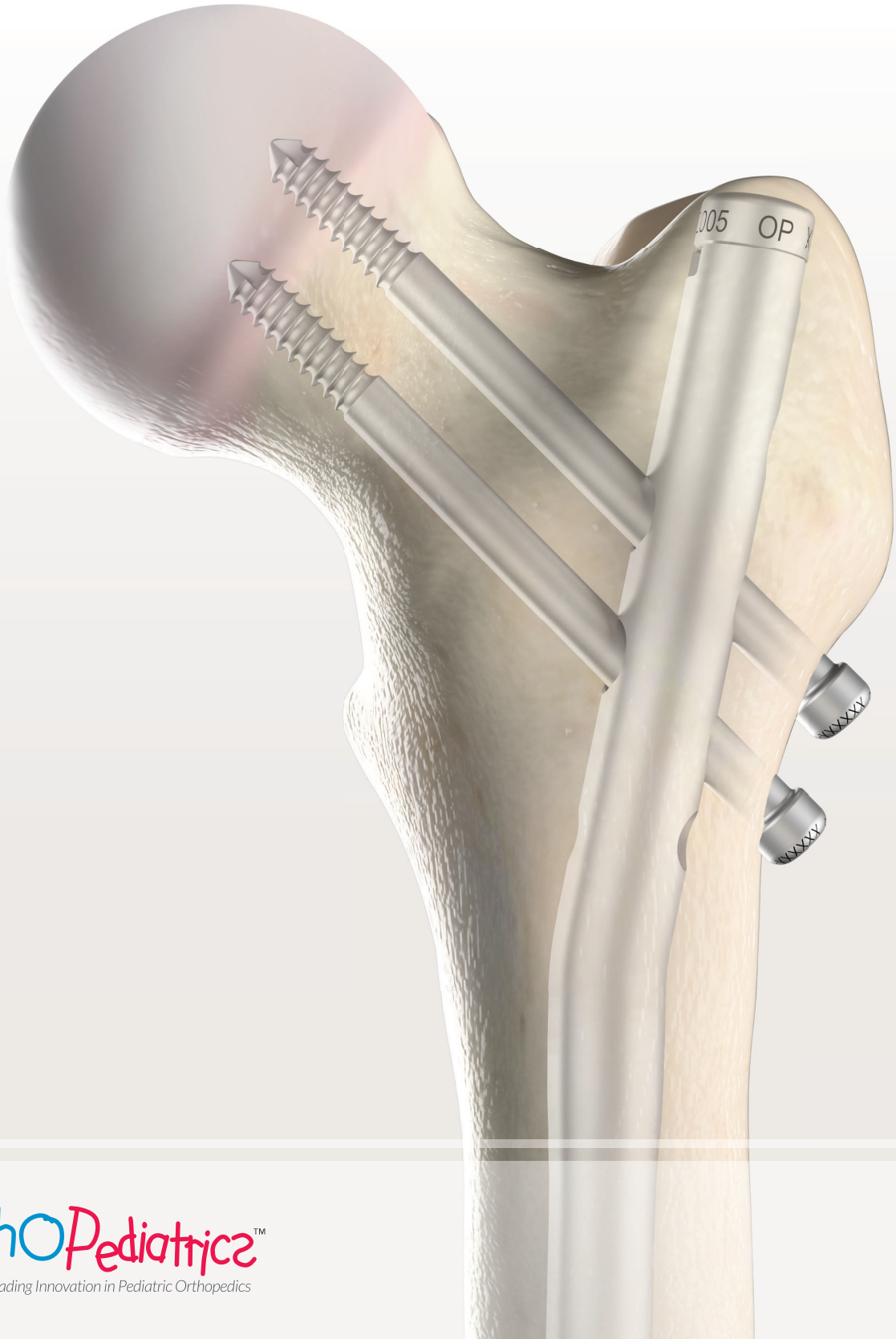
Pediatric Nailing Platform | FEMUR

SURGICAL TECHNIQUE



OrthoPediatrics™

Leading Innovation in Pediatric Orthopedics

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System Overview

Surgical Technique

Product Information

SYSTEM FEATURES

	CHILD Nails		
	7mm	8mm	9mm
Nails			
Material	316L Stainless Steel		
Head Diameter	9mm		
Shaft Diameter	7mm	8mm	9mm
Lengths, 2cm Increments	20-38cm	24-42cm	28-42cm
Proximal Bend	10°		
Radius of Curvature	1.45m		
Attachment Bolt	¼" - 28		
Guide Wire Exchange	Yes		
Proximal Locking			
Descending Oblique Screw	Yes		
Transverse Screw	Yes		
Recon Screw	Yes--one screw @ 135° NSA		
Anteversion	14°		
Screw Diameter	4.5mm Fully Threaded		
	4.5mm Partially Threaded		
Distal Locking			
Lateral-Medial Static	Yes		
Lateral-Medial Dynamic	Yes--5mm dynamization		
Anterior-Posterior Static	Yes		
Screw Diameter	3.8mm*	4.5mm	
All Screws			
Material	316L Stainless Steel		
Hex Size	3.5mm		
Head Diameter	6.5mm		
End Caps			
Material	316L Stainless Steel		
Hex Size	3/16"		
Head Diameter	9mm, except Flush size		
Lengths	Flush, +5, +10, +15, +20		

CHILD Left Nails: 7mm x 28cm, 8mm x 32cm, 9mm x 36cm shown (left to right).

1 *Note: The 3.8mm unicortical peg is only used for distal locking of the 7mm nail.*

ADOLESCENT Right Nails: 9mm x 30cm, 10mm x 34cm, 11mm x 38cm, 12mm x 42cm shown (right to left).

ADOLESCENT Nails				
9mm	10mm	11mm	12mm	
Nails				
316L Stainless Steel				Material
10mm		11mm	12mm	Head Diameter
9mm	10mm	11mm	12mm	Shaft Diameter
28-42cm	30-42cm			Lengths, 2cm Increments
10°				Proximal Bend
1.45m				Radius of Curvature
5/16" - 24				Attachment Bolt
No				Guide Wire Exchange
Proximal Locking				
Yes				Descending Oblique Screw
Yes				Transverse Screw
Yes--two screws @ 130° NSA				Recon Screw
14°				Anteversion
5.0mm Fully Threaded				Screw Diameter
5.0mm Partially Threaded				Screw Diameter
Distal Locking				
Yes				Lateral-Medial Static
Yes--5mm dynamization				Lateral-Medial Dynamic
Yes				Anterior-Posterior Static
4.5mm	5.0mm			Screw Diameter
All Screws				
316L Stainless Steel				Material
3.5mm				Hex Size
6.5mm				Head Diameter
End Caps				
316L Stainless Steel				Material
3/16"				Hex Size
10mm, except Flush size				Head Diameter
Flush, +5, +10, +15, +20				Lengths

INDICATIONS

The OrthoPediatrics Pediatric Nailing Platform | Femur is designed for use in 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 (osteotomies) 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 Pediatric Nailing Platform | Femur is for single use only.

SIZES AVAILABLE

The OrthPediatrics Pediatric Nailing Platform | Femur is available in child and adolescent configurations. Child nails come in 7mm, 8mm, and 9mm diameters. Adolescent nails come in 9mm, 10mm, 11mm, and 12mm diameters. Nail lengths range from 20cm to 42cm depending on the nail diameter.

Screw interlocking options are available both proximally and distally.

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 safe 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:
1. Determination of anticipated nail diameter and nail length.
2. Establishment of appropriate anatomic landmarks, including the greater and lesser trochanters and physes.
3. In the case of rotational osteotomies, determination of the extent of correction needed.

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.

Choosing the length of the nail can be done intra-operatively using the Nail Measuring Tool. After passing the 800mm Reaming Rod into the distal fragment, a direct measurement can be made with the Nail Measuring Tool.

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. Take into consideration the thickness of the cortex at the isthmus when determining nail diameter.

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

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.

WARNING:
The use of the PNP|Femur system is not recommended for fractures or osteotomies in which all of the distal screw holes cannot be fully contained in the distal fragment.

WARNING:
The 7mm PNP|Femur nail is not recommended for patients weighing greater than 75kg.

ENTRY POINT AND ENTRY ANGLE

The Pediatric Nailing Platform | Femur intramedullary nail system is designed for use with a lateral trochanteric entry point for two reasons:

1. 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.

2. To avoid tethering the trochanteric growth plate, decreasing the risk of femoral neck narrowing and hip valgus.

The 10° 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).

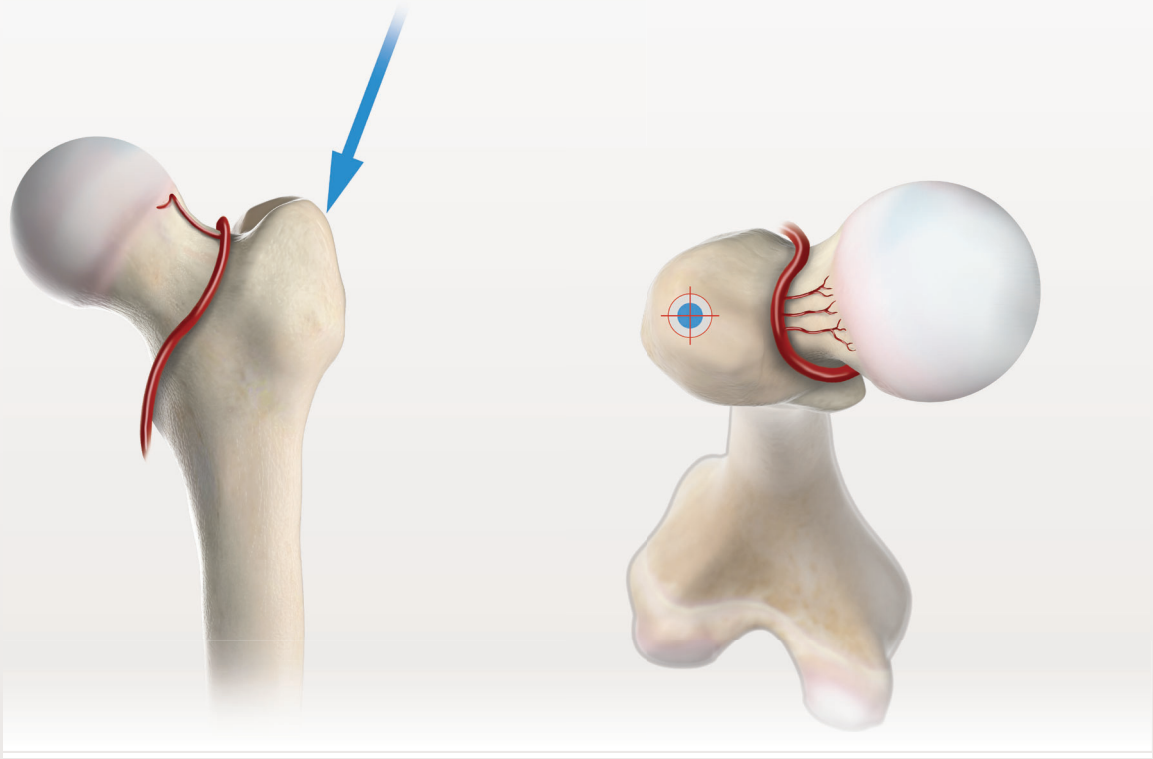


FIGURE 1: Entry point and entry angle.

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.

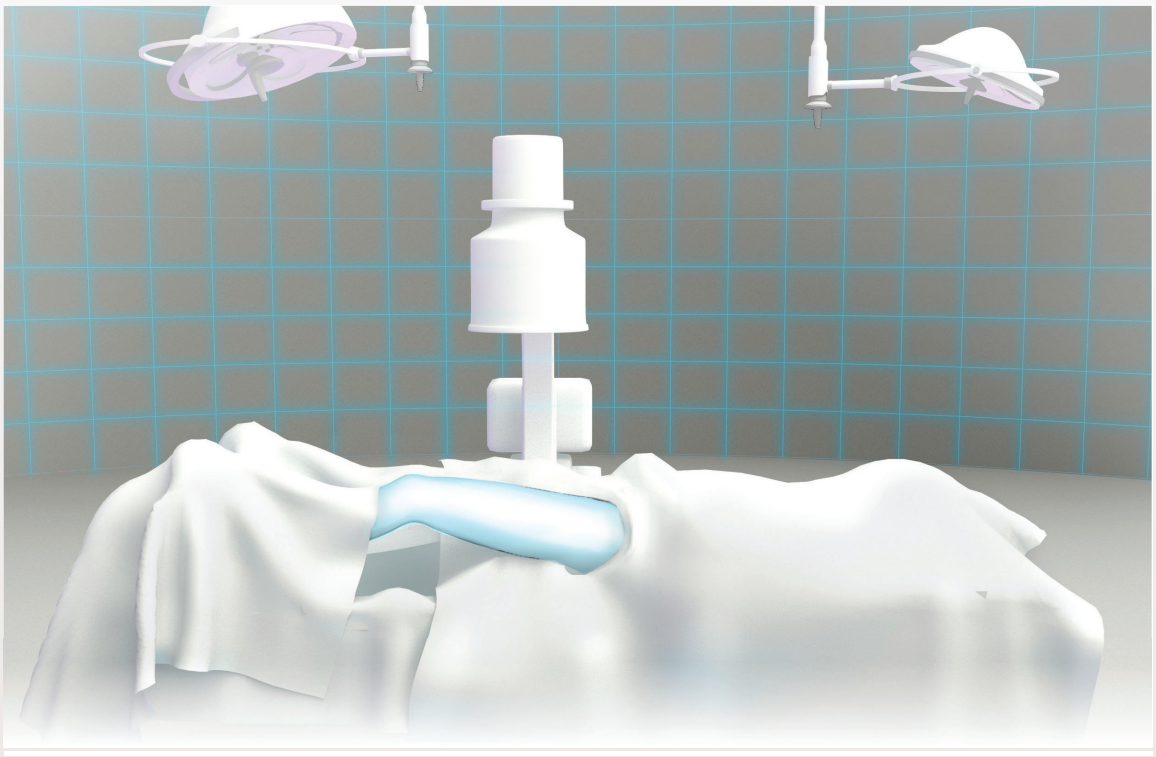


FIGURE 2: Patient positioning.

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 rotation 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.

1
APPROACH

Place the 3.2mm Entry Pin percutaneously through the lateral aspect of the greater trochanter at a point approximately halfway between the tip of the trochanter and the trochanteric physis.

Drive the 3.2mm Entry Pin 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 Entry Pin should be 1.0-1.5cm distal to the lesser trochanter at an angle of 10° from the femoral shaft axis (Figure 3).

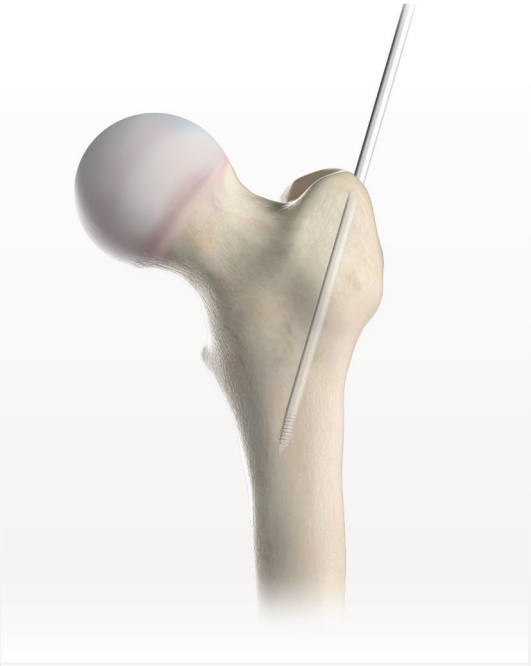


FIGURE 3: Insert Entry Pin into lateral aspect of greater trochanter.

Check a lateral radiograph to insure that the 3.2mm Entry Pin is in the center of the femoral canal and is not inserted too shallow or too steep (Figure 4).

1 *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.

If the initial Entry Pin is not in the desired position in the AP and lateral planes, the Secondary Pin Guide can be used to place a second 3.2mm Entry Pin. Utilizing the fan-shaped slot, pass the Secondary Pin Guide over the initial wire. The Secondary Pin Guide can be angulated up to 10° relative to the initial pin. Place a second 3.2mm Entry Pin through one of the three holes adjacent to the slot. The central hole will position the starting point 5mm lateral to the initial wire. The two holes to either side of the central hole will position the starting point 5mm lateral and 5mm anterior/posterior, depending on the operative side (Figure 5). If the second wire is in an acceptable position, remove the initial wire and then remove the Secondary Pin Guide (Figure 6).

FIGURE 5: Secondary Pin Guide.

FIGURE 6: Second Pin in desired position on AP and Lateral Planes.

Create a 1.5cm incision proximal to the 3.2mm Entry Pin entry site, passing the scalpel adjacent to the guide wire, down to the trochanter.

Place the 10mm side of the Tissue Protector over the 3.2mm Entry Pin and into the soft tissue to protect the surrounding skin and soft tissue while using the opening reamer (Figure 7).

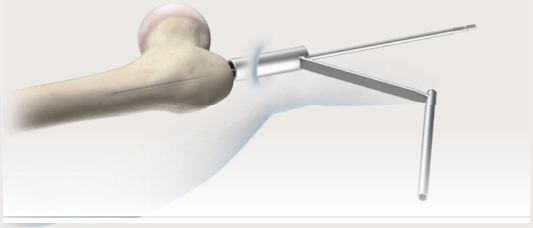


FIGURE 7: Place Tissue Protector over the 3.2mm Entry Pin and into soft tissue.

Advance the 7.5mm/9.5mm Stepped Entry Reamer over the 3.2mm Entry Pin through the trochanter into the femoral canal (Figures 8 - 10).

CAUTION:
Never use the entry reamer without the Entry Pin.

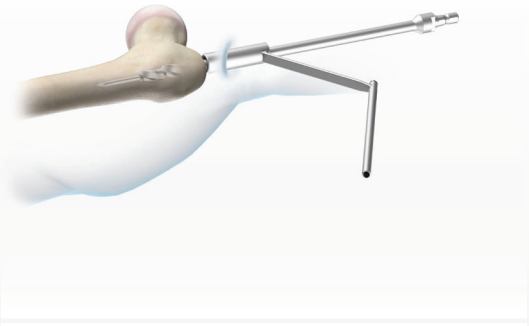


FIGURE 8: Advance 7.5mm/9.5mm Stepped Entry Reamer over 3.2mm Entry Pin.

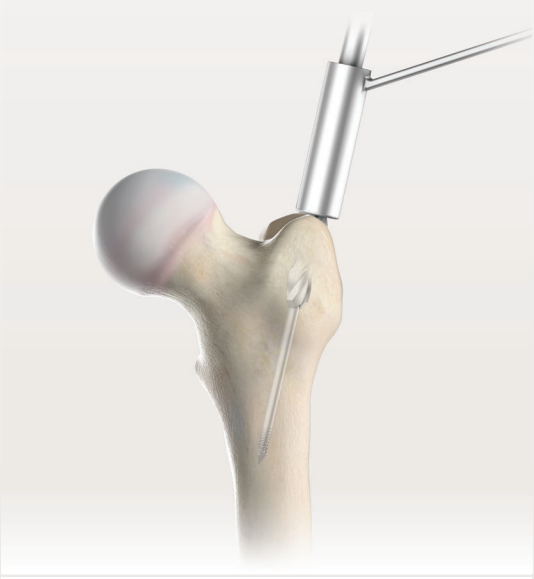


FIGURE 9: AP radiograph to confirm placement in femoral canal and starting point.

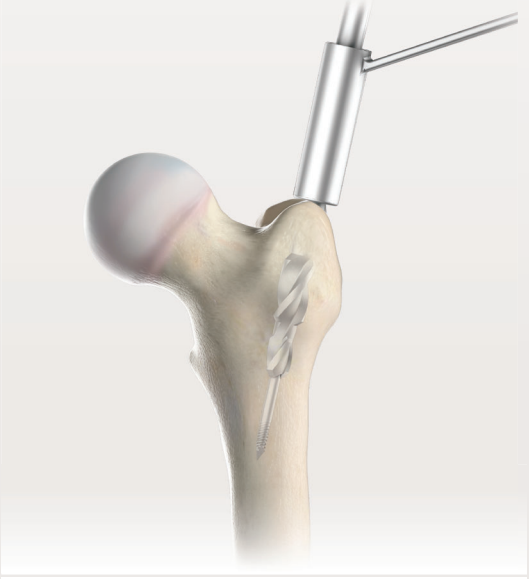


FIGURE 10: AP radiograph to check reamer.

CAUTION:
Do not advance the Entry Pin or entry reamer past the medial femoral cortex.

Withdraw the 7.5mm/9.5mm Stepped Entry Reamer, leaving the 3.2mm Entry Pin in place in the proximal femur (Figure 11).

FIGURE 11: Withdraw 7.5mm/9.5mm Stepped Entry Reamer.

1. *Note: If the 3.2mm Entry Pin appears to be lodged in the 7.5mm/9.5mm Stepped Entry Reamer, use the Guide Rod Obturator or Pusher, to ensure that the Pin remains in place upon removal of the reamer.*

2. *Note: Refer to Section 3: Reaming Technique (Reamer Use Guidelines).*

With the 3.2mm Entry Pin and Tissue Protector still in place, place the desired reaming rod through the tissue protector and into the proximal femur. Confirm the reaming rod is in the proximal femur fluoroscopically and then withdraw the 3.2mm Entry Pin and Tissue Protector.

REAMING ROD: CHILD NAILS

The Child Nails will not allow passage of the 2.7/3.75mm x 800mm Ball Tipped Guide Wire through its cannulation. The 2.7/3.75mm x 800mm Ball Tipped Guide Wire will need to be exchanged for the 2.0mm x 800mm Smooth Guide Wire via the Exchange Tube prior to inserting the nail. Pass the wire down the femoral canal by hand or, if resistance is encountered, with the aid of the Inserter and Large Collet.

To assemble the Inserter, press and hold the blue button, load the Large Collet in the direction indicated by the arrow, release the button, and thread on the Knob (Figure 12). Pass the smooth end of the Ball Tipped Guide Wire through the knob end of the inserter and tighten the knob at the desired position along the wire (Figure 13). The wire is straight but a small bend can be created at the ball-tip end to aid in directing the wire, if needed.

Note: The Large Collet is for use with 2.7mm/3.75mm x 800mm Ball Tip Guide Wire. The Small Collet is for use with the 2.0mm x 800mm Smooth Guide Wire.

FIGURE 12: Assemble the Inserter.

REAMING ROD: ADOLESCENT NAILS

The Adolescent Nails will allow passage of the 2.7/3.75mm x 800mm Ball Tipped Guide Wire through its cannulation. There is no need for a guide wire exchange. The same steps described above should be followed for placing the guide wire.

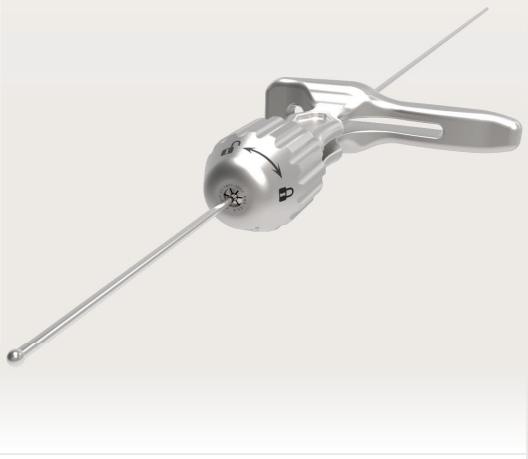


FIGURE 13: Pass the Ball Tip Guide Wire through the knob-end of the inserter and tighten the knob.

Advance the reaming rod down the femur to the distal metaphysis. If treating a fracture, stop at the level of the fracture and use fluoroscopy to verify passage of the reaming rod across the fracture (Figure 14)

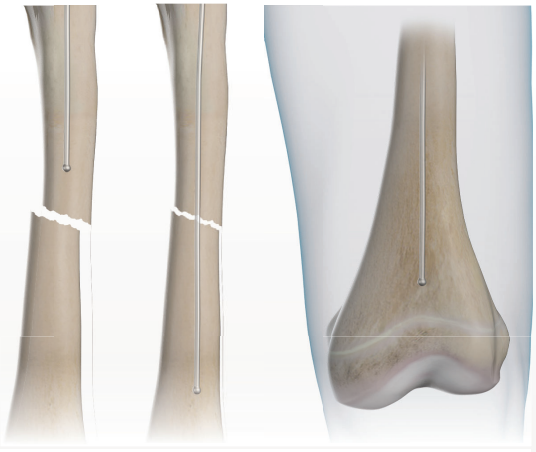


FIGURE 14: Pass the reaming rod down the femur, across the fracture, and to the distal metaphysis.

In subtrochanteric fractures the proximal fragment is often flexed, abducted, and externally rotated. In this setting, passing the reaming rod across the fracture can be challenging as the proximal fragment is difficult to control through traction and external manipulation. Use the Reduction Tool in the proximal fragment as a joystick to bring the fracture fragments into alignment, allowing passage of the reaming rod (Figure 15). Take care not to perforate the metaphysis with the Reduction Tool during manipulation.

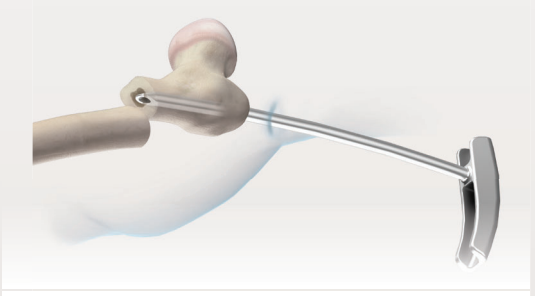


FIGURE 15: Use the Reduction Tool to control the proximal fragment in a subtrochanteric fracture.

1 *Note: Verify placement using AP and ML fluoroscopy that reaming rod is in the distal fragment.*

CAUTION:
Do not advance reaming rod into physis or joint space.

2
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 guide wire in the distal femur to avoid penetration of the distal femoral physis by the nail.

Unfold the Nail Measurement Tool and pass it over the reaming rod. The metal ring will allow visualization of the instrument fluoroscopically to ensure it is contacting the greater trochanter (Figures 16 and 17).

Read the measurement from the back of the wire (Figure 18). The measurement obtained is a measure of the insertion depth of the guide wire. The surgeon should select a nail length using this measurement as a guide. Keep in mind that nails are often inserted 5mm below the surface of the greater trochanter.

1. *Note: It is advisable to verify nail length using a second measurement method (i.e. two equal length reaming rods).*

2. *Note: The Nail Measurement Tool is calibrated for use with an 800mm wire. Use with a wire that is not 800mm will yield an inaccurate measurement.*

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

Nail Length	Nail Diameter
20cm - 38cm	7mm Child
24cm - 42cm	8mm Child
28cm - 42cm	9mm Child
28cm - 42cm	9mm Adolescent
30cm - 42cm	10mm Adolescent
30cm - 42cm	11mm Adolescent
30cm - 42cm	12mm Adolescent

FIGURE 16: Unfold the Nail Measurement Tool.

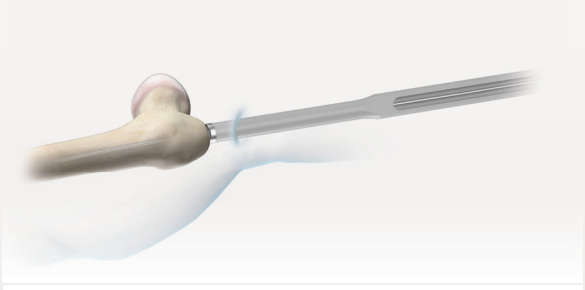


FIGURE 17: Pass the Nail Measurement Tool over the reaming rod and advance to the surface of the greater trochanter.

FIGURE 18: Read the measurement from the back of the wire.

IF PERFORMING A ROTATION OSTEOTOMY

Withdraw the guide wire to the level of the osteotomy. Using the 3.8mm or 4.3mm Dill Bit and Osteotomy Drill Guide, make a number of drill holes at the site of the osteotomy through a small skin incision (Figure 19). Creating drill holes at the level of the osteotomy, by venting the canal, will reduce the likelihood of pulmonary emboli, the cause of which is fat and marrow displaced into the blood stream during intramedullary reaming. Do not complete the osteotomy at this time.

Once the drill holes have been created, pass the guide wire back down the femur and enlarge the canal through distal reaming.

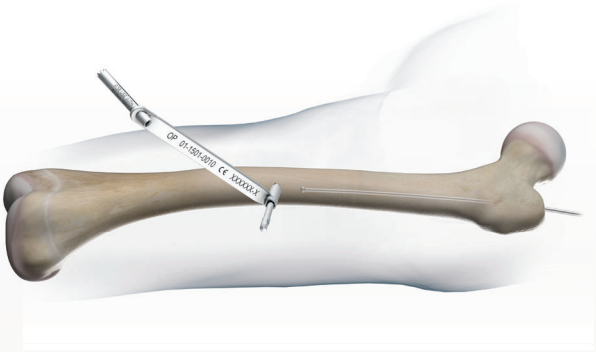


FIGURE 19: Create drill holes at the level of the osteotomy prior to distal reaming.

Protect the skin at the incision site by sliding the 14mm side of the Tissue Protector over the guide wire and passing it down into the soft tissue (Figure 20).

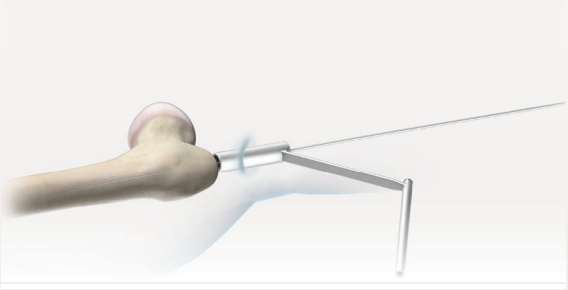


FIGURE 20: Protect skin at incision site with Soft Tissue Protector.

3
REAMING TECHNIQUE (REAMER USE GUIDELINES)

For most patients, utilize the flexible shaft with detachable side cutting reamer heads from 7.5mm to 14.0mm. The 14mm side of the tissue protector can be used with any size reamer. The 10mm side can only be used with reamers up to 10mm in size.

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 guide wire.

1. *Note: Frequently clean the reamer flutes to prevent clogging.*

If the reamer becomes stuck in the femoral canal, grasp the guide wire with a large needle holder or the Inserter and appropriate Collet and withdraw it 1 to 2cm while attempting to advance the reamer under power. If the reamer continues to be immovable, grasp the guide wire with a large needle holder or inserter and, using a mallet, tap on the inserter 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.

2. *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.*

3. *Note: Be certain to exchange the 2.7mm Ball Tipped Reaming Rod with the 2.0mm Guide Insertion Rod if using a CHILD nail.*

4. *Note: Be certain to use the Guide Rod Obturator or Pusher when withdrawing the reamers to maintain the guide wire in the femoral canal.*

CAUTION:
If a small bend is created at the distal end of the 2.7mm Reaming Rod, do not ream past the bend 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 1.5mm to 2.0mm over desired implant diameter.*

For an Adolescent Nail, no guide wire exchange is necessary. If a Child nail is being used, the 2.7mm/3.75mm x 800mm Ball Tip Guide Wire must be exchanged for the 2.0mm Smooth Guide Wire prior to nail insertion. Place the Exchange Tube over the 2.7mm/3.75mm x 800mm Ball Tipped Reaming Rod and insert into the reamed femoral canal (Figure 21). Verify placement on radiograph (Figure 22).

Remove the 2.7mm /3.75mm x 800mm Ball Tipped Guide Wire and replace with the 2.0mm Smooth Guide Wire (Figures 25).

Remove the Exchange Tube.

1 *Note: Removal of the 2.7mm/3.75mm x 800mm Ball Tipped Guide Wire without placement of the Exchange Tube or 2.0mm Guide Insertion Wire may result in loss of reduction.*

CAUTION:
If CHILD nail is implanted over 2.7mm/3.75mm x 800mm Ball Tipped Guide Wire, the guide wire will not be able to be removed.

FIGURE 21: Place Exchange Tube over Ball Tipped Guide Wire.

FIGURE 22: Verify placement of Exchange Tube.

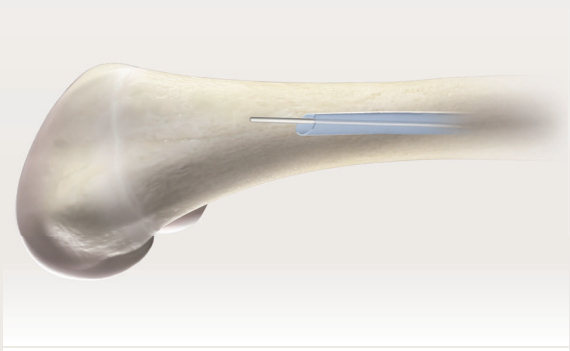


FIGURE 23: Remove Ball Tipped Guide Wire and replace with Smooth Guide Wire.

4
TARGETING GUIDE NAIL ASSEMBLY

Attach the selected nail to the corresponding Targeting Device with the Attachment Bolt using the provided Retaining Alignment Fixture (RAF). The RAF is provided in a stand-alone, integrated tray. It should not be disassembled.

Targeting guides and Attachment Bolts are labeled “CHILD” and “ADOLESCENT”.

Select RAF slot based on chosen nail size.

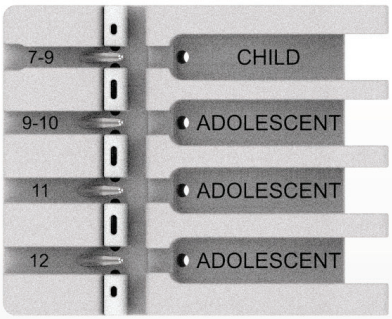


FIGURE 24: Retaining Alignment Fixture (RAF)

Insert nail into fixture with the guide pin into the most proximal screw hole (descending oblique). Apply pressure to the nail head to fully seat in slot.

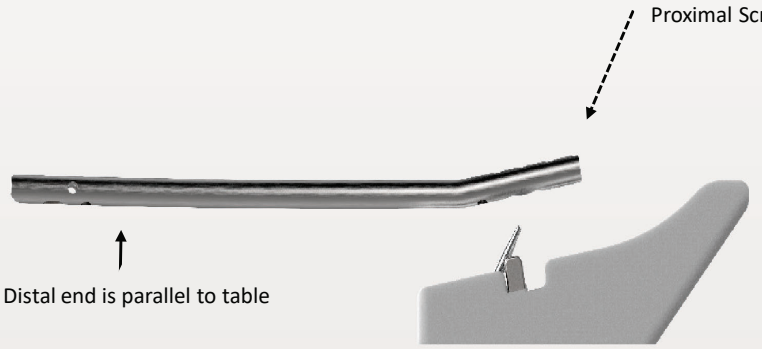


FIGURE 25: Load nail into RAF

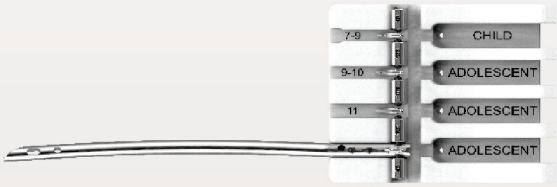


FIGURE 26: Properly loaded nail

Place corresponding Targeting Guide into the RAF. Slide to engage with nail head.

FIGURE 27: Place guide into RAF, engage nail head and insert attachment bolt

Insert Attachment Bolt through the Targeting Guide and into the nail. Utilize Ball Hex Driver to tighten bolt clockwise. ***If resistance is felt during the initial insertion of the bolt, STOP and reset.***

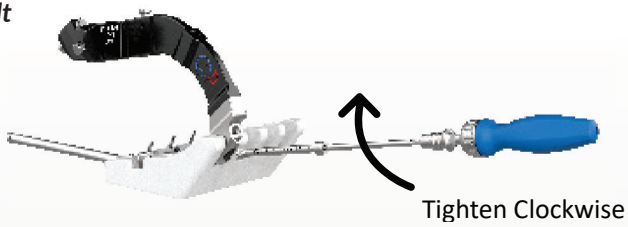


FIGURE 28: Insert Attachment Bolt and tighten turning clockwise

Lift Targeting Guide/Nail Assembly out of the RAF, pulling inline with descending oblique screw hole.

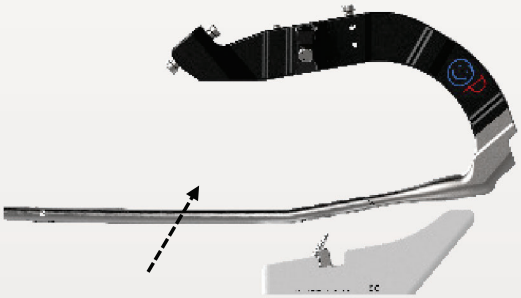


FIGURE 29: Remove assembled nail/targeting arm from RAF

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.

5
NAIL PLACEMENT

Attach the Impactor to the threaded hole in the Targeting Guide after attaching the nail.

FIGURE 30: Attach impactor to targeting device.

Prior to insertion of the nail, check alignment to ensure accurate targeting of the nail through the jig. Insert the Outer Screw Sleeve, the appropriate Inner Drill Sleeve, and the corresponding Trocar and make sure the Trocar passes through the interlocking holes in the nail (Figure 31).

Carefully pass the nail over the guide wire —2.7mm/3.75mm x 800mm Ball Tip Guide Wire for Adolescent Nails or the 2.0mm Smooth Guide Wire for Child Nails— 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. Starting with the Targeting Guide pointing up towards the ceiling, pass the nail into the proximal femur and rotate the Guide laterally as the nail is inserted (Figure 32). Using controlled strikes with the mallet, drive the nail into the distal femur.

FIGURE 31: Confirm that nail is oriented correctly.

1 *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.*

2 *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. If additional reaming is necessary, be sure to use the appropriate guide wire.*

FIGURE 32: With the Targeting Guide pointing up, pass the nail into the proximal femur.

For rotational osteotomies, advance the nail to the site of the osteotomy (Figure 33). Place a 3.2mm Entry Pin across the femoral condyles and a second 3.2mm Entry Pin into the proximal femur taking care to avoid the nail. Attach a Derotation Dial to each pin to determine the initial relative angle between the pins prior to completing the osteotomy (Figure 34). Once the angles of the pins have been determined, remove the Derotational Dials, pull the guide wire back to the level of the osteotomy, and complete the osteotomy. Immediately advance the guide wire across the osteotomy and down the canal and continue advancing the nail into the distal femur. Leave the 3.2mm Entry Pins in place.

FIGURE 33: Advance the nail to the level of the osteotomy.

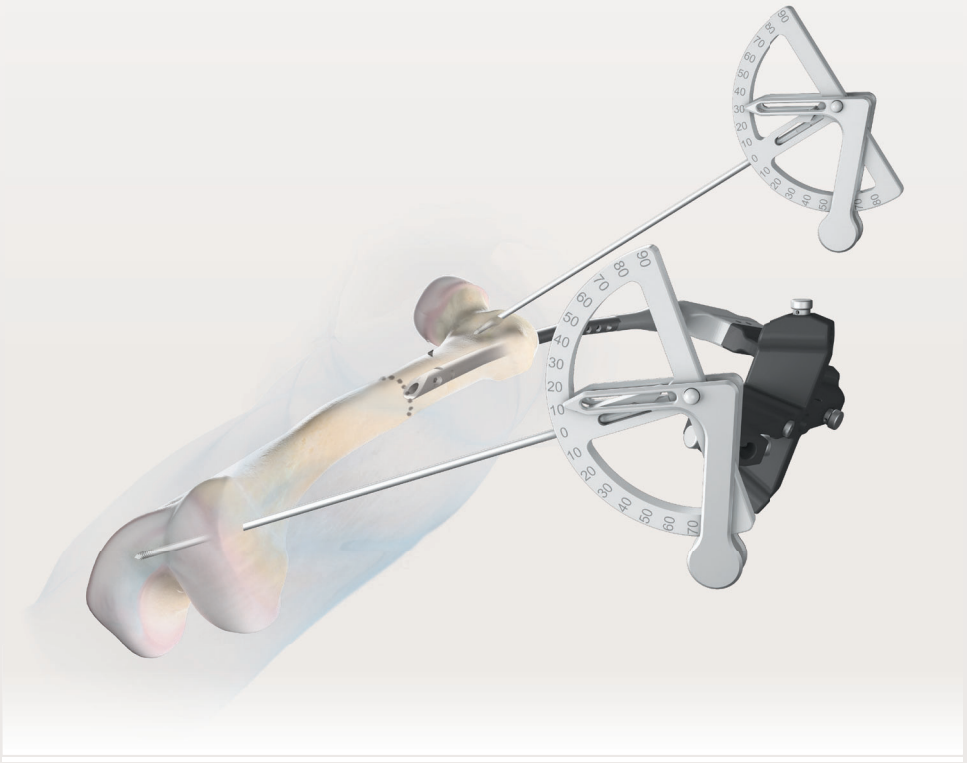


FIGURE 34: Place a 3.2mm Entry Pin above and below the osteotomy and measure the relative angle between them with the Derotation Dials.

If planning to perform a rotational osteotomy with a recon screw up the femoral neck, no pre-osteotomy angular measurement is needed. Instead, the Derotation Dial can be attached to the Targeting Guide via the Derotation Dial Attachment Pin (Figure 35). When the recon screw is placed in the center of the femoral neck, the dial will indicate the true version of the femoral neck compared to a 3.2mm Entry Pin placed across the femoral condyles.

FIGURE 35: The Derotation Dial can be attached to the Targeting Guide via the Derotation Dial Attachment Pin.

Impact the nail to approximately 5mm below the level of the trochanter but proximal to the trochanteric physis. The AP Position Jig and corresponding AP Template can be used to determine correct insertion depth (Figure 36). AP Templates indicate the head of the nail as well as the position of all proximal locking screws, as seen in the AP plane (Figure 37).

After the nail is inserted to the appropriate depth, remove the 2.0mm Guide Insertion Wire.

1. *Note: Failure to remove guide wire may result in instrumentation damage and metal debris.*
2. *Note: The AP Templates are labeled "Child" and "Adolescent", Left and Right. Be sure to use the correct card in the correct orientation.*
3. *Note: Be sure the image intensifier is positioned directly over the template ensure an accurate assessment of nail insertion depth and screw trajectories.*

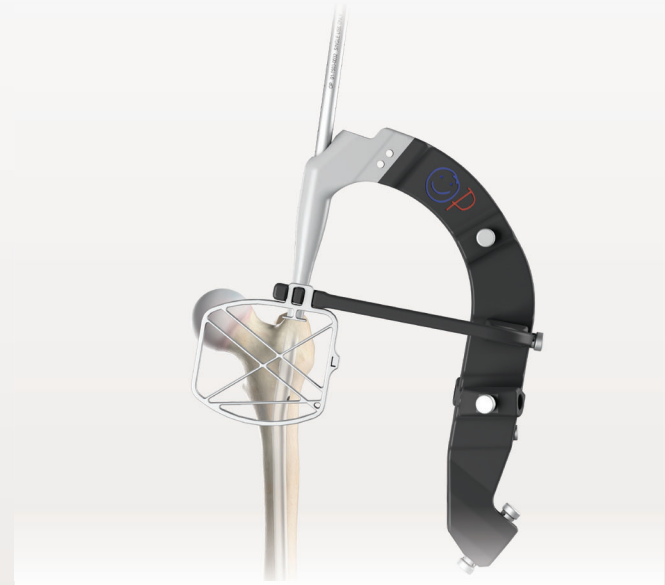


FIGURE 36: Use the AP Position Jig and AP Template to determine appropriate insertion depth of nail.

FIGURE 37: AP Templates: (A) Size; (B) Side; (C) Recon Screws; (D) Transverse Screw; (E) Descending Oblique Screw; (F) Nail Head.

If nail is inserted too deep, use the second slot of the Slotted Mallet to withdraw the nail slightly. Use short strokes with the mallet handle oriented in the same direction as the Impactor shaft.

Once the nail is seated in its final position, confirm the attachment bolt remains securely tightened with ball hex driver.

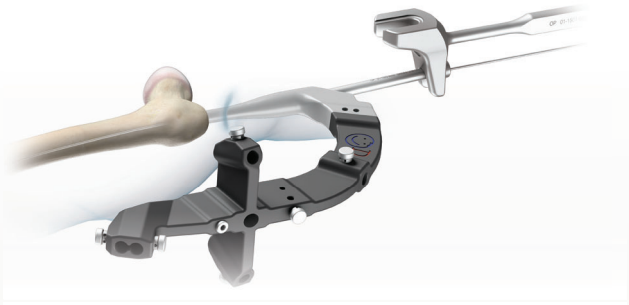


FIGURE 38: If inserted too deep, use Slotted Mallet to withdraw nail as needed.

6
PROXIMAL INTERLOCKING

Insert the Outer Screw Sleeve and appropriate Inner Drill Sleeve with corresponding Trocar through the desired hole in the Targeting Device and push down to the skin (Figure 39).

Note: Do not apply excessive force to the targeting construct or targeting might be compromised.

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

Make sure the Inner Drill Sleeve is advanced to the lateral cortex of the femur (Figure 40). Failure to do so will affect proximal screw measurement and insertion. Tighten the thumb screw on the Targeting Guide to lock the Outer Screw Sleeve in position. Do not over tighten the thumb screws.

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.

CHILD Nail Proximal Locking	4.5mm Fully Threaded Screws	3.8mm Drill Sleeve (1 Green Band)	3.8mm Trocar (1 Green Band)	3.8mm Drill (1 Green Band)
	4.5mm Partially Threaded Screws	4.5mm Drill Sleeve (2 Green Bands)	4.5mm Trocar (2 Green Bands)	3.0/4.5mm Stepped Drill (2 Green Bands)
ADOLESCENT Nail Proximal Locking	5.0mm Fully Threaded Screws	4.3mm Drill Sleeve (1 Black Band)	4.3mm Trocar (1 Black Band)	4.3mm Drill (1 Black Band)
	5.0mm Partially Threaded Screws	5.0mm Drill Sleeve (2 Black Bands)	5.0mm Trocar (2 Black Bands)	3.5/5.0mm Stepped Drill (2 Black Bands)

FIGURE 39: Inner Drill Sleeve, Trocar, and Drill Bit combinations.

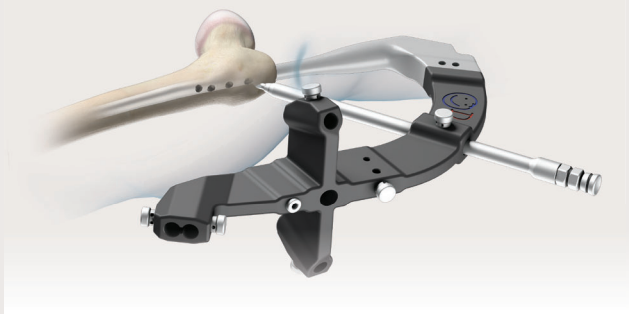


FIGURE 40: Advance sleeve assembly to the lateral cortex and secure in place with thumb screw.

Remove the Trocar and insert the appropriate Calibrated Drill Bit. Drill through the near cortex (Figure 41).

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

FIGURE 41: Insert Calibrated Drill Bit through the near cortex.

Advance the Drill Bit through the far cortex. Detach the drill bit from the drill and leave in place while selecting the appropriate screw. The screw caddy is labeled with screw size/type as well as with application and drill size. Take care to select the correct screw from the caddy.

Remove the Drill Bit and Inner Drill Sleeve. Insert the screw through the Outer Screw Sleeve 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 42).

Note: If it is necessary to re-engage the screwdriver into the screw head, it is recommended that the Outer Screw Sleeve is reinserted into the Targeting Device first.

See page 34 for information regarding the various screw drivers available in this system.

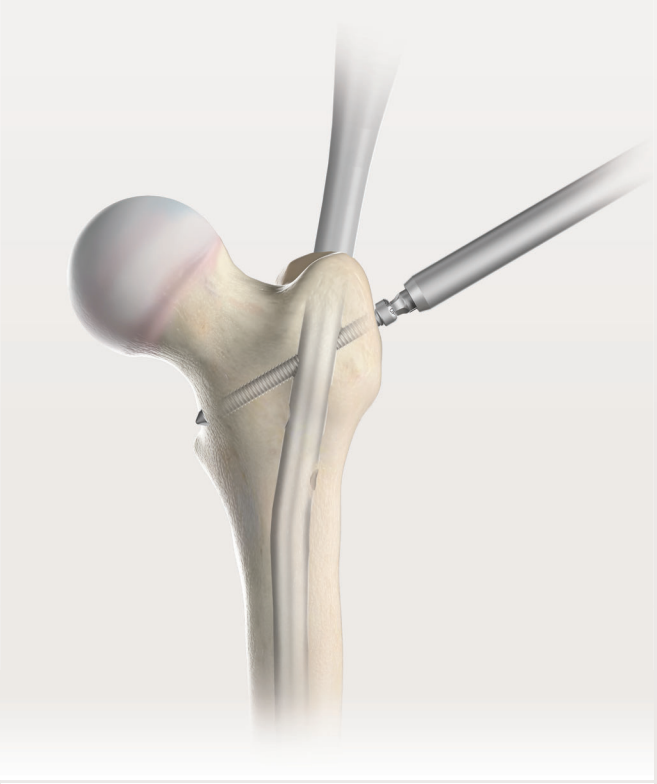


FIGURE 42: Verify screw position and length.

If a recon screw is to be used, place the Outer Screw Sleeve, appropriate Inner Drill Sleeve, and corresponding Trocar through the appropriate hole in the Targeting 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 appropriate calibrated stepped Drill Bit and measure. Insert the necessary length screw (Figure 43). The screw caddy is labeled with screw size/type as well as application and drill size. Take care to select the correct screw from the caddy.

FIGURE 43: Preparation of recon screw.

For rotational osteotomies after proximally locking the nail, reattach the Derotation Dials to each 3.2mm Entry Pins. Rotate the distal femur to correct for the excessive anteversion. The difference between the initial relative angle and the final relative angle of the pins is the amount of rotation performed. For example, if the relative angle between the pins pre-osteotomy is 0° (pins parallel) and 25° post-osteotomy, then 25° of correction was achieved. Adjust the distal femur until the desired correction is reached.

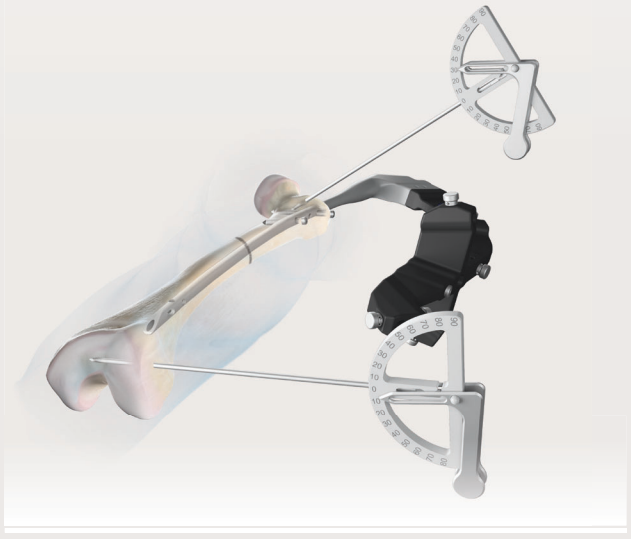


FIGURE 45: Measure relative angle between 3.2mm guide pins using the Derotation Dials.

7
DISTAL INTERLOCKING

Distal interlocking is carried out using the free hand technique.

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

Place the image intensifier so that the interlocking hole makes a perfect circle in the center of the fluoroscopy monitor screen (Figure 45).

Make an incision over the center of the hole on either the anterior or lateral distal thigh depending on which interlocking hole is to be used. Select the appropriate drill bit for the nail implanted (Figure 46). Dissect bluntly through the soft tissue down to bone and position the drill bit over the center of the hole (Figure 47). If dynamization is desired, place the drill bit at the bottom of the slot. 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.

WARNING:
Distal interlocking with a single dynamic screw is not recommended for length-unstable fractures at any location or length-stable fractures/osteotomies within 3cm of the superior-most distal screw hole.

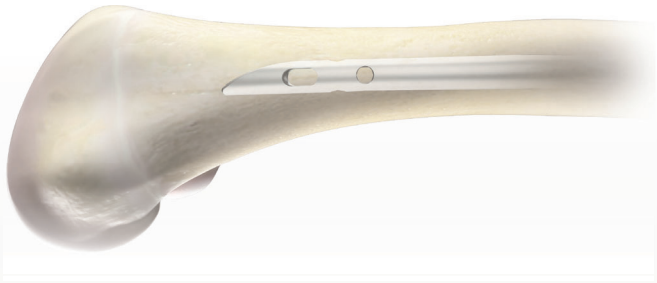


FIGURE 45: Perfect circle distal interlocking.

CHILD Nail Distal Locking	7mm Nails	3.8mm Unicortical Screw	3.8mm Drill Bit
	8mm Nails	4.5mm Fully Threaded Screws	
	9mm Nails		
ADOLESCENT Nail Distal Locking	9mm Nails	4.5mm Fully Threaded Screws	3.8mm Drill Bit
	10mm Nails	5.0mm Fully Threaded Screws	4.3mm Drill Bit
	11mm Nails		
	12mm Nails		

FIGURE 46: Distal interlocking screw and drill bit combinations.

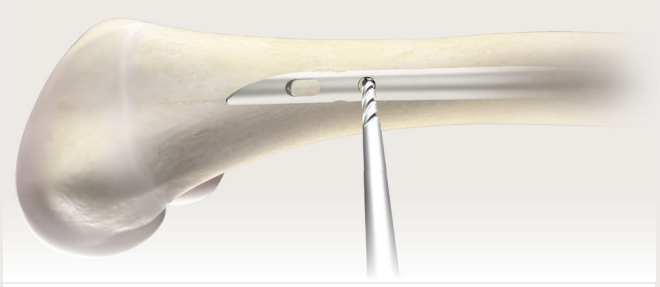


FIGURE 47: Position drill bit over the center of the hole.

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 (Figure 48). Screw length is determined by working length and does not include the screw head.

Leaving the depth gauge in place, select the appropriate screw. The screw/end cap is labeled with screw size/type as well as with application and drill size. Take care to select the correct screw from the caddy.

When the appropriate screw is ready, remove the depth gauge and insert the screw. 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 49).

Repeat if two distal screws are desired.

Confirm final position of all implants—nail and screws—radiographically. After confirmation is complete, remove the Targeting Guide with the Ball Hex Driver

FIGURE 48: Measure for screw length with Depth Gauge.

If an End Cap is desired, reinsert the 3.2mm Entry Pin into the proximal portion of the nail. End Caps come in flush, +5, +10, +15, and +20mm lengths. They are also CHILD and ADOLESCENT nail specific. The Screw/End Cap Caddy is labeled with End Cap length/type. Chose an End Cap size so that the End Cap will sit at or just below the surface of the cortex. Take care to select the correct End Cap from the caddy.

Place the chosen End Cap onto the Cannulated T-Handle Hex Driver and pass it over the 3.2mm Entry Pin. End Caps feature a smooth projection below the threads to assist in orienting the End Cap to the nail. Screw the End Cap into the nail.

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

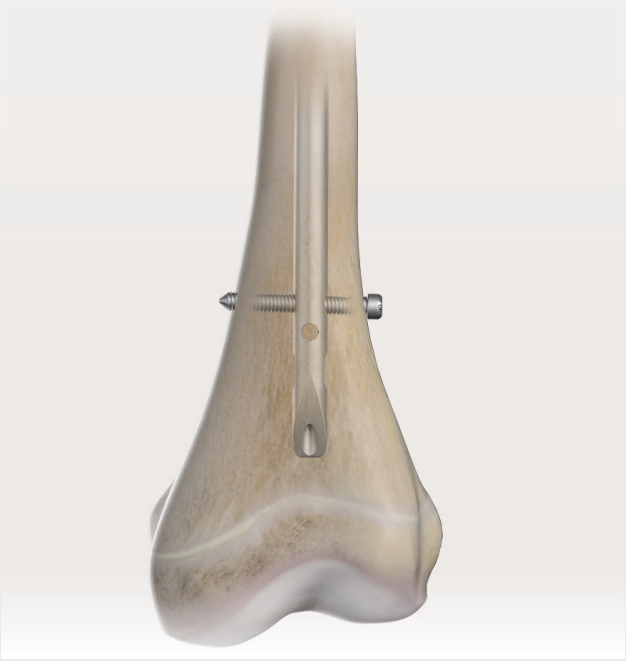


FIGURE 49: Check the screw for proper placement and length.

8
CLOSURE AND POST-OPERATIVE CARE

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.

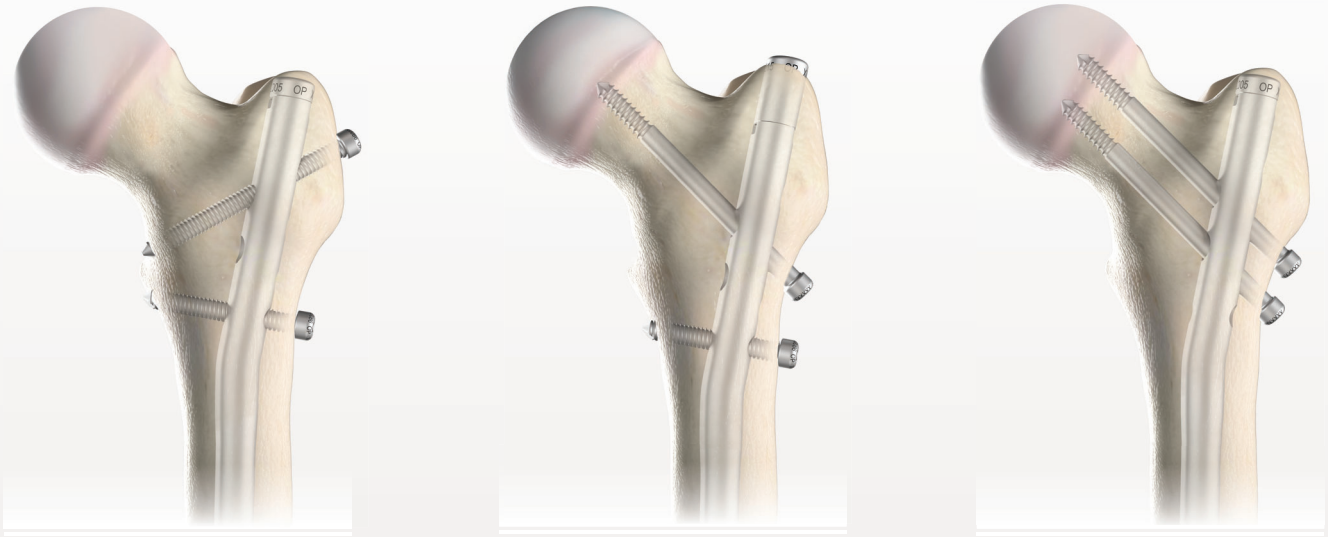


FIGURE 50: Possible ADOLESCENT Nail proximal locking configurations.

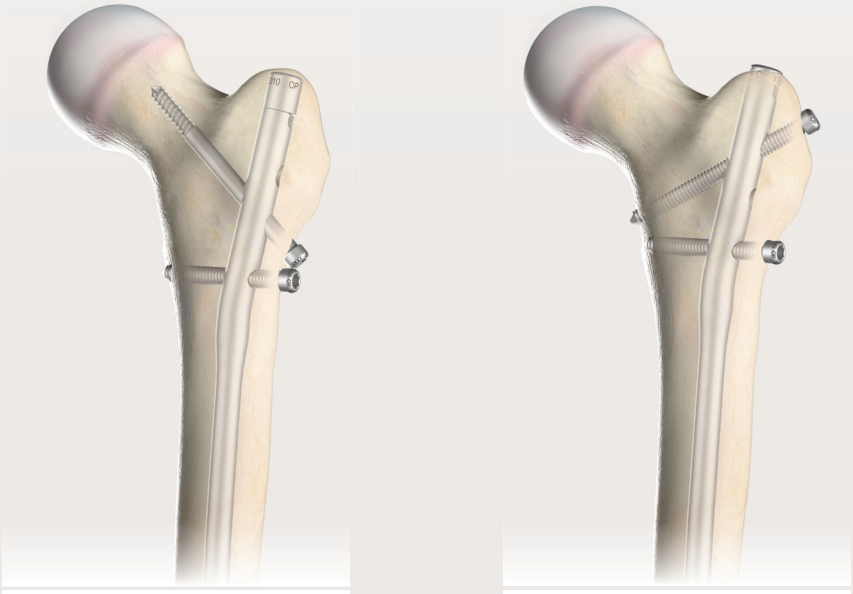


FIGURE 51: Possible CHILD Nail proximal locking configurations.

9
NAIL REMOVAL

1 *Note: The Extraction Adaptors undergo significant stress when removing intramedullary nails. It is recommended that these items be used once and discarded. The Targeting Guide and Attachment Bolt are not intended for explantation.*

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 3.2mm Entry Pin (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 52).

If necessary, advance the 7.5mm/9.5mm Stepped Entry Reamer over the pin to the nail in order to remove bone or fibrous tissue over the proximal end of the nail (Figure 53).

WARNING:
Do not allow reamer to contact metal implant.

If End Cap is in place, advance the 3.2mm Entry Pin through the hole in the End Cap and nail and pass the Cannulated T-Handle driver over the Guide Wire to the End Cap. Remove the End Cap (Figure 54).

2 *Note: Do not impact Cannulated T-handle driver.*

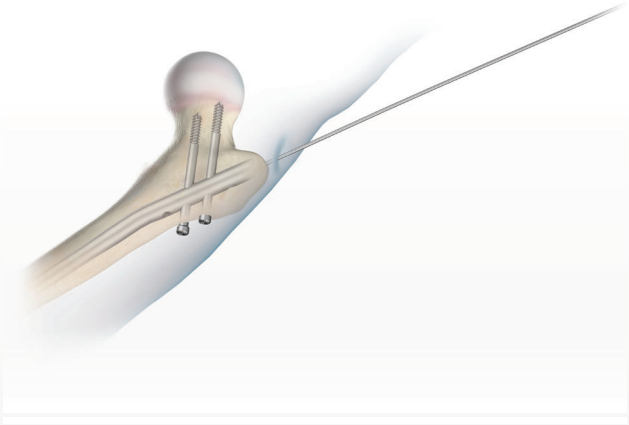


FIGURE 52: Place 2.0mm wire.

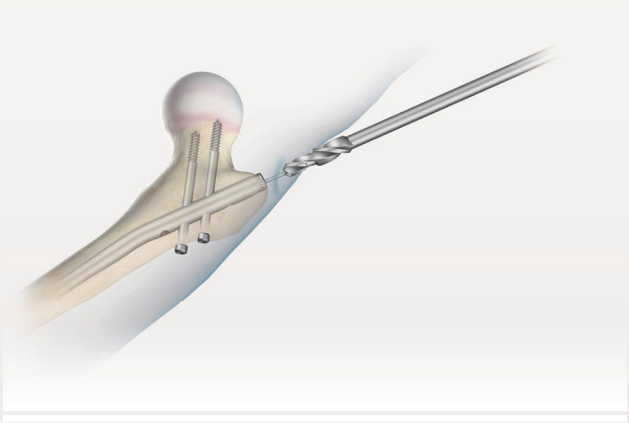


FIGURE 53: If necessary, remove bone or fibrous tissue.

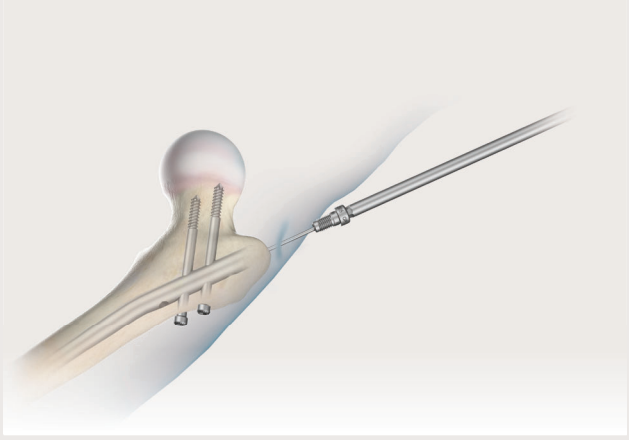


FIGURE 54: Remove end cap.

Conical Extraction Adaptors feature a conical thread and reliefs to assist in clearing debris and ease mating. Compatible with 2.0mm CHILD and 3.2mm ADOLESCENT Guide Wires.

FIGURE 55: Conical Extraction Adaptor.

Mate the appropriate Extraction Adaptor (CHILD or ADOLESCENT) with the nail (Figure 56).

1 *Note: Ensure that the Extraction Adaptor is tight to avoid fracture of the nail.*

FIGURE 56: Pass Extraction Adaptor.

Remove all proximal and distal locking screws (Figure 57).

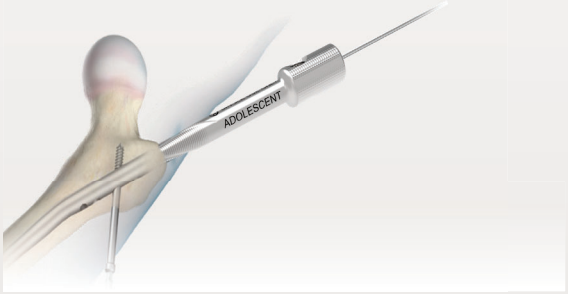


FIGURE 57: Remove locking screws.

Remove Guide Wires, then attach the Extractor to the Extraction Adaptor and gently extract the nail using the Slotted Mallet.

Irrigate the wounds and close in the usual fashion.

FIGURE 58: Gently extract the nail.

SCREW DRIVER OPTIONS

Implantation Driver - Tapered Hex

The 3.5mm Tapered Hex Driver allows for easy retention of the screw on the driver with no moving parts (Figure 59). It is available in Long and Short lengths for proximal and distal interlocking, respectively.

Implantation Driver - Screw Capturing

The 3.5mm Captured Screw Driver is a two-piece driver - Shaft and Sleeve - that captures the head of the screw. The Sleeve has two positions, disengaged and engaged. In the disengaged position the 3.5mm hex is exposed for docking with the screw (Figure 60). Once the hex is docked with the screw, the Sleeve can be advanced to the engaged position where it can capture the screw head (Figure 61).

The 3.5mm Captured Screw Driver is available in Long and Short lengths for proximal and distal interlocking, respectively.

When using the long version through the Outer Screw Sleeve for proximal interlocking, the Outer Screw Sleeve prevents disengagement of the sleeve from the screw head. To release the screw, first unlock the Outer Screw Sleeve from the Targeting Guide by turning the thumb screw counterclockwise. Next, withdraw the Outer Screw Sleeve until it contacts the collar of the Captured Screw Driver Sleeve (Figure 62). Continue to pull the Outer Screw Sleeve against the collar until the screw head is released.

The Captured Screw Driver Shaft and Sleeve components reside disassembled in the instrument case.

FIGURE 59: 3.5mm Tapered Hex Driver.

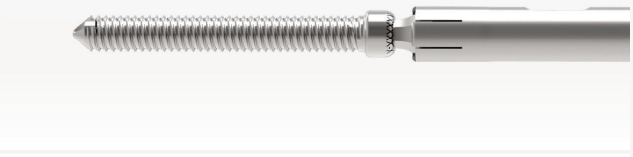


FIGURE 60: Captured Screw Driver in disengaged position locked with screw.

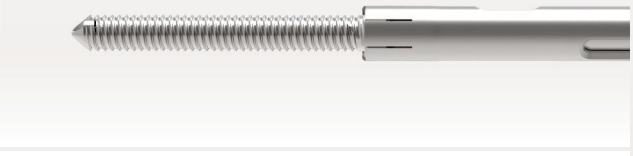


FIGURE 61: Captured Screw Driver in engaged position capturing screw head.

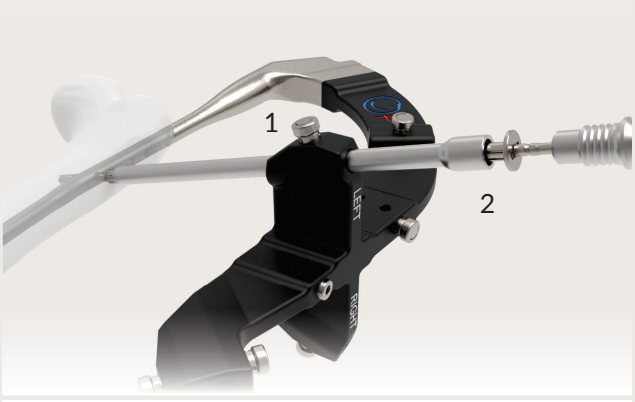


FIGURE 62: Loosen thumb screw (1) and then withdraw Outer Screw Sleeve against Captured Screw Driver Sleeve collar (2).

Explantation Driver

The 3.5mm Explantation Driver is a two-piece driver - Shaft and Sleeve - that clamps onto the head of the screw. It is only available in Short length and will not function through the Targeting Guide. It is intended for screw removal.

The Sleeve has two positions, unlocked and locked. In the unlocked position the 3.5mm hex is exposed for docking with the screw. For screw removal, dock the 3.5mm hex with the screw (Figure 63). With the Sleeve in the unlocked position, back the screw out approximately two turns so that the screw head is completely clear of the cortex (Figure 64). Once the screw head is clear of the cortex, hold the driver handle stationary and turn the Sleeve clockwise to the locked position where it can clamp onto the screw head (Figure 65).

The Explant Driver Shaft and Sleeve components reside disassembled in the instrument case.

FIGURE 63: Explant Driver in unlocked position docked with screw.

FIGURE 64: Screw backed out two turns with Sleeve in unlocked position.

FIGURE 65: Explant Driver Sleeve in locked position.

CHILD LEFT FEMORAL NAILS

Item Number	Qty	Description	Length (mm)
00-1501-0720	1	7mm x 20cm CHILD Left Nail	200
00-1501-0722	1	7mm x 22cm CHILD Left Nail	220
00-1501-0724	1	7mm x 24cm CHILD Left Nail	240
00-1501-0726	1	7mm x 26cm CHILD Left Nail	260
00-1501-0728	1	7mm x 28cm CHILD Left Nail	280
00-1501-0730	1	7mm x 30cm CHILD Left Nail	300
00-1501-0732	1	7mm x 32cm CHILD Left Nail	320
00-1501-0734	1	7mm x 34cm CHILD Left Nail	340
00-1501-0736	1	7mm x 36cm CHILD Left Nail	360
00-1501-0738	1	7mm x 38cm CHILD Left Nail	380
00-1501-0824	1	8mm x 24cm CHILD Left Nail	240
00-1501-0826	1	8mm x 26cm CHILD Left Nail	260
00-1501-0828	1	8mm x 28cm CHILD Left Nail	280
00-1501-0830	1	8mm x 30cm CHILD Left Nail	300
00-1501-0832	1	8mm x 32cm CHILD Left Nail	320
00-1501-0834	1	8mm x 34cm CHILD Left Nail	340
00-1501-0836	1	8mm x 36cm CHILD Left Nail	360
00-1501-0838	1	8mm x 38cm CHILD Left Nail	380
00-1501-0840	1	8mm x 40cm CHILD Left Nail	400
00-1501-0842	1	8mm x 42cm CHILD Left Nail	420
00-1501-0928	1	9mm x 28cm CHILD Left Nail	280
00-1501-0930	1	9mm x 30cm CHILD Left Nail	300
00-1501-0932	1	9mm x 32cm CHILD Left Nail	320
00-1501-0934	1	9mm x 34cm CHILD Left Nail	340
00-1501-0936	1	9mm x 36cm CHILD Left Nail	360
00-1501-0938	1	9mm x 38cm CHILD Left Nail	380
00-1501-0940	1	9mm x 40cm CHILD Left Nail	400
00-1501-0942	1	9mm x 42cm CHILD Left Nail	420

CASE & TRAY

01-1501-0054	1	PEDIATRIC NAILING PLATFORM CHILD LEFT NAILS CASE AND LID

CHILD RIGHT FEMORAL NAILS

Item Number	Qty	Description	Length (mm)
00-1502-0720	1	7mm x 20cm CHILD Right Nail	200
00-1502-0722	1	7mm x 22cm CHILD Right Nail	220
00-1502-0724	1	7mm x 24cm CHILD Right Nail	240
00-1502-0726	1	7mm x 26cm CHILD Right Nail	260
00-1502-0728	1	7mm x 28cm CHILD Right Nail	280
00-1502-0730	1	7mm x 30cm CHILD Right Nail	300
00-1502-0732	1	7mm x 32cm CHILD Right Nail	320
00-1502-0734	1	7mm x 34cm CHILD Right Nail	340
00-1502-0736	1	7mm x 36cm CHILD Right Nail	360
00-1502-0738	1	7mm x 38cm CHILD Right Nail	380
00-1502-0824	1	8mm x 24cm CHILD Right Nail	240
00-1502-0826	1	8mm x 26cm CHILD Right Nail	260
00-1502-0828	1	8mm x 28cm CHILD Right Nail	280
00-1502-0830	1	8mm x 30cm CHILD Right Nail	300
00-1502-0832	1	8mm x 32cm CHILD Right Nail	320
00-1502-0834	1	8mm x 34cm CHILD Right Nail	340
00-1502-0836	1	8mm x 36cm CHILD Right Nail	360
00-1502-0838	1	8mm x 38cm CHILD Right Nail	380
00-1502-0840	1	8mm x 40cm CHILD Right Nail	400
00-1502-0842	1	8mm x 42cm CHILD Right Nail	420
00-1502-0928	1	9mm x 28cm CHILD Right Nail	280
00-1502-0930	1	9mm x 30cm CHILD Right Nail	300
00-1502-0932	1	9mm x 32cm CHILD Right Nail	320
00-1502-0934	1	9mm x 34cm CHILD Right Nail	340
00-1502-0936	1	9mm x 36cm CHILD Right Nail	360
00-1502-0938	1	9mm x 38cm CHILD Right Nail	380
00-1502-0940	1	9mm x 40cm CHILD Right Nail	400
00-1502-0942	1	9mm x 42cm CHILD Right Nail	420

CASE & TRAY

01-1502-0054	1	PEDIATRIC NAILING PLATFORM CHILD RIGHT NAILS CASE AND LID

ADOLESCENT LEFT FEMORAL NAILS

Item Number	Qty	Description	Length (mm)
00-1503-0928	1	9mm x 28cm ADOLESCENT Left Nail	280
00-1503-0930	1	9mm x 30cm ADOLESCENT Left Nail	300
00-1503-0932	1	9mm x 32cm ADOLESCENT Left Nail	320
00-1503-0934	1	9mm x 34cm ADOLESCENT Left Nail	340
00-1503-0936	1	9mm x 36cm ADOLESCENT Left Nail	360
00-1503-0938	1	9mm x 38cm ADOLESCENT Left Nail	380
00-1503-0940	1	9mm x 40cm ADOLESCENT Left Nail	400
00-1503-0942	1	9mm x 42cm ADOLESCENT Left Nail	420
00-1503-1030	1	10mm x 30cm ADOLESCENT Left Nail	300
00-1503-1032	1	10mm x 32cm ADOLESCENT Left Nail	320
00-1503-1034	1	10mm x 34cm ADOLESCENT Left Nail	340
00-1503-1036	1	10mm x 36cm ADOLESCENT Left Nail	360
00-1503-1038	1	10mm x 38cm ADOLESCENT Left Nail	380
00-1503-1040	1	10mm x 40cm ADOLESCENT Left Nail	400
00-1503-1042	1	10mm x 42cm ADOLESCENT Left Nail	420
00-1503-1130	1	11mm x 30cm ADOLESCENT Left Nail	300
00-1503-1132	1	11mm x 32cm ADOLESCENT Left Nail	320
00-1503-1134	1	11mm x 34cm ADOLESCENT Left Nail	340
00-1503-1136	1	11mm x 36cm ADOLESCENT Left Nail	360
00-1503-1138	1	11mm x 38cm ADOLESCENT Left Nail	380
00-1503-1140	1	11mm x 40cm ADOLESCENT Left Nail	400
00-1503-1142	1	11mm x 42cm ADOLESCENT Left Nail	420
00-1503-1230	1	12mm x 30cm ADOLESCENT Left Nail	300
00-1503-1232	1	12mm x 32cm ADOLESCENT Left Nail	320
00-1503-1234	1	12mm x 34cm ADOLESCENT Left Nail	340
00-1503-1236	1	12mm x 36cm ADOLESCENT Left Nail	360
00-1503-1238	1	12mm x 38cm ADOLESCENT Left Nail	380
00-1503-1240	1	12mm x 40cm ADOLESCENT Left Nail	400
00-1503-1242	1	12mm x 42cm ADOLESCENT Left Nail	420

CASE & TRAY

01-1503-0054	1	PEDIATRIC NAILING PLATFORM ADOLESCENT LEFT NAILS CASE AND LID

ADOLESCENT RIGHT FEMORAL NAILS

Item Number	Qty	Description	Length (mm)
00-1504-0928	1	9mm x 28cm ADOLESCENT Right Nail	280
00-1504-0930	1	9mm x 30cm ADOLESCENT Right Nail	300
00-1504-0932	1	9mm x 32cm ADOLESCENT Right Nail	320
00-1504-0934	1	9mm x 34cm ADOLESCENT Right Nail	340
00-1504-0936	1	9mm x 36cm ADOLESCENT Right Nail	360
00-1504-0938	1	9mm x 38cm ADOLESCENT Right Nail	380
00-1504-0940	1	9mm x 40cm ADOLESCENT Right Nail	400
00-1504-0942	1	9mm x 42cm ADOLESCENT Right Nail	420
00-1504-1030	1	10mm x 30cm ADOLESCENT Right Nail	300
00-1504-1032	1	10mm x 32cm ADOLESCENT Right Nail	320
00-1504-1034	1	10mm x 34cm ADOLESCENT Right Nail	340
00-1504-1036	1	10mm x 36cm ADOLESCENT Right Nail	360
00-1504-1038	1	10mm x 38cm ADOLESCENT Right Nail	380
00-1504-1040	1	10mm x 40cm ADOLESCENT Right Nail	400
00-1504-1042	1	10mm x 42cm ADOLESCENT Right Nail	420
00-1504-1130	1	11mm x 30cm ADOLESCENT Right Nail	300
00-1504-1132	1	11mm x 32cm ADOLESCENT Right Nail	320
00-1504-1134	1	11mm x 34cm ADOLESCENT Right Nail	340
00-1504-1136	1	11mm x 36cm ADOLESCENT Right Nail	360
00-1504-1138	1	11mm x 38cm ADOLESCENT Right Nail	380
00-1504-1140	1	11mm x 40cm ADOLESCENT Right Nail	400
00-1504-1142	1	11mm x 42cm ADOLESCENT Right Nail	420
00-1504-1230	1	12mm x 30cm ADOLESCENT Right Nail	300
00-1504-1232	1	12mm x 32cm ADOLESCENT Right Nail	320
00-1504-1234	1	12mm x 34cm ADOLESCENT Right Nail	340
00-1504-1236	1	12mm x 36cm ADOLESCENT Right Nail	360
00-1504-1238	1	12mm x 38cm ADOLESCENT Right Nail	380
00-1504-1240	1	12mm x 40cm ADOLESCENT Right Nail	400
00-1504-1242	1	12mm x 42cm ADOLESCENT Right Nail	420

CASE & TRAY

01-1504-0054	1	PEDIATRIC NAILING PLATFORM ADOLESCENT RIGHT NAILS CASE AND LID

IM NAIL END CAPS

Item Number	Qty	Description	Length (mm)
00-1501-2000	1	CHILD Nail End Cap, Flush	0
00-1501-2005	1	CHILD Nail End Cap, 5mm	5
00-1501-2010	1	CHILD Nail End Cap, 10mm	10
00-1501-2015	1	CHILD Nail End Cap, 15mm	15
00-1501-2020	1	CHILD Nail End Cap, 20mm	20
00-1503-2000	1	ADOLESCENT Nail End Cap, Flush	0
00-1503-2005	1	ADOLESCENT Nail End Cap, 5mm	5
00-1503-2010	1	ADOLESCENT Nail End Cap, 10mm	10
00-1503-2015	1	ADOLESCENT Nail End Cap, 15mm	15
00-1503-2020	1	ADOLESCENT Nail End Cap, 20mm	20

INTERLOCKING SCREWS

Length, mm	Qty	3.8mm Unicortical Peg	4.5mm Fully Threaded Screw	4.5mm Partially Threaded Recon Screw	5.0mm Fully Threaded Screw	5.0mm Partially Threaded Recon Screw
25	2	00-1506-1025	00-1506-2025		00-1506-4025	
27.5	2	00-1506-1027	00-1506-2027		00-1506-4027	
30	2	00-1506-1030	00-1506-2030		00-1506-4030	
32.5	2	00-1506-1033	00-1506-2033		00-1506-4033	
35	2	00-1506-1035	00-1506-2035		00-1506-4035	
37.5	2	00-1506-1037	00-1506-2037		00-1506-4037	
40	2	00-1506-1040	00-1506-2040		00-1506-4040	
42.5	2	00-1506-1043	00-1506-2043		00-1506-4043	
45	2	00-1506-1045	00-1506-2045	00-1506-3045	00-1506-4045	00-1506-5045
47.5	2	00-1506-1047	00-1506-2047	00-1506-3047	00-1506-4047	00-1506-5047
50	2	00-1506-1050	00-1506-2050	00-1506-3050	00-1506-4050	00-1506-5050
52.5	2	00-1506-1053	00-1506-2053	00-1506-3053	00-1506-4053	00-1506-5053
55	2	00-1506-1055	00-1506-2055	00-1506-3055	00-1506-4055	00-1506-5055
57.5	2	00-1506-1057	00-1506-2057	00-1506-3057	00-1506-4057	00-1506-5057
60	2	00-1506-1060	00-1506-2060	00-1506-3060	00-1506-4060	00-1506-5060
62.5	2		00-1506-2063	00-1506-3063	00-1506-4063	00-1506-5063
65	2		00-1506-2065	00-1506-3065	00-1506-4065	00-1506-5065
67.5	2		00-1506-2067	00-1506-3067	00-1506-4067	00-1506-5067
70	2		00-1506-2070	00-1506-3070	00-1506-4070	00-1506-5070
75	2		00-1506-2075	00-1506-3075	00-1506-4075	00-1506-5075
80	2		00-1506-2080	00-1506-3080	00-1506-4080	00-1506-5080
85	2		00-1506-2085	00-1506-3085	00-1506-4085	00-1506-5085
90	2			00-1506-3090		00-1506-5090
95	2			00-1506-3095		00-1506-5095
100	2			00-1506-3100		00-1506-5100

SCREW/END CAP CADDY

01-1501-0050	1	PEDIATRIC NAILING PLATFORM SCREW/END CAP CADDY with LID

INSTRUMENT CASE 1

Item Number	Description	Item Number	Description
11-1500-001	3.2mm Entry Pin	01-1501-0033	3.8mm Drill Sleeve Obturator
01-1501-0006	Secondary Pin Guide	01-1501-0034	4.5mm Drill Sleeve Obturator
01-1501-0009	Tissue Protector	01-1503-0033	4.3mm Drill Sleeve Obturator
01-1500-0001	Stepped Entry Reamer 7.5mm/9.5mm	01-1503-0034	5.0mm Drill Sleeve Obturator
		01-1501-0018	3.8mm Drill Bit, Short
01-1501-0010	Osteotomy Drill Guide	01-1501-0019	3.8mm Drill Bit, Calibrated
01-1501-0011	Reduction Tool	01-1501-0020	4.5mm Stepped Drill Bit, Calibrated
01-1501-0005	Derotation Dial (Toulouse Protractor)	01-1503-0018	4.3mm Drill Bit, Short
		01-1503-0019	4.3mm Drill Bit, Calibrated
11-1500-005	Exchange Tube	01-1503-0020	5.0mm Stepped Drill Bit, Calibrated
01-1001-1001	Inserter Body	01-1501-0021	Depth Gauge, Outer Tube
01-1001-1003	Inserter Knob, Solid	01-1501-0022	Scale, 10-100mm
01-1501-0036	Collet, Small	01-1501-0023	3.5mm Tapered Screw Driver, Short
01-1501-0037	Collet, Large	01-1501-0040	3.5mm Tapered Screw Driver, Long
01-1501-0013	Nail Measurement Tool	01-1501-0025	3.5mm Captured Screw Driver Shaft, Short
01-1501-0014	Guide Rod Obturator	01-1501-0038	Captured Screw Driver Sleeve, Short
01-1500-031	Pusher	01-1501-0039	3.5mm Captured Screw Driver Shaft, Long
01-1501-0015	Outer Screw Sleeve	01-1501-0041	Captured Screw Driver Sleeve, Long
01-1501-0016	Inner Drill Sleeve, 3.8mm Drill	01-1030-001	AO QC Ratcheting Handle
01-1501-0017	Inner Drill Sleeve, 4.5mm Drill	01-1501-0024	T-Handle Hex Driver, Cannulated
01-1503-0016	Inner Drill Sleeve, 4.3mm Drill	01-1500-9019	Ball Hex Driver
01-1503-0017	Inner Drill Sleeve, 5.0mm Drill		

01-1501-0051	Pediatric Nailing Platform Instrument Case #1 with Lid

INSTRUMENT CASE 2

Item Number	Description	Item Number	Description
01-1501-0032	Child Nail Attachment Bolt, Single Use	01-1501-0004	Child Nail AP Position Template
01-1503-0032	Adolescent Nail Attachment Bolt, Single Use	01-1503-0004	Adolescent Nail AP Position Template
01-1501-0002	Child Nail Proximal Targeting Guide	01-1501-0027	3.5mm Explant Driver Shaft
01-1503-0002	Adolescent Nail Proximal Targeting Guide	01-1501-0042	Explant Driver Sleeve
01-1501-0026	Derotation Dial Targeting Guide Attachment	01-1501-0128	Child Nail Extraction Adaptor
01-1501-0003	AP Nail Positioning Jig	01-1503-0128	Adolescent Nail Extraction Adaptor
		01-1501-0029	Extractor
		01-1501-0008	Slotted Mallet
		01-1501-0035	Impactor, Solid

01-1501-0052	Pediatric Nailing Platform Instrument Case #2 with Lid

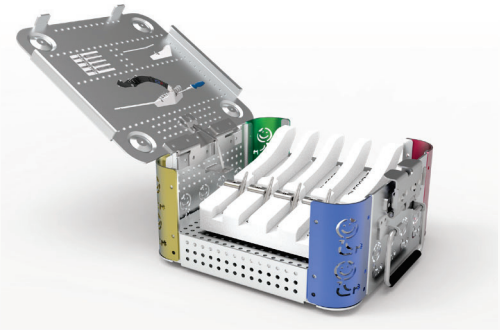
IM REAMER CASE

Item Number	Description	Item Number	Description
01-1501-0060	6.0mm One Piece Flexible Reamer	01-1500-100	10.0mm Modular Reamer Head
01-1501-0065	6.5mm One Piece Flexible Reamer	01-1500-105	10.5mm Modular Reamer Head
01-1501-0070	7.0mm One Piece Flexible Reamer	01-1500-110	11.0mm Modular Reamer Head
01-1500-060	Flexible Reamer Shaft	01-1500-115	11.5mm Modular Reamer Head
01-1500-075	7.5mm Modular Reamer Head	01-1500-120	12.0mm Modular Reamer Head
01-1500-080	8.0mm Modular Reamer Head	01-1500-125	12.5mm Modular Reamer Head
01-1500-085	8.5mm Modular Reamer Head	01-1500-130	13.0mm Modular Reamer Head
01-1500-090	9.0mm Modular Reamer Head	01-1500-135	13.5mm Modular Reamer Head
01-1500-095	9.5mm Modular Reamer Head	01-1500-140	14.0mm Modular Reamer Head

01-1501-0053	Pediatric Nailing Platform IM Reamer Case with Lid

RETAINING ALIGNMENT FIXTURE TRAY

Item Number	Description
01-1501-0100	Retaining Alignment Fixture



MISCELLANEOUS INSTRUMENTS (NOT IN INSTRUMENT CASES)

Item Number	Description
01-1501-0800	2.7mm /3.75mm x 800mm Ball Tipped Guide Wire
01-1501-0801	2.0mm x 800mm Smooth Guide Wire

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 7mm PNP|Femur nail is not recommended for patients weighing greater than 75kg.
- The use of the PNP|Femur system is not recommended for fractures or osteotomies in which all the distal screw holes cannot be fully contained in the distal fragment.
- Distal interlocking with a single dynamic screw is not recommended for length-unstable fractures at any location or length-stable fractures/osteotomies within 3cm of the superior-most distal screw hole.
- The PNP|Femur I 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 design. We decline all responsibility in the case of implants from different sources being mixed.
- 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.

IMPORTANT MEDICAL INFORMATION (CONT.)

MRI Safety Information

In non-clinical testing the OrthoPediatrics Nails 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 F2182-11a, 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.

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.

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