Surgical
Technique

ATLAS◇ TFN

Tibia Fracture Nail

ADLER®

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Nota Bene

The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient

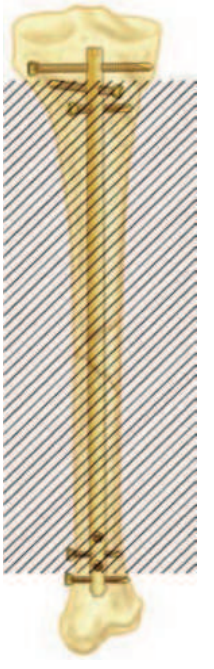
Warning

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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 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

Nail Cap: 0 mm, 5 mm & 10 mm

3 proximal locking options (1 Transverse & 2 oblique)

Herzog bend – 10 degree

5 mm diameter internal hex captured locking screws (gold) for 10, 11.5 & 13 mm nails

4.5 mm diameter internal hex captured locking screws (green) for 8.5 mm nails

•Nail length range:
- 8.5 mm from 26 cm to 40 cm
- 10, 11.5 & 13 mm from 26 cm to 50 cm

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

Distal nail diameters – 8.5 mm, 10 mm, 11.5 mm & 13 mm

- 4 distal locking options in 10,11.5 &13mm nails (2 AP & 2 ML including 1 dynamic slot).
- 3 distal locking options in 8.5mm nails (1 AP, 2 ML including 1 dynamic slot)

Bevelled distal tip for ease of entry

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

Incision and Entry point

A 3cm incision is made in-line with the intramedullary canal. This may be patellar splitting, medial or lateral parapatellar in its orientation.

The entry point is located just medial to the lateral tibial eminence in the AP view, and in line with the anterior cortex and intramedullary canal in the lateral view.

Surgical Technique

Entry Portal acquisition

Position the ***Entry Protection Sleeve (I0505.2015)***(2)such that the handle faces anteriorly. Insert through the incision down to bone. Introduce the ***Entry Drill Sleeve (I0505.1532)(1)*** through the protection sleeve.

Align the entry drill sleeve with the axial line of the tibial shaft in the AP and lateral image views. Attach the ATLAS◇ Guide Pin 3.2 (I0547.32) to power and insert the Guide pin when the axial alignment is acceptable and centered along the tibia. Alternatively, cannulated curved awl(5) can also be used for entry point.

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.

Following fluoroscopic confirmation of correct guide pin placement attach the ***Proximal Entry Reamer (I0569.01)(4)*** to power. Ream the proximal tibia over the guide pin 3.2. 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.

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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

Intramedullary Reaming

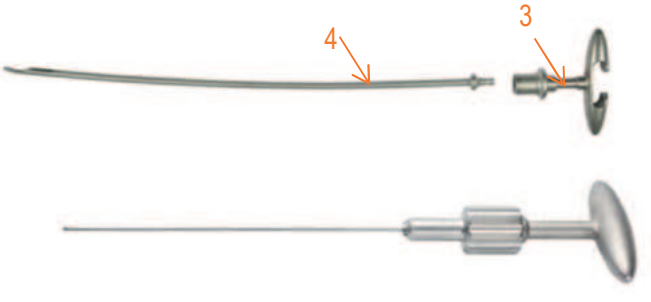
Fracture Reduction

Insert the back end of the ***2.8mmball tip guide wire (C1501.3010)(1)*** into the **ATLAS° Keyless Chuck (I0565.00)** and tighten the locking screw. Introduce the 2.8mm ball tip guide wire into the intramedullary canal through the entry protection sleeve. Fracture reduction must be achieved by close manipulation under fluoroscopic control prior to passing the guide rod across the fracture site.

Optional

Snap the ***Quick Connect T-Handle (I0560.00)(3)*** onto the ***ATLAS Reducer (I0561.00)(4)***. Insert the reducer through the entry protection sleeve and advance into the distal medullary canal to reduce the fracture. Attach the ATLAS keyless chuck to the ATLAS ball tip guide wire dia 2.8 mm and introduce it into the medullary canal through the reducer.

The guide wire can be positioned by rotating the reducer while placing the wire into the medullary canal. Once the guide wire is in position, loosen the keyless chuck locking screw and remove the reducer, if used, from the intramedullary canal. Slide the ***ATLAS Obturator (I0537.00)(2)*** into the back of the T-handle during extraction in order to maintain guide wire position within the canal.



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.*

Surgical Technique

Nail Selection/ Measurement

Under fluoroscopy, use the length gauge to measure the require length of the nail and select the appropriate diameter. Never insert a nail that has a larger diameter than the last reamer used.

The ***ATLAS® Length Gauge (I0567.00)(1)*** enables selection of the desired nail length with the help of the image intensifier.

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Note:

- ✓ *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 or soft tissue problems and may contribute to early implant failure.*

Surgical Technique

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 - 1.5 mm larger than the selected nail diameter. Be certain to maintain the fracture in a reduced position throughout the reaming process to ensure final proper alignment of fracture fragments.

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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.*
- ✓ *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)**(1) has been included in the instrument set for this purpose*
- ✓ *If a guide wire tip is bent intra-operatively to facilitate reduction, the extent of bending should be checked for easy passage through the exchange tube prior to using the bent tip wire for fracture reduction.*

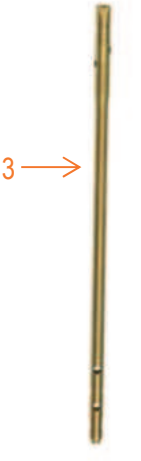
Nail Insertion

Nail Assembly

ATLAS® TFN has 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(3) with the ***Drill Guide (I0541.01)(2)*** using the ***Quick Bolt (I0541.02)/ Self Aligning Quick Bolt (I0541.02A)(1)***. Orient the drill guide medial to the nail since the transverse & medial oblique screws will be inserted in the medial orientation as stated above.

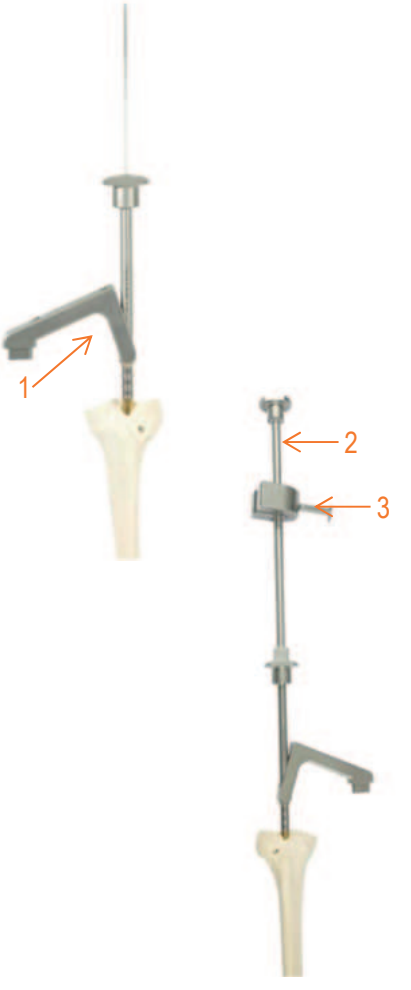


Nail Insertion

Insertion

Assemble the ***Proximal Locking Guide (I0541.03)(1)*** 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 assembly over the ball tip guide wire and carefully pass the fracture. The ***ATLAS° impactor-Long (I0563.00)(2)*** can be connected to the top of the quick bolt or directly be used with the ***ATLAS Slotted Hammer (I0564.00)(3)*** 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*

Check Insertion nail depth

Proximal

To confirm proximal nail insertion depth orient the C arm in the AP plane and pass the 3.2mm guide wire through proximal locking drill guide.

Distal

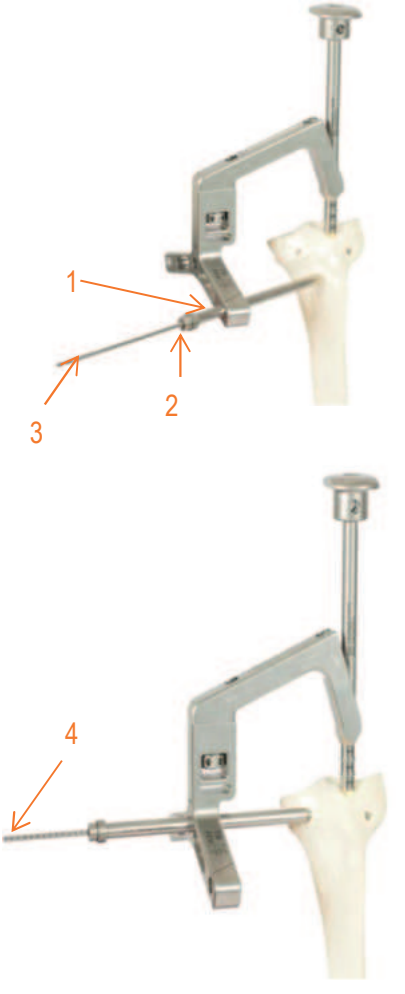
In the AP and lateral views, confirm that the nail has been inserted to the desired depth. Distal third tibial fractures require at least three locking screws to maintain stability, so optimal insertion depth is essential. Remove the guide wire once the nail has been fully seated.

Surgical Technique
Proximal locking

Transverse and Medial Oblique screw Placement

Insert the ***Outer Drill Sleeve, 9mm (I0556.901)(1)*** through the proximal holes. Make a skin incision and insert the sleeve to bone.

The ***Inner Drill Sleeve, 4mm (I0557.401)(2)*** is introduced through the Outer Drill Sleeve, 9mm. Attach the ***4.0 mm Long Pilot Drill (I0572.4002)(3)*** to power. Insert the long pilot drill through both cortices. Length may be read directly on the calibrated drill bit or via ***ATLAS® Depth Gauge (I0506.06)(4)*** used through the Outer Sleeve.



Note

- ✓ *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.*
- ✓ *While using the depth gauge, through the outer drill sleeve, the depth gauge tip must contact the lateral cortex to ensure correct length measurement.*

Proximal locking

The appropriate length screw is selected and attached to the ***ATLAS° Hex Driver, (I0555.48)****(1)*. Attach the hexdriver to power or use the ***Quick Connect T-Handle (I0560.00)****(2)* with the hex driver and place the screws in bone through the outer drill sleeve. The screwdriver is etched with laser-marked rings. The ring marked HFN/TFN should be stopped just 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 quick connect 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.
- ✓ 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.
- ✓ Once screw is seated, insert the *ATLAS Key for retaining rod (I0570.00)* into the cannulation of the T-handle and turn counter clockwise. The key for retaining rod unscrews the retaining rod and releases the screw from the screwdriver without the need to remove the T-handle

Proximal locking

Proximal Lateral Oblique Screw Placement

For insertion of the lateral oblique screw, the quick bolt/ Self aligning quick bolt is loosened and back- turned three complete revolutions. This allows the drill guide assembly to be lifted and rotated 180°. After rotating drill guide assembly, retighten the quick bolt/ Self aligning 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 for distal locking. 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. Depending on selected nail diameter either 4.5mm or 5mm screw is attached to the ***ATLAS Hex Driver, (I0555.48)(1)***. Attach the screwdriver to power or use the quick connect T-handle(2) 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*
- ✓ *Nicking the nail hole with the drill bit during free hand drilling may weaken the nail and increase the risk of early implant failure*
- ✓ *Once screw is seated, insert the ATLAS Key for retaining rod (I0570.00)(3) into the cannulation of the T-handle and turn counter clockwise. The key for retaining rod releases the screw from the screwdriver without the need to remove the T-handle.*

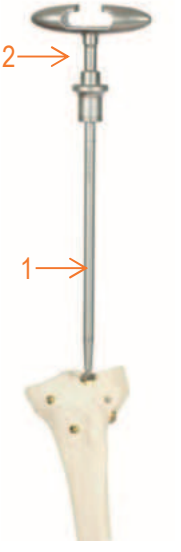
Nail Cap Insertion

A Nail 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 / Self aligning quick bolt.

Attach the selected nail cap to the ***ATLAS° hex driver(I0555.48)(1)***, couple the assembly with the quick connect T-handle(2) and thread the nail cap into the proximal end of the implanted nail.

0 mm, 5 mm & 10 mm nail caps (3)are available for appropriate selection based on requirements.



Note:

- ✓ *Once nail cap is seated, insert the ATLAS Key for retaining rod (I0570.00) into the cannulation of the T-handle and turn counter clockwise. The key for retaining rod releases the nail cap from the screwdriver without the need to remove the T-handle*

ATLAS◇ TFN Nail Extraction Technique

Standard technique

Remove the nail cap if implanted and all of the distal locking screws with the ATLAS hex driver/T-handle assembly.

Remove all of the proximal locking screws except for one in the same manner. Thread the ***ATLAS Impactor-Long (I0563.00)*** into the back of the ***ATLAS Large Extractor (I0538.00)****(1)* and then thread the assembly into the top of the nail. Remove the remaining proximal locking screw and then extract the nail with a back-slapping motion using the ***ATLAS Slotted Hammer (I0564.00)***.

ATLAS◇ TFN Nail Extraction Technique

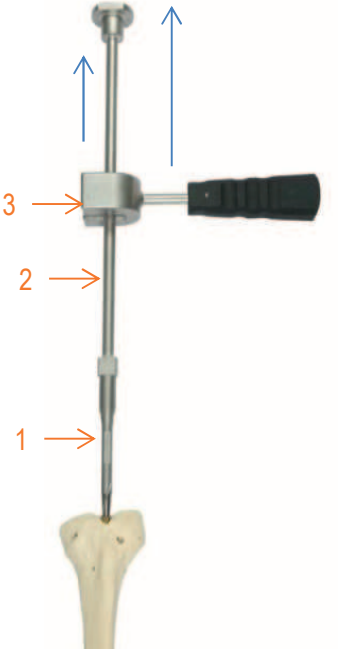
Percutaneous technique

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 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.

Thread the ATLAS Large Extractor (I0538.00)(1) to the proximal threads of the nail. Use the Hex Driver (I0555.48) shaft as a tommy bar to securely tighten the Large Extractor onto the Nail threads.

Thread the ATLAS Impactor Long (I0563.00)(2) onto the threads of the Large Extractor to form the complete assembly to extract the nail. Once this is done, remove the last locking screw. Support the lower part of the assembly while back-slapping the Long Impactor using the ATLAS Slotted Hammer(3) to extract the nail from bone.



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.*
- ✓ *Recommended usage for extractor: 7-10 times.*

ATLAS◇ TFN implants catalog

ATLAS TFN 10mm Nails	
I0140.1026	ATLAS TFN, 10mm x 26cm
I0140.1028	ATLAS TFN, 10mm x 28cm
I0140.1030	ATLAS TFN, 10mm x 30cm
I0140.1032	ATLAS TFN, 10mm x 32cm
I0140.1034	ATLAS TFN, 10mm x 34cm
I0140.1036	ATLAS TFN, 10mm x 36cm
I0140.1038	ATLAS TFN, 10mm x 38cm
I0140.1040	ATLAS TFN, 10mm x 40cm
I0140.1042	ATLAS TFN, 10mm x 42cm
I0140.1044	ATLAS TFN, 10mm x 44cm
I0140.1046	ATLAS TFN, 10mm x 46cm
I0140.1048	ATLAS TFN, 10mm x 48cm
I0140.1050	ATLAS TFN, 10mm x 50cm
ATLAS TFN 11.5mm Nails	
I0140.1126	ATLAS TFN, 11.5mm x 26cm
I0140.1128	ATLAS TFN, 11.5mm x 28cm
I0140.1130	ATLAS TFN, 11.5mm x 30cm
I0140.1132	ATLAS TFN, 11.5mm x 32cm
I0140.1134	ATLAS TFN, 11.5mm x 34cm
I0140.1136	ATLAS TFN, 11.5mm x 36cm
I0140.1138	ATLAS TFN, 11.5mm x 38cm
I0140.1140	ATLAS TFN, 11.5mm x 40cm
I0140.1142	ATLAS TFN, 11.5mm x 42cm
I0140.1144	ATLAS TFN, 11.5mm x 44cm
I0140.1146	ATLAS TFN, 11.5mm x 46cm
I0140.1148	ATLAS TFN, 11.5mm x 48cm
I0140.1150	ATLAS TFN, 11.5mm x 50cm
ATLAS TFN 13mm Nails	
I0140.1326	ATLAS TFN, 13mm x 26cm
I0140.1328	ATLAS TFN, 13mm x 28cm
I0140.1330	ATLAS TFN, 13mm x 30cm
I0140.1332	ATLAS TFN, 13mm x 32cm
I0140.1334	ATLAS TFN, 13mm x 34cm
I0140.1336	ATLAS TFN, 13mm x 36cm
I0140.1338	ATLAS TFN, 13mm x 38cm
I0140.1340	ATLAS TFN, 13mm x 40cm
I0140.1342	ATLAS TFN, 13mm x 42cm
I0140.1342	ATLAS TFN, 13mm x 42cm
I0140.1344	ATLAS TFN, 13mm x 44cm
I0140.1346	ATLAS TFN, 13mm x 46cm
I0140.1348	ATLAS TFN, 13mm x 48cm
I0140.1350	ATLAS TFN, 13mm x 50cm

ATLAS◇ TFN implants catalog

ATLAS TFN 8.5mm Nails	
I0141.0826	ATLAS TFN, 8.5mm x 26cm
I0141.0828	ATLAS TFN, 8.5mm x 28cm
I0141.0830	ATLAS TFN, 8.5mm x 30cm
I0141.0832	ATLAS TFN, 8.5mm x 32cm
I0141.0834	ATLAS TFN, 8.5mm x 34cm
I0141.0836	ATLAS TFN, 8.5mm x 36cm
I0141.0838	ATLAS TFN, 8.5mm x 38cm
I0141.0840	ATLAS TFN, 8.5mm x 40cm

ATLAS TFN Nail Caps	
I0303.00	ATLAS TFN Nail Cap, 0 mm
I0303.05	ATLAS TFN Nail Cap, 5mm
I0303.10	ATLAS TFN Nail Cap, 10mm

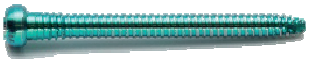
ATLAS TFN Implant set	
D0101.2602	ATLAS TFN Implant Case
D0102.2102	ATLAS TFN Implant Case Middle Tray
D0102.2103	ATLAS TFN Implant Case Upper Tray
D0102.2104	ATLAS TFN Implant Case, Screw Caddy

***Note:** ATLAS TFN implant set comes with the below configuration:

1. ATLAS Titanium 4.5mm Locking Screws, from 25mm to 65mm, 4 ea.
2. ATLAS Titanium 5mm Locking Screws, from 25mm to 85mm, 4 ea.
3. ATLAS TFN 8.5mm Nails, from 28cm to 36cm, 1 ea.
4. ATLAS TFN 10mm Nails, from 26cm to 42cm, 1 ea.
5. ATLAS TFN 11.5mm Nails, from 26cm to 42cm, 1 ea.
6. ATLAS TFN 13mm Nails, from 32cm to 42cm, 1 ea.
7. ATLAS TFN Nail Caps (all sizes), 1 ea.

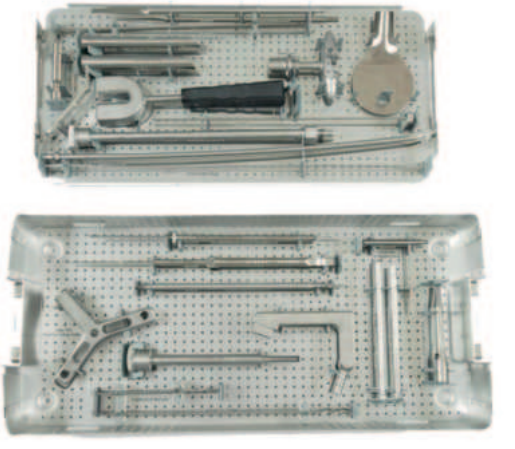
ATLAS◇ TFN implants catalog

ATLAS Titanium Locking Screw 4.5mm	
I0210.4525	ATLAS Titanium Locking Screw 4.5MM X 25MM
I0210.4530	ATLAS Titanium Locking Screw 4.5MM X 30MM
I0210.4535	ATLAS Titanium Locking Screw 4.5MM X 35MM
I0210.4540	ATLAS Titanium Locking Screw 4.5MM X 40MM
I0210.4545	ATLAS Titanium Locking Screw 4.5MM X 45MM
I0210.4550	ATLAS Titanium Locking Screw 4.5MM X 50MM
I0210.4555	ATLAS Titanium Locking Screw 4.5MM X 55MM
I0210.4560	ATLAS Titanium Locking Screw 4.5MM X 60MM
I0210.4565	ATLAS Titanium Locking Screw 4.5MM X 65MM
ATLAS Titanium Locking Screw 5.0 mm	
I0211.5025	ATLAS Titanium Locking Screw 5.0MM X 25MM
I0211.5030	ATLAS Titanium Locking Screw 5.0MM X 30MM
I0211.5035	ATLAS Titanium Locking Screw 5.0MM X 35MM
I0211.5040	ATLAS Titanium Locking Screw 5.0MM X 40MM
I0211.5045	ATLAS Titanium Locking Screw 5.0MM X 45MM
I0211.5050	ATLAS Titanium Locking Screw 5.0MM X 50MM
I0211.5055	ATLAS Titanium Locking Screw 5.0MM X 55MM
I0211.5060	ATLAS Titanium Locking Screw 5.0MM X 60MM
I0211.5065	ATLAS Titanium Locking Screw 5.0MM X 65MM
I0211.5070	ATLAS Titanium Locking Screw 5.0MM X 70MM
I0211.5075	ATLAS Titanium Locking Screw 5.0MM X 75MM
I0211.5080	ATLAS Titanium Locking Screw 5.0MM X 80MM
I0211.5085	ATLAS Titanium Locking Screw 5.0MM X 85MM
I0211.5090	ATLAS Titanium Locking Screw 5.0MM X 90MM
I0211.5095	ATLAS Titanium Locking Screw 5.0MM X 95MM
I0211.5100	ATLAS Titanium Locking Screw 5.0MM X 100MM
I0211.5105	ATLAS Titanium Locking Screw 5.0MM X 105MM
I0211.5110	ATLAS Titanium Locking Screw 5.0MM X 110MM



ATLAS◇ TFN Instrumentation

ATLAS TFN Catalogue No	ATLAS TFN Part Name (Catalog)
I0572.4002	4.0MM Long Pilot Drill
I0572.4001	4.0MM Short Pilot Drill
I0505.1532	Entry Drill Sleeve 15.5/3.2
I0505.2015	Entry Protection Sleeve 20/15.5
I0569.01	Proximal Entry Reamer
I0537.00	ATLAS Obturator
I0561.00	ATLAS Reducer
I0567.00	ATLAS Length Gauge
I0541.01	Drill Guide 135 Deg.
I0541.02	Quick Bolt for Drill Guide
I0541.03	ATLAS TFN Proximal Locking Guide
I0563.00	ATLAS Impactor-Long
I0564.00	ATLAS Slotted Hammer
I0556.901	Outer Drill Sleeve, 9mm
I0557.401	Inner Drill Sleeve, 4mm
I0555.48	ATLAS Hex Driver, 4.75 A/F
I0506.06	ATLAS Depth Gauge
I0560.00	Quick Connect T-Handle
I0538.00	ATLAS Large Extractor
I0547.32	ATLAS Guide Pin 3.2
I0570.00	ATLAS Key for Retaining Rod
I0525.00	Exchange Tube
I0541.02A	Self Aligning Quick Bolt
I0565.00	ATLAS HFN Keyless Chuck
I0566.00	ATLAS HFN Curved Cannulated Awl
D0207.05	Screw Holding Forceps
C1501.3010*	ATLAS Ball Tip Guide Rod Wire 2.8 x 1000



ATLAS TFN instrument set	
D0101.2601	ATLAS TFN Instrument Case
D0102.2101	ATLAS TFN Instrument Tray
D0102.2603	ATLAS TFN Instrument Case (India)
D0102.2105	ATLAS TFN Instrument Tray (India)

***Note:** ATLAS Ball Tip Guide Rod Wire 2.8 x 1000 (C1501.3010) is not part of the set and needs to be ordered separately

IFU in the Attachment

Important Information on ATLAS® Tibial Fracture Nail
For use by an Accredited Orthopaedic Surgeon only

Device Description:
The ATLAS TFN (Tibial Fracture Nail) is designed to handle tibial fracture indications in diameters 8.5mm, 10mm, 11.5mm, and 13mm in length range from 26cm to 50cm. It consists of tibia nails in the preceding length and diameter sizes, distal locking screw, and nail cap screw.

The ATLAS TF Nail system includes implantable nails and screws, which are provided in a variety of lengths and types to accommodate the prescribed fixation technique. The system includes instrumentation trays, which house the instrument that are needed for installation and removal of the implantable assembly. The Atlas TF Nails, Screws and Caps are made from titanium-vanadium alloy Ti-6Al-4V material complying to ISO 5832-3.

Summary:
Operating surgeons should be aware of the following aspects related to the use of metallic implants.

1. Proper size, length, side and type selection, as well as proper handling and use of the TF nails are essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. TF Nails are NOT substitutes for skeletal healing, and proper follow-up care is essential to safe and effective use. See WARNINGS, POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

Notes:
Metallic surgical implants are intended to be used as aids to normal fracture healing. Such implants are NOT replacements for skeletal structures. Healing of fractures treated with metallic surgical implants must be confirmed prior to permitting weight bearing on the bones. Weight bearing on bones that have failed to heal or healed partially or improperly can cause stress and fatigue in metallic surgical implants with consequent breakage or failure of the implants. Surgeons should consider the following information and should inform patients of pertinent information relevant to the patients' health and safety. The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

Indications:
The ATLAS TF Nail is indicated for shaft fractures between the proximal and distal third of the Tibia. This includes transverse, comminuted, spiral, oblique, and segmental fractures. It may also be used for nonunions, malunions, prophylactic nailings of impending pathological fractures.

Contraindications:
ATLAS TF Nail should not be used in:

1. Crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia, and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.

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