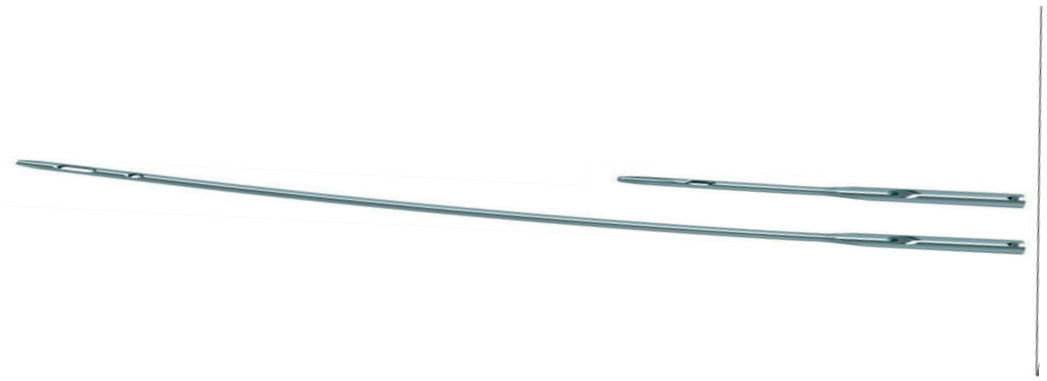
# TRAFFON II NAIL
# SURGICAL TECHNIQUE

# Index

## 1. Description of Surgical Technique



**Material:** SS 316L and Titanium grade 5

**Color:** grey

**Diameters:** 9 to 12 mm (short nails, 1 mm increments)

9 and 12 mm (long nails)

All nails have a proximal diameter of

16.5 mm with a lateral flattened surface

***Lengths short & Regular Nails:***

180 mm small

240 mm

***Lengths long Nails:***

340mm – 420mm

(with20mmincrements) 340mm – 420mm

(left and right nails)

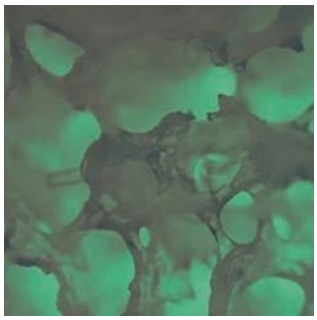
**CCD-Angle:** 130°

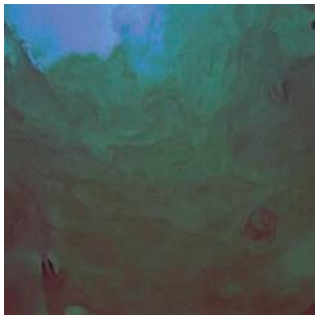
**Cannulation:** All nails are cannulated

## 2. Feature & Benefits

**Compaction of cancellous bone:**

Inserting the Proximal blade compacts the Cancellous bone providing additional anchoring, which is especially important in osteoporoticbone.





The proximal blade is automatically locked to prevent rotation of the blade and femoral head.

## 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

**TRAFFON II (SMALL)-130*SHORT & REGULAR (Length 180 mm – 240 mm)**

- Per trochanteric fractures
- Intertrochanteric fractures
- High subtrochanteric fractures

**TRAFFRON II 130 long length**

- Low and extended sub tro chanteric fractures
- Ipsilateral tro chanteric fractures
- Combination fractures (in the proximal femur)
- Pathological fractures

## 5. Intended Purpose

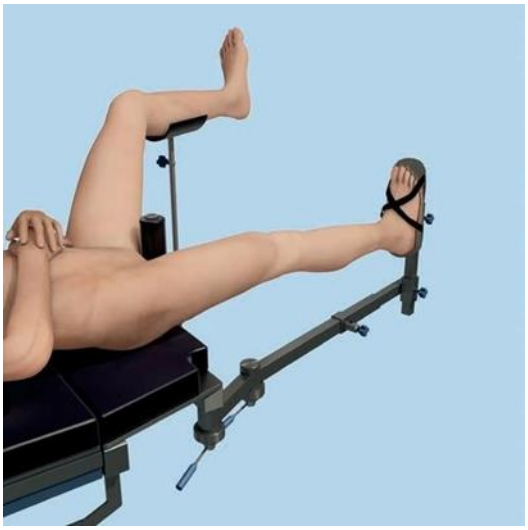
Taffron nail intended to be used for combination fracture in proximal femur, subtrochantric fracture, trochantric fracture and pathological fracture.

## 6. Contraindications

- Low sub trochanteric fractures
- Femoral shaft fractures
- Isolated or combined medial femoral neck fractures
- 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**



Position the patient supine on an extension table or a radiolucent operating table. Abduct the unaffected leg as far as possible and place it on a leg support, so that it allows free fluoroscopic examinations. This should be tested preoperatively.

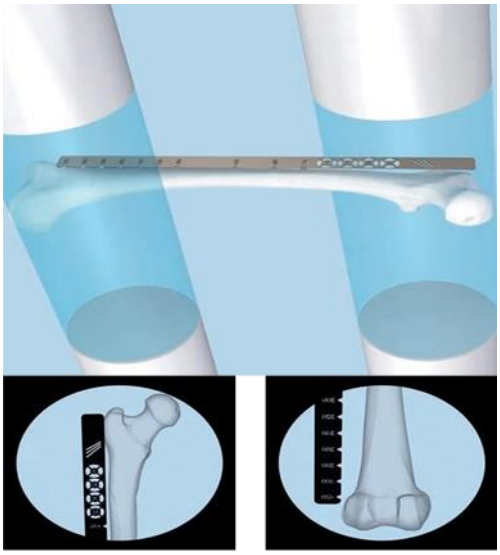
For unimpeded access to the medullary cavity, abduct the up- per body by about 10–15°to the unaffected side (or adduct the affected leg by 10–15°).

**Reduce fracture**

Perform closed reduction of the fracture under image intensifier control. If the result is not satisfactory, perform open reduction.

**Note:** Exact anatomical reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result. Handle devices with care and dispose worn bone cutting instruments in an approved sharps container.

**Confirms nail length and diameter**



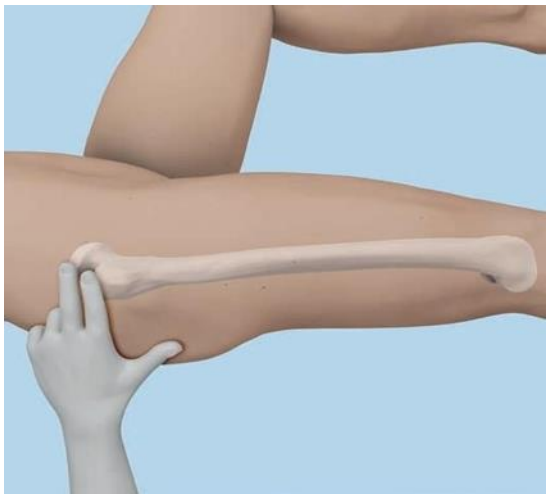
The required nail length must be determined after reduction of the femoral fracture. Position the C-arm for an AP view of the proximal femur. With long forceps, hold the template alongside the lateral thigh, parallel to and at the same level as the femur. Adjust the template until the proximal end is at the desired nail insertion position. Mark the skin at the proximal end of the template.

Move the C-arm distally. Align the proximal end of the developing template to thes kin mark, and take an AP image of the distal part. Verify fracture reduction going from proximal to the fracture to distal. Read the nail length directly from the template image. For long nails, select the measurement at or just proximal to thee piphys ealscar, or atthach osen insertion position

Read the nail length directly from the template image. For long nails, select the measurement at or just proximal to thee piphysealscar, or atthech osenin sertion position.

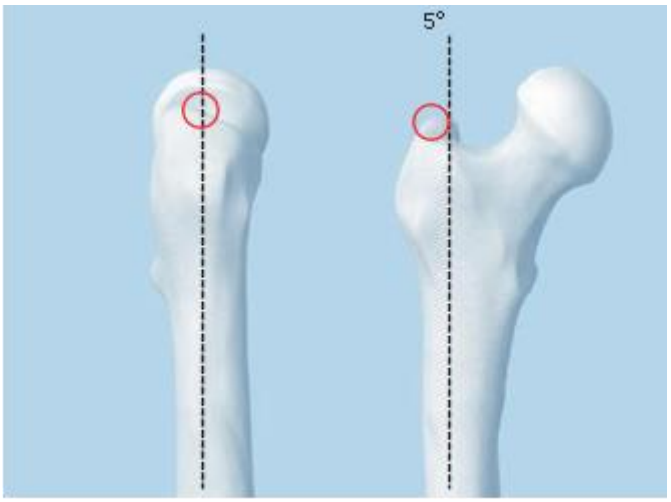
Note: When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.

**Approach:**



Palpate the trochanter major. Make a 5 cm incision proximal from the tip of the greater trochanter. Make a parallel incision of the fasciae of the gluteus Medius and split the gluteus Medius in line with the fibers.

**Open Femur**




**Determine entry point:**

In AP view, the S.S. TRAFFON II (SMALL)-130*entry point is on the tip or slightly lateral to the tip of the greater trochanter in the curved extension of the medullary cavity, as the ML angle of the S.S. TRAFFON II (SMALL)-130* is 5°.

In lateral view then try point is in line with the axis of the Intramedullary canal.

**Insert guide wire :**

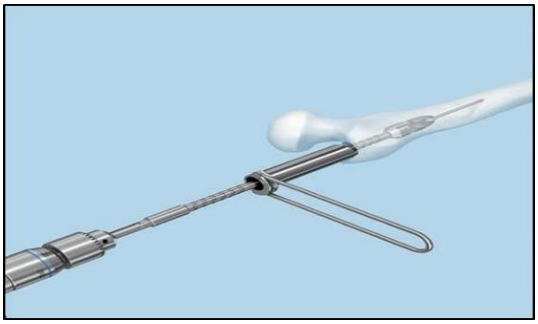
Secure the guide pin in the power tool. Alternatively, the universal chuck with T-handle can be used to insert the guide pin manually.

Position both the needle sleeve at the insertion point.

Insert the guide pin through the protection sleeve and the drill sleeve. Remove the power tool and the inner needle sleeve. To correct the placement of the guide pin, leave the first guide pin in place and insert a second guide pin through needle sleeve.

Note: The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide pin, position a guide pin ventrally on the femur and check under image intensifier control.

**Open femur with proximal core drill**

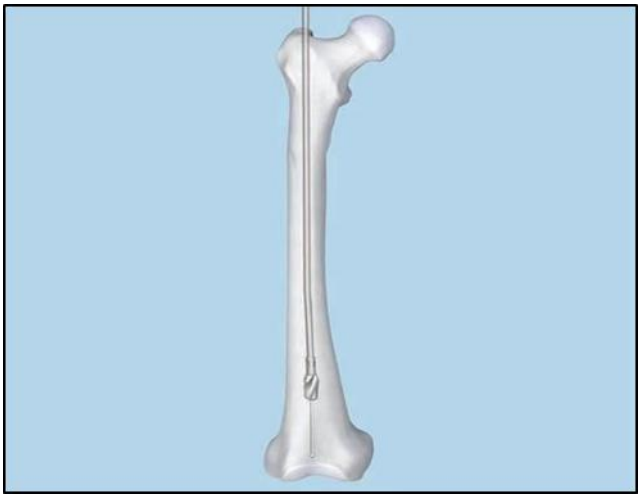


Guide the proximal core drill through the needle sleeve over the guide pin and drill the cavity for the proximal part of the S.S.TRAFFON II (SMALL)-130*nail with the power tool. Remove the proximal core drill, the needle sleeve and the guide pin.

**Precaution:** It is recommended to open the femur by using a power tool at high speed or carefully by hand. To prevent dislocating the fracture fragments, avoid lateral movements or excessive compression force.

**Rim medullary canal :**

Insert reaming rod



Insert the reaming rod into the medullary canal to the desired insertion depth. The tip must be correctly positioned in the medullary canal since it determines the final distal position of the long S.S.TRAFFON II (SMALL)-130*nail.

**Reaming**

Starting with the 9 mm diameter reaming head, ream to a diameter of 1mm greater than then a diameter. Ream in 1 mm increments and advance the drill with steady, moderate pressure. Do not force the soft expanding drill. Partially retract the drill repeatedly to clear debris from the medullar canal. Use the holding forceps to retain the reaming rod while reaming and to prevent it from rotating. Remove the reaming rod before locking the Intramedullary nail.

**Insert nail Assemble S.S.TRAFFON II**

Guide the connecting bolt through the insertion handle barand secure the desired TRAFFON II (SMALL)-130*to the handle bar using the connecting bolt universal wrench

**Insert Traffon T3**

Use image intensifier control to insert the TRAFFON T3

Carefully insert the S.S.TRAFFON II (SMALL)-130*manually using slight bidirectional turns of the handle bar as far as possible into the femoral opening. If the S.S.TRAFFON II (SMALL)-130*cannot be insert ed, select a smaller size S.S.TRAFFON II (SMALL)-

130*diameter or ream the medullary cavity to a diameter that is at least 1 mm larger than that of the selected nail.

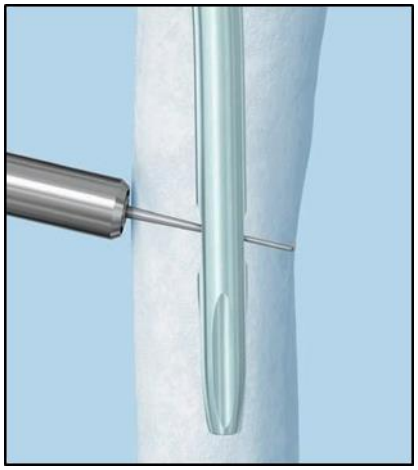
The correct S.S.TRAFFON II (SMALL)-130*insertion depth is reached as soon as the projected proximal blade is positioned in the center of the femoral head. A too cranial or too caudal S.S.TRAFFON II (SMALL)-130*position should be avoided as it can lead to mal position of the proximal blade.

**Drill**

Use the drill bit to drill through both cortices. The tip of the drill bit should protrude by 2 to 4 mm. Just after drilling both cortices, confirm the drill bit position. Ensure that the drill sleeve is pressed firmly to then ear cortex and read the measurement from the calibrated drill bit at the back of the drill sleeve. This measurement corresponds to the appropriate length of the locking bolt. Remove the drill bit (limiting drill) and the drill sleeve.

Precaution: Always make sure that no diastases has occurred intra operatively before beginning distal locking. Diastasis can cause delayed healing.

**Determine length of locking bolts**



After drilling both cortices, remove the drill bit and the drill sleeve.

Insert the distal locking hole depth sounder through the protection sleeve to the near cortex and advance the hook through both cortices.

Drawback the hook until it engages in the opposite cortex. Read the measurement from the depth gauge. Add 2 to 4 mm to the measured length to ensure good engagement of the locking bolt in the opposite cortex.

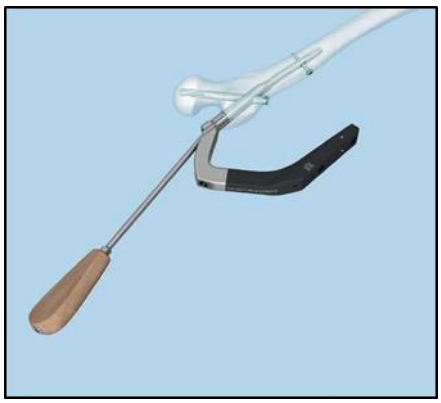
**Insert locking bolt**

Insert a locking bolt of the measured length with the distal locking screw/tail cap wrench through the protection sleeve until the locking bolt head lies against the near

cortex. The tip of the locking bolt should not project more than 1–2 mm beyond the far cortex.

Remove the distal locking screw/tail cap wrench and the protection sleeve.

## 8. Implant Removal



Remove the guide. Loosen the connection bolt with the connecting bolt universal wrench. Remove the connecting bolt and the handle bar.

Note: The endcap with 0 mm extension can be inserted through the insertion handle barrel. Only remove the connecting bolt and leave the handle baring place.

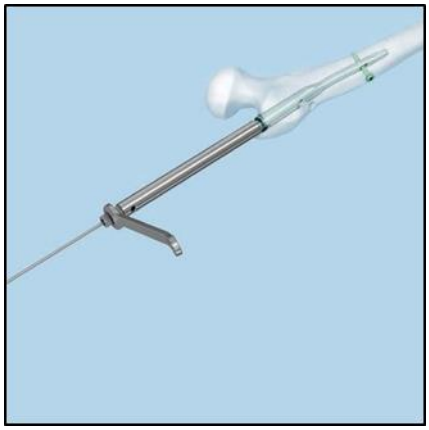
**Remove proximal blade**


Implant removal is an elective procedure. After an incision through the old scars,

Locate the proximal blade by palpation or under image intensifier control. Insert the thread needle roughs the cannulated Proximal blade. Push the spiral blade screw driver over the thread needle and use gentle pressure to screw it counter clockwise into the Proximal blade (note" attach" marking on the extraction screw shaft).

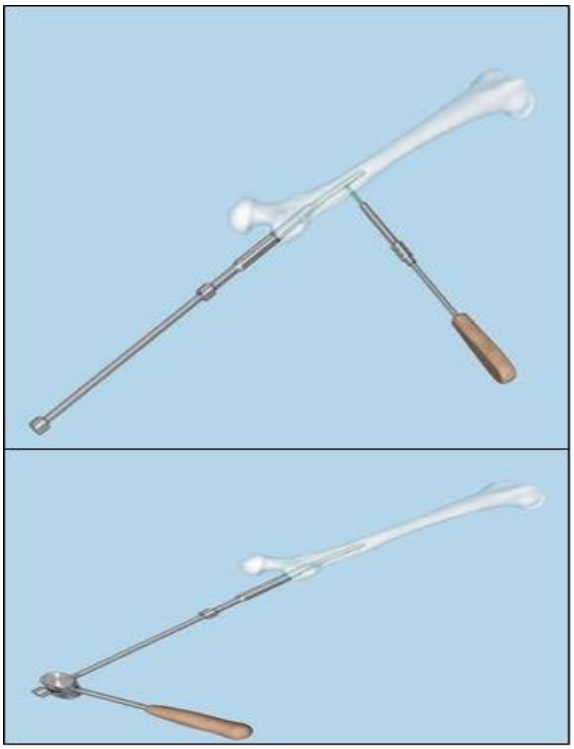
Extract the proximal blade by applying gentle blows with the hammer.

**Remove end cap**



Insert the hook of the guide wire with hook through the end cap. Guide the cannulated hexagonal socket over the thread needle to the end cap. Remove the end cap with the tail cap ball head wrench.

**Remove locking bolt and nail**



Before removing the locking bolt, screw the hammer guide into the S.S.TRAFFON II (SMALL)-130*and tighten it.

Remove the locking bolt with the hexagonal screwdriver. Mount the large holding sleeve onto the hexagonal screw- driver to facilitate removal of the locking bolt.

Extract the nail by applying gentle blows with the 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

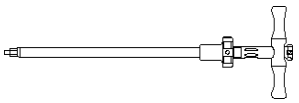
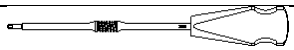
**IMPORTANT:**

- Yogeshwar Implants (I) Pvt. Ltd. implants are manufactured from SS 316L and Titanium Grade 5 material 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 | |
|---|---|
| **Sr No.** | **Product Name** |
| 01 | TRAFFON II (SMALL) - 130* |
| | Dia Length |
| | 9MM - 180MM |
| | 10MM - 180MM |
| | 11MM - 180MM |
| | 12MM - 180MM |
| 02 | **TRAFFON II (REGULAR) - 130*** |
| | Dia Length |
| | 9MM - 240MM |
| | 10MM - 240MM |
| | 11MM - 124MM |
| | 12MM - 240MM |
| 03 | **LONG TRAFFON II NAIL - 130° - RIGHT** |
| | Dia Length |
| | 9MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |
| | 10MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |
| | 11MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |
| 04 | **LONG TRAFFON II NAIL - 130° - LEFT** |
| | Dia Length |
| | 9MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |
| | 10MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |
| | 11MM - 300MM, 340MM, 360MM, 380MM, 400MM, 420MM |

**Instruments used**

| Name of instrument | Image |
|---|---|
| T3 LAG SCREW DRIVER |  |
| T3 FLEXIBLE SCREW DRIVER |  |
| T3 SELF SUSTAINING PIN |  |

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