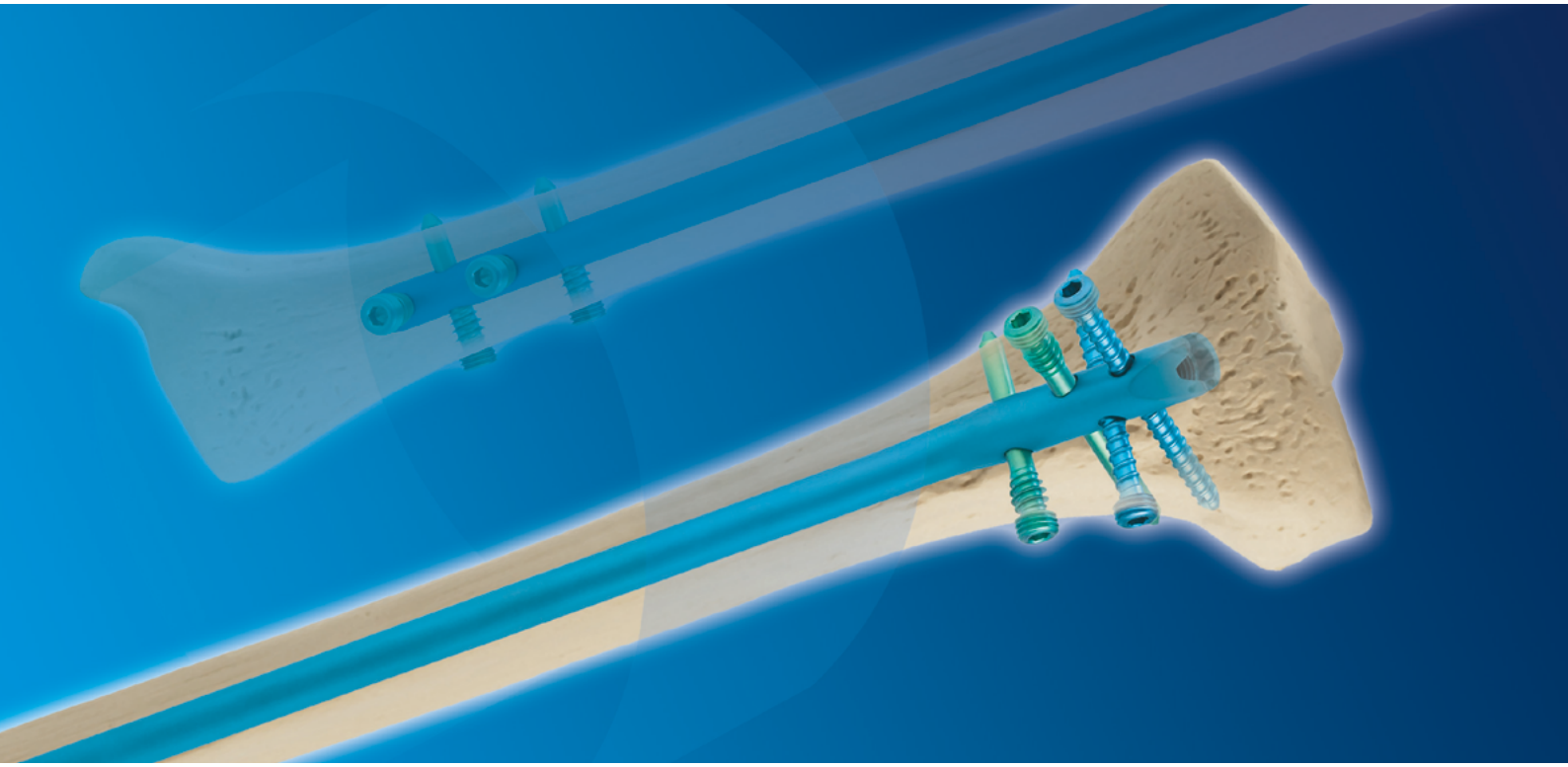
OPERATIVE TECHNIQUE

CentroNail®

Titanium Tibial Nail



The Centronail Titanium Tibial Nailing System

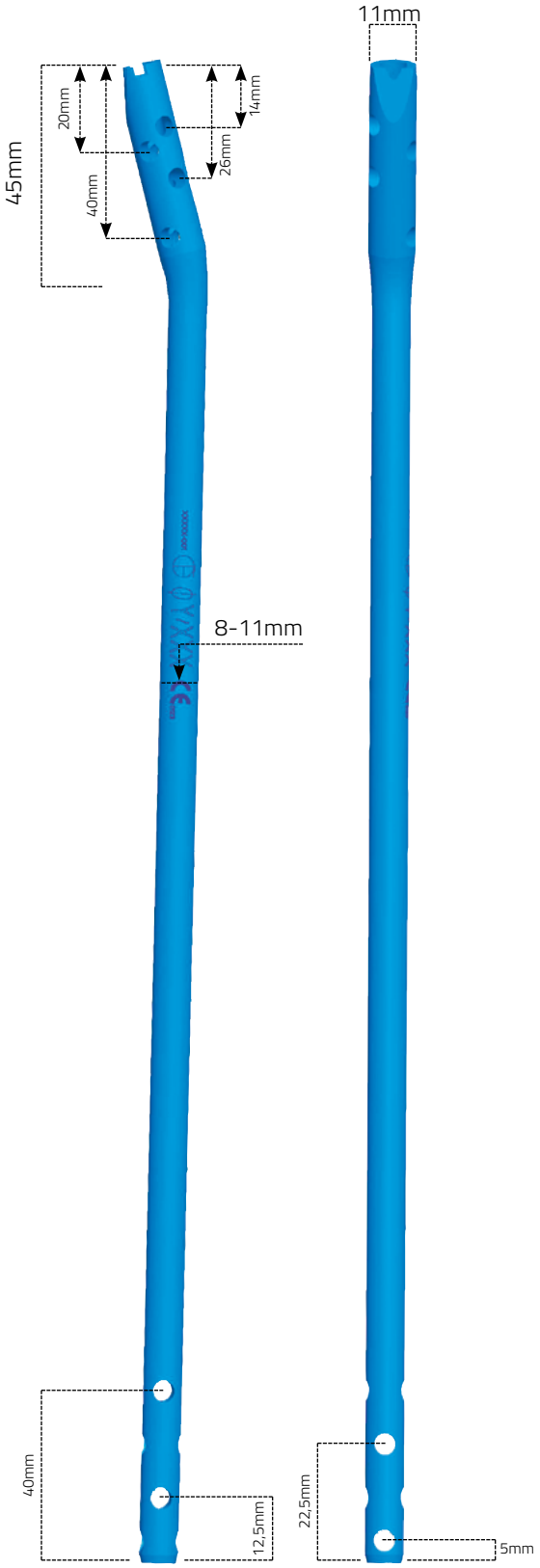
ORTHOFIX® ORTHOPEDICS

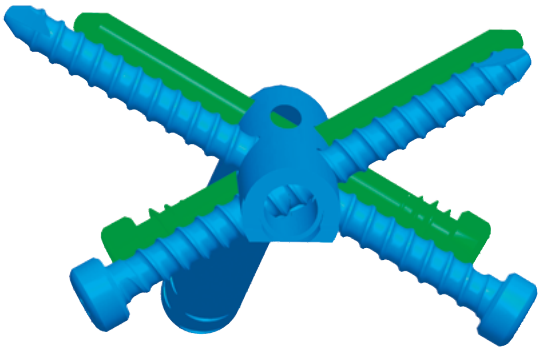
Orthofix wishes to thank
the following surgeons for their contribution
to the development of the technique:

S. BERKI, MD
Department of General, Trauma and Hand Surgery,
University and County Hospital, Szentes, Hungary

W. KLEIN, MD
Department of Trauma Surgery, Wolfsburg Hospital,
Wolfsburg, Germany

FEATURES AND BENEFITS





Titanium nail and locking screws
Allows MRI investigation, if necessary

11mm proximal diameter

8-11mm distal diameter
8mm is solid

One design for Left and Right tibia

15° proximal angle

275-410mm (15mm increments)

Locking screws

TITANIUM STANDARD LOCKING SCREWS

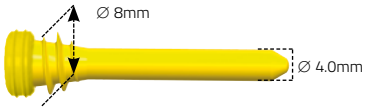
6.8mm thread diameter
4.8mm shaft diameter
4.8mm drill bit

For 8mm nail:
6.0mm thread diameter
4.0mm shaft diameter
4.0mm drill bit

TITANIUM REVISION LOCKING SCREWS

8mm thread diameter
Better purchase in poor quality bone
4.8mm shaft diameter
4.8mm drill bit

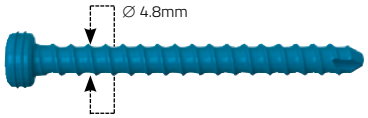
For 8mm nail:
4.0mm shaft diameter
4.0mm drill bit



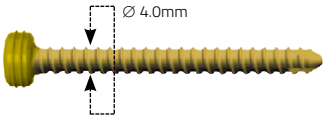
Smooth diameter, unthreaded shaft: maximises fatigue strength.
Reverse thread on screw head: easy screw removal.
Conical tip: helps insertion.

TITANIUM THREADED LOCKING SCREWS

4.0mm drill bit



3.2mm drill bit



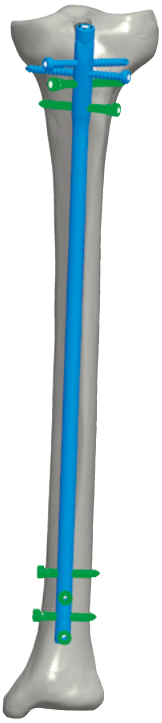
Fully threaded shaft: good purchase in cancellous bone near articular surface. Normally used only in the proximal 2 locking holes, but occasionally useful in very distal fractures. 4.0mm screws ONLY for use in the distal 8mm nail.

Reverse thread on screw head
Easy screw removal

Conical tip
Helps insertion

INDICATIONS

Diaphyseal fractures



EQUIPMENT REQUIRED

Centronail Titanium Tibial Intramedullary Nails		
Ø 8 L 275	Solid	99-T748275
Ø 8 L 290	Solid	99-T748290
Ø 8 L 305	Solid	99-T748305
Ø 8 L 320	Solid	99-T748320
Ø 8 L 335	Solid	99-T748335
Ø 8 L 350	Solid	99-T748350
Ø 8 L 365	Solid	99-T748365
Ø 8 L 380	Solid	99-T748380
Ø 9 L 275	Cannulated	99-T749275
Ø 9 L 290	Cannulated	99-T749290
Ø 9 L 305	Cannulated	99-T749305
Ø 9 L 320	Cannulated	99-T749320
Ø 9 L 335	Cannulated	99-T749335
Ø 9 L 350	Cannulated	99-T749350
Ø 9 L 365	Cannulated	99-T749365
Ø 9 L 380	Cannulated	99-T749380
Ø 9 L 395	Cannulated	99-T749395
Ø 9 L 410	Cannulated	99-T749410
Ø 10 L 275	Cannulated	99-T740275
Ø 10 L 290	Cannulated	99-T740290
Ø 10 L 305	Cannulated	99-T740305
Ø 10 L 320	Cannulated	99-T740320
Ø 10 L 335	Cannulated	99-T740335
Ø 10 L 350	Cannulated	99-T740350
Ø 10 L 365	Cannulated	99-T740365
Ø 10 L 380	Cannulated	99-T740380
Ø 10 L 395	Cannulated	99-T740395
Ø 10 L 410	Cannulated	99-T740410
Ø 11 L 320	Cannulated	99-T741320
Ø 11 L 335	Cannulated	99-T741335
Ø 11 L 350	Cannulated	99-T741350
Ø 11 L 365	Cannulated	99-T741365
Ø 11 L 380	Cannulated	99-T741380
Ø 11 L 395	Cannulated	99-T741395
Ø 11 L 410	Cannulated	99-T741410

End Caps	
L 0mm	99-T740000
L 5mm	99-T740005
L 10mm	99-T740010

4.8mm Titanium Threaded Locking Screws

Code	Length (mm)
99-T746025	25
99-T746030	30
99-T746035	35
99-T746040	40
99-T746045	45
99-T746050	50
99-T746055	55
99-T746060	60
99-T746065	65
99-T746070	70
99-T746075	75
99-T746080	80

4.0mm Titanium Locking Screws

Code	Length (mm)
99-T74420	20
99-T74425	25
99-T74430	30
99-T74435	35
99-T74440	40
99-T74445	45
99-T74450	50
99-T74455	55
99-T74460	60
99-T74465	65
99-T74470	70
99-T74475	75
99-T74480	80

Cleaning, disinfection, sterilisation and maintenance of instrumentation

Orthofix supplies the Centronail Titanium Tibial Nail, locking screws and end caps in a STERILE package, while the instruments are supplied NONSTERILE. 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 sterilised instruments used during the operation may be cleaned, disinfected and re-sterilised in an autoclave, as described in the instructions for use PQ TNS-s that accompany the product. If the package is damaged, or if there are doubts about its sterility, the implant may be re-sterilised in an autoclave, using a validated sterilisation protocol. 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 TNS-s.

NB: Disassemble all instruments for thorough cleaning and disinfection prior to sterilization.

4.8mm Titanium Standard Locking Screws

Code	Length (mm)
99-T79925	25
99-T79930	30
99-T79935	35
99-T79940	40
99-T79945	45
99-T79950	50
99-T79955	55
99-T79960	60
99-T79965	65
99-T79970	70
99-T79975	75
99-T79980	80
99-T79985	85
99-T79990	90
99-T79995	95
99-T79900	100
99-T79905	105
99-T79910	110

4.8mm Titanium Revision Locking Screws

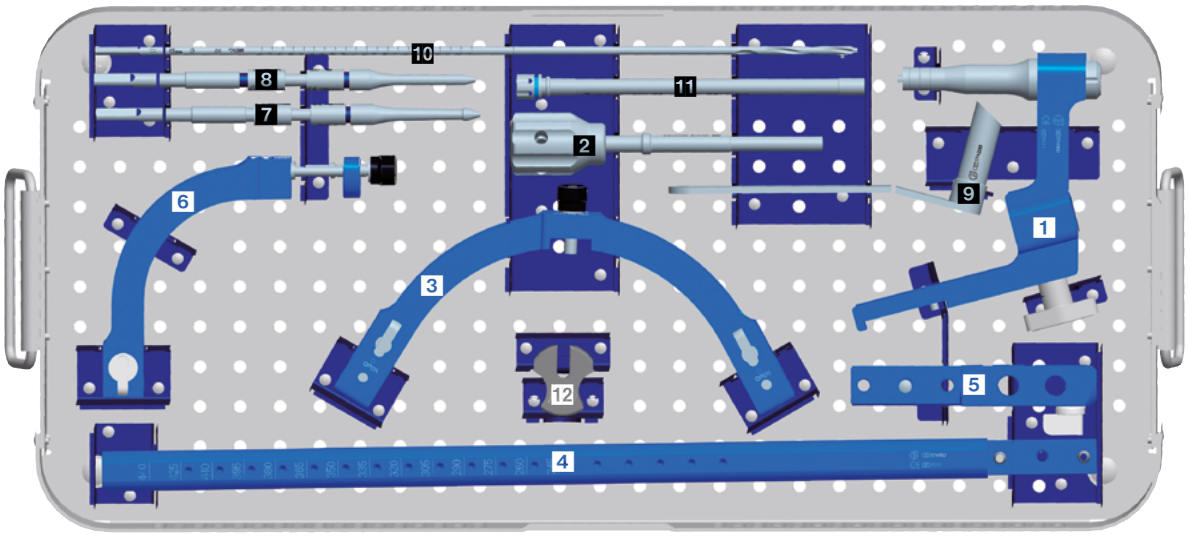
Code	Length (mm)
99-T74530	30
99-T74535	35
99-T74540	40
99-T74545	45
99-T74550	50
99-T74555	55
99-T74560	60
99-T74565	65
99-T74570	70
99-T74575	75
99-T74580	80
99-T74585	85
99-T74590	90
99-T74595	95
99-T74500	100
99-T74505	105
99-T74510	110

4.0mm Titanium Revision Locking Screws

Code	Length (mm)
99-T785020	20
99-T785025	25
99-T785030	30
99-T785035	35
99-T785040	40
99-T785045	45
99-T785050	50
99-T785055	55
99-T785060	60
99-T785065	65
99-T785070	70
99-T785075	75
99-T785080	80

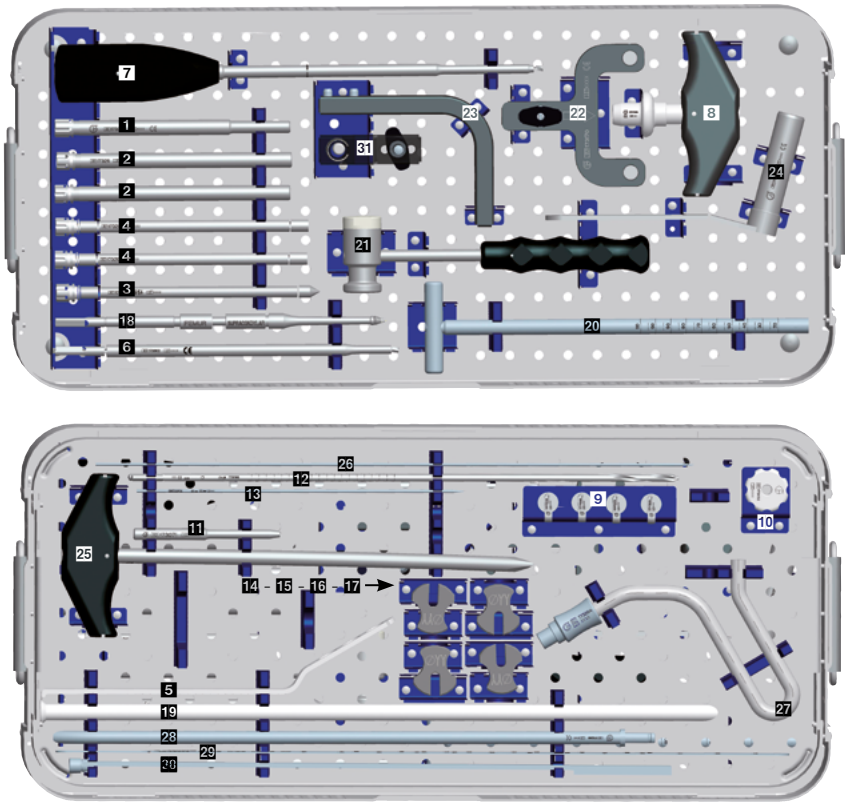
4.0mm Titanium Threaded Locking Screws

Code	Length (mm)
99-T786020	20
99-T786025	25
99-T786030	30
99-T786035	35
99-T786040	40
99-T786045	45
99-T786050	50
99-T786055	55
99-T786060	60
99-T786065	65
99-T786070	70
99-T786075	75
99-T786080	80



TIBIAL SPECIFIC INSTRUMENTS BOX, EMPTY (174991) can accommodate:

Part #		Description	Qty
174100	1	HANDLE	1
174110	2	LOCKING ROD	1
174130	3	PROXIMAL ARM	1
174150	4	DISTAL ARM	1
174160	5	DISTAL ADAPTER	1
174170	6	DISTAL TARGETING ARM	1
174031	7	TIBIAL STABILIZING ROD M6	1
174041	8	TIBIAL STABILIZING ROD M5	1
174230	9	TIBIAL REAMER SLEEVE	1
174286	10	DRILL BIT D. 4X365MM	1
174213	11	DRILL GUIDE 4.0MM	1
173051	12	SPACER NAIL 8MM	1



GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

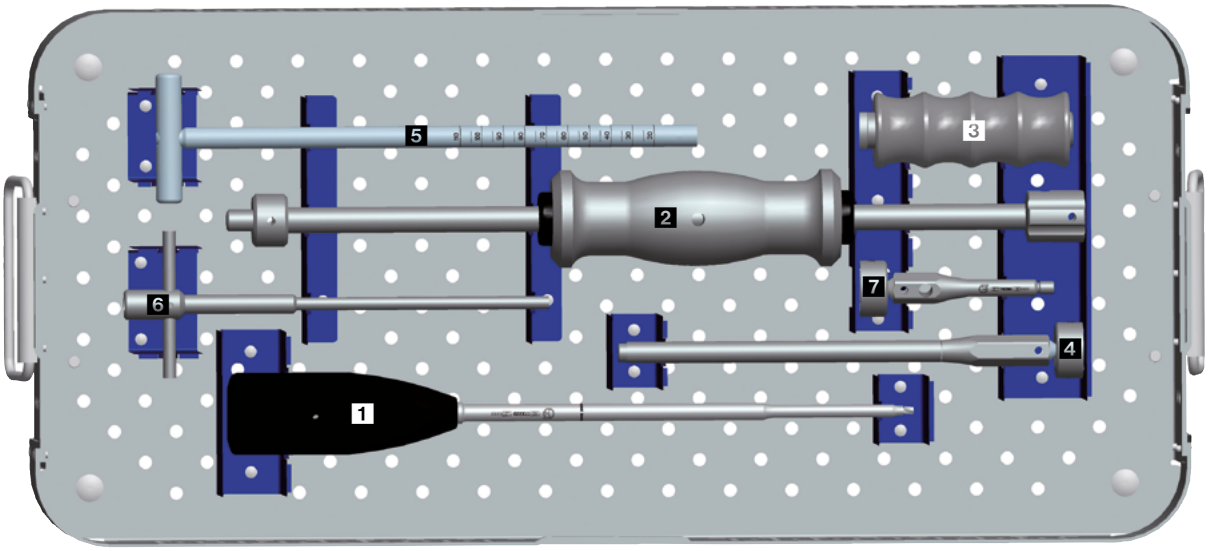
Part #		Description	Qty
173201	1	STABILIZING SLEEVE	1
173211	2	SCREW GUIDE	2
173212	3	TROCAR	1
173213	4	DRILL GUIDE	1
173301	5	SCREW SCALE	1
173302	6	CANNULATED SCREW WRENCH ADAPTER	1
173320	7	CANNULATED SCREW DRIVER	1
173350	8	T HANDLE	1
173026	9	LOCKING CAM	4
173032	10	LOCKING NUT	1
173071	11	IMPACTOR	1
173286	12	DRILL BIT D. 4,8 X 365MM	2
173287	13	K-WIRE 2MM	1
173052	14	SPACER NAIL 9MM	1
173053	15	SPACER NAIL 10MM	1
173054	16	SPACER NAIL 11MM	1

GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

Part #		Description	Qty
173055	17	SPACER NAIL 12MM	1
173031	18	STABILIZING ROD	1
17353	19	GUIDE WIRE EXCHANGE TUBE	1
17652	20	LOCKING SCREW EXTRACTOR	1
173380	21	HAMMER	1
173170	22	AP ARM CONNECTOR	1
173180	23	AP ARM CONNECTOR	1
173230	24	FEMORAL REAMER SLEEVE	1
173260	25	AWL	1
80122	26	X-WIRE WITHOUT OLIVE DIAMETER 2MM LENGTH 400MM	1
173264	27	REDUCTION TOOL HANDLE	1
173265	28	REDUCTION TOOL	1
173275	29	RULER	1
173276	30	RULER SUPPORT	1
173185	31	AP CENTERING JIG	1

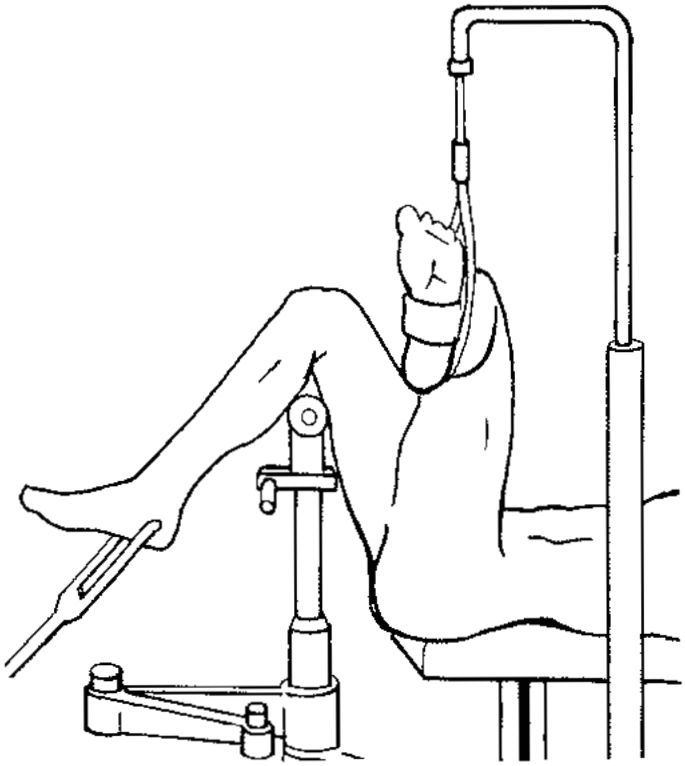
Sterile Packaged Instruments

Part #	Description
99-173285	CANNULATED DRILL BIT 6MM STERILE
99-173281	GUIDE WIRE WITH OLIVE D.3X980MM STERILE
99-176281	GUIDE WIRE WITHOUT OLIVE D.2.5X980MM STERILE



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



OPERATIVE TECHNIQUE

Patient Positioning

The patient is placed supine on an operating table or fracture table, either with the knee flexed and the affected leg hanging vertically down, or with the knee flexed over a padded bar, taking care to avoid any pressure on the fibular head (common peroneal nerve). In cases where reduction cannot be achieved with the leg in this position, traction is exerted through a Steinmann-type pin inserted through the os calcis, with the flexed knee placed over a padded bar, which acts as counter-traction. Skeletal traction is particularly recommended for distal fractures, in order to achieve good control of alignment. The leg is then cleaned and sterilized from mid-thigh to toes, and draped separately. If skeletal traction is being used, care should be taken to exclude the traction pin from the operating field.

Entry Portal

Make a 5 cm incision just medial to the patellar tendon. Retract the tendon laterally, palpate the anterior margin of the tibial plateau. Gently push the fat pad posteriorly to expose the surface of the plateau anterior to the insertion of the anterior cruciate ligament. (If necessary use a diathermy to separate the fat pad). Place the tip of the Awl (173260) on the anterior edge of the tibial plateau, in line with the medullary canal.

Insert a Guide Wire with olive (99-173281) until its tip sits 0.5-1 cm proximal to the ankle joint, taking care to ensure that it is exactly in the midline. Use image intensification when passing the fracture.

If it is not possible to pass the Guide Wire into the distal fragment, the Reduction Tool (173265)can be used with its Handle (173264) to manipulate the proximal fragment. Before it can be used, the proximal fragment must be reamed to 10mm.

INSTRUMENTATION

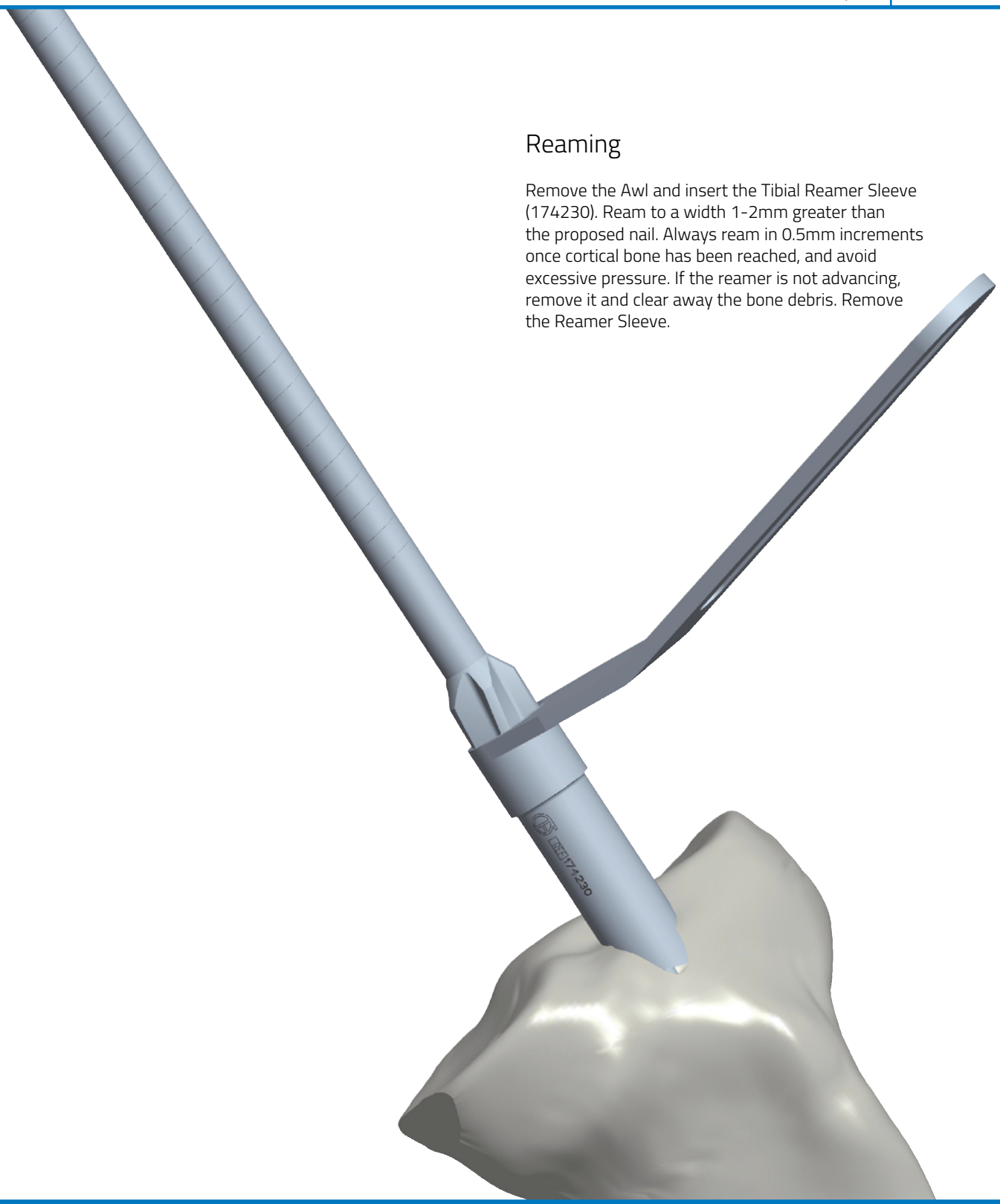
173260
Awl

173265
Reduction Tool

173264
Reduction Tool
Handle

Reaming

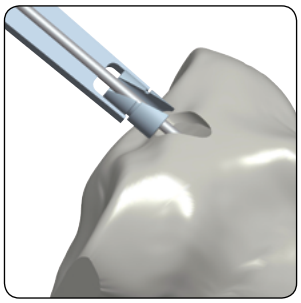
Remove the Awl and insert the Tibial Reamer Sleeve (174230). Ream to a width 1-2mm greater than the proposed nail. Always ream in 0.5mm increments once cortical bone has been reached, and avoid excessive pressure. If the reamer is not advancing, remove it and clear away the bone debris. Remove the Reamer Sleeve.

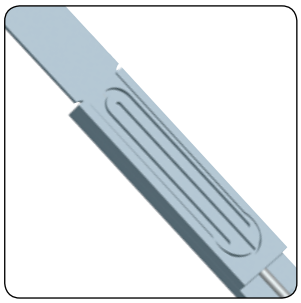


174230
Tibial Reamer Sleeve

Measurement of Nail Length

Ensure that the tip of the Guide Wire is at the level desired for the end of the nail. The tip of the Ruler Support (173276) is engaged over the Guide Wire and positioned in the entry portal. Attach the Ruler (173275) to the Ruler Support with the correct side for guide wire length facing forwards (normally the 980mm Guide Wire is used for femoral and tibial nailing, and the 800mm Guide Wire used for the humerus).



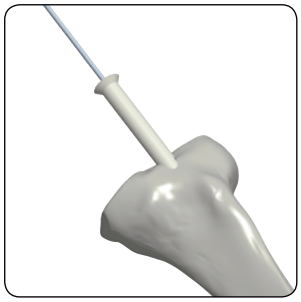


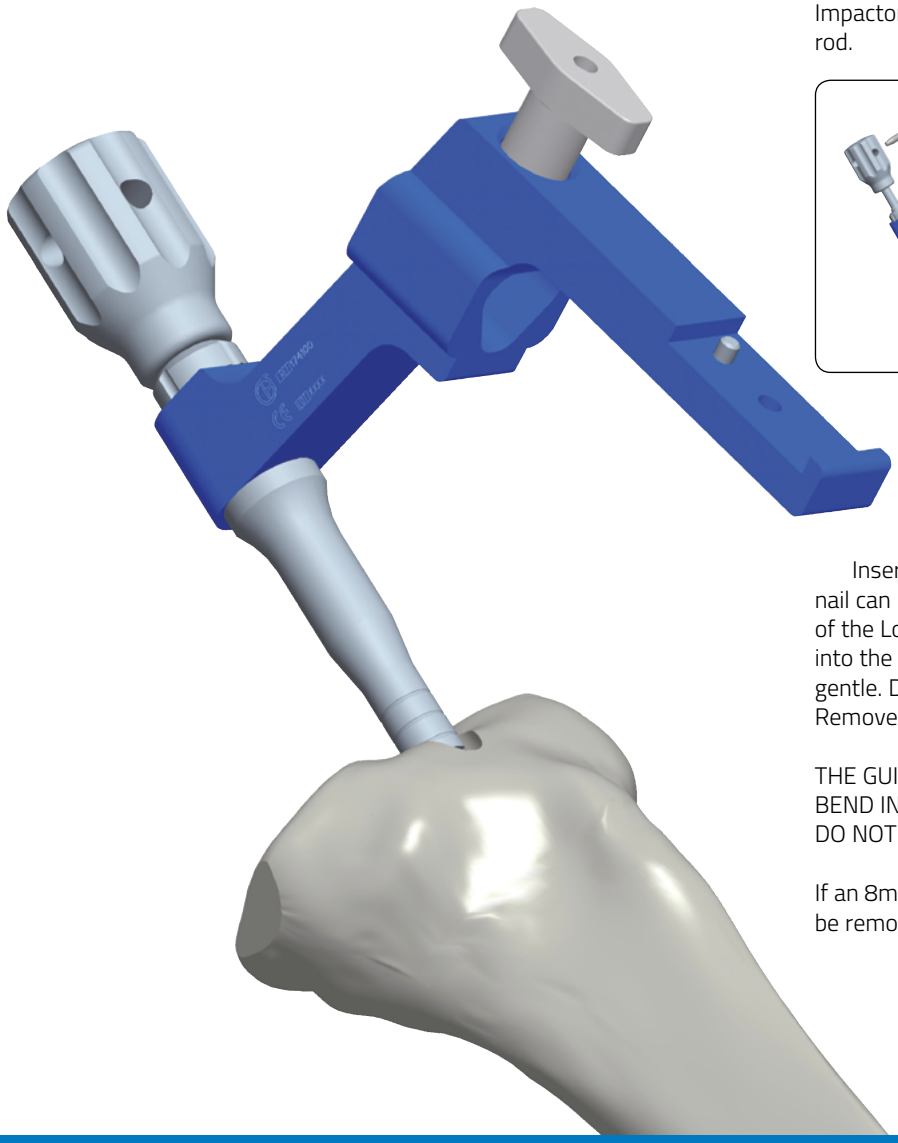
The correct nail length is read at the proximal tip of the Guide Wire. Please note, that if different Guide Wire lengths are used, the difference must be deducted for shorter Guide Wires or added for longer Guide Wires to the measured length.

INSTRUMENTATION

173276
Ruler Support

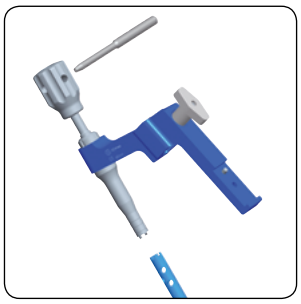
173275
Ruler

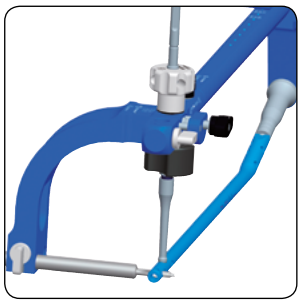




Nail Insertion

The Guide Wire Exchange Tube (17353) is inserted over the Guide Wire with olive, which is then replaced with a Guide Wire without olive (99-176281). After confirming that the tip of the Guide Wire is in the correct position, the Guide Wire Exchange Tube is removed. Insert the Locking Rod (174110) into the back of the Handle (174100) 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.





Before inserting the nail it is important to check the alignment between the distal holes in the nail and the distal arm, as shown in the inset.

Insert the nail over the Guide Wire. If necessary the nail can be hammered into place by tapping on the end of the Locking Rod, or by screwing the sliding hammer into the Locking Rod. Hammering should always be gentle. Do not persist if the nail is not advancing. Remove it and ream some more.

THE GUIDE WIRE MUST BE REMOVED WHEN THE BEND IN THE NAIL REACHES THE ENTRY PORTAL. DO NOT HAMMER THE HANDLE.

If an 8mm nail is being used, the Guide Wire must be removed before insertion as the nail is solid.

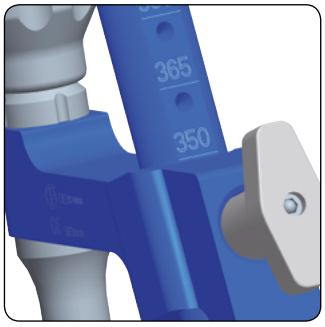
17353
Guide Wire Exchange Tube

174110
Locking Rod

174100
Handle

173071
Impactor

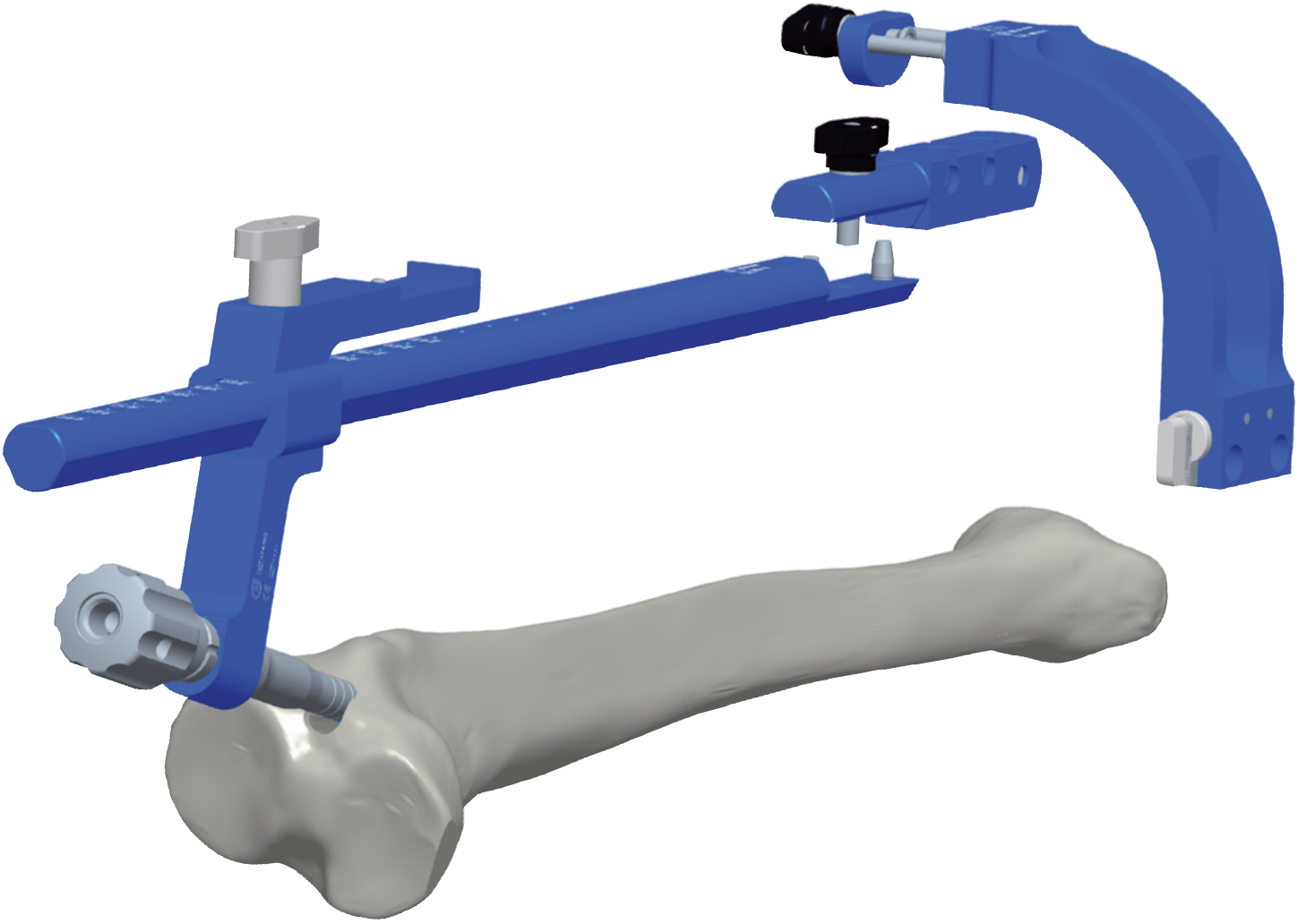
99-176281
Guide Wire without olive



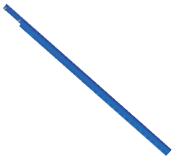
Distal Locking

Insert the Distal Arm (174150) into the Handle, adjust its position to the number corresponding to the selected nail length. Lock the arm firmly into place. If the surgeon prefers, it is possible to use the freehand technique for distal locking.

Mount the Distal Adapter (174160) on the Distal Arm, and mount the Distal Targeting Arm (174170) normally on the medial side. Tighten both knobs firmly.



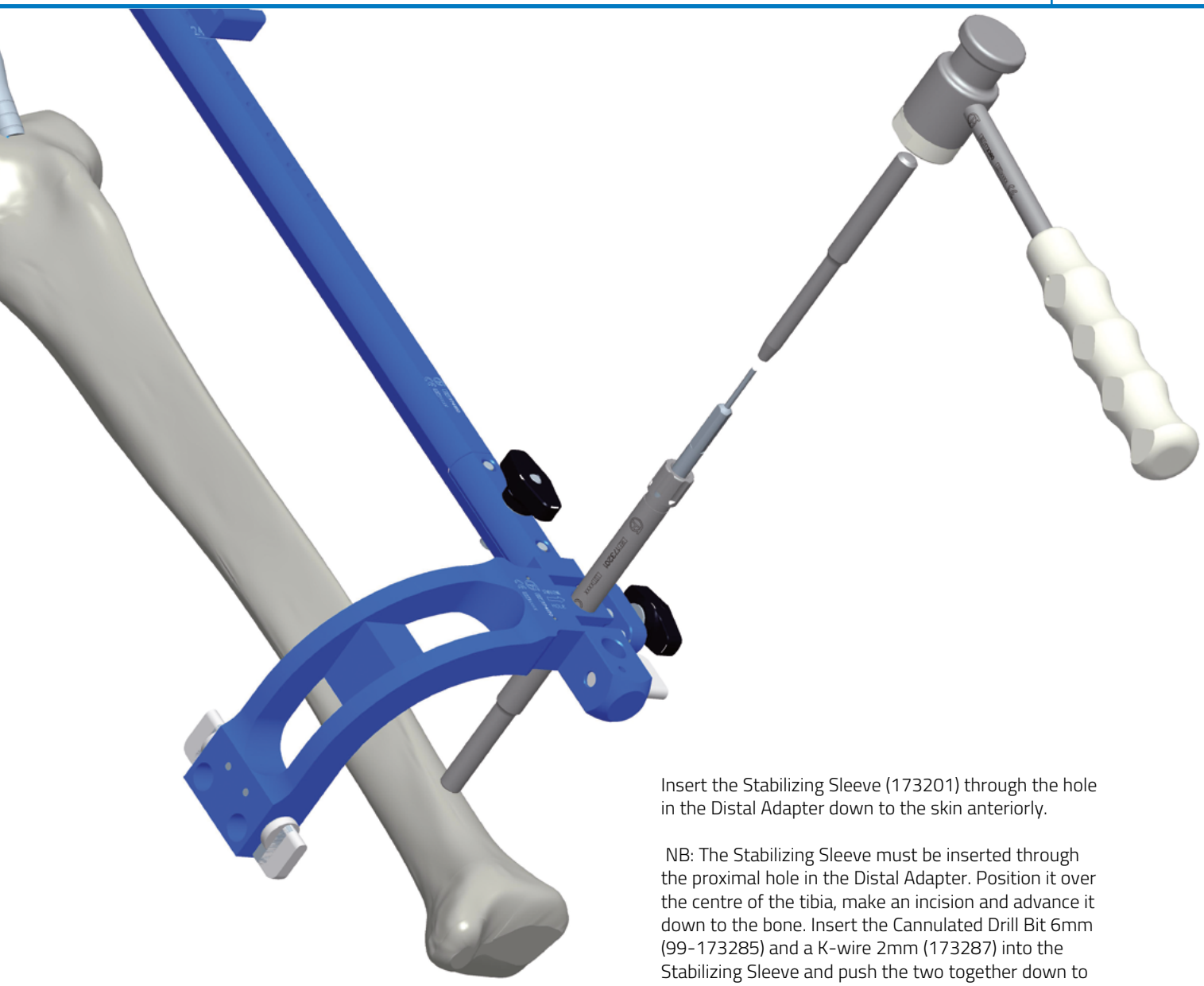
INSTRUMENTATION



174150
Distal Arm

174160
Distal Adapter

174170
Distal
Targeting Arm



Insert the Stabilizing Sleeve (173201) through the hole in the Distal Adapter down to the skin anteriorly.

NB: The Stabilizing Sleeve must be inserted through the proximal hole in the Distal Adapter. Position it over the centre of the tibia, make an incision and advance it down to the bone. Insert the Cannulated Drill Bit 6mm (99-173285) and a K-wire 2mm (173287) into the Stabilizing Sleeve and push the two together down to the bone. Using the Hammer (173380) and the Impactor (173071), tap the K-wire until it is flush with the end of the Cannulated Drill Bit. Drill the anterior cortex only.

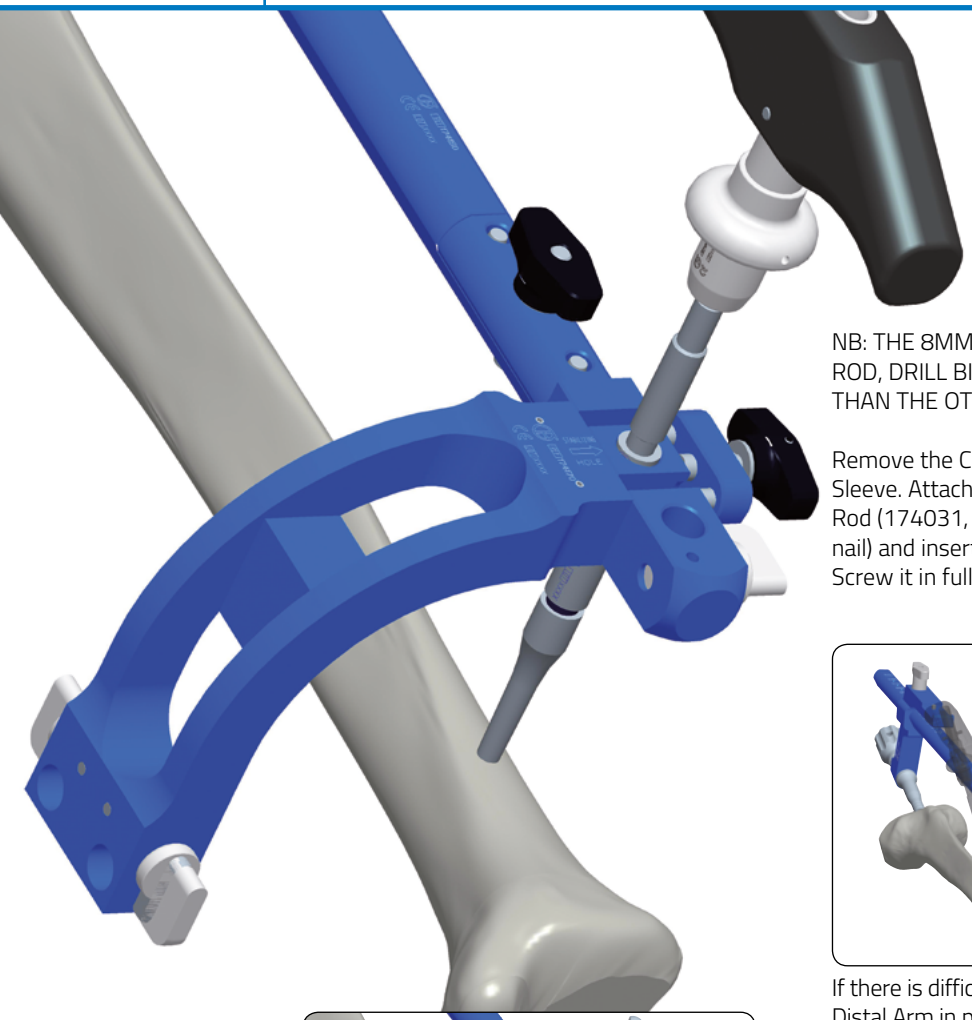
NB: The Cannulated Drill Bit is SINGLE USE ONLY.

173201
Stabilizing Sleeve

99-173285
Cannulated Drill Bit 6mm

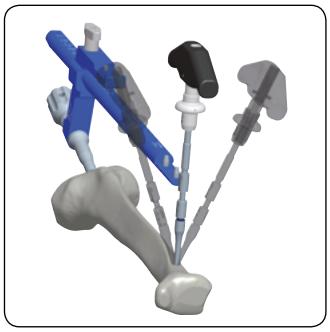
173380
Hammer

173071
Impactor

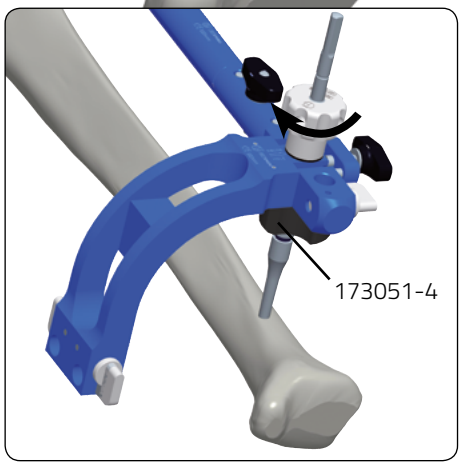


NB: THE 8MM NAIL REQUIRES A SMALLER STABILISING ROD, DRILL BIT, DRILL GUIDE AND LOCKING SCREWS THAN THE OTHER NAILS. SEE TEXT.

Remove the Cannulated Drill Bit, K-wire and Stabilizing Sleeve. Attach the T Handle (173350) to the Stabilizing Rod (174031, or 174041 for the 8mm diameter tibial nail) and insert it into the AP hole in the nail.
Screw it in fully.



If there is difficulty in finding the hole in the nail with the Distal Arm in place, it can be removed with the Distal Adapter, so that a probing technique can be used to find the hole in the nail. This can often be done quickly by feel, but in case of difficulty it may be useful to use the Image Intensifier in an AP view to position the tip of the stabilizing rod over the hole in the nail.



NB: Provided that the AP arm connector has been positioned over the correct length on the guide bar, it should only be necessary to move the stabilizing rod medio-laterally during this manoeuvre. Once the AP hole has been found, remove the T Handle and insert the Distal Arm and Distal Adapter over the Stabilizing Rod.

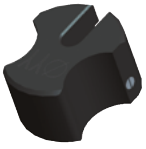
Screw the Locking Nut (173032) to the Rod.
Attach the correct Spacer (173051-4) for the diameter (8-11mm) of the nail and tighten the nut fully with the nail diameter facing the surgeon.

INSTRUMENTATION

173350
T Handle

174031
Stabilizing Rod

173032
Locking Nut



173051-4
Spacer

Screw the Trocar (173212) into the Screw Guide (173211) and insert them both into one of the two holes in the Distal Targeting Arm. Make a 15mm stab incision where it touches the skin, and split the tissues down to the bone. 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 Drill Guide (173213, or 174213 for 8mm nails). Drill with the 4.8mm Drill Bit (173286), or with the 4.0mm Drill Bit (174286) in case of an 8mm nail, until the drill tip is against the second cortex. Use the Image Intensifier if there is any doubt about the position of the tip of the drill bit. The screw length required is read from the scale on the Drill Bit immediately above the top of the Drill Guide (see inset - if the position is between graduations, choose the longer value). Drill the second cortex. Insert the screw using the 3.5mm Cannulated Screw Driver (173320) until the mark on the shaft of the Screw Driver reaches the top of the Screw Guide. One more full turn should be made to tighten the screw fully. NB: 4.0mm locking screws should be used distally in the 8mm diameter tibial nail only.

Repeat the procedure for the second hole.

A third screw can be inserted in the AP direction using the distal hole in the Distal Adapter following the procedure described. If a fourth screw is required, a 4.8mm revision locking screw can be used (4.0mm for the 8mm nail). Remove the Spacer and Stabilizing Rod with the T Handle. Insert a Screw Guide and Drill Guide. Drill through the 1st and 2nd cortex with a 4.8mm Drill Bit or 4.0mm Drill Bit for the 8mm diameter tibial nail. Insert the revision locking screw.

NB: The 8mm diameter nail takes 4.0mm diameter locking screws distally (coloured gold). All other nails take 4.8mm diameter screws (coloured green).

Occasionally there may be an undisplaced or reduced single fragment of distal metaphysis that can be held in position by 1 or 2 locking screws. In this case fully threaded screws may be more effective, after drilling with a 4.0mm drill bit. However, for safe early weightbearing, the standard 4.8mm peg screws are recommended.

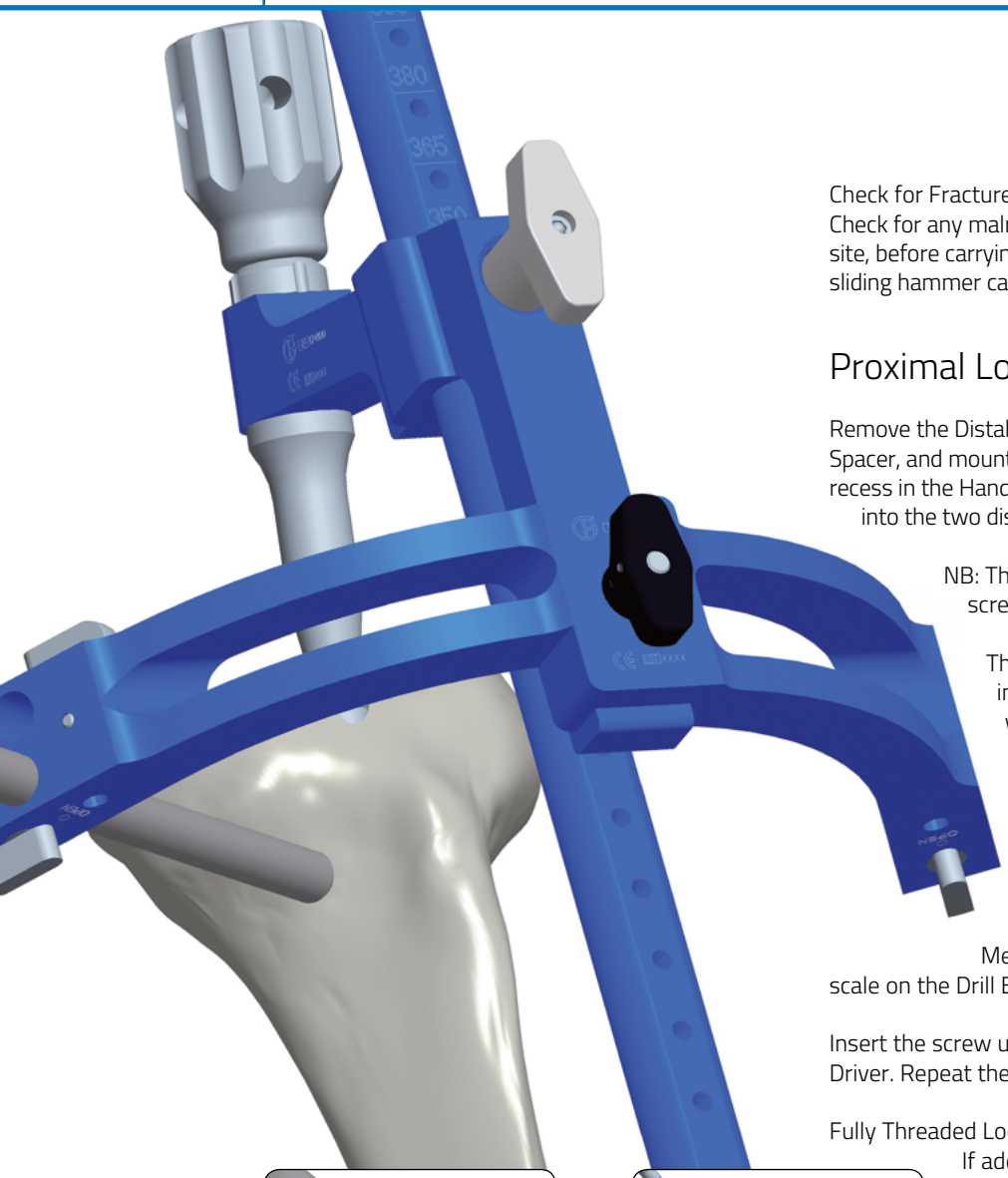
173212
Trocar

173211
Screw Guide

173213
Drill Guide

173286
4.8mm
Drill Bit

173320
3.5mm
Cannulated
Screw Driver



Check for Fracture Distraction
Check for any malrotation or distraction of the fracture site, before carrying out proximal locking. If necessary the sliding hammer can be used to close a fracture gap.

Proximal Locking

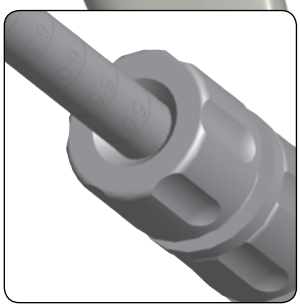
Remove the Distal Targeting Arm, Stabilizing Rod and Spacer, and mount the Proximal Arm (174130) on the recess in the Handle. Insert two Screw Guides (173211) into the two distal holes in the Proximal Arm.

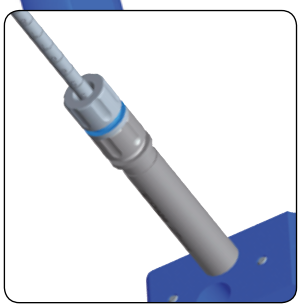
NB: The two most distal of the proximal screw holes should always be filled.

The medial hole is drilled first. Make an incision and advance the screw guide with the Trocar down to the cortex. Unscrew the Trocar and push the screw guide until it is flush against the bone surface. Tighten the Screw Guide using the Locking Cam. Remove the Trocar and screw in a 4.8mm Drill Guide. Drill with the 4.8mm Drill Bit as before. Measure the screw length using the scale on the Drill Bit.

Insert the screw using the 3.5mm Cannulated Screw Driver. Repeat the procedure for the lateral hole.

Fully Threaded Locking Screws
If additional locking is required proximally, two fully threaded locking screws can be inserted using the two proximal holes in the proximal arm. Drilling is performed using the 4.0mm Drill Bit and Drill Guide (blue colour coded).

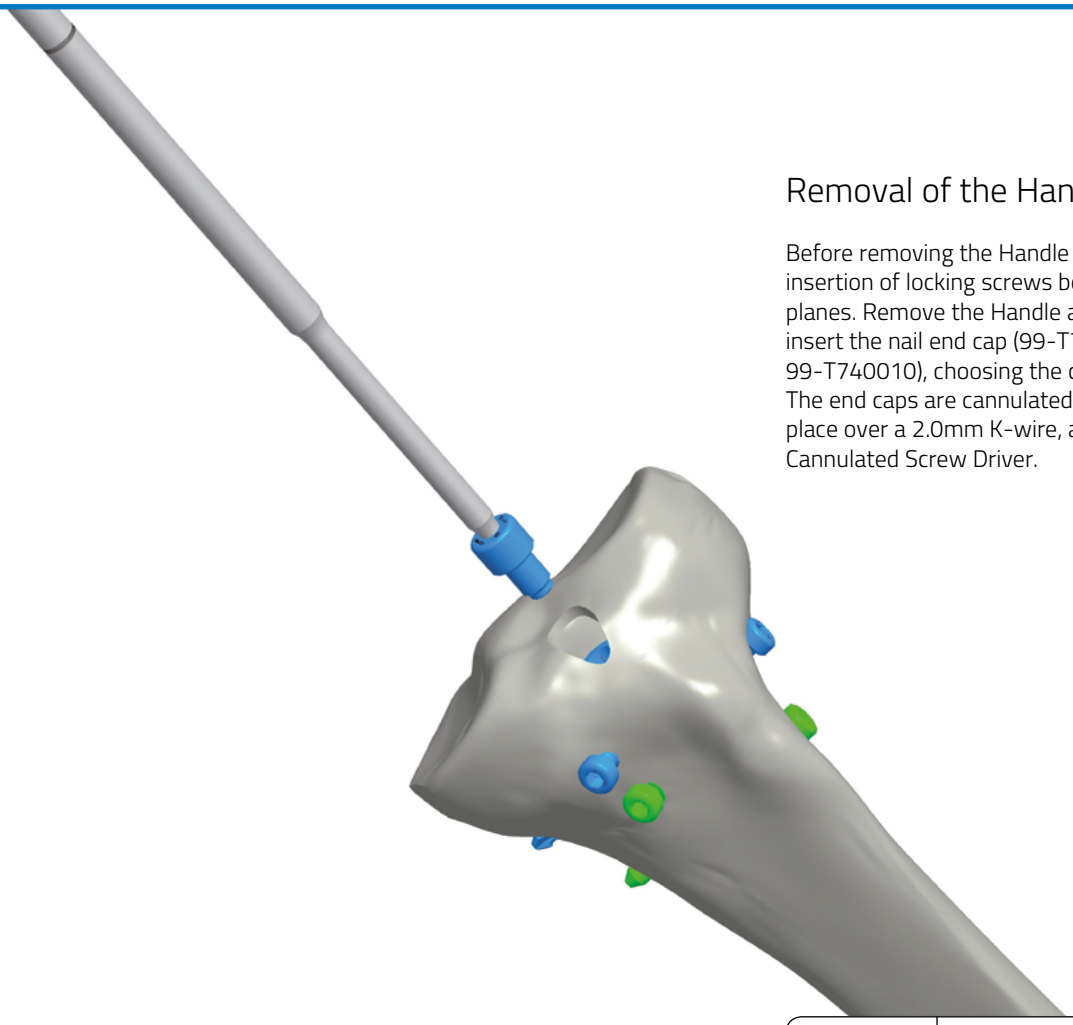




INSTRUMENTATION

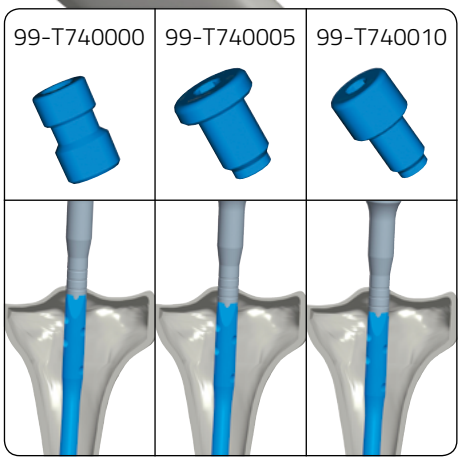
174130
Proximal Arm

173211
Screw Guide



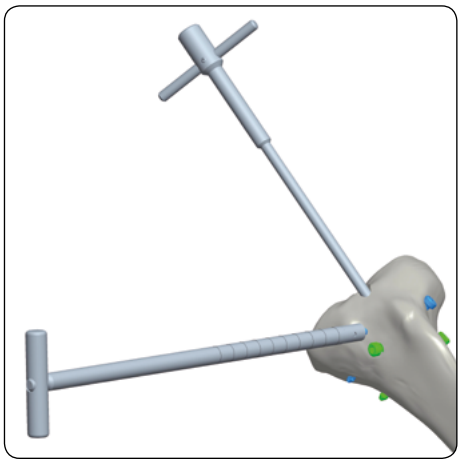
Removal of the Handle and Closure

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 insert the nail end cap (99-T740000, 99-T740005, 99-T740010), choosing the correct length (0, 5, 10). The end caps are cannulated, and can be guided into place over a 2.0mm K-wire, and screwed tight with the Cannulated Screw Driver.



Nail Removal

The Extraction Instruments Box is needed for nail removal. The nail end cap is removed with the 3.5mm Cannulated Screw Driver. The Tibial Nail Extractor (174220) is screwed fully into the nail. The locking screws are now all removed using the Locking Screw Extractor (17652). The Sliding Hammer (173370) is screwed onto the Tibial Extractor. The nail is then removed by reverse hammering.



INSTRUMENTATION

174220
Tibial Nail Extractor

17652
Locking Screw Extractor

173370
Sliding Hammer

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.

Instructions for Use: See actual package insert for Instructions for Use

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.

Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone +39 045 6719000,
Fax +39 045 6719380
www.orthofix.com

Rx Only

CE 0123

Distributed by:

orthofix.com

CN-0702-OPT-E0 F 11/21 (424935)

ORTHOFIX® ORTHOPEDICS