

ATLAS[®] TFN

Tibial Fracture Nail

Surgical Technique



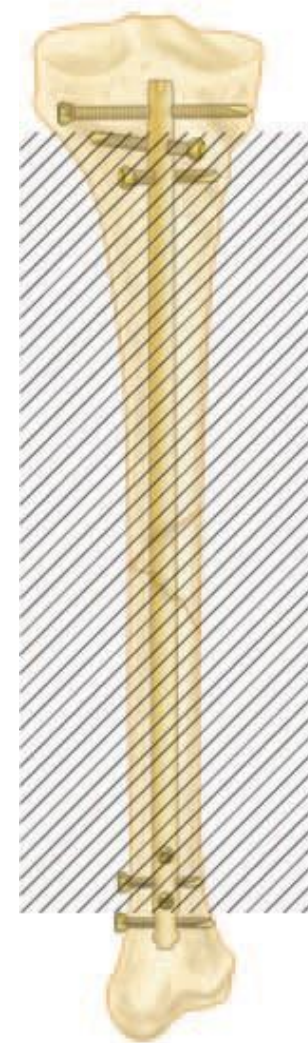
Surgical Technique

The technique described herein is provided as an educational tool. When making final determinations in product usage and technique execution, it is the responsibility of operating medical professionals to exercise their judgment and rely on their own medical training and experience. Prior to performing this technique, or utilizing any product referenced herein, please conduct a thorough review of each product's indications, contraindication, warnings, precautions and instructions as detailed in the product's information for use (IFU) .

Indications

ATLAS° TFN Tibia Fracture Nail is indicated for shaft fractures between the proximal and distal third of the tibia.

Indications include transverse, comminuted, spiral, oblique, peri-prosthetic and segmental fractures. ATLAS TFN Tibia Fracture Nail may also be used for treatment of non unions or malunions as well as prophylactic nailing of impending pathological fractures.



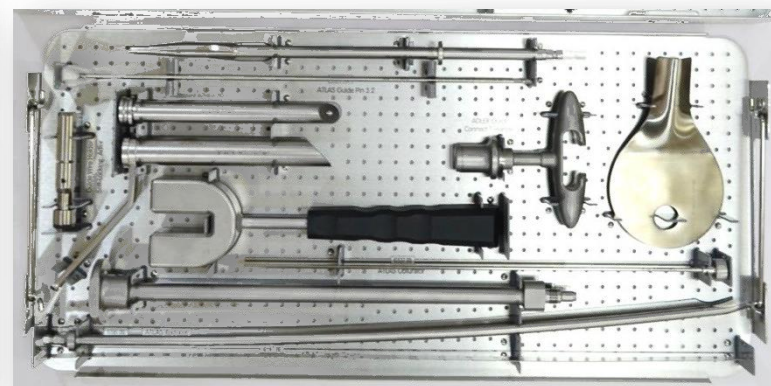
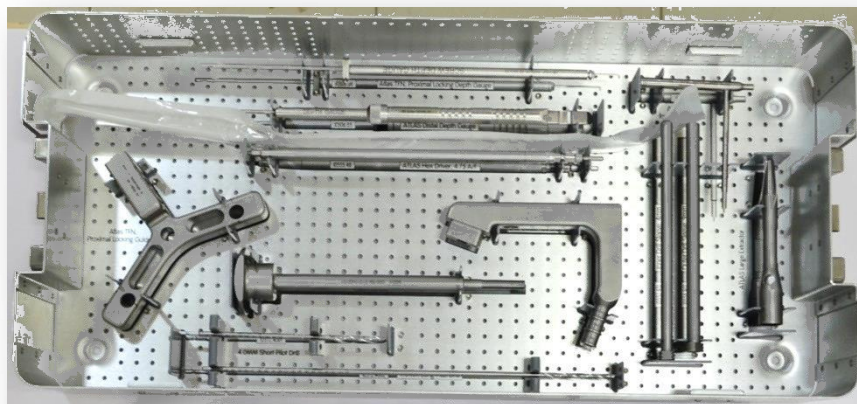
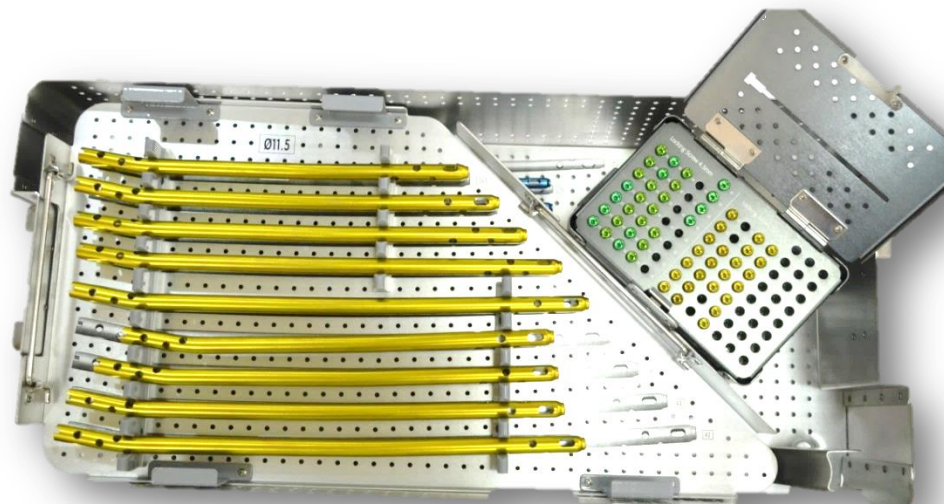
ATLAS[◇] TFN Design Features

- 3 proximal locking options (1 Transverse & 2 oblique)
- 4 distal locking options (2 AP & 2 ML including 1 dynamic slot)
- Herzog bend – 10 degree
- Titanium alloy for biocompatibility
- Nail diameters – 8.5 mm, 10 mm, 11.5 mm & 13 mm
- Nail length range:
 - 8.5 mm from 28 cm to 40 cm
 - 10, 11.5 & 13 mm from 26 cm to 50 cm
- Screws
 - 5 mm screws (gold) for 10, 11.5 & 13 mm nails
 - 4.5 mm screws (green) for 8.5 mm nails
- End Cap: 0 mm, 5 mm & 10 mm



ATLAS[◇] TFN Implant & Instrument Set

Syncera[◇]
Powered by  smith&nephew



Surgical Technique

Patient Preparation

Position the patient supine on a radiolucent table with the unaffected limb extended away from the affected limb.

Alternatively, a fracture table may be used with a pin inserted through the calcaneus to place the leg in traction. Flex the affected limb 80-90° and check for length and rotation by comparison to the unaffected limb. Use a bolster or radiolucent triangle to maintain limb position. Rotate the C-Arm to ensure optimal AP and lateral visualization of the entire tibia. A distraction device may also be applied to obtain and/or maintain traction.



Entry Portal

A 3cm incision is made in-line with the intramedullary canal. This may be patellar splitting, medial or lateral parapatellar in its orientation. Position the Entry Protection Sleeve 20/15.5 (I0505.2015) such that the Handle faces anteriorly. Insert through the incision down to bone. Introduce the Entry Drill Sleeve (I0505.1532) through the Protection Sleeve.

Align the Entry Drill Sleeve with the axial line of the tibial shaft in the A/P and lateral image views. Attach the ATLAS Guide Pin 3.2 (I0547.32) to power.

Insert the Guide Pin when axial alignment is acceptable and centered along the tibia. The target zone should be just lateral to the medial tibial tubercle. The Entry Drill Sleeve may be backed out as needed to confirm that the pilot hole is started correctly. Insert the Guide Pin approximately 3 cm in depth. Once proper placement of the Guide Pin has been established, the “Entry Drill Sleeve” may be removed

Note: Make sure that entry point and the placement of guide wire is correct in the medullary canal by checking both AP & lateral views during insertion.



Surgical Technique

Attach the Proximal Entry Reamer (I0569.01) to power. Ream the proximal tibia over the ATLAS[®] Guide Pin 3.2 (I0547.32). Ensure the Reamer is directed anteriorly to prevent perforation of the posterior tibial cortex.

The Entry Protection Sleeve functions as a soft tissue protector. The reamer should be advanced into the medullary canal of the tibia, approximately 4-5 cm. When the Entry Reamer is used through the Entry Protection Sleeve, the 'stopper' on the Reamer will prevent it from advancing more than 5cm. After confirming reamer position with AP/Lat views, withdraw the Reamer and Guide Pin.



Fracture Reduction

Snap the Quick Connect T-Handle (I0560.00) onto the ATLAS[®] Reducer (I0561.00). Insert the Reducer through the Entry Protection Sleeve and advance into the distal medullary canal to reduce the fracture.

Attach the Guide Wire Holder, (C1906.00) to the ATLAS Ball Tip Guide Wire Dia 2.8 x 1000 (C1501.3010) and introduce it into the medullary canal through the Reducer. The Guide Wire can be positioned by rotating the Reducer while placing the rod into the medullary canal. Remove the Guide Wire Holder from the Guide Wire to allow for removal of the Reducer. With the Guide Wire in place in the canal, remove the Reducer.

The ATLAS Obturator (I0537.00) may be used for easy removal of the Reducer.

Note: The Reducer may be too large to use if the patient has a small diameter intramedullary canal. If this is the case, reduce the fracture manually.



Canal Preparation

Canal preparation is dependent on surgical decision. If reaming is planned, use progressive reamers through the Entry Protection Sleeve .

Unreamed nails are selected based on preoperative planning, but should be of sufficient size to provide translational fill of the intramedullary canal in the mid-diaphysis. If reaming is selected, proceed to sequentially ream the tibial shaft beginning with the 8 mm reamer head. Sequentially ream in half millimeter increments to a diameter that is 1.0 mm to 1.5 mm larger than the selected nail size.

The Tissue Protector (C2411.00) may be used during flexible reaming to avoid soft tissue damage.



Note:

Flexible Reamers are not included in the ATLAS TFN instrument set.

The Syncera° ATLAS° Flexible Reamer Set is compatible with the Ball Tip Guide Wire C1501.3010).

The Ball Tip Guide Wire C1501.3010 is compatible with TFN nails as a Nailing Wire and does not require Guide Wire Exchange.

If any other Reaming System is used, the operating surgeon should verify compatibility for reaming and nailing steps as needed. Any other Guide Wire used would not be compatible with Guide Wire Holder C1906.00).

Exercise caution while using flexible reamers. Accidentally hitting the “reverse” or anti-clockwise function of the Power System can cause the Flexible Shaft to uncoil in the medullary canal.

Nail Selection

Determine nail diameter from image intensifier, templating, or sounding the canal. Never insert a nail that has a larger diameter than the last reamer used.

The ATLAS[®] Length Gauge (I0567.00) enables selection of the desired nail length with the help of the image intensifier.

Note:

Prior to Nail insertion, if any third-party Reaming Guide Wire / Reaming system has been used, the same may need to be exchanged with a Nailing Guide Wire. An Exchange Tube (I0525.00) has been included in the instrument set for this purpose.

Make provision in the nail length for countersinking the tibial nail to minimize impingement problems at the knee and/or to allow for reduction of the fracture, if fracture dynamization is required.

Improper implant selection or technique may lead to inadequate fixation and may contribute to early implant failure.



Drill Guide Assembly – Nail Positioning

Atlas TFN nails have three proximal locking options, transverse, medial oblique and lateral oblique.

The transverse and medial oblique screws are inserted with the drill guide assembly oriented medial to the nail. The lateral oblique screw is placed with the Drill Guide Assembly oriented lateral to the nail.

Assemble the selected Nail with the Drill Guide (I0541.01) using the Quick Bolt for Drill Guide (I0541.02). Orient the Drill Guide medial to the Nail since the transverse & medial oblique screws will be inserted in the medial orientation as stated above. Assemble the Proximal Locking Guide (I0541.03) with the Drill Guide. The Drill Guide is keyed so that the Proximal Locking Guide will only fit one way. Secure the Proximal Locking Guide to the Drill Guide by tightening the “knurled knob” by hand.

Advance the nail over the Guide Wire and carefully pass the fracture. The ATLAS Impactor-Long (I0563.00) can be connected to the top of the quick bolt or directly be used with the ATLAS Slotted Hammer (I0564.00) for easier nail insertion. Countersink the nail approximately 2-5 mm into the tibia proximally. Confirm rotation as is appropriate. Remove the Guide Wire.

Note:

Ensure that the Quick Bolt is securely tightened to the Nail threads before impaction to prevent Quick Bolt bending or breakage.

Ensure that the Guide Wire is not kinked or bent prior to introducing the Nail into the canal. If excessive impaction is found to be needed, withdraw the Nail, ream the canal to the next larger size of reamer and attempt to introduce the nail again. Excessive impaction without adequate canal preparation may cause nail bending or breakage during insertion.



Proximal Locking

Transverse and Medial Oblique Placement — Insert the Outer Drill Sleeve, 9mm (I0556.901) through the proximal holes. Make a skin incision and insert the sleeve to bone.

A. Pre-drilling Technique — The Inner Drill Sleeve, 4mm (I0557.401) is introduced through the Outer Drill Sleeve, 9mm (I0556.901). Attach the 4.0MM Long Pilot Drill (I0572.4002) to power. Insert the Long Pilot Drill through both cortices. Length may be read directly on the calibrated drill bit. Alternately, the Atlas Depth Gauge (I0506.06) may be used through the Outer Sleeve.

NOTE:

1. If the drill bit calibrations are used to read length, ensure that the Inner Drill Sleeve is in contact with the lateral cortex and also flush with the Outer Drill Sleeve to prevent calibration error.
2. While using the Depth Gauge (I0506.06), through the Outer Drill Sleeve, the Depth Gauge must contact the Lateral Cortex to ensure correct length measurement.

The appropriate length screw is selected and attached to the ATLAS Hex Driver, 4.75 A/F (I0555.48). Attach the Screwdriver to power or use the Quick Connect T-Handle (I0560.00) with the Hex Driver and place the screws in bone through the Outer Drill Sleeve. The Screwdriver is etched with a laser-marked ring. This ring should be stopped short of the Outer Drill Sleeve to prevent final seating of the screw by power. Final tightening of the screws should always be done manually using the T-Handle and Hex Driver.

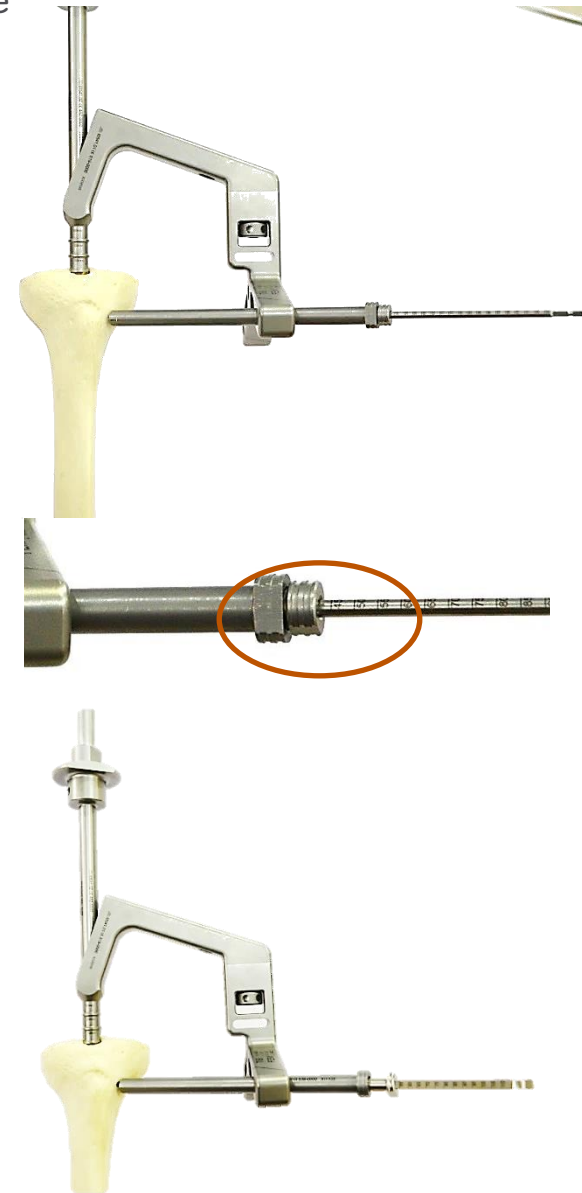
Note:

Make sure guide wire is withdrawn before drilling for proximal locking. Not doing so may result in drill bit breakage.

Before drilling for proximal locking, ensure nail is securely locked to the Drill Guide with the Quick Bolt to prevent miss-targeting.

Not for distribution. For Limited Market Release only.

Syncera
Powered by  smith&nephew



Note: 5.0 mm (GOLD) screws are to be used with 10 mm, 11.5 mm and 13 mm Nails. 4.5 mm (GREEN) screws are used with 8.5 mm Nails.

Note: Once screw is seated, insert the ATLAS Key for Retaining Rod (I0570.00) into the cannulation of the T-Handle and turn counterclockwise. The Key for Retaining Rod releases the screw from the screwdriver without the need to remove the T-Handle

Lateral Screw Placement

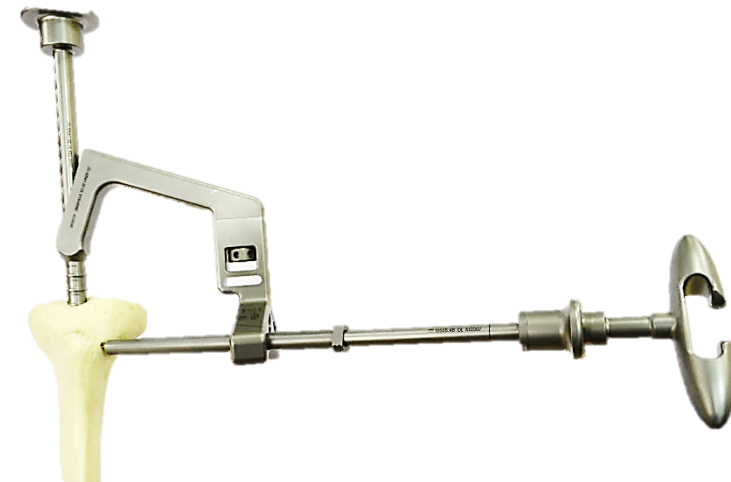
Drill Guide Assembly is oriented lateral to the nail since the lateral oblique screw will be inserted in the lateral orientation as stated before.

Insert the Outer Drill Sleeve, 9mm (I0556.901) through the proximal hole. Make a skin incision and insert the sleeve to bone.

For insertion of the lateral oblique screw, the Quick Bolt for Drill Guide (I0541.02) is loosened and back- turned two complete revolutions. This allows the Drill Guide Assembly to be lifted and rotated 180°.

After rotating Drill Guide Assembly, retighten the Quick Bolt, making sure the key is engaged. The guide is now in correct position for placement of the lateral oblique screw.

Proceed to insert and lock the lateral oblique screw using the same steps as described earlier.



Distal Locking

There are four distal locking options in the 10, 11.5 and 13mm nails and three in the 8.5mm nail.

The freehand technique is used. First, ensure that tibial rotation is satisfactory. Next, the image intensifier is used to obtain perfect circles radiographically on the distal tibial medial view or the anterior view. After perfect circles are confirmed, a stab incision is made over the holes and the 4.0MM Short Pilot Drill (I0572.4001) is inserted on power through both cortices.

The ATLAS[®] Depth Gauge (I0506.06)) is used to determine screw length. The selected screw is attached to the ATLAS Hex Driver, 4.75 A/F (I0555.48). Attach the Screwdriver to power or use the Quick Connect T-Handle to place the screws in bone. It is recommended that final tightening of the screw should always be done manually using the Quick Connect T-Handle.

Note:

Make sure that screw length is gauged correctly as it may result in soft tissue irritation. In the advent of an unexpected broken screw, removal is essential to avoid secondary fracture & allow easy nail removal.

Care should be taken while selecting correct screw diameter and inserting the screw into the implanted nail as the use of an oversized screw or incorrectly targeted screw may result in damage to the nail and the assembly.

If planning for nail dynamization, nail length selection should take into account the distal travel of the nail during dynamization.

Damaging the nail hole with the drill bit during free hand drilling may weaken the nail and increase the risk of early implant failure.



Nail End Cap Insertion:

A Nail End Cap can be used to prevent bone ingrowth to enable easy Nail removal and/or to extend nail length in cases of excessive countersinking.

After final nail seating and completion of proximal and distal locking, detach the Drill Guide Assembly by unscrewing the Quick Bolt.

Attach the selected End Cap to the Hex Driver, couple the assembly with the Quick Connect T-handle and thread the End Cap into the proximal end of the implanted Nail.

0 mm, 5 mm & 10 mm nail end caps are available for appropriate selection based on requirements.



Nail Extraction

After prepping and draping, remove any distal screws and all but one proximal screw from the nail, leaving the screw closest to the driving end of the nail. Under fluoroscopy, percutaneously place an ATLAS Guide Pin 3.2 (I0547.32) into the threaded end of the nail. (If a cap is on the nail, an incision must be made and the cap removed.) A mallet may be used to insert this guide pin, but usually power equipment can be used for percutaneous placement.

When the guide pin is in the nail, make a one- inch incision about the pin and advance the Proximal Entry Reamer (I0569.01) over the pin to remove the tissue and ingrowth overlying the nail. Note that the tip of the reamer is straight for approximately 1/2 an inch before flaring out. It is this portion of the reamer that enters the nail. After reaming, remove the reamer and the guide pin and insert the ATLAS Ball Tip Guide Wire Dia 2.8 x 1000 (C1501.3010). Attach the ATLAS Large Extractor (I0538.00) to the ATLAS Impactor-Long (I0563.00) and tighten, then thread the extractor into the nail (with the guide wire in place). Place the screwdriver shaft into the Impactor-Long slot and turn until the impactor is securely engaged. This can be verified by fluoroscopy.



Nail Extraction

After the impactor is securely engaged in the nail, remove the last locking screw. Attach the Guide Wire Holder (C1906.00) to the guide wire adjacent to the end of the impactor. The Guide Wire Holder will provide a handle for the surgeon to use while backslapping the impactor with the slotted hammer when extracting the nail.

Note: Use extreme caution not to exert any side loads on the impactor-extractor assembly. Excessive pulling and pushing on the end of the impactor handle could result in pre-mature failure of the extraction device. In the event of extractor failure, pull the guide rod until the ball tip engages the extractor, hold the Guide Wire using a suitable Wire Gripping Plier (not included in the instrument set) adjacent to the impactor and proceed with the extraction. Recommended usage for extractor: 7-10 times.

