

SURGICAL TECHNIQUE

Intralock Femoral Intramedullary Nail

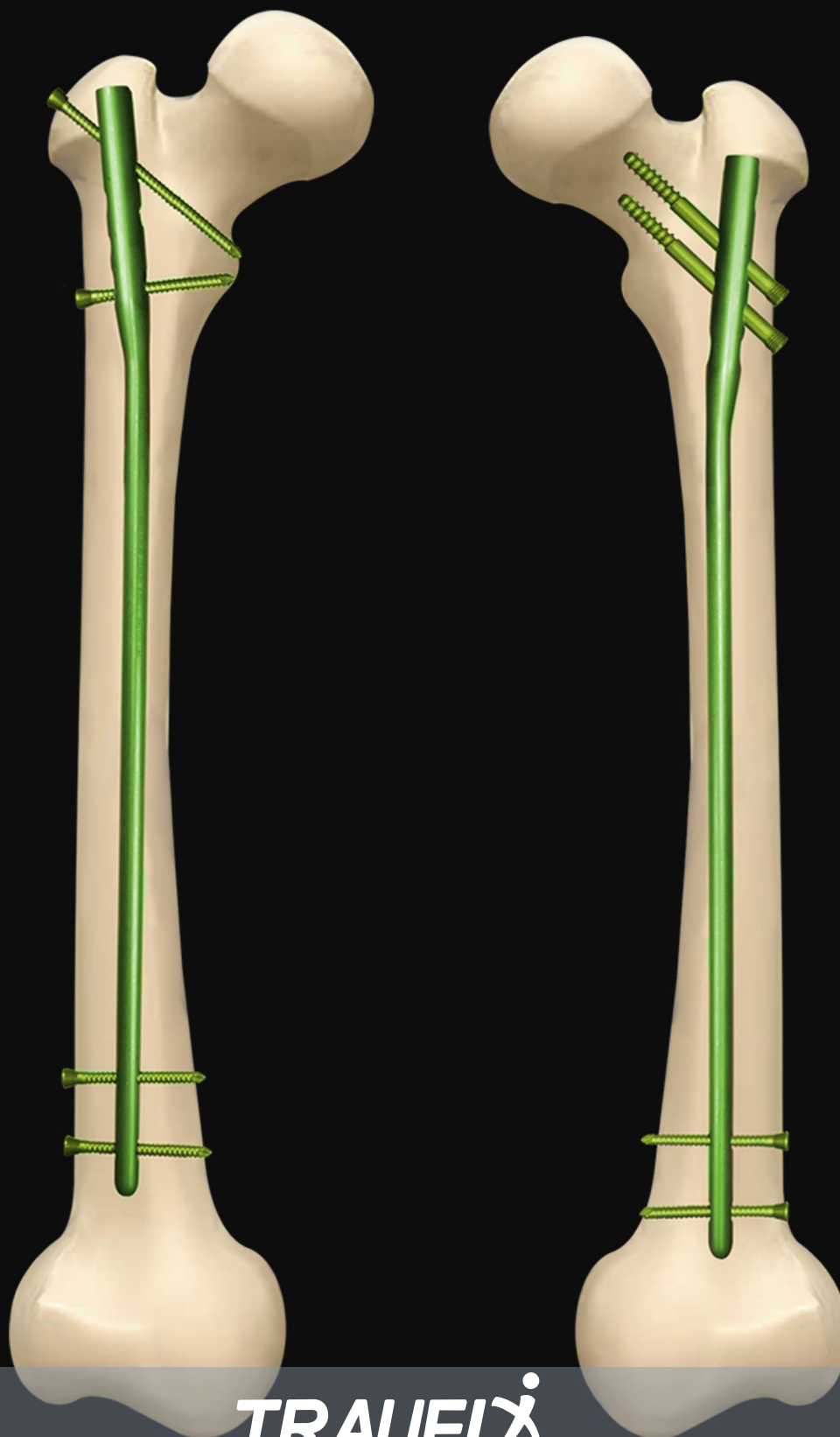
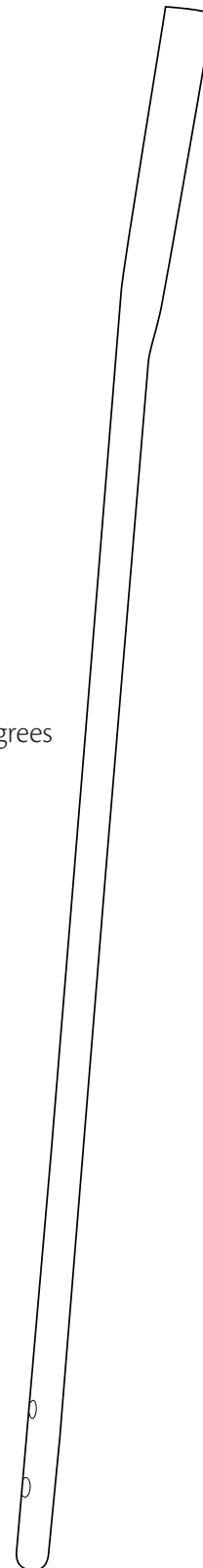


TABLE OF CONTENTS

| | |
|----|---|
| P. | |
| 3 | Technological advantages |
| 4 | Specifications |
| 7 | Surgical indications |
| 7 | General contraindications |
| 8 | Blocking options |
| 9 | Description of surgical technique |
| 9 | Device calibration |
| 10 | 1.Pre-surgical planning |
| 10 | 2.Patient Preparation |
| 11 | 3.Approach |
| 11 | 4.Insertion of the nail |
| 14 | 5.Distal locking |
| 16 | 6.Dynamic hole fixing |
| 17 | 7.Anterograde compression and anterograde static compression at 130 degrees |
| 18 | 8.Femoral neck and head fixation |
| 24 | 9.Locking distal screw for 240mm nail |
| 28 | 10. End cap placing |
| 30 | Instruments |



TECHNOLOGICAL ADVANTAGES

The Intralock femoral intramedullary nail is made of titanium (Ti6Al4V ELI), has an innovative locking system with two 6.5 cannulated screws with an anatomical angulation of 130°, thus obtaining a static reduction with fixation to the femoral neck and head useful in cervical fractures associated before or after diaphysary fixation as well as in subtrochanteric fractures.

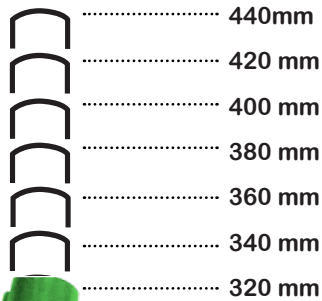
Obtaining a static reduction by using a threaded head screw with anterograde angulation of 130 degrees achieving a blockage through the major trochanter towards the minor trochanter useful in subtrochanter fractures.

It has an innovative and exclusive system of locking screws with threaded head in its distal and proximal zone, placed by means of an adjustable strip in a distal and lateral direction (+/- 20mm) which allows a fast and safe lock even without the use of an image intensifier. Increasing the stabilization of the fracture and indicating its use in diaphysary fractures facilitating primary compression or secondary dynamization in a controlled manner. And improving reduction either open or closed, decreasing surgical time and tissue damage, compared to other treatment techniques.

SPECIFICATIONS

The Intralock femoral intramedullary nail is made of high quality titanium of 9, 10, 11 and 12 mm diameter with lengths from 320 mm to 480 mm, in its left and right presentation

INTRALOCK FEMORAL INTRAMEDULLARY NAIL 9mm



| Left | | Right | |
|---------|---------------|---------|---------------|
| 136.32* | 9 mm X 320 mm | 138.32* | 9 mm X 320 mm |
| 136.34* | 9 mm X 340 mm | 138.34* | 9 mm X 340 mm |
| 136.36* | 9 mm X 360 mm | 138.36* | 9 mm X 360 mm |
| 136.38* | 9 mm X 380 mm | 138.38* | 9 mm X 380 mm |
| 136.40* | 9 mm X 400 mm | 138.40* | 9 mm X 400 mm |
| 136.42 | 9 mm X 420 mm | 138.42 | 9 mm X 420 mm |
| 136.44 | 9 mm X 440 mm | 138.44 | 9 mm X 440 mm |

INTRALOCK FEMORAL INTRAMEDULLARY NAIL 10 mm

| Left | 10mm | Right | 10mm |
|---------|----------------|---------|----------------|
| 137.32* | 10 mm X 320 mm | 139.32* | 10 mm X 320 mm |
| 137.34* | 10 mm X 340 mm | 139.34* | 10 mm X 340 mm |
| 137.36* | 10 mm X 360 mm | 139.36* | 10 mm X 360 mm |
| 137.38* | 10 mm X 380 mm | 139.38* | 10 mm X 380 mm |
| 137.40* | 10 mm X 400 mm | 139.40* | 10 mm X 400 mm |
| 137.42 | 10 mm X 420 mm | 139.42 | 10 mm X 420 mm |
| 137.44 | 10 mm X 440 mm | 139.44 | 10 mm X 440 mm |

INTRALOCK FEMORAL INTRAMEDULLARY NAIL 11 mm

| Left | 11mm | Right | 11mm |
|---------|----------------|---------|----------------|
| 180.32* | 11 mm X 320 mm | 181.32* | 11 mm X 320 mm |
| 180.34* | 11 mm X 340 mm | 181.34* | 11 mm X 340 mm |
| 180.36* | 11 mm X 360 mm | 181.36* | 11 mm X 360 mm |
| 180.38* | 11 mm X 380 mm | 181.38* | 11 mm X 380 mm |
| 180.40* | 11 mm X 400 mm | 181.40* | 11 mm X 400 mm |
| 180.42 | 11 mm X 420 mm | 181.42 | 11 mm X 420 mm |
| 180.44 | 11 mm X 440 mm | 181.44 | 11 mm X 440 mm |

* Contained in the standard implant set.

INTRALOCK FEMORAL INTRAMEDULLARY NAIL 12 mm

| Left | 12mm | Right | 12mm |
|--------|----------------|--------|----------------|
| 214.32 | 12 mm X 320 mm | 215.32 | 12 mm X 320 mm |
| 214.34 | 12 mm X 340 mm | 215.34 | 12 mm X 340 mm |
| 214.36 | 12 mm X 360 mm | 215.36 | 12 mm X 360 mm |
| 214.38 | 12 mm X 380 mm | 215.38 | 12 mm X 380 mm |
| 214.40 | 12 mm X 400 mm | 215.40 | 12 mm X 400 mm |
| 214.42 | 12 mm X 420 mm | 215.42 | 12 mm X 420 mm |
| 214.44 | 12 mm X 440 mm | 215.44 | 12 mm X 440 mm |

INTRALOCK TROCHANTERIC INTRAMEDULLARY NAIL 9 mm

| | |
|---------|---------------|
| 157.18 | 9 mm X 180 mm |
| 157.20* | 9 mm X 200 mm |
| 157.22 | 9 mm X 220 mm |
| 157.24* | 9 mm X 240 mm |

INTRALOCK TROCHANTERIC INTRAMEDULLARY NAIL 10 mm

| | |
|---------|----------------|
| 158.18 | 10 mm X 180 mm |
| 158.20* | 10 mm X 200 mm |
| 158.22 | 10 mm X 220 mm |
| 158.24* | 10 mm X 240 mm |

INTRALOCK TROCHANTERIC INTRAMEDULLARY NAIL 11 mm

| | |
|---------|----------------|
| 216.18 | 11 mm X 180 mm |
| 216.20* | 11 mm X 200 mm |
| 216.22 | 11 mm X 220 mm |
| 216.24* | 11 mm X 240 mm |

INTRALOCK TROCHANTERIC INTRAMEDULLARY NAIL 12 mm

| | |
|--------|----------------|
| 217.18 | 12 mm X 180 mm |
| 217.20 | 12 mm X 200 mm |
| 217.22 | 12 mm X 220 mm |
| 217.24 | 12 mm X 240 mm |



* Contained in the standard implant set.

4.5mm LOCKING SCREW FOR INTRALOCK INTRAMEDULLARY NAIL

| | |
|---------|-----------------|
| 166.15 | 4.5 mm X 15 mm |
| 166.20 | 4.5 mm X 20 mm |
| 166.25 | 4.5 mm X 25 mm |
| 166.30 | 4.5 mm X 30 mm |
| 166.35 | 4.5 mm X 35 mm |
| 166.40 | 4.5 mm X 40 mm |
| 166.45 | 4.5 mm X 45 mm |
| 166.50 | 4.5 mm X 50 mm |
| 166.55 | 4.5 mm X 55 mm |
| 166.60 | 4.5 mm X 60 mm |
| 166.65 | 4.5 mm X 65 mm |
| 166.70 | 4.5 mm X 70 mm |
| 166.75 | 4.5 mm X 75 mm |
| 166.80 | 4.5 mm X 80 mm |
| 166.85 | 4.5 mm X 85 mm |
| 166.90 | 4.5 mm X 90 mm |
| 166.95 | 4.5 mm X 95 mm |
| 166.100 | 4.5 mm X 100 mm |



END CAP FOR FEMORAL INTRAMEDULLARY NAIL

Code 168.12



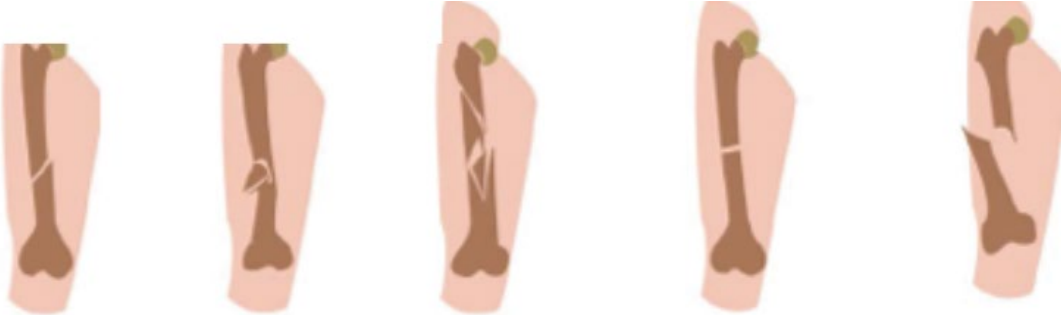
6.5 mm SUBTROCHANTERIC INTRALOCK SLIDING SCREW

| | |
|---------|-----------------|
| 167.55 | 6.5 mm X 55 mm |
| 167.60 | 6.5 mm X 60 mm |
| 167.65 | 6.5 mm X 65 mm |
| 167.70 | 6.5 mm X 70 mm |
| 167.75 | 6.5 mm X 75 mm |
| 167.80 | 6.5 mm X 80 mm |
| 167.85 | 6.5 mm X 85 mm |
| 167.90 | 6.5 mm X 90 mm |
| 167.95 | 6.5 mm X 95 mm |
| 167.100 | 6.5 mm X 100 mm |
| 167.105 | 6.5 mm X 105 mm |
| 167.110 | 6.5 mm X 110 mm |
| 167.115 | 6.5 mm X 115 mm |
| 167.120 | 6.5 mm X 120 mm |



SURGICAL INDICATIONS

Traufix intramedullary nails are indicated for diaphysary, subtrochanteric, femoral neck, and intertrochanteric femur fractures such as:



Oblique

32 A2

Of butterfly

32 B1
32 B2
32 B3

Comminute

32 C1
32 C2

Transverse

32 A3

Spiral

32 A1

GENERAL CONTRAINDICATIONS

- Systemic inflammatory response syndrome (to be evaluated by the surgeon).
- Septicemia.
- Osteomyelitis.
- Patient unable to comply with post-operation care.
- Hypersensitivity to materials (titanium).

LOCKING OPTIONS



Antegrade static fixation at 130° degrees



Compression approached at 130°



Femoral Neck and Head Fixation

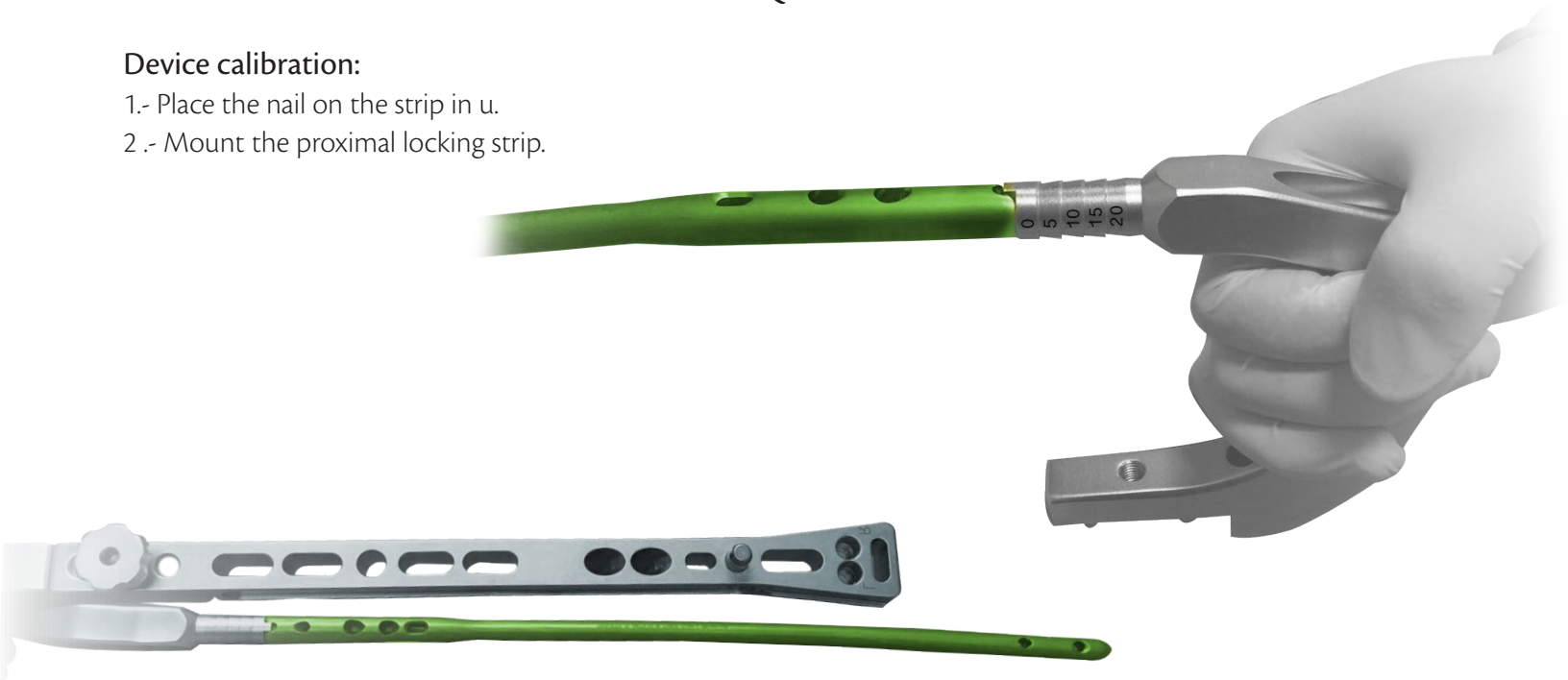


Dynamic fixation

DESCRIPTION OF THE SURGICAL TECHNIQUE

Device calibration:

- 1.- Place the nail on the strip in u.
- 2.- Mount the proximal locking strip.



- 3.- Place graduated strip matching the gradation of the strip with the length of the chosen nail.



- 4- Assemble mobile head.



Note: Confirm calibration of distal locks (mobile strip) as well as proximal locks (fixed strip).

5.- Place the 6.3 sleeve and calibrate using the 6.3mm bit matching with the butterfly hole for distal locking.



6.- Remove strips to enhance nail insertion procedure.



1.Pre-surgical planning

Determine the diameter and length of the nail to be used as well as the locks that will be needed. It is recommended to use radiographic strips.

Caution

This description of the technique is not suitable for immediate clinical application. Practical learning with an experienced surgeon is strongly recommended.

2. Preparation of the patient:

Place the patient in a position of lateral decubit or supine decubit, in case of performing the technique for neck locking and femoral head (fig.1), it is suggested the use of image intensifier placing it in a position that allows us to take anteroposterior projections (fig.2), as well as side projections.

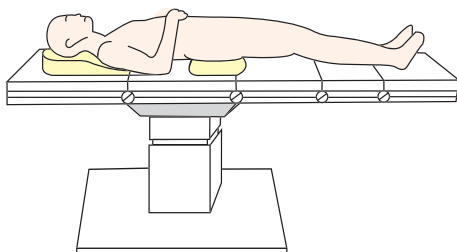


Figure 1

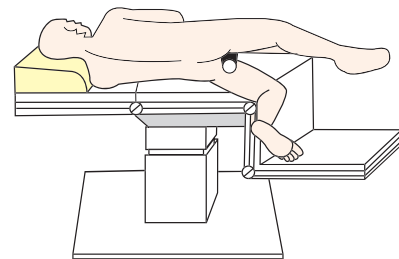


Figure 2

3.Approach

A lateral approach of approximately 3 to 6 cm long, between 7 and 15 cm above the tip of the major trochanter, is enhanced in the direction of the femoral diaphysis.

For the realization of the approach in femur by anterograde means the insertion point will be slightly lateral to the major trochanter i.e. 10° lateral to the axis of the medullary channel from the anteroposterior point of view (fig. 3) and following the diaphysary axis in its side view (fig.4) and corroborate the depth by means of image intensifier once the insertion of the centromedullary nail has been performed (fig. 5).

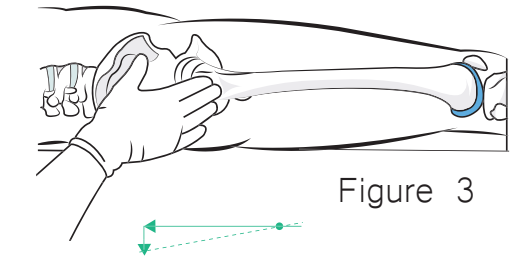


Figure 3

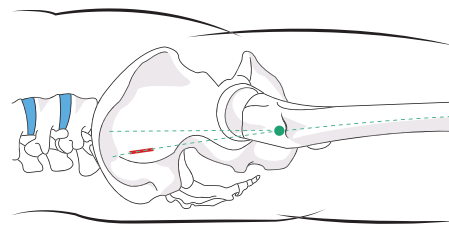
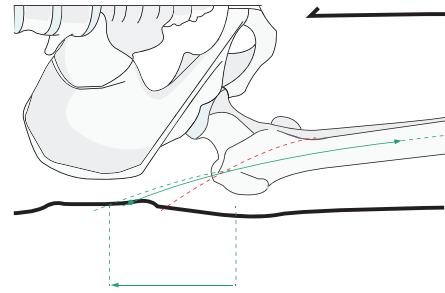


Figure 4



4.Insertion of the nail

Drilling is performed with the initiating punch in the pyriform pit, olive guide is placed through the puncture cannulation on the back. If necessary, rely on the reducing guide to reduce the fracture.

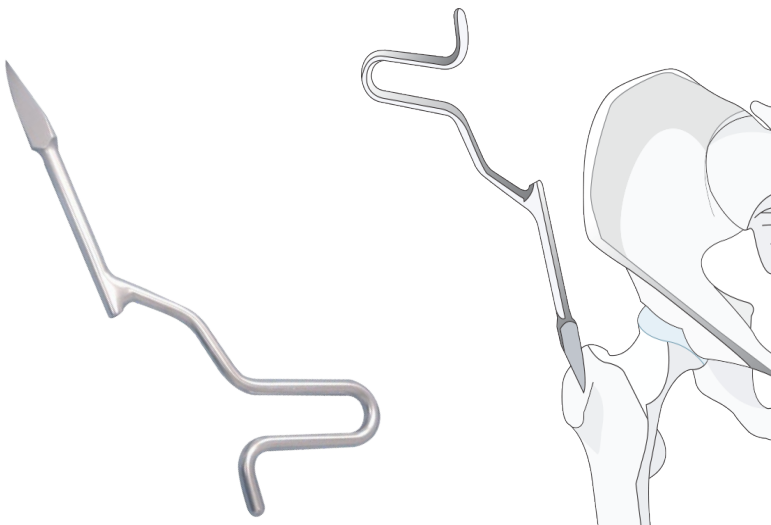


Figure 5

Preparation of the centromedullary channel is performed using the system of flexible reamers with interchangeable tips (8.5 to 13mm).



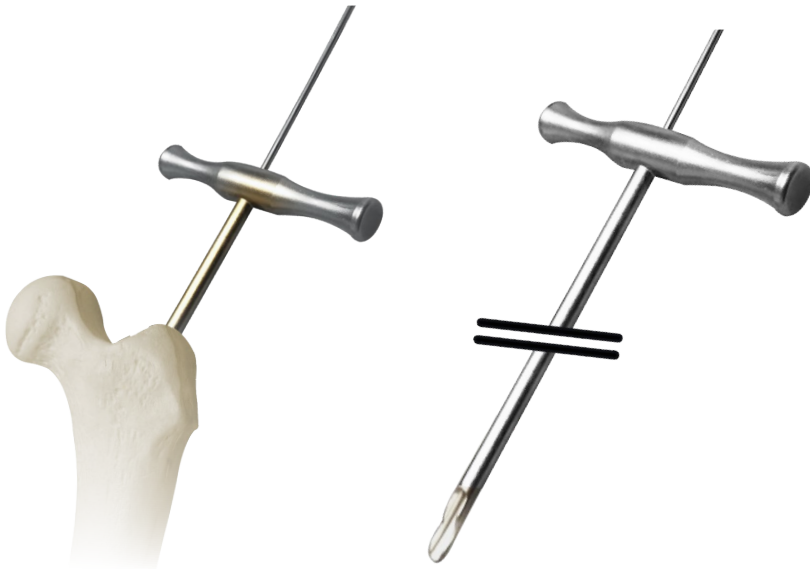
It is reamed according to the diameter of the nail chosen: to place 9mm nail reaming to 10mm is recommended, and to place nail 10 mm reaming of 11 mm is recommended reaming them to enhance the portal in the insertion zone is recommended when using 13 mm for easy insertion of the chosen nail.

| Ø | Nail | Recommended reamer |
|---|-------|--------------------|
| | 9 mm | 10 mm |
| | 10 mm | 11 mm |
| | 11 mm | 12 mm |
| | 12 mm | 13 mm |

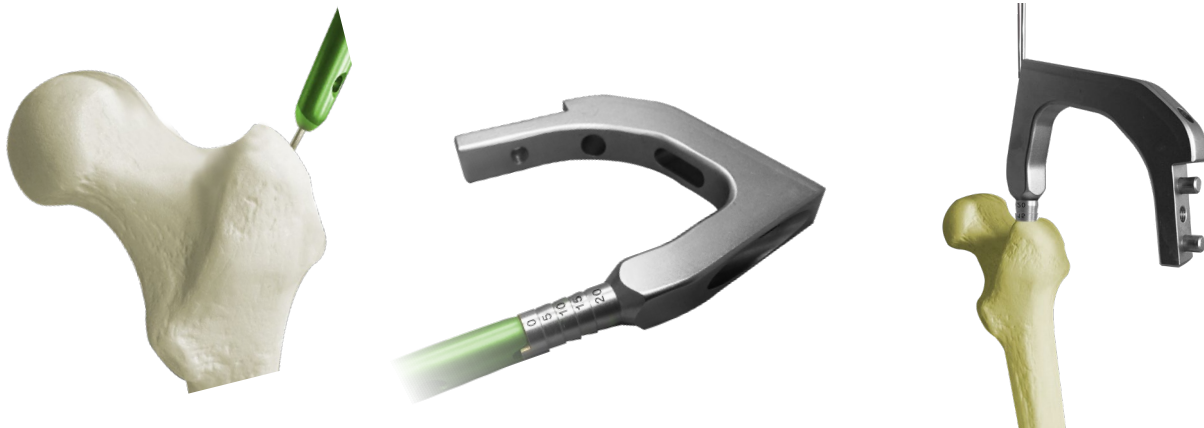
8mm to 13mm



Swap the guide with olive for the olive-free guide inside the medullary channel with the help of the reducing guide to maintain reduction.



Prepare medullary channel with 12mm bit to receive the nail. Insert the medullary center nail in the channel by means of a rotating movement by moving the nail to the desired position according to the gradation in the distal zone of the U-strip (5,10,15 and 20mm).

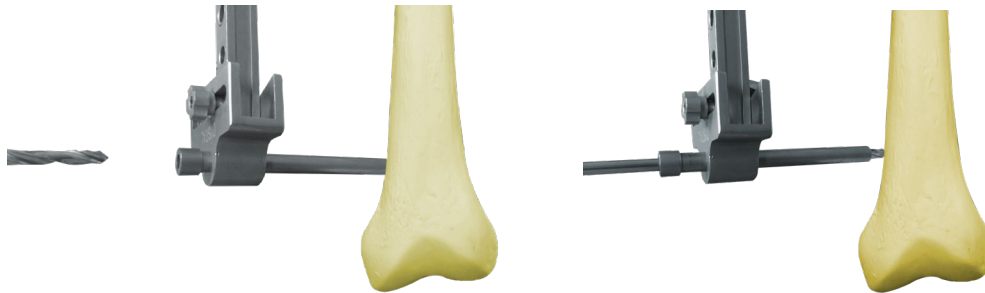


Optionally, the intralock impactor can be used to the intralock impactor to facilitate the insertion of the nail in its final trajectory.



5. Distal locking

Place the armed strip as well as the locking sleeve on the calibration hole and drill the first cortical with the 6.3 mm drill bit.



Remove the strips and place the distal locking device in the drilled hole, turning until a noticeable lock of the system rotation is obtained.



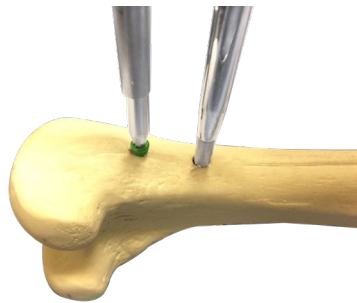
With the device locked, external sleeve of 10mm and internal sleeve of 4.3 mm is placed using a bit 4.0 drill both corticals in the proximal hole.



Inner sleeve 4.3 is removed obtaining the length of the screw by means of the intralock depth meter, in case of it being in diaphysary zone, the use of a 4.5mm tap is recommended in the first cortical.



Insert the locking screw with the threaded head.

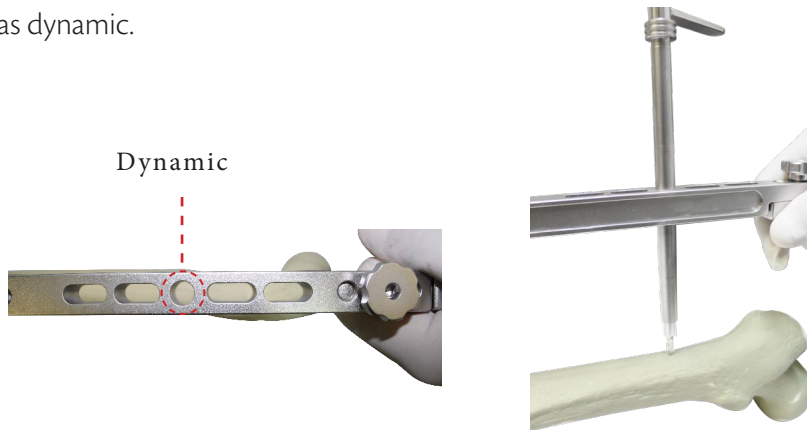


Repeat this step with the proximal hole.



6. Dynamic hole fixing

10mm outer sleeve and 4.3 inner sleeve are placed in the hole marked as dynamic.



Inner sleeve 4.3 is removed obtaining the length of the screw by means of the intralock depth meter, in case of it being in diaphysary zone, the use of a 4.5mm tap is recommended in the first cortical.

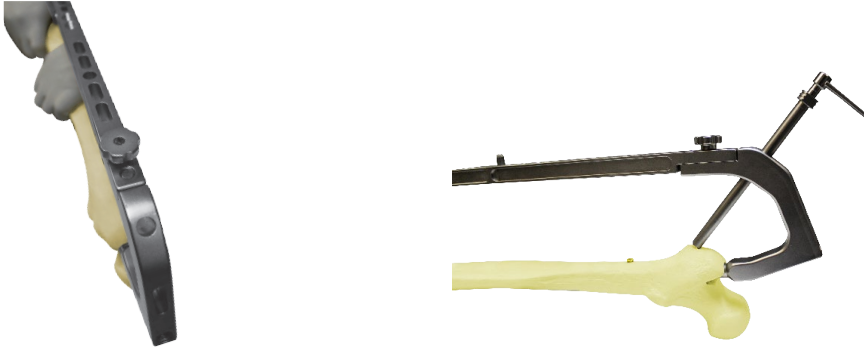


Insert the locking screw with the threaded head for dynamic fixation.



7. Anterograde compression and anterograde static compression at 130 degrees

10mm outer sleeve and 4.3 inner sleeve is placed in the hole marked as 130 degree anterograde.



Inner sleeve 4.3 is removed obtaining the length of the screw by means of the intralock depth meter, in case of it being in diaphysary zone, the use of a 4.5mm tap is recommended in the first cortical.



Insert the locking screw with the threaded head.



8. Femoral neck and head fixation

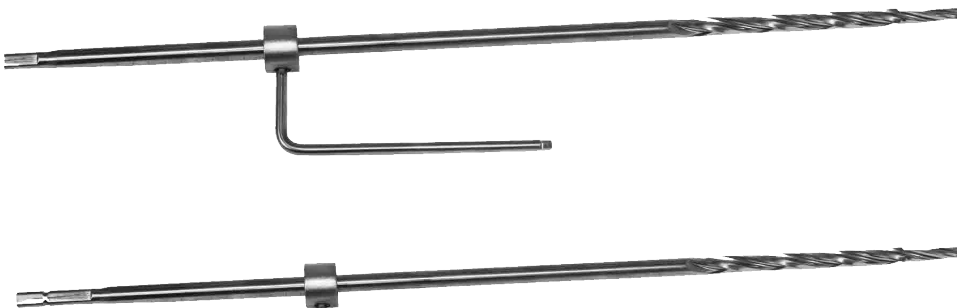
10mm outer sleeve and 2.5 inner sleeve are placed in the hole marked neck, guide wire 2.0 is inserted and the depth is checked by means of image intensifier in proximal and distal hole.



Remove sleeves 2.5 to obtain screw length using Intralock depth meter



Adjust the top of the 6.4mm cannulated guide according to the length.



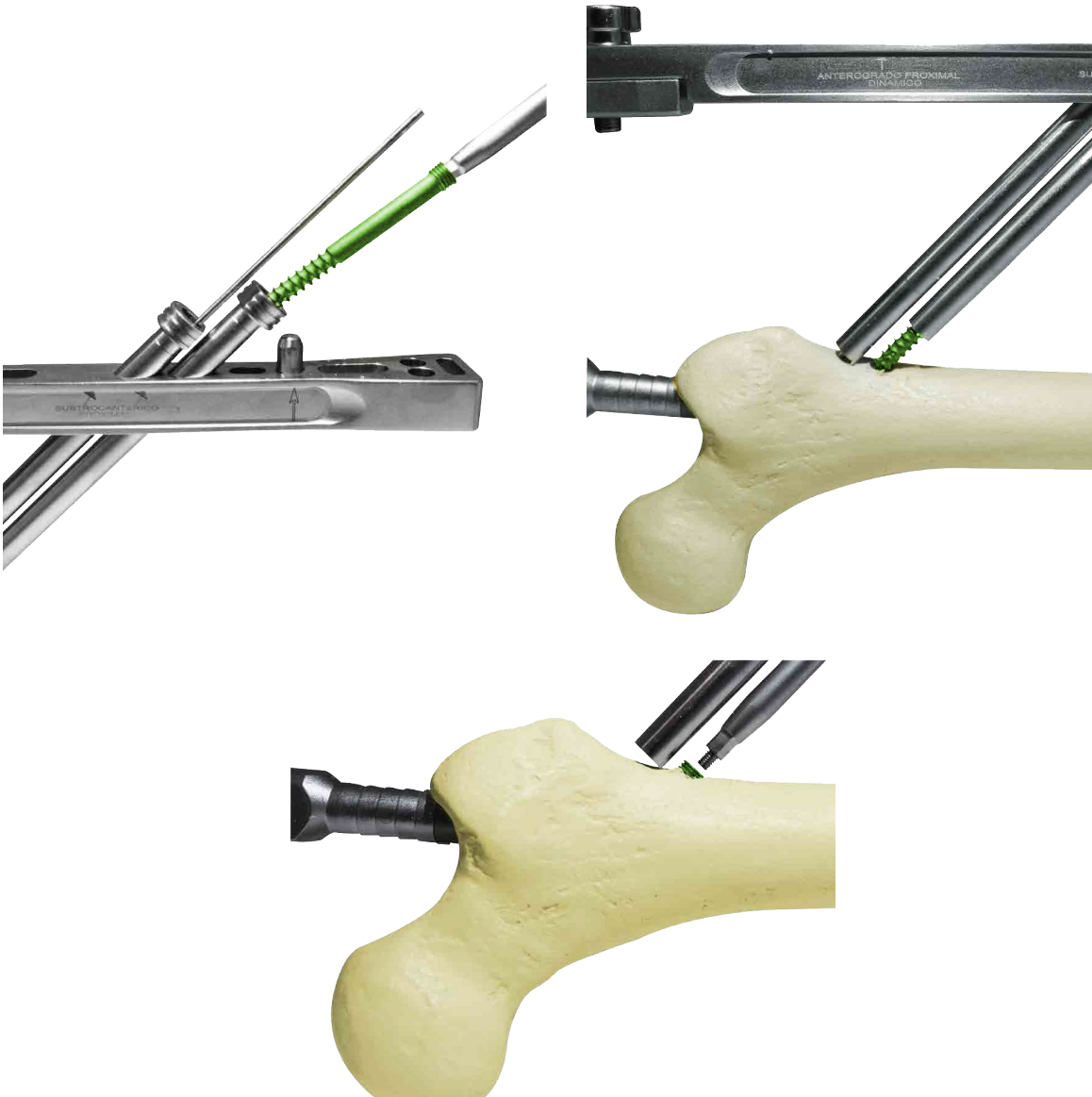
Place 6.4 guide and drill through the guide wires.



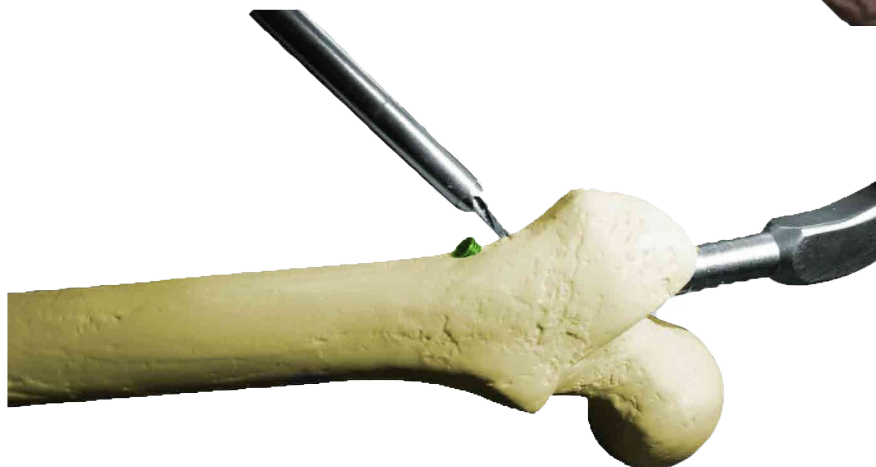
Hold the screw in the flex handle.

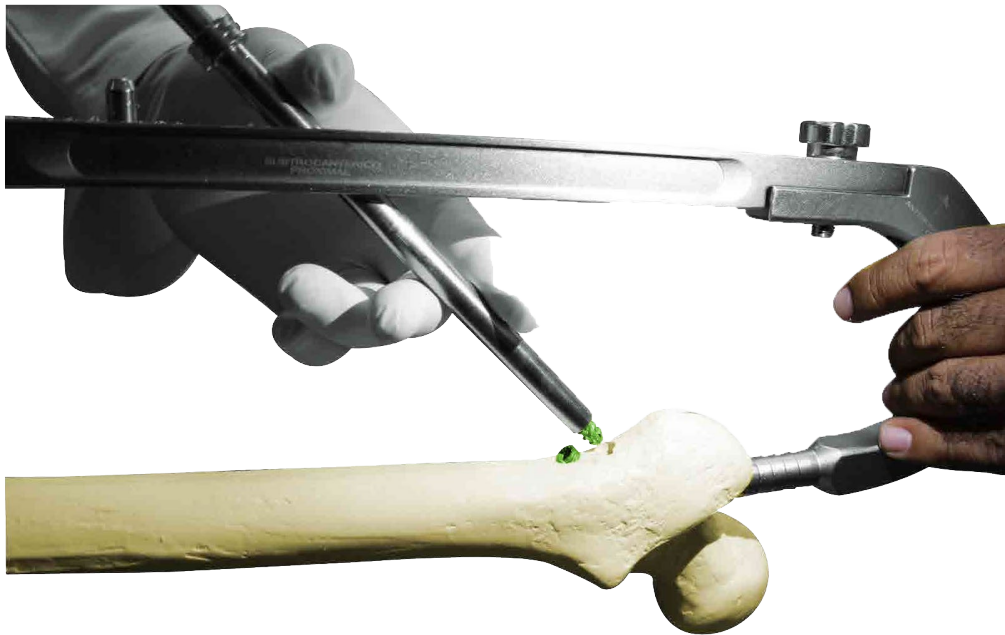
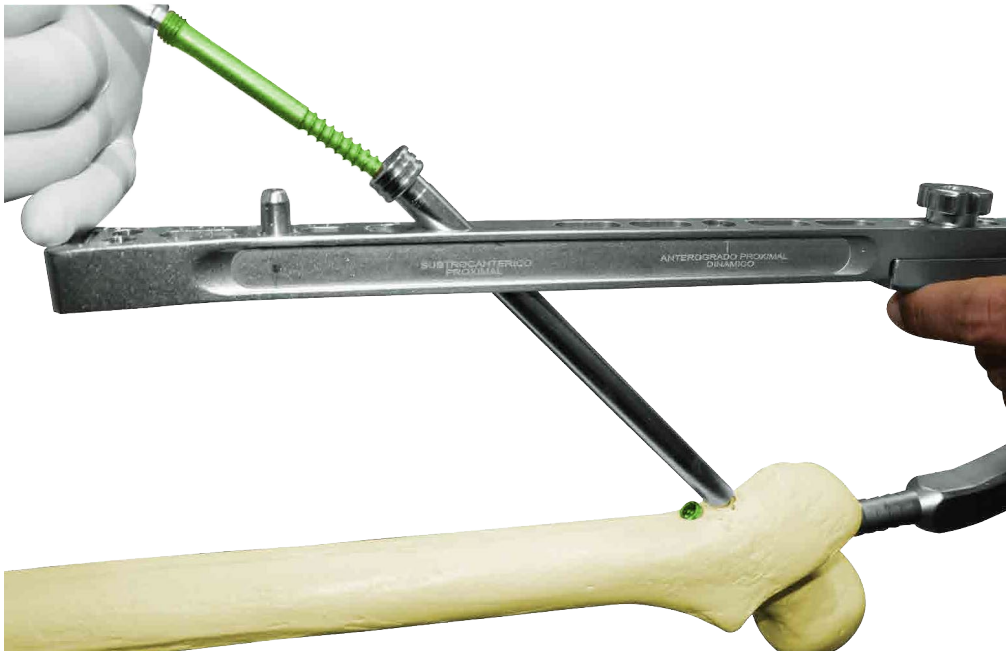


Remove 6.4 sleeve and insert screw. once placed, remove flex handle.



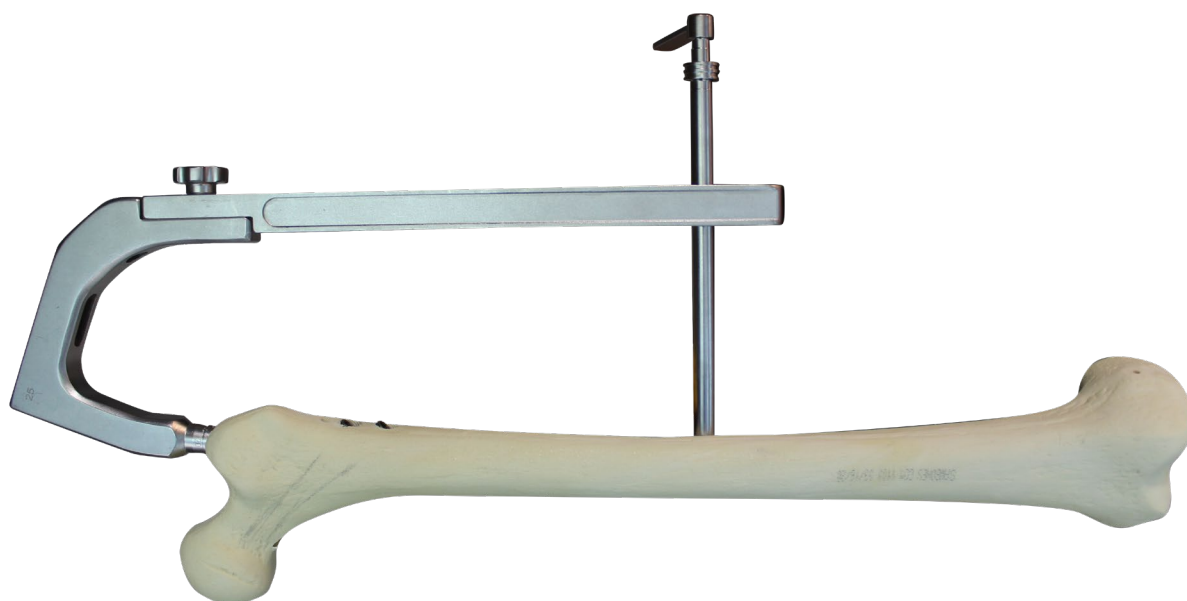
Repeat steps with the second hole.



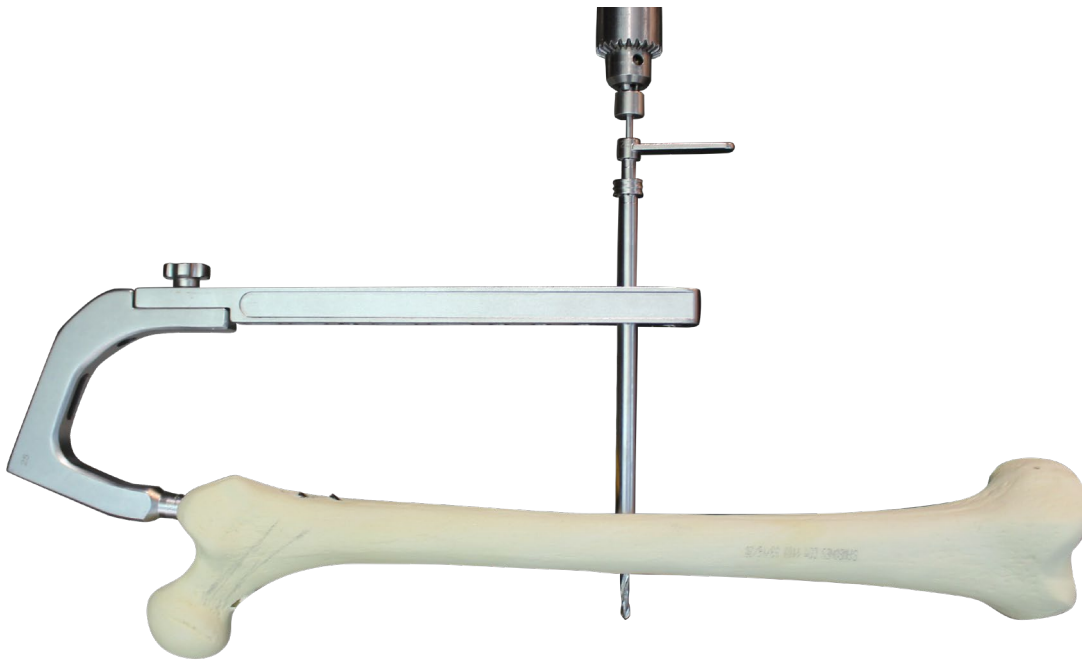


9. Locking distal screw for 240mm nail

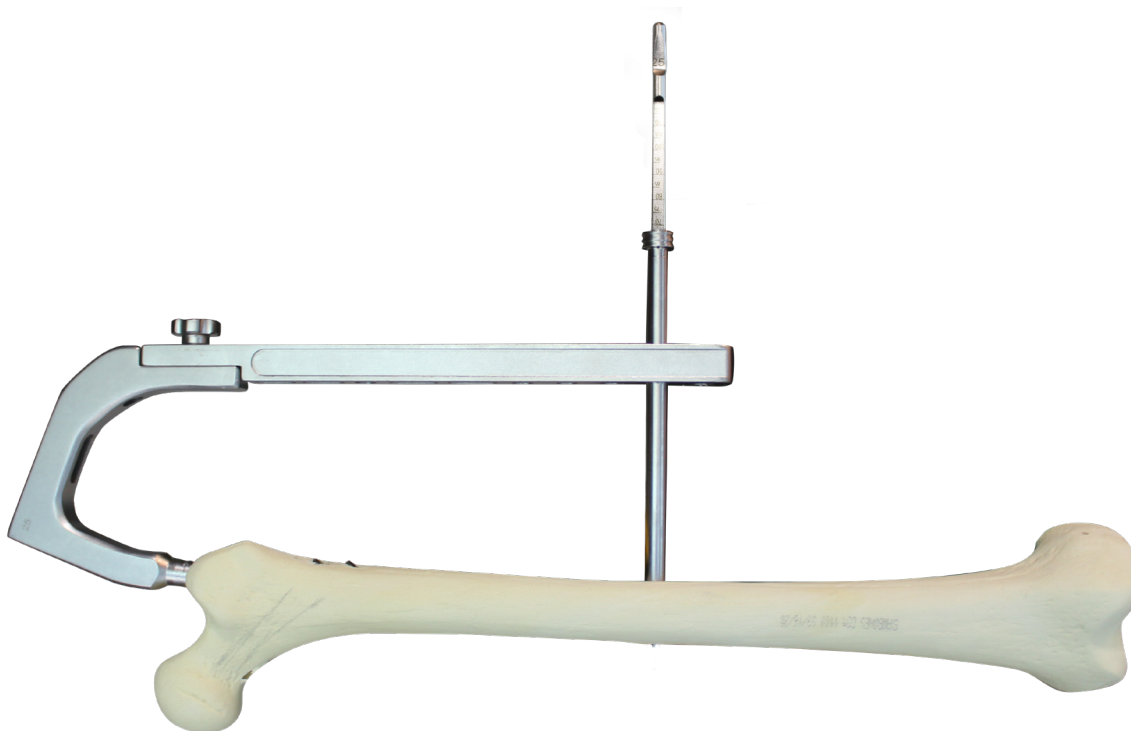
An external 11 mm sleeve and 4.3 mm inner sleeve is placed in the first hole of the distals.



Both corticals are drilled with 4.3mm drill bit.



Measurement with depth meter is performed.



Before placing screw, external sleeve of 5.2mm is placed and proceed to make countersink of the first cortical.

Locking screw is placed up to the mark indicated on the screwdriver, it is suggested to give 3 to 4 turns to anchor head in cortical.

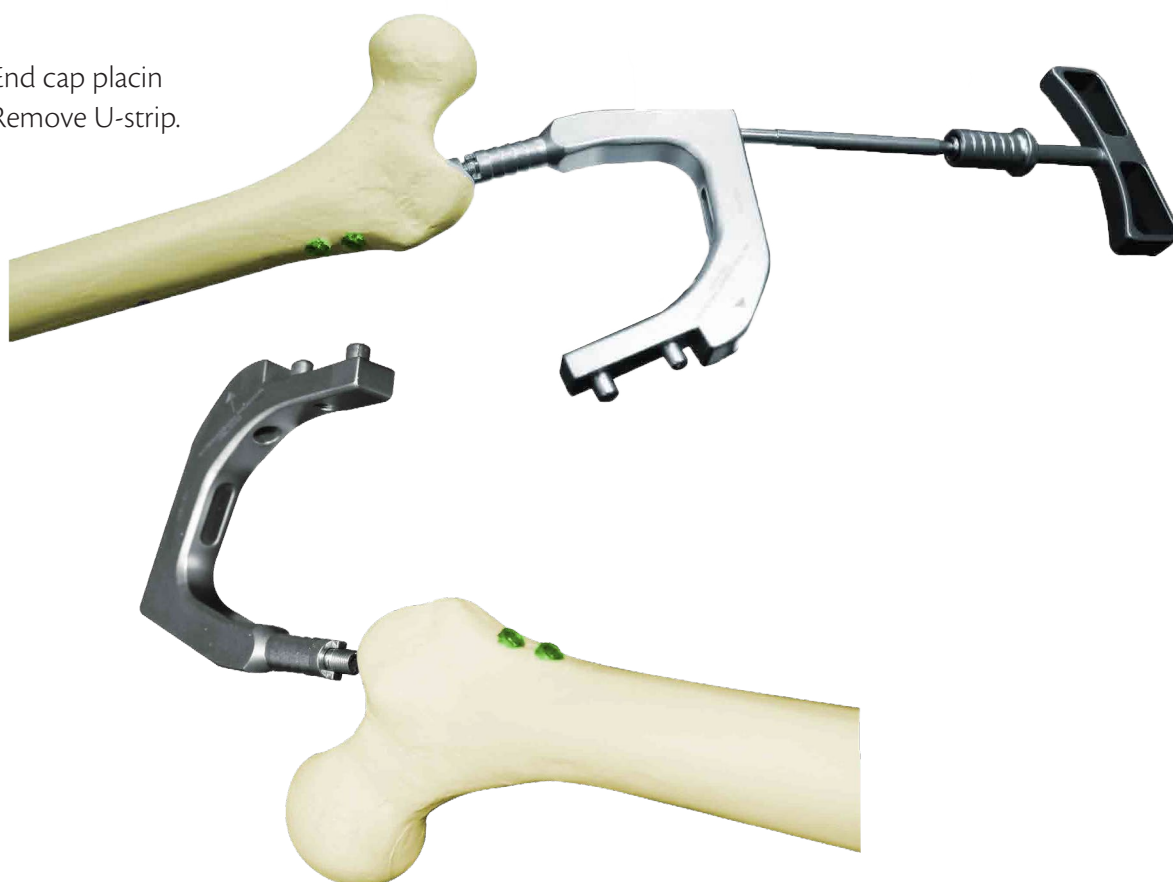


The same procedure described above for the second distal locking hole is performed.

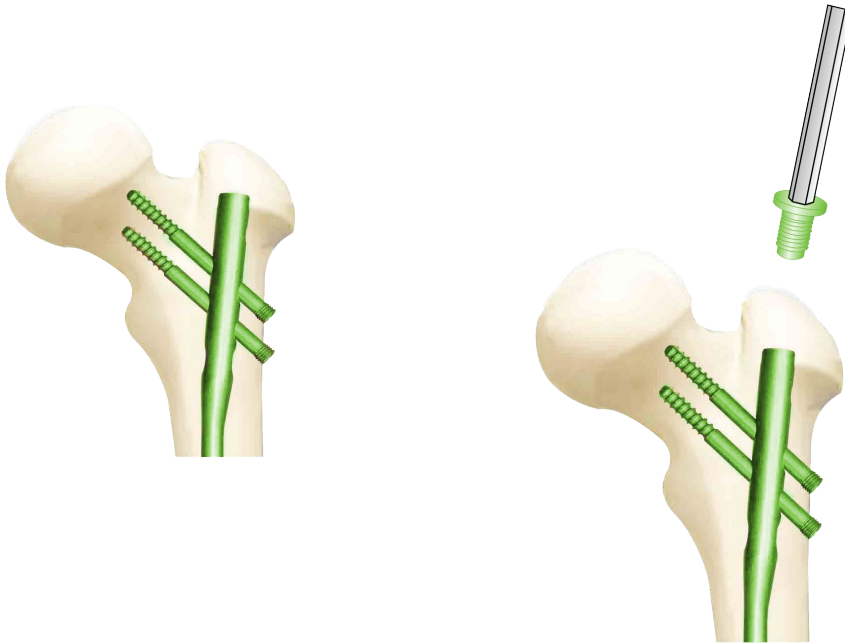




End cap placin
Remove U-strip.



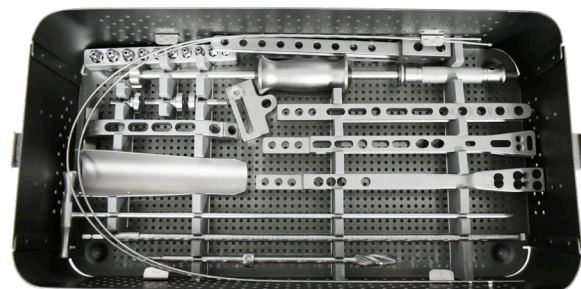
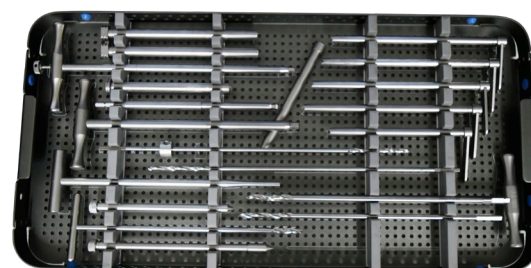
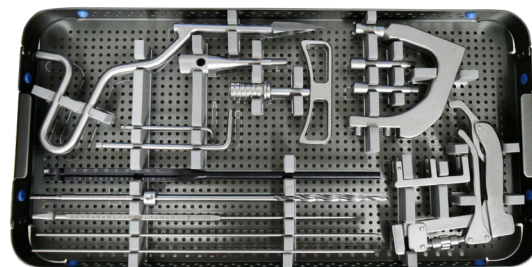
Finally, the stability of the nail is checked and the end cap is placed.



INSTRUMENTS

QTY

| | |
|----|--|
| 1 | Initiator punch |
| 1 | Universal extractor |
| 1 | Small Allen wrench |
| 1 | Big Allen Wrench |
| 1 | Fast anchor T-handle |
| 1 | Guide Wire Meter 120 |
| 1 | Graduated drill bit with stop 6.4 |
| 6 | Depth meter 115 mm |
| 1 | Guide wire (3 threaded tips/3 smooth) 2.5 x 35cm |
| 1 | Nail fastener screw |
| 1 | U-blocking strip |
| 1 | Guide wire positioner |
| 2 | Distal probe block |
| 1 | Outer sleeve 8.0 |
| 1 | Sliding screw screwdriver 6.5 |
| 1 | Short Outer Sleeve 8.0 |
| 1 | Hexagonal disarm tip with quick anchor for nail clamping 6.5 |
| 1 | Hexagonal disarm with T-handle for bolt 4.5 |
| 1 | T-handled probe |
| 1 | Short Tissue Dilator (Punch) - 8.0 |
| 1 | T-handled drill 5.0 |
| 1 | Long-tissue dilator (Punch) - 8.0 |
| 1 | Inner sleeve 2.5 |
| 1 | inner sleeve 6.4 |
| 1 | Inner sleeve 4.3 |
| 1 | Inner sleeve 4.3 |
| 1 | Inner sleeve 5.2 |
| 1 | Bit with stop 4.3 x 30cm |
| 1 | Bit 4.3 x 30cm |
| 1 | Hexagonal T-handle screwdriver |
| 10 | Bit 5.2 x 25 cm |
| 1 | Reamer-tipped set Ø 8.5 Ø 9.0 Ø 9.5 Ø 10.0 Ø10.5 Ø11.0 Ø 11.5 Ø12.0 Ø12.5 Ø13.0 |



| | |
|---|---|
| 3 | Impactor/pin |
| 1 | Strip screw |
| 1 | Distal/palpable locking devices |
| 1 | Tissue protector |
| 1 | T-handle tramodular guide |
| 1 | Flexible Reamer |
| 1 | Initiator bit with stop 13 |
| 1 | Distal strip 180-240 |
| 1 | Proximal and subtrotroter blockage strip (Block to femoral head) |
| 1 | Distal strip 320-440 |
| 1 | Olive-tipped wire guide 2.5 |
| 1 | Bit 6.3 |
| 1 | Sleeve 6.3 |
| 1 | Olive-free guide |
| 1 | Accessory |
| 1 | Screw for accessory |
| 1 | Special strip |
| 1 | Retrograde strip |
| 1 | Distal locking device |



Exclusive distributor in Mexico



Exclusive distributor in Peru



FIXIER S.A. DE C.V.

Carretera Doctor Mora a San Miguel de Allende km 3.4,
C.P. 37967, Comunidad de San Rafael, Doctor Mora,
Guanajuato, México.
Tel. +52 419 688 1191