ELASTIC NAIL
SURGICAL TECHNIQUE

Index

1. Description of Surgical Technique

Name - ELASTIC NAIL

Elastically-stable intramedullary nailing with the TEN Titanium Elastic Nail is used primarily for the management of diaphyseal and metaphyseal fractures in children. Whether the TEN is indicated or not depends upon the age of the patient and the type and site of the fracture.

Available in SS316L & Titanium Gr. 5 materials.

2. Feature of Benefits

Stable Fixing

Naill Tip - Facilitates nail insertion and sliding along the medullary canal

Nail Diameters – Multiple nail diameters for all indications

Available in Titanium and SS material

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

- Humerus and forearm in adults
- Polytrauma in combination with craniocerebral trauma, even outside the age range specified above
- Prophylactic stabilization with juvenile bone cysts
- Osteogenesis imperfect

5. Intended Purpose

Elastic Nail is intended for the management of diaphyseal and certain metaphyseal/ epiphyseal fractures of long bones in children and young adults.

6. Contraindications

- Intra articular fractures
- Complex femoral fractures, particularly in connection with overweight (50–60 kg) and/or age (15–16 years)
- 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

This surgical technique is explained using the example of a femoral shaft fracture and the ascending technique. Variants of this standard technique are described in "Additional applications" on page 12.

Careful preoperative planning, the correct choice of implant and a precise rotation check on the basis of the non-operated extremity are all vital for a good surgical result.

- **Position child**

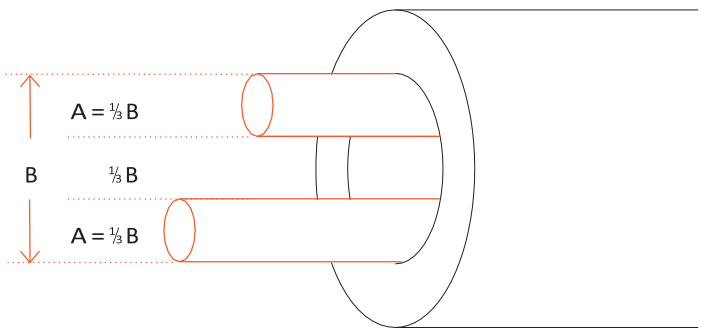
Place the child in a supine position on a radiolucent operating table. The extension table can be used for larger children.
Secure small children to the operating table. The assistant ex- tends the injured extremity. Free positioning allows better control of the nail position and rotation. Position the image intensifier so that AP and lateral X-rays can be recorded over the full length of the femur.

- **Reduce fracture**

If the extension table is used, reduce the fracture preoperatively, while closed, under image intensifier control. If the child is freely positioned, the fracture is reduced during the operation. For complex fractures, cover both legs with sterile sheets so that a rotation comparison can be performed during operation.

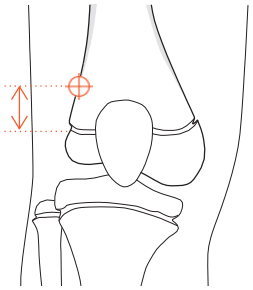
Fracture reduction can be facilitated by the use of the small F-tool (359.209). Position the F-tool at the level of the fracture so that the two identically aligned arms of the lever bring the fragments into the desired position.

- **Determine nail diameter**



Measure the isthmus of the medullary cavity on the X-ray image. The diameter of the individual nail (A) should be 30–40% of the diameter of the medullary cavity (B). Choose nails with identical diameter to avoid various or valgus mal- position.

- **Determine nail insertion points**



For the ascending technique, the insertion points on the femur are 1–2 cm proximal to the distal epiphyseal plate. In children, this is about one fingerbreadth proximal to the upper pole of the patella.

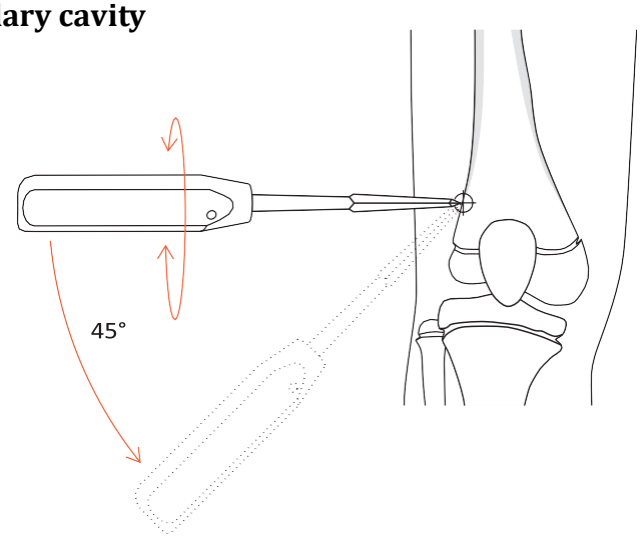
If necessary, check the intended insertion points under the image intensifier.

- **Perform incisions**

Make the opposing medial and lateral skin incisions at the planned insertion points and cut distally for 3–4 cm, depending on the size of the child. On the lateral side especially, the incision of the fascia should be of the same length.

Important: Ensure that the insertion points are outside the joint capsule and be careful to avoid the epiphyseal plates.

- **Open medullary cavity**



Precisely matched opening of the medullary cavity on both sides is essential for optimal symmetrical bracing.

Divide the fascia lata over a sufficient length. Vertically insert the Awl down to the bone and firmly make a centre mark. With rotating movements, lower the awl down to an angle of 45° in relation to the shaft axis and continue perforating the cortical bone at an upward angle. The opening should be slightly larger than the selected nail diameter.

Check the position and insertion depth of the awl with the image intensifier.

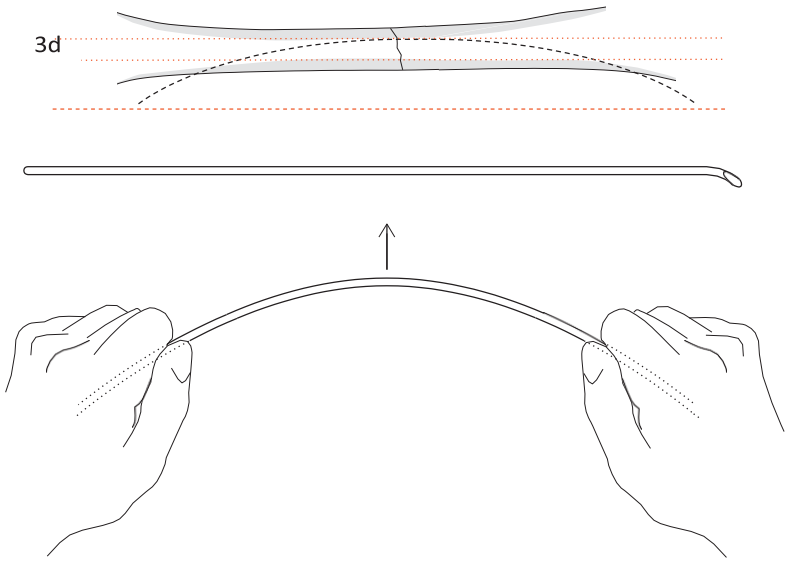
Repeat this procedure for access on the opposite side.

Alternative

If the cortical bone is very hard, open up the medullary cavity with the corresponding Drill Bit and the Double Drill Guide. Check the position and insertion depth of the drill bit with the image intensifier.

Note: Lower the drill by 45° only when the drill is running, otherwise the tip may break

- **Pre-bend nails**

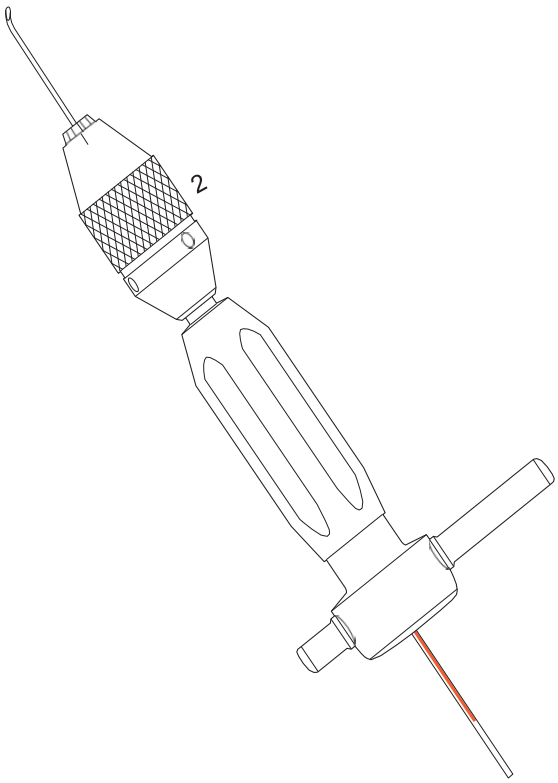


We recommend pre-bending of the implanted part of the nails to three times the diameter of the medullary canal. The vertex of the arch should be located at the level of the fracture zone. The nail tip should form the continuation of the arch. Pre-bend both nails in exactly

the same way.

Note: The pressure applied internally can be increased by pre- bending the nails to a smaller diameter, thus shifting the nail crossover points more towards the metaphysis. This can in- crease the stability in complex fractures.

- **Load first nail in the inserter**



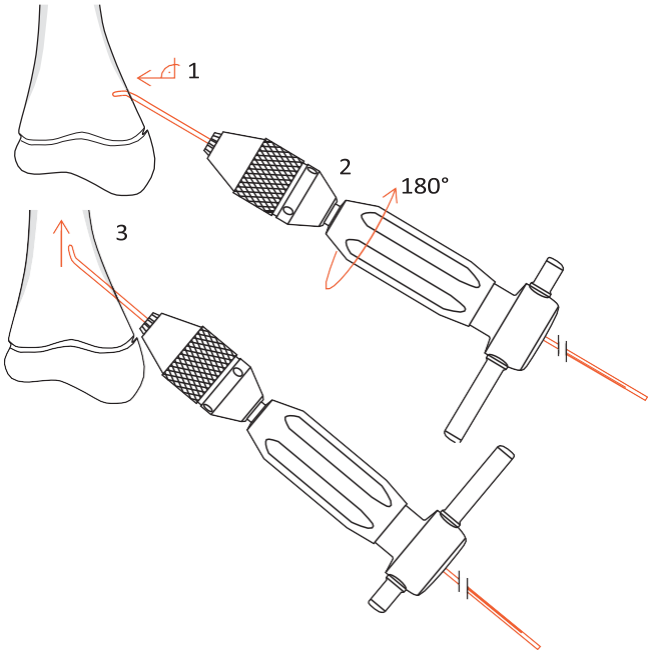
Load the first nail in the inserter (359.219). Align the laser marking on the end of the nail with one of the guide markings on the inserter (laser markings at the tip, asymmetrical trans- verse bolts at the end). This permits direct visual control of the alignment and rotation of the nail tip in the bone without an image intensifier, thus preventing excessive crossover of the nails (corkscrew effect).

Tighten the nail in the inserter in the desired position using the Pin Wrench or the Spanner Wrench.

Alternative

Use the long Inserter or the Universal Drill Chuck with T-Handle. Do not, under any circumstances, strike the universal drill chuck with T-handle with a hammer.

- **Insert first nail**



Insert the nail into the medullary cavity with the nail tip at right angles to the bone shaft (1). Turn the inserter through 180° (2) and align the nail tip with the axis of the medullary cavity (3). If necessary, check the position of the nail tip with the image intensifier.

Note: The laser marking on the end of the nail shows the nail tip alignment. This facilitates nail insertion and helps reduce the X-ray exposure time.

- **Advance first nail to the fracture zone**

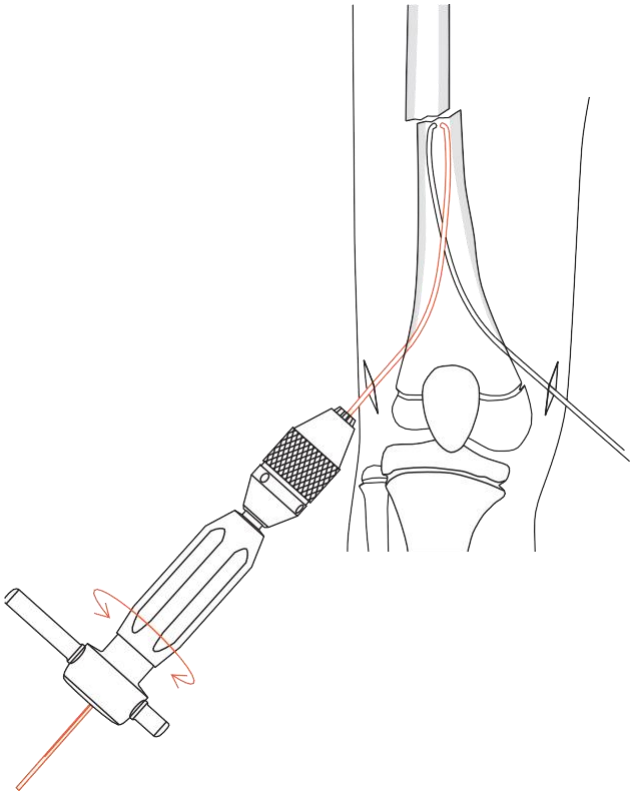
Advance the nail manually up to the fracture site, using rotating movements or gentle taps of the Combined Hammer (359.221) against the striking surface of the inserter. Do not strike the T-pieces.

Option if more forceful hammer blows prove necessary, or if the nail needs to be moved back and forth in a targeted manner to achieve further reduction, screw the hammer Guide (359.218) firmly into the inserter, if necessary, with the aid of the pin wrench Use the combined hammer or Slotted hammer

- **Insert second nail**

Repeat steps 8 to 10 for the second nail at the opposing insertion point, thereby producing the first crossover of the nail.

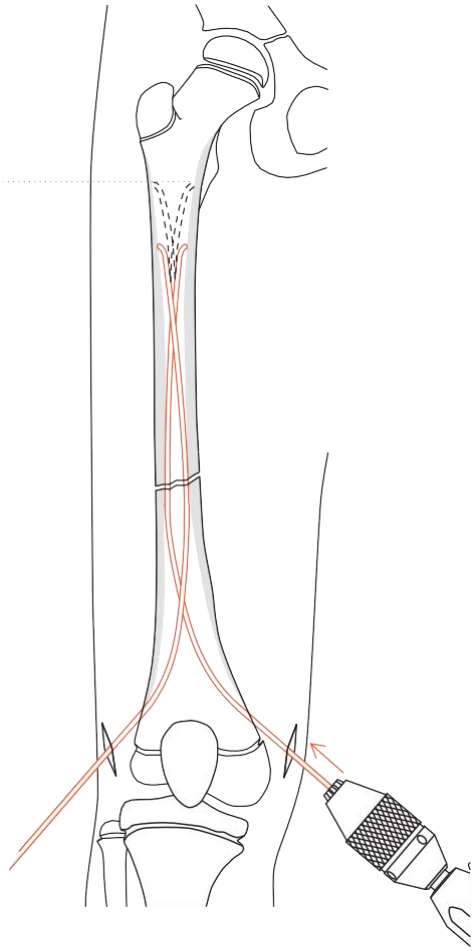
- **Advance nails**



If necessary, perform indirect fracture reduction either by turning the nails, pulling the leg or using the F-tool. Then advance the nails alternately across the fracture zone. Survey the passage of the nails with the image intensifier in both planes also on the other side of the fracture zone.

Note: Any nails that buckle as a result of the reduction manipulations must be replaced and discard.

- **Check position of nail tips**



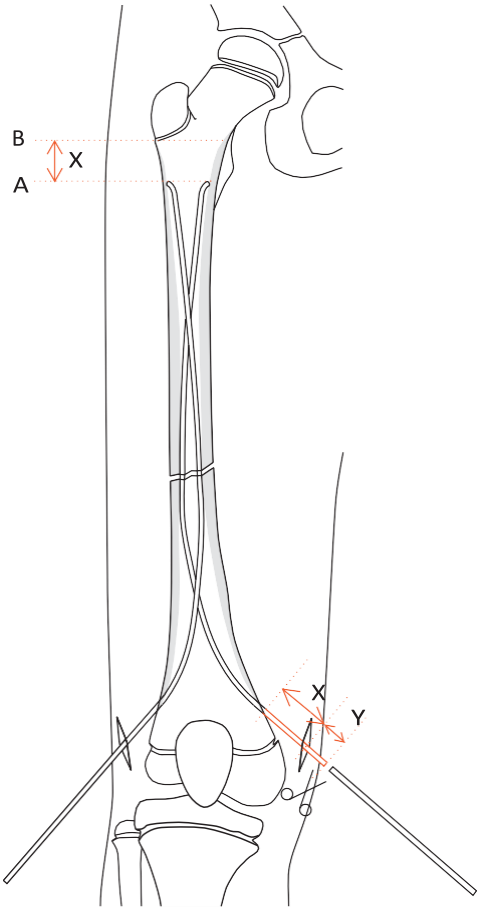
Correctly align the nail tips in the proximal fragment in relation to the medullary cavity in the frontal plane. If the tips are correctly located, advance the nails in a proximal direction until the fracture is secured. The tips of the nails should only just reach the metaphysis (A). Ensure that the nails cross over for the second time only after they have passed the fracture zone.

Note: Do not, under any circumstances, turn the nail through more than 180° about its own axis or produce a "corkscrew effect" (more than two nail crossover points

- **Check rotation**

When the fracture is provisionally but firmly fixed, check rotation before final anchoring and, if necessary, align the nail tips correctly. If an extension table is used, aseptically release the leg from the extension so that the image intensifier can be used to check the axial alignment in the proximal femur.

- **Trim nails**



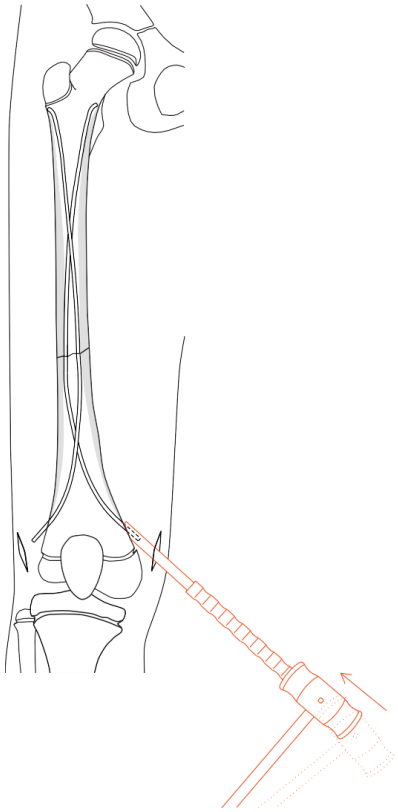
The nails must be trimmed to the desired length during the operation. The ideal cutting point is measured from the bone to the distal end of the nail.

Starting at the proximal end, estimate the distance (X) between the current position of the nail tips (A) and the definitive an- choiring position (B) on the image intensifier projection. This distance plus an extraction length of approx. 1 cm (Y) produces the distance from the bone to the cutting point.

The nails can be trimmed using the Cutter for TEN (359.217). See page 11 for assembly and handling instructions.

Note: Excessively long nail ends result in pseudo bursa for- mat ion and prevent free flexion of the knee. They can also per-for ate the skin and cause infections

- **Final positioning and anchoring of nails**



Advance the nails to the planned final position by applying gentle hammer taps to the beveled Impactor (359.206).

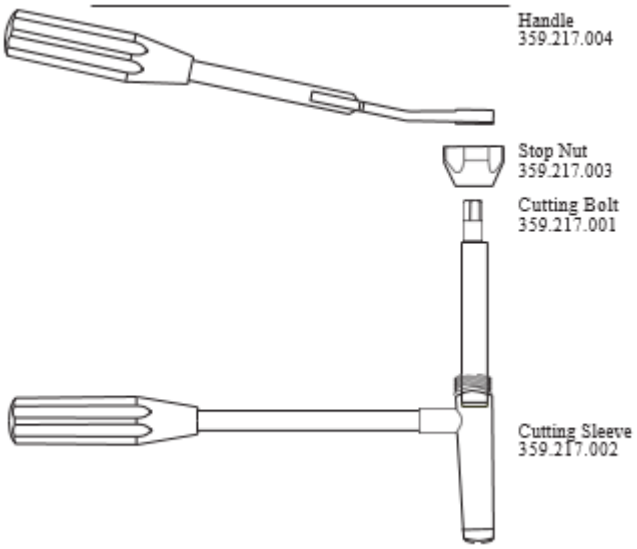
The bevelled part of the impactor must reach the cortical bone. This will ensure a projection of approx. 1 cm (Y) for subsequent removal.

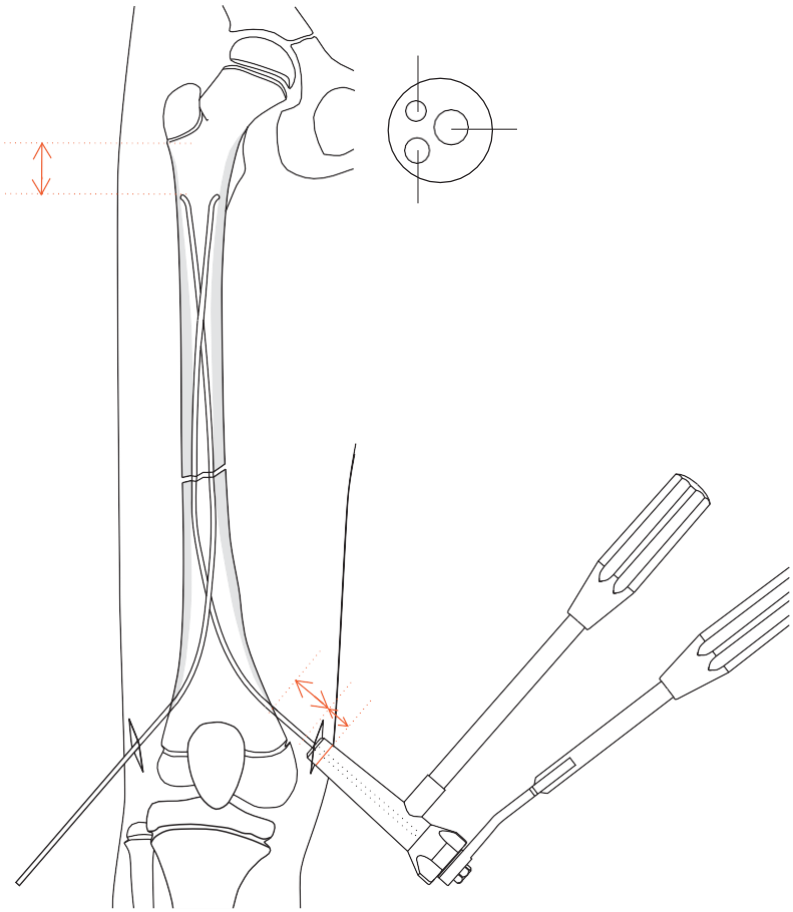
Bend the nail ends upwards slightly with the bevelled impactor to facilitate subsequent implant removal.

Option

If deeper insertion of the nails is desired, apply careful taps with the straight Impactor.

- **Assembly and handling instructions for the Cutter for TEN**





Loosen the stop nut on the cutter and turn the inner cutting bolt to the neutral position, i.e. engage the cutting bolt so that the lettering TOP is at the top. Retighten the stop nut.

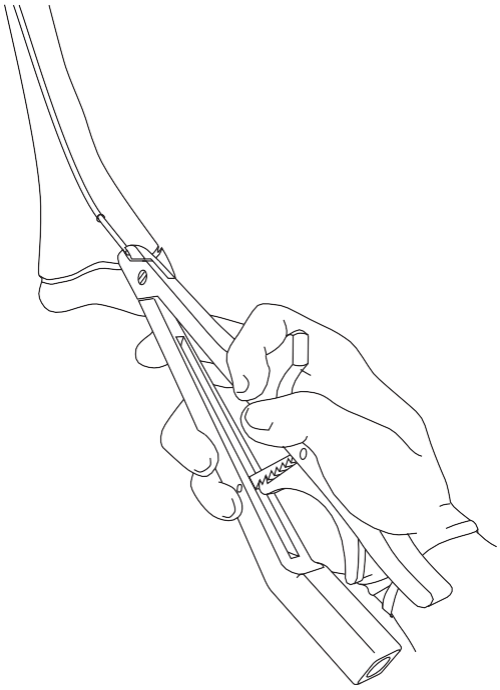
Introduce the nail end to be cut through the appropriate opening of the cutting sleeve until the black marker ring on the out- side of the sleeve reaches the desired cutting point

on the nail. Locate the handle with ratchet over the cutting bolt and trim the nail.

After trimming, open the stop nut and remove the cut nail end.

If the cutting surface of the cutting bolt has become rough-ended, send the cutter to your representative for regrinding.

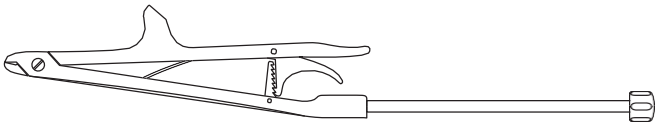
8. Implant Removal



The following description for removing the TEN is independent of the indication.

Enter through the old incision site and expose the nail end. Using the Extraction Pliers (359.215) grasp the nail, bend upward slightly and withdraw. If the nail end is tight up against the bone, the bevelled Impactor (359.206) can be used to help bend the end upward.

Option



If necessary, screw the Hammer Guide tightly into the connecting thread of the extraction pliers using the Ø 4.5 mm Pin Wrench and knock the nail out by firm blows along the hammer guide with the Combined Hammer.

Repeat the procedure for the second nail.

Alternative

Remove the nails using the flat-nosed Pliers and the combined hammer or the 500 g 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.

Yogeshwar Implants (I) Pvt. Ltd.

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