

austofixUTN

UNIVERSAL TIBIAL NAIL

Surgical Technique



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Disclaimer

This document is intended to be read by experienced orthopaedic trauma surgeons familiar with I.M. Nailing of the long bones.

This publication is intended as the recommended procedure for using the Austofix nailing system. It offers guidance only. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

For further advice please contact your local Austofix representative.
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Introduction

Austofix is an Australian medical device manufacturer and distributor specialising in orthopaedic trauma. Since 1993, Austofix has designed, manufactured and marketed its range of implants throughout the world.

In collaboration with Australian surgeons, Austofix has introduced innovative, cost-effective implant systems that improve patient outcomes whilst supporting safe and efficient operating procedures. Austofix continues to develop its range of products through collaboration with new expertise, technologies and partnerships with surgeons and scientific institutions.

Austofix products are distributed globally from our offices based in Thebarton, Australia. Our well-trained product specialists and customer service staff are available for all customer enquiries and product support and understand the needs of the orthopaedic market.

Austofix is dedicated to excellence in every aspect of medical device design, manufacture and product service.

austofix **UTN** UNIVERSAL TIBIAL NAIL

The Austofix Universal Tibial Nail is based upon the successful Austofix tibial nail range. With a 15 year clinical history and unique Austofix design principles, the Universal Tibial nail incorporates the best features of the Austofix Cannulated and Proximal Tibial nails into one user friendly new generation system for the treatment of most tibial fractures.

This “universal” IM nail has been designed to offer treatment options for fractures of the tibial shaft as well as metaphyseal fractures of the proximal and distal tibia. A distal anteroposterior hole has been added to enable fixation of even the most distal

fractures. The proximal oblique screw holes of the nail are a standard feature of the cannulated Universal Tibial Nail, reducing inventory requirements.

As with all Austofix IM nails, the instrumentation and surgical procedure are simple and robust, allowing for the fastest possible operative times.

Design Details

Nails

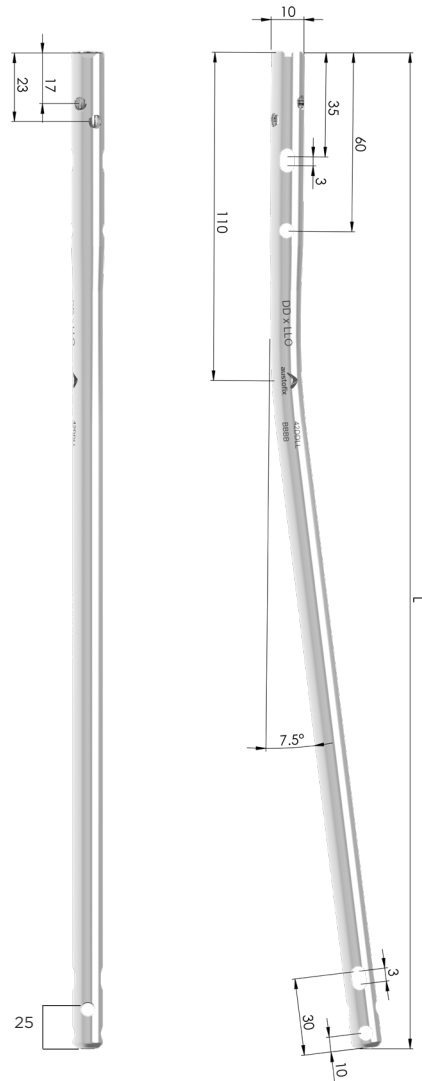
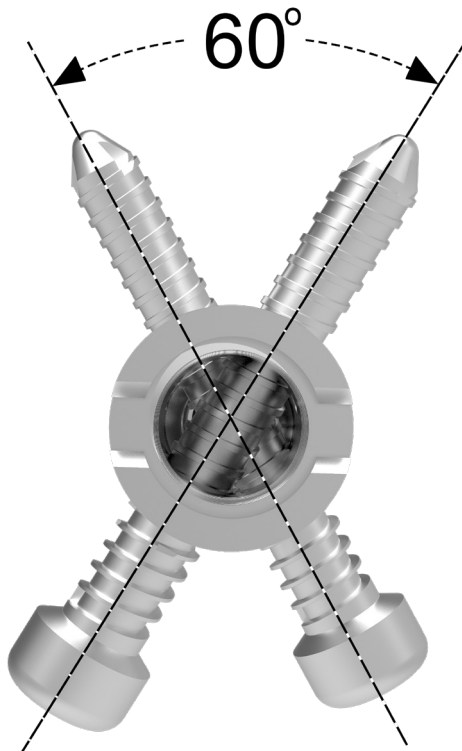
The Austofix Universal Tibial Nail incorporates the best features of the Austofix Cannulated and Proximal Tibial nails into one new generation system for the treatment of most tibial fractures.

- Universal design.
- Length: 260mm to 420mm.
- 8, 9, 10 & 11mm titanium cannulated nails are made from ISO 5832-3 (Titanium).

All nails have two proximal and two distal medio-lateral transverse holes. Each hole has a slot for optional 3mm dynamisation and easier distal targeting.

An anteroposterior distal hole enables nailing of fractures only 25mm above the ankle joint.

The cannulated nails have proximal oblique holes for nailing fractures 30mm below the knee joint. These holes are tapped so that 4.8 screws (which have a 5.4mm proximal thread) can be fully screwed in, creating an angular stable construct.



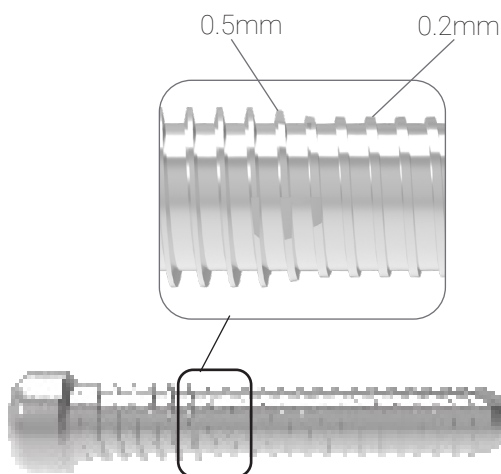
Screws

All Austofix screws are made from ISO 5832-3 Titanium (Ti).

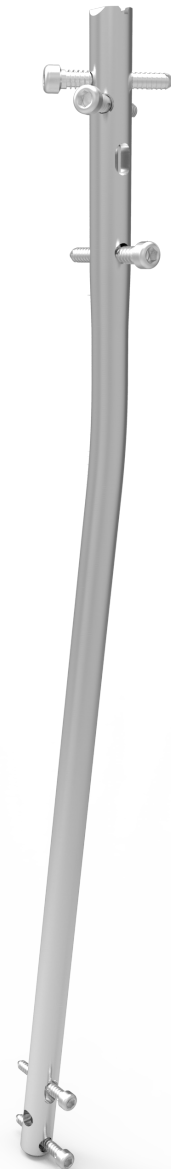
- The 4.0mm Locking Screws are used for all Transverse holes in the 8mm and 9mm nails.
- The 4.8mm Locking Screws are used in all holes of the 10mm and 11mm Nails and oblique holes in 8mm and 9mm.
- Both 4.0mm and 4.8mm screws are fully threaded for ease of insertion, but with minimal loss of bending strength. The first 3/4 of the thread is shallow (0.2mm), being just enough to draw the screw in as it is turned. The last 1/4 expands (0.5mm) to grip the lateral cortex and resist backout. This part is larger than the hole in the nail. The core of the thread (minor diameter) matches in both parts, so the screws can be smoothly inserted and extracted.



4.0mm Locking Screw



4.8mm Locking Screw



Indications & Pre-operative Planning

Where possible, the nail is selected preoperatively. The width of the isthmus is measured on the radiographs (allow 10% to 15% for X-ray magnification). The length of the nail is determined by measuring the injured limb in traction or by measuring the uninjured limb. For very distal fractures where more accurate measurement is necessary, the Nail Length Guidewire Gauge (600069) can be used, see use of Gauge on page 9.

Cannulated 8mm nails are appropriate for small patients or those with exceptionally narrow medullary canals, and 9mm diameter cannulated nails are generally used for patients of average to large build.

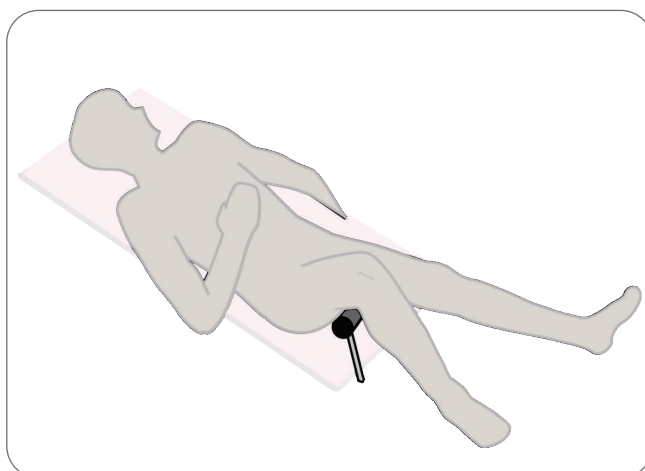
Cannulated nails, 10mm diameter are suitable for most patients, reserving the 11mm nails for exceptionally heavy patients or those with large medullary canals.

Decide pre-operatively whether reaming is necessary, and when in doubt it is safer to ream to 1.5mm oversize. Distal fractures and comminuted fractures place extra stress on the screws and should usually be treated with 10mm or 11mm nails. These nails use the larger 4.8mm screws.



Patient Positioning

Any standard tibial nailing position can be used, with the knee flexed to at least 90°. Traction can be applied by strapping the foot to a plate or by using a calcaneal pin.



Incision & Bone Preparation

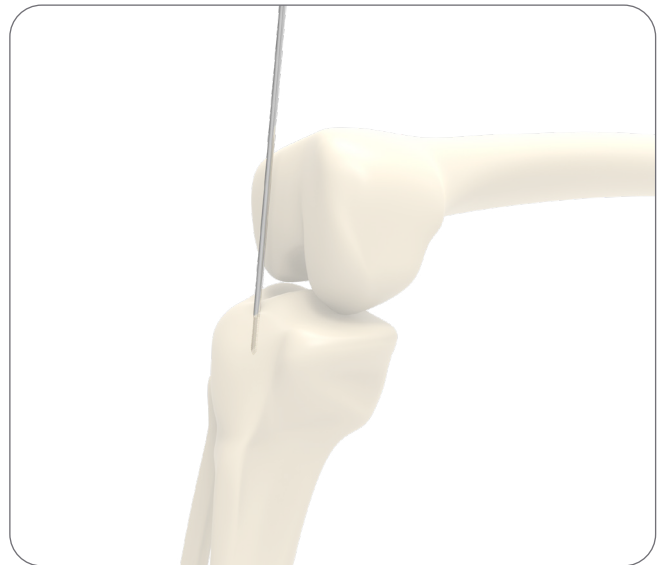
Incision

The incision can be made either by splitting the patellar tendon or passing along the medial border of the patellar tendon.

Entry Point

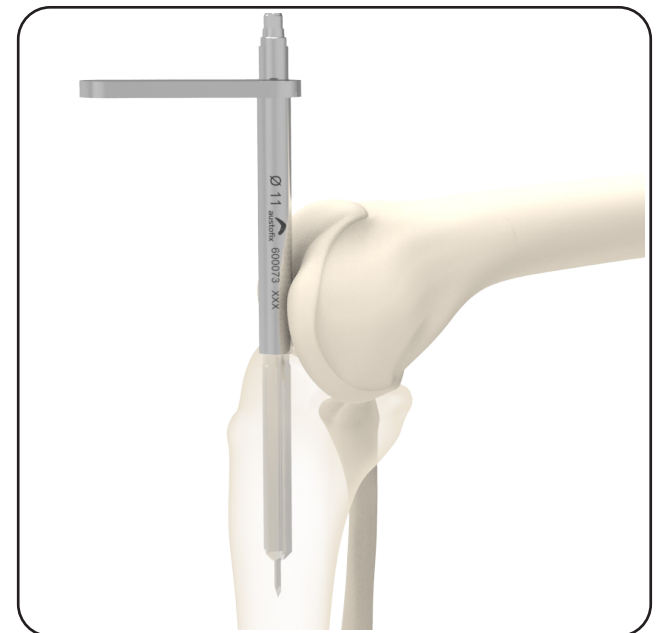
Insert a 2.5x250mm Guide Pin (512525) for 2-3cm at the anterosuperior corner of the tibia. Confirm the position on anteroposterior and lateral X-ray views and re-insert the Guide Pin if necessary.

Note: The Cannulated Awl (600040C) or 8mm Hand Reamer (600008) may be used to assist in preparation of the entry hole.



Drilling Hole Entry

Pass the 11mm Cannulated Drill Reamer (521121) through the 11mm Tissue Guard (600073) and over the Guide Pin. Hold the Tissue Guard against the bone and slowly advance the 11mm Drill Reamer for approximately 70-100mm, frequently checking alignment on X-ray.

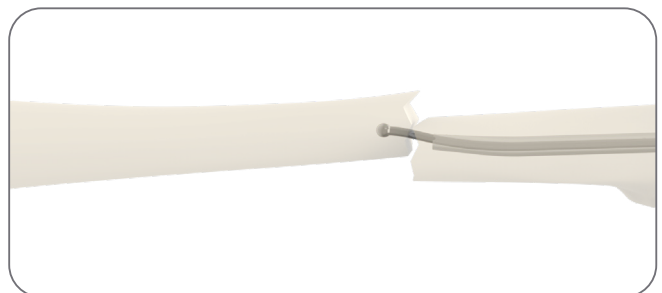


Inserting Ball-tipped Guidewire

While keeping the Tissue Guard against the bone, remove the 11mm Cannulated Drill Reamer and Guide Pin. Insert a 3x900mm Ball-tip Guidewire (533900) to the depth intended for the nail. If difficult to insert, form a pathway in the medullary canal with the 8mm Hand Reamer (600008). If it cannot be passed across the fracture, ream the proximal fragment with 11mm Flexible Reamers (543110)* and insert the Guidewire Director (531002) to the fracture site. Rotate and manipulate the Guidewire Director to align the Ball-tip Guidewire with the distal fragment. The Guidewire will fit through the nail and the connecting instruments. Hence, the Guidewire can be pulled back after nail insertion.

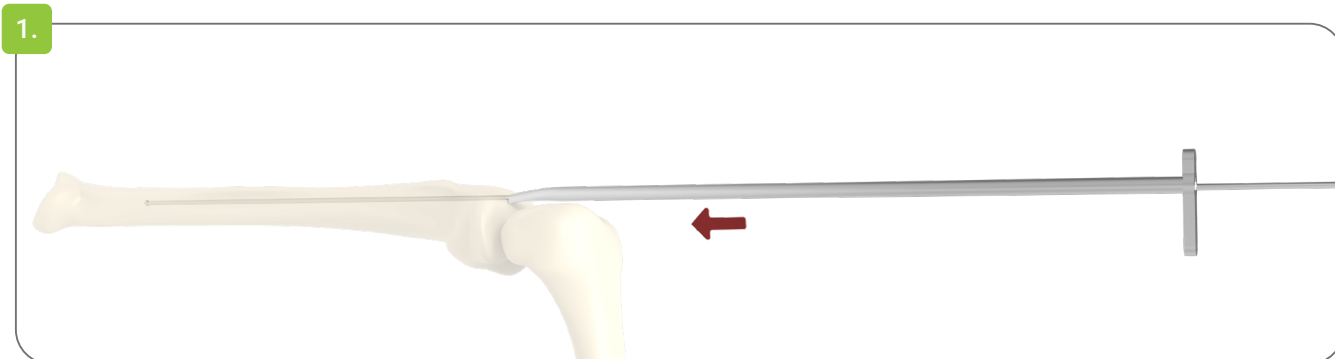
Note:

- If the guidewire is excessively bent, it may need to be changed to a straight wire after reaming.
- Flexible Reamer Tray (621050) supplied on request.

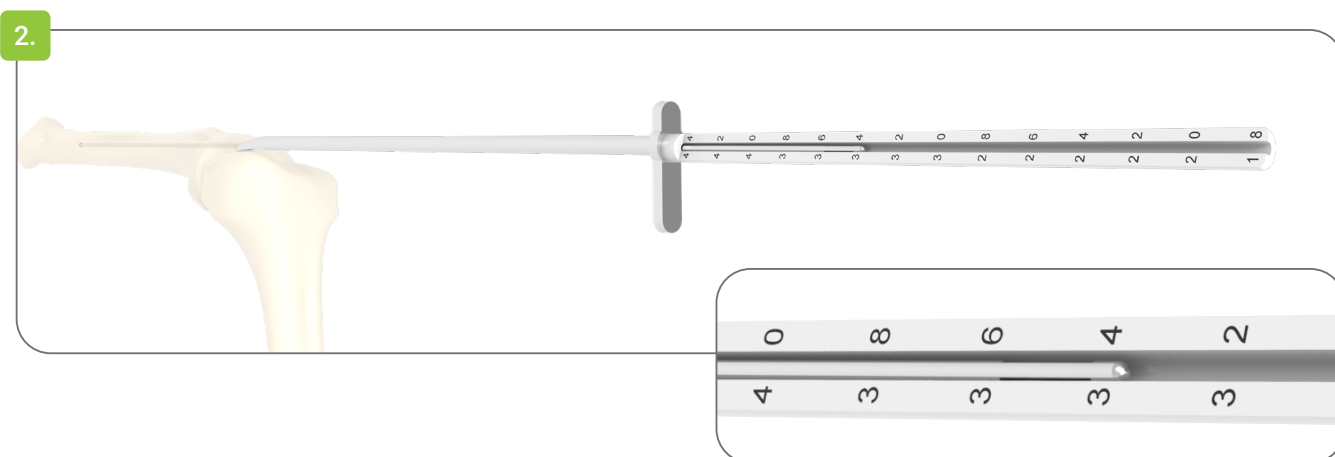


Nail Length Gauge

1. With the Ball-tip Guidewire inserted to the intended position of the nail, pass the Guidewire Director over the Guidewire to the entry point.



2. Use the Nail Length Guidewire Gauge (600069) to determine the appropriate length of nail.



Reaming

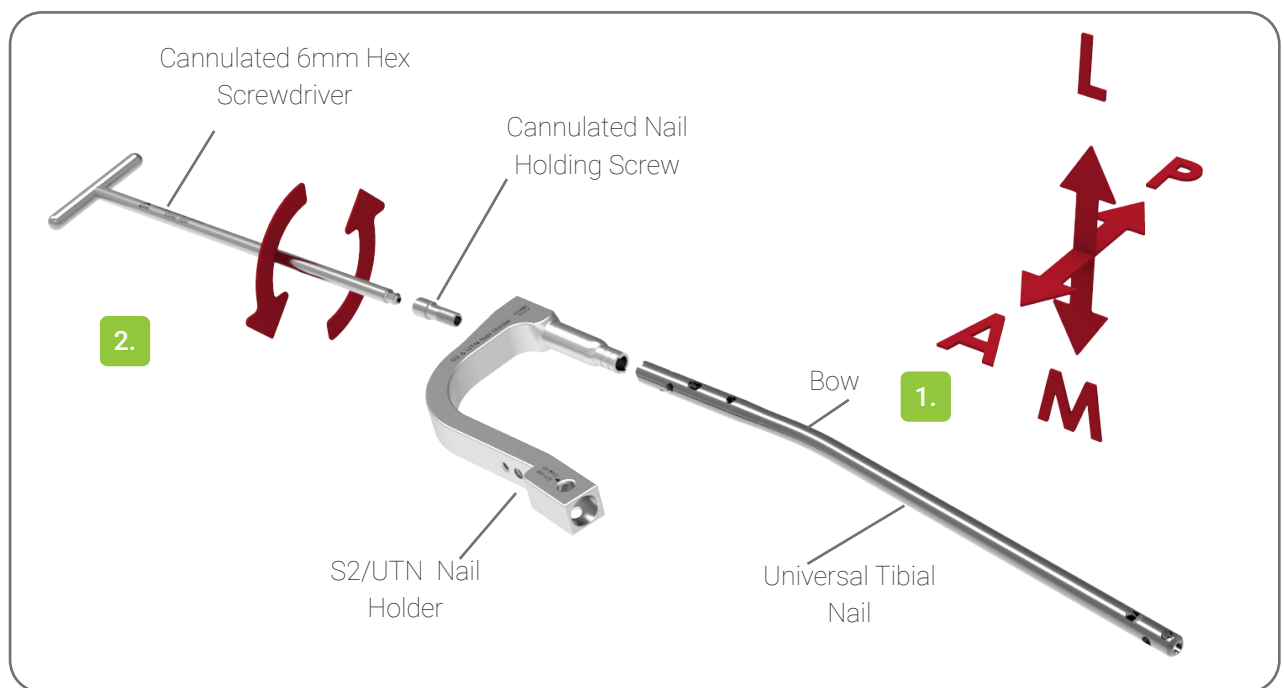
Pass a Flexible Reamer over the Ball-tip Guidewire and ream. Start with an 8mm or 9mm Reamer and progress in 0.5mm increments to 1-1.5mm more than the diameter of the nail selected. Repeatedly withdraw and advance the reamer. Clean the bone debris from the reamer head when not advancing easily.

Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer. The large end is pressed against the Guidewire until it is flush with the Drill, then the Guidewire Pusher is turned around so it can pass inside the Drill and Reamer shaft.

Instrument Assembly

1. As per diagram below, assemble the nail onto the UTN & S2 Nail Holder (600083) with the bow of the nail pointing in the posterior position.
2. Use the Cannulated 6mm Hex Ball Driver (600045) to pass the Cannulated Nail Holding Screw (600029) through the Universal Tibial Nail Holder and into the nail.

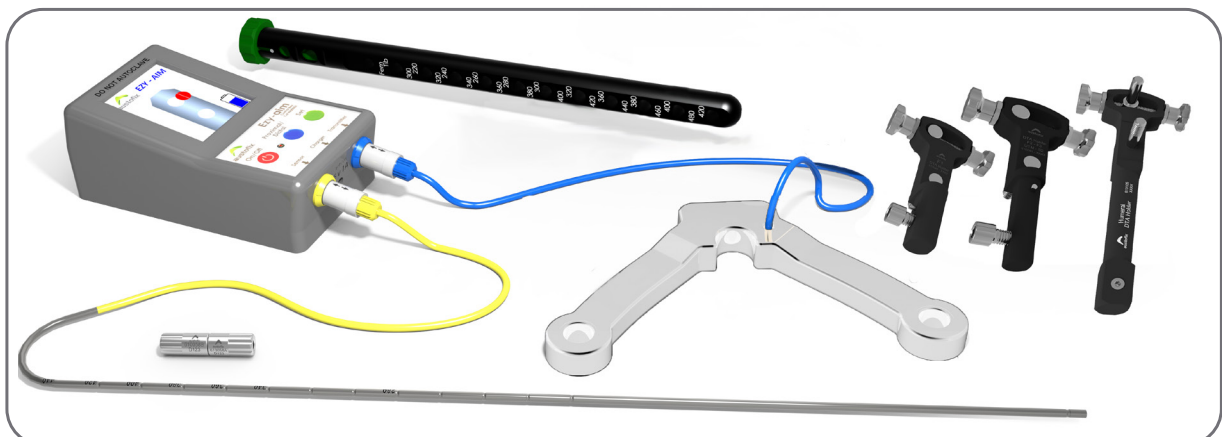
WARNING: Ensure nail is attached in the correct orientation



Ezy-Aim Distal Targeting System

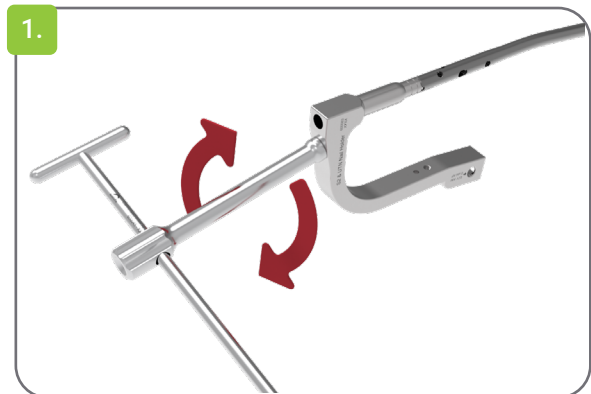
Please refer to the Ezy-Aim Distal Targeting System Surgical Technique for instructions on how to calibrate the cannulated UTN Nail for distal hole targeting.

Once calibrated, return to this Surgical Technique for further instruction on how to insert this nail.

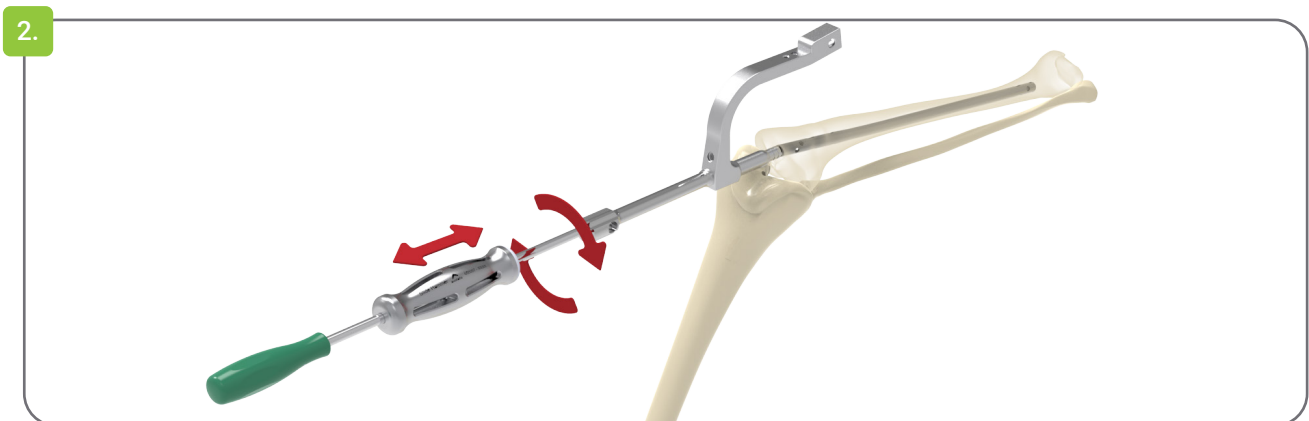


Nail Insertion

1. Attach the Impactor (600028) and tighten firmly with the Cannulated 6mm Hex Ball Driver (600045). A loose fit will risk breakage during hammering.



2. Insert the nail using a mallet. Check instruments for loosening and maintain tightness throughout hammering. Check progress on the Image Intensifier and manipulate the nail across the fracture site. If this causes difficulty, the nail can be withdrawn and advanced by attaching the Slide Hammer (600097) to the Impactor.



3. Insert the nail until lateral X-rays show it is beneath the bone surface.



Distal Screws

For the distal screws, either the Austofix Ezy-Aim Distal Targeting System or a freehand method can be used.

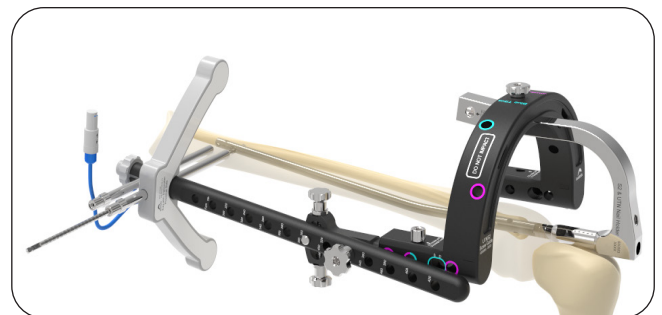
The Austofix Ezy-aim Targeting System reduces radiation exposure and improves targeting accuracy. Prior familiarisation with this system is recommended. Occasionally if nail bending is excessive, the range of adjustment of this Targeting System will be exceeded, and freehand targeting is required.

Austofix Ezy-Aim Distal Targeting System

The Ezy-aim Distal Targeting Instrument Set (SET-INS-EZY) is required.

The technique is described in the Austofix Ezy-Aim Distal Targeting System Surgical Technique.

Note: Requires the distal screws to be implanted before the proximal screws.



Freehand Targeting

It is assumed the surgeon is proficient in freehand targeting.

The Image Intensifier is aligned on the target hole and adjusted until a round image of the hole is obtained. A suitable long pointed instrument such as the 8mm Hand Reamer (600008) is used to determine the position for a short skin incision overlying the hole.

For 10 and 11mm Nails 4.8 Screws are required. Align the 4.5 x 340mm Drill (514534) on the hole and drill through. Care is needed to avoid flexing and drill breakage. A shorter 4.5 x 155mm Drill (514514) is available if preferred.

For 8 and 9mm Nails use the 3.7 x 270mm Drill (513727) and 4.0 Screws. The Drill Sleeve can be used as a tissue guard.

Use the Universal 3.7-4.5 Depth Gauge (610069) to determine screw length.

Compression Slot

If early dynamisation is indicated, such as in stable transverse fractures, place the screw in the lower part of the distal slot.

Proximal Screws

Proximal Transverse Screws

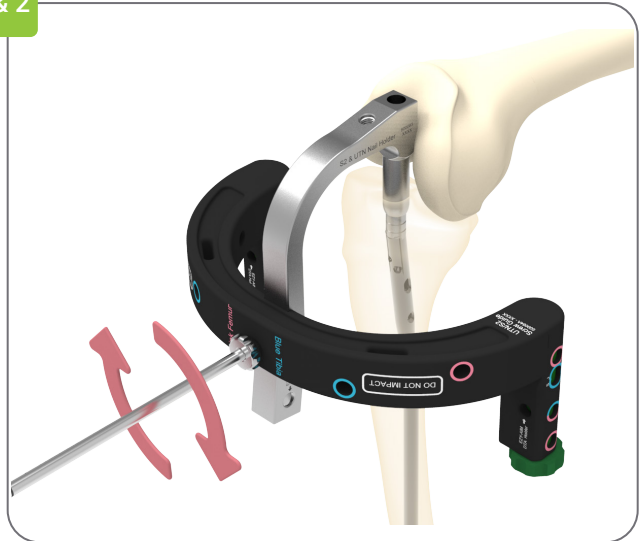
Either proximal or distal screws may be inserted first. However, the distal screws must be inserted first if:

- the Ezy-aim Distal Targeting System is used,
- the nail needs to be adjusted to correct distal targeting errors, and
- fracture impaction required by “backslapping” using the Slide Hammer Assembly.

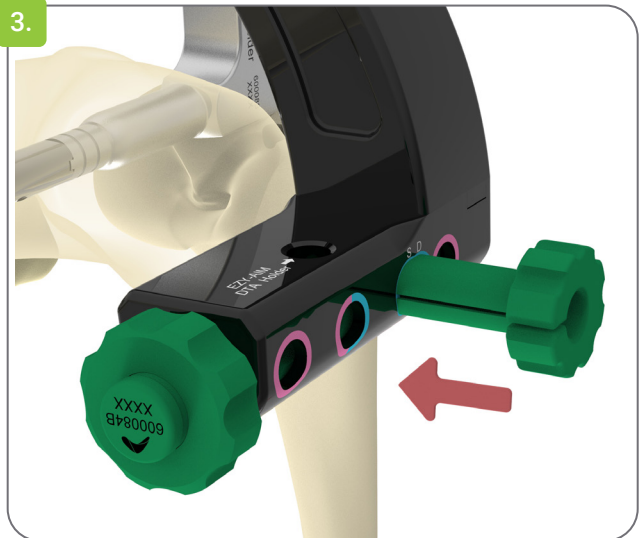
Note: UTN/S2 Screw Guide colour coded for different systems- Blue text for tibial and Pink text for femoral nail

1. Attach the UTN/S2 Screw Guide (600084A) with the Cannulated 6mm Hex Ball Driver (600045). Recheck the tightness of the Cannulated Nail Holding Screw (600029), then proceed according to the type of proximal fixation required.
2. Insert the UTN/S2 Screw Guide Locking Sleeve (600084B) in the UTN/S2 Screw Guide (600084A)
3. If using the proximal transverse hole, insert the 3mm Static Dynamic Insert (600084C) in the oval hole. According to whether Dynamic or Static mode is required, rotate the insert 180 deg.
4. Pass the assembled Outer Sleeve (610065), Drill Sleeve (610064) and Trocar (610063) through the guide hole in the Tibial Proximal Screw Guide, and through a 1cm stab wound. Push the Drill Sleeve up to the bone. Tighten the UTN/S2 Screw Guide Locking Sleeve (600084B) then remove the Trocar.

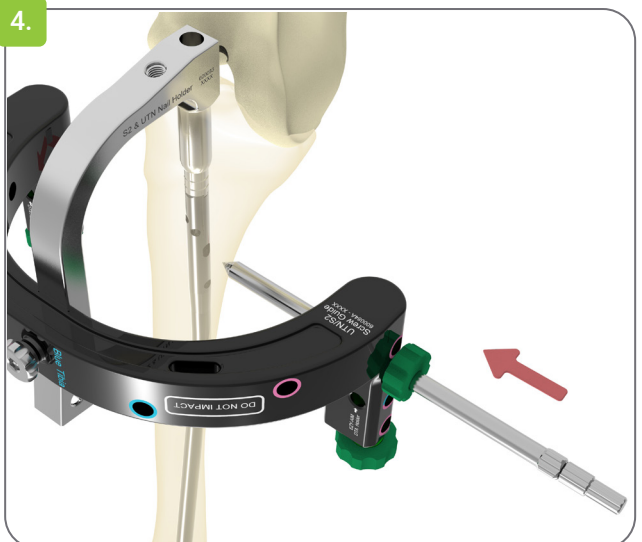
1 & 2



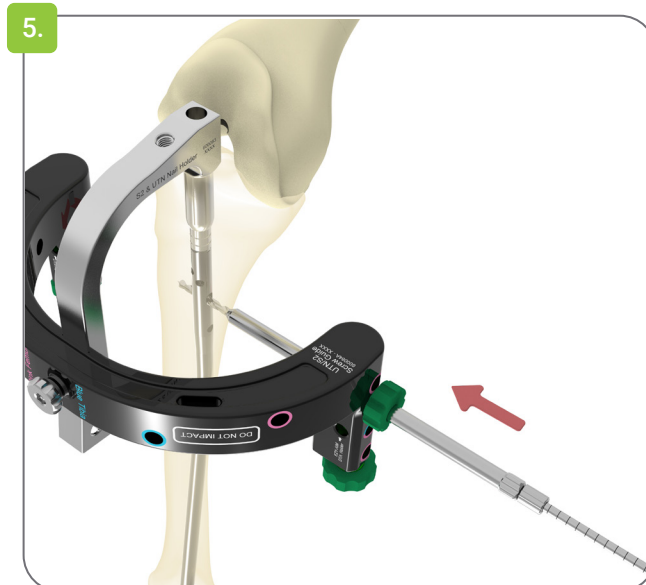
3.



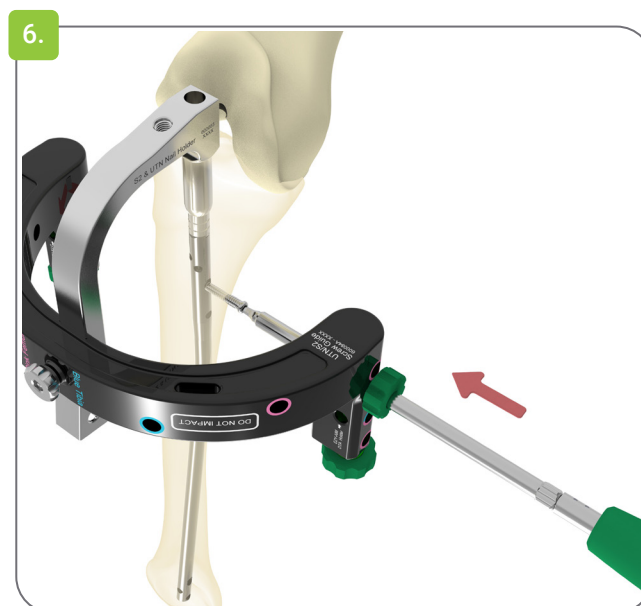
4.



5. The 3.7x270mm Drill (513727) (8 & 9mm nails) or 4.5x340mm Drill (514534) (10 & 11mm nails) is used to drill through to the far cortex. Note the length indicated on the depth scale marked on the Drill. Then drill through and add 5mm to determine the length of screw required. Alternatively, for more accuracy, check on X-ray when the drill is just protruding through the bone or remove the Drill Sleeve and use the Universal 3.7-4.5 Depth Gauge (610069).

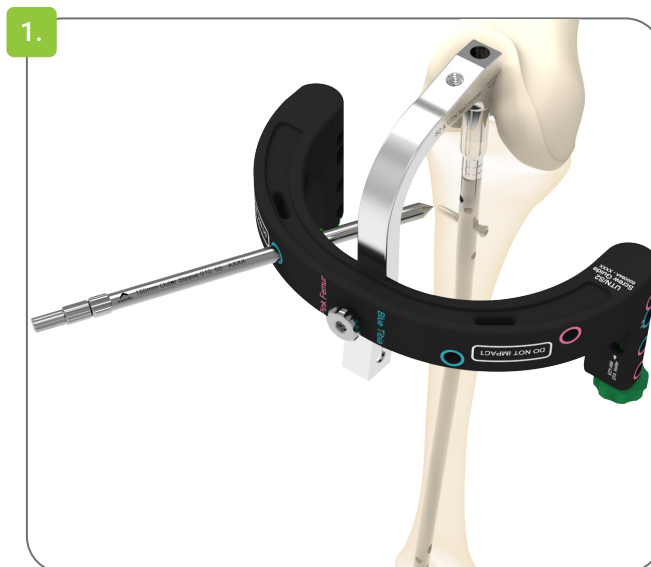


6. Remove the Drill Sleeve and insert a locking screw of the appropriate length, a 4.0mm locking screw for 8 and 9mm nails or 4.8mm locking screw for 10 and 11mm nails. Use the Power Screwdriver (610068) near to the mark indicated, then tighten by hand with the 3.5 Hex 250mm Screwdriver (610067).

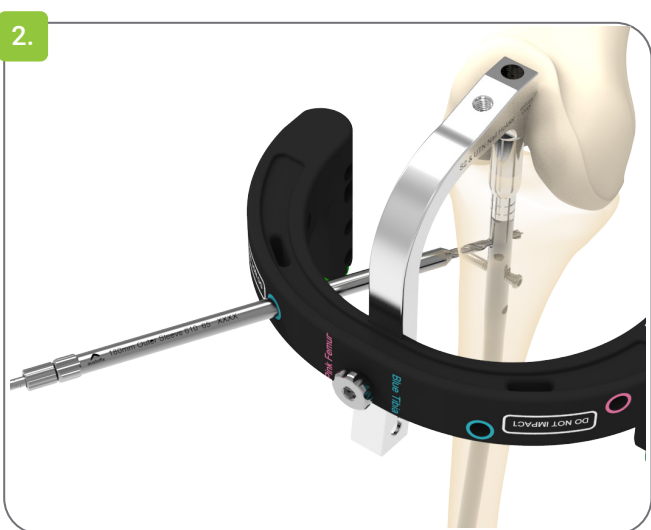


Proximal Oblique Screws

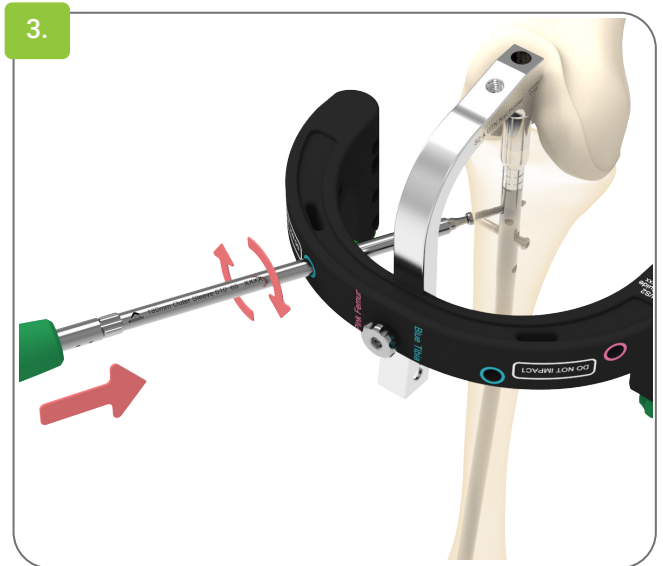
1. Pass the assembled Outer Sleeve (610065), Drill Sleeve (610064) and Trocar (610063) through either guide hole in the UTN/S2 Screw Guide then remove the Trocar.



2. Use the or 4.5x340mm Drill (514534) to drill through. Note the length indicated on the depth scale marked on the Drill. Remove the Drill Sleeve and if necessary for accurate depth measurement, use the Universal 3.7-4.5 Depth Gauge (610069).



3. Remove the Drill Sleeve and insert a 4.8mm Locking Screw of the appropriate length. Use the Power Screwdriver (610068) near to the mark indicated, then tighten by hand with the 3.5 Hex 250mm Screwdriver (610067).
4. Repeat steps 1, 2 and 3 for the other proximal oblique hole.



End Cap

To deter bone ingrowth End Caps can be inserted into the Nail using a 3.5mm Hex 250mm Screwdriver (610067).

Note: A Titanium End Cap length of more than 1mm can be used as necessary for Nail extension up to 20mm.



Aftercare

Postoperatively, no orthosis is normally necessary and elderly patients should be encouraged to gently take full weight on the leg. In young patients, with comminuted fractures, weightbearing should be restricted for the first six weeks.

Nail Extraction

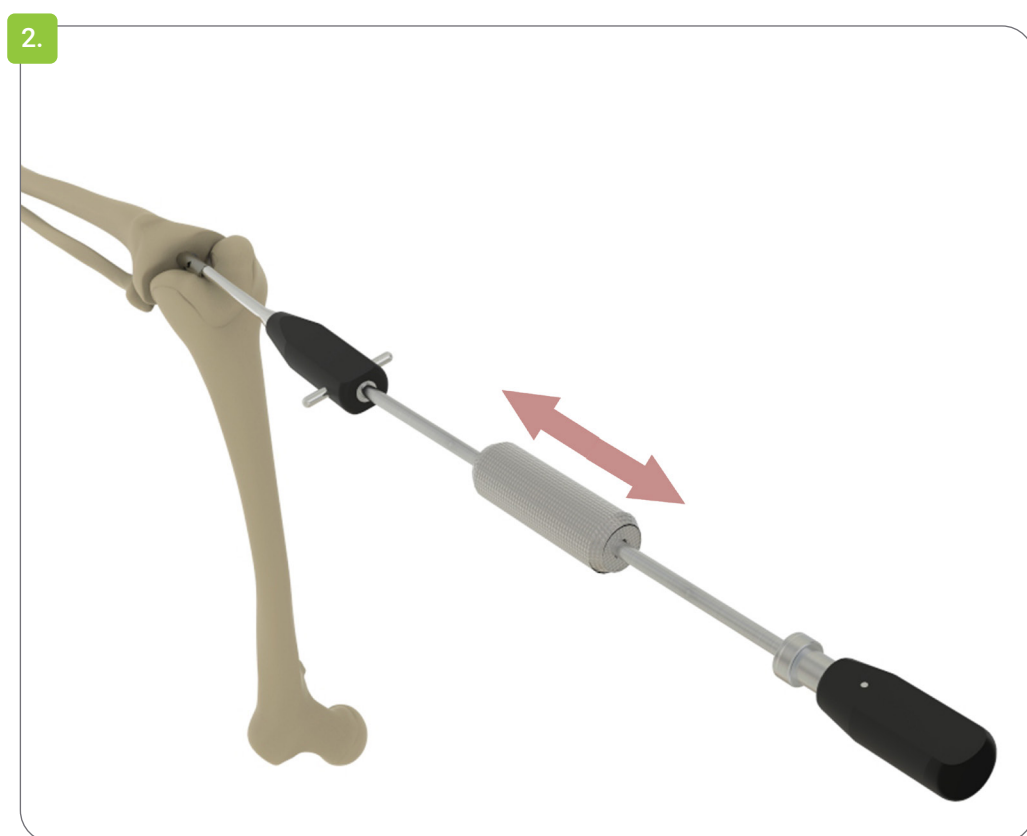
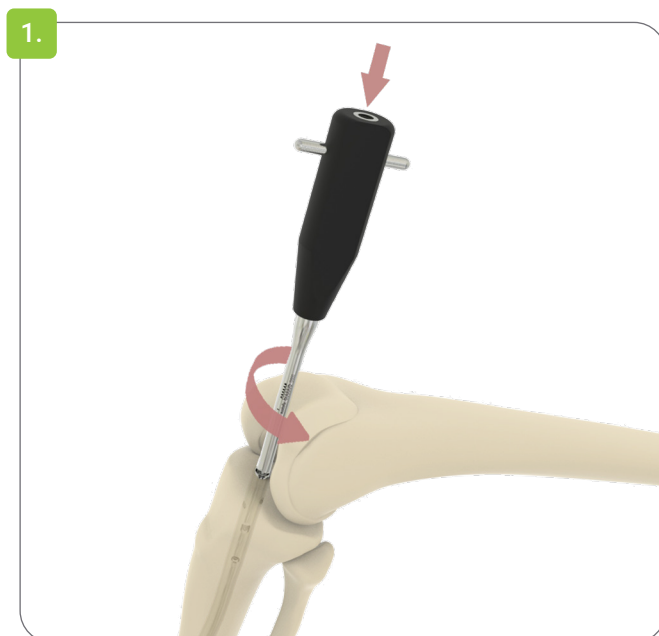
Screw Removal

Austofix screws are fitted with a conventional 3.5mm hexagon. They can be removed either with a conventional AO large fragment screwdriver or with the Austofix Screwdriver.

Nail Removal

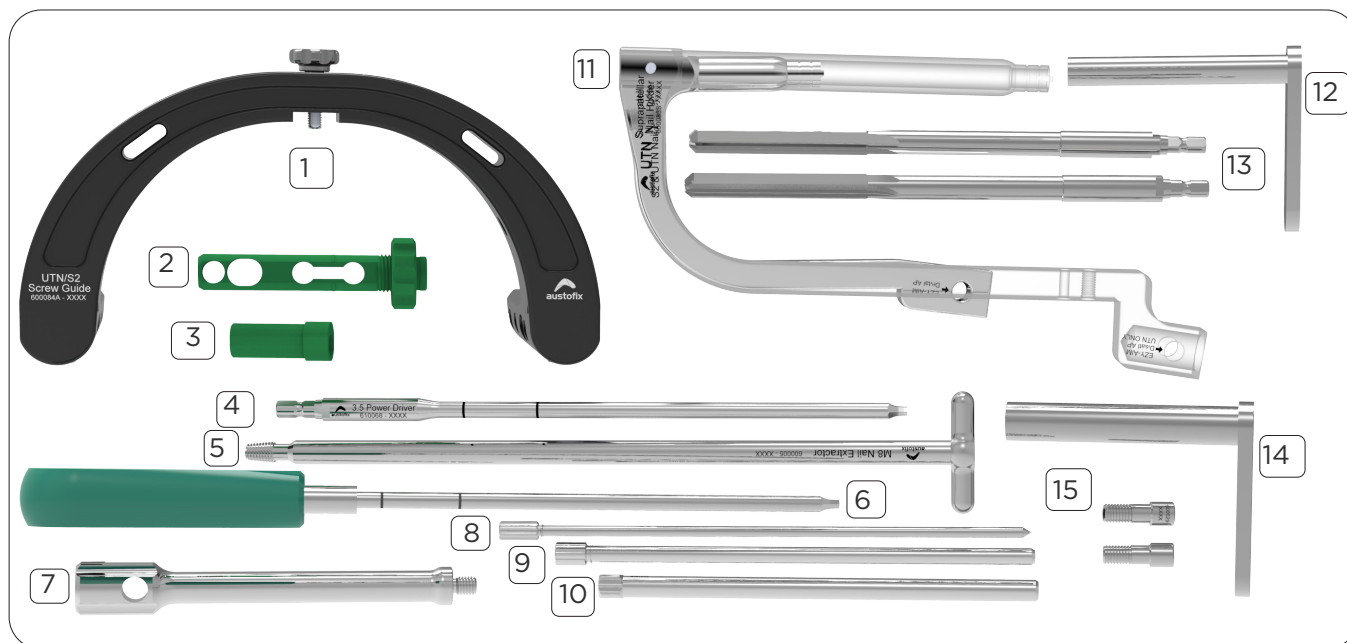
1. The Nail Extractor (600005) is screwed into the nail. The trocar tip facilitates entry.
2. Once firm in the nail, attach the slide hammer assembly onto the nail extractor and withdraw the nail.

Note: The Nail Extractor should be screwed into the nail before the last screw is removed, to avoid the problem of unwanted nail rotation or distal migration. Then the screw is removed and the Slide Hammer assembly is attached.



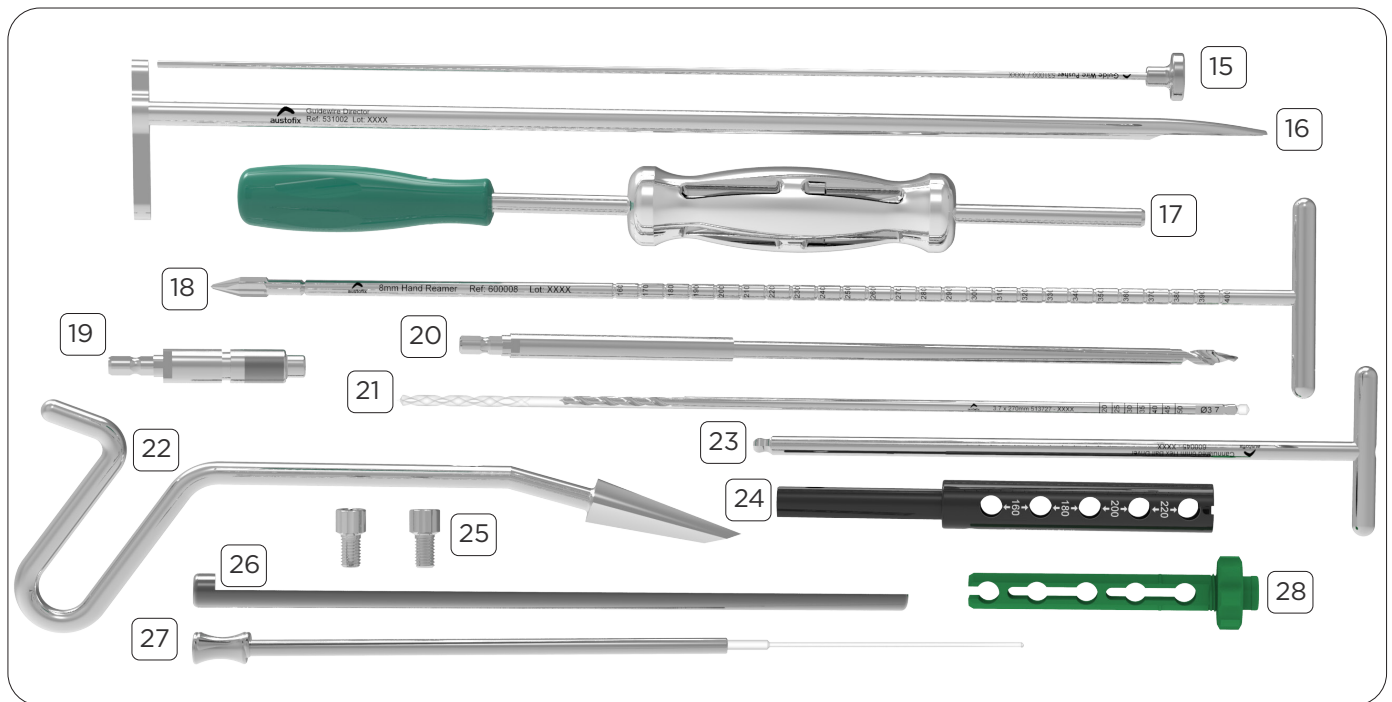
Instruments

Outer case assembly



1. 600084A UTN/S2 Screw Guide
2. 600084B Locking Sleeve
3. 600084C Static-Dynamic Insert
4. 610068 3.5 Power Screwdriver
5. 600005 M8 Nail Extractor
6. 610067 3.5 Hex Screwdriver
7. 600028 Impactor
8. 610063 Trocar
9. 610064 Drill Sleeve
10. 610065 Outer Sleeve
11. 600083 UTN/S2 Universal Nail Holder
600083S Suprapatellar UTN Nail Holder (UTN Only)
12. 600073 11mm Tissue Guard (UTN Only)
13. 521121 11mm Cannulated Reamer (UTN Only)
521421 14mm Cannulated Reamer (S2 Only)
14. 600066 14.5mm Tissue Guard (S2 Only)
15. 600029 Cannulated Holding Screw

Instruments



15. 531000 Guide Wire Pusher
16. 531002 Guide Wire Director
17. 600097 Slide Hammer
18. 600008 8mm Hand Reamer
19. 600042 Long AO-ZH Adaptor
20. 526521 6.5mm Drill (S2 Only)
21. 514534 4.5mm x 340mm Drill
514514 4.5mm x 155mm Drill
513727 3.7mm x 270mm Drill (UTN only)
22. 600040C Cannulated Awl
23. 600045 Cannulated 6mm Hex Ball Driver
24. 600110A S2 Straight Nail Screw Guide (S2 Only)
25. 632007 M8 Mounting Screw
26. 600069 Nail Length Guidewire Gauge
27. 610069A Depth Gauge Outer
610069B Depth Gauge Inner
28. S2 Straight Nail Locking Sleeve (S2 Only)

Titanium Implants

Universal Tibial Nail - 8mm Cannulated

| Product Code | Nail Diameter | Nail Length | Locking Screw |
|--------------|---------------|-------------|---------------|
| 440826 | 8 | 260 | 4.0 |
| 440828 | 8 | 280 | 4.0 |
| 440830 | 8 | 300 | 4.0 |
| 440832 | 8 | 320 | 4.0 |
| 440834 | 8 | 340 | 4.0 |
| 440836 | 8 | 360 | 4.0 |

Universal Tibial Nail - 9mm Cannulated

| Product Code | Nail Diameter | Nail Length | Locking Screw |
|--------------|---------------|-------------|---------------|
| 440926 | 9 | 260 | 4.0 |
| 440928 | 9 | 280 | 4.0 |
| 440930 | 9 | 300 | 4.0 |
| 440932 | 9 | 320 | 4.0 |
| 440934 | 9 | 340 | 4.0 |
| 440936 | 9 | 360 | 4.0 |
| 440938 | 9 | 380 | 4.0 |

Universal Tibial Nail - 10mm Cannulated

| Product Code | Nail Diameter | Nail Length | Locking Screw |
|--------------|---------------|-------------|---------------|
| 441030 | 10 | 300 | 4.8 |
| 441032 | 10 | 320 | 4.8 |
| 441034 | 10 | 340 | 4.8 |
| 441036 | 10 | 360 | 4.8 |
| 441038 | 10 | 380 | 4.8 |
| 441040 | 10 | 400 | 4.8 |

Universal Tibial Nail - 11mm Cannulated

| Product Code | Nail Diameter | Nail Length | Locking Screw |
|--------------|---------------|-------------|---------------|
| 441130 | 11 | 300 | 4.8 |
| 441132 | 11 | 320 | 4.8 |
| 441134 | 11 | 340 | 4.8 |
| 441136 | 11 | 360 | 4.8 |
| 441138 | 11 | 380 | 4.8 |
| 441140 | 11 | 400 | 4.8 |
| 441142 | 11 | 420 | 4.8 |

4.0mm Locking Screw

| Product Code | Screw Length |
|--------------|--------------|
| 364020 | 20 |
| 364025 | 25 |
| 364030 | 30 |
| 364032 | 32.5 |
| 364035 | 35 |
| 364037 | 37.5 |
| 364040 | 40 |
| 364045 | 45 |
| 364050 | 50 |
| 364055 | 55 |
| 364060 | 60 |
| 364065 | 65 |
| 364070 | 70 |

4.8mm Locking Screw

| Product Code | Screw Length |
|--------------|--------------|
| 364820 | 20 |
| 364825 | 25 |
| 364830 | 30 |
| 364832 | 32.5 |
| 364835 | 35 |
| 36437 | 37.5 |
| 364840 | 40 |
| 364845 | 45 |
| 364850 | 50 |
| 364855 | 55 |
| 364860 | 60 |
| 364865 | 65 |
| 364870 | 70 |
| 364875 | 75 |
| 364880 | 80 |
| 364885 | 85 |
| 364890 | 90 |

End Cap M8

| Product Code | Length |
|--------------|--------|
| 368000 | 00 |
| 368001 | 01 |
| 368005 | 05 |
| 368010 | 10 |
| 368015 | 15 |
| 368020 | 20 |

Single Use Items

| Guidewire | |
|--------------|--------------------------------|
| Product Code | Description |
| 512525 | 2.5x250mm K-Wire (Twin Packed) |
| 533900 | 3.0x900mm Ball-tip Guidewire |



| Drill | |
|--------------|---|
| Product Code | Description |
| 514534 | 4.5x340mm Drill (for 4.8mm Screw) |
| 514514 | 4.5x155mm Drill (Optional for 4.8mm Screw) |
| 513727 | 3.7x270mm Drill (for 4.0mm Screw) (UTN Only) |



MRI Safety

Austofix has not evaluated its devices for safety and compatibility in a Magnetic Resonance (MR) environment. However, the materials used in their manufacture are known to have minimal ferromagnetism, with minimal risk to patients in strong magnetic fields.

Austofix has performed a review of published, peer-reviewed data, which confirms that only minor rises in MRI-related heating are observed from devices manufactured from the same titanium materials. Trauma devices are considered unlikely to produce injury to patients, including in the worst-case 3.0T systems.

The devices and materials observed in the literature experience forces too weak to cause significant displacement; the risk being further mitigated by their implantation in bone. Risks of imaging artifacts are known to MRI operators, and can be reduced by choosing appropriate pulse sequences and optimizing scanning parameters by using a large bandwidth, small field-of-view and appropriate echo train length.

Average temperature changes have been observed in studies at 0.48°C. Rises in temperature in clinical situations may depend on individual patient factors. It should be recommended that patients be thoroughly monitored when undergoing MR scanning, and that impaired patient thermoregulation be considered a contraindication for MRI procedures.

Sources:

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Notes:



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