

F1+

Long Proximal 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.

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 and Dr Tony Ingman, 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.



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.

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.

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+ Femoral 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 may be reduced significantly when using the F1+ Nail.

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

Nail Features

Long Nail

- 340-460mm Lengths
- 15.5mm Proximal Diameter
- 10, 11, 12mm Distal Diameters
- Type II Anodised Titanium

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

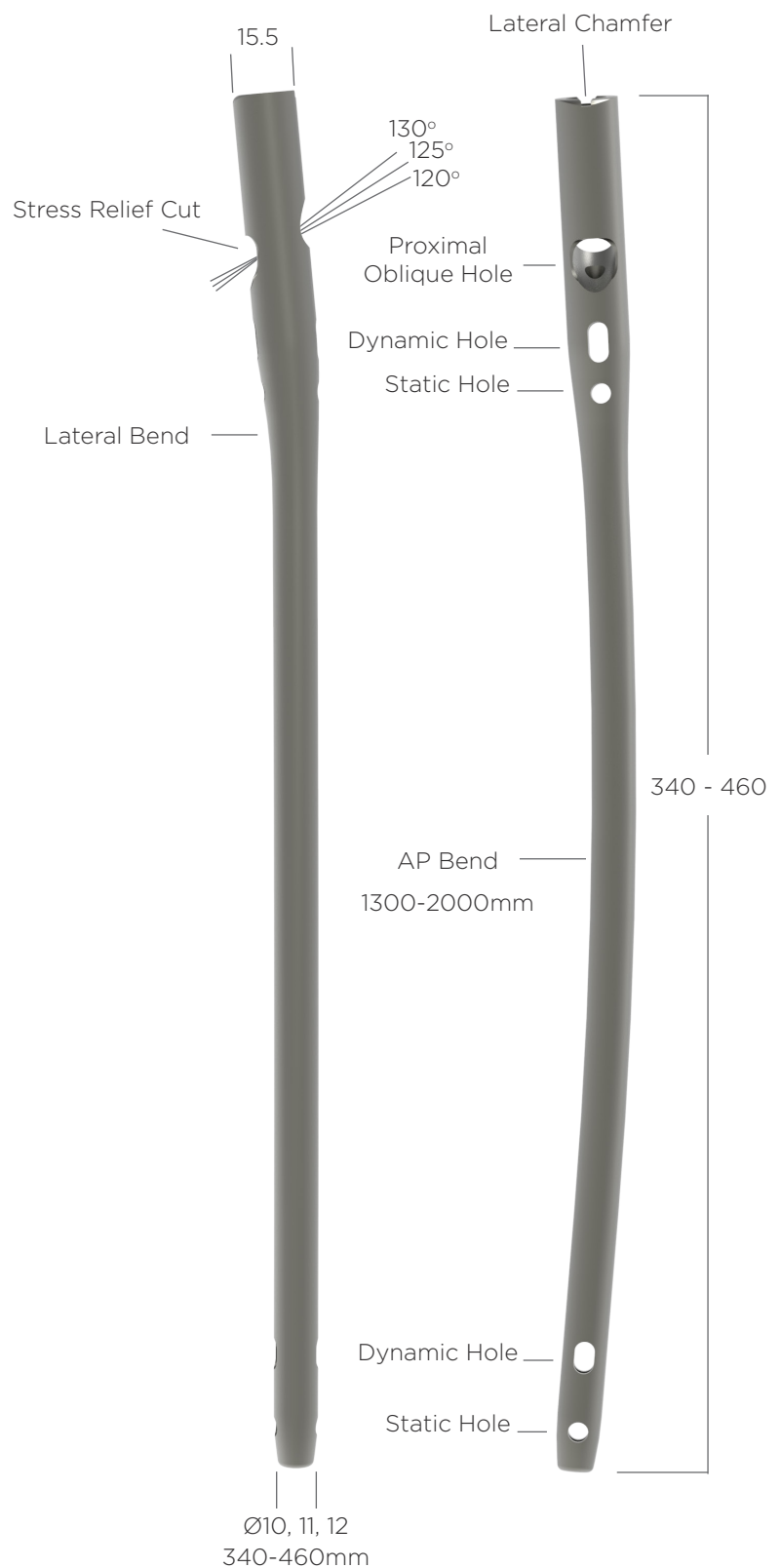
- Decreased Procedure Time.
- Enhanced safety.

Lateral Chamfer

- Reduces tendon irritation.

Nail Bends

- Lateral Bend
- Variable Anterior-Posterior (AP) Bend



Screws & End Caps

The following are used with the F1+ Long Nail:

10.4mm Hip Screw*

- Provides stable load transfer between the femoral head and nail for secure fracture healing
- Includes lateral shoulder preventing medial migration through the nail



10.4mm Hip Screw

10.4mm Helical Blade*

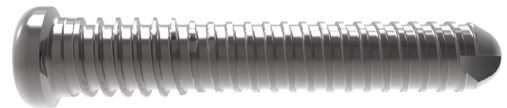
- Provides improved resistance to varus collapse
- Enhances rotational control
- Reduces bone removal
- Includes lateral shoulder preventing medial migration through the nail



10.4mm Helical Blade

4.8mm Locking Screw

- Fully threaded for ease of insertion
- The last 1/4 of threads expands to grip the lateral cortex and resist backout
- Low profile head to avoid soft tissue irritation



4.8mm Locking Screw

M10 End Cap

- Features proximal shoulder to prevent irritation



M10 End Cap

In-Built Set Screw

- Pre-assembled to reduce operating time
- Increases patient safety
- Both static and sliding locking option
- Self-centering chamfer assists in connecting the articulating driver

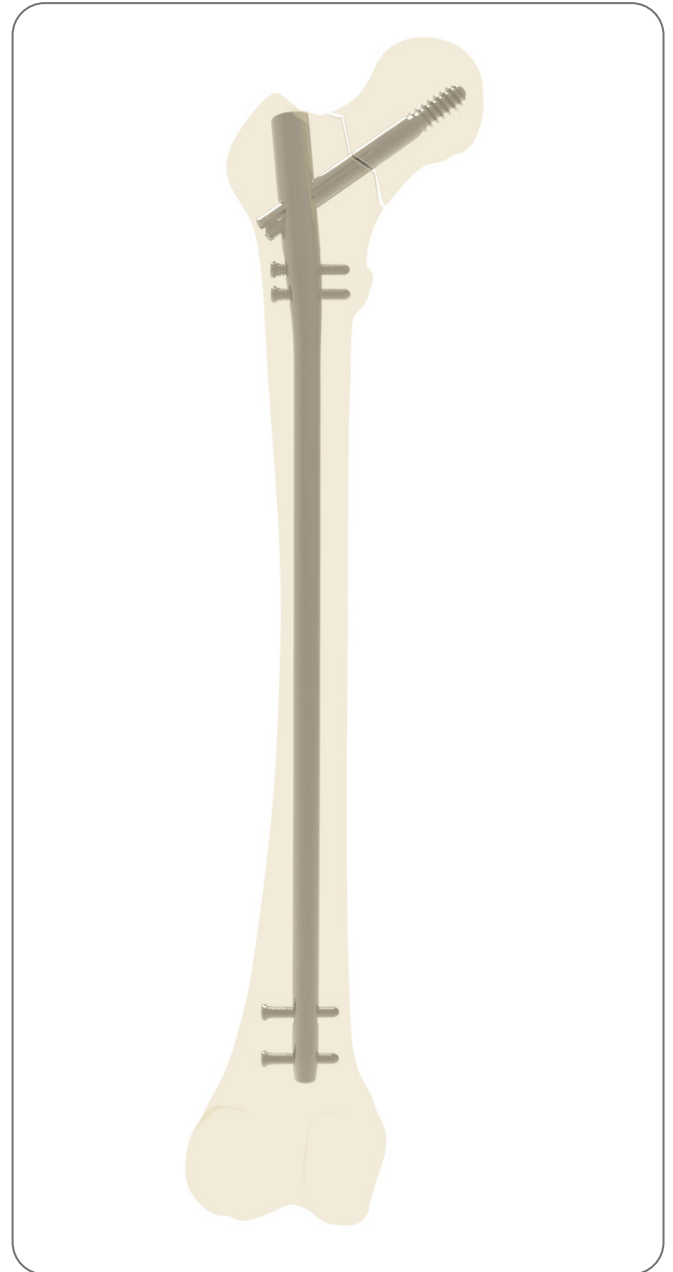


In-Built Set Screw

***Note:** Lag screw should be selected as per the surgeons preference.

Indications & Pre-Operative Planning

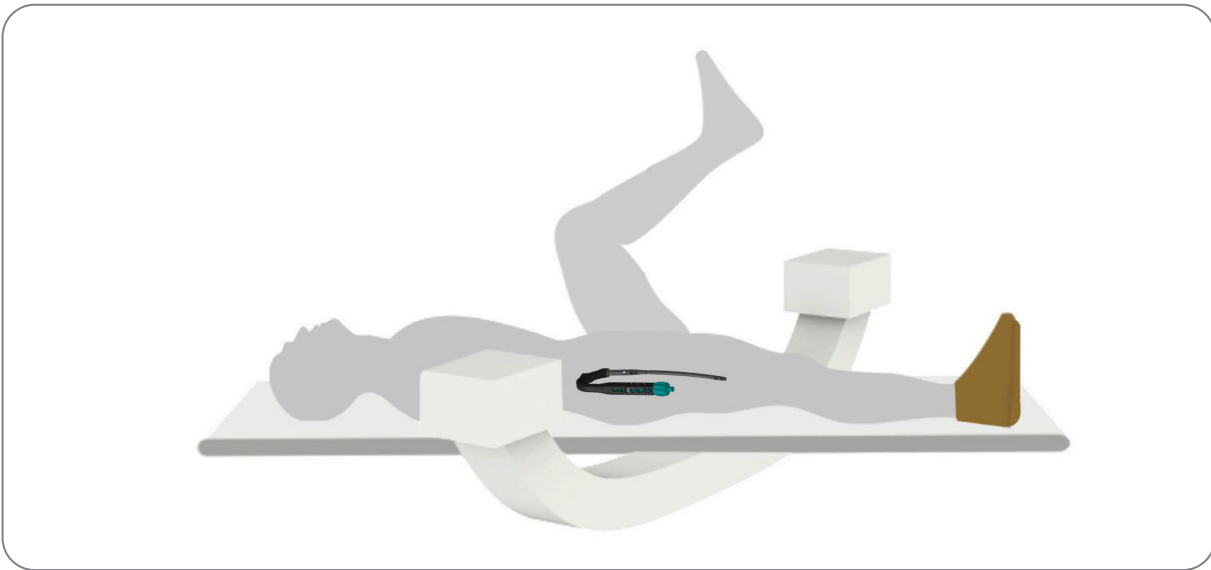
The medullary canal must be checked on radiographs to determine whether reaming is necessary. The canal is wider on lateral radiographs, so true anteroposterior views are necessary. This is usually available from the contralateral limb.



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

Skin 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.

Guidewire Insertion

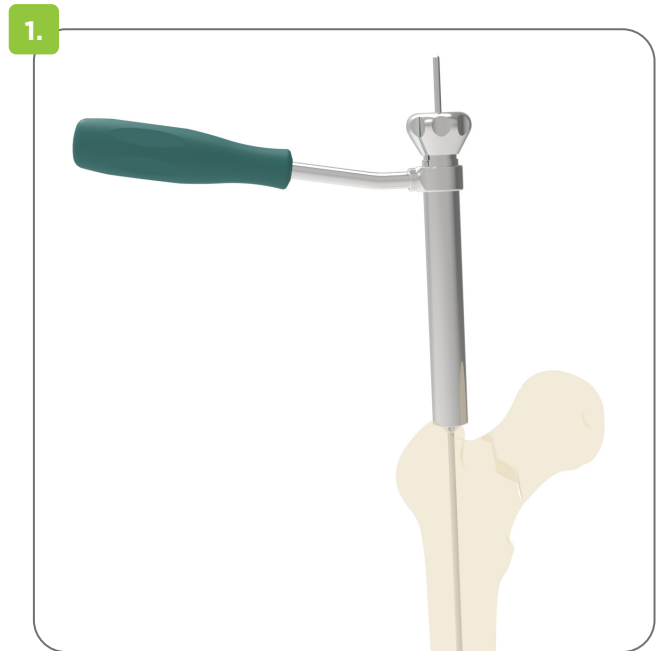
1. Insert the 3.2x400mm Guidewire (533235) at the tip of the Greater Trochanter using the assembled 16mm Tissue Guard (610090) and Tissue Guard Trocar (610089).

Tissue Guard Trocar

2. The Tissue Guard Trocar can be used to ensure the Guidewire is concentric or to offset the entry point by 4.0, 4.5, 5.0 or 5.5mm. The variable offset provides more precise insertions away from the centre point as required and to assist with revising the entry point position by inserting an additional 3.2x400mm Guidewire.

Entry Point

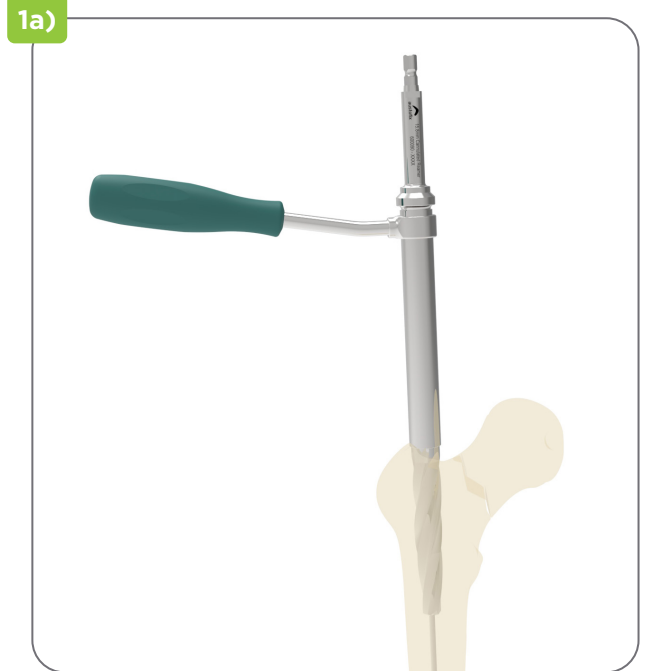
3. The Cannulated Awl (600040C) can be used to make the initial entry into the medullary canal. Check the position in AP & lateral X-ray views.



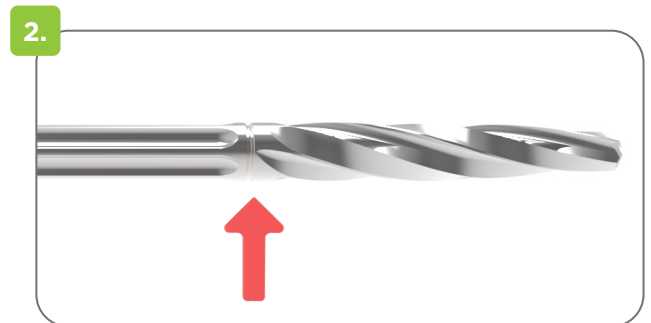
Reaming & Guidewire Insertion

Drilling & Reaming Entry Hole

1. a) Pass the 15.8 mm Cannulated Reamer (600090) over the guidewire and through the Tissue Guard to prepare the bone. Advance the reamer with a power drill until the stopper contacts the Tissue Guard
b) Alternatively, the T-handle (531004) can be used to ream by hand.



2. If the Tissue Guard is not used, II (Image Intensifying) x-ray monitoring can be employed to observe when the grooves on the Reamer reach the femoral head signalling sufficient depth. Ensure the Reamer advances into the subtrochanteric region

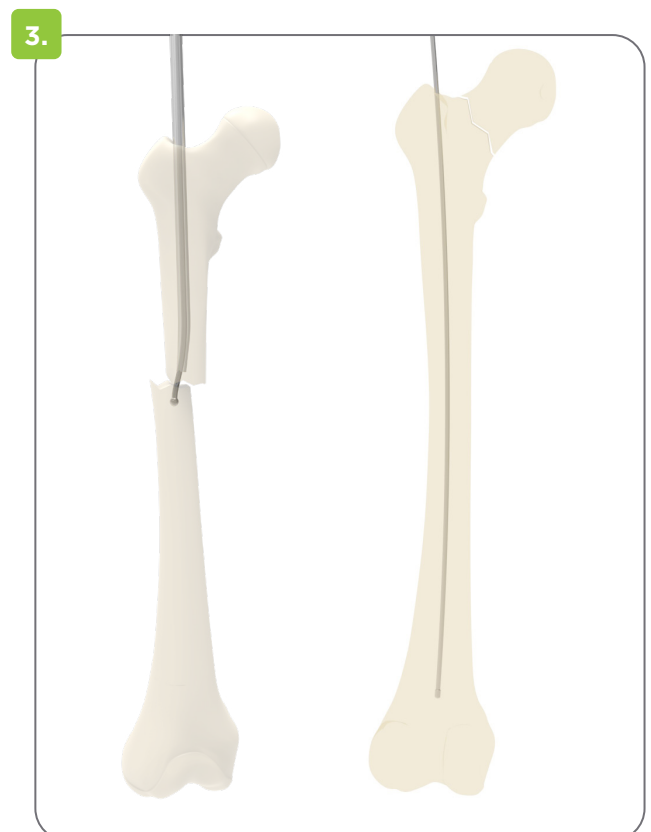


Insertion of Ball-Tip Guidewire

3. 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.

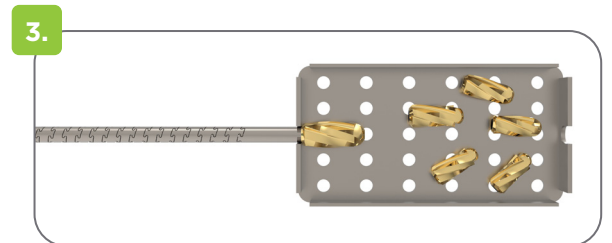
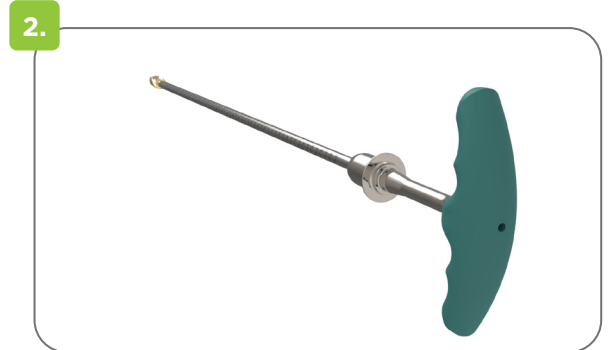
Note:

- If the guidewire is excessively bent, it may need to be changed to a straight wire after reaming.
- 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.



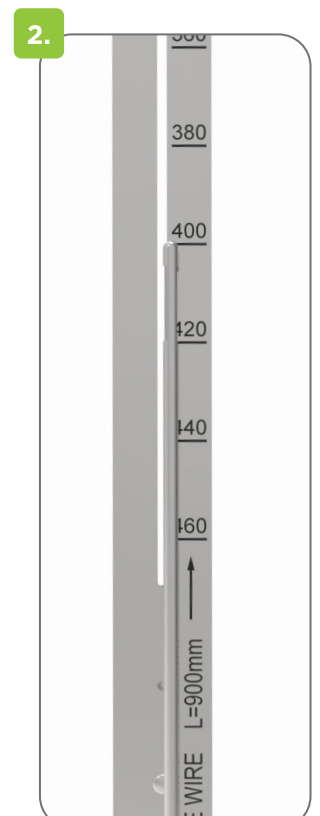
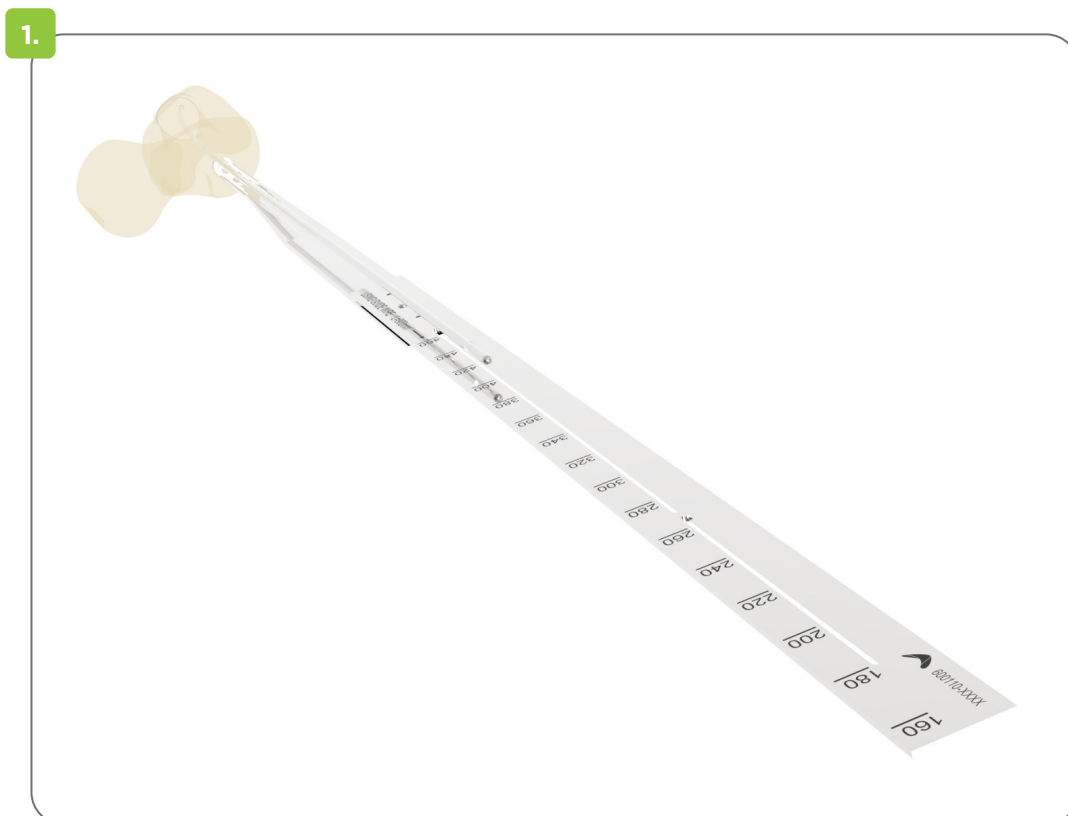
Flexible Reamer

1. Connect the Flexible Reamer Shaft (543047) with the Ø8mm Reamer Head (543008) and pass it over the Ball-Tip Guidewire.
2. Advance the reamer using power, or alternatively with the T-Handle by hand. Progress in 0.5 mm increments until 1-1.5 mm larger than the selected nail diameter. Repeatedly withdraw and advance the reamer, cleaning bone debris from the head if resistance is encountered.
3. Use the Removal Caddy (621052) to safely and efficiently remove used reamer heads.
4. Use the Guidewire Pusher (531000) to prevent guidewire displacement during reamer withdrawal. The large end is first pressed against the guidewire until flush with the drill, then reversed so it can pass inside the drill and reamer shaft.



Nail Length Measurement

1. Once the Ball-tip Guidewire is positioned at the intended nail location, extend the Fold Out Depth Gauge (600110) and slide it over the guidewire until it reaches the Greater Trochanter.
2. Use the Fold Out Depth Gauge as shown to determine the appropriate nail length. In this example, a 400mm Nail should be selected.



Nail Holder Assembly

1. Insert the 6 mm Hex Ball Driver (600045) into the In-Built Nail Holding Screw and secure it. Confirm that the screw threads extend beyond the F1 Nail Holder.

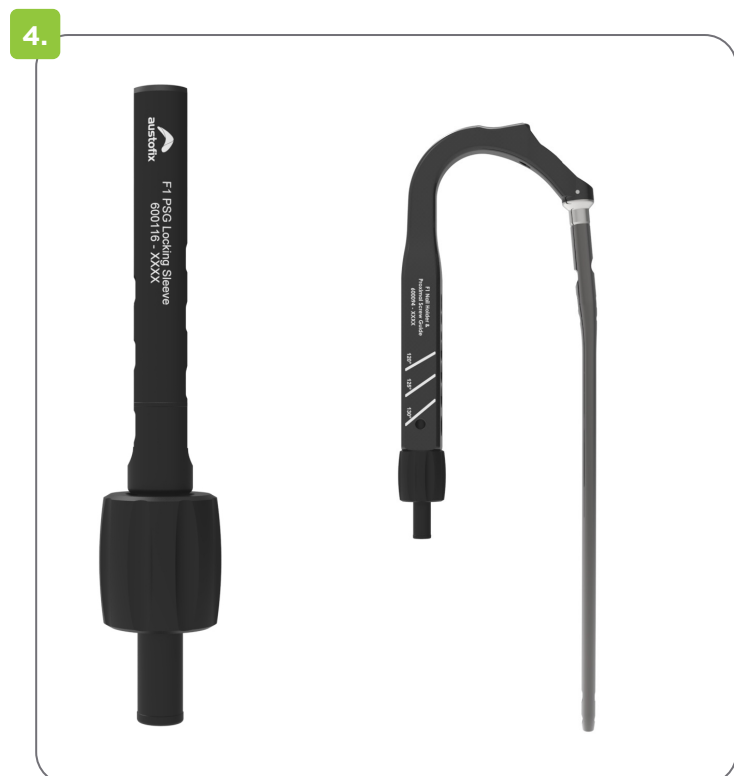
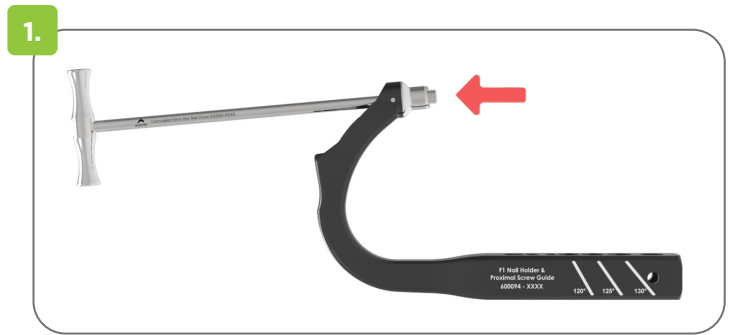
2. While holding the Screw steady with the Hex Ball Driver, partially thread the F1 Nail onto the Screw.

3. Once engaged, rotate the Nail and align the tabs with the Nail Holder. When the tabs are aligned, tighten the In-Built Nail Holding Screw with the Hex Ball Driver to secure the Nail in place.

Note: The tabs ensure the Nail is aligned in the correct orientation, accounting for the anterior bow and lateral deviation from the subtrochanter to the femoral shaft distally.

4. Slide the Proximal Screw Guide (PSG) Locking Sleeve (600116) into the Nail Holder, making sure the pin aligns with the dedicated slot.

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



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 Image Intensifying X-rays/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.

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

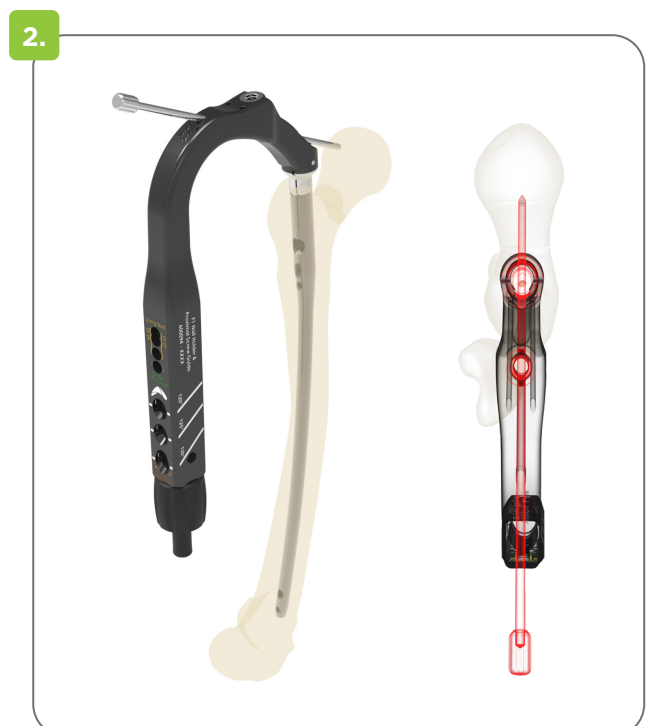
If the Nail is not loose in the bone, align the rotary position while inserting the last 1-2cm, taking into account the anteversion of the femoral neck. Use the Slide Hammer assembly (600097) if extraction and reinsertion is required.



Nail Rotation

2. Remove the Ball-Tip Guidewire and use the Single Shot Pin (600092) with the X-ray 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.



Hip Screw Insertion

For Helical Blade Insertion, go to Page 16.

Guidewire Insertion

1. Assemble the F1 Lag Screw Trocar (610088) with the Screw/Blade Sleeve (610101). Ensure threads are engaged.
2. Align the flats of the Screw/Blade Sleeve with the Nail Holder and pass through until the F1 Lag Screw Trocar contacts the Cortical Bone.
Warning: Ensure that the angle in the PSG Locking Sleeve matches the angle of the nail hole.
3. Disengage the threads of the Trocar and advance the Screw/Blade Sleeve until it contacts the Bone. This assembly can be secured by tightening the PSG Locking Sleeve nut.
4. Replace the Lag Screw Trocar with the Guidewire Sleeve (610092), ensuring the sleeves contact the lateral cortex.

Insert the 3.2x400mm Guidewire (533235) to the medial tip of the femoral head.

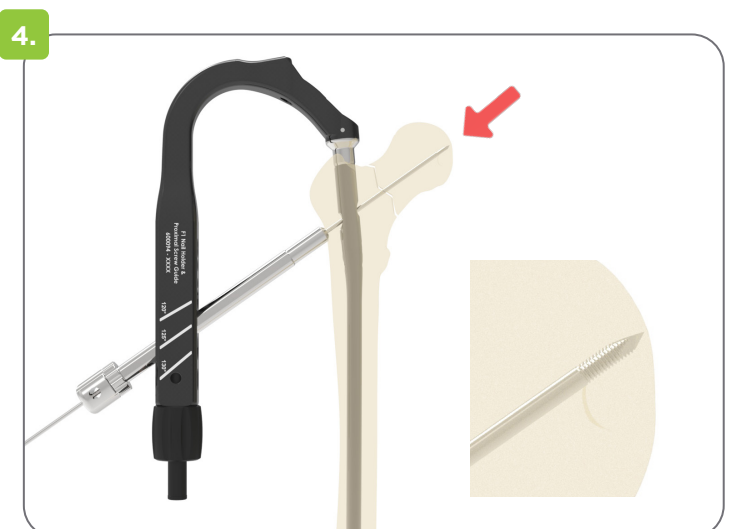
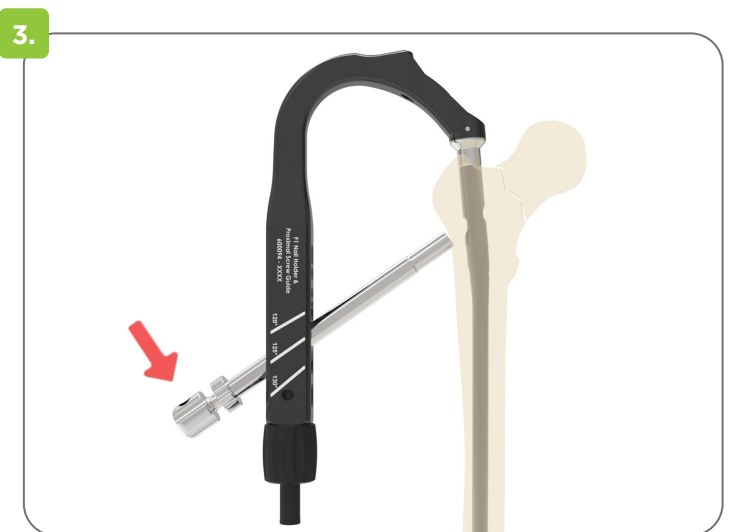
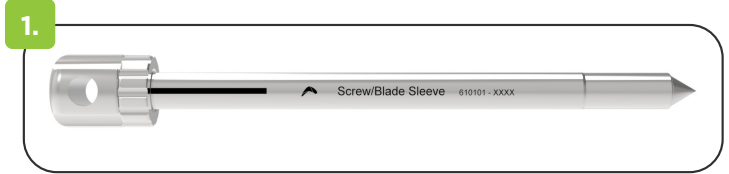
Note: Check for guidewire deflection that may have occurred as it passed into the femoral head, before and after drilling.

Note: Confirm location, using II X-ray imaging, that the tip of the guidewire is located on the medial side of the femoral head. This will ensure your lag screw measurement will be correct.

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.

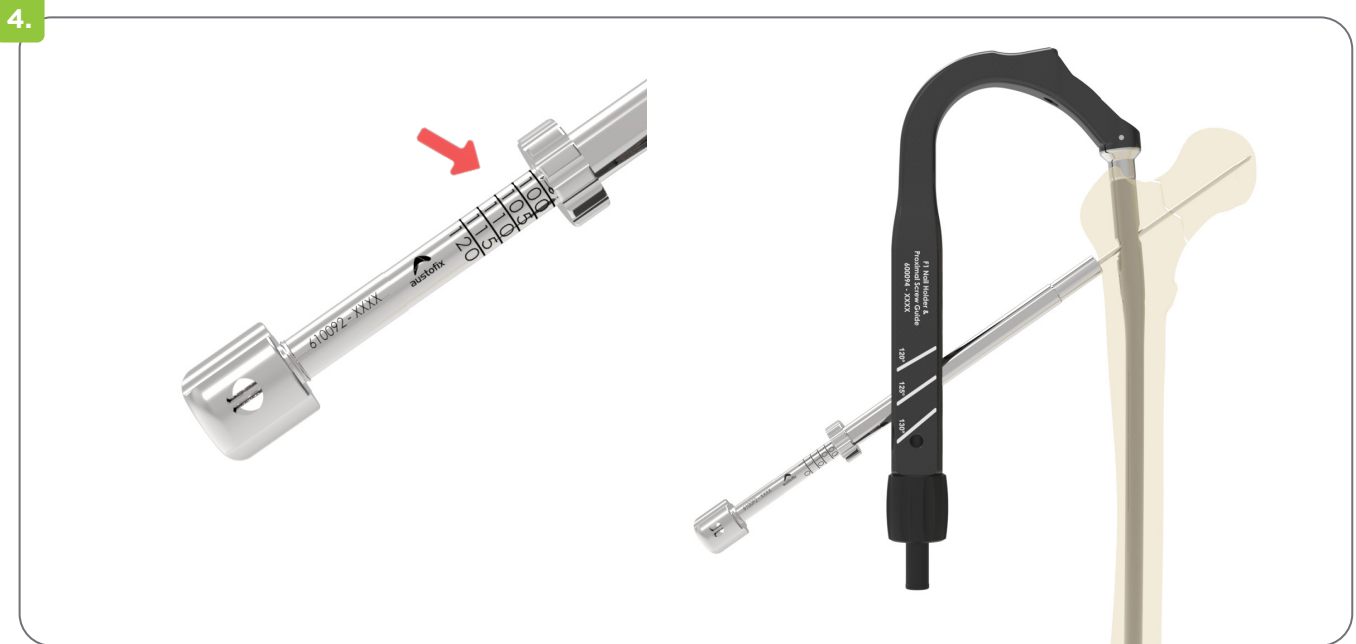
Then, remove the Guidewire and perform distal locking as described in the Ezy-Aim Distal Targeting Surgical Technique, after which the Guidewire is re-inserted to continue the Proximal Lag Screw Insertion Surgical Technique.



Length Measurement

- Pull the Guidewire Sleeve back to the end of the Guidewire and take the measurement. In the example below, the reading is 100, so a 100mm Hip Screw would be selected.

Note: Markings will automatically calculate 10mm tolerance between the Hip Screw and medial tip of the femoral head. This ensures the Hip Screw does not protrude out of the medial side of the femoral head.



Reaming

- For Reaming, the Step Drill (610094) can be used or the Bone Conserving Reamer (600106) if bone conservation is desired.
- Based on the length measurement reading, press and hold the button on the Step Drill Stop (640090) and slide it along the selected reamer until the reading value is seen on the medial side of the Stop.

Note: As shown in the illustration, the reaming depth is 100mm.

Warning: Check if there was any guidewire deflection that may have occurred as it passed into the femoral head/neck, both before and after drilling.
- Drill or hand ream the 7-10.5mm Step Drill (610094) until the Step Drill Stop contacts the Screw/Blade Sleeve. Ensure the Nail Holder orientation does not alter.
- Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer.



Assembly and Insertion

8. Screw the Compression Nut (610097) onto the Screw/Blade Holder (610100), ensuring the edge of the Nut and groove are properly aligned.

Align the tabs of the Screw/Blade Holder (610100) with the 10.4mm Hip Screw tabs, then screw in the Screw Holder Retainer (610096) to secure the hip screw.

Warning: The Compression Nut must be mounted on the Screw/Blade Holder before the Hip Screw is inserted.

9. Pass the assembly through the Screw/Blade Sleeve and insert the Hip Screw until the Compression Nut contacts the Screw/Blade Sleeve.

Ensure that guidewire placement has not altered to optimise Lag Screw location.

Note: II X-rays should be used during Lag Screw insertion to monitor Positioning.

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

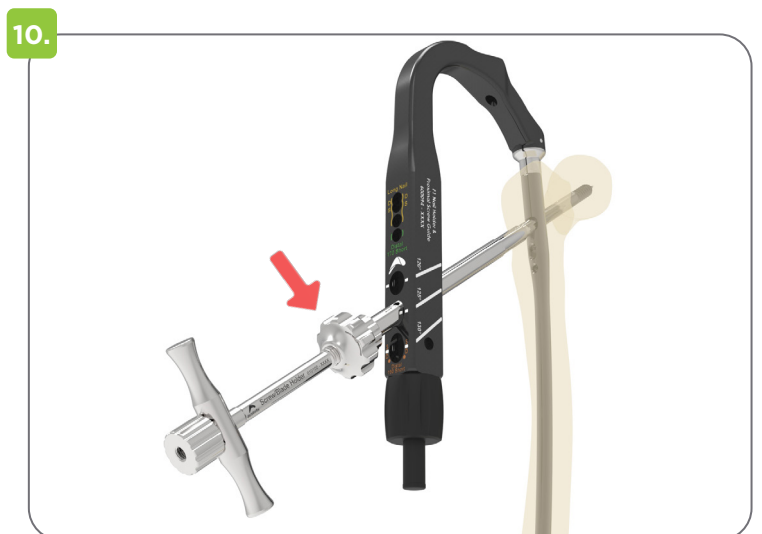
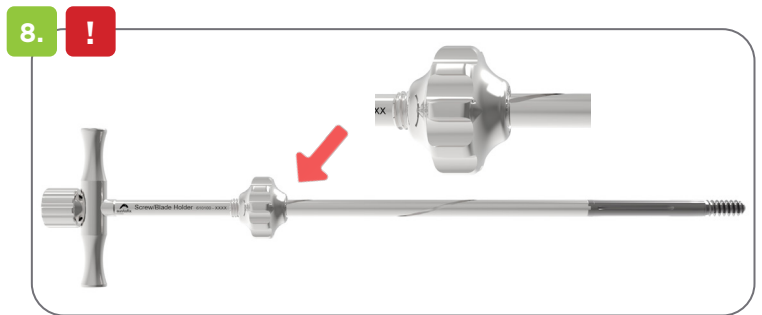
Rotate the Compression Nut clockwise to apply compression, up to a maximum of 15 mm. Check on X-ray for optimal fracture reduction.

Note: If compression is required, the Hip Screw length should be chosen shorter based on the expected amount of compression.

11. The correct depth for the 10.4mm Hip Screw is indicated when the groove on the Screw/Blade Holder is flush with the Screw/Blade Sleeve.

Ensure the handle of the Screw/Blade Holder is positioned either parallel or perpendicular to the Proximal Screw Guide (600094) to properly align the grooves on the 10.4mm Hip Screw. This alignment ensures the set screw will engage with the Hip Screw.

Note: Only turn Screw/Blade Holder handle clockwise, anticlockwise turning compromises the fixation.



Helical Blade Insertion

If a Hip Screw was selected, continue with Page 20.

Guidewire Insertion

1. Assemble 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.

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. Align the flats of the Screw/Blade Sleeve with the Nail Holder and pass through until the F1 Lag Screw Trocar contacts the Cortical Bone.

Warning: Ensure that the angle in the PSG Locking Sleeve matches the angle of the nail hole.

3. Disengage the threads of the Trocar and advance the Screw/Blade Sleeve until it contacts the Bone. This assembly can be secured by tightening the PSG Locking Sleeve nut.

4. Replace the Lag Screw Trocar with the Guidewire Sleeve (610092), ensuring the sleeves contact the lateral cortex. Insert the 3.2x400mm Guidewire (533235) to the medial tip of the femoral head.

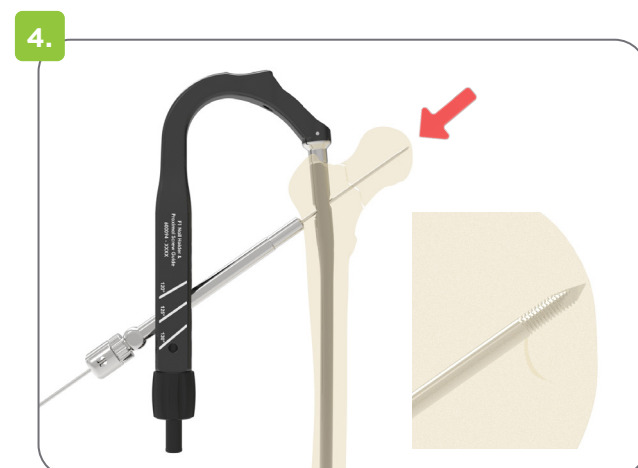
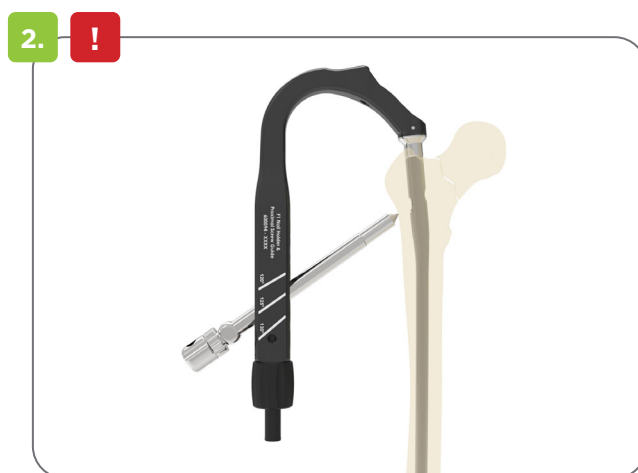
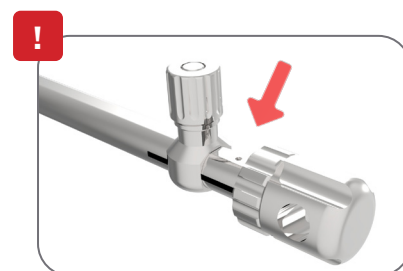
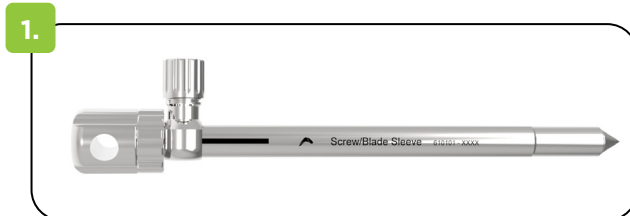
Note: Check for guidewire deflection that may have occurred as it passed into the femoral head, before and after drilling.

Note: Confirm location, using II X-ray imaging, that the tip of the guidewire is located on the medial side of the femoral head. This will ensure your lag screw measurement will be correct.

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 Insertion Surgical Technique.



Length Measurement

- Pull the Guidewire Sleeve back to the end of the Guidewire and take the measurement. In the example below, the reading is 100, so a 100mm Hip Screw would be selected.

Note: Markings will automatically calculate 10mm tolerance between the Hip Screw and medial tip of the femoral head. This ensures the Hip Screw does not protrude out of the medial side of the femoral head.

4.



Reaming

- For Reaming, the Step Drill (610094) can be used or the Bone Conserving Reamer (600106) if bone conservation is desired.
- To set the correct drilling depth, press and hold the button on the Step Drill Stop (640090) and slide it along the selected Reamer till the Helical Blade laser marking is reached.

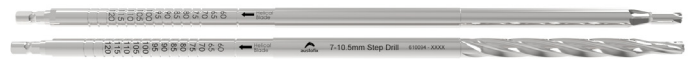
Ensure the reading on the medial side of the Step Drill Stop is the Helical Blade, seen in Figure 6.

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

Warning: Check if there was any guidewire deflection that may have occurred as it passed into the femoral head/neck, both before and after drilling.

- Drill or hand ream the 7-10.5mm Step Drill (610094) until the Step Drill Stop contacts the Screw/Blade Sleeve. Ensure the Nail Holder orientation does not alter.
- Use the Guidewire Pusher (531000) to stop the Guidewire from coming out while removing the Reamer.

5.



6. **!**



7.



Assembly and Insertion

- Screw the Compression Nut (610097) onto the Screw/Blade Holder (610100), ensuring the edge and groove are properly aligned.

Align the grooves of the Screw/Blade Holder (610100) with the 10.4mm Helical Blade tabs, then screw in the Screw Holder Retainer (610096) to secure the hip screw.

Note: The Compression Nut must be mounted on the Screw/Blade Holder before the Helical Blade is inserted.

- Pass the assembly through the Screw/Blade Sleeve and insert until the Helical Blade contacts the lateral cortex.

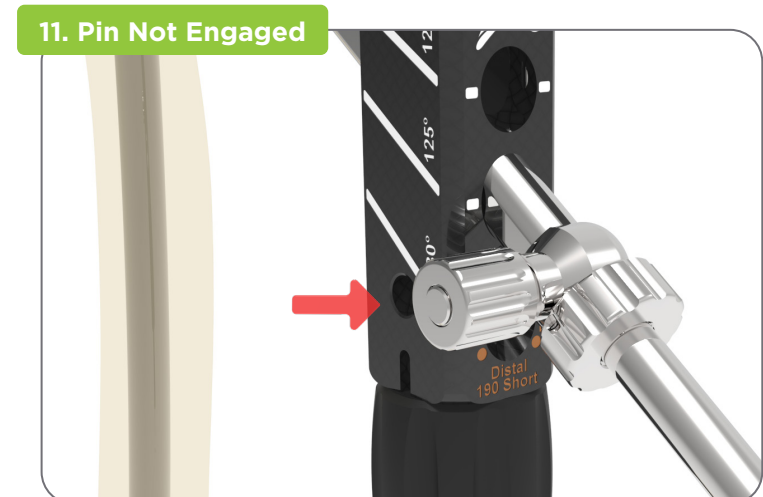
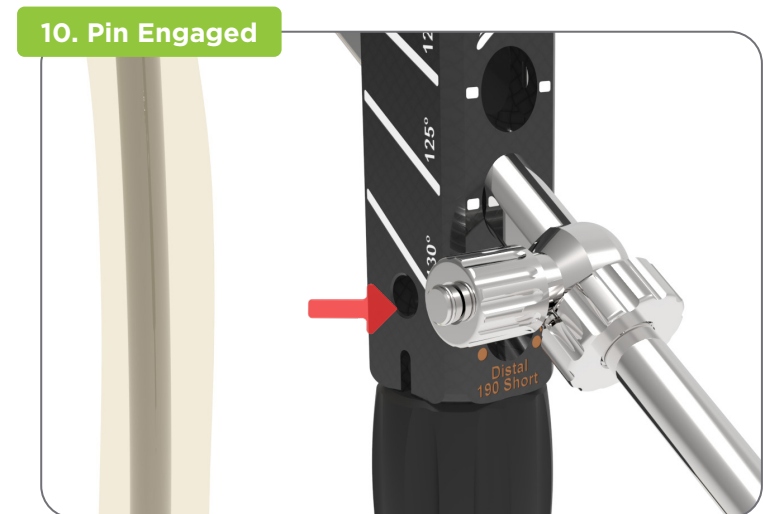
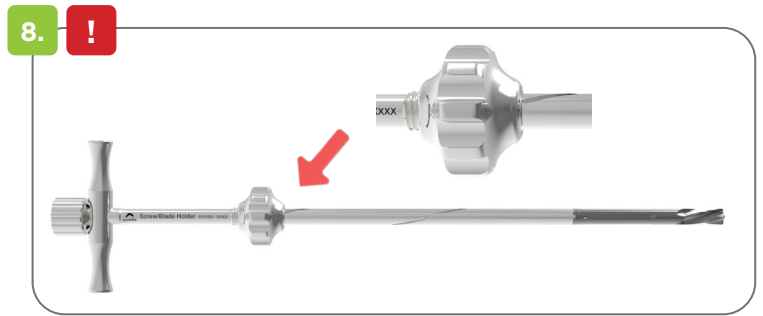
Ensure that guidewire placement has not altered to optimise Lag Screw location.

Note: II X-rays should be used during Lag Screw insertion to monitor positioning.

- With the Spiral Pin Alignment Instrument (610102) against the Lag Screw/Blade Sleeve, twist the cap clockwise to insert the pin into the groove of the Screw/Blade Holder.

Note: The Screw/Blade Holder can be rotated until the pin slots into the groove, confirmed by an audible click or the Holder no longer spins.

- After the pin is engaged, turn the Holder clockwise & anti-clockwise to ensure the pin has entered the groove, then tighten the cap.

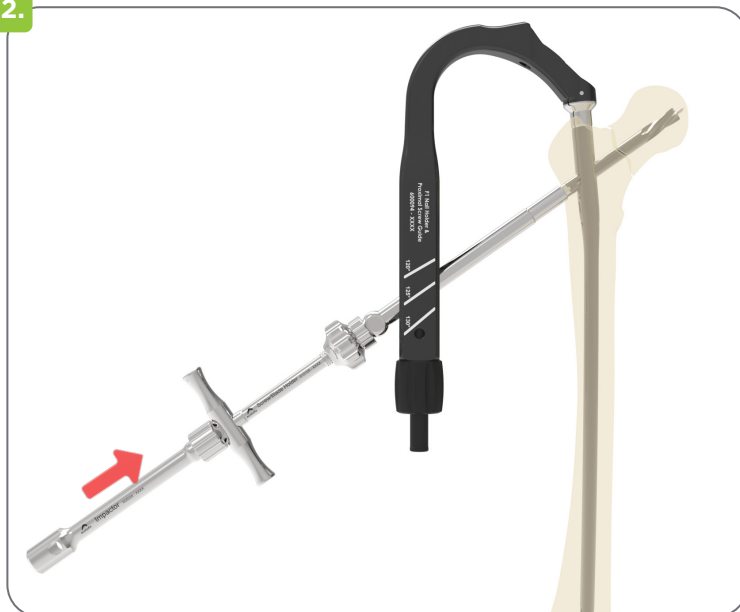


12. Attach Impactor (600028) to the Screw Holder Retainer and advance the Helical Blade into the femoral head by hand and then gently tapping the Impactor with a mallet.

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

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.

12.



13. Ensure the handle of the Screw/Blade Holder is positioned either parallel or perpendicular to the Proximal Screw Guide (600094) to properly align the grooves on the 10.4mm Helical Blade. This alignment ensures the set screw will engage with the Helical Blade.

Note: Only turn Screw/Blade Holder handle anticlockwise, clockwise turning compromises the fixation.

13.



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 Hip Screw/Helical Blade. This will ensure that the Hip Screw/Helical Blade will not back out of the bone.

Note: Four turns are required to lock the set screw. If it continues to turn the articulating driver hasn't engaged the set screw.

2. To confirm the Set Screw is correctly positioned, gently turn the Screw/Blade Holder clockwise and counterclockwise. There should be only minimal movement.

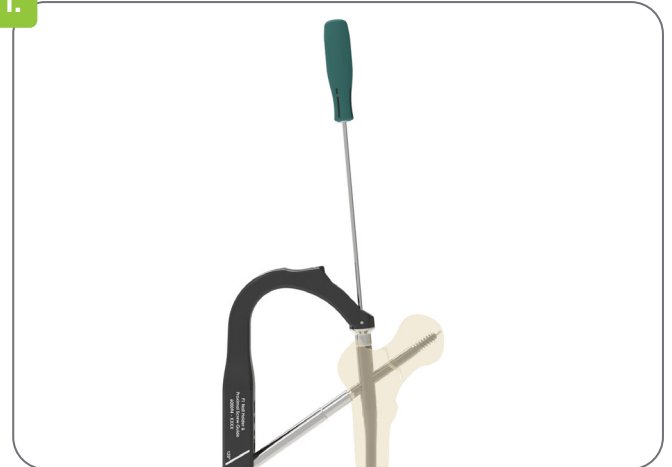
If the Screw/Blade Holder still rotates freely, adjust the handle position and re-tighten the Set Screw until it engages with one of the four grooves on the Hip Screw/Helical Blade.

3. After securing the Set Screw, it should then be loosened by a quarter (1/4) turn, using the laser markings on the Hex Driver as a guide. This will allow slight sliding of the Hip Screw/Helical Blade.

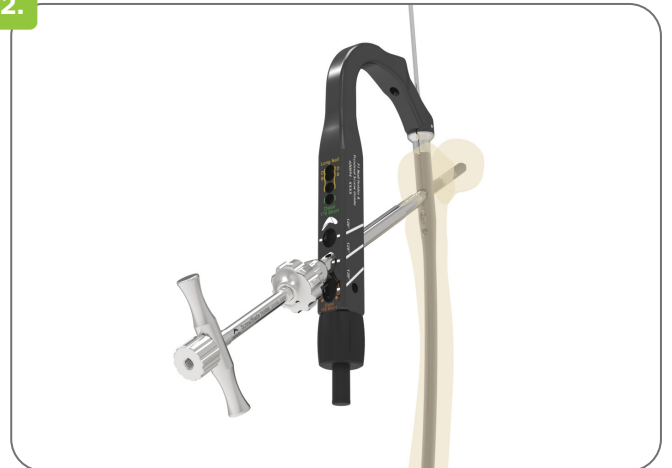
4. Loosen the Screw Holder Retainer and remove the Screw/Blade Holder along with the corresponding instruments, including the guidewire.

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.

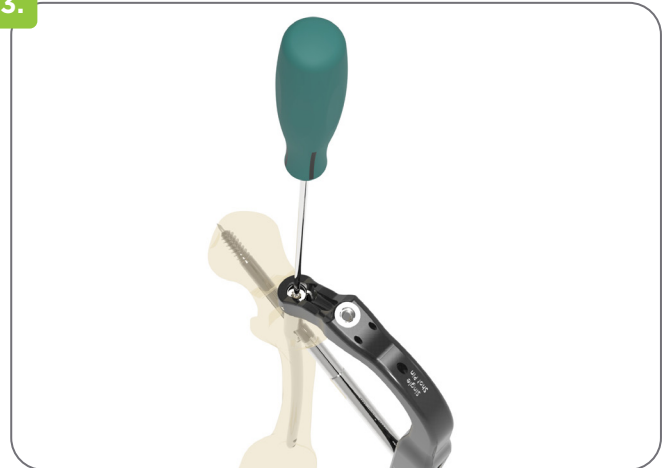
1.



2.



3.

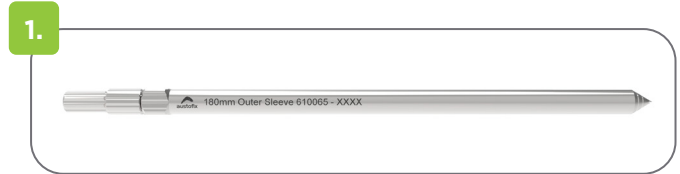


4.



Proximal Locking Screw Insertion

1. Pre-assemble the 180 mm Outer Sleeve (610065) and 4.5x180 mm Drill Sleeve (610064) with the 180 mm Trocar (610063).

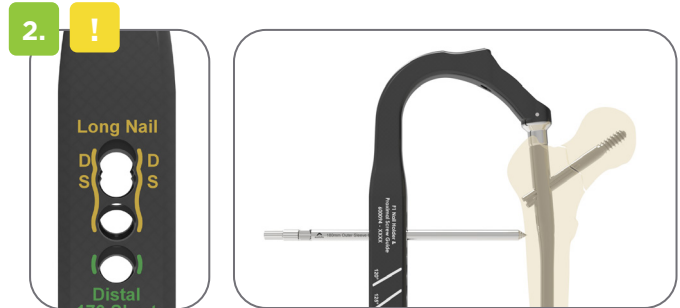


2. The Long Nail has either a “Static” or “Dynamic” option, determined by the “Long Nail” yellow holes on the F1 Combination Nail Holder.

Pass the assembly through the insert until the Trocar contacts the Bone.

Tighten the Locking Sleeve Nut before removing the Trocar.

Caution: Ensure the fascia lata incision is concentric with the sleeve axis to prevent soft tissue pressure on the sleeve.

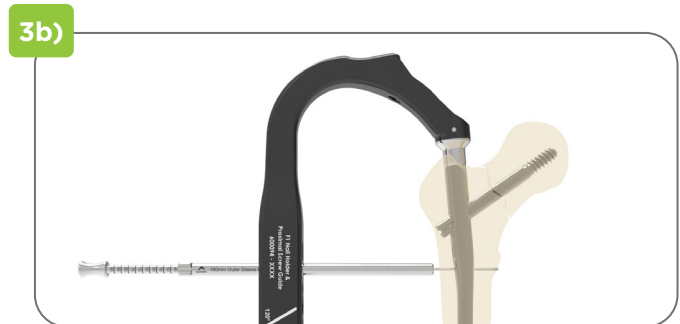


3. a) Drill to the far cortex using the Ø4.5 mm Drill (514534) and measure the screw length using the laser markings on the Drill. Following, remove the Drill Sleeve from the Outer Sleeve.

Caution: Neutralise the power tool weight during drilling and do not apply force to the Nail Holder. Start the power tool before the drill contacts the bone.



- b) Alternatively, remove the Drill and Drill Sleeve, and insert the Outer Sleeve Depth Gauge (610071) to measure screw length.

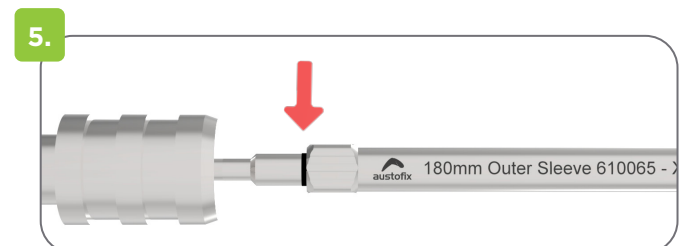
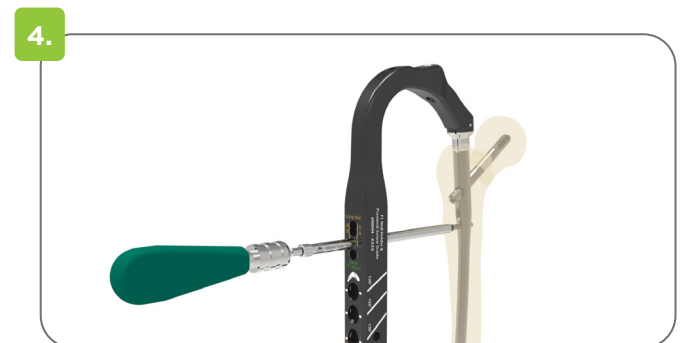


4. Select the appropriate Locking Screw length based on the measurement obtained.

Assemble the Quick Coupling Handle (610444) with the 3.5 Hex Screwdriver Shaft (Long) (610443) and attach the Locking Screw.

Pass the through the Outer Sleeve and insert the Locking Screw into the bone.

Note: Alternately, power can be used to insert distal screw.



Distal Locking Screw Insertion

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 freehand method if proximal screws are inserted at the proximal end first.

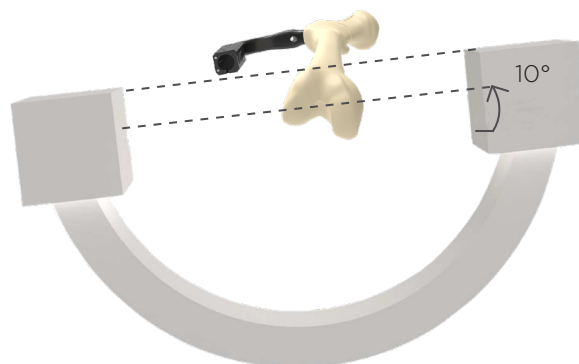
Surgeons may perform freehand targeting based on their proficiency or as guided below:

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.
5. Use the 100mm Depth Gauge (212000699) to determine screw length.
6. Assemble the Quick Coupling Handle (610444) with the 3.5 Hex Screwdriver Shaft (Short) (610442) and insert the 4.8mm Locking Screw.

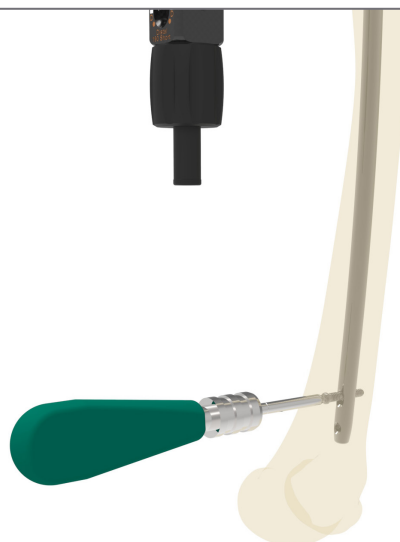
***Note 1:** Austofix Nails do not have anteversion of the proximal holes because this would make the Ezy-aim distal targeting system too complex. If using freehand distal targeting, set up traction table the same way with the patella facing up, but start searching for 'round holes' with the C-arm tilted about 10° so it is parallel with the Nail Holder.

Note 2: 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 1.



6.



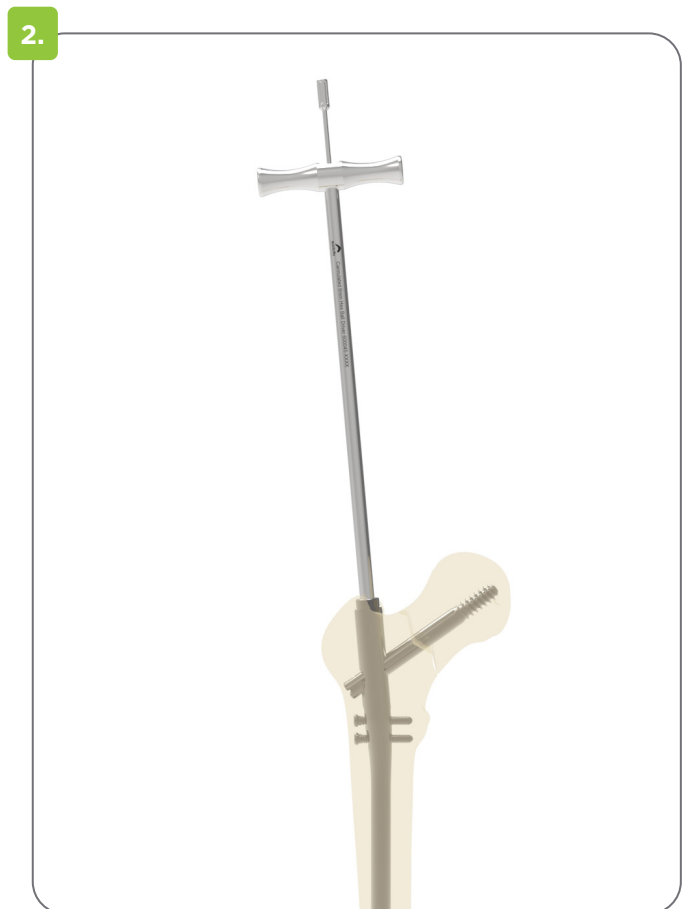
End Cap Insertion

Note: If an End Cap is desired, ensure the correct length is chosen. It is recommended that an End Cap is used to provide protection against soft-tissue irritation and simplifies future removal.

1. Insert the End Cap Retainer (600093) through the Cannulated 6mm Hex Ball Driver (600045) 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.

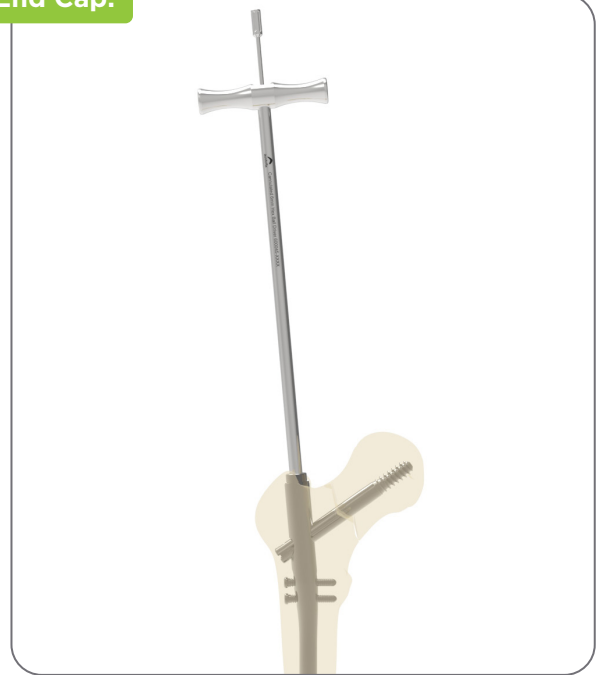


Nail Extraction

The instruments required for an F1+ extraction are:

| Product Code | Description |
|--------------|--------------------------------------|
| 600107 | M10 Nail Extractor |
| 610444 | Quick Coupling Handle |
| 610442 | 3.5mm Hex Screw Driver Shaft (Short) |
| 610443 | 3.5mm Hex Screw Driver Shaft (Long) |
| 600045 | Cannulated 6mm Hex Ball Driver |
| 610098 | 5mm Articulating Hex Driver |
| 600028 | Impactor |
| 600093 | End Cap Retainer |
| 600097 | Slide Hammer |
| 610100 | Screw/Blade Holder |
| 610096 | Screw Holder Retainer |
| 533235 | 3.2 x 400mm Guidewire |

End Cap.



End Cap

1. Insert the End Cap Retainer (600093) through the Cannulated 6mm Hex Ball Driver (600045) and screw into the chosen End Cap.
2. Once engaged, remove the End Cap by rotating the Cannulated Hex Ball Driver counter-clockwise.

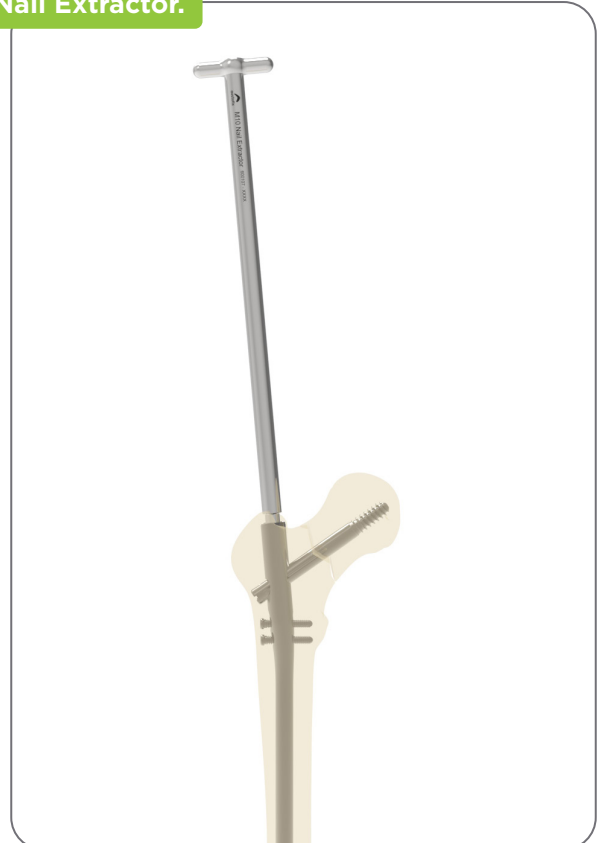
Set Screw.



In-Built Set Screw

1. Insert the 5mm Articulating Hex Driver (610098) into the In-Built Set Screw and rotate counter-clockwise to loosen.

Nail Extractor.



M10 Nail Extractor

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

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.

Hip Screw

1. Align the tabs on the Screw/Blade Holder (610100) with the Hip Screw. Once engaged, slide the Screw Holder Retainer (610096) through and screw into the Hip Screw.
2. Once secure, rotate the assembly counter-clockwise to loosen and remove the Hip Screw.

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

Hip Screw.



Helical Blade

1. Align the tabs on the Screw/Blade Holder (610100) with the Helical Blade. Once engaged, slide the Screw Holder Retainer (610096) through and screw into the Helical Blade.
2. Once assembled, attach the Slide Hammer (600097) onto the Screw Holder Retainer and withdraw the Helical Blade.

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

Helical Blade.



4.8mm Locking Screws

1. Locking screws inserted proximally and distally can be removed using the Quick Coupling Handle (610444), fitted with either the Short (610442) or Long (610443) Shaft.
2. Once assembled, remove the locking screws by turning the handle counter-clockwise.

Note: The selection of the 3.5 Hex Screwdriver Shaft length is based on preference.

Locking Screws.



Nail Extraction

1. Assemble the Slide Hammer (600097) and with the M10 Nail Extractor (600107).

Note: Impactor (600028) can be attached to Extractor before Slide Hammer if extra length is required.

2. Once assembled, use the Slide Hammer to withdraw the nail from the bone.

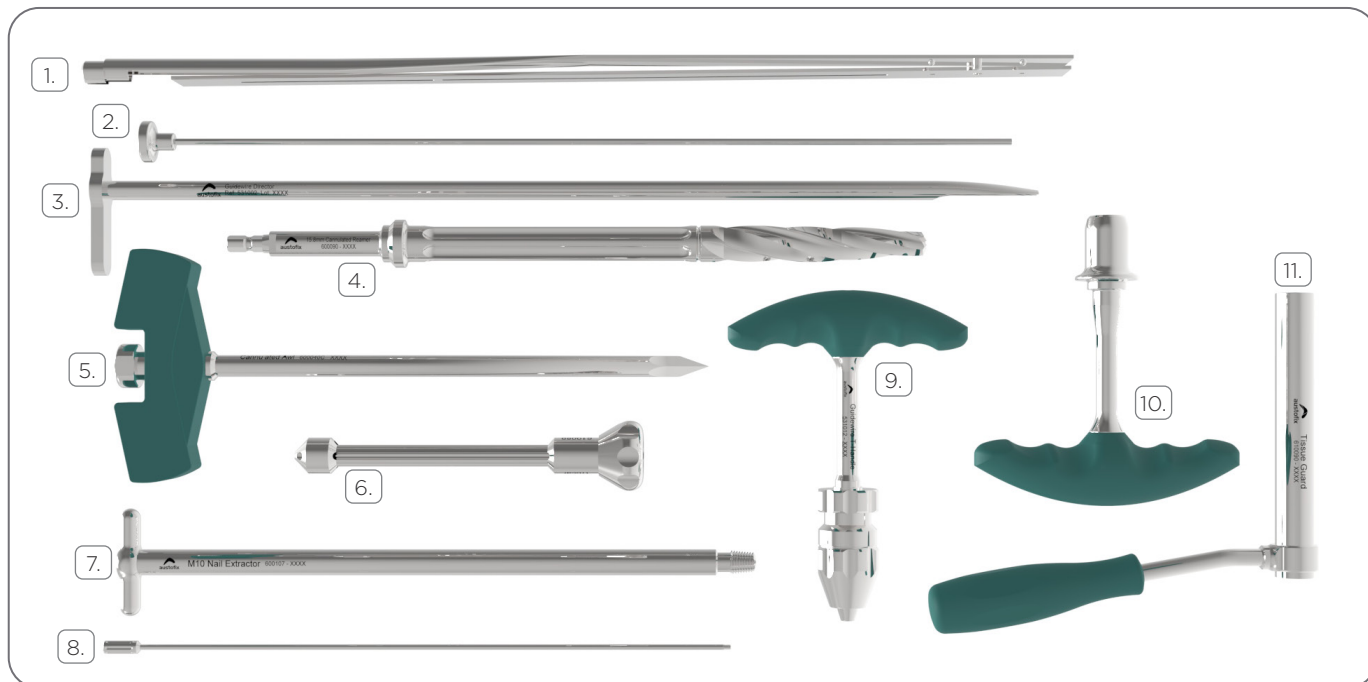
Note: When attaching the Slide Hammer onto the Nail Extractor, avoid rotating the nail inside the femur.

Nail Extraction.



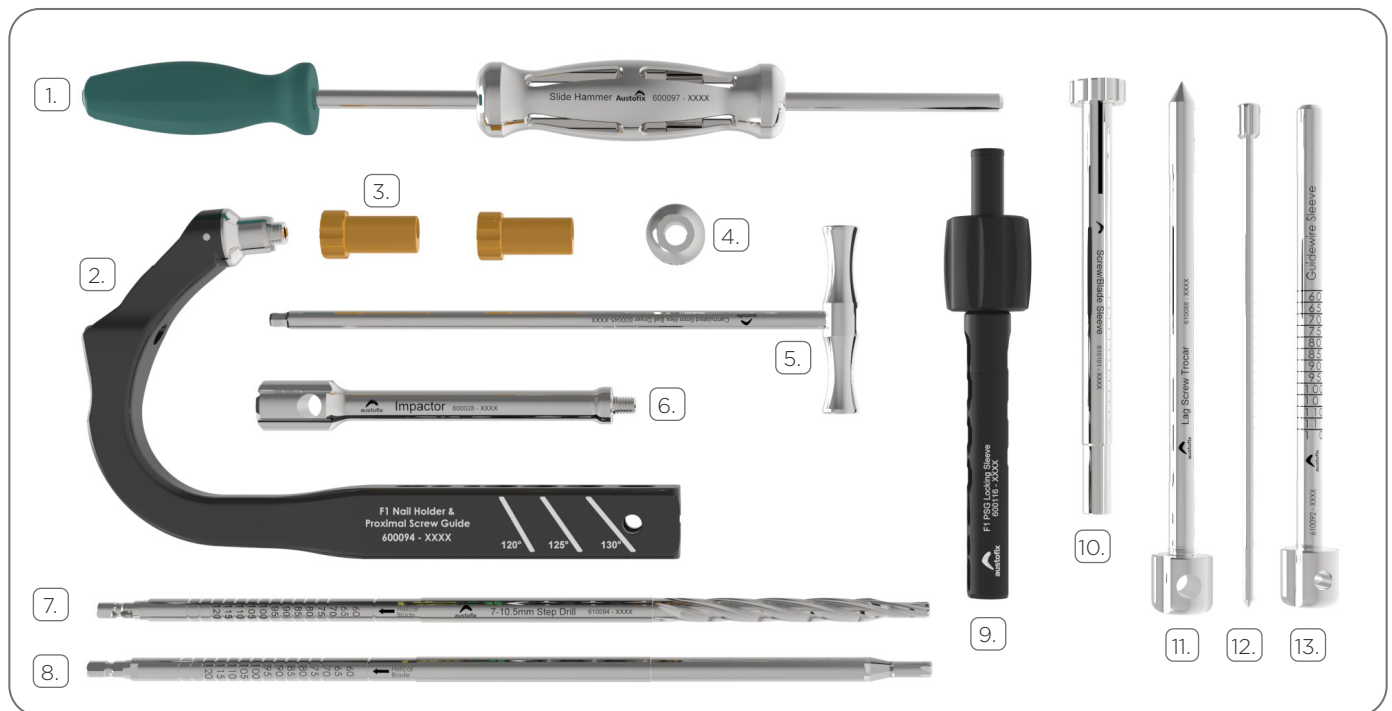
Instruments

Tray 1



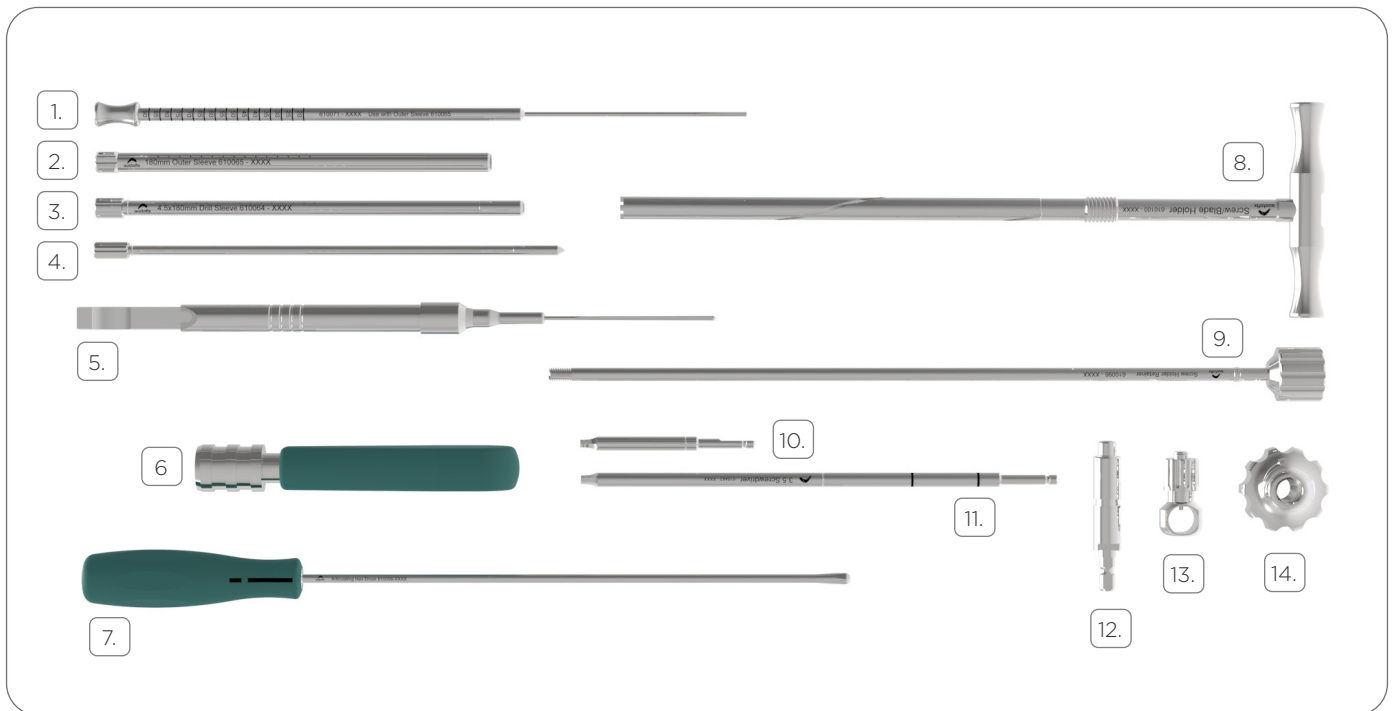
- | | | | | | | | |
|----|---------|---|--------------------------|-----|--------|---|--------------------|
| 1. | 600110 | - | Fold Out Depth Gauge | 7. | 600107 | - | M10 Nail Extractor |
| 2. | 531000 | - | Guidewire Pusher | 8. | 600093 | - | End Cap Retainer |
| 3. | 531002 | - | Guidewire Director | 9. | 531012 | - | Guidewire T-Handle |
| 4. | 600090 | - | 15.8mm Cannulated Reamer | 10. | 531004 | - | T-Handle |
| 5. | 600040C | - | Cannulated Awl | 11. | 610090 | - | 16mm Tissue Guard |
| 6. | 610089 | - | Tissue Guard Trocar | | | | |

Tray 2 - Top Tier



- | | | | | | | | |
|----|---------|---|---------------------------------|-----|--------|---|------------------------------|
| 1. | 600097 | - | Slide Hammer | 8. | 600106 | - | 7-10.5mm Conservation Reamer |
| 2. | 600094 | - | F1 Combination Nail Holder | 9. | 600116 | - | PSG Locking Sleeve |
| 3. | 600099B | - | PSG Locking Sleeve 190mm Insert | 10. | 610101 | - | Screw/Blade Sleeve |
| 4. | 640090 | - | 7-10.5mm Step Drill Stop | 11. | 610088 | - | F1 Lag Screw Trocar |
| 5. | 600045 | - | Cannulated 6mm Hex Ball Driver | 12. | 600092 | - | Single Shot Pin |
| 6. | 600028 | - | Impactor | 13. | 610092 | - | Guidewire Sleeve |
| 7. | 610094 | - | 7-10.5mm Step Drill | | | | |

Tray 2 - Bottom Tier



- | | | | | | |
|----|-----------|-------------------------------|-----|--------|--|
| 1. | 610071 | - Outer Sleeve Depth Gauge | 8. | 610100 | - Screw/Blade Holder |
| 2. | 610065 | - 180mm Outer Sleeve | 9. | 610096 | - Screw Holder Retainer |
| 3. | 610064 | - 4.5x180mm Drill Sleeve | 10. | 610442 | - 3.5mm Hex Screw Driver Shaft (Short) |
| 4. | 610063 | - 180mm Trocar | 11. | 610443 | - 3.5mm Hex Screw Driver Shaft (Long) |
| 5. | 212000699 | - 3.5mm Depth Gauge | 12. | 600042 | - AO/ZH Adaptor |
| 6. | 610444 | - Quick Coupling Handle | 13. | 610102 | - Spiral Pin Alignment Instrument |
| 7. | 610098 | - 5mm Articulating Hex Driver | 14. | 610097 | - Screw Holder Compression Nut |

Sterile Consumable Items

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

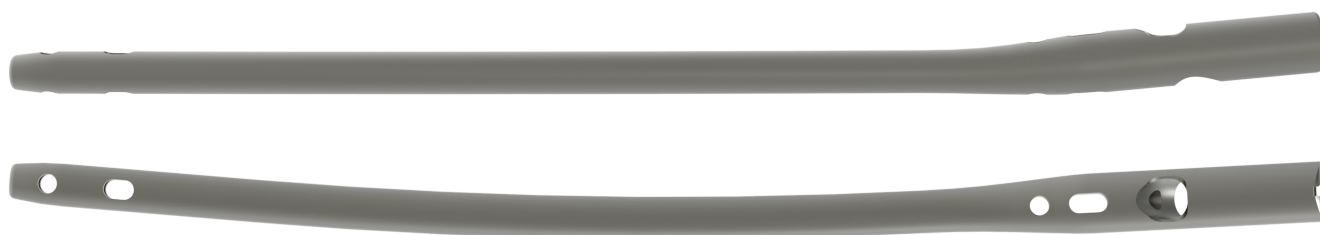


| Drills | |
|--------------|-----------------|
| Product Code | Description |
| 514534 | 4.5x340mm Drill |
| 514514 | 4.5x155mm Drill |



Implants

| 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 | 37111240R |
| 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 |



| 10.4mm Hip Screw | |
|------------------|-------------------|
| Product Code | Screw Length (mm) |
| 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 |



| 10.4mm Helical Blade | |
|----------------------|-------------------|
| Product Code | Screw Length (mm) |
| 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 (mm) |
| 364820 | 20 |
| 364825 | 25 |
| 364830 | 30 |
| 364832 | 32.5 |
| 364835 | 35 |
| 364837 | 37.5 |
| 364840 | 40 |
| 364842 | 42.5 |
| 364845 | 45 |
| 364847 | 47.5 |
| 364850 | 50 |
| 364855 | 55 |
| 364860 | 60 |
| 364865 | 65 |
| 364870 | 70 |
| 364875 | 75 |
| 364880 | 80 |
| 364885 | 85 |
| 364890 | 90 |



| End Cap | |
|--------------|------------------|
| Product Code | Head Length (mm) |
| 363401 | 1 |
| 363405 | 5 |
| 363410 | 10 |
| 363415 | 15 |



| Set Screw (Pre-Assembled) | |
|---------------------------|--------------|
| Product Code | Screw Angles |
| 370100A + 370120B | 120° |
| 370100A + 370125B | 125° |
| 370100A + 370130B | 130° |



MRI Safety

Austofix devices have not been evaluated for safety or compatibility in a Magnetic Resonance (MR) environment, unless otherwise specified on the product label or in the surgical technique guide. They have not been tested for potential heating or migration when exposed to MR conditions. As a result, the safety of these devices in an MR environment is unknown, and conducting an MR examination on a patient with one of these devices may lead to injury or device malfunction. However, due to their minimal ferromagnetic properties and the fact that they are fixed in bone, these devices may be considered MR Conditional for MRI environments up to 3.0 T, provided the following recommendations are observed.

- For highest risk lower limb nails (femoral and tibial), non-clinical testing of similar devices shows very low risk of injury in up to 3.0T systems when running standard lower extremity musculoskeletal protocols for up to 30 minutes.
- These tests consisting of a short-tau inversion recovery sequence, turbo spin echo T1-weighted sequence, and 3 planes of a proton density weighted turbo spin echo sequence, repeating the short-tau inversion recovery sequence.
- MRI metallic artifacts may be reduced in 3.0T machines by using a large bandwidth, small FOV and appropriate echo train length, as well as using an appropriate pulse sequence, such as fast spin echo.

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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