




























INTRAMEDULLARY OSTEOSYNTHESIS OF FIBULA AND FOREARM BONES

- *IMPLANTS*
- *INSTRUMENT SET 15.0417.100*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTION

	Titanium or titanium alloy		Cannulated
	Steel		Locking
	Left		Diameter
	Right		Inner diameter
	Available versions: left/right		Recommended length range for a particular nail
	Length		Angle
	Torx drive		Available lengths
	Torx drive cannulated		Available in sterile/ non- sterile condition
	Hexagonal drive		
	Hexagonal drive cannulated		

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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Document No ST/07E
 Date of issue 25.07.2019
 Review date P-001-18.11.2020

*The manufacturer reserves the right to introduce design changes.
 Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu*

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I. INTRODUCTION

INTRAMEDULLARY OSTEOSYNTHESIS OF FIBULA AND FOREARM BONES consists of:

- implants (*intramedullary nail, locking screws, compression screw or end cap*),
- instrument set for implants insertion and extraction after finished treatment,
- surgical technique.

The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of quality management systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

Intramedullary osteosynthesis of fibula and forearm bones provides stable fragments reduction and fixation of shaft of ulna, radius and fibula in closed or open fractures and also in osteoporotic bone injuries.

Indications:

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

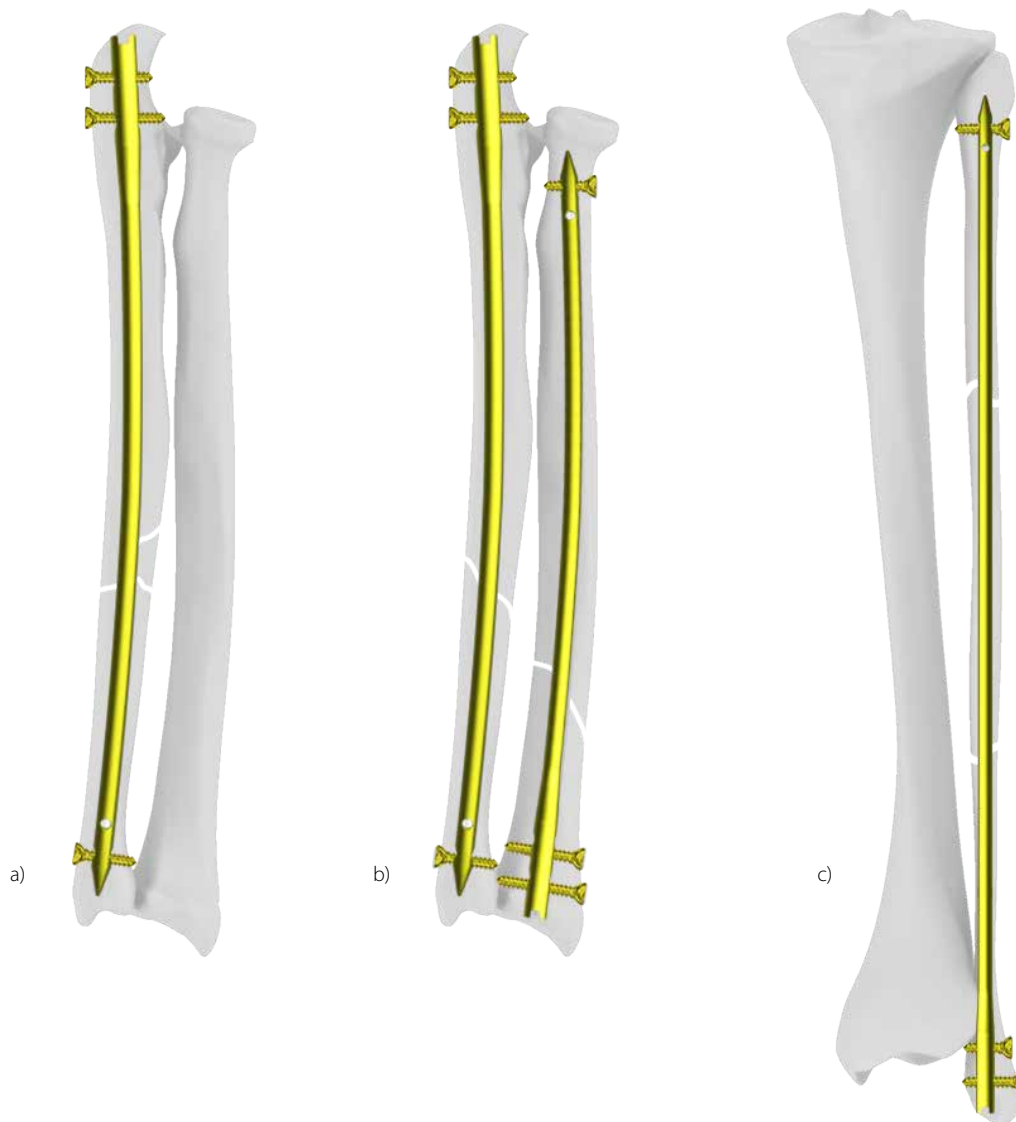


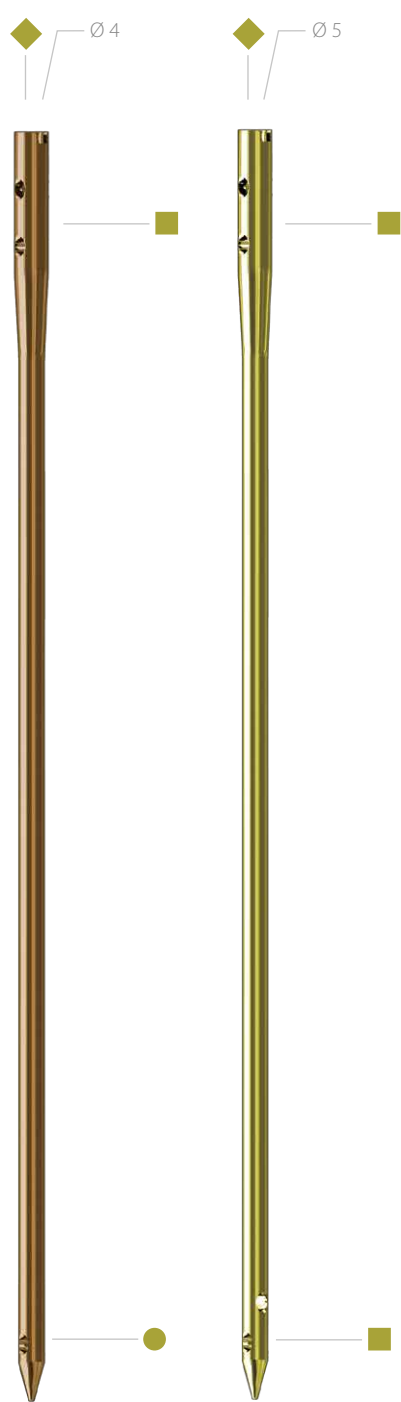
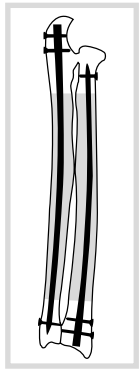
FIG. 1. Examples of forearm and fibula bone fractures treated with IM nails:

- a) comminuted 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.*

II. IMPLANTS



CHARFIX FOREARM AND FIBULA NAIL

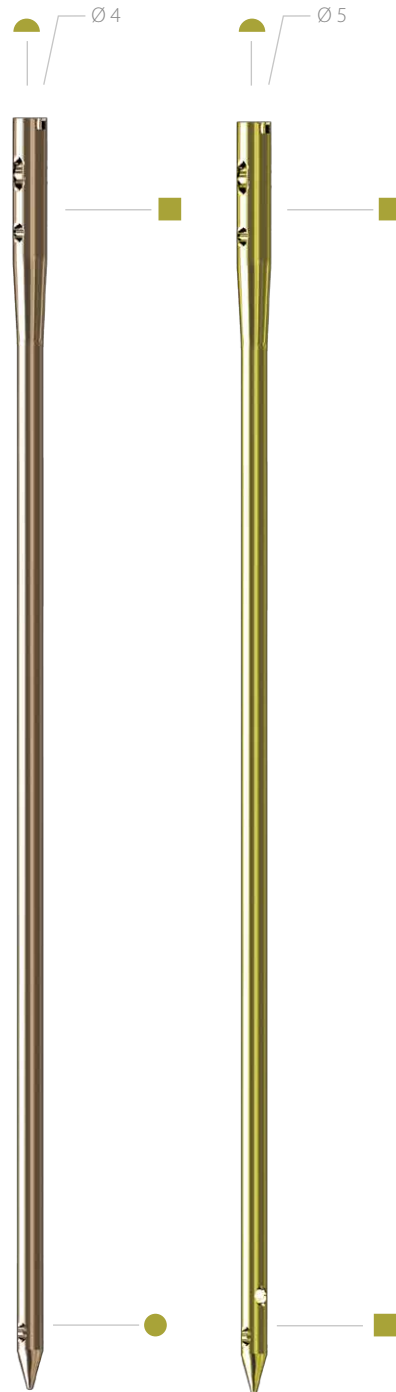
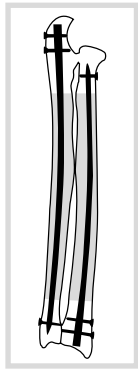


	Len	Ti
4	180	3.2102.180
	200	3.2102.200
	220	3.2102.220
	240	3.2102.240
	260	3.2102.260
5	180	3.2103.180
	200	3.2103.200
	220	3.2103.220
	240	3.2103.240
	260	3.2103.260

available	Ø	pitch
●	3 mm ÷ 6 mm	1 mm
L	70 mm ÷ 400 mm	5 mm

Ti	✓	2.7	14÷40	■
3.5157.xxx	✓	2.7	14÷40	■
3.1033.xxx	✓	1.5/2.7	14÷40	●
3.2367.002	✓			◆

CHARFIX FOREARM AND FIBULA NAIL



	Len	Ti
4	180	3.2360.180
	200	3.2360.200
	220	3.2360.220
	240	3.2360.240
	260	3.2360.260
5	180	3.2361.180
	200	3.2361.200
	220	3.2361.220
	240	3.2361.240
	260	3.2361.260

available	Ø	pitch
●	3 mm ÷ 6 mm	1 mm
L	70 mm ÷ 400 mm	5 mm

	Ti	Locking	Thread	Length	Head
	3.5157.xxx	✓	2.7	14÷40	■
	3.1033.xxx	✓	1.5/2.7	14÷40	●
	3.2359.000	✓			◐

LOCKING ELEMENTS



DISTAL SCREW 2.7



16	3.5157.016
18	3.5157.018
20	3.5157.020
22	3.5157.022
24	3.5157.024
26	3.5157.026
28	3.5157.028
30	3.5157.030
32	3.5157.032
34	3.5157.034



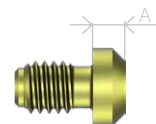
DISTAL SCREW 1.5/2.7



16	3.1033.016
18	3.1033.018
20	3.1033.020
22	3.1033.022
24	3.1033.024
26	3.1033.026



END CAP M4X0.7



A	
+2.5	3.2367.002

COMPRESSION SCREW M4








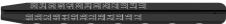














3.2359.000



Stand for forearm nails
(set with container without implants)

40.8538.000

III. INSTRUMENT SET

INSTRUMENT SET FOR FOREARM AND FIBULA BONES 15.0417.100	Name	Pcs	Catalogue No.
	Proximal targeter B	1	40.4585.100
	Clamping screw M4	1	40.4586.100
	Impactor-extractor	1	40.6725.000
	Protective guide 7/5	1	40.4589.100
	Kirschner guide B 7/2	1	40.8533.000
	Screw length measure	1	40.4591.100
	Targeter D	1	40.1344.200
	Mallet	1	40.4595.000
	Connector M4/M8	1	40.4596.100
	Hexagonal screwdriver S2.5	1	40.0321.100
	Nail trial	5	40.4581.000
	Rod bender 6.0 left	1	40.8091.000
	Rod bender 6.0 right	1	40.8092.000
	Kirschner wire 2.0	3	40.8535.000
	Kirschner wire 1.5/180	3	40.8536.000
	Cannulated drill 6.0/2.2/150	1	40.4584.000
	Star screwdriver T25	1	40.0671.100
	Screwdriver T8 with holder	1	40.8534.000
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand	1	14.0417.100
	Container with solid bottom 1/1 595x275x86mm	1	12.0750.100

IV. SURGICAL TECHNIQUE



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

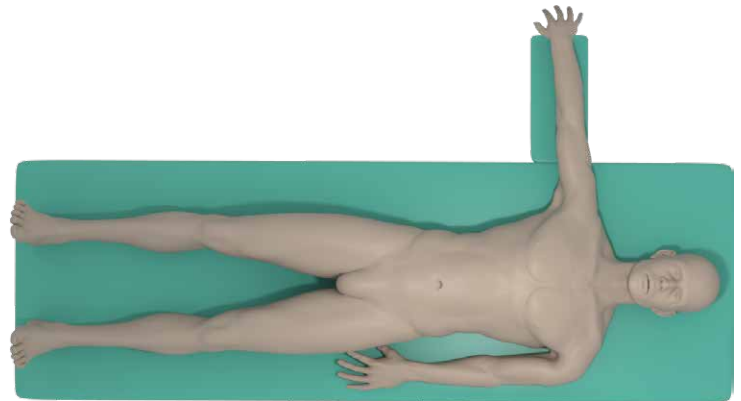
V. SURGERY PLANNING



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

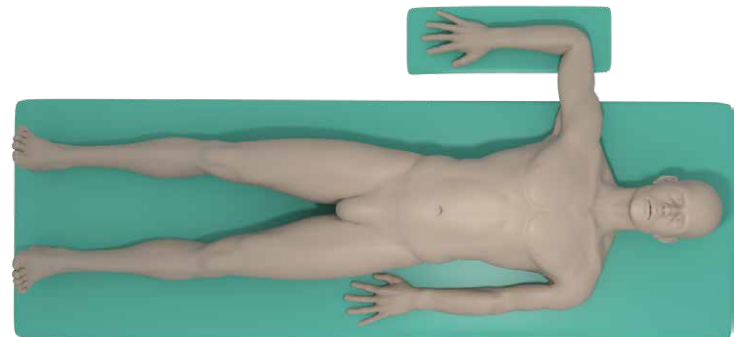
Patient positioning for radius surgery

Place the patient supine. The fractured limb should be abducted in humerus joint at an angle of 90° , with the wrist in the free fall and fixed in a traction clamp.



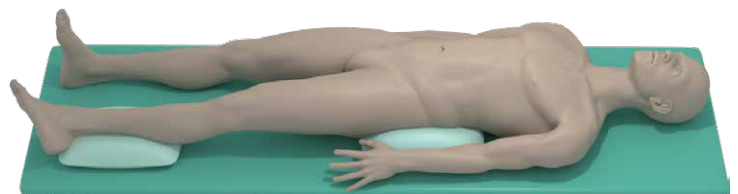
Patient positioning for ulna surgery

Place the patient supine. The fractured limb should be abducted in humerus joint at the angle of 90° , bent in elbow joint at the angle of 90° and fixed in a traction clamp. Position the X-Ray device perpendicular to the anterior area of the forearm.



Patient positioning for fibula surgery

Place the patient supine. Internal rotation of the limb improves the access to the place of nail insertion. It is important to place a surgery pillows under the pelvis and the affected leg to allow easier surgical approach and X-Ray control during the operation. Apply the traction clamp.



V.1. NAILING POINT

Preparation of surgical approach and nailing point for ulna

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 and nailing point for radius

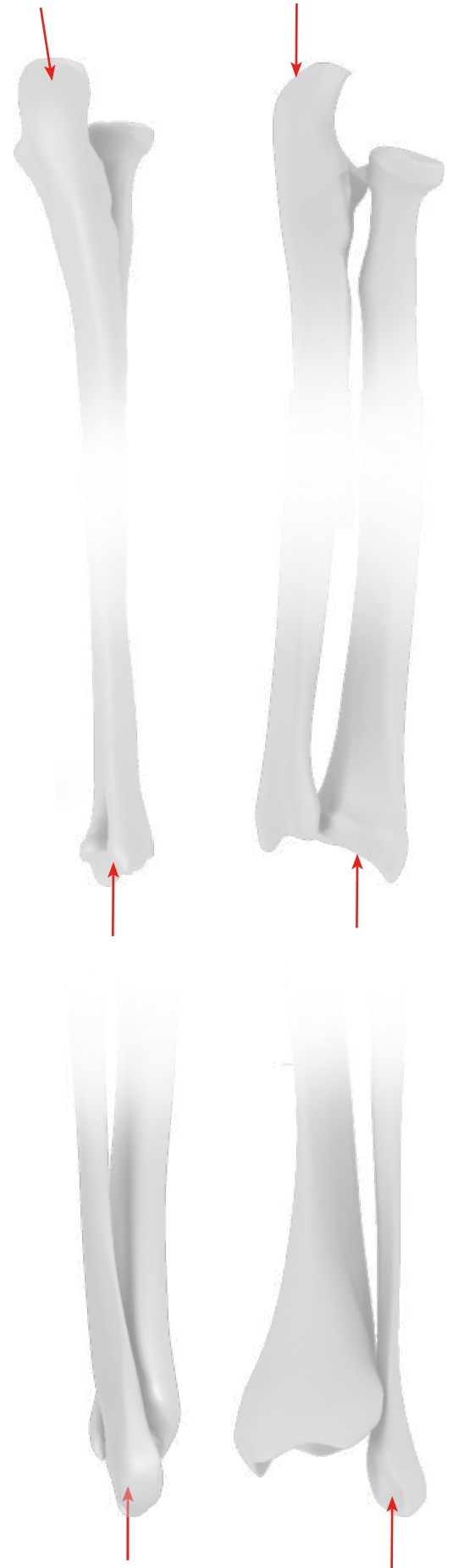
Make 2.5-3cm longitudinal skin incision over the area of distal wrist above the fourth extensor compartment (*distal part of radius*) to prepare surgical approach for radius nailing. Make blunt dissection of subcutaneous tissues to avoid injury to the dorsal radial nerve branches. The extensor digitorum 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 and nailing point for fibula

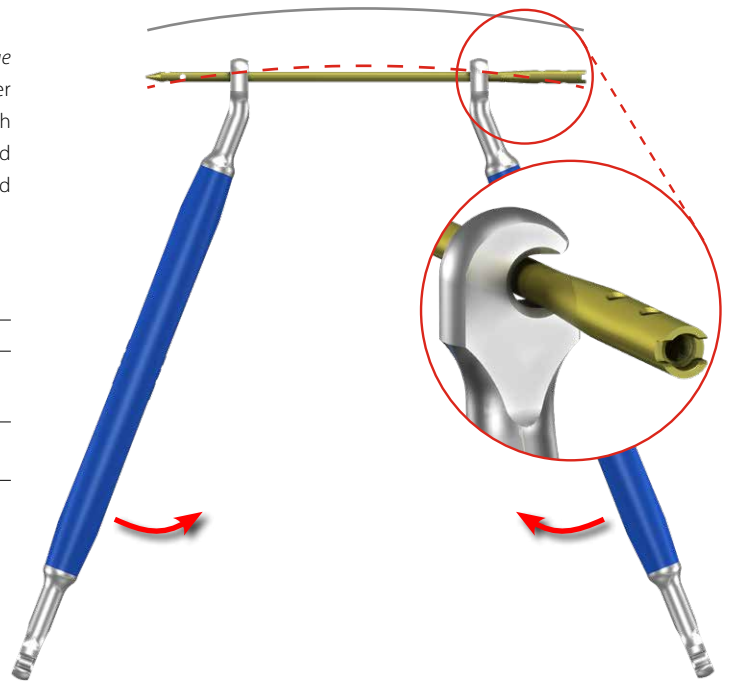
Make 2cm longitudinal skin incision in the area of ankle joint (*distal part of fibula*) to prepare surgical approach for fibula nailing. The incision should be performed posterior to the distal fibula downwards to the fourth metatarsal, between the sural and superficial peroneal nerve branches.

The entry point for intramedullary nail is in line with the centre of the medullary canal, at the medial line of lateral ankle.

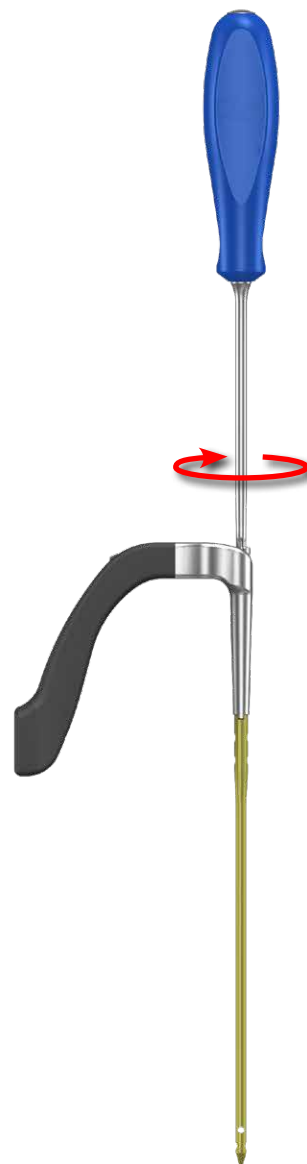


V.2. PREPARATION OF THE INTRAMEDULLARY NAIL

1 Having taken the X-Ray image of the fractured bone (*X-Ray image of the healthy limb is also recommended*), define the length, diameter and shape of nail using the nail trial **[40.4581]**. The bending is carried out with the use of rod bender 6.0 left **[40.8091]** and rod bender 6.0 right **[40.8092]**. 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 **[40.4585.100]** with clamping screw M4 **[40.4586.100]** using star screwdriver T25 **[40.0671.100]**.



V.3. OPENING OF THE MEDULLARY CANAL

- 3 After preparing the surgical approach and locating the entry point for the nail, use the electric drive to insert Kirchner wire 2.0 [40.4583] into the medullary canal.



Image intensifier should be used to control the process.

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

40.8535.000



- 4 Open the medullary canal using the cannulated drill 6/2.2/150 [40.4584] mounted on the surgical drive, and led via Kirchner wire 2.0.

Remove cannulated drill and Kirchner wire.

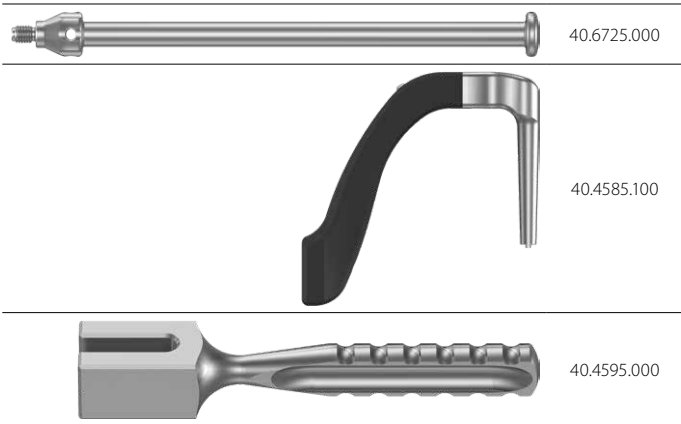
40.4584.000

40.8535.000

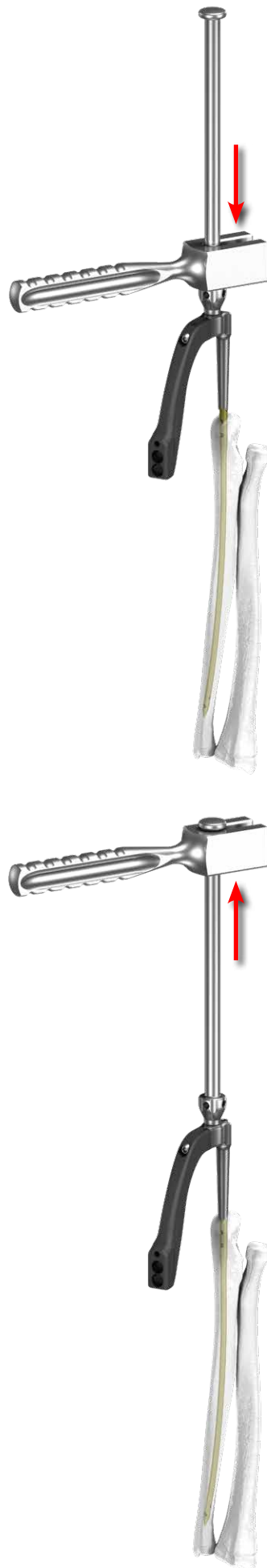
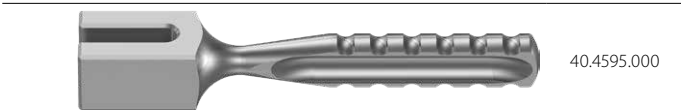


V.4. NAIL INSERTION

- 5 Connect the impactor-extractor [40.6725] to the proximal targeter B [40.4585.100]. Carefully insert the nail into medullary canal using the mallet [40.4595].



- 6 Some circumstances may force the surgeon to extract the nail (or remove it partially from the medullary canal) without its disconnecting from the targeter. This process shall be done with use of mallet [40.4595].



V.5. DISTAL LOCKING OF THE NAIL

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



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

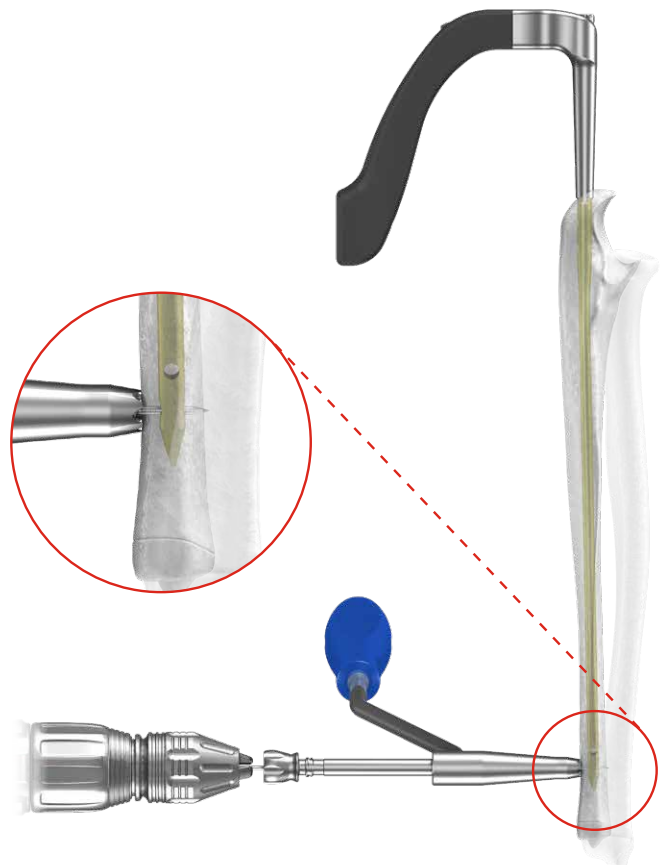
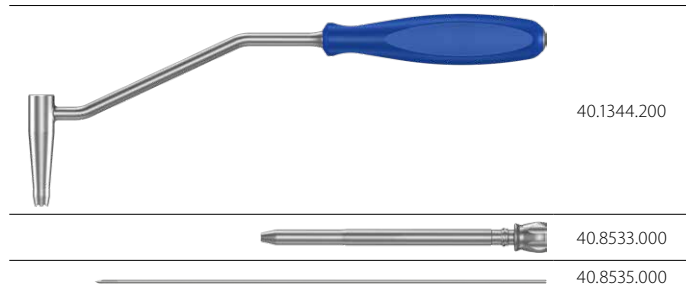
It is recommended to use an angular attachment with the surgical drive when drilling the holes, so that surgeon's hands are not directly exposed to X-Rays. After marking the drill entry point on the skin, 1.5 cm long incision shall be made.

- 7 Using X-Ray device, place the targeter D [40.1344.200] in line with the nail hole. The holes in the nail and in the targeter D have to correspond. The teeth of the targeter D have to be immersed into the ulnar cortex. Introduce the drill guide 7/2 [40.8533] into the targeter D. Mount Kirschner wire 2.0 [40.8535] (for nails diameter of 4.5mm and more) in the electric drive and leading it through the drill guide, drill the hole in the bone through both cortices so that the tip of the blade only slightly exits the bone.



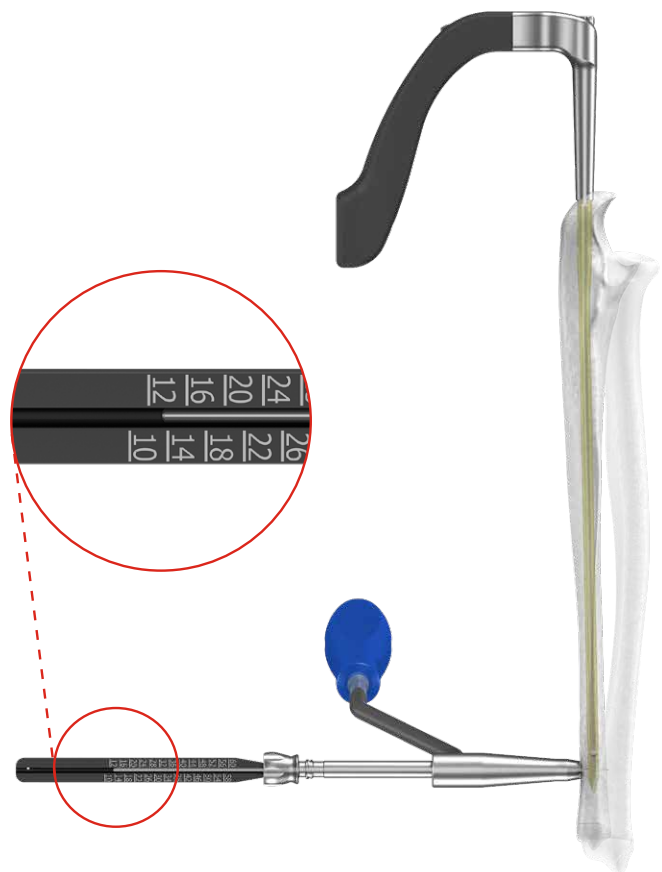
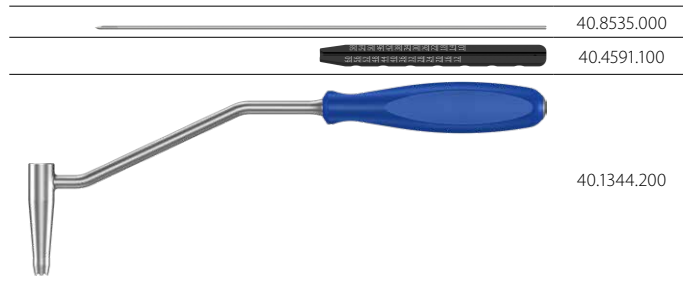
Use the image intensifier to control drilling process.

Leave the Kirschner wire, guide and targeter in place.



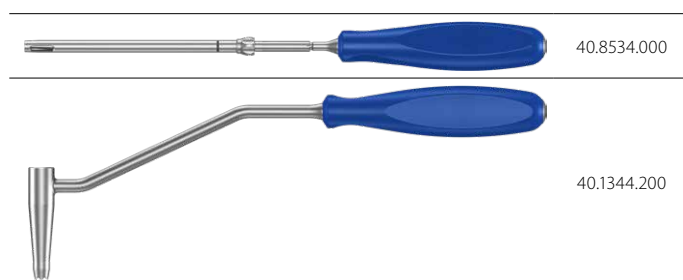
- 8 Place the screw length measure [40.4591.100] onto the Kirschner wire 2.0 [40.8535] until its tip rests on the drill guide 7/2 [40.8533]. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire.

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



- 9 Introduce the tip of the screwdriver T8 with holder [40.8534] into the socket of the defined locking screw. Attach the thread end of the gripping sleeve of the screwdriver onto the threaded head of the screw (the screw can also be inserted with the screwdriver with the gripping sleeve removed). Then advance both into the targeter D hole [40.1344.200] and in the prepared hole until the head of the screw reaches the bone cortex. While inserting the screw, the gripping sleeve releases the screw, simultaneously.

Remove screwdriver and targeter.



V.6. PROXIMAL LOCKING OF THE NAIL

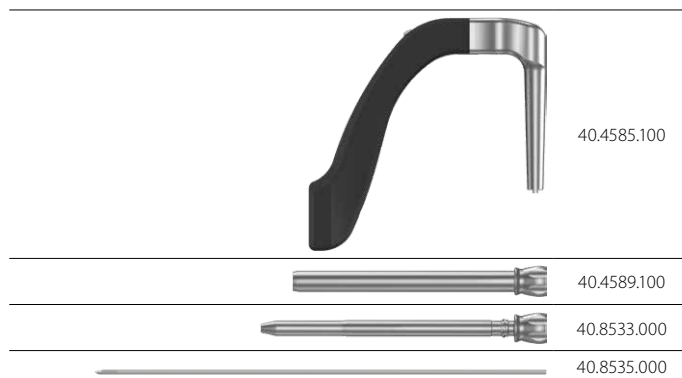
Proximal locking of the nail in the ulna is made using two locking screws.

- 10** Insert the drill guide 7/2 [40.8533] and protective guide 9/7 [40.4589.100] into the distal hole in the proximal targeter B [40.4585.100]. Mount Kirschner wire 2.0 [40.8535] (for nails diameter of 4.5mm and more) in the electric drive and leading it through the drill guide, drill the hole in the bone through both cortices so that the tip of the blade only slightly exits the bone.



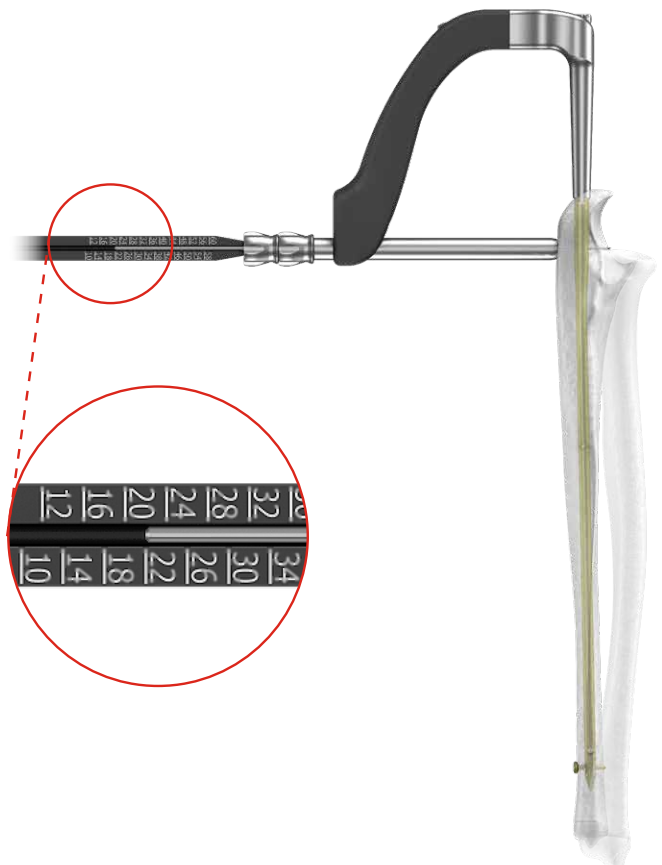
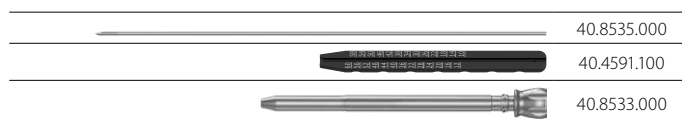
Image intensifier should be used to control the drilling process.

Leave Kirschner wire and the guides in place.



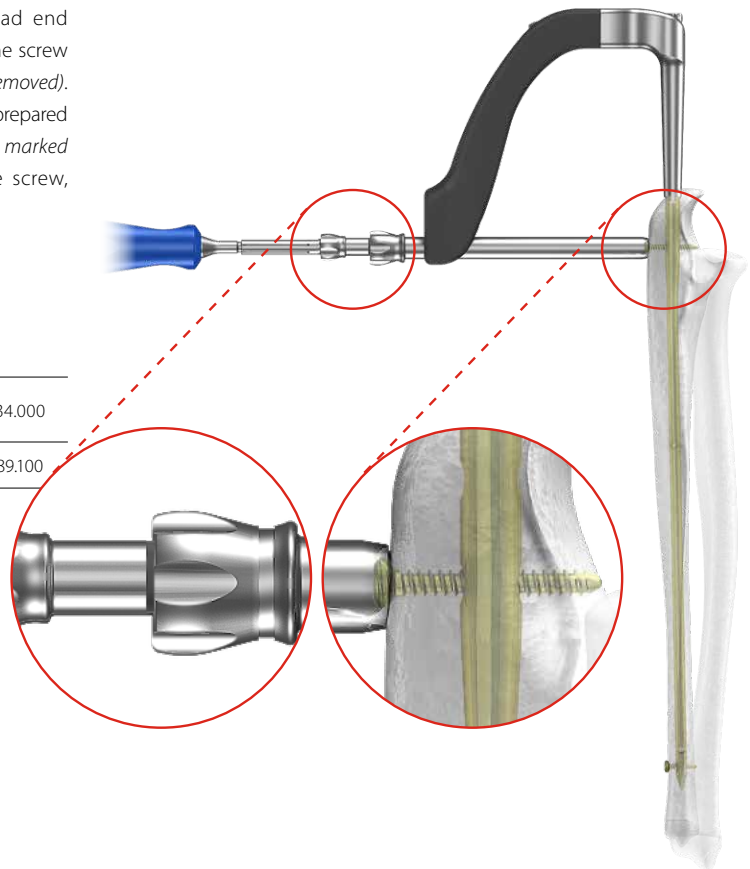
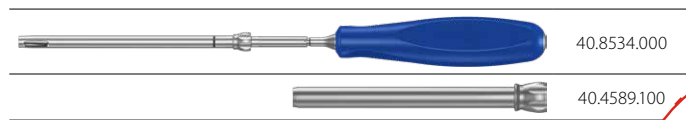
- 11** Place the screw length measure [40.4591.100] onto the Kirschner wire 2.0 [40.8535] until its tip rests on the drill guide 7/2 [40.8533]. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire.

Remove the measure, Kirschner wire and drill guide.

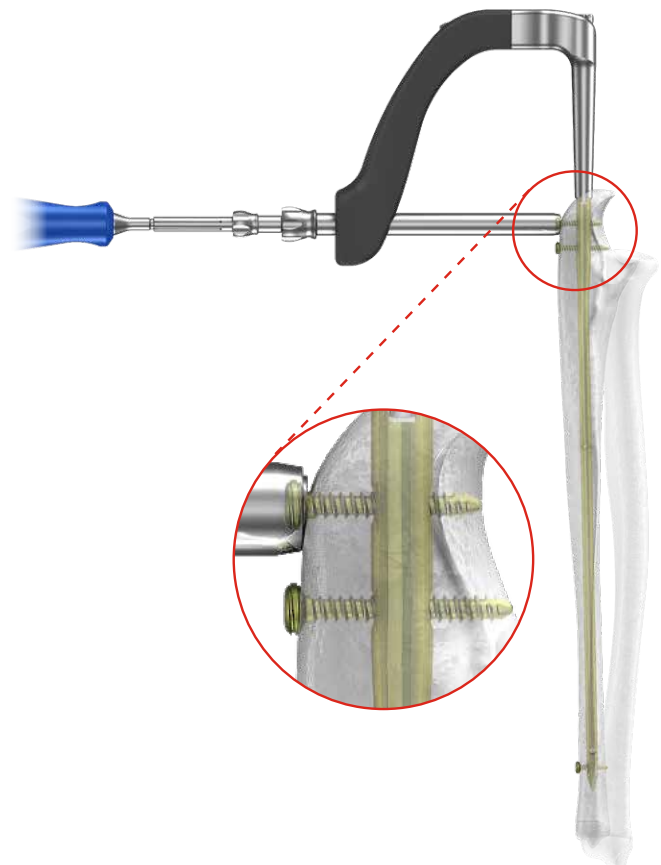


- 12 Introduce the tip of the screwdriver T8 with holder **[40.8534]** into the socket of the defined locking screw. Attach the thread end of the gripping sleeve of the screwdriver onto the threaded head of the screw (the screw can also be inserted with the screwdriver with the gripping sleeve removed). Then advance both into the protective guide 9/7 **[40.4589.100]** and in the prepared hole until the head of the screw reaches the bone cortex (black line marked on the screwdriver reaches the protective guide). While inserting the screw, the gripping sleeve releases the screw, simultaneously.

Remove screwdriver and protective guide.

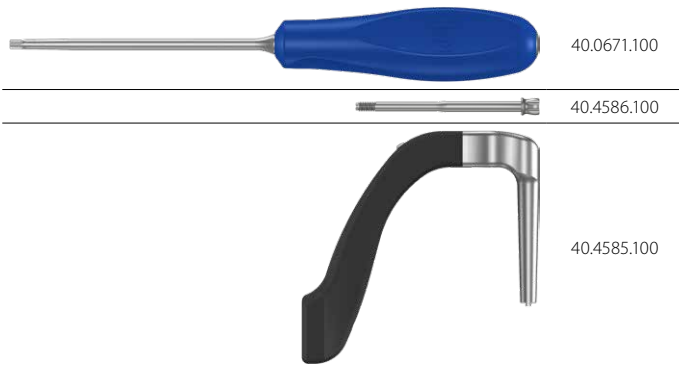


- 13 Locking the nail with the other locking screw should be performed using proximal hole in the proximal targeter B **[40.4585.100]**, acc. to steps 10 to 12 of the instructions.

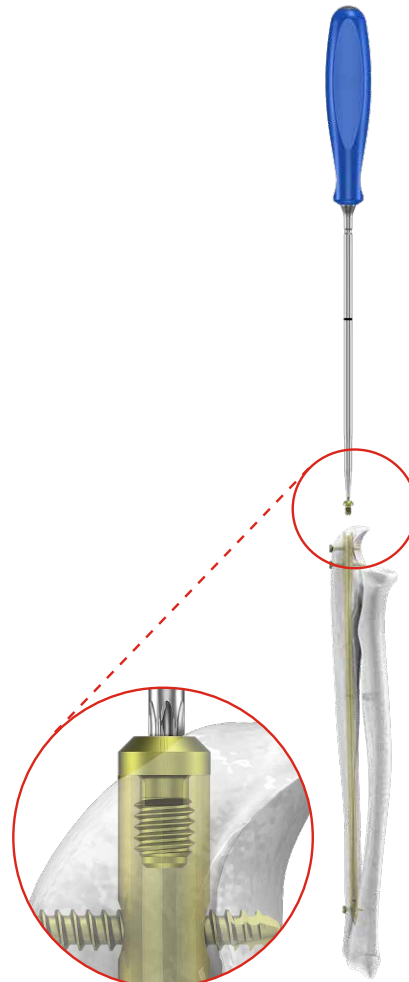


V.7. END CAP INSERTION

- 14 Use star screwdriver T25 to remove the clamping screw M4 [40.4586.100] from the intramedullary nail. Remove proximal targeter B [40.4585.100] from the nail locked in the medullary canal.



- 15 In order to secure the inner thread of the nail against bone ingrowth, insert end cap M4x0.7 [3.2367.002] into the threaded hole using screwdriver T8 with holder [40.8534.000].

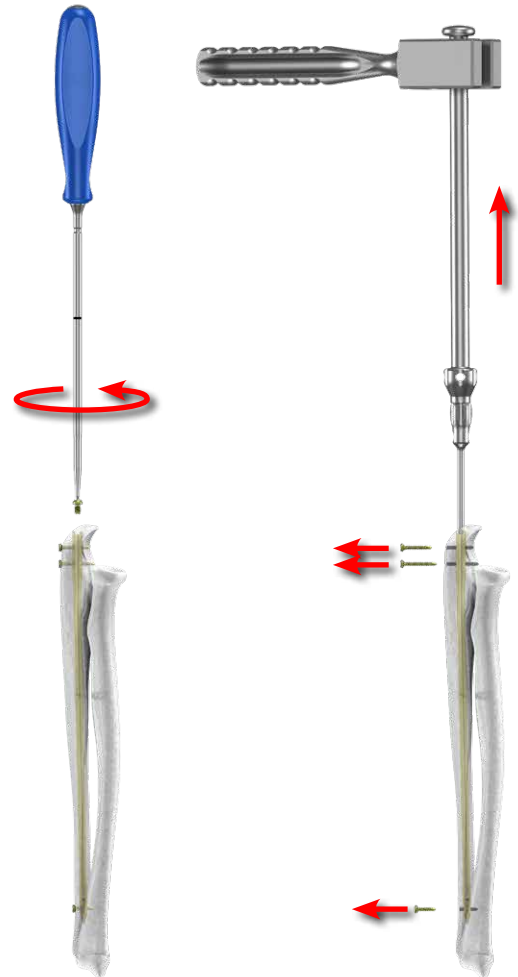
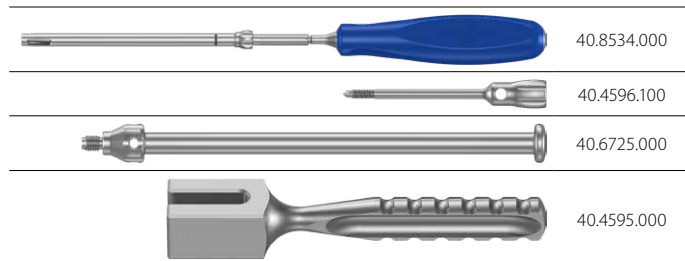


V.8. NAIL EXTRACTION

- 16 Use screwdriver T8 with holder **[40.8534]** (with the gripping sleeve removed) to remove end cap M4x0.7 **[3.2367.002]** or compression screw M4 **[3.2359]** from the nail shaft.

Attach connector M4/M8 **[40.4596.100]** and impactor-extractor **[40.6725]**. Use mallet **[40.4595]** to remove the nail from the medullary canal.

Use screwdriver T8 to remove all the locking screws.



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