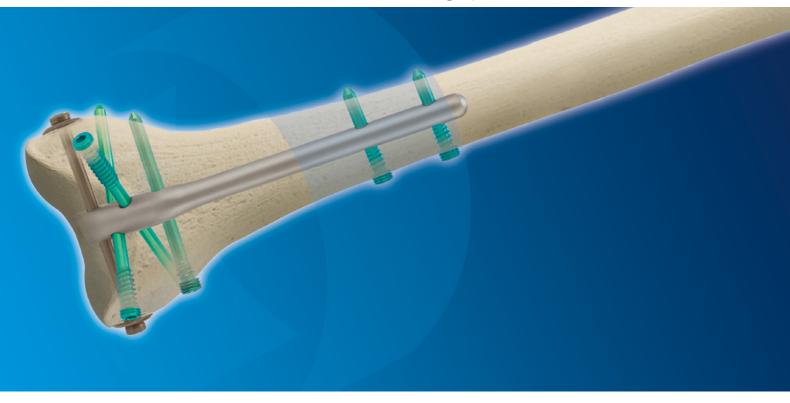


# **CentroNail®**

Nailing System



The Centronail
Titanium Supracondylar
and Retrograde
Nailing System



- 1 FEATURES AND BENEFITS
- 2 Locking Screws
- 2 INDICATIONS
- **3 EQUIPMENT REQUIRED**

# **OPERATIVE TECHNIQUE**

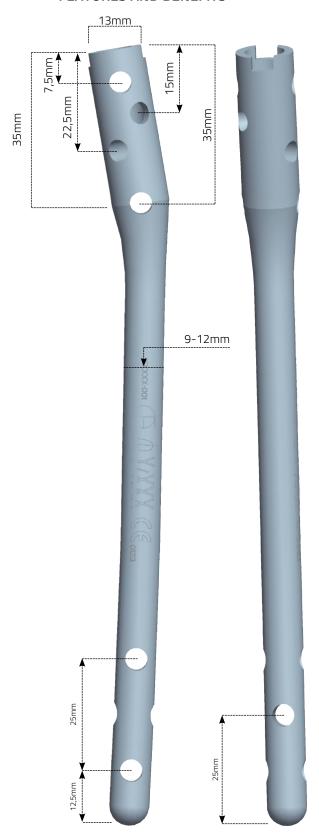
- 7 Entry Portal
- 8 Measurement of Nail Length
- **9** Reaming
- 10 Nail Insertion
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- 14 Proximal Locking
- 20 Removal of the Handle and Closure
- 21 Nail Removal

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 Allow MRI investigation, if necessary

13mm proximal diameter

9-12mm distal diameter 9mm is solid

10° Angle

One design for Left and Right femur

130-375mm (25mm increments)

Radius of curve 2500mm

# Locking screws

#### TITANIUM STANDARD LOCKING SCREWS

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



#### TITANIUM REVISION LOCKING SCREWS

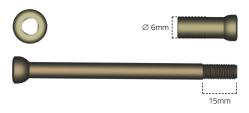
8mm thread diameter Better purchase in poor quality bone 4.8mm shaft diameter 4.8mm drill bit



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

#### TITANIUM CONDYLAR COMPRESSION SCREWS

- 4.8mm diameter
- 4.8mm drill bit
- 6.0mm drill bit in 2nd cortex for nut

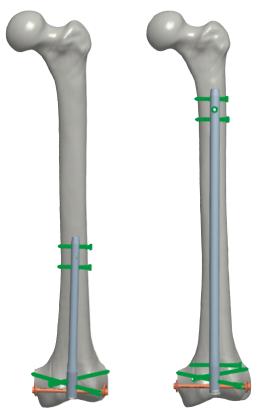


Cannulated: easy placement of condylar washer and nut over a K-wire.

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

#### **INDICATIONS**

Inter- and supra-condylar Supra-condylar fractures fractures with diaphyseal extension



### **EQUIPMENT REQUIRED**

| Centronail Titanium Sup | racondylar Intram <u>edulla</u> | ıry Nails  |
|-------------------------|---------------------------------|------------|
| Ø 9 L 130               | Solid                           | 99-T769130 |
| Ø 9 L 150               | Solid                           | 99-T769150 |
| Ø 9 L 175               | Solid                           | 99-T769175 |
| Ø 10 L 130              | Cannulated                      | 99-T760130 |
| Ø 10 L 150              | Cannulated                      | 99-T760150 |
| Ø 10 L 175              | Cannulated                      | 99-T760175 |
| Ø 10 L 200              | Cannulated                      | 99-T760200 |
| Ø 10 L 225              | Cannulated                      | 99-T760225 |
| Ø 11 L 130              | Cannulated                      | 99-T761130 |
| Ø 11 L 150              | Cannulated                      | 99-T761150 |
| Ø 11 L 175              | Cannulated                      | 99-T761175 |
| Ø 11 L 200              | Cannulated                      | 99-T761200 |
| Ø 11 L 225              | Cannulated                      | 99-T761225 |
| Ø 11 L 250              | Cannulated                      | 99-T761250 |
| Ø 11 L 275              | Cannulated                      | 99-T761275 |
| Ø 11 L 300              | Cannulated                      | 99-T761300 |
| Ø 11 L 325              | Cannulated                      | 99-T761325 |
| Ø 11 L 350              | Cannulated                      | 99-T761350 |
| Ø 11 L 375              | Cannulated                      | 99-T761375 |
| Ø 12 L 130              | Cannulated                      | 99-T762130 |
| Ø 12 L 150              | Cannulated                      | 99-T762150 |
| Ø 12 L 175              | Cannulated                      | 99-T762175 |
| Ø 12 L 200              | Cannulated                      | 99-T762200 |
| Ø 12 L 225              | Cannulated                      | 99-T762225 |
| Ø 12 L 250              | Cannulated                      | 99-T762250 |
| Ø 12 L 275              | Cannulated                      | 99-T762275 |
| Ø 12 L 300              | Cannulated                      | 99-T762300 |
| Ø 12 L 325              | Cannulated                      | 99-T762325 |
| Ø 12 L 350              | Cannulated                      | 99-T762350 |
| Ø 12 L 375              | Cannulated                      | 99-T762375 |

| End Caps |            |
|----------|------------|
| L 0mm    | 99-T760000 |
| L 10mm   | 99-T760010 |
| L 20mm   | 99-T760020 |

#### 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

| The Vision Educating Serieurs |             |  |  |  |
|-------------------------------|-------------|--|--|--|
| 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

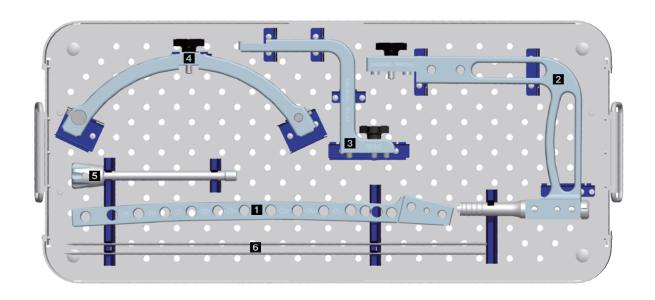
Orthofix supplies the Centronail Titanium Supracondylar and Retrograde Nail, locking screws and end caps in a STERILE package, while the instruments are supplied NONSTERILE. Please check the sterility of each device on the product label.

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.

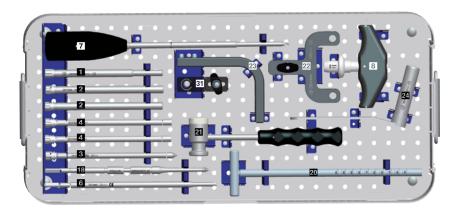
#### 4.8mm Titanium Condylar Screw Kit

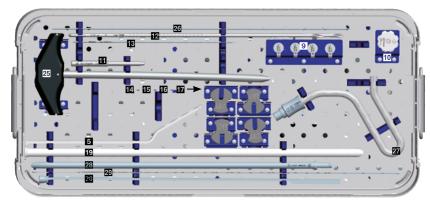
| •          |             |
|------------|-------------|
| Code       | Length (mm) |
| 99-T766060 | 60          |
| 99-T766065 | 65          |
| 99-T766070 | 70          |
| 99-T766075 | 75          |
| 99-T766080 | 80          |
| 99-T766085 | 85          |
| 99-T766090 | 90          |
| 99-T766095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



# SUPRACONDYLAR AND RETROGRADE SPECIFIC INSTRUMENTS BOX, EMPTY (176991) can accommodate:

| Part # |   | Description                                    | Qty |
|--------|---|--|-----|
| 176101 | 1 | SC DISTAL ARM                                  | 1   |
| 176110 |   | SC HANDLE                                      | 1   |
| 176120 | 3 | SC MIDDLE ARM                                  | 1   |
| 176130 | 4 | SC CURVED ARM                                  | 1   |
| 176140 | 5 | SC LOCKING ROD                                 | 1   |
| 80122  | 6 | X-WIRE WITHOUT OLIVE DIAMETER 2MM LENGTH 400MM | 3   |





# GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

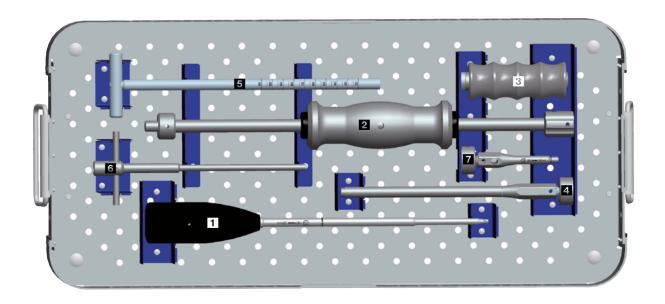
| Part # |    | Description                     | Qty |
|--------|----|---------------------------------|-----|
| 173201 | 1  | STABILIZING SLEEVE              | 1   |
| 173211 |    | SCREW GUIDE                     | 2   |
| 173212 | 3  | TROCAR                          | 1   |
| 173213 |    | DRILL 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<br>STERILE |

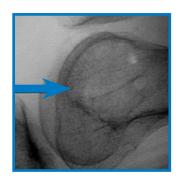
# GENERAL INSTRUMENTS BOX, EMPTY (173997) can accommodate:

| 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  | 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   |



# 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   |
|        |   |                                   |     |

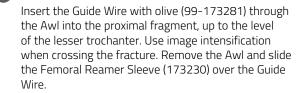


## **OPERATIVE TECHNIQUE**

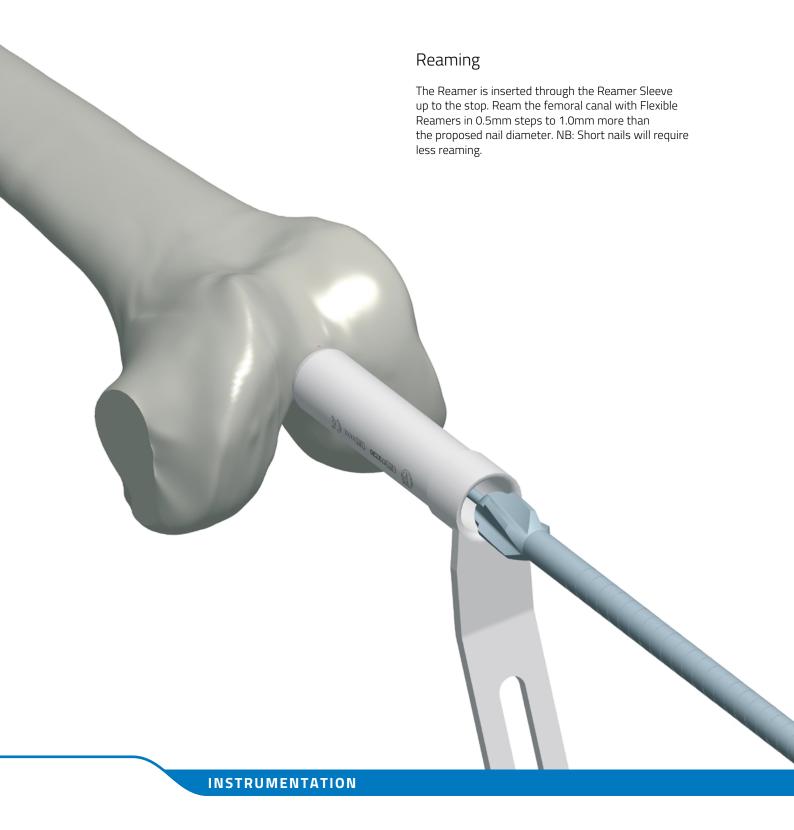
Whenever possible, femoral fractures should be stabilized within the first 24 hours following injury, provided the patient's condition will allow it. Do not start surgery unless the fracture is well reduced.

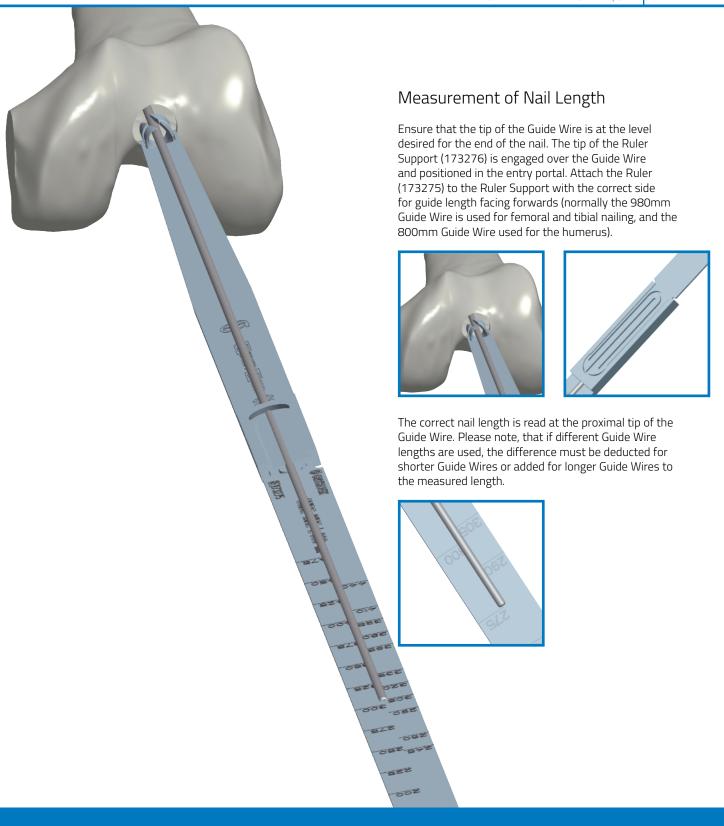
# **Entry Portal**

The patient is placed supine with the knee flexed at 50°. Make a 4-6 cm medial para-patellar incision and retract the patellar tendon and fat pad to the lateral side. With the Awl (173260) make the entry point in the intercondylar notch, in Line with the long axis of the femoral shaft in both the AP and coronal planes, using Blumensaat's line in the lateral view.









**173270** Cannulated Rigid Reamer

**173276** Ruler Support **173275** Ruler



The Exchange Tube (17353) is inserted into the reamed femur over the Guide Wire, checking that it extends past the fracture. The Olive Tipped Guide Wire is removed, and the plain 2.5x980mm Guide Wire (99–176281) inserted, checking that the tip is central in the femoral canal.

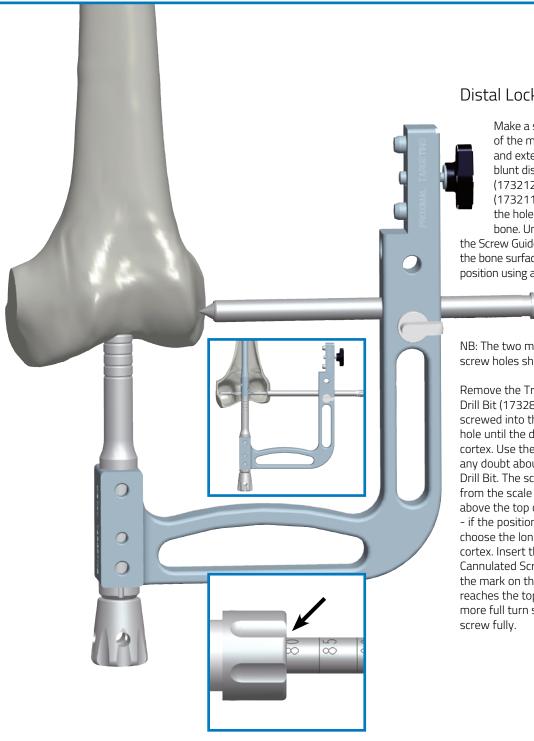
## Nail Insertion

Insert the Supracondylar (SC) Locking Rod (176140) into the back of the SC Handle (176110) and the nail of correct diameter and length into the nail support. Check that the wings are engaged in the nail correctly so that the nail curvature corresponds to the curvature of the femur to be treated and tighten the Locking Rod using the Impactor (173071) inserted in the holes in the 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. Hammering should always be gentle. Do not persist if the nail is not advancing. Remove it and ream some more. The distal end of the nail must be proximal to the surface of the intercondylar notch, to prevent the nail end protruding into the knee joint. Use the rings on the nail support to confirm that the end of the nail is inside the bone.

DO NOT HAMMER THE HANDLE ITSELF.
THE GUIDE WIRE MUST NOW BE REMOVED.





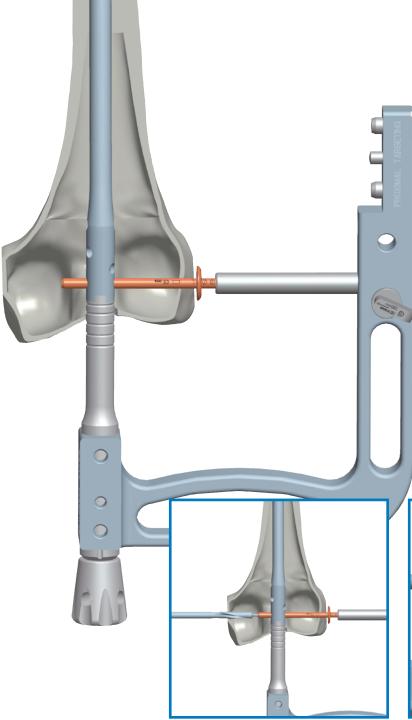
# Distal Locking

Make a stab incision at the level of the most distal hole in the Handle 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 Handle, 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 using a Locking Cam (173026).

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

Remove the Trocar and, using a 4.8mm Drill Bit (173286) and Drill Guide (173213) screwed 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



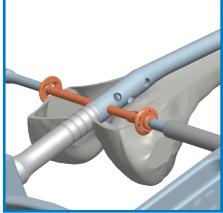


If a condylar compression locking screw is inserted, lift the Screw Guide and slip a condylar washer (T766005) underneath it with the curved side

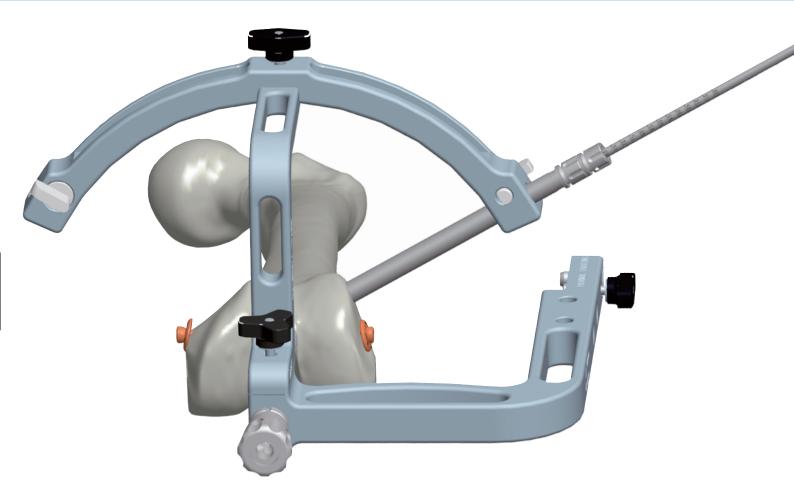
facing outwards. Insert the screw using the 3.5mm Cannulated Screw Driver. Insert a K-wire 2mm, 400mm long (80122) through the compression screw to locate the position of the incision on the medial side. Incise the skin and ream the pilot hole in the bone to 6mm for a depth of 20mm with the Cannulated Drill Bit 6mm (99-173285).

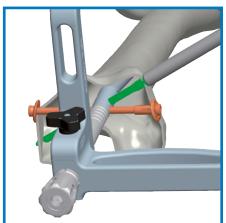
Insert a Condylar Nut (T766000) with washer and tighten both as shown to achieve compression. The condylar locking screw head must be fixed with the 3.5mm Cannulated Screw Driver while the condylar nut is tightened with the Screw Wrench Adapter (173302) attached to the T Handle (173350). If adequate compression cannot be achieved, replace with a shorter screw.

Insert the second transverse locking screw.







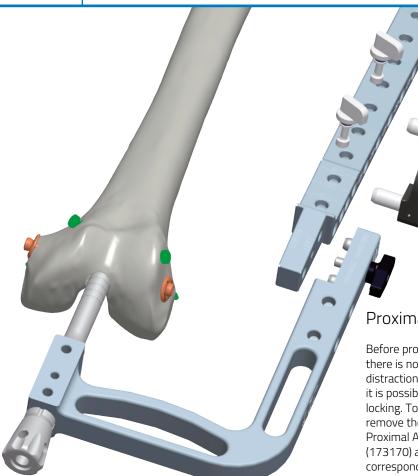


If oblique locking screws are required, attach the SC Middle Arm (176120) and then the SC Curved Arm (176130) to the Handle. Tighten both knobs firmly. Screw the Trocar into the Screw Guide and insert them into the lateral hole in the curved arm. Push them down to the bone. Unscrew the Trocar and push 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 screwed into the Screw Guide, drill the hole. Measure the correct screw length as before.

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







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, remove the distal locking arms and mount the SC Proximal Arm (176101) 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.

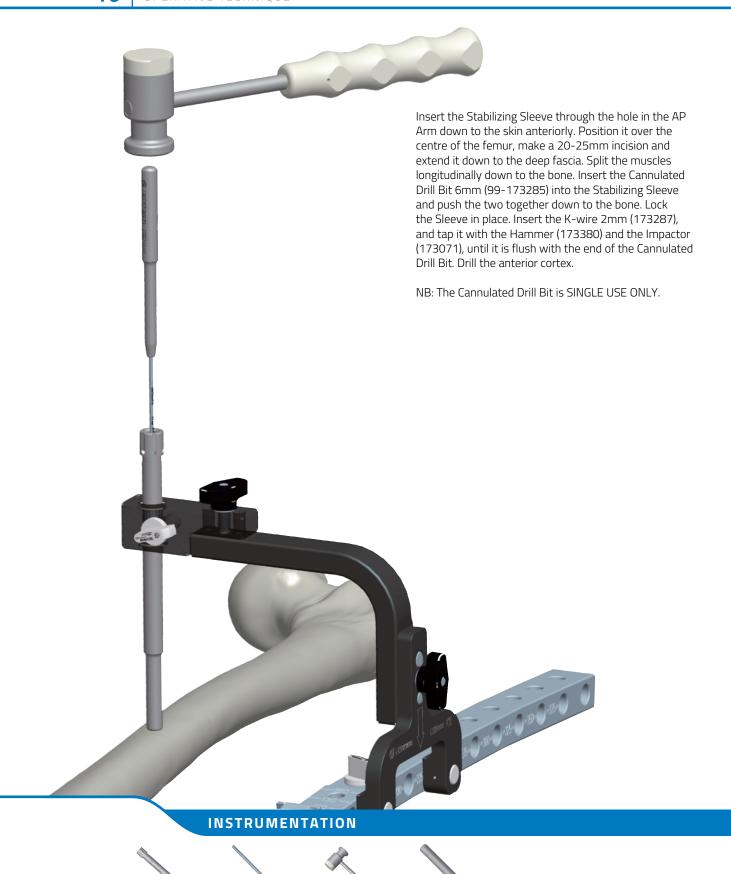




Mount the AP Arm (173180) with the AP Centering Jig. The hole in the Centering Jig (173185) has two targeting rings to enable it to be centred over the nail. The Image Intensifier is positioned over the Jig so that the two rings appear as one ring. If the rings are not central over the nail hole the Jig is moved medially or laterally until they are centered.

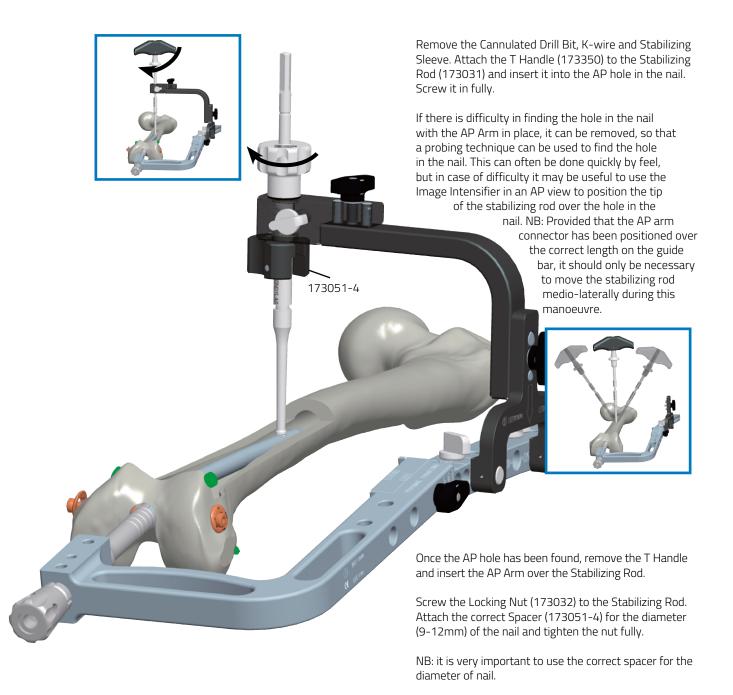






**173201** Stabilizing Sleeve

99-173285 Cannulated Drill Bit 6mm **173380** Hammer **173071** Impactor



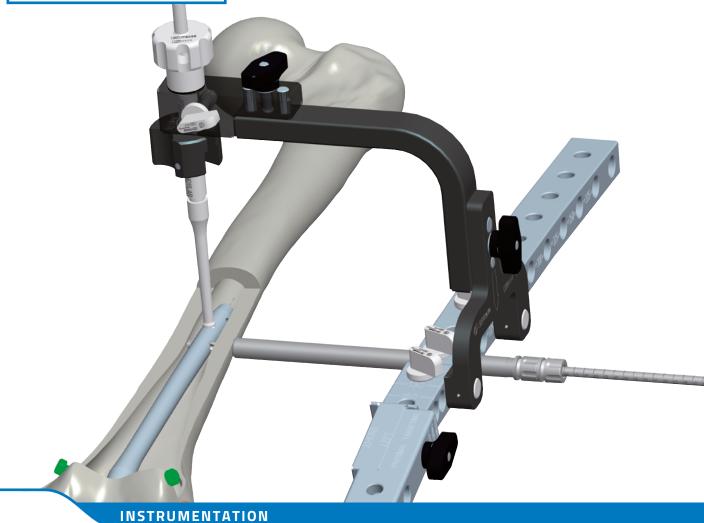


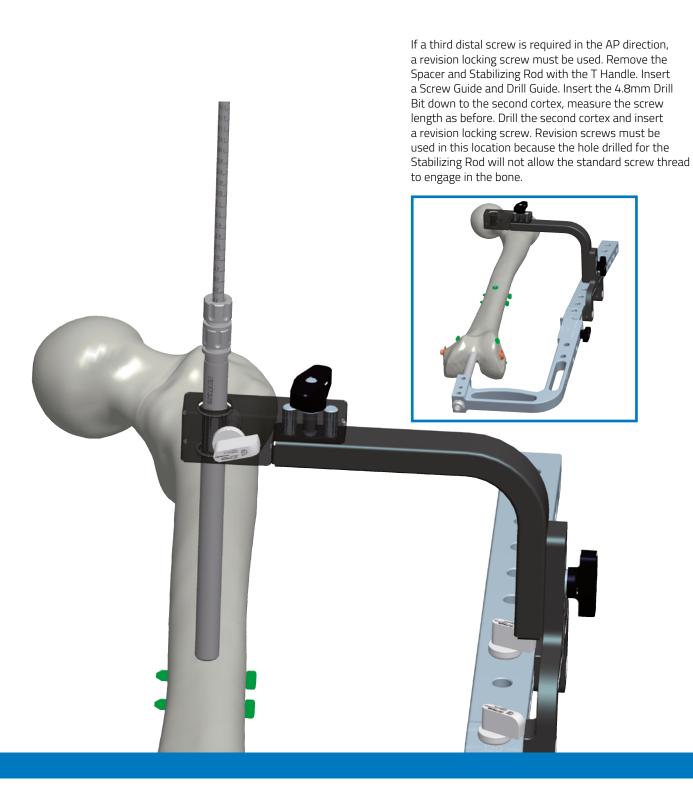


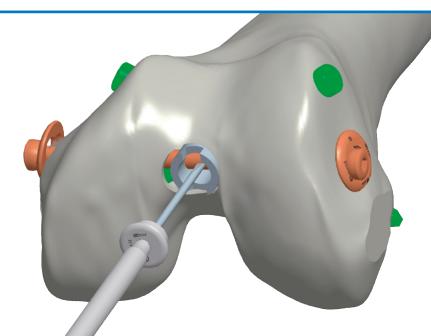
Screw the Trocar into the Screw Guide and insert them both into one of the two holes in the SC Proximal Arm (176101). Unscrew the Trocar and push the Screw Guide until it is sitting flush against the bone surface. Tighten the Screw Guide with the Locking Cam. Remove the Trocar and screw the Drill Guide 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 (173320).

Repeat the procedure for the second hole.



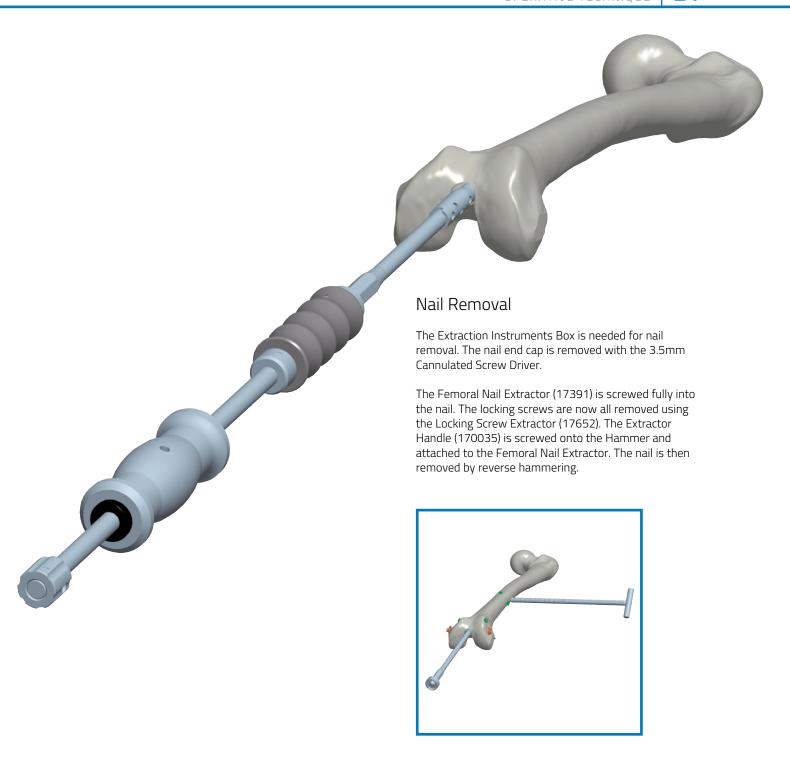




# Removal of the Handle and Closure

Before removing the Handle from the nail, check correct insertion of locking screws both in the AP and lateral planes. Remove the Handle and Locking Rod and, using the 3.5mm Cannulated Screw Driver, insert the nail end cap over a K-wire (99-T760000, 99-T760010, 99-T760020), choosing the correct length (0, 10, 20), and avoiding protrusion into the joint.







# **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.



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





