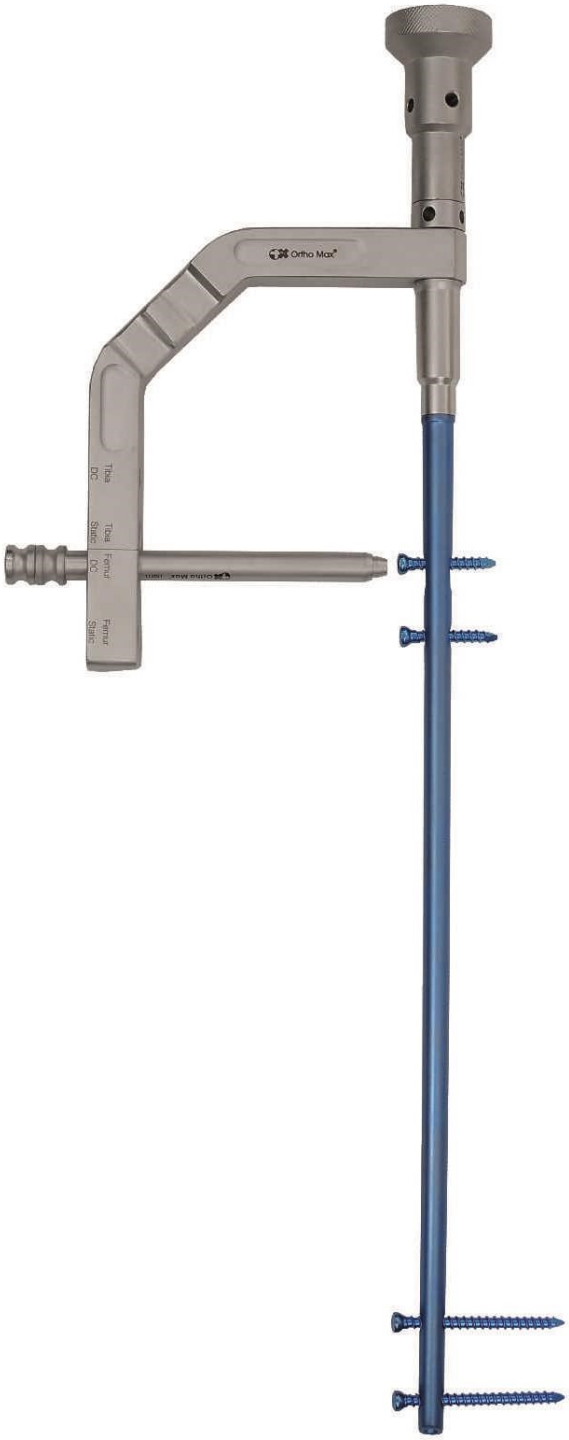
FEMUR INTERLOCKING NAIL SYSTEM
SURGICAL TECHNIQUE

CE 1023



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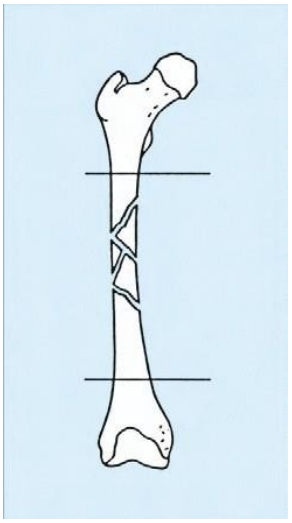
FEMORAL NAILING TECHNIQUE

INDICATIONS

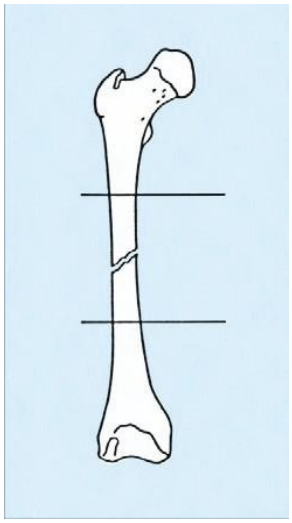
Femur fractures with bony support (stable fracture in the middle third of the femur, with or without locking):

- transverse fractures
- short oblique fractures
- pseudarthroses



Indications for Locking Technique Femur fractures without bony support (unstable fracture in 60% of the femoral length):

- fractures near the metaphysis
- long torsional fractures
- segmental fractures
- comminuted fractures
- fractures with bone defects



Contraindications:

There are no specific contraindications but do not use the Ultra Lock Tibia Nail in cases of:

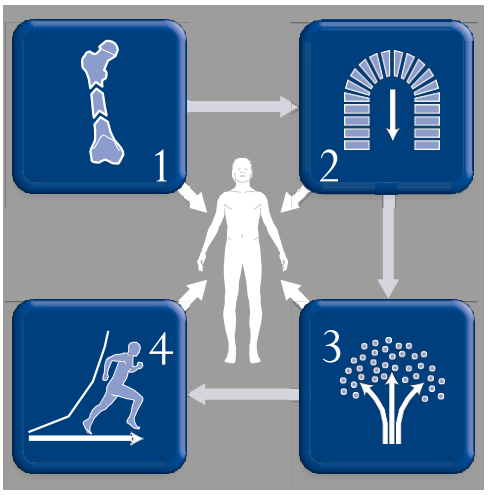
- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance

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

AO Principles

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.

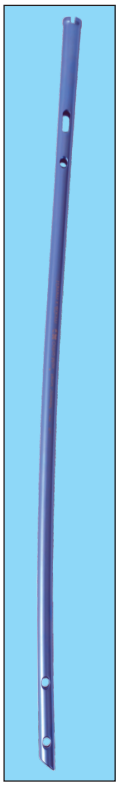
Stable fixation

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.

PREOPERATIVE PLANNING

NAIL SELECTION



Although definitive nail length and diameter are deter- mined intra operatively, nail selection should be part of the preoperative plan.

An approximate nail length is determined by measuring the patient from the tip of the greater trochanter to the knee joint space and subtracting 2 cm.

An approximate nail diameter is determined by measuring the isthmus of the affected medullary canal from an X-ray. If the isthmus is obliterated by the fracture pat- tern, a measurement is made from the contralateral side.

The Radiographic Ruler, available separately may also be used to determine approximate nail size. The ruler depicts the nails 15 % larger than actual size, to compensate for the magnification which occurs when taking an X-ray at the standard tube-to-film distance of one meter. Placing the ruler directly over the preoperative X-ray of the uninjured leg provides an estimation of nail length and diameter.

Based on these measurements, a minimum of three diameters of nails in three lengths should be available for surgery.

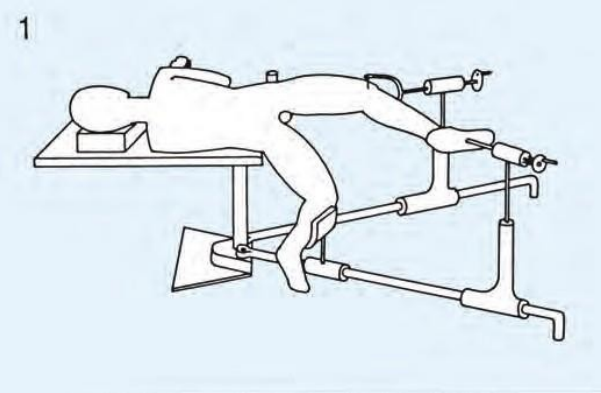
Dynamisation / Use of bone graft:

In nailing of Femur fractures, secondary Dynamisation (removal of the static proximal Interlocking screws) during the healing process might be important. Dynamisation should be considered, if a fracture gap could not be avoided during primary surgery and in cases of radiographic absence of callus. In defect situations, cancellous bone grafting should be considered. Decision making for Dynamisation or bone grafting should be considered within 6–8 weeks after nailing.

PATIENT POSITIONING

The fracture may be reduced using open or closed technique. Closed reduction is the preferred method, with the patient positioned on a fracture table or radiolucent operating table; an image intensifier is needed. Correction of rotation and reduction should be carried out before sterile draping, because it is difficult to achieve reduction intra operatively.

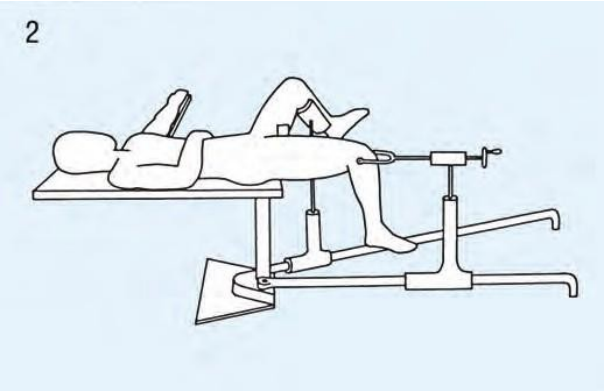
1 Lateral Positioning on a Fracture Table



A fracture table with long cantilevers is used. The patient is placed in a lateral decubitus position. The pelvis is held vertical with the supports on each side of the table. The patient is slid downwards on the table until the perineum rests on a well-cushioned perineal post.

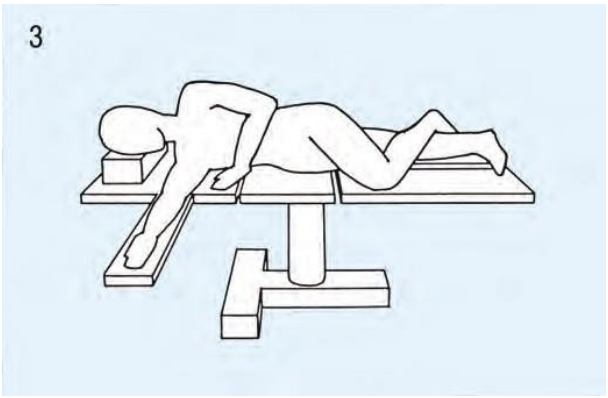
A traction pin is placed in the intercondylar area of the injured leg to apply traction and aid reduction. The foot of the injured leg is placed in a boot. The uninjured leg is flexed at the hip and knee, and supported by a brace. The uninjured leg should be externally rotated to allow the image intensifier to be adjusted freely.

2. Supine Positioning on Fracture Table



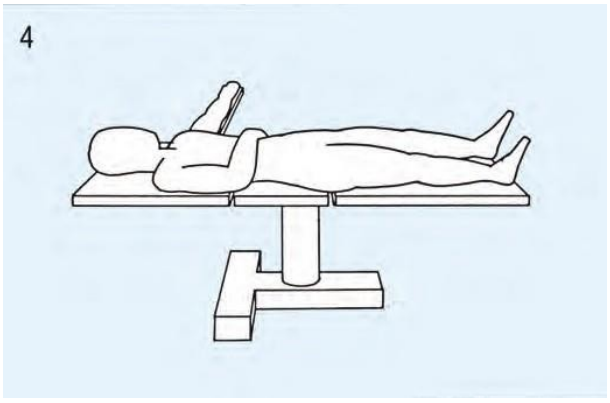
With the patient in the supine position, the leg of the in- jured femur is allowed to hang with the knee flexed 90°. The patient's pelvis should be positioned flat, providing correct rotational alignment of the femur. To allow ac- cess to the proximal femur, either adduct the injured leg, or shift the torso to the uninjured side, while keeping the pelvis flat. The uninjured leg is placed in a support.

3. Lateral Positioning on a Standard Table



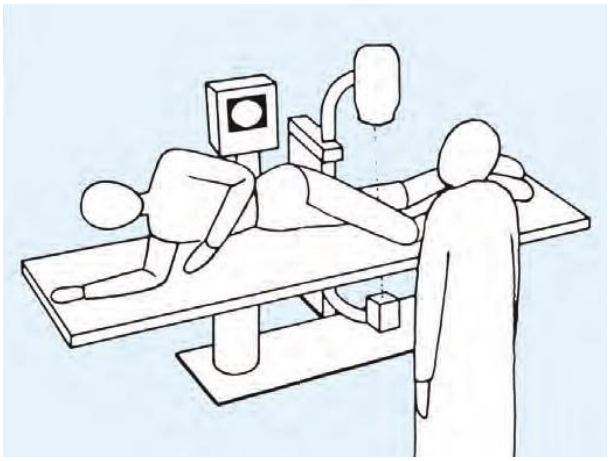
The operating table must be radiolucent. The patient is placed in a lateral position (a vacuum mattress may be helpful for this purpose). The injured leg is flexed for- ward 45°, and with the knee bent 90°, is placed over the uninjured leg. The Large Femoral Distractor can be used to aid reduction and correct rotational alignment.

4. Supine Positioning on a Standard Table



The operating table must be radiolucent. The patient is placed in a supine position. To allow access to the proxi- mal femur, the uninjured leg is abducted as far as possi- ble, and the injured leg is adducted. The Large Distractor is used to aid reduction and correct rotational alignment.

Use of the Image Intensifier

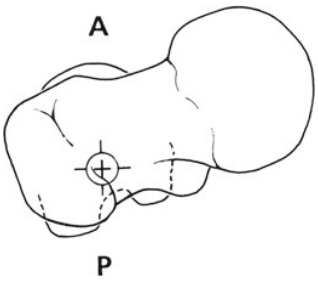


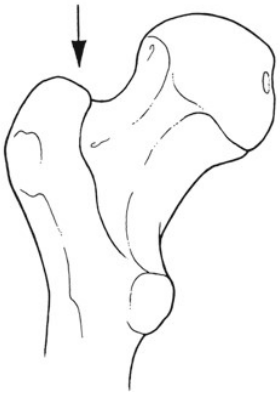
An image intensifier is required for both closed reduc- tion and distal locking techniques. The image intensifier allows controlled viewing of the fracture zone for inser- tion of the reaming rod, medullary reamer heads, and universal nail.
Proper positioning of the image intensifier is extremely important for locating the distal locking holes. With the patient in the lateral decubitus or supine position, the ra- diation source should be placed on the medial aspect of the femur. This will facilitate the aiming process, which is performed laterally.

NAIL INSERTION

Entry Point

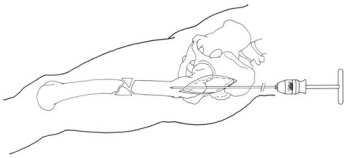
Selecting the proper entry point is important to prevent complications during nail insertion. This entry point must be in line with the medullary canal. Studies of the geometry of the medullary canal show that the ideal entry point is immediately in or just posterolateral to the piriformis fossa.





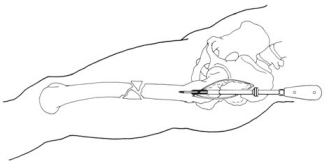
Opening the Medullary Canal

Make a longitudinal incision proximal to the greater trochanter and make entry point with Bone awl straight to open the medullary canal.



Enlarge the Entry Point

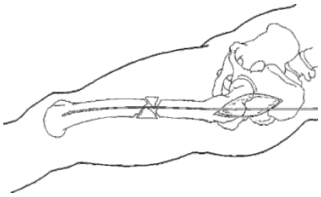
Pass and Rotate the Bone awl , place its tip at the correct entry point, and turn it to open the medullary canal to a minimum depth of 5 cm. (Image intensification may be required.)



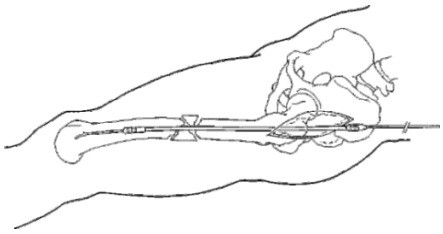
Note: For pseudarthroses or hypertrophic -non unions, use fixed hand reamers sequentially to open the canal.

Inserting the Guide Wire

Under image intensification, insert the 2.5 mm Guide wire into the canal, across the fracture site, and into the distal metaphysis. The Chuck with T-Handle may be used to facilitate insertion.

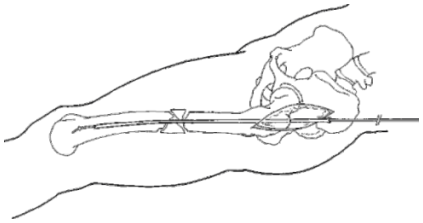


Reaming the Medullary Canal



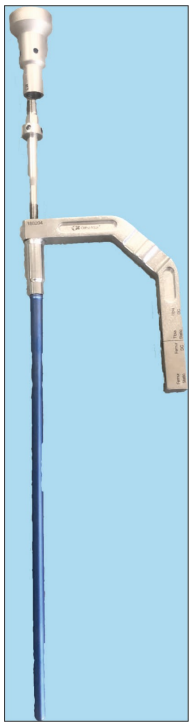
Use the Fixed Cannulated Reamer or Flexible Shaft (Not in Ortho Max scope) with the front-cutting 8mm Reamer Head to begin reaming.
To protect the soft tissue, place the Tissue Protector medial to the Reamer shaft.
Reaming progresses in 1mm in case of fixed reamer and 0.5mm increments using the flexible interchangeable Medullary Reamer Heads.
The diameter of the nail to be used will match the diameter of the last reamer used.
Over reaming the medullary canal by 0.5 mm–1.0 mm facilitates nail insertion but is not absolutely necessary.

Measuring for the Nail



Determine the appropriate nail length by subtracting the exposed length of the Guide Wire from its overall length of 92cm. Confirm the diameter of the selected nail with the Measuring Gauge.

Proximal Jig Assembly



1 Slide the femoral nail over the 2.5 mm Guide Wire. Manually insert the nail into the medullary canal as far as possible.

2 Put the proximal jig on femoral nail, match the slot and Screw the nail holding bolt into the proximal end of the nail. The proximal jig should be oriented laterally.

3 Using the proximal jig handle to control nail rotation, tighten the nail holding bolt with the socket wrench with T handle.

4 Fix the impactor head on nail holding bolt and screw it onto the end of the bolt.

Nail Insertion

Inserting the Nail

With controlled blows of the hammer, insert the nail into the canal. Image intensification should be used to monitor the passage of the nail across the fracture. Control rotation of the nail using the Jig Handle.

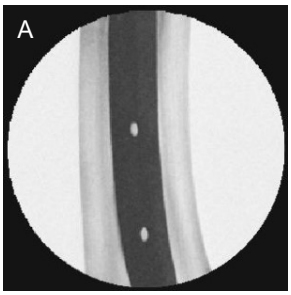
The nail should advance in the medullary canal with each blow of the hammer. If resistance is encountered, remove the nail and ream the canal to an additional 0.5mm to 1 mm.

When the nail is fully seated, remove the Impactor head and guide wire. If the nail needs to be locked, the Proximal jig assembly shall remain on the nail.

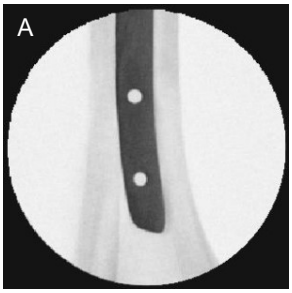
DISTAL LOCKING

Distal Locking with the Free Hand Technique:

1 Align the image intensifier with the most distal hole in the nail. Adjust until a perfect circle is visible (Fig. A).

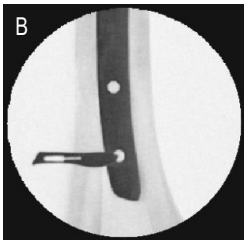


Incorrect position

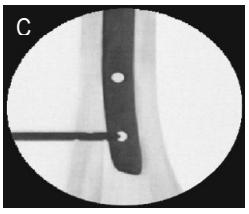


Correct position

2 Under image intensification, place a scalpel or Steinman pin on the skin with the tip of the blade or point of pin over the center of the hole to determine the stab incision point. Make a stab incision (Fig. B).

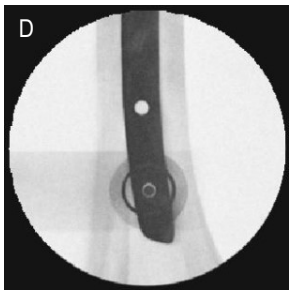


3 Insert the 4mm x10" Drill Bit into the stab incision point. Under image intensification, place the tip of the drill bit oblique to the X-ray beam, into the stab incision and onto the femur, until the tip of the drill bit is centered in the locking hole (Fig. C).



Distal Locking

4 Tilt the beam until the drill bit is in line with the X-ray beam and appears in the center of the hole.The drill bit will nearly fill in the locking hole. Hold the drill firmly in this position and drill through both cortices. Use image intensification to keep the drill bit centered.(Fig. D).

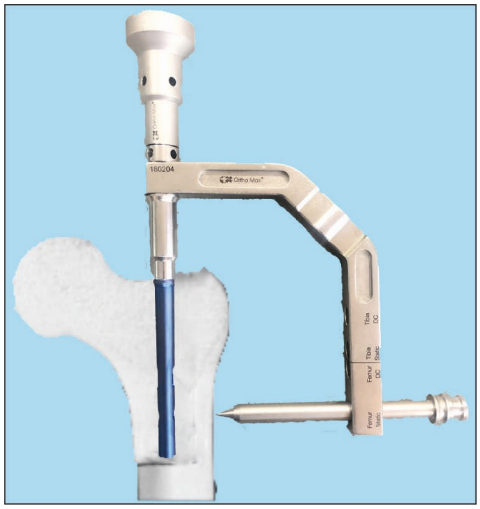


5 Measure the hole with the Long Depth Gauge 4.9mm for Interlocking screws. Add 2 mm to this reading to ensure that the interlocking screw will engage the far cortex. Insert the Interlocking screw and tighten with the long hexagonal screwdriver 4.9mm.

6 Reposition the image intensifier to align with the second distal hole, and repeat steps 1 through 5.

PROXIMAL LOCKING

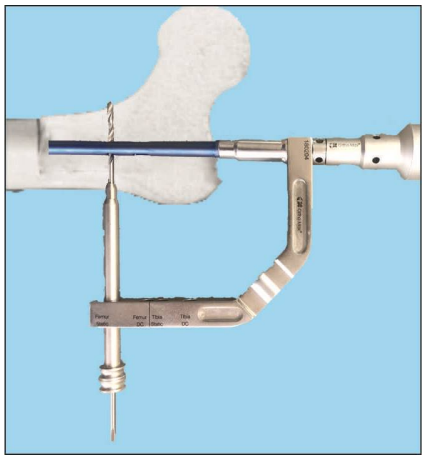
Decide the first hole to be locked and based on selection of holes DC or Static, Insert the Protection Sleeve, with Trocar inserted, through the appropriate drill hole in the Proximal Jig. The Jig shows marking of DC or ST holes .Make a stab incision through the skin at the point where the trocar touches the skin. Pass the protection sleeve with trocar through the incision and onto the bone.



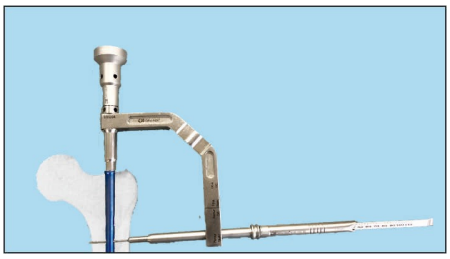
Remove the trocar. The protection sleeve remains in place until the Interlocking screw is completely inserted.

Proximal Locking

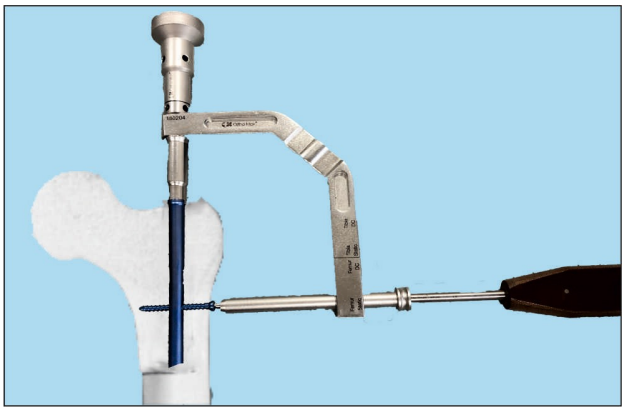
2 Insert the 4 mm Drill Sleeve through the protection sleeve and Drill through both cortices using the 4 mm Drill Bit.



3 Remove the drill sleeve. Using the long Depth Gauge for 4.9mm, measure for the proper length 4.9 mm Interlocking screw. Add 2 mm to the measurement to ensure engagement of the far cortex.



4 Insert the Interlocking screw through the Protection Sleeve.
If an additional proximal Interlocking screw is to be placed, repeat steps 1 through 4.
Remove the remaining proximal jig instruments.



REMOVING THE NAIL

Nail Removal:

The Universal Femoral Nails' threaded proximal ends greatly simplify removal. The thread provides a secure connection with the nail holding bolt for smooth and accurate transmission of forces during nail extraction.

Selection of the appropriate nail holding bolt is critical to avoid complications or damage to the nail during extraction. The Universal Femur Nail uses one nail holding bolt for all nail diameters, simplifying removal.

Interlocking screws must be removed prior to nail extraction. Make a short incision over the heads of the Interlocking screw. Use a curette and sharp hook to remove tissue in growth in the hex recess. Using the Long Hexagonal Screwdriver 4.9mm, insert the screwdriver into the hexagonal recess of the Interlocking screw and Remove the Interlocking screws.

Note: The final decision of removing the Nail shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patients.

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

Product Details:

TIBIA & FEMUR

Implants — **Tibia & Femur Interlocking Nails System**

Interlocking Nails For Femur - "Universal"
Cannulated

Intended Use	For Intramedullary Fixation & Locking of Femur Shaft Fracture
Profile	3mm Gun Drill Hole Cannulation, 4.9 mm Hole Dia.
Nail Diameter	9mm, 10mm, 11mm & 12mm
Size	32cm To 46cm - 2 cm diff.

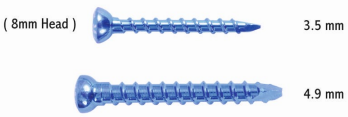
Material	Reference
SS 316L	176.932 To 176.1246
Titanium	237.932 To 237.1246

* Also Available in Solid Nail

Interlocking Nails For Femur - "Universal - Solid

Material	Reference
SS 316L	2032.934 To 2032.1244
Titanium	2031.934 To 2031.1244

Interlocking Screws



Intended Use	For Locking Nails in Bi-Cortical Fixation
Profile	Core Dia 2.7mm for 3.5mm, 4.0 for 4.9 mm
Screw Diameter	3.5mm (For 8mm Tibia Nails) & 4.9mm (For All 9mm To 12mm Nails)
Size	3.5mm x 24mm To 50mm, 4.9mm x 24mm To 50mm - 2mm diff. 55mm To 90mm - 5mm diff.

Material	Reference
SS 316L	184.3524 To 184.4990
Titanium	238.3524 To 238.4990

Interlocking Nail Cap

Intended Use	To be used with interlocking nails to plug threaded hole
Profile	Head dia. 9mm, Length 15mm

Material	Reference
SS 316L	185.001
Titanium	239.001

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Ortho Max®
Mfg. Co. Pvt. Ltd.

Tibia & Femur Interlocking Nails System — Instruments

Guide Wire - Long

Reference	Size
940.2530	Tibia - 2.5mm x30"

Reference	Size
940.2536	Femur - 2.5mm x36"

Bone Awl

Reference	
Straight	639.001
Curved	639.002

Tissue Protector

Reference
649.001

Protection Sleeve

Reference
726.004

Drill Sleeve - 4mm

Reference
726.005

Drill Sleeve - 2.7mm

Reference
726.006

Nail Holding Bolt

Reference
726.003

Socket Wrench 'T' Handle

Reference
727.014

Proximal Jig For Tibia & Femur Nails

Reference
946.001

Trocar Awl with T Handle

Reference
941.001

Ortho Max® Mfg. Co. Pvt. Ltd.

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Instruments — Tibia & Femur Interlocking Nails System

Drill Bits

Reference	Size
552.2710	2.7mm x 10"
552.410	4mm x 10"

Depth Gauge - Long

4.9mm

Reference	Size
561.335	3.5mm
561.349	4.9mm

Tommy Bar

Reference
942.001

Hexagonal Long Screw Driver

4.9mm

Reference
569.249

Impactor Head

Reference
938.001

Extractor Set

Rod

Reference
939.001

Reference
939.002

Head

Ram

Reference
939.003

Interlocking Set Container for Tibia & Femur Nails

Reference
800.004

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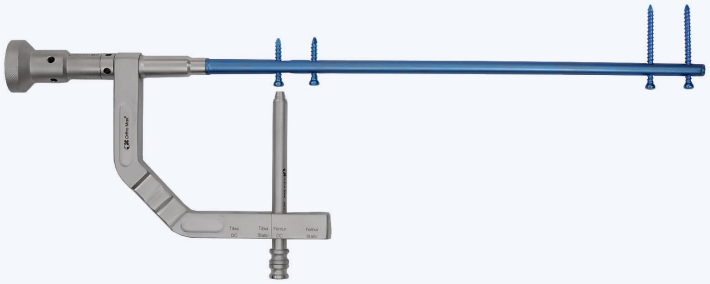
Ortho Max® Mfg. Co. Pvt. Ltd.

Femur Universal Interlocking Nails Set

Femur Universal Nail Jig Assembly



Contents :

Implants :-	Qty
Interlocking Nail for Femur - "Universal" (Cannulated)	
- 9, 10, 11, 12mm x 34, 36, 38, 40, 42, 44cm - 1 each	24 Nos
Interlocking Screws	
- 4.9mm x 28mm To 90mm - 3 each	60 Nos
Instruments :-	
- Bone Awl - Straight	01 No
- Guide Wire - 2.5mm x 36"	02 Nos
- Tissue Protector	01 No
- Proximal Jig for Universal Femur Nail	01 No
- Nail Holding Bolt	01 No
- Protection Sleeve	01 No
- Drill Sleeve - 4mm	01 No
- Socket Wrench 'T' Handle	01 No
- Trocar Awl with T Handle	01 No
- Drill Bits 4mm x 10"	02 No
- Tommy Bar	01 No
- Depth Gauge - Long 4.9mm	01 No
- Hexagonal Long Screw Driver - 4.9mm	01 No
- Impactor Head	01 No
- Extractor Set with Bolt	01 Set
- Interlocking Set Container for Femur Universal	01 No

Implants certified by ITC: CE 1023

Instruments certified by self declaration: CE

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 : info@orthomaxindia.net
admin@orthomaxindia.net