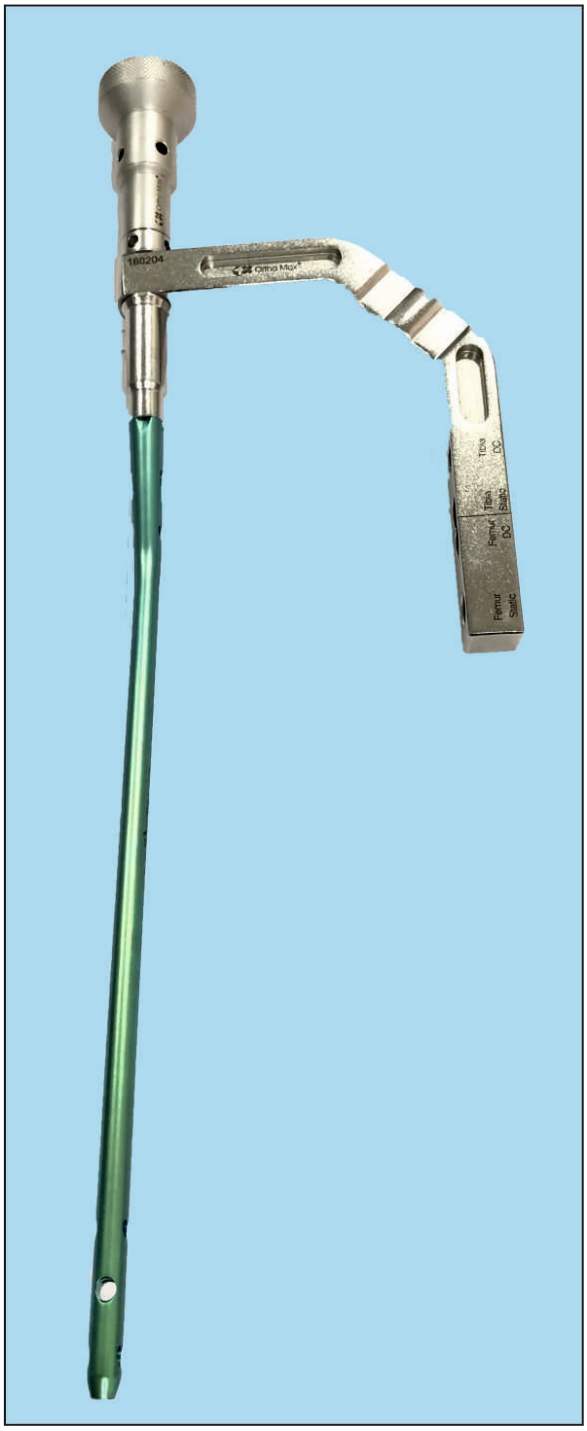
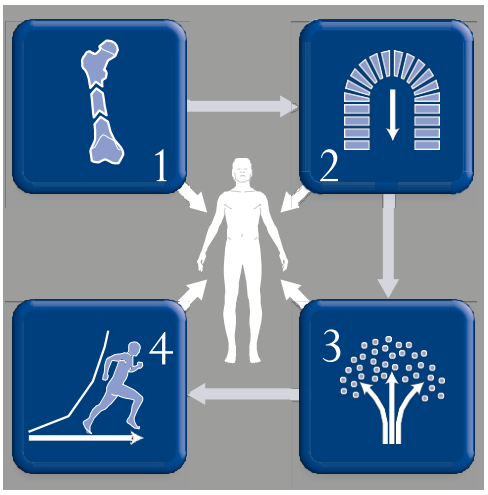
MODIFIED TIBIA INTERLOCKING NAIL SYSTEM
SURGICAL TECHNIQUE

CE 1023



AOPrinciples

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



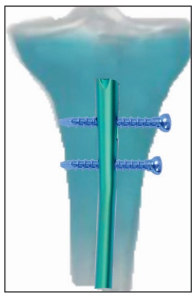
Anatomic reduction
Fracture reduction and fixation to restore anatomical relationships.
Early, active mobilization Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

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

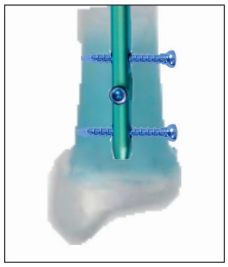
Preservation of blood supply Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

INDICATIONS:

The Modified Tibia nail is intended to stabilize fractures of the Upper or Middle Third Tibia and distal tibia, open and closed Tibial shaft fractures, certain pre and postisthmic fractures, and tibial malunions and non-unions.



Proximal



Distal

Shaft

CONTRAINDICATIONS :

There are no specific contraindications but do not use the Modified 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.

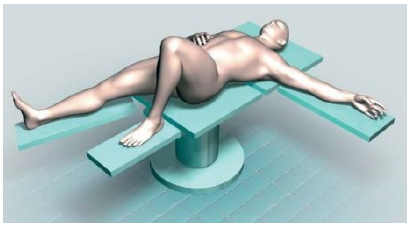
Preoperative Planning:

Use the Radiographic ruler for the tibial nail to estimate nail diameter and nail length. To estimate nail diameter, place the on the ruler on AP or lateral x-ray of the uninjured tibia and measure the diameter of the medullary canal at the narrowest part that will contain the nail.

To estimate nail length, place the template on the AP x-ray of the uninjured tibia and select the appropriate nail length based on patient anatomy. When selecting nail size, consider canal diameter, fracture pattern, patient anatomy, and post-operative protocol.

Opening the Tibia:

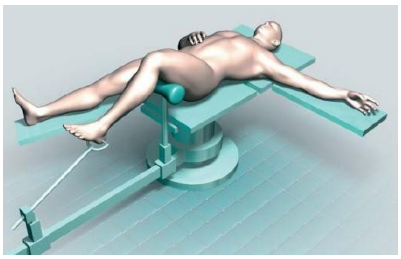
1 Position patient



Position the patient supine on the radiolucent table. Ensure that the knee of the injured leg can be flexed at least 90°. Position the image intensifier so that visualization of the tibia, including the articular surface proximally and distally, is possible in AP and lateral views.

optionally, the procedure can be performed on a fracture table with the leg placed in traction.

Note: The knee roll can be placed under the lower part of the thigh if it obstructs the view of the tibial plateau in the AP view.



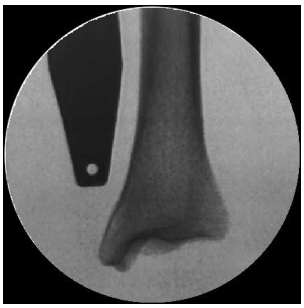
2. Reduce Fracture

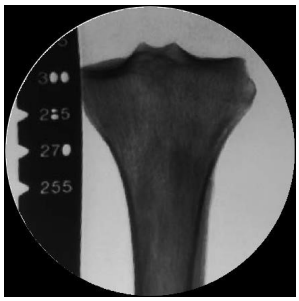
Perform closed reduction manually by axial traction under image intensification. The use of the Femoral Large distractor may be appropriate in certain circumstances.

Note: the reduction can be temporarily fixed with reduction clamps. In epiphyseal sractures the condyles or the pilon are fixed first in order to enable the nail insertion.

3. Conform nail length and diameter

The required nail length must be determined after reduction of the lower leg fracture.

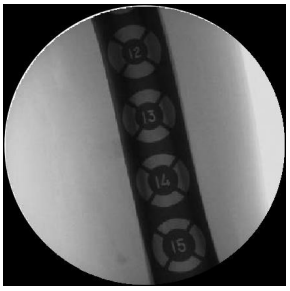




Position the c-arm for an AP view of the distal tibia. Hold the radiographic ruler* along the leg, parallel to and at the same level as the tibia. Adjust the ruler until the distal tip is at the level of the physeal scar or the desired nail insertion depth. Mark the skin at that site.

Move the c-arm to the proximal tibia, replace the distal end of the ruler at the skin mark, and take an AP image of the proximal tibia. Read nail length directly from the ruler image, selecting the measurement at or just below the level of the anterior edge of the tibial plateau.

When using the femoral large distractor, measure the distance from the inferior border of the distal pin to the superior border of the proximal pin to determine optimal nail length.



Position the c-arm for an AP or lateral view of the tibia at the level of the isthmus. hold the radiographic ruler over the tibia so that the diameter gauge is centered over the narrowest part of the medullary canal. read the diameter measurement on the circular indicator that fills the canal.

Note: Compression or dynamization must be taken into account when determining the nail length. A shorter nail should be chosen when active compression is planned for the procedure. The dynamic locking option allows for 7 mm of travel.

Important: The ruler is not at the same level as the tibia. This affects the accuracy of the measurement, providing only an estimate of the canal diameter.

*** Radiographic ruler is not part of the Ortho Max instruments set and is available on request.**

4. Approach

Make an incision in line with the central axis of the intramedullary canal. Depending on the anatomy of the patient, this incision can be transpatellar, medial or even lateral parapatellar.

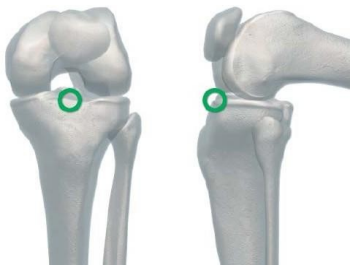
The incision starts proximally at the distal third of the patella along the patellar ligament down to the tibial tuberosity.

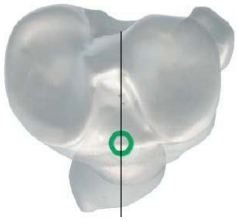
Mobilize the infrapatellar corpus adiposum laterally and dorsally without opening the synovia. Free access of the nail to the insertion point must be guaranteed.

Prepare the entry site of the nail on the ventral edge of the tibial plateau.

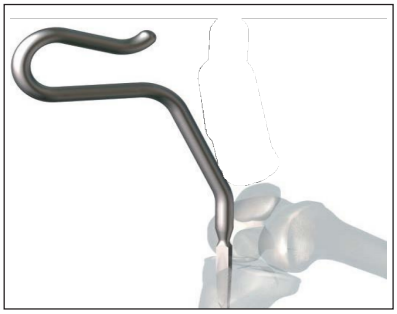
5. Determine entry point

The entry point defines the optimal position of the nail in the intramedullary canal. In AP view, the entry point is in line with the axis of the intramedullary canal and with the lateral tubercle of the intercondylar eminence.In lateral view, the entry point is at the ventral edge of the tibial plateau.



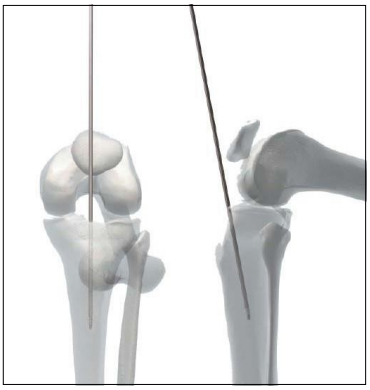


6. Open Medullary canal:



Slightly punch mark the insertion point at a 10° angle to the shaft axis in the lateral view.
Place the Tissue Protector and the Bone Awl curved over the entry point of the bone. Insert Bone Awl to a depth of approximately 8 cm– 10 cm. The Bone awl tip should not touch the posterior cortex.
Remove Bone Awl.

7. Insert Guide wire:



Hold a nail on the side of the lower leg with its distal end parallel to the tibia shaft. The curved proximal nail end determines the angle of insertion for the guide wire.

Insert the 2.5mm dia. guide wire for approximately 8 cm– 10 cm and check the position under image intensification in the AP and lateral views.

8. Reaming medullary canal (optional)

If necessary, enlarge the tibial canal with the flexible medullary reamer*, to the desired diameter.

Important : Never use Fixed medullary canal reamers in tibial shaft
Check fracture reduction under the image intensification.
Insert the Guide wire with a ball tip into the medullary canal, using the T Handle or any other holding device to the desired insertion depth**.**

Reaming
Starting with the 8mm diameter fixed flexible reaming head, ream to a diameter of 0.50 mm– 1.0 mm greater than the nail diameter. Ream in 0.5 mm increments and advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer often to clear debris from the medullary canal.

Note: All nails in the Modified Tibial Nail System should not be inserted over the Guide wire with ball tip. Guide wire with plain tip should be exchanged with ball tip before inserting the Modified Tibial nail.

*** Flexible reamers are not part of Ortho Max Tibial Nailing System.**

Nail Insertion:

1. Assemble the Proximal Jig Assembly

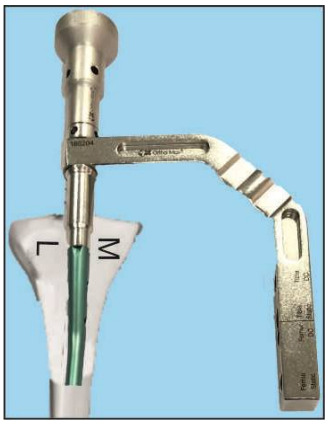
Orient the Jig assembly anteriorly, and match the teeth on the Jig to the notch in the nail.

Place the Nail Holding Bolt into the Jig and thread it into the proximal nail end, first manually and then using hex spanner with T handle. Please take care while threading the nail, pull back the nail holding bolt if not fit smoothly.

Verify the nail is oriented properly on the Jig Assembly; secure the assembly with Hex. Spanner with T handle. Fix the Impactor Head on Nail Holding Bolt. The Impactor Head should sit firmly on nail holding bolt without leaving any gap in between.

2 Insert nail

Note: Hyperflex the knee to aid nail insertion into the medullary canal.



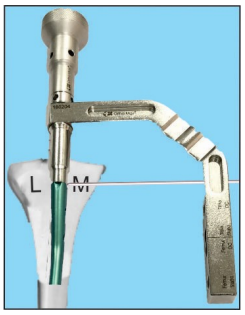
Insert the nail into the intramedullary canal. Use a twisting motion to advance the nail.

Monitor the nail passage across the fracture; control in two planes to avoid malalignment. Insert the nail until it is at or below the tibial opening. Check final nail position in AP and lateral views. If needed, use light, controlled hammer on impactor head to seat the nail.

Note: If nail insertion is difficult, choose a smaller diameter tibial nail or ream the medullary canal to a larger diameter.

Important: Confirm that the nail is securely connected to the proximal jig assembly, especially after hammering, Do not Hammer on Jig assembly directly.

3. Check proximal nail position



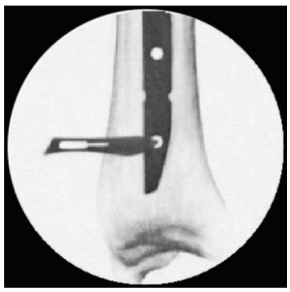
Insert a 2.5mm K wire through the hole as shown in the image.
The tip of the K wire indicates the exact proximal position of the tibial nail.
Remove the Impactor Head.
Remove the Proximal Jig, unless proximal locking is the next step.
Check proximal nail position under image intensification in the lateral view.
If primary compression or secondary dynamization are planned, it is recommended to over insert the nail by more than 7 mm, which corresponds to the maximum distance between the positions in static and dynamic modes.

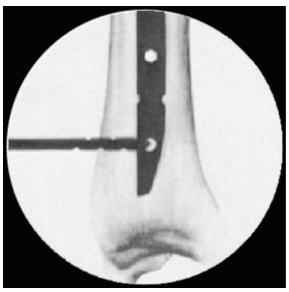
4. Check distal nail position

Check final nail position under image intensification in AP and lateral views.
Remove the guide wire.
Important: Confirm that the nail is securely connected to the Jig Assembly, especially after hammering.

5. Determine incision point

Place a scalpel blade on the skin over the center of the hole to mark the incision point and make a stab incision.





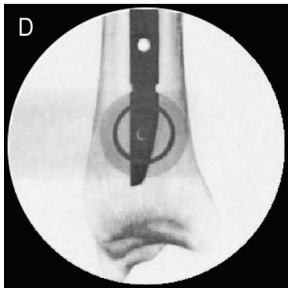
6. Distal Locking

A. Align image

Check the reduction, correct alignment of the fragments, and leg length before locking the nail.

Align the c-arm with the hole in the nail closest to the fracture until a perfect circle is visible in the center of the screen. (distal ML hole shown in illustration).

B. Distal Locking

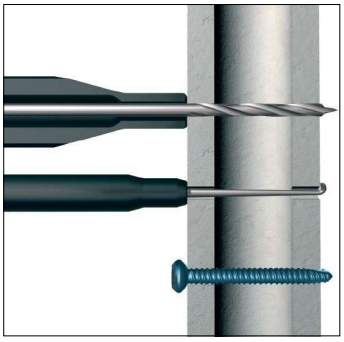


C. Drill

Under image intensification, insert the tip of the appropriate Drill bit through the incision and down to the bone.

Note: Use 2.7mm Drill bit in case of Distal Locking in 8mm Tibia Nail and Use 4mm Drill bit in case of 9mm and 10mm Tibia Nails.

Ensure that the tip of the drill bit is centered over the locking hole. The drill bit should almost completely fill the circle of the locking hole. Hold the drill bit in this position and drill through both cortices.

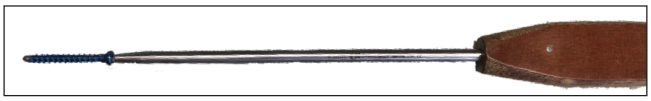


Technique tip: For greater drill bit control, discontinue drill power after perforating the near cortex. Manually guide the drill bit through the nail before resuming power to drill the far cortex.

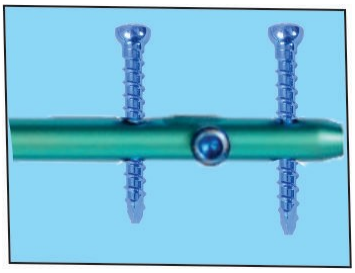
Measure the locking screw length using the Long Depth gauge 3.5mm or 4.9mm for Interlocking screws. Ensure the outer sleeve is in contact with the bone and the hook grasps the far cortex.

Read the Interlocking screw length directly from the depth gauge scale at the back of the outer sleeve.

D. Insert Interlocking screw

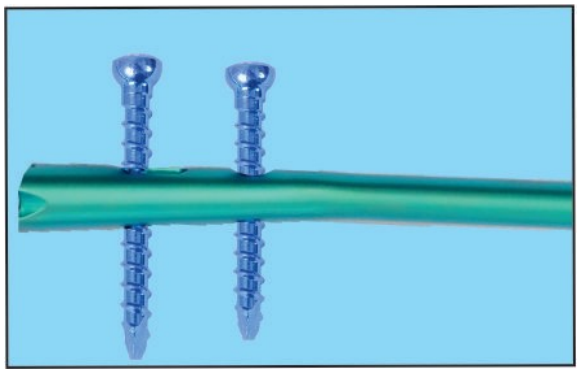


Insert the appropriate length of Interlocking screw using the Hex. Screw driver long 3.5mm OR 4.9mm.
Verify locking screw length under image intensification. If needed, a second locking screw may be inserted using the same technique.



7. PROXIMAL SCREW LOCKING

A. Choose Interlocking screws and instruments



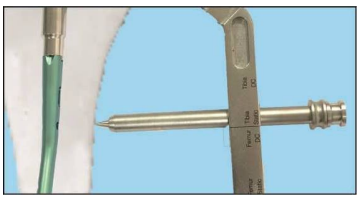
Use the correct Interlocking screw 4.9mm dia irrespective nail dia., Protection Sleeve & Drill sleeve 4mm, Trocar Awl with T handle and drill bit 4mm dia.
Two proximal ML locking options can be targeted using the Proximal jig assembly:

- The Dynamic locking option (DC) corresponds to the upper position of the proximal locking slot. This type of locking allows primary compression or secondary, controlled dynamization of the bone fragments.
- Static (ST) corresponds to the lower position of the proximal locking slot. This type of locking does not allow primary compression or secondary controlled dynamization.
- **Dynamisation / Use of bone graft:**

  In nailing of Tibia 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

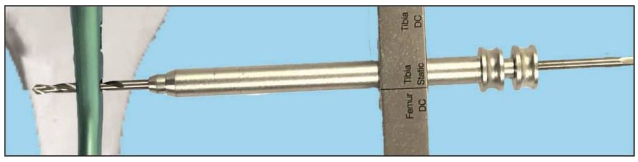
Two proximal ML locking options can be targeted using the Proximal Jig assembly:

B. Use Trocar Awl with T handle

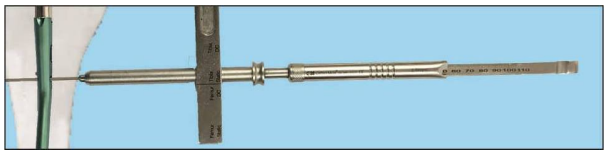


Insert the Trocar Awl with T handle through protection sleeve in the desired ML hole in the Proximal Jig assembly and make a stab incision to insert the trocar to the bone. Remove the trocar awl with T handle.

C. Drilling for screw

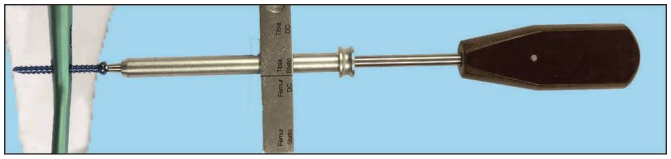


Ensure that the drill sleeve is pressed firmly to the near cortex, using the corresponding drill bit of 4mm for 4.9mm Interlocking screws, drill through both cortices until the tip of the drill bit penetrates the far cortex.
Remove drill bit and pass Long Depth Gauge 4.9mm into the protection sleeve to measure screw length.



Ensure that the drill sleeve is pressed firmly to the near cortex and make sure that the hook grasps the far cortex and that the protection sleeve is on the bone. Read the measurement from the scale at the back of the Long Depth Gauge. This measurement corresponds to the appropriate length of Interlocking screw. Remove the Long Depth Gauge.

D. Insert Interlocking screw 4.9mm



Insert the appropriate length of Interlocking screw 4.9mm through the protection sleeve using the Long Hex. Screw driver 4.9mm. Verify Interlocking screw length under image intensification. The tip of the Interlocking screw should not project More than 1mm to 2mm beyond the far cortex.
Repeat Steps 2 to 4 for the second proximal ML Interlocking screw.

End cap can be fixed with Hex. Long Screw Driver 4.9mm after removing Proximal Jig Assembly.

Nail Removal:

1. Remove End cap and Interlocking screws

Implant removal is an optional procedure.

Clear the Hex. Socket of the end cap for of any tissue ingrowth. Remove the end cap with the Hex. Long screw driver 4.9mm.

Remove all Interlocking screws except one of the proximal locking screws, using the Hex long screwdriver 4.9mm.

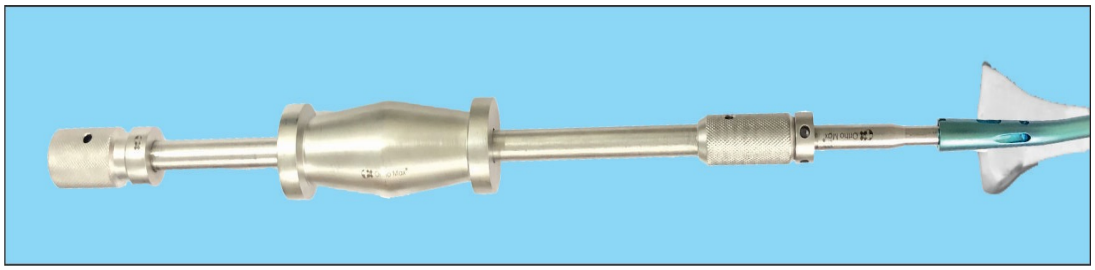
2. Attach Extractor Rod with head and Ram

Before removing the final Interlocking screw, screw the Nail Holding Bolt and Extractor rod with ram inside and head at other end into the tibial nail and tighten it to prevent rotation or displacement of the nail posteriorly below the tibial plateau.

Remove the remaining Interlocking screw with the Hex. long screwdriver 4.9mm.

3. Remove Nail

Extract the nail by applying gentle blows with the Ram. Check nail holding Bolt securely fitted with the nail in between extraction process



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 Nail For Tibia - "Modified"
Cannulated

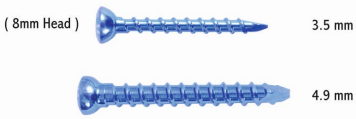
Intended Use	For Intramedullary Fixation & Locking of Tibial Shaft Fracture
Profile	2.5mm Gun Drill hole cannulation, 3.5mm hole dia. for 8mm 4.9mm Hole dia. For 9,10mm
Nail Diameter	8mm, 9mm & 10mm
Size	28 cm To 40 cm - 2cm diff.

Material	Reference
SS 316L	174.828 To 174.1040
Titanium	236.828 To 236.1040

* Also Available in Solid Nail
Interlocking Nails For Tibia - "Modified" - Solid

Material	Reference
SS 316L	175.828 To 175.1040
Titanium	235.828 To 235.1040

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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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

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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

Head

Reference
939.002

Ram

Reference
939.003

Interlocking Set Container for Tibia & Femur Nails

Reference
800.004

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Tibia Interlocking Nails Set

Tibia Modified Nail Assembly

Implants :-	Qty
Interlocking Nail for Tibia - "Modified" (Cannulated)	
- 8, 9, 10mm x 28, 30, 32, 34, 36, 38cm - 1 each	18 Nos
Interlocking Screws	
- 3.5mm (8mm Head) x 24mm To 50mm - 2 each	28 Nos
- 4.9mm x 24mm To 50mm - 3 each	42 Nos
x 55, 60mm - 3 each	06 Nos
Instruments :-	
- Bone Awl - Curved	01 No
- Guide Wire - 2.5mm x 30"	02 Nos
- Tissue Protector	01 No
- Proximal Jig for Tibia Modified	01 No
- Nail Holding Bolt	01 No
- Protection Sleeve	01 No
- Drill Sleeve - 2.7mm	01 No
- Drill Sleeve - 4mm	01 No
- Hexagonal Spanner with 'T' Handle	01 No
- Trocar Awl with T Handle	01 No
- Drill Bits 2.7mm x 10"	02 Nos
- Drill Bits 4mm x 10"	02 Nos
- Tommy Bar	01 No
- Depth Gauge - Long 3.5mm, 4.9mm -1each	02 Nos
- Hexagonal Long Screw Driver - 4.9mm	01 No
- Impactor Head	01 No
- Extractor Set with Bolt	01 Set
- Interlocking Set Container for Tibia Modified Nails	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