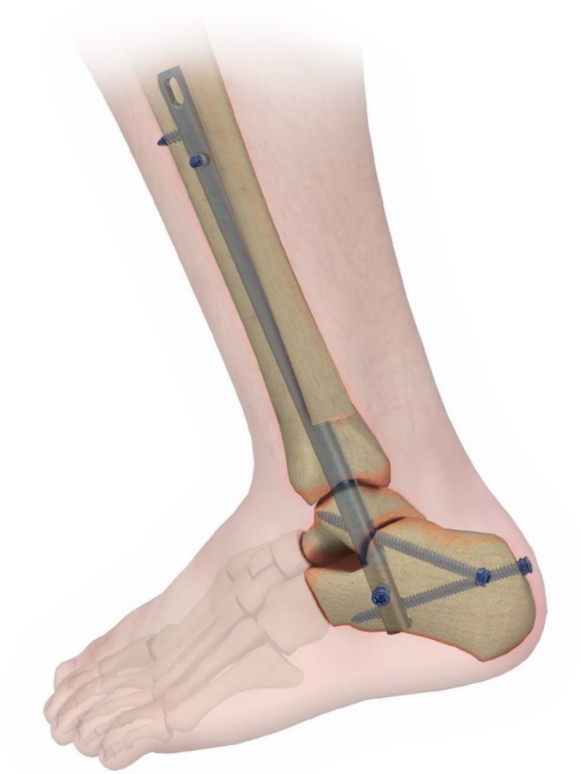
ChM®

CHARFIX system 2

INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA
retrograde method

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



SYMBOLS DESCRIPTIONS

Ti	Titanium or titanium alloy	H	H length [mm]
Co	Cobalt		Angle
L	Left	88 - 340	available lengths
R	Right	4-22	Available number of holes
L R	Available versions: left/right	1.8	Thickness [mm]
Len	Length	1:1	Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive	VA	Variable angle
	Hexagonal drive cannulated	C	Cortical
	Cannulated		Cancellous
	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
	Diameter [mm]		Refer to surgical technique

	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.
	Before using the product, carefully read the Instructions for Use supplied with the product. 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.

www.chm.eu

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The manufacturer reserves the right to introduce design changes.

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.

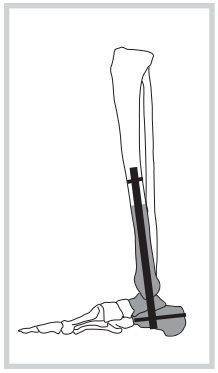
Indications for retrograde nailing:

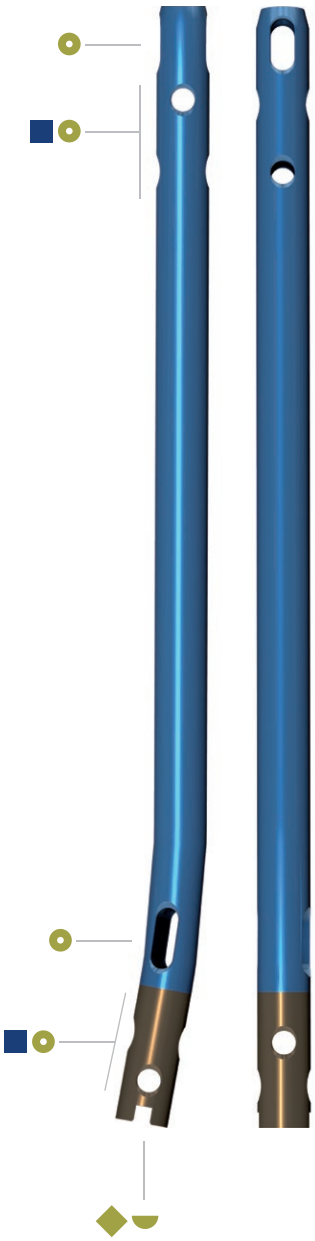
- tibiocalcaneal arthrodesis;
- combined arthrodesis of talocrural joint and talocalcaneal joint;
- avascular necrosis of talocalcaneal joint and talocrural joint;
- rheumatoid arthritis;
- severe, secondary deformity of untreated congenital club foot (*talipes equinovarus*) or in the case of the neuromuscular 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

CHARFIX system 2



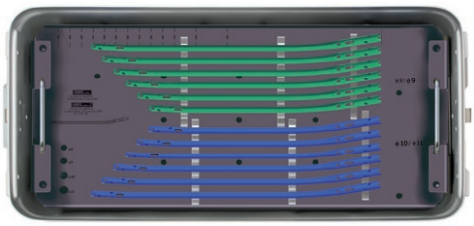


Ster
Non Ster

	Len	L	R
10	180	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	3.5679.300	3.5680.300
	320	3.5679.320	3.5680.320
11	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	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
12	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	8 mm ÷14 mm	pitch	1 mm
	L	130 mm ÷ 400 mm		5 mm

	Ti					
3.5160.xxx	✓	✓		5.5	30÷100	
3.5159.xxx	✓			5.0	30÷100	
3.5162.006	✓		✓			
3.5161.006	✓					



Stand for tibial nails CHARFIX/CHARFIX2 (implants not included) 40.5750.000

LOCKING ELEMENTS

Ti Ster Non Ster

CHARFIX system 2

CHARFIX2 DISTAL SCREW 5.0

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

16 ÷ 100

CHARFIX2 DISTAL SCREW 5.5

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

CHARFIX2 COMPRESSION SCREW M7X1

3.5162.006

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

40.5058.200

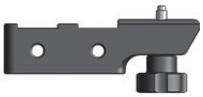
ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 86 86 100, fax + 48 85 86 86 101, chm@chm.eu, www.chm.eu

III. INSTRUMENT SET

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

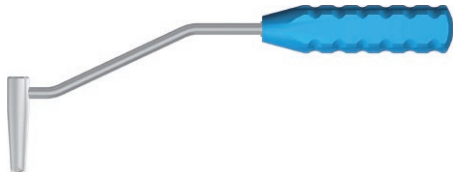
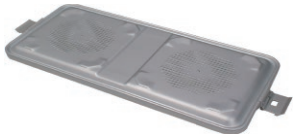
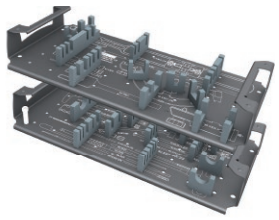
INSTRUMENT SET FOR TIBIAL NAILS **40.5300.500**

CHARFIX system 2

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

INSTRUMENT SET FOR TIBIAL NAILS **40.5300.500**

CHARFIX system 2

40.5300.500	Name	Pcs	Catalogue No.
	Trocar 6.5	1	40.5534.100
	Nail length measure	1	40.4798.500
	Guide rod handle	1	40.1351.000
	Teflon pipe guide 8/400	1	40.3700.000
	Drill with scale 3.5/150	1	40.5343.002
	Targeter D	1	40.1344.100
	Drill guide short 7/3.5	1	40.1358.100
	Trocar short 7	1	40.1354.100
	Aiming insert 9.0	2	40.5065.009
	Guide rod 2.5/580	1	40.3673.580
	Screwdriver T25	1	40.5575.400
	Drill with scale 3.5/350	2	40.5339.002
	Screw length measure	1	40.5530.100
	Hole depth measure	1	40.2665.000
	Curved awl 8.0	1	40.5523.000
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand for tibial nails	1	40.5319.500

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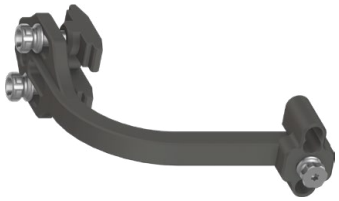
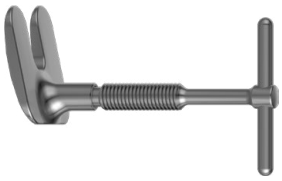
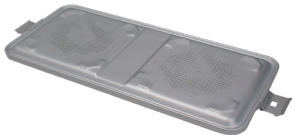
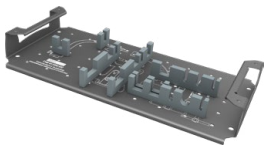
INSTRUMENT SET FOR TIBIAL NAILS **40.5300.500**

CHARFIX system 2

40.5300.500	Name	Pcs	Catalogue No.
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

INSTRUMENT SET FOR RETROGRADE TIBIAL NAILS CHARFIX2 40.5380.500

CHARFIX system 2

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

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IV. SURGICAL TECHNIQUE

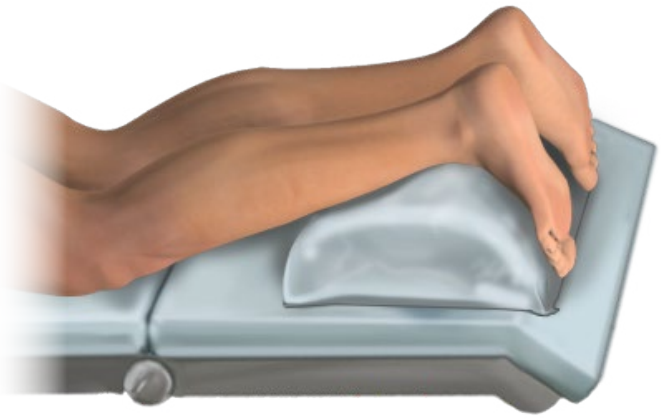
The following description covers the most important steps during the implantation of retrograde tibial nails. Nevertheless, it is not a detailed instruction of conduct.
The surgeon decides about choosing the operating technique and its application in each individual case.

IV.1. SURGERY PLANNING

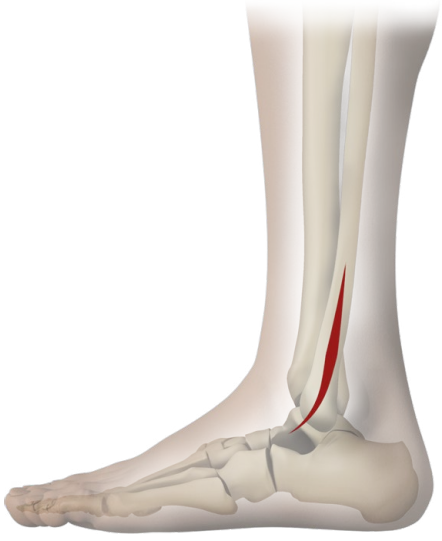
Each procedure must be planned accordingly. Prior to surgery, take an X-Ray image of the fractured extremity as to determine the type and location of the fracture and to determine the size of the nail to be implanted. It is recommended to take the AP, PA and lateral images.
Implantation procedure should be conducted on the operating table equipped with a real-time X-Ray imaging system.

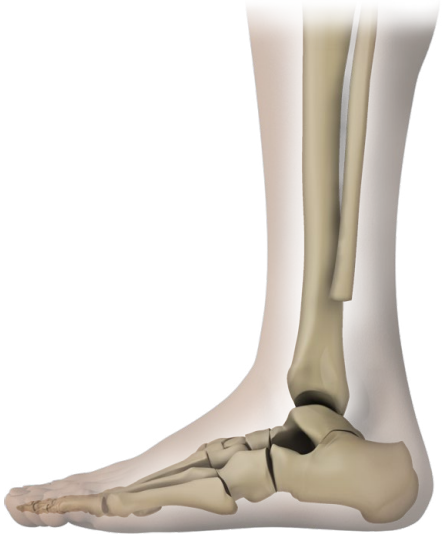
IV.2. SURGICAL APPROACH

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



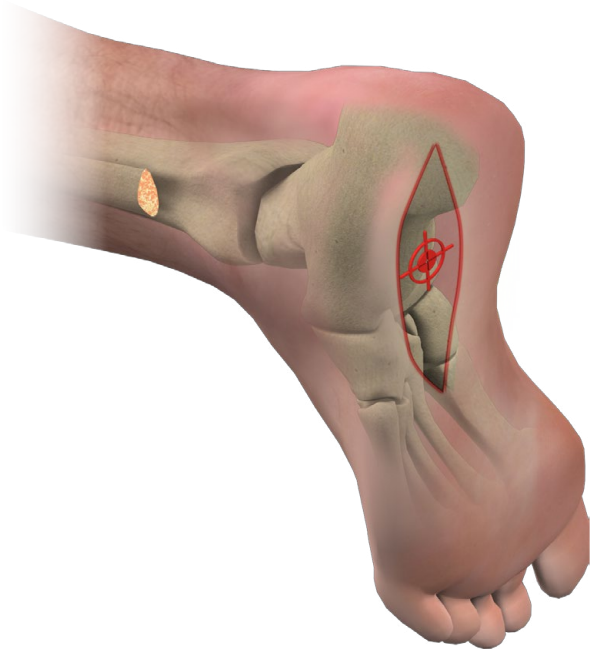
In order to obtain the access to the tibiotalar joint, perform a 5-6cm lateral incision in line with the distal lateral malleolus, and then perform a resection of the distal fibula (*see figure below*). This will allow for adequate exposure of the tibiotalar joint. Resect the distal end of the fibula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



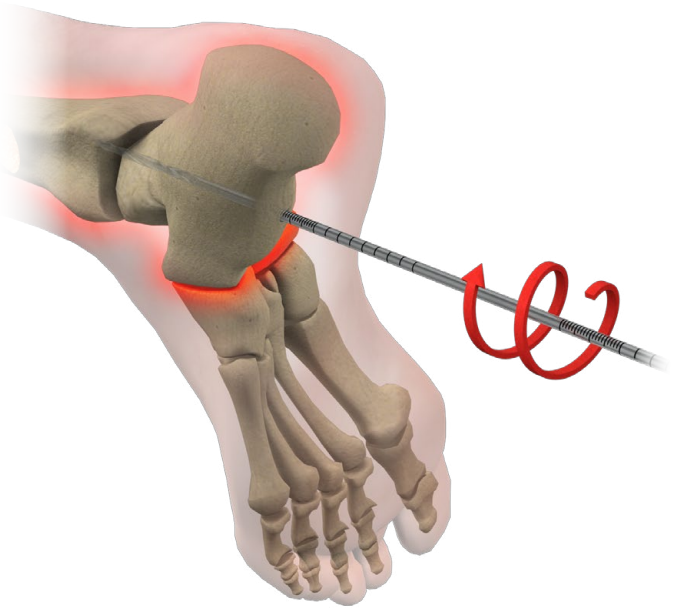
IV.3. MEDULLARY CANAL OPENING


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.



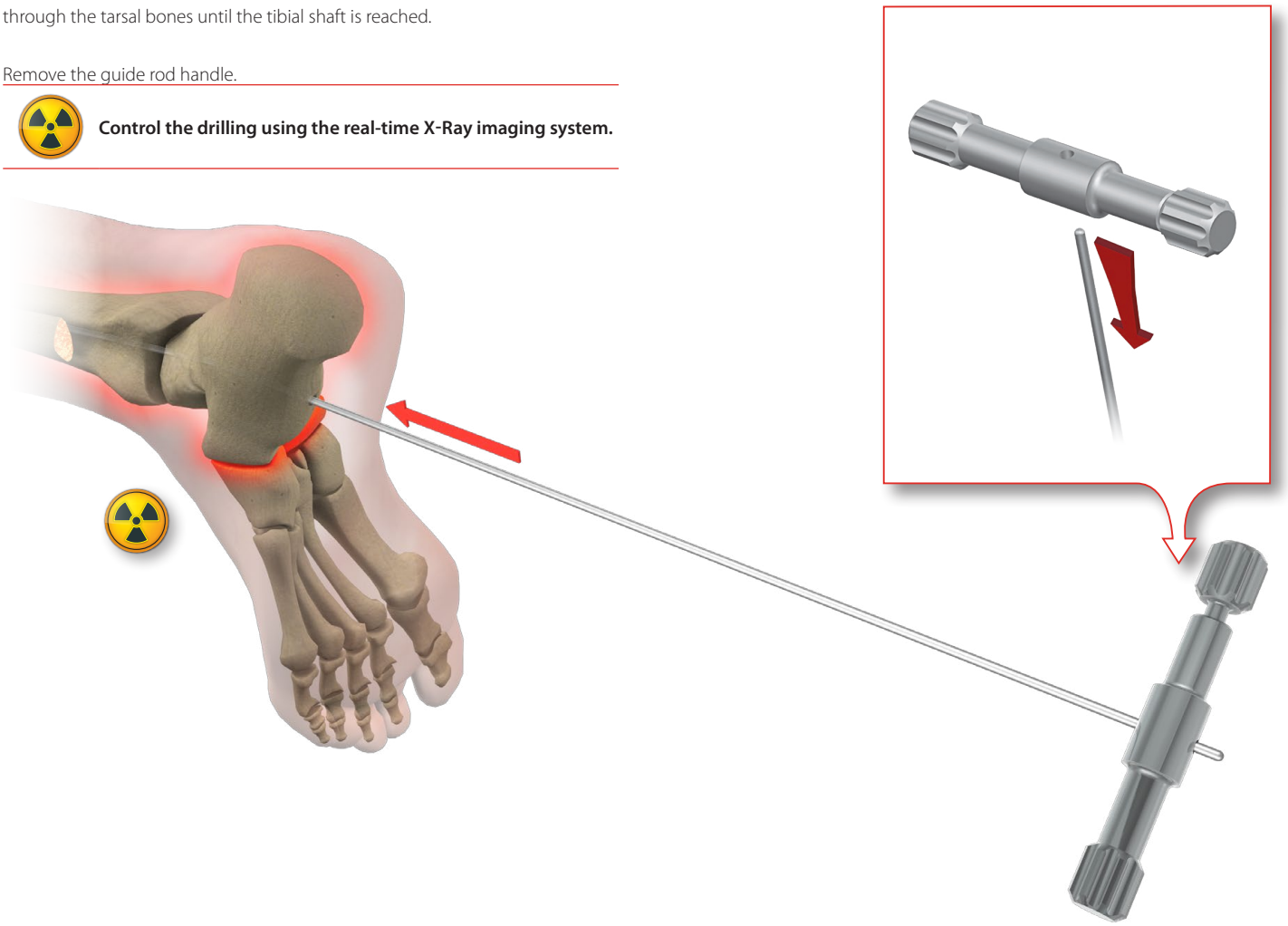
40.3673.580

40.1351.000

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.

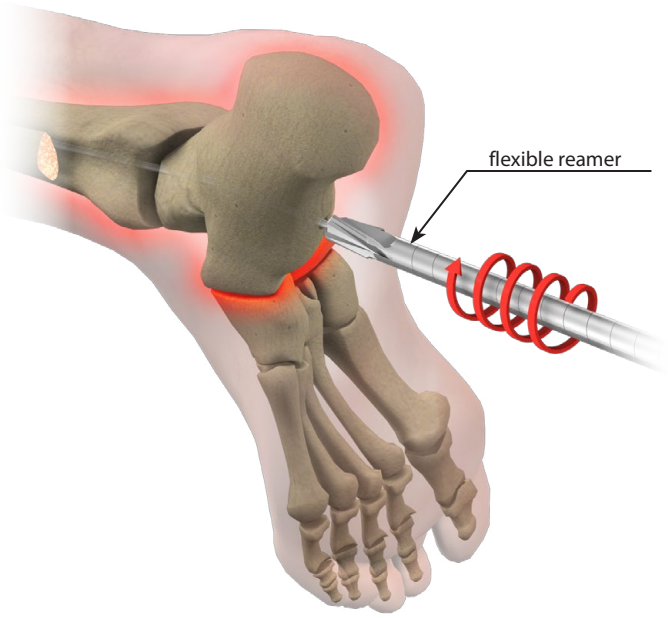


40.3673.580

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.

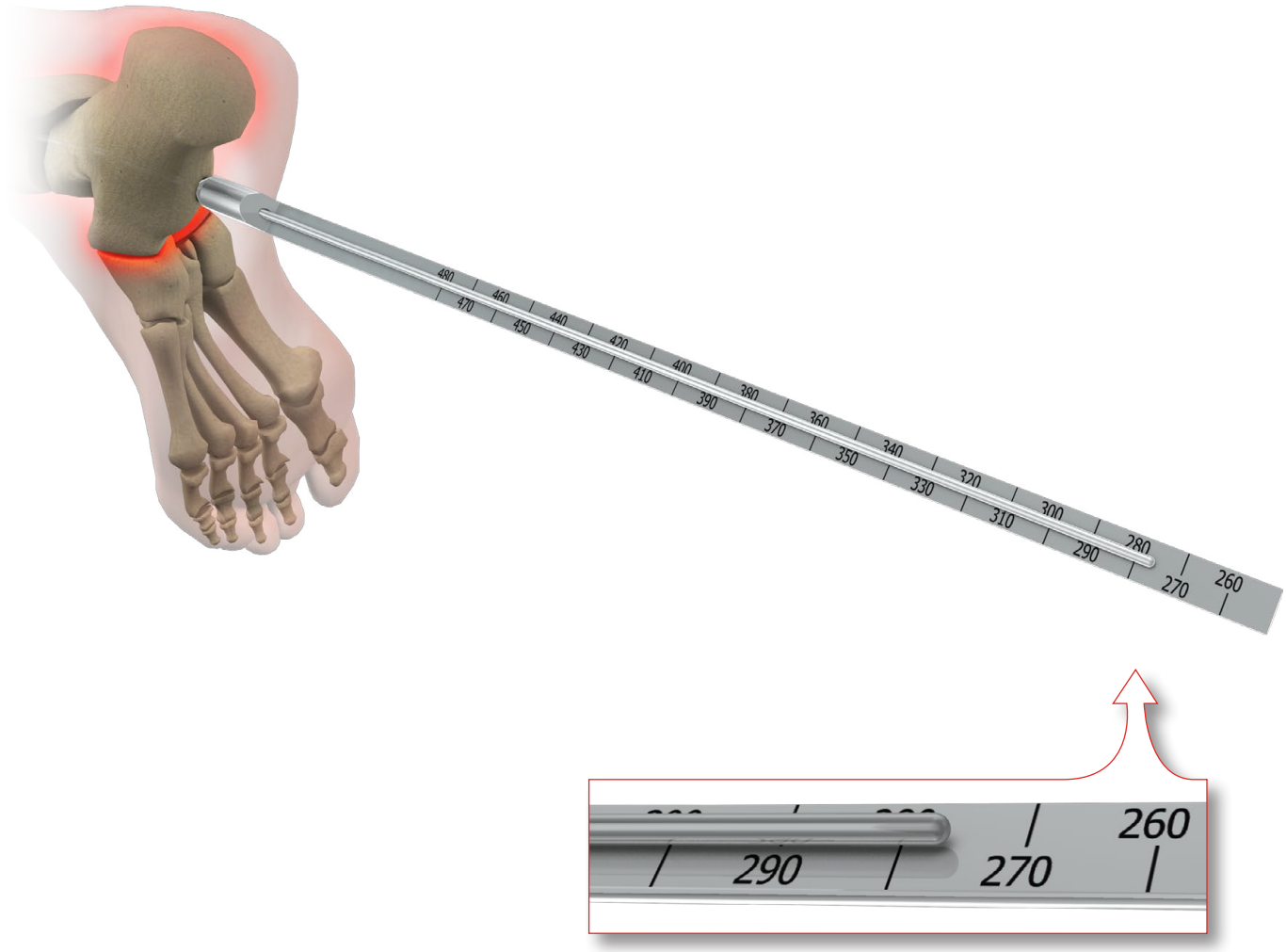



40.4798.500

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

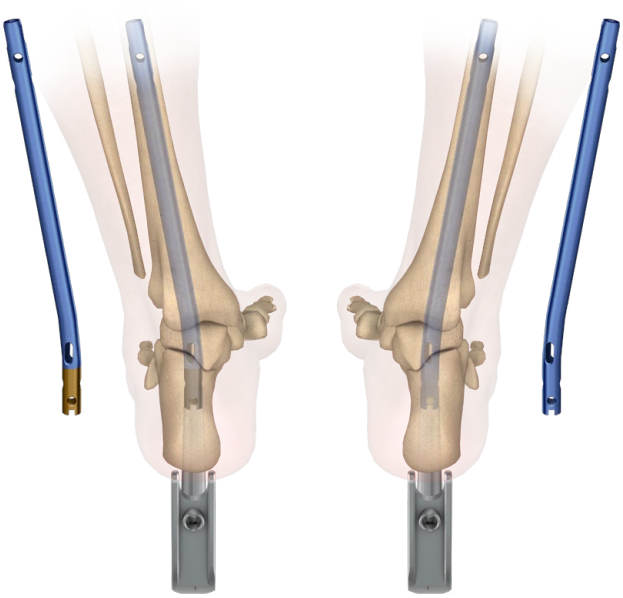
3.5162.006

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

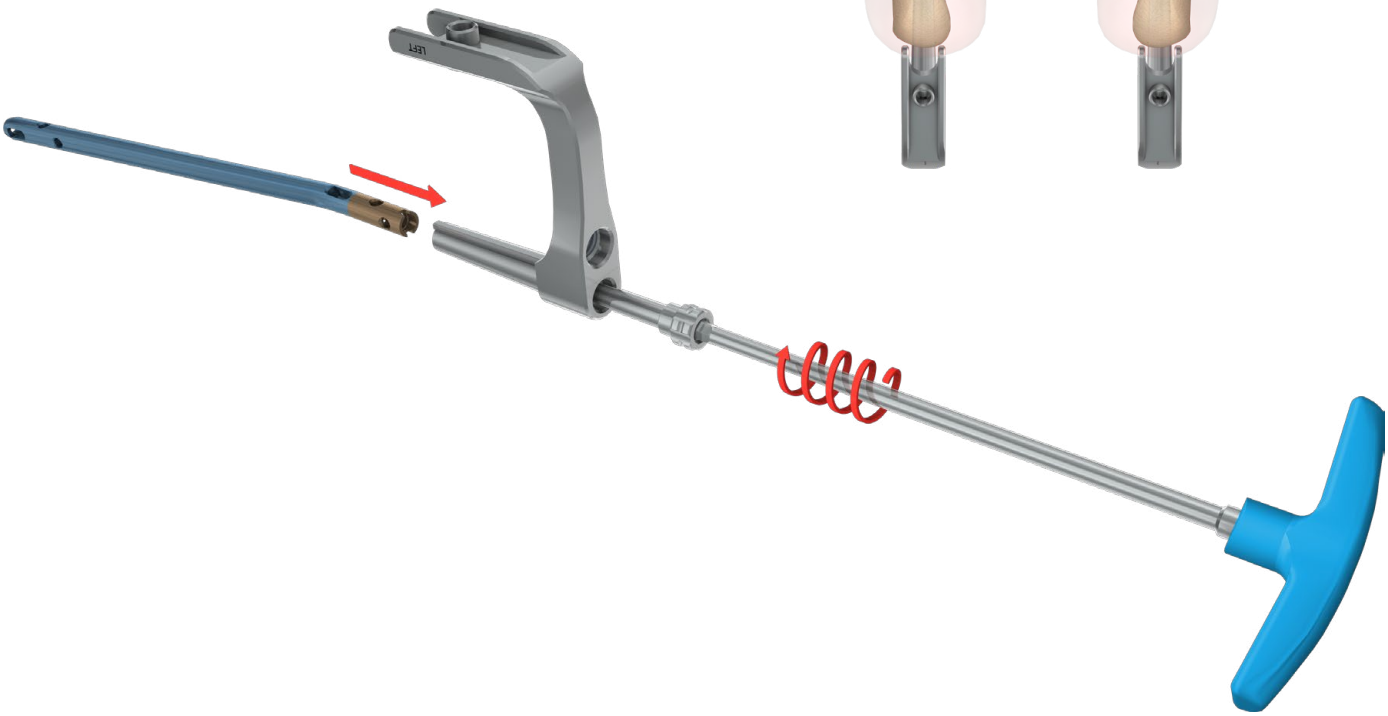
40.5301.000

40.5385.000

40.5304.000



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 the targeter arm B **[40.5301]**.




40.5302.100


40.5384.000


40.5301.000

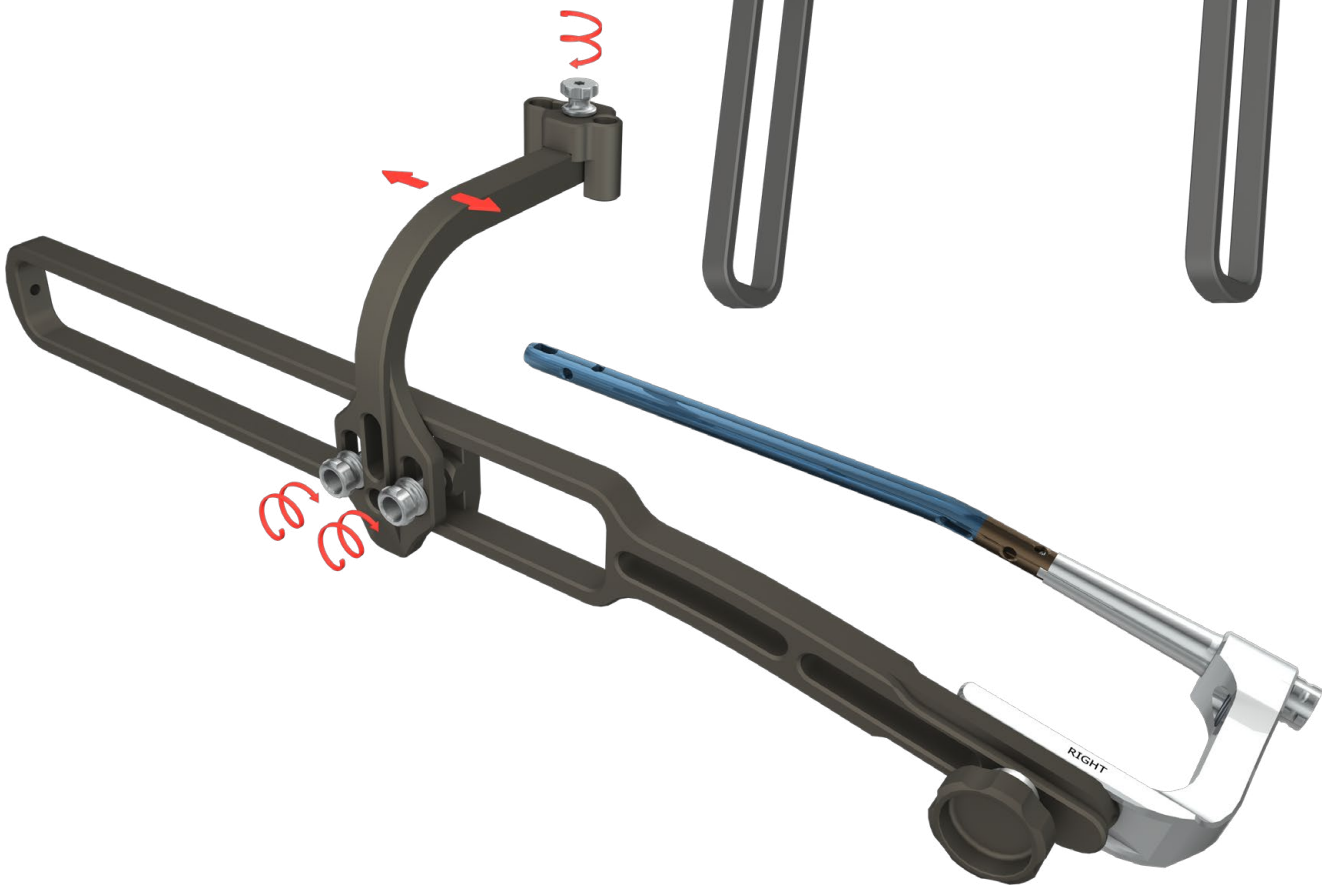
7 **Setting the slider of the targeter D [40.5302.100] and lateral distal targeter [40.5384] to the nail.**

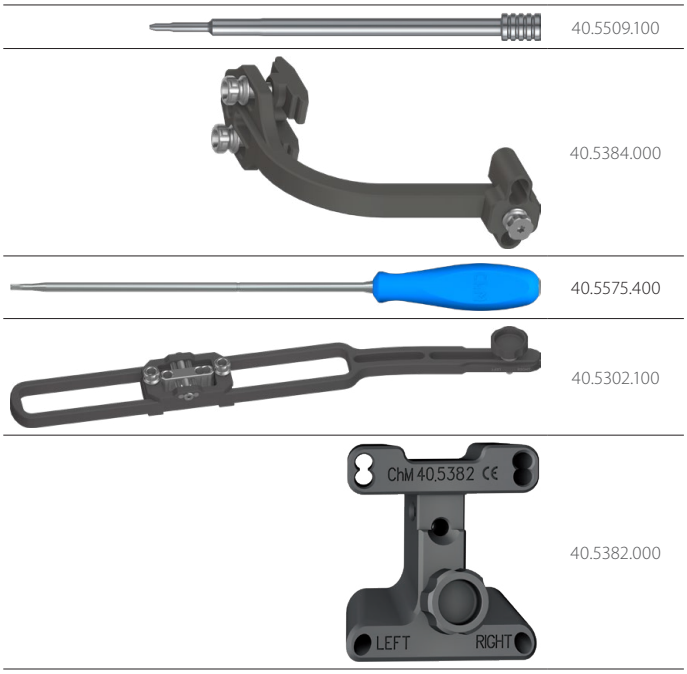
Prior to the insertion of a nail, set the lateral distal targeter **[40.5384]** in relation to the holes of the distal nail.

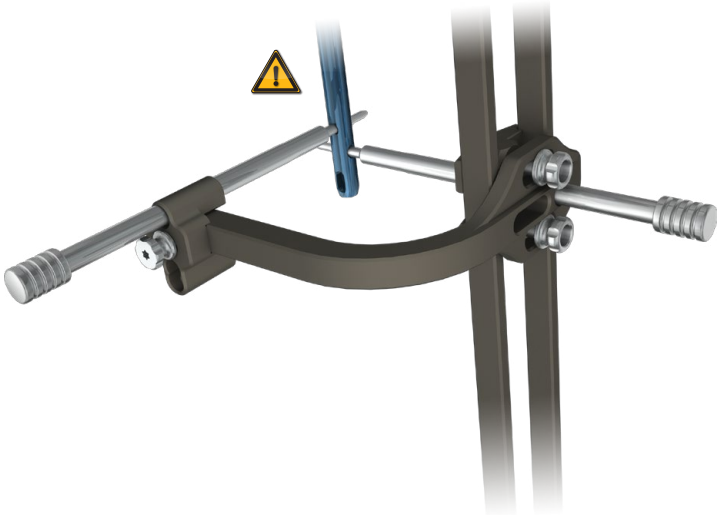
Attached targeter D **[40.5302.100]** to the targeter arm B **[40.5301]**. Inclination of the targeter D should be consistent with the inclination of the nail.

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.

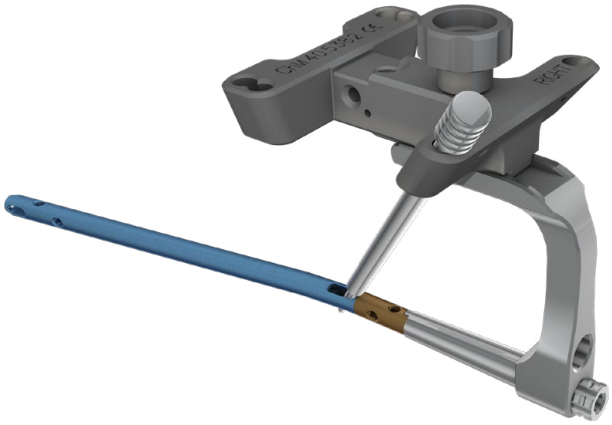






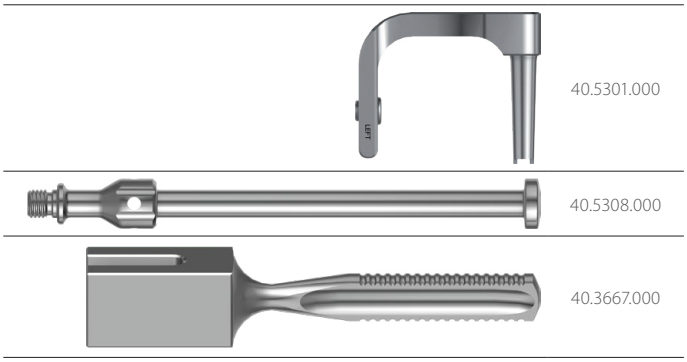
Using two set blocks 9/5.0 **[40.5509.100]**, set the targeter to the nail locking holes in the lateral and fibular plane. Lock the slider of the lateral distal targeter **[40.5384]** and the targeter itself using a screwdriver T25 **[40.5575.400]**.

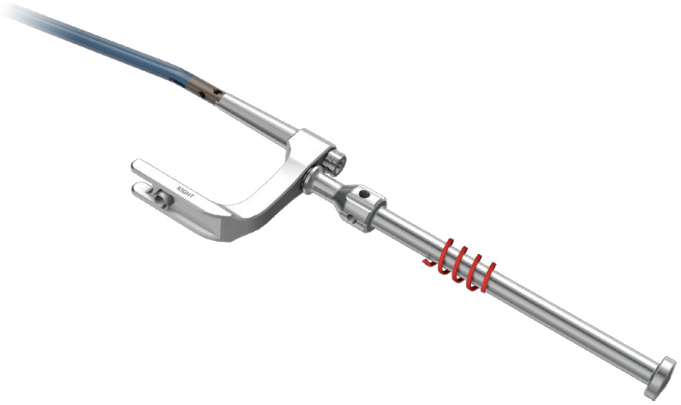
When the targeter slider is properly set and locked, set blocks should go through the nail holes freely.



Remove set blocks from the targeter slider.
Disconnect targeter **[40.5302.100]** from targeter arm.

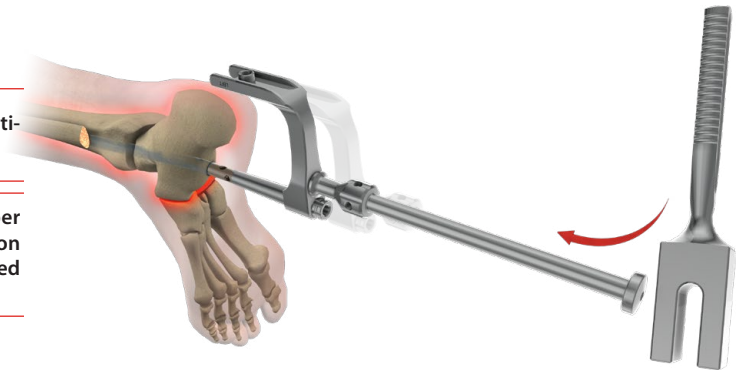
Prior to implantation, verify whether the proximal targeter holes overlap with the holes in the nail. To do so, insert the set block [40.5509.100] into the proximal targeter hole [40.5382].





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*).


40.5301.000

40.5382.000


40.5510.200


40.5534.100

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 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.


40.5510.200


40.5511.200

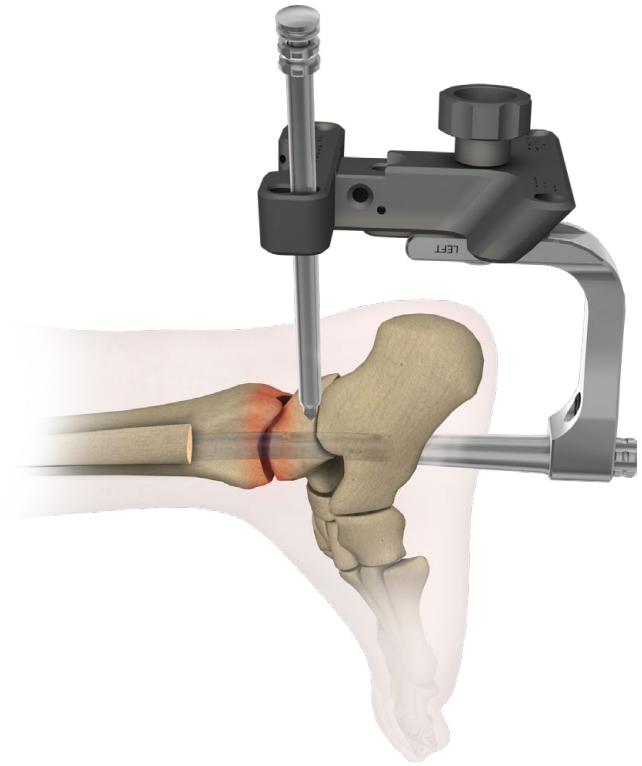

40.5339.002

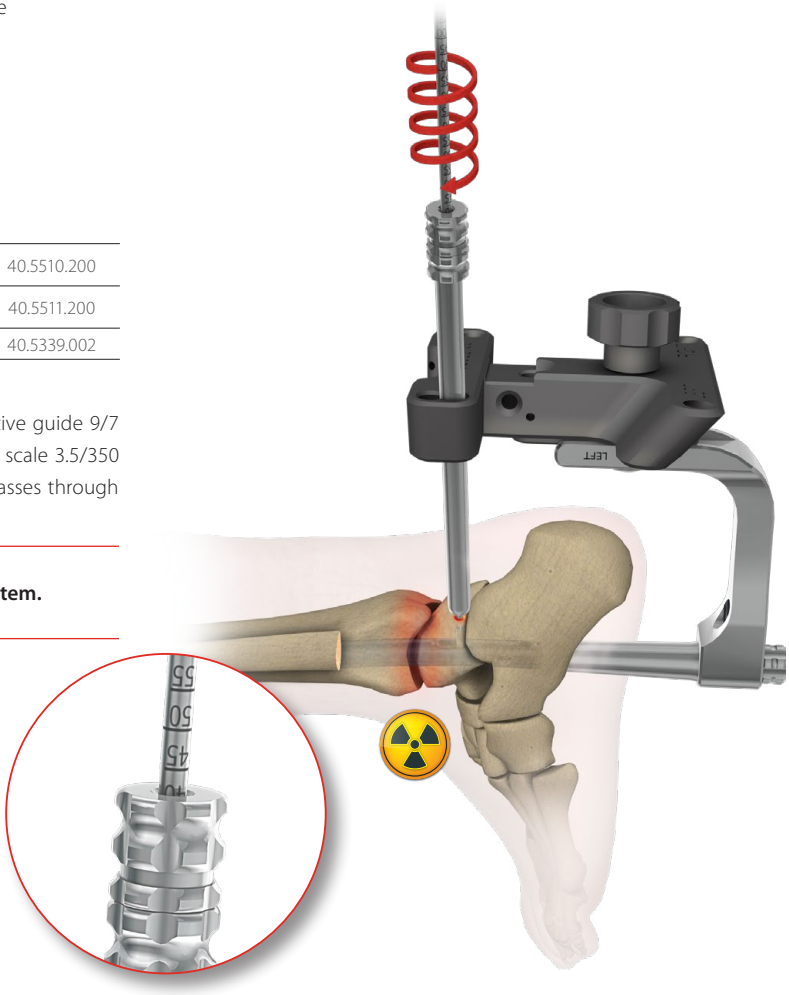
10 Insert drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7 **[40.5510.200]**. Using a drilling machine and a drill with scale 3.5/350 **[40.5339.002]**, drill a hole via the drill guide in the talus that passes through the nail hole to the adequate depth.

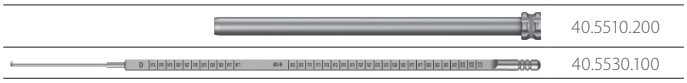
Control drilling using real-time X-Ray imaging system.

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

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





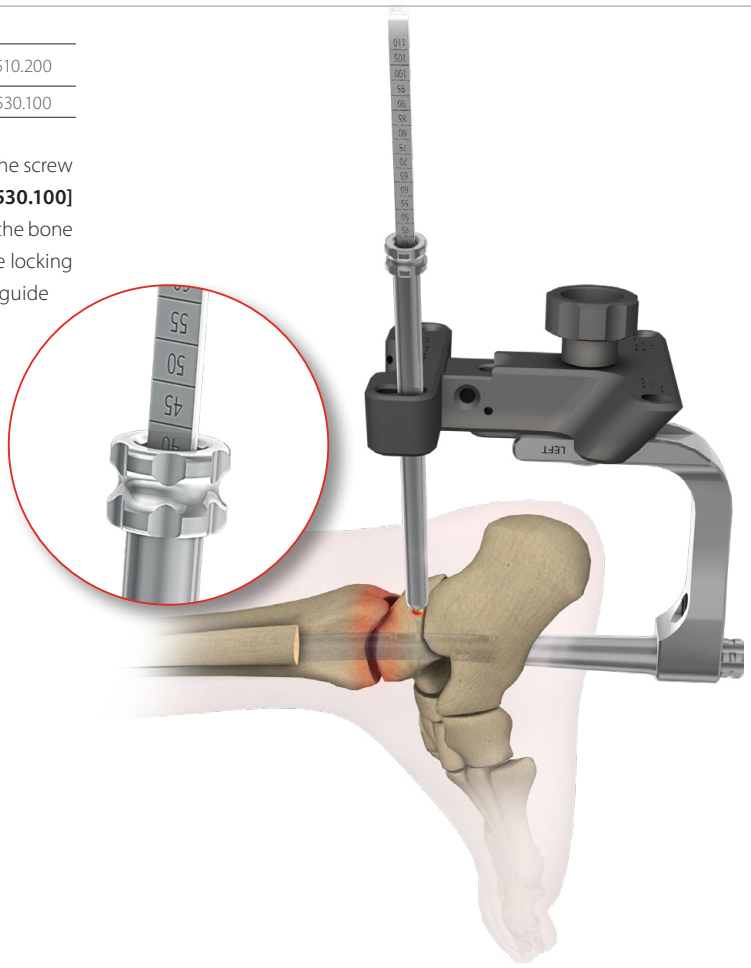


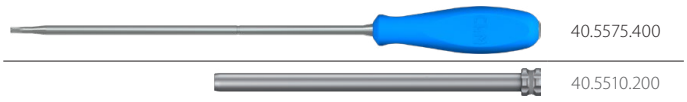
40.5510.200

40.5530.100

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 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.



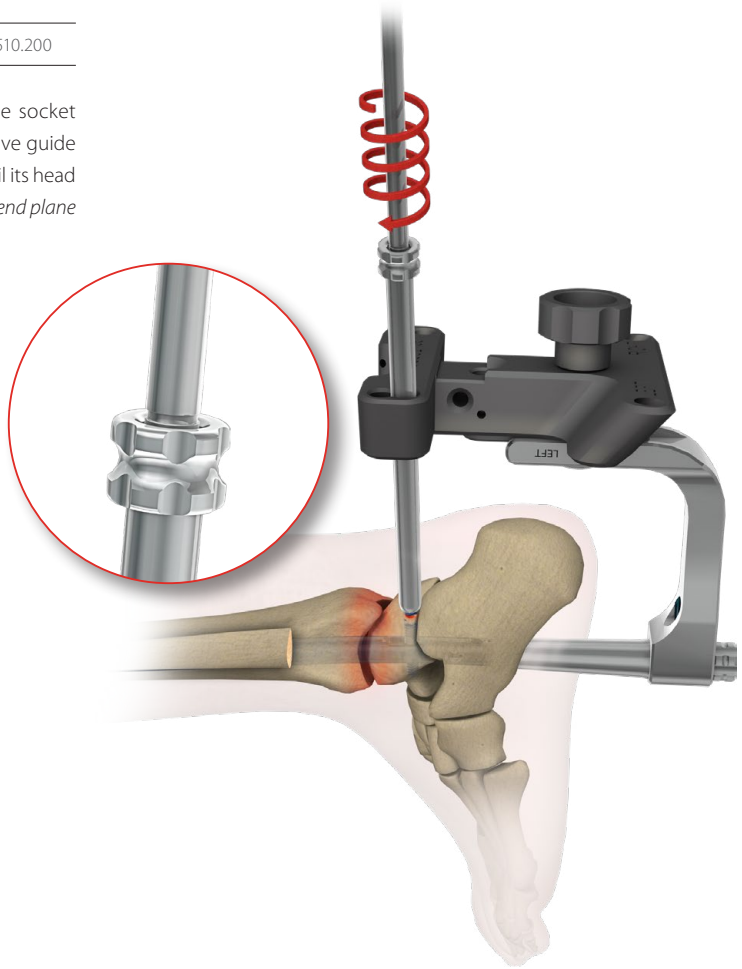


40.5575.400

40.5510.200

12 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*).

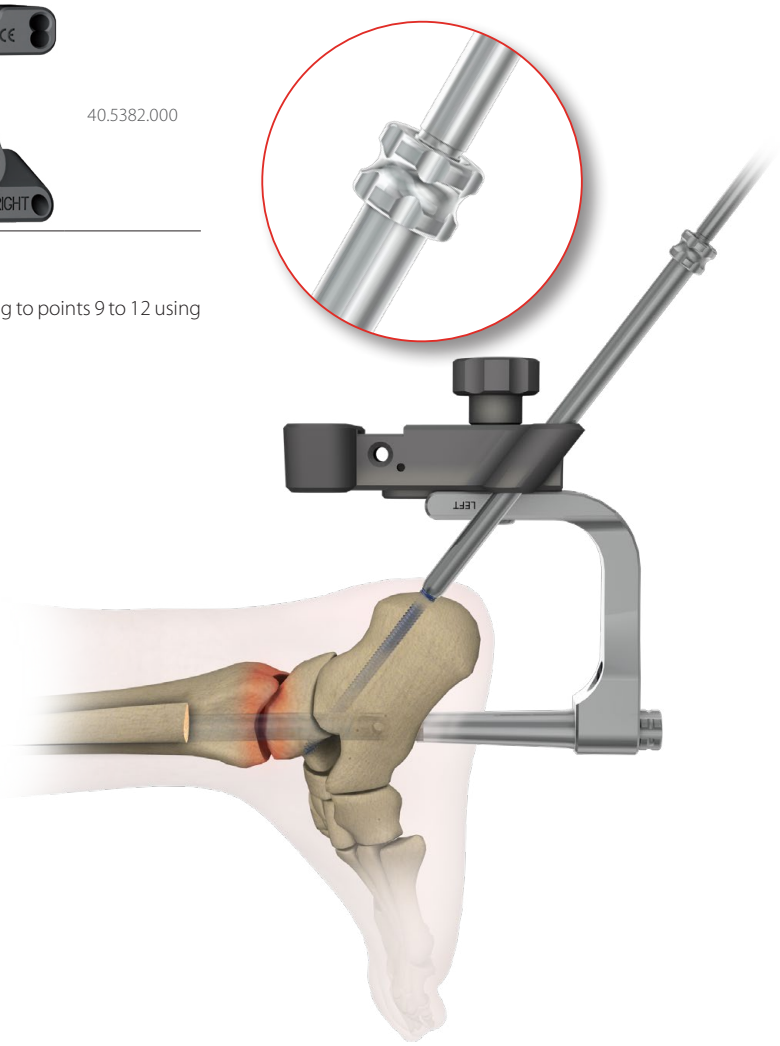
Remove the screwdriver and protective guide.
Detach the proximal targeter.



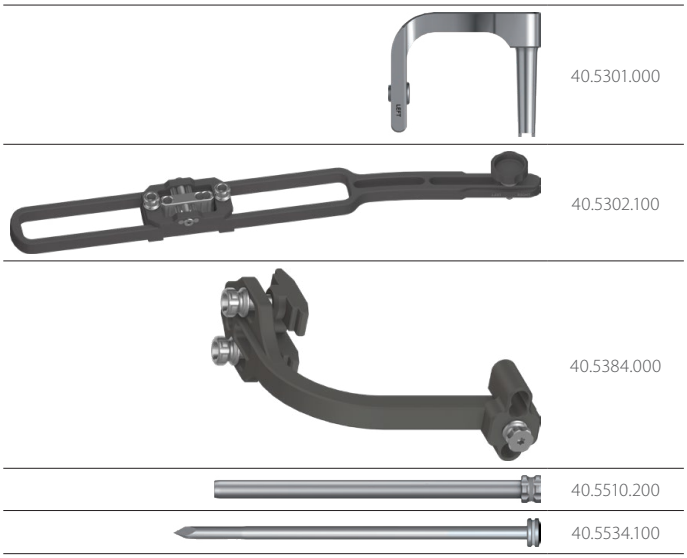
IV.6. OBLIQUE LOCKING THROUGH TALOCALCANEONAVICULAR JOINT - OPTIONAL

40.5382.000

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

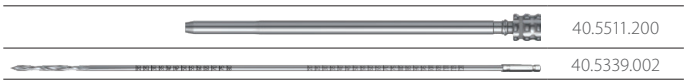


IV.7. PROXIMAL NAIL LOCKING



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.
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.

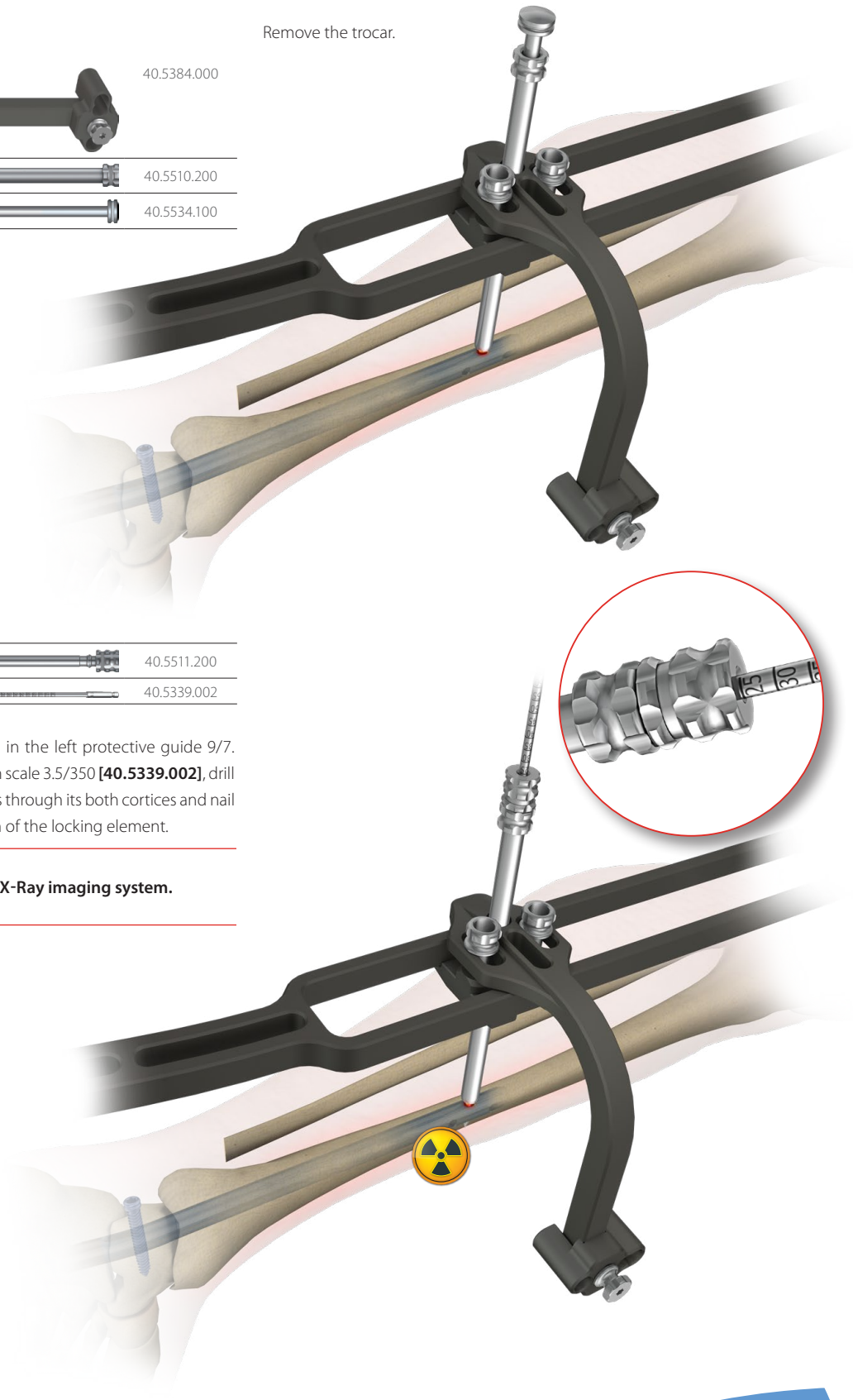
Remove the trocar.



15 Insert drill guide 7/3.5 **[40.5511.200]** 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.



40.5384.000

40.5510.200

40.5534.100

16 Insert the protective guide 9/7 **[40.5510.200]** with the trocar 6.5 **[40.5534.100]** in the other 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.

40.5510.200

40.5511.200

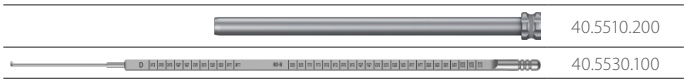
40.5339.002

17 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 and nail hole. The scale on the drill indicates the length of the locking element.

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

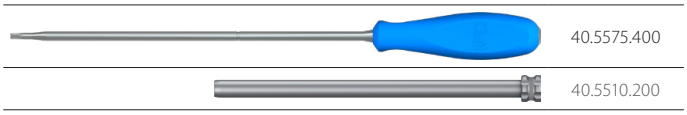
Remove the drill and drill guide.
Leave the protective guide in the hole of the targeter.

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



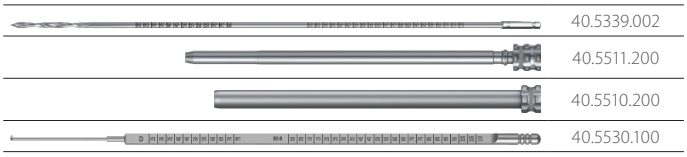
18 Insert screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole in the bone until its hook reaches the "*exit*" plane of the hole. Read the length of the locking screw on the scale. During taking the measure, the end of the protective guide should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

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



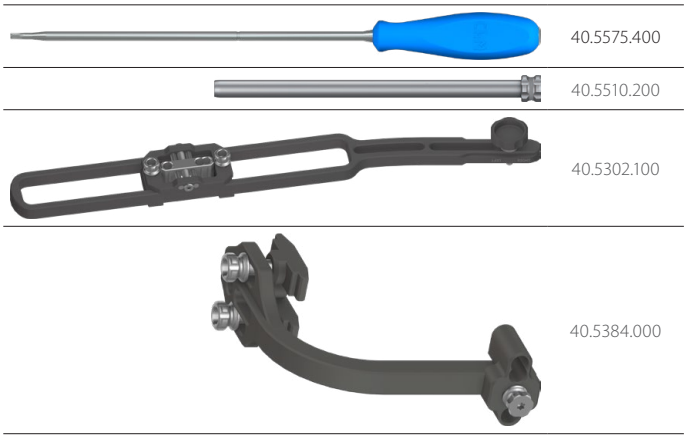
19 Insert the tip of the screwdriver T25 **[40.5575.400]** into the socket of a specified locking screw. Insert the system into the protective guide 9/7 **[40.5510.200]** and screw in the locking screw in the drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches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

Remove the screwdriver and protective guide.



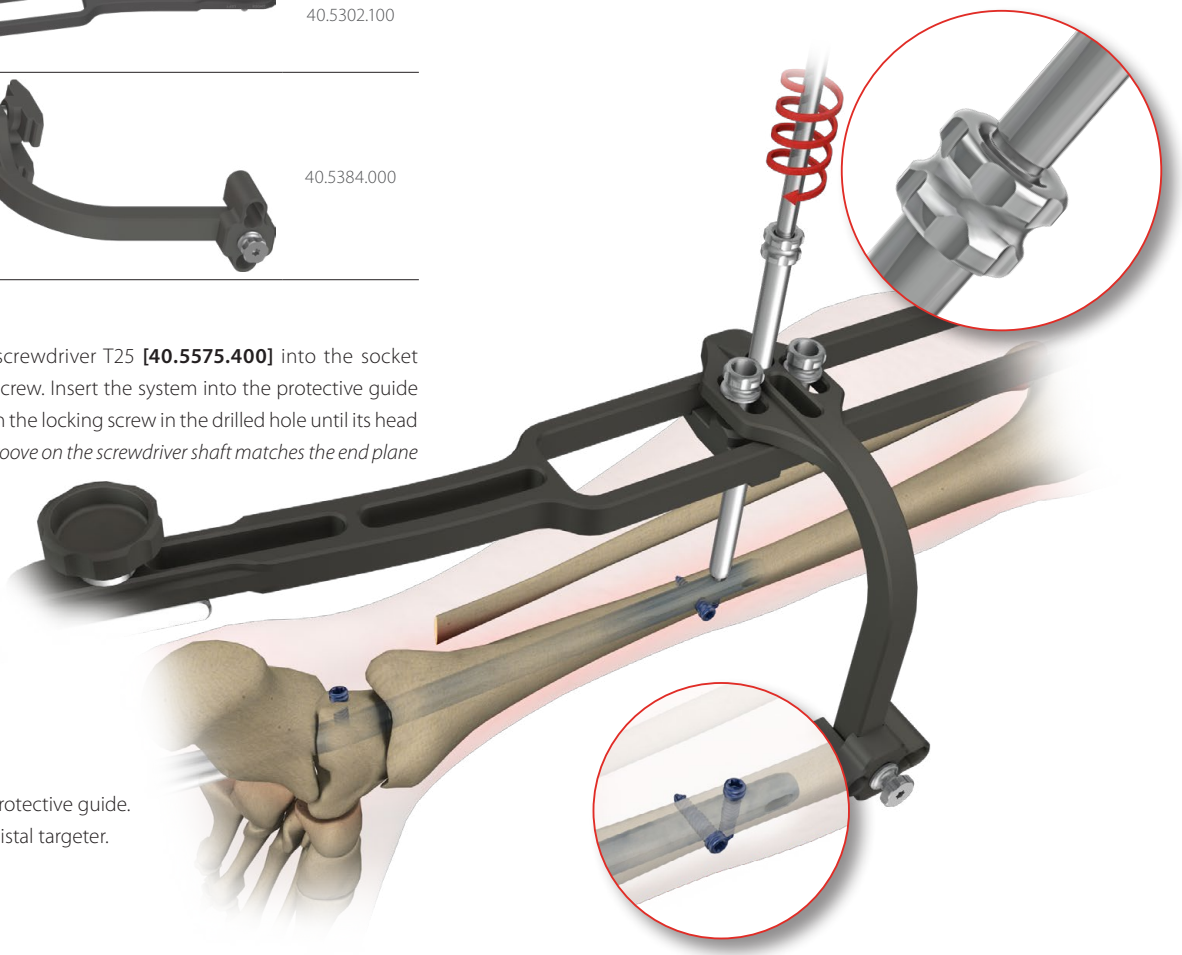
20 Remove the drill **[40.5339.002]** and the drill guide **[40.5511.200]** from the other hole of the targeter slider.
Leave protective guide **[40.5510.200]** in the hole of the slider. Insert screw length measure **[40.5530.100]** through the protective guide into the drilled hole in the bone until its hook reaches the "*exit*" plane of the hole. Read the length of the locking screw on the 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.

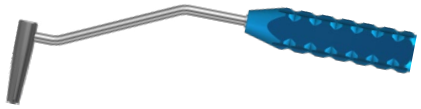


21 Insert the tip of the screwdriver T25 **[40.5575.400]** into the socket of a specified locking screw. Insert the system into the protective guide 9/7 **[40.5510.200]** and screw in the locking screw in the drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches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

Remove the screwdriver and protective guide. Detach targeter D and lateral distal targeter.



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



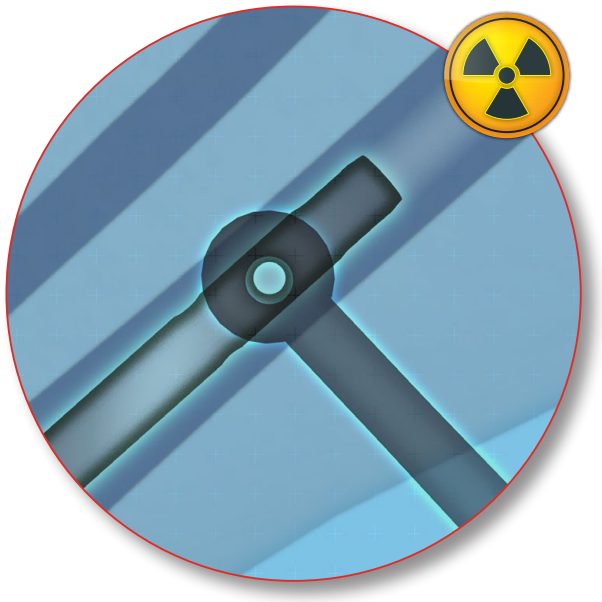
40.1344.100

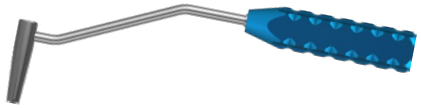
22 Proximal locking of the nail is carried out using "*free-hand*" technique and targeter D **[40.1344.100]**.

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.



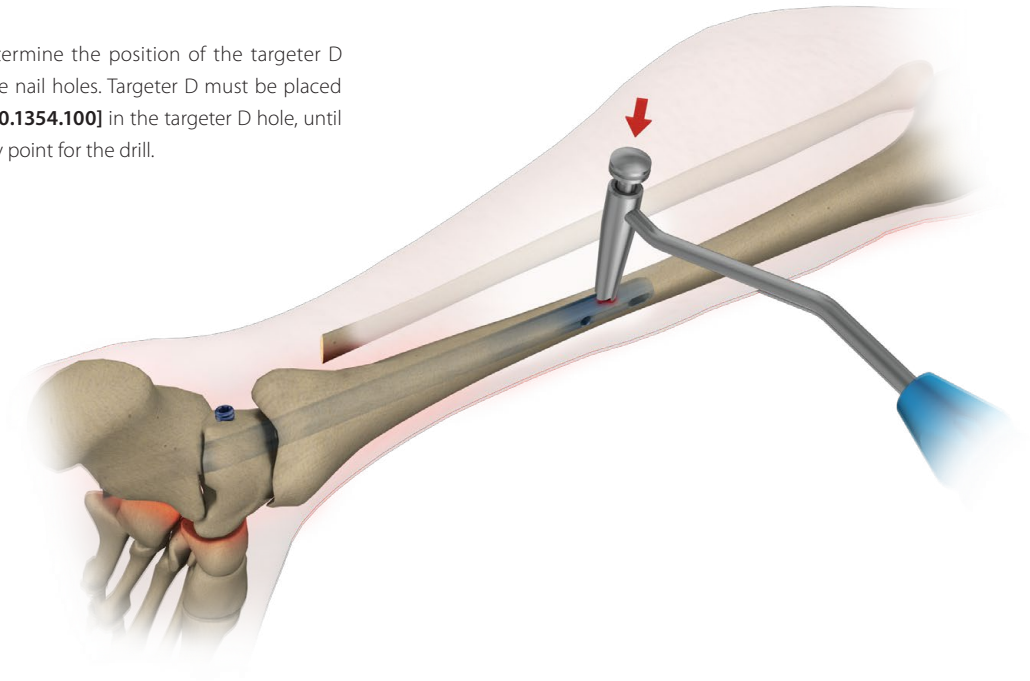


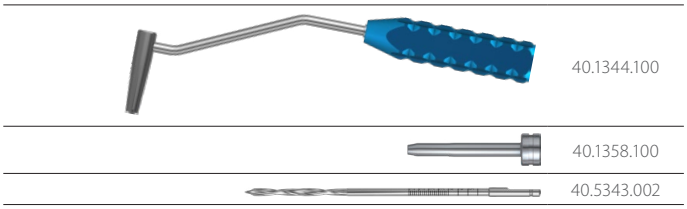
40.1344.100

40.1354.100

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.

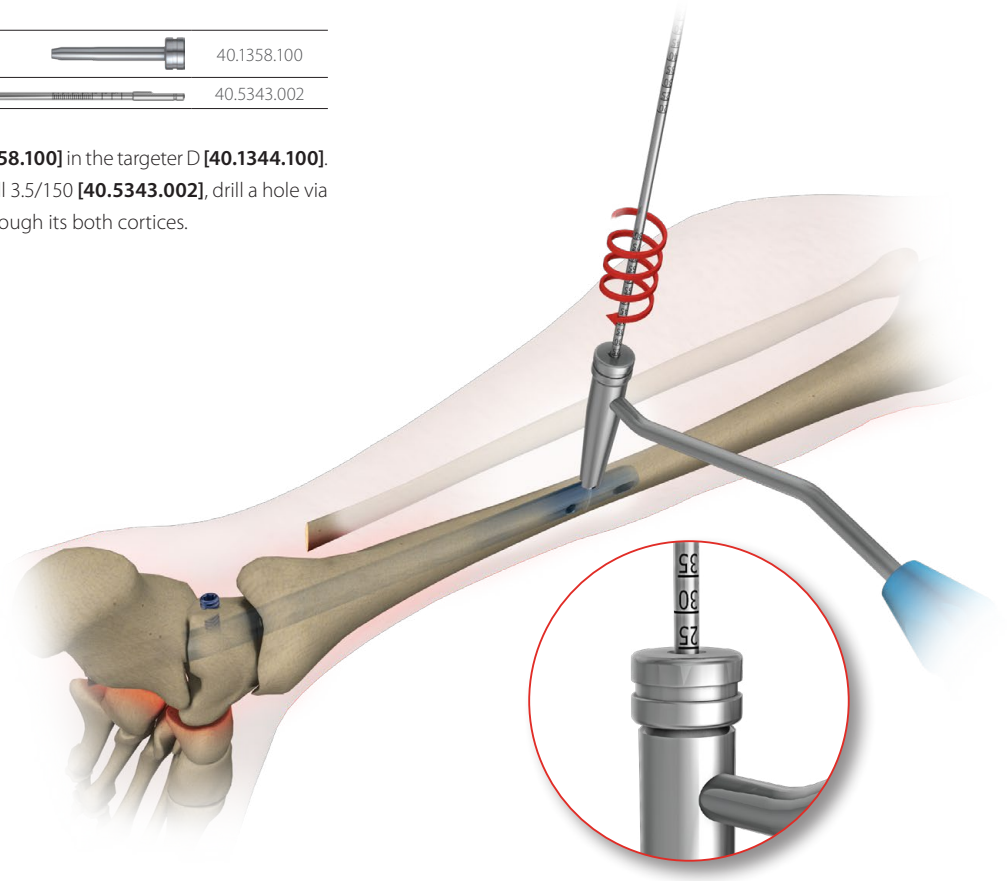
Remove the trocar.
Leave targeter D in place.

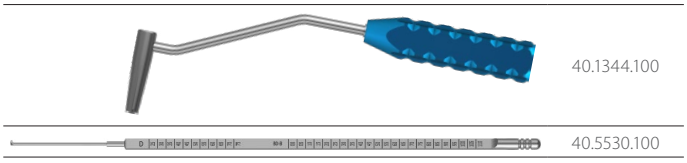




24 Insert drill guide short 7/3.5 **[40.1358.100]** in the targeter D **[40.1344.100]**. Using a drilling machine and a drill 3.5/150 **[40.5343.002]**, drill a hole via the drill guide in the bone that passes through its both cortices.

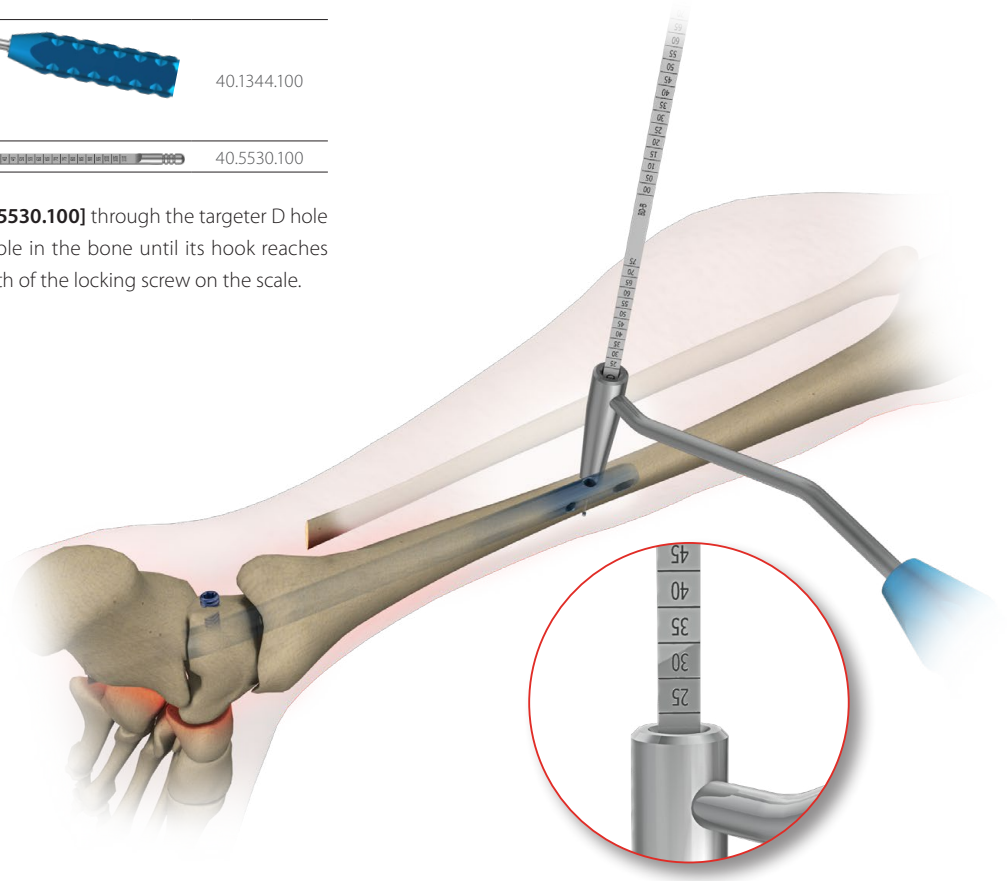
Remove the drill and drill guide.
Leave targeter D in place.

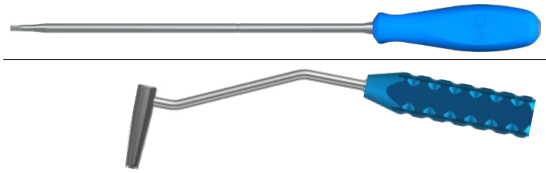




25 Insert screw length measure **[40.5530.100]** through the targeter D hole **[40.1344.100]** into the drilled hole in the bone until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the scale.

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

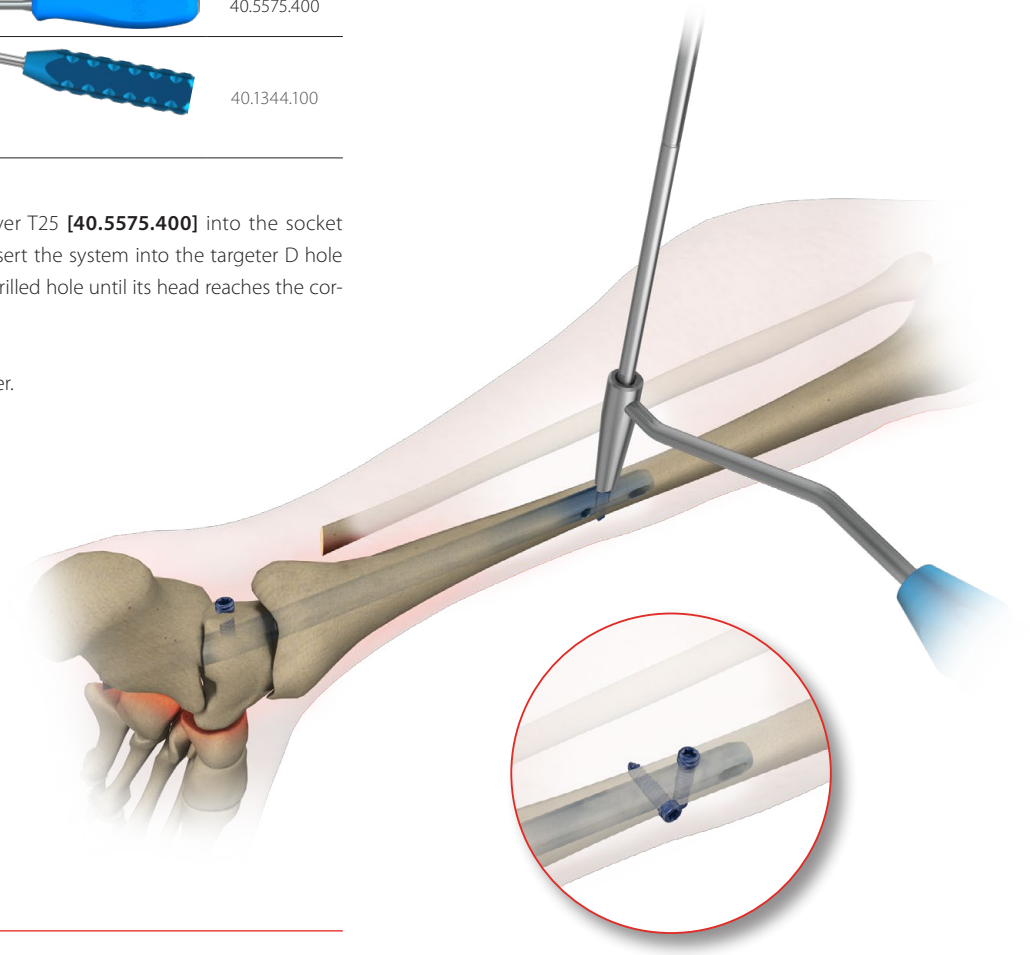



40.5575.400

40.1344.100

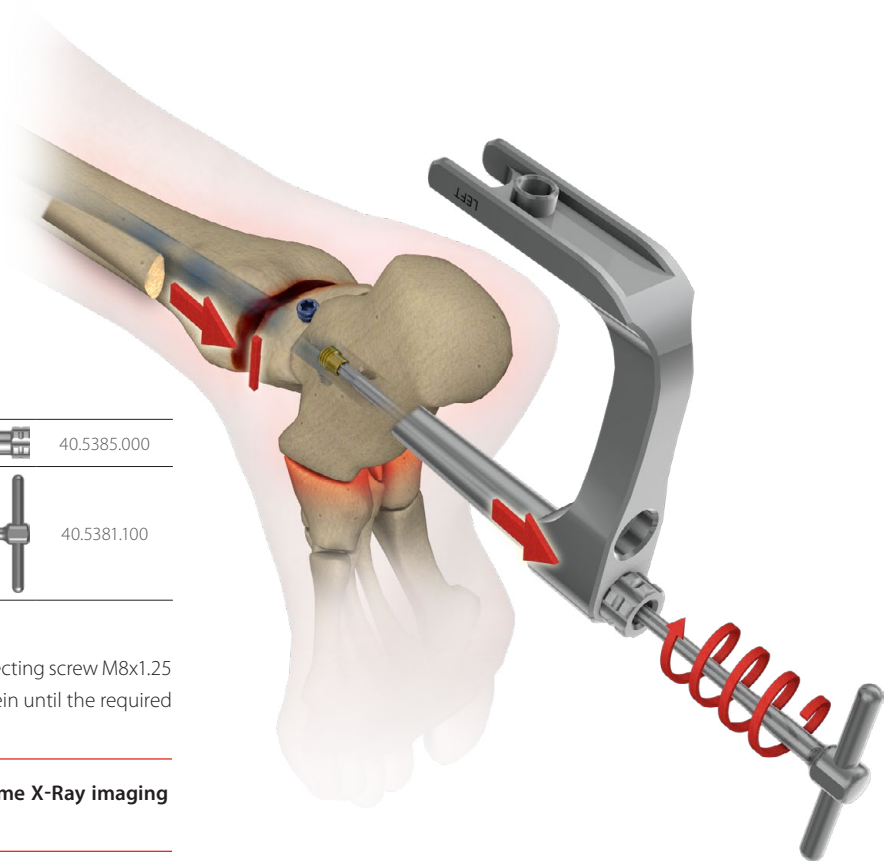
26 Insert the tip of the screwdriver T25 **[40.5575.400]** into the socket of a specified locking screw. Insert the system into the targeter D hole and screw in the locking screw in the drilled hole until its head reaches the cortex bone.

Remove the screwdriver and the targeter.



Perform nail locking in the other proximal hole according to steps 22-26 of this surgical technique.

IV.9. TALOCRURAL JOINT COMPRESSION



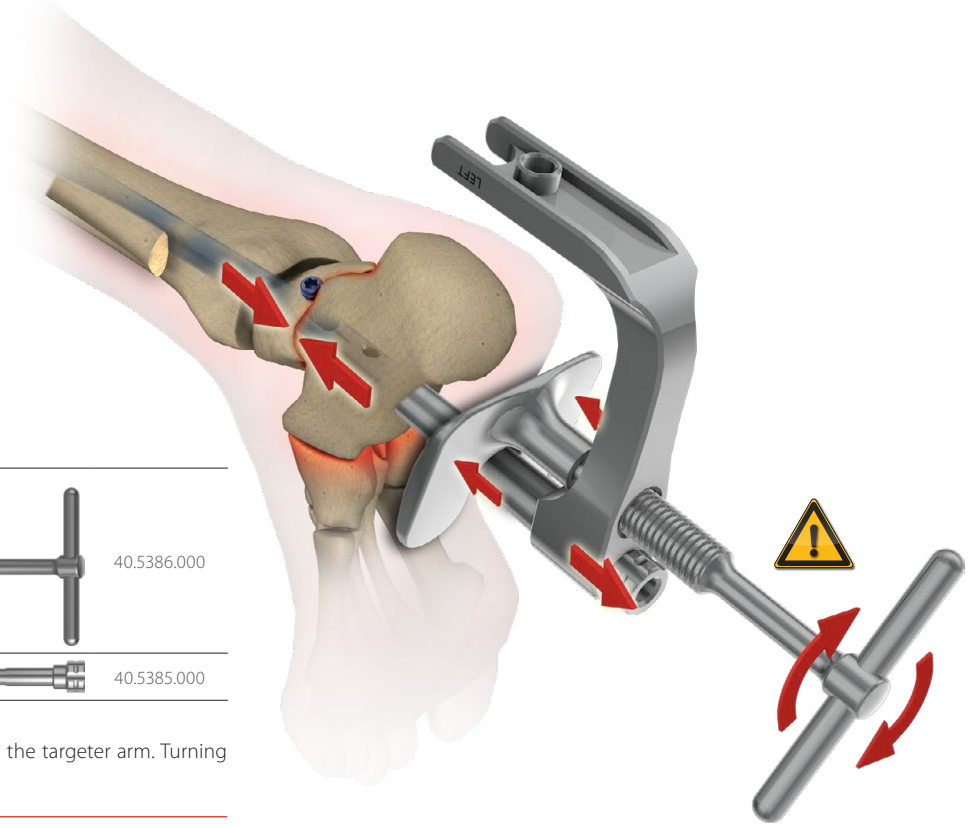

40.5385.000

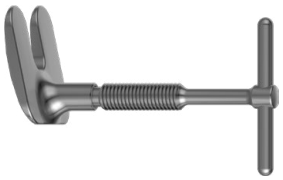

40.5381.100

27 Insert screwdriver T25 **[40.5381.100]** through connecting screw M8x1.25 **[40.5385]** and tighten the compression screw therein until the required level of compression is achieved.

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

IV.10. TALOCALCANEONAVICULAR JOINT COMPRESSION




40.5386.000


40.5385.000

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

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

IV.11. NAIL LOCKING IN THE CALCANEUM


40.5301.000

40.5382.000


40.5383.000

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.

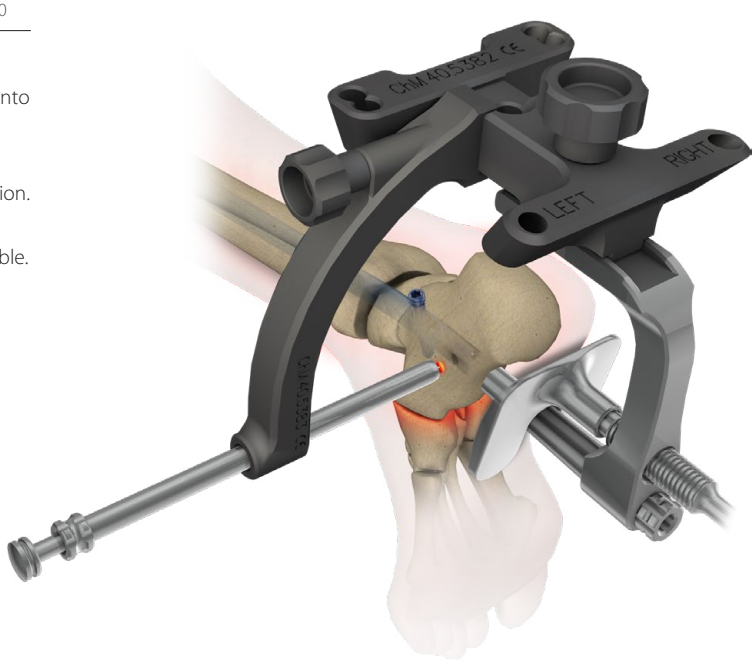

40.5510.200

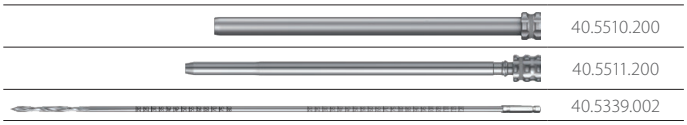

40.5534.100

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.
Leave the protective guide in the hole of the targeter.

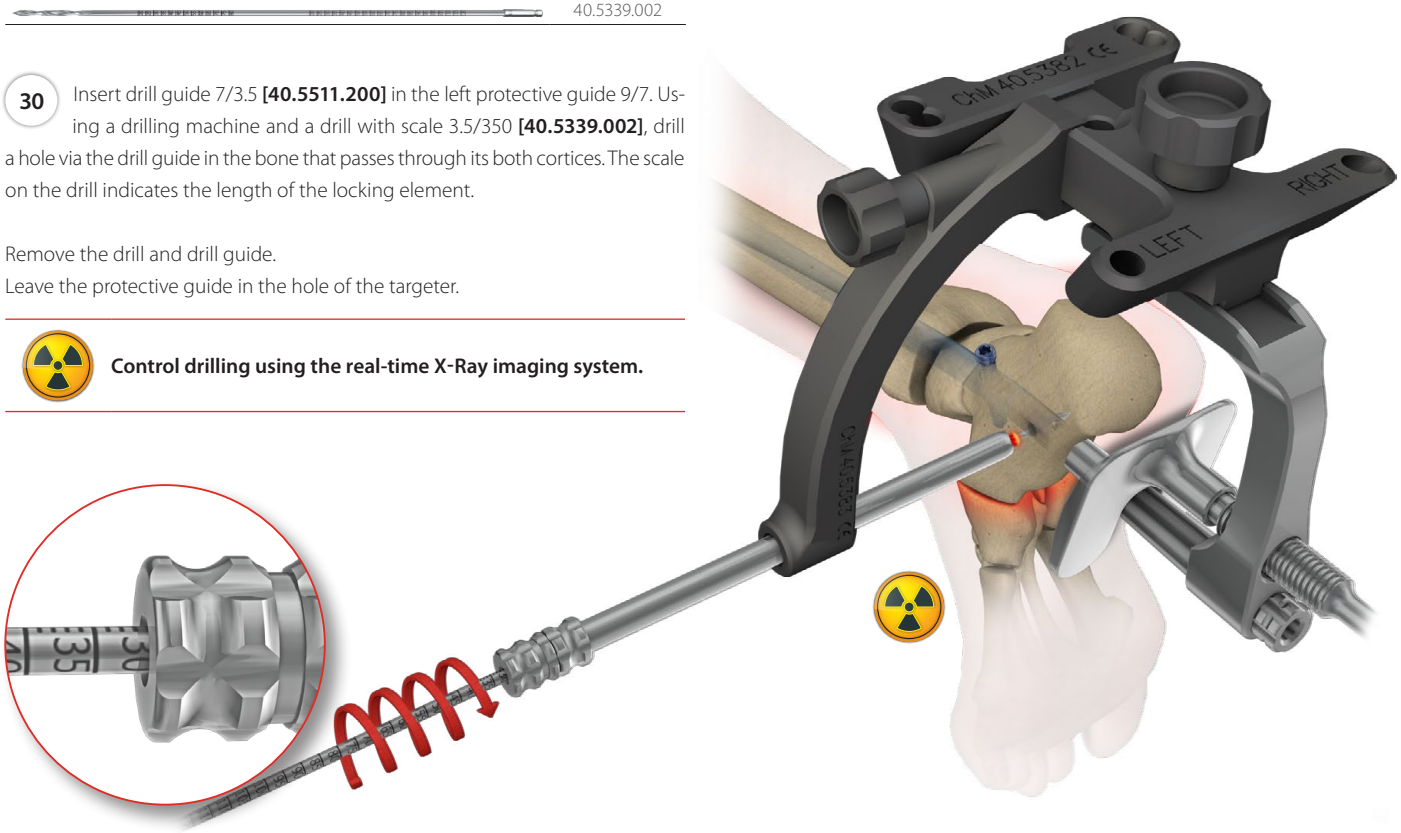


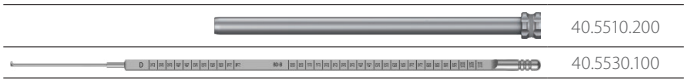


30 Insert drill guide 7/3.5 **[40.5511.200]** in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 **[40.5339.002]**, drill a hole via the drill guide in the bone that passes through its both cortices. The scale on the drill indicates the length of the locking element.

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 the 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.


40.5575.400


40.5510.200

32 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*).

40.5382.000

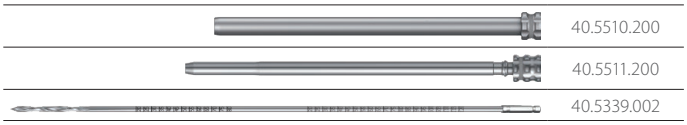

40.5510.200


40.5534.100

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.

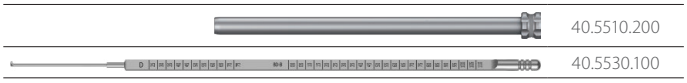
Remove the trocar.
Leave the protective guide in the hole of the targeter.



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.

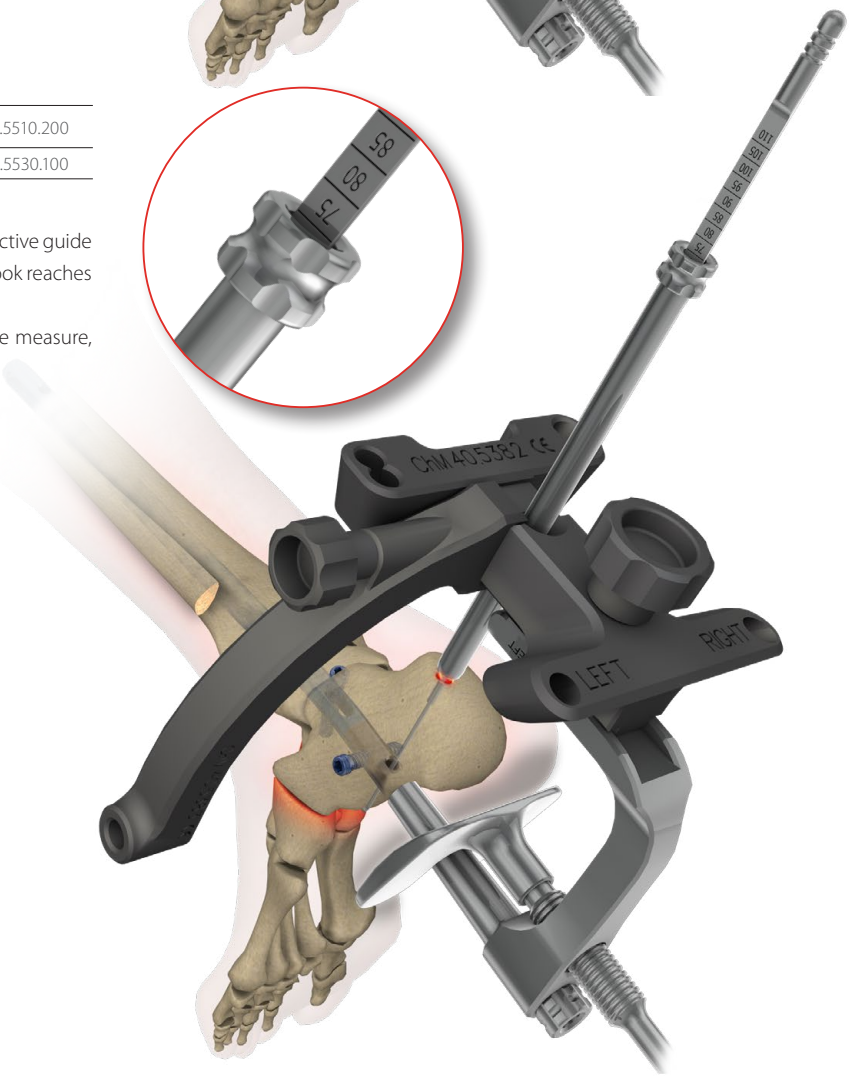
Remove the drill and drill guide.
Leave the protective guide in the hole of the targeter.

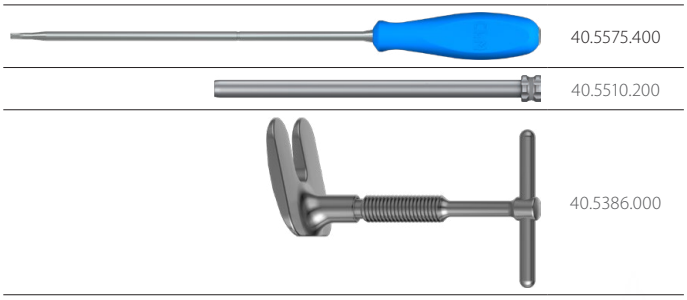
Control drilling using the real-time X-Ray imaging system.



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 the 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 **[40.5575.400]** 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]**.

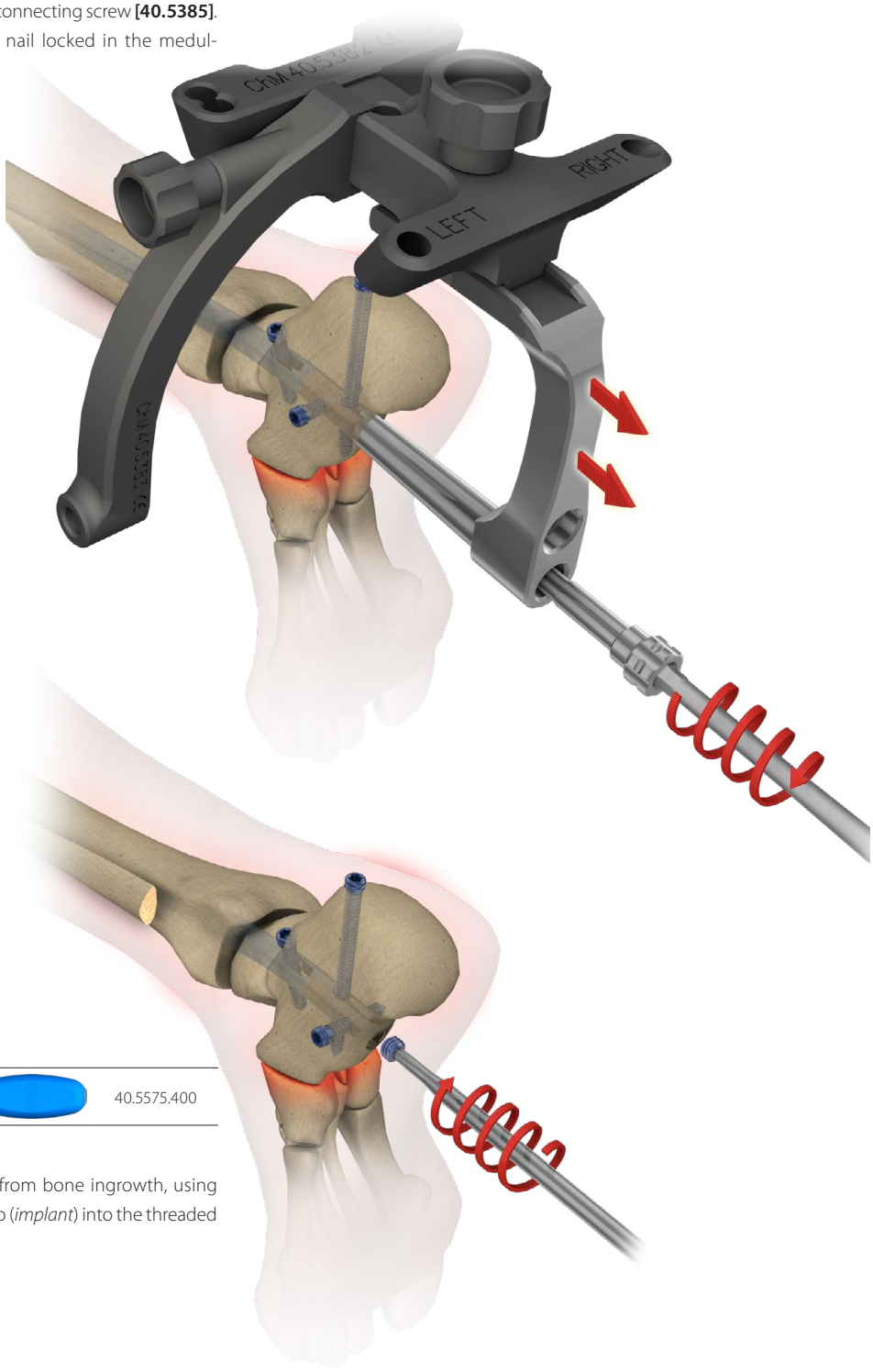
IV.12. END CAP INSERTION


40.5304.000


40.5385.000


40.5301.000

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.



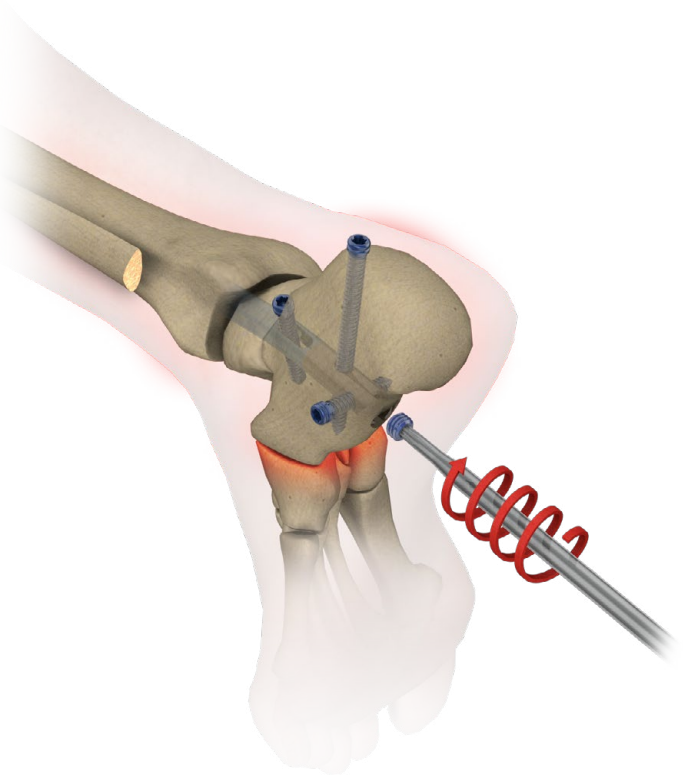

40.5575.400

In order to protect the internal thread of the nail from bone ingrowth, using the screwdriver T25 **[40.5575.400]** insert the end cap (*implant*) into the threaded hole of the nail shaft.

IV.13. NAIL REMOVAL

40.5575.400

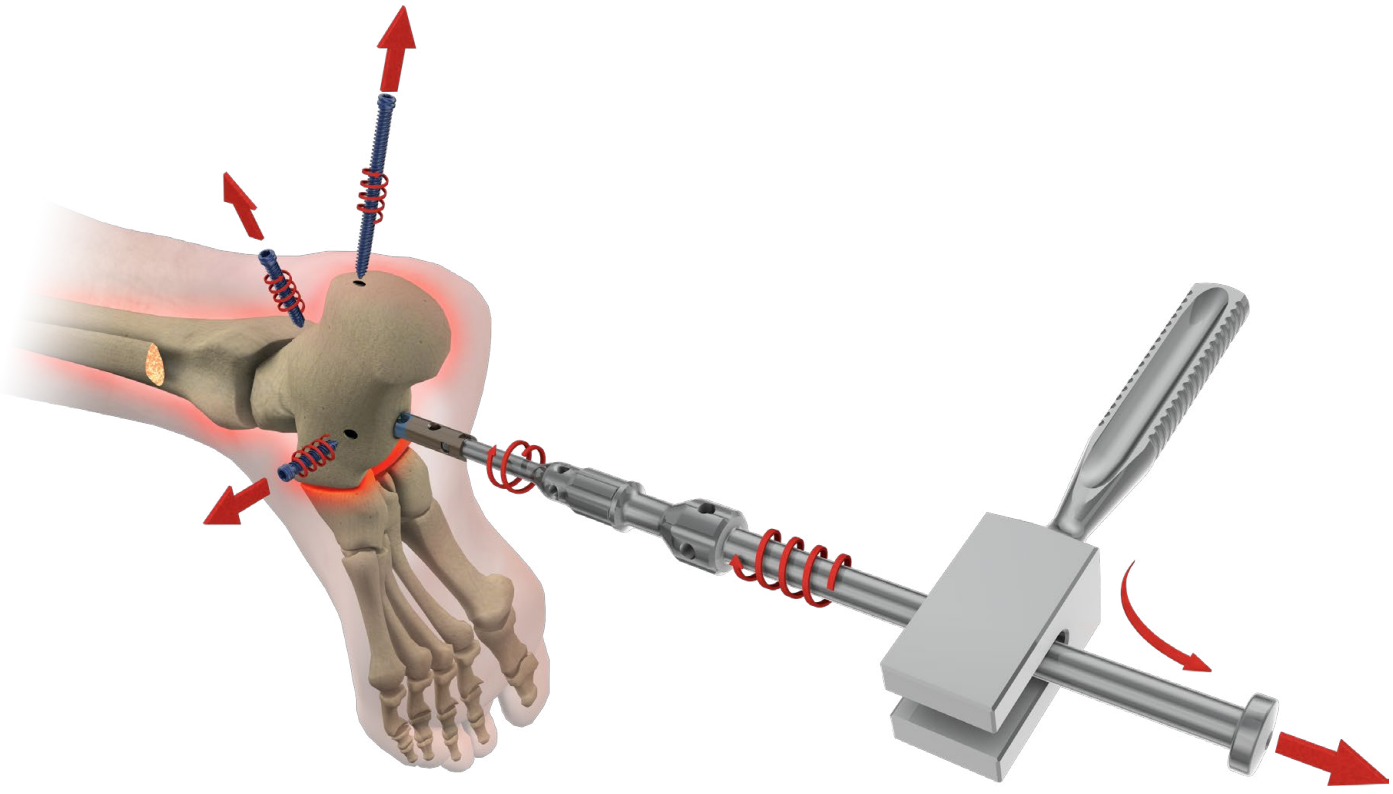
38 Using the screwdriver T25 **[40.5575.400]**, remove the end cap from the nail shaft.



40.5873.000

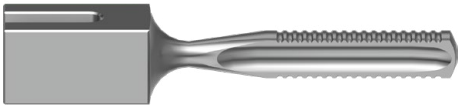
40.5308.000

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



40.5575.400

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



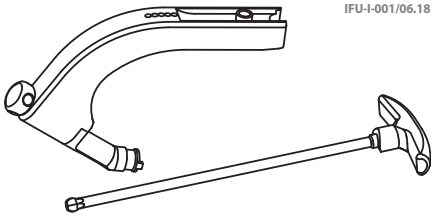
40.3667.000

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

GB

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/06.18



GB

INSTRUCTIONS FOR USE

REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

1 INDICATIONS

1. Surgical and orthopaedic instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.

2 DESCRIPTION

1. The unit package contains one piece of the product in non-sterile condition. Clear plastic bags are a typical packaging material. The products may also be supplied as a complete set *(arranged on palettes and placed into specially designed sterilization containers)*. This Instructions For Use is attached both to the unit packages and the sets.
2. The package is equipped with the product label. The label *(as a primary label)* contains, among others:
   1) Logo ChM and the address of the manufacturer.
   2) Catalogue number *(REF)*, e.g.: 40.XXXX.XXX, and device name and size.
   3) Production batch number *(LOT)*, e.g. XXXXXXX.
   4) NON-STERILE sign - indicates non-sterile product.
   5) Information symbols *(described in the footer of this Instructions For Use)*.
   6) CE conformity mark.
3. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

3 MATERIALS

1. For the production of instruments, ChM sp. z o.o. uses mainly: steel, aluminum alloys and plastics, approved for use in surgical instruments and in accordance with applicable procedures.
2. Instruments are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the device due to high content of chromium.
3. Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. 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 of its surface.
4. Devices made of aluminium with processed layer have good corrosion resistance. However, 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.
5. Devices produced of plastics are mainly stands, palettes, cuvettes and some parts of instruments such as e.g. handles. Plastics used in the manufacture of instruments are mainly: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)*, teflon *(PTFE - Polytetrafluoroethylene)* and silicone. 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 a pH value from 4 to 10.8.
6. Steel surgical instruments with a hardened insert are more durable than steel products. The advantage of the product is the sintered carbide insert placed in the working part of the instrument. This insert is characterized by great hardness and abrasion resistance.
7. If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

4 WARNINGS AND PRECAUTIONS

1. Instruments are intended for use only by skilled and trained medical professionals who are familiar with their use and application.
2. Improper, careless and inconsistent with the recommendations provided below handling of the instruments can lead to their chemical, electrochemical or mechanical damage which can adversely affect corrosion resistance and shorten the service life of the devices.
3. 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 to the instrument.
4. The surgeon should be familiar with all components of the device before use and should personally verify if all components and instruments are present before the surgery begins.
5. Before the procedure begins, all instruments should be carefully inspected for their condition and proper functioning. They should be undamaged and without any signs of corrosion. Blades and cutting edges should be sharp and undamaged. Damaged or corroded instruments should be immediately replaced. The use of bent, damaged or corroded instruments is not allowed.
6. Tissue structures close to the operative site must be protected.
7. Collision of the instrument with metal operating equipment, retractor or other device may cause damage that necessitates intraoperative replacement of that instrument.
8. Do not apply excessive force when using the instrument – it may lead to its permanent damage and, in consequences, to mal-function of the device.
9. Instruments are subject to constant wear processes. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive forces are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed. Should breakage occur, the instrument parts must be removed and disposed of immediately in accordance with valid medical facility procedures.
10. In order to confirm the removal of all undesired metal fragments from the surgical field, intraoperative X-Ray examination is recommended.
11. 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.
12. 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.
13. Instrument which had contact with tissues or body fluids of another patient cannot be re-used prior to its reprocessing due to a potential risk of cross-infection caused by viruses, bacteria and prions.
14. Middle and working part of the surgical devices with hardened insert shall be used during the surgical procedure. Improper or inconsistent with the intended purpose usage of the product may lead to damage of the working part e.g. damage to the inserts.

5 CLEANING, DISINFECTION, STERILIZATION

1. Prior to use of a non-sterile device, the following rules apply:
   1) The device must undergo cleaning, disinfection and sterilization procedures.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, automated)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process, etc.
   3) The hospital facility remains responsible for the effectiveness of the conducted cleaning, packaging and sterilization processes with the use of existing equipment, materials and properly trained personnel.
2. Preparation at the place of use.
   1) Immediately after use, remove from instrument blood and other contaminants with disposable cloth or paper towels. Additionally, it is recommended to rinse the instrument under running water or to place it in the aqueous disinfectant solution. Do not let blood, tissues, body fluids or other biological impurities dry out on the surface of the device.
   2) In order to prevent blood and debris from drying out on the instrument surface, transport the product to the processing area in a closed container or covered with a damp cloth.
   3) In order to avoid contamination during transportation, the dirty instruments should be separated from the clean ones.
3. Preparation for washing and disinfection *(for all methods)*.
   1) The used instruments should be reprocessed as soon as possible.
   2) If the instrument can be disassembled, it must be done before cleaning processes.
   3) Rinse under running water and remove surface debris using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Particular attention should be paid to openings and places difficult to be cleaned. Very dirty devices should be soaked in an aqueous solution of a detergent or a washing-disinfecting agent, e.g. neodisher® MediClean forte, at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
   4) CAUTION: It is forbidden to use brushes made of metal, bristles or materials which could damage the product.
4. Cleaning and disinfection process.
   1) This Instructions for Use describes two ChM-approved cleaning and disinfection methods: manual with ultrasound cleaning and automated method. It is recommended to use automated cleaning and disinfection procedures *(in a washer-disinfector)*.
   2) The chosen washing and disinfecting agents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 10.4 and 10.8. ChM used the following materials during the validation process of the described recommendations for cleaning and disinfection. It is allowed to use other materials than those listed below which may also give a comparable effect:
      a) detergent - Dr.Weigert *(producer)* neodisher® MediClean forte *(name of the detergent)*;
      b) disinfectant - Dr.Weigert *(producer)* neodisher® Septo Active *(name of disinfectant)*.
   3) To prevent product damage *(pitting, rust, discoloration)*, do not use aggressive cleaning agents *(NaOH, NaOCl)*, saline solutions and unsuitable cleaning agents.
   4) Where possible, it is recommended to use demineralized water to avoid the formation of spots and stains caused by chlorides and other compounds present in ordinary water.
   5) Manual with ultrasound cleaning.
      a) Equipment and materials: a device for ultrasound cleaning, soft, lint-free cloths, plastic brushes, syringes, aqueous solutions of cleaning agent.
      b) Manual cleaning: Initial manual cleaning must be performed prior to ultrasound cleaning.
      c) Rinse under running water until the product is visually clean. Use plastic brushes to remove heavy or large debris.
      d) Soak the product for at least 10 minutes in an aqueous solution of a detergent at temperature of 40+/- 2°C and pH of 10.4-10.8 *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      e) Rinse the product under cold water for at least 2 minutes, paying particular attention to the holes and places difficult to be cleaned.
      f) Prepare fresh washing solution. Clean the surfaces and gaps of the product, carefully. Use suitable brushes to clean the holes. Clean the product immersed in the solution.
      g) Rinse the product thoroughly under warm running water for at least 2 minutes, paying special attention to the gaps, blind holes, hinges and joints. When cleaning, use brushes and perform multiple reciprocating movements on the surface of the product.
      h) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-h until the product is visually clean.
      i) Ultrasound cleaning: prepare an aqueous cleaning solution at a temperature of 40 +/- 2°C and pH of 10.4 - 10.8 *(follow the information contained in the instructions prepared by the manufacturer of the cleaning agent, in respect of temperature, concentration, exposure time and water quality)*. Immerse fully the product in the aqueous cleaning solution and have it washed in ultrasounds for 15 minutes.
      j) Rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      k) Visually inspect the entire surface of the product for debris and impurity. Repeat the steps described in subsections c-k until the product is visually clean.
      l) Use demineralized water for final rinsing of the device.
      m) Dry the device thoroughly using disposable, soft, lint-free cloth or compressed air.
      n) Prepare an aqueous solution of disinfecting agent at a temperature of 20+/-2 °C using 20g of the agent per 1 liter of water. Immerse the product in the solution, exposure time – 15min *(follow the information contained in the instructions prepared by the manufacturer of the agent, in respect of temperature, concentration, exposure time and water quality)*.
      o) After the exposure time, rinse the product thoroughly under demineralized water, paying particular attention to the holes and places difficult to be cleaned.
      p) The cannulated instruments should be treated using a compressed air or air supplied from the syringe.
      q) Dry the device thoroughly. It is recommended to dry the product in a dryer at a temperature ranging from 90°C to 110°C.
      r) Visually inspect the entire surface of the device.
      s) CAUTION: If the obstruction in the cannula cannot be removed as indicated in the Instructions for Use, the device should be considered at the end of its useful life and should be discarded in accordance with facility procedures and guidelines.
   6) The automated method using a washer - disinfector.
      a) Equipment and materials: a washer - disinfector, aqueous solutions of cleaning agent.
      b) Cleaning in the washer-disinfector must be preceded by a manual and ultrasound cleaning, following the procedure described in subsections c-h of paragraph 5.
      c) CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883. Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washer-disinfector manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer.
      d) The device should undergo the process of machine washing in the washer-disinfector using the following cycle parameters: *(1)* - pre-washing in cold tap water, duration – 2min; *(2)* - washing in an aqueous solution of cleaning agent at 55+/-2°C and pH of 10.4 - 10.8, duration – 10min; *(3)* - rinsing under demineralized water, duration – 2min; *(4)* - thermal disinfection in demineralised water at 90°C, minimal duration – 5min; *(5)* - drying at the temperature ranging from 90°C to 110°C, duration - 40min.
5. Inspection
   1) Each time before re-use and re-sterilization, all medical devices should be inspected.
   2) All parts of the product should be checked for visible dirt and corrosion. Particular attention should be paid to:
      b) Holes, grooves and gaps the debris could have been pressed into during use.
      a) Places where dirt can be found, such as joints, latches, etc.
   3) Generally unmagnified visual inspection under good light conditions is sufficient.
   4) Each time before re-use and re-sterilization, the functional check of the product should be performed, consisting of:
      a) Verifying the connections in the mating instruments, such as tips, shafts and quick coupling devices.
      b) Verifying the correct functioning of mechanisms, e.g. screw, ratchet, snap mechanism, etc.
      c) Verifying all rotating devices for straightness *(this can be simply achieved by rolling the device on a flat surface)*.
      d) Verifying cutting edges for sharpness.
      e) Verifying instruments for damage to material structure *(cracks, dents, peels, etc.)*.
   5) Damaged or defective product cannot be approved for further use.
   6) Prior to storage, the instrument must be checked for dryness.
   7) CAUTION:
      a) The ChM sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful and proper use reduces the risk of damage to the product and extends its serviceable life.
      b) The manufacturer does not recommend using any preservatives on medical devices.
6. Packaging
   1) Washed and dried devices shall be stored *(if possible)* in suitable stands placed in special sterilization containers. Separate items should be packed in a packaging intended for the recommended steam sterilization. Sterilization containers, item packaging and packaging process itself have to meet the requirements of ISO 11607 standards. The packaging procedure must be performed in controlled purity conditions. The device must be packed so that during its removal from the packaging, when used, there is no risk for its re-contamination
7. Sterilization
   1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
      a) temperature: 134°C,
      b) minimum exposure time: 7 min,
      c) minimum drying time: 20 min.
   2) CAUTION:
      a) The sterilization process must be validated and routinely monitored in accordance with the requirements of EN ISO 17665-1.
      b) Sterilization must be effective and in accordance with requirements of the EN 556-1 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
      c) Device must not be sterilized in the packaging in which it was delivered, except specially designed sterilization containers.
      d) The method of sterilization using ethylene oxide, gas plasma and dry heat should not be used, unless the Instructions for Use for the product contains sterilization recommendations using these methods.
      e) The sterilization temperature for plastic products *(PPSU, PEEK, PTFE, silicone)* cannot be higher than 140°C.

6 STORAGE

1. 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 a clean and dry room, at room temperature and off the direct sunlight. If possible, instruments should be stored in suitable palettes placed into specially designed sterilization containers.

7 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. Instrument calibration is performed by the manufacturer. Any attempt of unauthorized modifications to the construction or factory setting of the torque devices can lead to a potential injury or damage to the product and is prohibited.

8 COMPATIBILITY

1. ChM specialist instrument sets are designed for insertion of ChM implants. A specific, illustrated operating technique that describes the proper use of instruments included in the instrument set that is designed for particular implant system, is provided together with such instrument set. It is not allowed to combine ChM instruments with products from other manufacturers. The physician bears all responsibility for the use of the ChM instruments together with implants and instruments from other manufacturers.

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**

IFU-I-001/06.18; Date of verification: June 2018

SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 86 86 100 fax: +48 85 86 86 101
e-mail: chm@chm.eu www.chm.eu

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 86 86 100
fax +48 85 86 86 101
chm@chm.eu
www.chm.eu

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