



INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA (Retrograde method)

- IMPLANTS
- INSTRUMENT SET 40.5000.600
- SURGICAL TECHNIQUE



www.chm.eu

SYMBOLS DESCRIPTION

(Ti)	Titanium or titanium alloy	(\circ)	Cannulated
St	Steel		Locking
	Left		Diameter
R	Right		Inner diameter
LR	Available versions: left/right		Recommended length range for a particular nail
Len	Length		Angle
	Torx drive	16 ÷ 90	Available lengths
	Torx drive cannulated	Ster Non Ster	Available in sterile/ non- sterile condition
	Hexagonal drive		
	Hexagonal drive cannulated		
<u> </u>	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
i	Information about the next stages of a procedure.		
	Proceed to the next stage.		
	Return to the specified stage and repeat the activity.		

Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.

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

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



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I. INTRODUCTION

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

Indications for retrograde nailing:

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

The nail has 6 holes for locking screws in its proximal and distal part. Locking is performed using the targeters included in the instrument set and additional targeters.

II. IMPLANTS

The tibial implants for retrograde nailing include:

- solid and cannulated retrograde tibial nails,
- locking screws Ø4.5
- end cap M8.

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

Solid:

- diameter: Ø8 Ø14 in 1mm increments,
- length: 130-400mm in 5mm increments.

Cannulated:

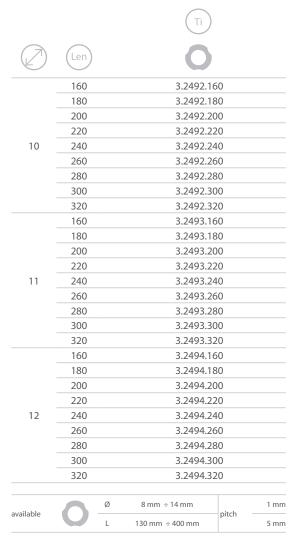
- diameter: Ø8-Ø14 in 1 mm increments,
- length: 130-400 mm in 5 mm increments.

CHARFIX RETROGRADE TIBIAL NAIL













CHARFIX RETROGRADE TIBIAL NAIL



		Ti		
	Len			
	160	3.2482.160		
-	180	3.2482.180		
-	200	3.2482.200		
	220	3.2482.220		
10	240	3.2482.240		
	260	3.2482.260		
	280	3.2482.280		
	300	3.2482.300		
-	320	3.2482.320		
	160	3.2483.160		
-	180	3.2483.180		
-	200	3.2483.200		
-	220	3.2483.220		
11	240	3.2483.240		
-	260	3.2483.260		
-	280	3.2483.280		
-	300	3.2483.300		
-	320	3.2483.320		
	160	3.2484.160		
	180	3.2484.180		
-	200	3.2484.200		
-	220	3.2484.220		
12	240	3.2484.240		
	260	3.2484.260		
	280	3.2484.280		
	300	3.2484.300		
-	320	3.2484.320		
available		Ø 8 mm ÷ 14 mm	1 mm	
		L 130 mm ÷ 400 mm	5 mm	

Use with instrument set [40.5000.600], with targeter B-D [40.5372], lateral targeter [40.5378], or with instrument set [40.5000.000]/[40.5000.100]/ [40.5000.500], with angular targeter 90° [40.5007.000] – left, [40.5007.100] – right, connecting screw M8x1,25 [40.5008], targeter D [40.5010].

LOCKING ELEMENTS









CHARFIX DISTAL SCREW 4.5



25	3.1654.025
30	3.1654.030
35	3.1654.035
40	3.1654.040
45	3.1654.045
50	3.1654.050
55	3.1654.055
60	3.1654.060
65	3.1654.065
70	3.1654.070
75	3.1654.075
80	3.1654.080
85	3.1654.085
90	3.1654.090
95	3.1654.085
100	3.1654.100



ChFN END CAP M8x1.25





Α	
+3	3.2104.003



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

40.4686.200



INSTRUMENT SET FOR TIBIAL NAILS 40.5000.600

CHARFIX system

40 5000 600	N	D	Catalania N
40.5000.600	Name	Pcs	Catalogue No.
	Targeter arm B	1	40.5301.000
	Distal targeter D	1	40.5322.000
STAT STAT	Targeter B	1	40.5373.000
	Wrench S8	1	40.5304.000
	Connecting screw M8x1.25 L-91	1	40.5325.000
	Reconstruction targeter	1	40.5377.000
	Impactor-extractor	1	40.5308.000
	Connector M8x1.25/M14	1	40.5309.000
	Compression screw	1	40.5324.000
	Curved awl 8.0	1	40.5523.000
	Mallet	1	40.3667.000
	Protective guide 9/6.5	2	40.3614.000
	Drill guide 6.5/3.5	2	40.3615.000
	Set block 9/4.5	2	40.3616.000

INSTRUMENT SET FOR TIBIAL NAILS 40.5000.600

(HARFIX system

40.5000.600	Name	Pcs	Catalogue No.
	Trocar 6.5	1	40.3617.000
	Drill guide 6.5/4.5	1	40.3696.000
□ □ 元元元章章章章章 元 100 元元元章章章章 元元 □ □ □ □ □ □ □ □ □ □ □ □ □ □	Screw length measure	1	40.1374.000
	Hole depth measure	1	40.2665.000
Sent Francisco (50 400 440 400 400 300	Nail length measuring	1	40.4798.500
	Targeter D	1	40.1344.000
	Trocar short 7	1	40.1354.000
	Drill guide short 7/3.5	1	40.1358.000
	Guide rod handle	1	40.1351.000
	Teflon pipe guide 8/400	1	40.3700.000
	Aiming insert 9.0	2	40.5065.009
	Guide rod 2.5/580	1	40.3673.580
	Hexagonal screwdriver S 3.5	1	40.3619.000
MARKET TITLE MARKET TITLE TO THE TOTAL TOTAL	Drill with scale 3.5/270	2	40.5330.001
CIRCLE BARABABARA (,)	Drill with scale 3.5/150	1	40.5343.001
	Drill 4.5/270	1	40.1387.001
	Perforated aluminumcover 1/1 595x275x15mm gray	1	12.0750.200
The state of the s	Stand	1	40.5379.500
	Container with solid bottom 1/1 595x275x135mm	1	12.0750.102

ADDITIONAL INSTRUMENTS

CHARFIX system

Name	Pcs	Catalogue No.
Targeter B-D	1	40.5372.000
Lateral targeter	1	40.5378.000



III. 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.

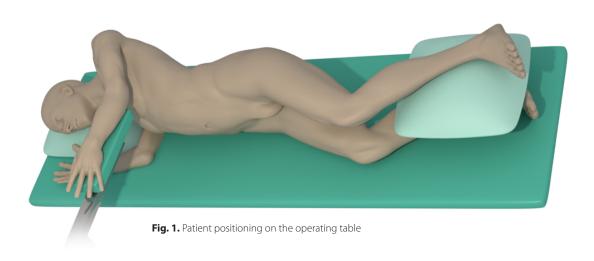
III.1. INTRODUCTION

Each procedure must be planned accordingly. Prior to surgery, take an X-Ray picture 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 film.

Implantation procedure should be conducted on the operating table equipped with X-Ray camera with video channel.

III.2. SURGICAL APPROACH

Position the patient on his healthy side as to achieve the surgical approach to the fractured limb. Depending on the bone injury, it is also possible to position the patient on the back or abdomen with stabilizing supporters . Pneumatic tourniquet should be applied on the upper part of the thigh, providing a bloodless surgical field.



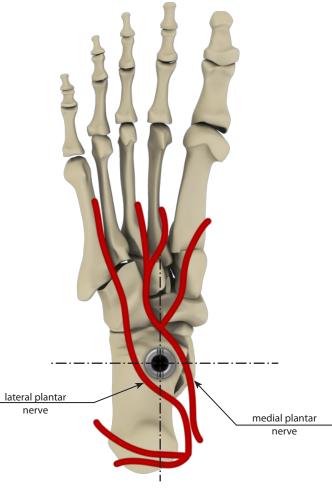
In order to obtain the access to the tarsus, perform 5-6cm lateral incision in the line of the lateral ankle, and then perform a resection of the distal fibula (see figure below). This will allow for adequate exposure of the tarsus. Cut off the distal end of the fibula which, if required, can be a source of bone graft.







When the bone fracture is properly reduced, perform lateral or longitudinal incision for the length of 3cm on the plantar side of the heel. To make it easier to find the entry point for the nail and to protect the neurovascular structures, stretch soft tissues using forceps. Open the plantar fascia down to the calcaneum. Nail insertion point should be in line that goes from the second hallux to the middle of the fascia in the medial / lateral plane, overlapping at the same time with the vertical axis of the tibia.





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

Fig. 3. Tibial retrograde nail insertion point

III.3. MEDULLARY CANAL OPENING

40.5330.001

When surgical approach is prepared and the nail entry point is located (description: section IV.1 Introduction), mark on the bone the entry point of the nail holding the foot in the correct position. Using electric drive and a Drill [40.5330.001], 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.





Mount the guide rod Ø2,5/580 [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 guide rod handle.



40.3673.580

Insert flexible reamer (not included in the instrument set) through the guide rod Ø2,5/580 [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.

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.





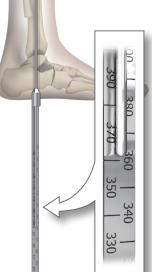
40.4798.500



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.



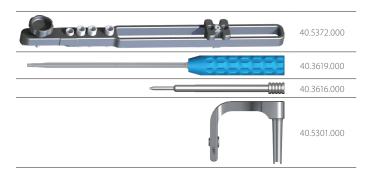
III.4. NAIL AND TARGETER ASSEMBLY AND TIBIAL NAIL IMPLANTATION



Retrograde tibial nail is universal and fits both left and right limb. Therefore, it is important to mount properly lateral targeter **[40.5378]** on the targeter arm **[40.5301]** and the targeter B-D **[40.5372]** on the left or right side.



RIGHT



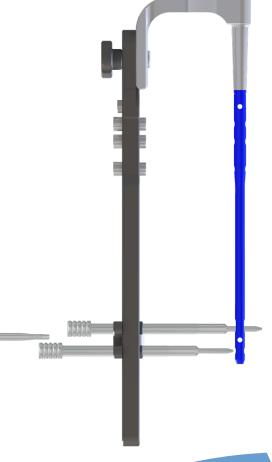
Setting targeter D [40.5372] in relation to the nail.
Using screwdriver [40.3619], set the sliding element of the targeter in the center of the slider. Set the targeter slider to match the locking holes of the nail in its distal part using two set blocks [40.3616]. Lock the targeter slider with the screw and screwdriver [40.3619].



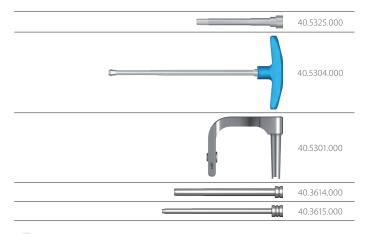
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When the targeter slider is properly set and locked, set blocks should go through the nail holes freely.

Remove set blocks from the targeter slider. Disconnect targeter **[40.5372]** from targeter arm **[40.5301]**.



LEFT

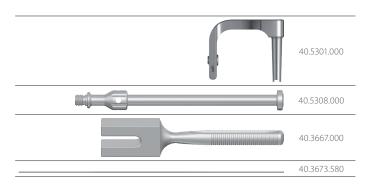


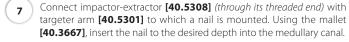


Using connecting screw M8 **[40.5325]** and wrench S8 **[40.5304]** attach chosen intramedullary nail to the targeter B arm **[40.5301]** The nail in its distal part has a threaded hole that allows for such connection.



Prior to implantation, verify whether the targeter holes overlap with the holes in the nail and whether the protective guide goes freely through the holes in the targeter. To do so, insert the protective guide 9/6.5 (one groove on the handle) [40.3614] and the drill guide 6.5/3.5 [40.3615] in the angular targeter hole.







Cannulated nail is introduced into the medullary canal through

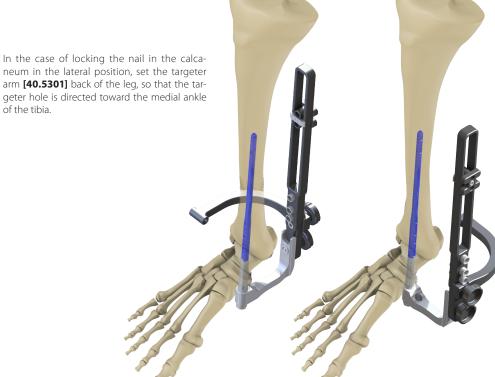
the guide rod. Solid nail is introduced directly into the medullary canal without the use of the guide rod.

Remove impactor-extractor from the targeter and remove the guide rod [40.3673.580].



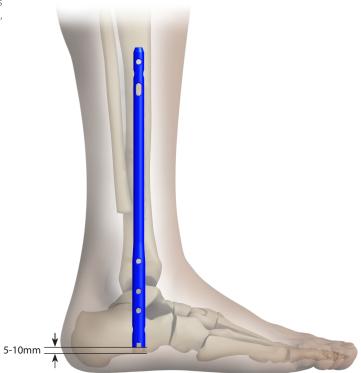


40.5301.000



In the case of locking the nail in the calcaneum posteriorly, set the arm targeter **[40.5301]** from the fibula side, so that the targeter hole is directed toward the calcaneal tuberosity.

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.





III.5. DISTAL LOCKING OF THE NAIL

Nail locking in the bone depends on the targeters positions and the mounted nail in relation to the tibia.

The place the nail is locked in its distal part depends on a damage type.



This is the surgeon who decides on the place the nail in the tarsal bone will be locked.

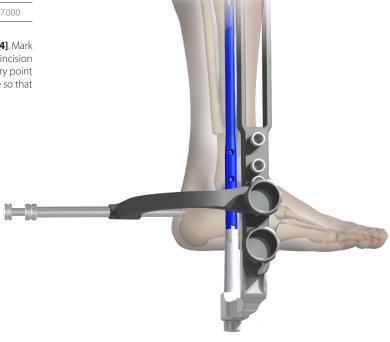


Verify using X-Ray vision track the mutual position of the hole in the lateral targeter and the hole in the distal part of the nail.



8 Insert trocar 6.5 [40.3617] into the protective guide 9/6.5 [40.3614]. Mark on the skin the entry point for a locking screw and perform an incision of soft tissues. Advance the trocar to the cortex and mark the entry point for the drill. Simultaneously with the trocar, advance the protective guide so that its end is as close to the bone as possible.

Remove the trocar. Leave the protective guide in place.



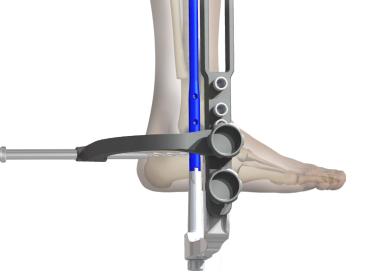
	40.3614.000
	40.3615.000
**** **** ****************************	40.5330.001

9 Insert drill guide Ø6.5/3.5 [40.3615] (two grooves) in the left protective guide 9/6.5 [40.3614]. Using a drilling machine and a drill with scale Ø3.5/270 [40.5330.001], drill a hole via the drill guide in the calcaneal bone that passes through the nail hole to the adequate depth.



Control drilling using X-Ray vision track.

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.



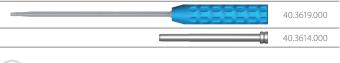




The length of the locking screw can also be determined using the screw length measure. To do so, insert screw length measure [40.1374] through the protective guide 9/6.5 [40.3614] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

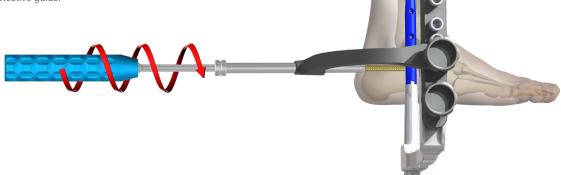
Remove the screw length measure. Leave the protective guide in the hole of the targeter.





Insert the tip of the hexagonal screwdriver S3.5 [40.3619] into the socket of a specified locking screw. Insert the system into the protective guide 9/6.5 [40.3614] and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone (the groove on the screwdriver shaft matches the end plane of the protective guide).

Remove the screwdriver and protective guide.





Locking of the nail in the subsequent distal holes is carried out the same as in standard tibial nails.



Insert the protective guide 9/6.5 [40.3614] with the trocar [40.3617] in the targeter hole. Mark on the skin the entry point for the locking screw and perform the soft tissue incision passing through this point for the length of about 1.5 mm.

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.



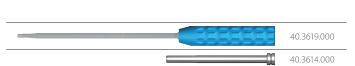
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	40.3615.000
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Insert drill guide 6.5/3.5 [40.3615] in the left protective guide 9/6.5 [40.3614]. Using a drilling machine and a drill with scale 3.5/270 [40.5330.001], drill a hole via the drill guide in the bone that passes through its both cortices. The scale on the drill indicates the length of the locking element. The length of the locking screw can also be determined using the screw length measure (description of point 10).



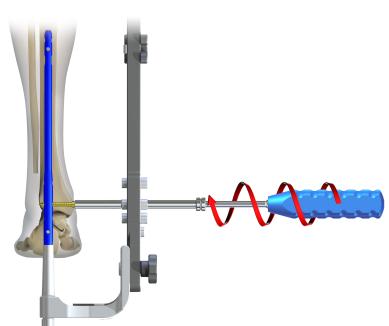
Control drilling using X-Ray vision track.

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



Insert the tip of the hexagonal screwdriver S3.5 [40.3619] into the socket of a specified locking screw. Insert the system into the protective guide 9/6.5 [40.3614] and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone (the groove on the screwdriver shaft matches the end plane of the protective guide).

Remove the screwdriver and protective guide.





III.6. PROXIMAL NAIL LOCKING



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Insert the protective guide **[40.3614]** (1 groove in the handle) with trocar **[40.3617]** into one of the holes in the targeter slider (distal hole preferred).

Mark on the skin the entry point for the locking screw and perform the soft tissue incision passing through this point. Insert the protective guide with trocar in that incision so that its end is placed as close to the cortical bone as possible.

Using trocar, mark the entry point for the drill. Remove the trocar.

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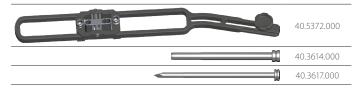
Insert drill guide 6.5/3.5 **[40.3615]** (two grooves) in the left protective quide 9/6.5

[40.3614]. Using a drilling machine and a drill with scale 3.5/270 **[40.5330.001]**, 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.



Control drilling using X-Ray vision track.

Leave the drill in the drilled hole.

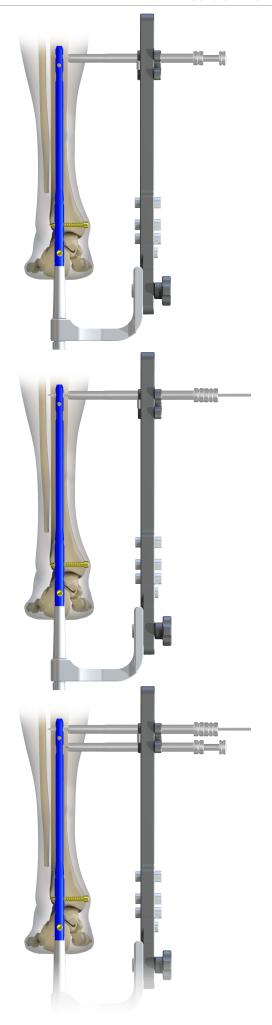


Insert the protective guide 9/6.5 **[40.3614]** with the trocar **[40.3617]** in the second targeter B-D hole **[40.5372]**. Mark on the skin the entry point for the locking screw and perform the soft tissue incision passing through this point.

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.

Leave the protective guide in the hole of the targeter.



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Insert drill guide 6.5/3.5 [40.3615] (two grooves) in the left protective guide 9/6.5 [40.3614]. Using a drilling machine and a drill with scale 3.5/270 [40.5330.001], 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.



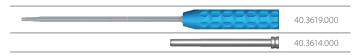
Control drilling using X-Ray vision track.

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

 40.3614.000
 40.1374.000

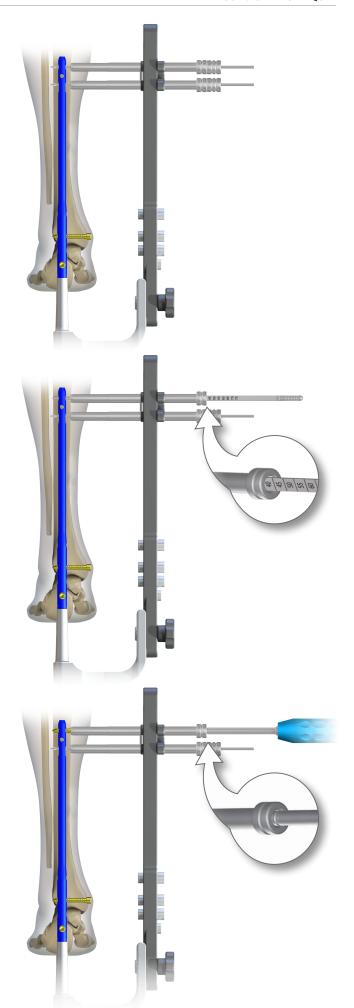
Insert screw length measure [40.1374] through the protective guide 9/6.5 [40.3614] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

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



Insert the tip of the hexagonal screwdriver S3.5 [40.3619] into the socket of a specified locking screw. Insert the system into the protective guide 9/6.5 [40.3614] and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone (the groove on the screwdriver shaft matches the end plane of the protective guide).

Remove the screwdriver

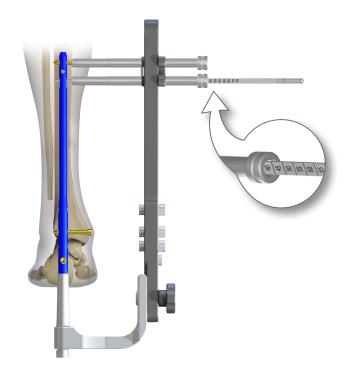


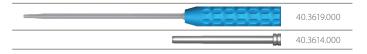


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	40.3615.000
	40.3614.000
	40.1374.000

Remove the drill [40.5330.001] and the drill guide [40.3615] from the second hole of the targeter slider. Leave protective guide [40.3614] in the hole of the slider. Insert screw length measure [40.1374] through the protective guide 9/6.5 [40.3614] into the drilled hole in the bone until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on B-D scale. During taking the measure, the end of the protective guide should lean against the cortex bone.

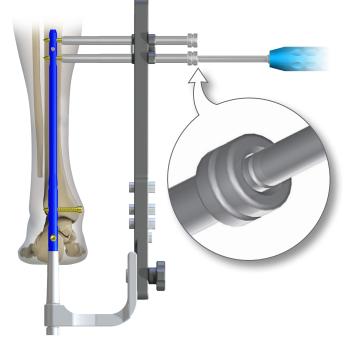
Remove the screw length measure. Leave the protective guide in the hole of the targeter.





Insert the tip of the hexagonal screwdriver S3.5 [40.3619] into the socket of a specified locking screw. Insert the system into the protective guide 9/6.5 [40.3614] and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone (the groove on the screwdriver shaft matches the end plane of the protective guide).

Remove the screwdriver and protective guide.





III.7. PROXIMAL NAIL LOCKING USING "FREE-HAND" TECHNIQUE

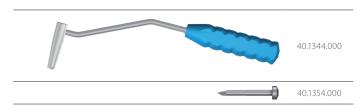


Proximal locking of the nail is carried out using "free-hand" technique and targeter D [40.1344].

Using "free-hand" technique, to determine the location of drill holes and while drilling, current radiological control is necessary. While drilling, it is recommended to use angular drill attachment so that the operator's hands are not under direct X-Rays exposure. Mark on the skin the entry points and perform soft tissue incision passing through these points for the length of about 1.5 cm.

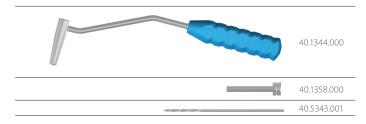


Control drilling using X-Ray vision track.



Using the X-Ray machine, determine the position of the targeter D [40.1344] in relation to the nail holes. Targeter D must be placed in cortical bone. Insert trocar short [40.1354] 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.



Insert drill guide short 7/3.5 [40.1358] in the targeter D [40.1344]. Using a drilling machine and a drill 3.5/150 [40.5343.001], 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.





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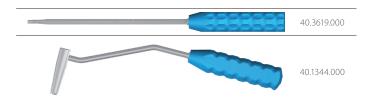
Insert screw length measure **[40.1374]**through the targeter D hole **[40.1344]** into the drilled hole in the bone until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on D scale.

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



The holes in the nail and the targeter have to overlap. The sharp edges of the targeter should be in the cortical bone.



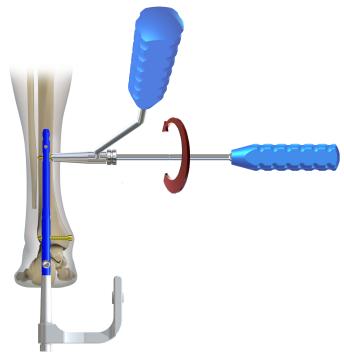


lnsert the tip of the hexagonal screwdriver S3.5 [40.3619] into the socket of a specified locking screw. Insert the system into the targeter D hole and screw in the locking screw in the previously drilled hole until its head reaches the cortex bone.

Remove the screwdriver and the targeter.

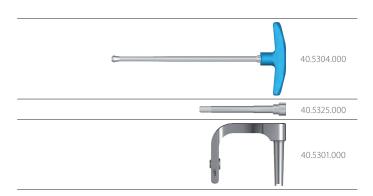


Perform nail locking in the second proximal hole according to steps 23-26 of this instructions.

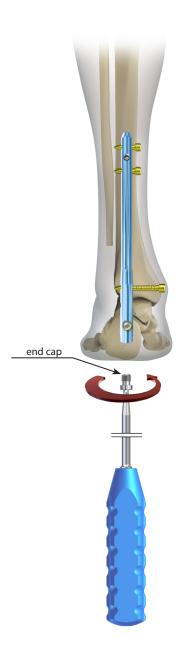




III.8. END CAP INSERTION



Using a wrench S8 [40.5304] remove the connecting screw [40.5325]. Remove targeter arm [40.5301] from the locked in the medullary cavity nail.





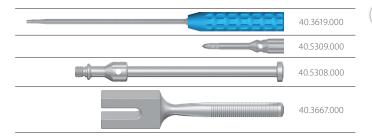
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40.3619.000

In order to protect the internal thread of the nail from bone ingrowth, using hexagonal screwdriver S3.5 **[40.3619]** insert the end cap *(implant)* into the threaded hole of the nail shaft.

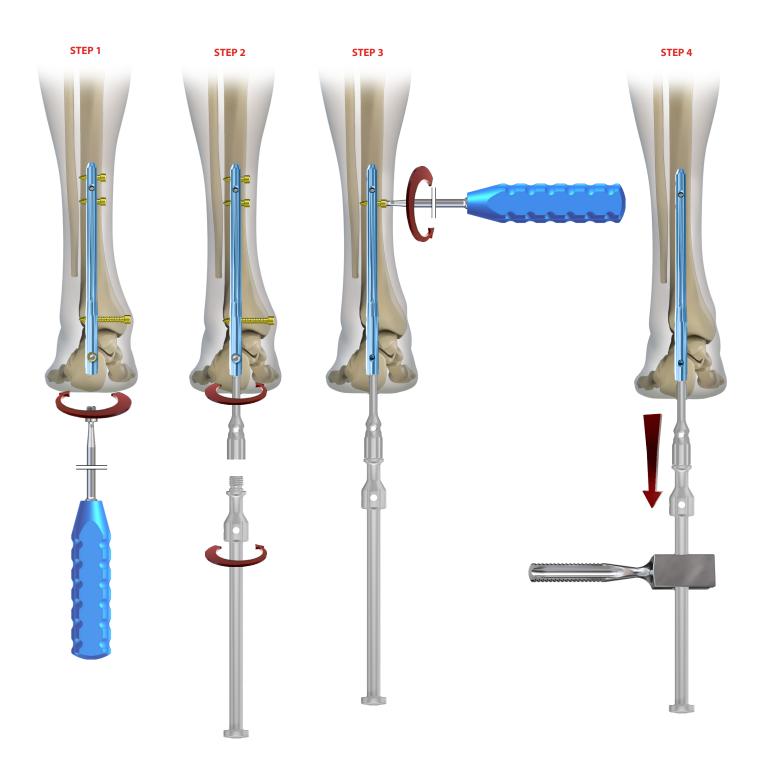


III.9. NAIL REMOVAL





- STEP 1: Using hexagonal screwdriver S3.5 **[40.3619]**, remove the end cap from the nail shaft,
- STEP 2: Attach Connector M8x1.25/M14 **[40.5309]** and then impactor-extractor **[40.5308]** to the threaded shaft hole of the nail.
- STEP 3: Using hexagonal screwdriver S3.5 **[40.3619]**, remove all the locking screws and then,
- STEP 4: Using the mallet **[40.3667]**, remove the tibial nail from the medullary canal.



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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