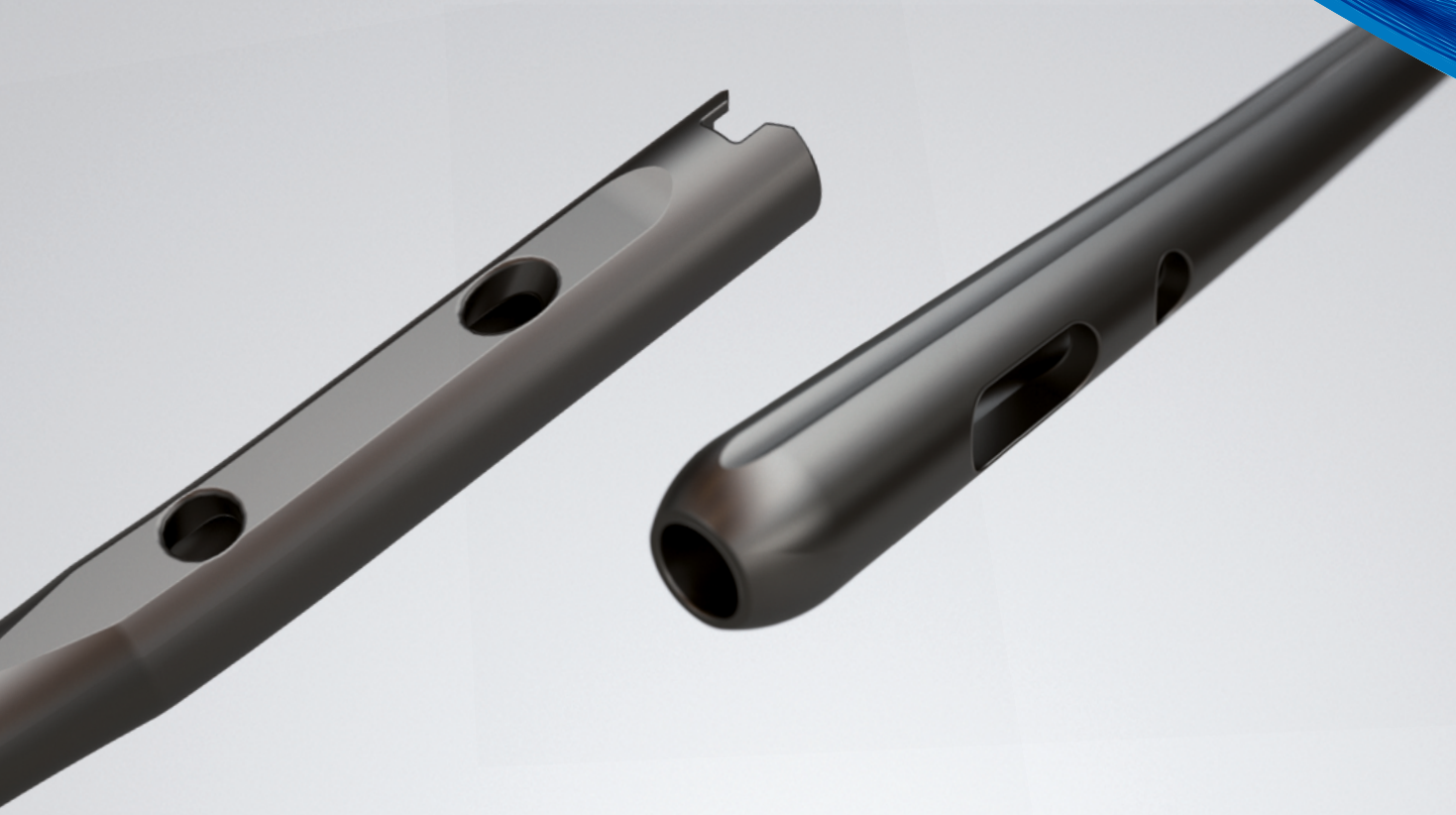
OPERATIVE TECHNIQUE

# Agile Nail™

System



ORTHOFIX®
ORTHOPEDICS

# Agile Nail™
System

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## GENERAL DESCRIPTION

The AGILE NAIL™ is designed to address femoral fractures and deformity correction procedures.
The AGILE NAIL™ consists of antegrade intramedullary nails for the femur with respective end-caps and locking screws. The intramedullary nails feature proximal and distal holes to accept locking screws. Nails, end-caps and screws are available in several sizes and are manufactured from a titanium alloy. All implantable devices are designed for single use only.

## INDICATIONS FOR USE

The AGILE NAIL™ is intended for insertion in the medullary canal of a femur for the alignment and the stabilization of fractures and for the correction of deformities. It is indicated for the treatment of subtrochanteric fractures and of femoral shaft fractures in pediatric patients, with the exception of newborns and infants, and in adult patients with an appropriate medullary canal.
The indications include:

- prophylactic nailing of impending pathologic fractures;
- fixation of femurs that have been surgically prepared (osteotomy);
- nonunions and malunions;
- reconstruction following tumor resection and grafting and bone lengthening and shortening.

## FEATURES AND BENEFITS

- Dedicated for Femoral Fractures/Deformity Treatments
- Specifically developed for Adolescent Patients and Small Adults
- Double locking option for the distal screw (static or dynamic)
- Sterile implants
- Anodization to increase the fatigue resistance

### Surgeon Benefits

- Diameter from 7 up to 10mm
- Titanium alloy implants
- Procurvation design for easy insertion
- Optimized and lean instrumentation
- Jig with patented locking mechanism

### Patient Benefits

- Minimally invasive (with a small diameter for the nails and the screws)
- Early weight-bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel
- 10° proximal bending to facilitate the lateral insertion of the nail and to reduce the impact on the growth plate
- Small proximal diameter of the nail to reduce the invasiveness

## SALES CONFIGURATIONS

### All implants available in sterile packaging

| AGILE NAIL™ - LEFT, sterile | | | | |
|---|---|---|---|---|
| Nail Length (mm) | Specific Cases ø7 | Usual femur fractures | | |
| | | ø8 | ø9 | ø10 |
| 180 | 99-T837180L | | | |
| 200 | 99-T837200L | | | |
| 220 | 99-T837220L | | | |
| 240 | 99-T837240L | 99-T838240L | 99-T839240L | 99-T830240L |
| 260 | 99-T837260L | 99-T838260L | 99-T839260L | 99-T830260L |
| 280 | 99-T837280L | 99-T838280L | 99-T839280L | 99-T830280L |
| 300 | 99-T837300L | 99-T838300L | 99-T839300L | 99-T830300L |
| 320 | 99-T837320L | 99-T838320L | 99-T839320L | 99-T830320L |
| 340 | 99-T837340L | 99-T838340L | 99-T839340L | 99-T830340L |
| 360 | 99-T837360L | 99-T838360L | 99-T839360L | 99-T830360L |
| 380 | 99-T837380L | 99-T838380L | 99-T839380L | 99-T830380L |
| 400 | | 99-T838400L | 99-T839400L | 99-T830400L |

| AGILE NAIL™ - RIGHT, sterile | | | | |
|---|---|---|---|---|
| Nail Length (mm) | Specific Cases ø7 | Usual femur fractures | | |
| | | ø8 | ø9 | ø10 |
| 180 | 99-T837180R | | | |
| 200 | 99-T837200R | | | |
| 220 | 99-T837220R | | | |
| 240 | 99-T837240R | 99-T838240R | 99-T839240R | 99-T830240R |
| 260 | 99-T837260R | 99-T838260R | 99-T839260R | 99-T830260R |
| 280 | 99-T837280R | 99-T838280R | 99-T839280R | 99-T830280R |
| 300 | 99-T837300R | 99-T838300R | 99-T839300R | 99-T830300R |
| 320 | 99-T837320R | 99-T838320R | 99-T839320R | 99-T830320R |
| 340 | 99-T837340R | 99-T838340R | 99-T839340R | 99-T830340R |
| 360 | 99-T837360R | 99-T838360R | 99-T839360R | 99-T830360R |
| 380 | 99-T837380R | 99-T838380R | 99-T839380R | 99-T830380R |
| 400 | | 99-T838400R | 99-T839400R | 99-T830400R |

| |
|---|
| Core Offer |
| Optional |
| Oversize |

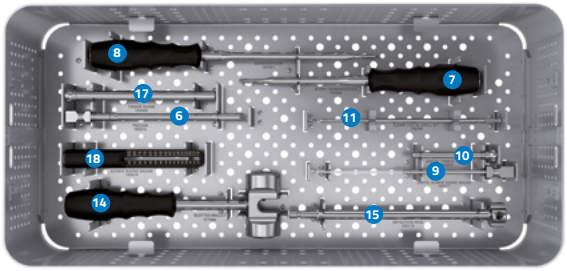
| 4.0mm LOCKING SCREWS, sterile | |
|---|---|
| Length (mm) | Part# |
| 18 | 99-T834018 |
| 20 | 99-T834020 |
| 22 | 99-T834022 |
| 24 | 99-T834024 |
| 26 | 99-T834026 |
| 28 | 99-T834028 |
| 30 | 99-T834030 |
| 32 | 99-T834032 |
| 34 | 99-T834034 |
| 36 | 99-T834036 |
| 38 | 99-T834038 |
| 40 | 99-T834040 |
| 42 | 99-T834042 |
| 44 | 99-T834044 |
| 46 | 99-T834046 |
| 48 | 99-T834048 |
| 50 | 99-T834050 |
| 55 | 99-T834055 |
| 60 | 99-T834060 |
| 65 | 99-T834065 |
| 70 | 99-T834070 |
| 75 | 99-T834075 |
| 80 | 99-T834080 |
| 85 | 99-T834085 |

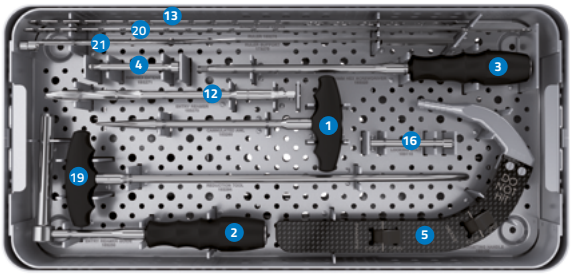
| 3.2mm PEG SCREWS, sterile (For 7mm Solid Nail Distal Locking ONLY) | |
|---|---|
| Length (mm) | Part# |
| 18 | 99-T833018 |
| 20 | 99-T833020 |
| 22 | 99-T833022 |
| 24 | 99-T833024 |
| 26 | 99-T833026 |
| 28 | 99-T833028 |
| 30 | 99-T833030 |
| 32 | 99-T833032 |
| 34 | 99-T833034 |
| 36 | 99-T833036 |
| 38 | 99-T833038 |
| 40 | 99-T833040 |
| 42 | 99-T833042 |
| 44 | 99-T833044 |
| 46 | 99-T833046 |
| 48 | 99-T833048 |
| 50 | 99-T833050 |
| 55 | 99-T833055 |
| 60 | 99-T833060 |

| END CAPS | |
|---|---|
| Length (mm) | Part# |
| 0 | 99-T830000 |
| 5 | 99-T830005 |
| 10 | 99-T830010 |
| 15 | 99-T830015 |
| 20 | 99-T830020 |

## EQUIPMENT REQUIRED

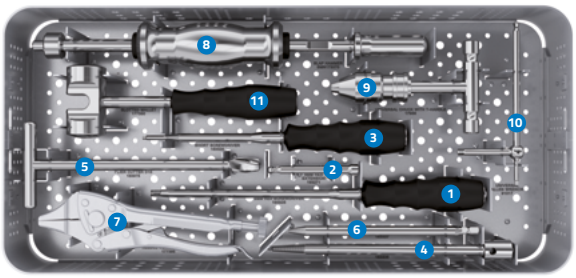
| 183990 AGILE NAIL™ Instrument Box, complete | | | |
|---|---|---|---|
| **Part#** | | **Description** | **Q.ty** |
| 183260 | 1 | Cannulated Awl | 1 |
| 183230 | 2 | Entry Reamer Guide | 1 |
| 193325 | 3 | 6mm Hex Screwdriver | 1 |
| 193271 | 4 | 6mm Hex Extension | 1 |
| 183100 | 5 | Targeting Handle | 1 |
| 183212 | 6 | Trocar | 1 |
| 183320 | 7 | Short Screwdriver | 1 |
| 183321 | 8 | Screwdriver | 1 |
| 183277 | 9 | Distal Screw Sizing Gauge | 1 |
| 183213 | 10 | Distal Tissue Guide | 1 |
| 183285 | 11 | Distal Drill Bit D 3.2mm | 1 |
| 183270 | 12 | Entry Reamer | 1 |
| 183275 | 13 | Sizing Guide | 1 |
| 177380 | 14 | Slotted Mallet | 1 |
| 193115 | 15 | Impaction Rod | 1 |
| 183110 | 16 | Locking Bolt | 1 |
| 183302 | 17 | Tissue Guide | 1 |
| 183274 | 18 | Screw Sizing Gauge | 1 |
| 183264 | 19 | Reduction Tool | 1 |
| 173276 | 20 | Ruler Support | 1 |
| 183276 | 21 | Ruler | 1 |




| STERILE PACKAGED INSTRUMENTS | |
|---|---|
| **Part#** | **Description** |
| 99-183288 | Guide Wire L 300mm D 3.2mm |
| 99-183281 | Guide Wire with olive L 980mm D 2.8mm |

| 183991 AGILE NAIL™ Extraction Box, complete | | | |
|---|---|---|---|
| **Part#** | | **Description** | **Q.ty** |
| 193325 | 1 | 6mm Hex Screwdriver | 1 |
| 193271 | 2 | 6mm Hex Extension | 1 |
| 183320 | 3 | Short Screwdriver | 1 |
| 183336 | 4 | M7 Conical Mallet Adaptor | 1 |
| 183978 | 5 | Plier Cutter D 15mm | 1 |
| 183337 | 6 | Screw Extractor Size 3.5-9mm | 1 |
| 177395 | 7 | Needle Nose Vise Grips | 1 |
| SMN173370 | 8 | SMN System Sliding Hammer Assembly | 1 |
| 17955 | 9 | Universal Chuck with T-Handle | 1 |
| 91017 | 10 | Universal Allen Wrench | 1 |
| 177380 | 11 | Slotted Mallet | 1 |



## PATIENT POSITIONING

PRECAUTIONS:
- **Take care to achieve and maintain a correct reduction throughout the procedure.**

- **Fracture distraction for any time should be avoided during the operation, and fractures should never be locked in distraction, since this may cause delayed union and/or compartment syndrome.**

### Fracture reduction in the frontal plane

The patient is placed supine on a fracture table **(Fig.1)**, and initial reduction obtained by traction under image intensification. Traction and abduction are then adjusted if necessary to achieve anatomic reduction.

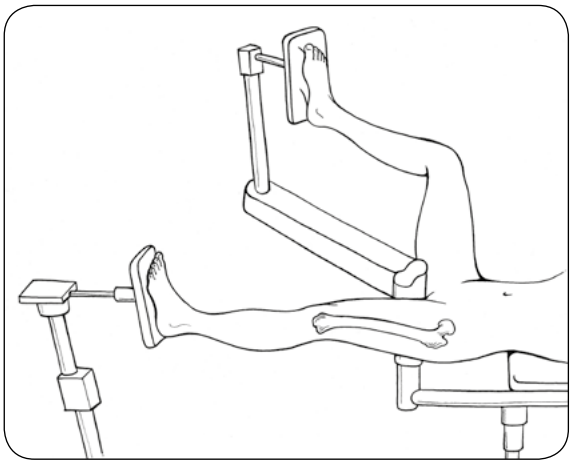


**Fig.1**

### Fracture reduction in the sagittal plane with the "PORD™"

Any posterior sagging at the fracture site should now be corrected and maintained using the dedicated Posterior Reduction Device (PORD™). This device is easily attached to most fracture tables.

A Slide the Clark Attachment onto the side rail of the fracture table. Insert the vertical post of the Box Bracket into the Clark Attachment from beneath and tighten the clamp on the post so that the bracket is held securely.

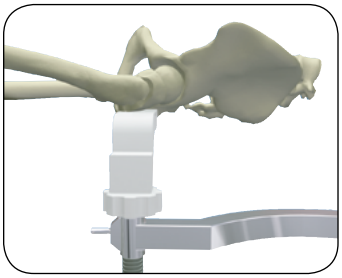
B Assemble the PORD™ in the following way: Slide the Horizontal Bar through the Box Bracket with its curved portion facing the fracture table. This curved section is designed to allow for unobstructed multiple plane imaging using the C-arm of the Image Intensifier.

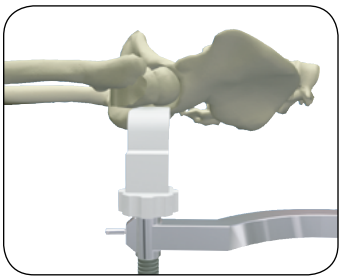
C The Screw Jack of the Limb Support should be positioned in the housing at the end of the horizontal bar, with the nut under the radiolucent support. Turning the nut clockwise will then raise the support.

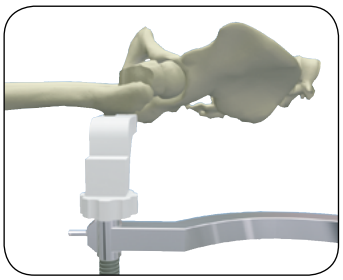
## Limb support positioning

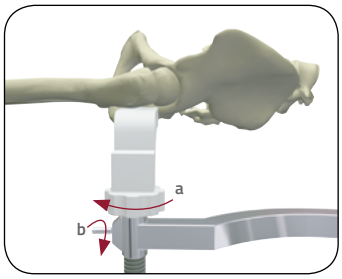
The Limb Support is positioned beneath that portion of the fracture that requires elevating. The correct position of the support is confirmed on the AP view (the shadow of the support can be seen). Using the lateral view, the limb support is raised by turning the nut (a) clockwise until exact posterior reduction has been achieved. The position of the Support is now maintained by tightening the Lug Screw on the housing (b). There is tendency for the Limb Support to rotate when its position is being adjusted, due to the conical cross-section of the thigh.
It should therefore be held firmly during this procedure and while tightening the Lug Screw.

The PORD™ will now remain in position throughout surgery. Following use, the PORD™ should be washed thoroughly in a soapy solution and dried completely. It may be necessary to use forced air to dry out the housing of the Lug Screw. (See User's Manual)









## SURGICAL STEPS

### PRIOR TO USE INFORMATION

### Warnings

- It is essential that the operative technique as supplied by Orthofix be followed for implantation.
- Do not combine AGILE NAIL™ implantable components with those from other systems, unless specified.
- Do not use if packaging is compromised or if a component is believed to be faulty, damaged or suspect.
- Nails, end caps and screws must not be reused. If any implant has come into contact with any body fluid, it should be considered to have been used. In case repositioning of implants is required, new implants should be used.
- Loosening, bending, cracking or breakage of the implants can cause loss of stabilization.
- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

### Precautions

- Ensure that all components needed for the operation are asvailable in the operating theatre.
- Examine all components carefully prior to use. Product integrity, sterility (in the case of sterile products) and performance are assured only if the packaging is undamaged.
- Be careful in the handling and storage of the components. The implants should not be scratched, notched or otherwise damaged as these may reduce the functional strength of the component.
- Check the fit and functioning of nail and instruments assembly prior to implantation.
- Take care to assemble all components correctly and to lock them securely.
- Cannulated instruments should be inspected prior to use to confirm that the cannulation is free from obstruction. The correctly sized wire should be passed through it, making sure that it slides easily.
- During the introduction of any instrument or implant over a wire, the wire tip should be screened, using fluoroscopy, to exclude inadvertently driving the wire further than intended. This is particularly important when the wires are pointing towards potentially dangerous locations, such as the physis.
- For screw extractions take care to revert the power drill to avoid advancing them towards potentially dangerous locations.

### MRI safety information

The AGILE NAIL™ has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the AGILE NAIL™ in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## OPENING THE FEMUR

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 99-183288 | Guide Wire L300mm D3.2mm |
| 183230 | Entry Reamer Guide |
| 183260 | Cannulated AWL |
| 183270 | Entry Reamer |

### Approach

Position the patient supine or in the lateral decubitus position on a fracture table. To aid access to the medullary canal, abduct the upper part of the body approximately 10°–15° to the contralateral side and adduct the affected limb by 10°–15°. Palpate the posterior edge of the greater trochanter and make a 2-3cm skin incision proximal to the tip of the greater trochanter, in line with the shaft of the proximal femur.

### Entry point targeting

The entry point will vary with individual anatomy; it's on the lateral aspect of the greater trochanter, halfway between its anterior and posterior extent **(Fig. 2)**.

Position the C-arm to allow visualization of the proximal femur in both the AP and ML planes and use a 3.2mm guide wire (Part#: 99-183288) to find the entry point.

**WARNING: The lateral aspect of the greater trochanter as an entry point is mandatory to decrease the probability of damaging the medial circumflex artery and aids in decreasing the risk of avascular necrosis of the femoral head.**

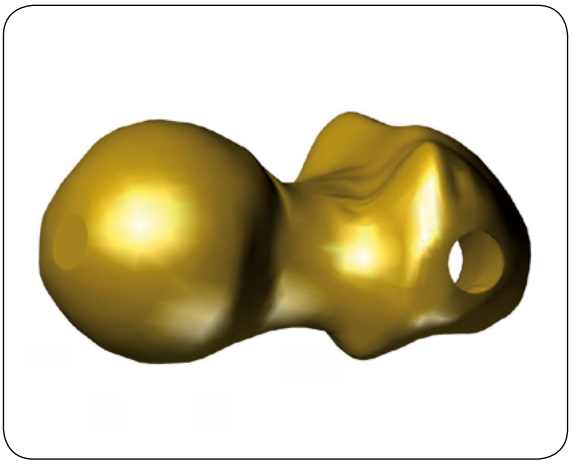


**Fig. 2** Entry point targeting

Using the Image Intensifier, the entry point should be slightly lateral to the tip of the greater trochanter on the AP view, while on the ML view the entry point should be in the midpoint of the greater trochanter.

Insert the 3.2mm guide wire towards a point 1-2cm distal of the lesser trochanter **(Fig. 3)**.

**PRECAUTION: Under fluoroscopy, verify that the 3.2mm guide wire position allows adequate clearance on the lateral side of the femur for the opening awl and for the entry reamer.**

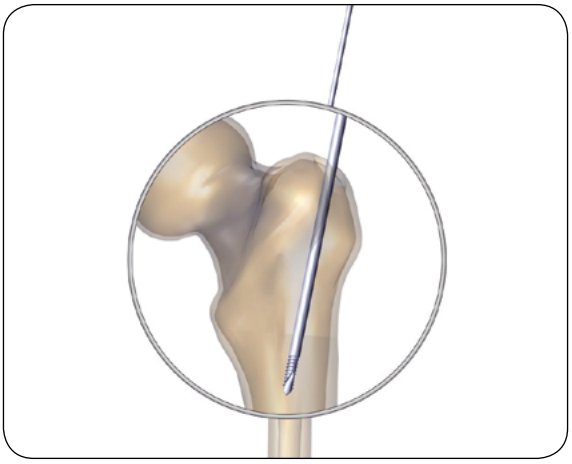


**Fig. 3** Guide wire insertion

## Entry point opening

Insert the entry reamer guide (Part#: 183230) over the 3.2mm guide wire at the level of the entry point followed by the cannulated awl (Part#: 183260).

Open the entry point by gently advancing the cannulated awl over the 3.2mm guide wire with a twisting motion avoiding to pass the medial cortex **(Fig. 4)**.

Remove the cannulated awl leaving the 3.2mm guide wire in the desired position.

**PRECAUTION: If the 3.2mm guide wire used for opening the entry point is damaged or bent, a new guide wire must be used for insertion of the proximal reamer.**

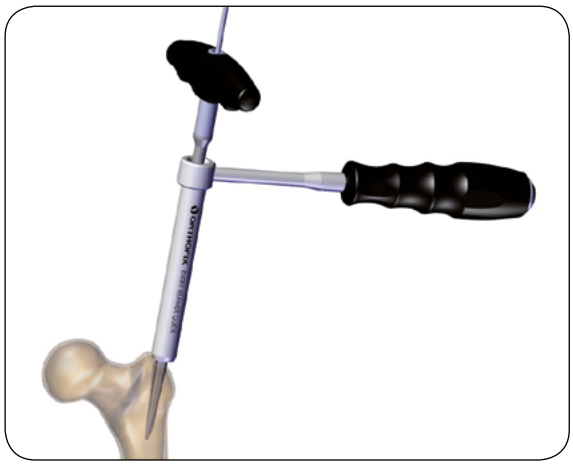


**Fig. 4** Entry point opening

## PROXIMAL REAMING

Advance the entry reamer (Part#: 183270) over the 3.2mm guide wire under power **(Fig. 5)**.

**PRECAUTION: The entry reamer tip should be screened to avoid inadvertently driving the reamer further than intended (pay particular attention not to ream further than the medial cortex).**

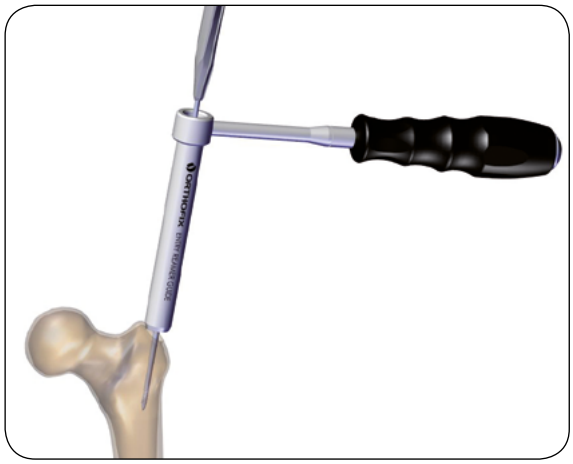


**Fig. 5** Proximal reaming

The correct insertion depth for the entry reamer can be verified according to the following options:

- **Option 1:** stop reaming when the proximal groove of the entry reamer is at the level of entry reamer guide **(Fig. 6A)**.
- **Option 2:** under fluoroscopy, stop reaming when the distal groove of the entry reamer is at the level of the greater trochanter **(Fig. 6B)**.

Remove the entry reamer, the entry reamer guide and the 3.2mm guide wire.

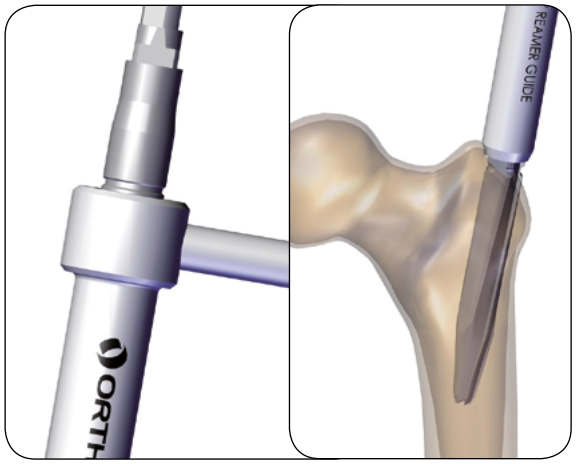



**Fig. 6A** Option 1 **Fig. 6B** Option 2

## GUIDE WIRE CHANGING

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 99-183281 | Guide Wire With Olive L980mm D2.8mm |
| 183264 | Reduction Tool |

If needed, gently advance the cannulated reduction tool (Part#: 183264) in the medullary canal through the fracture line **(Fig. 7)**. Use the shaped tip of the reduction tool to assist passing through the fracture line.

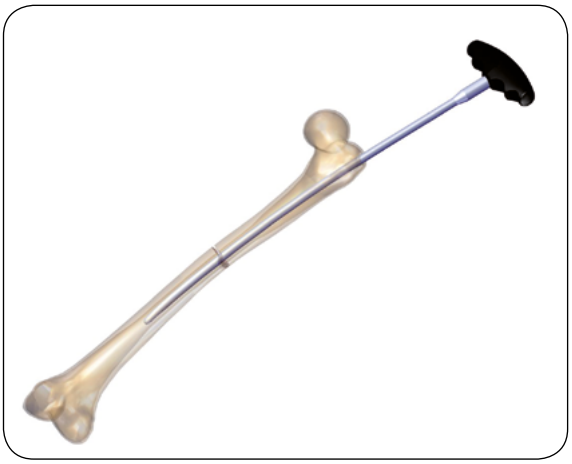


**Fig. 7** Reduction tool insertion

Manually insert the guide wire with olive (Part#: 99-183281) in the cannulated reduction tool to the desired depth **(Fig. 8)**.

**PRECAUTION: Under fluoroscopy, verify fracture reduction and the final position of the guide wire with olive to exclude inadvertently damaging the distal femoral physis.**

Remove the cannulated reduction tool leaving the guide wire with olive in the desired position.

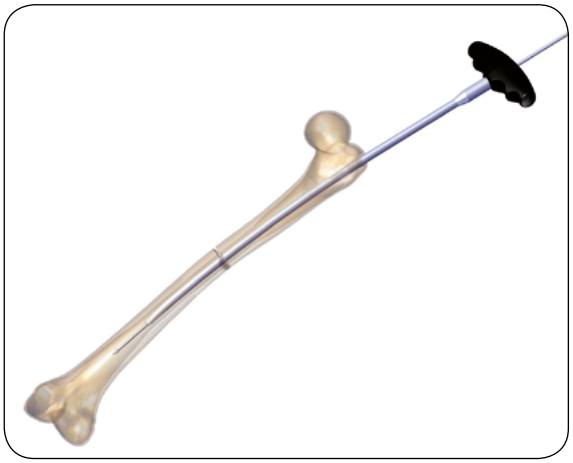


**Fig. 8** Guide wire with olive insertion

## PROXIMAL SCREW AND NAIL SELECTION

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183275 | Sizing Guide |
| 173276 | Ruler Support |
| 183276 | Ruler |

Choose the appropriate size and position of nail and screws according to the fracture position and pattern as well as patient characteristics. Improper positioning of nail and screws may result in loosening, bending, cracking, or fracture of the device or bone or both.

**WARNING:** The nails are labeled "LEFT" or "RIGHT" on the proximal nail end: ensure to select the appropriate nail according to the leg to be treated.

**PRECAUTION:** Nail and proximal locking screw positioning must be selected after reduction of the fracture or creation of the osteotomy.

### Proximal screw selection

Align the sizing guide (Part#: 183275) over the femoral axis at the level of the entry point at the desired nail insertion, and select the optimal proximal screw angle, 120° (oblique) or 0° (transverse), under Image Intensifier by positioning a guide wire over the corresponding marking on the sizing guide.

**PRECAUTION: Depending on the position of the nail and bone anatomy, it is recommended to direct the tip of the proximal locking screw towards the lesser trochanter, avoiding as much as possible damaging the physis (Fig. 9).**

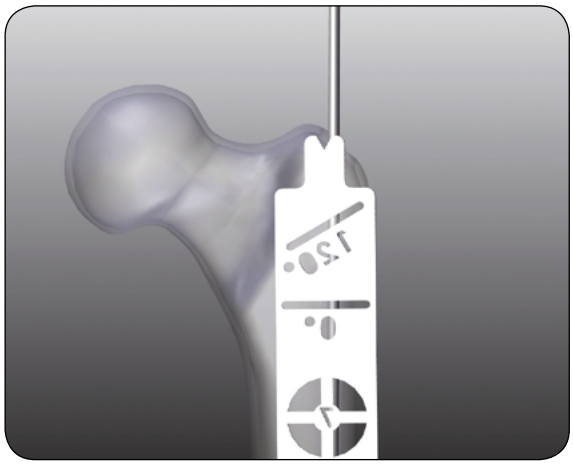


**Fig. 9** Proximal screw positioning

### Optimal nail diameter selection

Position the C-arm for an AP or ML view of the femur at the level of the isthmus. Hold the sizing guide over the femoral axis with the diameter gauge centered over the narrowest part of the medullary canal. Under Image Intensifier select the nail diameter on the circular indicator that best fills the canal **(Fig. 10)**.

**PRECAUTION: The diameter of the selected nail should be smaller than narrowest part of the medullary canal.**

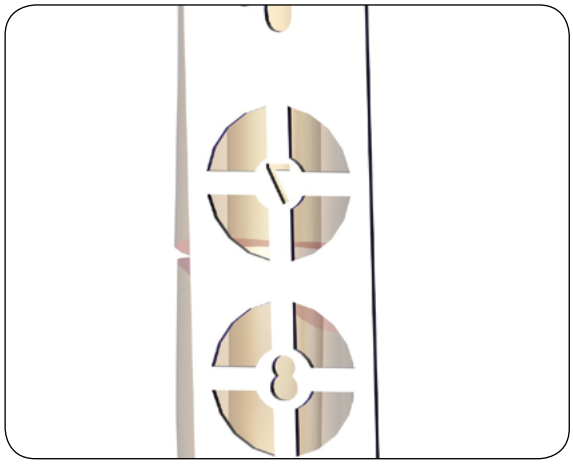


**Fig. 10** Nail diameter selection

## Optimal nail length selection

Two options are available to select the optimal nail length

**PRECAUTION: Choose a nail length that avoids damaging the physis. Back-hammering to close a fracture gap and/or dynamization must be taken into account. A shorter nail should be considered when back hammering or dynamization is planned.**

- **Option A:** Using Image Intensifier, align the sizing guide over the femoral axis from the entry point to the distal femur **(Fig. 9)**. Under Image Intensifier read the optimal nail length directly on the sizing guide, selecting the measurement at the desired insertion depth **(Fig. 11)**.

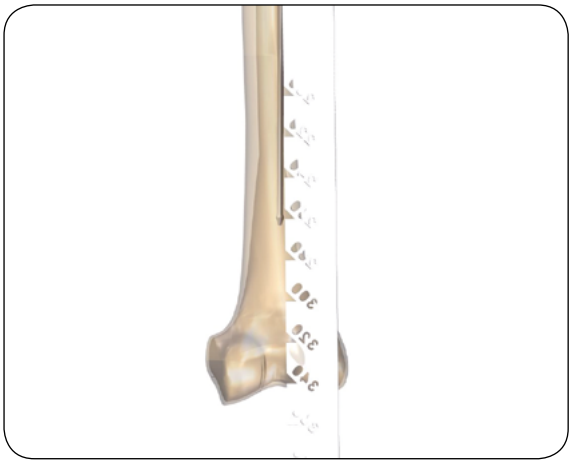


**Fig. 11** Nail length selection

- **Option B:** Consider that the position of the olive of the guide wire will be the final position of the distal tip of the nail. Under Image Intensifier, position the olive at the desired insertion depth.

  Assemble the ruler (Part#: 183276) on the ruler support (Part#: 173276) and place the tip of the ruler support on the greater trochanter at the level of the entry point **(Fig. 12A)**.

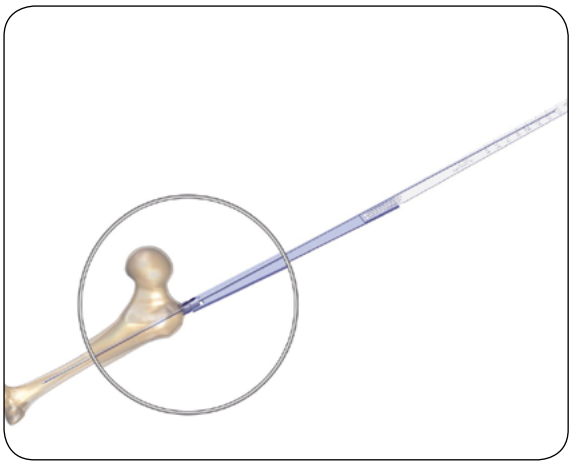


**Fig. 12A** Ruler support positioning

  Align the protruding portion of the guide wire with the ruler and read the nail length directly on the ruler at the level of guide wire end **(Fig. 12B)**.

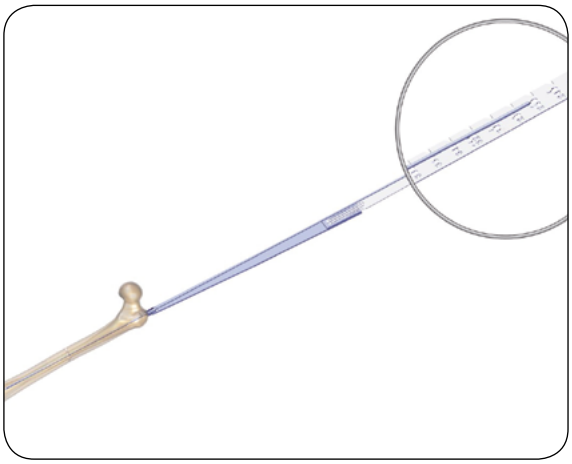


**Fig. 12B** Nail length selection

## DISTAL REAMING (OPTIONAL)

**NOTE: The nail may be inserted with or without reaming, depending on patient characteristics, fracture type and bone diameter and quality.**

**PRECAUTION: If necessary, progressively enlarge the femoral canal (preferably in 0.5mm steps) with the flexible reamer to at least 1.0mm greater than the selected nail diameter.**

Ensure that the cannulated flexible reamer system is compatible with the 2.8mm guide wire with olive (Part#: 99-183281).

Place the entry reamer guide over the guide wire with olive on the greater trochanter at the level of the entry point. Insert the reamer over the guide wire and ream the medullary canal to the desired final diameter **(Fig. 13)**.

**PRECAUTION: Advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer often to clear debris from the medullary canal.**

**Advancement of the reamer tip should be screened using fluoroscopy to prevent inadvertently damaging the distal femoral physis.**

**After reaming, check the guide wire with olive using fluoroscopy: if the guide wire is damaged or bent, use a new guide wire for insertion of cannulated nail.**

Remove the reamer and the entry reamer guide leaving the guide wire with olive in the desired position.

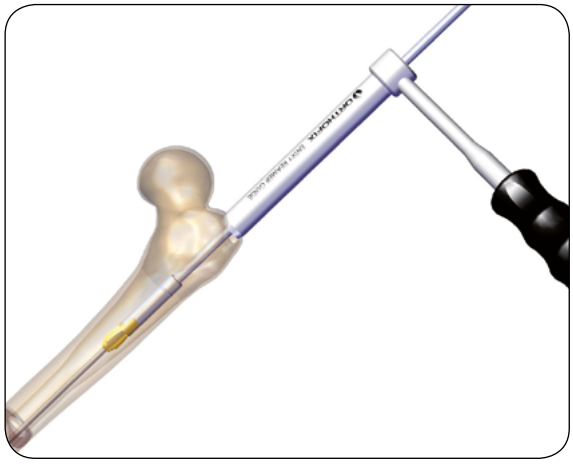


**Fig. 13** Distal reaming

## PROXIMAL LOCKING CHECK

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183100 | Targeting Handle |
| 183110 | Locking Bolt |
| 193325 | 6mm Hex Screwdriver |
| 183302 | Tissue Guide |
| 183212 | Trocar |
| 99-183288 | Guide Wire L300mm D3.2mm |

**PRECAUTION: Make sure the holes of the targeting handle and the holes of the nail are perfectly aligned prior to surgery.**

Connect the selected nail to the targeting handle (Part#: 183100) by aligning the tabs on the handle with the appropriate slots on the top of the nail **(Fig. 14A)**.

Insert the locking bolt (Part#: 183110) into the targeting handle **(Fig. 14B)** and lock it into the proximal nail-end by using the 6mm hex screwdriver (Part#: 193325) **(Fig. 14C)**.

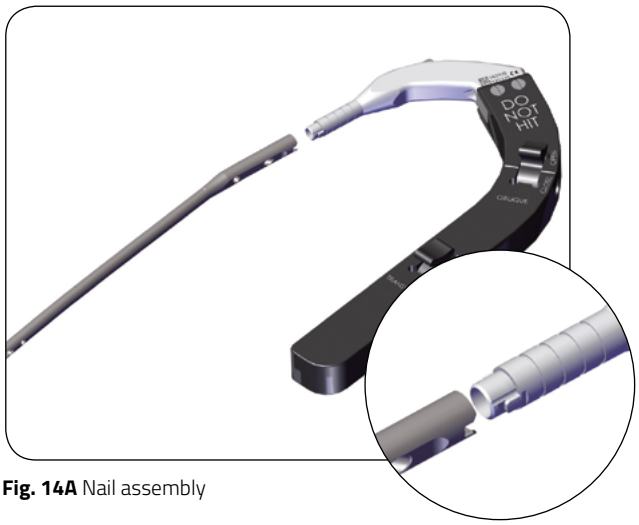



**Fig. 14A** Nail assembly

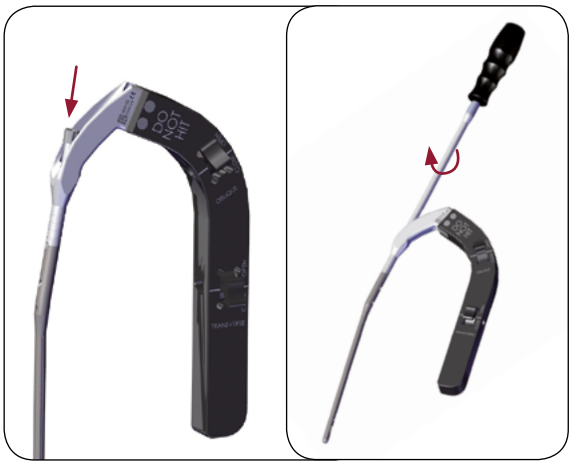


**Fig. 14B** Locking bolt insertion **Fig. 14C** Locking bolt tightening

Insert the tissue guide (Part#: 183302) in the transverse hole of the targeting handle, the trocar (Part#: 183212) into the tissue guide and then the 3.2mm guide wire into the trocar **(Fig. 15A)**.
The 3.2mm guide wire should be advanced through the nail hole without impingement.

Repeat the same procedure for the oblique hole of the targeting handle **(Fig. 15B)**.

**Fig. 15A** Transverse hole check **Fig. 15B** Oblique hole check

## NAIL INSERTION

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 193115 | Impaction Rod |
| 177380 | Slotted Mallet |

Orient the targeting handle in an anterior position. Insert the cannulated nail through the entry point over the guide wire with olive.

**NOTE: If a solid nail was selected to treat the fracture, the guide wire with olive must be removed before inserting the nail directly in the medullary canal.**

Rotate the targeting handle from an anterior to a lateral position approximately 90° during insertion. If the nail does not rotate to the lateral position, take out the nail and reinsert it with the handle slightly lateral to the sagittal plane.

Monitor the nail when it passes the fracture, and control bone alignment in two planes to avoid malalignment.

Insert the nail until its head is at or slightly below the femoral opening **(Fig. 16)**.

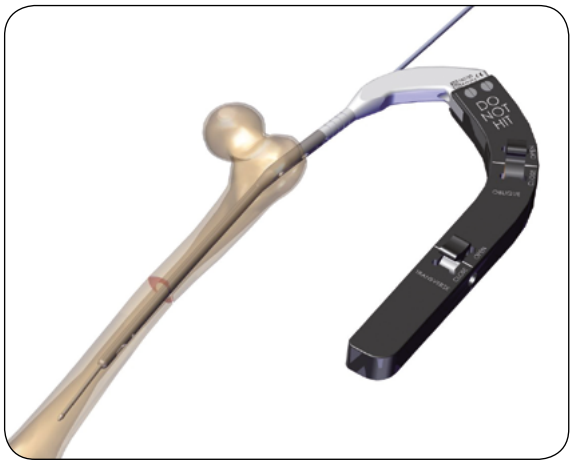



**Fig. 16** Cannulated nail insertion

If necessary, thread the impaction rod on top of the targeting handle for hammering and insert the nail hammering gently **(Fig. 17)**.

**WARNING: Do not hammer directly on the targeting handle. Hammering of the nail must only be performed through the impaction rod assembled on the targeting handle.**

**PRECAUTION: Hammering should always be gentle; vigorous hammering should never be necessary. The surgeon should never persist with hammering if the implant is not advancing, but should review the situation, and consider further reaming.**

Re-verify fracture or osteotomy reduction and final nail position under fluoroscopy.
Remove the impaction rod.

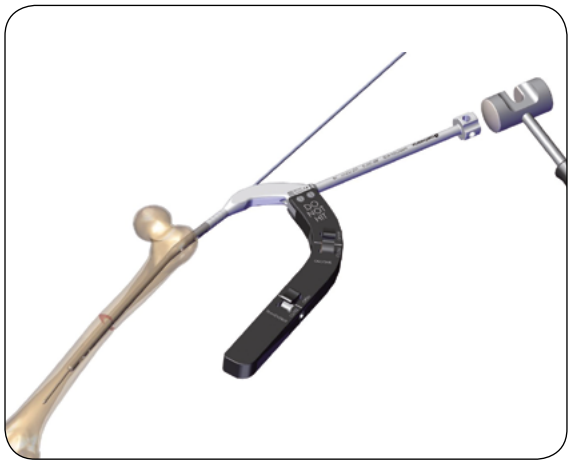


**Fig. 17** Hammering of the nail

## PROXIMAL LOCKING

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183274 | Screw Sizing Gauge |
| 183302 | Tissue Guide |
| 183212 | Trocar |
| 99-183288 | Guide Wire L300mm D3.2mm |

**WARNING: For proximal locking of the nail, use only a 4.0mm threaded locking screw (Part#: T8340XX). Peg screws (Part#: T8330XX) must not be used for proximal locking.**

Example of 4.0mm threaded locking screw (Part#: T8340XX)

The nail must be locked with only one proximal locking screw, inserted in either the transverse or the oblique hole. The transverse and the oblique proximal locking screws are convergent and must not be inserted together.

**PRECAUTION: Choosing the appropriate length for the proximal locking screw is critical for the effective and safe stabilization of bone fragments. The length of the screw should be determined by using the dedicated instruments as described in the operative technique.**

**NOTE: If a cannulated nail was inserted, remove the guide wire with olive before inserting the proximal locking screw.**

Figures 18, 19, 20, 21, 22, 23, 24 and 25 refer to procedure for the transverse hole option. If the oblique option was selected for proximal locking screw insertion, surgical steps for screw length selection and insertion are exactly the same through the oblique hole option of the targeting handle.

## Proximal screw length selection

Insert the trocar into the tissue guide. Insert this assembly in the appropriate hole of the targeting handle according to the selected proximal locking screw position (transverse or oblique). Advance the tissue guide and the trocar to the skin to determine the incision point **(Fig. 18)**.

Make a 1-2cm incision at this point. Gently advance the tissue guide and the trocar down to the bone by rotating the trocar.

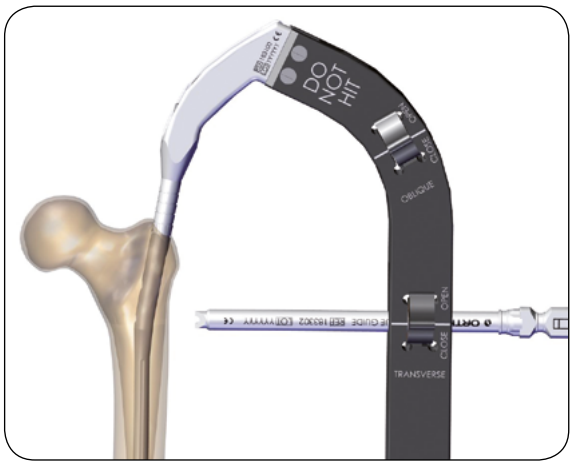



**Fig. 18** Tissue guide and trocar insertion (transverse hole option)

**PRECAUTION: To ensure choosing the correct proximal locking screw length, the tip of the trocar must be correctly orientated to go flat against the bone.**

Lock the tissue guide to the targeting handle by closing the locking knob **(Fig. 19)**.

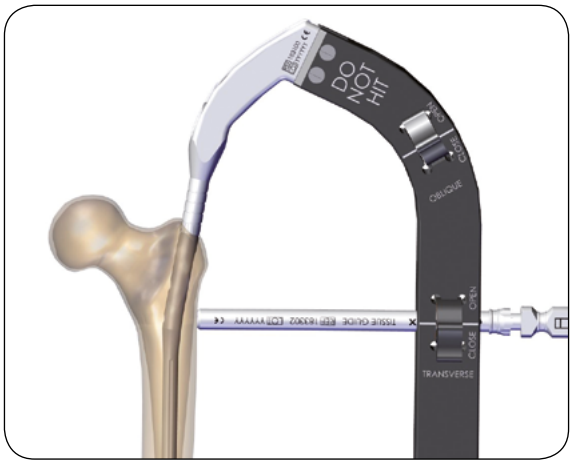



**Fig. 19** Locking knob closure

Insert a 3.2mm guide wire in the bone through the trocar with a power tool until the far cortex is reached **(Fig. 20)**.

Check the final position of the guide wire under Image Intensifier: the tip of the 3.2mm guide wire defines the final position of the proximal locking screw.

**PRECAUTION: To ensure choosing the correct proximal locking screw length, make sure the 3.2mm guide wire is not damaged or bent by previous usages. Use a new guide wire if necessary.**

**The tip of the guide wire should not protrude more than 2mm to 4mm beyond the far cortex. Care should be taken not to excessively penetrate the soft tissue to avoid possible neurovascular damage.**

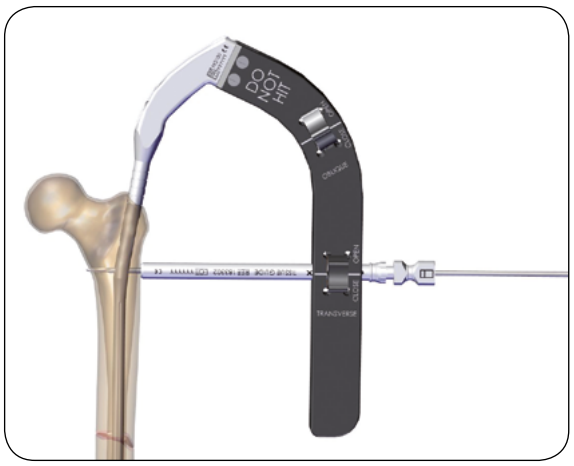


**Fig. 20** Guide wire insertion

Place the screw sizing gauge (Part#: 183274) over the 3.2mm guide wire **(Fig 21)**.

**PRECAUTION: To ensure the correct proximal locking screw length, the tip of the trocar must go flat against the bone and the screw sizing gauge must go flat against the trocar.**

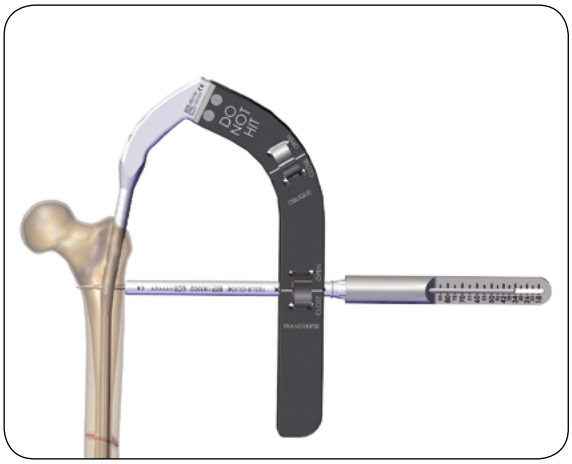


**Fig. 21** Sizing gauge insertion

Read the correct length of the proximal locking screw on the scale of the screw sizing gauge at the level of the end of the 3.2mm guide wire **(Fig. 22)**.

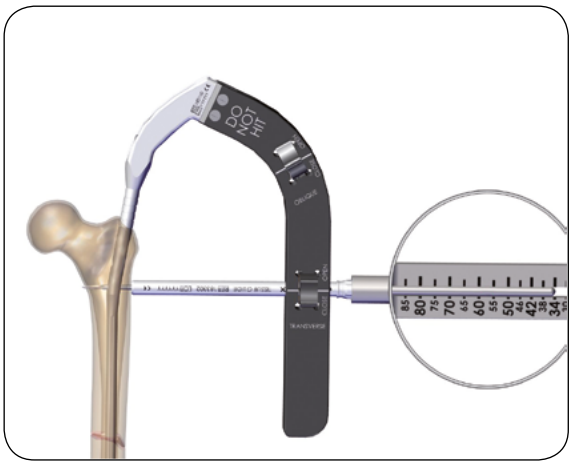


**Fig. 22** Correct length reading

## Proximal screw insertion

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183321 | Screwdriver |

Remove the 3.2mm guide wire and the trocar leaving the tissue guide locked on the targeting handle.

**PRECAUTION: After proximal locking screw length measurements, make sure to hold the targeting handle in the same position: any movement of the targeting handle may result a mistmatch between the drill bit and the hole.**

Grab the selected proximal locking screw with the retaining screwdriver (Part#: 183321) **(Fig. 23)**.

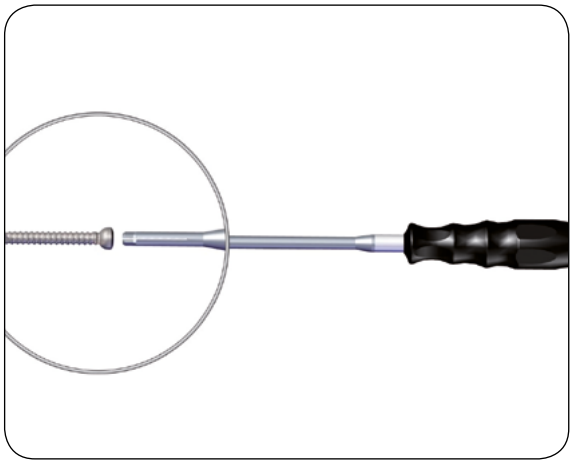


**Fig. 23** Screw assembly

Insert the locking screw through the tissue guide and the predrilled hole and screw it into the bone **(Fig. 24)**.

Verify the locking screw position under image intensification.

**PRECAUTION: Overtightening of the screw should be avoided and the head of the screw should come just in contact with the cortex. Stop insertion when resistance is felt.**

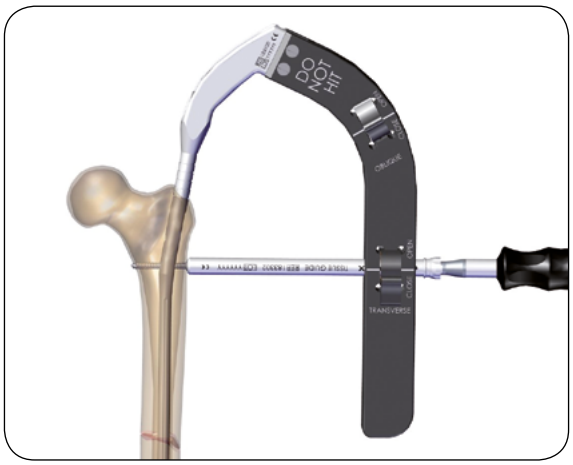


**Fig. 24** Proximal screw insertion

Remove the tissue guide from the targeting handle by opening the locking knob **(Fig. 25)**.

**Fig. 25** Tissue guide removal

## Distal locking

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183285 | Distal Drill Bit D3.2mm |
| 183213 | Distal Tissue Guide |
| 183277 | Distal Screw Sizing Gauge |

## DISTAL LOCKING OPTIONS

One hole and one oval slot are provided on the distal end of the nails for three different distal locking options:

**A.** For static locking, insert one screw in the proximal end of the oval slot or, alternatively, one screw in the hole. **(Fig. 26A)**.

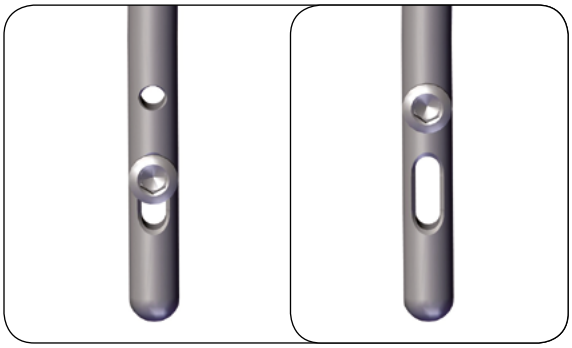


**Fig. 26A** Static locking

**B.** For immediate dynamization, insert one screw in the distal end of the slot **(Fig. 26B)**. The oval slot allows 7mm of movement.

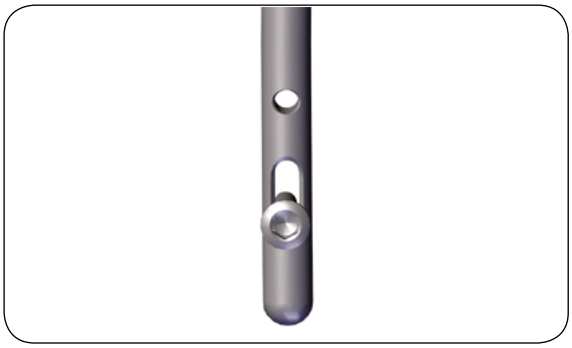


**Fig. 26B** Dynamic locking

**C.** If dynamization may be required in the future, insert one screw in the hole and one screw in the distal end of the oval slot to obtain an immediate static locking of the nail that potentially can be converted in a dynamic locking by removing the screw from the hole **(Fig. 26C)**. The oval slot allows 7mm of movement.

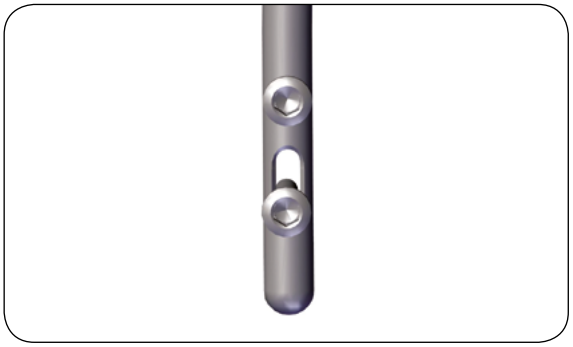


**Fig. 26C** Static but potentially dynamic locking

## Distal screw length selection

Align the C-arm with the distal hole of the nail until a perfect circle is visible in the ML view.

Using the Image Intensifier, place a guide wire on the skin to mark the selected hole or slot and make an incision accordingly. Manually insert the tip of the distal drill bit (Part#: 183285) through the incision and down to the bone.

Under fluoroscopy and using the freehand technique, center the tip of the distal drill bit over the selected hole or slot.

Holding the distal drill bit exactly in this position, insert the distal tissue guide over the distal drill bit and under power drill the near cortex first and then through the nail to the far cortex **(Fig. 27A)**.

Check the final position of the distal drill bit under Image Intensifier: the tip of the distal drill bit defines the final position of the distal screw.

To ensure choosing the correct distal screw length, make sure that the graduated drill bit is not damaged or bent by previous use. Use a new bit if necessary.

**PRECAUTION: The tip of the graduated drill bit should not protrude more than 2mm to 4mm beyond the far cortex. Care should be taken not to excessively penetrate the soft tissue to avoid possible neurovascular damage.**

**To ensure choosing the correct distal screw length, the distal tissue guide must be correctly orientated to go flat against the bone.**

Read the correct distal screw length on the scale of the graduated distal drill bit at the level of the end of the distal tissue guide **(Fig. 27B, Option A)**.

Remove the distal graduated drill bit and insert the distal screw sizing gauge beyond the far cortex **(Fig. 28A)**. Move back distal screw sizing gauge until its hook is fully in contact with the far cortex avoiding the tool furtherly draw back **(Fig. 28B)**.

Read the correct distal screw length on the scale of the distal screw sizing gauge at the level of the end of the distal tissue guide **(Fig. 28C)**.

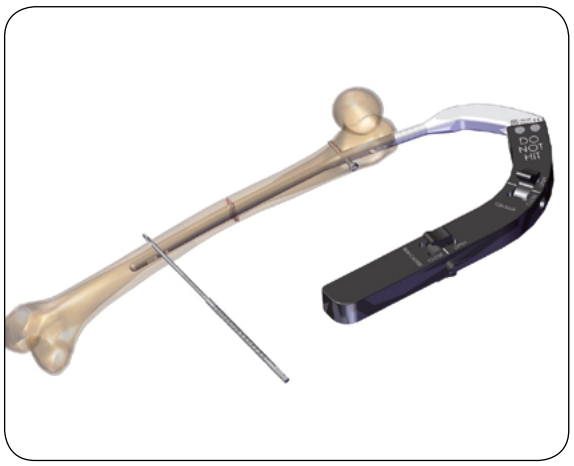


**Fig. 27A** Graduated drill bit insertion

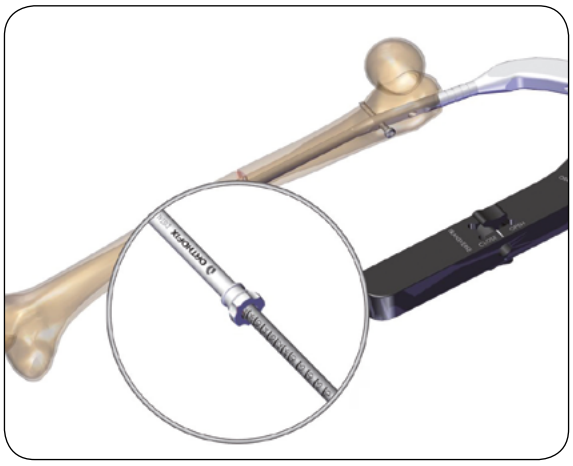
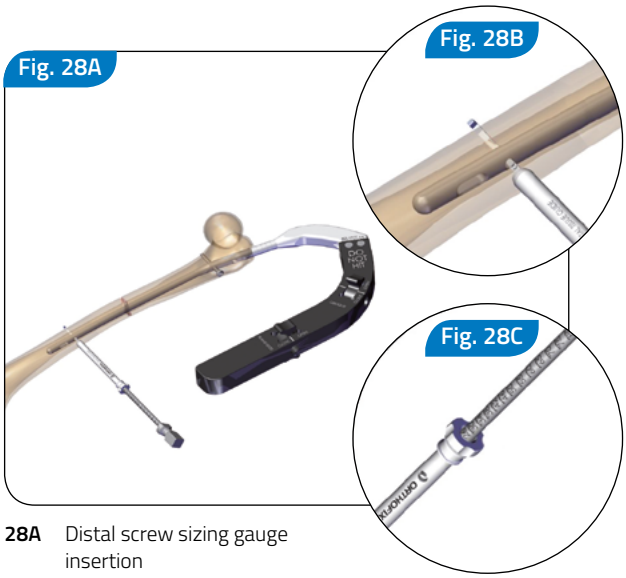


**Fig. 27B** Distal screw length selection **(Option A)**

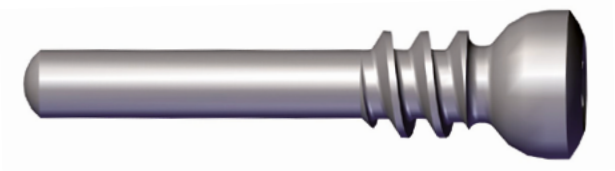



**28A** Distal screw sizing gauge insertion
**28B** Distal screw sizing gauge correct positioning
**28C** Distal screw length selection **(Option B)**

## Distal screw insertion

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183320 | Short Screwdriver |

**WARNING: Choose the distal screw type according to the inserted nail:**
- **to lock a cannulated nail distally, use only 4.0mm threaded locking screws (Part#:T8340XX)**
- **to lock a 7mm solid nail distally, use only 3.2mm peg screws (Part#: T8330XX)**



Example of 3.2mm peg screw
(Part#: T8330XX)

**PRECAUTION: Before definitively locking the nail, re-verify the reduction and correct alignment of the fragments and leg length.**

Remove the distal tissue guide. Connect the selected distal screw with the short retaining screwdriver (Part#: 183320) and tighten it on the predrilled hole in the bone **(Fig. 29)**.

**PRECAUTION: Overtightening of the screw should be avoided and the head of the screw should come just in contact with the cortex. Stop insertion when resistance is felt.**

Verify screw position under image intensification.

**NOTE: If the static but potentially dynamic locking option (Fig. 26C) was selected, repeat the distal screw insertion steps to insert the second screw.**

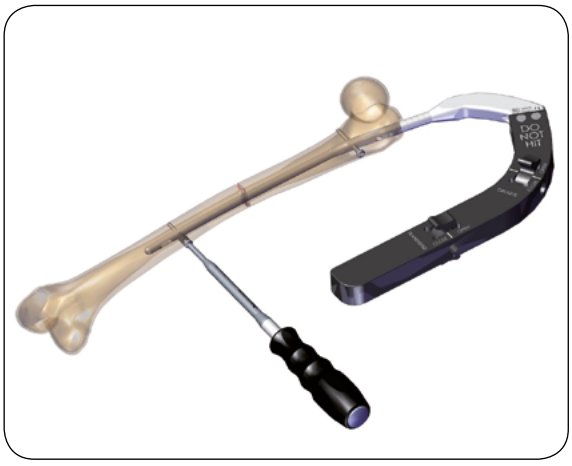



**Fig. 29** Distal screw insertion

## END CAP INSERTION

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 193325 | 6mm Hex Screwdriver |
| 193271 | 6mm Hex Extension |

**PRECAUTION: The use of an end cap aids in the removal of the nail by limiting bone in-growth.**

Before removing the targeting handle, under image intensification, select the appropriate size of the end cap from the marking lines at the top of the targeting handle.

Starting from the distal mark (0mm) to the proximal one, each mark represents 5mm increments in size
(5, 10, 15 or 20mm). If the length measured is between two marks, the smaller reading should be selected **(Fig. 30)**.

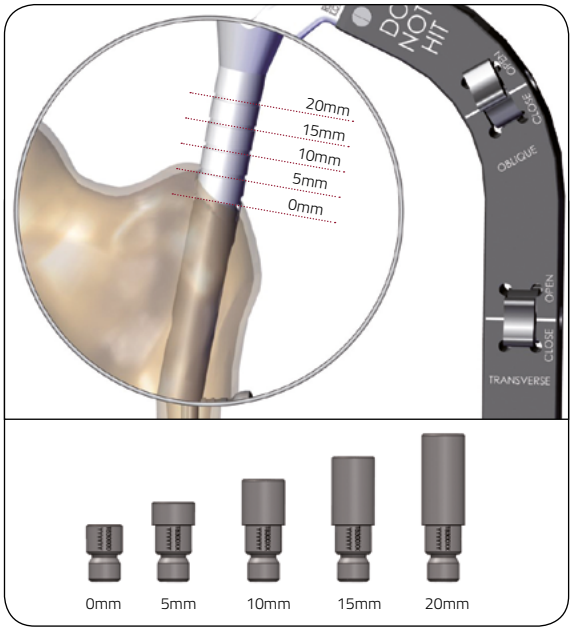



**Fig. 30** End cap size selection

Remove the locking bolt and targeting handle by using the 6mm hex screwdriver **(Fig. 31)**. If necessary to facilitate the procedure, connect the screwdriver with the 6mm hex extension (Part#: 193271).

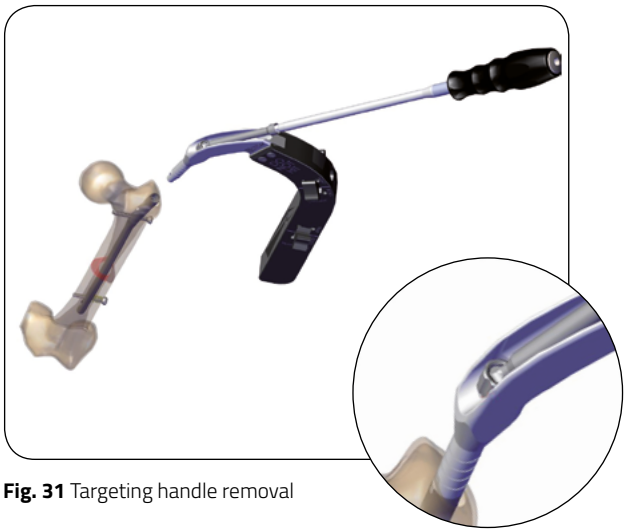


**Fig. 31** Targeting handle removal

Insert a 3.2mm guide wire into the proximal end of the nail **(Fig. 32)**.

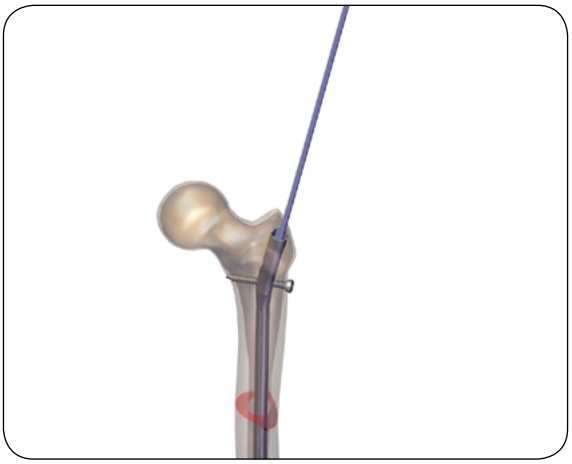


**Fig. 32** Guide wire insertion

Connect the selected end cap to the cannulated 6mm hex screwdriver. Insert the end cap over the guide wire and tighten it on the proximal end of the nail **(Fig. 33)**. Remove the guide wire.

After the procedure, check that fracture reduction and the position of all implants are correct using the Image Intensifier.

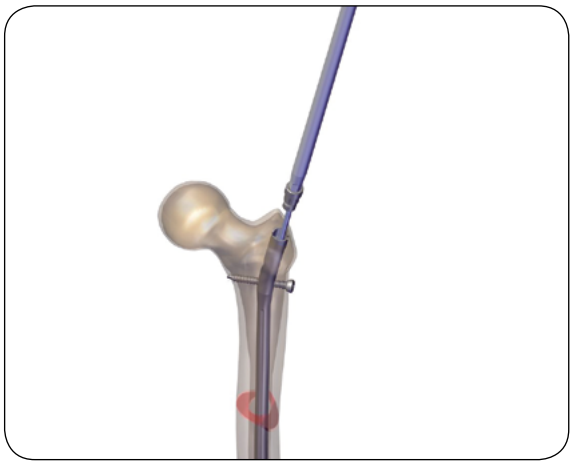


**Fig. 33** End cap insertion

## POST OPERATIVE CARE

Carefully monitor the healing progress in all patients. Choose the appropriate post-operative care for each patient and application. The following are suggestions given by Orthofix, however, post-operative care will always remain the full responsibility of the surgeon:

- Usually, there is no need for a cast and the use of crutches is optional (for comfort).
- Mobility and full weight bearing should be encouraged as early as possible, within pain limits, and according to the surgeon's discretion.
- The patient may be allowed to sit up on the first post-operative day. In stable fractures with dynamic locking, full weight bearing should begin immediately. In less stable fractures, with static locking, the patient will generally regulate the amount of weight bearing, depending on the compaction and/or callus formation.
- Physical therapy is seldom required.
- Patients should be instructed to report any adverse or unanticipated effects to the treating surgeon.

**NOTE: The nail and/or the screws can bend, crack or even break when subjected to the increased loading associated with delayed union, non-unions and/or improper alignment. Internal fixation devices are load sharing devices that are intended to hold fractured bone surfaces in position to facilitate healing. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.**

**PRECAUTION: If callus is slow to or fails to develop, the implant may eventually break due to metal fatigue: to avoid this, further measures may be required, including dynamization to promote callus formation or replacement of the implant**.

## IMPLANT REMOVAL

| INSTRUMENTATION | |
|---|---|
| **Part#** | **Description** |
| 183336 | M7 Conical Mallet Adaptor |
| 183978 | Plier Cutter D15mm |
| 183337 | Screw Extractor Size 3.5-9mm |
| 177395 | Needle Nose Vise Grips |
| SMN173370 | Slap Hammer |
| 17955 | Universal Chuck With T-Handle |
| 91017 | Universal Allen Wrench |

**PRECAUTION: When appropriate, the implants should be removed at conclusion of treatment.**

The surgeon should make the final decision whether an implant can be removed. Implant removal should be followed by adequate post-operative management to avoid re-fracture.

### End cap and screw removals

### Approach

Position the patient supine or in the lateral decubitus position on a fracture table.
To aid the exposure of the posterior edge of the greater trochanter, abduct the upper part of the body approximately 10°–15° to the contralateral side and adduct the affected limb by 10°–15°. Palpate the posterior edge of the greater trochanter and make a 2-3cm skin incision proximal to the tip of the greater trochanter, in line with the shaft of the proximal femur.

Using Image Intensifier, insert a 3.2mm guide wire on the lateral aspect of the greater trochanter, halfway between its anterior and posterior extent, up to the level of the end cap located on the head of the nail **(Fig. 34)**.

Verify the position of the guide wire in the AP and LM planes to ensure it's centered on the end cap.

In case of heterotopic ossification around the head of the nail, insert the cannulated plier cutter (Part#: 183978) over the guide wire and gently remove the bone grown around the nail to expose the end cap **(Fig. 35)**.

**Fig. 34** Guide wire insertion

**Fig. 35** Bone grown removal

Insert the cannulated 6mm hex screwdriver over the guide wire into the end cap, and remove the end cap by rotating it counterclockwise **(Fig. 36)**.

Remove the guide wire.

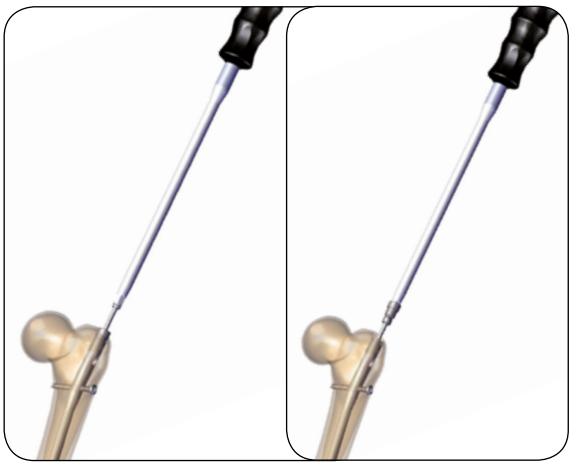


**Fig. 36** End cap removal

**NOTE: If necessary, remove the guide wire and connect the screwdriver to the 6mm hex extension (Part#: 193271) (Fig. 37).**

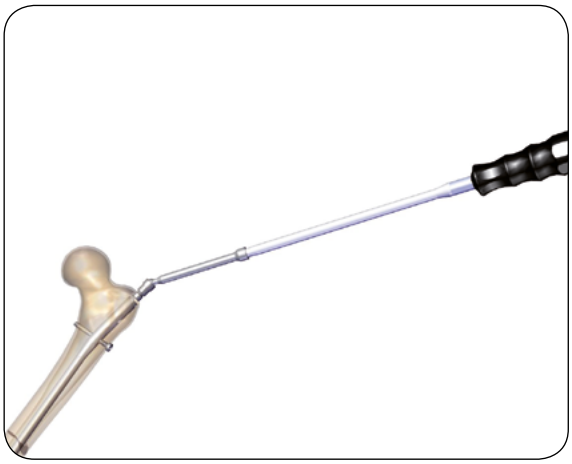


**Fig. 37** End cap removal with 6mm extension

**NOTE: In case the hexagon on the end cap is stripped, remove the guide wire, assemble the screw extractor (Part#:183337) to the universal chuck with T-handle (Part#: 17955) and manually remove the end cap by rotating it counterclockwise (Fig. 38).**

**PRECAUTION: Do not use the screw extractor on power.**

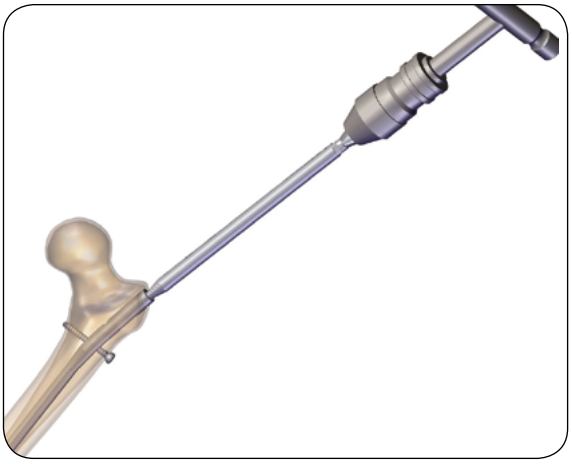


**Fig. 38** Stripped end cap removal

Screw the mallet adaptor (Part#: 183336) clockwise into the head of the nail and tighten it by using the universal Allen Wrench (Part#: 91017)
**(Fig. 39)**.

**PRECAUTION: To prevent nail rotation and over insertion, insert the mallet adaptor before removing the screws**.

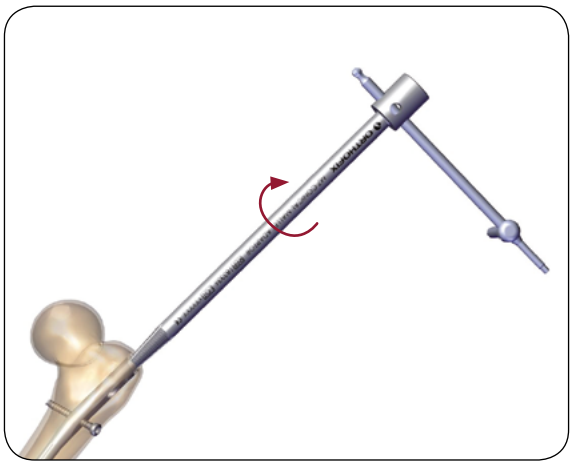


**Fig. 39** Mallet adaptor assembly

Using Image Intensifier, determine the position of the proximal locking screw in the ML plane and make a 1-2cm incision at this point. Remove the proximal locking screw with the short screwdriver by rotating it counterclockwise **(Fig. 40)**.

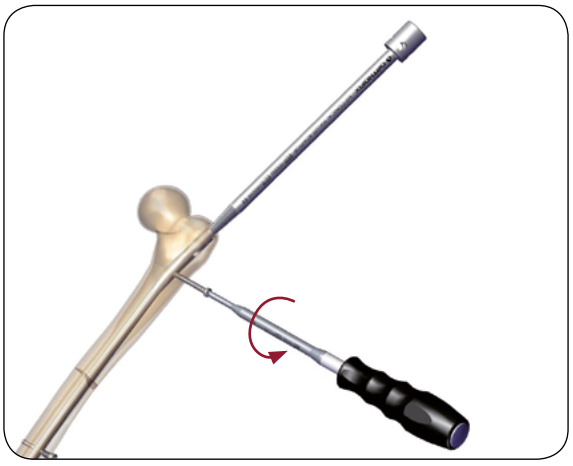


**Fig. 40** Proximal screw removal

**NOTE: In case the head of the screw is stripped, assemble the screw extractor (Part#:183337) to the universal chuck with T-handle (Part#: 17955) and manually remove the screw by rotating it counterclockwise (Fig. 41).**

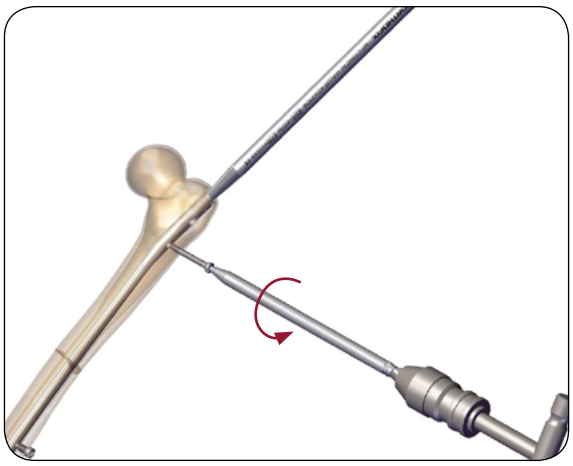


**Fig. 41** Stripped screw removal

**NOTE: In case the thread of the screw is stripped or broken, grab the screw with the needle nose vise grips (Part#: 177395) and pull it out (Fig. 42).**

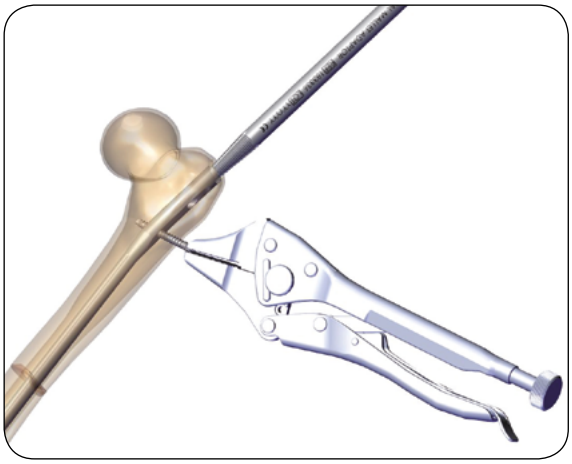


**Fig. 42** Stripped or broken screw pull out

Using Image Intensifier, determine the position of the distal screw in the ML plane and make a 1-2cm incision at this point. Remove the distal locking screw with the screwdriver by rotating it counterclockwise **(Fig. 43)**.

**NOTE: As for the proximal screw, in case the thread of the screw is stripped or broken, remove the screw using the extractor (Fig. 41) or the needle nose vise grips (Fig. 42).**

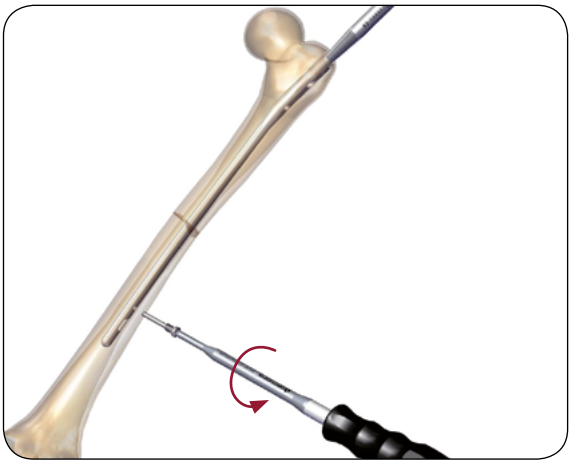


**Fig. 43** Distal screw removal

## Nail extraction

**WARNING: Make sure to remove all locking screws prior to nail removal.**

- **Option A:** Extract the nail by gently hammering with the slotted mallet on the pre-assembled mallet adaptor **(Fig. 44)**.

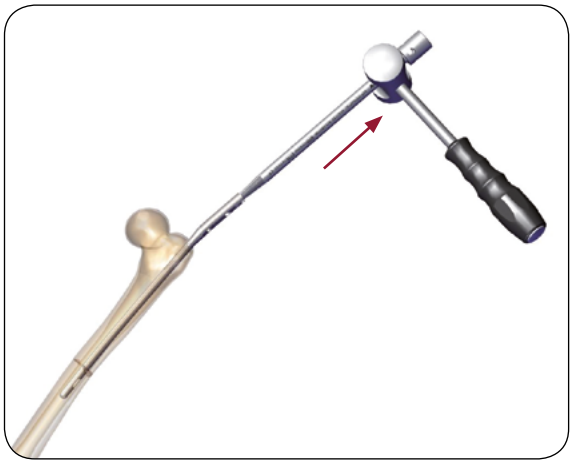


**Fig. 44** Nail extraction using slotted mallet

- **Option B:** Connect the slap hammer to the pre-assembled mallet adaptor **(Fig. 45)** and extract the nail by gently hammering **(Fig. 46)**.

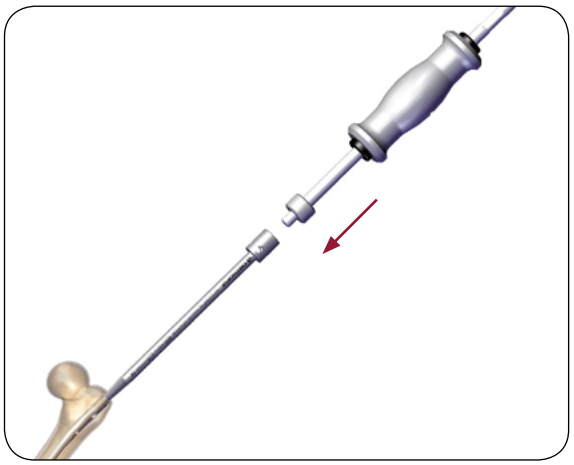


**Fig. 45** Slap hammer assembly

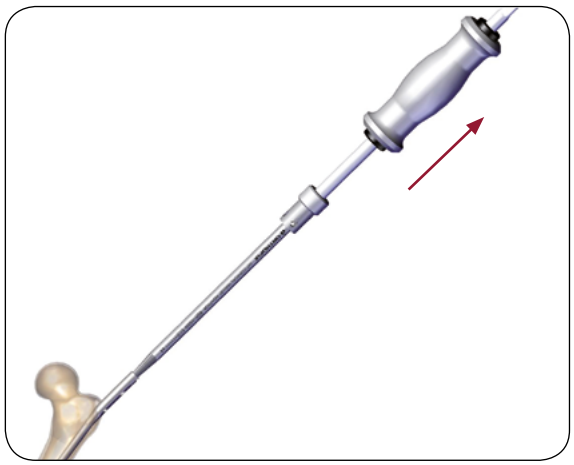


**Fig. 46** Nail extraction using slap hammer

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