ST/07D

ChM®

CHARFIX system

# INTRAMEDULLARY OSTEOSYNTHESIS OF FIBULA AND FOREARM BONES

- *IMPLANTS*
- *INSTRUMENT SET 40.4580.500*
- *SURGICAL TECHNIQUE*

www.chm.eu

SYMBOLS DESCRIPTION

| | |
|---|---|
| Ti | Titanium or titanium alloy |
| St | Steel |
| L | Left |
| R | Right |
| L R | Available versions: left/right |
| Len | Length |
| | Torx drive |
| | Torx drive cannulated |
| | Hexagonal drive |
| | Hexagonal drive cannulated |
| | Cannulated |
| | Locking |
| | Diameter |
| | Inner diameter |
| | Recommended length range for a particular nail |
| | Angle |
| 16 ÷ 90 | Available lengths |
| Ster Non Ster | Available in sterile/ non- sterile condition |

| | |
|---|---|
| | 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/07D |
| Date of issue | 04.05.2010 |
| Review date | P-005-26.11.2020 |


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

# I. INTRODUCTION

**CHARFIX** system – 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.

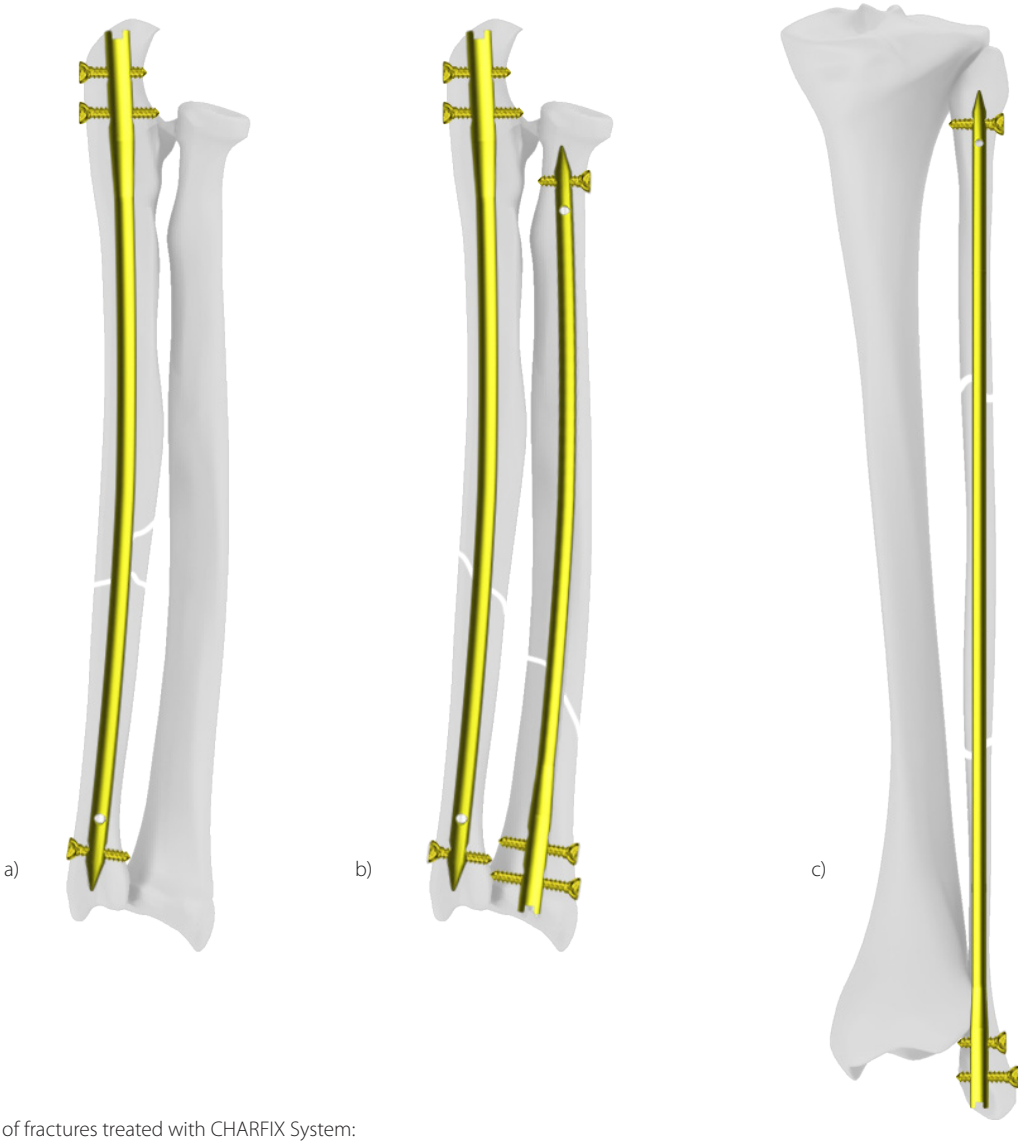
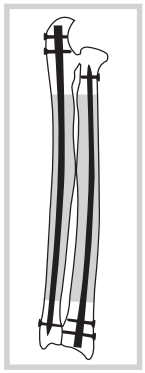


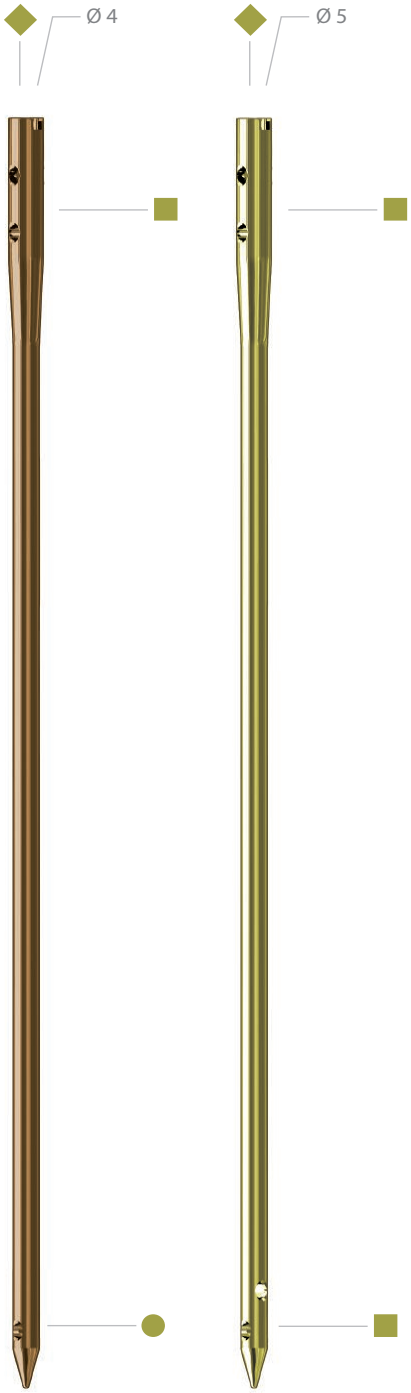

FIG. 1. Examples of fractures treated with CHARFIX System:
*a) multi-fragmental fractures of the ulna shaft,*
*b) oblique fractures of the ulna and radius shaft,*
*c) fibula fractures in the ankle joint area with simultaneous transverse shaft fracture.*

# II. IMPLANTS

## CHARFIX FOREARM AND FIBULA NAII

CHARFIX system






Ster
Non
Ster

| | 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 | 3 mm ÷ 6 mm | pitch | 1 mm |
| | | L | 70 mm ÷ 400 mm | | 5 mm |

| | Ti | | | | |
|---|---|---|---|---|---|
|  | 3.1203.xxx | ✓ | 2.7 | 16÷34 | ■ |
|  | 3.1022.xxx | ✓ | 1.5/2.7 | 16÷26 | ● |
|  | 3.2104.004 | ✓ | | | ◆ |



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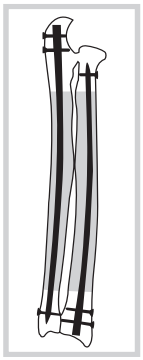
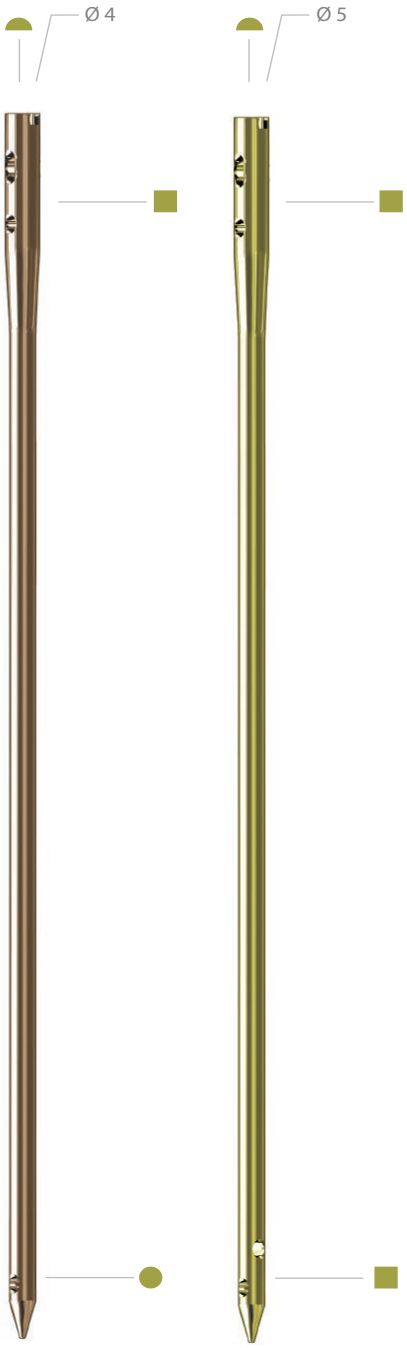
# CHARFIX FOREARM AND FIBULA NAIL

CHARFIX system

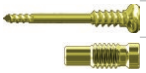





Ster
Non
Ster

| | 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 | 3 mm ÷ 6 mm | pitch | 1 mm |
|---|---|---|---|---|---|
| | | L | 70 mm ÷ 400 mm | | 5 mm |

| | Ti | | | | |
|---|---|---|---|---|---|
|  | 3.1203.xxx | ✓ | | 2.7 | 16÷34 |
|  | 3.1022.xxx | ✓ | | 1.5/2.7 | 16÷26 |
|  | 3.2106.006 | ✓ | | | |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# LOCKING ELEMENTS

Ti

Ster
Non
Ster

CHARFIX system

## CORTICAL SELF - TAPPING SCREW 2.7

| | |
|---|---|
| 16 | 3.1203.016 |
| 18 | 3.1203.018 |
| 20 | 3.1203.020 |
| 22 | 3.1203.022 |
| 24 | 3.1203.024 |
| 26 | 3.1203.026 |
| 28 | 3.1203.028 |
| 30 | 3.1203.030 |
| 32 | 3.1203.032 |
| 34 | 3.1203.034 |

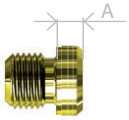
6 ÷ 40

## CORTEX SELF - TAPPING SCREW 1.5/2.7

| | |
|---|---|
| 16 | 3.1022.016 |
| 18 | 3.1022.018 |
| 20 | 3.1022.020 |
| 22 | 3.1022.022 |
| 24 | 3.1022.024 |
| 26 | 3.1022.026 |

8 ÷ 70

## CHARFIX END CAP M4X0.7




| A | |
|---|---|
| +2.5 | 3.2104.004 |

## CHARFIX COMPRESSION SCREW M4

| | |
|---|---|
| | 3.2106.006 |

Stand for CHARFIX nail locking elements (set with a box without implants) 40.4686.200



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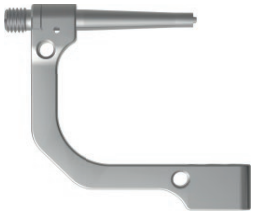
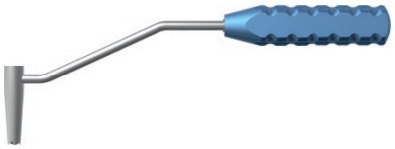
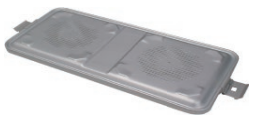
# III. INSTRUMENT SET

CHARFIX system

| 40.4580.500 | Name | Pcs | Catalogue No. |
|---|---|---|---|
|  | Proximal targeter B | 1 | 40.4585 |
|  | Clamping screw M4 | 1 | 40.4586 |
|  | Socket wrench S6 | 1 | 40.4587 |
|  | Impactor-extractor | 1 | 40.4588 |
|  | Protective guide 7/5 | 1 | 40.4589 |
|  | Kirschner guide B 5/2 | 1 | 40.4590 |
|  | Screw length measure | 1 | 40.4591 |
|  | Targeter D | 1 | 40.1344 |
|  | Mallet | 1 | 40.4595 |
|  | Connector M4 | 1 | 40.4596 |
|  | Hexagonal screwdriver S2.5 | 1 | 40.0321 |
|  | Nail trial | 5 | 40.4581 |
|  | Bender | 2 | 40.4511 |
|  | Kirschner wire 2.0 | 3 | 40.4583 |
|  | Cannulated drill 6.0/2.2/150 | 1 | 40.4584 |
|  | Kirschner wire 1.5/180 | 3 | 40.4592.180 |
|  | Perforated aluminumcover 1/1 595x275x15mm gray | 1 | 12.0750.200 |
|  | Stand for instruments for small bones | 1 | 40.4597.500 |
|  | Container with solid bottom 1/1 595x275x86mm | 1 | 12.0750.100 |

# SURGICAL TECHNIQUE

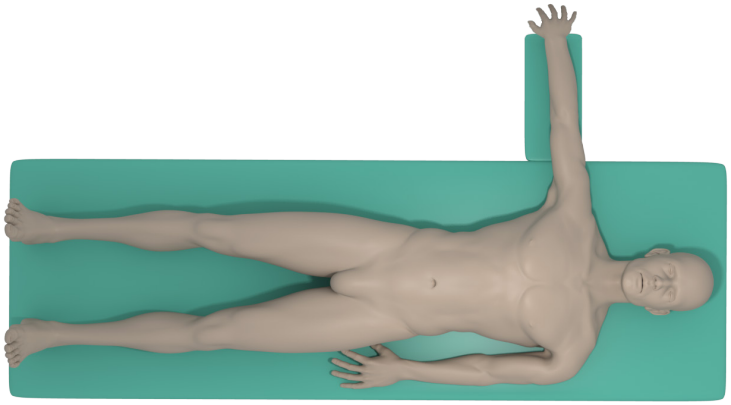
Given description contains the most important stages of the forearm and fibula bones intramedullary nailing procedure, but does not form strict directions for use. A surgeon decides about the surgical technique and its implementation for specific case.

## III.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.

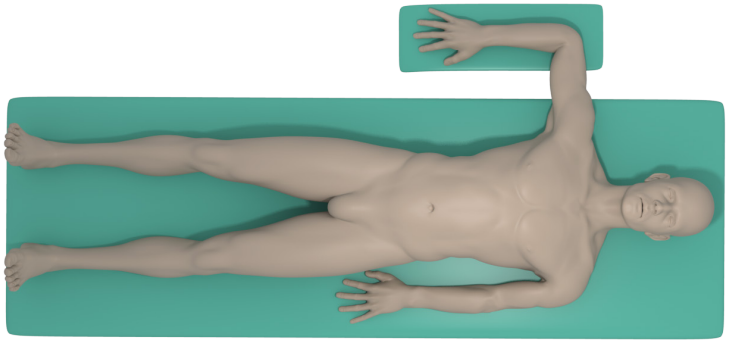
**Patient positioning for radius operation**

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.



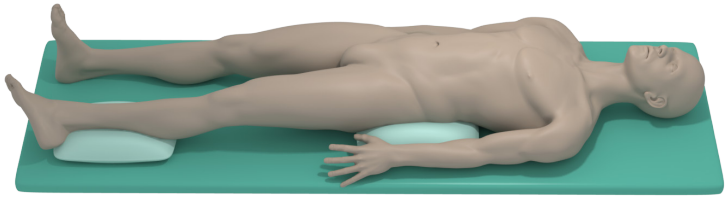
**Patient positioning for ulna operation**

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.





*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

## III.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**

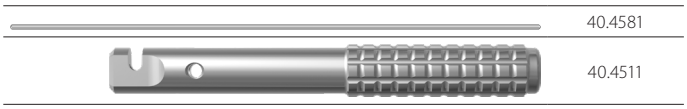
Make 2.5-3cm longitudinal skin incision over the area of distal wrist above the fourth extensor compartment *(distal part of radius)* to prepare surgical approach for radius nailing. Make blunt dissection of subcutaneous tissues to avoid injury to the dorsal radial nerve branches. The extensor digitorum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

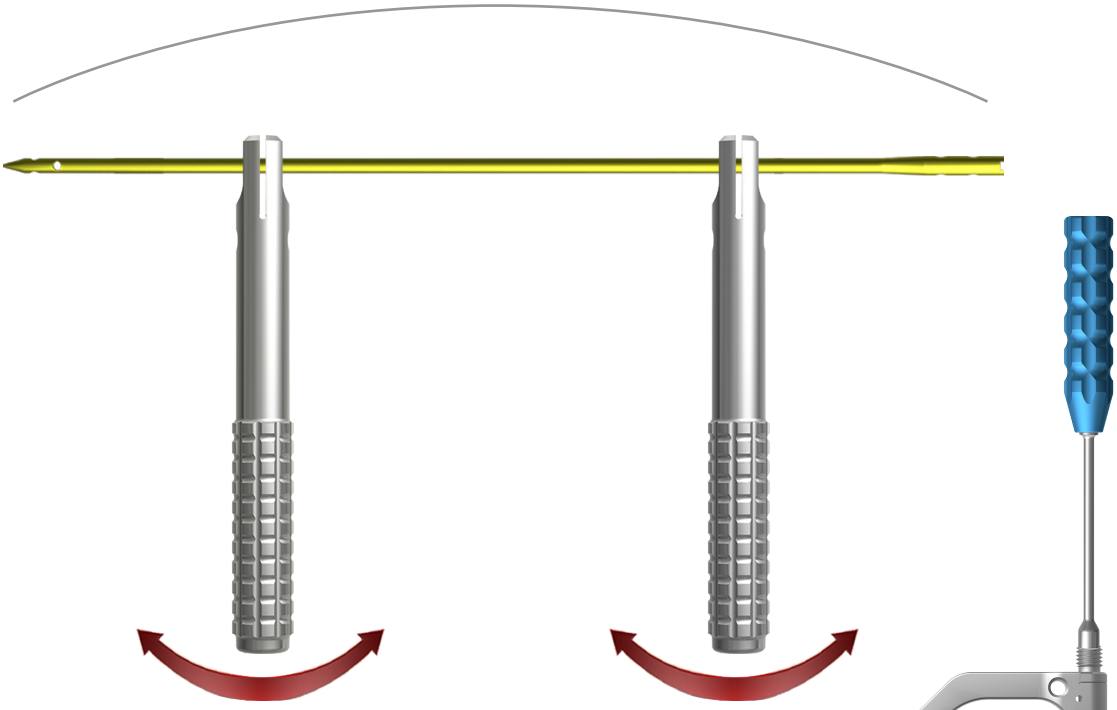
## III.3. PREPARATION OF THE INTRAMEDULLARY NAIL

**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 **[40.4581]**. The bending is carried out with use of two benders **[40.4511]**. 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.

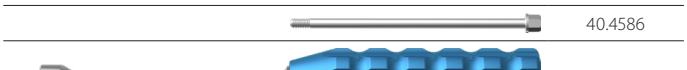


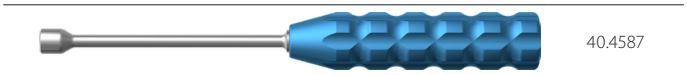


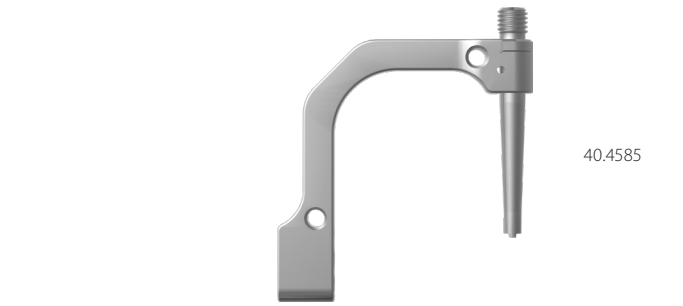


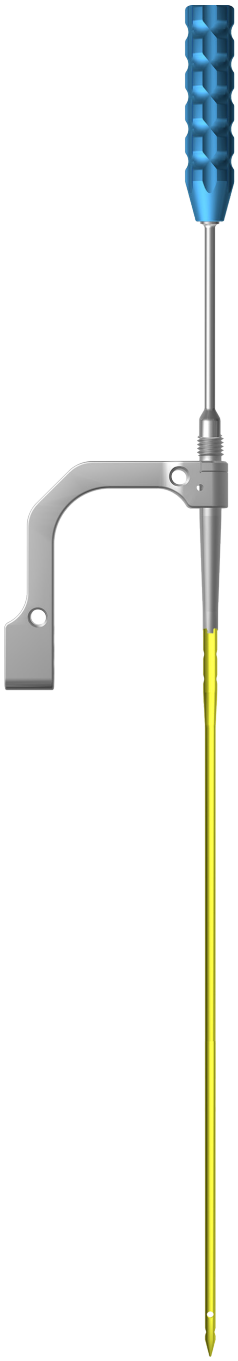


**2** Fix the intramedullary nail to the proximal targeter B **[40.4585]** with the clamping screw M4 **[40.4586]** using the socket wrench S6 **[40.4587]**.



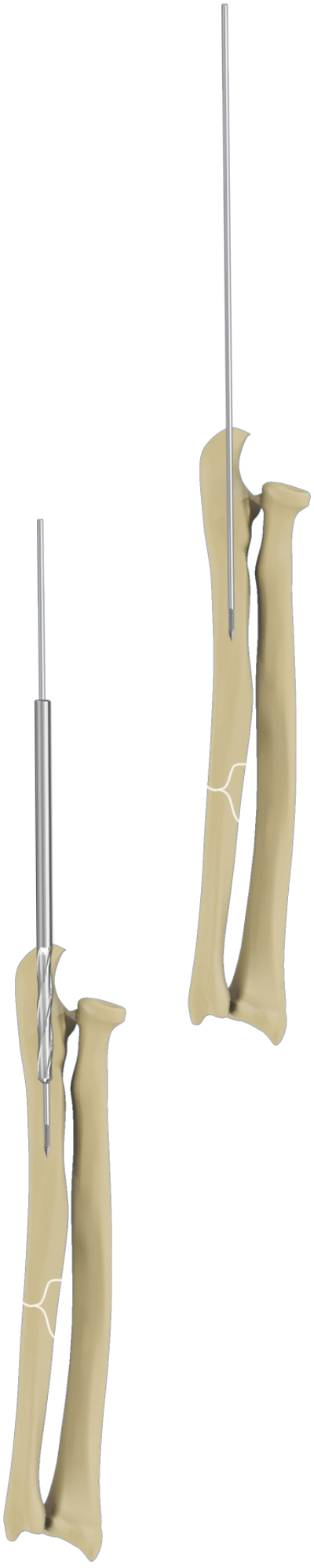
## III.4. OPENING THE MEDULLARY CANAL

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


40.4583



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


40.4584


40.4583

*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

## III.5. NAIL INSERTION INTO MEDULLARY CANAL

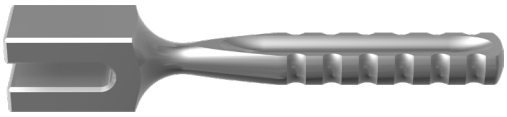
**5** Connect the impactor-extractor **[40.4588]** to the proximal targeter B **[40.4585]** *(insert it onto the threaded top)*. Carefully insert the nail into medullary canal using the mallet **[40.4595]**.

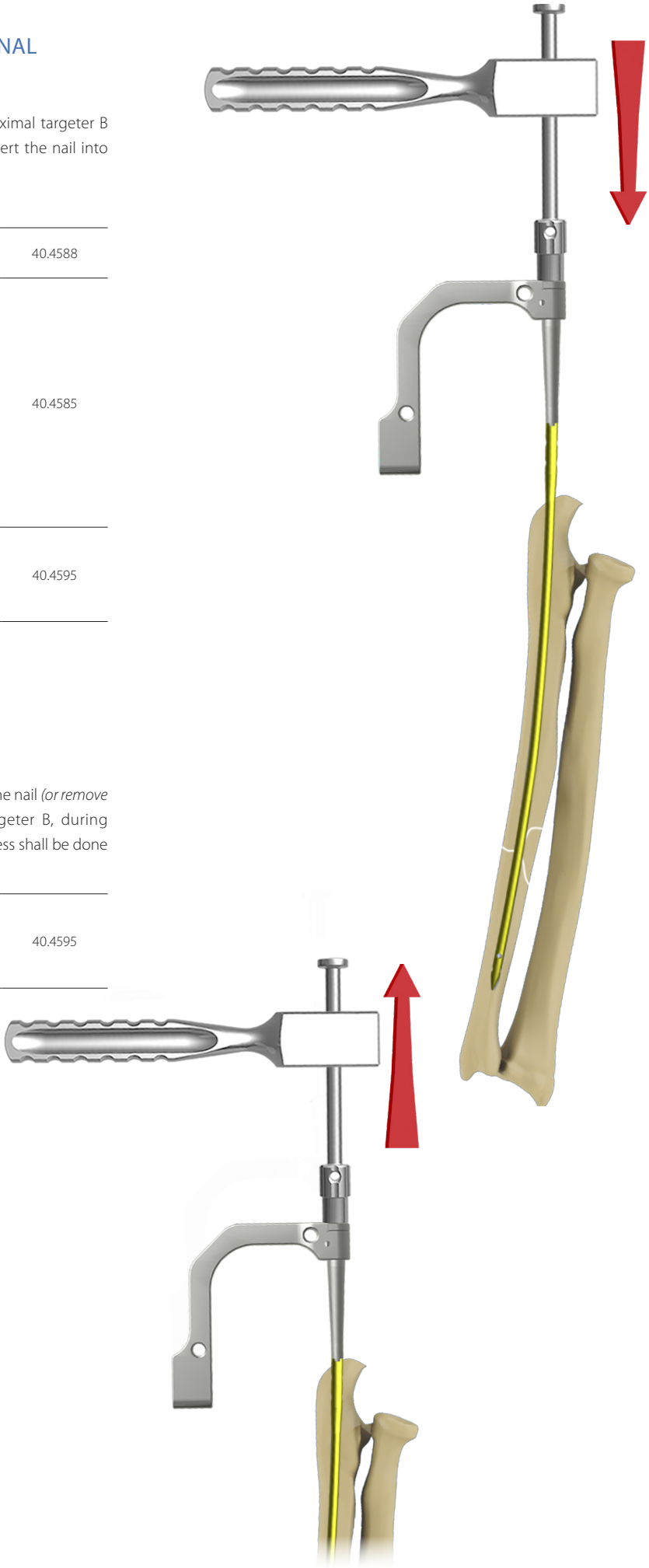

40.4588


40.4585


40.4595

**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 **[40.4595]**.


40.4595



## III.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.

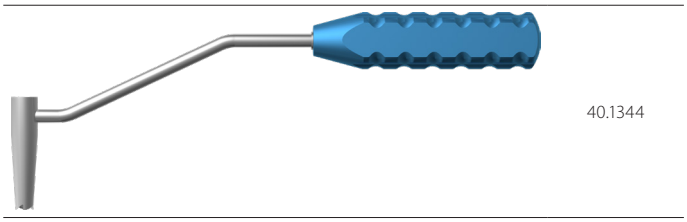
**With this technique an image intensifier is used to determine the drilling point and to drill the hole.**

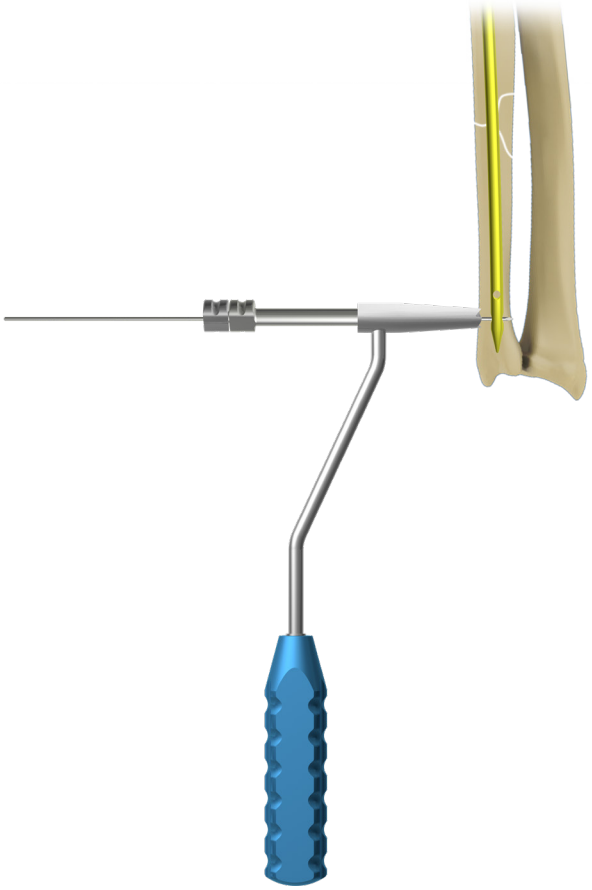
It is recommended to use angular attachment with the surgical drive when drilling the holes, so that surgeon's hands are not directly exposed to X-Rays.
After marking the entry point on the skin for drilling the hole in the bone, 1.5 cm long incision shall be made through the soft tissues.

**7** Using X-Ray machine, place the targeter D **[40.1344]** 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 **[40.4589]** and the Kirschner guide B 5/2 **[40.4590]** into the hole in the targeter D. Mount Kirschner wire **[40.4583]** 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.**

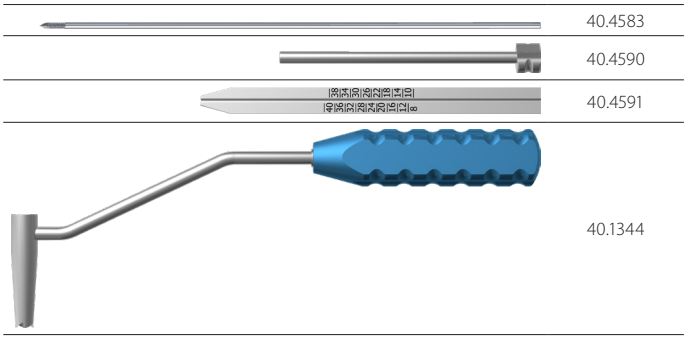
Leave Kirschner wire, guides and the targeter in place.

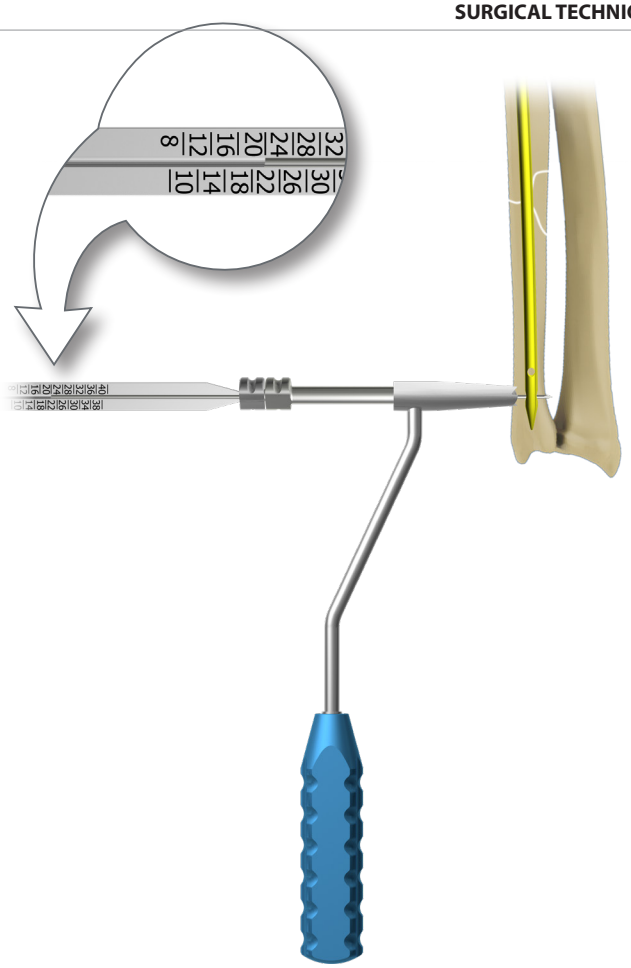


**8** Place the screw length measure **[40.4591]** onto the Kirschner wire **[40.4583]** *(left in the Kirschner guide B 5/2* **[40.4590]***)* until its tip rests on the guide. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire.

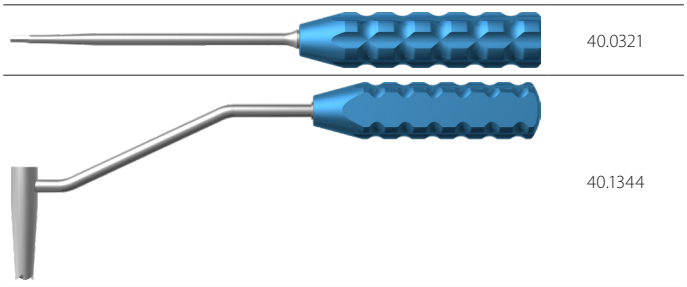
Remove the measure, Kirschner wire and both guides.
Leave the targeter D in place.

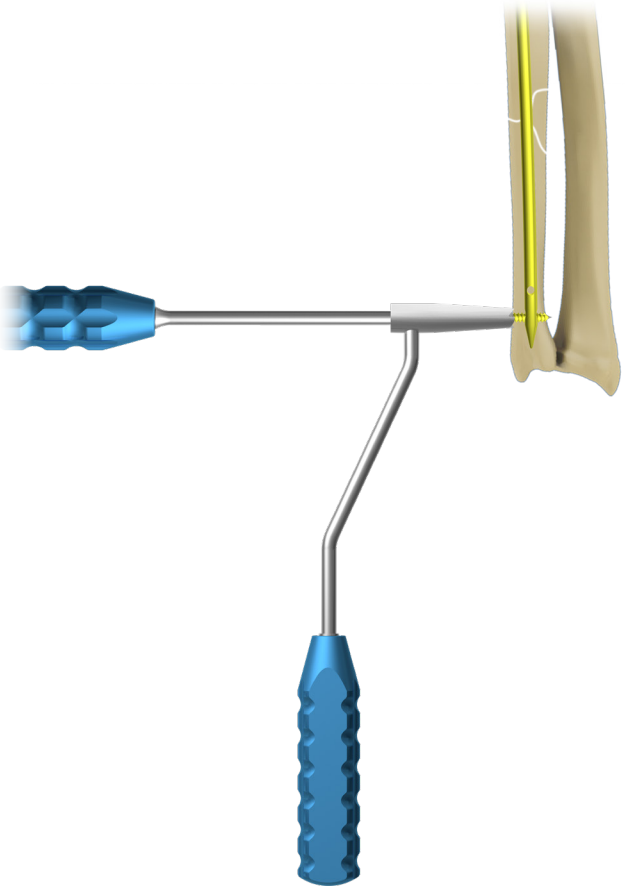


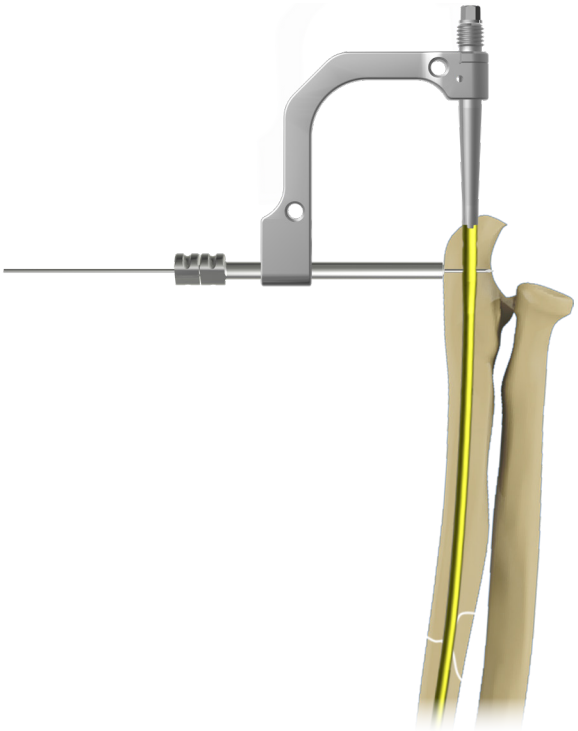
**9** Introduce the tip of the hexagonal screwdriver S2.5 **[40.0321]** into the hexagonal socket of the selected locking screw. Then advance both into the targeter D **[40.1344]** and insert the locking screw in the prepared hole until the head of the screw reaches the bone cortex.

Remove the screwdriver and the targeter D.



## III.7. PROXIMAL LOCKING OF THE INTRAMEDULLARY NAIL

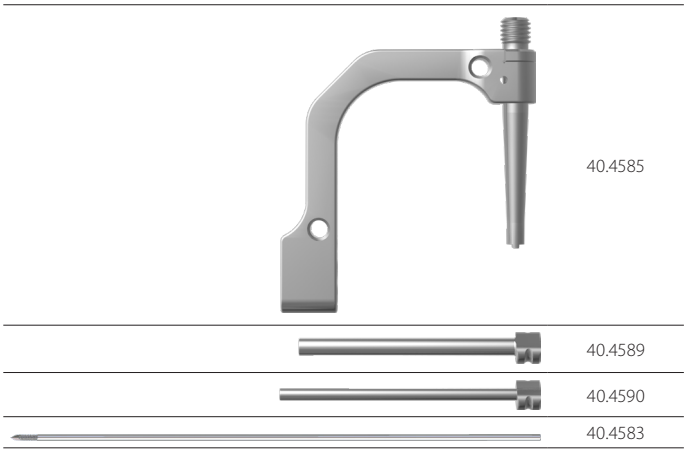


Proximal locking of the intramedullary nail in the ulna is made using two locking screws.

**10** Insert the protective guide 7/5 **[40.4589]** with the Kirschner guide B 5/2 **[40.4590]** into the distal hole in the proximal targeter B **[40.4585]**. Mount Kirschner wire **[40.4583]** in the electric drive and leading through the Kirschner guide, drill the hole in the bone through both cortices.

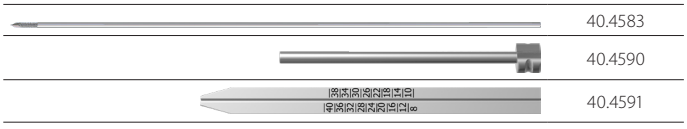
**Image intensifier should be used to control the drilling process.**

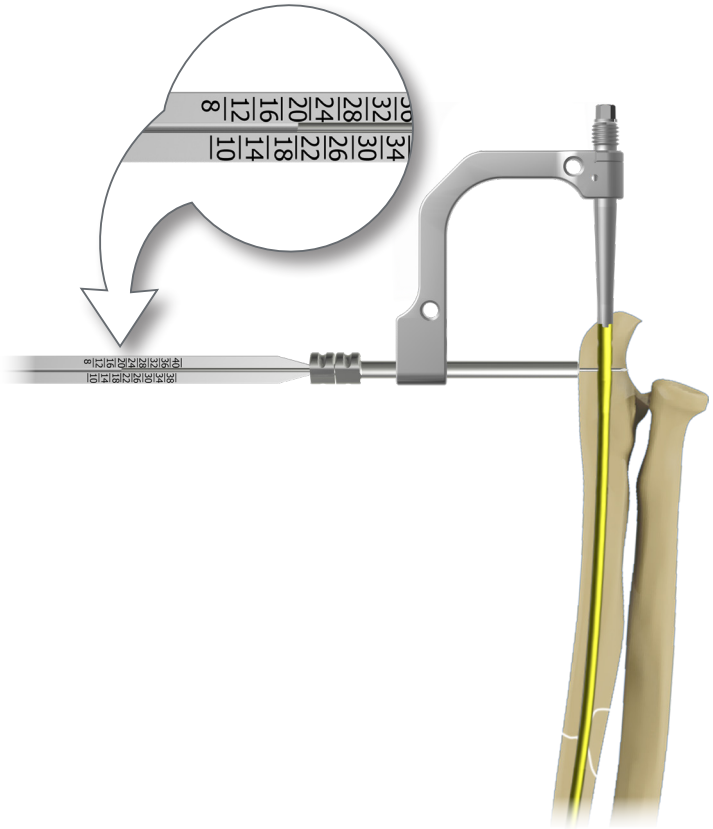
Leave the Kirschner wire and the guides in place.




**11** Place the screw length measure **[40.4591]** on Kirschner wire **[40.4583]** *(left in the Kirschner guide B 5/2* **[40.4590]***)* 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.

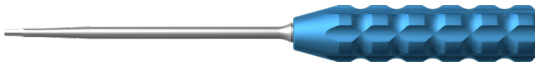
Remove the measure, Kirschner wire and the Kirschner guide.



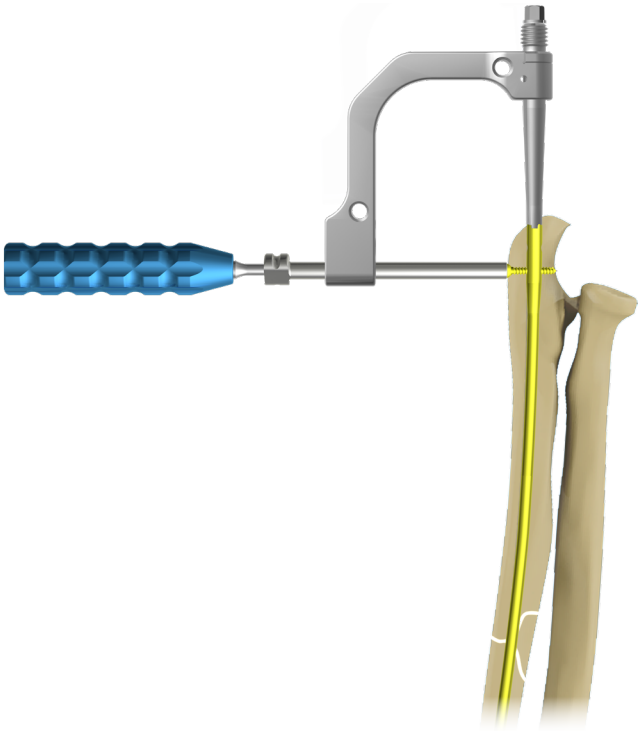



**12** Insert the tip of the hexagonal screwdriver S2.5 **[40.0321]** into the hexagonal socket of the selected locking screw. Then advance both into the protective guide 7/5 **[40.4589]** and insert the locking screw in the prepared hole until the head of the screw reaches the bone cortex.

Remove the screwdriver and the protective guide.

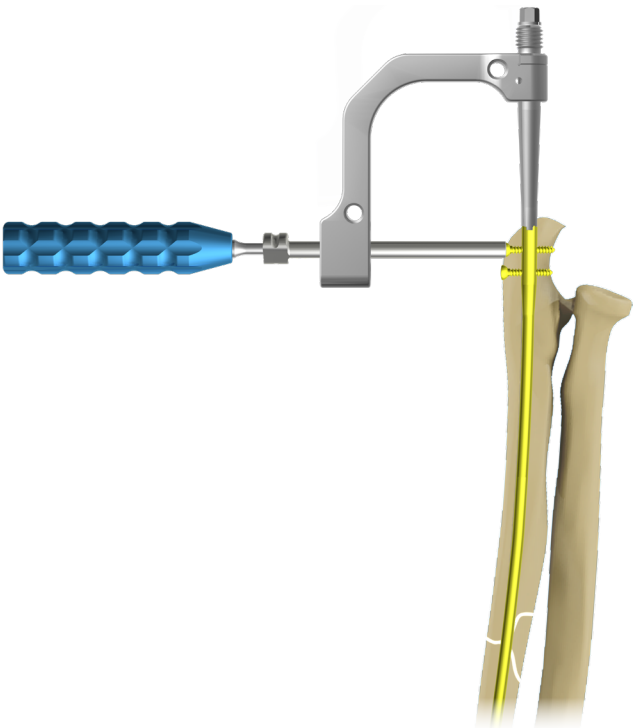

40.0321


40.4589



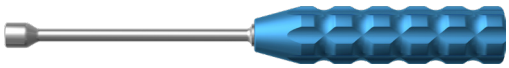
**13** Locking the nail with the other locking screw should be performed using proximal hole in the targeter B **[40.4585]** and according to steps 10 to 12 of the instructions.


40.4585



## III.8. PLACEMENT OF END CAP

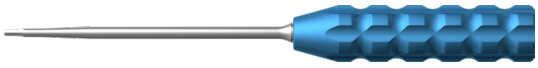
**14** Unscrew the clamping screw M4 **[40.4586]** from the shaft of the intramedullary nail with use of the socket wrench S6 **[40.4587]**. Remove the targeter B **[40.4585]** from the nail locked in the medullary canal.


40.4587


40.4586


40.4585

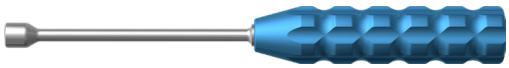
**15** In order to secure the inner thread of the nail against bone ingrowth, insert CHARFIX End cap M4x0.7 **[3.2104.004]**. *(implant)* into the threaded hole using the hexagonal screwdriver S2.5 **[40.0321]**.


40.0321

## III.9. INTRAMEDULLARY NAIL EXTRACTION

**16** Use the hexagonal screwdriver S2.5 **[40.0321]** to remove CHARFIX End cap M4x0.7 **[3.2104.004]**. from the nail shaft. Using the socket wrench S6 **[40.4587]** insert the connector M4 **[40.4596]** into the threaded hole in the nail shaft.
Unscrew all the locking screws using the screwdriver.
Attach the impactor-extractor **[40.4588]** to the connector and with help of the mallet **[40.4595]** remove the nail from the medullary canal.

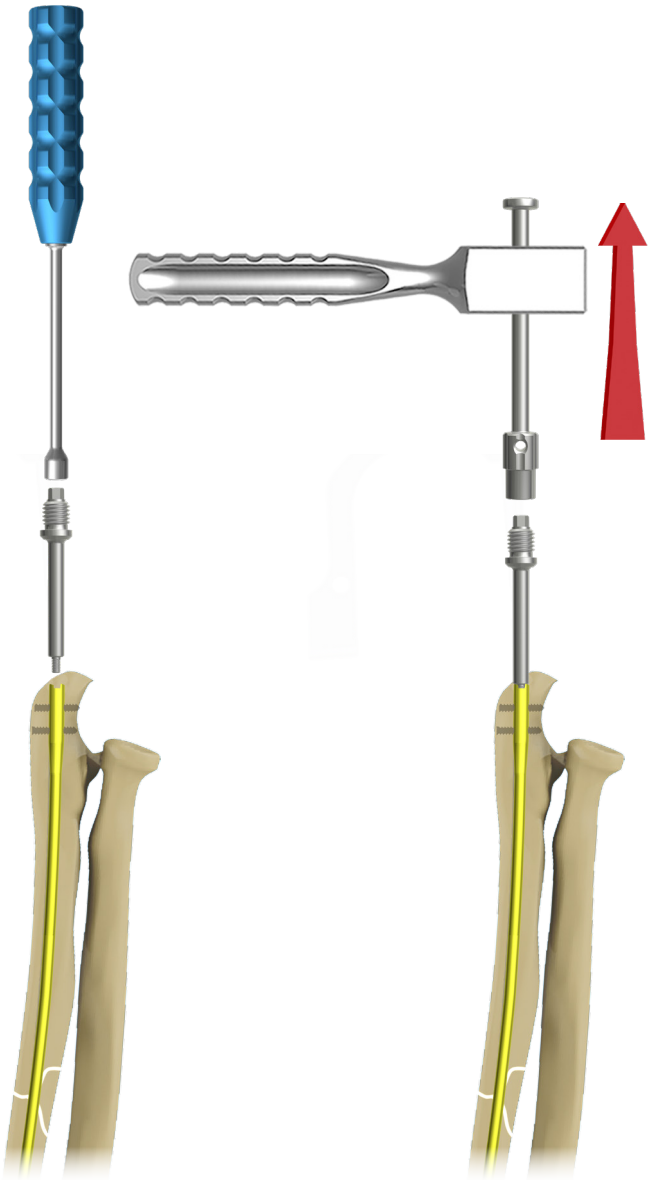

40.0321


40.4587


40.4596


40.4588


40.4595



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