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Indications/Contraindications SHORT PFN:

Indications

- Pertrochanteric fractures
- Inter trochanteric fractures
- High sub trochanteric fractures

Contraindications

- Low sub trochanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures

Long PFN:

Indications

- Low and extended sub trochanteric fractures
- Ipsilateral trochanteric fractures
- Combination of fractures (trochanteric area/shaft)
- Pathological fractures

Contraindications

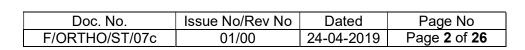
Isolated or combined medial femoral neck fractures

ADVERSE REACTIONS

- Adverse reactions may include but are not limited to:
- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.



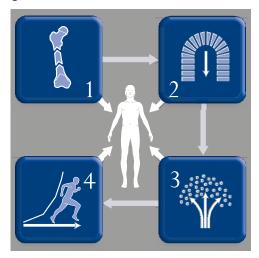






AOPrinciples

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.



Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.

Early, active mobilization Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

Stable fixation

Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

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Preparation

Patient positioning

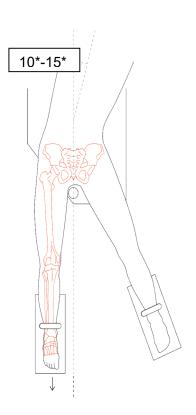
Position patient supine on an extension table or a radiolucent operating table. Position the C-arm of the image intensifier in such a way that it can visualize the proximal femur exactly in the lateral and AP planes.

For unimpeded access to the medullary cavity, abduct the upper part of the body by about 10–15° to the contralateral side (or adduct the affected leg by 10–15°).

Determine CCD angle

Take an AP X-ray of the unaffected side preoperatively. Determine the CCD angle using a Radiographic Ruler.

Short PFN is available in 125°/130°/135°.



Reduce fracture

If possible, carry out closed reduction of the fracture under Image intensifier control. Under Exact reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

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Precautions:

- Instruments and screws may have sharp edges or moving joints that may pinch or tear user's glove or skin.
- Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

Determine nail diameter

Under image intensifier control, place the Radiographic Ruler on the femur and position the square marking over the isthmus. If the transition to the cortex is still visible to the left and right of the marking, the corresponding nail diameter may be used.



Note: When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.

Approach

Palpate the greater trochanter.

Make a 5 cm incision approximately 5 to 8cm proximal from the tip of the greater trochanter. Make a parallel incision in the fasciae of the gluteus medius and split the gluteus medius inline with the fibers.

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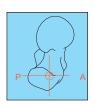
Surgical Technique for Short PFN:

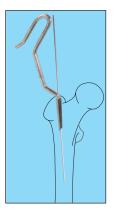
1. Determine nail insertion point and insert Guide Wire

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity. The mediolateral angle of the implant amounts to 6º. This means that the short 2.5 mm Guide Wire must be inserted laterally at an angle of 6º to the shaft. The short guide wire can be inserted either through Cannulated Bone Awl manually with the T-Handle with Chuck.

In lateral view, place the guide wire in the centre of the medullary cavity to a depth of about 15 cm.

Enlarge the entry point with the help of Cannulated Bone Awl. Remove the Bone Awl.





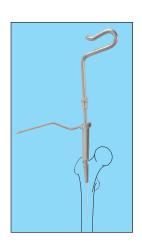
Note: A correctly selected insertion point and angle are essential for a good surgical result. Check the correct position of the guide wire with the aid of x-rays and by positioning a nail anteriorly on the femur.

2. Opening of the femur

Insert the Initial Step Reamer over the guide wire through the protection sleeve with handle and ream manually as far as the stop on the protection sleeve. Remove protection sleeve and guide wire.

Precautions:

- Dispose of the used guide wires, do not reuse them.
- Particularly careful drilling is required with unstable multi fragment fractures. Specially, avoid varus displacement of the medial fragment by making sure that the hole is drilled both in the medial fragment and the lateral part of the femur.



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3. Assemble instruments:

Pass the Nail Holding Bolt through Targeting Device/ Nail Holder and secure the nail tightly to the Targeting Device using the Socket Wrench with T handle. The nail diameter has already been determined during preparations for surgery.

Ensure that the connection is tight to avoid deviations when inserting the Lag screws through the Targeting Device.



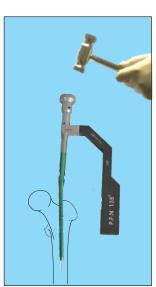
Carefully insert the nail manually as far as possible into the femoral opening. Slight twisting hand movements help insertion. If the nail cannot be inserted, select a smaller size nail diameter.

Insertion can be supported by light blows with the Hammer on the Impactor Head.

Precautions:

- If the medullary canal is too narrow, it should be reamed to at least 10 mm.
- Make sure that the nail is tightly screwed to the Targeting Device before inserting the nail.
- Tap gently on the Targeting Device. The use of excessive force will result in loss of reduction or bone fracture. Apply taps only to the Impactor part.
- An excessively cranial or caudal nail position will result in incorrect placement of the screws and should therefore be avoided at all.





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5. Checking Nail position:

Tightly secure the appropriate the Targeting Device.

The position of the tip of the nail can be checked by inserting a guide wire of 2.5mm through the Targeting Device.

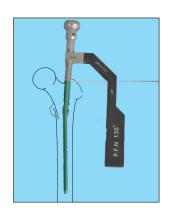


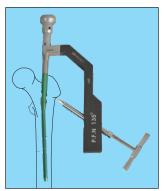
Make a stab incision and insert the Protection Sleeve for 8mm through the Targeting Device to the bone. Mark the femur with Lag Screw Awl for 8mm.

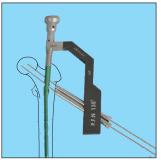
Insert a **new Threaded 2.5mm** Guide Wire through the Guide Sleeve, check direction and position under image Intensifier in AP and lateral views. Choose a position in the caudal area of the femoral head so that both proximal screws can be inserted. Insert the guide wire 5mm deeper into the femoral head than the planned femoral head screw 8mm. The final position of the guide wire should be in the lower half of the femoral neck. In lateral view, the wire should be positioned in the centre of the femoral neck.

Note: If the nail has to be repositioned, remove guide wire, protection sleeve and guide sleeve. The nail can now be repositioned by rotation, deeper insertion or partial retraction. Then reinsert the sleeve system and guide wire.

Precaution: Make sure the Targeting Device is not moved before inserting the guide wire. Reaming over a bent guide wire can result in Reamer breakage or damaging of the nail itself.





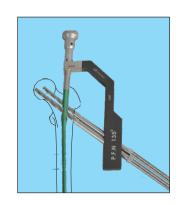


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7. Insertion of guide wire for Lag Screw 6.4mm:

Insert the Protection Sleeve for 6.4mm with guide sleeve through the Targeting Device to the bone. Make an initial mark with Lag screw Awl for 6.4mm and then remove the awl and insert a second new threaded 2mm guide wire through the guide sleeve in to the bone. The tip of the guide wire should be positioned at least 20mm medial of the fracture line and 5mm deeper than the planned lag screw 6.4mm, but approximately 15–20 mm less deep than the planned femoral lag screw 8mm.



Note: Verify that the guide wires are parallel in both planes and that their tips form a horizontal line on the AP view. **Note:** As only the femoral lag screw 8mm has a load-bearing function, the hip lag screw 6.4mm should always be 15–20 mm shorter than the femoral lag screw 8mm.



8. Measure length of hip lag screw 6.4mm

It is recommended to start with the insertion of the hip lag screw 6.4mm to prevent possible rotation of the medial fragment when inserting the femoral lag screw 8mm.

Remove the guide sleeve and ream with the 6.4mm cannulated reamer. The length of the required lag screw 6.4mm can be verified from the calibration given on the reamer.

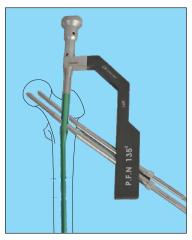
The length of this lag screw is indicated on the reamer shaft and calculated to end 5 mm before the tip of the guide wire.

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9. Procedure in hard bone

In hard or young bone, tapping with the cannulated 6.4mm Tap and/or 8mm is recommended up to the length of the lag screw previously measured.

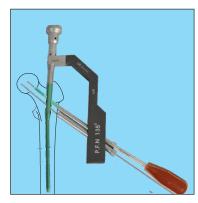


10.Insertion of Lag screw 6.4mm:

Use the cannulated Screwdriver for lag screw to insert the selected lag screw over the guide wire to the stop.

Remove and discard the 2mm guide wire of the lag screw 6.4mm.

Precaution: Do not insert the lag screw with undue force. Ensure that the lateral end of the lag screw clearly protrudes from the lateral cortex. Check under image intensification that the lag screw is not inserted too far.

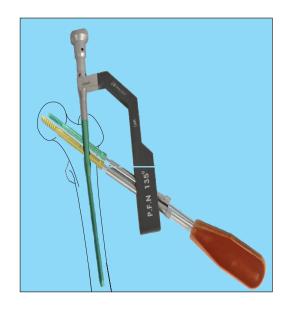


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12. Measure length of lag screw 8mm:

Remove the Guide sleeve 2.5mm and insert the cannulated reamer 8mm over the second 2.5mm guide wire through the protection sleeve 8mm until it touches bone. Start reaming until approx. 5mm before the tip of the guide wire. Now check the measured length on the 8mm Reamer by setting the appropriate position. The correct length is indicated on the tip of the protection sleeve.



Note: Tapping is not required due to the self-tapping tip of the lag screw.

Precautions:

If the guide wire has been bent slightly during insertion, the reamer can be guided over it using careful forward and backward movements.

If the guide wire has been bent to a greater extent, it should be reinserted or replaced by a new one. However, in some cases it is possible to cautiously complete reaming without a guide wire.

13. Insertion of Lag Screw 8mm:

Engage the Cannulated Screw Driver for lag screw and secure it tightly to the selected lag screw. Insert the lag screw over the 2.5mm guide wire to the stop. Remove the cannulated screw driver.

Remove and discard the 2.5mm guide wire of the lag screw. Finally, remove both protection sleeves from the Targeting Device. Check under image intensification that the lag screw 8mm protrudes slightly over the lateral cortex.

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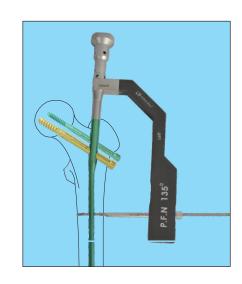


14. Drilling the distal locking hole:

Distal locking is usually performed with a single interlocking screw 4.9mm.

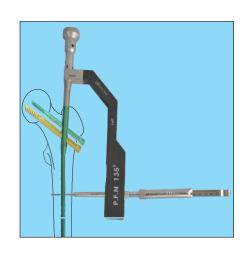
Use the cranial locking hole only for static interlocking, and the caudal locking hole for dynamic interlocking.

Subtrochanteric fractures may be locked in both distal holes. Postoperative removal of the static locking screw allows secondary dynamization. Make a stab incision and insert the distal protection sleeve through the Interlocking hole selected in the Targeting Device to the bone. Use Lag screw awl 6.4mm to mark the cortex. Remove the lag screw awl and drill through both cortices using the 4mmx10" Drill Bit. Insert the Long Depth Gauge to read the length of the required Interlocking screw. Ensure that the front sleeve of the depth gauge has good bone contact to get exact reading. The reading shows length without the head of the screw.



Precautions:

- Before distal locking, ensure that no diastasis has occurred intraoperatively. Healing may be delayed if the distal locking screws are secured despite the presence of diastasis.
- Ensure that all connections between the nail,
 Targeting Device and Nail holding bolt are still secure, otherwise the nail itself may be damaged during drilling of the distal locking holes.



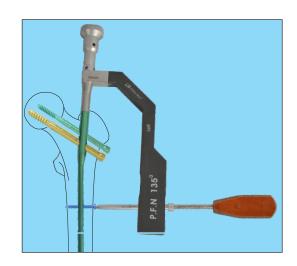
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15. Insertion of Interlocking screw:

Insert the Interlocking screw through the protection sleeve using the long Hexagonal Screwdriver 4.9mm. Ensure firm grip in the head of the screw.

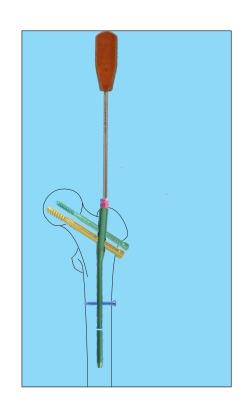
Remove the protection sleeve and the Targeting Device using the Socket Wrench with T Handle.



16. Insertion of End Cap

Align the end cap with the nail axis using the cannulated lag screwdriver in order to prevent tilting. Screw the end cap completely onto the nail until its collar touches the proximal end of the nail.

In order to avoid losing the end cap and to facilitate insertion, the end cap can also be inserted on guide wire 2.5mm. First pass the guide wire on nail till it goes and then slide the end cap over guide wire. Pass the cannulated lag screwdriver over guide wire and tighten the end cap with the cannulated lag screwdriver.



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Surgical Technique for Long PFN

Note:

This surgical technique for Long PFN is based on the Short PFN surgical technique. In order to follow the correct procedure, please refer to the respective steps in the Short PFN Surgical technique shown above in page nos. 5 to 12 for Patient positioning- Reduction- Approach-Opening femur canal- nail insertion and lag screw fixation. This part only shows the steps regarding insertion and distal interlocking of the long PFN which differ from the standard short PFN technique.

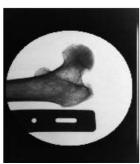
Usually, the 130° nail is suitable for most indications. In some cases, however, the use of a 135° nail may be indicated.

1. Determine nail length:

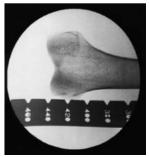
Position the image intensifier for an AP view of the proximal femur. Use long forceps to hold the Radiographic Ruler alongside the lateral aspect of the thigh parallel to and at the same level as the femur. Adjust the C-arm so the beam is centered between the femur and ruler, this will reduce magnification errors. Adjust the ruler until the top is level with the tip of the greater trochanter. Mark the skin at the top of the ruler.

Move the image intensifier to the distal femur, place the proximal end of the Radiographic Ruler at the skin mark, and take an AP image of the distal femur. Verify fracture reduction. Read nail length directly from the ruler image, selecting the measurement that is at or just proximal to the physeal scar, or at the chosen insertion depth.

Consider the nail range of 34, 38 and 42cm.



Position the Radiographic Ruler



Check nail length

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2. Determine nail insertion point and insert long guide wire:

In the AP view, the nail insertion point is normally found on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity. The mediolateral angle of th e implant amounts to 6°. This means that the 2.5mm Long Guide Wire must be inserted laterally at an angle of 6° to the shaft. The long guide wire can be inserted manually with the T-Handle with chuck.

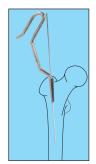
Enlarge the entry point with the help of Cannulated Bone Awl. Remove the Bone Awl.

In the lateral view, place the guide wire in the centre of the medullary cavity.



The long guide wire is already in the medullary canal, if the reduction has been achieved by means of the reduction technique. For initial reaming, the fixed or flexible shaft (not a part of Ortho Max Instruments System) is required with 8mm Reamer Head.





Use the Electric reaming handpiece for flexible shaft or Rigid reamer with T handle and slight but uniform force to advance the reamer in the medullary canal. Move the reamer shaft forwards and backwards to remove the bone chips from the reamer cutting flutes. This prevents jamming of the reamer in the medullary canal. Ream to the desired dia. in 0.5 mm increments in case of flexible reamer or 1mm increments in case of rigid reamers. Always remember to remove the guide wire before locking the intramedullary nail.

Note: Choose the appropriate nail for the left or right leg.

4. Insert long Proximal Femoral Nail

If no reaming has been performed, the guide wire may help nail insertion, but is usually not necessary. Carefully insert the nail manually (be it over the guide wire or not) as far as possible into the femoral opening. Slight twisting hand movements help insertion. If necessary, insertion can be supported by light hammering blows on impactor head. Remove the guide wire.

Precautions:

Avoid unnecessary use of force and only hit the hammer on the impactor head. Do not hit the most proximal end of the guide wire.

If too much force is needed for insertion, the nail should be removed and the femoral shaft should be reamed again.

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It is important to check that the nail is always tightly connected to the Targeting Device. This has to be checked especially after hammering.

5. Insertion of Lag screws 6.4mm and 8mm:

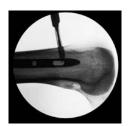
Please refer to the Short PFN surgical technique and choose the 135° or 130° Targeting Device for the corresponding CCD-angle of the chosen nail. The rest of the technique remains same as shown on page nos.5 to 12.

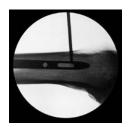
6. Distal locking in Long PFN (Free Hand Technique):

Distal locking is usually performed with two Interlocking screws. For static interlocking position the Interlocking screw 4.9mm at the proximal end of the hole, for dynamic interlocking position it at the distal end of the hole. If immediate dynamization is required, only use the dynamic hole slot. For secondary dynamization insert both Interlocking screws and remove the static screw at a later date.

Reconfirm reduction/alignment of the distal fragment.

Align the image intensifier with the cranial hole in the nail until a perfect circle is visible in the centre of the screen. Determine the incision point on the skin by placing point of Drill bit 4mmx10" and make a stab incision.







Under image intensification, insert the tip of the 4mm Drill Bit into the incision and place the bit oblique to the X-ray beam until the tip is centered in the locking hole. Tilt the drive until the drill bit is in line with the beam and appears as a radio-opaque solid circle in the centre of the outer ring. The drill bit will nearly fill the locking hole image. Hold the drill in this position and drill through both cortices.

Measure the needed Interlocking screw length using the Long Depth Gauge 4.9mm, adding 2–3 mm to the reading to ensure thread engagement in the far cortex. Insert the Interlocking screw using the long Hexagonal Screwdriver 4.9mm. Repeat the procedure for the second distal Interlocking screw.

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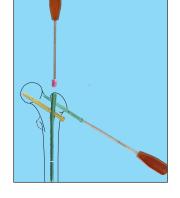
7. Insert End Cap

Please refer to the Short PFN surgical technique to insert the end cap.

Implant Removal

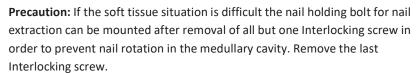
1. Remove Lag Screws 6.4mm and 8mm:

Having made an incision through the old scar, the screws can be localized using palpation or the image intensifier in some cases, the instruments have a better grip on the screws if a 2.5mm Guide Wire is inserted. First remove the end cap using cannulated lag screw driver and insert the Nail Holding Bolt into the Proximal nail Threaded end. Only then may the lag screws of 6.4mm, 8mm be removed by using cannulated lag screw driver and the Interlocking screws may be removed by using long hexagonal screw driver 4.9mm. To extract the Interlocking screws of distal end , Hexagonal screw driver with quick coupling sleeve-4.5mm may be required additionally for better grip in reverse force.



2. Extract nail

To remove the nail, mount the extractor rod, head and ram onto the nail holding bolt. Ensure that the nail holding bolt is firmly seated in the nail, the tommy bar may be used for this purpose. Now extract the nail with slight hammer blows.



Note: If the removal of the nail is not possible with the standard extractor set, use the Universal nail extractor set with 6 bolts for Tibia, Femur Nails, PFN, TFN and PFNAR and the corresponding surgical technique.



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CAUTION:

Used Implants:

Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuses of implants are strictly not recommended.

Disposal of Used Implants:

Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

PACKAGING MATERIAL DISPOSAL:

The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such ways that keep out of reach of children and stray animals.

SINGLE BRAND USAGE:

Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

MRI SAFETY INFORMATION

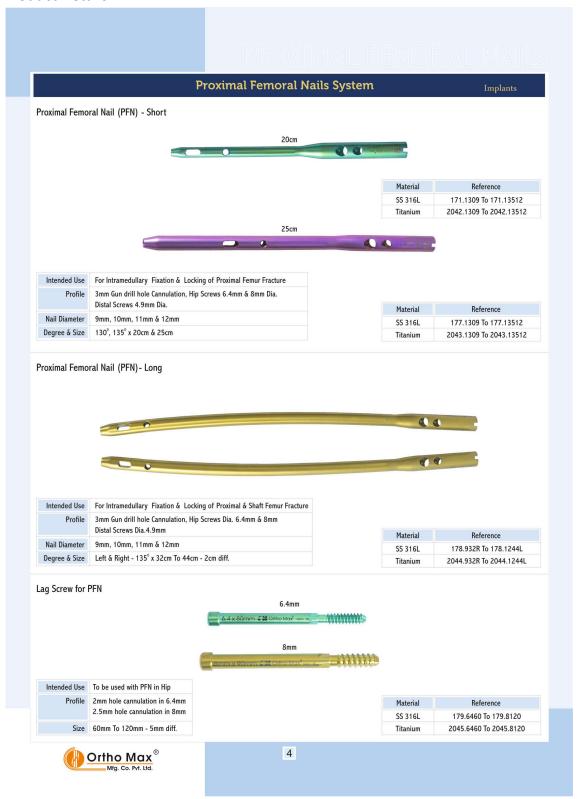
- Ortho Max Mfg. Co Pvt. Ltd. implants are manufactured from Titanium Gr.2, SS316L, SS316LVM material for Bone Plate & Titanium Gr.5, SS316L, SS316LVM material for Bone Screw, Pins & Wires, both are non-magnetic material, hence it do not pose any safety risk.
- Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment.
- Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.
- The Ortho Max Mfg. Co Pvt. Ltd. implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks. The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

END OF SURGICAL TECHNIQUE.

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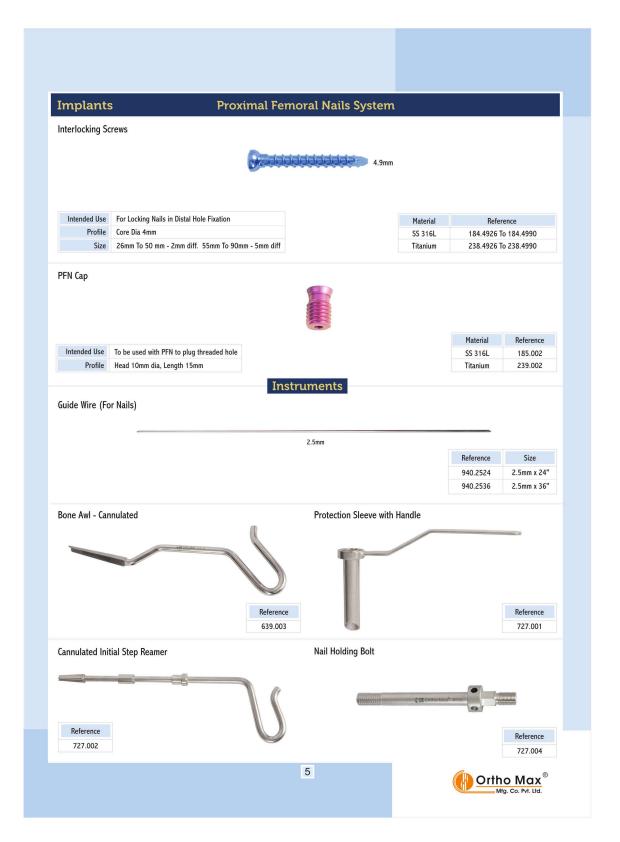


Product Details:



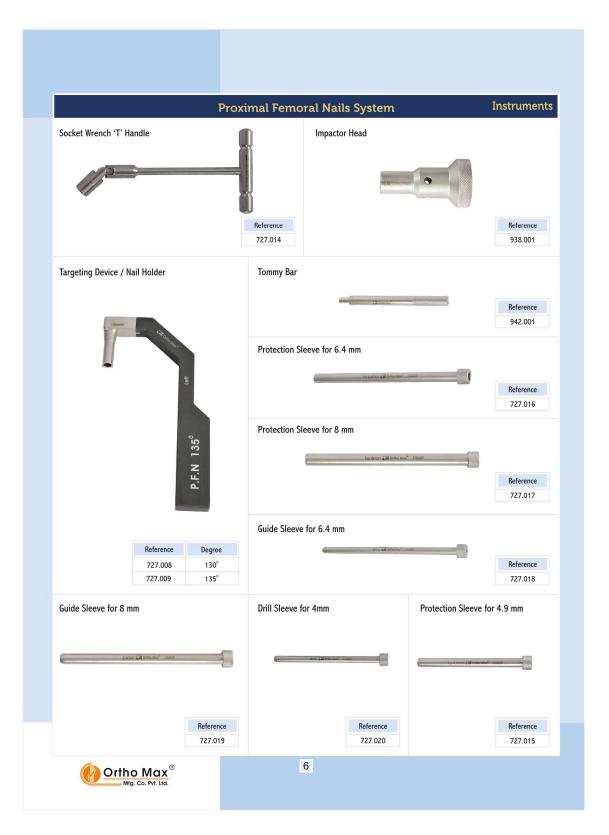
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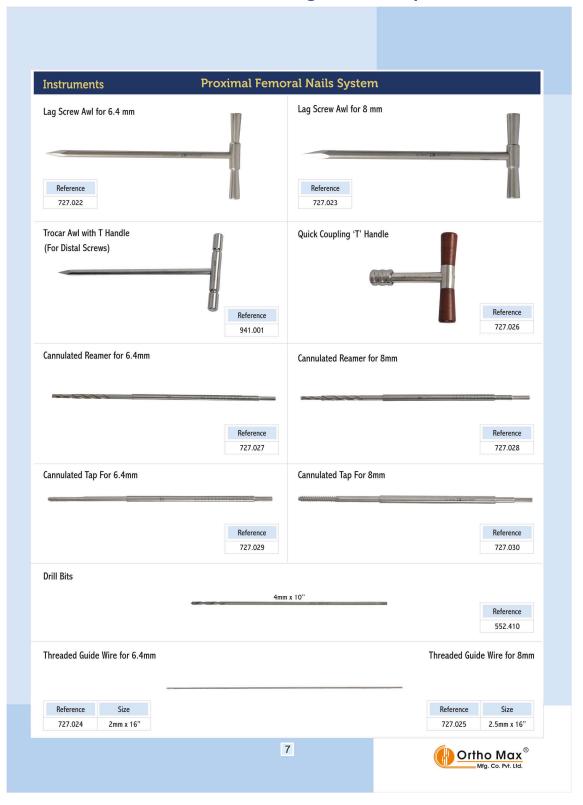
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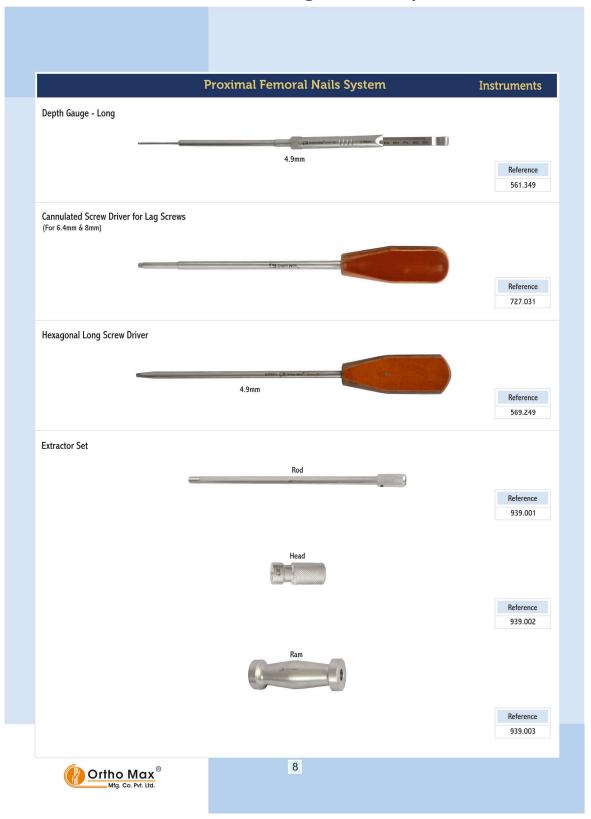
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PFN Nail Targeting Device Assembly P.F.N 135° Left

PFN SET SHORT SERIES CONTENTS:

Implants :-	Qty
Proximal Femoral Nail (PFN) - Short - 130°. 135° x 9, 10, 11, 12mm x 20 cm or 25cm - 2 each	16 Nos
Lag Screws for PFN	
- 6.4mm x 60mm, 100mm -1 each	02 Nos
x 65mm To 95mm - 2 each	14 Nos
- 8mm x 70, 75, 80mm - 1 each	03 Nos
x 85mm To 105mm - 2 each	10 Nos
x 110, 115, 120mm - 1 each	03 Nos
Interlocking Screws	
- 4.9mm x 28mm To 50mm - 3 each	36 Nos

PFN SET SHORT & LONG SERIES CONTENTS:

Implants :-	Qty
Proximal Femoral Nail (PFN) - Short - 130°. 135° x 9, 10, 11, 12mm x 20 cm or 25cm - 1 each	08 Nos
Proximal Femoral Nail (PFN) - Long (Left & Right) - 135° x 9, 10, 11mm x 36, 38, 40, 42cm - 1 each	24 Nos
Lag Screws for PFN - 6.4mm x 60mm, 100mm -1 each	02 Nos 14 Nos 03 Nos 10 Nos 03 Nos
Interlocking Screws - 4.9mm x 28mm To 85mm - 3 each	57 Nos

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Instruments :-	
- Bone Awl - Cannulated	01 No
- Guide Wire - 2.5mm x 24"	02 Nos
- Guide Wire - 2.5mm x 36"	02 Nos
- Protection Sleeve with Handle	01 No
- Cannulated Initial Step Reamer	01 No
- Nail Holding Bolt	01 No
- Socket Wrench 'T' Handle	01 No
- Targeting Device/Nail Holder 130°,135°	02 Nos
- Protection Sleeve for 6.4mm	01 No
- Protection Sleeve for 8mm	01 No
- Protection Sleeve for 4.9mm	01 No
- Guide Sleeve for 6.4mm	01 No
- Guide Sleeve for 8mm	01 No
- Drill Sleeve for 4mm	01 No
- Tommy Bar	01 No
- Impactor Head	01 No
- Quick Coupling 'T' Handle	01 No
- Lag Screw Awl for 6.4mm	01 No
- Lag Screw Awl for 8mm	01 No
- Trocar Awl with T Handle	01 No
- Cannulated Reamer for 6.4mm, 8mm	02 Nos
- Cannulated Tap for 6.4mm, 8mm	02 Nos
- Drill Bits 4mm x 10"	02 Nos
- Threaded Guide Wire for 6.4mm	02 Nos
- Threaded Guide Wire for 8mm	02 Nos
- Depth Gauge - Long 4.9mm	01 No
- Cannulated Screw Driver for Lag Screws	01 No
- Hexagonal Long Screw Driver 4.9mm	01 No
- Extractor Set with Bolt	01 Set
- All in One PFN - Implants & Instruments Set Container	01 No



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Implants Certified by ITC:

Instruments Certified by Self Declaration :



MFG. UNIT & REGD. OFFICE C-1-B/886/4, G.I.D.C. ESTATE MAKARPURA, VADODARA – 390 010 GUJ. INDIA

Tel: +91-89800 15555 +91-89800 25555

E-mail: <u>info@orthomaxindia.net</u>

admin@orthomaxindia.net

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