








**CHARFIX** *system 2*

## INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA retrograde method

- *IMPLANTS*
- *INSTRUMENT SET 40.5300.500*
- *INSTRUMENT SET 40.5380.500*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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*The manufacturer reserves the right to introduce design changes.*

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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.

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;
- after a failed total ankle replacement with talocalcaneal joint intrusion.

The nail has 6 holes for locking screws in its proximal and distal part.

Locking is performed using the targeters included in the instrument set and additional targeters.

## II. IMPLANTS

The tibial implants for retrograde nailing include:

- solid and cannulated retrograde tibial nails,
- locking screws,
- end cap M8spec,
- compression screw M7x1.


**CHARFIX2** system includes retrograde tibial nails in stainless steel and titanium versions of the following types and sizes:

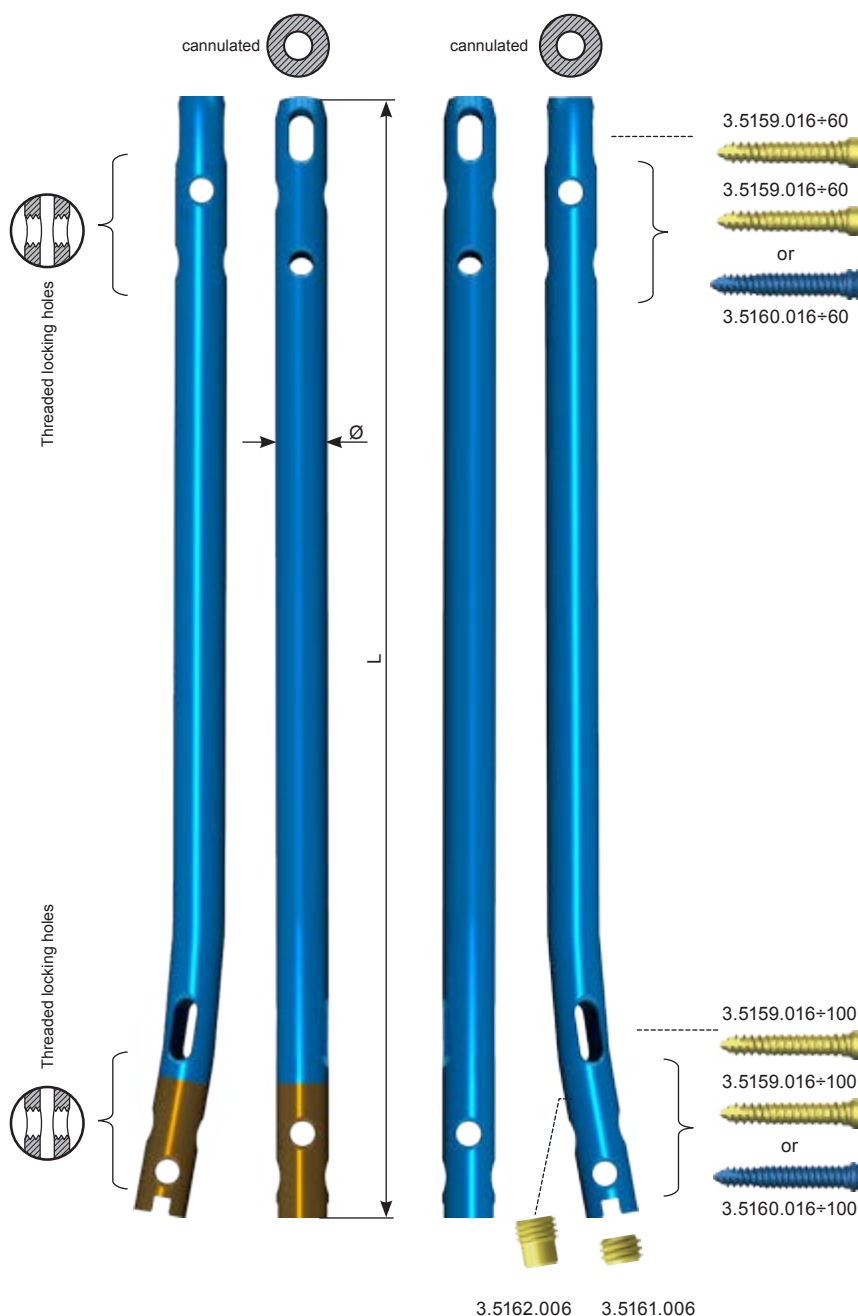
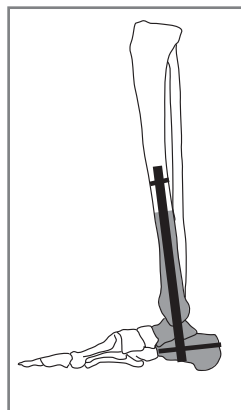
- diameter: Ø8 – Ø16 in 1mm increments,
- length: 180-400mm in 5mm increments.

### II.1. NAILS

#### Retrograde tibia nail

Catalogue no.			
L [mm]	Ø	left	right
180	10	3.5679.180	3.5680.180
200		3.5679.200	3.5680.200
220		3.5679.220	3.5680.220
240		3.5679.240	3.5680.240
260		3.5679.260	3.5680.260
280		3.5679.280	3.5680.280
300	11	3.5679.300	3.5680.300
320		3.5679.320	3.5680.320
180		3.5681.180	3.5682.180
200		3.5681.200	3.5682.200
220		3.5681.220	3.5682.220
240		3.5681.240	3.5682.240
260	12	3.5681.260	3.5682.260
280		3.5681.280	3.5682.280
300		3.5681.300	3.5682.300
320		3.5681.320	3.5682.320
180		3.5683.180	3.5684.180
200		3.5683.200	3.5684.200
220		3.5683.220	3.5684.220
240		3.5683.240	3.5684.240
260		3.5683.260	3.5684.260
280		3.5683.280	3.5684.280
300		3.5683.300	3.5684.300
320		3.5683.320	3.5684.320

available	
Ø [mm] pitch 1 mm	8÷14
L [mm] pitch 5 mm	130÷400



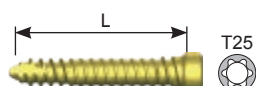
left			right		
Ø8	Ø9	Ø10	Ø11	Ø12	
colours					

## II.2. LOCKING ELEMENTS

TITANIUM ALLOY



## Distal screw 5.0

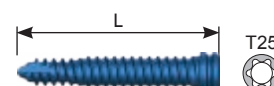


L [mm]	Catalogue no.
26	3.5159.026
28	3.5159.028
30	3.5159.030
35	3.5159.035
40	3.5159.040
45	3.5159.045
50	3.5159.050
55	3.5159.055
60	3.5159.060
65	3.5159.065
70	3.5159.070
75	3.5159.075
80	3.5159.080
85	3.5159.085
90	3.5159.090
95	3.5159.095
100	3.5159.100

available

L [mm]	16 ÷ 90
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## Distal screw 5.5



L [mm]	Catalogue no.
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
95	3.5160.095
100	3.5160.100

available

L [mm]	16 ÷ 90
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## Compression screw M7x1



Catalogue no.
3.5162.006














## End cap M8 spec.
















Catalogue no.
3.5161.006

### III. INSTRUMENT SET








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

Instrument set for tibial nails 40.5300.500				
No.		Name	Catalogue no.	Pcs
1		Targeter arm B	40.5301.000	1
2		Targeter D	40.5302.100	1
3		Targeter B	40.5303.100	1
4		Wrench S8	40.5304.000	1
5		Connecting screw M8x1.25 L-89	40.5305.000	1
6		Connecting screw M8x1.25 L-22	40.5306.000	1
7		Reconstruction targeter	40.5307.100	1
8		Impactor-extractor	40.5308.000	1
9		Connector M8x1.25/M14	40.5309.000	1
10		Targeter arm B short	40.5312.000	1
11		Compression screw	40.5313.000	1
12		Mallet	40.3667.000	1
13		Set block 9/5.0	40.5509.100	2
14		Protective guide 9/7	40.5510.200	2

Instrument set for tibial nails 40.5300.500				
No.		Name	Catalogue no.	Pcs
15		Drill guide 7/3.5	40.5511.200	2
16		Trocac 6.5	40.5534.100	1
17		Nail length measure	40.4798.500	1
18		Guide rod handle	40.1351.000	1
19		Teflon pipe guide 8/400	40.3700.000	1
20		Drill with scale 3.5/150	40.5343.002	1
21		Targeter D	40.1344.100	1
22		Drill guide short 7/3.5	40.1358.100	1
23		Trocac short 7	40.1354.100	1
24		Aiming insert 9.0	40.5065.009	2
25		Guide rod 2.5/580	40.3673.580	1
26		Screwdriver T25	40.5575.100	1
27		Drill with scale 3.5/350	40.5339.002	2
28		Screw length measure	40.5530.100	1
29		Hole depth measure	40.2665.000	1
30		Curved awl 8.0	40.5523.000	1
31		Stand for tibial nails	40.5319.500	1



## Complementary instrument set for retrograde tibial nails CHARFIX2 40.5380.500

No.		Name	Pcs	Catalogue no.
32		Proximal targeter	1	40.5382.000
33		Lateral distal targeter	1	40.5384.000
34		Connecting screw M8x1.25 L-84	1	40.5385.000
35		Lateral targeter	1	40.5383.000
36		Screwdriver T25	1	40.5381.000
37		Compression screw	1	40.5386.000
38		Connector M8x1.25/M14	1	40.5873.000
39		Stand for instrument set of retrograde tibial nails	1	40.5389.500

Additional instruments that are considered basic devices of operating theater used for orthopedic procedures are necessary to carry out the surgery. Among them are:

- drive,
  - a set of flexible intramedullary reamers with a diameter of 8.0 ÷ 13.0 mm with a guide and handle,
  - a set of drills,
  - Kirschner wires,
  - mallets,
- and others.

## 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. INTRODUCTION

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 pictures.

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 on the abdomen.

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



**Fig. 1.** Patient positioning on the operating table

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.



**Fig. 2.** Surgical approach to tibiotalar joint

When the bone fracture is properly reduced, perform 3cm long lateral 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 hallux to the middle of the fascia in the medial / lateral plane, overlapping at the same time with the vertical axis of the tibia.



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



**Fig. 3.** Tibial retrograde nail insertion point

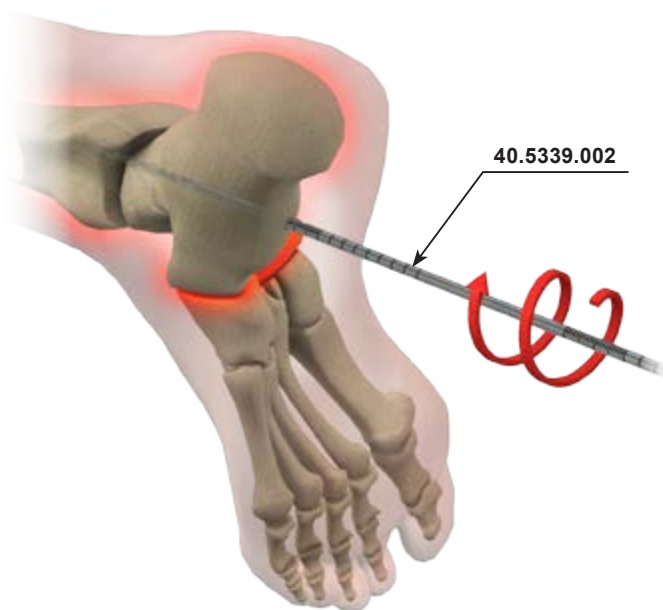
#### IV.3. MEDULLARY CANAL OPENING

**1** When surgical approach is prepared and the nail entry point is located (*description: section IV.1 Introduction*), 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 **[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.

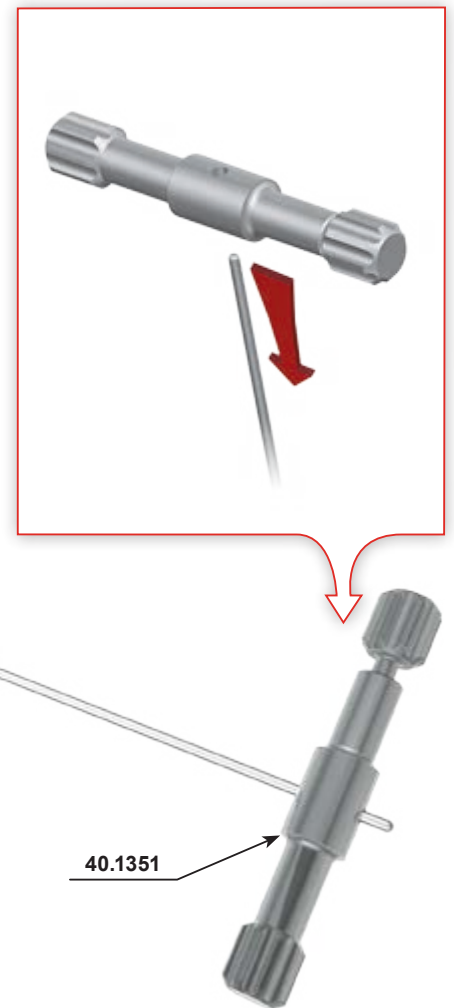


- 2 Mount the guide rod 2.5/580 [40.3673.580] to the guide rod handle [40.1351] and insert the system into the hole in the medullary cavity through the tarsal bones until the tibial shaft is reached.

Remove the guide rod handle.



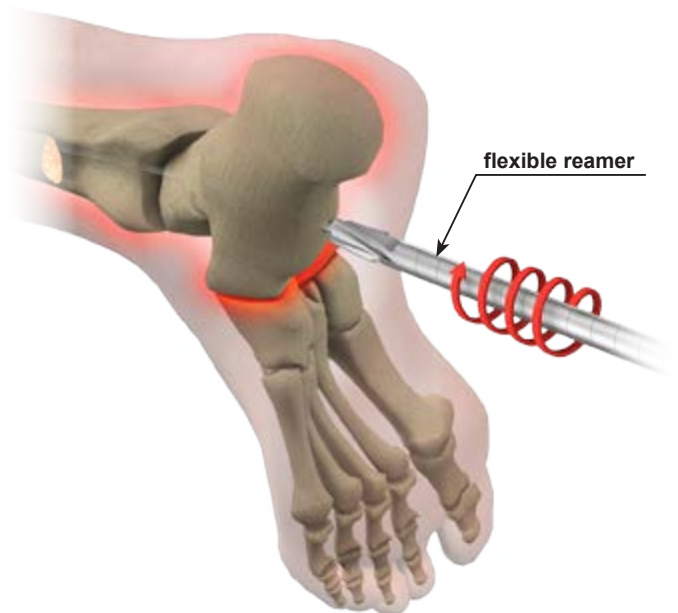
Control the drilling using the real-time X-Ray imaging system.



- 3 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 ÷ 1.0mm 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.

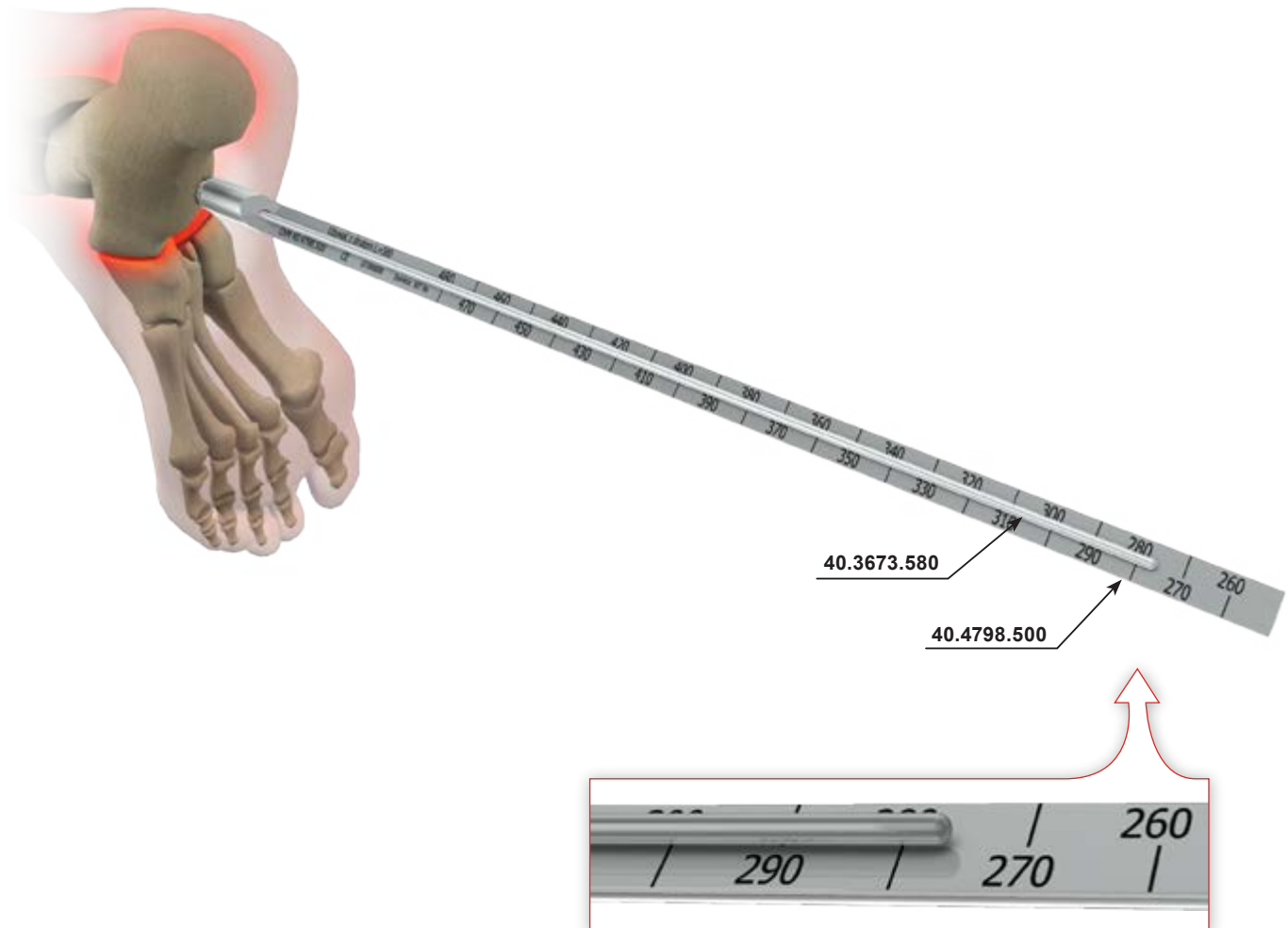
It is advisable to use help in supporting the foot in the correct position as to reduce the fracture during reaming the canal.



- 4 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.

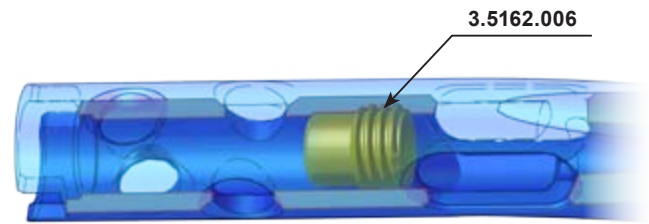
Remove nail length measure from the guide rod.

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

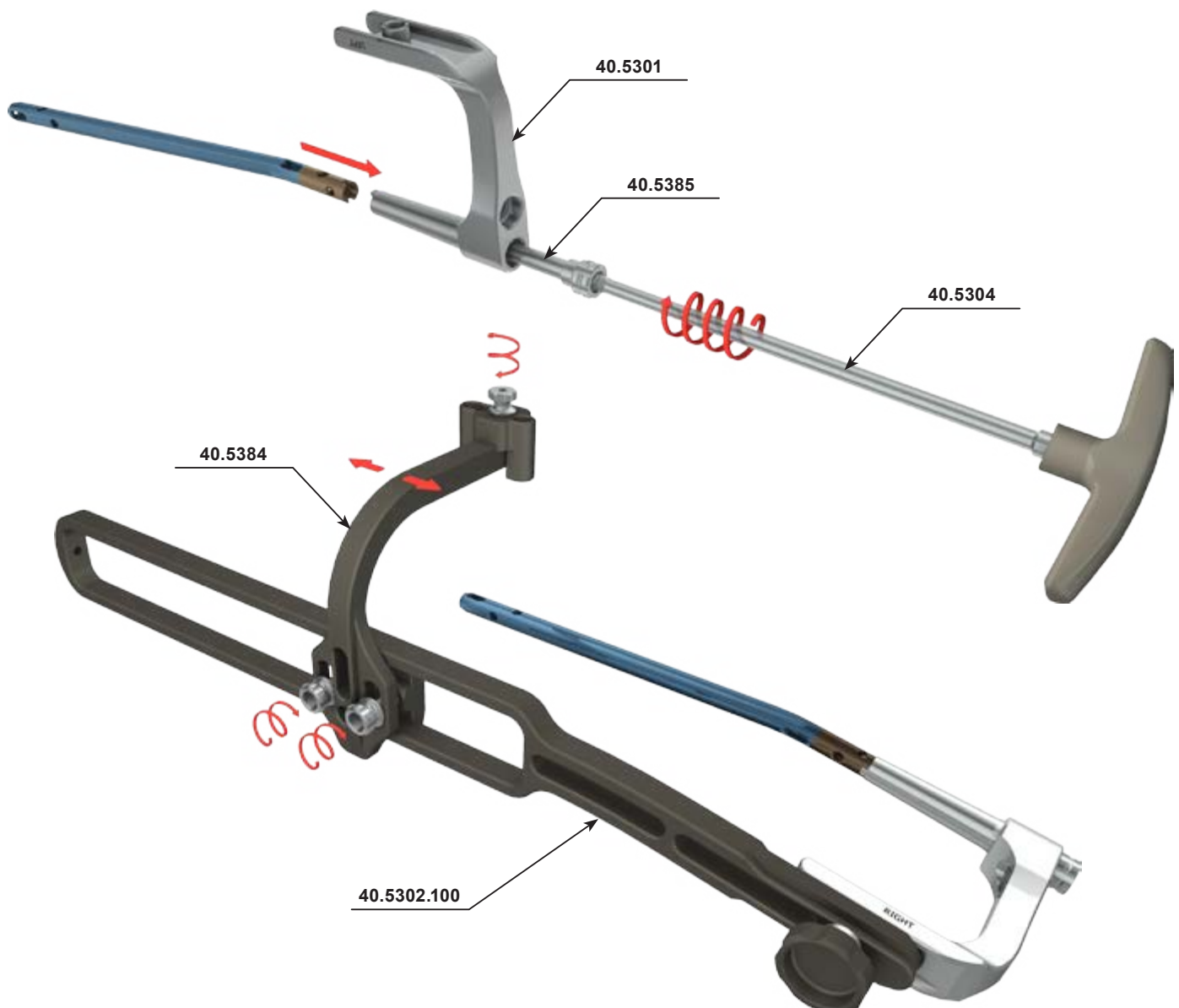


## IV.4. NAIL AND TARGETER ASSEMBLY AND TIBIAL NAIL IMPLANTATION

5 Insert compression screw M7x1 [3.5162.006] (implant) to the intramedullary nail, between the second circular and oval-shaped hole. Compression screw cannot obscure any of the holes.



6 Retrograde tibial nail is produced either for left or right limb. Therefore, it is important to mount properly the implant to the targeter arm B [40.5301] with left or right inclination respectively. Using connecting screw M8x1.25 L-84 [40.5385] and wrench S8 [40.5304], mount the nail to the targeter arm B [40.5301].



7 **Setting the slider of the targeter D [40.5302.100] and lateral distal targeter [40.5384] to the nail.**  
 Prior to the insertion of a nail, set the lateral distal targeter [40.5384] in relation to the holes of the distal nail. Attached targeter D [40.5302.100] to the targeter arm B [40.5301]. Inclination of the targeter D should be consistent with the inclination of the nail.  
 Remove the slider which is a standard part of this targeter.  
 Mount the lateral distal targeter [40.5384] on the outer side of the targeter D.



Using two set blocks [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 [40.5575.100].



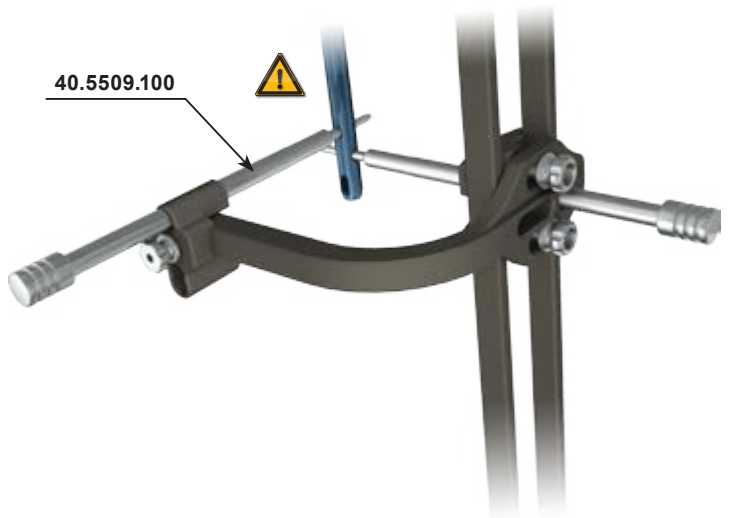
When the targeter slider is properly set and locked, set blocks should go through the nail holes freely.

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.

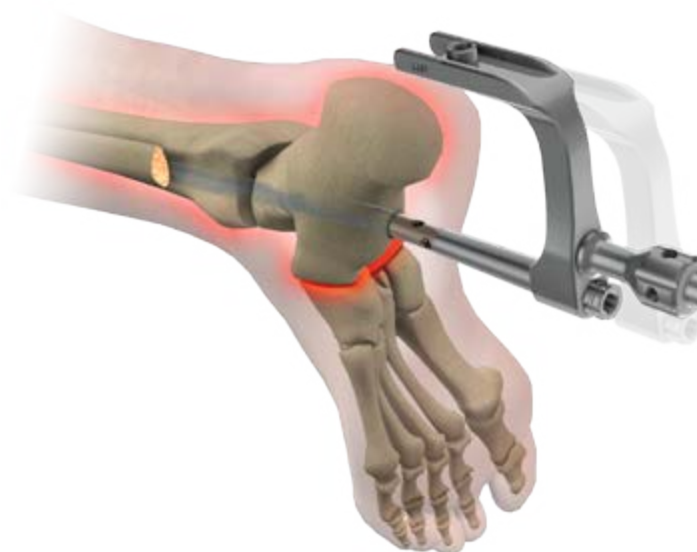
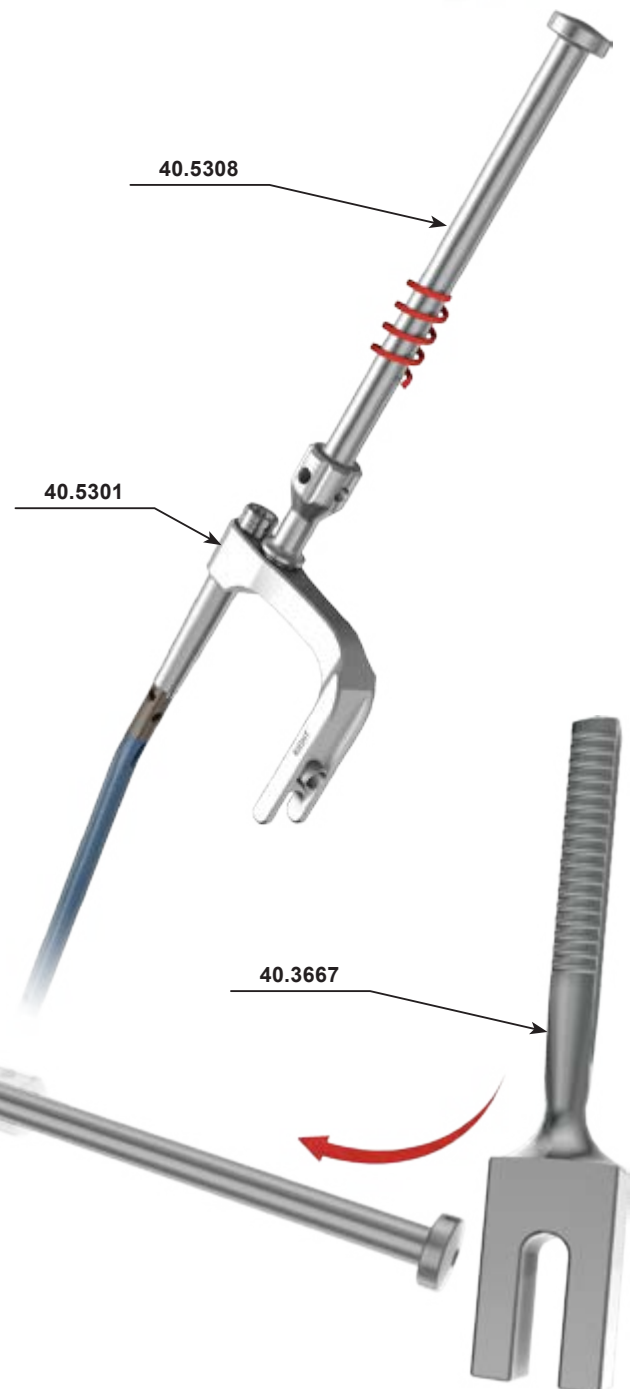
Remove impactor-extractor [40.5308].



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*).

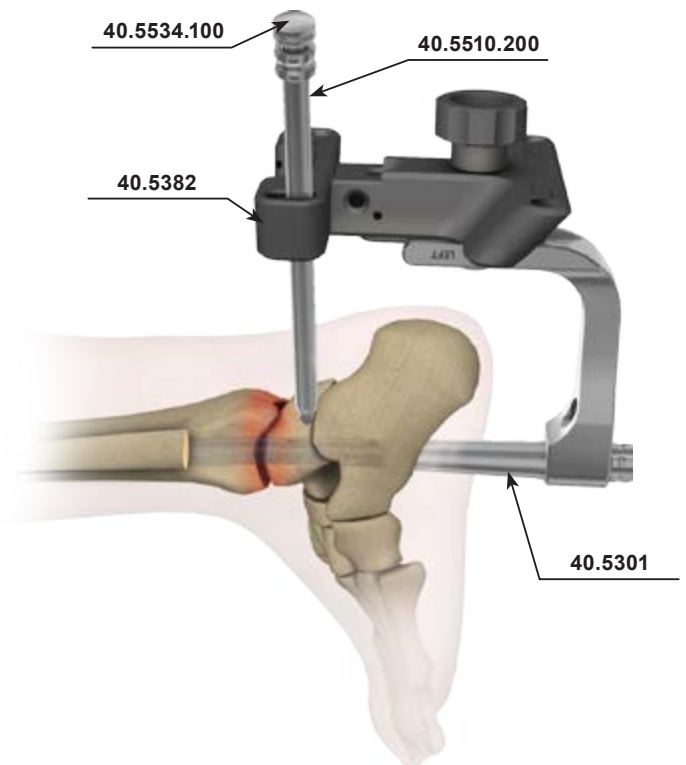
- 9 Attach proximal targeter [40.5382] to the targeter arm B [40.5301].

Depending on the limb, use the holes on the right or left side of the targeter. Insert trocar 6.5 [40.5534.100] to the protective guide 9/7 [40.5510.200].

Advance the trocar to the cortex and mark the entry point for the drill. Together with the trocar simultaneously advance the protective guide so that its end is as close to the bone as possible.

Remove the trocar.

Leave the protective guide in place.



- 10 Insert drill guide 7/3.5 [40.5511.200] (two grooves) 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.

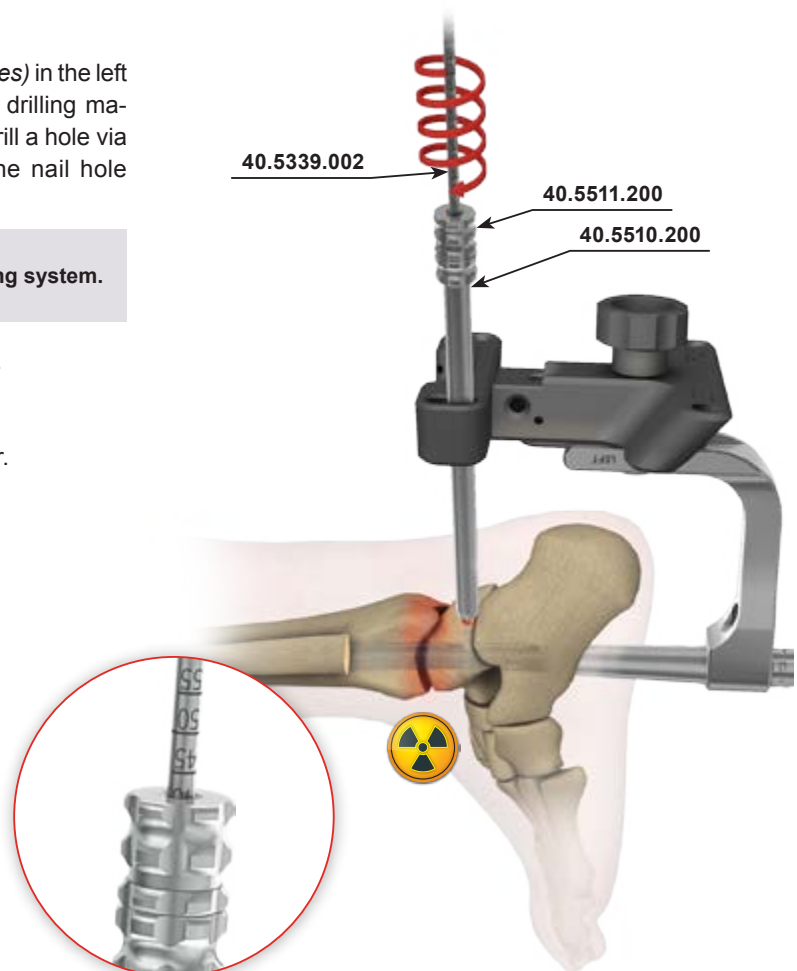


Control drilling using real-time X-Ray imaging system.

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

Remove the drill and drill guide.

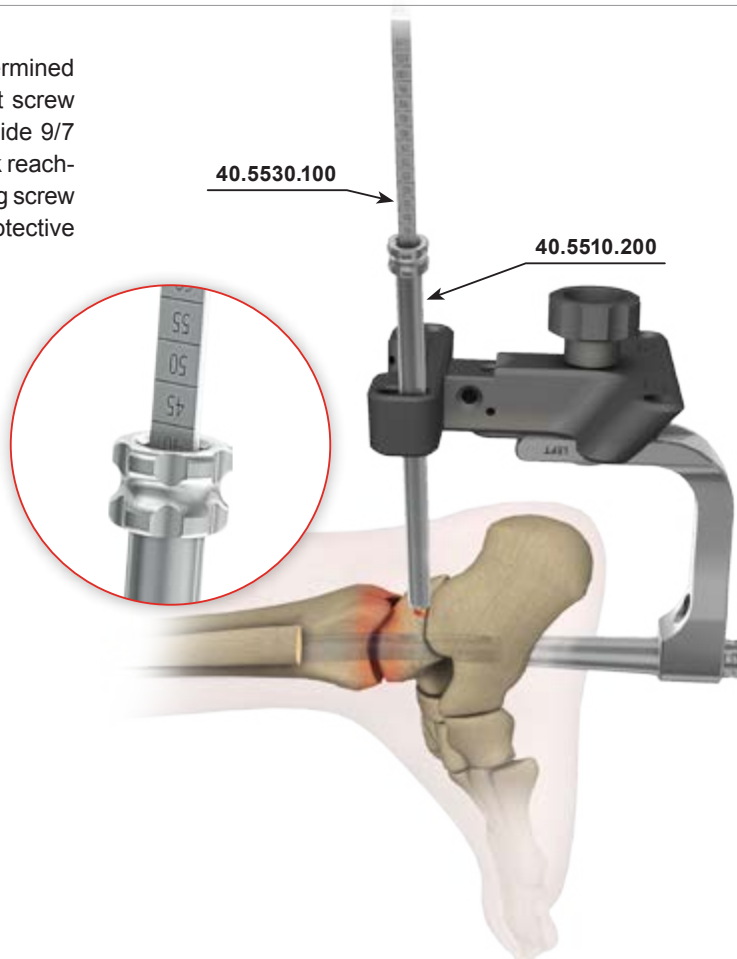
Leave the protective guide in the hole of the targeter.





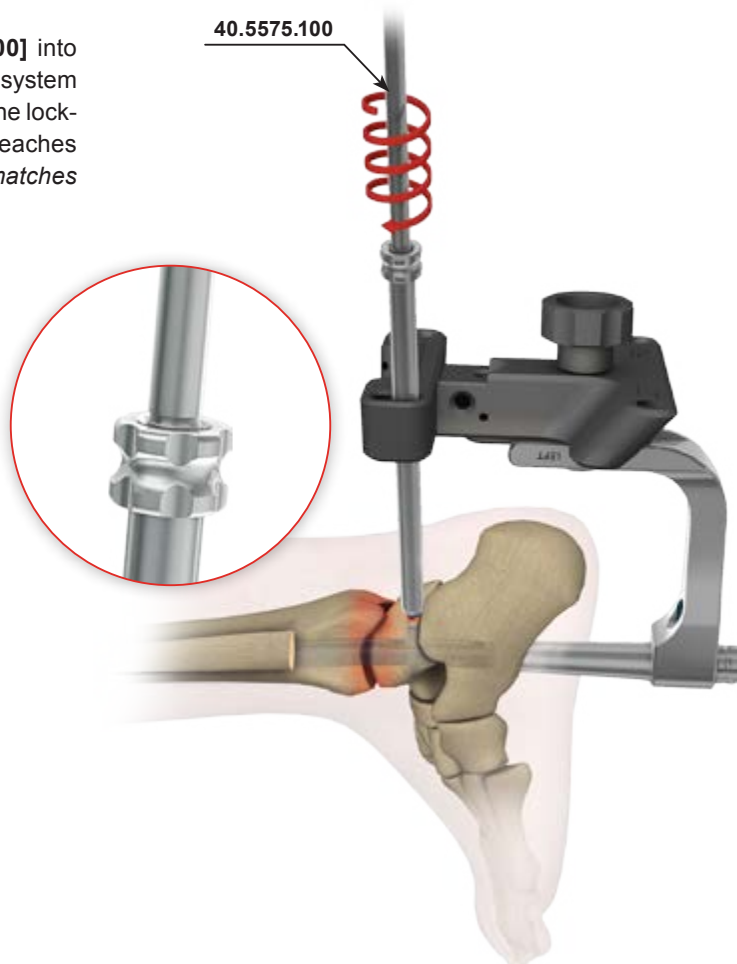
- 11 The length of the locking screw can also be determined using the screw length measure. To do so, insert screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D 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.



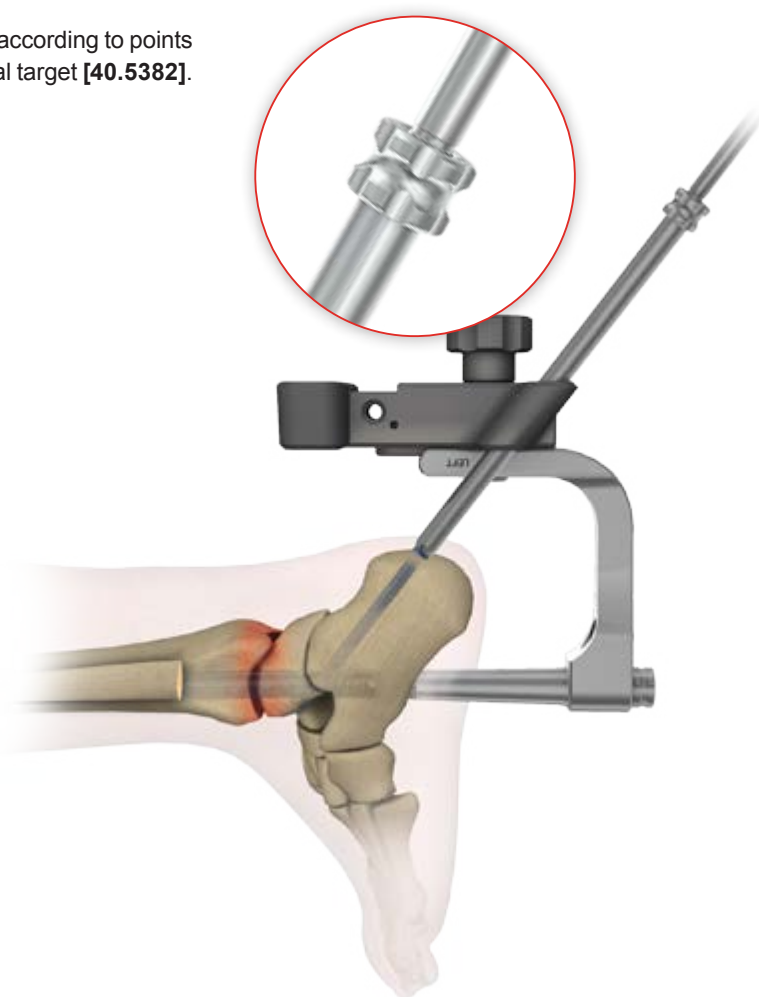
- 12 Insert the tip of the screwdriver T25 **[40.5575.100]** into the socket of a specified locking screw. Insert the system into the protective guide 9/7 **[40.5510.200]** and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).

Remove the screwdriver and protective guide.  
Detach the targeter.



## IV.6. OBLIQUE LOCKING THROUGH TALOCALCANEONAVICULAR JOINT - OPTIONAL

- 13 Locking of the nail should be carried out according to points 9 to 12 using oblique hole of the proximal target **[40.5382]**.



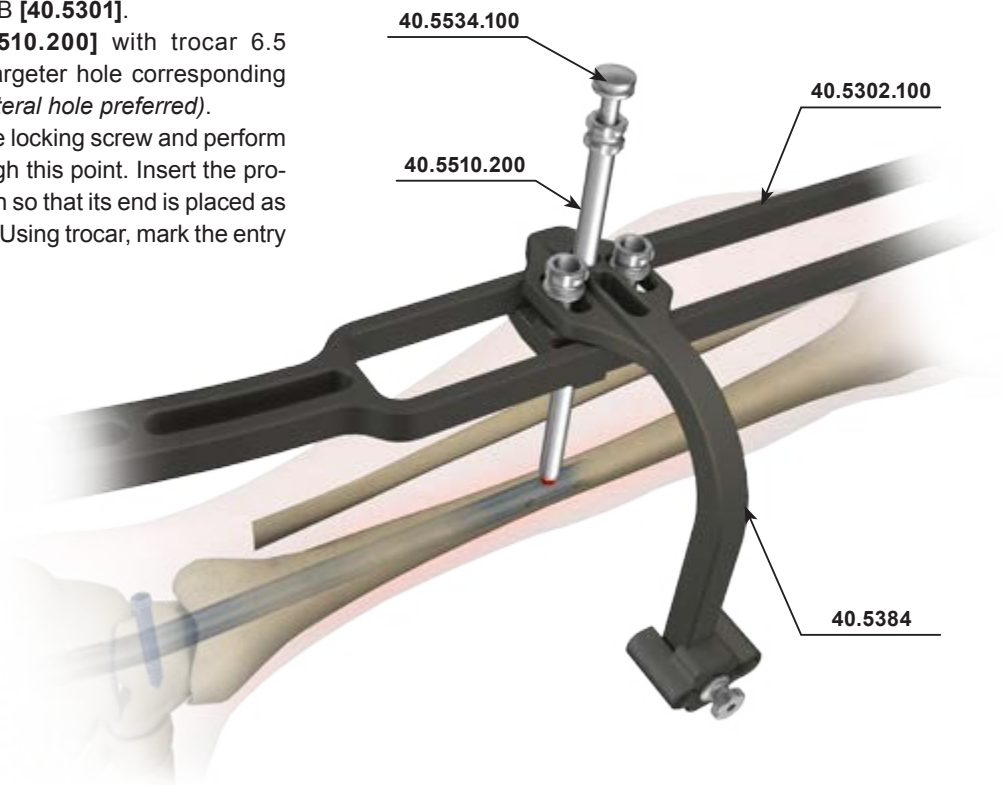
## IV.7. PROXIMAL NAIL LOCKING

- 14 Attach targeter D [40.5302.100] with lateral distal targeter [40.5384] to the targeter arm B [40.5301].

Insert protective guide 9/7 [40.5510.200] with trocar 6.5 [40.5534.100] to the lateral distal targeter hole corresponding to the round hole of the nail (*distal lateral hole preferred*).

Mark on the skin the entry point for the locking screw and perform the soft tissue incision passing through this point. 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.

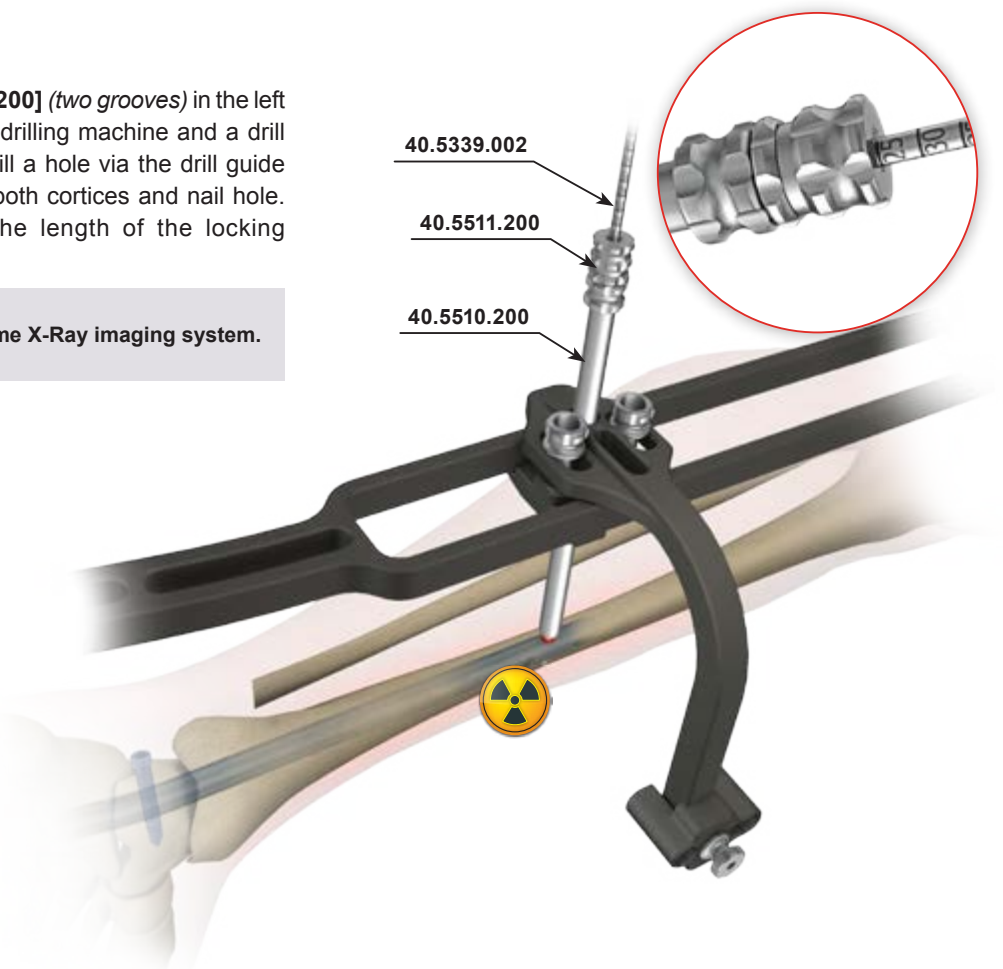


- 15 Insert drill guide 7/3.5 [40.5511.200] (two grooves) in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the bone that passes through its both cortices and nail hole. The scale on the drill indicates the length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



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

Remove drilling machine.  
Leave the drill in the hole.

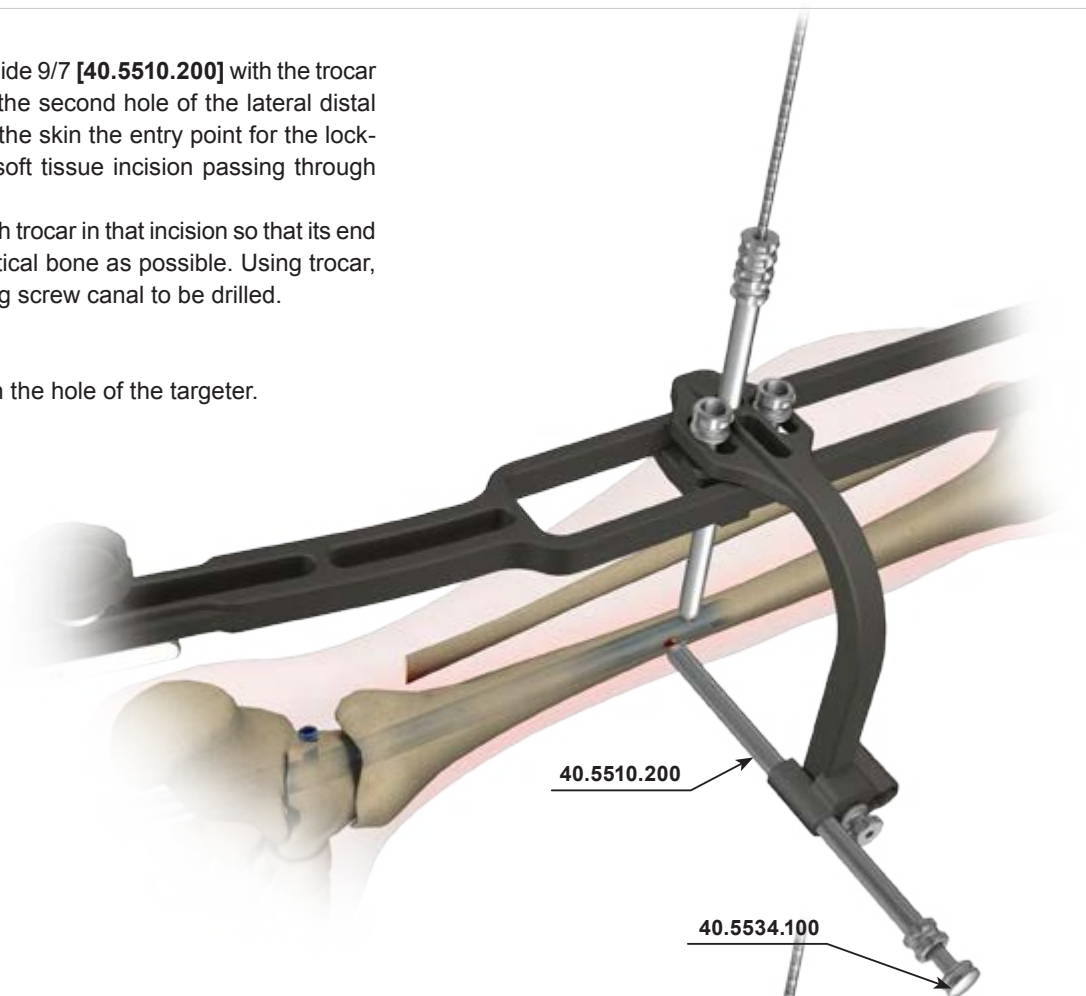


- 16 Insert the protective guide 9/7 **[40.5510.200]** with the trocar 6.5 **[40.5534.100]** in the second hole of the lateral distal targeter **[40.5384]**. Mark on the skin the entry point for the locking screw and perform the soft tissue incision passing through this point.

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 place for the locking screw canal to be drilled.

Remove the trocar.

Leave the protective guide in the hole of the targeter.



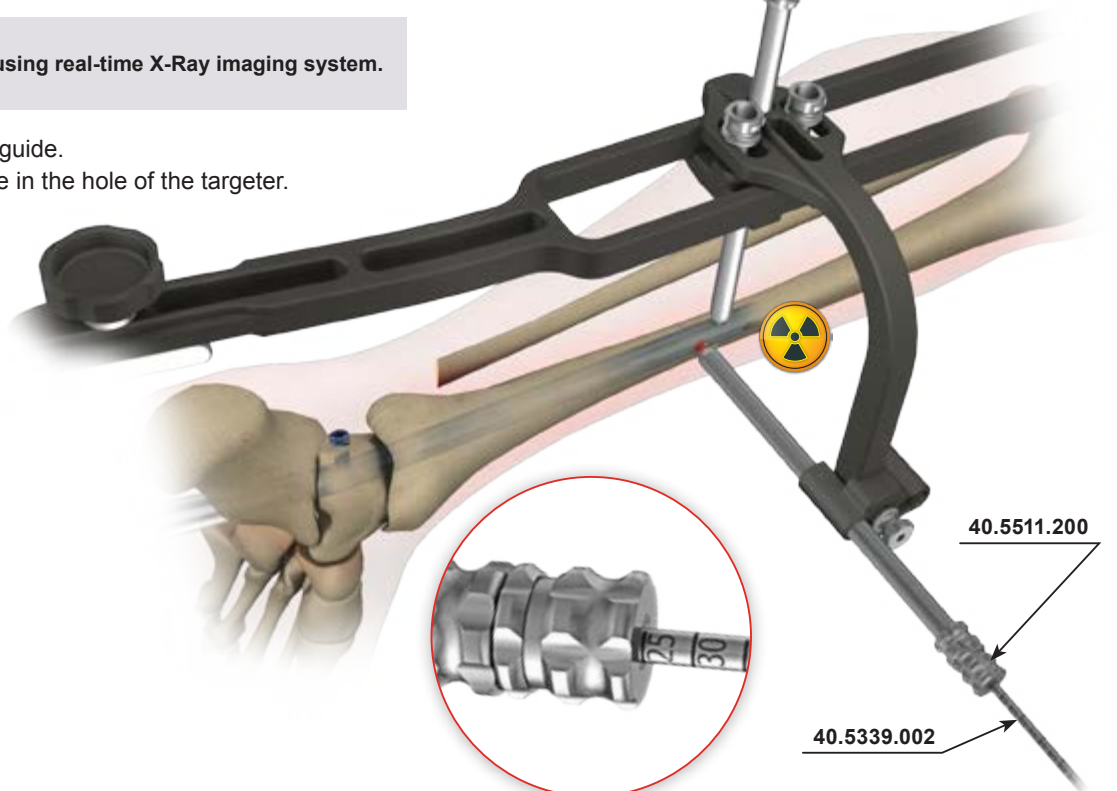
- 17 Insert drill guide 7/3.5 **[40.5511.200]** (two grooves) in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 **[40.5339.002]**, drill a hole via the drill guide in the bone that passes through its both cortices and nail hole. The scale on the drill indicates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



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

Remove the drill and drill guide.

Leave the protective guide in the hole of the targeter.

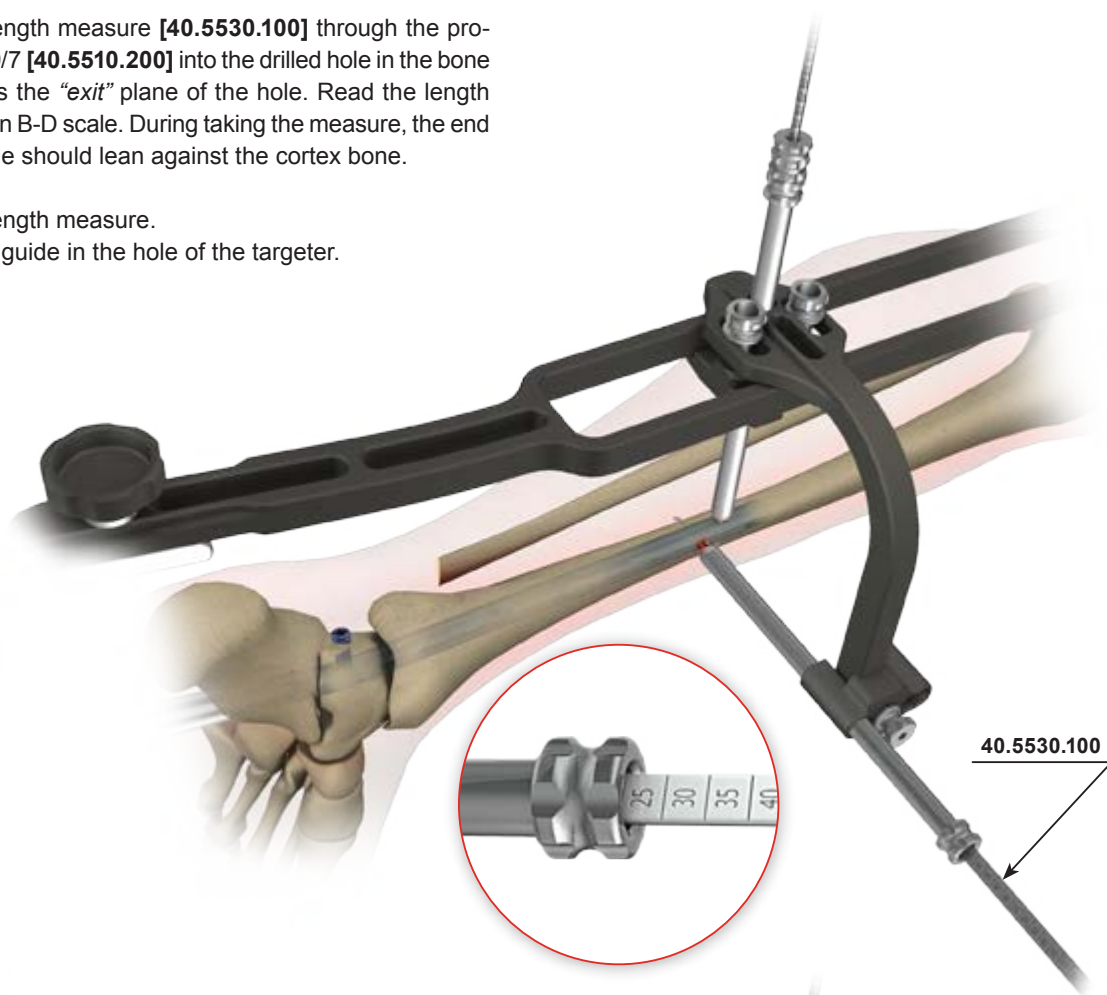




- 18 Insert screw length measure [40.5530.100] through the protective guide 9/7 [40.5510.200] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

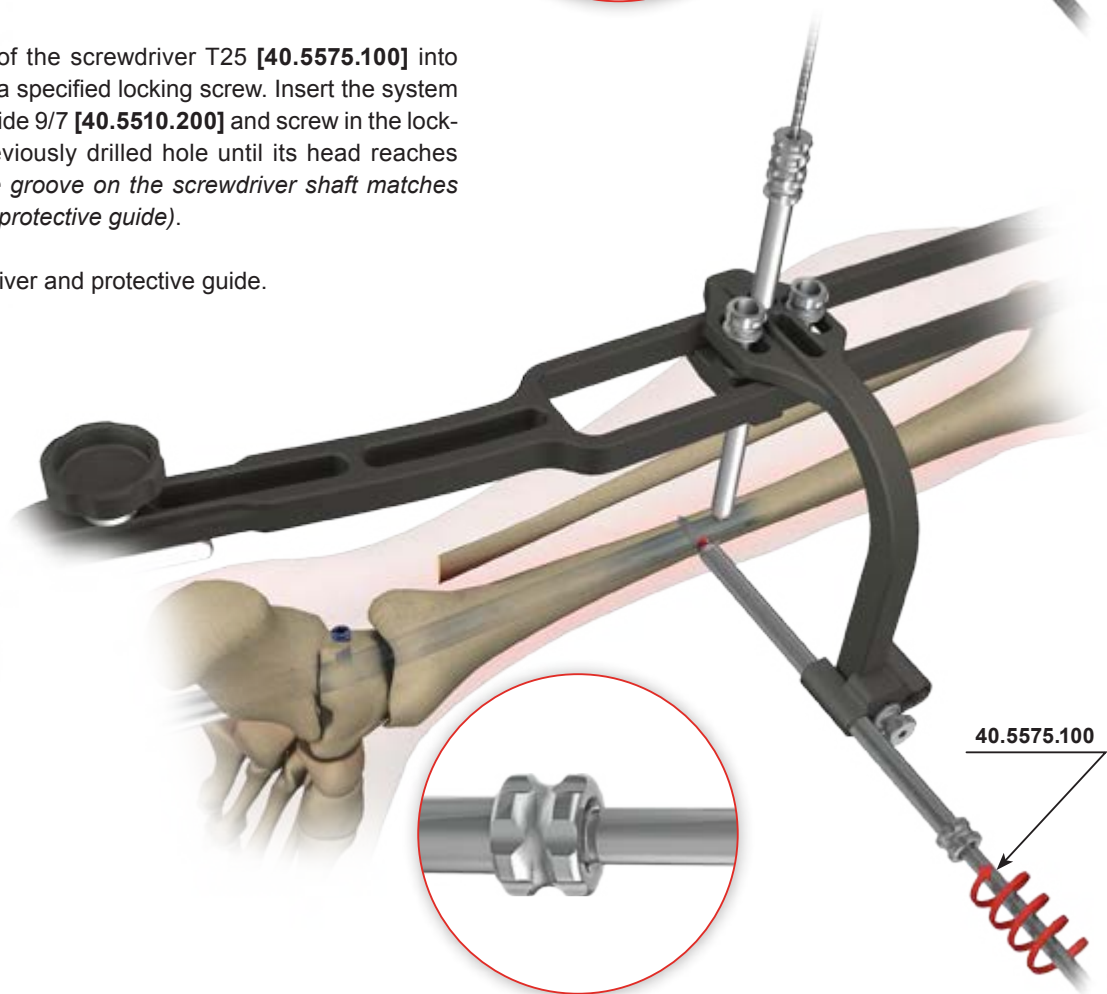
Remove the screw length measure.

Leave the protective guide in the hole of the targeter.



- 19 Insert the tip of the screwdriver T25 [40.5575.100] 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 previously 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.

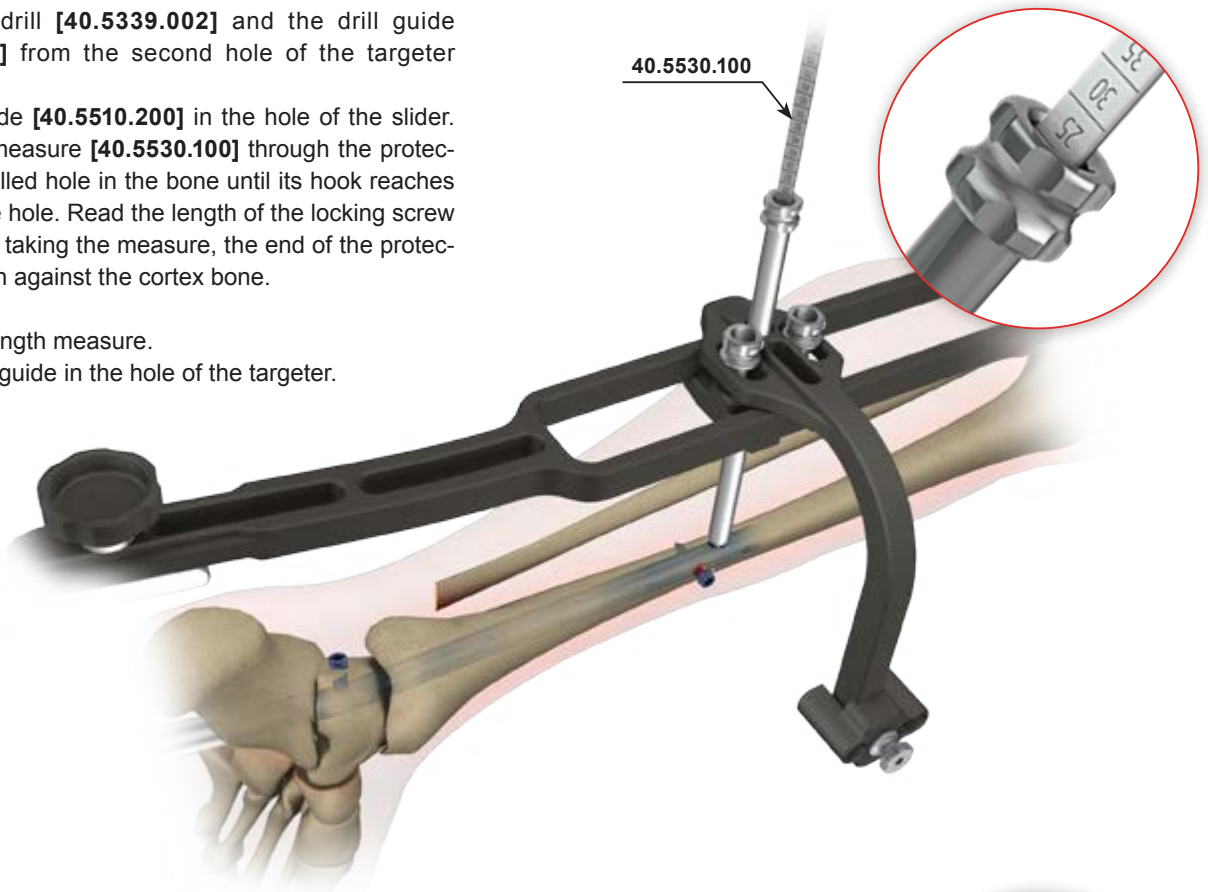


- 20 Remove the drill [40.5339.002] and the drill guide [40.5511.200] from the second hole of the targeter slider.

Leave protective guide [40.5510.200] in the hole of the slider. Insert screw length measure [40.5530.100] through the protective guide 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 B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

Remove the screw length measure.

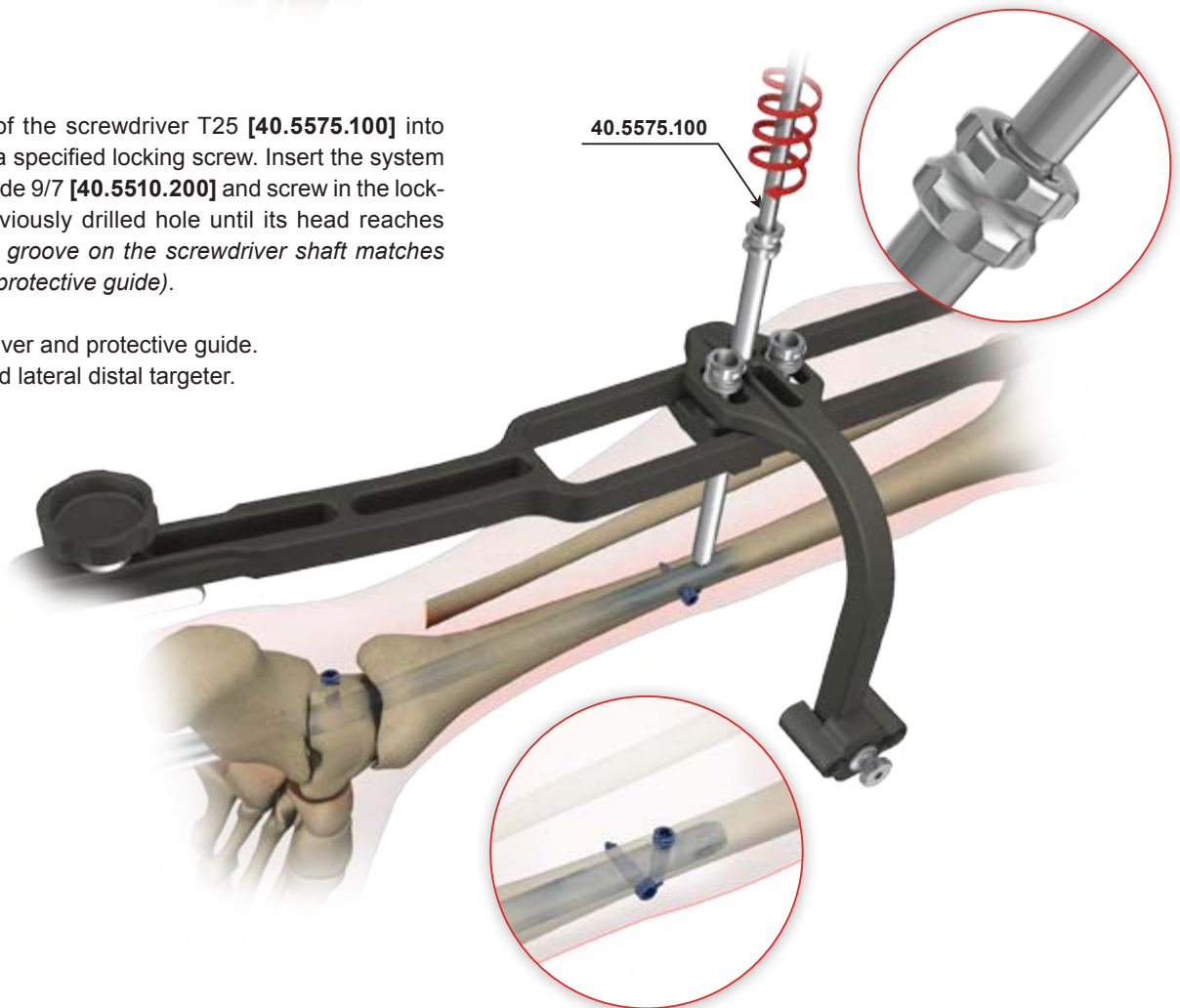
Leave the protective guide in the hole of the targeter.



- 21 Insert the tip of the screwdriver T25 [40.5575.100] 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 previously 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 targeter D and lateral distal targeter.



## IV.8. PROXIMAL NAIL LOCKING USING “FREE-HAND” TECHNIQUE

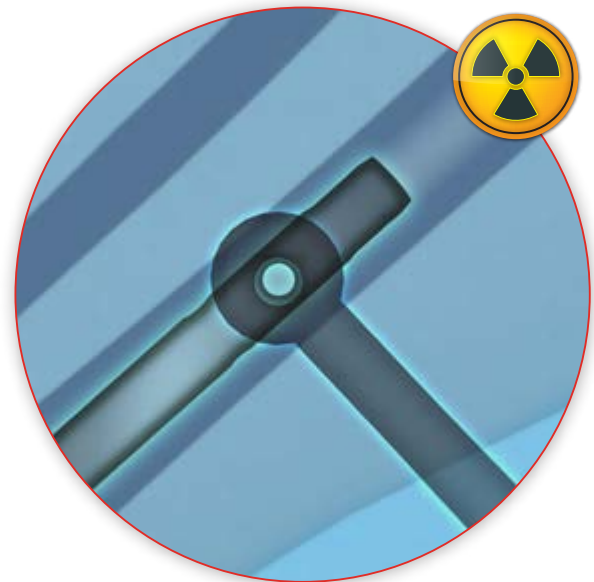
- 22 Proximal locking of the nail is carried out using “free-hand” technique and targeter D [40.1344.100].

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.

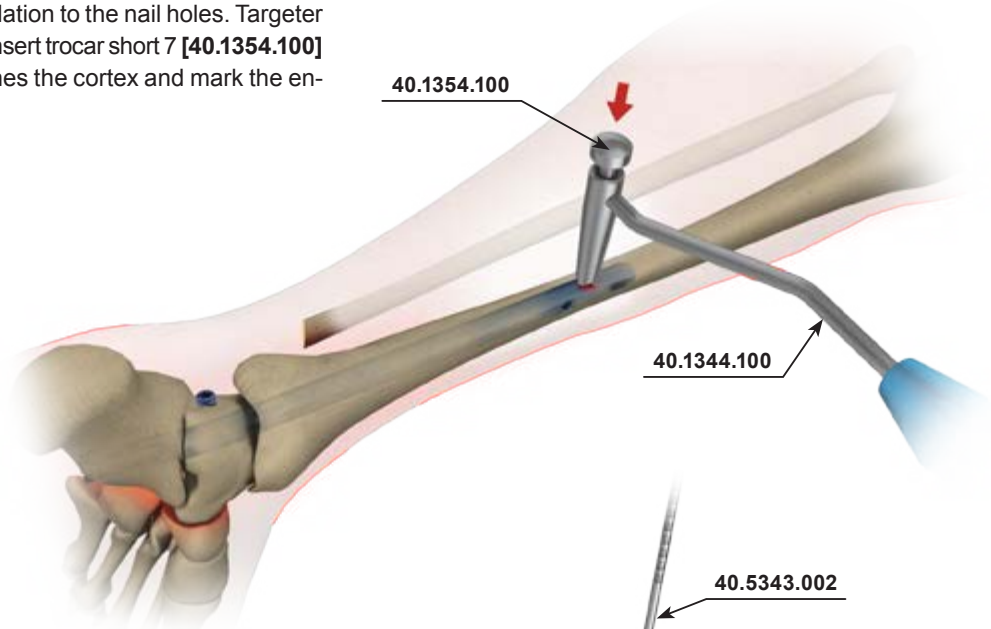


Control using the real-time X-Ray imaging system.



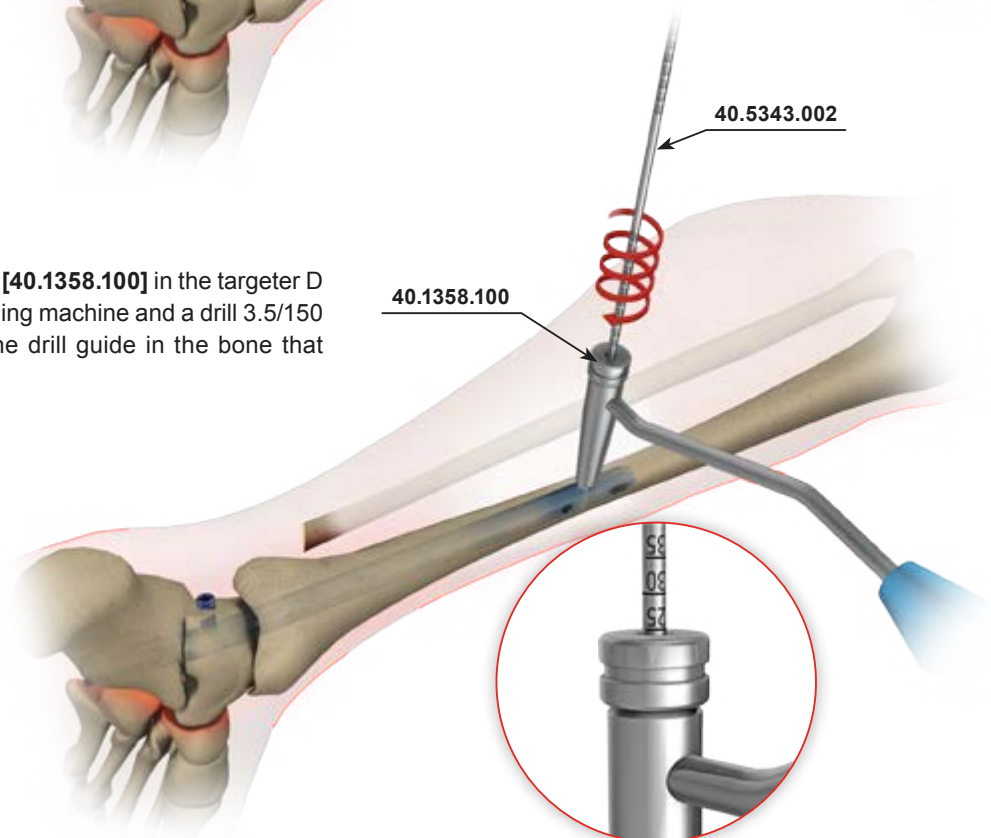
- 23 Using the X-Ray machine, determine the position of the targeter D [40.1344.100] in relation to the nail holes. Targeter D must be placed in cortical bone. Insert trocar short 7 [40.1354.100] in the targeter D hole, until it reaches the cortex and mark the entry point for the drill.

Remove the trocar.  
Leave targeter D in place.



- 24 Insert drill guide short 7/3.5 [40.1358.100] in the targeter D [40.1344.100]. Using a drilling machine and a drill 3.5/150 [40.5343.002], drill a hole via the drill guide in the bone that passes through its both cortices.

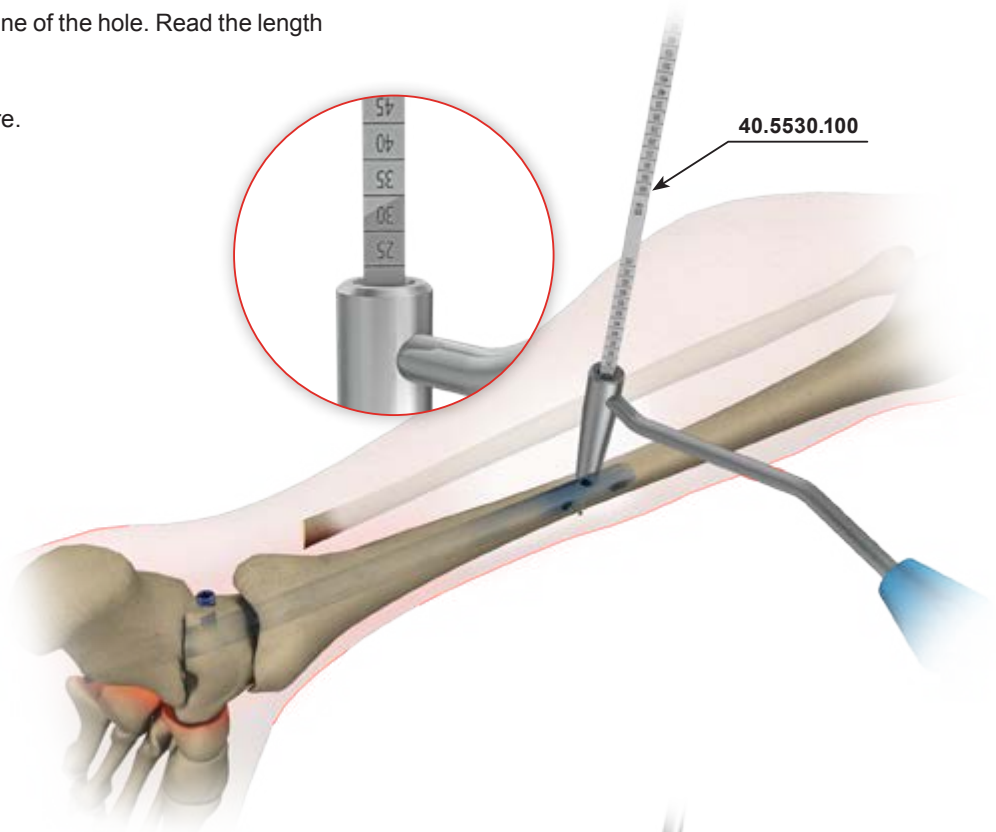
Remove the drill and drill guide.  
Leave targeter D in place.





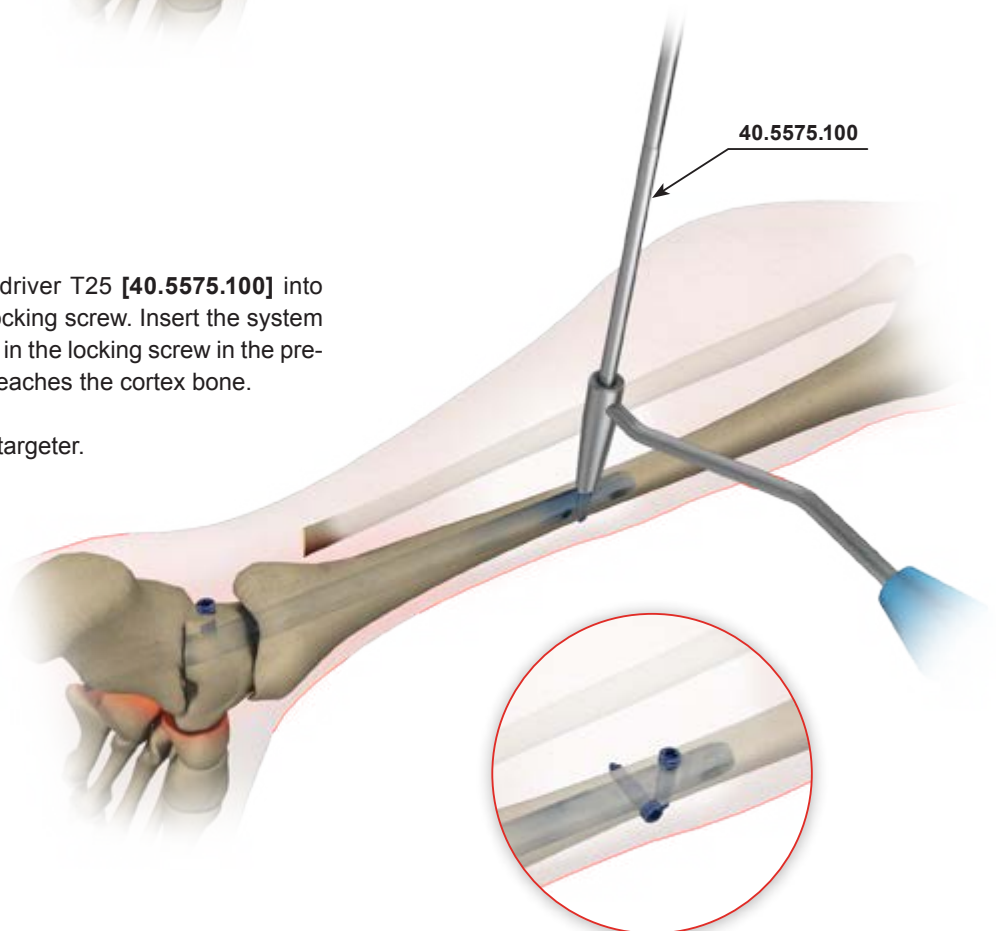
- 25 Insert screw length measure **[40.5530.100]** through the targeter D hole **[40.1344.100]** into the drilled hole in the bone until its hook reaches the “exit” plane of the hole. Read the length of the locking screw on D scale.

Remove the screw length measure.  
Leave targeter D in place.



- 26 Insert the tip of the screwdriver T25 **[40.5575.100]** into the socket of a specified locking screw. Insert the system into the targeter D hole and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone.

Remove the screwdriver and the targeter.



Perform nail locking in the second proximal hole according to steps 22-26 of this Instructions For Use.

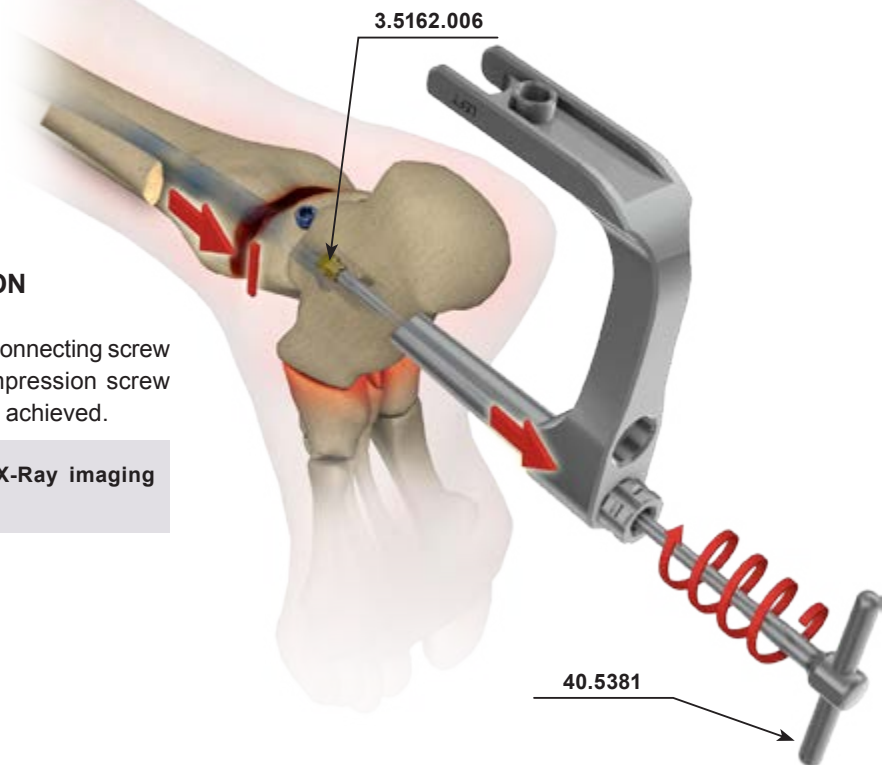


#### IV.9. TALOCRURAL JOINT COMPRESSION

- 27 Insert screwdriver T25 [40.5381] through connecting screw M8x1.25 [40.5385] and tighten the compression screw therein until the required level of compression is achieved.



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

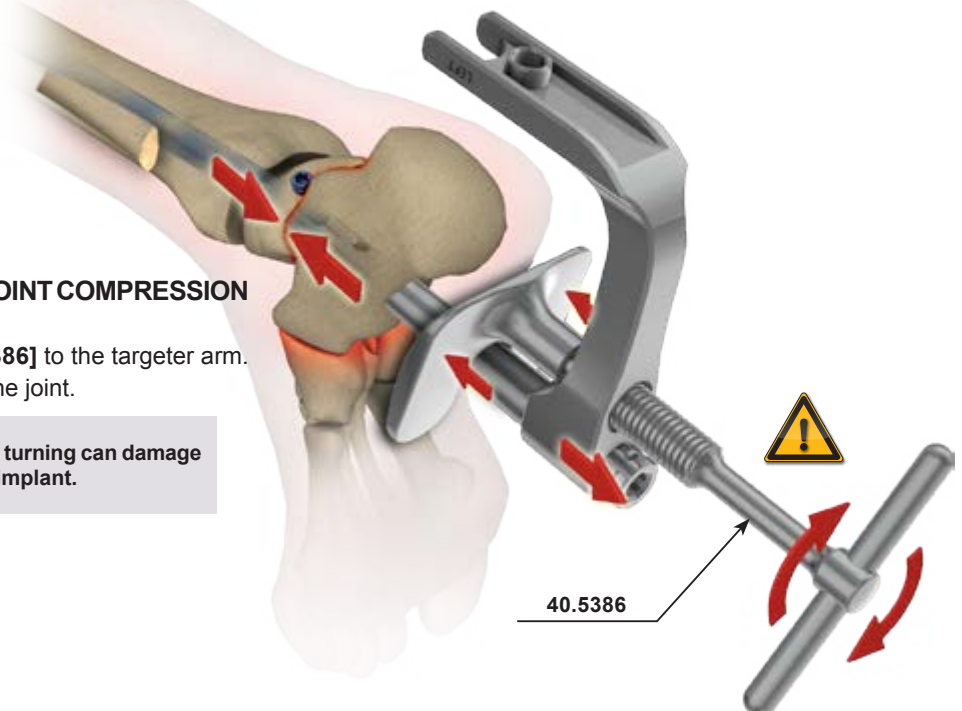


#### IV.10. TALOCALCANEONAVICULAR JOINT COMPRESSION

- 28 Attach the compression screw [40.5386] to the targeter arm. Turning the knob gently, compress the joint.

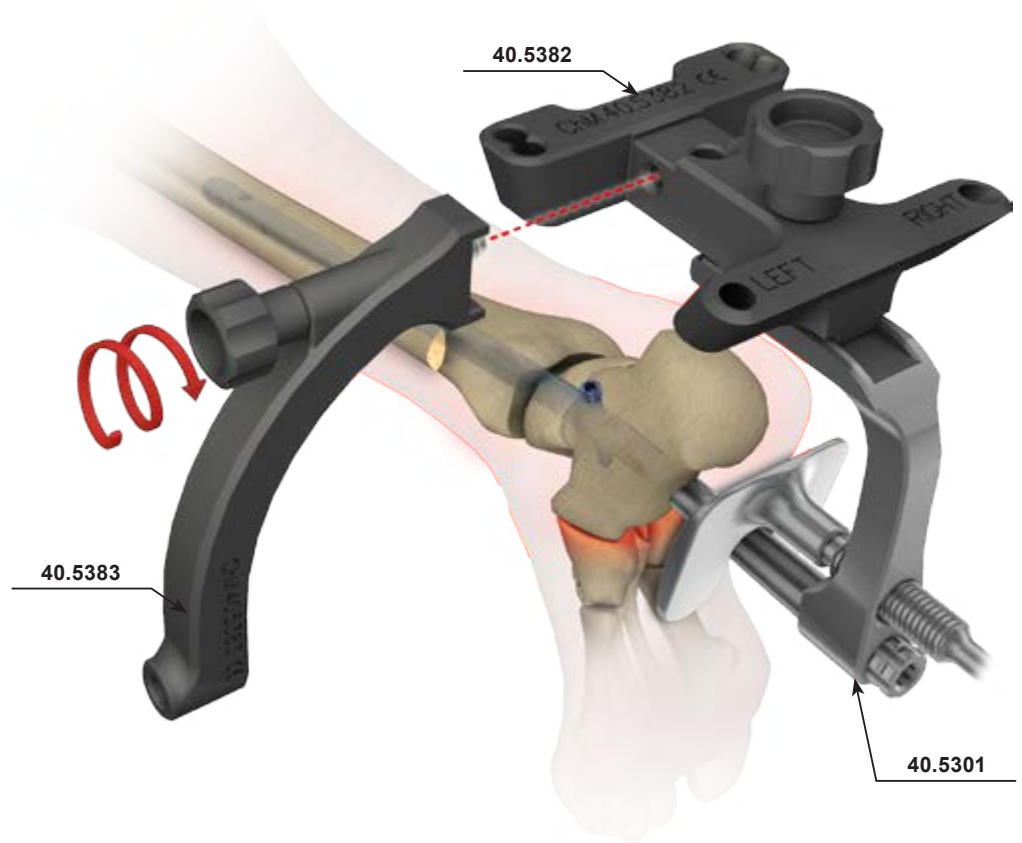


Excessive compression screw knob turning can damage the connecting screw [40.5385] or implant.



## IV.11. NAIL LOCKING IN THE CALCANEUM

- 29 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.

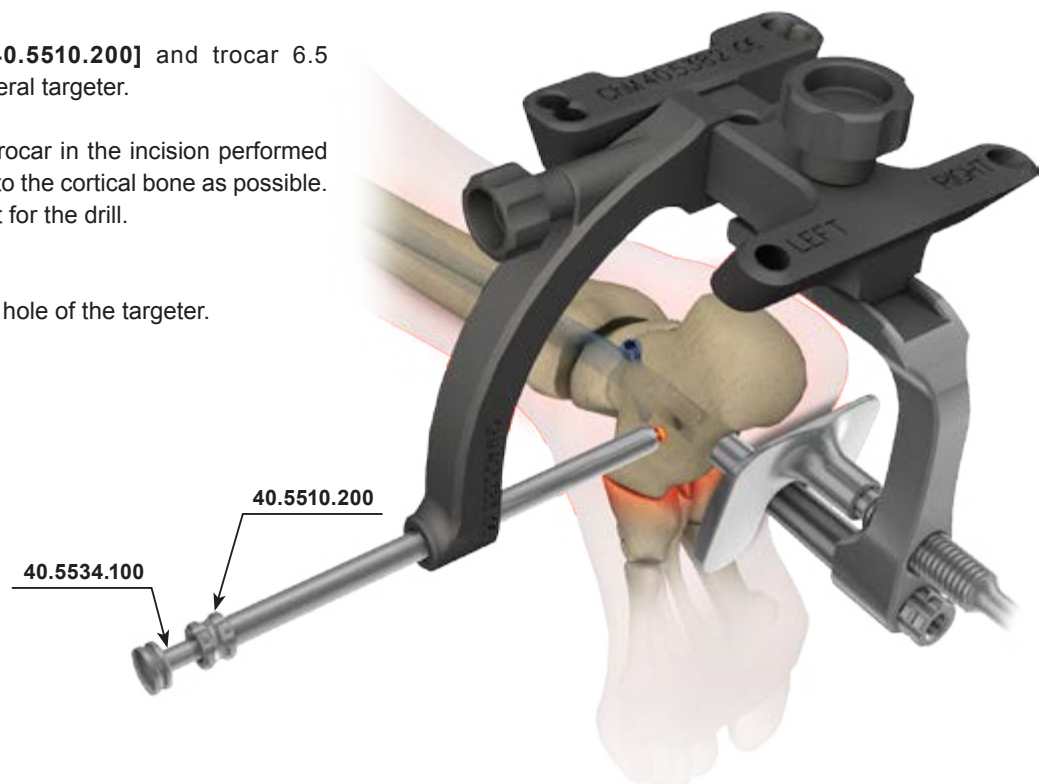


Insert protective guide 9/7 [40.5510.200] and trocar 6.5 [40.5534.100] into the hole of lateral targeter.

Insert the protective guide with trocar in the incision performed 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.

Leave the protective guide in the hole of the targeter.



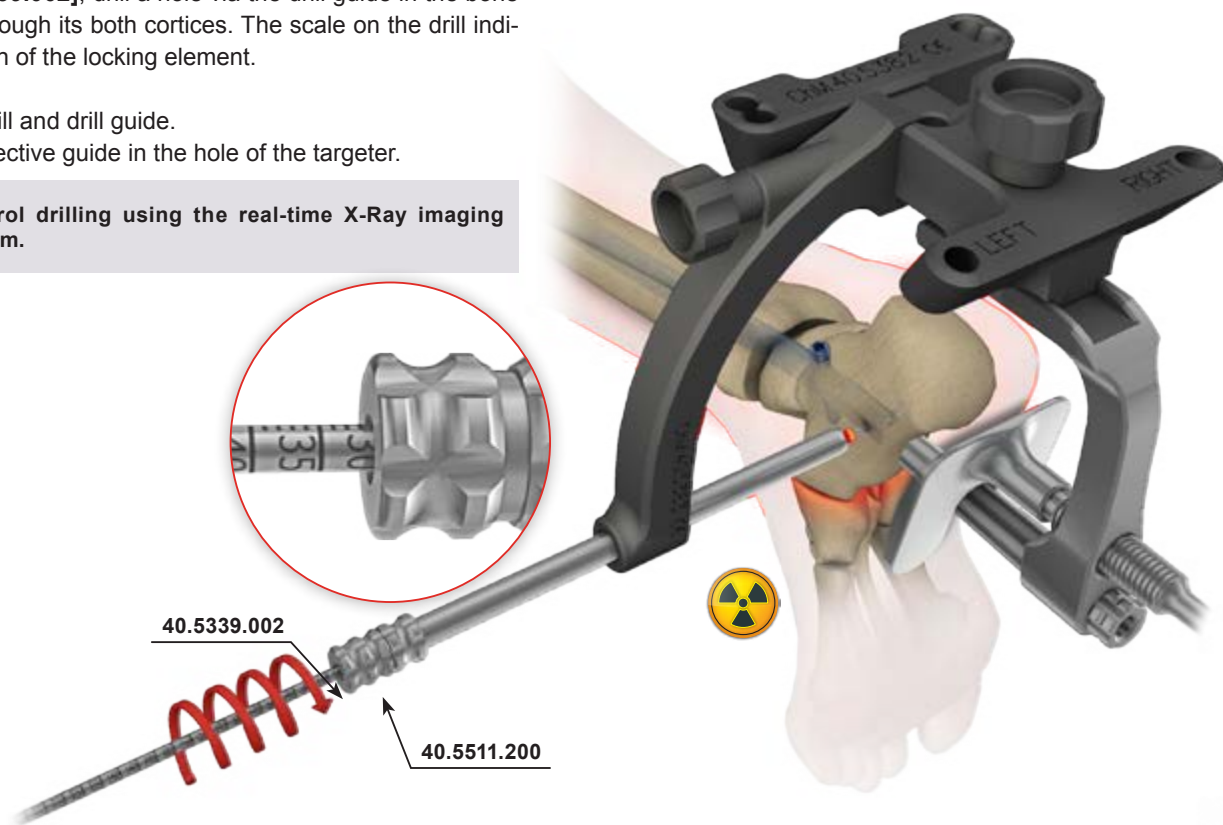
30 Insert drill guide 7/3.5 [40.5511.200] in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the bone that passes through its both cortices. The scale on the drill indicates the length of the locking element.

Remove the drill and drill guide.

Leave the protective guide in the hole of the targeter.



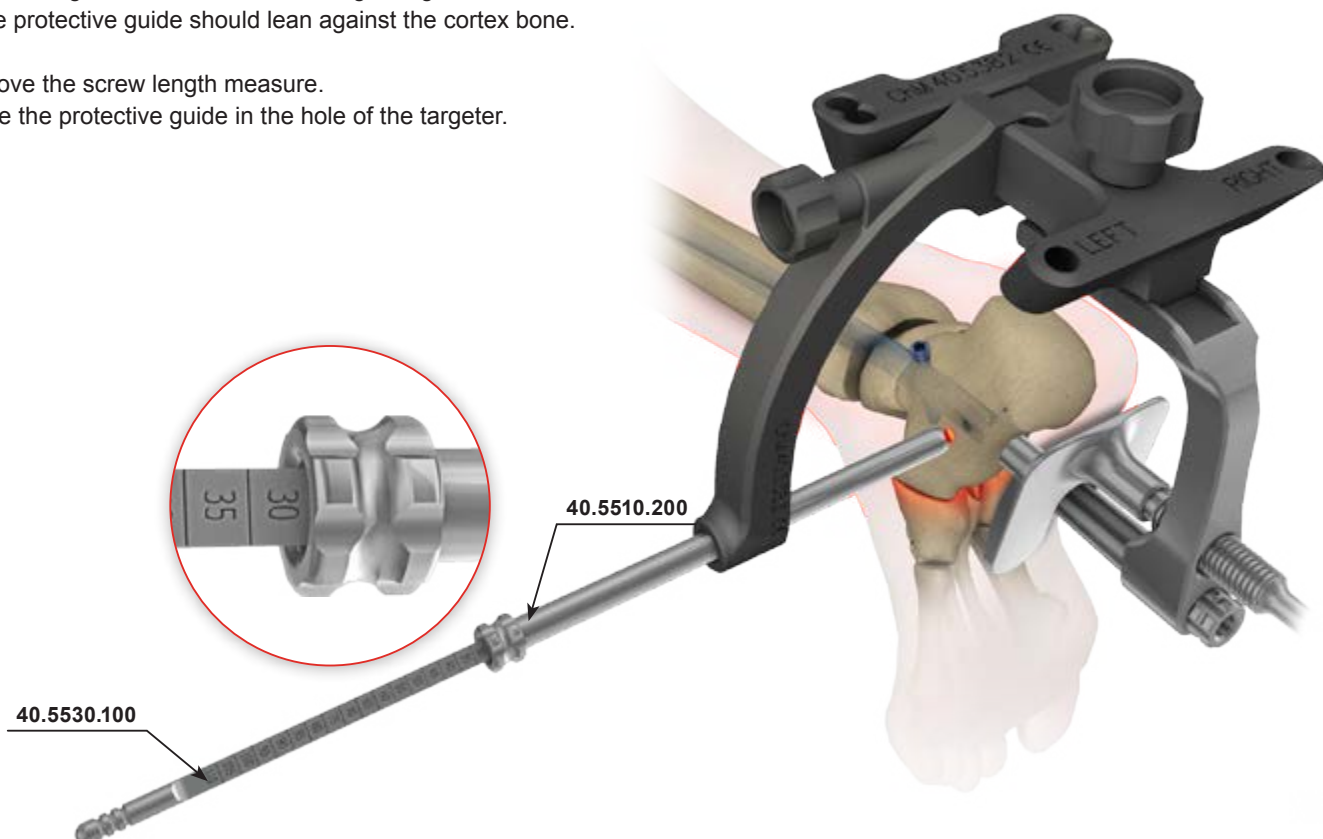
Control drilling using the real-time X-Ray imaging system.



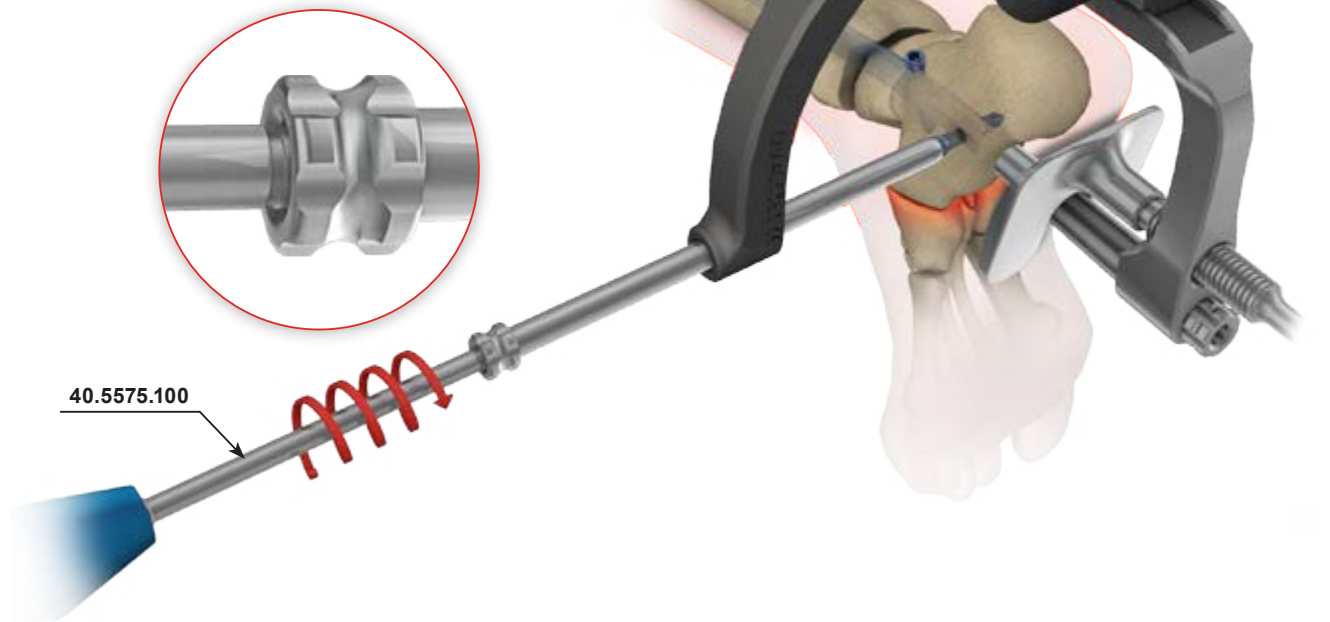
31 Insert screw length measure [40.5530.100] through the protective guide 9/7 [40.5510.200] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

Remove the screw length measure.

Leave the protective guide in the hole of the targeter.



- 32 Insert the tip of the screwdriver T25 [40.5575.100] 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 previously drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).



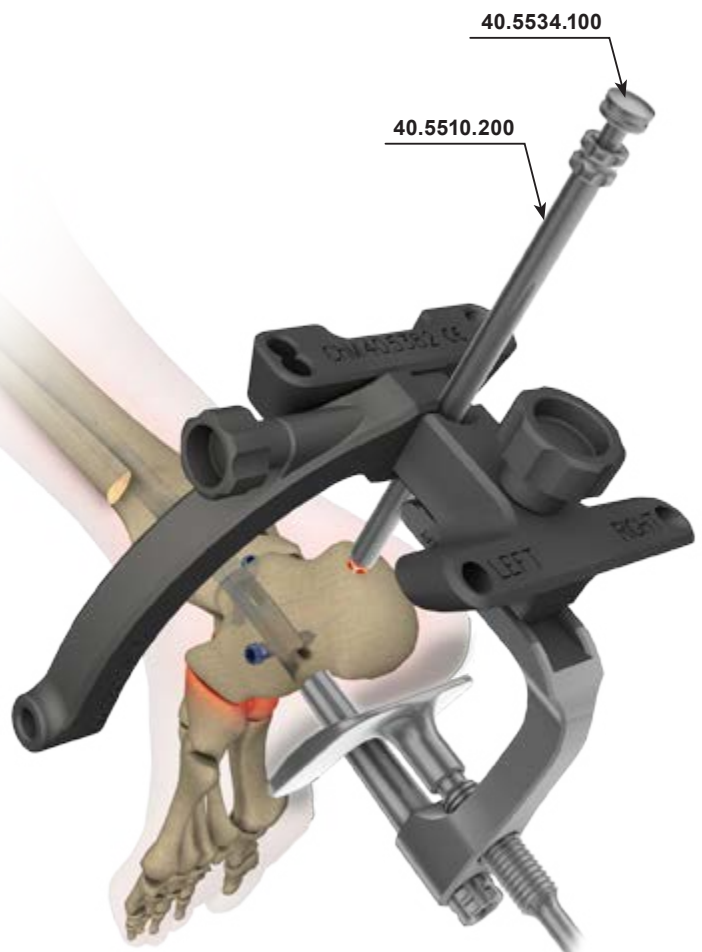
- 33 Insert protective guide 9/7 [40.5510.200] and trocar 6.5 [40.5534.100] into the hole of proximal targeter [40.5534.100].

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.

Leave the protective guide in the hole of the targeter.





- 34 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.



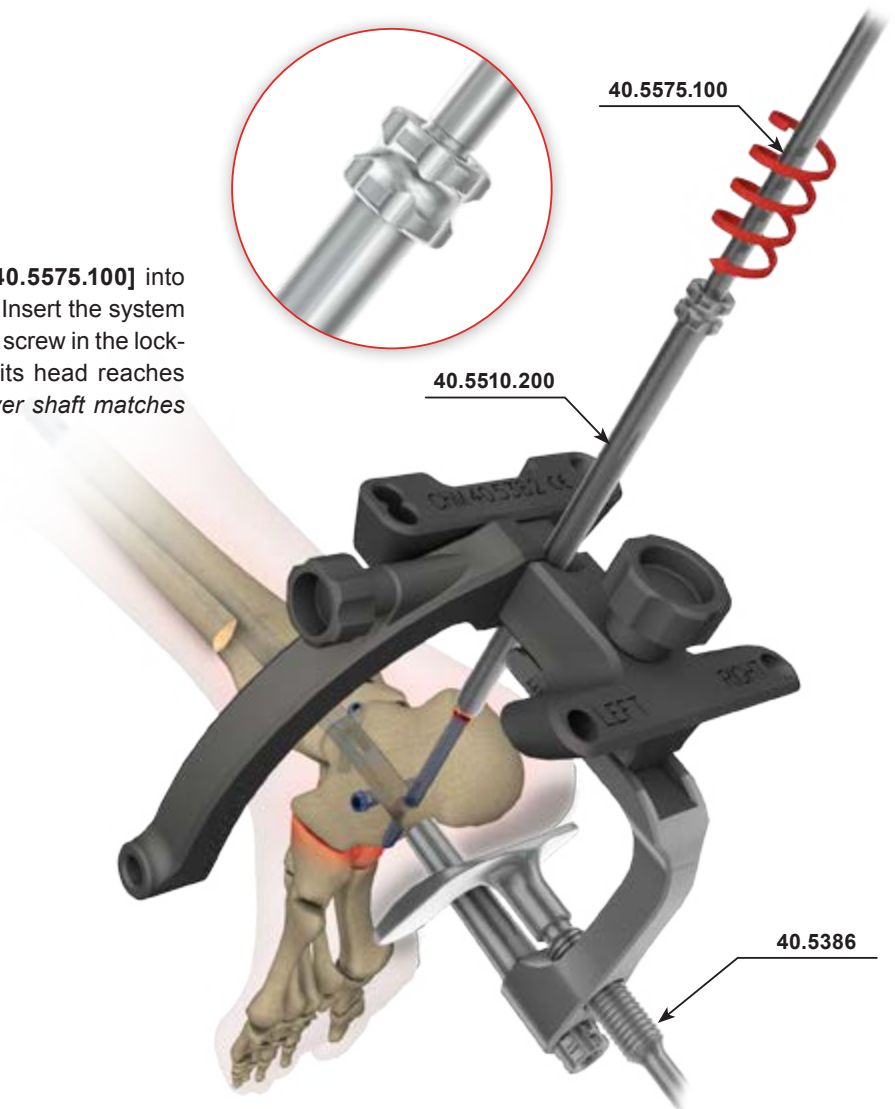
- 35 Insert screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

Remove the screw length measure.

Leave the protective guide in the hole of the targeter.

- 36 Insert the tip of the screwdriver T25 [40.5575.100] 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 previously drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).

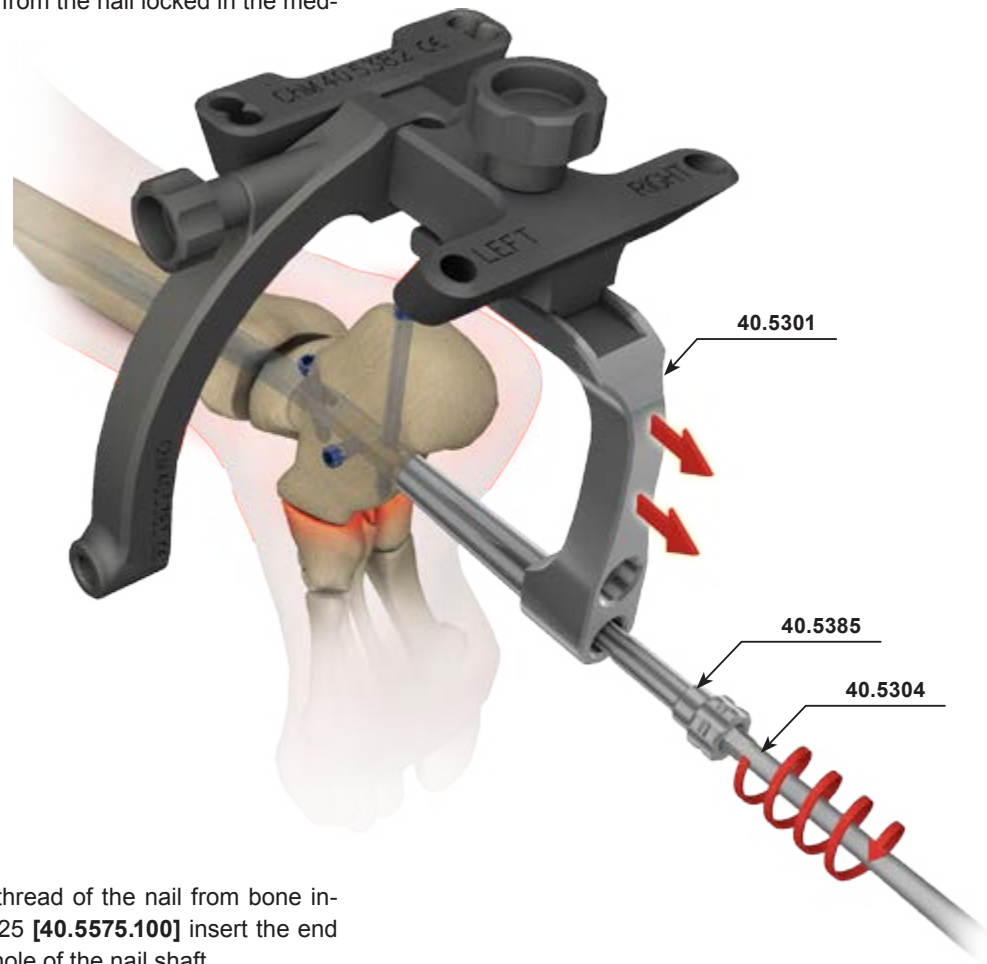
Remove screwdriver [40.5575.100].  
Remove protective guide [40.5510.200].  
Remove compression screw [40.5386].



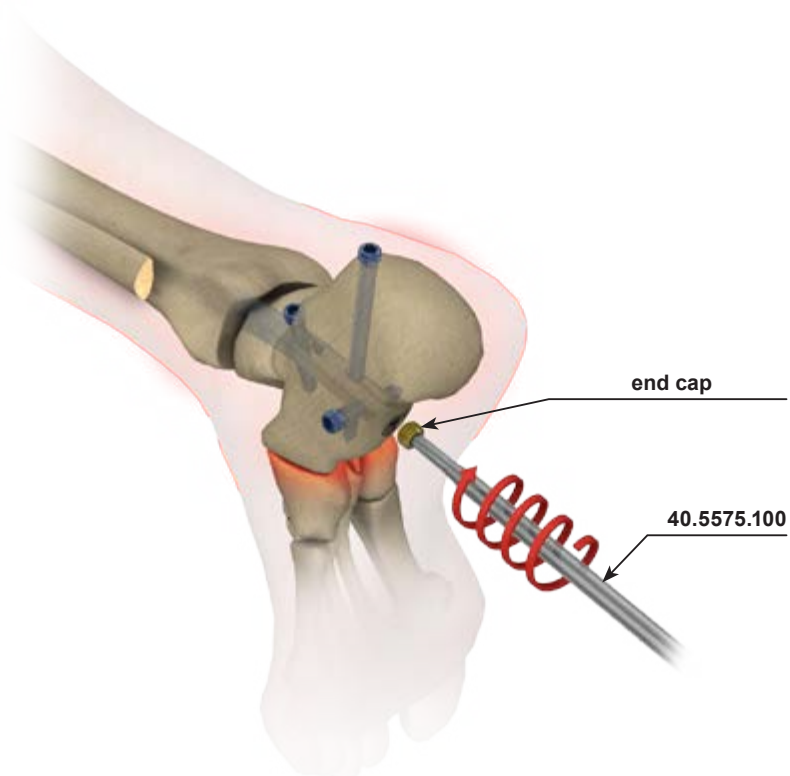
#### IV.12. END CAP INSERTION

- 37 Using the wrench S8 [40.5304] remove the connecting screw [40.5385].

Remove targeter arm [40.5301] from the nail locked in the medullary cavity.

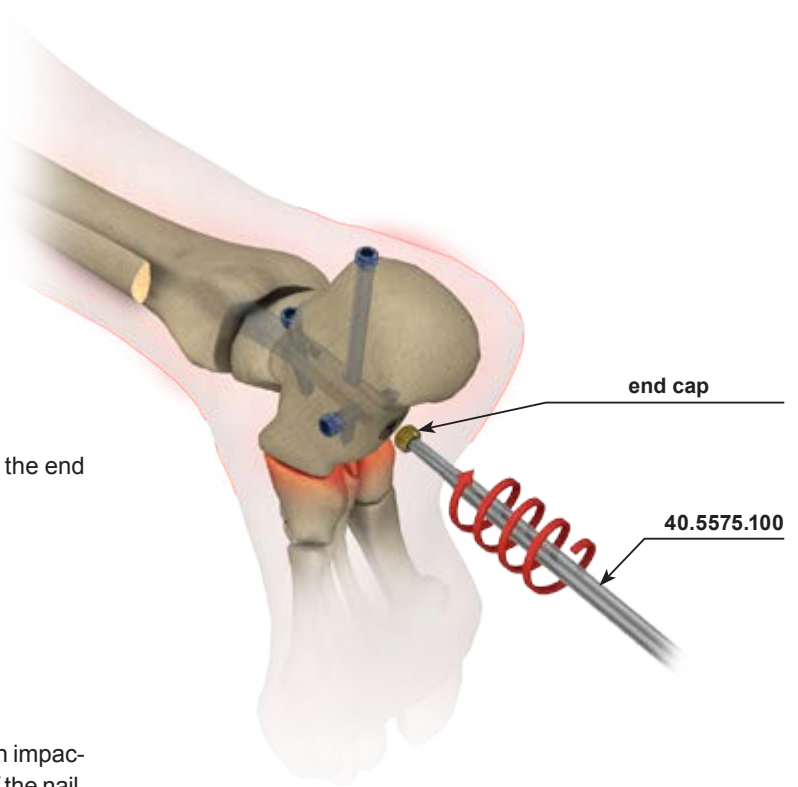


In order to protect the internal thread of the nail from bone in-growth, using the screwdriver T25 [40.5575.100] insert the end cap (implant) into the threaded hole of the nail shaft.

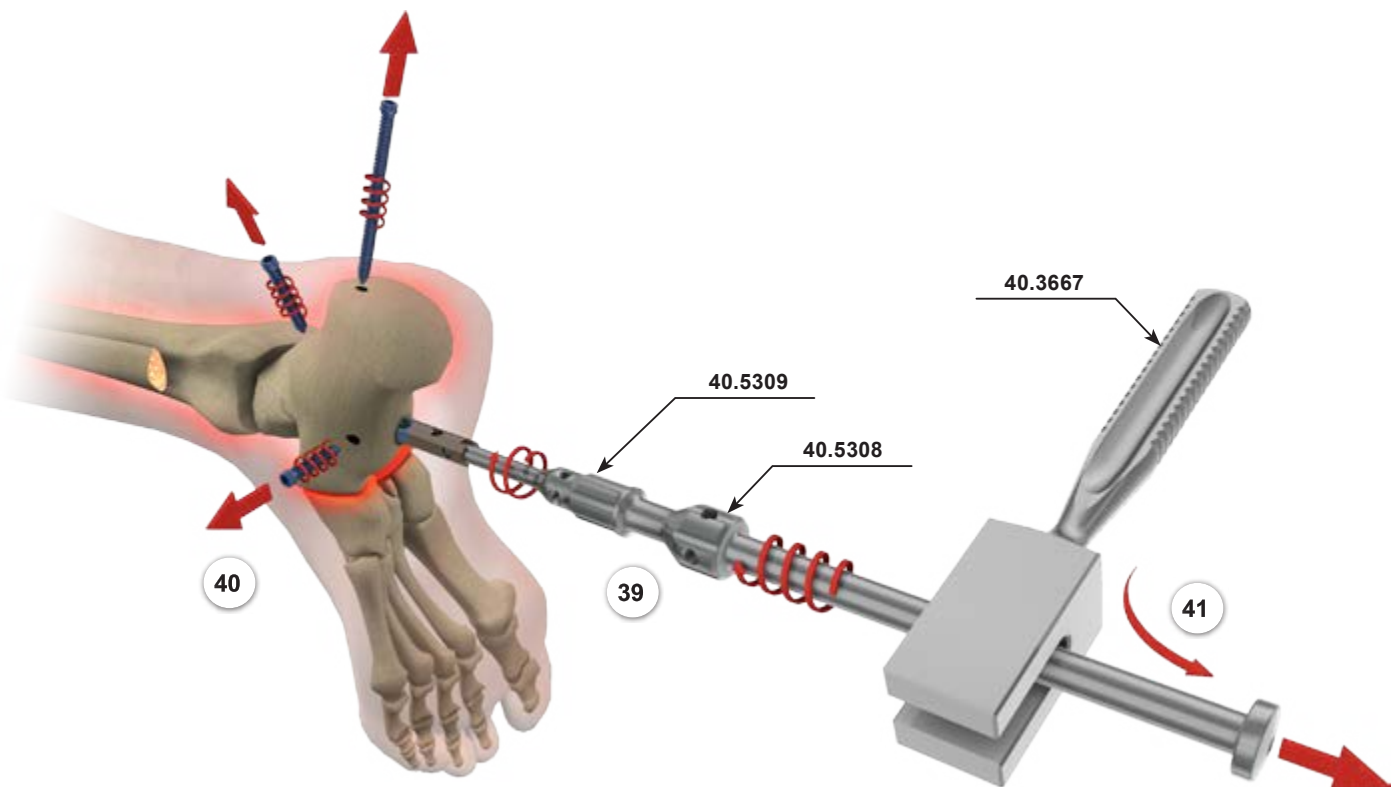


## IV.13. NAIL REMOVAL

- 38 Using the screwdriver T25 [40.5575.100], remove the end cap from the nail shaft.



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



- 40 Using hexagonal screwdriver T25 [40.5575.100], remove all locking screws.

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





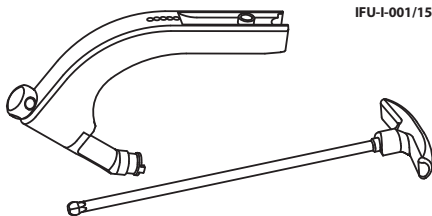
GB

ChM®

ISO 9001/ ISO 13485



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GB  
INSTRUCTIONS FOR USE  
REUSABLE ORTHOPAEDIC AND SURGICAL  
INSTRUMENTS

## DESCRIPTION AND INDICATIONS

Instruments manufactured by ChM sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed to corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instruments durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets (arranged on trays and placed into specially designed sterilization containers).

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:

- ChM logo and the manufacturer's address,
- name, size and catalogue number of the device (REF), e.g.: 40.XXXX.XXX,
- production batch number (LOT), e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols (described in the footer of this Instructions For Use).

Depending on the size or type of the product, the following information may be marked on its surface: ChM logo, production batch no. (LOT), catalogue no. (REF), type of material and device size.

## MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer (passive layer) against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cassettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour (silvery-grey), is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU (Polyphenylsulfone), PEEK (Polyetheretherketone) and teflon (PTFE - Polytetrafluoroethylene).

The above mentioned materials can be processed (washed, cleaned, sterilized) at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

## WARNINGS AND PRECAUTIONS

- Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
- The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
- Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition. Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
- Tissue structures close to operative site must be protected.
- Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
- Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
- While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
- In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
- In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
- Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
- Reusable orthopaedic and surgical instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and – in consequences – damage of the instrument.
- It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments (see CALIBRATION). Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction. If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

## CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure (washer-disinfector) for cleaning and disinfecting.

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning (manual, ultrasound, with the use of washing/disinfecting machine), the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

## Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes (nylon brushes are recommended).

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

## Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

## CAUTION:

To avoid product damage (pitting, rust), DO NOT use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.

## Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

## CAUTION:

- Never use metal brushes, files or sponges for contaminants removal.
- Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.
- Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.
- If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.

## Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector (use washing-disinfecting agents recommended for medical devices).

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° (soak for at least 10 minutes in demineralized water) without the use of detergents.

## Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

## Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

## CAUTION:

The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

ATTENTION! The manufacturer does not recommend using any preservatives on surgical and orthopaedic devices.

## Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

## Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage (cracks, fractures, bending, peeling). Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization (with water vapor under overpressure):

- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

## CAUTION:

Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10<sup>6</sup> (SAL=10<sup>-6</sup>, where SAL stands for Sterility Assurance Level).

Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.

- Validated sterilization methods are allowed.
- Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.
- Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

## STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges (nick or dull) and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

## CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device (e.g. 4 Nm).

To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.

2. The calibration is conducted by the manufacturer – ChM sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

If this instructions appears unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available on the following website: [www.chm.eu](http://www.chm.eu)

IFU-I-001/15; Date of verification: December 2015

SYMBOL TRANSLATION - OBJASNIENIA SYMBOLI - ПОЯСНЕНИЕ ОБЪЯСНЕНИЙ - EXPLICACIÓN DE LOS SÍMBOLOS - SYMBOLBETÄKLÄRUNG - SYMBOLY PŘEKLADY - TRADUZIONI SIMBOLI	
	Do not reuse - Nie używać ponownie - Не использовать повторно - No reutilizar - Nicht wiederverwenden - Neopozivljete opakovan - Non riutilizzare
	Do not sterilize - Nie sterylizować ponownie - Не стерилизовать повторно - No reesterilizar - Nicht reesterilisieren - Neopozivljete sterilizaciju - Non riesterilizzare
	Do not use if package is damaged - Nie używać jeśli opakowanie jest uszkodzone - Не использовать при повреждении упаковки - No utilizar si el empaque está dañado - Nicht verwenden falls Verpackung beschädigt ist - Neopozivljete, pokud je obal poškozen - Non utilizzare se la confezione è danneggiata
	Consult instructions for use - Zaznejte do instrukcí užívání - Обратитесь к инструкции по применению - Consultar instrucciones de uso - Siehe die Gebrauchsanweisung - Rilevi se il manuale è presente - Consultare le istruzioni per l'uso
	Non-sterile - Нестерильн - Не стерильно - Non sterile - Unsteril - Nesteril - Non sterile
	Caution - Ostrzeżenie - Осторожно - Advertencia - Vorsicht - Varoitus - Attenzione leggere il foglio illustrativo
	Sterilized using irradiation - Sterylizowany przez naświetlanie - Радиационная стерилизация - Esterilizado mediante radiación - Sterilisiert durch Bestrahlung - Sterilизован злученням - Sterilizzato mediante irradiazione
	Sterilized using hydrogen peroxide - Sterylizowany nadtlenkiem wodoru - Стерилизован перекисью водорода - Esterilizado con peróxido de hidrógeno - Sterilisiert mit Wasserstoffperoxid - Sterilизовано с перекисью водорода - Sterilizzato mediante perossido di idrogeno
	Catalogue number - Numer katalogowy - Номер по каталогу - Número de catálogo - Katalognummer - Katalogový číslo - Numero di catalogo
	Batch code - Код партии - Код партии - Código de lote - Chargennummer - Číslo série - Codice del lotto
	Material - Material - Материал - Material - Material - Materiale
	Quantity - Колич - Количество - Cantidad - Menge - Množství - Quantità
	Use by - Уżyć до - Использовать до - Usar antes de - Verwenden bis - Použítje do - Da utilizzare entro il

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CE 0197  
ISO 9001  
ISO 13485