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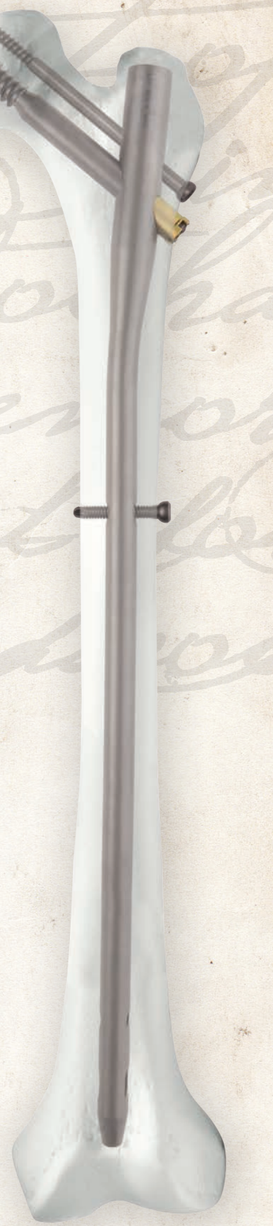


Galileo™

TROCHANTERIC NAIL SYSTEM

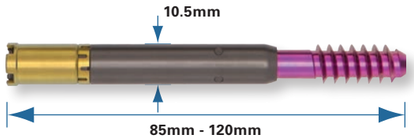
Surgical Technique

Contents

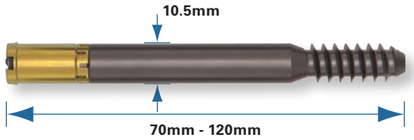
This Surgical Technique sets forth detailed recommended procedures for using AOS devices and instruments. It offers guidance, but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. Surgeons must always rely on their own professional clinical judgement when deciding which products and surgical treatments to use with their patients. Refer to package insert for information on indications, warnings, precautions and contraindications.

Implant Features

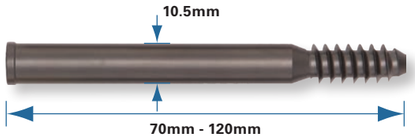
Galileo™ Lag Screw



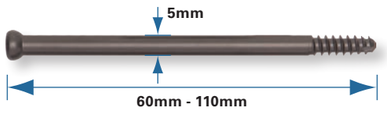
Solid Locking Lag Screw



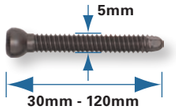
Lag Screw



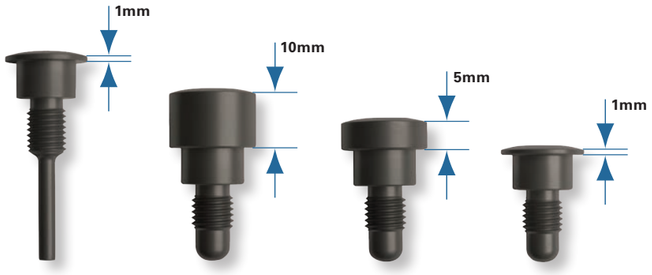
Anti-Rotation Screw

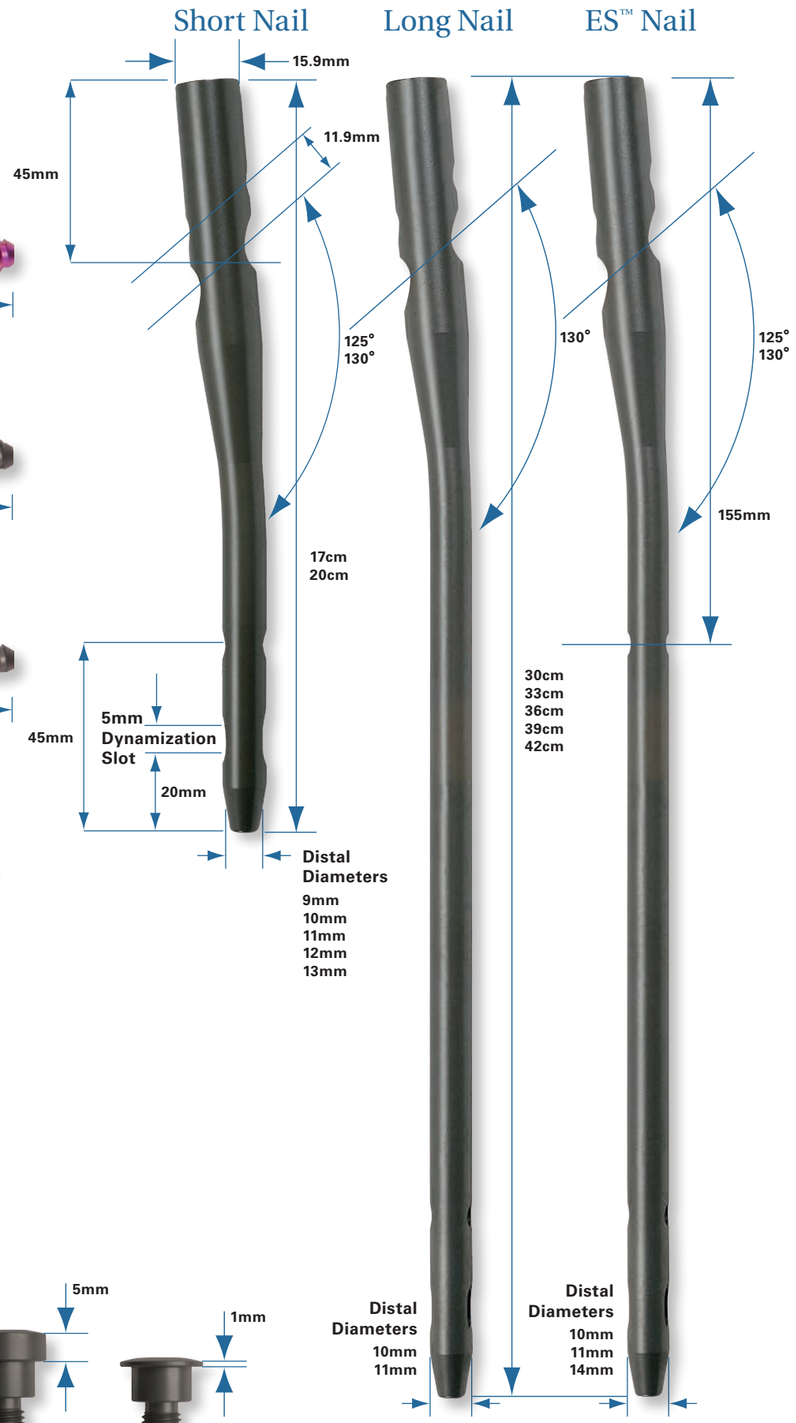


Captured Cortical Screw



Captured End Caps





Galileo™ Trochanteric Nail System
Surgical Technique

1. Indications

The AOS Trochanteric Nail System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric, and high subtrochanteric fractures and combinations of these fractures. The AOS Long Trochanteric Nail is additionally indicated for subtrochanteric fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subrochanteric fractures, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revision procedures.

2. Preoperative Planning

Preoperative radiographs of the uninjured femur may be used to establish proper nail diameter, expected amount of reaming (if necessary), proximal screw angle, nail length and the length of the lag screw. X-rays of the contralateral hip may be helpful to ascertain normal neck shaft angle.

3. Patient Positioning

The patient is placed in a supine position on the fracture table **(Fig.1)**. The uninjured leg is flexed and abducted in a stirrup. A distal foot holder and peroneal post are used for traction of the affected limb. A trunk roll is placed beneath the patient's trunk, just above the iliac crest to support the trunk to allow the maximum abduction of the limb for greater access to the incision site. If a Long Trochanteric Nail is used the contra lateral extremity may be over extended and moved inferiorly to place distal interlocking screws.

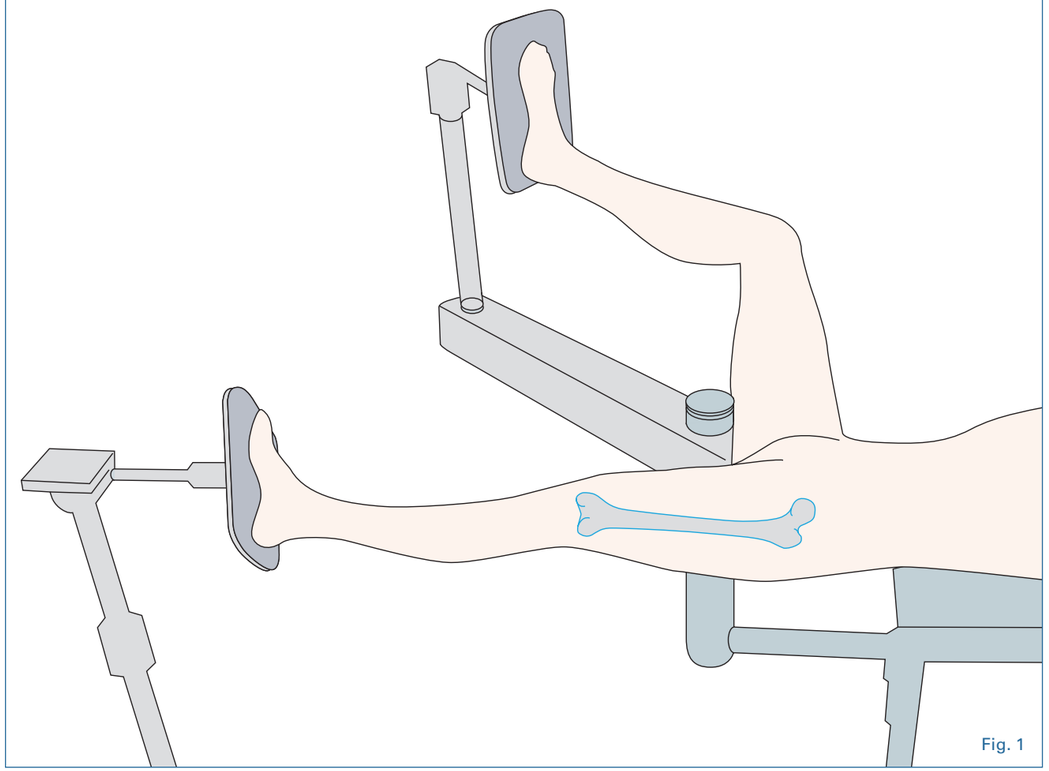


Fig. 1

4. Incision

Make a 1 to 3cm skin incision depending on the size or obesity of the patient, proximal to the greater trochanter. The incision is carried down through the skin and subcutaneous tissue, and the muscles are split in line with their course.

5. Entry Point

The entry point for the nail is located on the tip of the greater trochanter (Fig 2). On the AP image, the starting point should be on the tip of the greater trochanter. On the lateral image, the starting point should be in the midpoint of the greater trochanter.

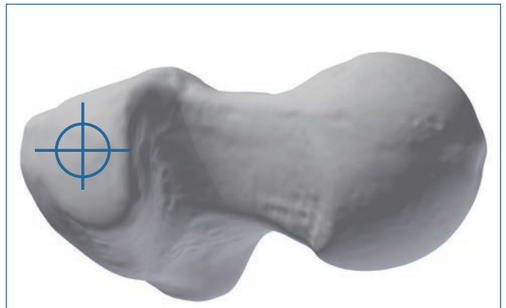


Fig. 2

Option 1

Assemble the **3.2mm Pin Guide (0304)** into the **Soft Tissue Protector (0623)** and place it through the incision. Align the Soft Tissue Protector with the axial line of the femoral shaft in the A/P and lateral image views. Insert a **3.2mm Guide Pin (0100)** so that it is placed in the tip of the greater trochanter

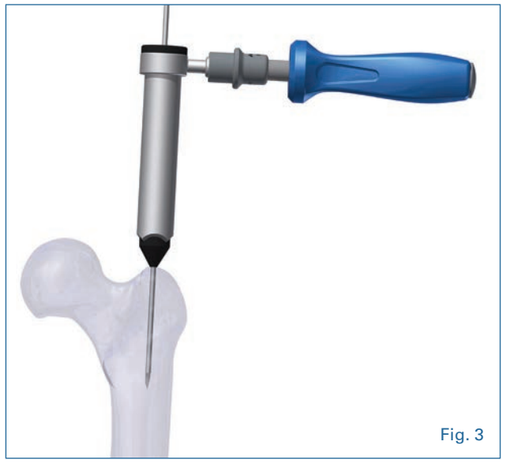


Fig. 3

and aligned with the axial line of the femoral shaft in the A/P and lateral image views **(Fig. 3)**.

Place the **16.5mm Cannulated Entry Reamer (0257)** over the Guide Pin and ream the proximal fragment of the femur through the **Soft Tissue Protector (Fig. 4)**. This leaves 0.5mm clearance around the proximal portion of the nail. The entry reamer has depth indication grooves which are read from the top of the Soft Tissue Protector. The depth grooves allow for the nail to be placed flush, 5mm and 10mm deep.

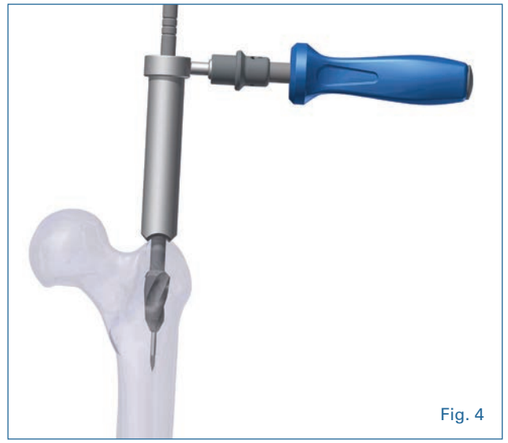


Fig. 4

Option 2

Alternatively, for both short and long trochanteric nailing procedures, the surgeon may open the greater trochanter with a **Cannulated Curved Awl (0256) (Fig. 5)**, followed with a **3.0mm Ball Nose Guide Wire (0101-900)** that is placed through the Curved Awl and placed to the desired depth **(Fig. 6)**. The curved Awl is then removed from the bone allowing the guide wire to stay properly positioned.

Option 2

Fig. 5

Option 2

Fig. 6

6. Guide Wire Insertion & Fracture Reduction

In general, it is not necessary to use flexible reamers to ream the femoral canal when fixing proximal femoral fractures using the Short Trochanteric Nail. When fixing fractures using the ES™ Trochanteric Nail or Long Trochanteric Nail, reaming may be necessary.

To assist in fracture reduction for the reamed technique, a **Reduction Tool (0804)** may be utilized **(Fig. 7)**. Introduce the 3.0mm Ball Nose Guide Wire (0101-900) by means of the **Guide Wire Gripper (0481)** to the level of the fracture. Confirm its containment within the femur by means of A/P and lateral views. Reduce the proximal fragment to the distal fragment and advance the Guide Wire until it is centered in the distal fragment. Verify the containment of the Guide Wire within the femur by image intensification.

Fig. 7

Note: Guide Wire Gripper can be utilized through the guide wire cannula or the side groove option **(Fig. 9 & 10)**.

For reamed applications use the **Flex Shaft (0233)** and **Reamer Heads (0234-095 to 140)** (9.5mm – 14.0mm) over the 3.0mm Ball Nose Guide Wire. Ream the entire femur in 0.5mm increments until the desired diameter has been achieved. The femoral canal should be reamed to a diameter of at least 1.0-1.5mm larger than the nail to be used. Never insert a nail that has a larger diameter than the last reamer used.

7. Nail Selection

For the ES™ Trochanteric Nail and Long Trochanteric Nails, the proper nail length is determined by sliding the **Guide Wire Depth Gauge (0512)** over the guide wire to the greater trochanter, and reading the appropriate length directly from the calibrated line on the guide wire **(Fig. 8)**.

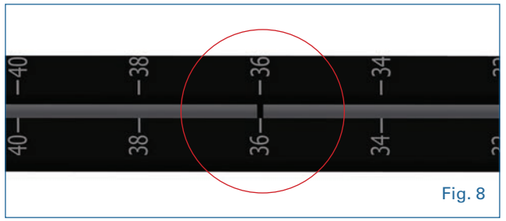


Fig. 8

Option 1

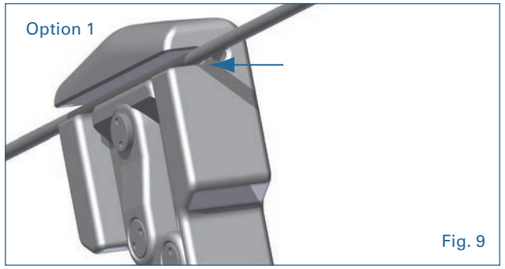


Fig. 9

Option 2

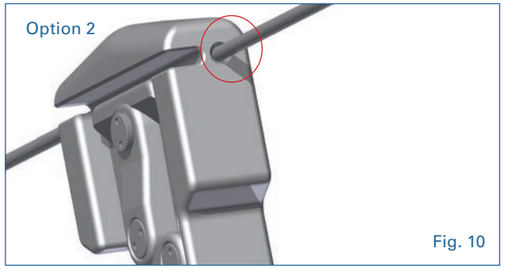


Fig. 10

8. Nail Insertion

Attach the **125°/130° Radiolucent Targeting Arm (1267/1268)** to the nail using the **Ball Hex Driver (0474) (Fig. 11)**.
Introduce the nail into the proximal femur using the Radiolucent Targeting Arm to control nail rotation. If a guide wire is used, pass the nail over the guide wire **(Fig. 12)**. If the nail does not enter the femur easily, use a gentle blow of a mallet on the **Impactor Pad (0826)**. It is very important to never hit directly on the Targeting Arm.

Note: Avoid the use of excessive force which may produce comminution of the femoral shaft.

Fig. 11

Fig. 12

9. Proximal Targeting

Once the nail has been correctly placed, insert the **Lag Screw Triple Sheath Assembly (0617, 0616, 0312)** by pressing on the corresponding button located on the Targeting Module and mark the incision location on the skin. Once the incision is made, insert the Lag Screw Triple Sheath until it contacts the lateral cortex of the femur **(Fig. 13**). Remove the **Obturator (0616)** and place the **3.2mm Guide Pin (0100)** through the **Guide Pin Drill Guide (0312)**.

Fig. 13

Once the 3.2mm Guide Pin is directed within the Drill Guide, insert it into the femoral head **(Fig. 14)**. The location of the Guide Pin should be checked on both A/P and lateral views. The Guide Pin should be centered A/P in the femoral head to slightly inferior with the tip of the Guide Pin approximately 5mm from the subcondylar bone. A lateral view of the femoral head is then taken to ensure the Guide Pin has been placed centrally.

Note: If there is intraoperative instability of the femoral head and neck, the Lag Screw Sheath, A/R Screw Sheath and guides may be inserted into the targeting module at the same time. The 3.2mm Guide Pin or A/R Drill may then be used to stabilize the head and neck while inserting either the Lag Screw or A/R Screw.

Fig. 14

10. Galileo™ & Solid Locking Lag Screw Insertion

Place the **Guide Pin Depth Gauge (0506)** under the 3.2mm Guide Pin and against the Pin Guide. Read the required length from the Depth Gauge, assuring that the sheath is touching the bone **(Fig. 15)**. The length is transferred to the **10.3mm Cannulated Lag Screw Drill (0258)** by placing the **Adjustable Stop (0261)** over the shaft of the drill and locking it into position at the appropriate depth indication **(Fig. 16)**. The Adjustable Stop should be set at a depth at least 5mm less than the depth of the Guide Pin to ensure that the tip of the drill does not pass beyond the tip of the Guide Pin. Remove the Guide Pin Guide.

The 10.3mm Cannulated Lag Screw Drill is inserted over the Guide Pin, and the femoral head is drilled to the stop on the drill. The tip of the drill should be at least 5mm from the tip of the Guide Pin **(Fig 17)**. Remove the drill.

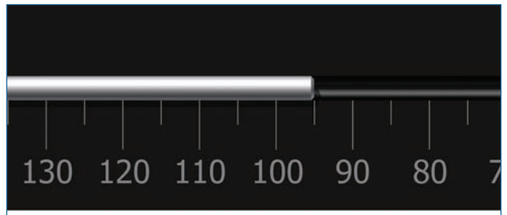


Fig. 15

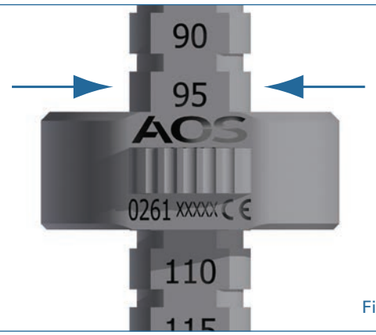


Fig. 16

Fig. 17

Fig. 18

Note: In dense bone it is advisable to tap the femoral head to receive the lag screw. Place the **Lag Screw Tap (0259)** over the Guide Pin and through the sheath and tap the femoral head. Using the calibrations on the Lag Screw Tap, tap the femoral head to the same depth that was set on the 10.3mm Cannulated Lag Screw Drill.

Thread the **Compression Sleeve (0465)** over the L**ag Screw Inserter (0454)**. Place the Lag Screw Capturing Rod through the Lag Screw Inserter and capture the selected 10.5mm Galileo™ or Solid Locking Lag Screw onto the inserter. Insert the Galileo™ or Solid Locking Lag Screw over the Guide Pin and through the sheath until the Lag Screw is screwed into place **(Fig. 19)**.

Fig. 19

Rotate the compression sleeve clockwise over the sheath until it contacts the Targeting Arm **(Fig. 20)**. If intraoperative compression is required, continue rotating the Compression Sleeve clockwise until the desired compression is achieved or the compression reaches its maximum capacity. To ensure that the Lag Screw inserted in the proper location, verify that the red indicator band is not visible **(Fig. 20 & 21)**. Lag Screw positioning should also be verified with x-ray in A/P and Lateral views.

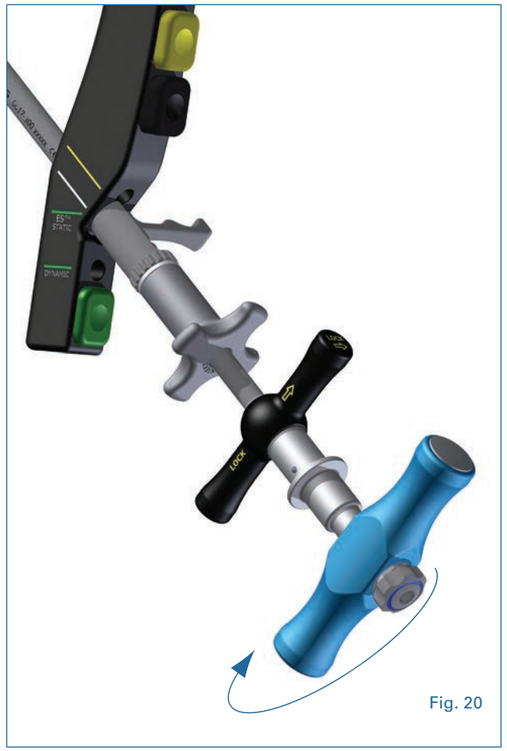


Fig. 20

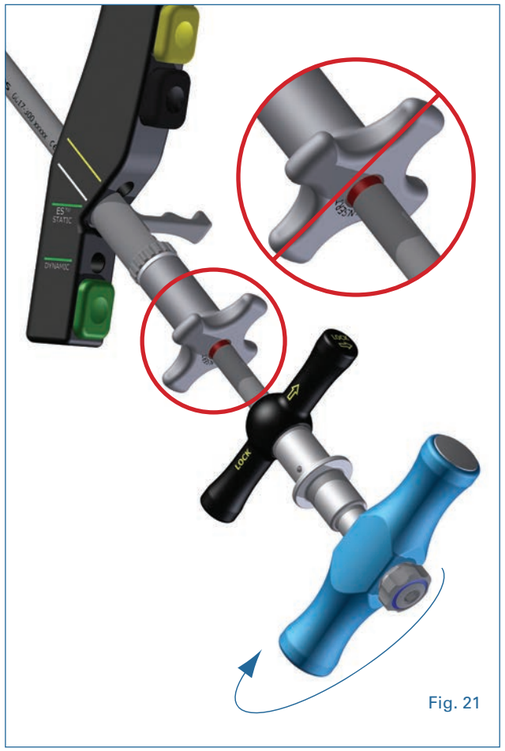


Fig. 21

To lock the Galileo™ or Solid Locking Lag Screw, hold the blue **Galileo™ Lag Screw Insertion Handle (0454)** stationary and turn the black **Galileo™ Locking T-handle (0456)** clockwise until firm resistance is achieved **(Fig. 22)**.

Remove the Galileo™ Lag Screw insertion instrumentation by removing the **Capturing Rod (0455)**.

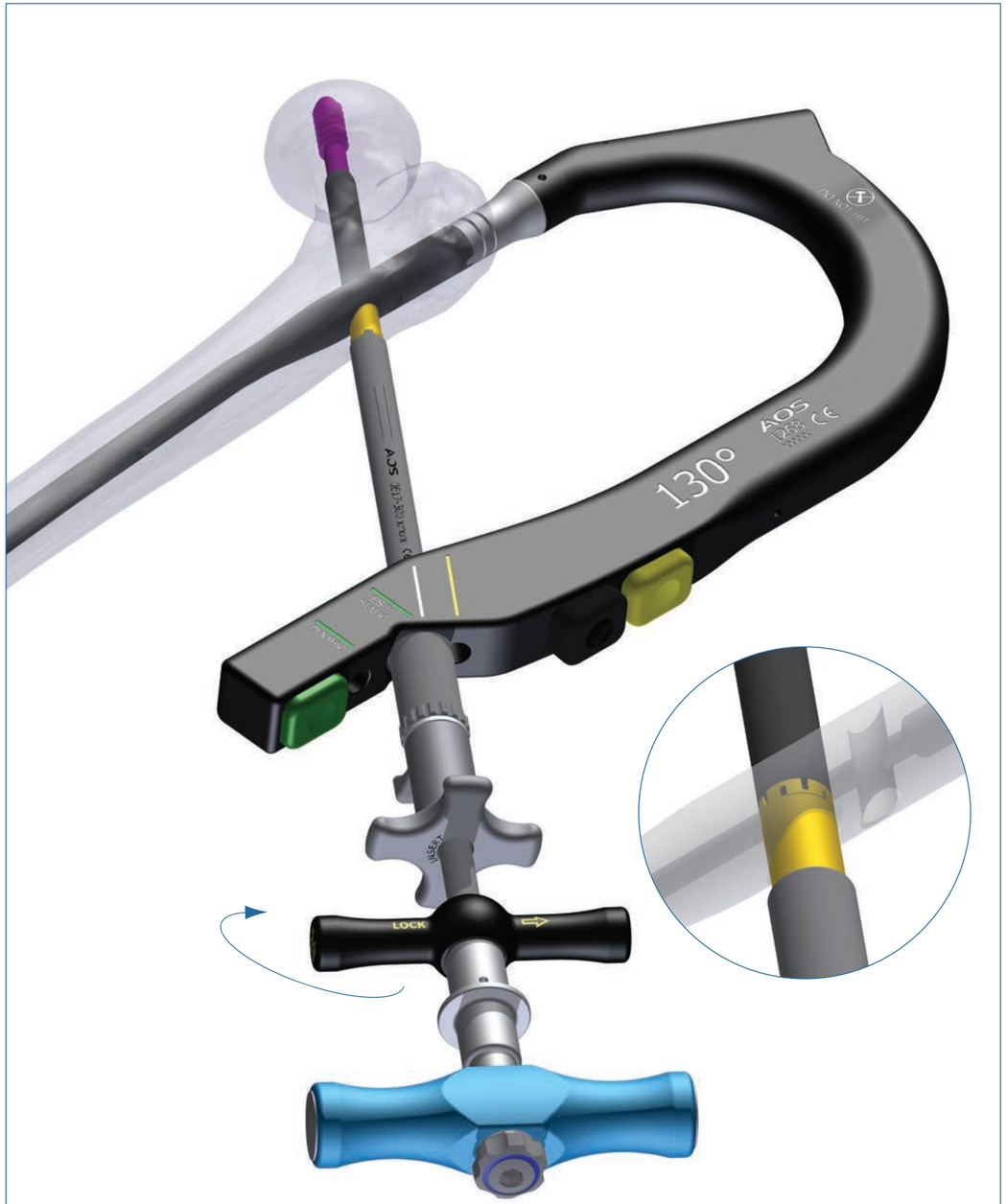


Fig. 22

To allow functional post-operative compression in the Galileo™ Lag Screw, remove the activation sleeve by inserting the **Activation Tool (0457)** through the sheath. Disengage the Activation Sleeve by turning the Activation Tool counterclockwise until the Activation Sleeve is removed. The turquoise colored Activation Sleeve will be visible at the tip of the Activation Tool once removed **(Fig 23)**.

The Activation Sleeve must always be removed directly after locking the Galileo™ Lag Screw to the AOS Trochanteric Nail.

NOTE: Do not use the End Cap with Post in conjunction with the Galileo™ or Solid Locking Lag Screw as the post may damage the Locking Ring which locks the Lag Screw to the nail.

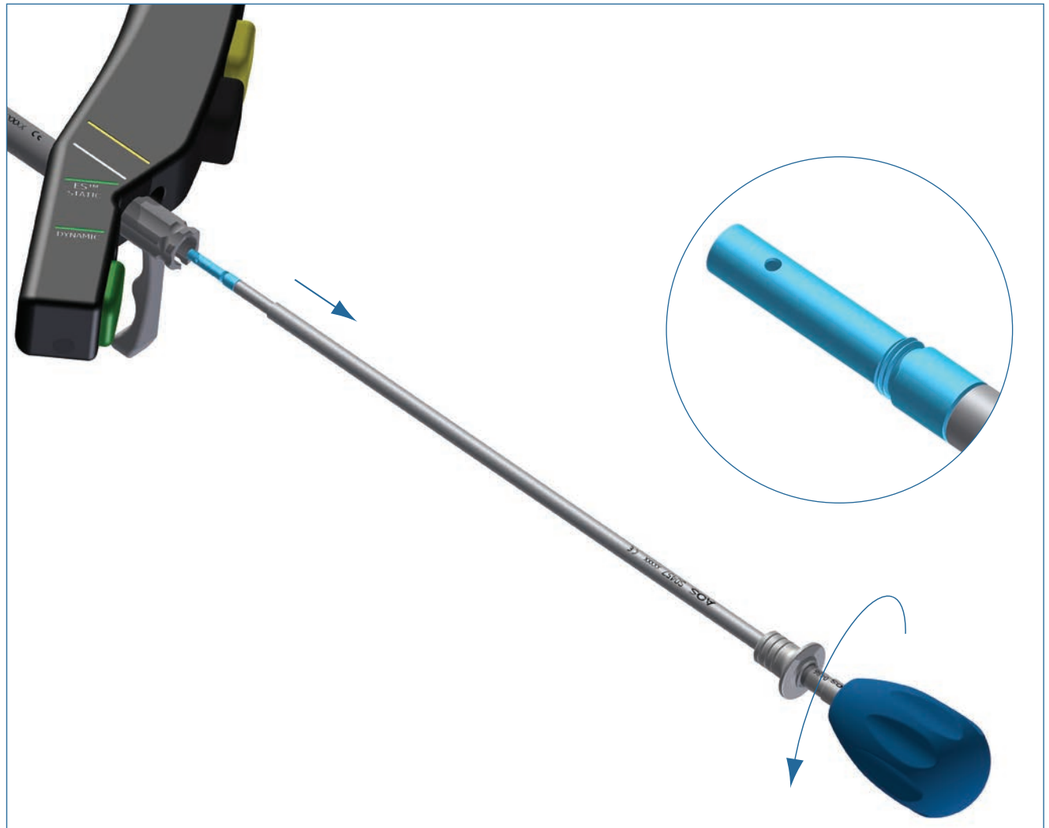


Fig. 23

11. Anti-Rotation Screw Insertion (Optional)

If there is rotational instability during insertion of the 10.5mm Lag Screw, a 5.0mm Anti-Rotation Screw may be used to prevent rotation of the femoral head. Place the **A/R Screw Triple Sheath Assembly (0313, 0620 & 0621)**, into the anti-rotation hole in the Targeting Module and mark the location on the skin for the incision.

Make the incision and insert the A/R Triple Sheath Assembly to the lateral cortex of the bone. Remove the Obturator and drill to the appropriate depth under image intensification using the **5.0mm Calibrated A/R Drill (0209)** and measure the length of the screw from the end of the Drill Guide using the calibration on the drill **(Fig. 24)**.

Remove the Drill Guide from the Sheath and insert the selected Anti-Rotation Screw using the **3.5mm Hex Driver (0471) (Fig. 25)**.

Fig. 24

Fig. 25

13. ES™ & Short Nail Distal Targeting

For the ES™ and Short Nail, distal locking is accomplished using the Targeting Module. Place the **Distal Screw Triple Sheath Assembly (0315, 0621 & 0622)** through the appropriate distal hole in the Targeting Module and mark the skin. Make the incision and place the Distal Screw Triple Sheath Assembly to the lateral cortex of the bone **(Fig. 26)**. Remove the **Obturator (0622)**.

Fig. 26

Drill the bone using a **4.0mm Calibrated Drill (0219)** and measure the length of the screw from the end of the Drill Guide using the calibration on the drill **(Fig. 27)**.

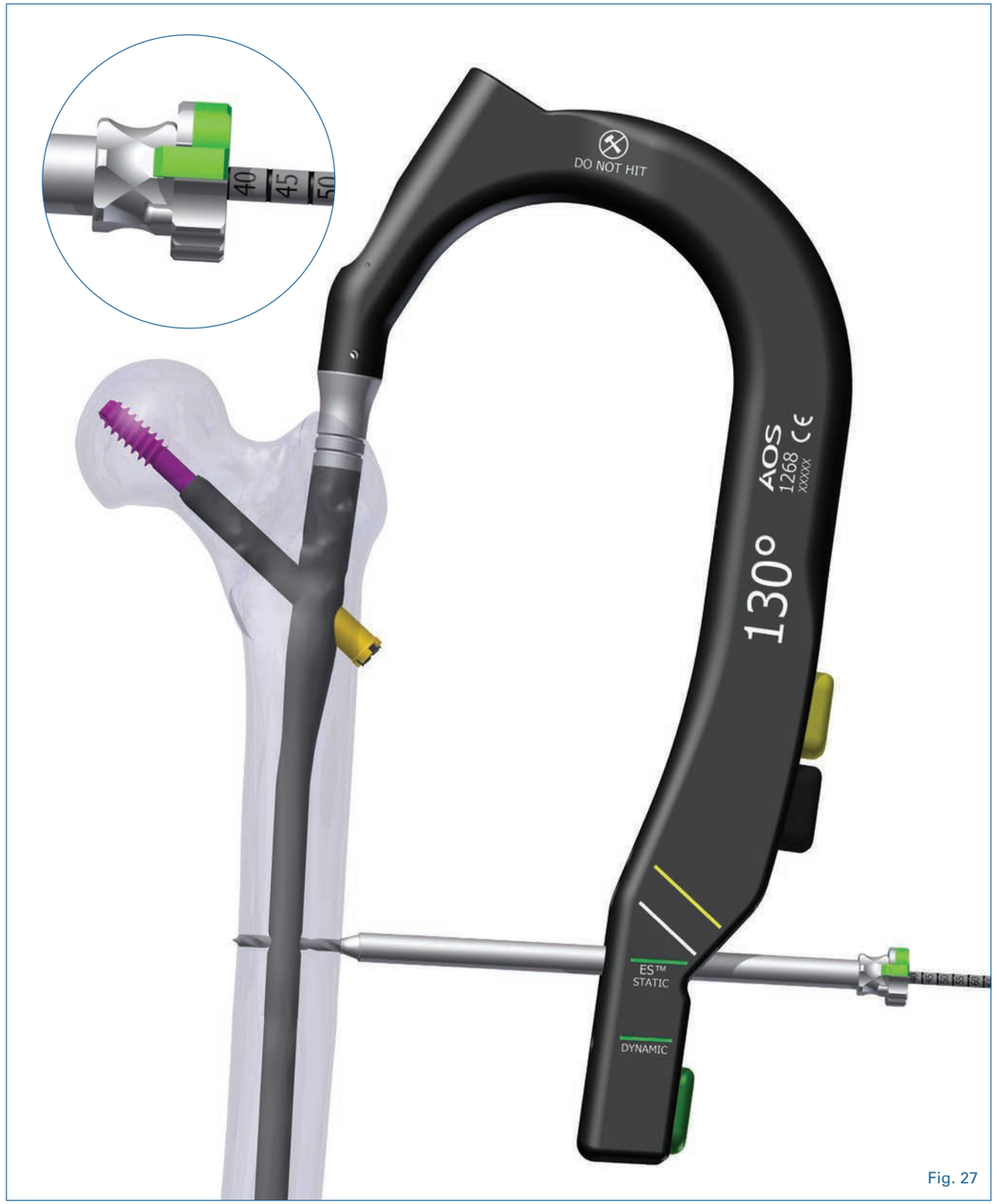


Fig. 27

Remove the Drill and Drill Guide and place the screw directly through the sheath using the **5.0mm Cannulated Hex Driver (0472) (Fig. 28)**.

For the Long Nail, distal locking is accomplished using the freehand technique and confirming the screw length from the calibrated line on the **4.0mm Short Drill (0210)** using the **Distal Depth Gauge (0514)**.

14. End Cap Insertion

Choose the proper end cap based on the depth of countersink of the nail, flush, 5mm or 10mm. Using the **Ball Hex Driver (0474)** insert the appropriate End Cap through the incision and tighten it into the nail.

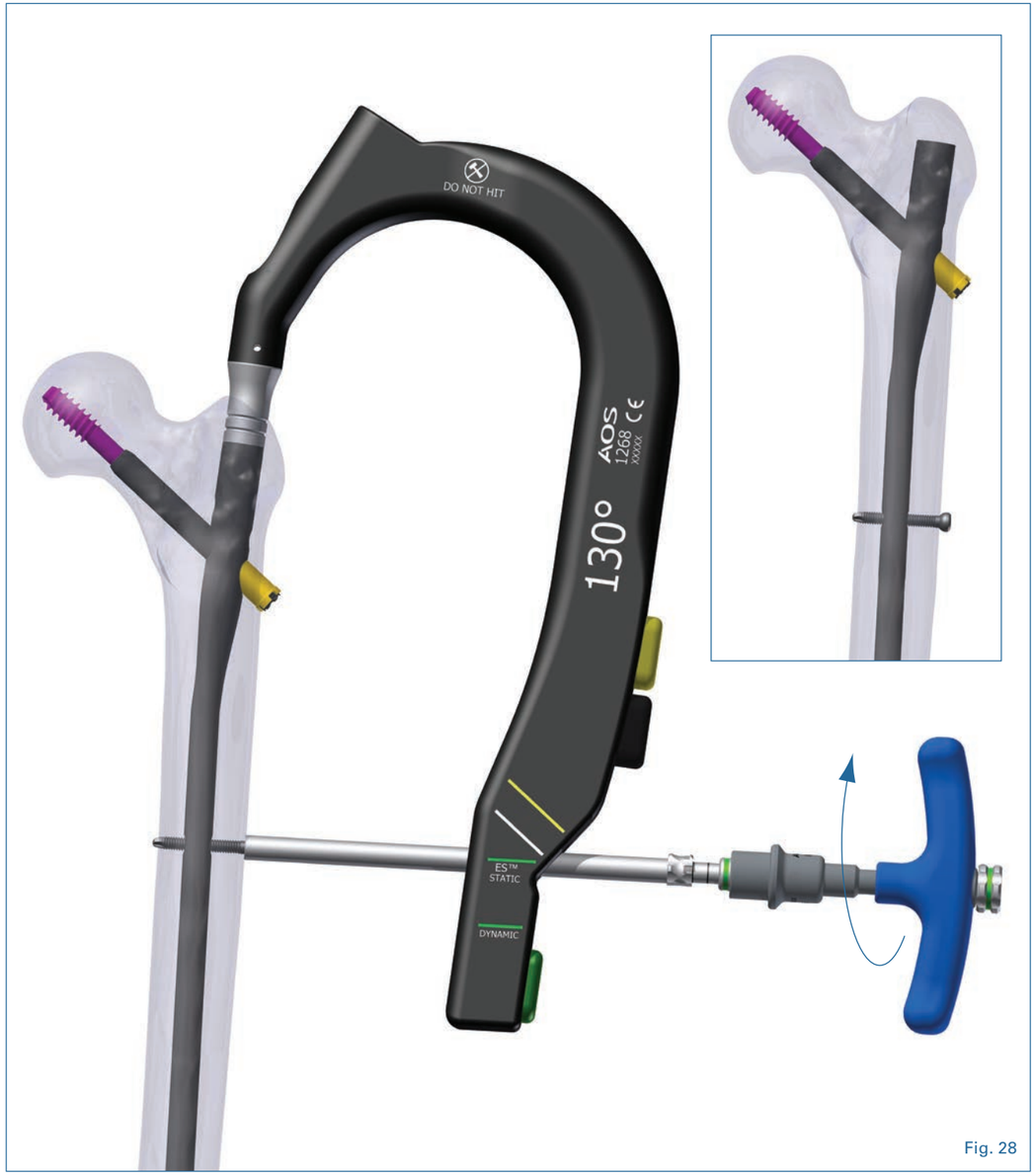


Fig. 28

15. Galileo™ & Solid Locking Lag Screw Removal

To extract the Galileo™ or Solid Locking Lag Screw, place the Lag Screw Inserter into the Sheath and engage into the lateral end of the Lag Screw. Attach the instrument by tightening the Capturing Rod.

While holding the blue Galileo™ Lag Screw Insertion Handle stationary, pull back the trigger located between the T-Handles and turn the black Galileo™ Lag Screw Locking Handle counterclockwise to unlock the screw from the nail. Once disengaged, turn the blue Insertion Handle counterclockwise until the screw is removed from the bone and nail.

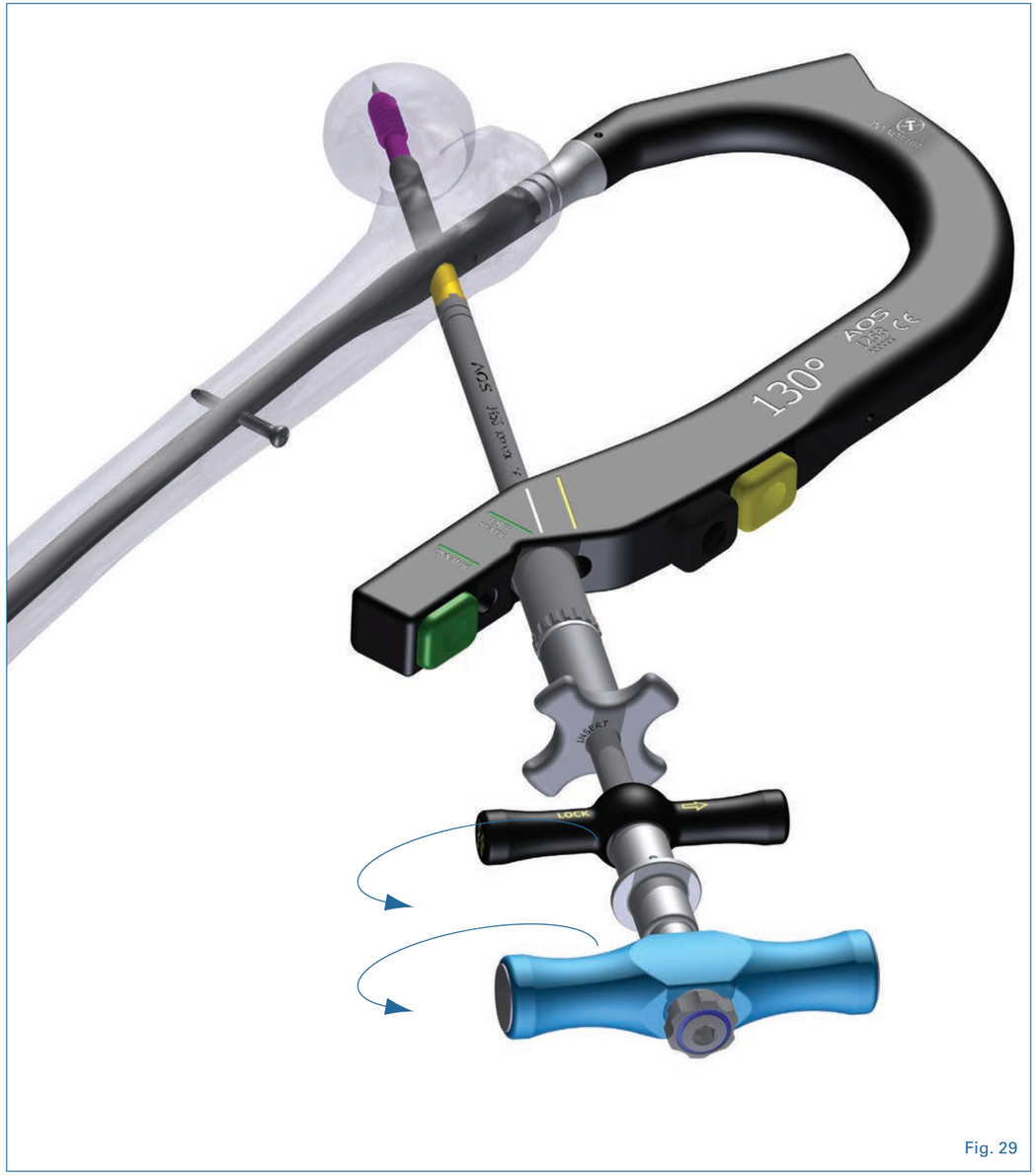


Fig. 29

16. Nail Removal

To extract the nail, remove End Cap, Lag Screw, Anti-Rotation Screw and Cortical Locking Screws and attach the **Extractor Bolt (0828)** to the proximal end of the nail. Attach the **Impactor Pad (0826)** to the Extraction Bolt. Then apply backward blows with a mallet **(Fig. 30)**. Be careful to avoid levering the nail/ extractor assembly.

Fig. 30