YOGESHWAR IMPLANTS (I) PVT. LTD.

SUPRACONDYLAR NAILS

SURGICAL TECHNIQUE

Index

1. Description of surgical techniques

	Dia	-	Length
1608.1015-1025	10MM	-	150 , 200 , 250MM
1608.1115-1125	11MM	-	150 , 200 , 250MM
1608.1215-1225	12MM	-	150 , 200 , 250MM

9MM & ABOVE 250MM 'ORDER TO MAKE BASIS'

Name- Supracondylar Nail

Supracondylar Nail provides fixation in the cases of fractures above the knee joint or multi fragment fractures of condyle. Supracondylar Nail system provides nail with diameters 9mm 10mm, 11mm & 12mm, 13mm and length between 150mm, 200mm and 250mm.

Description: The product is available in SS 316L and Titanium Grade 5 material.

2. Feature & Benefits

- Easy to use
- Versatile
- Nail connected distal targeting - accurate screw insertion and reduced X-ray exposure
- Design provides great biomechanical strength

3. AO Principle

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

1. Anatomic reduction Fracture reduction and fixation to restore anatomical relationships.
2. Early, active mobilization Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.
3. Stable fixation Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.
4. Preservation of blood supply Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

4. Indications

- The Supracondylar Nail is Indicated for use in case of:
- Inter and supracondylar Femur Fracture
- Supra Condylar fracture with diaphyseal extension

5. Intended Purpose

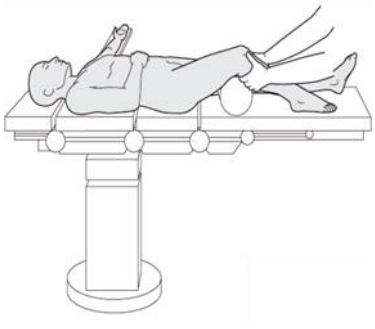
The intended purpose of Supracondylar Nail is to treat fractures of inter and supracondylar Femur Fracture and Supra Condylar fracture with diaphyseal extension.

6. Contraindications

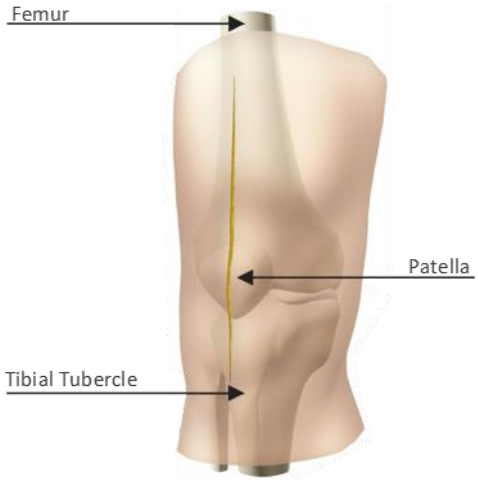
- Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.
- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the device.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site.
- Previous history of infections.
- Any neuromuscular deficit which could interfere with the patient's ability to limit weight bearing.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Malignancy in the fracture area.
- Mental, physical or neurological conditions which may impair the patient's
- Ability to cooperate with the post-operative regimen.
- Patients with a compromised immune system.
- Pre-existing internal fixation that prohibits proper pin placement

7. Surgical Steps

Patient Positioning:

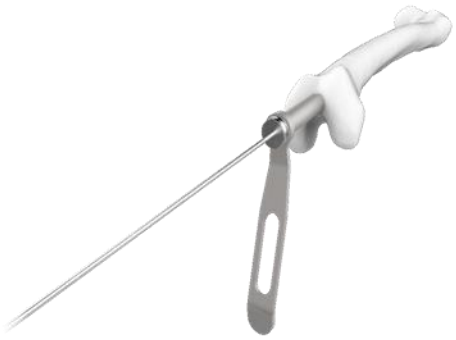


Place the patient in the supine position on a fracture or radiolucent imaging table. Place the knee in approximately 45 degrees of flexion. Use manual traction, a femoral distract or an external fixator to reduce severely displaced fractures and maintain length. Special attention is needed to maintain proper length when using a retrograde approach to treat a comminute fracture.



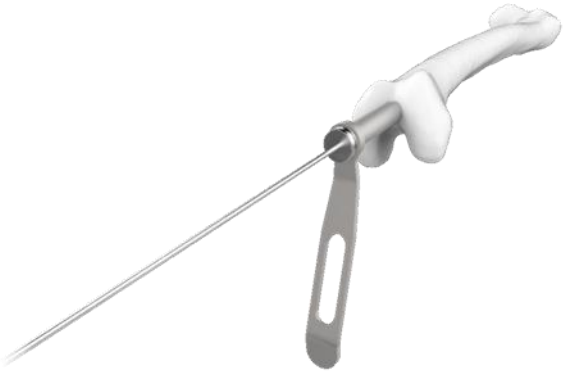
Approach: Approach the distal femur through a midline longitudinal incision between the patella and the tibial tubercle. Obtain access to the intercondylar notch by splitting the tendon longitudinally or displacing the tendon laterally.

Alternative approach: Approach the distal femur through a longitudinal incision from the superior pole of the patella to the tibial tubercle, placed along the medial border of the patellar tendon. Expose the intercondylar notch by using retractors to reflect the patellar tendon laterally or perform the procedure percutaneously.



Entry Point: Entry Wire Guide is inserted into the Entry Drill Guide Now this assembly is placed in line with the intercondylar notch. The3mm guide pin wire is inserted through the entry guide wire about 6-8cm into the bone.

Remove the Entry Wire Guide and insert the Entry Reamer into the Entry Drill Guide along the threaded guidewire. Ream along the guide wire in order to get access to the Intramedullary canal. No wire move the Entry reamer and the threaded guide wire along with the Entry drill guide. As an alternate to Entry Reamer, the Four cornered pointed awl could also be used to access the intramedullary canal



Guide wire insertion: The Reducer is advanced into the intramedullary canal past the fracture site for the reduction. The curved end of the reducer helps in guiding the guide wire with sphere head to the proximal region of the femur. The guide wire with sphere head is inspected in both. AP and lateral views for its final placement in the femur bone using the image intensifier. Finally the reducer is removed from the bone.

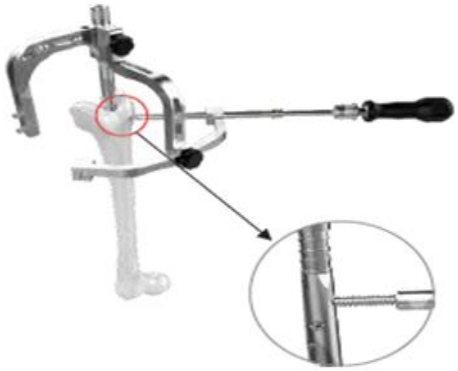
Nail Measurement: The Radiographic ruler is used to measure the size of the desired nail to be inserted. Place the Radiographic ruler in line with the femur bone. Now move the Car move rit and check the required nail length in AP view according to the marking son the ruler.

To measure the required diameter of the nail, the radiographic ruler is placed perpendicular to the femoral axis so that the diameter gauge is located over the intramedullary canal. Now from gauge choose the largest diameter nail that fits into the intramedullary canal.

Nail Jig Assembly: Align the nail slots with the slot son the Nail holding guide. Now insert the nail holding bolt into the nail through the Nail hold in guide and rotate it until the thread son the locking bolt sits and lock with the thread so the nail.

After verifying all the holes alignment, remove the aiming devices. Insert the nail and Nail holding guide assembly along the guide wire and attach the impactor to the Nail holding guide. Now the combined hammer is used to gradually tap on the impactor so that the nail is inserted and sits properly into the intramedullary canal up to the required depth. Finally, the guide wire is removed.

Proximal Locking: Attach the Proximal/Distal Aiming attachment to the Nail holding guide and fix it with the locking bolt on the Proximal/Distal Aiming attachment. Further attach the Proximal Aiming Arm to the Proximal/Distal Aiming attachment in order to aim at the Proximal threaded holes of the nail. The sleeve for locking screw is inserted through Proximal Aiming Arm in which the sleeve for drill bit is further inserted. Through the sleeve for drill bit, a long trocar is inserted in order to make a small incision at the site of screw. Now both the sleeves are pushed through the incision hole until it sits on the bone. Remove the Trocar and insert 4.0mm drill bit to drill a hole across both the cortices through the threaded hole in the nail Insert the Depth Gauge through the sleeve for locking screw and measure the required locking bolt length from the readings on the gauge.



Attach the 4.9mm locking bolt of required length to the screw driver and insert the locking bolt into the predrill hole through the sleeve. Similarly insert the second locking bolt through these threaded hole in the nail using the second hole in the

Proximal Aiming Arm

The Proximal/ Distal short nail Aiming Device is attached to the Nail holding guide Two distal holes on the Aiming Device are used for drilling the holes along the two distal non-threaded holes in the nail using the similar technique as used for the threaded holes as mentioned above. Again, the Depth Gauge is used to select the locking bolt of appropriate length.

End Cap Insertion: The end cap is attached to the screw driver and is finally inserted and locked into the distal open end of the nail.

8. Implant Removal

Nail Removal: There are two approaches of removing the nail listed below:

First all the locking bolts and the end cap is removed and the extractor rod is screwed into the distal open end of the nail. The combined Hammer is placed in line with the hammer guide as show in the image. Now with reverse hammering, then it removed. According to second approach, first all the locking bolts and the end cap is removed and then the extractor rod is attached to the nail. The handle for extractor is screwed on top of the Nail holding guide and on top of which the hammer guide is attached. The combined hammer is placed in line with the hammer guide and with reverse hammering, the nail is removed.

9. 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, reuse of implants is strictly not recommended.

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

10. Disposal of 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.

11. Packaging Material Disposal

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

12. MRI Information

IMPORTANT:

- Yogeshwar Implants (I) Pvt. Ltd. implants are manufactured from SS 316L and Titanium Grade 5 material 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 Yogeshwar Implants (I) 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.

13. Note

This above surgical technique is also applicable for all below mention product	
CAT NO.	Product Name
1768	DISTAL FEMUR NAIL
	Dia Length
	10MM - 150MM, 200MM, 250MM
	10MM - 300MM, 320MM, 340MM
	10MM - 360MM, 380MM, 400MM, 420MM
	11MM - 150MM, 200MM, 250MM
	11MM - 300MM, 320MM, 340MM
	11MM - 360MM, 380MM, 400MM, 420MM
	12MM - 150MM, 200MM, 250MM
	12MM - 300MM, 350MM

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