



INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA retrograde method

- IMPLANTS
- INSTRUMENT SET 40.5300.500
- INSTRUMENT SET 40.5380.500
- SURGICAL TECHNIOUE



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SYMBOLS DESCRIPTION

		_	
Ti	Titanium or titanium alloy	\odot	Cannulated
St	Steel		Locking
	Left		Diameter
R	Right		Inner diameter
LR	Available versions: left/right		Recommended length range for a particular nail
Len	Length		Angle
	Torx drive	16 90	Available lengths
	Torx drive cannulated	Ster Non Ster	Available in sterile/ non- sterile condition
	Hexagonal drive	_	
	Hexagonal drive cannulated	_	
\triangle	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
(i)	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 related to the use of the product.	, among others, inc	dications, contraindications, side effects, recommendations and warnings

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/46A

 Date of issue
 04.05.2010

 Review date
 P-006-28.01.2021

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

CHARFIX2 tibial retrograde intramedullary nails manufactured by **ChM** company are designed for stable osteosynthesis of the tarsus and distal tibia, for the treatment of degenerations and deformities of the tarsal joints.

The system consists of:

- implants (intramedullary nail, locking screws, compression screw, end cap),
- instrument set for implants insertion and removal,
- · 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.

Indications for retrograde nailing:

- tibiocalcaneal arthrodesis;
- combined arthrodesis of talocrural joint and talocalcaneal joint;
- avascular necrosis of talocalcaneal joint and talocrural joint;
- · rheumatoid arthritis;
- severe, secondary deformity of untreated congenital club foot (talipes equinovarus) or in the case of the neuromuscular disease;
- seriously deformed foot / ankle, arthritic deformity of ankle with associated stiffness in the talocalcaneal joint;
- osteoarthritis
- · instability and skeletal defects after tumor resection;
- · distal tibial fracture non-unions;
- tibial and/or talus plafond fracture where reconstruction is not possible;
- severe multifragmentary fractures with associated damage to the talocalcaneal joint;
- fractures, dislocations of the ankle combined with serious arthritic changes and loss of function;
- above-ankle non-union combined with stiffness in the talocalcaneal joint;
- · mal-union of ankle;
- failed total ankle replacement with talocalcaneal joint intrusion.

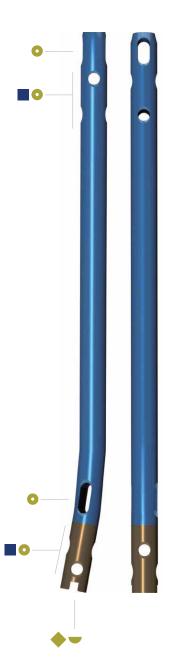


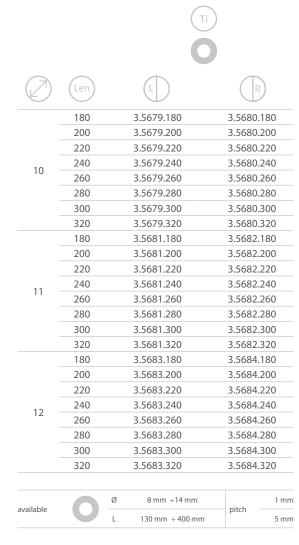
II. IMPLANTS

CHARFIX2 RETROGRADE TIBIAL NAIL

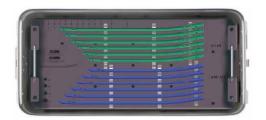












Stand for tibial nails CHARFIX/CHARFIX2 (implants not included)

40.5750.000

LOCKING ELEMENTS









CHARFIX2 DISTAL SCREW 5.0



CHARFIX2 DISTAL SCREW 5.5







26	3.5159.026
28	3.5159.028
30	3.5159.030
35	3.5159.035
40	3.5159.040
45	3.5159.045
50	3.5159.050
55	3.5159.055
60	3.5159.060
65	3.5159.065
70	3.5159.070
75	3.5159.075
80	3.5159.080
85	3.5159.085
90	3.5159.090



26	3.5160.026
28	3.5160.028
30	3.5160.030
35	3.5160.035
40	3.5160.040
45	3.5160.045
50	3.5160.050
55	3.5160.055
60	3.5160.060
65	3.5160.065
70	3.5160.070
75	3.5160.075
80	3.5160.080
85	3.5160.085
90	3.5160.090
16	



100

CHARFIX2 END CAP M8 SPEC.











3.5161.006

3.5162.006



Stand for CHARFIX2 nail locking elements (set with a box without implants)

40.5058.200



III. INSTRUMENT SET

To carry out tibial osteosynthesis, use instrument set for **CHARFIX2** tibial nails **[40.5300.500]** and instrument set **[40.5380.500]**.

INSTRUMENT SET FOR TIBIAL NAILS 40.5300.500



40.5300.500	Name	Catalogue No.	Pcs
	Targeter arm B	40.5301.000	1
	Targeter D	40.5302.100	1
	Targeter B	40.5303.100	1
	Wrench S8	40.5304.000	1
	Connecting screw M8x1.25 L-89	40.5305.000	1
	Connecting screw M8x1.25 L-22	40.5306.000	1
	Reconstruction targeter	40.5307.100	1
	Impactor-extractor	40.5308.000	1
	Connector M8x1.25/M14	40.5309.000	1
	Targeter arm B short	40.5312.000	1
=======================================	Compression screw	40.5313.000	1
TARATAMATAMATAMATAMATAMATAMATAMATAMATAMA	Mallet	40.3667.000	1
	Set block 9/5.0	40.5509.100	2
	Protective guide 9/7	40.5510.200	2
	Drill guide 7/3.5	40.5511.200	2
	Trocar 6.5	40.5534.100	1



40.5300.500	Name	Catalogue No.	Pcs
**************************************	Nail length measure	40.4798.500	1
	Guide rod handle	40.1351.000	1
	Teflon pipe guide 8/400	40.3700.000	1
kekelebekeleb	Drill with scale 3.5/150	40.5343.002	1
	Targeter D	40.1344.100	1
	Drill guide short 7/3.5	40.1358.100	1
	Trocar short 7	40.1354.100	1
	Aiming insert 9.0	40.5065.009	2
	Guide rod 2.5/580	40.3673.580	1
	Screwdriver T25	40.5575.400	1
DODOCOCO BRANCAPARACE BRANCAPARARAGA ()	Drill with scale 3.5/350	40.5339.002	2
	Screw length measure	40.5530.200	1
	Hole depth measure	40.2665.000	1
	Curved awl 8.0	40.5523.000	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
	Stand for tibial nails	40.5319.500	1
	Container with solid bottom 1/1 595x275x185mm	12.0750.103	1



INSTRUMENT SET FOR RETROGRADE TIBIAL NAILS CHARFIX2 40.5380.500



40.5380.500	Name	Catalogue No.	Pcs
Chm 40,5382 CE 8	Proximal targeter	40.5382.000	1
	Lateral distal targeter	40.5384.000	1
	Connecting screw M8x1.25 L-84	40.5385.000	1
	Lateral targeter	40.5383.000	1
	Screwdriver T25	40.5381.100	1
	Compression screw	40.5386.000	1
	Connector M8x1.25/M14	40.5873.000	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
	Stand for instrument set of retrograde tibial nails	40.5389.500	1
	Container with solid bottom 1/1 595x275x185mm	12.0750.100	1



IV. SURGICAL TECHNIQUE



The following description covers the most important steps during the implantation of retrograde tibial nails. Nevertheless, it is not a detailed instruction of conduct.

The surgeon decides about choosing the operating technique and its application in each individual case.

IV.1. SURGERY PLANNING

Each procedure must be planned accordingly. Prior to surgery, take an X-Ray image of the fractured extremity as to determine the type and location of the fracture and to determine the size of the nail to be implanted. It is recommended to take the AP, PA and lateral images.

Implantation procedure should be conducted on the operating table equipped with a real-time X-Ray imaging system.

IV.2. SURGICAL APPROACH

Position the patient prone.

Pneumatic tourniquet should be applied on the upper part of the thigh, providing a bloodless surgical field.



In order to obtain the access to the tibiotalar joint, perform a 5-6cm lateral incision in line with the distal lateral malleolus, and then perform a resection of the distal fibula (*see figure below*). This will allow for adequate exposure of the tibiotalar joint. Resect the distal end of the fibula which, if required, can be used as bone graft.





When the bone fracture is properly reduced, perform 3cm long transverse or longitudinal incision on the plantar surface of the heel. To make it easier to find the entry point for the nail and to protect the neurovascular structures, stretch soft tissues using forceps. Open the plantar fascia down to the calcaneum.

Nail insertion point should be in line that goes from the second toe to the middle of the fascia in the medial / lateral plane, overlapping at the same time with the vertical axis of the tibia.



When incising and placing the nail, be careful not to damage the neurovascular structures.



IV.3. MEDULLARY CANAL OPENING

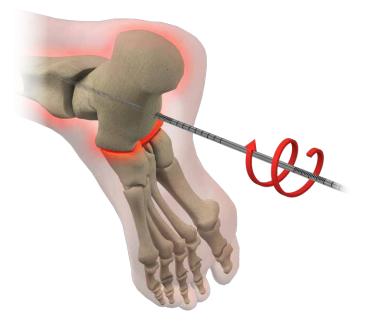
40.5339.002

1 When surgical approach is prepared and the nail entry point is located, mark on the bone the entry point of the nail while holding the foot in the correct position. Using an electric drive and a drill with scale 3.5/350 [40.5339.002], penetrate the cortex and insert it into the medullar cavity.



Make sure that the drill was inserted through the designated point along the axis of the tibia and through the calcaneum, talus and tibia.

Remove the drill.



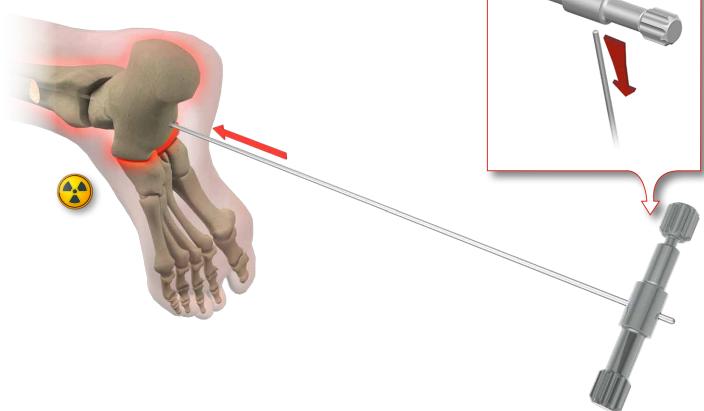


Mount the guide rod 2.5/580 **[40.3673.580]** to the guide rod handle **[40.1351]** and insert the system into the hole in the medullary cavity through the tarsal bones until the tibial shaft is reached.

Remove the guide rod handle.



Control the drilling using the real-time X-Ray imaging system.



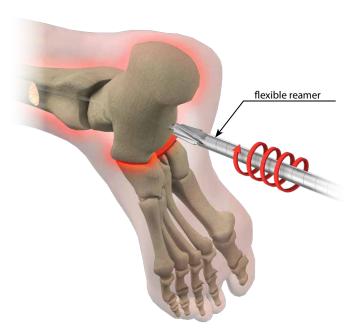
40.3673.580

Insert flexible reamer (not included in the instrument set) through the guide rod 2.5/580 **[40.3673.580]** Gradually ream the medullary cavity until the canal $0.5 \div 1.0$ mm greater than the diameter of the intramedullary nail to be implanted is reached.

It is recommended to drill the canal to a depth slightly longer than the length of the implant.

Remove flexible reamer.

It is advisable to use help in supporting the foot in the correct position as to reduce the fracture during reaming the canal.



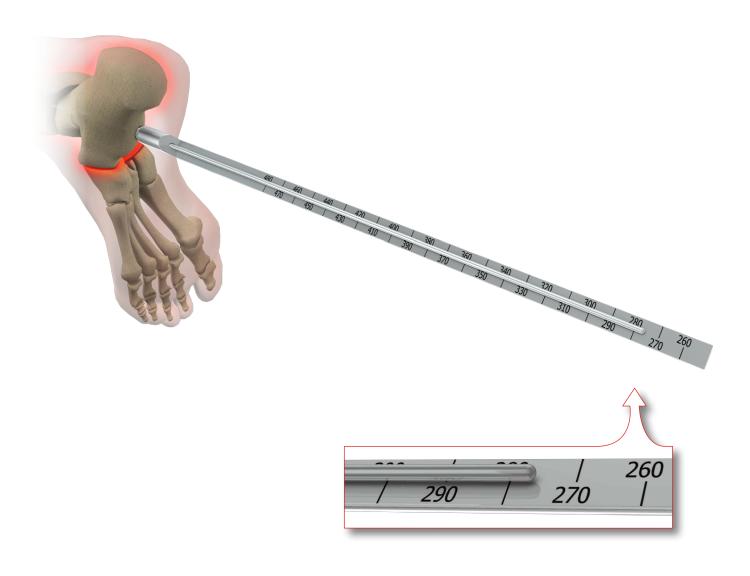




Insert nail length measure [40.4798.500] through the guide rod. Place the nail length measure beginning in the entry point of the nail. Read the length of the nail on the scale.

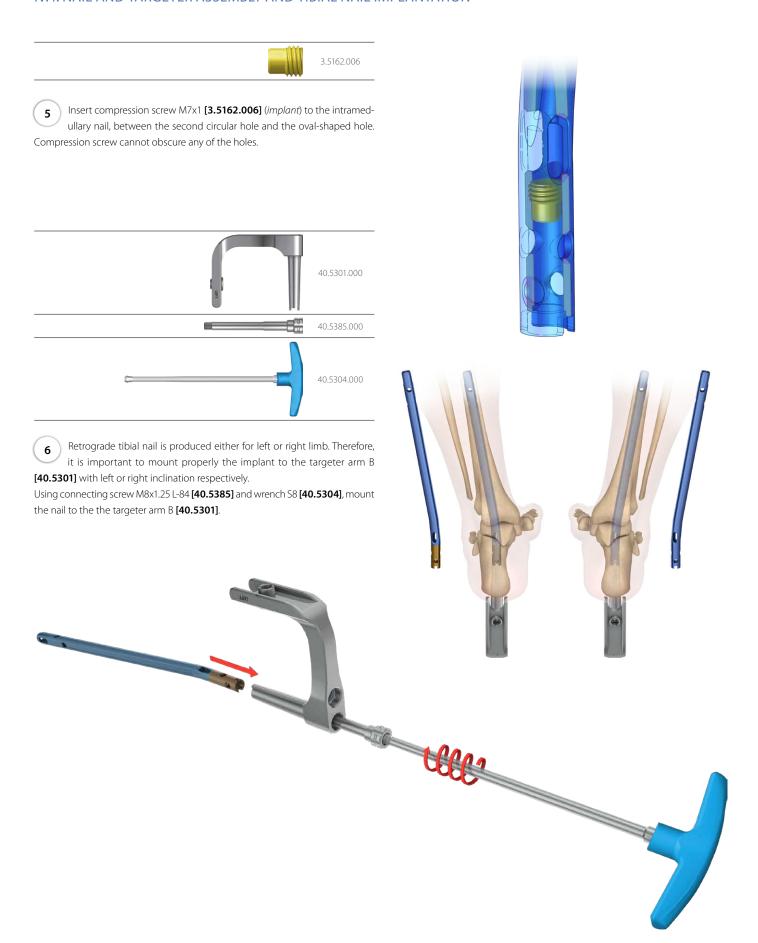
Remove nail length measure from the guide rod.

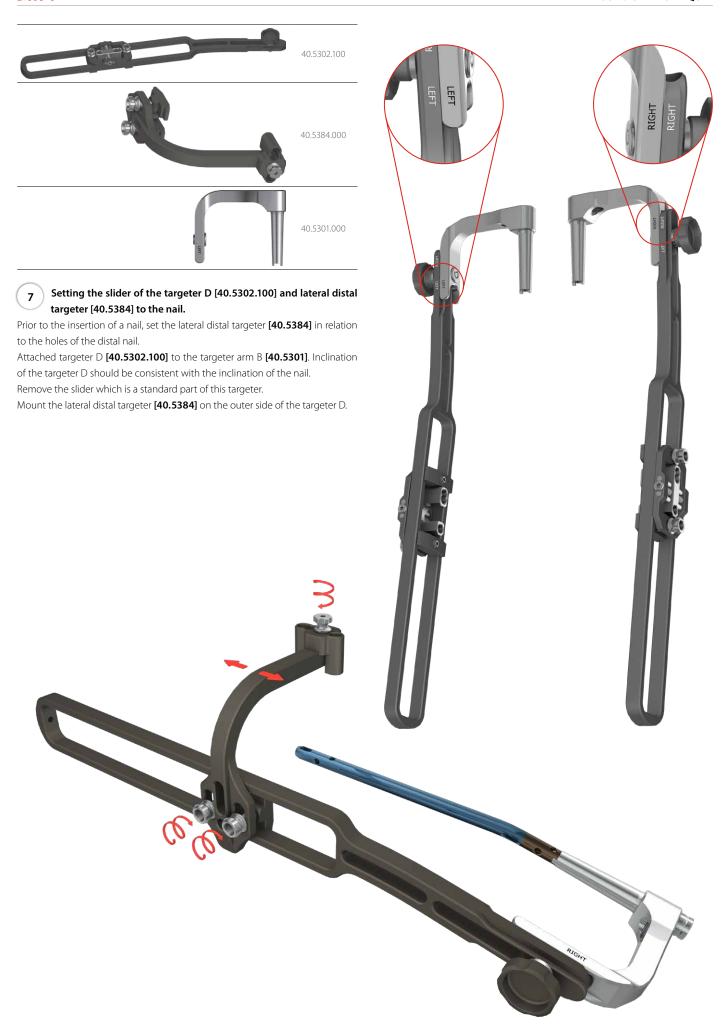
Should a solid nail be implanted, remove the guide rod from the medullary canal.





IV.4. NAIL AND TARGETER ASSEMBLY AND TIBIAL NAIL IMPLANTATION







Using two set blocks 9/5.0 **[40.5509.100]**, set the targeter to the nail locking holes in the lateral and fibular plane. Lock the slider of the lateral distal targeter **[40.5384]** and the targeter itself using a screwdriver T25 **[40.5575.400]**.



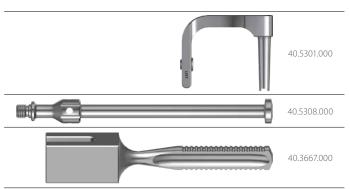
When the targeter slider is properly set and locked, set blocks should go through the nail holes freely.

Remove set blocks from the targeter slider.

Disconnect targeter [40.5302.100] from targeter arm.



Prior to implantation, verify whether the proximal targeter holes overlap with the holes in the nail. To do so, insert the set block [40.5509.100] into the proximal targeter hole [40.5382].



8 Connect impactor-extractor [40.5308] (through its threaded end) to the targeter arm B [40.5301] to which a nail is mounted. Using the mallet [40.3667], insert the nail to the desired depth into the medullary canal.

Remove impactor-extractor [40.5308].



When inserting the nail, targeter arm B [40.5301] shall be vertically positioned (from the heel).



Ideally, the nail should be inserted about 5-10mm deeper than plantar-calcaneus cortex. In some cases where reduction of the calcaneum or tarsus is required, the nail can be inserted deeper.









IV.5. NAIL LOCKING IN TALUS



Locking the first screw in the talus allows for a separate compression between: tibia and talus (talocrural joint), and between the calcaneus and talus (talocalcaneonavicular joint).



Attach proximal targeter [40.5382] to the targeter arm B [40.5301]. Depending on the limb, use the holes on the right or left side of the targeter. Insert protective guide 9/7 [40.5510.200] and trocar 6.5 [40.5534.100] to the chosen hole of the proximal targeter.

Mark on the skin the entry point for the locking screw and perform soft tissue incision. Use the trocar to mark on the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible

Remove the trocar.

Leave the protective guide in place.

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· Del	40.5511.200
Biologic et et et en product et et et en	40.5339.002

Insert drill guide 7/3.5 [40.5511.200] in the left protective guide 9/7 [40.5510.200]. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the talus that passes through the nail hole to the adequate depth.



Control drilling using real-time X-Ray imaging system.

Read the length of the locking screw on a drill scale.

Remove the drill and drill guide.

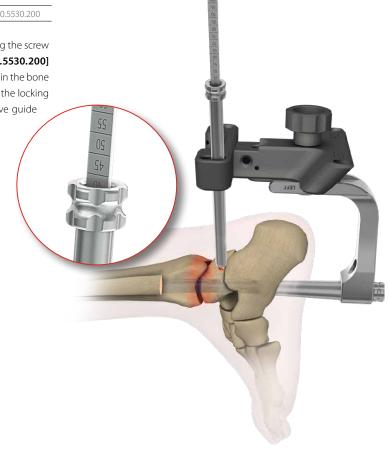


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The length of the locking screw can also be determined using the screw length measure. To do so, insert screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on scale. During the measurement, the end of the protective guide should lean against the cortex bone.

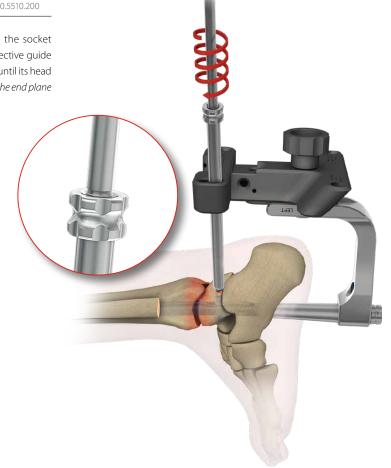
Remove the screw length measure. Leave the protective guide in the hole of the targeter.





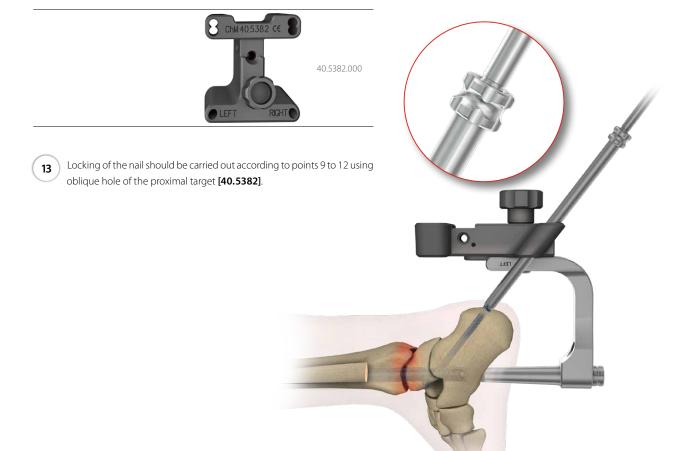
Insert the tip of the screwdriver T25 **[40.5575.400]** into the socket of a specified locking screw. Insert the system into the protective guide 9/7 **[40.5510.200]** and screw in the locking screw in the drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).

Remove the screwdriver and protective guide. Detach the proximal targeter.

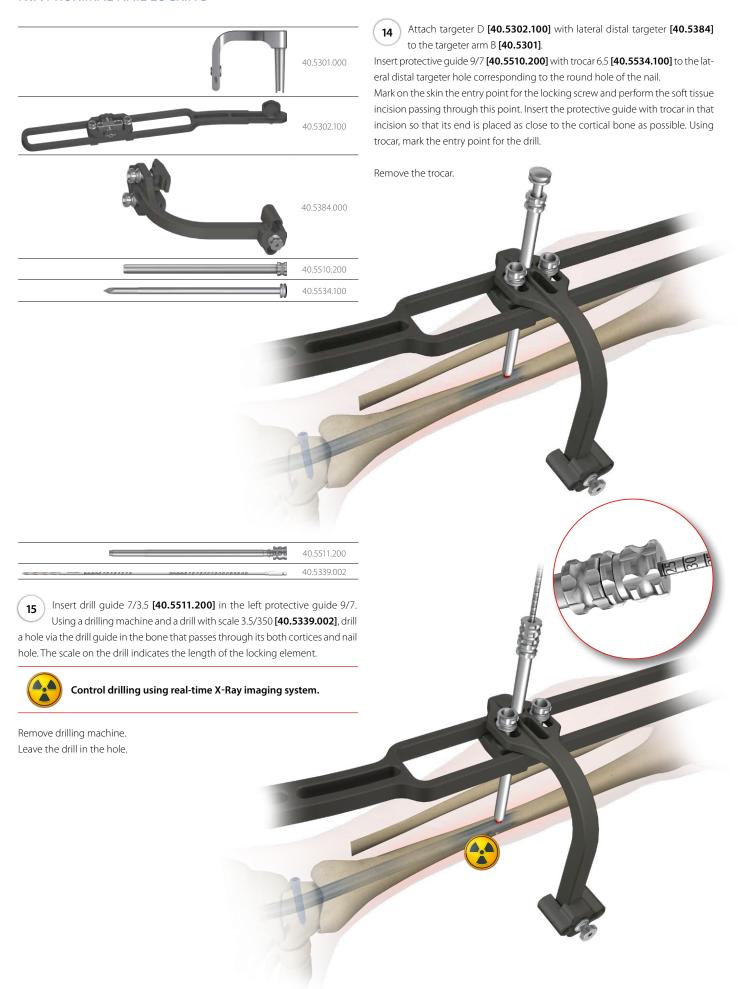


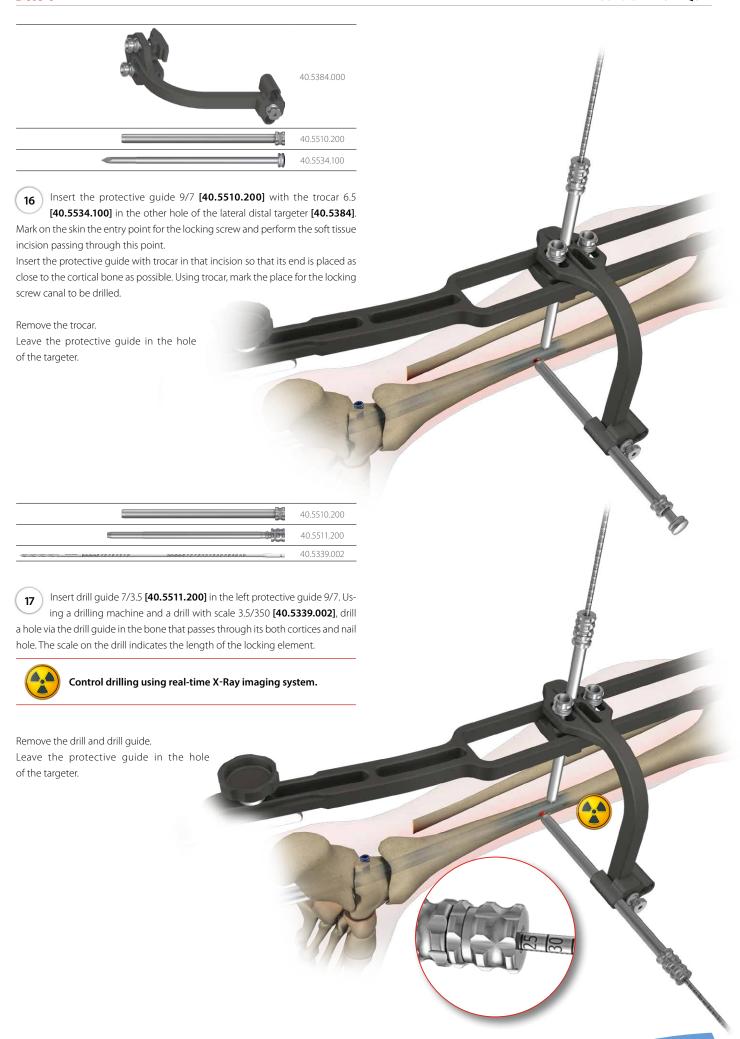


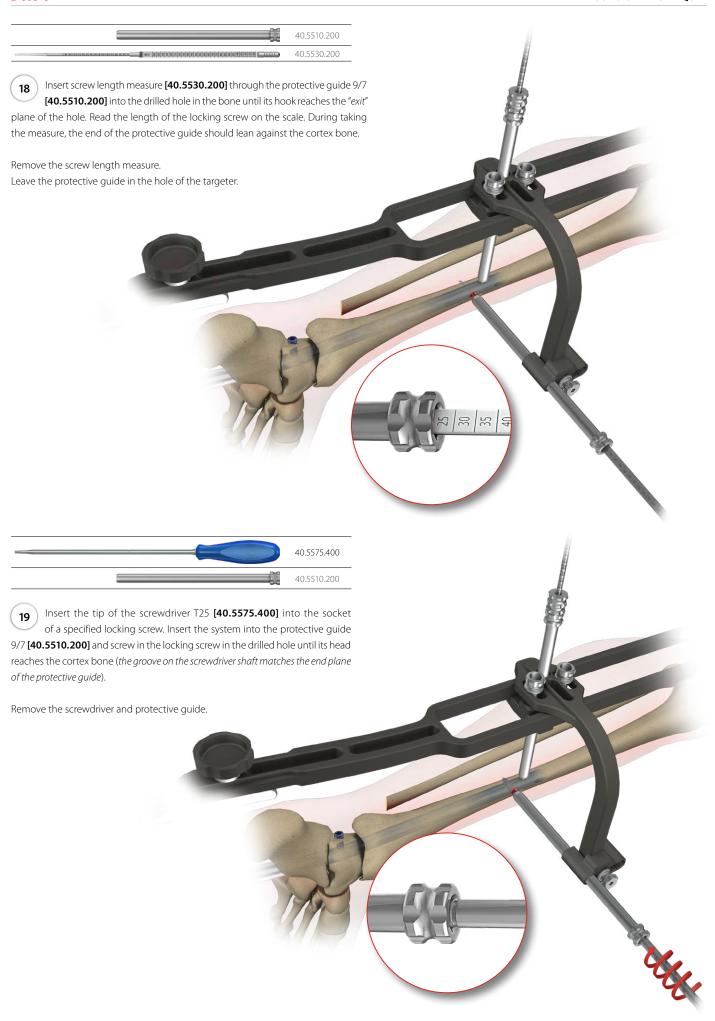
IV.6. OBLIQUE LOCKING THROUGH TALOCALCANEONAVICULAR JOINT - OPTIONAL

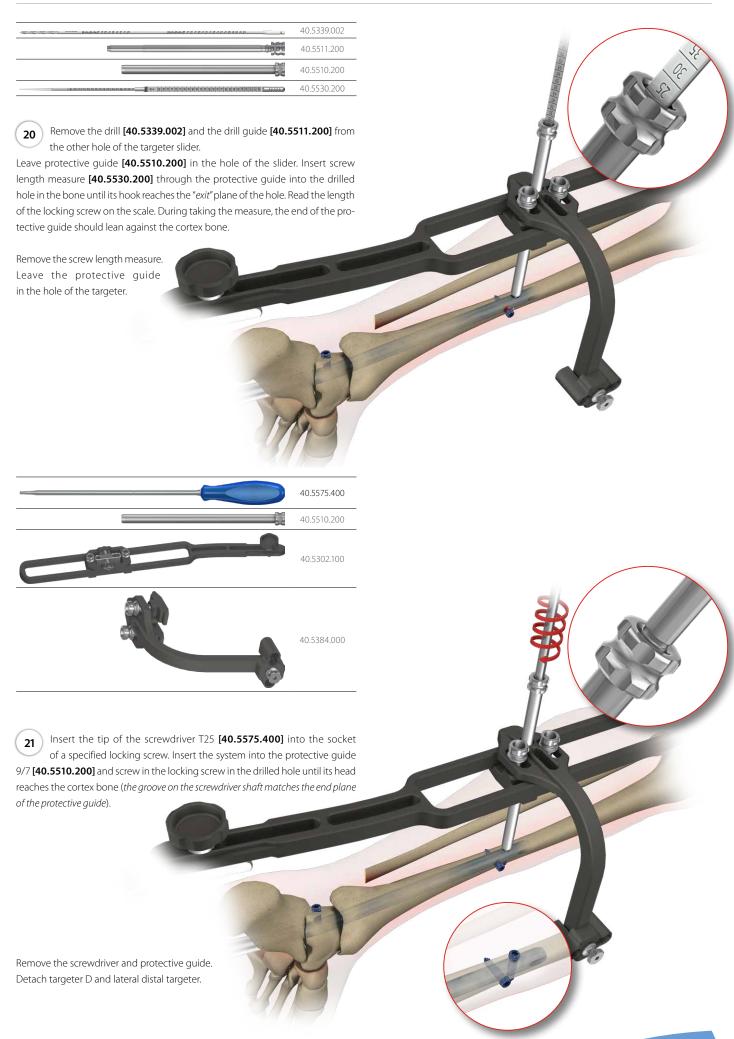


IV.7. PROXIMAL NAIL LOCKING









IV.8. PROXIMAL NAIL LOCKING USING "FREE-HAND" TECHNIQUE



40.1344.100



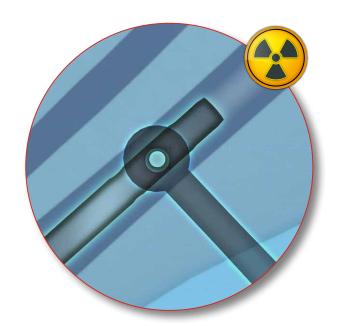
Proximal locking of the nail is carried out using "free-hand" technique and targeter D [40.1344.100].

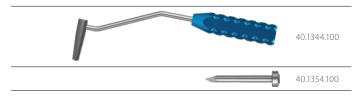
While drilling, it is recommended to use angular drill attachment so that the operator's hands are not directly exposed to X-Rays.

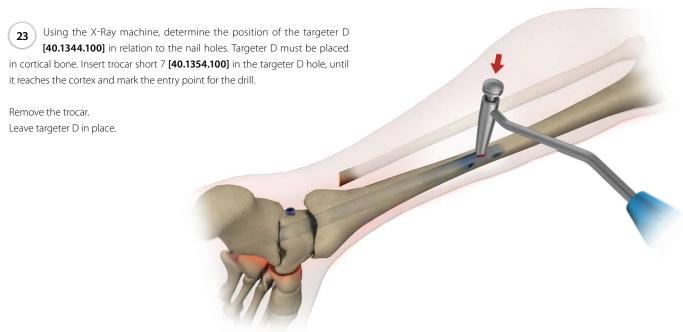
Mark on the skin the entry points and perform soft tissue incision passing through these points for the length of about 1.5 cm.

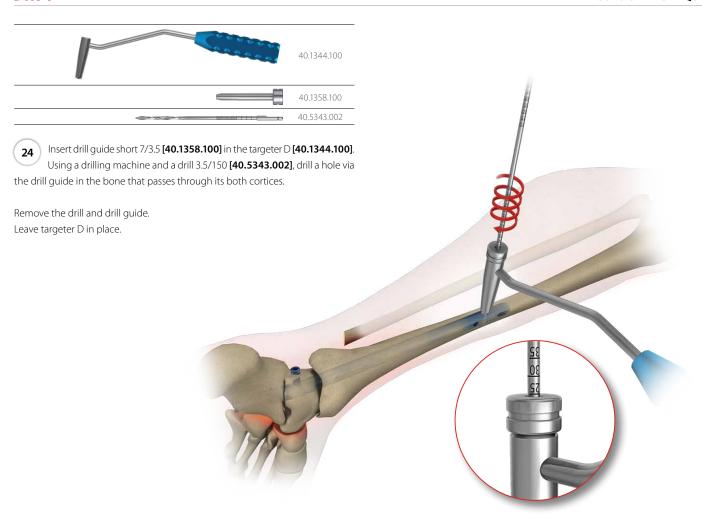


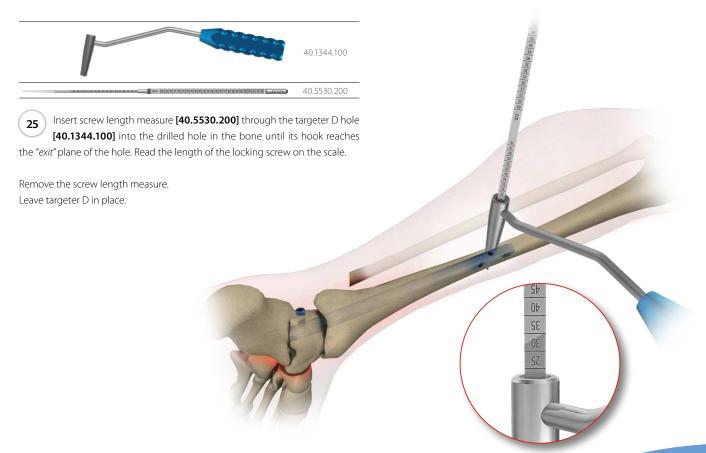
Control using the real-time X-Ray imaging system.

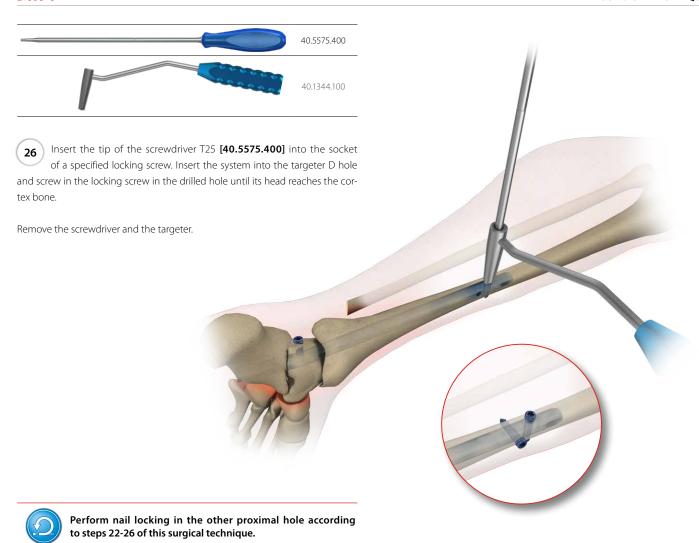




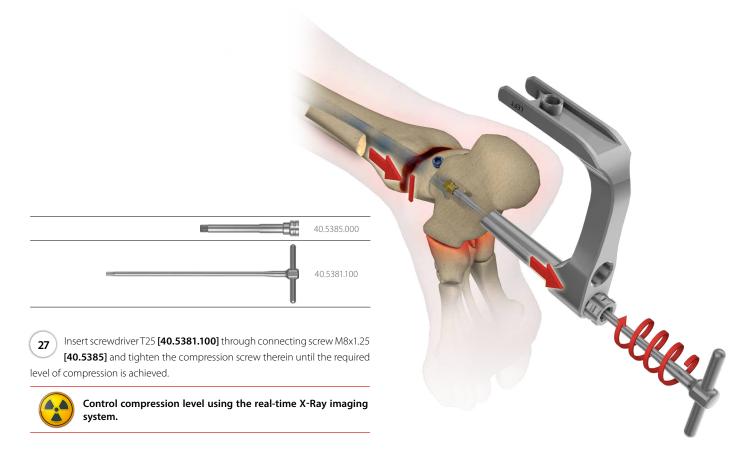




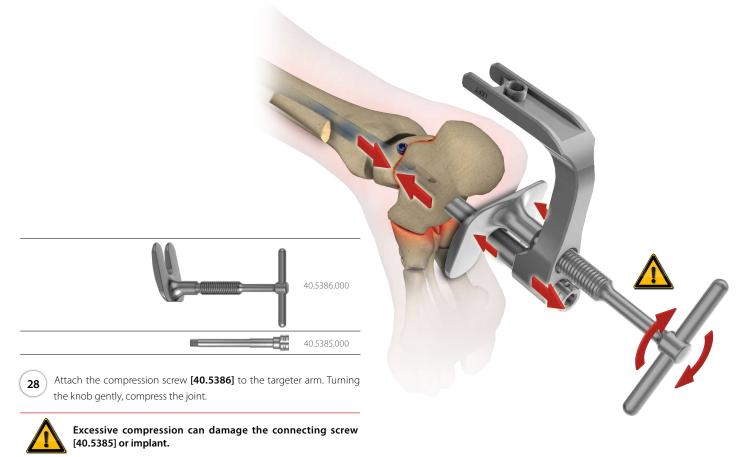




IV.9. TALOCRURAL JOINT COMPRESSION



IV.10. TALOCALCANEONAVICULAR JOINT COMPRESSION





IV.11. NAIL LOCKING IN THE CALCANEUM







Attach proximal targeter **[40.5382]** to the targeter arm B **[40.5301]** and then lateral targeter **[40.5383]** to the proximal one from the side.



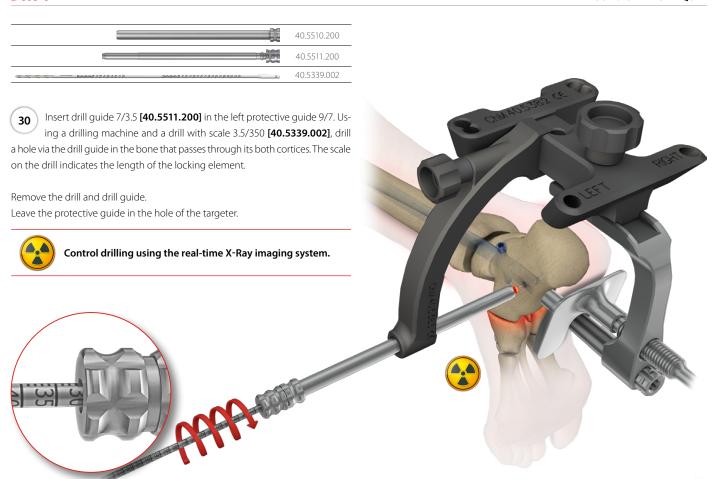
Insert protective guide 9/7 **[40.5510.200]** and trocar 6.5 **[40.5534.100]** into the hole of lateral targeter.

Mark on the skin the entry point for the screw and perform soft tissue incision. Use the trocar to mark on the cortex the entry point for the drill.

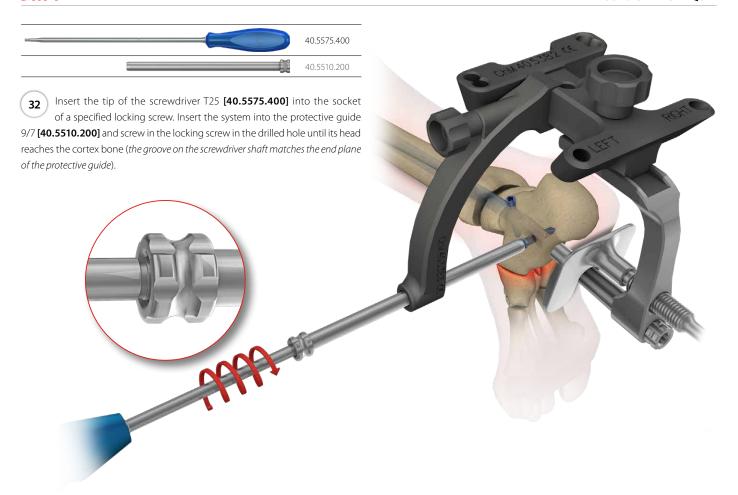
At the same time advance the protective guide as close to the bone as possible.

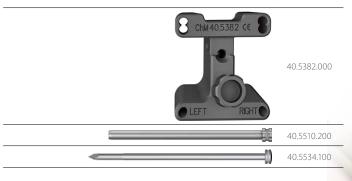
Remove the trocar.











33 Insert protective guide 9/7 [40.5510.200] and trocar 6.5 [40.5534.100] into the hole of proximal targeter [40.5534.100].

Mark on the skin the entry points and perform soft tissue incision passing through these points about 1.5cm in length.

Insert the protective guide with trocar in that incision so that its end is placed as close to the cortical bone as possible. Using trocar, mark the entry point for the drill.

Remove the trocar.





Insert drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 **[40.5339.002]**, drill a hole via the drill guide in the bone that passes through its both cortices. The scale on the drill indicates the length of the locking element.

Remove the drill and drill guide. Leave the protective guide in the hole of the targeter.



Control drilling using the real-time X-Ray imaging system.

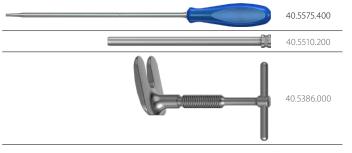


Insert screw length measure **[40.5530.200]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole in the bone until its hook reaches the "exit" plane of the hole.

Read the length of the locking screw on the scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

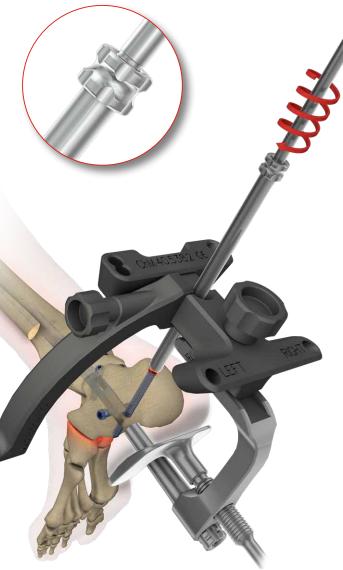
Remove the screw length measure.





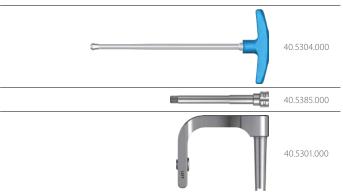
Insert the tip of the screwdriver T25 **[40.5575.400]** into the socket of a specified locking screw. Insert the system into the protective guide 9/7 **[40.5510.200]** and screw in the locking screw in the drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).

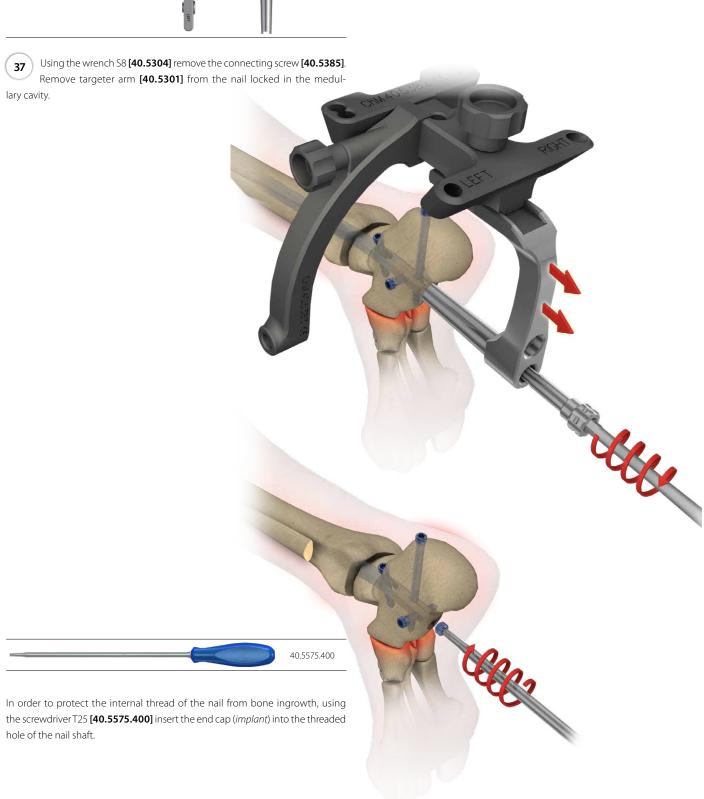
Remove screwdriver **[40.5575.400]**. Remove protective guide **[40.5510.200]**. Remove compression screw **[40.5386]**.





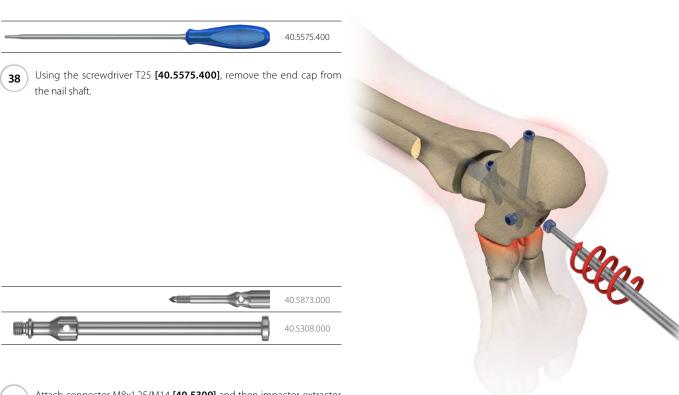
IV.12. END CAP INSERTION



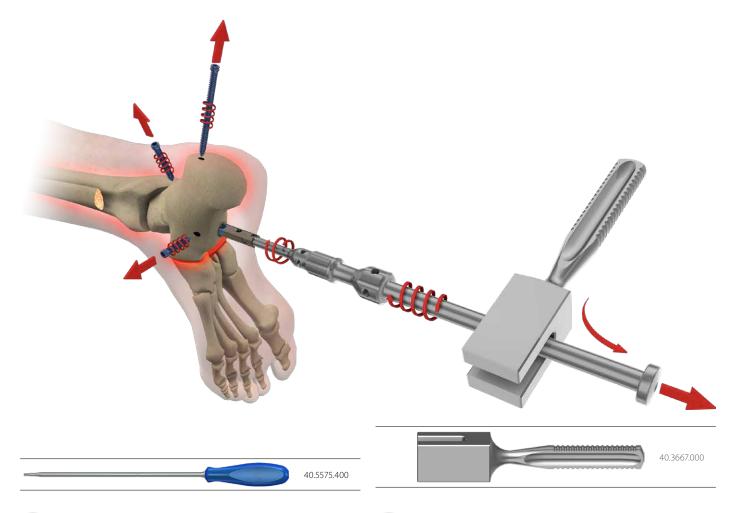




IV.13. NAIL REMOVAL



Attach connector M8x1.25/M14 [40.5309] and then impactor-extractor [40.5308] to the threaded shaft hole of the nail.



40 Using screwdriver T25 [40.5575.400], remove all locking screws.

Using the mallet [40.3667], remove the tibial nail from the medullary canal.

ChM sp. z o.o.

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