

CentroNail®

Titanium Humeral Nail



The Centronail
Titanium Humeral Nailing System



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37 NAIL REMOVAL

Orthofix wishes to thank the following surgeons for their contribution to the development of the technique:

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Department of Trauma and Orthopaedics, "Versilia"
Hospital, Viareggio, Italy

FEATURES AND BENEFITS

PROXIMAL HUMERAL NAIL

SHORT (150mm) 10mm 10mm 10mm 7-9mm 7-9mm 7-9mm 5.5-7.5mm

Titanium nail and locking screws Allows MRI investigation, if necessary

10mm proximal diameter

7-9mm distal diameter

One design for Left and Right humerus

Proximal bend 15°

DIAPHYSEAL HUMERAL NAIL



Titanium nail and locking screws Allows MRI investigation, if necessary

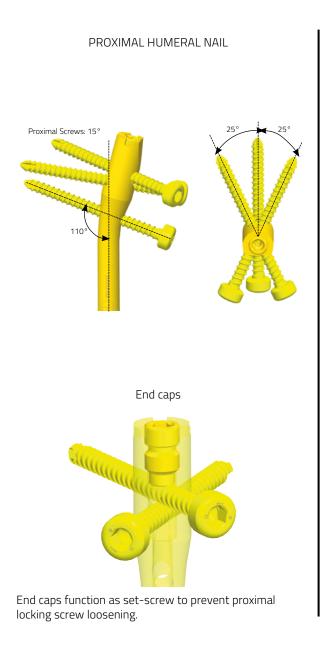
7-9mm diameter In the 7mm nail, the proximal 25mm is 8mm in diameter

One design for Left and Right humerus Antegrade and retrograde insertion

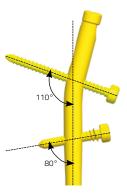
185-320mm long (15mm increments)

Proximal bend 15°

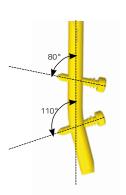
Proximal locking



DIAPHYSEAL HUMERAL NAIL Antegrade



Retrograde



Locking screws

TITANIUM STANDARD LOCKING SCREWS

6.0mm thread diameter 4.0mm shaft diameter



TITANIUM REVISION LOCKING SCREWS

8mm thread diameter Better purchase in poor quality bone 4.0mm shaft diameter



Smooth diameter, unthreaded shaft: Maximises fatigue strength Reverse thread on screw head: Easy screw removal Conical tip: Helps insertion

TITANIUM THREADED LOCKING SCREWS



Fully threaded shaft: Improves purchase in cancellous bone near articular surface. Reverse thread on screw head: Easy screw removal Conical tip: Helps insertion

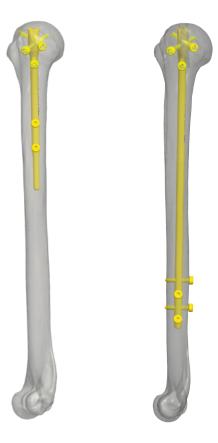
TITANIUM PROXIMAL THREADED LOCKING SCREWS



To be used only in the humeral head. Improves purchase in osteoporotic bone. The low profile of the locking screw head reduces the risk of muscle impingement or interference.

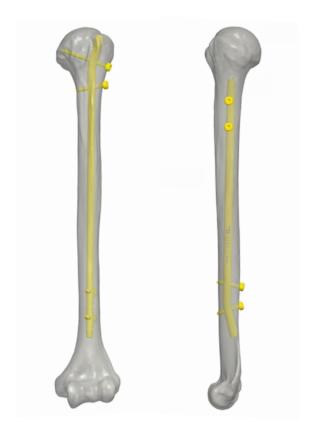
INDICATIONS

PROXIMAL HUMERAL NAIL



- Proximal Fractures
- Non-Union
- Mal-Union
- Pathological Fractures

DIAPHYSEAL HUMERAL NAIL



- Diaphyseal FracturesNon-Union

- Mal-UnionPathological Fractures

EQUIPMENT REQUIRED

Centronail Titaniun		
Ø 7 L 150mm	Cannulated	99-T787150
Ø 8 L 150mm	Cannulated	99-T788150
Ø 9 L 150mm	Cannulated	99-T789150
Ø 7 L 185mm	Cannulated	99-T787185PL
Ø 7 L 200mm	Cannulated	99-T787200PL
Ø 7 L 215mm	Cannulated	99-T787215PL
Ø 7 L 230mm	Cannulated	99-T787230PL
Ø 7 L 245mm	Cannulated	99-T787245PL
Ø 7 L 260mm	Cannulated	99-T787260PL
Ø 7 L 275mm	Cannulated	99-T787275PL
Ø 7 L 290mm	Cannulated	99-T787290PL
Ø 7 L 305mm	Cannulated	99-T787305PL
Ø 7 L 320mm	Cannulated	99-T787320PL
Ø 8 L 185mm	Cannulated	99-T788185PL
Ø 8 L 200mm	Cannulated	99-T788200PL
Ø 8 L 215mm	Cannulated	99-T788215PL
Ø 8 L 230mm	Cannulated	99-T788230PL
Ø 8 L 245mm	Cannulated	99-T788245PL
Ø 8 L 260mm	Cannulated	99-T788260PL
Ø 8 L 275mm	Cannulated	99-T788275PL
Ø 8 L 290mm	Cannulated	99-T788290PL
Ø 8 L 305mm	Cannulated	99-T788305PL
Ø 8 L 320mm	Cannulated	99-T788320PL
Ø 9 L 185mm	Cannulated	99-T789185PL
Ø 9 L 200mm	Cannulated	99-T789200PL
Ø 9 L 215mm	Cannulated	99-T789215PL
Ø 9 L 230mm	Cannulated	99-T789230PL
Ø 9 L 245mm	Cannulated	99-T789245PL
Ø 9 L 260mm	Cannulated	99-T789260PL
Ø 9 L 275mm	Cannulated	99-T789275PL
Ø 9 L 290mm	Cannulated	99-T789290PL
Ø 9 L 305mm	Cannulated	99-T789305PL
Ø 9 L 320mm	Cannulated	99-T789320PL

4.0mm Titanium T Locking Screws	hreaded
99-T786020	20mm
99-T786025	25mm
99-T786030	30mm
99-T786035	35mm
99-T786040	40mm
99-T786045	45mm
99-T786050	50mm
99-T786055	55mm
99-T786060	60mm
99-T786065	65mm
99-T786070	70mm
99-T786075	75mm
99-T786080	80mm

4.0mm Titanium Proximal Threaded Locking Screws*				
99-T784030	30mm			
99-T784035	35mm			
99-T784040	40mm			
99-T784045	45mm			
99-T784050	50mm			
99-T784055	55mm			
99-T784060	60mm			
99-T784065	65mm			

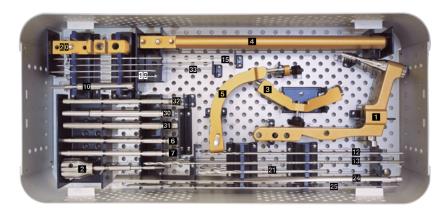
^{*}not available in all markets

Centronail Titanium Humeral Nail	
Ø 7 L 185mm Cannulated	99-T787185
Ø 7 L 200mm Cannulated	99-T787200
Ø 7 L 215mm Cannulated	99-T787215
Ø 7 L 230mm Cannulated	99-T787230
Ø 7 L 245mm Cannulated	99-T787245
Ø 7 L 260mm Cannulated	99-T787260
Ø 7 L 275mm Cannulated	99-T787275
Ø 7 L 290mm Cannulated	99-T787290
Ø 7 L 305mm Cannulated	99-T787305
Ø 7 L 320mm Cannulated	99-T787320
Ø 8 L 185mm Cannulated	99-T788185
Ø 8 L 200mm Cannulated	99-T788200
Ø 8 L 215mm Cannulated	99-T788215
Ø 8 L 230mm Cannulated	99-T788230
Ø 8 L 245mm Cannulated	99-T788245
Ø 8 L 260mm Cannulated	99-T788260
Ø 8 L 275mm Cannulated	99-T788275
Ø 8 L 290mm Cannulated	99-T788290
Ø 8 L 305mm Cannulated	99-T788305
Ø 8 L 320mm Cannulated	99-T788320
Ø 9 L 185mm Cannulated	99-T789185
Ø 9 L 200mm Cannulated	99-T789200
Ø 9 L 215mm Cannulated	99-T789215
Ø 9 L 230mm Cannulated	99-T789230
Ø 9 L 245mm Cannulated	99-T789245
Ø 9 L 260mm Cannulated	99-T789260
Ø 9 L 275mm Cannulated	99-T789275
Ø 9 L 290mm Cannulated	99-T789290
Ø 9 L 305mm Cannulated	99-T789305
Ø 9 L 320mm Cannulated	99-T789320

End Caps	
L 0mm	99-T780000
L 5mm	99-T780005
L 10mm	99-T780010

4.0mm Titanium Locking Screw	
99-T74420	20mm
99-T74425	25mm
99-T74430	30mm
99-T74435	35mm
99-T74440	40mm
99-T74445	45mm
99-T74450	50mm
99-T74455	55mm
99-T74460	60mm
99-T74465	65mm
99-T74470	70mm
99-T74475	75mm
99-T74480	80mm

4.0mm Titanium	
Revision Locking S	crew
99-T785020	20mm
99-T785025	25mm
99-T785030	30mm
99-T785035	35mm
99-T785040	40mm
99-T785045	45mm
99-T785050	50mm
99-T785055	55mm
99-T785060	60mm
99-T785065	65mm
99-T785070	70mm
99-T785075	75mm
99-T785080	80mm





HUMERAL SPECIFIC INSTRUMENTS BOX, EMPTY (178991) can accommodate:

Part #		Description	Qty
178100	1	HANDLE	1
178110	2	LOCKING ROD	1
178120	3	PROXIMAL HUMERAL OUTRIGGER	1
178130	4	GUIDE BAR	1
178170	5	TARGETING ARM	1
178213	6	DRILL GUIDE 3.2 MM	2
174213	7	DRILL GUIDE 4.0 MM	1
178215	8	RETROGRADE INSERTION TEMPLATE	1
178230	9	HUMERAL REAMING SLEEVE	1
178261	10	ANTEROGRADE CANNULATED REAMER	1
178284	11	RETROGRADE INSERTION DRILL	1
178286	12	DRILL BIT D. 3,2X280 MM	2
174286	13	DRILL BIT D. 4X365 MM	1
178041	14	STABILIZING ROD	1
178287	15	ANTEGRADE INSERTION WIRE D. 2X250 MM	1

Sterile Packaged Instruments

Part #	Description
99-178285	CANNULATED DRILL BIT KIT 6 MM STERILE
99-178283	GUIDE WIRE WITH OLIVE D.2X780 MM STERILE
99-178282	GUIDE WIRE WITHOUT OLIVE D.2.5X780 MM STERILE

HUMERAL SPECIFIC INSTRUMENTS BOX, EMPTY (178991) can accommodate:

Part #		Description	Qty
173058	16	SPACER NAIL 7 MM	1
173051	17	SPACER NAIL 8 MM	1
173052	18	SPACER NAIL 9 MM	1
11146	19	X-WIRE WITHOUT OLIVE DIAMETER 2 MM LENGTH 150 MM	3
178160		DISTAL ADAPTER	1
1100101	21	DRILL BIT DIAMETER 4.8 MM LENGTH 180 MM	1
11129		TROCAR D 6 MM LENGTH 240 MM	1
178265	23	BENDED AWL SMALL	1
173276		RULER SUPPORT	1
178275	25	HUMERAL RULER	1
178353	26	HUMERAL WIRE EXCHANGE TUBE	1
173026	27	LOCKING CAM	4
173032	28	LOCKING NUT	1
173071	29	IMPACTOR	1
173201	30	STABILIZING SLEEVE	1
173211	31	SCREW GUIDE	2
173212	32	TROCAR	1
173287	33	K-WIRE 2 MM	1
173320	34	CANNULATED SCREW DRIVER	1
173350	35	T HANDLE	1
173380	36	HAMMER	1



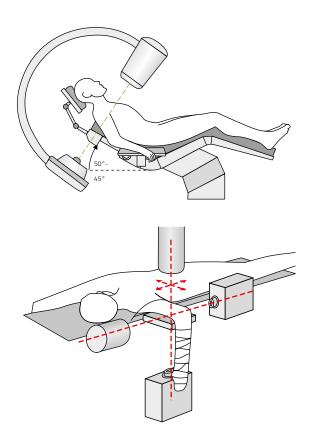
EXTRACTION INSTRUMENTS BOX, EMPTY (173998) can accommodate:			
Part #		Description	Qty
173320	1	CANNULATED SCREW DRIVER	1
173370	2	SLIDING HAMMER	1
170035	3	BLACK HANDLE WITH BAYONET FITTING	1
17391	4	FEMORAL NAIL EXTRACTOR	1
17652	5	LOCKING SCREW EXTRACTOR	1
174220	6	TIBIAL EXTRACTOR	1
178390	7	HUMERAL NAIL EXTRACTOR	1

Cleaning, disinfection, sterilisation and maintenance of instrumentation

Orthofix supplies the Centronail Titanium Universal Humeral Nail, locking screws and end caps in a STERILE package, while the instruments are supplied NON-STERILE. Please check the sterility of each device on the product label.

The surgeon must check that the package has not been damaged and has not expired. The instruments are supplied in a non-sterile state and therefore must be cleaned before use, as described for new products. The whole cleaning, disinfection and sterilisation cycle must be followed before each use, as described in the instructions for use PQ ISP.

N.B. Disassemble all instruments for thorough cleaning and disinfection prior to sterilization.



OPERATIVE TECHNIQUE

Patient Positioning

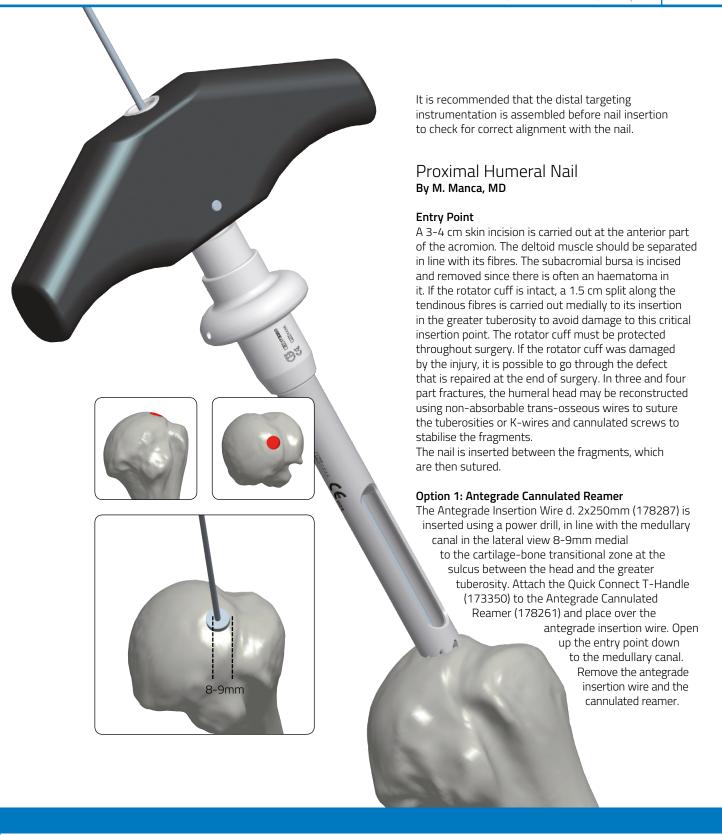
Standard X-rays should be taken. In proximal fractures, a CT-scan will help to identify the size and position of the fragments. Nail length and diameter are determined by assessing the extent of the fracture and by measuring the medullary canal. Positioning of the Nail Locking Screws should be included in the planning.

Antegrade Insertion

The patient should be positioned in a beach chair position. The humerus should be freely mobile on the side of the operating table with an unobstructed image intensifier view.

Retrograde Insertion

The patient is placed on a radiolucent table in the prone position. The arm is supported on an arm board or hand table. The shoulder is in 90° abduction, the elbow joint flexed in a 90° position. Make sure that the elbow can be flexed by 120° to avoid impingement at the level of the olecranon. Patient positioning should be checked to ensure that imaging of the entry point is possible in both planes. Good visualisation of the proximal humerus is also important for locking of the nail in the proximal end.















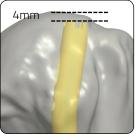
Short Proximal Humeral Nail

Nail Insertion

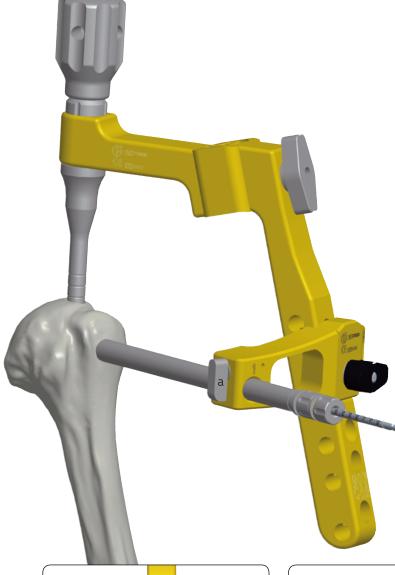
Insert the Locking Rod (178110) into the back of the Handle (178100) and the nail of correct diameter into the nail support. Tighten the locking rod using the Impactor (173071) inserted in the holes in the locking rod.

Under image intensification, insert the nail using gentle manoeuvres avoiding bending between the nail and the handle. Always ensure that the proximal end of the nail is at least 4mm below the bone surface.









Proximal Locking

Three 4.0mm titanium fully threaded locking screws are used for proximal locking in the humeral head.

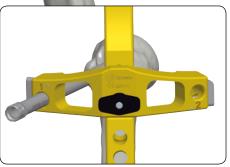
Attach the Proximal Humeral Outrigger (178120) to the handle. The two most proximal screws are inserted first following the numerical order marked on the proximal humeral outrigger.

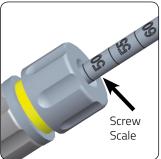
Screw a Trocar (173212) into a Screw Guide (173211) and insert them together into the hole marked "1". Make a stab incision where they touch the skin, split the tissues down to the bone, and push them down to the bone. Unscrew the trocar and advance the screw guide until it is sitting flush against the bone surface. Tighten the screw guide in place with the locking cam (a).

N.B. The surgeon should be aware of the position of the axillary nerve during this procedure.

Remove the trocar and screw in the 3.2mm Drill Guide (178213). Drill with the 3.2mm Drill Bit (178286), ensuring that the drill does not penetrate the articular surface. The screw length required is read from the scale on the drill bit immediately above the top

of the drill guide (see inset). It is advisable to position the drill bit and drill guide exactly at right angles to the Image Intensifier.







INSTRUMENTATION



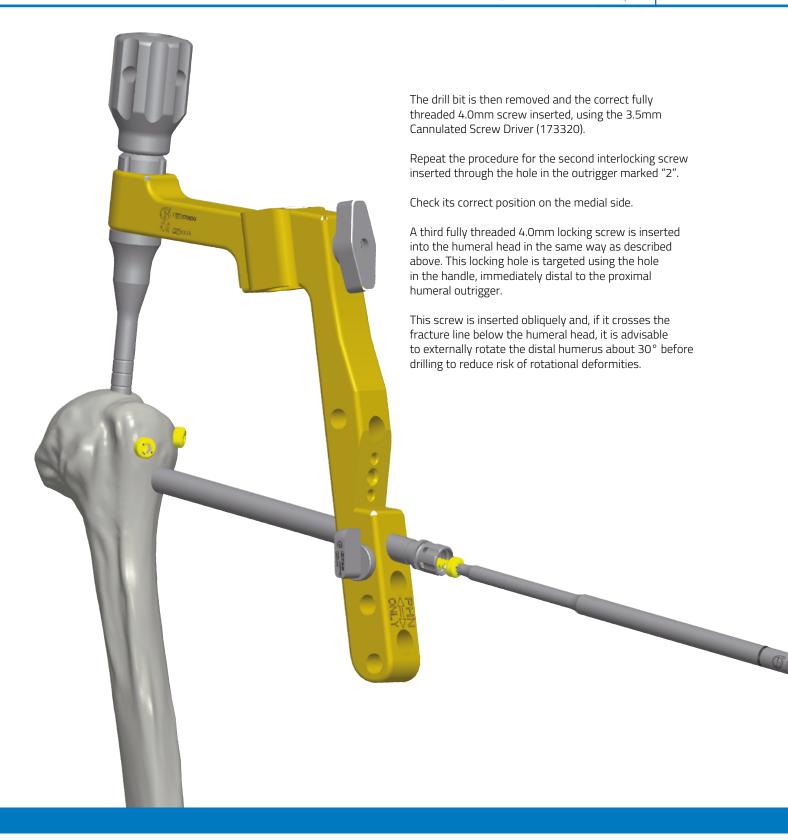
Proximal Humeral Outrigger

Trocar

173211 Screw Guide

178213 3.2mm Drill Guide

178286 3.2mm Drill Bit







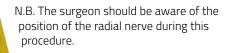
Distal Locking

Check for any rotational deformity or distraction of the fracture site before carrying out distal locking.

Distal locking is carried out using 4.0mm standard (partially threaded) locking screws. Two locking screws are used distally if the bone quality is poor. The most proximal of the distal holes should always be filled. Screw the trocar (173212) into the screw guide (173211) and insert them both into the proximal

of the two holes that are marked 'PHN ONLY'.

Make a stab incision where they touch the skin,
split the tissues down to the bone, and push both
down to the bone. Unscrew the trocar and push
the screw guide until it is sitting flush against
the bone surface. Tighten the screw guide
in place with the locking cam.



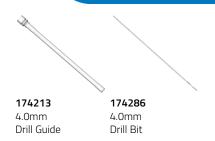
Remove the trocar and screw in the 4.0mm Drill Guide (174213). Drill with the 4.0mm Drill Bit (174286) until the drill tip is

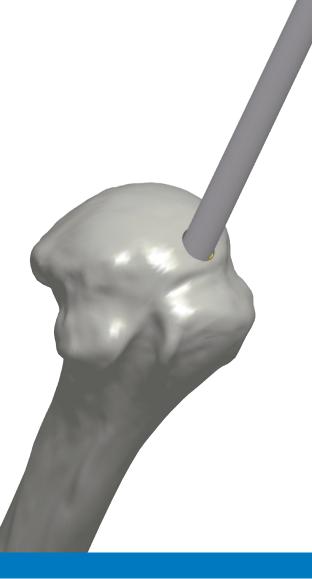
2-3mm through the second cortex.

The screw length required is read from the scale on the drill bit immediately above the top of the drill guide (see inset). Insert the locking screw using the 3.5mm cannulated screw driver (173320).

Repeat the procedure for the most distal locking screw if required.

For "Removal of the Handle and Closure" see on page 22.





Long Proximal Humeral Nail

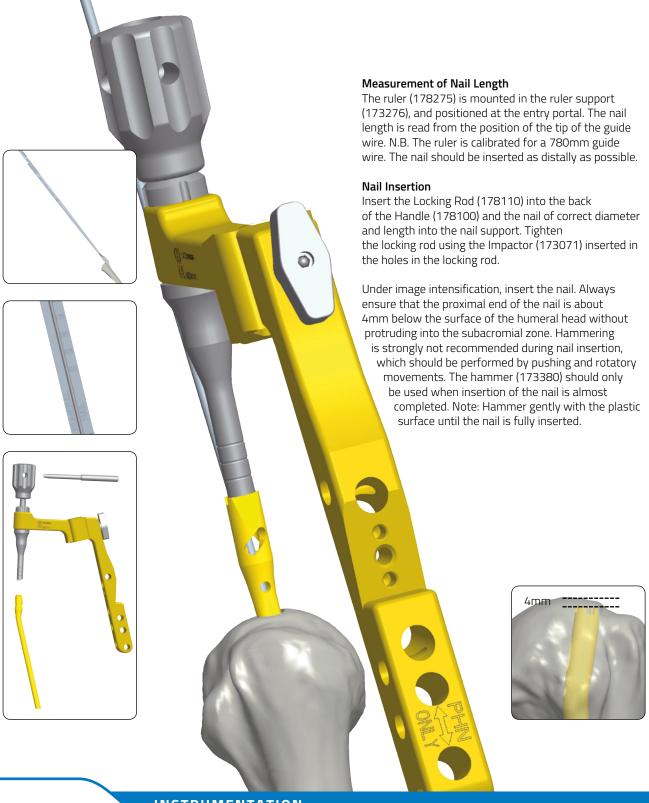
Reaming

It is necessary to ream the distal part of the humerus before nail insertion. The chosen nail should be as long as possible to prevent damage to the radial nerve during distal locking. This decision will depend on bone dimensions and quality. Over-reaming is not normally required, but an additional 0.5mm may be necessary to facilitate insertion. Reaming is always advisable in order to insert the nail easily without force. A guide wire with olive should be inserted and also used for initial fracture reduction. Fracture reduction should not be accomplished with the nail and the handle as leverage arm. Use the Humeral Reamer Sleeve (178230) to protect soft tissues when reaming. If power reaming is required, the olive-tipped guide wire should be used and exchanged for a plain guide wire before nail insertion.

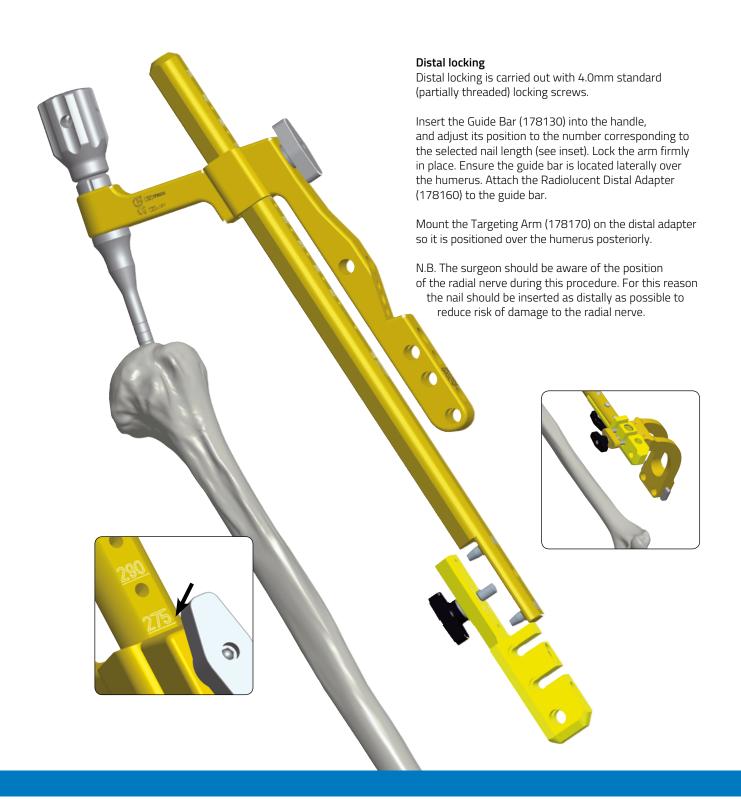
After reaming, replace the guide wire with olive with a plain guide wire, using the Guide Wire Exchange Tube (178353). Check the position of the radio opaque marker under image intensification. Confirm that the tip of the plain guide wire is in the correct position and remove the Plastic Exchange Tube.

178353 178230 Guide Wire Exchange Humeral Reaming Tube Sleeve

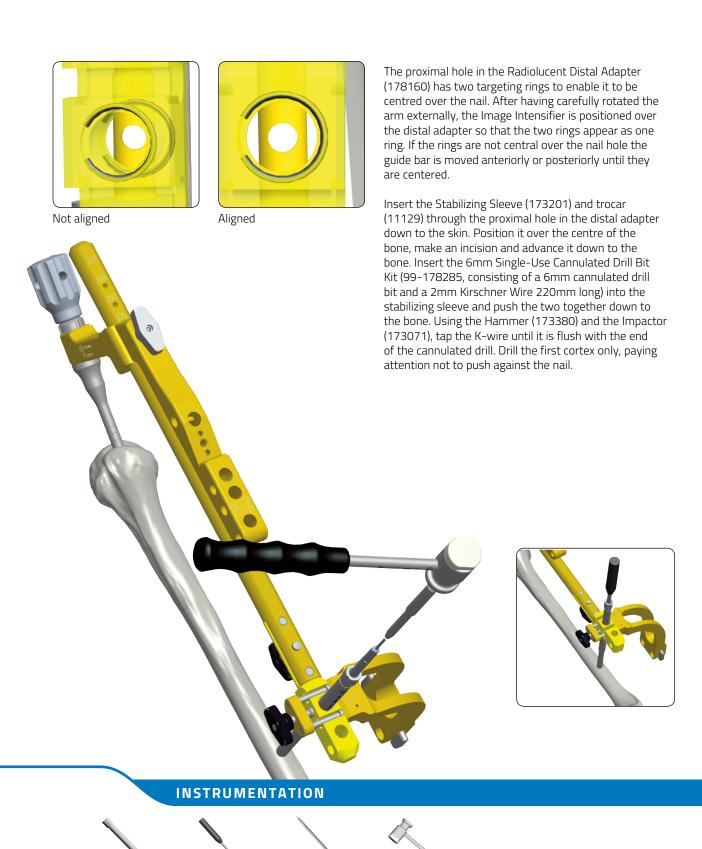
99-178283 Guide Wire with olive 2x780mm 99-178282 Guide Wire without olive 2.5x780mm











99-178285

Cannulated Drill Bit Kit

6mm

173201

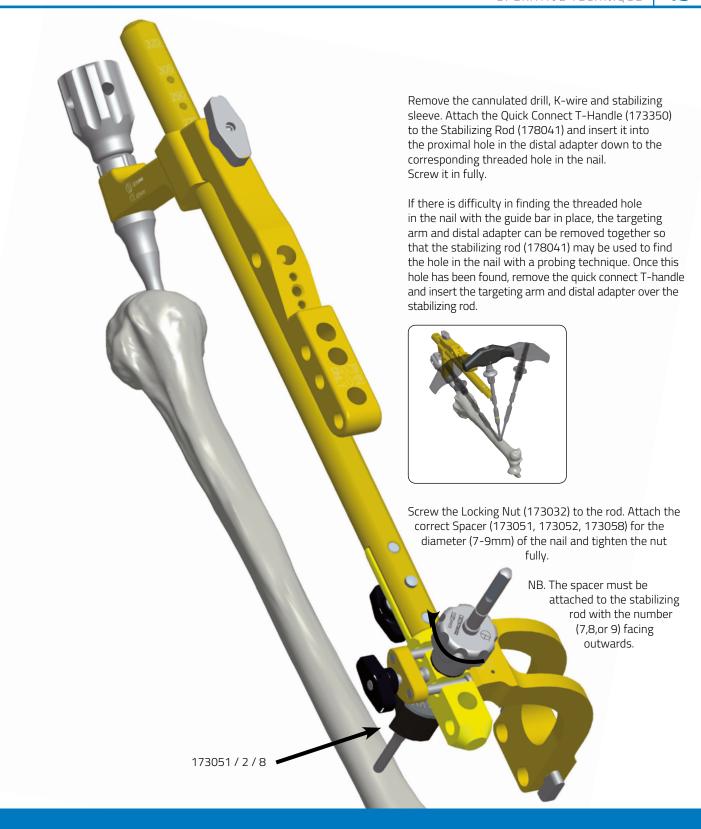
Stabilizing Sleeve

11129

Trocar

173380

Hammer







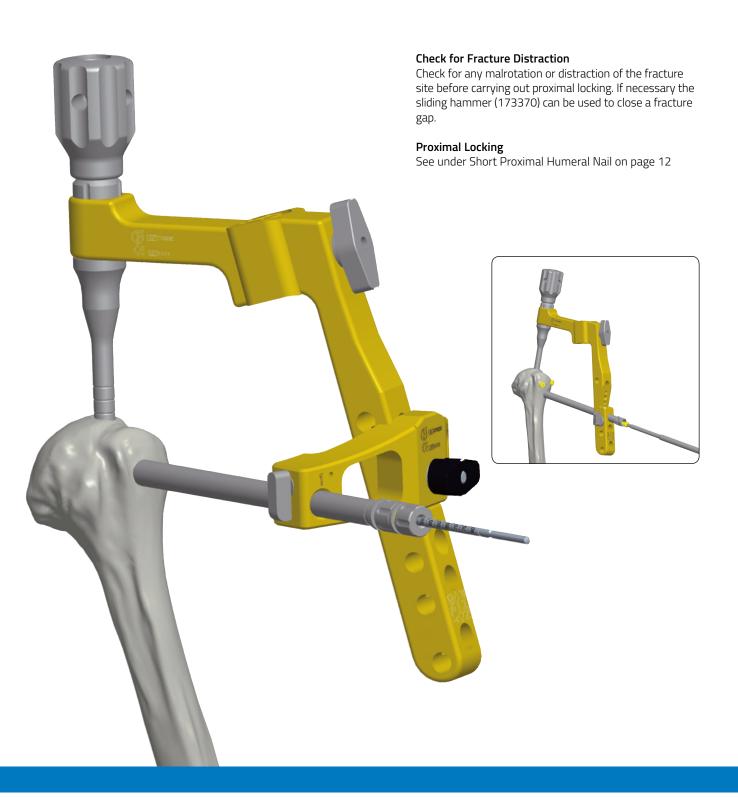




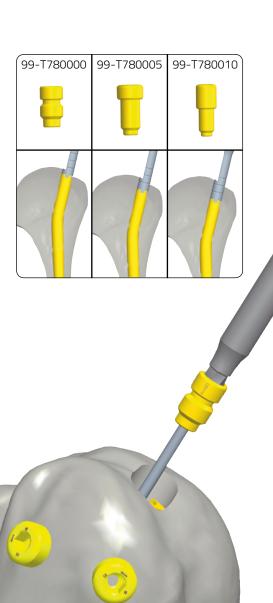
173350 T Handle









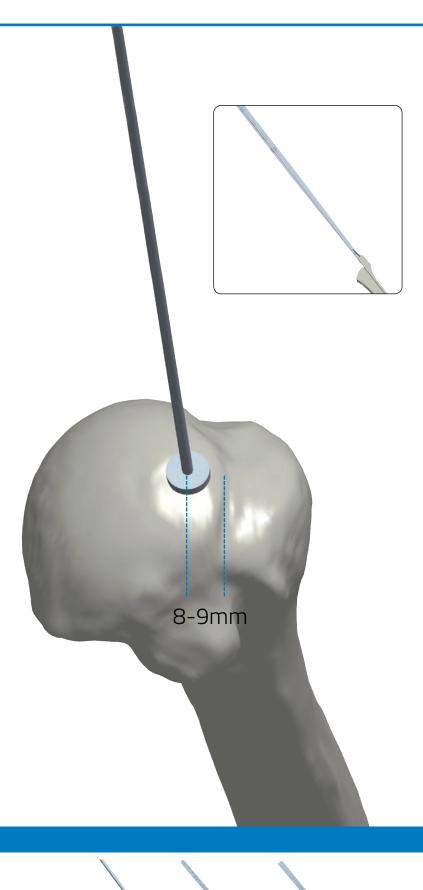


Removal of the Handle and Closure

Before removing the handle from the nail, check correct insertion of locking screws both in the AP and lateral planes. Remove the handle and the locking rod and, using the 3.5mm cannulated screw driver (173320), insert the nail end cap (99-T780000, 99-T780005, 99-T780010) over a K-wire, choosing the correct length (0, 5, 10) and avoiding protrusion above the bone surface.

N.B. At the end of surgery, remove the deltoid fibres from the locking screw heads and mobilise the arm in all directions, including internal and external rotation.





Diaphyseal Humeral Nail

Antegrade Insertion By M. Manca, MD

Entry point

See under Short Proximal Humeral Nail on page 9.

Reaming

See under Long Proximal Humeral Nail on page 15.

Measurement of Nail Length

The ruler (178275) is mounted in the ruler support (173276), and positioned at the entry portal. The nail length is read from the position of the tip of the guide wire.

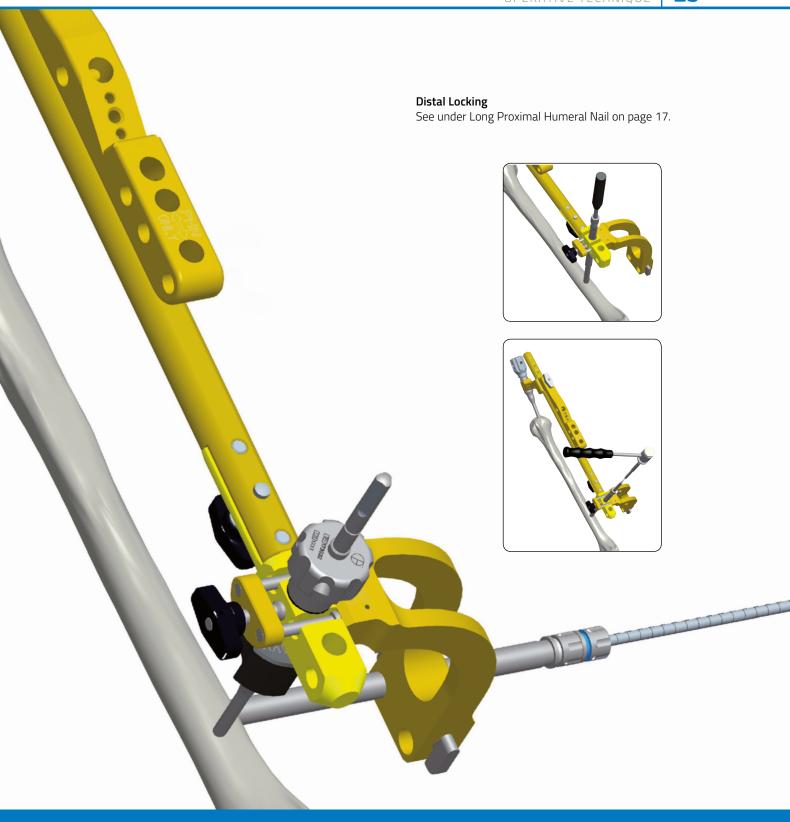
N.B. The ruler is calibrated for a 780mm guide wire. The nail should be inserted as distally as possible.

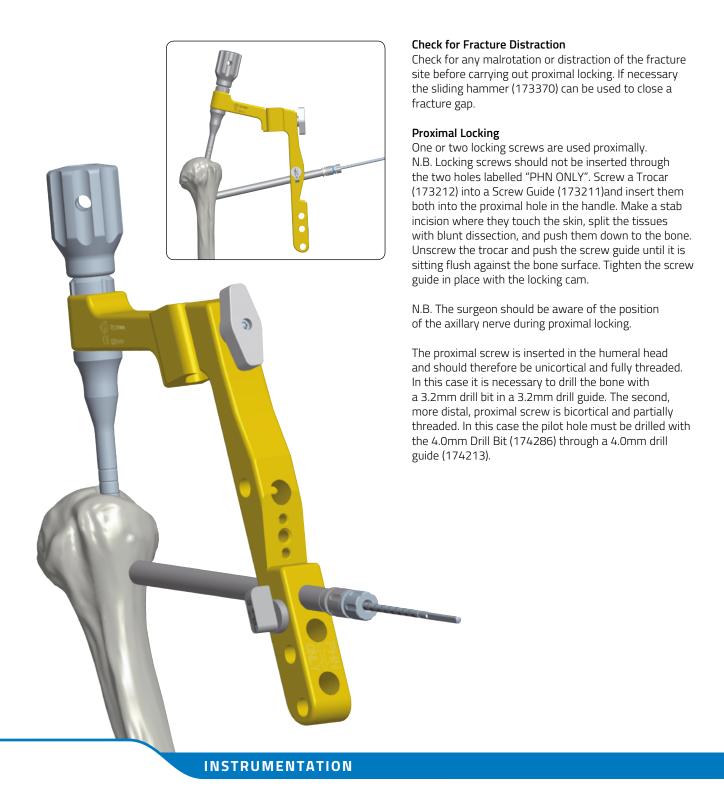


99-178282 Guide Wire without olive 2.5x780mm

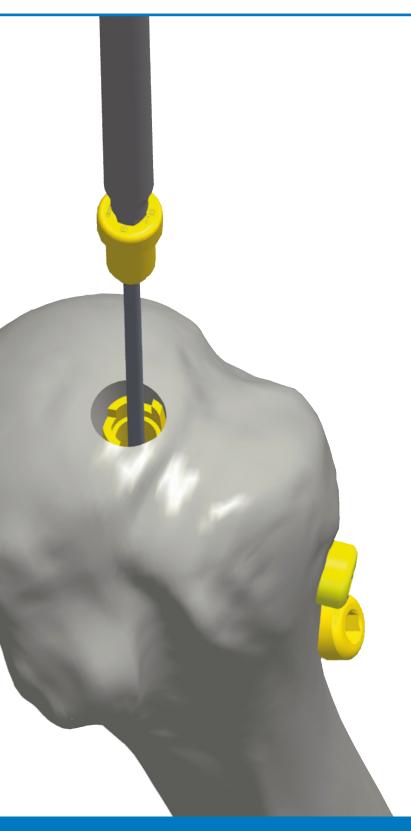
178275 Humeral Ruler **173276** Ruler Support







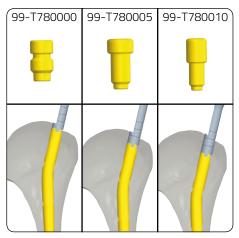




Removal of the Handle and Closure

Before removing the handle from the nail, check correct insertion of locking screws both in the AP and lateral planes. Remove the handle and the locking rod and, using the 3.5mm cannulated screw driver (173320), insert the nail end cap (99-T780000, 99-T780005, 99-T780010) over a K-wire, choosing the correct length (0, 5, 10) and avoiding protrusion above the bone surface.

N.B. At the end of surgery, remove the deltoid fibres from the locking screw heads and mobilise the arm in all directions, including internal and external rotation.



Retrograde Insertion By R. Giancola, MD

Entry Point

Using a triceps-splitting incision, expose the dorsal side of the humerus 8-10 cm proximal from the tip of the olecranon. Retract the triceps.

Place the Retrograde Insertion Template (178215) on the bone surface with the most distal hole positioned at the proximal edge of the olecranon fossa, in line with the medullary canal. Secure the template in place using up to three K-wires (11146).

Using a 4.8mm Drill Bit (1100101), make four holes through the template. Ensure the second cortex is not penetrated. Remove the template.

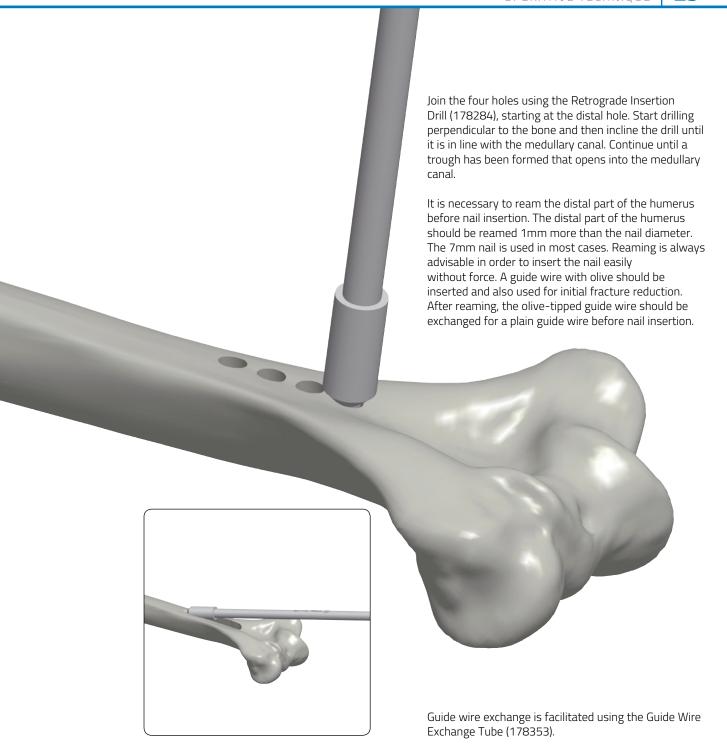


INSTRUMENTATION



178215 Retrograde Insertion Template

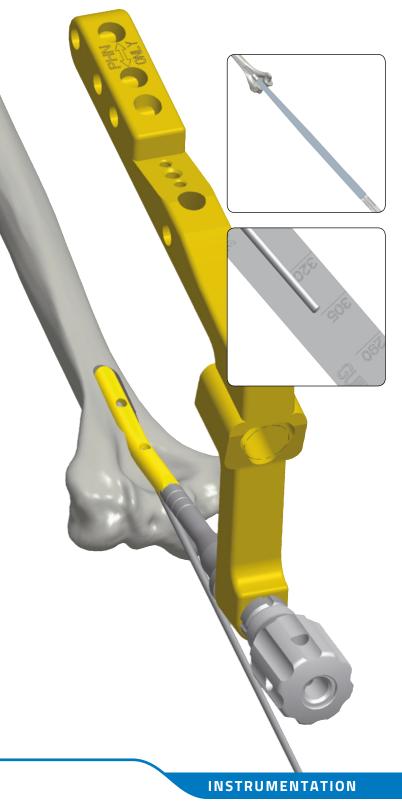
11146 2mm K-wire **1100101**Drill Bit
4.8mm



INSTRUMENTATION



178353Guide Wire
Exchange Tube



Measurement of Nail Length

The ruler (178275) is mounted in the ruler support (173276), and positioned at the entry portal. The nail length is read from the position of the tip of the guide wire.

N.B. The ruler is calibrated for a 780mm guide wire.

Nail Insertion

Insert the Locking Rod (178110) into the back of the Handle (178100) and the nail of correct diameter and length into the nail support. Tighten the locking rod using the Impactor (173071) inserted in the holes in the locking rod.

Insert the nail gently over the guide wire, using rotatory movements if necessary. If insertion is difficult, do not hammer but ream again the medullary canal. Alternatively, use a smaller diameter nail.

Under image intensification, insert the nail until it is beneath the insertion site and not protruding.

IF USED, THE GUIDE WIRE MUST NOW BE REMOVED.





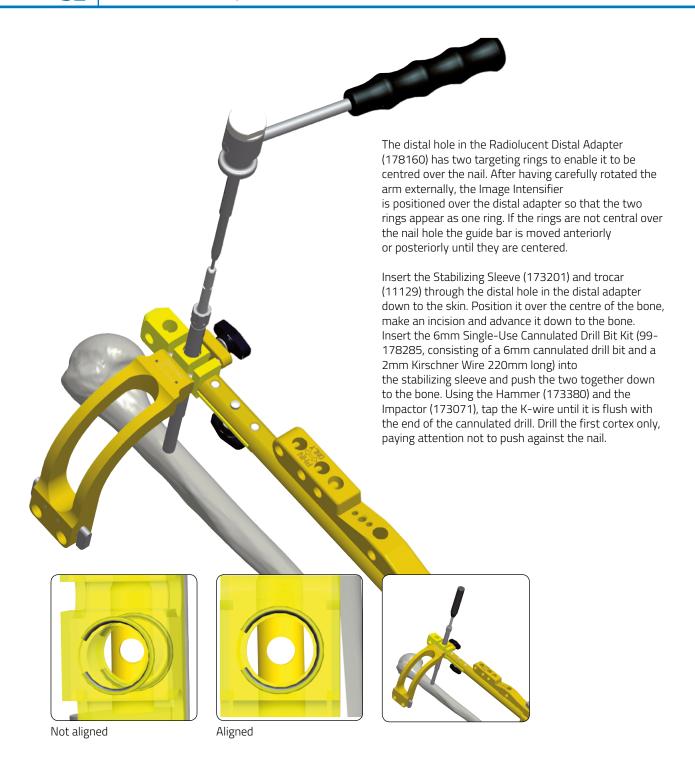


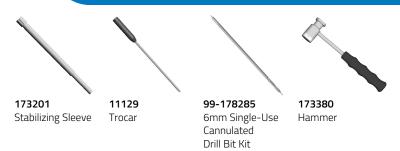
Handle

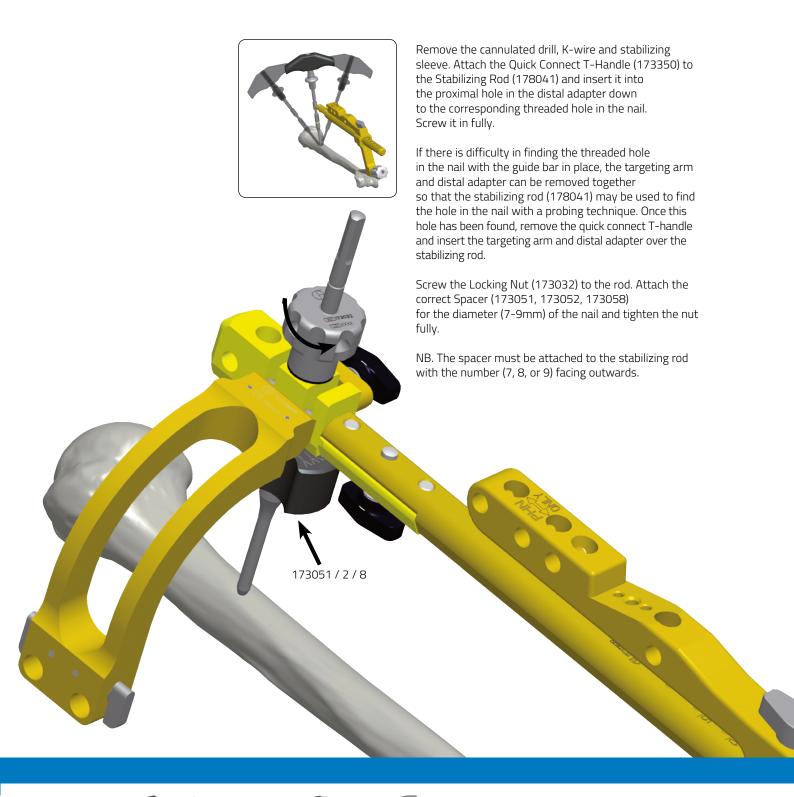














173350Quick Connect
T-Handle



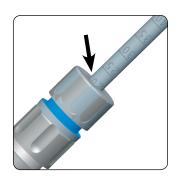
178041 Stabilizing Rod



173032 Locking Nut



173051 / 2 / 8 Spacer



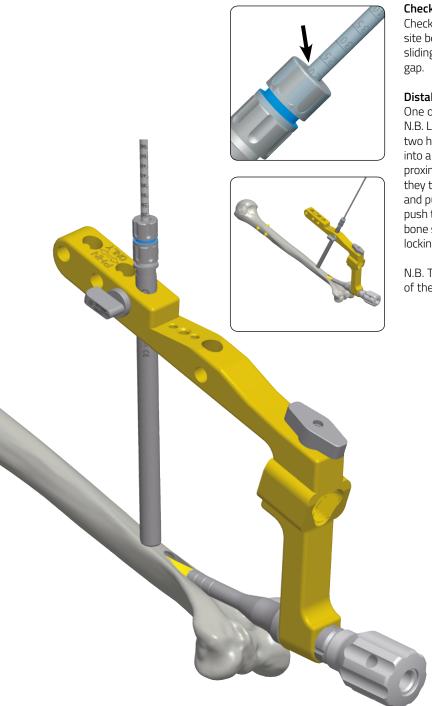
Screw a Trocar (173212) into a Screw Guide (173211) and insert them both into one of the two holes in the targeting arm. Make a stab incision where they touch the skin posteriorly, split the tissues down to the bone, and push them down to the bone on the posterior surface of the humerus. Unscrew the trocar and advance the screw guide until it is sitting flush against the bone surface. Tighten the screw guide in place with the locking cam.

Remove the trocar and screw in the 4.0mm Drill Guide

(174213). Drill with the 4.0mm Drill Bit (174286) until the drill bit is 2-3mm beyond the second cortex. The screw length required is read from the scale on the drill bit immediately above the top of the drill guide (see inset). Insert a 4.0mm partially threaded screw using the 3.5mm Cannulated Screw Driver (173320). Repeat the procedure for the second hole. A third screw can be inserted in the lateral direction using the proximal hole in the distal adapter following the procedure described above. If a fourth screw is required, a 4.0mm revision locking screw must be used: remove the spacer and stabilizing rod using the quick connect T-handle. Insert a screw guide and drill guide. Drill through the second cortex with a 4.0mm drill bit. Insert the revision locking screw.

N.B. The surgeon should be aware of the position of the axillary nerve during proximal locking.





Check for Fracture Distraction

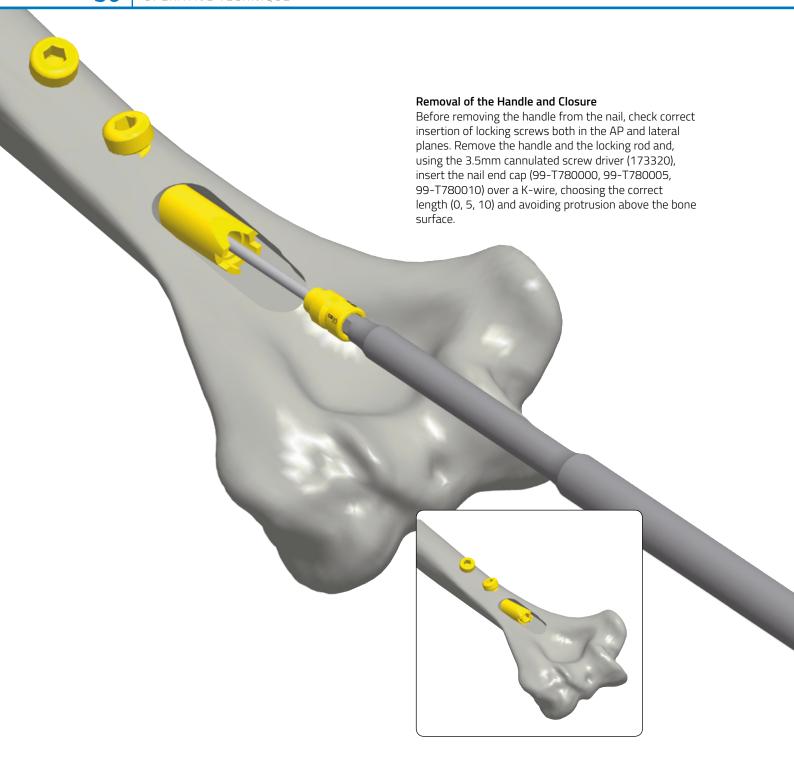
Check for any malrotation or distraction of the fracture site before carrying out distal locking. If necessary the sliding hammer (173370) can be used to close a fracture gap.

Distal Locking

One or two locking screws are used distally. N.B. Locking screws should not be inserted through the two holes labelled "PHN ONLY". Screw a Trocar (173212) into a Screw Guide (173211) and insert them both into the proximal hole in the handle. Make a stab incision where they touch the skin, split the tissues with blunt dissection, and push them down to the bone. Unscrew the trocar and push the screw guide until it is sitting flush against the bone surface. Tighten the screw guide in place with the locking cam.

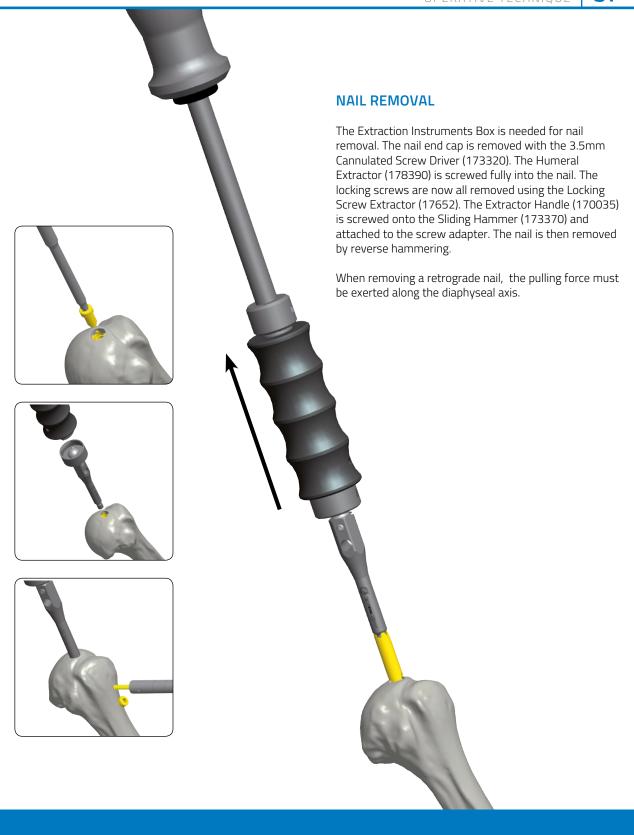
N.B. The surgeon should be aware of the position of the radial nerve during proximal locking.





INSTRUMENTATION

11146 2mm K-wire









CENTRONAIL OPERATIVE TECHNIQUES

CN-0701-OPT The Centronail Titanium Universal Femoral Nailing System

CN-0702-OPT The Centronail Titanium Tibial Nailing System

CN-0703-OPT The Centronail Titanium Supracondylar and Retrograde Nailing System

CN-0704-OPT The Centronail Titanium Humeral Nailing System

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Electronic Instructions for use available at the website http://ifu.orthofix.it

Electronic Instructions for use - Minimum requirements for consultation:

- Internet connection (56 Kbit/s)
- Device capable to visualize PDF (ISO/IEC 32000-1) files
- Disk space: 50 Mbytes

Free paper copy can be requested from customer service (delivery within 7 days): tel $+39\,045\,6719301$, fax $+39\,045\,6719370$, e-mail: customerservice@orthofix.it

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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