

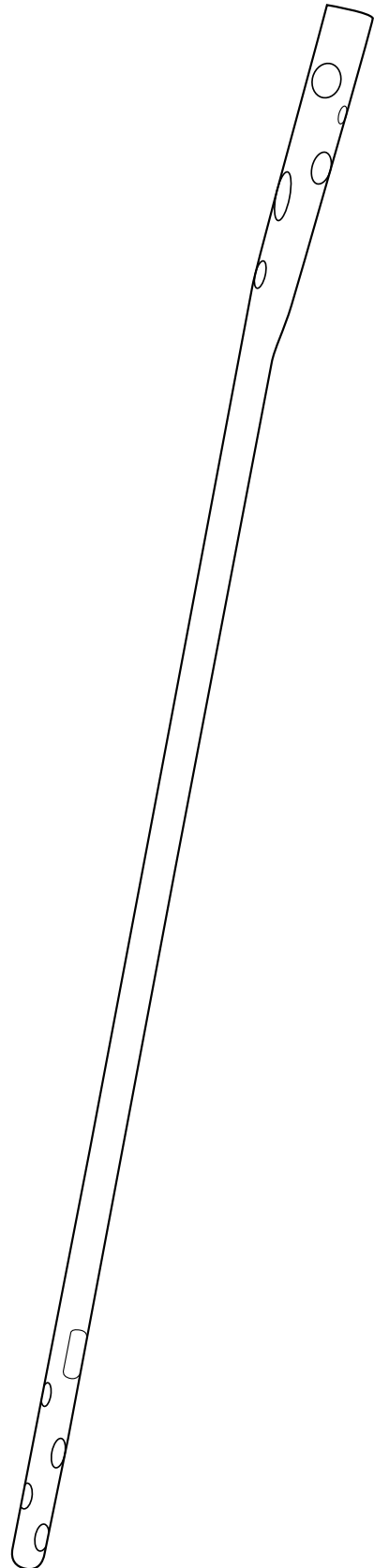
SURGICAL TECHNIQUE

Tibial Intramedullary Nail



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TECHNOLOGICAL ADVANTAGES

The tibial intramedullary nail allows stable intramedullary fixation for the reduction of most tibia shaft, proximal, and distal tibial fractures.

The tibial intramedullary nail was created to facilitate the reduction of complex fractures, allowing an early and active rehabilitation.

The tibial intramedullary nail is designed to adjust to the intramedullary canal of the tibia, obtaining anatomical reduction of the fracture.

The tibial intramedullary nail system consists of a series of cannulated nails manufactured in **Ti6Al4V ELI** titanium. Up to five proximal and four distal locking screws can be used at the same time.

The system provides stable fixation by incorporating two oblique locking holes in the proximal and distal section of the nail.

The tibial intramedullary nail system has three innovative locking options which increases the stability of the proximal fragment.

The locking option facilitates use in methaphyseal tibial fractures.

The tibial intramedullary nail system has two lateral locking options that allow primary compression or controlled secondary dynamization. The secondary dynamization improves stability in combination with locking screws, thereby facilitating open or closed reduction of the fracture, and a reduction of the surgical time and a reduction of tissue damage, compared to other techniques.

SPECIFICATIONS

TIBIAL INTRAMEDULLARY NAIL

Diameter 8.5, 9.5, 10.5, and 11.5mm

Length 255mm to 465mm

For reaming and non-reaming techniques, which allow insertion of the nail over the guide wire.

TIBIAL INTRAMEDULLARY NAIL 8.5 mm

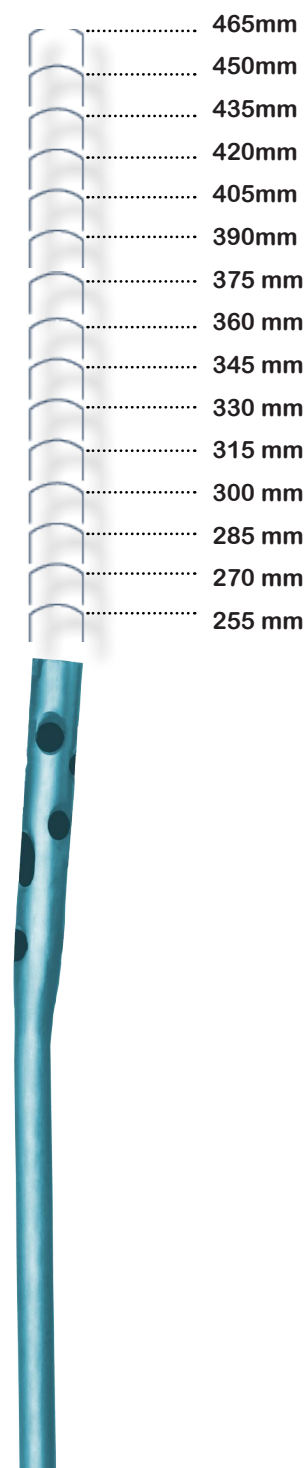
163.255*	8.5 mm X 255 mm
163.270*	8.5 mm X 270 mm
163.285*	8.5 mm X 285 mm
163.300*	8.5 mm X 300 mm
163.315*	8.5 mm X 315 mm
163.330*	8.5 mm X 330 mm
163.345*	8.5 mm X 345 mm
163.360*	8.5 mm X 360 mm
163.375*	8.5 mm X 375 mm
163.390	8.5 mm X 390 mm
163.405	8.5 mm X 405 mm
163.420	8.5 mm X 420 mm
163.435	8.5 mm X 435 mm
163.450	8.5 mm X 450 mm
163.465	8.5 mm X 465 mm

* Contained in the standard implant set.

TIBIAL INTRAMEDULLARY NAIL 9.5 mm

162.255*	9.5 mm X 255 mm
162.270*	9.5 mm X 270 mm
162.285*	9.5 mm X 285 mm
162.300*	9.5 mm X 300 mm
162.315*	9.5 mm X 315 mm
162.330*	9.5 mm X 330 mm
162.345*	9.5 mm X 345 mm
162.360*	9.5 mm X 360 mm
162.375*	9.5 mm X 375 mm
162.390	9.5 mm X 390 mm
162.405	9.5 mm X 405 mm
162.420	9.5 mm X 420 mm
162.435	9.5 mm X 435 mm
162.450	9.5 mm X 450 mm
162.465	9.5 mm X 465 mm

* Contained in the standard implant set.



**TIBIAL INTRAMEDULLARY
NAIL 10.5 mm**

220.255	10.5 mm X 255 mm
220.270	10.5 mm X 270 mm
220.285	10.5 mm X 285 mm
220.300	10.5 mm X 300 mm
220.315	10.5 mm X 315 mm
220.330	10.5 mm X 330 mm
220.345	10.5 mm X 345 mm
220.360	10.5 mm X 360 mm
220.375	10.5 mm X 375 mm
220.390	10.5 mm X 390 mm
220.405	10.5 mm X 405 mm
220.420	10.5 mm X 420 mm
220.435	10.5 mm X 435 mm
220.450	10.5 mm X 450 mm
220.465	10.5 mm X 465 mm

**TIBIAL INTRAMEDULLARY
NAIL 11.5 mm**

221.255	11.5 mm X 255 mm
221.270	11.5 mm X 270 mm
221.285	11.5 mm X 285 mm
221.300	11.5 mm X 300 mm
221.315	11.5 mm X 315 mm
221.330	11.5 mm X 330 mm
221.345	11.5 mm X 345 mm
221.360	11.5 mm X 360 mm
221.375	11.5 mm X 375 mm
221.390	11.5 mm X 390 mm
221.405	11.5 mm X 405 mm
221.420	11.5 mm X 420 mm
221.435	11.5 mm X 435 mm
221.450	11.5 mm X 450 mm
221.465	11.5 mm X 465 mm

**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 TIBIAL NAIL
CODE
169.11


SURGICAL INDICATIONS

Trafix intramedullary nails are indicated for diaphysary fractures, proximal methaphysary fractures, and distal methaphysary fractures of the tibia.

The tibial intramedullary nail is a good option for the treatment of tibia fractures. The nail can be used in simple and complex fractures because locking system provides great stability for the reduction of fractures.

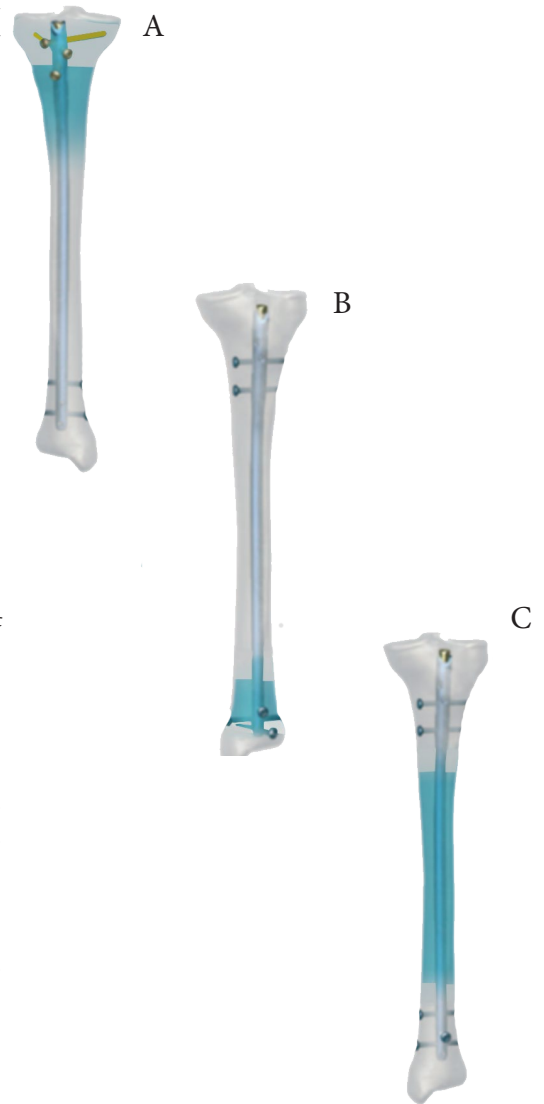
The ideal segment for the centromedullary nailing system is found in the diaphysis of the tibia. The locking system prevents axial rotation of the nail. Therefore, the locking system ensures a reduction of the fractures.

In proximal tibial methaphysis fractures it is essential to confirm that the joint area is not involved.

In case the joint area is involved, the system will not be able to provide the required stability. If the fracture line is in the methaphysary region, the result obtained is satisfactory because the proximal locking system employs two cross screws that offer greater stability in this type of fracture.

Note: Fractures of the proximal tibia with associated diaphysary fractures require special evaluation by the surgeon. In case of methaphysary fractures of the distal tibia assessment of the joint region is required.

The tibial intramedullary nail is an excellent fixation system for the non-articular methaphysary fractures because the nail has two distal screws placed on the medial side. There is an option to attach two anteroposterior screws to secure the fragment.



GENERAL CONTRAINDICATIONS

- Systemic inflammatory response syndrome (to be assessed by the surgeon)
- Blood Poisoning
- Osteomyelitis
- Patient unable to comply with postoperative care
- Hypersensitivity to materials (titanium)

DESCRIPTION OF THE SURGICAL TECHNIQUE

Patient Preparation

It is recommended to complete the radiographic evaluation as well as the pre-operation planning.

Radio diagnostic studies should be used to estimate the approximate diameter and length of the nail.

Place the patient supine on the radiolucent operating table.

Make sure that the knee of the injured limb, can be flexed at least 90°.

Optionally, position the image intensifier so that visualization of the articular surface, as well as in the anteroposterior and lateral views, is possible.

Approach

To facilitate the incision at the access site, some form of support is usually required to keep the tibia in alignment, either by means of a fracture table or an assistant.

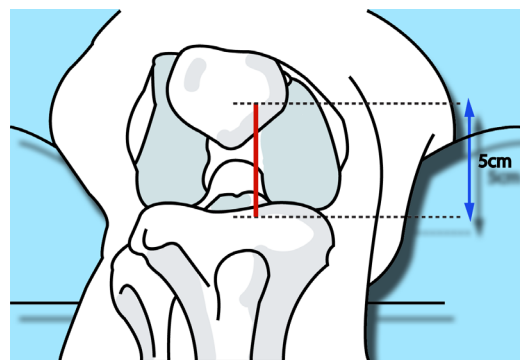
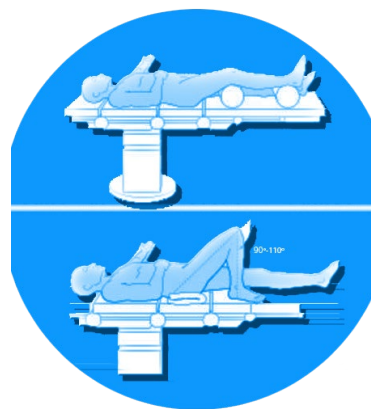
Generally, a small incision of 4cm to 7cm over the course of the patellar tendon is sufficient. The patellar tendon is incised over its midline and gently retracted to expose the nail entry site. Some authors prefer internal access to the patellar tendon so as not to injure it, so the entry point may remain eccentric, requiring radiological control to verify the correct position.

In the frontal plane, the entry point is in line with the medullary canal. In the sagittal plane, the entry point should be located just distal to the angle between the tibial plateau and the anterior tibial metaphysis.

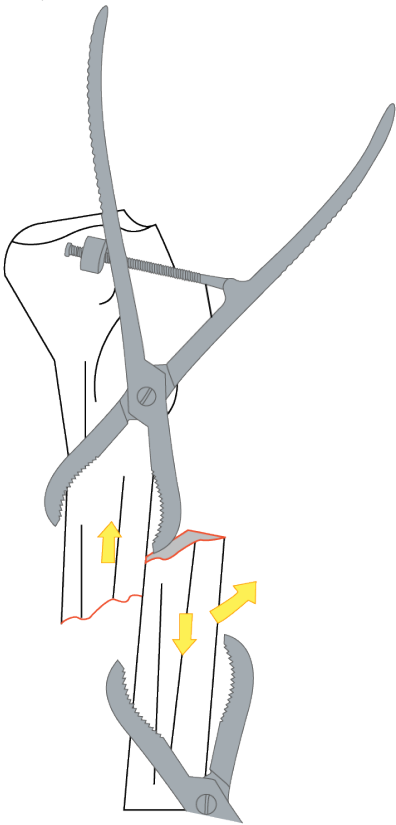
a) Perform fracture line reduction.

Caution

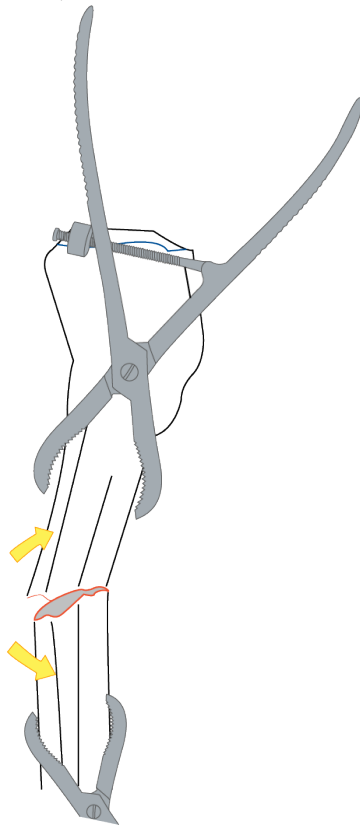
This description of the technique is not sufficient for its immediate clinical application. Hands-on learning with an experienced surgeon is highly recommended.



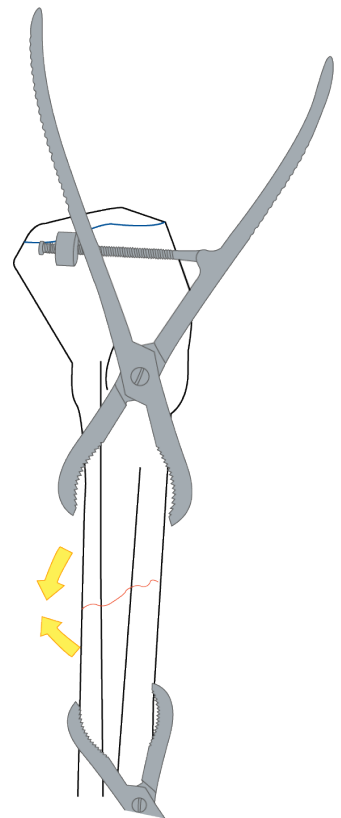
1)



2)



3)





Nail length and diameter confirmation

After reduction of the fracture, the required nail length should be determined using the radiographic ruler for tibial nail, length 375 mm.

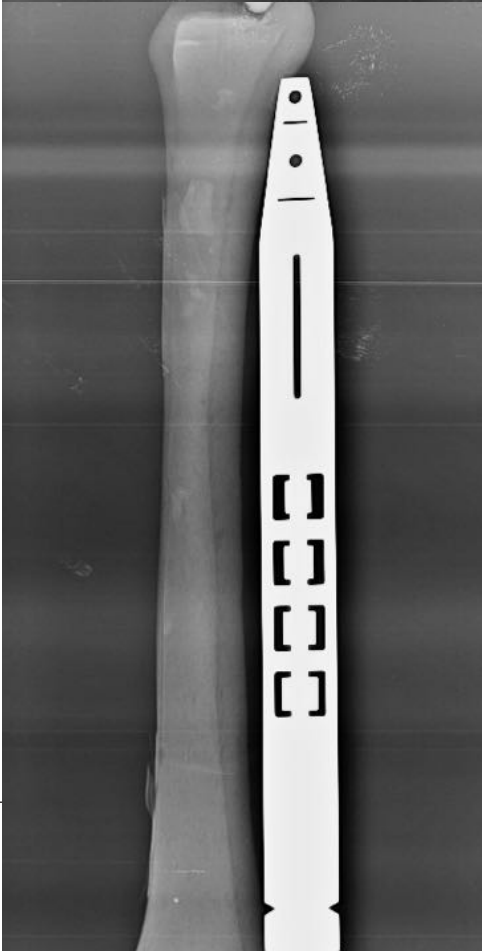
Position the C-arm for an AP view of the distal tibia. With long forceps, hold the strip along the leg, parallel and at the same height as the tibia. Adjust the strip until the distal tip is at the desired nail insertion depth.

Move the C-arm toward the proximal tibia. Replace the distal end of the ruler with a skin mark. Take an AP image of the proximal tibia. Read the nail length directly from the strip image, selecting the measurement at or just below the anterior edge of the tibial plateau.

Position the C-arm for an AP view of the tibia, at the level of the isthmus. Hold the ruler on the tibia so that the diameter meter is centered in the narrowest part of the medullary canal. Read the diameter measurement on the square indicator that fills the canal.

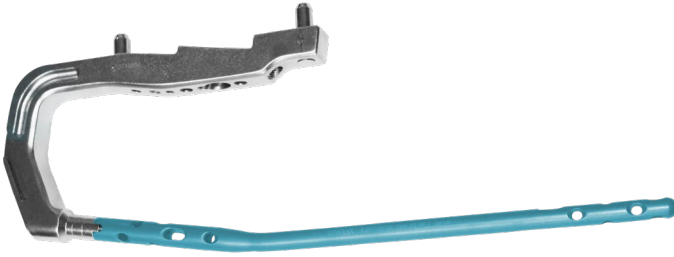
Note: When determining nail length, the possibility of compression or dynamization must be taken into account. A shorter nail will be chosen if active compression is planned for the procedure.

Dynamic lock option allows 7mm offset.



Calibration of the device (assembly):

1. Place nail on the insertion handle securing it with the nail fastener screw.

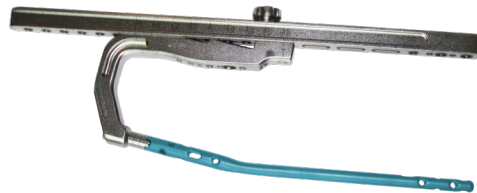


2. Assemble the strip with screw matching the graduation of the strip to the length of the chosen nail.

1)



2)



3. Place the sleeve for 6.3mm drill bit and using the drill bit Ø6.3mm match the hole for the distal locking device.

1)



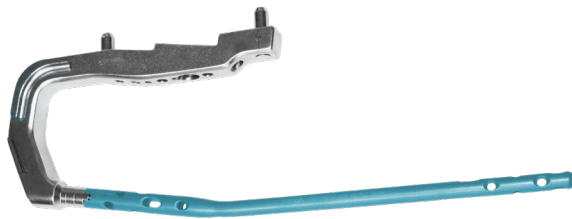
2)



3)



4. Remove the strip to perform the nail insertion procedure.



Insertions steps:

1. Insert a threaded tip guide.



2. Drill with the awl at the insertion site, at an angle of 10-15 degrees and rotating until 85 degrees are obtained with reference to the tibial diaphysis.

3. Remove the awl keeping the guide through the medullary canal.

4. Drill with the cannulated starter drill bit Ø12.5mm in the insertion site. Remove the drill bit and threaded tip guide.

5. Place an olive-tip guide wire through the guide wire protector.

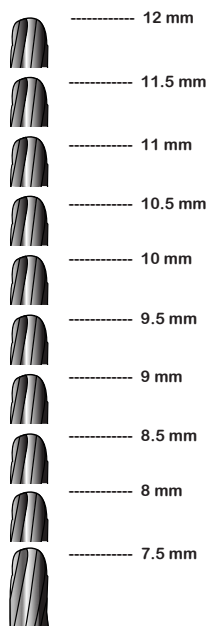
6. Prepare the centromedullary canal using the flexible interchangeable reamers tips (7.5mm to 12mm).



1)



2)



7. Performing reaming according to the diameter of the chosen nail:



- To place the 8.5 mm nail, reaming up to 9 mm is recommended.
- To place a 9.5mm nail, reaming up to 10mm is recommended.
- To place nail 10.5 we recommend reaming up to 11.
- To place nail 11.5 we recommend reaming up to 12.

8. The olive-tip guide wire can be exchanged for the olive-free guide wire inside the medullary canal.

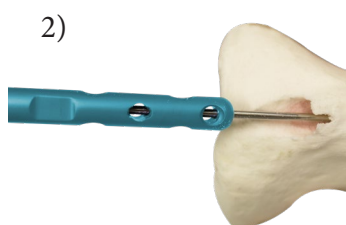
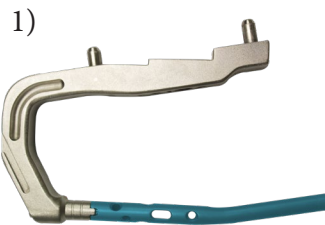


9. Place the guide wire protector to maintain reduction.



10. Insert the centromedullary nail into the canal by means of rotary movement, advancing the nail to the desired position according to the graduation of the strip (5 and 10 mm).

Optional : the sliding hammer system can be used to facilitate insertion of the centromedullary nail in its final trayjectory.



11. Place the graduated strip again. Place the sleeve for 6.3mm drill bit in the hole and drill the first cortex layer with the drill bit Ø6.3mm.

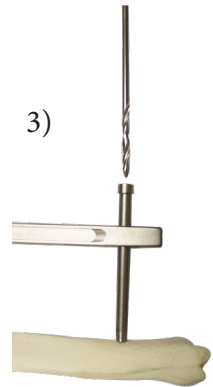
1)



2)



3)



12. Remove the strip. Place the distal locking device in the hole. Rotate until a perceptible twist lock is obtained in the system.

Note: The direction of distal locks is medial to lateral.

1)

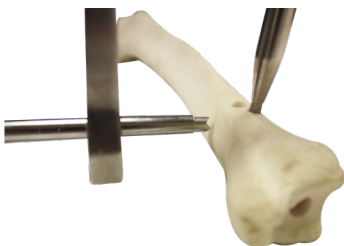


2)



13. With the device locked, place the outer sleeve in the proximal hole, together with the inner sleeve Ø4.0mm. Drill both cortical layers with the drill bit Ø4.0mm.

1)



2)



3)



14. Using the depth meter, verify the length of the screw. It is suggested to drill the first cortical bone layer with the T-handle drill Ø5.0mm.

1)



2)



3)

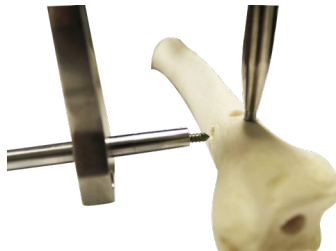


15. Insert the threaded head screw. Repeat this step with the distal hole.

1)



2)



3)



Distal screw lock (Optional)

In the event that additional blocking is required in the distal region or if greater rotational stability is required, place the strip and use the anterior distal hole.

1)

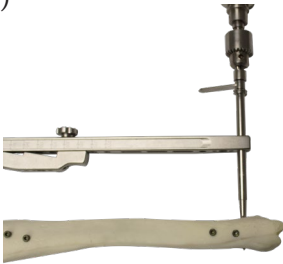


2)



Place the outer sleeve in the distal (static) hole, as well as the inner sleeve Ø4.0mm. Drill both cortical bone layers with the drill bit Ø4.0mm.

1)



2)



Using the depth meter, verify the length of the screw. It is suggested to drill the first cortical layer with the T-handle drill Ø5.0mm. Insert the screw.

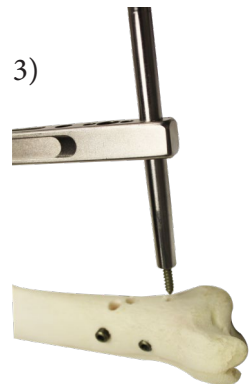
1)



2)



3)



Proximal Locking

Insert the compression screw to dynamize before locking. Place the proximal locking system in the distal holes of the insertion handle for static and dynamic locking. Perform the dynamic first. Place the outer sleeve in the distal (dynamic) hole, as well as the inner sleeve Ø4.0mm. Drill both cortical layer with the drill bit Ø4.0mm.



Screw to dynamize

1)



2)



3)

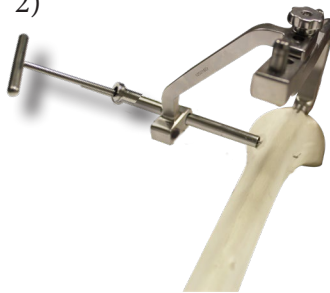


Using the depth meter, verify the screw length. It is suggested to drill the first cortical layer with the T-handle drill Ø5.0mm. Insert the selected screw.

1)



2)



3)



Repeat this step for the proximal (static) hole.



Proximal screw locking (Optional)

In the event that additional locking is required, depending on the type of fracture line or if greater rotational stability is required, place the proximal fixation system in the proximal holes.



Place the outer sleeve in the distal (static) hole, as well as the inner sleeve Ø3.2mm. Drill both cortical layer with the graduated drill bit Ø3.2mm.



Using the depth meter, check the length of the screw. Insert the chosen screw.



It also has a more distal proximal screw lock (optional).

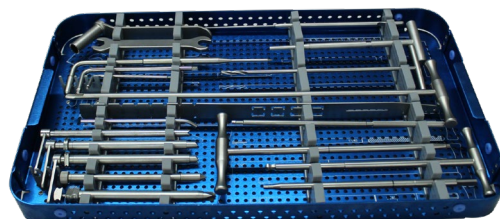
Finally, check the stability of the nail and insert the ending cap.



INSTRUMENTS

QTY. DESCRIPTION (CODE)

1	T-handle with AO anchor (12.02.01)
1	Cannulated starter drill bit Ø12.5mm (13.05.125)
1	T-handle with hexagonal tip (12.03.01)
1	Awl (31.09.01)
1	Connector for nail extractor (19.09.01)
1	Compression screw (39.03.01)
1	Drill bit Ø5.2mm (13.03.52)
2	Graduated drill bit Ø3.2mm (13.07.32)
1	Graduated drill bit with stop Ø3.2mm (13.05.32)
3	Threaded tip guide Ø3.0mm x 300mm (23.01.30)
2	Drill bit Ø4.0mm (13.07.40)
1	Drill bit with stop Ø4.0mm (13.05.40)
2	Flexible reamer (24.06.80)
2	Nail fastener screw (39.01.01)
1	Tissue protector (43.02.02)
1	Drill guide Ø12mm (18.05.12)
1	Open-end wrench Ø11mm (27.01.11)
1	Lock tester (41.01.01)
1	Large allen wrench 5.0 (26.02.50)
1	Small allen wrench 3.0m (26.02.30)
1	Ruler 255 - 375mm (16.03.375)
1	Wrench Ø4mm (27.01.40)
2	Inner sleeve Ø4.0mm (18.10.40)
2	Outer sleeve Ø8.0mm (18.11.80)
1	Inner sleeve Ø5.2mm (18.10.52)
1	Short trocar (Awl) Ø8.0mm (31.03.80)
1	Outer and inner sleeve with awl Ø8.5mm, 3.2mm (31.10.32)
1	Depth meter 90mm (16.01.90)
1	Position rod (42.01.01)
1	T-handle drill Ø5mm (13.11.50)
1	Guide wire protector (23.09.01)
1	Nail fastener for extraction SW3.5 (39.01.35)
1	Hexagonal screwdriver with T-handle for 4.5mm screws (11.07.35)
1	Hexagonal screwdriver with T-handle Ø6.5mm (11.07.65)
1	Hexagonal AO screwdriver tip for 4.5mm screw SW3.5 (11.04.35)
1	Proximal locking device (40.07.01)



- 1 Distal locking device (40.05.01)
- 1 Distal targeting device (40.10.01)
- 1 Nail extraction guide (18.15.01)
- 2 Positioning screw (39.04.60 & 39.04.80)
- 1 Strip with screw (40.11.375)
- 1 Nail fastener for extraction (39.02.01)
- 1 Set of Reaming tips (24.05.01): Ø7.5mm (24.04.75), Ø8.0mm (24.04.80), Ø8.5mm (24.04.85), Ø9.0mm (24.04.90), Ø9.5mm (24.04.95), Ø10mm (24.04.10), Ø10.5mm (24.4.105), Ø11mm (24.04.11), Ø11.5mm (24.04.115), and Ø12mm (24.24.12)
- 1 Handle for guide wire (12.07.01)
- 1 Insertion handle (40.01.01)
- 1 Stabilizing device (12.08.01)
- 1 Cannulated chisel (48.01.01)
- 1 Olive-free guide wire Ø2.4mm x 1000mm (211.24)
- 1 Sleeve for 6.3mm drill bit (191.01)
- 1 Sleeve for 4.0mm drill bit (191.02)
- 1 Distal locking device (210.04)
- 1 Sliding hammer (32.01.01)
- 1 Olive-tip guide wire Ø2.4mm x 1000mm (27.01.01)
- 1 Drill bit Ø 6.3mm x 250mm with AO anchor (13.01.25)
- 1 Tibial nail instruments tray (28.05.01)
- 1 Tibial nail implants tray (BT-045)



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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