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17 **UNITED STATES DISTRICT COURT**

18 **CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION**

19 ADVANCED ORTHOPAEDIC
20 SOLUTIONS, INC., a California
corporation,

21 Plaintiff/
22 Counter-Defendant,

23 vs.

24 BIOMET, INC., an Indiana corporation,
Defendant/
25 Counterclaimant, and

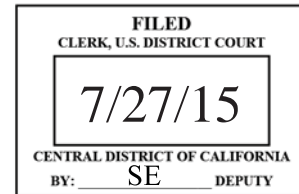
26 ZIMMER BIOMET HOLDINGS, INC,
an Indiana corporation,
27 Defendant.

Case No. 2:14-cv-06354-ODW-MAN

**FIRST AMENDED COMPLAINT
DEMAND FOR JURY TRIAL**

**Final Pre-Trial Conference Date:
May 23, 2016**

Trial Date: June 14, 2016



1 Plaintiff Advanced Orthopaedic Solutions, Inc. brings this Complaint for Patent
2 Infringement against Defendants alleging as follows:

3 **THE PARTIES**

4 1. Plaintiff Advanced Orthopaedic Solutions, Inc. (“AOS” or “Plaintiff”) is
5 a California corporation with its principal place of business at 3203 Kashiwa Street,
6 Torrance, California 90505.

7 2. On information and belief, Defendant Biomet, Inc. (“Biomet” or
8 “Defendant”) is an Indiana Corporation with its principal place of business at 56 East
9 Bell Drive, Warsaw, Indiana 46681.

10 3. On information and belief, Defendant Zimmer Biomet Holdings, Inc.
11 (“Zimmer Biomet” or “Defendant”) is an Indiana Corporation with its principal place
12 of business at 56 East Bell Drive, Warsaw, Indiana 46681.

13 **JURISDICTION AND VENUE**

14 4. This is a civil action for patent infringement arising under the patent laws
15 of the United States, 35 U.S.C. §101, et seq.

16 5. This Court has subject matter jurisdiction over this action under 28
17 U.S.C. §§1331 and 1338.

18 6. Defendants are subject to personal jurisdiction within the Central District
19 of California, and resides within the Central District of California, within the meaning
20 of 28 U.S.C. §§ 1391 and 1400. Defendants are registered to do business within the
21 State of California as a foreign corporation(s) and maintain an agent, located in

1 Bakersfield, California, for service of process within the State of California. In
2 addition, a substantial part of the events giving rise to the claim alleged herein
3 occurred within the Central District of California.

4 7. Pursuant to 28 U.S.C. §§ 1391 and 1400(b), venue for this civil action
5 properly lies in the Central District of California.

6 GENERAL ALLEGATIONS

7 8. AOS brings this action against Biomet and Zimmer Biomet for
8 infringement of a patent owned by AOS, U.S. Patent No. 8,702,707 entitled “Fixation
9 Instrument for Treating a Bone Fracture” (the ‘707 patent).

10 9. AOS brings this action against Biomet and Zimmer Biomet for
11 infringement of a patent owned by AOS, U.S. Patent No. 8,092,454 entitled “Fixation
12 Instrument for Treating a Bone Fracture” (the ‘454 patent).

13 10. On information and belief, Biomet manufactured, offered for sale, and
14 sold a lag screw fixation system identified as the Affixus™ Hip Fracture Nail shown
15 in Exhibit A.

16 11. On information and belief, on or about June 24, 2015, Zimmer Holdings,
17 Inc. acquired Biomet and in connection with the acquisition Zimmer Holdings, Inc.
18 changed its corporate name to Zimmer Biomet Holdings, Inc.

19 12. On information and belief, Zimmer Biomet manufactures, offers for sale,
20 and sells a lag screw fixation system identified as the Affixus™ Hip Fracture Nail
21 shown in **Exhibit A**.

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1 which Plaintiff is entitled to injunctive relief and damages in an amount to be
2 determined at trial.

3 **SECOND CLAIM FOR RELIEF**

4 **(INFRINGEMENT OF PATENT NO. 8,092,454)**

5 19. AOS incorporates paragraphs 1-18 as if set forth full herein.

6 20. AOS is the owner of the entire right, title, and interest in and to the ‘454
7 patent and has the right to bring and maintain this action.

8 21. The ‘454 patent was duly and legally issued by the U. S. Patent and
9 Trademark Office on January 10, 2012. A copy of the ‘454 patent is attached as
10 **Exhibit C.**

11 22. Upon information and belief, subsequent to the issuance of the ‘454
12 patent, Defendants, directly or through the actions of their employees, divisions,
13 and/or subsidiaries commenced infringing, infringed, are infringing, and unless
14 enjoined, will continue to infringe, literally and/or under the doctrine of equivalents,
15 one or more claims of the ‘454 patent by making, using, offering to sell, and selling
16 within the United States a lag screw fixation system, including but not limited to the
17 system identified as the Affixus™ Hip Fracture Nail.

18 23. Plaintiff has been irreparably damaged by reason of Defendants’
19 infringement, and unless Defendants are enjoined by this Court, Defendants will
20 continue acts of patent infringement to Plaintiff’s irreparable harm.

21 24. As a direct and proximate consequence of Defendants’ infringement of

1 the '454 patent, Plaintiff has been, is being, and until such acts and practices are
2 enjoined by this Court, will continue to be damaged in its business and property, for
3 which Plaintiff is entitled to injunctive relief and damages in an amount to be
4 determined at trial.

5 **PRAYER FOR RELIEF**

6 WHEREFORE, AOS respectfully requests that the Court enter judgment
7 against Biomet as follows:

8 A. A determination by this Court that Defendants have infringed and
9 continue to infringe one or more claims of the '707 patent;

10 B. A determination by this Court that Defendants have infringed and
11 continues to infringe one or more claims of the '454 patent;

12 C. An order preliminarily and permanently enjoining Defendants, their
13 respective officers, agents servants, directors and employees, and all persons acting in
14 concert, participation or privity with them or on their behalf including their
15 subsequent subsidiaries, divisions, successors and assigns from further acts of
16 infringement of the '707 patent and the '454 patent;

17 D. An accounting and award for damages to adequately compensate AOS
18 for Defendants' infringement of the '707 patent and the '454 patent, pre-judgment and
19 post-judgment interest, and attorneys' fees and costs as allowed by law; and

20 E. For such other and further relief as the Court may deem just and proper.

21 ///

1 DATED: July 24, 2015

Respectfully submitted,

2 Burgess Law Office, PLLC

3 /s/ Joseph G Burgess

4 JOSEPH G. BURGESS (*pro hac vice*)

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DATED: July 24, 2015

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/ / /

EXHIBIT A



Biomet Trauma Transition

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Intramedullary Nail:

AFFIXUS® Hip Fracture

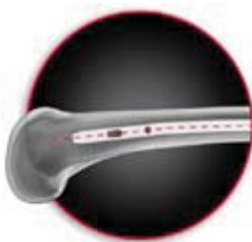


Overview

Features & Benefits

Sizes & Accessories

The AFFIXUS® Hip Fracture Nail System treats a wide range of proximal femoral fracture indications using a single set of user-friendly instruments, and combines the principles of a compression hip screw with the biomechanical advantages of an intramedullary nail. Listed below are just a few of the main features that make this system unique:



The anatomic bends of the nail are important features. This hip fracture nail has a 3° distal bend paired with a chamfer on the front of the distal tip of the nail in addition to its 1.8m radius of curvature. The combination of the proximal 1.8m radius of curvature and the 3° distal bend provides a resultant bow that is comparable to a proximal 1.5M radius of curvature with a minimal offset. These features result in an implant that accommodates the anterior bow of the femur as well as facilitating ease of insertion through the proximal intertrochanteric/subtrochanteric region while minimizing the risk of anterior cortex penetration.



GOAL POST™ Technology is designed to facilitate visualization of the femoral neck on the lateral view in order to more accurately place the guide pin for the lag screw placement. The anterior and posterior metal posts on the proximal aspect on the insertion jig allow for an unobstructed fluoroscopic view down to the base of the femoral neck, and assist with fine tuning of the guide pin before it is fully seated in the femoral head.



The AFFIXUS® Hip Fracture Nail comes with a pre-assembled set screw to eliminate fiddle factor and save time in the OR. This pre-assembled set screw engages with the lag screw to create a non-rotational or non-compression device. This set screw can engage the lag screw before or after inserting an optional anti-rotational screw. If compression is needed, one quarter back will allow for dynamic compression.

Additional product information:

[Essential Product Information - AFFIXUS® Hip Fracture Nail](#)

[AFFIXUS® Hip Fracture Nail Surgical Technique - BMET0022.2](#)

[Intramedullary Nailing Portfolio - BMET0032.0](#)

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AFFIXUS®
HIP FRACTURE NAIL

Surgical Technique

BIOMET®

One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

AFFIXUS[®] Hip Fracture Nail

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AFFIXUS® Hip Fracture Nail



Strength and Stability in the Proximal Femur

- Optimal lag screw design for resistance to cut-out
- Easy-to-use instrumentation and targeting jig, which includes Goal Post™ technology, aids in lag screw placement
- Extensive range of neck/shaft angles, distal diameters, and nail lengths – combined with a small proximal nail diameter – allows the surgeon to achieve a close match for each patient's anatomy
- Unique distal bend facilitates entry through the proximal 1/3 of the femur and reduces potential for anterior cortex penetration

AFFIXUS® Hip Fracture Nail

A system of **choices** for effective treatment of proximal femoral fractures

- Short (180 mm) and long (260 - 460 mm) nail options treat a wide range of proximal fracture indications using a single set of user-friendly instruments
- 15.6 mm proximal nail diameter
- Proximal 4° lateral bend allows for greater trochanteric entry site
- 125° and 130° neck angles provide a range of anatomical options
- 10° of proximal anteversion built into the nails
- 10.5 mm diameter cannulated lag screw for bone preservation
- Unique thread spacing and design of the lag screw helps to resist displacement and cut-out
- Chamfer on the front distal tip helps facilitate insertion and minimizes risk of stress on the anterior cortex in the distal femur
- 3° distal bend facilitates ease of insertion through the proximal intertrochanteric/subtrochanteric region
- Pre-loaded set screw for ease of use
- 5.0 mm anti-rotation (AR) screw for rotational control (optional)
- Shouldered lag screw and AR screw help prevent medial screw disengagement
- Long nail maintains a 1.8 m radius of curvature to closely match the femoral anatomy
- 5.0 mm diameter distal interlocking screws have a large core diameter for strong fixation
- Static or dynamic distal locking options with a 6 mm dynamization range





Multiple locking options for optimal implant stability



The AFFIXUS® Hip Fracture Nail System, comprised of short and long nails, provides surgeons with an intramedullary hip screw to stabilize fractures of the proximal femur. The AFFIXUS® Hip Fracture Nail combines the principles of a compression hip screw with the biomechanical advantages of an intramedullary nail.



Figure 1

AFFIXUS® Hip Fracture Nail



AFFIXUS® Hip Fracture Nail
Short – (180 mm)



AFFIXUS® Hip Fracture Nail
Long – (260 - 460 mm)

Indications and Pre-op Planning

The AFFIXUS® Hip Fracture Nail System* is designed for antegrade trochanteric insertion to treat the following fractures (Figure 1):

The AFFIXUS® Hip Fracture Nail System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

Note: Bone screws referenced in this material are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical thoracic or lumbar spine.

* System includes short (180 mm) and long (260-460 mm) nails, in 20 mm increments.

AFFIXUS® Hip Fracture Nail

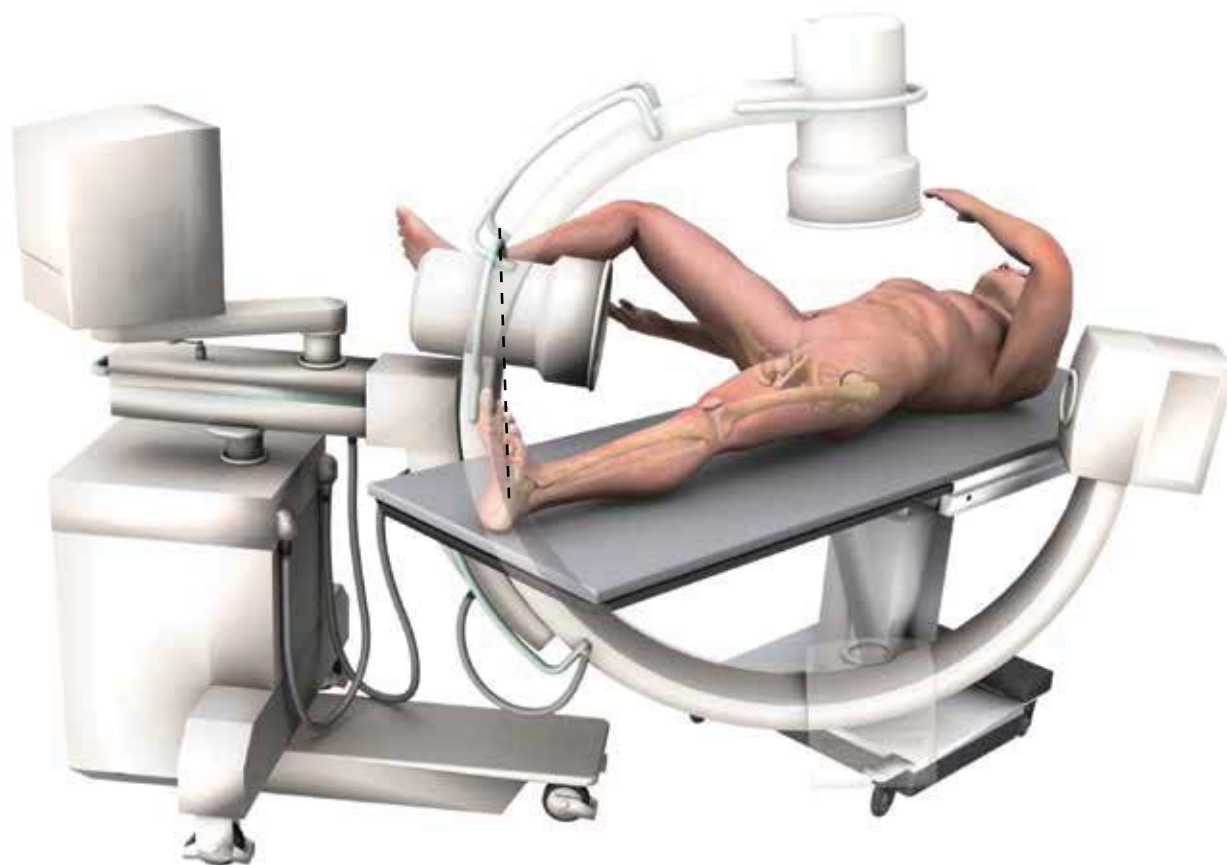


Figure 2

Patient Positioning and Reduction

Place the patient in the supine or lateral position on a fracture table or radiolucent imaging table. Lateral access to the proximal femur is required. Intraoperative image intensification with a C-arm is required to obtain AP and lateral imaging of the operative area during preoperative preparation (reduction) and throughout the procedure for nail insertion, nail locking, and anteversion alignment. Avoid excessive abduction of the hip during reduction as the access to the starting point and nail insertion may be impeded. The trunk may be laterally flexed away from the operative side to improve access to the starting point. The contralateral leg may be flexed at the hip or scissored below the affected leg in the supine position (Figure 2).

Closed Fracture Reduction

Fluoroscopy must be used to verify proper fracture reduction.

- Acceptable fracture alignment must be obtained prior to implant insertion
- Surgeon must avoid varus malreductions
- Use a combination of traction, rotation, adduction, and flexion/extension of the leg to obtain an acceptable reduction
- Open reductions may be required for more complicated fracture patterns and should be used when an acceptable closed reduction cannot be obtained (see page 10)

Initial Incision

Make an incision proximal to the tip of the greater trochanter in line with the femoral axis. Divide the fascia lata in line with its fibers and access the tip of the greater trochanter.



Trochanteric entry point

Figure 3

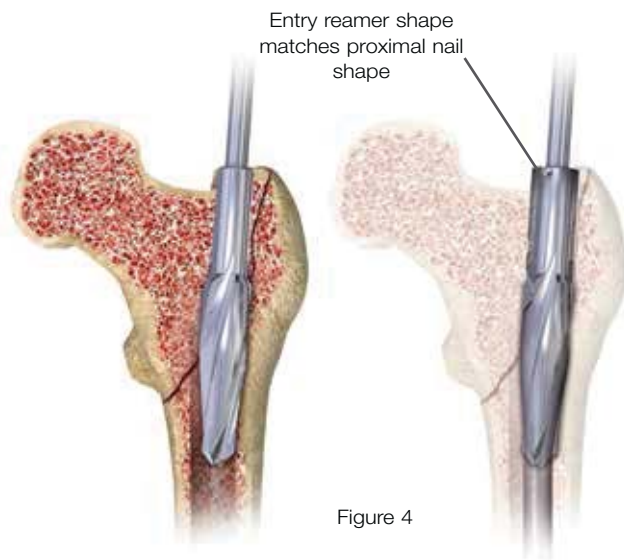


Figure 4



Figure 5

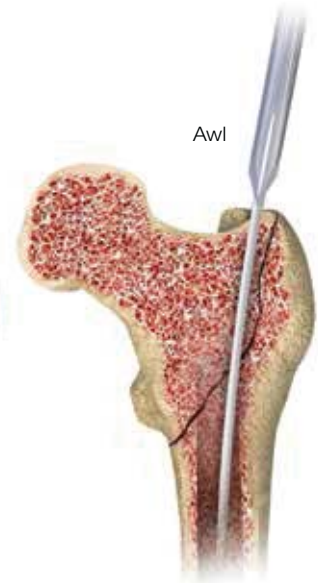


Figure 6

Entry and Canal Preparation

Femoral Entry Preparation

Attach the standard 3.2 mm guide pin to the pistol guidewire gripper (2810-01-001) or power source and pass it through the tip of the greater trochanter into the center of the femoral canal. Position the entry on the tip of the greater trochanter (Figure 3). Confirm on AP and lateral fluoroscopy views that the entry pin is centered on the trochanter.

Option 1:

Cannulated Entry Reamer (One-step 16.6 mm) Attach the cannulated entry reamer (2112-01-102 or 2112-01-103) to the power source and pass it over the guide pin through the entry portal (Figure 4).

It is essential to ream until the reamer's proximal shaft passes with the greater trochanter's cortical bone as the shape of the entry reamer matches the nail shape and the top of the cylindrical segment of the reamer corresponds to the top of the nail (Figure 4). Reaming should continue until the tip of the entry reamer is at the level of the lesser trochanter and not beyond.

Option 2: Cannulated Awl

Pass the cannulated awl over the guide pin and introduce with a rotation motion until the awl is buried to at least half its blade length (Figure 5 & 6).

AFFIXUS® Hip Fracture Nail



Figure 7



Figure 8

Open Fracture Reduction

Once access to the femoral canal has been gained, place the ball nose guide wire into the entry site utilizing the pistol guide wire gripper (2810-01-001) (Figure 7).

Obtain appropriate anatomic reduction in order to restore length, anatomic axis alignment, and rotation of the injured limb. Reduction can be achieved through the surgeon's preferred method such as traction, external fixator, external aids, or joysticks. To aid in manipulating the fracture fragments and passing the ball nose guide wire, long (7.5 mm diameter, 2810-01-007) and short (6.5 mm diameter, 2810-01-008) reduction tools are available.

Insert the reduction tool into the medullary canal, past the fracture site. Once the fracture is in alignment, pass the ball nose guide wire, available in both 80 cm (2810-01-080) and 100 cm (2810-01-100) lengths, across the fracture site. Remove the reduction tool (Figure 8).



Figure 9



Figure 10

Canal Preparation

Short Nail

Confirm that the femoral diaphysis is wide enough and long enough to allow the selected nail diameter to pass. Ream as necessary to enlarge the diaphysis to accept the selected nail.

Long Nail

Achieve proper alignment of the injured limb prior to reaming. Maintain alignment throughout the reaming process to avoid eccentric reaming. Commence reaming by placing the flexible reamer over the ball nose guide wire (Figure 9).

Ream the medullary canal in millimeter increments until cortical bone is reached and in half-millimeter increments thereafter. Surgeon preference should dictate the actual extent of intramedullary reaming. Monitor the reaming procedure using image intensification to avoid eccentric or excessive cortical reaming.

Note: It is recommended to over-ream the diaphysis by 2 mm.

Nail Length Selection

With the tip of the ball nose guide wire at the level of the desired depth of nail insertion, slide or snap the nail depth gauge (Cat. No. 2112-01-106) onto the ball nose guide wire until it contacts the bone, ensuring that the tip does not fall into the existing trochanteric entry canal, thus providing an inaccurate measurement. To obtain the appropriate nail length, read the measurement mark on the nail depth gauge that is closest to the beginning of the black transition area on the guide wire (Figure 10). If a nail of the exact measured length is not available, choose a shorter nail of the next closest available length. A direct measurement can also be taken of the uninjured extremity using either radiographs with magnification markers, or directly on the uninjured limb.

AFFIXUS® Hip Fracture Nail

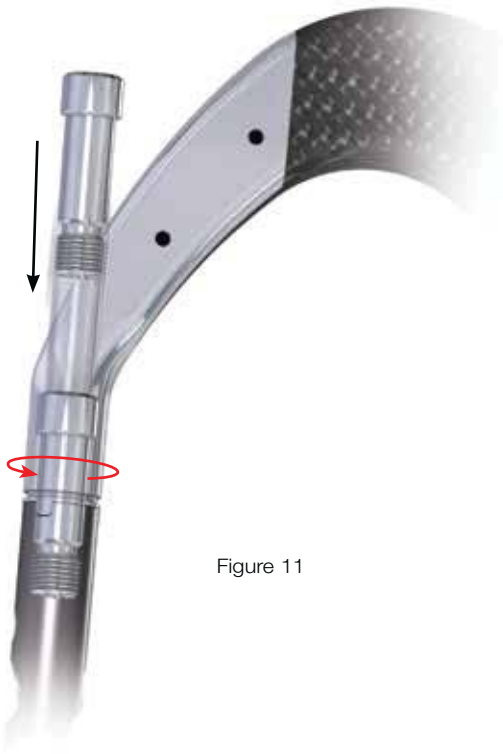


Figure 11



Figure 12

Nail Insertion

Jig Assembly

Select the appropriate targeting jig that corresponds to the neck shaft angle of the implant selected. Insert the jig bolt through the targeting jig using the jig bolt driver (Cat. No. 2810-13-037 or 2810-13-006) (Figure 11).

Note: 130° neck angle is most commonly used (Figure 12).



Figure 13A



Figure 13B

When assembling the nail to the insertion jig, ensure that the jig tabs align with the slots on the nail so that the nail fully seats in the targeting jig (Figure 13A). Once the nail is fully seated, securely tighten the jig bolt using the jig bolt driver (2810-13-037 or 2810-13-006).

Note: If it is difficult to attach the nail to the jig, double-check that the nail and jig are identified with the same angle. The nail will only align with the jig if they have the same neck-shaft angle.

Check the assembly prior to nail introduction. Pass the lag screw sheath through the targeting jig. A properly assembled nail and jig will allow the lag screw drill to be directed through the sleeve and through the center of the lag screw hole in the nail.

When using a short (180 mm) nail, confirm the targeting alignment of the distal interlocking screws using the green sheaths and drill bits in the same manner (Figure 13B).

AFFIXUS® Hip Fracture Nail



Figure 14

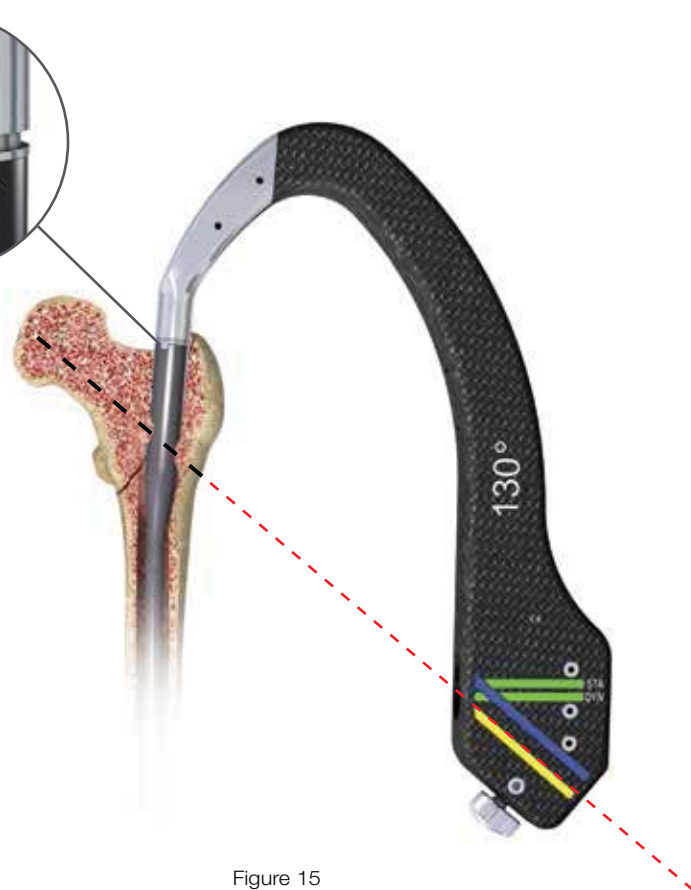


Figure 15

Nail Insertion

Insert the nail by hand over the 3 mm ball nose guide wire into the medullary canal. Take care not to strike the jig or targeting arm with the mallet. A curved impaction tool (Cat. No. 2112-01-204) is included in the set and is meant to be used for gentle taps of the mallet to fine tune the final seating of the nail.

Note: The insertion jig should not be hammered on.

It may be helpful to preliminarily insert the trochanteric nail utilizing its bow to facilitate clearance of the medial femoral cortex of the proximal fragment. To do this, rotate the insertion jig anteriorly (toward the ceiling). In this position the distal bend in the nail will be angled laterally to aid in passing the nail through the greater trochanteric entry site, and avoid medial cortical penetration.

As the nail passes the medial cortex of the proximal fragment, slowly derotate the jig handle into the usual lateral position, so that the anterior bow of the nail now corresponds with the anterior bow of the femur (Figure 14). If the nail requires substantial force to advance, remove it and ream an additional millimeter. Avoid excessive force when inserting the nail. Advance the nail until the lag screw aligns to the desired position into the femoral head and neck to allow ideal placement of the lag screw (Figure 15).

Maintenance of reduction must be confirmed prior to lag screw insertion. If the reduction has shifted to a suboptimal position, further hip adduction, traction, and rotational adjustments can be made prior to lag screw placement. Remove the ball nose guide wire.

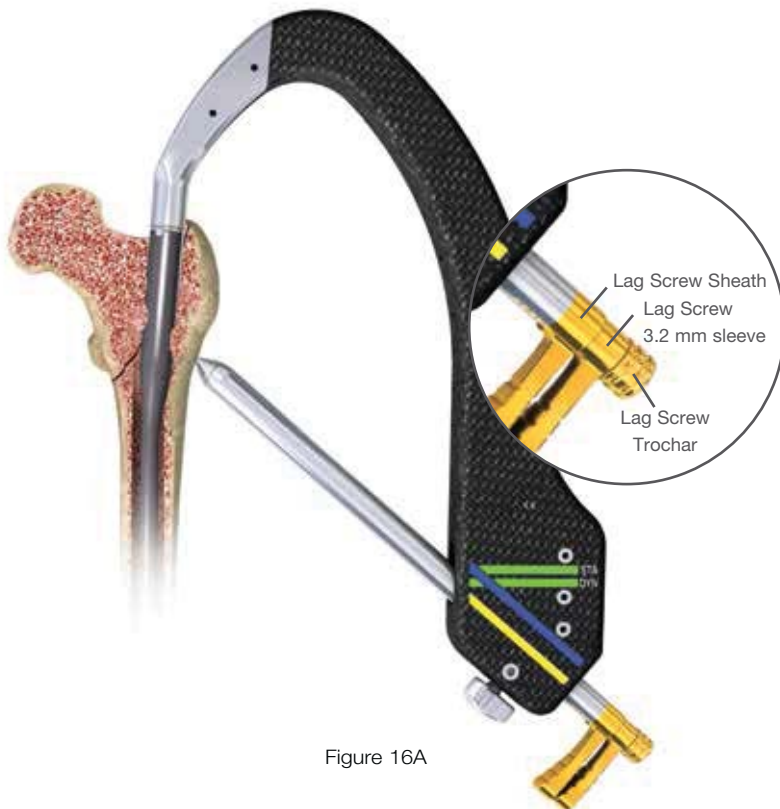


Figure 16A



Figure 16B

Proximal Locking

Lag Screw Guide Pin Introduction

Insert the lag screw sheath assembly (lag screw sheath—2112-01-300, lag screw trochar—2112-01-301, lag screw 3.2 mm sleeve—2112-01-302) through the lag screw hole in the jig. Pass the trochar through the sheath and make an appropriate skin incision where the trochar contacts the skin. Advance the trochar through the tissue until the tip is seated against the lateral femoral cortex and confirm with fluoroscopy. The trochar may be impacted into the lateral cortex with a mallet to create a starting point for the guide pin and minimize migration during insertion (Figure 16A).

Remove the trochar and maintain the lag screw sheath position against the lateral femoral cortex.

Note: At the distal end of the jig assembly, the jig knob can be tightened to secure the position of the lag screw sheath to maintain contact against the lateral femoral cortex.

Introduce the 3.2 mm guide pin into the 3.2 mm sleeve and drill into position under fluoroscopic guidance. Check the guide pin position within the center of the femoral head and neck in both AP and lateral planes. Advance the guide pin to a distance within 5 mm from the subchondral bone (Figure 16B).

Note: If at any time a guide pin is bent, replace it immediately.

AFFIXUS® Hip Fracture Nail

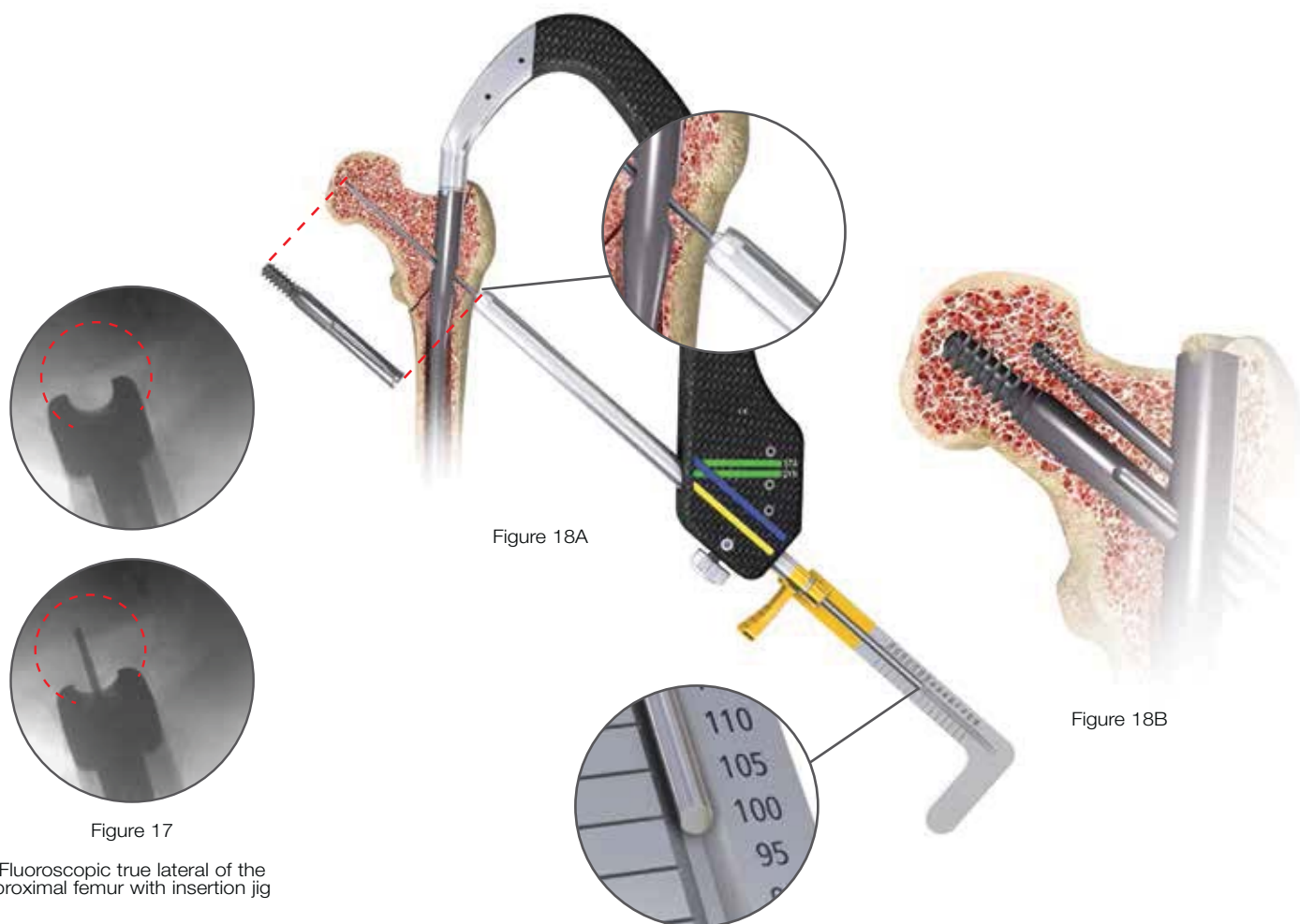


Figure 17

Fluoroscopic true lateral of the proximal femur with insertion jig

Figure 18A

Figure 18B

Goal Post™ Technology

The Goal Post™ Technology is designed to facilitate visualization of the femoral neck on the lateral view in order to more accurately place the guide pin for the lag screw. The anterior and posterior metal posts on the proximal aspect of the insertion jig allow for an unobstructed fluoroscopic view down to the base of the femoral neck (Figure 17) and assist with finetuning of the guide pin before it is fully seated in the femoral head.

Lag Screw Length Selection

Before selecting a lag screw length, verify that the lag screw sheath and 3.2 mm sleeve are in place and fully seated against the lateral femoral cortex.

- The depth gauge seats against the lag screw sheath, not the 3.2 mm sleeve
- The system measures to the tip of the guide pin
- The measurement represents the length of a lag screw that begins at the end of the lag screw sheath and terminates at the tip of the guide pin (Figure 18A and 18B)

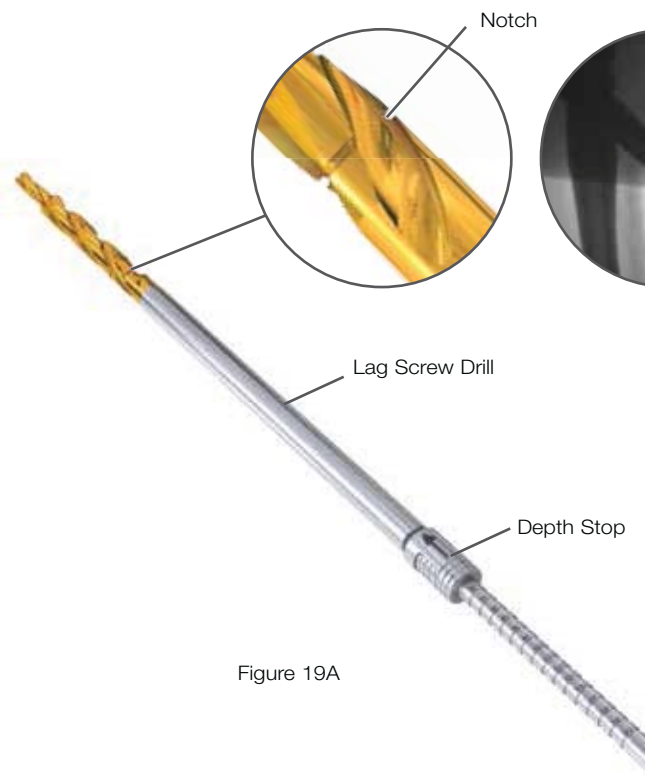


Figure 19A

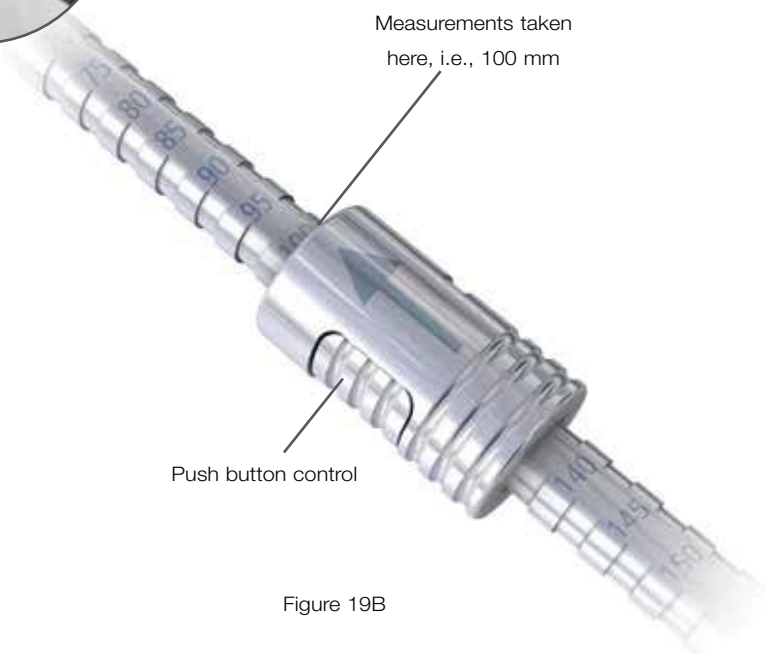


Figure 19B

Depth Stop Adjustment

Adjust the depth stop on the lag screw drill (2112-01-303) to the desired depth. The measurement on the depth stop should be set to the depth measured by the lag screw depth gauge (2112-01-304) (Figure 19A).

Adjust the depth stop by pushing in the button and sliding the stop forward or backward until desired depth is seen on the end of the depth stop closest to the gold drill bit tip (Figure 19B).

Note: There is a “notch” on the lag screw drill that is visible under fluoroscopy; this “notch” references 100 mm (Figure 19A).

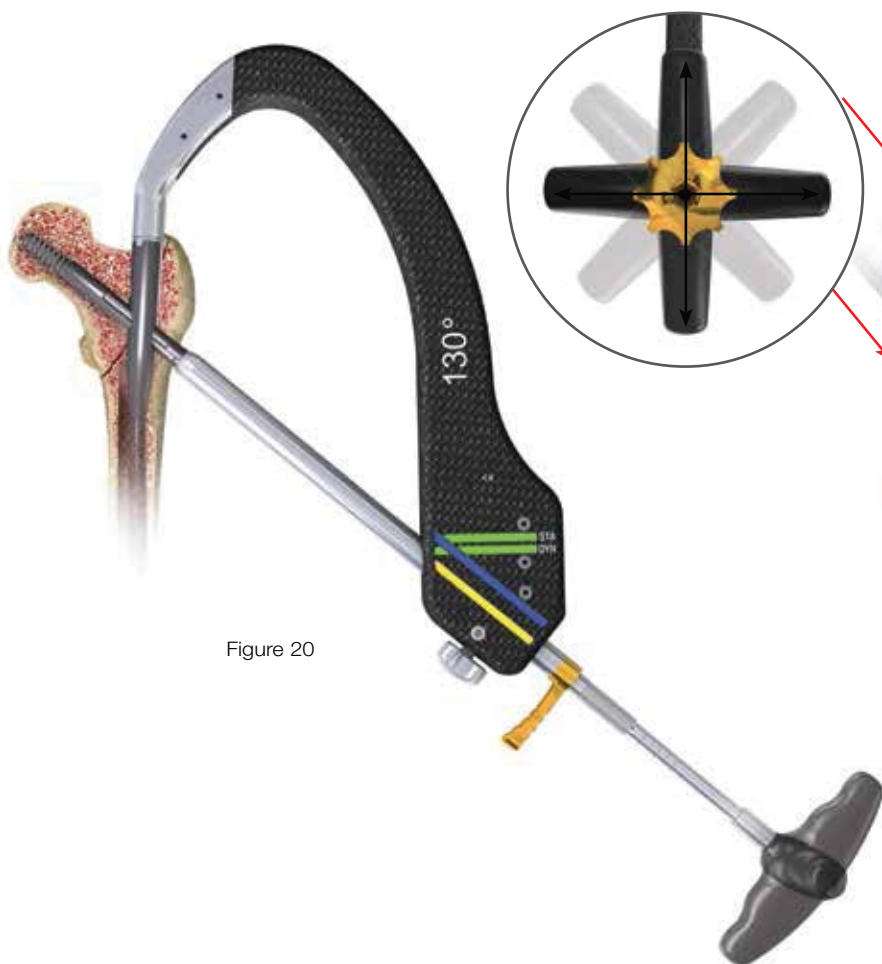
Lag Screw Drilling and Tapping

Advance the lag screw drill over the guide pin and drill to the desired depth. Use fluoroscopy to confirm the position of the lag screw drill and that the guide pin is not advanced into the hip joint or acetabulum by the drill.

If the bone is particularly dense, use the cannulated tap (2112-01-310) to cut a thread for the lag screw.

Note: There is a guide pin repositioning tool (2112-01-312) to aid in reinserting the guide pin if it backs out with removal of the lag screw drill.

AFFIXUS® Hip Fracture Nail



Lag Screw Insertion

Insert the lag screw coupling rod (Cat. No. 2112-01-306) through the lag screw driver (Cat. No. 2112-01-307) and position the selected lag screw on the end of the lag screw driver. Tighten the coupling rod to secure the lag screw to the driver.

Advance the lag screw manually into the femoral neck and head over the guide pin. Confirm the terminal position of the lag screw with fluoroscopy, with a goal of seating the screw between 5 and 10 mm from the subchondral bone.

The handle of the lag screw driver must be positioned either parallel or perpendicular to the targeting jig when the lag screw has been advanced to the desired depth (Figure 20). This will ensure that the set screw will engage one of the grooves of the lag screw.

Fracture Compression

Compression of the intertrochanteric component of the fracture, if desired, can be achieved by utilizing the compression wheel (Cat. No. 2112-01-308). Once the lag screw has been fully seated, release traction from the leg and firmly seat the lag screw sheath against the lateral cortex. Confirm that the sheath is tightly secured in the jig by tightening the jig knob, and place the compression wheel on the lag screw driver and advance against the lateral side of the sheath. In osteoporotic bone, care should be taken to avoid pulling the lag screw out of the femoral head with this technique (Figure 21).

Note: Hash marks on lag screw driver represent 5 mm intervals. It is recommended that no more than 4-6 mm of compression is applied and should be applied prior to placing the Anti-Rotation (AR) screw.



Figure 22A



Figure 22B

Cross section of set screw
engaging lag screw

Lag Screw Fixation

The set screw is pre-loaded in the nail. Using the 5 mm set screw hex driver (2112-01-309), engage the set screw and advance in a clockwise direction 2 to 3 full rotations until the set screw contacts the lag screw in one of the four lag screw grooves (Figure 22A & 22B).

To confirm proper position of the set screw, gently attempt to rotate the lag screw both clockwise and counterclockwise. If there is firm resistance and the lag screw will not rotate, the set screw has properly engaged the lag screw grooves. However, if you are able to rotate the lag screw, the set screw has not engaged a groove and the lag screw handle should be realigned and the set screw tightened again.

The set screw may be backed off one-quarter turn to allow dynamic compression of the lag screw in the nail, while still providing rotational control of the lag screw.

Note: The set screw can be engaged before or after inserting the AR screw (if the AR screw is to be used). The AR screw will align through an oblong hole within the set screw.

AFFIXUS® Hip Fracture Nail

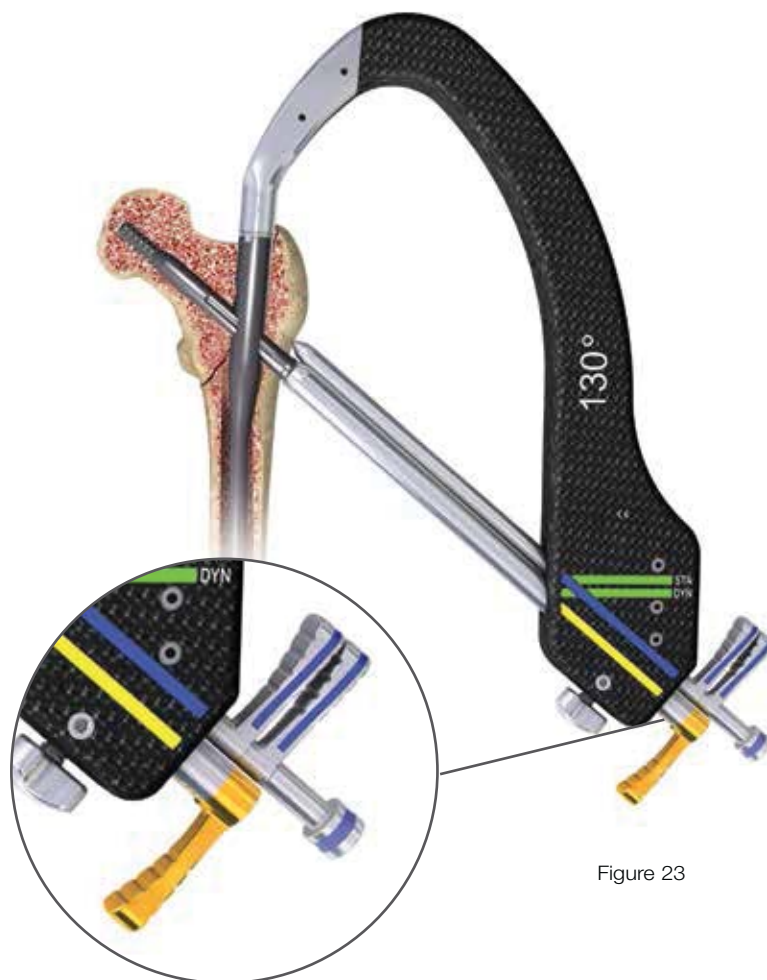


Figure 23

Anti-rotation (AR) Guide Pin and Screw Placement (optional)

This system allows multiple techniques for placement of an anti-rotation (AR) screw if desired.

- The AR screw may be inserted either before or after the lag screw is placed, based upon surgeon preference and the fracture pattern.
- The surgeon has the option to place a guide pin through the AR hole to provisionally stabilize the fracture during lag screw placement, or he/she may choose to use an AR screw. The guide pin used through the AR hole is also useful to assist in stabilizing the femoral neck and head segment during lag screw placement to resist rotation around the axis of the femoral neck. Once the lag screw has been placed and secured, the surgeon may choose to remove the guide pin from the AR hole and place a screw in this position to provide further rotational control.

Place the AR screw sheath (Cat. No. 2112-01-501) and trochar (Cat. No. 2112-01-502) through the AR hole in the insertion jig. Make a small incision where the trochar meets the skin and advance the trochar to the lateral aspect of the femoral cortex. Alternatively, in cases where the lag screw has already been inserted, extend the incision for the lag screw proximally to allow the AR screw sheath and trochar to be seated against the femur (Figure 23).

Note: When the anti-rotation and lag screw sheaths are seated at the same time, they must be rotated so the groove on the lag screw sheath faces the anti-rotation screw sheath (so the colored handles are 180 degree to each other) in order to allow both sheaths to fully seat (Figure 23).

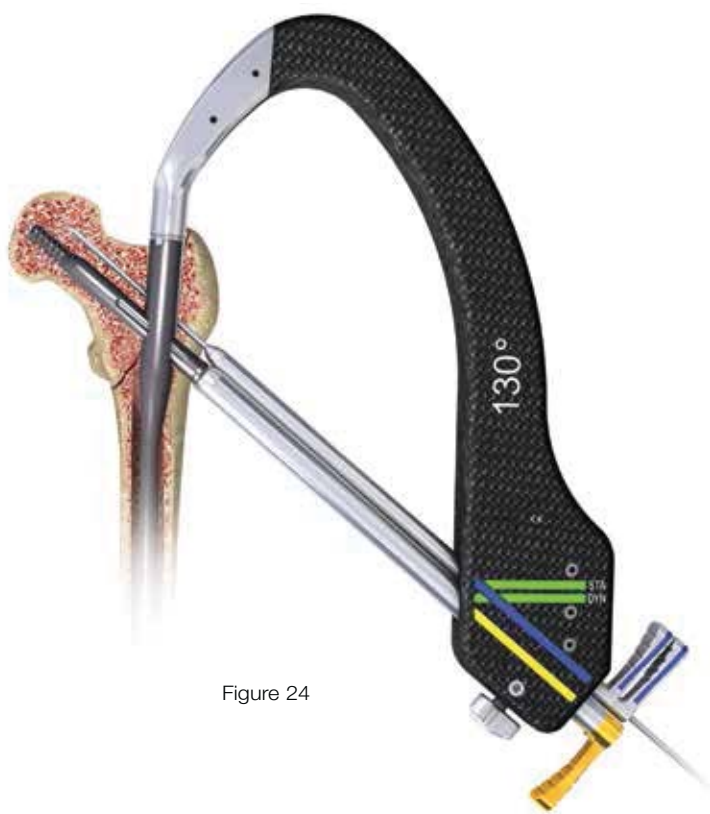


Figure 24

Remove the trochar and insert the AR 3.2 mm sleeve (Cat. No. 2112-01-503). Insert the 3.2 mm guide pin and advance into desired position. It is recommended to leave the AR guide pin 15-20 mm from the subchondral bone (Figure 24).

Note: In cases where very dense cortical bone is encountered, the cortex may be opened up with the anti-rotation screw drill prior to advancing the 3.2 mm guide pin to prevent the guide pin from “walking” up the lateral cortex.

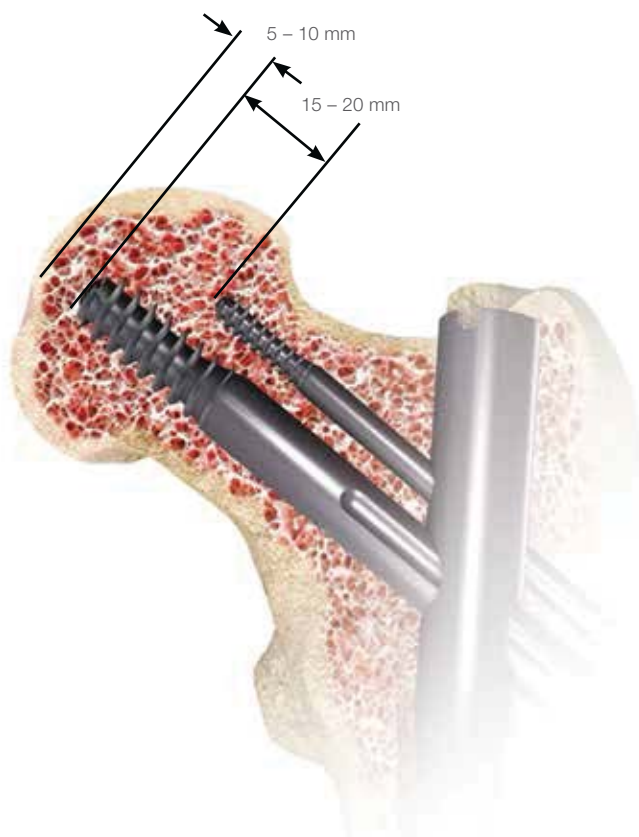


Figure 25

Remove the guide pin and 3.2 mm sleeve. Confirm that the screw sheath is advanced against the lateral femoral cortex and use the AR drill to drill to the desired depth. Measure the length of the desired screw by reading the depth of the AR drill against the screw sheath.

Note: It is recommended that the tip of the AR screw be 15-20 mm shorter than the lag screw to avoid perforation of the femoral head (Figure 25).

AFFIXUS® Hip Fracture Nail



Figure 26

Select an AR screw of the desired length. Place the AR screw on the 3.5 mm hex driver (Cat. No. 2112-01-504) and manually insert the screw into the femur through the AR screw sheath.

Advance until the tip of the screw reaches the desired depth and confirm with fluoroscopy. The screwdriver and sheath may now be removed.

Securing the AR Screw (optional)

The AR screw may be secured with an impinging in cap that is inserted through the end of the nail.

Note: The impinging in cap will make the AR screw a static construct and is recommended to only be used when the lag screw is also fixed in a static position (this can be achieved by not backing off the pre-loaded set

screw a quarter turn). Otherwise there is risk of creating the Z-effect.

It is recommended to only lock the AR screw in instances in which the set screw has been left fully engaged into the lag screw, thus preventing any collapse of the 10.5 mm compression screw (Figure 26).

The impinging in cap may be utilized at the end of the case, after the set screw for the lag screw has been tightened, and the insertion jig has been removed.



Figure 27



Figure 28

Distal Locking

Distal Locking (short nails)

The short nail may be locked either statically, dynamically, or left unlocked based on the particular fracture pattern and stability (Figure 27).

Pass the distal screw sheath (2112-01-401) and trochar (2112-01-402) through the hole labeled “static” on the insertion jig and advance to the lateral femoral cortex. Remove the trochar and use the distal screw drill sleeve (2112-01-403) and 4.3 mm graduated drill bit (2112-01-405). Drill until the far cortex is either reached or penetrated. The drill is calibrated and may be used to determine screw length by reading the depth off the end of the distal screw drill sleeve (Figure 28).

An optional distal screw depth gauge (2112-01-404) is available to confirm screw length. This gauge measures off of the lateral side of the 4.3 mm distal screw drill sleeve (2112-01-403).

Select a 5.0 mm diameter screw of the desired depth and use the 3.5 mm hex driver long (Cat. No. 2112-01-504) to introduce the screw through the screw sheath and advance until it is fully seated against the lateral cortex.

Repeat the above steps for dynamic locking, except pass the distal screw sheath and trochar through the hole labeled “dynamic” on the insertion jig.

Note: Maintain contact of the drill sheath on the lateral femoral cortex to ensure accurate measurement of the distal locking screw. Verify screw position using AP and lateral fluoroscopy imaging.

Note: There are two 4.3 mm drill bits available. Use the long bit (Cat. No. 2112-01-405) when drilling through the jig assembly and use the short bit (2112-01-406) when performing the freehand approach.

AFFIXUS® Hip Fracture Nail

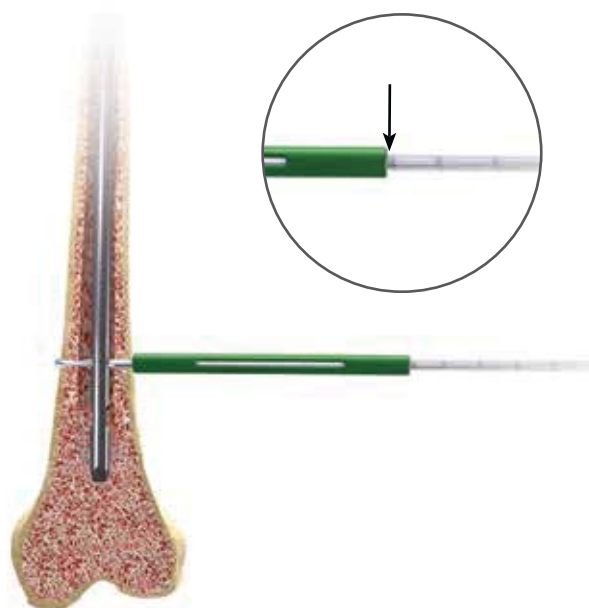


Figure 29

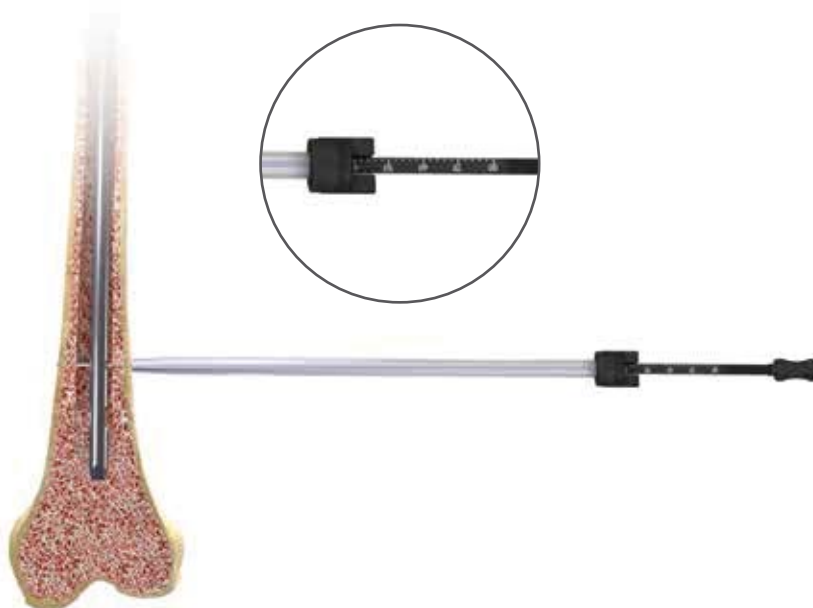


Figure 30

Distal Locking (long nails)

Prior to locking the distal screw(s), check femoral length and rotation under fluoroscopy. Distal locking of long nails should be conducted using the standard image intensification freehand technique.

Option 1

Using the short 4.3 mm graduated drill (2112-01-406) and the 4.3 mm drill measuring sleeve (2112-01-410), drill until the far cortex is either reached or penetrated. Verify the drill bit position fluoroscopically prior to taking any measurements. Read the calibration directly off of the 4.3 mm graduated drill by using the drill measuring sleeve. The measurement should be taken from the end of the measuring sleeve, closest to the power source (Figure 29).

Option 2

Using the short 4.3 mm graduated drill (2112-01-406), drill until the far cortex is either reached or penetrated. Remove the 4.3 mm graduated drill and measure using the distal screw depth gauge (2112-01-404). Ensure that the sheath of the distal screw depth gauge is fully seated on the bone (Figure 30).

Remove the drill bit and advance the 5.0 mm screw using the solidlok screwdriver or 3.5 mm hex driver (2112-01-409). Repeat the above steps for additional screw placement.



Figure 31

End Cap Placement

End Cap Placement (optional)

Unscrew the jig bolt that connects the insertion jig to the end of the nail using the jig bolt driver (2810-13-037 or 2810-13-006). Remove the insertion jig and use fluoroscopy to determine the length of the end cap desired, with a goal of leaving the proximal aspect of the end cap flush with the tip of the greater trochanter.

Attach the end cap to the 5 mm end cap hex driver (2112-01-600 or 2112-01-601) and insert into the end of the nail. Tighten the end cap by turning clockwise until the end cap fully seats against the top of the nail. If fixation of the AR screw is desired, select the impinging in cap instead of the standard end cap (Figure 31).

AFFIXUS® Hip Fracture Nail



Figure 32



Figure 33

Implant Removal

Identify the proximal end of the nail by opening the same incision used for insertion of the implant. Clear bone from the proximal end of nail if necessary or remove the end cap (if present) with the 5 mm end cap hex driver (Cat. No. 2112-01-600 or 2112-01-601).

- Remove the distal screw using the 3.5 mm hex driver (Cat. No. 2112-01-409) after making an incision through the scar site.
- If an AR screw is present, use the AR screw removal tool (Cat. No. 2112-01-506) to extract the AR screw prior to loosening the set screw.
Reminder: The set screw should NOT be loosened prior to removing the AR screw.
- Use the 5 mm set screw hex driver (Cat. No. 2112-01-309) to loosen the set screw. This will allow the lag screw to rotate counterclockwise. Typically 2 to 3 full rotations is all that is necessary.
- Attach the lag screw driver (Cat. No. 2112-01-307) and coupling rod (Cat. No. 2112-01-306) to the lateral end of the lag screw and confirm that it will freely rotate in a counterclockwise direction.

- Insert the cannulated extraction bolt (Cat. No. 2112-01-666) into the proximal end of the nail (Figure 32).

Note: If the extraction bolt is not threading into the proximal end of the nails, the set screw may have been backed out too far and should be advanced clockwise.

- Attach the extraction rod (Cat. No. 1095) to the extraction bolt.
- Remove the lag screw by turning counterclockwise and then remove the distal interlocking screws.
- Use the sliding hammer (Cat. No. 1796 or 1096) or slotted mallet (Cat. No. 2112-01-606) over the extraction rod and back slap to remove the nail (Figure 33).

Note: It is recommended that the extraction rod and bolt be attached to the nail prior to removing the final screw to prevent the nail from being forced down the intramedullary canal.

Note: The conical extractor (Cat. No. 2112-01-605) is designed to cross thread onto the nail, and it is recommended that it is tightly secured to the nail before the lag screw is removed to prevent the nail from rotating in the femoral canal.

Implant Diagrams



Distal Screw, 20-80 mm
Sterile: 8145-50-0XX

- Diameter 5.0 mm
- 3.5 mm Hex Driver Socket



Anti-rotation Screw, 50-110 mm
Sterile: 8145-01-XXX

- Diameter 5.0 mm
- 3.6 mm Hex Driver Socket
- 3 mm Inner Thread for Removal
- Self Tapping Threads



Lag Screw, 70-130 mm
Sterile: 8145-10-XXX

- Diameter 10.5 mm
- Reverse Buttress Thread
- 6.5 mm Square Driver Socket
- Self Tapping Threads



AFFIXUS® Hip Fracture Nail

Product Ordering Information

Rights

Lefts

Long Nails, 9 mm, 125°

8143-09-260	8144-09-260	125° 9 mm X 260 mm
8143-09-280	8144-09-280	125° 9 mm X 280 mm
8143-09-300	8144-09-300	125° 9 mm X 300 mm
8143-09-320	8144-09-320	125° 9 mm X 320 mm
8143-09-340	8144-09-340	125° 9 mm X 340 mm
8143-09-360	8144-09-360	125° 9 mm X 360 mm
8143-09-380	8144-09-380	125° 9 mm X 380 mm
8143-09-400	8144-09-400	125° 9 mm X 400 mm
8143-09-420	8144-09-420	125° 9 mm X 420 mm
8143-09-440	8144-09-440	125° 9 mm X 440 mm
8143-09-460	8144-09-460	125° 9 mm X 460 mm

Long Nails, 11 mm, 125°

8143-11-260	8144-11-260	125° 11 mm X 260 mm
8143-11-280	8144-11-280	125° 11 mm X 280 mm
8143-11-300	8144-11-300	125° 11 mm X 300 mm
8143-11-320	8144-11-320	125° 11 mm X 320 mm
8143-11-340	8144-11-340	125° 11 mm X 340 mm
8143-11-360	8144-11-360	125° 11 mm X 360 mm
8143-11-380	8144-11-380	125° 11 mm X 380 mm
8143-11-400	8144-11-400	125° 11 mm X 400 mm
8143-11-420	8144-11-420	125° 11 mm X 420 mm
8143-11-440	8144-11-440	125° 11 mm X 440 mm
8143-11-460	8144-11-460	125° 11 mm X 460 mm

Long Nails, 13 mm, 125°

8143-13-260	8144-13-260	125° 13 mm X 260 mm
8143-13-280	8144-13-280	125° 13 mm X 280 mm
8143-13-300	8144-13-300	125° 13 mm X 300 mm
8143-13-320	8144-13-320	125° 13 mm X 320 mm
8143-13-340	8144-13-340	125° 13 mm X 340 mm
8143-13-360	8144-13-360	125° 13 mm X 360 mm
8143-13-380	8144-13-380	125° 13 mm X 380 mm
8143-13-400	8144-13-400	125° 13 mm X 400 mm
8143-13-420	8144-13-420	125° 13 mm X 420 mm
8143-13-440	8144-13-440	125° 13 mm X 440 mm
8143-13-460	8144-13-460	125° 13 mm X 460 mm

Rights

Lefts

Long Nails, 9 mm, 130°

8145-09-260	8146-09-260	130° 9 mm X 260 mm
8145-09-280	8146-09-280	130° 9 mm X 280 mm
8145-09-300	8146-09-300	130° 9 mm X 300 mm
8145-09-320	8146-09-320	130° 9 mm X 320 mm
8145-09-340	8146-09-340	130° 9 mm X 340 mm
8145-09-360	8146-09-360	130° 9 mm X 360 mm
8145-09-380	8146-09-380	130° 9 mm X 380 mm
8145-09-400	8146-09-400	130° 9 mm X 400 mm
8145-09-420	8146-09-420	130° 9 mm X 420 mm
8145-09-440	8146-09-440	130° 9 mm X 440 mm
8145-09-460	8146-09-460	130° 9 mm X 460 mm

Long Nails, 11 mm, 130°

8145-11-260	8146-11-260	130° 11 mm X 260 mm
8145-11-280	8146-11-280	130° 11 mm X 280 mm
8145-11-300	8146-11-300	130° 11 mm X 300 mm
8145-11-320	8146-11-320	130° 11 mm X 320 mm
8145-11-340	8146-11-340	130° 11 mm X 340 mm
8145-11-360	8146-11-360	130° 11 mm X 360 mm
8145-11-380	8146-11-380	130° 11 mm X 380 mm
8145-11-400	8146-11-400	130° 11 mm X 400 mm
8145-11-420	8146-11-420	130° 11 mm X 420 mm
8145-11-440	8146-11-440	130° 11 mm X 440 mm
8145-11-460	8146-11-460	130° 11 mm X 460 mm

Long Nails, 13 mm, 130°

8145-13-260	8146-13-260	130° 13 mm X 260 mm
8145-13-280	8146-13-280	130° 13 mm X 280 mm
8145-13-300	8146-13-300	130° 13 mm X 300 mm
8145-13-320	8146-13-320	130° 13 mm X 320 mm
8145-13-340	8146-13-340	130° 13 mm X 340 mm
8145-13-360	8146-13-360	130° 13 mm X 360 mm
8145-13-380	8146-13-380	130° 13 mm X 380 mm
8145-13-400	8146-13-400	130° 13 mm X 400 mm
8145-13-420	8146-13-420	130° 13 mm X 420 mm
8145-13-440	8146-13-440	130° 13 mm X 440 mm
8145-13-460	8146-13-460	130° 13 mm X 460 mm

Long Nails, 15 mm, 130°

8145-15-320	8146-15-320	130° 15 mm X 320 mm
8145-15-360	8146-15-360	130° 15 mm X 360 mm
8145-15-400	8146-15-400	130° 15 mm X 400 mm
8145-15-440	8146-15-440	130° 15 mm X 440 mm

Short Nails, 125°

8143-09-180	125° 9 mm X 180 mm
8143-11-180	125° 11 mm X 180 mm
8143-13-180	125° 13 mm X 180 mm

Short Nails, 130°

8145-09-180	130° 9 mm X 180 mm
8145-11-180	130° 11 mm X 180 mm
8145-13-180	130° 13 mm X 180 mm

Lag Screws

8145-10-070	LAG SCREW 10.5 mm X 70 mm
8145-10-075	LAG SCREW 10.5 mm X 75 mm
8145-10-080	LAG SCREW 10.5 mm X 80 mm
8145-10-085	LAG SCREW 10.5 mm X 85 mm
8145-10-090	LAG SCREW 10.5 mm X 90 mm
8145-10-095	LAG SCREW 10.5 mm X 95 mm
8145-10-100	LAG SCREW 10.5 mm X 100 mm
8145-10-105	LAG SCREW 10.5 mm X 105 mm
8145-10-110	LAG SCREW 10.5 mm X 110 mm
8145-10-115	LAG SCREW 10.5 mm X 115 mm
8145-10-120	LAG SCREW 10.5 mm X 120 mm
8145-10-125	LAG SCREW 10.5 mm X 125 mm
8145-10-130	LAG SCREW 10.5 mm X 130 mm

Anti-Rotation Screws

8145-01-050	A/R SCREW 50 mm
8145-01-055	A/R SCREW 55 mm
8145-01-060	A/R SCREW 60 mm
8145-01-065	A/R SCREW 65 mm
8145-01-070	A/R SCREW 70 mm
8145-01-075	A/R SCREW 75 mm
8145-01-080	A/R SCREW 80 mm
8145-01-085	A/R SCREW 85 mm
8145-01-090	A/R SCREW 90 mm
8145-01-095	A/R SCREW 95 mm
8145-01-100	A/R SCREW 100 mm
8145-01-105	A/R SCREW 105 mm
8145-01-110	A/R SCREW 110 mm

Distal Screws

8145-50-020	CORTICAL BONE SCR 5.0 mm X 20 mm
8145-50-022	CORTICAL BONE SCR 5.0 mm X 22 mm
8145-50-024	CORTICAL BONE SCR 5.0 mm X 24 mm
8145-50-026	CORTICAL BONE SCR 5.0 mm X 26 mm
8145-50-028	CORTICAL BONE SCR 5.0 mm X 28 mm
8145-50-030	CORTICAL BONE SCR 5.0 mm X 30 mm
8145-50-032	CORTICAL BONE SCR 5.0 mm X 32 mm
8145-50-034	CORTICAL BONE SCR 5.0 mm X 34 mm
8145-50-036	CORTICAL BONE SCR 5.0 mm X 36 mm
8145-50-038	CORTICAL BONE SCR 5.0 mm X 38 mm
8145-50-040	CORTICAL BONE SCR 5.0 mm X 40 mm
8145-50-042	CORTICAL BONE SCR 5.0 mm X 42 mm
8145-50-044	CORTICAL BONE SCR 5.0 mm X 44 mm
8145-50-046	CORTICAL BONE SCR 5.0 mm X 46 mm
8145-50-048	CORTICAL BONE SCR 5.0 mm X 48 mm
8145-50-050	CORTICAL BONE SCR 5.0 mm X 50 mm
8145-50-052	CORTICAL BONE SCR 5.0 mm X 52 mm
8145-50-054	CORTICAL BONE SCR 5.0 mm X 54 mm
8145-50-056	CORTICAL BONE SCR 5.0 mm X 56 mm
8145-50-058	CORTICAL BONE SCR 5.0 mm X 58 mm
8145-50-060	CORTICAL BONE SCR 5.0 mm X 60 mm
8145-50-065	CORTICAL BONE SCR 5.0 mm X 65 mm
8145-50-070	CORTICAL BONE SCR 5.0 mm X 70 mm
8145-50-075	CORTICAL BONE SCR 5.0 mm X 75 mm
8145-50-080	CORTICAL BONE SCR 5.0 mm X 80 mm

End Caps

8145-03-000	END CAP FLUSH
8145-03-005	END CAP 5 mm
8145-03-101	IN CAP FLUSH IMPINGING

AFFIXUS® Hip Fracture Nail

Product Ordering Information



AFFIXUS® Hip Fracture Nail System

2112-01-000	Instrument Case 2
2112-01-001	Instrument Case 1
2112-01-800	Full Anatomy (FA) Instrument Case

General

2810-01-004	T-Handle Hudson
8261-66-000	Ratchet Screwdriver Handle Small

Entry

2112-01-100	1 - AWL
2112-01-102	2 - Entry Reamer Solid Shaft
2112-01-103	3 - Entry Reamer Flexible Shaft
2112-01-104	4 - Entry Portal
2810-13-004	5 - Entry Portal Trochar

Reduction

9030-03-004	Threaded Guide Pin 3.2 mm*
2810-01-080	Ball Nose Guidewire 80 cm*
2810-01-100	Ball Nose Guidewire 100 cm*
2810-01-001	6 - Pistol Guidewire Gripper
2810-01-026	7 - Guidewire Pusher
2810-01-007	8 - Long Reduction Tool
2142-02-012	9 - Ball Spike Pusher
2112-01-003	10 - Bone Hook
2141-19-000	11 - Femoral Bone Clamp
2810-01-175	3.2 mm x 444 mm Threaded Guide Pin Sterile*

* Products are disposable.



Nail Insertion

2112-01-106	12 - Nail Depth Gauge
2112-01-200	13 - Insertion jig 125°
2112-01-207	FA Insertion jig 125°
2112-01-201	14 - Insertion jig 130°
2112-01-208	FA Insertion jig 130°
2112-01-202	15 - Insertion jig bolt
2112-01-209	FA Insertion jig bolt
2112-01-205	Jig knob
2112-01-206	Jig knob retainer
2810-13-037	16 - Flexible jig bolt driver 8 mm
2810-13-006	Jig bolt driver 8 mm
2112-01-204	17 - Impaction tool

Lag Screw Placement

2112-01-300	18 - Lag Screw Sheath
2112-01-301	19 - Lag Screw Trochar
2112-01-302	20 - Lag Screw 3.2 mm Sleeve
2112-01-304	21 - Lag Screw Depth Gauge
2112-01-303	22 - Lag Screw Drill
2112-01-310	23 - Lag Screw Tap
2112-01-307	24 - Lag Screw Driver
2112-01-306	25 - Lag Screw Coupling Rod
2112-01-308	26 - Compression Wheel
2112-01-309	27 - 5 mm Hex Driver - Set Screw
2112-01-320	FA 5 mm Hex Driver - Set Screw
2112-01-312	28 - Guide Pin Positioning Tool

AFFIXUS® Hip Fracture Nail

Product Ordering Information



AR Screw Placement

2112-01-501	29 - A/R Screw Sheath
2112-01-502	30 - A/R Screw Trochar
2112-01-503	31 - A/R Screw 3.2 mm sleeve
2112-01-505	32 - A/R Screw Drill*
2112-01-504	33 - 3.5 mm Hex Driver Long-A/R Distal Screw
2112-01-506	34 - A/R Screw Removal Tool

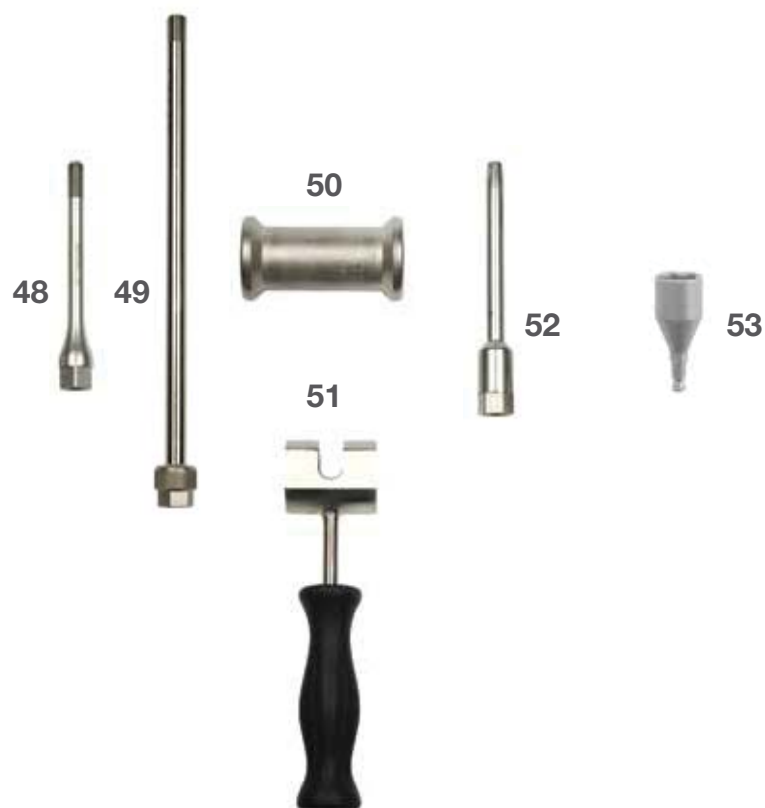
End Cap Placement

2112-01-600	35 - 5 mm Hex Driver End Cap
2112-01-601	5 mm Hex Can Driver End Cap
2112-01-602	36 - End Cap Removal Tool

Distal Screw Insertion

2112-01-401	37 - Distal Screw Sheath
2112-01-402	38 - Distal Screw Trochar
2112-01-403	39 - Distal Screw Drill Sleeve
2112-01-404	40 - Distal Screw Depth Gauge
2112-01-406	41 - 4.3 mm Distal Graduated Drill Short*
2112-01-405	42 - 4.3 mm Distal Graduated Drill Long*
2112-01-410	43 - 4.3 mm Drill Measuring Sleeve*
2112-01-409	44 - 3.5 mm Hex Driver Short - Distal Screw
2810-01-020	45 - SolidLok Screwdriver Handle
2810-01-021	46 - SolidLok Driver Inner Shaft
2810-01-019	SolidLok Hex Tip 3.5 mm*
2112-01-504	33 - 3.5 mm Hex Driver Long - AR/Distal Screw

* Products are disposable.



Extraction

2112-01-666	48 - Cannulated Extraction Bolt
1095	49 - Extraction Rod
1796	50 - Sliding Hammer Small
1096	Sliding Hammer Large
2112-01-606	51 - Slotted Mallet
2112-01-605	52 - Conical Extractor
2810-01-027	53 - 3/4 in Hex Driver

Flexible Reamers

2810-02-400	400 mm Nitinol Modular Reamer Hudson
2810-02-470	470 mm Nitinol Modular Reamer Hudson
2810-02-015	150 mm Reamer Extension
2810-02-081	8 mm MNBLC Endcut Reamer Hudson
2810-02-091	9 mm MNBLC Endcut Reamer Hudson
2810-04-090	9.0 mm Modular Reamer Head
2810-04-095	9.5 mm Modular Reamer Head

2810-04-100	10.0 mm Modular Reamer Head
2810-04-105	10.5 mm Modular Reamer Head
2810-04-110	11.0 mm Modular Reamer Head
2810-04-115	11.5 mm Modular Reamer Head
2810-04-120	12.0 mm Modular Reamer Head
2810-04-125	12.5 mm Modular Reamer Head
2810-04-130	13.0 mm Modular Reamer Head
2810-04-135	13.5 mm Modular Reamer Head
2810-04-140	14.0 mm Modular Reamer Head
2810-04-145	14.5 mm Modular Reamer Head
2810-04-150	15.0 mm Modular Reamer Head
2810-04-155	15.5 mm Modular Reamer Head
2810-04-160	16.0 mm Modular Reamer Head
2810-04-165	16.5 mm Modular Reamer Head
2810-04-170	17.0 mm Modular Reamer Head

Screws, Plates, Intramedullary Nails, Compression Hip Screws, Pins and Wires

Important:

This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

The use of metallic surgical appliances (screws, plates, intramedullary nails, compression hip screws, pins and wires) provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

The AFFIXUS® Hip Fracture Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections

Contraindications:

Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

Additional Contraindication for Orthopaedic Screws and Plates only:

Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

Additional Contraindication for Retrograde Femoral Nailing:

A history of septic arthritis of the knee and knee extension contracture with inability to attain at least 45° of flexion.

Additional Contraindications for Compression Hip Screws only:

Inadequate implant support due to the lack of medial buttress.

Warnings and Precautions:

Bone screws and pins are intended for partial weight bearing and non-weight bearing applications. These components cannot be expected to withstand the unsupported stresses of full weight bearing.

Adverse Events:

The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection and allergies and adverse reactions to the device material. Surgeons should take care when targeting and drilling for the proximal screws in any tibial nail with oblique proximal screws. Care should be taken as the drill bit is advanced to penetrate the far cortex. Advancing the drill bit too far in this area may cause injury to the deep peroneal nerve. Fluoroscopy should be used to verify correct positioning of the drill bit.

Additional Adverse Events for Compression Hip Screw only:

Screw cutout of the femoral head (usually associated with osteoporotic bone).

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One Surgeon. One Patient.®

Responsible Manufacturer

Biomet Trauma
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA

EXHIBIT B



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(12) **United States Patent**
Sohnngen

(10) **Patent No.:** **US 8,702,707 B2**
(45) **Date of Patent:** **Apr. 22, 2014**

(54) **FIXATION INSTRUMENT FOR TREATING A BONE FRACTURE**

(76) Inventor: **Gary W. Sohnngen**, San Pedro, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/335,696**

(22) Filed: **Dec. 22, 2011**

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Related U.S. Application Data

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(60) Provisional application No. 60/552,229, filed on Mar. 11, 2004.

(51) **Int. Cl.**
A61B 17/56 (2006.01)
A61B 17/58 (2006.01)

(52) **U.S. Cl.**
USPC **606/62; 606/64**

(58) **Field of Classification Search**
USPC **606/62, 64-67**
See application file for complete search history.

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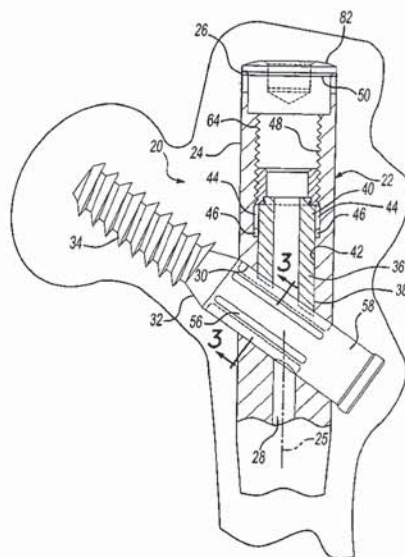
Primary Examiner — Nicholas Woodall

(74) *Attorney, Agent, or Firm* — Burgess Law Office, PLLC

(57) **ABSTRACT**

A fixation instrument for treating a bone fracture including a bone screw and a nail, wherein the bone screw extends through an opening in the head or proximal end of the nail. A movable insert is disposed within a chamber located at the proximal end of the nail. The insert engages the bone screw to prevent rotation thereof once the bone screw is placed in position.

10 Claims, 7 Drawing Sheets



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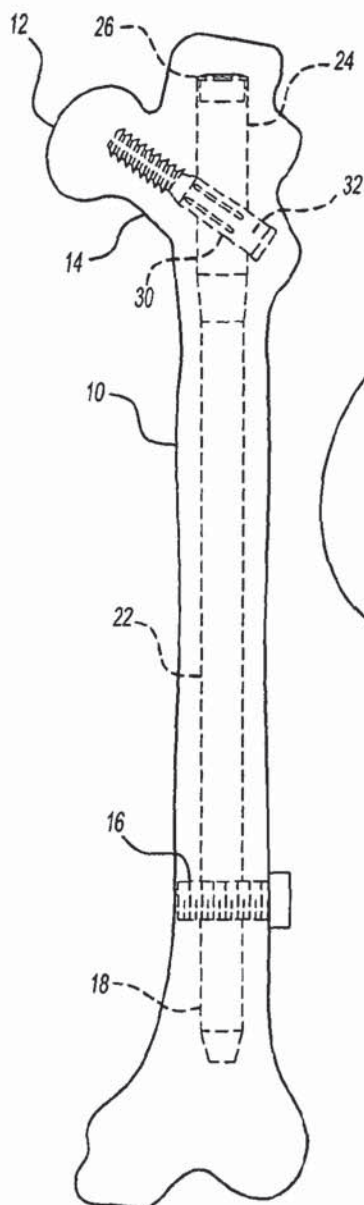


Fig-1

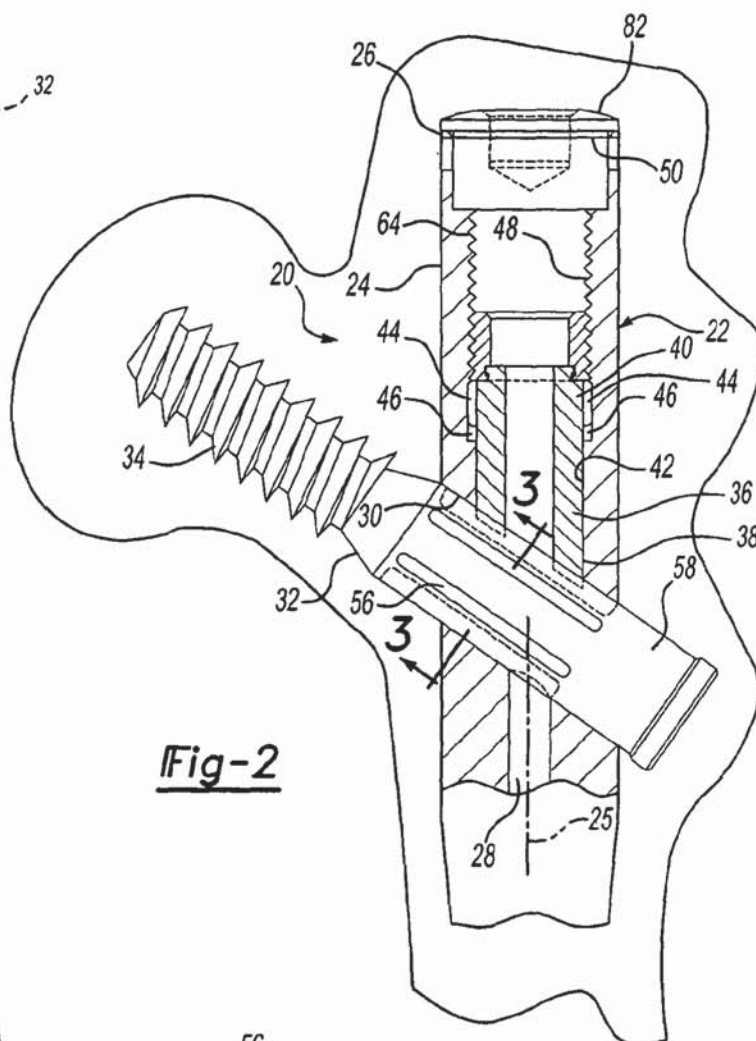


Fig-2

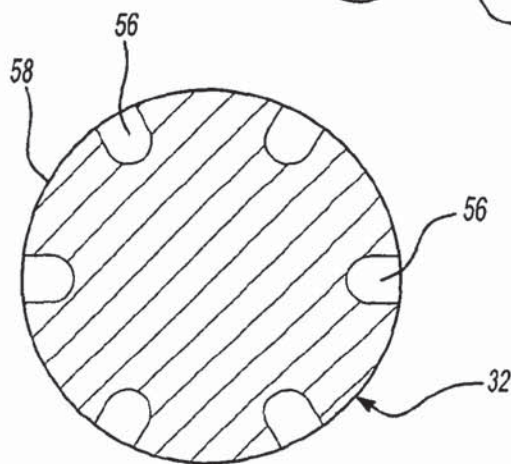


Fig-3

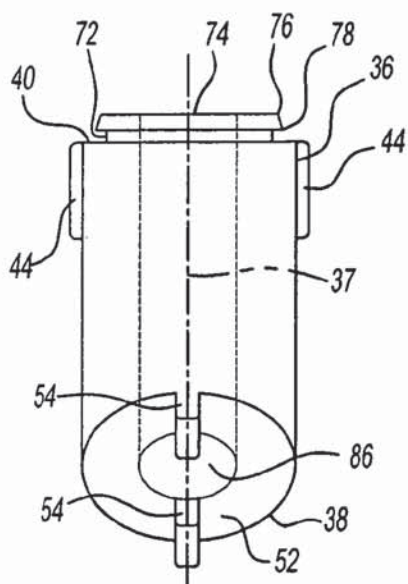


Fig-4A

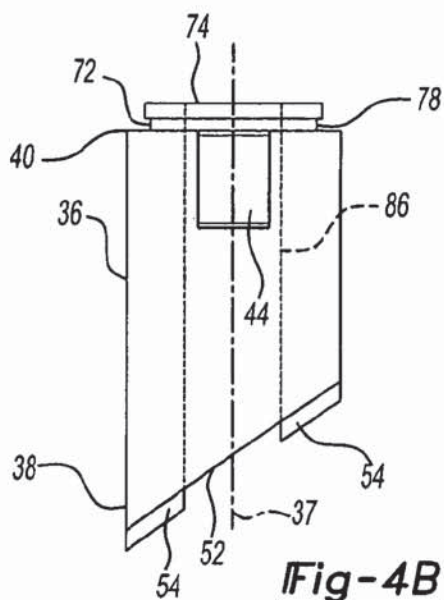


Fig-4B

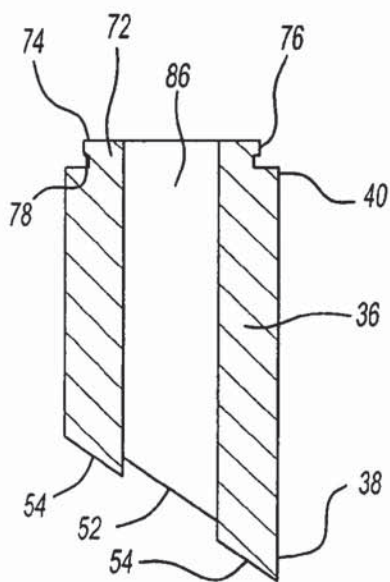


Fig-4C

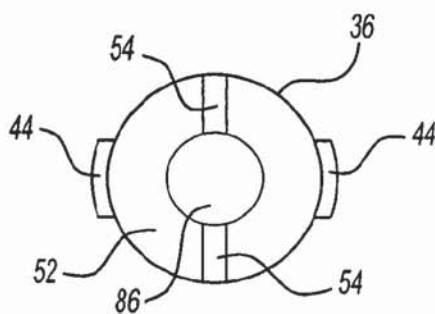


Fig-4D

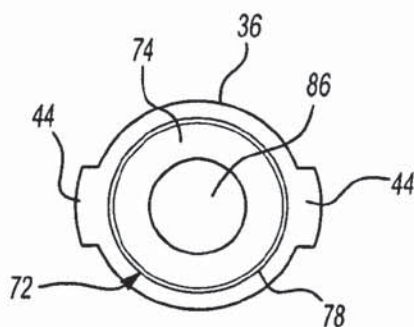


Fig-4E

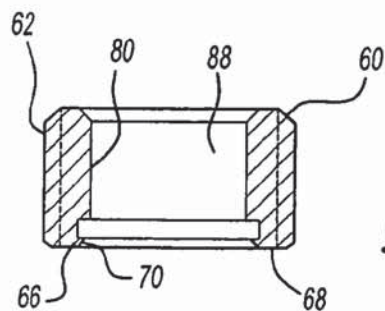


Fig-5

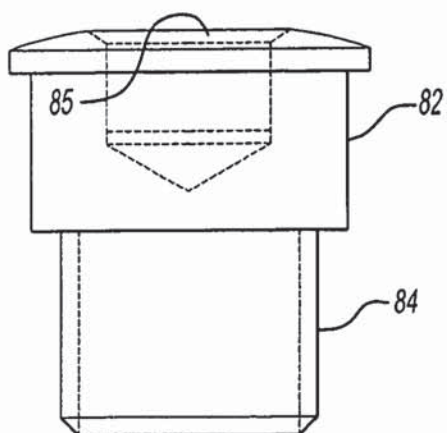


Fig-6

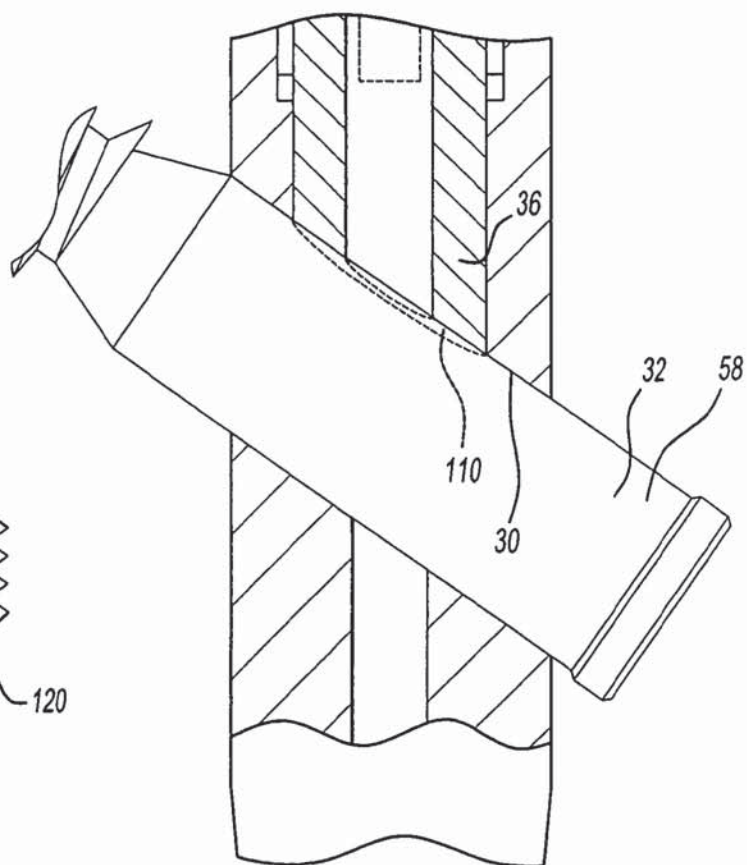


Fig-7

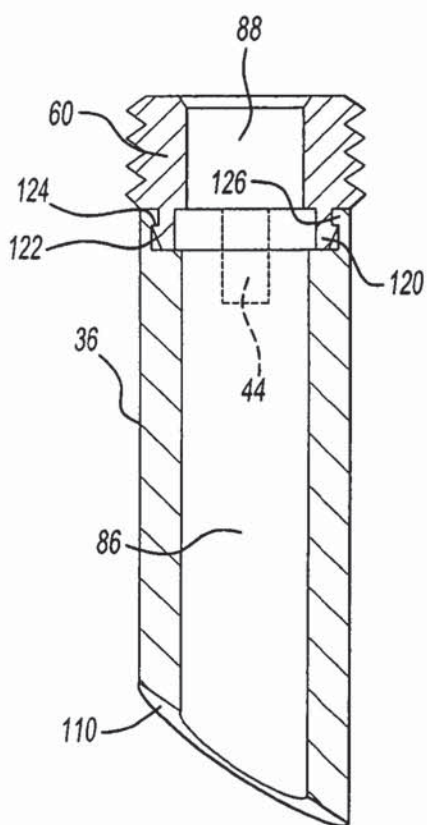


Fig-8A

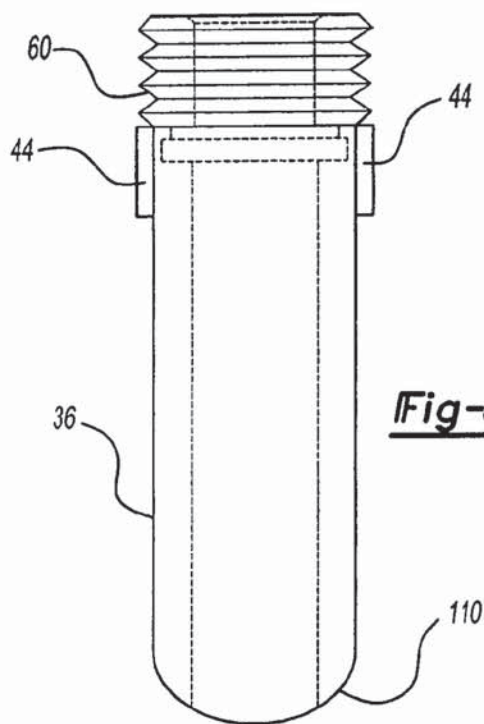


Fig-8B

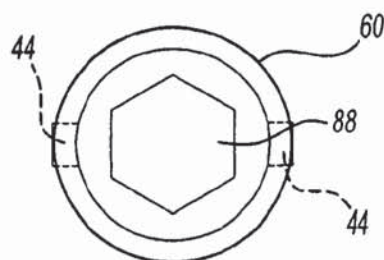


Fig-8C

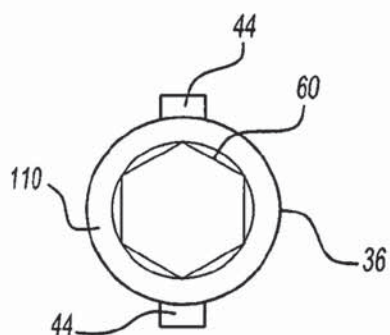


Fig-8D

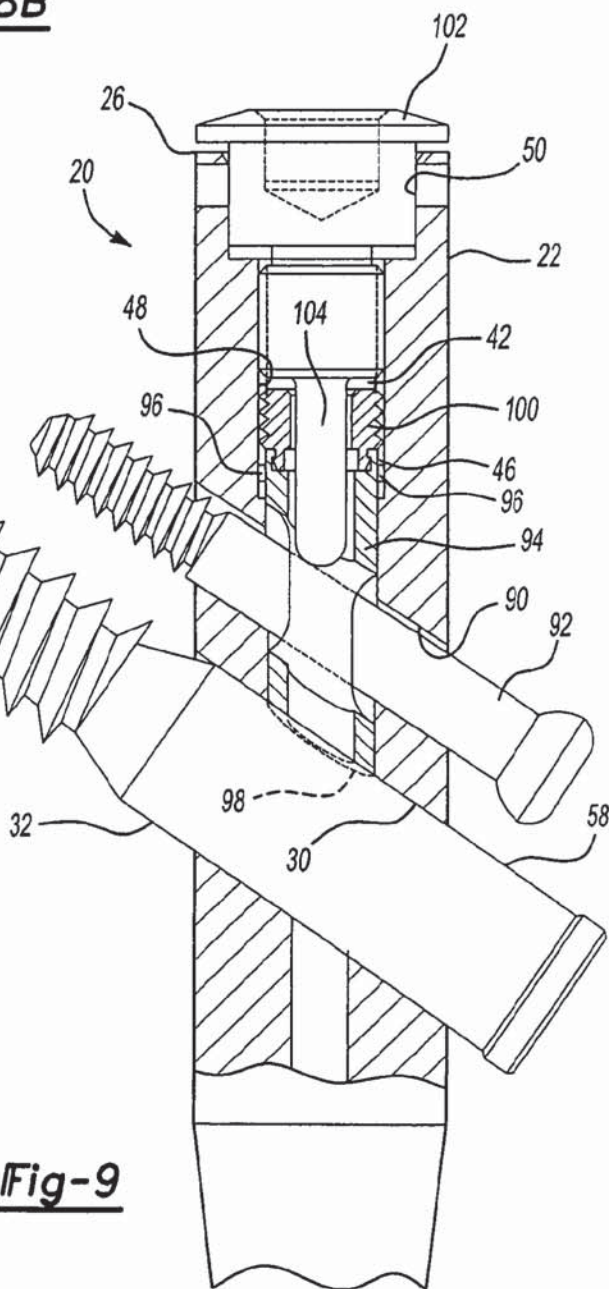
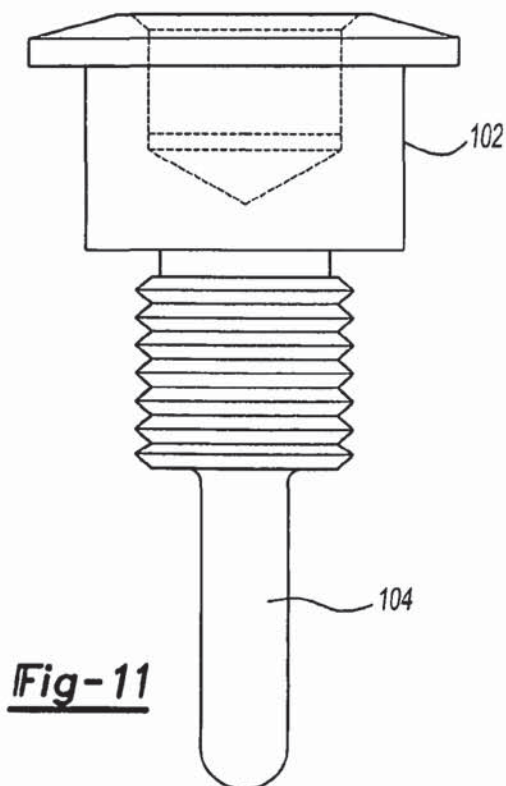
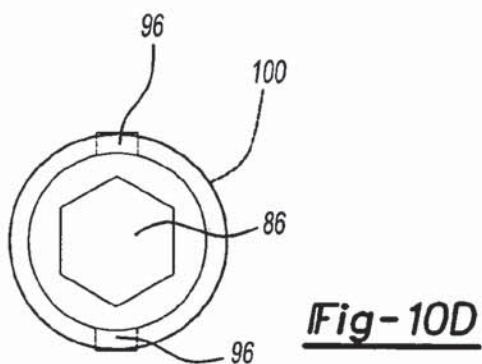
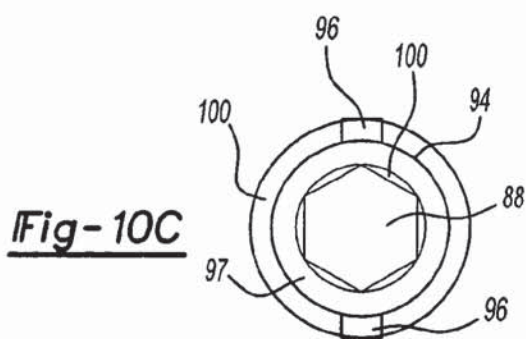
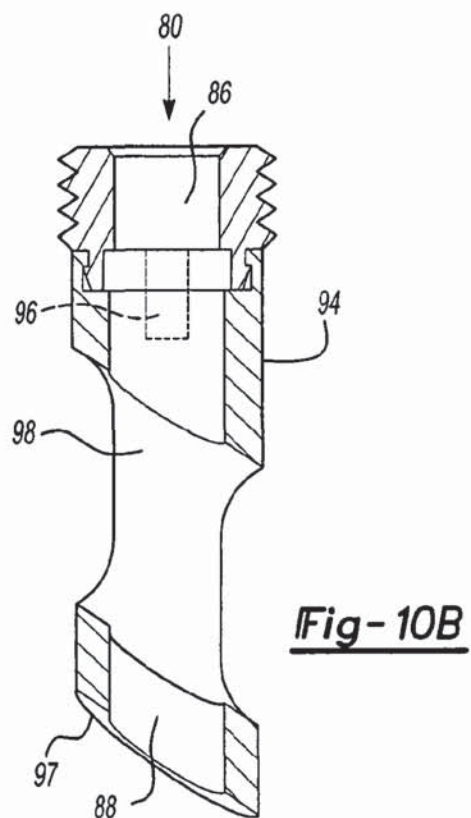
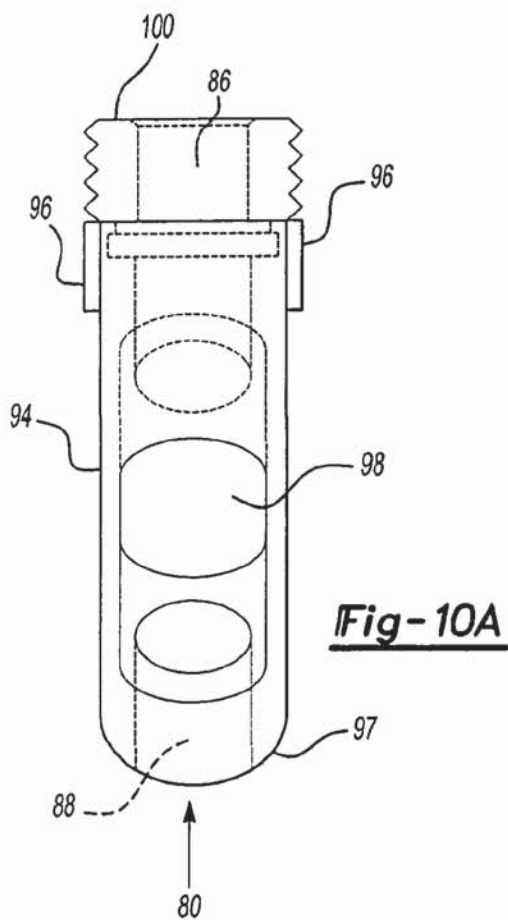


Fig-9



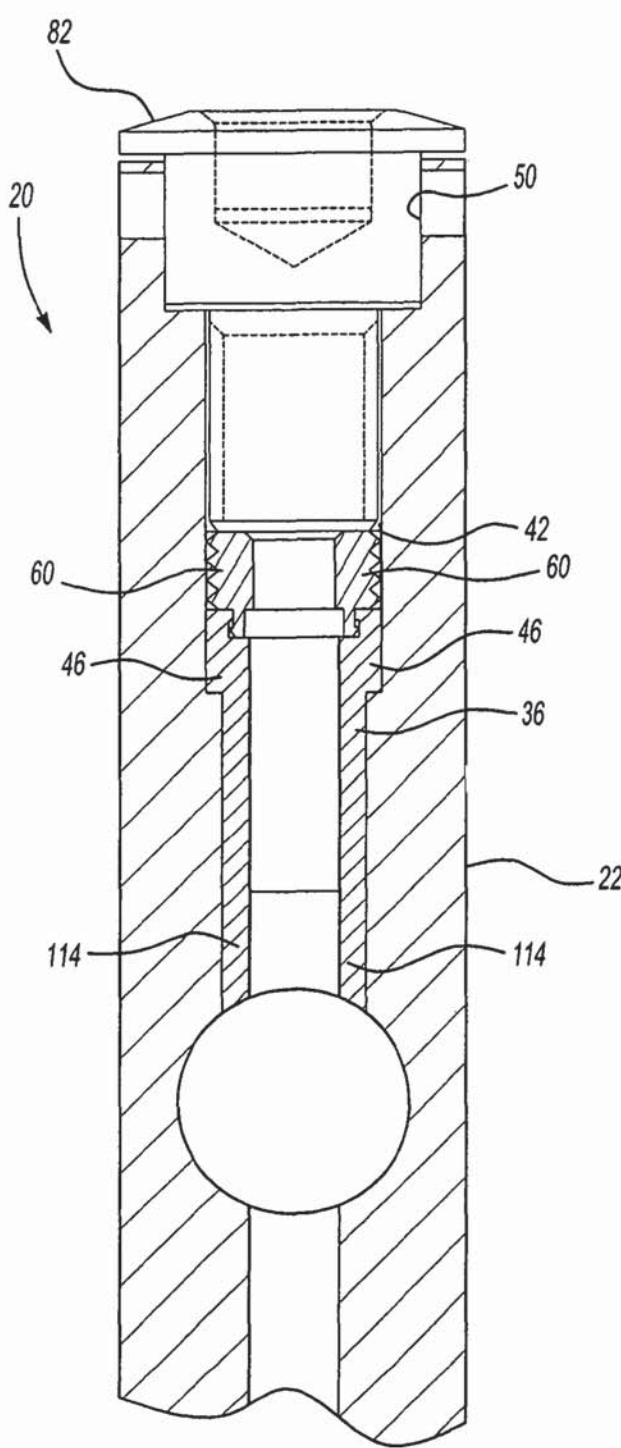


Fig-12

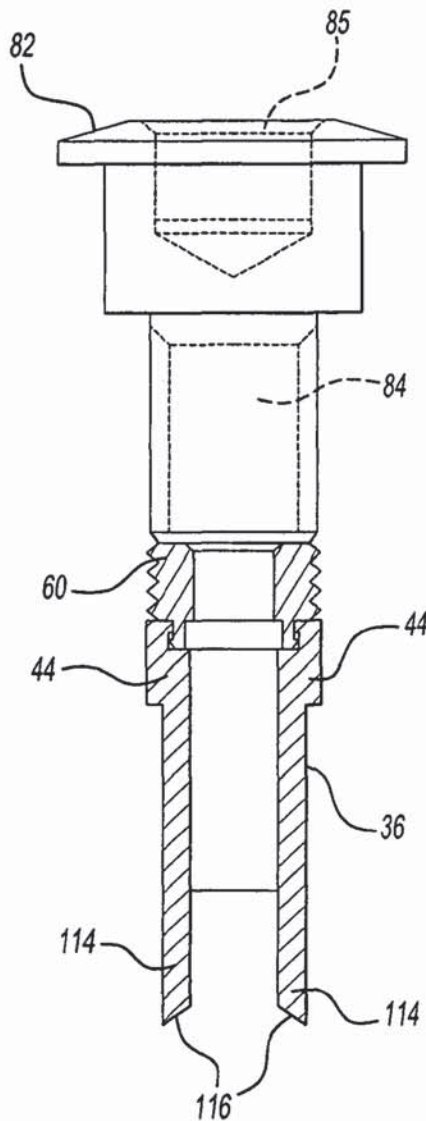


Fig-13

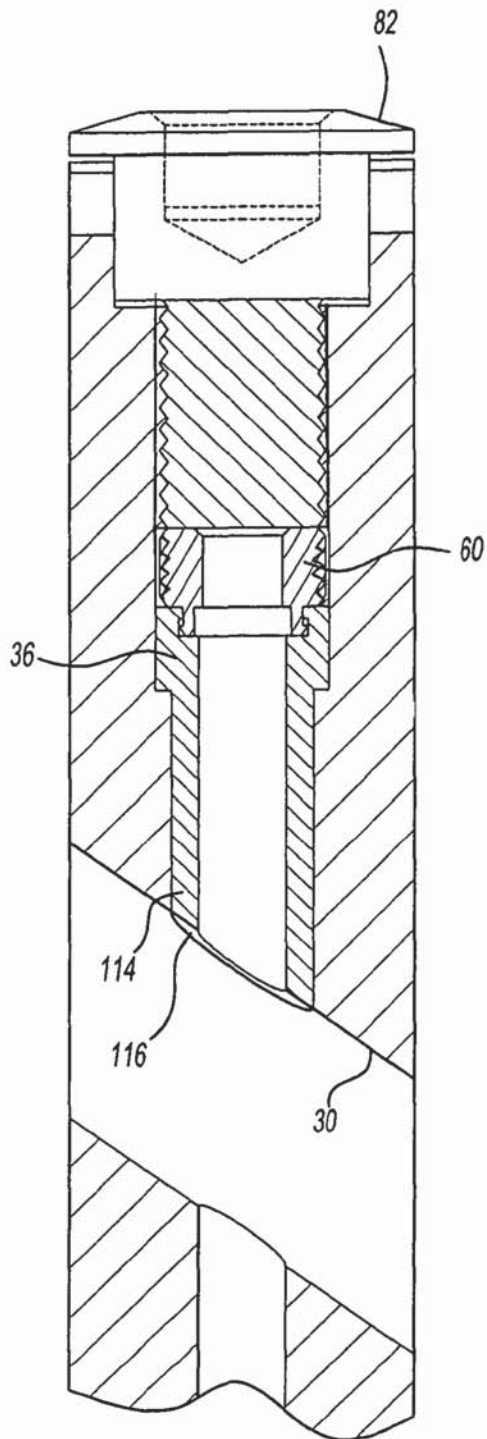


Fig-14

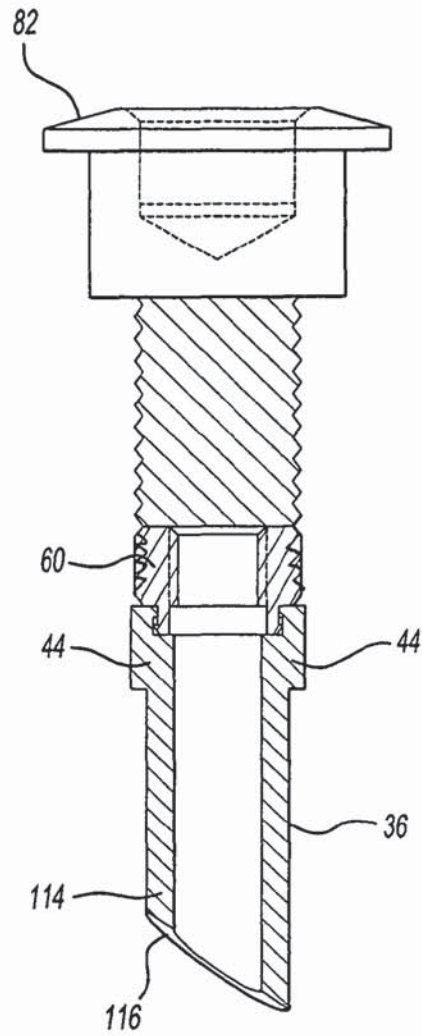


Fig-15

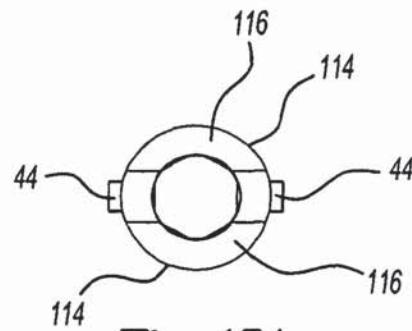


Fig-15A

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FIXATION INSTRUMENT FOR TREATING A BONE FRACTURE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Non-Provisional application Ser. No. 11/078,750, filed on Mar. 11, 2005, which claims the benefit of U.S. Provisional Application No. 60/552,229, filed Mar. 11, 2004.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a fixation instrument for treating bone fractures. More specifically, a nail and bone screw combination used to treat a fracture of the femur including trochanteric, intertrochanteric and femoral neck fractures.

2. Background of the Invention

Orthopedic fixation systems used for stabilizing a fracture often include an internal fixation device, typically an elongated implant such as a nail, screw or pin, inserted into the intramedullary canal of the bone to stabilize the fracture and promote healing. Such fixation systems are often used with a fracture of the femur. The femur generally includes an elongated shaft, a ball shaped head that fits into the hip socket and a neck connecting the ball to the shaft. The shaft often includes a greater trochanter and a lesser trochanter.

Typically, the nail is inserted in the marrow canal of the bone and is positioned to span the fracture. Nails are also used to treat fractures of the neck, head, intertrochanter, subtrochanteric, pathologic and certain ipsilateral shaft and neck fractures of the femur. For example, if the neck of the femur sustains a fracture a bone screw inserted through an aperture in the nail spans the fracture and threadably engages the femoral head.

Typically, the aperture in the end of the nail is a smooth bore in which the bone screw rotates as it threadably engages the femoral head. Once the bone screw is suitably tightened, it is left in place during the healing process. Bone screw migration is one problem that may occur during the healing process. Specifically, during loading or movement of the femur, the bone screw may migrate or loosen, thus creating a risk of failure at the fracture. Accordingly, there is in need for a fixation instrument that resists bone screw migration and rotation.

SUMMARY OF THE INVENTION

Accordingly, the present invention is a fixation instrument including a bone nail and bone screw combination for use in repairing a bone fracture. The bone nail extends within the shaft portion of a bone such as a femur. An opening in the head or proximal end of the nail receives a bone screw that, in the case of a femoral neck fracture, extends into the femoral head.

In accordance with an aspect of the present invention, a locking insert disposed within the nail engages the bone screw and prevents rotation thereof. Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic front view of a fixation instrument according to the present invention shown implanted within a femur.

FIG. 2 is an enlarged front view of the proximal end of the fixation instrument according to the present invention with portions removed for clarity and illustration.

FIG. 3 is a cross-sectional view of the bone screw shown in FIG. 2 taken along lines 3-3.

FIGS. 4A-4E are various views of an insert for use with the fixation instrument according to the present invention.

FIG. 5 is a side view of a locking ring for use with the fixation instrument according to the present invention.

FIG. 6 is a side view of a cap for use with the fixation instrument according to the present invention.

FIG. 7 is a front view of an alternative embodiment of a fixation instrument according to the present invention with portions removed for clarity and illustration.

FIGS. 8A-8D are various views of an alternative embodiment of an insert for use with the fixation instrument according to the alternative embodiment of FIG. 7.

FIG. 9 is a front view of an additional alternative embodiment of a fixation instrument according to the present invention with portions removed for clarity and illustration.

FIGS. 10A-10D are various views of the additional alternative embodiment of an insert for use with the fixation instrument according to the alternative embodiment of FIG. 9.

FIG. 11 is a side view of a cap for use with the fixation instrument according to the alternative embodiment of FIG. 9.

FIG. 12 is a front view of a further alternative embodiment of a fixation instrument according to the present invention.

FIG. 13 is a front view, with portions removed for clarity, of the cap and insert assembly used in connection with the fixation instrument according to the embodiment of FIG. 12.

FIG. 14 is a side view of the further alternative embodiment of the fixation instrument shown in FIG. 12.

FIG. 15 is a side view of the cap and insert assembly shown in FIG. 12 used in connection with the fixation instrument according to the embodiment of FIG. 12, with FIG. 15A being a bottom view of the insert assembly of FIG. 15.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a fixation instrument, seen generally at 20, according to one embodiment of the present invention placed in an assembled condition within a bone 10, illustrated here as a femur. The fixation instrument 20 includes a nail member 22 formed of a metallic alloy, such as a titanium alloy. The nail member 22 includes a distal end 18 and a proximal end 24. The distal end 18 typically includes at least one transverse aperture that receives a bone screw 16 used to fix the distal end 18 of the nail member 22 in place in the bone 10. The proximal end 24 includes a trailing or rear edge 26.

Turning now to FIGS. 2-6, a passageway 28 extends longitudinally through the nail member 22 between the proximal end 24 and the distal end 18. The passageway 28 receives insertion and extraction instrumentation, such as a guide wire (not shown), used to position the nail member 22 within the bone 10. Typically, the distal end 18 of the nail member 22 is inserted into the bone 10 first and follows the path of the guide wire.

The proximal end 24 includes an aperture 30 extending through the proximal end 24 in a direction that is typically angled with respect to the longitudinal axis 25 of the nail

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member 22. A bone screw 32 having a threaded portion 34 on one end thereof extends through the aperture 30 such that the threaded portion 34 engages the femoral head 12 for sliding compression of a femoral neck 14 or intratrochanteric fracture.

An insert 36 having a distal end 38 and a proximal end 40 is disposed within a chamber 42 located in the proximal end 24 of the nail member 22. The insert 36 further has a pair of tabs or guide/locating members 44 that extend radially outward from the body of the insert 36. The tabs or guide/locating members 44 cooperate with a pair of grooves or channels 46 that extend longitudinally along the sidewalls 48 of the chamber 42. The proximal end 24 of the nail member 22 includes an opening 50 at the trailing or rear edge 26 of the nail member 22. The opening 50 provides access to the chamber 42.

The insert 36 further includes a lower surface 52 having a pair of locking projections 54 extending longitudinally downward/outward from the lower surface 52. The insert 36 is placed in the chamber 42 through the opening 50, such that the tabs or guide/locating members 44 are received in the grooves or channels 46 located in the sidewalls 48 of the chamber 42. Accordingly, the insert 36 is slidably received and prevented from rotating in the chamber 42. The lower surface 52 of the insert 36 extends or is oriented at an angle that is substantially the same as the angle of the aperture 30 extending through the proximal end 24 of the nail member 22. As set forth below, the insert 36 engages the bone screw 32 disposed in the aperture 30 in the nail member 22.

The bone screw 32 further includes a plurality of longitudinally extending grooves 56 located on the outer surface 58 of the bone screw 32. The grooves 56 are of a size and shape that are complementary to the locking projections 54 located on the lower surface 52 of the insert 36. As seen in FIG. 2, when the insert 36 travels longitudinally in the chamber 42 it reaches a point wherein the lower surface 52 and locking projections 54 of the insert 36 are adjacent the bone screw 32. Since the purpose of the locking projections 54 is to engage the grooves 56 to secure and prevent rotation of the bone screw 32 it may be necessary to rotate the bone screw 32 slightly to align the grooves 56 of the bone screw 32 with the locking projections 54 of the insert 36. Once properly aligned, the insert 36 is driven further within or into the chamber 42 until the lower surface 52 of the insert 36 engages the outer surface 58 of the bone screw 32 and the locking projections 54 of the insert 36 extend into the grooves 56 of the bone screw 32.

A locking ring 60 controls the position of the insert 36 within the chamber 42. The locking ring 60 has a plurality of threads 62 disposed about the outer surface of the locking ring 60. The locking ring 60 threadably engages a plurality of threads 64 disposed on the sidewalls 48 of the chamber 42. As shown in FIG. 5, the locking ring 60 includes a post portion 66 located on or forming a portion of the lower surface 68 of the locking ring 60. The post portion 66 further includes an inwardly projecting finger 70. The post portion 66 may be formed as an annular member that extends all the way around the lower surface 68 or it may be formed as a plurality of individual post members spaced about the lower surface 68 of the locking ring 60.

The inwardly projecting finger 70 cooperates with a retaining member 72 formed on the upper surface 74 of the proximal end 40 of the insert 36. The retaining member 72 further includes an annular member 76 having an outwardly extending lip 78. Accordingly, the locking ring 60 is placed on or attached to the insert 36 using a snap or press fit arrangement. Specifically, the locking ring 60 is placed on the upper surface

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74 of the insert 36 and a sufficient force is exerted on the locking ring 60 to deflect the inwardly projecting fingers 70 and correspondingly the post portion 66 outward over the annular member 76. Upon clearing the annular member 76, the fingers 70 snap back into place whereby they engage the underside of the lip 78 and rotatably secure the locking ring 60 to the insert 36. It should be understood that such an arrangement enables the locking ring 60 to rotate about the longitudinal axis 37 of the insert 36 while remaining attached to the insert 36.

The locking ring 60 has an aperture or opening 80 having a hexagonal shape that functions as a drive portion of the locking ring 60. Accordingly, a suitable tool, such as a T-handle hexagonal wrench, may be inserted into the opening 80 to rotate or turn the locking ring 60. This arrangement enables the insert 36 to be placed in the chamber 42 prior to the nail member 22 being inserted into the bone. Other configurations may function or comprise the drive portion, including putting a slot in the upper surface of the locking ring 60 that receives a driving tool such as a screwdriver.

The insert 36 is placed within the chamber 42 such that the tabs or guide/locating members 44 engage the grooves/channels 46 located in the sidewalls 48 of the chamber 42. Since the overall outer diameter of the insert 36 is less than the inner diameter of the threads 64 in the sidewalls 48 of the chamber 42, the insert 36 slides freely in the longitudinal direction and is constrained against rotation by the tabs or guide/locating members 44. As shown, the locking ring 60 is rotatably attached to the insert 36. Accordingly, when the threads 62 on the locking ring 60 engage the threads 64 in the sidewall 48 of the chamber 42 and when the locking ring 60 is rotated by a suitable tool, the locking ring 60 moves the insert 36 longitudinally within the chamber 42. As set forth above, the insert 36 and locking ring 60 combination is placed within the chamber 42 prior to inserting or installing the nail member 22 in the bone 10.

In use, once the nail member 22 is installed in the bone 10, the bone screw 32 is placed in and extends through the aperture 30 whereby it engages the femoral head 12. After tightening the bone screw 32 to compress the fracture, a suitable tool engages and rotates the locking ring 60 to move the insert 36 downwardly within the chamber 42 until the locking projections 54 engage the grooves 56 on the outer surface 58 of the bone screw 32. If necessary, it may be required to rotate the bone screw 32 slightly in order to have the locking projections 54 line up with the grooves 56. Once the insert 36 and bone screw 32 are properly aligned, tightening the locking ring 60 maintains engagement between the locking projections 54 and the grooves 56 and prevents rotation of the bone screw 32.

After tightening the locking ring 60, the opening 50 at the trailing or rear edge 26 of the nail member 22 is closed by a cap 82 threadably received in the chamber 42. The cap 82 includes a threaded post 84, the threads being of a suitable size and configuration to engage the threads 64 located in the sidewall 48 of the chamber 42. The cap 82 further includes a socket 85 suitable for receiving a driving tool to rotate and secure the cap 82 in the opening 50.

It should be understood that the insert 36 and locking ring 60 both have longitudinal passageways 86, 88 that allow the nail member 22 to be inserted within the bone 10 and follow a guide wire (not shown), with both the insert 36 and locking ring 60 installed or positioned within the chamber 42 of the nail member 22. Accordingly, the present invention enables the insert 36 to be pre-positioned or placed in the nail member 22 prior to installation, thus eliminating the need and diffi-

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culty of having to thread the insert 36 in place after the nail member 22 is placed within the bone 10.

FIGS. 7-8 disclose an additional embodiment of a fixation instrument 20, according to the present invention. Specifically, the lower surface 110 of the insert 36 has an arcuate surface having a shape complementary to the outer diameter of the bone screw 32. This embodiment does not use the locking projections of the previous embodiment, nor does the bone screw 32 have longitudinal grooves contained therein. The arcuate shape of the lower surface 110 creates a greater amount of surface area of the insert 36 that contacts the outer surface 58 of the bone screw 32. Thus, tightening the locking ring 60 provides a sufficient force to create friction fit between the insert 36 and the bone screw 32 that prevents rotation of the bone screw 32 within the aperture 30 of the nail member 22.

FIG. 8A further illustrates an alternative embodiment of a rotatable connection between the locking ring 60 and the insert 36. As shown therein, the locking ring 60 includes a downwardly projecting finger 120 having an inwardly beveled surface 122 and a lip 124. The insert 36 includes an inwardly extending flange 126. As with the previous embodiment, the locking ring 60 is rotatably attached to the insert 36 using a snap or press fit arrangement. Specifically, applying a force to the locking ring 60 causes the beveled surface 122 of the downwardly projecting finger 120 to engage the inwardly extending flange 126 and deflect the finger 120 radially inward until the lip 124 of the locking finger 120 clears the flange 126 and whereby the locking finger 120 snaps outwardly and the lip 124 engages the underside of the flange 126 to rotatably secure the locking ring 60 to the insert 36.

FIGS. 9-11 show an alternative embodiment of a fixation instrument 20 according to the present invention. As shown in FIG. 9, the proximal end 24 of the nail member 22 has an additional aperture 90 for receiving a second bone screw 92. As set forth in the previous embodiment, the insert 94 includes tabs or guide/locating members 96 that are received in the grooves/channels 46 located on the sidewalls 48 of the chamber 42 whereby the insert 94 is slidably fit within the chamber 42. The insert 94 has an arcuate lower surface 97 having a degree of curvature corresponding to the radius of the bone screw 32. Accordingly, as set forth above, rotating the locking ring 100 causes the arcuate lower surface 97 of the insert 36 to engage the outer surface 58 of the bone screw 32 to prevent rotation of the bone screw 32 within the aperture 30 of the nail member 22. The insert 94 also includes an aperture 98 extending at an angle with respect to the longitudinal axis of the insert 94 for receiving the second bone screw 92. The aperture 98 is elongated in the longitudinal direction to allow for travel of the insert 36 within the passageway 28 without engaging the second bone screw 92.

A cap 102 including an elongated tab or locking projection 104 is used to secure the second bone screw 92. When the cap 102 is inserted into the opening 50 on the trailing or rear edge 26 of the nail member 22, the elongated tab or locking projection 104 engages the second bone screw 92 to prevent rotation thereof via a frictional fit. In addition, the elongated tab or locking projection 104 may include an engagement portion which sits within a groove located on the second bone screw 92, as with the previous embodiments, to further prevent rotation of the second bone screw 92. This arrangement prevents rotation of both the first and second bone screws 32, 92 with respect to the nail member 22.

FIGS. 12-15 show a further alternative embodiment of a fixation instrument 20 according to the present invention, wherein the insert 36 has a lower surface formed of a pair of downwardly extending fingers 114. Each of the downwardly

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extending fingers 114 has an arcuate engagement surface 116 having a curvature or radius of curvature complementary to the diameter of the bone screw 32. The arcuate engagement surfaces 116 form the lower or contact surface of the insert 36. Accordingly, each of the fingers 114 engages the bone screw 32 to secure or prevent rotation of the bone screw 32 within the aperture 30. The insert 36 is positioned in and secured within the chamber 42 in a manner similar to the first embodiment. As with the previous embodiments, the locking ring 60 is used to position and secure the insert 36 whereby the arcuate engagement surfaces 116 of the fingers 114 engage the bone screw 32 and prevent rotation thereof.

It should be understood that the mounting relationship between the locking ring 60 and the insert 36 is one that enables the locking ring 60 to turn or rotate freely on the insert 36. In the case of the disclosed embodiments, the insert 36 travels longitudinally within the grooves or channels 46 located in the sidewalls 48 of the chamber 42. Thus, the apparatus and corresponding components forming the snap or press fit mounting relationship between the locking ring 60 and the insert 36, as shown in the disclosed embodiments, including the inwardly projecting finger and lip on the annular member, may be positioned on either the respective locking ring 60 or insert 36; i.e., the finger may be on the insert 36 or the locking ring 60 as long as the complementary component, the lip, is on the corresponding member.

Thus, it will be seen that the objects of the invention have been fully and effectively accomplished. It will be realized, however, that the foregoing specific embodiments have been shown and described for the purposes of illustrating the functional and structural principles of the invention and is subject to change without departure from such principles. Therefore, this invention includes all modifications encompassed within the scope of the following claims.

What is claimed is:

1. A fixation instrument for treating a bone fracture comprising:

a nail member, having a longitudinal axis, a distal end and a proximal end, said proximal end having a transverse aperture extending therethrough and said nail member having a chamber located in said proximal end;

a bone screw, having a threaded portion, said bone screw extending through said aperture;

an insert having a longitudinal axis, a distal end, a proximal end and a passageway extending longitudinally through said insert from said proximal end to said distal end, said insert having a retaining member located on said proximal end of said insert, said insert positioned and constrained against rotation about said longitudinal axis of said insert within said chamber;

a locking ring, having a longitudinal passageway extending therethrough, said locking ring including a lower surface having an engagement portion, said locking ring received in said chamber and said engagement portion engaging said retaining member of said insert to attach said locking ring to said insert, said locking ring operative to secure said insert within said chamber; and

said bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is received in one of said grooves to resist rotation of said bone screw within said aperture.

2. A fixation instrument for treating a bone fracture as set forth in claim 1 including:

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said aperture extending at an angle through the proximal end of the nail member; and

said distal end of said insert includes a locking projection, said locking projection having a portion thereof that extends at an angle substantially the same as the angle of said aperture, wherein said portion of said locking projection that extends at an angle substantially the same as the angle of said aperture extends into and is located in one of said grooves of said bone screw.

3. A fixation instrument for treating a bone fracture as set forth in claim 1 including said insert having a locating member configured to be received by a corresponding channel extending longitudinally on an inner surface of chamber, said locating member operative to constrain said insert from rotation within said chamber.

4. A fixation instrument for treating a bone fracture as set forth in claim 1 including:

said chamber having an inner surface and a plurality of threads located on said inner surface; and

said locking ring having an outer surface and a plurality of threads located on said outer surface, wherein said threads located on said locking ring engage said threads on said inner surface of said chamber.

5. A fixation instrument for treating a bone fracture as set forth in claim 1 including said engagement portion and said retaining member configured such that when said engagement portion engages said retaining member said locking ring may rotate about said longitudinal axis of said insert while remaining attached to said insert.

6. A fixation instrument for treating a bone fracture comprising:

a nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough at an angle with respect to said longitudinal axis of said nail member, said nail member having a chamber located in said proximal end, said chamber having an inner surface and a plurality of threads located on said inner surface;

a bone screw having a threaded portion, said bone screw extending through said aperture;

an insert, said insert having a longitudinal axis, a distal end, a proximal end and a passageway extending longitudinally through said insert from said proximal end to said

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distal end, said insert having a lower surface, said insert positioned within said chamber;

a locking ring having a longitudinal passageway extending therethrough and an outer surface, a plurality of threads located on said outer surface, wherein said threads located on said outer surface of said locking ring engage said threads on said inner surface of said chamber, said locking ring rotatably connected to said insert; and

said bone screw having a longitudinal axis and having a plurality of longitudinally extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein at least a portion of said distal end of said insert is located in one of said grooves to resist rotation of said bone screw within said aperture.

7. A fixation instrument for treating a bone fracture as set forth in claim 6 including:

said locking ring having a downwardly projecting finger having a lip; and

said insert having an inwardly extending flange whereby said flange cooperates with said lip to rotatably secured the locking ring to the insert.

8. A fixation instrument for treating a bone fracture as set forth in claim 7 including:

said chamber having a groove extending along a side wall of said chamber; and

said insert including a locating member extending radially outward from a body of said insert, said locating member cooperating with said groove whereby said insert moves in said chamber in a longitudinal direction and is constrained against rotation by the locating member.

9. A fixation instrument for treating a bone fracture as set forth in claim 8 including said insert having an overall outer diameter less than an inner diameter of said chamber formed by said threads on said inner surface of said chamber.

10. A fixation instrument for treating a bone fracture as set forth in claim 8 wherein said portion of said lower surface engaging said grooves in said locking screw extends at an angle substantially the same as the angle of said aperture.

* * * * *

EXHIBIT C



US008092454B2

(12) **United States Patent**
Sohnngen

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(45) **Date of Patent:** **Jan. 10, 2012**

(54) **FIXATION INSTRUMENT FOR TREATING A BONE FRACTURE**

(76) Inventor: **Gary W. Sohnngen**, San Pedro, CA (US)

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(22) Filed: **Mar. 11, 2005**

(65) **Prior Publication Data**

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(51) **Int. Cl.**

A61B 17/58 (2006.01)

(52) **U.S. Cl.** **606/67; 606/62**

(58) **Field of Classification Search** **606/62, 606/64, 65, 66, 67**

See application file for complete search history.

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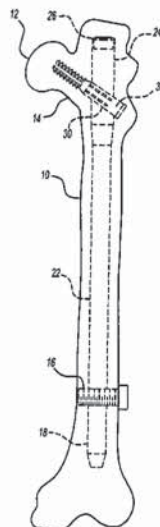
(74) *Attorney, Agent, or Firm* — Burgess Law Office, PLLC

(57)

ABSTRACT

A fixation instrument for treating a bone fracture including a bone screw and a nail, wherein the bone screw extends through an opening in the head or proximal end of the nail. A movable insert is disposed within a chamber located at the proximal end of the nail. The insert engages the bone screw to prevent rotation thereof once the bone screw is placed in position.

20 Claims, 7 Drawing Sheets



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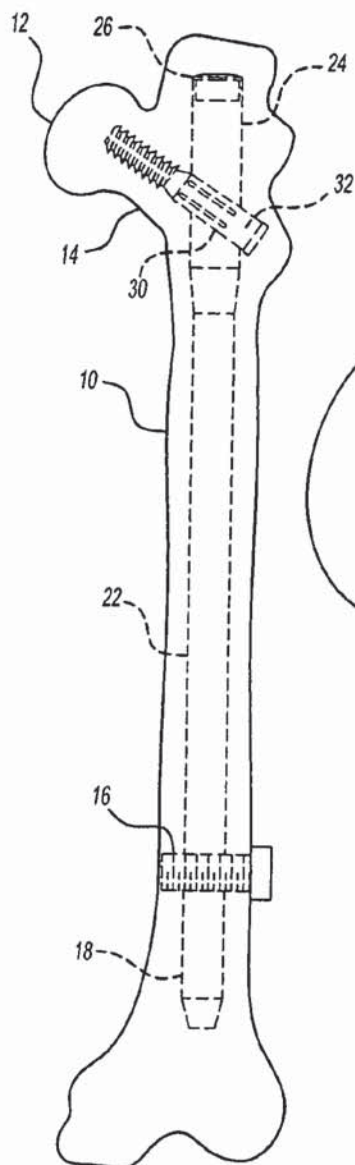


Fig-1

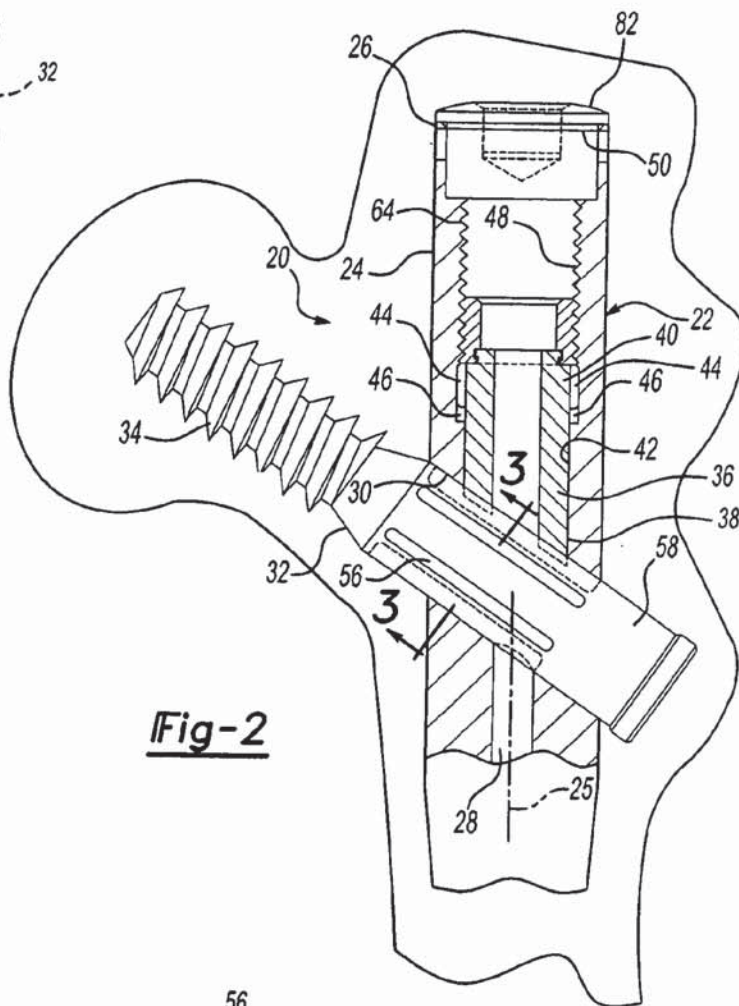


Fig-2

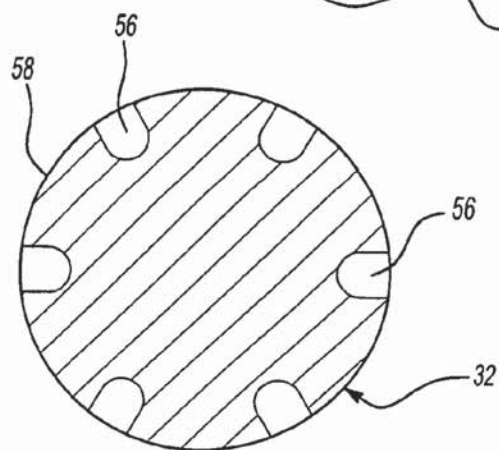
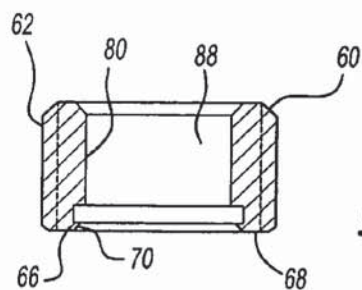
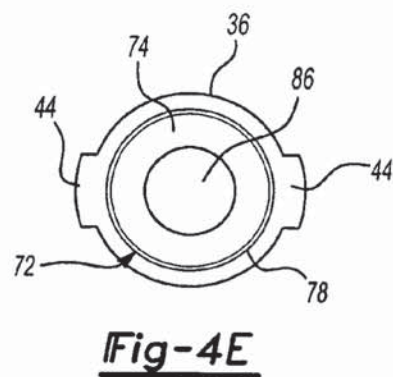
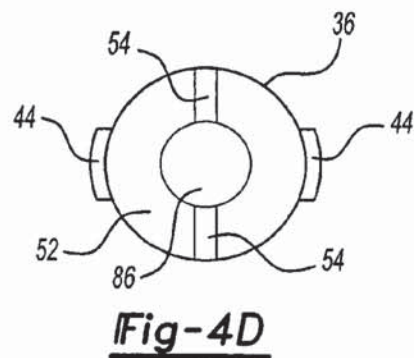
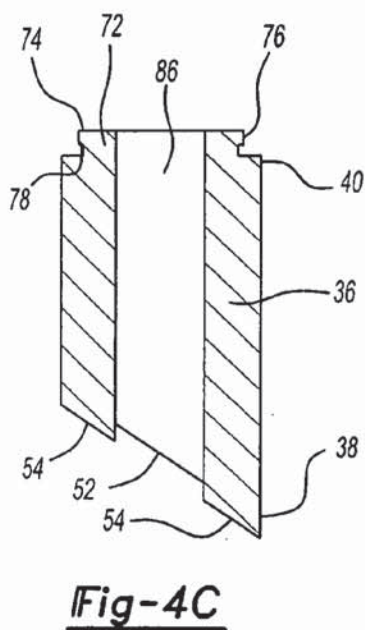
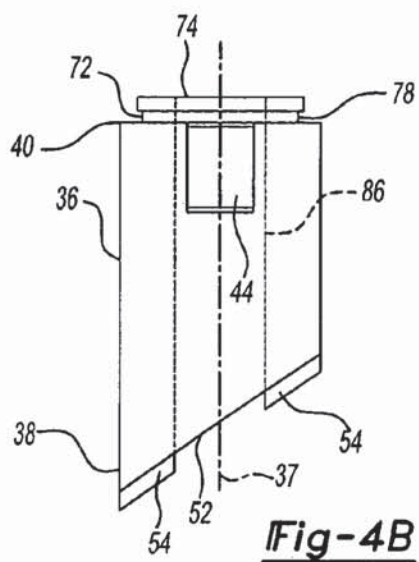
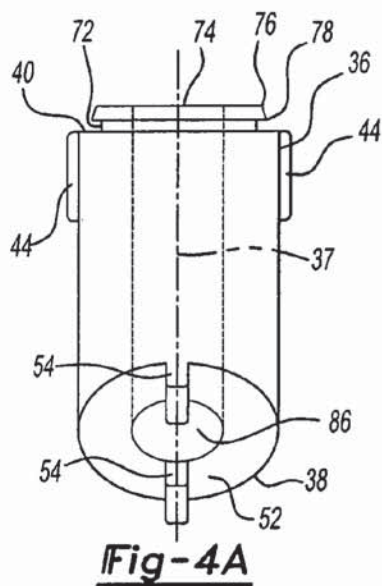


Fig-3



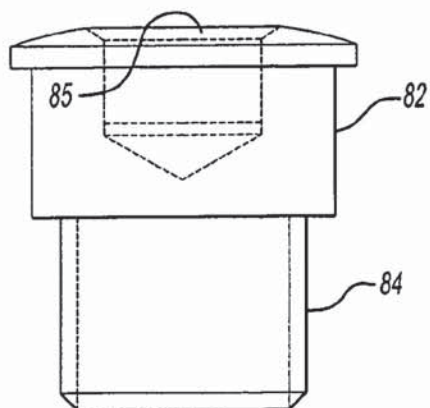


Fig-6

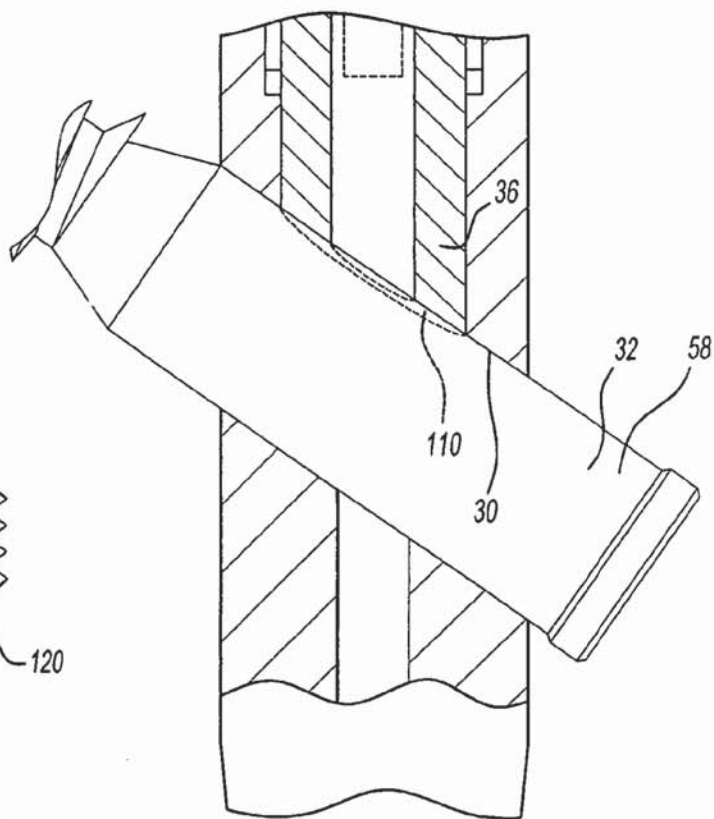


Fig-7

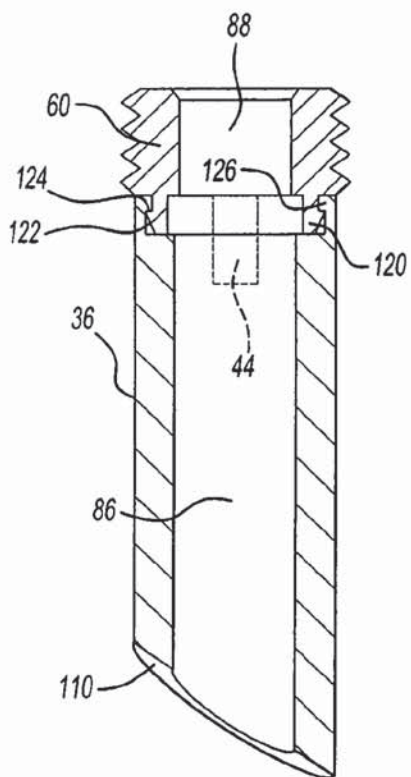


Fig-8A

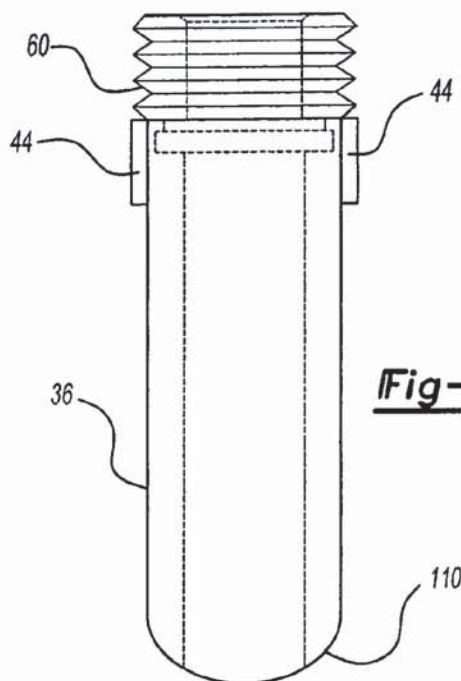


Fig-8B

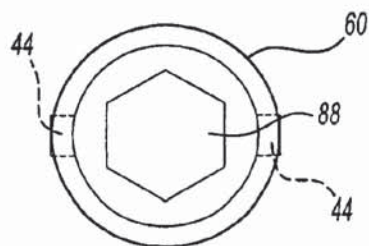


Fig-8C

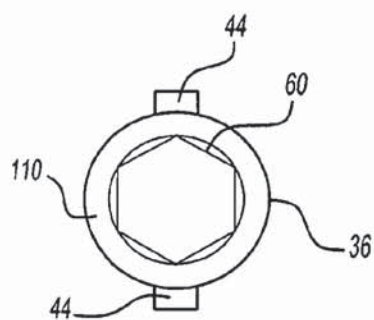


Fig-8D

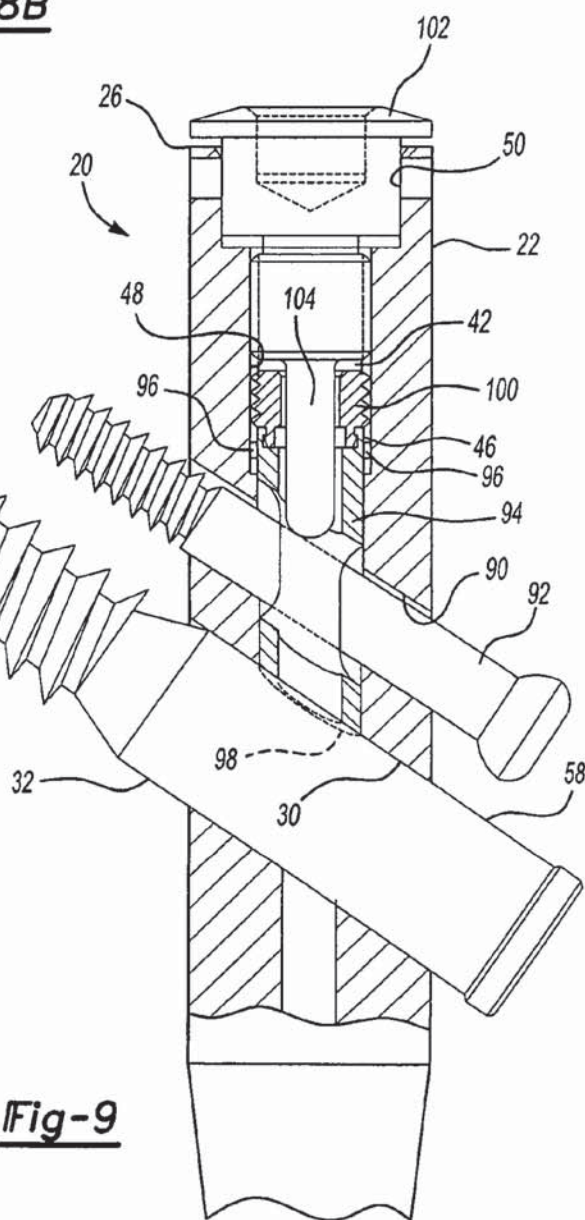
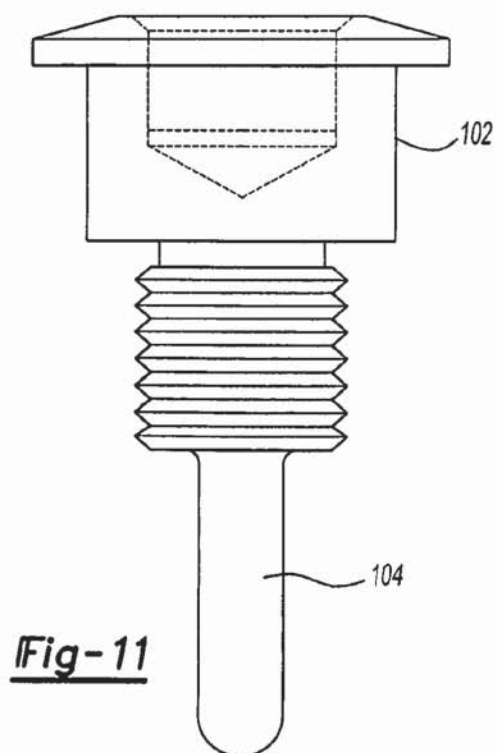
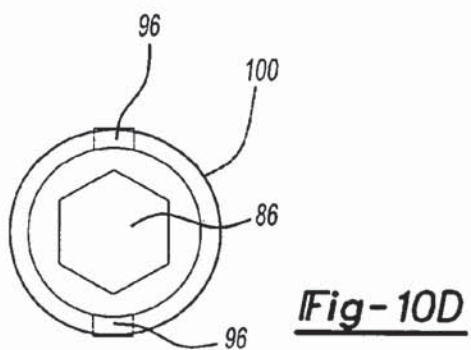
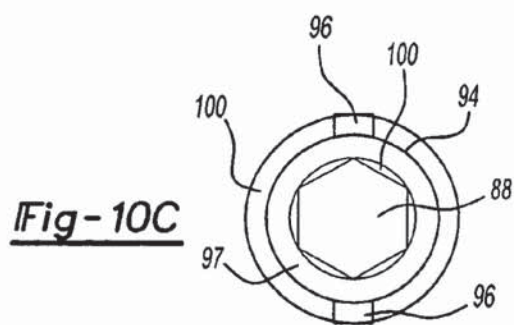
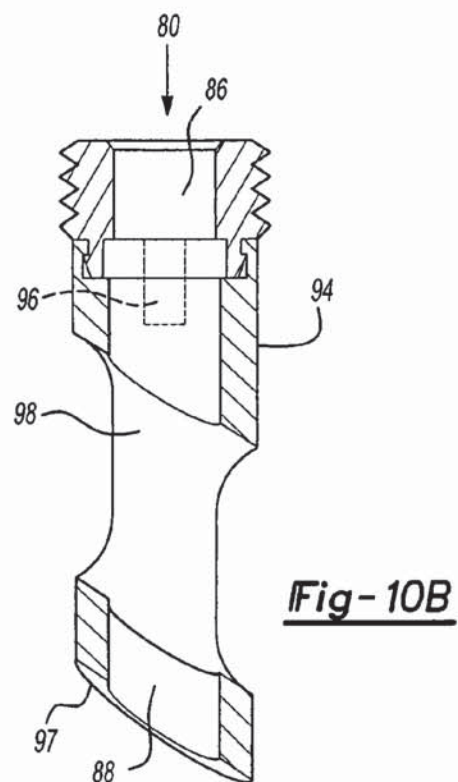
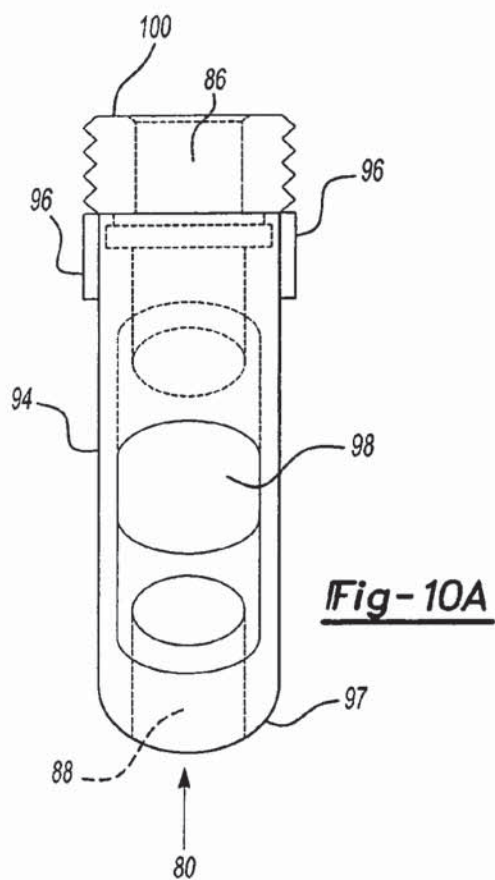


Fig-9



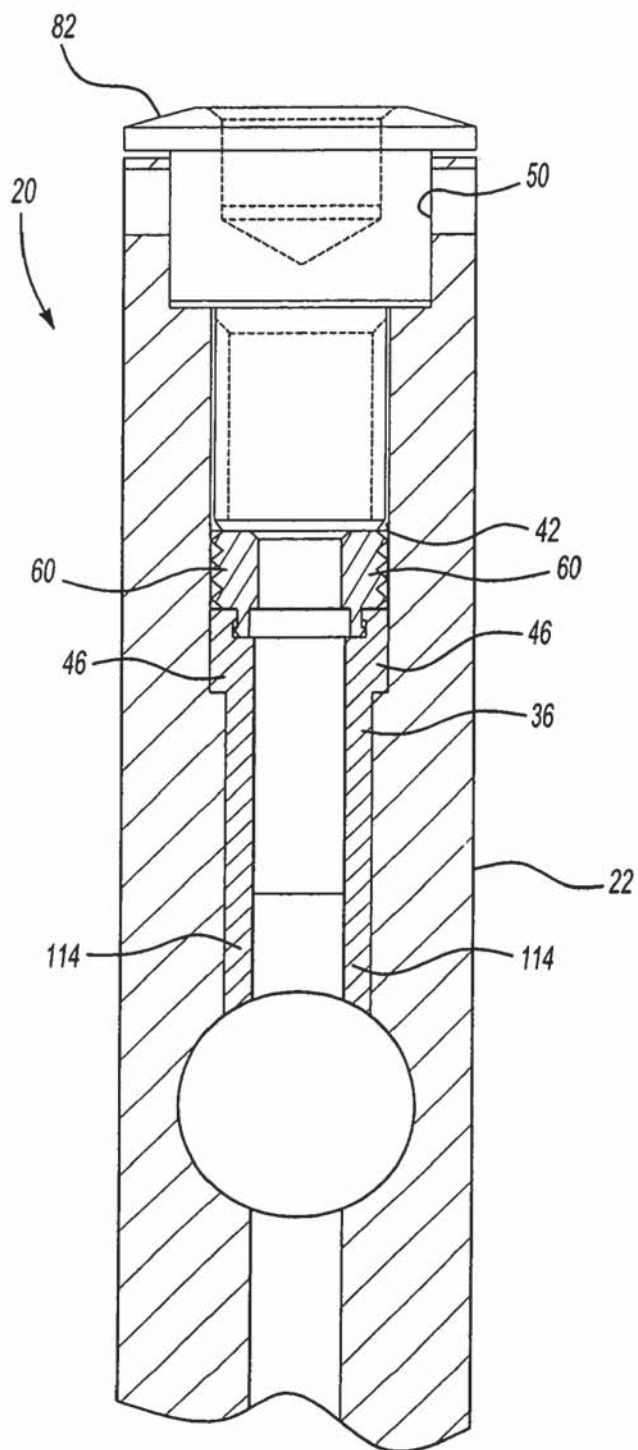


Fig-12

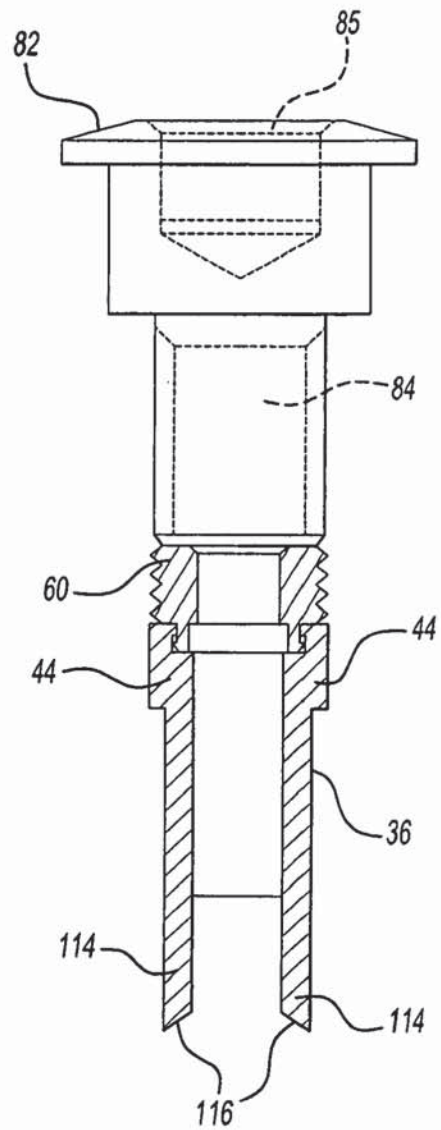


Fig-13

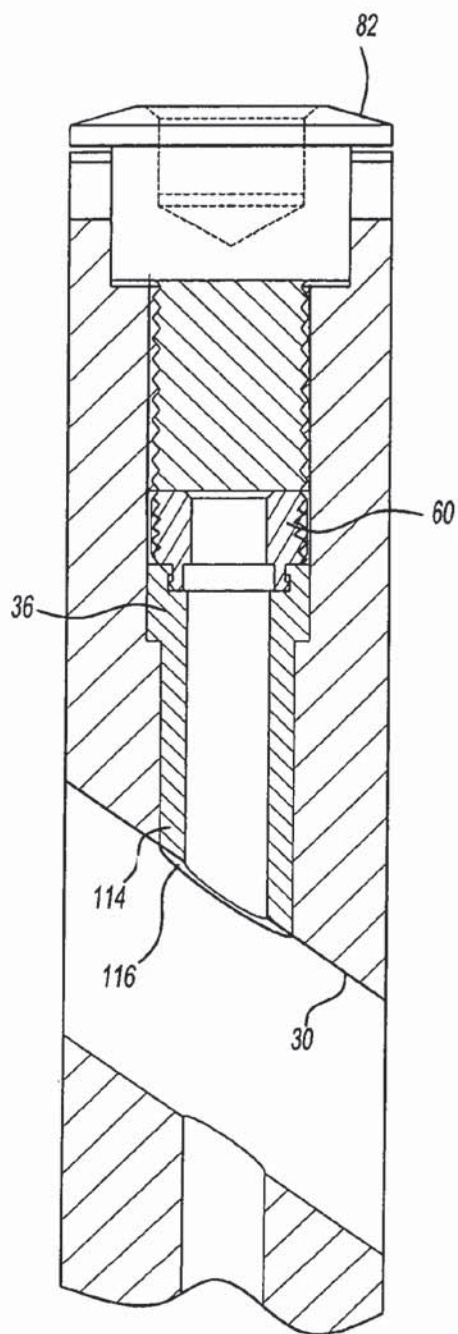


Fig-14

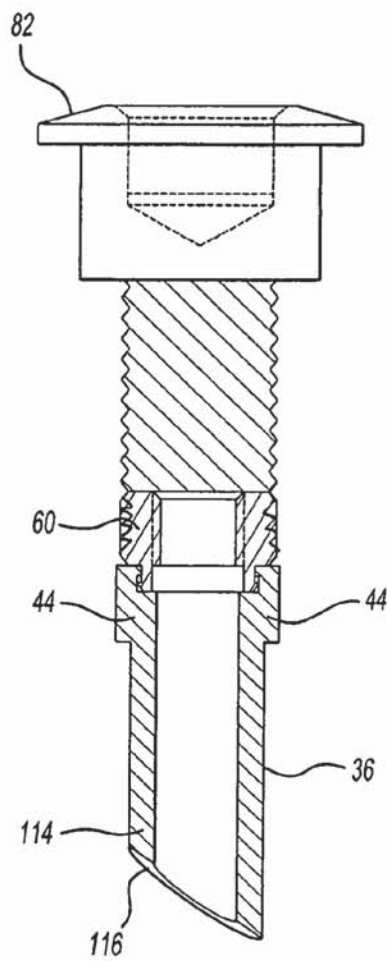


Fig-15

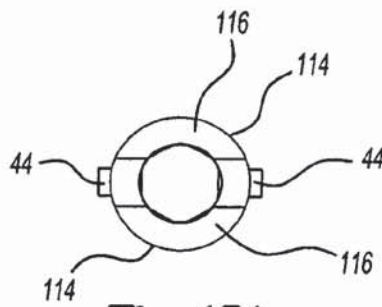


Fig-15A

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FIXATION INSTRUMENT FOR TREATING A BONE FRACTURE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 60/552,229, filed Mar. 11, 2004.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a fixation instrument for treating bone fractures. More specifically, a nail and bone screw combination used to treat a fracture of the femur including trochanteric, intertrochanteric and femoral neck fractures.

2. Background of the Invention

Orthopedic fixation systems used for stabilizing a fracture often include an internal fixation device, typically an elongated implant such as a nail, screw or pin, inserted into the intramedullary canal of the bone to stabilize the fracture and promote healing. Such fixation systems are often used with a fracture of the femur. The femur generally includes an elongated shaft, a ball shaped head that fits into the hip socket and a neck connecting the ball to the shaft. The shaft also includes a greater trochanter and a lesser trochanter.

Typically, the nail is inserted in the marrow canal of the bone and is positioned to span the fracture. Nails are also used to treat fractures of the neck, head, intertrochanter, subtrochanteric, pathologic and certain ipsilateral shaft and neck fractures of the femur. For example, if the neck of the femur sustains a fracture a bone screw inserted through an aperture in the nail spans the fracture and threadably engages the femoral head.

Typically, the aperture in the end of the nail is a smooth bore in which the bone screw rotates as it threadably engages the femoral head. Once the bone screw is suitably tightened, it is left in place during the healing process. Bone screw migration is one problem that may occur during the healing process. Specifically, during loading or movement of the femur, the bone screw may migrate or loosen, thus creating a risk of failure at the fracture. Accordingly, there is in need for a fixation instrument that resists bone screw migration and rotation.

SUMMARY OF THE INVENTION

Accordingly, the present invention is a fixation instrument including a bone nail and bone screw combination for use in repairing a bone fracture. The bone nail extends within the shaft portion of a bone such as a femur. An opening in the head or proximal end of the nail receives a bone screw that, in the case of a femoral neck fracture, extends into the femoral head.

In accordance with an aspect of the present invention, a locking insert disposed within the nail engages the bone screw and prevents rotation thereof. Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagrammatic front view of a fixation instrument according to the present invention shown implanted within a femur.

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FIG. 2 is an enlarged front view of the proximal end of the fixation instrument according to the present invention with portions removed for clarity and illustration.

FIG. 3 is a cross-sectional view of the bone screw shown in FIG. 2 taken along lines 3-3.

FIGS. 4A-4E are various views of an insert for use with the fixation instrument according to the present invention.

FIG. 5 is a side view of a locking ring for use with the fixation instrument according to the present invention.

FIG. 6 is a side view of a cap for use with the fixation instrument according to the present invention.

FIG. 7 is a front view of an alternative embodiment of a fixation instrument according to the present invention with portions removed for clarity and illustration.

FIGS. 8A-8D are various views of an alternative embodiment of an insert for use with the fixation instrument according to the alternative embodiment of FIG. 7.

FIG. 9 is a front view of an additional alternative embodiment of a fixation instrument according to the present invention with portions removed for clarity and illustration.

FIGS. 10A-10D are various views of the additional alternative embodiment of an insert for use with the fixation instrument according to the alternative embodiment of FIG. 9.

FIG. 11 is a side view of a cap for use with the fixation instrument according to the alternative embodiment of FIG. 9.

FIG. 12 is a front view of a further alternative embodiment of a fixation instrument according to the present invention.

FIG. 13 is a front view, with portions removed for clarity, of the cap and insert assembly used in connection with the fixation instrument according to the embodiment of FIG. 12.

FIG. 14 is a side view of the further alternative embodiment of the fixation instrument shown in FIG. 12.

FIG. 15 is a side view of the cap and insert assembly shown in FIG. 12 used in connection with the fixation instrument according to the embodiment of FIG. 12, with FIG. 15A being a bottom view of the insert assembly of FIG. 15.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a fixation instrument, seen generally at 20, according to one embodiment of the present invention placed in an assembled condition within a bone 10, illustrated here as a femur. The fixation instrument 20 includes a nail member 22 formed of a metallic alloy, such as a titanium alloy. The nail member 22 includes a distal end 18 and a proximal end 24. The distal end 18 typically includes at least one transverse aperture that receives a bone screw 16 used to fix the distal end 18 of the nail member 22 in place in the bone 10. The proximal end 24 includes a trailing or rear edge 26.

Turning now to FIGS. 2-6, a passageway 28 extends longitudinally through the nail member 22 between the proximal end 24 and the distal end 18. The passageway 28 receives insertion and extraction instrumentation, such as a guide wire (not shown), used to position the nail member 22 within the bone 10. Typically, the distal end 18 of the nail member 22 is inserted into the bone 10 first and follows the path of the guide wire.

The proximal end 24 includes an aperture 30 extending through the proximal end 24 in a direction that is typically angled with respect to the longitudinal axis 25 of the nail member 22. A bone screw 32 having a threaded portion 34 on one end thereof extends through the aperture 30 such that the threaded portion 34 engages the femoral head 12 for sliding compression of a femoral neck 14 or intratrochanteric fracture.

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An insert 36 having a distal end 38 and a proximal end 40 is disposed within a chamber 42 located in the proximal end 24 of the nail member 22. The insert 36 further has a pair of tabs or guide/locating members 44 that extend radially outward from the body of the insert 36. The tabs or guide/locating members 44 cooperate with a pair of grooves or channels 46 that extend longitudinally along the sidewalls 48 of the chamber 42. The proximal end 24 of the nail member 22 includes an opening 50 at the trailing or rear edge 26 of the nail member 22. The opening 50 provides access to the chamber 42.

The insert 36 further includes a lower surface 52 having a pair of locking projections 54 extending longitudinally downward/outward from the lower surface 52. The insert 36 is placed in the chamber 42 through the opening 50, such that the tabs or guide/locating members 44 are received in the grooves or channels 46 located in the sidewalls 48 of the chamber 42. Accordingly, the insert 36 is slidably received and prevented from rotating in the chamber 42. The lower surface 52 of the insert 36 extends or is oriented at an angle that is substantially the same as the angle of the aperture 30 extending through the proximal end 24 of the nail member 22. As set forth below, the insert 36 engages the bone screw 32 disposed in the aperture 30 in the nail member 22.

The bone screw 32 further includes a plurality of longitudinally extending grooves 56 located on the outer surface 58 of the bone screw 32. The grooves 56 are of a size and shape that are complementary to the locking projections 54 located on the lower surface 52 of the insert 36. As seen in FIG. 2, when the insert 36 travels longitudinally in the chamber 42 it reaches a point wherein the lower surface 52 and locking projections 54 of the insert 36 are adjacent the bone screw 32. Since the purpose of the locking projections 54 is to engage the grooves 56 to secure and prevent rotation of the bone screw 32 it may be necessary to rotate the bone screw 32 slightly to align the grooves 56 of the bone screw 32 with the locking projections 54 of the insert 36. Once properly aligned, the insert 36 is driven further within or into the chamber 42 until the lower surface 52 of the insert 36 engages the outer surface 58 of the bone screw 32 and the locking projections 54 of the insert 36 extend into the grooves 56 of the bone screw 32.

A locking ring 60 controls the position of the insert 36 within the chamber 42. The locking ring 60 has a plurality of threads 62 disposed about the outer surface of the locking ring 60. The locking ring 60 threadably engages a plurality of threads 64 disposed on the sidewalls 48 of the chamber 42. As shown in FIG. 5, the locking ring 60 includes a post portion 66 located on or forming a portion of the lower surface 68 of the locking ring 60. The post portion 66 further includes an inwardly projecting finger 70. The post portion 66 may be formed as an annular member that extends all the way around the lower surface 68 or it may be formed as a plurality of individual post members spaced about the lower surface 68 of the locking ring 60.

The inwardly projecting finger 70 cooperates with a retaining member 72 formed on the upper surface 74 of the proximal end 40 of the insert 36. The retaining member 72 further includes an annular member 76 having an outwardly extending lip 78. Accordingly, the locking ring 60 is placed on or attached to the insert 36 using a snap or press fit arrangement. Specifically, the locking ring 60 is placed on the upper surface 74 of the insert 36 and a sufficient force is exerted on the locking ring 60 to deflect the inwardly projecting fingers 70 and correspondingly the post portion 66 outward over the annular member 76. Upon clearing the annular member 76, the fingers 70 snap back into place whereby they engage the

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underside of the lip 78 and rotatably secure the locking ring 60 to the insert 36. It should be understood that such an arrangement enables the locking ring 60 to rotate about the longitudinal axis 37 of the insert 36 while remaining attached to the insert 36.

The locking ring 60 has an aperture or opening 80 having a hexagonal shape that functions as a drive portion of the locking ring 60. Accordingly, a suitable tool, such as a T-handle hexagonal wrench, may be inserted into the opening 80 to rotate or turn the locking ring 60. This arrangement enables the insert 36 to be placed in the chamber 42 prior to the nail member 22 being inserted into the bone. Other configurations may function or comprise the drive portion, including putting a slot in the upper surface of the locking ring 60 that receives a driving tool such as a screwdriver.

The insert 36 is placed within the chamber 42 such that the tabs or guide/locating members 44 engage the grooves/channels 46 located in the sidewalls 48 of the chamber 42. Since the overall outer diameter of the insert 36 is less than the inner diameter of the threads 64 in the sidewalls 48 of the chamber 42, the insert 36 slides freely in the longitudinal direction and is constrained against rotation by the tabs or guide/locating members 44. As shown, the locking ring 60 is rotatably attached to the insert 36. Accordingly, when the threads 62 on the locking ring 60 engage the threads 64 in the sidewall 48 of the chamber 42 and when the locking ring 60 is rotated by a suitable tool, the locking ring 60 moves the insert 36 longitudinally within the chamber 42. As set forth above, the insert 36 and locking ring 60 combination is placed within the chamber 42 prior to inserting or installing the nail member 22 in the bone 10.

In use, once the nail member 22 is installed in the bone 10, the bone screw 32 is placed in and extends through the aperture 30 whereby it engages the femoral head 12. After tightening the bone screw 32 to compress the fracture, a suitable tool engages and rotates the locking ring 60 to move the insert 36 downwardly within the chamber 42 until the locking projections 54 engage the grooves 56 on the outer surface 58 of the bone screw 32. If necessary, it may be required to rotate the bone screw 32 slightly in order to have the locking projections 54 line up with the grooves 56. Once the insert 36 and bone screw 32 are properly aligned, tightening the locking ring 60 maintains engagement between the locking projections 54 and the grooves 56 and prevents rotation of the bone screw 32.

After tightening the locking ring 60, the opening 50 at the trailing or rear edge 26 of the nail member 22 is closed by a cap 82 threadably received in the chamber 42. The cap 82 includes a threaded post 84, the threads being of a suitable size and configuration to engage the threads 64 located in the sidewall 48 of the chamber 42. The cap 82 further includes a socket 85 suitable for receiving a driving tool to rotate and secure the cap 82 in the opening 50.

It should be understood that the insert 36 and locking ring 60 both have longitudinal passageways 86, 88 that allow the nail member 22 to be inserted within the bone 10 and follow a guide wire (not shown), with both the insert 36 and locking ring 60 installed or positioned within the chamber 42 of the nail member 22. Accordingly, the present invention enables the insert 36 to be pre-positioned or placed in the nail member 22 prior to installation, thus eliminating the need and difficulty of having to thread the insert 36 in place after the nail member 22 is placed within the bone 10.

FIGS. 7-8 disclose an additional embodiment of a fixation instrument 20, according to the present invention. Specifically, the lower surface 110 of the insert 36 has an arcuate surface having a shape complementary to the outer diameter

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of the bone screw 32. This embodiment does not use the locking projections of the previous embodiment, nor does the bone screw 32 have longitudinal grooves contained therein. The arcuate shape of the lower surface 110 creates a greater amount of surface area of the insert 36 that contacts the outer surface 58 of the bone screw 32. Thus, tightening the locking ring 60 provides a sufficient force to create friction fit between the insert 36 and the bone screw 32 that prevents rotation of the bone screw 32 within the aperture 30 of the nail member 22.

FIG. 8A further illustrates an alternative embodiment of a rotatable connection between the locking ring 60 and the insert 36. As shown therein, the locking ring 60 includes a downwardly projecting finger 120 having an inwardly beveled surface 122 and a lip 124. The insert 36 includes an inwardly extending flange 126. As with the previous embodiment, the locking ring 60 is rotatably attached to the insert 36 using a snap or press fit arrangement. Specifically, applying a force to the locking ring 60 causes the beveled surface 122 of the downwardly projecting finger 120 to engage the inwardly extending flange 126 and deflect the finger 120 radially inward until the lip 124 of the locking finger 120 clears the flange 126 and whereby the locking finger 120 snaps outwardly and the lip 124 engages the underside of the flange 126 to rotatably secure the locking ring 60 to the insert 36.

FIGS. 9-11 show an alternative embodiment of a fixation instrument 20 according to the present invention. As shown in FIG. 9, the proximal end 24 of the nail member 22 has an additional aperture 90 for receiving a second bone screw 92. As set forth in the previous embodiment, the insert 94 includes tabs or guide/locating members 96 that are received in the grooves/channels 46 located on the sidewalls 48 of the chamber 42 whereby the insert 94 is slidably fit within the chamber 42. The insert 94 has an arcuate lower surface 97 having a degree of curvature corresponding to the radius of the bone screw 32. Accordingly, as set forth above, rotating the locking ring 100 causes the arcuate lower surface 97 of the insert 36 to engage the outer surface 58 of the bone screw 32 to prevent rotation of the bone screw 32 within the aperture 30 of the nail member 22. The insert 94 also includes an aperture 98 extending at an angle with respect to the longitudinal axis of the insert 94 for receiving the second bone screw 92. The aperture 98 is elongated in the longitudinal direction to allow for travel of the insert 36 within the passageway 28 without engaging the second bone screw 92.

A cap 102 including an elongated tab or locking projection 104 is used to secure the second bone screw 92. When the cap 102 is inserted into the opening 50 on the trailing or rear edge 26 of the nail member 22, the elongated tab or locking projection 104 engages the second bone screw 92 to prevent rotation thereof via a frictional fit. In addition, the elongated tab or locking projection 104 may include an engagement portion which sits within a groove located on the second bone screw 92, as with the previous embodiments, to further prevent rotation of the second bone screw 92. This arrangement prevents rotation of both the first and second bone screws 32, 92 with respect to the nail member 22.

FIGS. 12-15 show a further alternative embodiment of a fixation instrument 20 according to the present invention, wherein the insert 36 has a lower surface formed of a pair of downwardly extending fingers 114. Each of the downwardly extending fingers 114 has an arcuate engagement surface 116 having a curvature or radius of curvature complementary to the diameter of the bone screw 32. The arcuate engagement surfaces 116 form the lower or contact surface of the insert 36. Accordingly, each of the fingers 114 engages the bone screw 32 to secure or prevent rotation of the bone screw 32 within

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the aperture 30. The insert 36 is positioned in and secured within the chamber 42 in a manner similar to the first embodiment. As with the previous embodiments, the locking ring 60 is used to position and secure the insert 36 whereby the arcuate engagement surfaces 116 of the fingers 114 engage the bone screw 32 and prevent rotation thereof.

It should be understood that the mounting relationship between the locking ring 60 and the insert 36 is one that enables the locking ring 60 to turn or rotate freely on the insert 36. In the case of the disclosed embodiments, the insert 36 travels longitudinally within the grooves or channels 46 located in the sidewalls 48 of the chamber 42. Thus, the apparatus and corresponding components forming the snap or press fit mounting relationship between the locking ring 60 and the insert 36, as shown in the disclosed embodiments, including the inwardly projecting finger and lip on the annular member, may be positioned on either the respective locking ring 60 or insert 36; i.e., the finger may be on the insert 36 or the locking ring 60 as long as the complementary component, the lip, is on the corresponding member.

Thus, it will be seen that the objects of the invention have been fully and effectively accomplished. It will be realized, however, that the foregoing specific embodiments have been shown and described for the purposes of illustrating the functional and structural principles of the invention and is subject to change without departure from such principles. Therefore, this invention includes all modifications encompassed within the scope of the following claims.

What is claimed is:

1. A fixation instrument for treating a bone fracture comprising:

a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough and said nail member having a chamber located in said proximal end; an insert having a longitudinal axis, said insert positioned and constrained against rotation about said longitudinal axis of said insert within said chamber;

a bone screw, having a threaded portion, said bone screw extending through said aperture;

a locking ring received in said chamber and engaging said insert, said locking ring operative to secure said insert within said chamber; and

said insert having a distal end and a proximal end, a concave lower surface located at said distal end of said insert, said concave lower surface being that portion of the insert spaced farthest from the proximal end and engaging a convex surface of said bone screw, said convex surface complementary to said concave lower surface of said insert, when said bone screw extends through said aperture.

2. A fixation instrument for treating a bone fracture as set forth in claim 1 wherein said nail member has an opening adjacent a rear edge of said nail member to provide access to said chamber.

3. A fixation instrument for treating a bone fracture as set forth in claim 1 including said chamber having a plurality of threads located on an inner surface thereof;

said locking ring having a plurality of threads located on an outer surface thereof, said threads on said locking ring complementary to said threads on said inner surface of said chamber; and

said locking ring having a drive portion, whereby a suitable tool engages said drive portion and is used to move said locking ring.

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4. A fixation instrument for treating a bone fracture as set forth in claim 1 including said concave lower surface having a shape complementary to an outer diameter of said bone screw.

5. A fixation instrument for treating a bone fracture as set forth in claim 4 including said aperture extending through said nail member at an angle with respect to the longitudinal axis of said nail member; and

said lower surface extending at an angle substantially the same as the angle of said aperture.

6. A fixation instrument for treating a bone fracture comprising:

a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough and said nail member having a chamber located in said proximal end;

an insert adapted to be positioned within said chamber and having a lower surface, said lower surface operative to contact a bone screw extending through said aperture;

a locking ring received in said chamber and engaging said insert, said locking ring operative to secure said insert within said chamber;

a locking projection located on said lower surface of said insert; and

said bone screw having a longitudinal axis and having a plurality of longitudinal extending grooves, said grooves extending substantially parallel to said longitudinal axis of said bone screw on an outer surface of said bone screw wherein said locking projection is located in one of said grooves when said lower surface contacts said bone screw.

7. A fixation instrument for treating a bone fracture as set forth in claim 6 including said aperture extending through said nail member at an angle with respect to the longitudinal axis of said nail member; and

said lower surface extending at an angle substantially the same as the angle of said aperture.

8. A fixation instrument for treating a bone fracture as set forth in claim 6 wherein each of said insert and said locking ring have longitudinal passageways extending therethrough, wherein said longitudinal passageway extending through said insert terminates at said lower surface.

9. A fixation instrument for treating a bone fracture as set forth in claim 6 wherein said locking ring is rotatably connected to said insert.

10. A fixation instrument for treating a bone fracture as set forth in claim 9 wherein said locking ring includes a post portion having an inwardly projecting finger; and

said insert having a retaining member located on a distal end thereof, said retaining member including an outwardly extending lip wherein said locking finger engages said lip to rotatably secure said locking ring to said insert.

11. A fixation instrument for treating a bone fracture as set forth in claim 6 including a cap, said cap operative to close said opening located at said rear edge of said nail member.

12. A fixation instrument for treating a bone fracture as set forth in claim 6 wherein said lower surface is an arcuate surface.

13. A fixation instrument for treating a bone fracture comprising:

a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough at an angle with respect to the longitudinal axis of said nail member and said nail member having a chamber located in said proximal end;

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a bone screw;

an insert adapted to be positioned within said chamber, said insert having a proximal end and a distal end, said distal end terminating at said lower surface, said lower surface extending at an angle substantially the same as the angle of said aperture extending through said nail member and engaging said bone screw when said bone screw extends through said aperture;

a locking ring received in said chamber and engaging said insert, said locking ring operative to secure said insert within said chamber;

said nail member having a second aperture extending therethrough for receiving a bone screw; and

said insert having an aperture therein extending at an angle with respect to a longitudinal axis of said insert, said angle substantially the same as the angle of said second aperture extending through said nail member, said aperture for receiving a bone screw.

14. A fixation instrument for treating a bone fracture as set forth in claim 13 wherein said insert includes a longitudinal passageway extending through said insert;

said locking ring having a longitudinal passageway extending through said locking ring; and

a cap, said cap having an elongated locking projection, said elongated locking projection extending through said passageway in said locking ring and into said passageway in said insert, said elongated locking projection operative to engage a bone screw extending through said aperture in said insert.

15. A fixation instrument for treating a bone fracture as set forth in claim 14 wherein said locking ring is rotatably connected to said insert.

16. A fixation instrument for treating a bone fracture comprising:

a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having an aperture extending therethrough at an angle with respect to said longitudinal axis, said nail member having a chamber located in said proximal end, said chamber having a plurality of threads located on an inner surface thereof and at least one groove located in said chamber;

an insert having a distal end and a proximal end adapted to be positioned within said chamber, said insert having at least one locating member, said locating member cooperating with said groove located in said chamber, said insert having a concave lower surface forming said distal end, said distal end and correspondingly said concave lower surface operative to engage a convex surface of said bone screw when said bone screw extends through said aperture; and

a locking ring received in said chamber and engaging said insert, said locking ring having a plurality of threads located on an outer surface thereof, said threads complementary to said threads on said inner surface of said chamber wherein said locking ring is threadably received in said chamber, said locking ring operative to secure said insert within said chamber.

17. A fixation instrument for treating a bone fracture as set forth in claim 16 wherein said locking ring is rotatably connected to said insert.

18. A fixation instrument for treating a bone fracture as set forth in claim 16 wherein said insert and said locking ring each have a longitudinal passageway extending therethrough.

19. A fixation instrument for treating a bone fracture comprising:

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a nail member, said nail member having a longitudinal axis, a distal end and a proximal end, said proximal end having a plurality of apertures extending therethrough, each aperture extending at an angle with respect to said longitudinal axis and said nail member having a chamber located in said proximal end, said chamber having a plurality of threads located on an inner surface thereof and at least one groove located in said chamber;
 an insert adapted to be positioned within said chamber, said insert having at least one locating member, said locating member cooperating with said groove located in said chamber, said insert including an aperture extending therethrough at an angle with respect to a longitudinal axis of said insert and including a longitudinal passageway extending therethrough, said insert having a lower surface, said longitudinal passageway extending to said lower surface, said lower surface operative to engage a bone screw extending through said aperture;
 a locking ring received in said chamber and engaging said insert, said locking ring having a plurality of threads located on an outer surface thereof, said threads comple-

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mentary to said threads on said inner surface of said chamber wherein said locking ring is threadably received in said chamber, said locking ring having a longitudinal passageway therethrough and a drive portion suitable to receive a tool used to rotate said locking ring in said chamber, said locking ring operative to secure said insert within said chamber; and
 a cap, said cap threadably received in said chamber and having an elongated locking projection, said elongated locking projection extending into said passageway and said locking ring and said insert and operative to engage a bone screw extending through said aperture in said insert.
20. A fixation instrument for treating a bone fracture as set forth in claim **19** including said aperture extending through said nail member at an angle with respect to the longitudinal axis of said nail member; and
 said lower surface extending at an angle substantially the same as the angle of said aperture.

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