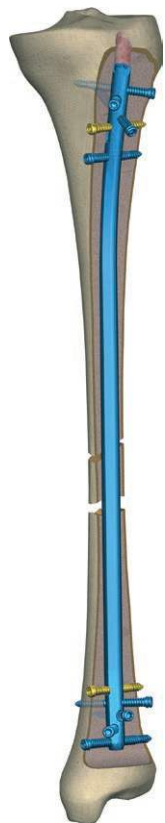


CHM[®]








CHARFIX^{system 2}

INTRAMEDULLARY TIBIA OSTEOSYNTHESIS
WITH CHARFIX2 NAILS

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



SYMBOLS DESCRIPTION

	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.

www.chm.eu

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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

CHARFIX_{system 2} - INTRAMEDULLARY TIBIA OSTEOSYNTHESIS consists of:

- implants (*intramedullary nail, locking screws, end cap or compression screw*),
- instrument set for insertion and implant removal after treatment is finished,
- instructions for use.

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

Intramedullary osteosynthesis of tibia provides stable fixation of tibial shaft fractures.

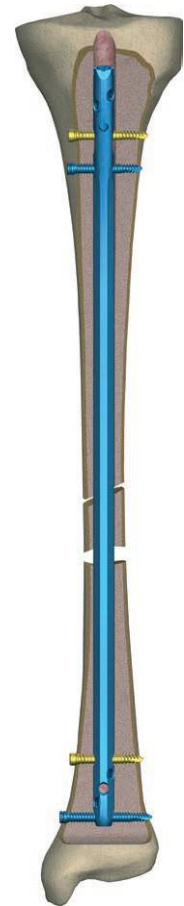
Indications for use:

- multi-fragment fractures of tibial shaft,
- fractures of tibia and fibula,
- fractures with knee ligaments injury,
- tibial fractures with compartment syndrome,
- open fractures I, II, IIIA degree by Gustillo-Anderson,
- pathological fractures,
- malunion of tibia shaft fragments due to treatment with other methods.

Depending on the type of fracture, **CHARFIX_{system 2}** allows for different types of stabilization when fixing the tibia shaft fragments.

Static stabilization

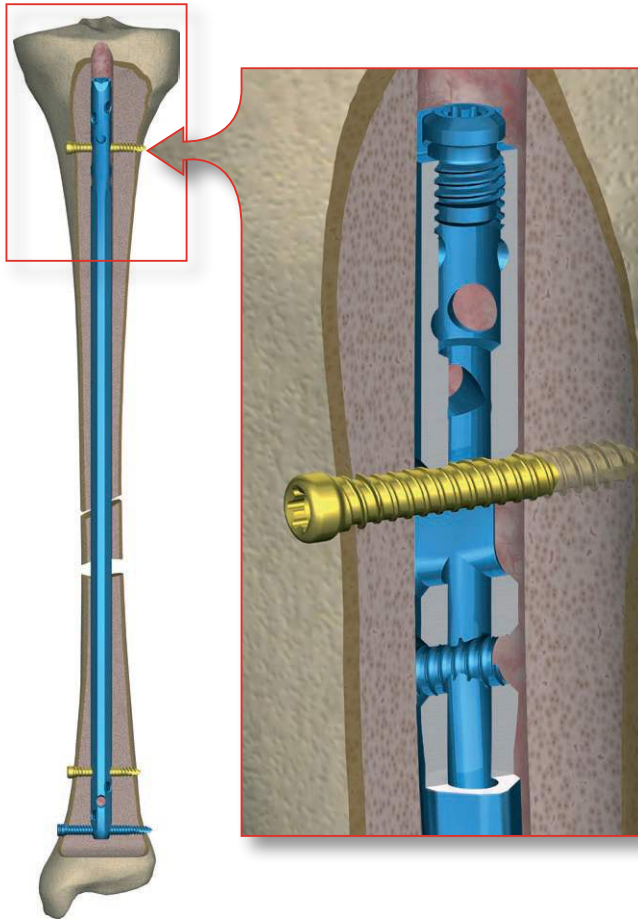
Static stabilization is utilized for multi-fragmentary fractures, when there is no axial stability of adjacent bone fragments. When using the static stabilization, at least two distal and two proximal holes should be used for locking the nail with screws.



Reconstructive stabilization

Holes placed at the top of the nail allow for multiaxial fixation of fractures of the proximal tibia.



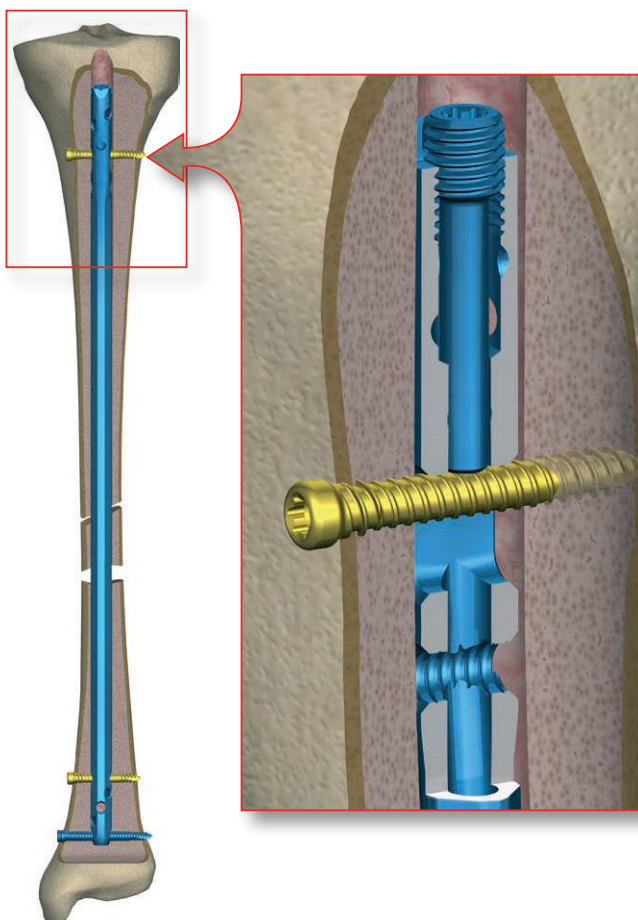


Dynamic stabilization

Dynamic fixation may be used in the case of good cortical contact of bone fragments in transverse or oblique fractures, and in the false joints.

In this fixation two distal holes and one oval-shaped hole in the proximal part of the intramedullary tibial nail should be used.

Dynamic fixation enables axial movement of bone fragments during limb loading so that physiological stimulus for bone scar formation and its remodeling into lamellar bone may occur.



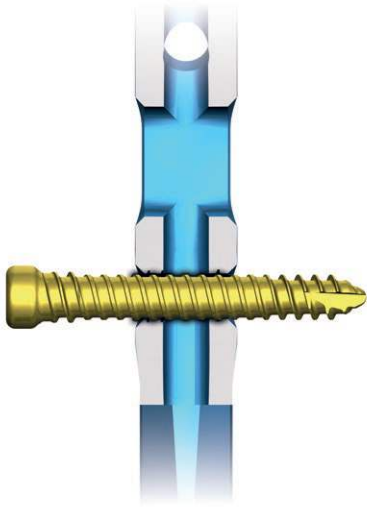
Dynamic stabilization with compression

During the dynamic stabilization with compression (*compressive fixation*) a compression screw axially inserted into the internal socket of intramedullary nail shaft is used to put pressure on the nail locking screw.

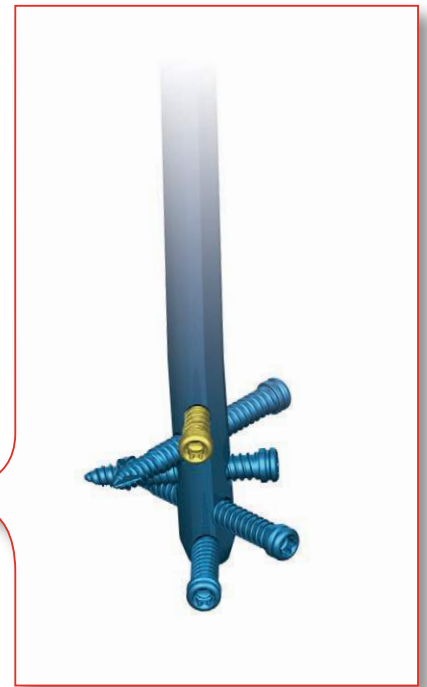
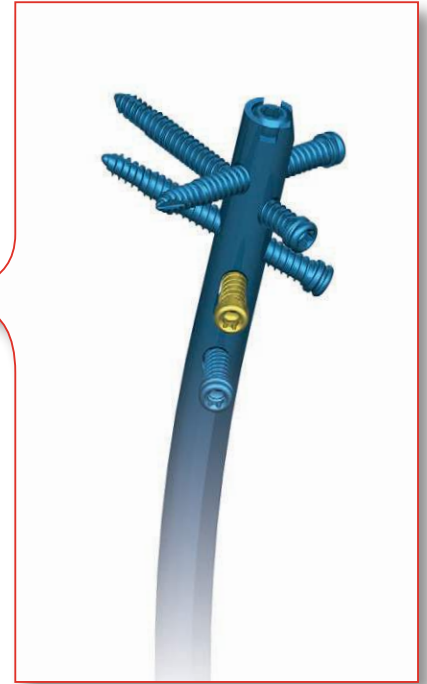
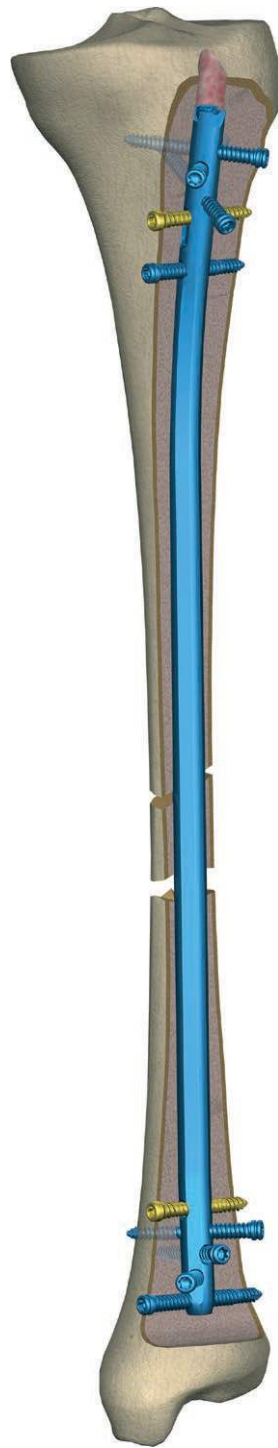
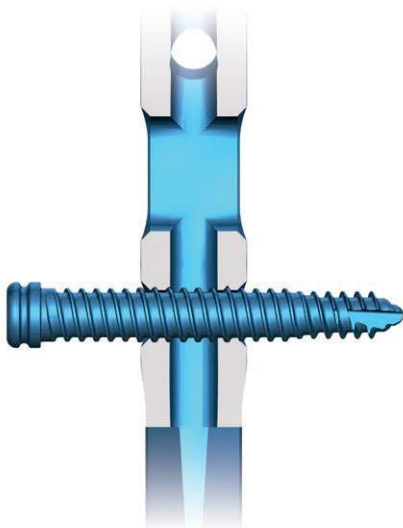
The compressive fixation eliminates all micromovements in the initial stage of the treatment.

Threaded holes allow for optional locking with the use of:

- **CHARFIX2** distal screw 4.0 or **CHARFIX2** distal screw 5.0



- **CHARFIX2** distal screw 4.5 or **CHARFIX2** distal screw 5.5 that prevent angular displacement and movement of the fragments (by using the threaded hole in the nail).



Diameter of intramedullary nail				
Ø8 and Ø9 mm		Ø10 mm and larger		
	Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole	CHARFIX2 Distal screw 4.0 (turquoise)	CHARFIX2 Distal screw 4.5 (brown)	CHARFIX2 Distal screw 5.0 (gold)	CHARFIX2 Distal screw 5.5 (blue)
Oval hole	CHARFIX2 Distal screw 4.0 (turquoise)		CHARFIX2 Distal screw 5.0 (gold)	



CHARFIX2 TIBIAL NAIL

II. IMPLANTS





	Len	
8	270	3.2651.270
	285	3.2651.285
	300	3.2651.300
	315	3.2651.315
	330	3.2651.330
	345	3.2651.345
	360	3.2651.360
	375	3.2651.375
	390	3.2651.390
	9	270
285		3.2652.285
300		3.2652.300
315		3.2652.315
330		3.2652.330
345		3.2652.345
360		3.2652.360
375		3.2652.375
390		3.2652.390
10		270
	285	3.2653.285
	300	3.2653.300
	315	3.2653.315
	330	3.2653.330
	345	3.2653.345
	360	3.2653.360
	375	3.2653.375
	390	3.2653.390
	11	270
285		3.2654.285
300		3.2654.300
315		3.2654.315
330		3.2654.330
345		3.2654.345
360		3.2654.360
375		3.2654.375
390		3.2654.390
12		270
	285	3.2655.285
	300	3.2655.300
	315	3.2655.315
	330	3.2655.330
	345	3.2655.345
	360	3.2655.360
	375	3.2655.375
	390	3.2655.390


	Ti					
3.5160.xxx	✓	✓		5.5	30÷90	■
3.5159.xxx	✓			5.0	30÷90	●
3.5170.xxx	✓	✓		4.5	25÷80	●
3.5169.xxx	✓			4.0	25÷80	○
3.5162.002	✓					◐
3.5161.1xx	✓		✓		0÷15	◆

available		Ø	8 mm ±14 mm	pitch	1 mm
		L	210 mm ±600 mm		5

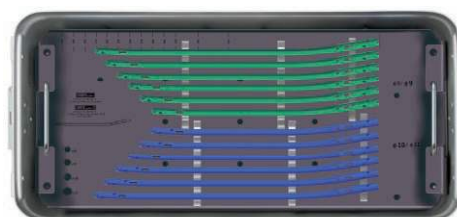
CHARFIX2 TIBIAL NAIL



		
	Len	Ti
8	270	3.2665.270
	285	3.2665.285
	300	3.2665.300
	315	3.2665.315
	330	3.2665.330
	345	3.2665.345
	360	3.2665.360
	375	3.2665.375
	390	3.2665.390
9	270	3.2666.270
	285	3.2666.285
	300	3.2666.300
	315	3.2666.315
	330	3.2666.330
	345	3.2666.345
	360	3.2666.360
	375	3.2666.375
	390	3.2666.390
10	270	3.2667.270
	285	3.2667.285
	300	3.2667.300
	315	3.2667.315
	330	3.2667.330
	345	3.2667.345
	360	3.2667.360
	375	3.2667.375
	390	3.2667.390

available		Ø	8 mm ÷ 14 mm	pitch	1 mm
		L	210 ÷ 600 mm		5 mm

Use with instrument set [40.5300.500]



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

40.5750.000



LOCKING ELEMENTS



CHARFIX2 DISTAL SCREW 4.0



25	3.5169.025
30	3.5169.030
35	3.5169.035
40	3.5169.040
45	3.5169.045
50	3.5169.050
55	3.5169.055
60	3.5169.060
65	3.5169.065
70	3.5169.070
75	3.5169.075
80	3.5169.080



CHARFIX2 DISTAL SCREW 4.5



25	3.5170.025
30	3.5170.030
35	3.5170.035
40	3.5170.040
45	3.5170.045
50	3.5170.050
55	3.5170.055
60	3.5170.060
65	3.5170.065
70	3.5170.070
75	3.5170.075
80	3.5170.080



CHARFIX2 DISTAL SCREW 5.0



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



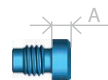
CHARFIX2 DISTAL SCREW 5.5



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



CHARFIX2 END CAP M8



A	
0	3.5161.100
+5	3.5161.105
+10	3.5161.110
+15	3.5161.115

CHARFIX2 COMPRESSION SCREW M8X1.25



3.5162.002




















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















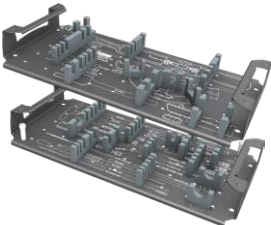

40.5058.200

III. INSTRUMENT SET

Instrument set [40.5300.500] is used to fix fragments of the tibial shaft, and to remove the implants after the treatment period. All instruments are placed in a stand with a container and lid to enable sterilization and transportation to the operating suite.

CHARFIX *system 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
	Nail length measure	40.4798.500	1

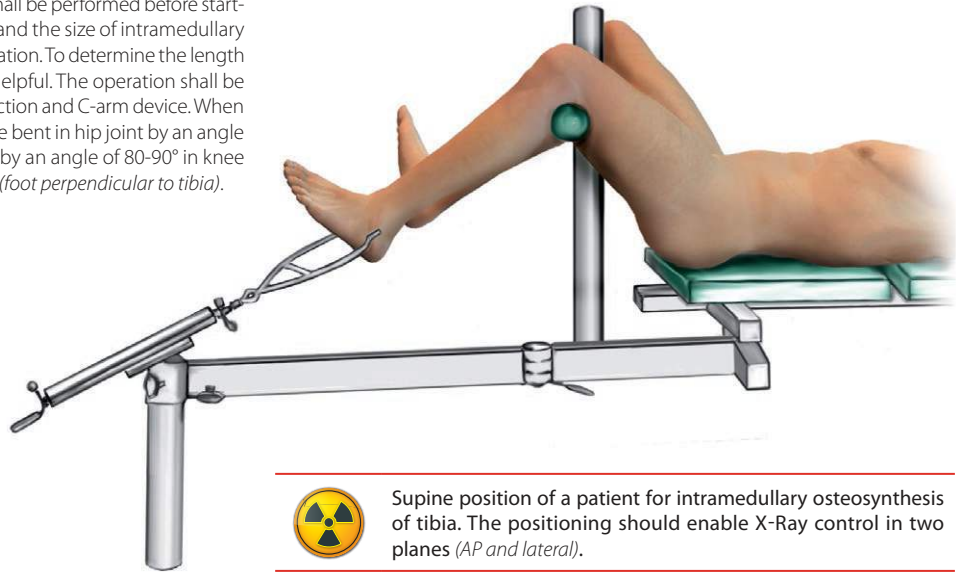
40.5300.500	Name	Catalogue No.	Pcs
	Guide rod handle	40.1351.000	1
	Teflon pipe guide 8/400	40.3700.000	1
	Drill with scale 3.5/150	40.5343.002	1
	Targeter D	40.1344.100	1
	Drill guide short 7/3.5	40.1358.100	1
	Trocar short 7	40.1354.100	1
	Aiming insert 9.0	40.5065.009	2
	Guide rod 2.5/580	40.3673.580	1
	Screwdriver T25	40.5575.300	1
	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
	Container with solid bottom 1/1 595x275x185mm	12.0750.103	1

IV. SURGICAL TECHNIQUE

IV.1. INTRODUCTION

Each surgical procedure must be carefully planned.

X-Ray of the tibial fracture in AP and lateral position shall be performed before starting the operation in order to define type of fracture and the size of intramedullary nail (*length, diameter*) that should be used for implantation. To determine the length of the nail, the fibula length measurement is often helpful. The operation shall be performed on the operating table equipped with traction and C-arm device. When patient is placed supine, the operated limb should be bent in hip joint by an angle of 70-90°, abducted by an angle of 10-20° and bent by an angle of 80-90° in knee joint; the ankle joint should stay in neutral position (*foot perpendicular to tibia*).



Supine position of a patient for intramedullary osteosynthesis of tibia. The positioning should enable X-Ray control in two planes (AP and lateral).

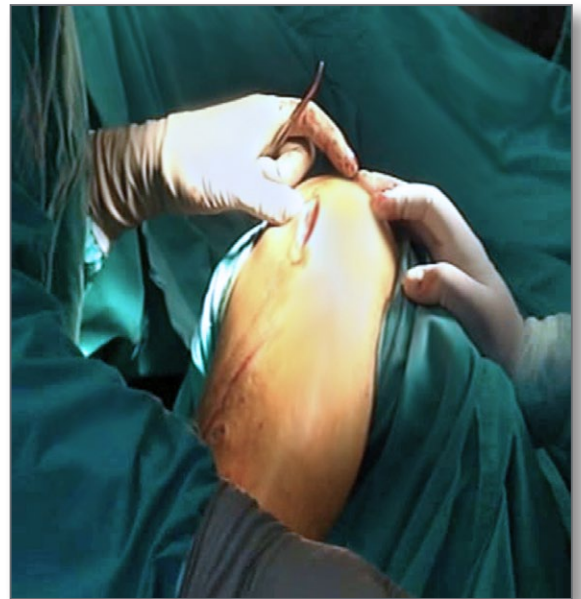
Surgical approach should be prepared by:

- longitudinal skin incision from the lower pole of patella to the point placed medially from tuberosity of tibia,
- incision along medial edge of patella tendon as well as its aside move.

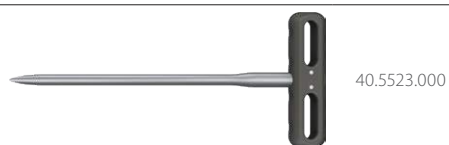
Insertion point is placed on extension of the line proceeding in the middle of intramedullary canal (*X-Ray in AP position*) and is also located on edge of tibial tuberosity and its front edge of epiphysis.

Intramedullary canal should be 1.5-2.0 mm wider than the diameter of the tibial nail.

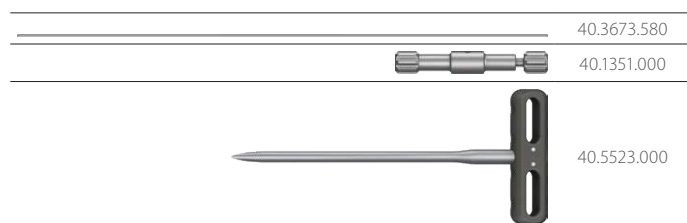
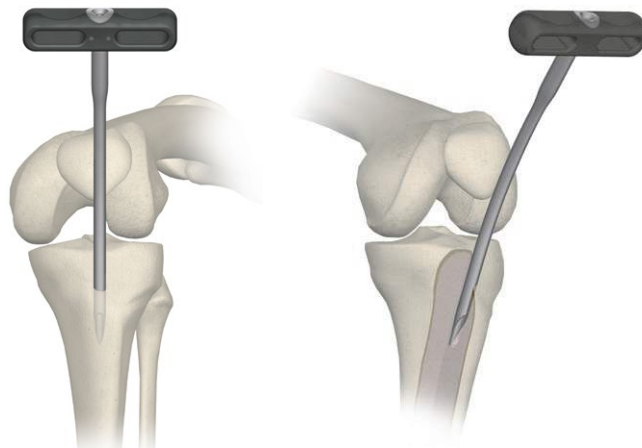
In the case of reaming, intramedullary canal should be 1.5-2.0 mm wider than the diameter of the tibial nail. The proximal part of intramedullary canal should be reamed in depth of 5 cm and for width of 12 mm diameter.



IV.2. OPENING THE MEDULLARY CANAL

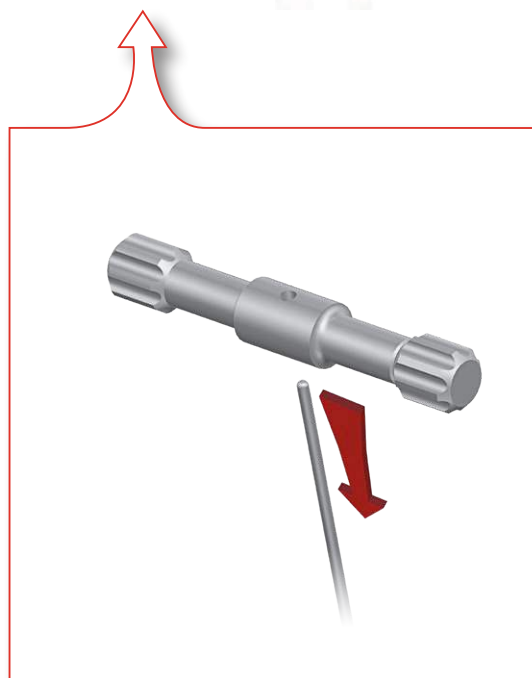
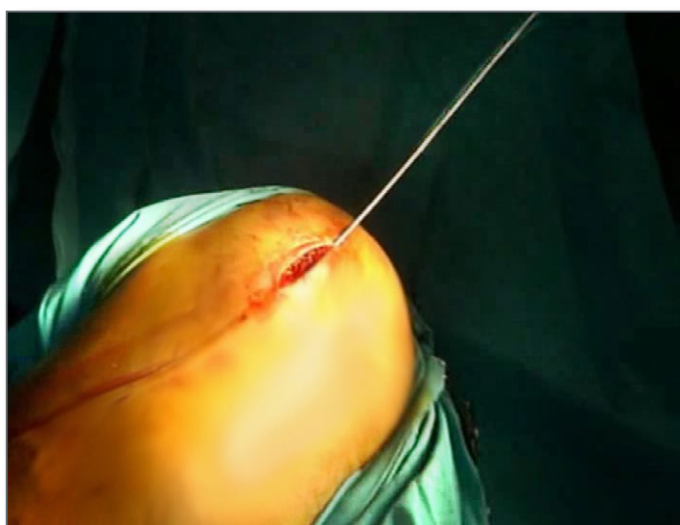
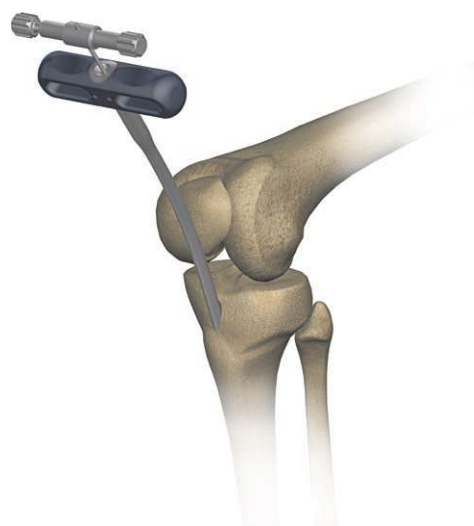


- 1 Use the curved awl 8,0 [40.5523.000] to open the medullary canal. Insert the awl at an angle of 10° in relation to the main axis of the medullary canal.



- 2 Mount the guide rod handle [40.1351] onto the guide rod 2,5/580 [40.3673.580]. Advance both via the curved awl 8,0 [40.5523.000] into the hole until it reaches the distal epiphysis of tibia reducing the fracture at the same time.

Remove the guide rod handle [40.1351] and the curved awl [40.5523.000].



IV.3. PREPARATION OF MEDULLARY CANAL FOR NAIL INSERTION

IV.4. OPTION I: Reamed canal

40.3673.580

3 Gradually widen the medullary cavity with flexible reamers, with steps of 0.5 mm, until the diameter of the canal is from 1.5 to 2 mm wider than the diameter of the nail, at a depth at least equal to the nail length. In case of using the nail of a diameter of 10 mm or smaller, the proximal part of the medullary canal shall be widened to the diameter of 12 mm to a depth of 5 cm.

Remove the flexible reamer.
Leave the guide rod in the medullary canal.



IV.4.1. OPTION II: Unreamed canal

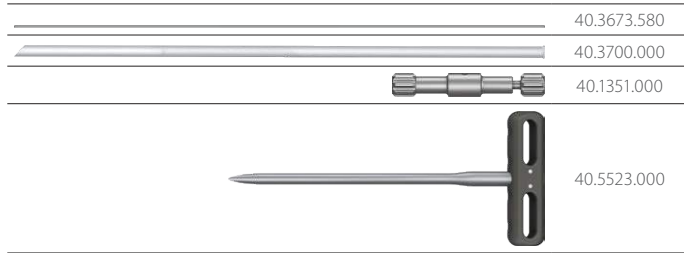
40.3673.580

4 Widen the proximal part of the medullary canal with reamers to a depth of 5 cm.

For nails with diameter of 10 mm or smaller - to 12 mm of diameter of the canal, for nails of diameter of 11 mm or larger - to the diameter from 1.5 to 2 mm wider than the diameter of the nail.

Remove the flexible reamer.
Leave the guide rod in the medullary canal.



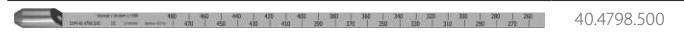


5 In case of using a different reamer guide than the guide rod 2.5/580 [40.3673.580] provided in the instrument set, replace the guide for the guide rod 2.5/580 [40.3673.580] when taking the nail length measurement.

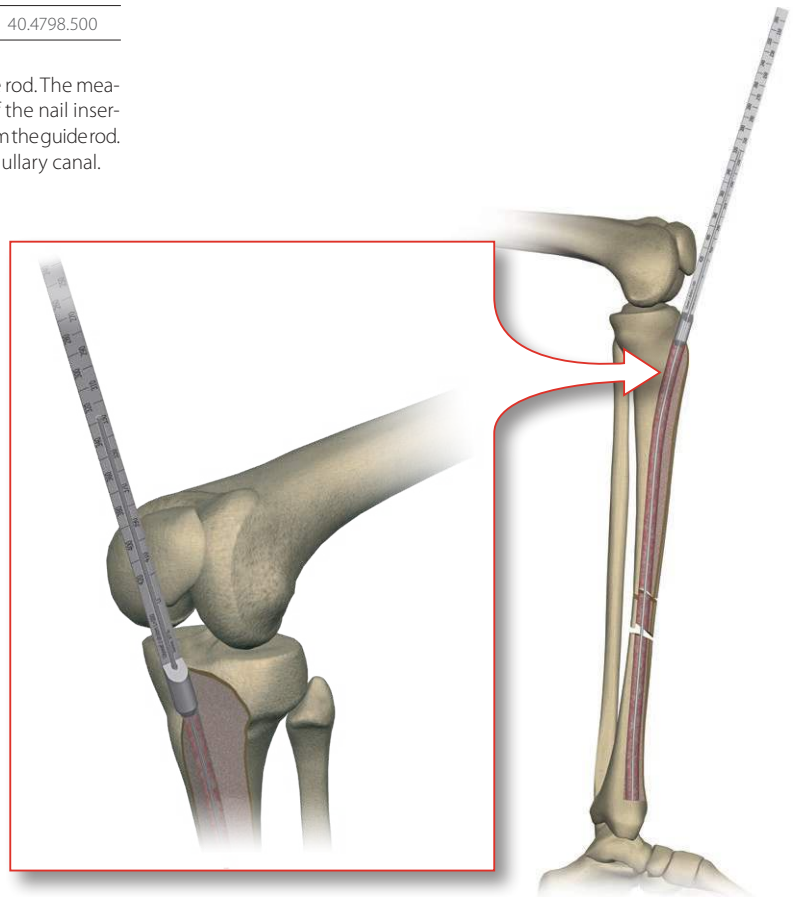
Insert the teflon pipe guide [40.3700] into the medullary canal over the flexible reamer guide. Remove the reamer guide. Mount the guide rod 2.5/580 [40.3673.580] (cannulated nail guide) in the guide rod handle [40.1351] and insert it into the teflon pipe guide [40.3700] until its end tip reaches the distal tibia metaphysis.

Remove the handle from the guide rod.

Remove the teflon pipe guide.



6 Insert the nail length measure [40.4798.500] via the guide rod. The measure beginning should be placed at a demanded depth of the nail insertion. Read the length on the nail measure scale. Remove the measure from the guide rod. In case of using the solid nail, remove the guide rod from the medullary canal. The medullary canal is ready for nail insertion.



IV.5. NAIL INSERTION



7 Before the nail insertion, the slider of the targeter D [40.5302.100] should be set in relation to the distal holes of the nail. There are two types of proximal targeters.

**Option I:**

Targeter arm B [40.5301] + connecting screw M8x1.25 L-89 [40.5305]

**Option II:**

Targeter arm B short [40.5312] + connecting screw M8x1.25 L-22 [40.5306]



The way of mounting the targeter arm B with targeter D [40.5302.100] and the position of the slider in distal part depends on the operated limb (*left or right*). It is recommended to place the targeter during the assembly in such a way that its proximal part is directed to an operator and the distal bent part is directed upward.

Right leg:

- connective part of the targeter D should be inserted into socket of the targeter arm B from the right side and mounted using cap,
- slider of the targeter D in distal part should be arranged in such a way, that fixing and mounting elements are placed on the left side.

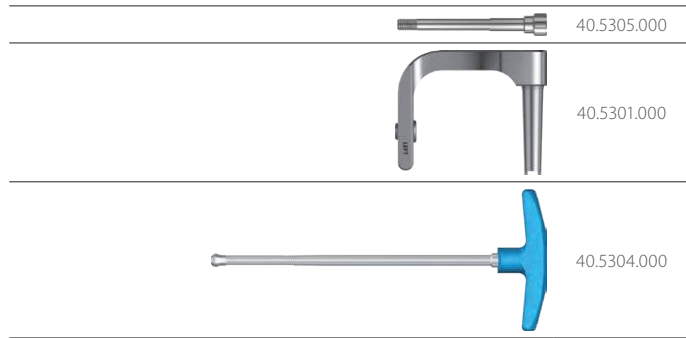
Left leg:

- connective part of the targeter D should be inserted into socket of the targeter arm B from left side and mounted using cap,
- slider of the targeter D in distal part should be arranged in such a way, that fixing and mounting elements are placed on the right side.



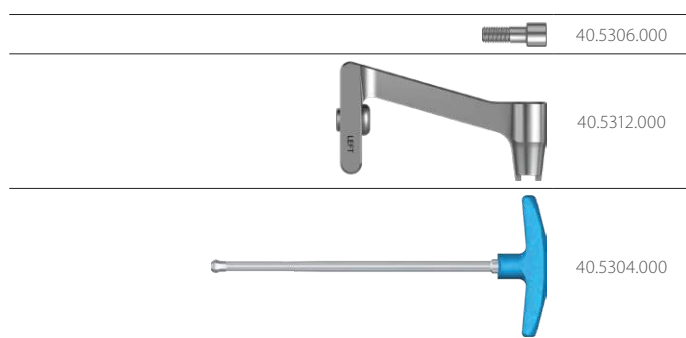
configuration for left leg surgery

configuration for right leg surgery

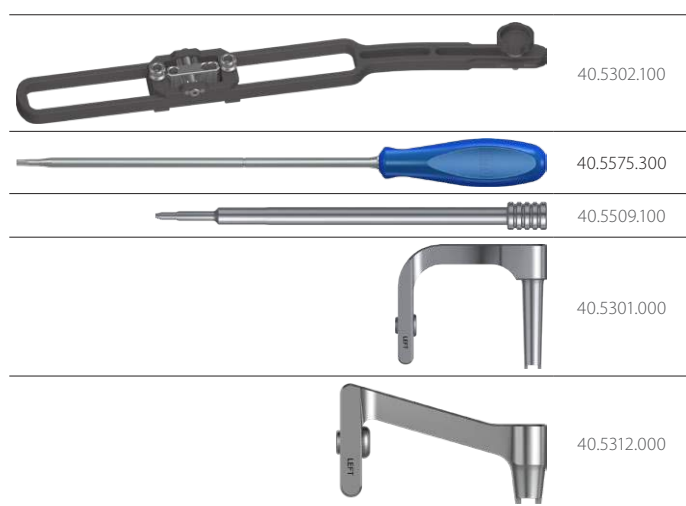


8 Mounting the nail into targeter arm.

Option I:
Fix the intramedullary nail to the targeter arm B [40.5301] with the connecting screw M8 [40.5305] using the wrench S8 [40.5304].



Option II:
Fix the intramedullary nail to the targeter arm B short [40.5312] with the connecting screw M8 [40.5306] using the wrench S8 [40.5304].



9 Fixing the targeter D [40.5302.100] to the nail.

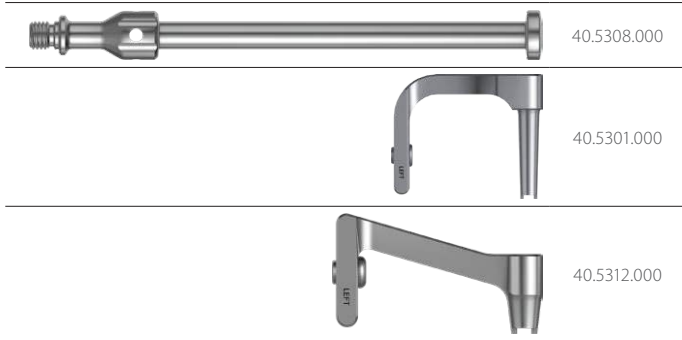


When the guide and the nail are correctly mounted, the directions of deflection of distal parts of the nail and targeter D [40.5302.100] are the same.

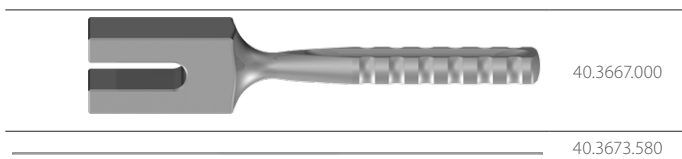
With the help of a screwdriver T25 [40.5575.300] set the slider of the targeter in the middle of the slider plate. Using two set blocks 9/5.0 [40.5509.100] set the slider in line with distal locking holes of the intramedullary nail. Lock the slider with a screw using the screwdriver T25 [40.5575.300].

Remove the set blocks from the targeter's slider. Detach the targeter D [40.5302.100] from the targeter arm B [40.5301] or [40.5312].





- 10 Attach the impactor-extractor [40.5308] to the targeter arm B [40.5301] or [40.5312].



- 11 Use the mallet [40.3667] to insert the nail into the intramedullary canal at an appropriate depth.



Cannulated nail should be inserted into the medullary canal via the guide rod 2.5/580 [40.3673.580]. Solid nail should be inserted directly into the medullary canal (without the use of a guide rod).

Detach the impactor-extractor from the targeter arm.
Remove the guide rod (in case of implantation of a cannulated nail).



IV.6. DISTAL LOCKING OF INTRAMEDULLARY NAIL



It is possible to lock the nail in its distal part maximally on four levels. Targeter D [40.5302.100] utilizes one round and one oval hole, which are located laterally.

		Diameter of intramedullary nail			
		Ø8 and Ø9 mm		Ø10 mm and larger	
		Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole		CHARFIX2 Distal screw 4.0 (turquoise)	CHARFIX2 Distal screw 4.5 (brown)	CHARFIX2 Distal screw 5.0 (gold)	CHARFIX2 Distal screw 5.5 (blue)
Oval hole		CHARFIX2 Distal screw 4.0 (turquoise)		CHARFIX2 Distal screw 5.0 (gold)	

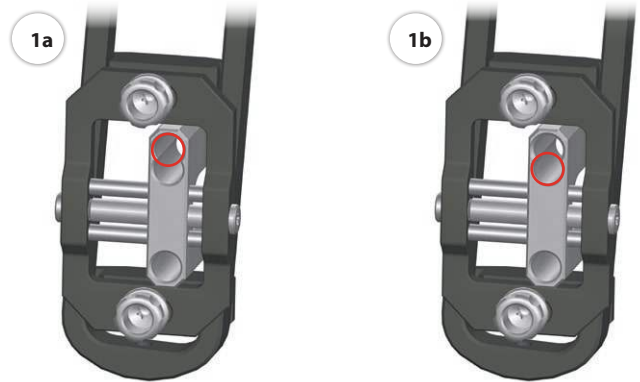
Depending on the method of bone fragments stabilization it is possible to insert the distal screws into the nail oval-shaped hole:

a) static method:

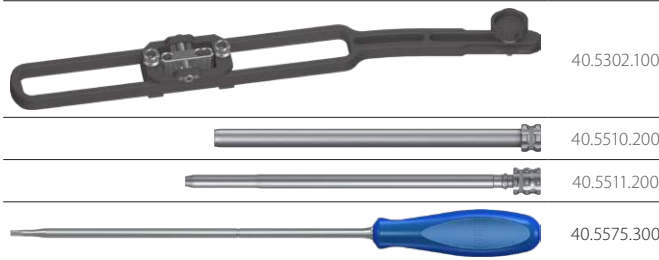
12 Instruments from the instrument set [40.5300.500] are inserted into the proximal part of the dual hole.

b) dynamic method with compression:

13 Instruments from the instrument set [40.5300.500] are inserted into the distal part of the dual hole.



IV.6.1. OPTION I: With X-Ray control

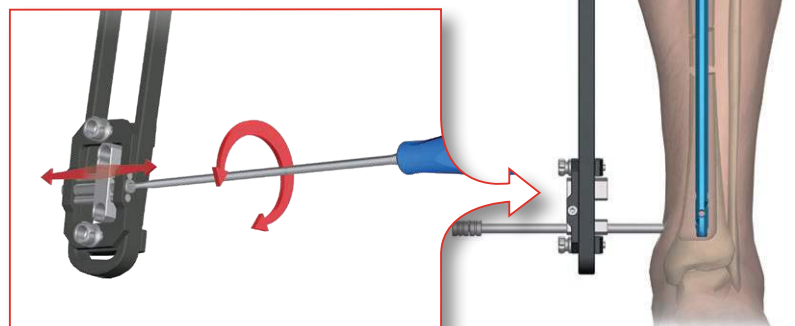


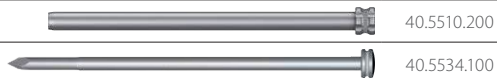
14 Use the image intensifier to verify the mutual position of holes in the targeter slider and in the distal part of the intramedullary nail.

Mount the targeter D [40.5302.100] to the targeter arm. Place the image intensifier in such a way that the image displayed shows round holes (proximal and distal). Insert the protective guide 9/7 [40.5510.200] and drill guide 7/3.5 [40.5511.200] into the appropriate hole of the targeter slider - the tip of the drill guide should rest on soft tissue of the lower limb.

Use the image intensifier to verify the mutual position of holes in the drill guide and intramedullary nail.

The holes in the nail and drill guide must coincide - the display should show a circle (shape similar to circle is acceptable). The targeter position should be corrected if the shape on display differs from circle. Use the screwdriver T25 [40.5575.300] to shift the targeter slider (by turning the screw left or right) until the shape on display is a circle (shape similar to circle is acceptable).

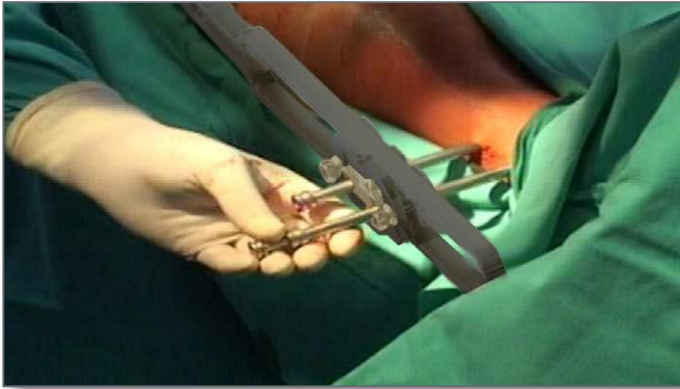




- 15** Remove the drill guide from the protective guide. Insert the protective guide 9/7 [40.5510.200] (one groove on the handle) together with the trocar 6.5 [40.5534.100] into one of the slider holes. Mark the entry point for the locking screws, then perform incision through the soft tissues along the marked point.

Reach the cortical layer of bone with the trocar and mark the entry point for the drill. Simultaneously advance the protective guide and the trocar until they reach the bone.

Remove the trocar.



- 16** Insert the drill guide 7/3.5 [40.5511.200] into the left protective guide. Use the electric drive with a drill with scale 3.5/350 [40.5539.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers and the nail hole. The scale on the drill indicates the length of the locking element.



The drilling process should be controlled with image intensifier.

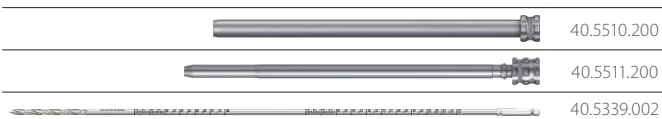
After disconnecting the drive the drill should remain in the drilled hole.





- 17** Insert the protective guide 9/7 [40.5510.200] with trocar 6.5 [40.5534.100] into the second slider hole of the targeter D [40.5302.100]. Advance the protective guide with trocar into the incision until they reach the cortex layer of the bone.

Remove the trocar.



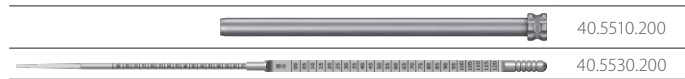
- 18** Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200]. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers and the nail hole. The scale on the drill indicates the length of the locking element.



The drilling process should be controlled with image intensifier.

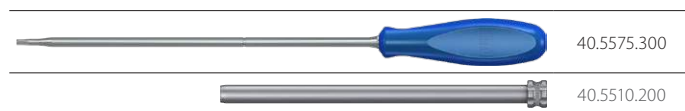
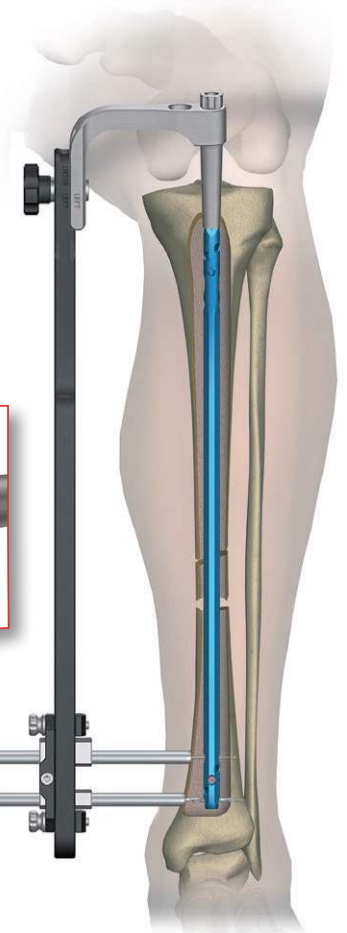
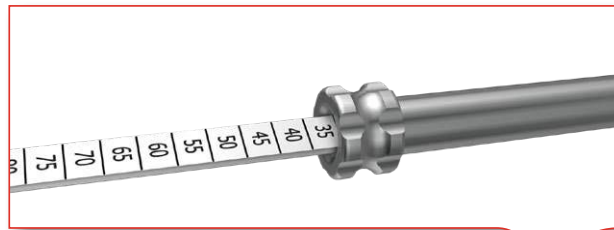
Remove the drill and the drill guide.
Leave the protective guide in the slider hole.



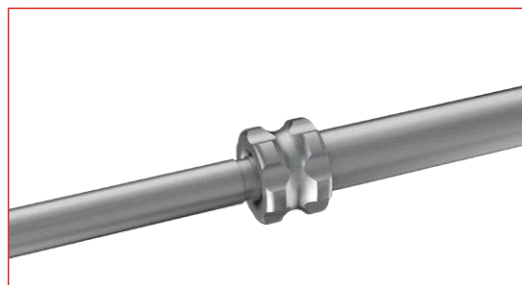






19 Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D scale. During the measurement, the tip of the protective guide should rest on the cortical layer of bone.

Remove the screw length measure.
Leave the protective guide in the slider hole.



20 Insert the tip of the screwdriver T25 [40.5575.300] into the socket of a locking screw. Then insert them into the protective guide 9/7 [40.5510.200] and insert the locking screw into the drilled hole until the screw head reaches the cortical layer of bone (the groove on the screwdriver shaft should match the edge of protective guide ending).






	40.5339.002
	40.5511.200
	40.5510.200
	40.5530.200

- 21** Remove the drill with scale 3.5/350 [40.5339.002] and drill guide 7/3.5 [40.5511.200] from the distal hole in the slider. Leave the protective guide 9/7 [40.5510.200] in the slider hole. Insert the screw length measure [40.5530.200] through the protective guide into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

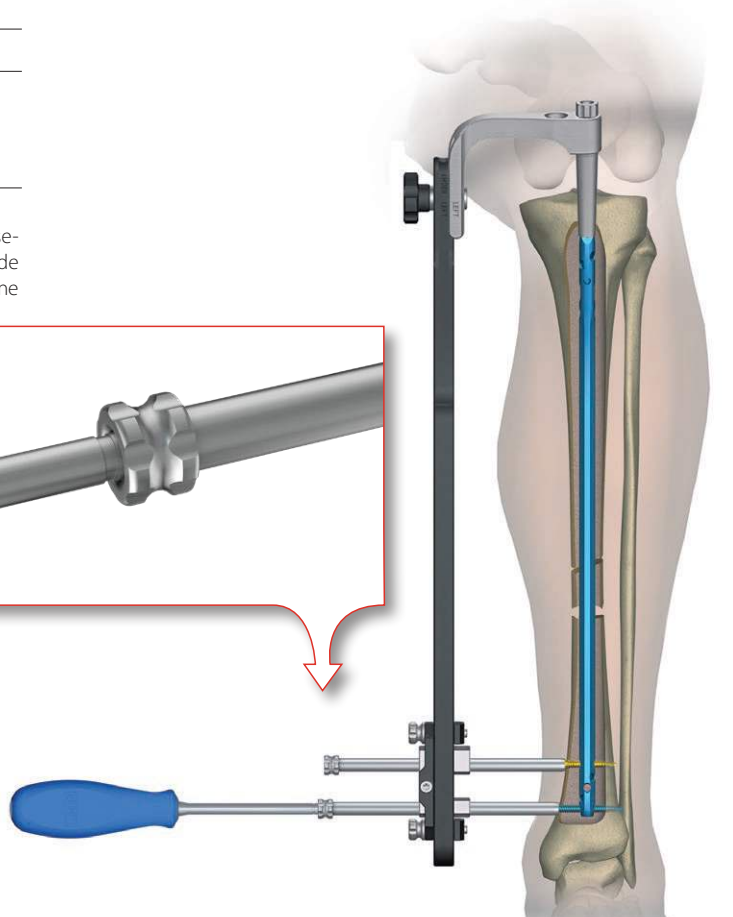
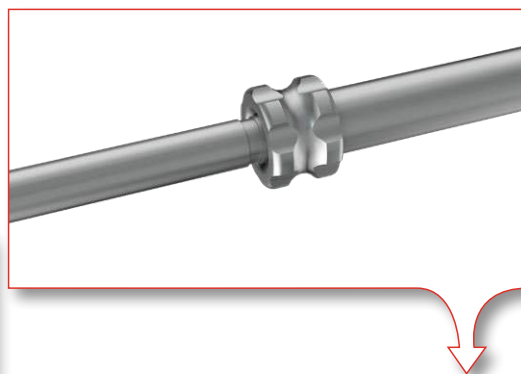
Remove the screw length measure.
Leave the protective guide in the slider hole.



	40.5575.300
	40.5510.200
	40.5302.100

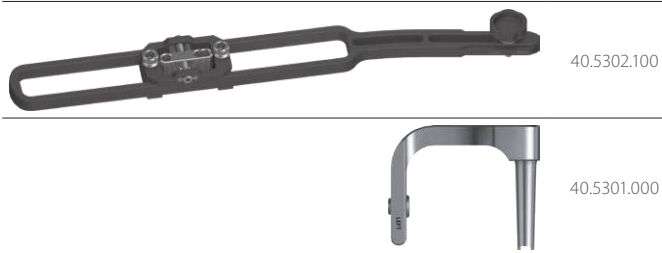
- 22** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*).

Remove the screwdriver and the protective guides.
Remove the targeter D [40.5302.100].

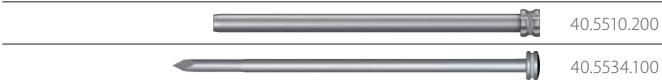


IV.6.2. OPTION II: Without X-Ray control

a) determine the location of the nail holes by adjusting the position of targeter D slider.



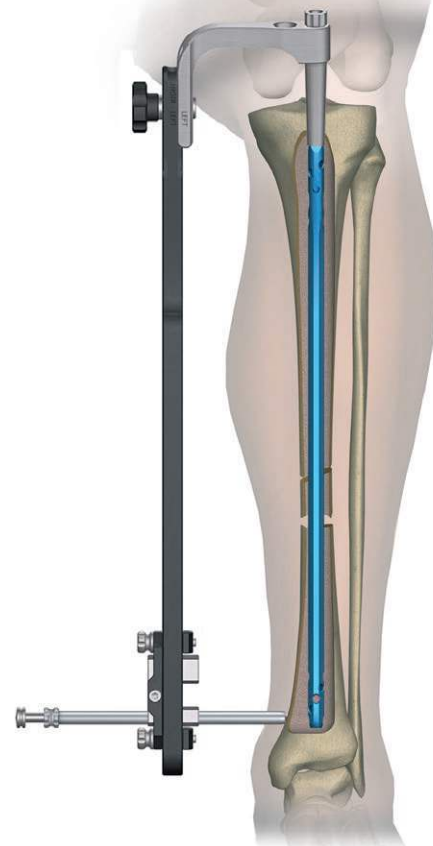
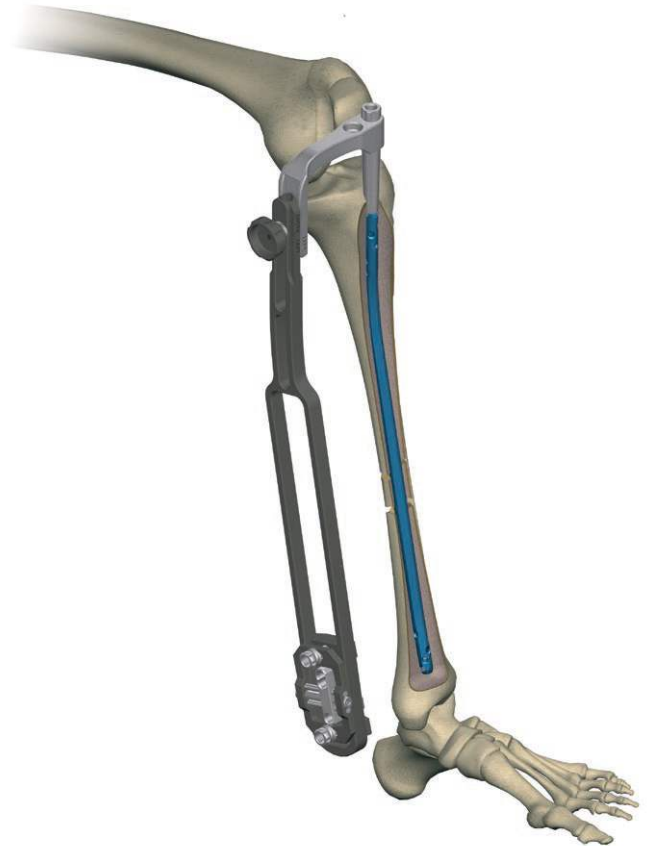
23 Mount the targeter D [40.5302.100] on the targeter arm B [40.5301].






24 Insert the protective guide 9/7 [40.5510.200] and trocar 6.5 [40.5534.100] into one of the slider holes (*distal hole is preferred*).

Mark the entry point on the skin for the locking screws and make the incision of soft tissues that include this point. Then advance the protective guide and trocar until they reach the cortical layer of bone and mark the entry point for the drill.



Remove the trocar.



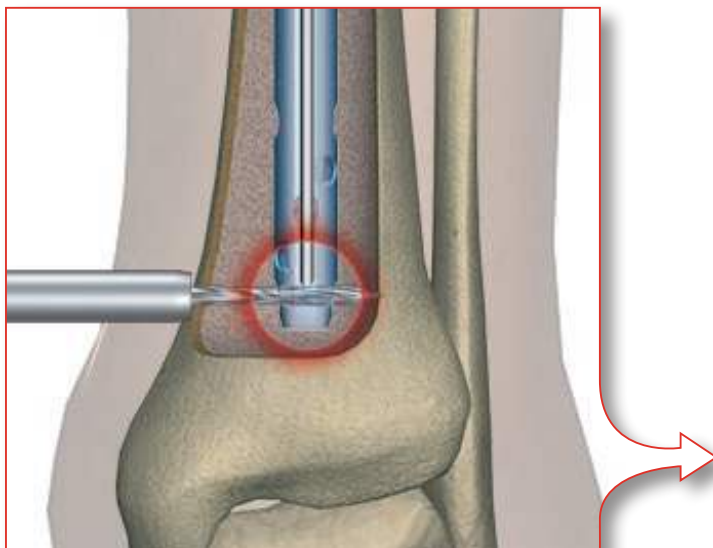
	40.5510.200
	40.5511.200
	40.5339.002

25 Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200] until the drill guide end rests on the bone. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its first cortical layer and the nail hole.



	40.3673.580
	40.5305.000

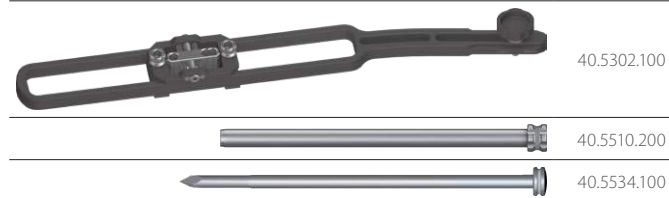
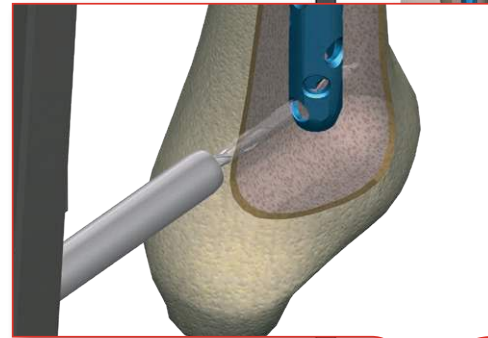
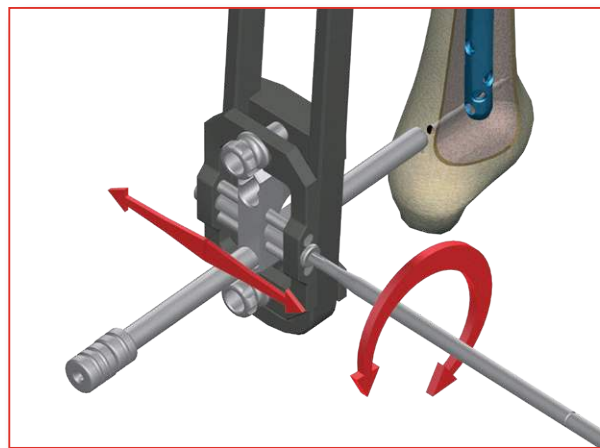
26 Correct placement of the drill may be controlled by the guide rod 2.5/580 [40.3673.580], which is inserted into the connecting screw M8 [40.5305] and oval-shaped hole of the nail. The drill inside the nail hole creates resistance for the guide rod.



27 If the drill goes through the first cortical layer but misses the hole, then:

- back the drill to enable slider to move,
- turn the knob of the slider regulation screw in desired direction by four full turns. Turn of the knob clockwise moves the slider „up“, counter-clockwise - moves the slider „down“.




If the drill goes through the nail hole, drill through the other layer of the cortical bone. After disconnecting the drive, the drill should remain in the drilled hole. Scale on the drill determines the length of the locking element.



28 Insert the protective guide 9/7 [40.5510.200] with trocar 6.5 [40.5534.100] into the second (*proximal*) slider hole of the targeter D [40.5302.100]. Advance the protective guide and trocar into the incision until they rest on the cortical bone. Use the trocar to mark the entry point for the drill.

Remove the trocar.
Leave the protective guide in the slider hole.



	40.5510.200
	40.5511.200
	40.5339.002

29 Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200] until the drill guide end rests on the soft tissue of the lower limb. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its first cortical layer and the nail hole.



If the drill misses the nail hole then use the first hole in the targeter slider to find the hole.

Use the guide rod to check whether the drill is actually located in the hole (*tip of the guide rod leans against the surface of the drill*).

If the drill goes through the nail hole, then drill through the other cortical layer of the bone. Disconnect the electric drive from the drill and leave the drill inside the hole. The scale on the drill indicates the locking element length.

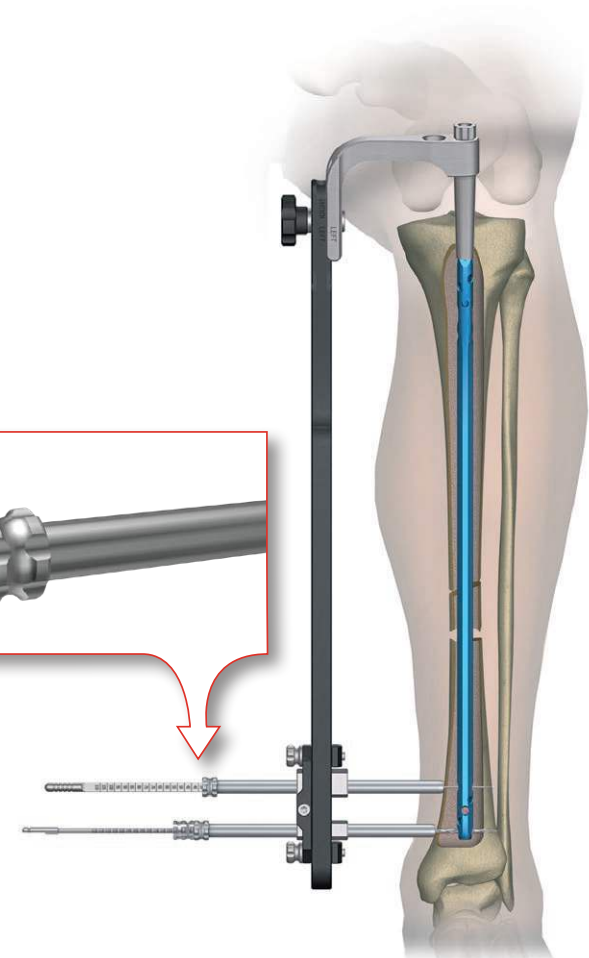
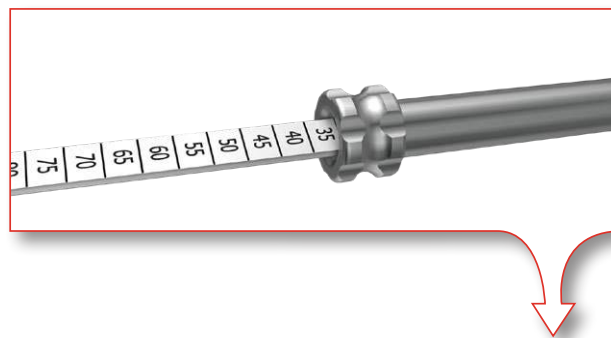
Remove the drill and drill guide.
Leave protective guide in place.

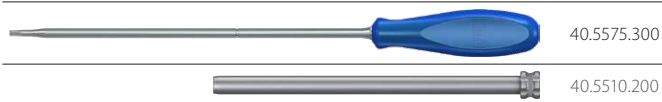


	40.5510.200
	40.5530.200

30 Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

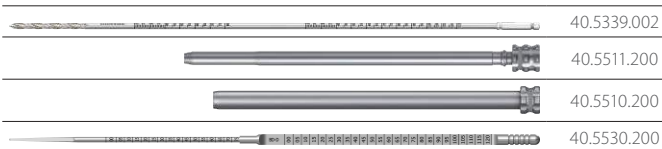
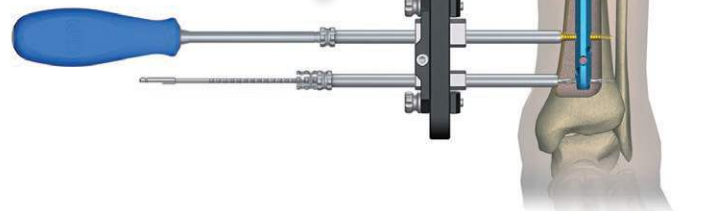
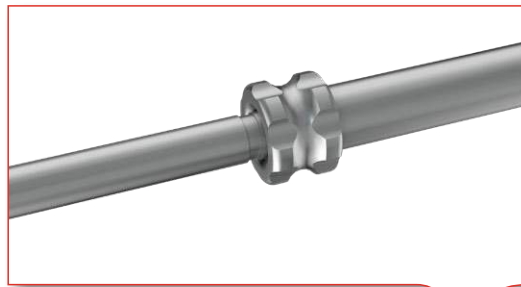
Remove the screw length measure.
Leave the protective guide in the slider hole.





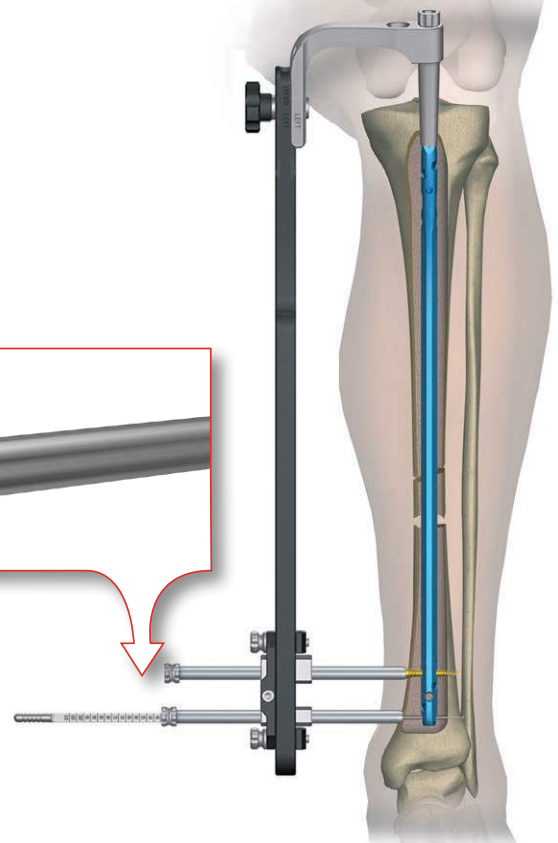
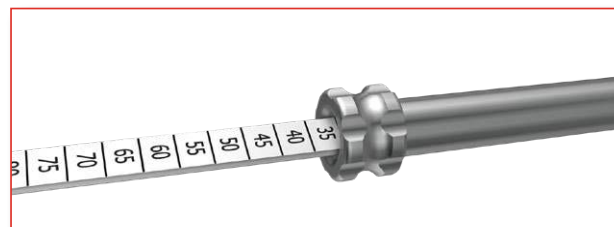
- 31** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*).

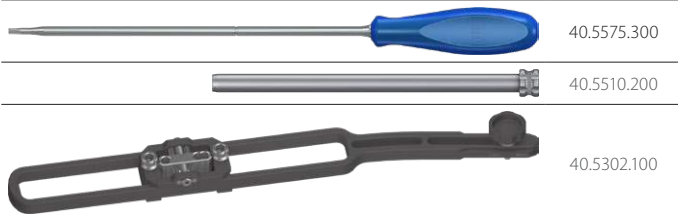
Remove the screwdriver.
Leave the protective guide.



- 32** Remove the drill with scale 3.5/350 [40.5339.002] and drill guide 7/3.5 [40.5511.200] from the second hole of the targeter slider, but leave the protective guide 9/7 [40.5510.200] in the slider hole. Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

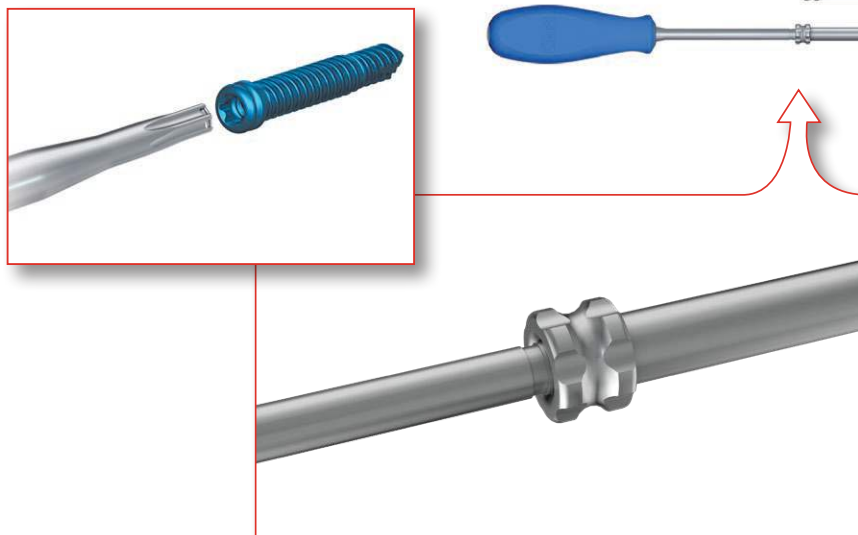
Remove the screw length measure.
Leave the protective guide in the slider hole.





33 Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*).

Remove the screwdriver, protective guides and targeter D [40.5302.100]



		Diameter of intramedullary nail			
		Ø8 and Ø9 mm		Ø10 mm and larger	
		Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole	CHARFIX2 Distal screw 4.0 (turquoise)	CHARFIX2 Distal screw 4.5 (brown)	CHARFIX2 Distal screw 5.0 (gold)	CHARFIX2 Distal screw 5.5 (blue)	
Oval hole	CHARFIX2 Distal screw 4.0 (turquoise)		CHARFIX2 Distal screw 5.0 (gold)		

IV.7. PROXIMAL LOCKING OF INTRAMEDULLARY NAIL



CHARFIX2 tibial nail has 5 holes in its proximal part. The decision regarding the number and place of locking screws to be inserted depends on the fracture fixated and is made by the surgeon.

IV.8.1. Dynamic fixation and dynamic fixation with compression
(compressive fixation)

40.5303.100

Proximal part of the targeter B [40.5303.100] has two lateral holes for locking the nail in the oval-shaped hole.

When the dynamic fixation or dynamic fixation with compression is used, the proximal locking of the nail should be performed through the proximal targeter hole (the oval-shaped hole in the intramedullary nail).

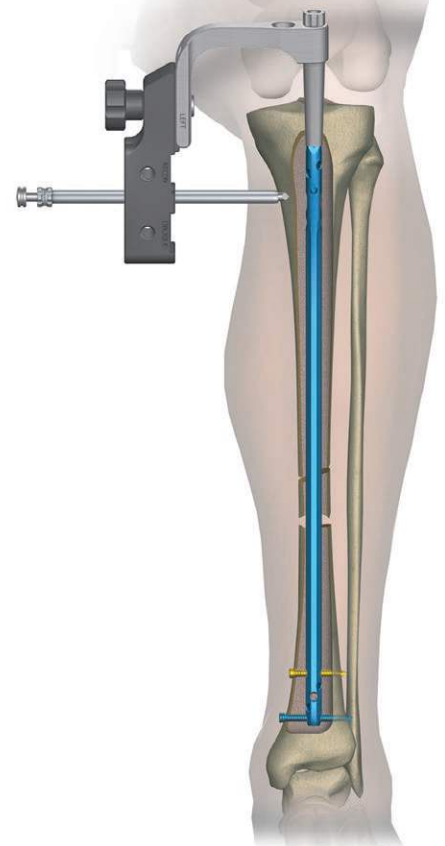
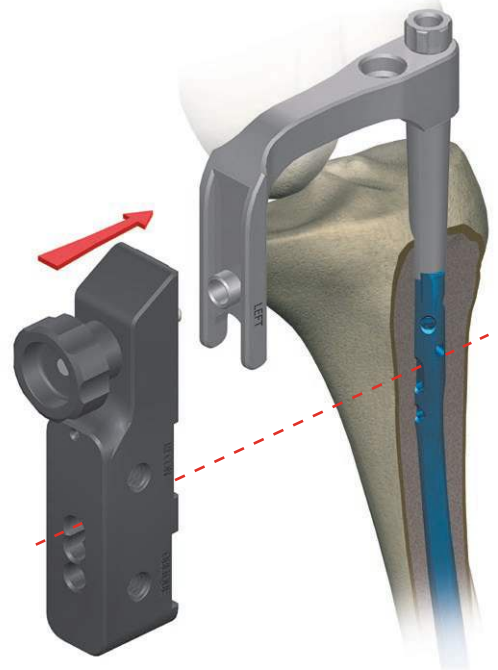
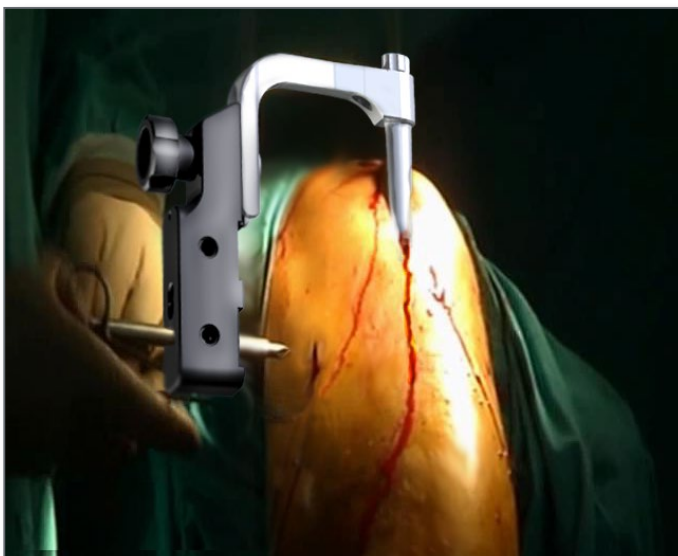


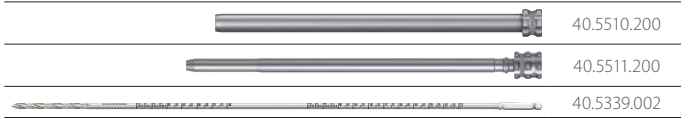
40.5510.200

40.5534.100

- 34** Insert the protective guide 9/7 [40.5510.200] together with the trocar 6.5 [40.5534.100] into the proximal part of the targeter. Mark the entry point for the locking screw, then perform incision through the soft tissues along the marked point with a length of about 1.5 cm. Advance the protective guide with trocar into the incision to place it as close to the cortical layer of bone as possible. Use the trocar to mark the entry point for the drill.

Remove the trocar.
Leave the protective guide in the targeter slider.



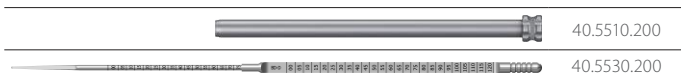
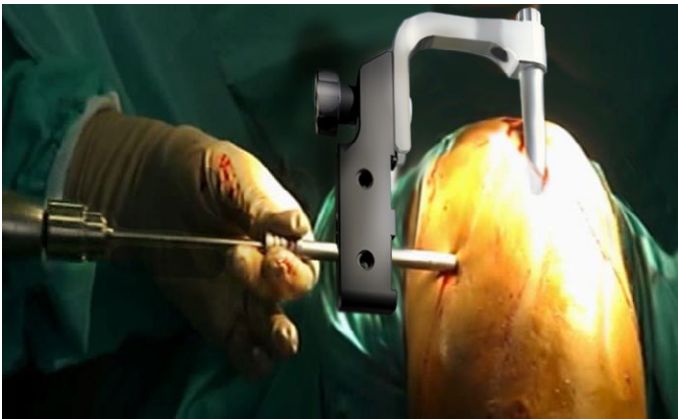


- 35** Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200]. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates the length of the locking element.



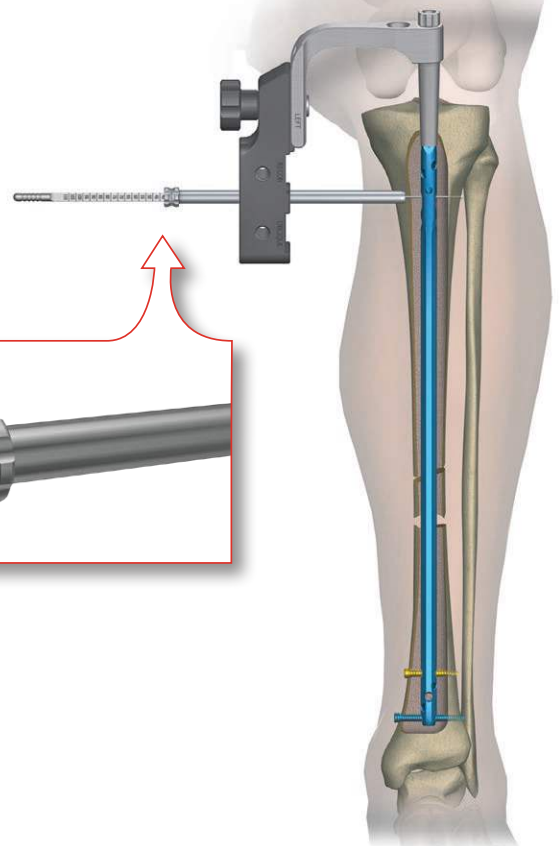
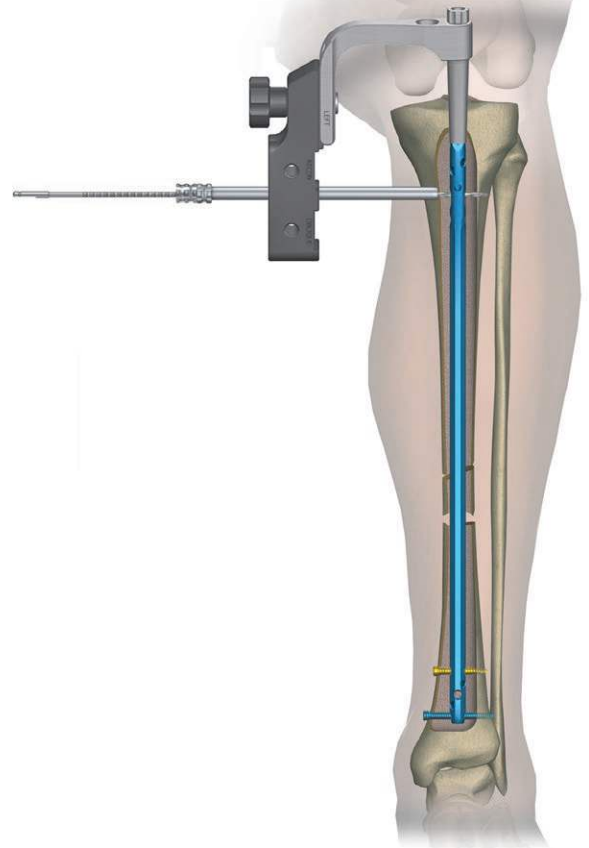
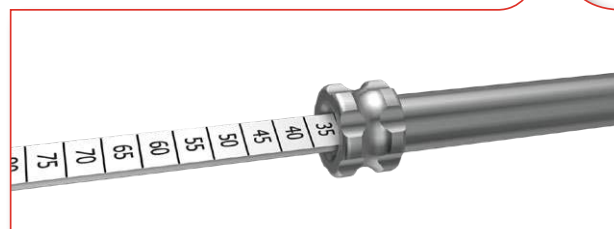
The drilling process should be controlled with image intensifier.

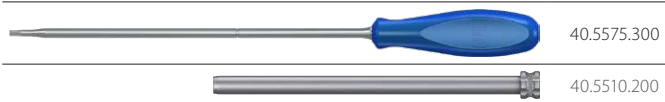
Remove the drill and drill guide.
Leave the protective guide in the targeter hole.



- 36** Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the „exit“ of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

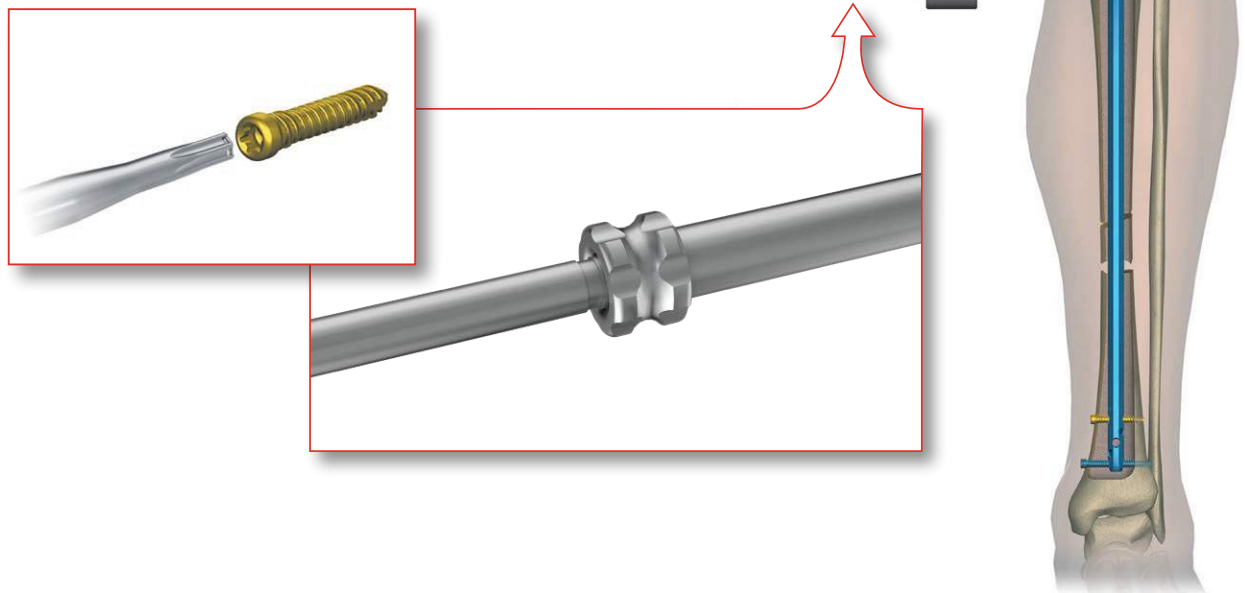
Remove the screw length measure.
Leave the protective guide in the slider hole.









- 37** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*).

Remove the screwdriver and protective guide.



IV.8.2. Intraoperative compression of fractures

	40.5301.000
	40.5313.000
	40.5305.000
	40.5575.300




38 The targeter arm B [40.5301] allows for intraoperative compression of bone fragments without the necessity to detach the targeter from the nail. It is possible thanks to the compression screw [40.5313] inserted into the connecting screw [40.5305]. To perform the compression the distal fragment should be locked in any nail hole, while the proximal fragment should be locked in the oval-shaped hole in the proximal part.



Nail locking in the distal part should be performed in accordance with steps 14-22

Nail locking in the proximal part should be performed in accordance with steps 34-37

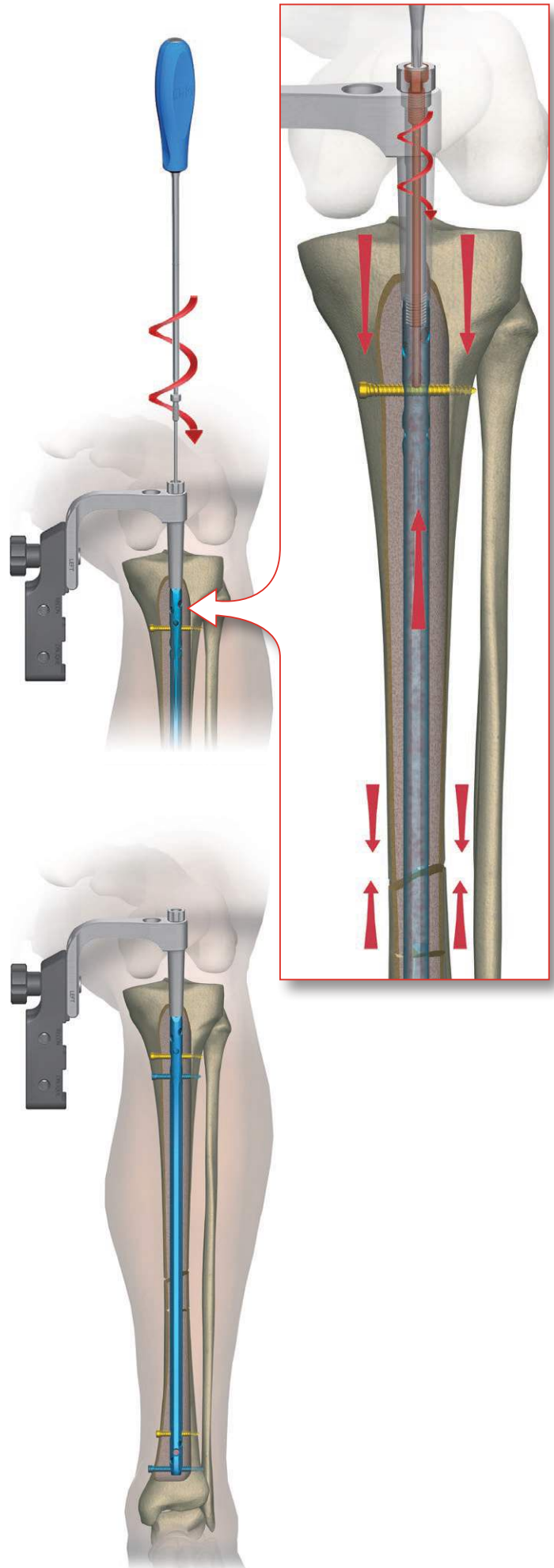
Use the screwdriver T25 [40.5575.300] to insert the compression screw (screw it until the resistance is felt) into the connecting screw, which is used to connect the targeter arm B with the intramedullary nail. Further screwing-in causes bone fragments compression by 1 mm at one screw turn.

	40.5303.100
	40.5307.100
	40.5313.000

39 After compression is performed it is possible to lock the nail in the proximal part in the second lateral hole of the nail by using the targeter B [40.5303.100].

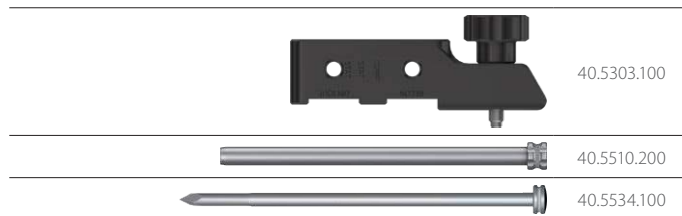
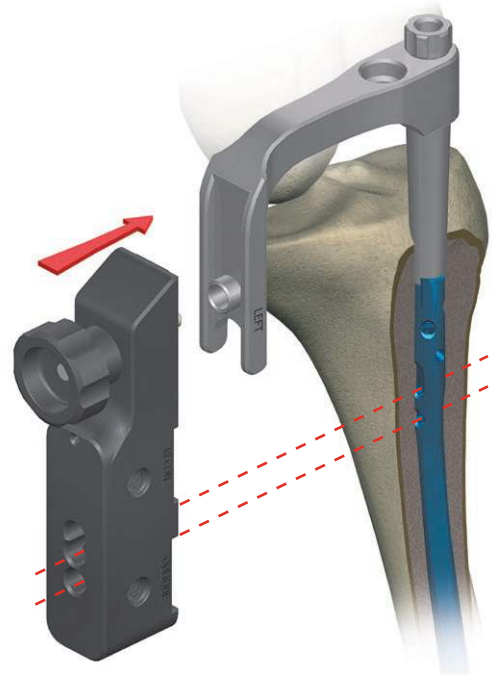


Remove the compression screw [40.5313] during locking in the reconstructive and oblique holes when using the reconstruction targeter [40.5307.100].



IV.8.3. Static fixation




When using the static fixation, it is recommended to lock the nail in the proximal part with two screws. In each case of locking the nail the distally located round hole shall be used.



40 Insert the protective guide 9/7 [40.5510.200] together with the trocar 6.5 [40.5534.100] into the distally located hole in the targeter B [40.5303.100]. Use the trocar to mark on the skin the starting point for an incision of soft tissues to be made with a length of about 1.5 cm. Advance the protective guide with trocar into the incision to place it as close to the bone as possible. Use the trocar to mark the entry point for the drill.

Remove the trocar.
Leave protective guide in targeter's hole.



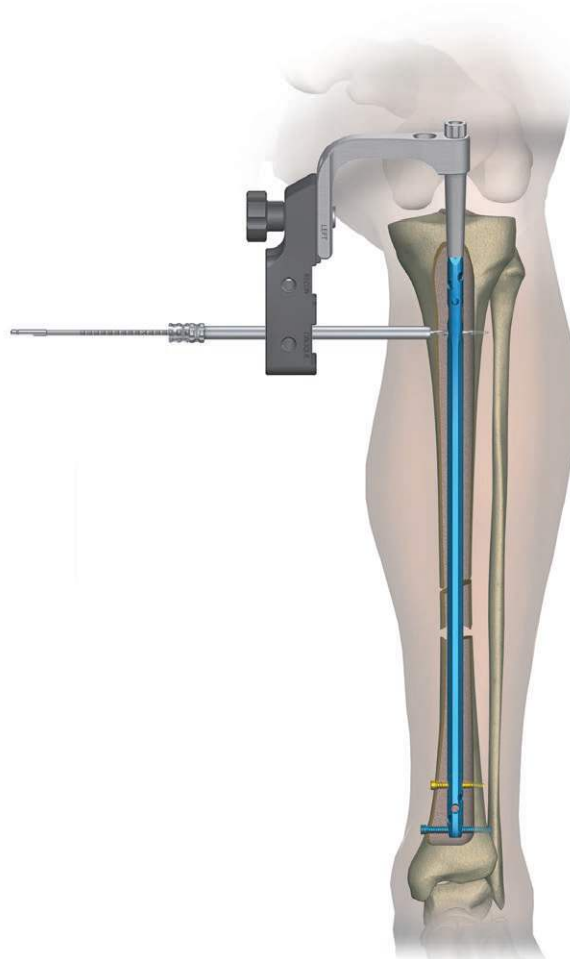
	40.5510.200
	40.5511.200
	40.5339.002



- 41** Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200]. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates the length of the locking element.

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



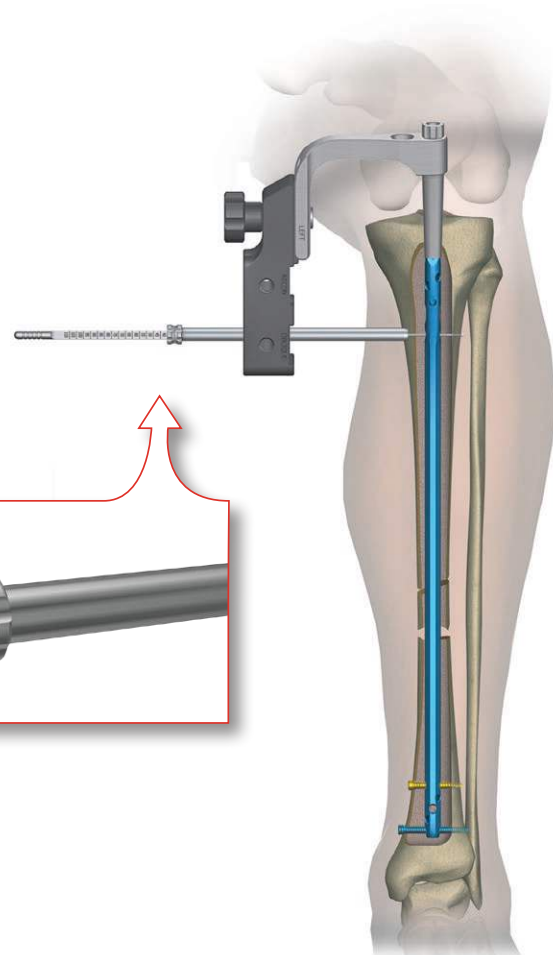
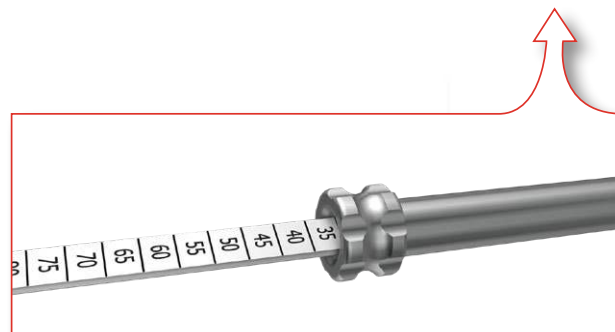
The drilling process should be controlled with image intensifier.











	40.5510.200
	40.5530.200

- 42** Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

Remove the screw length measure.
Leave the protective guide in the slider hole.

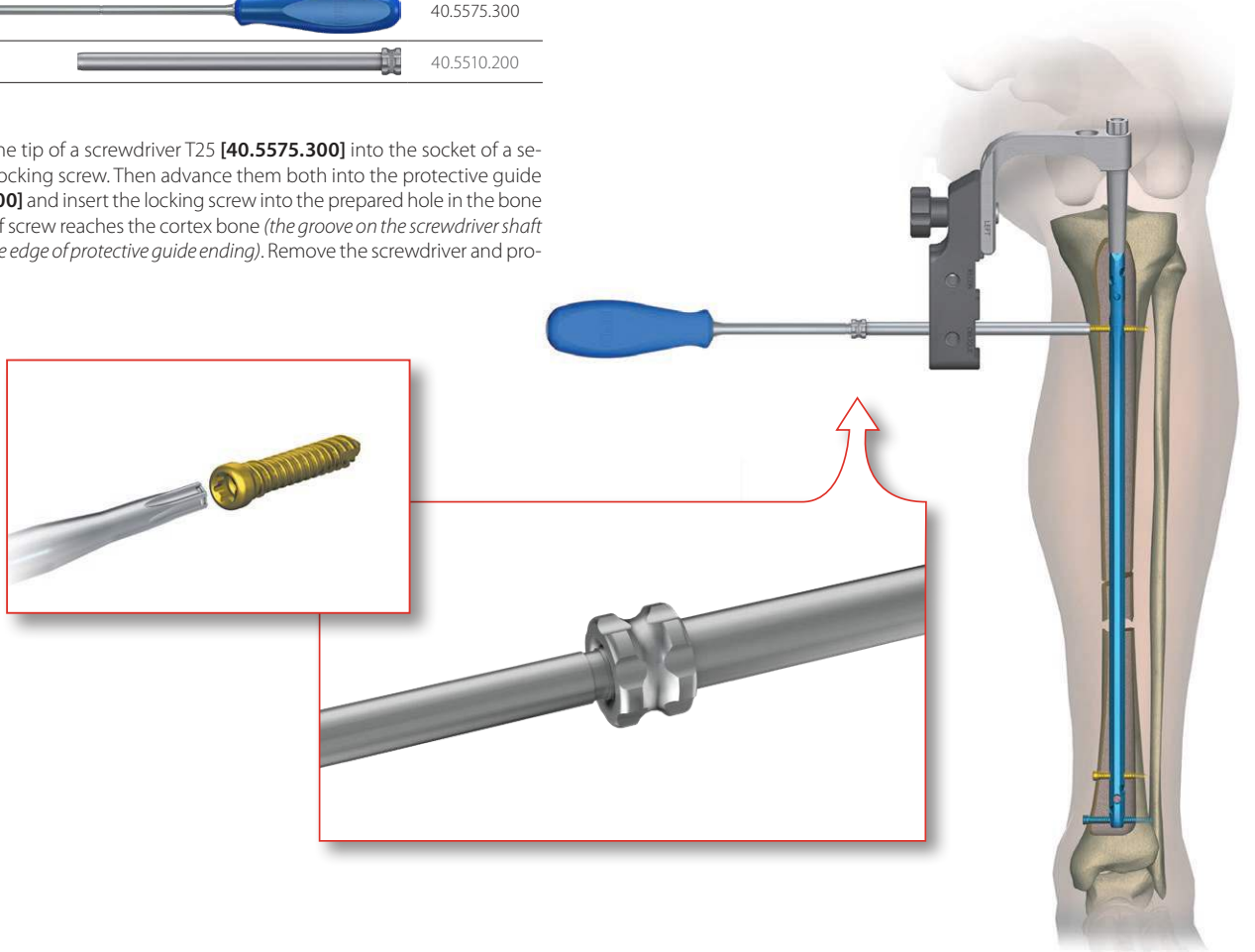


43 The following screws may be used to lock the nail:


		Diameter of intramedullary nail			
		Ø8 and Ø9 mm		Ø10 mm and larger	
		Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole		CHARFIX2 Distal screw 4.0 (turquoise) 	CHARFIX2 Distal screw 4.5 (brown) 	CHARFIX2 Distal screw 5.0 (gold) 	CHARFIX2 Distal screw 5.5 (blue) 
Oval hole		CHARFIX2 Distal screw 4.0 (turquoise) 		CHARFIX2 Distal screw 5.0 (gold) 	



44 Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (the groove on the screwdriver shaft should match the edge of protective guide ending). Remove the screwdriver and protective guide.

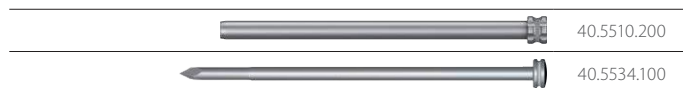
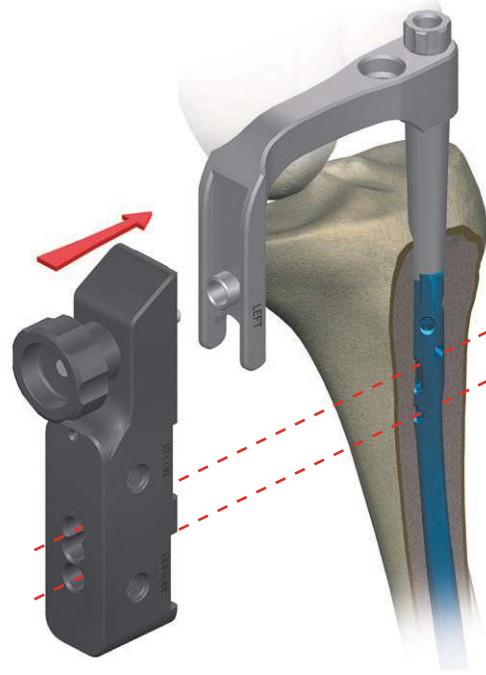


45 The nail may be locked in the proximal part with a second locking screw by using the central hole of the targeter B [40.5303.100].

 Nail locking should be performed in accordance with steps 44-48.

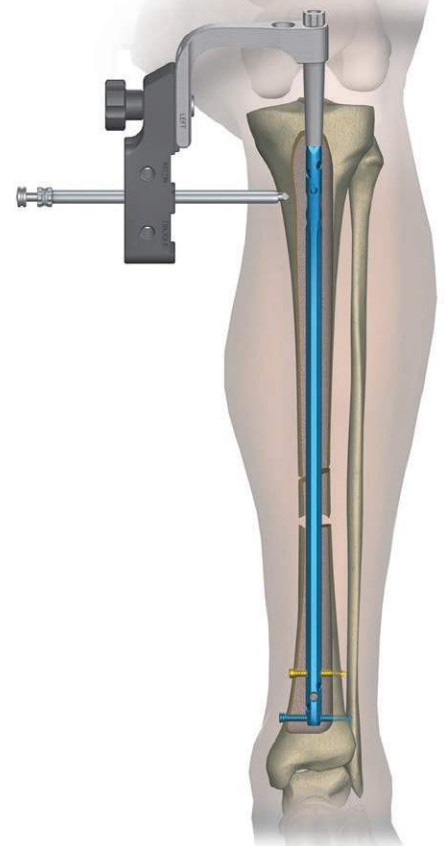
IV.8.4. Static fixation with later dynamization




When using the static fixation, it is recommended to lock the nail in its proximal part with two screws - dynamically in the oval-shaped hole and statically in the round hole below the oval-shaped hole. The dynamization is obtained in the subsequent period by removing the locking screw from round hole.



- 46** Insert the protective guide 9/7 [40.5510.200] together with the trocar 6.5 [40.5534.100] into the proximal hole of the targeter B [40.5303.100]. Use the trocar to mark on the skin the starting point for an incision of soft tissues to be made with a length of a 1.5 cm. Advance the protective guide with trocar into the incision to place it as close to the cortical layer of bone as possible. Use the trocar to mark the entry point for the drill.

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



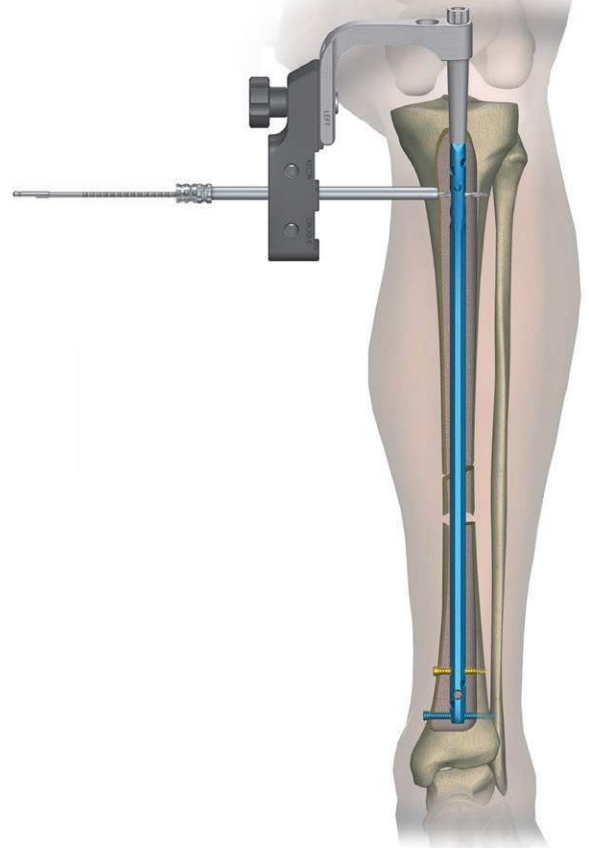
	40.5510.200
	40.5511.200
	40.5339.002



- 47 Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200]. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates the length of the locking element.



The drilling process should be controlled with image intensifier.

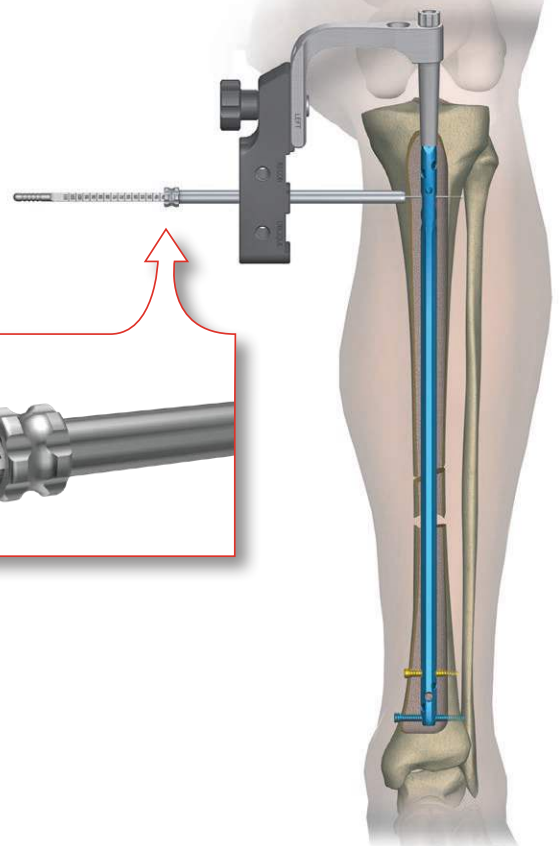
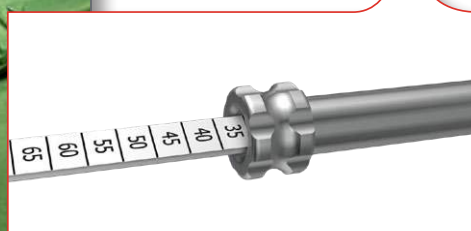
Remove the drill and drill guide.
Leave the protective guide in the targeter hole.



	40.5510.200
	40.5530.200

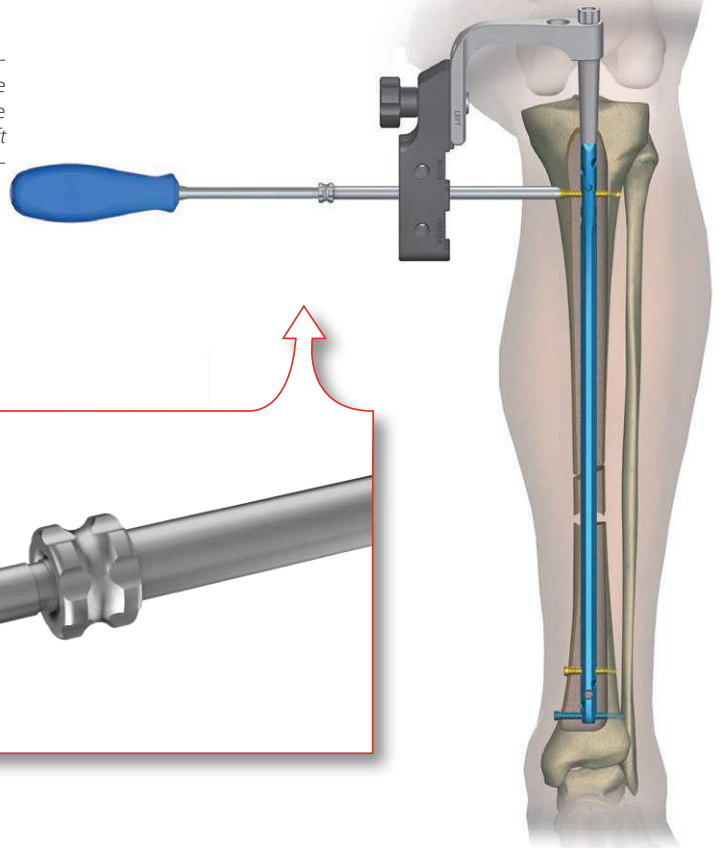
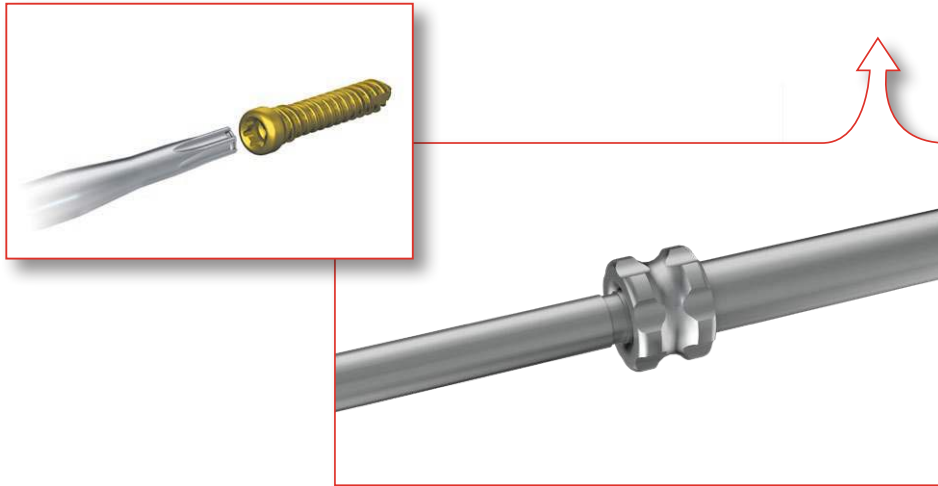
- 48 Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

Remove the screw length measure.
Leave the protective guide in the slider hole.





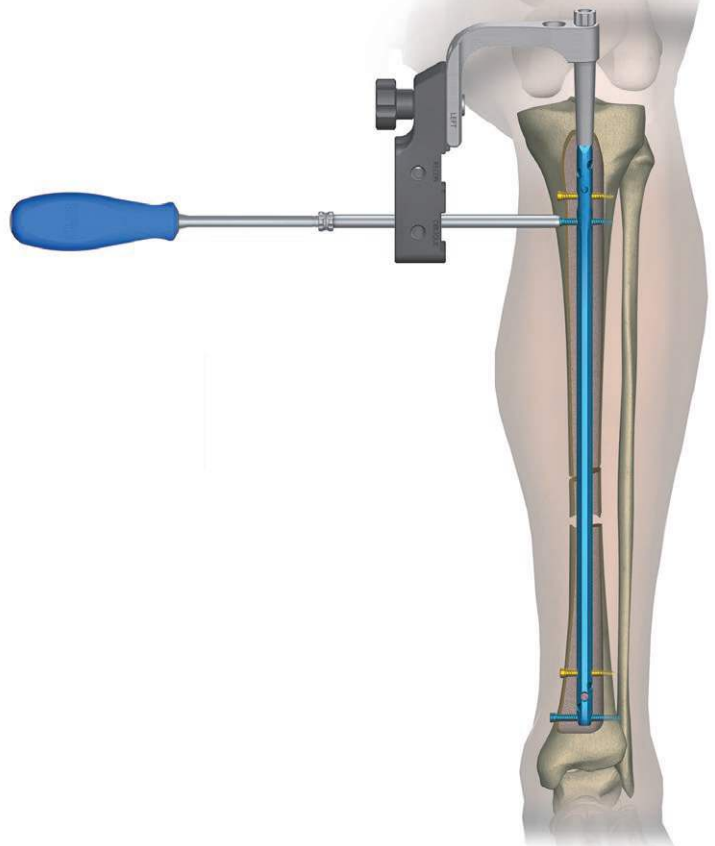
- 49** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*). Remove the screwdriver and protective guide.



- 50** The nail may be locked in the proximal part with a second locking screw by using the distal hole of the targeter B [40.5303.100].



Nail locking should be performed in accordance with steps 44-48.



IV.8.5. Reconstruction and oblique fixation



40.5303.100

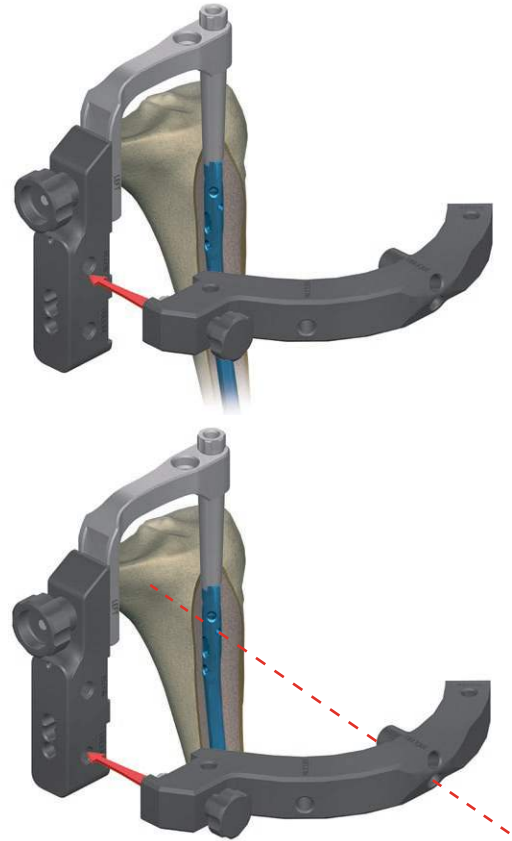


40.5307.100

In order to lock the tibial nail in the reconstructive holes it is necessary to mount the reconstruction targeter [40.5307.100] onto the targeter B [40.5303.100]. The targeter B [40.5303.100] has two sockets for the reconstruction targeter.

51 During reconstructive locking the RECON socket of the targeter B [40.5303.100] and the RECON hole of the reconstruction targeter are used. Threaded rod of the reconstruction targeter is to be inserted into the lateral hole of the arm of targeter B [40.5303.100], and then connected to each other by tightening.

52 During oblique locking the OBLIQUE socket of the targeter B [40.5303.100] and the OBLIQUE hole of the reconstruction targeter are used. Threaded rod of the reconstruction targeter is to be inserted into the lateral hole of the arm of targeter B [40.5303.100], and then connected to each other by tightening.



IV.8.5.A. Reconstructive fixation



40.5307.100



40.5303.100



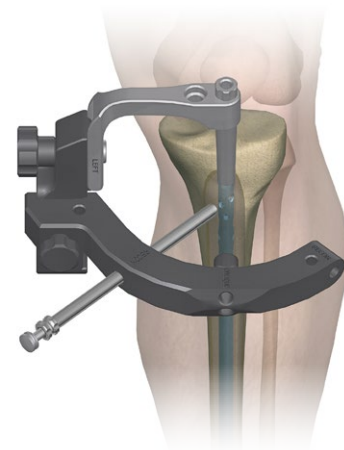
40.5510.200

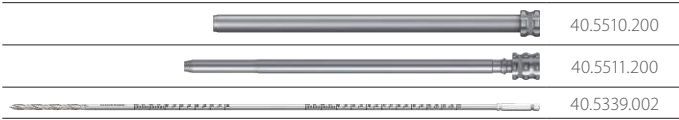


40.5534.100

53 Attach the reconstruction targeter [40.5307.100] to the targeter B [40.5303.100] using the socket described as RECON. Insert the protective guide 9/7 [40.5510.200] together with the trocar 6.5 [40.5534.100] into the selected hole of the reconstruction targeter. Use the trocar to mark on the skin the starting point for an incision of soft tissues to be made with a length of about 1.5 cm. Advance the protective guide with trocar into the incision to place it as close to the cortical layer of bone as possible. Use the trocar to mark the entry point for the drill.

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



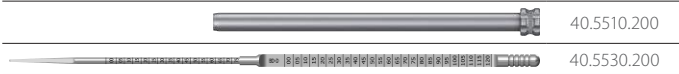
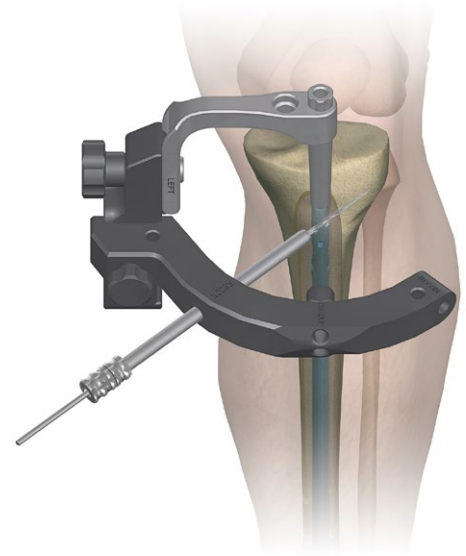


54 Insert the drill guide 7/3.5 [40.5511.200] into the protective guide 9/7 [40.5510.200]. Use the electric drive with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates the length of the locking element.



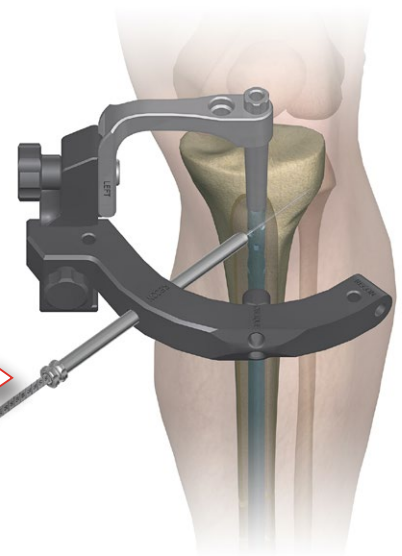
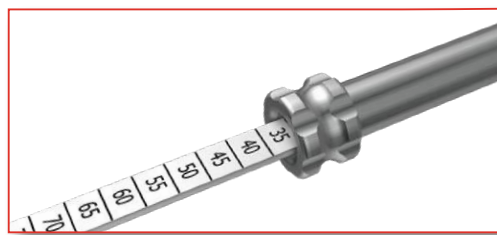
The drilling process should be controlled with image intensifier.

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



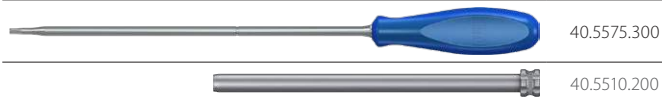
55 Insert the screw length measure [40.5530.200] through the protective guide 9/7 [40.5510.200] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

Remove the screw length measure.
Leave the protective guide in the slider hole.



56 The following screws may be used to lock the nail:

		Diameter of intramedullary nail			
		Ø8 and Ø9 mm		Ø10 mm and larger	
		Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole	CHARFIX2 Distal screw 4.0 (turquoise)	CHARFIX2 Distal screw 4.5 (brown)	CHARFIX2 Distal screw 5.0 (gold)	CHARFIX2 Distal screw 5.5 (blue)	
Oval hole	CHARFIX2 Distal screw 4.0 (turquoise)		CHARFIX2 Distal screw 5.0 (gold)		

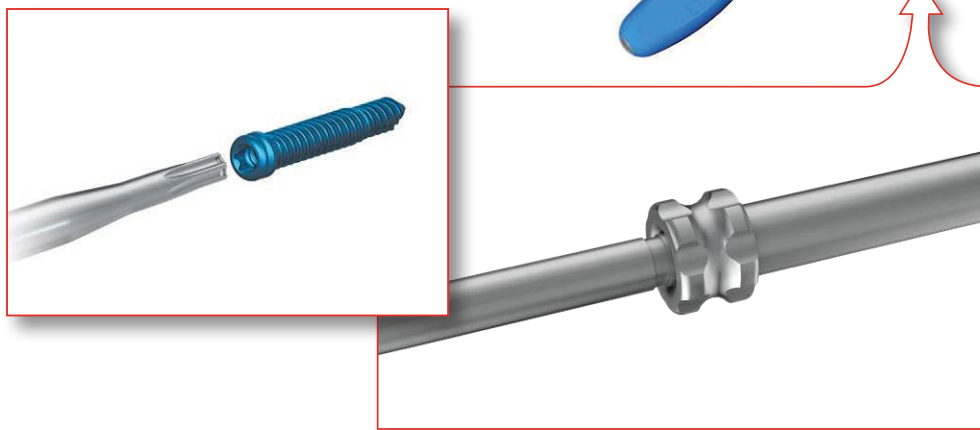


57 Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 [40.5510.200] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone (*the groove on the screwdriver shaft should match the edge of protective guide ending*).

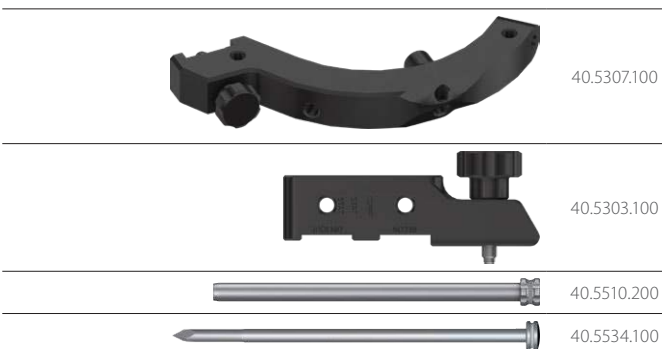
Remove the screwdriver and protective guide.



Nail locking in the second reconstructive hole should be performed in accordance with steps 57-61.



IV.8.5.B. Oblique fixation



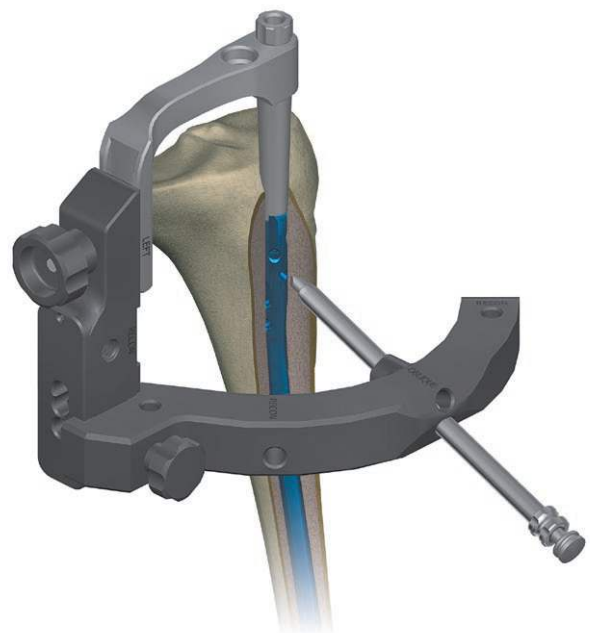
58 Attach the reconstruction targeter [40.5307.100] to the targeter B [40.5303.100] using the socket described as OBLIQUE. Insert the protective guide 9/7 [40.5510.200] together with the trocar 6.5 [40.5534.100] directed "upwards" into the hole of the reconstruction targeter described as OBLIQUE. Use the trocar to mark on the skin the starting point for an incision of soft tissues to be made with a length of about 1.5 cm. Advance the protective guide with trocar into the incision to place it as close to the cortical layer of bone as possible. Use the trocar to mark the entry point for the drill.

Remove the trocar.

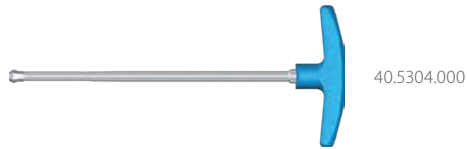
Leave the protective guide in the targeter hole.



Further procedures should be performed in accordance with steps 54-57.



IV.9. PLACING COMPRESSION SCREW OR END CAP



40.5304.000



40.5305.000



40.5306.000



40.5301.000



40.5303.100



40.5302.100

Use the wrench S8 [40.5304] to remove the connecting screw [40.5305] or [40.5306] from the intramedullary nail shaft. Detach the targeter arm [40.5301] with targeter B [40.5303.100] and targeter D [40.5302.100] from the nail locked in the medullary canal.

Insertion of the compression screw or end cap



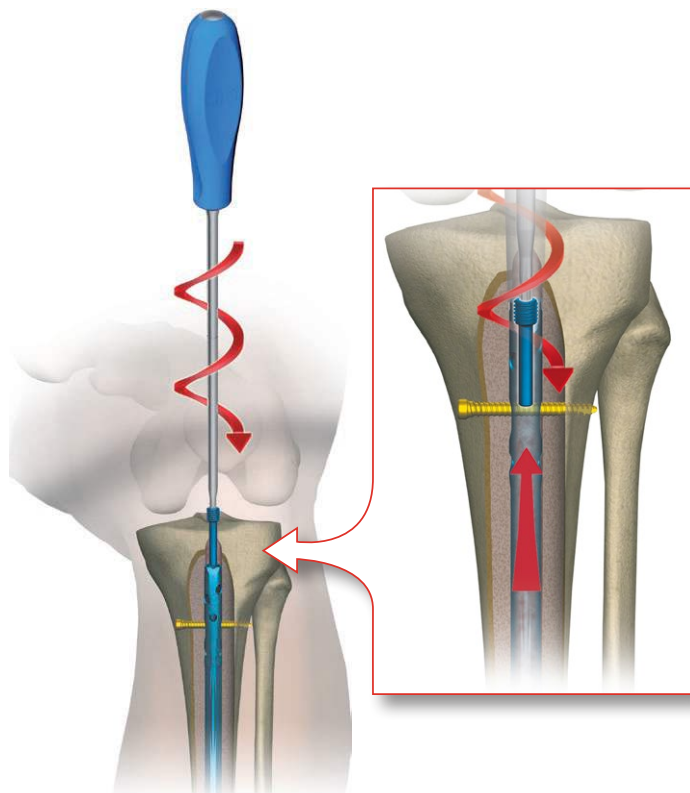
40.5575.300



40.5575.300

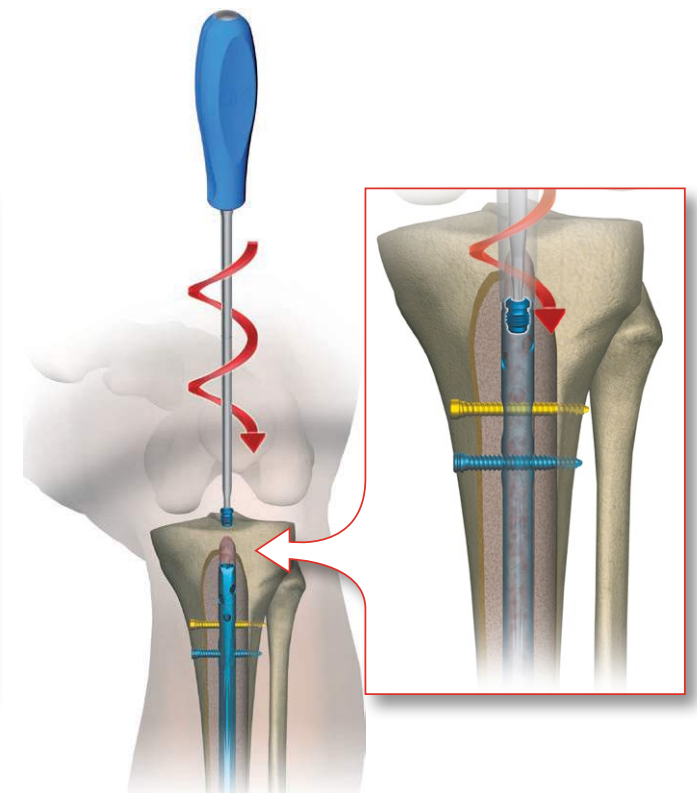
59 **OPTION I:** Insertion of the compression screw - for dynamic fixation with compression (*compressive fixation*).

Use the screwdriver T25 [40.5575.300] to insert the compression screw (*implant*) into the threaded hole of the nail shaft.



60 **OPTION II:** Insertion of the end cap - for dynamic and static fixation.

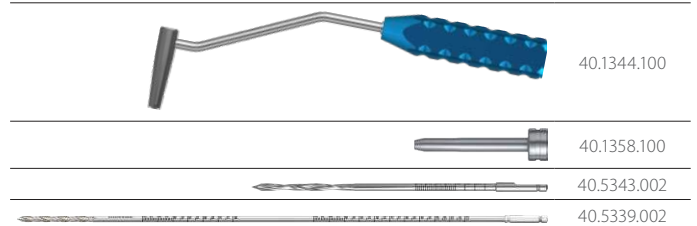
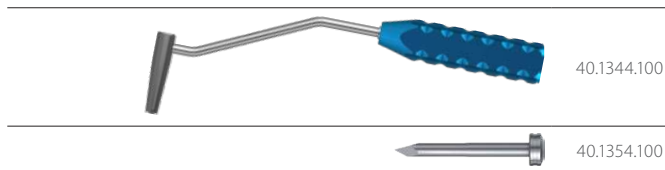
To secure the internal thread of the nail against the bone tissue ingrowth, use the screwdriver T25 to insert the end cap (*implant*) into the threaded hole of the nail shaft.



V. LOCKING THE INTRAMEDULLARY NAIL WITH USE OF TARGETER D [40.1344.100] AND FREEHAND TECHNIQUE

V.1. NAIL LOCKING WITH USE OF TARGETER D

When using this method, a constant radiological control is required to determine the drilling site of holes and during the drilling process. It is recommended to use an angle drill attachment when drilling, so the operator's hands are outside the field of direct X-Ray exposure. After marking the points for holes to be drilled in the bone shaft, it is required to make an incision of soft tissues along the marked points that is about 1.5 cm long.



61 Use the image intensifier to establish the position of the targeter D [40.1344.100] in relation to the holes in the intramedullary nail. The holes in the nail and targeter must coincide. The teeth of the targeter must be sunk in the cortical layer of bone. Insert the trocar short 7 [40.1354.100] into the targeter D hole and advance trocar until it reaches the cortical layer and marks the entry point for the drill.

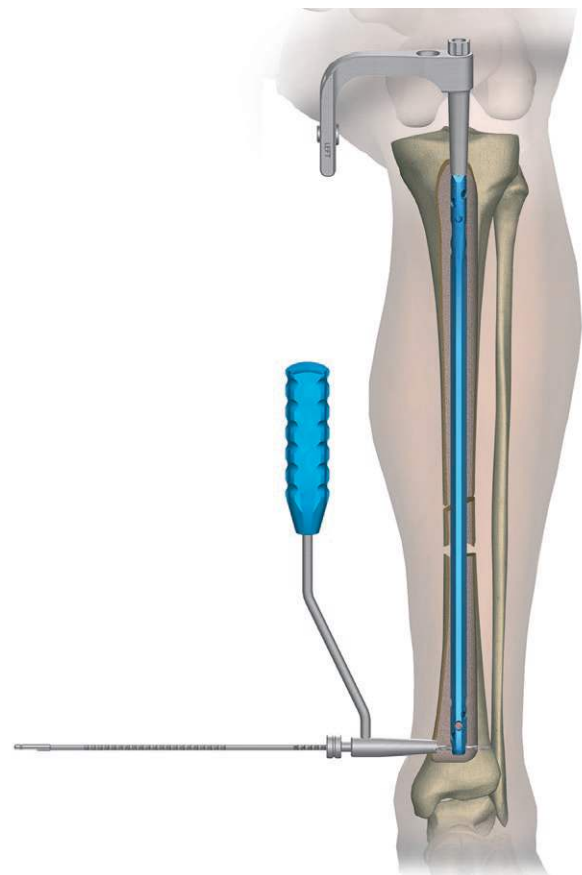
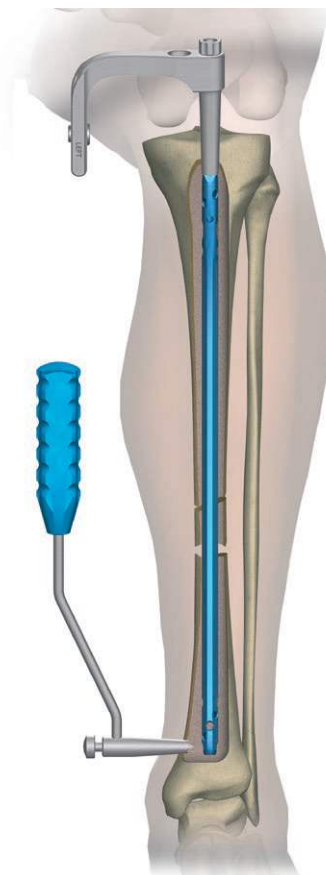
Remove the trocar.
Leave the targeter D in place.

62 Insert the drill guide short 7/3.5 [40.1358.100] into the hole of targeter D [40.1344.100]. Use the electric drive with a drill with scale 3.5/150 [40.5343.002] or with a drill with scale 3.5/350 [40.5339.002] led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the selected drill indicates the length of the locking element.



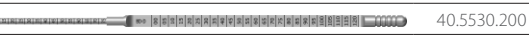
The drilling process should be controlled with image intensifier.

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





40.1344.100



40.5530.200

- 63** Insert the screw length measure [40.5530.200] through the hole of a targeter D [40.1344.100] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the D scale.

Remove the screw length measure.



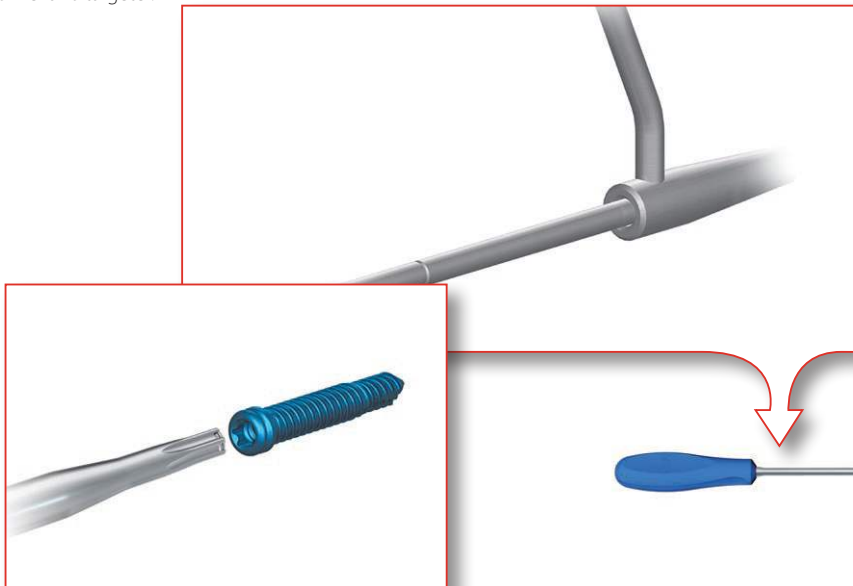
40.5575.300



40.1344.100

- 64** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both into the hole of targeter D [40.1344.100] and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortical layer of bone.

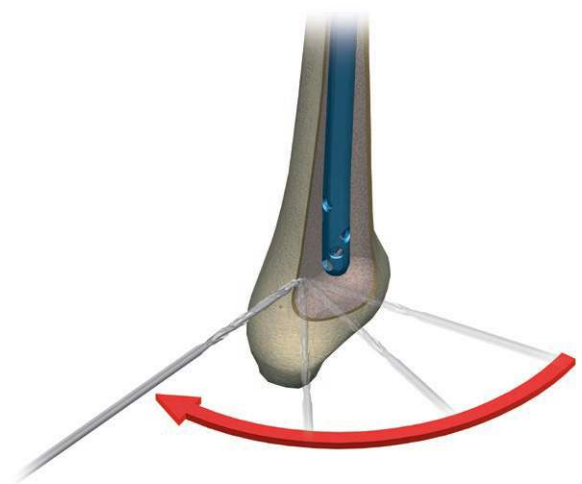
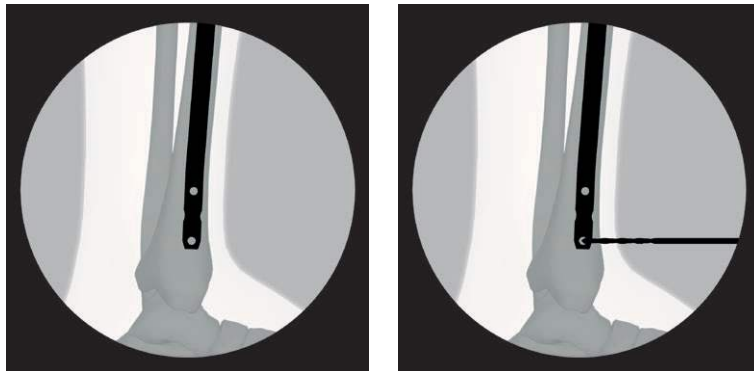
Remove the screwdriver and targeter.



V.2. FREEHAND TECHNIQUE LOCKING

When using this method, a constant radiological control is required to determine the drilling site of holes and during the drilling process. It is recommended to use an angle drill attachment when drilling, so the operator's hands are outside the field of direct X-Ray exposure. After marking the points for holes to be drilled in the bone shaft, it is required to make an incision of soft tissues along the marked points that is about 1.5 cm long.

Use the image intensifier to establish the position of the drill in relation to the hole in the intramedullary nail.



 40.5343.002

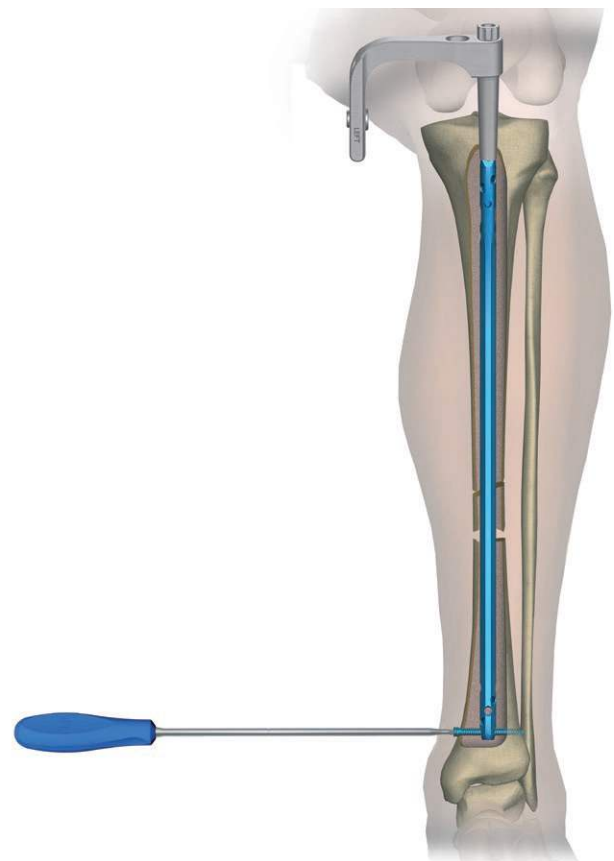
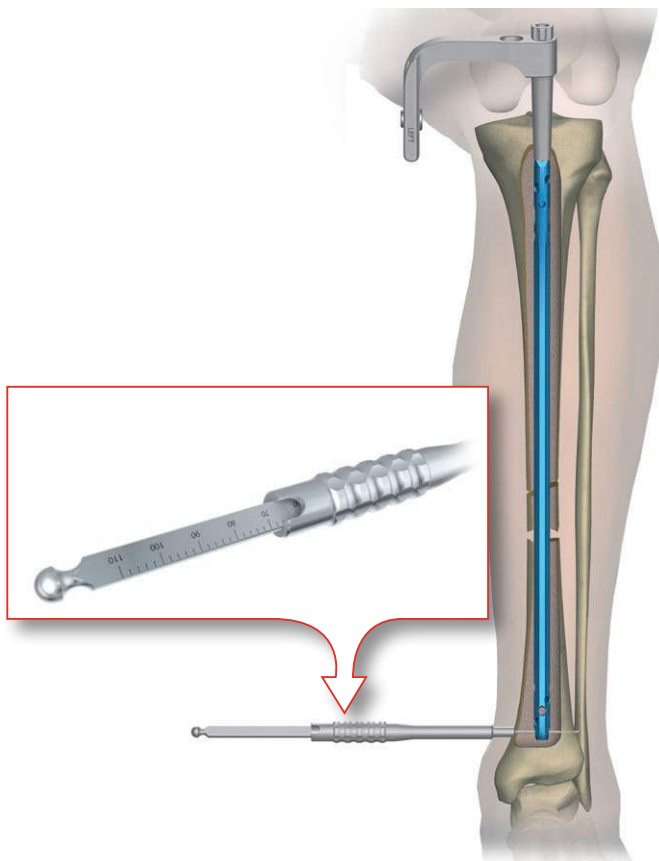
- 65** Use the drill with scale 3.5/150 [40.5343.002] to make a hole going through both cortical layers and the hole in the nail. Remove the drill.

 40.2665.000

- 66** Insert the hole depth measure [40.2665] into the drilled hole until the end of measure reaches the "exit" of the hole. Read the length of a locking screw on the scale.

 40.5575.300

- 67** Insert the tip of a screwdriver T25 [40.5575.300] into the socket of a selected locking screw. Then advance them both and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortical layer of bone.

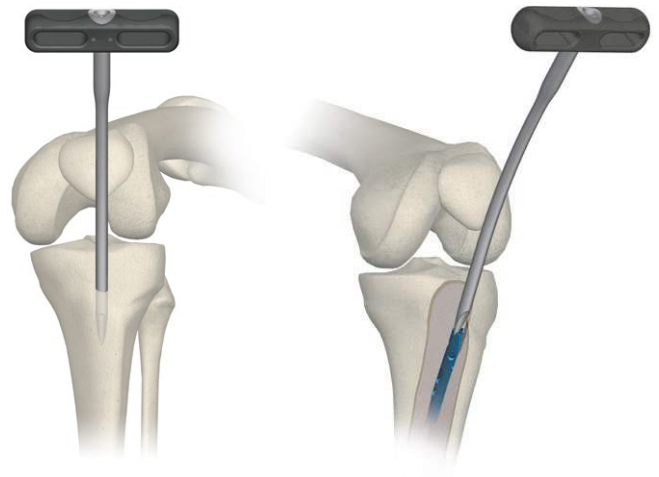


VI. NAIL EXTRACTION

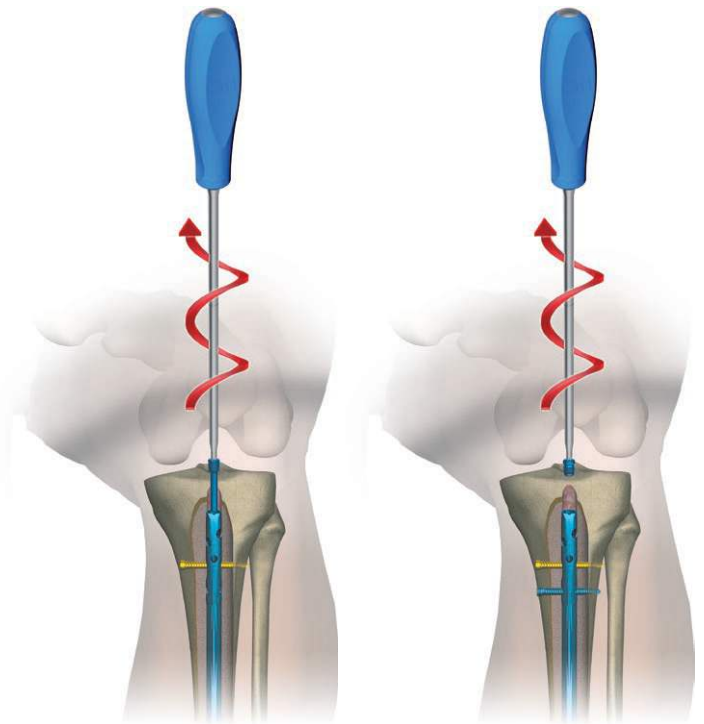


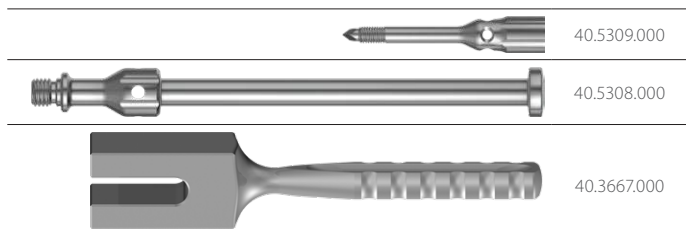
68 Open the canal using the curved awl 8.0 [40.5523.000].

Insert the awl at the angle of 10° in relation to the main axis of the medullary canal.

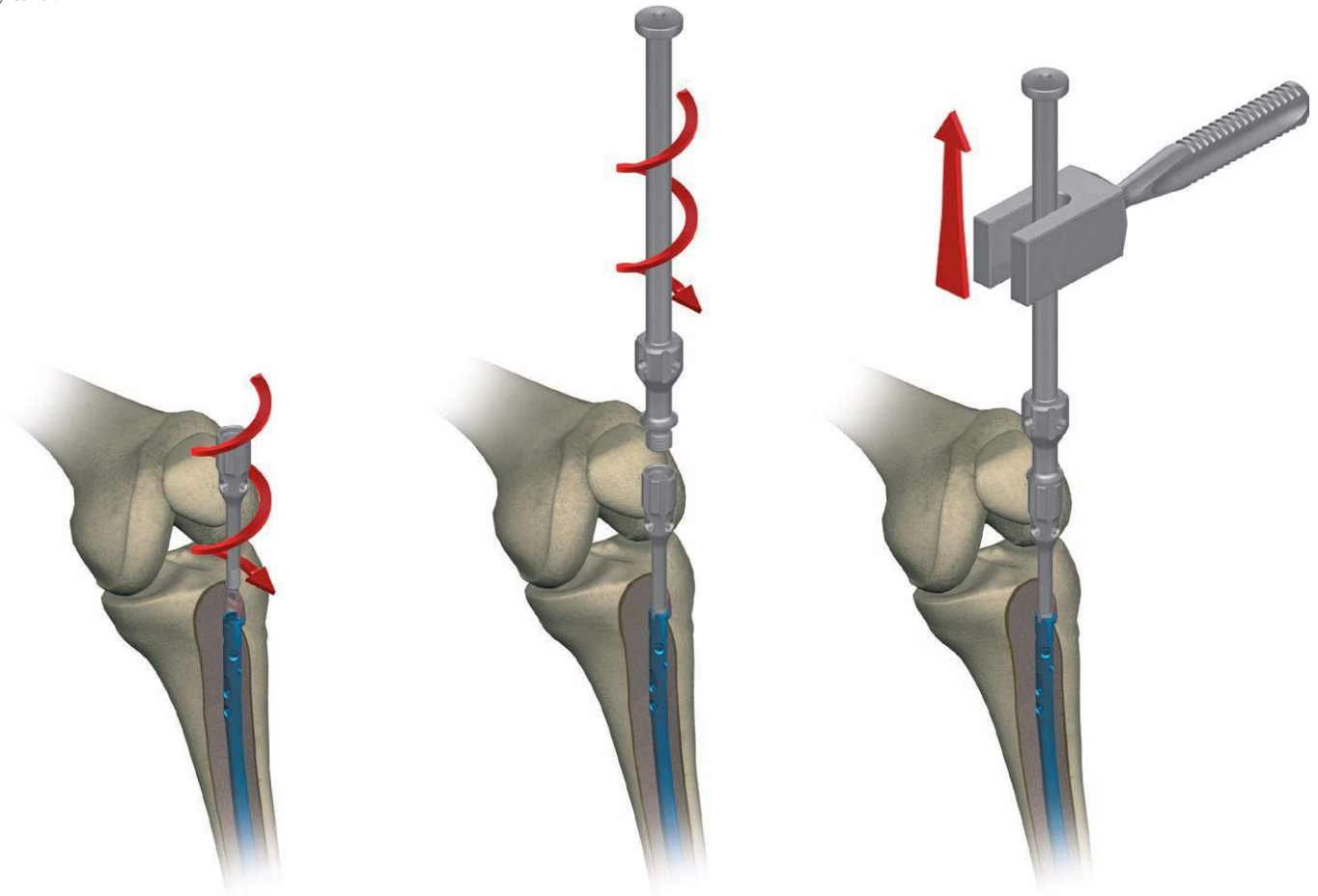


69 Use the screwdriver T25 [40.5575.300] to remove the end cap (or compression screw) and all locking screws.





70 Insert the connector M8x1,25/M14 [40.5309] into the threaded hole in the intramedullary nail shaft. Attach the impactor-extractor [40.5308] to the connector and use the mallet [40.3667] to remove the nail from the medullary canal.



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