

SURGICAL TECHNIQUE

Femoral Intramedullary Nail

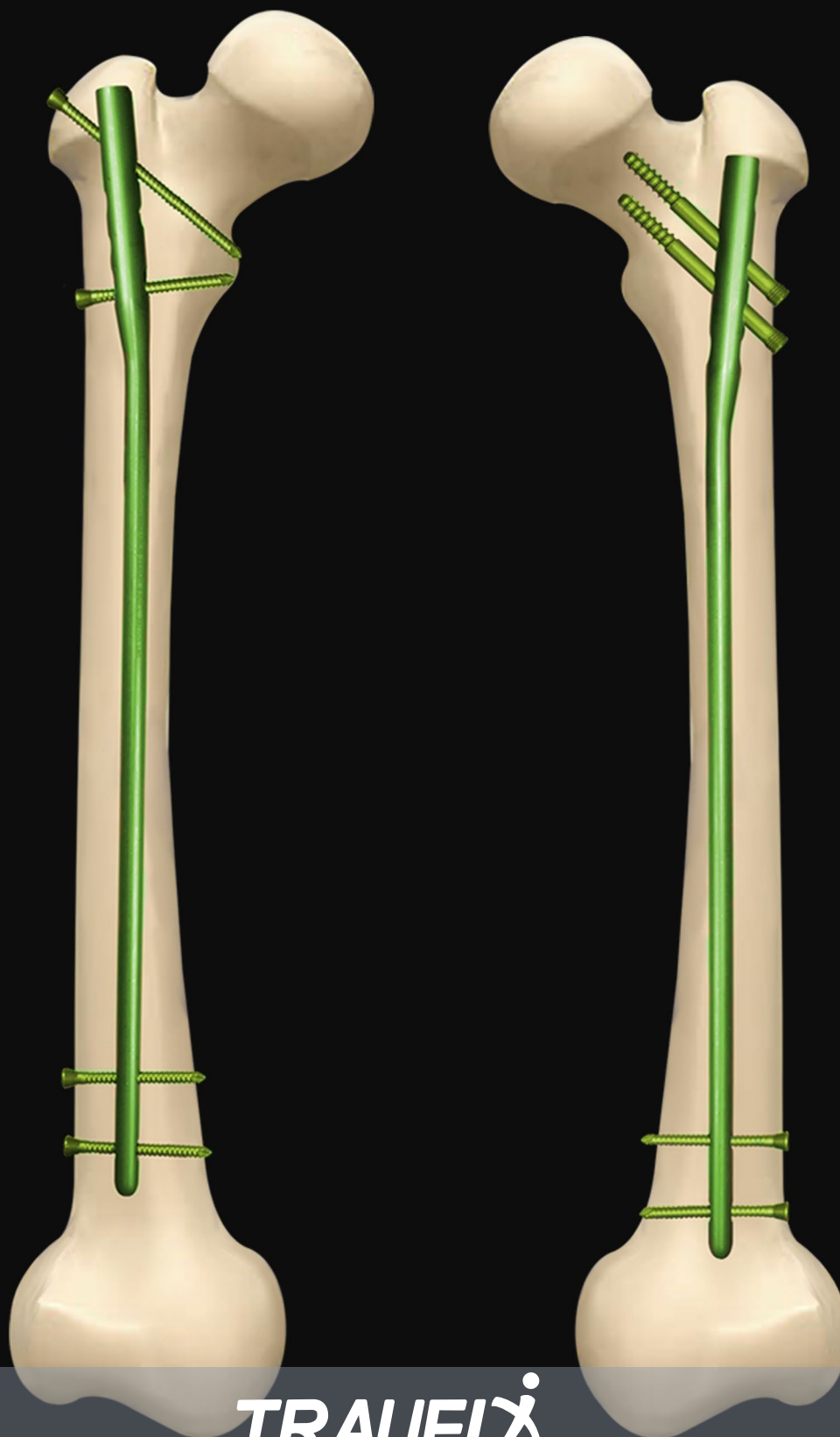
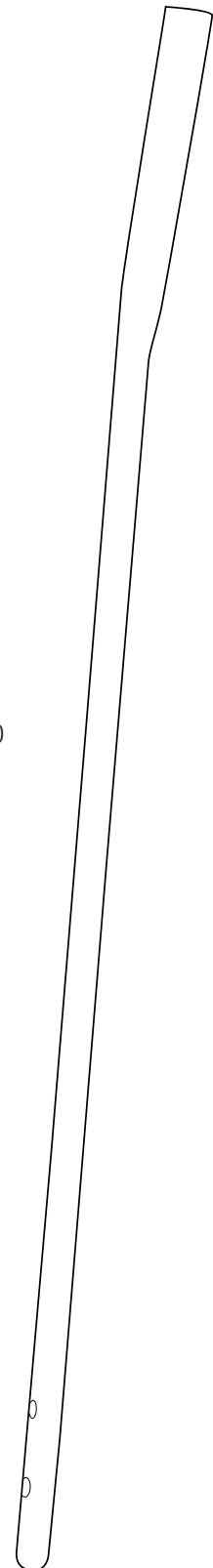


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TECHNOLOGICAL ADVANTAGES

The femoral intramedullary nail is made of titanium (Ti6Al4V ELI), has an innovative locking system with two 6.5mm 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 diaphysiary fixation as well as in subtrochanteric fractures.

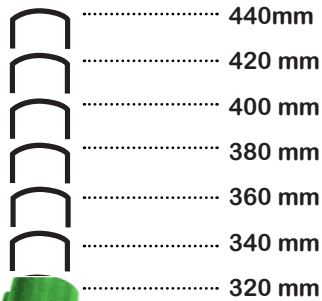
The femoral intramedullary nail allows a static reduction by using a threaded head screw with anterograde angulation of 130 degrees achieving a compression through the major trochanter towards the minor trochanter useful in subtrochanter fractures.

The femoral intramedullary nail 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. The locking system increases the stabilization of the fracture and indicates its use in diaphysiary fractures by facilitating primary compression or secondary dynamization in a controlled manner. The system also improves reduction either open or closed, thereby decreasing surgical time and tissue damage when compared to other treatment techniques.

SPECIFICATIONS

The femoral intramedullary nail is made of high quality titanium of 9, 10, 11 and 12 mm diameter with lengths from 320 mm to 440 mm, in its left and right presentation

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

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

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.

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

TROCHANTERIC 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

TROCHANTERIC 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

TROCHANTERIC 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

TROCHANTERIC 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 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 NAIL

Code 168.12



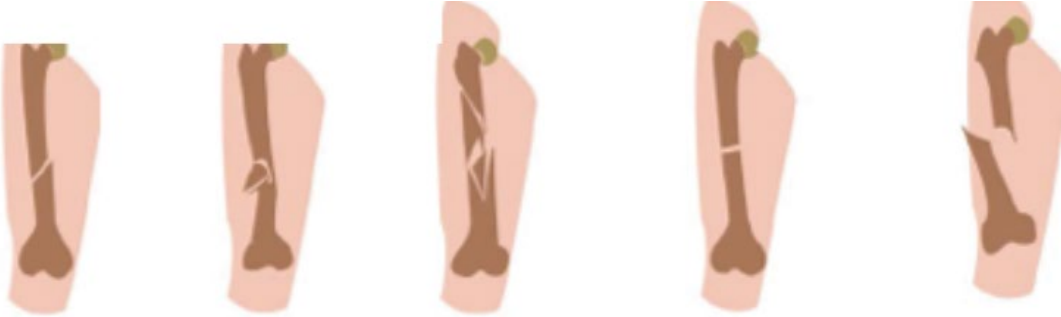
6.5 mm SUBTROCHANTERIC LAG SCREW

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

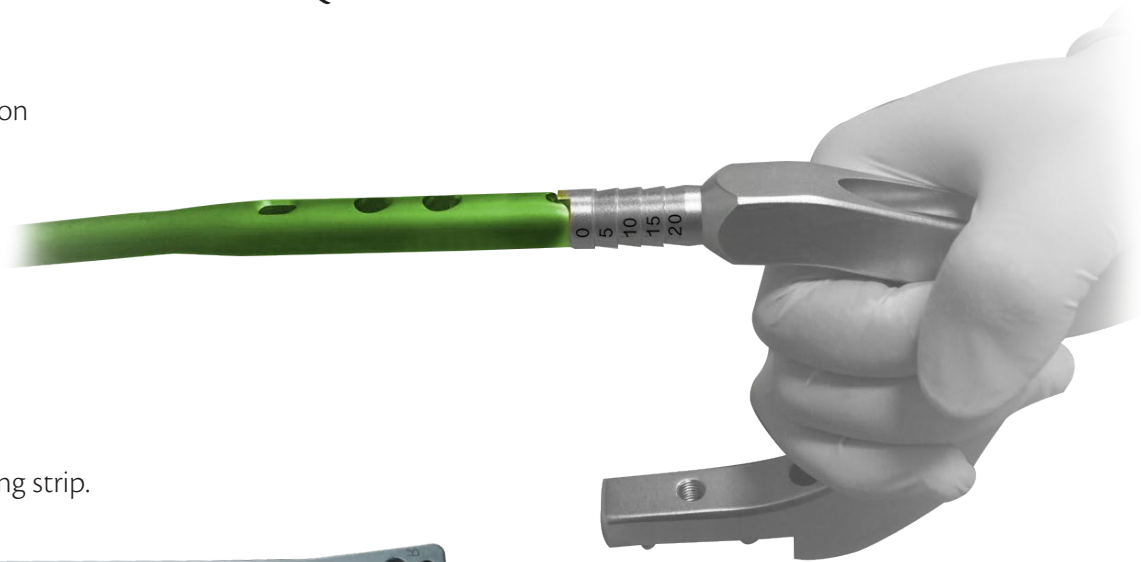


Dynamic fixation

DESCRIPTION OF THE SURGICAL TECHNIQUE

Device assembly:

1.- Place the nail on the insertion handle



2.- Mount the proximal locking strip.



3.- Place Intralock distal locking strip matching the graduation of the strip with the length of the chosen nail.

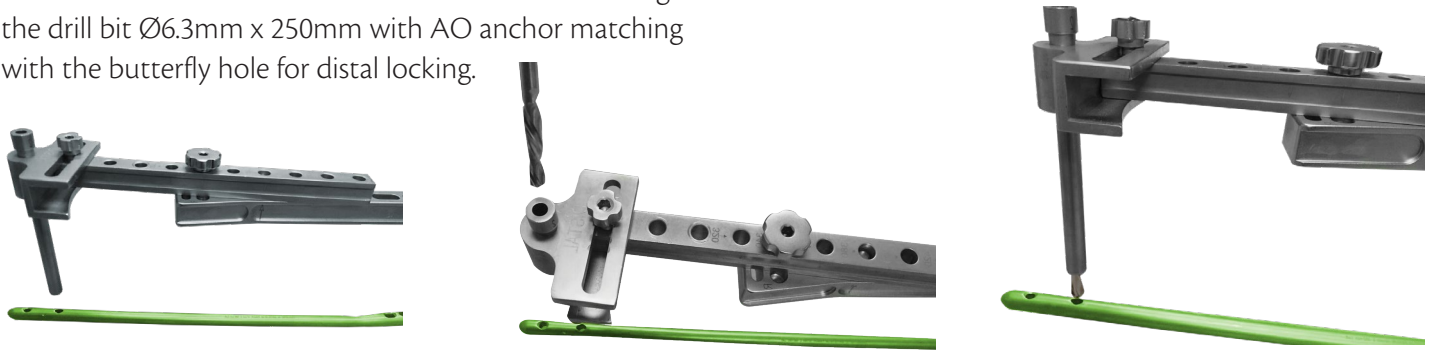


4- Assemble the head for Intralock strip.



Note: Verify the targeting accuracy of distal lock (in the head for Intralock strip).

5.- Place the sleeve for 6.3mm drill bit and calibrate using the drill bit Ø6.3mm x 250mm with AO anchor 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 rulers.

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 decubitus or supine decubitus, 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 lateral projections.

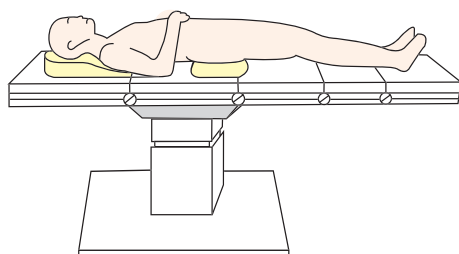


Figure 1

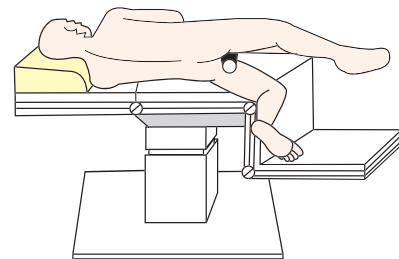


Figure 2

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).

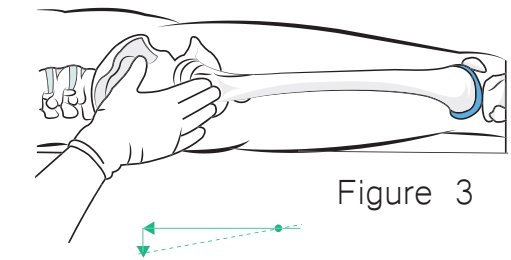


Figure 3

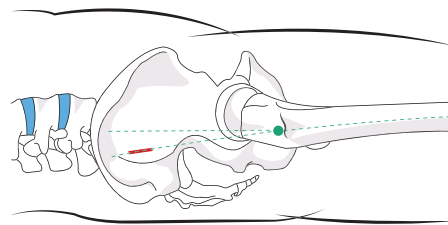


Figure 4

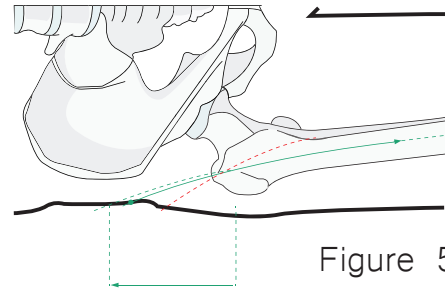
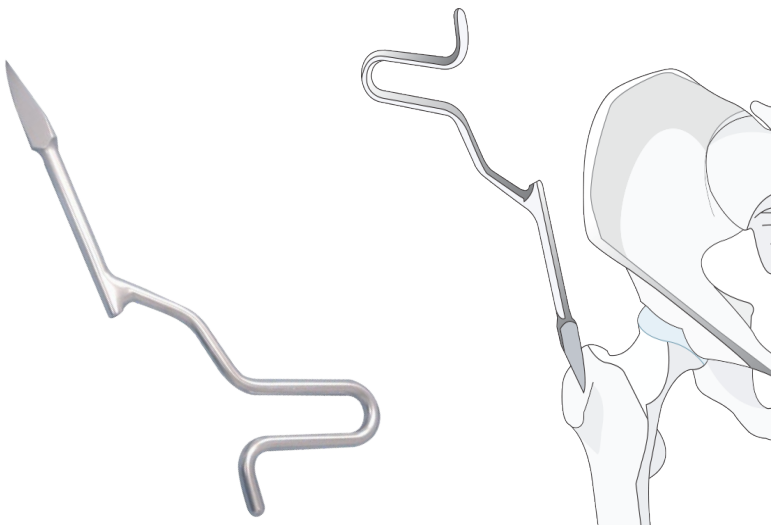


Figure 5

4.Insertion of the nail

Drill with the awl in the pyriform fossa. Place the olive- tip guide wire through the awl cannulation on the back. If necessary, rely on the reducing guide to reduce the fracture.



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



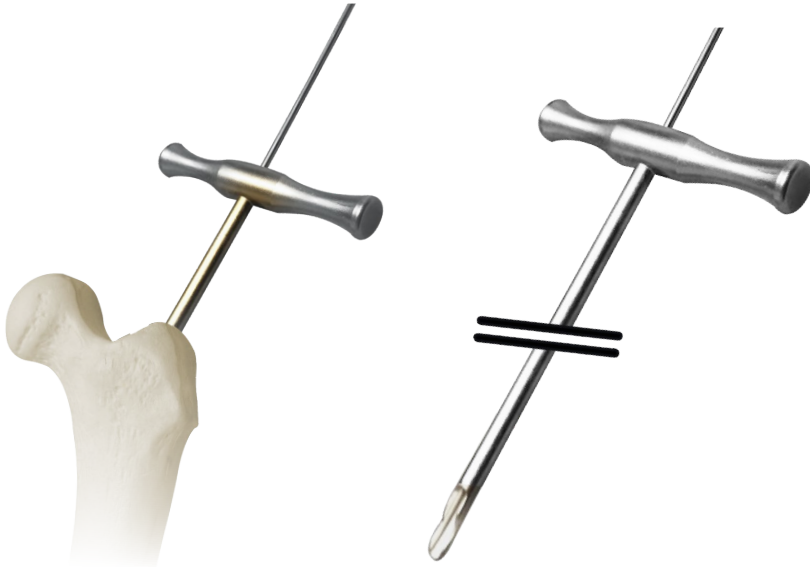
It is reamed according to the diameter of the nail chosen: to place 9mm nail reaming to 10mm is recommended, and to place nail 10 mm reaming of 11 mm is recommended reaming them to enhance the portal in the insertion zone is recommended when using 13 mm for easy insertion of the chosen nail.

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

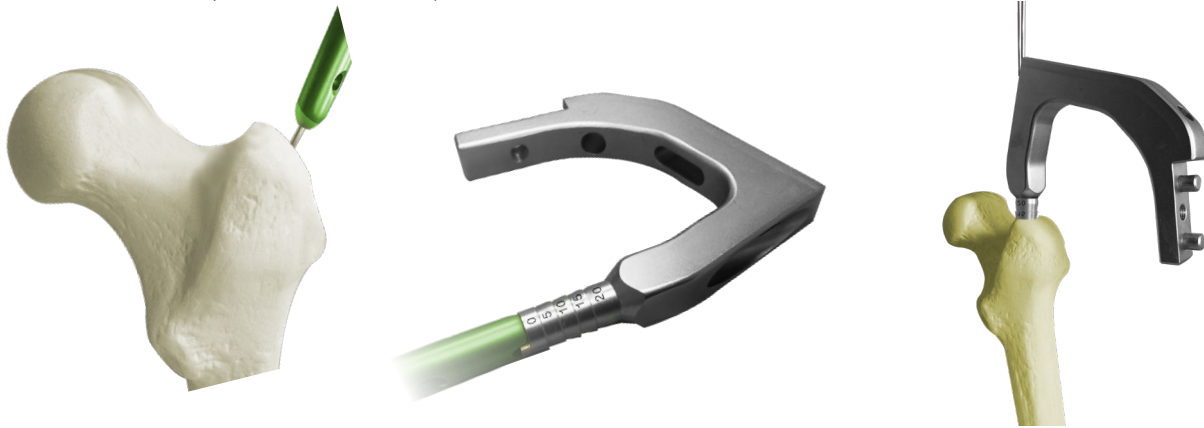
8.5mm to 13mm



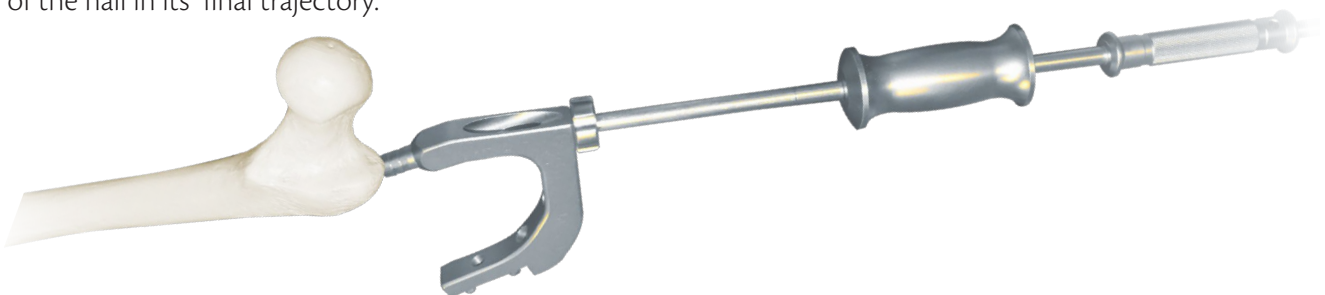
Swap the olive-tip guide wire for the olive-free guide wire inside the medullary channel with the help of the centromedullary guide with T-handle to maintain reduction.



Prepare medullary channel with the starter drill with stop Ø13mm to receive the nail. Insert the intramedullary 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 insertion handle (5,10,15 and 20mm).

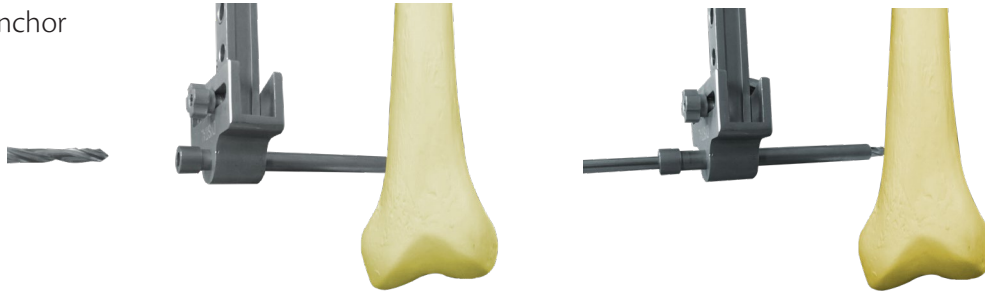


Optionally, the impactor can be used to facilitate the insertion of the nail in its final trajectory.



5. Distal locking

Place the assembled strips (proximal and Intralock locking strip with head) as well as the sleeve for 6.3mm drill bit on the calibration hole and drill the first cortical with the drill bit $\varnothing 6.3\text{mm} \times 250\text{mm}$ with AO anchor



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



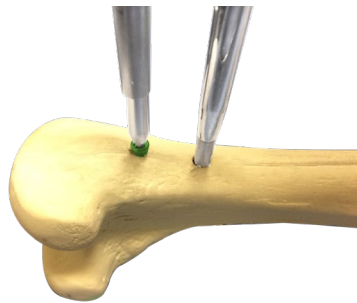
With the device locked, outer and inner sleeve $\varnothing 4.3\text{mm}$ are placed, using a drill bit $\varnothing 4.3\text{mm}$, drill both corticals in the proximal hole.



Inner sleeve Ø4.3mm is removed obtaining the length of the screw by means of the depth meter 115mm or 120mm, in case of it being in diaphysary zone, the use of the T-handle drill Ø5.0mm is recommended in the first cortical layer.



Insert the locking screw with the threaded head.

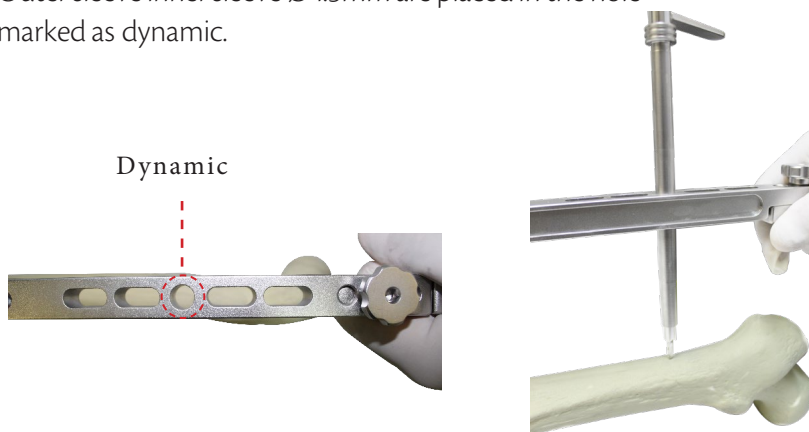


Repeat this step with the proximal hole.



6. Dynamic hole fixing

Outer sleeve inner sleeve $\varnothing 4.3\text{mm}$ are placed in the hole marked as dynamic.



Inner sleeve $\varnothing 4.3\text{mm}$ is removed obtaining the length of the screw by means of the depth meter, in case of it being in diaphysary zone, the use of the T-handle drill $\varnothing 5.0\text{mm}$ is recommended in the first cortical layer.

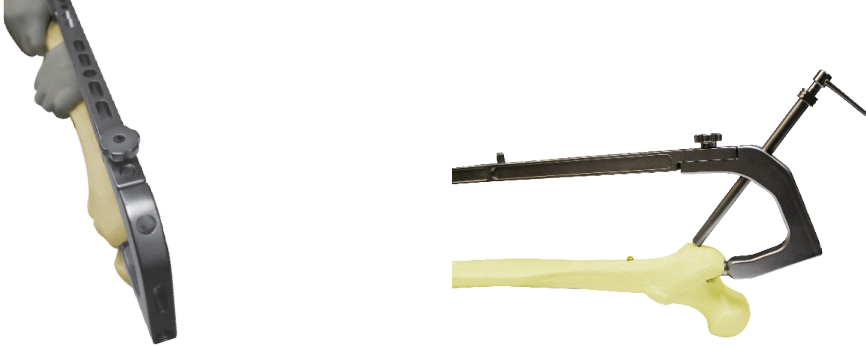


Insert the locking screw with the threaded head for dynamic fixation.



7. Anterograde compression and anterograde static compression at 130 degrees

Outer sleeve and inner sleeve Ø4.3mm are placed in the hole marked as 130 degree anterograde.



Inner sleeve 4.3mm is removed obtaining the length of the screw by means of the depth meter, in case of it being in diaphysary zone, the use of the T-handle drill 5.0mm is recommended in the first cortical layer.



Insert the locking screw with the threaded head.



8. Femoral neck and head fixation

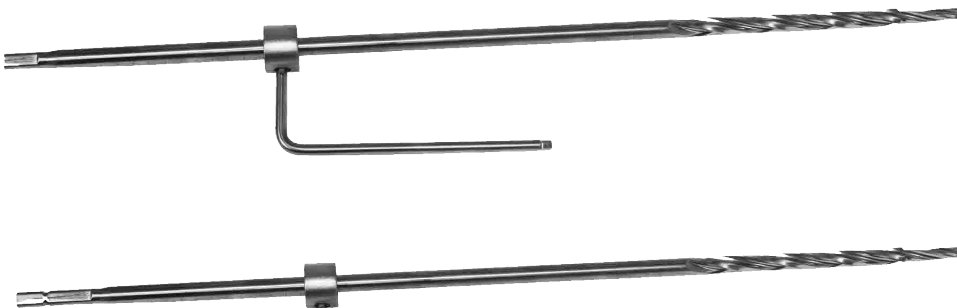
Outer sleeve and inner sleeve Ø2.5mm are placed in the hole marked neck, threaded guide Ø2.0mm is inserted and the depth is checked by means of image intensifier in both AP and lateral views.



Remove inner sleeve 2.5mm to obtain screw length using the guide wire meter 120mm.



Adjust the stop of the graduated drill bit with stop Ø6.4mm according to the length.



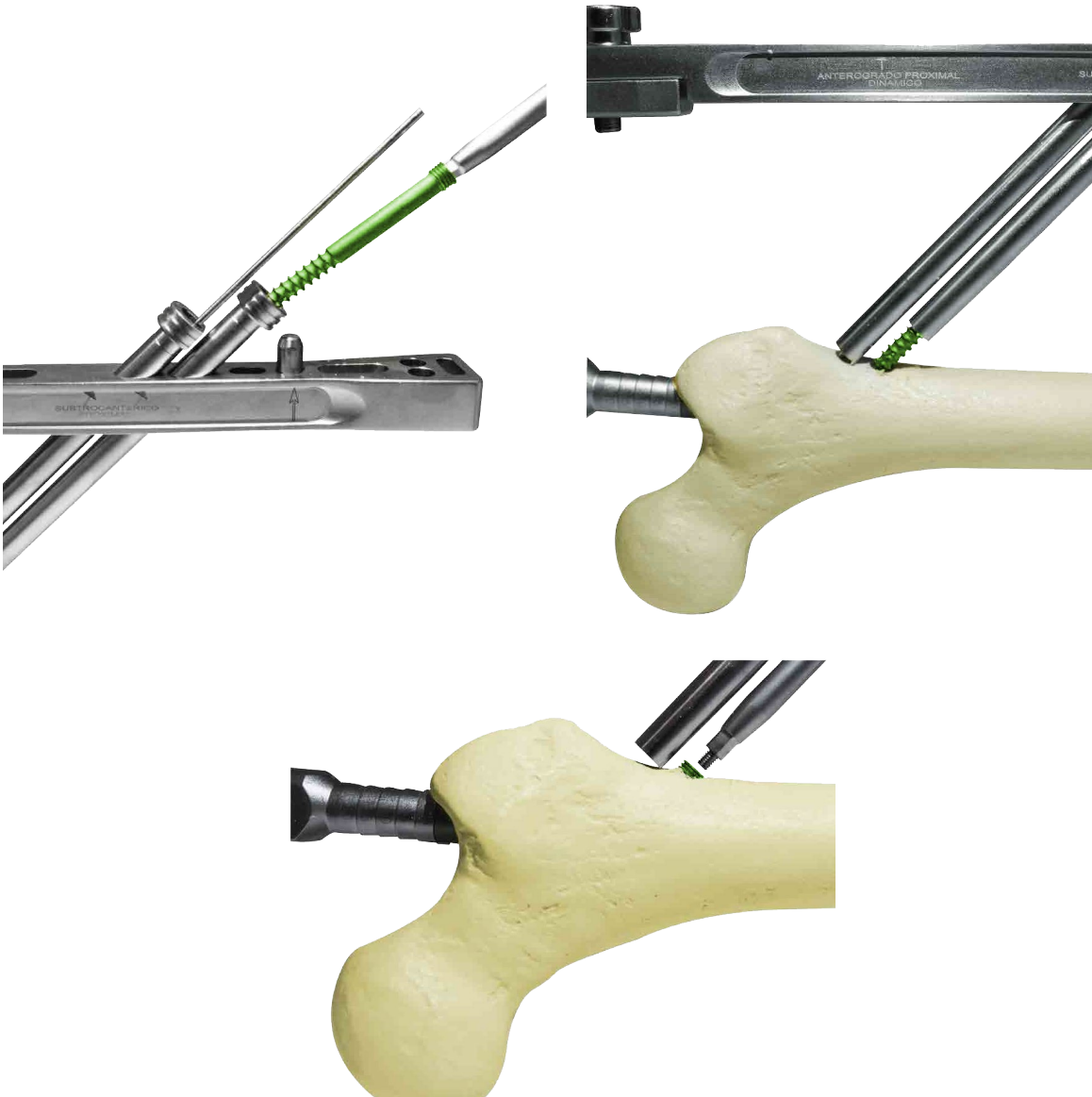
Place the inner sleeve Ø6.4mm and drill through the threaded guides.



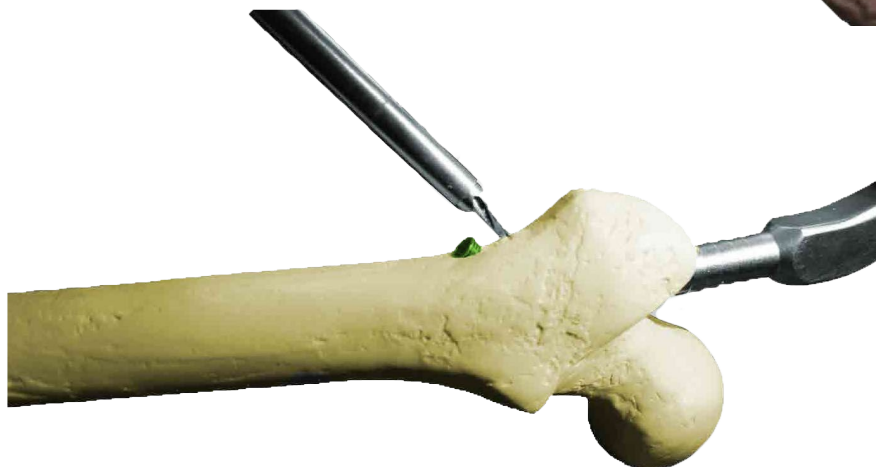
Hold the screw in the hexagonal screwdriver with T-handle for Ø6.5mm screws.

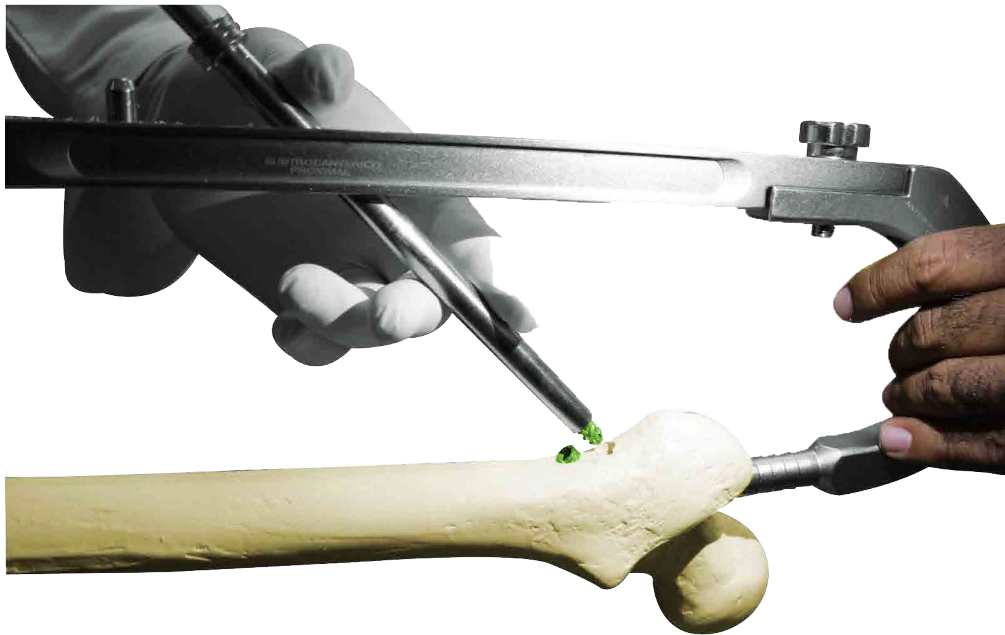


Remove inner sleeve Ø6.4mm and insert screw. Once placed, remove the hexagonal screwdriver with T-handle for Ø6.5mm screws.



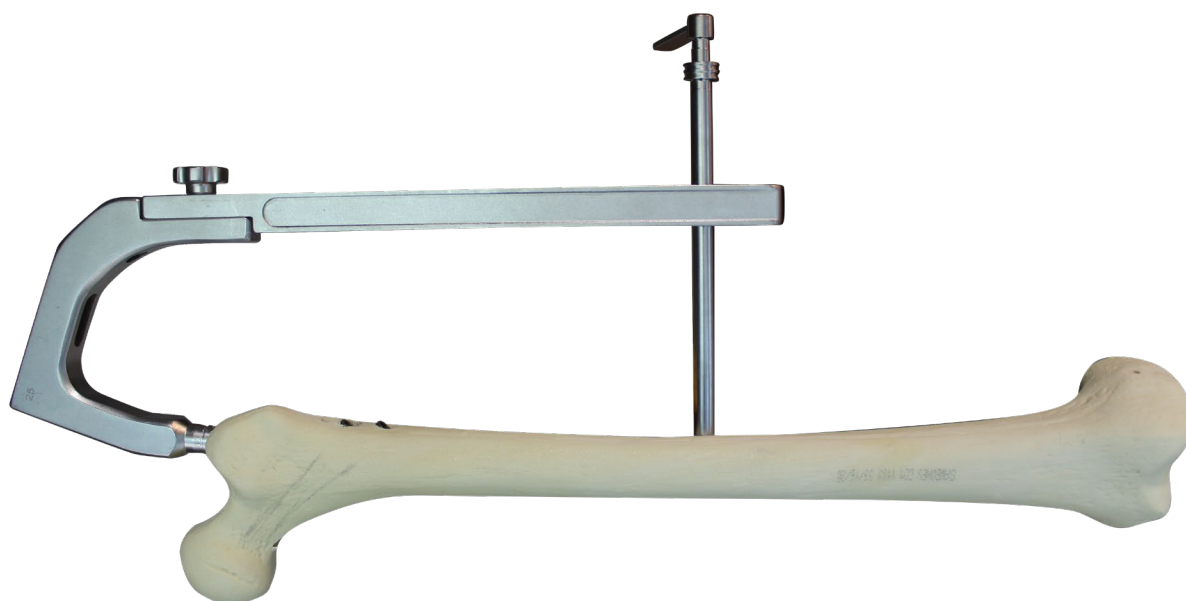
Repeat steps with the second hole.



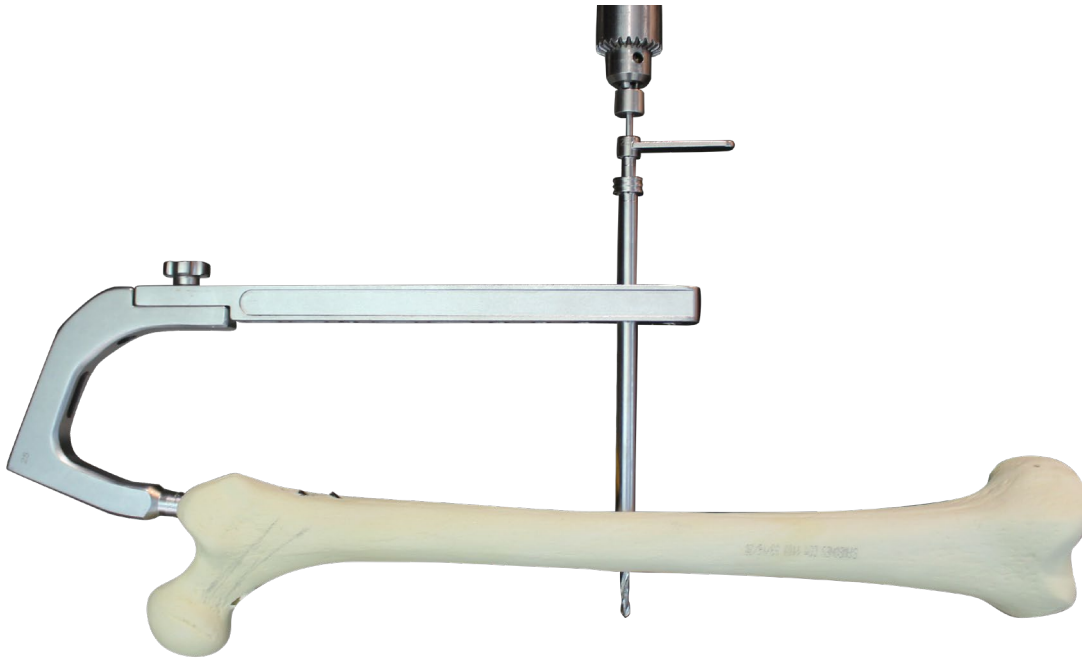


9. Locking distal screw for trochanteric nail

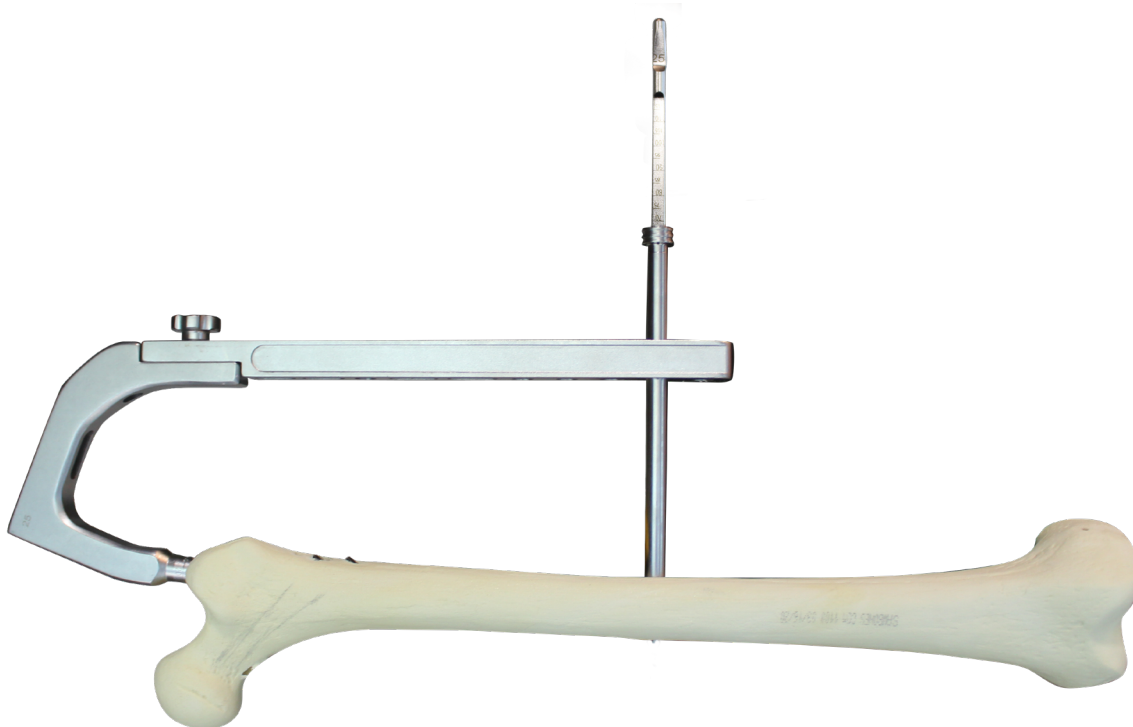
An outer sleeve and inner sleeve Ø4.3mm are placed in the first hole of the distal strip 180 - 240mm.



Both corticals are drilled with the drill bit Ø4.3mm.

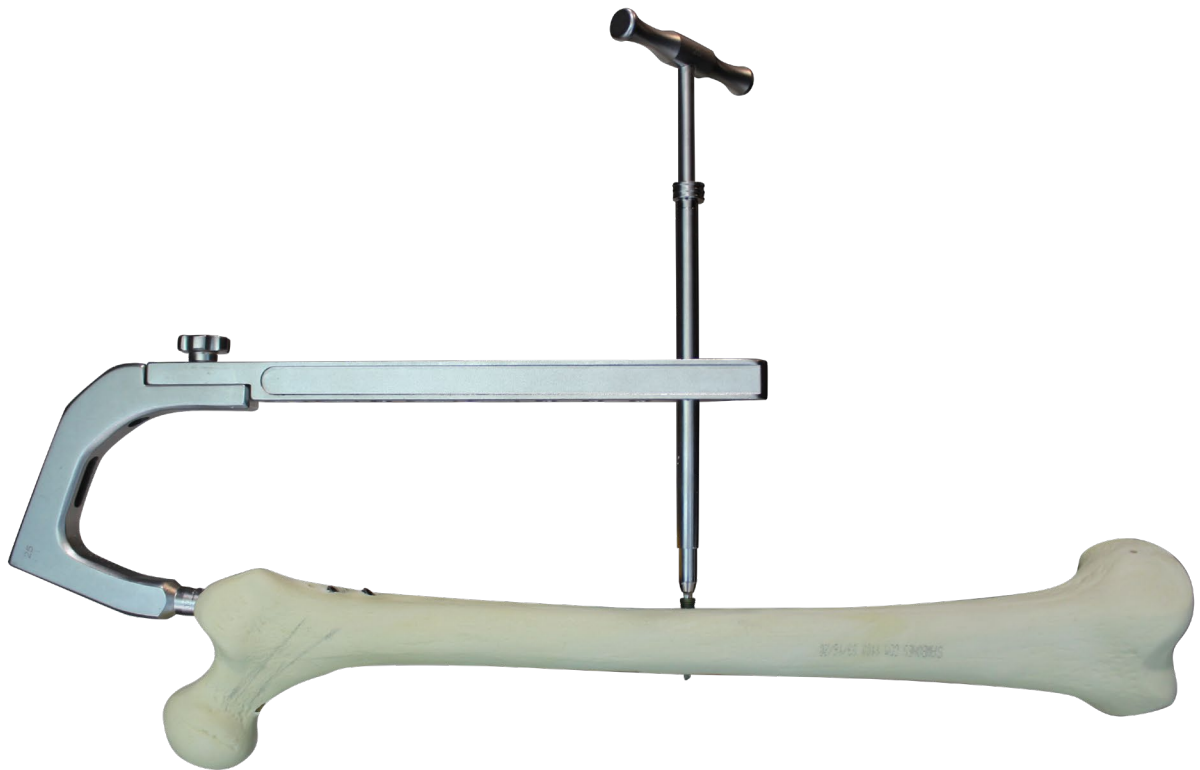


Measurement with depth meter is performed.



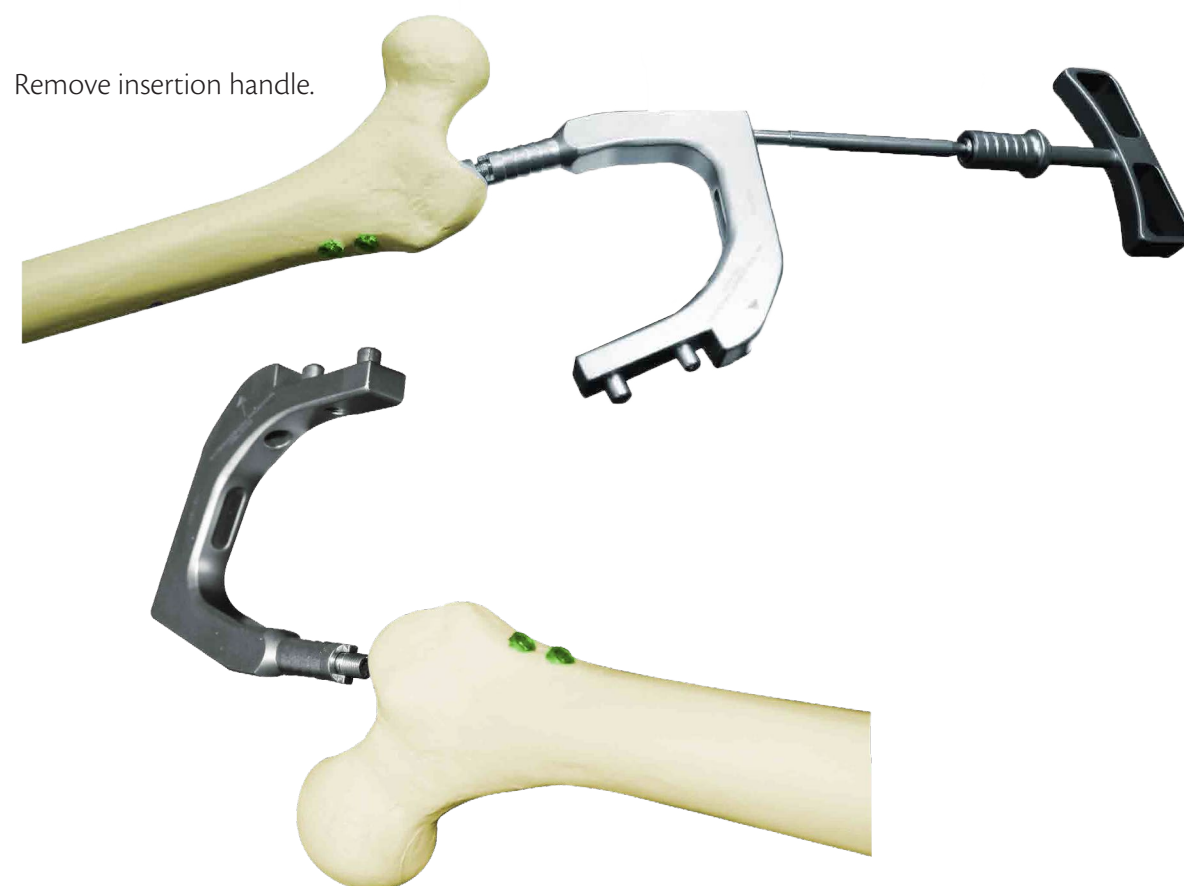
Before placing screw, outer sleeve is placed to proceed to make countersink of the first cortical layer with the T-handle drill Ø5.0mm .

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.



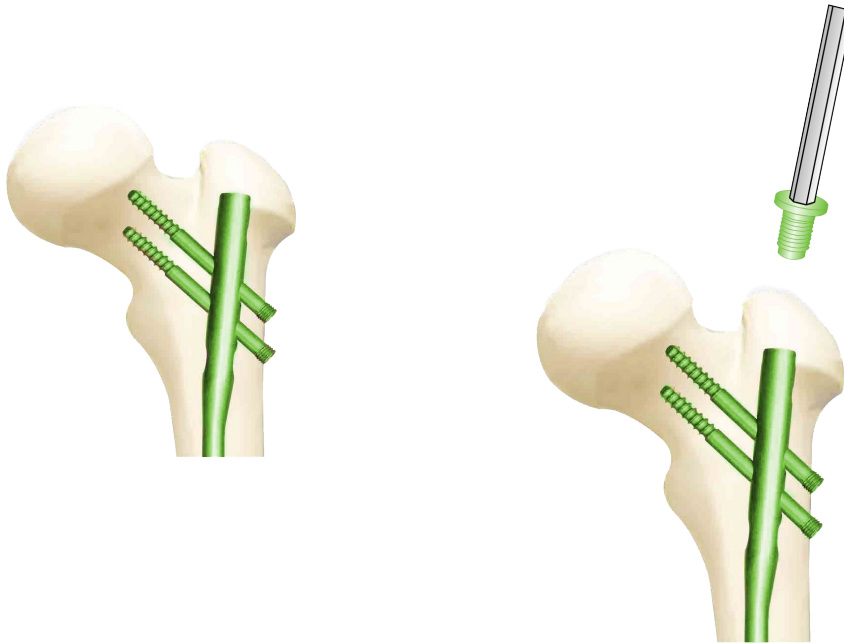
The same procedure described above for the second distal locking hole is performed.





10. End cap placing

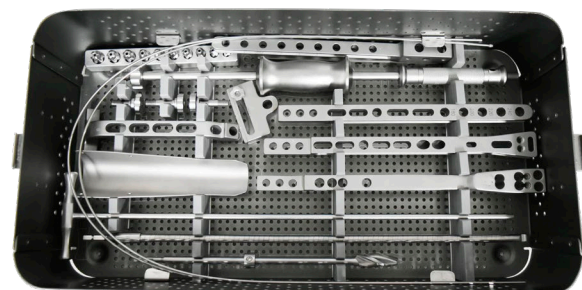
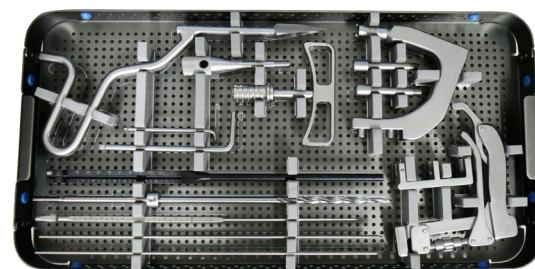
Finally, the stability of the nail is checked and the end cap is placed.



INSTRUMENTS

QTY Description (Code)

1	Awl (31.02.01)
1	Universal extractor (19.03.01)
1	Small allen wrench 3.0 (26.02.30)
1	Large allen wrench 5.0 (26.02.50)
1	T-handle for quick anchoring (12.02.01)
1	Guide wire meter 120mm (16.02.120)
1	Graduated drill bit with stop 6.4mm (13.06.64)
1	Depth meter 115 mm or 120mm (16.01.115 / 16.01.120)
3	Threaded tip guide wire Ø2.5mm x 35cm (23.01.25)
3	Smooth tip guide wire Ø2.5mm x 35cm (23.05.25)
1	Nail fastener screw (39.01.01)
1	Insertion handle (40.01.01)
1	Guide wire positioner (12.04.01)
2	Stabilizing device (41.01.01)
1	Outer sleeve Ø8.0mm (18.11.80)
1	Lag screw screwdriver 6.5mm (11.06.65)
1	Short outer sleeve Ø8.0mm (18.12.80)
1	Hexagonal screwdriver bit with quick coupling for holding Ø 6.5 mm screws (11.04.65)
1	Hexagonal screwdriver with T-handle for Ø6.5mm screw (11.07.65)
1	Position rod (42.01.01)
1	Short trocar (Awl) Ø8.0mm (31.03.80)
1	T-handled drill Ø5.0mm (13.11.50)
1	Long trocar (Awl) Ø8.0mm (31.04.80)
1	Inner sleeve Ø2.5mm (18.10.25)
1	Inner sleeve Ø6.4mm (18.10.64)
1	Inner sleeve Ø4.3mm (18.10.43)
1	Inner sleeve Ø4.3mm (18.10.43)
1	Inner sleeve Ø5.2mm (18.10.52)
1	Drill bit with stop Ø4.3mm x 30cm (13.12.43)
1	Drill bit Ø4.3mm x 30cm (13.01.43)
1	Hexagonal screwdriver with T-handle for Ø4.5mm screws (11.07.40)
1	Drill bit Ø5.2mm x 25 cm (13.01.52)
10	Reaming tips set (24.05.01): Ø 8.5mm (24.04.85), Ø 9.0mm (24.04.90), Ø 9.5mm (24.04.95), Ø10.0mm (24.04.10), Ø10.5mm (24.04.105), Ø11.0mm (24.04.11), Ø11.5mm (24.04.115), Ø12.0mm (24.04.12), Ø12.5mm (24.04.125), and Ø13.0mm (24.04.13).



- 1 Impactor (30.04.01)
- 3 Screws for strip (39.02.01 & 39.02.02)
- 1 Distal targeting device (40.05.01)
- 1 Tissue protector (43.01.01)
- 1 Centromedullary guide with T-handle (18.13.01)
- 1 Flexible Reamer Ø8.0mm (24.06.80)
- 1 Starter drill with stop Ø13mm (13.14.01)
- 1 Distal strip 180mm-240mm (40.06.240)
- 1 Proximal locking strip (40.07.01)
- 1 Distal strip 320mm-440mm (40.06.440)
- 1 Olive-tip guide wire Ø2.5mm (23.07.25)
- 1 Drill Bit Ø6.3mm x 250mm with AO anchor (13.01.25)
- 1 Sleeve for 6.3mm drill bit (**191.01**)
- 1 Olive-free guide wire Ø2.4mm x 1000mm (211.24)
- 1 Head for Intralock strip (189.01)
- 1 Intralock strip head screw (188.01)
- 1 Intralock distal locking strip (190.01)
- 1 Retrograde strip (190.02)
- 1 Distal locking device (210.03)
- 2 Threaded guide Ø2.0mm x 320mm (005.2032)
- 1 Femoral nail instruments tray (28.04.01)
- 1 Femoral nail implants tray (BT-046)



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