YOGESHWAR IMPLANTS (I) PVT. LTD.

INTERLOCKING NAIL FOR FEMUR
SURGICAL TECHNIQUE

Index

1. Description of Surgical Technique

Name: Interlocking Nail for Femur

Available in SS316L & Titanium Gr. 5 materials.

2. Feature of Benefits

Design:

- Anatomically correct longer, accurate profile proximal end for easier insertion.
- Anatomic design for easier insertion and improved fit
- Transverse locking holes to allow use of one nail in either left or right extremity
- Conical threads for secure connection to insertion/extraction instruments
- Crimping cross section for the best interference fit in the medullary canal
- Designed to prevent penetration of posterior cortex during insertion, and to glide easily through medullary canal.
- Featured with both dynamic & static transverse.
- Two transverse locking holes.
- Anatomical proximal end to prevent soft tissue irritation
- Wide range of available sizes: 9mm to 12mm diameters and 340mm–440mm Length.

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. Stable fixation: Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.
3. Preservation of blood supply: Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

Early, active mobilization: Early and Safe Mobilization and rehabilitation of the injured part and the patient as a whole.

4. Indications

- Subtrochanteric fractures
- Intertrochanteric fractures
- Ipsilateral neck/shaft fractures
- Comminuted proximal femoral shaft fractures
- Femoral fixation required as a result of pathological disease
- Temporary stabilization of fractures of the femoral shaft – ranging from the femoral neck to the supracondylar regions of the femur.

5. Intended Purpose

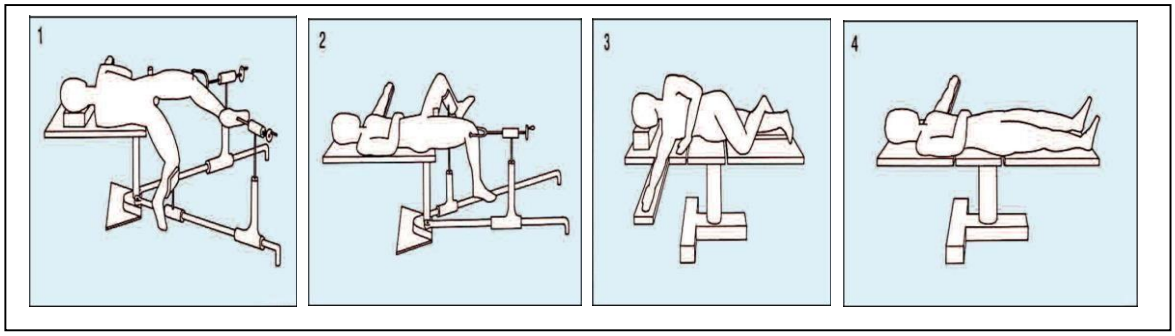
The Interlocking Nail for Femur is intended to repair fractures of the femur.

6. Contraindications

- Intertrochanteric Fractures
- Intracapsular fracture of neck femur
- Basal neck fracture
- 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:**



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.

With the patient in the supine position, the leg of the injured 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 access 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.

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

- **Use of the Image Intensifier**

An image intensifier is required for both closed reduction and distal locking techniques. The image intensifier allows controlled viewing of the fracture zone for insertion of the reamer and 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 radiation source should be placed on the medial aspect of the femur. This will facilitate the aiming process, which is performed laterally.

- **Finding of Entry point & medullary canal opening:**

The insertion point at piriformis fossa offers benefits with regard to possible lesions of the tendons.

- **Proximal Reaming:**

Under image intensification, insert the 2.5 mm guide wire into the canal, across the fracture site, and into the distal metaphysis. Coupling T handle may be used to facilitate insertion. Hand Reamer is followed by guide wire which is used to reaming the proximal portion of nail, proximal reamer is use for reaming.

- **Nail and insertion handle assembly:**

After reaming proximal canal, nail is inserted in femur bone. Curved jig is attached with nail with the use of conical bolt. For hammering purpose, force is applied by extraction rod, handle for extractor & round hammer, which pushes the jig so that nail can insert properly. Insertion Head for introducer is an optional part locked with conical bolt which also used for hammering.

- **Proximal Locking:**

Protection Sleeve 8.0 mm is passed through curved jig. With the use of trocar Ø8.0mm, entry point of drill identified. Trocar is passed through protection sleeve. Then after trocar is replaced by I.L. Drill Sleeve 4.0 mm which is guide the drill bit 4.0mm 200mm long. Depth gauge is used to measure the drill length. With the help of hex screw driver long 4.5mm, 4.9mm locking bolt is inserting in proximal holes of nail through protection sleeve.

- **Distal Locking:**

Distal locking is done with free hand technique with the help of Steinman pin & image intensifier.

- **End-cap insertion:**

End cap is inserted with the use of screw driver at proximal threaded portion of Interlocking nail for femur

- **Cautions:**

Prior to reaming, it is important to check the cantered intramedullary position of the Guide Wire with the image in - testifier. Lateral displacement of the Guide Wire could lead to resection of more bone on the lateral side of the wire, which in turn will lead to an offset position of the nail and increase the risk of a shaft fracture.

The nail must progress smoothly, without excessive force. If too much resistance is encountered, removal of the nail and additional reaming is recommended.

- **Warnings:**

Prior to advancing the K-Wire, check the correct guidance through the K-Wire Sleeve. Do not use bent K-Wires.

Correct placement of the K-Wire tip in subchondral bone must be checked with image intensifier in both A/P and M/L views.

Do not use the cannulated Recon Step drill for Lag Screw over a deflected K-Wire.

8. Implant Removal

Interlocking Nail for Femur

Remove interlocking bolt having made an incision through the old scar, the screws can be localized using palpation or the image intensifier. In some cases, the instruments have a better grip on the bolt. First remove the end cap and insert the Extraction Rod into the proximal nail end.

Note: If the soft tissue situation is difficult, the Extraction rod for nail extraction can be mounted after removal of all but one locking bolt in order to prevent nail rotation in the medullary cavity. Remove the last locking bolt.

Extract nail

Extract the nail using extractor rod, handle for extractor & round hammer.

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 for Intramedullary Nail, both are non-magnetic material, hence it does 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.

Instruments

STANDARD SET

CURVED BONE AWL 287.01

I.L.GUIDE WIRE - 2.5MM * 900MM 287.02

SOCKET WRENCH - 10MM 287.03

HEAD FOR INTRODUCER 287.05

CURVED JIG 287.06

CONICAL BOLT (SP.) 287.07
8 - 9 MM

CONICAL BOLT (SP.) 287.08
10 -13 MM

S.S.DRILL BIT (SP.) 287.10
3.2 MM (200 MM) 287.11
4.0 MM (200 MM)

I.L.DRILL SLEEVE 287.13
3.2 MM 287.14
4.0 MM

PROTECTION SLEEVE - 8.0MM 287.19

I .L . DEPTH GUAGE 287.26

POINTER 287.27

Implants Used:

4.9mm Interlocking bolts

INTERLOCKING NAIL FOR FEMUR

1602

	Dia	-	Length
1602.934-944	9MM	-	340MM To 440MM
1602.934-944	10MM	-	340MM To 440MM
1602.1134-1144	11MM	-	340MM To 440MM
1602.1234-1244	12MM	-	340MM To 440MM

(Difference of 10MM each)

8 ,13MM & ODD SIZES ARE ON 'ORDER TO MAKE BASIS'

INTERLOCKING BOLTS

1702
1703

	Dia	-	Length
1702.3922-3938	3.9MM	-	22 TO 38MM (Difference of 2MM each)
1702.3940-3950	3.9MM	-	40 TO 50MM (Difference of 2MM each)
1703.4922-4938	4.9MM	-	22 TO 38MM (Difference of 2MM each)
1703.4940-4950	4.9MM	-	40 TO 50MM (Difference of 2MM each)
1703.4952-4960	4.9MM	-	52 TO 60MM (Difference of 2MM each)
1703.4964-4980	4.9MM	-	64,68,72,76,80MM
1703.4985-49100	4.9MM	-	85,90,95,100MM

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