

Surgical Technique

Konzept Fibula & Forearm Nailing System

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements



INTRODUCTION

KONZEPT FIBULA & FOREARM NAIL

INTRAMEDULLARY OSTEOSYNTHESIS OF FIBULA AND FOREARM BONES consists of:

- implants (intramedullary nail, locking screws, compression screw and end cap),
- instrument set for implants implantation and extraction after finished treatment,
- instructions for use.

Intramedullary osteosynthesis of fibula and forearm bones provides stable fragments reduction of shaft of ulnar and radial bones (forearm) and fibula in closed or open fractures and also in osteoporotic bone injuries.

Indications:

- transverse, oblique and multifragmental fractures of the shaft of ulna, radius and fibula,
- fractures of fibula in ankle joint area.



FIG. 1. Examples of fractures treated with **KONZEPT FIBULA & FOREARM NAIL**:

- a) multi-fragmental fractures of the ulna shaft,
- b) oblique fractures of the ulna and radius shaft,
- c) fibula fractures in the ankle joint area with simultaneous transverse shaft fracture.

WARNING:

Given description contains the most important stages of the forearm and fibula bones intramedullary nailing procedure, but does not form strict directions for use. A surgeon decides about the surgical technique and its implementation for specific case.

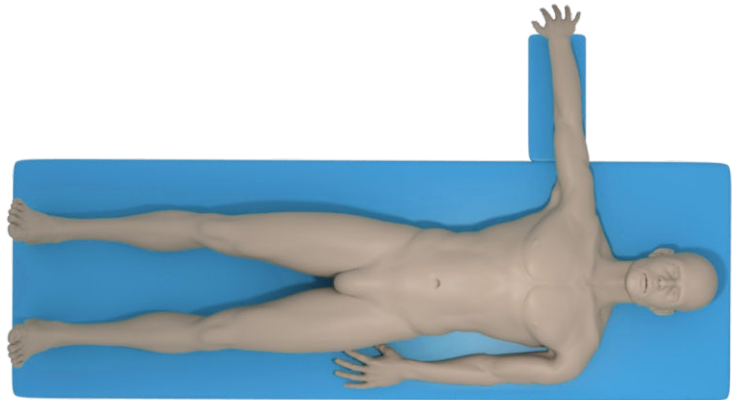
1. SURGERY PLANNING

Every surgical procedure has to be planned in an appropriate way. X-Ray of the fractured bone in AP and lateral position shall be performed before starting the operation in order to define the fracture type as well as intramedullary nail size and bending.

Given description contains the most important stages of the forearm and fibula bones through advance nailing procedure, but does not form strict directions for use. A surgeon decides about the surgical technique and its implementation for specific case.

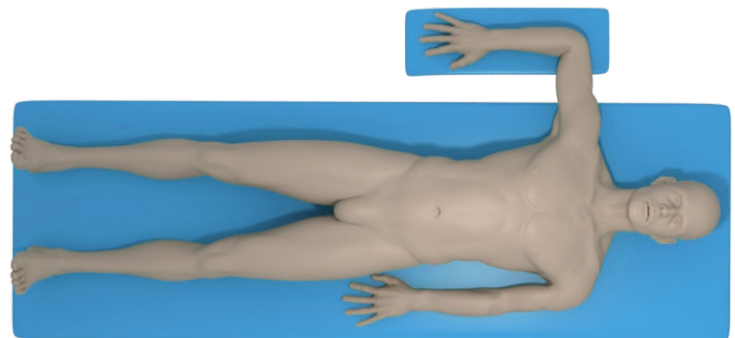
Patient positioning for radius operation

In case of radius operation, the patient should be positioned supine. The fractured limb should be abducted in humerus joint at an angle of 90°, bent in wrist by free fall of the hand and fixed in a traction clamp



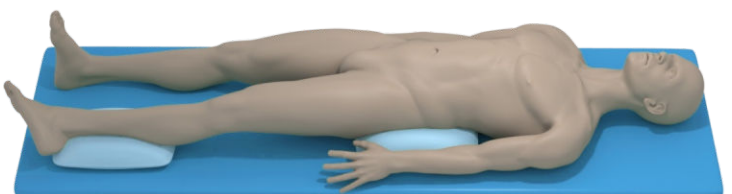
Patient positioning for ulna operation

In case of ulna fracture treatments, the patient should be positioned supine. The fractured limb should be abducted in humerus joint at the angle of 90° and bent in elbow joint at the angle of 90° and fixed in a traction clamp. X-Ray set with display monitor should be located perpendicular to the anterior area of forearm.



Patient positioning for fibula operation

In case of fibula operation the patient should be positioned supine. Internal rotation of the limb improves access to the place of nail insertion. It is important to place surgery pillows under the pelvis and the leg to allow easier surgical approach and X-Ray control during the operation. Fix the limb in a traction clamp.



2. NAILING POINT

Preparation of surgical approach for ulna operation and setting the entry point for nail insertion

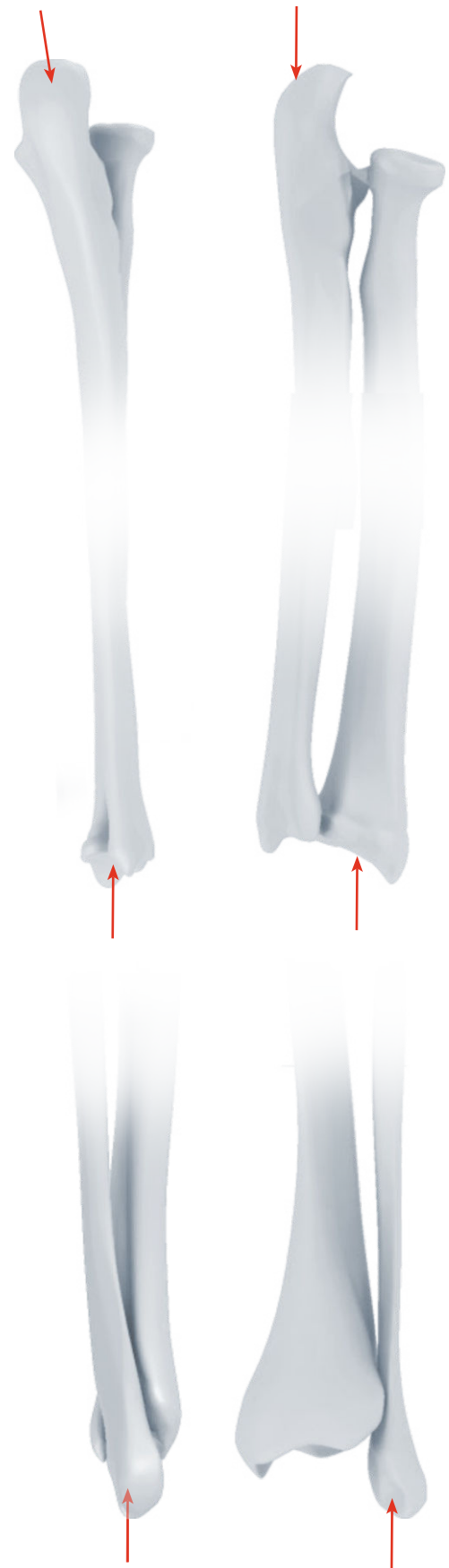
To prepare surgical approach for ulna nailing, uncover the olecranon process by making longitudinal 1cm skin incision above the olecranon tip (proximal part of ulna). The entry point for intramedullary nail is in line with the centre of the medullary canal and in the centre of the upper olecranon process. Care should be taken of the rotation of fragments of fractured bone (coronoid process of the ulna should be positioned at an angle of 180° against the styloid process of ulna).

Preparation of surgical approach for radius operation and setting the entry point for nail insertion

Make 2.5-3cm longitudinal skin incision over the area of distal wrist above the fourth extensor compartment (distal part of radius) to prepare surgical approach for radius nailing. Make blunt dissection of subcutaneous tissues to avoid injury to the dorsal radial nerve branches. The extensor digitorum tendons are retracted to the direction of the ulna. The entry point for intramedullary nail is located 5 mm from the articular space, on the elbow side of Lister tubercle. Care should be taken of the anatomical position of deep radial nerve branch and the rotation of fragments of fractured bone (tuberosity of the radius should be positioned at an angle of 180° against the styloid process of radius).

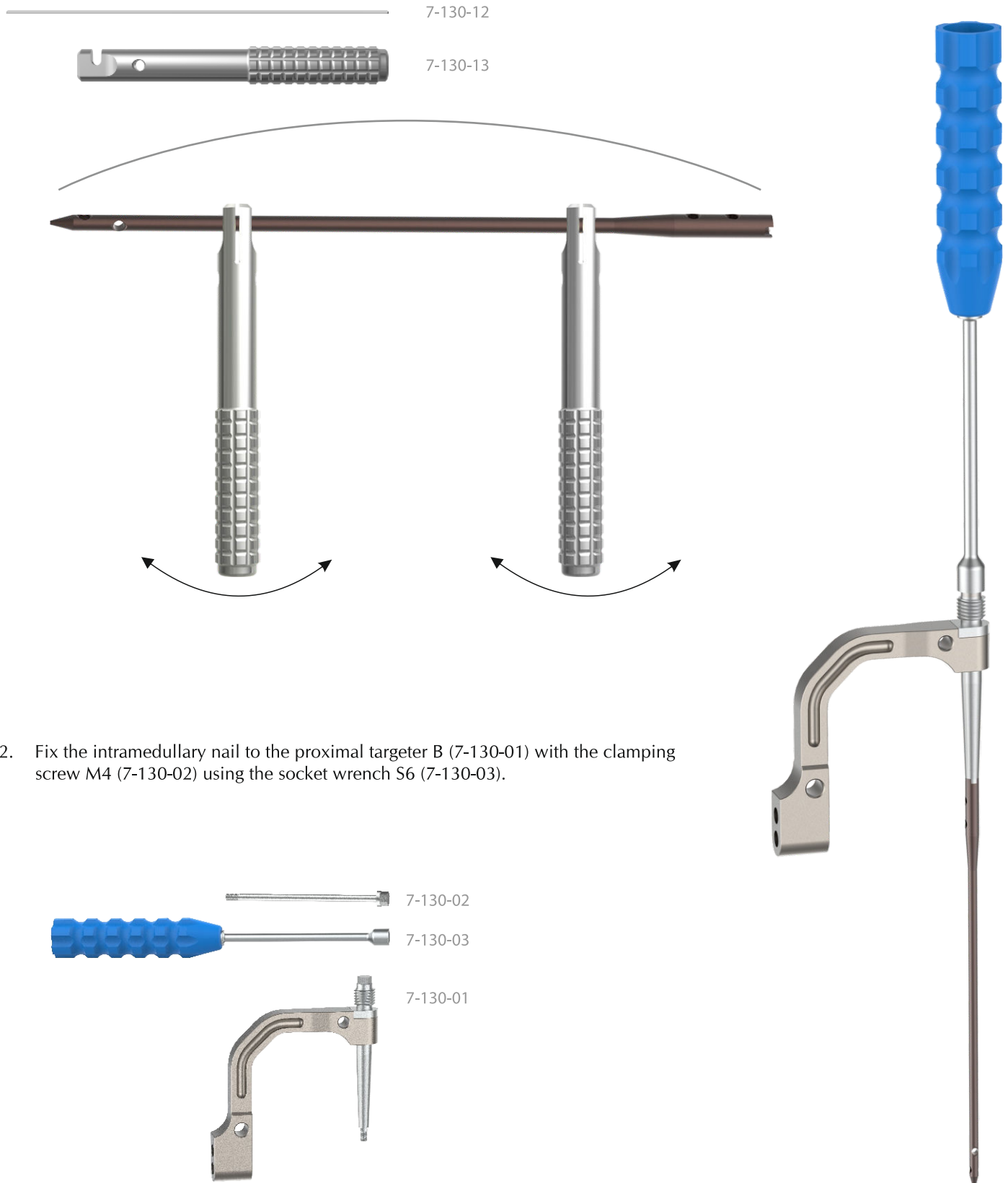
Preparation of surgical approach for fibula operation and setting the entry point for nail insertion

Make 2cm longitudinal skin incision in the area of ankle joint (distal part of fibula) to prepare surgical approach for fibula nailing. The incision should be performed posterior to the distal fibula anteriorly directed to the fourth metatarsal, between the sural and superficial peroneal nerve branches. The entry point for intramedullary nail is in line with the centre of the medullary canal, at the medial line of lateral ankle.



3. PREPARATION OF THE INTRAMEDULLARY NAIL

1. After X-Ray of fractured bone (also X-Ray of healthy limb is recommended), define the length and diameter of nail and its shape using the nail trial (7-130-12). The bending is carried out with use of two benders (7-130-13). Hold the nail using the benders and bend the nail applying hand force. Do not hold the nail ends (outside the holes), as it could cause damage in holes area.



2. Fix the intramedullary nail to the proximal targeter B (7-130-01) with the clamping screw M4 (7-130-02) using the socket wrench S6 (7-130-03).

4. OPENING THE MEDULLARY CANAL

3. After preparing the surgical approach and locating the entry point for the nail, use the electric drive to insert Kirschner wire (7-130-14) into the medullary canal.

Image intensifier should be used to control the process.

The Kirchner wire acts as a guide for cannulated drill.
The Kirchner wire is a single use instrument.

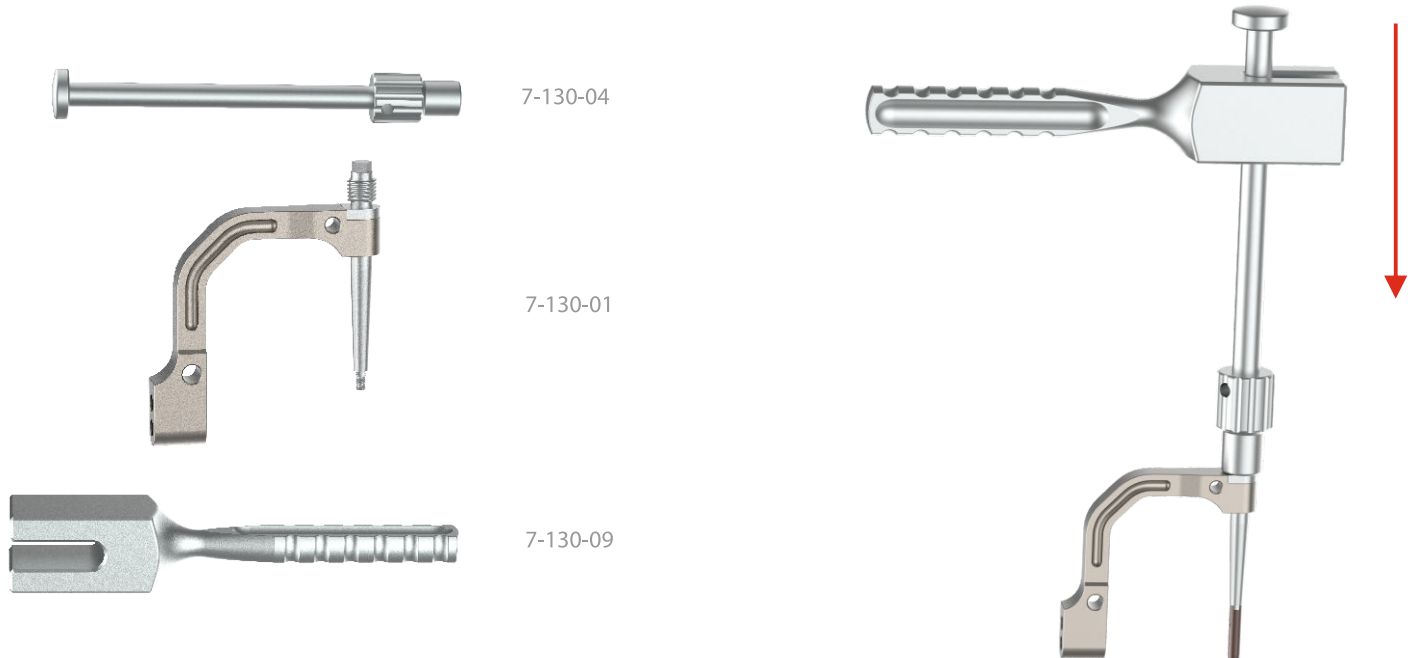


4. Open the medullary canal using the cannulated drill 6/2.2/150 (7-130-15) mounted on the surgical drive, and led via Kirschner wire. remove the cannulated drill and Kirschner wire.

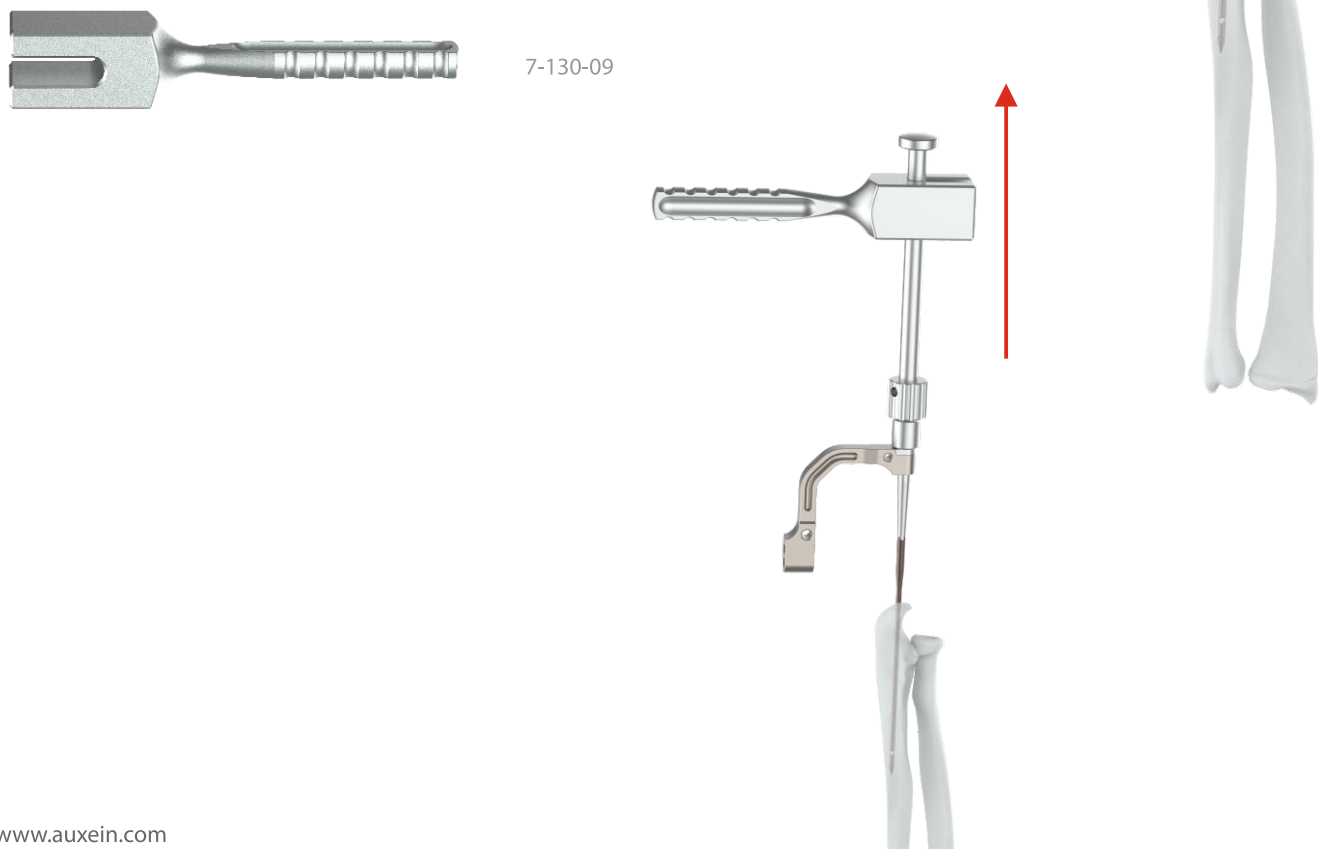


5. NAIL INSERTION INTO MEDULLARY CANAL

5. Connect the impactor-extractor (7-130-04) to the proximal targeter B (7-130-01) (insert it onto the threaded top). Carefully insert the nail into medullary canal using the mallet (7-130-09).



6. Some circumstances may force the surgeon to extract the nail (or remove it partially) without its disconnecting from the targeter B, during the intramedullary nail insertion into medullary canal. This process shall be done with use of mallet (7-130-09)



6. DISTAL LOCKING OF THE INTRAMEDULLARY NAIL

Distal locking of the intramedullary nail in the ulna is made using one locking screw (there is a possibility to use two locking screws) by so-called "freehand" technique.

With this technique an image intensifier is used to determine the drilling point and to drill the hole.

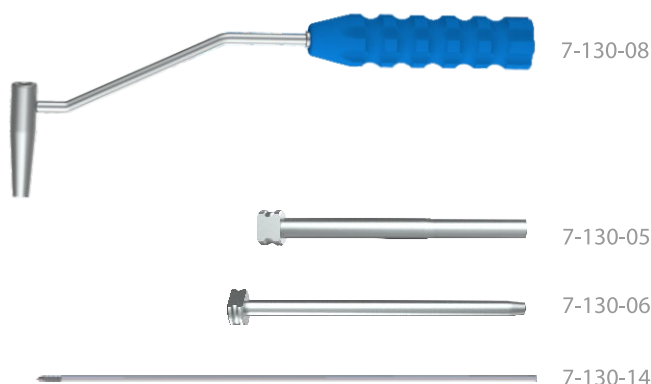
It is recommended to use angular attachment with the surgical drive when drilling the holes, so that surgeon's hands are not directly exposed to X-Rays.

After marking the entry point on the skin for drilling the hole in the bone, 1.5 cm long incision shall be made through the soft tissues.

7. Using X-Ray machine, place the targeter D (7-130-08) in line with the nail hole. The hole in the nail and in the targeter D have to correspond. The teeth of the targeter D have to be inserted into the ulnar cortex. Introduce the protective guide 7/5 (7-130-05) and the Kirschner guide B 5/2 (7-130-06) into the hole in the targeter D. Mount Kirschner wire (7-130-14) in the electric drive and leading through the Kirschner guide, drill the hole in the bone through both cortices.

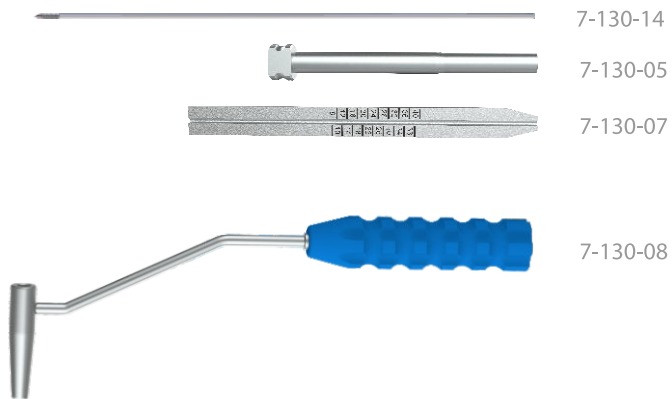
Use the image intensifier to control drilling process.

Leave Kirschner wire, guides and the targeter in place.



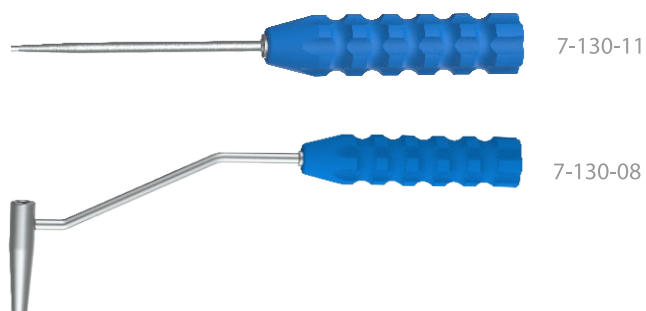
8. Place the screw length measure (7-130-07) onto the Kirschner wire (7-130-14) (left in the Kirschner guide B 5/2 (7-130-05)) until its tip rests on the guide. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire.

Remove the measure, Kirschner wire and both guides. Leave the targeter D in place.



9. Introduce the tip of the hexagonal screwdriver S2.5 (7-130-11) into the hexagonal socket of the selected locking screw. Then advance both into the targeter D (7-130-08) and insert the locking screw in the prepared hole until the head of the screw reaches the bone cortex.

Remove the screwdriver and the targeter D.



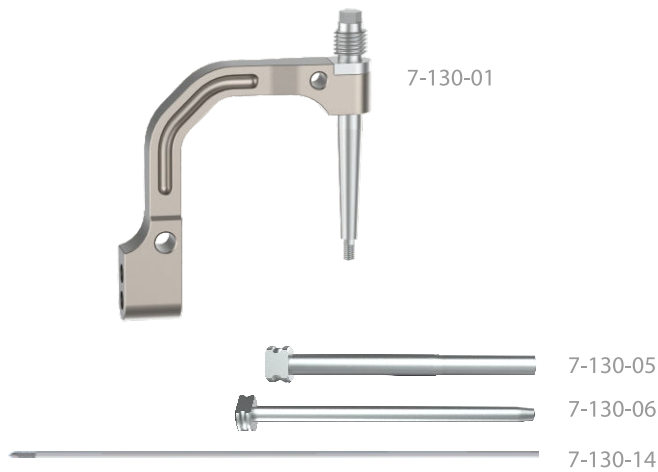
7. PROXIMAL LOCKING OF THE INTRAMEDULLARY NAIL

Proximal locking of the intramedullary nail in the ulna is made using two locking screws.

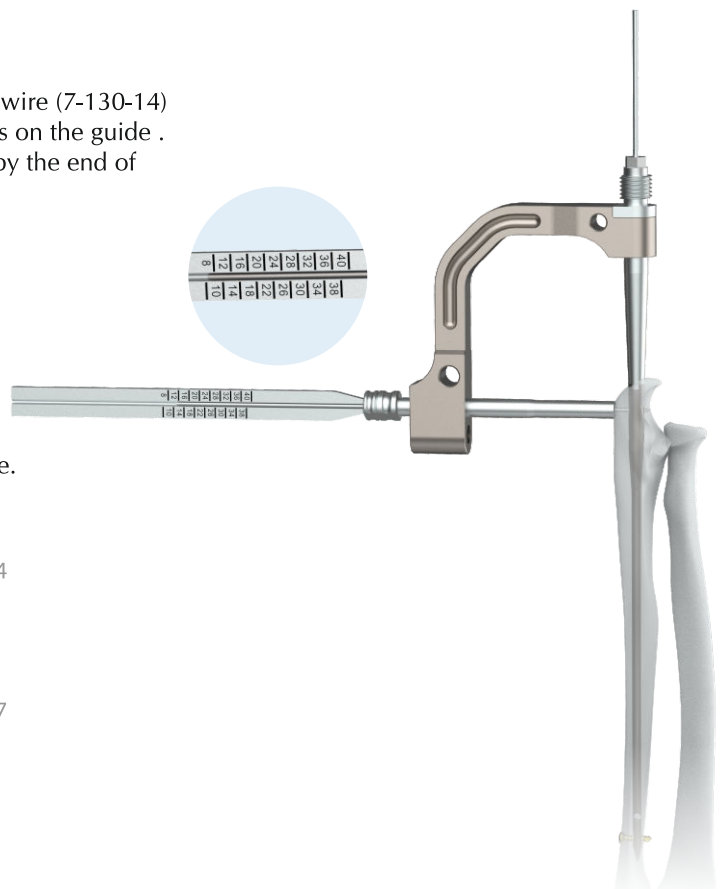
10. Insert the protective guide 7/5 (7-130-05) with the Kirschner guide B 5/2 (7-130-06) into the distal hole in the proximal targeter B (7-130-01). Mount Kirschner wire (7-130-14) in the electric drive and leading through the Kirschner guide, drill the hole in the bone through both cortices.

Image intensifier should be used to control the drilling process.

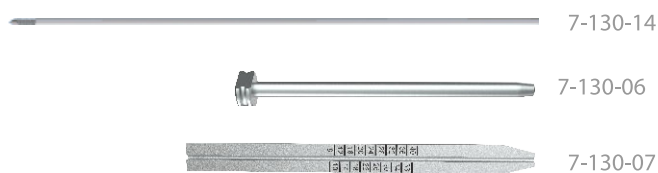
Leave the Kirschner wire and the guides in place.



11. Place the screw length measure (7-130-07) on Kirschner wire (7-130-14) (left in the Kirschner guide B 5/2 (7-130-06)) until its tip rests on the guide. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire.

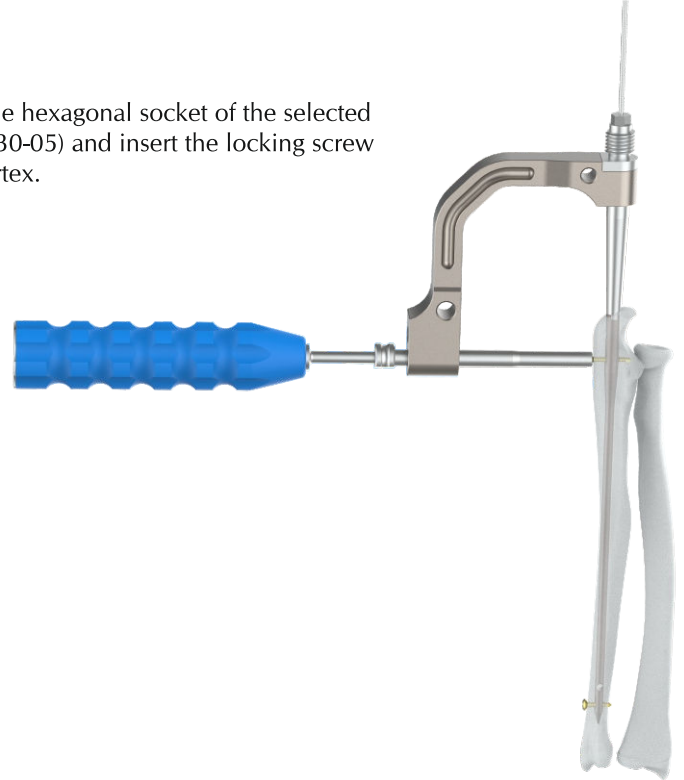
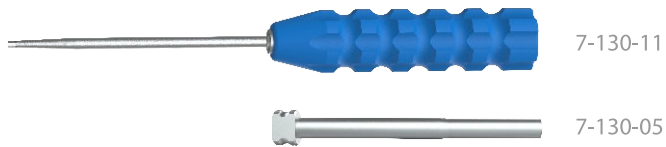


Remove the measure, Kirschner wire and the Kirschner guide.

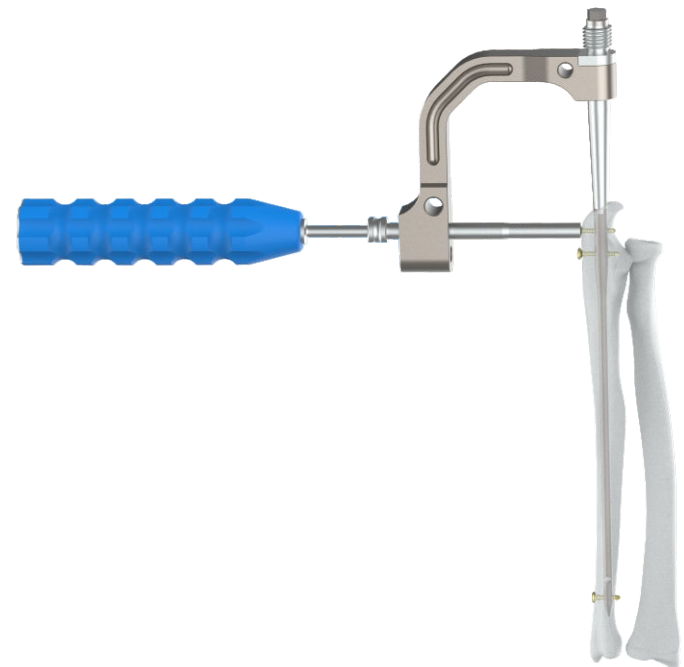
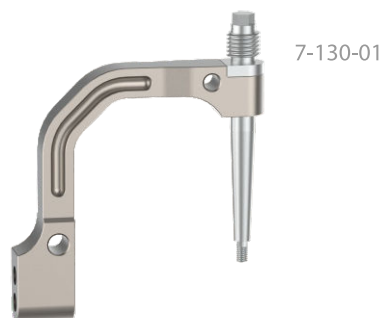


12. Insert the tip of the hexagonal screwdriver S2.5 (7-130-11) into the hexagonal socket of the selected locking screw. Then advance both into the protective guide 7/5 (7-130-05) and insert the locking screw in the prepared hole until the head of the screw reaches the bone cortex.

Remove the screwdriver and the protective guide.

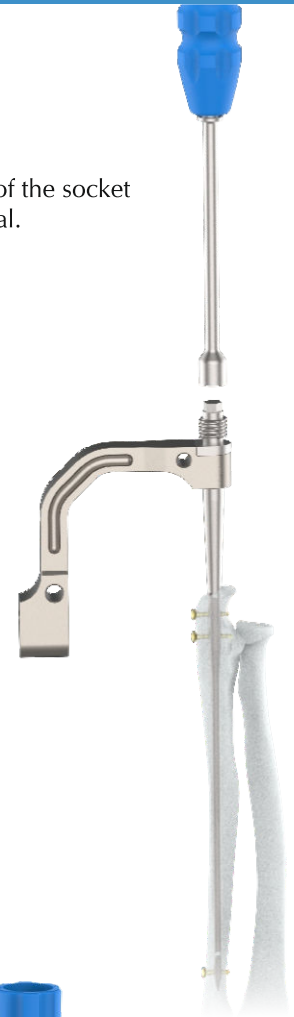
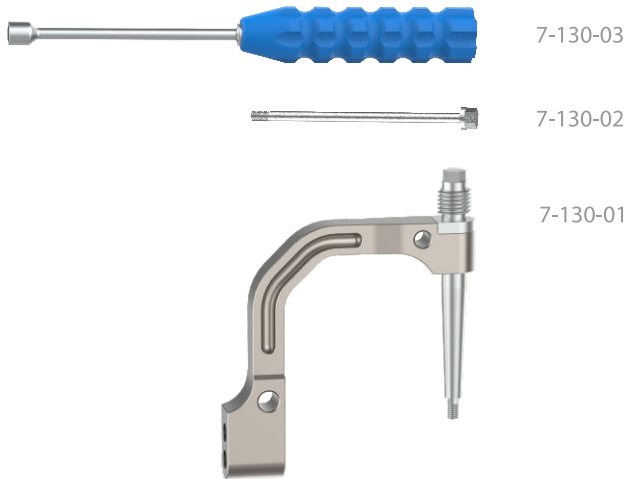


13. Locking the nail with the other locking screw should be performed using proximal hole in the targeter B (7-130-01) and according to steps 10 to 12 of the instructions.



8. PLACEMENT OF END CAP

14. Unscrew the clamping screw M4 (7-130-02) from the shaft of the intramedullary nail with use of the socket wrench S6 (7-130-03). Remove the targeter B (7-130-01) from the nail locked in the medullary canal.



15. In order to secure the inner thread of the nail against bone ingrowth, insert KONZEPT FIBULA & FOREARM NAIL End cap M4x0.7 (1-042-01TI). (implant) into the threaded hole using the hexagonal screwdriver S2.5 (7-130-11).

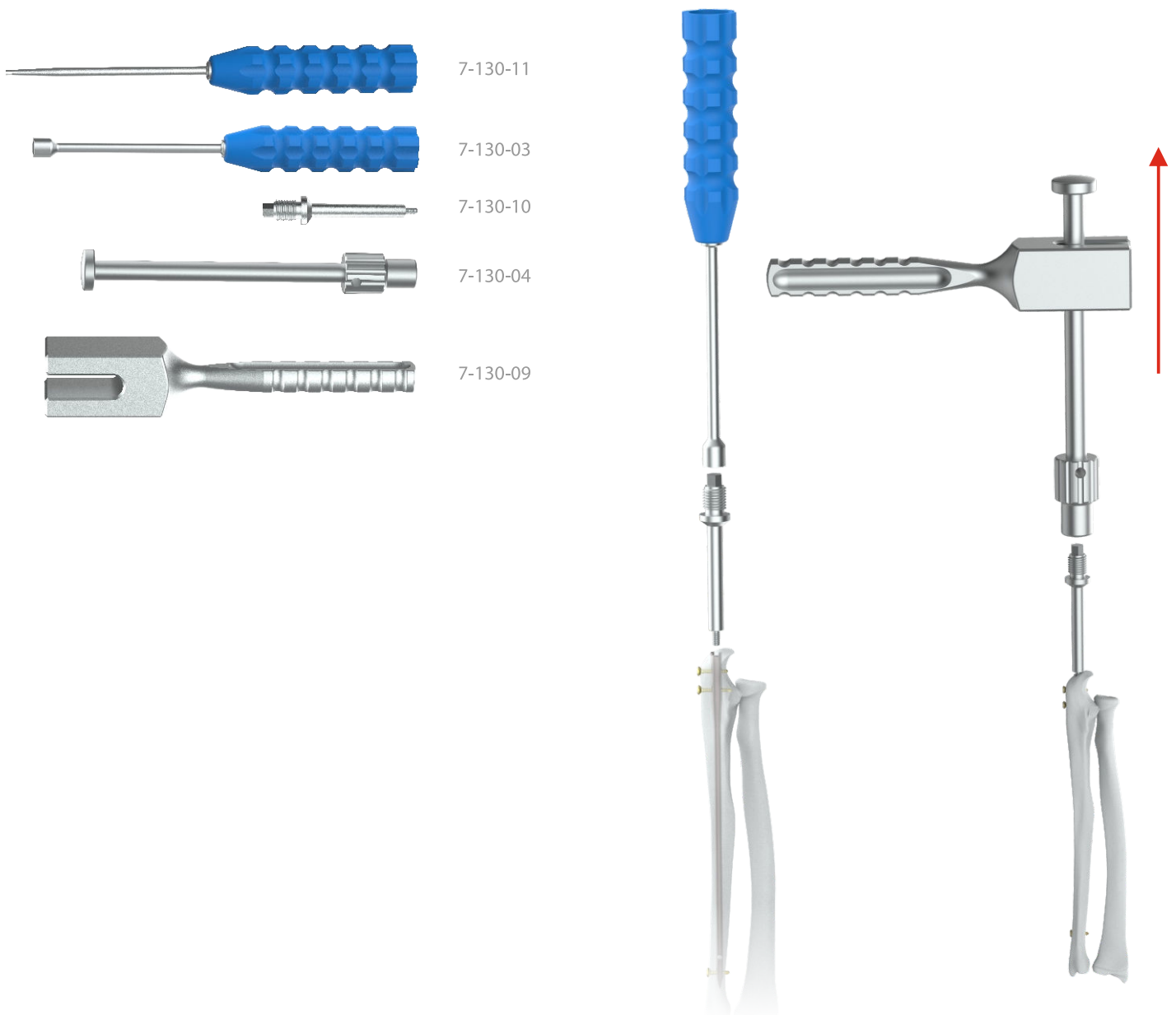


9. INTRAMEDULLARY NAIL EXTRACTION

Use the hexagonal screwdriver S2.5 (7-130-11) to remove KONZEPT FIBULA & FOREARM NAIL End cap M4x0.7 (1-042-01TI) from the nail shaft. Using the socket wrench S6 (7-130-03) insert the connector M4 (7-130-10) into the threaded hole in the nail shaft.

Unscrew all the locking screws using the screwdriver.

Attach the impactor-extractor (7-130-04) to the connector and with help of the mallet (7-130-09) remove the nail from the medullary canal.



Konzept Fibula & Forearm Nail

Ø Dia	Length (mm)	Titanium
Ø4mm	180mm	1-023-001TI
Ø4mm	200mm	1-023-002TI
Ø4mm	220mm	1-023-003TI
Ø4mm	240mm	1-023-004TI
Ø4mm	260mm	1-023-005TI
Ø5mm	180mm	1-024-001TI
Ø5mm	200mm	1-024-002TI
Ø5mm	220mm	1-024-003TI
Ø5mm	240mm	1-024-004TI
Ø5mm	260mm	1-024-005TI



Konzept Fibula & Forearm Nail with Compression

Ø Dia	Length (mm)	Titanium
Ø4mm	180mm	1-040-001TI
Ø4mm	200mm	1-040-002TI
Ø4mm	220mm	1-040-003TI
Ø4mm	240mm	1-040-004TI
Ø4mm	260mm	1-040-005TI
Ø5mm	180mm	1-041-001TI
Ø5mm	200mm	1-041-002TI
Ø5mm	220mm	1-041-003TI
Ø5mm	240mm	1-041-004TI
Ø5mm	260mm	1-041-005TI



End Cap, M4

Titanium

1-042-01TI



Compression End Cap, M4

Titanium

1-043-02TI



Cortical Screw, Self-Tapping (Hex Head)

Ø Dia	Length (mm)	Titanium
Ø1.5/2.7mm	16mm	1-044-01TI
Ø1.5/2.7mm	18mm	1-044-02TI
Ø1.5/2.7mm	20mm	1-044-03TI
Ø1.5/2.7mm	22mm	1-044-04TI
Ø1.5/2.7mm	24mm	1-044-05TI
Ø1.5/2.7mm	26mm	1-044-06TI



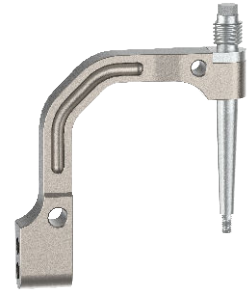
2.7mm Cortical Screw, Self Tapping (Hex Head)

Length (mm)	Titanium
16	TI-103.216
18	TI-103.218
20	TI-103.220
22	TI-103.222
24	TI-103.224
26	TI-103.226
28	TI-103.228
30	TI-103.230
32	TI-103.232
34	TI-103.234



Code	Set Consisting of	Qty.
1-023-001TI	Konzept Fibula & Forearm Nail, Ø4mm x Length 180mm, Titanium	1
1-023-002TI	Konzept Fibula & Forearm Nail, Ø4mm x Length 200mm, Titanium	1
1-023-003TI	Konzept Fibula & Forearm Nail, Ø4mm x Length 220mm, Titanium	1
1-023-004TI	Konzept Fibula & Forearm Nail, Ø4mm x Length 240mm, Titanium	1
1-023-005TI	Konzept Fibula & Forearm Nail, Ø4mm x Length 260mm, Titanium	1
1-024-001TI	Konzept Fibula & Forearm Nail, Ø5mm x Length 180mm, Titanium	1
1-024-002TI	Konzept Fibula & Forearm Nail, Ø5mm x Length 200mm, Titanium	1
1-024-003TI	Konzept Fibula & Forearm Nail, Ø5mm x Length 220mm, Titanium	1
1-024-004TI	Konzept Fibula & Forearm Nail, Ø5mm x Length 240mm, Titanium	1
1-024-005TI	Konzept Fibula & Forearm Nail, Ø5mm x Length 260mm, Titanium	1
1-040-001TI	Konzept Fibula & Forearm Nail with Compression, Ø4mm x Length 180mm, Titanium	1
1-040-002TI	Konzept Fibula & Forearm Nail with Compression, Ø4mm x Length 200mm, Titanium	1
1-040-003TI	Konzept Fibula & Forearm Nail with Compression, Ø4mm x Length 220mm, Titanium	1
1-040-004TI	Konzept Fibula & Forearm Nail with Compression, Ø4mm x Length 240mm, Titanium	1
1-040-005TI	Konzept Fibula & Forearm Nail with Compression, Ø4mm x Length 260mm, Titanium	1
1-041-001TI	Konzept Fibula & Forearm Nail with Compression, Ø5mm x Length 180mm, Titanium	1
1-041-002TI	Konzept Fibula & Forearm Nail with Compression, Ø5mm x Length 200mm, Titanium	1
1-041-003TI	Konzept Fibula & Forearm Nail with Compression, Ø5mm x Length 220mm, Titanium	1
1-041-004TI	Konzept Fibula & Forearm Nail with Compression, Ø5mm x Length 240mm, Titanium	1
1-041-005TI	Konzept Fibula & Forearm Nail with Compression, Ø5mm x Length 260mm, Titanium	1
1-042-01TI	End Cap, M4	2
1-043-02TI	Compression End Cap, M4	2
1-044-01TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 16mm, Titanium	2
1-044-02TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 18mm, Titanium	2
1-044-03TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 20mm, Titanium	2
1-044-04TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 22mm, Titanium	2
1-044-05TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 24mm, Titanium	2
1-044-06TI	Cortical Screw, Self-Tapping (Hex Head), Ø1.5/2.7mm, Length 26mm, Titanium	2
TI-103.216	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 16mm, Titanium	2
TI-103.218	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 18mm, Titanium	2
TI-103.220	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 20mm, Titanium	2
TI-103.222	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 22mm, Titanium	2
TI-103.224	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 24mm, Titanium	2
TI-103.226	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 26mm, Titanium	2
TI-103.228	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 28mm, Titanium	2
TI-103.230	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 30mm, Titanium	2
TI-103.232	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 32mm, Titanium	2
TI-103.234	2.7mm Cortical Screw, Self Tapping (Hex Head), Length 34mm, Titanium	2

7-130-01 Proximal Targeter B for Knozept Fibula & Forearm Nail



7-130-02 Clamping Screw M4



7-130-03 Socket Wrench, Hex 7mm



7-130-04 Impactor - Extractor for Konzept Fibula & Forearm Nail



7-130-05 Protective Guide Ø7/5mm



7-130-06 Kirschner Wire Guide B Ø5/2mm



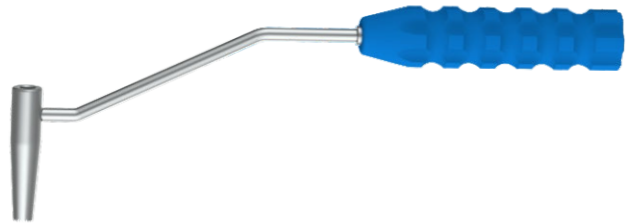
7-130-07

Screw Length Measure upto 40mm



7-130-08

Targeter D for Konzept Fibula & Forearm Nail



7-130-09

Mallet for Konzept Fibula & Forearm Nail



7-130-10

Connector M4



7-130-11

Screwdriver, Hex 2.0mm for Konzept Fibula & Forearm Nail



7-130-12

Nail Trail



7-130-13

Bender



7-130-14

Kirschner Wire one side Trocar Tip, Ø2.0mm x Length 200mm



7-130-15

Cannulated Drill, Ø6.0 x 2.2 x 150mm



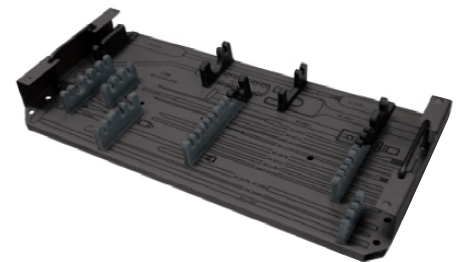
7-130-16

Kirschner Wire Threaded Ti, Ø1.5mm x Thread Length 7.5mm x Length 180mm



7-130-17

Instrument Tray for Konzept Fibula & Forearm Nail Instrument Set



7-130-18

Container with Lid for Konzept Fibula & Forearm Nail Instrument Set



7-130 Konzept Fibula & Forearm Nail Instrument Set

Code	Set Consisting of	Qty.
7-130-01	Proximal Targeter B for Knozept Fibula & Forearm Nail	1
7-130-02	Clamping Screw M4	1
7-130-03	Socket Wrench, Hex 7mm	1
7-130-04	Impactor - Extractor for Konzept Fibula & Forearm Nail	1
7-130-05	Protective Guide Ø7/5mm	1
7-130-06	Kirschner Wire Guide B Ø5/2mm	1
7-130-07	Screw Length Measure upto 40mm	1
7-130-08	Targeter D for Konzept Fibula & Forearm Nail	1
7-130-09	Mallet for Konzept Fibula & Forearm Nail	1
7-130-10	Connector M4	1
7-130-11	Screwdriver, Hex 2.0mm for Konzept Fibula & Forearm Nail	1
7-130-12	Nail Trail	5
7-130-13	Bender	2
7-130-14	Kirschner Wire one side Trocar Tip, Ø2.0mm x Length 200mm	3
7-130-15	Cannulated Drill, Ø6.0 x 2.2 x 150mm	1
7-130-16	Kirschner Wire Threaded Ti, Ø1.5mm x Thread Length 7.5mm x Length 180mm	3
7-130-17	Instrument Tray for Konzept Fibula & Forearm Nail Instrument Set	1
7-130-18	Container with Lid for Konzept Fibula & Forearm Nail Instrument Set	1



USA

Auxein Inc.
1500 Nw 89th Court, Suite 107-108
Doral, Florida 33172
Tel: +1 305 395 6062
E Fax: +1 305 395 6262
Email: USoffice@auxein.com

MEXICO

Auxein México, S.A. de C.V.
Tepic 139 int 801, Colonia Roma Sur,
Alcaldía Cuauhtémoc, CDMX,
México, C.P. 06760
Tel: +521 55 7261 0318
Email: info@auxein.mx

INDIA

Auxein Medical Pvt. Ltd.
Plot No. 168-169-170, Phase-4,
Kundli Industrial Area,
HSIIDC, Sector-57, Sonapat - 131028, Haryana
Tel: +91 99106 43638 | Fax: +91 86077 70197
Email: info@auxein.com