ST/46A





INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA retrograde method

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



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SYMBOLS DESCRIPTION

Ti	Pure titanium	\odot	Cannulated
TiA	Titanium alloy		Locking
St	Steel		Diameter
	Left		Inner diameter
R	Right	\bigcirc	Recommended length range for a particular nail
LR	Available versions: left/right	\bigcirc	Angle
Len	Length	16 ÷ 90	Available lengths
\bigcirc	Torx drive	Ster Non Ster	Available in sterile/ non- sterile condition
Ø	Torx drive cannulated		
\bigcirc	Hexagonal drive		
\bigcirc	Hexagonal drive cannulated	-	
	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
i	Information about the next stages of a procedure.		
	Proceed to the next stage.		
\bigcirc	Return to the specified stage and repeat the activity.		
	Before using the product, carefully read the Instructions for Use. It contains related to the use of the product.	s, among others, ind	dications, contraindications, side effects, recommendations and warnings
	The above description is not a detailed instruction of conduct. The surgeor	n decides about ch	noosing the operating procedure.

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

I. INTRODUCTION	4
II. IMPLANTS	5
III. INSTRUMENT SET	7
IV. SURGICAL TECHNIQUE	10
IV.1. SURGERY PLANNING	10
IV.2. SURGICAL APPROACH	10
IV.3. MEDULLARY CANAL OPENING	11
IV.4. NAIL AND TARGETER ASSEMBLY AND TIBIAL NAIL IMPLANTATION	14
IV.5. NAIL LOCKING IN TALUS	17
IV.6. OBLIQUE LOCKING THROUGH TALOCALCANEONAVICULAR JOINT - OPTIONAL	19
IV.7. PROXIMAL NAIL LOCKING	20
IV.8. PROXIMAL NAIL LOCKING USING "FREE-HAND" TECHNIQUE	24
IV.9. TALOCRURAL JOINT COMPRESSION	27
IV.10. TALOCALCANEONAVICULAR JOINT COMPRESSION	27
IV.11. NAIL LOCKING IN THE CALCANEUM	28
IV.12. END CAP INSERTION	33
IV.13. NAIL REMOVAL	34

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.

CHARFIX system 2

CHARFIX2 RETROGRADE TIBIAL NAIL

II. IMPLANTS

		•			Len			R				
					180		3.5679.180	3.5680.	.180			
					200		3.5679.200	3.5680.	.200			
					220		3.5679.220	3.5680.	.220			
				10	240		3.5679.240	3.5680.	.240			
				10	260		3.5679.260	3.5680.	.260			
					280		3.5679.280	3.5680.	.280			
1					300		3.5679.300	3.5680.	.300			
					320		3.5679.320	3.5680.	.320			
		1.12			180		3.5681.180	3.5682.	.180			
					200		3.5681.200	3.5682.	.200			
									220		3.5681.220	3.5682.
			240		3.5681.240	3.5682.	.240					
			Ster	11	260		3.5681.260	3.5682.	.260			
			Ster		280		3.5681.280	3.5682.	.280			
			\bigcirc		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			
							10	240		3.5683.240	3.5684.	.240
						12	260		3.5683.260	3.5684.	.260	
					280		3.5683.280	3.5684.	.280			
					300		3.5683.300	3.5684.	.300			
C					320		3.5683.320	3.5684.	.320			
						Ø	8 mm ÷14 mm		1 mm			
-				available	U	L	130 mm ÷ 400 mm	pitch	5 mm			



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

40.5750.000

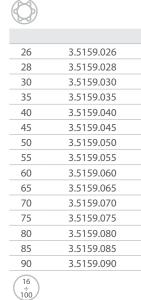




Ti

CHARFIX2 DISTAL SCREW 5.0





CHARFIX2 END CAP M8 SPEC.



CHARFIX2 DISTAL SCREW 5.5

3.5160.026

3.5160.028

3.5160.030

3.5160.035

3.5160.040

3.5160.045

3.5160.050

3.5160.055

3.5160.060

3.5160.065

3.5160.070

3.5160.075

3.5160.080

3.5160.085

3.5160.090

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90

16 ÷ 100







3.5162.006

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

40.5058.200



III. INSTRUMENT SET

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

INSTRUMENT SET FOR TIBIAL NAILS 40.5300.500

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

ChM

INSTRUMENTS

40.5300.500	Name	Catalogue No.	Pcs
	Nail length measure	40.4798.500	1
	Guide rod handle	40.1351.000	1
	Teflon pipe guide 8/400	40.3700.000	1
	Drill with scale 3.5/150	40.5343.002	1
	Targeter D	40.1344.100	1
ii	Drill guide short 7/3.5	40.1358.100	1
	Trocar short 7	40.1354.100	1
	Aiming insert 9.0	40.5065.009	2
	Guide rod 2.5/580	40.3673.580	1
	Screwdriver T25	40.5575.300	1
Contrology Bedersperser Bedersterstersterstersterstersterstersterst	Drill with scale 3.5/350	40.5339.002	2
	Screw length measure	40.5530.200	1
	Hole depth measure	40.2665.000	1
	Curved awl 8.0	40.5523.000	1
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	1
	Stand for tibial nails	40.5319.500	1
Contraction of the second seco	Container with solid bottom 1/1 595x275x185mm	12.0750.103	1

INSTRUMENT SET FOR RETROGRADE TIBIAL NAILS CHARFIX2 40.5380.500

(HARFIX system 2

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

IV. SURGICAL TECHNIQUE



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

IV.1. SURGERY PLANNING

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

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

IV.2. SURGICAL APPROACH

Position the patient prone.

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



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



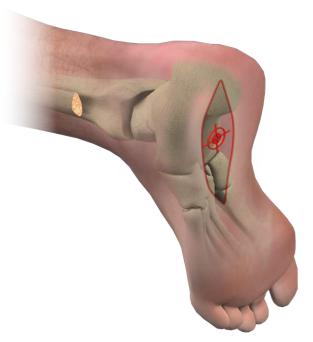


When the bone fracture is properly reduced, perform 3cm long transverse or longitudinal incision on the plantar surface of the heel. To make it easier to find the entry point for the nail and to protect the neurovascular structures, stretch soft tissues using forceps. Open the plantar fascia down to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

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



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



IV.3. MEDULLARY CANAL OPENING

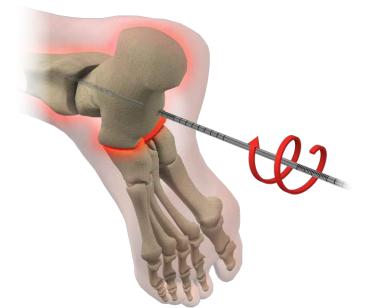
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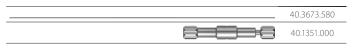
 When surgical approach is prepared and the nail entry point is located, mark on the bone the entry point of the nail while holding the foot in the correct position. Using an electric drive and a drill with scale 3.5/350
[40.5339.002], penetrate the cortex and insert it into the medullar cavity.



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

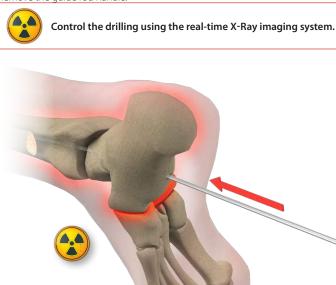
Remove the drill.

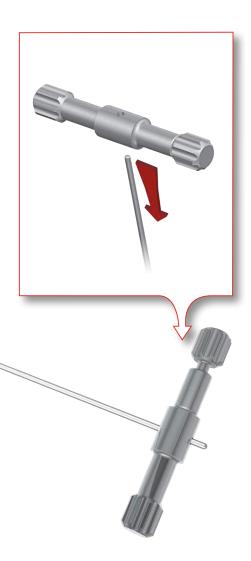




2 Mount the guide rod 2.5/580 **[40.3673.580]** to the guide rod handle **[40.1351]** and insert the system into the hole in the medullary cavity through the tarsal bones until the tibial shaft is reached.

Remove the guide rod handle.





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.

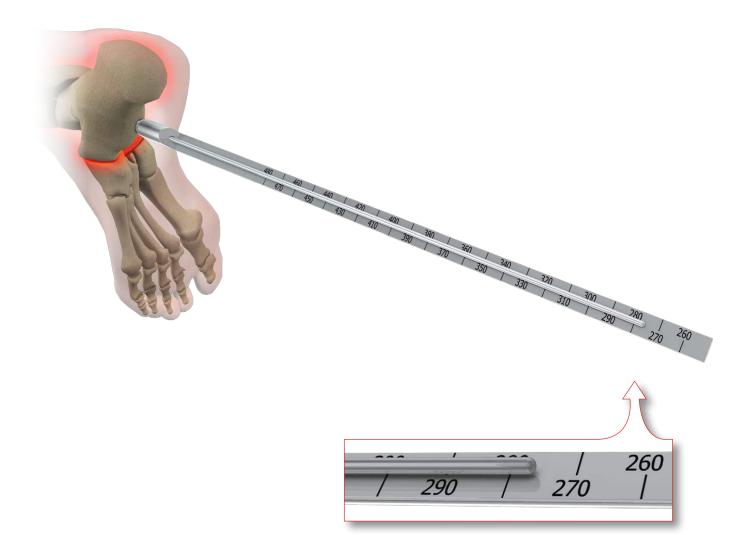


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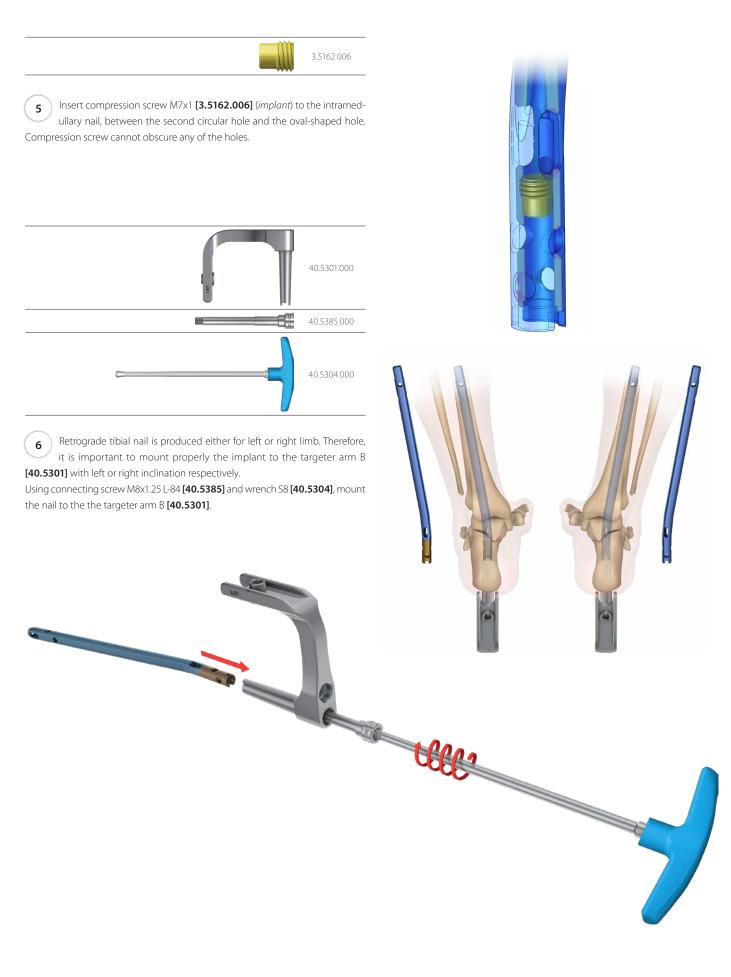
4 Insert nail length measure **[40.4798.500]** through the guide rod. Place the nail length measure beginning in the entry point of the nail. Read the length of the nail on the scale.

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



RIGHT

LEFT



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.

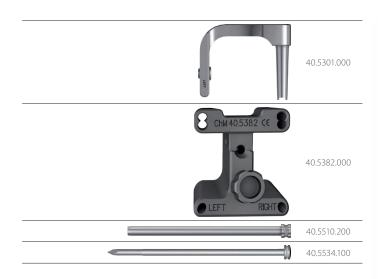
Mount the lateral distal targeter **[40.5384]** on the outer side of the targeter D.



IV.5. NAIL LOCKING IN TALUS



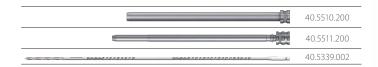
Locking the first screw in the talus allows for a separate compression between: tibia and talus (talocrural joint), and between the calcaneus and talus (talocalcaneonavicular joint).



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

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

Remove the trocar. Leave the protective guide in place.



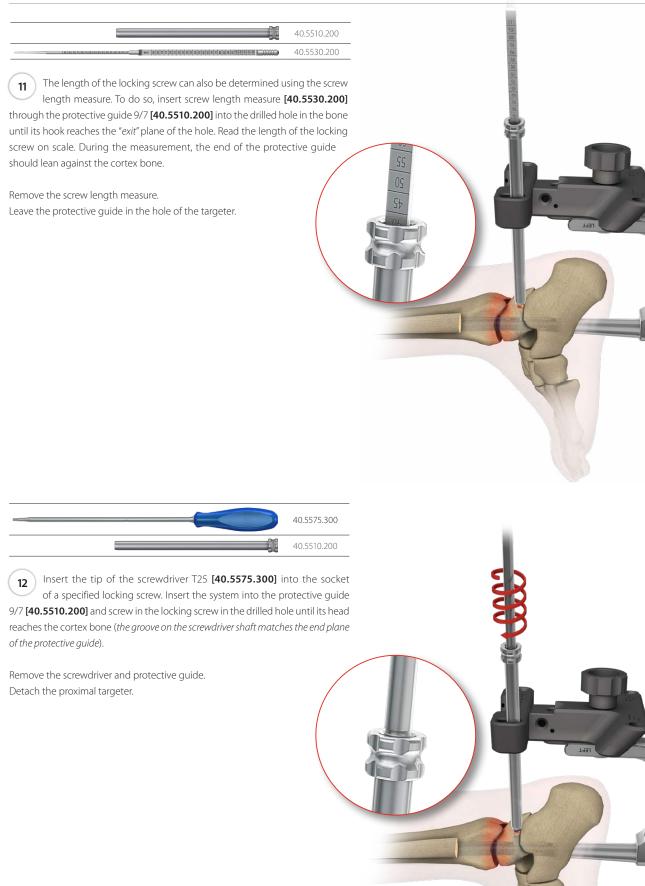
10 Insert drill guide 7/3.5 [40.5511.200] in the left protective guide 9/7 [40.5510.200]. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the talus that passes through the nail hole to the adequate depth.



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

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

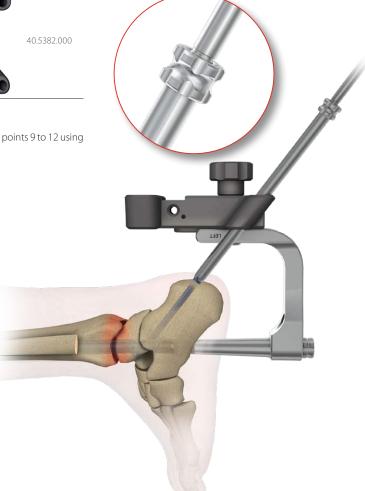
Remove the drill and drill guide. Leave the protective guide in the hole of the targeter.



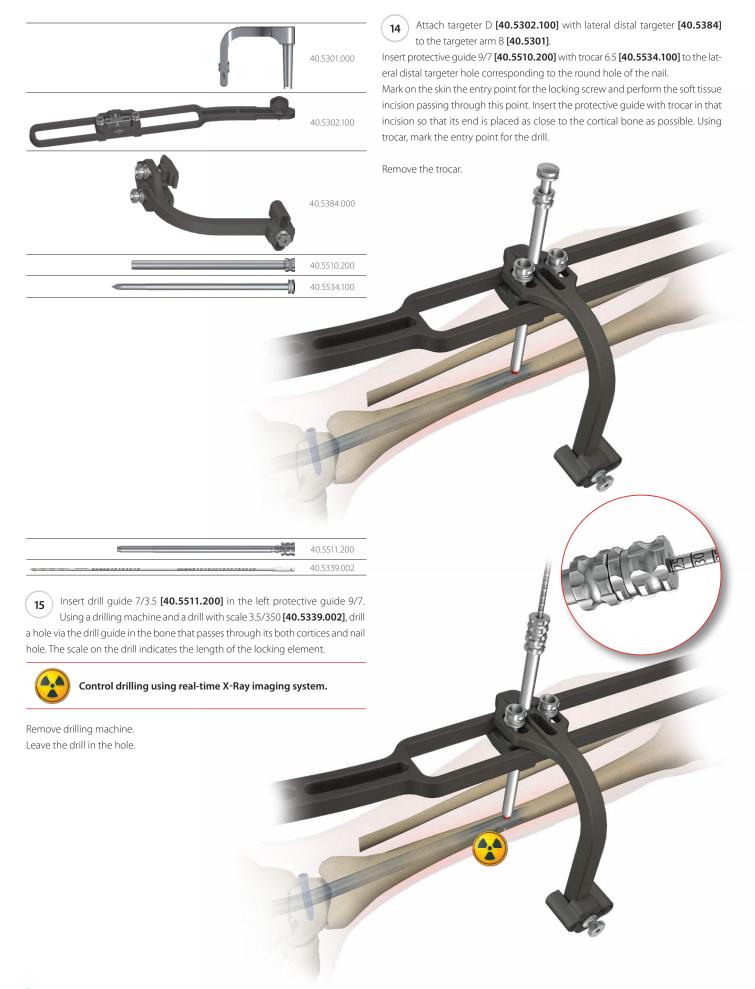
IV.6. OBLIQUE LOCKING THROUGH TALOCALCANEONAVICULAR JOINT - OPTIONAL

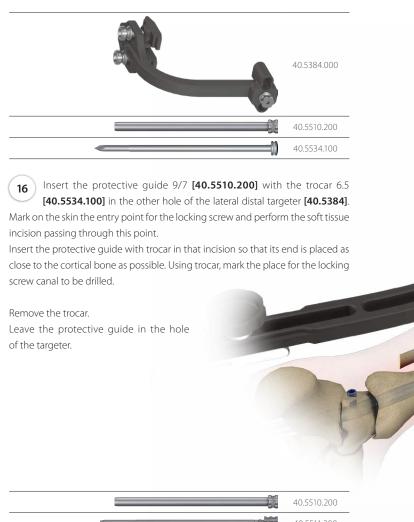


13 Locking of the nail should be carried out according to points 9 to 12 using oblique hole of the proximal target [40.5382].



IV.7. PROXIMAL NAIL LOCKING





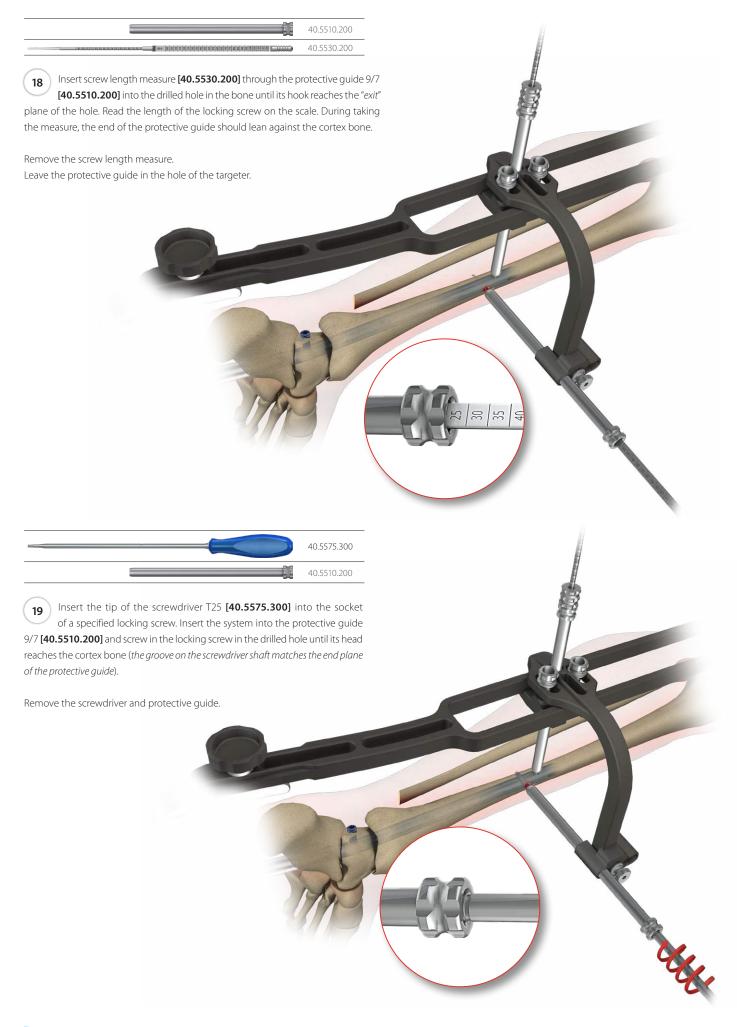


17 Insert drill guide 7/3.5 [40.5511.200] in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the bone that passes through its both cortices and nail hole. The scale on the drill indicates the length of the locking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

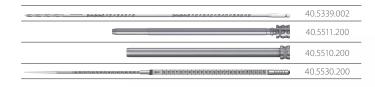


Control drilling using real-time X-Ray imaging system.

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









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 **[40.5530.200]** 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 **[40.5575.300]** 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





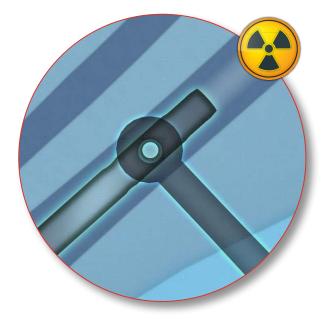
Proximal locking of the nail is carried out using "free-hand" technique and targeter D [40.1344.100].

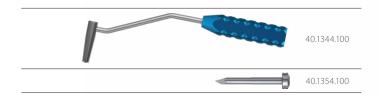
While drilling, it is recommended to use angular drill attachment so that the operator's hands are not directly exposed to X-Rays.

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



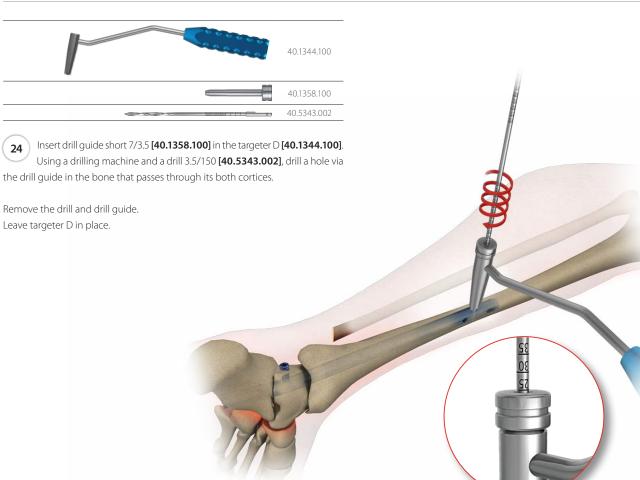
Control using the real-time X-Ray imaging system.





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.

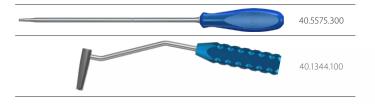




(25) Insert screw length measure [40.5530.200] through the targeter D hole [40.1344.100] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the scale.

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

42



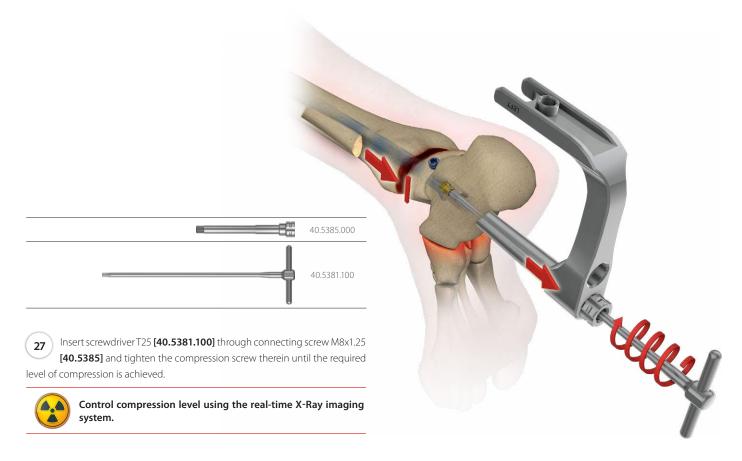
26 Insert the tip of the screwdriver T25 **[40.5575.300]** into the socket of a specified locking screw. Insert the system into the targeter D hole and screw in the locking screw in the drilled hole until its head reaches the cortex bone.

Remove the screwdriver and the targeter.

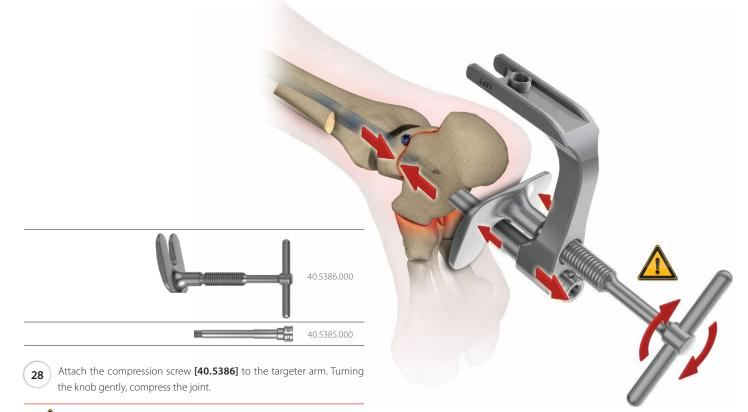


Perform nail locking in the other proximal hole according to steps 22-26 of this surgical technique.

IV.9. TALOCRURAL JOINT COMPRESSION



IV.10. TALOCALCANEONAVICULAR JOINT COMPRESSION

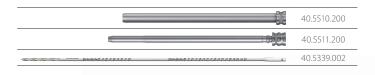




Excessive compression can damage the connecting screw [40.5385] or implant.

IV.11. NAIL LOCKING IN THE CALCANEUM

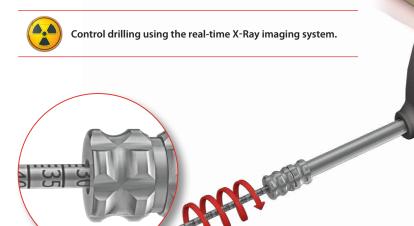


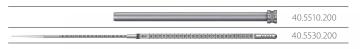


(30) Insert drill guide 7/3.5 [40.5511.200] in the left protective guide 9/7. Using a drilling machine and a drill with scale 3.5/350 [40.5339.002], drill a hole via the drill guide in the bone that passes through its both cortices. The scale on the drill indicates the length of the locking element.

Remove the drill and drill guide.

Leave the protective guide in the hole of the targeter.

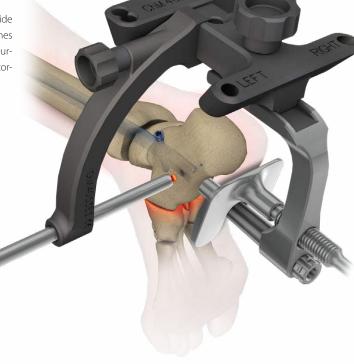




(31) Insert screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

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







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].

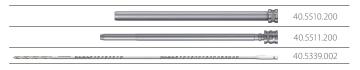
Mark on the skin the entry points and perform soft tissue incision passing through these points about 1.5cm in length.

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.

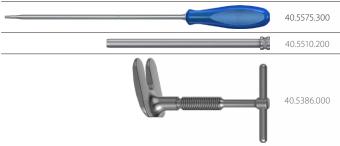
 40.5510.200
40.5530.200

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

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

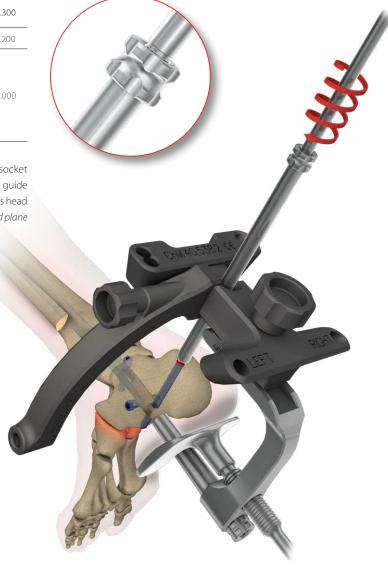
Remove the screw length measure.

Leave the protective guide in the hole of the targeter.

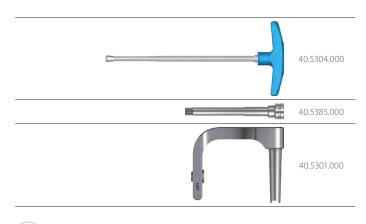


Insert the tip of the screwdriver T25 [40.5575.300] into the socket of a specified locking screw. Insert the system into the protective guide 9/7 [40.5510.200] and screw in the locking screw in the drilled hole until its head reaches the cortex bone (*the groove on the screwdriver shaft matches the end plane of the protective guide*).

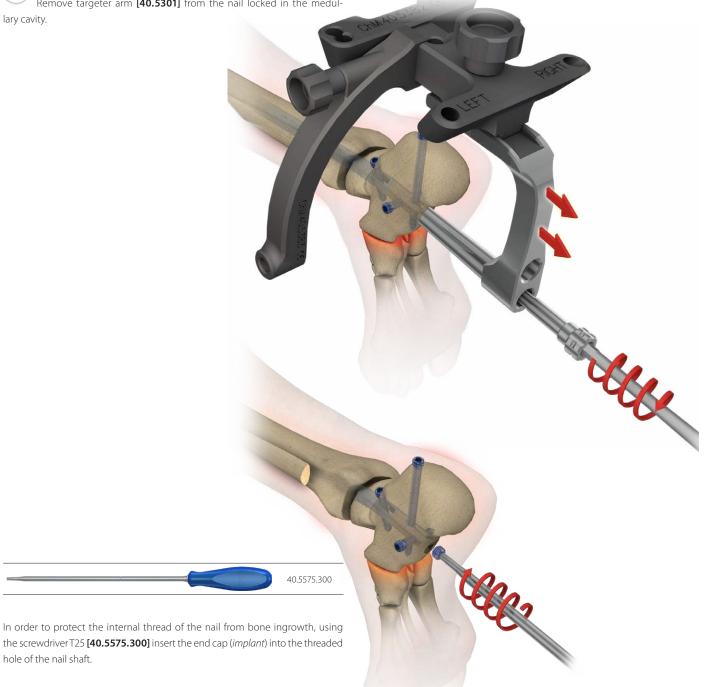
Remove screwdriver **[40.5575.300]**. Remove protective guide **[40.5510.200]**. Remove compression screw **[40.5386]**.



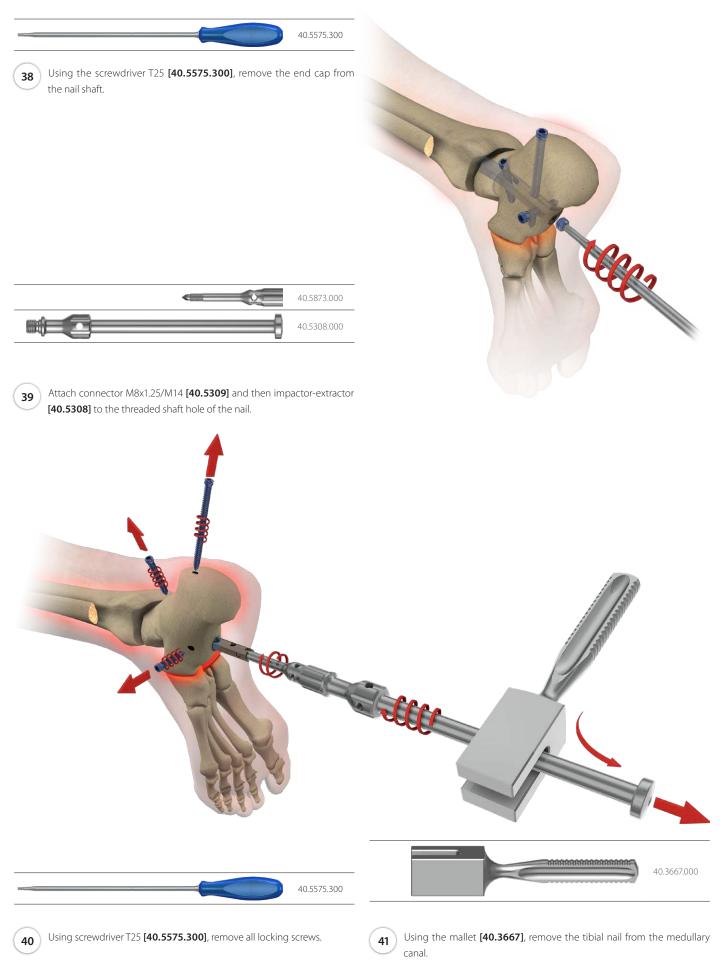
IV.12. END CAP INSERTION



37 Using the wrench S8 [40.5304] remove the connecting screw [40.5385]. Remove targeter arm [40.5301] from the nail locked in the medul-



IV.13. NAIL REMOVAL



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