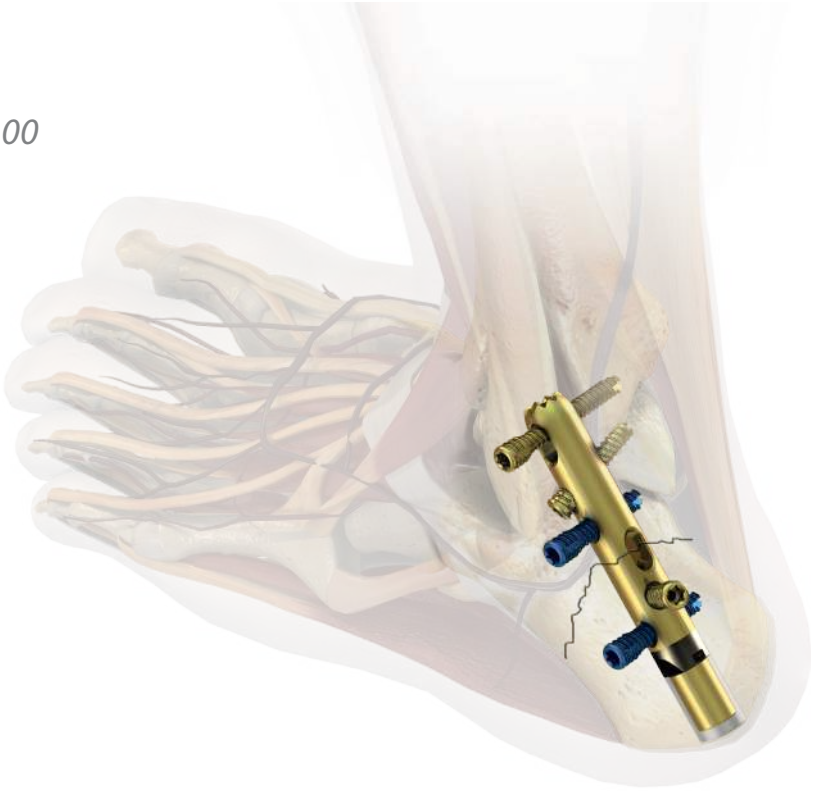
ST/83A

ChM®

CHARFIX system 2

CALCANEAL NAIL

- *IMPLANTS*
- *INSTRUMENT SET 15.0428.100*
- *SURGICAL TECHNIQUE*



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SYMBOLS DESCRIPTION

Ti	Pure titanium
TiA	Titanium alloy
St	Steel
L	Left
R	Right
L R	Available versions: left/right
Len	Length
	Torx drive
	Torx drive cannulated
	Hexagonal drive
	Hexagonal drive cannulated
	Cannulated
	Locking
	Diameter
	Inner diameter
	Recommended length range for a particular nail
	Angle
16 ÷ 90	Available lengths
Ster Non Ster	Available in sterile/ non- sterile condition

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	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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Date of issue 07.09.2018
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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

1. INTRODUCTION

CHARFIX system 2 - INTRAMEDULLARY OSTEOSYNTHESIS OF CALCANEUM

Intramedullary osteosynthesis of calcaneum consists of:

- implants *(intramedullary nail, locking screws, end cap)*,
- instrument set for implants insertion and removal,
- surgical technique.

Intramedullary osteosynthesis with calcaneal nails of **CHARFIX2** system allows for stable reduction of fracture fragments or stable bone immobilization during arthrodesis.

Indicated use:

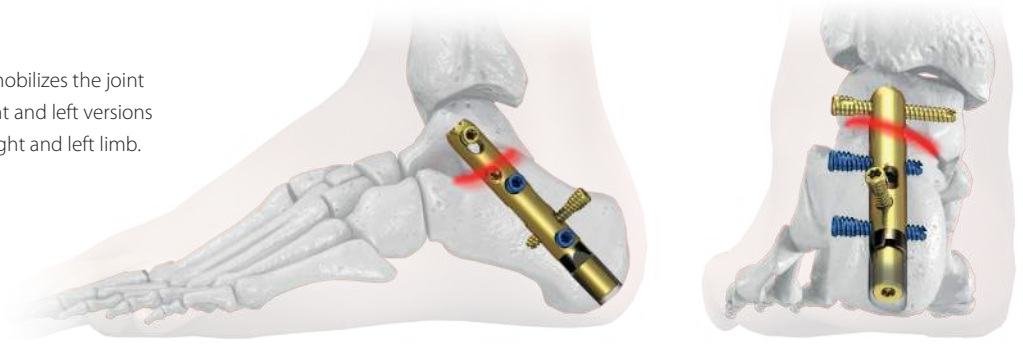
- simple and comminuted fractures of the calcaneus,
- interarticular fractures of the calcaneus,
- delayed or non-union after other treatment methods,
- subtalar arthrodesis.

Reconstruction method

In the reconstruction method, the bone fragments are anatomically aligned due to angular positioning of the screws. The right and left versions of the nail are used, respectively for the right and left limb.

Arthrodesis of the joint

In the ankle joint arthrodesis, the nail immobilizes the joint surfaces in relation to each other. The right and left versions of the nail are used, respectively for the right and left limb.

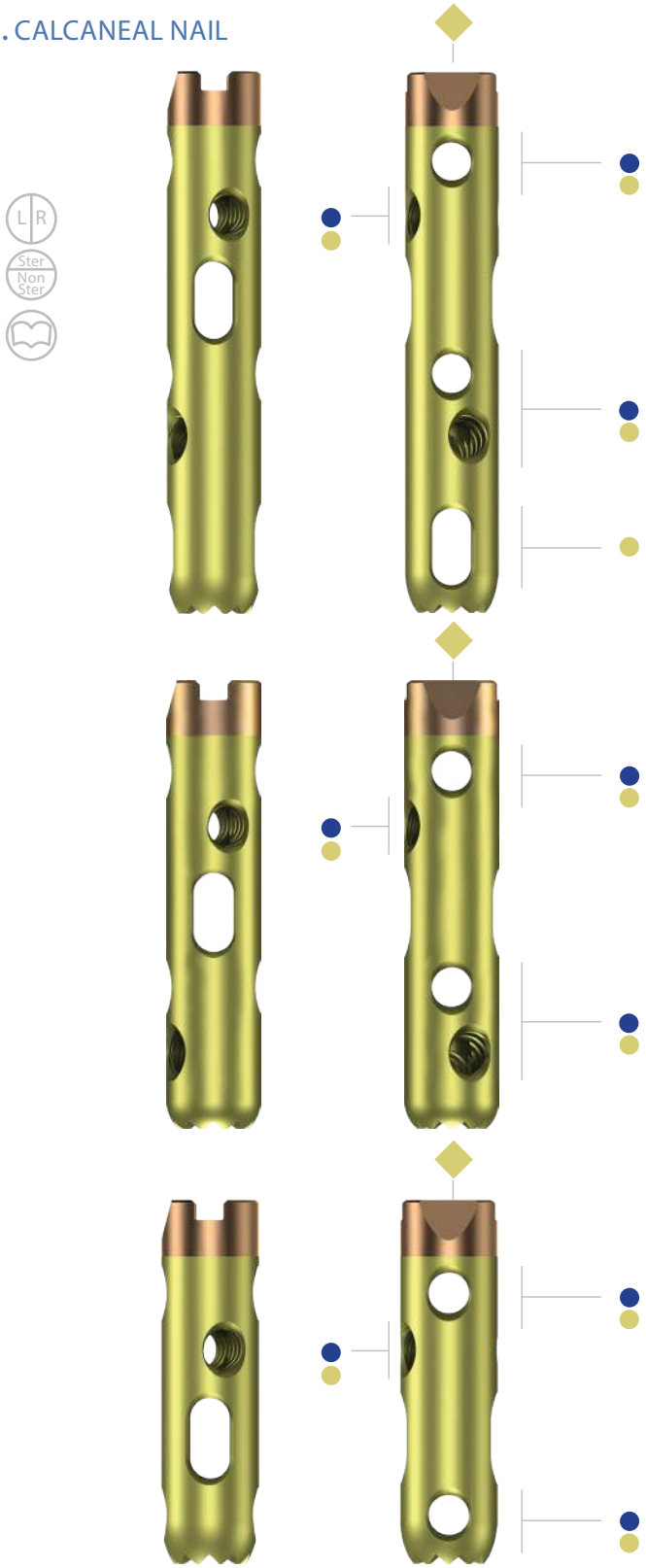


The presented range of implants is made of titanium and its alloys and implantable stainless steel in accordance with ISO 5832 standards.

2. IMPLANTS

CHARFIX system 2

2.1. CALCANEAL NAIL



TiA	Len	L	R
10	45	3.6385.045	3.6386.045
	55	3.6385.055	3.6386.055
	70	3.6385.070	3.6386.070
12	45	3.6389.045	3.6390.045
	55	3.6389.055	3.6390.055
	70	3.6389.070	3.6390.070

Colour-marking system

	L	R
10		
12		

TiA					
3.5155.xxx	T25		✓	5.0	20-60
3.5156.xxx	T25	✓	✓	5.5	20-60
3.5161.8xx	T25		✓		0-20

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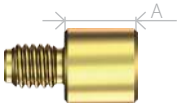
2.2. LOCKING ELEMENTS

CHARFIX system 2

TiA | Ster Non Ster

CHARFIX2 End cap M6



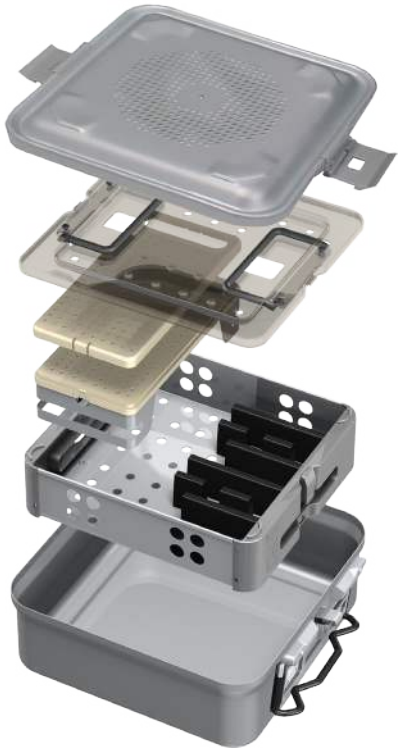
A	TiA
+0	3.5161.800
+5	3.5161.805
+10	3.5161.810
+15	3.5161.815
+20	3.5161.820

CHARFIX2 Distal screw 5.0

	TiA
20	3.5155.020
22	3.5155.022
24	3.5155.024
26	3.5155.026
28	3.5155.028
30	3.5155.030
32	3.5155.032
34	3.5155.034
36	3.5155.036
38	3.5155.038
40	3.5155.040
42	3.5155.042
45	3.5155.045
50	3.5155.050
55	3.5155.055
60	3.5155.060
20 ÷ 60	

CHARFIX2 Distal screw 5.5

	TiA
20	3.5156.020
22	3.5156.022
24	3.5156.024
26	3.5156.026
28	3.5156.028
30	3.5156.030
32	3.5156.032
34	3.5156.034
36	3.5156.036
38	3.5156.038
40	3.5156.040
42	3.5156.042
45	3.5156.045
50	3.5156.050
55	3.5156.055
60	3.5156.060
20 ÷ 60	

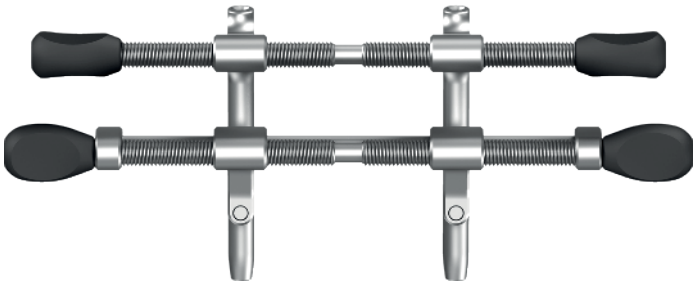


Stand for calcaneal nails **15.0428.601**

3. INSTRUMENT SET

CHARFIX system 2

The instrument set **[15.0428.100]** is used to implant and remove the nail when the treatment is complete. Instruments included in the instrument set are placed on the stands and covered with a cover to facilitate their storage and transportation to the operating theater.

15.0428.100	Name	Catalogue No.	Pcs
	Targeter arm	40.6716.000	1
	Lateral targeter	40.6719.000	1
	Targeter arm right	40.6718.000	1
	Targeter arm left	40.6717.000	1
	Distractor	40.6715.100	1
	Connector M6/M8	40.6724.000	1
	Compactor	40.6727.000	1
	Elevator	40.6728.000	1
	Screwdriver T25	40.6726.000	1
	Impactor-extractor	40.6725.000	1
	Mallet	40.4595.000	1

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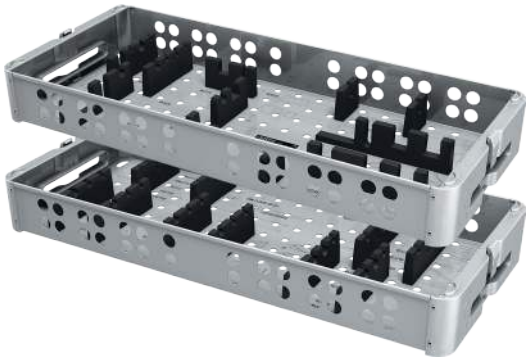
15.0428.100	Name	Catalogue No.	Pcs
	Protective guide	40.6706.000	1
	Protective guide 9/7	40.6707.000	2
	Drill guide 7/4	40.6710.000	2
	Drill guide 7/2	40.6709.000	2
	Trephine 11	40.6702.000	1
	Trephine 13	40.6703.000	1
	Drill 11	40.6704.000	1
	Drill 13	40.6705.000	1
	Cannulated drill 4.0/2.2/210	40.6713.000	2
	Compression screw	40.6722.000	1
	Repositor	40.6723.000	1
	Screw M5	40.6721.000	1
	Connecting screw M6	40.6720.000	1
	Screw length measure	40.6712.000	1
	Trocar 7.0	40.6708.000	1
	Pin 5.0	40.6714.100	4
	Guide rod 2.8/270/13	40.6700.000	1
	Guide rod 2.8/245/13	40.6701.000	1
	Guide rod 2.8/270/13	40.6729.000	1
	Guide rod 2.8/245/13	40.6711.000	1
	Kirschner wire 2.0/250	40.4452.000	4

15.0428.100	Name	Catalogue No.	Pcs
	Perforated aluminum lid 1/1 595x275x15mm Gray	12.0750.200	
	Stand	14.0428.100	
	Container with solid bottom 1/1 595x275x185mm	12.0750.103	

Additionally, to carry out the procedure, the basic equipment for orthopedic procedures is required, such as: drive,

- Kirschner wires,
- mallets,
- other.

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4. SURGICAL TECHNIQUE

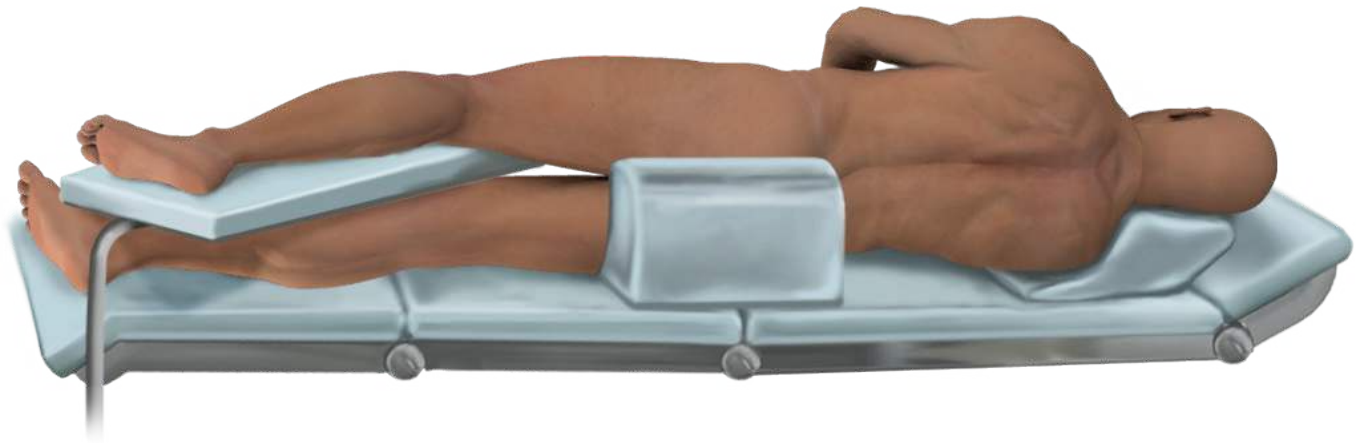
4.1. PREPARATION FOR THE SURGERY

NOTE: The following description covers the most important stages of the implantation of the calcaneal nails; however, it is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure and its application in each individual case.

Each surgical treatment must be planned carefully. Prior to surgery, appropriate X-Ray images *(or CT)* of the affected foot, together with the joint part of the tibia and fibula, should be taken. X-Rays of the lateral, axial and dorsoplantar view of the calcaneus are recommended. Particular attention should be paid to lesions or arthrosis of the subtalar and talotibial joints.

4.2. PATIENT POSITIONING

The procedure has to be carried out on an operating table with C-arm and with a patient in a lateral position. The involved extremity should be placed parallel to the operating table.

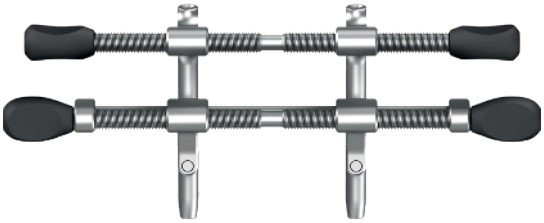


4.3. SURGICAL APPROACH

The surgical approach is prepared by vertical incision at a length of about 1.5-2 cm. The incision should start below the Achilles tendon attachment, slightly lateral to the calcaneal tuberosity.

4.4. BONE FRAGMENTS REDUCTION

Use distractor **[40.6715.100]** for proper reconstruction of a broken bone or for adequate arthrodesis of the subtalar joint.



40.6715.100

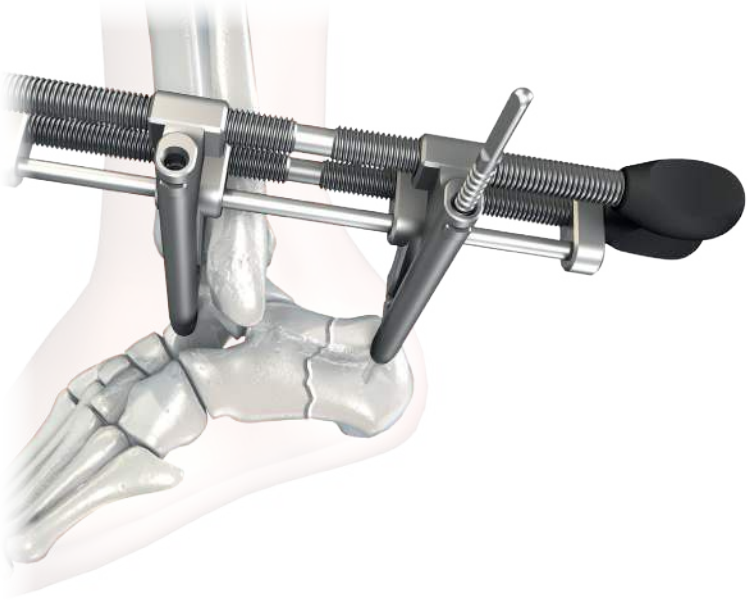
Choose the right insertion place of the first pin, depending on the fracture type.

For both ‚tongue' type and crush fractures, it is recommended to place the first pin in the calcanean tuber, so that it is inserted above the bone tunnel performed in the subsequent stages *(as shown in the picture)*.

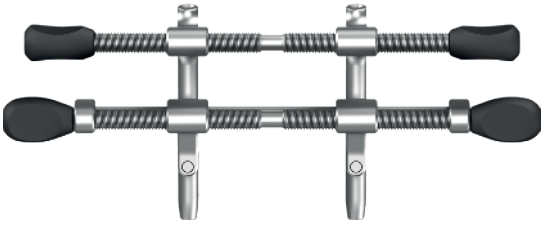
1 Use a drive to insert a pin 5.0 **[40.6714.100]** perpendicular to the lateral plane of the calcaneus, to a depth of about 40 mm.

40.6714.100

2 Insert one of the distractor's **[40.6715.100]** guides onto the fixed pin **[40.6714.100]** so that the guide end is positioned against the bone. Make sure the pin got locked in the distractor's guide.



To facilitate later locking of the nail, position the distractor with the adjustment screws towards the tibia.



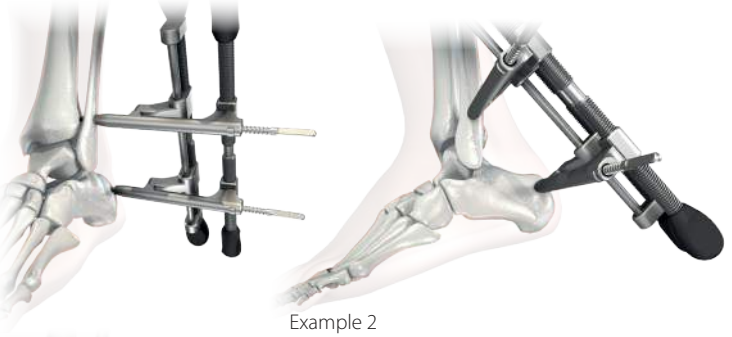
40.6715.100

3 Position the other of the distractor's **[40.6715.100]** guides along the long axis of the foot, above the talus or fibula *(as presented in example 1 or example 2. Example 3 illustrates alternative possibility of inserting the other pin into the calcaneus near the talocalcaneonavicular joint)* and insert the other pin 5.0 **[40.6714.100]** to a depth of about 40 mm. Make sure the pin got locked in the distractor's guide.

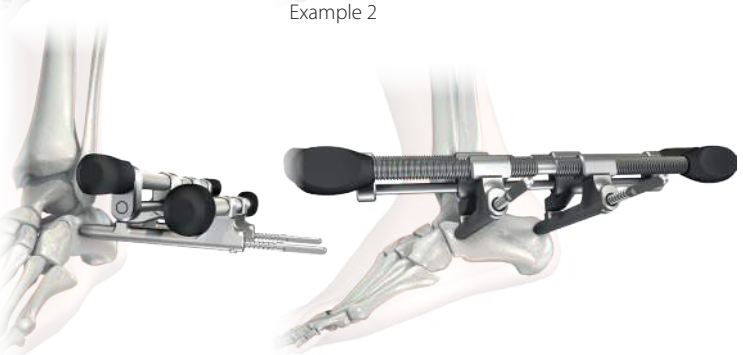
Example 1

Ensure that the pin will not interfere with the nail to be introduced later on.

40.6714.100



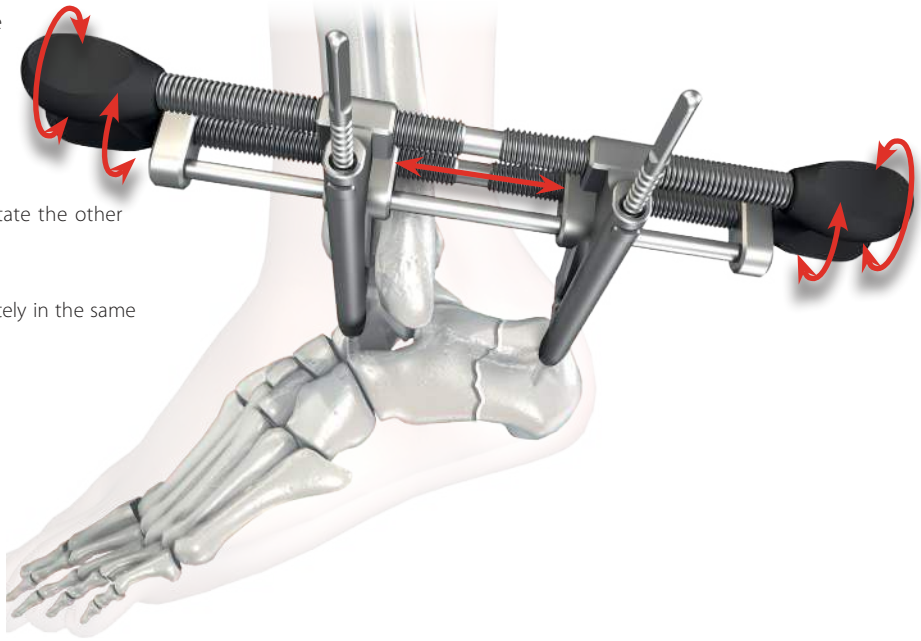
Example 2



Example 3

4 Use the adjustment knobs to perform the required bone or bone fragments reposition.

For valgus/varus deformed bones, correction of the angular position of the bone and the distance between the bones *(bone fragments)* are achieved by rotating the knobs properly.



For angular correction, keep one of the screws fixed and rotate the other to position the bone.

For distance correction in one plane, rotate the screws alternately in the same direction with the same angle of rotation.

4.5. RECONSTRUCTION METHOD

Determine the length, diameter and insertion method of the implant on the basis of X-Ray or CT examination performed for the affected and, optionally, the healthy limb.

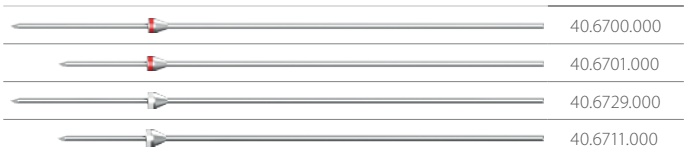
5 Perform the bone tunnel starting with the guide rod insertion.

NOTE! **Before use, make sure the guide rod is straight, as this may affect the further steps in the preparation of the bone tunnel.**

The rod should be selected depending on the length and diameter of the nail to be used, as presented below in Table 1.

Guide rod	Nail diameter	Nail length
2.8/270 **[40.6700]**	Ø10	> 45 mm
2.8/245 **[40.6701]**		= 45 mm
2.8/270/13 **[40.6729]**	Ø12	> 45 mm
2.8/245/13 **[40.6711]**		= 45 mm

Table 1



Insert the rod into the calcaneus and towards the center of the calcaneocuboid joint or talocalcaneonavicular joint, along the bone trabecules, starting at the contact point of the planta and the back of the heel, until the guide rod limiter rests against the bone.
Depending on the location of the original fracture line, it is recommended to place the guide rod in a larger bone fragment.

Remove the drive and leave the guide rod in the bone.

The above should be performed under X-Ray control.

6 Insert a protective guide **[40.6706]** as close to the bone as possible. Use trephine *(acc. to Table 2)* to create the bone tunnel to a depth of 5-10 mm greater than the nail length. Do not penetrate the joints. Read the drilling depth on the instrument scale.

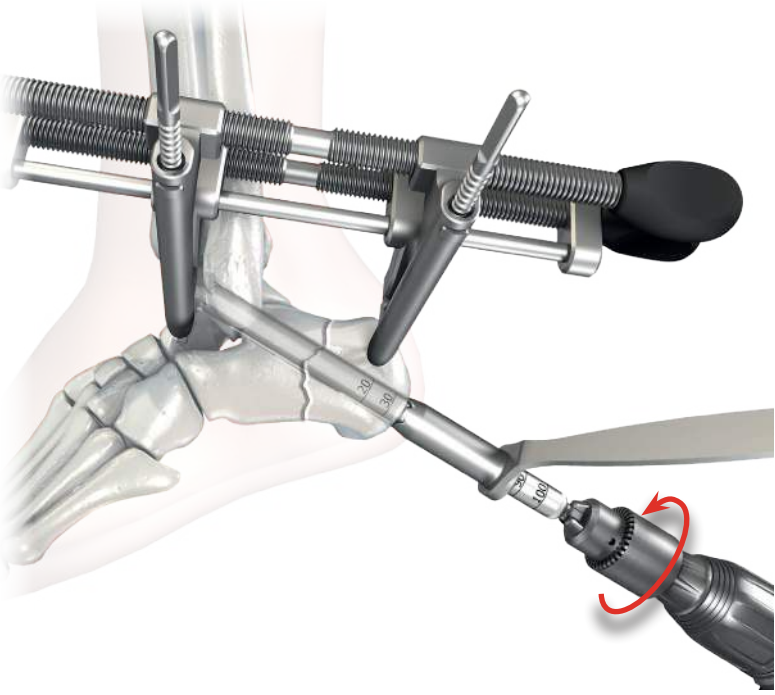
Trephine	Guide rod
11	2.8/270 **[40.6700]**
	2.8/245 **[40.6701]**
13	2.8/270 /13 **[40.6729]**
	2.8/245 /13 **[40.6711]**

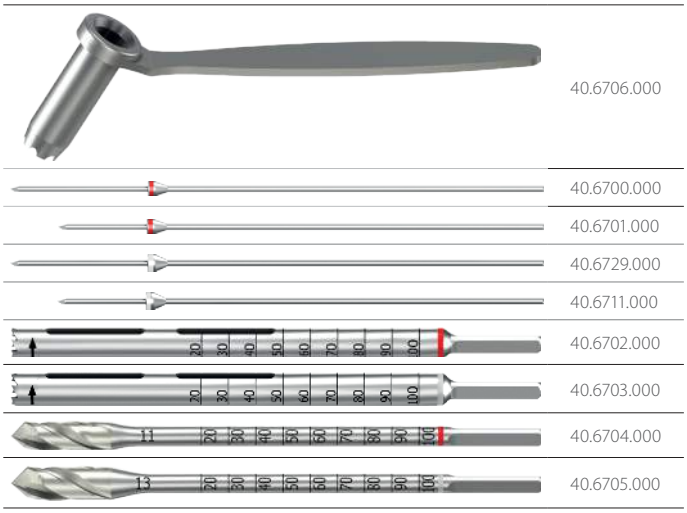
Table 2

The above should be performed under X-Ray control. If axial symmetry between the rod and trephine is not maintained, remove the trephine and re-drill. Do not damage the guide rod.

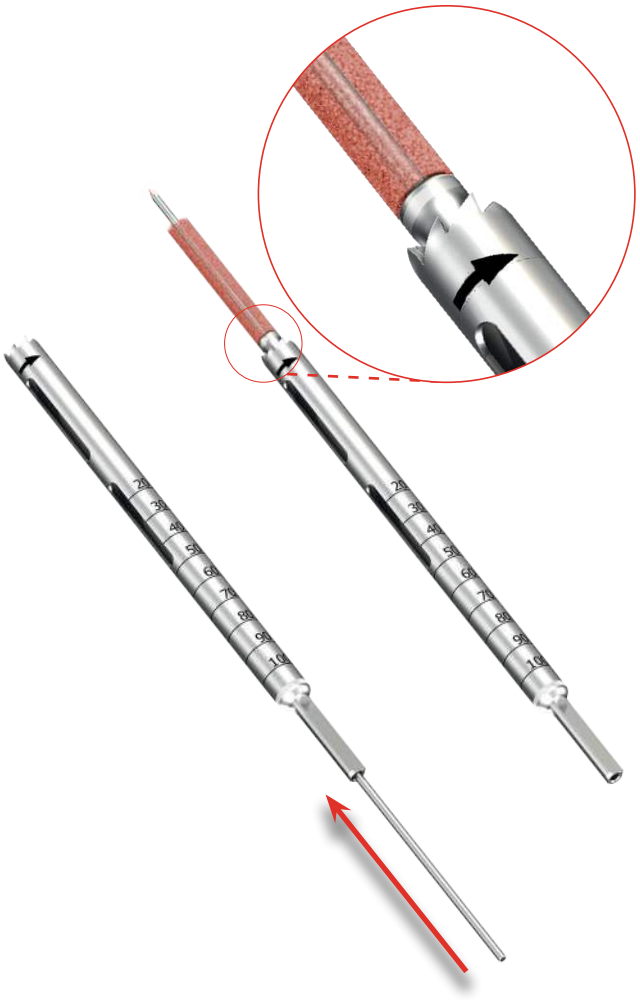
Remove the trephine, guide rod and protective guide.

Optionally, to create the bone tunnel, a drill 11 **[40.6704]** or drill 13 **[40.6705]** instead of the guide rod and trephine can be used *(depending on the diameter of the nail)*. The drill should be inserted with the use of protective guide **[40.6706]**.





40.6706.000
40.6700.000
40.6701.000
40.6729.000
40.6711.000
40.6702.000
40.6703.000
40.6704.000
40.6705.000



7 When a trephine was used for drilling the hole, the bone material that remains on the guide rod can be used as a filling of an oval hole in the nail.

8 Use a compactor **[40.6727]** for bone compaction in the prepared tunnel and for direct intrafocal reduction of an articular surface fracture.
For bone fractures repositioning, additional correction *(e.g., free space creation)* can be performed with the help of the distractor. The distractor may also facilitate the use of compactor or elevator.

If need be, the use of an elevator **[40.6728]** is possible.


40.6727.000

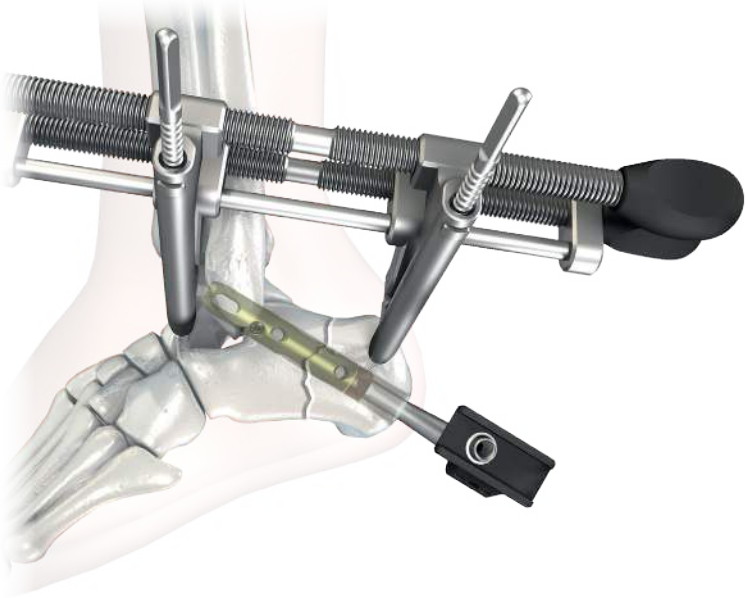

40.6728.000

9 Use a connecting screw M6 **[40.6720]** to attach the nail to a targeter arm **[40.6716]**. A flattening on the nail and targeter must be in line.


40.6720.000

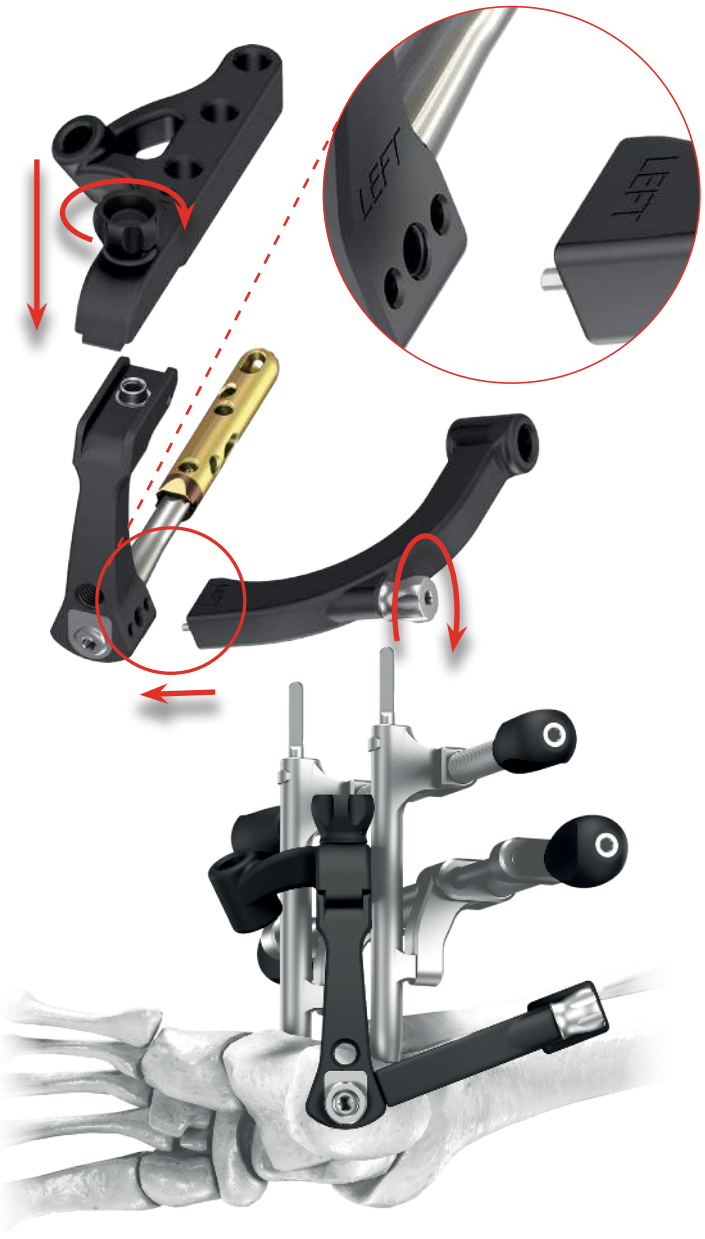

40.6716.000

10 Insert the nail into the bone tunnel.



Optionally, for comminuted fracture, a Kirschner wire 2.0/250 **[40.4452]** can be used for nail implantation and for reduction and stabilization of bone fragments.

11 Use the knob to attach the targeter arm right **[40.6718]** or targeter arm left **[40.6717]** to the targeter arm **[40.6716]**, corresponding to the version of the nail *(right or left nail)*. Use a screw M5 **[40.6721]** to attach a lateral targeter **[40.6719]** from the corresponding side of the targeter arm. Consistent RIGHT or LEFT markings determine the nail version *(right or left nail)*.



40.6718.000

40.6717.000

40.6721.000

40..6719.000

It is recommended to start locking the nail from the most distal hole in the nail.

12 Insert a protective guide 9/7 **[40.6707]** together with trocar 7.0 **[40.6708]** in the hole of the targeter arm right **[40.6718]** or left **[40.6717]**. Mark on the skin the entry point for a locking screw and perform soft tissue incision. Use the trocar to mark on the cortex the entry point for the Kirschnera wire 2.0/250 **[40.4452]**. At the same time, advance the protective guide as close to the bone as possible.

Remove the trocar.

 40.6707.000

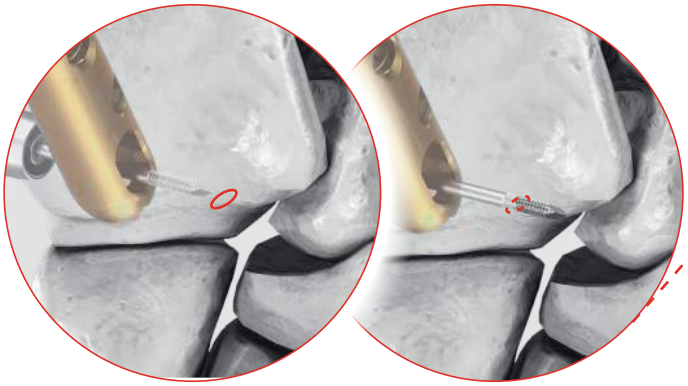
 40.6708.000

13 Insert a drill guide 7/2 **[40.6709]** into the protective guide 9/7 **[40.6707]**. Use a drive to introduce the Kirschner wire 2.0/250 **[40.4452]** through the both cortex layers and nail hole. The threaded wire should not protrude from the bone.
Remove the drive. Leave Kirschner wire and guide in place.

The wire insertion should be performed under X-Ray control.

 40.6709.000

 40.4452.000



correct wire insertion incorrect wire insertion

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

14 Insert a screw length measure **[40.6712]** on the Kirschner wire 2.0/250 **[40.4452]** until its end rests on the drill guide 7/2 **[40.6709]**. Read the length of the locking screw on the scale indicated by the end of the Kirschner wire. During the measurement, the protective guide 9/7 **[40.6707]** should rest on the cortex.

Remove the screw length measure and drill guide.
Leave the Kirschner wire and protective guide in place.

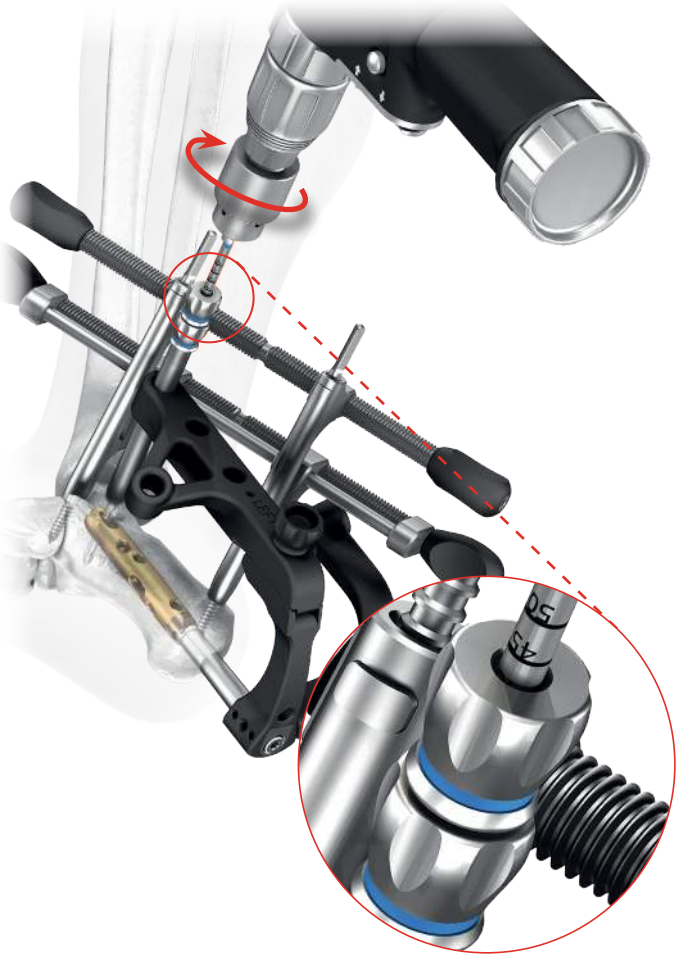
40.6712.000

15 Insert a drill guide 7/4 **[40.6710]** in the protective guide 9/7 **[40.6707]**. Using the drive and a cannulated drill 4.0/2.2/210 **[40.6713]** led in the drill guide, drill a hole in the bone extending through both layers of the cortex and the hole in the nail.

Remove drill and drill guide.
Leave the Kirschner wire and protective guide in place.

40.6710.000

40.6713.000



16 Insert the tip of the screwdriver T25 **[40.6726]** into the socket of a selected locking screw and, using the Kirschner wire, into the protective guide 9/7 **[40.6707]**. Insert the screw in the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft shall match the edge of protective guide)*.

40.6726.000

17 Should bone fragments compression be required, remove the distractor **[40.6715.100]** and attach the compression screw **[40.6722]** and repositor **[40.6723]** to the targeter arm **[40.6716]**. Turn gently the compression screw and compress the fragments.

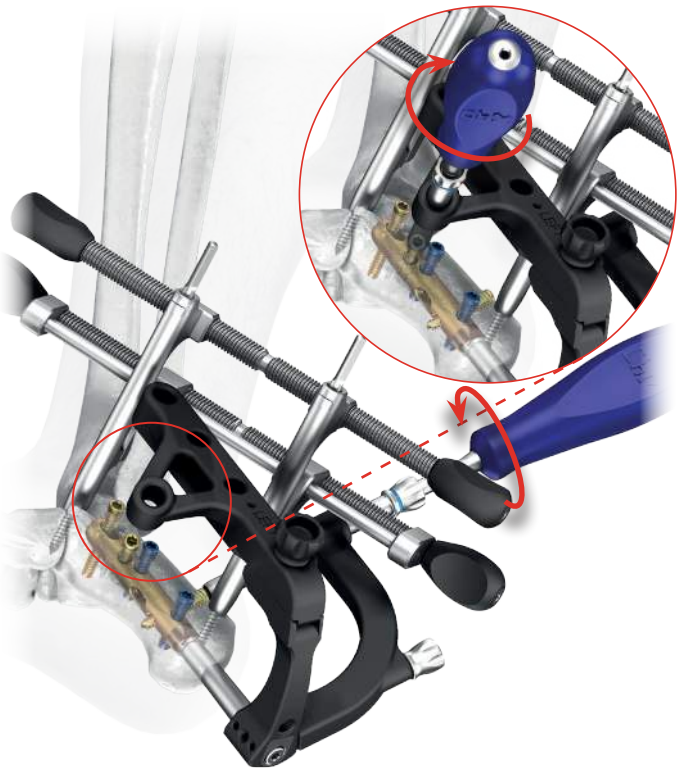
NOTE: Excessive rotation of the compression screw can lead to damage to the connecting screw M6 **[40.6720]**, implant or to additional bone damage. Maintain the compression until the last locking element is inserted.

40.6722.000

40.6723.000

40.6720.000

18 The subsequent locking should be performed in accordance with points 12÷16.



19 Use screwdriver T25 **[40.6726]** to remove the connecting screw M6 **[40.6720]** from the nail shaft. Remove the targeter arm **[40.6716]** from the nail locked in the bone.

40.6726.000

20 In order to protect the internal thread of the nail against bone ingrowth, insert an end cap *(implant)* into the threaded hole of the nail using the screwdriver T25 **[40.6726]**.

40.6726.000

4.6. ANKLE JOINT ARTHRODESIS

Based on the X-Ray *(or CT)* images of the broken bone and the healthy one *(if performed)*, the doctor determines the length and diameter of the implant, and the method of nail insertion.

21 Perform the bone tunnel starting with the guide rod insertion.

NOTE! **Before use, make sure the guide rod is straight, as this may affect the further steps in the preparation of the bone tunnel.**

The rod should be selected depending on the diameter of the nail to be used, as presented below in Table 3.

Guide rod	Nail diameter
2.8/270 **[40.6700]**	Ø10
2.8/245 **[40.6701]**	
2.8/270/13 **[40.6729]**	Ø12
2.8/245/13 **[40.6711]**	

Table 3

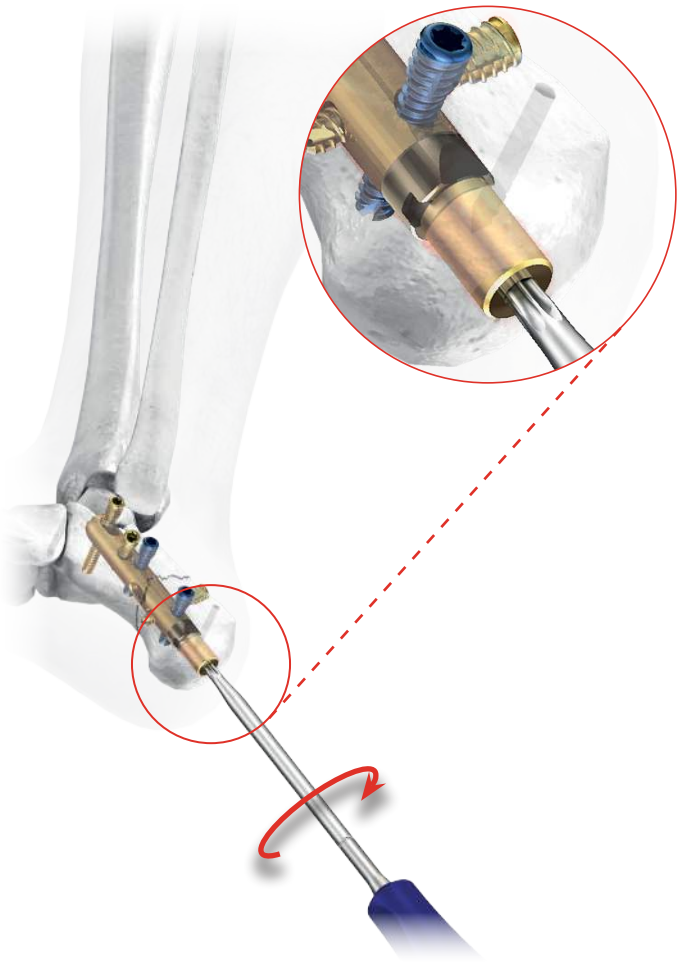
Insert the rod into the calcaneus and towards the center of the calcaneocuboid joint, along the bone trabecules of the calcaneus, starting at the contact point of the planta and the back of the heel, until the talus is reached. Do not penetrate the upper cortical surface.

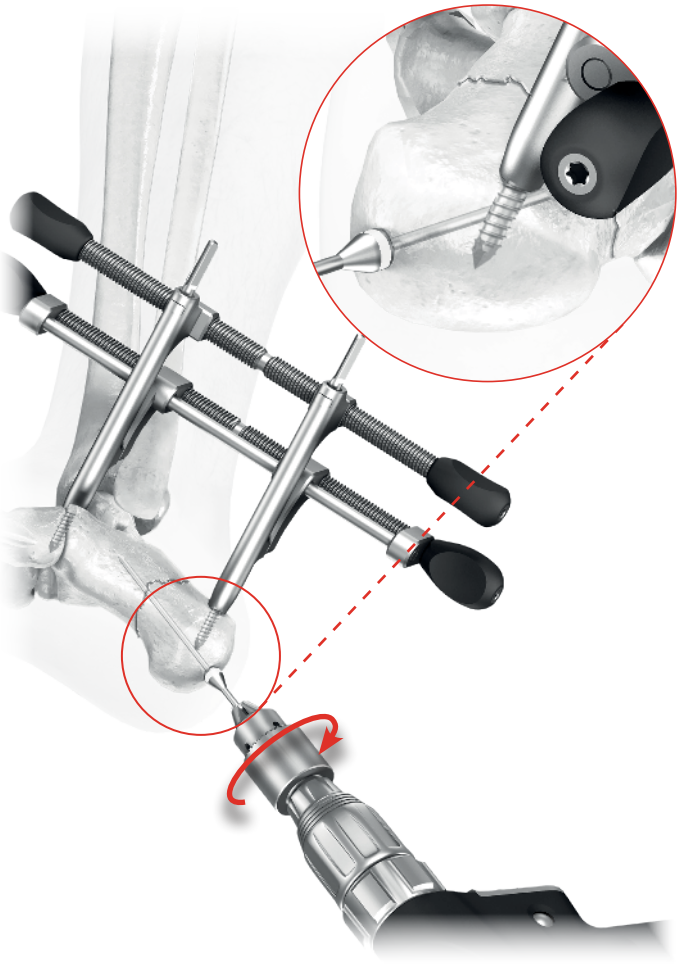
Remove the drive. Leave the guide rod in place.

The above should be performed under X-Ray control.

For valgus/varus deformed bones, before guide rod insertion, perform deformation correction using the distractor **[40.6715.100]** *(as described in section 4)*.

One pin should be inserted into the posterior part of the calcaneus *(location depends on the fracture - see point 1)*, and the other into the lateral tubercle, in the middle of the trochlea of talus, perpendicular to the lateral plane of the bone, along the long axis of the foot.





22

Insert protective guide **[40.6706]** as close to the bone as possible. Use trephine *(acc. to Table 4)* to create the bone tunnel. It is recommended to perform the tunnel in two stages; first in the calcaneus *(with removal of bone material from the guide rod)*, and then in the talus. Read the drilling depth on the instrument scale. The bone material can be used as a graft between the calcaneus and talus.

NOTE! The above should be performed under X-Ray control. If axial symmetry between the rod and trephine is not maintained, remove the trephine and re-drill. Do not damage the guide rod.

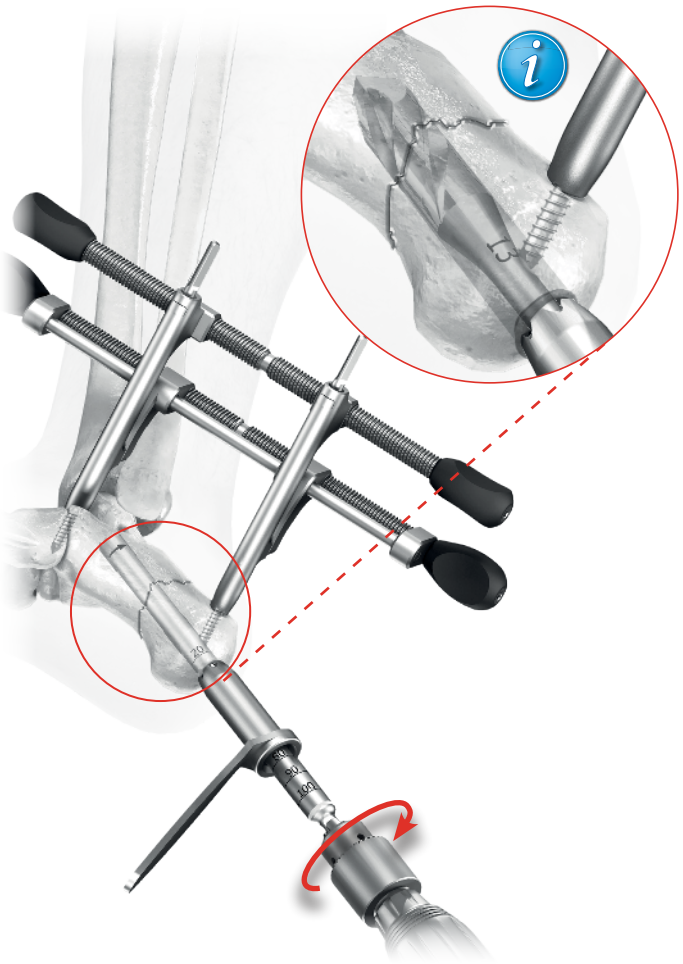
Trephine	Guide rod
11	2.8/270 **[40.6700]**
13	2.8/270 /13 **[40.6729]**

Table 4

Remove the trephine, guide rod and protective guide.

Preparation for the nail implantation and locking should be performed in accordance with stages 9÷20.

NOTE! If locking of the most distal hole of the nail is impossible, partial removal of the fibula should be considered.



5. CALCANEAL NAIL REMOVAL

23 Use screwdriver T25 **[40.6726]** to remove all the locking screws and end cap from the nail.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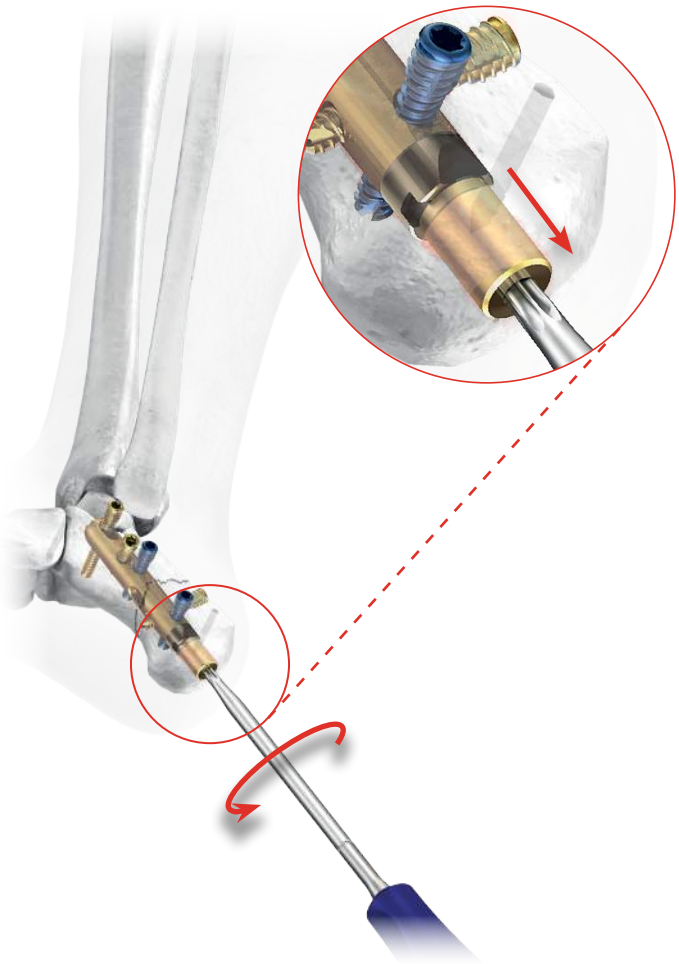

24 Insert the connector M6/M8 **[40.6724]** in the threaded hole of the nail and then impactor-extractor **[40.6725]** to the connector.

Use the mallet **[40.4595]** to remove the nail.


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40.6725.000


40.4595.000

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