

austofix F1

Surgical Technique



austofix.com.au

Contents

3
4
4
5
6
7
8
9
10
11
13
13
16
20
21
24

Disclaimer

This document is intended to be read by experienced orthopaedic trauma surgeons familiar with I.M. Nailing of the long bones. This publication is intended as the recommended procedure for using the Austofix nailing system. It offers guidance only. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

For further advice please contact your local Austofix representative. © This document is copyright to Austofix Pty Ltd, and may not be reproduced in whole or part without permission.

Introduction

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

Austofix is dedicated to excellence in every aspect of medical device design, manufacture and product service. In collaboration with Australian surgeons we have introduced innovative, cost-effective implant systems that improve patient outcomes whilst ensuring the fastest operative times. Austofix continues to develop its capabilities through the addition of new expertise, technologies and partnerships with surgeons and scientific institutions.

Austofix distributes the Austofix range of orthopaedic trauma products throughout Australia and overseas in conjunction with international partners. As a specialist in orthopaedic trauma, our product specialists understand the need for product support and service.

austofix F1

There is emergent evidence to suggest that 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 cutout 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 intramedullary nails over screw and plate fixation are attributed to a reduced distance between the hip joint and the implant, which diminishes the bendina moment across the implant/fracture construct. Also, nails can 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.4

Design Details

Nail - Titanium

Long Nail

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

Multiple Proximal Oblique Screw Angles

Stress Relief Cut

Lateral Bend

- 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.



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 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

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 lateral to the tip of the Greater Trochanter. Use Cannulated Awl 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 can be used 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.

Drilling & Reaming Entry Hole

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

Insertion Ball-tipped Guidewire

While keeping the Tissue Guard against the bone, remove the Drill Reamer and Guide Pin. Then insert the Ball-tip Guidewire 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 to the fracture site. Rotate and manipulate the Guidewire Director to align the Ball-tip Guidewire with the distal fragment.

Note:

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







Nail Length Gauge

1. With the Ball-tip Guidewire (532590) inserted to the intended position of the nail, pass the Guidewire Director (531002) over the guidewire to the Greater Trochanter.



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

			-			
	24808	6				
3 2 2	300-	·320-	ن -0-	<u>а</u> 60-	ё õ	

Alternatively: a ruler can be supplied on request.

Reaming

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

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

Instrument Assembly

Nail Holder and Proximal Screw Guide

Align the Nail's proximal groove to the Nail Holder.

Use the 6mm Hex Driver to fasten the In-built Nail Holding Screw.

Slide in the Proximal Screw Guide Locking Sleeve Long (yellow) into the Proximal Screw Guide ensuring the pin is aligned in the slot.



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 (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 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

Use the Single Shot Pin 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.





Secure Rotation

If using the Ezy-Aim distal targeting system, secure the position in the proximal fragment by Inserting two 2.5mm K wires through the Nail Holder and into the femoral head. Perform distal targeting as described in Ezy-Aim Distal Targeting Surgical Technique.



Insertion of Screws

Proximal Oblique Screw

- Assemble the Lag Screw Trocar and Lag Screw Sleeve and pass through the Proximal Screw Guide until it contacts the Cortical Bone. Then secure Locking Sleeve. Note: Ensure that the angle in the Proximal Screw Guide matches the angle of the Nail.
- Replace the Lag Screw Trocar with the Guide Wire Sleeve, 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. Push the Length Gauge up to the Lag Screw Sleeve and take the reading from the lateral point of the Guidewire.

Use the closest 5mm interval to determin 10.4 Hip Screw Length.





 Use the Stepdrill Stop for accurate drilling depth.
Ensure the reading on the medial side of the Stepdrill Stop is the same as the desired 10.4

Hip Screw length.

5. Drill or hand ream the 7-10.5mm Step Drill until the Stop contacts the Lag Screw Sleeve.

Note: the 7-10.5mm Bone Conserving Reamer can be used if bone conservation is desired.

Hip Screw continue to step 6 below. Helical Blade go to page 16.

6. Drill until the Stepdrill Stop contacts the Lag Screw Sleeve.

7. Align the Screw Holder to the 10.4 Hip Screw, then screw in the Screw Holder Retainer and instert the Lag Screw.







8. A Compression Nut can be used to reduce the fracture in the femoral Head. 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.



 Correct 10.4 Hip Screw depth is indicated by when the groove in the Screw Holder is flush with the Lag Screw Sleeve.
Ensure the Screw Holder handle is either parallel or perpendicular to the Proximal Screw Guide.



In-built Set Screw

 Use the 5mm Articulating Hex Driver to firmly fasten the Set Screw.
If desired, turn the Driver back a quarter of a turn to allow lateral movement.
Use the Screw Holder to ensure the desired toggle has been achieved.



Helical Blade

1. Temporarily remove the Outer Sleeve, slide the Alignment Pin over the Outer Sleeve, ensuring the pin does not secure in the hole on the Outer Sleeve. Then place back into the Proximal Screw Guide

2. Ensure the line on the Outer Sleeve aligns with the centre number and the Locking Sleeve is firmly secured.





3. Screw the Compression Nut onto the Screw Holder, ensuring the edge lines up with the groove on the Blade Holder.



4. Insert the Lag Screw Retainer through the Blade Holder.

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



Helical Blade Insertion

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



2. Ensure the Alignment Pin is pushed against the back end of the Outer Sleeve and then spin until an audible click is heard or the Alignment Pin no longer spins.



- 3. Spin the Nail Holder until an audible click is heard or the Nail Holder no longer spins.
- 4. Remove the 3.2x400mm Guidepin.



 Advance the Helical Blade through the femoral head by gently tapping the Screw Holder Retainer with a mallet.
Note: continue to check that the line on the Outer Sleeve is aligned to the centre number on the Proximal Screw Guide. The Locking Sleeve Nut may need to be re-tightened.

 Continue to insert the Helical Blade until the Compression Nut (or groove on Nail Holder) contacts the Outer Sleeve.
Check that the Screw Holder Handle is either perpendicular or parallel to the Proximal Screw Guide.





 Insert the Articulating Driver and tighten the Internal Set Screw in the Nail, then back off 90° (use lines on Articulating Driver for reference) Note: please check the Set Screw has engaged by wriggling the Screw Holder.



8. Untighten the Screw Holder Retainer and remove the Screw Holder and corresponding instruments.



Proximal 4.8mm Locking Screws

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

1. Pre-assemble the Outer and Inner Sleeves, select either the static or dynamic hole and insert through the Proximal Screw Guide. Drill using the Ø4.5mm Drill.

Markings on the drill can be used to determine screw length.

A universal Depth Gauge can also be used to determine screw length.



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. To maintain alignment of the proximal instruments, place two 2.5x250mm K-wires through the anterior and posterior holes in the F1 Nail Holder and into the femoral head. Remove the Drill. Perform distal locking as described in the Ezy-Aim Distal Targeting Surgical Technique. Then perform 10.4 Hip Screw Insertion



In-built Set Screw

Note: Set Screw can be fastened before 4.8mm Locking Screw has been inserted.

 Use the 5mm Articulating 5mm Hex Driver to firmly fasten the Set Screw.
If desired, turn the Driver back a quarter of a turn to allow lateral sliding. Use marking on driver handle to indicate 90°.



End Cap

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

Instruments



Тор

Middle



Base

9.



610098 Articulating Hex Driver 610098 -

Single Use Items

Guidewire				
Product Code	Description			
533235	3.2x400mm Guidewire (Twin Packed)			
512525	2.5x250mm K Wire (Twin Pack)			
532590	2.5x900mm Ball-tip GW			
Drill				
Product Code	Description			
514527	4.5 x 270mm Drill			

4.5x340mm Drill

514534

Implants

F1 Nail Long - Titanium						
Nominal Length	Ø10		Ø11		Ø12	
	Left	Right	Left	Right	Left	Right
		1	L20° Part Num	bers		
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

F1 10.4mm Hip Screw Ti			
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 Ti			
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		



Homme Locking Screw H				
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			

Mercelinononoo

M10 End Cap Ti			
Product Code	Head Length		
363405	5		
363410	10		
363415	15		
363420	20		



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



Notes

austofix

Head Office

Austofix 28 Dalgleish Street Thebarton, SA, 5031 AUSTRALIA

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

austofix.com.au

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