

PediNail™ Pediatric Femoral Nail



PediNail™ Surgical Technique

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The proximal end of PediNail™ accepts a single greater to lesser trochanter screw or a single recon screw.



The distal end of PediNail™ accepts two medial to lateral screws or one anterior to posterior screw.

PediNail™ Surgical Technique

Indications

The OrthoPediatics PediNail™ system is designed for use in pediatric and small stature adult patients 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 OrthoPediatics' PediNail™ is for single use only.

Patient Positioning

First, place the patient on a fracture table in a supine position (Fig. 1). Carefully pad the post to protect the perineum. 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. The proximal femur can be best visualized by arcing the 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 anteroposterior projection.

Alternatively, the patient can be positioned supine on a radiolucent table. The limb (or both limbs in the case of bilateral fractures) can be prepared and draped free. This facilitates simultaneous irrigation and debridement of open femur fractures 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.

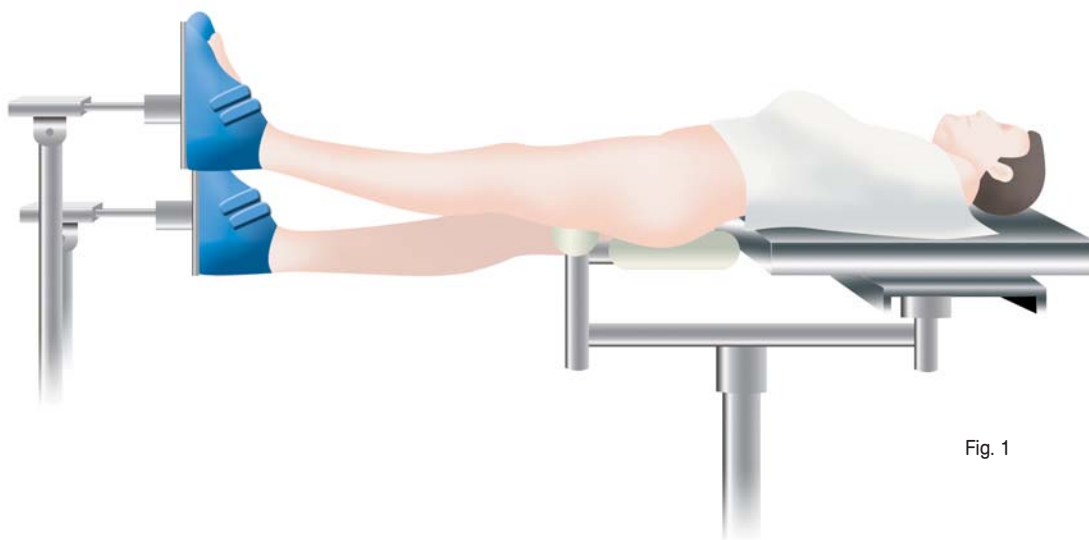


Fig. 1

PediNail™ Surgical Technique

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 (Fig. 2).

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.

Create a 1.5cm incision proximal to the guide wire entry site, passing the proximal incision blade over the guide wire, down to the trochanter.

Place a 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.

Advance the 9.5mm cannulated opening reamer over the 3.2mm threaded tipped guide wire through the trochanter and into the femoral canal (Fig. 3). Withdraw the 9.5mm cannulated opening reamer, leaving the 3.2mm threaded tipped guide wire in the proximal femur. Place the proximal exchange tube into the femoral canal and withdraw the 3.2mm threaded tipped guide wire. Insert the 2.7mm ball tipped reaming rod into the femur to the level of the fracture.

Remove the proximal 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 reaming rod.

After the fracture is reduced, pass the 2.7mm ball tipped reaming rod into the distal femur and impact it in the lateral femoral metaphysis (Fig. 4).



Fig. 2



Fig. 3



Fig. 4

PediNail™ Surgical Technique

Reaming

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 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 (Fig. 5). Insert the measurement gauge into the reamed hole to the appropriate depth. Keep in mind that the nail will usually be countersunk approximately 1.0cm. Select a potential nail. Use the desired nail length to assess the nail diameters that could be used with a given nail length.

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. Beginning with the front cutting 6.0mm reamer with flexible shaft, ream the femoral canal. Increase reaming diameter by 0.5mm increments. Using the front cutting reamers with flexible shaft, ream 6.0mm, 6.5mm and 7.0mm. switch to the flexible shaft and detachable side cutting reamers beginning with the 7.5mm reamer. Utilize the flexible shaft with detachable side cutting reamer heads from 7.5mm to 12.0mm (Fig. 6).

It is not necessary to “fill” the canal or to continue reaming until “chatter” is noted.

If difficulty is encountered passing the reamer across the bend in the 2.7mm ball tipped reaming rod proximally just distal to the greater trochanter, withdraw the reamer and clean the flutes of impacted bone as they can become clogged with cancellous bone. If the reamer does not advance past the bend in the 2.7mm ball tipped reaming rod in the proximal femur, the reamer may be stuck on the bend at the proximal end. To advance the reamer if this happens, grasp the reaming rod with a large needle holder or vise grip and withdraw it 1.0 to 2.0cm and advance the reamer under power.

NOTE: Exchange the 2.7mm ball tipped reaming rod with the 2.0mm smooth guide wire.

Place the exchange tube over the 2.7mm ball tipped reaming rod and insert into the reamed femoral canal. Remove the 2.7mm ball tipped reaming rod and replace with the 2.0mm smooth guide rod. Remove the exchange tube.

Confirm the length measurement taken previously. Place the measurement gauge over the 2.0mm smooth guide wire. Insert the measurement gauge into the reamed hole to the appropriate depth. Keep in mind that the nail will usually be countersunk approximately 1.0cm.



Fig. 5



Fig. 6

PediNail™ Surgical Technique

Nail Placement

Attach the pre-selected nail to the targeting device with the attachment bolt (Fig. 7). Confirm that the nail is oriented correctly and the holes in the nail line up with the guide holes in the targeting device. Prior to insertion of the nail, check for correct orientation by inserting the outer and inner drill sleeves and drill bit. Make sure the drill bit is in line with the interlocking holes in the nail.

Attach the impact rod to the threaded holes in the targeting device for impaction of the nail.

Carefully pass the nail over the 2.0mm smooth guide wire and into the femoral canal. Using controlled blows with the mallet, drive the nail into the distal femur. Impact the nail to approximately 1.0cm 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 smooth guide wire.



Fig. 7

PediNail™ Surgical Technique

Proximal Interlocking

Insert the outer and inner guide tubes into the targeting device and push down to the skin. Mark the skin with the drill sleeves and make a longitudinal incision. Bluntly dissect down to bone. Use the trocar and light blows with a mallet to make a notch in the lateral cortex of the femur. (This is done to insure that the drill bit does not slip off the cortex while drilling.)

Remove the central trocar and insert the 3.2mm calibrated drill bit. Drill through the near cortex. When the far cortex is reached, stop and measure from the calibration on the drill bit.

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.

If a recon screw into the femoral neck is required, the outer and inner guide tubes are placed through the appropriate holes in the targeting guide and lined up radiographically with the center of the femoral neck.

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

Note: The PediNail targeting device was designed to accommodate large and small patient body habitus. In order for it to work as designed, care must be taken to align the targeting device with the holes in the nail.

- *Be certain that the nail is inserted to the appropriate depth before the incision is made for the interlocking screws.*
- *Advance the guide tubes through the handle and dimple the skin where the incision is to be made.*
- *After the incision is made and blunt dissection achieved, use the trocar to notch the cortex to prevent the drill bit from deflecting.*



Fig. 8

Distal Interlocking

Distal interlocking is carried out using the free hand technique (Fig. 9). 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. 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 insure that the drill bit has passed through the nail.

Remove the drill bit from the hole and insert the depth gauge. 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. Check the screw for proper placement and length. Repeat if necessary if two distal screws are desired.



Fig. 9

Closure and Postoperative 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.

If an end cap is desired, reinsert the 2.0mm smooth guide 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 smooth guide 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.) Remove the 2.0mm smooth guide wire.

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

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. First, remove all proximal and distal locking screws. Place the 3.2mm threaded tipped guide wire through the scar and under image intensification drive it down to the proximal end of the nail through the lateral aspect of the greater trochanter, in line with the proximal end of the nail. Check position in both the AP and lateral planes. Open the old incision sharply and dissect down along the guide wire to the trochanter. Advance the 9.5mm cannulated rigid reamer over the guide wire to the nail. If an end cap is in place, advance the 2.0mm smooth guide wire through the hole and pass the cannulated screwdriver over the guide wire to the cap. Remove after engaging the end cap. Pass the extraction adapter over the 2.0mm smooth guide wire, under image intensification, and engage the nail. Tighten the extraction adapter onto the nail.

Remove the 2.0mm smooth guide wire. Attach the slap hammer to the extraction adapter. Gently extract the nail using the slap hammer and extraction adapter.

Irrigate the wounds and close in the usual fashion.

PediNail™ – Left Femur Implant

Medial-Lateral View



7mm 9mm
(not shown actual size)

PRODUCT	PRODUCT #	LENGTH (mm)
7mm X 20cm IM Femoral Nail	10-1500-071	200
7mm X 22cm IM Femoral Nail	10-1500-072	220
7mm X 24cm IM Femoral Nail	10-1500-073	240
7mm X 26cm IM Femoral Nail	10-1500-074	260
7mm X 28cm IM Femoral Nail	10-1500-075	280
7mm X 30cm IM Femoral Nail	10-1500-076	300
8mm X 24cm IM Femoral Nail	10-1500-081	240
8mm X 26cm IM Femoral Nail	10-1500-082	260
8mm X 28cm IM Femoral Nail	10-1500-083	280
8mm X 30cm IM Femoral Nail	10-1500-084	300
8mm X 32cm IM Femoral Nail	10-1500-085	320
8mm X 34cm IM Femoral Nail	10-1500-086	340
8mm X 36cm IM Femoral Nail	10-1500-087	360
9mm X 28cm IM Femoral Nail	10-1500-091	280
9mm X 30cm IM Femoral Nail	10-1500-092	300
9mm X 32cm IM Femoral Nail	10-1500-093	320
9mm X 34cm IM Femoral Nail	10-1500-094	340
9mm X 36cm IM Femoral Nail	10-1500-095	360
9mm X 38cm IM Femoral Nail	10-1500-096	380
Nail End Cap		
5mm End Cap	10-1500-0005	
10mm Nail End Cap	10-1500-0010	
15mm Nail End Cap	10-1500-0015	
20mm Nail End Cap	10-1500-0020	

PediNail™ – Right Femur Implant

PRODUCT	PRODUCT #	LENGTH (mm)
7mm X 20cm IM Femoral Nail	10-1500-021	200
7mm X 22cm IM Femoral Nail	10-1500-022	220
7mm X 24cm IM Femoral Nail	10-1500-023	240
7mm X 26cm IM Femoral Nail	10-1500-024	260
7mm X 28cm IM Femoral Nail	10-1500-025	280
7mm X 30cm IM Femoral Nail	10-1500-026	300
8mm X 24cm IM Femoral Nail	10-1500-031	240
8mm X 26cm IM Femoral Nail	10-1500-032	260
8mm X 28cm IM Femoral Nail	10-1500-033	280
8mm X 30cm IM Femoral Nail	10-1500-034	300
8mm X 32cm IM Femoral Nail	10-1500-035	320
8mm X 34cm IM Femoral Nail	10-1500-036	340
8mm X 36cm IM Femoral Nail	10-1500-037	360
9mm X 28cm IM Femoral Nail	10-1500-041	280
9mm X 30cm IM Femoral Nail	10-1500-042	300
9mm X 32cm IM Femoral Nail	10-1500-043	320
9mm X 34cm IM Femoral Nail	10-1500-044	340
9mm X 36cm IM Femoral Nail	10-1500-045	360
9mm X 38cm IM Femoral Nail	10-1500-046	380
Nail End Cap		
5mm End Cap	10-1500-0005	
10mm Nail End Cap	10-1500-0010	
15mm Nail End Cap	10-1500-0015	
20mm Nail End Cap	10-1500-0020	

Anterior-Posterior View



Screws – 4.0mm and 4.5mm

PRODUCT	PRODUCT #	LENGTH (mm)
4.0 mm (For 7 mm Distal Locking ONLY)		
4.0 X 15	10-1500-2015	15
4.0 X 20	10-1500-2020	20
4.0 X 25	10-1500-2025	25
4.0 X 30	10-1500-2030	30
4.0 X 35	10-1500-2035	35
4.0 X 40	10-1500-2040	40
4.0 X 45	10-1500-2045	45
4.0 X 50	10-1500-2050	50
4.0 X 55	10-1500-2055	55
4.0 X 60	10-1500-2060	60

4.5 mm		
4.5 X 16 Locking Screw	10-1500-3016	16
4.5 X 18 Locking Screw	10-1500-3018	18
4.5 X 20 Locking Screw	10-1500-3020	20
4.5 X 22 Locking Screw	10-1500-3022	22
4.5 X 24 Locking Screw	10-1500-3024	24
4.5 X 26 Locking Screw	10-1500-3026	26
4.5 X 28 Locking Screw	10-1500-3028	28
4.5 X 30 Locking Screw	10-1500-3030	30
4.5 X 32 Locking Screw	10-1500-3032	32
4.5 X 34 Locking Screw	10-1500-3034	34
4.5 X 36 Locking Screw	10-1500-3036	36
4.5 X 38 Locking Screw	10-1500-3038	38
4.5 X 40 Locking Screw	10-1500-3040	40
4.5 X 42 Locking Screw	10-1500-3042	42
4.5 X 44 Locking Screw	10-1500-3044	44
4.5 X 46 Locking Screw	10-1500-3046	46
4.5 X 48 Locking Screw	10-1500-3048	48
4.5 X 50 Locking Screw	10-1500-3050	50
4.5 X 55 Locking Screw	10-1500-3055	55
4.5 X 60 Locking Screw	10-1500-3060	60
4.5 X 65 Locking Screw	10-1500-3065	65
4.5 X 70 Locking Screw	10-1500-3070	70
4.5 X 75 Locking Screw	10-1500-3075	75
4.5 X 80 Locking Screw	10-1500-3080	80
4.5 X 85 Locking Screw	10-1500-3085	85

Screws – 4.5mm continued

PRODUCT	PRODUCT #	LENGTH (mm)
4.5 mm		
4.5 X 45 Recon Locking Screw	10-1500-4045	45
4.5 X 50 Recon Locking Screw	10-1500-4050	50
4.5 X 55 Recon Locking Screw	10-1500-4055	55
4.5 X 60 Recon Locking Screw	10-1500-4060	60
4.5 X 65 Recon Locking Screw	10-1500-4065	65
4.5 X 70 Recon Locking Screw	10-1500-4070	70
4.5 X 75 Recon Locking Screw	10-1500-4075	75
4.5 X 80 Recon Locking Screw	10-1500-4080	80
4.5 X 85 Recon Locking Screw	10-1500-4085	85
4.5 X 90 Recon Locking Screw	10-1500-4090	90
4.5 X 95 Recon Locking Screw	10-1500-4095	95
4.5 X 100 Recon Locking Screw	10-1500-4100	100



4.0mm Screw



4.5mm Screw



4.5mm Recon Screw

(not shown actual size)

Instruments

PRODUCT	PRODUCT #
3.2mm Threaded Tipped Guide Wire	11-1500-001
2.7mm Ball Tipped Reaming Rod	11-1500-006
2.0mm Guide Wire (for nail insertion)	11-1500-002
Exchange Tube	11-1500-004
7.0mm Tissue Protector	01-1500-007
10.0mm Tissue Protector	01-1500-010
12.0mm Tissue Protector	01-1500-012
9.5mm Opening Reamer	01-1500-008
IM Reducer W/ T-Handle	01-1500-9011
Nail Measuring Device	01-1500-014
3.5mm Hex Driver Long Shaft	01-1500-9017
3.5mm Hex Driver Short Shaft	01-1500-9020
Impact Rod	01-1500-9012
Slotted Hammer	01-1500-018
Slap Hammer	01-1500-9013
Targeting Guide	
Insertion Handle	21-1500-9001
Modular Targeting Guide Right	21-1500-9003
Modular Targeting Guide Left	21-1500-9002
2.9mm Drill Bit	01-1500-021
3.2mm Calibrated Drill Bit	01-1500-9015
4.5mm Calibrated Drill Bit	01-1500-9016
3.2mm Drill Bit	01-1500-024
Outer Guide Tube	21-1500-9006
4.5mm Guide Tube	21-1500-9007
3.2mm Guide Tube	21-1500-9008
Ball Hex Driver	01-1500-9019
T-Handle	01-1500-026
3.2mm Trocar	01-1500-9014
Obturator	01-1500-031
Extraction Adapter	01-1500-9018
AO to Zimmer Adapter	01-1500-034
Depth Gauge	01-1500-035
AO Q/C Handle	01-1030-001
T-Handle Chuck	01-1500-036

Instruments

PRODUCT	PRODUCT #
7.5mm Reamer Head	01-1500-075
8.0mm Reamer Head	01-1500-080
8.5mm Reamer Head	01-1500-085
9.0mm Reamer Head	01-1500-090
9.5mm Reamer Head	01-1500-095
10.0mm Reamer Head	01-1500-100
10.5mm Reamer Head	01-1500-105
11.0mm Reamer Head	01-1500-110
11.5mm Reamer Head	01-1500-115
12.0mm Reamer Head	01-1500-120
Flexible Reamer Shaft	01-1500-060
Sterilization Case Part # (regulatory use)	
6.0mm One Piece Reamer	01-1500-0160
6.5mm One Piece Reamer	01-1500-0165
7.0mm One Piece Reamer	01-1500-0170

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

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

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

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

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.*

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