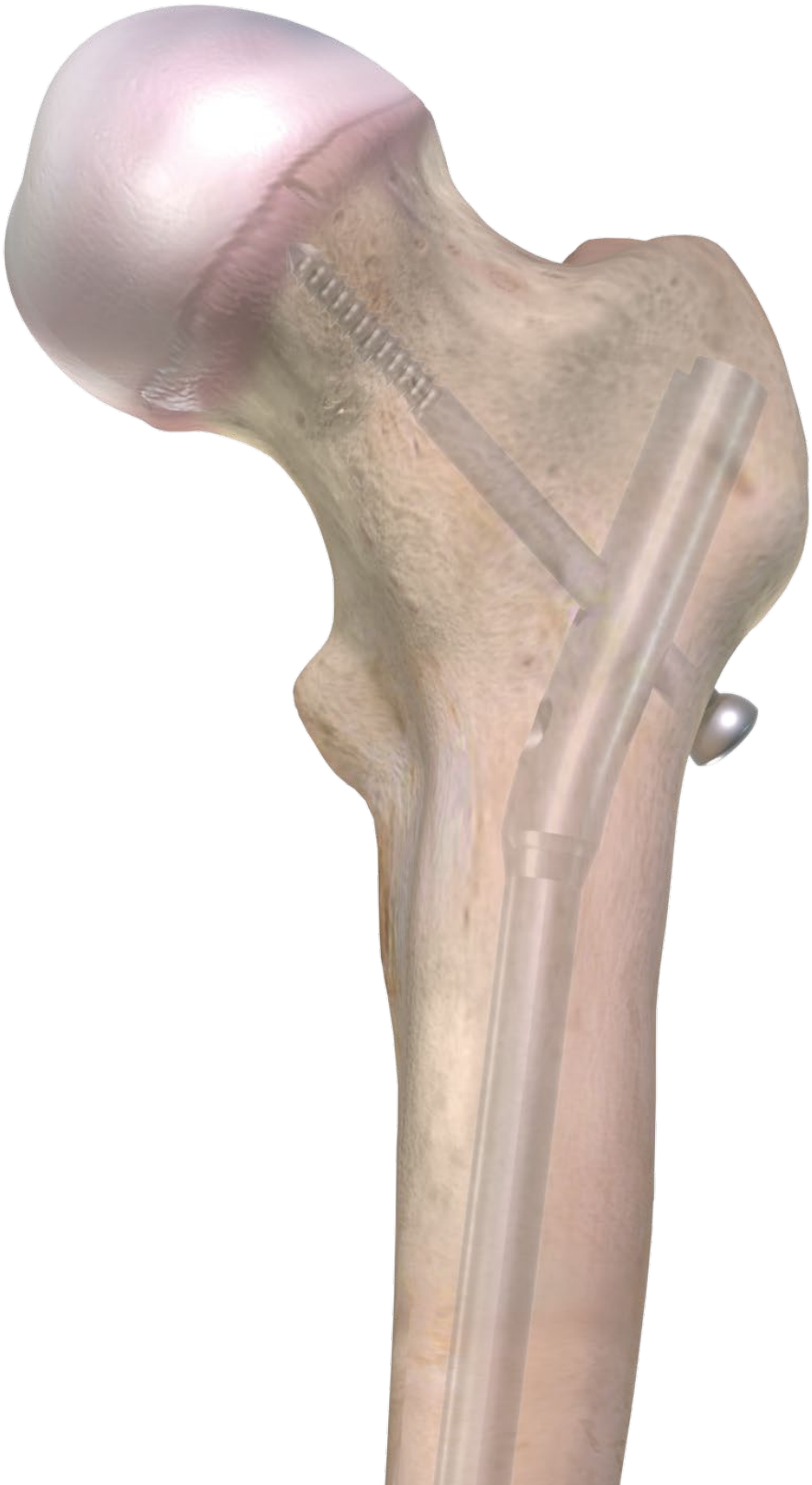
PediNail™ Pediatric Femoral Nail

SURGICAL TECHNIQUE



OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

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INDICATIONS

The OrthoPediatrics PediNail system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.

Additional indications include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; polytrauma and multiple fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; fixation of fractures that occur in and between the proximal and distal third of the long bones being treated. The OrthoPediatrics PediNail is for single use only.

When used in the European Union and the United Kingdom, the OrthoPediatrics PediNail Intramedullary Nailing System is indicated for rotational osteotomy for excessive femoral anteversion and femoral fractures in pediatric patients. The System implants are for single use only. The System is indicated for patients 8 years or older; however, should the clinical situation dictate, and provided the recommended technique is followed, the use of this implant in younger patients is at the discretion of the surgeon.

AVAILABLE OPTIONS

The OrthoPediatrics PediNail™ System is available in 7mm, 8mm, 9mm, and 10mm diameters and lengths from 20cm to 42cm depending on the nail diameter.

Screw interlocking options are available both proximally and distally.

Proximal Locking Options:

- The proximal locking options for the 7mm nail include a single 4.5mm screw placed from the greater trochanter to the lesser trochanter and a single 4.5mm reconstruction screw placed into the femoral neck.
- The proximal locking options for the 8mm nail include a single 4.5mm screw placed from the greater trochanter to the lesser trochanter and a single 4.5mm reconstruction screw placed into the femoral neck.
- The proximal locking options for the 9mm nail include a single 4.5mm screw placed from the greater trochanter to the lesser trochanter and a single 4.5mm reconstruction screw placed into the femoral neck. In addition, the proximal locking options for the 9mm nail include a single transverse 4.5mm screw distal to the greater/lesser and reconstruction screw.
- The proximal locking options for the 10mm nail include a single 4.5mm screw placed from the greater trochanter to the lesser trochanter and a single 4.5mm reconstruction screw placed into the femoral neck. In addition, the proximal locking options for the 10mm nail include a single transverse screw distal to the greater/lesser and reconstruction screw.

Distal Locking Options:

- The distal locking options for the 7mm nail include a single anterior to posterior 4.0mm locking screw and two lateral to medial 4.0mm locking screws.
- The distal locking options for the 8mm nail include a single anterior to posterior 4.5mm locking screw and two lateral to medial 4.5mm locking screws.
- The distal locking options for the 9mm nail include a single anterior to posterior 4.5mm locking screw and two lateral to medial 4.5mm locking screws.
- The distal locking options for the 10mm nail include a single anterior to posterior 4.5mm locking screw and two lateral to medial 4.5mm locking screws.

NOTE: The 4.0mm locking screw is only used for distal locking of the 7mm nail.

PREOPERATIVE PLANNING

Effective preoperative planning allows the surgeon to predict the impact of different interventions in order to perform the correction in the most accurate and safest manner. Optimal intramedullary nail fit, landmarking for entry point, entry angle, and assessment of alignment and rotation can be evaluated through preoperative radiographic analysis. Preoperative planning also allows the surgeon to have the appropriate implants available at the time of surgery.

The objectives of preoperative planning include:

- Determination of anticipated nail diameter and nail length.
- Establishment of appropriate anatomic landmarks, including the greater and lesser trochanters and physes.

The overall objective of preoperative planning is to enable the surgeon to gather anatomic parameters which will allow accurate intra-operative placement of the implant.

NAIL SIZE SELECTION

Choosing the appropriate nail diameter and length are crucial to a successful surgical procedure. When selecting the diameter of the intramedullary nail to be used, it is not necessary to fill the entire intramedullary canal to achieve a tight isthmic fit with the nail. Generally speaking, an 8mm diameter nail is sufficient for most children and adolescents. In smaller patients, a 7mm nail may be used, and in larger patients a 9mm or 10mm nail may be used.

> **NOTE:** The 7mm and 8mm nails do not allow for proximal transverse locking bolt fixation. This should be taken into consideration when preoperatively planning.

Choosing the length of the nail can be done intraoperatively using the nail measuring gauge. After passing the 2.7mm Ball Tipped Reaming Rod into the distal fragment, a direct measurement can be made with the Nail Measuring Guide.

Alternatively, use the OrthoPediatrics PediNail templates to estimate nail length and diameter. To estimate nail diameter, place the template on the AP or lateral x-ray of the femur and measure the diameter of the medullary canal at the isthmus.

To estimate nail length, place the template on the AP x-ray of the uninjured femur and select the appropriate nail length based on patient anatomy.

Additionally, the 2.7mm Ball Tipped Reaming Rod and the 2.0mm Guide Insertion Wire can be used to measure nail length, since they are equal in length (810mm). With either of the rods in place (gently seated in the distal femoral metaphysis), a measurement can be taken by placing the other rod adjacent to the rod inside the canal. Using a hemostat, clip the second rod (the one outside the femoral canal) at the end of the rod extending from the canal. Use the measuring gauge on the inside surface of the sterilization lid.

> **NOTE:** When selecting nail size, consider canal diameter, fracture pattern, patient anatomy and postoperative protocol.

Templates are available in 115% magnification in which the image is enlarged 15% to correspond to typical radiographic magnification; however, variations in magnification levels are common.

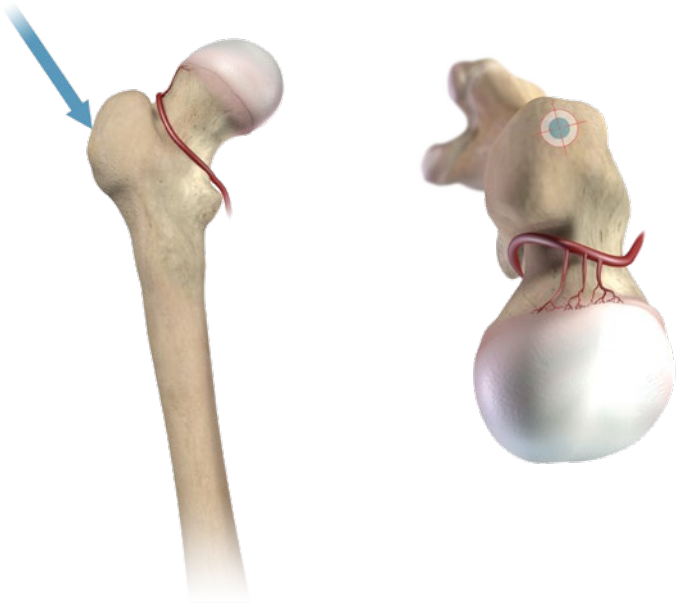


Figure 1: Entry point and entry angle

Entry Point and Entry Angle

The PediNail™ intramedullary nail system is designed for use with a lateral trochanteric entry point for two reasons:

- To avoid the piriformis fossa and subsequently the blood vessels of the medial circumflex artery supplying blood to the head of the femur, thus reducing the likelihood of iatrogenic femoral head avascular necrosis.
- To avoid tethering the trochanteric growth plate, decreasing the risk of femoral neck narrowing and hip valgus.

The 15° proximal bend allows the entry point to be approximately 1 finger breadth lateral to the tip of the greater trochanter. The entry angle is measured from the entry point to a point inferior to the lesser trochanter (Figure 1).

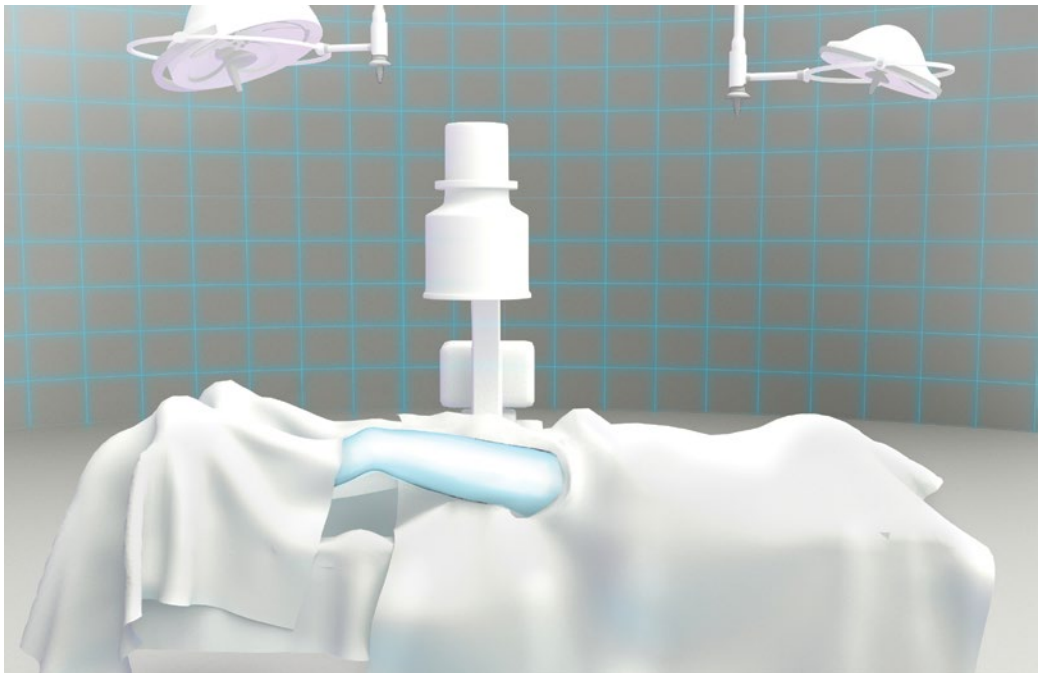


Figure 2: Patient positioning

Patient Positioning

First, place the patient on a fracture table in the supine position.

Apply traction to the affected limb using a well-padded boot. Slightly externally rotate the limb to match the proximal fragment which tends to externally rotate slightly when the patient is positioned on the fracture table. Prep and drape the lower extremity using split sheets to allow circumferential access to the thigh. Cover the image intensifier with a sterile drape to visualize the hip and femur (Figure 2).

The proximal femur can be best visualized by arcing the image intensifier so the beam is directed from posteromedial to anterolateral. This allows the surgeon to see the externally rotated proximal femur in a non-rotated AP projection.

NOTE: Alternatively, the patient may be positioned supine on a radiolucent table. The limb (or both limbs in the case of bilateral procedures) can be prepared and draped free. This facilitates simultaneous irrigation and debridement of open femur fractures, bilateral derotation osteotomy, or fixation of an ipsilateral tibial fracture.

In order to bring the fracture out to length, an assistant may be required to apply manual traction.

Approach

Place the 3.2mm Threaded Tipped Guide Wire percutaneously through the lateral aspect of the greater trochanter at a point approximately halfway between the tip of the trochanter and the trochanteric physis (Figure 3).

Drive the 3.2mm Threaded Tipped Guide Wire under power with a drill through the trochanteric physis and into the medullary canal up to, but not through, the medial aspect of the proximal femur at an angle inferior to the lesser trochanter.

The 3.2mm Threaded Tipped Guide Wire should be 1.0-1.5cm distal to the lesser trochanter at an angle of 10-15° from the femoral shaft axis.

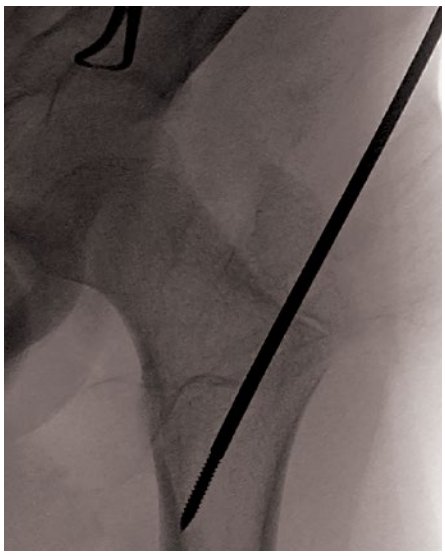


Figure 3: Insert Guide Wire into lateral aspect of greater trochanter

Check a lateral radiograph to insure that the 3.2mm Threaded Tipped Guide Wire is in the center of the femoral canal and is not inserted too shallow or too steep

> **NOTE:** Inspect pins and wires for any damage prior to use. Utilizing damaged instruments may adversely affect the outcome of the procedure.

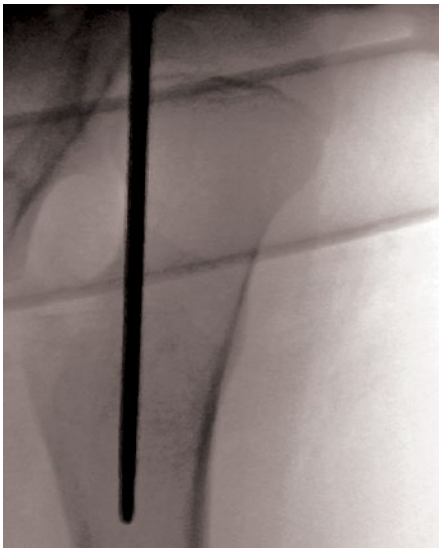


Figure 4: Lateral radiograph to ensure position in center of femoral canal

Approach (cont.)

Create a 1.5cm incision proximal to the 3.2mm Threaded Tipped Guide Wire entry site, passing the scalpel adjacent to the guide wire, down to the trochanter (Figure 5).

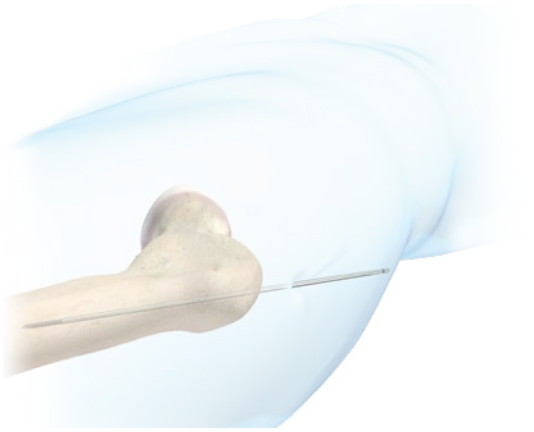


Figure 5: 1.5cm incision proximal to the 3.2mm Threaded Tipped Guide Wire entry site

Place either a 10mm or a 12mm Tissue Protector over the 3.2mm Threaded Tipped Guide Wire and into the soft tissue to protect the surrounding skin and soft tissue while using the opening reamer (Figure 6).

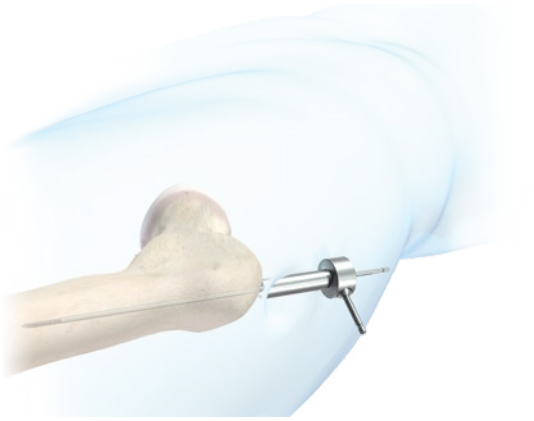


Figure 6: Place Tissue Protector over the 3.2mm Threaded Tipped Guide Wire and into soft tissue

Approach (cont.)

Advance the 9.5mm Cannulated Entry Reamer over the 3.2mm Threaded Tipped Guide Wire through the trochanter into the femoral canal (Figures 7-9).

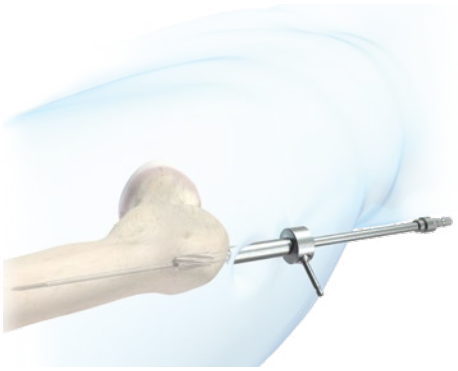


Figure 7: Advance 9.5mm Cannulated Entry Reamer over 3.2mm Threaded Tipped Guide Wire

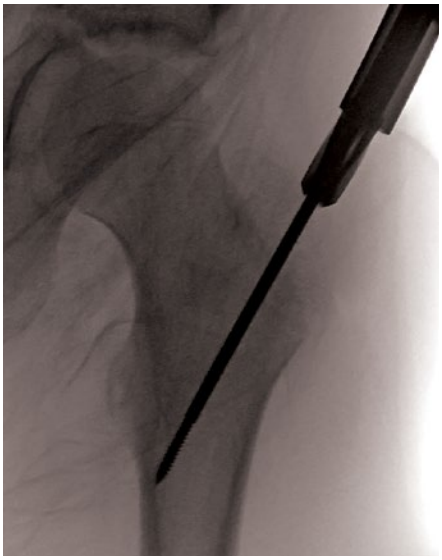


Figure 8: AP radiograph to confirm placement in femoral canal and starting point

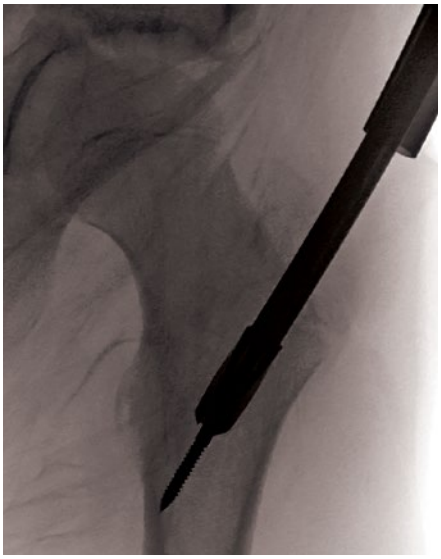


Figure 9: AP radiograph to check reamer

CAUTION: Do not advance the guide wire or entry reamer past the medial femoral cortex.

Approach (cont.)

Withdraw the 9.5mm Cannulated Entry Reamer, leaving the 3.2mm Threaded Tipped Guide Wire in place in the proximal femur (Figure 10).

NOTE: If the 3.2mm Threaded Tipped Guide Wire appears to be lodged in the 9.5mm Cannulated Entry Reamer, use the Obturator to ensure that the Guide Wire remains in place upon removal of the reamer.

NOTE: Refer to Section 3: Reaming Technique (Reamer Use Guidelines).

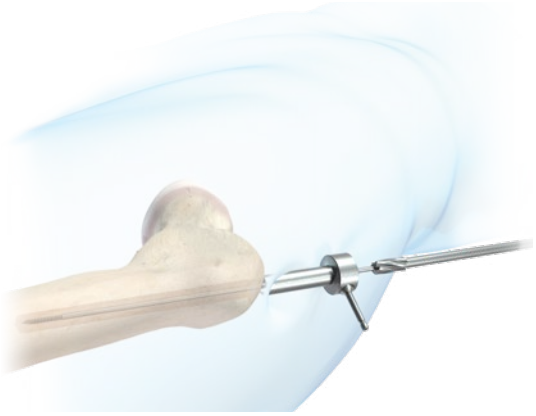


Figure 10: Withdraw 9.5mm Cannulated Entry Reamer

Approach (cont.)

Replace the 10 or 12mm Tissue Protector with the 7mm Exchange Tube (Figure 11).

Place the 7mm Exchange Tube into the femoral canal and withdraw the 3.2mm Threaded Tipped Guide Wire (Figures 12 & 13).

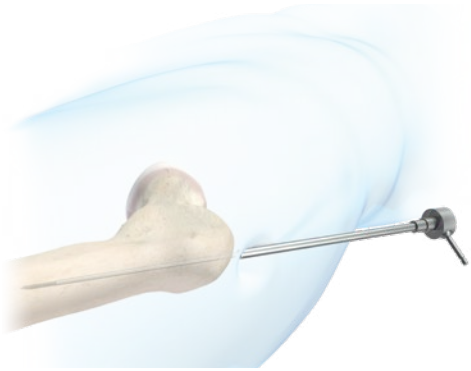


Figure 11: Replace Tissue Protector with 7mm Exchange Tube

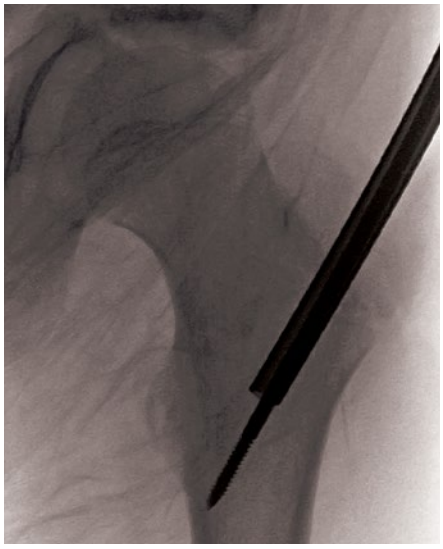


Figure 12: Verify placement of 7mm Exchange Tube

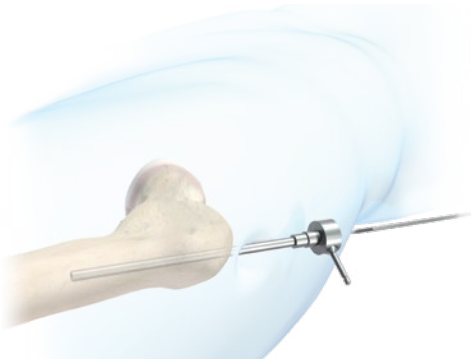


Figure 13: Leave Exchange Tube in place and withdraw the guide wire

Approach (cont.)

Leaving the 7mm Exchange Tube in place, insert the 2.7mm Ball Tipped Reaming Rod (Figure 14). Check placement on radiograph (Figure 15).

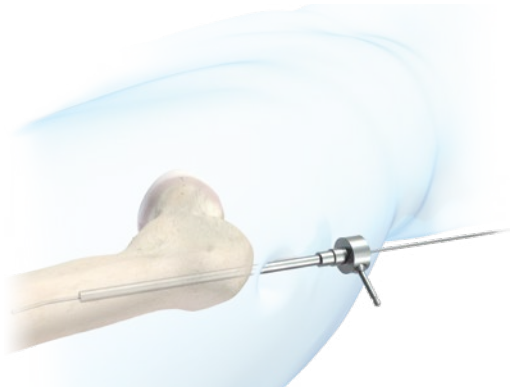


Figure 14: Insert 2.7mm Ball Tipped Reaming Rod

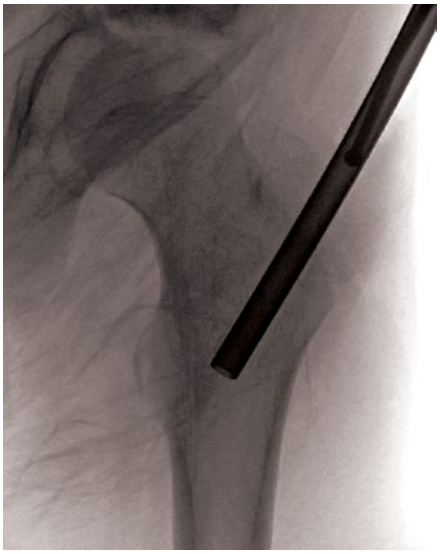


Figure 15: Check placement on radiograph

Approach (cont.)

Advance the 2.7mm Ball Tipped Reaming Rod to the femur to the level of the fracture (Figure 16). Using a radiograph, verify placement of the Ball Tipped Reaming Rod (Figures 17a & 17b).

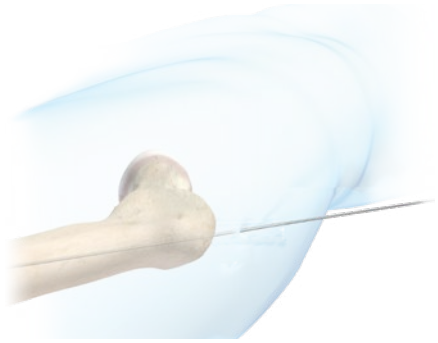


Figure 16: Pass 2.7mm Ball Tipped Reaming Rod to the level of the fracture

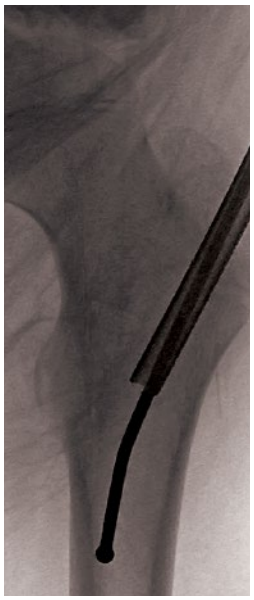


Figure 17a: Check for placement at the level of the fracture

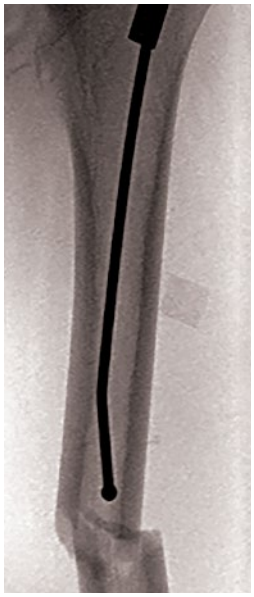


Figure 17b: Check for placement at the level of the fracture

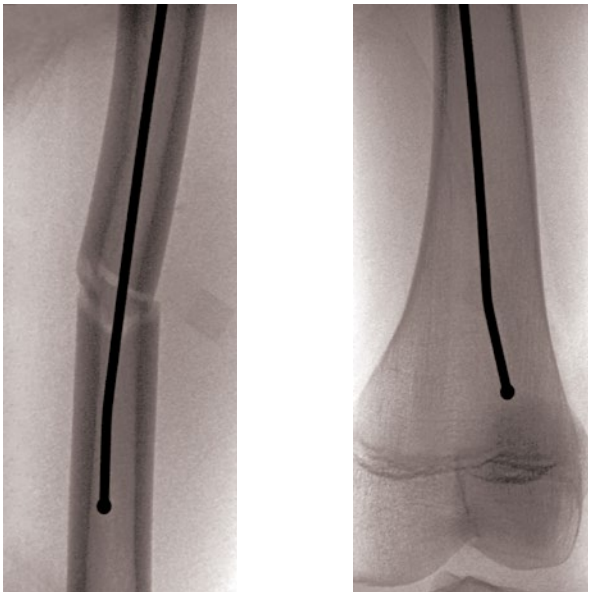
Approach (cont.)

Remove the 7mm Exchange Tube and reduce the fracture. If it is difficult to pass the 2.7mm Ball Tipped Reaming Rod across the fracture site, use the Reduction Tool to assist in passing the 2.7mm Ball Tipped Reaming Rod.

After the fracture is reduced, pass the 2.7mm Ball Tipped Reaming Rod into the distal femur and impact it into the lateral femoral metaphysis to a depth of approximately 1cm proximal to the distal femoral physis (Figures 18a & 18b).

NOTE: Verify placement using AP and ML fluoroscopy to ensure 2.7mm Ball Tipped Reaming Rod is in the distal fragment.

CAUTION: Do not advance 2.7mm Ball Tipped Reaming Rod into physis or joint space.



Figures 18a & 18b: Pass 2.7mm Ball Tipped Reaming Rod into the distal femur

Measuring

Prior to reaming, measure for the nail. When determining nail length, take care to accommodate for any distraction at the fracture site as well as the position of the 2.7mm Ball Tipped Reaming Rod or guide wire in the distal femur to avoid penetration of the distal femoral physis by the nail.

Place the Measurement Gauge over the 2.7mm Ball Tipped Reaming Rod (Figures 19 & 20).

> **NOTE:** It is advisable to verify nail length using a second measurement method (i.e. two equal length reaming rods or confirmation with nail scale, found on the inside of tray lid). If the guide wire is not visible in the window, the 42mm length nail should be selected.

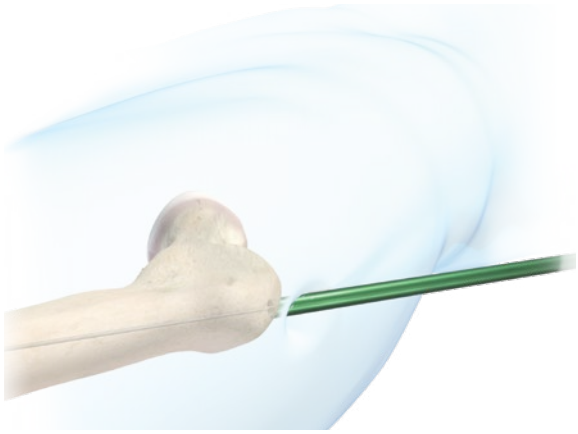


Figure 19: Place Measurement Guide over 2.7mm Ball Tipped Reaming Rod

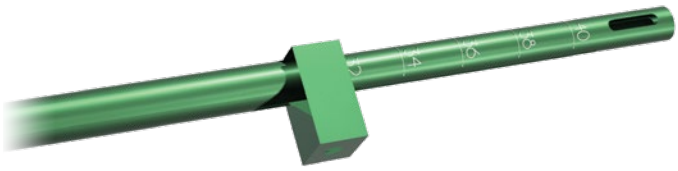


Figure 20: Measure for nail

Measuring (cont.)

Insert the Measurement Gauge into the reamed hole to the appropriate depth. Keep in mind that the nail will usually be countersunk approximately 5mm (Figure 21).

Select a potential nail. Use the desired nail length to assess the nail diameters that could be used.

Nail Length	Nail Diameter
20cm - 30cm Standard	7mm
32cm - 38cm XL	7mm
24cm - 36cm Standard	8mm
38cm - 42cm XL	8mm
28cm - 38cm Standard	9mm
40cm - 42cm XL	9mm
30cm - 42cm Standard	10mm

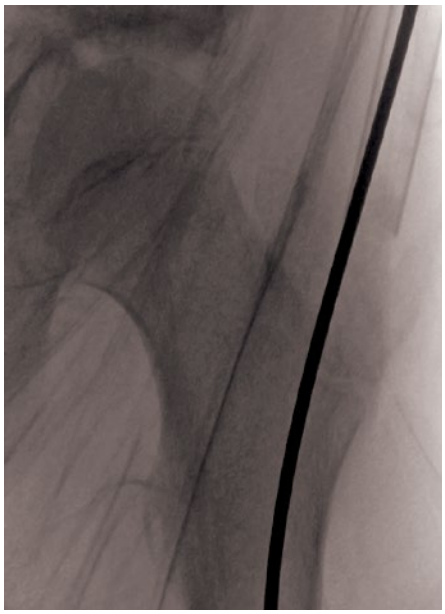


Figure 21: Insert Measurement Gauge into reamed hole

Measuring (cont.)

Protect the skin at the incision site by sliding the Soft Tissue Protector over the 2.7mm Ball Tipped Reaming Rod and passing it down into the soft tissue (Figure 22).

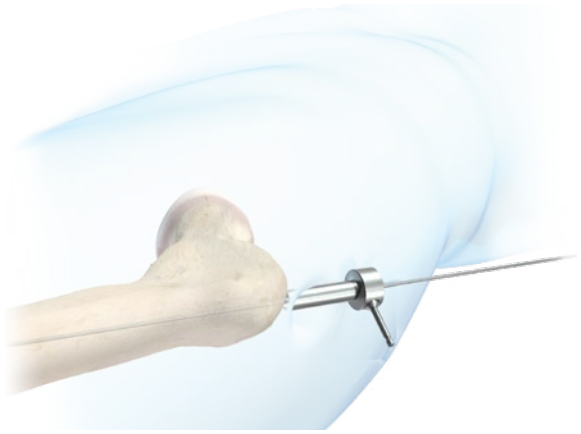


Figure 22: Protect skin at incision site with Soft Tissue Protector

Reaming Technique (Reamer Use Guidelines)

For most patients, utilize the flexible shaft with detachable side cutting reamer heads from 7.5mm to 12.0mm.

Under power, advance the reamer into the femoral canal. Keep advancing the reamer the entire length of the femur in a forward motion, up and down the entire length of the femur.

CAUTION: **ALWAYS FORWARD**. Use power tool in the forward setting at all times.

ALWAYS ON. Do not stop the power tool.

Using fluoroscopy, confirm that the reamer has reached the distal end of the 2.7mm Ball Tipped Reaming Rod.

NOTE: Frequently clean the reamer flutes to prevent clogging.

If the reamer becomes stuck in the femoral canal, grasp the 2.7mm Ball Tipped Reaming Rod with a large needle holder or vise grip and withdraw it 1 to 2cm while attempting to advance the reamer under power. If the reamer continues to be immovable, grasp the reaming rod with a large needle holder or vise grip and using a mallet tap on the vise grip in a retrograde manner in order to remove the reamer and guide wire together.

CAUTION: Never reverse the reamer, as this could lead to reamer shaft failure.

Switch to the detachable side cutting reamers at size 7.5mm and continue reaming to desired diameter.

NOTE: It is not necessary to "fill" the canal or to continue reaming until "chatter" is noted. Appropriate selection of nail diameter is not dependent upon getting a tight fit in the isthmus of the femur.

CAUTION: Do not ream past the distal bend in the 2.7mm Reaming Rod, as this may cause the reamer to bind and/or rupture.

WARNING: When performing a femoral osteotomy, to reduce the likelihood of pulmonary emboli, prepare the osteotomy prior to reaming or create vent holes in the femur.

CAUTION: For 6mm, 6.5mm, 7.0mm one piece front cutting reamers:

Start with the 6mm reamer and go up in 0.5mm increments.

Do not use in hard cortical bone.

Recommended to over-ream 1 to 1.5mm over desired implant diameter.

Reaming Technique (Reamer Use Guidelines) (cont.)

Place the Exchange Tube over the 2.7mm Ball Tipped Reaming Rod and insert into the reamed femoral canal (Figure 23). Verify placement on radiograph (Figure 24).

Remove the 2.7mm Ball Tipped Reaming Rod and replace with the 2.0mm Guide Insertion Wire (Figures 25a & 25b).

Remove the Exchange Tube.

NOTE: Removal of the 2.7mm Ball Tipped Reaming Rod without placement of the Exchange Tube or 2.0mm Guide Insertion Wire may result in loss of reduction.

CAUTION: If nail is implanted over 2.7mm Ball Tipped Reaming Rod, the reaming rod will not be able to be removed.

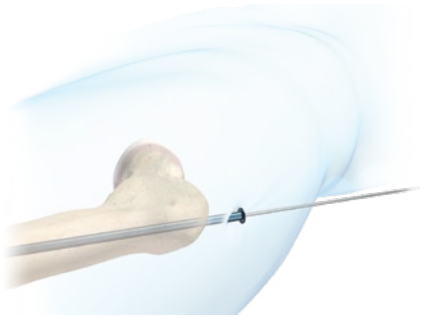


Figure 23: Place Exchange Tube over Ball Tipped Reaming Rod

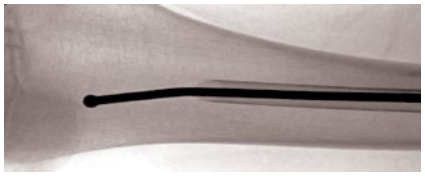


Figure 24: Verify placement

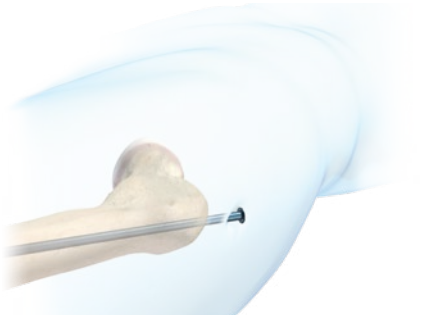


Figure 25a: Remove Ball Tipped Reaming Rod

Figure 25b: Insert 2.0mm Guide Insertion Wire

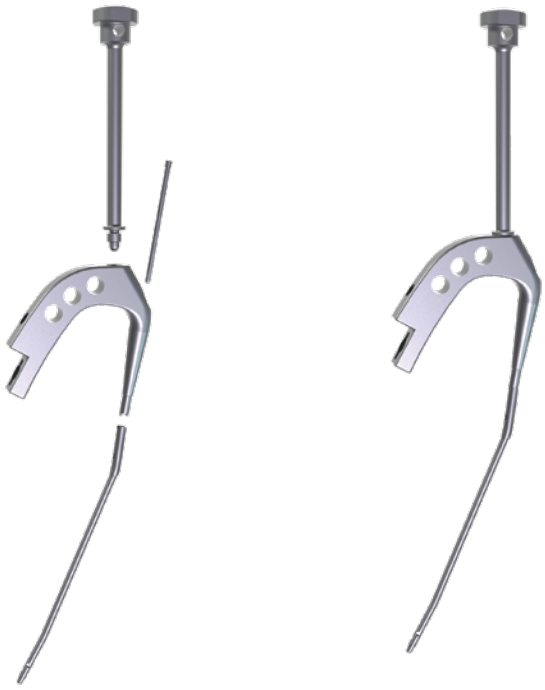
Nail Placement

Attach the pre-selected nail to the Targeting Device with the Attachment Bolt (Figures 26a & 26b).

CAUTION: Be certain that the attachment bolt remains tight throughout the impaction process. Failure to do so may lead to bolt breakage.

CAUTION: Attachment Bolt is a single-use device. It may be used to perform a bi-lateral procedure on a single patient.

NOTE: Use the Ball Hex Driver to perform final tightening of components prior to insertion of the nail.



Figures 26a & 26b: Attach nail to Targeting Device with Attachment Bolt

Nail Placement (cont.)

Prior to insertion of the nail, check alignment to ensure accurate targeting of the nail through the jig. Insert the outer and inner guide tubes and drill bit and make sure the drill bit is in line with the interlocking holes in the nail (Figure 27).

Attach the Impaction Rod to the threaded hole in the targeting device for impaction of the nail.

> **NOTE:** Be certain that the impaction rod is fully seated with the flange on the impaction rod resting on the targeting guide. Maintain tightness and flange to targeting guide contact throughout the impaction process.

Carefully pass the nail over the 2.0mm Guide Insertion Wire and into the femoral canal to maintain location of the canal opening and to ease in insertion of the nail. Be sure that the nail slides freely over the guide wire to prevent advancement of the guide wire distally. Using controlled strikes with the mallet, drive the nail into the distal femur.

> **NOTE:** If advancement of the nail is difficult, remove the nail and ream another 0.5mm. It is common to over ream the canal by 1-1.5mm.

Figure 27: Confirm that nail is oriented correctly

Nail Placement (cont.)

Impact the nail to approximately 5mm below the level of the trochanter but proximal to the trochanteric physis.

After the nail is inserted to the appropriate depth, remove the 2.0mm Guide Insertion Wire (Figures 28 & 29).

NOTE: Failure to remove Smooth Guide Wire may result in instrumentation damage and metal debris.

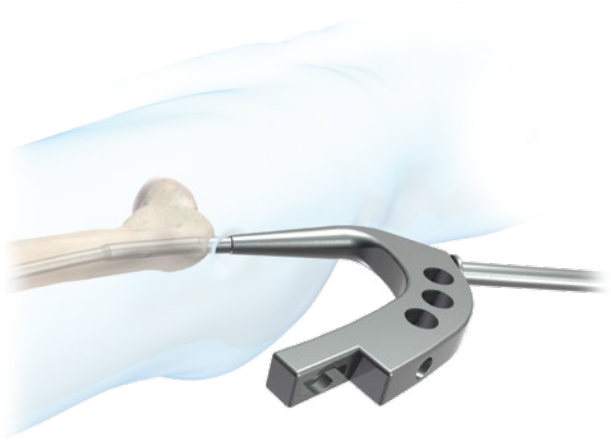


Figure 28: Impact the nail

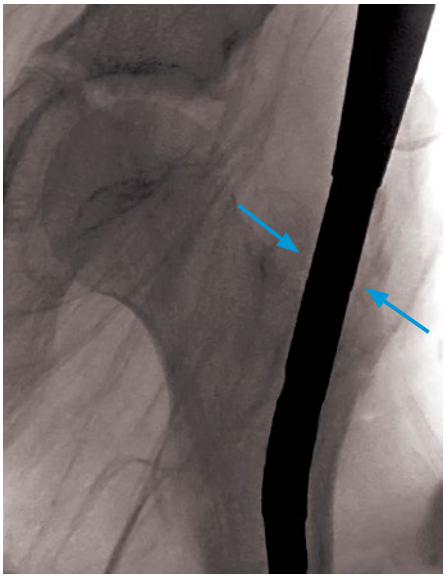


Figure 29: Check position of nail impaction

Proximal Interlocking

Insert the Outer Guide Tube and Inner Guide Tubes into the Targeting Device and push down to the skin (Figure 30).

> **NOTE:** Do not apply excessive force to the targeting construct or targeting might be compromised.

Mark the skin with the drill sleeves and make a longitudinal incision. Bluntly dissect down to bone.

> **NOTE:** Carefully remove the inner C-springs and clean thoroughly. Be sure to replace the inner C-springs after cleaning. If the inner C-springs are missing from the guide tubes, the tubes will not be self-retaining.

Make sure the inner and outer guide tubes are advanced to the lateral cortex of the femur. Failure to do so will effect proximal screw measurement and insertion.

Blue Guide Tubes = 3.5mm
Green Guide Tubes = 4.5mm

Optional: Use the Trocar and light blows with a mallet to make a notch in the lateral cortex of the femur. This is done to ensure that the drill bit does not slip off the cortex ("skyve") while drilling (Figure 31).

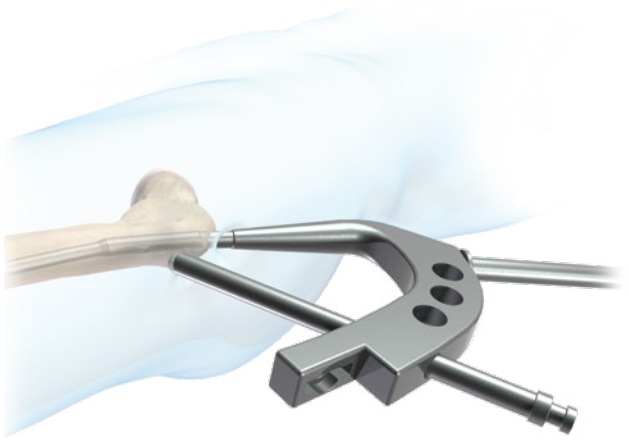


Figure 30: Insert Outer Guide Tube and Inner Guide Tube into Targeting Device

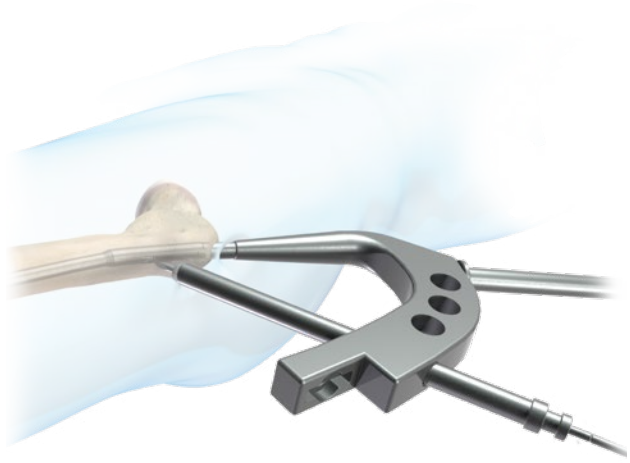


Figure 31: Use Trocar and Mallet to make a notch in lateral cortex (Optional)

Proximal Interlocking (cont.)

Remove the central trocar and insert the 3.2mm Calibrated Drill Bit. Drill through the near cortex (Figure 32).

When the far cortex is reached, stop and measure from the calibration on the drill bit.

Figure 32: Insert Calibrated Drill Bit through the near cortex

Advance the 3.2mm Drill Bit through the far cortex. Detach the drill bit from the drill and leave in place while selecting the appropriate screw.

Remove the 3.2mm Drill Bit and inner guide tube. Insert the screw through the outer guide tube and into the bone. Tighten the screw and remove the outer drill sleeve.

Verify screw position and length on AP and lateral image intensification (Figure 33).

> **NOTE:** If it is necessary to re-engage the screwdriver into the screw head, it is recommended that the Inner Guide Tube is reinserted into the Targeting Device first.

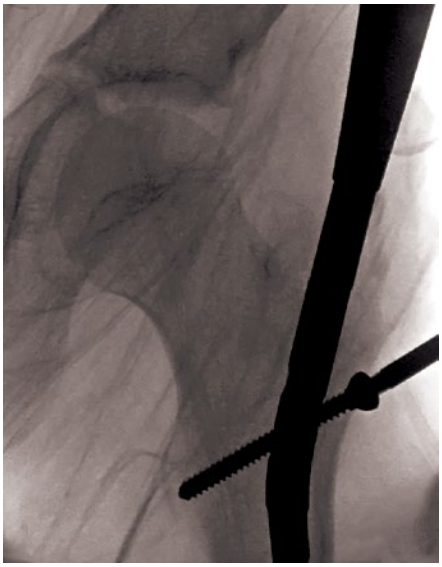


Figure 33: Verify screw position and length

Proximal Interlocking (cont.)

If a recon screw is to be used, place the outer and inner drill sleeves into the appropriate guide and make a skin incision in line with the trajectory of the guide.

Advance the drill sleeves through the soft tissue, onto the bone. Be sure to notch the cortex with the trocar before drilling.

Drill with the calibrated 3.2mm Drill Bit and measure. Insert the appropriate length screw (Figure 34).

If resistance is encountered during screw insertion, remove the screw and drill the outer cortex with the 4.5mm drill. Insert the screw.

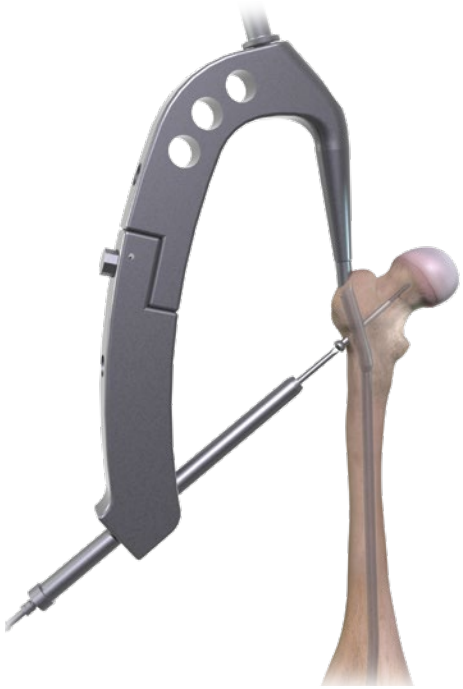


Figure 34: Preparation of recon screw

Distal Interlocking

Distal interlocking is carried out using the free hand technique (Figure 35).

Check rotation and length carefully prior to placing interlocking screws by examining the patient and examining the fracture site radiographically.

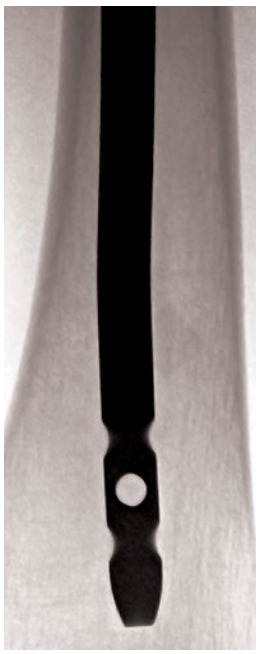


Figure 35: Free hand perfect circle distal interlocking

Place the image intensifier so that the interlocking hole makes a perfect circle in the center of the fluoroscopy monitor screen (Figure 36).

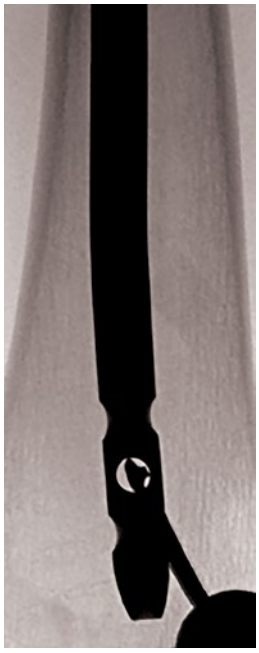


Figure 36: Verify position of perfect circle with drill bit

Distal Interlocking (cont.)

Make an incision over the center of the hole on either the anterior or lateral distal thigh depending on which interlocking hole has been selected. Dissect bluntly through the soft tissue down to bone and position the drill bit over the center of the hole. Drill through both cortices and disconnect the drill bit from the drill. Check radiographically to ensure that the drill bit has passed through the nail.

Remove the drill bit from the hole and insert the depth gauge. Slide the hook of the depth gauge through the drilled hole and grab the far cortex with the hook. Slide outer sleeve against the near cortex and measure.

Measure for the screw. Leaving the depth gauge in place, select the appropriate screw.

When the appropriate screw is ready, remove the depth gauge and insert the screw through the outer guide tube. Check the screw for proper placement and length on AP and lateral image intensification. Verify radiographically (ML/AP) that screw is in distal locking hole of nail (Figure 37).

Repeat if two distal screws are desired.

If using a 4.0mm distal locking screw, utilize the 2.9mm Short Drill Bit. If using a 4.5mm distal lock screw, utilize the 3.2mm Short Drill Bit.

If an End Cap is desired, reinsert the 2.0mm Guide Insertion Wire into the proximal portion of the nail. (This can be done before or after the targeting arm is removed.) Place the End Cap onto the Cannulated Screwdriver and pass it over the 2.0mm Guide Insertion Wire. Screw the End Cap into the nail.

NOTE: The 0mm End Cap is not cannulated and must be inserted without the 2.0mm Smooth Guide Wire.

NOTE: Do not final tighten End Cap with cannulated T-handle. Do not impact cannulated T-handle. Perform final tightening with Ball Hex Driver.

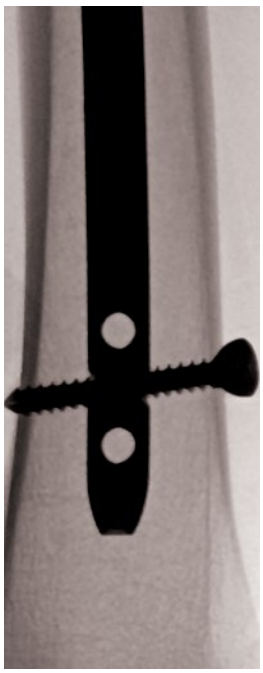


Figure 37: Check the screw for proper placement and length

Closure and Post-Operative Care

Confirm position of the nail and all locking screws. After confirmation is complete, remove the targeting device. Check for motion at the fracture site and rotational stability.

Irrigate and close the surgical wounds in layers.

If adequate fixation has been achieved, no cast immobilization is required. The patient can be allowed toe-touch weight bearing or weight bearing as tolerated on crutches or a walker depending on the patient size and fracture stability.

Nail Removal

NOTE: For nail removal, the Bullet Tipped Extractor or Extraction Bolt may be used. The Bullet Tipped Extractor is not standard in the PediNail™ set. If the Bullet Tipped Extractor is to be used, contact Customer Service prior to nail removal.

NOTE: If a 0mm End cap is used, it must be removed prior to inserting the Guide Wire.

NOTE: The Bullet Tipped Extractor and the Extraction Bolt undergo significant stress when removing intramedullary nails. It is recommended that these items be used once and discarded.

Intramedullary nail removal, if desired, should be deferred, if possible, until after closure of the trochanteric physis (usually by age 13 to 14). For nail removal, position the patient supine on a radiolucent table with the hip and limb prepared and draped. Alternatively, the patient can be positioned in a lateral decubitus position to facilitate management of the soft tissue.

Make an incision through the scar created when inserting the nail. Bluntly dissect down to the greater trochanter. Place the 2.0mm Guide Insertion Wire, or any 2.0mm K-wire of adequate length, into the proximal end of the nail. Check position in both the AP and lateral planes (Figure 38).

If necessary, advance the 9.5mm Cannulated Rigid Reamer over the guide wire to the nail in order to remove bone or fibrous tissue over the proximal end of the nail (Figure 39).

WARNING: Do not allow reamer to contact metal implant.

NOTE: Do not impact Cannulated T-handle driver.

If End Cap is in place, advance the 2.0mm Guide Insertion Wire through the hole in the End Cap and nail and pass the Cannulated Screwdriver over the Guide Wire to the End Cap. Remove after engaging the End Cap (Figure 40).

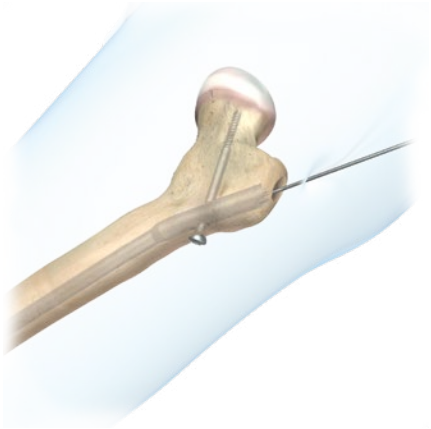


Figure 38: Place 2.0mm wire

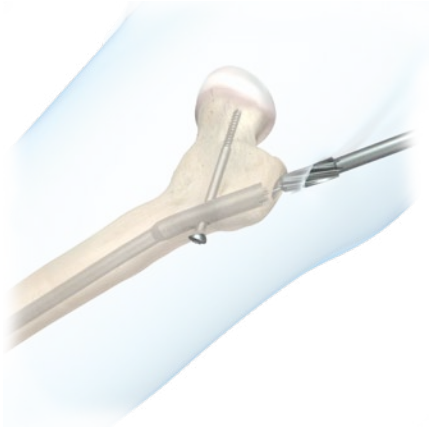


Figure 39: If necessary, remove bone or fibrous tissue

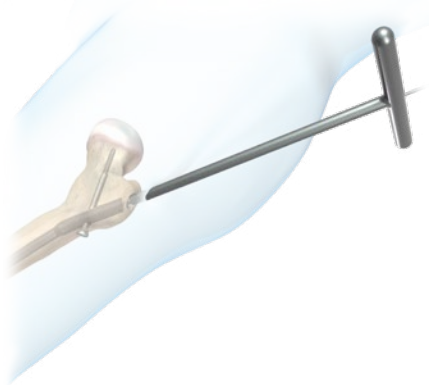


Figure 40: Remove end cap

Nail Removal (cont.)

Pass the Extraction Adapter over the 2.0mm Guide Insertion Wire (Figure 41).

> **NOTE:** Ensure that the Extraction Adapter is tight to avoid fracture of the nail.

Remove all proximal and distal locking screws (Figure 42).

Remove the 2.0mm Guide Insertion Wire (Figure 43).

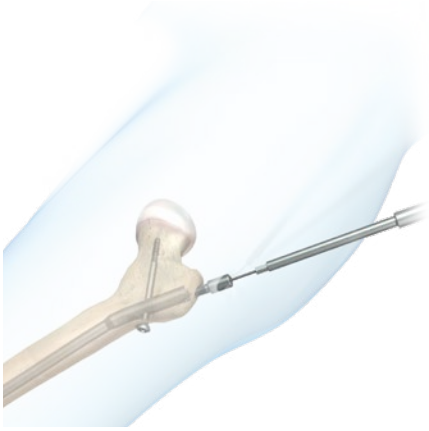


Figure 41: Pass Extraction Adapter

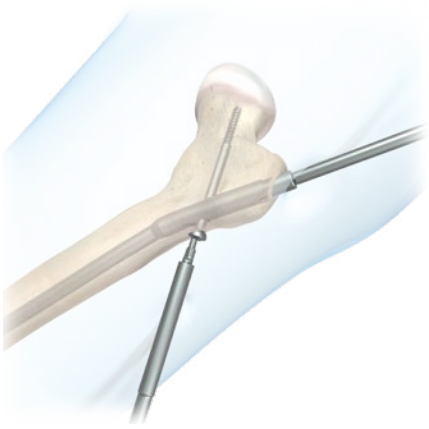


Figure 42: Remove locking screws

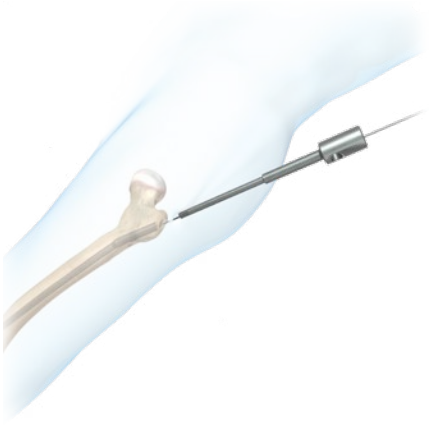


Figure 43: Remove Guide Insertion Wire

Nail Removal (cont.)

Attach the Slap Hammer to the Extraction Adapter (Figure 43).

Gently extract the nail using the Slap Hammer and Extraction Adapter (Figure 44).

Irrigate the wounds and close in the usual fashion.

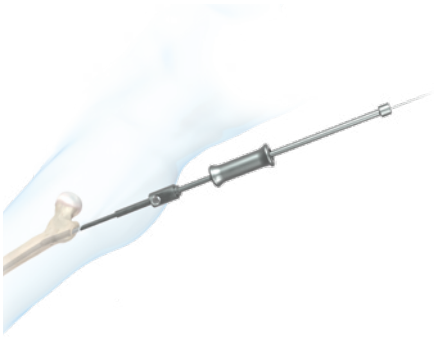


Figure 43: Attach the Slap Hammer

Figure 44: Gently extract the nail

PRODUCT INFORMATION

LEFT FEMUR IMPLANT

Item Number	Qty	Description	Length (mm)
10-1500-071	1	7mm x 20cm Pediatric Femoral IM Nail	200
10-1500-072	1	7mm x 22cm Pediatric Femoral IM Nail	220
10-1500-073	1	7mm x 24cm Pediatric Femoral IM Nail	240
10-1500-074	1	7mm x 26cm Pediatric Femoral IM Nail	260
10-1500-075	1	7mm x 28cm Pediatric Femoral IM Nail	280
10-1500-076	1	7mm x 30cm Pediatric Femoral IM Nail	300
10-1500-081	1	8mm x 24cm Pediatric Femoral IM Nail	240
10-1500-082	1	8mm x 26cm Pediatric Femoral IM Nail	260
10-1500-083	1	8mm x 28cm Pediatric Femoral IM Nail	280
10-1500-084	1	8mm x 30cm Pediatric Femoral IM Nail	300
10-1500-085	1	8mm x 32cm Pediatric Femoral IM Nail	320
10-1500-086	1	8mm x 34cm Pediatric Femoral IM Nail	340
10-1500-087	1	8mm x 36cm Pediatric Femoral IM Nail	360
10-1500-091	1	9mm x 28cm Pediatric Femoral IM Nail	280
10-1500-092	1	9mm x 30cm Pediatric Femoral IM Nail	300
10-1500-093	1	9mm x 32cm Pediatric Femoral IM Nail	320
10-1500-094	1	9mm x 34cm Pediatric Femoral IM Nail	340
10-1500-095	1	9mm x 36cm Pediatric Femoral IM Nail	360
10-1500-096	1	9mm x 38cm Pediatric Femoral IM Nail	380

CASE & TRAY

Item Number	Qty	Description	Length (mm)
01-1500-0307	1	PediNail Implant Base Left	--
01-1500-0308	1	PediNail Implant Tray Left	--
01-1500-0302	1	PediNail Lid	--

LEFT XL FEMUR IMPLANT

Item Number	Qty	Description	Length (mm)
10-1500-077	1	7mm x 32cm Pediatric Femoral IM Nail	320
10-1500-078	1	7mm x 34cm Pediatric Femoral IM Nail	340
10-1500-079	1	7mm x 36cm Pediatric Femoral IM Nail	360
10-1500-080	1	7mm x 38cm Pediatric Femoral IM Nail	380
10-1500-088	1	8mm x 38cm Pediatric Femoral IM Nail	380
10-1500-089	1	8mm x 40cm Pediatric Femoral IM Nail	400
10-1500-090	1	8mm x 42cm Pediatric Femoral IM Nail	420
10-1500-097	1	9mm x 40cm Pediatric Femoral IM Nail	400
10-1500-098	1	9mm x 42cm Pediatric Femoral IM Nail	420
10-1500-101	1	10mm x 30cm Pediatric Femoral IM Nail	300
10-1500-102	1	10mm x 32cm Pediatric Femoral IM Nail	320
10-1500-103	1	10mm x 34cm Pediatric Femoral IM Nail	340
10-1500-104	1	10mm x 36cm Pediatric Femoral IM Nail	360
10-1500-105	1	10mm x 38cm Pediatric Femoral IM Nail	380
10-1500-106	1	10mm x 40cm Pediatric Femoral IM Nail	400
10-1500-107	1	10mm x 42cm Pediatric Femoral IM Nail	420

CASE & TRAY

Item Number	Qty	Description	Length (mm)
01-1500-0405	1	PediNail XL Implant Base Left	--
01-1500-0406	1	PediNail XL Implant Tray Left	--
01-1500-0302	1	PediNail Lid	--

RIGHT FEMUR IMPLANT

Item Number	Qty	Description	Length (mm)
10-1500-021	1	7mm x 20cm Pediatric Femoral IM Nail	200
10-1500-022	1	7mm x 22cm Pediatric Femoral IM Nail	220
10-1500-023	1	7mm x 24cm Pediatric Femoral IM Nail	240
10-1500-024	1	7mm x 26cm Pediatric Femoral IM Nail	260
10-1500-025	1	7mm x 28cm Pediatric Femoral IM Nail	280
10-1500-026	1	7mm x 30cm Pediatric Femoral IM Nail	300
10-1500-031	1	8mm x 24cm Pediatric Femoral IM Nail	240
10-1500-032	1	8mm x 26cm Pediatric Femoral IM Nail	260
10-1500-033	1	8mm x 28cm Pediatric Femoral IM Nail	280
10-1500-034	1	8mm x 30cm Pediatric Femoral IM Nail	300
10-1500-035	1	8mm x 32cm Pediatric Femoral IM Nail	320
10-1500-036	1	8mm x 34cm Pediatric Femoral IM Nail	340
10-1500-037	1	8mm x 36cm Pediatric Femoral IM Nail	360
10-1500-041	1	9mm x 28cm Pediatric Femoral IM Nail	280
10-1500-042	1	9mm x 30cm Pediatric Femoral IM Nail	300
10-1500-043	1	9mm x 32cm Pediatric Femoral IM Nail	320
10-1500-044	1	9mm x 34cm Pediatric Femoral IM Nail	340
10-1500-045	1	9mm x 36cm Pediatric Femoral IM Nail	360
10-1500-046	1	9mm x 38cm Pediatric Femoral IM Nail	380

CASE & TRAY

Item Number	Qty	Description	Length (mm)
01-1500-0311	1	PediNail Implant Base Right	--
01-1500-0315	1	PediNail Implant Tray Right	--
01-1500-9316	1	PediNail Screw Caddy Lid	--

RIGHT XL FEMUR IMPLANT

Item Number	Qty	Description	Length (mm)
10-1500-027	1	7mm x 32cm Pediatric Femoral IM Nail	320
10-1500-028	1	7mm x 34cm Pediatric Femoral IM Nail	340
10-1500-029	1	7mm x 36cm Pediatric Femoral IM Nail	360
10-1500-030	1	7mm x 38cm Pediatric Femoral IM Nail	380
10-1500-038	1	8mm x 38cm Pediatric Femoral IM Nail	380
10-1500-039	1	8mm x 40cm Pediatric Femoral IM Nail	400
10-1500-040	1	8mm x 42cm Pediatric Femoral IM Nail	420
10-1500-047	1	9mm x 40cm Pediatric Femoral IM Nail	400
10-1500-048	1	9mm x 42cm Pediatric Femoral IM Nail	420
10-1500-051	1	10mm x 30cm Pediatric Femoral IM Nail	300
10-1500-052	1	10mm x 32cm Pediatric Femoral IM Nail	320
10-1500-053	1	10mm x 34cm Pediatric Femoral IM Nail	340
10-1500-054	1	10mm x 36cm Pediatric Femoral IM Nail	360
10-1500-055	1	10mm x 38cm Pediatric Femoral IM Nail	380
10-1500-056	1	10mm x 40cm Pediatric Femoral IM Nail	400
10-1500-057	1	10mm x 42cm Pediatric Femoral IM Nail	420

CASE & TRAY

Item Number	Qty	Description	Length (mm)
01-1500-0407	1	PediNail XL Implant Base Right	--
01-1500-0408	1	PediNail XL Implant Tray Right	--
01-1500-0302	1	PediNail Lid	--

IM NAIL END CAP

Item Number	Qty	Description	Length (mm)
10-1500-027	1	7mm x 32cm Pediatric Femoral IM Nail	320
10-1500-028	1	7mm x 34cm Pediatric Femoral IM Nail	340
10-1500-029	1	7mm x 36cm Pediatric Femoral IM Nail	360
10-1500-030	1	7mm x 38cm Pediatric Femoral IM Nail	380
10-1500-038	1	8mm x 38cm Pediatric Femoral IM Nail	380

4.0MM CORTICAL SCREW

Item Number	Qty	Description	Length (mm)
10-1500-2015	2	4.0mm x 15mm Cortical Screw	15
10-1500-2020	2	4.0mm x 20mm Cortical Screw	20
10-1500-2025	2	4.0mm x 25mm Cortical Screw	25
10-1500-2030	2	4.0mm x 30mm Cortical Screw	30
10-1500-2035	2	4.0mm x 35mm Cortical Screw	35
10-1500-2040	2	4.0mm x 40mm Cortical Screw	40
10-1500-2045	2	4.0mm x 45mm Cortical Screw	45
10-1500-2050	2	4.0mm x 50mm Cortical Screw	50
10-1500-2055	2	4.0mm x 55mm Cortical Screw	55
10-1500-2060	2	4.0mm x 60mm Cortical Screw	60

4.5MM CORTICAL SCREW

Item Number	Qty	Description	Length (mm)
10-1500-3016	2	4.5mm x 16mm Cortical Screw	16
10-1500-3018	2	4.5mm x 18mm Cortical Screw	18
10-1500-3020	2	4.5mm x 20mm Cortical Screw	20
10-1500-3022	2	4.5mm x 22mm Cortical Screw	22
10-1500-3024	2	4.5mm x 24mm Cortical Screw	24
10-1500-3026	2	4.5mm x 26mm Cortical Screw	26
10-1500-3028	2	4.5mm x 28mm Cortical Screw	28
10-1500-3030	2	4.5mm x 30mm Cortical Screw	30
10-1500-3032	2	4.5mm x 32mm Cortical Screw	32
10-1500-3034	2	4.5mm x 34mm Cortical Screw	34
10-1500-3036	2	4.5mm x 36mm Cortical Screw	36
10-1500-3038	2	4.5mm x 38mm Cortical Screw	38
10-1500-3044	2	4.5mm x 44mm Cortical Screw	44
10-1500-3046	2	4.5mm x 46mm Cortical Screw	46

4.5MM CORTICAL SCREW (cont.)

Item Number	Qty	Description	Length (mm)
10-1500-3048	2	4.5mm x 48mm Cortical Screw	48
10-1500-3050	2	4.5mm x 50mm Cortical Screw	50
10-1500-3055	2	4.5mm x 55mm Cortical Screw	55
10-1500-3060	2	4.5mm x 60mm Cortical Screw	60
10-1500-3065	2	4.5mm x 65mm Cortical Screw	65
10-1500-3070	2	4.5mm x 70mm Cortical Screw	70
10-1500-3075	2	4.5mm x 75mm Cortical Screw	75
10-1500-3080	2	4.5mm x 80mm Cortical Screw	80
10-1500-3085	2	4.5mm x 85mm Cortical Screw	85

4.5MM CORTICAL RECON SCREW

Item Number	Qty	Description	Length (mm)
10-1500-4045	2	4.5mm x 45mm Cortical Recon Screw	45
10-1500-4050	2	4.5mm x 50mm Cortical Recon Screw	50
10-1500-4055	2	4.5mm x 55mm Cortical Recon Screw	55
10-1500-4060	2	4.5mm x 60mm Cortical Recon Screw	60
10-1500-4065	2	4.5mm x 65mm Cortical Recon Screw	65
10-1500-4070	2	4.5mm x 70mm Cortical Recon Screw	70
10-1500-4075	2	4.5mm x 75mm Cortical Recon Screw	75
10-1500-4080	2	4.5mm x 80mm Cortical Recon Screw	80
10-1500-4085	2	4.5mm x 85mm Cortical Recon Screw	85
10-1500-4090	2	4.5mm x 90mm Cortical Recon Screw	90
10-1500-4095	2	4.5mm x 95mm Cortical Recon Screw	95
10-1500-4100	2	4.5mm x 100mm Cortical Recon Screw	100

SCREW CADDY

Item Number	Qty	Description	Length (mm)
10-1500-3016	2	4.5mm x 16mm Cortical Screw	16

TISSUE PROTECTORS

Item Number	Qty	Description	Length (mm)
01-1500-007	1	7mm Exchange Tube	--
01-1500-010	1	10mm Tissue Protector	--
01-1500-012	1	12mm Tissue Protector	--

REAMER HEADS

Item Number	Qty	Description	Length (mm)
01-1500-075	1	7.5mm IM Reamer Head	--
01-1500-080	1	8.0mm IM Reamer Head	--
01-1500-085	1	8.5mm IM Reamer Head	--
01-1500-090	1	9.0mm IM Reamer Head	--
01-1500-095	1	9.5mm IM Reamer Head	--
01-1500-100	1	10.0mm IM Reamer Head	--
01-1500-105	1	10.5mm IM Reamer Head	--
01-1500-110	1	11.0mm IM Reamer Head	--
01-1500-115	1	11.5mm IM Reamer Head	--
01-1500-120	1	12.0mm IM Reamer Head	--

REAMER SHAFTS

Item Number	Qty	Description	Length (mm)
01-1500-008	1	9.5mm Cannulated Entry Reamer	--
01-1500-060	2	Flexible IM Reamer Shaft	--
01-1500-0160	1	6.0mm One Piece Flexible Reamer Shaft	--
01-1500-0165	1	6.5mm One Piece Flexible Reamer Shaft	--
01-1500-0170	1	7.0mm One Piece Flexible Reamer Shaft	--

DRILLS

Item Number	Qty	Description	Length (mm)
01-1500-021	2	2.9mm Short Drill	--
01-1500-024	2	3.2mm Short Drill	--
01-1500-9015	2	3.2mm Calibrated Drill Bit	--
01-1500-9016	1	4.5mm Calibrated Drill Bit	--

GUIDE WIRES

Item Number	Qty	Description	Length (mm)
11-1500-002	1	2.0mm Guide Insertion Wire	--
11-1500-006	1	2.7mm x 81cm Ball Tipped Reaming Rod	--

GUIDE TUBES

Item Number	Qty	Description	Length (mm)
21-1500-9006	2	Outer Guide Tube	--
21-1500-9007	2	4.5mm Guide Tube	--
21-1500-9008	2	3.2mm Guide Tube	--

HEX DRIVERS

Item Number	Qty	Description	Length (mm)
01-1500-9017	1	3.5mm Hex Driver Long Shaft	--
01-1500-9019	1	Ball Hex Driver	--
01-1500-9020	1	3.5mm Hex Driver Short Shaft	--
01-1500-026	1	T-Handle Hex Driver for Targeting Device	--

GUIDE WIRES

Item Number	Qty	Description	Length (mm)
11-1500-001	2	3.2mm Threaded Tipped Guide Wire	--
01-1500-008	1	9.5mm Entry Reamer	--
01-1500-014	1	Nail Measuring Gauge	--
01-1500-034	1	Mini Q/C Chuck	--
01-1500-035	1	Depth Gauge Long (10-100mm)	--
01-1500-036	1	T-Handle Wire Inserter	--
01-1500-9011	1	IM Reducer	--
01-1500-9014	1	Trocar	--
01-1030-001	1	AO Q/C Handle	--
11-1500-005	1	Exchange Tube	--
01-1500-018	1	Slotted Mallet	--
01-1500-9012	1	Impaction Rod	--
01-1500-9013	1	Slap Hammer	--
01-1500-9018	1	Extraction Adapter	--
01-1500-9000	1	Modular Targeting Device	--
21-1500-9005	1	Targeting Device Attachment Bolt	--
01-1500-9304	1	PediNail Instrument #1 Base	--
01-1500-9305	1	PediNail Instrument #1 Tray	--
01-1500-9301	1	PediNail Instrument #2 Base	--
01-1500-9302	1	PediNail Lid	--

IMPORTANT MEDICAL INFORMATION

Contra-Indications

Metallic bone fixation devices should not be used in patients with:

- active infections in or near the fixation site,
- a demonstrated sensitivity to metals,
- an inability to follow a post-operative regimen.

Warnings

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

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
- The PediNail System is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.
- Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument system.
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact.
- The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and sign. We decline all responsibility in the case of implants from different sources being mixed.
- USA: The System has not been tested for safety and compatibility with MRI. Risks of heating, migration, or image artifacts may exist. Physician experience should dictate acceptability of the use of MRI.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatrics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients.
- Routine removal of internal fixation devices after healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.

MR conditions have been established by non-clinical testing for use Outside the United States.

MRI Safety Information for PediNail™ Intramedullary Nail System

In non-clinical testing the OrthoPediatrics PediNail Intramedullary Nail System implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient magnetic field of 2000 Gauss/cm or less
- Maximum whole body average specific absorption rate (SAR) of 1.0 W/kg or less for 15 minutes of scanning per pulse sequence.

MRI-Related Heating

Based on measurements and calculations of RF heating according to ASTM F2182, the OrthoPediatrics Rigid Nails are expected to produce a maximum temperature rise of 6.1 °C for a whole body SAR of 1.0 W/kg for a 15-minute scan.

Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position to OrthoPediatrics implants. The maximum artifact beyond the implant was 55 mm for the spin echo sequence and 60 mm for the gradient echo sequence in a 3.0 Tesla MR system (GE Signa HDxt MR System). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

Adverse Effects

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Delayed or non-union that may lead to breakage of the implant
- Loss of fixation, attributable to non-union, osteoporosis, unstable comminuted fractures
- Bending, fracture, or migration of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- Limb shortening, or decrease in bone density, due to compression of the fracture or bone resorption
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Necrosis of bone
- Infection, both deep and superficial
- Death
- Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

Notes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document in of general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

The information contained in this document was gathered and compiled by medical experts and qualified OrthoPediatrics employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of the understanding of the information used and presented.

OrthoPediatrics does not assume any liability, however, for the timeliness, accuracy, completeness or quality of the information and excludes any liability for tangible or intangible losses that may be caused by the use of this information.

Instructions For Use (IFU), cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatrics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

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