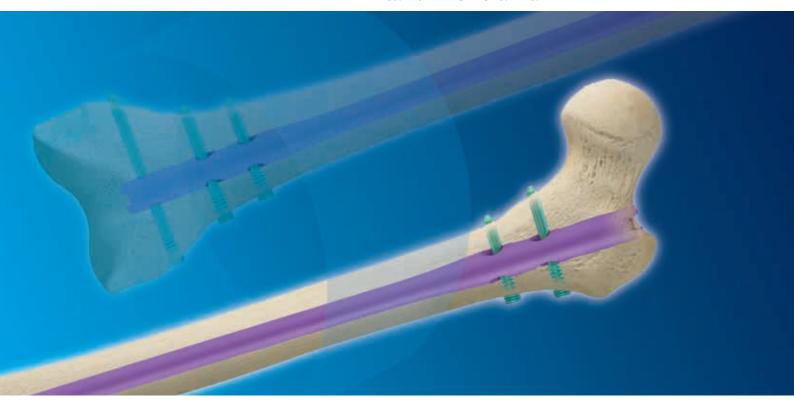


CentroNail®

Titanium Femoral Nail



The Centronail
Titanium Universal
Femoral Nailing System



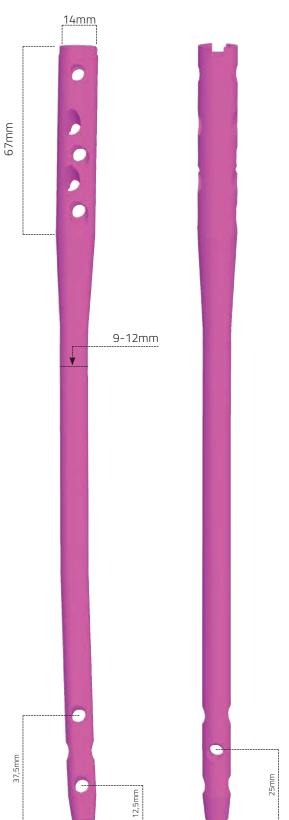
- 1 FEATURES AND BENEFITS
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- **42 NAIL REMOVAL**

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

14mm proximal diameter

9-12mm distal diameter 9mm is solid

One design for Left and Right femur

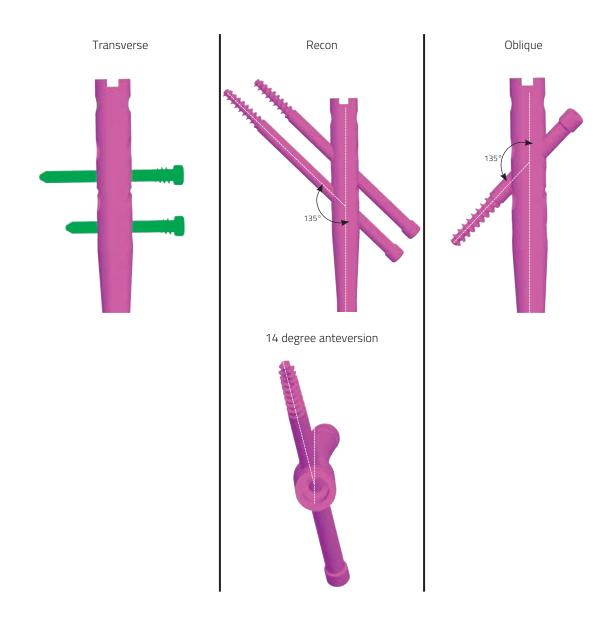
Antegrade and retrograde insertion

275-475mm (25mm increments)

Radius of curve 2500mm

Proximal locking

Three possible configurations:



Locking screws

TITANIUM STANDARD LOCKING SCREWS

6.8mm thread diameter 4.8mm shaft diameter



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

TITANIUM REVISION LOCKING SCREWS

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



TITANIUM RECON/OBLIQUE SCREWS

6.5-5.7mm thread diameter 6.5mm shaft diameter



Solid: maximises fatigue strength.

Reverse thread on screw head: easy screw removal.

TITANIUM CONDYLAR COMPRESSION SCREWS

4.8mm diameter

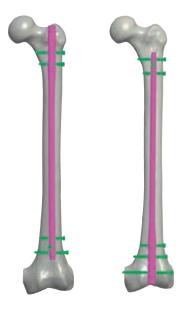


Cannulated: easy placement of condylar washer and nut over a K-wire.

Cloverleaf washer design: adapts to contour of bone surface and permits excellent compression.

INDICATIONS

Transverse Diaphyseal fractures



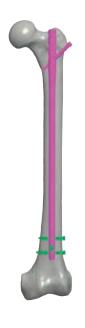
Retrograde insertion is indicated in patients:

- obese
- pregnant
- with proximal femoral implants or total hip joints
- polytraumatized
- with bilateral femoral shaft fractures

Recon Neck and diaphyseal fractures Pertrochanteric fractures Subtrochanteric fractures



Oblique Subtrochanteric fractures Shaft fractures



EQUIPMENT REQUIRED

| C 1 177 : F | 11.1 | II NI II |
|-----------------------|------------|--------------|
| Centronail Titanium F | | ıllary Nails |
| Ø 9 L 275mm Solid | 99-T739275 | |
| Ø 9 L 300mm Solid | 99-T739300 | |
| Ø 9 L 325mm Solid | 99-T739325 | |
| Ø 9 L 350mm Solid | 99-T739350 | |
| Ø 9 L 375mm Solid | 99-T739375 | |
| Ø 9 L 400mm Solid | 99-T739400 | |
| Ø 9 L 425mm Solid | 99-T739425 | |
| Ø 10 L 275mm | Cannulated | 99-T730275 |
| Ø 10 L 300mm | Cannulated | 99-T730300 |
| Ø 10 L 325mm | Cannulated | 99-T730325 |
| Ø 10 L 350mm | Cannulated | 99-T730350 |
| Ø 10 L 375mm | Cannulated | 99-T730375 |
| Ø 10 L 400mm | Cannulated | 99-T730400 |
| Ø 10 L 425mm | Cannulated | 99-T730425 |
| Ø 11 L 325mm | Cannulated | 99-T731325 |
| Ø 11 L 350mm | Cannulated | 99-T731350 |
| Ø 11 L 375mm | Cannulated | 99-T731375 |
| Ø 11 L 400mm | Cannulated | 99-T731400 |
| Ø 11 L 425mm | Cannulated | 99-T731425 |
| Ø 11 L 450mm | Cannulated | 99-T731450 |
| Ø 11 L 475mm | Cannulated | 99-T731475 |
| Ø 12 L 325mm | Cannulated | 99-T732325 |
| Ø 12 L 350mm | Cannulated | 99-T732350 |
| Ø 12 L 375mm | Cannulated | 99-T732375 |
| Ø 12 L 400mm | Cannulated | 99-T732400 |
| Ø 12 L 425mm | Cannulated | 99-T732425 |
| Ø 12 L 450mm | Cannulated | 99-T732450 |
| Ø 12 L 475mm | Cannulated | 99-T732475 |
| | | |

| End Caps | |
|----------|------------|
| L 0mm | 99-T730000 |
| L 10mm | 99-T730010 |
| L 20mm | 99-T730020 |

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 |

Cleaning, disinfection, sterilisation and maintenance of instrumentation

Orthofix supplies the Centronail Titanium Universal Femoral 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 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.

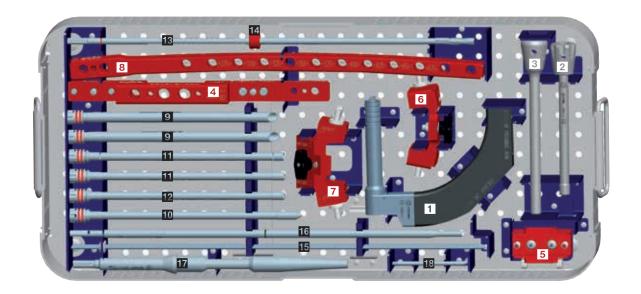
NB: Disassemble all instruments for thorough cleaning and disinfection prior to sterilization.

6.5mm Titanium Recon-Oblique Screws

| Length (mm) |
|-------------|
| 50 |
| 55 |
| 60 |
| 65 |
| 70 |
| 75 |
| 80 |
| 85 |
| 90 |
| 95 |
| 100 |
| 105 |
| 110 |
| 115 |
| 120 |
| |

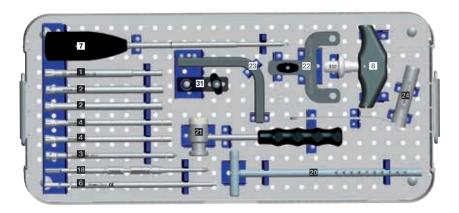
4.8mm Titanium Condylar Screw Kit

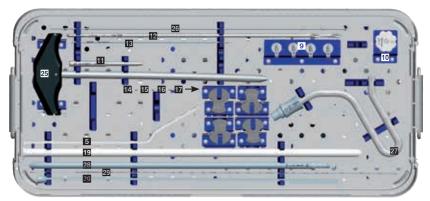
| Code | Length (mm) |
|------------|-------------|
| 99-T766060 | 60 |
| 99-T766065 | 65 |
| 99-T766070 | 70 |
| 99-T766075 | 75 |
| 99-T766080 | 80 |
| 99-T766085 | 85 |
| 99-T766090 | 90 |
| 99-T766095 | 95 |
| 99-T766100 | 100 |
| 99-T766105 | 105 |
| 99-T766110 | 110 |
| 99-T766115 | 115 |
| 99-T766120 | 120 |



FEMORAL SPECIFIC INSTRUMENTS BOX, EMPTY (173991) can accommodate: Part # Description

| Part # | | Description | Qty |
|--------|----|-------------------------|-----|
| 173100 | 1 | HANDLE | 1 |
| 173110 | 2 | LOCKING ROD | 1 |
| 173115 | 3 | INSERTION KNOB | 1 |
| 173120 | 4 | UF PROXIMAL ARM | 1 |
| 173130 | 5 | TRANSVERSE JIG | 1 |
| 173140 | | OBLIQUE JIG | 1 |
| 173150 | 7 | RECON JIG | 1 |
| 173161 | 8 | UF DISTAL ARM | 1 |
| 173221 | 9 | RECON SCREW GUIDE | 2 |
| 173222 | 10 | RECON TROCAR | 1 |
| 173223 | 11 | RECON WIRE GUIDE | 2 |
| 173224 | | RECON DRILL GUIDE | 1 |
| 173283 | 13 | RECON DRILL BIT | 1 |
| 173295 | | RECON DRILL BIT STOP | 1 |
| 173288 | 15 | THREADED WIRE 3X400MM | 2 |
| 173304 | 16 | LONG SCREW WRENCH | 1 |
| 173270 | 17 | CANNULATED RIGID REAMER | 1 |
| 10012 | 18 | ALLEN WRENCH, 3MM | 1 |





GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

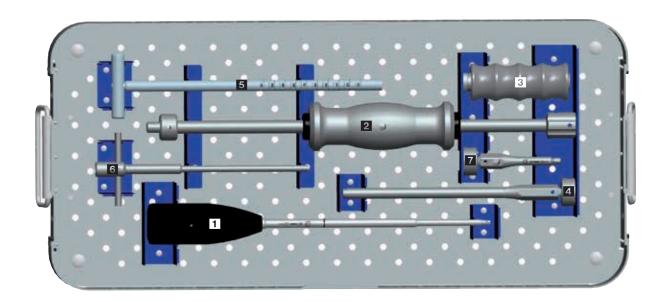
| Part # | | Description | Qty |
|--------|----|---------------------------------|-----|
| 173201 | 1 | STABILIZING SLEEVE | 1 |
| 173211 | 2 | SCREW GUIDE | 2 |
| 173212 | 3 | TROCAR | 1 |
| 173213 | | DRILL GUIDE | 1 |
| 173301 | 5 | SCREW SCALE | 1 |
| 173302 | 6 | CANNULATED SCREW WRENCH ADAPTER | 1 |
| 173320 | 7 | CANNULATED SCREW DRIVER | 1 |
| 173350 | | 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 | | SPACER NAIL 9MM | 1 |
| 173053 | 15 | SPACER NAIL 10MM | 1 |
| 173054 | 16 | SPACER NAIL 11MM | 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 |

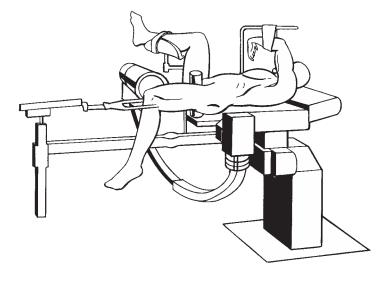
GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

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



EXTRACTION INSTRUMENTS BOX, EMPTY (173998) can accommodate:

| Part # | | Description | Qty |
|--------|---|-----------------------------------|-----|
| 173320 | 1 | CANNULATED SCREW DRIVER | 1 |
| 173370 | | 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 |
| | | | |





Whenever possible, femoral fractures should be stabilized within the first 24 hours following injury, provided the patient's condition will allow it. Do not start surgery unless the fracture is well reduced.

ANTEGRADE INSERTION

Fracture reduction and patient positioning All nail insertions in acute cases should be performed using a traction table or a reduction device. This serves not only to reduce the fracture, but also permits free access to the greater trochanter. The patient is positioned supine on the traction table. Access is improved by inclining the trunk towards the uninjured side by about 25°. The position of the trunk is secured by supports mounted on the side of the operating table. The uninjured limb is positioned on a gynecological leg rest to allow the Image Intensifier free access to the whole of the fractured femur. The Image Intensifier should have free access to the entire femur in both planes.













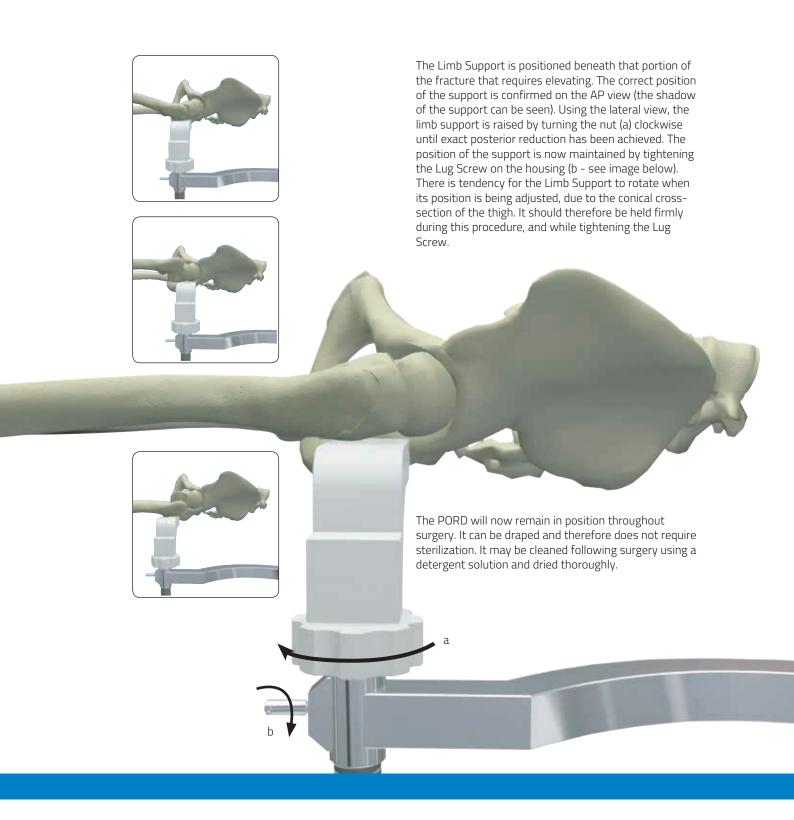
Fracture reduction in the sagittal plane with the "PORD"

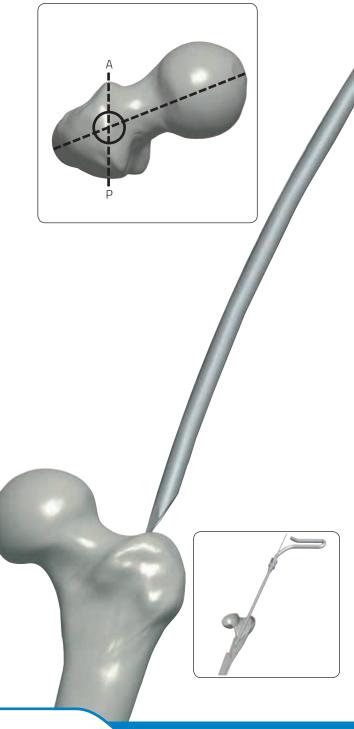
Any posterior sagging at the fracture site should now be corrected and maintained using the dedicated Posterior Reduction Device (PORD™). This device is easily attached to most fracture tables.

- 1 Slide the Clark Attachment on to the side rail of the fracture table. Insert the vertical post of the Box Bracket into the Clark Attachment from beneath and tighten the clamp on the post so that the bracket is held securely.
- 2 Assemble the PORD™ in the following way: Slide the Horizontal Bar through the Box Bracket with its curved portion facing the fracture table. This curved section is designed to allow for unobstructed multiple plane imaging using the C-arm of the Image Intensifier.
- **3** The Screw Jack of the Limb Support should be positioned in the housing at the end of the horizontal bar, with the nut under the radiolucent support. Turning the nut clockwise will then raise the support.



110000 PORD





Entry Portal

The patient is prepped and draped in the normal manner. A skin incision of about 2-3 cm is made proximal to the greater trochanter.

The entry point should be in line with the medullary canal. Depending on the individual anatomy this may be in the piriform fossa or on the apex of the greater trochanter.

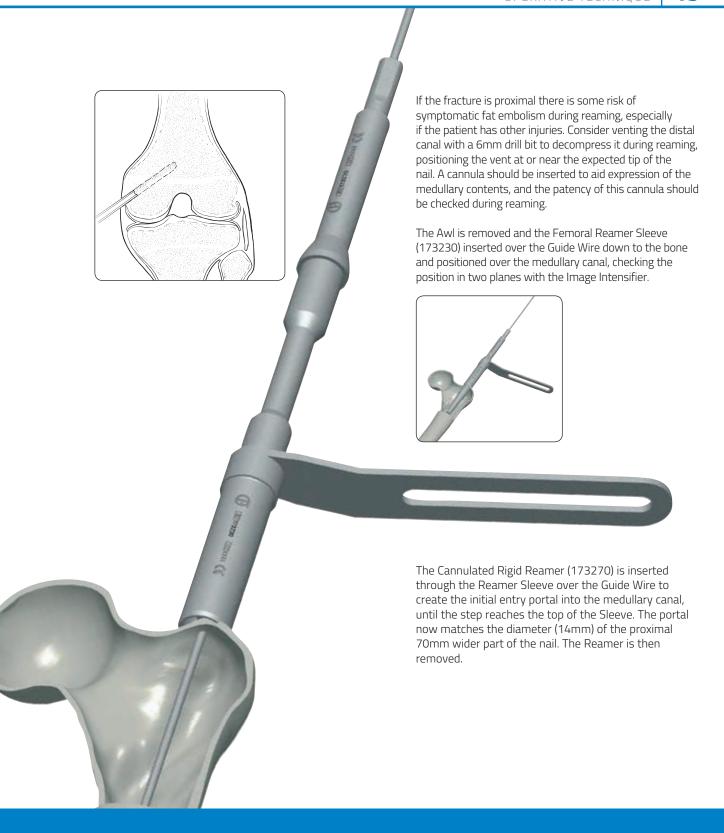
NB: The point of insertion should never be too medial, in order to avoid injury to the Circumflex Femoral Artery.

In proximal third fractures the proximal fragment may be flexed and abducted. Direct manipulation of this fragment may be necessary with a suitable percutaneous instrument such as a Steinmann Pin, before the correct entry point becomes accessible. Possible rotational malalignment must be considered. The outline of the lesser trochanter should be compared with that of the opposite side, and the two cortical fragments should have a similar shape with no step between them.

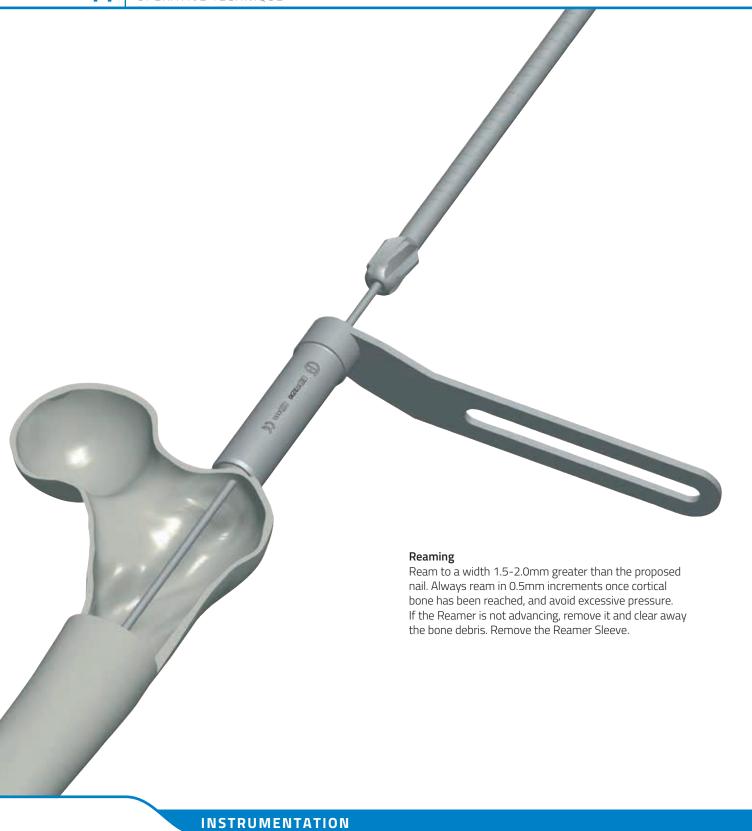
Make the entry point with the Awl (173260). The Guide Wire with Olive (99-173281) is inserted through the Awl down the medullary canal, until its tip sits in the subchondral bone exactly on the roof of the intercondylar notch, midway between the femoral condyles. Use image intensification when passing 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.









Measurement of Nail Length

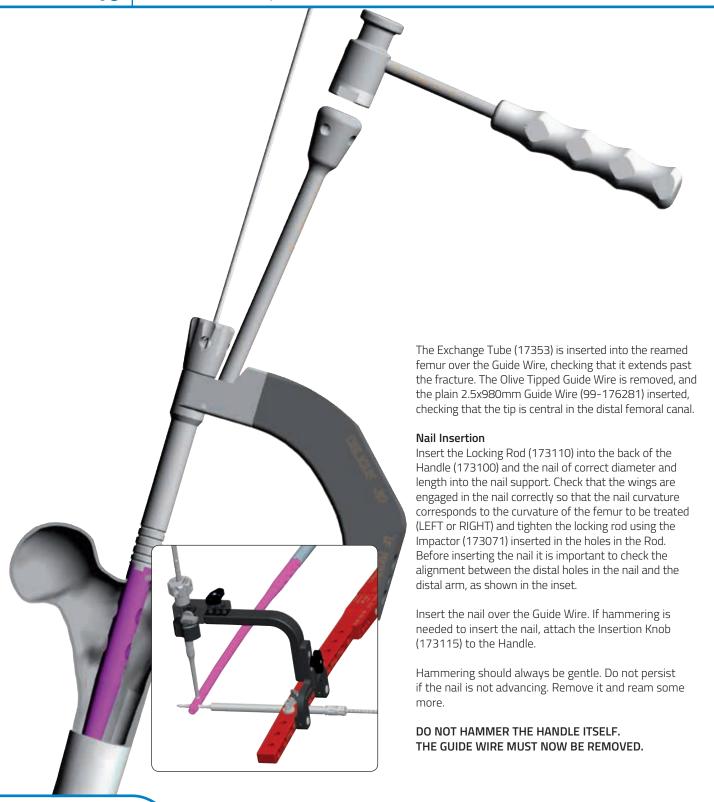
Ensure that the tip of the Guide Wire is at the level desired for the end of the nail. The tip of the Ruler Support (173276) is engaged over the Guide Wire and positioned in the entry portal. Attach the Ruler (173275) to the Ruler Support with the correct side for guide length facing forwards (normally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

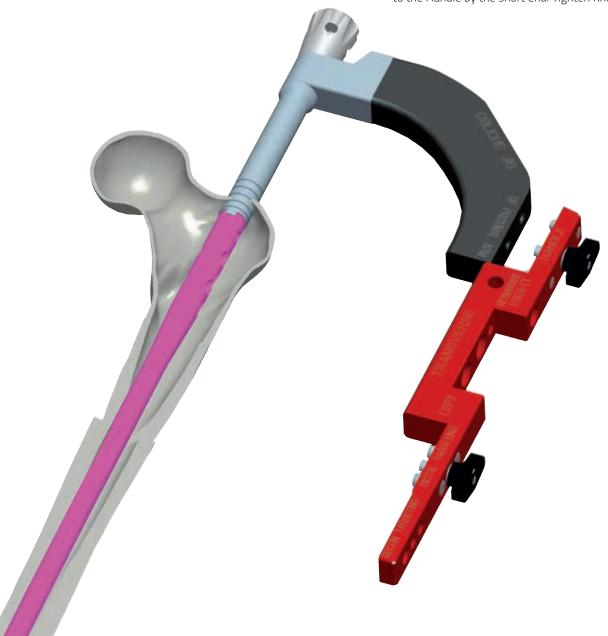






Transverse Proximal Screws

Proximal LockingAttach the Universal Femur (UF) Proximal Arm (173120) to the Handle by the short end. Tighten Knob firmly.







If standard proximal locking is to be used, it is possible to do the distal locking first (see next page). If Recon Locking is required proximally, this must be done first (see page 28).

Add the Transverse Jig (173130) with the writing "TRANSVERSE" facing upwards. Make a stab incision at the level of one of the two holes in the guide bar and extend it down to the bone with blunt dissection. Screw the Trocar (173212) into the Screw Guide (173211) and insert them through the hole in the Jig, down to the bone. Unscrew the Trocar and push the Screw Guide until it is sitting flush against the bone surface. Lock the Screw Guide into position.

Remove the Trocar and, using a 4.8mm Drill Bit (173286) with the Drill Guide (173213) inserted into the Screw Guide, drill the first hole 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.

Repeat the procedure for the second proximal locking screw.



















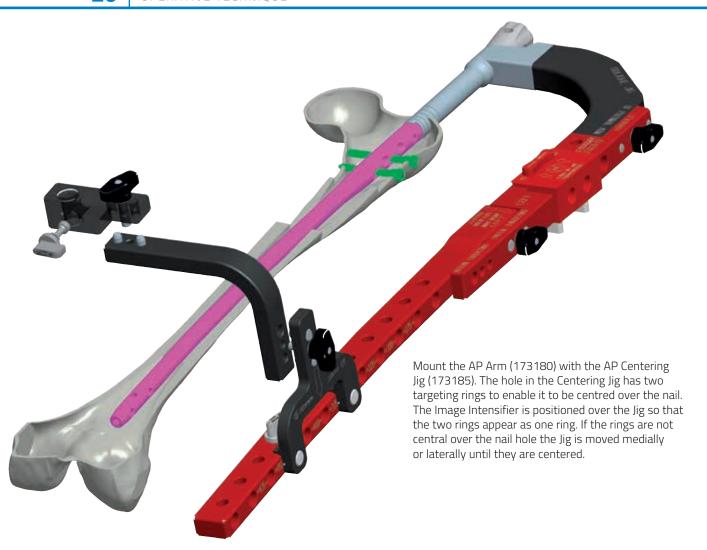




Connector



173026 Locking Cam



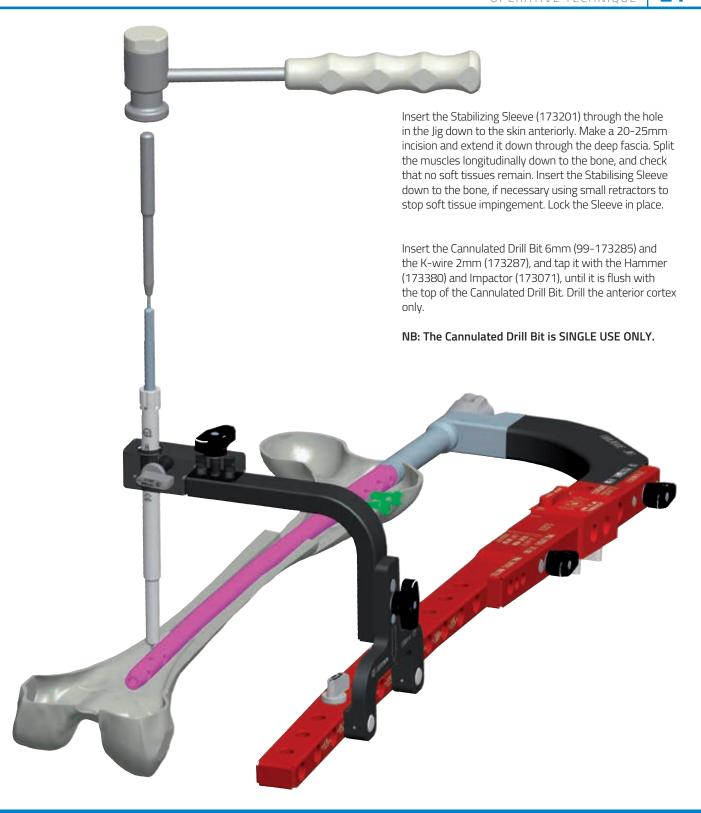






Aligned









Remove the Cannulated Drill Bit, K-wire and Stabilizing Sleeve. Attach the T Handle (173350) to the Stabilizing Rod (173031) 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 AP Arm in place, it can be removed, 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 AP Arm over the Stabilizing Rod.

> Screw the Locking Nut (173032) on the Stabilizing Rod. Attach the correct Spacer (173052-5) for the diameter (9-12mm) of the nail with the nail diameter facing the surgeon and tighten the nut fully.





173350 T Handle



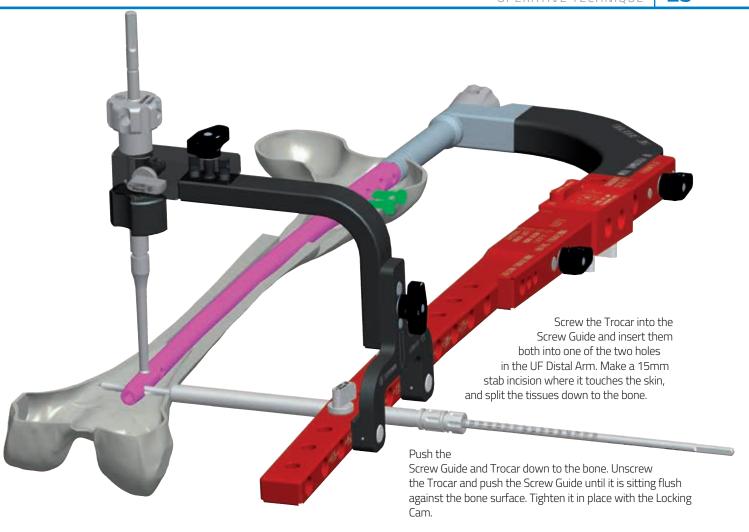
Stabilizing Rod



173032 Locking Nut



173052-5 Spacer



Remove the Trocar and screw the Drill Guide into the Screw Guide. Drill with the 4.8mm Drill Bit as before. Stop at the second cortex and measure the screw length using the scale on the Drill Bit. Complete drilling, and insert the screw using the 3.5mm Cannulated Screw Driver. Repeat the procedure for the second hole.



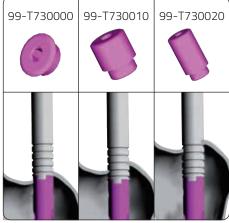






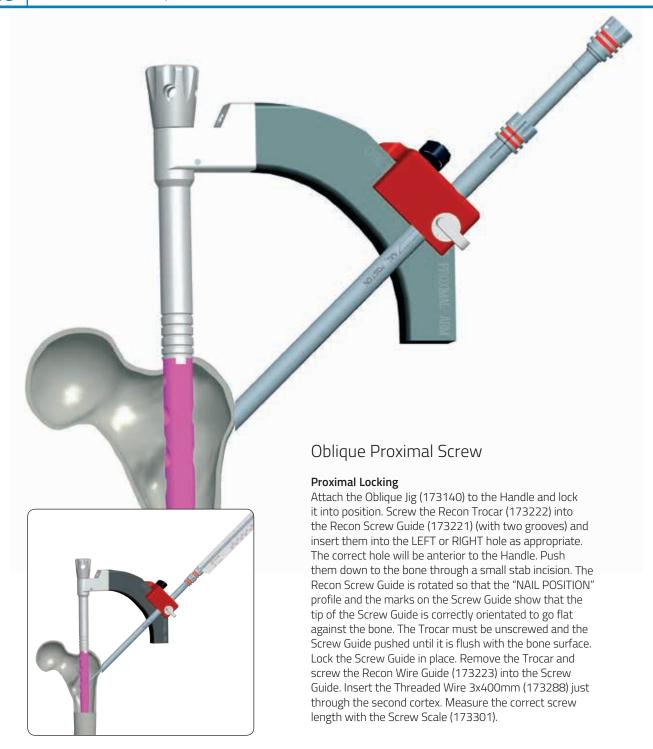
Removal of the Handle and Closure

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, insert the nail end cap over a K-wire (99-T730000, 99-T730010, 99-T730020), choosing the correct length (0, 10, 20) to leave the top of the nail end cap flush with, or just above, the tip of the greater trochanter.









INSTRUMENTATION



Oblique Jig

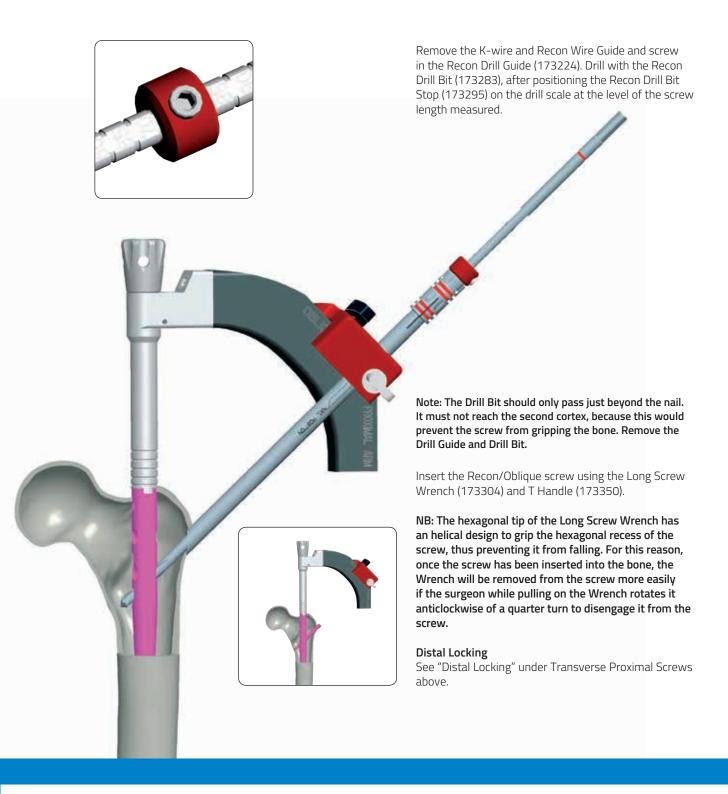
Recon Trocar



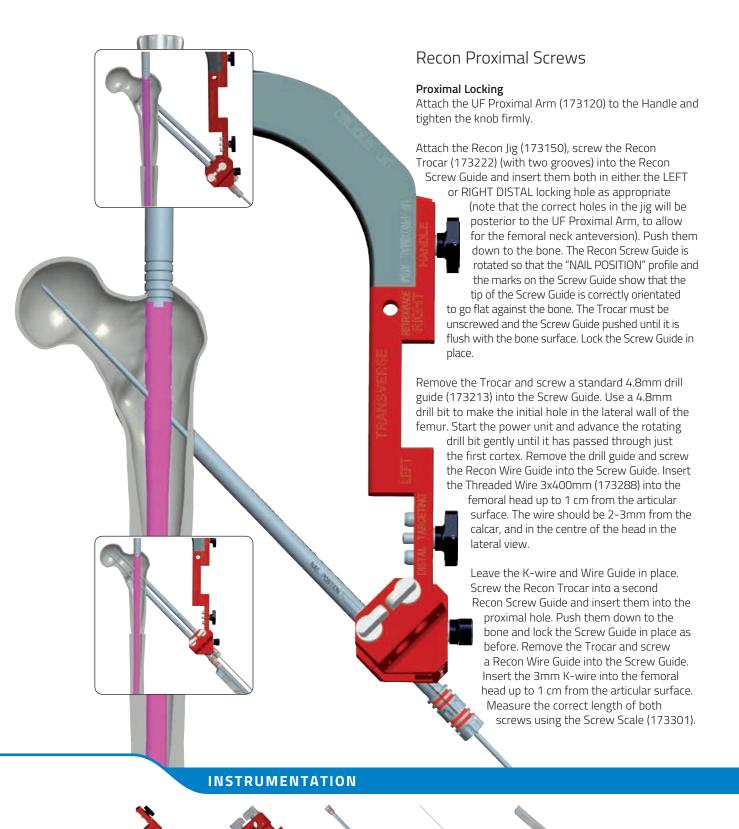
Recon
Wire Guide

Threaded Wire 3x400mm





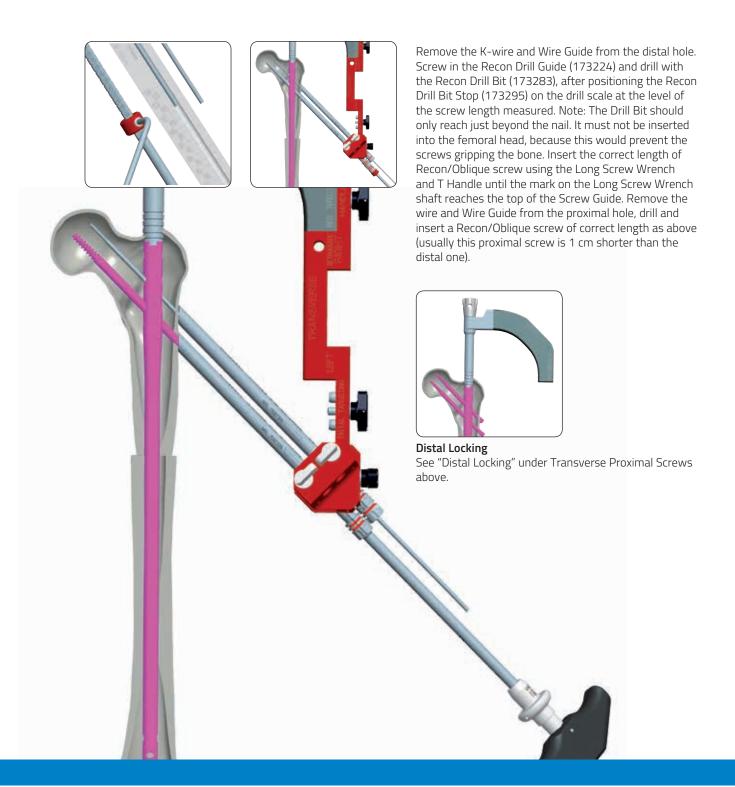


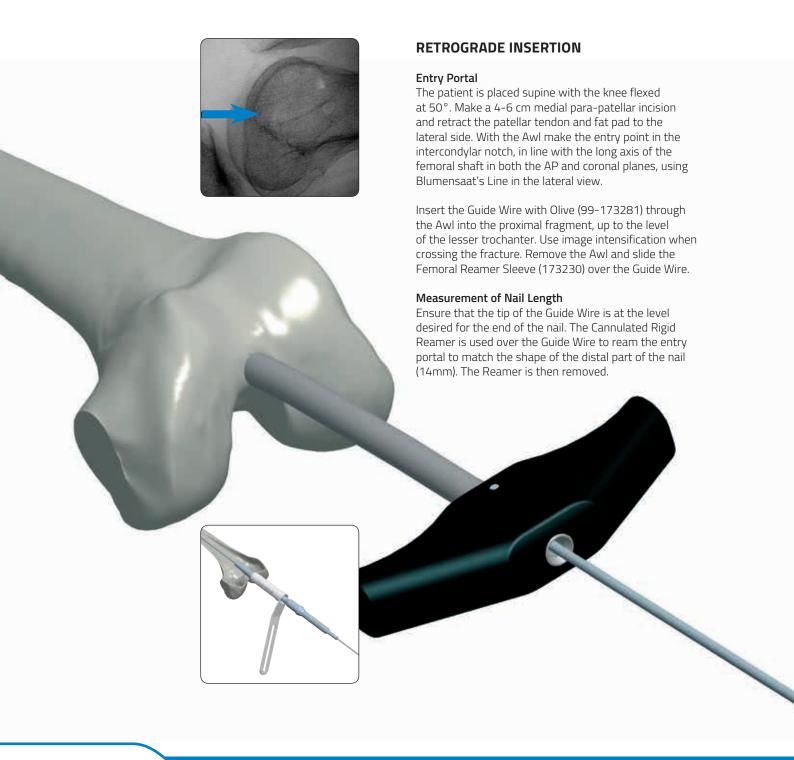


173120 UF Proximal Arm 173150 Recon Jig

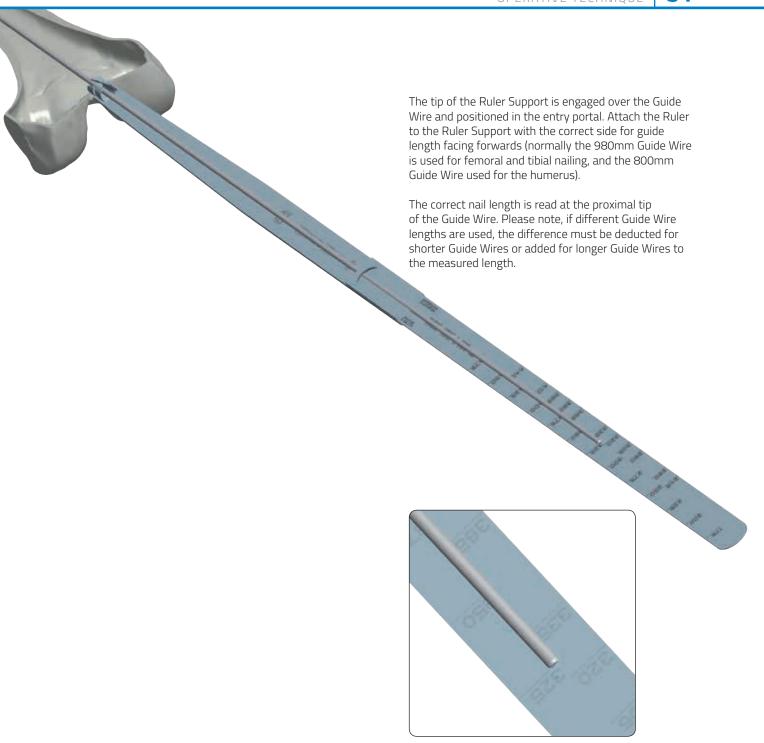
173222 Recon Trocar **173288** Threaded Wire 3x400mm

173301Screw Scale

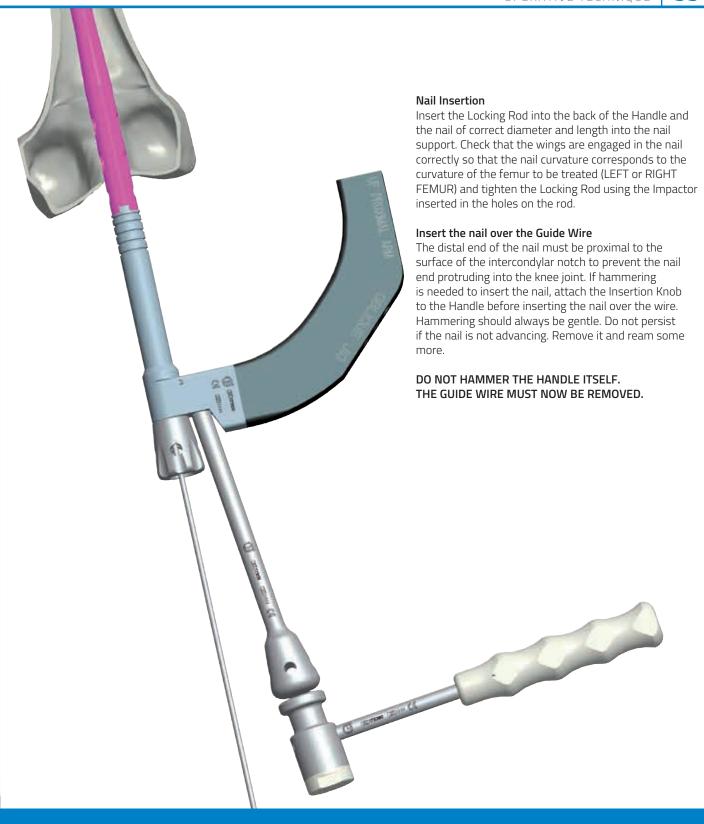


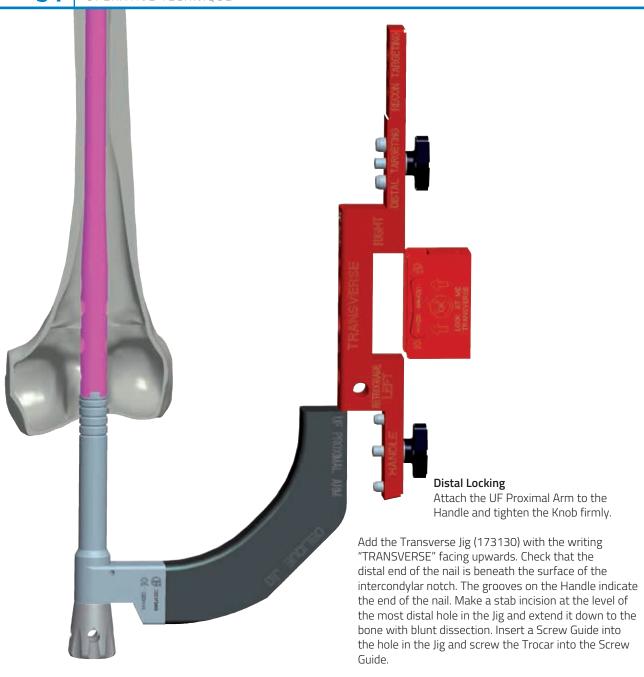






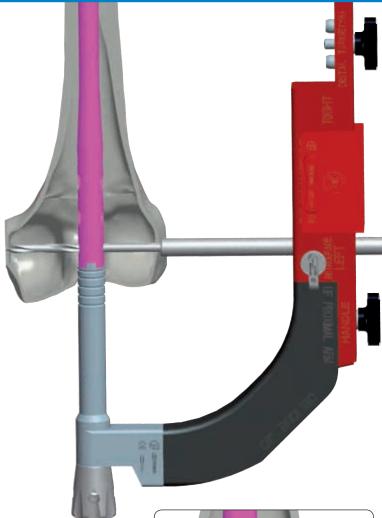






Push them both down to the bone. Unscrew the Trocar and push the Screw Guide until it is sitting flush against the bone surface. Lock the Screw Guide into position.





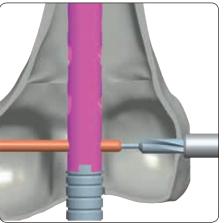
Remove the Trocar and, using a 4.8mm Drill Bit and Drill Guide inserted into the Screw Guide, drill the first hole down to the second cortex. Measure the correct screw length using the scale on the Drill Bit, and drill the second cortex. Insert the screw using the 3.5mm Cannulated Screw Driver.

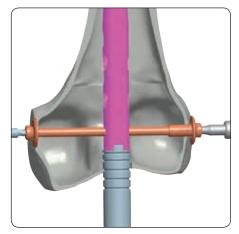
NB: If a compression screw is to be used, choose a screw one size shorter.

Repeat the procedure for the second distal locking screw

Two more screws may be inserted through the transverse Jig.

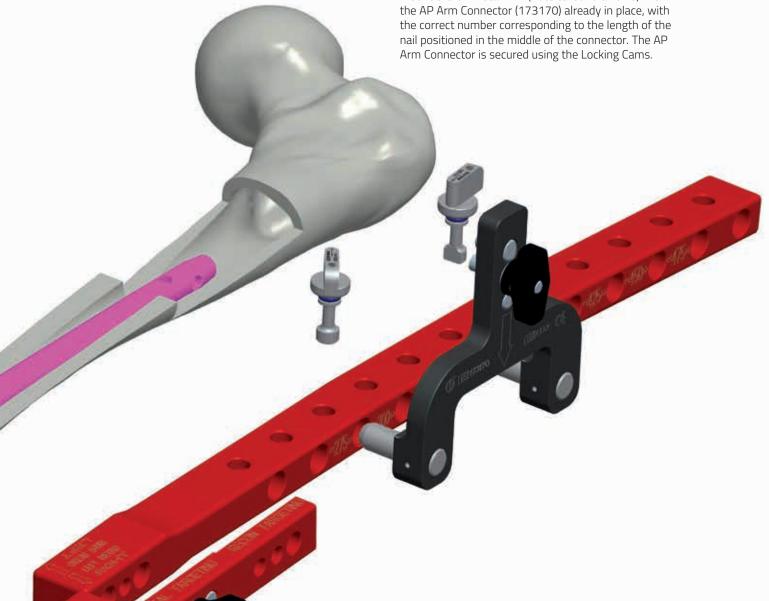
NB: Condylar compression locking screws can be used in any of the 3 distal locking holes. The bone on the side where the nut is to go must be reamed to 6mm for a depth of 20mm with the cannulated 6mm drill.





Proximal Locking

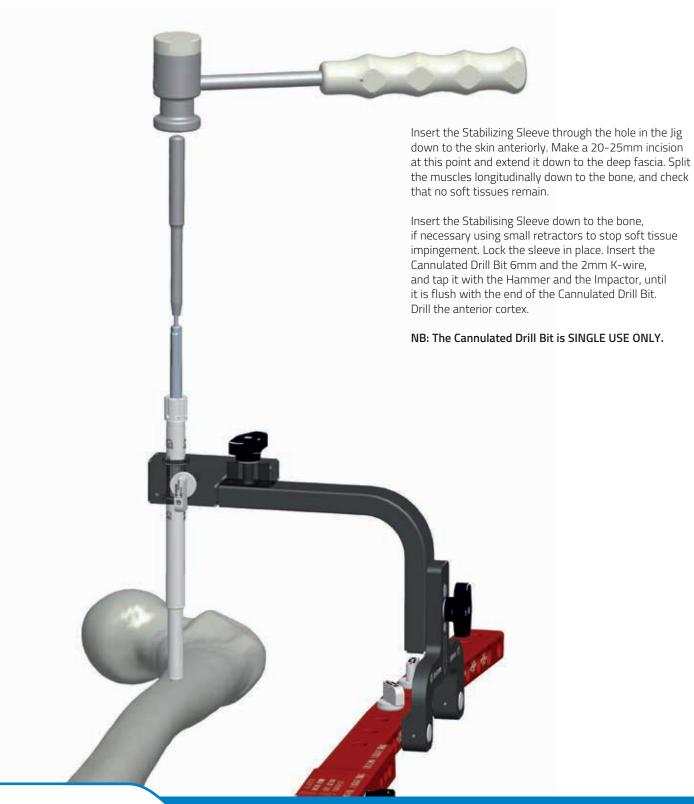
Before proceeding with proximal locking, check that there is no rotational deformity, and that there is no distraction of the fracture site. If the surgeon prefers, it is possible to use the freehand technique for proximal locking. To use the mechanical distal targeting system, mount the UF Distal Arm (note text and arrows) with the AP Arm Connector (173170) already in place, with the correct number corresponding to the length of the nail positioned in the middle of the connector. The AP Arm Connector is secured using the Locking Cams.



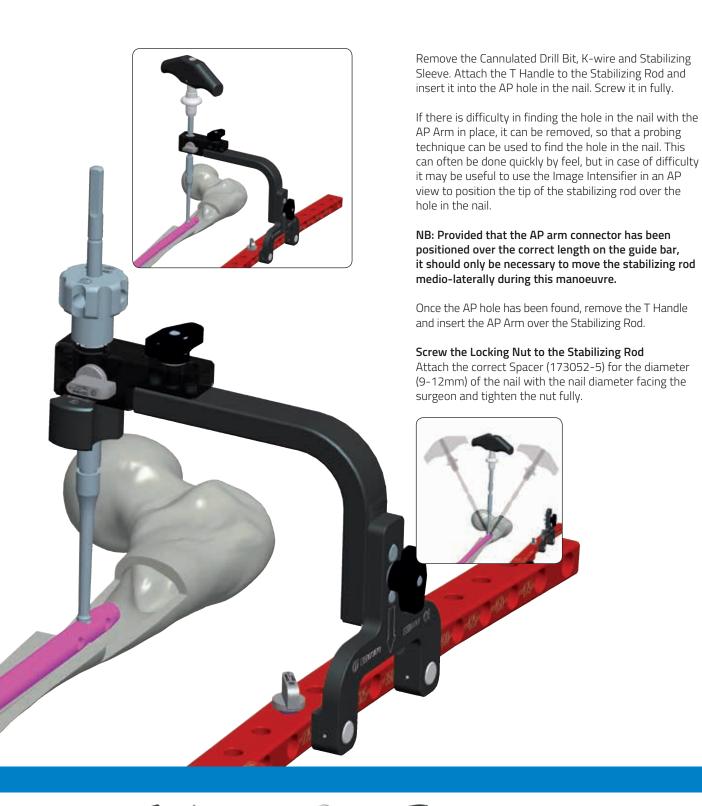












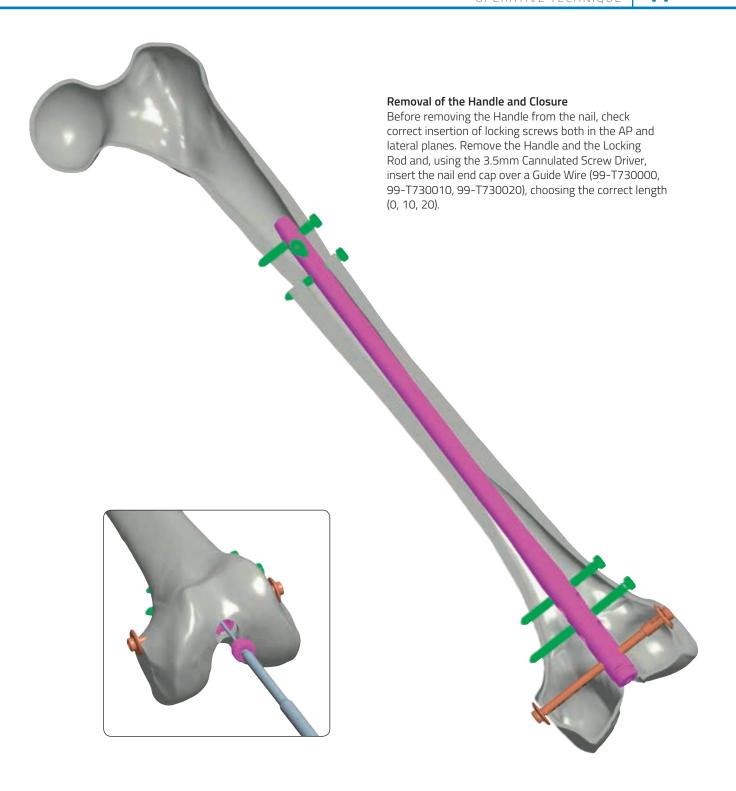


Screw the Trocar into the Screw Guide and insert them both into one of the two holes in the UF Distal Arm. Unscrew the Trocar and push the Screw Guide until it is flush against the bone. Tighten the Screw Guide with the Locking Cam. Remove the Trocar and screw in the Drill Guide. Drill with the 4.8mm Drill Bit as before. Stop at the second cortex and measure the screw length using the scale on the Drill Bit. Complete drilling the second cortex, and insert the screw using the 3.5mm Cannulated Screw Driver. Repeat the procedure for the second hole. If a third screw is required in the AP direction, a revision locking screw must be used. Remove the Spacer and Stabilizing Rod with the T Handle. Insert the Screw Guide and Drill Guide. Insert the 4.8mm Drill Bit down to the second cortex, measure the screw length as before. Drill the second cortex, and insert the revision locking It should be noted that inserting a long nail, above the

lesser trochanter into the trochanteric region of the femur, may result in excess local loading of the nail

during weightbearing.

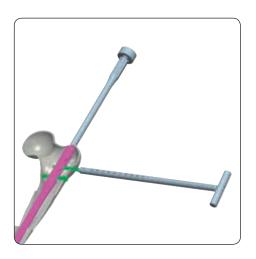
Therefore we recommend the use of both screws from the lateral side and, if required, the AP screw also. In this situation, weightbearing should be limited until callus is seen on the X-ray. Generally a retrograde nail should never be inserted above the lesser trochanter.





NAIL REMOVAL

The Extraction Instruments Box is needed for nail removal. The nail end cap is cleaned of bony ingrowth including the hexagonal recess, and removed with the 3.5mm Cannulated Screw Driver. If seating the Screw Driver is difficult, it may be useful to insert a 2mm K-wire first, and pass the Screw Driver over it. The Femoral Nail Extractor (17391) is screwed fully into the nail. The locking screws are now all removed using the Locking Screw Extractor (17652), which is turned anti-clockwise to engage the reverse thread on the screw heads. The Extractor Handle (170035) is screwed onto the Sliding Hammer (173370 and attached to the Femoral Nail Extractor. The nail is then removed by reverse hammering.





17391Femoral
Nail Extractor





170035 Extractor Handle



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. | |
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