION NO. 1344**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

**FORMALITIES LETTER**

*OC000000040469377*

Date Mailed: 03/08/2010

## NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

**FILED UNDER 37 CFR 1.53(b)**

***Filing Date Granted***

**Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 9/11/14/16-18.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **$65** for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this notice.

**SUMMARY OF FEES DUE:**

Total additional fee(s) required for this application is **$65** for a small entity
- **$65** Surcharge.

**Items Required To Avoid Processing Delays:**

06/15/2010 CCHAU1 00000008 230420 12658680

01 FC:2051 65.00 DA

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A new oath or declaration, identifying this application number is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:
- does not identify the residence (e.g., city and either state or foreign country) of each inventor.
- does not identify the complete mailing or post office address of each inventor.
- does not identify the citizenship of each inventor.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/ebanaybanay/

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Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

OPAP IAP6 JUN 14 2010 PATENT & TRADEMARK OFFICE

PTO/SB/22 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE
Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| **PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)**<br>**FY 2009**<br>***(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*** | Docket Number (Optional)<br>277-042 |
|---|---|
| Application Number 12/658,680 | Filed 02/12/2010 |
| For AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | |
| Art Unit TBD | Examiner TBD |

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

| | Fee | Small Entity Fee | |
|---|---|---|---|
| ☑ One month (37 CFR 1.17(a)(1)) | $130 | $65 | $ 65.00 |
| ☐ Two months (37 CFR 1.17(a)(2)) | $490 | $245 | $ |
| ☐ Three months (37 CFR 1.17(a)(3)) | $1110 | $555 | $ |
| ☐ Four months (37 CFR 1.17(a)(4)) | $1730 | $865 | $ |
| ☐ Five months (37 CFR 1.17(a)(5)) | $2350 | $1175 | $ |

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 23-0420.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 62,110

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Octavio T. DaCosta — Signature

June 8, 2010 — Date

Octavio T. DaCosta — Typed or printed name

908-277-3333 — Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

06/15/2010 CCHAU1 00000008 230420 12658680

02 FC:2251 65.00 DA

Doc Code: TRAN.LET
Document Description: Transmittal Letter

OPAP
JUN 14 2010
PATENT & TRADEMARK OFFICE

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission: 16

| | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 12, 2010 |
| First Named Inventor | Jamy Gannoe |
| Art Unit | TBD |
| Examiner Name | TBD |
| Attorney Docket Number | 277-042 |

## ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [x] Reply to Missing Parts/ Incomplete Application
  - [x] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [x] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):
  1. Executed Declaration
  2. Preliminary Amendment
  3. Replacement Drawings
  4. Copy of Missing Parts
  5. Return Receipt Postcard

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Ward & Olivo | | |
| Signature | Octavio T. DaCosta | | |
| Printed name | Octavio T. DaCosta | | |
| Date | June 8, 2010 | Reg. No. | 62,110 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

| | | | |
|---|---|---|---|
| Signature | Melissa C. Hunte | | |
| Typed or printed name | Melissa C. Hunte | Date | June 8, 2010 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

OPAP JUN 14 2010 PATENT & TRADEMARK OFFICE

PTO/SB/17 (10-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

*Effective on 12/08/2004.*
*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*

# FEE TRANSMITTAL
## For FY 2009

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 130.00

| Complete if Known | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 12, 2010 |
| First Named Inventor | Jamy Gannoe |
| Examiner Name | TBD |
| Art Unit | TBD |
| Attorney Docket No. | 277-042 |

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 23-0420 Deposit Account Name: Ward & Olivo

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| Application Type | FILING FEES Fee ($) | FILING FEES Small Entity Fee ($) | SEARCH FEES Fee ($) | SEARCH FEES Small Entity Fee ($) | EXAMINATION FEES Fee ($) | EXAMINATION FEES Small Entity Fee ($) | Fees Paid ($) |
|---|---|---|---|---|---|---|---|
| Utility | 330 | 165 | 540 | 270 | 220 | 110 | 0 |
| Design | 220 | 110 | 100 | 50 | 140 | 70 | |
| Plant | 220 | 110 | 330 | 165 | 170 | 85 | |
| Reissue | 330 | 165 | 540 | 270 | 650 | 325 | |
| Provisional | 220 | 110 | 0 | 0 | 0 | 0 | |

**2. EXCESS CLAIM FEES**

| Fee Description | Fee ($) | Small Entity Fee ($) |
|---|---|---|
| Each claim over 20 (including Reissues) | 52 | 26 |
| Each independent claim over 3 (including Reissues) | 220 | 110 |
| Multiple dependent claims | 390 | 195 |

| Total Claims | Extra Claims | Fee ($) | Fee Paid ($) |
|---|---|---|---|
| _____ - 20 or HP = | _____ | x _____ | = 0 |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | Extra Claims | Fee ($) | Fee Paid ($) |
|---|---|---|---|
| _____ - 3 or HP = | _____ | x _____ | = 0 |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims Fee ($) | Multiple Dependent Claims Fee Paid ($) |
|---|---|
| _____ | 0 |

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof | Fee ($) | Fee Paid ($) |
|---|---|---|---|---|
| _____ - 100 = | _____ | / 50 = _____ (round up to a whole number) | x _____ | = 0 |

**4. OTHER FEE(S)**

| | Fees Paid ($) |
|---|---|
| Non-English Specification, $130 fee (no small entity discount) | 0 |
| Other (e.g., late filing surcharge): Surcharge Fee, 1 Month Extension of Time Fee | $130.00 |

**SUBMITTED BY**

| | | | |
|---|---|---|---|
| Signature | Octavio T. DaCosta | Registration No. (Attorney/Agent) 62,110 | Telephone 908-277-3333 |
| Name (Print/Type) | Octavio T. DaCosta | | Date June 8, 2010 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*




PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Jamy Gannoe, et al.

Serial No.: 12/658,680 Group Art Unit: 3733

Filed: February 12, 2010 Examiner: TBD

Atty. Doc. No.: 277-042

For: AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

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

**PRELIMINARY AMENDMENT**

Sir:

Prior to substantive review of the subject application, please enter the following amendments:

**AMENDMENTS** to the Drawings begin on page 2 of this paper.

**IN THE DRAWINGS**

In response to the Notice to File Missing Parts dated March 8, 2010, please find enclosed replacement sheets for drawing Figs. 9, 11, 14 and 16-18, which include the figures identified in the Notice to File Missing Parts. The replacement sheets of drawings are being submitted to replace the original submitted drawings for ONLY Figs. 9, 11, 14 and 16-18. The other originally submitted drawings are not being replaced and remain for consideration in the subject application. No new matter has been added.

## REMARKS

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. If any 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 & Olivo.

Respectfully submitted,

Date: June 8, 2010

Octavio T. DaCosta
Reg. No. 62,110
Ward & Olivo
382 Springfield Avenue
Summit, New Jersey 07901
(908) 277-3333

OPAP
JUN 14 2010
IAP6
PATENT & TRADEMARK OFFICE

ATTORNEY DOCKET NO. 277-042

**DECLARATION**
**AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below at 201 et seq. underneath my name.

I believe I am the original, first and sole inventor if only one name is listed at 201 below, or an original, first and joint inventor if plural names are listed at 201 et seq. below, of the subject matter which is claimed and for which a patent is sought on the invention entitled AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE, the specification of which:

☐ is attached hereto ■ was filed on February 12, 2010, as application serial no. 12/658,680

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119/§172 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED PRIOR TO THE FILING DATE OF THE APPLICATION | | | |
|---|---|---|---|
| APPLICATION NUMBER | COUNTRY | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 35 U.S.C. 119/172 |
| N/A | | | YES ☐ NO ☐ |
| | | | YES ☐ NO ☐ |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

| APPLICATION SERIAL NO. | FILING DATE | STATUS | | |
|---|---|---|---|---|
| | | | | |
| 12/456,808 | 06/23/2009 | | | |
| | | | | |

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

| PROVISIONAL APPLICATION NUMBER(S) | FILING DATE (day, month, year) |
|---|---|
| **61/132,932** | **06/24/2008** |
| | |

POWER OF ATTORNEY: As a named inventor, I hereby appoint Practitioners at Customer Number 27776; jointly, and each of them severally, my/our attorney(s) or agents(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent and to transact all business in the Patent and Trademark Office connected therewith.

I hereby direct that all correspondence and telephone calls in connection with this application be addressed to the Correspondence address associated with Customer Number 27776.

| | | | | | |
|---|---|---|---|---|---|
| 201 | FULL NAME OF INVENTOR | LAST NAME: TYBER | FIRST NAME: JEFF | MIDDLE NAME: | |
| | | CITY: BETHLEHEM | STATE OR FOREIGN COUNTRY: PENNSYLVANIA | COUNTRY OF CITIZENSHIP: UNITED STATES | |
| | | POST OFFICE ADDRESS: 4201 ANTHONY DRIVE | CITY: BETHLEHEM | STATE OR COUNTRY: PENNSYLVANIA | ZIP CODE: 18020 |
| 202 | FULL NAME OF INVENTOR | LAST NAME: GANNOE | FIRST NAME: JAMY | MIDDLE NAME: | |
| | | CITY: WEST MILFORD | STATE OR FOREIGN COUNTRY: NEW JERSEY | COUNTRY OF CITIZENSHIP: UNITED STATES | |
| | | POST OFFICE ADDRESS: 85 GREEN TERRACE WAY | CITY: WEST MILFORD | STATE OR COUNTRY: NEW JERSEY | ZIP CODE: 07480 |
| 203 | FULL NAME OF INVENTOR | LAST NAME: KIEFER | FIRST NAME: LAWRENCE | MIDDLE NAME: | |
| | | CITY: LAFAYETTE | STATE OR FOREIGN COUNTRY: NEW JERSEY | COUNTRY OF CITIZENSHIP: UNITED STATES | |
| | | POST OFFICE ADDRESS: 95 BEAVER RUN ROAD | CITY: LAFAYETTE | STATE OR COUNTRY: NEW JERSEY | ZIP CODE: 07848 |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| | | |
|---|---|---|
| SIGNATURE OF INVENTOR 201 | SIGNATURE OF INVENTOR 202 | SIGNATURE OF INVENTOR 203 |
| JEFF TYBER 3/30/10 | JAMY GANNOE 3/30/10 | LAWRENCE KIEFER 3/30/10 |
| DATE | DATE | DATE |
| SIGNATURE OF INVENTOR 204 | SIGNATURE OF INVENTOR 205 | SIGNATURE OF INVENTOR 206 |
| DATE | DATE | DATE |

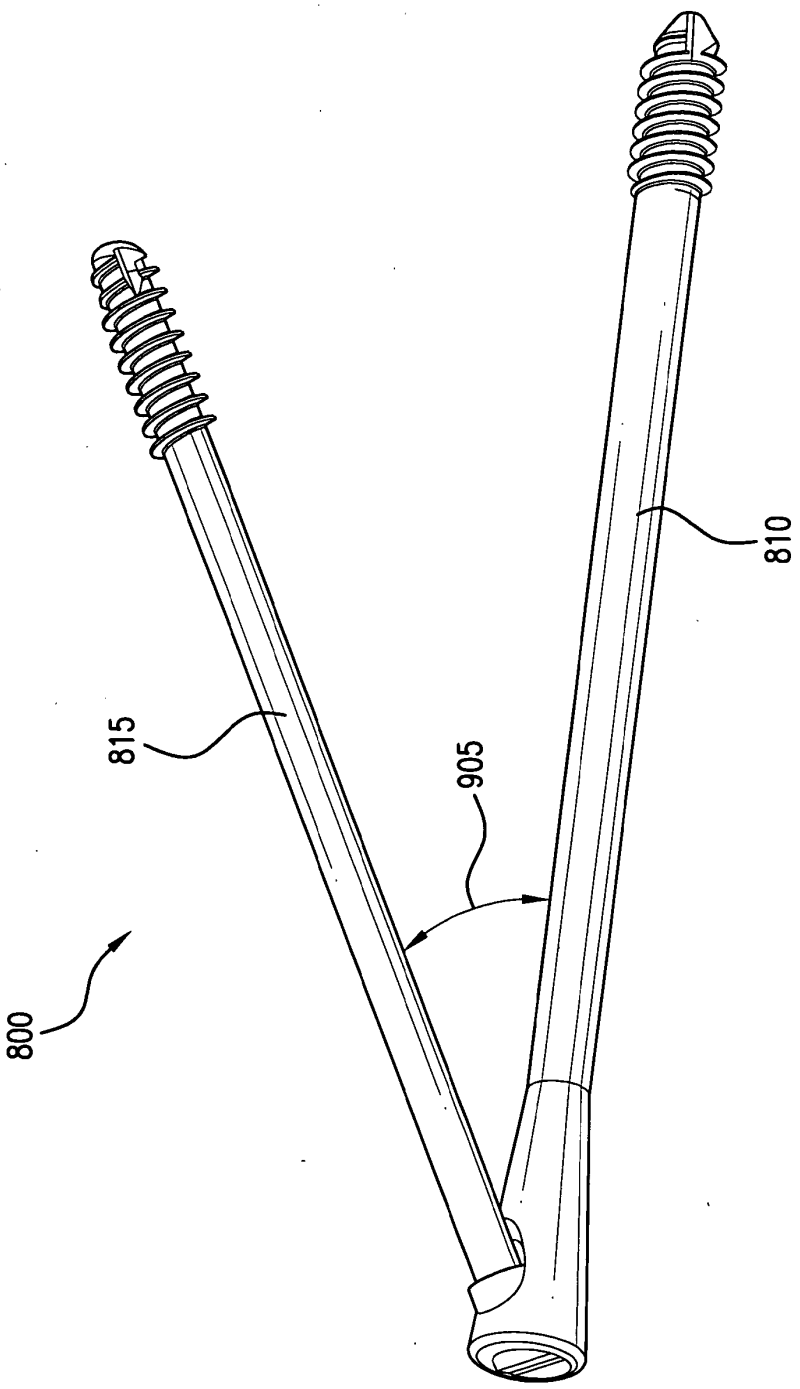



FIG. 9

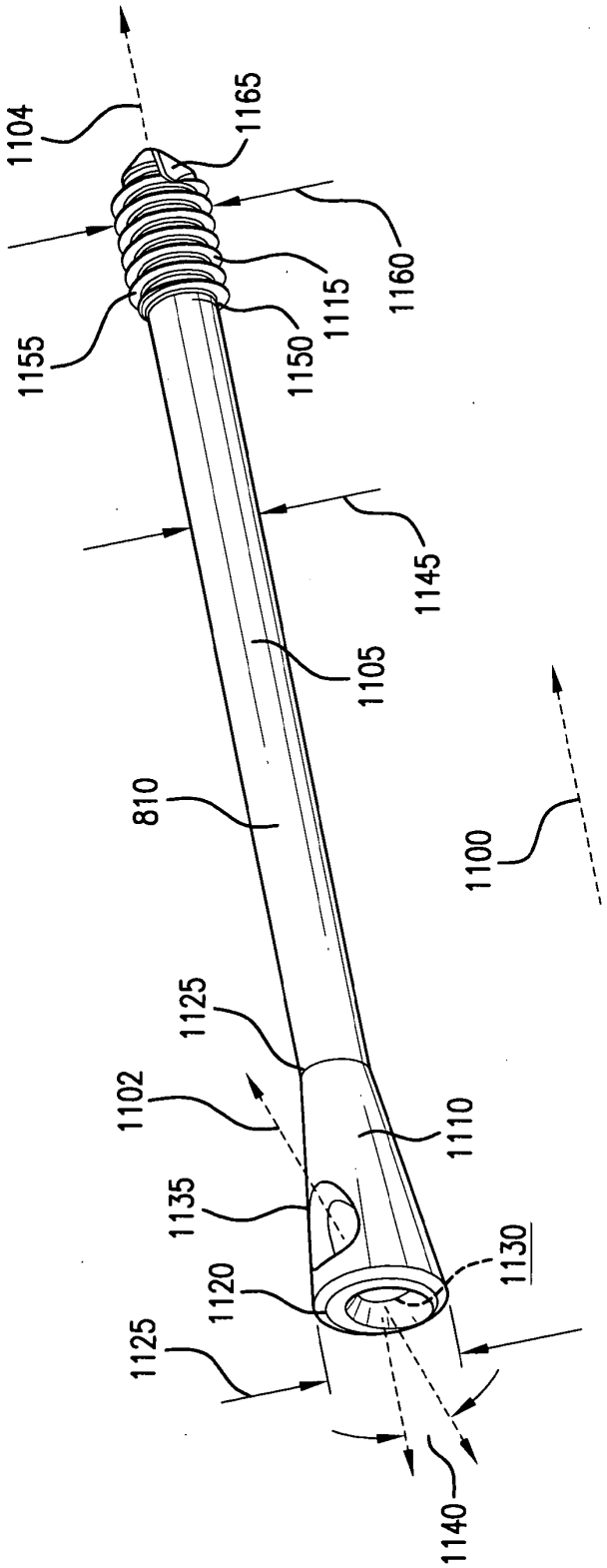

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FIG. 11

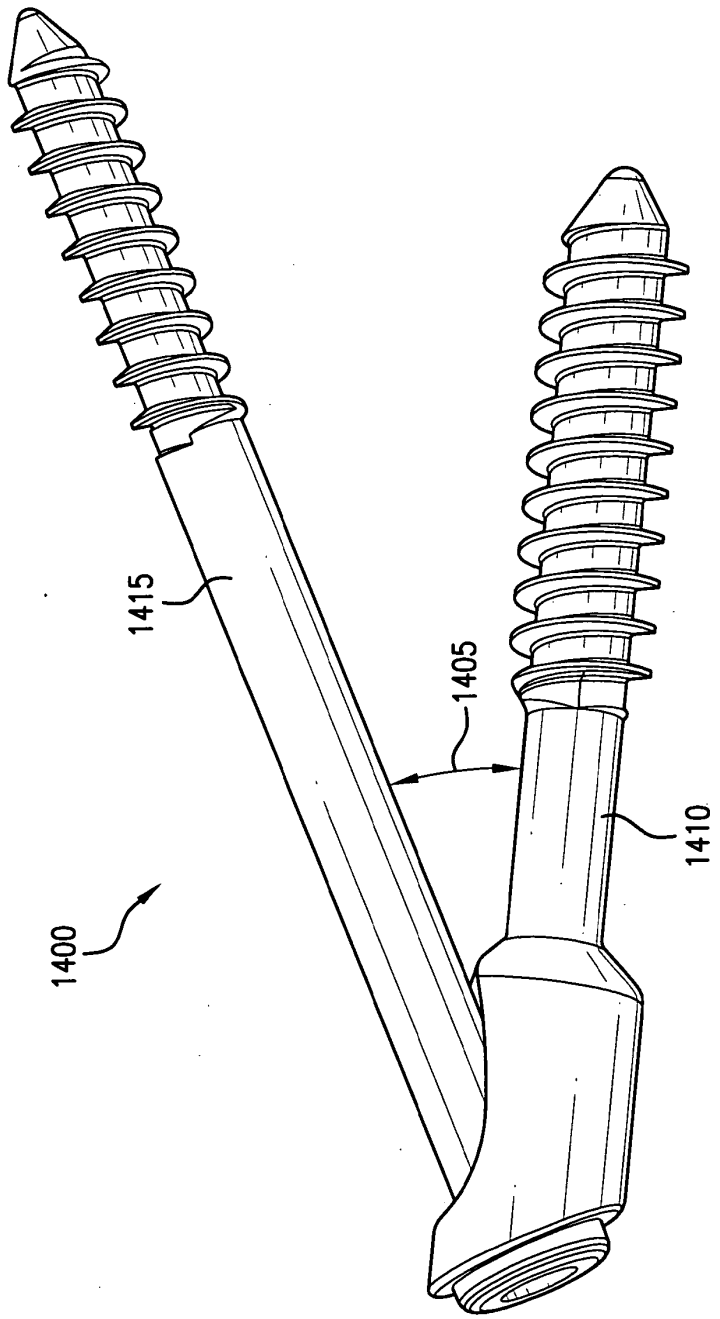



FIG. 14

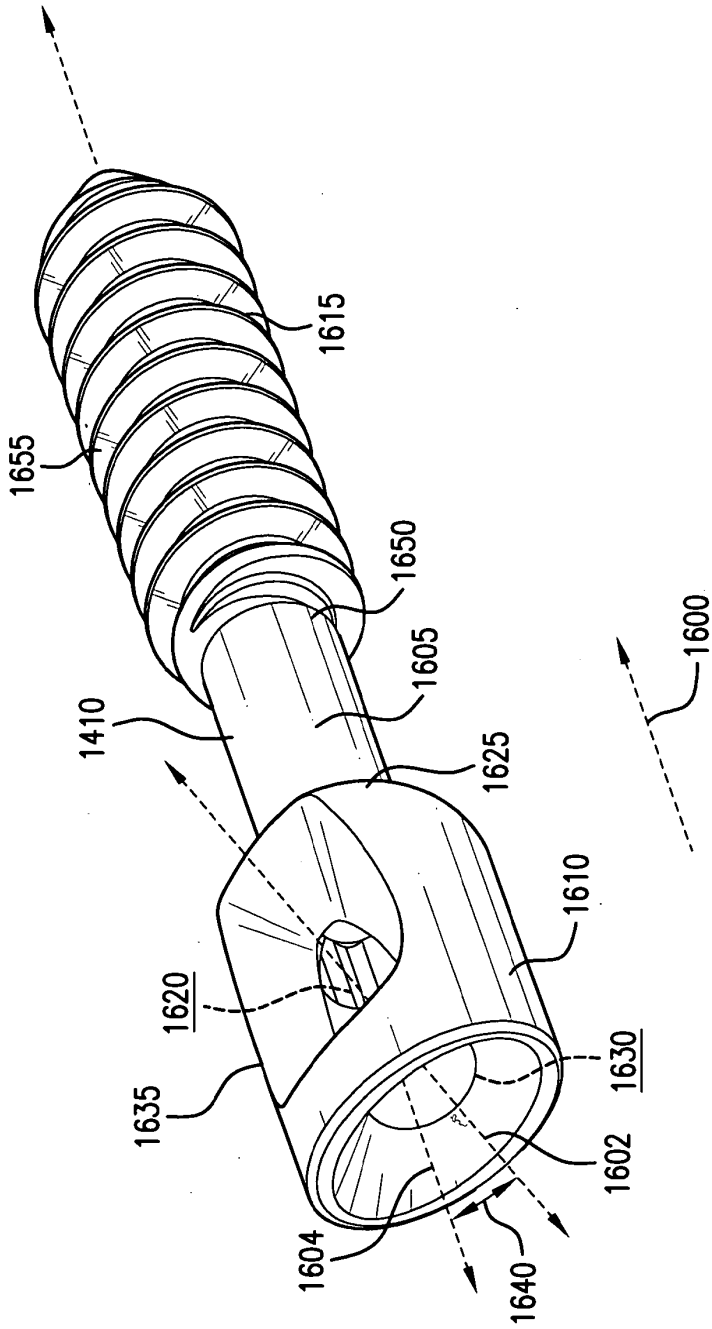

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FIG. 16

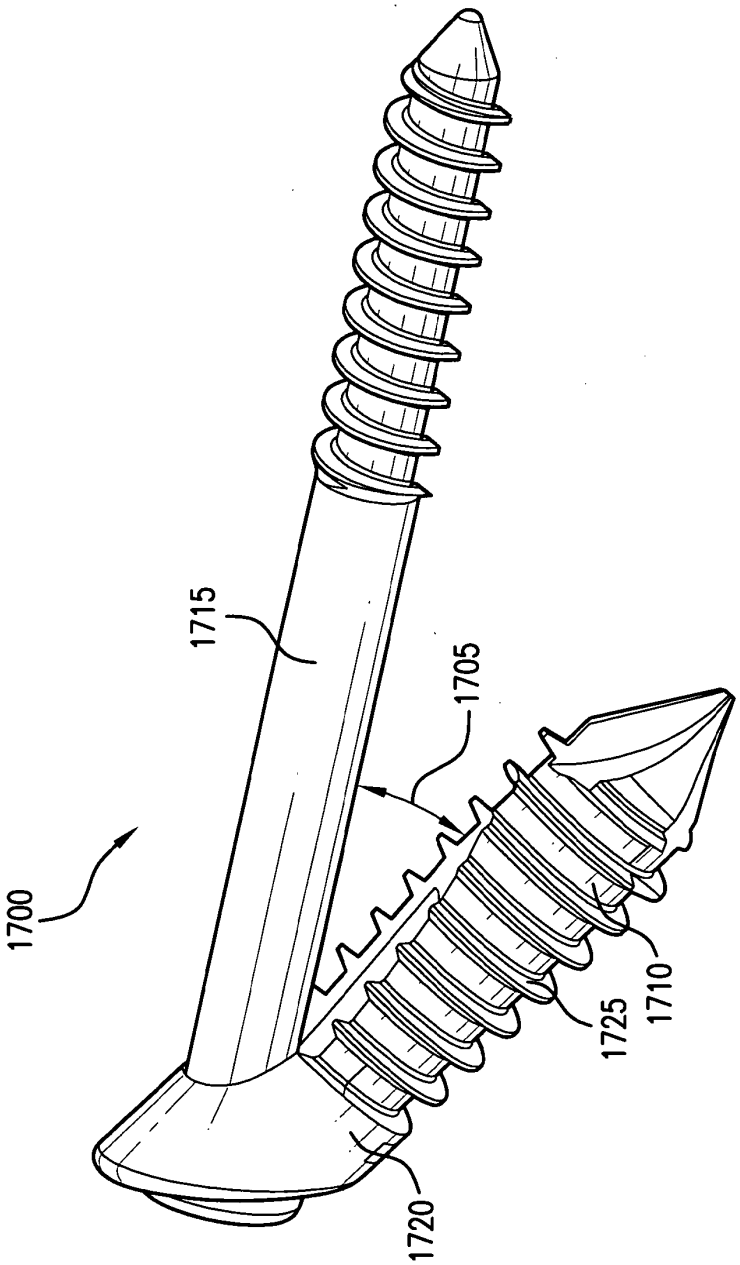



FIG. 17

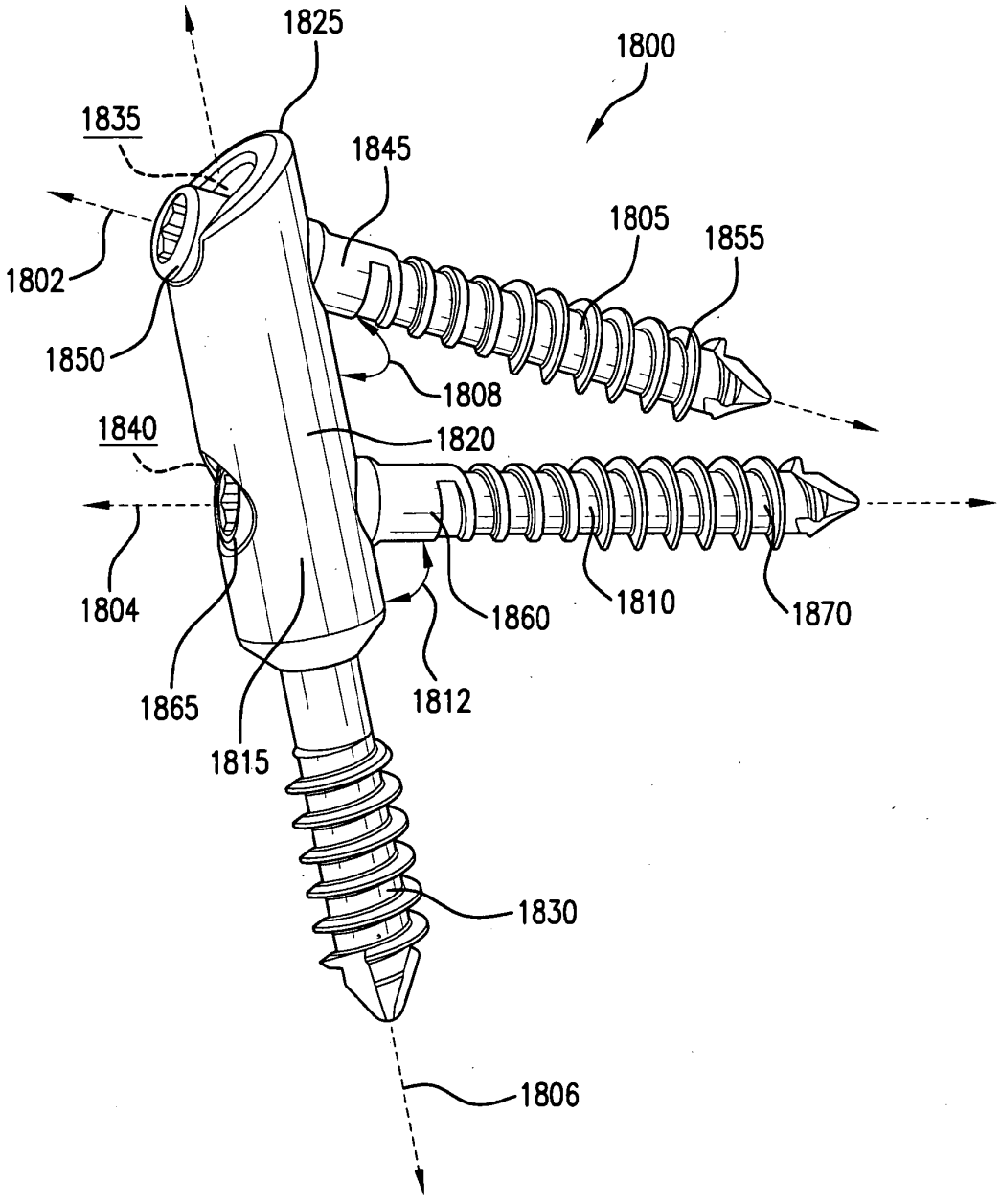

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FIG. 18




PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Jamy Gannoe et al.

Serial No.: 12/658,680 Group Art Unit: 3733

Filed: 02/11/2010 Conf. No.: 1344

For: AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

Atty. Doc. No.: 277-042

Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT**

S I R:

Prior to substantive review of the subject application, please enter the following amendment:

**REMARKS**

Applicants respectively submit this Petition to request the United States Patent and Trademark Office to correct the filing receipt by according a February 11, 2010 filing date as indicated in the attached corrected filing receipt. Attached herewith in support of this Petition is: 1) a copy of the USPS Express Mail label indicating the February 11, 2010 "date-in"; and 2) a copy of the Return Receipt Postcard received from the PTO.

If any 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 & Olivo.

In view of the foregoing, Applicants respectfully request a Filing Receipt Correction for the aforementioned Application Serial Number 12/658,680.

Respectfully submitted,

Date: June 17, 2010

By Octavio T. DaCosta

Octavio T. DaCosta
Reg. No. 62,110
Ward & Olivo
382 Springfield Avenue
Summit, New Jersey 07901
(908) 277-3333

OPAP IAP6
JUN 21 2010
PATENT & TRADEMARK OFFICE

D

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 12/658,680 | ~~02/12/2010~~ 02/11/2010 | 3733 | 1949 | 277-042 | 74 | 3 |

**CONFIRMATION NO. 1344**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

**FILING RECEIPT**

OC000000040469376

Date Mailed: 03/08/2010

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

**Applicant(s)**

Jamy Gannoe, West Milford, NJ;
Jeff Tyber, Bethlehem, PA;
Luis A. Arellano, Fair Lawn, NJ;
Lawrence Kiefer, Residence Not Provided;

**Power of Attorney:** None

**Domestic Priority data as claimed by applicant**

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**Foreign Applications**

**If Required, Foreign Filing License Granted:** 03/05/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/658,680**

**Projected Publication Date:** To Be Determined - pending completion of Missing Parts

**Non-Publication Request:** No

**Early Publication Request:** No
** SMALL ENTITY **

**Title**

Intraosseous intramedullary fixation assembly and method of use

**Preliminary Class**

606

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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## Title 35, United States Code, Section 184

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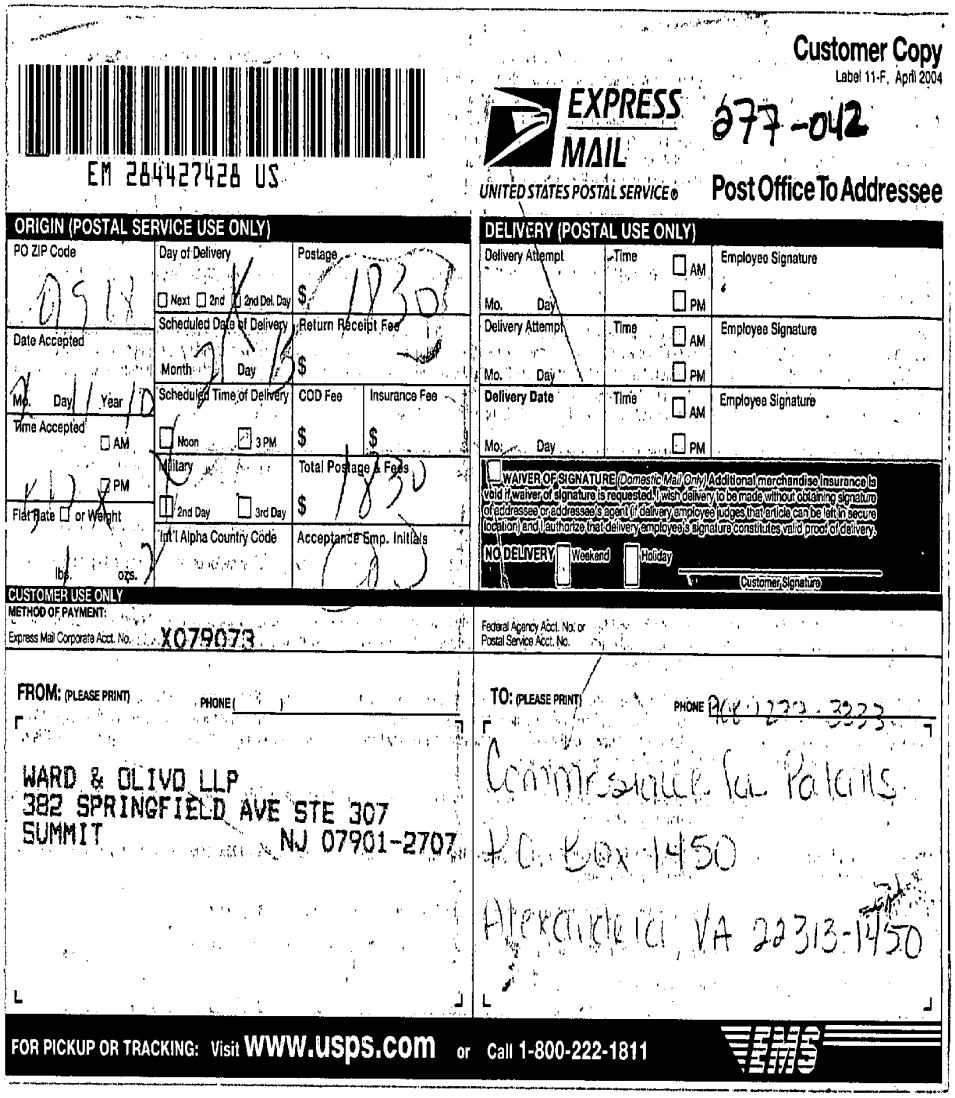
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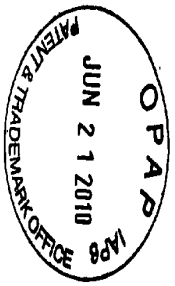
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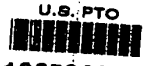
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In re Application of: Jamy Gannoe, *et al.*
Atty. Docket Number: 277-042
Serial Number: TBD
Art Unit: TBD
For: AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE
Filed: February 11, 2010
Enclosed Herewith:
1. Utility Patent Application Transmittal
2. Fee Transmittal
3. Specification (53 Pages)
4. Drawings (20 Pages)
5. Declaration and Power of Attorney (2 Pages)
6. Check for $1,949.00 (Check No. 23733)
**Dated: February 11, 2010**

Express Mail No.: EM 284427428 US.




12658680
021210

Doc Code: TRAN.LET
Document Description: Transmittal Letter

OPAP IAP6 JUN 21 2010 PATENT & TRADEMARK OFFICE

PTO/SB/21 (07-09)
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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Total Number of Pages in This Submission | 9 |

| | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jamy Gannoe |
| Art Unit | 3733 |
| Examiner Name | TBD |
| Attorney Docket Number | 277-042 |

## ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):
  1. Preliminary Amendment
  2. Corrected Filing Receipt
  3. Copy of Express Mail Label
  4. Copy of Original Postcard

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | Ward & Olivo | | |
| Signature | Octavio T. DaCosta | | |
| Printed name | Octavio T. DaCosta | | |
| Date | June 17, 2010 | Reg. No. | 62,110 |

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|---|---|---|---|
| Signature | Melissa C. Hunte | | |
| Typed or printed name | Melissa C. Hunte | Date | June 17, 2010 |

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*Effective on 12/08/2004.*
*Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).*

# FEE TRANSMITTAL
## For FY 2009

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($)

| Complete if Known | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jamy Gannoe |
| Examiner Name | TBD |
| Art Unit | 3733 |
| Attorney Docket No. | 277-042 |

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 23-0420 Deposit Account Name: Ward & Olivo

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayments

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**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | |
|---|---|---|---|---|---|---|---|
| **Application Type** | **Fee ($)** | **Small Entity Fee ($)** | **Fee ($)** | **Small Entity Fee ($)** | **Fee ($)** | **Small Entity Fee ($)** | **Fees Paid ($)** |
| Utility | 330 | 165 | 540 | 270 | 220 | 110 | 0 |
| Design | 220 | 110 | 100 | 50 | 140 | 70 | |
| Plant | 220 | 110 | 330 | 165 | 170 | 85 | |
| Reissue | 330 | 165 | 540 | 270 | 650 | 325 | |
| Provisional | 220 | 110 | 0 | 0 | 0 | 0 | |

**2. EXCESS CLAIM FEES**

| Fee Description | Fee ($) | Small Entity Fee ($) |
|---|---|---|
| Each claim over 20 (including Reissues) | 52 | 26 |
| Each independent claim over 3 (including Reissues) | 220 | 110 |
| Multiple dependent claims | 390 | 195 |

| Total Claims | | Extra Claims | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|
| _____ | - 20 or HP = | _____ | x _____ | = | 0 |

HP = highest number of total claims paid for, if greater than 20.

| Indep. Claims | | Extra Claims | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|
| _____ | - 3 or HP = | _____ | x _____ | = | 0 |

HP = highest number of independent claims paid for, if greater than 3.

| Multiple Dependent Claims | |
|---|---|
| **Fee ($)** | **Fee Paid ($)** |
| _____ | 0 |

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

| Total Sheets | | Extra Sheets | | Number of each additional 50 or fraction thereof | Fee ($) | | Fee Paid ($) |
|---|---|---|---|---|---|---|---|
| _____ | - 100 = | _____ | / 50 = | _____ (round up to a whole number) | x _____ | = | 0 |

**4. OTHER FEE(S)**

| | Fees Paid ($) |
|---|---|
| Non-English Specification, $130 fee (no small entity discount) | 0 |
| Other (e.g., late filing surcharge): _____ | 0 |

**SUBMITTED BY**

| | | | |
|---|---|---|---|
| Signature | Octavio T. DaCosta | Registration No. (Attorney/Agent) 62,110 | Telephone 908-277-3333 |
| Name (Print/Type) | Octavio T. DaCosta | | Date June 17, 2010 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 12/658,680 | 02/12/2010 | 3733 | 2014 | 277-042 | 74 | 3 |

**CONFIRMATION NO. 1344**

**UPDATED FILING RECEIPT**

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*OC00000042286735*

Date Mailed: 06/25/2010

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

**Applicant(s)**

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**Power of Attorney:** The patent practitioners associated with Customer Number 27776

**Domestic Priority data as claimed by applicant**

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**Foreign Applications**

**If Required, Foreign Filing License Granted:** 03/05/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/658,680**

**Projected Publication Date:** 10/07/2010

**Non-Publication Request:** No

**Early Publication Request:** No
**** SMALL ENTITY ****

**Title**

Intraosseous intramedullary fixation assembly and method of use

**Preliminary Class**

606

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PTO/SB/08a (07-09)
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 1 of 1

| Complete if Known | |
|---|---|
| Application Number | 12/658680 |
| Filing Date | 2010-02-12 |
| First Named Inventor | Jeff Tyber |
| Art Unit | 3733 |
| Examiner Name | TBD |
| Attorney Docket Number | 277-042 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Document Number Number-Kind Code[2] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|
| | 1 | US- 20060206044 | 2006-09-14 | Simon | |
| | 2 | US- 7771428 | 2010-08-10 | Siravo, Mark et al. | |
| | 3 | US- 7763021 | 2010-07-27 | Cole et al. | |
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**FOREIGN PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Foreign Patent Document Country Code[3]–Number[4]–Kind Code[5] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T[6] |
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|---|---|
| **EFS ID:** | 8273953 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Octavio T. DaCosta |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 23-AUG-2010 |
| **Filing Date:** | 12-FEB-2010 |
| **Time Stamp:** | 19:00:48 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

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|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Information Disclosure Statement (IDS) Filed (SB/08) | 277_042_IDS.pdf | 175121<br>89a8d8f1100c33cbba0f1cca8b2047aa1c673b84 | no | 1 |

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| APPLICATION NUMBER | FILING OR 371(C) DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO./TITLE |
|---|---|---|---|
| 12/658,680 | 02/12/2010 | Jeff Tyber | 277-042 |

**CONFIRMATION NO. 1344**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

**PUBLICATION NOTICE**




**Title:**Intraosseous intramedullary fixation assembly and method of use

**Publication No.**US-2010-0256638-A1
**Publication Date:**10/07/2010

## NOTICE OF PUBLICATION OF APPLICATION

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| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | 3733 | 2014 | 277-042 | 74 | 3 |

**CONFIRMATION NO. 1344**

**CORRECTED FILING RECEIPT**

27776
WARD & OLIVO
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901




Date Mailed: 10/18/2010

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Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**Power of Attorney:** The patent practitioners associated with Customer Number 27776

**Domestic Priority data as claimed by applicant**

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**Foreign Applications**

**If Required, Foreign Filing License Granted:** 03/05/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/658,680**

**Projected Publication Date:** Not Applicable

**Non-Publication Request:** No

**Early Publication Request:** No
**** SMALL ENTITY ****

**Title**

Intraosseous intramedullary fixation assembly and method of use

**Preliminary Class**

606

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Jamy Gannoe, et al.

| | | | |
|---|---|---|---|
| Serial No.: | 12/658,680 | Confirmation No.: | 1344 |
| Filed: | February 11, 2010 | Art Unit: | 3733 |
| For: | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: | 277-042 |

Mail stop Amendment
Honorable Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## PRELIMINARY AMENDMENT

SIR:

Prior to substantive review of the subject application, please amend as follows:

**Amendments to the Claims** begin on page 2 of this paper.

**Remarks** are reflected on page 15 of this paper.

**IN THE CLAIMS:**

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

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member ~~coupled~~ for coupling to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, wherein the tubular portion comprises an opening disposed at an end of the tubular portion.

**2. (Original)** The intramedullary assembly of claim 1, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**3. (Currently amended)** The intramedullary assembly of claim 1, wherein the fixed angle is in the range of about 0 to about 90 degrees.

**4. (Currently amended)** The intramedullary assembly of claim [[3]] 1, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**5. (Original)** The intramedullary assembly of claim 4, wherein the taper provides for an interference lock with the tapered screw member.

**6. (Currently amended)** The intramedullary assembly of claim [[5]] 1, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Currently amended)** The intramedullary assembly of claim [[6]] 1, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

**8. (Original)** The intramedullary assembly of claim 7, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

**9. (Currently amended)** The intramedullary assembly of claim [[8]] 7, wherein the orifice is provided to receive a complementary shaped end of an instrument.

**10. (Currently amended)** The intramedullary assembly of claim [[9]] 1, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Currently amended)** The intramedullary assembly of claim [[10]] 1, 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 lag screw member.

**12. (Currently amended)** The intramedullary assembly of claim [[11]] 1, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

**13. (Original)** The intramedullary assembly of claim 12, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**14. (Original)** The intramedullary assembly of claim 13, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**15. (Currently amended)** The intramedullary assembly of claim [[14]] 13, wherein the first internal aperture further includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Original)** The intramedullary assembly of claim 15, wherein the opening is provided to receive a complementary shaped member.

**17. (Currently amended)** The intramedullary assembly of claim [[16]] 13, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**18. (Currently amended)** The intramedullary assembly of claim [[17]] 13, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein

the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**19. (Currently amended)** The intramedullary assembly of claim [[18]] 13, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**20. (Currently amended)** The intramedullary assembly of claim [[19]] 1, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**21. (Currently amended)** The intramedullary assembly of claim [[20]] 1, 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 tapered screw member.

**22. (Currently amended)** The intramedullary assembly of claim [[21]] 1, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

**23. (Currently amended)** The intramedullary assembly of claim [[25]] 22, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Original)** The intramedullary assembly of claim [[23]] 1, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

**25. (Original)** The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**26. (Currently amended)** A method for bone fusion, comprising:

~~providing an intramedullary assembly, wherein the intramedullary assembly further comprises:~~

providing a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

providing a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

~~drilling~~ forming a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

~~drilling~~ forming a second medullary canal in the first bone;

~~slideably~~ coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

applying ~~compression~~ torque to the lag screw member to lock the tapered screw member to the lag screw member, thereby ~~fusing~~ compressing the first bone to the second bone.

**27. (Original)** The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**28. (Currently amended)** The method of claim 27, wherein the fixed angle is in the range of approximately 0 to approximately 90 degrees.

**29. (Currently amended)** The method of claim [[28]] 26, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**30. (Original)** The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

**31. (Currently amended)** The method of claim [[30]] 26, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**32. (Currently amended)** The method of claim [[31]] 26, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

**34. (Currently amended)** The method of claim [[33]] 32, further comprising receiving a complementary shaped end of an instrument in the orifice.

**35. (Currently amended)** The method of claim [[34]] 26, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**36. (Currently amended)** The method of claim [[35]] 26, 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 lag screw member.

**37. (Currently amended)** The method of claim [[36]] 26, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

**38. (Original)** The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

**39. (Original)** The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**40. (Currently amended)** The method of claim [[39]] 38, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**41. (Original)** The method of claim 40, further comprising receiving a complementary shaped member in the opening.

**42. (Currently amended)** The method of claim [[41]] 38, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**43. (Currently amended)** The method of claim [[42]] 38, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**44. (Currently amended)** The method of claim [[43]] 38, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**45. (Currently amended)** The method of claim [[44]] 26, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**46. (Currently amended)** The method of claim [[45]] 26, 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 tapered screw member.

**47. (Currently amended)** The method of claim [[46]] 26, further comprising inserting the lag screw member into at least a first medullary canal of bone.

**48. (Original)** The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

**49. (Currently amended)** The method of claim [[48]] 26, ~~wherein the intramedullary assembly comprises~~ further comprising providing a cover portion coupled to the bulbous portion of the lag screw member.

**50. (Original)** The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**51. (Currently amended)** An intramedullary assembly for bone fusion, comprising:

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member ~~coupled to~~ adapted for coupling to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and wherein the tubular portion comprises an opening at the fourth end[[.]];

wherein the bulbous portion is semi-spherical for providing angular rotation of the lag screw member.

**52. (Original)** The intramedullary assembly of claim 51, wherein the lag screw member is slideably coupled to the tapered screw member and makes an angle with the tapered screw member.

**53. (Original)** The intramedullary assembly of claim 52, wherein the angle varies between 0 and 90 degrees.

**54. (Canceled)**

**55. (Currently amended)** The intramedullary assembly of claim [[54]] 51, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Currently amended)** The intramedullary assembly of claim [[55]] 51, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

**57. (Original)** The intramedullary assembly of claim 56, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

**58. (Currently amended)** The intramedullary assembly of claim [[57]] 56, wherein the orifice is provided to receive a complementary shaped end of an instrument.

**59. (Currently amended)** The intramedullary assembly of claim [[58]] 51, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**60. (Currently amended)** The intramedullary assembly of claim [[59]] 51, 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 lag screw member.

**61. (Currently amended)** The intramedullary assembly of claim [[60]] 51, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

**62. (Original)** The intramedullary assembly of claim 61, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**63. (Original)** The intramedullary assembly of claim 62, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**64. (Currently amended)** The intramedullary assembly of claim [[63]] 61, wherein the first internal aperture further includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Original)** The intramedullary assembly of claim 64, wherein the opening is provided to receive a complementary shaped member.

**66. (Currently amended)** The intramedullary assembly of claim [[65]] 62, wherein the tapered aperture traverses the second elongated body from the fourth end to an exterior surface on the second elongated body.

**67. (Currently amended)** The intramedullary assembly of claim [[66]] 62, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the fourth end.

**68. (Currently amended)** The intramedullary assembly of claim [[67]] 62, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**69. (Currently amended)** The intramedullary assembly of claim [[68]] 51, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**70. (Currently amended)** The intramedullary assembly of claim [[69]] 51, 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 tapered screw member.

**71. (Currently amended)** The intramedullary assembly of claim [[70]] 51, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

**72. (Currently amended)** The intramedullary assembly of claim [[71]] 51, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Currently amended)** The intramedullary assembly of claim [[72]] 51, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

**74. (Original)** The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

## REMARKS

In view of the foregoing, the Applicants respectfully submit that the present invention represents a patentable contribution to the art, and the application is in condition for allowance. Early and favorable action is accordingly solicited.

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. If a petition and/or any 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 & Olivo.

Respectfully submitted,

Date: March 4, 2011

/Octavio T. DaCosta/

Octavio T. DaCosta
Reg. No. 62,110
Ward & Olivo
382 Springfield Avenue
Summit, New Jersey 07901
(908) 277-3333

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 9588541 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Octavio T. DaCosta/Jamie Reinhardt |
| **Filer Authorized By:** | Octavio T. DaCosta |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 04-MAR-2011 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 14:38:21 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Preliminary Amendment | 277_042_Preliminary_Amendment.pdf | 52910<br>3afc35e1cf4b7b2b10694a1d631e70aeabd42932 | no | 15 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |

| Total Files Size (in bytes): | 52910 |
|---|---|

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**
**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

| Application or Docket Number | Filing Date | ☐ To be Mailed |
|---|---|---|
| 12/658,680 | 02/11/2010 | |

## APPLICATION AS FILED – PART I

| | (Column 1) | (Column 2) | SMALL ENTITY ☒ | | OR | OTHER THAN SMALL ENTITY | |
|---|---|---|---|---|---|---|---|
| FOR | NUMBER FILED | NUMBER EXTRA | RATE ($) | FEE ($) | | RATE ($) | FEE ($) |
| ☐ BASIC FEE (37 CFR 1.16(a), (b), or (c)) | N/A | N/A | N/A | | | N/A | |
| ☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | N/A | N/A | N/A | | | N/A | |
| ☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | N/A | N/A | N/A | | | N/A | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | minus 20 = | * | X $ = | | OR | X $ = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | minus 3 = | * | X $ = | | | X $ = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | TOTAL | | | TOTAL | |

## APPLICATION AS AMENDED – PART II

| AMENDMENT | 03/04/2011 | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total (37 CFR 1.16(i)) | * 73 | Minus | ** 74 | = | X $ = | | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * 3 | Minus | ***3 | = | X $ = | | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | | OR | TOTAL ADD'L FEE | |

| AMENDMENT | | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | RATE ($) | ADDITIONAL FEE ($) | | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total (37 CFR 1.16(i)) | * | Minus | ** | = | X $ = | | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X $ = | | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | | OR | TOTAL ADD'L FEE | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/RAMONA D. WILSON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 07/22/2011

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/22/2011 | 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) | |
|---|---|---|---|
| | 12/658,680 | TYBER 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 *1* 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 *04 March 2011*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ 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**

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-74* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ 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).

11)☐ 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**

12)☐ 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)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, 51-74, drawn to an intramedullary assembly for bone fusion, classified in class 606, subclass 062.

II. Claims 26-50, drawn to a method for bone fusion, classified in class 606, subclass 86R.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used by another method, specifically one that does not include forming a first and second medullary canals.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because at least the following reason(s) apply the inventions require a different field of search (e.g., searching different classes /subclasses or electronic resources, or employing different search strategies or search queries).

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species. If Applicant elects Group I above, then Applicant must choose one of the following patentably distinct species:

A) Figs 1-6

B) Figs 8-16

C) Fig 17

D) Fig 18

E) Fig 19

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is a search and/or examination burden for the patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of**

**patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A call was made to Attorney Vincent Ferraro but no election was made over the phone. Mr. Ferraro requested the restriction be mailed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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.

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

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | | | | | | | | |
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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
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| Final | Original | 07/11/2011 | | | | | | | | |
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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
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| Final | Original | 07/11/2011 | | | | | | | | |
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Electronically filed August 15, 2011

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: Jamy Gannoe, et al. | Confirmation No.:1344 |
| Serial No.: 12/658,680 | Examiner: Stuart Bray |
| Filed: February 11, 2010 | Art Unit: 3733 |
| For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.:277-042 |

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

## RESPONSE TO RESTRICTION REQUIREMENT

SIR:

In response to the restriction requirement mailed July 22, 2011, applicants elect for prosecution Group I (clams 1 – 25 and 51 – 74). Further applicants elect species B (Figs. 8 -16) for prosecution.

Please amend the claims as set forth below.

**IN THE CLAIMS:**

Please revise the claims to read a follows.

**1. (Previously presented)** An intramedullary assembly for bone fusion, comprising:

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member for coupling to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, wherein the tubular portion comprises an opening disposed at an end of the tubular portion.

**2. (Original)** The intramedullary assembly of claim 1, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**3. (Previously presented)** The intramedullary assembly of claim 1, wherein the fixed angle is in the range of about 0 to about 90 degrees.

**4. (Previously presented)** The intramedullary assembly of claim 1, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**5. (Original)** The intramedullary assembly of claim 4, wherein the taper provides for an interference lock with the tapered screw member.

**6. (Previously presented)** The intramedullary assembly of claim 1, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Previously presented)** The intramedullary assembly of claim 1, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

**8. (Original)** The intramedullary assembly of claim 7, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

**9. (Previously presented)** The intramedullary assembly of claim 7, wherein the orifice is provided to receive a complementary shaped end of an instrument.

**10. (Previously presented)** The intramedullary assembly of claim 1, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Previously presented)** The intramedullary assembly of claim 1, 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 lag screw member.

**12. (Previously presented)** The intramedullary assembly of claim 1, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

**13. (Original)** The intramedullary assembly of claim 12, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**14. (Original)** The intramedullary assembly of claim 13, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**15. (Previously presented)** The intramedullary assembly of claim 13, wherein the first internal aperture further includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Original)** The intramedullary assembly of claim 15, wherein the opening is provided to receive a complementary shaped member.

**17. (Previously presented)** The intramedullary assembly of claim 13, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**18. (Previously presented)** The intramedullary assembly of claim 13, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**19. (Previously presented)** The intramedullary assembly of claim 13, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**20. (Previously presented)** The intramedullary assembly of claim 1, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**21. (Previously presented)** The intramedullary assembly of claim 1, 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 tapered screw member.

**22. (Previously presented)** The intramedullary assembly of claim 1, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

**23. (Previously presented)** The intramedullary assembly of claim 22, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Original)** The intramedullary assembly of claim 1, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

**25. (Original)** The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**26. (Withdrawn)** A method for bone fusion, comprising:

providing a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

providing a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

forming a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

forming a second medullary canal in the first bone;

coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

applying torque to the lag screw member to lock the tapered screw member to the lag screw member, thereby compressing the first bone to the second bone.

**27. (Withdrawn)** The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**28. (Withdrawn)** The method of claim 27, wherein the fixed angle is in the range of approximately 0 to approximately 90 degrees.

**29. (Withdrawn)** The method of claim 26, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**30. (Withdrawn)** The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

**31. (Withdrawn)** The method of claim 26, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**32. (Withdrawn)** The method of claim 26, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

**34. (Withdrawn)** The method of claim 32, further comprising receiving a complementary shaped end of an instrument in the orifice.

**35. (Withdrawn)** The method of claim 26, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**36. (Withdrawn)** The method of claim 26, 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 lag screw member.

**37. (Withdrawn)** The method of claim 26, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

**38. (Withdrawn)** The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

**39. (Withdrawn)** The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**40. (Withdrawn)** The method of claim 38, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**41. (Withdrawn)** The method of claim 40, further comprising receiving a complementary shaped member in the opening.

**42. (Withdrawn)** The method of claim 38, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**43. (Withdrawn)** The method of claim 38, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**44. (Withdrawn)** The method of claim 38, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**45. (Withdrawn)** The method of claim 26, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**46. (Withdrawn)** The method of claim 26, 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 tapered screw member.

**47. (Withdrawn)** The method of claim 26, further comprising inserting the lag screw member into at least a first medullary canal of bone.

**48. (Withdrawn)** The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

**49. (Withdrawn)** The method of claim 26, further comprising providing a cover portion coupled to the bulbous portion of the lag screw member.

**50. (Withdrawn)** The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**51. (Previously presented)** An intramedullary assembly for bone fusion, comprising:

a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a tapered screw member adapted for coupling to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and wherein the tubular portion comprises an opening at the fourth end

wherein the bulbous portion is semi-spherical for providing angular rotation of the lag screw member.

**52. (Original)** The intramedullary assembly of claim 51, wherein the lag screw member is slideably coupled to the tapered screw member and makes an angle with the tapered screw member.

**53. (Original)** The intramedullary assembly of claim 52, wherein the angle varies between 0 and 90 degrees.

**54. (Canceled)**

**55. (Previously presented)** The intramedullary assembly of claim 51, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Previously presented)** The intramedullary assembly of claim 51, wherein the bulbous portion further includes an orifice longitudinally coextensive with a length of the bulbous portion.

**57. (Original)** The intramedullary assembly of claim 56, wherein the orifice has a hexagonal shape, a star shape, or a square shape.

**58. (Previously presented)** The intramedullary assembly of claim 56, wherein the orifice is provided to receive a complementary shaped end of an instrument.

**59. (Previously presented)** The intramedullary assembly of claim 51, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**60. (Previously presented)** The intramedullary assembly of claim 51, 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 lag screw member.

**61. (Previously presented)** The intramedullary assembly of claim 51, wherein the tapered screw member further comprises a plurality of apertures disposed in the second elongated body.

**62. (Original)** The intramedullary assembly of claim 61, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**63. (Original)** The intramedullary assembly of claim 62, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**64. (Previously presented)** The intramedullary assembly of claim 61, wherein the first internal aperture further includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Original)** The intramedullary assembly of claim 64, wherein the opening is provided to receive a complementary shaped member.

**66. (Previously presented)** The intramedullary assembly of claim 62, wherein the tapered aperture traverses the second elongated body from the fourth end to an exterior surface on the second elongated body.

**67. (Previously presented)** The intramedullary assembly of claim 62, wherein the tapered aperture is provided to receive the first elongated body of the lag screw member, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the fourth end.

**68. (Previously presented)** The intramedullary assembly of claim 62, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**69. (Previously presented)** The intramedullary assembly of claim 51, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**70. (Previously presented)** The intramedullary assembly of claim 51, 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 tapered screw member.

**71. (Previously presented)** The intramedullary assembly of claim 51, wherein the lag screw member is provided for insertion into at least a first medullary canal of bone.

**72. (Previously presented)** The intramedullary assembly of claim 51, wherein the tapered screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Previously presented)** The intramedullary assembly of claim 51, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

**74. (Original)** The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

## REMARKS

In response to the restriction requirement mailed July 22, 2011, applicants elect for prosecution Group I (claims 1 -25 and 51 – 74) and species B (Figs. 8 – 16). Claims 1 – 23 and 51 – 72 are believed to encompass species B.

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.

No fee is believed to be due for filing this response. If, however, a fee is due, 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: August 15, 2011

Francis E. Morris
Reg. No. 24,615
Ward & Zinna, LLC
382 Springfield Avenue
Summit, New Jersey 07901
(908) 277-3333

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 10740018 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Frank Morris/Jamie Reinhardt |
| **Filer Authorized By:** | Frank Morris |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 15-AUG-2011 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 17:27:41 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Response to Election / Restriction Filed | 2011_8_15_As_Filed_Response_to_Election_Restriction_277_042.pdf | 426998<br>f8d39c944eaacd31dd5f538fcd689c842db34ab9 | no | 15 |

**Warnings:**

**Information:**

| Total Files Size (in bytes): | 426998 |
|---|---|

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**
**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

| Application or Docket Number | Filing Date | ☐ To be Mailed |
|---|---|---|
| 12/658,680 | 02/11/2010 | |

## APPLICATION AS FILED – PART I

| | (Column 1) | (Column 2) | SMALL ENTITY ☒ | | OR | OTHER THAN SMALL ENTITY | |
|---|---|---|---|---|---|---|---|
| FOR | NUMBER FILED | NUMBER EXTRA | RATE ($) | FEE ($) | | RATE ($) | FEE ($) |
| ☐ BASIC FEE (37 CFR 1.16(a), (b), or (c)) | N/A | N/A | N/A | | | N/A | |
| ☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | N/A | N/A | N/A | | | N/A | |
| ☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | N/A | N/A | N/A | | | N/A | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | minus 20 = | * | X $ = | | OR | X $ = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | minus 3 = | * | X $ = | | | X $ = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | TOTAL | | | TOTAL | |

## APPLICATION AS AMENDED – PART II

| AMENDMENT | 08/15/2011 | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total (37 CFR 1.16(i)) | * 73 | Minus | ** 73 | = 0 | X $26 = | 0 | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * 3 | Minus | ***3 | = 0 | X $110 = | 0 | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | 0 | OR | TOTAL ADD'L FEE | |

| AMENDMENT | | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | RATE ($) | ADDITIONAL FEE ($) | OR | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total (37 CFR 1.16(i)) | * | Minus | ** | = | X $ = | | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X $ = | | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | | OR | TOTAL ADD'L FEE | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/CAROL BARNES/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 27776

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

| Name | Registration Number | Name | Registration Number |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 27776

OR

| | | | |
|---|---|---|---|
| ☐ Firm or Individual Name | | | |
| Address | | | |
| City | | State | Zip |
| Country | | | |
| Telephone | | Email | |

Assignee Name and Address:

Extremity Medical LLC
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

**A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.**

**SIGNATURE of Assignee of Record**

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

| | | | |
|---|---|---|---|
| Signature | | Date | 1/26/11 |
| Name | | Telephone | 973-993-2935 |
| Title | | | |

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/96 (07-09)
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# STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Extremity Medical LLC

Application No./Patent No.: 12/658,680 Filed/Issue Date: 02/12/2010

Titled:
Intraosseous Intramedullary Fixation Assembly and Method of Use

Extremity Medical LLC , a Corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. ☒ the assignee of the entire right, title, and interest in;

2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or

3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 026401, Frame 0438, or for which a copy therefore is attached.

**OR**

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____
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Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Francis E. Morris/ August 24, 2011
Signature Date

Francis E. Morris Attorney
Printed or Typed Name Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

# Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 10803270 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Frank Morris/Jamie Reinhardt |
| **Filer Authorized By:** | Frank Morris |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 24-AUG-2011 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 14:30:01 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Power of Attorney | 2011_8_24_As_Filed_POA_277_024.pdf | 425951<br>f2f80a462782ce7906964f3ba57b4beda27c5cac | no | 1 |

| | |
|---|---|
| **Warnings:** | |
| **Information:** | |

| | | | | | |
|---|---|---|---|---|---|
| 2 | Assignee showing of ownership per 37 CFR 3.73(b). | 2011_8_24_As_Filed_Statement_Under_37_CFR_3_73_277_042.pdf | 425172<br>0cf4f2e8a1f33be545a6d3225ebfc96ee6cf8f62 | no | 2 |

| | |
|---|---|
| **Warnings:** | |
| **Information:** | |
| **Total Files Size (in bytes):** | 851123 |

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 09/28/2011

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/28/2011 | 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) | |
|---|---|---|---|
| | 12/658,680 | TYBER 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 *15 August 2011*.

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) *1-53 and 55-74* is/are pending in the application.

5a) Of the above claim(s) *12-19,24-50,61-68,73 and 74* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-11,20-23,51-53,55-60 and 69-72* 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 *14 June 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)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group I and Species B in the reply filed on 8/15/2011 is acknowledged.

Claims 26-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (Group II).

Claims 12-19, 24-25, 61-68, and 73-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/15/2011. Claim 12 claims a plurality of apertures in the tapered member. Figures 8-16 (Species B) do not depict a plurality of apertures in the tapered member. Claims 13-19 depend from claim 12. Applicant stated in the response that claims 24-25 do not read on Species B. Claim 61 claims a plurality of apertures in the tapered member. Figures 8-16 (Species B) do not depict a plurality of apertures in the tapered member. Claims 62-68 depend from claim 61. Applicant stated in the response that claims 73-74 do not read on Species B.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 20-23 are provisionally rejected on the ground of nonstatutory double patenting over claims 114-136 of copending Application No. 12/456,808. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 114, 115, 123 discloses an intramedullary assembly for bone fusion, comprising: a lag screw member, wherein the lag screw member comprises a first elongated body (claim 114, line 2-3), and wherein the first elongated body includes a first threaded portion at a first end (claim 115, lines 1-2) and a bulbous portion at a second end (claim 114, line 2-3); and a tapered screw member for coupling to the lag screw member (claim 114, line 4-5), wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end (Claim 123 line 103), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (claim 114, line 5) disposed at an end of the tubular portion.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***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 negatived 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 1-10, 20, 22-23 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.

Regarding claim 1, Chang discloses an intramedullary assembly for bone fusion, comprising: a lag screw member (11), wherein the lag screw member comprises a first elongated body, and wherein the first elongated body (Fig 4) includes a first threaded portion (111) at a first end and a bulbous portion (112) at a second end; and a tapered screw member (10) for coupling to the lag screw member (11), wherein the tapered screw member includes a second elongated body (Fig 4), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (103) disposed at an end of the tubular portion. Chang does not disclose that the second elongated body comprises a second threaded portion at a third end. Stark discloses a second elongated body (intramedullary rod) 74 with a threaded portion in order to better “draw the pin into the bone.” (col 6, ll 19-25.) It would have been obvious to one of ordinary skill in art at the

time of the invention to construct the device of Chang with a threaded second elongated body to draw the pin into the bone.

Regarding claim 2, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that lag screw member (11) is slideably coupled to the tapered screw member and makes a fixed angle (Fig 4) with the tapered screw member (10).

Regarding claim 3, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the fixed angle is in the range of about 0 to about 90 degrees. The angle in figure 4 appears to be approximately 90 degrees.

Regarding claims 4 and 5, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the bulbous (112) portion comprises a taper (Fig 4) adapted for providing an interference fit or lock with said distal member (10).

Regarding claim 6, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is cannulated having a cross-section with said first elongated body. Para 0020.

Regarding claims 7-9, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the bulbous portion (112) further includes an orifice (113) with a hexagonal shape (Fig. 3) longitudinally coextensive with a length of the bulbous portion (112), adapted for receiving a complementary shaped end (442) of an instrument (40).

Regarding claim 10, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the first threaded portion (111) contains a plurality of bone threads (111) on an outer surface of the first threaded portion (111).

Regarding claim 20, Chang in view of Stark discloses the invention as claimed and discussed above but does not disclose that the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to put a plurality of threads (111) on a second threaded portion on an end of a shaft, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Regarding claims 22 and 23, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) and the tapered screw member (10) are provided for insertion into at least a first medullary canal of bone. (Fig 5)

Claims 11 and 21 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 Start and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al. (“Culbert”).

Regarding claims 11 and 21, Chang in view of Stark discloses the invention as claimed and discussed above but does not disclose that the second threaded portion comprises a self-tapping edge adapted for removing bone material. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in order to omit a separate step of drilling into the bone. Para 0226. 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 self-tapping screw in view of Culbert to eliminate a step of drilling into the bone, which removes bone material.

Claims 51- 53, 55-59, 69, 71-72 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 and in further view of U.S. Patent 6,669,700 to Farris et al. ("Farris"),

Regarding claims 51 and 69, Chang discloses an intramedullary assembly for bone fusion, comprising: a lag screw member (11), wherein the lag screw member comprises a first elongated body, and wherein the first elongated body (Fig 4) includes a first threaded portion (111) at a first end and a bulbous portion (112) at a second end; and a tapered screw member (10) for coupling to the lag screw member (11), wherein the tapered screw member includes a second elongated body (Fig 4), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (103) disposed at an end of the tubular portion. Chang does not disclose that the second elongated body comprises a second threaded portion at a third end. Stark discloses a second

elongated body (intramedullary rod) 74 with a threaded portion in order to better “draw the pin into the bone.” (col 6, ll 19-25.) It would have been obvious to one of ordinary skill in art at the time of the invention to construct the device of Chang with a threaded second elongated body to draw the pin into the bone.

Chang does 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 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.

Regarding claim 52, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is slideably coupled to the tapered screw member and makes an angle (Fig 4) with the tapered screw member (10).

Regarding claim 53, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the fixed angle is in the range of about 0 to about 90 degrees. The angle in figure 4 appears to be approximately 90 degrees.

Regarding claim 55, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is cannulated having a cross-section with said first elongated body. Para 0020.

Regarding claims 56-58, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the bulbous portion (112) further includes an orifice (113) with a hexagonal shape (Fig. 3) longitudinally coextensive with a length of the bulbous portion (112), adapted for receiving a complementary shaped end (442) of an instrument (40).

Regarding claim 59, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the first threaded portion (111) contains a plurality of bone threads (111) on an outer surface of the first threaded portion (111).

Regarding claims 71 and 72, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) and the tapered screw member (10) are provided for insertion into at least a first medullary canal of bone. (Fig 5)

Claims 60 and 70 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 and in further view of U.S. Patent 6,669,700 to Farris et al. (“Farris”) and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al. (“Culbert”).

Regarding claims 60 and 70, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above but do not disclose that the second threaded portion comprises a self-tapping edge adapted for removing bone material. Culbert discloses a “self-tapping or self-drilling bone stabilization device” in order to omit a separate step of drilling into the bone. Para 0226. 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 self-tapping screw in view of Culbert to eliminate a step of drilling into the bone, which removes bone material.

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.

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

| Notice of References Cited | Application/Control No. 12/658,680 | Applicant(s)/Patent Under Reexamination TYBER ET AL. | |
|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | Page 1 of 1 |

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| | B | US- | | | |
| | C | US- | | | |
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| | L | US- | | | |
| | M | US- | | | |

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| | W | |
| | X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

## EAST Search History

### EAST Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|---|---|---|---|---|---|---|
| L1 | 3187 | (606/54,62,80,96).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/23 10:22 |
| S1 | 3185 | (606/54,62,80,96).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:10 |
| S2 | 0 | S1 and (semi-sperical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S3 | 50 | S1 and (semi-spherical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S4 | 275 | screw and (semi-spherical adj head) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:15 |
| S5 | 92 | S4 and bone | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:16 |
| S6 | 83 | "6322562" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:17 |
| S7 | 1 | "20020045899" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:19 |
| S8 | 11 | "7175626" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:33 |
| S9 | 0 | 606/64,65 | USPAT | OR | OFF | 2011/09/22 16:04 |
| S10 | 0 | 606/64,65 | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/22 16:04 |
| S11 | 593 | (606/64,65).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/22 16:04 |

### EAST Search History (Interference)

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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
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| Final | Original | 07/11/2011 | 09/21/2011 | | | | | | | |
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| | 8 | ÷ | ✓ | | | | | | | |
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| | 11 | ÷ | ✓ | | | | | | | |
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| | 13 | ÷ | N | | | | | | | |
| | 14 | ÷ | N | | | | | | | |
| | 15 | ÷ | N | | | | | | | |
| | 16 | ÷ | N | | | | | | | |
| | 17 | ÷ | N | | | | | | | |
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| | 24 | ÷ | N | | | | | | | |
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| | 34 | ÷ | N | | | | | | | |
| | 35 | ÷ | N | | | | | | | |
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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | | | | | | | |
| | 37 | ÷ | N | | | | | | | |
| | 38 | ÷ | N | | | | | | | |
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| | 43 | ÷ | N | | | | | | | |
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| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | | | | | | | |
| | 73 | ÷ | N | | | | | | | |
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PTO/SB/08a (07-09)
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 1 of 1

| Complete if Known | |
|---|---|
| Application Number | 12/658680 |
| Filing Date | 2010-02-12 |
| First Named Inventor | Jeff Tyber |
| Art Unit | 3733 |
| Examiner Name | TBD |
| Attorney Docket Number | 277-042 |

**U. S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No.[1] | Document Number<br>Number-Kind Code[2] *(if known)* | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| | 3 | US- 7763021 | 2010-07-27 | Cole et al. | |
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# BIB DATA SHEET

**CONFIRMATION NO. 1344**

| SERIAL NUMBER | FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010<br>RULE | 606 | 3733 | 277-042 |

**APPLICANTS**

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**** CONTINUING DATA ***************************

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
03/05/2010

| Foreign Priority claimed ☐ Yes ☑ No<br>35 USC 119(a-d) conditions met ☐ Yes ☐ No<br>Verified and Acknowledged /STUART SAMUEL BRAY/ Examiner's Signature | ☐ Met after Allowance<br>Initials | STATE OR COUNTRY | SHEETS DRAWINGS | TOTAL CLAIMS | INDEPENDENT CLAIMS |
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| | | PA | 20 | 74 | 3 |

**ADDRESS**

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901
UNITED STATES

**TITLE**

Intraosseous intramedullary fixation assembly and method of use

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| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| SEARCHED | | | |
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| Class | Subclass | Date | Examiner |
| 606 | 54, 62, 80, 96 | 9/21/2011 | SSB |
| 606 | 64, 65 | 9/23/2011 | SSB |

| SEARCH NOTES | | |
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| Search Notes | Date | Examiner |
| Performed inventor search | 9/21/2011 | SSB |

| INTERFERENCE SEARCH | | | |
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| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 10/05/2011

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| BRAY, STUART SAMUEL | |
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|---|---|---|---|
| 12/658,680 | 11 February 2010 | TYBER ET AL. | 277-042 |

| EXAMINER |
|---|
| STUART S. BRAY |

| ART UNIT | PAPER |
|---|---|
| 3733 | 20110926 |

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SUITE 300
382 SPRINGFIELD AVENUE
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**Commissioner for Patents**

In the first Non-Final office action in this case, the PTO-892 was inadvertently not filled out. A properly filled out PTO-892 for this case is attached with this letter.

/EDUARDO C. ROBERT/
Supervisory Patent Examiner, Art Unit 3733

/STUART S BRAY/
Examiner, Art Unit 3733

PTO-90C (Rev.04-03)

| Notice of References Cited | Application/Control No. 12/658,680 | Applicant(s)/Patent Under Reexamination TYBER ET AL. | |
|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | Page 1 of 2 |

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| * | C | US-2009/0099571 | 04-2009 | Cresina et al. | 606/96 |
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| * | M | US-2010/0256638 | 10-2010 | Tyber et al. | 606/62 |

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|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | Page 2 of 2 |

**U.S. PATENT DOCUMENTS**

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| * | B | US-5,456,267 | 10-1995 | Stark, John G. | 128/898 |
| | C | US- | | | |
| | D | US- | | | |
| | E | US- | | | |
| | F | US- | | | |
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27776 7590 03/09/2012

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SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/09/2012 | PAPER |

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

| Applicant-Initiated Interview Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 12/658,680 | TYBER ET AL. | |
| | Examiner | Art Unit | |
| | STUART S. BRAY | 3733 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *STUART S. BRAY*.

(2) _____.

(3) *Frank Morris*.

(4) *Vin Ferraro*.

Date of Interview: *07 March 2012*.

Type: ☐ Telephonic ☐ Video Conference
☒ Personal [copy given to: ☐ applicant ☒ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1-11 and 20-23*.

Identification of prior art discussed: *Copending 12/456808*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

*Examiner and Applicant discussed the pending non-statutory double patenting rejection. Applicant stated that in addition to any amendments of the claims, a provisional terminal disclaimer will likely be filed.* .

**Applicant recordation instructions:** The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

**Examiner recordation instructions**: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

| /STUART S BRAY/<br>Examiner, Art Unit 3733 | |
|---|---|

# Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

**Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Electronically filed March 28, 2012

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Jeff Tyber, et al. Confirmation No.: 1344

Serial No.: 12/658,680 Examiner: Bray, Stuart Samuel

Filed: February 11, 2010 Art Unit: 3733

For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE Atty. Doc. No.: 277-042

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

**RESPONSE TO OFFICE ACTION OF SEPTEMBER 28, 2011**

SIR:

This is an amendment and response to the office action mailed September 28, 2011. 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 CLAIMS** begin on page 8 of this paper.

**REMARKS** begin on page 23 of this paper.

**Amendments to Specification and Drawings** remarks begin on page 23 of this paper.

**Election/Restrictions** remarks begin on page 24 of this paper.

**35 U.S.C. § 103** remarks begin on page 24 of this paper.

**Double Patenting** remarks begin on page 27 of this paper.

**REPLACEMENT DRAWINGS** are attached and labeled REPLACEMENT SHEET.

**IN THE SPECIFICATION:**

Please revise the paragraph found on page 12, line 9 to page 13, line 11 of the specification or paragraph [0044] of U.S. Patent Application Publication No. 2010/0256638 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.

Please revise the paragraph found on page 14, lines 1-8 of the specification or paragraph [0046] of U.S. Patent Application Publication No. 2010/0256638 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.

Please revise the paragraph found on page 23, line 11 to page 24, line 12 of the specification or paragraph [0060] of U.S. Patent Application Publication No. 2010/0256638 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.

Please revise the paragraph found on page 29, lines 3-20 of the specification or paragraph [0067] of U.S. Patent Application Publication No. 2010/0256638 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).

Please revise the paragraph found on page 31, line 16 to page 32, line 15 of the specification or paragraph [0071] of U.S. Patent Application Publication No. 2010/0256638 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.

**IN THE CLAIMS:**

Please revise the claims to read a follows.

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

a ~~lag~~ first screw member, wherein the ~~lag~~ first screw member comprises a first elongated body extending along a first longitudinal axis, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a ~~tapered~~ second screw member for coupling to the ~~lag~~ first screw member, wherein the ~~tapered~~ second screw member includes a second elongated body having first and second ends and extending along a second longitudinal axis, wherein the second elongated body comprises a second threaded portion at ~~a third~~ the first end of the second elongated body, a first aperture ~~tubular portion~~ at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member, ~~wherein the tubular portion comprises an opening disposed at an end of the tubular portion~~ wherein the second longitudinal axis and the third axis define an angle,

wherein the first screw member couples to the second screw member by inserting the first screw member into the bore until the bulbous portion of the first screw member abuts the first aperture of the second screw member.

**2. (Currently amended)** The intramedullary assembly of claim 1, wherein the ~~lag~~ first screw member ~~is slideably coupled~~ couples to the ~~tapered~~ second screw member at the angle ~~and makes a fixed angle with the tapered screw member~~.

**3. (Currently amended)** The intramedullary assembly of claim 1, wherein the ~~fixed~~ angle is in the range of about 0 degrees to about 90 degrees.

**4. (Currently amended)** The intramedullary assembly of claim 1, wherein the bulbous portion includes a taper for providing an interference fit with the ~~tapered~~ second screw member.

**5. (Currently amended)** The intramedullary assembly of claim 4, wherein the taper provides for an interference lock with the ~~tapered~~ second screw member.

**6. (Currently amended)** The intramedullary assembly of claim 1, wherein the ~~lag~~ first screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Currently amended)** The intramedullary assembly of claim 1, wherein the bulbous portion ~~further~~ includes an ~~orifice~~ aperture disposed along the first longitudinal axis ~~longitudinally coextensive with a length of the bulbous portion~~.

**8. (Currently amended)** The intramedullary assembly of claim 7, wherein the ~~orifice~~ aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**9. (Currently amended)** The intramedullary assembly of claim 7, wherein the ~~orifice~~ aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**10. (Currently amended)** The intramedullary assembly of claim 1, wherein the first threaded portion ~~contains~~ comprises a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Currently amended)** The intramedullary assembly of claim 1, wherein the first threaded portion includes a self-tapping edge~~, wherein the self-tapping edge provides~~ for ~~removal of~~ removing bone material ~~during insertion of the lag screw member~~.

**12. (Currently amended)** The intramedullary assembly of claim 1, wherein the ~~tapered~~ second screw member ~~further~~ comprises an ~~plurality of apertures~~ internal aperture disposed in the second elongated body.

**13. (Canceled)** The intramedullary assembly of claim 12, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**14. (Currently amended)** The intramedullary assembly of claim [[13]] 12, wherein the ~~first~~ internal aperture is disposed along the second longitudinal axis ~~partially traverses the tubular portion at the fourth end~~.

**15. (Currently amended)** The intramedullary assembly of claim [[13]] 12, wherein the ~~first~~ internal aperture ~~further~~ includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Currently amended)** The intramedullary assembly of claim 15, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**17. (Canceled)** The intramedullary assembly of claim 13, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**18. (Currently amended)** The intramedullary assembly of claim 1[[3]], wherein the ~~tapered aperture~~ bore ~~is provided to~~ receives the first elongated body of the ~~lag~~ first screw member, wherein the bulbous portion ~~is contained~~ resides within the ~~tapered aperture~~ bore, and further wherein the bulbous portion abuts the ~~opening~~ first aperture at the second end of the second elongated body ~~of the tubular portion~~.

**19. (Canceled)** The intramedullary assembly of claim 13, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**20. (Currently amended)** The intramedullary assembly of claim 1, wherein the second threaded portion ~~contains~~ comprises a plurality of threads on an outer surface of the second threaded portion.

**21. (Currently amended)** The intramedullary assembly of claim 1, wherein the second threaded portion includes a self-tapping edge~~, wherein the self-tapping edge provides~~ for ~~removal of~~ removing bone material ~~during insertion of the tapered screw member~~.

**22. (Currently amended)** The intramedullary assembly of claim 1, wherein the ~~lag~~ first screw member is provided for insertion into at least a first medullary canal of a bone.

**23. (Currently amended)** The intramedullary assembly of claim 22, wherein the ~~tapered~~ second screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Withdrawn)** The intramedullary assembly of claim 1, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

**25. (Withdrawn)** The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**26. (Withdrawn)** A method for bone fusion, comprising:

providing a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

providing a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body

comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

forming a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

forming a second medullary canal in the first bone;

coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

applying torque to the lag screw member to lock the tapered screw member to the lag screw member, thereby compressing the first bone to the second bone.

**27. (Withdrawn)** The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**28. (Withdrawn)** The method of claim 27, wherein the fixed angle is in the range of approximately 0 to approximately 90 degrees.

**29. (Withdrawn)** The method of claim 26, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**30. (Withdrawn)** The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

**31. (Withdrawn)** The method of claim 26, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**32. (Withdrawn)** The method of claim 26, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

**34. (Withdrawn)** The method of claim 32, further comprising receiving a complementary shaped end of an instrument in the orifice.

**35. (Withdrawn)** The method of claim 26, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**36. (Withdrawn)** The method of claim 26, 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 lag screw member.

**37. (Withdrawn)** The method of claim 26, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

**38. (Withdrawn)** The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

**39. (Withdrawn)** The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**40. (Withdrawn)** The method of claim 38, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**41. (Withdrawn)** The method of claim 40, further comprising receiving a complementary shaped member in the opening.

**42. (Withdrawn)** The method of claim 38, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**43. (Withdrawn)** The method of claim 38, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is

contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**44. (Withdrawn)** The method of claim 38, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**45. (Withdrawn)** The method of claim 26, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**46. (Withdrawn)** The method of claim 26, 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 tapered screw member.

**47. (Withdrawn)** The method of claim 26, further comprising inserting the lag screw member into at least a first medullary canal of bone.

**48. (Withdrawn)** The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

**49. (Withdrawn)** The method of claim 26, further comprising providing a cover portion coupled to the bulbous portion of the lag screw member.

**50. (Withdrawn)** The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**51. (Currently amended)** An intramedullary assembly for bone fusion, comprising:

a ~~lag~~ first screw member, wherein the ~~lag~~ first screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a ~~tapered~~ second screw member ~~adapted~~ for coupling to the ~~lag~~ first screw member, wherein the ~~tapered~~ second screw member includes a second elongated body having first and second ends, wherein the second elongated body comprises a second threaded portion at ~~a third~~ the first end of the second elongated body[[,]] and a tubular portion at ~~a fourth~~ the second end of the second elongated body, ~~and~~ wherein the tubular portion comprises ~~an opening~~ a first aperture at a terminal end of the ~~fourth~~ second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member,

wherein the bulbous portion is semi-spherical for providing angular rotation of the ~~lag~~ first screw member.

**52. (Currently amended)** The intramedullary assembly of claim 51, wherein the ~~lag~~ first screw member ~~is slideably coupled~~ couples to the ~~tapered~~ second screw member at an angle ~~and makes an angle with the tapered screw member~~.

**53. (Currently amended)** The intramedullary assembly of claim 52, wherein the angle varies between about 0 degrees and about 90 degrees.

**54. (Canceled)**

**55. (Currently amended)** The intramedullary assembly of claim 51, wherein the ~~lag~~ first screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Currently amended)** The intramedullary assembly of claim 51, wherein the bulbous portion ~~further~~ includes an ~~orifice~~ aperture ~~longitudinally coextensive with a length of the bulbous portion~~.

**57. (Currently amended)** The intramedullary assembly of claim 56, wherein the ~~orifice~~ aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**58. (Currently amended)** The intramedullary assembly of claim 56, wherein the ~~orifice~~ aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**59. (Currently amended)** The intramedullary assembly of claim 51, wherein the first threaded portion ~~contains~~ comprises a plurality of bone threads on an outer surface of the first threaded portion.

**60. (Currently amended)** The intramedullary assembly of claim 51, wherein the first threaded portion includes a self-tapping edge~~, wherein the self-tapping edge provides~~ for removing ~~removal of~~ bone material ~~during insertion of the lag screw member~~.

**61. (Currently amended)** The intramedullary assembly of claim 51, wherein the ~~tapered~~ second screw member ~~further~~ comprises ~~a plurality of apertures~~ an internal aperture disposed in the second elongated body.

**62. (Canceled)** The intramedullary assembly of claim 61, wherein the plurality of apertures includes a first internal aperture and a tapered aperture.

**63. (Currently amended)** The intramedullary assembly of claim [[62]] 61, wherein the ~~first~~ internal aperture partially traverses the tubular portion at the ~~fourth~~ second end of the second elongated body.

**64. (Currently amended)** The intramedullary assembly of claim 61, wherein the ~~first~~ internal aperture ~~further~~ includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Currently amended)** The intramedullary assembly of claim 64, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**66. (Canceled)** The intramedullary assembly of claim 62, wherein the tapered aperture traverses the second elongated body from the fourth end to an exterior surface on the second elongated body.

**67. (Currently amended)** The intramedullary assembly of claim [[62]] 51, wherein the ~~tapered aperture~~ bore ~~is provided to~~ receives the first elongated body of the ~~lag~~ first screw member, wherein the bulbous portion ~~is contained~~ resides within the ~~tapered aperture~~ bore, and further wherein the bulbous portion abuts the ~~opening~~ first aperture at the ~~fourth~~ second end of the second elongated body.

**68. (Currently amended)** The intramedullary assembly of claim [[62]] 51, wherein the ~~tapered aperture~~ bore forms a predetermined angle with the second elongated body.

**69. (Currently amended)** The intramedullary assembly of claim 51, wherein the second threaded portion ~~contains~~ comprises a plurality of threads on an outer surface of the second threaded portion.

**70. (Currently amended)** The intramedullary assembly of claim 51, wherein the second threaded portion includes a self-tapping edge~~, wherein the self-tapping edge provides~~ for ~~removal of~~ removing bone material ~~during insertion of the tapered screw member~~.

**71. (Currently amended)** The intramedullary assembly of claim 51, wherein the ~~lag~~ first screw member is provided for insertion into at least a first medullary canal of a bone.

**72. (Currently amended)** The intramedullary assembly of claim [[51]] 71, wherein the ~~tapered~~ second screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Withdrawn)** The intramedullary assembly of claim 51, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

**74. (Withdrawn)** The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**75. (New)** The intramedullary assembly of claim 1, wherein the bore is adapted for retaining the bulbous portion.

**76. (New)** The intramedullary assembly of claim 4, wherein the bore comprises a taper for providing an interference fit with the taper of the bulbous portion.

**77. (New)** The intramedullary assembly of claim 2, wherein the angle is adapted to cause the intramedullary assembly to couple to at least a first bone and translate compression applied to bone fragments across the first screw member and the second screw member, thereby drawing the bone fragments together.

**78. (New)** The intramedullary assembly of claim 2, wherein the angle is adapted to cause the intramedullary assembly to couple to at least a first bone and translate compression applied to bone fragments by the second screw member and the first screw member into uniform compression through a plurality of points of fixation.

**79. (New)** The intramedullary assembly of claim 1, wherein the bulbous portion comprises a spherical portion adapted to allow the first screw member to couple to the second screw member at a plurality of possible angles ranging from about 0 degrees to about 90 degrees.

**80. (New)** The intramedullary assembly of claim 79, wherein the spherical portion is adapted to allow the first screw member to rotate within the bore to set an angle between the first screw member and the second screw member to at least one of the plurality of possible angles.

**81. (New)** The intramedullary assembly of claim 1, wherein the second screw member comprises a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises the first aperture and the bore, and wherein the second aperture is on an exterior surface of the tubular portion.

## REMARKS

Applicants first wish to thank the Examiner for his helpful suggestions made during the course of an Examiner Interview held with Applicants' representatives on March 7, 2012.

Claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 are pending in this application. Please amend claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, and 67-72, cancel claims 13, 17, 19, 62, and 66 and add new claims 75-81. Claim 54 remains canceled and claims 24-50 and 73-74 remain withdrawn. 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 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 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

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. ELECTION/RESTRICTIONS

The Examiner indicated that claims 12-19, 24-25, 61-68, and 73-74 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. (See Office Action dated September 28, 2011, p. 2). Further, the Examiner indicated that because claims 12 and 61 claim a plurality of apertures in the tapered member not depicted in elected Figures 8-16, these claims are withdrawn from further consideration. (See id.). The Examiner also indicated that since claims 13-19 depend from claim 12 and claims 62-68 depend from claim 61, claims 13-19 and claims 62-68 are withdrawn for the same reason. (See id.). Applicants respectfully traverse the Examiner's election restriction, and submit that amended claims 12, 14-16, 18, 61, 63-65, and 67-68 are depicted in elected Figures 8-16. As such, Applicants respectfully request the Examiner to re-enter and examine claims 12, 14-16, 18, 61, 63-65, and 67-68.

## III. THE 35 U.S.C § 103 REJECTION

The Examiner rejected claims 1-11, 20-23, 51-60, and 69-72 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"), U.S. Patent No. 5,456,267 to Stark (hereinafter "Stark"), U.S. Patent Publication No. 2009/0149857 to Culbert, et al. (hereinafter "Culbert"), and U.S. Patent

No. 6,669,700 to Farris, et al. (hereinafter "Farris"). Applicants respectfully traverse the Examiner's rejection, and submit that Chang, Stark, Culbert, and Farris, alone or in combination, do not discuss or disclose every element of claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81.

Referring first to claim 1, Applicants submit that Chang, Stark, Culbert, and Farris, alone or in combination, do **not** discuss, and are in fact missing at least the following element, *inter alia*, "wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body, a first aperture at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member," as required by currently amended independent claim 1. In fact, Chang specifically and only discloses through holes (101 and 102) that are merely provided along the shaft of the nail. (See Chang, FIGS. 1-5, Abstract and paragraphs [0017] and [0024]). Notably, Chang does not discuss or disclose providing an aperture at a terminal end of the nail. Nor does Change discuss or disclose a bore that extends from that aperture to an exterior surface of the nail. Likewise, Stark, Culbert, and Farris all fail to discuss or disclose these same features.

In light of the remarks above, Applicants respectfully submit that Chang, Stark, Culbert, and Farris, 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, Stark, Culbert, and Farris. Further, as claims 2-12, 14-16, 18, 20-23, and 75-81 depend either directly or indirectly from independent claim 1, they contain all of the elements and limitations of at least claim 1. Claims 2-12, 14-16, 18, 20-23, and 75-81 are therefore patentable over Chang, Stark, Culbert, and Farris, for at least the same reasons as

discussed above regarding independent claim 1. Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 1-12, 14-16, 18, 20-23, and 75-81.

Referring now to claim 51, Applicants submit that Chang, Stark, Culbert, and Farris, alone or in combination, do **not** discuss, and are in fact missing at least the following element, *inter alia*, "wherein the tubular portion comprises a first aperture at a terminal end of the second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member," as required by currently amended independent claim 51. For the same reasons discussed above with respect to claim 1, Chang, Stark, Culbert, and Farris, alone or in combination, do not discuss or disclose this limitation.

In light of the remarks above, Applicants respectfully submit that Chang, Stark, Culbert, and Farris, alone or in combination, do not teach, suggest or render obvious the features of currently amended claim 51. Accordingly, Applicants respectfully submit that claim 51 is patentable over Chang, Stark, Culbert, and Farris. Further, as claims 52-53, 55-61, 63-65, and 67-72 depend either directly or indirectly from independent claim 51, they contain all of the elements and limitations of at least claim 51. Claims 52-53, 55-61, 63-65, and 67-72 are therefore patentable over Chang, Stark, Culbert, and Farris, for at least the same reasons as discussed above regarding independent claim 51. Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 51-53, 55-61, 63-65, and 67-72.

## IV. THE DOUBLE PATENTING REJECTION

The Examiner provisionally rejected claims 1-11 and 20-23 on the ground of non-statutory double patenting over claims 114-136 of co-pending Application No. 12/456,808. (See Office Action dated September 28, 2011, pp. 2-4). In view of the extensive amendments to claim 1, as discussed above, Applicants submit the non-statutory double patenting rejection of claims 1-11 and 20-23 should be withdrawn and action to that end is respectfully requested.

## 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 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81.

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.

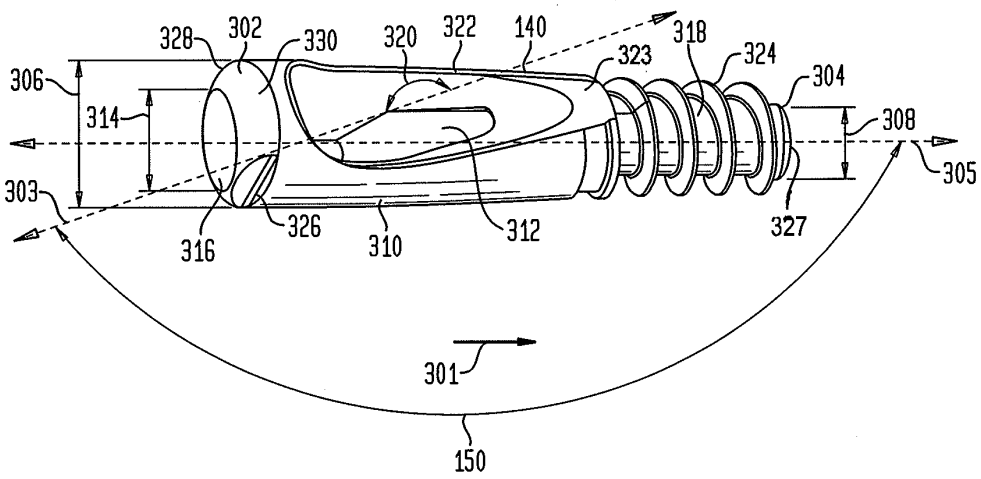
This response is being filed with a petition for a three month extension of time. If any other petitions and/or other fees are required, the Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 23-0420 in the name of Ward & Zinna, LLC.

Respectfully submitted,

Date: March 28, 2012

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Reg. No. 24,615
Ward & Zinna, LLC
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Summit, New Jersey 07901
(908) 277-3333

FIG. 3A


328
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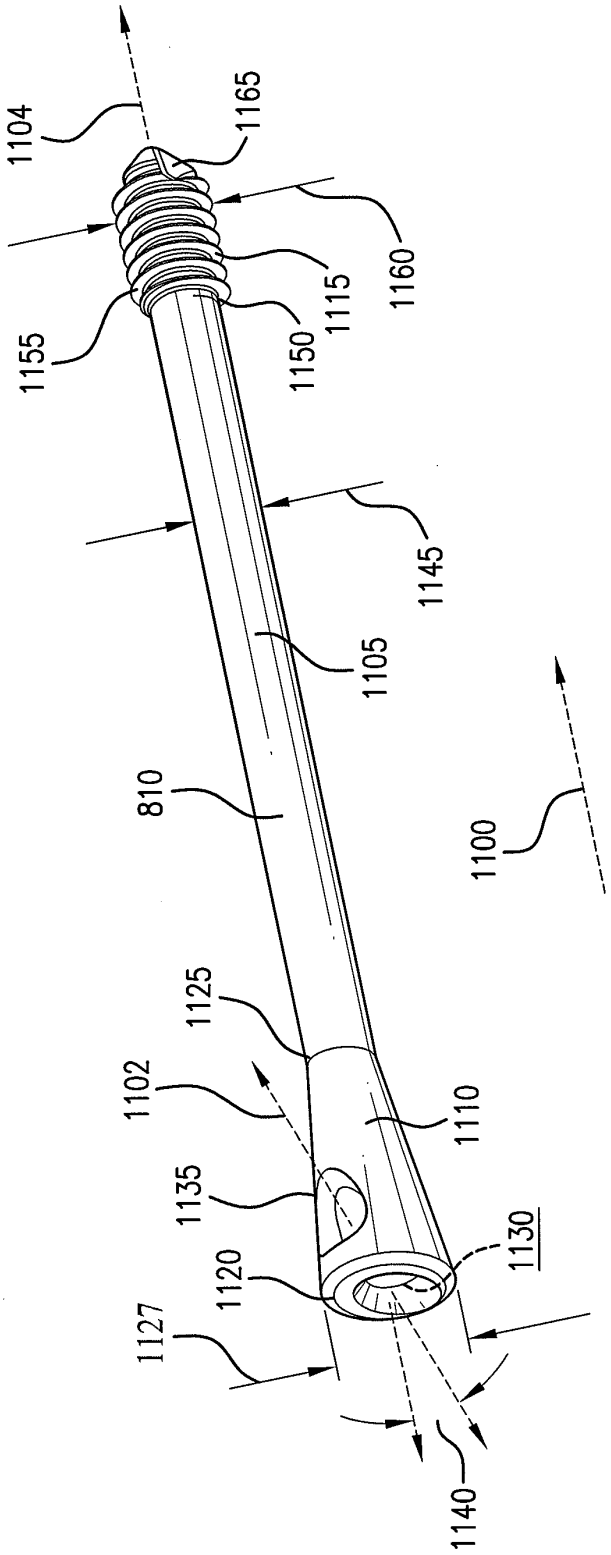

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FIG. 11

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | 12658680 |
| **Filing Date:** | 11-Feb-2010 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Filer:** | Frank Morris/Vincent Ferraro |
| **Attorney Docket Number:** | 277-042 |

Filed as Small Entity

## Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Basic Filing:** | | | | |
| **Pages:** | | | | |
| **Claims:** | | | | |
| Claims in excess of 20 | 2202 | 2 | 30 | 60 |
| **Miscellaneous-Filing:** | | | | |
| **Petition:** | | | | |
| **Patent-Appeals-and-Interference:** | | | | |
| **Post-Allowance-and-Post-Issuance:** | | | | |
| **Extension-of-Time:** | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| Extension - 3 months with $0 paid | 2253 | 1 | 635 | 635 |
| **Miscellaneous:** | | | | |
| | | **Total in USD ($)** | | **695** |

| Electronic Acknowledgement Receipt | |
|---|---|
| **EFS ID:** | 12417770 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Frank Morris/Vincent Ferraro |
| **Filer Authorized By:** | Frank Morris |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 28-MAR-2012 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 18:33:04 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | $695 |
| RAM confirmation Number | 5812 |
| Deposit Account | 230420 |
| Authorized User | |
| The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:<br>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)<br>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) | |

| | |
|---|---|
| Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) | |
| Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees) | |
| Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges) | |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Amendment/Req. Reconsideration-After Non-Final Reject | Response_277_042.pdf | 963614<br>0528ee0daa15258c50fd58214fe32ae3de21106b | no | 27 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 2 | Drawings-only black and white line drawings | Replacement_Figs_277_042.pdf | 26703<br>86d7ca9aab8e7a1a86898967237775a6fd47ad8e2 | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 3 | Fee Worksheet (SB06) | fee-info.pdf | 31515<br>e8f798757aca3b375e61b2bdfdeca03543492e78 | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | **Total Files Size (in bytes):** | 1021832 | | |

**This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.**

**New Applications Under 35 U.S.C. 111**
**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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# PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

| Application or Docket Number | Filing Date | ☐ To be Mailed |
|---|---|---|
| 12/658,680 | 02/11/2010 | |

## APPLICATION AS FILED – PART I

| | (Column 1) | (Column 2) | SMALL ENTITY ☒ | | OR | OTHER THAN SMALL ENTITY | |
|---|---|---|---|---|---|---|---|
| FOR | NUMBER FILED | NUMBER EXTRA | RATE ($) | FEE ($) | | RATE ($) | FEE ($) |
| ☐ BASIC FEE (37 CFR 1.16(a), (b), or (c)) | N/A | N/A | N/A | | | N/A | |
| ☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | N/A | N/A | N/A | | | N/A | |
| ☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | N/A | N/A | N/A | | | N/A | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | minus 20 = | * | X $ = | | OR | X $ = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | minus 3 = | * | X $ = | | | X $ = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | TOTAL | | | TOTAL | |

## APPLICATION AS AMENDED – PART II

| AMENDMENT | 03/28/2012 | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total (37 CFR 1.16(i)) | * 75 | Minus | ** 73 | = 2 | X $30 = | 60 | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * 3 | Minus | ***3 | = 0 | X $125 = | 0 | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | 60 | OR | TOTAL ADD'L FEE | |

| AMENDMENT | | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | RATE ($) | ADDITIONAL FEE ($) | OR | RATE ($) | ADDITIONAL FEE ($) |
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| | Total (37 CFR 1.16(i)) | * | Minus | ** | = | X $ = | | OR | X $ = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X $ = | | OR | X $ = | |
| | ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| | ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | | TOTAL ADD'L FEE | | OR | TOTAL ADD'L FEE | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/LASHAWN MARKS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**
**( Not for submission under 37 CFR 1.99)**

| | |
|---|---|
| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Tyber, Jeff |
| Art Unit | 3733 |
| Examiner Name | Bray, Stuart Samuel |
| Attorney Docket Number | 277-042 |

| U.S.PATENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
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| | Application Number | 12658680 |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
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| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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|---|---|---|
| | Application Number | 12658680 |
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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
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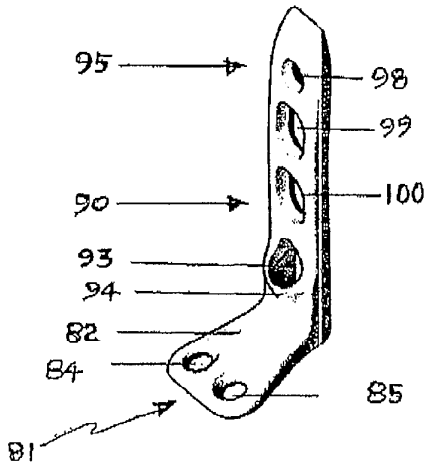
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(54) Title: ANKLE FUSION PLATE




(57) Abstract: A fusion plate for arthrodesis, the plate comprising: a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposing surface, a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface, a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface. The first portion includes at least one opening which receives at least one fixation means. The second portion includes at least one opening which receives at least one fixation means and the third portion includes at least one opening which receives at least one fixation screw.

WO 2007/131287 A1

# ANKLE FUSION PLATE

## BACKGROUND

The present invention relates to prosthetic devices and more particularly relates to an ankle fusion plate for fusion of the anterior ankle. More particularly the invention relates to an ankle plate in which openings in the plate receive fixation screws allowing compression of bones being fused. The invention further, relates to a method of insertion of an anterior ankle plate so that optimal compression is achieved in anterior ankle joint fusion. This invention further relates to a kit including a selection of ankle fusion plates and a selection of fasteners for fixation of the ankle plate in a prescribed manner such that orientation of the screws provide optimal compression and therefore mechanical advantage. More particularly, this invention relates to an improved apparatus for fusion of ankle joints.

## PRIOR ART

The prior art is replete with orthopaedic devices for repairing bones and particularly diseased bones and bone fractures. The prior art teaches a variety of bone fixation systems using plates and screws.

For example, United States Patent 6,235,034 discloses a bone plate comprising a base plate having at least two screw holes and at least two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone. The bone screws have heads shaped to toggle within the screw holes. A retaining plate is provided that is fixedly attachable to the base plate. The retaining plate covers at least a portion of each of the bone screws. The retaining plate and base plate each contain set screw apertures. A set screw is provided to retain the retaining plate in place over the base plate by screwing the set screw through the set screw apertures in the retaining plate and base plate. This design prevents the bone screw from backing out from the bone once screwed in through the base plate.

Another example of plate fixation by screw is disclosed in United States Patent 5,951,558 which discloses a fixation device for keeping two or more bone pieces together, either pieces of a broken bone or two distinct bones, for undergoing junction of the pieces by natural welding. The device described is capable of immobilizing flat or round bones, long or short bones, for example, parts of a broken femur or two contiguous vertebrae. The device comprises a fixation plate and fixation screws, the plate having orifices for passing the screws through the plate and fastening the screws into the bone tissue. A screw blocking or locking mechanism is provided in the plate to block the screws in the fastening position once the screws have been passed through the plate and screwed into the bone pieces, for preventing the screws from unscrewing from the bone pieces and moving out of the fixation plate once and after the fixation plate and the screws have been firmly installed in the bones.

Another prior art bone fusion device is taught in United States Patent 6,830,589 which describes expandable bone fusion devices and methods of use. The fusion device according to the invention described in that patent includes a first member and a second member which can be deployed and locked into an expanded configuration to stabilize the adjacent bone during fusion of the bone.

More generally United States Patent 6,663,669 discloses a total ankle replacement system and novel surgical method for total ankle replacement. Novel surgical tools for performing the surgical method are also described. The total ankle replacement system includes the calcaneus in fixation of a lower prosthesis body, thereby significantly increasing the amount of bone available for fixation of the lower prosthesis body and allowing the lower prosthesis body to be anchored with screws. The total ankle replacement system further includes a long tibial stem which can also be anchored into the tibia with, for example, screws, nails, anchors, or some other means of attachment.

Bones which have been fractured, either by accident or severed by surgical procedure, must be kept together for lengthy periods of time in order to permit the recalcification and bonding of the severed parts. Accordingly, adjoining parts of a severed or fractured bone are typically clamped together or attached to one another by means of plates, pins or screws driven through the rejoined parts. Movement of the pertinent part of the body may then be kept at a minimum, such as by application of a cast, brace, splint, or other conventional technique, in order to promote healing and avoid mechanical stresses that may cause the bone parts to separate during bodily activity. The surgical procedure of attaching two or more parts of a bone with a pin-like device normally requires an incision into the tissue surrounding the bone and the drilling of a hole through the bone parts to be joined. Due to the significant variation in bone size, configuration, and load requirements, a wide variety of bone fixation devices have been developed in the prior art. In general, the current methods rely upon a variety of metal wires, screws, plates and clamps to stabilize the bone fragments during the healing process. Following a sufficient bone healing period of time, the site may require re-opening to permit removal of the bone fixation device.

The internal fixation techniques commonly followed today frequently rely upon the use of wires, intramedullary pins, plates and screws, and combinations thereof. The particular device or combination of devices is selected to achieve the best anatomic and functional condition of the traumatized bone with the simplest operative procedure and with a minimal use of foreign-implanted stabilizing material. It is important in bone repair that the fracture be stable axially, torsionally and rotationally.

ANKLE FUSION

The goal of ankle replacement is to resurface the ankle joint with mechanical parts that allow continued ankle motion and function without pain. The models currently used include the Agility Ankle and the Scandinavian Total Ankle Replacement (STAR). Not all known systems are approved for use. Like hip and knee replacements, these devices are constructed of metals and plastics, and, as such, are mechanical parts that can wear out. Currently, patients who are best served by an ankle

replacement are those who will put low mechanical demands on their artificial joints. These include average or lightweight patients who would like to stand and walk with limited or no pain. Certain patient groups are less likely to have good and long-lasting results from ankle replacements, including patients with; previous deep ankle infection, lower limb neuropathy, osteoporosis, high physical demands, obesity, poor skin or vascular problems. Ankle arthroplasty for post-traumatic tibiotalar arthritis remains controversial. The current literature strongly recommends arthrodesis, especially in those patients who will overload the joint: the young, the active and overweight patients. Total ankle arthroplasty has become a viable alternative to ankle arthrodesis. Selected patients can be offered a total ankle replacement as an alternative option to arthrodesis in the treatment of end-stage ankle arthritis. The optimal total ankle replacement patient is an older person who applies low loads and has multiple joint problems.

The ankle joint is a comparatively small joint relative to the weight bearing and torque it must withstand. Total ankle replacement systems attempting to address pain control and improved function have in the past experienced significant failure rates due to the technical difficulty of simulating ankle geometry and loadings. The main alternative to total ankle replacement is arthrodesis. Both procedures are intended to reduce pain but the total ankle replacement is additionally intended to improve function. If an arthrodesis or ankle replacement is not properly aligned, significant gait abnormalities may result. The principal limitations of past total ankle replacement have been loosening of the prosthesis, requiring revision. If the prosthesis requires removal, a subsequent arthrodesis can be considered. Different prostheses require different amounts of removal of bone, potentially compromising the success of a subsequent arthrodesis. Some ankles with implant components often require revision or arthrodesis. Ankle arthrodesis is currently a widely accepted surgical procedure but good, uniform results are not always achievable. Patients treated by compression ankle arthrodesis do not always have an effective fusion rate. The commonly used external fixation devices afford stability in only one plane and do not give rigid

immobilization. A device known as a Triangular Compression Device has been used successfully. A successful Arthrodesis of the ankle can result in a painless, normal walking gait. However, complications in ankle arthrodesis can be major, and can occur when anatomy, deformity, or bony deficiency is not properly addressed. Arthrodesis is usually considered after conservative treatment ( such as arthroscopy) fails. Infections, deformity, sensory deficiencies, and bony defects are complications which require special consideration. External compression enhances the likelihood of a successful arthrodesis.

Presently ankle fusion has had a rate of failure in the literature between 15% and 70%. It is believed that this is largely a result of Initial fixation that is not rigid enough. As in other areas of the skeletal body, superior fusion rates have been achieved by plating rather than fixation by other means Pantalar fusion has been achieved with a revision foot rod. This has been a very technically difficult device to use with poor fusion rates.

Attempts have in the past been made in the prior art to bend and shape an already existing plate on the market but this does not fulfil the requirements, as screws cannot be placed in the desired places or angles to achieve optimal fixation.

A known plate marketed under the trade mark name Tomofix ™ has been crudely adapted for anterior arthrodesis of the ankle but this is unsatisfactory because the plate is designed for stable fixation of osteotomies close to the knee.

Proper plate fixation relies on the integrity of the screw bone interface, screw insertion angle, screw tightness and effective co operation between screw head and the screw insertion hole. These requirements dictate plate design for a particular anatomical location and repair objective. To date there is no arthrodesis plate and particularly ankle arthrodesis plate which

satisfies the requisite fixation criteria and which is purpose designed to overcome the prior art disadvantages of the known plates.

Since the ankle is the only joint which to date does not have a specific plate for arthrodesis, there is a long felt want in the field to provide a fusion plate that is effective and useful in primary ankle fusion and which will reduce or eliminate fusion failure rates and which provides appropriate geometry to facilitate integrity of the screw bone interface, screw insertion angle, screw tightness and effective co operation between screw head and the screw insertion hole.

INVENTION

The present invention seeks to ameliorate or eliminate the aforesaid problems inherent in the prior art devices and apparatuses and particularly those used in ankle arthrodesis.

The present invention provides an improved arthrodesis fusion plate for fusion of the anterior ankle. More particularly the invention provides an ankle plate in which openings in the plate receive fixation screws allowing compression of bones being fused and orientation of the fixation screws to optimise accommodation of bone loading for efficient and effective fusion. The invention further provides a method of insertion of an anterior ankle plate so that optimal compression is achieved and fixation screws are inserted at appropriate angles in anterior ankle joint fusion. This invention further relates to a kit including an anterior ankle fusion plate and which includes a selection of fasteners for fixation of the ankle plate in a prescribed manner so that the orientation of the screws provide optimal compression and bone fusion.

This ankle fusion plate according to the invention can be inserted into the anterior ankle joint and is used in primary ankle fusion, covetin severe hind foot deformity, pantalar fusion and also in the salvage of ankle replacement.

Although the invention will be described with reference to its application to ankle fusion it will be appreciated by persons skilled in the art that the

invention may be applied to the repair/ fusion of other bones requiring axial alignment.

In one broad form the present invention comprises:

a fusion plate for arthrodesis, the plate comprising:

a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposing surface,

a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,

a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface,

the first portion including at least one opening which receives at least one fixation means;

the second portion including at least one opening which receives at least one fixation means ;

the third portion including at least one opening which receives at least one fixation screw.

In another broad form the present invention comprises:

an implant kit for arthrodesis fusion the kit comprising:

a fusion plate; and

a set of plate fixation screws;

the plate comprising, a first portion disposed in a first plane and having inner and outer surfaces, the inner surface opposing a bone surface, the first portion including at least one opening including a formation which receives at least one bone fixation screw in a first orientation, a second portion disposed in a second plane and having inner and outer surfaces, the inner surface opposing a bone surface, the second portion including at least one opening including a formation which receives a bone fixation screw in at least one orientation, a third portion disposed in a third plane and having inner and outer surfaces, the inner surface opposing a bone surface, the third portion including at least one opening which receives at least one bone fixation screw in a first orientation.

In its broadest form the present invention comprises:

a fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposite surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means.

Preferably the inner surface of the first portion of the plate opposes the anterior tibia. Preferably the inner surface of the second portion of the plate also opposes the anterior tibia. Preferably, the inner surface of the third portion of the plate disposed in the first plane opposes the talus. The first portion includes at least one opening including a formation which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region. The second portion of the plate includes a slotted opening which receives a screw of a second type which is of sufficient length to penetrate the tibia, talus and Calcaneus bones. The third portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the Talus.

According to one embodiment, the first portion has a region at is extremity which is thinner.

The screws in each portion of the plate are directed at required angles according to the joint/s required for arthrodesis. This is also necessary to achieve maximal compression of the fusion site/s. The fixation screw design is adapted to ensure the above plate fitting objectives are achieved. According to a preferred embodiment, the plate depth changes at different locations. Preferably, the depth at the beginning arid end points of the L shaped contour over the ankle joint in the second region will be at it's maximum thickness. This location adjacent the ankle joint will preferably be

the thickest part of the plate and will preferably fall within the range 4-8mm. Thickness throughout this specification will refer to the dimension measured from the bone engaging face to an opposite outer face The plate will taper at at least one but preferably two different points of the plate. A first taper will occur at a proximal point of the plate over the tibia. The desired effect is for the plate to taper in and decrease in thickness proximally. The taper decreases down to around 1mm in thickness and at its proximal extent it is 4mm in width. The second point of plate depth and width change is over the phalanges at the distal point of the plate. At this point the plate according to one embodiment, tapers out and again the thickness at this point would be in the order of about 1mm. These points will preferably resemble and conform to the typical geometry of the anatomical region. In locations where this does not occur, further manipulation or moulding of the plate geometry can be achieved as required. Preferably, the plates are configured to generally conform to the anatomic contours of the ankle joint. A range of different plate sizes ( at least five) is contemplated with differences in the range of contour and degree of angle over the ankle joint and lengths both proximally and distally. In practice 2- 3 three plate sizes are likely to provided a complete inventory.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described in more detail according to a preferred, but non limiting embodiment and with reference to the accompanying illustrations wherein:

FIGURE. 1 shows a side elevation view of a plate according to one embodiment and attached via fixation screws to an abbreviated ankle joint ( dotted lines)

FIGURE. 2 shows a front elevation view of the plate of figure 1 showing alignment and spacing of predrilled holes for fixation screws.

FIGURE. 3 shows an elevation view of a first screw type according to one embodiment adapted for insertion in openings for the tibia.

FIGURE 4 shows an elevation view of a second screw type according to one embodiment adapted for insertion in the plate of figures 1 and 2 and allowing adjustable orientation.

FIGURE 5 shows a side cross sectional elevation view of a plate according to a preferred embodiment isolated from an ankle joint.

FIGURE 6 shows a front elevation view of the plate of figure 5 with corresponding numbering .

FIGURE 7 shows a perspective view of the plate of figure 5 with corresponding numbering .

FIGURE 8 shows a cross sectional view of the plate of figure 5 taken at A-A in figure 6.

FIGURE 9 shows the cross sectional side elevation view of the plate of figure 5 ( taken along line A of figure 10) showing a non limiting geometry of the plate according to one embodiment.

FIGURE 10 shows a front elevation view of the plate of figure 9 showing a non limiting geometry of the plate according to one embodiment.

FIGURE 11 shows a cross sectional view of the plate of figure 10 taken at D-D in figure 10 showing a non limiting geometry of the plate according to one embodiment.

FIGURE 12 shows an enlarged view of detail B in figure 9 showing a non limiting geometry of the opening.

FIGURE 13 shows an enlarged view of detail C in figure 9 showing a non limiting geometry of the opening.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to **figure 1** there is shown a side elevation generally schematic view of a fusion plate 1 for arthrodesis according to one embodiment. Plate 1 is attached to an ankle joint 2 opposing the Talus bone 3 and Tibial bone 4.

Plate 1 according to the embodiment shown comprises a portion 5 disposed in a first plane which generally aligns with an anterior surface 6 of the talus 3. Portion 5 has an outer surface 7 and inner surface 8 which opposes talus surface 6 for fixation thereto. Disposed in portion 5 are fixation screws 9 and 10 which pass through openings 11 and 12 of portion 5 and engage talus 3 at different orientations. Screws 9 and 10 are disposed at different angles to a vertical resulting in each having different respective horizontal and vertical components of force along orthogonal X and Y axes. Each of openings 11 and 12 have formations which direct respective screws 9 and 10 in the orientations shown. For example the angle of orientation of countersink in formation 13 of opening 12 directs screw 10 at a predetermined angle which optimises fixation.

Portion 20 of plate 1 has an outer surface 21 and inner surface 22 which opposes anterior surface 23 of tibia 4 for fixation thereto. Disposed in portion 20 is fixation screw 25 which passes through opening 26 in formation 27. Formation 27 is configured so that screw 25 is implanted at an angle within a predetermined allowable angular range. The allowable range will preferably be within a 40 degree arc. Screw 25 engages tibia 4, talus 3, and calcaneus 28 effectively providing three points of fixation according to this embodiment. Portion 20 is angled relative to portion 5 at about 100 degrees. This angel is non limiting and may be greater or less than 100 degrees according to the dictates of design.

Portion 30 of plate 1 has an inner surface 31 and an outer surface 32 and preferably disposed normal or near normal to the plane of portion 5. Portion 30 includes openings 33, 34 and 35 which receive fastening screws 36, 37 and 38 each preferably in the same orientation and which engage tibia 4. Screws 36, 37 and 38 are according to one embodiment 4.5mm in diameter and may be of the same screw type as those used for screws 9 and 10 fixing

portion 5. This diameters is non limiting. Also a different type of fixation screw to the configuration of that shows may be employed.

As may be seen from figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis. This is also necessary to achieve maximal compression of the fusion site/s.

Preferably, portion 30 is disposed in a first plane which generally aligns with an opposing face of tibia 4. Portion 20 lies in a second plane at a first angle relative to the first plane and aligns with an opposing face of the distal tibia. Portion 5 lies in a third plane at a second angle relative to the first plane and engages the talus.

**Figure 2** shows a front elevation view of the plate of figure 1 showing alignment and spacing of predrilled holes for fixation screws. Figure 2 has corresponding numbering for corresponding parts. From this view it may be seen that according to this embodiment, plate 1 undergoes changes along its length depending upon the bone each part of the plate opposes. Region 30 is narrower than region 20 tapering as the tibia narrows heading proximally. In addition, the loads at region 30 can be absorbed by the thinner profile as internal moments are less. As the plate moves distally, the thickness preferably increases to accommodate the increased compression and rotational loads. The waisted region 50 generally confirms to the contour of the tibia. Openings 33, 34 and 35 are preformed and receive a first preferably countersunk screw type such as that shown in figure 3. Opening 27 which is also preformed, receives a countersink screw which is allowed adjustable orientation. The enlarged slotted holes allow a fine adjustment of the attitude of the screws within a range of around 30 degrees, although it will be appreciated that this range can be narrowed or extended..

**Figure 3** shows an elevation view of a first screw type 60 according to one embodiment adapted for insertion in openings 33, 35 and 36 for the tibial region fixation.

**Figure 4** shows an elevation view of a second screw type 70 according to one embodiment adapted for insertion in the plate of figures 1 and 2 and allowing adjustable orientation. Screw type 70 has a longer shank to increase

depth of penetration and has an abbreviated threaded portion to allow the majority of the shank to slide through aligned tibial and talus screw holes finally anchoring in the calcaneus bone.

**Figure 5** shows a side elevation view of a plate 80 according to a preferred embodiment isolated from an ankle joint. Plate 80 which is attachable to an ankle joint opposing the Talus bone and Tibial bone, comprises a portion 81 disposed in a first plane which generally aligns with an anterior surface of the talus. Portion 81 has an outer surface 82 and inner surface 83 which opposes a talus for fixation thereto. Disposed in portion 81 are fixation screws ( not shown) which pass through openings 84 and 85 of portion 81 engaging the talus at selected orientations. Screws inserted in openings 84 and 85 are preferably disposed at different angles to a vertical resulting in each having different respective horizontal and vertical components of force along orthogonal X and Y axes. Each of openings 84 and 85 have formations 86 and 87 which direct screws in a particular orientation. The angle of orientation of countersink formations 86 and 87 directs screws at a predetermined angle which optimises fixation.

Portion 90 of plate 80 has an outer surface 91 and inner surface 92 which opposes an anterior surface of tibia for fixation thereto. Disposed in portion 90 is a fixation screw which passes through opening 93 in formation 94. Formation 94 is configured so that a fixation screw is directed at an angle within a predetermined allowable angular range. Portion 90 is angled relative to portion 81 at a non limiting angle of about 100 degrees.

Portion 95 of plate 1 has an inner surface 96 and an outer surface 97 and preferably disposed normal or near normal to the plane of portion. Portion 95 includes openings 98 and 99 which receive fastening screws each preferably in the same orientation and which engage the tibia. Screws which fix plate 80 via openings 98 and 99 may be of the same screw type as those used for fixation through openings 84 and 85.

As may be seen from figure 1 the screws are placed in a particular orientation and required angle to the joint/s required for arthrodesis. This is also necessary to achieve maximal compression of the fusion site/s.

Preferably, portion 95 is disposed in a first plane which generally aligns with an opposing face of a tibia. Portion 90 lies in a second plane at a first angle relative to the first plane and also aligns with an opposing face of the distal tibia. Portion 5 lies in a third plane at a second angle relative to the first plane and engages the talus. Openings 99 and 100 are elongated to allow alignment adjustments.

**Figure 6** shows a front elevation view of the plate of figure 5 with corresponding numbering .

**Figure 7** shows a perspective view of the plate of figure 5 with corresponding numbering .

**Figure 8** shows a cross sectional and plan views of the plate of figure 5 taken at A-A in figure 6.

According to a preferred embodiment the depth/ thickness of the plate 80 will change at different locations on the plate. The depth at the beginning and end points of the generally L shaped contour over the ankle joint formed by portions 81 and 90 will be at it's maximum thickness as it is at this region that the highest loading will occur in normal use. This depth (the thickest part of the plate) will be within the range 5-6mm. The plate will taper at two different points on the plate. Firstly, the proximal end region of the plate over the tibia. The desired effect is for the plate to taper in and decrease depth at its extremities where loading is least. This would decrease down to around 1mm in thickness and 4mm in width. The second point of plate depth and width change would be over the phalanges at the distal point of the plate. At this point the plate would taper out and again the depth would be that of around the 1mm mark. These points will resemble the average geometry of this anatomical region in the cases where this is not occurring it is at these points that further manipulation or moulding can be achieved if required.

In view of the anatomic contour of ankle joint, there are at least five different sized plates with differences in the range of contour and degree of angle over the ankle joint and lengths both proximally and distally. Typically a kit selection or inventory would provide choice of two or three plate sizes .

Preferably, the custom shaped L- plate would need to be moulded to an angle in the region of 110 degrees at the point of the contact with the patient bone surface. The range in sizes for this would preferably be 95, 100, 105 110 and 115 degrees, with corresponding lengths to suit.

An ideal tibial length of the plate would be approximately 80mm. The contour of geometry over the distal aspect of the tibia will be incorporated into the design of the plate. The length from the L point out to the phalanges would be about 25mm in length and at this point the plate would taper out to around 35mm. The plate width before tapering in or out would be in the region of 11 mm. One preferred material for the plate is chrome Cobalt.

**Figure 9** shows the cross sectional side elevation view of the plate of figure 5 with corresponding numbering ( taken along line A of figure 10) showing a non limiting geometry of the plate according to one embodiment. The dimensions indicated are in millimetres and indicate proportionality of the geometry of the preferred embodiment plate. Shown are distances between openings, size of openings relative angles of separate portions 81, 90 and 95 of the plate. **Figure 10** shows a front elevation view of the plate of figure 9 showing a non limiting geometry of the plate according to one embodiment. **Figure 11** shows a cross sectional view of the plate of figure 10 taken at D-D in figure 10 showing a non limiting geometry of the plate according to one embodiment. **Figure 12** shows an enlarged view of detail B of opening 100. in figure 9 showing a non limiting geometry of the opening. **Figure 13** shows an enlarged view of detail C of opening 98 in figure 9 showing a non limiting geometry of the opening.

This plate significantly increases the ease of pantalar fusion and also allows the ability to start with ankle fusion and add the pantalar arthrodesis component as required. It is believed that in the pantatar fusion setting, one of the reasons for failure is necrosis of the talus, which occurs due to the multiple incisions that are needed. Avoiding amedial incision in this procedure will reduce the rate of talus necrosis after pantalar fusion. This plate also significantly increases the ease of pantalar fusion and also allows the ability to start with ankle fusion and add the pantalar arthrodesis component as required.

The specific dimensions of any of the bone fixation plate of the present invention can be readily varied depending upon the intended application, as will be apparent to those of skill in the art in view of the disclosure herein. Moreover, although the present invention has been described in terms of certain preferred embodiments, other embodiments of the invention including variations in dimensions, configuration and materials will be apparent to those of skill in the art in view of the disclosure herein. In addition, all features discussed in connection with any one embodiment herein can be readily adapted for use in other embodiments herein. The use of different terms or reference numerals for similar features in different embodiments does not imply differences other than those which may be expressly set forth. Accordingly, the present invention is not limited to the preferred embodiments disclosed herein.

The invention may also be provided as a kit including a plurality of plates and associated fixation screws. Typically a kit may comprise three to five plates for a surgeon to select from depending upon the particular anatomy of the patient. One significant advantage of the plate described herein is the oblique screw portal allowing for various angles and the ability to incorporate more joints into the arthrodesis as required. Screw sizes may be adjusted to allow for particular insertion points and specific characteristics (e.g. bone density) of bone at points of fixation. The plate may also be manufactured with varied thickness at regions requiring additional strength and contoured to a geometry to best suit ankle anatomy. Screw openings

may be offset to allow three point talar fixation and plate compression. Another advantage of the plate is its pliability at regions when bending may be required for conformity with bone anatomy. The plate allows the talus to be fused with the tibia thereby providing a supporting bridge which is helpful for patients with large ankle defects. The plate also reduces the number of incisions in the patient and may be inserted through an anterior section of joint using the same incision required for a total ankle replacement. For example if a surgeon is revising a total ankle replacement, the same incision can be used as that used when removing a joint replacement and treating with arthrodesis. This techniques provides improved results in a case where large amounts of bone dissection following a total ankle replacement.

ANALYSIS OF SIMULATED IN - VIVO PERFORMANCE

Studies and testing of a preferred embodiment of the fusion plate have been conducted which determine capacity of the plate to withstand anticipated loadings. The testing considers ankle fusion plate's response to in-vivo loads. The objective of the study was to determine finite element stresses in the plate which result from applied loads and was intended to simulate as closely as possible the in vivo static and dynamic loading conditions. Mechanical properties were taken as that specified as minima in the relevant ISO standards or as specified by the material supplier.

Equipment used in the testing

DELL INSPIRON 5150
ANSYS/ WORKBENCH V11 .0
SOLIDEDGE V 19.0

The loading regimes selected for the plate system and parameters was used for load simulation are listed below:

| Load Case | Normal Load (N) | Loaded surface |
|---|---|---|
| 1 | 1,200 | Distal face |

| | | |
|---|---|---|
| 2 | 3600 | Distal face |

The plate was screw fixed along its the proximal length onto an idealised tibia. Each screw was initially rigidly fixed into the simulated bone side and had a simulated friction effect of sliding against the plate counter faces.

A second simulation was performed to determine the effects of variable bone density on the distal tibia.

Properties for the 316L stainless steel (BioDur 108) alloy were selected as Young's Modulus. E 200 GPa, Poisson's ratio = 0.3 and a tensile yield strength of 938MPa and ultimate tensile strength of 1269 MPa. The bone stiffness was varied from 0.5GPa to 3 GPa and Poisons ratio of 0.3.

The following load conditions were simulated:

| | |
|---|---|
| 1. Screws rigidly fixed, | 1 ,200N (120kg) Distally fixed. |
| 2. Bone with low stiffness, | 1 ,200N (120kg) Distally loaded. |
| 3. Bone with high stiffness, | 1,200N (120kg) Distally loaded. |
| 4. Bone with low stiffness, | 3,600N (360kg) Distally loaded. |

The resulting stress distributions in the neck and stem were compared.

The simulations were solved as non-linear elastic stress analysis, mesh refinement was applied to the regions of high stress concentration. An initial mesh size was selected as 1mm, the resulting stresses were recorded. A subsequent run was performed with a refined mesh around high stress locations. A mesh density of half was used and the subsequent change in stress was compared to the original run, the results of these simulations was within 10%, thus a mesh density of 1mm was selected for all simulations.

Observations from Results.

The initial simulation (1,200N - 120kg load) simulated the fixation screws rigidly fixed into the bone, i.e. the bone did not allow the screws to be pulled with the bone. This simulation would be analogous to hard cortical bone fixation of the screws. As would be anticipated the results showed that the highest stresses occur on the inner surface of the plate approximately were a change in section thickness occurs just above the angled screw formation. This is due to the reduction in effective ( cross sectional) area of the plate at that location. The magnitude of peak tensile stress at that location was 495 MPa, which is approximately 47% less than the yield strength of the material, thus providing a factor of safety of 1.9 which well satisfies engineering design standards.

When the bone quality is reduced (stiffness of supporting bone reduces) the stress increases. The stress increases over a range from 495 to 713 to 910 MPa moving from optimally stiff bone to low bone quality respectively. The location in the plate of the high stress concentration region was unchanged with the magnitude increasing with decreased bone quality. The testing found that for poor distal tibia bone quality the factor of safety is reduced to approximately 1, as the maximum tensile stress is approximately at the yield strength of the material. The maximum deformation in the plate occurs at the tip of the distal surface ( toe) of the plate and varies from 0.37 to 0.53 and 0.97mm for the highest to lowest bone quality respectively.

A simulation was performed to determine the integrity of the plate with a 3,600N load (360kg) on the rigidly supported "home run" lag screw. The maximum stress in the plate is in the same location as before with the exception that it has increased from 495MPa to 1 ,484MPa for the 1,200N (120kg) and 3,600N (360kg) loads respectively. The ultimate tensile strength of the BioDurlO8 alloy is approximately 1269MPa. Thus, for the applied load of 3,600N (360 kg) the material failed at the region of the screw opening ( distal tibia engagement region) where the effective cross sectional area of the plate is reduced to accommodate the fixation screw at that point.

It can be estimated that the maximum load the tested plate can take prior to failure is 3,075N (308kg).

For perfect (rigid) tibial bone quality the plate can carry 1 ,200N (120kg) with a factor of safety of 1.9. Decreasing the bone quality decreases the load carry capacity of the plate. With the lowest bone quality (stiffness of 1.0 GPa) for an applied load of 1,200N (120kg) the stress in the plate increased to 910MPa just below the yield strength of the material. The plate tested will only carry approximately 3,000N (300kg) when rigidly fixed to the tibia, at a load of 3,600N (360kg) the stress in the plate exceeds the ultimate strength of the alloy.

The above tests provide performance indications for a plate of the particular type and geometry tested. Arthrodesis plates with different geometry and dimension such as alternative thickness distributions and angulations may result in different measured loadings and plate response. Alternative plates made from different materials and different geometry will be likely to have different load capacity results for equivalent in vivo simulations but without compromise to fusion result provided the right plate is selected from the particular patient. Accordingly, the above observations and findings should be taken as a non limiting example of tested simulated in vivo performance for one plate of a particular size, geometry and material and should not be construed as limiting of load capacities and performance of alternative ankle fusion plates made in accordance with the present invention. Proportionate plate sizes may vary from patient to patient but consistency of plate performance in vivo will be geometry of the plate

It will be recognised by persons skilled in the art that numerous variations and modifications maybe made to the invention as broadly described herein without departing from the overall spirit and scope of the invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1 A fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposing surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
a third portion disposed in a third plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means ;
the third portion including at least one opening which receives at least one fixation screw.

2 A fusion plate according to claim 1 wherein, the second portion of the plate body is disposed at a first angle relative to the first plane and the third portion is disposed at a second angle relative to the first plane.

3 A fusion plate according to claim 2 wherein the second angle is greater than the first angle .

4 A fusion plate according to claim 3 wherein, the first portion includes an opening of a first size and a second opening of a second size.

5 A fusion plate according to claim 4 wherein the second portion includes a first opening of a first size and a second opening of a second size.

6 A fusion plate according to claim 5 wherein the third portion includes at least two openings of the same size.

7 A fusion plate according to claim 6 wherein a second opening in the first portion is larger than the first opening.

8 A fusion plate according to claim 7 wherein the second opening in the first portion is elongated.

9 A fusion plate according to claim 8 wherein the first opening in the second portion is the same size as the second opening in the first portion.

10 A fusion plate according to claim 9 wherein the second opening in the second portion is circular.

11 A fusion plate according to claim 10 wherein, the opposing face of the second portion includes a formation which includes said second opening .

12 A fusion plate according to claim 11 wherein the formation is a shoulder including a countersunk recess for receiving a fastener head.

13 A fusion plate according to claim 12 wherein the first and second portion of the plate body are approximately the same width.

14 A fusion plate according to claim 13 wherein the third portion of the plate body has a first proximal narrow end and a second distal flared end.

15 A fusion plate according to claim 14 wherein the flared end has two openings to receive fixation screws.

16 A fusion plate according to claim 15 wherein the plate is symmetrical about a longitudinal axis but asymmetric about a transverse axis normal the longitudinal axis .

17 An implant kit for arthrodesis fusion, the kit comprising:
at least one fusion plate; and

at least one set of plate fixation screws;

each plate comprising, a first portion disposed in a first plane and having inner and outer surfaces, the inner surface opposing a bone surface, the first portion including at least one opening including a formation which receives at least one bone fixation screw in a first orientation, a second portion disposed in a second plane and having inner and outer surfaces, the inner surface opposing a bone surface, the second portion including at least one opening including a formation which receives a bone fixation screw in at least one orientation, a third portion disposed in a third plane and having inner and outer surfaces, the inner surface opposing a bone surface, the third portion including at least one opening which receives at least one bone fixation screw in a first orientation.

18 A kit according to claim 17 wherein the plate geometry is arranged to at least partially conform to the shape of the anatomy of bones to which the plate is fixed.

19 A kit according to claim 18 further comprising a selection of said fixation screws of at least two types.

20 A kit according to claim 19 further comprising a selection of said fixation screws of at least two sizes.

21 A kit according to claim 20 wherein the plate is fixed to ankle bones.

22 A kit according to claim 21 wherein the inner surface of the first portion of the plate disposed in the first plane, when fitted to a patient opposes the anterior tibia..

23 A kit according to claim 22 wherein the inner surface of the second portion of the plate, when fitted to a patient, opposes the anterior tibia.

24 A kit according to claim 23 wherein the inner surface of the third portion of the plate, when fitted to a patient, opposes the anterior talus.

25 A kit according to claim 24 wherein the first portion preferably has two spaced apart openings which receive at least one of a first screw type which are implanted into the tibia

26 A kit according to claim 25 wherein the second portion of the plate includes a slotted opening which receives a screw of a second type which is of sufficient length to penetrate the tibia, talus and Calcaneus bones.

27 A kit according to claim 26 wherein the first portion includes at least one opening which receives a plurality of bone screws of said first type and which on insertion of the plate are disposed normal to the plane of the plate at that region.

28 A kit according to claim 27 wherein the openings in the plate are arranged so that fixation screws may each be directed at a predetermined angle.

29 A kit according to claim 28 wherein the plate thickness varies at different locations and wherein the portion of the plate which lays over the ankle joint has maximum thickness.

30 A kit according to claim 29 wherein the thickest part of the plate will be within the range 4-8mm.

31 A kit according to claim 30 wherein the plate has a first taper at a proximal point of the plate over the tibia.

32 A kit according to claim 31 wherein there are at least five plates in the kit.

33 A fusion plate according to claim 3 wherein the first plane is a longitudinal tibial plane, the second is a tibia-talar joint plane including an oblique formation and the third plane is a talar plane lying along the talus.

34 A fusion plate according to claim 33 wherein the first plane extends from the tibia-talar plane proximally along the tibia for approximately 60-65mm.

35 A fusion plate according to claim 33 wherein as the plate extends along the tibia its thickness decreases from 2.5mm to 2mm.

36 A fusion plate according to claim 33 wherein as the plate extends along the tibia width decreases from 12.5mm to 8mm.

37 A fusion plate according to claim 36 wherein the first portion has two screw openings the first being of smaller size than the second.

38 A fusion plate according to claim 37 wherein the first screw is 4 millimeters in diameter and the second screw opening is elongated.

39 A fusion plate according to claim 38 wherein the elongated opening is 10mm in length and 4.5mm in width.

40 A fusion plate according to claim 39 wherein the elongated opening receives 4.5mm cortical screws.

41 A fusion plate according to claim 40 wherein, the tibia-talar joint plane terminates distally in a generally L shaped convex bend.

42 A fusion plate according to claim 41 wherein the L shaped bend is the thickest part of the plate.

43 A fusion plate according to claim 42 wherein, the plate is 3.5mm thick at the bend.

44 A fusion plate according to claim 43 wherein the plate is 12.5mm thick at the bend.

45 A fusion plate according to claim 44 wherein the second portion includes a shoulder which includes an oblique screw opening.

46 A fusion plate according to claim 45 wherein, the oblique opening receives a 6.5mm cannulated fastening screw.

47 A fusion plate according to claim 46 wherein the oblique opening allow the screw to be inserted at one of a plurality of available angles.

48 A fusion plate according to claim 47 wherein, the third portion lies over the talar bone.

49 A fusion plate according to claim 48 wherein the third portion splays outward distally from a width of about 12.5mm to 20mm.

50 A fusion plate according to claim 49 wherein the thickness of the third portion decreases distally from about 3.5mm to 2mm.

51 A fusion plate according to claim 50 wherein the plate the angle between the first portion and the third portion is within the range of 95 – 115 degrees.

52 A fusion plate according to claim 51 wherein, the length of the plate along the tibia is between 60 – 65mm.

53 A fusion plate according to claim 52 wherein the length of the plate over the talus is within the range of 20 – 23mm.

54 A fusion plate according to claim 53 wherein the plate is manufactured from materials selected from stainless steel, titanium, polyethylene, plastics or other biomedical material.

55 A fusion plate for arthrodesis, the plate comprising:
a plate body including a first portion disposed in a first plane and having a first bone engaging surface and a second opposite surface,
a second portion disposed in a second plane and having a first bone engaging surface and a second opposing surface,
the first portion including at least one opening which receives at least one fixation means;
the second portion including at least one opening which receives at least one fixation means.

56 A fusion plate according to claim 55 wherein, the second portion of the plate body is disposed at a first angle relative to the first plane.

57 A fusion plate according to claim 56 wherein, the first portion includes an opening of a first size and a second opening of a second size.

58 A fusion plate according to claim 57 wherein the second portion includes a first opening of a first size and a second opening of a second size.

59 A fusion plate according to claim 58 wherein a second opening in the first portion is larger than the first opening.

60 A fusion plate according to claim 59 wherein the second opening in the first portion is elongated.

61 A fusion plate according to claim 60 wherein the first opening in the second portion is the same size as the second opening in the first portion.

62 A fusion plate according to claim 61 wherein the second opening in the second portion is circular. the third portion includes at least two openings of the same size.

63 A fusion plate according to claim 62 wherein, the opposing face of the second portion includes a formation which includes said second opening .

64 A fusion plate according to claim 63 wherein the formation is a shoulder including a countersunk recess for receiving a fastener head.

65 A fusion plate according to claim 64 wherein a third portion of the plate body has a first proximal narrow end and a second distal flared end.

66 A fusion plate according to claim 65 wherein the first and second portions of the plate body are approximately the same width.

67 A fusion plate according to claim 66 wherein the flared end has two openings to receive fixation screws.

68 A fusion plate according to claim 67 wherein the plate is symmetrical about a longitudinal axis but asymmetric about a transverse axis normal the longitudinal axis .

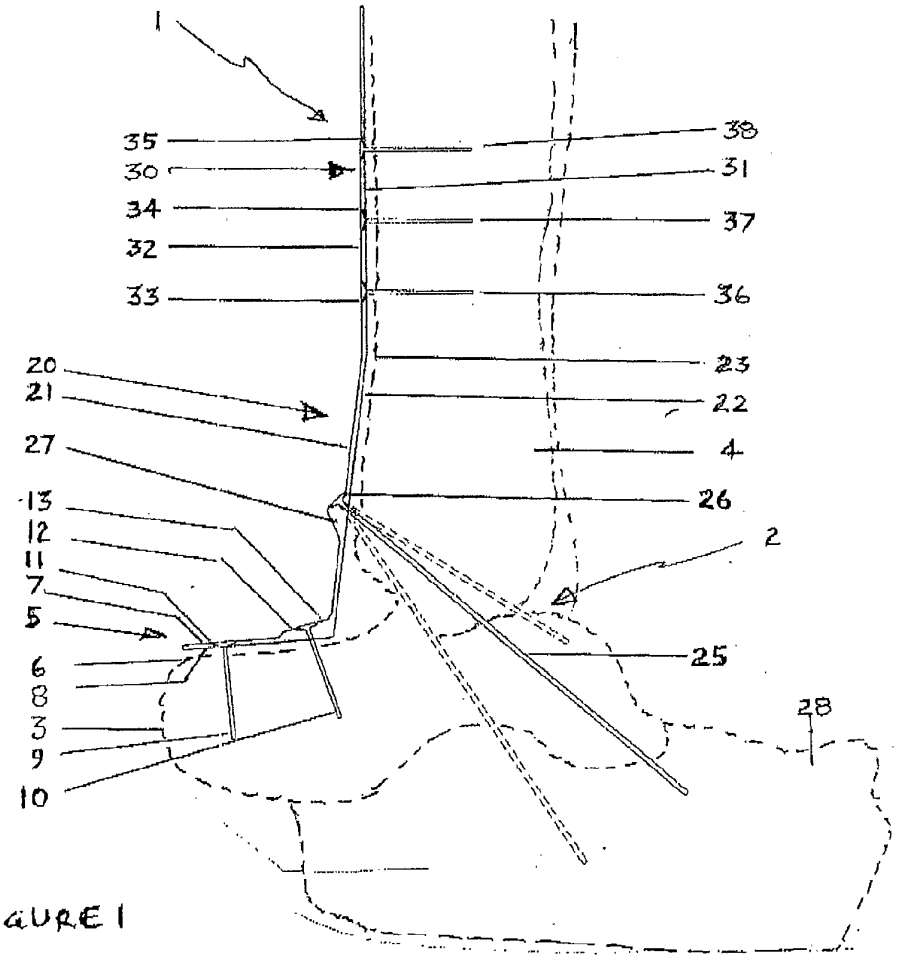

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FIGURE 1

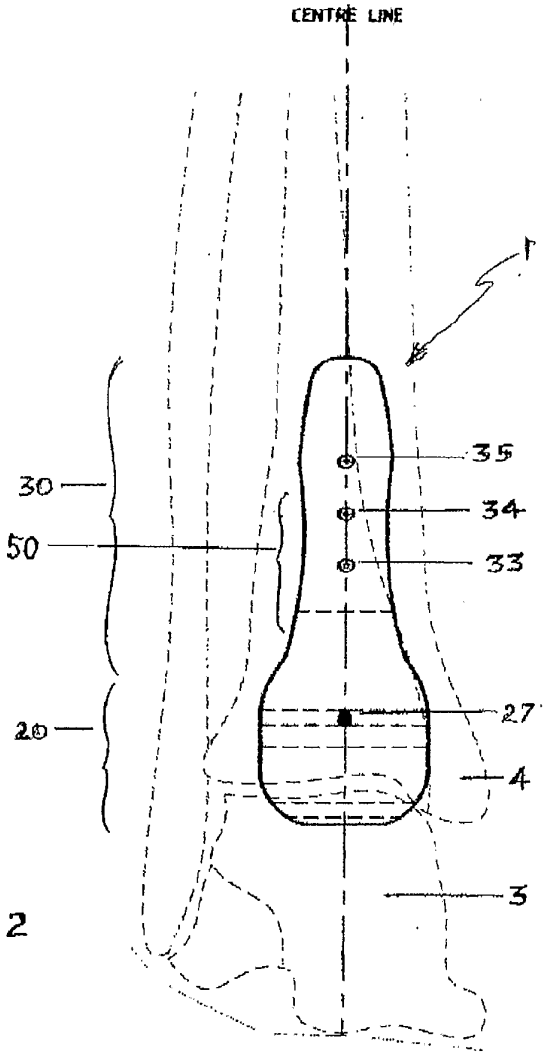



FIGURE 2

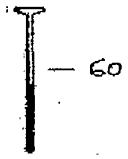



FIGURE 3

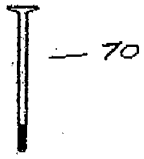



FIGURE 4

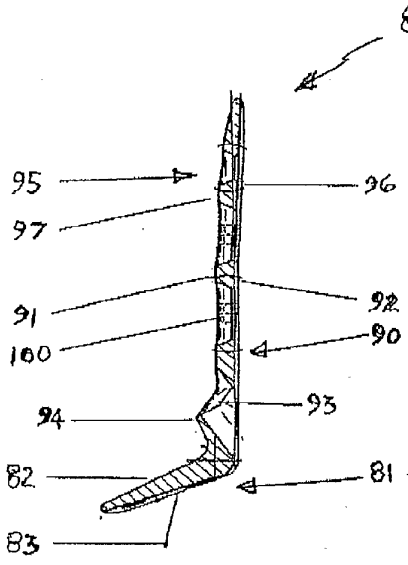



FIGURE 5

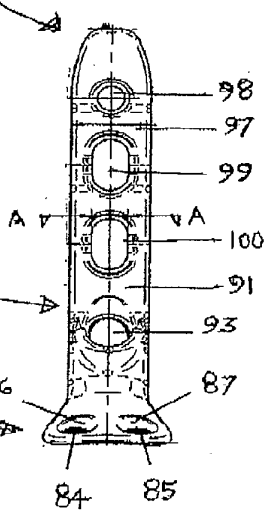



FIGURE 6

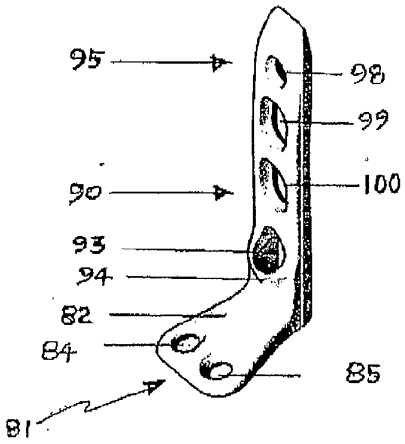



FIGURE 7

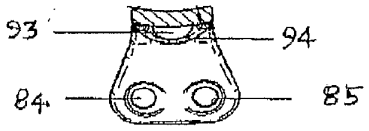



FIGURE 8

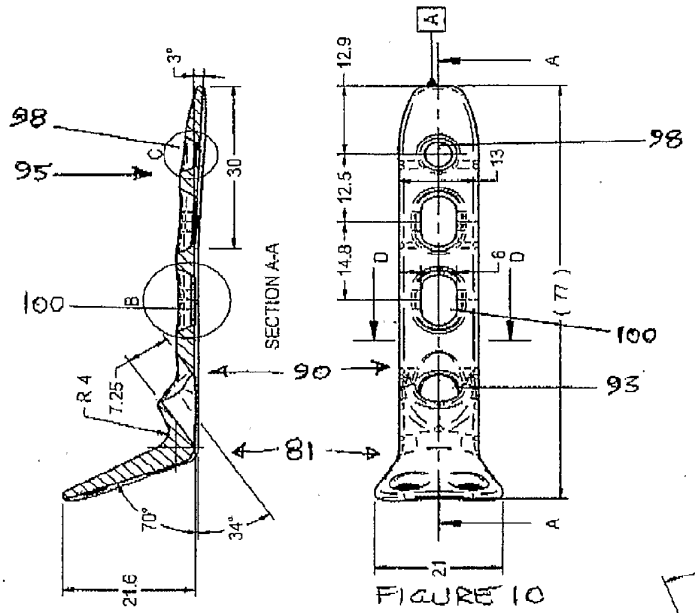



FIGURE 9




FIGURE 10

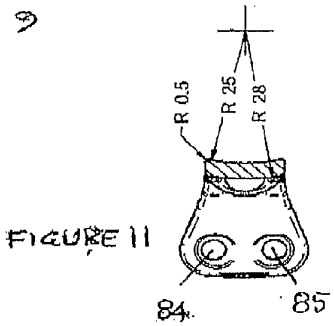



FIGURE 11

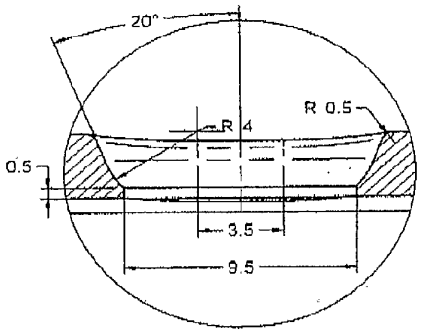
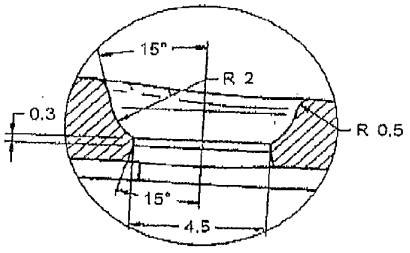



FIGURE 12

2 * DETAIL B
4:1




DETAIL C
5:1

FIGURE 13

# INTERNATIONAL SEARCH REPORT

International application No.
**PCT**/AU2007/000656

A. CLASSIFICATION OF SUBJECT MATTER.

Int. Cl.

***A61B 17/58*** (2006.01) ***A61B 17/62*** (2006.01)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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

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

DWPI: IPC A61B 17/- & keywords: (bone, osteo+, oss+, fuse, plate, arthrodesis, or joint, ankle or foot, feet, angle, angular, bend, non-linear) and similar terms.
USPTO: arthrodesis, ankle, plate, fuse
Espace: (arthrodesis) and (ankle) and (plate) and (fuse) and similar words.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>A | DE 3332765 A1 (STRELI) 15 March 1984<br>Whole document | 55-64<br>1-54, 65-68 |
| X<br>A | US 6355041 B1 (MARTIN) 12 March 2002<br>Whole document | 55-64<br>1-54, 65-68 |

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

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"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

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 July 2007 | 17 JUL 2007 |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized officer<br>**KAREN VIOLANTE**<br>AUSTRALIAN PATENT OFFICE<br>(ISO 9001 Quality Certified Service)<br>Telephone No : (02) 6283 7933 |

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## INTERNATIONAL SEARCH REPORT

International application No.
**PCT**/AU2007/000656

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>A | US 6440131 B1 (HAIDUKEWYCH) 27 August 2002<br>Whole document | 55-64<br>1-54, 65-68 |
| X<br>A | JP 8-126650 A (MEDICAL YG) 21 May 1996<br>Whole document | 55-64<br>1-54, 65-68 |
| X<br>A | US 2003/0060827 A1 (COUGHLN) 27 March 2003<br>Whole document | 55-64<br>1-54, 65-68 |
| X<br>A | US 2004/0102778 A1 (HUEBNER ET AL) 27 May 2004<br>Whole document | 55-64<br>1-54, 65-68 |
| A | US 2004/0039394 A1 (CONTI ET AL) 26 February 2004<br>Whole document | 1-68 |

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
**PCT/AU2007/000656**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| DE | 3332765 | AT | 341382 | AT | 378324 | GB | 2126903 |
| | | US | 4565193 | | | | |
| US | 6355041 | | NONE | | | | |
| US | 6440131 | US | 2002128653 | | | | |
| JP | 8126650 | | NONE | | | | |
| US | 2003060827 | EP | 1297793 | FR | 2829920 | HK | 1054494 |
| | | JP | 2003102744 | | | | |
| US | 2004102778 | AU | 2003291114 | AU | 2003294342 | AU | 2003294414 |
| | | AU | 2003295749 | EP | 1567071 | EP | 1572045 |
| | | GB | 2412590 | GB | 2412875 | KR | 2005007544 |
| | | KR | 2005008391 | US | 7090676 | US | 7153309 |
| | | US | 7189237 | US | 2004102775 | US | 2004102776 |
| | | US | 2004102777 | US | 2004102788 | US | 2005085818 |
| | | WO | 2004045384 | WO | 2004045389 | WO | 2004045455 |
| | | WO | 2005037114 | WO | 2005046494 | | |
| US | 2004039394 | AU | 2003235085 | EP | 1393696 | JP | 2004130109 |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(30) Priority Data:
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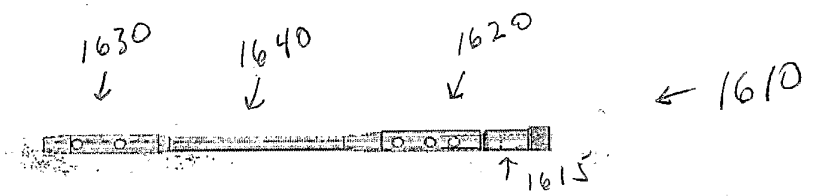
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 2006/116164 A1

(54) Title: OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE




(57) Abstract: Bone fracture fixation devices, systems and methods of use and manufacture are provided. One such bone fixation device includes an elongate element having a responsive zone. The element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when coupled thereto. In some embodiments, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol, to apply compressive pressure across the fracture or fusion site for longer periods of time than standard bone screws.

# OSTEOSYNTHETIC IMPLANTS AND METHODS OF USE AND MANUFACTURE

## CROSS-REFERENCES TO RELATED APPLICATIONS

**[0001]** The present application is a continuation-in-part of U.S. Patent Application No. 11/112,865 filed April 21, 2005, and is related to U.S. Provisional Patent Application No. 60/563,952, filed April 21, 2004, the complete disclosures of which are incorporated herein by reference for all purposes.

## BACKGROUND OF THE INVENTION

**[0002]** The present application relates generally to bone fracture repair, and more specifically, to osteosynthetic implants for fracture repair and methods of their use and manufacture.

**[0003]** In 1959, a group of Swiss Orthopedic and General Surgeons formed the Arbeitsgemeinschaft fur Osteosynthesefragen (AO), also known as the Association for the Study of Internal Fixation (ASIF). The AO/ASIF is now a multi-national group of doctors and scientists with the expressed purpose of studying bone healing and continuous development of fracture fixation techniques for patient care. In the United States, as well as most other countries, AO/ASIF guidance regarding skeletal fixation has become the standard of care for traumatic fracture as well as therapeutic osteotomy fixation techniques. It is under these AO/ASIF guidelines that the surgeon plans and carries out procedures to achieve the desired end result of bone healing and skeletal function.

**[0004]** Problems can arise when the bone fracture or fusion site is not sufficiently stabilized during the healing timeframe. Depending on the nature of the fracture, screws and plates may be used alone, or in combination. One objective of osteosynthetic implants is the anatomic reduction of the fracture. Another objective would be to minimize or eliminate interfragmentary motion. Still another objective involves increasing or maximizing blood supply to the fracture site by reducing or minimizing additional vascular damage. Sustained compressive therapy can also be osteoinductive, due to its piezoelectric effects on osteoblasts themselves. Excessive interfragmentary motion results in the formation of fibrous, unmineralized scar tissue (resulting in a non-union or pseudo-arthrosis) versus the

regeneration of bone. The unmineralized scar tissue is not load supporting and skeletal function is lost. A sufficient blood supply must be maintained to support skeletal metabolism, bone regeneration, and remodeling of the fracture site. The current standard of care includes osteosynthetic devices that are made of either stainless steel or titanium.

**[0005]** The use of stainless steel or titanium in osteosynthetic devices has a long history and reasonable record of success. Over time, however, the stainless steel and titanium fixation constructs (both screws and plates) do not maintain compression across the fracture fragments. The reduction of compression of certain standard material constructs has been observed to be thirty-two percent (32%) over a two week period. As the necrotic surfaces of the fracture are resorbed, a non-load bearing gap develops between the fragments, thereby decreasing compression and increasing the risk of interfragmentary motion and scar tissue formation. Loss of compression is contrary to the objectives of fracture fixation in general, and osteosynthetic implants in particular. Improvements are desired to help maintain compressive load across the fracture site over a longer period of healing.

## BRIEF SUMMARY OF THE INVENTION

**[0006]** The present application relates generally to bone fracture repair and bone fusion, and more specifically, to osteosynthetic implants for fracture/fusion repair and methods of their use and manufacture. Fracture repair devices, systems and methods include those for repairing intentional fracture sites, such as but not limited to osteotomies, for reconstructive purposes. Bony fusions of surgically resected joints throughout the body are included as well within the scope of the present invention. Fracture fixation devices, systems and methods of the present invention help maintain compressive loads across the fracture site for longer periods of time compared to prior devices. In some embodiments, the use of shape memory materials, including nickel titanium, delivers improved fracture repair characteristics. The present invention further includes methods of use and methods of manufacture of such bone fixation devices and systems.

**[0007]** In one embodiment, a bone fixation device according to the present invention includes an elongate element having a responsive zone. The elongate element is a plate, a nail, or a bone screw in alternative embodiments. The elongate element is adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone. The responsive zone is adapted to apply a desired pressure to the bone when

coupled thereto. In a preferred embodiment, the responsive zone comprises a shape memory material, which may be nickel titanium or Nitinol.

**[0008]** In some embodiments, the elongate element comprises nitinol, while in other aspects, the responsive zone is pseudoelastic at a body temperature. In this manner, the elongate element may be used to apply desired forces at the fracture site. In some embodiments, the responsive zone is generally centrally located in the elongate element. In one aspect, the responsive zone has a smaller overall cross section than a cross section of an end of the elongate element. Such a configuration helps locate the stresses or pressures at a desired location within the elongate element, and more specifically, at the responsive zone.

**[0009]** In some aspects, the bone fixation device further includes a coupler adapted to couple the elongate element to the bone. The coupler may include one or more bone screws, which in some embodiments comprise a shape memory material. In a particular embodiment, the elongate element has first and second end sections each with at least one hole adapted to receive a coupler therethrough to couple the element to the bone. Other embodiments may use two, three, four, or more holes in one or both end sections to fixedly couple the device to the fractured bone.

**[0010]** The present invention further provides bone fixation systems. In one embodiment, the system includes an elongate element having a responsive zone of shape memory material, for example in its pseudoelastic state, and a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone. In some embodiments, the system includes a removable clamp, with the clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the element to the bone, and may further be adapted to be removed from the elongate element after coupling of the element to the bone. In one aspect, the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

**[0011]** The present invention further provides methods of stabilizing a fractured bone. In one such embodiment, the method includes providing an elongate element, which may be a plate, an intermedullary or intramedullary nail, a bone screw, a pin, or related devices. The elongate element has a responsive zone of a shape memory material, with the responsive zone adapted to apply a desired pressure to the bone when coupled thereto. The method includes coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone.

**[0012]** In one aspect, the method includes applying a force to the elongate element to lengthen the responsive zone a desired amount, maintaining the element in the lengthened position, coupling the element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site, and releasing the elongate element. In some aspects, a clamp is used to maintain the element in the lengthened position. In this manner, the elongate element may be released by removing the clamp. As a result, the stress formed in the responsive zone can be applied to the bone to facilitate fracture and fusion site compression, stability, healing, and the like.

**[0013]** In a particular aspect, coupling the elongate element to the bone includes attaching a first coupler to the element and to the bone on a first side of the fracture site, and attaching a second coupler to the element and to the bone on a second side of the fracture site. In this manner, the responsive zone is positioned adjacent the fracture site. In one aspect, the force applied to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the element is coupled thereto. Again, the shape memory material may be nitinol, or other shape memory materials compatible with the human body.

**[0014]** In one aspect, embodiments of the present invention provide a bone fixation system. The sytem can include a bone fixation device having a responsive zone, and a clamp configured to be received at least partially within an internal lumen of the bone fixation device, where the internal lumen disposed along an axial length of the bone fixation device. The clamp can be adjustable between a first mode that induces or maintains a first amount of strain in the responsive zone along the axial length of the bone fixation device, and a second mode that induces or maintains a second amount of strain in the responsive zone along the axial length of the bone fixation device. The clamp may be removably coupled with the bone fixation device. In some instances, the clamp includes an end cap and an internal brace. The end cap can be adjustably engaged with the bone fixation device at an end cap first section, and adjustably engaged with the internal brace at an end cap second section. Relatedly, the end cap can be threadably engaged with the bone fixation device at an end cap first section, and i threadably engaged with the internal brace at an end cap second section. In some aspects, a central longitudinal axis defined by the internal lumen of the bone fixation device is collinear with a central longitudinal axis defined by the internal brace. In related aspects, the central longitudinal axis defined by the lumen of the bone fixation device is collinear with a central longitudinal axis defined by the end cap.

**[0015]** The bone fixation device can be, for example, an intramedullary or intermedullary nail, a screw, a plate, a pin, a compression rod, a vertebral fixation device, and the like. The responsive zone can have a physical characteristic similar to human tissue. In some cases, the physical characteristic is a modulus such as an elastic modulus. For example, the modulus can have a value in a range from between about 10 GPa to about 70 GPa. In some cases, the human tissue is bone. Often, the responsive zone includes a shape memory material, which may be a shape memory alloy. A shape memory alloy can include a nickel alloy, a copper alloy, and the like. In some cases, the shape memory alloy includes a nickel titanium alloy, a copper zinc aluminum alloy, a copper aluminum nickel alloy, or the like. The responsive zone is configured to provide a predetermined or preset compressive force across a bone fracture or fusion site when the clamp is removed or inactivated. Similarly, the responsive zone can be configured to recover to a predetermined or preset length when the clamp is removed or inactivated.

**[0016]** In another aspect, embodiments provide a bone fixation device that includes a machined responsive zone having a hardness value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales. The responsive zone may include a nickel titanium alloy. In still another aspect, embodiments provide a method of preparing a bone fixation system. The method can include providing a bone fixation device having a responsive zone, inserting a clamp at least partially within an internal lumen of the bone fixation device, where the internal lumen disposed along an axial length of the bone fixation device, and inducing, maintaining, controlling, or modulating a strain in the responsive zone along the axial length of the bone fixation device with the clamp. Such methods can also include threadably engaging an end cap of the clamp with the bone fixation device at an end cap first section, and threadably engaging the end cap with an internal brace of the clamp at an end cap second section.

**[0017]** In yet another aspect, embodiments include methods of deploying a bone fixation device in a patient. Such methods can include, for example, providing a bone fixation device having a first portion, a second portion, and a responsive zone disposed therebetween, and inserting a clamp at least partially within an internal lumen of the bone fixation device. The internal lumen can be disposed along an axial length of the bone fixation device. The method may also include inducing, maintaining, controlling, or modulating a strain in the responsive zone along the axial length of the bone fixation device with the clamp, coupling the bone fixation device with a bone of the patient by attaching the first portion of device to a first

bone location, and attaching the second portion of the device to a second bone location. The bone typically includes a fracture or fusion site disposed between the first and second bone locations. The method can further include securing the bone fixation device to an external brace assembly, removing the clamp from the bone fixation device, and removing the external brace assembly from the bone fixation device. The bone fixation device can remain coupled with the patient's bone, and the responsive zone can be allowed to relax so as to transmit a compressive force to the fracture or fusion site of the patient's bone via the bone fixation device.

**[0018]** In one aspect, embodiments include methods of processing a shape memory material for use in a bone fixation device. Methods may include, for example, treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state, machining the shape memory material while it is in the second state, and treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state. The first treatment may include a first heat cycle of at least 5 minutes at a temperature of about 600° C. The first treatment may also include a second heat cycle of at least 5 minutes at a temperature within a range from between about 200° C to about 550° C. In some embodiments, the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value. The first state can have a first shape recovery value, the third state can have a third shape recovery value, and the third shape recovery value may be at least 95% of the first shape recovery value. In some cases, the shape memory material includes a shape memory alloy such as a nickel titanium alloy, a copper zinc aluminium alloy, or a copper aluminium nickel alloy. The third state may have an optimal pseudoelastic property profile for the shape memory material. In some aspects, the first state can have a first hardness value, the third state can have a third hardness value, and a difference between the first hardness value and the third hardness value may be less than about 3 HRC on the Rockwell C Hardness Scale. In some cases, the difference may be less than about 10 HRC.

**[0019]** In another aspect, embodiments encompass methods of preparing a bone fixation device. Methods may include providing a bone fixation device comprising a shape memory material, and machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenitic transition temperature. In some

aspects, the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite phase during the machining.

**[0020]** Additional embodiments and features are set forth in part in the description that follows, and in part will become apparent to those skilled in the art upon examination of the specification or may be learned by the practice of the invention. The features and advantages of the invention may be realized and attained by means of the instrumentalities, combinations, and methods described in the specification.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0021]** Fig. 1A is an overall view of a dynamic compression bone screw according to an embodiment of the present invention;

**[0022]** Figs. 1B and 1C are simplified views of steps for forming the dynamic compression bone screw depicted in Fig. 1A;

**[0023]** Figs. 2A-2C schematically depict the use of the dynamic compression bone screw of Fig. 1A for repairing a bone fracture;

**[0024]** Fig. 3A is a side view of the dynamic compression bone screw of Fig. 1A;

**[0025]** Figs. 3B and 3C are close-up views of the screw head and threaded portion, respectively, for the bone screw depicted in Fig. 3A;

**[0026]** Fig. 3D is a longitudinal cross-sectional view of the bone screw depicted in Fig. 3A;

**[0027]** Fig. 3E is a top view of the bone screw depicted in Fig. 3A;

**[0028]** Fig. 3F is an overall view of the bone screw depicted in Fig. 3A;

**[0029]** Fig. 3G is an overall view of a dynamic compression bone screw according to an alternative embodiment of the present invention;

**[0030]** Fig. 4 is an overall view of two bone fixation devices according to an embodiment of the present invention;

**[0031]** Fig. 5A is an overall view of the bone fixation device shown in Fig. 4;

**[0032]** Figs. 5B-5I are additional views of the fixation device shown in Fig. 5A, including a bottom view (Fig. 5A), a top view (Fig. 5B), a longitudinal cross-sectional view (Fig. 5C), a

close-up bottom view of an expansive zone (Fig. 5D), an end view (Fig. 5E) and a side view (Fig. 5F);

**[0033]** Figs. 6A and 6B are overall views of a fixation device coupled to a bone having a fracture site;

**[0034]** Figs. 7A and 7B are exploded and assembled overall views, respectively, of a bone fixation system according to an embodiment of the present invention using the fixation device shown in Fig. 4;

**[0035]** Fig. 8 is an overall view of a bone fixation device according to an alternative embodiment of the present invention;

**[0036]** Figs. 9A and 9B are graphical views of material properties of bone fixation screws and devices according to an embodiment of the present invention; and

**[0037]** Figs. 10A and 10B are graphical depictions of characteristics of bone screws and fixation devices according to embodiments of the present invention.

**[0038]** Figs. 11 and 11B illustrate an end cap according to embodiments of the present invention.

**[0039]** Fig. 12 shows an internal brace according to embodiments of the present invention.

**[0040]** Fig. 13A and 13B show a bone fixation system according to embodiments of the present invention.

**[0041]** Fig 14 shows a jig or external fixation device according to embodiments of the present invention.

**[0042]** Fig. 15 shows a restrainer bar according to embodiments of the present invention.

**[0043]** Fig. 16 illustrates a bone fixation device according to embodiments of the present invention.

**[0044]** Fig. 17 depicts a patient's leg and a jig and restrainer bar according to embodiments of the present invention.

**[0045]** Fig. 18 depicts a patient's leg, a jig and restrainer bar, and a bone fixation device according to embodiments of the present invention.

**[0046]** Fig. 19 depicts a patient's leg, a jig and restrainer bar, a bone fixation device, and cross pins according to embodiments of the present invention.

**[0047]** Fig. 20 depicts a patient's leg and a bone fixation device according to embodiments of the present invention.

**[0048]** Fig. 21 depicts a patient's leg, a jig and restrainer bar, cross pins, a bone fixation device, and bone screws according to embodiments of the present invention.

**[0049]** Figs 22A and 22B show a patient's leg, a jig and restrainer bar, cross pins, a bone fixation device, and bone screws according to embodiments of the present invention.

**[0050]** Fig. 23 depicts a patient's leg, a bone fixation device, and bone screws according to embodiments of the present invention.

**[0051]** Figs 24A to 24H show a prototypical intramedullary nail having exemplary dimensions.

**[0052]** Fig. 25 shows a hardness versus heat treatment graph according to embodiments of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

**[0053]** It has been determined that when a bone is set and a compressive force is applied to the fracture or fusion fixation device, the force between the fragments ends decreases rapidly as a function of time. Ideally, the fixation device is able to maintain a compressive force, which will allow for the continuation of healing through reduction of the fracture gap, and stability of the fracture gap. If this does not occur, a loss of compression may be followed by the lack of union and stability of the fracture site, which in turn reduces the healing. A fracture fixation device is put in place to stabilize the fracture site, however, if the compressive force is not present then micro-motion between the fracture ends may occur. This, in turn, may cause unnecessary resorption, which will lead to non-union of the bone or the presence of large voids. These reasons show the importance of a device to actively match the changes in the body, as well as have a similar response as bone.

**[0054]** Embodiments of the present invention include bone fixation devices, including plates, bone nails such as intramedullary nails, bone screws, and the like, that can provide sustained compression (spontaneous dynamic compression) across a bone fracture over time.

The dynamic compressive forces are stable or generally stable as a function of bone surface resorption at the fracture site, facilitating improved bone healing and reducing non-union rates. Some bone fixation devices of the present invention will allow for approximately six percent (6%) relaxation before compressive force loss. In contrast, typical stainless steel or titanium bone screws lose their compressive forces after about one percent (1%) resorption at the fracture surface.

**[0055]** Figs. 1A-2C depict a dynamic compression bone screw 100 according to an embodiment of the present invention. Bone screw 100 shown in Fig. 1A is further described in conjunction with Figs. 3A-3F. In a particular embodiment, bone screw 100 is formed from nickel titanium, a shape memory alloy referred to as Nitinol. As shown in Fig. 1B and 1C, screw 100 is formed from a Nitinol stock or block, and may be heat treated to produce desired characteristics. Shape memory alloys, such as Nitinol, exhibit the capacity to recover relatively large strains (e.g., about 6%) by the application of heat (shape memory) or by gradual unloading (pseudo-elasticity). The present invention exploits the large strain capacity and recovery behavior of shape memory alloys such as Nitinol for bone repair with novel devices, systems, and methods. In one embodiment, the fixation devices, such as screw 100, are machined from a shape memory material such as Nitinol that is thermally treated to exhibit pseudo-elasticity at body temperature. The overall screw geometry, responsive element geometry, and material heat treatment will be specified to sustain the necessary compressive forces as a function of fracture or fusion site conditions.

**[0056]** The shape memory effect of Nitinol is the temperature-induced transformation between the malleable martensite (lower temperature) phase and the more rigid austenite phase (higher temperature) that exhibits the desired pre-set shape. Exploitation of the thermally driven phase change helps some embodiments of the present invention deliver desired bone fixation results. The pseudoelastic effect of Nitinol refers to the return to its pre-set austenite configuration upon unloading after elastic deformation. The initiation of superelastic behavior of Nitinol requires the formation of stress induced martensite (SIM) from the austenite phase, such as by the application of an external load or stress. Reduction of the external load or stress induces formation of the austenite phase and hence its pre-set configuration. Nitinol is able to accumulate large deflection (strain) at a nearly constant load (stress). The relatively flat region of the Nitinol load-to-deflection relationship can be used for some devices of the present invention.

**[0057]** Some embodiments of the present invention take advantage of the stress/strain (modulus) of NiTi, depicted in Fig. 9A. Such characteristics of NiTi are beneficial in the development and use of improved total joint implants, for example. This property of NiTi decreases overall bone to implant interface stresses, resulting in a longer implant lifetime. Embodiments of the present invention, particularly those using NiTi, help the bone maintain load, which increases healing and helps smaller implants to maintain the same or similar stability as larger ones in similar areas of fixation by reducing stress/strain and sheering forces.

**[0058]** Formation of SIM phase within a responsive zone of screw 100, or other osteosynthetic implants and devices, may be achieved prior to surgical placement or as a result of surgical placement. For the bone screws 100 depicted in Fig. 1A, the responsive zone of screw will be designed to initiate SIM formation as a result of the installation process. This occurs, at least in part, due to the elongating forces applied to the screw when the screw is used. Additional details on the responsive zone are discussed in conjunction with Figs. 3A-3F.

**[0059]** One technique for fracture fixation is the placement of a lag screw across the appositional ends of a break in the bony cortex. Inserting the screw across the fracture site helps generate the dynamic force capacity in the screw. As shown in Fig. 2A, bone screw 100 is inserted at an angle relative to a fracture site 210. Screw 100 is rotated to draw the two bone fragments 220 towards one another, creating a compressive force therebetween. The rotational torque used to turn screw 100 is translated into axial compression between bone fragments 220. The result is the proper alignment of bone fragments 220 as shown in Fig. 2B. Screw 100 maintains a compressive force on bone fragments 220 for a much longer period of time than traditional bone screws formed of steel, titanium, or the like. As a result, a more fully healed fracture site 210 results (Fig. 2C). During healing and bone absorption, the force generated by prior-art screws can decrease leaving a less compressive force acting across the fracture site 210 over time. In contrast, bone screws 100 of the present invention are a dynamic screw that can maintain higher compression values over a longer course of healing. Advantages of screw 100 includes better promotion of direct bone healing, reduction in non-union rates in high risk fracture sites, and a reduction in bone implant site resorption. In some embodiments, at least some of these advantages are achieved by the use of a shape memory material, such as Nitinol, and its inherently similar stress/strain properties to those of bone.

**[0060]** Fig. 3A-3F depict further details on bone screw 100 according to an embodiment of the present invention. It will be appreciated by those skilled in the art that Figs. 3A-3F depict a particular example, and the present invention is not limited to the dimensions and configurations shown therein. As can best be seen in Figs. 3A, 3D, and 3F, bone screw 100 has a shank portion 110 with a diminished thickness or radius compared to the radius or thickness of a threaded portion 120 or of a head 130. In this manner, the reduced area of shank portion 110 allows for a stress concentration to be localized over shank portion 110, which allows shank portion 110 to elongate to form a responsive element or zone. In one embodiment, the elongation of shank portion 110 occurs during the insertion process into the fractured bone, as depicted in Fig. 2B. By using the responsive element or shank portion 110, bone screw 100 is able to localize the force caused by the SIM over the fracture site. The non-responsive screw portions, such as head 130, stays generally strain-free and contributes little force to the bone due to SIM.

**[0061]** In an alternative embodiment, a bone screw 300 depicted in Fig. 3G has a generally uniform diameter through a shank portion 310. In this embodiment, only shank portion 310 is formed of a shape memory material, with threaded end portion 320 comprising a stiffer region less susceptible to elongation.

**[0062]** Turning now to Fig. 4, a bone fixation device 400 according to an embodiment of the present invention will be described. Bone fixation device 400 allows for a longer and greater sustained compressive force. For example, current bone plates applied to a fractured surface tend to lose compressive force within two days to two weeks after surgery, thus slowing the healing process. Additional problems with prior-art plates, such as deflections and rigidness, also result in a greater chance of refracture and slow healing. In one embodiment of the present invention, bone fixation device 400 comprises a shape memory alloy, that may be Nitinol or the like. Fixation device 400 is a dynamic device that can change over time with the human body into which it is inserted. In a preferred embodiment, device 400 comprises Nitinol, due in part to its capacity to recover large strains over time. In one embodiment, this is accomplished through the creation of device 400 having a responsive zone section 410. In some embodiments, responsive zone 410 has a smaller overall cross-sectional area than the non-responsive zone(s) of device 400. Responsive zone 410 is used to localize the elongation of device 400 to that area. In one embodiment, device 400 is elongated based on the application of a force similar to or the same as the force required to stabilize the fracture to which device 400 is applied. Device 400 will be elongated based on

the force required to stabilize the fracture and apply the necessary healing force. After device 400 has been elongated, in one embodiment it is held in an elongated state by an external clamp or similar structure to prevent recovery motion of device 400. After device 400 is affixed to the fracture site, the clamp, or other retaining mechanism can be removed. Further details on the use of device 400 are discussed in conjunction with Figs. 7A and 7B.

**[0063]** Figs. 5A-5I depict various views of device 400 or portions of device 400, according to particular embodiments of the present invention. Again, the dimensions, including the lengths, widths, thicknesses and radii of curvature, may vary within the scope of the present invention from those shown in the figures. More specifically, the figures include a longitudinal cross-sectional view (Fig. 5C), a top view (Fig. 5B), a bottom view (Fig. 5A), a side view (Fig. 5F), an end view (Fig. 5E), and a close-up bottom view of expansive zone 410 (Fig. 5D), of device 400. In a preferred embodiment, device 400 is coupled to a bone having a fracture site so that responsive zone 410 is disposed adjacent the fracture site. This arrangement can be seen in Figs. 6A and 6B.

**[0064]** As shown, device 400 has one or more holes 430 disposed on each side of responsive zone 410 so that device 400 may be coupled to a fractured bone 600. While Figs. 6A and 6B depict four holes 430 on each side of the fracture site, a greater or lesser number of holes 430 may be used within the scope of the present invention. In some embodiments, holes 430 are adapted to receive a screw or other fixation element to affix device 400 to bone 600. The coupling of device 400 to bone 600 preferably positions responsive zone 410 across or adjacent a bone fracture site 610. This may involve attaching one end of device 400 to one bone segment 620 and the second end of device 400 to the opposing bone segment 620. In some embodiments, the screw or fixation element used to couple device 400 to bone segment 620 comprises a bone screw, which may be made of stainless steel, titanium or the like. In a particular embodiment, screws or fixation elements used to coupled device 400 to bone 600 comprise a shape memory alloy, such as Nitinol.

**[0065]** Figs. 7A and 7B depict a bone fixation system 700 according to an embodiment of the present invention. System 700 includes fixation device 400 as previously described, and a clamp 710. While Fig. 7A depicts a single example of clamp 710, other clamp types fall within the scope of the present invention. Further, alternative devices may be used in lieu of clamp 710, provided the alternative devices are capable of attaching to device 400, and preferably are capable of holding device 400 in a desired position or elongated state. In

operation, an elongating force is applied to device 400 to stretch or elongate device 400 to a prescribed length. As described further below, the application of the prescribed force is determined at least in part by the necessary force to provide healing effect to the bone to which device 400 will be applied. Once device 400 is elongated to the desired length, clamp 710 is used to maintain device 400 in the elongated position. Clamp 710 maintains the elongated position of device 400 until device 400 is attached to the fractured bone. Once device 400 is attached to the fractured bone, clamp 710 may be removed from device 400. In this manner, device 400 is attached to the fractured site and, upon the release of clamp 710, device 400 provides the desired compressive force through the fractured location. Again, in some embodiments device 400 comprises a shape memory material, and in a particular embodiment comprises Nitinol. Preferably, the application of the compressive force is of sufficient duration to facilitate healing as well as to avoid some or all of the other problems associated with prior-art devices constructed of stainless steel, titanium, or similar materials.

**[0066]** In the depicted embodiment, clamp 710 comprises a main component 712, first and second device-engaging components 714, and a wedge element 716. In one embodiment, device-engaging components 714 are disposed so that screws, lugs, posts or the like 718 extending from components 714 pass at least partially through corresponding holes 430 in device 400. Main component 712 is then coupled to device-engaging components 714 with wedge element 716 positioned therebetween. By rotating or depressing a pressure applicator 720, which in one embodiment is a screw, a force is applied to wedge 716. The application of a force to wedge 716 in the direction shown by arrow 722 causes an outward force to be applied to components 714, as shown by arrows 724. As can be seen in Fig. 7A, the force depicted by arrows 724 results in an elongating force being applied to device 400 through the use of screws, lugs, or posts 718. By controlling the physical relationship between pressure applicator 720 and components 714, the elongating force to device 400 may be controlled. The coupled configuration of clamp 700 with device 400 is generally depicted in Fig. 7B.

**[0067]** In another embodiment, a separate device or system is used to apply the elongating force to device 400. This may occur, for example, by pulling on opposing ends of device 400 to create an elongating force similar to that represented by arrows 724. Once device 400 has been elongated the desired amount, clamp 710 may be coupled to device 400 in the manner substantially as described above to hold device 400 in the elongated position. In this embodiment, pressure applicator 720 is operated so that the screws, lugs, or posts 718 engage holes 430 to hold device 400 in its desired elongated state. Again, device 400 is then coupled

to bone 600, which preferably positions responsive zone 410 across or adjacent bone fracture site 610. This may involve attaching one end of device 400 to one bone segment 620 and the second end of device 400 to the opposing bone segment 620. Once device 400 is coupled to bone 600, clamp 700 is removed.

**[0068]** The present invention further provides bone fixation rods, nails and the like. In one embodiment, a bone fixation rod or nail 800 has a first end 810 and a second end 812, with a middle section 814 disposed therebetween. In one embodiment, some or all of rod 800 comprises a shape memory alloy, that in a preferred embodiment comprises Nitinol. For example, in one embodiment, middle section 814 comprises Nitinol. In this manner, middle section 814 is a responsive zone having the characteristics as generally described herein. In another embodiment, one or both of first end 810 and second end 812 comprise Nitinol. In still another embodiment, the entire rod 800 is Nitinol.

**[0069]** In one embodiment, rod 800 is a dynamic intramedullary nail. Such a device may be used, for example, in retrograde tibio-talo-calcaneal fusions. Nail 800 addresses fusion or fracture site compression problems, as described generally herein in conjunction with prior embodiments, as well as vascular preservation issues. For example, rod 800 may provide dynamic compression across a fusion site in a manner that allows for the use of smaller rods 800, or nails. By having a smaller diameter rod or nail 800 compared to prior art nails of titanium or the like, this would aid in preserving the endosteal/medullary blood supply.

**[0070]** As shown in Fig. 8, rod or nail 800 is inserted into a bone 850. Rod 800 insertion occurs, in one embodiment, by reaming the bone's medullary canal, and hammering or otherwise driving nail 800 into place. Nail 800 then may be locked relative to the bone with one or more interference or locking screws 820. While the embodiment shown in Fig. 8 depicts a single screw 820 near end 810 and two screws 820 near end 812, it will be appreciated by those skilled in the art that the number of screws 820 may vary within the scope of the present invention. Further, the interference or locking screws 820 may comprise nails, pins or the like. The dimensions of rod 800 and screws 820, including the lengths, widths, diameters, and thicknesses, may vary within the scope of the present invention and may determined, at least in part, by the particular bone(s) and/or joint(s) into which the device is being inserted or otherwise coupled.

**[0071]** In some embodiments, nail or rod 800 is designed to allow for the release of the responsive element or zone portion thereof, allowing the rod or nail 800 to shorten. This is

accomplished, at least in part, by having the responsive zone of rod 800 comprise a shape memory alloy such as Nitinol as described above in conjunction with screw 300. In this manner, the release of the responsive element-portion of nail 800 draws locking screws 820 on opposing sides of the responsive zone closer together. Dynamic compression on bone 850 results. In one embodiment, the responsive zone, which may include ends 810, 812 and/or middle section 814, is positioned at a desired location(s) within bone 850 or joint 860 to facilitate bone healing. For example, the responsive zone may be positioned adjacent or spanning a fracture site within bone 850, may be positioned within a joint 860, or at other locations at which increased and/or sustained dynamic pressure is desired.

**[0072]** Bone fixation devices of the present invention, including nails 800, screws 300 and plates 400, may be inserted with one or more sets of instrumentation that also are included within the scope of the present invention. For example, the instrumentation for implantation may be comprised of screws and plates, hammers or other compression devices, clamps or other holding devices, torsion devices such as screwdrivers, torque wrenches or the like for inserting screws, rods and plates. In one embodiment, a torque wrench is provided having a preloaded setting that allows the surgeon to determine whether the screw 300 pseudo elasticity has been activated upon insertion at the fracture site.

**[0073]** Figs. 9A depicts the stress-strain diagram for living tissues and a nickel titanium alloy. Nickel titanium, and in particular Nitinol, exhibits desirable strain recovery characteristics. The temperature at which Nitinol recovers is known as the transformation temperature ($T_t$). The transformation temperature may be determined using various heat treatments on the material. The material then may demonstrate pseudo elastic (PE) and shape memory (SM) properties, depending at least in part on the relationship between $T_t$ and the surrounding temperature $T_a$ (e.g., atmospheric temperature, internal body temperature, or the like). The PE state is observed when $T_a$ is greater than $T_t$. When the material is stretched from an applied force, a permanent strain is observed. When the force is removed, the material recovers the strain. The SM state occurs when $T_t$ is greater than $T_a$. The material is deformed at above $T_a$, and remains deformed until a temperature is applied which is above $T_t$. These characteristics are useful for fashioning fixation devices according to some embodiments of the present invention. Fig. 9B depicts the inventors experimental results showing the affect of total strain on the unloading profile of SIM Nitinol.

**[0074]** The force that the physician wants to place over fracture site 210 or 610 with screw 100, nail 800, plate 400 or other fixation devices within the scope of the present invention can be defined as $F_R$. The physician also can determine the anticipated change in length ($\Delta L$) of relaxation/resorption needed to maintain the stability in the fracture. This may involve determining the distant or amount the bone and/or surrounding tissues will relax during the healing period. From this information the cross sectional area and length of a bone fixation device, such as screw 100, nail 800 and/or device 400 can be calculated, respectively.

**[0075]** Using equation (1) below, the cross sectional area can be calculated. Using equation (2) below, the total length of the responsive element can be calculated. In these equations, A is the cross-sectional area, $F_R$ is the physician-specified recovery force, $\sigma_R$ is the tensile recovery stress (a material property), L is the length of the responsive zone or element, $\Delta L$ is the physician-specified change in length of the responsive zone or element, and $\epsilon$ is the tensile strain (a material property). The total length and cross sectional area are used for the manufacturing of the plate or screw in order to meet the physician's needs. Figs. 10A and 10B show an example of possible areas and length, that can be determined by the physician.

$$A=F_R/\sigma_R \qquad (1) \qquad\qquad L=\Delta L/\epsilon \qquad (2)$$

**[0076]** The responsive element or responsive zone, in a preferred embodiment, has a smaller cross sectional area than the non-responsive part. This reduction of the area allows for the stress to be localized over the element or zone, which in turn elongates only the responsive element or zone. By using the responsive element or zone, the application is able to localize the force caused by the Stress Induced Martensite (SIM) over the fracture, while the non-responsive element stays generally strain free and contributes minimal forces to the bone due to SIM.

**[0077]** Several devices and systems of the present invention are developed from a Shape Memory Alloy (SMA) to actively respond to the changes of the human body, especially in the bone response. In some embodiments, the inventors studied and used the SMA nickel titanium, or Nitinol. NiTiNOL is biologically compatible with the endoskeleton structure, as well as being strong and durable. Several embodiments of the present invention harness the material characteristics of NiTiNOL.

**[0078]** The below discussion covers the steps to manufacture a dynamic compression bone screw, nail, bone fixation device or plate, and other active devices from NiTiNOL, and the

machining of NiTiNOL devices. A brief description of the heat treating, composition and deformation techniques used will be addressed. It will be appreciated by those skilled in the art that the manufacturing techniques described represent just some of the embodiments of the present invention.

Material Preprocesses

**[0079]** It is desirable to develop an accurate stress strain response for various states of the NiTiNOL. Below are the steps used to characterize a particular composition of an SMA of NiTiNOL according to an embodiment of the present invention:

1. Bars of Hot Rolled Ti-50.9% at %Ni, and Cold Drawn Ti-50.9% at.%Ni. were obtained from Special Metals.
2. The materials are cut into desired bone plate, nail and screw shapes from the bars using Electro Discharge Machining (EDM). This process allowed for the presence of mechanical work to be minimal in the samples. The specimens were cut into dog bone samples for tension and rectangular blocks for compression. All tests are run in monotonic strain control.
3. Various heat treatments were applied to the Hot Rolled Material, based on the use of $Ti_3Ni_4$ precipitants to move the Martensite start ($M_s$) and finish ($M_f$) temperatures, as well as the Austenite start ($A_s$) and finish temperatures ($A_f$). The results were determined through the transformation peaks being observed using a Differential Scanning Calorimeter.
4. The various stress-strain responses were examined with regard to heat treatment. This allows for certain characteristics to be harnessed in the design. The uses of various heat treatments allow for the stress recovery and strain recovery to be changed.
5. Using the material response in its loaded condition, a cross sectional area is designed as briefly discussed in conjunction with Figs. 10A-10B.

Bone Screw/Nail

**[0080]** Some embodiments of bone fixation devices of the present invention are developed to actively adapt to the resorption across the fracture site. One such bone screw manufacturing process according to the present invention is provided below. The

manufacture of other fixation devices within the scope of the present invention follow a similar or same process.

1. Using the manufacturing results 1-5 above, the actual design of the responsive element or responsive zone can be determined. The specific calculations of the responsive element for the bone screw are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. The bars of NiTiNOL are sent to be EDM into smaller cylindrical sections. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

3. The smaller cylinders are heat treated for about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a state more susceptible to machining.

4. The screw is machined, such as on a lathe, at a cutting speed similar to stainless steel (e.g., about 300 RPMs). Concurrently, the NiTiNOL is flooded with cutting fluid to reduce the work hardening effects of the cutting surface.

5. After machining, the final part is heat treated to the appropriate temperature based on the material characterization and design phase, listed above. In a particular embodiment, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

6. The screw is autoclaved and deployed. The reactive element is stretched using the principle of the screws head and threads.

Bone Fixation Device or Plate

**[0081]** Use of a bone fixation device or a bone plate may be necessary to add a large area of stabilization over the fracture site. The device or plate may be used in unison with a bone screw. The bone fixation device or plate actively adapts to the resorption of a fracture site and compensates for the resorption located at the head and threads of the screws. Below are the instructions used to develop a NiTiNOL bone plate according to an embodiment of the present invention.

1. Using the manufacturing results 1-5, the actual design of the responsive element can be determined. The specifics of the responsive element are discussed briefly in conjunction with Figs. 10A-10B, and in more detail in Provisional Application No. 60/563,952, previously incorporated herein by reference.

2. Based on the type of fracture and amount of resorption expected, the final compressive force required for the plate to respond to the bone is designed using the stress / strain diagram.

3. The bars of the NiTiNOL are sent to be EDM into the final design of the plates. At this time, no heat treatment has been applied and the material is said to be in its as-received state.

It is possible to use the above "softening" heat treatment to machine the plates on a mill. The smaller rectangles will be cut from the bar, and then heat treated at about 600°C for about 30 minutes, which in turn reduces the hardness and places the material in a more "machining friendly" state.

4. The plate has its oxide layer left from the EDM mechanically removed.

5. Based on the results of the material characterization stage, the as-received bone plates are heat treated to get the desired properties. Similar to the screw, the heat treatment related to the material composition of 50.9 is about 350°C for about 1.5 hours.

6. Once the application of the plate is known, it is stretched using an external device to a predetermined strain and held fixed in place with a brace.

7. The entire setup is then sterilized by autoclave and finally deployed over the fracture site.

Other NiTiNOL Devices Including a Responsive Element

**[0082]** Other devices can benefit from the use of NiTiNOL or other SMA in an active responsive element. For example an interlocking bone marrow nail can be formed. The design of the nail is similar to the screw, and encompasses a similar responsive element. The design comes from the characterization of the NiTiNOL as discussed herein. Still other devices that could incorporate the responsive element include an artificial disk replacement used in a patient's vertebra. The responsive element could be designed to allow different forces between particular vertebrae. For example, a person with a large upper torso has

different stress contribution between the upper vertebrae and lower vertebrae, than a person with a smaller torso. Other uses of SMAs such as Nitinol also exist for creating actively responsive elements.

Bone Fixation Systems and Methods of Use and Manufacture

**[0083]** In some embodiments, a bone fixation system can include a bone fixation device having a responsive zone, and a clamp having an end cap and an internal brace. Figs. 11A and 11B illustrate an end cap 1110 according to one embodiment of the present invention. End cap 1110 includes a first section 1112 and a second section 1114. In some embodiments, an end cap can be designed to couple with or sit at a distal end of an intramedullary nail and provide additional support to a jig. An end cap can also provide a connection for an internal brace. In some cases, an end cap can be manufactured from Ti6Al-4V and can have an internal threaded cavity or other threaded surface. Fig. 12 shows an internal brace 1210 according to one embodiment of the present invention. Internal brace 1210 includes a first section 1212 and a second section 1214. Typically, end cap 1110 and internal brace 1210 are configured for adjustable cooperation. For example, end cap first section 1112 and internal brace first section 1212 can be threadably engaged. In some embodiments, an internal brace can be designed to sit inside an intramedullary nail and provide a barrier or impediment to premature recovery of the nail. An internal brace can be threaded into an end cap, and can be designed to allow for a guide rod to be inserted inside both the brace and the nail construct. In some cases, the internal brace is manufactured from Ti6Al-4V and has an internal threaded cavity or other threaded surface.

**[0084]** Figs. 13A and 13B show a bone fixation system 1310 according to one embodiment of the present invention. Bone fixation system 1310 includes a bone fixation device 1320 having a responsive zone 1322, and a clamp 1330 having an end cap 1340 and an internal brace 1350. Clamp 1330 is disposed partially within an internal lumen of bone fixation device 1320, where the internal lumen is disposed along an axial length of bone fixation device 1320. Clamp 1330 can be adjusted to a first mode, as shown in Fig. 13A, that induces or maintains a first amount of strain in responsive zone 1322 along the axial length of bone fixation device 1320. Similarly, clamp 1330 can be adjusted to a second mode, as shown in Fig. 13B, that induces or maintains a second amount of strain in responsive zone 1322 along the axial length of bone fixation device 1320. Often, adjustment to or between the first or second mode involves adjusting the length of clamp 1330. In some cases, the amount of

strain in the first or second mode can be zero. Clamp 1330 can operate to prevent, inhibit, or otherwise control or modulate recovery in responsive zone 1322. Clamp 1330 may be removably coupled with bone fixation device 1320. It is appreciated that the device may be provided in a packaged state, where the device is held stretched by an end cap and internal brace.

**[0085]** As seen in Figs. 13A and 13B, end cap first section 1342 is adjustably engaged or coupled with bone fixation device 1320, and end cap second section 1344 is adjustably engaged or coupled with internal brace first section 1352. Relatedly, end cap first section 1342 can be threadably engaged with bone fixation device 1320, and end cap second section 1344 can be threadably engaged with internal brace first section 1352. In some embodiments, a central longitudinal axis 1326 defined by an internal lumen of bone fixation device 1320 can be collinear with a central longitudinal axis 1356 defined by internal brace 1350. In some embodiments, central longitudinal axis 1326 can be collinear with a central longitudinal axis 1346 defined by end cap 1340. Relatedly, central longitudinal axis 1356 can be collinear with central longitudinal axis 1346. It is appreciated that bone fixation device can include any of a variety of osteopathic devices, such as nails, screws, plates, rods, compression rods, vertebral and other fixation devices, and the like.

**[0086]** Responsive zone 1322 can be manufactured or otherwise adapted to have a physical characteristic similar to human tissue, such as bone. For example, the physical characteristic can be a modulus value, for example an elastic modulus value. In some cases, the modulus of the responsive zone can be within a range from about 10 GPa to about 70 GPa. Responsive zone 1322 can include a shape memory material, which may be a shape memory nickel or copper alloy. The shape memory material may include a nickel titanium alloy, a copper zinc aluminum alloy, a copper aluminum nickel alloy, and the like. In some embodiments, responsive zone 1322 is configured to provide a predetermined or preset compressive force across a bone fracture site when the clamp is removed or inactivated. For example, a predetermined or preset compressive force may be within a range from about 2kN to about 4 kN for AO. It is appreciated that therapeutic loads may lie within, below, or beyond this range. Relatedly, responsive zone 1322 can be configured to recover to a predetermined or preset length, for example when clamp 1330 is removed or inactivated so that it no longer imparts a tension to bone fixation device 1320. In some embodiments, the present invention provides a bone fixation device that includes a machined responsive zone having a hardness

value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales.

**[0087]** The present invention also contemplates method embodiments for preparing bone fixation systems. For example, bone fixation system 1310 can be prepared by providing bone fixation device 1320 having responsive zone 1322, and inserting clamp 1330 at least partially within an internal lumen of bone fixation device 1320. A strain in responsive zone 1322 along the axial length of bone fixation device 1320 can be induced, maintained, or adjusted by setting clamp 1330 to the appropriate configuration. In some embodiments, bone fixation device 1320 is an intramedullary nail manufactured from NiTiNOL using a series of heat treatments to reduce the hardness from the bulk material. After the nail is manufactured an aging treatment can be supplied to the nail to induce a pseudoelastic response at body temperature (e.g. about 37° C) from the bulk material. The nail can be designed so that during an elongation method only the responsive element will stretch. This can allow for the main recovery of resorption to occur over a bone fracture site. The nail can be designed to recover immediately or quickly upon unloading, thus a clamp or other internal restrain system can be designed to package and maintain the stretched section of the nail.

**[0088]** Fig. 14 illustrates an external fixation device or jig device 1410 that is designed to maintain the stretched form of a bone fixation device when a clamp is removed therefrom. In some embodiments, a jig can be designed to maintain a stretched form of an intramedullary nail when an internal brace is removed therefrom. An external fixation device or jig can also provide functionality for implantation and locking screw placement. A jig can be preset so that screw holes of the nail, inside the bone, are aligned with screw holes in the jig, outside the leg, thus aiding placement of the locking screws through the soft tissues and bones. Fig. 15 shows a restrainer bar 1510 that can be used to fix an end cap relative to a jig and prevent or inhibit the nail from prematurely traveling up or within the intramedullary cavity. An intramedullary nail, an internal brace, and an end cap can be designed to slip through a restrainer bar until a flange of the end cap comes into contact with the bar. This can lock the intramedullary nail into place and can help align the jig into place. The jig may be configured in any of a variety of suitable shapes. For example, the jig may have a "U" shape.

**[0089]** In some embodiments, the present invention provides a method of deploying a bone fixation device in a patient. The bone fixation device 1610 shown in Fig. 16 is coupled with a clamp 1615 and includes a first portion 1620, a second portion 1630, and a responsive zone

1640 disposed therebetween. In some embodiments, this can represent the stretching and holding of a nail, whereby the nail is held fixed with an internal brace and an end cap. Clamp 1615 is partially disposed within an internal lumen of device 1610, where the internal lumen is disposed along an axial length of device 1610. Claim 1615 can be configured to induce or maintain a strain in responsive zone 1640 along the axial length of device 1610.

**[0090]** In an exemplary procedure, a surgeon performs standard techniques to prepare a patient's ankles and subtalar joints for ankle fusion. Fig. 17 depicts an external brace assembly 1710 that includes a jig 1720 and a restrainer bar 1730. Also shown here, relative to external brace assembly 1710, is a patient's lower leg 1740. The external brace assembly can assist the surgeon in properly aligning the ankle for surgery. Using a suitably placed guide wire, a surgeon can ream a hole in the intramedullary cavity to an appropriate size for an outer diameter of an intramedullary nail. In some embodiments, a jig can be placed over a patient's foot or other body part and attach to an intramedullary nail via an end cap at a distal end of the body part, for example at a distal end of the ankle.

**[0091]** As shown in Fig. 18, a bone fixation device 1810 can be placed adjacent or inside of a patient's bone 1820, and the first portion 1830 of device 1810 can be coupled with the restrainer bar 1830. In some embodiments, a stretched intramedullary nail construct is inserted into an intermediary cavity until the construct comes into contact with the restrainer bar. When contact is made between the construct and the bar, the restrainer bar can be used to align the nail into the proper position. Fig. 19 shows cross pins 1910 effectively coupling bone fixation device 1920 with a first location 1922 of patient's bone 1930 and stabilizing bone 1930 relative to the jig 1940. Cross pins can also be used to similarly fix a second location of the patient's bone to the bone fixation device and may contain a drill tip. Typically, the bone includes a fracture site disposed between the first and second bone locations. Bone fixation device 1920 can therefore be secured relative to jig 1940. In some embodiments, once an intramedullary nail is embedded and aligned inside of an intermediary canal, the surgeon can drill 2-3 holes to place cross pins across a proximal side of the tibia. The cross pins can be designed to provide a fixation point to transfer a load from an internal brace or nail to a jig. As seen in Fig. 20, once the cross pins are installed, the surgeon can preload the jig by removing the internal brace 2010 using an appropriate device such as a hex Allen key drill or hand tool. As the brace is removed the load is transferred through the intramedullary nail and end cap into the jig. The surgeon can monitor external brace and nail placement.

**[0092]** As illustrated in Fig. 21, after the internal brace has been removed and the load transferred across to the jig, the surgeon can install calcaneal screws 2110 first on the distal side of the ankle and then the proximal/tibial side locking screws can be placed. Bone screws can allow the nail to apply compression through the ankle. As seen in Fig. 22A and 22B, once the screws have been installed on both ends of the intramedullary nail, the end cap 2210 can be slowly loosened or removed using an appropriate tool, such as an Allan key wrench. The gradual unscrewing of end cap 2210 can transfer the load from the external brace 2220 to the intramedullary nail and ankle. In some embodiments, multiple screws may be installed prior to full end cap removal. As depicted in Fig. 23, after the end cap is fully removed, the cross bars or pins can be removed and replaced with bone screws 2310 to secure the remaining portion of the nail. Once the end cap is removed, the nail is in a dynamic state and applies a constant compressive force across the fusion site. A solid end cap can then be placed in the nail to secure the distal end. The surgeon can then suture the remaining incisions and prepare for post-op. The jig can then be dismantled and removed from the patient's foot. The nail is fully loaded and installed.

**[0093]** The techniques described herein can be used at any part of the body where dynamic axial compressive load is desired. For example, these approaches can be used for treating fractures in long bones fractures, including humeral, radial, tibial, and femoral fractures. Advantageously, these techniques provide for reproducible, true dynamic load, applied from an internal fixation device. Relatedly, these techniques can be used in opposite applications to apply a dynamic distraction force across a site. For example, such opposite applications can be used in limb lengthening procedures or for large "long bone defect implants" for example humeral replacement status post osteosarcoma resection in a non-skeletally mature patient. These systems and methods can also be used to apply controlled distraction/compression in increments activated by radio-frequency or magnetic manipulation. Moreover, the systems and methods can be used to couple a responsive zone with an existing or current implant such as a total hip or a total knee, to allow for greater surgeon margin or error with regard to limb length discrepancies status post joint replacement. In some embodiments, these techniques allow for adjustments months or years after an implant has been placed and the patients individual resorptive bone response has occurred. It is appreciated that these approaches can be implemented in a variety of controllable compression/distention practices involving an internal implant.

**[0094]** Figs. 24A-24H show a prototypical intramedullary nail with exemplary dimensions. Fig. 25 shows multiple hardness responses achievable from aging of NiTi. Hardness can be related to machinability of a material. In some embodiments, the softer a material is, the easier it is to machine. When a shape memory material such as NiTi behaves pseudoelastically (superelastic) the hardness is at a peak. Thus, the material can be difficult to machine. It may be helpful to age the material into a low hardness state, machine it, then erase the low hardness state and reprogram it to the high hardness state.

**[0095]** In one embodiment, a method of processing a shape material for use in a bone fixation device can include treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state, machining the shape memory material while it is in the second state, and treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state. Often, the treatments are designed to establish or optimize pseudoelastic or shape memory characteristics in the material. The first treatment may include a first heat cycle of at least 5 minutes, or in some cases of about 5 minutes to about 1.5 hours, at a temperature of about 600° C or above. It is appreciated that depending on the type of material being processed, the duration and temperature may vary. The first treatment may further include a second heat cycle of at least 5 minutes, or in some embodiments of about 5 minutes to about 1.5 hours, at a temperature of 300° C, 350° C, 400° C, 450° C, 500° C, or 550° C, or at a temperature within a range between about 200° C to about 550° C. In some embodiments, the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value. Relatedly, in some cases the first state has a first shape recovery value, the third state has a third shape recovery value, and the third shape recovery value is at least 95% of the first shape recovery value. The shape memory material can include a shape memory alloy such as a nickel titanium alloy, a copper zinc aluminum alloy, or a copper aluminum nickel alloy, or any precipitated shape memory alloy.

**[0096]** The third state can exhibit an optimal pseudoelastic or superelastic property profile for the shape memory material. Similarly, the third state may also exhibit an optimal shape memory state. In some embodiments, the first state can have a first hardness value, the third state can have a third hardness value, and a difference between the first hardness value and the third hardness value can be less than about 3 HRC on the Rockwell C Hardness Scale. In some cases, this difference may be less than about 10 HRC.

**[0097]** In another embodiment, the present invention provides a method of preparing a bone fixation device. The method includes providing a bone fixation device that includes a shape memory material, and machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenite or r-phase transition temperature. In some embodiments, during the machining the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite.

**[0098]** Embodiments of the invention have now been described in detail. However, it will be appreciated that the invention may be carried out in ways other than those illustrated in the aforesaid discussion, and that certain changes and modifications may be practiced within the scope of the appended claims. Accordingly, the scope of this invention is not intended to be limited by those specific examples, but rather is to be accorded the scope represented in the following claims.

WHAT IS CLAIMED IS:

1. A bone fixation device, comprising:

an elongate element comprising a responsive zone, the element adapted to be coupled to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone; and

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

2. The bone fixation device as in claim 1 wherein the responsive zone comprises a shape memory material.

3. The bone fixation device as in claim 2 wherein the responsive zone comprises Nitinol.

4. The bone fixation device as in claim 1 wherein the elongate element comprises Nitinol.

5. The bone fixation device as in claim 1 wherein the responsive zone is pseudoelastic at a body temperature.

6. The bone fixation device as in claim 1 wherein the responsive zone is generally centrally located in the elongate element, the responsive zone having a smaller overall cross section than a cross section of an end of the elongate element.

7. The bone fixation device as in claim 1 further comprising a coupler adapted to couple the elongate element to the bone.

8. The bone fixation device as in claim 7 wherein the coupler comprises at least one bone screw.

9. The bone fixation device as in claim 8 wherein the bone screw comprises a shape memory material.

10. The bone fixation device as in claim 1 wherein the elongate element comprises a plate, the plate having first and second end sections each comprising at least one hole adapted to receive a coupler therethrough to couple the plate to the bone.

11. The bone fixation device as in claim 1 wherein the elongate element comprises a bone screw.

12. The bone fixation device as in claim 1 wherein the elongate element comprises a nail.

13. A bone fixation system, comprising:

an elongate element comprising a responsive zone of shape memory material; and

a coupler adapted to couple the elongate element to the bone so that the responsive zone is positioned adjacent a fracture or fusion site in the bone.

14. The bone fixation system as in claim 13 further comprising a removable clamp, the removable clamp adapted to maintain the elongate element responsive zone in a desired position prior to coupling of the elongate element to the bone.

15. The bone fixation system as in claim 14 wherein the removable clamp is adapted to be removed from the elongate element after coupling of the elongate element to the bone.

16. The bone fixation system as in claim 13 wherein the responsive zone is adapted to apply a desired pressure to the bone when the elongate element is coupled to the bone.

17. The bone fixation system as in claim 13 wherein the responsive zone has a smaller cross-sectional area than a cross-sectional area of an end of the elongate element.

18. The bone fixation system as in claim 13 wherein the responsive zone comprises Nitinol.

19. The bone fixation system as in claim 13 wherein the elongate element comprises an intramedullary nail.

20. A method of stabilizing a fractured bone, the method comprising:

providing an elongate element comprising a responsive zone of a shape memory material; and

coupling the elongate element to the bone so that the responsive zone is positioned adjacent a fracture site in the bone;

wherein the responsive zone is adapted to apply a desired pressure to the bone when coupled thereto.

21. The method as in claim 20 further comprising:

applying a force to the elongate element to lengthen the responsive zone a desired amount;

maintaining the elongate element in the lengthened position;

coupling the elongate element to the bone so that the lengthened responsive zone is positioned adjacent the fracture site in the bone; and

releasing the elongate element.

22. The method as in claim 21 wherein applying the force to the elongate element to lengthen the responsive zone the desired amount corresponds to a desired compressive force to be applied to the fractured bone when the elongate element is coupled thereto.

23. The method as in clam 20 wherein coupling the elongate element to the bone comprises attaching a first coupler to the elongate element and to the bone on a first side of the fracture site, and attaching a second coupler to the elongate element and to the bone on a second side of the fracture site.

24. The method as in claim 20 wherein the shape memory material comprises Nitinol.

25. The method as in claim 20 wherein the elongate element comprises a bone screw.

26. The method as in claim 20 wherein the elongate element comprises an intramedullary nail.

27. A bone fixation system, comprising:

a bone fixation device having a responsive zone; and

a clamp configured to be received at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device;

wherein the clamp is adjustable between a first mode that induces or maintains a first amount of strain in the responsive zone along the axial length of the bone fixation device, and a second mode that induces or maintains a second amount of strain in the responsive zone along the axial length of the bone fixation device.

28. The bone fixation system as in claim 27, wherein the clamp is removably coupled with the bone fixation device.

29. The bone fixation system as in claim 27, wherein the clamp comprises an end cap and an internal brace.

30. The bone fixation system as in claim 29, wherein the end cap is adjustably engaged with the bone fixation device at an end cap first section, and is adjustably engaged with the internal brace at an end cap second section.

31. The bone fixation system as in claim 29, wherein the end cap is threadably engaged with the bone fixation device at an end cap first section, and is threadably engaged with the internal brace at an end cap second section.

32. The bone fixation system as in claim 29, wherein a central longitudinal axis defined by the internal lumen of the bone fixation device is collinear with a central longitudinal axis defined by the internal brace.

33. The bone fixation system as in claim 32, wherein the central longitudinal axis defined by the lumen of the bone fixation device is collinear with a central longitudinal axis defined by the end cap.

34. The bone fixation system as in claim 27, wherein the bone fixation device comprises a member selected from the group consisting of a nail, a screw, a plate, a pin, a compression rod, and a vertebral fixation device.

35. The bone fixation system as in claim 27, wherein the responsive zone comprises a physical characteristic similar to human tissue.

36. The bone fixation system as in claim 35, wherein the physical characteristic comprises an elastic modulus.

37. The bone fixation system as in claim 36, wherein the modulus comprises a value between a range from about 10 GPa to about 70 GPa.

38. The bone fixation system as in claim 35, wherein the human tissue comprises bone.

39. The bone fixation system as in claim 27, wherein the responsive zone comprises a shape memory material.

40. The bone fixation system as in claim 39, wherein the shape memory material comprises a shape memory alloy.

41. The bone fixation system as in claim 40, wherein the shape memory alloy comprises a member selected from the group consisting of a nickel alloy and a copper alloy.

42. The bone fixation system as in claim 40, wherein the shape memory alloy comprises a member selected from the group consisting of a nickel titanium alloy, a copper zinc aluminum alloy, and a copper aluminum nickel alloy.

43. The bone fixation system as in claim 27, wherein the responsive zone is configured to provide a predetermined compressive force across a bone fracture site when the clamp is removed or inactivated.

44. The bone fixation system as in claim 27, wherein the responsive zone is configured to recover to a preset length when the clamp is removed or inactivated.

45. A bone fixation device comprising a machined responsive zone having a hardness value within a range from about 5 HRB to about 60 HRC on the Rockwell B and C Hardness Scales.

46. The bone fixation device as in claim 45, wherein the responsive zone comprises a nickel titanium alloy.

47. A method of preparing a bone fixation system, comprising:

providing a bone fixation device having a responsive zone;

inserting a clamp at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device; and

inducing or maintaining a strain in the responsive zone along the axial length of the bone fixation device with the clamp.

48. The method of preparing a bone fixation system as in claim 47, comprising threadably engaging an end cap of the clamp with the bone fixation device at an end cap first section, and threadably engaging the end cap with an internal brace of the clamp at an end cap second section.

49. A method of deploying a bone fixation device in a patient, comprising:

providing a bone fixation device having a first portion, a second portion, and a responsive zone disposed therebetween;

inserting a clamp at least partially within an internal lumen of the bone fixation device, the internal lumen disposed along an axial length of the bone fixation device;

inducing or maintaining a strain in the responsive zone along the axial length of the bone fixation device with the clamp;

coupling the bone fixation device with a bone of the patient by attaching the first portion of device to a first bone location, and attaching the second portion of the device to a second bone location, wherein the bone includes a fracture site disposed between the first and second bone locations;

securing the bone fixation device to an external brace assembly;

removing the clamp from the bone fixation device; and

removing the external brace assembly from the bone fixation device;

wherein the bone fixation device remains coupled with the patient's bone, and the responsive zone is allowed to relax so as to transmit a compressive force to the fracture or fusion site of the patient's bone via the bone fixation device.

50. A method of processing a shape memory material for use in a bone fixation device, comprising:

treating the shape memory material with a first treatment to transform the shape memory material from a first state to a second state;

machining the shape memory material while it is in the second state; and

treating the machined shape memory material with a second treatment to transform the shape memory material from the second state to the third state.

51. The method as in claim 50, wherein the first treatment comprises a first heat cycle of at least 5 minutes at a temperature of about 600° C.

52. The method as in claim 50, wherein the first treatment further comprises a second heat cycle of at least 5 minutes at a temperature within a range from about 200° C to about 550° C.

53. The method as in claim 50, wherein the first state has a first hardness value, the second state has a second hardness value, and the first hardness value is between about 100% and about 500% of the second hardness value.

54. The method as in claim 50, wherein the first state has a first shape recovery value, the third state has a third shape recovery value, and the third shape recovery value is at least 95% of the first shape recovery value.

55. The method as in claim 50, wherein the shape memory material comprises a shape memory alloy selected from the group consisting of a nickel titanium alloy, a copper zinc aluminium alloy, and a copper aluminium nickel alloy.

56. The method as in claim 50, wherein the third state comprises an optimal pseudoelastic property profile for the shape memory material.

57. The method as in claim 50, wherein the first state has a first hardness value, the third state has a third hardness value, and a difference between the first hardness value and the third hardness value is less than about 3 HRC on the Rockwell C Hardness Scale.

58. A method of preparing a bone fixation device, comprising:

providing a bone fixation device comprising a shape memory material; and

machining the shape memory material while the temperature of the shape memory material is maintained at or above an austenitic transition temperature.

59. The method as in claim 58, wherein during the machining the shape memory material remains in a stiff austenite phase and does not transition to a malleable austenite phase.

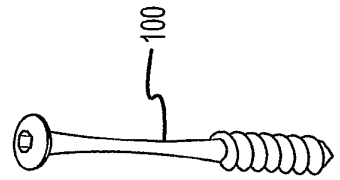



FIG.1A

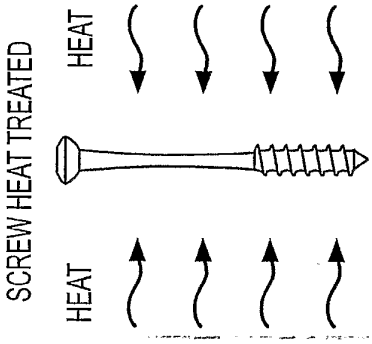



FIG.1C

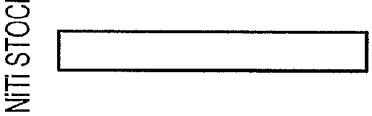



FIG.1B

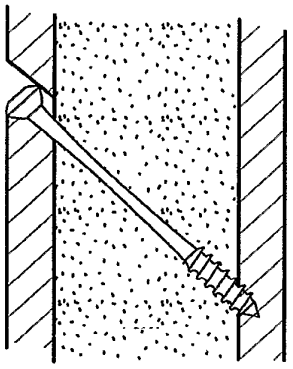



FIG.2C

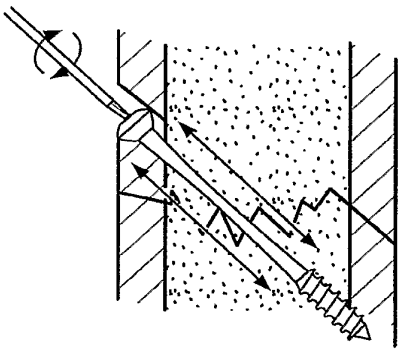



FIG.2B

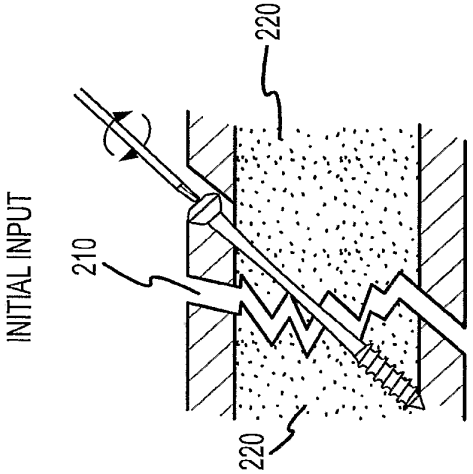



FIG.2A

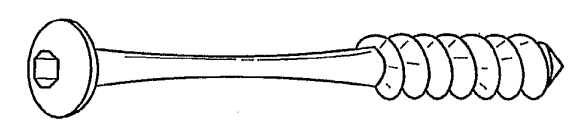


FIG.3F

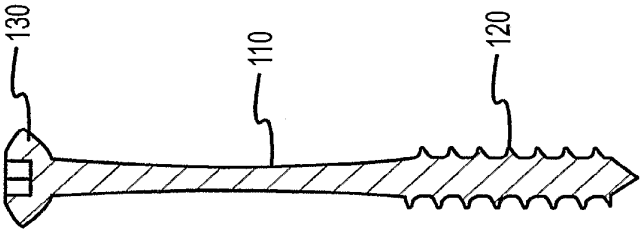



FIG.3D

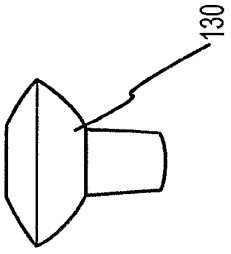



FIG.3B

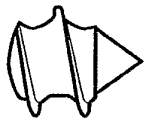


FIG.3C

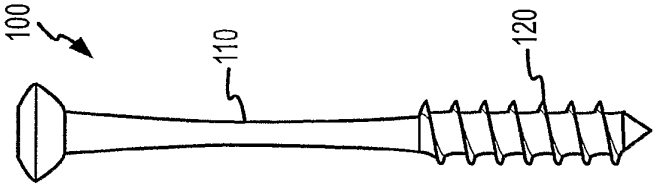



FIG.3A

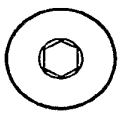


FIG.3E

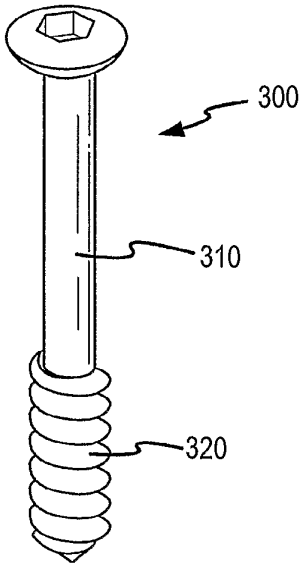



FIG.3G

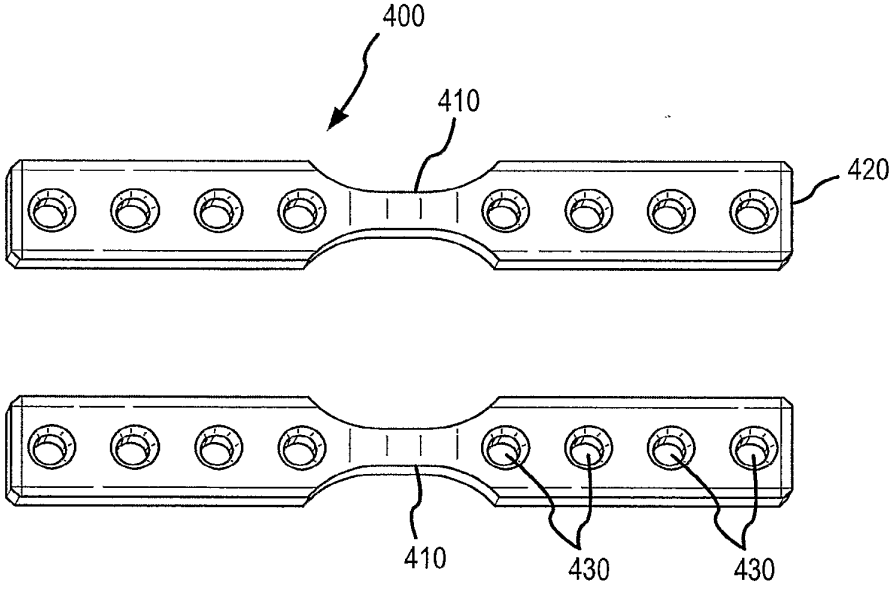
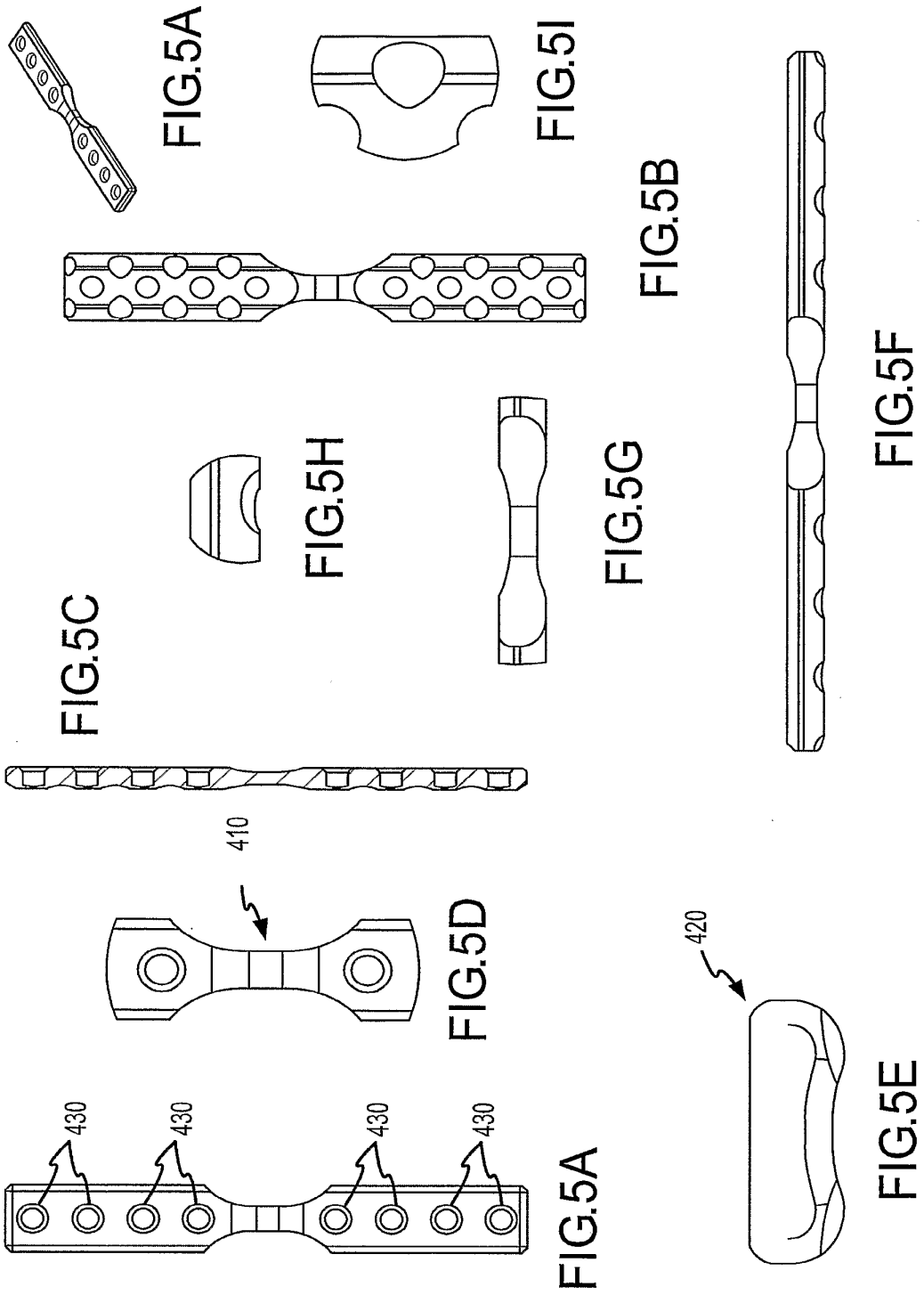



FIG.4


FIG.5A
FIG.5I
FIG.5B
FIG.5H
FIG.5G
FIG.5F
FIG.5C
410
FIG.5D
420
FIG.5E
430
430
430
430
FIG.5A

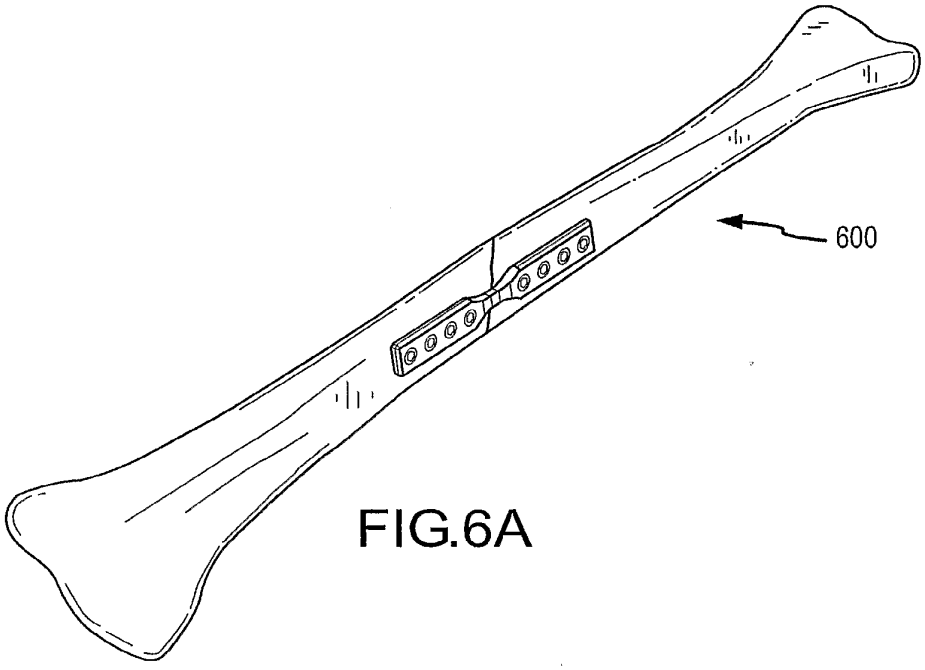



FIG.6A

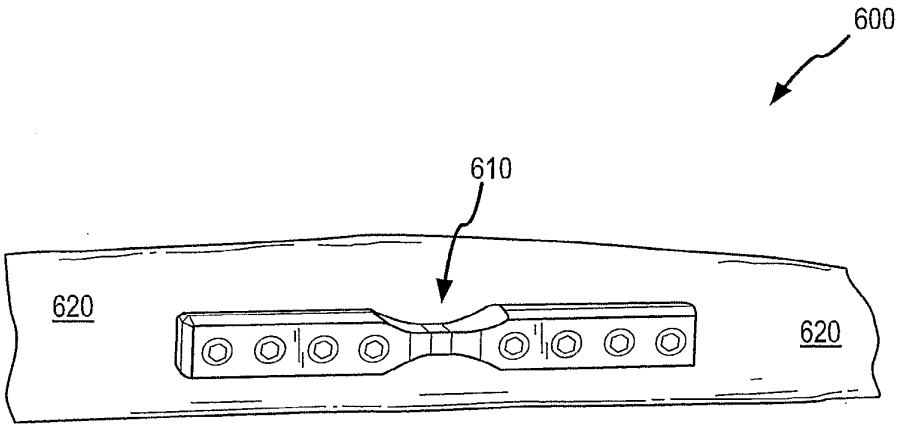



FIG.6B

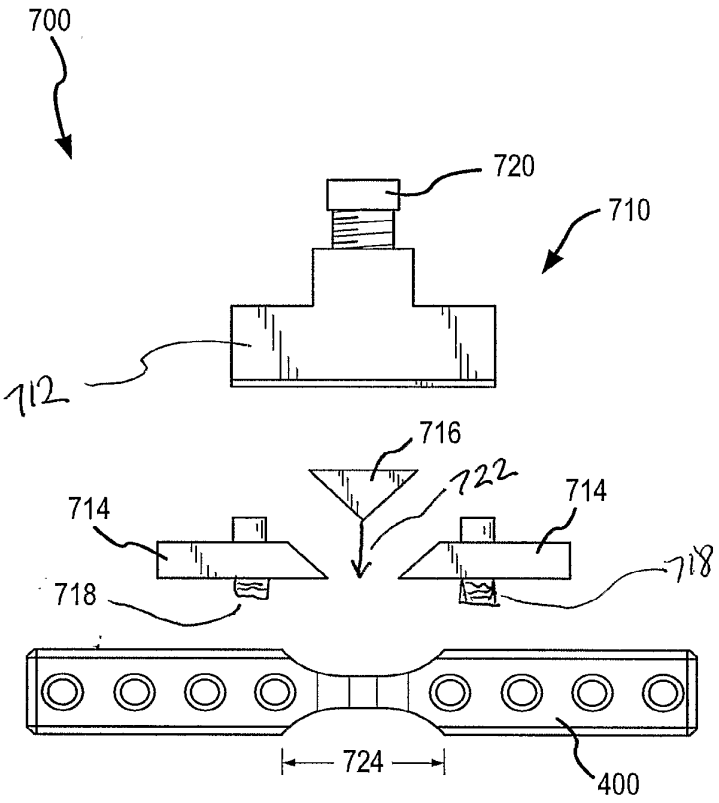



FIG.7A

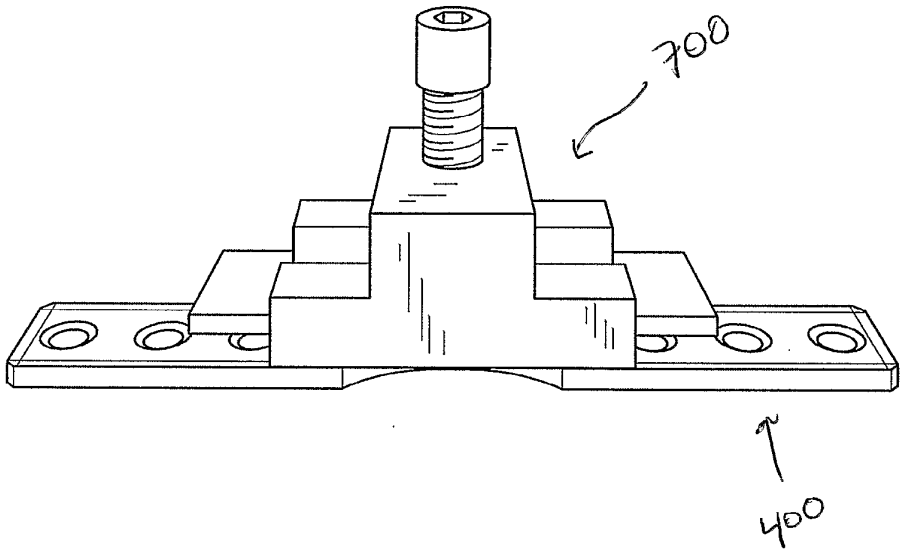



FIG.7B

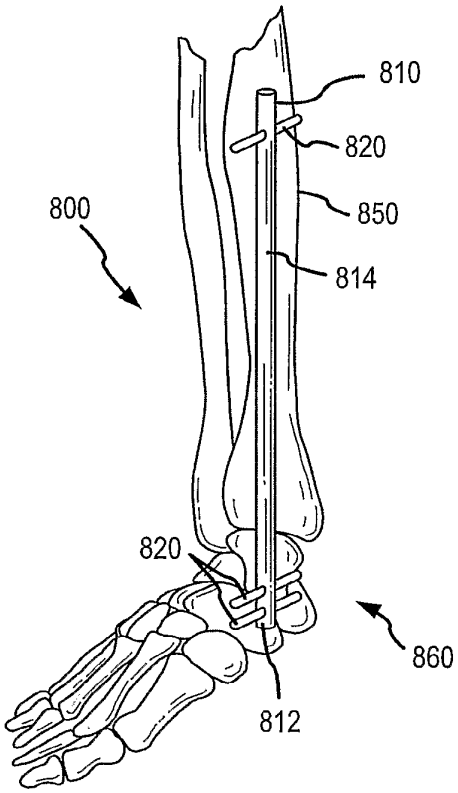
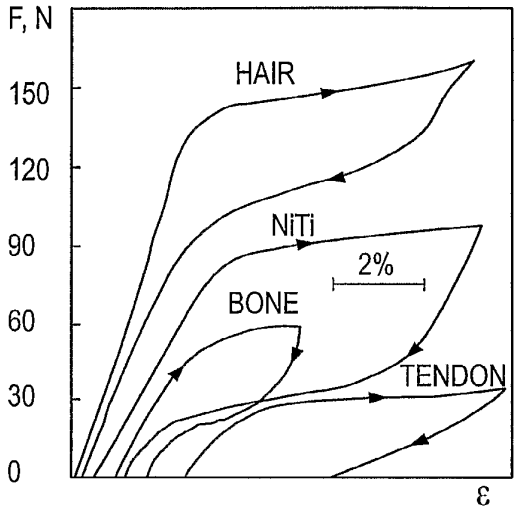



FIG.8




THE STRESS-STRAIN DIAGRAM FOR LIVING TISSUES AND A NiTi ALLOY [I].

FIG.9A

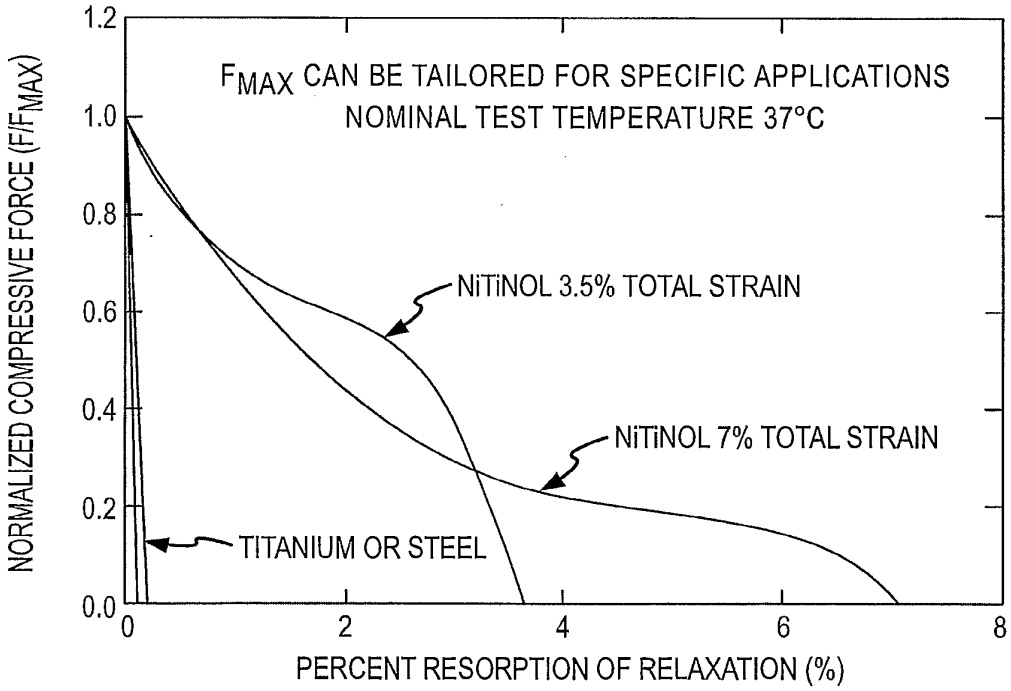



FIG.9B

$A=F_R/\sigma_R$ (1) $L=\Delta L/\varepsilon$ (2)

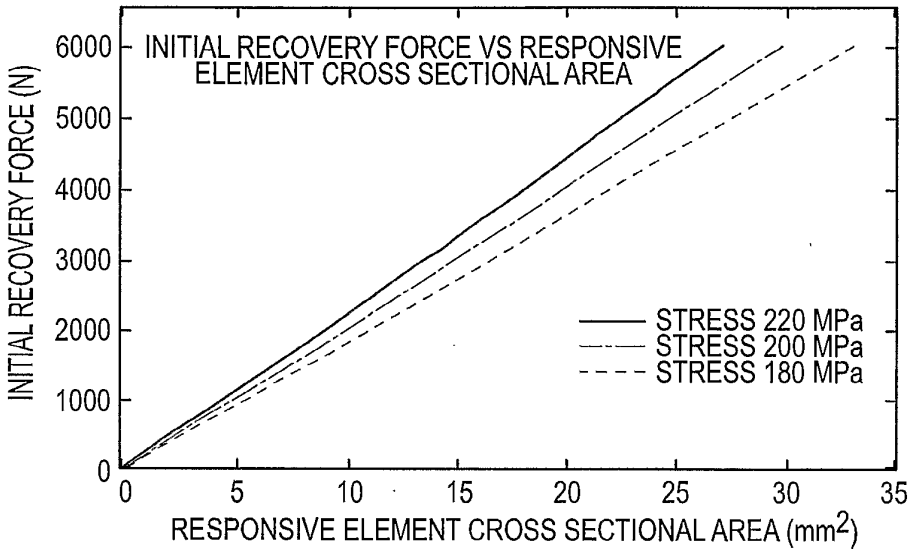



FIG.10A

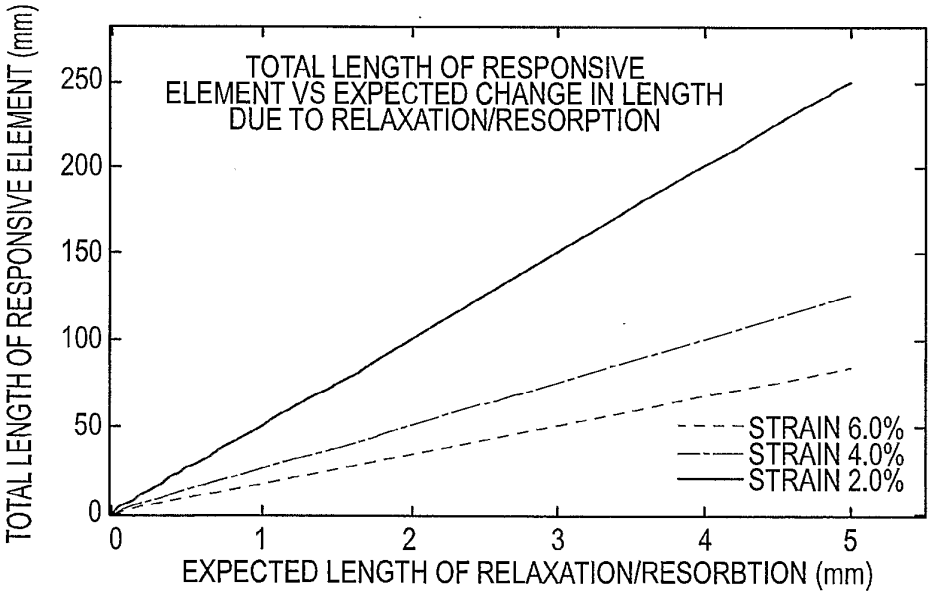



FIG.10B

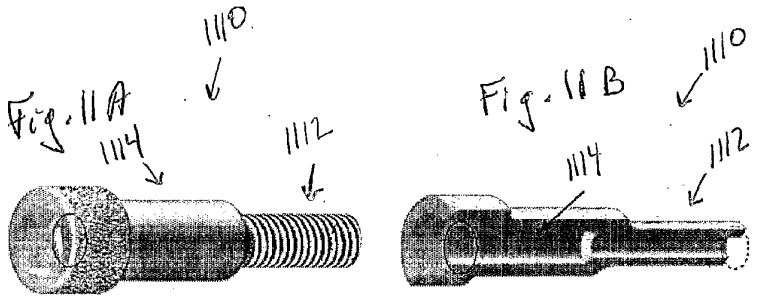



Fig. 11A

Fig. 11B

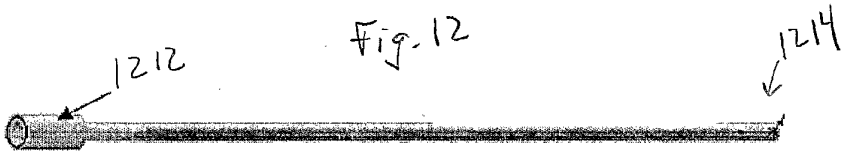



Fig. 12

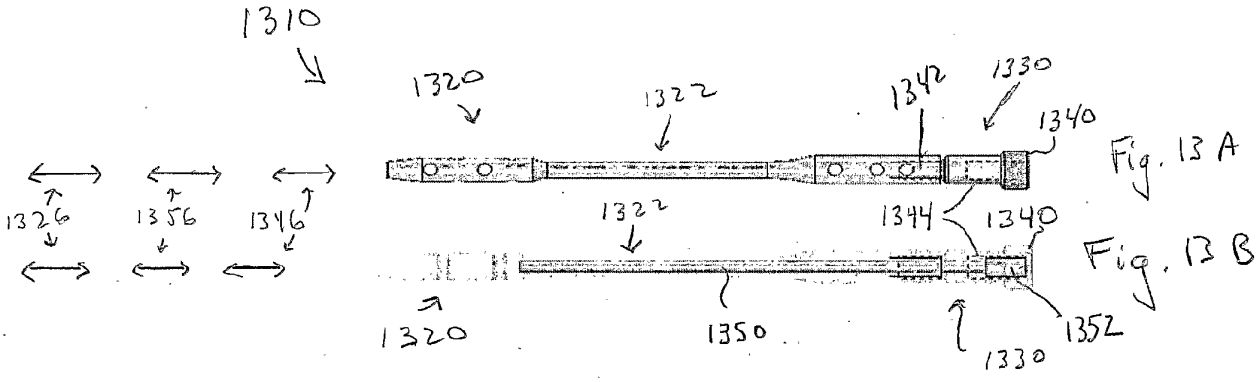



Fig. 13A

Fig. 13B

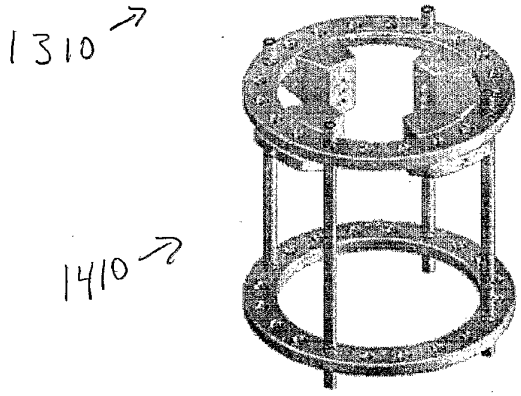



Fig. 14

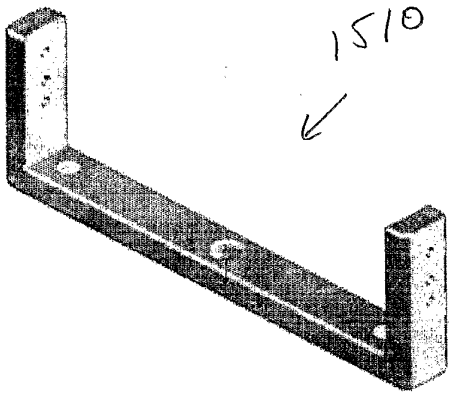
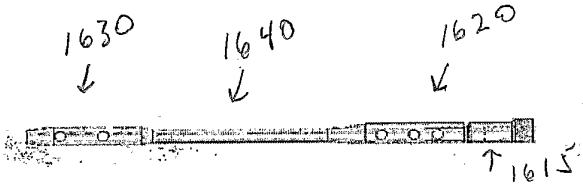



Fig. 15

Fig. 16



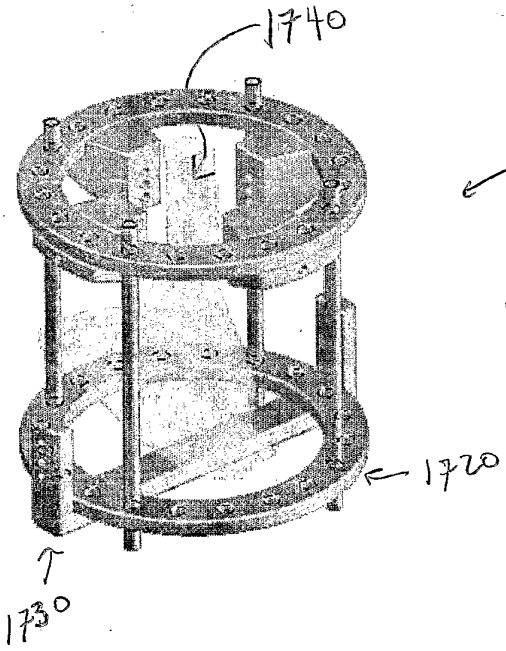




Fig. 17

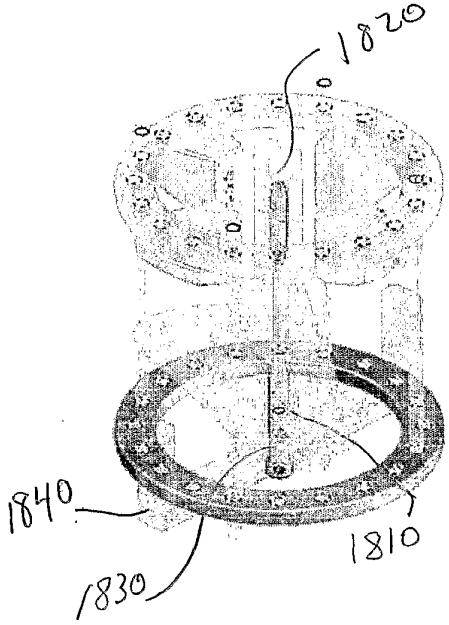



Fig. 18

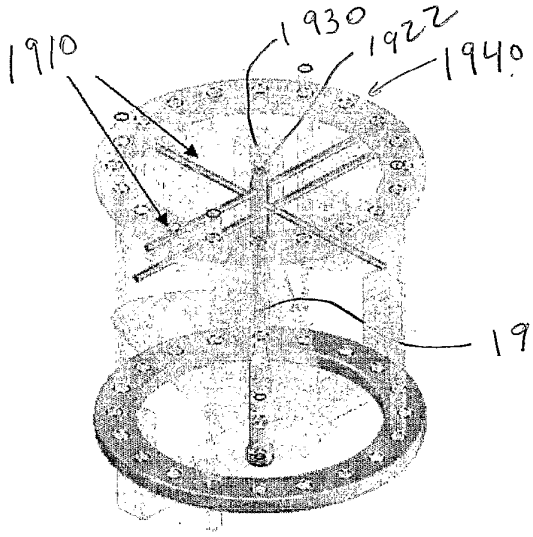



Fig. 19

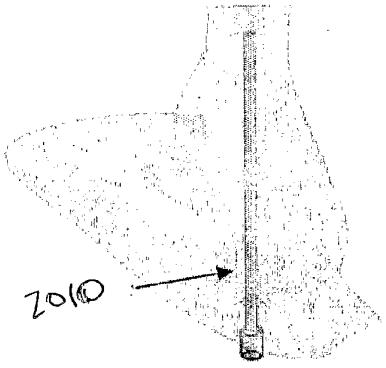



Fig. 20

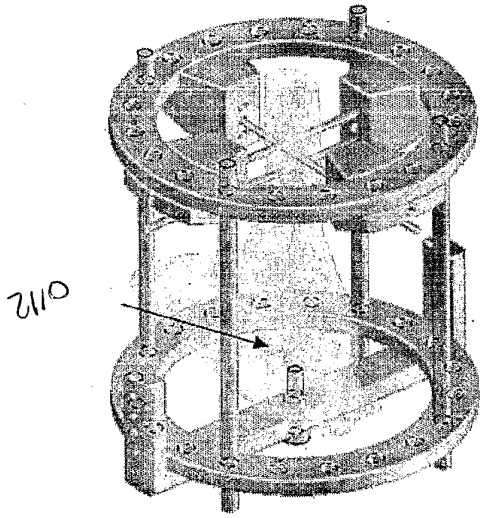



Fig. 21

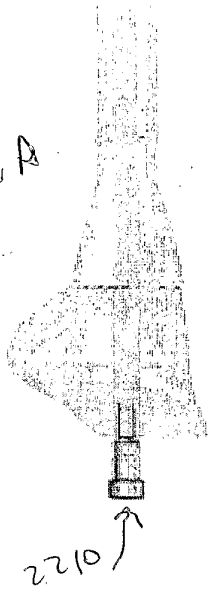



Fig. 22A

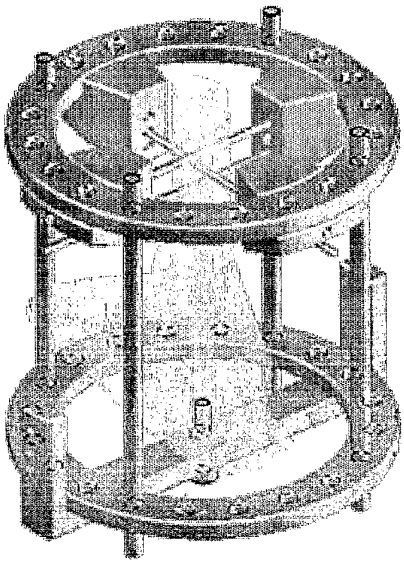



Fig. 22B

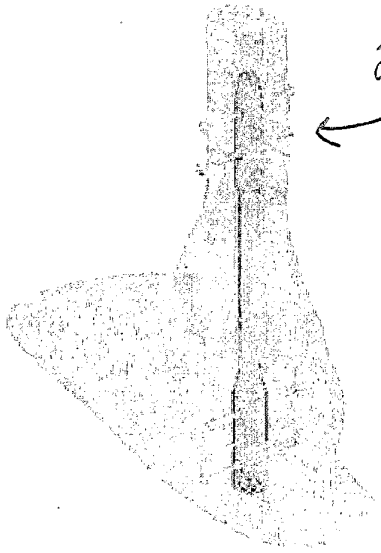



Fig. 23

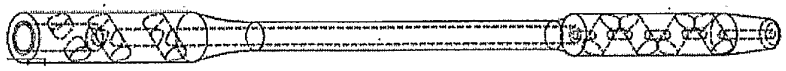


Fig. 24H

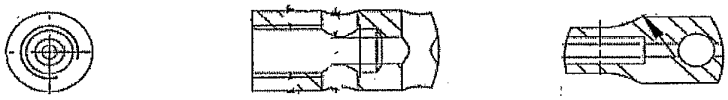


Fig. 24E

Fig. 24F

Fig. 24G

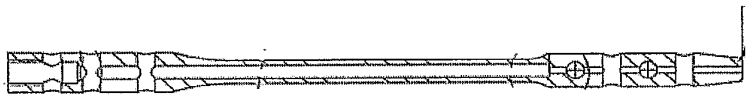


Fig. 24D



Fig. 24B

Fig. 24C

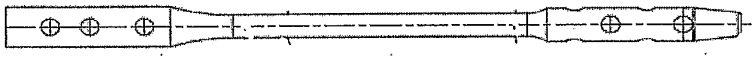
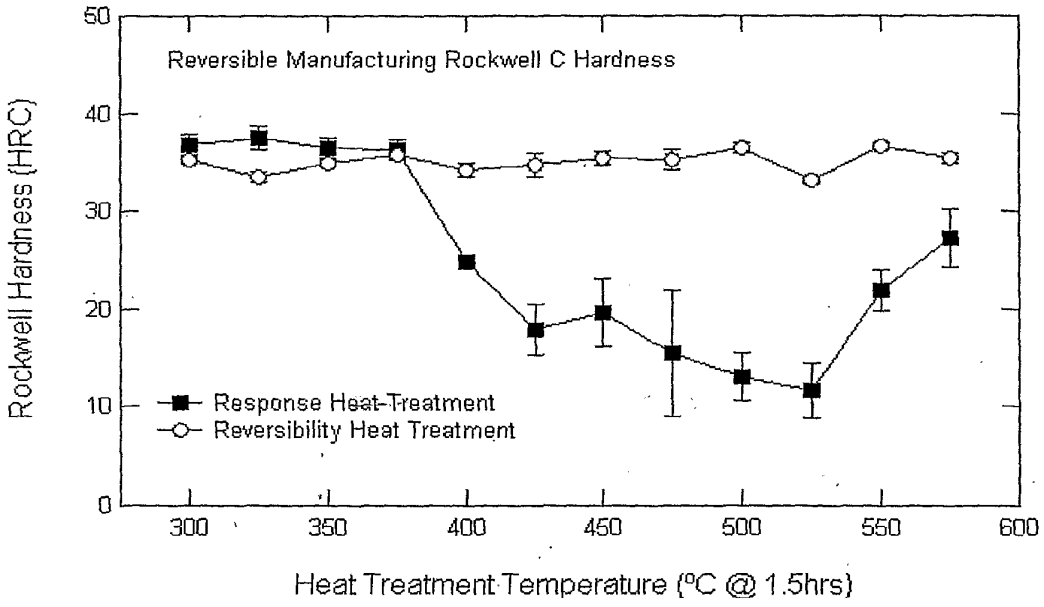


Fig. 24A

Fig. 25


Reversible Manufacturing Rockwell C Hardness
Rockwell Hardness (HRC)
Heat Treatment Temperature (°C @ 1.5hrs)
Response Heat-Treatment
Reversibility Heat Treatment
0
10
20
30
40
50
300
350
400
450
500
550
600

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/15207

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/56**( 2006.01)

USPC: 606/72
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/72, 61, 73

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5,120,175 A (ARBEGAST et al) 09 June 1992 (09.06.1992), see whole document. | 1-59 |
| X | US 6,688,828 B1 (POST) 10 February 2004 (10.02.2004), see whole document. | 1-59 |
| A | US 6,637,995 B1 (WHITE) 28 October 2003 (28.10.2003), see whole document. | 1-59 |
| A | US 5,265,456 A (KENNEDY et al) 30 November 1993 (30.11.1993), see whole document. | 1-59 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search
09 July 2006 (09.07.2006)

Date of mailing of the international search report
18 AUG 2006

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Authorized officer
Eduardo Robert

Telephone No. 000-0000

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | 12658680 |
| **Filing Date:** | 11-Feb-2010 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Filer:** | Frank Morris/Vincent Ferraro |
| **Attorney Docket Number:** | 277-042 |

Filed as Small Entity

## Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Basic Filing:** | | | | |
| **Pages:** | | | | |
| **Claims:** | | | | |
| **Miscellaneous-Filing:** | | | | |
| **Petition:** | | | | |
| **Patent-Appeals-and-Interference:** | | | | |
| **Post-Allowance-and-Post-Issuance:** | | | | |
| **Extension-of-Time:** | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Miscellaneous:** | | | | |
| Submission- Information Disclosure Stmt | 1806 | 1 | 180 | 180 |
| | | **Total in USD ($)** | | **180** |

| Electronic Acknowledgement Receipt | |
|---|---|
| **EFS ID:** | 12460050 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Frank Morris/Vincent Ferraro |
| **Filer Authorized By:** | Frank Morris |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 03-APR-2012 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 16:34:58 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

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| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | $180 |
| RAM confirmation Number | 3163 |
| Deposit Account | 230420 |
| Authorized User | |
| The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:<br>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)<br>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) | |

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## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | | IDS_277_042.pdf | 557167<br>24c702833a2ef56452b980e21d4b6574ff818a7b | yes | 16 |

**Multipart Description/PDF files in .zip description**

| Document Description | Start | End |
|---|---|---|
| Miscellaneous Incoming Letter | 1 | 1 |
| Information Disclosure Statement (IDS) Form (SB08) | 2 | 16 |

**Warnings:**

**Information:**

| | | | | | |
|---|---|---|---|---|---|
| 2 | Foreign Reference | WO2007131287.pdf | 1456312<br>a45b5e219c5392eded265af21c1958f3cdc96984 | no | 35 |

**Warnings:**

**Information:**

| | | | | | |
|---|---|---|---|---|---|
| 3 | Foreign Reference | WO2006116164.pdf | 2769418<br>6cee0d7582da9d6c0c846d55516f4aceb1b442fc | no | 54 |

**Warnings:**

**Information:**

| | | | | | |
|---|---|---|---|---|---|
| 4 | Fee Worksheet (SB06) | fee-info.pdf | 29416<br>61c24cb8d6ea6eea74dd168f48c1be521a05d63c | no | 2 |

**Warnings:**

**Information:**

| | |
|---|---|
| **Total Files Size (in bytes):** | 4812313 |

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**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

Electronically filed April 3, 2012

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| In re Application of: | Jeff Tyber, et al. | Confirmation No.: | 1344 |
| Serial No.: | 12/658,680 | Group Art Unit: | 3733 |
| Filed: | February 11, 2010 | Examiner: | Bray |
| For: | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: | 277-042 |

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

**COVER LETTER**

S I R:

Applicants submit herewith an Information Disclosure Statement pursuant to 37 CFR § 1.97(c)(2). No admission is made that any of the references cited on the attached Information Disclosure Statement qualify as prior art under 35 U.S.C. §§ 102 and 103 or are material to patentability.

Applicants submit herewith the fee of $180 as set forth under 37 CFR 1.17(p). If a petition and/or an additional fee is 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.

Respectfully submitted,

Date: April 3, 2012

Francis E. Morris
Reg. No. 24,615
Ward & Zinna, LLC
382 Springfield Avenue, Suite 300
Summit, New Jersey 07901
(908) 277-3333

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 05/03/2012

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/03/2012 | 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) | |
|---|---|---|---|
| | 12/658,680 | TYBER 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 *28 March 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) *1-12,14-16,18,20-53,55-61,63-65 and 67-81* is/are pending in the application.

5a) Of the above claim(s) *12-19,24-50,61-68 and 73-81* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-11,20-23,51-53,55-60 and 69-72* 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 *28 March 2012* 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)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/3/2012*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Newly submitted amended claims 1-11, 20-23, 51-53, 55-60, and 69-72 and new claims 75-81 are directed to an invention and species that is independent or distinct from the invention originally claimed for the following reasons: the elected invention in claims 1-25, 51-74 (8/15/2011) do not include a "first screw", a "second screw", a "first longitudinal axis", a "second longitudinal axis", a "terminal end", a "third axis".

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly amended claims 1-12, 14-16, 18, 20-23, 75-81 and 51-53, 55-61, 63-65, 67-72 are withdrawn from consideration as being directed to a non-elected invention and species. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly claims 12-19, 24-25, 61-68, and 73-74, which were withdrawn in the prior office action, remain withdrawn.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 20-23 are provisionally rejected on the ground of nonstatutory double patenting over claims 114-136 of copending Application No. 12/456,808. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 114, 115, 123 discloses an intramedullary assembly for bone fusion, comprising: a lag screw member, wherein the lag screw member comprises a first elongated body (claim 114, line 2-3), and wherein the first elongated body includes a first threaded portion at a first end (claim 115, lines 1-2) and a bulbous portion at a second end (claim 114, line 2-3); and a tapered screw member for coupling to the lag screw member (claim 114, line 4-5), wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end (Claim 123 line 103), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (claim 114, line 5) disposed at an end of the tubular portion.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 112***

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

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 14-16, 18, 20-23, 75-81 and 51-53, 55-61, 63-65, 67-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed provides no support for claims 1-12, 14-16, 18, 20-23, 75-81 and 51-53, 55-61, 63-65, 67-72, for example: "first screw", a "second screw", a "first longitudinal axis", a "second longitudinal axis", a "terminal end", or a "third axis".

***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 negatived 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 1-10, 20, 22-23 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.

Regarding claim 1, Chang discloses an intramedullary assembly for bone fusion, comprising: a lag screw member (11), wherein the lag screw member comprises a first elongated body, and wherein the first elongated body (Fig 4) includes a first threaded portion (111) at a first end and a bulbous portion (112) at a second end; and a tapered screw member (10) for coupling to the lag screw member (11), wherein the tapered screw member includes a second elongated body (Fig 4), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (103) disposed at an end of the tubular portion. Chang does not disclose that the second elongated body comprises a second threaded portion at a third end. Stark discloses a second elongated body (intramedullary rod) 74 with a threaded portion in order to better "draw the pin into the bone." (col 6, ll 19-25.) It would have been obvious to one of ordinary skill in art at the time of the invention to construct the device of Chang with a threaded second elongated body to draw the pin into the bone.

Regarding claim 2, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that lag screw member (11) is slideably coupled to the tapered screw member and makes a fixed angle (Fig 4) with the tapered screw member (10).

Regarding claim 3, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the fixed angle is in the range of

about 0 to about 90 degrees. The angle in figure 4 appears to be approximately 90 degrees.

Regarding claims 4 and 5, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the bulbous (112) portion comprises a taper (Fig 4) adapted for providing an interference fit or lock with said distal member (10).

Regarding claim 6, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is cannulated having a cross-section with said first elongated body. Para 0020.

Regarding claims 7-9, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the bulbous portion (112) further includes an orifice (113) with a hexagonal shape (Fig. 3) longitudinally coextensive with a length of the bulbous portion (112), adapted for receiving a complementary shaped end (442) of an instrument (40).

Regarding claim 10, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the first threaded portion (111) contains a plurality of bone threads (111) on an outer surface of the first threaded portion (111).

Regarding claim 20, Chang in view of Stark discloses the invention as claimed and discussed above but does not disclose that the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion. However, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to put a plurality of threads (111) on a second threaded portion on an end of a shaft, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Regarding claims 22 and 23, Chang in view of Stark discloses the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) and the tapered screw member (10) are provided for insertion into at least a first medullary canal of bone. (Fig 5)

Claims 11 and 21 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 Start and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al. ("Culbert").

Regarding claims 11 and 21, Chang in view of Stark discloses the invention as claimed and discussed above but does not disclose that the second threaded portion comprises a self-tapping edge adapted for removing bone material. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in order to omit a separate step of drilling into the bone. Para 0226. 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 self-tapping screw in view of Culbert to eliminate a step of drilling into the bone, which removes bone material.

Claims 51- 53, 55-59, 69, 71-72 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 and in further view of U.S. Patent 6,669,700 to Farris et al. ("Farris"),

Regarding claims 51 and 69, Chang discloses an intramedullary assembly for bone fusion, comprising: a lag screw member (11), wherein the lag screw member comprises a first elongated body, and wherein the first elongated body (Fig 4) includes a first threaded portion (111) at a first end and a bulbous portion (112) at a second end; and a tapered screw member (10) for coupling to the lag screw member (11), wherein the tapered screw member includes a second elongated body (Fig 4), a tubular portion at a fourth end, wherein the tubular portion comprises an opening (103) disposed at an end of the tubular portion. Chang does not disclose that the second elongated body comprises a second threaded portion at a third end. Stark discloses a second elongated body (intramedullary rod) 74 with a threaded portion in order to better "draw the pin into the bone." (col 6, ll 19-25.) It would have been obvious to one of ordinary skill in art at the time of the invention to construct the device of Chang with a threaded second elongated body to draw the pin into the bone.

Chang does 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 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.

Regarding claim 52, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is slideably coupled to the tapered screw member and makes an angle (Fig 4) with the tapered screw member (10).

Regarding claim 53, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the fixed angle is in the range of about 0 to about 90 degrees. The angle in figure 4 appears to be approximately 90 degrees.

Regarding claim 55, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) is cannulated having a cross-section with said first elongated body. Para 0020.

Regarding claims 56-58, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the bulbous portion (112) further includes an orifice (113) with a hexagonal shape (Fig. 3) longitudinally coextensive with a length of the bulbous portion (112), adapted for receiving a complementary shaped end (442) of an instrument (40).

Regarding claim 59, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the first

threaded portion (111) contains a plurality of bone threads (111) on an outer surface of the first threaded portion (111).

Regarding claims 71 and 72, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above and Chang further discloses that the lag screw member (11) and the tapered screw member (10) are provided for insertion into at least a first medullary canal of bone. (Fig 5)

Claims 60 and 70 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 and in further view of U.S. Patent 6,669,700 to Farris et al. ("Farris") and in further view of U.S. Patent Publication 2009/0149857 to Culbert et al. ("Culbert").

Regarding claims 60 and 70, Chang in view of Stark and in further view of Farris disclose the invention as claimed and discussed above but do not disclose that the second threaded portion comprises a self-tapping edge adapted for removing bone material. Culbert discloses a "self-tapping or self-drilling bone stabilization device" in order to omit a separate step of drilling into the bone. Para 0226. 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 self-tapping screw in view of Culbert to eliminate a step of drilling into the bone, which removes bone material.

## ***Conclusion***

**THIS ACTION IS MADE FINAL.** 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 mailing 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**.**

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

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**
**( Not for submission under 37 CFR 1.99)**

| | |
|---|---|
| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Tyber, Jeff |
| Art Unit | 3733 |
| Examiner Name | Bray, Stuart Samuel |
| Attorney Docket Number | 277-042 |

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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| | | | | | | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Attorney Docket Number | 277-042 |

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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2]i | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
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| | 1 | WO 2007131287 | WO | | 2007-11-22 | Slater | | ☐ |
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**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | 1 | | ☐ |

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**EXAMINER SIGNATURE**

| Examiner Signature | /Stuart Bray/ | Date Considered | 04/25/2012 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.



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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Francis E. Morris/ | Date (YYYY-MM-DD) | 2012-04-03 |
|---|---|---|---|
| Name/Print | Francis E. Morris | Registration Number | 24615 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| SEARCHED | | | |
|---|---|---|---|
| Class | Subclass | Date | Examiner |
| 606 | 54, 62, 80, 96 | 9/21/2011 | SSB |
| 606 | 64, 65 | 9/23/2011 | SSB |
| | UPdated | 4/27/2012 | SSB |

| SEARCH NOTES | | |
|---|---|---|
| Search Notes | Date | Examiner |
| Performed inventor search | 9/21/2011 | SSB |

| INTERFERENCE SEARCH | | | |
|---|---|---|---|
| Class | Subclass | Date | Examiner |
| | | | |

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| /STUART S BRAY/<br>Examiner.Art Unit 3733 | |

**EAST Search History**

**EAST Search History (Prior Art)**

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
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| S1 | 3185 | (606/54,62,80,96).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:10 |
| S2 | 0 | S1 and (semi-sperical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S3 | 50 | S1 and (semi-spherical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S4 | 275 | screw and (semi-spherical adj head) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:15 |
| S5 | 92 | S4 and bone | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:16 |
| S6 | 83 | "6322562" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:17 |
| S7 | 1 | "20020045899" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:19 |
| S8 | 11 | "7175626" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:33 |
| S9 | 0 | 606/64,65 | USPAT | OR | OFF | 2011/09/22 16:04 |
| S10 | 0 | 606/64,65 | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/22 16:04 |
| S11 | 593 | (606/64,65).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/22 16:04 |
| S12 | 3187 | (606/54,62,80,96).CCLS. | US-PGPUB; | OR | OFF | 2011/09/23 10:22 |

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| | | | USPAT; USOCR | | | |
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**EAST Search History (Interference)**

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# BIB DATA SHEET

**CONFIRMATION NO. 1344**

| SERIAL NUMBER | FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010<br>RULE | 606 | 3733 | 277-042 |

**APPLICANTS**

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**** CONTINUING DATA **************************

This application is a CIP of 12/456,808 06/23/2009
which claims benefit of 61/132,932 06/24/2008

**** FOREIGN APPLICATIONS **************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
03/05/2010

| Foreign Priority claimed ☐ Yes ☑ No<br>35 USC 119(a-d) conditions met ☐ Yes ☐ No<br>Verified and Acknowledged /STUART SAMUEL BRAY/ Examiner's Signature | ☐ Met after Allowance<br>Initials | STATE OR COUNTRY | SHEETS DRAWINGS | TOTAL CLAIMS | INDEPENDENT CLAIMS |
|---|---|---|---|---|---|
| | | PA | 20 | 74 | 3 |

**ADDRESS**

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901
UNITED STATES

**TITLE**

Intraosseous intramedullary fixation assembly and method of use

| FILING FEE RECEIVED | | |
|---|---|---|
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BIB (Rev. 05/07).

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | | | | | | |
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| | 2 | ÷ | ✓ | ✓ | | | | | | |
| | 3 | ÷ | ✓ | ✓ | | | | | | |
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| | 5 | ÷ | ✓ | ✓ | | | | | | |
| | 6 | ÷ | ✓ | ✓ | | | | | | |
| | 7 | ÷ | ✓ | ✓ | | | | | | |
| | 8 | ÷ | ✓ | ✓ | | | | | | |
| | 9 | ÷ | ✓ | ✓ | | | | | | |
| | 10 | ÷ | ✓ | ✓ | | | | | | |
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| | 21 | ÷ | ✓ | ✓ | | | | | | |
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| | 23 | ÷ | ✓ | ✓ | | | | | | |
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| | 34 | ÷ | N | N | | | | | | |
| | 35 | ÷ | N | N | | | | | | |
| | 36 | ÷ | N | N | | | | | | |

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| | STUART S BRAY | 3733 |

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|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | | | | | | |
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| | 49 | ÷ | N | N | | | | | | |
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| | 54 | ÷ | - | - | | | | | | |
| | 55 | ÷ | ✓ | ✓ | | | | | | |
| | 56 | ÷ | ✓ | ✓ | | | | | | |
| | 57 | ÷ | ✓ | ✓ | | | | | | |
| | 58 | ÷ | ✓ | ✓ | | | | | | |
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| | 70 | ÷ | ✓ | ✓ | | | | | | |
| | 71 | ÷ | ✓ | ✓ | | | | | | |
| | 72 | ÷ | ✓ | ✓ | | | | | | |

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| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | | | | | | |
| | 73 | ÷ | N | N | | | | | | |
| | 74 | ÷ | N | N | | | | | | |
| | 75 | | | N | | | | | | |
| | 76 | | | N | | | | | | |
| | 77 | | | N | | | | | | |
| | 78 | | | N | | | | | | |
| | 79 | | | N | | | | | | |
| | 80 | | | N | | | | | | |
| | 81 | | | N | | | | | | |

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 08/01/2012

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 08/01/2012 | 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.

| **Applicant-Initiated Interview Summary** | **Application No.** | **Applicant(s)** | |
|---|---|---|---|
| | 12/658,680 | TYBER ET AL. | |
| | **Examiner** | **Art Unit** | |
| | STUART S. BRAY | 3733 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *STUART S. BRAY*. (3)_____.

(2) _____. (4)_____.

Date of Interview: *25 July 2012*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☒112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1 and 51*.

Identification of prior art discussed: *Chang*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

*Applicants discussed whether the 112 rejection could be overcome with specific annotation of the claims to refer to where in the specification support could be found. Examiner stated that properly mapped reference to the specification could overcome the 112 rejection. Examiner also directed the Applicant to additional classes and subclasses to search before submitting new claims: 606/305-308,310,319. These classes relate to screws extending through other screws*.

**Applicant recordation instructions:** The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

**Examiner recordation instructions**: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

| /STUART S BRAY/<br>Examiner, Art Unit 3733 | /Alvin J. Stewart/<br>Primary Examiner, AU 3774 |
|---|---|

# Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

**Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

OPAP
OCT 09 2012
PATENT & TRADEMARK OFFICE

Aff/RCE/#

PTO/SB/30 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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# Request for Continued Examination (RCE) Transmittal

Address to:
Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

| | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jeff Tyber |
| Art Unit | 3733 |
| Examiner Name | Stuart Samuel Bray |
| Attorney Docket Number | 277-042 |

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☑ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. 23-0420.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☑ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☐ Payment by credit card (Form PTO-2038 enclosed)

10/12/2012 SDIRETA1 00000029 230420 12658680
01 FC:2801 465.00 DA

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

***SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED***

| | | | |
|---|---|---|---|
| Signature | /Francis E. Morris/ | Date | October 3, 2012 |
| Name (Print/Type) | Francis E. Morris | Registration No. | 24,615 |

***CERTIFICATE OF MAILING OR TRANSMISSION***

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

| | | | |
|---|---|---|---|
| Signature | /Vincent M. Ferraro/ | | |
| Name (Print/Type) | Vincent M. Ferraro | Date | October 3, 2012 |

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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OCT 09 2012
PATENT & TRADEMARK OFFICE

PTO/SB/22 (09-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARMENT OF COMMERCE
Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) | Docket Number (Optional) 277-042 |
|---|---|
| Application Number 12/658,680 | Filed February 11, 2010 |
| For INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | |
| Art Unit 3733 | Examiner Stuart Samuel Bray |

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

| | Fee | Small Entity Fee | |
|---|---|---|---|
| ☐ One month (37 CFR 1.17(a)(1)) | $150 | $75 | $ |
| ☑ Two months (37 CFR 1.17(a)(2)) | $560 | $280 | $ 280 |
| ☐ Three months (37 CFR 1.17(a)(3)) | $1270 | $635 | $ |
| ☐ Four months (37 CFR 1.17(a)(4)) | $1980 | $990 | $ |
| ☐ Five months (37 CFR 1.17(a)(5)) | $2690 | $1345 | $ |

10/12/2012 SDIRETA1 00000029 230420 12658680
02 FC:2252 280.00 DA

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 23-0420.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 24,615

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

| /Francis E. Morris/ | October 3, 2012 |
|---|---|
| Signature | Date |
| Francis E. Morris | (908) 277-3333 |
| Typed or printed name | Telephone Number |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

OPAP WP19 OCT 09 2012 PATENT & TRADEMARK OFFICE

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Jeff Tyber, et al.

Confirmation No.: 1344

Serial No.: 12/658,680

Examiner: Bray, Stuart Samuel

Filed: February 11, 2010

Art Unit: 3733

For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

Atty. Doc. No.: 277-042

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

**REQUEST FOR CONTINUED EXAMINATION AND RESPONSE TO FINAL OFFICE ACTION OF MAY 3, 2012**

SIR:

This is a Request for Continued Examination and an amendment and response to the office action of May 3, 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 CLAIMS** begin on page 2 of this paper.

**REMARKS** begin on page 16 of this paper.

**Election/Restriction** remarks begin on page 16 of this paper

**Double Patenting** remarks begin on page 17 of this paper.

**35 U.S.C. § 112** remarks begin on page 18 of this paper.

**35 U.S.C. § 103** remarks begin on page 19 of this paper.

**IN THE CLAIMS:**

The following listing of claims will replace all prior versions and listings of claims in the subject application:

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

a first screw member, wherein the first screw member comprises a first elongated body extending along a first longitudinal axis, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a second screw member for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, [[and]] the second elongated body extending along a second longitudinal axis, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body, a first aperture at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the second longitudinal axis and the third axis define an angle,

wherein the first screw member couples to the second screw member by inserting the first screw member into the bore until the bulbous portion of the first screw member abuts the first aperture of the second screw member.

**2. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the first screw member couples to the second screw member at the angle.

**3. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the angle is in the range of about 0 degrees to about 90 degrees.

**4. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the bulbous portion includes a taper for providing an interference fit with the second screw member.

**5. (Currently amended):** The ~~intramedullary~~ assembly of claim 4, wherein the taper provides for an interference lock with the second screw member.

**6. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the bulbous portion includes an aperture disposed along the first longitudinal axis.

**8. (Currently amended):** The ~~intramedullary~~ assembly of claim 7, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**9. (Currently amended):** The ~~intramedullary~~ assembly of claim 7, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**10. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**12. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**13. (Canceled).**

**14. (Currently amended):** The ~~intramedullary~~ assembly of claim 12, wherein the internal aperture is disposed along the second longitudinal axis.

**15. (Currently amended):** The ~~intramedullary~~ assembly of claim 12, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Currently amended):** The ~~intramedullary~~ assembly of claim 15, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**17. (Canceled).**

**18. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within

the bore, and further wherein the bulbous portion abuts the first aperture at the second end of the second elongated body.

**19. (Canceled).**

**20. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**21. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**22. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**23. (Currently amended):** The ~~intramedullary~~ assembly of claim 22, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Withdrawn):** The intramedullary assembly of claim 1, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

**25. (Withdrawn):** The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**26. (Withdrawn):** A method for bone fusion, comprising:

providing a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

providing a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

forming a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

forming a second medullary canal in the first bone;

coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

applying torque to the lag screw member to lock the tapered screw member to the lag screw member, thereby compressing the first bone to the second bone.

**27. (Withdrawn):** The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**28. (Withdrawn):** The method of claim 27, wherein the fixed angle is in the range of approximately 0 to approximately 90 degrees.

**29. (Withdrawn):** The method of claim 26, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**30. (Withdrawn):** The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

**31. (Withdrawn):** The method of claim 26, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**32. (Withdrawn):** The method of claim 26, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

**34. (Withdrawn):** The method of claim 32, further comprising receiving a complementary shaped end of an instrument in the orifice.

**35. (Withdrawn):** The method of claim 26, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**36. (Withdrawn):** The method of claim 26, 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 lag screw member.

**37. (Withdrawn):** The method of claim 26, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

**38. (Withdrawn):** The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

**39. (Withdrawn):** The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**40. (Withdrawn):** The method of claim 38, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**41. (Withdrawn):** The method of claim 40, further comprising receiving a complementary shaped member in the opening.

**42. (Withdrawn):** The method of claim 38, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**43. (Withdrawn):** The method of claim 38, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**44. (Withdrawn):** The method of claim 38, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**45. (Withdrawn):** The method of claim 26, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**46. (Withdrawn):** The method of claim 26, 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 tapered screw member.

**47. (Withdrawn):** The method of claim 26, further comprising inserting the lag screw member into at least a first medullary canal of bone.

**48. (Withdrawn):** The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

**49. (Withdrawn):** The method of claim 26, further comprising providing a cover portion coupled to the bulbous portion of the lag screw member.

**50. (Withdrawn):** The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

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

a first screw member, wherein the first screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a second screw member for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body and a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises a first aperture at a terminal end of the second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member,

wherein the bulbous portion is semi-spherical for providing angular rotation of the first screw member relative to the second screw member, and

wherein the first screw member couples to the second screw member by inserting the first screw member into the bore until the bulbous portion of the first screw member abuts the first aperture of the second screw member.

**52. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the first screw member couples to the second screw member at an angle.

**53. (Currently amended):** The ~~intramedullary~~ assembly of claim 52, wherein the angle varies between about 0 degrees and about 90 degrees.

**54. (Canceled).**

**55. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the bulbous portion includes an aperture.

**57. (Currently amended):** The ~~intramedullary~~ assembly of claim 56, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**58. (Currently amended):** The ~~intramedullary~~ assembly of claim 56, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**59. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**60. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**61. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**62. (Canceled).**

**63. (Currently amended):** The ~~intramedullary~~ assembly of claim 61, wherein the internal aperture partially traverses the tubular portion at the second end of the second elongated body.

**64. (Currently amended):** The ~~intramedullary~~ assembly of claim 61, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Currently amended):** The ~~intramedullary~~ assembly of claim 64, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**66. (Canceled).**

**67. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within the bore, and further wherein the bulbous portion abuts the first aperture at the second end of the second elongated body.

**68. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the bore forms a predetermined angle with the second elongated body.

**69. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**70. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**71. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**72. (Currently amended):** The ~~intramedullary~~ assembly of claim 71, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Withdrawn):** The intramedullary assembly of claim 51, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

**74. (Withdrawn):** The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**75. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the bore is adapted for retaining the bulbous portion.

**76. (Currently amended):** The ~~intramedullary~~ assembly of claim 4, wherein the bore comprises a taper for providing an interference fit with the taper of the bulbous portion.

**77. (Currently amended):** The ~~intramedullary~~ assembly of claim 2, wherein the angle is adapted to cause the ~~intramedullary~~ assembly to couple to at least a first bone and translate compression applied to bone fragments across the first screw member and the second screw member, thereby drawing the bone fragments together.

**78. (Currently amended):** The ~~intramedullary~~ assembly of claim 2, wherein the angle is adapted to cause the ~~intramedullary~~ assembly to couple to at least a first bone and translate compression applied to bone fragments by the second screw member and the first screw member into uniform compression through a plurality of points of fixation.

**79. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the bulbous portion comprises a spherical portion adapted to allow the first screw member to couple to the

second screw member at a plurality of possible angles ranging from about 0 degrees to about 90 degrees.

**80. (Currently amended):** The ~~intramedullary~~ assembly of claim 79, wherein the spherical portion is adapted to allow the first screw member to rotate within the bore to set an angle between the first screw member and the second screw member to at least one of the plurality of possible angles.

**81. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, wherein the second screw member comprises a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises the first aperture and the bore, and wherein the second aperture is on an exterior surface of the tubular portion.

## REMARKS

Applicants first wish to thank the Examiner for his helpful suggestions made during the course of an Examiner Interview held with Applicants' representatives on July 25, 2012.

Claims 1 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 81 are pending in this application. Please amend claims 1 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 81. 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 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 81 is patentable over the prior art.

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

### I. THE ELECTION/RESTRICTIONS

In a communication to the PTO dated August 15, 2011, Applicants elected claims 1-25 and 51-74 and the species depicted in FIGS. 8-16 for prosecution. Applicants have since amended claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, and 67-72 and added new claims 75-81 in a communication to the PTO dated March 28, 2012. In the Office Action of May 3,

2012, the Examiner withdrew amended claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 for being directed to an invention and species that is independent or distinct from the invention originally claimed. Specifically, the Examiner indicated that the elected invention in claims 1-25 and 51-74 from Applicant's August 15, 2011 communication do not include a "first screw," a "second screw," a "first longitudinal axis," a "second longitudinal axis," a "terminal end," or a "third axis."

However, during an Examiner interview between the Examiner and Applicants' representatives held on July 25, 2012, the Examiner agreed that amended claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 are indeed drawn to the originally elected invention and species. Moreover, for the Examiner's convenience, Applicants have enclosed annotated versions of amended claim 1 and 51 to further illustrate that the elements identified by the Examiner as not included in the originally elected species are, to the contrary, included in the previously elected species, depicted in FIGS. 8-16. As such, Applicants submit that the Examiner's withdrawal of claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 from consideration has been obviated and, therefore, Applicants respectfully request the Examiner to reinstate claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, and 75-81 for prosecution.

## II. THE DOUBLE PATENTING REJECTION

The Examiner provisionally rejected claims 1 – 11 and 20 – 23 on the ground of non-statutory double patenting over claims 114 – 136 of co-pending Application No. 12/456,808. Since no claims have issued in that application, Applicants respectfully request the Examiner to hold the rejection of claims 1-11 and 20-23 on this ground in abeyance.

## III. THE 35 U.S.C. § 112 REJECTION

The Examiner rejected claims 1 – 12, 14 – 16, 18, 20 – 23, 75 – 81 and 51 – 53, 55 – 61, 63 – 65, and 67 – 72 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner pointed out that the specification as originally filed provides no support for, for example, a "first screw", a "second screw", a "first longitudinal axis", a "second longitudinal axis", a "terminal end", or a "third axis."

Applicants respectfully disagree and submit that the claims are supported by the originally filed specification. In particular, Applicants wish to draw the Examiner's attention to Figures 8 – 11 and Figures 14 – 16 and paragraphs [0054] through [0061] and [0065] through [0071] of U.S. Patent Application Publication No. 2010/0256638. For example, a "first screw" member is disclosed as lag screw member 815 as shown in Figure 10 and described in paragraph [0056]; a "first longitudinal axis" is disclosed as longitudinal axis 1002 as shown in Figure 10 and described in paragraph [0056]; a "second screw" member is disclosed as tapered screw member 810 as shown in Figure 11 and described in paragraph [0059]; a "second longitudinal axis" is disclosed as longitudinal axis 1104 as shown in Figure 11 and described in paragraph [0059]; a "terminal end" is disclosed as end 1120 as shown in Figure 11 and described in paragraph [0060]; and a "third axis" is disclosed as axis 1102 as shown in Figure 11 and described in paragraph [0060]. For the Examiner's convenience, Applicants have enclosed annotated versions of claim 1 and 51 to further indicate where the support in the specification can be found for the particular elements of claim 1 and 51 that the Examiner deemed as failing to comply with the written description requirement of 35 U.S.C. § 112, paragraph 1.

In light of the remarks above, Applicants respectfully submit that claims 1 – 12, 14 – 16, 18, 20 – 23, 75 – 81 and 51 – 53, 55 – 61, 63 – 65, and 67 – 72 comply with the written

description requirement. Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 1 – 12, 14 – 16, 18, 20 – 23, 75 – 81 and 51 – 53, 55 – 61, 63 – 65, and 67 – 72.

## IV. THE 35 U.S.C § 103 REJECTION

The Examiner rejected claims 1 – 11, 20 – 23, 51 – 53, 55 – 60, 69 – 72 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"), U.S. Patent No. 5,456,267 to Stark (hereinafter "Stark"), U.S. Patent Publication No. 2009/0149857 to Culbert, et al. (hereinafter "Culbert"), and U.S. Patent No. 6,669,700 to Farris, et al. (hereinafter "Farris"). Applicants respectfully traverse the Examiner's rejection, and submit that Chang, Stark, Culbert, and Farris, alone or in combination, do not discuss or disclose every element of claims 1 – 12, 14 – 16, 18, 20 – 23, 75 – 81 and 51 – 53, 55 – 61, 63 – 65, and 67 – 72.

Referring first to claim 1, Applicants submit that Chang, Stark, Culbert, and Farris, alone or in combination, do **not** discuss, and are in fact missing at least the following element, *inter alia*, "wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body, a first aperture at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member," as required by currently amended independent claim 1. In fact, Chang specifically and only discloses through holes (101 and 102) that are merely provided along the shaft of the nail. (See Chang, FIGS. 1-5, Abstract and paragraphs [0017] and [0024]). Notably, Chang does not discuss or disclose a structure having

an aperture at a terminal end of the nail. Likewise, Stark, Culbert, and Farris all fail to discuss or disclose this feature.

In light of the remarks above, Applicants respectfully submit that Chang, Stark, Culbert, and Farris, alone or in combination, do not teach, suggest or render obvious currently amended claim 1. Accordingly, Applicants respectfully submit that claim 1 is patentable over Chang, Stark, Culbert, and Farris. Dependent claims 2 – 12, 14 – 16, 18, 20 – 23 and 75 – 81 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 – 12, 14 – 16, 18, 20 – 23 and 75 – 81.

Referring now to claim 51, Applicants submit that Chang, Stark, Culbert, and Farris, alone or in combination, do **not** discuss, and are in fact missing at least the following element, *inter alia*, "wherein the tubular portion comprises a first aperture at a terminal end of the second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member," as required by currently amended independent claim 51. For the same reasons discussed above with respect to claim 1, Chang, Stark, Culbert, and Farris, alone or in combination, do not discuss or disclose this limitation.

In light of the remarks above, Applicants respectfully submit that Chang, Stark, Culbert, and Farris, alone or in combination, do not teach, suggest or render obvious currently amended claim 51. Accordingly, Applicants respectfully submit that claim 51 is patentable over Chang, Stark, Culbert, and Farris. Dependent claims 52 – 53, 55 – 61, 63 – 65 and 67 – 72 are patentable by virtue of their dependency on claim 51. For at least these reasons, Applicants

respectfully request reconsideration and withdrawal of the rejection and allowance of claims 51 – 53, 55 – 61, 63 – 65 and 67 – 72.

## CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections and allowance of pending claims 1 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 81.

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 Request for Continue Examination and a fee of $465.00 under 37 C.F.R. § 1.17(e). This Response is also being filed with a two month extension of time. In the event that any additional fee is required for the entry of this response the Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 23-0420 in the name of Ward & Zinna.

Respectfully submitted,

Date: October 3, 2012

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**ANNOTATED CLAIMS:**

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

a first screw member [815, Fig. 10, ¶ [0056] and/or 1415, Fig. 15, ¶ [0066]*], wherein the first screw member comprises a first elongated body extending along a first longitudinal axis [1002, Fig. 10, ¶ [0056] and/or 1502, Fig. 15, ¶ [0067]], and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a second screw member [810, Fig. 11, ¶ [0059] and/or 1410, Fig. 16, ¶ [0069]] for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, the second elongated body extending along a second longitudinal axis [1104, Fig. 11, ¶ [0059] and/or 1640, Fig. 16, ¶ [0070]], wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body, a first aperture [1130, Fig. 11, ¶ [0060] and/or 1630, Fig. 16, ¶ [0070]] at a terminal end [1120, Fig. 11, ¶ [0060]] of the second end of the second elongated body, and a bore extending along a third axis [1102, Fig. 11, ¶ [0060] and/or 1602, Fig. 16, ¶ [0070]] from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the second longitudinal axis and the third axis define an angle,

wherein the first screw member couples to the second screw member by inserting the first screw member into the bore until the bulbous portion of the first screw member abuts the first aperture of the second screw member.

**51. (Previously presented):** An intramedullary assembly for bone fusion, comprising:

a first screw member [815, Fig. 10, ¶ [0056] and/or 1415, Fig. 15, ¶ [0066]*], wherein the first screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

a second screw member [810, Fig. 11, ¶ [0059] and/or 1410, Fig. 16, ¶ [0069]] for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body and a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises a first aperture [1130, Fig. 11, ¶ [0060] and/or 1630, Fig. 16, ¶ [0070]] at a terminal end [1120, Fig. 11, ¶ [0060]] of the second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member,

wherein the bulbous portion is semi-spherical for providing angular rotation of the first screw member.

* All references are made to U.S. Pat. App. Pub. No. 20100256638.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|---|---|
| In re Application of: Jeff Tyber, et al. | Confirmation No.: 1344 |
| Serial No.: 12/658,680 | Group Art Unit: 3733 |
| Filed: February 11, 2010 | Examiner: Bray, Stuart Samuel |
| For: AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: 277-042 |

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

## COVER LETTER

S I R:

Applicants submit herewith an Information Disclosure Statement pursuant to 37 CFR § 1.97(b)(4). No admission is made that any of the references cited on the attached Information Disclosure Statement qualify as prior art under 35 U.S.C. §§ 102 and 103 or are material to patentability.

No fee is believed to be due with this filing. If a petition and/or any fee is 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.

Respectfully submitted,

Date: October 3, 2012

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**( Not for submission under 37 CFR 1.99)**

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| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Tyber, Jeff |
| Art Unit | 3733 |
| Examiner Name | Bray, Stuart Samuel |
| Attorney Docket Number | 277-042 |

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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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|---|---|---|---|---|---|---|
| | 86 | 7144399 | | 2006-12-05 | Hayes, et al. | |

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**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code[1] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
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| | 1 | 20010021852 | | 2001-09-13 | Chappius | |
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| | 3 | 20030158555 | | 2003-08-20 | Sanders | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | 9 | 20060122612 | | 2006-06-08 | Justin et al | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
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| | Application Number | 12658680 |
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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | 20 | 20110282398 | | 2011-11-17 | Overes et al | |
| | 21 | 20110301651 | | 2011-12-08 | Kirschman | |
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| | 26 | 20020197134 | | 2002-12-26 | Huber | |
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| | 28 | 20060052787 | | 2006-03-09 | Re et al. | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
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| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | 31 | 20100076499 | | 2010-03-25 | McNamara, et al. | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
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| | Application Number | 12658680 |
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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| | | | | | | |
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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | 53 | 20100121325 | | 2010-05-13 | Tyber, et al. | |
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If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] i | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
| | 1 | | | | | | | ☐ |

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**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | 1 | | ☐ |

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**EXAMINER SIGNATURE**

| Examiner Signature | | Date Considered | |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Francis E. Morris/ | Date (YYYY-MM-DD) | 2012-10-03 |
|---|---|---|---|
| Name/Print | Francis E. Morris | Registration Number | 24615 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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OCT 09 2012
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Document Description: Transmittal Letter

PTO/SB/21 (07-09)
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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

| | |
|---|---|
| Total Number of Pages in This Submission | 43 |

| | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jeff Tyber |
| Art Unit | 3733 |
| Examiner Name | Stuart Samuel Bray |
| Attorney Docket Number | 277-042 |

## ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment/Reply
  - [x] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [x] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):
  Request for Continued Examination
  Return Receipt Postcard

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|---|---|---|---|
| Firm Name | WARD & ZINNA, LLC | | |
| Signature | /Francis E. Morris/ | | |
| Printed name | Francis E. Morris | | |
| Date | October 3, 2012 | Reg. No. | 24,615 |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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| Signature | /Vincent M. Ferraro/ | | |
| Typed or printed name | Vincent M. Ferraro | Date | October 3, 2012 |

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PTO/SB/17 (03-12)
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# FEE TRANSMITTAL

| Complete if known | |
|---|---|
| Application Number | 12/658,680 |
| Filing Date | February 11, 2010 |
| First Named Inventor | Jeff Tyber |
| Examiner Name | Stuart Samuel Bray |
| Art Unit | 3733 |
| Practitioner Docket No. | 277-042 |

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 745.00

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 23-0420 Deposit Account Name: Ward & Zinna

For the above-identified deposit account, the Director is hereby authorized to (check all that apply):

☑ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☑ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☑ Credit any overpayment of fee(s)

**WARNING**: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**FEE CALCULATION**

**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

| | FILING FEES | | SEARCH FEES | | EXAMINATION FEES | | |
|---|---|---|---|---|---|---|---|
| **Application Type** | **Fee ($)** | **Small Entity Fee ($)** | **Fee ($)** | **Small Entity Fee ($)** | **Fee ($)** | **Small Entity Fee ($)** | **Fees Paid ($)** |
| Utility | 380 | 190 | 620 | 310 | 250 | 125 | |
| Design | 250 | 125 | 120 | 60 | 160 | 80 | |
| Plant | 250 | 125 | 380 | 190 | 200 | 100 | |
| Reissue | 380 | 190 | 620 | 310 | 750 | 375 | |
| Provisional | 250 | 125 | 0 | 0 | 0 | 0 | |

**2. EXCESS CLAIM FEES**

| **Fee Description** | **Fee ($)** | **Small Entity Fee ($)** |
|---|---|---|
| Each claim over 20 (including Reissues) | 60 | 30 |
| Each independent claim over 3 (including Reissues) | 250 | 125 |
| Multiple dependent claims | 450 | 225 |

**Total Claims** _____ -20 or HP = _____ **Extra Claims** _____ x **Fee ($)** _____ = **Fee Paid ($)** _____

HP = highest number of total claims paid for, if greater than 20.

**Indep. Claims** _____ -3 or HP = _____ **Extra Claims** _____ x **Fee ($)** _____ = **Fee Paid ($)** _____

HP = highest number of independent claims paid for, if greater than 3.

**Multiple Dependent Claims** **Fee ($)** _____ **Fee Paid ($)** _____

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

**Total Sheets** _____ - 100 = **Extra Sheets** _____ / 50 = **Number of each additional 50 or fraction thereof** _____ (round **up** to a whole number) x **Fee ($)** _____ = **Fee Paid ($)** _____

**4. OTHER FEE(S)** **Fees Paid ($)**

Non-English specification, $130 fee (no small entity discount) _____

**Non-electronic filing fee under 37 CFR 1.16(t) for a utility application, $400 fee ($200 small entity)** _____

Other (e.g., late filing surcharge): Request for Continued Examination ($465.00) and Two-month Extension of Time ($280) $745.00

SUBMITTED BY

| | | | |
|---|---|---|---|
| Signature | /Francis E. Morris/ | Registration No. (Attorney/Agent) 24,615 | Telephone (908) 277-3333 |
| Name (Print/Type) | Francis E. Morris | | Date October 3, 2012 |

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/06 (07-06)
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# PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

| Application or Docket Number | Filing Date | ☐ To be Mailed |
|---|---|---|
| 12/658,680 | 02/11/2010 | |

## APPLICATION AS FILED – PART I

| FOR | (Column 1) NUMBER FILED | (Column 2) NUMBER EXTRA | SMALL ENTITY ☒ RATE ($) | SMALL ENTITY ☒ FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | OTHER THAN SMALL ENTITY FEE ($) |
|---|---|---|---|---|---|---|---|
| ☐ BASIC FEE (37 CFR 1.16(a), (b), or (c)) | N/A | N/A | N/A | | | N/A | |
| ☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m)) | N/A | N/A | N/A | | | N/A | |
| ☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q)) | N/A | N/A | N/A | | | N/A | |
| TOTAL CLAIMS (37 CFR 1.16(i)) | minus 20 = | * | X $ = | | OR | X $ = | |
| INDEPENDENT CLAIMS (37 CFR 1.16(h)) | minus 3 = | * | X $ = | | | X $ = | |
| ☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) | If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). | | | | | | |
| ☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) | | | | | | | |
| * If the difference in column 1 is less than zero, enter "0" in column 2. | | | TOTAL | | | TOTAL | |

## APPLICATION AS AMENDED – PART II

AMENDMENT 10/09/2012

| | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | SMALL ENTITY RATE ($) | SMALL ENTITY ADDITIONAL FEE ($) | OR | OTHER THAN SMALL ENTITY RATE ($) | OTHER THAN SMALL ENTITY ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|
| Total (37 CFR 1.16(i)) | * 75 | Minus | ** 75 | = 0 | X $31 = | 0 | OR | X $ = | |
| Independent (37 CFR 1.16(h)) | * 3 | Minus | ***3 | = 0 | X $125 = | 0 | OR | X $ = | |
| ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | TOTAL ADD'L FEE | 0 | OR | TOTAL ADD'L FEE | |

AMENDMENT

| | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | (Column 3) PRESENT EXTRA | RATE ($) | ADDITIONAL FEE ($) | OR | RATE ($) | ADDITIONAL FEE ($) |
|---|---|---|---|---|---|---|---|---|---|
| Total (37 CFR 1.16(i)) | * | Minus | ** | = | X $ = | | OR | X $ = | |
| Independent (37 CFR 1.16(h)) | * | Minus | *** | = | X $ = | | OR | X $ = | |
| ☐ Application Size Fee (37 CFR 1.16(s)) | | | | | | | | | |
| ☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | OR | | |
| | | | | | TOTAL ADD'L FEE | | OR | TOTAL ADD'L FEE | |

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/BURNELL ROSS/

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PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**
( **Not for submission under 37 CFR 1.99)**

| | |
|---|---|
| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Tyber |
| Art Unit | 3733 |
| Examiner Name | BRAY |
| Attorney Docket Number | 277-042 |

| U.S.PATENTS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 5456267 | | 1995-10-10 | Stark | |
| | 2 | 6579293 | | 2003-06-17 | Chandran | |
| If you wish to add additional U.S. Patent citation information please click the Add button. | | | | | | |

| U.S.PATENT APPLICATION PUBLICATIONS | | | | | | |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Publication Number | Kind Code[1] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 20040193162 | | 2004-09-30 | Bramlet | |
| | 2 | 20050240190 | | 2005-10-27 | Gall | |
| | 3 | 20060200141 | | 2006-09-07 | Janna | |
| | 4 | 20070162028 | | 2007-07-12 | Jackson | |

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| | Art Unit | 3733 |
| | Examiner Name | BRAY |
| | Attorney Docket Number | 277-042 |

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|---|---|---|---|---|---|---|
| | 5 | 20020032445 | | 2002-03-14 | Fujiwara | |
| | 6 | 20090326534 | | 2009-12-31 | Yamazaki | |
| | 7 | 20100174284 | | 2010-07-08 | Schwammberger | |
| | 8 | 20100234846 | | 2010-09-16 | Eglseder | |
| | 9 | 20110137313 | | 2011-06-09 | Jensen | |
| | 10 | 20090149857 | | 2009-06-11 | Culbert | |
| | 11 | 20100121324 | | 2010-05-13 | Tyber | |

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**FOREIGN PATENT DOCUMENTS**

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| | Art Unit | 3733 |
| | Examiner Name | BRAY |
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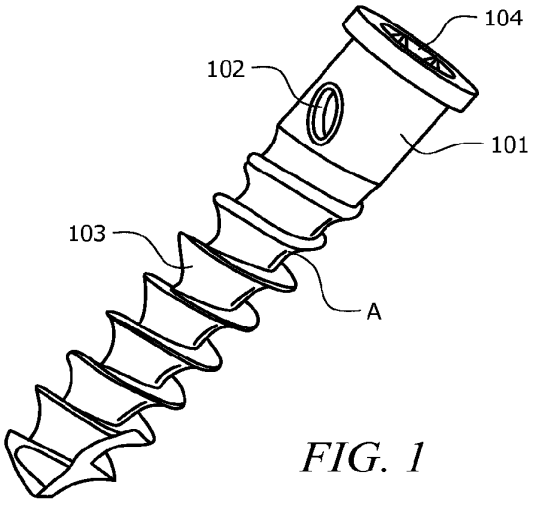



*FIG. 1*

(57) Abstract: An anchoring device and method for attaching an object to a bone comprises an anchoring member having proximal and distal ends, with the proximal end being adapted to hold the object to the bone while the distal end is in the bone, and a locking member having proximal and distal ends, with the proximal end adapted to secure the anchoring member into the bone and oppose its pull-out or loosening by stopping its backing or preventing its unscrewing while the distal end is in the bone. Also provided are first and second fasteners, with the first fastener adapted to fit to the proximal end of the anchoring member, and the second fastener adapted to fit to the proximal end of the locking member. The end of the second fastener can have an angle that matches an angle of the locking member.

# UNIVERSAL ANCHOR FOR ATTACHING OBJECTS TO BONE TISSUE

**[0001]** The present invention claims priority to U.S. Provisional Application Serial No. 61/039,464, filed March 26, 2008, which is incorporated by reference herein in its entirety.

## FIELD OF THE INVENTION

**[0002]** The present invention relates to devices for attaching various objects, such as prostheses or implants, to bones, and in certain cases for anchoring spinal instruments to the vertebrae of the human rachis.

## BACKGROUND OF THE INVENTION

**[0003]** The fast-growing aging population represents an important orthopedic market with a very specific need related to its low-quality cancelous or spongy bone (osteoporosis). Osteosynthesis procedures in such people are jeopardized by the risk of loosening in relation with the pullout or back-out of anchors in the bone. The reliability of an anchoring system depends on its ability to resist pulling out of the bone. Removal of an anchor may lead to extrusion, or even worse, loosening of any object attached to the bone. Known anchoring systems propose several solutions: Divergent or convergent screws have been proposed to oppose to pull out forces by increasing the grip. Locking mechanisms intended to secure the anchor within the object (such as locking screw or anti-reverse systems) avoid the pull out of the anchor but not the extrusion of the entire construct. Bicortical screwing may be dangerous and can make the construct too rigid. This can lead to the breakage of the implant itself. Special features like conical core, self-tapping profile and roughened surfaces of the anchor have been developed to increase the grip to the cancelous bone. Expandable mechanisms (such as threaded peg expanded with a coaxial inner member or "Molly screw") crush and split fragile bone tissue and then creates an empty room around the buried part of the anchor. This can lead the construct to toggle and therefore to a condition for pull out or loosening in response to physiological micro-motions.

**[0004]** U.S. Patent 6,695,844 to Bramlet et al discloses an expandable-winged fastener made up of an outer member and an inner mechanism able to protract or retract wings intended not only to increase the interface between the bone and the device but also to expand within the cancelous bone. Although the wings are blunted, the bone-implant interface is

weakened as the wings expand or retract because the expanded wings broach through the bone as they pivot and therefore require the bone to remodel.

**[0005]** Other solutions use an interlocking mechanism, such as a K-wire which intersect a bone screw ("An Interlocking Screw for Fixation in Osteoporotic Bone" described by McKoy and al. in "internal fixation in osteoporotic bone" authored by Yuehuei H. An in 2002) or two members connected by their ends through a threaded connection ("Anchoring System for Fixing Object to bones" US Patent Application Serial No. 10/275,710 to Lionel Sevrain).

**[0006]** Connecting solutions address some of the problems, and provide increased strength and reliability, but require an aiming system that may represent a hurdle not only from a marketing standpoint but also from an anatomical standpoint. There is therefore a need for an improved anchoring system and installation method for anchoring an object to bone.

**[0007]** It would be desirable to provide a novel anchoring system for securing various objects to bones, such as spinal devices or instrumentations to the rachis, and to provide an anchoring system well adapted to prevent a pull out of the anchor and therefore the extrusion and/or the loosening of the object over time. It would also be desirable to provide an anchoring system to bring the needed reliability in such osteoporotic bone, without the hassle of an additional aiming guide.

## SUMMARY OF THE INVENTION

**[0008]** Therefore, in accordance with a first aspect, there is provided an anchoring device for attaching an object to a bone, comprising an anchoring member having proximal and distal ends, the proximal end being adapted to hold the object to the bone while the distal end is in the bone, and a locking member having proximal and distal ends, with the proximal end adapted to secure the anchoring member into the bone and oppose its pull-out or loosening by stopping its backing or preventing its unscrewing, while the distal end is in the bone.

**[0009]** Also in accordance with another aspect, there is provided first and second fasteners, the first fastener being adapted to fit to the proximal end of the anchoring member, and the second fastener being adapted to fit to the proximal end of the locking member. More specifically, the second fastener is adequately designed to match the angulation of the locking member.

**[0010]** Further in accordance with another aspect, there is provided a method for mounting an object to a bone, comprising the steps of: (a) providing anchoring member and locking member each having proximal and distal ends, (b) introducing the anchoring member in the bone wherein said proximal end holds an object to the bone, (c) positioning the locking member into the proximal end of the anchoring member, and (d) preventing the anchoring member of loosening.

**[0011]** In one embodiment of the invention, there is a system for attaching one or more objects to bone tissue, comprising: an anchoring member having proximal and distal ends, wherein the proximal end comprises a socket and an aperture, wherein the aperture is oblique to the axis of the length of the anchoring member; and a locking member having proximal and distal ends, wherein the proximal end comprises a socket; wherein the aperture of the anchoring member is adapted for insertion of the locking member therethrough. In a specific embodiment, the system further comprises at least one fastener, wherein the fastener is adapted to fit to a socket in the proximal end of the anchoring member, adapted to fit to a socket in the proximal end of the locking member, or both. In one specific embodiment, the system further comprises first and second fasteners, wherein the first fastener is adapted to fit to a socket in the proximal end of the anchoring member and the second fastener is adapted to fit to a socket in the proximal end of the locking member.

**[0012]** In another embodiment of the invention, the angle on the head of the second fastener corresponds to the angulation of the locking member inserted into the anchoring member. In other specific embodiments, the anchoring member, the locking member, or both have a rough surface. In certain aspects, the surface of the inner wall of the aperture is smooth, rough, or threaded. In particular aspects of the invention, the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 1 and 89 degrees, between 10 and 75 degrees, between 10 and 50 degrees, between 10 and 35 degrees, or between 25 and 30 degrees.

**[0013]** In a specific embodiment of the invention, the shape of the socket of the anchoring member and/or the shape of the socket of the locking member is hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, or star-shaped. In a particular aspects of the invention, the second fastener is a ball end hexagonal fastener.

**[0014]** In one embodiment of the invention, there is a method of affixing one or more objects to bone, comprising the step of anchoring the object to the bone using the system(s) or composition(s) of the invention. In another embodiment of the invention, there is a kit comprising the system(s) or composition(s) of the invention.

**[0015]** The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0016]** Having thus generally described the nature of the invention, reference will now be made to the accompanying drawings, showing by way of illustration a particular embodiment thereof.

**[0017]** Fig. 1 is a schematic perspective view of an anchoring member in accordance with the present invention.

**[0018]** Fig. 2a is a schematic cross-sectional plan view of an anchoring member.

**[0019]** Fig. 2b is a top plan schematic view of the proximal end of the anchoring member.

**[0020]** Fig. 3 is a schematic perspective view of an anchoring member with the locking member.

**[0021]** Fig. 4 is a schematic cross-sectional plan view of an anchoring member with the locking member

**[0022]** Fig. 5 is a perspective view of an anchoring member holding an object (plate).

**[0023]** Fig. 6a is a cross-sectional view of the shaft (Hex Key) of one embodiment of the first fastener F1.

**[0024]** Fig. 6b is a schematic perspective view of the distal end (ball end hex tool) of the first fastener F1.

**[0025]** Fig. 6c is a lateral view of the first fastener F1.

**[0026]** Fig. 7 is a schematic perspective view of a differential that can be used for the second fastener F2.

**[0027]** Fig. 8a is an enlarged perspective view of the distal end (ball end hex tool) of the first fastener F1.

**[0028]** Fig. 8b is an enlarged lateral view of the distal end (ball end hex tool) showing a 25 to 30 degree angle entry to the hex tool.

**[0029]** Fig. 8c is an example of oblique insertion.

**[0030]** Fig. 8d is a lateral view of the first fastener F1 engaged within a hex screw.

**[0031]** Fig. 9a is a lateral view of a cortical-type locking member L.

**[0032]** Fig. 9b is a lateral view of a cancelous-type locking member L.

**[0033]** Fig. 9c is a lateral view of a headless-type locking member L.

**[0034]** Fig. 10 illustrates various angulation patterns of the interlocking anchor and locking members.

**[0035]** Fig. 11 illustrates one embodiment of a locking member within an anchoring member, in addition to the respective fastener having a corresponding angulation to the angulation of the locking member within the anchoring member.

**[0036]** Fig. 12 illustrates an exemplary embodiment of a fastener and its corresponding locking member within the anchoring member.

**[0037]** From the foregoing disclosure and the following more detailed description of various particular embodiments it will be apparent to those skilled in the art that the present invention provides a significant advance in the art of bone anchoring devices. Additional features and advantages of various particular embodiments will be better understood in view of the detailed description provided below.

## DETAILED DESCRIPTION OF THE INVENTION

**[0038]** The present invention incorporates by reference herein in its entirety U.S. Provisional Patent Application Serial No. 60/896,960, filed March 26, 2007.

**[0039]** The term "a" or "an" as used herein in the specification may mean one or more. As used herein in the claim(s), when used in conjunction with the word "comprising", the words "a" or "an" may mean one or more than one. As used herein "another" may mean at least a second or more. Some embodiments of the invention may consist of or consist essentially of one or more elements, method steps, methods and/or systems of the invention. It is contemplated that any system, method, or composition described herein can be implemented with respect to any other method or composition described herein.

### I. The Present Invention

**[0040]** It will be apparent to those skilled in the art, that is, to those who have knowledge or experience in this area of technology, that many variations are possible for the system for anchoring bone disclosed herein. The following detailed discussion of various and particular features and embodiments will illustrate the general principles of the invention with reference to an improved bone anchoring device for use in mammalian bone, including vertebrae, for example. Other embodiments suitable for other applications will be apparent to those skilled in the art given the benefit of this disclosure.

**[0041]** Any mammalian bone, including human bone, may have the inventive systems, methods, and/or compositions of the present invention applied thereto. Examples include long, short, flat, irregular, accessory, and sesamoid bones. Particular examples include but are not limited to vertebrae, femur, humerus, radius, ulna, femur, tibia, fibula, clavicle, rib, metacarpals, metatarsals, phalanges, skull bones, sternum, scapulae, innominates, vertebrae, maxillae, sphenoid, carpus, tarsus, patella, interfrontal bone, epipteric bone, coronal ossicle, bregmatic ossicle, sagittal ossicle, lambdoid ossicle, and squame-parietal ossicle.

**[0042]** The materials of the components of the present invention may be of any suitable kind. Materials of the anchor and locking member are biocompatible, in certain embodiments. Examples of materials include biomedical metallic materials, including stainless steel; alloys (Al, Co, Ni, Ta, W, V, *etc.*); cobalt-based alloys; or titanium and its alloys. Other examples of materials include polymeric biomaterials, such as synthetic non-biodegradable polymers: polyethylene (high density polyethylene –HDPE-, ultrahigh molecular weight polyethylene –UHMWPE-), poly (ether ether ketone) or PEEK. Polymer matrix composite biomaterials may be employed and include fiber-reinforced composites (for example, carbon fiber or kevelar).

**[0043]** The shape, diameter, length, and any associated angles of the anchor, locking member, and, by extrapolation, fastener(s) of the invention maybe of any kind, so long as the locking member is able to be positioned within the anchor at an angle to generate a V-shaped (or L-shaped, in a 90 degree configuration) configuration and so long as the corresponding fastener(s) can be inserted in the respective socket **104** in the head of anchor and/or locking member to apply torque for affixing them into bone.

**[0044]** Referring now to Figs. 1 to 9, in accordance with an illustrative embodiment of the present invention, an anchoring device or implant, generally referred to using the numeral **100**, will now be described. The anchoring system **100** is generally comprised of an anchoring member A and a locking member L (see Fig. 3)

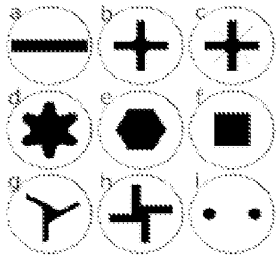
**[0045]** Fig. 1 illustrates an anchoring member A in accordance with a certain embodiment. The anchoring member A generally has cancelous screws' features such as a 2-portion shaft comprising an optionally coarse, self-tapping thread **103**, designed to anchor in the softer medullary or cancelous bone, and topped by a smooth unthreaded portion **101** that allows

it to act as a lag screw. The unthreaded upper portion **101** presents an oblique aperture **102** having an angle (for example, of about 25°) with respect to an axial plane of the anchoring member's shaft. The proximal end of the anchoring member A has a proximal end socket **104** such that it can be engaged by a fastener like a key, screwdriver, or wrench (see Fig. 2b). In specific embodiments, the proximal end of the anchoring member A has a Hex (hexagonal) type's proximal end socket **104** such that it can be engaged by a Hex tip fastener like a key or wrench (see Fig. 2b).

**[0046]** The term "fastener" as used herein refers to a tool, such as a wrench, key, or screwdriver, that is employed to insert the corresponding anchor in the bone *via* the head of the anchor and/or to insert the corresponding locking member in the anchor *via* the socket **104** of the head of the locking member.

**[0047]** Although the socket **104** of the head of the anchor or locking member may be of any shape, the embodiment presented herein wherein both heads are hexagonal is merely illustrative. That is, the shape of the socket **104** for insertion of the respective fastener in the anchor or locking member may be of any shape, including hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, star-shaped, and so forth, for example. In a specific embodiment, the head of the locking member is smaller than the head of the anchor, although in other embodiments the head of the locking member is the same size as the head of the anchor. In another specific embodiment, the socket **104** of the proximal end of the anchor and the socket **104** of the proximal end of the locking member are identical in shape and/or size, whereas in other specific embodiments the socket **104** of the proximal end of the anchor and the socket **104** of the proximal end of the locking member are not identical in shape and/or size.

**[0048]** Fig. 2 shows a cross-sectional view of the anchoring member (Fig. 2a) and a top plan of the proximal end of the anchoring member (Fig. 2b). The shape of the socket **104** for insertion of the respective fastener in the anchor or locking member may be of any shape, including hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, star-shaped, and so forth, for example (see below); these may be referred to as slotted, Phillips, Pozidriv, torx, Hex key, Robertson, Tri-Wing, Torq-Set, or Spanner, for example.

[0049] 

[0050] However, an exemplary hexagonal (Hex) socket in the head (**104**) of the anchoring member brings the following advantage: a ball end hex key (or wrench) can be used for angulated screwing and insertion, the contact surfaces of the screw are protected from external damage, the tool can be used with a headless screw, there are six contact surfaces between screw and driver, the socket's depth are less prone to stripping, and this room can be used for cannulation, for example.

[0051] Fig. 3 illustrates the anchoring system **100** comprising the anchoring member A and the locking member L. The angle $\alpha$ between the two members is fixed and set up at 25 degrees in a certain embodiment. This angle allows using a standard hex second fastener F2 (wherein F1 fastener refers to the fastener for the anchor and F2 fastener refers to the fastener for the locking member) equipped with an end ball hex end since it can be used with an angulation up to 30 degrees. In other embodiments, the angle can be set up to another value comprised between 1 to 90 degrees. In a specific embodiment, the angle can be 15-25 degrees. Beyond 30 degrees angulation, another embodiment of the second fastener F2 with an inclinable hex tip end may be used (differential inner mechanism).

[0052] Fig. 4 is a schematic cross-sectional plan view of the anchoring system **100**. In this representation, a headless locking member L is engaged into a oblique aperture (**111**) within the exemplary hex-shaped socket (**104**) of the head of the anchoring member A. The surface of the inner wall of the aperture may be threaded, smooth, or rough. One end of the aperture is at the proximal head of the anchor, and the opposite end is on one side of the anchor.

[0053] Fig. 5 is a perspective view of an anchoring member holding an exemplary object (plate) P.

**[0054]** Fig. 6 illustrates the first fastener F1 with its Hex type tip (**112**). In this representation, the fastener comprises a head or tip that engages with the socket of the anchor to apply torque by rotating the tip, such as but not limited to a screwdriver, key or wrench. The tip is not limited to hex type. The second fastener F2 in certain aspects comprises a ball end hex type end to allow screwing of the locking member. The second fastener F2 can have the same features as the first fastener F1 when used in a particular embodiment *e.g.* with an angle α between the two members equal at 25 degrees, or inferior at 30 degrees at the maximum, in accordance with the working angle (25 to 30 degrees) of such ball end hex tip. In this case, only the size differs from the first fastener F1, the second fastener F2 being thinner than the first fastener F1 in order to be able to slid within the inner socket **104** of the first fastener F1, in particular embodiments.

**[0055]** In another embodiment an angle β, higher than the angle α, *e.g.* superior at 30 degrees between the two members A and L, is set up. In this embodiment, the second fastener F2 presents an inclinable tip able to match the angle β and is equipped with an inner mechanism applying the torque in accordance with an oblique transmission of the rotating motion imparted to the handle of the fastener. Such mechanism can be but is not limited to a differential, a screw gear, or a set of gears. Fig. 7 illustrates the principle of such mechanism and shows a schematic conceptual view of a differential. Such a fastener can be rotated manually or by an electric or other motor.

**[0056]** Whatever the mechanism can be, it is intended to allow an oblique screwing while the handle of the fastener remains straight forward, in certain embodiments. Such a feature is useful when the local anatomical requirements forbid the tool to be tilted. For example, when a surgery using a minimally invasive approach through a small incision is performed, the instruments must go through this small cutaneous aperture, and therefore can not be angulated in order to avoid damaging soft tissue.

**[0057]** Fig. 8a is an enlarged perspective view of the distal end (ball end hex tool) of the fastener. The concept by which ball ends slide into a screw head is known as funnel insertion. Basically, it means that the sides of the ball end direct (funnel) it into place. This allows fast funnel entry, eliminates wasted time even in blind applications, and the full depth engagement reduces "stripping" problems.

**[0058]** Fig. 8b is an enlarged lateral view of the distal end (ball end hex tool) showing a 25 to 30 degree angle entry to hex. As maximum allowable angle increases, neck size decreases, and strength also decreases. By contrast, increasing the strength of a ball-end tool requires a corresponding increase in neck size and decrease in maximum allowable angle. Designing the perfect ball-end tool means choosing the ideal balance between strength and allowable angle. Fig. 8c is an example of oblique insertion. Fig. 8d is a lateral view of the first fastener F1 engaged within a hex screw.

**[0059]** Fig. 9 illustrates the three possible designs of the locking member L. In certain embodiments, the locking member L is thinner than the anchoring member A so that it can be slid through the oblique aperture and positioned within the empty room of the hexagonal socket of the anchoring member. Its length can be smaller, equal or bigger than the anchoring member. Its proximal end can be equipped with a head (**105**) or be wide-mouthed (**106**) to block within the anchoring member's head, or be headless (**107**). Whatever the type of the locking member L can be (headed 105, wide-mouthed **106** or headless **107**), the socket has a hex type shape, in certain embodiments. The locking member can be a cortical type screw (Fig. 9a) with a fine thread (**108**) all along its shaft and therefore screwed into an oblique threaded canal within the anchoring member's head, or a cancelous type screw (Fig. 9b) with a coarser thread (**109**), designed to anchor the bone and a smooth, unthreaded portion (**110**), designed to slid within an oblique unthreaded canal within the anchoring member's head. Depending of its type, the locking member L can just act as an anti-rotational device and prevent the unscrewing of the anchoring member A in the cortical type design, or be both a blocking system as described above and an additional fastening device intended to secure and reinforce the grip within the medullary bone in the cancelous type design. Moreover, due to its divergent positioning, it brings to the construct a V-shaped design which opposes to pull-out forces. Whatever cancelous or cortical type design be used, the adjunction of a second divergent member (locking member L) advantageously increases both the grip and the purchase within the bone, especially in cancelous and/or osteoporotic bone and therefore opposes to pull-out and secures the fixation of any object to the bone.

**[0060]** Fig. 10 illustrates various angulation patterns of the interlocking anchor and locking members. Upon certain angulations of the locking member within the anchoring member, and therefore, certain angulations required for the corresponding fastener to screw the

locking member, the proximal end of the anchoring member requires a cavity at its socket to allow the fastener access to the locking member.

**[0061]** Fig. 11 illustrates one embodiment of a locking member within an anchoring member, in addition to the respective fastener having a corresponding angulation to the angulation of the locking member within the anchoring member. In this specific embodiment, the proximal end of the anchoring member has a cavity that allows insertion of the fastener for the locking member.

**[0062]** Fig. 12 illustrates an exemplary embodiment of a fastener and its corresponding locking member within the anchoring member. The proximal end of the anchoring member comprises a cavity that allows insertion of the fastener for the locking member.

**[0063]** In certain embodiments, the anchor and locking member are coated with antibiotic or other medicine useful upon implantation of an implant on and/or in a bone. In other embodiments, the surface of the anchor and/or locking member is rough for a better grip within the bone.

**[0064]** Any of the compositions described herein may be comprised in a kit. Where there are more than one components in the kit, the kit also may contain a second, third or other additional container into which the additional components may be separately placed. The kits of the present invention may include a means for containing the invention component(s) in close confinement for commercial sale. Such containers may include injection or blow molded plastic containers into which the components are retained, for example.

**[0065]** The kit may comprise the anchor, locking member, and/or fastener(s). In some cases, all components are sold separate, whereas in other cases all or a subset of components are sold together. Irrespective of the number and/or type of containers, the kits of the invention may also comprise, and/or be packaged with, an instrument other than a fastener(s) of the invention for assisting with placing the anchor/locking member within the body of an animal.

**[0066]** In particular embodiments of the invention, a variety of anchors, locking members, and/or fasteners may be provided in a kit. For example, a variety of lengths,

diameters, socket shapes, and/or angles of the corresponding anchors, locking members, and/or fastener(s) may be provided in a kit.

**[0067]** From the foregoing disclosure and detailed description of certain embodiments, it will be apparent that various modifications, additions and other alternative embodiments are possible without departing from the true scope and spirit of the invention. The embodiments discussed were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to use the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

## CLAIMS

What is claimed is:

1. A system for attaching one or more objects to bone tissue, comprising:

an anchoring member having proximal and distal ends, wherein the proximal end comprises a socket and an aperture, wherein the aperture is oblique to the axis of the length of the anchoring member; and

a locking member having proximal and distal ends, wherein the proximal end comprises a socket;

wherein the aperture of the anchoring member is adapted for insertion of the locking member therethrough.

2. The system of claim 1, further comprising at least one fastener, wherein the fastener is adapted to fit to a socket in the proximal end of the anchoring member, adapted to fit to a socket in the proximal end of the locking member, or both.

3. The system of claim 1, further comprising first and second fasteners, wherein the first fastener is adapted to fit to a socket in the proximal end of the anchoring member and the second fastener is adapted to fit to a socket in the proximal end of the locking member.

4. The system of claim 3, wherein the angle on the head of the second fastener corresponds to the angulation of the locking member inserted into the anchoring member.

5. The system of claim 1, wherein the anchoring member, the locking member, or both have a rough surface.

6. The system of claim 1, wherein the surface of the inner wall of the aperture is smooth, rough, or threaded.

7. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 1 and 89 degrees.

8. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 75 degrees.

9. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 50 degrees.

10. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 10 and 35 degrees.

11. The system of claim 2, wherein the angle between the axis of the length of the anchoring member and the axis of the length of the locking member is between 25 and 30 degrees.

12. The system of claim 1, wherein the shape of the socket of the anchoring member and/or the shape of the socket of the locking member is hexagonal, pentagonal, square, triangular, cross-shaped, plus sign-shaped, linear, or star-shaped.

13. The system of claim 3, wherein the second fastener is a ball end hexagonal fastener.

14. A method of affixing one or more objects to bone, comprising the step of anchoring the object to the bone using the system of claim 1.

15. A kit comprising the system of claim 1.

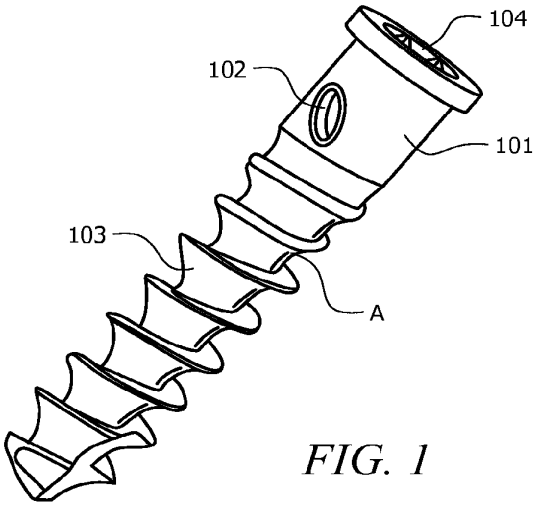



FIG. 1

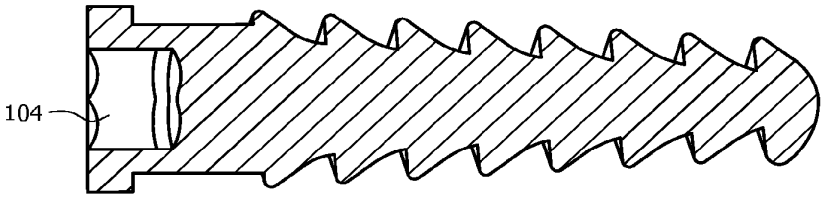



FIG. 2A

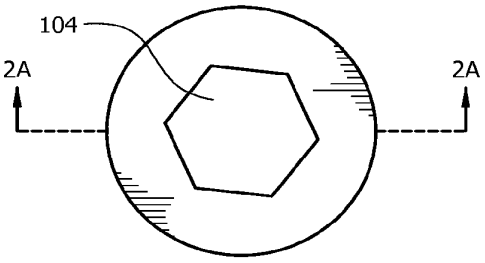



FIG. 2B

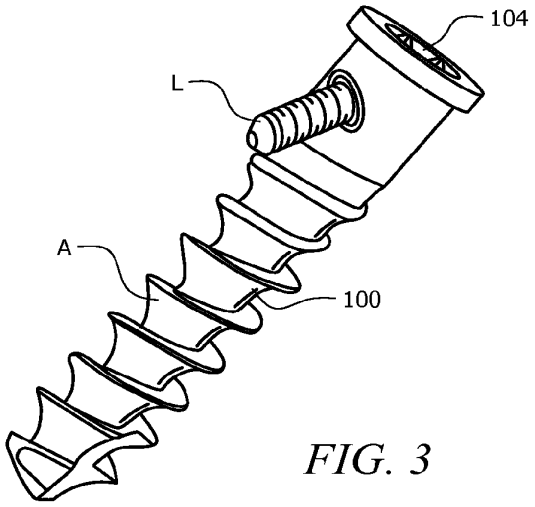



FIG. 3

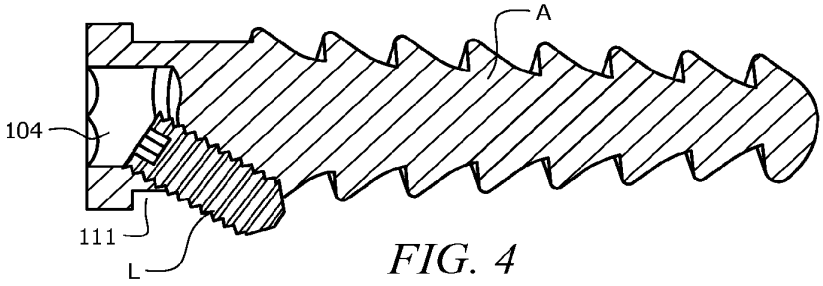



FIG. 4

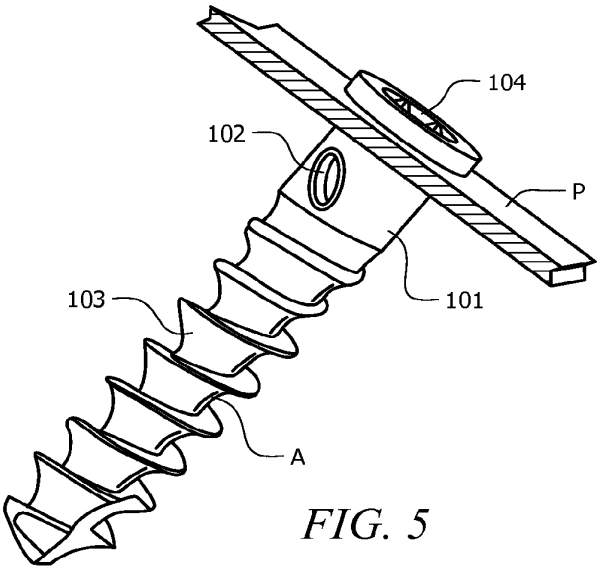



FIG. 5

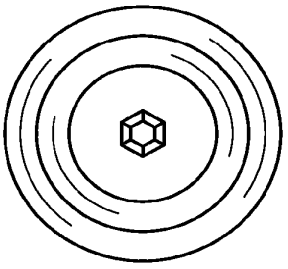


FIG. 6A

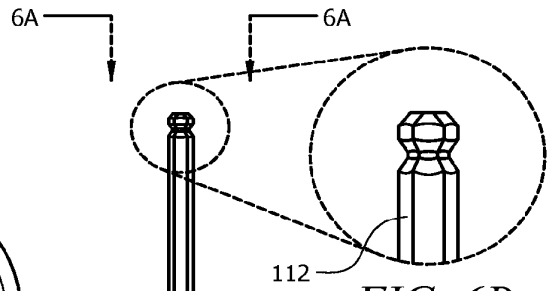



FIG. 6B

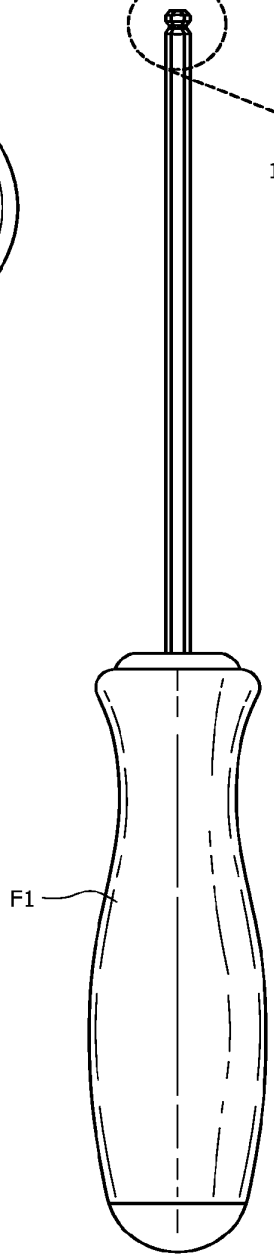



FIG. 6C

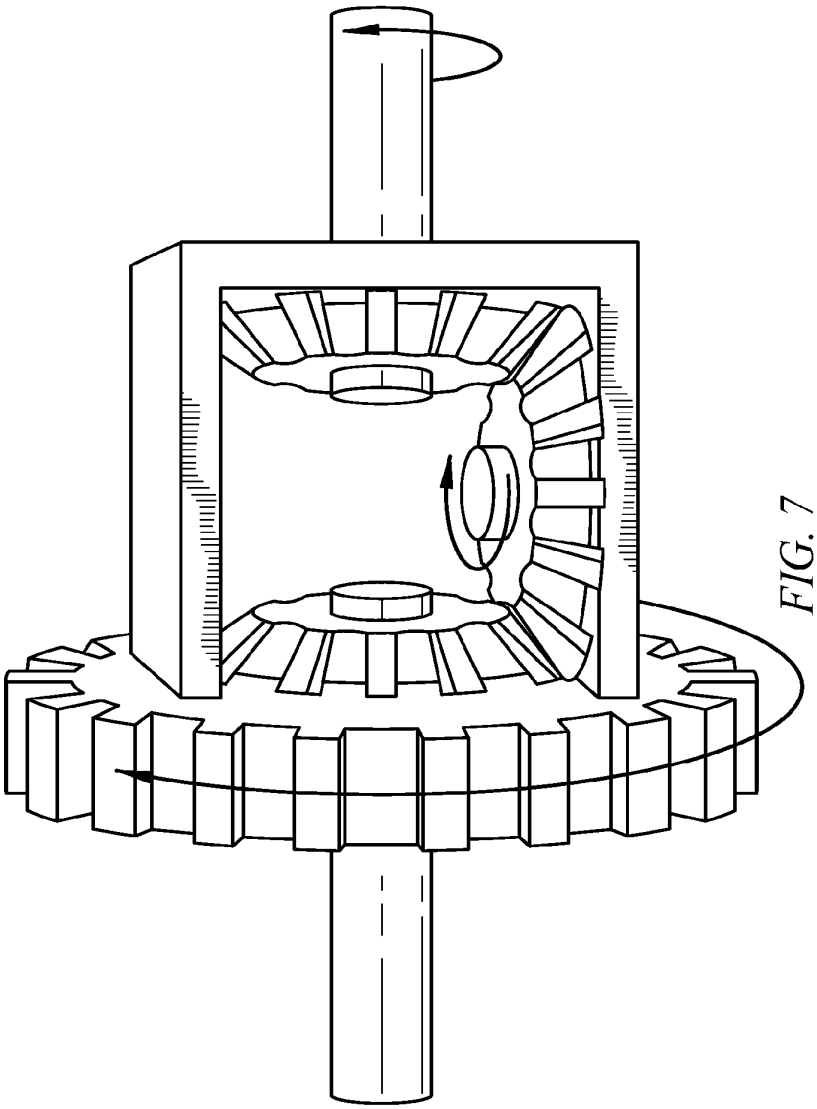


FIG. 7

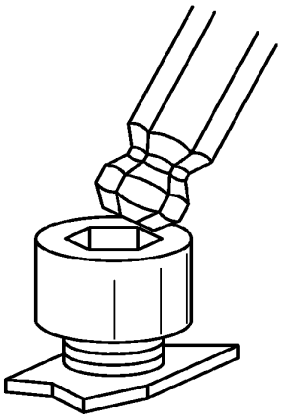


FIG. 8A

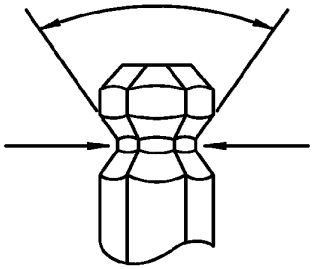


FIG. 8B

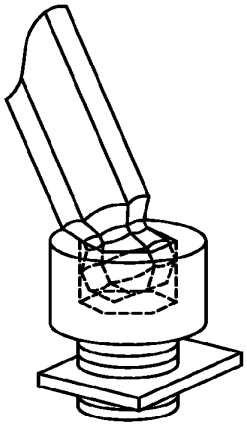


FIG. 8C

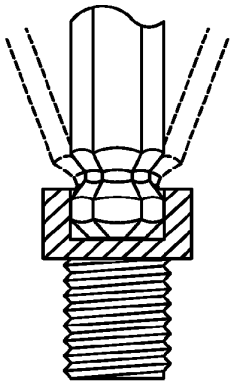


FIG. 8D

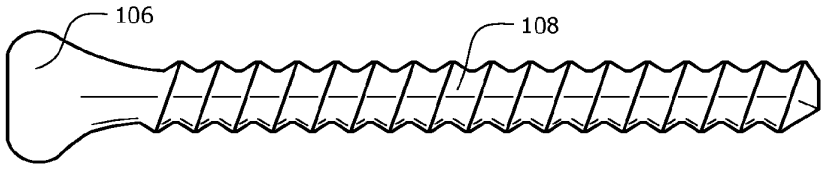



FIG. 9A

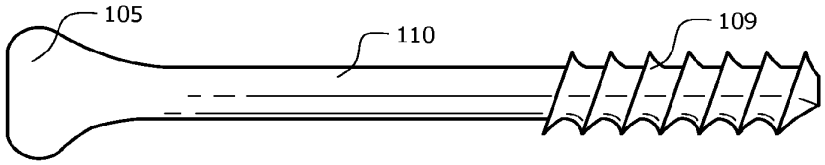



FIG. 9B

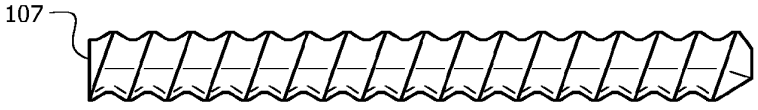



FIG. 9C

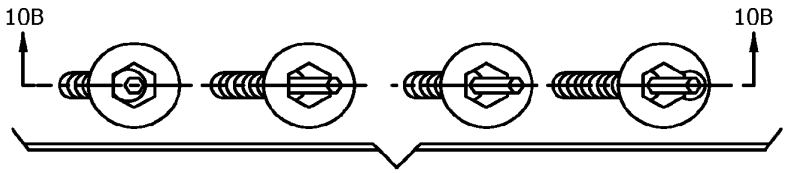



FIG. 10A

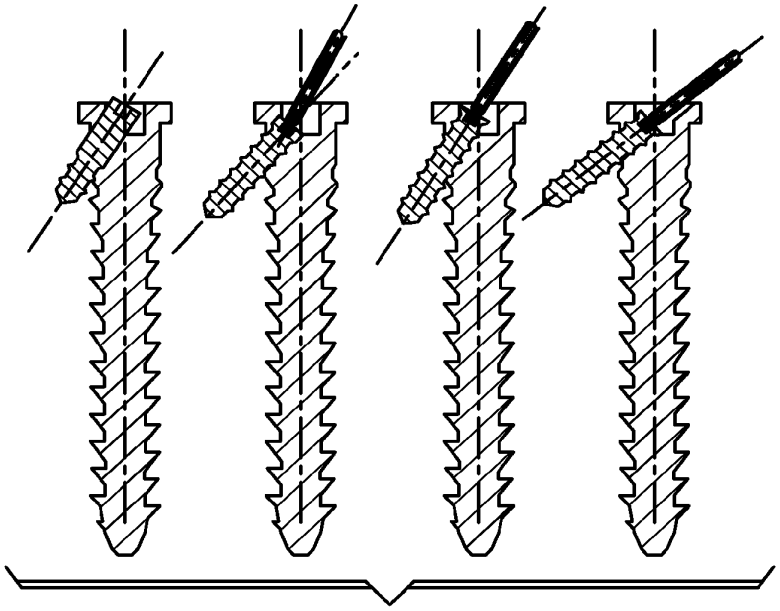


FIG. 10B

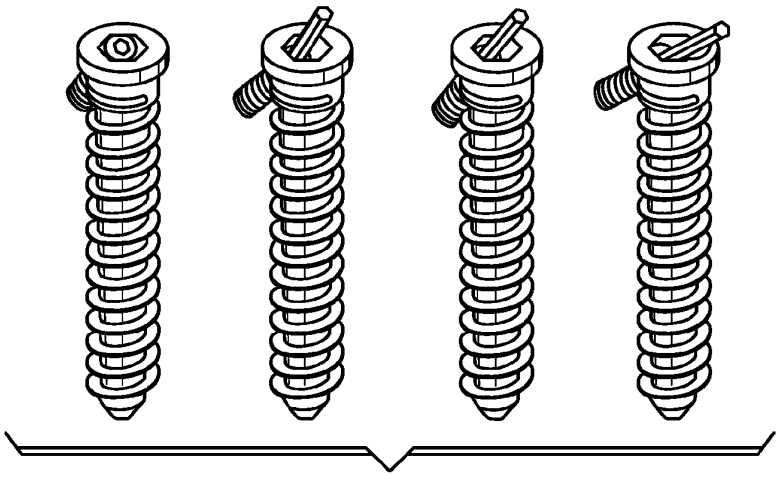


FIG. 10C

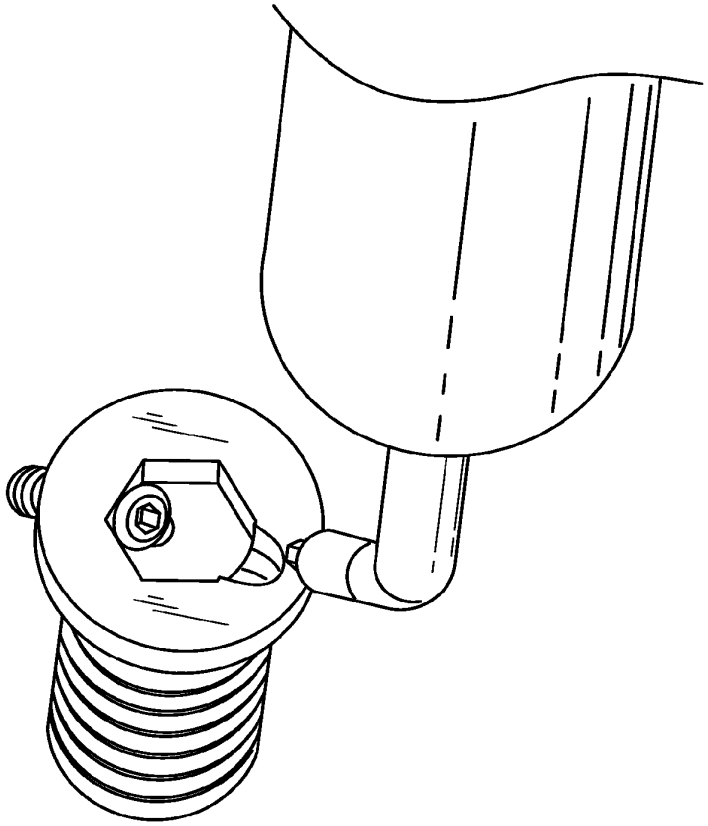


FIG. 11

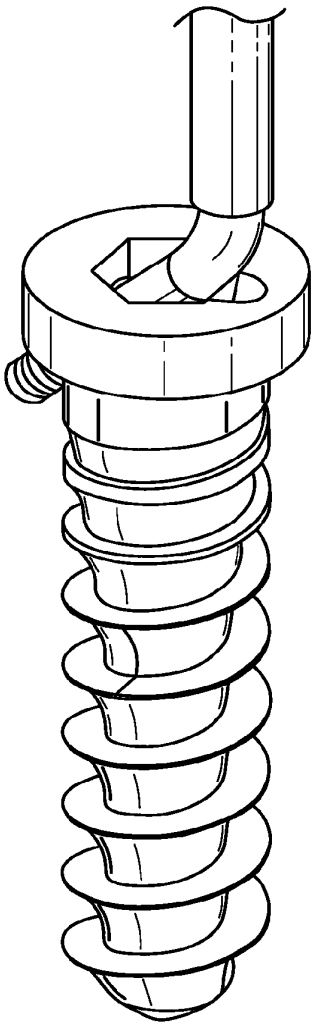


FIG. 12

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 15473896 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Hanna Bondarik Mosolygo/Melissa Nardone |
| **Filer Authorized By:** | Hanna Bondarik Mosolygo |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 09-APR-2013 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 17:04:40 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

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| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Miscellaneous Incoming Letter | CoverLetterIDS277_042.pdf | 59858<br>8ca2d67f16a878e8739549abc7dcce535167b691 | no | 1 |

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|---|---|
| **Warnings:** | |
| **Information:** | |

| | | | | | |
|---|---|---|---|---|---|
| 2 | Information Disclosure Statement (IDS) Form (SB08) | updated_IDSfiling277042.pdf | 33393<br>d2ae97e5f99e365049be2312014d9d0a4c1c612e | no | 5 |
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| This is not an USPTO supplied IDS fillable form | | | | | |
| 3 | Foreign Reference | WO2009120852.pdf | 898633<br>2d88ea46882b32aa6f7bb77ccdfd309396771a64 | no | 27 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | **Total Files Size (in bytes):** | 991884 | | |

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**New Applications Under 35 U.S.C. 111**
**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

Electronically filed April 9, 2013

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | | | |
|---|---|---|---|
| In re Application of: | Jeff Tyber, et al. | Confirmation No.: | 1344 |
| Serial No.: | 12/658,680 | Group Art Unit: | 3733 |
| Filed: | 2/11/2010 | Examiner: | Bray |
| For: | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: | 277-042 |

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

**COVER LETTER**

S I R:

Applicants submit herewith an Information Disclosure Statement pursuant to 37 CFR § 1.97(b). No admission is made that any of the references cited on the attached Information Disclosure Statement qualify as prior art under 35 U.S.C. §§ 102 and 103 or are material to patentability.

No fee is believed to be due. If a fee and/or a petition is 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: April 9, 2013

___/Hanna Bondarik Mosolygo/__
Hanna Bondarik Mosolygo
Reg. No. 66,475
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382 Springfield Avenue, Suite 300
Summit, New Jersey 07901
(908) 277-3333

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 05/22/2014

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| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/22/2014 | 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. 12/658,680 | Applicant(s) TYBER ET AL. | |
|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | AIA (First Inventor to File) Status No |

*-- 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* MONTHS 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 *10/9/2012*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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) *1-12,14-16,18,20-53,55-61,63-65 and 67-81* is/are pending in the application.

5a) Of the above claim(s) *24-50,73 and 74* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-12,14-16,18,20-23,51-53,55-61,63-65,67-72 and 75-81* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

**Application Papers**

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *3/28/2012* 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).

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

**Certified copies:**

a)☐ All b)☐ Some** c)☐ None of the:

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)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *10/9/2012 4/9/2013*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

The present application is being examined under the pre-AIA first to invent provisions.

## DETAILED ACTION

### *Election/Restrictions*

Applicant has requested notice that claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72 and 75-81 are pending in the application as drawn to an elected species. Claims 24-50 and 73-74 remain withdrawn.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim 1-11, 20-23, 51-53,55-61, 63-65, 67-72, 75-81 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18, 35-54, 56, 60 of U.S. Patent No. 8,303,589. Although the claims at issue are not identical, they are not patentably distinct from each other because the ‘589 patent claims a first screw member with a head and a shaft (claims 1, 35, 56, 60) a second screw member for coupling to

the first, with a threaded end, elongated body a bore extending to an aperture. The claims do not disclose a bulbous head on the second screw but it would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the head of the second screw to be bulbous, because the bulbous shape is an obvious design choice to allow an interference fit, with some movement, and disallow the first screw from passing through the bore in the second screw as is taught in Figure 2 of the '859 patent.

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there does not appear to be sufficient explanation of the plurality of points of fixation and uniform compression (what is being uniformly compressed) as recited in claim 78, which is rejected under 112 2nd below.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
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 78 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 78 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the plurality of points of fixation. The claim is unclear what these points are. It is unclear whether the plurality of points of fixation is associated with the first screw member or the second. The meaning of "uniform compression" is also unclear.

***Claim Rejections - 35 USC § 103***

The following is a quotation of pre-AIA 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 negatived 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 pre-AIA 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, 10, 11, 18, 20-23, 51-53, 59-61, 67-72, 75-80 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,542,326 to Dierks in view of U.S. Patent 7,204,838 to Jackson.

Regarding claims 1-5, 10, 11, 18, 20-23, 51-53, 59-61, 67-72, 75-77, 79-81 Dierks teaches a second screw member with first and second ends along a second axis, a threaded portion at the second end, first and second apertures connected by a bore, along a third axis, through the head of the screw. Dierks teaches 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 (between 0 and 90 degrees). Because the bulbous portion is partially spherical, the angle is variable when not locked/fixed. The angle is adapted to cause compression applied to bone fragments to translate and draw bones together. This is possible because the head of the first screw isn't locked within the bore of the second screw and as the first screw is rotated into a bone, the bone is drawn up the helix and toward the head of the screw, which brings that bone closer to the bone of the second screw. Because the fastener is interpreted to include a bone screw, which is obvious and well known in the art, it is interpreted that

Dierks discloses the second screw to have bone threads and a self-tapping edge like the first screw. Dierks does not disclose that the first internal surface is partially spherical, however, Jackson teaches a bone screw receiver with a hemispherical (partially spherical) internal surface (43, fig 4, Col 4 ln 59- Col 5 ln 5). It would have been obvious to one ordinarily skilled in the art at the time of the invention to modify the internal surface of Dierks with a partially spherical shape, as taught by Jackson, for a positive engagement with the bulbous head of the screw. Both screws are capable of being inserted into a medullary canal of a bone. The bore is adapted for retaining the bulbous portion. The second screw has a tubular portion with the bore and aperture.

Regarding claim 78 and in light of the 112 rejection above, the angle is also adapted for the compression to go through a plurality of points of fixation.

Claim 6-9, 12-16, 55-58, 63-65 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Dierks in view of Jackson and in further view of 2009/0240252 to Chang.

Dierks in view of Jackson teaches 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.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-12, 14-16, 18, 20-23, 51-53, 55-61, 63-65, 67-72, 75-81 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

### *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.

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

/ELLEN C HAMMOND/
Primary Examiner, Art Unit 3733

| Notice of References Cited | Application/Control No. 12/658,680 | Applicant(s)/Patent Under Reexamination TYBER ET AL. | |
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| | Examiner STUART S. BRAY | Art Unit 3733 | Page 1 of 3 |

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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

| Notice of References Cited | Application/Control No. 12/658,680 | Applicant(s)/Patent Under Reexamination TYBER ET AL. | |
|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | Page 2 of 3 |

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| Notice of References Cited | Application/Control No. 12/658,680 | Applicant(s)/Patent Under Reexamination TYBER ET AL. | |
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# BIB DATA SHEET

**CONFIRMATION NO. 1344**

| SERIAL NUMBER | FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010<br>RULE | 606 | 3733 | 277-042 |

**APPLICANTS**

**INVENTORS**

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**** CONTINUING DATA ***************************

This application is a CIP of 12/456,808 06/23/2009 PAT 8303589
which claims benefit of 61/132,932 06/24/2008

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
03/05/2010

| Foreign Priority claimed | ☐ Yes ☑ No | ☐ Met after Allowance | STATE OR COUNTRY | SHEETS DRAWINGS | TOTAL CLAIMS | INDEPENDENT CLAIMS |
|---|---|---|---|---|---|---|
| 35 USC 119(a-d) conditions met | ☐ Yes ☐ No | | PA | 20 | 74 | 3 |
| Verified and Acknowledged | /STUART SAMUEL BRAY/ Examiner's Signature | Initials | | | | |

**ADDRESS**

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SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901
UNITED STATES

**TITLE**

Intraosseous intramedullary fixation assembly and method of use

| FILING FEE RECEIVED | FEES: Authority has been given in Paper | ☐ All Fees |
|---|---|---|
| 2074 | No._____ to charge/credit DEPOSIT ACCOUNT | ☐ 1.16 Fees (Filing) |
| | No._____ for following: | ☐ 1.17 Fees (Processing Ext. of time) |
| | | ☐ 1.18 Fees (Issue) |
| | | ☐ Other _____ |
| | | ☐ Credit |

BIB (Rev. 05/07).

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| CPC- SEARCHED | | |
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| CPC COMBINATION SETS - SEARCHED | | |
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| US CLASSIFICATION SEARCHED | | | |
|---|---|---|---|
| Class | Subclass | Date | Examiner |
| 606 | 54, 62, 80, 96 | 9/21/2011 | SSB |
| 606 | 64, 65 | 9/23/2011 | SSB |
| | UPdated | 4/27/2012 | SSB |
| | updated | 5/16/2014 | SSB |
| 606 | 305-308,310,319 | 5/16/2014 | SSB |

| SEARCH NOTES | | |
|---|---|---|
| Search Notes | Date | Examiner |
| Performed inventor search | 9/21/2011 | SSB |
| referred to sibling case 12/906454 | 5/16/2014 | SSB |

| INTERFERENCE SEARCH | | | |
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| US Class/ CPC Symbol | US Subclass / CPC Group | Date | Examiner |
| | | | |

| /STUART S BRAY/<br>Examiner.Art Unit 3733 | |
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| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | | | | | |
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| | 22 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 23 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 24 | ÷ | N | N | N | | | | | |
| | 25 | ÷ | N | N | N | | | | | |
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| | 31 | ÷ | N | N | N | | | | | |
| | 32 | ÷ | N | N | N | | | | | |
| | 33 | ÷ | N | N | N | | | | | |
| | 34 | ÷ | N | N | N | | | | | |
| | 35 | ÷ | N | N | N | | | | | |
| | 36 | ÷ | N | N | N | | | | | |

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | | | | | |
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| | 38 | ÷ | N | N | N | | | | | |
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| | 50 | ÷ | N | N | N | | | | | |
| | 51 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 52 | ÷ | ✓ | ✓ | ✓ | | | | | |
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| | 54 | ÷ | - | - | - | | | | | |
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| | 68 | ÷ | N | N | ✓ | | | | | |
| | 69 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 70 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 71 | ÷ | ✓ | ✓ | ✓ | | | | | |
| | 72 | ÷ | ✓ | ✓ | ✓ | | | | | |

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

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|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | | | | | |
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| | 74 | ÷ | N | N | N | | | | | |
| | 75 | | | N | ✓ | | | | | |
| | 76 | | | N | ✓ | | | | | |
| | 77 | | | N | ✓ | | | | | |
| | 78 | | | N | ✓ | | | | | |
| | 79 | | | N | ✓ | | | | | |
| | 80 | | | N | ✓ | | | | | |
| | 81 | | | N | ✓ | | | | | |

**EAST Search History**

**EAST Search History (Prior Art)**

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
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| S29 | 22 | "7204838" | USPAT | OR | OFF | 2014/05/15 15:20 |
| S30 | 4 | "12456808" | USPAT | OR | OFF | 2014/05/16 14:02 |

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**EAST Search History (Interference)**

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: Jeff Tyber, et al. | Confirmation No.: 1344 |
| Serial No.: 12/658,680 | Group Art Unit: 3733 |
| Filed: February 11, 2010 | Examiner: Bray, Stuart Samuel |
| For: AN INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: 277-042 |

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

**COVER LETTER**

S I R:

Applicants submit herewith an Information Disclosure Statement pursuant to 37 CFR § 1.97(b)(4). No admission is made that any of the references cited on the attached Information Disclosure Statement qualify as prior art under 35 U.S.C. §§ 102 and 103 or are material to patentability.

No fee is believed to be due with this filing. If a petition and/or any fee is 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.

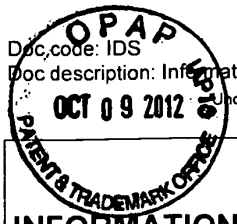
Respectfully submitted,

Date: October 3, 2012

/Francis E. Morris/
Francis E. Morris
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./




Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**( Not for submission under 37 CFR 1.99)**

| | |
|---|---|
| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Tyber, Jeff |
| Art Unit | 3733 |
| Examiner Name | Bray, Stuart Samuel |
| Attorney Docket Number | 277-042 |

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| | Application Number | 12658680 |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
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| | Application Number | 12658680 |
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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Application Number | 12658680 |
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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Art Unit | 3733 |
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| | Attorney Docket Number | 277-042 |

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**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code[1] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
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| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Application Number | 12658680 |
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| | Art Unit | 3733 |
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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| | | | | | | |
|---|---|---|---|---|---|---|
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**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] i | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
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| | 1 | | ☐ |

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**EXAMINER SIGNATURE**

| Examiner Signature | /Stuart Bray/ | Date Considered | 05/16/2014 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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| | First Named Inventor | Tyber, Jeff |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Francis E. Morris/ | Date (YYYY-MM-DD) | 2012-10-03 |
|---|---|---|---|
| Name/Print | Francis E. Morris | Registration Number | 24615 |

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| | First Named Inventor | Tyber |
| | Art Unit | 3733 |
| | Examiner Name | BRAY |
| | Attorney Docket Number | 277-042 |

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|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
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| If you wish to add additional U.S. Patent citation information please click the Add button. | | | | | | |

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| Receipt date: 04/09/2013 | Application Number | 12658680 12658680 - GAU: 3733 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | Filing Date | 2010-02-11 |
| | First Named Inventor | Tyber |
| | Art Unit | 3733 |
| ( **Not for submission under 37 CFR 1.99)** | Examiner Name | BRAY |
| | Attorney Docket Number | 277-042 |

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| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] i | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
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| | First Named Inventor | Tyber |
| | Art Unit | 3733 |
| | Examiner Name | BRAY |
| | Attorney Docket Number | 277-042 |

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| Examiner Signature | /Stuart Bray/ | Date Considered | 05/16/2014 |
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|---|---|---|---|
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| | First Named Inventor | Tyber | |
| | Art Unit | 3733 | |
| | Examiner Name | BRAY | |
| | Attorney Docket Number | 277-042 | |

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☐ See attached certification statement.

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☒ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Hanna Bondarik Mosolygo/ | Date (YYYY-MM-DD) | 2013-04-09 |
|---|---|---|---|
| Name/Print | Hanna Bondarik Mosolygo | Registration Number | 66475 |

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 09/12/2014

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/12/2014 | 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.

| ***Applicant-Initiated Interview Summary*** | **Application No.** 12/658,680 | **Applicant(s)** TYBER ET AL. | |
|---|---|---|---|
| | **Examiner** STUART S. BRAY | **Art Unit** 3733 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *STUART S. BRAY*.

(3) *Hanna Mosolygo*.

(2) _____.

(4) _____.

Date of Interview: *09 September 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1 and 51*.

Identification of prior art discussed: *Dierks, Overes*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

*Atty Mosolygo called to discuss potential claim amendments in response to the 5/22/2014 non final action. Applicant's proposed amendments that specified that the first screw extended out of the aperture in the head of the second screw and that the scrwe heads abutted appear to overcome the 102 rejection to Dierks. However, examiner pointed out that the art to Overes would likely be applicable as 102 or 103 art, in light of the proposed amendments*.

**Applicant recordation instructions:** The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

**Examiner recordation instructions**: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

| /STUART S BRAY/<br>Examiner, Art Unit 3733 | |
|---|---|

# Summary of Record of Interview Requirements

**Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record**
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

**Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews**
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

**Examiner to Check for Accuracy**

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Electronically filed on September 17, 2014

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: Jeff Tyber, et al. | Confirmation No.: 1344 |
| Serial No.: 12/658,680 | Examiner: Bray, Stuart Samuel |
| Filed: February 11, 2010 | Art Unit: 3733 |
| For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: 277-042 |

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

**AMENDMENT AND RESPONSE TO THE OFFICE ACTION OF MAY 22, 2014**

SIR:

This is an amendment and response to the office action of May 22, 2014. 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.

**IN THE CLAIMS:**

The following listing of claims will replace all prior versions and listings of claims in the subject application:

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

a first screw member, wherein the first screw member comprises a first elongated body extending along a first longitudinal axis, and wherein the first elongated body includes a first threaded portion at a first end for advancing said first screw member into a first bone or bone fragment and a bulbous portion at a second end comprising an exterior surface; and

a second screw member for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, the second elongated body extending along a second longitudinal axis, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment, a first aperture at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the bore comprises an interior surface at the first aperture, wherein the second longitudinal axis and the third axis define an angle,

wherein the first screw member couples to the second screw member by being inserted ~~inserting the first screw member~~ into and through the bore until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment, wherein the first screw member and the

second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together.

**2. (Previously presented):** The assembly of claim 1, wherein the first screw member couples to the second screw member at the angle.

**3. (Previously presented):** The assembly of claim 1, wherein the angle is in the range of about 0 degrees to about 90 degrees.

**4. (Currently amended):** The assembly of claim 1, wherein the exterior surface of the bulbous portion includes a taper for providing an interference fit with the second screw member.

**5. (Previously presented):** The assembly of claim 4, wherein the taper provides for an interference lock with the second screw member.

**6. (Previously presented):** The assembly of claim 1, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Previously presented):** The assembly of claim 1, wherein the bulbous portion includes an aperture disposed along the first longitudinal axis.

**8. (Previously presented):** The assembly of claim 7, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**9. (Previously presented):** The assembly of claim 7, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**10. (Previously presented):** The assembly of claim 1, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Previously presented):** The assembly of claim 1, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**12. (Previously presented):** The assembly of claim 1, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**13. (Canceled)**.

**14. (Previously presented):** The assembly of claim 12, wherein the internal aperture is disposed along the second longitudinal axis.

**15. (Previously presented):** The assembly of claim 12, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Previously presented):** The assembly of claim 15, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**17. (Canceled)**.

**18. (Currently amended):** The assembly of claim 1, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within the bore, and further wherein the bulbous portion abuts the interior surface of the bore at the first aperture at the second end of the second elongated body.

**19. (Canceled)**.

**20. (Previously presented):** The assembly of claim 1, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**21. (Previously presented):** The assembly of claim 1, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**22. (Previously presented):** The assembly of claim 1, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**23. (Previously presented):** The assembly of claim 22, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Withdrawn):** The intramedullary assembly of claim 1, further comprising a cover portion for coupling to the bulbous portion of the lag screw member.

**25. (Withdrawn):** The intramedullary assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**26. (Withdrawn):** A method for bone fusion, comprising:

providing a lag screw member, wherein the lag screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end and a bulbous portion at a second end; and

providing a tapered screw member coupled to the lag screw member, wherein the tapered screw member includes a second elongated body, wherein the second elongated body comprises a second threaded portion at a third end, a tubular portion at a fourth end, and an opening at the fourth end;

making an incision in the foot;

forming a first medullary canal in a first bone;

inserting the tapered screw member into the first medullary canal;

aligning the tapered screw member in the first medullary canal;

forming a second medullary canal in the first bone;

coupling the lag screw member to the tapered screw member;

inserting the lag screw member into the second medullary canal;

applying torque to the lag screw member to lock the tapered screw member to the lag screw member, thereby compressing the first bone to the second bone.

**27. (Withdrawn):** The method of claim 26, wherein the lag screw member is slideably coupled to the tapered screw member and makes a fixed angle with the tapered screw member.

**28. (Withdrawn):** The method of claim 27, wherein the fixed angle is in the range of approximately 0 to approximately 90 degrees.

**29. (Withdrawn):** The method of claim 26, wherein the bulbous portion includes a taper for providing an interference fit with the tapered screw member.

**30. (Withdrawn):** The method of claim 29, wherein the taper provides for an interference lock with the tapered screw member.

**31. (Withdrawn):** The method of claim 26, wherein the lag screw member is cannulated having a circular cross-section with said first elongated body.

**32. (Withdrawn):** The method of claim 26, wherein the bulbous portion includes an orifice longitudinally coextensive with a length of the bulbous portion.

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

**34. (Withdrawn):** The method of claim 32, further comprising receiving a complementary shaped end of an instrument in the orifice.

**35. (Withdrawn):** The method of claim 26, wherein the first threaded portion contains a plurality of bone threads on an outer surface of the threaded portion.

**36. (Withdrawn):** The method of claim 26, 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 lag screw member.

**37. (Withdrawn):** The method of claim 26, wherein the tapered screw member comprises a plurality of apertures disposed in the second elongated body.

**38. (Withdrawn):** The method of claim 37, wherein the plurality of apertures comprises a first internal aperture and a tapered aperture.

**39. (Withdrawn):** The method of claim 38, wherein the first internal aperture partially traverses the tubular portion at the fourth end.

**40. (Withdrawn):** The method of claim 38, wherein the first internal aperture comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**41. (Withdrawn):** The method of claim 40, further comprising receiving a complementary shaped member in the opening.

**42. (Withdrawn):** The method of claim 38, wherein the tapered aperture traverses the second elongated body from the end of the tubular portion to an exterior surface on the second elongated body.

**43. (Withdrawn):** The method of claim 38, further comprising receiving the first elongated body of the lag screw member in the tapered aperture, wherein the bulbous portion is contained in the tapered aperture, and further wherein the bulbous portion abuts the opening at the end of the tubular portion.

**44. (Withdrawn):** The method of claim 38, wherein the tapered aperture forms a predetermined angle with the second elongated body.

**45. (Withdrawn):** The method of claim 26, wherein the second threaded portion contains a plurality of threads on an outer surface of the second threaded portion.

**46. (Withdrawn):** The method of claim 26, 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 tapered screw member.

**47. (Withdrawn):** The method of claim 26, further comprising inserting the lag screw member into at least a first medullary canal of bone.

**48. (Withdrawn):** The method of claim 47, further comprising inserting the tapered screw member into at least the first medullary canal of the bone.

**49. (Withdrawn):** The method of claim 26, further comprising providing a cover portion coupled to the bulbous portion of the lag screw member.

**50. (Withdrawn):** The method of claim 49, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**51. (Currently amended):** An assembly for bone fusion, comprising:

a first screw member, wherein the first screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end <u>for advancing said first screw member into a first bone or bone fragment</u> and a bulbous portion at a second end <u>comprising an exterior surface</u>; and

a second screw member for coupling to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment and a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises a first aperture at a terminal end of the second end of the second elongated body and a bore extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the bore comprises an interior surface,

wherein the bulbous portion is semi-spherical for providing angular rotation of the first screw member relative to the second screw member, and

wherein the first screw member couples to the second screw member by being inserted ~~inserting the first screw member~~ into and through the bore until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment, wherein the first screw member and the second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together.

**52. (Previously presented):** The assembly of claim 51, wherein the first screw member couples to the second screw member at an angle.

**53. (Previously presented):** The assembly of claim 52, wherein the angle varies between about 0 degrees and about 90 degrees.

**54. (Canceled).**

**55. (Previously presented):** The assembly of claim 51, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Previously presented):** The assembly of claim 51, wherein the bulbous portion includes an aperture.

**57. (Previously presented):** The assembly of claim 56, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**58. (Previously presented):** The assembly of claim 56, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**59. (Previously presented):** The assembly of claim 51, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**60. (Previously presented):** The assembly of claim 51, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**61. (Previously presented):** The assembly of claim 51, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**62. (Canceled)**.

**63. (Previously presented):** The assembly of claim 61, wherein the internal aperture partially traverses the tubular portion at the second end of the second elongated body.

**64. (Previously presented):** The assembly of claim 61, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Previously presented):** The assembly of claim 64, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**66. (Canceled)**.

**67. (Currently amended):** The assembly of claim 51, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within the bore, and further wherein the bulbous portion abuts the internal surface of the bore at the first aperture at the second end of the second elongated body.

**68. (Previously presented):** The assembly of claim 51, wherein the bore forms a predetermined angle with the second elongated body.

**69. (Previously presented):** The assembly of claim 51, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**70. (Previously presented):** The assembly of claim 51, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**71. (Previously presented):** The assembly of claim 51, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**72. (Previously presented):** The assembly of claim 71, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Withdrawn):** The assembly of claim 51, further comprising a cover portion coupled to the bulbous portion of the lag screw member.

**74. (Withdrawn):** The intramedullary assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**75. (Previously presented):** The assembly of claim 1, wherein the bore is adapted for retaining the bulbous portion.

**76. (Currently amended):** The assembly of claim 4, wherein the interior surface of the bore comprises a taper for providing an interference fit with the taper of the bulbous portion.

**77. (Cancelled)**.

**78. (Currently amended):** The assembly of claim [[2]] 1, wherein uniform compression is translated across the first screw member and the second screw member to the first bone or bone fragment and the second bone or bone fragment ~~the angle is adapted to cause the assembly to couple to at least a first bone and translate compression applied to bone fragments by the second screw member and the first screw member into uniform compression through a plurality of points of fixation~~.

**79. (Previously presented):** The assembly of claim 1, wherein the bulbous portion comprises a spherical portion adapted to allow the first screw member to couple to the second screw member at a plurality of possible angles ranging from about 0 degrees to about 90 degrees.

**80. (Previously presented):** The assembly of claim 79, wherein the spherical portion is adapted to allow the first screw member to rotate within the bore to set an angle between the first screw member and the second screw member to at least one of the plurality of possible angles.

**81. (Previously presented):** The assembly of claim 1, wherein the second screw member comprises a tubular portion at the second end of the second elongated body, wherein the tubular

portion comprises the first aperture and the bore, and wherein the second aperture is on an exterior surface of the tubular portion.

## REMARKS

Claims 1 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 76, and 78 – 81 are pending in this application. Please amend claims 1, 4, 18, 51, 67, 76, and 78 and cancel claim 77. 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 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 76, and 78 – 81 is patentable over the prior art.

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

### I. THE DOUBLE PATENTING REJECTION

The Examiner provisionally rejected claims 1 – 11, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72, and 75 – 81 on the ground of non-statutory double patenting over claims 1 – 18, 35 – 54, 56, and 60 of U.S. Patent No. 8,303,589. It is respectfully requested that the filing of a terminal disclaimer be deferred until the Examiner has given an indication of allowable claims.

### II. SPECIFICATION AND THE 35 U.S.C. § 112 REJECTION

The Examiner objected to the specification because, according to the Examiner, there does not appear to be sufficient explanation of the plurality of points of fixation and uniform

compression (i.e., what is being uniformly compressed) as recited in claim 78. Consequently, the Examiner rejected claim 78 under 35 U.S.C. § 112, second paragraph, because, according to the Examiner, the claim is unclear what the plurality of points of fixation are and whether the plurality of points of fixation is associated with the first screw member or the second. The Examiner also noted that the meaning of "uniform compression" is also unclear.

Claim 78 has been amended to recite that "uniform compression is translated across the first screw member and the second screw member to the first bone or bone fragment and the second bone or bone fragment." Support for this amendment is found in paragraph [0055] of U.S. App. Pub. No. 20100256638, which recites:

> The fixed angle between the tapered screw member 810 and the lag screw member 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. . . 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 is apparent in Figures 8-9, the interaction of members 810 and 815 cause compression to be applied to bone fragments across the length of members 810 and 815 — the compression being uniformly applied to the bone fragments between and across members 810 and 815. In light of the amendment to claim 78 and the remarks above, Applicants respectfully submit that claim 78 complies with 35 U.S.C. § 112, second paragraph. Accordingly, for at least these reasons, Applicants respectfully request reconsideration and withdrawal of the objection and the rejection.

## III. THE 35 U.S.C § 103 REJECTION

The Examiner rejected claims 1 – 5, 10, 11, 18, 20 – 23, 51 – 53, 59 – 61, 67 – 72, and 75 – 80 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,542,326 to Dierks ("Dierks") in view of U.S. Patent No. 7,204,838 to Jackson ("Jackson").

Applicants thank the Examiner for an Interview conducted on September 9, 2014. During the interview, the undersigned and the Examiner discussed the Dierks reference, the foregoing amendments to independent claims 1 and 51, and the arguments discussed below. In addition, the Examiner pointed out the likely applicability of U.S. Pat. App. Pub. No. 20110282398 to Overes ("Overes"). However, Applicants submit that Overes is not a proper 35 U.S.C. § 102 or 103 reference. Overes was filed on May 9, 2011 and claims the benefit of a provisional application filed on May 13, 2010. The subject application, however, was filed on February 11, 2010 — prior to the earliest filing date Overes can claim. Accordingly, any rejection in light of Overes would be improper.

The bone fusion assembly 800 of the present invention, as claimed in independent claim 1 and as shown in Figures 9-11 reproduced below, comprises a first screw member 815 and a second screw member 810 for coupling to the first screw member 815.

Figure 9

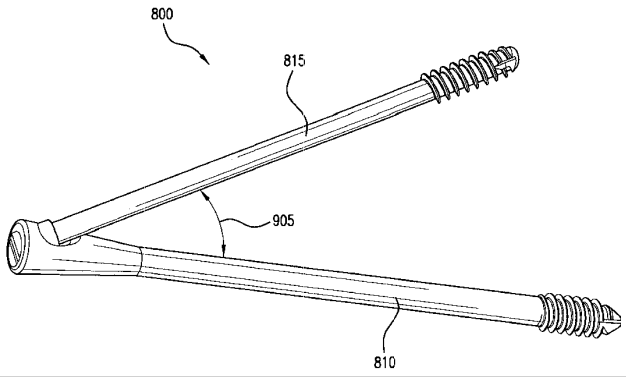



Figure 10

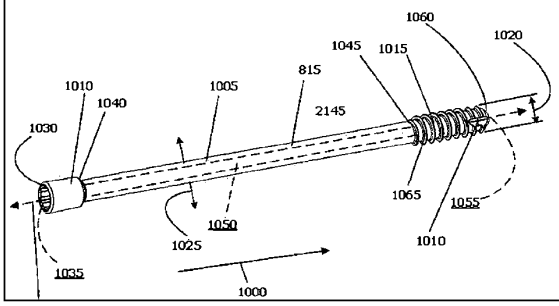
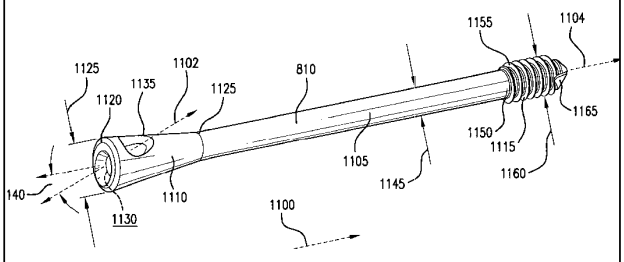



Figure 11

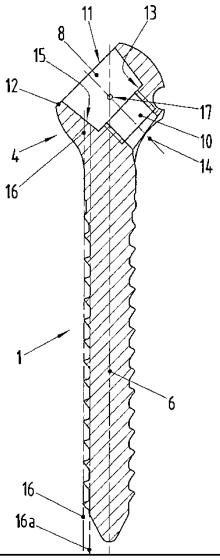
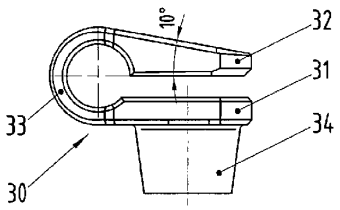
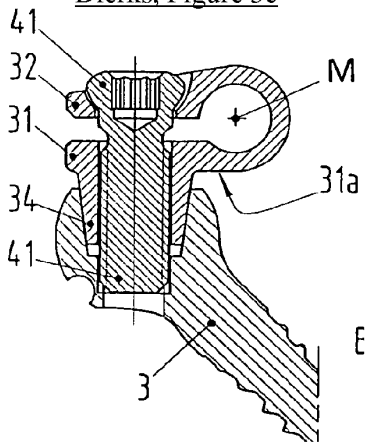


The first screw member 815 comprises a first elongated body extending along a first longitudinal axis 1002. The first elongated body includes a first threaded portion 1015 at a first end 1045 for advancing the first screw member 815 into a first bone or bone fragment as shown in Figure 8. The first elongated body further includes a bulbous portion 1010 at a second end 1040 comprising an exterior surface, as shown in Figure 10.

The second screw member 810 includes a second elongated body having first 1150 and second 1125 ends, the second elongated body extending along a second longitudinal axis 1104. The second elongated body comprises a second threaded portion 1115 at the first end 1150 of the second elongated body for advancing the second screw member 810 into a second bone or bone fragment, as shown in Figure 8. The second elongated body further comprises a first aperture 1130 at a terminal end 1120 of the second end of the second elongated body, and a bore extending along a third axis 1102 from the first aperture 1130 to a second aperture on an exterior surface 1135 of the second screw member 810. As shown in Figure 11, the bore comprises an interior surface at the first aperture 1130. The second longitudinal axis 1104 and the third axis 1102 define an angle.

When assembled, the first screw member 815 couples to the second screw member 810 by being inserted into and through the bore until the exterior surface of the bulbous portion 1010 of the first screw member 815 abuts the interior surface of the bore at the first aperture 1130 of the second screw member 810 and the first threaded portion 1015 extends out of the second aperture to engage the first bone or bone fragment. Importantly, as shown in Figure 8, the first screw member 815 and the second screw member 810 translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together.

Applicants submit that Dierks fails to disclose or teach the present invention as claimed in claim 1. Dierks fails to disclose an assembly that translates compression to first and second bones or bone fragments. Instead, as shown below, Dierks discloses a bone screw 1 for attaching a spinal longitudinal rod (not shown) to a vertebra. (*See* Dierks, col. 7, lns. 14-18).

| Dierks, Figure 1f | Dierks, Figure 2c | Dierks, Figure 3c |
|---|---|---|
|   |   |   |

Specifically, as shown in Figure 2c, a fastening device 30 comprises an arch-shaped retaining area 33 for receiving the spinal longitudinal rod. (*See* Dierks, col. 8, lns. 56-61). As shown in Figure 3c, the fastening device 30 is secured to bone screw 1 via threaded screw or stud 41. (*See* Dierks, col. 7, lns. 36-42). Stud 41, however, is not equivalent to the first screw member 815 of the present invention and stud 41 does not couple in the same way to bone screw 1 as the first screw member 815 couples to the second screw member 810 in the present invention. Contrary to the present invention, the threaded portion of stud 41 is not advanced into any bone — instead, as shown in Figure 3c, the threaded portion of stud 41 is advanced into the threaded hole 10 (Figure 1f) of bone screw 1. Specifically, the threads of stud 41 do not extend out of the aperture at the side surface of the bone screw 1 to engage the first bone or bone fragment, as required by

amended independent claim 1. In addition, the head portion of stud 41 does not abut any bore or interior surface of bone screw 1. Instead, as shown in Figure 3c, the head portion of stud 41 engages a hole in leg 32 of the fastening device 30.

As shown above, Dierks fails to disclose, and is in fact missing, the following limitations of independent claim 1: "wherein the first elongated body includes a first threaded portion at a first end for advancing said first screw member into a first bone or bone fragment," "wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment," "wherein the first screw member couples to the second screw member by being inserted into and through the bore until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment," and "wherein the first screw member and the second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together."

Jackson was simply cited for teaching a partially spherical internal surface.

In light of the remarks above, Applicants respectfully submit that Dierks and Jackson, alone or in combination, do not teach, suggest or render obvious currently amended claim 1. Accordingly, Applicants respectfully submit that claim 1 is patentable over Dierks and Jackson. Dependent claims 2 – 12, 14 – 16, 18, 20 – 23, 75 – 76, and 78 – 81 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 – 12, 14 – 16, 18, 20 – 23, 75 – 76, and 78 – 81.

Referring to independent claim 51, Applicants submit that Dierks and Jackson, alone or in combination, do not discuss, and are in fact missing at least the following elements, *inter alia*, required by currently amended independent claim 51: "wherein the first elongated body includes a first threaded portion at a first end for advancing said first screw member into a first bone or bone fragment," "wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment," "wherein the first screw member couples to the second screw member by being inserted into and through the bore until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment," and "wherein the first screw member and the second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together." For the same reasons discussed above with respect to claim 1, Dierks and Jackson, alone or in combination, do not discuss or disclose these limitations. Dependent claims 52 – 53, 55 – 61, 63 – 65 and 67 – 72 are patentable by virtue of their dependency on claim 51. For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejection and allowance of claims 51 – 53, 55 – 61, 63 – 65 and 67 – 72.

## CONCLUSION

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections and allowance of pending claims 1 – 12, 14 – 16, 18, 20 – 23, 51 – 53, 55 – 61, 63 – 65, 67 – 72 and 75 – 76, and 78 – 81.

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 one month extension of time. In the event that any additional fee is required for the entry of this response the Patent and Trademark Office is specifically authorized to charge such fee to Deposit Account No. 23-0420 in the name of Ward & Zinna.

Respectfully submitted,

Date: September 17, 2014

/ Hanna Bondarik Mosolygo/

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Summit, New Jersey 07901
(908) 277-3333

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | 12658680 |
| **Filing Date:** | 11-Feb-2010 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Filer:** | Hanna Bondarik Mosolygo |
| **Attorney Docket Number:** | 277-042 |

Filed as Small Entity

## Utility under 35 USC 111(a) Filing Fees

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Basic Filing:** | | | | |
| **Pages:** | | | | |
| **Claims:** | | | | |
| **Miscellaneous-Filing:** | | | | |
| **Petition:** | | | | |
| **Patent-Appeals-and-Interference:** | | | | |
| **Post-Allowance-and-Post-Issuance:** | | | | |
| **Extension-of-Time:** | | | | |
| Extension - 1 month with $0 paid | 2251 | 1 | 100 | 100 |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
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| **Miscellaneous:** | | | | |
| Submission- Information Disclosure Stmt | 2806 | 1 | 90 | 90 |
| | | **Total in USD ($)** | | **190** |

# Electronic Acknowledgement Receipt

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|---|---|
| **EFS ID:** | 20160459 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | Intraosseous intramedullary fixation assembly and method of use |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Hanna Bondarik Mosolygo |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 17-SEP-2014 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 11:03:32 |
| **Application Type:** | Utility under 35 USC 111(a) |

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| 1 | Information Disclosure Statement (IDS) Form (SB08) | 277-042_IDS.pdf | 612534<br>ac943203ee45c742b04ad41fc8e70a56cad29870 | no | 4 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 2 | Foreign Reference | FR2861576A1.pdf | 274018<br>1ebd9a8a4f4e9dfec593edb78f91df389fbe5de3 | no | 9 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 3 | Foreign Reference | WO9722301A1.PDF | 4013539<br>697ab03d9c3626fa64b96794fecec29c54ffdc01 | no | 120 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 4 | Foreign Reference | WO2008024373A2.PDF | 2562568<br>f916096587e77446a5c608a8ffa9d75cecb850b2 | no | 69 |
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| 6 | Amendment/Req. Reconsideration-After Non-Final Reject | 2014-09-17_ROA_277-042.pdf | 193447<br>4da473229b238108c5e5937688ebf197284b500b | no | 24 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 7 | Fee Worksheet (SB06) | fee-info.pdf | 31652<br>191110ce8c45575c286309f534cf4e555369c925 | no | 2 |
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| | |
|---|---|
| Application Number | 12658680 |
| Filing Date | 2010-02-11 |
| First Named Inventor | Jeff Tyber |
| Art Unit | 3733 |
| Examiner Name | Bray, Stuart Samuel |
| Attorney Docket Number | 277-042 |

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| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|---|
| | 1 | 4011863 | | 1977-03-15 | Zickel | |
| | 2 | 5417692 | | 1995-05-23 | Goble, et al. | |
| | 3 | 6379354 | | 2002-04-30 | Rogozinski | |

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| | 1 | 20060015123 | | 2006-01-19 | Fencl et al. | |
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|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Jeff Tyber |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
| | 1 | FR2861576A1 | FR | | | Cognet | | ☐ |
| | 2 | WO2009067831A1 | WO | | | Klaue | | ☐ |
| | 3 | WO2008024373A2 | WO | | | Samy | | ☐ |
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|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Jeff Tyber |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
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| Signature | /Hanna Bondarik Mosolygo/ | Date (YYYY-MM-DD) | 2014-09-17 |
| Name/Print | Hanna Bondarik Mosolygo | Registration Number | 66475 |

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(51) Int Cl[7] : **A 61 B 17/72**

# (12) DEMANDE DE BREVET D'INVENTION A1

(22) **Date de dépôt :** 31.10.03.

(30) **Priorité :**

(43) **Date de mise à la disposition du public de la demande :** 06.05.05 Bulletin 05/18.

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(60) **Références à d'autres documents nationaux apparentés :**

(71) **Demandeur(s) :** *COGNET JEAN MICHEL* — FR.

(72) **Inventeur(s) :** COGNET JEAN MICHEL.

(73) **Titulaire(s) :**

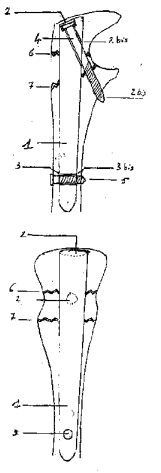
(74) **Mandataire(s) :**

## (54) DISPOSITIF D'OSTEOSYNTHESE DES FRACTURES DE L'EXTREMITE PROXIMALE DU CUBITUS.

(57) L'invention concerne un dispositif permettant de réaliser une ostéosynthèse des fractures de l'olécrane telle que l'on puisse entreprendre une rééducation post-opératoire immédiate, et sans qu'il soit nécessaire de ré-intervenir secondairement pour réaliser l'ablation du dispositif du fait du caractère non gênant de celui-ci.

Il est constitué d'un clou (1) présentant un orifice ou tunnel proximal (2) et au moins deux orifice vis à vis l'un de l'autre ou un tunnel distal (3) dans lesquels seront introduites des vis, l'une en situation proximale (4), et l'autre (5) ou les autres en situation distale.

Le dispositif selon l'invention est particulièrement destiné à l'ostéosynthèse des fractures de l'olécrane.



FR 2 861 576 - A1

La présente invention concerne un dispositif d'ostéosynthèse des fractures de l'extrémité proximale du cubitus (olécrane).

Les dispositifs existant actuellement nécessitent pour la plupart leur ablation à moyen terme en raison de la gène occasionnée par le matériel (saillie sous la peau). Cette ablation se fait au bloc opératoire sous anesthésie, ce qui implique une seconde intervention (avec une augmentation de la morbidité inhérente à toute intervention) et une nouvelle hospitalisation.

Il s'agit soit de dispositifs constitués de 2 broches qui, introduites de part et d'autre du foyer de fracture en assurent la tenue grâce à un fil d'acier passé en 8 autour des broches (hauban), soit de plaques vissées qui constituent une gène de part leur épaisseur en situation sous cutanée, soit de clous intra médullaire ne permettant pas d'assurer une stabilité du foyer de fracture telle qu'on puisse entreprendre une rééducation rapide.

Le dispositif selon l'invention permet de remédier à ces inconvénients. Il comporte en effet selon une première caractéristique un clou traversé par au moins deux vis permettant l'ancrage de ce clou dans l'os. Le clou peut être plein ou creux. Si le clou est plein, il comporte des tunnels permettant aux vis de le traverser. Si le clou est creux il comporte des orifices permettant aux vis de le traverser.L'extrémité supérieure de ce clou est biseautée et suit la courbure naturelle de l'os à cet endroit de l'anatomie évitant ainsi son extériorisation. Le diamètre proximal du clou est supérieur à son diamètre le plus distal. Un orifice ou un tunnel est présent au sommet du clou et suit un trajet descendant oblique, en direction de l'apophyse coronoïde. Ce trajet descendant oblique est destiné à recevoir une vis selon un passage de la partie proximale vers la partie distale qui permet l'ancrage osseux du clou et la compression du foyer de fracture. Ce clou présente également au moins un orifice ou un tunnel situé à la partie distale du clou, perpendiculaire à l'axe de celui-ci, et destiné à recevoir une vis qui permet l'ancrage osseux du clou, évite sa mobilisation vers la partie proximale de l'olécrane et empêche la rotation du foyer de fracture. L'ensemble du dispositif permet ainsi d'entreprendre une rééducation précoce en post-opératoire immédiat grâce à une synthèse stable et un matériel enfoui dans l'os.

Selon les variations anatomiques des patients à opérer et les modes particuliers de réalisation :

Le diamètre et la longueur du clou peuvent varier

Le clou peut être plein ou creux

Le diamètre et la longueur des vis peuvent varier

Le matériau utilisé pour la fabrication du clou ou des vis peut varier

L'angulation du tunnel proximal avec l'axe du clou peut varier

Le nombre et la position des tunnels distaux peuvent varier

Les dessins annexés illustrent l'invention :

La figure 1 représente en coupe sagittale le dispositif de l'invention

La figure 2 représente en coupe frontale le dispositif de l'invention

En référence à ces dessins, le dispositif comporte un clou (1) qui peut être plein ou creux. Si le clou est creux, il comporte au moins 4 orifices ; un orifice au sommet (2), un autre à sa partie moyenne (2 bis) et au moins deux autres à sa partie distale (3 et 3 bis). Si le clou est plein, il comporte au moins deux tunnels ; un tunnel partant du sommet du clou selon une direction oblique par rapport à l'axe du clou (2), et au moins un tunnel situé à la partie distale du clou et perpendiculaire à l'axe de celui-ci (3). Ces tunnels sont destinés à recevoir chacun une vis permettant leur ancrage dans l'os. La vis passant dans le tunnel proximal (4) permet d'assurer la compression du foyer de fracture (6 et 7). La ou les vis en situation distale (5) permettent de bloquer les rotations et d'empêcher l'ascension du clou.

La partie proximale du clou comportant à son sommet un orifice (2) est d'un diamètre supérieur au diamètre de sa partie distale. Cette différence de diamètre permet une meilleure stabilité du clou dans la partie proximale du cubitus, plus large au niveau de l'olécrane. Cette partie proximale du clou prend une forme biseautée de telle sorte qu'elle s'adapte à l'anatomie de l'olécrane.

La vis proximale (4) comporte un filetage sur sa partie distale uniquement. Ce filetage est destiné à assurer sa prise dans l'os. La partie proximale et distale de cette vis est lisse et ne comporte pas de filetage ; il s'agit de la partie en contact avec le clou. Le sommet de la vis comporte une tête, d'un diamètre plus large que le diamètre du corps de la vis et que le tunnel (2) par lequel passe la vis ce qui permet d'arrêter la progression de la vis dans son tunnel et d'obtenir un effet de compression au niveau du foyer de fracture.

La ou les vis distale(s) (5) comporte(ent) un filetage continue de telle sorte que la prise puisse se faire sur les deux corticales de l'os. Elle dispose(ent) également d'une tête d'un diamètre supérieur au diamètre du corps de la (des) vis et du tunnel (3) qu'emprunte(ent) cette (ces) vis.

Le dispositif d'ostéosynthèse précédemment décrit est associé à un ancillaire destiné à faciliter la pose du dit matériel et notamment à réaliser le vissage par visée automatique.

Le dispositif selon l'invention est particulièrement destiné au traitement des fractures de l'olécrane.

Revendications

1°) Dispositif d'ostéosynthèse des fractures de l'extrémité supérieure de l'ulna (olécrane) caractérisé en ce qu'il est constitué d'un clou (1) pourvu à sa partie supérieure d'un moyen permettant de positionner une vis (4) de fixation supérieure en position oblique par rapport à l'axe du clou (1) et à sa partie inférieure d'au moins un moyen (3) permettant de positionner une ou plusieurs vis (5) de fixation en position perpendiculaire par rapport à l'axe du clou (1).

2°) Dispositif selon la revendication 1 caractérisé en ce que le clou (1) est plein

3°) Dispositif selon la revendication 1 caractérisé en ce que le clou (2) est creux

4°) Dispositif selon les revendications 1 et 2 caractérisé en ce que le moyen permettant de positionner la vis (4) de fixation supérieure en position oblique est constitué d'un tunnel permettant le passage de la vis (4) dans le clou (1).

5°) Dispositif selon les revendications 1 et 3 caractérisé en ce que le moyen permettant de positionner la vis (4) de fixation supérieure en position oblique est constitué de deux orifices (2, 2 bis) permettant le passage de la vis (4) dans le clou (1), l'un (2)au sommet du clou, le second (2 bis)situé dans la partie moyenne du clou (1).

6°) Dispositif selon les revendications 1, 2 et 4 caractérisé en ce que le moyen permettant de positionner la ou les vis (5) de fixation inférieure en position perpendiculaire à l'axe du clou (1) comporte au moins un tunnel (3) permettant le passage de la vis (5) dans le clou (1).

7°) Dispositif selon les revendications 1, 3 et 5 caractérisé en ce que le moyen permettant de positionner la ou les vis (5) de fixation inférieure en position perpendiculaire à l'axe du clou (1) comporte au moins deux orifices (3 bis) vis à vis l'un de l'autre permettant le passage d'au moins une vis (5) dans le clou (1).

8°) Dispositif selon la revendication 1 caractérisée en ce qu'il comporte une partie proximale d'un diamètre supérieur à son extrémité distale.

9°) Dispositif selon la revendication 1 caractérisé en ce que son extrémité proximale est biseautée de telle sorte qu'elle s'adapte à l'anatomie de l'olécrane.

Planche clinique

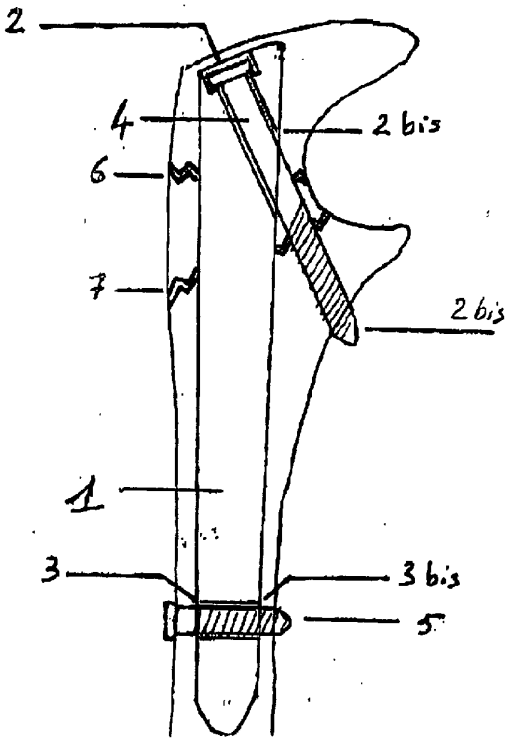



figure 1

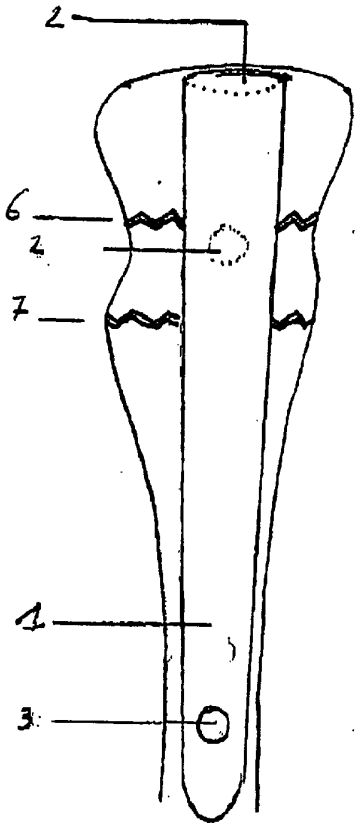



figure 2

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# RAPPORT DE RECHERCHE PRÉLIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

N° d'enregistrement national

FA 644598
FR 0312825

| DOCUMENTS CONSIDÉRÉS COMME PERTINENTS | | Revendication(s) concernée(s) | Classement attribué à l'invention par l'INPI |
|---|---|---|---|
| Catégorie | Citation du document avec indication, en cas de besoin, des parties pertinentes | | |
| X | EP 1 095 626 A (SULZER ORTHOPEDICS LTD) 2 mai 2001 (2001-05-02) * colonne 3, ligne 4 - ligne 35; figures 1,2 * | 1,2,4-9 | A61B17/72 |
| X | WO 99/35989 A (HABERNEK HANS ; HERZA CLAUS (AT)) 22 juillet 1999 (1999-07-22) * abrégé * | 1-9 | |
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| | | | DOMAINES TECHNIQUES RECHERCHÉS (Int.CL.7) |
| | | | A61B |

| Date d'achèvement de la recherche | Examinateur |
|---|---|
| 22 juin 2004 | Ducreau, F |

CATÉGORIE DES DOCUMENTS CITÉS

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|---|---|---|---|
| EP 1095626 A | 02-05-2001 | EP 1095626 A1 | 02-05-2001 |
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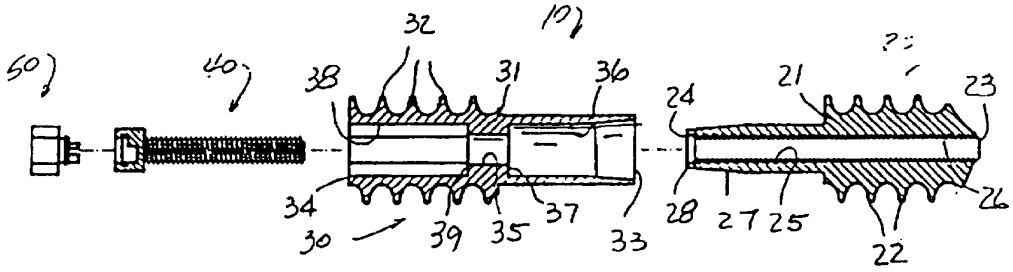
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**(54) Title:** MULTIPIECE INTERFRAGMENTARY FIXATION ASSEMBLY




**(57) Abstract**

This invention is a multipiece, interfragmentary, fixation assembly (10) for interconnecting bone fragments across a fracture therebetween. The fixation assembly (10) comprises a first axially elongated fastener (20) having external threading (22) for anchoring the first fastener (20) into the bone substance of the first bone fragment. The first fastener (20) defining a coaxial through bore (25) with internal threading (26) extending along the length thereof. The fixation assembly (10) also includes a second fastener (30) attachable in non-movable relation relative to the second bone fragment. An elongated connector (40) operably interconnects the fasteners (20, 30) such that rotation of the connector (40) draws the fasteners (20, 30) and the bone fragments attached to each into a predetermined compressive relationship relative to each other. A retaining apparatus (50) prevents the connector (40) from inadverteently turning and thereby maintains the predetermined compressive relationship between the fasteners (20, 30) and the bone fragments to promote healing of the fracture.

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# MULTIPIECE INTERFRAGMENTARY FIXATION ASSEMBLY

## Related Applications

This patent application is a continuation-in-part of my copending patent application serial No. 08/576,813 filed December 21, 1996.

## Field of the Invention

The present invention generally relates biological medical instruments and, more particularly, to a multipiece fixation assembly for interconnecting two pieces of a fractured bone under a predetermined and substantially constant compressive force to promote optimum healing of the fracture.

## Background of the Invention

The scaphoid represents one of the most frequently injured bones of the wrist. Unfortunately, it also represents one of the most frequently missed wrist injuries. Scaphoid fractures commonly result from an acute dorsiflexion stress such as occurs following a fall on an outstretched hand. If the fracture is initially recognized and properly immobilized, healing rates approaching 95% have been documented for acute fractures.

Fractures have historically been divided into three types based on the level of the fracture. The fractures through the middle one-third of the scaphoid are most common and occur approximately 70% of the time. Fractures through the proximal one-third of the scaphoid occur approximately 20% of the time, and are at greater risk for developing avascular necrosis.

Fractures of the distal scaphoid are very uncommon, occurring approximately 10% of the time, and have a very high union rate with proper immobilization.

Fractures of the scaphoid have also been classified based on the orientation of the fracture line in relation to the longitudinal axis of the scaphoid. The majority of fractures occur transverse to the longitudinal axis of the scaphoid and will sometimes heal with as little as six weeks of immobilization. Horizontal oblique fractures are the second most common, occurring approximately 35% of the time, with vertical oblique fractures being quite rare. Both horizontal and oblique fractures can require a longer period of immobilization to obtain union between the fractured bone fragments. The vast majority of scaphoid fractures will heal with twelve weeks of immobilization, and anything past four months may be regarded as a delayed union. Fractures that have not healed within six months of immobilization from the time of injury, and that have definite sclerotic margins at the fracture lines, can be considered to be an established non-union of the fractured bone fragments.

Several factors contribute to the ability of the fractured bone fragments to be united with each other. The unique anatomy of the blood supply to the carpal navicular is one factor. The degree of injury to the supporting soft tissues and the degree of displacement of the bone fragments relative to each other are other factors. Associated carpal instability is still another factor that must be considered when evaluating the likelihood of the bone fractures to unite relative to each other. Early detection and proper immobilization of the fractured scaphoid are still further factors that contribute to the development of the non-union of the fractured scaphoid segments.

Scaphoid fractures have been classified as stable based upon a minimal degree of displacement at the fracture site. Fractures that are displaced greater than one millimeter are considered to be unstable and are frequently accompanied by rupture of the supporting ligaments of the scaphoid. Increased displacement is typically associated with a higher incidence of non-union of the fractured bone fragments.

Failure to disclose, to reduce, or to adequately immobilize scaphoid fractures is directly responsible for development of delayed union or non-union. Technetium bone scans have been used both for early detection of scaphoid fractures and for detection of scaphoid pseudarthrosis. Trispiral tomography is helpful both in the initial detection of scaphoid fractures, in evaluating the degree of displacement of the fractured bone fragments relative to each other, and in determining union following bone grafting of a non-union or a prolonged period of cast immobilization.

Significant limitations of wrist motion can occur secondary to a scaphoid non-union. Without intervention, patient's with an established scaphoid non-union have an extremely high likelihood of developing an arthritic wrist. This most commonly follows the pattern of Scapho-Lunate Advanced Collapse (SLAC) with sparing of the radio-lunate joint and radius-proximal scaphoid fragment joint. Patient's with an asymptomatic scaphoid non-union should be advised the development of an arthritic wrist is highly probable.

Surgical fastener assemblies for rejoining and holding fractured or broken bone fragments in place are known in the art. Where cross-fixation of the bone fragments is required, maintaining and holding both bone fragments in compression relative to each other enhances the likelihood of success of the surgical procedure. As will be readily appreciated, a gap or

displacement between the adjacent bone fragments is highly undesirable because fibrous tissue will grow therebetween before the fracture can heal with boney unions. Thus delaying the healing process. Space between the bone fragments also tends to allow the bone fragments to shift or displace relative to each other thus adding to the retardation of the healing process. On the other hand, if the surgeon is able to bring the bone fragments into contact relative to each other and maintain the bone fragments in contact with each other, the space between the bone fragments is minimized and the bone fragments are inhibited from shifting, thus promoting the healing process. Moreover, when the bone fragments heal in proper alignment relative to each other, there is a reduction in the risk of the secondary development of arthritis.

In many instances, the entire fastener assembly is wholly arranged or completely buried within the bone substance. Screws commonly used in securing fractured bone fragments to each other typically include an elongated threaded portion that terminates, toward one end, in an enlarged head portion. Certain surgical repair procedures, however, do not lend themselves to use of a headed bone screw. For example, a headed bone screw does not lend itself to those situations wherein there is inadequate bone substance or stock to allow countersinking of the enlarged head portion of the bone screw. Providing a countersunk configuration in the bone substance, however, also often destroys cartilage needed in a joint for its proper functioning.

Moreover, severe problems can result from use of these types of bone screws. That is, after the biological operation has been completed, the bone tissue about the bone screw tends to recede by boney resorption thereby allowing the bone screw to loosen, thus destroying the compressive force that maintains the bone fragments in close proximity relative to each other. Besides those problems mentioned above that can result when the bone fragments are not

maintained in close proximity, and as will be appreciated, as the bone screw loosens, it is not uncommon for the head portion to protrude through the skin of the patient having such fracture. This, of course, results in significant additional problems including the possibility of additional surgery requirements to correct the problem. Additional surgery means additional expenses for the patient and loss of employment during the surgical recuperation period.

Responding to the above noted problems, attempts have been made to improve upon bone screws. U.S. Patent No. 4,175,555 issued November 27, 1979 to T. J. Herbert discloses a bone screw device for interconnecting two bone fragments under compression and which lacks the drawbacks associated with a headed bone screw and allows the bone screw device to be totally or wholly embedded within the bone substance of the patient. The Herbert device has screw threads which are like handed but of different pitch on its leading and trailing ends. More specifically, the pitch of the threads at the leading end exceeds the thread pitch at the trailing end. Thus, the leading end of the screw advances at a slightly faster rate than the trailing end thereby causing the bone fragments to be brought together under some degree of compression.

While offering certain advantages over heretofore known bone screw devices, the Herbert device also has certain drawbacks. Because of the relatively small difference in the thread pitch between the leading and trailing threads, the Herbert device has a limited ability to draw the fractured bone fragments that are not already proximate to each other into compressive relationship relative to each other. Moreover, and because the thread pitch of the leading and trailing threads differs, the diameter of the leading threads must be smaller than the core of the root diameter of the trailing threads to prevent binding of the screw. Accordingly, the leading end of the Herbert screw has a lesser or weaker bone material purchase than does the trailing

end. This lesser degree of bone purchase can have an adverse effect on the ability of the bone screw to remain fixed in the bone when subjected to pulling forces applied thereagainst.

The surgeon generally judges the proper compressive force to be applied between the fractured bone components by "feeling" for tightness. The Herbert device, however, does not afford the surgeon this luxury. When the Herbert device is used to secure two bone fragments across the fracture thereof, the trailing threads are not and cannot be tapped into the bone fragment because of thread synchronization problems. Accordingly, during use of the Herbert device, the surgeon feels only the resistance necessary to allow penetration of the trailing threads into the bone thus resulting in the possibility of sub-optimal repairs.

U.S. Patent No. 4,858,601 to R. R. Glisson discloses a compression screw assembly including a pair of externally threaded members that are interconnected in an axially fixed and abutting relationship relative to each other by a spindle. After insertion of the spindle through both members of the screw assembly, the spindle is fixedly connected to one of the threaded members. By turning the screw assembly in a first direction, the surgeon can thread both screw members and the spindle into the bone substance of the fragments that are to be repaired or joined to each other. Thereafter, one screw member is rotated or turned in an opposite direction and relative to the other screw member to draw the bone fragments toward each other.

Surgical repair of fractured bones involves complicated procedures. The Glisson device only serves to furthermore complicate an already complex surgical procedure. That is, with the Glisson device the surgeon must initially rotate or turn the screw assembly in a first direction and then turn only one screw member of the assembly in a second direction, opposite to the first direction. As will be appreciated by those skilled in the art, initially turning both screws in a

first direction and then turning one of the screw members in a second and opposite direction detracts from the ability of the screw assembly to establish and maintain a strong purchase with the bone substance or tissue of fragmented bones that are to be joined to each other. Nothing is provided on the Glisson device, however, for preventing the screw members from rotating relative to each other for a prolonged time period after the screw assembly is initially inserted into the patient. Thus, the setting between the screw members initially selected by the surgeon can readily be lost or destroyed simply by the screw members turning relative to each other. Furthermore, nothing associated with the Glisson device suggests to a person skilled in the art how it could be used to facilitate reattachment of ligamentous tissues to bone fragments.

Frequently, with an acute hyperextension injury to the wrist the scaphoid will not fracture but instead a series of ligamentous damage can occur about the wrist of the patient. The volar wrist ligaments certainly contribute to instability about the wrist. Many are of the opinion, however, that the dorsal scapholunate interosseous ligament is a primary constraining force that, when ruptured, leads to disassociation between the scaphoid and lunate bones. Failure to reconstruct this ligament can lead to the development of progressive arthritis about the wrist.

Various techniques and devices have been proposed to reconstruct the ligaments between the scaphoid and lunate bone. One common technique involves arthroscopy of the wrist and the percutaneous pinning between the scaphoid and lunate that have been manipulated back into the proper positions. With a failure of this technique, which frequently occurs in clinical situations, there is scapholunate instability. A number of soft tissue ligamentous techniques for reconstructing these ligaments have been described, but these known techniques frequently lead to failure, due to the reconstructed ligaments stretching out and losing their degree of stability

between the two bones. This can result in progressive loss of the integrity of the reconstructed ligament, resulting in the development of a scapholunate advanced collapse pattern of the wrist. Alternative techniques such as fusing the scaphoid bone to the lunate have been fraught with a high rate of non-union.

Although the Herbert device is not particularly suited for ligament reattachment, alternative anchoring devices have been proposed to attach ligaments to bone. There are a paucity of devices, however, wherein a ligament, with an attached fragment of bone can be readily reattached to a bone using a compression screw. A toggle bolt type mechanism does not allow for adequate reattachment of a bony fragment with sufficient tolerances to enable adequate strength of compression of the bone ligament construct to effect a rigid enough period of compression to heal within the channel created in the scaphoid when a bone ligament bone construct is utilized to reconstruct the scaphoid lunate interosseous ligament.

Thus, there remains a need and a desire for a bone screw assembly that permits first and second bone fragments to be interconnected to each other under compression and wherein the proper compression between the bone fragments is measured by the surgeon's feel of the bone screw. Moreover, there is a clear need for a more universal system for facilitating the reattachment of ligaments to bone fragments.

## SUMMARY OF THE INVENTION

In view of the above, and in accordance with the present invention, there is provided a multipiece interfragmentary fixation assembly that is wholly contained within the bone substance such that it can serve a number of useful purposes for dealing with fractures and reconstructive

procedures in the field of orthopedic surgery. The interfragmentary fixation assembly of the present invention includes a first axially elongated fastener that defines an elongated axis and has external threading for anchoring the first fastener into a first bone fragment and a second fastener that is attachable in non-movable relation relative to a second bone fragment. The first fastener defines a coaxial opening with internal threading extending along at least a portion of the length thereof. The coaxial opening permits endwise passage of a guide therethrough thus facilitating proper placement and anchoring of the first fastener within the first bone fragment.

To allow the first and second fasteners and thereby the first and second bone fragments to be drawn toward and ultimately into compressive relationship relative to each other, the fixation assembly further includes an elongated connector that interconnects the first and second fasteners and allows the surgeon to adjust the proper compressive force between the bone fragments as a function of "feel." The connector includes a head portion and a shank portion. The head portion of the connector is configured to accommodate a driving tool. The shank portion of the connector includes external threading corresponding to the internal threading on the first fastener. The shank portion of the connector is configured to extend endwise through the second fastener and into threaded engagement with the first fastener while the head portion of the connector operably engages with the second fastener such that rotation of the connector draws the first and second fasteners toward and into compressive relationship relative to each other. The connector is prevented from inadvertently rotating relative to the fastener with which a threaded connection is established thereby maintaining the predetermined compressive relationship between the bone fragments and thereby promoting healing and union therebetween.

In a preferred form of the invention, the first fastener is formed from a bone compatible material form the class of: stainless steel, titanium, or a cobalt chromium molybdenum alloy. The external threading on the first fastener has a substantially uniform pitch. To promote engagement with bone substance, a leading end of the first fastener preferably has a pointed end configuration. A trailing end of the first fastener is configured to accommodate a driving tool capable of turning the first fastener such that the external threading thereon threadably engages and anchors the first fastener within the bone fragment. In a most preferred form of the invention, the first fastener has a reduced diameter portion axially extending from the terminal end of the threading. The reduced portion of the first fastener has an axially tapering configuration along an outer surface thereof.

According to one aspect of the present invention, the second fastener has an axially elongated configuration with external threading for anchoring the second fastener within the bone substance of the second bone fragment. The external threading on this preferred form of the invention has a substantially uniform pitch along the length thereof that corresponds to the pitch on the external threading of the first fastener. The second fastener is formed from a bone compatible material from the class including: stainless steel, titanium, or a cobalt chromium molybdenum alloy. In this embodiment of the invention, the second fastener has a coaxial opening extending endwise therethrough for allowing the second fastener to be initially guided into generally axial alignment and operable relationship with said first fastener. The trailing end of this embodiment of the second fastener is configured to accommodate a driving tool capable of turning the second fastener such that the external threading threadably engages and anchors the second fastener into the bone substance of the second bone fragment.

In a most proffered form of the present invention, the axial bore defined by the second fastener has a first lengthwise portion that opens to a trailing end of the second fastener and a second lengthwise portion that opens to a leading end of the second fastener. The second lengthwise portion of the second fastener has a configuration that is specifically sized such that only the threaded shank portion of the connector can endwise extend therethrough. Moreover, the second portion of the axial bore in the second fastener is specifically configured to coact with the axially tapering extension on the first fastener. Preferably, the configuration of the axial bore defined by the second fastener has an axially tapering configuration that complements the tapered configuration on the first fastener whereby effecting axially alignment of the fasteners and thereby the fractured bone fragments relative to each other thus promoting the healing process.

According to another aspect of the present invention, the second fastener comprises a member configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from the central section. An apertured hemi-spherically shaped element is adapted to be seated for rocking movement within the central section of the member. The shank portion of the connector is configured to endwise extend through the member and the element into threaded engagement with the first fastener. The head portion of the connector being operably engagable with the element such that rotation of the connector draws the member and the first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other such that minimal tissue growth is effected between the fractured bone fragments whereby enhancing union of the bone fragments to each other. In this preferred form of the invention, the central section of the member defines

an enlarged opening that permits the member to rock relative to the connector and the element thereby enhancing the attachment of the prongs to the second bone fragment.

To promote the attachment of ligament pieces to bone fragments, another aspect of the present invention configures the second fastener as an apertured disk. The apertured disk fits about the shank portion of the connector and operably engages an underside of the head portion of the connector to permit relative rotation therebetween. The disk has a series of apertures that permit the second bone fragment to be secured thereto as with stitches, sutures, or the like.

Still another aspect of the present invention concerns configuring the second fastener to maintain the second bone fragment in a hole or bore provided by the surgeon in the first bone fragment. To accomplish such ends, the second fastener is configured as an elongated member having first and second ends and an axial bore for allowing the shank portion of the connector to extend endwise through the second fastener and into threaded engagement with the first fastener. In this embodiment of the invention, the member of the second fastener further includes a rigid bone fragment retainer extending radially away from the elongated member. In a most preferred form of the invention, the elongated member has a generally cylindrical configuration between opposite ends thereof. Alternatively, the elongated member of the second fastener has a frusto-conical configuration between opposite ends thereof.

The interfragmentary fixation assembly of the present invention can also be utilized for arthrodesis of small joints. An alternative variation for use in a joint where flexion is desired, such as a proximal interphalangeal or metacarpal joint, involves alternatively configuring the second fastener as a plate-like member that fixedly attaches to the second bone fragment. The plate-like member has upper and lower generally parallel surfaces with an indentation or

depression having a closed margin defined by the periphery of the plate-like member and including a wall depending at an acute angle relative to the upper surface of the plate-like member. The indentation or depression fits into a recess formed in the bone fragment to which the plate-like member is attached to allow smooth gliding of tendons overlying the second fastener. The wall defined by the indentation is apertured to allow the shank portion of the connector to endwise extend into threaded engagement with the internal threading on said first fastener. The wall of the indentation maintains the head portion of the connector on an opposite side of the plate from the first fastener. Moreover, in a preferred form of the invention, the upper and lower surfaces of the plate-like member have a generally convex configuration that generally parallels the outer surface configuration of the bone fragment to which this second fastener is attached.

In the preferred form of the invention, the enlarged head portion of the connector operably engages with the second fastener thus causing the second fastener to move toward and, ultimately, into a compressive relationship with the first fastener in response to its threaded engagement with and rotation of the connector relative to the first fastener. The free end of the connector's head portion is preferably configured with a socket for releasably accommodating a driving tool.

According to the present invention, the connector is inhibited from inadvertently rotating relative to the fastener with which a threaded connection is established. In one form of the invention, a retaining apparatus or element having a cross-sectional configuration that complements the cross-sectional configuration of the first portion of the axial bore defined by the second fastener and opening to the trailing end of the second fastener serves to engage with

the connector in a manner preventing rotation of the connector relative to the fastener with which the connector has a threaded engagement. Moreover, in this form of the invention, the element or retainer apparatus is releasably coupled to the head portion of the connector thereby preventing rotation of the connector and, thus, maintaining substantially constant predetermined compressive force initially established by the surgeon between the first and second fasteners so as to promote the healing process.

Alternatively, the retaining apparatus of the present invention comprises a non-metal insert preferably arranged lengthwise along the internal threading of the first fastener. In this embodiment of the invention, as the connector threadably engages and moves along the length of the internal threading on the first fastener it likewise engages with the non-metal insert thereby inhibiting inadvertent rotation of the connector after the surgeon establishes that degree of compression desired between the first and second fasteners. Because the insert prevents inadvertent rotation of the connector, the first and second fasteners are maintained under the predetermined compressive force established by the surgeon thus maintaining the fractured bone pieces not only in compression but also in close proximity thereby enhancing the healing process.

In still another form of the invention, an internal locking thread form is defined within the fastener with which the connector is threadably fastened so as to prevent the connector from inadvertently rotating relative to the fastener. That is, the internal locking thread form coacts with the conventional external threading on the connector to prevent inadvertent rotation of the connector thereby maintaining the predetermined compression between the fasteners and, thus,

the bone fragments, as a function of the surgeon's "feel". Moreover, the use of an internal locking thread form simplifies the design of the fixation assembly.

According to another aspect of the present invention, there is provided an interfragmentary compression kit. The kit includes a collection of first axially elongated fasteners. Each fastener in the collection has a different length from other like fasteners in the collection. Each fastener in the collection can be further distinguished by the diameter of the threaded portion. The different shapes and sizes of the fasteners in the collection allows the surgeon to chose which particular fastener has the desired maximum purchase with the particular bone fragment being repaired. The kit further includes a series of second fasteners. To provide the surgeon with the appropriate fastener, each fastener in the series of second fasteners is different from other fasteners in the series of fasteners to provide the surgeon with the maximum ability to interchange fasteners and select the best for the particular bone fragment being repaired. Moreover, a set of elongated connectors are likewise arranged in the kit. The connectors in the kit have different configurations from other connectors in the set. Suffice it to say, the kit of the present invention allows the surgeon to chose the appropriate fasteners and connectors for the particular surgical procedure and patient.

The present invention advantageously provides a biological fixation assembly that is wholly embedded within the bone substance of the patient and permits the bone fragments to be interconnected to each other with abutting surfaces of the bone fragments arranged in close proximity and under a predetermined level of compression relative to each other. The interfixation assembly further includes a retaining apparatus that maintains that predetermined level of compression between the bone components thus promoting healing. Moreover, the

fixation assembly of the present invention prevents the connector from inadvertently becoming unthreaded thus eliminating the problem of the connector backing out of the bone and potentially protruding through the skin of the patient. In that embodiment of the invention wherein both fasteners are threaded, the fixation assembly has equal pull out strength on opposite sides of the fracture. Another important feature of the present invention is that the level of compression is adjustable to provide the surgeon with the proper "feel" of tightness.

These and other objects, aims and advantages of the present invention will become readily apparent from the following detailed description, appended claims, and the following drawings.

**Detailed Description of the Drawings**

FIGURE 1 is a schematic representation of the various bones contained in the hand of a patient;

FIGURE 2 is an enlarged cross section view similar to FIGURE 1 showing an embodiment of a multipiece interfragmentary fixation assembly according to the present invention wholly embedded within a fractured scaphoid;

FIGURE 3 is an enlarged elevational view of that embodiment of the multipiece interfragmentary fixation assembly shown in FIGURE 2;

FIGURE 4 is a right end view of the multipiece interfragmentary fixation assembly illustrated in FIGURE 3;

FIGURE 5 is a left end view of the multipiece interfragmentary fixation assembly illustrated in FIGURE 4;

FIGURE 6 is a perspective view of components of the fixation assembly illustrated in longitudinally spaced relation relative to each other;

FIGURE 7 is a longitudinal sectional view of component parts of the present invention shown in separated relation relative to each other;

FIGURE 8 is a sectional view taken along line 8-8 of FIGURE 3;

FIGURE 9 is a perspective view of one component fastener forming part of the present invention;

FIGURE 10 is a left end view of the component fastener illustrated in FIGURE 9;

FIGURE 11 is a right end view of the component fastener illustrated in FIGURE 9;

FIGURE 12 is a sectional view taken along line 12-12 of FIGURE 10;

FIGURE 13 is a perspective view of another component fastener forming part of the present invention;

FIGURE 14 is a left end view of the component fastener illustrated in FIGURE 13;

FIGURE 15 is a right end view of the component fastener illustrated in FIGURE 13;

FIGURE 16 is a longitudinal sectional view taken along line 16-16 of FIGURE 14;

FIGURE 17 is a perspective view, with sections being broken away, of a connector forming part of the present invention;

FIGURE 18 is another perspective view, with sections being broken away, of the connector illustrated in FIGURE 17;

FIGURE 19 is a left end view of the connector illustrated in FIGURES 17 and 18;

FIGURE 20 is an elevational view of the connector with a head portion thereof being shown in section as seen along line 20-20 of FIGURE 19;

FIGURE 21 is a perspective view of one embodiment of a retainer apparatus forming part of the present invention;

FIGURE 22 is an elevational view of the retainer apparatus illustrated in FIGURE 21;

FIGURE 23 is a left end view of the retainer apparatus illustrated in FIGURE 22;

FIGURE 24 is a right end view of the retainer apparatus illustrated in FIGURE 22;

FIGURE 25 is an enlarged schematic view of a fractured scaphoid bone;

FIGURE 26 is a cross section of a fractured scaphoid having a guide passing through both scaphoid fragments;

FIGURE 27 is a cross section of a fractured scaphoid showing a cannulated drill arranged along and about the guide;

FIGURE 28 is a cross section of a fractured scaphoid showing the cannulated drill passing downwardly through the fractured scaphoid bone;

FIGURE 29 is a cross section of the fractured scaphoid bone fragments after the cannulated drill is removed therefrom;

FIGURE 30 is a cross section of the fractured scaphoid showing a cannulated tap arranged along and about the guide for insertion into a drilled bore formed by the cannulated drill;

FIGURE 31 is a cross section of the fractured scaphoid showing the tap fully inserted therein;

FIGURE 32 is a cross section of the fractured scaphoid with the tap being removed therefrom;

FIGURE 33 is a cross section of the fractured scaphoid showing a fastener similar to that illustrated in FIGURES 9 through 11 being arranged for sliding movement over and along the guide;

FIGURE 34 is a cross section of the fractured scaphoid showing the first fastener fully inserted in one of the bone fragments and wherein the trailing end of the first fastener is rotated by a driving tool;

FIGURE 35 is a cross section of the fractured scaphoid showing a second fastener similar to that illustrated in FIGURES 13 through 16 being arranged for guided sliding movement over and along the guide;

FIGURE 36 is a cross section of the fractured scaphoid showing the second fastener fully inserted in the second scaphoid bone fragment and wherein the second fastener is rotated by a driving tool;

FIGURE 37 is a cross sectional view similar to FIGURE 36 but showing the driving tool for the second fastener being removed therefrom;

FIGURE 38 is a cross section of the fractured scaphoid showing the guide removed from the scaphoid;

FIGURE 39 is a perspective view, partly in section, showing the first and second fasteners of one embodiment of the present invention in axially spaced relation relative to each other;

FIGURE 40 is a perspective view similar to FIGURE 39, and partly shown in section, showing the first and second fasteners in partially overlapping relation relative to each other;

FIGURE 41 is a perspective view, partly broken away, showing a connector similar to that illustrated in FIGURES 17 through 20 passing partially endwise through the second fastener and into threaded engagement with a trailing end of the first fastener;

FIGURE 42 is a perspective view, partly in section, showing the connector as it serves to draw the second fastener into compressed axial relationship relative to the first fastener;

FIGURE 43 is a cross section of the fractured scaphoid showing a tool for rotating the connector into threaded engagement with the first fastener;

FIGURE 44 is a cross section of the fractured scaphoid showing a retainer apparatus similar to that illustrated in FIGURES 21 through 24 being inserted into operable engagement with other components of the fixation assembly of the present invention;

FIGURE 45 is a perspective view, partly in section, and similar to FIGURE 44 but enlarged to show the retainer apparatus being inserted into operable association with other components of the fixation assembly of the present invention;

FIGURE 46 is a view similar to FIGURE 45, and partly in section, showing the fastener apparatus inserted further into operable engagement with components of the fastener assembly of the present invention;

FIGURE 47 is a cross section of the fractured scaphoid showing a tool for inserting the retainer apparatus into operable engagement with the other components of the fixation assembly of the present invention;

FIGURE 48 is an enlarged perspective view showing the retainer apparatus and the headed end of the connector in axially spaced relation relative to each other with parts broken away to show detail;

FIGURE 49 is an elevational view, partially in section, of the retainer apparatus and connector shown in FIGURE 48;

FIGURE 50 is an enlarged perspective view showing the retainer apparatus and the headed end of the connector, partially in section, arranged in partial combination relative to each other;

FIGURE 51 is an elevational view, partly in section, showing one form of retainer apparatus and connector in partial operable combination relative to each other;

FIGURE 52 is an enlarged perspective view, partly in section, showing the retainer apparatus arranged in full engagement with the headed end of the connector;

FIGURE 53 is an elevational view, partly in section, showing the retainer apparatus schematically illustrated in FIGURE 52 in full engagement with the headed end of the connector;

FIGURE 54 is a perspective view, with parts broken away, showing one form of retainer apparatus in operable combination with the connector;

FIGURE 55 is a perspective view, similar to FIGURE 54, showing one form of retainer apparatus arranged in operable combination with the connector;

FIGURE 56 is a sectional view similar to FIGURE 12 but showing an alternative embodiment of retainer apparatus;

FIGURE 57 is a longitudinal sectional view of the fixation assembly of the present invention with component parts, including the fastener shown in FIGURE 56, illustrated in axially spaced relation relative to each other and with;

FIGURE 58 is a perspective view of the fixation assembly schematically illustrated in FIGURE 57;

FIGURE 59 is a longitudinal sectional view of the fixation assembly of the present invention with component parts, including the fastener shown in FIGURE 56, illustrated in assembled relation relative to each other;

FIGURE 60 is a view similar to FIGURES 12 and 56 but showing another alternative embodiment of retainer apparatus;

FIGURE 61 is a perspective view of a fixation assembly according to the present invention having an alternative embodiment of a retainer apparatus;

FIGURE 62 is an elevational view showing a second fastener, a connector, and the alternative embodiment of a retainer apparatus as schematically illustrated in FIGURE 61;

FIGURE 63 is a longitudinal sectional view of the fixation assembly illustrated in FIGURE 61;

FIGURE 63A is a fragmentary and enlarged longitudinal sectional view of an alternative form of fixation assembly according to the present invention;

FIGURE 63B is an enlarged sectional view of the area encircled in FIGURE 63A;

FIGURE 64 is a perspective view of another embodiment of the interfragmentary fixation assembly of the present invention;

FIGURE 65 is a perspective view of an alternative embodiment of a second fastener and connector for the fixation assembly of the present invention;

FIGURE 66 is a partial sectional view of the alternative embodiment of the second fastener illustrated in FIGURE 65, with components of the second fastener being shown in spaced relation relative to each other and showing the connector adapted to pass endwise therethrough;

FIGURE 67 is a view similar to FIGURE 66 showing the component parts of the second fastener arranged in operable combination with each other and with the connector passing therethrough; with the phantom lines showing the range of motion of the second fastener;

FIGURE 68 is a cross sectional view of a fractured bone showing the alternative embodiment of the interfragmentary fixation assembly illustrated in FIGURES 65 through 67 arranged in operable combination therewith;

FIGURE 69 is a schematic representation of the bones in a patient's hand with a particular area shown for harvesting a section of bone-ligament-bone for grafting;

FIGURE 70 is a schematic view similar to FIGURE 69 but showing a lunate bone channeled to accept a bone-ligament-bone graft;

FIGURE 71 is a schematic view similar to FIGURE 70 but showing a lunate and scaphoid bone channeled to accept a bone-ligament-bone graft;

FIGURE 72 is a schematic view similar to FIGURE 71 but showing K-wires inserted into lunate and scaphoid bones for movement control;

FIGURE 73 is a perspective view of another alternative embodiment of the interfragmentary fixation assembly with component parts thereof shown in axially spaced relation relative to each other;

FIGURE 74 is a perspective view of the alternative embodiment of a second fastener used in combination with the fixation assembly schematically illustrated in FIGURE 73;

FIGURE 75 is a left end view of the alternative embodiment of fixation assembly shown in FIGURE 73;

FIGURE 76 is a right end view of the fixation assembly illustrated in FIGURE 73;

FIGURE 77 is a partial sectional view taken along line 77-77 of FIGURE 75;

FIGURE 78 is a schematic view of a bone-ligament-bone graft shown secured to components parts of alternative embodiments of the second fastener;

FIGURE 79 is a schematic view similar to FIGURE 72 (with K-wires omitted for clarity), but showing a first fastener of the interfragmentary fixation assembly inserted into a lunate;

FIGURE 80 is a view similar to FIGURE 79 with a first fastener of the fixation assembly secured into a scaphoid;

FIGURE 81 is a schematic view similar to FIGURE 79 showing the fixation assembly of the present invention used to partially attach the bone-ligament-bone graft to a lunate;

FIGURE 82 is a view similar to FIGURE 81 but showing another fixation assembly according to the present invention being used to attach an opposite portion of the bone-ligament-bone graft to the scaphoid;

FIGURE 83 is a schematic view similar to FIGURE 82 but showing a bone-ligament-bone graft procedure completed;

FIGURE 84 is a cross section of a scaphoid with another embodiment of the fixation assembly of the present invention having a bone graft attached thereto;

FIGURE 85 is an end view of the scaphoid shown in FIGURE 84;

FIGURE 86 is a perspective view of an alternative embodiment of the second fastener used in combination with a fixation assembly of the type illustrated in FIGURE 84 and having a connector passing endwise therethrough;

FIGURE 87 is a perspective view of the alternative embodiment of the second fastener illustrated in FIGURE 86;

FIGURE 88 is a bottom plan view of the second fastener illustrated in FIGURE 87;

FIGURE 89 is an elevational view of the second fastener illustrated in FIGURE 87;

FIGURE 90 is a top plan view of the second fastener illustrated in FIGURE 87;

FIGURES 91 through 99 are perspective views of alternative embodiments of the second fastener similar to that illustrated in FIGURE 87;

FIGURE 100 is a schematic view showing an alternative embodiment of the fixation assembly as used in combination with a small joint arthrodesis;

FIGURE 101 is an enlarged view of that area encircled in FIGURE 100;

FIGURE 102 is a top plan view of an alternative embodiment of the second fastener;

FIGURE 103 is an elevational view of the alternative embodiment of second fastener illustrated in FIGURE 102;

FIGURE 104 is a right end view of the second fastener illustrated in FIGURE 102;

FIGURE 105 is a sectional view taken along line 105-105 of FIGURE 103;

FIGURE 106 is a sectional view taken along line 106-106 of FIGURE 102; and

FIGURE 107 is an illustration of an interfragmentary fixation kit according to one aspect of the present invention.

**Detailed Description of the Present Invention**

While the present invention is susceptible of embodiment in various forms, there are shown in the drawings and will hereinafter be described preferred embodiments of the invention with the understanding that the present disclosure is to be considered as setting forth

exemplifications of the invention which are not intended to limit the invention to the specific embodiments illustrated.

Referring now to the drawings, wherein like reference numerals refer to like parts throughout several views, in FIGURE 1, there is schematically represented a scaphoid which is fractured into two fragments. The scaphoid fracture is used as a model wherein the interfragmentary fixation assembly of the present invention can be utilized to compress the bone fragments under a predetermined force selected by the surgeon to enhance healing thereof. As would be appreciated, the present invention is equally applicable to other situations beyond repair of the scaphoid as will be described below.

One embodiment of the multipiece interfragmentary fixation assembly is shown in FIGURE 2 as being wholly embedded within the scaphoid and is represented in its entirety by reference numeral 10. As illustrated in FIGURE 2, a leading portion of the fixation assembly 10 is secured or attached to the bone substance of the proximal fragment 12 of the scaphoid while a trailing portion of the fixation assembly 10 is secured or attached to the bone substance of a distal fragment 14 of the scaphoid.

As shown in FIGURE 3, the multipiece interfragmentary fixation assembly 10 includes first and second fasteners 20 and 30, respectively. Returning to FIGURE 2, the first fastener 20 is attachable in nonmovable relation to the first bone fragment 12 and the second fastener 30 is attachable in nonremovable relation to the second bone fragment 14.

As shown in FIGURES 3 and 4, the first fastener 20 comprises an elongated member 21 having external threading 22 extending axially rearwardly from a generally pointed end 23 thereof. In this preferred form of the invention, the first fastener 20 has a trailing end 24 that

cooperates and combines with the second fastener 30 to affect alignment of the fractured bone fragments 12 and 14 (FIGURE 2).

Turning to FIGURES 3 and 5, in this illustrated embodiment of the invention, the second fastener 30 comprises an elongated member 31 having external threading 32 extending axially forwardly from a trailing end 34 thereof. In this preferred form of the invention, the second fastener 30 has a leading end 33 that combines with the first fastener 20 to affect alignment of the fractured bone fragments 12 and 14 (FIGURE 2).

As shown in FIGURES 6, 7 and 8, the multipiece interfragmentary fixation assembly 10 further includes any elongated threaded connector 40 and an apparatus 50 for inhibiting inadvertent or free turning rotation of the connector 40. The connector 40 serves to operably interconnect the first and second fasteners 20 and 30, respectively, under a predetermined compressive force selected by the surgeon. Notably, the compressive force selected by the surgeon is developed as a result of the surgeon's "feel" as the first and second fasteners 20 and 30, respectively and the bone fragments 12 and 14 connected to each fastener are drawn into confronting relation relative to each other. The fixation assembly 10 is further configured to maintain the compressive force between the first and second fasteners 20 and 30, respectively, and the bone fragments attached to each thereby preventing inadvertent turning movement of the connector so as to promote union between the bone fragments and healing of the fracture.

Turning to FIGURE 9, the elongated member 21 of the first fastener 20 is preferably fabricated from a biocompatible material selected from a class comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. The external threading 22 extends axially lengthwise of member 21 and has a uniform pitch between leading and trailing ends thereof.

In the illustrated embodiment of the fastener 20, the external threading 22 axially extends for a distance equal to about one-half the distance between the proximal and distal ends 23 and 24, respectively, of member 21.

As shown in FIGURES 9 through 12, member 21 defines an axial bore 25 that extends through member 21 and opens to the leading and trailing ends 23 and 24, respectively, thereof. For at least a portion and preferably for the entire length thereof, bore 25 defines conventional internal threading 26 which is preferably of uniform pitch. The internal threading 26 axially extends from the trailing end 24 toward the leading end 23 for at least a portion of the length of the axial bore 25. In a most preferred form of the invention, the internal threading 26 extends along the entire axial length of bore 25. As shown in FIGURES 9, 10 and 12, in this preferred form of fastener 20, member 21 further defines an axial lengthwise section or portion 27 having a diameter which is less than or reduced from the diameter of the threaded portion 22 and extending axially and forwardly from the trailing end 24 of the fastener 20. Moreover, this reduced diameter portion 27 of fastener 20 has an axially tapered configuration. In the illustrated embodiment, the diameter of the reduced portion 27 of member 21 increases as a function of the distance measured from the trailing end 24 of the fastener 20.

Fastener 20 is further configured to allow a suitable driving tool (FIGURE 34) to be releasably connected to the fastener 20 to affect the rotation thereof. In the illustrated embodiment shown in FIGURES 9, 10 and 12, the trailing end 24 of member 21 is configured with a transverse slot 28 that releasably accommodates a flat tip of a screwdriver or other suitable tool. As will be appreciated, other tool receiving configurations would likewise suffice as long as such configurations are capable of releasably accommodating a driving tool capable

of turning the first fastener 20 such that the external threading 22 threadably engages with the respective bone fragment thereby anchoring the fastener to the respective bone fragment.

Turning to FIGURE 13, the elongated member 31 of the second fastener 30 is preferably fabricated from a biocompatible material preferably selected from the class comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. As shown in FIGURES 13 through 16, member 31 of the second fastener defines an axial bore 35 that extends through member 31 and opens to the leading and trailing ends 33 and 34 thereof. Notably, the external threading 32 extending along the axial length of member 31 has a uniform pitch between leading and trailing ends thereof. It is also important to note, the external threading 32 extending axially along the length of the second fastener 30 is like-handed and generally corresponds to the pitch of the threading of the external threading 22 extending axially along the first fastener 20. In the illustrated embodiment of the second fastener 30, the external threading 32 axially extends for a distance equal to about one-half the length between distal and proximal ends 33 and 34, respectively, of the second fastener 30. Suffice it to say, that the external threading 22, 32 on the fasteners 20, 30, respectively, has a relatively course pitch such that a substantive holding force or purchase will be developed when the fasteners are threadably secured within the respective bone fragments.

As shown in FIGURES 15 and 16, the axial bore 35 defined by member 31 includes a counterbore portion 36 extending axially away from the proximal or leading end 33 of fastener 30. As shown in FIGURE 16, in this embodiment of the second fastener 30, the counterbore portion 36 has a larger inside diameter than is the inside diameter of bore 35 thus defining an annular shoulder 37 axially spaced a predetermined distance inwardly from the

leading end 33 of fastener 30. Moreover, the counterbore portion 36 of bore 35 has an inside diameter generally equal to the outside diameter of the reduced diameter portion 27 of the first fastener 20. In a most preferred form of the second fastener, the counterbore portion 36 has an axially tapering configuration that compliments the axially tapering configuration on the reduced diameter portion 27 of the first fastener 20.

As shown in FIGURES 14 and 16, the axial bore 35 defined by member 31 also includes a counterbore portion 38 extending axially inwardly from the distal or trailing end 34 of fastener 30. In this preferred form of the second fastener 30, the counterbore portion 38 has a specific cross-sectional shape extending the axial length thereof. In this particular embodiment of the second fastener, the counterbore portion 38 has a generally hexagonal cross-sectional shape extending inwardly from the distal or trailing end 34 of the second fastener 30. The cross-sectional shape of the counterbore 38, of course, could be other than hexagonal, such as triangular, square, octagonal or pentagonal without detracting from the spirit and scope of the present invention. Amongst other features described below, the counterbore portion 38 is configured to allow a suitable driving tool (FIGURE 36) to be releasably connected to the fastener 30 such that the driving tool is capable of turning the second fastener 30 such that the external threading 32 threadably engages with the second bone fragment 14 of the scaphoid. Because of the different cross-sectional configurations of bore 35 and counterbore 38, however, a shoulder 39 (FIGURE 16) is defined therebetween.

One form of connector 40 is illustrated in FIGURES 17 through 20. As shown, the connector includes an enlarged head portion 42 and an axially elongated externally and conventionally threaded shank portion 44. The external threading on the shank portion 44 of

connector 40 has a pitch that corresponds to the pitch of the internal threading 26 extending along at least a portion of the bore 25 defined by the first fastener 20. In the embodiment of the connector 40 shown, the diameter of the shank portion 44 is specifically sized to fit endwise through the smallest diameter portion of the axial bore 35 defined by the second fastener 30 so as to allow the proximal end of the shank portion 44 of connector 40 to threadably engage with the internal threading 26 of the axial bore 25 of the first fastener 20. Moreover, the head portion 42 is sized to endwise move through the counterbore portion 38 of the second fastener and engage the shoulder 39 that acts as a stop for the connector 40.

As shown in FIGURE 19, the head portion 42 of connector 40 defines a blind socket 46 that opens to a distal end of the head portion 42 of connector 40 and is configured to releasably accommodate a driving tool (FIGURE 43) capable of imparting turning movement to the connector 40. In a most preferred form, the blind socket 46 of connector 40 has a hexagonal cross-sectional configuration although other like configurations would equally suffice.

In the illustrated form, the head portion 42 of the connector 40 includes at least one finger 47 that axially projects through the blind socket 46 and toward the open end thereof. In a most preferred form of the connector 40, and as shown in FIGURE 19, three equally spaced and axially extending fingers 47 are provided in the blind socket 46 and project toward the open end thereof.

The head portion 42 of the connector 40 preferably further includes an annular channel 48 having a diameter that is greater than the blind socket opening 46. Notably, the annular channel 48 defines an outer surface 49 that is spaced a predetermined distance from the blind or closed end of cavity 46.

The means for retaining the connector 40 against rotation and thereby maintaining the predetermined compressive relationship between the fasteners 20, 30 and, thus, the bone fragments secured to each, can take a myriad of different forms. The retainer apparatus 50 is arranged in operable combination with and holds the connector 40 against rotation thereby maintaining the predetermined compressive relationship between the fasteners 20, 30. One form of retainer apparatus 50 is illustrated in FIGURES 21 through 24. As shown, the retainer apparatus 50 includes an element 52 formed from a biocompatible material selected from the class comprised of: nylon or an ultra high molecular weight polyethylene. In its illustrated form, element 52 of retainer apparatus 50 includes a body portion 54 with a cross-sectional configuration that generally corresponds to the cross-sectional configuration of the counterbore 38 in the second fastener 30. Suffice it to say, the body portion 54 of element 52 has a cross-sectional configuration that operates in combination with the cross-sectional configuration of the counterbore 38 to prevent rotation of the element 52 relative to the second fastener 30.

In the illustrated embodiment of the retainer apparatus 50 shown in FIGURES 21, 22 and 24, element 52 further includes an axial extension 56 that projects from a proximal end thereof. At its free end, the axial extension 56 defines at least one finger 57 that is adapted to cooperate and combine with finger 47 defined in the blind socket 46 of the connector 40. In a most preferred form of the invention, and as shown in FIGURE 24, the axial extension 56 of element 52 includes three equally spaced fingers 57 that project from the free end of the axial extension 56.

In this particular illustrated form of the retainer apparatus 50, the axial extension 56 furthermore includes an annular ring 58 having an outside diameter that is generally equal to the inside diameter of the channel 48 of connector 40. Preferably, the annular ring 58 on the axial extension 56 is formed from a pliable material that is biocompatible with the bone and tissue substance wherein the fixation assembly of the present invention is adapted for use. Suffice it to say, the annular ring 58 is formed of a material that allows the ring to compress and subsequently snap into the channel 48 and combine with surface 49 of channel 48 to prevent inadvertent axial displacement of the element 52 toward the trailing end 34 of the second fastener 30. As shown in FIGURES 22 and 23, element 52 further defines a threaded bore 59 for purposes to be described hereinafter.

Turning to FIGURE 25, the proximal and distal bone fragments 12 and 14, respectively, of scaphoid 10 are schematically shown with a fracture extending generally transverse to the longitudinal axis of the scaphoid 10. Next, and as schematically shown in FIGURE 26, the bone fragments 12 and 14 are drilled to define a bore 62 extending through both fragments and a guide 64 is tightly inserted into the bore 62.

As shown in FIGURE 27, a conventional cannulated drill 66 is axially fitted over and slides along the guide 64. As shown in FIGURE 28, the drill 66 is operated to provide a bore 68 that passes through the bone substance of fragment 14 and for a substantial distance into the bone substance of fragment 12. Because the drill 66 moves endwise along guide 64, that portion of bore 68 defined by fragment 14 is axially aligned with that portion of bore 68 defined by fragment 12. After the bore 68 is provided, drill 66 is removed from the guide 64 as shown in FIGURE 29.

Next, a conventional cannulated tap 70 is arranged along the guide 64 as shown in FIGURE 30. As is typical, tap 70 is passed along the guide 64, as shown in FIGURE 31, to provide internal threading 72 to the bore 68. Notably, the internal threading 72 extends through the bone substance of fragment 14 and for a substantial axial distance of bone fragment 12. Also, it is to be noted, that the internal threading 72 provided by tap 70 is of like hand and corresponds to the external threading 22 and 32 provided on fasteners 20 and 30, respectively. After the tapping operation is complete, the tap 70 is removed from the bore 68 as shown in FIGURE 32.

The first fastener 20 is next inserted into the fractured scaphoid. As shown in FIGURE 33, the bore 25 in the elongated member 21 allows fastener 20 to be guided and vertically positioned proximate to the end of fragment 14. Thereafter, a suitable tool is used to engage the transverse slot 28 at the distal end of member 21. The surgeon rotates the fastener 20 with the tool whereby the external threading 22 of member 21 engages and follows the interior threading 72 in the bone fragments 12 and 14. As shown in FIGURE 34, the surgeon rotates the first fastener 20 until the entire fastener 20 is thready buried within the bone substance of the first fragment 12. Then, the surgeon removes the tool used to drive the first fastener 20.

Next, the second fastener 30 is inserted into the fractured scaphoid and into operable combination with the first fastener 20. As shown in FIGURE 35, the bore 35 in the elongated member 31 allows the fastener 30 to be vertically guided and positioned proximate the end of fragment 14. Thereafter, and as shown in FIGURE 36, a suitable tool is inserted into the cross-sectioned counterbore 38 of fastener 30 at the distal end thereof. The surgeon rotates the fastener 30 with the tool whereby the external threading 31 engages and follows the internal

threading 72 in bone fragment 14 until the entire fastener 30 is thready buried within the bore substance of the second fragment 14. Thereafter, the surgeon removes the tool used to drive the second fastener 30 as shown in FIGURE 37.

With the first and second fasteners 20 and 30, respectively, secured or buried in the bone fragments 12 and 14, the surgeon removes the guide 64 as shown in FIGURE 38.

FIGURE 39 schematically represents the axial alignment of the first and second fasteners 20 and 30, respectively. As shown in FIGURES 33, 34 and 39, when the first fastener 20 is threadably inserted into the bone substance of the scaphoid, the pointed end 23 is arranged to initially engage the internal threading 72 in the bone substance thereby facilitating threaded engagement of the fastener 20 within the bone substance and with the reduced diameter portion 27 preferably projecting axially toward the open end of bore 68. As shown in FIGURE 39, the open ended counterbore portion 36 of the second fastener 30 is then inserted first into the bore 68 in the bone fragment.

Turning to FIGURES 36 and 40, and as mentioned above, as the second fastener 30 is threaded into the bore 68, the counterbore portion 36 of fastener 30 fits over and into operable combination with the reduced diameter portion 27 of fastener 20 to effect axial alignment of the fasteners 20 and 30 and the bone fragments 12 and 14. As will be appreciated, the axially tapering configuration on the reduced diameter portion 27 of fastener 20 cooperates with the complimentary tapered configuration at the leading end of the counterbore portion 36 to facilitate and act as a cam to effect axial alinement of the first and second fasteners 20 and 30 and the bone fragments 12 and 14 fastened thereto, respectively. Moreover, it is within the spirit and scope of the present invention that the configurations at the trailing and leading ends of the first

and second fasteners 20 and 30, respectively, could be reversed without detracting or departing from the spirit and scope of the present invention.

Turning now to FIGURES 41 and 42, after the first and second fasteners 20 and 30, respectively, are threaded into the bone substance of the scaphoid, the connector 40, as shown in FIGURES 17 through 20, is inserted into combination with the fasteners 20, 30. As shown, the shank portion 42 of connector 40 endwise passes first through the counterbore portion 38, then through bore 35, and finally through the counterbore portion 36 of fastener 30 and, ultimately, into threaded engagement with the internal threading 26 axially extending along a least portion of the length of the bore 25 of fastener 20. As shown in FIGURE 43, a suitable tool releasably fits into the open end of the blind socket 46 to turn the connector 40 relative to the first and second fasteners 20 and 30.

It will be appreciated at this point in the procedure some degree of gap or separation may exist between the bone fragments 12 and 14. Notably, and as schematically illustrated in FIGURE 42, the head end or portion 42 of connector 40 is larger than bore 35 defined by fastener 30 thus preventing passage of the head portion 42 past the shoulder 39 defined by the second fastener 30. Any gap or separation existing between the bone fragments 12, 14 is narrowed by the surgeon rotating the connector 40. That is, with the head portion 42 of connector 40 in operable engagement with the shoulder 39 of the second fastener 30, continued rotation of the connector 40 will cause and result in the first and second fasteners 20 and 30, respectively, and the bone fragments attached to each being drawn toward each other. Ultimately, the bone fragments 12, 14 are preferably drawn into abutting relationship under a predetermined compression relative to each. Since the fasteners 20 and 30 are already fixed in

the bone substance, the ability to rotate the connector 40 allows the surgeon an appropriate "feel" when the bone fragments 12, 14 are drawn into a predetermined and proper compressive relationship relative to each other.

Next, and as shown in FIGURE 44, a preferred form of retainer apparatus 50 is placed in operable combination with the fastener 30 to maintain the predetermined and proper level of compression between the fasteners 20, 30 and the bone fragments 12, 14 to promote the healing process. As shown in FIGURE 45, the element 52 of the retainer apparatus 50 is initially and slidably positioned into the counterbore portion 38 of the fastener 30 with the axial extension 56 and fingers 57 directed toward the connector 40. As shown in FIGURE 47, a suitable tool is releasably connected to the element 52 to facilitate axial placement of the retainer apparatus 50 into combination with the fastener 30 and connector 40. As shown in FIGURES 48 and 49, the fingers 57 of this preferred form of retainer apparatus 50 are initially spaced from the fingers 47 in the blind socket 46 defined by the head portion 42 of connector 40.

Turning now to FIGURE 46, the element 52 of the retainer apparatus 50 is slidably moved toward the connector 40 such that the fingers 57 on the axial projection 56 of element 52 operably engage with the fingers 47 in the blind cavity 46 of the head portion 42 of connector 40. The relationship of the fingers 47 on the connector to the fingers 57 on the retaining apparatus is further illustrated in FIGURES 50 and 51.

As illustrated in FIGURES 52 and 53, the element 52 of retainer apparatus 50 is further axially moved toward the connector until the annular ring 58 resiliently snaps into the channel 48 defined by the head portion 42 of the connector 40. When the retainer ring 58 snaps into the channel 48, the retainer apparatus 50 is prevented from inadvertently moving away from the

connector 40 while concomitantly preventing the connector 40 from turning thereby maintaining the predetermined level of compression between the fasteners 20 and 30 and the fragments 12 and 14, respectively, carried thereby to promote the healing process.

The retainer apparatus 50 is maintained in operable combination with the connector 40, as shown in FIGURES 54 and 55, until a suitable tool is used to purposefully remove the retainer apparatus 50. To affect removal of the retainer apparatus 50 from operable combination with the connector 40, in the illustrated form of the invention, the releasable tool used to position the retainer apparatus 50 is threadably engaged with the threaded bore 59 (FIGURES 22 and 23) defined by the element 52. Forcible retraction of the tool will likewise cause the retainer ring 58 to disengage from the channel 48 and thereby allow the retainer apparatus 50 to be removed from operable association with the connector 40.

FIGURE 56 schematically illustrates an alternative form of retainer apparatus 150. As shown, this alternative retainer apparatus 150 comprises an insert 152 arranged axially along and in combination with the internal threading 26 of the first fastener 20. The insert 152 is formed from a biocompatible material preferably chosen from the class consisting of: nylon, or an ultra high molecular weight polyethylene.

Turning to FIGURE 57, the alternative form of retainer apparatus is preferably positioned proximate to the trailing end 24 of the first fastener 20 and in combination with a trailing end of the internal threading 26. As shown in FIGURES 57 and in 58, the second fastener 30 of the multi-piece interfragmentary fixation assembly of the present invention remains substantially the same as discussed above.

As schematically in shown in FIGURES 57 and 59, the alternative retainer apparatus 150 allows a conventional socket headed screw or connector 140 to be used in combination with the fasteners 20 and 30. That is, the connector 140 includes an enlarged head 142 and a shank portion 144 with external conventional threading that corresponds to the internal threading 26 extending along the axial bore 25 of the first fastener 20. The connector 140 functions in an analogous manner to that described above with respect to connector 40. As the connector 140 passes inwardly along the internal threading 26 of the first fastener 20, the external threading on the shank portion 144 of fastener 140 engages with the retainer apparatus 150 in a manner preventing inadvertent turning of the connector 140 and thereby maintaining the compressive force preselected by the surgeon between the fasteners 20 and 30 to promote the healing process.

FIGURE 60 schematically illustrates another alternative form of retainer apparatus 250. As shown, this alternative retainer apparatus 250 comprises an annular insert 252 arranged axially along and in combination with the internal threading 26 of the first fastener 20. The annular insert 252 is preferably formed from a biocompatible material preferably chosen from the class consisting of: nylon, or an ultra high molecular weight polyethylene. The retainer apparatus 250 functions in an analogous manner to that described above regarding the alternative form of retainer apparatus 150. Thus, no further detailed description need be provided therefor for a complete understanding of its function and operation.

Still another form of retainer apparatus 350 is schematically illustrated in FIGURES 61 through 63. In this embodiment, the retainer apparatus 350 comprises an element 352 including a body portion 354 with a cross-sectional configuration generally corresponding to the cross-sectional configuration of the counter bore 38 in the second fastener 30. Suffice it to say, the

body portion 354 of element 352 has a cross-sectional configuration that operates in combination with the cross-sectional configuration of the counterbore 38 to prevent rotation of the element 352 relative to the second fastener 30. In this embodiment, element 352 of the retainer apparatus 350 includes a retaining ring 358 that is carried by the body 354 of element 352.

This alternative form of retainer apparatus 350 is adapted to operate in combination with a conventional socket headed screw or connector 340. The connector 340 functions in an analogous manner to that discussed above with respect to connector 40 except that connector 340 does not require the specifically shaped blind socket portion as does connector 40.

As schematically illustrated in FIGURES 62 and 63, the second fastener 30 defines an annular channel 348 that is spaced a predetermined distance from the shoulder 39 defined by the second fastener. The predetermined distance separating channel 348 and shoulder 39 is equal to the axial length of the headed portion 342 of connector 340 and the axial length the ring 358 is disposed from a leading edge of the body portion 354 of element 352. Preferably, the annular ring 358 on the element 352 is formed from a pliable material that is biocompatible with the bone and tissue substance wherein the fixation assembly of the present invention is adapted for use. Suffice it to say, the annular ring 358 is formed from a material that allows the ring 358 to compress and subsequently snap into and combine with the channel 348 in a manner preventing inadvertent axial displacement of the element 352 toward the trailing end of the fastener 30. Accordingly, once the surgeon selects the predetermined level of compression between the fasteners, the retainer apparatus 350 is inserted until the annular ring 358 snaps into the annular channel 348 thereby preventing the fastener 30 from turning with the second fastener

30 and thereby maintaining the predetermined level of compression between the fasteners 20 and 30.

As shown in FIGURES 62 and 63, element 352 of retainer apparatus 350 further defines a threaded bore 359. As will be appreciated, the retainer apparatus 350 is maintained in operable combination with the second fastener 30 and prevents inadvertent rotation of the fastener 340 until a suitable tool removes the retainer apparatus 350 from association with the connector 340. To effect the removal of retainer apparatus 350, in this illustrated form of the invention, a releasable tool is threadably engaged with the threaded bore 359 defined by the element 352. Forcible retraction of the tool will likewise cause the retainer ring 358 to disengage from the channel 348 and thereby allow the retainer apparatus 352 to be removed from the interfragmentary fixation assembly 10.

FIGURE 63A illustrates still another alternative configuration for retaining the fasteners 20 and 30 of the fixation assembly 10 in a preset or predetermined compressive relationship relative to each other. This alternative configuration includes the conventional socket headed screw or connector 340 mentioned above. As mentioned above regarding connector 140, the connector 340 includes an enlarged head portion 342 and a shank portion 344 with conventional external threading 346 extending axially therealong. The connector 340 functions in an analogous manner to that described above with respect to connectors 40 and 140.

In this embodiment of the invention, an internal locking thread form 326 (FIGURE 63B) is defined along at least a portion of the axial length of the bore 25 defined by the first fastener 20. In a preferred form of the invention, the internal locking thread form 326 extends an axial lengthwise distance from the trailing end 24 of member 21 and along the bore 25 of fastener 20.

It should be appreciated, the internal locking thread form 326 can extend the entire or a distance somewhat less than the entire length of bore 25. In a most preferred form of the invention, the internal locking device 326 is sold under the trademark SPIRALOCK by Detroit Tool Industries and offers preload locking between the connector and threadably interconnected fastener through a unique internal thread configuration.

As shown in FIGURE 63B, and in the illustrated form of the invention, the unidirectional internal thread form 326 has an added 30° wedge ramp 327 at the root of each internal thread defined by fastener 20. The internal thread from 326 still mates with the standard or conventional 60° threading on the external threading 346 of the shank portion 344 of connector 340.

When a clamp load is applied to the connector 340 thereby drawing the fasteners 20 and 30 into predetermined compressive relationship relative to each other, the internal thread form or configuration 326 defined by fastener 20 locks the standard or conventional male threading 346 extending along the length of shank 344 of fastener 340 tightly against the wedge ramp 327 thereby preventing movement of the connector 340 relative to fastener 20 and thereby maintaining the predetermined compressive relationship between the fasteners 20, 30. At this point, the crests of the conventional external threading 346 are drawn tightly against the ramp surfaces 327 of the thread form 326 thus eliminating radial clearances and creating a continuous spiral, line contact along the entire length of thread engagement. This continuous line contact spreads the clamp force more evenly over all the engaged threads thus reducing fatigue failure and increasing the integrity of the threaded connection between connector 340 and fastener 20. Moreover, the internal thread form 326 for preventing the connector 340 from rotating following

establishment of the predetermined compressive relationship between fastener 20, 30 furthermore yields the surgeon with the ability to "feel" the proper relationship n the identical fashion the surgeon is accustomed to working with using other arrangements. As will be appreciated, other internal thread forms could likewise be used along the length of axial bore 25 and the external threading 346 of connector 340 without detracting or departing from the spirit and scope of the present invention.

The use of an internal thread form or configuration 326 for preventing inadvertent rotation of the connector used to join the fasteners of the present invention offers several benefits. First, the internal thread form 326 is a tested and proven technique which works well under severe conditions. Second, the internal thread form 326 simplifies the fixation assembly design. Notably, when the internal thread form 326 is utilized, a conventional connector 340 is used to draw the fasteners 20, 30 into a predetermined compressive relationship relative to each other. Moreover, when a thread form 326 is used in connection with the present invention, the design of fastener 30 is simplified. That is, the counterbore 38 defined by fastener 30 is a simplified counterbore having no specific cross-sectional configuration thereto. For these and other reasons, an internal thread form is preferably used to inhibit rotation of the connector 340 relative to the fasteners thereby maintaining the preselected compressive force between the fasteners 20, 30 and, thus, the bone fragments secured to each fastener.

Not all types of bone fractures will necessarily lend themselves to the embodiment of the invention schematically illustrated in FIGURES 3 through 8 wherein two axially elongated fasteners are maintained in a compressive and end-to-end relationship relative to each other.

Accordingly, the present invention contemplates alternative forms of the multipiece interfragmentary fixation assembly.

An alternative form of the multipiece interfragmentary fixation assembly is illustrated in FIGURES 64 through 68 and is generally designated by reference numeral 400. As with the first embodiment of the invention, the multipiece interfragmentary fixation assembly 400 functions to maintain bone fragments 412 and 414 in compressive relationship relative to each other. The elements of this alternative embodiment of the fixation assembly 400 that are identical or functionally analogous to those in earlier embodiments discussed above are designated by reference numerals identical to those used above with the exception that this alternative embodiment reference numerals are in the 400 series.

As shown in FIGURE 68, this alternative embodiment of the fixation assembly 400 includes a first axially elongated fastener 420 secured to bone fragment 412, a second fastener 430 that is secured to bone fragment 414, a connector 440 that serves to maintain the first and second fasteners 420 and 430 and the bone fragments 412 and 414 attached to each, respectively, in compressive relationship relative to each other, and an apparatus 450 for maintaining the compressive relationship between the first and second fasteners 420 and 430, respectively, and the bone fragments attached to each. Suffice it to say, the first fastener 420 and the connector 440 are substantially similar to that embodiment of the invention illustrated in FIGURES 56 through 59. Moreover, this alternative embodiment of the fixation assembly further includes a retainer apparatus similar to that illustrated in FIGURES 56 or 60. It should be appreciated, however, the apparatus 450 for holding the connector 440 against rotation could involve an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed above in

detail. Accordingly, no further detailed description need be provided therefor for a complete understanding of those features of the invention.

The alternative embodiment of the second fastener 430 is best illustrated in FIGURES 65 through 67. The second fastener 430 comprises a member 431 and element 432 arranged in operable combination relative to each other. Member 431 of a fastener 430 is configured with a generally concave shaped and apertured section 433 that is generally centralized between a plurality of prongs 434 that project radially outward and away from the central section 433. Although the second fastener 430 is illustrated as having four prongs 434 extending therefrom, it will be readily appreciated by those skilled in the art that less than four prongs could radially extend away from the central section 433 of the fastener without departing or detracting from the spirit and scope of the present invention. As shown, the central section 433 defines a hemispherical shaped recess with an aperture 435 opening thereto. Element 432 likewise has a hemispherical shape that complements the concave shaped section 433. Moreover, element 432 defines an aperture 436 and element 432 is sized to permit the externally threaded shank portion 444 of fastener 440 to pass endwise therethrough while preventing the enlarged headed portion 442 of fastener 440 to pass endwise therethrough.

In an assembled relationship as shown in FIGURES 67, element 432 sits within the apertured central section 433 of member 431 and is permitted to rockingly move within the socket defined by element 431. Returning now to FIGURE 68, the first fastener 420 is initially threaded into the bone substance of bone fragment 412 and the external threading 422 fixedly maintains the fastener 420 in place. The connector 440 is then passed endwise through the element 432 and member 431 of the second fastener and into threaded engagement with the

internal threading 426 axially extending along at least a portion of the length of the bore 425 of fastener 420.

At this point in the procedure, some degree of gap or separation may exist between the bone fragments 412 and 414. Notably, and as illustrated in FIGURES 66 and 67, the head end 442 of connector 440 is larger than the bore 436 defined in element 432 of fastener 430. Any gap or separation existing between the bone fragments 412 and 414 is narrowed by the surgeon rotating the connector 440. That is, with the head portion 442 of connector 440 in operable engagement with the element 432 of the second fastener 430, continued rotation of the connector 440 will cause and result in the first and second fasteners 420 and 430, respectively, and the bone fragments attached to each being drawn toward each other. Ultimately, the bone fragments 412 and 414 are preferably drawn into abutting relationship under predetermined compression relative to each other. The ability to rotate the connector 440 allows the surgeon an appropriate "feel" when the bone fragments 412, 414 are drawn into a predetermined proper compressive relationship relative to each other. The predetermined and proper compressive relationship between the fasteners 420 and 430 and, thereby, the fragments 412 and 414 relative to each other is maintained by preventing the connector 440 from inadvertently turning as through a retainer apparatus similar to that described in detail above.

Notably, the aperture 435 in member 431 is sized and configured such that the member 431 of the second fastener 430 is permitted to rock about the elongated axis of connector 440. As such, the prongs 434 extending radially outwardly from the central section 431 of member 430 are better able to graspingly secure to the bone fragment 414. Moreover, and as shown in

FIGURE 64, the prong configuration of member 431 readily lends itself to having a ligament L attached thereto.

Frequently, with an acute hyperextension injury to the wrist, the scaphoid will not fracture but instead a series of ligamentous damage can occur about the wrist. The volar wrist ligaments certainly contribute to instability about the wrist. The dorsal scapholunate interosseous ligament is a primary constraining force that when ruptured leads to disassociation between the scaphoid and lunate bones. Failure to reconstruct this ligament can lead to the development of progressive arthritis about the wrist. Another alternative embodiment of the fixation assembly of the present invention readily lends itself to replacement and/or repair of ligaments between adjacent bones. Although a bone-ligament-bone graft is hereinafter illustrated in combination with lunate and scaphoid bones, it should be appreciated that other bones in a patient's body are equally susceptible to the present invention and the present invention should not be limited to that shown for exemplary purposes.

FIGURE 69 shows the bones of a patient's hand with a particular area shown for harvesting a bone-ligament-bone for grafting. After the bone-ligament-bone section is harvested, the surgeon configures the lunate bone LB to accept the graft as shown in FIGURE 70. The surgeon then conditions or configures the scaphoid bone SB to accept the graft as shown in FIGURE 71. As shown in FIGURE 72, conventional K-wires are then inserted into the lunate bone and scaphoid bone for movement control.

Another embodiment of the fixation assembly according to the present invention is illustrated in FIGURES 73 through 77 and is designated generally by reference numeral 500. The fixation assembly 500 functions to secure the bone-ligament-bone graft to the lunate bone

LB and the scaphoid bone SB. The elements of this alternative embodiment of the fixation assembly 500 that are identical or functionally analogous to other components mentioned above are designated by reference numerals identical to those used above with the exception that this embodiment reference numerals are in the 500 series.

As shown in FIGURE 73, this alternative embodiment of the fixation assembly 500 includes a first axially elongated fastener 520, a second fastener 530, a connector 540 and a retaining apparatus 550 (FIGURE 77). The first fastener 520, the connector 540 and the retaining apparatus 550 may each be similar to those similar components illustrated in FIGURES 56 through 59 and discussed in detail above. Alteratively, an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could likewise be used to prevent rotation of the connector 540 without detracting or departing from the spirit and scope of the present invention. Thus, no further detailed description need be provided therefor at this time.

This alternative embodiment of the second fastener 530 is best illustrated in FIGURES 73, 74 and 77. The second fastener 530 is formed from a biocompatible material to the bone tissue wherein the fastener is used and preferably from the class consisting of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. As shown, the second fastener 530 comprises a generally planar member 531 having upper and lower generally parallel surfaces 532 and 533. The planar member 531 also defines a preferably centralized through bore 534 that permits a shank portion 544 of connector 540 to pass endwise therethrough and is specifically sized to prohibit the head portion 542 of the connector 540 from passing therethrough. The

second fastener 530 is further provided with a plurality of holes or apertures 535 arranged in a generally circumferential relation relative to the centralized through bore 534.

Turning now to FIGURE 78, the bone-ligament-bone graft is fixedly attached to the second fastener 530. As shown, a bore is provided in each bone fragment of the bone-ligament-bone graft such that access is provided to the head portion 542 of each connector 540. Notably, sutures or other suitable fastening apparatus passes through the apertures 535 in the second fastener and about the bone of the bone-ligament-bone graft thereby securing a bone fragment to the second fastener.

Turning to FIGURE 79, after configuring or channelling the lunate bone LB, the first fastener 520 of the fixation assembly is threadably secured within the bone substance of the lunate bone. As shown in FIGURE 80, a first fastener 520 of this embodiment of the fixation assembly is threadably secured within the bone substance of the scaphoid bone. Notably, the pitch of the threads on the first fastener 520 prohibit the fastener from becoming dislodged from the bone substance of the respective bone fragment.

Turning to FIGURE 81, the bone-ligament-bone graft is then secured within the channel or configuration of the lunate/scaphoid bone. As shown in FIGURE 81, a suitable tool is used to threadably secure the bone graft to the first fastener in the lunate bone. Preferably, such tool includes a flexible shank portion. Because the second fastener is fixedly attached to the bone fragment, the rotating action of the connector 540 forcibly draws the bone fragment into the channelled configuration of the lunate bone LB. Turning to FIGURE 82, the other bone fragment is secured in the channelled configuration of the scaphoid bone in a similar manner.

FIGURE 83 schematically illustrates the bone-ligament-bone graft secured in place between the lunate bone LB and scaphoid bone SB.

Still another embodiment of the multipiece fixation assembly according to the present invention is schematically illustrated in FIGURES 84 and 85. In this embodiment of the invention, the fixation assembly is utilized to affix a bone plug 614 to a scaphoid bone 612. This alternative embodiment of fixation assembly is schematically illustrated in FIGURES 84 and 85 and is designated generally therein by reference numeral 600. As with the other embodiments of the invention, the fastener assembly 600 functions to maintain the bone plug 614 in a proper compressive relationship relative to the scaphoid bone fragment 612. The elements of this alternative embodiment of the fixation assembly that are identical or functionally analogous to those in earlier embodiments discussed above are designated by reference numerals identical to those used above with the exception that the reference numerals in this alternative embodiment are in the 600 series.

As shown in FIGURE 84, this alternative embodiment of the fixation assembly 600 includes a first axially elongated fastener 620, a second fastener 630, a connector 640 and a retainer apparatus (not shown). The first fastener 620, connector 640, and retainer apparatus (not shown) can be like those elements schematically illustrated in FIGURES 56 through 59. Alteratively, an internal thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could likewise be used to prevent rotation of the connector 640 without detracting or departing from the spirit and scope of the present invention.

The alternative embodiment of the second fastener 630 is illustrated in FIGURES 86 through 90. The second fastener 630 comprises a member 631 defining a coaxial bore extending

therethrough and having a plurality of prongs extending radially outwardly away from member 631.

In the embodiment illustrated in FIGURES 86 through 90, member 631 of fastener 630 has an axially elongated frusto-conically shaped configuration. Preferably, the prongs 634 extend from that end of member having a larger diameter. Member 631 of fastener 630 is formed from a biocompatible material preferably from a class of materials comprised of: titanium, stainless steel, or a cobalt chromium molybdenum alloy. Alternatively, an outer surface of the member comprising fasteners 620 and 630 can be treated in a well known manner to promote bone growth.

As shown in FIGURE 86, the throughbore or aperture 632 defined by member 631 of the second fastener 630 is specifically sized relative to the connector 640. More specifically, the throughbore 632 is sized to allow an externally threaded shank portion 644 of connector 640 to extend axially through the second fastener 630 and into threaded engagement with the internal threading (not shown) of the first fastener 620. The head portion 642 of the connector 640 is prohibited, however, from passing endwise through the second fastener 630.

With this embodiment of the invention, the bone plug 614 is placed into the configured channel of the scaphoid bone 612. Thereafter, the first fastener 620 is secured within the bone substance of the bone fragment 612 in a manner discussed in detail above. Thereafter, the threaded connector 640 is passed through the second fastener and threadably engaged with the first fastener. As will be appreciated, rotation of the connector 640 will draw the second fastener 630 toward the first fastener 620 thereby allowing the prong 634 on the second fastener to forcibly move the bone plug 614 into compressive relationship relative to the bone fragment

612. Continued rotation of the connector 640 will continue until the surgeon develops the appropriate "feel" of the fasteners 620, 630 relative to each other thereby establishing a predetermined level of compression between the fasteners and, thus, the bone plug 614 and bone fragment 612. As discussed in detail above, the retaining apparatus (not shown) associated with this embodiment of the invention will maintain the first and second fastener 620 and 630, respectively, in the predetermined compressive relationship by prohibiting the connector 640 from turning thereby maintaining the bone plug 614 and bone fragment 612 in a predetermined compressive relationship during the healing process and in a manner promoting tissue growth therebetween.

FIGURES 91 through 99 schematically illustrate other forms of fasteners that would be equally applicable for use with this embodiment of the invention.

Another alternative embodiment of the present invention is likewise useful regarding repair of a small joint such as in the finger of a patient. As shown in FIGURE 100, this alternative embodiment of the fixation assembly of the present invention is used to secure bone 712 to bone 714 under a predetermined compressive force.

For use in combination with such an environment, an alternative embodiment of the multi-piece fixation assembly according to the present invention is illustrated in FIGURES 100 and 101 and is designated generally by reference numeral 700. The fixation assembly 700 is similar, and functions in a similar manner, to the other embodiments of the fixation assembly described above. The elements of this alternative embodiment of the fixation assembly 700 that are identical or functionally analogous to those of other embodiments of the fixation assembly are designated by reference numerals identical to those used for the alternative embodiments with

the exception that this embodiment reference numerals are in the 700 series. As shown in FIGURE 101, this alternative embodiment of the fixation assembly 700 includes the first axially elongated fastener 720 secured to bone 712, a second fastener 730 fixedly attached to bone 714, a connector 740 for interconnecting the first and second fasteners 720 and 730, respectively, and a retaining apparatus (not shown).

The first fastener 720, the connector 740 and the retainer apparatus (not shown) used in combination with this embodiment of the invention are substantially similar to those components schematically illustrated in FIGURES 56 through 59 and discussed in detail above. Alternatively, a thread form similar to that disclosed in FIGURES 63A and 63B and discussed in detail above could be used to prevent inadvertent rotation of the connector 740 without detracting or departing from the spirit and scope of the present invention. Therefore, no further detail description need be provided therefor for complete understanding of the present invention.

The alternative embodiment of the second fastener 730 is illustrated in FIGURES 102 through 106. The second fastener 730 is formed from a bone compatible material preferably chosen from the class consisting of: titanium, stainless steel, or a cobalt chromium molybdenum alloy and is attachable to an exterior of the second bone 714 (FIGURE 101). As shown in FIGURES 102 through 104, the second fastener 730 comprises an elongated and narrowed plate-like member 731. Member 731 has upper and lower generally parallel surfaces 732 and 733, respectively. The plate-like member 731 further includes an indentation 734 preferably extending longitudinally of member 731 and has a closed margin defined within the periphery 735 of member 731 and including a wall 736 depending in an acute angle relative to the upper surface 732 of the plate-like member 731. The depending wall 736 defines an aperture 737.

Notably, the aperture 737 defined by the plate-like member 731 is sized such that the shank portion 744 (FIGURE 101) of the connector 740 is permitted to endwise pass therethrough. Moreover, the aperture 737 in plate-like member 731 is sized such that the head portion 742 (FIGURE 101) of the connector 740 is prevented from passing endwise therethrough. Instead, the head portion 742 of connector 740 abuts with the depending wall 736 of the plate-like member 731.

Returning to FIGURE 101, the first fastener 720 is secured in the bone substance of bone 712. Notably, the external threading 722 on the first fastener 720 is sufficient to prevent the fastener 720 from becoming dislodged from the bone substance when subjected to axial forces applied thereagainst. Next, the surgeon configures the bone fragment 714 to accept the indentation 734 defined by the plate-like member 731. More specifically, the bone 714 is configured with a step against which wall 736 is permitted to abut. Thereafter, the shank portion 744 of connector 740 passes through bore 737 and into threaded engagement with the first fastener 720.

It will be appreciated at this point in the procedure that some degree of gap or separation may exist between bones 712 and 714. Notably as mentioned above, the head end or portion 742 of connector 740 is larger than bore 737 defined by depending wall 736 of indentation 734 thus preventing passage of the head portion 742 of connector 740 past the wall 736 of plate-like member 731. Any gap or separation existing between the bone 712 and 714 is narrowed by the surgeon rotating the connector 740. That is, with the head portion 742 of connector 740 in operable engagement with wall 736 of plate-like member 731 and with wall 736 abutting against the configured bone 714, continued rotation of the connector 740 will cause and result in the

first and second fasteners 720 and 730, respectively, and the bones attached to each being drawn toward each other. Ultimately, the bone 712 and 714 are preferably drawn into abutting relationship under a predetermined compression relative to each. Since the fasteners 720 and 730 are already fixed to the bone substance of each bone 712 and 714, the ability to rotate the connector 740 allows the surgeon an appropriate "feel" when the bones 712, 714 are drawn into a predetermined and proper compressive relationship relative to each other. Moreover, the retaining apparatus (not shown) associated with this embodiment of the invention prevents the connector 740 from inadvertently turning thus maintaining the predetermined compressive relationship between the fasteners 720 and 730 and the bones 712 and 714, respectively, connected to each.

Another aspect of the present invention relates to providing an interfragmentary fixation kit as schematically illustrated in FIGURE 107. The interfragmentary fixation kit comprises a collection of first axially elongated fasteners. Each fastener in the collection has an elongated length that is different from the elongated length of other fasteners in the collection. Notably, each fastener in the collection has external threading for anchoring the first fastener into a bone fragment. The configuration of the external threading of each fastener in the collection may differ from other fasteners in the collection. Accordingly, the surgeon is permitted to choose from the interfragmentary fixation kit the appropriate sized fastener. The interfragmentary fixation kit further includes a series of second fasteners. Each of said second fasteners in the series is adapted for attachment in nonmovable relation to the second bone in the patient and has a different configuration than the other fasteners in the series of second fasteners, thus yielding a selection from which the surgeon can chose the most appropriate fastener from the particular

fracture being repaired. Moreover, a set of elongated connectors are provided in combination with the interfragmentary fixation kit. Each connector in the set of connectors has a head portion that accommodates a driving tool and an elongated lengthwise shank portion having external uniformly pitched threading that corresponds to the internal threading of each fastener in the collection of first fasteners. Understandably, the length of the shank portion of each connector in the set of connectors varies from one another to allow various fasteners to be used in combination relative to each other. Accordingly, the surgeon is permitted to mix and match sets of components to the appropriate circumstances which require repair.

Regardless of the particular fixation assembly embodiment used, the multipiece interfragmentary fixation assembly permits first and second bone fragments to be connected under compression. Another important feature of the present invention is that the interfragmentary fixation assembly allows the bone fragments to be interconnected under adjustable compression that is preselected by the surgeon during the connection process. Thus, with the present invention, the surgeon is provided with a "feel" for the level or degree of compression to be established between the fasteners and, thus, bone fragments to promote healing of bone fragments. Although some of the components of the fixation assembly of the present invention are completely buried within the bone substance of the bone fragments requiring repair, a salient feature of the present invention is the provision of a retainer mechanism that maintains the predetermined level of compression between the fasteners by preventing the connector between the fasteners from inadvertently turning.

From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present

invention. It will be appreciated that the present disclosure is intended as an exemplification of the invention, and is not intended to limit the invention to the specific embodiment illustrated. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

**WHAT IS CLAIMED IS:**

1. A multipiece interfragmentary fixation assembly for connecting portions of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener defining an elongated axis and having external threading for anchoring said first fastener into a first bone fragment, said first fastener defining an coaxial opening with internal uniformly pitched threading extending along at least a portion of the length thereof;

a second fastener attachable in non-movable relation with a second bone fragment;

an elongated connector including a head portion that accommodates a tool and a shank portion having external uniformly pitched threading corresponding to the internal threading of said first fastener, and wherein the shank portion of said connector extends endwise through the second fastener and into threaded engagement with said first fastener while the head portion of said connector operably engages with said second fastener such that rotation of said connector draws the first and second fasteners and thereby the first and second bone fragments into compressive and proper relation relative to each other; and

a retaining apparatus for preventing said connector from inadvertently rotating relative to said second fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

2. The multipiece interfragmentary fixation assembly according to Claim 1 wherein a leading end of said first fastener has a pointed configuration while a trailing end of said first

fastener is configured to accommodate a driving tool capable of turning said first fastener such that the external threading threadably engages with said first bone fragment.

3. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener has an elongated configuration with external threading for anchoring said second fastener in said second bone fragment.

4. The multipiece interfragmentary fixation assembly according to Claim 3 wherein said second fastener has a coaxial opening extending between leading and trailing ends thereof.

5. The multipiece interfragmentary fixation assembly according to Claim 4 wherein the trailing end of said second fastener is configured to accommodate a driving tool capable of turning said second fastener such that the external threading threadably engages with said second bone fragment.

6. The multipiece interfragmentary fixation assembly according to Claim 4 wherein said retaining apparatus comprises an insert fitted within said coaxial opening and operably associated with said second fastener for preventing inadvertent rotation of said connector thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

7. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises a member formed from a bone compatible material and

configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from said central section, and an apertured hemi-spherically shaped element that is seated for rocking movement within said central section of said member, and wherein the shank portion of said elongated connector extends endwise through the said member and said element into threaded engagement with said first fastener, with the head portion of said connector being operably engagable with said element such that rotation of said connector draws the member and said first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other.

8. The multipiece interfragmentary fixation assembly according to Claim 7 wherein the concave centralized section of said member defines an enlarged opening that permits said member to rock relative to said connector and said element thereby enhancing attachment of said prongs to said second bone fragment.

9. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of the coaxial opening of said first fastener for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

10. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises apertured disk that fits about the shank portion of said connector and operably engages an underside of the head portion of said connector to permit relative

rotation therebetween, the apertures in said disk permitting said second bone fragment to be attached thereto.

11. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises an elongated member having first and second ends and an axial bore for allowing the shank portion of said connector to extend endwise therethrough and into threaded engagement with said first fastener, the elongated member of said second fastener further including a bone fragment retainer extending radially away from said elongated member.

12. The multipiece interfragmentary fixation assembly according to Claim 11 wherein the elongated member of said second fastener has a generally cylindrical configuration between opposite ends thereof.

13. The multipiece interfragmentary fixation assembly according to Claim 11 wherein the elongated member of said second fastener has a frusto-conical configuration between opposite ends thereof.

14. The multipiece interfragmentary fixation assembly according to Claim 1 wherein said second fastener comprises a plate having upper and lower generally parallel surfaces with an indentation having a closed margin defined by said plate and including a wall depending at an acute angle relative to the upper surface of said plate, said wall defining an aperture through which the shank portion of said connector extends into threaded engagement with the internal

threading of said first fastener while the wall of said indentation maintains the head portion on an opposite side of said plate from said first fastener.

15. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments to each other across a fracture defined therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener formed from a bone compatible material and having external threading for anchoring said first fastener within an interior of the first bone fragment, said first fastener defining an opening with internal uniformly pitched threading;

a second fastener formed from a bone compatible material and attachable to an exterior of the second bone fragment, said second fastener comprising a member configured with a generally concave shaped and apertured section that is generally centralized between prongs extending radially outward and away from the central section of said member, said second fastener further including an apertured hemi-spherically shaped element configured to rockingly seat within the central section of said member;

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated threaded shank portion having external uniform pitched threading extending over the length thereof corresponding to the internal threading of said first fastener, and wherein the shank portion of said connector extends endwise through the apertured element and the apertured center section of the member of said second fastener and into threaded engagement with said internal threading of said first fastener while the enlarged head portion of said connector operably engages with the element of said second fastener such that rotation of

said connector draws the first and second fasteners and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein the apertured center section of the member of said second fastener is configured to allow said member to rock relative to said element with the connector passing therethrough to enhance the ability of the prongs of said member to positively engage the exterior of said second bone fragment to the fullest extend possible; and

wherein said first fastener further includes a retaining apparatus arranged along the internal threading thereof for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector thus maintaining the preselected compressive relationship between said first and second fasteners and the first and second bone fragments attached thereto.

16. The multipiece interfragmentary fixation assembly according to Claim 15 wherein said retaining apparatus comprises a non-metallic ring arranged along the length of the internal threading of said first fastener for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector thus maintaining the preselected compressive relationship between the first and second fasteners.

17. A multipiece interfragmentary fixation assembly for connecting portions of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

an axially elongated fastener having external threading for anchoring said first fastener into a first bone fragment, said first fastener defining a coaxial opening with internal uniformly pitched threading extending the length thereof;

a generally planar member having upper and lower generally parallel surfaces, said planar member defining a generally centralized throughbore with a plurality of apertures arranged in generally circumferential relation relative to said throughbore;

an elongated connector including an enlarged head portion that accommodates a driving tool and is configured to prevent its movement through said throughbore of said planar member but is smaller than the spacings between opposed apertures defined by said planar member, said connector further including a shank portion defining an elongated axis and that is sized to extend endwise through said throughbore defined by said planar member whereby said planar member is free to turn beneath said enlarged head of said member about said axis defined by said shank portion, and wherein said shank portion has external uniformly pitched threading corresponding to the internal threading of said first fastener; and

a retaining apparatus arranged along the internal threading thereof for operably engaging the external threading of said connector and thereby preventing inadvertent rotation of said connector relative to said fastener.

18. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading for anchoring said first bone screw in said first bone fragment, said first bone screw defining an axial bore having uniformly pitched internal threading along the majority length thereof;

a second bone screw having external threading for anchoring said second bone screw in said second bone fragment, said second bone screw defining an axial bore extending therethrough;

an elongated connector including a head portion that is configured to accommodate a tool and an elongated shank portion with external uniformly pitched threading that corresponds to the internal threading of said first screw, and wherein the shank portion of said connector extends endwise through the axial bore defined by said second fastener and into threaded engagement with said the axial bore defined in said first fastener while the head of the connector operable engages with the second fasteners such that rotation of said connector draws said first and second fasteners and thereby the first and second bone fragments toward and into compressive relationship relative to each other; and

a retainer apparatus for preventing said connector from turning relative to said second fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

19. The multipiece interfragmentary fixation assembly according to Claim 18 wherein a first end of said first bone screw has a pointed configuration while a second end of said first bone screw is configured to accommodate a driving tool capable of turning said first bone screw such that the external threading engages with said first bone fragment.

20. The multipiece interfragmentary fixation assembly according to Claim 18 wherein the external threading on said first and second bone screws generally correspond relative to each other.

21. The multipiece interfragmentary fixation assembly according to Claim 18 wherein a trailing end of the axial bore defined by said second bone screw is configured to accommodate a driving tool capable of turning said second bone screw such that the external threading threadably engages with said second bone fragment.

22. The multipiece interfragmentary fixation assembly according to Claim 18 wherein the axial bore defined by said second bone screw has a first lengthwise portion that opens to a trailing end of said second bone screw and has a non-circular cross-sectional configuration that is sized to allow the head portion and shank portion of said connector to pass endwise therethrough and a second lengthwise portion that opens to a leading end of said second bone screw and is sized to allow only said shank portion of said connector to pass endwise therethrough.

23. The multipiece interfragmentary fixation assembly according to Claim 22 wherein said retainer apparatus comprises a element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with said second bone screw for

preventing the connector from inadvertently turning in a direction whereby loosening the compressive relationship between the fasteners beyond a preset amount.

24. The multipiece interfragmentary fixation assembly according to Claim 22 wherein the head portion of said connector defines a socket and an annular recess radially extending outwardly from the socket, and wherein said retainer apparatus comprises an element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with the annular recess in the socket defined by said connector, and wherein said element further includes a finger that axially extends from said element into said socket and operably engages with said connector for preventing said connector from turning relative to said second member.

25. The multipiece interfragmentary fixation assembly according to Claim 24 wherein said element includes a plurality of fingers that axially extend from one end of said element and into the socket and operable engagement with said connector for preventing inadvertent turning movement of said connector relative to said second bone screw.

26. The multipiece interfragmentary fixation assembly according to Claim 18 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of the internal

threading of said axial bore for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

27. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading axially extending away from a proximal end of said first screw along a lengthwise portion of said screw for anchoring said first bone screw in said first bone fragment and a reduced diameter portion extending from said external threading to a distal end of said first screw, with said reduced diameter portion of said screw having an axially tapering configuration along an outer surface thereof, said first bone screw defining an axial bore having uniformly pitched internal threading along the majority length thereof;

a second bone screw having external threading axially extending away from a distal end of said second screw and along a lengthwise portion of said second screw for anchoring said second bone screw in said second bone fragment and a reduced diameter portion extending from said external threading to a proximal end of said second screw, said second bone screw defining an axial bore extending therethrough, and wherein the axial bore defined by said second screw includes a counterbore portion extending axially away from the distal end of said screw, said counterbore having an axially tapered configuration that complements the tapered configuration on the reduced diameter portion of said first screw;

an elongated connector including a head portion that is configured to accommodate a tool and an elongated shank portion with external uniformly pitched threading that corresponds to the

internal threading of said first screw, and wherein the shank portion of said connector extends endwise through the axial bore defined by said second fastener and into threaded engagement with said the axial bore defined in said first fastener while the head of the connector operable engages with the second fasteners such that rotation of said connector draws said first and second fasteners and thereby the first and second bone fragments toward and into a predetermined compressive relationship relative to each other and with the reduced diameter portion of said first screw fitting axially into the counterbore portion defined by said second screw whereby effecting alignment of the bone fragments relative to each other.

28. The multipiece interfragmentary fixation assembly according to Claim 27 further including a retaining apparatus for preventing said connector from inadvertently rotating relative to said bone screws thereby maintaining the predetermined compressive relationship between the screws and the bone fragments attached thereto.

29. The multipiece interfragmentary fixation assembly according to Claim 27 wherein a trailing end of the axial bore defined by said second bone screw is configured to accommodate a driving tool capable of turning said second bone screw such that the external threading threadably engages with said second bone fragment.

30. The multipiece interfragmentary fixation assembly according to Claim 27 wherein the axial bore defined by said second bone screw has a first lengthwise portion that opens to a trailing end of said second bone screw and has a non-circular cross-sectional configuration that

is sized to allow the head portion and shank portion of said connector to pass endwise therethrough and a second lengthwise portion that opens to a leading end of said second bone screw and is sized to allow only said shank portion of said connector to pass endwise therethrough.

31. The multipiece interfragmentary fixation assembly according to Claim 30 wherein said retainer apparatus comprises a element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with an annular grove disposed along the length of said first portion of said axial bore defined by said second bone screw for preventing the connector from inadvertently turning in a direction whereby loosening the compressive relationship between the fasteners beyond a preset amount.

32. The multipiece interfragmentary fixation assembly according to Claim 30 wherein the head portion of said connector defines a socket and an annular recess radially extending outwardly from the socket, and wherein said retainer apparatus comprises an element having a cross-sectional configuration generally corresponding to the cross-section of the first portion of the axial bore defined by said second bone screw whereby said element is prevented from turning relative to said second bone screw, said element having a pliant annular ring that operably engages with the annular recess in the socket defined by said connector, and wherein said element further includes a finger that axially extends from said element into said socket and

operably engages with said connector for preventing said connector from turning relative to said second member.

33. The multipiece interfragmentary fixation assembly according to Claim 32 wherein said element includes a plurality of fingers that axially extend from one end of said element and into the socket and operable engagement with said connector for preventing inadvertent turning movement of said connector relative to said second bone screw.

34. The multipiece interfragmentary fixation assembly according to Claim 28 wherein said retaining apparatus comprises a non-metallic insert disposed along the length of said coaxial opening for engaging the external threading on said connector and thereby preventing inadvertent rotation of said connector.

35. A multipiece interfragmentary fixation assembly for connecting fragments of bone across a fracture therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener with external threading for anchoring said first fastener into a first bone fragment;

a second fastener configured for non-movable attachment to a second bone fragment; and

a rotatable and elongated connector for drawing the first and second fasteners and thereby the bone fragments attached to each into compressive and proper relationship relative to each other, with the connector and said first fastener being threadably interconnected to each other along at least a portion of their length, and wherein at least a portion of the threadable

connection being configured to prevent the connector from inadvertently rotating relative to said first fastener thereby maintaining the proper compressive relationship between the fasteners and the bone fragments.

36. The multipiece interfragmentary fixation assembly according to Claim 35 wherein a leading end of said first fastener has a pointed configuration while a trailing end of said first fastener is configured to accommodate a driving tool capable of turning said first fastener such that the external threading threadably engages with said first bone fragment.

37. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener has an elongated configuration with external threading for anchoring said second fastener in said second bone fragment.

38. The multipiece interfragmentary fixation assembly according to Claim 37 wherein said second fastener has a coaxial opening extending between leading and trailing ends thereof.

39. The multipiece interfragmentary fixation assembly according to Claim 38 wherein the trailing end of said second fastener is configured to accommodate a driving tool capable of turning said second fastener such that the external threading threadably engages with said second bone fragment.

40. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises a member formed from a bone compatible material and configured with a generally concave shaped section that is generally centralized between multiple prongs extending radially away from said central section, and an apertured hemi-spherically shaped element that is seated for rocking movement within said central section of said member, and wherein a shank portion of said elongated connector extends endwise through the said member and said element into threaded engagement with said first fastener, with a head portion of said connector being operably engagable with said element such that rotation of said connector draws the member and said first fastener and the respective bone fragments engaged by each toward and into compressive relationship relative to each other.

41. The multipiece interfragmentary fixation assembly according to Claim 40 wherein the concave centralized section of said member defines an enlarged opening that permits said member to rock relative to said connector and said element thereby enhancing attachment of said prongs to said second bone fragment.

42. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises an apertured disk that fits about a shank portion of said connector and operably engages an underside of a head portion of said connector to permit relative rotation therebetween, the apertures in said disk permitting said second bone fragment to be attached thereto.

43. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises an elongated member having first and second ends and an axial bore for allowing a shank portion of said connector to extend endwise therethrough and into threaded engagement with said first fastener, the elongated member of said second fastener further including a bone fragment retainer extending radially away from said elongated member.

44. The multipiece interfragmentary fixation assembly according to Claim 35 wherein the elongated member of said second fastener has a generally cylindrical configuration between opposite ends thereof.

45. The multipiece interfragmentary fixation assembly according to Claim 35 wherein said second fastener comprises a plate having upper and lower generally parallel surfaces with an indentation having a closed margin defined by said plate and including a wall depending at an acute angle relative to the upper surface of said plate, said wall defining an aperture through which a shank portion of said connector extends into threaded engagement with the internal threading of said first fastener while the wall of said indentation maintains a head portion of said connector on an opposite side of said plate from said first fastener.

46. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments to each other across a fracture defined therebetween, said interfragmentary fixation assembly comprising:

a first axially elongated fastener formed from a bone compatible material and having external threading for anchoring said first fastener within an interior of the first bone fragment;

a second fastener formed from a bone compatible material and attachable to an exterior of the second bone fragment, said second fastener comprising a member configured with a generally concave shaped and apertured section that is generally centralized between prongs extending radially outward and away from the central section of said member, said second fastener further including an apertured hemi-spherically shaped element configured to rockingly seat within the central section of said member;

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated and externally threaded shank portion extending endwise through the apertured element and the apertured center section of the member of said second fastener and into threaded engagement with internal threading of said first fastener while the enlarged head portion of said connector operably engages with the element of said second fastener such that rotation of said connector draws the first and second fasteners and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein the apertured center section of the member of said second fastener is configured to allow said member to rock relative to said element with the connector passing therethrough to enhance the ability of the prongs of said member to positively engage the exterior of said second bone fragment to the fullest extend possible, and wherein at least a lengthwise portion of the internal threading of said fastener is configured such that when the preselected compressive relationship is established between the fasteners the external threading on the connector is wedged against the internal threading of the first fastener to prevent inadvertent rotation of the

connector thereby maintaining the preselected compressive relationship between the fasteners and the bone fragments connected thereto.

47. A multipiece interfragmentary fixation assembly for interconnecting first and second bone fragments, comprising:

a first bone screw having external threading axially extending away from a proximal end of and along a lengthwise portion of said first bone screw for anchoring said first bone screw to said first bone fragment;

a second bone screw having external threading along a lengthwise portion thereof for anchoring said second bone screw in said second bone fragment, said second bone screw defining an axial bore extending therethrough; and

an elongated screw connector including an enlarged head portion that accommodates a driving tool and an elongated and externally threaded shank portion extending endwise through the axial bore of said second bone screw and into threaded engagement with internal threading of said first bone screw while the enlarged head portion of said connector operably engages with the second bone screw such that rotation of said connector draws the first and second bone screws and thereby the first and second bone fragments toward and into preselected compressive relationship relative to each other, and wherein at least a lengthwise portion of the internal threading of said first bone screw is configured such that when the preselected compressive relationship is established between the bone screws the external threading on the connector is wedged against the internal threading of the first bone screw to prevent inadvertent rotation of

the connector thereby maintaining the preselected compressive relationship between the bone screws and the bone fragments connected thereto.

48. The interfragmentary fixation assembly according to Claim 47 wherein the internal threading defined by said first bone screw further includes a wedge ramp at a root of each thread defined by said first bone screw.

49. The interfragmentary fixation assembly according to Claim 1 wherein said retaining apparatus comprises a unidirectional thread form extending axially along the internal threading defined by said first elongated fastener such that crest areas of the external threading on said connector coact therewith in a manner preventing the connector form inadvertently rotating relative to said second fastener.

50. An interfragmentary fixation kit, comprising:

a collection of first axially elongated fasteners, each fastener in said collection having an elongated length that is different from the elongated length of another fastener in said collection, and with each fastener in said collection having external threading for anchoring said first fastener into a first bone fragment, and wherein each fastener in said collection of fasteners having a coaxial bore extending therethrough with internal uniformally pitched threading extending the length of said bore;

a series of second fasteners, with each fastener in said series of fasteners being adapted for attachment in non-movable relation relative to a second bone fragment and having a different configuration than the other fasteners in said series of second fasteners;

a set of elongated connectors, each connector in said set of connectors having a head portion that accommodates a driving tool and an elongated lengthwise shank portion having external uniformly pitched threading corresponding to the internal threading of each fastener in said collection of first fasteners, and wherein the length of the shank portion of each connector in said set of connectors varies from one another, and wherein the shank portion of each connector in said set of connectors is configured to extend endwise through each fastener in said series of second fasteners and into threaded engagement with the internal threading of a fastener chosen from said collection of first fasteners while the head portion of said connector is adapted to operably engage with a second fastener chosen from said series of second fasteners such that rotation of the connector draws the first and second fasteners chosen from said collection of first fasteners and the series of second fasteners into a predetermined compressive relationship relative to each other and thereby drawing the bone fragments attached to the respective fasteners into a predetermined compressive relationship relative to each other.

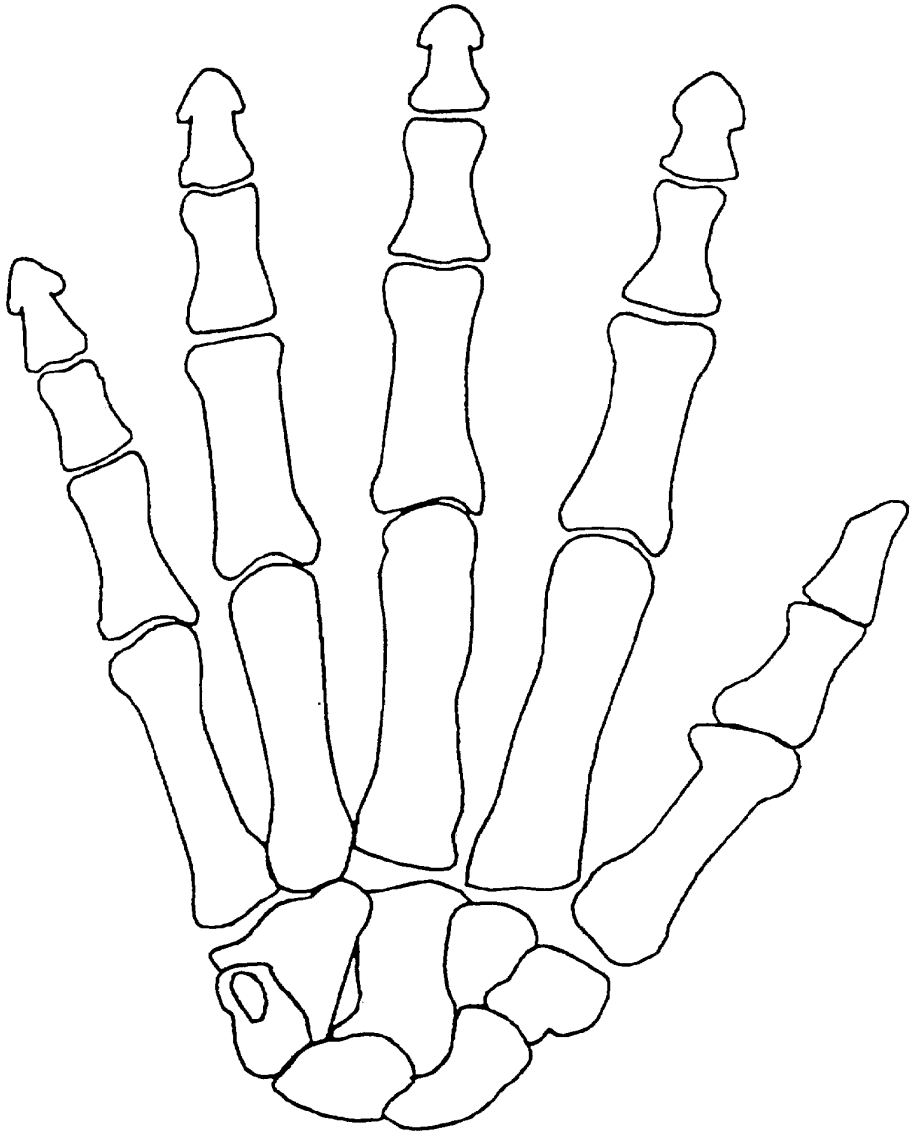
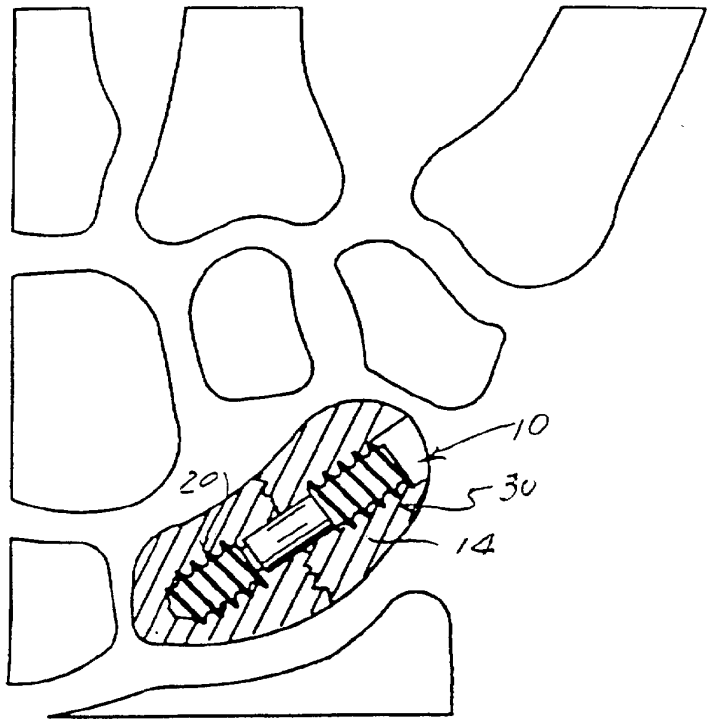


FIG. 1




2 FIG. 2

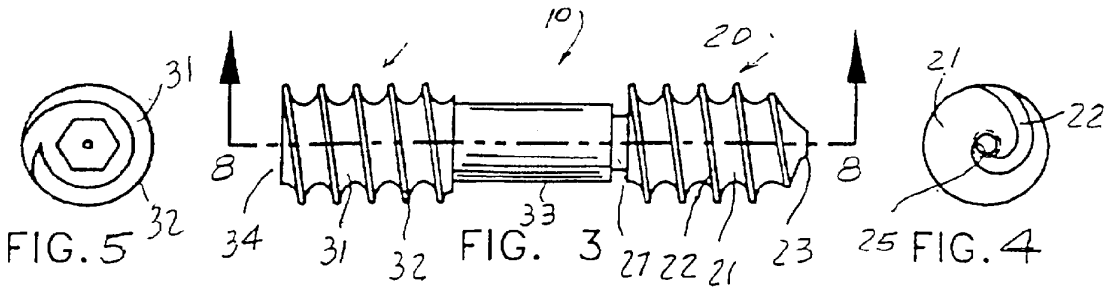



FIG. 5 FIG. 3 FIG. 4

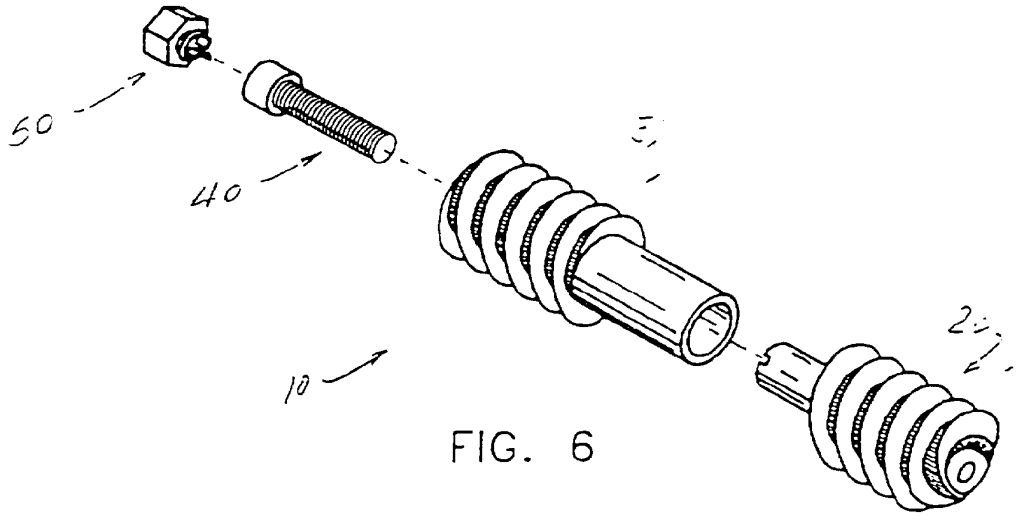



FIG. 6

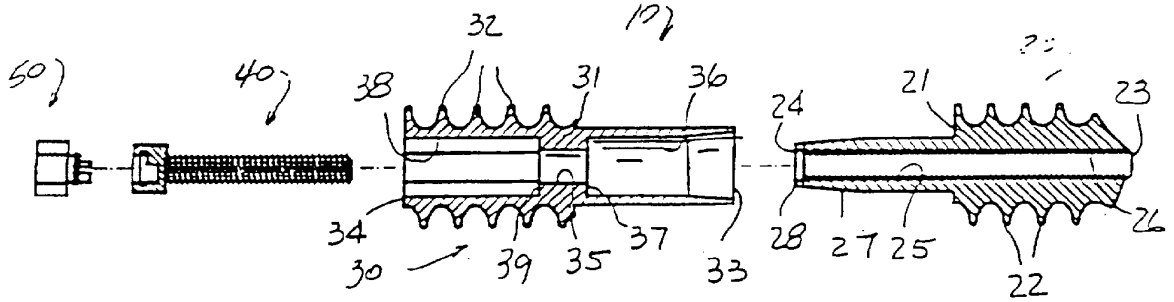



FIG. 7

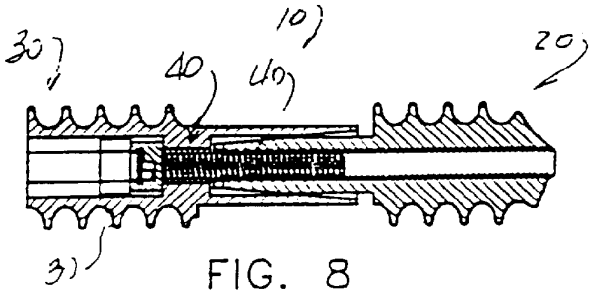



FIG. 8

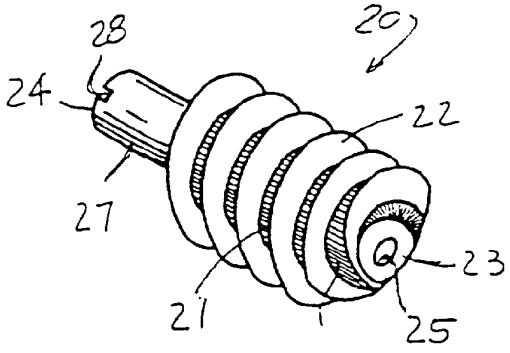



FIG. 9

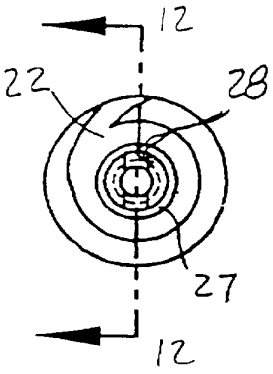



FIG. 10

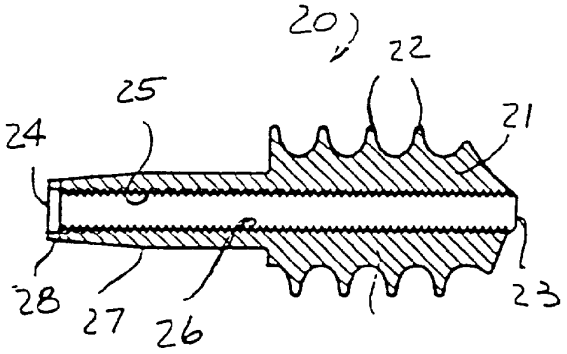



FIG. 12

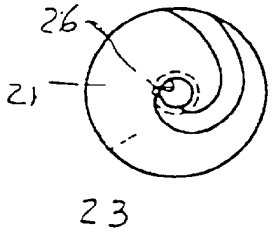



FIG. 11

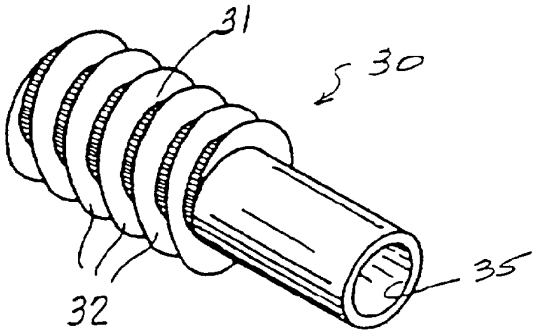



FIG. 13

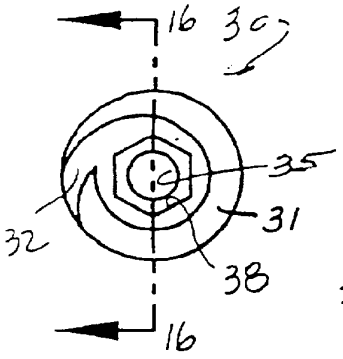



FIG. 14

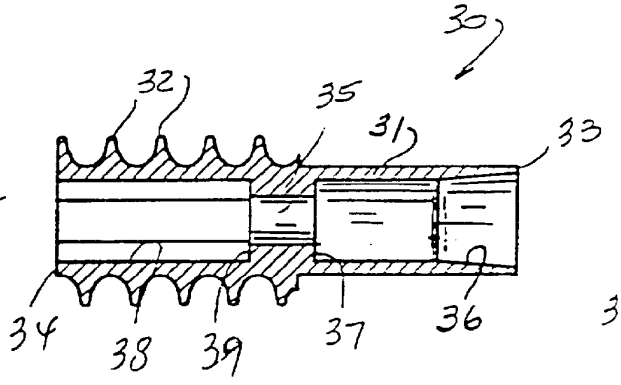



FIG. 16

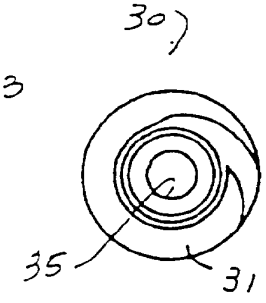



FIG. 15

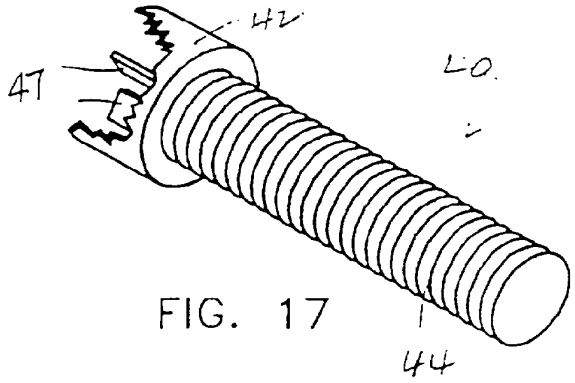



FIG. 17

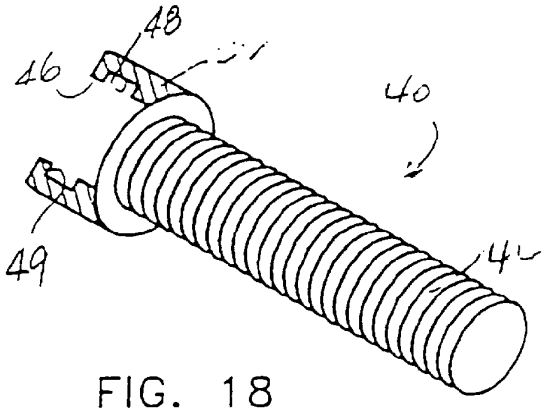



FIG. 18

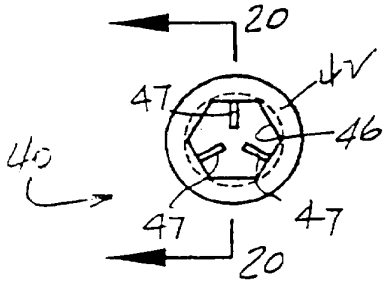



FIG. 19

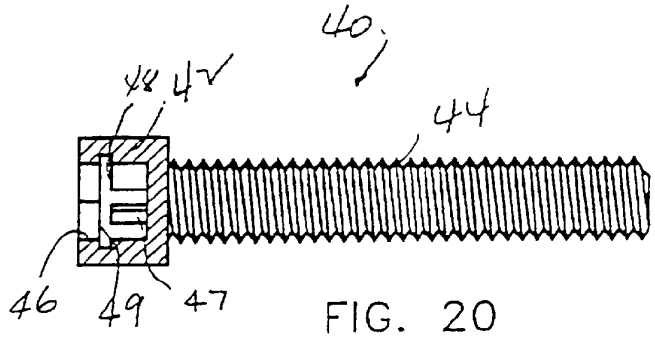



FIG. 20

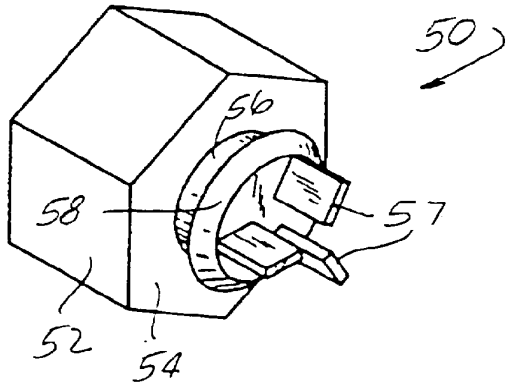



FIG. 21

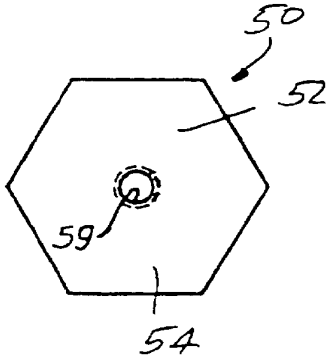



FIG. 23

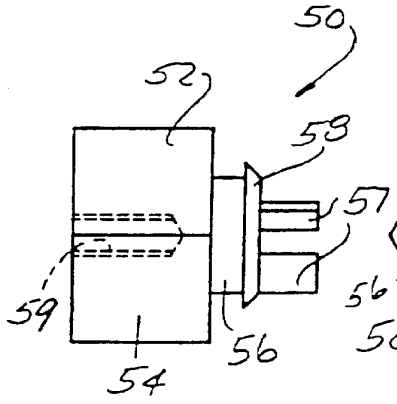



FIG. 22

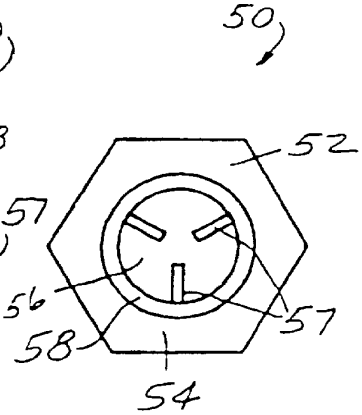



FIG. 24

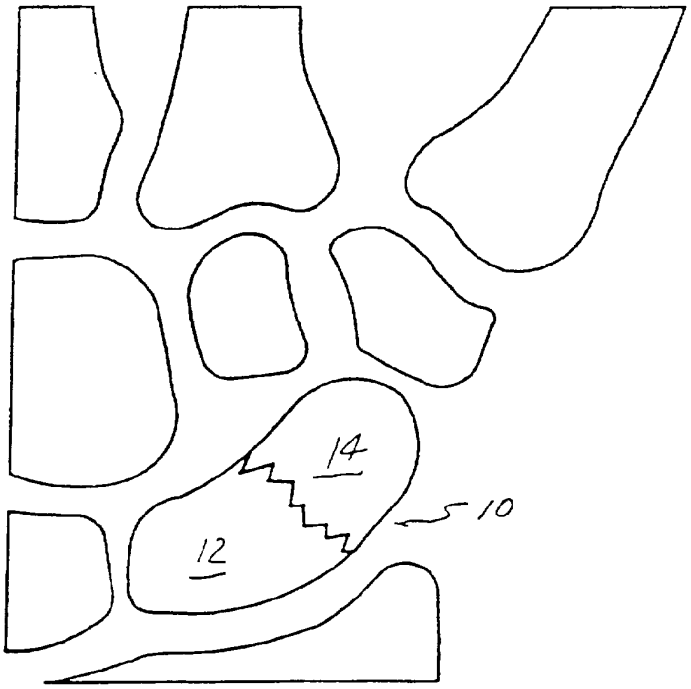



FIG. 25

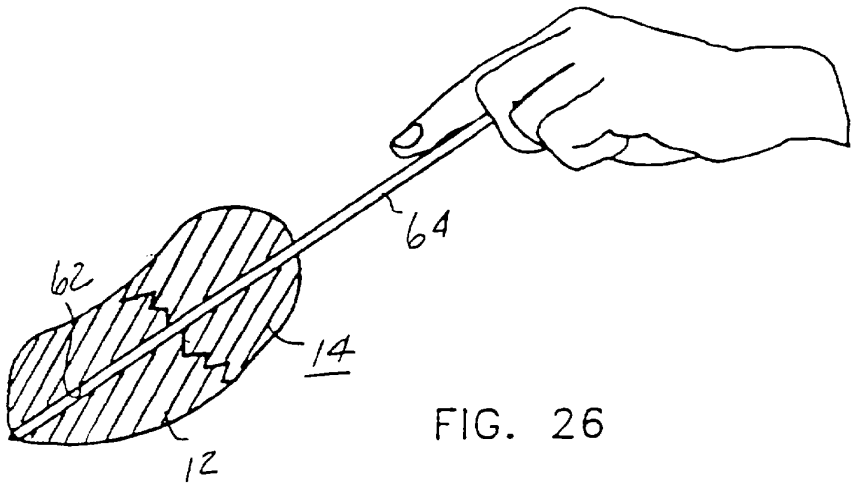



FIG. 26

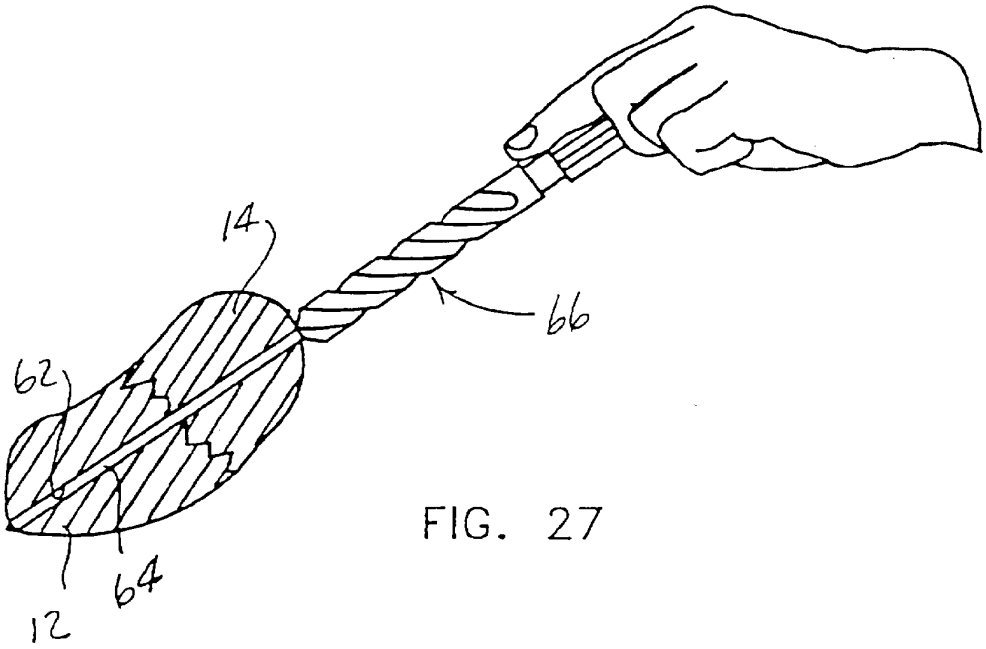



FIG. 27

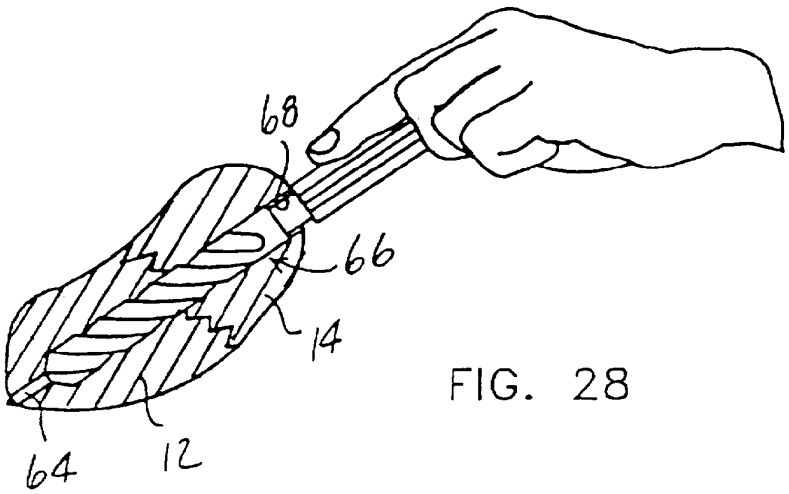



FIG. 28

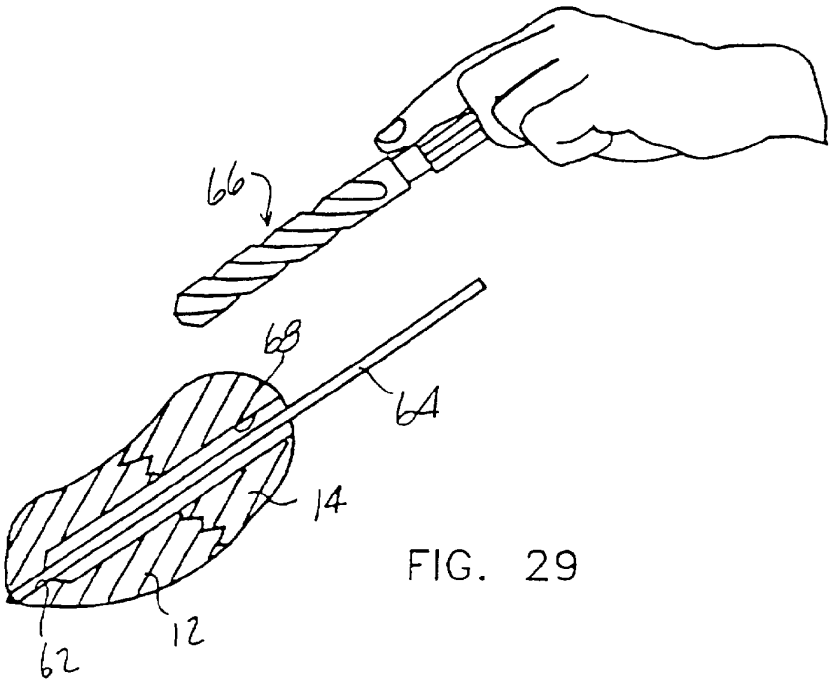



FIG. 29

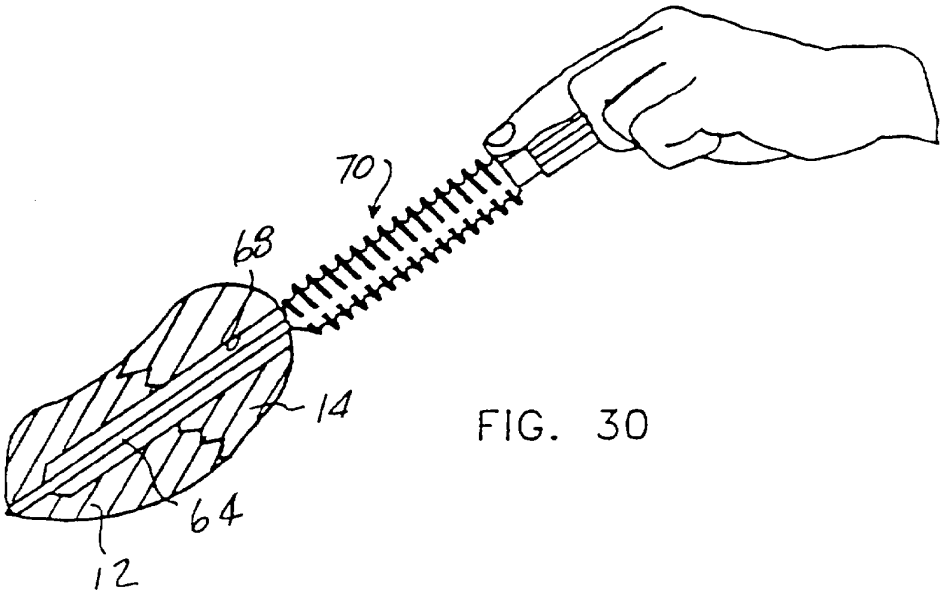



FIG. 30

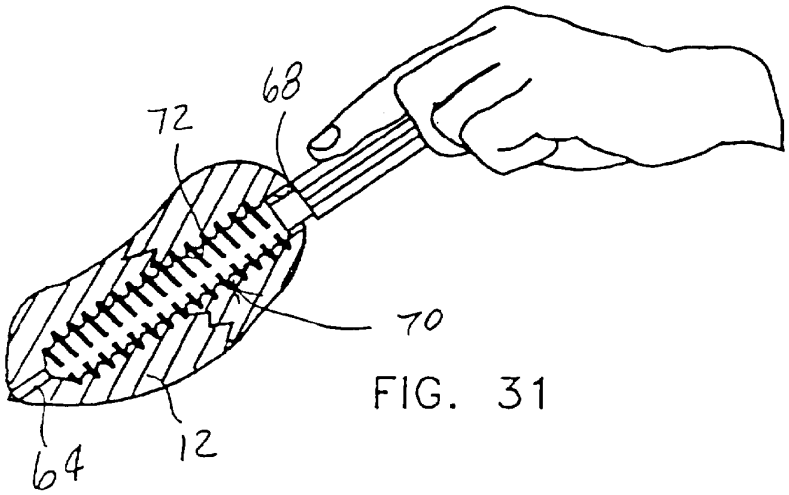



FIG. 31

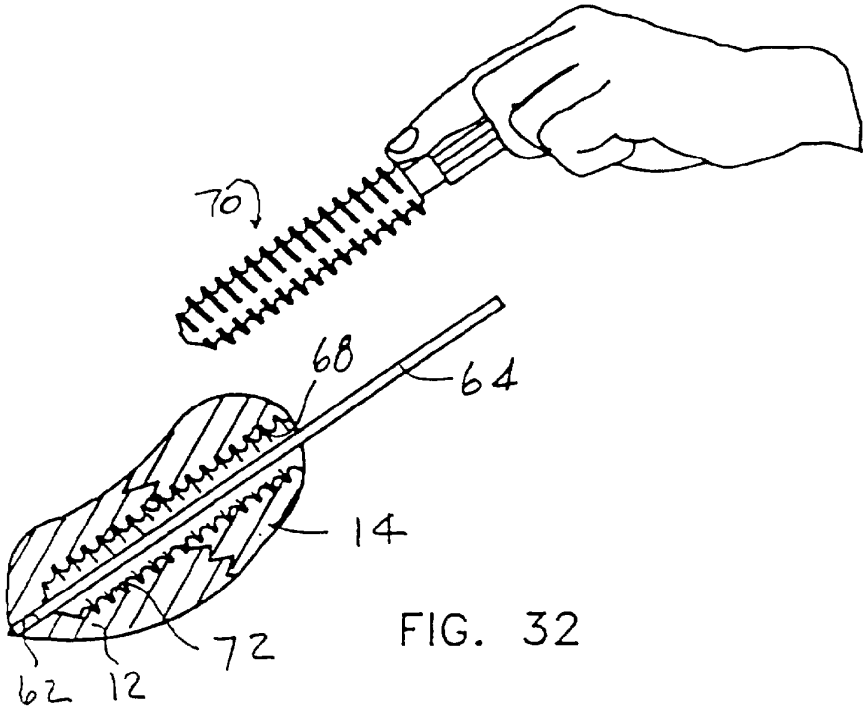



FIG. 32

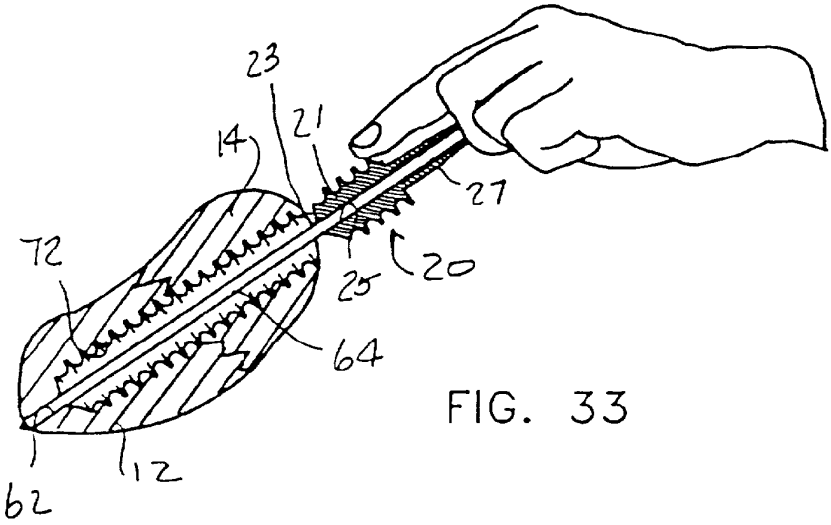



FIG. 33

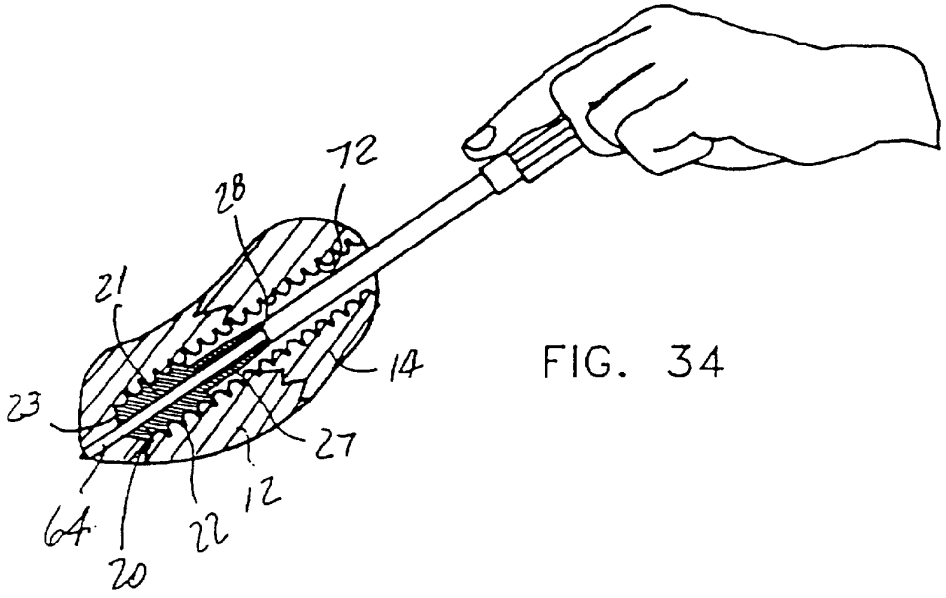



FIG. 34

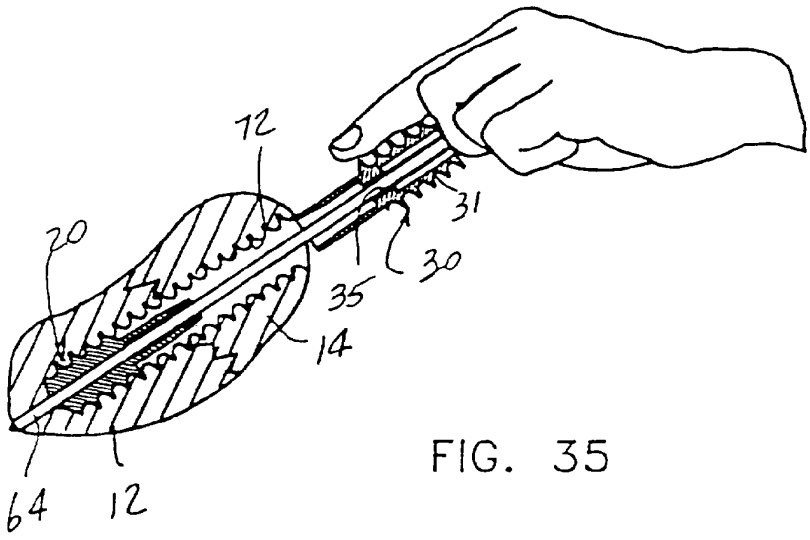



FIG. 35

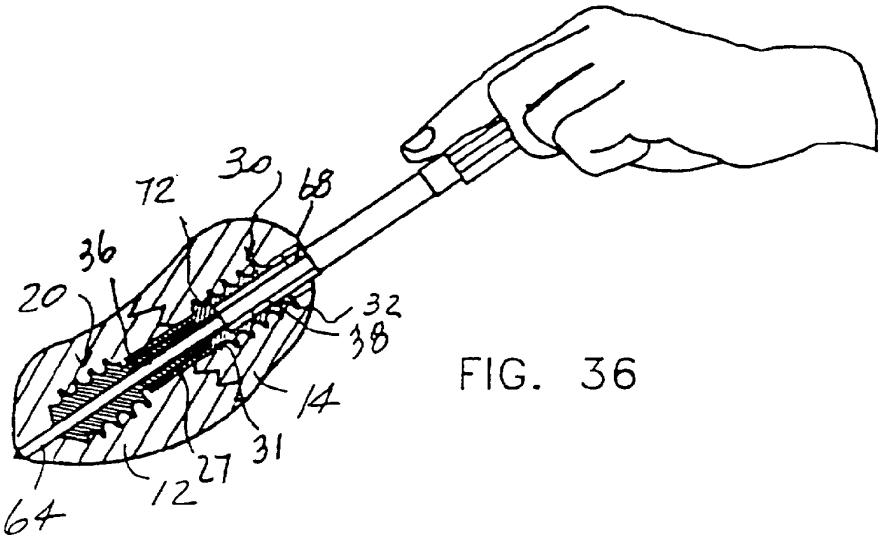



FIG. 36

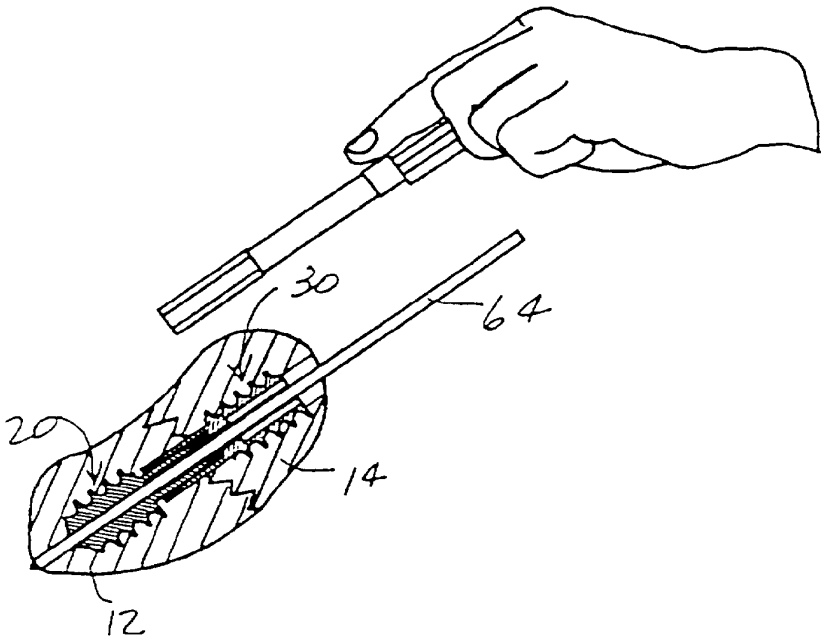



FIG. 37

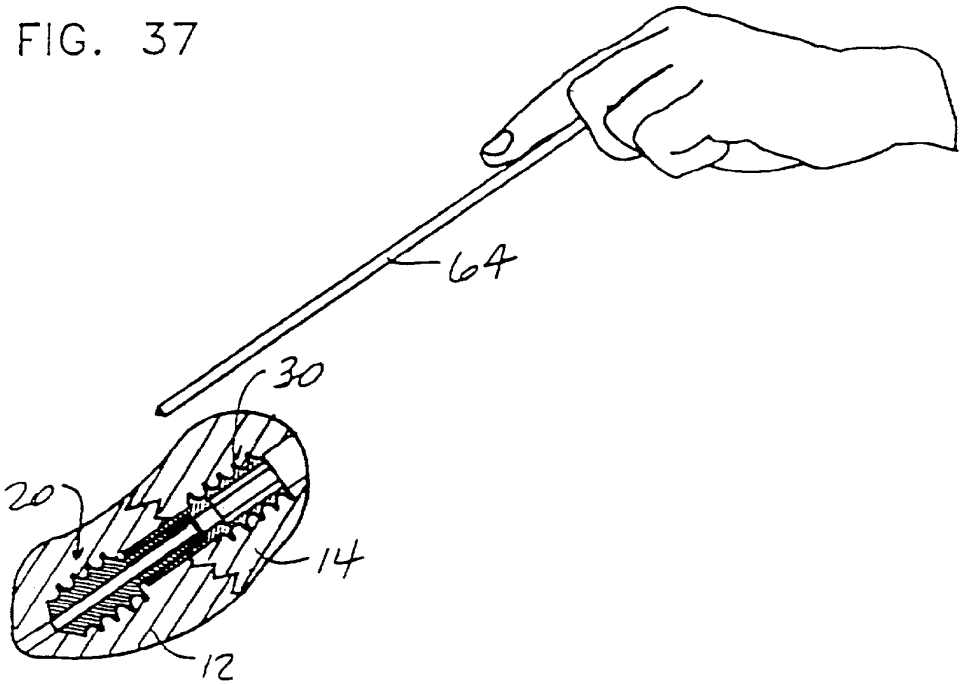



FIG. 38

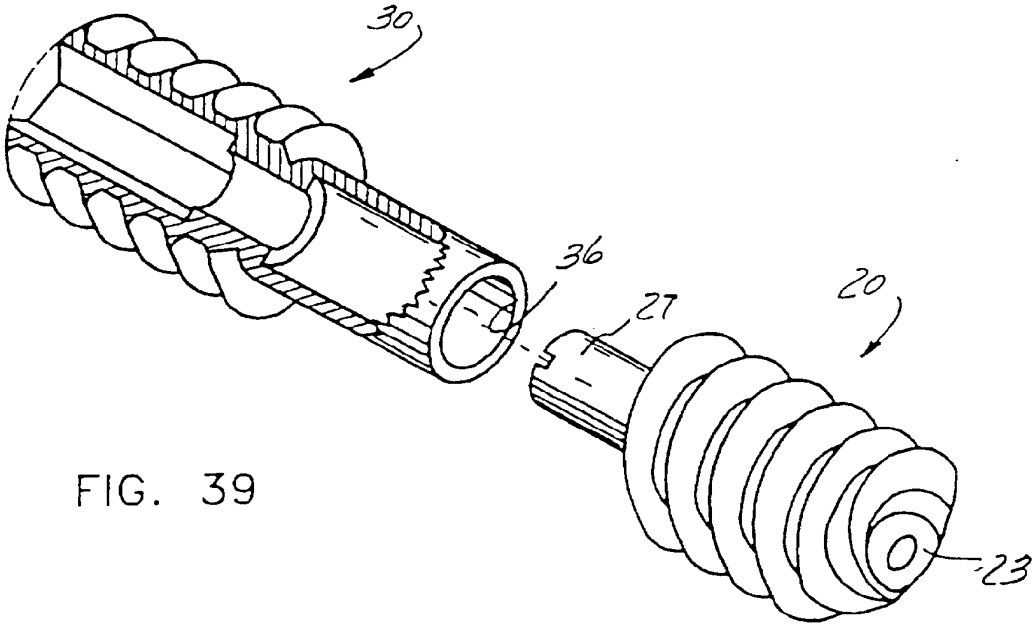



FIG. 39

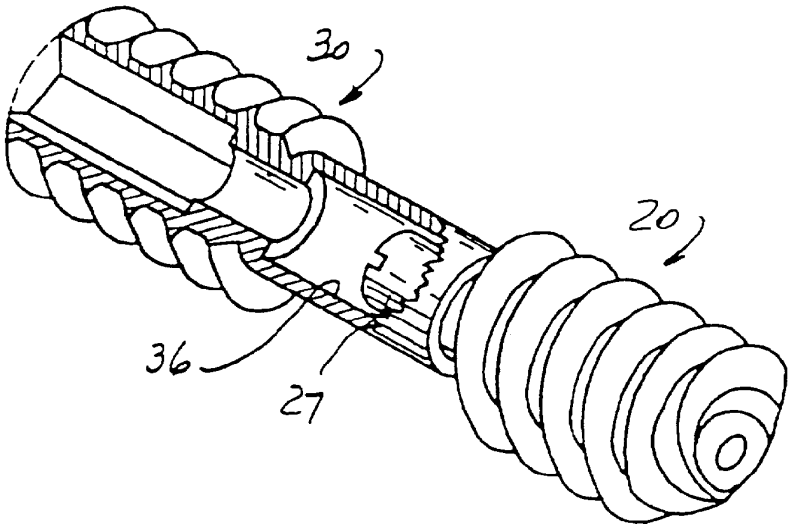



FIG. 40

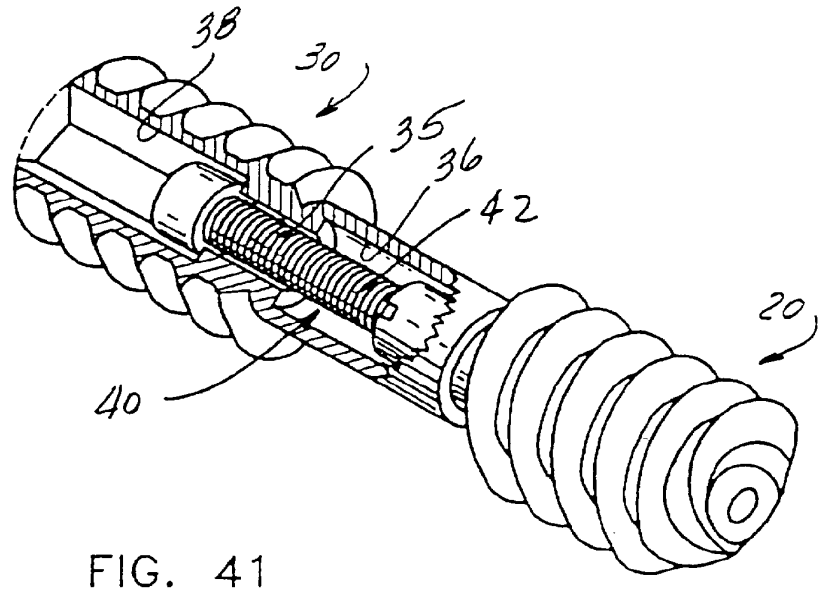



FIG. 41

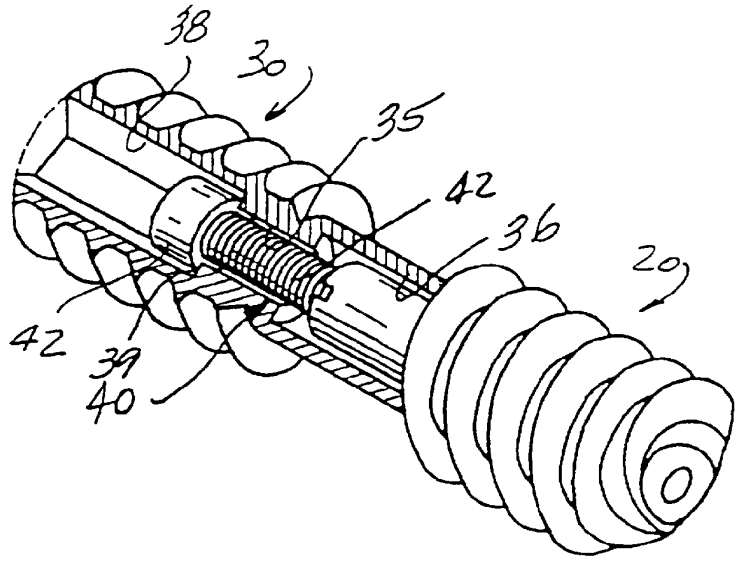



FIG. 42

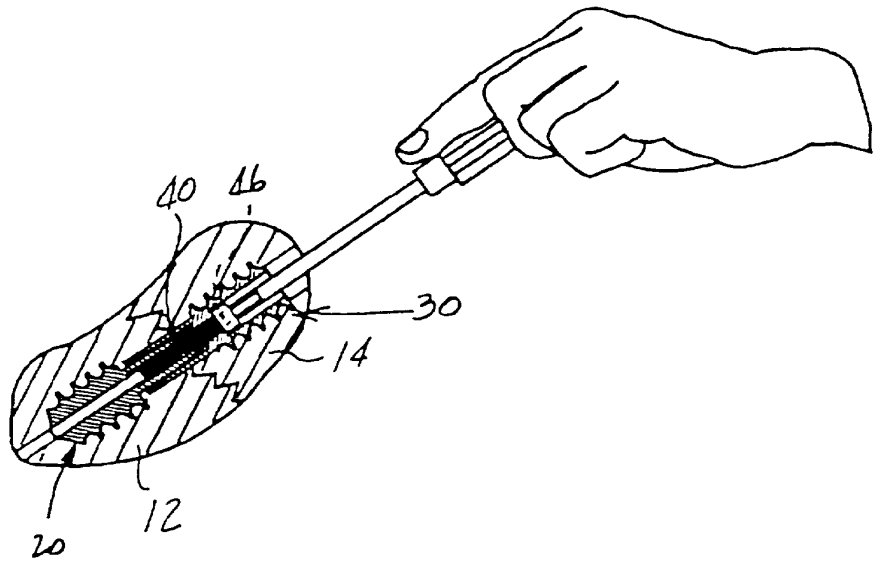



FIG. 43

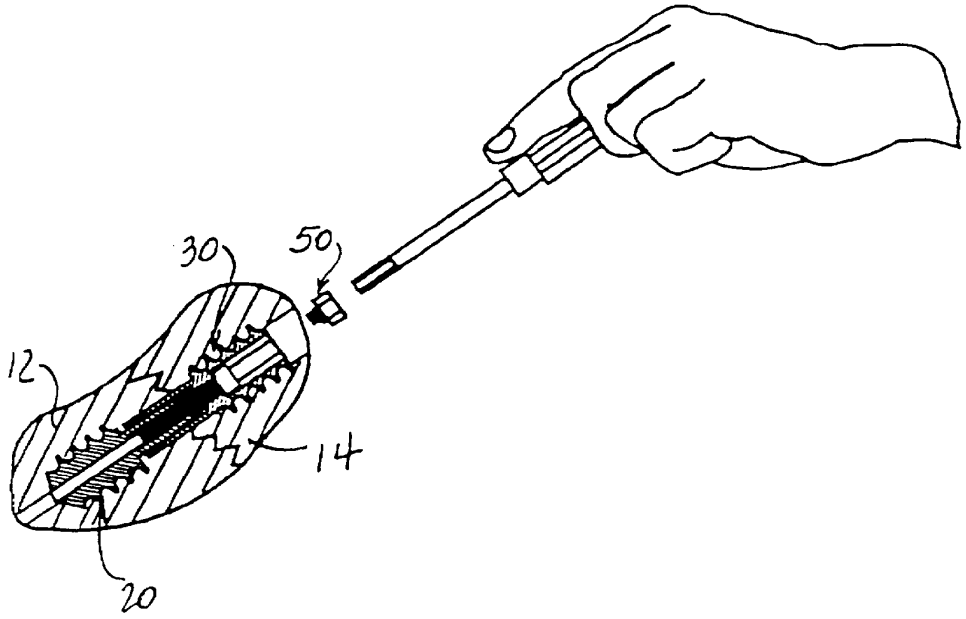



FIG. 44

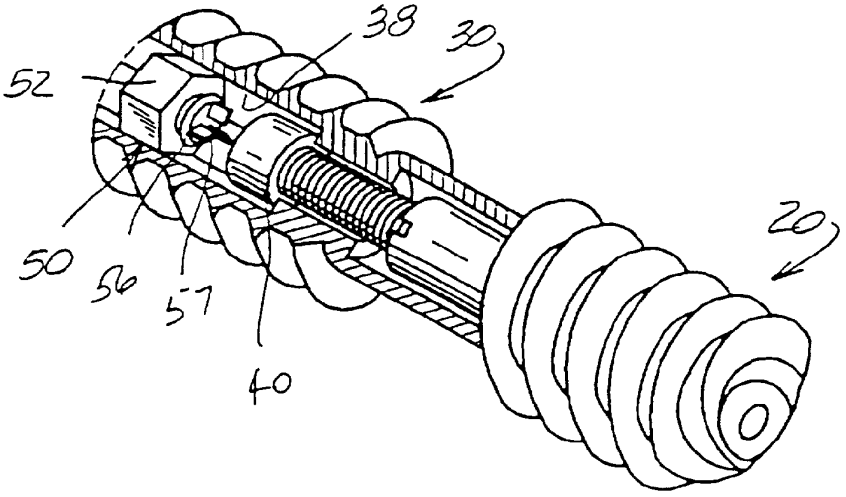



FIG. 45

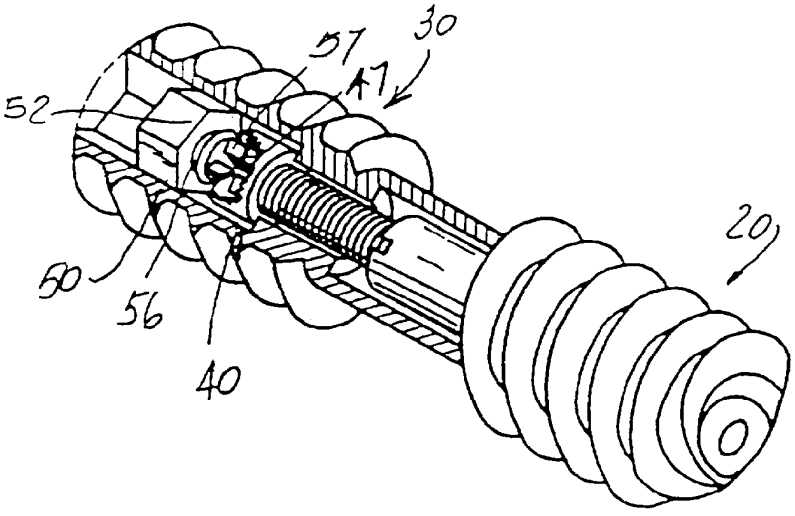



FIG. 46

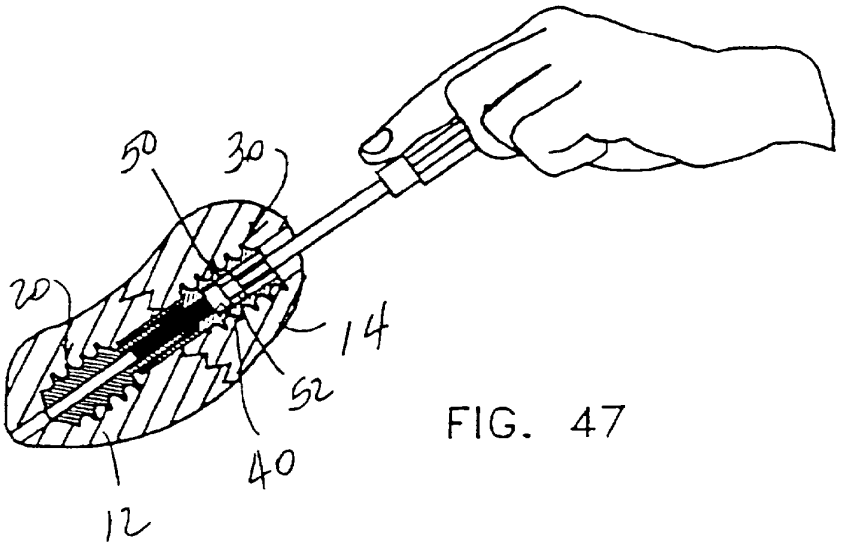



FIG. 47

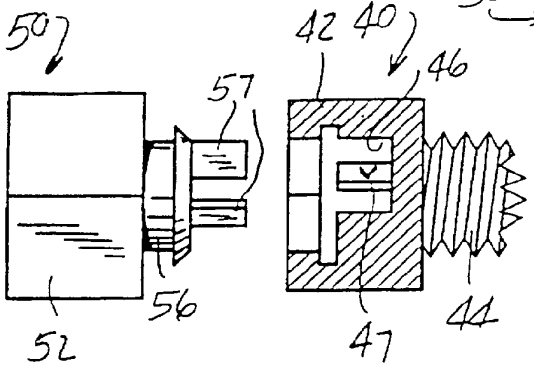



FIG. 49

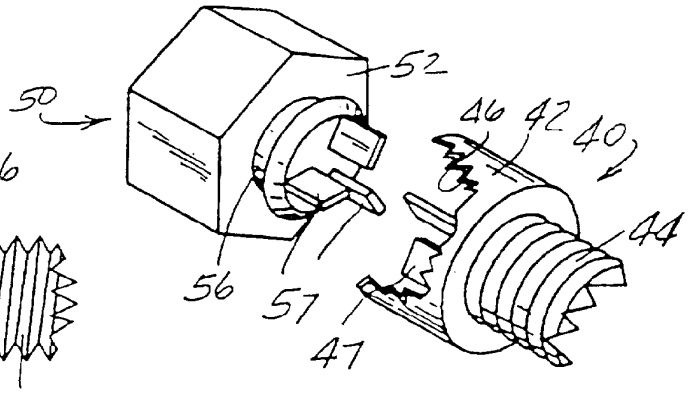



FIG. 48

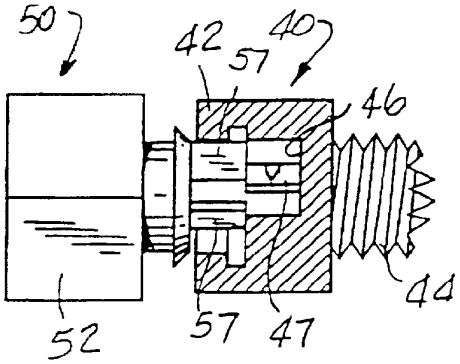



FIG. 51

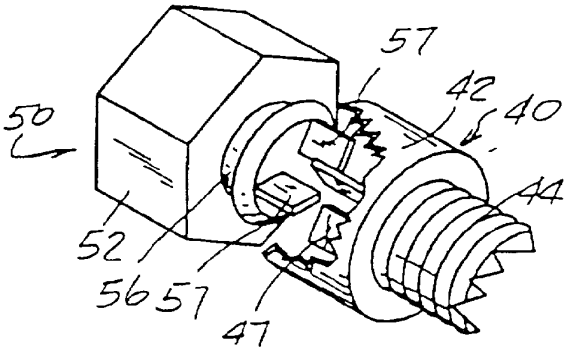



FIG. 50

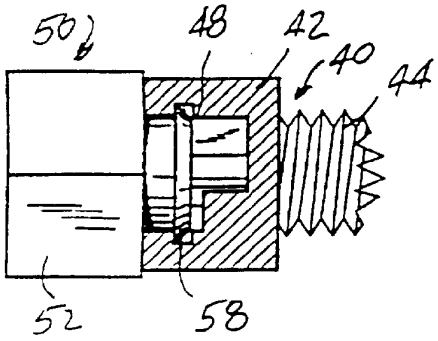



FIG. 53

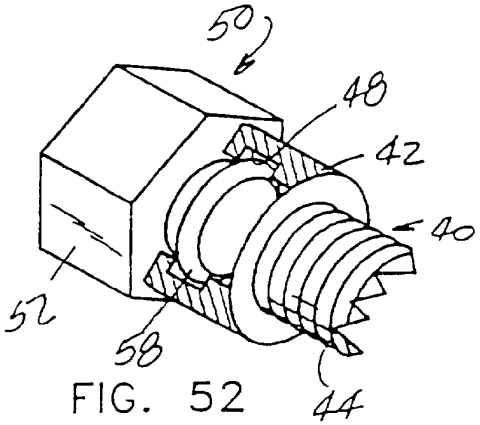



FIG. 52

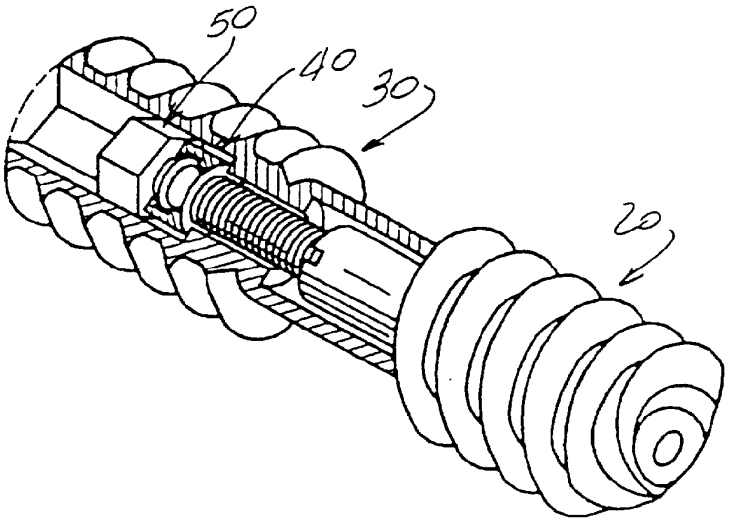



FIG. 54

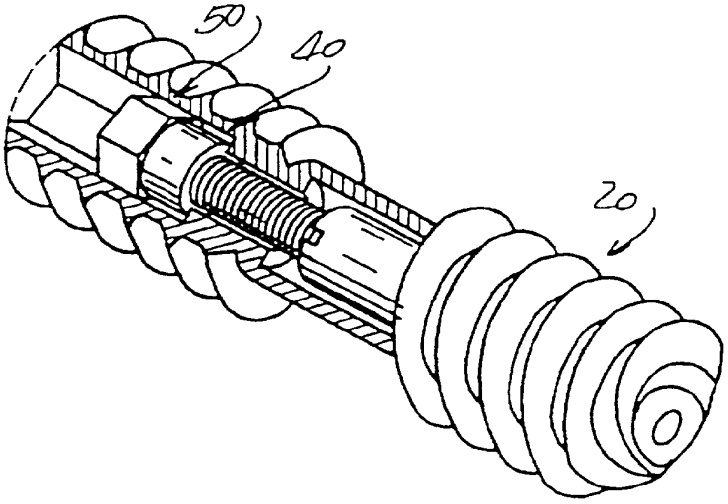



FIG. 55

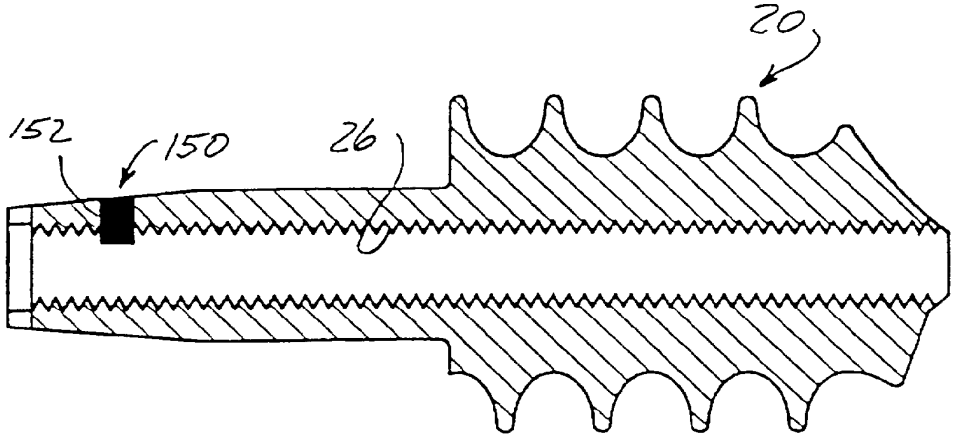



FIG. 56

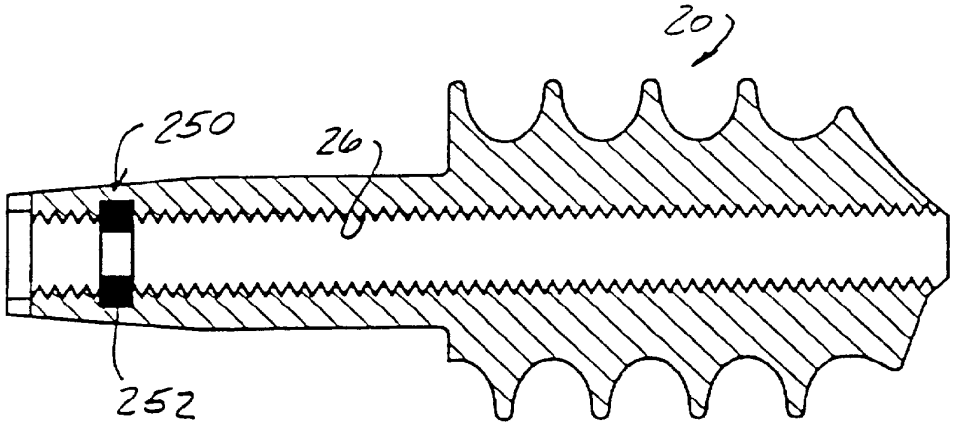



FIG. 60

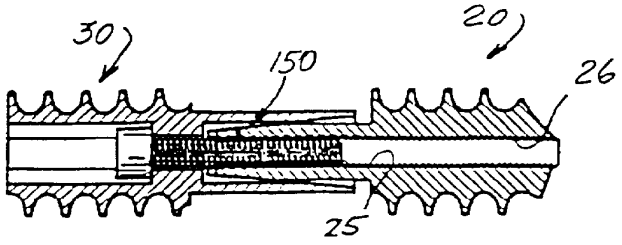



FIG. 59

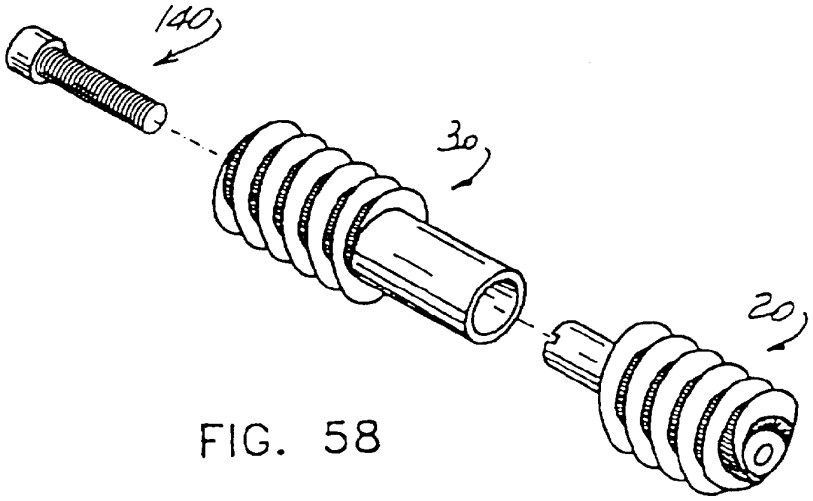



FIG. 58

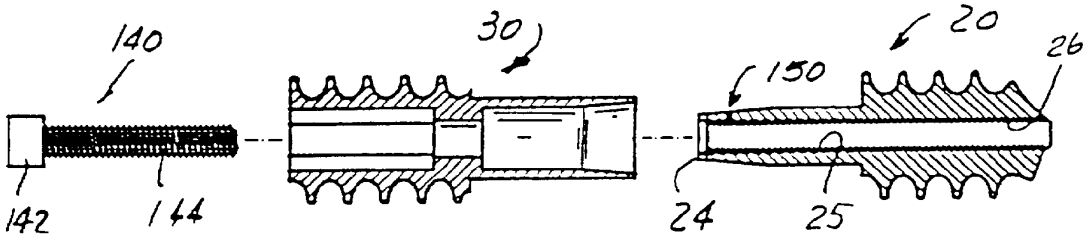



FIG. 57

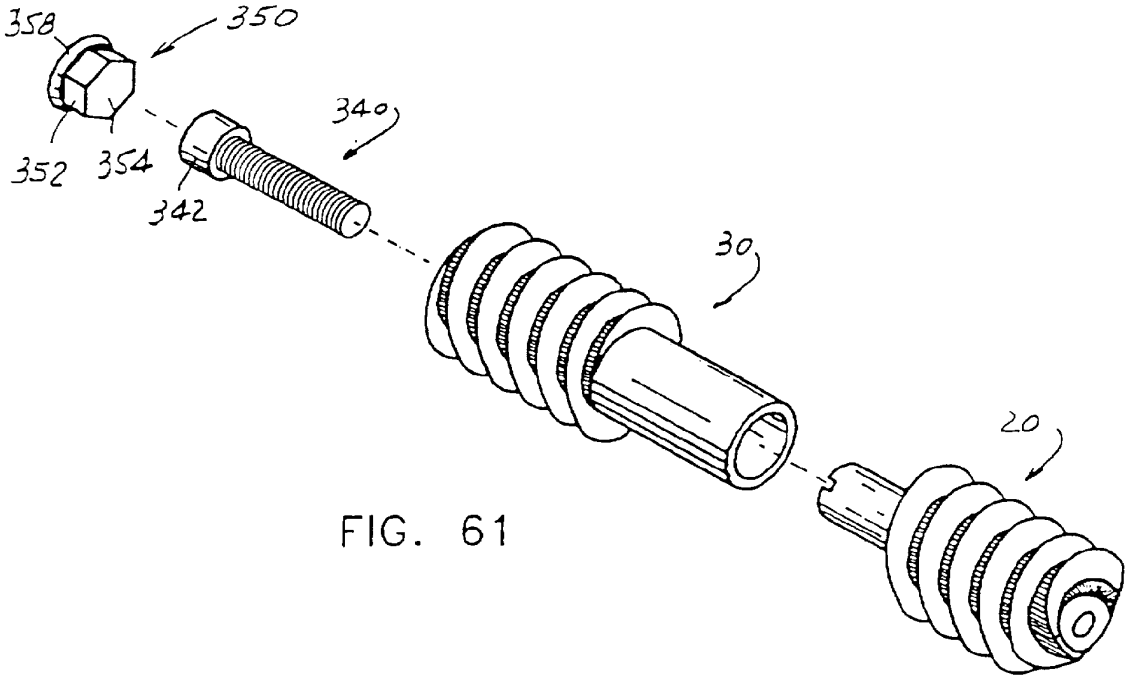



FIG. 61

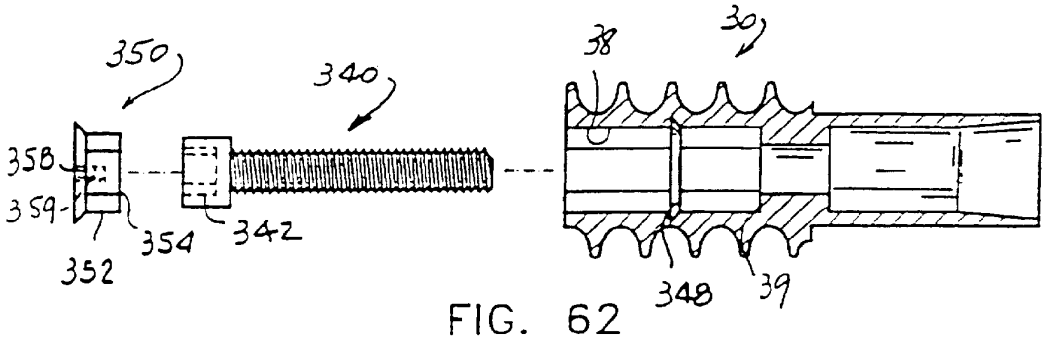



FIG. 62

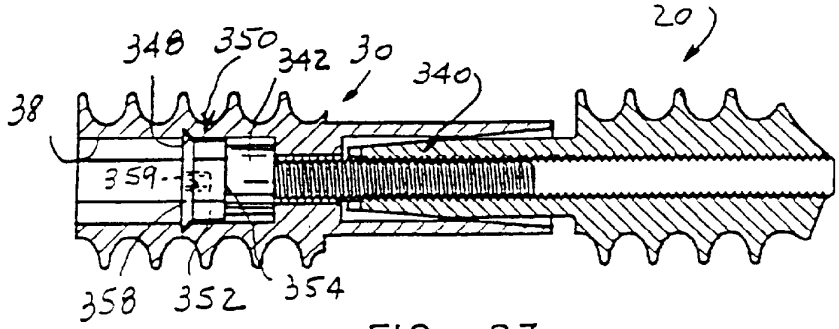



FIG. 63

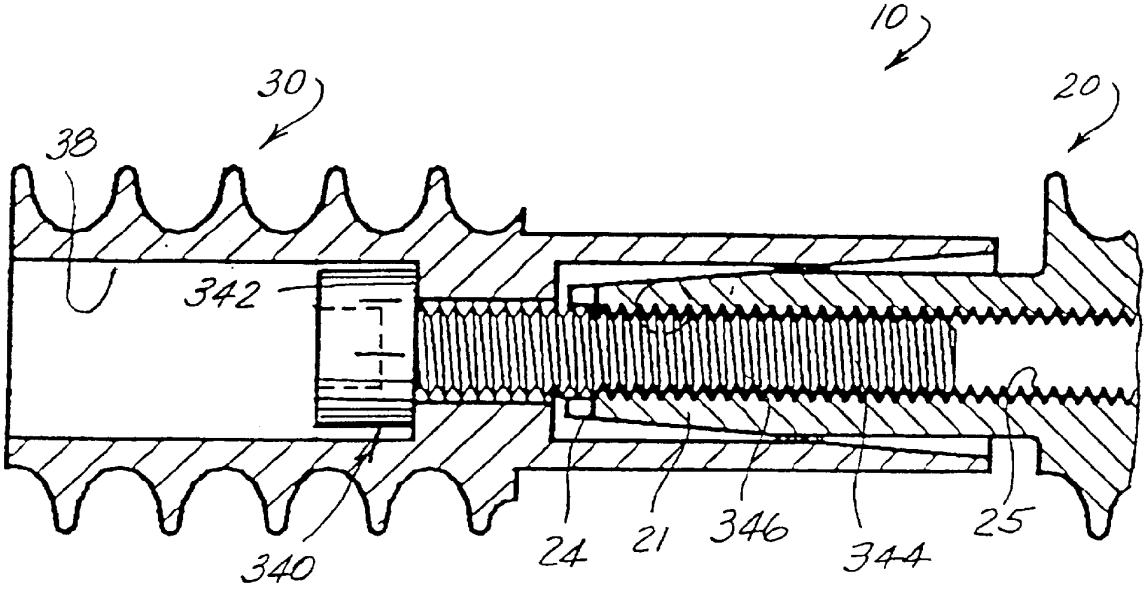



FIG. 63A

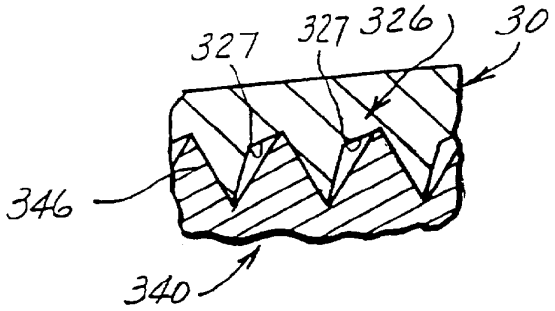



FIG. 63B

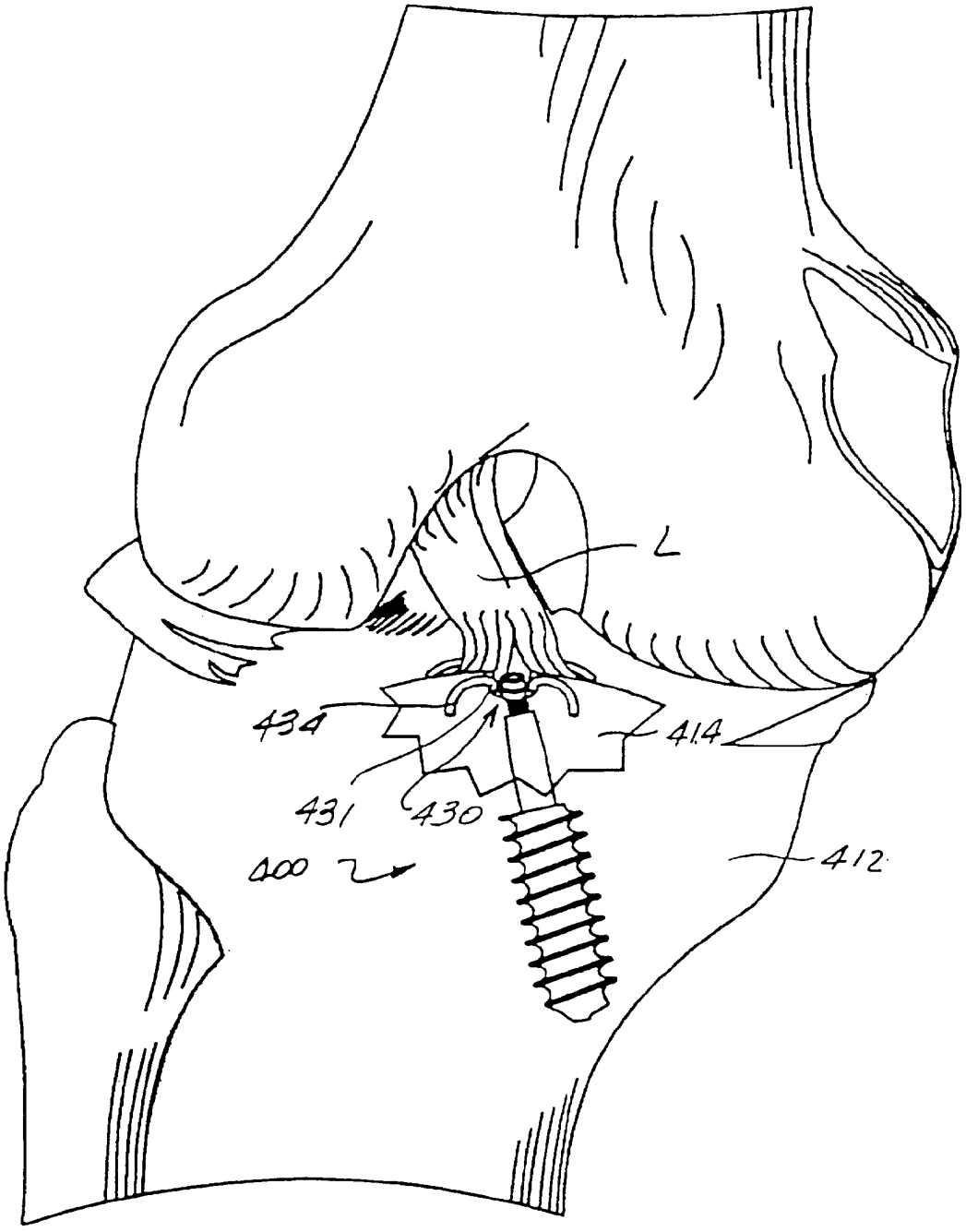



FIG. 64

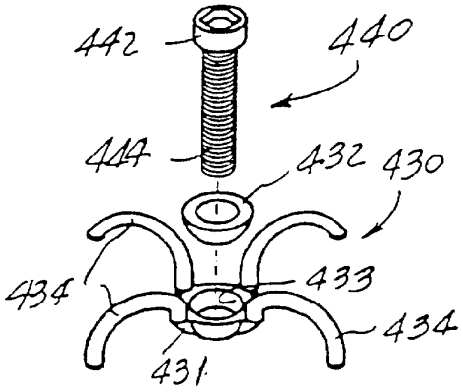



FIG. 65

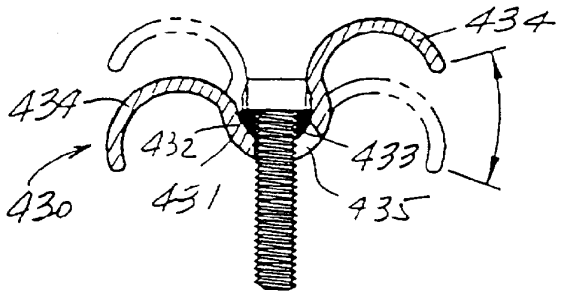



FIG. 67

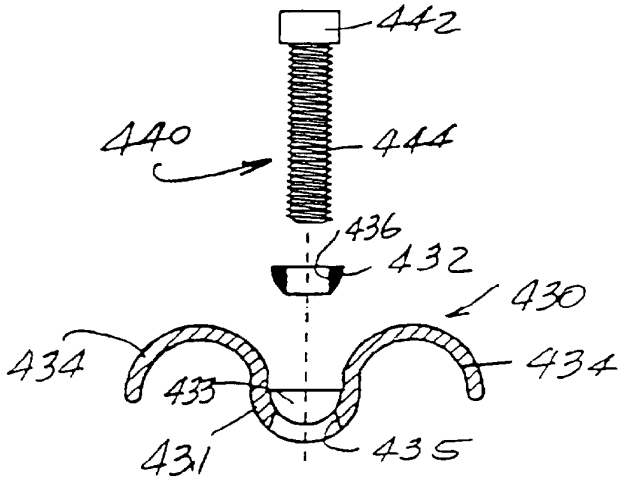



FIG. 66

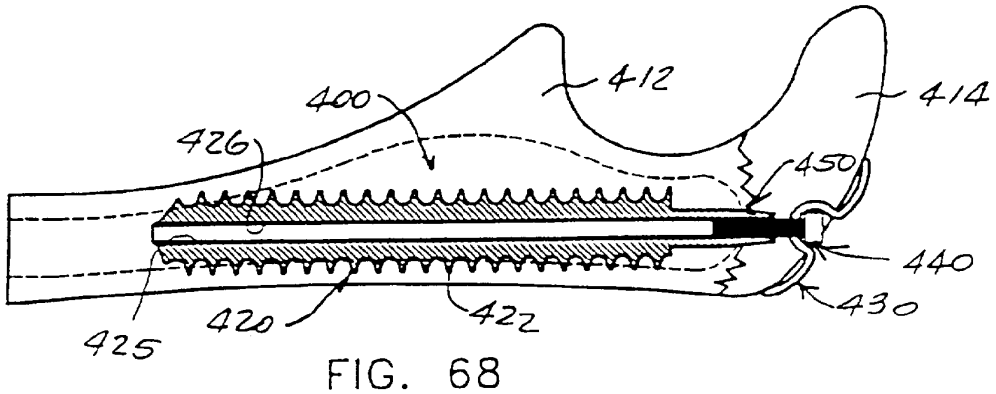



FIG. 68

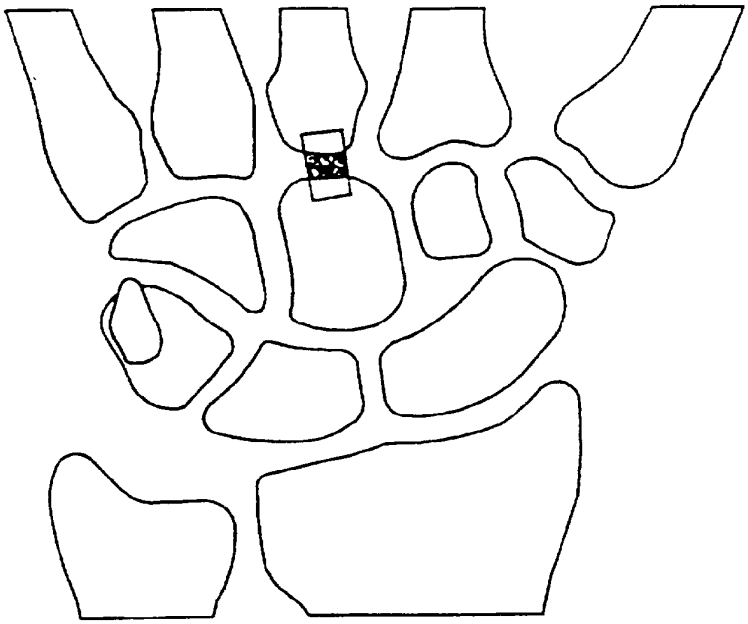


FIG. 69

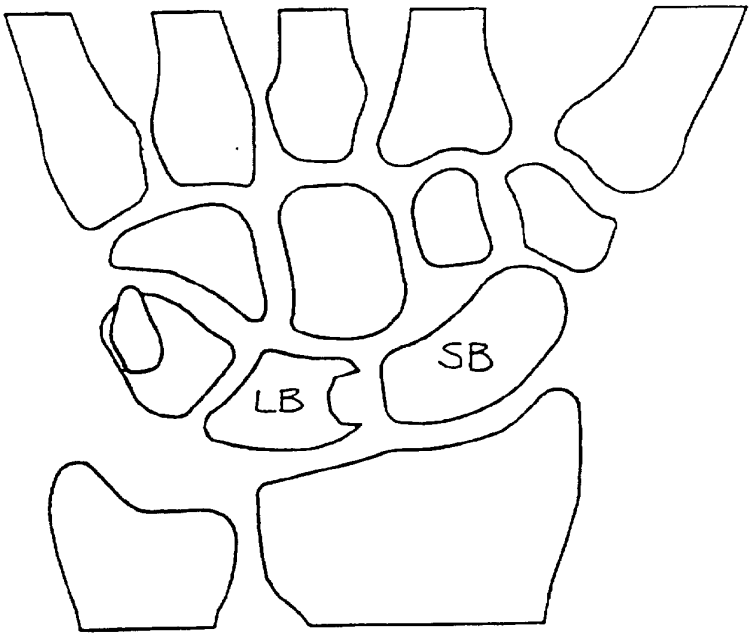



FIG. 70

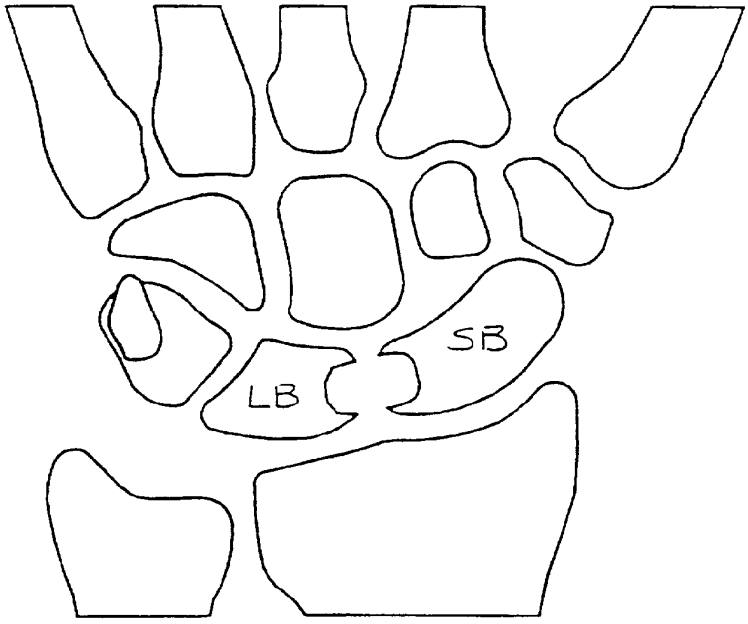



FIG. 71

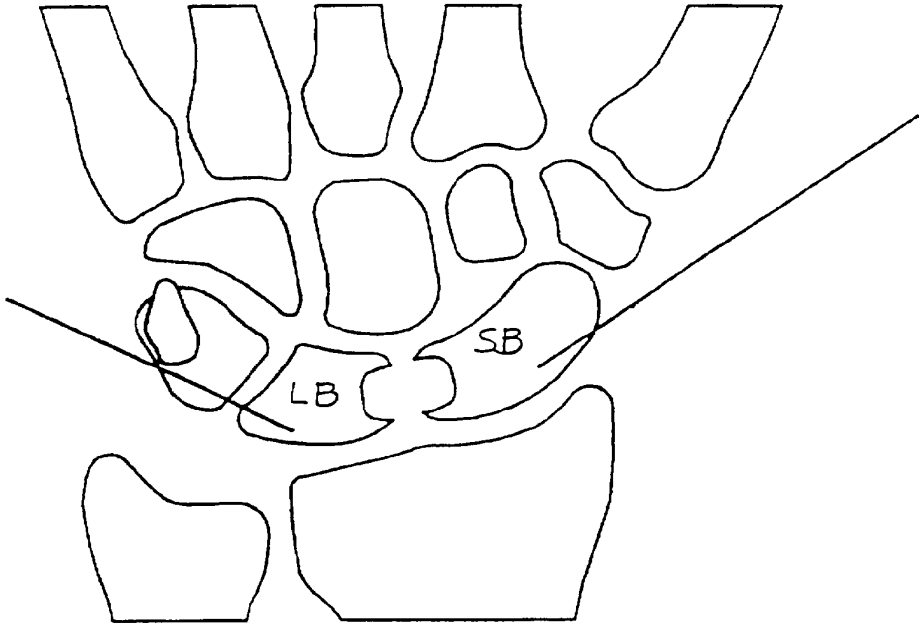



FIG. 72

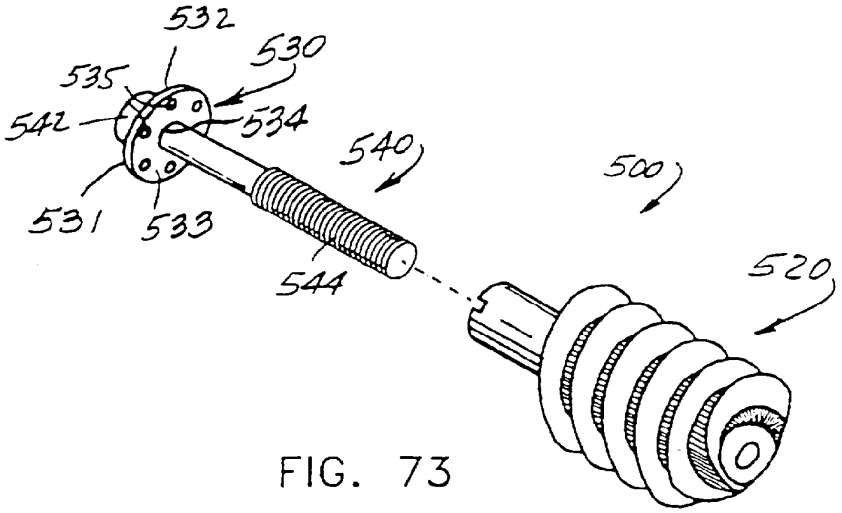



FIG. 73

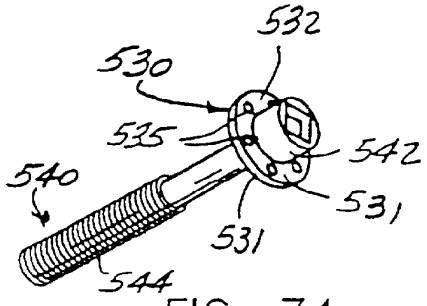



FIG. 74

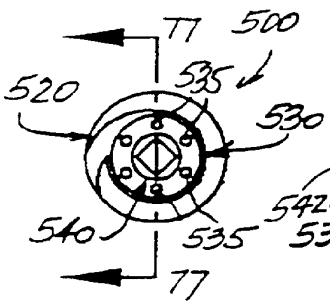



FIG. 75

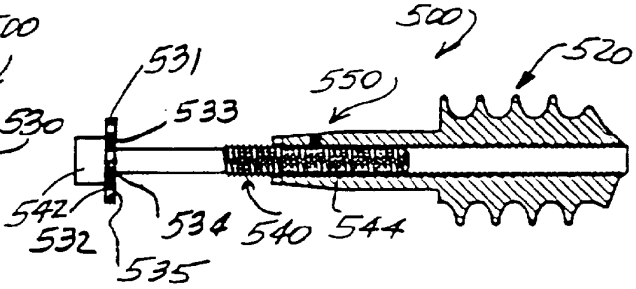



FIG. 77

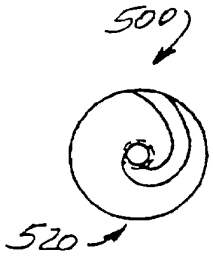



FIG. 76

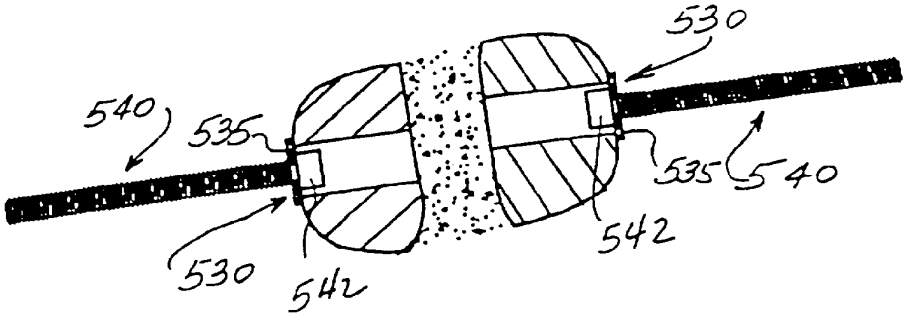



FIG. 78

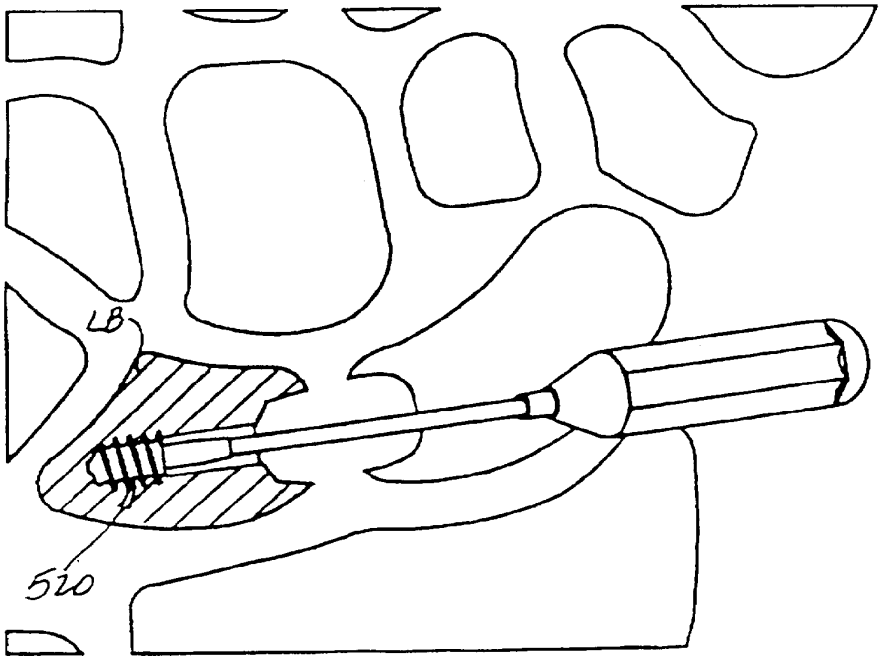



FIG. 79

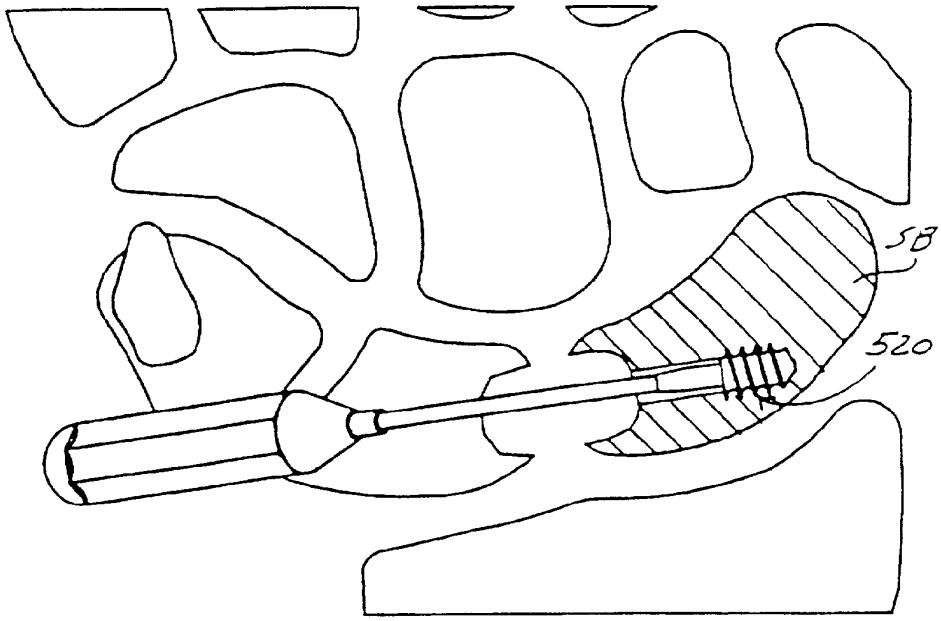



FIG. 80

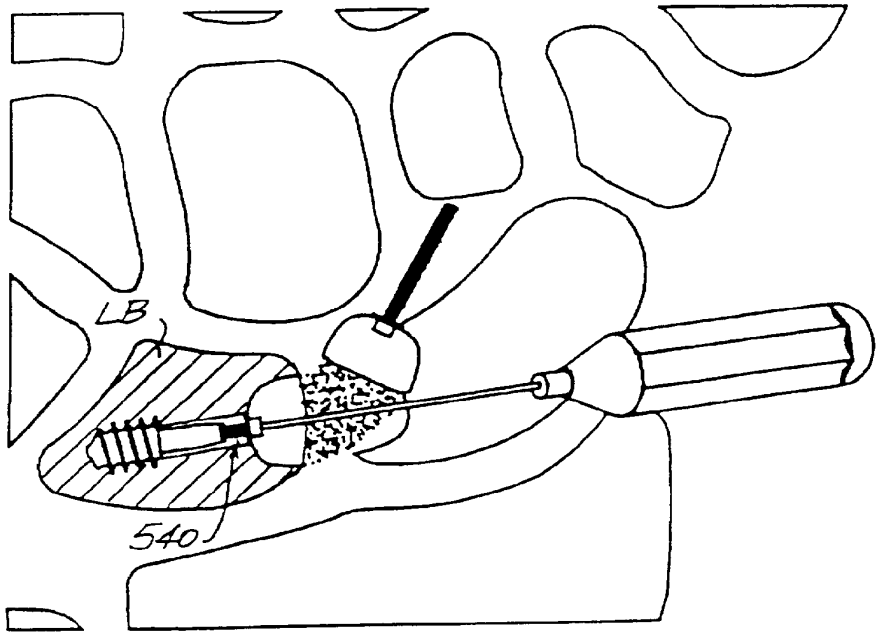



FIG. 81

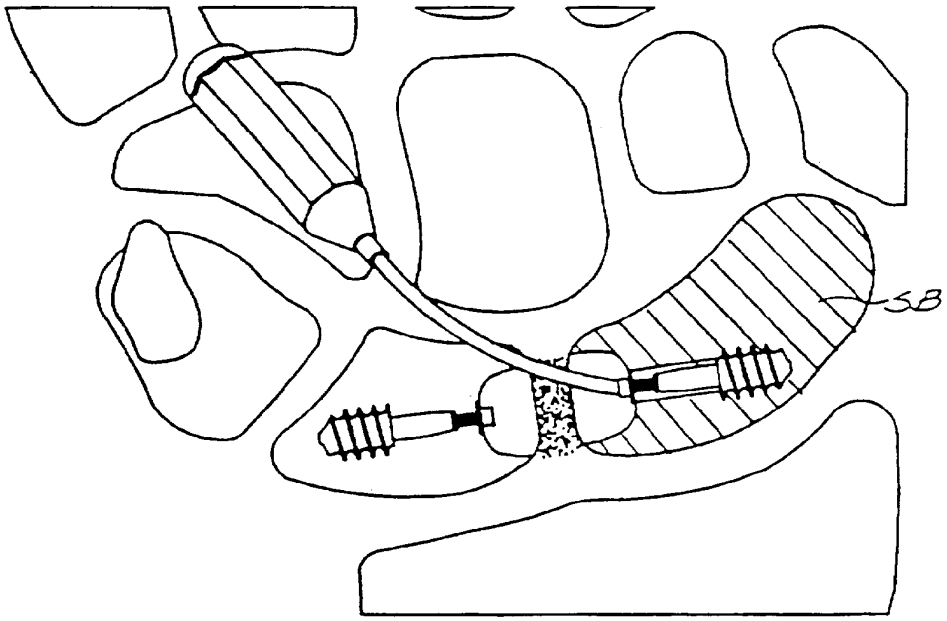



FIG. 82

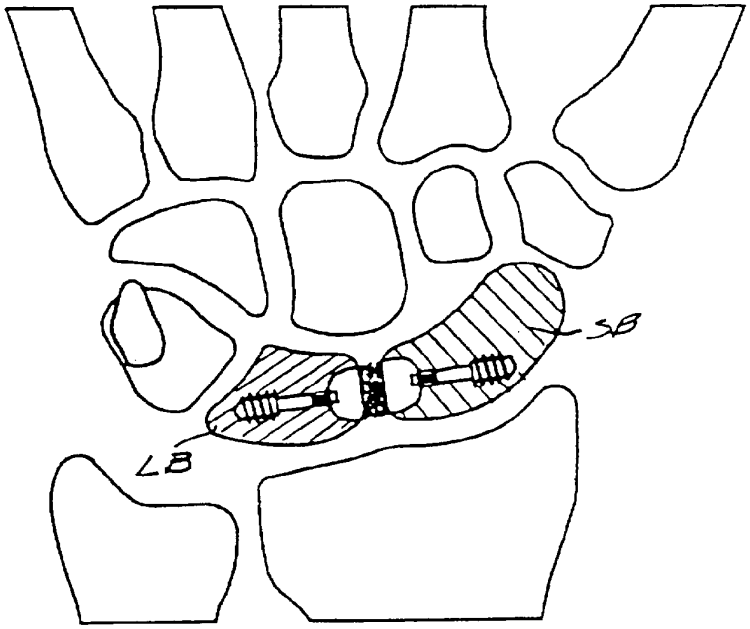



FIG. 83

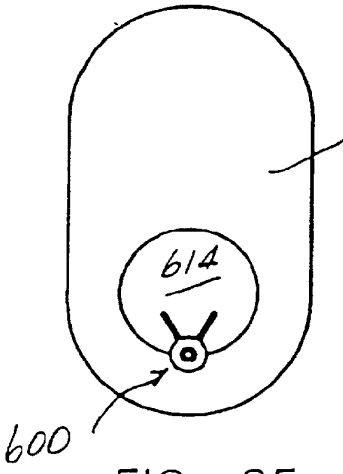



FIG. 85

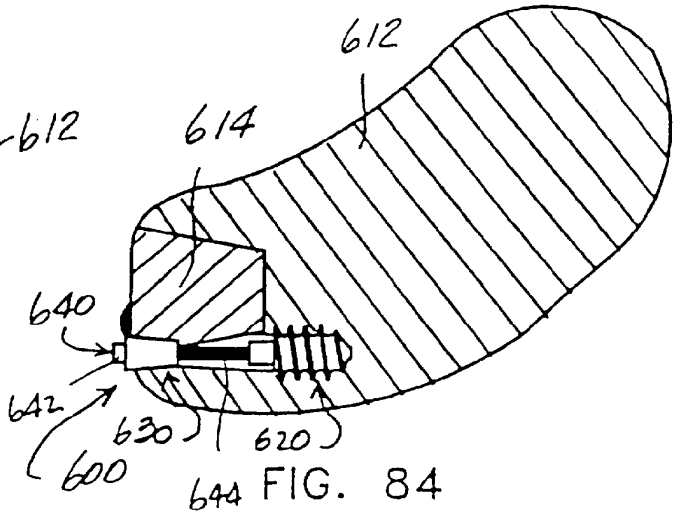



FIG. 84

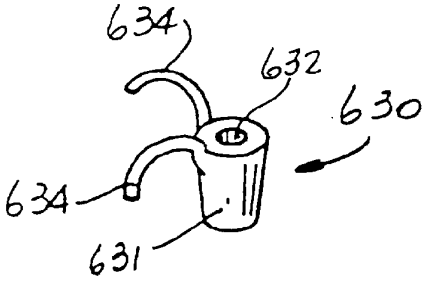



FIG. 87

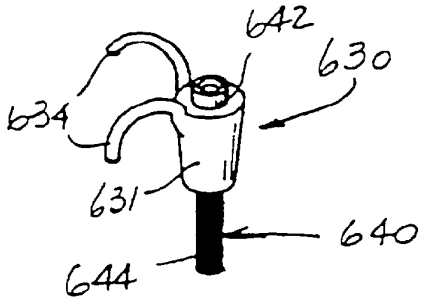



FIG. 86

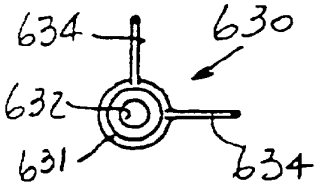



FIG. 88

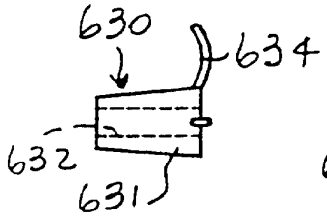



FIG. 89

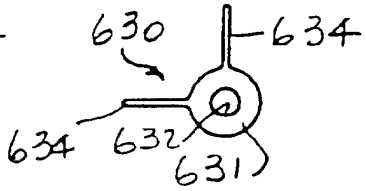



FIG. 90

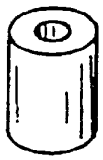


FIG. 91

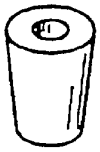


FIG. 92

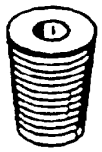


FIG. 93

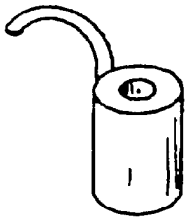


FIG. 94

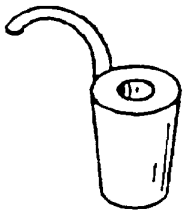


FIG. 95

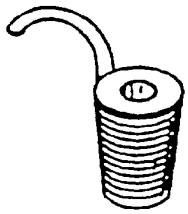


FIG. 96

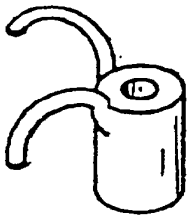


FIG. 97

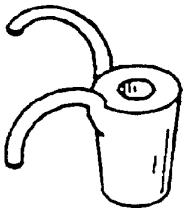


FIG. 98

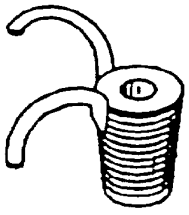


FIG. 99

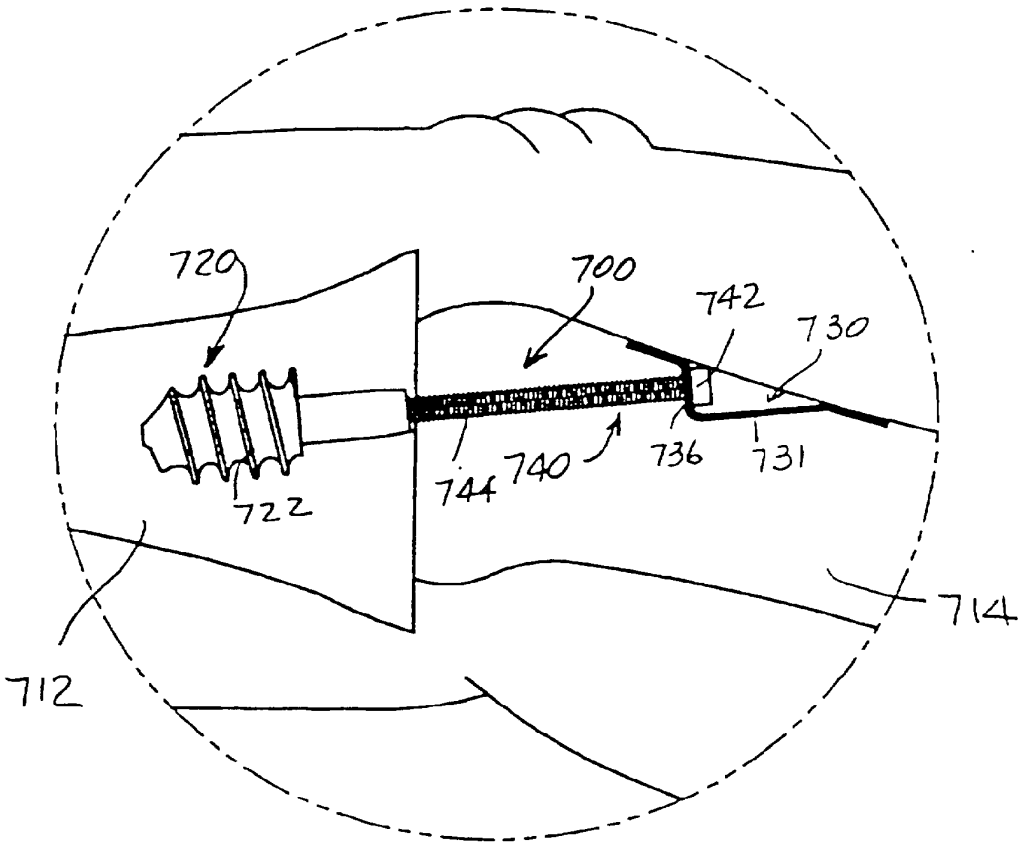



FIG. 101

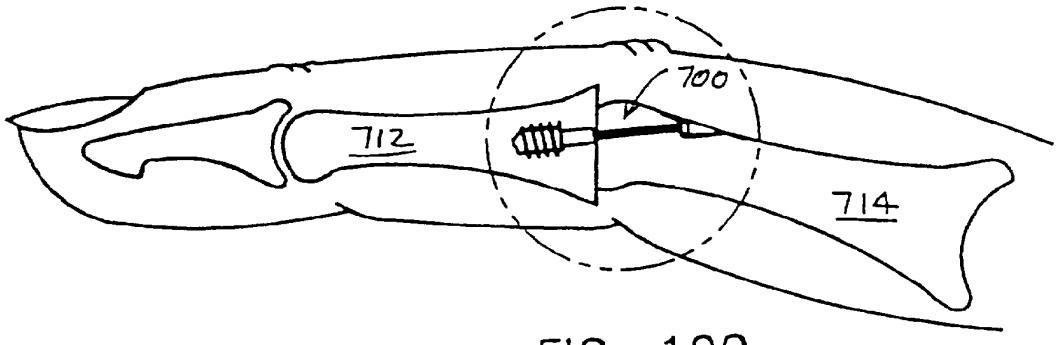



FIG. 100

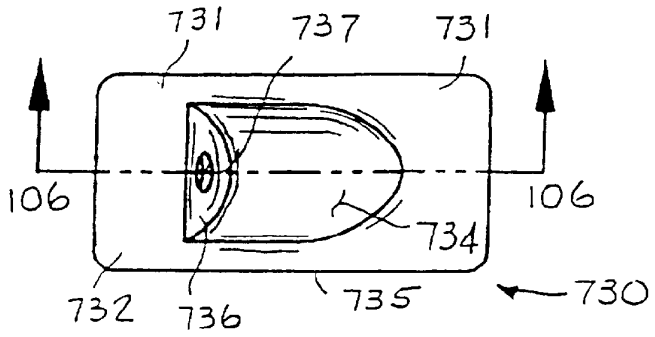



FIG. 102

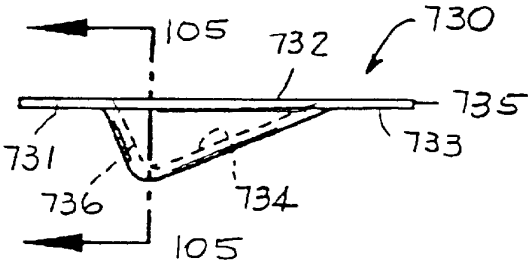



FIG. 103

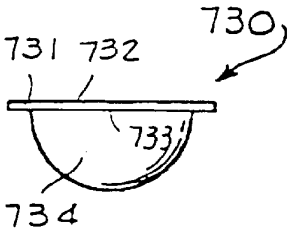



FIG. 104

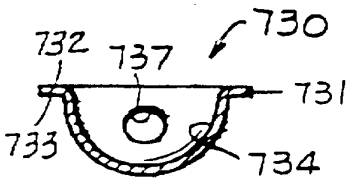



FIG. 105

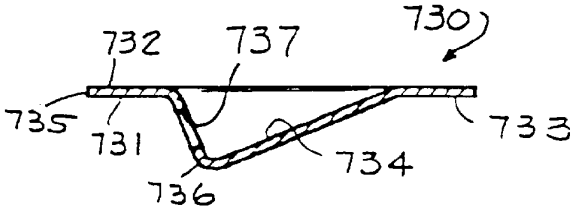



FIG. 106

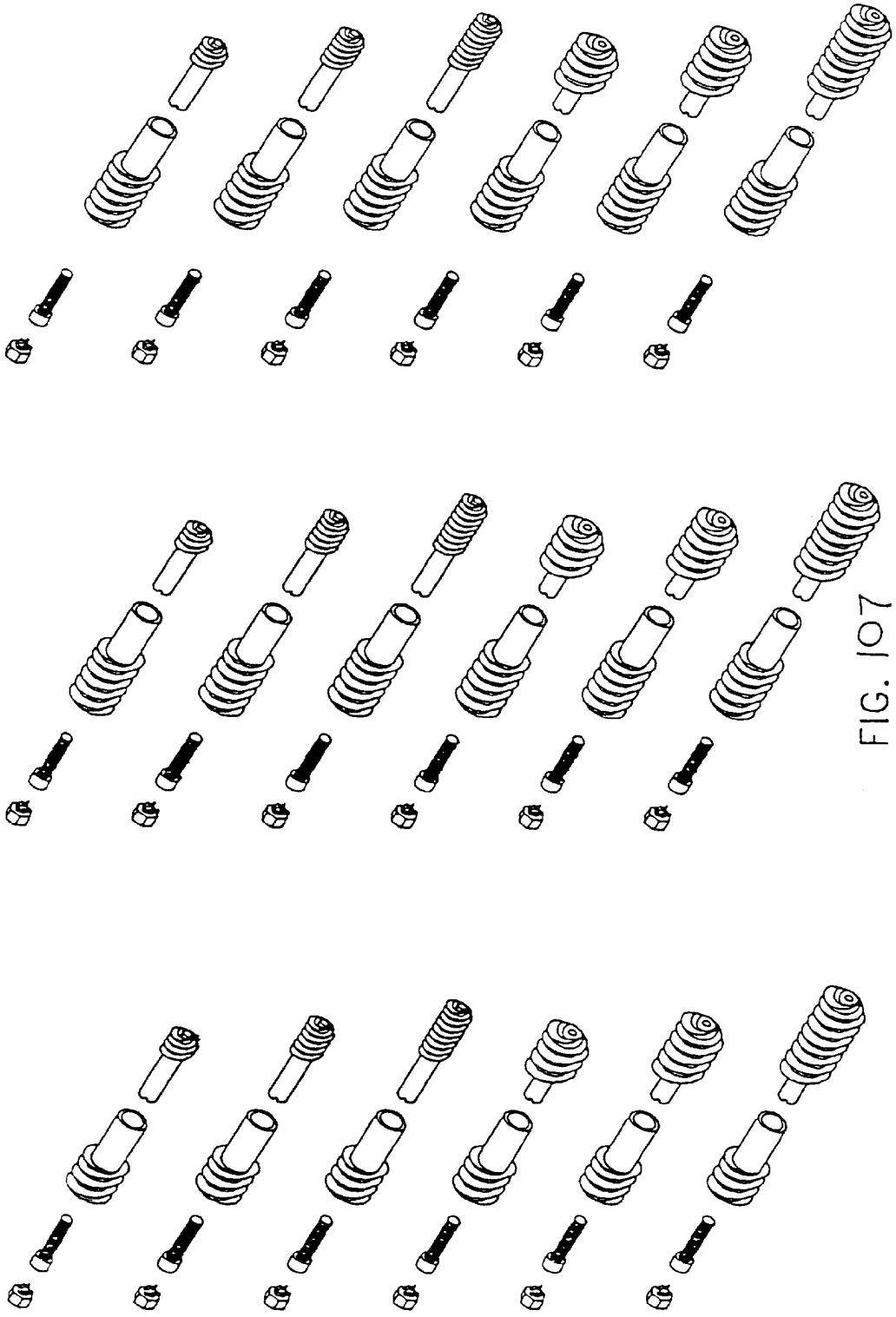


FIG. 107

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20588

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 17/00; A61F 5/04
US CL :411/81, 166; 606/72, 73, 104, 105
According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

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

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

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 3,990,438 A (PRITCHARD) 09 November 1976, Figs. 6-8. | 1-50 |
| A | US 5,100,405 A (McLAREN) 31 March 1992, Figs. 5-8. | 1-50 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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

"E" earlier document published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 07 MARCH 1997 | 25 MAR 1997 |
| Name and mailing address of the ISA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231<br>Facsimile No. (703) 305-3590 | Authorized officer<br>JULIAN W. WOO<br>Telephone No. (703) 308-0421 |

Form PCT/ISA/210 (second sheet)(July 1992)★

B. FIELDS SEARCHED
Minimum documentation searched
Classification System: U.S.

411/81, 83, 86, 87, 96, 102, 110, 121, 123, 124, 140, 166, 172, 321, 322, 324, 357, 372, 373, 377, 508, 509, 512, 517, 523, 537, 530, 548; 606/66, 72, 73, 104, 105

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 February 2008 (28.02.2008)

PCT

(10) International Publication Number
WO 2008/024373 A2

(51) International Patent Classification:
*A61B 17/56* (2006.01)

(21) International Application Number:
PCT/US2007/018524

(22) International Filing Date: 21 August 2007 (21.08.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| 60/839,014 | 21 August 2006 (21.08.2006) | US |
| 60/921,570 | 3 April 2007 (03.04.2007) | US |

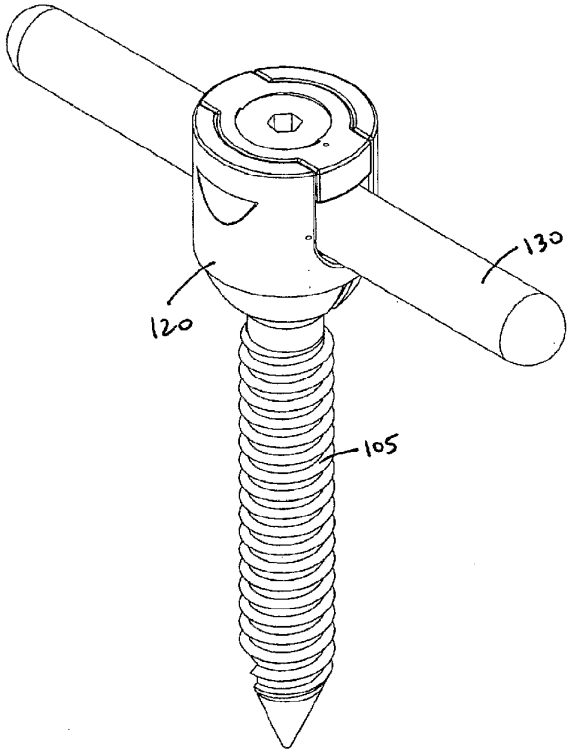
(71) Applicant and
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(57) Abstract: The distal bone screw segment of a bone screw system is driven into bone. In a first state, the assembly permits relative motion between its component parts in order to facilitate the placement and correct alignment of an interconnecting rod that is used to couple multiple bone screw systems and/or other orthopedic devices. In a second state, the assembly provides relative immobilization between the assembly components and the inter-connecting rod.

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# BONE SCREW SYSTEMS AND METHODS OF USE

## REFERENCE TO PRIORITY DOCUMENT

This application claims priority of co-pending U.S. Provisional Patent Application Serial No. 60/839,014, filed August 21, 2006 and co-pending U.S. Provisional Patent Application Serial No. 60/921,570, filed April 3, 2007. Priority of the aforementioned filing dates is hereby claimed and the disclosures of the Provisional Patent Applications are hereby incorporated by reference in their entirety.

## BACKGROUND

The present disclosure is related to orthopedic devices that are affixed onto skeletal segments. The implanted devices are used to adjust and maintain the spatial relationship(s) of adjacent bones. Depending on the implant design, the motion between the skeletal segments may be returned to normal, increased, modified, limited or completely immobilized.

Whether from degenerative disease, traumatic disruption, infection or neoplastic invasion, alterations in the anatomical relationships between the spinal vertebras can cause significant pain, deformity and disability. Spinal disease is a major health problem in the industrialized world and the surgical treatment of spinal pathology is an evolving discipline. The traditional surgical treatment of abnormal vertebral alignment and aberrant motion is the complete immobilization and bony fusion of the involved spinal segment. More recently, preservation of vertebral motion during the treatment of the spinal pathology has been the preferred strategy and many surgical techniques have been formulated to accomplish this treatment objective.

Regardless of whether the vertebral motion is abolished or preserved, many surgeons employ implantable orthopedic devices that adjust, align, support and/or maintain the spatial relationship(s) of the adjacent vertebral bones. The effectiveness of theses devices is vitally dependant on the adequacy of their fixation onto the underlying bone. Inadequate device fixation will effectively uncouple the device from the vertebral column and marginalize the beneficiary effects of the implant. Further, poorly anchored devices may damage the

attached bone by fracturing and/or avulsing bone fragments at the attachment sites.

Screw fixation into the pedicle portion of the vertebral body has emerged as the most common method of device fixation onto the vertebral column. However, it is known that repeated loading and unloading of these screws will lead to screw loosening and eventual pull-out. Implantable devices that promote spinal fusion must bear load for the few months needed to produce bone graft maturation and solid vertebral fusion. In contrast, devices that preserve vertebral motion must bear the cyclical load of movement for the remainder of the patient's life. With the change in treatment strategy towards motion preservation, the integrity of the bone/device interface and the durability of the device fixation sites are emerging as major determinants of implant's functional life span.

There remains a significant need in the art for bone screw assemblies and methods of implantation that provide superior fixation onto the vertebral column. This need will increase further as surgeons widen the application of the motion preservation procedures.

## SUMMARY

This application discloses bone screw systems that are adapted to provide superior anchor fixation onto the vertebral bones and to increase the resistance to anchor pull-out from the underlying bone.

In an embodiment, the distal bone screw segment of a bone screw system is driven into bone. In a first state, the assembly permits relative motion between its component parts in order to facilitate the placement and correct alignment of an interconnecting rod that is used to couple multiple bone screw systems and/or other orthopedic devices. In a second state, the assembly provides relative immobilization between the assembly components and the inter-connecting rod. In an embodiment, the bone screw system is transitioned from a first state to a second state by the advancement of a locking member. Engagement of the locking member produces a downward force onto the interconnecting rod and a rotational movement of an inner housing member relative to an outer housing member about an abutment surface between the two housing members. With

rotation, the inner housing member functions as a grasping claw that applies a compressive force onto a portion of the bone screw. In this way, the bone screw and the bone to which it is attached are retained by the assembly and affixed onto the rod.

In another embodiment, the force needed to transition the system from a first state to a second state is provided by the action of a locking instrument that is transiently used during system implantation but is not a component of the screw assembly. As before, engagement of the locking instrument produces a downward force onto the interconnecting rod and a rotational movement of an inner housing member relative to an outer housing member about an abutment surface between the two housing members. With rotation, the inner housing member functions as a grasping claw that applies a compressive force onto a portion of the bone screw and onto the rod. The force placed on the rod propels it into a fixed position relative to the inner housing and maintains it in that locked position even after removal of the locking instrument.

In another embodiment, the bone screw segment of the system contains a sub-segment that is partially composed of bone, bone substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between the bone and the bone screw. In an embodiment, the sub-segment is intimately retained within a recess of the bone screw and provides a mineralized shoulder within the bone screw that will tenaciously resist screw migration. In other embodiments, the sub-segment forms a feature that may be actuated to protrude into the surrounding bone. These bone screw features may be used with any of the disclosed screw system designs.

In one aspect, there is disclosed an orthopedic anchoring system that is adapted to fixate implants onto the skeletal bone of a human or animal subject, comprising: a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant; an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second

state requires non-linear movement between the housing members of the assembly; and a lock member that is contained within the assembly, wherein actuation of the lock member provides a force that causes the assembly to transition from the first state to the second state.

In another aspect, there is disclosed an orthopedic anchoring system that is adapted to fixate an implant onto the skeletal bone of a human or animal subject, comprising: a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant; an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and a locking member coupled to the assembly wherein a force required to transition the assembly from the first state to the second state must be provided by an external instrument that is not contained within the assembly and wherein the assembly is capable of passively maintaining a locking force to maintain the assembly in the second state after removal of the external instrument that produced the force.

Other features and advantages will be apparent from the following description of various embodiments, which illustrate, by way of example, the principles of the disclosed devices and methods.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows perspective views of a first embodiment of a bone screw system.

Figures 2A-2C show top and side views of the system.

Figure 3 shows the system in an exploded state.

Figure 4 shows perspective and side cross-sectional views of the system.

Figure 5 shows a lock nut assembly of the system in an exploded state.

Figures 6 and 7 show perspective and cross-sectional views of the exploded lock nut assembly.

Figure 8 shows a top, cross-sectional view of the immobilized screw system that is taken through the lock nut assembly.

Figure 9 shows another embodiment of a lock nut assembly.

Figure 10 shows another embodiment of a bone screw system assembly in an exploded state.

Figure 11A shows the bone screw system of Figure 10 inserted into a pedicle segment of a vertebral body.

Figure 11B illustrates an alternative method of screw fixation onto the vertebral pedicle.

Figure 12 shows the bone screw system at the time of screw assembly removal. The screw head and the remainder of the locking assembly have been removed.

Figure 13 shows another embodiment of a bone screw system assembly in an exploded state.

Figures 14A and 14B show an exemplary embodiment of an outer shank member in a relaxed state and an engaged state, respectively.

Figures 15A and 15B show the bone screw system of Figure 13 mounted into bone with the shank assembly in the relaxed state and the engaged state, respectively.

Figures 16A and 16B show another embodiment of an inner shank member and outer shank member.

Figure 17 shows a cross-sectional view of the outer shank member.

Figure 18A and 18B show a cross-sectional view of the outer shank member before and after insertion of the inner screw shank member, respectively.

Figure 19 shows a perspective view of another embodiment of a bone screw system.

Figure 20 shows an exploded view of the system of Figure 19.

Figure 21 shows perspective and cross-sectional views of the system of Figure 19.

Figure 22 shows another embodiment of a bone screw system.

Figure 23 shows the system in an exploded state.

Figure 24 and 25 show cross-sectional views of the assembled system prior to rod placement.

Figures 26 and 27 show cross-sectional views of the assembly after the rod is placed. The assembly is in the locked configuration.

Figure 28 shows another embodiment of a bone screw system.

Figure 29 shows the system in an exploded state.

Figure 30 shows perspective and side cross-sectional views of an upper region of the system.

Figure 31 shows another embodiment of a bone screw system.

Figure 32 shows the system in an exploded state.

Figure 33 shows perspective and side cross-sectional views of an upper region of the system.

Figure 34 shows a perspective view of another embodiment of a bone screw system.

Figure 35 shows an exploded view of the bone screw system.

Figure 36A shows vertical sectional views of the device of Figure 35 taken through a hinge member.

Figure 36B shows a horizontal sectional view of the device of Figure 35 taken through the hinge members.

Figure 37 shows an alternative hinged system embodiment.

Figures 38A and 38B show an additional embodiment in perspective and exploded views, respectively.

Figure 39 shows cross-sectional views of the system.

Figures 40A and 40B show top views of the device of Figure 38 in the unlocked and locked configurations, respectively.

Figures 41A to 41C show views of another system embodiment.

Figures 42A and 42B show exploded views of the embodiment of Figure 41.

Figures 43A and 43B show cross-sectional views of the device of Figure 41.

Figures 44A and 44B illustrate the outer and inner saddle members, respectively.

Figures 45A and 45B show the assembly in the locked and unlocked configurations, respectively.

Figures 46A and 46B illustrate an additional embodiment.

Figure 47 shows an exploded view of the device in Figure 46.

Figures 48A and 48B show cross-sectional views of the device in Figure 46.

Figure 49 shows side views of an alternative inner saddle member.

Figure 50 shows the cross-sectional features using phantom lines.

Figures 51A-51C show perspective, exploded and cross-sectional views of an illustrative embodiment.

Figures 52A and 52B show an alternative embodiment adapted to allow a range of movement for the bone screw which is biased towards a preferred direction.

Figure 53 shows an alternative embodiment that biases the bone screw towards a preferred direction.

## DETAILED DESCRIPTION

Figure 1 shows perspective views of a first embodiment of a bone screw system. Figures 2A-2C show top and side views of the system. Figure 3 shows the system in an exploded state and Figure 4 shows perspective and side cross-sectional views of the system. The system includes a bone screw having a

shank 105 that extends from a head 110. The shank 105 can be screwed into bone. In the assembled system, the head is seated within a saddle assembly that includes an outer saddle member 120 that removably couples to a pair of inner saddle members 125. The inner saddle members 125 fit partially inside the outer saddle member 125 with a portion of the inner saddle members 125 protruding downwardly therefrom. The inner saddle members 125 collectively form a seat that receives the screw head 110, as shown in Figure 4. The inner saddle members 125 also form a receptacle or seat that receives a second implant such as a rod 130, which also sits in a slot in the outer saddle members 120. As shown in Figure 4, the outer saddle member 120 mates with the inner saddle members 125 via a complementary-shaped interface therebetween. The interface holds the inner saddle and outer saddle in a connected relationship that can be tightened and locked via a lock nut assembly, which is described below with reference to Figures 3 and 5. When the lock nut assembly is fully tightened, the rod 130 and screw head 110 are immobilized relative to the saddle assembly.

With reference to Figure 3, the system further includes a lock nut assembly 135 that can be used to immobilize the screw head 110 and rod 130 relative to the saddle assembly, as described in detail below. The lock nut assembly 135 fits within and mates with an interior portion of the outer saddle member 120, as shown in Figure 1.

Figure 5 shows the lock nut assembly 135 in an exploded state. The lock nut assembly 135 includes an outer component 505, an inner component 510, and an annular or partially annular ring 518. The outer component 505 has a pair of laterally-extending wings 515 that are adapted to fit within the slots in the outer saddle member 120, as shown in Figure 1. The outer component 505 also has a threaded bore 520 that is sized to receive the complementary-shaped inner component 510 which can be a locking nut, as described below. An annular groove or slot 525 is located on the wall of the bore 520 wherein the slot 525 is sized and shaped to receive the ring 518, as described more fully below.

Figures 6 and 7 show perspective and cross-sectional views of the lock nut assembly in an exploded state. A plurality of radial-extending bore holes 610 are interspersed around the circumference of the threaded bore 520 of the outer

component 505. The bore holes 610 form openings in the slot 525 of the bore 520 and in the exterior of the outer component 505. A spherical ball 615 is movably positioned within each of the bore holes 610. The balls 615 are sized and shaped relative to the bore holes 610 such that the balls 615 can move along the length of the bore holes 610 but cannot be moved out of the bore holes 610.

The ring 518 is biased toward an enlarged state. The ring 518 can be compressed to a size that permits the ring 518 to be inserted into the bore 520 of the outer component 505 and into the annular slot 525. When the lock nut assembly 135 is in an assembled state, the ring is positioned within the slot 525. The ring 518 expands radially outward within the slot 525 to force the balls 615 toward an extended position wherein at least a portion of each of the balls 615 protrudes outside of the outer component 505, as shown in Figure 7. The compressible nature of the ring 518 permits the balls 610 to move radially inward in response to inward forces on the balls, unless the ring 518 is prohibited from being compressed, as described below. The assembled lock nut assembly 135 also includes the inner component 510, which is at least partially threaded into the bore 520 of the outer component 505. In this manner, the lock nut assembly 135 is essentially a unitary assembly that can be easily handled and manipulated.

In assembly, the inner saddles 125 are coupled to the outer saddle 120 with the head 110 of the bone screw seated in the inner saddle 120. The device is maintained in the assembled configuration by the action of assembly pins 126 and given to the surgeon as a unitary device. In use, screw 105 is driven into the underlying bone. Inter-connecting rod 130 is then lowered into the slot in the outer saddle 120 such that the rod 130 is seated within inner saddle members 125. After rod 130 is properly positioned, lock nut assembly 135 is then lowered into the outer saddle 120. Although the balls 615 are biased outward by the ring 518, the inner aspect of the outer saddle 120 pushes the balls 615 and the compressible ring 518 inward as the lock nut assembly 135 is advanced into the outer saddle 120. The lock nut assembly 135 is lowered until the balls 615 reach an annular groove 405 (Figure 4) in the inner aspect of the outer saddle 120. At this point, the ring 518 forces the balls to snap into the groove 405. The balls interface with the groove to retain the lock nut assembly 135 in the outer saddle

120. At this stage, the rod 130 and the screw head 110 are movably positioned relative to the saddle assembly and the rod position can be adjusted further. This feature permits the surgeon to apply a compressive or distractive force between individual screw systems before the systems are locked.

After the rod 130 is appropriately positioned, the screw system is immobilized by advancing the inner component 510 of the lock nut assembly 135 deeper into the outer components 505. As component 510 is advanced, it covers the inner aspect of the ring 518 so that the ring is no longer compressible. When the ring 518 becomes incompressible, the balls 615 are locked in the extended position within the grove of the outer saddle member. As the inner component 505 is advanced further, it exerts a downward force onto rod 130 and advances the rod relative to inner saddle member 125. The side walls of the rod-receiving potion of inner saddle member 125 are inclined, as shown in Figure 4, so that the upper portions of the side walls are separated by a greater distance than the lower portions of the side walls. Because of this wall configuration, advancement of rod 130 creates a distractive force between the side walls of the rod-receiving potion of inner saddle member 125 and produces rotation (i.e., non-linear movement) of each inner saddle member 125 relative to outer saddle member 120 about the abutment protrusions 129 of the outer saddle member. With rotation, the inferior segments of the inner saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. In this way, the assembly is rigidly immobilized relative to rod 130. A longitudinal cross-sectional view of the immobilized device is shown in Figure 4. A horizontal cross-sectional view of the locking nut assembly 135 is shown in Figure 8. As illustrated, ring 518 retains balls 615 in the extended state and, in the locked state, nut 510 prevents the compression of ring 518.

Figure 9 shows another embodiment of the lock nut assembly 135. In this embodiment, the ring and balls of the previous embodiment are replaced by a snap ring 905 that is biased toward a radially-expanded state. The snap ring 905 includes at least one protrusions 910 that fits into holes 915 in the outer member 505. The protrusions have sloped bottom surfaces such that the protrusions 910

are automatically forced inward as the lock nut assembly is lowered into the outer saddle 120. The protrusions 910 snap into the groove in the inner aspect of the outer saddle 120 in the same manner that the balls of the previous embodiment snap into the groove. Holes 911 are adapted to accept a removal instrument, wherein the instrument can exert a compressive force onto the ring 905 and remove the lock nut assembly 135. The illustrated lock nut assemblies provide retractable members that transiently retract on insertion to pass a screw assembly protrusion and then expand to occupy a position within a screw assembly indentation. In this way, the lock nut assembly forms an interference feature that retains the rod within the screw system assembly and, with advancement of the central nut of the lock nut assembly, rigidly locks the screw system components. It should be appreciated that this functional mechanism can be provided by lock nut assemblies that vary in structure from the illustrated embodiments.

Figure 10 shows another embodiment of a bone screw system in an exploded state. In this embodiment, the saddle and lock nut assembly features are similar or the same as in the previous embodiment but the bone screw has been modified in order to provide superior bone fixation. The bone screw is formed of multiple components, including a multi-piece shank assembly that removably couples to the head 110. The shank assembly includes an inner shank member 1005 that at least partially inserts into an internal bore in the outer shank member 1010. The inner shank member 1005 has an upper region 1015 that slidably mates into the bore within the outer shank member 1010, and a lower region 1020 that is threaded for locking onto bone. Upper region 1015 of inner shank 1005 has protrusion 1016 that cooperatively fits within a complimentary indentation or slit within outer shank member 1010. Protrusion 1016 functions to prevent rotation of outer member 1010 relative to inner shank member 1005. Outer member 1010 is preferably at least partially made of bone, bone graft substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between outer member 1010 and the surrounding vertebral bone. A coupler 1025, such as a threaded coupler, removably mates with the head 110 in the assembled device, as illustrated in Figure 11A, which shows the bone screw system inserted into a pedicle segment

of a vertebral body. The outer shank member 1010 is intimately applied to the upper region 1015 of inner shank 1005 so that, with bone in-growth into member 1010, a mineralized shoulder is formed within the substance of the bone screw. The mineralized segment will tenaciously resist screw migration and significantly increase the pull-out resistance of the screw.

Figure 11A illustrates screw placement within the pedicle portion P of the vertebra. Biomechanical research has shown that the pedicle P forms an optimal bone-attachment site for bone screws and other orthopedic devices. As with other segments of bone, the pedicle has a tough outer wall and a more spongy interior that is marrow-like in consistency. The pedicle is substantially cylindrical and roughly forms a circular or elliptical outline in coronal cross-section. Engagement of at least a portion of the tough outer wall increases the strength of fixation. Fixation can be additionally enhanced by the "capture" of the outer wall of the pedicle (along the long axis) within a segment of the bone screw. This fixation method may be accomplished in several ways. In Figure 11B, a pedicle is captured between a distal and a proximal protrusion segment of a bone screw. Alternatively, as shown in Figure 11A, a bone screw may have an intermediate member that is captured between two segments of the bone screw, wherein the intermediate member forms a mineralized connection with the surrounding bone. In the latter embodiment (Figure 11A), the tough outer pedicle surface is essentially extended into the substance of the bone screw by the action of the mineralized connection with the intermediate member.

After the mineralized connection has been established between a screw segment and the bone, the screw assembly can still be removed, when desired, by removal of the proximal segment – as illustrated in Figure 12. The distal screw is then attached to a bone drill and a ring of bone is cut around the screw segment that remains embedded in the vertebral bone. After cutting the mineralized connection, the retained screw segment can be backed-out without difficulty.

In additional embodiments, the outer shank member 1010 of the bone screw can be actuated to change configuration. The inner shank member 1005 may be configured in one of various ways such that, upon actuation, it can alter

the structural configuration of the outer shank member. For example, in an embodiment illustrated in Figures 13 to 15, actuation of the screw system causes the outer shank member 1010 to expand outward and into the surrounding bone.

Figure 13 shows an exemplary embodiment, wherein the outer shank member is composed of a central member that is preferably at least partially made of bone, a bone graft substitute and/or a feature adapted to promote bone in-growth or establish a mineralized connection between outer member 1010 and the surrounding vertebral bone. At least one defect is found in member 1010 wherein a deformable member is housed. Figure 14A shows member 1010 with the deformable member in a first, un-deployed state while Figure 14B shows the deformable member in a second, deployed state. Note that the residual connecting bridge at the inferior aspect of member 1010 is broken by the deployment of the deformable member from the first to second state. The deformable member is actuated between the first and second states by the rotation of head 110 relative to shank 1005. This action shortens the height of the deformable member and increases its width, thereby producing the configuration change of member 1010 that is shown in Figure 14B. Figures 15A and 15B show cross-sectional views of the screw system of Figure 13 implanted within a vertebra, wherein Figure 15A shows the deformable member in a first, un-deployed state and Figure 15B shows the deformable member in a second, deployed state.

Figures 16A and 16B show another embodiment of an inner shank member and outer shank member. In this embodiment, the outer shank member 1010 has a head 110 with an opening 1105 that receives the inner shank member 1005. The inner shank member 1005 fits within an internal bore in the outer shank member. Figure 17 shows a cross-sectional view of the outer shank member 1010. The internal bore 1705 has an upper threaded region that mates with outer threads on the inner shank member 1005. The lower region of the bore 1705 is non-threaded. With insertion of the inner shank member 1005 into the bore 1705, the configuration of the inner bore 1705 is forced to conform to that of the inner shank member 1005. This alters the outer configuration of the outer shank member 1010 such that it undergoes a shape change. Figures 18A

and 18B show the structural configuration of the outer shank member before and after insertion of the inner shank member, respectively. Figure 18A shows the outer shank member alone in the "relaxed" configuration while Figure 18B shows the outer shank with the inner screw member in the "engaged" state. In the "engaged" configuration of the outer shank member, sections of the screw are propelled in pre-determined directions without an overall expansion of the screw or an increase in its size. This configuration change will increase the bone holding capability of the entire assembly and increase its resistance to pull-out.

While the bone screw is mainly embedded in bone, the portion of the screw system that provides the locking feature rests above the bone and below the skin. As previously described, the force required to lock the assembly is provided by lock nut assembly 135. In order to reduce the overall height of this segment and lower the profile of the system, several embodiments are disclosed in which the force required to lock the assembly is provided by the action of a locking instrument that is transiently used during screw system implantation but is not a component of the screw assembly itself. Figure 19 illustrates a perspective assembled and locked view of the current embodiment while Figure 20 shows an exploded view of the system. Figure 21 shows perspective and cross-sectional views of the system.

The system includes a bone screw having a shank 105 and a head 110. The head 110 sits in a saddle assembly that includes an outer saddle member 1905 which mates with a pair of inner saddle members 1910. The inner saddle members 1910 fit partially inside the outer saddle member 1905 with a portion of the inner saddle members 1910 protruding downwardly therefrom. The inner saddle members collectively form a seat that receives the screw head 110, as shown in Figure 21. In use, the device is maintained in the assembled configuration by the action of assembly pins and given to the surgeon as a unitary device.

The inner saddle members also form a seat that supports the rod 130, wherein the side walls of the rod-receiving seat of the inner saddle members are inclined, as shown in Figure 21, so that the upper portions of the side walls are separated by a greater distance than the lower portions of the side walls.

Because of this wall configuration, advancement of rod 130 creates a distractive force between the side walls of the rod-receiving seat of inner saddle member and produces rotation of each inner saddle member relative to outer saddle member 1905 about the abutment protrusions 1915 of the outer saddle member. With rotation, the inferior segments of the inner saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. The locking force is provided by a separate implantation instrument (not shown) and the locking force is maintained even after the instrument is removed by ridged protrusions, indentations or other retaining features on the inner aspects of the rod-receiving seat of the inner saddle members.

Figure 22 shows another embodiment of a bone screw system. Figure 23 shows the system in an exploded state and Figure 24 shows the system prior to rod placement. As in the embodiment of Figures 19-21, a locking nut is not employed in this embodiment. The system includes a bone screw with a head 110 that sits in a saddle assembly. The saddle assembly includes an inner saddle member 2310 having a seat that receives the rod 130. The saddle assembly further includes intermediate saddle members 2315 that collectively receive the inner saddle member 2310. The saddle assembly further includes an outer saddle member 2320 in which the intermediate saddle members 2315 can be positioned. In Figure 24, the inner saddle member 2310 extends above the top surface of the screw. In this position, the upper aspect of the inner saddle member 2310 expands sufficiently to permit placement of the rod 130 into the inner saddle member 2310.

Figure 25 shows an enlarged cross-sectional view of the device prior to rod placement. As mentioned, the head 110 is positioned in a seat collectively formed by the intermediate saddle members 2315. Each of the intermediate saddle members 2315 has a protrusion 2325 that mates with an opening in the outer saddle member 2320. The saddle assembly components are freely movable relative to the bone screw.

The saddle assembly can be moved into a locked configuration by pushing the rod 130 downward into the inner saddle member 2310. Figures 26 and 27

show cross-sectional views of the assembly in the locked configuration. As a downward force is exerted onto the rod 130, the inner saddle member 2310 is pushed into a cavity within the confines of the intermediate saddle members 2315. As shown in Figure 27, the protrusions 2325 are positioned within indentations 2705 of the outer saddle member 2320. The inner saddle member 2310 exerts an outward force onto the upper aspect of the intermediate members 2315. This causes the members 2315 to rotate relative to the center of the protrusion 2325 and push the bottom potion of each of the intermediate saddle members 2315 towards one another. In this way, the intermediate saddle members 2315 lock onto the spherical head 110 of the bone screw. A Morse taper exists between the outer surface of the inner saddle member 2310 and the inner surface of the members 2315 and provides a locking mechanism for the assembly. Alternatively, or additionally, one or more interference locks could be used to maintain the locking force after the locking instrument has been removed.

Figure 28 shows another embodiment of a bone screw system. Figure 29 shows the system with a saddle assembly in an exploded state. As in some of the previous embodiments, a locking nut is not employed in this embodiment. The saddle assembly includes an outer saddle member 2805 and a pair of inner saddle members 2810 that are positionable within the outer saddle member 2805. An upper region of the inner saddle members 2810 collectively define a seat in which the rod 130 can be positioned. A lower region of the inner saddle members 2810 collectively form a spherical or partially spherical member 3005, as shown in the cross-sectional views of Figure 30.

With reference to the cross-sectional views of Figure 30, the spherical member 3005 is rotationally positioned within the head 3010 of the bone screw. The head 3010 is sized and shaped so at the form a spherical cup or seat in which the spherical member 3005 of the inner saddle members 2810 is positioned. A pair of protrusions 3015 are located on the inner aspect of the outer saddle member 2805. The protrusions abut an outer aspect of the inner saddle members 2810, which are coupled to one another via a protrusion 3020.

The saddle assembly is locked by pushing the rod 130 downward into the inner saddle members 2810 and pulling the outer saddle member 2805 upward

relative to the inner saddle members 2810. As the outer saddle member 2805 is pulled upward relative to the inner saddle members 2810, protrusions 3015 produce an inward directed force onto the outer walls of the inner saddle members 2810. The force causes the upper aspects of the inner saddle members 2810 to rotate about the center of protrusion 3020 so that the lower aspects of members 2810 move away from each other. The lower aspects of the inner saddle members 2810 forcefully constrain the bone screw head 3010 and immobilize the assembly.

Figure 31 shows another embodiment of a bone screw system. Figure 32 shows the system in an exploded state. Figure 33 shows perspective and side cross-sectional views of the system. The system includes a bone screw with a head 3010 that is configured in the same manner as the head in the embodiment of Figure 30. The saddle assembly includes an outer saddle member 3105 that houses a pair of intermediate saddle members 3110. In the assembled device, an inner saddle member 3115 is positioned between the intermediate saddle members such that the inner saddle member and intermediate saddle members collectively form a seat for the rod 130, as shown in Figure 33.

A pair of protrusions 3310 extend inward from an inner aspect of the outer saddle member 3105. As shown in Figure 33, the protrusions sit within a slot in the intermediate saddle members 3110. The rod 130 is pushed down to lock the saddle assembly. As the rod 130 is pushed down, it places a downward force onto inner saddle member 3115. The force causes each of the intermediate saddle members 3110 to rotate about the center of the protrusion 3310 so that the lower aspects of the intermediate members 3110 move away from each other. The lower aspects of the intermediate saddle members 3110 forcefully constrain the bone screw head 3010. As a result, the assembly and rod are immobilized.

Figure 34 illustrates perspective views of another device embodiment. Figure 35 shows an exploded view while Figure 36A illustrates longitudinal sectional views through a hinge member of the device. In Figure 36B, a horizontal sectional view through the hinge members is shown. With reference to Figure 35, the device is comprised of two saddle members 7215, bone screw 105

with head 110 and a rod receptacle that is formed by opposing angled walls 7230 (Figure 36A) of members 7215. Each saddle member 7215 contains at least one side cut-out 7234 that is adapted to at least partially contain a segment of a hinge member 7238.

In assembly, two hinge members 7238 are used to interconnect the two saddle members 7215, wherein, one end of each hinge member 7238 is affixed to a saddle member 7215 by pin 7241 as shown in Figures 35 and 36. The device is maintained in the assembled configuration by the action of assembly pins 7241 and given to the surgeon as a unitary device. Note that hinge members 7238 and cut-outs 7234 are collectively configured to insure that the two bottom aspect of each saddle member 7215 can rotate towards but not away from one another. This feature insures that head 110 of screw 105 is securely retained within the assembly even when the device is in the unlocked state. Figure 36A illustrates longitudinal sectional views through a hinge member of the device. In Figure 36B, a horizontal sectional view through the hinge members is shown, wherein the line "D" illustrates the section of Figure 36A.

In application, the bone screw is driven into the underlying bone. A rod 130 is positioned within the rod receptacle formed by opposing angled walls 7230 of members 7215. Because of the angled wall configuration, advancement of rod 130 creates a distractive force between the walls 7230 of the rod-receiving seat of saddle members 7215 and produces rotation of the saddle member relative to the hinge members 7238. With rotation, the inferior segments of the saddle members are driven towards one another and they collectively function as a grasping claw that applies a compressive force onto head 110 of the bone screw. The locking force is provided by a separate implantation instrument (not shown) that pulls upwards onto ledge 7248 as it pushes down onto rod 130. The locking force is maintained even after the instrument is removed by ridged protrusions 7245 or, alternatively, by indentations, ratchets or other retaining features that may be placed on the inner aspects of the rod-receiving seat of the members 7215.

The saddle members of an additional hinged device embodiment are shown in Figure 37. The hinge features are shown as integral members of each

member 7215. Unlike the prior embodiment in which there was two rational axis that were off center relative to the long axis of the rod receptacle, the current embodiment has a single central axis of saddle member rotation. The remaining device features are similar to the preceding embodiment.

Figure 38A shows a perspective view of an additional embodiment. Figure 38B illustrates an exploded view and Figure 39 shows cross-sectional views of the embodiment. In this device, a rotational locking member 8233 is positioned between an inner and an outer saddle member. In assembly, the device is maintained in the assembled configuration by the action of assembly pins that movably couple the two saddle members and given to the surgeon as a unitary device. In application, the bone screw is driven into bone. A rod 130 is appropriately positioned within the rod receptacle portion of the saddle members and protrusions 8236 of rotational locking member 8233 are grasped by a locking instrument (not shown). The instrument straddles rod 130 and rotates the protrusions 8236 relative to the stationary rod 130 in order to transition the assembly into the locked configuration. Figures 40A and 40B shows a top view of the device in the unlocked and locked configurations, respectively. Note the cooperation between the features of the inner aspect of rotational locking member 8233 and the complimentary features on the outer wall of the inner saddle members. These features produce the inward movement of both inner saddle members and immobilize the device member, bone screw and rod relative to one another. Additional features on the inner aspect of the outer saddle member and the outer aspect of locking member 8233 insure that the locking member rotates smoothly.

Figures 41A-41C show top and side views of another embodiment of a bone screw system. Figures 42A and 42B show the system in an exploded state. The system includes a bone screw and a saddle assembly that includes an outer saddle member 3705 that removably receives an inner saddle member 3710. As shown in the cross-sectional views of Figures 43A and 43B, the inner saddle member 3710 forms a pair of seats that support the head 110 of the bone screw and the rod 130.

Figures 44A show perspective views of the outer saddle member 3705. The outer saddle member 3705 has a pair of slots 3905 for receipt of the rod 130. An outwardly extending shoulder or lip 3910 is positioned along an upper aspect of the outer saddle member 3705. A small slot 3915 is located in the upper aspect between the slots 3905. The outer saddle member 3705 defines a seat that is sized and shaped to receive the inner saddle member 3710.

Figures 44B show perspective views of the inner saddle member 3710. A seat 4010 is located on the upper aspect of the inner saddle member 3710 for the rod 130. A slot 4015 extends through the inner saddle member 3710 such that opposed sides of the inner saddle member 3710 are separated by the slot 4015. The slot 4015 permits the opposed sides to flex toward and away from one another. A protrusion 4020 on one side of the inner saddle member 3710 has an opening 4023 that is sized and shaped to receive a pin 4030 (Figure 42). The opening 4023 is sized such that the pin 4030 can move within the opening 4023 when the pin is positioned therein. A borehole 4025 extends into the inner saddle member 3710 on one side.

Figures 45A and 45B show cross-sectional views of the saddle assembly in different states of movement. In Figure 45A, the inner saddle member 3710 is fully seated in the outer saddle member 3705. The outer saddle member 3705 has an inwardly extending lip 4110 that abuts an outer surface of the inner saddle member 3710. The pin 4030 is positioned in the opening 4023 in the inner saddle member 3710. The pin 4030 also communicates with an opening 3715 (shown in Figures 42) in the outer saddle member 3705. The pin 4030 links the inner and outer saddle members and serves to limit or govern movement of the inner saddle member within the outer saddle member by virtue of the pin's interaction with the opening 4023. The opening 4023 is larger than the diameter of the pin 4030 to permit the pin to move up and down within the limits of the opening's size.

Figure 45B shows the saddle assembly with the inner saddle member 3710 moved relative to the outer saddle member 3705. Note that the pin 4030 has moved within the opening 4023 relative to the position shown in Figure 45A. Moreover, a side region of the inner saddle member 3710 has moved upward

relative to the outer saddle member 3705. The lip 4110 provides a bearing surface against the outer surface of the inner saddle member 3710 to guide movement between the inner and outer saddle members. In the assembled device, the head of the bone screw is positioned within the space 4120 such that the bone screw head can move along with the inner saddle relative to the outer saddle.

While all of the previous embodiments provide relative movement between the screw system assembly and the bone screw in the unlocked state, some surgical applications may require a greater angle of allowable movement during screw system implantation. Figure 46A shows a perspective view of an assembled screw system embodiment that permits greater movement between the locking assembly and the bone screw. Figure 46B shows side views of the device. Figure 47 illustrates an exploded view while Figures 48A and 48B show cross-sectional views. The bone screw has a threaded shank 105 and a toroid head 110 with central aperture 112. A second, complimentary toroid member 118 is positioned within aperture 112 and forms an articulation with the bone screw. Toroid member 118 can move freely relative to the bone screw in each of two substantially perpendicular planes but can not rotate independent of the bone screw. An outer housing 122 houses the bone screw and member 118. The proximal end of housing 122 has threads 124 that are adapted to engage the threads of a complimentary locking nut 126. The distal end of housing 122 has an aperture 127 that is of lesser diameter that the diameter of toroid member 118. In assembly, member 118 is positioned within the central aperture 112 of the bone screw and both members are retained within housing 122 by distal aperture 127. This screw system design allows more than one hundred degrees of movement between the bone screw and the housing member 122 in each of the two perpendicular planes of allowable movement.

In application, the bone screw is anchored into an underlying bone. The bone screw is rotated and driven into bone by a screw driver (not shown) that is adapted to engage and rotate "eye screw" bolts. These screw drivers are well known in the art and are commonly available. Housing 122 is appropriately positioned relative to the bone screw and rod 130 is placed within the rod-

receiving seat of housing 122. Locking nut 126 engages threads 124. With rotation and advancement, nut 126 will propel rod 130 into contact with a segment of toroid head 110 of the bone screw. With continued nut advancement, rod 130 will exert a downward force onto the bone screw and an upward force upon housing 122. In this way, the bone screw, toroid member 118, rod 130 and housing member 122 will be collectively immobilized relative to one another. In Figure 48A, the locked assembly is shown in sectional views that are perpendicular to the log axis of rod 130 while Figure 48B illustrates sectional views in the direction of the rod.

Devices embodiments without a locking nut can be also designed to permit a greater angle of movement between the locking assembly and the bone screw prior to assembly immobilization. With reference to the embodiment of Figures 41 to 45, for example, the inner saddle member may be modified to provide a larger angle of movement between the bone screw and the assembly in a desired direction. Figure 49 illustrates an inner saddle member that has a sloped bottom surface 4215 and allows greater movement relative to the bone screw, as described below. The inner saddle member 4210 is sized and shaped relative to the outer saddle member 3705 to provide greater relative movement therebetween in a desired direction than the previous embodiment of the inner saddle member 3710. Figure 50 shows side views of the inner saddle member with cross-sectional features shown in phantom lines.

These modifications of the inner saddle member can be similarly employed in other device embodiments. A representative embodiment of those devices without a locking nut, for example, is shown in Figures 51. The assembled device is illustrated in Figure 51A, the exploded device is shown in Figure 51B and a sectional view is shown in Figure 51C. Cross-sectional views of the modified device containing an inner saddle member with a slopped bottom surface is shown in Figures 52 and the screw's range of movement is illustrated. The head of the bone screw can rotate within the seat formed by the inner saddle member. The sloped bottom surface of the modified inner saddle member permits the bone screw to rotate to a greater left-most position than if the bottom surface were not sloped. Figure 53 shows a cross-sectional view of another

embodiment of the assembled system in which the upper surfaces of both the inner and outer saddle members are sloped in order to permit a sloped orientation of the rod 130.

The disclosed devices or any of their components can be made of any biologically adaptable or compatible materials. Materials considered acceptable for biological implantation are well known and include, but are not limited to, stainless steel, titanium, tantalum, combination metallic alloys, various plastics, resins, ceramics, biologically absorbable materials and the like. Any components may be also coated/made with osteo-conductive (such as demineralized bone matrix, hydroxyapatite, and the like) and/or osteo-inductive (such as Transforming Growth Factor "TGF-B," Platelet-Derived Growth Factor "PDGF," Bone-Morphogenic Protein "BMP," and the like) bio-active materials that promote bone formation. Further, any surface may be at least partially made with bone, bone substitute and/or a porous ingrowth surface (such as titanium wire mesh, plasma-sprayed titanium, tantalum, porous CoCr, and the like), provided with a bioactive coating, made using tantalum, and/or helical rosette carbon nanotubes (or other carbon nanotube-based coating) in order to promote bone in-growth or establish a mineralized connection between the bone and the implant, and reduce the likelihood of implant loosening. Lastly, the system or any of its components can also be entirely or partially made of a shape memory material or other deformable material.

Although embodiments of various methods and devices are described herein in detail with reference to certain versions, it should be appreciated that other versions, embodiments, methods of use, and combinations thereof are also possible. Therefore the spirit and scope of the appended claims should not be limited to the description of the embodiments contained herein.

## CLAIMS

WHAT IS CLAIMED IS:

1. An orthopedic anchoring system that is adapted to fixate implants onto the skeletal bone of a human or animal subject, comprising:

a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant;

an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and

a lock member that is contained within the assembly, wherein actuation of the lock member provides a force that causes the assembly to transition from the first state to the second state.

2. An orthopedic anchoring system that is adapted to fixate an implant onto the skeletal bone of a human or animal subject, comprising:

a bone anchor that attaches onto bone and a receptacle that is adapted to mate with a second implant;

an assembly including housing members coupled to the bone anchor, wherein the assembly transitions between a first state and a second state, wherein the first state permits relative motion between the anchor and the receptacle and the second state immobilizes the anchor relative to the receptacle

and wherein transition from the first state to the second state requires non-linear movement between the housing members of the assembly; and

a locking member coupled to the assembly wherein a force required to transition the assembly from the first state to the second state must be provided by an external instrument that is not contained within the assembly and wherein the assembly is capable of passively maintaining a locking force to maintain the assembly in the second state after removal of the external instrument that produced the force.

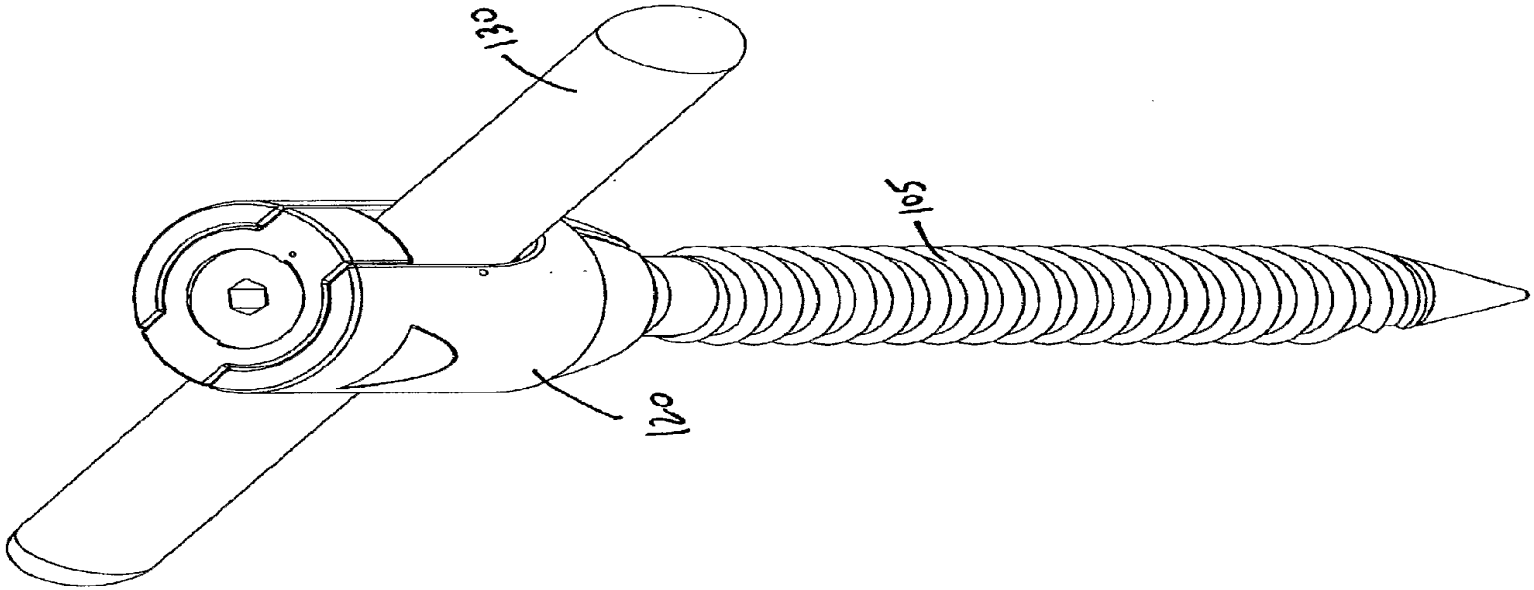



Fig. 1

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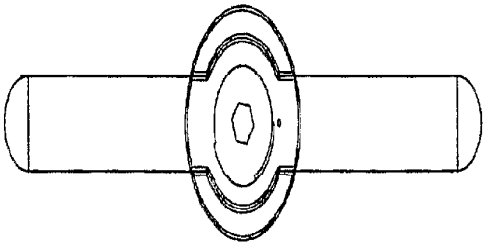


Fig. 2A

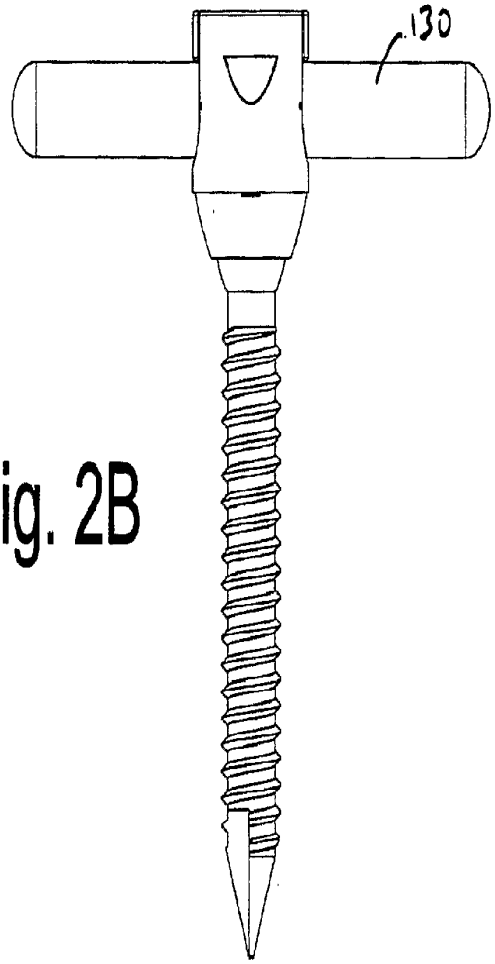



Fig. 2B

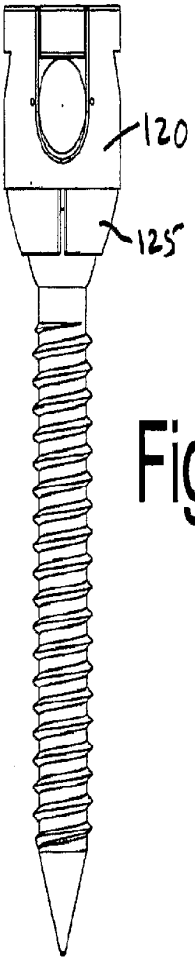



Fig. 2C

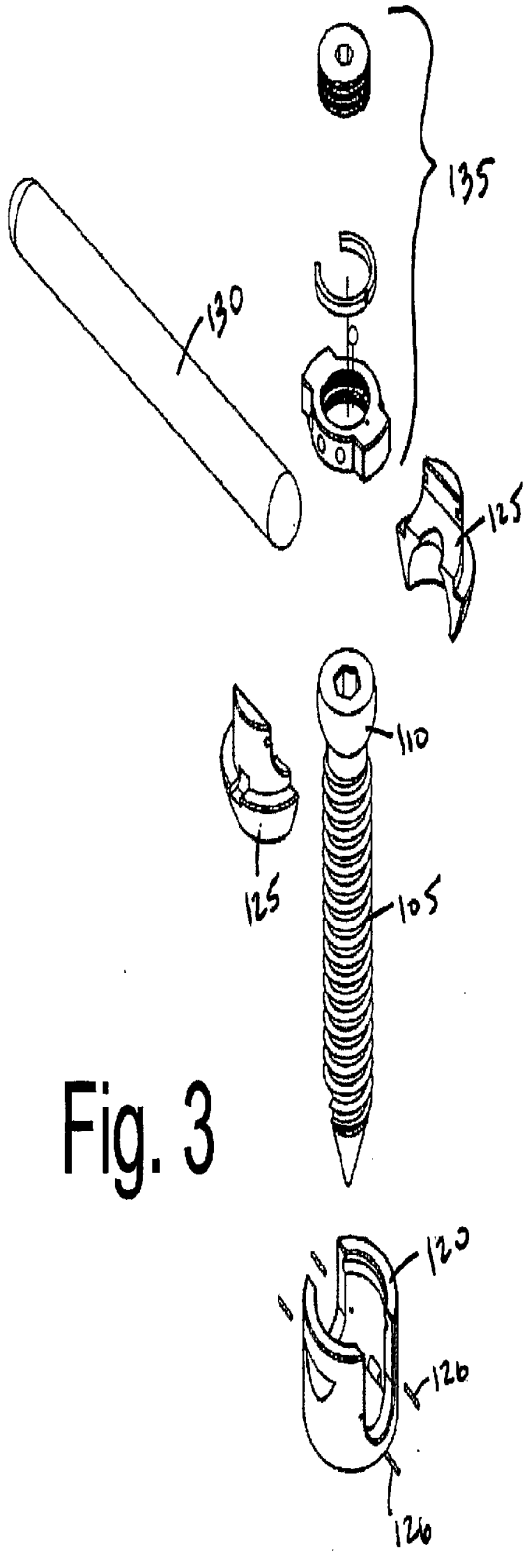



Fig. 3

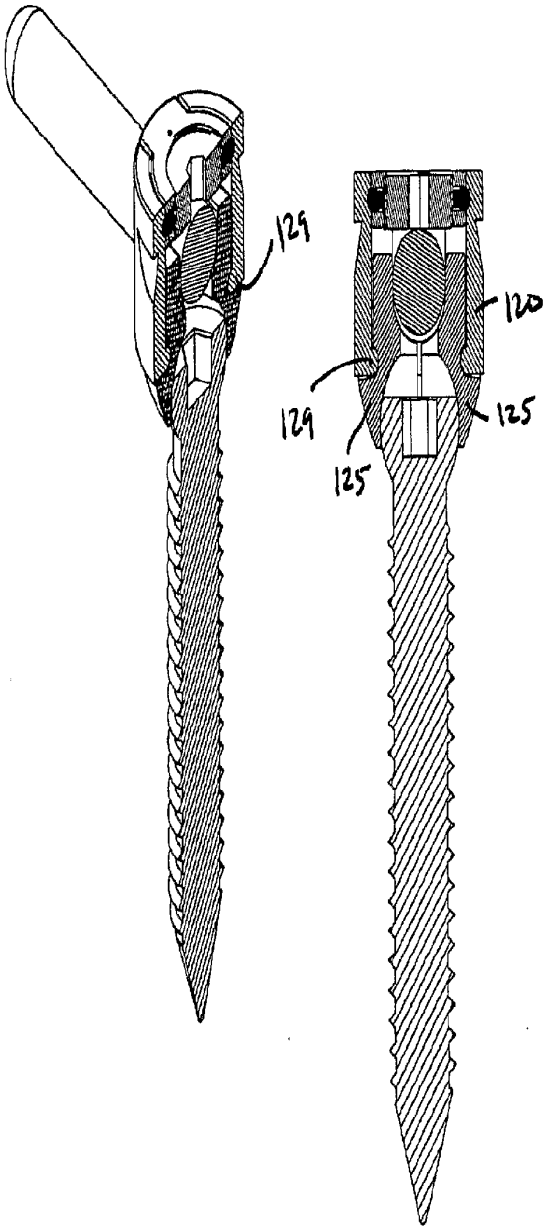



Fig. 4

Fig. 5

Fig. 6




Fig. 7

Fig. 8




Fig. 9

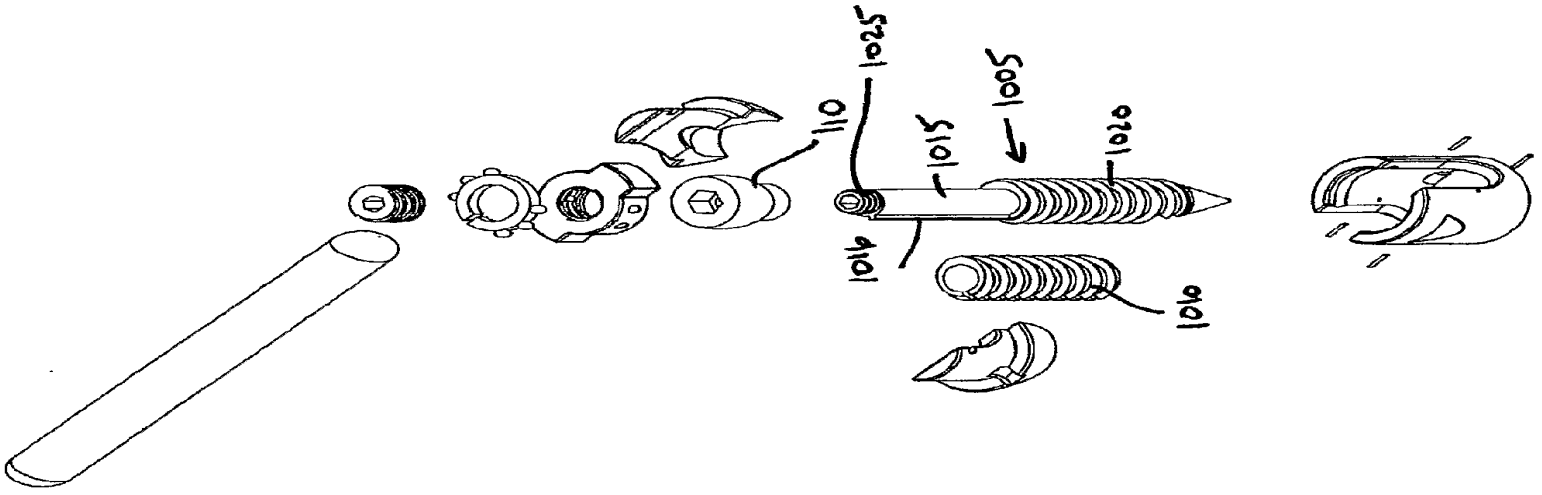



Fig. 10

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Fig. 11A



Fig. 11B

Fig. 12

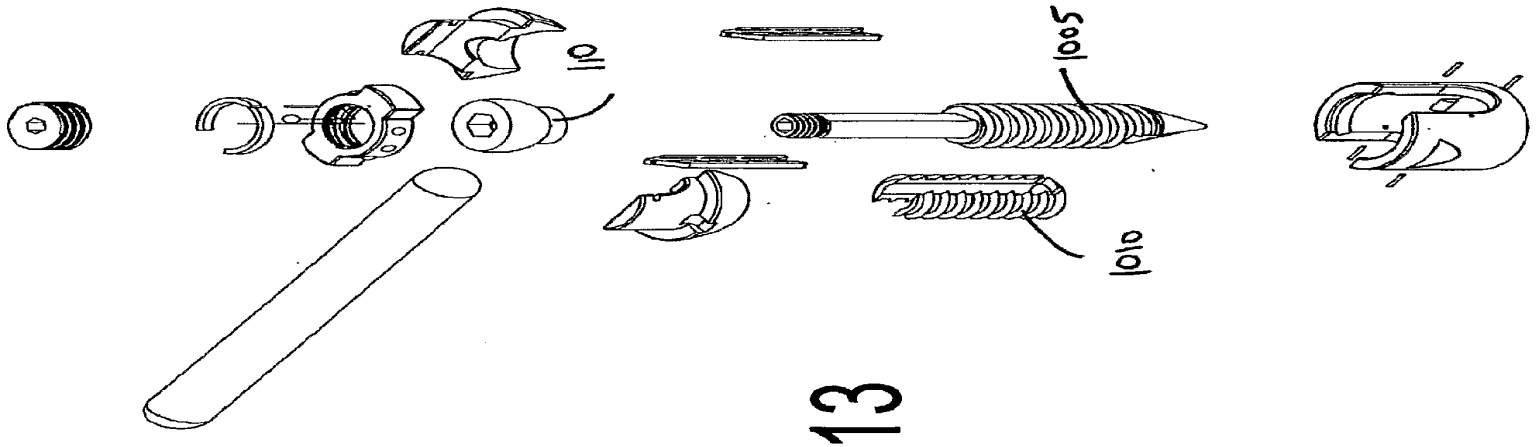



Fig. 13

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Fig. 14A



Fig. 14B

Fig. 15A



Fig. 15B

Fig. 16A




Fig. 16B

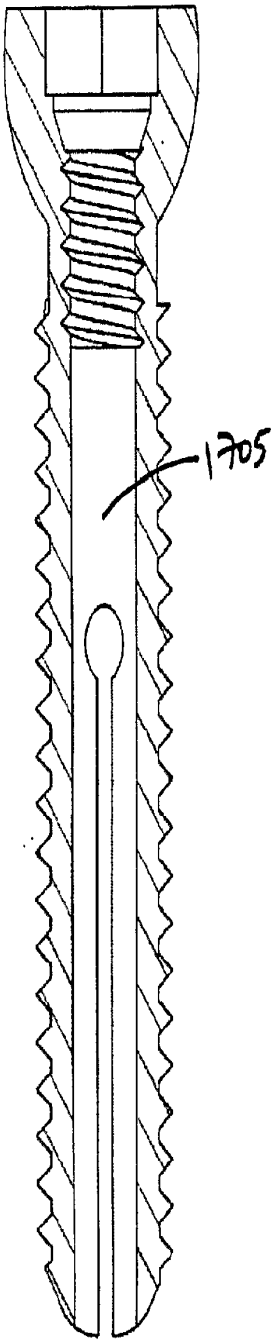



Fig. 17

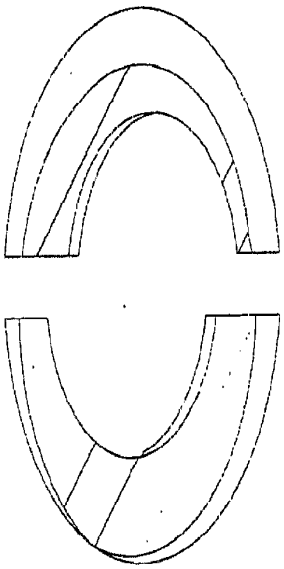


Fig. 18A

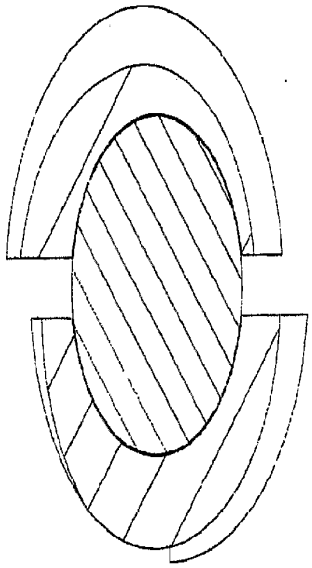


Fig. 18B

Fig. 19




Fig. 20

Fig. 21

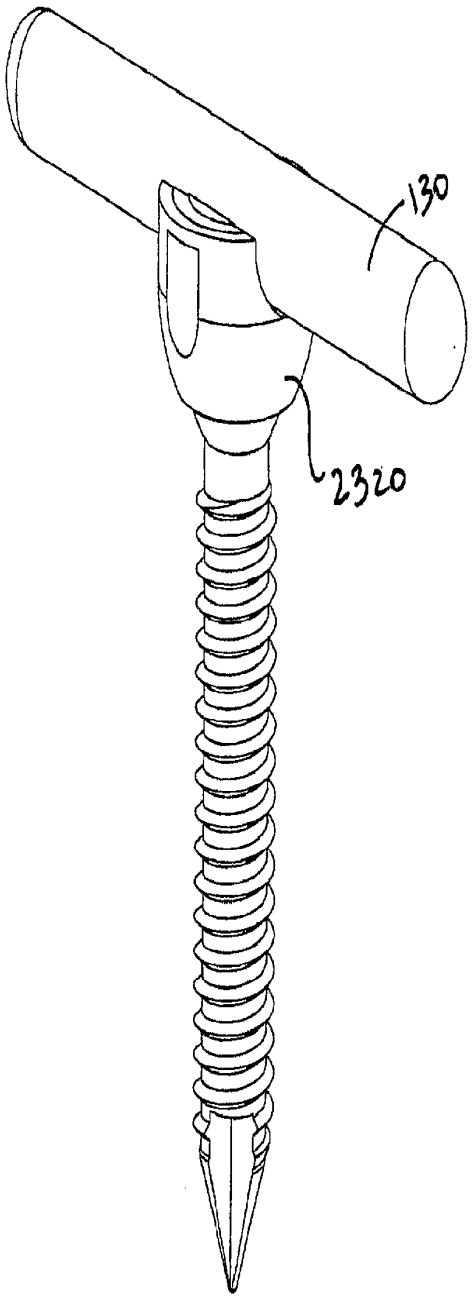



Fig. 22

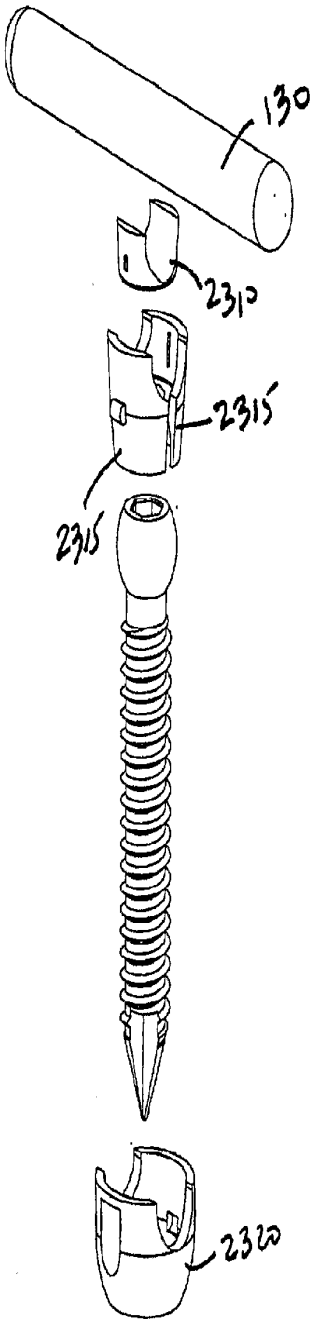



Fig. 23

Fig. 24




Fig. 25

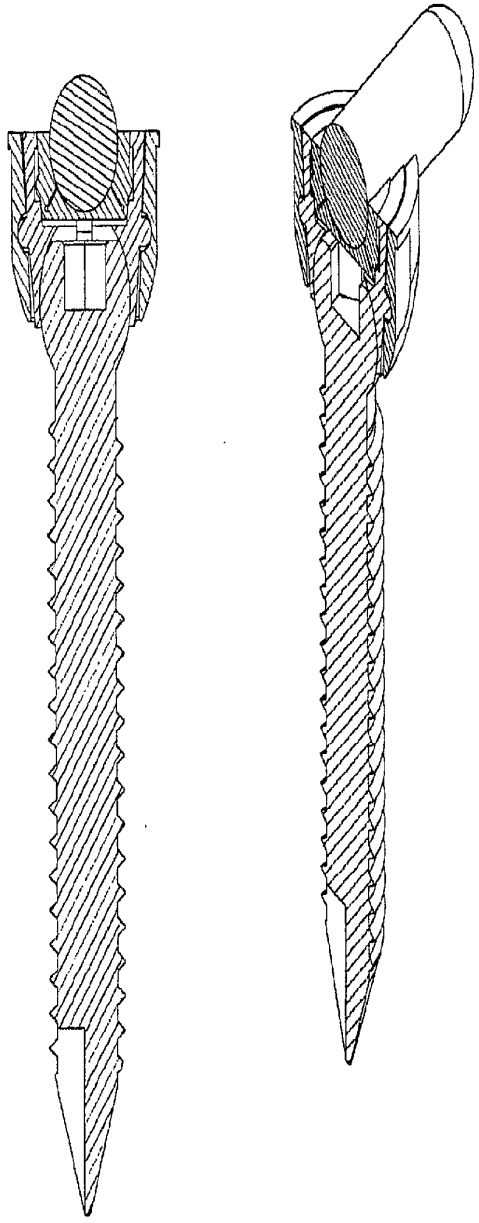


Fig. 26

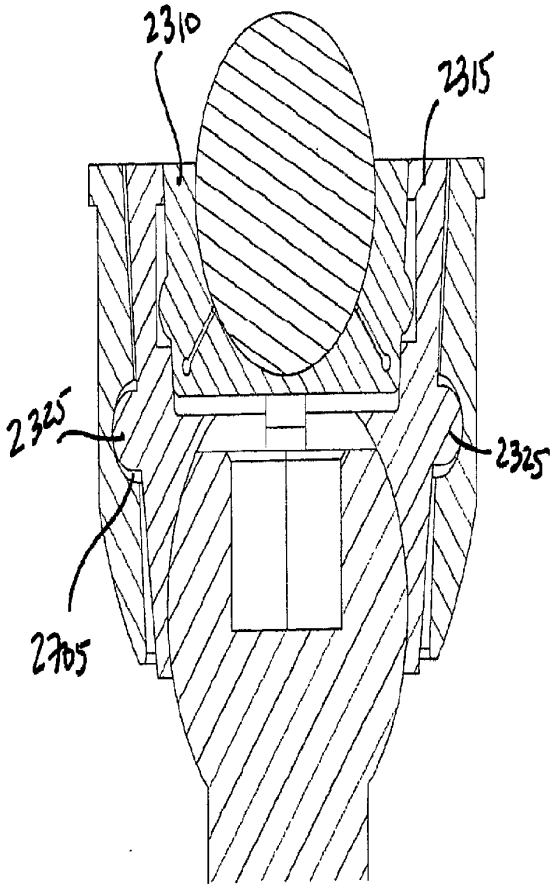



Fig. 27

Fig. 28

Fig. 29

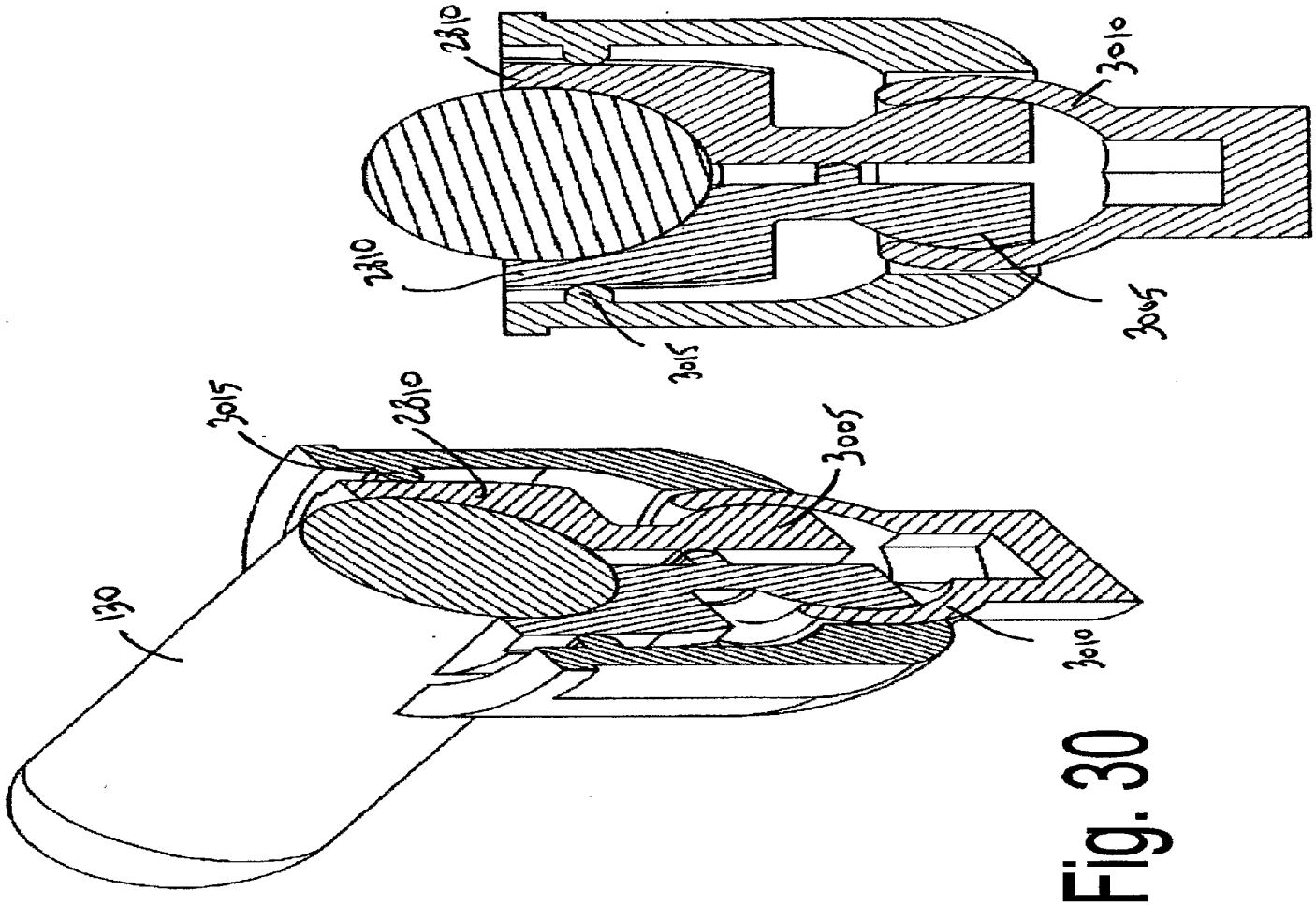



Fig. 30

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Fig. 31




Fig. 32

Fig. 33

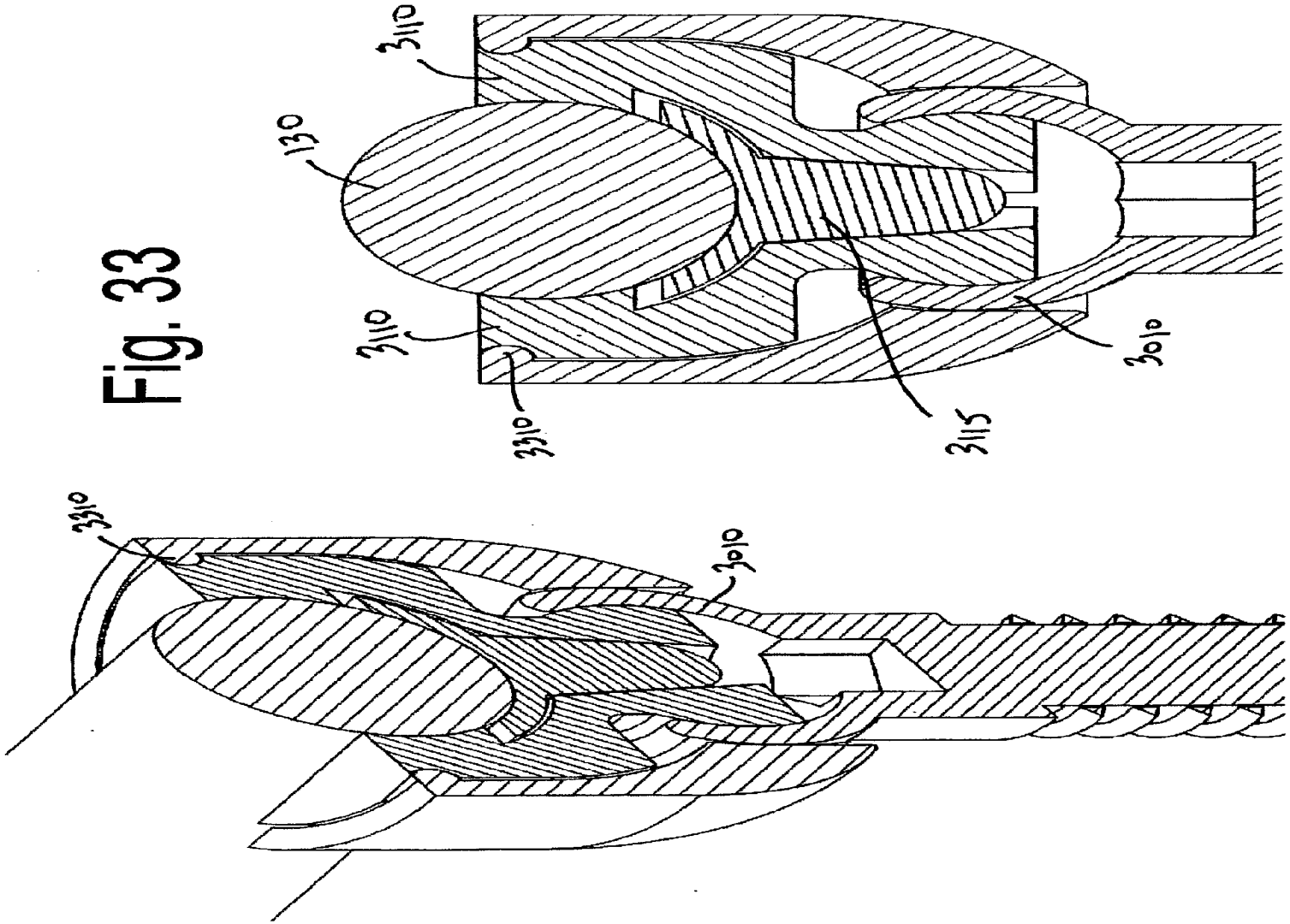



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Fig. 34

Fig. 35

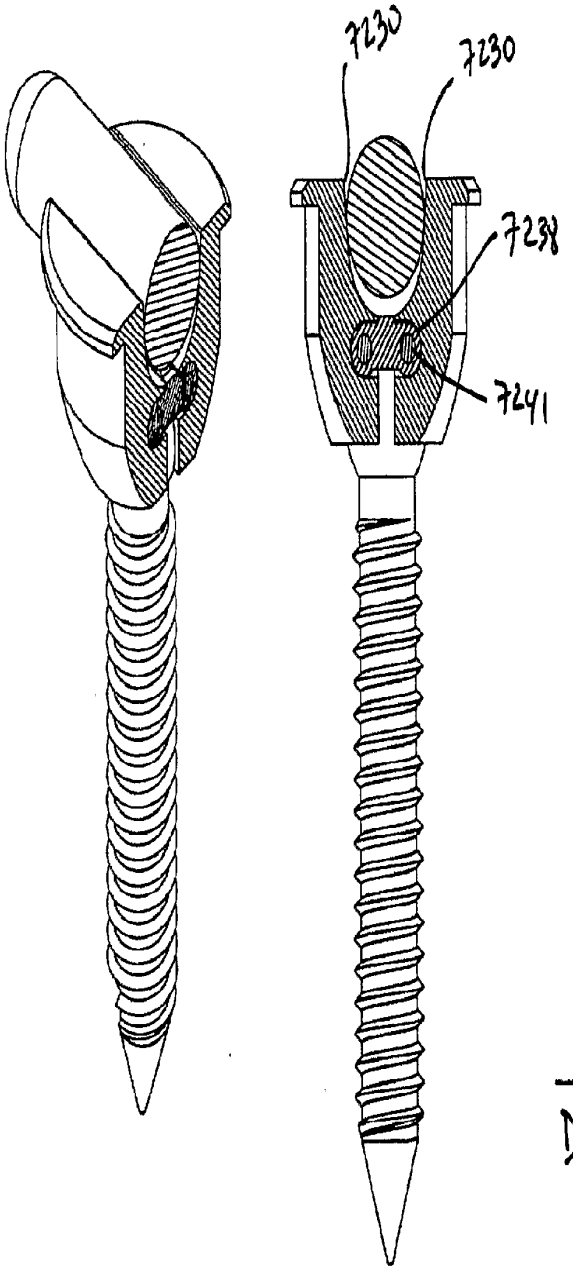



Fig. 36A

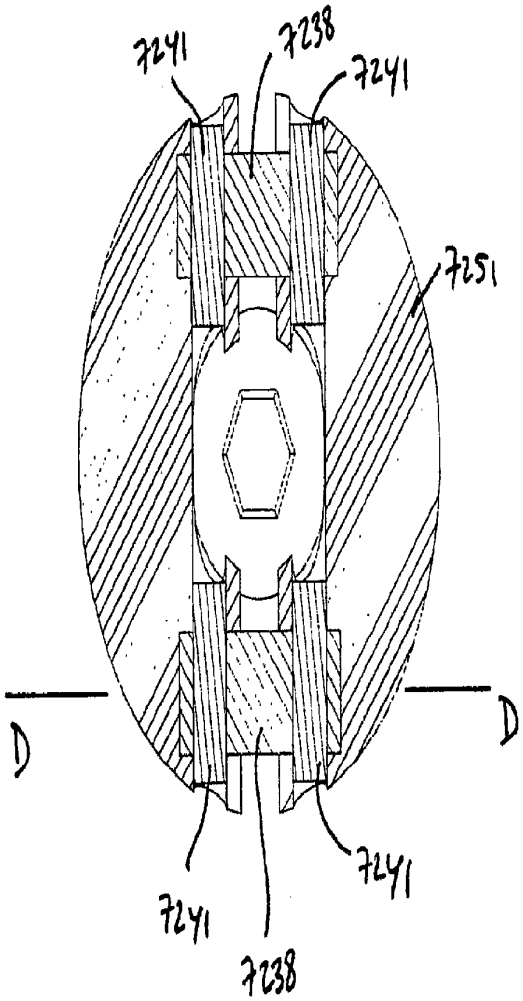



Fig. 36B

Fig. 37

Fig. 38A




Fig. 38B

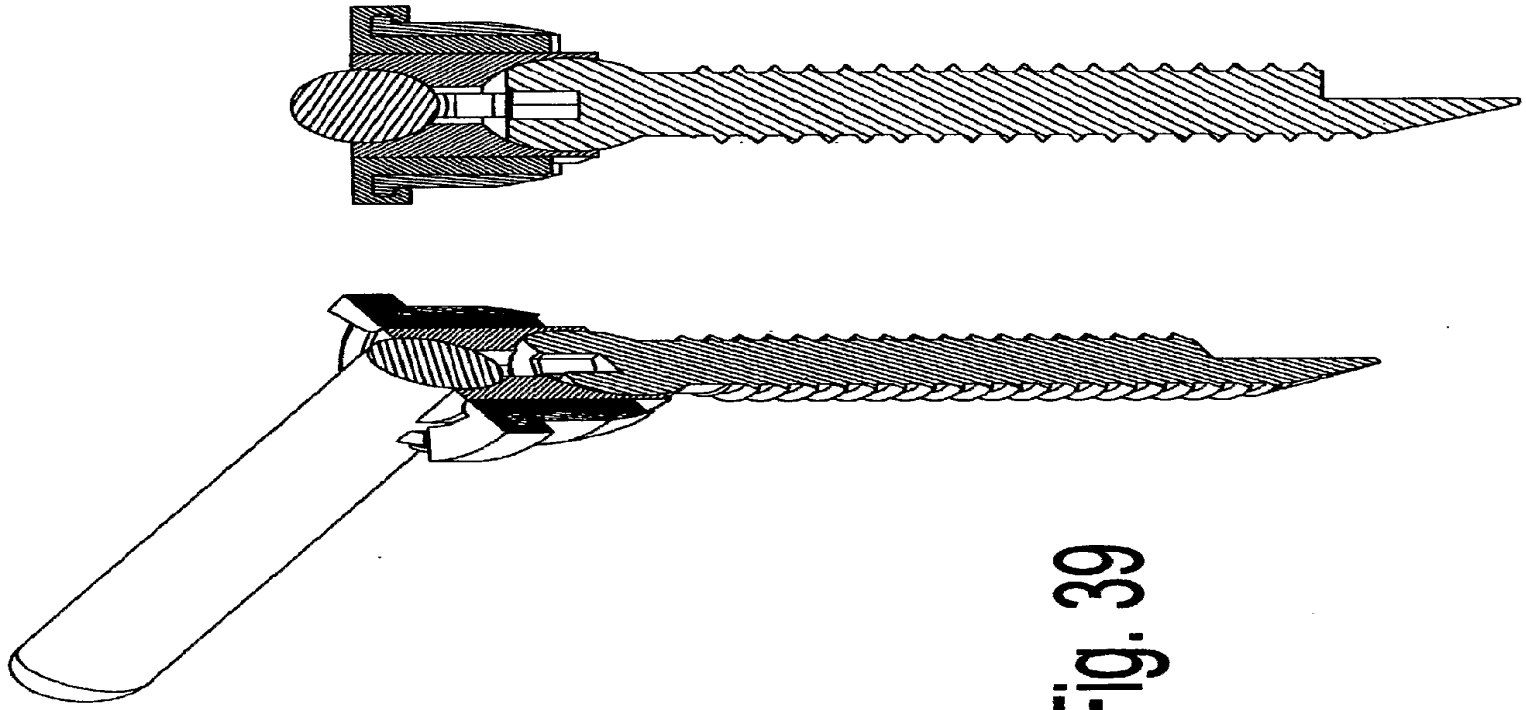


Fig. 39

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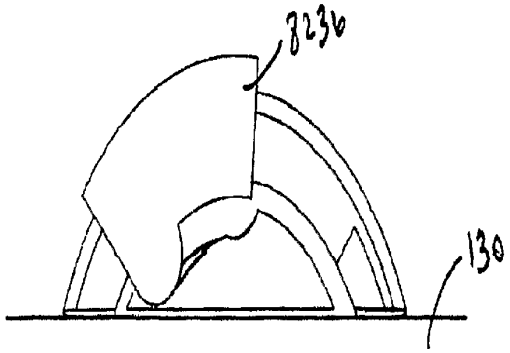
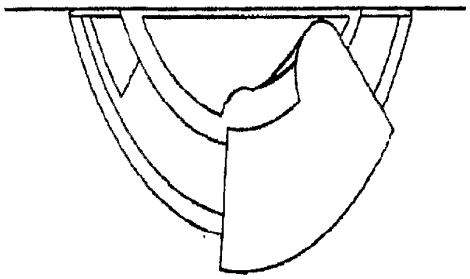



Fig. 40B



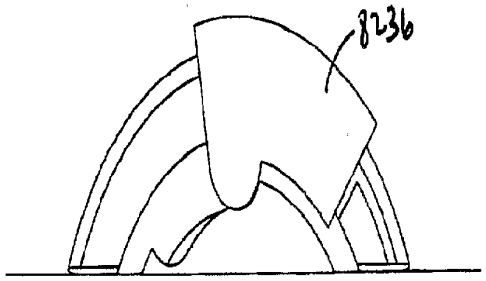
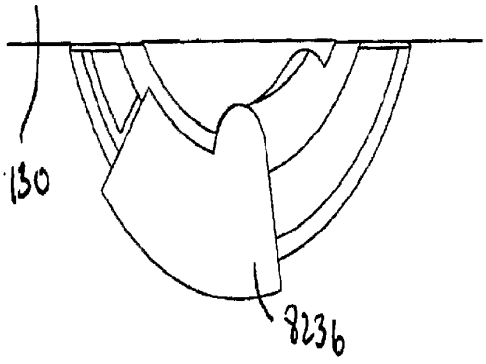



Fig. 40A



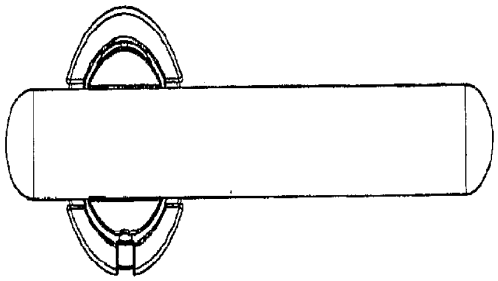


Fig. 41A

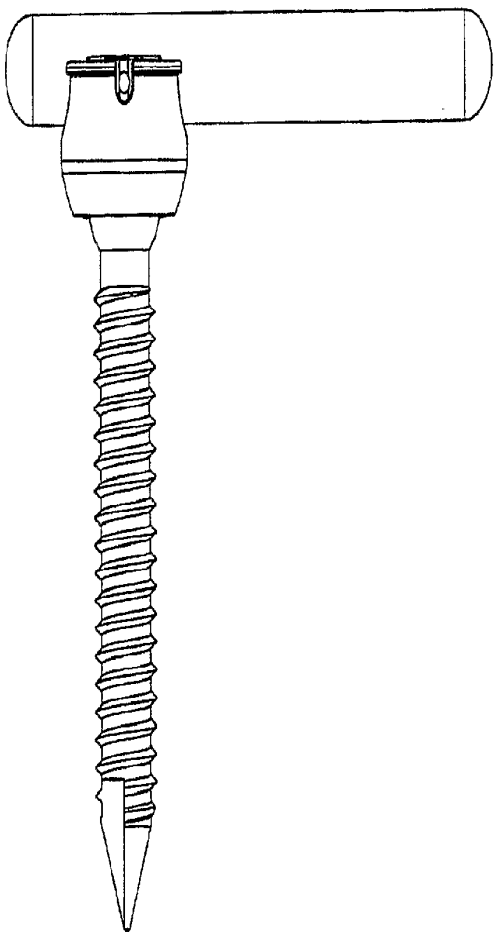


Fig. 41B

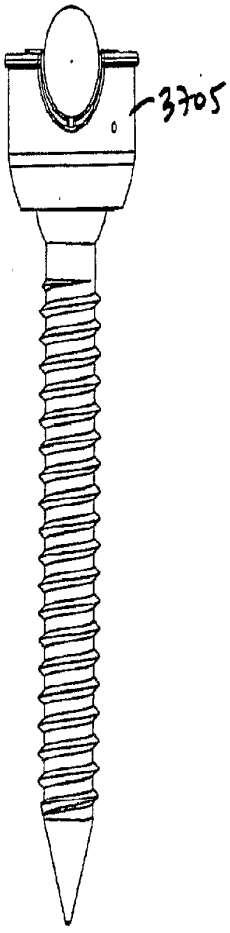



Fig. 41C

Fig. 42A




Fig. 42B

Fig. 43A




Fig. 43B

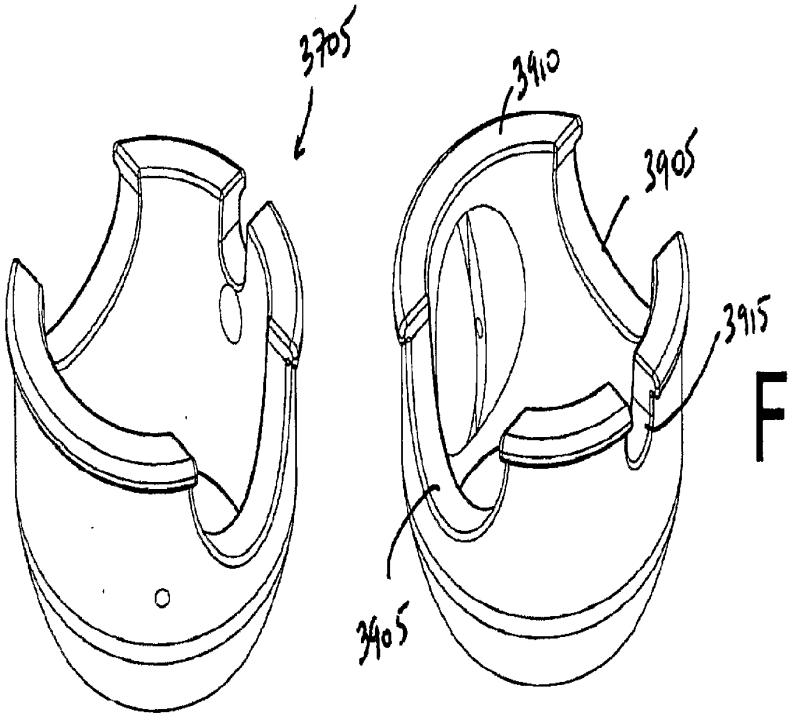



Fig. 44A

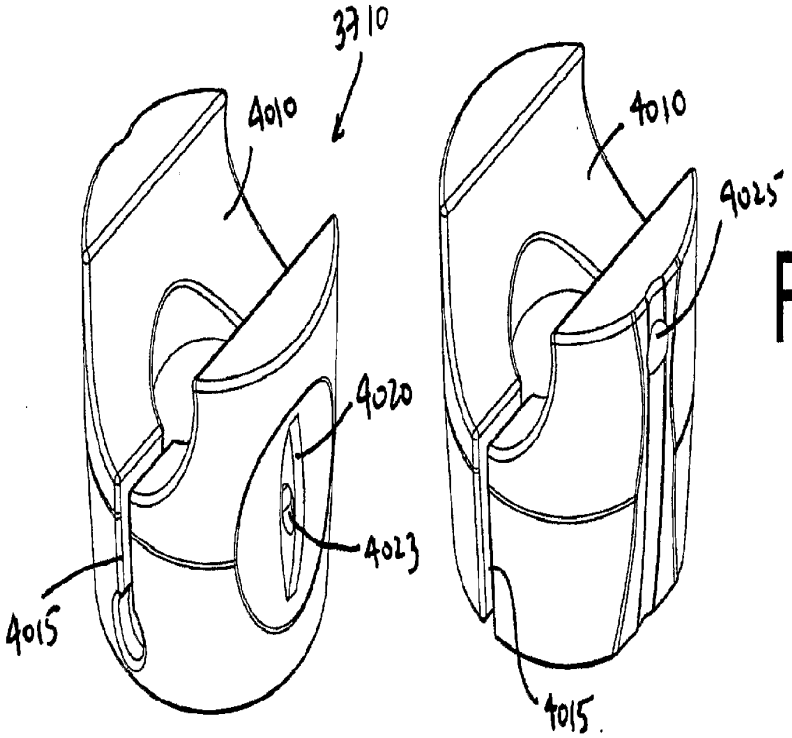



Fig. 44B

Fig. 45A




Fig. 45B

Fig. 46A



Fig. 46B

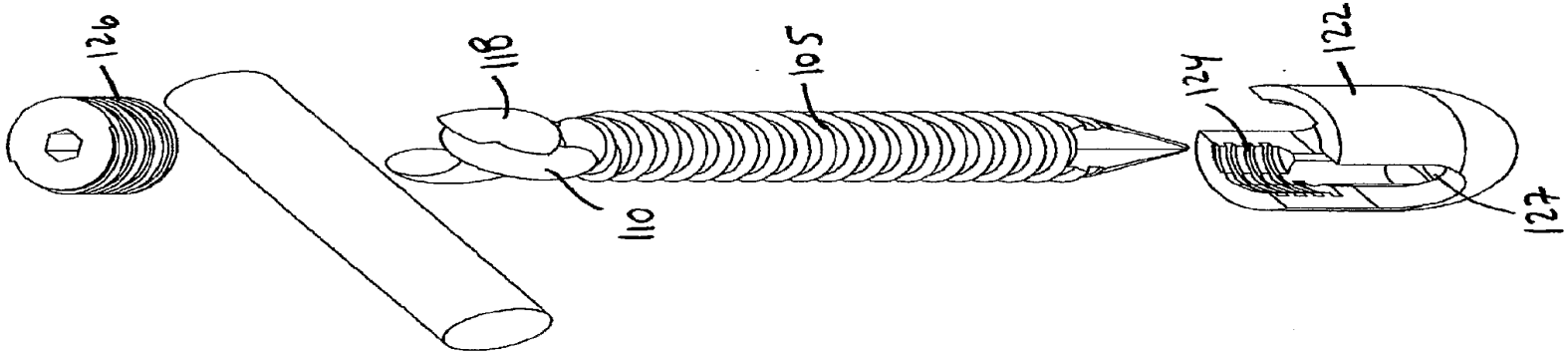



Fig. 47

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Fig. 48A




Fig. 48B

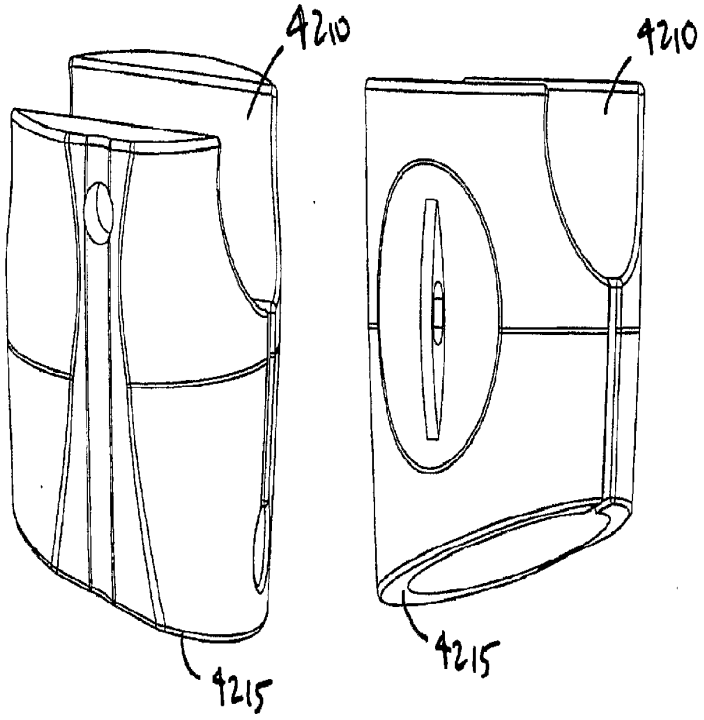



Fig. 49

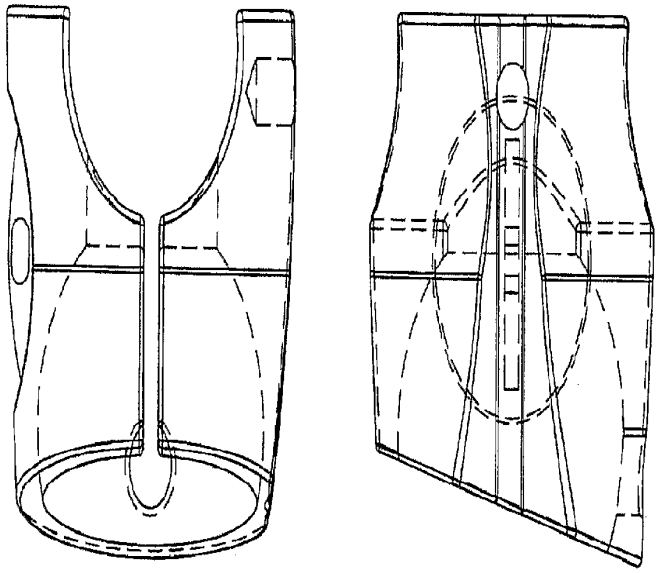


Fig. 50

Fig. 51A



Fig. 51B



Fig. 51C

Fig. 52A



Fig. 52B

Fig. 53

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
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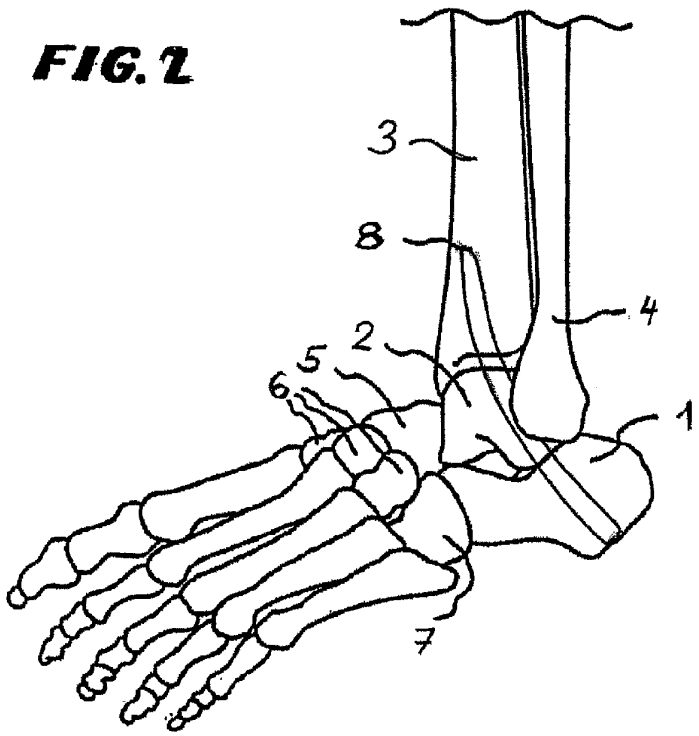
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(54) **Title:** BONE NAIL FOR THE HEEL

(54) **Bezeichnung:** KNOCHENNAGEL FÜR DIE FERSE

FIG. 1




(57) **Abstract:** The bone nail is intended for the heel. It comprises a front part (15) that is intended to be inserted in the bone and is provided with a tip (17) and it also comprises a rear part (16) having an end (18). The rear part (16) is rigid at a length of at least 120 mm, starting from the end (18). The bone nail is curved in a plane and the curvature for each infinitesimal section of the bone nail has a curvature radius that is at least 130 mm. The key advantages that can be achieved with the bone nail according to the invention and thanks to the surgical technique that becomes possible with it are the possibility to adjust the heel with high precision relative to the lower leg and knee axis, the avoidance of the risk of an injury to the plantar nerves, and a less invasive implant compared to known surgical techniques using other nails.

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*mit internationalem Recherchenbericht*

**(57) Zusammenfassung:** Der Knochennagel ist für die Ferse vorgesehen. Er weist einen vorderen zur Einführung in den Knochen bestimmten Teil (15) mit einer Spitze (17) sowie einem hinteren Teil (16) mit einem Ende (18) auf. Der hintere Teil (16) ist auf einer Länge von mindestens 120 mm, vom Ende (18) aus gerechnet, steif. Der Knochennagel ist in einer Ebene gekrümmt und die Krümmung weist für jeden infinitesimalen Abschnitt des Knochennagels einen Krümmungsradius auf, der mindestens 130 mm beträgt. Die wesentlichen Vorteile, die sich mit dem erfindungsgemässen Knochennagel und dank der damit möglichen Operationstechnik erzielen lassen sind die Möglichkeit der hochgenauen Einstellung des Rückfusses im Verhältnis zur Unterschenkel- und Knicachse, die Vermeidung des Risikos einer Verletzung der Plantar-Nerven; sowie eine weniger invasive Implantation im Vergleich zu bekannten Operationstechniken mit anderen Nägeln.

**Knochennagel für die Ferse**

Die Erfindung bezieht sich auf einen Knochennagel für die Ferse gemäss dem Oberbegriff des Patentanspruchs 1, auf ein Osteosynthese-Kit gemäss dem Oberbegriff des Patentanspruchs 16 sowie auf die Verwendung eines Knochennagels für die tibio-calcaneare Arthrodese gemäss dem Patentanspruch 17.

Marknägel, welche in einem Teilbereich eine Krümmung aufweisen sind schon lange bekannt. Beispielhaft können hier die sogenannten ENDER-Nägel angeführt werden. Allerdings sind diese bekannten Nägel aufgrund ihres Verwendungszweckes elastisch und flexibel ausgebildet, so dass sie sich schon bei geringen Belastungen durchbiegen. Wegen der Flexibilität dieser bekannten Nägel ist es auch gleichgültig, dass der Mittelteil geradlinig ist und keine Krümmung aufweist. Die bekannten ENDER-Nägel zeichnen sich weiter durch ihre verhältnismässige Länge und Dünne aus. Das Verhältnis zwischen Nageldurchmesser zur Nagellänge liegt bei ENDER im Bereich von 1:60 bis 1:110. Eine Verwendung im Fersenbereich scheidet auch aus diesem Grunde aus.
Im Weiteren sind auch Tibia-Nägel bekannt, welche teilweise gekrümmt sind, allerdings sind die Krümmungsradien dieser bekannten Nägel vergleichsweise klein, nämlich im Bereich von 100 und 120 mm, so dass sie für eine Anwendung im Fersenbereich ebenfalls nicht in Frage kommen.

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde einen Knochennagel für die Ferse zu schaffen, der dank seiner Form und Materialeigenschaften durch den Calcaneus und Talus bis in den Markraum der Tibia einführbar ist. Medizinisch handelt es sich um eine sogenannte tibio-calcaneare Arthrodese, welche manchmal auch „double arthrodese" genannt wird.

Die Erfindung löst die gestellte Aufgabe mit einem Knochennagel, welcher die Merkmale gemäss Anspruch 1 aufweist, einem Osteosynthese-Kit, welches die Merkmale des Anspruchs 16 aufweist, sowie mit einer Verwendung eines Knochennagels gemäss Anspruch 17.

Die wesentlichen Vorteile, die sich mit dem erfindungsgemässen Knochennagel und dank der damit möglichen Operationstechnik erzielen lassen sind die folgenden:

- Möglichkeit der hochgenauen Einstellung des Rückfusses im Verhältnis zur Unterschenkel- und Knieachse;
- Vermeidung des Risikos einer Verletzung der Plantar-Nerven; sowie
- eine weniger invasive Implantation im Vergleich zu anderen Techniken, welche mit Nägeln gemäss dem Stand der Technik angewendet werden müssen.

Dank dem erfindungsgemässen Knochennagel sind nun auch neuartige Indikationen behandelbar, wie z.B. die Behandlung von:

- diabetischen Füssen;
- schmerzhaften Arthrosen des oberen und unteren Sprunggelenkes;
- Nekrose des Talus; und
- Patienten mit Durchblutungsstörungen.

Bei einer besonderen Ausführungsform weist der Knochennagel einen Krümmungsradius von höchstens 240 mm, vorzugsweise höchstens 210 mm auf. Typischerweise beträgt der Krümmungsradius ca. 190 mm. Zweckmässigerweise variiert der Krümmungsradius über die gesamte Länge des Knochennagels nicht mehr als um 1 % und ist vorzugsweise konstant. Alternativ kann der Krümmungsradius aber auch im vorderen Teil zur Spitze des Knochennagels hin vorzugsweise stetig zunehmen.

Bei einer besonderen Ausführungsform ist der Knochennagel über seine gesamte Länge steif ausgebildet. Diese Ausgestaltung ist für die Ausführungsform als Fräserführungsdorn am zweckmässigsten.

Bei einer anderen Ausführungsform ist der vordere Teil weniger steif ausgebildet als der hintere Teil und vorzugsweise plastisch deformierbar. Diese Ausgestaltung ist für die Ausführungsform als Implantat am zweckmässigsten.

Im vorderen Teil des Knochennagels können auch Längsrillen vorgesehen sein, so dass der vordere Teil einen kleineren Querschnitt aufweist als der hintere Teil. Durch die Schwächung des Querschnitts ergibt sich eine Flexibilisierung des vorderen Teils gegenüber dem steifen hinteren Teil, was bei der Ausführungsform als Implantat

Vorteile bietet. Der Marknagel kann auch in der Spitzenhälfte rohrförmig ausgestaltet sein, vorzugsweise mit einer Wanddicke von 0,5 mm.
Der vordere Teil weist zweckmässigerweise höchsten 50 % der Steifigkeit des hinteren Teils auf.
Sowohl der vordere Teil als auch der hintere Teil des Knochennagels können 30 bis 70 % der Gesamtlänge des Knochennagels ausmachen.

In einer Ausführungsform ist der Knochennagel als Implantat ausgebildet mit einem Durchmesser $D_I$ von 9 bis 13 mm. In einer anderen Ausführungsform ist der Knochennagel als Fräserführungsdorn ausgebildet mit einem Durchmesser $D_D$ im Bereich von 3 bis 7 mm.

Der Knochennagel ist vorzugsweise biegesteif und kann beispielsweise aus einem gehärteten Stahl bestehen. Die Biegesteifigkeit B berechnet sich gemäss Wikipedia nach der Formel: $B = E \times I$ , wobei
I das Flächenmoment 2. Grades in $mm^4$ und E das E-Modul in $N / mm^2$ ist.
I ist abhängig von der gewählten Biegeachse; spielt aber bei rotationssymmetrischen Querschnittsflächen keine Rolle.

Der Krümmungsradius R des Knochennagels liegt zweckmässigerweise im Bereich von 140 bis 240 mm, vorzugsweise von 150 bis 210 mm. Diese Bereiche für den Krümmungsradius gestatten ein optimales Einbringen der Knochenbohrung über den Fräserführungsdorn und - nach erfolgter Auffräsung - ein optimales Einbringen des Implantats in die drei betroffenen Knochen: Calcaneus, Talus und Tibia. Vorteilhafterweise ist der Krümmungsradius R über die gesamte Länge des Knochennagels konstant. Da der Knochennagel – sowohl in seiner Ausgestaltung als Fräserführungsdorn als auch als Implantat - steif ist und sich somit kaum verbiegen kann, ist die konstante Krümmung vorteilhaft, um den Knochennagel mit möglichst geringem Aufwand in die betroffenen Knochen einschlagen zu können.

Der Knochennagel ist zweckmässigerweise über seine gesamte Länge, vorzugsweise stetig, gekrümmt. Diese Ausgestaltung führt zu einer möglichst leichten Einführung des Knochennagels: Ein Knochennagel mit einem gerader Abschnitt (neben gekrümmten

Abschnitten) würde die Einführung durch Anstossen des Knochennagels an der Bohrungswand erschweren.

Bei einer besonderen Ausführungsform weist der als Implantat ausgebildete Knochennagel eine Länge $L_I$ kleiner als 160 mm, vorzugsweise kleiner als 150 mm auf. Bei dieser Länge reicht das Implantat bis zu einem Bereich der Tibia, wo dank der Weite des Markkanals ein gewisser Ausgleich stattfinden kann; bei einer grösseren Nagellänge würde die Spitze des Knochennagels in einen weiter verengten Bereich des Tibia-Markkanals gelangen, was die Einführung erschweren würde. Die Länge $L_I$ ist aber zweckmässigerweise grösser als 125 mm, vorzugsweise grösser als 130 mm.

Bei einer besonderen Ausführungsform erstreckt sich der als Implantat ausgebildete Knochennagel über einen Kreisbogen von 38° - 70°, vorzugsweise von 48° - 55°.

Bei einer anderen Ausführungsform weist der als Fräserführungsdorn ausgebildete Knochennagel eine Länge $L_D$ im Bereich von 220 bis 260 mm auf.

Der als Implantat ausgebildete Knochennagel weist zweckmässigerweise ein Verhältnis $L_I/D_I$ zwischen seiner Länge $L_I$ und seinem Durchmesser $D_I$ auf, welches kleiner als 16, vorzugsweise kleiner als 14 ist. Der als Fräserführungsdorn ausgebildete Knochennagel weist zweckmässigerweise ein Verhältnis $L_D/D_D$ zwischen seiner Länge $L_D$ und seinem Durchmesser $D_D$ im Bereich von 30 – 90 auf.

Bei einer besonderen Ausführungsform weist der Knochennagel mindestens eine Querbohrung zur Aufnahme einer Verriegelungsschraube auf, wobei die Längsachse der Querbohrung vorzugsweise in der Krümmungsebene des Knochennagels liegt. Die Querbohrung kann z.B. im Kopfbereich des Knochennagels liegen und dessen Längsachse kann einen Winkel alpha von vorzugsweise 10° bis 20° mit der Längsachse des Knochennagels einschliessen.

Bei einer besonderen Ausführungsform weist der als Fräserführungsdorn ausgebildete Knochennagel eine scharfe Spitze auf, vorzugsweise in Form einer Meisselspitze. Die Meisselspitze ist vorteilhafterweise nur auf einer Seite abgeschrägt, vorzugsweise auf der Aussenseite der Krümmung des Knochennagels.

In einer weiteren Ausführungsform beträgt der Krümmungsradius des Knochennagels oder des als Fräserführungsdorn ausgebildeten Knochennagels mindestens 190 mm, vorzugsweise mindestens 200 mm.

In einer anderen Ausführungsform weist der Knochennagel mindestens im vorderen Teil einen Längsschlitz auf.

In einer weiteren Ausführungsform weist der Knochennagel mindestens im vorderen Teil ein kleeblattförmiges Querschnittsprofil auf.

In wiederum einer anderen Ausführungsform ist der hintere Teil des Knochennagels steif ausgebildet.

In einer weiteren Ausführungsform umfasst der Knochennagel zwischen dem vorderen Teil und dem hinteren Teil einen intermediären Teil, dessen Steifigkeit gegen den hinteren Teil zunimmt.

In einer anderen Ausführungsform umfassst der Knochennagel mindestens im vorderen Teil einen zur Längsachse parallelen Hohlraum.

Mindestens ein als Implantat ausgebildeter Knochennagel zusammen mit mindestens einem als Fräserführungsdorn ausgebildeten Knochennagel können zu einem Osteosynthese-Kit zusammengefasst werden, wobei die Krümmungsradien des Implantats und des Fräserführungsdorns gleich gross sein müssen. Die Länge $L_D$ des Fräserführungsdorns in einem solchen Kit ist vorteilhafterweise 80 bis 120 mm, vorzugsweise 90 bis 110 mm länger als die Länge $L_I$ des Implantats.

Die Erfindung und Weiterbildungen der Erfindung werden im Folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine schematische Schräg-Ansicht der Unterschenkel- und Fuss-Knochen;

Fig. 2 eine Ausführungsform des in die Knochen implantierten erfindungsgemässen Knochennagels;

Fig. 3 eine schematische Ansicht des erfindungsgemässen Knochennagels nach Fig. 2 in seiner Ausgestaltung als Implantat;

Fig. 4 eine schematische Ansicht des erfindungsgemässen Knochennagel in seiner Ausgestaltung als Fräserführungsdorn;

Fig. 5 den im Knochen implantierten Knochennagel gemäss den Fig. 2 und 3 von schräg vorne und seine Verriegelung mit drei Verriegelungsschrauben;

Fig. 6 die Lage des implantierten Knochennagels gemäss den Fig. 2 und 3 von plantar her gesehen;

Fig. 7 eine schematische Ansicht von antero-lateral einer weiteren Ausführungsform des in den Knochen implantierten erfindungsgemässen Knochennagels;

Fig. 8 einen Querschnitt bei der Linie X – Y in Fig. 7;

Fig. 9 einen Querschnitt bei der Linie Z – Y in Fig. 7; und

Fig. 10 einen Querschnitt bei der Linie W – Y in Fig. 7.

Die Fig. 1 zeigt den Unterschenkel in einer Position, in welcher er um ca. 45° nach Innen gedreht ist. Es sind diejenigen Knochen dargestellt, welche für die Anwendung des erfindungsgemässen Knochennagels von Bedeutung sind. Es handelt sich primär um den Calcaneus 1, den Talus 2 und die Tibia 3. Die ebenfalls dargestellte Fibula 4, Os naviculare 5, Ossa cuneiformia 6 und Os cuboideum 7 sind nur der Vollständigkeit halber eingezeichnet.

In Fig. 2 ist der erfindungsgemässe als Implantat 8 ausgebildete Knochennagel eingezeichnet, welcher durch den Calcaneus 1 und den Talus 2 bis in den unteren Teil

der Tibia 3 implantiert ist. Wie in Fig. 3 dargestellt ist das Implantat 8 in einer Ebene stetig gekrümmt mit einem Krümmungsradius R von typischerweise 190 mm. Die Krümmung erstreckt sich über die gesamte Länge $L_I$ des Implantats 8, welche typischerweise 140 mm beträgt. Sein Durchmesser $D_I$ beträgt typischerweise 11 mm. Das Verhältnis $L_I/D_I$ zwischen Länge $L_I$ und Durchmesser $D_I$ des Implantats 8 beträgt typischerweise 12,7.

Das Implantat 8 weist eine Anzahl von Querbohrungen 9, 10, 11, 12 auf, in welche Verriegelungsschrauben 30 eingeführt werden können. Drei der Querbohrungen 9, 11, 12 liegen in der gleichen Ebene in welcher das Implantat 8 gekrümmt ist. Eine vierte Querbohrung 12 liegt am proximalen Ende des Implantats 8 und verläuft senkrecht zur erwähnten Krümmungsebene.

Die Längsachse 13 der am distalen Ende des Implantats 8 liegenden Querbohrung 9 schliesst mit der Längsachse 14 des Implantats 8 einen Winkel alpha von 15° ein.

Das Implantat 8 besteht aus einem steifen Material - insbesondere bezüglich Biegung – und besteht beispielsweise aus einem der bekannten Implantatstähle, welche vorzugsweise gehärtet worden sind, um die Biegesteifigkeit des Implantats 8 weiter zu erhöhen.

Um das Implantat 8 in den Knochen einführen zu können ist es je nach Knochenqualität vorteilhaft die betroffenen Knochen 1, 2, 3 zuvor aufzubohren. Dies geschieht mittels des in Fig. 4 dargestellten Knochennagels in seiner Ausgestaltungsform als Fräserführungsdorn 20 für eine Knochenfräse. Der Fräserführungsdorn 20 muss notwendigerweise die gleiche – in einer Ebene liegende - Krümmung aufweisen wie der als Implantat 8 ausgebildete Knochennagel und ebenfalls aus einem steifen Material bestehen. Er ist aber länger ausgebildet – typischerweise etwa 100 mm länger – als der als Implantat 8 ausgebildete Knochennagel und notwendigerweise dünner als letzterer, typischerweise beträgt sein Durchmesser ungefähr 5 mm.

Der Fräserführungsdorn 20 besitzt ein scharf ausgebildete Spitze 17 in Form einer Meisselspitze 21 um leicht in den Calcaneus 1 einschlagbar zu sein. Die Meisselspitze 21 ist nur auf einer Seite abgeschrägt und zwar auf der Aussenseite der Krümmung des Fräserführungsdorns 20.

In Fig. 5 ist der Fuss mit dem Unterschenkel um ca. 45° nach Innen gedreht. Das Implantat 8 ist in seiner endgültigen implantierten Lage dargestellt. Eine erste Verriegelungsschraube 30 in der Querbohrung 9 sichert das Implantat 8 im Calcaneus

1 und im Talus 2. Eine zweite Verrieglungsschraube 31 in der Querbohrung 10 blockiert das Implantat 8 im Talus 2. Eine dritte Verrieglungsschraube 32 in der Querbohrung 11 blockiert das Implantat 8 in der Tibia 3 und im Talus 2. Somit werden die drei Knochen Tibia 3, Talus 2 und Calcaneus 1 zusammen versteift und zwar – was wichtig ist – in einer anatomisch richtigen Stellung.

Fig. 6 zeigt einen linken Rückfuss (Skelett) mit der Lage des Eintritt-Orts des erfindungsgemässen als Implantat 8 ausgebildeten Knochennagels und dessen Verlauf im Knochen in einer plantaren Ansicht.

In den Fig. 7 – 10 ist eine weitere Ausführungsform des Implantates 8 in Form eines Knochennagels dargestellt, welche sich von den Ausführungsformen gemäss den Fig. 2 – 6 nur darin unterscheidet, dass der Knochennagel:

a) in seinem vorderen Teil 15 ein kleeblattförmiges Querschnittsprofil 22 (Fig. 8), einen zur Längsachse 14 parallelen Hohlraum 26 und einen zur Längsachse 14 parallelen Längsschlitz 19 umfasst; und
b) zwischen seinem vorderen Teil 15 und seinem hinteren Teil 16 einen intermediären Teil 25 umfasst, welcher als Übergangsbereich zwischen dem vorderen Teil 15 mit kleiner Steifigkeit und dem hinteren Teil 16 mit hoher Steifigkeit ausgebildet ist, so dass die Steifigkeit des Knochennagels gegen den hinteren Teil 16 kontinuierlich zunimmt.

Durch den Hohlraum 26 erhält der Knochennagel im vorderen Teil 15 ein dünnwandiges Querschnittsprofil 22 mit einer peripheren eine geringe Wandstärke aufweisenden Wand 28, welche zudem durch den Längsschlitz 19 parallel zur Längsachse 14 durchtrennt ist. Die Kleeblattform im Querschnittsprofil 22 ergibt sich durch die Ausbildung der Wand 28 mit zwei sich parallel zur Längsachse 14 erstreckenden Einbuchtungen 29 im vorderen Teil 15. Die zwei Einbuchtungen 29 sind derart auf dem Umfang des Knochennagels angeordnet, dass eine dem Längsschlitz 19 diametral gegenüberliegende, sich ebenfalls parallel zur Längsachse erstreckende konvexe Ausbuchtung 27 der Wand 28 gebildet wird. Im intermediären Teil 25 nimmt die Steifigkeit vom vorderen Teil 15 gegen den hinteren Teil 16 durch eine gegen den hinteren Teil 16 zunehmende Wandstärke der Wand 28 zu. Diese zunehmende

Wandstärke wird einerseits durch ein kontinuierliches Verengen des Hohlraums 26 und andererseits dadurch erreicht, dass die radiale gemessene Tiefe der Einbuchtungen 29 in der Wand 28 gegen den hinteren Teil 16 kontinuierlich abnimmt, so dass ein kontinuierlicher Übergang vom kleeblattförmigen Querschnittsprofil 22 im vorderen Teil 15 zum kreisförmigen Querschnittsprofil 24 im hinteren Teil 16 gebildet wird. Vor der Implantation hat der intermediäre Teil 25 und der vordere Teil 15 des Knochennagels eine gekrümmte Form (gestrichelt dargestellt) mit demselben Krümmungsradius r wie der hintere Teil 16. Durch die geringere Steifigkeit des intermediären Teils 25 und insbesondere des vorderen Teils 15 können sich diese während des Einbringens in die Tibia 3 deformieren, so dass der vordere Teil 15 nach der Implantation einen erheblich grösseren Krümmungsradius aufweisen kann oder sogar geradlinig geformt sein kann.

Im Folgenden wird die generelle Operationsmethode definiert:

1. Entknorpelung der Gelenke und Mobilisation der drei Knochen: Tibia 3; Talus 2 und Calcaneus 1.
2. Einstellung der gewünschten Position der oben erwähnten drei Knochen bezüglich Winkelstellung und Verschiebung.
3. Fixation der oben erwähnten drei Knochen bezüglich ihrer relativen eingestellten Position mittels des als Implantat 8 ausgebildeten Knochennagels; und
4. Optionale Verriegelung des Implantats 8 mit den Verrieglungsschrauben 30.

Im Folgenden wird eine etwas ausführlichere Operationstechnik für den als Implantat 8 ausgebildeten Knochennagel beschrieben:

a) Patient in Rücken-, Bauch-, oder Seitenlage bringen;
b) durch einen gezielten, begrenzten, vorderen, Seiten-, oder postero-lateralen Zugang werden beide Gelenke (oberes und subtalares) angegangen und der Restknorpel entfernt;
c) Tibia 3, Talus 2 und Calcaneus 1 sollen frei beweglich sein um die gewünschte Reorientierung (Einstellung) zu erreichen;
d) die angezielte Position wird mit perkutan eingebrachten, festen Kirschnerdrähten (3 mm Durchmesser) fixiert;
e) Zugang von ca. 2 – 3 cm Länge an der lateralen Ferse;
f) Aufsuchen des postero-lateralen Calcaneusrandes (tuber calcanei);

g) Aufbohren der Corticalis (dünn) mit einem 5 – 7 mm Bohrer;

h) Einführen in den Calcaneus 1 eines gebogenen, an seiner Spitze einseitig geschliffenen erfindungsgemässen Knochennagels in seiner Ausgestaltungsform als Fräserführungsdorn 20 (Durchmesser 6 mm) in einer schrägen Ebene zum Rückfuss (ca. 45° von postero-lateral, gesehen von der Sagittal- oder Frontalebene) [Siehe Fig. 6];

i) Durchquerung des Calcaneus 1 und des Talus 2 auf Höhe der posterioren subtalaren Gelenksfazette;

j) Proximale Durchquerung des Talus 2 auf Höhe des Doms;

k) Die Metaphyse der Tibia 3 wird aufgefädelt, bis dass der Fräserführungsdorn 20 auf der postero-lateralen Corticalis anstösst;

l) der Fräser (Durchmesser 11 mm) wird auf den Fräserführungsdorn 20 aufgefädelt und der Weg für den als Implantat 8 ausgebildeten Knochennagel gefräst;

m) Herausziehen des Fräsers und des Fräserführungsdorns 20;

n) Einbringen des Implantats 8 mit eventuellem Zielgriff, der Bohrungen für die Verrieglungsschrauben 30 enthält;

o) Einbringen perkutan der eventuellen Verrieglungsschrauben 30 (für die Tibia 3, den Talus 2, und den Calcaneus 1); und

p) Anbringen der Hautnaht.

Patentansprüche

1. Knochennagel für die Ferse mit

A) einem vorderen zur Einführung in den Knochen bestimmten Teil (15) mit einer Spitze (17);

B) einem hinteren Teil (16) mit einem Ende (18)

**dadurch gekennzeichnet, dass**

C) der hintere Teil (16) auf einer Länge von mindestens 120 mm, vom Ende (18) aus gerechnet, steif ist;

D) der Knochennagel in einer Ebene gekrümmt ist; und

E) die Krümmung für jeden infinitesimalen Abschnitt des Knochennagels einen Krümmungsradius aufweist, der mindestens 130 mm beträgt.

2. Knochennagel nach Anspruch 1, dadurch gekennzeichnet, dass der Krümmungsradius höchstens 240 mm, vorzugsweise höchstens 210 mm beträgt.

3. Knochennagel nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass der Krümmungsradius im vorderen Teil (15) zur Spitze (17) hin vorzugsweise stetig zunimmt.

4. Knochennagel nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass der vordere Teil (15) weniger steif ist als der hintere Teil (16) und vorzugsweise plastisch deformierbar ausgebildet ist.

5. Knochennagel nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass er als Implantat (8) ausgebildet ist und das Verhältnis $L_I/D_I$ zwischen seiner Länge $L_I$ und seinem Durchmesser $D_I$ kleiner als 16, vorzugsweise kleiner als 14 ist.

6. Knochennagel nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass er als Implantat (8) ausgebildet ist und mindestens eine Querbohrung (9;10;11;12) zur Aufnahme einer Verriegelungsschraube (30) aufweist, wobei die Längsachse der Querbohrung vorzugsweise in der Krümmungsebene des Knochennagels liegt.

7. Knochennagel nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass er als Fräserführungsdorn (20) ausgebildet ist mit einem Durchmesser $D_D$ im Bereich von 3 bis 7 mm.

8. Knochennagel nach einem der Ansprüche 1 bis 4 oder 7, dadurch gekennzeichnet er als Fräserführungsdorn (20) ausgebildet ist und das Verhältnis $L_D/D_D$ zwischen seiner Länge $L_D$ und seinem Durchmesser $D_D$ im Bereich von 30 – 90 liegt.

9. Knochennagel nach einem der Ansprüche 1 bis 4 oder 7-8, dadurch gekennzeichnet, dass er als Fräserführungsdorn (20) ausgebildet ist und die Spitze (17) scharf ausgebildet ist, vorzugsweise in Form einer Meisselspitze (21).

10. Knochennagel nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass der Krümmungsradius mindestens 190 mm, vorzugsweise mindestens 200 mm beträgt.

11. Knochennagel nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass er mindestens im vorderen Teil (15) einen Längsschlitz (19) aufweist.

12. Knochennagel nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, dass er mindestens im vorderen Teil (15) ein kleeblattförmiges Querschnittsprofil (22) aufweist.

13. Knochennagel nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass sein hinterer Teil (16) steif ausgebildet ist.

14. Knochennagel nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, dass der Knochennagel zwischen dem vorderen Teil (15) und dem hinteren Teil (16) einen intermediären Teil (25) umfasst, dessen Steifigkeit gegen den hinteren Teil (16) zunimmt.

15. Knochennagel nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass der Knochennagel mindestens im vorderen Teil (15) einen zur Längsachse (14) parallelen Hohlraum (26) umfasst.

16. Osteosynthese-Kit umfassend einen als Implantat (8) ausgebildeten Knochennagel nach einem der Ansprüche 1 bis 6 oder 10 bis 15 und einen als Fräserführungsdorn (20) ausgebildeten Knochennagel nach einem der Ansprüche 1 bis 4 oder 7 bis 9. dadurch gekennzeichnet, dass die Krümmungsradien des Implantats (8) und des Fräserführungsdorns (20) gleich gross sind.

17. Verwendung eines Knochennagels nach einem der Ansprüche 1 bis 15 für die tibio-calcaneare Arthrodese.

FIG. 1

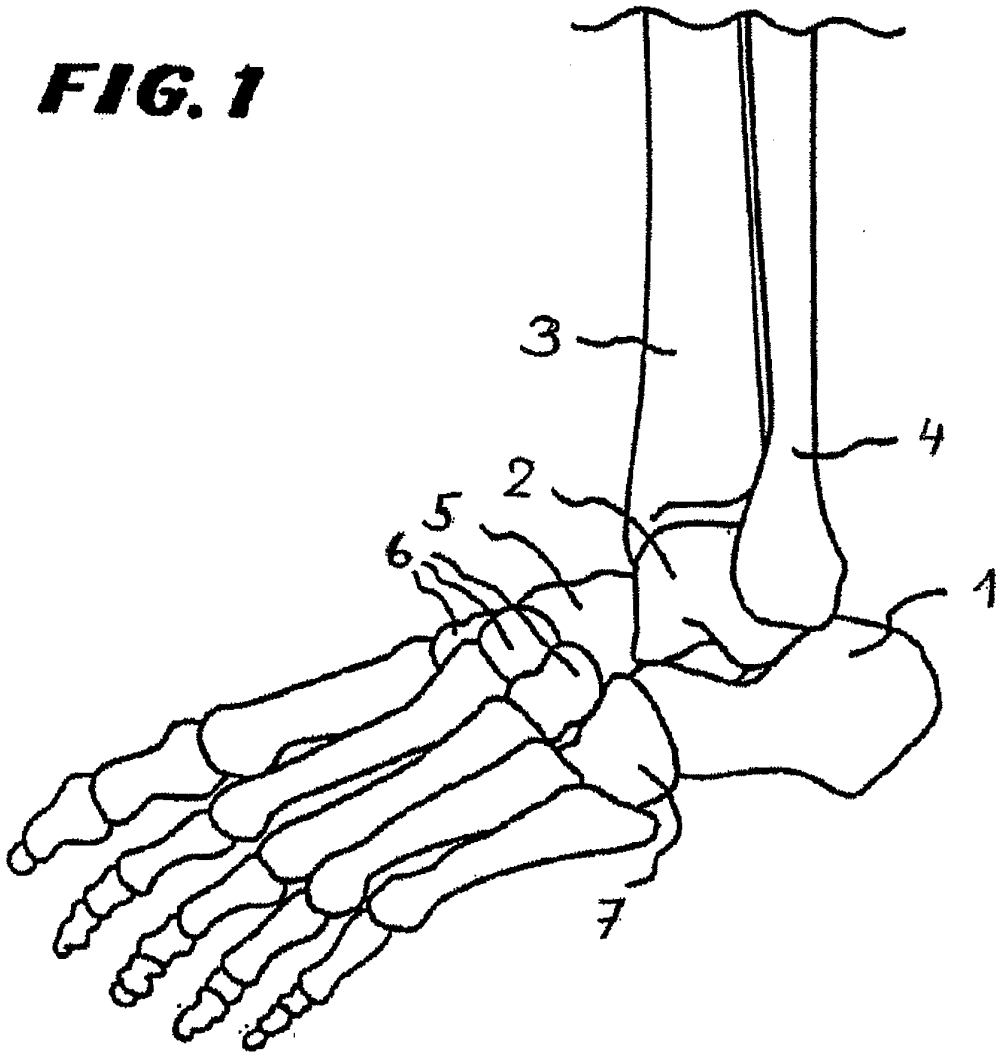
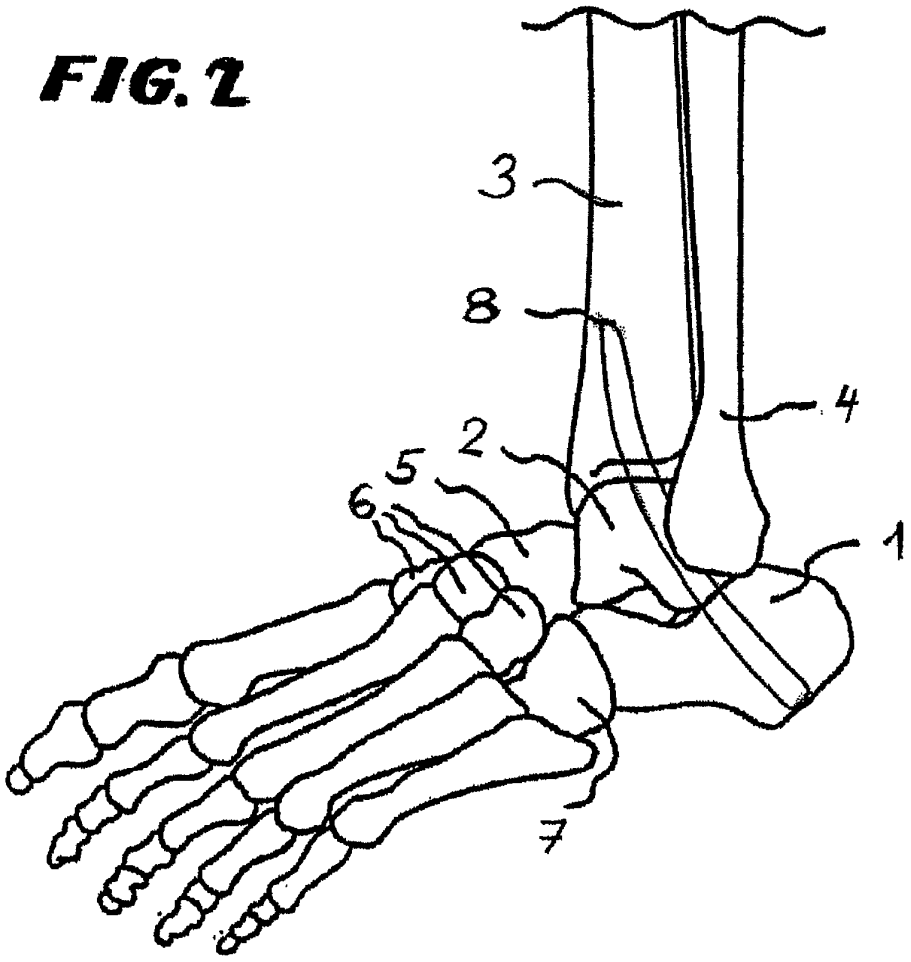


FIG. 2



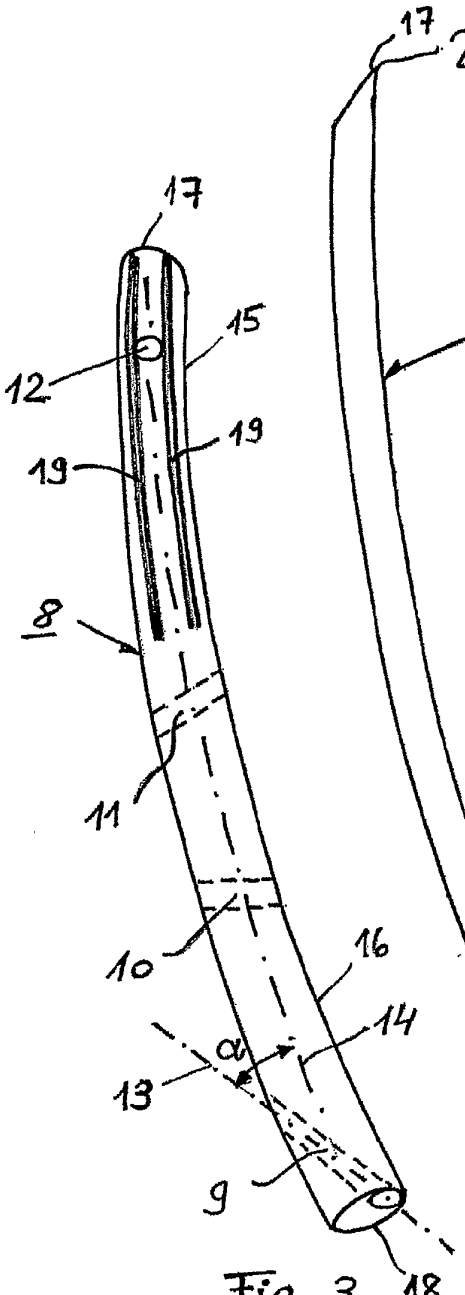



Fig. 3

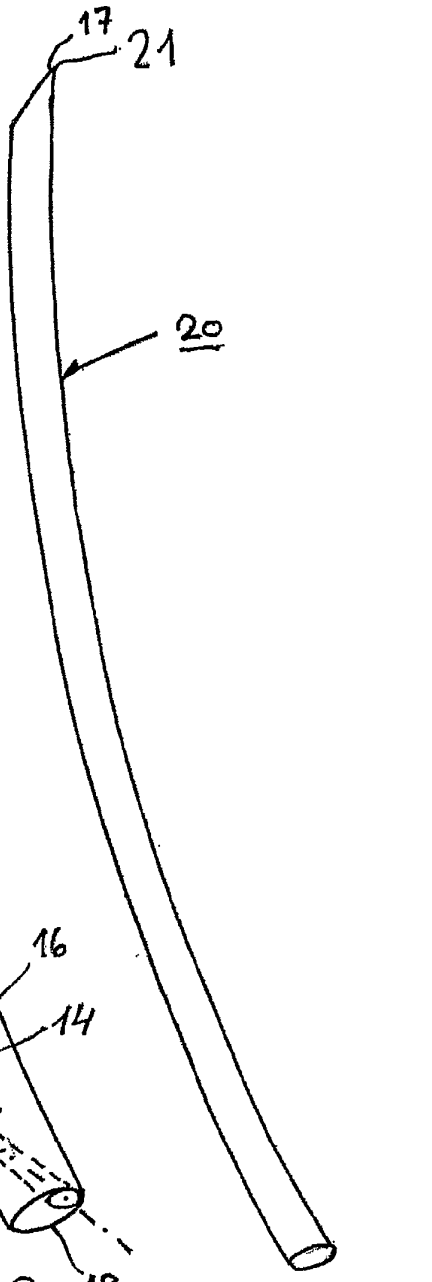



Fig. 4

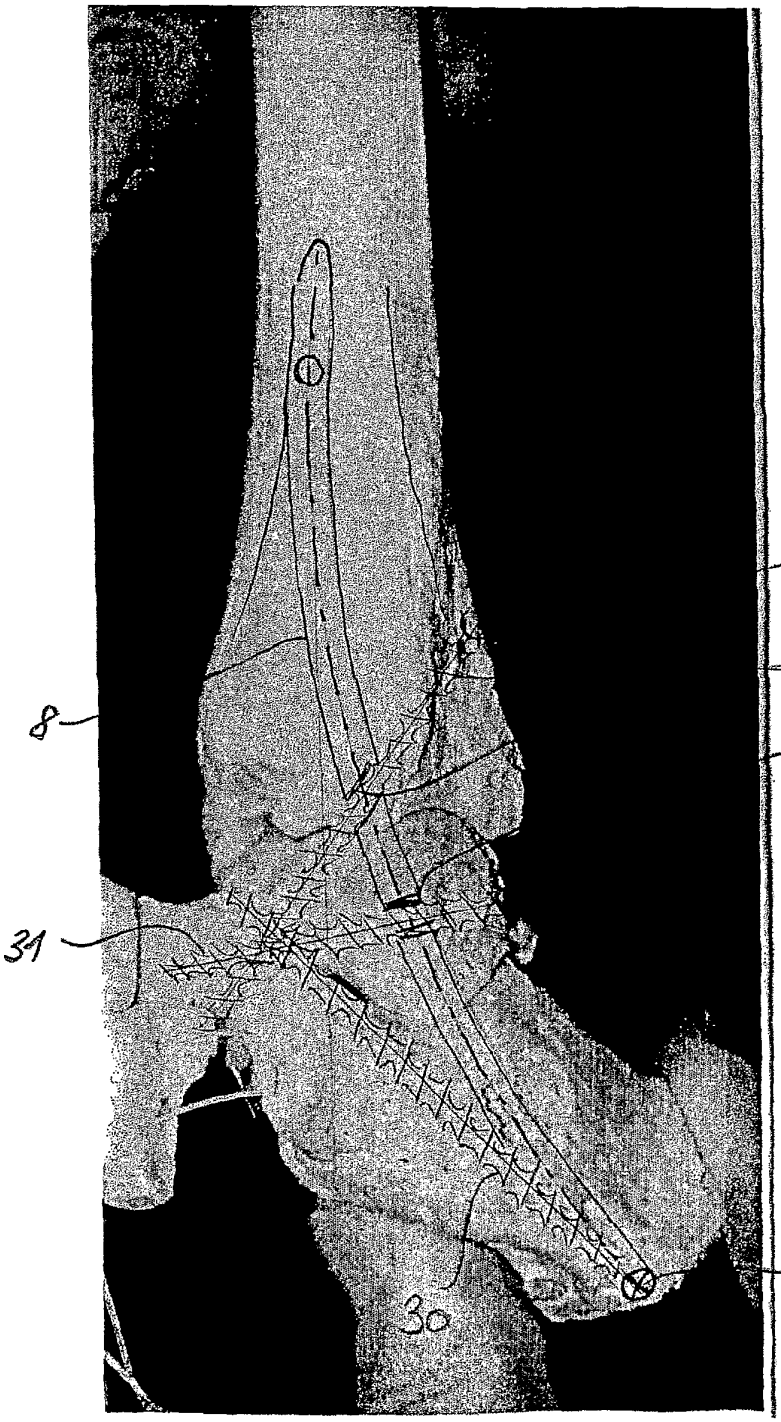



Fig. 5

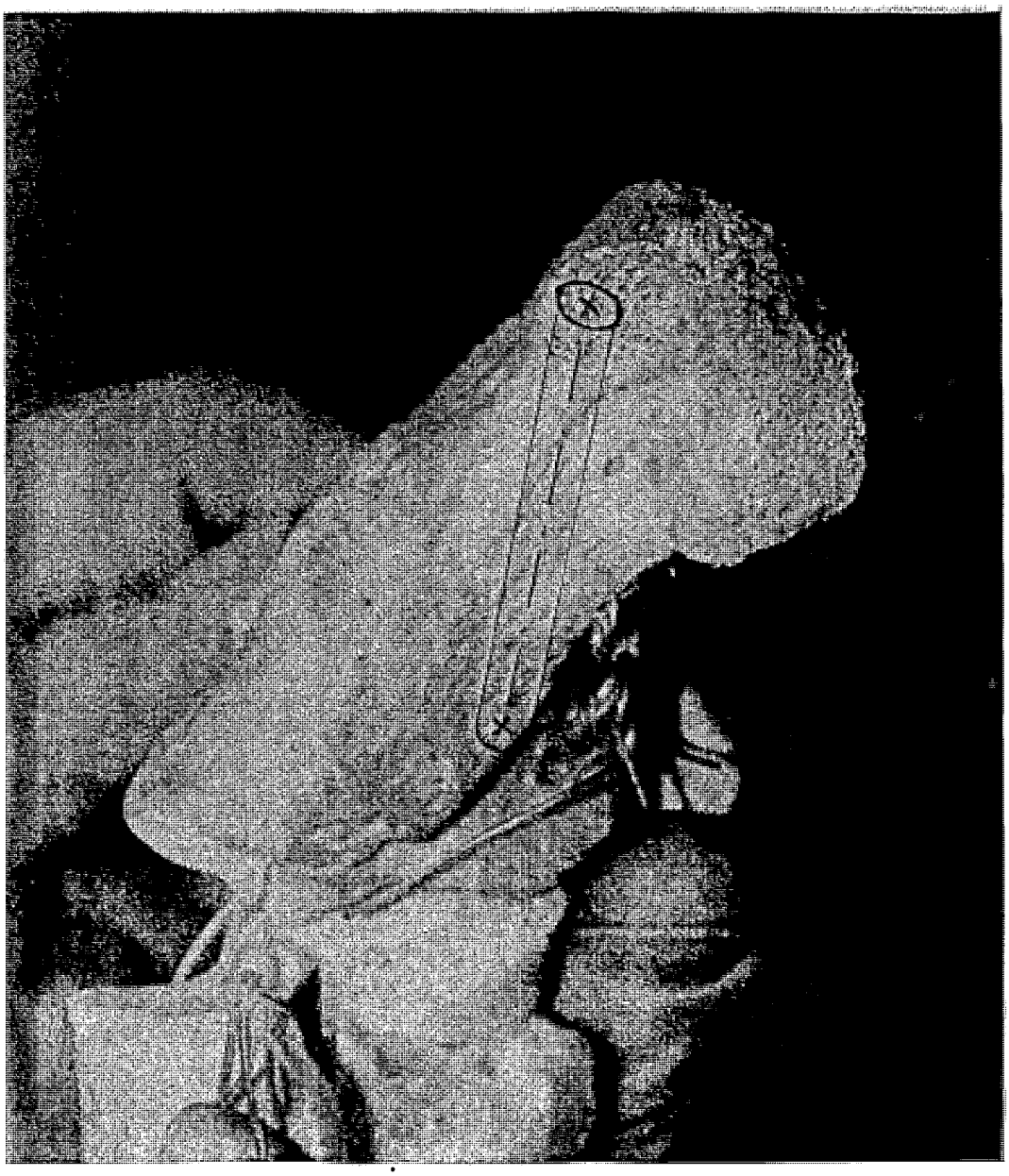


Fig. 6

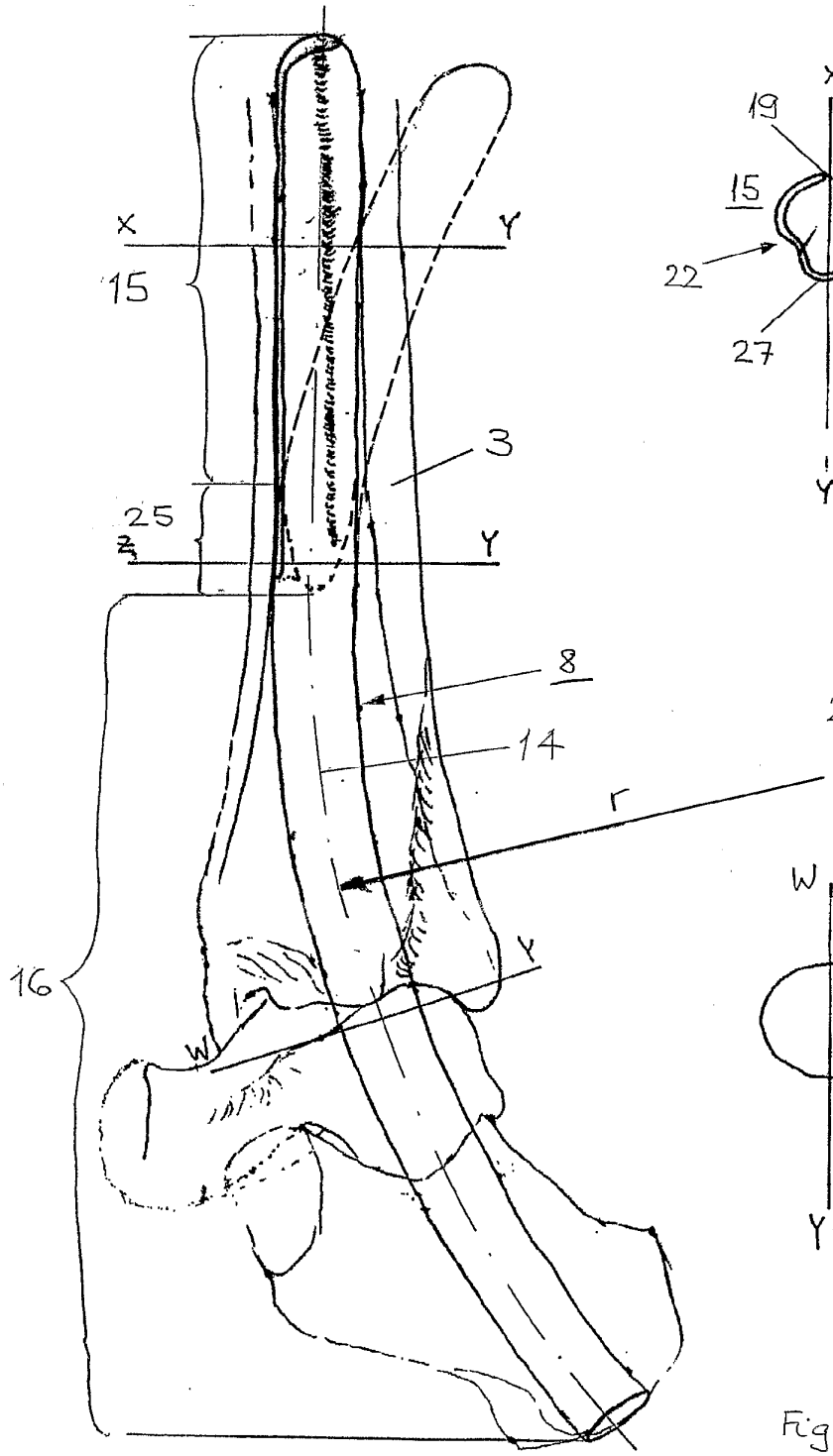



Fig. 7

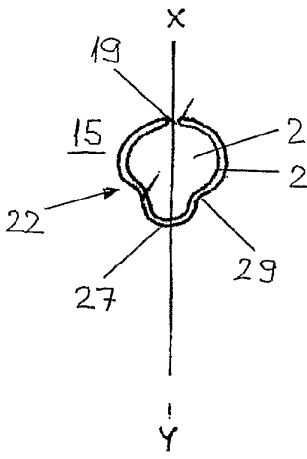



Fig. 8

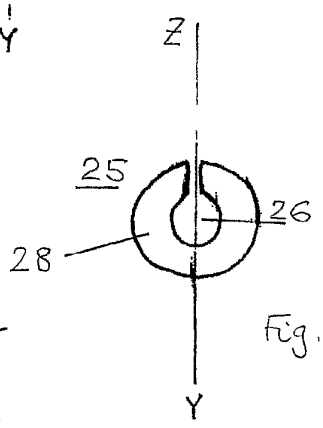



Fig. 9

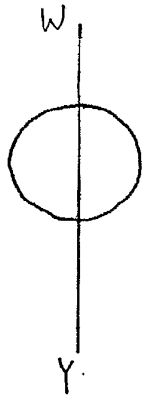



Fig. 10.

# INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2008/000474

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17 A61B17/68
ADD. A61B17/16 A61B17/72

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | WO 2007/120539 A (HUROWITZ ELI [US])<br>25 October 2007 (2007-10-25)<br><br>figures 1-3<br>page 4, line 2 - page 6, line 19 | 1,2,<br>5-13,15,<br>16 |
| X | WO 2006/119659 A (KLAUE KAJ [CH])<br>16 November 2006 (2006-11-16)<br>figures 3,4<br>page 7, last paragraph<br>page 9, last paragraph | 1,2,5,<br>10,13 |
| Y | | 1,2,<br>5-13,15,<br>16 |

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 18 Dezember 2008 | 08/01/2009 |

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

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

# INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2008/000474

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | WO 03/017822 A (REILEY MARK A [US])<br>6 March 2003 (2003-03-06)<br>figures 5,6,5a<br>page 9, line 17 - page 10, line 2<br>page 11, line 14 - line 31 | 1,7,16 |
| A | US 6 579 293 B1 (CHANDRAN RAMA E [US])<br>17 June 2003 (2003-06-17)<br>figures 2-5 | 1,6,16 |
| A | WO 2007/053960 A (SYNTHES GMBH [CH]; FRIGG ROBERT [CH]; SCHORI PASCAL [CH])<br>18 May 2007 (2007-05-18)<br>figures 1,2 | 1,16 |
| Y | WO 90/12550 A (BIOCON OY [FI])<br>1 November 1990 (1990-11-01)<br>figures 1-3 | 11,12,15 |

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH2008/000474

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.: **17**
because they relate to subject matter not required to be searched by this Authority, namely:

PCT Rule 39.1(iv) - 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:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CH2008/000474

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 2007120539 A | 25-10-2007 | US 2007288097 A1 | 13-12-2007 |
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Form PCT/ISA/210 (patent family annex) (April 2005)

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2008/000474

**A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES**
INV. A61B17/17 A61B17/68
ADD. A61B17/16 A61B17/72

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

**B. RECHERCHIERTE GEBIETE**

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole )
A61B

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal

**C. ALS WESENTLICH ANGESEHENE UNTERLAGEN**

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile | Betr. Anspruch Nr. |
|---|---|---|
| Y | WO 2007/120539 A (HUROWITZ ELI [US])<br>25. Oktober 2007 (2007-10-25)<br><br>Abbildungen 1-3<br>Seite 4, Zeile 2 - Seite 6, Zeile 19 | 1,2,<br>5-13,15,<br>16 |
| X | WO 2006/119659 A (KLAUE KAJ [CH])<br>16. November 2006 (2006-11-16)<br>Abbildungen 3,4<br>Seite 7, letzter Absatz<br>Seite 9, letzter Absatz | 1,2,5,<br>10,13 |
| Y | | 1,2,<br>5-13,15,<br>16 |

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen [X] Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden
"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

| Datum des Abschlusses der internationalen Recherche | Absendedatum des internationalen Recherchenberichts |
|---|---|
| 18. Dezember 2008 | 08/01/2009 |

| Name und Postanschrift der Internationalen Recherchenbehörde | Bevollmächtigter Bediensteter |
|---|---|
| Europäisches Patentamt, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Hübner, Jens |

Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

## INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2008/000474

C. (Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

| Kategorie* | Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile | Betr. Anspruch Nr. |
|---|---|---|
| A | WO 03/017822 A (REILEY MARK A [US])<br>6. März 2003 (2003-03-06)<br>Abbildungen 5,6,5a<br>Seite 9, Zeile 17 - Seite 10, Zeile 2<br>Seite 11, Zeile 14 - Zeile 31 | 1,7,16 |
| A | US 6 579 293 B1 (CHANDRAN RAMA E [US])<br>17. Juni 2003 (2003-06-17)<br>Abbildungen 2-5 | 1,6,16 |
| A | WO 2007/053960 A (SYNTHES GMBH [CH]; FRIGG ROBERT [CH]; SCHORI PASCAL [CH])<br>18. Mai 2007 (2007-05-18)<br>Abbildungen 1,2 | 1,16 |
| Y | WO 90/12550 A (BIOCON OY [FI])<br>1. November 1990 (1990-11-01)<br>Abbildungen 1-3 | 11,12,15 |

## INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH2008/000474

**Feld Nr. II Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)**

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein internationaler Recherchenbericht erstellt:

1. [X] Ansprüche Nr. 17
weil sie sich auf Gegenstände beziehen, zu deren Recherche diese Behörde nicht verpflichtet ist, nämlich

Regel 39.1(iv) PCT - Verfahren zur chirurgischen Behandlung des menschlichen oder tierischen Körpers

2. [ ] Ansprüche Nr.
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, dass eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich

3. [ ] Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefasst sind.

**Feld Nr. III Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)**

Diese Internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere Erfindungen enthält:

1. [ ] Da der Anmelder alle erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.

2. [ ] Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung solcher Gebühren aufgefordert.

3. [ ] Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.

4. [ ] Der Anmelder hat die erforderlichen zusätzlichen Recherchengebühren nicht rechtzeitig entrichtet. Dieser internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfasst:

**Bemerkungen hinsichtlich eines Widerspruchs**

[ ] Der Anmelder hat die zusätzlichen Recherchengebühren unter Widerspruch entrichtet und die gegebenenfalls erforderliche Widerspruchsgebühr gezahlt.

[ ] Die zusätzlichen Recherchengebühren wurden vom Anmelder unter Widerspruch gezahlt, jedoch wurde die entsprechende Widerspruchsgebühr nicht innerhalb der in der Aufforderung angegebenen Frist entrichtet.

[ ] Die Zahlung der zusätzlicher Recherchengebühren erfolgte ohne Widerspruch.

## INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/CH2008/000474

| Im Recherchenbericht angeführtes Patentdokument | | Datum der Veröffentlichung | Mitglied(er) der Patentfamilie | | Datum der Veröffentlichung |
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| | | | CH 697414 | B1 | 30-09-2008 |
| | | | CN 101175448 | A | 07-05-2008 |
| | | | EP 1890620 | A1 | 27-02-2008 |
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| | | | JP 3505537 | T | 05-12-1991 |

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

# NOTICE OF ALLOWANCE AND FEE(S) DUE

27776 7590 01/26/2015

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

| EXAMINER |
|---|
| BRAY, STUART SAMUEL |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3733 | |

DATE MAILED: 01/26/2015

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | SMALL | $480 | $0 | $0 | $480 | 04/27/2015 |

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

**HOW TO REPLY TO THIS NOTICE:**

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**



PTOL-85 (Rev. 02/11)

## PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail** **Mail Stop ISSUE FEE**
**Commissioner for Patents**
**P.O. Box 1450**
**Alexandria, Virginia 22313-1450**
**or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27776 7590 01/26/2015
Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|---|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | SMALL | $480 | $0 | $0 | $480 | 04/27/2015 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| BRAY, STUART SAMUEL | 3733 | 606-062000 |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29
  NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status.
  NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____



PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

27776 7590 01/26/2015

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SUMMIT, NJ 07901

| EXAMINER | |
|---|---|
| BRAY, STUART SAMUEL | |
| ART UNIT | PAPER NUMBER |
| 3733 | |

DATE MAILED: 01/26/2015

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## Privacy Act Statement

**The Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

| Notice of Allowability | Application No. 12/658,680 | Applicant(s) TYBER ET AL. | |
|---|---|---|---|
| | Examiner STUART S. BRAY | Art Unit 3733 | AIA (First Inventor to File) Status No |

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment 9/17/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ 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.
3. ☒ The allowed claim(s) is/are *1-12,14-16,18,20-25,51-53,55-61,63-65,67-76 and 78-81*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   **Certified copies:**

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**.

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   **Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 9/17/2014
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20141229* .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

| /STUART S BRAY/<br>Examiner, Art Unit 3733 | /THOMAS J SWEET/<br>Supervisory Patent Examiner, Art Unit 3738 |
|---|---|

The present application is being examined under the pre-AIA first to invent provisions.

Claims 1-12, 14-16, 18, 20-25, 51-53, 55-61, 63-65, 67-76, 78-81 are allowable. The restriction requirement, as set forth in the Office action mailed on 7/22/2011, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Specifically, the restriction requirement of claims 24-25 and 73-74 is withdrawn. Claims 24-25 and 73-74, directed to a different species is no longer withdrawn from consideration because the claim(s) requires all the limitations of allowable claims 1 and 51, respectively. These claims are rejoined.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Hanna Mosolygo on 12/29/2014.

The application has been amended as follows:

In the claims (9/17/2014)

Claim 1:

Line 6: "for coupling" is **deleted and replaced with** - - that couples - -

Line 16: - - the first aperture - - **is inserted before** "and through the bore"

Line 16: - - and out of the second aperture - - **is inserted after** "and through the bore"

Claim 51:

Line 6: "for coupling" is **deleted and replaced with** - - that couples - -

Line 17: - - the first aperture - - **is inserted before** "and through the bore"

Line 17: - - and out of the second aperture - - **is inserted after** “and through the bore”

Claims 26-50 are **CANCELLED**

The following is an examiner’s statement of reasons for allowance: the claims in the instant application have not been rejected using prior art because no reference or reasonable combination thereof could be found which disclose or suggest an intramedullary fixation assembly for bone fusion including a first and second bone screw, whereby the first screw is inserted through an aperture in the bulbous portion of the head of the second screw, passes through a bore in the second screw, and emerges from an aperture located on exterior surface of the second screw, and wherein the first and second screws engage and compress two different bones, as in claims 1 and 51. This is distinguishable over the prior art in structure and in function, as the prior art function to anchor a first screw to a single bone using a second screw.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

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.

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

/THOMAS J SWEET/

Supervisory Patent Examiner, Art Unit 3738

| Examiner-Initiated Interview Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 12/658,680 | TYBER ET AL. | |
| | Examiner | Art Unit | |
| | STUART S. BRAY | 3733 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) *STUART S. BRAY*.

(3) *Hanna Mosolygo*.

(2) _____.

(4) _____.

Date of Interview: *29 December 2014*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: _____.

Identification of prior art discussed: *Overes, Sevrain, Gorek*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

*Examiner called to discuss the relevance of the above prior art to the claim and to discuss amending the independent claims to tighten the language for the use of the invention. Regarding the cited art, Atty Mosolygo argued that the cited art does not disclose a first screw passing through a bore, from the head to the shaft of a second screw, in order to apply compression to two different bones or fragments. The prior art does not have an aperture in the shaft, rather the head of the screw, and the second screw is configured to anchor the first screw into a bone. The structural and functional language in the (examiner amended) claims are deemed allowable in light of this.* .

**Applicant recordation instructions**: It is not necessary for applicant to provide a separate record of the substance of interview.

**Examiner recordation instructions**: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

| /STUART S BRAY/<br>Examiner, Art Unit 3733 | /THOMAS J SWEET/<br>Supervisory Patent Examiner, Art Unit 3738 |
|---|---|

| Search Notes | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| CPC- SEARCHED | | |
|---|---|---|
| Symbol | Date | Examiner |
| a61b17/7291 | 12/30/2014 | SSB |

| CPC COMBINATION SETS - SEARCHED | | |
|---|---|---|
| Symbol | Date | Examiner |
| | | |

| US CLASSIFICATION SEARCHED | | | |
|---|---|---|---|
| Class | Subclass | Date | Examiner |
| 606 | 54, 62, 80, 96 | 9/21/2011 | SSB |
| 606 | 64, 65 | 9/23/2011 | SSB |
| | UPdated | 4/27/2012 | SSB |
| | updated | 5/16/2014 | SSB |
| 606 | 305-308,310,319 | 5/16/2014 | SSB |
| | updated | 12/30/2014 | SSB |

| SEARCH NOTES | | |
|---|---|---|
| Search Notes | Date | Examiner |
| Performed inventor search | 9/21/2011 | SSB |
| referred to sibling case 12/906454 | 5/16/2014 | SSB |

| INTERFERENCE SEARCH | | | |
|---|---|---|---|
| US Class/ CPC Symbol | US Subclass / CPC Group | Date | Examiner |
| 606/64 a61b17/7291 | interference search printout | 12/30/2014 | SSB |

| | |
|---|---|
| /STUART S BRAY/ Examiner.Art Unit 3733 | |

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# BIB DATA SHEET

**CONFIRMATION NO. 1344**

| SERIAL NUMBER | FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010<br>RULE | 606 | 3733 | 277-042 |

**APPLICANTS**

**INVENTORS**

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

**** CONTINUING DATA ***************************

This application is a CIP of 12/456,808 06/23/2009 PAT 8303589
which claims benefit of 61/132,932 06/24/2008

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
03/05/2010

| Foreign Priority claimed | ☐ Yes ☑ No | ☐ Met after Allowance | STATE OR COUNTRY | SHEETS DRAWINGS | TOTAL CLAIMS | INDEPENDENT CLAIMS |
|---|---|---|---|---|---|---|
| 35 USC 119(a-d) conditions met | ☐ Yes ☐ No | | PA | 20 | 74 | 3 |
| Verified and Acknowledged | /STUART SAMUEL BRAY/ Examiner's Signature | Initials | | | | |

**ADDRESS**

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901
UNITED STATES

**TITLE**

Intraosseous intramedullary fixation assembly and method of use

| FILING FEE RECEIVED | FEES: Authority has been given in Paper | |
|---|---|---|
| 2074 | No._____ to charge/credit DEPOSIT ACCOUNT<br>No._____ for following: | ☐ All Fees<br>☐ 1.16 Fees (Filing)<br>☐ 1.17 Fees (Processing Ext. of time)<br>☐ 1.18 Fees (Issue)<br>☐ Other _____<br>☐ Credit |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12658680 |
| | Filing Date | 2010-02-11 |
| | First Named Inventor | Jeff Tyber |
| | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| U.S.PATENTS | | | | | | Remove |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 4011863 | | 1977-03-15 | Zickel | |
| | 2 | 5417692 | | 1995-05-23 | Goble, et al. | |
| | 3 | 6379354 | | 2002-04-30 | Rogozinski | |
| If you wish to add additional U.S. Patent citation information please click the Add button. | | | | | | Add |

| U.S.PATENT APPLICATION PUBLICATIONS | | | | | | Remove |
|---|---|---|---|---|---|---|
| Examiner Initial* | Cite No | Publication Number | Kind Code[1] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 20060015123 | | 2006-01-19 | Fencl et al. | |
| | 2 | 20090118772 | | 2009-05-07 | Diederich | |
| | 3 | 20020128712 | | 2002-09-12 | Michelson | |
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EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

| Receipt date: 09/17/2014 | Application Number | 12658680 12658680 - GAU: 3733 |
|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | Filing Date | 2010-02-11 |
| | First Named Inventor | Jeff Tyber |
| **( Not for submission under 37 CFR 1.99)** | Art Unit | 3733 |
| | Examiner Name | Bray, Stuart Samuel |
| | Attorney Docket Number | 277-042 |

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
| | 1 | FR2861576A1 | FR | | | Cognet | | ☐ |
| | 2 | WO2009067831A1 | WO | | | Klaue | | ☐ |
| | 3 | WO2008024373A2 | WO | | | Samy | | ☐ |
| | 4 | WO9722301A1 | WO | | | Bramlet | | ☐ |

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**NON-PATENT LITERATURE DOCUMENTS** Remove

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | 1 | | ☐ |

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**EXAMINER SIGNATURE**

| Examiner Signature | /Stuart Bray/ | Date Considered | 12/30/2014 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EFS Web 2.1.17 ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

| Receipt date: 09/17/2014 | Application Number | 12658680 | 12658680 - GAU: 3733 |
|---|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( **Not for submission under 37 CFR 1.99)** | Filing Date | 2010-02-11 | |
| | First Named Inventor | Jeff Tyber | |
| | Art Unit | 3733 | |
| | Examiner Name | Bray, Stuart Samuel | |
| | Attorney Docket Number | 277-042 | |

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| Signature | /Hanna Bondarik Mosolygo/ | Date (YYYY-MM-DD) | 2014-09-17 |
|---|---|---|---|
| Name/Print | Hanna Bondarik Mosolygo | Registration Number | 66475 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

**Privacy Act Statement**

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | 12/30/2014 | | | | |
| 1 | 1 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 18 | 2 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 19 | 3 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 6 | 4 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 7 | 5 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 20 | 6 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 9 | 7 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 10 | 8 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 11 | 9 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 21 | 10 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 22 | 11 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 2 | 12 | ÷ | N | N | ✓ | = | | | | |
| | 13 | ÷ | N | - | - | - | | | | |
| 5 | 14 | ÷ | N | N | ✓ | = | | | | |
| 3 | 15 | ÷ | N | N | ✓ | = | | | | |
| 4 | 16 | ÷ | N | N | ✓ | = | | | | |
| | 17 | ÷ | N | - | - | - | | | | |
| 23 | 18 | ÷ | N | N | ✓ | = | | | | |
| | 19 | ÷ | N | - | - | - | | | | |
| 24 | 20 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 25 | 21 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 12 | 22 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 13 | 23 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 14 | 24 | ÷ | N | N | N | = | | | | |
| 15 | 25 | ÷ | N | N | N | = | | | | |
| | 26 | ÷ | N | N | N | - | | | | |
| | 27 | ÷ | N | N | N | - | | | | |
| | 28 | ÷ | N | N | N | - | | | | |
| | 29 | ÷ | N | N | N | - | | | | |
| | 30 | ÷ | N | N | N | - | | | | |
| | 31 | ÷ | N | N | N | - | | | | |
| | 32 | ÷ | N | N | N | - | | | | |
| | 33 | ÷ | N | N | N | - | | | | |
| | 34 | ÷ | N | N | N | - | | | | |
| | 35 | ÷ | N | N | N | - | | | | |
| | 36 | ÷ | N | N | N | - | | | | |

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | 12/30/2014 | | | | |
| | 37 | ÷ | N | N | N | - | | | | |
| | 38 | ÷ | N | N | N | - | | | | |
| | 39 | ÷ | N | N | N | - | | | | |
| | 40 | ÷ | N | N | N | - | | | | |
| | 41 | ÷ | N | N | N | - | | | | |
| | 42 | ÷ | N | N | N | - | | | | |
| | 43 | ÷ | N | N | N | - | | | | |
| | 44 | ÷ | N | N | N | - | | | | |
| | 45 | ÷ | N | N | N | - | | | | |
| | 46 | ÷ | N | N | N | - | | | | |
| | 47 | ÷ | N | N | N | - | | | | |
| | 48 | ÷ | N | N | N | - | | | | |
| | 49 | ÷ | N | N | N | - | | | | |
| | 50 | ÷ | N | N | N | - | | | | |
| 28 | 51 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 36 | 52 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 37 | 53 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| | 54 | ÷ | - | - | - | - | | | | |
| 42 | 55 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 33 | 56 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 34 | 57 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 35 | 58 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 43 | 59 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 44 | 60 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 29 | 61 | ÷ | N | N | ✓ | = | | | | |
| | 62 | ÷ | N | N | - | - | | | | |
| 32 | 63 | ÷ | N | N | ✓ | = | | | | |
| 30 | 64 | ÷ | N | N | ✓ | = | | | | |
| 31 | 65 | ÷ | N | N | ✓ | = | | | | |
| | 66 | ÷ | N | N | - | - | | | | |
| 45 | 67 | ÷ | N | N | ✓ | = | | | | |
| 46 | 68 | ÷ | N | N | ✓ | = | | | | |
| 47 | 69 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 48 | 70 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 38 | 71 | ÷ | ✓ | ✓ | ✓ | = | | | | |
| 39 | 72 | ÷ | ✓ | ✓ | ✓ | = | | | | |

| Index of Claims | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S BRAY | 3733 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ✓ | Rejected | - | Cancelled | N | Non-Elected | A | Appeal |
| = | Allowed | ÷ | Restricted | I | Interference | O | Objected |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| CLAIM | | DATE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Final | Original | 07/11/2011 | 09/21/2011 | 04/27/2012 | 05/16/2014 | 12/30/2014 | | | | |
| 40 | 73 | ÷ | N | N | N | = | | | | |
| 41 | 74 | ÷ | N | N | N | = | | | | |
| 49 | 75 | | | N | ✓ | = | | | | |
| 8 | 76 | | | N | ✓ | = | | | | |
| | 77 | | | N | ✓ | - | | | | |
| 26 | 78 | | | N | ✓ | = | | | | |
| 16 | 79 | | | N | ✓ | = | | | | |
| 17 | 80 | | | N | ✓ | = | | | | |
| 27 | 81 | | | N | ✓ | = | | | | |

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | **Examiner** | **Art Unit** |
| | STUART S BRAY | 3733 |

| CPC | | | | | | |
|---|---|---|---|---|---|---|
| **Symbol** | | | | | **Type** | **Version** |
| A61B | | 17 | / | 7291 | F | 2013-01-01 |
| A61B | | 17 | / | 1717 | I | 2013-01-01 |
| A61B | | 17 | / | 72 | I | 2013-01-01 |
| A61B | | 17 | / | 8605 | I | 2013-01-01 |
| A61B | | 17 | / | 8625 | I | 2013-01-01 |
| A61F | | 2002 | / | 4238 | A | 2013-01-01 |
| A61B | | 2017 | / | 1775 | A | 2013-01-01 |
| A61B | | 2017 | / | 1782 | A | 2013-01-01 |
| | | | / | | | |
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| CPC Combination Sets | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Symbol** | | | | | **Type** | **Set** | **Ranking** | **Version** |
| | | | / | | | | | |
| | | | / | | | | | |

| /STUART S BRAY/<br>Examiner.Art Unit 3733 | 12/30/2014 | **Total Claims Allowed:** | |
|---|---|---|---|
| (Assistant Examiner) | (Date) | 49 | |
| /THOMAS J SWEET/<br>Supervisory Patent Examiner.Art Unit 3738 | 01/12/2015 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 9 |

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | **Examiner** | **Art Unit** |
| | STUART S BRAY | 3733 |

| US ORIGINAL CLASSIFICATION | | INTERNATIONAL CLASSIFICATION | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CLASS | SUBCLASS | CLAIMED | | | | | NON-CLAIMED | | | | | |
| 606 | 64 | A | 6 | 1 | B | 17 / 56 (2006.0) | | | | | | |
| CROSS REFERENCE(S) | | | | | | | | | | | | |
| CLASS | SUBCLASS (ONE SUBCLASS PER BLOCK) | | | | | | | | | | | |
| 411 | 457 | 469 | | | | | | | | | | |

| | | | |
|---|---|---|---|
| /STUART S BRAY/<br>Examiner.Art Unit 3733 | 12/30/2014 | **Total Claims Allowed:** | |
| (Assistant Examiner) | (Date) | 49 | |
| /THOMAS J SWEET/<br>Supervisory Patent Examiner.Art Unit 3738 | 01/12/2015 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 9 |

| Issue Classification | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|---|---|---|
| | 12658680 | TYBER ET AL. |
| | **Examiner** | **Art Unit** |
| | STUART S BRAY | 3733 |

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

| Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 | | 17 | | 33 | | 49 | 31 | 65 | 27 | 81 | | | | |
| 18 | 2 | 23 | 18 | | 34 | | 50 | | 66 | | | | | | |
| 19 | 3 | | 19 | | 35 | 28 | 51 | 45 | 67 | | | | | | |
| 6 | 4 | 24 | 20 | | 36 | 36 | 52 | 46 | 68 | | | | | | |
| 7 | 5 | 25 | 21 | | 37 | 37 | 53 | 47 | 69 | | | | | | |
| 20 | 6 | 12 | 22 | | 38 | | 54 | 48 | 70 | | | | | | |
| 9 | 7 | 13 | 23 | | 39 | 42 | 55 | 38 | 71 | | | | | | |
| 10 | 8 | 14 | 24 | | 40 | 33 | 56 | 39 | 72 | | | | | | |
| 11 | 9 | 15 | 25 | | 41 | 34 | 57 | 40 | 73 | | | | | | |
| 21 | 10 | | 26 | | 42 | 35 | 58 | 41 | 74 | | | | | | |
| 22 | 11 | | 27 | | 43 | 43 | 59 | 49 | 75 | | | | | | |
| 2 | 12 | | 28 | | 44 | 44 | 60 | 8 | 76 | | | | | | |
| | 13 | | 29 | | 45 | 29 | 61 | | 77 | | | | | | |
| 5 | 14 | | 30 | | 46 | | 62 | 26 | 78 | | | | | | |
| 3 | 15 | | 31 | | 47 | 32 | 63 | 16 | 79 | | | | | | |
| 4 | 16 | | 32 | | 48 | 30 | 64 | 17 | 80 | | | | | | |

| | | | |
|---|---|---|---|
| /STUART S BRAY/<br>Examiner.Art Unit 3733<br><br>(Assistant Examiner) | 12/30/2014<br><br>(Date) | **Total Claims Allowed:**<br>49 | |
| /THOMAS J SWEET/<br>Supervisory Patent Examiner.Art Unit 3738<br><br>(Primary Examiner) | 01/12/2015<br><br>(Date) | O.G. Print Claim(s)<br>1 | O.G. Print Figure<br>9 |

**EAST Search History**

**EAST Search History (Prior Art)**

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|---|---|---|---|---|---|---|
| L1 | 547 | 606/64.ccls. | US-PGPUB; USPAT; USOCR | OR | OFF | 2014/12/30 12:06 |
| L2 | 353 | a61b17/7291.cpc. | US-PGPUB; USPAT; USOCR | OR | OFF | 2014/12/30 12:06 |
| S1 | 3185 | (606/54,62,80,96).CCLS. | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:10 |
| S2 | 0 | S1 and (semi-sperical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S3 | 50 | S1 and (semi-spherical) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:12 |
| S4 | 275 | screw and (semi-spherical adj head) | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:15 |
| S5 | 92 | S4 and bone | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:16 |
| S6 | 83 | "6322562" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:17 |
| S7 | 1 | "20020045899" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:19 |
| S8 | 11 | "7175626" | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/21 12:33 |
| S9 | 0 | 606/64,65 | USPAT | OR | OFF | 2011/09/22 16:04 |
| S10 | 0 | 606/64,65 | US-PGPUB; USPAT; USOCR | OR | OFF | 2011/09/22 16:04 |
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| S28 | 15 | "7524326" | USPAT | OR | OFF | 2014/05/15 15:19 |
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**EAST Search History (Interference)**

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|---|---|---|---|---|---|---|
| L3 | 224 | a61b17/7291.cpc. | US-PGPUB | OR | OFF | 2014/12/30 12:07 |
| L4 | 230 | 606/64.ccls. | US-PGPUB | OR | OFF | 2014/12/30 12:08 |
| L5 | 183 | (first and second and screw and bone and aperture and bore).clm. | US-PGPUB | OR | OFF | 2014/12/30 12:09 |
| L6 | 12 | (first and second and screw and bone and aperture and bore and compress).clm. | US-PGPUB | OR | OFF | 2014/12/30 12:09 |
| L7 | 12 | (first and screw and bone and aperture and bore and compress).clm. | US-PGPUB | OR | OFF | 2014/12/30 12:09 |
| L8 | 25 | (first and screw and aperture and bore and compress).clm. | US-PGPUB | OR | OFF | 2014/12/30 12:10 |

**12/30/2014 12:10:54 PM**
**C:\Users\sbray1\Documents\EAST\Workspaces\12658680.wsp**

Electronically filed February 3, 2015

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: Jeff Tyber, et al. | Confirmation No.: 1344 |
| Serial No.: 12/658,680 | Examiner: Bray, Stuart Samuel |
| Filed: February 11, 2010 | Art Unit: 3733 |
| For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: 277-042 |

**Mail Stop Issue Fee**
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Alexandria, VA 22313-1450

**AMENDMENT AFTER NOTICE OF ALLOWANCE PURSUANT TO 37 CFR 1.312**

Sir:

Please amend the above-identified application as set forth on the following pages.

**IN THE CLAIMS:**

This listing of claims will replace all prior versions and listings of claims in the application:

**1. (Previously presented):** An assembly for bone fusion, comprising:

a first screw member, wherein the first screw member comprises a first elongated body extending along a first longitudinal axis, and wherein the first elongated body includes a first threaded portion at a first end for advancing said first screw member into a first bone or bone fragment and a bulbous portion at a second end comprising an exterior surface; and

a second screw member that couples to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, the second elongated body extending along a second longitudinal axis, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment, a first aperture at a terminal end of the second end of the second elongated body, and a bore extending along a third axis from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the bore comprises an interior surface at the first aperture, wherein the second longitudinal axis and the third axis define an angle,

wherein the first screw member couples to the second screw member by being inserted into the first aperture and through the bore and out of the second aperture until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment,

wherein the first screw member and the second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together.

**2. (Previously presented):** The assembly of claim 1, wherein the first screw member couples to the second screw member at the angle.

**3. (Previously presented):** The assembly of claim 1, wherein the angle is in the range of about 0 degrees to about 90 degrees.

**4. (Previously presented):** The assembly of claim 1, wherein the exterior surface of the bulbous portion includes a taper for providing an interference fit with the second screw member.

**5. (Previously presented):** The assembly of claim 4, wherein the taper provides for an interference lock with the second screw member.

**6. (Previously presented):** The assembly of claim 1, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**7. (Previously presented):** The assembly of claim 1, wherein the bulbous portion includes an aperture disposed along the first longitudinal axis.

**8. (Previously presented):** The assembly of claim 7, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**9. (Previously presented):** The assembly of claim 7, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**10. (Previously presented):** The assembly of claim 1, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**11. (Previously presented):** The assembly of claim 1, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**12. (Previously presented):** The assembly of claim 1, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**13. (Canceled).**

**14. (Previously presented):** The assembly of claim 12, wherein the internal aperture is disposed along the second longitudinal axis.

**15. (Previously presented):** The assembly of claim 12, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**16. (Previously presented):** The assembly of claim 15, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**17. (Canceled)**.

**18. (Previously presented):** The assembly of claim 1, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within the bore, and further wherein the bulbous portion abuts the interior surface of the bore at the first aperture at the second end of the second elongated body.

**19. (Canceled)**.

**20. (Previously presented):** The assembly of claim 1, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**21. (Previously presented):** The assembly of claim 1, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**22. (Previously presented):** The assembly of claim 1, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**23. (Previously presented):** The assembly of claim 22, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**24. (Currently amended):** The ~~intramedullary~~ assembly of claim 1, further comprising a cover portion for coupling to the bulbous portion of the ~~lag~~ first screw member.

**25. (Currently amended):** The ~~intramedullary~~ assembly of claim 24, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening ~~partially disposed in the second elongated body~~.

**26. – 50. (Canceled).**

**51. (Previously presented):** An assembly for bone fusion, comprising:

a first screw member, wherein the first screw member comprises a first elongated body, and wherein the first elongated body includes a first threaded portion at a first end for advancing said first screw member into a first bone or bone fragment and a bulbous portion at a second end comprising an exterior surface; and

a second screw member that couples to the first screw member, wherein the second screw member includes a second elongated body having first and second ends, wherein the second elongated body comprises a second threaded portion at the first end of the second elongated body for advancing said second screw member into a second bone or bone fragment and a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises a first aperture at a terminal end of the second end of the second elongated body and a bore

extending through the tubular portion from the first aperture to a second aperture on an exterior surface of the second screw member, wherein the bore comprises an interior surface,

wherein the bulbous portion is semi-spherical for providing angular rotation of the first screw member relative to the second screw member, and

wherein the first screw member couples to the second screw member by being inserted into the first aperture and through the bore and out of the second aperture until the exterior surface of the bulbous portion of the first screw member abuts the interior surface of the bore at the first aperture of the second screw member and the first threaded portion extends out of the second aperture to engage the first bone or bone fragment,

wherein the first screw member and the second screw member translate compression to the first bone or bone fragment and the second bone or bone fragment thereby drawing the bones or bone fragments together.

**52. (Previously presented):** The assembly of claim 51, wherein the first screw member couples to the second screw member at an angle.

**53. (Previously presented):** The assembly of claim 52, wherein the angle varies between about 0 degrees and about 90 degrees.

**54. (Canceled).**

**55. (Previously presented):** The assembly of claim 51, wherein the first screw member is cannulated having a circular cross-section with said first elongated body.

**56. (Previously presented):** The assembly of claim 51, wherein the bulbous portion includes an aperture.

**57. (Previously presented):** The assembly of claim 56, wherein the aperture of the bulbous portion has a hexagonal shape, a star shape, or a square shape.

**58. (Previously presented):** The assembly of claim 56, wherein the aperture of the bulbous portion is provided to receive a complementary shaped end of an instrument.

**59. (Previously presented):** The assembly of claim 51, wherein the first threaded portion comprises a plurality of bone threads on an outer surface of the first threaded portion.

**60. (Previously presented):** The assembly of claim 51, wherein the first threaded portion includes a self-tapping edge for removing bone material.

**61. (Previously presented):** The assembly of claim 51, wherein the second screw member comprises an internal aperture disposed in the second elongated body.

**62. (Canceled)**.

**63. (Previously presented):** The assembly of claim 61, wherein the internal aperture partially traverses the tubular portion at the second end of the second elongated body.

**64. (Previously presented):** The assembly of claim 61, wherein the internal aperture includes a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening partially disposed in the second elongated body.

**65. (Previously presented):** The assembly of claim 64, wherein the hexagonally shaped opening, the star-shaped opening, or the square-shaped opening is provided to receive a complementary shaped member.

**66. (Canceled)**.

**67. (Previously presented):** The assembly of claim 51, wherein the bore receives the first elongated body of the first screw member, wherein the bulbous portion resides within the bore, and further wherein the bulbous portion abuts the internal surface of the bore at the first aperture at the second end of the second elongated body.

**68. (Previously presented):** The assembly of claim 51, wherein the bore forms a predetermined angle with the second elongated body.

**69. (Previously presented):** The assembly of claim 51, wherein the second threaded portion comprises a plurality of threads on an outer surface of the second threaded portion.

**70. (Previously presented):** The assembly of claim 51, wherein the second threaded portion includes a self-tapping edge for removing bone material.

**71. (Previously presented):** The assembly of claim 51, wherein the first screw member is provided for insertion into at least a first medullary canal of a bone.

**72. (Previously presented):** The assembly of claim 71, wherein the second screw member is provided for insertion into at least the first medullary canal of the bone.

**73. (Currently amended):** The ~~intramedullary~~ assembly of claim 51, further comprising a cover portion coupled to the bulbous portion of the ~~lag~~ first screw member.

**74. (Currently amended):** The ~~intramedullary~~ assembly of claim 73, wherein the cover portion comprises a hexagonally shaped opening, a star-shaped opening, or a square-shaped opening ~~partially disposed in the second elongated body~~.

**75. (Previously presented):** The assembly of claim 1, wherein the bore is adapted for retaining the bulbous portion.

**76. (Previously presented):** The assembly of claim 4, wherein the interior surface of the bore comprises a taper for providing an interference fit with the taper of the bulbous portion.

**77. (Canceled)**.

**78. (Previously presented):** The assembly of claim 1, wherein uniform compression is translated across the first screw member and the second screw member to the first bone or bone fragment and the second bone or bone fragment.

**79. (Previously presented):** The assembly of claim 1, wherein the bulbous portion comprises a spherical portion adapted to allow the first screw member to couple to the second screw member at a plurality of possible angles ranging from about 0 degrees to about 90 degrees.

**80. (Previously presented):** The assembly of claim 79, wherein the spherical portion is adapted to allow the first screw member to rotate within the bore to set an angle between the first screw member and the second screw member to at least one of the plurality of possible angles.

**81. (Previously presented):** The assembly of claim 1, wherein the second screw member comprises a tubular portion at the second end of the second elongated body, wherein the tubular portion comprises the first aperture and the bore, and wherein the second aperture is on an exterior surface of the tubular portion.

## REMARKS

In the Notice of Allowability mailed January 26, 2015, the Examiner indicated that the restriction requirement of claims 24-25 and 73-74 has been withdrawn, and as a result, these claims are rejoined. By this amendment, claims 24-25 and 73-74 have been amended to correspond to the previous amendments made to the independent claims 1 and 51, and thereby correct antecedent basis. Specifically, claims 24-25 and 73-74 have been amended to delete "intramedullary". Claims 24 and 73 have been amended to replace "lag" screw member with "first" screw member. Claims 25 and 74 have been amended to delete "partially disposed in the second elongated body." Applicant submits that these amendments merely embody the correction of formal matters without changing the scope of the claims. Applicant further submits that no new matter was added by these amendments. Accordingly, Applicant respectfully requests that the amendment be entered. If any questions remain or additional information is needed, please contact the undersigned.

This amendment is believed to be timely filed. If any petitions and/or fees are required, the Patent and Trademark Office is specifically authorized to charge such fees to Deposit Account No. 23-0420 in the name of Ward & Zinna, LLC.

Respectfully submitted,

Date: February 3, 2015

/ Hanna Bondarik Mosolygo/

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Ward & Zinna LLC
382 Springfield Avenue
Suite 300
Summit, New Jersey 07901
(908) 277-3333

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 21379851 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Hanna Bondarik Mosolygo |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 03-FEB-2015 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 10:33:16 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

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## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Amendment after Notice of Allowance (Rule 312) | 2015-02-03_AmendmentafterAllowance_277-042.pdf | 90576<br>77b74a358ef3cce2b257dba8cad61c878488f0613 | no | 12 |

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|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

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|---|---|
| 3733 | |

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| 03/24/2015 | 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.

| Response to Rule 312 Communication | Application No. | Applicant(s) |
|---|---|---|
| | 12/658,680 | TYBER ET AL. |
| | Examiner | Art Unit |
| | STUART S. BRAY | 3733 |

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

1. ☒ The amendment filed on *03 February 2015* under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☒ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

Claim amendments from Applicant merely correct antecedent basis in previously rejoined and allowed claims. No new claims or subject matter has been added.

| | |
|---|---|
| /EDUARDO C. ROBERT/<br>Supervisory Patent Examiner, Art Unit 3733 | /STUART S BRAY/<br>Examiner, Art Unit 3733 |

OK TO ENTER: /S.B./

OK TO ENTER: /S.B./

Electronically filed February 3, 2015

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

| | |
|---|---|
| In re Application of: Jeff Tyber, et al. | Confirmation No.: 1344 |
| Serial No.: 12/658,680 | Examiner: Bray, Stuart Samuel |
| Filed: February 11, 2010 | Art Unit: 3733 |
| For: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE | Atty. Doc. No.: 277-042 |

**Mail Stop Issue Fee**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**AMENDMENT AFTER NOTICE OF ALLOWANCE PURSUANT TO 37 CFR 1.312**

Sir:

Please amend the above-identified application as set forth on the following pages.

OK TO ENTER: /S.B./

OK TO ENTER: /S.B./

OK TO ENTER: /S.B./

## PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail** **Mail Stop ISSUE FEE**
**Commissioner for Patents**
**P.O. Box 1450**
**Alexandria, Virginia 22313-1450**
**or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27776 7590 01/26/2015
Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

| |
|---|
| (Depositor's name) |
| (Signature) |
| (Date) |

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 02/11/2010 | Jeff Tyber | 277-042 | 1344 |

TITLE OF INVENTION: INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|---|---|---|---|---|---|---|
| nonprovisional | SMALL | $480 | $0 | $0 | $480 | 04/27/2015 |

| EXAMINER | ART UNIT | CLASS-SUBCLASS |
|---|---|---|
| BRAY, STUART SAMUEL | 3733 | 606-062000 |

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Ward & Zinna, LLC
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Extremity Medical LLC
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Parsippany, NJ

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 23-0420 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Hanna Bondarik Mosolygo/ Date 4/27/2015
Typed or printed name Hanna Bondarik Mosolygo Registration No. 66475



PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | 12658680 |
| **Filing Date:** | 11-Feb-2010 |
| **Title of Invention:** | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Filer:** | Hanna Bondarik Mosolygo/Melissa Hegedus |
| **Attorney Docket Number:** | 277-042 |

Filed as Small Entity

**Filing Fees for Utility under 35 USC 111(a)**

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Basic Filing:** | | | | |
| **Pages:** | | | | |
| **Claims:** | | | | |
| **Miscellaneous-Filing:** | | | | |
| **Petition:** | | | | |
| **Patent-Appeals-and-Interference:** | | | | |
| **Post-Allowance-and-Post-Issuance:** | | | | |
| Utility Appl Issue Fee | 2501 | 1 | 480 | 480 |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Extension-of-Time:** | | | | |
| **Miscellaneous:** | | | | |
| | | | **Total in USD ($)** | **480** |

| Electronic Acknowledgement Receipt | |
|---|---|
| **EFS ID:** | 22170228 |
| **Application Number:** | 12658680 |
| **International Application Number:** | |
| **Confirmation Number:** | 1344 |
| **Title of Invention:** | INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE |
| **First Named Inventor/Applicant Name:** | Jeff Tyber |
| **Customer Number:** | 27776 |
| **Filer:** | Hanna Bondarik Mosolygo/Melissa Hegedus |
| **Filer Authorized By:** | Hanna Bondarik Mosolygo |
| **Attorney Docket Number:** | 277-042 |
| **Receipt Date:** | 27-APR-2015 |
| **Filing Date:** | 11-FEB-2010 |
| **Time Stamp:** | 09:23:59 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | $480 |
| RAM confirmation Number | 10990 |
| Deposit Account | 230420 |
| Authorized User | NARDONE, MELISSA |
| The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: | |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Issue Fee Payment (PTO-85B) | 2015_04_27IssueFee277_042.pdf | 102188<br>7b5b6f4cac577270d2e2871223bee572d058ee18 | no | 1 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30441<br>9e5adb56b25a37e80f30f47bed22100d7fddc615 | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | **Total Files Size (in bytes):** | 132629 | | |

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**New Applications Under 35 U.S.C. 111**
**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**
**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

| Receipt date: 09/17/2014 | Application Number | 12658680 | 12658680 - GAU: 3733 |
|---|---|---|---|
| **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** | Filing Date | 2010-02-11 | |
| **( Not for submission under 37 CFR 1.99)** | First Named Inventor | Jeff Tyber | |
| | Art Unit | 3733 | |
| | Examiner Name | Bray, Stuart Samuel | |
| | Attorney Docket Number | 277-042 | |

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
| | 1 | FR2861576A1 | FR | | 2005-05 | Cognet | | ☐ |
| Change(s) applied to document. /D.H.P./ 3/11/2015 | 2 | WO2009067831A1 | WO | | 2009-06 | Klaue | | ☐ |
| | 3 | WO2008024373A2 | WO | | 2008-02 | Samy | | ☐ |
| | 4 | WO9722301A1 | WO | | 1997-06 | Bramlet | | ☐ |

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

**NON-PATENT LITERATURE DOCUMENTS** Remove

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | 1 | | ☐ |

If you wish to add additional non-patent literature document citation information please click the Add button Add

**EXAMINER SIGNATURE**

| Examiner Signature | /Stuart Bray/ | Date Considered | 12/30/2014 |
|---|---|---|---|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.



ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | ISSUE DATE | PATENT NO. | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 12/658,680 | 06/02/2015 | 9044282 | 277-042 | 1344 |

27776 7590 05/13/2015

Ward & Zinna, LLC
SUITE 300
382 SPRINGFIELD AVENUE
SUMMIT, NJ 07901

# ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

**Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)**
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 151 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Jeff Tyber, Bethlehem, PA;
Jamy Gannoe, West Milford, NJ;
Lawrence Kiefer, Lafayette, NJ;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Doc Code : PET.DEC.AUTO
Description : ePetition Grant Letter

UNITED STATES
PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

# GRANT LETTER

| APPLICATION # | DECISION DATE | DECISION ON PETITION # | ATTORNEY DOCKET NUMBER |
|---|---|---|---|
| 12/658,680 | 06/07/2023 | UNDER CFR 1.378(b) | 024664-0003 |

## Title of Invention

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

In re Patent # **9044282**
Issue date: **06/02/2015**
Filing date: **02/11/2010**

This is an electronic decision on the petition under 37 CFR 1.378(b), filed June 07, 2023 to accept unintentional delayed payment of the 7.5 year maintenance fee for the above-identified patent.

The petition is **GRANTED.**

The maintenance fee is accepted, and the above-identified patent reinstated as of June 07, 2023. This decision also constitutes notice that the fee has been accepted. An electronic copy of the petition and this decision has been created as an entry in the Image File Wrapper. Nevertheless, petitions should print and retain an independent copy.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

Office of Petitions

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

# ELECTRONIC PAYMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| 12/658,680 | 06/07/2023 12:04:41 PM ET | 024664-0003 |

## Title of Invention

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | 9044282 |
| CONFIRMATION # | 1344 | FILED BY | Alan Gardner |
| PATENT CENTER # | 62223301 | AUTHORIZED BY | - |
| CUSTOMER # | 27776 | FILING DATE | 02/11/2010 |
| CORRESPONDENCE ADDRESS | - | FIRST NAMED INVENTOR | Jeff Tyber |

## Payment Information

| PAYMENT METHOD | PAYMENT TRANSACTION ID | PAYMENT AUTHORIZED BY |
|---|---|---|
| CARD / 2938 | E202367C06527407 | Alan Gardner |

| FEE CODE | DESCRIPTION | ITEM PRICE($) | QUANTITY | ITEM TOTAL($) |
|---|---|---|---|---|
| 2552 | MAINTENANCE FEE DUE AT 7.5 YEARS | 1504.00 | 1 | 1504.00 |
| 2558 | PETITION FOR THE DELAYED PAYMENT OF THE FEE FOR MAINTAINING A PATENT IN FORCE | 840.00 | 1 | 840.00 |
| | | | TOTAL AMOUNT: | $2,344.00 |

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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# ELECTRONIC ACKNOWLEDGEMENT RECEIPT

| APPLICATION # | RECEIPT DATE / TIME | ATTORNEY DOCKET # |
|---|---|---|
| **12/658,680** | **06/07/2023 12:04:41 PM ET** | **024664-0003** |

## Title of Invention

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

## Application Information

| | | | |
|---|---|---|---|
| APPLICATION TYPE | Utility - Nonprovisional Application under 35 USC 111(a) | PATENT # | 9044282 |
| CONFIRMATION # | 1344 | FILED BY | Alan Gardner |
| PATENT CENTER # | 62223301 | FILING DATE | 02/11/2010 |
| CUSTOMER # | 27776 | FIRST NAMED INVENTOR | Jeff Tyber |
| CORRESPONDENCE ADDRESS | - | AUTHORIZED BY | - |

## Documents

**TOTAL DOCUMENTS: 1**

| DOCUMENT | PAGES | DESCRIPTION | SIZE (KB) |
|---|---|---|---|
| petition-request.pdf | 2 | ePetition Request Form | 30 KB |

## Digest

| DOCUMENT | MESSAGE DIGEST(SHA-512) |
|---|---|
| petition-request.pdf | 0544D671416DA6D0E41DF5FBB3AE08D769E7AC8404142EAEF<br>20F512626D71B582845FD41B9350AB4CF0E127D51C8477CD86<br>F3346B72E0DC9424A1429A043F61A |

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as

described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

**National Stage of an International Application under 35 U.S.C. 371**

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**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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# PETITON TO ACCEPT UNINTENTIONAL DELAYED PAYMENT OF MAINTENANCE FEE (37 CFR 1.378(b))

| APPLICATION # | FIRST NAMED INVENTOR | ATTORNEY DOCKET # | FILING DATE |
|---|---|---|---|
| 12658680 | Jeff Tyber | 024664-0003 | 02/11/2010 |

**Title of Invention**

INTRAOSSEOUS INTRAMEDULLARY FIXATION ASSEMBLY AND METHOD OF USE

In re Patent #: 9044282

Issue date: 06/02/2015}

The delay in the payment of the maintenance fee to the above-identified patent was unintentional.

## PETITIONER(S) REQUEST THAT THE DELAYED PAYMENT OF THE MAINTENANCE FEE BE ACCEPTED AND THE PATENT REINSTATED

(1) Petition fee under 37 CFR 1.17(m) is attached

**Applicant claims the following entity status**
Small

(2) Statement
The delay in the payment of the maintenance fee to this patent was unintentional

- Petitioner(s) is reminded that a delay resulting from a deliberately chosen course of action or a change in circumstance is not an unintentional delay.

- Petitioner(s) is further reminded that a person seeking reinstatement of an expired patent should not make a statement that the delay in payment of the maintenance fee was unintentional unless the entire delay was unintentional, including the period from discovery that the maintenance fee was not timely paid until payment of the maintenance fee. For example, a statement that the delay in payment of the maintenance fee was unintentional would not be proper when the patentee becomes aware of an unintentional failure to timely pay the maintenance fee and then intentionally delays filing a petition for reinstatement of the patent under 37 CFR 1.378. See MPEP 2590.

NOTE: Where the petition under 37 CFR 1.378 is filed more than two years after the date the patent expired for nonpayment of

the maintenance fee, the United States Patent and Trademark Office requires an additional explanation of the circumstances surrounding the delay that establishes the entire delay was unintentional. This requirement is in addition to the requirement to provide a statement that the entire delay was unintentional. See Clarification of the Practice for Requiring Additional Information in Petitions Filed in Patent Applications and Patents Based on Unintentional Delay, 85 FR 12222 (March 2, 2020). See MPEP 711.03(c)(II)(C)-(F) for additional guidance on the information required to establish that the entire delay was unintentional.

## Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

| Signature | Name | Registration # |
|---|---|---|
| /Alan D. Gardner/ | Alan Gardner | 69495 |

---

PETAUTO SB64.0