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austofix F1
LONG 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.

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 F1
LONG FEMORAL NAIL

There is emergent evidence to suggest that intramedullary (IM) nails are a superior implant for the treatment of unstable intertrochanteric fractures.

It has been shown that with unstable intertrochanteric fractures, problems with compression hip screw fixation such as excessive fracture collapse and implant cut-out increase. Fractures classified as AO 31-A3 are often referred to as “reverse obliquity” fractures and in these cases the rates of failure for compression hip screws are too high to recommend its use. In these cases, IM nails can be shown to provide clinical advantage.

Theoretical mechanical advantages of IM nails over screw and plate fixation are attributed to a reduced distance between the hip joint and the implant, which diminishes the bending moment across the implant/fracture construct.

Nails can also be inserted percutaneously, thereby reducing both operating time and soft-tissue damage. Importantly, the nail acts as an intramedullary buttress to prevent excessive shaft medialisation.

Using Titanium alloy (ISO5832-3), the Austofix F1 Hip Nail offers superior strength combined with the smallest diameter available for a proximal femoral nail.

The instruments have been developed through clinical trials to be simple to use and enable the screws to be easily aligned in the femoral head. Operative times can be reduced significantly when using the F1 Hip Nail.

The Austofix F1 Hip Nail complements the Austofix Nail Range for antegrade femoral nailing indications. The S2 Supracondylar Nail is used for retrograde femoral nailing.

Design Details

Nail - Titanium

Long Nail

- 340-460mm Lengths
- 15.5mm Proximal Diameter
- 10, 11, 12mm Distal Diameters

Multiple Proximal Oblique Screw Angles

- 120°
- 125°
- 130°

Stress Relief Cuts

- Reduces Nail Fatigue.

Proximal 4.8mm Screw options

- Midshaft fractures
- Dynamic & Static locking options

Distal 4.8mm Screw holes

- Dynamic & Static locking options

Intuitive Instrument Set

- Decreased Procedure Time.
- Enhanced safety.

Lateral Chamfer

- Reduces tendon irritation.

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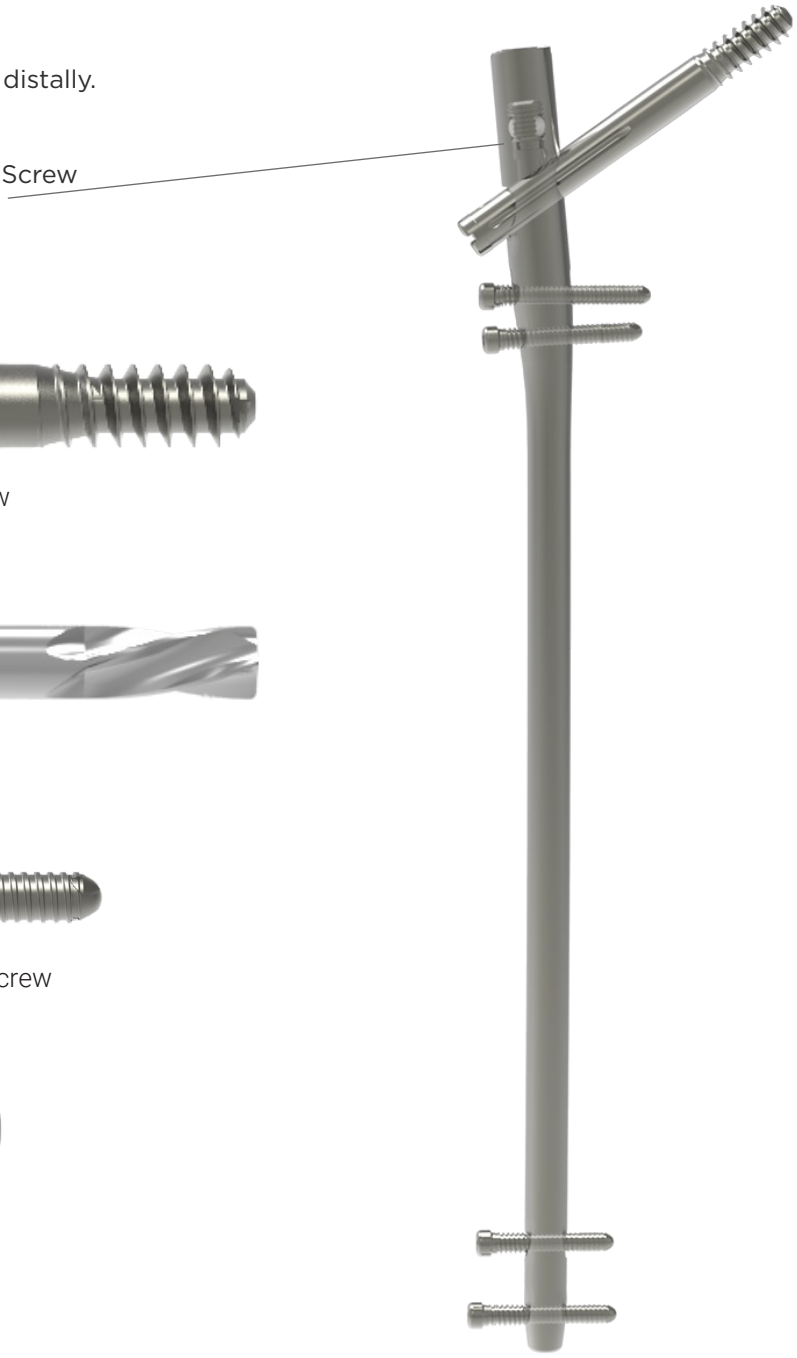
Screws & End Caps - Titanium

The following are used with the F1 Long Nail:

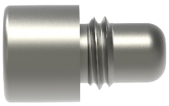
- 10.4 Hip Screw
- Helical Blade
- 4.8mm Locking Screws used distally.
- M10 End Cap
- F1 Proximal Femoral Nail Set Screw (Pre-assembled in the Nail)



10.4 Hip Screw

Helical Blade

4.8mm Locking Screw



M10 End Cap

Indications & Pre-Operative Planning

The medullary canal must be checked on radiographs to determine whether reaming is necessary. The canal is wider on lateral radiographs, so true anteroposterior views are necessary. This is usually available from the contralateral limb.

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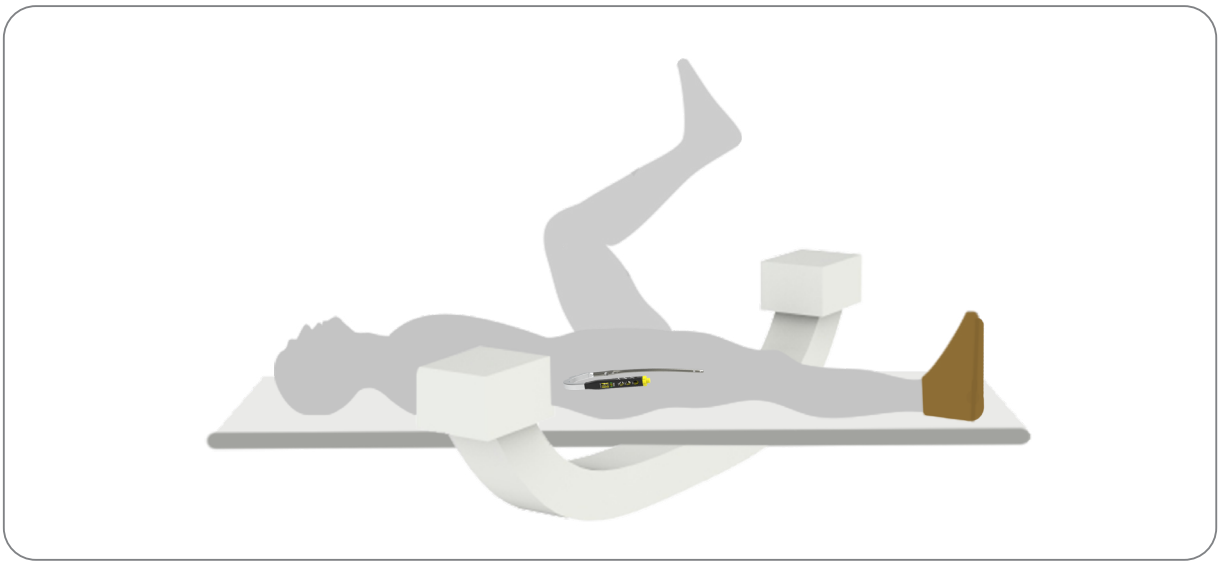
Patient Positioning

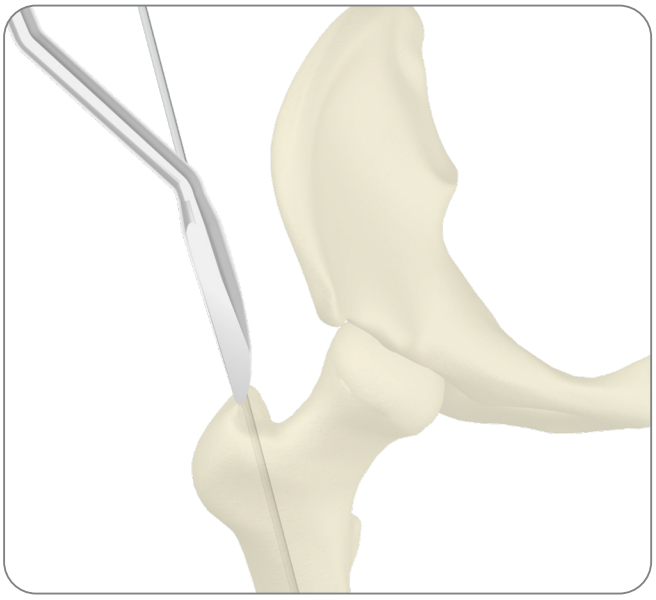
A traction table and Image Intensifier are used in the same manner as for most other types of hip nail. The affected hip is in neutral or slight flexion and 5° adduction. The traction boot should be carefully applied. The reduction should be checked on both views and rotation is adjusted as necessary. Neutral rotation is normally appropriate for trochanteric fractures, while displaced cervical fractures require manipulation and internal rotation. The opposite hip should be either fully extended or flexed, preferable in a high lithotomy position to allow good lateral X-ray views (image below).



Incision & Bone Preparation

Incision

The incision begins 1 cm above the Greater Trochanter and extends upward from 3 to 4cm. Pass the knife obliquely downward to incise the fascia over the top of the Greater Trochanter (Right).

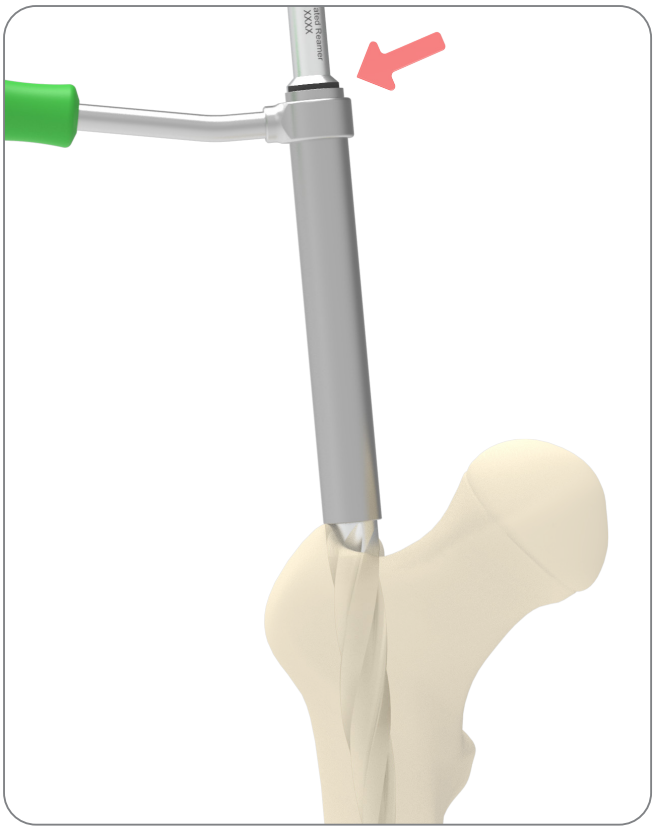


Entry Point

Insert the 3.2x400mm Guidewire (533235) lateral to the tip of the Greater Trochanter. Use Cannulated Awl (600040C) to make the initial entry into the medullary canal. Check the position in AP & lateral X-ray views.

Tissue Guard Trocar

The Tissue Guard Trocar (610089) can be used to ensure the Guidewire is concentric to the 16mm Tissue Guard (610090) or to offset the entry point by 4.0, 4.5, 5.0 or 5.5mm.



Drilling & Reaming Entry Hole

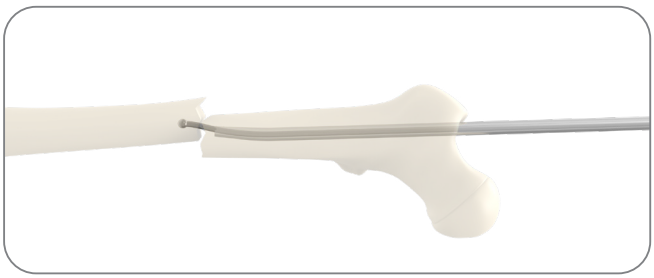
Use the Tissue Guard with the 15.8 Cannulated Reamer (600090) for bone preparation (right). The Reamer can be used by hand with the T-handle or with a drill. Ensure the Reamer passes into the subtrochanteric area.

Insertion of Ball-tipped Guidewire

While keeping the Tissue Guard against the bone, remove the Reamer and 3.2x400mm Guidewire. 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* 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.

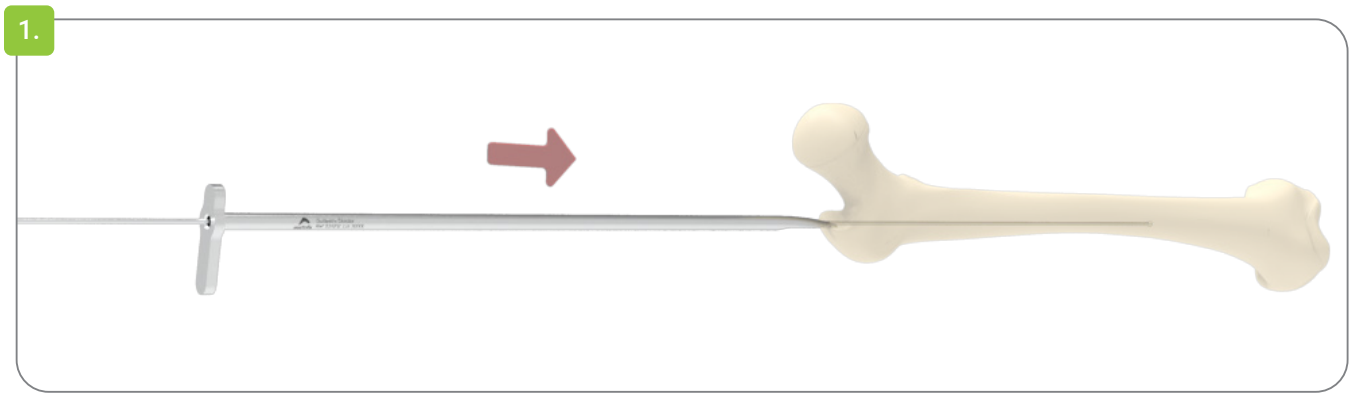
Note:

- 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 screw 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 (SET-INS-REAM) supplied on request.

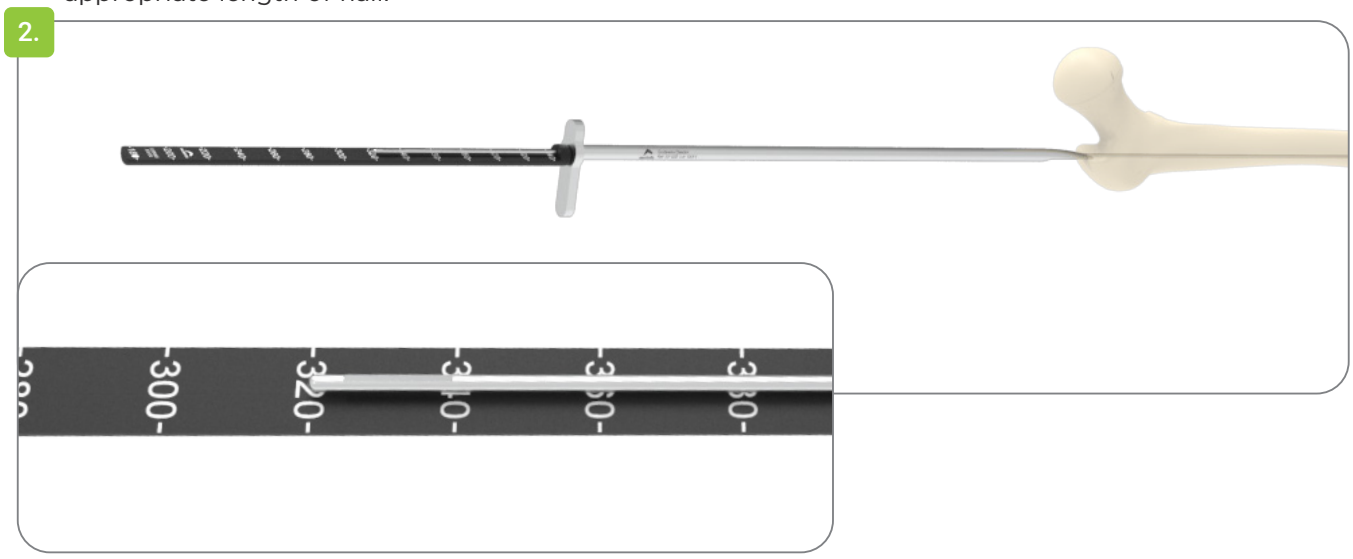


Nail Length Gauge

1. With the Ball-tip Guidewire inserted to the intended position of the nail, pass the Guidewire Director over the guidewire to the Greater Trochanter.



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



A Nail Length Gauge (600025) can be supplied on request.

Reaming

1. Pass a Flexible Reamer over the Ball-tip Guidewire.
2. Then, 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.
3. 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.

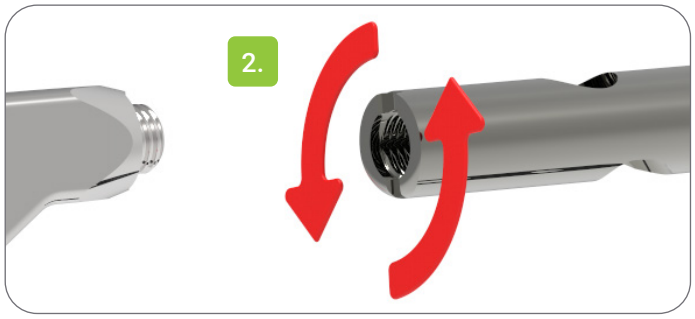
Instrument Assembly

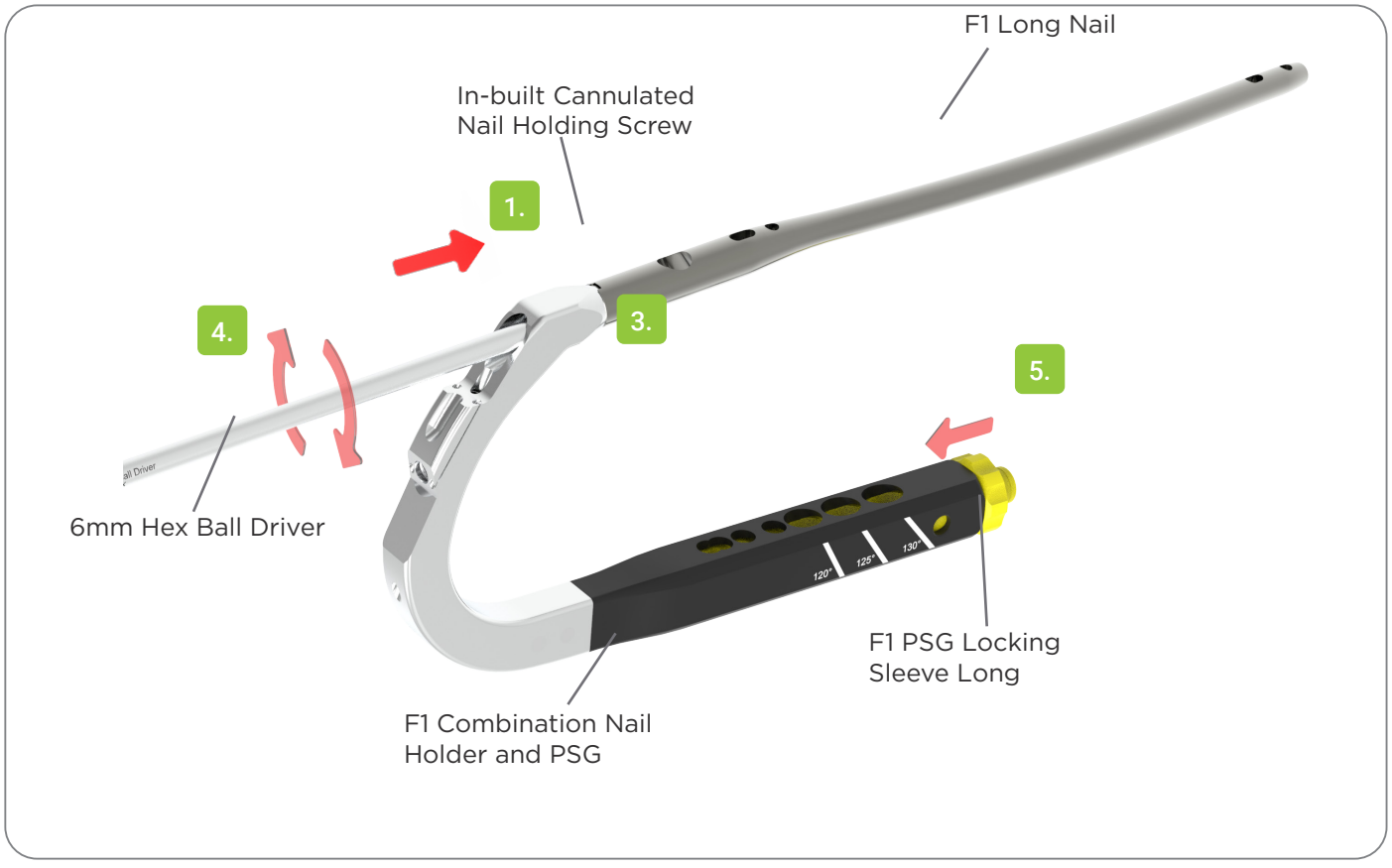
F1 Combination Nail Holder & PSG

1. Use the 6mm Hex Ball Driver to stabilise the F1 Long Nail Holding Screw.
2. With the Nail Holding Screw now fixed, turn the Nail onto the Nail Holding Screw.
3. Align the Nail's proximal groove to the F1 Combination Nail Holder & PSG (600094) with the bow of the Nail facing anteriorly.
4. Use the Cannulated 6mm Hex Ball Driver (600045) to fasten the In-built Nail Holding Screw.
5. Slide the Proximal Screw Guide (PSG) Locking Sleeve Long (yellow) (600096) into the Proximal Screw Guide 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 F1 Long Nail shown

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Nail Insertion

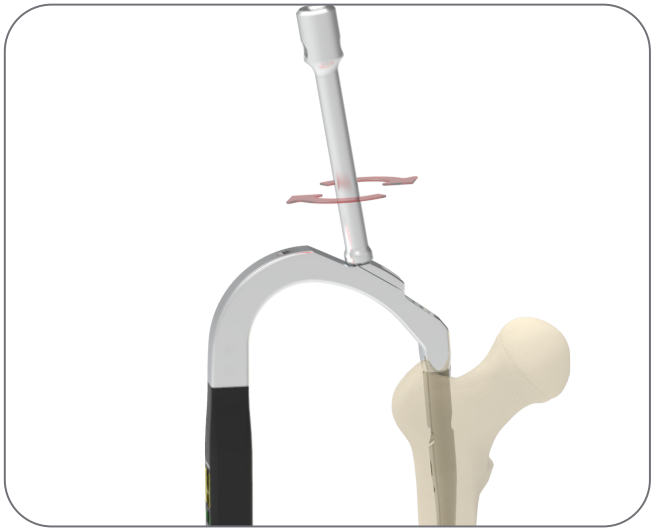
Nail Depth

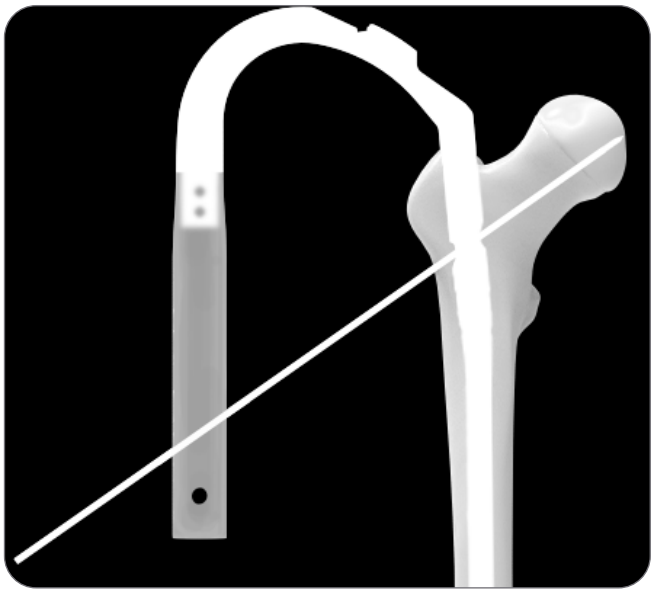
Depth is assessed initially by using the X-ray outline of the oblique holes to estimate the path of the screws. Normally this is when anteroposterior radiographs indicate the top of the Nail is 5mm below the tip of the Greater Trochanter. Adjust Nail depth as necessary until the screw track is just above the calcar and below the centre of the femoral head.

If use of a mallet is required, attach the Impactor (600028) (right).

If the Nail is not loose in the bone, align the rotary position while inserting the last 1-2cm. Use the Slide Hammer assembly (600097) if extraction and reinsertion is required.

Note: An End Cap may be added if the top of the Nail is sitting sub-flush or if bone ingrowth is a concern.

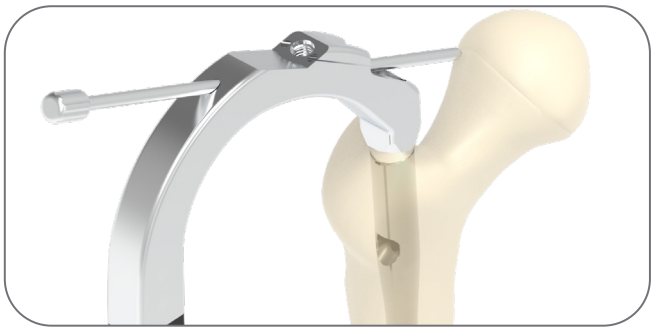


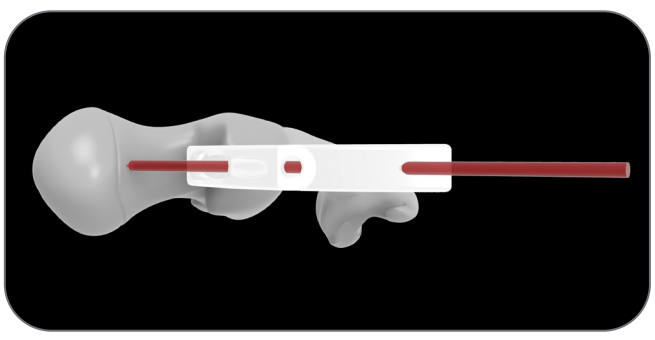


Nail Rotation

Remove the Ball-tip Guidewire and use the Single Shot Pin (600092) with the Xray aligned on a lateral image of the Nail Holder for correct Nail Rotation. The Pin is to be centred or slightly posterior on the femoral head.

Note: The impactor must be removed to obtain the lateral X-ray view.





Lag Screw

For Helical Blade, go to Page 16.

Guidewire Insertion

1. Assemble the F1 Lag Screw Trocar (610088) and Lag Screw/Blade Sleeve (610101) and pass through the PSG Locking Sleeve Long (600096) until it contacts the Cortical Bone. Then secure the PSG Locking Sleeve nut.

   Note: Ensure that the angle in the PSG Locking Sleeve Long (600096) matches the angle of the nail hole.

1.

2. Replace the Lag Screw Trocar with the Guidewire Sleeve (610092), ensuring the sleeves contact the lateral cortex.

   Insert the 3.2x400mm Guidewire to the medial tip of the femoral head.

   Note: Confirm location on X-ray.

2.

If using the **Ezy-Aim** distal targeting system:

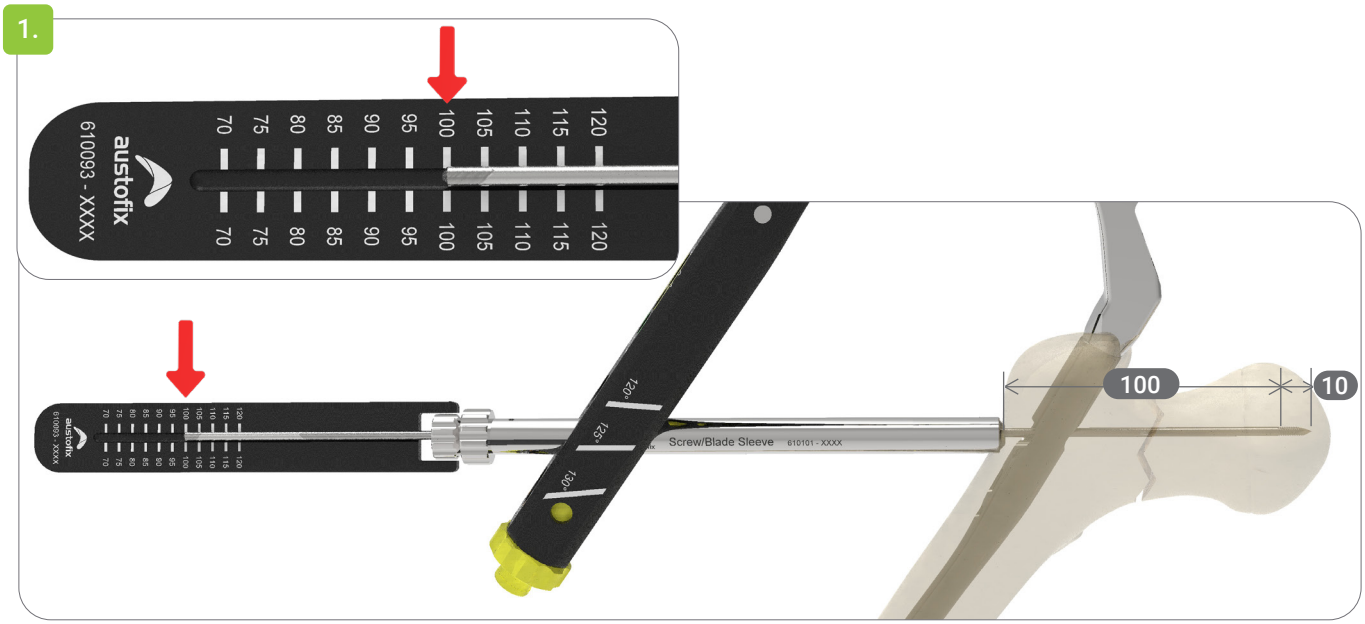
Firstly, secure the position in the proximal fragment by inserting two 2.5 x 250mm K-Wires (512525) through the Nail Holder and into the femoral head.

Then, remove the Guidewire and perform distal locking as described in the Ezy-Aim Distal Targeting Surgical Technique, after which the Guidewire is re-inserted to continue the Proximal Lag Screw/Helical Blade Insertion Surgical Technique.

Length Measurement

1. Push the Lag Screw Depth Gauge (610093) up to the Lag Screw/Blade Sleeve and take the reading from the lateral point of the Guidewire. Use the closest 5mm interval to determine 10.4 Lag Screw Length.

Note: The Depth Gauge already calculates the 10mm tolerance within the provided measurements to ensure the lag screw/blade does not protrude out of the medial side of the bone.



Reaming

1. Use the 7-10.5mm Step Drill Stop (640090) for accurate drilling depth.

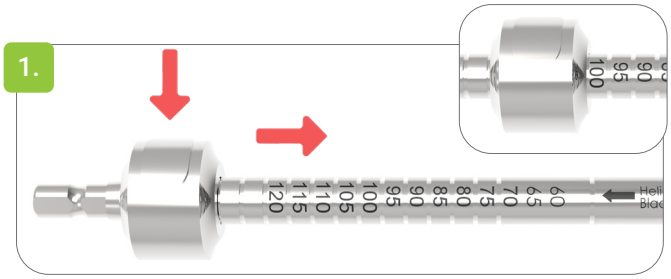
   Ensure the reading on the medial side of the Step Drill Stop is the same as the desired 10.4 Lag Screw length.

2. Drill or hand ream the 7-10.5mm Step Drill (610094) until the Stop contacts the Lag Screw /Blade Sleeve. Ensure the Nail Holder orientation does not alter.

   Note: Check for guidewire deflection that may have occured as it passed into the femoral head/neck before and after drilling.

   (OPTIONAL) The 7-10.5mm Bone Conserving Reamer (600106) can be used if bone conservation is desired.

3. Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer.



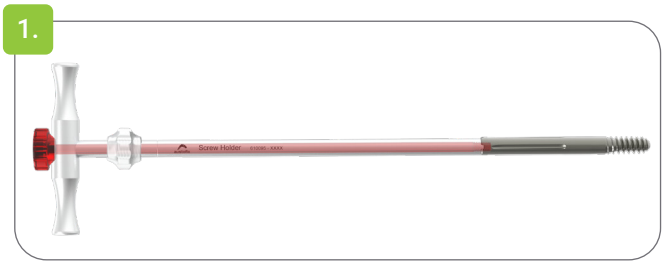
Assembly and Insertion

1. Screw the Compression Nut (610097) onto the Screw Holder, ensuring the edge lines up with the groove on the Screw Holder (610095).

   Align the Lag Screw Holder (610095) grooves to the 10.4mm Lag Screw tabs. Then, screw in the Screw Holder Retainer (610096).

   Note: The Compression Nut must be mounted on the Lag Screw Holder **before** the Lag Screw is inserted.

1.

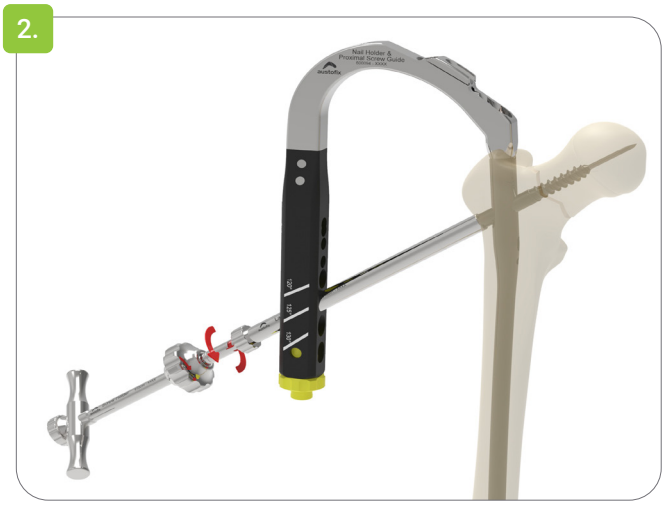


2. Drill until the Step Drill Stop contacts the Lag Screw/Blade Sleeve.

   Note: X-ray should be used during lag screw insertion to monitor Positioning.

   Ensure that guidewire placement has not altered to optimise lag screw location.

2.

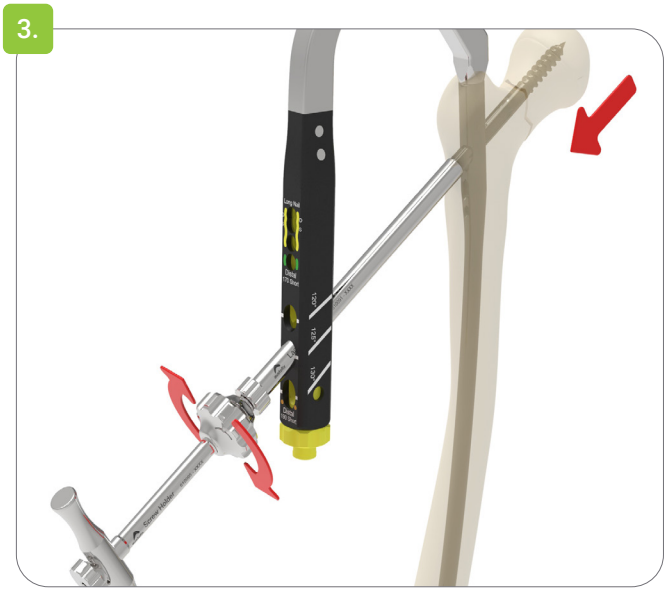


3. Screw Holder Compression Nut (610097) can be used to reduce the fracture.

   Rotate the Compression Nut Clockwise for reduction. Check on X-ray for optimal fracture reduction.

   Note: The Compression Nut must be mounted on the Lag Screw Holder **before** the Lag Screw is inserted.

3.

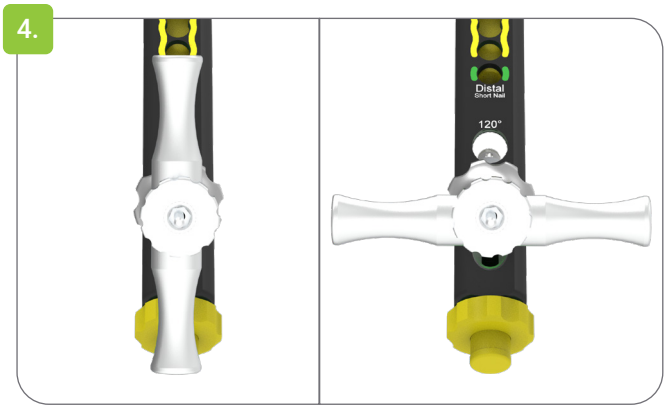


4. Correct 10.4mm Lag Screw depth is indicated when the groove in the Screw Holder is flush with the Lag Screw/Blade Sleeve.

   Ensure the Screw Holder handle is either parallel or perpendicular to the F1 Combination Nail Holder & PSG (600094).

   Note: Only turn Screw Holder Handle clockwise, anticlockwise turning compromises the fixation.

4.



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Helical Blade

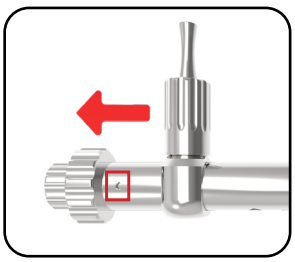
Guidewire Insertion

1. Asssemble the F1 Lag screw Trocar (610088), Lag Screw/Blade sleeve (610101) and Spiral pin alignment instrument (610102).

   Note: The Spiral Pin Alignment Instrument has a spring loaded cap. Ensure the cap is not rotated more than four times from the tightest position.

   Pass through the PSG Locking Sleeve Long (600096) until it contacts the Cortical Bone. Then secure the PSG Locking Sleeve nut.

   Note: Ensure that the angle in the PSG Locking Sleeve Long (600096) matches the angle of the nail. hole.

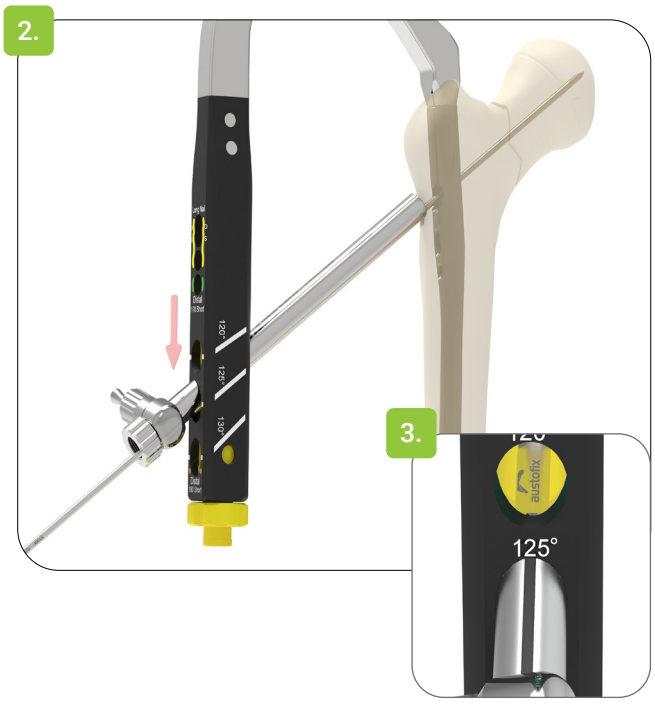


WARNING: The pin must not be engaged in the hole on the Lag screw/ blade sleeve. Drilling with the pin engaged in the hole will damage instrumentation.

2. Replace the Lag Screw Trocar with the Guidewire Sleeve (610092), ensuring the sleeves contact the lateral cortex.

   Insert the 3.2x400mm Guidewire to the medial tip of the femoral head.

   Note: Confirm location on X-ray.



3. Ensure the line on the Lag Screw/Blade Sleeve aligns with the centre number and the Proximal Screw Guide Locking Sleeve - Long (600096) is firmly secured.

If using the **Ezy-Aim** distal targeting system:

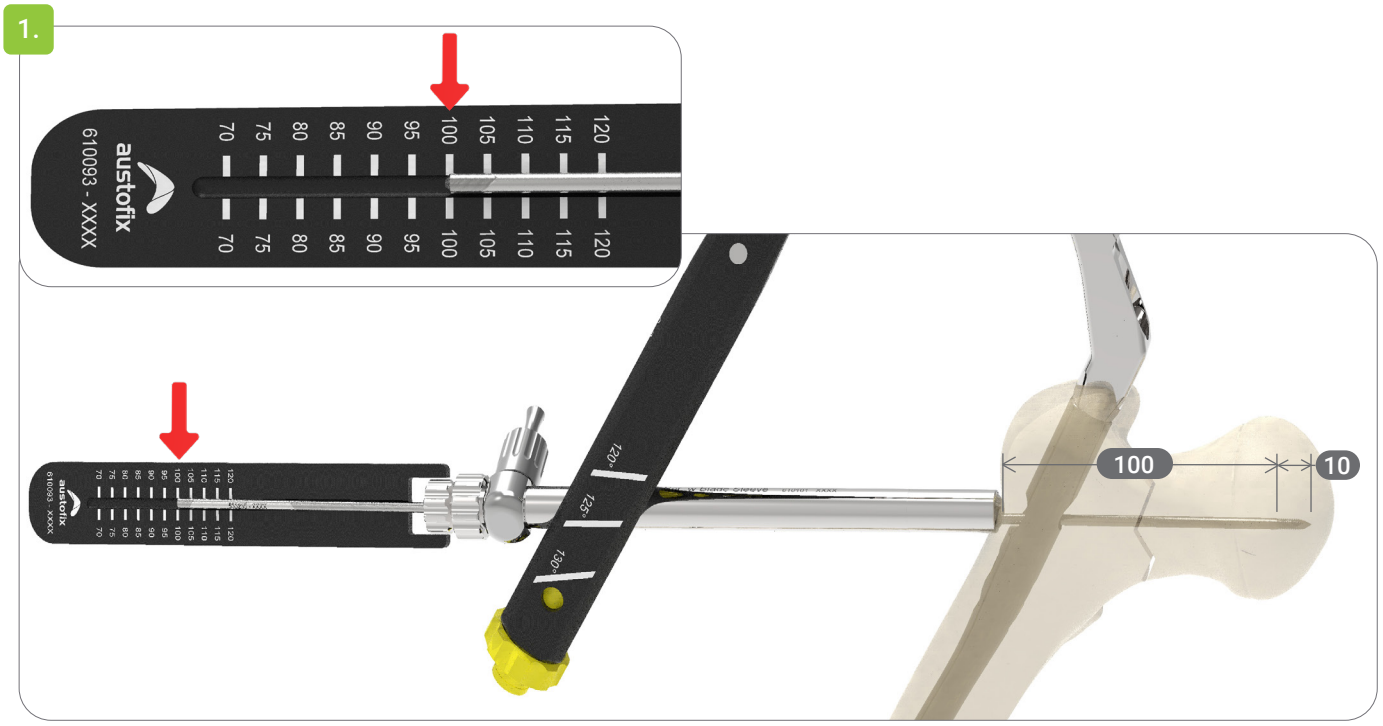
Firstly, secure the position in the proximal fragment by inserting two 2.5 x 250mm K-Wires (512525) through the Nail Holder and into the femoral head.

Then, remove the Guidewire and perform distal locking as described in the Ezy-Aim Distal Targeting Surgical Technique, after which the Guidewire is re-inserted to continue the Proximal Lag Screw/Helical Blade Insertion Surgical Technique.

Length Measurement

1. Push the Lag Screw Depth Gauge (610093) up to the Lag Screw/Blade Sleeve and take the reading from the lateral point of the Guidewire. Use the closest 5mm interval to determine 10.4 Helical Blade Length.

Note: The Depth Gauge already calculates the 10mm tolerance within the provided measurements to ensure the lag screw/blade does not protrude out of the medial side of the bone.



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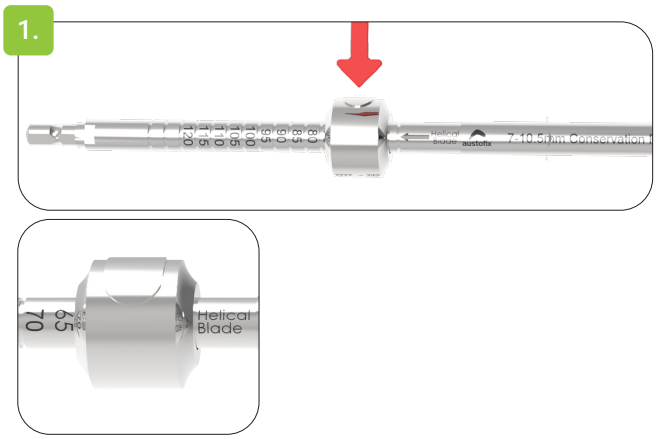
Reaming

1. Use the 7-10.5mm Step Drill Stop for accurate drilling depth.

   Ensure the reading on the medial side of the Step Drill Stop is the **Helical Blade** laser marking to open the lateral cortex.



WARNING: The pin must not be engaged in the hole on the Lag Screw/Blade Sleeve while drilling.

2. Drill or hand ream the 7-10.5mm Step Drill until the Stop makes contact with the screw/blade sleeve

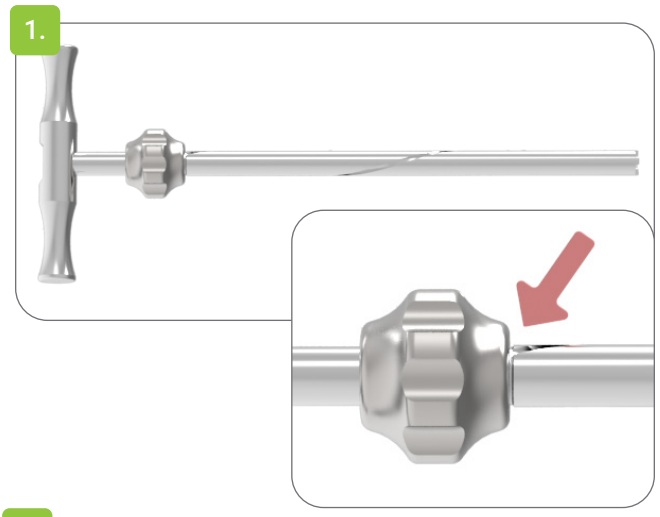
   Note: Check for guidewire deflection that may have occured as it passed into the femoral head/neck before and after drilling.

   Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer.

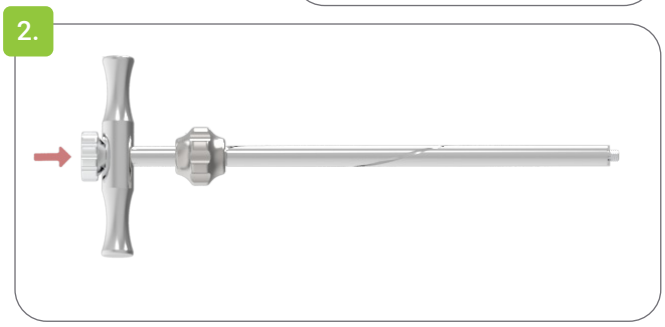
   (OPTIONAL) The 7-10.5mm Bone Conserving Reamer (600106) can be used if bone conservation is required.

Assembly and Insertion

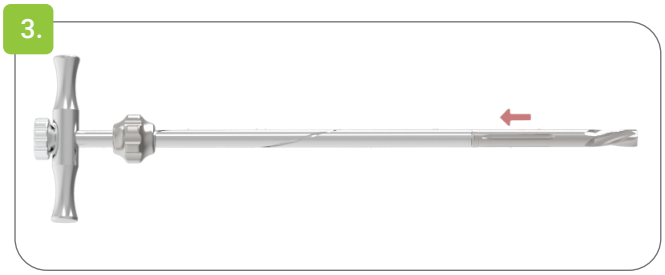
1. Screw the Compression Nut (610097) onto the Screw Holder, ensuring the edge lines up with the groove on the Screw/Blade Holder (610100).



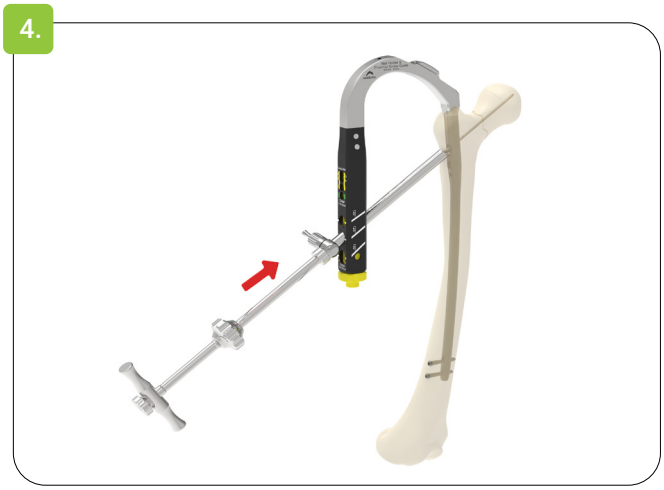
2. Insert the Lag Screw Retainer (610096) through the Screw/Blade Holder.



3. Screw on the desired Helical Blade, ensuring it is tightly fastened and the Helical Blade grooves are fitted within the Blade Holder tabs.



4. Pass the assembled Helical Blade, Screw/Blade Holder, Retainer and Compression Nut through the Lag Screw/Blade Sleeve until Helical Blade contacts the near cortex.



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5. Ensure the Spiral Pin Alignment Instrument is pushed against the back end of the Lag Screw/ Blade Sleeve and then rotate until an audible click is heard and the Alignment Pin no longer spins.

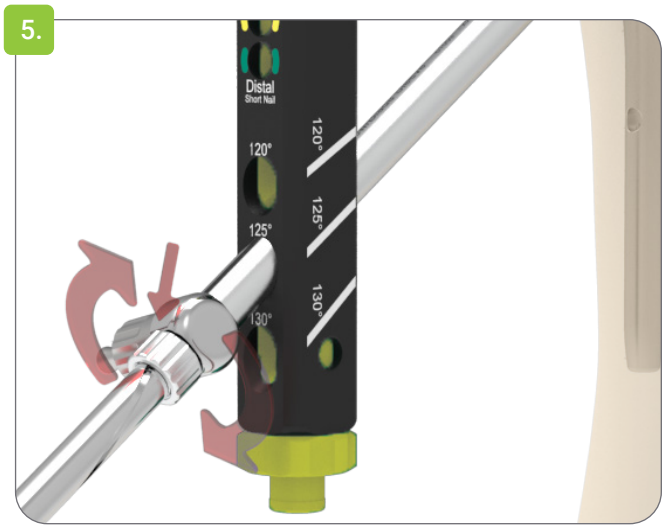
   This secures the pin into the lag screw/blade sleeve.

6. Rotate the Lag Screw/Blade Holder until an audible click is heard or the Screw/blade Holder no longer spins.

   After the spin & click, turn the device clockwise & anticlockwise to ensure that the pin has entered the groove, then lightly tighten the cap.

   This ensures the pin is adequately seated in the groove, but it will still slide freely.

   This secures the pin in the lag screw/blade sleeve into the blade holder groove.



7. Advance the Helical Blade through the femoral head by hand and then gently tapping the Screw Holder Retainer with a mallet.

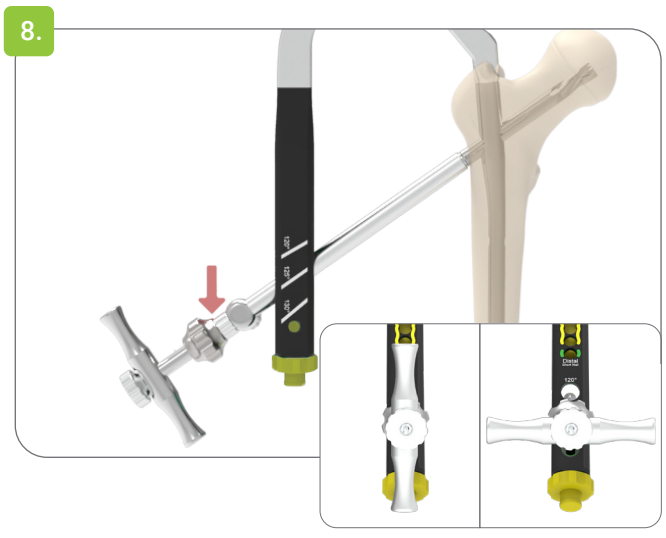
   Continue to check that the solid line laser marking on the Lag Screw/Blade Sleeve is aligned to the centre number on the Proximal Screw Guide. The Locking Sleeve Nut may need to be re-tightened.

   Note: X-ray should be used during helical blade insertion to monitor positioning.

   Ensure that guidewire placement has not altered to optimise helical blade location.

8. Continue to insert the Helical Blade until the Compression Nut (or groove on Nail Holder) contacts the Sleeve.

   Check that the Screw/Blade Holder Handle is either perpendicular or parallel to the Proximal Screw Guide.



In-built Set Screw Insertion

Note: Set Screw should be fastened before locking Screw has been inserted **unless** using the Ezy Aim System.

1. Use the 5mm Articulating Hex Driver (610098) to firmly fasten the Set Screw in the groove of the Lag Screw/Helical Blade.

2. Turn the Lag Screw/Blade Holder in the Set Screw to ensure the placement in the Lag Screw/Helical Blade groove.

   To verify the correct position of the Set Screw, try to turn the Lag Screw/Helical Blade Holder gently clockwise and counterclockwise. There should be only a small amount of toggle.

   If the Lag Screw/Helical Blade Holder still moves freely, correct the handle position and tighten the Set Screw again until it engages in one of the four grooves.

3. After slightly tightening the Set Screw it should then be unscrewed by one quarter (¼) of a turn, so that there can be slight sliding of the Lag Screw/Helical Blade.

4. Untighten the Screw Holder Retainer and remove the Screw/Blade Holder and corresponding instruments including guidewire.

Note: If alignment and insertion of the Articulating Hex Driver is difficult due to obesity, adduct the leg as much as possible. As the fracture is now fixed, there is no loss of fracture reduction.

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Proximal 4.8mm Locking Screws

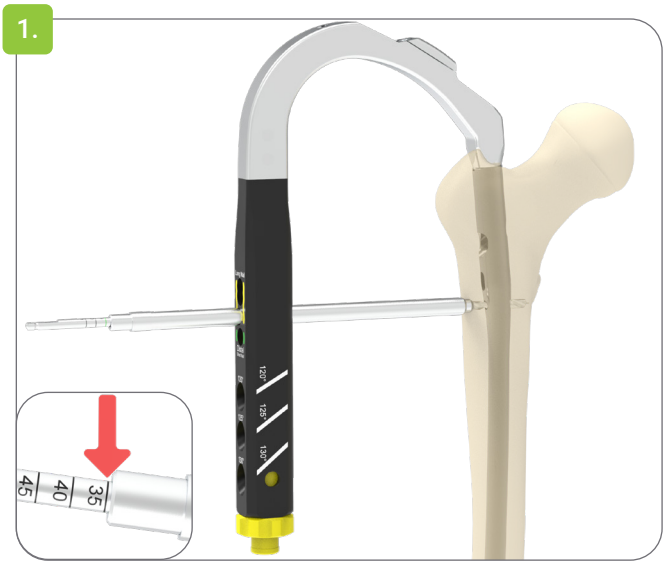
Note: These are normally only used with shaft fractures, when a Lag Screw/Blade is not necessary.

1. Pre-assemble the 180mm Outer Sleeve (610065) and 4.5x180mm Drill Sleeve (610064) with 180mm Trocar (610063), select either the static or dynamic hole and insert through the F1 Combination Nail Holder & PSG (600094).

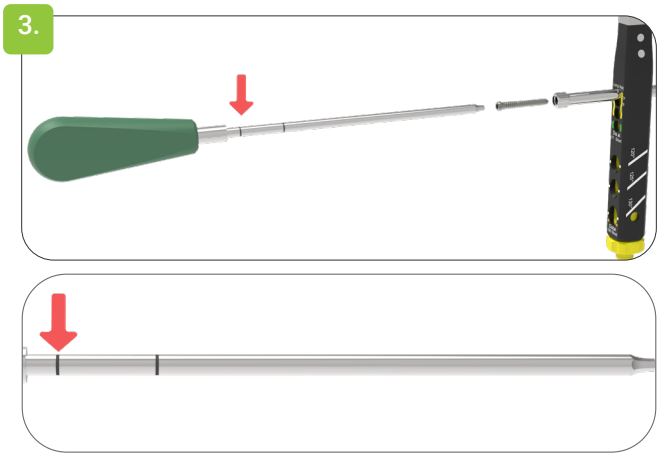
   Tighten the Locking Sleeve Nut before removing the Trocar.

   Drill using the Ø4.5mm Drill to the far cortex.

   Screw length can be measured from the Drill or the Universal 3.7-4.5 Depth Gauge (610069) can be used if desired.

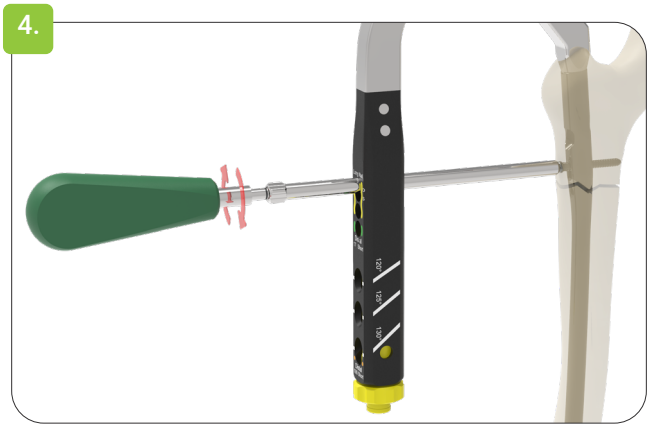


2. Select the desired Locking Screw length as per measurement above.
3. Remove the Inner Sleeve and pass the 3.5mm Hex Screwdriver (610067) with Locking Screw through Outer Sleeve. (3a)



4. Ensure the screw is completely inserted. Rotate the 3.5mm Hex Screwdriver until the laser marking closest to the screwdriver handle (3b) is level with the top of the Drill Sleeve. Then, tightly fasten.

   OPTIONAL: 3.5mm Hex Power Screwdriver (610068) can be used instead of the 3.5mm Hex Screwdriver (610067).

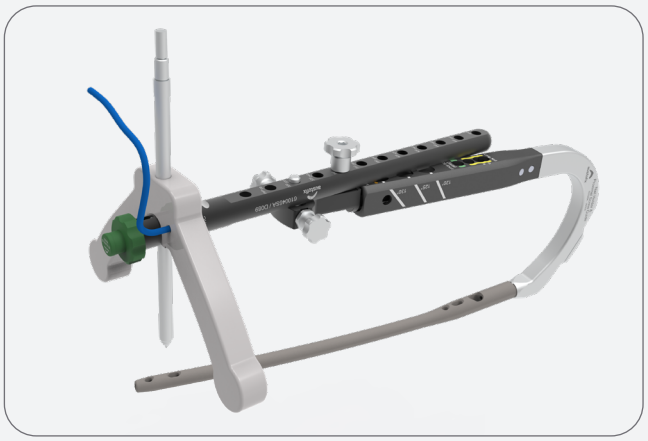


Distal 4.8mm Locking Screws

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.

First, maintain the alignment by placing two 2.5x250mm K-Wires (512525) through the anterior and posterior holes in the F1 Nail Holder and into the femoral head.

Following this, perform the distal locking method as described in the Ezy-Aim Distal Targeting Surgical Technique.



Freehand Targeting

Distal screws can also be inserted with fre hand method if proximla screws are inserted at the proximal end first.

Surgeons may perform freehand targeting based on their proficiency or as guided below:

1. Align the image intensifier with the target-incision hole until it appears circular.
2. Use a drill tip or a scalpel blade to mark the incision point at centre of the hole, and make an incision.
3. Insert the drill through the incision, and down to the bone, keeping the tip centred over the locking hole.
4. Drill through both cortices while ensuring that no shielding is produced from the back of the drill.

Note: The Drill Sleeve (610064) 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.

End Cap Insertion

Note: If an End Cap is desired, ensure correct length is chosen and the Nail Holder is removed.

1. Insert the End Cap Retainer (600093) through the Cannulated 6mm Hex Ball Driver and screw into the chosen End Cap.

2. Pass the assembled instrument and End Cap through the incision. Push down on the Cannulated 6mm Hex Ball Driver and screw until the End Cap engages the nail. Then remove the End Cap Retainer and tighten the End Cap with the 6mm Hex Ball Driver.

Nail Extraction

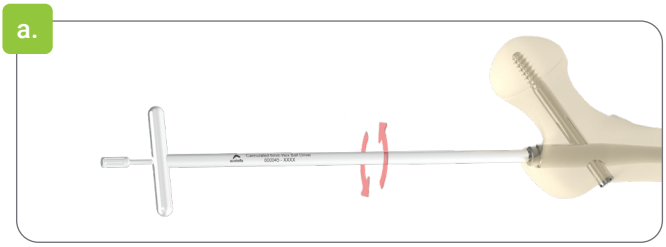
The instruments required for extraction of Austofix F1 Nails are listed below:

Product Code	Description
600107	M10 Nail Extractor
610067	3.5mm Hex Screwdriver
610068	3.5mm Hex Power Screwdriver
610098	5mm Articulating Hex Driver
600045	Cannulated 6mm Hex Ball Driver
600093	End Cap Retainer
600097	Slide Hammer
610100	Screw/Blade Holder
610096	Screw Holder Retainer
533235	3.2 x 400mm Guidewire
610102	Spiral Pin Instrument (Helical Blade only)

In-Built Set Screw

1. If an End Cap is present, assemble the Hex Ball Driver by sliding the End Cap Retainer (600093) through the Cannulated Hex Ball Driver (600045).
2. Engage and remove the End Cap with counter-clockwise rotation using the Cannulated Hex Ball Driver and End Cap Retainer assembly (Figure a).
3. Engage the in-built Set Screw using the 5mm Articulating Hex Driver (610098) and turn counter-clockwise to loosen the Set Screw.

a.

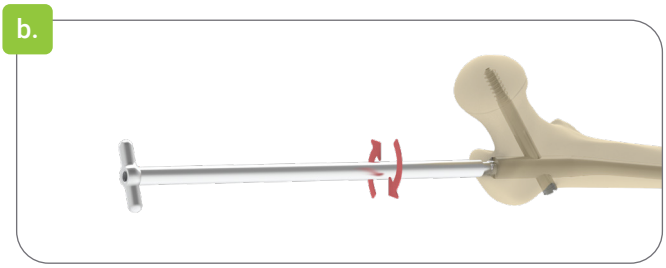


M10 Nail Extractor

1. The M10 Nail Extractor (600107) is screwed into the nail (Figure b).

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

b.

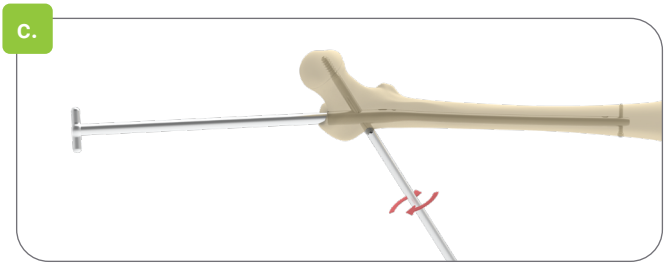


Lag Screw Removal

1. Slide the Screw Holder Retainer (610096) through the Screw/Blade Holder (610100).
2. Engage the end of the Hip Screw with the Screw Holder Retainer and Screw Holder assembly and turn counter-clockwise to loosen and remove the Hip Screw (Figure c).

Note: A 3.2 x 400mm Guidewire (533235) can be used for alignment and to facilitate Screw Holder entry.

c.



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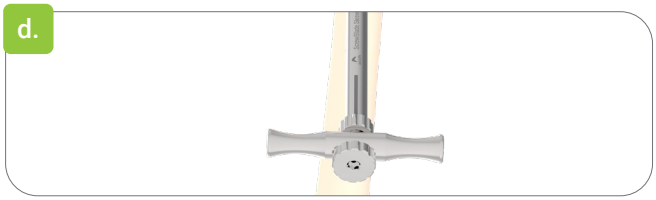
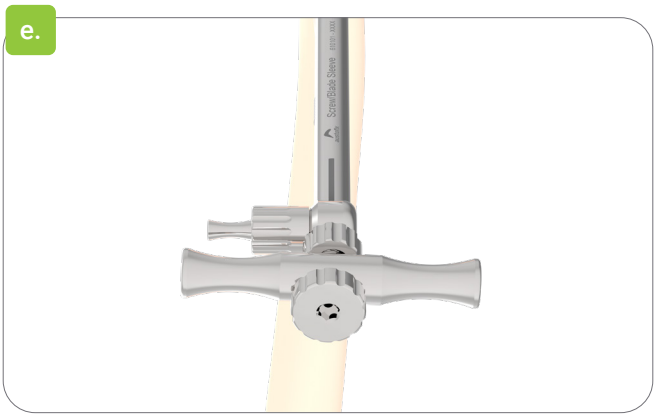
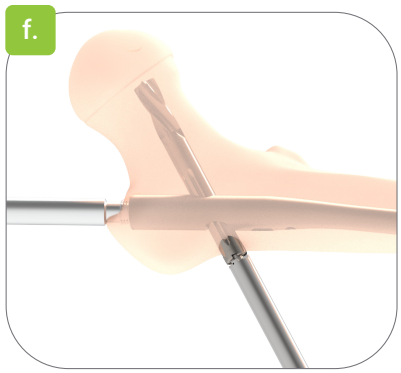
Helcial Blade Removal

1. Slide the Screw Holder Retainer (610096) through the Screw/Blade Holder (610100).
2. Assemble the Lag Screw/Blade Sleeve (610101) and the Screw/Blade Holder assembly. Rotate the assembly to ensure the solid laser marking line on the lag screw/blade sleeve is on the top. (figure d)
3. Slide the Pin Alignment Instrument (610102) over the screw/blade sleeve.
4. Ensure the Spiral Pin Alignment Instrument is pushed against the back end of the Lag Screw/ Blade Sleeve and then rotate until an audible click is heard and the Alignment Pin no longer spins. This secures the pin into the lag screw/blade sleeve.
5. Rotate the Lag Screw/Blade Holder until an audible click is heard or the Screw/blade Holder no longer spins. This secures the pin in the lag screw/ blade sleeve into the blade holder groove. (figure e)
6. Engage the end of the Helical Blade with the Screw Holder Retainer and Screw/Blade Holder assembly. (figure f)
7. Hold the lag screw/balde sleeve and pull out the screw/blade holder with the Helical Blade by hand and then tapping the Screw/blade Holder handle with a mallet. (figure g) As the Screw/Blade holder rotates, re-position the mallet.

Note: A 3.2 x 400mm Guidewire (533235) can be used for alignment and to facilitate Screw/blade Holder entry.

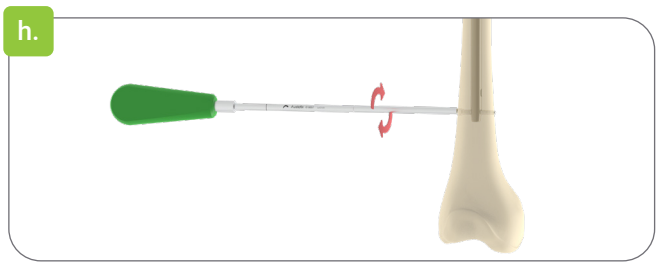






Distal Screw Removal

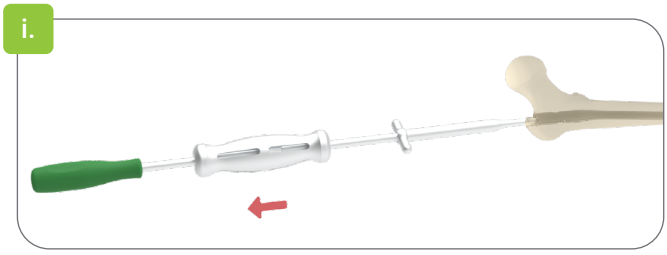
1. Austofix Screws are fitted with a conventional 3.5mm hexagonal drive. They can be removed either with the 3.5mm Hex Power Screwdriver (610068) or by hand with the 3.5mm Hex Screwdriver (610067) (Figure h).



Nail Removal

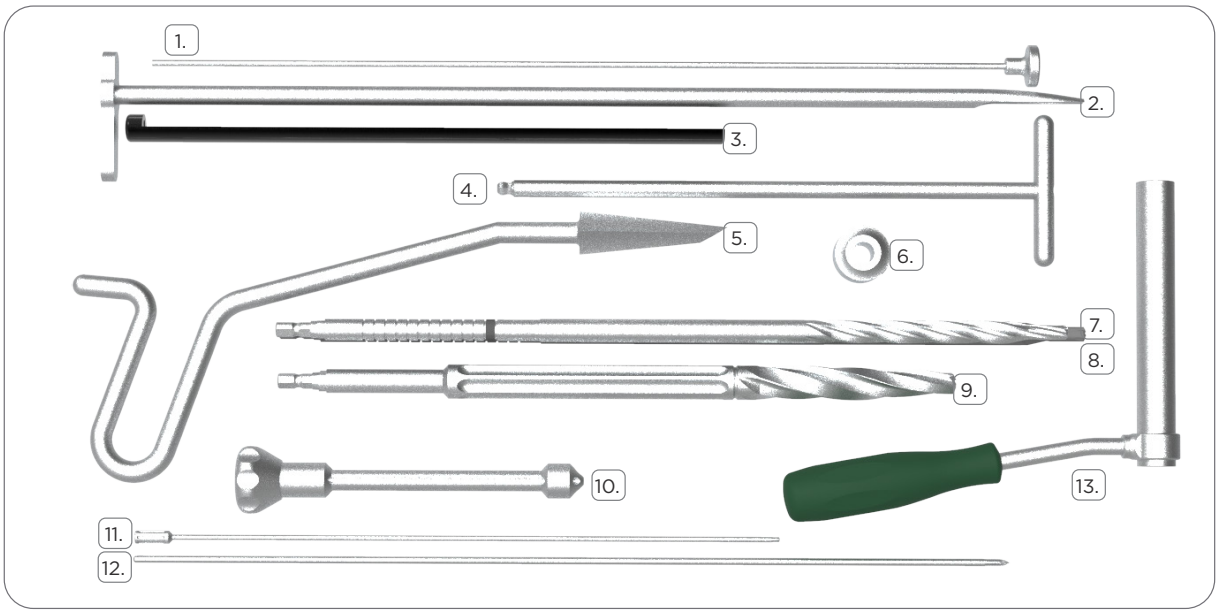
1. Attach the Slide Hammer (600097) assembly onto the Nail Extractor and withdraw the nail (Figure i).

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



Instruments

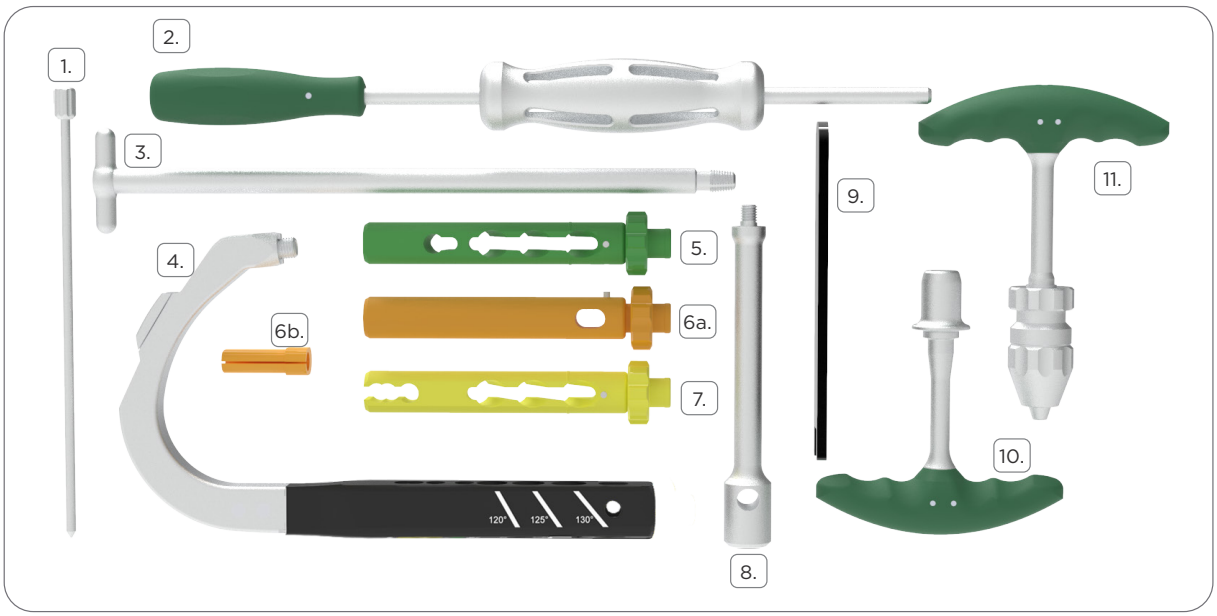
Top Layer



1.	531000	-	Guide Wire Pusher
2.	531002	-	Guidewire Director
3.	600069	-	Nail Length Guidewire Gauge
4.	600045	-	Cannulated 6mm Hex Ball Driver
5.	600040C	-	Cannulated Awl
6.	640090	-	7-10.5mm Step Drill Stop
7.	610094	-	7-10.5mm Step Drill
8.	600106	-	7-10.5mm Bone Conserving Step Drill
9.	600090	-	15.8mm Cannulated Reamer
10.	610089	-	Tissue Guard Trocar
11.	600093	-	End Cap Retainer
12.	533235	-	3.2x400mm Guidewire*
13.	610090	-	16mm Tissue Guard

* Supplied sterile/non-sterile

Middle Layer



1.	600092	-	Single Shot Pin
2.	600097	-	Slide Hammer
3.	600107	-	M10 Nail Extractor
4.	600094	-	F1 Combination Nail Holder & PSG
5.	600095	-	PSG Locking Sleeve Short
6a.	600099A	-	PSG Locking Sleeve 190mm
6b.	600099B	-	PSG Locking Sleeve 190mm Insert
7.	600096	-	PSG Locking Sleeve Long
8.	600028	-	Impactor
9.	610093	-	Lag Screw Depth Gauge
10.	531004	-	T-Handle
11.	531012	-	Guidewire T-Handle

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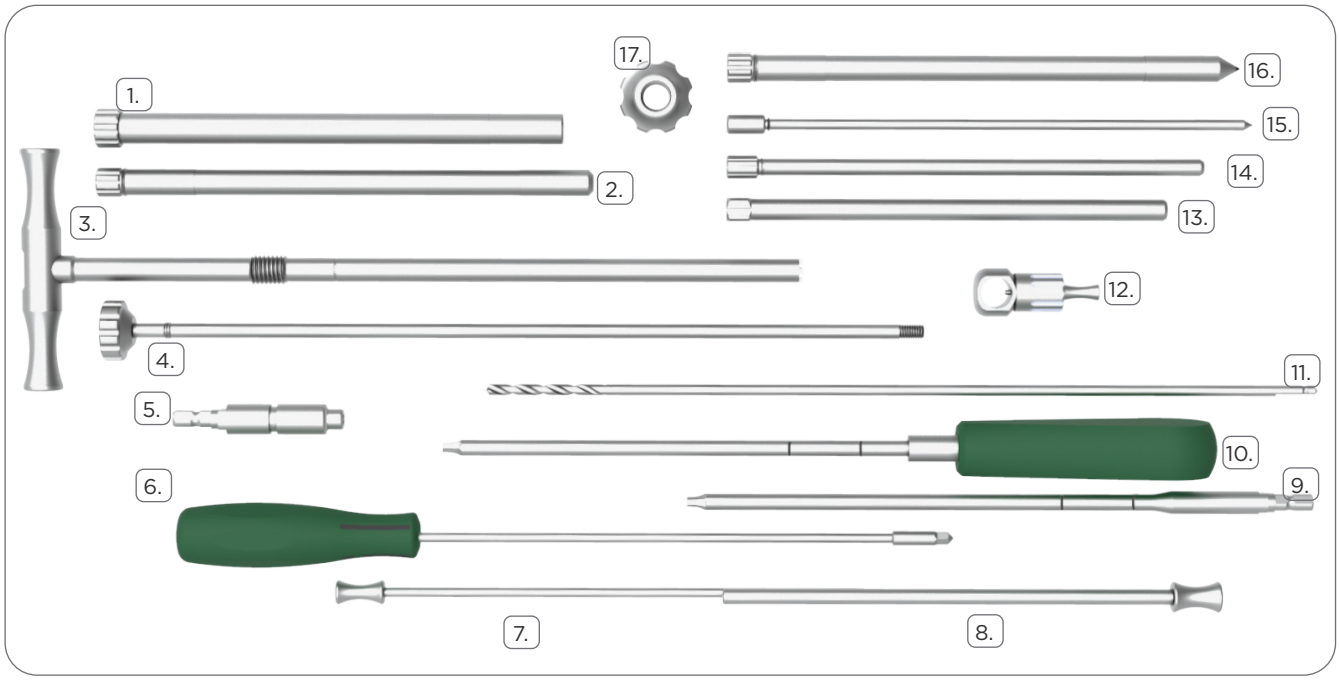
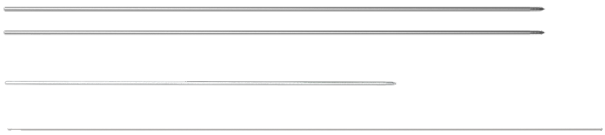
Base Layer



1.	610101	-	Lag Screw/Blade Sleeve
2.	610092	-	Guidewire Sleeve
3.	610100	-	Screw/Blade Holder
4.	610096	-	Screw Holder Retainer
5.	600042	-	AO-ZH Adaptor
6.	610098	-	Articulating Hex Driver
7.	610069B	-	Depth Gauge Inner
8.	610069A	-	Depth Gauge Outer
9.	610068	-	3.5 Power Screwdriver
10.	610067	-	3.5 Hex Screwdriver
11.	514534	-	4.5x340mm Drill*
12.	610102	-	Spiral Pin Instrument
13.	610065	-	180mm Outer Sleeve
14.	610064	-	4.5x180mm Drill Sleeve
15.	610063	-	180mm Trocar
16.	610088	-	F1 Lag Screw Trocar
17.	610097	-	Screw Holder Compression Nut

* Supplied sterile/non-sterile

Single Use Items



Guidewire	
Product Code	Description
533235	3.2x400mm Guidewire (Twin Packed)
512525	2.5x250mm K Wire (Twin Packed)
533900	3.0x900mm Ball-tip Guidewire

Drill	
Product Code	Description
514534	4.5x340mm Drill
514514	4.5x155mm Drill

Implants - Titanium

F1 Nail Long - Titanium						
Nominal Length	Ø10		Ø11		Ø12	
	Left	Right	Left	Right	Left	Right
120° Part Numbers						
340	37121034L	37121034R	37121134L	37121134R	37121234L	37121234R
360	37121036L	37121036R	37121136L	37121136R	37121236L	37121236R
380	37121038L	37121038R	37121138L	37121138R	37121238L	37121238R
400	37121040L	37121040R	37121140L	37121140R	37121240L	37121240R
420	37121042L	37121042R	37121142L	37121142R	37121242L	37121242R
440	37121044L	37121044R	37121144L	37121144R	37121244L	37121244R
460	37121046L	37121046R	37121146L	37121146R	37121246L	37121246R
125° Part Numbers						
340	37111034L	37111034R	37111134L	37111134R	37111234L	37111234R
360	37111036L	37111036R	37111136L	37111136R	37111236L	37111236R
380	37111038L	37111038R	37111138L	37111138R	37111238L	37111238R
400	37111040L	37111040R	37111140L	37111140R	37111240L	37121240R
420	37111042L	37111042R	37111142L	37111142R	37111242L	37111242R
440	37111044L	37111044R	37111144L	37111144R	37111244L	37111244R
460	37111046L	37111046R	37111146L	37111146R	37111246L	37111246R
130° Part Numbers						
340	37131034L	37131034R	37131134L	37131134R	37131234L	37131234R
360	37131036L	37131036R	37131136L	37131136R	37131236L	37131236R
380	37131038L	37131038R	37131138L	37131138R	37131238L	37131238R
400	37131040L	37131040R	37131140L	37131140R	37131240L	37131240R
420	37131042L	37131042R	37131142L	37131142R	37131242L	37131242R
440	37131044L	37131044R	37131144L	37131144R	37131244L	37131244R
460	37131046L	37131046R	37131146L	37131146R	37131246L	37131246R

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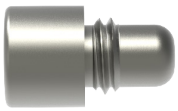
F1 10.4mm Hip Screw	
Product Code	Screw Length
361460	60
361465	65
361470	70
361475	75
361480	80
361485	85
361490	90
361495	95
361400	100
361405	105
361410	110
361415	115
361412	120

F1 Helical Blade Screw	
Product Code	Screw Length
360460	60
360465	65
360470	70
360475	75
360480	80
360485	85
360490	90
360495	95
360400	100
360405	105
360410	110
360415	115
360412	120

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

M10 End Cap	
Product Code	Head Length
363401	1
363405	5
363410	10
363415	15



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 and stainless-steel 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 in titanium and 0.74°C in stainless-steel. 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:

Chen CA, Chen W, Goodman SB, et al. New MR Imaging Methods for Metallic Implants in the Knee: Artifact Correction and Clinical Impact. 2011, 1121-1127.

Gill A, Shellock FG. Assessment of MRI issues at 3-Tesla for metallic surgical implants: findings applied to 61 additional skin closure staples and vessel ligation clips. J Cardiovasc Magn Reson. 2012, 14(1):3.

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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Notes

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