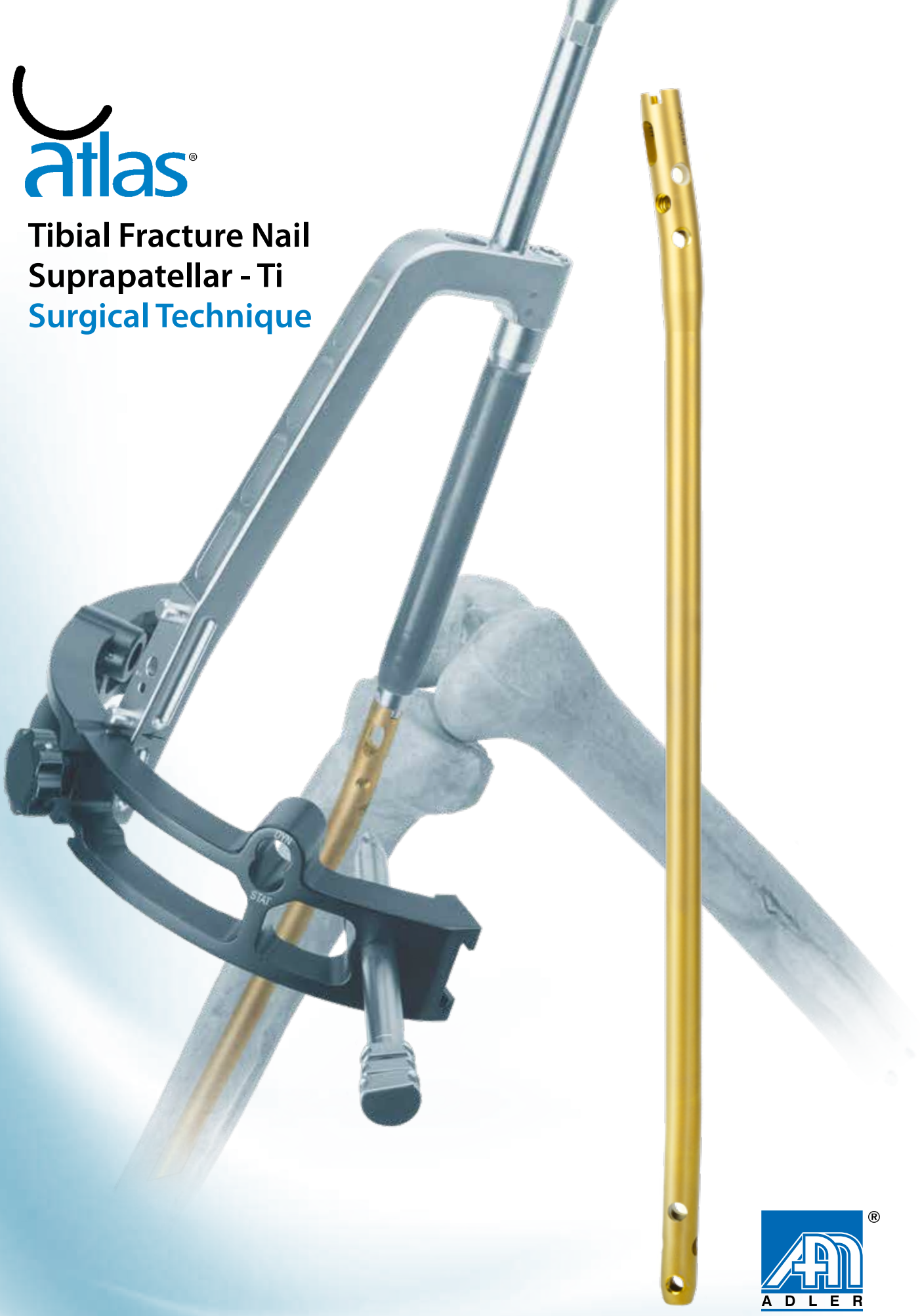
atlas®

Tibial Fracture Nail Suprapatellar - Ti

Surgical Technique



ADLER®

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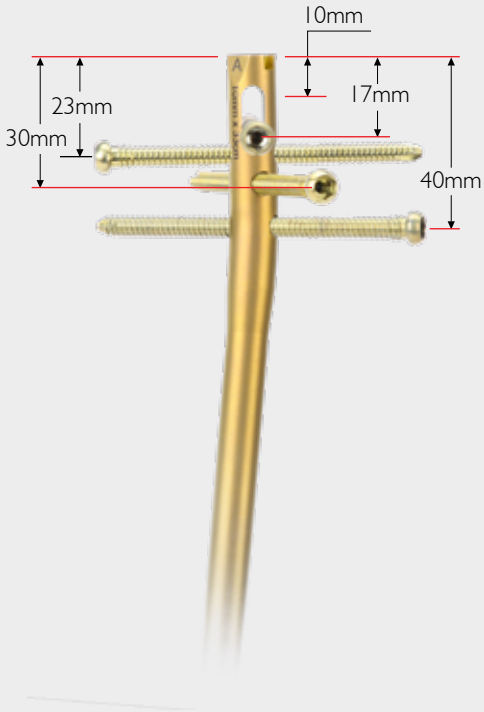
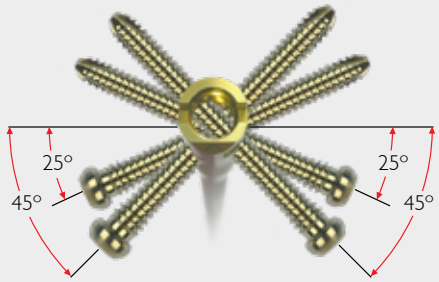
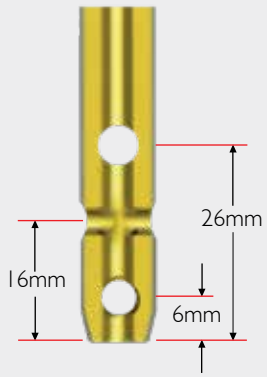
Indications for use

The Atlas® Tibial Nail is indicated for fractures of the proximal and distal third of the tibia, including the shaft, stable and unstable fractures, non-unions, mal-unions, and for the prophylactic nailing of impending pathological fractures.







ATLAS Ti Tibial Fracture Nail Suprapatellar Specifications

Material	Ti6Al4V
Diameters	8.5mm & 10.0mm
Lengths	28cm - 40cm
Nail Colour	Gold
Proximal Diameter Driving End	11.5mm
Distal Diameter - Nail Diameter	8.5mm & 10.0mm
Locking Bolt Threads	M8 x 1
Screw Diameter	Proximal Locking - 5mm Screw Distal Locking: 8.5mm Nail - 4.5mm Screw 10.0mm Nail - 5.0mm Screw
Screw Colour	4.5mm - Lime 5.0mm - Gold
Screw Lengths	4.5mm - 22.5mm to 65.0mm 5.0mm - 22.5mm to 80.0mm
Screw Socket	Hex 4.75mm
Proximal Locking	
Static Lock Locations/Orientations	17mm / 45° Screw with Cap 23mm / 45° Threaded with Bushing 30mm / 25° Threaded 40mm / 25° Threaded
Degree of Proximal Bend	9°
Distal Locking	
Distal Lock Locations/Orientations	26mm / ML 16mm / AP 6mm /ML (Threaded)
Degree of Distal Bend	2°

ATLAS Ti TFN Suprapatellar, Sterile

Code No.		Length cm
Ø 8.5mm	Ø 10.0mm	
I0144.8528	I0145.1028	28
I0144.8530	I0145.1030	30
	I0145.1031	31
I0144.8532	I0145.1032	32
I0144.8533	I0145.1033	33
I0144.8534	I0145.1034	34
I0144.8535	I0145.1035	35
I0144.8536	I0145.1036	36
I0144.8537	I0145.1037	37
I0144.8538	I0145.1038	38
I0144.8540	I0145.1040	40

ATLAS® Ti TFN/FFN Closing Cap

Code No.	Length mm
I0303.00	0
I0303.05	5
I0303.10	10

ATLAS Ti Locking Screw

Code No.		Length mm
Ø 4.5mm Color: Lime	Ø 5.0mm Color: Gold	
I0210.4520	I0211.5020	20.0
I0210.4523	I0211.5023	22.5
I0210.4525	I0211.5025	25.0
I0210.4528	I0211.5028	27.5
I0210.4530	I0211.5030	30.0
I0210.4533	I0211.5033	32.5
I0210.4535	I0211.5035	35.0
I0210.4538	I0211.5038	37.5
I0210.4540	I0211.5040	40.0
I0210.4543	I0211.5043	42.5
I0210.4545	I0211.5045	45.0
I0210.4548	I0211.5048	47.5
I0210.4550	I0211.5050	50.0
I0210.4553	I0211.5053	52.5
I0210.4555	I0211.5055	55.0
I0210.4558	I0211.5058	57.5
I0210.4560	I0211.5060	60.0
I0210.4563	I0211.5063	62.5
I0210.4565	I0211.5065	65.0
	I0211.5068	67.5
	I0211.5070	70.0
	I0211.5073	72.5
	I0211.5075	75.0
	I0211.5078	77.5
	I0211.5080	80.0
	I0211.5085	85.0
	I0211.5090	90.0
	I0211.5095	95.0
	I0211.5100	100.0
	I0211.5105	105.0
	I0211.5110	110.0

Surgical Technique

Patient Positioning

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.

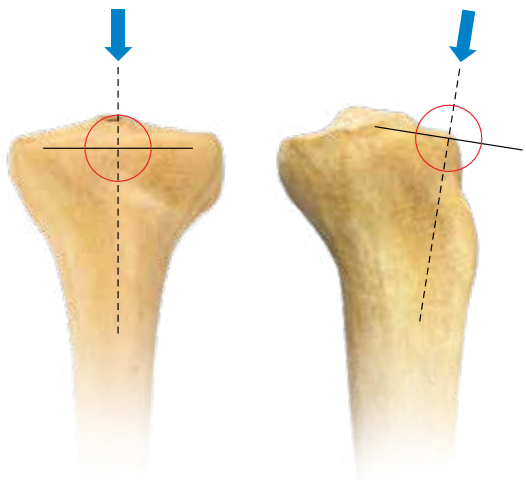
Use a bolster or radiolucent triangle to maintain limb position. Rotate the C-Arm to ensure optimal AP and lateral visualization of the entire tibia. A distraction device may also be applied to obtain and/or maintain traction.

Incision and Entry Point

Assemble the Atlas® Multiple Hole Sleeve (I0582.1332) and Atlas® Protection Sleeve 16/13 (I0582.1613). The pieces will lock in place securely at either 0° or 180°.

A 2cm 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.



Instruments for Opening the Proximal Tibia

Atlas®
Hollow Open Awl, Inner Part
I0587.01

Atlas®
Multiple Hole Sleeve, 13/3.2
I0582.1332

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

Atlas®
Guide Pin, 3.2 x 300
I0581.3230

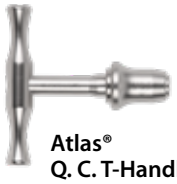
Atlas®
Driving End Cannulated Drill, 12.8/3.2
I0583.1232

Atlas®
Flexible Driving End Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Protection Sleeve, 16/13
I0582.1613

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Hollow Open Awl
I0587.00



Atlas®
Q. C. T-Handle
I0585.00

Surgical Technique - continued

Entry Portal Acquisition

insert 3.2mm Atlas® Guide Pin (I0581.3230 or I0581.3240) into the proximal tibia to a depth of 4-6cm. The Protection Sleeve instrumentation serves as a soft tissue protector.

In the instance of suboptimal Guide Pin insertion, rotate the Atlas® Multiple Hole Sleeve (I0582.1332) within the Atlas® Protection Sleeve 16/13 (I0582.1613) to the desired location and insert another Guide Pin. Avoid over-insertion of the Guide Pin as this can establish a false trajectory and lead to fracture malalignment.

Surgical Technique - continued

Entry Portal

After definitive Atlas® Guide Pin (I0581.3230 or I0581.3240) placement, remove the Atlas® Multiple Hole Sleeve (I0582.1332) from the Atlas® Protection Sleeve 16/13 (I0582.1613) along with any additionally inserted Guide Pins and attach the Atlas® Driving End Cannulated Drill, 12.8/3.2 (I0583.1232) to power or Atlas® Q. C. T-Handle (I0585.00). Advance over the Guide Pin through the Protection Sleeve to a depth of 4-6cm. Maintain alignment so as to avoid penetration of the posterior cortex.

Check position via radiographic imaging and then remove the Atlas® Driving End Cannulated Drill, 12.8/3.2 (I0583.1232) and 3.2mm Guide Pin.

Alternative Technique: Entry Portal

Insert the Atlas® Hollow Open Awl (I0587.00) into the proximal tibia to a depth of 4-6cm. Introduce the Atlas® Hollow Open Awl, Inner Part (I0587.01) into the back of the assembly prior to insertion in order to prevent awl slippage and accumulation of cortical bone within the cannulation.

Atlas®
Hollow Open Awl,
Inner Part
I0587.01

Atlas®
Hollow Open Awl
I0587.00

Instruments for Fracture Reduction & Reaming

Atlas®
Protection Sleeve, 16/13
I0582.1613

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Ball Guide Wire Measurer
I0591.00

Atlas®
Guide Wire Holder
I0589.00

Atlas®
Reduction Rod
I0588.00

Atlas®
Flexible Reamer, 8mm
I0592.08

Atlas®
Flexible Reamer, 9mm
I0592.09

Atlas®
Flexible Reamer, 10mm
I0592.10

Atlas®
Flexible Reamer, 11mm
I0592.11

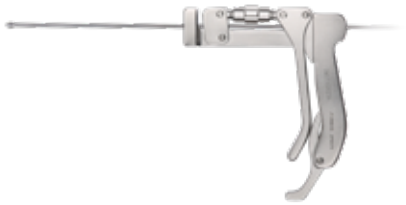
Atlas®
Flexible Reamer, 12mm
I0592.12

Atlas®
Ball Tip Guide Wire
4 x 1000mm
I0590.4100

Surgical Technique - continued

Fracture Reduction

Insert the back end of the 4.0 mm Ball Tip Guide Wire (I0590.4100) into the front of the Atlas® Guide Wire Holder (I0589.00) and gently close the trigger-grip. Connect the Atlas® Reduction Rod (I0588.00) to the T-Handle.



Advance the Reducer into the intramedullary canal and use the curved tip to direct the 4.0 mm Ball Tip Guide Wire past the fracture into the region of the distal epiphyseal scar. The Guide Wire should be center-center in the AP and lateral views.

Reduction Rod Removal

Once the Guide Wire is at the desired depth, detach the Guide Wire Holder and remove the Reduction Rod from the tibial canal.

Surgical Technique - continued

Implant Measurement

After Reduction Rod removal, re-confirm Guide Wire placement within the distal tibia and slide the Atlas® Ball Guide Wire Measurer (I0591.00) over the Guide Rod to the desired depth. The metal tip of the Ball Guide Wire Measurer denotes the driving end of the Atlas® TFN Suprapatellar Nail.

Confirm Guide Wire position in the window at the opposite end of the Ball Guide Wire Measurer as shown in order to ensure accurate implant measurement. Push down on the top of Ball Guide Wire Measurer until contact is made with the 4.0mm Ball Tip Guide Wire. Implant length is read from the exposed calibrations at the end of the Ball Guide Wire Measurer.

Note: Confirm fracture reduction so as not to underestimate correct implant length. Reference the fibula for accurate fracture distraction or compression.

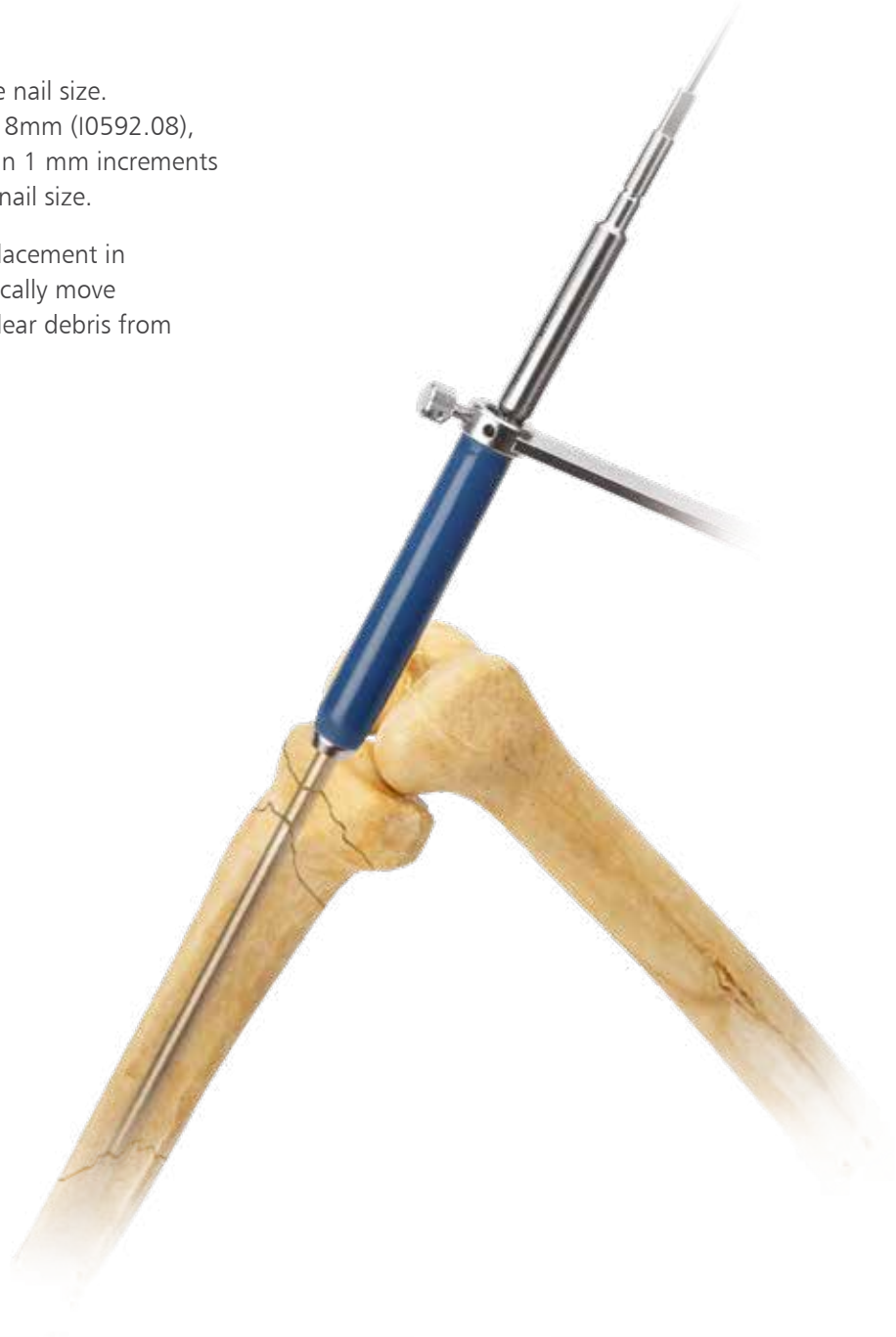
Note: Confirm that the Ball Guide Wire Measurer opens easily. Adjust the thumb-wheel connection at the end to allow for free movement.

Surgical Technique - continued

Reamed Technique

Intra-operative measurement will determine nail size. Beginning with the Atlas® Flexible Reamer, 8mm (I0592.08), ream the intramedullary canal sequentially in 1 mm increments to a size 1-1.5mm larger than the selected nail size.

Continue reaming to confirm Guide Wire placement in the distal tibia throughout reaming. Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes.



Instruments for Nail Assembly & Insertion.

Atlas®
Universal Wrench
I0597.00

Atlas®
SP Proximal Aiming Device
I0601.00

Atlas®
SP Drill Guide, Long
I0593.01

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Locking Screw Sleeve
11/8.6
I0602.1186

Atlas®
Drill Sleeve
8.6/4.3
I0603.8643

Atlas®
SP Drill Guide, Short
I0593.00

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Open Wrench 11mm A/F
I0599.11

Atlas®
Nail Connection Rod
I0598.00

Atlas®
SP Connection Bolt,
Short, 6.5 mm A/F
I0594.00

Atlas®
SP Connection Bolt,
Long, 6.5 mm A/F
I0594.01

Atlas®
Wrench for
Connection Rod
I0596.00

Atlas®
Limitation Wrench
4.3mm, 3mm A/F
I0606.431

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Sliding Hammer
I0611.00

Atlas®
Limitation
4.3mm, 3mm A/F
I0606.43

Atlas®
Aiming Device, Bolt
I0601.01

Atlas®
Trocar 4.3mm
I0604.43

Atlas®
Guide Pin, 3.2 x 300
I0581.3230

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

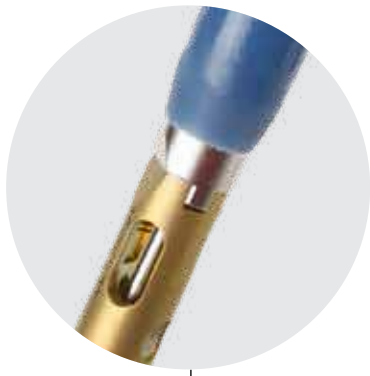
Surgical Technique - continued

Nail Assembly

Attach the Atlas® SP Drill Guide, Long (I0593.01) to the nail with the Atlas® SP Connection Bolt, Long, 6.5 mm A/F (I0594.01) and tighten with the Atlas® Universal Wrench (I0597.00) or Atlas® Wrench for Connection Rod (I0596.00). The nail is correctly aligned when:

1. The line on the insertion barrel matches the line of the nail
2. The "A" on the nail matches the bevel of on the insertion barrel
3. The apex of the nail's proximal Herzog Bend faces posterior and the Drill Guide is oriented anterior

The bevel on the front of the nail marks the connection to the Drill Guide and can be seen in the lateral view as a means for determining proximal insertion depth.



Note: It is recommended to use the Drill Guide long and Connection Bolt Long for compression or dynamic locking as the longer insertion barrel facilitates countersinking of the nail.

Note: The assembly and insertion of the 8.5mm diameter Atlas® Ti TFN Suprapatellar Nail follows the same technique as the 10mm nails.

Attach the Atlas® SP Proximal Aiming Device (I0601.00) to the Drill Guide and verify targeting accuracy by inserting a Atlas® Locking Screw Sleeve 11/8.6 (I0602.1186) and Atlas® Drill Sleeve 8.6/4.3 (I0603.8643) into the Proximal Aiming Device and passing a Atlas® Drill Bit 4.3/300 (I0605.4330) through the assembly. An incorrectly attached nail will not target.

Nail Insertion

Remove the Proximal Aiming Device and attach the Atlas® Nail Connection Rod (I0598.00) to the Drill Guide. Orient the Drill Guide assembly in the AP position and advance the nail over the Guide Wire by light blows from the Atlas® Sliding Hammer (I0611.00) to the desired depth.

Additional reaming of the intramedullary canal may be indicated if excessive force is required to insert the nail.

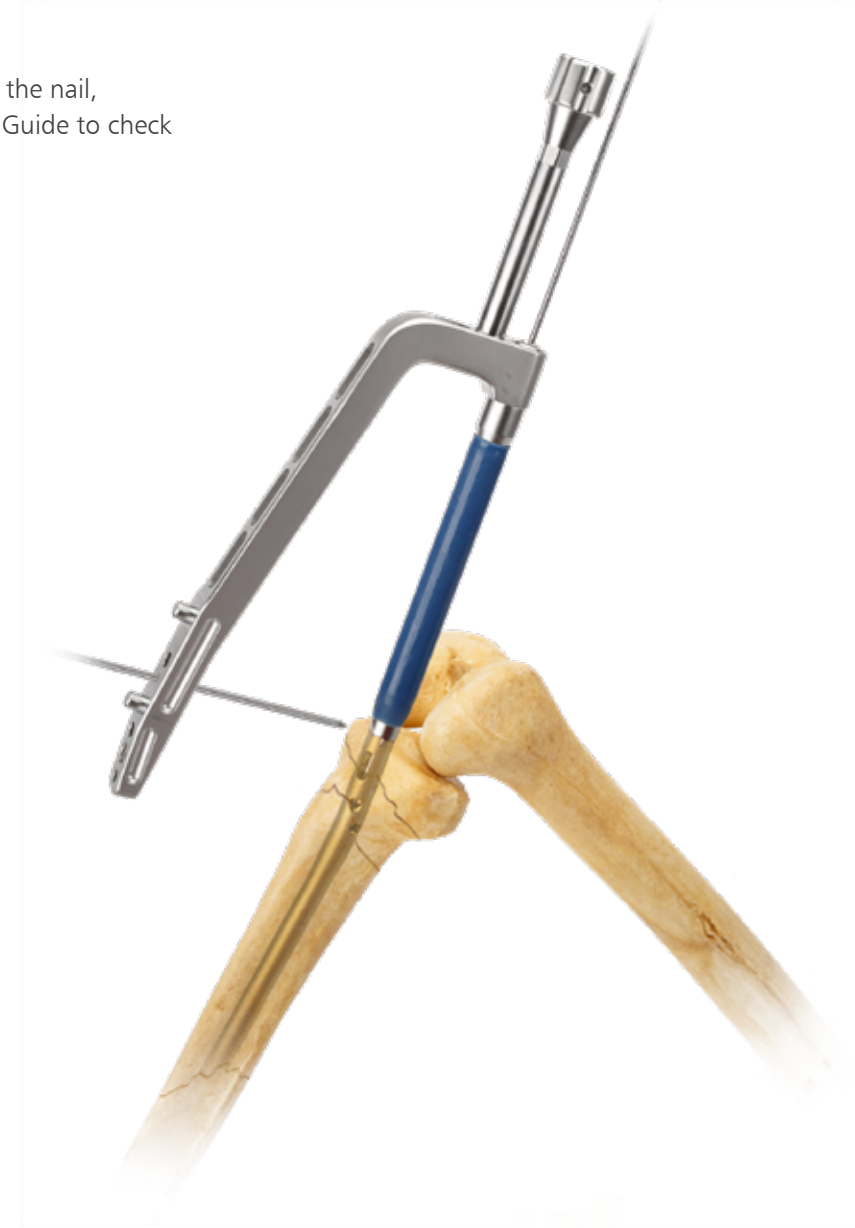
Verify fracture reduction as the nail crosses the fracture site paying close attention to rotation, length, alignment, distraction and/or shortening. Check final nail position in both the AP and lateral views for correct alignment.

For proximal interlocking with the leg in extension use the Atlas® SP Drill Guide, Short (I0593.00) and Atlas® SP Connection Bolt, Short, 6.5 mm A/F (I0594.00). The long insertion barrel of the Drill Guide Long may impinge upon the distal femoral condyles and prevent nail interlocking with the tibia in full extension.

Check Nail Depth

Proximal

In the lateral view, confirm the position of the nail, pass a 3.2mm Guide Pin through the Drill Guide to check proximal end of the nail.



Distal

In the AP and lateral views, confirm that the nail has been inserted to the desired depth. Distal third tibia 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 and attach the Proximal Aiming Device.

Note: Following nail insertion, confirm that the nail and Drill Guide are securely connected as hammering can loosen the Connection Bolt.

Instruments for Standard, Dynamic & Compression Locking

Atlas®
SP Proximal Aiming Device
I0601.00

Atlas®
Drill Sleeve 4.3 mm
I0603.43

Atlas®
SP Drill Sleeve 4mm
I0603.04

Atlas®
T-Locking Screwdriver, 4.75 mm
I0608.475

Atlas®
Drill Bit 4.3 x 150
I0610.4315

Atlas®
Drill Bit 4 x 150
I0610.4150

Atlas®
Drill Sleeve 8.6/4.3
I0603.8643

Atlas®
Depth Gauge for Driving End, SP/DF
I0607.00

Atlas®
Locking Screw Sleeve, 11/8.6
I0602.1186

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Depth Gauge for Non-Driving End, SP/DF
I0607.01

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
SP Compression Bolt Long, 6.5mm A/F
I0595.01

Atlas®
SP Compression Bolt Short, 6.5mm A/F
I0595.00

Surgical Technique - continued

Locking Screw Measurement

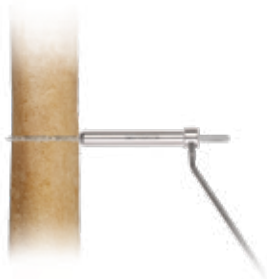
There are four (4) methods:

1. Atlas® Locking Screw Sleeve 11/8.6 (I0602.1186), Atlas® Drill Sleeve 8.6/4.3 (I0603.8643) and Drill Bit 4.3 x 300 (I0605.4330).

2. Locking Screw Sleeve 11/8.6 and Atlas® Depth Gauge for Driving End, SP/DF (I0607.00).

3. Atlas® SP Drill Sleeve 4mm (I0603.04) and Atlas® Drill Bit 4 x 150 (I0610.4150).

   Atlas® Drill Sleeve 4.3 mm (I0603.43) and Atlas® Drill Bit 4.3 x 150 (I0610.4315)



4. Atlas® Depth Gauge for Non-Driving End, SP/DF (I0607.01).

Surgical Technique - continued

Locking Screw Insertion

Proximal locking options include three (3) statically locked threaded holes and one (1) slot that allows for both fracture compression and/or dynamization. These are targeted through the Proximal Aiming Device.

Gold 5.0m locking screws are compatible with 8.5 mm and 10.0mm diameter nails.

Distal locking options include three (3) statically locked holes, two (2) ML and one (1) AP. The most distal ML hole is threaded for additional stability.

Gold 5.0mm locking screws are compatible with 10mm diameter nail Lime 4.5mm locking screws are compatible with 8.5mm diameter nail.

Proximal Locking: Static

Make a small incision at the site of screw entry and insert the Locking Screw Sleeve 11/8.6 and Drill Sleeve 8.6/4.3 through the static slot on the Proximal Aiming Device down to bone. Drill both cortices with the Drill Bit 4.3 x 300.

Measure for screw length using either the calibrations on the Drill Bit 4.3 x 300 or by removing the Drill Sleeve 8.6/4.3 and using the Depth Gauge for Driving End, SP/DF. Attach the appropriate length screw to the end of the Atlas® T-Locking Screwdriver 4.75mm (I0608.475) and insert through the Locking Screw Sleeve 11/8.6 until the laser etched ring on the screwdriver reaches the back of the Locking Screw Sleeve. Attach the T-Handle to the Atlas® Screwdriver 4.75 A/F (I0609.475) and tighten the screw by hand.

Proximal Locking: Dynamic

With the nail countersunk approximately 10mm, make a small incision at the site of screw entry and insert the Locking Screw Sleeve 11/8.6 and Drill Sleeve 8.6/4.3 through the dynamic slot on the Proximal Aiming Device down to bone. Drill both cortices with the Drill Bit 4.3 x 300. Screw measurement and insertion follows the previously described technique.

Surgical Technique - continued

Proximal Locking: Compression

With the nail countersunk approximately 10mm, lock the nail distally first (see below) to ensure effective compression and insert a screw through the proximal dynamic slot as previously described. Remove the Locking Screw Sleeve 11/8.6 and Screw Driver. Insert the Atlas SP Compression Bolt into the connection Bolt at the top of the nail until it contacts the most proximal 5.0mm locking screw. Turn the Compression Bolt clockwise by the Universal Wrench or Wrench for Connection Rod to drive the locking screw distally and compress the fracture up to 7mm.

Distal Locking

Distal locking is typically approached from the medial side using a free hand technique. Confirm fracture reduction and align the C-Arm in either the AP or lateral position depending on which locking screw is to be inserted. Obtain a "perfect circle" image of the locking hole and use a blunt object to approximate the location of the locking hole by dimpling the skin.

Make a stab incision at the site, insert the Drill Bit 4.3 x 150 for 10 mm diameter nail and drill both cortices. Measure for screw length using the Atlas® Depth Gauge for Non-Driving End, SP/DF (I0607.01). Alternatively, leave the Drill Bit 4.3 x 150 for 10 mm diameter nail in place, insert the Atlas® Drill Sleeve 4.3 mm (I0603.43) down to bone, and read the exposed calibrations off the drill. Insert the appropriate length screw using the Screwdriver assembly.

Note: For 8.5mm diameter nail distal locking - use SP Drill Bit 4 x 150 and Atlas® SP Drill Sleeve 4mm (I0603.04) and follow the same technique as the 10mm nail.

Surgical Technique - continued

Atlas® Nail Cap Insertion, Optional

Remove the Drill Guide/Proximal Aiming Device assembly. Attach the selected Nail Cap to the Atlas® End Cap Holder A/F 4.75 (I0608.00) and insert into the top of the nail. Use Screwdriver 4.75 A/F (I0609.475) for final tightening.

A Nail Cap cannot be used if a locking screw is inserted in the dynamic locking position. The tip of the Nail Cap will contact the locking screw and prevent complete engagement of the Nail Cap with the nail.

Note: If cross-threading occurs, rotate the Nail Cap counterclockwise until its threads line up with those of the nail. Proceed with insertion until tight.

Nail Cap Insertion Instruments

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
End Cap Holder A/F 4.75
I0608.00

ATLAS® Ti TFN/FFN
Closing Cap

Instruments for Implant Removal

Atlas®
Guide Pin, 3.2 x 300
I0581.3230

Atlas®
Nail Extractor
I0600.00

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

Atlas®
Driving End Cannulated Drill, 12.8/3.2
I0583.1232

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
Sliding Hammer
I0611.00

Atlas®
Flexible Driving End Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Open Wrench 11mm A/F
I0599.11

Surgical Technique - continued

Nail Extraction, Optional

Standard Technique

Remove the Nail Cap if implanted and all of the distal locking screws with the Atlas® Screwdriver 4.75 A/F (I0609.475) / Atlas® Q. C. T-Handle (I0585.00) / Atlas® Coupling Adaptor (I0586.00) assembly. Remove all of the proximal locking screws except for one in the same manner.

Thread the Atlas® Nail Extractor (I0600.00) into the top of the nail. With the help of Atlas® Open Wrench 11mm A/F (I0599.11) remove the remaining proximal locking screw and then extract the nail with a back-slapping motion using the Sliding Hammer.

Percutaneous Technique

This technique assumes the absence of a Nail Cap. Remove all distal locking screws and all but one of the proximal locking screws as previously described. Under fluoroscopy, insert a Guide Pin 3.2mm into the top of the nail on power or by hand. Make a 2cm incision around the pin and advance the Driving End Cannulated Drill 12.8/3.2 over the pin and into the top of the nail to remove any bony in-growth.

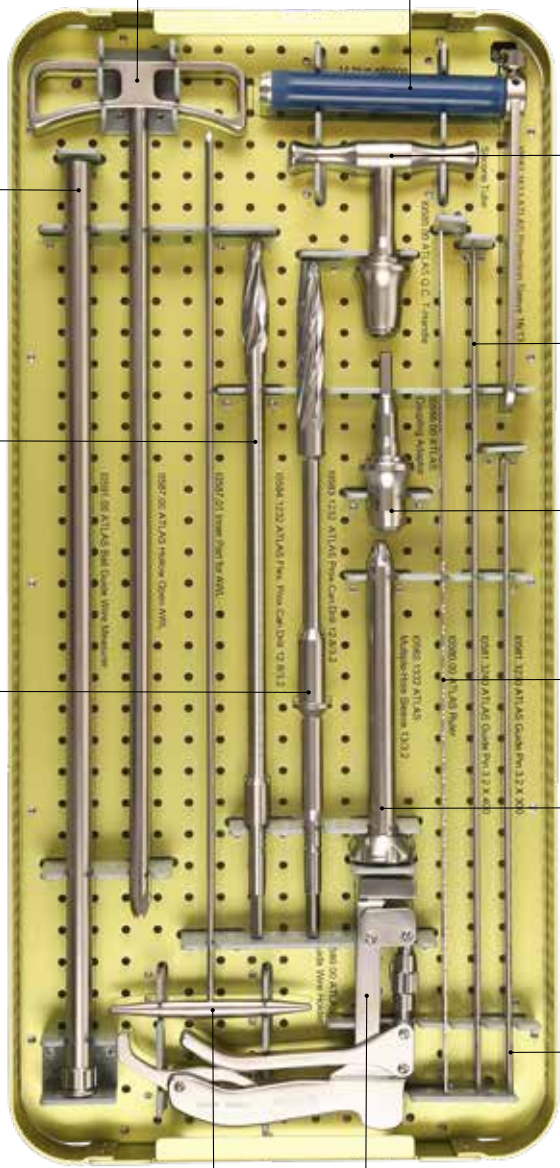
Thread the Atlas® Nail Extractor (I0600.00) into the top of the nail. Remove the remaining proximal locking screw and then extract the nail with a back-slapping motion.

Note: The tip of the Driving End Cannulated drill 12.8/3.2 is straight for approximately 1cm before flaring out. It is this portion of the Driving End Cannulated drill 12.8/3.2that enters the top of the nail.

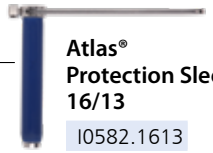
Catalogue Information

Instrument Set

Instruments for Tibial Fracture Nail Suprapatellar - Ti



Atlas®
Hollow Open Awl
I0587.00



Atlas®
Protection Sleeve, 16/13
I0582.1613

Atlas®
Q. C. T-Handle
I0585.00

Atlas®
Ball Guide Wire Measurer
I0591.00

Atlas®
Guide Pin, 3.2 x 400
I0581.3240

Atlas®
Flexible Driving End Cannulated Drill, 12.8/3.2
I0584.1232

Atlas®
Coupling Adaptor
I0586.00

Atlas®
Driving End Cannulated Drill, 12.8/3.2
I0583.1232

Atlas® Ruler
I0580.00

Atlas®
Multiple Hole Sleeve, 13/3.2
I0582.1332

Atlas®
Guide Pin, 3.2 x 300
I0581.3230

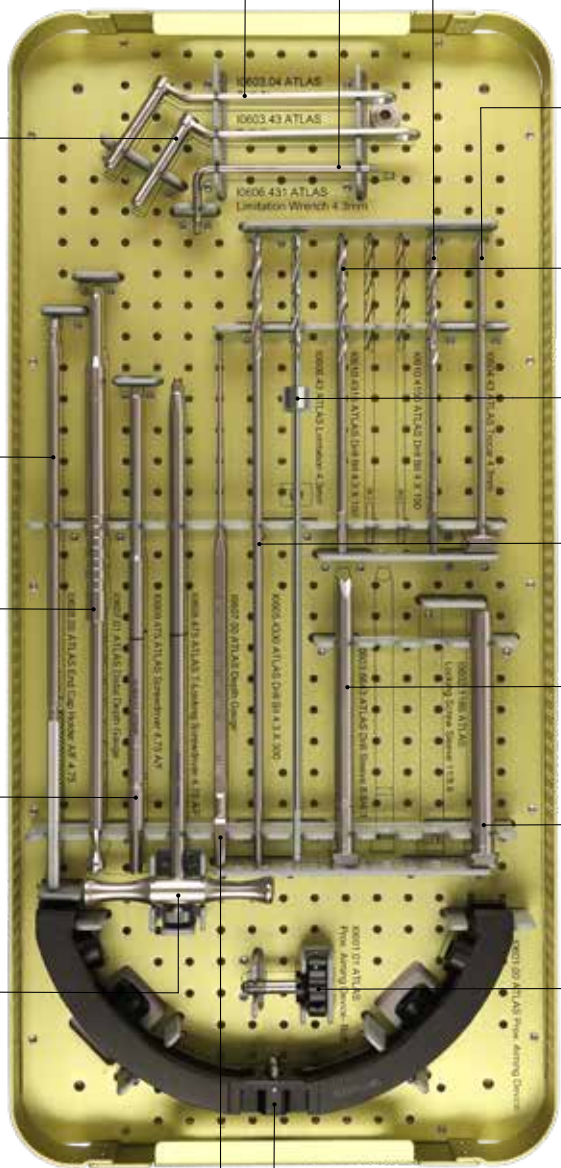
Atlas®
Hollow Open Awl, Inner Part
I0587.01

Atlas®
Guide Wire Holder
I0589.00

Catalogue Information - continued

Instrument Set

Instruments for Tibial Fracture Nail Suprapatellar - Ti, Continued



Atlas®
SP Drill Sleeve 4mm
I0603.04

Atlas®
Drill Sleeve 4.3 mm
I0603.43

Atlas®
End Cap Holder A/F 4.75
I0608.00

Atlas®
Depth Gauge for Non-Driving End, SP/DF
I0607.01

Atlas®
Screwdriver 4.75 A/F
I0609.475

Atlas®
T-Locking Screwdriver, 4.75 mm
I0608.475

Atlas®
Depth Gauge for Driving End, SP/DF
I0607.00

Atlas®
SP Proximal Aiming Device
I0601.00

Atlas®
Limitation Wrench 4.3mm, 3mm A/F
I0606.431

Atlas®
Drill Bit 4 x 150
I0610.4150

Atlas®
Trocar 4.3mm
I0604.43

Atlas®
Drill Bit 4.3 x 150
I0610.4315

Atlas®
Limitation 4.3 mm, 3mm A/F
I0606.43

Atlas®
Drill Bit 4.3/300
I0605.4330

Atlas®
Drill Sleeve 8.6/4.3
I0603.8643

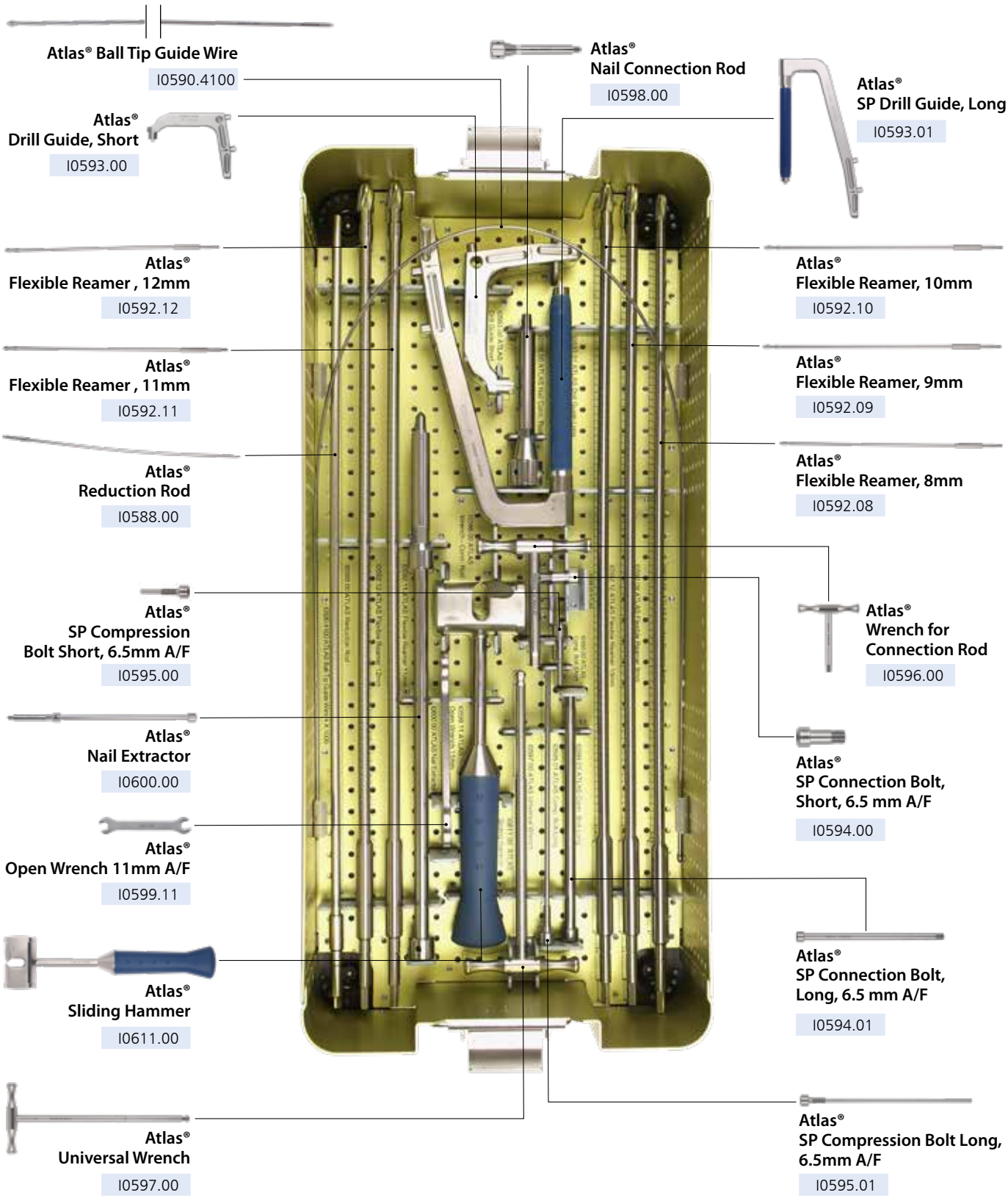
Atlas®
Locking Screw Sleeve, 11/8.6
I0602.1186

Atlas®
Aiming Device, Bolt
I0601.01

Catalogue Information - continued

Instrument Set

Instruments for Tibial Fracture Nail Suprapatellar - Ti, Continued



Important Information on ATLAS™ Tibial Fracture Nail Suprapatellar For use by an Accredited Orthopedic Surgeon only

Device Description:

The ATLAS™ TFN (Tibial Fracture Nail) Suprapatellar is designed to handle tibial fracture indications in diameters 8.5mm, 10mm in length range from 28cm to 40cm. It consists of tibia nails in the preceding length and diameter sizes, locking screw, and nail cap screw. The ATLAS™ TFN Suprapatellar 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 TFN Suprapatellar, Screws and Caps are made from titanium-vanadium alloy Ti-6Al-4V material complying to ASTM F136/ ISO 5832-3, Nail consist of UHMWPE Bush.

The ATLAS™ TFN (Tibial Fracture Nail) Suprapatellar is supplied in sterile condition. Locking screw & Nail Cap Screw supplied in non- sterile condition.

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 TFN Suprapatellar are essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. TFN Suprapatellar 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™ TFN Suprapatellar 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 nailing of impending pathological fractures.

Contraindications:

ATLAS™ TFN Suprapatellar 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

Preoperative Planning:

1. Surgical Technique: Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants.

2. Implant Selection: Selection of the proper size, shape and design of the complete set of Implants and Instruments is a crucial parameter for success of the operative procedure and to insure effective treatment of patients that must be ensured by the operative surgeon. All Implants, Instruments and its sub-assemblies should be checked for intact packaging on receipt. All implants and instruments must be carefully checked for completeness and should be carefully inspected for compatible dimensions.

3. The following factors should be considered:

• A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.

• A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.

• Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.

• If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.

• Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

4. Implant Alterations: Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with manufacturer's instructions. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

5. Component Compatibility: Components such as nails, screws are available in many styles and sizes and are manufactured from various types of metals. Use only components made from the same material together unless specifically approved by the manufacturer. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by a manufacturer of the components. Refer to manufacturers' literature for specific product information.

6. Implant Removal: The patient should be advised that a second procedure for the removal of implants may be necessary.

Warnings:

1. The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use largest possible components or improper positioning or the use of excessive forces during implantation may result in loosening, bending, cracking, or fracture of the device or bone or both.

2. The length of time for non or limited weight bearing should be correspondingly increased until solid bony union occurs.

3. The threads of an implanted screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.

4. Do not mix dissimilar metals. Use only ATLAS™ TF Titanium screws with ATLAS™ TFN Suprapatellar Titanium Nails.

5. Implant guiding devices such as guide pins, guide wires etc. should not be re-used to prevent potential damage to the implants, inaccurate measurements and other possible errors.

Postoperative Care:

1. Care Prior to Bony Union: Immobilize and/or externally support skeletal structures that have been implanted with surgical metallic implants until skeletal union is observed. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking of the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries. PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.

2. Care Subsequent to Bony Union: Even after bony union, the patient should be cautioned that a fracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of any locking holes provided in the nail. This would typically include distal most proximal locking hole and the proximal most distal locking hole. Greater stress is placed on the nail at these hole locations in these situations.

3. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

4. Implant Removal: The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Adler suggests that whenever possible, and after bony union is observed that implants be removed. Removal is particularly advisable for younger and more active patients. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not recommended. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue.

- Corrosion combined with localized pain or tissue reaction.
- Migration of position of the implant, resulting in injury.
- Bending, loosening or breakage of implant components, which may make removal more difficult or even impractical.
- Possibly increased risk of infection.
- Bone loss due to stress shielding.
- Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

Magnetic Resonance Imaging (MRI) Safety:

ATLAS™ TFN Suprapatellar System has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

No Reuse:

Metallic surgical implants are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation. Single use devices should not be reused due to risks of breakage, failure or patient infection.

Possible Adverse Effects:

1. Loosening, bending, cracking or fracture of the implant components.
2. Infections, both deep and superficial.
3. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
4. Leg length discrepancies and subsequent patient limp may occur.
5. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
6. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
7. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas may result from the surgery and concomitant use of internal fixation devices.
8. Implant Migration related to loss of fixation or poor fracture reduction.
9. Screw Back-out.
10. Pain at the surgical site as a normal consequence of the operative procedure.

Packaging and Labeling:

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Implant components supplied in sterile condition are packed in Double Blister with lid and are indicated as STERILE R on the label which must be properly sterilized by GAMMA Irradiation method. Also, Implant components supplied in non-sterile condition are packed in unwoven polyethylene and are indicated as NON STERILE on the label which must be properly sterilized by suitable method prior to surgery as indicated below. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Sterilization Instructions:

ATLAS™ TFN Suprapatellar are sterilized by gamma irradiation. The components of system are supplied in sterile to a Sterility Assurance Level (SAL) of 10-6. The method of sterilization is noted on the package label. The component of system supplied in non- sterile condition; Remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

Sterility and Handling for components of system supplied in sterile condition:

• Correct handling of the implants prior to and during surgery is decisive for the success of surgical procedure. Implant components supplied in pre-sterile condition are individually packed and correspondingly labeled, as gamma irradiation sterilized (gamma sterilization, 25 kGy min).

• Prior to opening a sterile packed implant, verify that the package is undamaged and shows no signs of tampering, the "sterile" sticker that seals the outer box is intact, the sterility indicator button is of the right color indicating a properly sterilized implant (red in case of Gamma Irradiation) and that the implant is within the sterility period indicated on the label.

• Ensure that the surfaces of the implants are not damaged under any circumstance. Under no circumstance should the implants be used that have been damaged, surgically implanted or removed.

Recommended steam sterilization cycle parameters for components of system supplied in non-sterile condition:

Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes and a minimum vacuum drying time of 30 minutes.

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

Storage Conditions:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

Important Information:

The operative surgeon is responsible for carrying out the surgical procedure correctly and must have mastered the acknowledged updated and latest operating techniques related to the type of surgery being performed, in theory and practice. Complications due to incorrect diagnosis and operating technique and limitations of the method of treatment or lack of aseptic conditions are not the responsibility of the manufacturer.

In addition to physiotherapy and muscle training, it is the responsibility of the operating surgeon to educate the patient about the limitations of metallic implants and precautions to be followed to avoid unnecessary stresses to the implant.

Detailed instructions must be given to the patient concerning the use and limitations of the implanted device. If partial weight bearing is required or recommended, the patient must be warned that loosening, bending and / or breakage of the device are complications which may occur due to early or excessive weight bearing or muscular activity. The patient should be warned to avoid falls or sudden jolts of any nature. If the patient is demented, debilitated or otherwise unable to use crutches or other supporting devices, the risk of loosening, bending and / or breakage may be increased. The patient must be made aware of this fact.

Any retrieved implant / External Fixator component should be treated in such a manner so as to render further use / re-use of the components, impossible. Used implants / External Fixator Component that appear undamaged may have internal and external defects caused through accumulated stresses while in use. Reuse of implant components predisposes such components to premature failure.

Implant components from one manufacturer should not be used with those of another.

Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to

adler-customer.care@adler-healthcare.com.

Manufactured & marketed by
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