austofix

austofix F1

SHORT PROXIMAL FEMORAL NAIL

Surgical Technique

Australian Made • Australian Owned

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Contents

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
SHORT PROXIMAL 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

Short Nail

- 170mm & 190mm Lengths
- 15.5mm Proximal Diameter
- 9mm, 10mm and 11mm Distal Diameters

Multiple Proximal Oblique Screw Angles

- 120°
- 125°
- 130°

Stress Relief Cuts

- Reduces Nail Fatigue

Proximal Hole

- Oblique Screw

Positioning of Distal Screw Hole

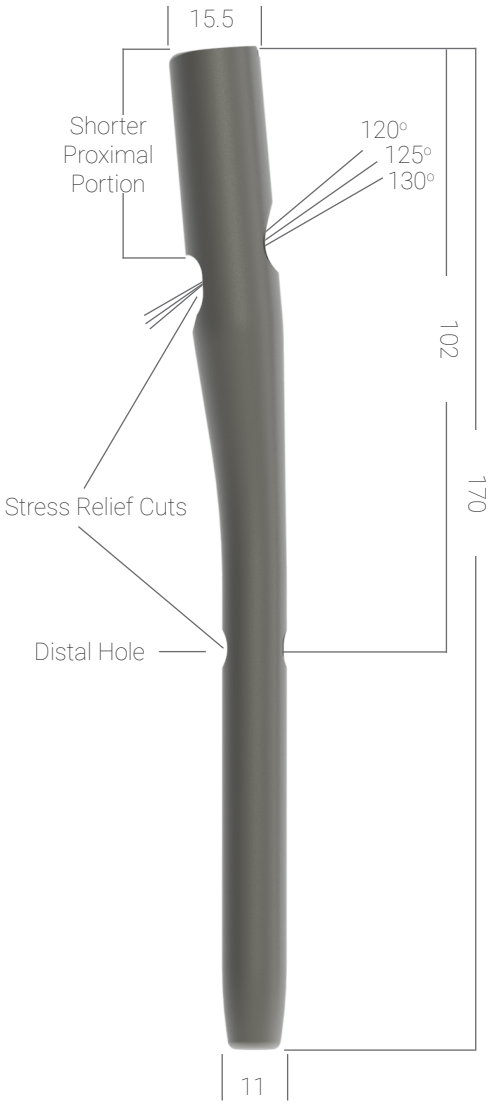
- More Proximal in 170mm Nail for Increased Strength and Stability for Intertrochanteric Fractures
- More Distal in 190mm Nail for Trochanteric Fracture Fixation with Subtrochanteric Extension

Intuitive Instrument Set

- Decreased Procedure Time
- Enhanced Safety

Lateral Chamfer

- Reduces Tendon Irritation



170mm

190mm

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Screws & End Caps - Titanium

The following are used with the F1 Short Nail:

- 10.4 Hip Screw
- Helical Blade
- 4.8mm Locking Screws used Distally
- 4.0mm Locking Screws (Ø9 Nails only)
- F1 Proximal Femoral Nail Set Screw
  (Pre-assembled in the Nail)
- M10 End Cap

10.4 Hip Screw

Helical Blade

4.8mm Locking Screw

4.0mm Locking Screw

M10 End Cap

Indications & Pre-Operative Planning

The medullary canal must be checked through radiography 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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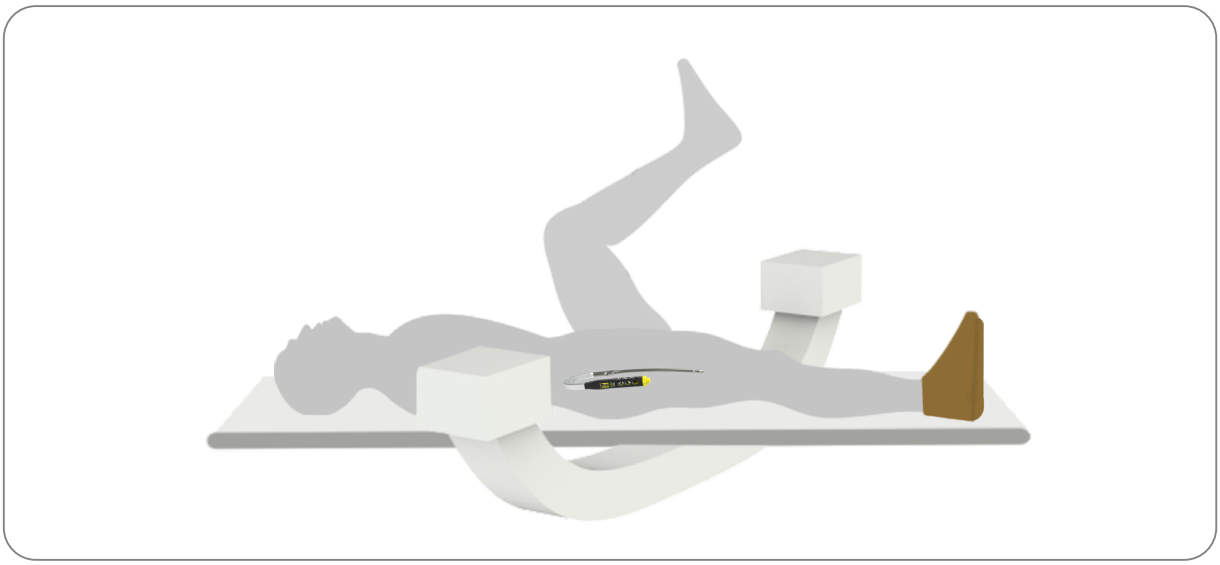
Patient Positioning

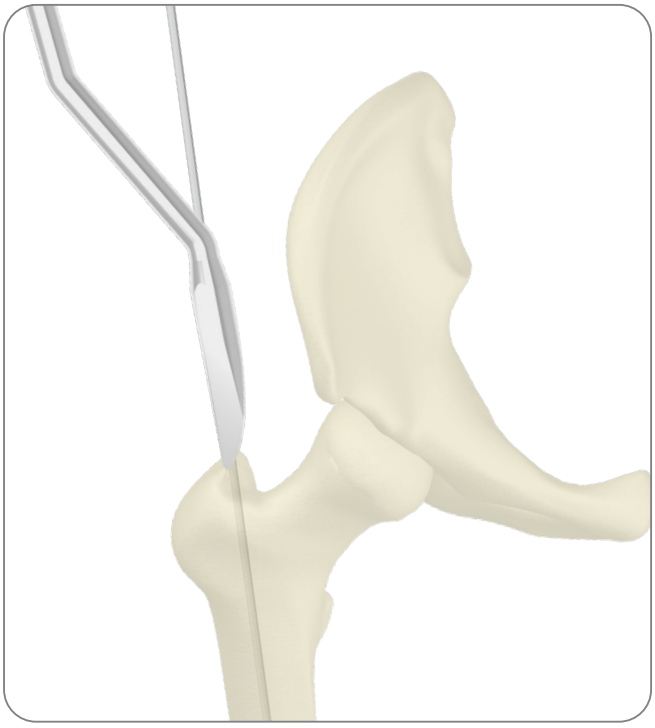
A traction table and Image Intensifier are used in the same manner as for most other types of hip nail. The affected hip is in neutral or slight flexion with 5° adduction. The traction boot should be carefully applied. The reduction should be checked on both views and rotation is adjusted as necessary. 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, preferably in a high lithotomy position to allow suitable lateral X-ray views (see 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).

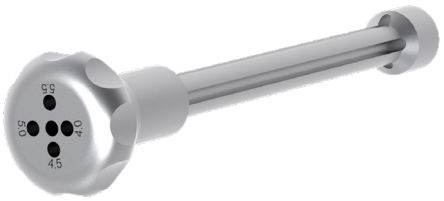


Entry Point

Insert the 3.2x400mm Guidewire (533235) at the tip of the Greater Trochanter. Use the Cannulated Awl (600040C) to make the initial entry into the medullary canal.

Tissue Guard Trocar

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

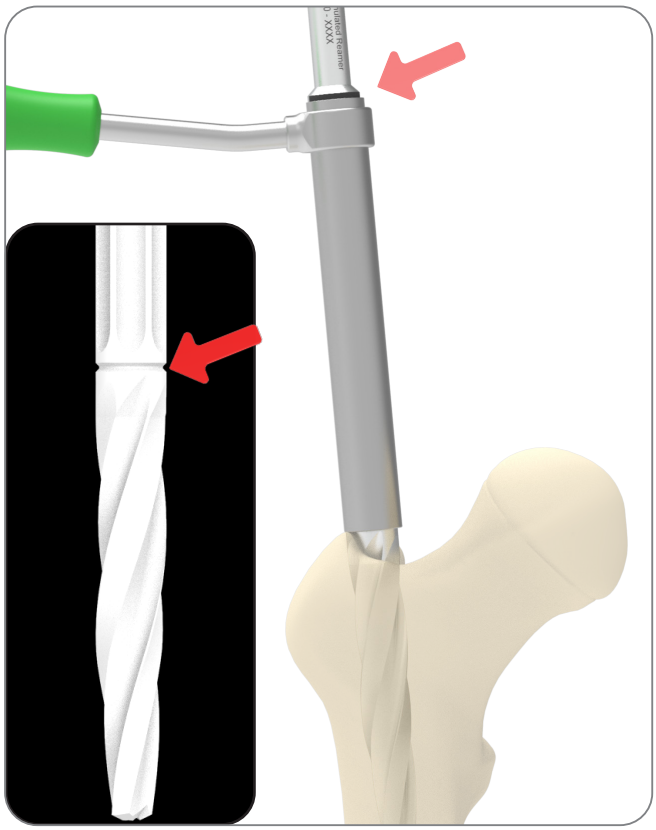


Tissue Guard Trocar

Reaming

Use the Tissue Guard with the 15.8 Cannulated Reamer (600090) for bone preparation. The Reamer can be used by hand with the T-handle or with a drill. Ensure the Reamer passes into the subtrochanteric area. Use marked band for reaming depth, or the groove under x-ray if not using a tissue guard.

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.



Nail Selection

Decide from the post-reduction X-ray the appropriate Nail: 120°, 125° or 130°. Since the line of the calcar femorale is usually well above the lower margin of the femoral head, the 10.4 Hip Screw must pass close to the calcar femorale. The apex distance should be 10-10.

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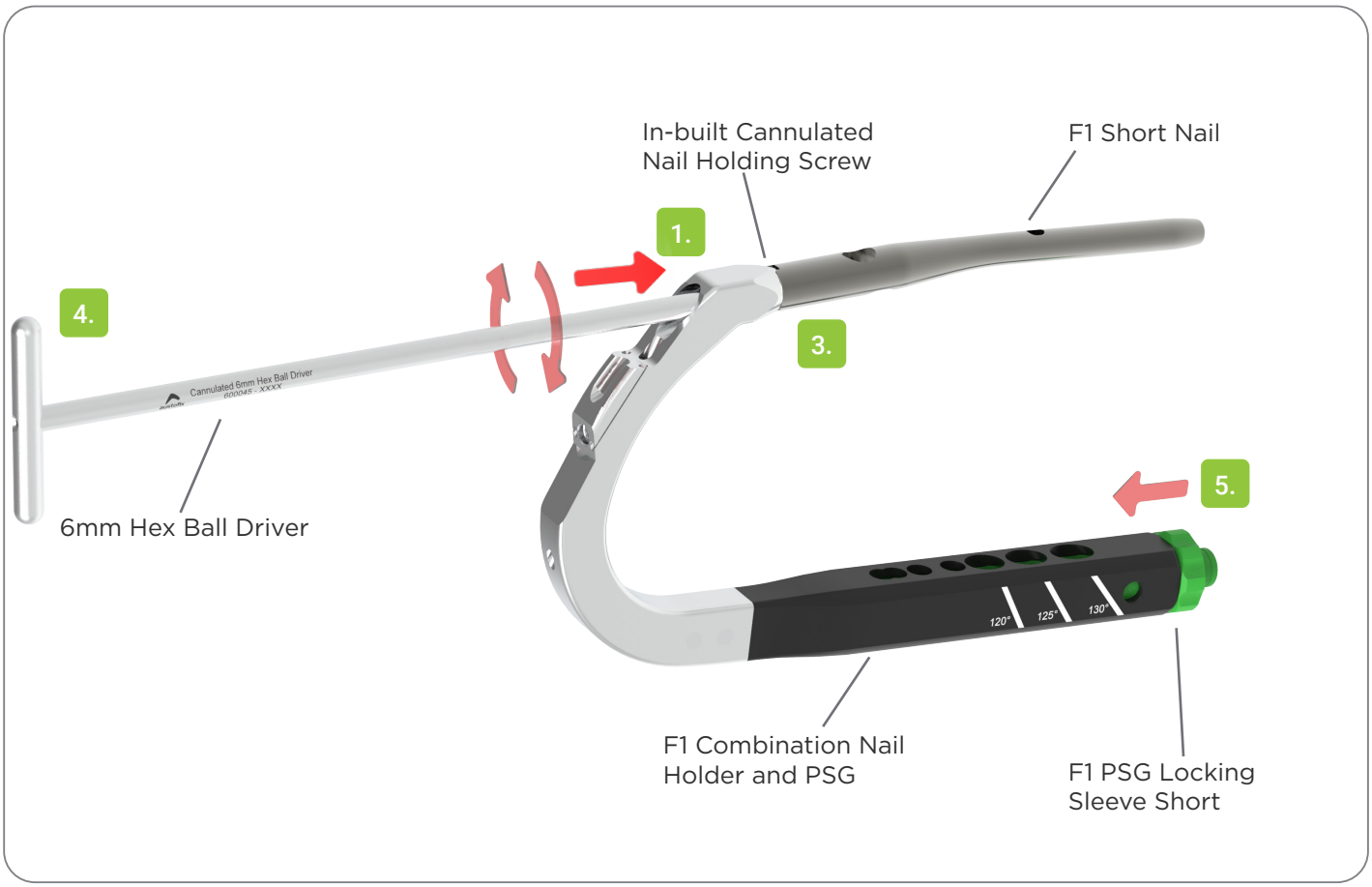
Instrument Assembly

F1 Combination Nail Holder & PSG

1. Use the hex driver to stabilise the 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 Locking Sleeve Short (green) (600095) 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.



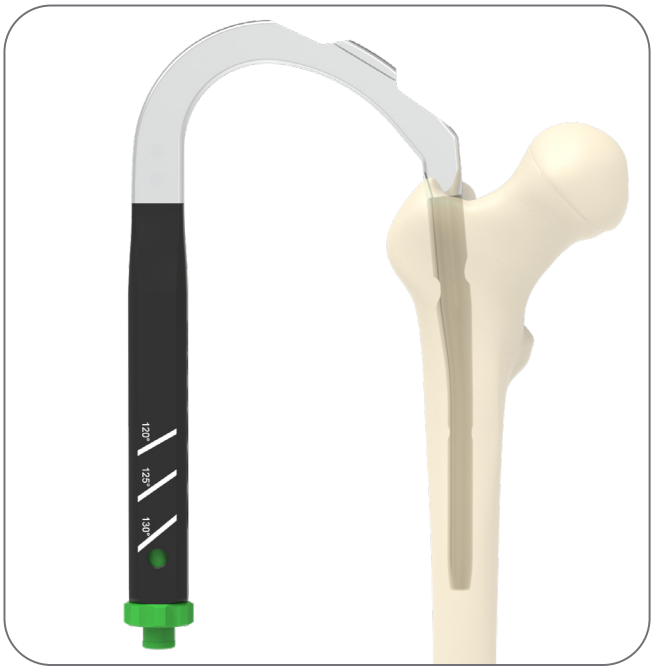
Note: Instrument Assembly for F1 Short Nail shown above.

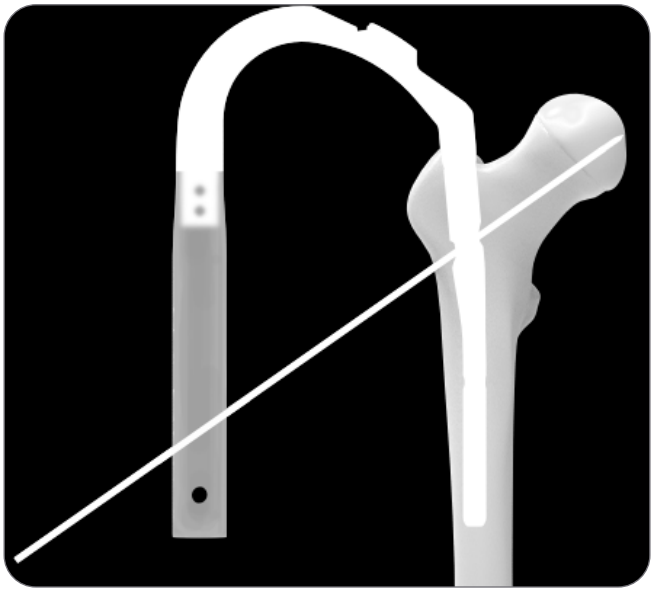
Nail Insertion

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.

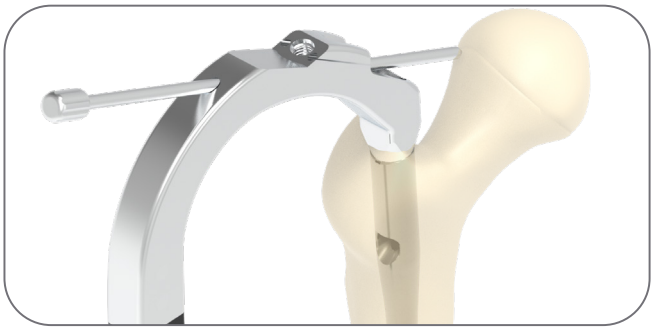
If the Nail is not loose in the bone, align the rotary position while inserting the last 1-2cm. Use the Slide Hammer assembly (600097) if extraction and reinsertion is required.

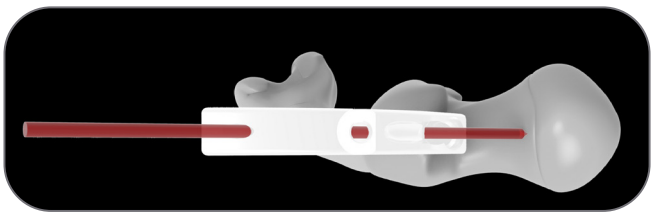




Nail Rotation

Remove the 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 on the femoral head.





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Lag Screw

For Helical Blade, go to Page 14.

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.

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.

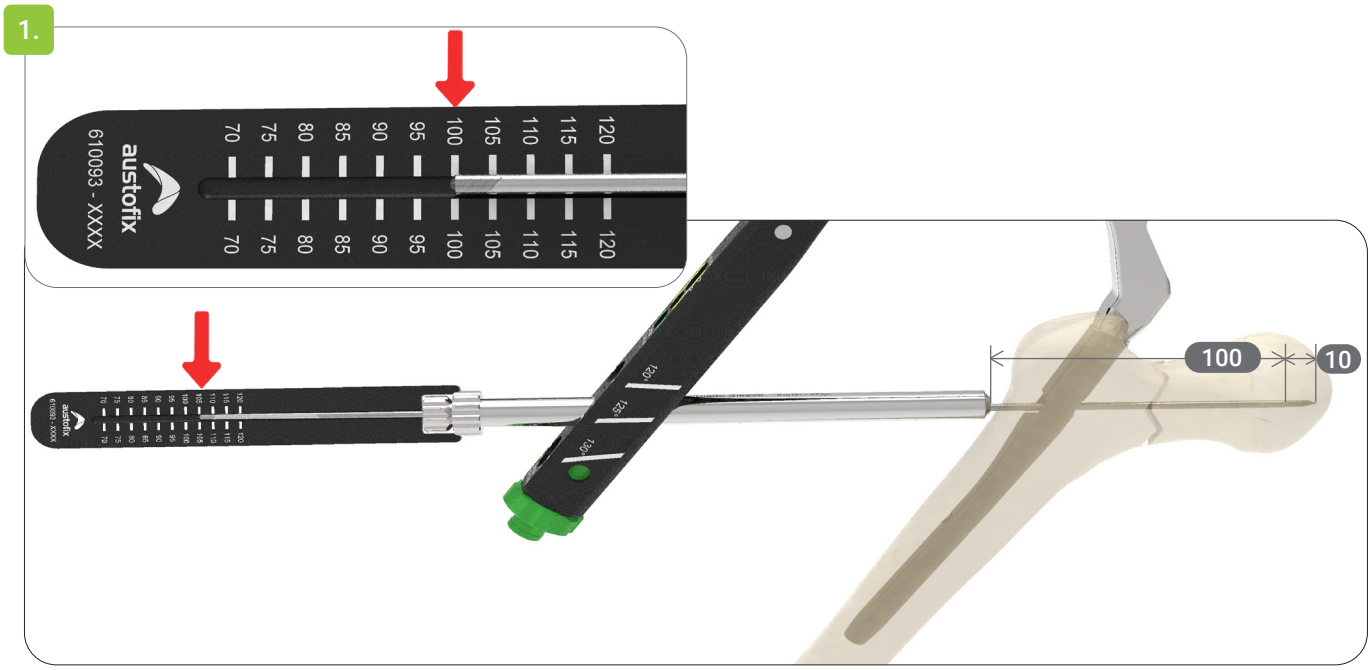
   Note: Confirm location on X-ray.

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.

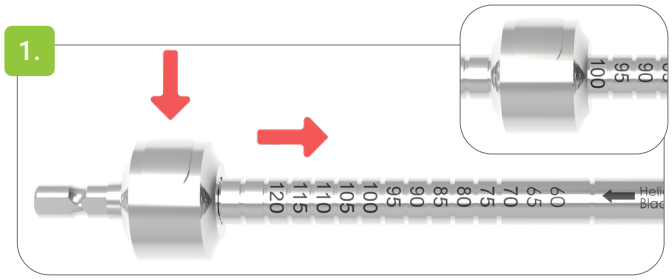
Note: The Depth Gauge already calculates the 10mm tolerance within the provided measurements to ensure the lag screw/blade does not protrude out of the medial side of the bone.



Reaming

1. Use the 7-10.5mm Step Drill Stop (640090) for accurate drilling depth. Hold down the step drill stop button and slide over the 7 -10.5mm Step Drill (610094).

   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.

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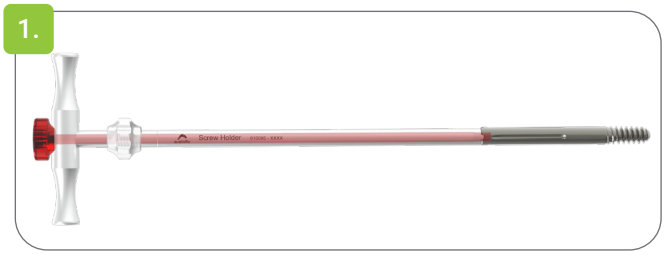
Assembly and Insertion

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

   Align the Lag Screw/Blade Holder (610100) 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.



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

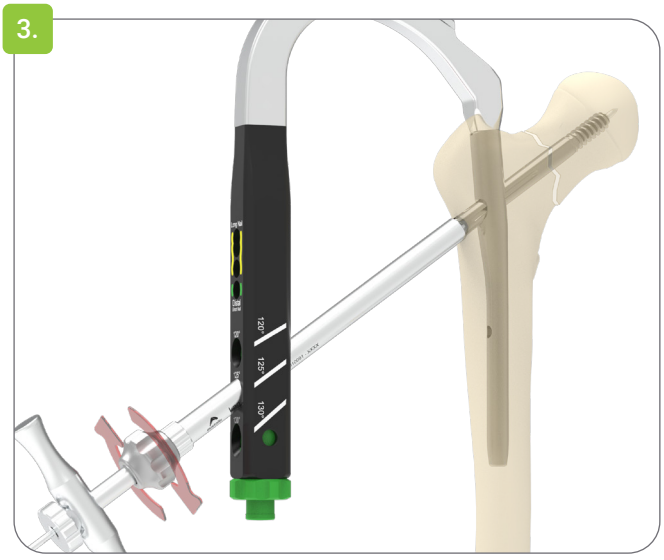
   Note: X-ray should be used during lag screw insertion to monitor Positioning.

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

3. A 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/blade Holder **before** the Lag Screw is inserted.



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

   Ensure the Screw/Blade Holder handle is either parallel or perpendicular to the Proximal Screw Guide.

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

Helical Blade

Guidewire Insertion

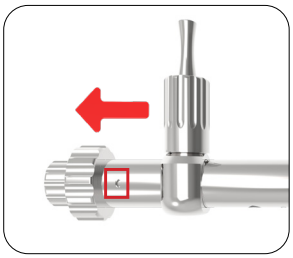
1. Asssemble the F1 Lag screw Trocar (610088), Lag Screw/Blade sleeve (610101) and Spiral Pin instrument (610102).

   Note: The Spiral Pin 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.

1.



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.

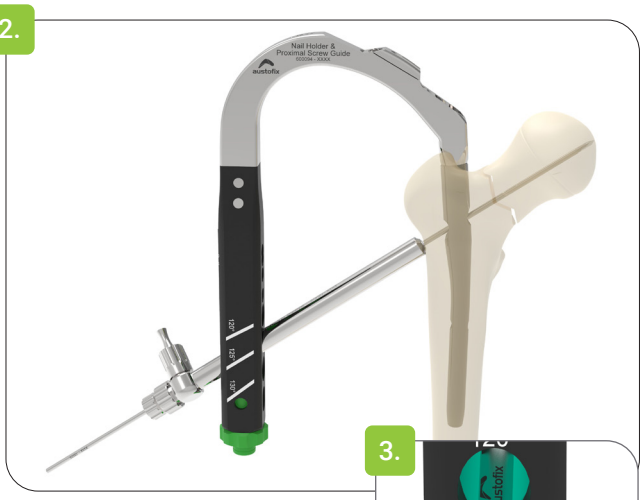
2. Replace the Lag Screw Trocar with the Guidewire Sleeve (610092), ensuring the sleeves contact the lateral cortex.

   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 Screw/Blade Sleeve aligns with the centre number and the Proximal Screw Guide Locking Sleeve - Short (600095) is firmly secured.

2.



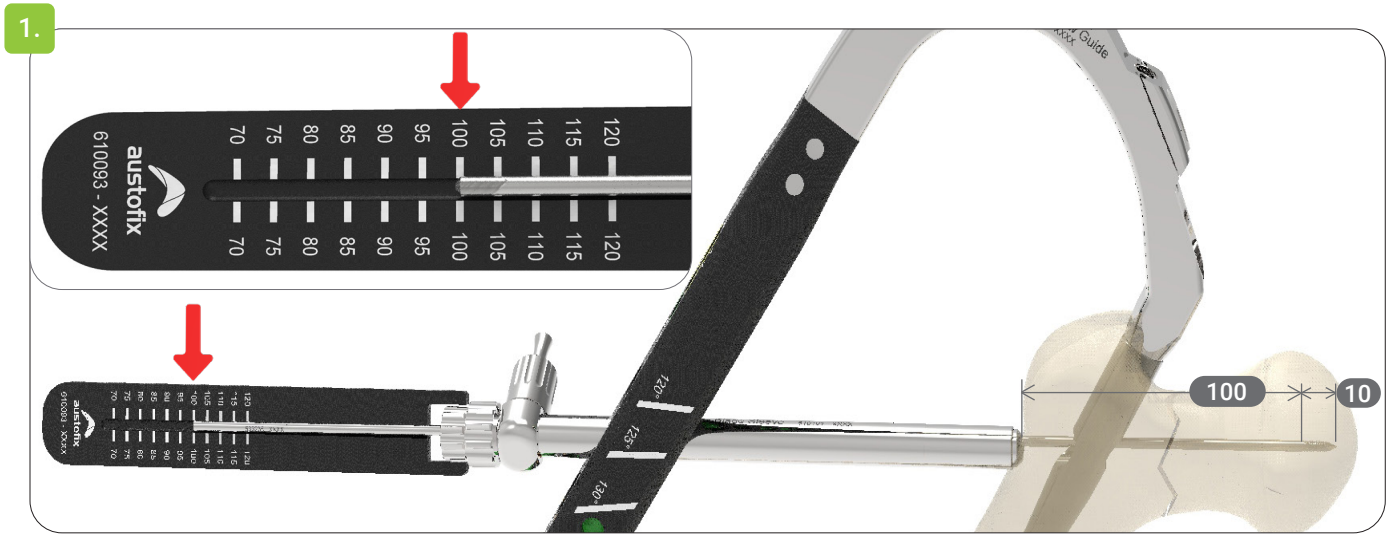
3.

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 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.

1.



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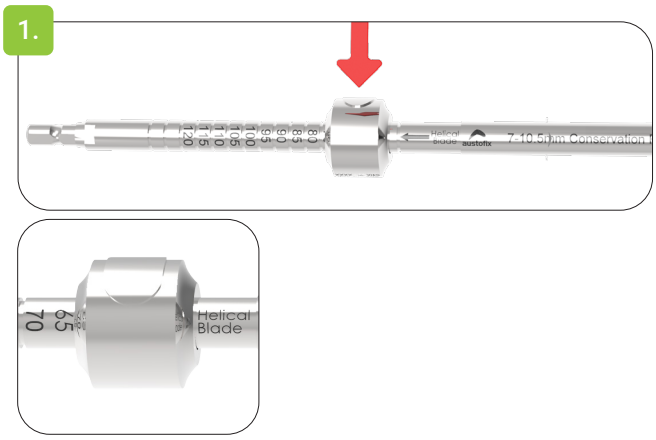
Reaming

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

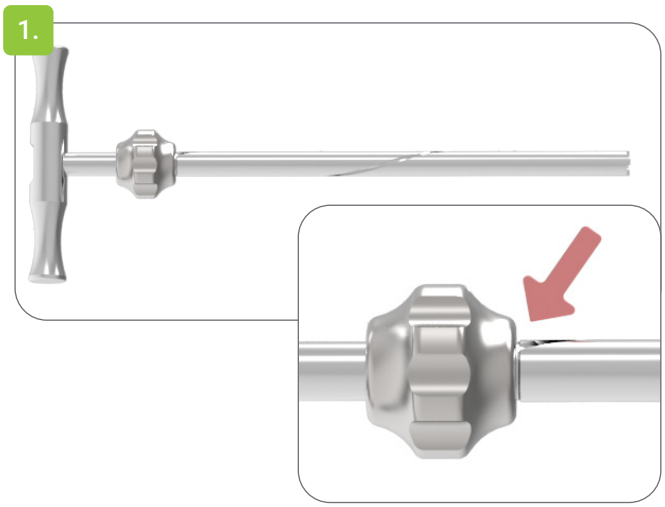
   Note: Check for guidewire deflection that may have occured as it passed into the femoral head/neck before and after drilling.

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

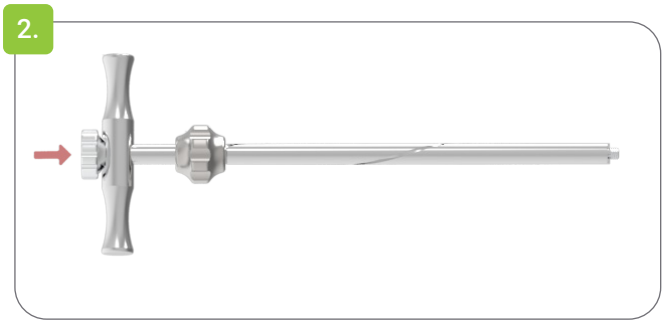
   (OPTIONAL) The 7-10.5mm Bone Conserving Reamer (600106) can be used if bone conservation is required.

Assembly and Insertion

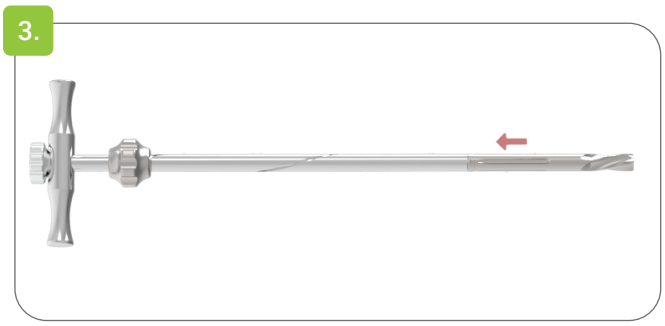
1. Screw the Compression Nut onto the Screw Holder, ensuring the edge lines up with the groove on the Screw/Blade Holder (610100)



2. Insert the Lag Screw Retainer through the Screw/ Blade Holder (610100).



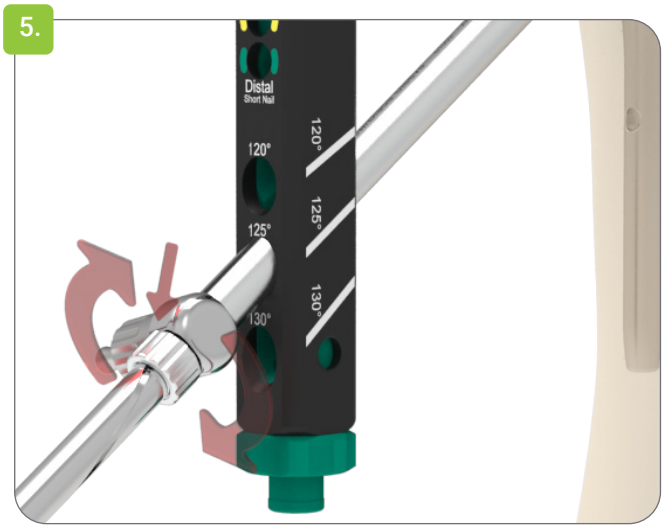
3. Screw on the desired Helical Blade length, ensuring it is tightly fastened.



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

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

   This securs the spiral pin into the lag screw/blade sleeve.



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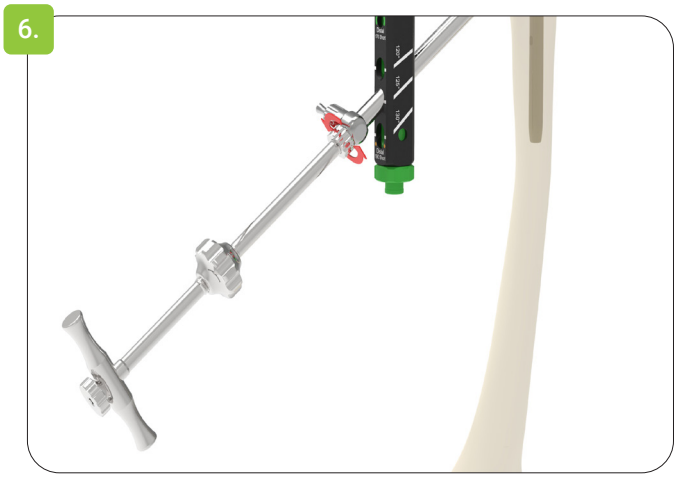
6. Rotate the Screw/Blade Holder until an audible click is heard or the Screw/Blade Holder no longer spins.

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

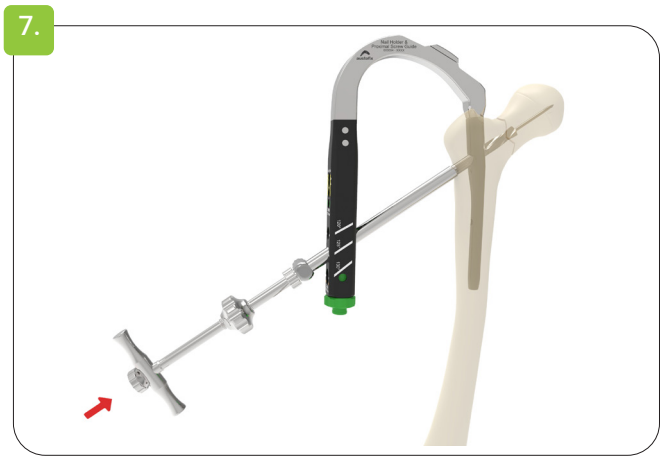
   This ensures the pin is adequately seated in the groove, but it will still slide freely.

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



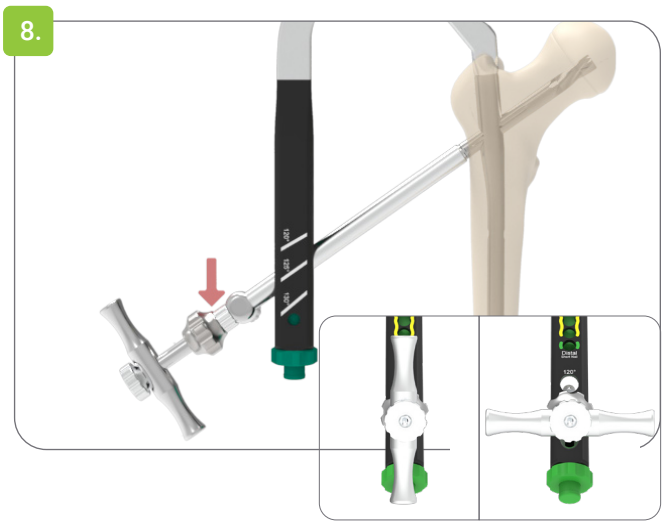
7. Advance the Helical Blade into the femoral head by gently tapping the Screw Holder Retainer with a mallet.

   Note: continue to check that the line on the Screw/Blade Sleeve is aligned to the centre number on the Proximal Screw Guide. The Nut on the Proximal Screw Guide Locking Sleeve - Short (600095) may need to be re-tightened.



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



In-built Set Screw

Note: Set Screw should be fastened before Distal Locking Screw has been inserted.

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

   Note: Articulating Hex Driver should be turned just over three quarter turns into the Set Screw.

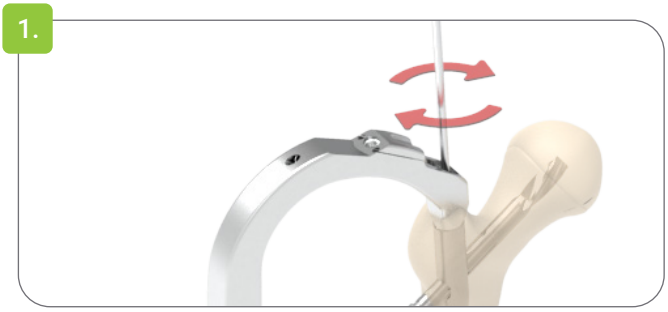
2. Turn the Screw/Blade Holder in the Set Screw to ensure the placement in the Lag Screw/ Blade groove.

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

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

1.



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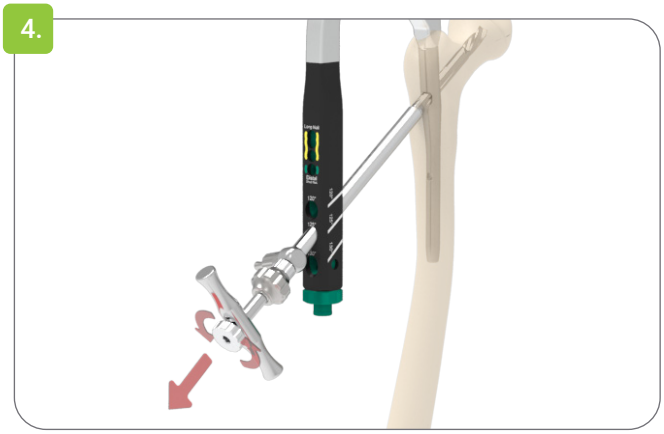

Note: If alignment and insertion of the Articulating Hex Driver is difficult due to obesity, adduct the leg as much as possible. As the fracture is now fixed, there is no loss of fracture reduction.

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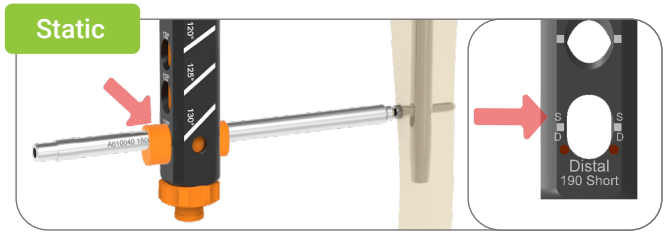
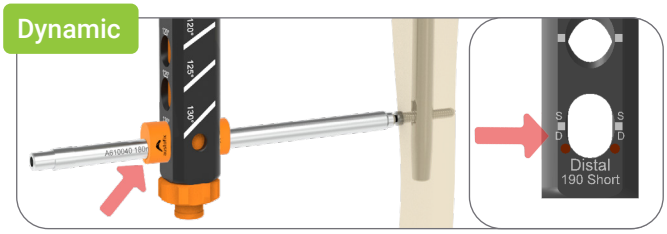
Distal Screw

190mm Nail: If using the F1 190mm Short Nail, swap out the F1 Short Proximal Screw Guide Locking Sleeve (600095 - Green) with the F1 190mm Proximal Screw Guide Locking Sleeve (600099A - Orange). Have the Insert (600099B) in chosen Static or Dynamic orientation (shown right).





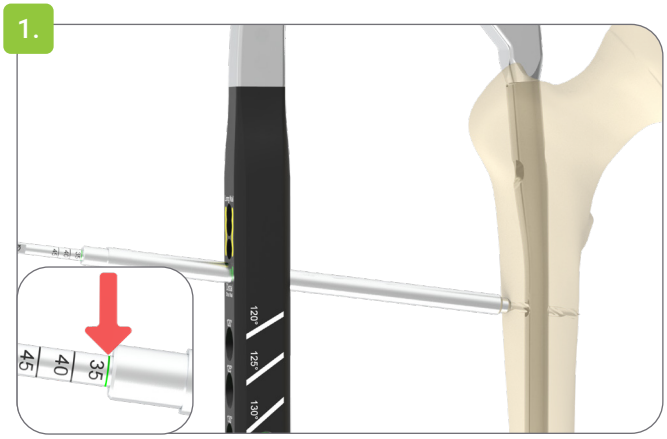
Follow the steps below using either the Static or Dynamic configuration:

1. Pre-assemble the 180mm Drill Sleeve (610064) and 180mm Outer Sleeve (610065) with 180mm Trocar (610063) and insert in:
   170mm Nail - the Short Distal Hole.
   190mm Nail - the Orange Insert.

   Tighten the Green or Orange locking sleeve.

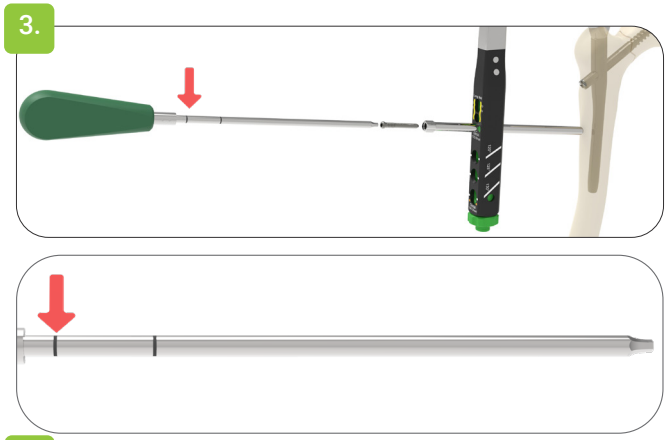
   Remove the Trocar and pass the 4.5x340mm Drill (514534) through the Drill Sleeve and drill to the far cortex.

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



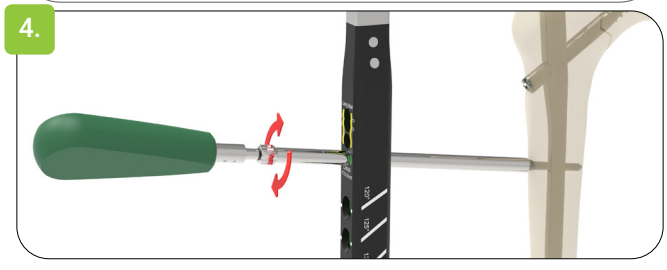
Note: Only the 9mm Short Nails use the 4.0mm Distal Locking Screw. The 3.7x270mm Drill (513727) is required for the 4.0mm Distal Locking Screw.

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.



4. Ensure the screw is completely inserted. Rotate the 3.5mm Hex Screwdriver until the laser marking closest to the screwdriver handle 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).



5. Remove Nail Holder with the 6mm Hex Driver.

End Cap Insertion

If a 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.

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Nail Extraction

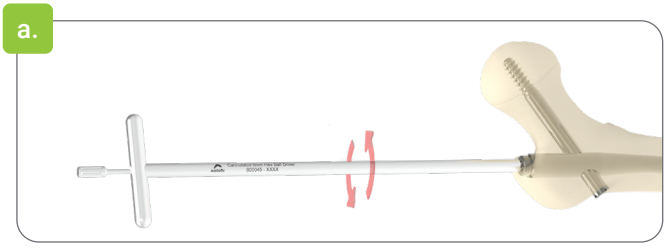
The instruments required for extraction of Austofix F1 Nails are listed below:

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.

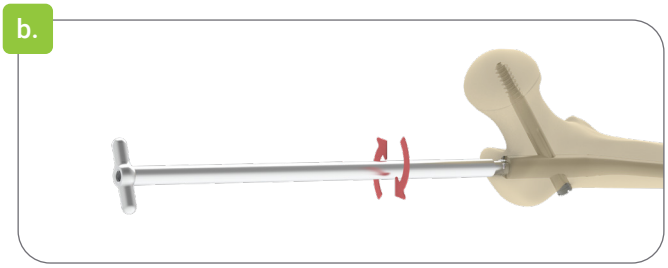


M10 Nail Extractor

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.

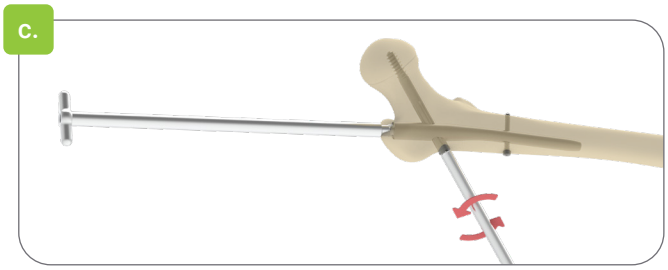


Hip Screw Removal

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.

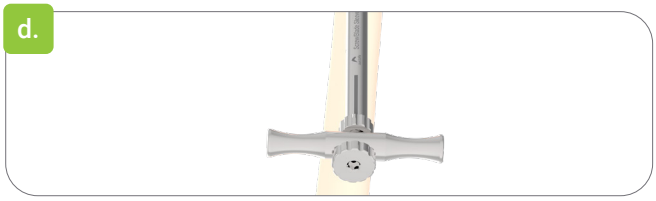
c.

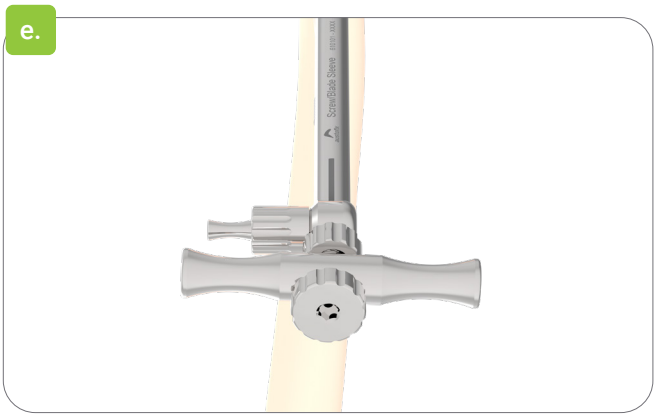


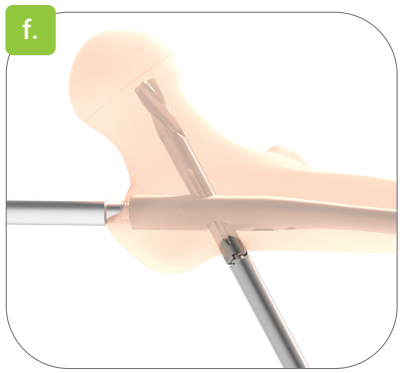
Helcial Blade Removal

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.

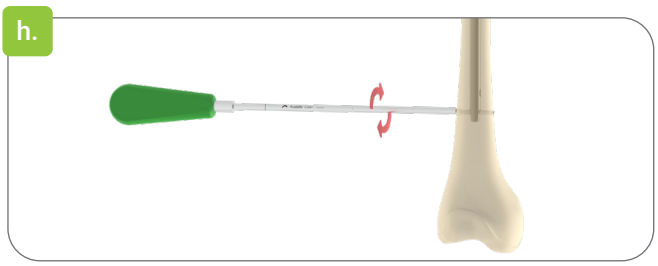






Distal Screw Removal

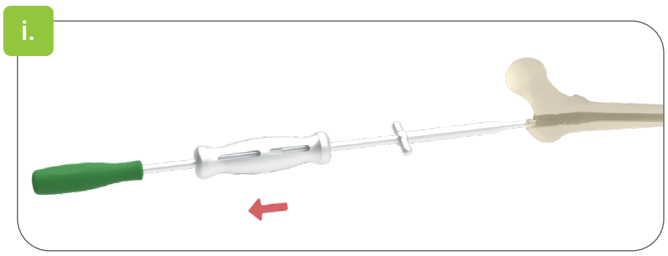
1. Austofix Screws are fitted with a conventional 3.5mm hexagonal drive. They can be removed either with the 3.5mm Hex Power Screwdriver (610068) or by hand with the 3.5mm Hex Screwdriver (610067) (Figure d).



Nail Removal

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

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



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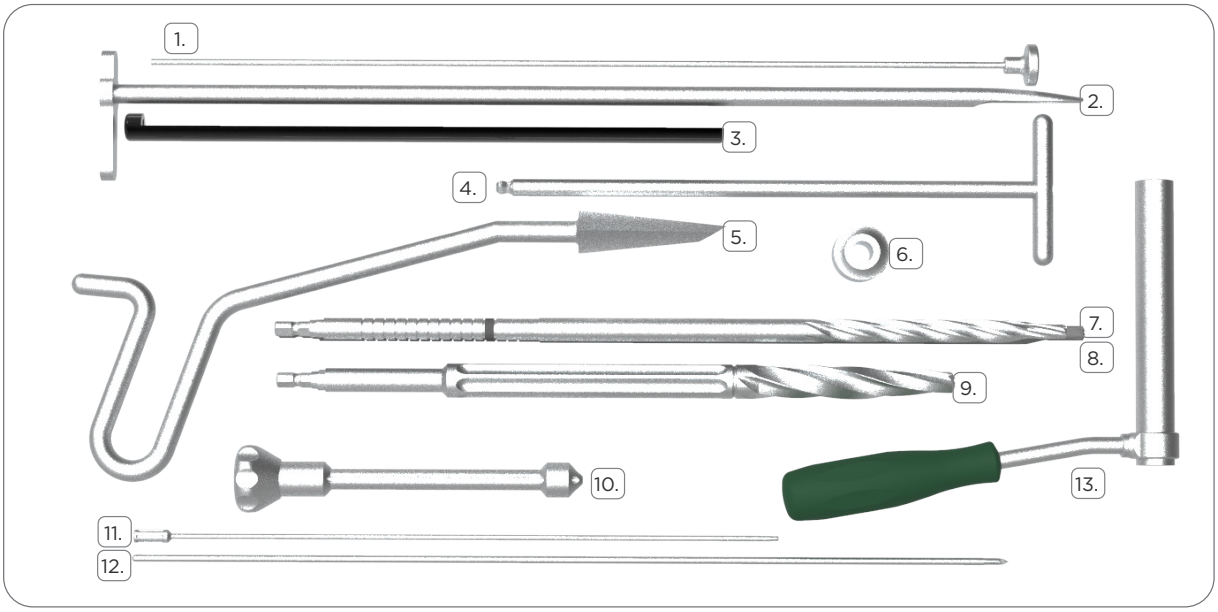
Instruments

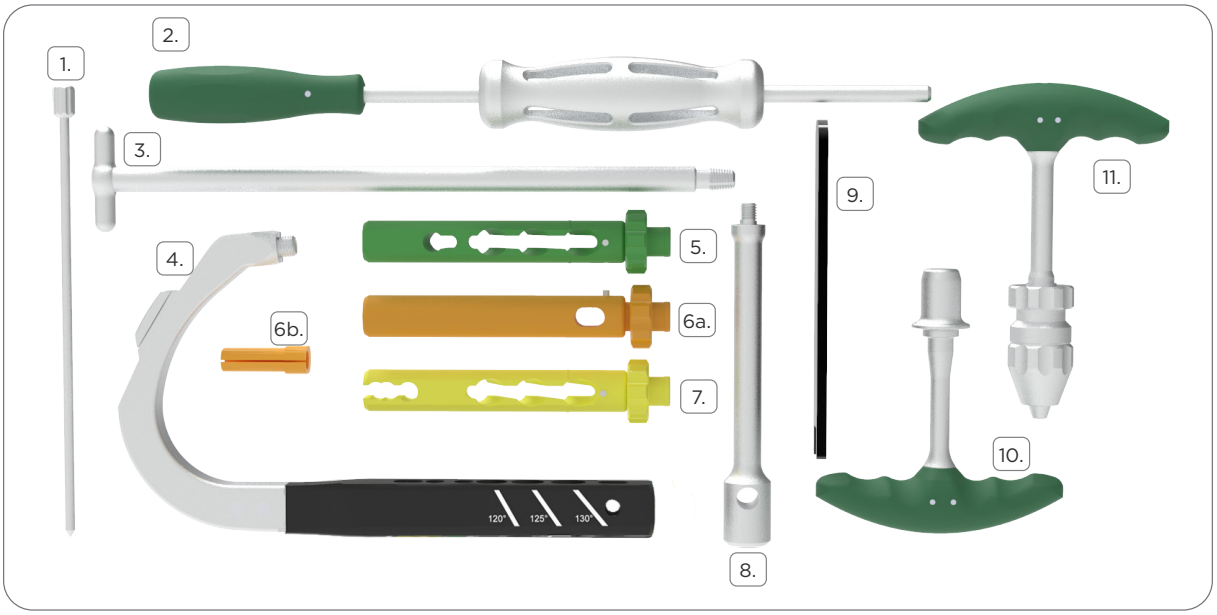
Top Layer



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

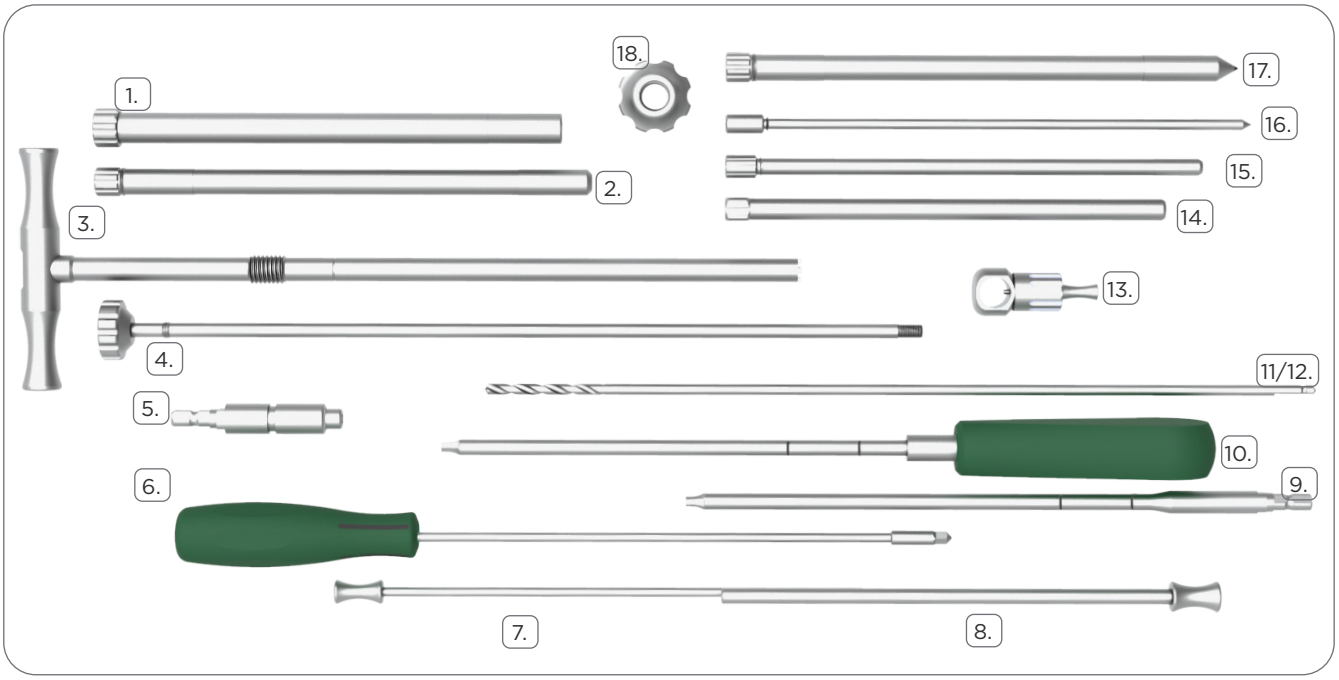
* Supplied sterile/non-sterile

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

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
10.	610067	-	3.5 Hex Screwdriver
11.	514534	-	4.5x340mm Drill*
12.	513727	-	3.7x270mm Drill
13.	610102	-	Spiral Pin Instrument
14.	610065	-	180mm Outer Sleeve
15.	610064	-	4.5x180mm Drill Sleeve
16.	610063	-	180mm Trocar
17.	610088	-	F1 Lag Screw Trocar
18.	610097	-	Screw Holder Compression Nut

* Supplied sterile/non-sterile

Single Use Items

Guidewire	
Product Code	Description
533235	3.2x400 Guidewire (Twin Packed)

Drill	
Product Code	Description
514534	4.5x340mm Drill (for 4.8mm Screw)
513727	3.7x270mm Drill (for 4.0mm Screw)

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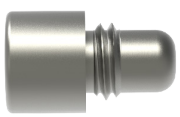
Implants - Titanium

F1 Nail - Titanium 170mm			
Nominal Length	Ø9	Ø10	Ø11
120° Part Numbers			
170	379200	370200	371200
125° Part Numbers			
170	379250	370250	371250
130° Part Numbers			
170	379300	370300	371300

F1 Nail - Titanium 190mm			
Nominal Length	Ø9	Ø10	Ø11
120° Part Numbers			
190	379202	370202	371202
125° Part Numbers			
190	379252	370252	371252
130° Part Numbers			
190	379302	370302	371302

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



Implants - Titanium

4.0mm Locking Screw	
Product Code	Screw Length
364020	20
364025	25
364030	30
364032	32.5
364035	35
364037	37.5
364040	40
364045	45
364050	50
364055	55
364060	60
364065	65
364070	70

F1 10.4 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
361420	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

10.4 Helical Blade	
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
360420	120

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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.

austofix

Legal Manufacturer
Australian Orthopaedic Fixations Pty Ltd
18 Kinkaid Avenue, North Plympton SA 5037, AUSTRALIA

Telephone: 1300 727 075
Fax: 1300 727 380
Email: sales@austofix.com.au

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EC REP Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swater, BKR 4013 Malta CE 2797

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