INTRAMEDULLARY SUPRACONDYLER(IMSC) FEMORAL NAIL – Surgical Technique

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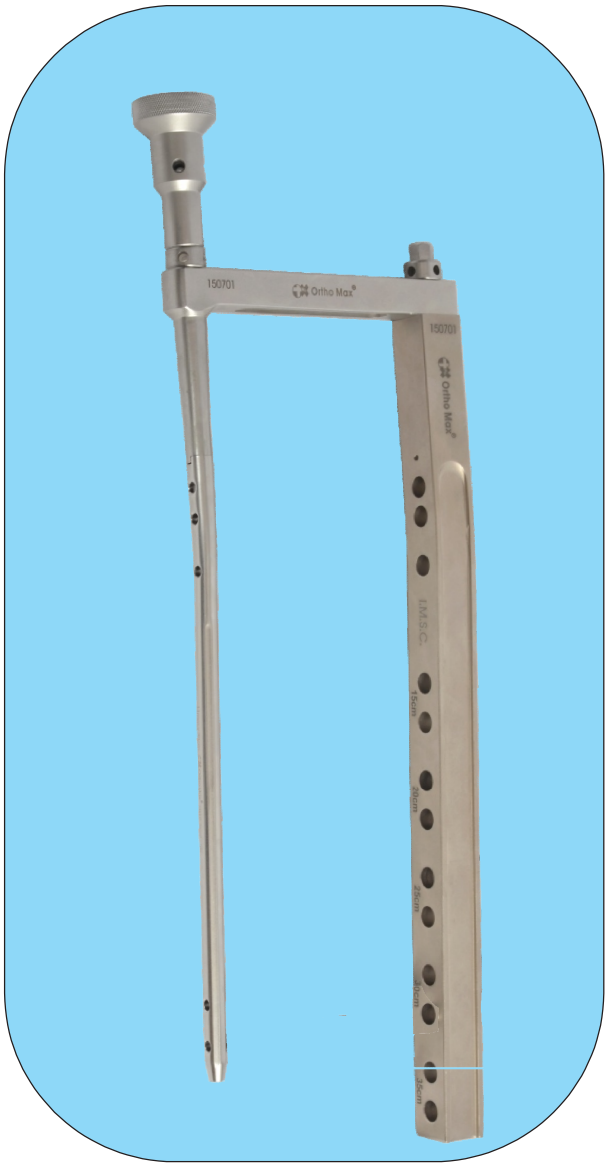

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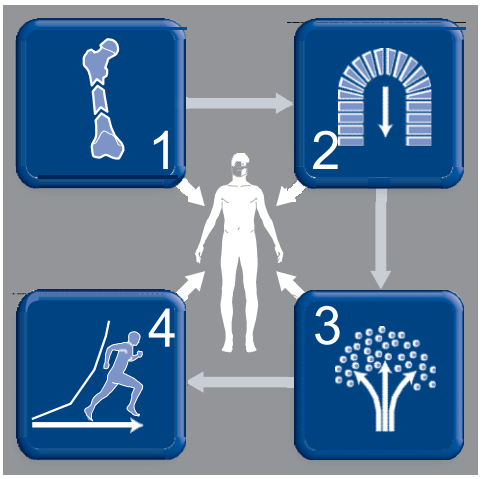
AO PRINCIPLES

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



Anatomic reduction

Fracture reduction and fixation torestore 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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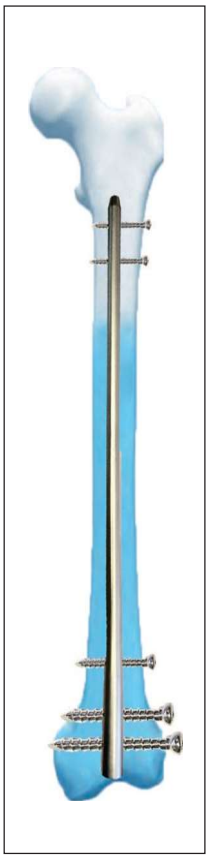
INDICATIONS AND CONTRAINDICATIONS



- **Indications for retrograde approach**
- In retrograde approach, the IMSC Femoral Nail is indicated for fractures in the distal femur.

- Additionally, the IMSC Femoral Nail is indicated for fractures in the femoral shaft (subtrochanteric fractures) in case of:
    - combination with fractured patella
    - ipsilateral femur/tibia fractures (loating knee)
    - combination with fractured acetabulum, pelvis, or femoral neck
    - combinations of the fractures mentioned above
    - pronounced adipositas
    - pregnancy
    - polytrauma (if numerous surgical teams are involved in treatment of patient)

- **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

OPENING THE DISTAL FEMUR

1. Position Patient

Position the patient supine on a radiolucent table. The knee of the injured leg should be flexed 70 to 90º allowing for correct reduction of the fracture and localisation of the nail entry point. A leg roll may be used to allow proper reduction and stabilisation of the fracture.
Position the image intensifier in such a way that visualisation of the femur including the proximal and distal ends is possible in AP and lateral view.
The contralateral leg should be flexed in the hip and in the knee and rested in an elevated position to enable visualisation by image intensfier.

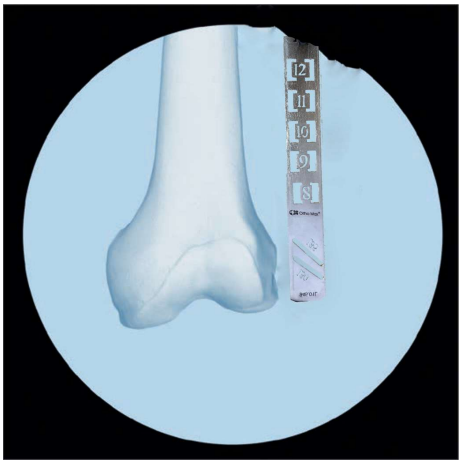
2. Reduce fracture

Perform closed reduction manually by axial traction under image intensifier. In case the fracture is older, then use of the large femoral distractor may be recommended under certain circumstances.

Note: Intra-articular fractures should be stabilized with interfragmentary screw fixation prior to insertion of the nail. The screws should be positioned to not interfere with the path of the nail.

3. Measure for length and diameter of nail

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



Position the image intensifier as for an AP view of the distal femur. Using long forceps, hold the radiographic ruler parallel to the femur on the lateral side of the upper leg. Position the ruler such that the distal end is at the desired nail insertion depth. Mark the skin at that site.

Move the image intensifier toward the proximal end of the femur, align the distal end of the ruler with the skin marking and record an AP x-ray of the proximal femur. Check the reduction and read off the required nail length on the ruler as it appears in the x-ray.

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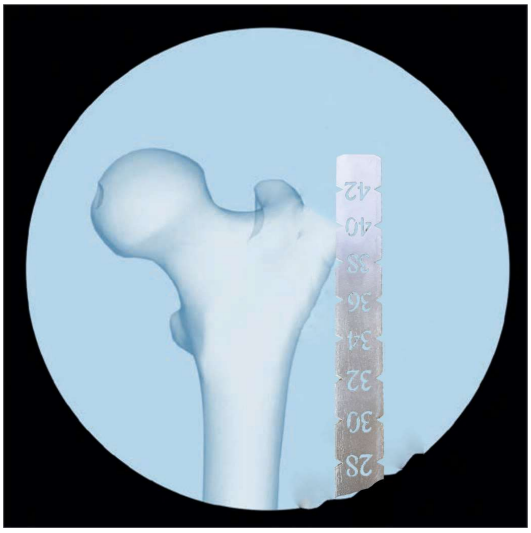
Precautions:



- It is recommended that the tip of the nail shall remain at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the femoralis and the branches of the femoralis. In cases where such long nails (>30cm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter.
- The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally.

Alternatives

Determine the nail length by the procedure above on the uninjured leg before draping (non-sterile) or compare the length of two identical Guide Wire of 2.5 mm.

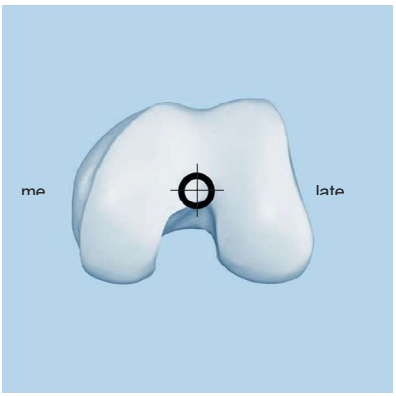
Place the radiographic ruler for nail diameters over the femur so that the measuring edge is located over the isthmus. Select the nail diameter shown when the medullary canal is still visible on both sides of the marking (e.g.12 mm in this example).

If the reamed technique is used, the diameter of the largest medullary reamer applied must be 0.5 to 1.5 mm larger than the nail diameter.

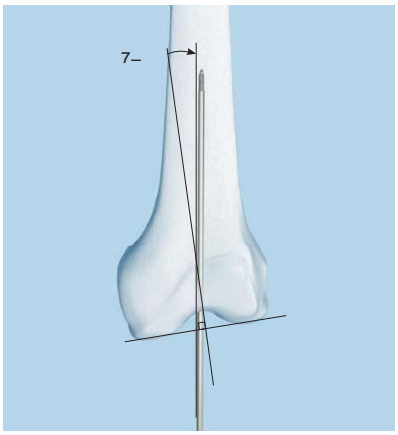
4. Approach

A transligamental (ligamentum patellae), a parapatellar incision , a medial or a lateral parapatellar approach can be used depending on the type and location of fracture.

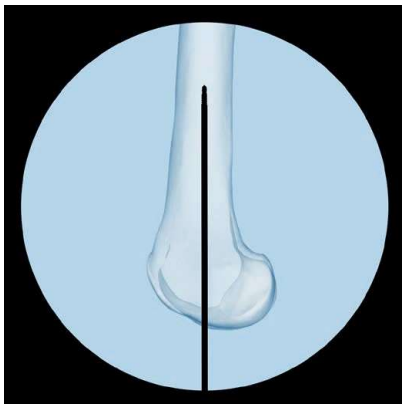
5. Determine the entry point

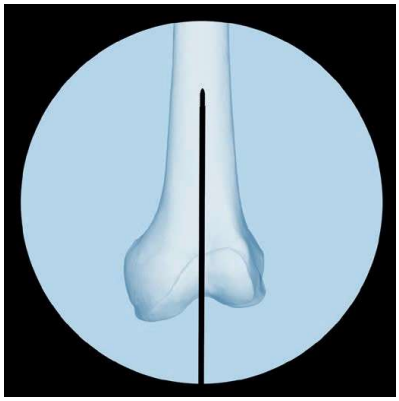


The entry point for the IMSC Femoral Nail is in line with the medullary canal. The point is at the top of the intercondylar notch, just anterior and lateral to the femoral attachment of the posterior cruciate ligament.



The entry point is determinant for the entire operation, especially for the final position of the nail in the medullary canal respecting the anatomical conditions. This is mostly important for distal metaphyseal fractures regarding correct fragment placement.





6. Insert guide wire

Insert the guide wire for approximately 10 to 15 cm in line with the anatomic axis of the femur, which is 7 to 9º in valgus, i.e. lateral to a line perpendicular to the articular surface.
Secure the guide wire in the T handle with chuck.
Insert the guide wire. Check the position under the image intensifier in AP and lateral views.

7. Open medullary canal

The Cannulated Bone awl is used to open the medullary canal. Push the awl over the guide wire and open the medullary canal. Remove the awl.

Precaution:

- Take care to not plunge the awl into the fracture site because this may displace the fracture.

8. Reaming medullary canal (optional)

If necessary, enlarge the femoral canal with the Cannulated fixed or flexible reamer up to the desired diameter.Check fracture reduction under the image intensifier. Insert the Guide wire 2.5mm into the medullary canal. Use ball tip guide wire first in case of use of flexible reamer with detachable heads.

Reaming

Starting with the smallest diameter, ream the medullary canal in 1mm increments in case of fixed reamer or 0.5mm in case of flexible reamer with detachable heads. The T handle with chuck can be used to control the rotation of the Guide wire. Advance the reamer with slight forward and backward movements. Do not use force. Continue reaming until the diameter of the canal is 0.5 to 1.5 mm larger than the nail diameter.

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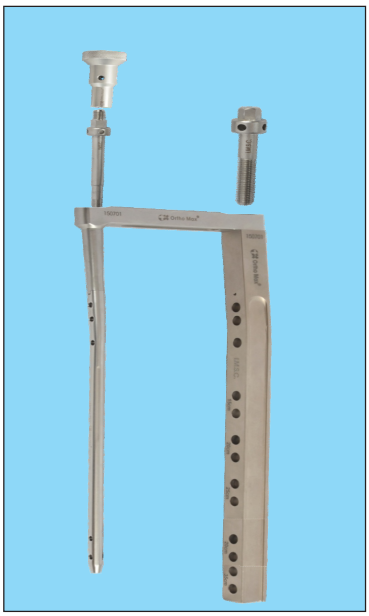
JIG ASSEMBLY

1. Mount the nail on Jig Assembly

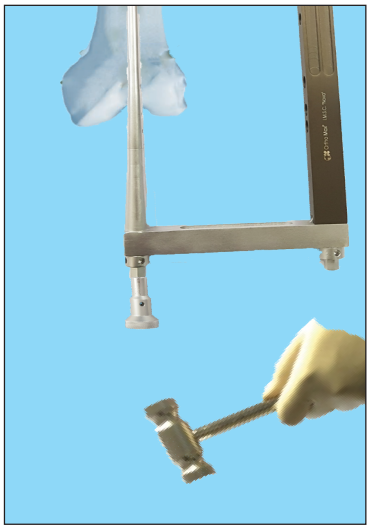
Slide the Nail holding bolt through the nail holder to screw onto the nail until it is fully secured and insert it into the insertion handle.

The anterior bow of the nail must be aligned with the anterior bow of the femur. Orient the insertion handle anteriorily, match the notch on the Nail holder to the nail, and tighten the Nail holding bolt. Fix the Impactor head over nail holding bolt.



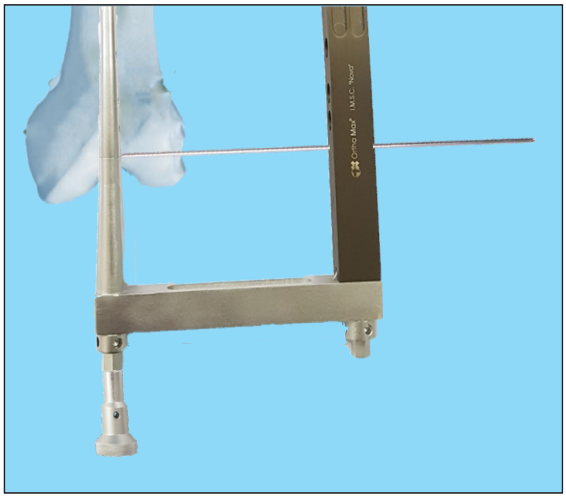
2. Insert nail

Using the Jig assembly, insert the nail over the guide wire into the medullary canal as far as possible by hand. Rotational movements of small amplitude can help to ease insertion. Monitor nail passage across the fracture, control in two planes to avoid malalignment. Use the Jig assembly to manipulate the nail across the fracture. Insert the nail until the distal end is inserted 2 to 5 mm beyond the articular cartilage. Light hammering can be applied in case resistance.



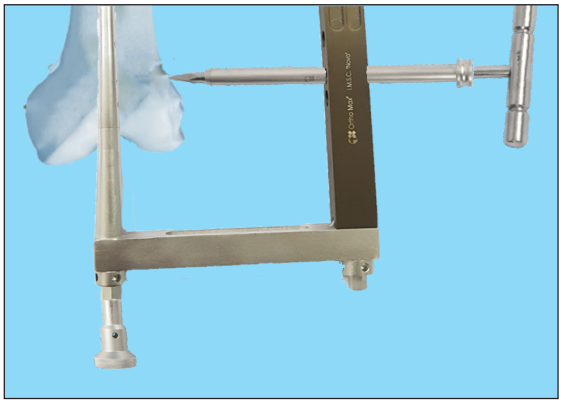
3. Check Nail position:

Tip of the nail position can be checked by inserting the K wire or Steinman pin of 2.5mm dia. Through the hole Given on start of the jig holes.



4. Insert Trocar assembly:

Assemble the protection sleeve and Trocar with T handle and insert it through the desired LM hole in the Proximal/Distal Jig. Make a stab incision and insert the trocar to the bone to mark the upper cortex wall to facilitate the easy insertion of drill bit on exact site.



Remove the Trocar with T handle.

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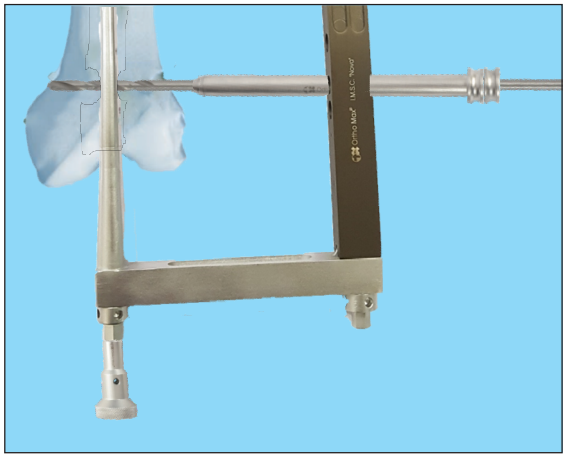
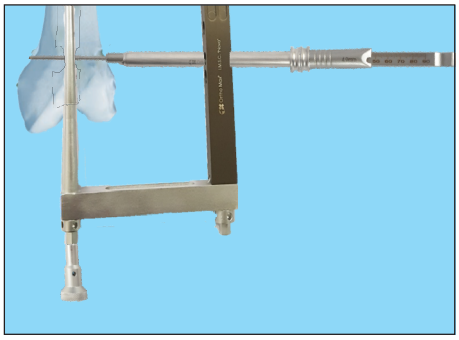
5. Drill :



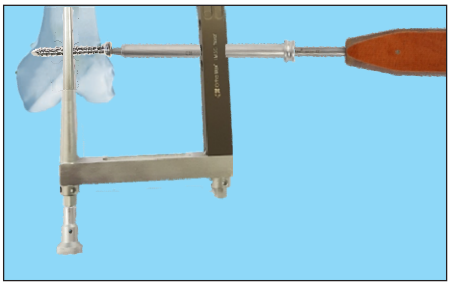
Using the drill bit of 4mmx 12”(300mm), drill through both the cortices until the tip of the drill bit just breaks through the far cortex.
Just after drilling both cortices, confirm drill bit position.
Remove the drill bit and the drill sleeve.

6. Measuring Length of Distal Screw:



Insert the long depth gauge of 4.9mm through the Protection sleeve to measure the length of the screw. Pass the tip of the depth gauge through the far cortex And engage the hook to the cortex edge. The scale marked On back side of the depth gauge shows the depth of the drill i.e. exact length of the screw to be inserted.

7. Insert Interlocking screw:



Insert the Interlocking screw of 4.9mm dia x the measured length with the long hexa. screwdriver through the protection sleeve until the Interlocking screw head lies against the near cortex. Repeat the steps 5 to 7 for the second, third distal Interlocking screw.

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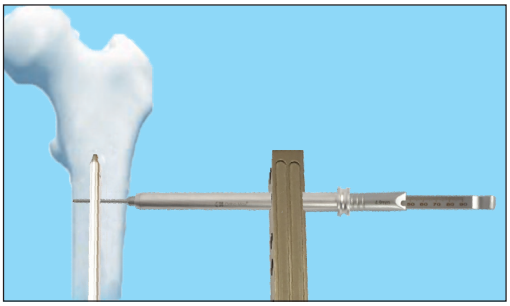
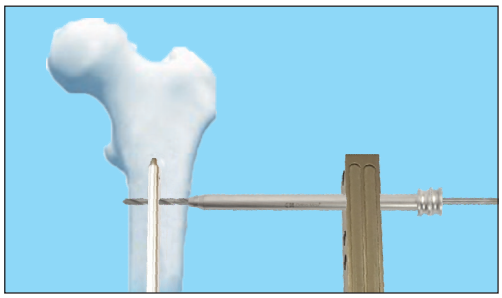
8. Insertion of Proximal Interlocking screws:

Locate the proximal hole by Nail length i.e. 25cm or 30cm marked on jig .

Repeat step 5 to 7 for screw insertion. Control the correct position of the hook of the depth gauge in regard to the far cortex of the femur.

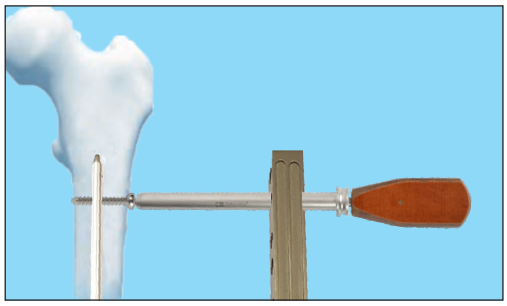
Read the measurement on the shaft of the depth gauge, which corresponds to the appropriate length of the Interlocking screw Note: Note: do not forget to add 2mm to the scale mark if tip is required to keep outside the far cortex wall. E.g. if scale shows 36mm length, 38mm screw should be inserted to allow the tip to remain outside the Far cortex wall. All screws are measured below the head length. The tip of the Interlocking screw should project beyond the far cortex by no more than 1 to 2 mm.





9. Insert Interlocking screw;

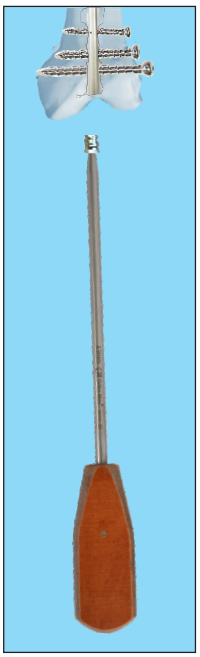
Insert the Interlocking screw of the correct length with the long hexa. Screwdriver 4.9mm.



Control the correct position and length of the Interlocking screws radiographically. Exchange the Interlocking screws with the appropriate length if necessary.

Repeat the steps 5 to 9 for the second proximal Interlocking screw.

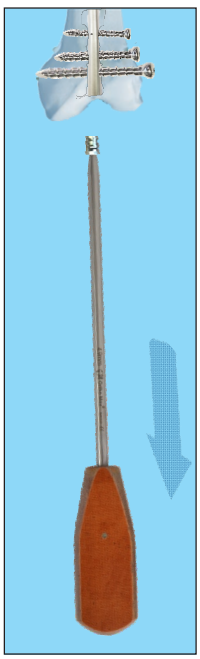
END CAP INSERTION



Remove the Jig assembly. Align the IMSC End cap using the Long Hexa. Screwdriver 4.9mm.

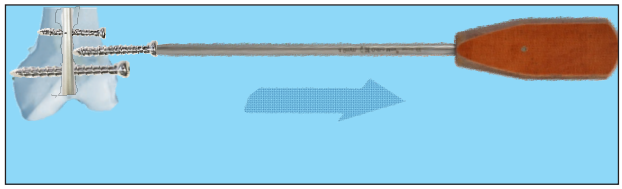
To minimise the chance of cross threading, turn the end cap counter-clockwise until the thread of the end cap aligns with that of the nail. By turning clockwise, screw the end cap into the nail and tighten it firmly. Check there is no over projection of end cap on nail.

IMPLANT REMOVAL



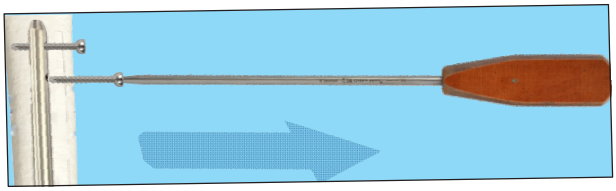
1. Remove the end cap

Remove the end cap with the help of Long hexa. Screwdriver
4.9mm.
Note: When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first remove bony part from the head and then use a hexa. long screw driver to loosen the end cap and Interlocking screws.



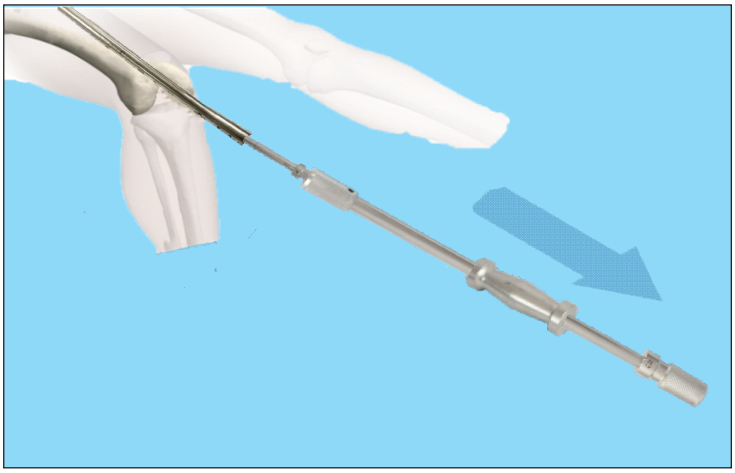
2. Remove Distal Interlocking Screws:

Use Long Hexa screwdriver to engage in proximal screw head. Take precaution to engage the screw driver tip firmly into the Screw head and turn counter clock wise to remove the screw With firm hold. The screw driver tip should not be engaged half way Otherwise head can be slipped off.



3. Remove proximal locking screws

Clear the hexagonal socket of the Interlocking screws from any ingrown tissue. Remove the proximal Interlocking screws using the Long Hexa. Screwdriver 4.9mm taking care as mentioned in step 2



4. Remove Nail

Clear the threaded socket of the IMSC nail from any ingrown tissue.Attach the Nail Holding Bolt on threaded part of the nail gently.
Do not use force to align the bolt on the nail's threads. Use socket wrench with T handle only after 2-3 initial threads are Inserted smoothly. If any extra resistance comes, take out the bolt back and realign the same after cleaning threaded socket. Tighten it firmly with nail and mount the extractor assembly with rod, head and ram over bolt.
Make gentle blow in reverse by ram to extract the nail.

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.

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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

INTRAMEDULLARY SUPRACONDYLER(IMSC) FEMORAL NAIL – Surgical Technique

Product Details:

IMSC

Implants — **Supracondylar (IMSC) Nail System**

Intramedullary Supracondylar Nails Cannulated

Intended Use	For Intramedullary Fixation of Supracondylar Femur Fracture
Profile	Proximal & Distal Hole Dia. 4.9 mm
Nail Diameter	9mm, 10mm, 11mm & 12mm
Size	15cm, 20cm, 25cm, 30cm, 35cm, 40cm

Material	Reference
SS 316L	183.915 To 183.1240

Interlocking Screws

4.9 mm

Intended Use	For Locking Nails in Bi-Cortical Fixation
Profile	Core Dia 4.0
Screw Diameter	4.9mm
Size	24mm To 50mm-2mm diff. 55mm To 90mm-5mm diff.

Material	Reference
SS 316L	184.4924 To 184.4990

IMSC Nail's Cap

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

Material	Reference
SS 316L	185.004

Instruments

Guide Wire - Short

2.5 mm x 24"

Reference
940.2524

Bone Awl - Curved

Reference
639.002

Nail Holding Bolt

Reference
724.003

Tissue Protector

Reference
649.001

Jig Holding Bolt

Reference
724.004

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Ortho Max®
Mfg. Co. Pvt. Ltd.

INTRAMEDULLARY SUPRACONDYLER(IMSC) FEMORAL NAIL – Surgical Technique

Supracondylar (IMSC) Nail System — Instruments

Nail & Jig Holder

Reference
724.001

Hexagonal Spanner with T Handle

Reference
937.001

Proximal /Distal Jig

Reference
724.002

Protection Sleeve

Reference
724.008

Drill Sleeve - 4mm

Reference
724.010

Tommy Bar

Reference
942.001

Trocar Awl with T Handle

Reference
941.001

Impactor Head

Reference
938.001

Drill Bits

4mm x 10"

Reference
552.410

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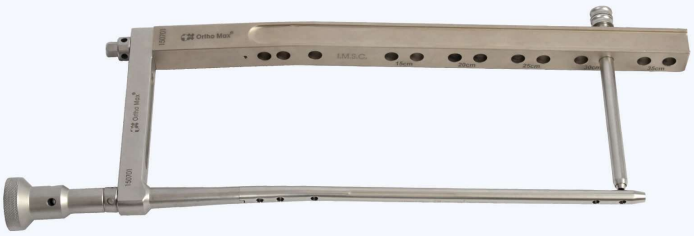
Instruments	Supracondylar (IMSC) Nail System	
Hexagonal Long Screw Driver		Reference 569.249
Depth Gauge - Long		Reference 561.349
Extractor Set	Rod 	Reference 939.001
	Head 	Reference 939.003
	Ram 	Reference 939.002
IMSC Nail Set Container		Reference 800.001

INTRAMEDULLARY SUPRACONDYLER(IMSC) FEMORAL NAIL – Surgical Technique

Supracondylar (IMSC) Nail System Set

IMSC Nails Jig Assembly



Contents :

Implants :-	Qty
Intramedullary Supracondylar Nails - Cannulated	
- 9, 10, 11, 12mm x 15, 20, 25, 30, 35cm - 1 each	20 Nos
Interlocking Screws	
- 4.9mm x 28mm To 90mm - 2 each	40 Nos
Instruments :-	
- Bone Awl - Curved	01 No
- Guide Wire - 2.5mm x 24"	02 Nos
- Tissue Protector	01 No
- Nail Holding Bolt	01 No
- Jig Holding Bolt	01 No
- Nail & Jig Holder	01 No
- Proximal / Distal Jig	01 No
- Trocar Awl with T Handle	01 No
- Hexagonal Spanner with T Handle	01 No
- Protection Sleeve	01 No
- Drill Sleeve 4mm	01 No
- Tommy Bar	01 No
- Impactor Head	01 No
- Drill Bits 4mm x 10"	01 No
- Hexagonal Long Screw Driver 4.9mm	01 No
- Depth Gauge - Long 4.9mm	01 No
- Extractor Set with Bolt	01 Set
- IMSC Nail Set Container	01 No

INTRAMEDULLARY SUPRACONDYLER(IMSC) FEMORAL NAIL – Surgical Technique

Implants Certified by ITC : CE 1023

Instruments Certified by Self Declaration : CE

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