

austofix CHN CANNULATED HUMERAL NAIL LONG

Surgical Technique

Retrograde



Australian Made • Australian Owned

austofix.com.au

Contents

Disclaimer

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

For further advice please contact your local Austofix representative. © 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 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, costeffective 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 CHN

There is now a broad variety of specialised proximal humeral fixation devices on the market. The Austofix CHN stands out as one of very few having a lengthy and well proven clinical history. The design dates back to pioneering Humeral Nail research in the early 1990s. Austofix was the first to introduce obliquely angled and "locked" screws through its Humeral Head Screw anti-backout feature. Independent bioengineering research has since confirmed that the unique characteristics of the Austofix CHN implant provides superior strength and rigidity when compared to other devices. These advantages may be the deciding factor in the successful healing of marginal osteoporotic multi-part fractures.

In 2006 Austofix has further improved this very successful product. By enabling precise positioning of the Humeral Head Screws and introducing smaller incremental sizes, the fixation device is making direct contact with the best quality subchondral bone.

The Long version of the CHN is also designed for antegrade insertion

Design Details

CHN Long

The CHN Long provides fixation options for fractures extending more than 90mm from the top of the humerus. Indicated for any fracture extending down the mid-shaft, and/or shaft fractures in isolation. The CHN Long can be inserted antegrade or retrograde.



Materials

All implants are made from Type II Anodised ISO 5832-3 Titanium made specially to Austofix specifications. This metal gives unrivalled strength and rigidity. Austofix insists on very tight tolerances which result in a high quality design which is narrower.

The company has been successfully making Humeral Nails to these demanding specifications since the early 1990s. This enables the insertion "footprint" to be the smallest possible, thus preserving the rotator cuff and enabling early mobilisation which makes full use of the device's great strength and stability. Independent cadaver testing has shown the Austofix CHN construct to be superior to a well known proximal humeral plate design.

Nails

The Austofix CHN Long is designed for fractures in the middle and distal shaft. It is available in lengths of 180-280mm (in 20mm increments). The CHN Long features a distal hole for static locking and a slot for dynamic locking.



Screws

3.5mm/4.0mm Nail Locking Screws

3.5mm & 4.0mm Locking Screws are used for the retrograde approach, with one or two screws used proximally, and one or two postero-anterior holes used distally. These screws feature a special thread design with 75% of the thread being shallow facilitating insertion and the final 25% expanding to grip the first cortex.

Note: 3.5mm Locking Screws are used proximally with Ø7mm Nails only. 4.0mm Locking Screws are used proximally and distally for Ø8mm & Ø9mm Nails, and distally for Ø7mm Nails.

4.3mm Humeral Head Screws

4.3mm Humeral Head Screws with an anti-backout mechanism. Used for antegrade Nail insertion, these screws are securely placed in a tapped hole in the Nail (proximal four holes only). The screws feature blunt contact tips and low profile heads, with incremental 2.5mm sizes offered to enable the closest possible placement to the subchondral bone.

Note: The Humeral Head Screws and Washer are not used for retrograde Nail insertion. All locking is done with 3.5mm and 4.0mm Locking Screws.

The Humeral Nail End Cap is available in the following lengths:

» 1, 5, 10, 15, 20mm





3.5mm Nail Locking Screw (Ø7mm Nail)



4.0mm Nail Locking Screw (Ø8mm & Ø9mm Nails)



4.3mm Humeral Head Screw (Antegrade Only)



Humeral Nail End Cap



Washer for Humeral Head Screw (Antegrade Only)

Indications & Pre-Operative Planning

Retrograde Approach

This approach can be used for all middle and distal humeral shaft fractures, but it is a more demanding technique. Normally the standard Ø8mm diameter CHN Long is suitable, but Ø7mm Nails are available for patients with small medullary canals.

It must be confirmed on pre-operative lateral radiographs that the distal humeral shaft has the normal slight anterior curve. Flexible reamers are always required, and care must be taken to avoid breaching the anterior cortex when making the entry hole and passing the first reamer. If the medullary canal is very narrow (less than 5-6mm), reaming will be difficult. Other methods of treatment should then be considered.

However, especially in young patients, retrograde Nailing avoids any possibility of damage to the rotator cuff. Also, recovery of function is faster, so it is of particular importance when walking aids are required, such as in the presence of associated lower limb fractures.

Note: The Humeral Head Screws are not used. All locking is done with 4.0mm Locking Screws (except where 3.5mm Locking Screws are used proximally with Ø7mm Nails).

One or two screws are used proximally, and one or two postero-anterior holes are used distally.



Patient Positioning

Elbow Support

Place the patient in a supine position as shown (top right) with the shoulder lying over the edge of the operating table. The elbow support is positioned as shown, with the metal shaft close to the patient's neck. Use any standard operating table fitting which is designed to clamp a vertical 16 mm (5/8") rod (swivelling connections are less satisfactory). The elbow is flexed over the support, which is adjusted so that the shoulder is abducted to 100° and the humerus is approximately 60° from the horizontal. The elbow must be flexed at least 120° to provide access to the Olecranon Fossa. Fasten the Elbow Support wrist strap.





Standard Prone Position

Place the patient in prone position, use pads on the ipsilateral edge of the table and to support the patient (see below). Use an additional arm board or armrest fastened to the table to support the fractured arm. Flex the elbow at 90°, allowing up to 120° if necessary. The surgeon can operate from the dorsal side.



Incision & Bone Preparation

Incision

1. The incision begins at the tip of the olecranon and extends proximally for 3-4 cm, passing through the triceps tendon into the extrasynovial fat. The elbow joint is not exposed. (Right Top).

Reaming

 Pass the 9mm Cannulated Drill Reamer (520921) over a 2.5x250mm K-Wire (512525) with the 10mm Tissue Guard (600001) down to the proximal side of the Olecranon Fossa. Hold the Tissue Guard against the bone and slowly advance the Drill Reamer for approximately 50mm, frequently checking alignment on X-ray.

Note: In hard bone a 3.7x240mm Drill (513724) can be used to start the hole for the K-Wire.

 Insert a 3.0x900mm Ball-tip Guidewire (533900) through the fracture site to the depth intended for the Nail. Use a 9.0mm Flexible Power Reamer (543090)* and begin reaming in 0.5mm increments, taking care to ream in the line of the humeral shaft and allowing the oblique entry hole to migrate more proximally as it enlarges. The shaft is reamed to 9mm only.

Note: These stages must be checked frequently on the lateral X-ray view to avoid excessive reaming of the anterior cortex.

Note: The 8mm Hand Reamer (600008) can be used if there is difficulty in reaming hard, cortical bone.

*Flexible Reamer Instrument Set (SET-INS-REAM) supplied on request.







Instrument Assembly

- 1. Align so that the inside of the bend of the Nail faces the Cannulated Humeral Nail Holder (610075).
- 2. Tighten the Cannulated Humeral Nail Holding Screw (610076) with the Cannulated 6mm Hex Ball Driver (600045).
- 3. Regularly check Nail Holding Screw for tightness throughout the operation. If this loosens, screw targeting will not be accurate.
- 4. An Impactor (600028) must be screwed into the Nail Holder if using a mallet or slap hammer.



Nail Insertion

With the Nail Holder posterior, insert the Nail by lightly tapping the Impactor with a mallet or Slap Hammer, and manipulate the Nail across the fracture site (Figure a). If extraction and reinsertion are needed, the Slide Hammer (600097) can be screwed into the end of the Impactor or directly to the Nail Holder.

There are three reference points to note when making sure the end of the Nail is correctly inserted inside the bone:

- The step in the instrument is designed as a visual rather than a radiological reference. It is 10mm above the end of the Nail (Figure b), and should be placed where the anterior corner is just beneath the oblique cortex of the Olecranon Fossa, as seen lateral X-ray views. This is important, as otherwise the Nail may impinge on the Olecranon.
- 2. The instrument tapers to the end of the Nail, and there is a slight difference in diameter between the instrument and the Nail, which appears as a small step. Both the taper and the small step should identify the top of the Nail radiologically.
- 3. As a final reference, the four proximal Screw holes will be visible on the X-ray image. The most proximal hole should be within 8mm of the top of the Nail, with all four proximal holes within 30mm of the top of the Nail.

If the fracture remains distracted, drive the Nail further in and insert the first Locking Screw at the shoulder end. Then release the traction and gently withdraw the Nail to impact the fracture.





Insertion of Screws

Screws at Shoulder End

The proximal screws should be inserted first because:

- The Nail can be rotated as required to align the holes in the X-ray beam.
- The Nail can be moved to correct errors in targeting.
- If the fracture remains distracted, the Nail can be driven in further, locked proximally, and then the traction is released and the Nail withdrawn to impact the fracture.

Note: Once traction is released, the arm moves down and proper lateral X-ray images of the proximal humerus are not obtainable

Both Freehand Targeting and the Austofix Ezy-Aim Electronic Targeting System can be used.

Freehand Targeting

Use standard free-hand targeting technique. The Drill Sleeves can be used as tissue guards.

Ezy-Aim Electronic Targeting System

Attach the DTA adaptor (600077) and follow "700402 Ezy-Aim Surgical Technique."



All Screws have the same method of insertion.

- Assemble the Trocar (610038), Drill Sleeve 1. (610039) and Outer Sleeve (610040) and pass through the Screw Guide/Ezy-Aim Transmitter and tighten the Locking Sleeve.
- 2. Ensure the Sleeves contact the near cortex then remove the Trocar.

- 3. Drill through the far cortex with a 3.7 x 240mm Drill (513724) for 8 & 9mm Nails, or with a 3.2 x 240mm Drill (513224) for 7mm Nails. Note the depth marking when far cortex is reached and add 5mm, or check depth on Image Intensifier. The ideal depth is with 2-3mm protruding through the far cortex. If necessary the Universal 3.7-4.5mm Depth Gauge (610069) can be used through the Outer Sleeve.
- 4. Remove the Drill and Drill Sleeve.

5. Use the 3.5mm Hex Screwdriver (610067) to secure the Locking Screw. The 3.5mm Hex Power Screwdriver (610068) can also be used. The first reference line on the Screwdriver shaft indicates the Screw is fully inserted.

Screws:

Shoulder end: 3.5 for 7mm Nails, 4.0 for 8 & 9mm Nails











Screws at Elbow End

1. Attach the Proximal Screw Guide (600078A) using the 3.5mm Hex Driver. Check that the Nail and humeral head are in the correct rotary position and the Cannulated Nail Holding Screw (600076) is tight (Figure a). The lesser tuberosity should face anteriorly and the Cannulated Humeral Nail Holder (600075) laterally.

Note: There is a hole for a K-Wire (512525) in the Proximal Screw Guide that aligns with top of Nail when alignment is correct (Figure b).



 Only the transverse AP holes are used, requiring 3.7 drills and 4.0 screws . Follow standard screw insertion method on page 12.



End Cap

An End Cap may be used to deter bone ingrowth or to increase the Nail's length. M7 End Caps can be inserted into the Nail using the 3.5mm Hex 250mm Screwdriver (610067).

Note: End Cap length is determined by surgeons preference. Lengths available include 1, 5, 10, 15 & 20mm.



Aftercare

Initially the arm is supported in a simple sling. Provided stable fixation has been obtained, shoulder and elbow mobilising activities should be encouraged as much as pain permits. Activity should remain light for the first 6 weeks.

Nail Extraction

End Caps

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

M7 Nail Extractor

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

1. The M7 Nail Extractor (600108) is screwed into the Nail (Figure a).

Locking Screw Removal

• 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 using the 3.5mm Hex Screwdriver (610067).

Nail Removal

• Attach the Slide Hammer assembly (600097) onto the Nail extractor and withdraw the Nail (Figure b).

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

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

Product Code	Description
600108	M7 Nail Extractor
610067	3.5mm Hex Screwdriver
610068	3.5mm Hex Power Screwdriver
600097	Slide Hammer

Instruments

Top Layer

б.

7.

8.

9.

1.	600001	-	10mm Tissue Guard
2.	600080	-	Humeral Nail Length Gauge
3.	531000	-	Guidewire Pusher
4.	600079	-	Humeral Guidewire Director
5.	520921	-	9mm Cannulated Drill Reamer

- 600008 8mm Hand Reamer
 - 600097 Slide Hammer
 - 600045 Cannulated 6mm Hex Ball Driver
- 600028 Impactor

1.	600075	-	Humeral Nail Holder
2.	600076	-	Humeral Nail Holding Screw
З.	600078A	-	CHN Proximal Screw Guide
4.	600078C	-	CHN PSG Locking Sleeve Short
5.	600078B	-	CHN PSG Locking Sleeve Long
б.	600077	-	Humeral Nail DTA Adaptor
7.	610067	-	3.5 Hex Screwdriver
8.	610068	-	3.5 Power Screwdriver

9.	610069A	-	Depth Gauge Outer
10.	610069B	-	Depth Gauge Inner
11.	513724	-	3.7x240mm Drill (4.0 & 4.3mm Screw)
12.	513224	-	3.2x240mm Drill (3.5mm Screw)
13.	610040	-	150mm Outer Sleeve
14.	610039	-	150mm Drill Sleeve
15.	610038	-	150mm Trocar

Single Use Items

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

Drill		
Product Code	Description	
513224	3.2 x 240mm Drill (for 3.5mm Screw)	
513724	3.7 x 240mm Drill (for 4.0 & 4.3mm Screw)	

Implants - Titanium

CHN Long - Titanium			
Nominal Length	Product Code		
	Ø7		
180	130718		
200	130720		
220	130722		
240	130724		
260	130726		
Ø8			
200	130820		
220	130822		
240	130824		
260	130826		
280	130828		
Ø9			
200	130920		
220	130922		
240	130924		
260	130926		
280	130928		

M7 End Cap			
Product Code	Cap Length		
190701	1		
190705	5		
190710	10		
190715	15		
190720	20		

4.011111 LOCKING SCIEW				
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			

4 Oppma Locking Con

4.3mm Humeral Head Screw				
Product Code	Screw Length			
134325	25			
134327	27.5			
134330	30			
134332	32.5			
134335	35			
134337	37.5			
134340	40			
134342	42.5			
134345	45			

5.5HIII LOCKING SCIEW		
Product Code	Screw Length	
133520	20	
133525	25	
133530	30	

www.austofix.com.au

Washer for Humeral Screws	Head
Product Code	
134301	

-	1300 727 075	F	1300 727 380	sales@austofiv.com.au

MRI Safety

Austofix has not evaluated its devices for safety and compatibility in a Magnetic Resonance (MR) environment. However, the materials used in their manufacture are known to have minimal ferromagnetism, with minimal risk to patients in strong magnetic fields.

Austofix has performed a review of published, peer-reviewed data, which confirms that only minor rises in MRI-related heating are observed from devices manufactured from the same titanium materials. Trauma devices are considered unlikely to produce injury to patients, including in the worst-case 3.0T systems.

The devices and materials observed in the literature experience forces too weak to cause significant displacement; the risk being further mitigated by their implantation in bone. Risks of imaging artifacts are known to MRI operators, and can be reduced by choosing appropriate pulse sequences and optimizing scanning parameters by using a large bandwidth, small field-of-view and appropriate echo train length.

Average temperature changes have been observed in studies at 0.48°C. Rises in temperature in clinical situations may depend on individual patient factors. It should be recommended that patients be thoroughly monitored when undergoing MR scanning, and that impaired patient thermoregulation be considered a contraindication for MRI procedures.

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. O-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 DISTRIBUTOR STICKER

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

austofix.com.au