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Phoenix™ Antegrade Femoral Nail System Featuring CoreLock™ Technology

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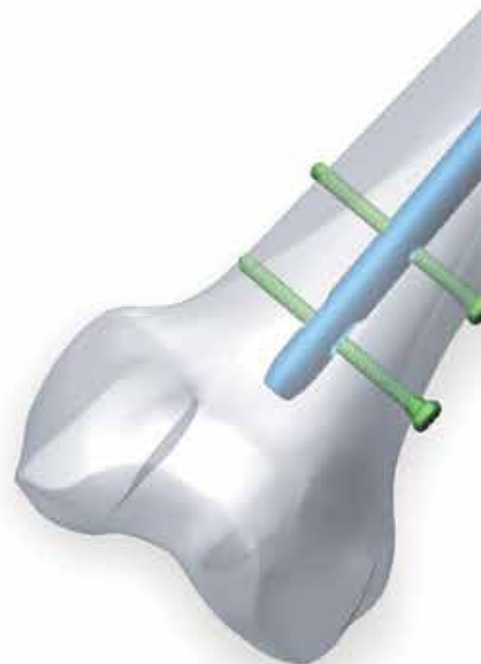
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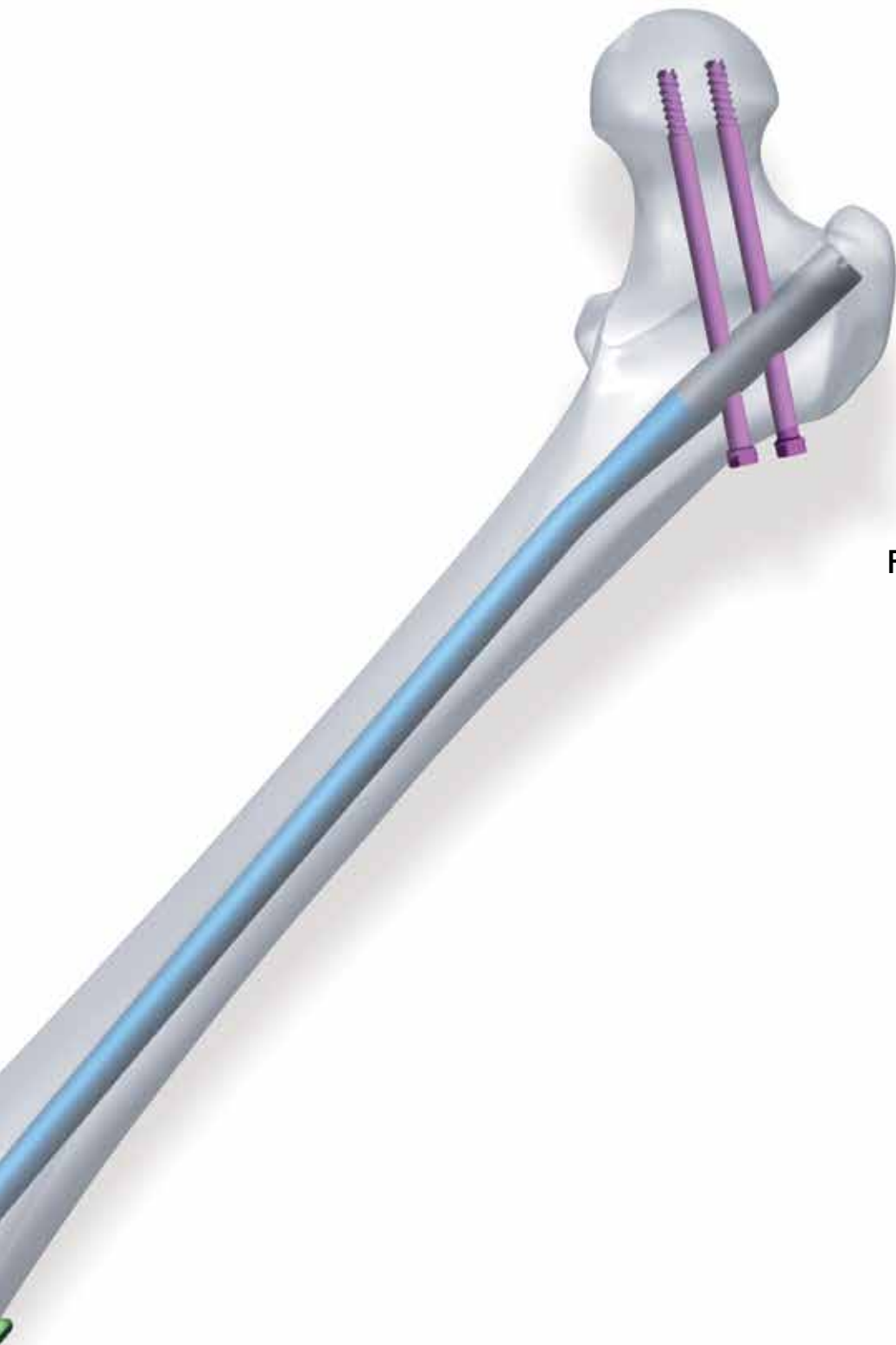
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Rx only.





Surgical Technique

Phoenix™ Antegrade Femoral Nail System

Featuring CoreLock™ Technology

- Trochanteric and Piriformis Fossa entry nails that allow for either reconstructive or interlock screw applications
- Each nail features CoreLock™ Technology, a preassembled, embedded locking mechanism that allows both 6.0mm reconstructive screws or 5.0mm interlock screw to be mechanically locked to provide enhanced proximal femoral fixation

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Introduction

The Phoenix™ Antegrade Femoral Nail System consists of trochanteric and piriformis fossa entry point nails that allow for either reconstructive or interlock screw applications. Each nail features patent pending CoreLock™ Technology, a preassembled, embedded locking mechanism that allows two 6.0mm self-drilling, self-tapping cannulated reconstructive screws or a 5.0mm interlock screw to be mechanically locked to provide enhanced proximal femoral fixation.

The trochanteric nail incorporates a 6° proximal bend for ease of insertion that is offered for left and right applications in the following diameters and lengths: 9.0mm (280mm – 460mm in 20mm increments), 10.5mm, 12.0mm, 13.5mm and 15.0mm (300mm – 480mm in 20mm increments). The proximal outer diameter of the 9mm, 10.5mm and 12mm nails is 12mm. The proximal outer diameter of the 13.5mm and 15mm is 13.5mm and 15mm respectively.

The piriformis fossa nail is available in the following outer diameters and lengths for left and right applications: 9.0mm (280mm – 460mm in 20mm increments), 10.5mm, 12.0mm, 13.5mm and 15.0mm (300mm – 480mm in 20mm increments). The proximal outer diameter of the 9mm, 10.5mm and 12mm nails is 12mm. The proximal outer diameter of the 13.5mm and 15mm is 13.5mm and 15mm respectively.

Each antegrade femoral nail is composed of titanium alloy and incorporates a 1.8m radius of curvature, 9° of built-in anteversion, a 128° femoral neck angle and allows for static or dynamic distal locking.

Additionally, the system features a modular Radiolucent Targeting Arm that permits multiplanar radiographic visualization that allows for accurate reconstructive or interlock targeting. With its easy to use color-coded instrumentation conveniently contained in a single tray and its innovative implant design, the Phoenix™ Antegrade Femoral Nail System is designed to address both patient and surgeon needs.

Indications & Contraindications

INDICATIONS

Phoenix Femoral Nail System

These devices are to be implanted into the femur for alignment, stabilization and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.



Design Features

Trochanteric Nails

9.0mm (280mm – 460mm)
(20mm increments)

10.5mm (300mm – 480mm)
(20mm increments)

12.0mm (300mm – 480mm)
(20mm increments)

13.5mm (300mm – 480mm)
(20mm increments)

15.0mm (300mm – 480mm)
(20mm increments)

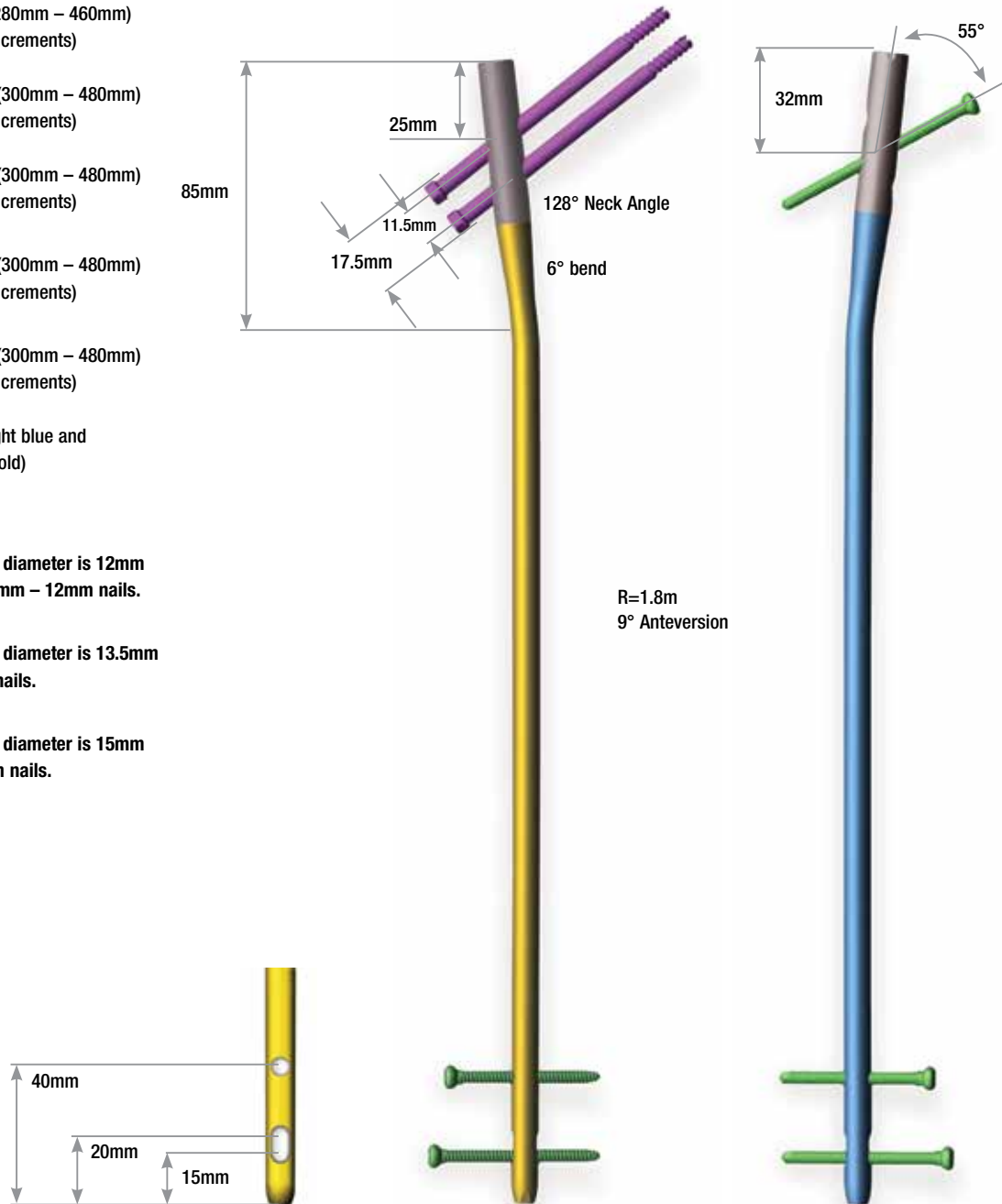
(Left – light blue and
Right – gold)

NOTE:

Proximal diameter is 12mm
for the 9mm – 12mm nails.

Proximal diameter is 13.5mm
for 13.5 nails.

Proximal diameter is 15mm
for 15mm nails.



Design Features (Continued)

Piriformis Fossa Nails

9.0mm (280mm – 460mm)
(20mm increments)

10.5mm (300mm – 480mm)
(20mm increments)

12.0mm (300mm – 480mm)
(20mm increments)

13.5mm (300mm – 480mm)
(20mm increments)

15.0mm (300mm – 480mm)
(20mm increments)

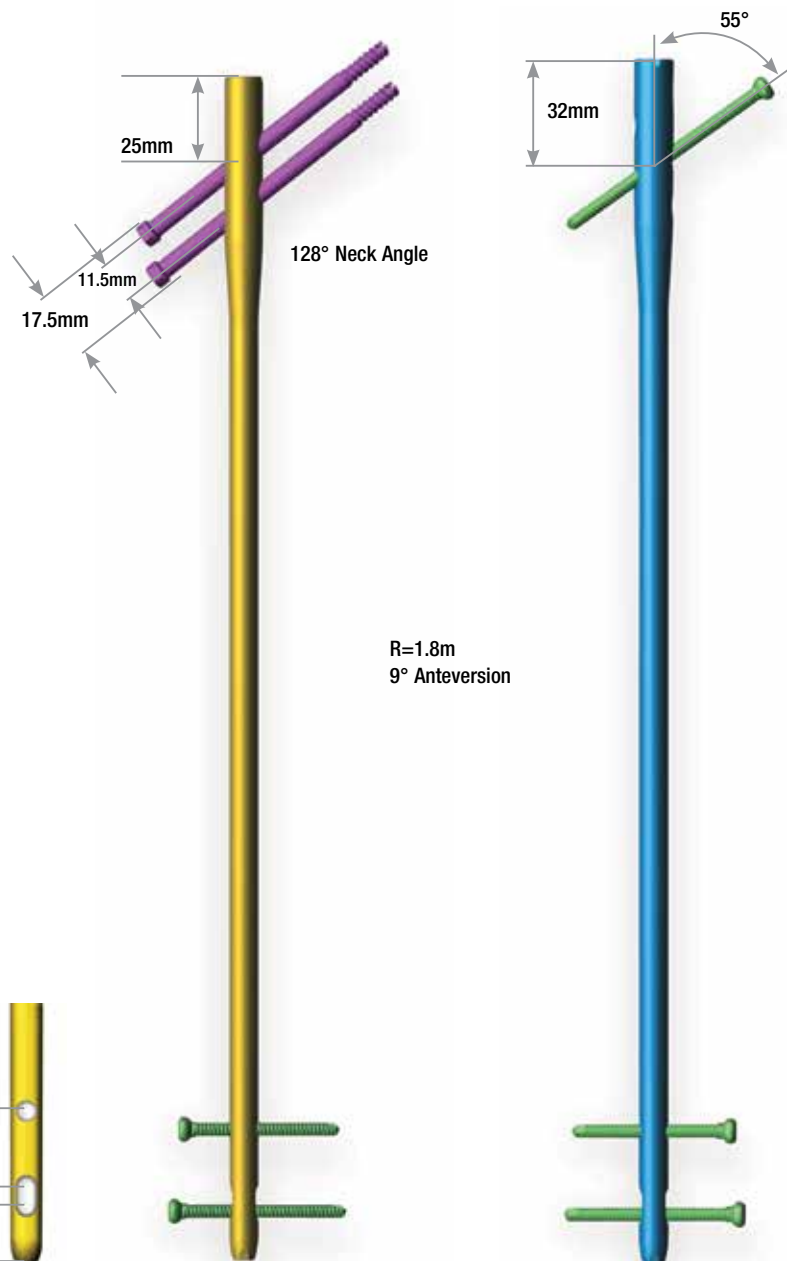
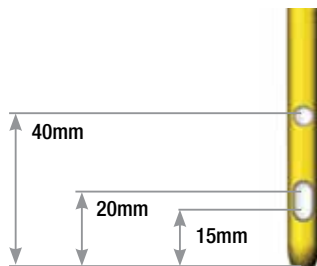
(Left – light blue and
Right – gold)

NOTE:

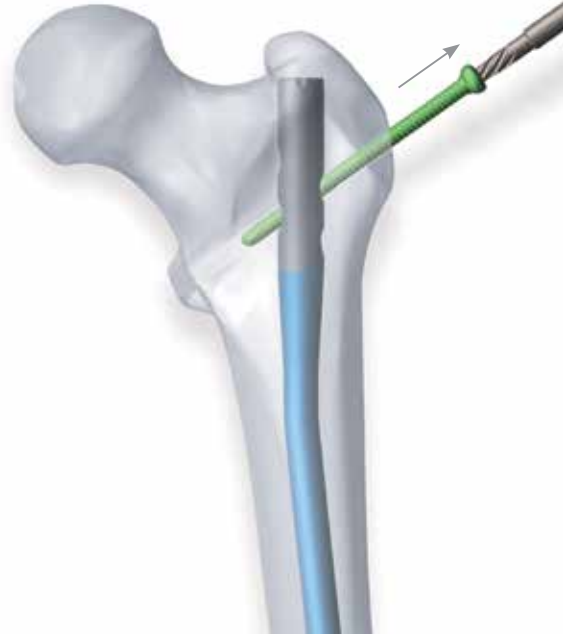
Proximal diameter is 12mm
for the 9mm – 12mm nails.

Proximal diameter is 13.5mm
for 13.5 nails.

Proximal diameter is 15mm
for 15mm nails.



The Phoenix™ Antegrade Femoral Nail features CoreLock™ Technology, a preassembled, embedded locking mechanism that allows two 6.0mm self-drilling, self-tapping cannulated reconstructive screws or a 5.0mm interlock screw to be mechanically locked to provide enhanced proximal femoral fixation.



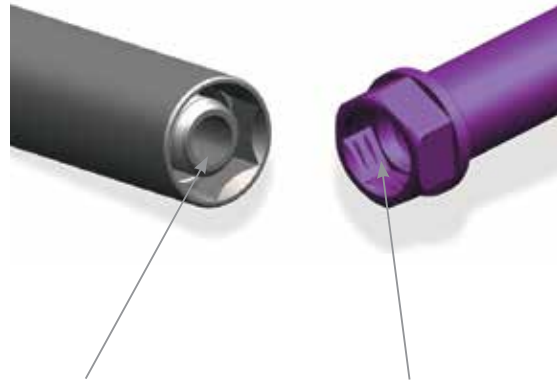
Proximal screw removal can be achieved without disengaging the embedded setscrew.

Design Features (Continued)

6mm Cannulated Partially Threaded Reconstructive Screws

- Composed of Titanium Alloy
- Self-tapping and self-drilling
- Interior of 6mm screw head is threaded for secure retention to inserter
- Color-coded magenta
- Interior of 6mm screw features left handed threads to mate with extraction instrumentation
- Interior of 6mm screw has 5mm hex for non-retained insertion and/or extraction

6mm Screw Lengths:
50mm – 130mm
(Available in 5mm increments)



Recon Inserter Connector retains head of screw

Interior of screw head is threaded for retention to driver allowing for manual insertion over guide wire

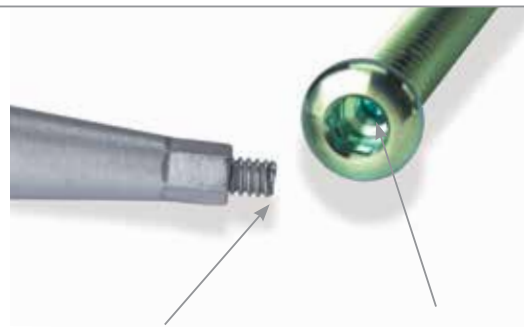
5mm Double-Lead Thread Screws

- Composed of Titanium Alloy
- Features a double-lead thread design for quick insertion
- Self-tapping tip
- Interior of 5mm cortical screw head is threaded for secure retention to inserter
- Threads are closer to screw head and screw tip for better bicortical purchase
- Color-coded light green
- Used for proximal interlocks and distal locking screws



5mm Screw Lengths:
20mm – 60mm
(Available in 2mm increments)

65mm – 110mm
(Available in 5mm increments)



3.5mm Inserter Connector (Long & Short) retains head of screw

Interior of screw head is threaded for retention to inserter

End Caps

3.5mm Inserter Connector retains head of end cap to facilitate easier insertion. End Caps offered in 0mm, 5mm, 10mm, 15mm, and 20mm sizes.

Surgical Technique

Step 1. Preparation/Positioning

The patient is positioned supine on a fracture table with the affected leg in a neutral position or slightly adducted. The unaffected leg is flexed at the hip and knee, positioned on an additional leg holder to allow image visualization of the proximal femur. Alternatively, the uninjured extremity can be abducted with the hip and knee extended or the two legs placed in a heel toe position with the uninjured below the injured leg. The patient can also be placed supine on a radiolucent table with a large bump under the ipsilateral buttock or positioned lateral on a fracture or radiolucent table. The fracture is reduced using longitudinal traction. The surgeon must assess the fracture reduction before prepping the patient and assure that unobstructive biplanar radiographic visualization of the entire proximal femur, including the hip joint, is obtainable. Inadequate visualization of the entire proximal femur can result in inappropriate locking screw length or positioning. The patient is draped using a shower curtain or split sheets; one should allow skin exposure proximally to the iliac crest and distally below the knee.



Step 2. Skin Incision

If using the trochanteric nail, a straight 1-2cm lateral incision is made approximately 3-4cm proximal to the tip of the greater trochanter; the gluteus maximus muscle is dissected in line with its fibers.

If using the piriformis fossa nail, place a guide wire on the proximal femur overlying piriformis fossa entry. Make skin incision at level of intersection of lateral margin of thigh.

Surgical Technique (Continued)

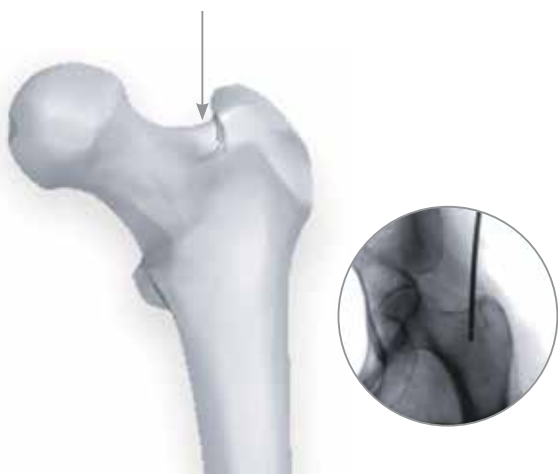
Step 3. Entry Point

Trochanteric Nail



If using the trochanteric nail, the entry point is at the tip of the greater trochanter, in line with the femur on the lateral radiograph.

Piriformis Fossa Nail



If using the piriformis fossa nail, the entry point is between the top of the femoral neck and bottom of the piriformis fossa.



Insert the Working Channel Trocar (Catalog #14-442016) into the Working Channel Soft Tissue Sleeve (Catalog # 14-442015). A 3.2mm x 460mm COCR Threaded Tip Guide Wire (Catalog #14-441054) is inserted through the trocar assembly and advanced into the proximal femur, verified with AP and lateral radiographs. Remove the Trocar.



**Piriformis Fossa Entry
Wire Inserted**

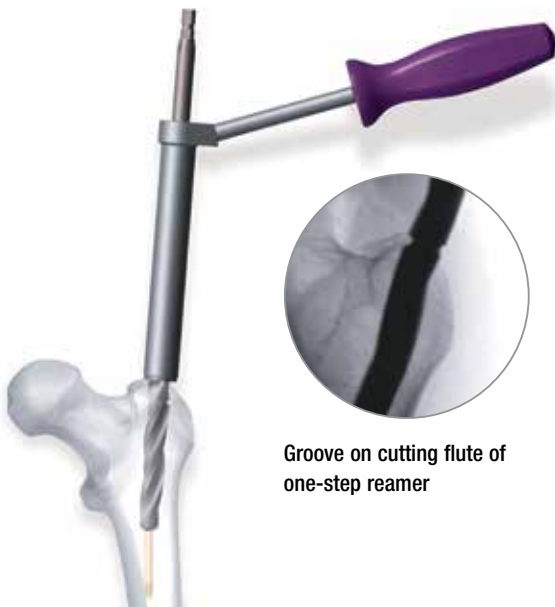


**Trochanteric Entry
Wire Inserted**

Step 4. Opening The Medullary Canal

Advance the 12.2mm One-Step Reamer (Catalog #14-442002) through the Working Channel Soft Tissue Sleeve, over the Threaded Tip Guide Wire to enlarge the entry side and drill until entering the canal. The Working Channel Soft Tissue Sleeve will facilitate a 16mm reamer head during intramedullary reaming.

NOTE: The one-step reamer has a groove on the cutting flutes to indicate, under radiographic visualization, the proper depth to accommodate the proximal outer diameter of the nail.



Groove on cutting flute of one-step reamer

Alternatively, a 12.2mm Curved Cannulated Awl (Catalog # 14-442003) attached to a Modular T-Handle, Non-Ratcheting (Catalog #29407) can be used to obtain the entrance portal.

NOTE: The curved awl should only be used for trochanteric entry.



If desired, the 4.3mm Trocar Interlock (Catalog #14-442014) can be inserted through the cannulation of the Curved Cannulated Awl, to provide an impact surface and help prevent penetration of bone debris into the awl.

Surgical Technique (Continued)

Step 5. Fracture Reduction And Guide Wire Placement

Fracture reduction is performed manually, with use of radiograph images to aide with positioning. A 3.0mm x 98cm Bead Tip Guide Wire (Catalog #27922) is inserted into the intramedullary canal and advanced past the fracture site, into the distal femur. Confirm position of Guide Wire to be center – center in the AP and lateral views. To help facilitate Guide Wire passage through the fracture site, the Keyless Chuck T-Handle (Catalog #14-442078) can be used.



In the event of a difficult fracture reduction, the 8.5mm Fracture Reducer (Bowed) (Catalog #14-442068) can be used to facilitate Guide Wire insertion and fracture reduction. In patients with tight canals, reaming to 9.5mm may help facilitate passage of reducer.



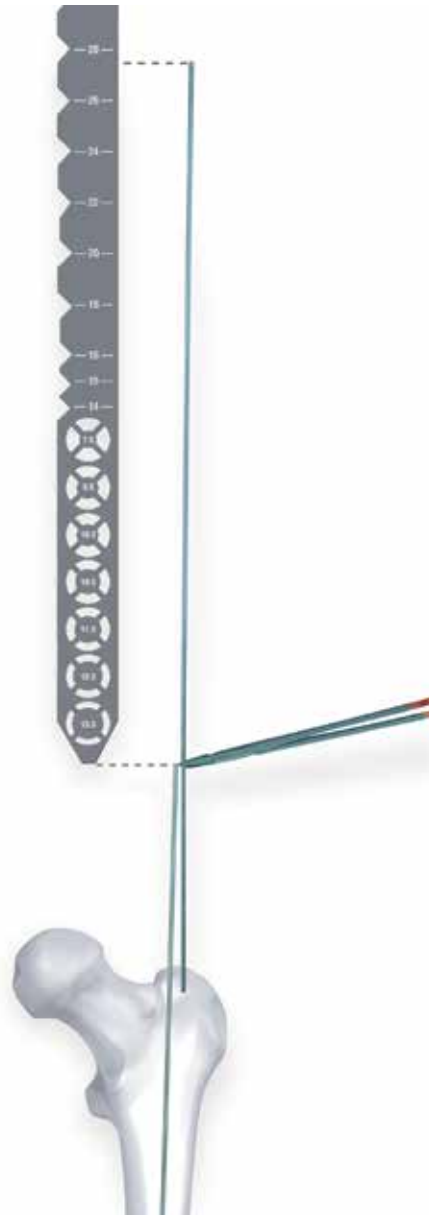
In the case of a non-union, where the path to the canal is blocked and unlikely to advance a guide wire or entry reamer across the fracture site, a Pseudarthrosis Pin Straight (Catalog #14-442073) or Curved (Catalog #14-442074) can be used to create an opening for the passage of a guide wire for canal reaming.



Surgical Technique (Continued)

Step 6. Determining Nail Length

A second Guide Wire of equal length can be used to measure the length of the medullary canal or a Medullary Canal and Length Estimator (Catalog #14-442075) can be used to determine nail diameter and length. The 98cm Telescoping Nail Measuring Gage (Catalog #14-440067) is placed over the 3.0mm Bead Tip Guide Wire with the foot resting on the proximal femur (the tip of the greater trochanter). With the Guide Wire resting in the desired distal femur, the telescoping tube is extended to the end of the Guide Wire. To measure nail length, a direct reading can be made at the junction of the two tubes. The nail should be countersunk to prevent any impingement. The nail length chosen should be at least 1cm shorter than the measured medullary canal to allow countersinking of the nail.



Step 7. Intramedullary Reaming

Upon attaching the 8mm diameter Modular Reamer Head to the Flexible Nitinol Reamer Shaft (52cm-Catalog #27940), begin reaming over the Bead Tip Guide Wire in 0.5mm increments to a size 1mm – 1.5mm greater than the diameter of the nail to be inserted.

During medullary canal reaming, the Wire Pusher (Catalog #41027) can be used to help retain the Bead Tip Guide Wire during reamer extraction.



Reamer head diameters available from 8mm to 16mm (0.5mm increments)

NOTE: The 8mm reamer head is the only forward cutting reamer head; all others are side-cutting.

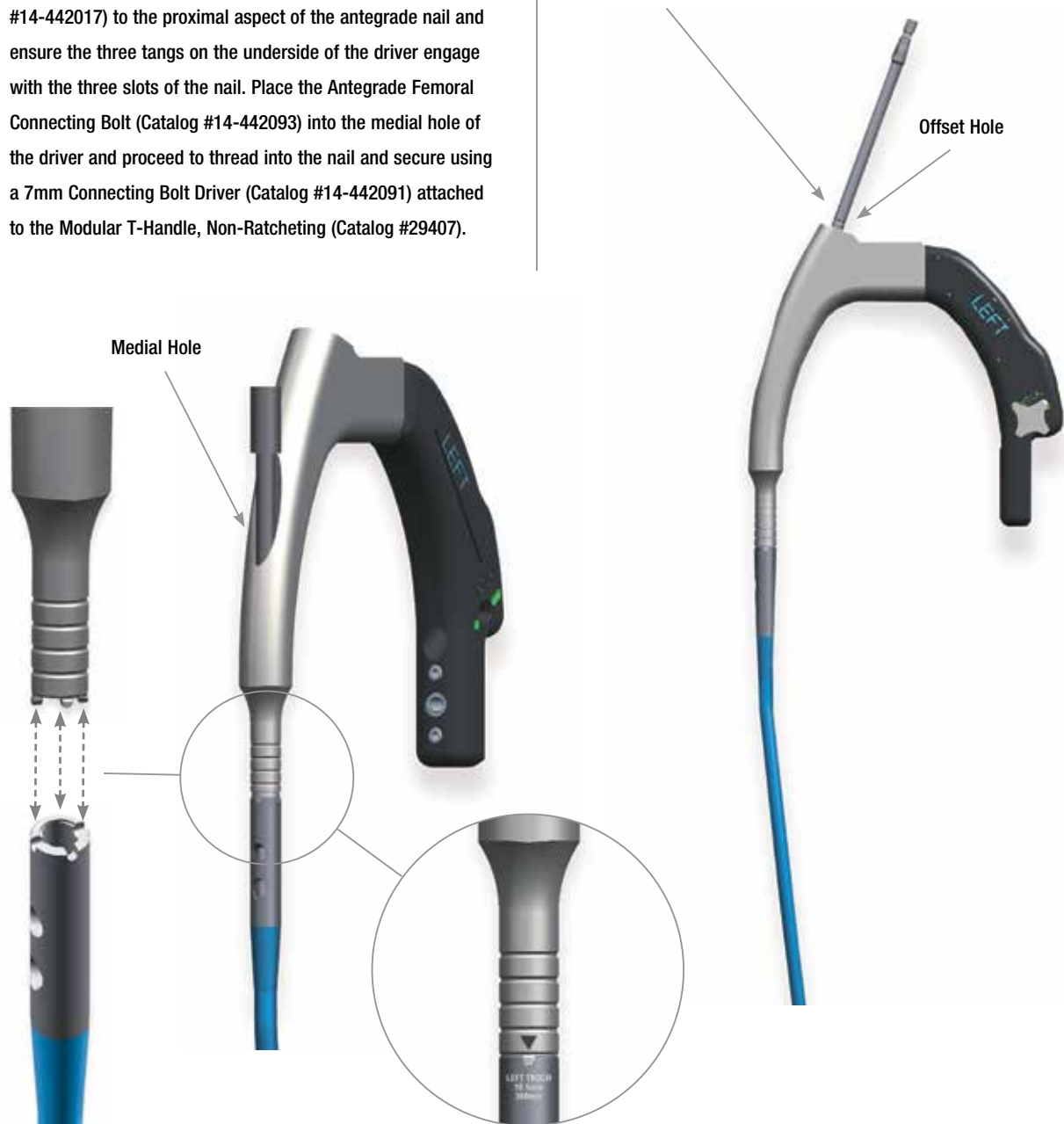
NOTE: Since the 3.0mm Bead Tip Guide Wire will pass through all Phoenix™ Antegrade Femoral Nail diameter cannula, an exchange technique is not required.

Surgical Technique (Continued)

Step 8. Nail Assembly

Attach the Antegrade Femoral Nail Driver (Catalog #14-442017) to the proximal aspect of the antegrade nail and ensure the three tangs on the underside of the driver engage with the three slots of the nail. Place the Antegrade Femoral Connecting Bolt (Catalog #14-442093) into the medial hole of the driver and proceed to thread into the nail and secure using a 7mm Connecting Bolt Driver (Catalog #14-442091) attached to the Modular T-Handle, Non-Ratcheting (Catalog #29407).

Line gauge on the 7mm connecting bolt driver indicates when the connecting bolt driver is fully seated into the connecting bolt, when entering the offset hole.



Alignment Check

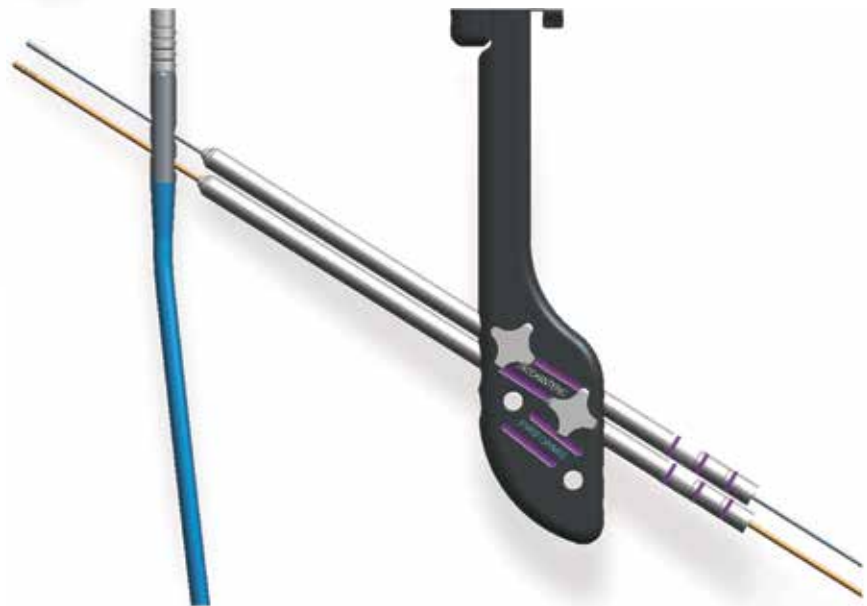
Prior to nail insertion, it is recommended to perform an alignment check to ensure accurate targeting for interlock or reconstructive mode.

For interlock mode, insert the Soft Tissue Guide, 4.3mm Drill Sleeve and 4.3mm Calibrated Drill Bit through the interlock slot of the driver to ascertain accuracy.

For reconstructive mode, insert an assembly of Soft Tissue Guide, Drill Sleeve, Guide Wire Sleeve and Guide Wire through both of the appropriate nail (trochanteric or piriformis fossa) recon slots of the target arm to ascertain accuracy. Upon confirming accurate trajectories, remove the guides if desired.



Interlock Mode Alignment Check



Reconstructive Mode Alignment Check

Surgical Technique (Continued)

Step 9. Nail Insertion

Insert the antegrade nail assembly over the Bead Tip Guide Wire and advance into the medullary canal to the desired depth. If needed, the Slotted Mallet (Catalog #14-442053) can be used to lightly tap the Slap Hammer Adapter (Catalog #14-442055) to seat the nail. It is recommended to attach the Targeting Arm for reconstructive applications to the Nail Driver once the antegrade nail has been completely seated into the canal, to avoid potential loosening.

NOTE: Do not strike the Nail Driver directly with the Slotted Mallet. This could damage the Nail Driver and cause misalignment.



The fracture should be adequately reduced and out to length during the insertion of the nail and should be monitored with radiographic images. The Bead Tip Guide Wire is removed after the nail passes the fracture site. The antegrade nail should be inserted past the tip of the greater trochanter. If inserting reconstructive screws, the nail should be inserted for optional screw position in the femoral neck and head. Final nail positioning should be checked in both the AP and lateral radiographs to ensure proper alignment.

NOTE: Be certain to make sure the Nail Driver connections are securely connected, prior to proximal locking.



NOTE: Grooves on the Driver Nose help indicate depth when countersinking.

Step 10. Nail and Screw Positioning

Prior to Guide Wire insertion, accurate nail and screw positioning can be identified in the lateral view by aligning the radiopaque solid markers embedded within the Nail Driver, so they are tangent to the outside diameter to the nail.



Radiopaque solid markers within the Nail Driver are shown anterior to the nail



Radiopaque solid markers within the Nail Driver are shown posterior to the nail



Radiopaque solid markers within the Nail Driver are shown in correct position

Surgical Technique (Continued)

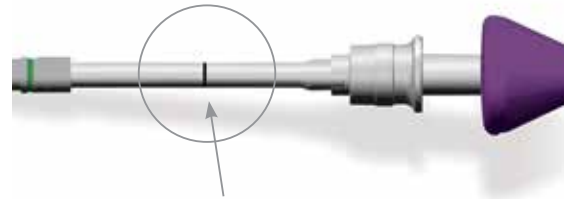
Interlock Femoral Mode Technique

Step 11A. Proximal Interlock Application

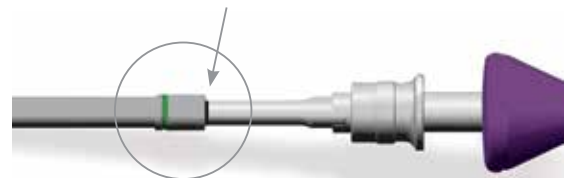
Assemble the 4.3mm Trocar (Catalog #14-442014), 4.3mm Drill Sleeve (Catalog #14-442013) and Soft Tissue Sleeve (Catalog #14-442012) together and insert through the interlock slot. Advance the assembly to bone and determine and mark the entry point. Remove the Trocar and advance the assembly to the near cortex. Secure the assembly to the Nail Driver with a Sleeve Locking Setscrew (Catalog #14-442056). Insert the 4.3mm Calibrated Drill Bit (Catalog #27961) through the Drill Sleeve to perforate the medial cortex. Appropriate 5mm screw length is measured off the Calibrated Drill Bit, at the end of the Drill Sleeve. Alternatively, the Screw Depth Gauge (Catalog #14-442081) can be used to determine and verify the length of the screw.



Attach the 3.5mm Inserter Connector, Long (Catalog #14-441043) through the cannula of either the Straight or T-Handle and connect the 3.5mm Inserter, Long (Catalog #14-441044). Retain the screw to the threaded hex tip of the Inserter Connector and turn the knob in a clockwise fashion. Insert the screw through the Soft Tissue Guide and into bone.



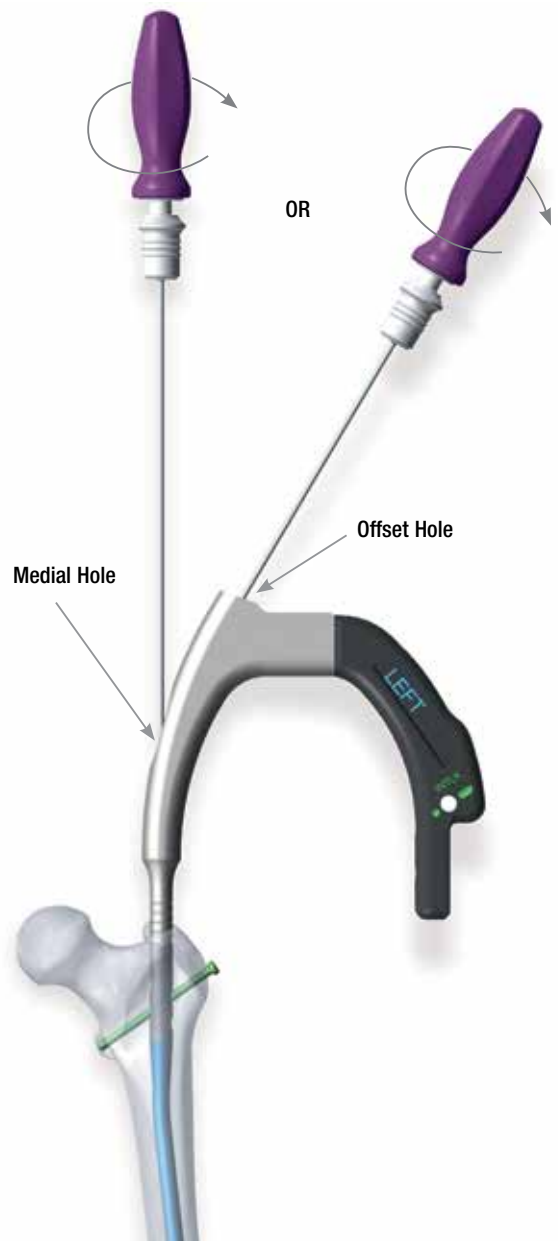
The line marked "Femoral" on the 3.5mm Inserter, Long indicates when the screw head is fully seated (Ensure the Soft Tissue Sleeve is firmly against bone).



NOTE: For final tightening 5.0mm screws, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.

Surgical Technique (Continued)

Once interlock screw insertion is complete, if fixed angled locked screw is desired, attach the Torque Limiting Handle (Catalog #27923) to the 4mm Setscrew Driver Shaft (Catalog #14-442005) and through either the medial hole or offset hole of the Nail Driver into the proximal aspect of the nail. Turn the handle in a clockwise motion – until it clicks – to engage the preassembled, embedded setscrew/locking mechanism to the interlock screw. When complete, remove the setscrew driver and disengage the Nail Driver from the nail with the 7mm Connecting Bolt Driver.



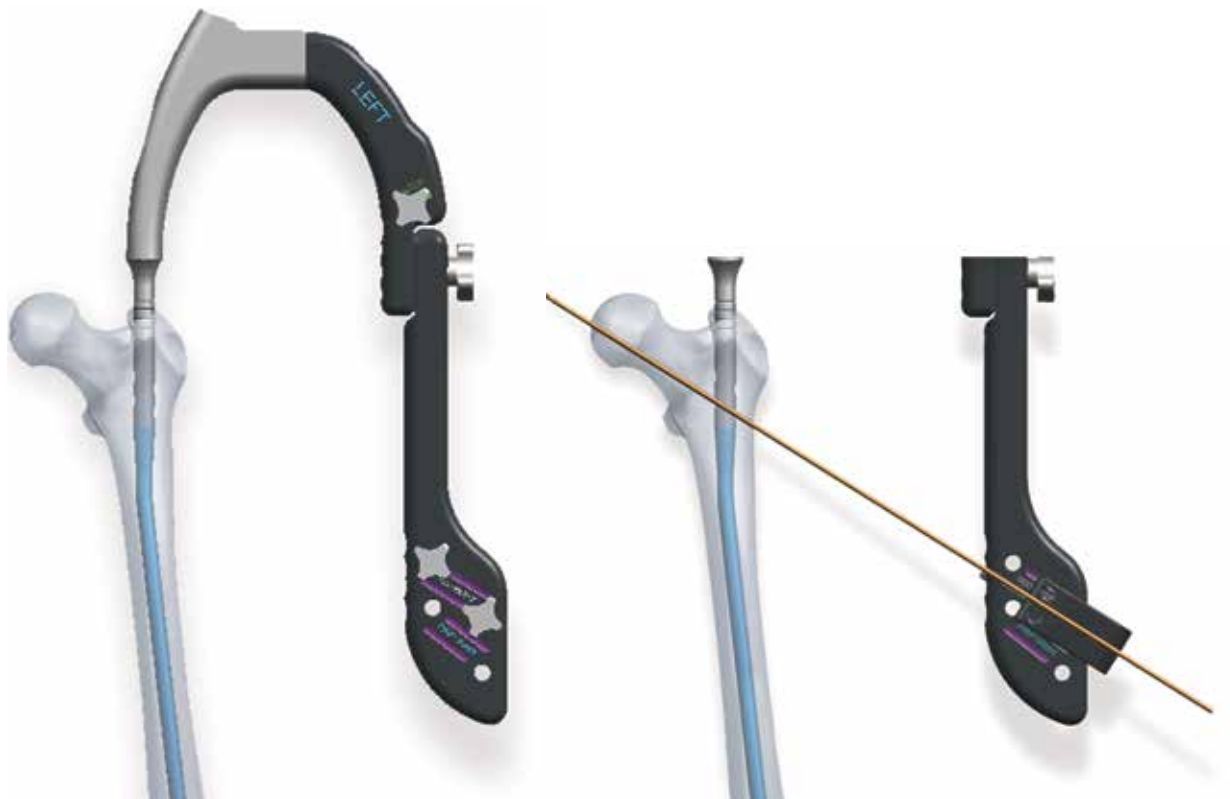
Reconstructive Femoral Mode Technique

Step 11B. Proximal Reconstructive Application

Attach the Recon Targeting Arm (Catalog #14-442018) to the Nail Driver and secure with the Thumb Screw (Catalog #41023).

In order to verify wire positioning, insert the Recon Target Wire Adapter (Catalog #14-442090) through the appropriate nail (trochanteric or piriformis fossa) recon slot of the target arm. Overlay two guide wires through the wire adapter to confirm positioning in the femoral neck and head.

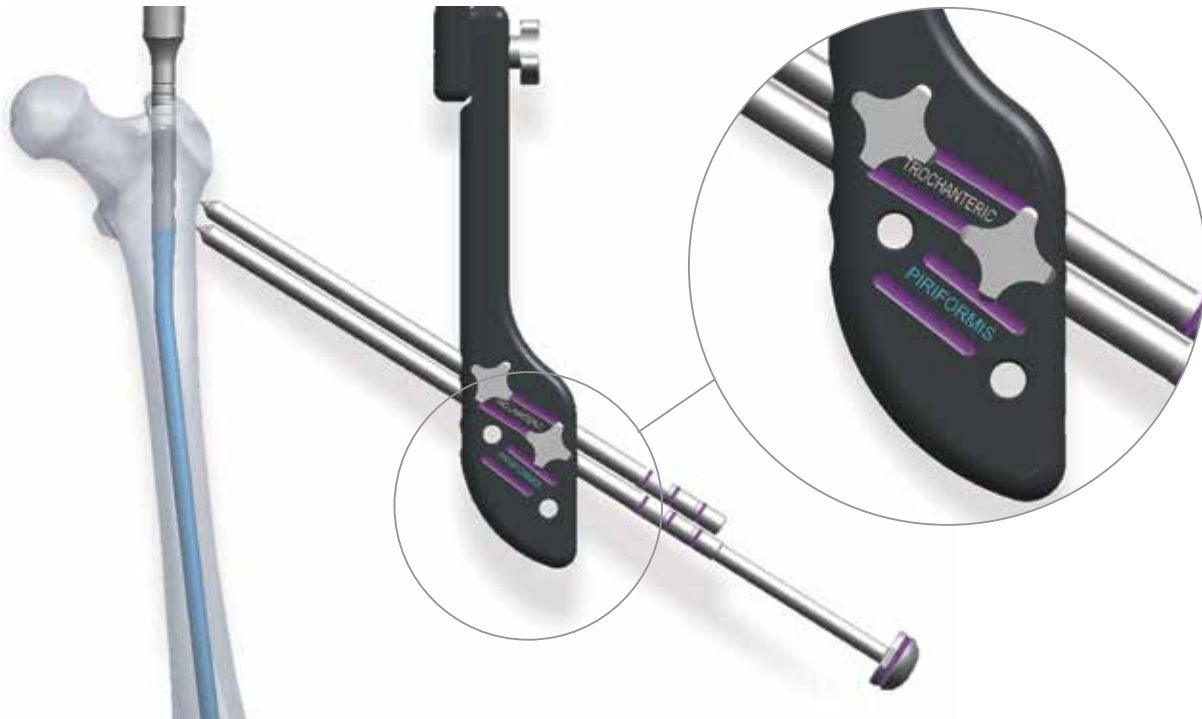
NOTE: If two wires appear, rotate the C-arm until only one wire is visible for a true AP image.



Surgical Technique (Continued)

Assemble the Recon 3.2mm Trocar (Catalog #14-442011), Recon 3.2mm Guide Wire Sleeve (Catalog # 14-442010), Recon 6mm Drill Sleeve (Catalog # 14-442009) and Recon Soft Tissue Sleeve (Catalog#14-442008) together and insert through the appropriate nail (trochanteric or piriformis fossa) recon slot of the targeting arm. Advance the assembly to bone and determine and mark the entry point.

Remove the Trocar and advance the assembly to the near cortex. Repeat with other sleeve assembly. Secure the assembly to the Nail Driver with two Sleeve Locking Setscrews (Catalog #14-442056).

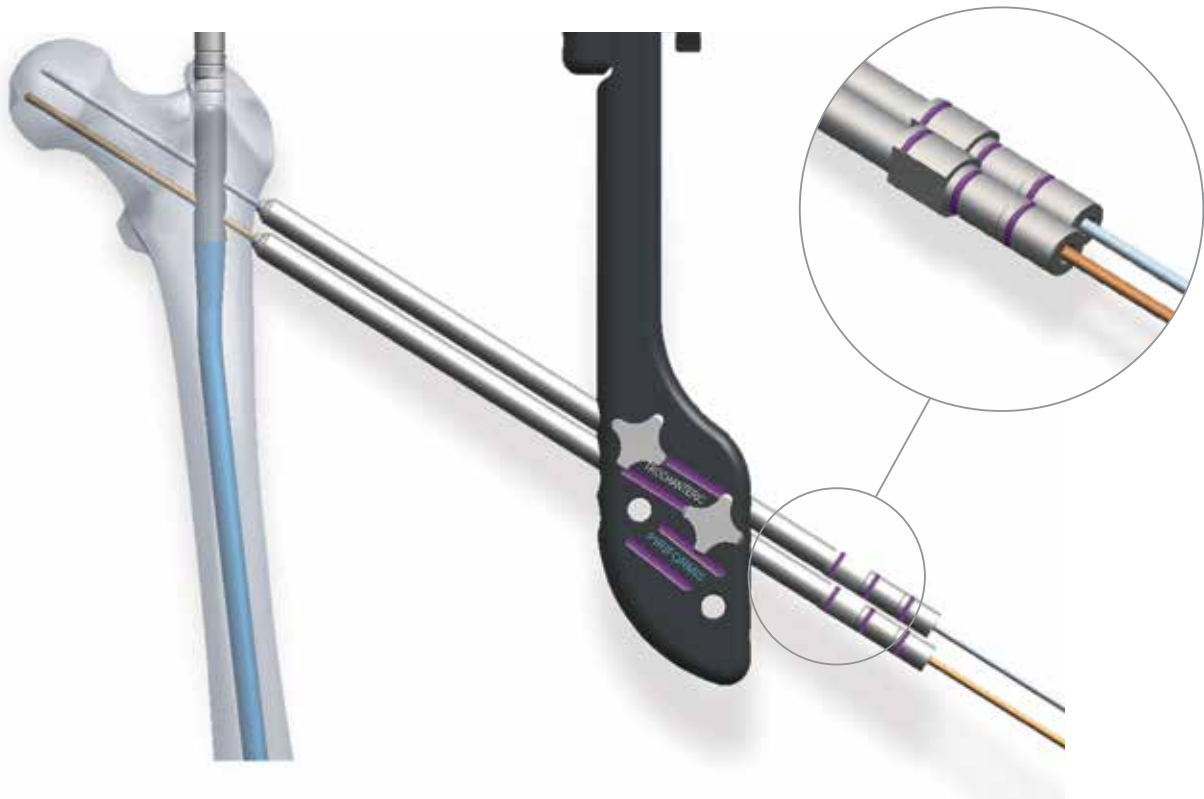


NOTE: Both sets of sleeves should be inserted into the targeting arm prior to guide wire insertion.

Insert the GOLD 3.2mm x 460mm COCR Threaded Tip Guide Wire (Catalog #14-441054) through the sleeve assembly into the femoral head. Confirm wire position with AP and lateral radiographs. Insert the SILVER 3.2mm x 560mm COCR Threaded Tip Guide Wire (Catalog #14-441053) through the other sleeve assembly into the femoral head.

Confirm wire position with AP and lateral radiographs. Both wires should be advanced to within 5mm of the subchondral bone of the femoral head.

The wires should be centrally located in the femoral head. If the wires are not oriented correctly, the nail may require adjustment. Remove the wires before adjusting.



NOTE: If Threaded Tip Guide Wire deflection is observed during insertion, it is recommended to remove the Guide Wire and proceed to use the 6.0mm Solid Recon Drill (Catalog #14-442083).

NOTE: The flats located on both sides of the Soft Tissue Sleeves should face each other. Incorrect positioning of the flats may cause misalignment.

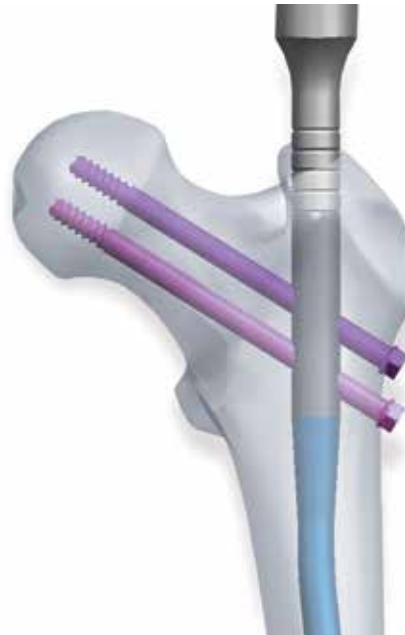
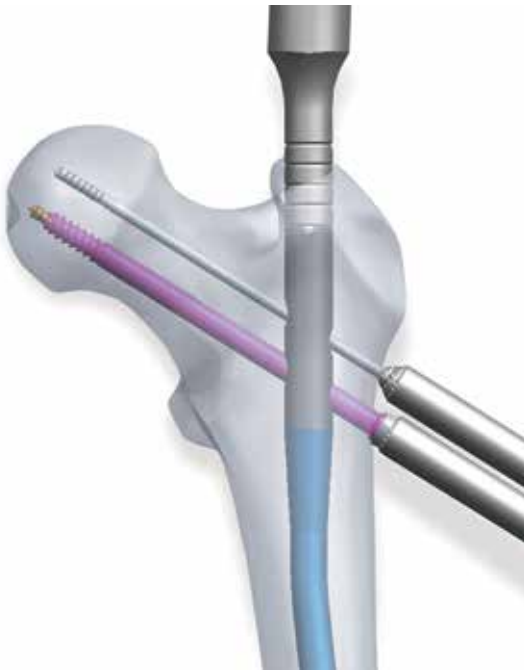
Surgical Technique (Continued)

After establishing accurate wire placement, the Dual Recon Wire Gauge (Catalog #14-442062) is used to measure the proper 6mm cannulated screw length. The wire gauge is intended to measure each individual wire separately. The GOLD markings indicated on the wire gauge are used to measure the GOLD 3.2mm x 460mm COCR Threaded Tip Guide Wire (Catalog #14-441054). The SILVER markings indicated on the wire gauge are used to measure the SILVER 3.2mm x 560mm COCR Threaded Tip Guide Wire (Catalog #14-441053). For accurate screw length readings, the sleeve assembly must be firmly against the lateral femoral cortex. After determining the screw length, remove the wire gauge and Recon 3.2mm Guide Wire Sleeve.



Insert the Recon Inserter Connector (Catalog #14-442051) through the cannula of the T-Handle and connect the 7mm Hex Recon Inserter (Catalog #14-442050). Retain the screw to the threaded hex tip of the Inserter Connector by turning the knob in a clockwise fashion. Insert the screw through the Soft Tissue Guide and advance into subchondral bone of the femoral head. Repeat insertion of second 6mm screw.

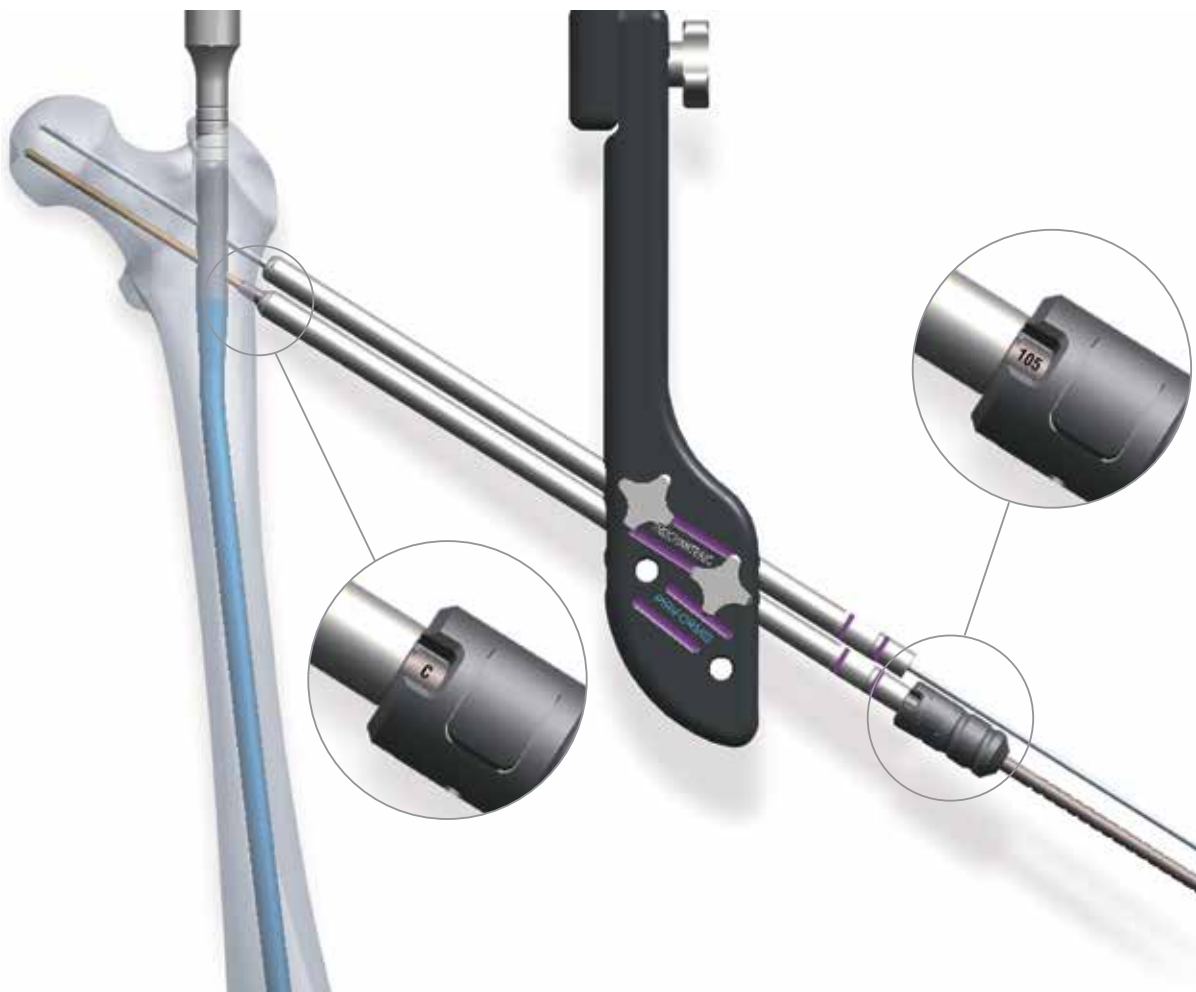
The 6mm cannulated screws have self-drilling and self-tapping features that allow for insertion into subchondral bone of the femoral head directly over the guide wire with the 7mm Hex Recon Inserter.



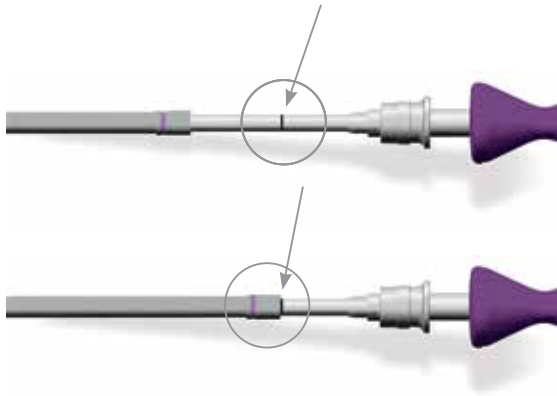
Surgical Technique (Continued)

In preparation for screw insertion in hard bone, a 6mm x 489mm Cannulated Tapered Recon Drill - Catalog #14-442023 (used over the guide wire) or a 6mm x 489mm Solid Recon Drill - Catalog #14-442083 (guide wire must be removed prior to use) can be used in both instances to either penetrate the lateral cortex or advance into subchondral bone of the femoral head. The Recon Drill Stop (Catalog #14-442057) can be attached to either drill and set to "C" for penetrating the lateral cortex or set directly to the screw length. Use radiographic imaging to protect against femoral head perforation.

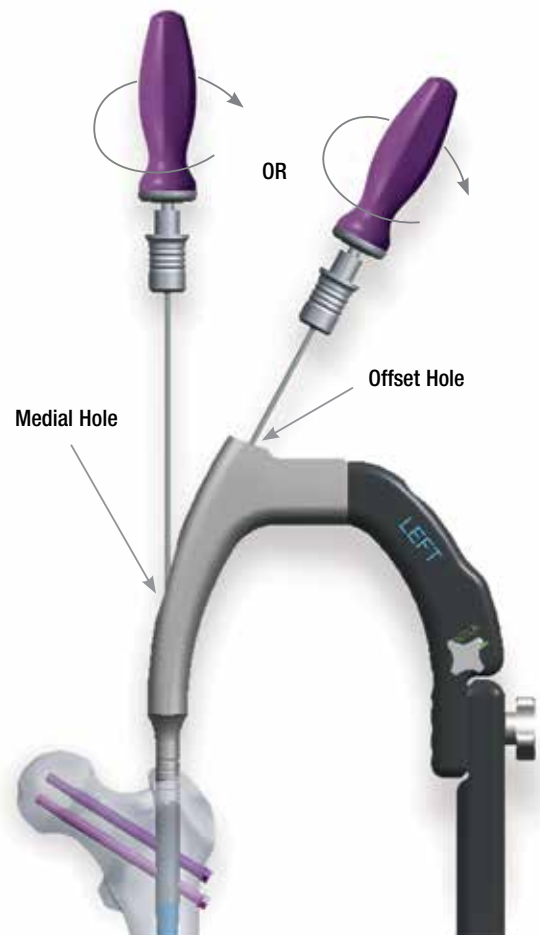
NOTE: When using the Recon Drill Stop, the 3.2mm Guide Wire Sleeves must be removed to allow penetration of lateral cortex.



The line mark on the 7mm Hex Recon Inserter indicates when the screw head is fully seated (Ensure the Soft Tissue Sleeve is firmly against bone).



Once reconstructive screw insertion is complete, if fixed angled locked screws are desired, attach the Torque Limiting Handle (Catalog #27923) to the 4mm Setscrew Driver Shaft (Catalog #14-442005) and insert through the medial hole or offset hole of the Nail Driver into the proximal aspect of the nail. Turn the handle in a clockwise motion – until it clicks – to engage the preassembled, embedded setscrew/locking mechanism to the recon screws. When complete, remove the setscrew driver and disengage the Nail Driver from the nail with the 7mm Connecting Bolt Driver.



Surgical Technique (Continued)

Distal Locking

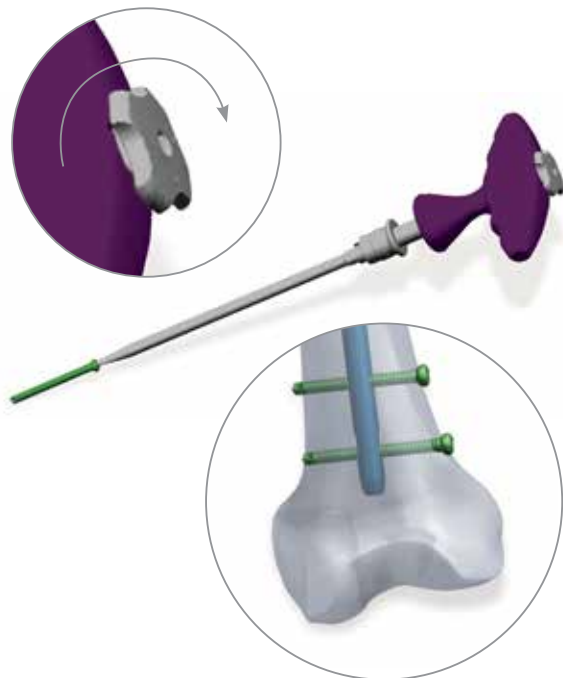
Distal locking is accomplished by using a free-hand technique or using the Biomet Radiolucent Targeting Device. For free-hand technique, align the C-Arm with the desired locking hole in the nail, such that the hole appears a perfect circle. A knife blade is placed on the skin, with the incision point verified with radiographic image and a 1cm incision is made over the hole in the nail.



The tip of the 4.5mm Crowe Point Twist Drill (Catalog #14-442095) appears as a solid circle in the center of the screw hole. Proceed to drill both cortices. The position of the drill bit is confirmed with radiographic image in both the AP and ML planes. To determine the length of the screw, overlay the drill bit with the 4.5mm Drill Measuring Sleeve (Catalog #14-442096) and read the screw measurement at the end of the drill bit.

Attach the 3.5mm Inserter Connector, Short (Catalog #14-441045) through the cannula of either the Straight or T-Handle and connect the 3.5mm Inserter, Short (Catalog #14-441046). Retain the screw to the threaded hex tip of the Inserter Connector by turning the knob in a clockwise fashion. Insert the screw into bone and repeat the locking procedure to insert the second screw if desired.

NOTE: For final tightening 5.0mm screws, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.



End Cap Insertion

If desired, one of five different profile end caps ranging from 0mm to 20mm (available in 5mm increments) can be inserted into the proximal end the Phoenix™ Antegrade Femoral Nail to prevent bony in-growth. Retain the end cap to the 3.5mm Inserter Connector assembly and insert into the proximal end of the nail.



NOTE: For final tightening end caps, the 3.5mm Solid Inserter-Long (Catalog #14-441051) or the 3.5mm Solid Inserter-Short (Catalog #14-441052) should be used.

Surgical Technique (Continued)

Nail Removal

Remove the end cap if implanted and all but one of the locking screws with the 3.5mm Inserter Connector. Leaving one screw in the nail helps prevent nail rotation when connecting the nail extractor to the nail. Alternatively, if all screws have been removed, the appropriate Drill Bit can be placed through any of the removed screw holes if rotation of the nail occurs during connection of the nail extractor. The 3.5mm Hex Screw Extractor (Catalog #14-442084) may be used to remove 5mm screws.

The 6mm reconstructive screws can be removed with the 7mm Hex Inserter and Recon Inserter Connector with the T-Handle. If needed, a Threaded Tip Guide Wire can be inserted into the 6mm screw and the 7mm Hex Inserter assembly may be passed over the wire to facilitate screw removal. Alternatively, a 1.6mm Trocar Point Wire (Catalog #35-351566) can be inserted into the 6mm screw and the Recon Screw Extractor (Catalog #14-442099) can be used in reverse motion to remove the 6mm screws. Also, a 5mm hex driver (not included) can be used to remove the 6mm screws.

Insert a Threaded Tip Guide Wire into the end of the nail to help guide the extractor to the proximal portion of the nail. Attach the 3/4" Driver (Catalog #14-442066) to the Modular T-Handle (Catalog #29407). Attach the driver assembly to the Nail Extractor Tap (Catalog #14-441048) and thread the assembly into the nail. A tight interference fit should be achieved. The extractor is meant to cross-thread into the proximal portion of the nail. Thread the Slap Hammer Shaft (Catalog #29448) into the Nail Extractor Tap and remove the remaining screw or drill bit. Extract the nail with a backslapping motion using the Slotted Mallet.

NOTE: Proximal screw removal can be achieved without disengaging the embedded setscrew.



Product Ordering Information

Trochanteric Entry Nails

Catalog#	Description
14-443128	Fem Nail Troch Left, 9.0mm x 280mm
14-443130	Fem Nail Troch Left, 9.0mm x 300mm
14-443132	Fem Nail Troch Left, 9.0mm x 320mm
14-443134	Fem Nail Troch Left, 9.0mm x 340mm
14-443136	Fem Nail Troch Left, 9.0mm x 360mm
14-443138	Fem Nail Troch Left, 9.0mm x 380mm
14-443140	Fem Nail Troch Left, 9.0mm x 400mm
14-443142	Fem Nail Troch Left, 9.0mm x 420mm
14-443144	Fem Nail Troch Left, 9.0mm x 440mm
14-443146	Fem Nail Troch Left, 9.0mm x 460mm
14-443330	Fem Nail Troch Left, 10.5mm x 300mm
14-443332	Fem Nail Troch Left, 10.5mm x 320mm
14-443334	Fem Nail Troch Left, 10.5mm x 340mm
14-443336	Fem Nail Troch Left, 10.5mm x 360mm
14-443338	Fem Nail Troch Left, 10.5mm x 380mm
14-443340	Fem Nail Troch Left, 10.5mm x 400mm
14-443342	Fem Nail Troch Left, 10.5mm x 420mm
14-443344	Fem Nail Troch Left, 10.5mm x 440mm
14-443346	Fem Nail Troch Left, 10.5mm x 460mm
14-443348	Fem Nail Troch Left, 10.5mm x 480mm
14-443530	Fem Nail Troch Left, 12mm x 300mm
14-443532	Fem Nail Troch Left, 12mm x 320mm
14-443534	Fem Nail Troch Left, 12mm x 340mm
14-443536	Fem Nail Troch Left, 12mm x 360mm
14-443538	Fem Nail Troch Left, 12mm x 380mm
14-443540	Fem Nail Troch Left, 12mm x 400mm
14-443542	Fem Nail Troch Left, 12mm x 420mm
14-443544	Fem Nail Troch Left, 12mm x 440mm
14-443546	Fem Nail Troch Left, 12mm x 460mm
14-443548	Fem Nail Troch Left, 12mm x 480mm

Catalog#	Description
14-443730	Fem Nail Troch Left, 13.5mm x 300mm
14-443732	Fem Nail Troch Left, 13.5mm x 320mm
14-443734	Fem Nail Troch Left, 13.5mm x 340mm
14-443736	Fem Nail Troch Left, 13.5mm x 360mm
14-443738	Fem Nail Troch Left, 13.5mm x 380mm
14-443740	Fem Nail Troch Left, 13.5mm x 400mm
14-443742	Fem Nail Troch Left, 13.5mm x 420mm
14-443744	Fem Nail Troch Left, 13.5mm x 440mm
14-443746	Fem Nail Troch Left, 13.5mm x 460mm
14-443748	Fem Nail Troch Left, 13.5mm x 480mm
14-443930	Fem Nail Troch Left, 15mm x 300mm
14-443932	Fem Nail Troch Left, 15mm x 320mm
14-443934	Fem Nail Troch Left, 15mm x 340mm
14-443936	Fem Nail Troch Left, 15mm x 360mm
14-443938	Fem Nail Troch Left, 15mm x 380mm
14-443940	Fem Nail Troch Left, 15mm x 400mm
14-443942	Fem Nail Troch Left, 15mm x 420mm
14-443944	Fem Nail Troch Left, 15mm x 440mm
14-443946	Fem Nail Troch Left, 15mm x 460mm
14-443948	Fem Nail Troch Left, 15mm x 480mm

Product Ordering Information (Continued)

Trochanteric Entry Nails (Continued)

Catalog#	Description
14-443228	Fem Nail Troch Right, 9.0mm x 280mm
14-443230	Fem Nail Troch Right, 9.0mm x 300mm
14-443232	Fem Nail Troch Right, 9.0mm x 320mm
14-443234	Fem Nail Troch Right, 9.0mm x 340mm
14-443236	Fem Nail Troch Right, 9.0mm x 360mm
14-443238	Fem Nail Troch Right, 9.0mm x 380mm
14-443240	Fem Nail Troch Right, 9.0mm x 400mm
14-443242	Fem Nail Troch Right, 9.0mm x 420mm
14-443244	Fem Nail Troch Right, 9.0mm x 440mm
14-443246	Fem Nail Troch Right, 9.0mm x 460mm
14-443430	Fem Nail Troch Right, 10.5mm x 300mm
14-443432	Fem Nail Troch Right, 10.5mm x 320mm
14-443434	Fem Nail Troch Right, 10.5mm x 340mm
14-443436	Fem Nail Troch Right, 10.5mm x 360mm
14-443438	Fem Nail Troch Right, 10.5mm x 380mm
14-443440	Fem Nail Troch Right, 10.5mm x 400mm
14-443442	Fem Nail Troch Right, 10.5mm x 420mm
14-443444	Fem Nail Troch Right, 10.5mm x 440mm
14-443446	Fem Nail Troch Right, 10.5mm x 460mm
14-443448	Fem Nail Troch Right, 10.5mm x 480mm
14-443630	Fem Nail Troch Right, 12mm x 300mm
14-443632	Fem Nail Troch Right, 12mm x 320mm
14-443634	Fem Nail Troch Right, 12mm x 340mm
14-443636	Fem Nail Troch Right, 12mm x 360mm
14-443638	Fem Nail Troch Right, 12mm x 380mm
14-443640	Fem Nail Troch Right, 12mm x 400mm
14-443642	Fem Nail Troch Right, 12mm x 420mm
14-443644	Fem Nail Troch Right, 12mm x 440mm
14-443646	Fem Nail Troch Right, 12mm x 460mm
14-443648	Fem Nail Troch Right, 12mm x 480mm

Catalog#	Description
14-443830	Fem Nail Troch Right, 13.5mm x 300mm
14-443832	Fem Nail Troch Right, 13.5mm x 320mm
14-443834	Fem Nail Troch Right, 13.5mm x 340mm
14-443836	Fem Nail Troch Right, 13.5mm x 360mm
14-443838	Fem Nail Troch Right, 13.5mm x 380mm
14-443840	Fem Nail Troch Right, 13.5mm x 400mm
14-443842	Fem Nail Troch Right, 13.5mm x 420mm
14-443844	Fem Nail Troch Right, 13.5mm x 440mm
14-443846	Fem Nail Troch Right, 13.5mm x 460mm
14-443848	Fem Nail Troch Right, 13.5mm x 480mm
14-443030	Fem Nail Troch Right, 15mm x 300mm
14-443032	Fem Nail Troch Right, 15mm x 320mm
14-443034	Fem Nail Troch Right, 15mm x 340mm
14-443036	Fem Nail Troch Right, 15mm x 360mm
14-443038	Fem Nail Troch Right, 15mm x 380mm
14-443040	Fem Nail Troch Right, 15mm x 400mm
14-443042	Fem Nail Troch Right, 15mm x 420mm
14-443044	Fem Nail Troch Right, 15mm x 440mm
14-443046	Fem Nail Troch Right, 15mm x 460mm
14-443048	Fem Nail Troch Right, 15mm x 480mm

Piriformis Fossa Entry Nails

Catalog#	Description
14-442128	Fem Nail PF Left, 9.0mm x 280mm
14-442130	Fem Nail PF Left, 9.0mm x 300mm
14-442132	Fem Nail PF Left, 9.0mm x 320mm
14-442134	Fem Nail PF Left, 9.0mm x 340mm
14-442136	Fem Nail PF Left, 9.0mm x 360mm
14-442138	Fem Nail PF Left, 9.0mm x 380mm
14-442140	Fem Nail PF Left, 9.0mm x 400mm
14-442142	Fem Nail PF Left, 9.0mm x 420mm
14-442144	Fem Nail PF Left, 9.0mm x 440mm
14-442146	Fem Nail PF Left, 9.0mm x 460mm
14-442330	Fem Nail PF Left, 10.5mm x 300mm
14-442332	Fem Nail PF Left, 10.5mm x 320mm
14-442334	Fem Nail PF Left, 10.5mm x 340mm
14-442336	Fem Nail PF Left, 10.5mm x 360mm
14-442338	Fem Nail PF Left, 10.5mm x 380mm
14-442340	Fem Nail PF Left, 10.5mm x 400mm
14-442342	Fem Nail PF Left, 10.5mm x 420mm
14-442344	Fem Nail PF Left, 10.5mm x 440mm
14-442346	Fem Nail PF Left, 10.5mm x 460mm
14-442348	Fem Nail PF Left, 10.5mm x 480mm
14-442530	Fem Nail PF Left, 12mm x 300mm
14-442532	Fem Nail PF Left, 12mm x 320mm
14-442534	Fem Nail PF Left, 12mm x 340mm
14-442536	Fem Nail PF Left, 12mm x 360mm
14-442538	Fem Nail PF Left, 12mm x 380mm
14-442540	Fem Nail PF Left, 12mm x 400mm
14-442542	Fem Nail PF Left, 12mm x 420mm
14-442544	Fem Nail PF Left, 12mm x 440mm
14-442546	Fem Nail PF Left, 12mm x 460mm
14-442548	Fem Nail PF Left, 12mm x 480mm

Catalog#	Description
14-442730	Fem Nail PF Left, 13.5mm x 300mm
14-442732	Fem Nail PF Left, 13.5mm x 320mm
14-442734	Fem Nail PF Left, 13.5mm x 340mm
14-442736	Fem Nail PF Left, 13.5mm x 360mm
14-442738	Fem Nail PF Left, 13.5mm x 380mm
14-442740	Fem Nail PF Left, 13.5mm x 400mm
14-442742	Fem Nail PF Left, 13.5mm x 420mm
14-442744	Fem Nail PF Left, 13.5mm x 440mm
14-442746	Fem Nail PF Left, 13.5mm x 460mm
14-442748	Fem Nail PF Left, 13.5mm x 480mm
14-442930	Fem Nail PF Left, 15mm x 300mm
14-442932	Fem Nail PF Left, 15mm x 320mm
14-442934	Fem Nail PF Left, 15mm x 340mm
14-442936	Fem Nail PF Left, 15mm x 360mm
14-442938	Fem Nail PF Left, 15mm x 380mm
14-442940	Fem Nail PF Left, 15mm x 400mm
14-442942	Fem Nail PF Left, 15mm x 420mm
14-442944	Fem Nail PF Left, 15mm x 440mm
14-442946	Fem Nail PF Left, 15mm x 460mm
14-442948	Fem Nail PF Left, 15mm x 480mm

Product Ordering Information (Continued)

Piriformis Fossa Entry Nails (Continued)

Catalog#	Description
14-442228	Fem Nail PF Right, 9.0mm x 280mm
14-442230	Fem Nail PF Right, 9.0mm x 300mm
14-442232	Fem Nail PF Right, 9.0mm x 320mm
14-442234	Fem Nail PF Right, 9.0mm x 340mm
14-442236	Fem Nail PF Right, 9.0mm x 360mm
14-442238	Fem Nail PF Right, 9.0mm x 380mm
14-442240	Fem Nail PF Right, 9.0mm x 400mm
14-442242	Fem Nail PF Right, 9.0mm x 420mm
14-442244	Fem Nail PF Right, 9.0mm x 440mm
14-442246	Fem Nail PF Right, 9.0mm x 460mm
14-442430	Fem Nail PF Right, 10.5mm x 300mm
14-442432	Fem Nail PF Right, 10.5mm x 320mm
14-442434	Fem Nail PF Right, 10.5mm x 340mm
14-442436	Fem Nail PF Right, 10.5mm x 360mm
14-442438	Fem Nail PF Right, 10.5mm x 380mm
14-442440	Fem Nail PF Right, 10.5mm x 400mm
14-442442	Fem Nail PF Right, 10.5mm x 420mm
14-442444	Fem Nail PF Right, 10.5mm x 440mm
14-442446	Fem Nail PF Right, 10.5mm x 460mm
14-442448	Fem Nail PF Right, 10.5mm x 480mm
14-442630	Fem Nail PF Right, 12mm x 300mm
14-442632	Fem Nail PF Right, 12mm x 320mm
14-442634	Fem Nail PF Right, 12mm x 340mm
14-442636	Fem Nail PF Right, 12mm x 360mm
14-442638	Fem Nail PF Right, 12mm x 380mm
14-442640	Fem Nail PF Right, 12mm x 400mm
14-442642	Fem Nail PF Right, 12mm x 420mm
14-442644	Fem Nail PF Right, 12mm x 440mm
14-442646	Fem Nail PF Right, 12mm x 460mm
14-442648	Fem Nail PF Right, 12mm x 480mm

Catalog#	Description
14-442830	Fem Nail PF Right, 13.5mm x 300mm
14-442832	Fem Nail PF Right, 13.5mm x 320mm
14-442834	Fem Nail PF Right, 13.5mm x 340mm
14-442836	Fem Nail PF Right, 13.5mm x 360mm
14-442838	Fem Nail PF Right, 13.5mm x 380mm
14-442840	Fem Nail PF Right, 13.5mm x 400mm
14-442842	Fem Nail PF Right, 13.5mm x 420mm
14-442844	Fem Nail PF Right, 13.5mm x 440mm
14-442846	Fem Nail PF Right, 13.5mm x 460mm
14-442848	Fem Nail PF Right, 13.5mm x 480mm
14-442030	Fem Nail PF Right, 15mm x 300mm
14-442032	Fem Nail PF Right, 15mm x 320mm
14-442034	Fem Nail PF Right, 15mm x 340mm
14-442036	Fem Nail PF Right, 15mm x 360mm
14-442038	Fem Nail PF Right, 15mm x 380mm
14-442040	Fem Nail PF Right, 15mm x 400mm
14-442042	Fem Nail PF Right, 15mm x 420mm
14-442044	Fem Nail PF Right, 15mm x 440mm
14-442046	Fem Nail PF Right, 15mm x 460mm
14-442048	Fem Nail PF Right, 15mm x 480mm

5mm Double Lead Thread Screws

Catalog#	Description
14-405020	5mm x 20mm Screw
14-405022	5mm x 22mm Screw
14-405024	5mm x 24mm Screw
14-405026	5mm x 26mm Screw
14-405028	5mm x 28mm Screw
14-405030	5mm x 30mm Screw
14-405032	5mm x 32mm Screw
14-405034	5mm x 34mm Screw
14-405036	5mm x 36mm Screw
14-405038	5mm x 38mm Screw
14-405040	5mm x 40mm Screw
14-405042	5mm x 42mm Screw
14-405044	5mm x 44mm Screw
14-405046	5mm x 46mm Screw
14-405048	5mm x 48mm Screw
14-405050	5mm x 50mm Screw
14-405052	5mm x 52mm Screw
14-405054	5mm x 54mm Screw
14-405056	5mm x 56mm Screw
14-405058	5mm x 58mm Screw
14-405060	5mm x 60mm Screw
14-405065	5mm x 65mm Screw
14-405070	5mm x 70mm Screw
14-405075	5mm x 75mm Screw
14-405080	5mm x 80mm Screw
14-405085	5mm x 85mm Screw
14-405090	5mm x 90mm Screw
14-405095	5mm x 95mm Screw
14-405100	5mm x 100mm Screw
14-405105	5mm x 105mm Screw
14-405110	5mm x 110mm Screw

6mm Cannulated Partially Threaded Reconstructive Screws

Catalog#	Description
14-406050	6mm x 50mm Cannulated Partial Thd Recon Screw
14-406055	6mm x 55mm Cannulated Partial Thd Recon Screw
14-406060	6mm x 60mm Cannulated Partial Thd Recon Screw
14-406065	6mm x 65mm Cannulated Partial Thd Recon Screw
14-406070	6mm x 70mm Cannulated Partial Thd Recon Screw
14-406075	6mm x 75mm Cannulated Partial Thd Recon Screw
14-406080	6mm x 80mm Cannulated Partial Thd Recon Screw
14-406085	6mm x 85mm Cannulated Partial Thd Recon Screw
14-406090	6mm x 90mm Cannulated Partial Thd Recon Screw
14-406095	6mm x 95mm Cannulated Partial Thd Recon Screw
14-406100	6mm x 100mm Cannulated Partial Thd Recon Screw
14-406105	6mm x 105mm Cannulated Partial Thd Recon Screw
14-406110	6mm x 110mm Cannulated Partial Thd Recon Screw
14-406115	6mm x 115mm Cannulated Partial Thd Recon Screw
14-406120	6mm x 120mm Cannulated Partial Thd Recon Screw
14-406125	6mm x 125mm Cannulated Partial Thd Recon Screw
14-406130	6mm x 130mm Cannulated Partial Thd Recon Screw

End Caps

Catalog#	Description
14-444180	0mm Offset End Cap, Low Profile
14-444181	12mm x 5mm Offset End Cap, Low Profile
14-444182	12mm x 10mm Offset End Cap, Low Profile
14-444183	12mm x 15mm Offset End Cap, Low Profile
14-444184	12mm x 20mm Offset End Cap, Low Profile
14-444191	13.5mm x 5mm Offset End Cap
14-444192	13.5mm x 10mm Offset End Cap
14-444193	13.5mm x 15mm Offset End Cap
14-444194	13.5mm x 20mm Offset End Cap
14-444195	15mm x 5mm Offset End Cap
14-444196	15mm x 10mm Offset End Cap
14-444197	15mm x 15mm Offset End Cap
14-444198	15mm x 20mm Offset End Cap

Product Ordering Information (Continued)

Disposables

Catalog #	Description
27922	3.0mm x 98mm Bead Tip Guide Wire
27961	4.3mm x 365mm Calibrated Drill
14-441053	3.2mm x 560mm COCR Thd Tip
14-441054	3.2mm x 460mm COCR Thd Tip
14-442002	12.2mm One-Step Reamer
14-442023	6.0mm x 489mm Cannulated Recon Drill
14-442083	6.0mm x 489mm Solid Recon Drill
14-442095	4.5mm Crowe Point Twist Drill
35-351566	1.6mm Trocar Point Wire, Both Ends

Instrumentation

Catalog #	Description
27923	Torque Limiting Handle
27939	NiTi Reamer Extension
27940	52cm Reamer Shaft
27977	Stryker/AO Power Adapter
29407	Modular T-Handle, Non-Ratcheting
29408	Modular Straight Handle, Ratcheting
29448	Slap Hammer Shaft
41023	Thumb Screw
41027	Wire Pusher
467534	8.0mm Reamer Head
467536	8.5mm Reamer Head
467538	9.0mm Reamer Head
467540	9.5mm Reamer Head
467542	10.0mm Reamer Head
467544	10.5mm Reamer Head
467546	11.0mm Reamer Head
467548	11.5mm Reamer Head
467550	12.0mm Reamer Head
467552	12.5mm Reamer Head

Instrumentation (Continued)

Catalog #	Description
467554	13.0mm Reamer Head
467556	13.5mm Reamer Head
467558	14.0mm Reamer Head
467560	14.5mm Reamer Head
467562	15mm Reamer Head
467564	15.5mm Reamer Head
467566	16mm Reamer Head
14-440067	98cm Nail Measuring Gage
14-441043	3.5mm Inserter Connector, Long
14-441044	3.5mm Inserter, Long
14-441045	3.5mm Inserter Connector, Short
14-441046	3.5mm Inserter, Short
14-441048	Nail Extractor Tap*
14-441051	3.5mm Solid Inserter Long
14-441052	3.5mm Solid Inserter Short
14-442000	Antegrade Femoral Nail Tray (Fully Kitted)
14-442001	Antegrade Femoral Nail Instrument Tray (Empty)
14-442003	Curved Cannulated Awl 12.2mm
14-442005	4mm Setscrew Driver Shaft
14-442008	Recon Soft Tissue Sleeve
14-442009	Recon 6.0mm Drill Sleeve
14-442010	Recon 3.2mm Guide Wire Sleeve
14-442011	Recon 3.2mm Trocar
14-442012	Interlock Soft Tissue Sleeve
14-442013	Interlock 4.3mm Drill Sleeve
14-442014	4.3mm Trocar Interlock Femoral
14-442015	Working Channel Soft Tissue Sleeve - 16mm

*Available sterile packed

Instrumentation (Continued)

Catalog #	Description
14-442016	Working Channel Trocar
14-442017	Antegrade Femoral Nail Driver
14-442018	Antegrade Femoral Recon Targeting Arm
14-442050	7mm Hex Recon Inserter
14-442051	Recon Inserter Connector
14-442053	Slotted Mallet
14-442055	Slap Hammer Adapter
14-442056	Sleeve Locking Setscrew
14-442057	Recon Drill Stop
14-442062	Dual Recon Wire Gauge
14-442066	3/4" Hex Driver
14-442068	8.5mm Fracture Reducer Bowed
14-442073	Pseudarthrosis Pin Straight
14-442074	Pseudarthrosis Pin Curved
14-442075	Medullary Canal And Length Estimator
14-442077	6mm Recon Screw Tap
14-442078	Keyless Chuck T-Handle
14-442081	Screw Depth Gauge (Extra Long)
14-442084	3.5mm Hex Screw Extractor*
14-442089	Hall/Stryker Power Adapter
14-442090	Recon Target Wire Adapter
14-442091	7mm Connecting Bolt Driver
14-442093	Antegrade Femoral Connecting Bolt
14-442096	4.5mm Drill Measuring Sleeve
14-442099	Recon Screw Extractor*

*Available sterile packed

Further Information

This brochure describes the surgical technique used by Michael S. Sirkin, M.D., Cory A. Collinge, M.D. and Kenneth J. Koval, M.D. Biomet Trauma, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

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Warsaw, IN 46581-0587
800.348.9500 x 1501
www.biomettrauma.com

DESCRIPTION

Biomet® manufactures a variety of titanium intramedullary nails intended to aid in the alignment and stabilization of fractures of bones in the skeletal system, in the skeletal system, and to aid in reconstructive surgery. Implant components used for these applications include: intramedullary nails, screws, and end caps. Osseotite screws may also be used with the Peritrochanteric Nail System.

MATERIALS

Titanium Alloy

UHMWPE

INDICATIONS

Phoenix Femoral Nail System

These devices are to be implanted into the femur for alignment, stabilization and fixation of fractures caused by trauma or disease, and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity, and for arthrodesis.

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS

Internal fixation devices aid the surgeon in the alignment and stabilization of skeletal fractures and provide a means of fracture management in reconstructive surgical applications. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Metallic bone fixation devices are internal splints that align the fracture until normal healing occurs.

The size and shape of bones and soft tissue place limitations on the size and strength of implants. If there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing, the implant could eventually break. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants. Bone screws, 3mm – 10mm in diameter and 10mm – 75mm in overall length are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

1. Correct selection of the implant is extremely important.

The potential for success in fracture fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing, or load bearing.

2. The devices can break when subjected to increased loading associated with nonunion or delayed union. Internal fixation devices are load-sharing devices that hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant can be expected to break, bend or fail. Loads produced by weight bearing, and activity levels may dictate the longevity of the implant.

3. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in

contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.

4. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.

5. Remove after fracture has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of, refracture in an active patient. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture should follow implant removal.

6. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instruction is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, and drug abuse may be at higher risk. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

7. Nails with a diameter of 9mm or less are intended for use in pediatric patients. Do not use these sizes in teenage or adult patients. The size and strength of these nails is inadequate for loads experienced with teenage or adult

patients. Laboratory testing demonstrates that 8mm and 9mm diameter nails have a fatigue life approximately one-fourth that of 12mm nails. Where possible, use 12mm or larger diameter nails. In cases where a small nail size was used, the surgeon may want to consider replacing the small nail with a larger nail after three months.

8. To reduce the driving force on the nail and the potential risk of nail damage, the physician should consider reaming 1/2mm to 1 1/2mm larger than the nail implanted.
9. Do not implant a nail with the distal holes or proximal holes at or within the fracture line. If nail is implanted with distal or proximal holes in the fracture line, effective screw fixation will be compromised which may lead to breakage or bending of the implant.
10. Difficult tibial fractures may take 8 to 12 months to heal. Treat with caution due to the extended healing time. When nonreaming techniques are used or when smaller diameter nails are used, the surgeon should consider one or more of the following treatments:
 - a) Graft the tibial fracture site at time of surgery.
 - b) Remove screws proximally or distally at 2 to 3 months.
 - c) Exchange the tibial nail for a larger diameter tibial nail at 3 to 4 months.
11. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

PRECAUTIONS

Device is single use only.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant.

Do not treat patients with implants that have been even momentarily placed in a different patient.

Instruments are available to aid in the accurate implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported.

Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture.

Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Limb shortening due to compression of the fracture or bone resorption.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensation due to the presence of the device.
8. Nerve damage due to surgical or preexisting trauma.
9. Necrosis of bone.
10. Postoperative bone fracture and pain.
11. Inadequate healing.
12. Early or late postoperative infection and allergic reaction.

MAGNETIC RESONANCE (MR) STATEMENT

The effects of the MR environment have not been determined for this device. This device has not been tested for heating or migration in the MR environment.

STERILITY

Biomet Intramedullary Nail implants are provided sterile and clearly marked "STERILE" on the packaging. These implants have been sterilized using a minimum dosage of 2.5 megaRad (25 kGy) of gamma radiation. Where specified, do not use implants after expiration date.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to
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