

austofix F3
FEMORAL NAIL

Surgical Technique



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Disclaimer

This document is intended to be read by experienced orthopaedic trauma surgeons familiar with intramedullary 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 distributes the Austofix range of orthopaedic trauma products throughout Australia and overseas. As a specialist in orthopaedic trauma, our product specialists understand the need for product support and service.

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



The science and clinical practice of intramedullary (IM) nailing has consistently improved over recent decades, spearheading the production of implants capable of treating a variety of fractures in the femoral diaphysis and metaphysis. Today's reconstructive femoral nails offer design features that facilitate faster operative times and improve patient outcomes. The Austofix F3 Femoral Nail is a modern, versatile design suitable for all antegrade femoral nailing indications. Building upon previous successful femoral nail designs, the F3 is a new generation implant for the treatment of both common and more complex femoral fractures.

Combining a reconstructive nail with a standard femoral nail design and trochanteric entry, the Austofix F3 is suitable for the treatment of sub-trochanteric and femoral shaft fractures. Utilising a high tensile strength Titanium alloy, the Austofix F3 Nails and Screws offer maximum structural stability while minimising nail diameter. As with all Austofix IM Nails, the F3 is supported by a simple and robust instrument platform that ensures the fastest operative times. The Austofix F3 complements the Austofix S2 Supracondylar Nail for retrograde femoral nailing and the Austofix F1 Short Proximal Femoral Nail for trochanteric fractures.

Design Details

Nails

The Austofix F3 Nail combines the best features of modern design in an implant suitable for all antegrade femoral nailing indications.

- Left and Right Configurations
- Manufactured from Titanium Alloy (ISO 5832-3)
- Type II Hard Anodised*
- Anatomical AP Bend with Variable Radius of Curvature: 1150mm to 2000mm
- 5.0° Lateral Bend to Facilitate Greater Trochanter Entry
- Lengths: 300mm to 460mm
- Nail Diameter: Ø9mm to Ø12mm
- Hip Screw Angle: 125° & 130°
- Ezy-Aim Compatible

*Improved surface finish, increased fatigue strength and improved biocompatibility.

The Austofix F3 Nail can be used in three different configurations. The distal locking remains the same, but there is a choice of proximal locking depending on fracture type:



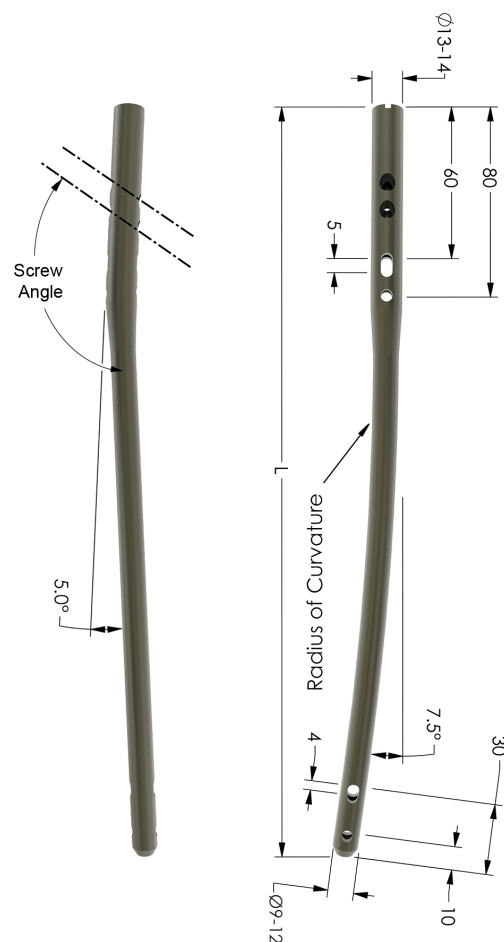
Transverse Static Mode



Transverse Dynamic Mode



'Recon' Mode



The Nail is locked proximally with the transverse hole 80mm from the top, for patients with unstable shaft fractures.

Slot 60mm below the top for cross-locking when fracture compression is desirable, such as with stable transverse or short oblique fracture patterns and with non-unions. The slot controls rotation but allows for 5mm of longitudinal movement. Continuing fracture impaction from weight-bearing encourages more rapid consolidation of the fracture union.

Two oblique 6.5mm holes for F3 femoral head screws at 125° or 130° to the line of the femoral shaft.

Screws & End Caps

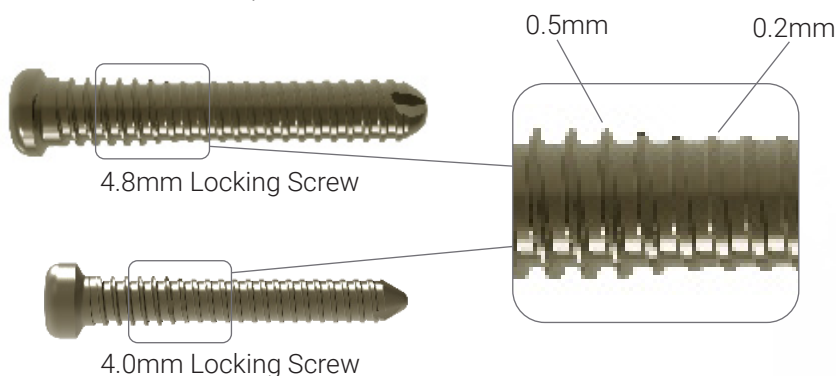
All Austofix screws are made from ISO 5832-3 Titanium (Ti) for increased strength and improved biocompatibility properties.

The following are used with the F3 Nail:

- 6.5mm Hip Screws
 - » Partially threaded for improved fixation within the Nail.
 - » Used proximally for the 'recon' mode in the femoral head.
- 4.0mm & 4.8mm Locking Screws
 - » Fully threaded for ease of insertion.
 - » First 3/4 of Screw thread shallow, with the remaining 1/4 expanded to grip the lateral cortex and resist backout.
 - » Low profile Screw heads resulting in reduced tendon irritation.
 - » Used proximally and distally with the F3 in a mediolateral direction.
 - » 4.0mm Locking Screws required for Ø9mm Nails
- End Cap
 - » Used to deter bone ingrowth.
 - » Used to increase Nail length.
 - » Length determined by surgeon's preference.

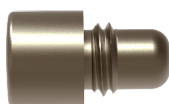


6.5mm Hip Screw



4.8mm Locking Screw

4.0mm Locking Screw



End Cap



Indications & Pre-Operative Planning

Nail Length

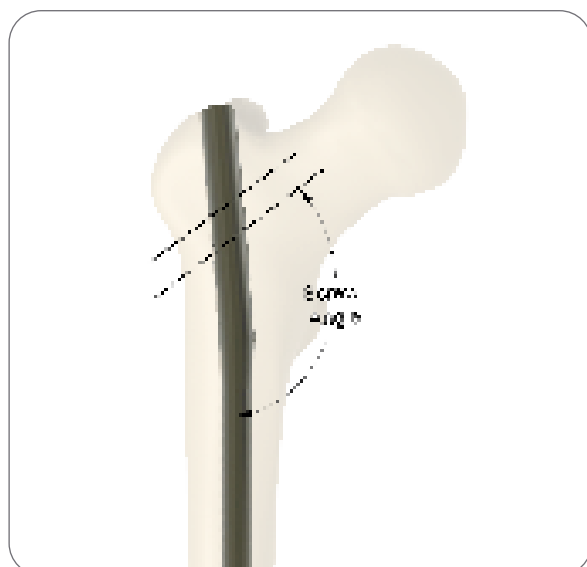
Where possible, the Nail is selected pre-operatively. The length of the Nail is determined by measuring the injured limb in traction or by measuring the uninjured limb. For very distal fractures where more accurate measurement is necessary, the Nail Length Guidewire Gauge (600069) can be used. See use of Gauge on page 9.

The general recommendation for selection of Austofix F3 Nail diameter is as follows:

- 9mm: For smaller patients with narrow medullary canals.
- 10mm: For narrow medullary canals.
- 11mm: For patients up to 80kg, and for narrow medullary canals.
- 12mm: For most patients over 80 kg and for wide medullary canals.

Extra caution is needed with weight bearing if the fracture is within 50mm of the distal cross-locking holes and for extremely comminuted fractures. Use the largest possible Nail diameter in these cases.

Decide pre-operatively whether reaming is necessary. When in doubt, it is safer to pass a reamer 1-1.5mm larger than the Nail. The width of the isthmus is measured on the radiographs (allowing 10% to 15% for X-ray magnification).



Hip Screw Angle

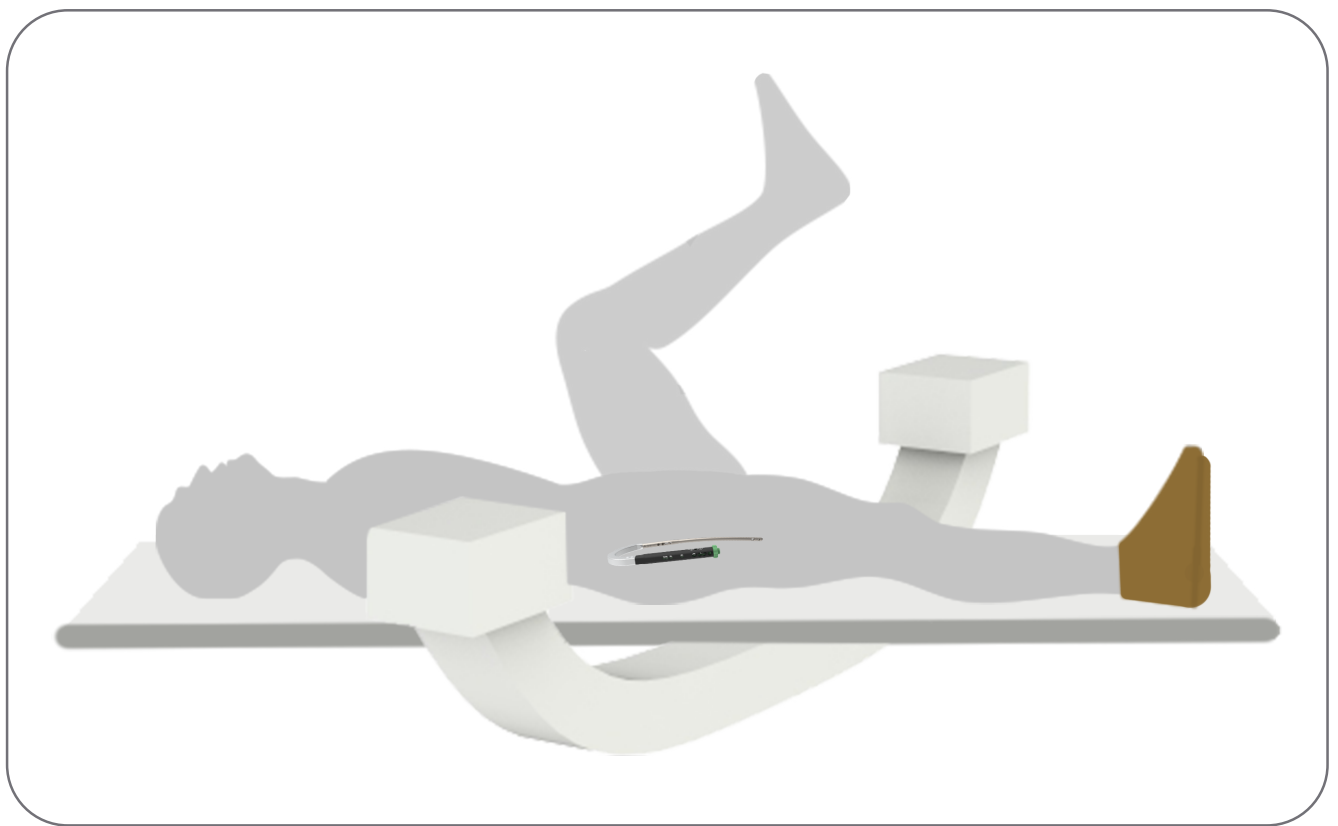
Through the examination of patient radiographs, decide pre-operatively whether the 125° or 130° F3 Nail is required, where a selection is made based on the femoral anatomy of the patient.

Anteroposterior X-ray views provide the best determination of Hip Screw angle.

Note: The 125° angle selection is suitable for most clinical situations.

Patient Positioning

Although any standard femoral nailing position can be used, the Austofix Instruments have been developed using the supine position. Traction is applied by a boot or a distal femoral pin. If the oblique holes are to be used, the contralateral limb should be flexed in the lithotomy position to facilitate visualisation of the femoral head on a lateral X-ray view. This position is also useful for checking the entry hole for the Nail (see below).



Incision & Bone Preparation

Incision

The incision begins 1-2cm above the greater trochanter and extends upwards for 3cm to 4cm. In obese patients, confirm the level on X-ray. Passing the knife obliquely downward, incise the fascia so that the greater trochanter can be felt with a finger.

Entry Point

Insert a 2.5x250mm K-Wire (512525) for 2-3cm at a point just lateral to the tip of the Greater Trochanter on the anteroposterior view and in line with the medullary canal on the lateral view. Confirm the position on anteroposterior and lateral X-ray views and re-insert the K-wire if necessary.

Note: The Cannulated Awl (600040C) may be used to assist in preparation of the entry hole.

Drilling & Entry Hole

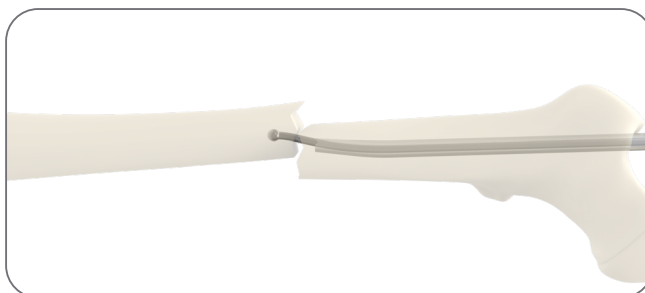
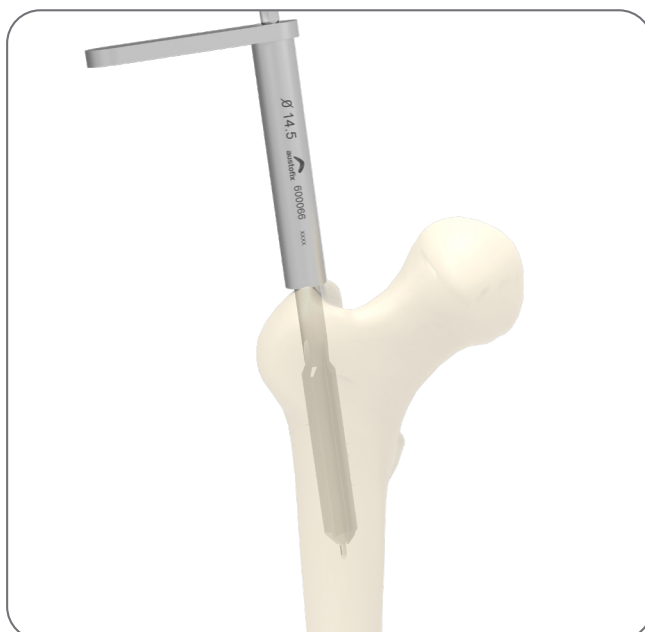
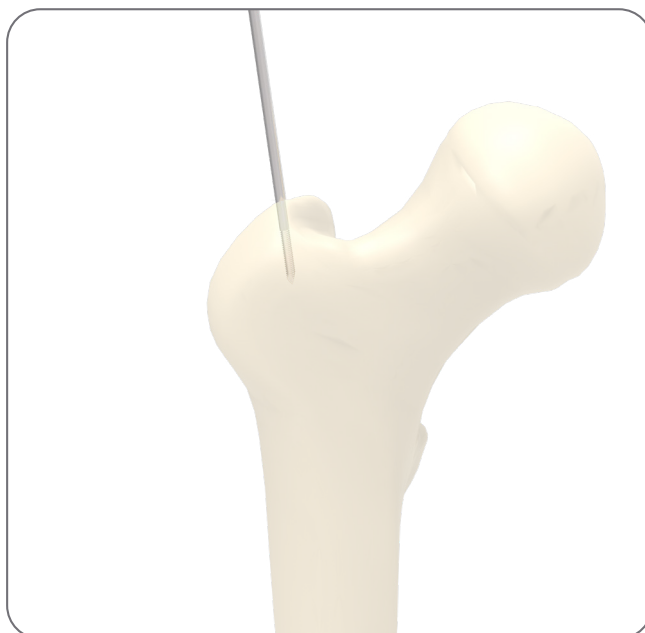
Pass the 14mm Cannulated Drill Reamer (521421) through the 14.5mm Tissue Guard (600066) and over the K-wire. Hold the Tissue Guard against the bone and slowly advance the 14mm Cannulated Drill Reamer for approximately 100mm, frequently checking alignment on X-ray.

Insertion of Ball-tipped Guidewire

While keeping the Tissue Guard against the bone, remove the 14mm Cannulated Drill Reamer and K-Wire. Then insert the 3.0x900mm Ball-tip Guidewire (533900) to the depth intended for the Nail. If it cannot be passed across the fracture, ream the proximal fragment to 11mm with a Flexible Reamer (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.

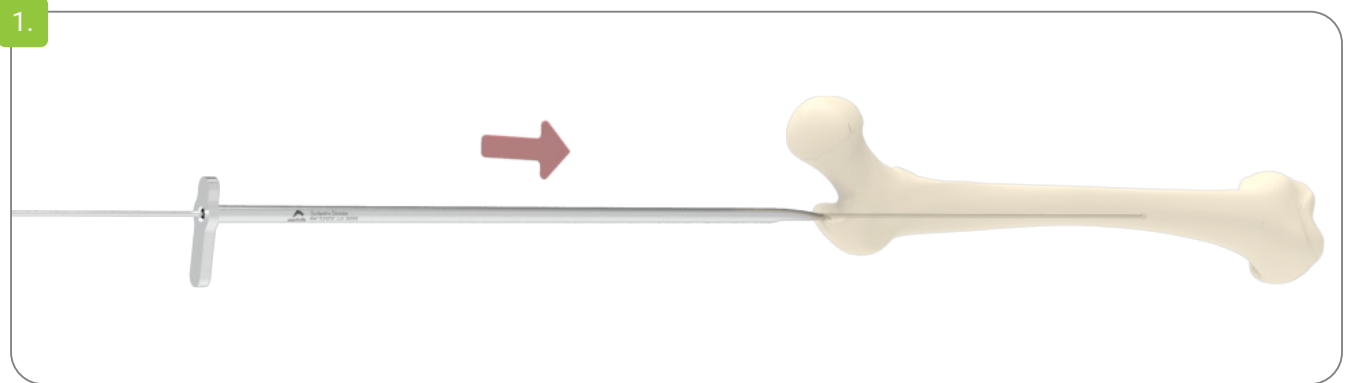
Note:

- If the Guidewire is excessively bent, it may need to be changed to a straight wire after reaming.
- For 'Recon' mode, a tight fit should be avoided as some manipulation of the Nail may be necessary to align the proximal screws in the femoral head.
- Subtrochanteric fractures often require a limited open reduction and this facilitates correct orientation of the entry hole.
- *Flexible Reamer Instrument Set (FLEX-INS-REAM) supplied on request.

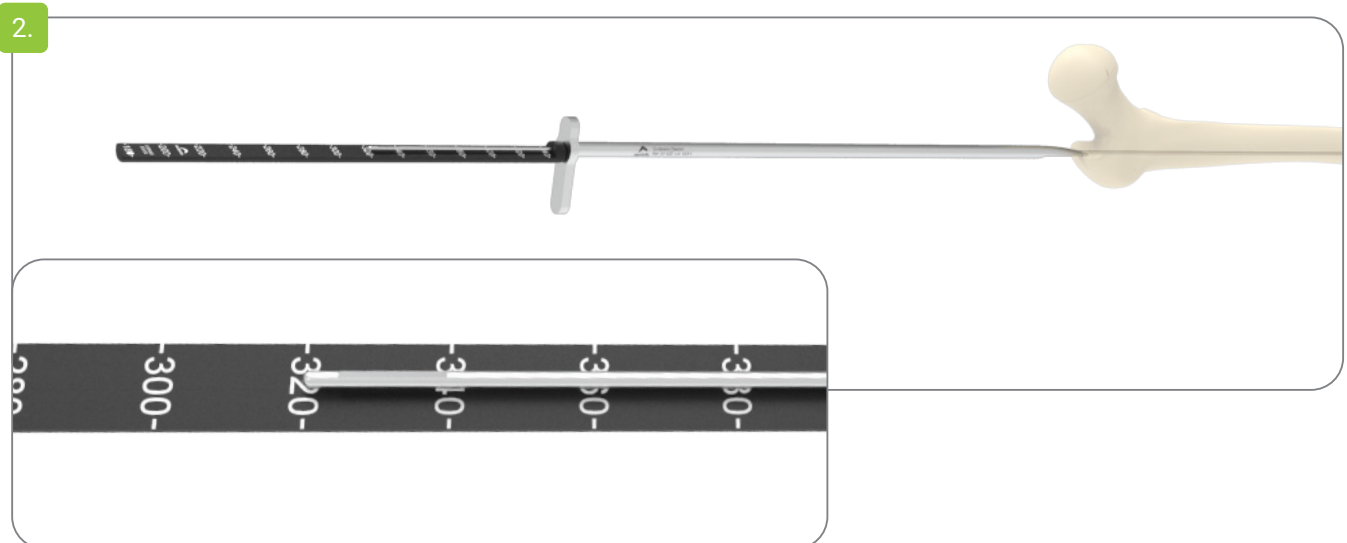


Nail Length Gauge

1. With the Ball-tip Guidewire (533900) inserted to the intended position of the Nail, pass the Guidewire Director (531002) over the Guidewire to the Greater Trochanter.



2. Then use the Nail Length Guidewire Gauge (600069) as shown to determine the appropriate length of Nail.



Reaming

Pass a Flexible Reamer over the Ball-tip Guidewire (533900) 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.

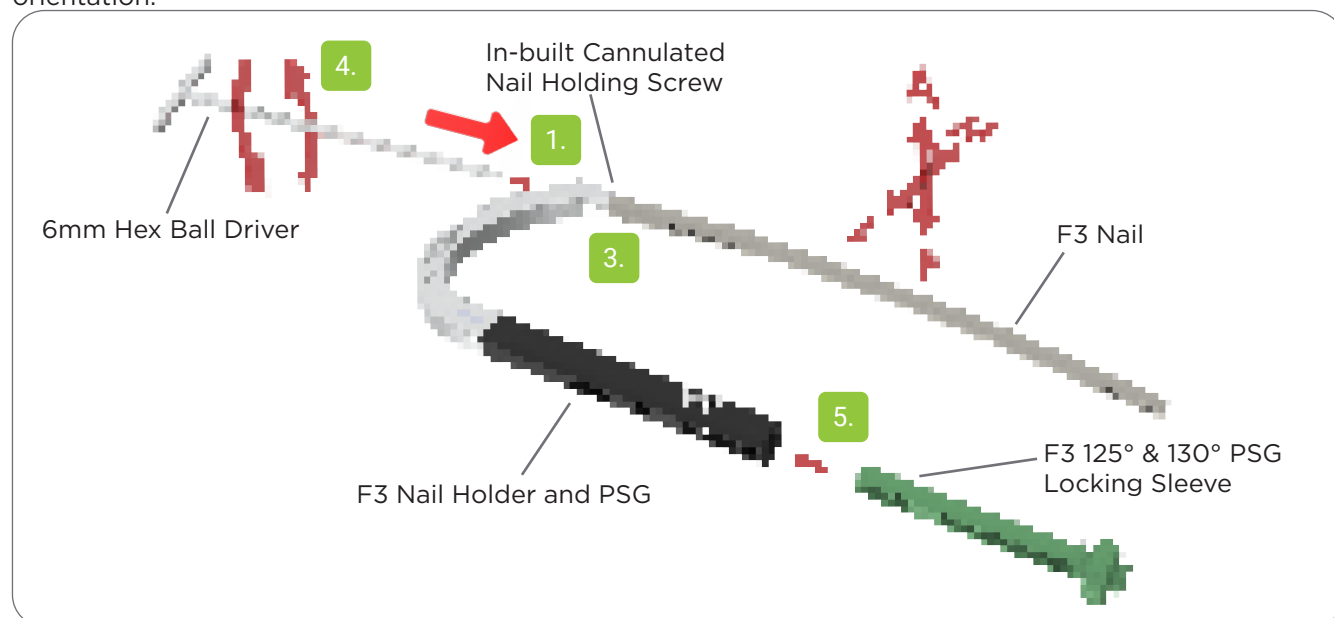
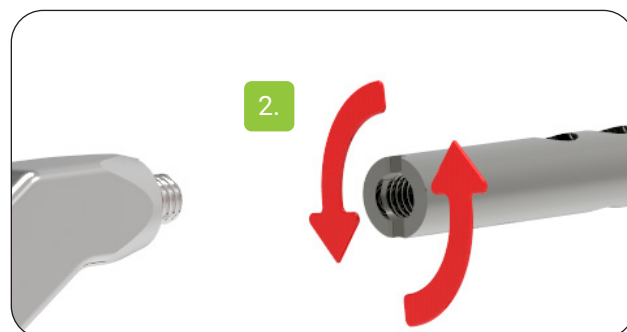
Instrument Assembly

Nail Holder and Proximal Screw Guide

1. Use the 6mm Hex Ball Driver (600045) to stabilise the F3 Nail Holding Screw.
2. With the Nail Holding Screw now fixed, turn the F3 Nail onto the Nail Holding Screw.
3. Align the Nail's proximal groove to the F3 Nail Holder & Proximal Screw Guide (PSG) (600109) with the bow of the Nail facing anteriorly.
4. Use the 6mm Hex Ball Driver (600045) to fasten the In-built Nail Holding Screw.
5. Slide in the F3 PSG Locking Sleeve (600064B) into the PSG ensuring the pin is aligned in the slot.

Note: Regularly check the Cannulated Nail Holding Screw for tightness throughout the operation. If this loosens, screw targeting will not be accurate.

Warning: Ensure Nail is attached in the correct orientation.

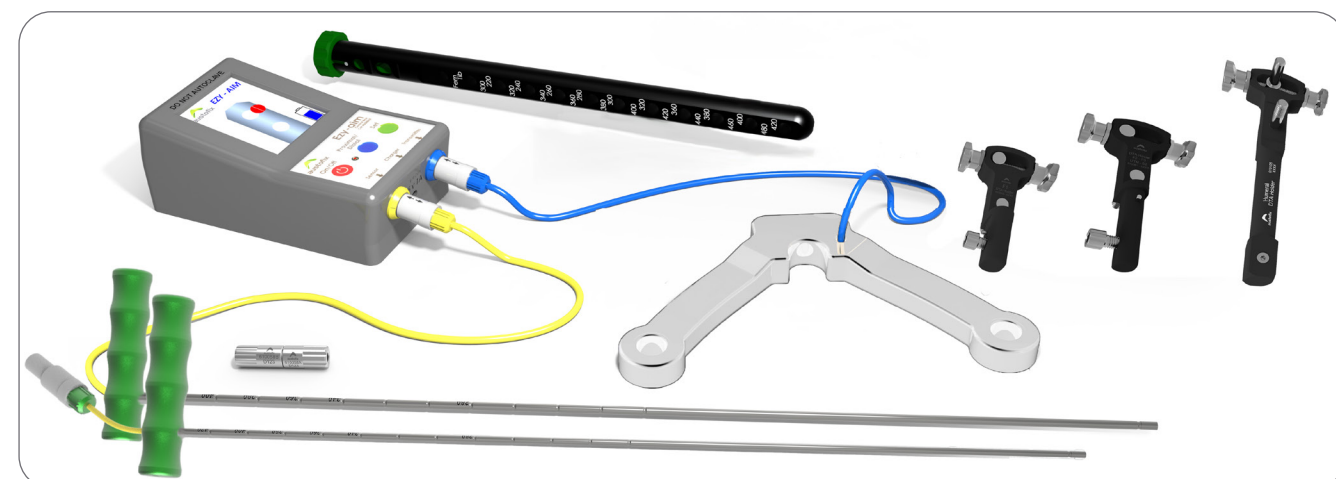


Note: Instrument Assembly for Right F3 Nail shown above.

Ezy-Aim Distal Targeting System

Please refer to the Ezy-Aim Distal Targeting System Surgical Technique for instructions on how to calibrate the F3 Nail for distal hole targeting.

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



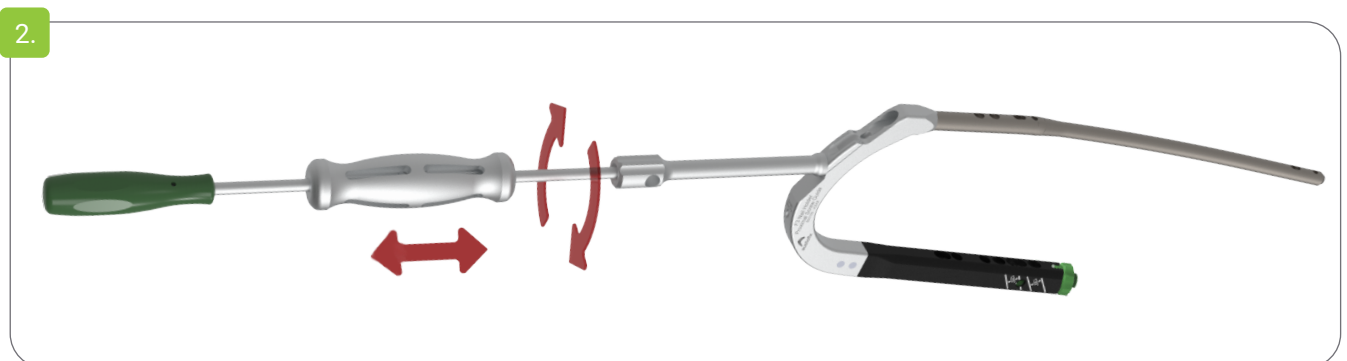
Nail Insertion

1. Screw the Impactor (600028) into the F3 Nail Holder (600109). This is finally tightened by using the Cannulated 6mm Hex Ball Driver (600045) as a lever through the hole in the Impactor. A loose fit will risk breakage during hammering.



2. Insert the Nail over the Guidewire using the Slide Hammer assembly (600097). 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 Assembly to the Impactor.

Insert the Nail until X-rays show it is flush with the tip of the greater trochanter (bottom right).



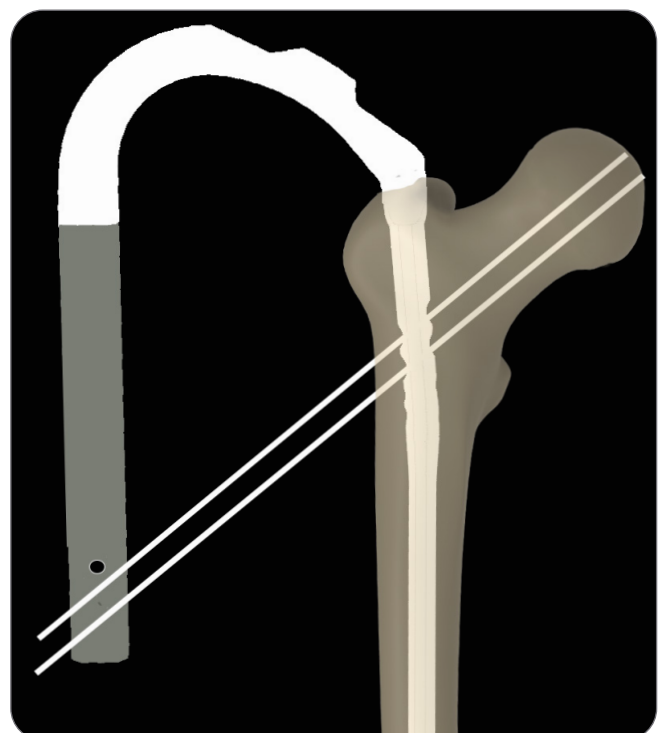
Insertion of Proximal Oblique Screws

The position of the Nail in regard to both depth and rotation must be adjusted to align the screws in the femoral head.

Nail Depth

Depth is assessed initially by using the X-ray outline of the oblique holes to estimate the path of the screws. Normally this is when anteroposterior radiographs indicate the top of the Nail is flush with the tip of the greater trochanter. Adjust Nail depth as necessary until the distal oblique screw track is just above the calcar and below the centre of the femoral head.

If the Nail is not loose in the bone, align the rotary position while inserting the last 1-2cm. Use the Slide Hammer assembly if extraction and reinsertion is needed.

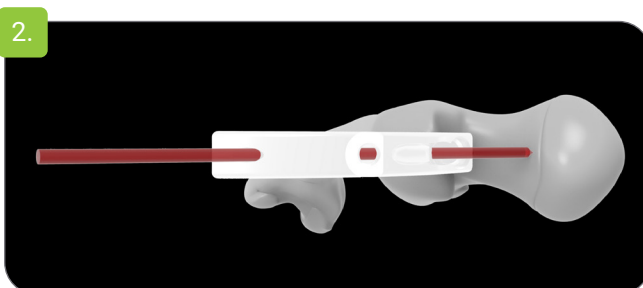


Nail Rotation Alignment

1. Remove Impactor (600028) and 3.0x900mm Ball-tip Guidewire (533900). Check the tightness of the Cannulated Nail Holding Screw.



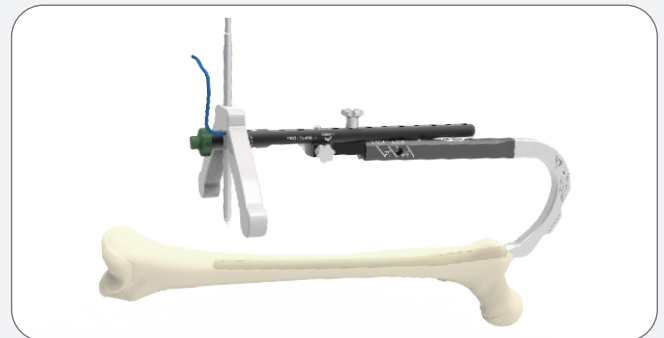
2. Use the Single Shot Pin (600092) with the C-arm in an oblique lateral view which is perpendicular to the femoral neck and is in the same plane as the instrument (shown in red). Adjust the rotation of the Nail as necessary so that the Pin is centred or slightly posterior on the femoral head.



Drilling

Proximal Oblique Screws

If using the Ezy-Aim Distal Targeting System the distal screws must be inserted before the proximal screws to enable passage of the Ezy-Aim Sensor (610057). To maintain alignment of the proximal instruments, place two 2.5x250mm K-Wires (512525) through the anterior and posterior holes in the F3 Nail Holder (600109) and into the femoral head. Remove the Drills and F3 125° & 130° PSG Locking Sleeve (600064B). Perform distal locking as described in the Ezy-Aim Distal Targeting Surgical Technique.



1. Assemble the Trocar (610063), Drill Sleeve (610064) and Outer Sleeve (610065). Pass the assembly through the appropriate (125° or 130°) distal oblique hole in the F3 Proximal Screw Guide and make an incision 2.5cm long through the skin and fascia. Insert the Trocar and Sleeves down to bone and tighten the F3 125° & 130° PSG Locking Sleeve (600064B).

Note: Selection of the appropriate distal oblique hole relates to the F3 Nail chosen pre-operatively (125° or 130°).



2. Remove the Trocar. Drill the more distal position with a 4.5x340mm Drill (514534) into the femoral neck until the subchondral bone is reached. Use X-ray to check position and that the Drill is close to the calcar femorale. The Single Shot Pin can now be removed.



3. Insert the proximal Drill using the same technique as the more distal position. Check progress as required. Check Drill Sleeves are placed against the lateral cortex on X-ray. Use the scale marked on the 4.5x340mm Drills to determine the screw lengths required.

Note: The Long AO/ZH Adaptor enables the second drill to be inserted without impingement on the first drill.

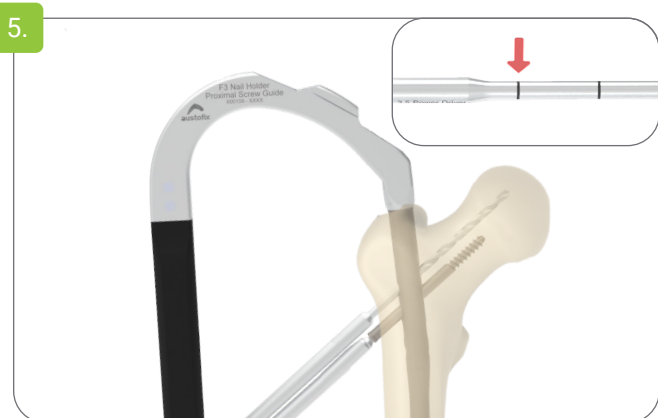


4. Withdraw the more distal 4.5x340mm Drill (514534) and Drill Sleeve (610064). Insert the 6.5x210mm Drill (526521) into the Outer sleeve and drill through the lateral cortex only. The step in the Drill prevents further drilling.

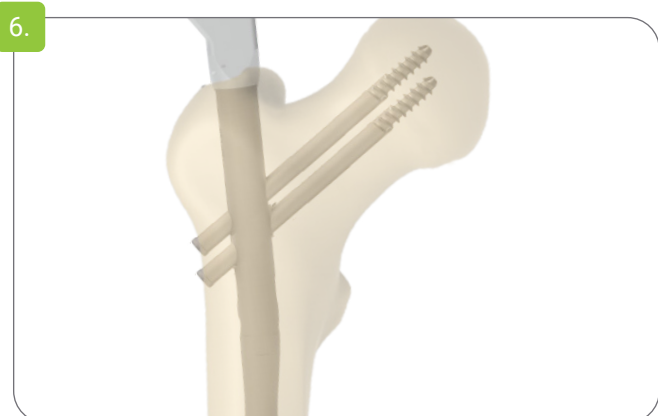
Note: Ensure the tip of the Drill engages the hole in the Nail, otherwise the Screw may be tight to insert.



5. Use the 3.5x270mm Power Screwdriver (610068) to insert the 6.5mm Hip Screw. Stop before the second laser mark band on the shaft of the Screwdriver and tighten the final position by hand using the 3.5 Hex 250mm Screwdriver (610067).



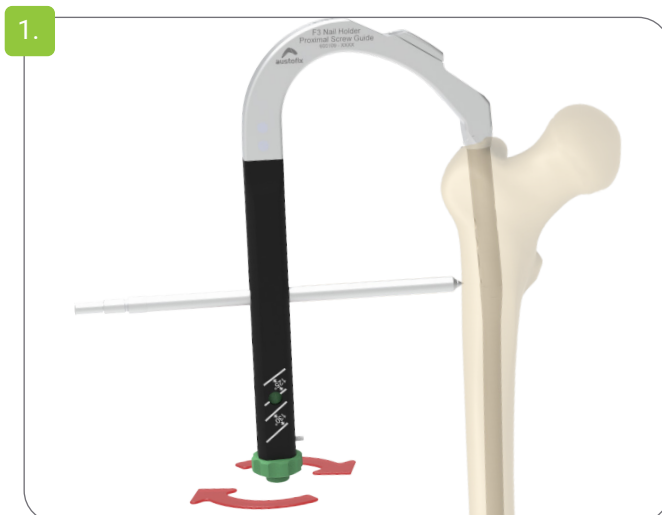
6. Repeat steps 4 and 5 for the other Hip Screw, and check placement of both screws on anteroposterior and lateral x-ray views.



Proximal Transverse Screws

Note: Distal Locking is done first if the Ezy-Aim Distal Targeting system is used.

1. Pass the assembled Trocar (610063), Outer Sleeve (610065) and Drill Sleeve (610064) through the 'static' or 'dynamic' hole of the F3 Proximal Screw Guide and through a 1cm stab wound. Tighten the F3 Proximal Screw Guide Locking Sleeve (600064B).



2. Replace the Trocar with the Drill and drill through both cortices. When the Drill strikes the far cortex, note the length indicated on the depth scale marked on the Drill. Add 5mm to determine the length of screw required. Alternatively use the Universal 3.7-4.5 Depth Gauge (610069).



3. Remove the Drill Sleeve and insert a Locking Screw of the appropriate length. Use the 3.5mm Hex Power Screwdriver (610068) near to the mark indicated, then tighten by hand with the 3.5 Hex 250mm Screwdriver (610067).

Note: Use the line on the Screwdriver as a guide to screw depth. Finally, check on a A-P X-ray view that the screw is fully seated.



Distal Screws

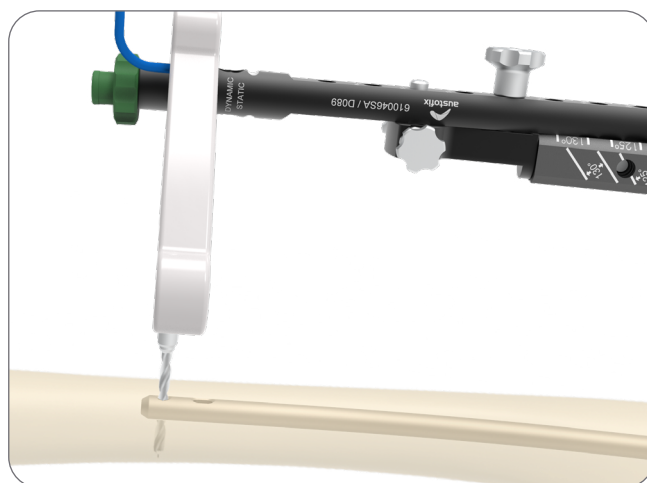
Either the Austofix Ezy-Aim Distal Targeting System or a freehand method can be used. The Austofix Ezy-aim Targeting System reduces radiation exposure and improves targeting accuracy. Prior familiarisation with this System is recommended. Occasionally if Nail bending is excessive, the range of adjustment 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 screw 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.

The Drill Sleeve can be used as a tissue guard. Use the Universal 3.7-4.5 Depth Gauge (610069) to determine screw length.

Care is needed to avoid flexing and drill breakage. If preferred, a shorter 4.5x155mm Drill (514514) is available. Align the tip of the 4.5x340mm Drill (514534) and drill through.

Note: The 9mm F3 Nail will require the 3.7x270mm Drill (513727) for the 4.0mm Distal Locking Screw.

Compression Slot

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

End Cap

An End Cap may be used to deter bone ingrowth or to increase the Nail's length, End Caps can be inserted into the Nail using a 3.5mm Hex 250mm Screwdriver (610067).

Note: Titanium End Cap length is determined by surgeons preference.



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 unstable comminuted fractures, weightbearing should be restricted for six weeks.

Nail Extraction

End Caps

1. If an End Cap is present, engage and remove with counter-clockwise rotation using the 3.5mm Hex Screwdriver (610067). (Figure a).

M8 Nail Extractor

1. The M8 Nail Extractor (600005) is screwed into the Nail (Figure b).

Note: The Nail Extractor should be screwed into the Nail before the proximal and distal Screws are removed. This is to avoid unwanted Nail rotation or distal migration.

Recon, Transverse & Distal Locking Screw Removal

1. Austofix Screws are fitted with a conventional 3.5mm hexagonal drive. They can be removed either with the 3.5mm Hex Power Screwdriver (610068) or by hand with the 3.5mm Hex Screwdriver (610067) (Figure c).

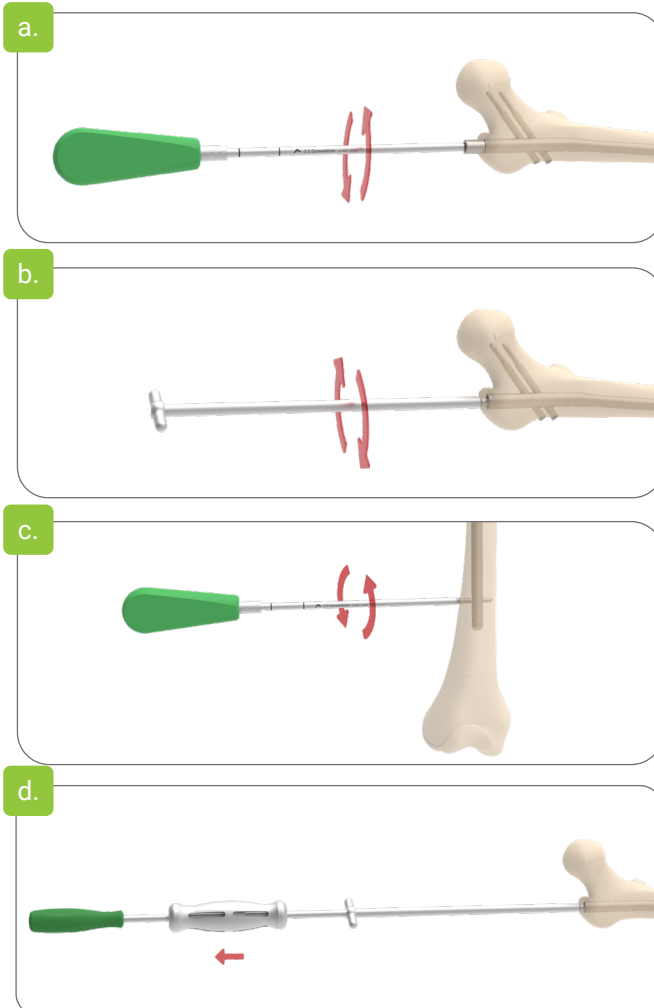
Nail Removal

1. Attach the Slide Hammer (600097) assembly onto the Nail Extractor and withdraw the Nail (Figure d).

Note: When attaching the Slide Hammer onto the Nail Extractor, avoid rotating the Nail inside the femur.

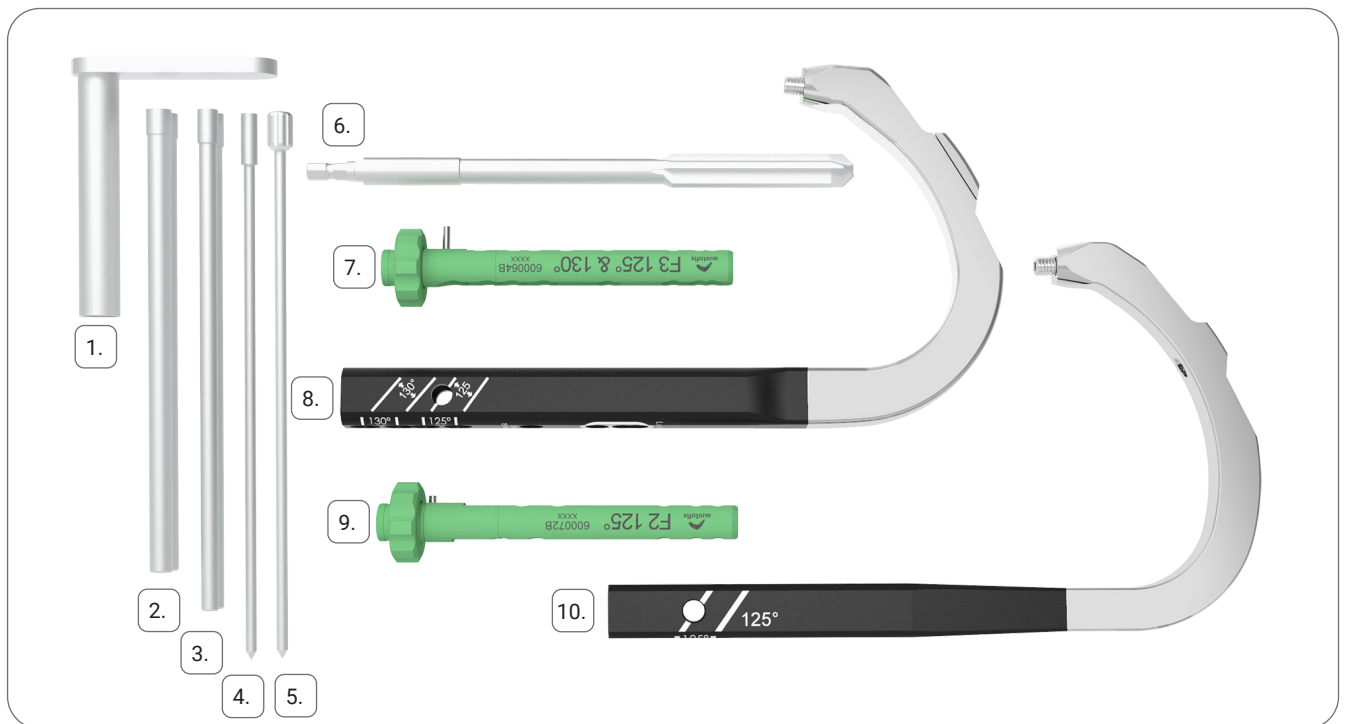
The instruments required for extraction of Austofix F1 Nails are listed below:

Product Code	Description
600005	M8 Nail Extractor
610067	3.5mm Hex Screwdriver
610068	3.5mm Hex Power Screwdriver
600097	Slide Hammer



Instruments

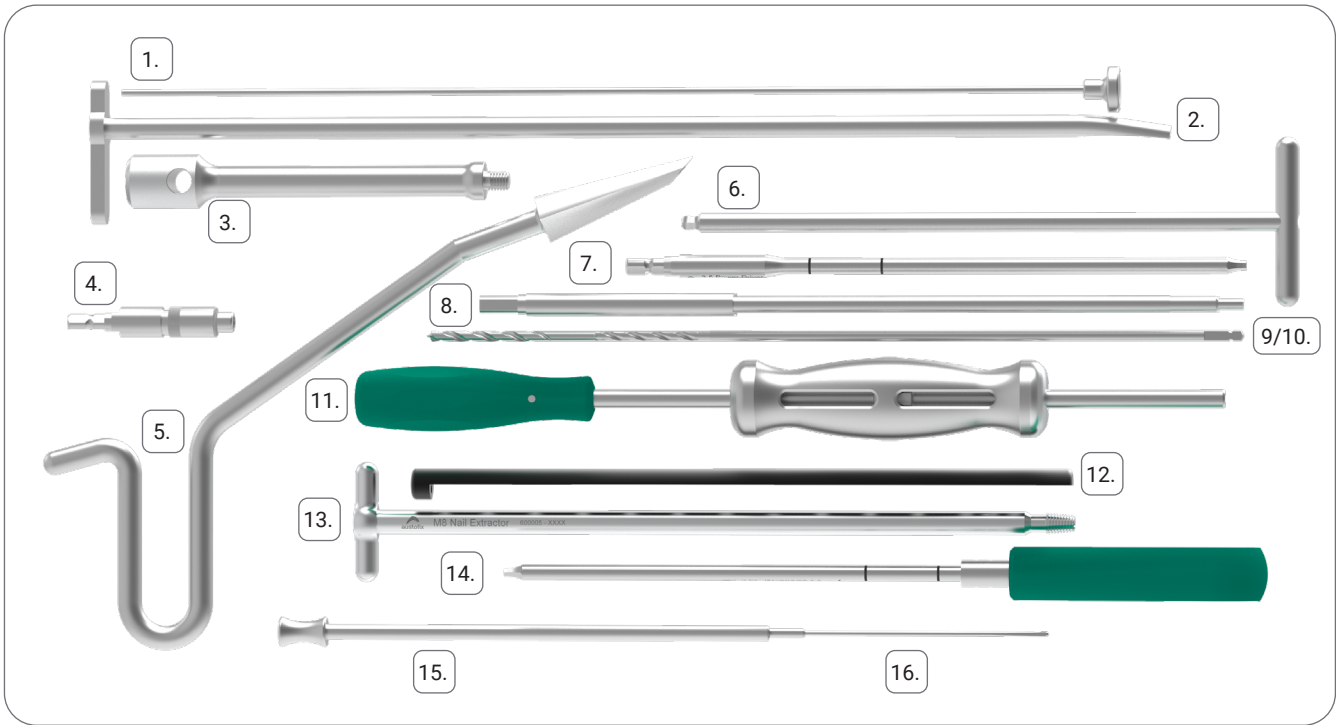
Top Layer



- | | | | | | | | |
|----|--------|---|------------------------------|-----|---------|---|-----------------------------------|
| 1. | 600066 | - | 14.5mm Tissue Guard | 6. | 521421 | - | 14mm Cannulated Reamer |
| 2. | 610065 | - | 180mm Outer Sleeve x 2 | 7. | 600064B | - | F3 125° & 130° PSG Locking Sleeve |
| 3. | 610064 | - | 4.5 x 180mm Drill Sleeve x 2 | 8. | 600109 | - | F3 Nail Holder and PSG |
| 4. | 610063 | - | 180mm Trocar | 9. | 600072 | - | F2 PSG Locking Sleeve* |
| 5. | 600092 | - | Single Shot Pin | 10. | 600071 | - | F2 Nail Holder and PSG* |

***Note:** Instruments used for F2 Nail insertion only.

Base Layer



1.	531000	-	Guidewire Pusher	9.	514534	-	4.5 x 340mm Drill (for 4.8mm Screw)
2.	531002	-	Guidewire Director	10.	513727	-	3.7 x 270mm Drill (for 4.0mm Screw)
3.	600028	-	Impactor	11.	600097	-	Slide Hammer
4.	600042	-	Long AO/ZH Adaptor	12.	600069	-	Nail Length Guidewire Gauge
5.	600040C	-	Cannulated Awl	13.	600005	-	M8 Nail Extractor
6.	600045	-	Cannulated 6mm Hex Ball Driver	14.	610067	-	3.5 Hex Screwdriver
7.	610068	-	3.5 Power Screwdriver	15.	610069A	-	Depth Gauge Outer
8.	526521	-	6.5 x 210mm Drill (for 6.5mm Screw)	16.	610069B	-	Depth Gauge Inner

Single Use Items

Guidewire	
Product Code	Description
512525	2.5 x 250mm K Wire (Twin Packed)
533900	3.0 x 900mm Ball-tip Guidewire



Drill	
Product Code	Description
526521	6.5 x 210mm Drill (for 6.5mm Screw)
514534	4.5 x 340mm Drill (for 4.8mm Screw)
513727	3.7 x 270mm Drill (for 4.0mm Screw)
514514	4.5 x 155mm Drill (Optional for 4.8mm Screw)



Implants - Titanium

F3 Nail - Titanium				
Nominal Length	Ø9			
	Left	Right	Left	Right
	125° Part Numbers		130° Part Numbers	
300	371930L	371930R	373930L	373930R
320	371932L	371932R	373932L	373932R
340	371934L	371934R	373934L	373934R
360	371936L	371936R	373936L	373936R
380	371938L	371938R	373938L	373938R

Note: The 9mm diameter F3 Nail is an Austofix Made to Order product. All Austofix Made to Order items will have a minimum order quantity and the delivery date will be discussed prior to manufacture.

F3 Nail - Titanium						
Nominal Length	Ø10		Ø11		Ø12	
	Left	Right	Left	Right	Left	Right
125° Part Numbers						
320	371032L	371032R	-	-	-	-
340	371034L	371034R	371134L	371134R	371234L	371234R
360	371036L	371036R	371136L	371136R	371236L	371236R
380	371038L	371038R	371138L	371138R	371238L	371238R
400	371040L	371040R	371140L	371140R	371240L	371240R
420	371042L	371042R	371142L	371142R	371242L	371242R
440	-	-	-	-	371244L	371244R
460	-	-	-	-	371246L	371246R
130° Part Numbers						
320	373032L	373032R	-	-	-	-
340	373034L	373034R	373134L	373134R	373234L	373234R
360	373036L	373036R	373136L	373136R	373236L	373236R
380	373038L	373038R	373138L	373138R	373238L	373238R
400	373040L	373040R	373140L	373140R	373240L	373240R
420	373042L	373042R	373142L	373142R	373242L	373242R
440	-	-	-	-	373244L	373244R
460	-	-	-	-	373246L	373246R



Implants - Titanium

6.5mm Hip Screw

Product Code	Screw Length
366560	60
366565	65
366570	70
366575	75
366580	80
366585	85
366590	90
366595	95
366500	100
366505	105
366510	110
366515	150
366520	120



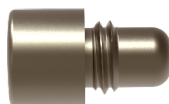
4.0mm Locking Screw

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



End Cap M8

Product Code	Length
368001	01
368005	05
368010	10
368015	15
368020	20



4.8mm Locking Screw

Product Code	Screw Length
364820	20
364825	25
364830	30
364832	32.5
364835	35
364837	37.5
364840	40
364845	45
364850	50
364855	55
364860	60
364865	65
364870	70
364875	75
364880	80
364885	85
364890	90



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.

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Shellock FG. Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3.0-Tesla MR System. 2002, 721-732.

Zou Y, Chu B, Wang C, Hu Z. Evaluation of MR issues for the latest standard brands of orthopedic metal implants, Plates and screws. Eur J Radiol. 2015, 84(3):450-457.



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