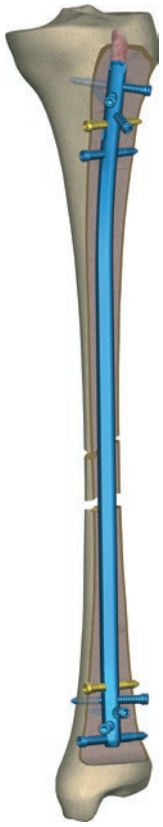
ST/38-1B

ChM®

CHARFIX system 2

INTRAMEDULLARY TIBIA OSTEOSYNTHESIS WITH CHARFIX2 NAILS

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



www.chm.eu

SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

www.chm.eu

Document No ST/38-1B
Date of issue 04.05.2010
Review date P-002-29.08.2016

I. INTRODUCTION

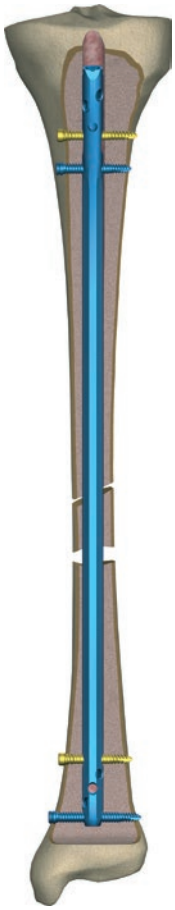
CHARFIX system 2 - INTRAMEDULLARY TIBIA OSTEOSYNTHESIS consists of:
- implants *(intramedullary nail, locking screws, end cap or compression screw)*,
- instrument set for insertion and implant removal after treatment is finished,
- instructions for use.

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 fixating the tibia shaft fragments.

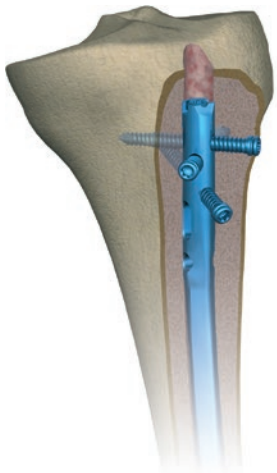
Static stabilization

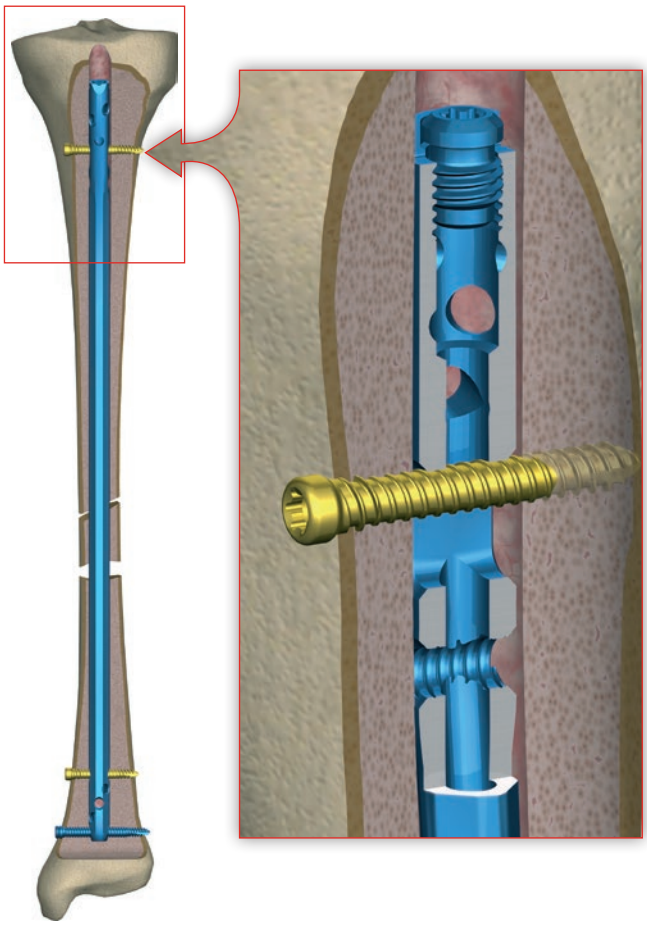
Static stabilization is utilized for multi-fragmentary fractures, when there is no axial stability of adjacent bone fragments.
When using the static stabilization, at least two distal and two proximal holes should be used for locking the nail with screws.



Reconstructive stabilization

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



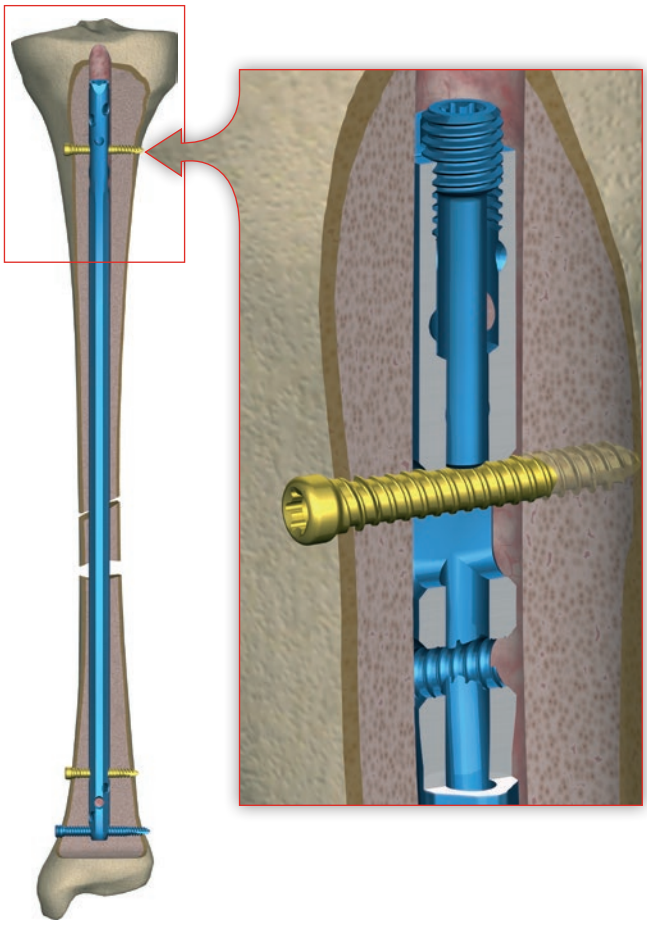


Dynamic stabilization

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.



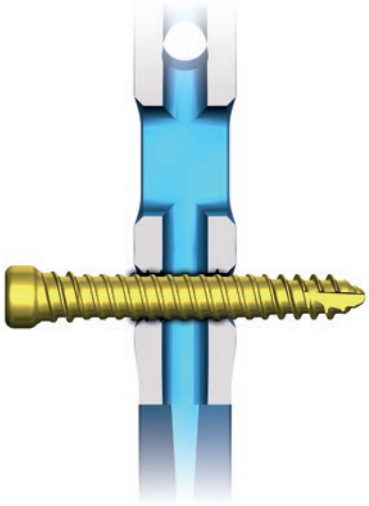
Dynamic stabilization with compression

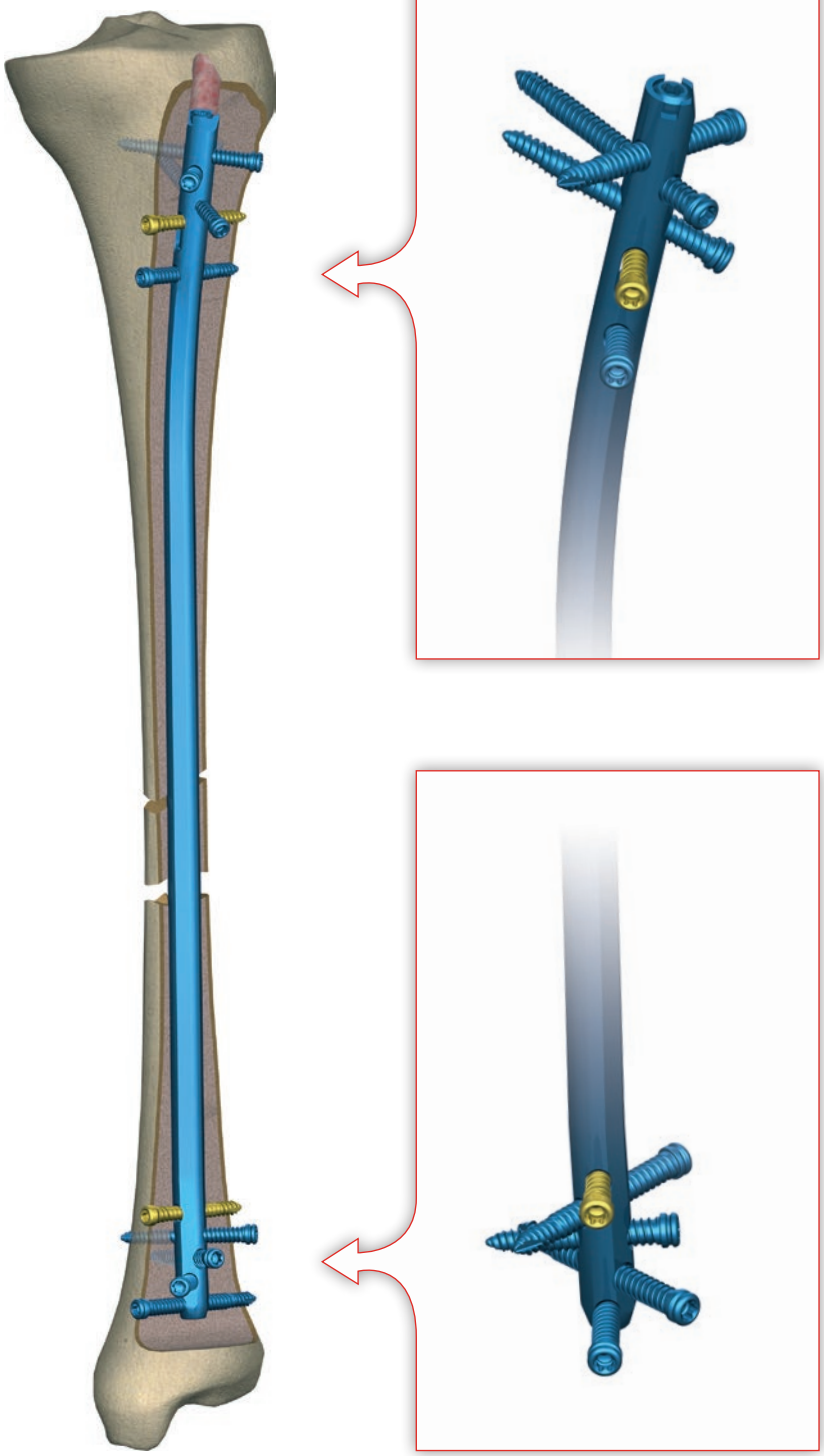
During the dynamic stabilization with compression *(compressive fixation)* a compression screw axially inserted into the internal socket of intramedullary nail shaft is used to put pressure on the nail locking screw.

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

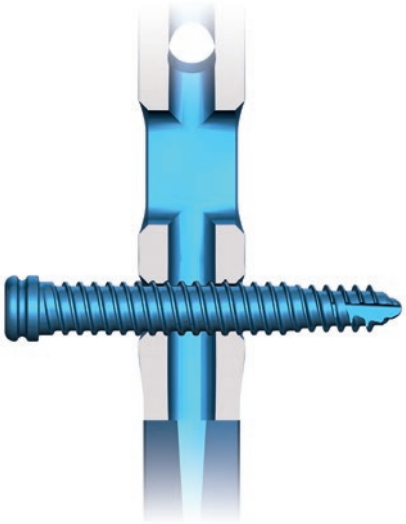
Threaded holes allow for optional locking with the use of:

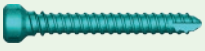
- ***CHARFIX2*** distal screw 4.0 or ***CHARFIX2*** distal screw 5.0





- ***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)*.



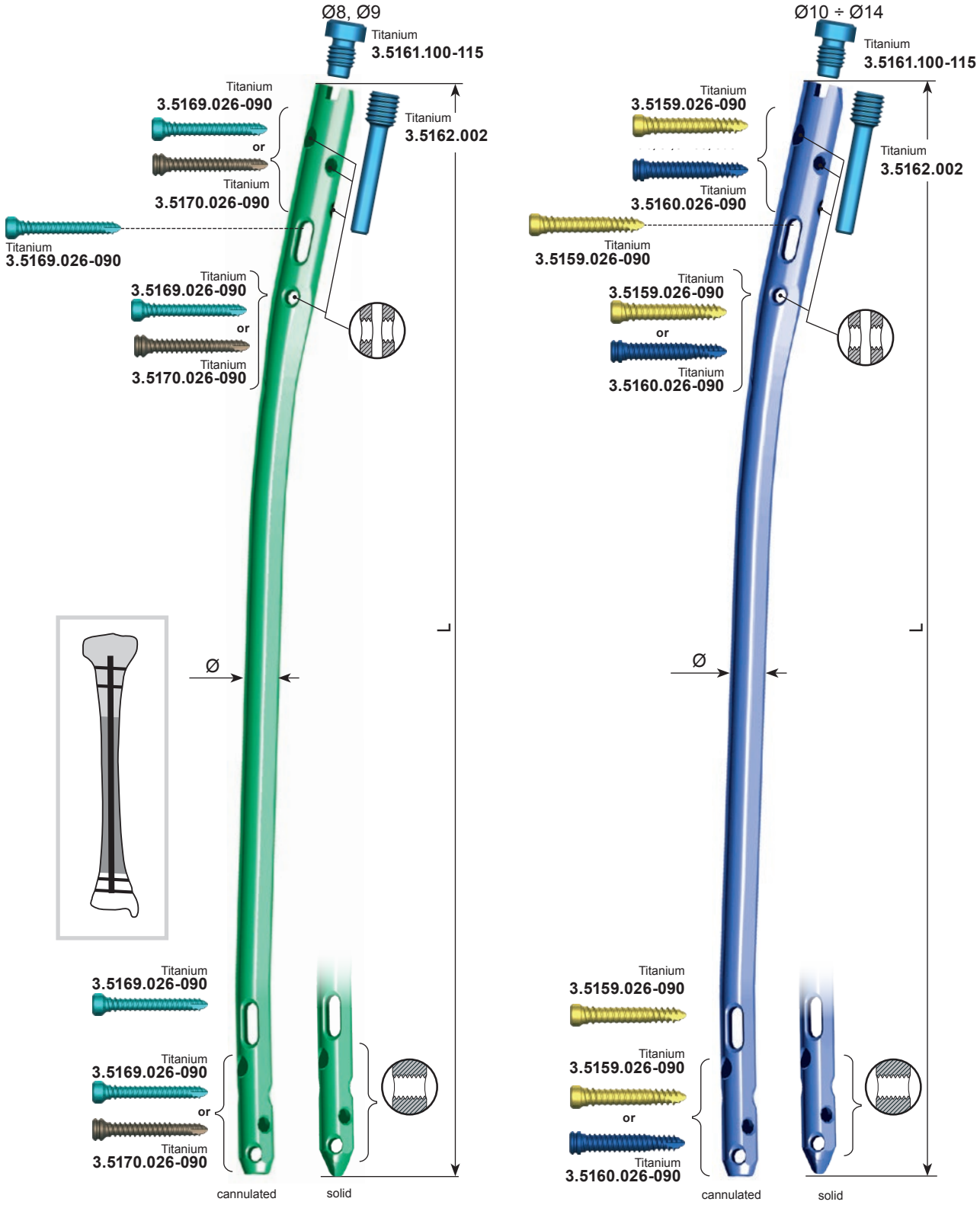
	Diameter of intramedullary nail			
	Ø8 and Ø9 mm		**Ø10 mm and larger**	
	Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole ○	***CHARFIX2*** Distal screw 4.0 *(turquoise)* 	***CHARFIX2*** Distal screw 4.5 *(brown)* 	***CHARFIX2*** 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)* 	

II. IMPLANTS

CHARFIX system 2

TITANIUM ALLOY Ti

TIBIAL NAIL



ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

II. IMPLANTS

CHARFIX system 2
TITANIUM ALLOY Ti

TIBIAL NAIL

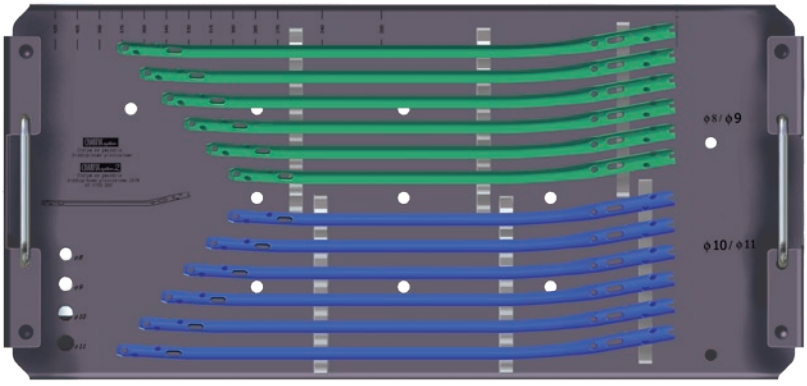
L [mm]	Ø	Titanium
270	8	3.2651.270
285		3.2651.285
300		3.2651.300
315		3.2651.315
330		3.2651.330
345		3.2651.345
360		3.2651.360
375		3.2651.375
390		3.2651.390
270	9	3.2652.270
285		3.2652.285
300		3.2652.300
315		3.2652.315
330		3.2652.330
345		3.2652.345
360		3.2652.360
375		3.2652.375
390		3.2652.390
270	10	3.2653.270
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
270	11	3.2654.270
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
270	12	3.2655.270
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

L [mm]	Ø	Titanium
270	8	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
270	9	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
270	10	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

Titanium

Ø8	Ø9	Ø10	Ø11	Ø12
colours				

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

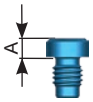


40.5750.000
Stand for tibial nails *CHARFIX/CHARFIX2* *(implants not included)*

III. LOCKING ELEMENTS

TITANIUM ALLOY

CHARFIX2 End cap M8



A	Catalogue no. Titanium
0	3.5161.100
+5	3.5161.105
+10	3.5161.110
+15	3.5161.115

CHARFIX2 Compression screw M8x1.25

Catalogue no. Titanium
3.5162.002

CHARFIX2 Distal screw Ø4.0

L [mm]	Catalogue no. Titanium
26	3.5169.026
28	3.5169.028
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
85	3.5169.085
90	3.5169.090

L [mm]	available
	16 ÷ 90

CHARFIX2 Distal screw Ø4.5

L [mm]	Catalogue no. Titanium
26	3.5170.0 26
28	3.5170.028
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
85	3.5170.085
90	3.5170.090

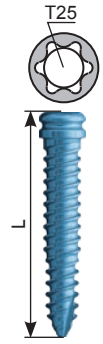
L [mm]	available
	16 ÷ 90

CHARFIX2 Distal screw Ø5.0

L [mm]	Catalogue no. Titanium
26	3.5159.026
28	3.5159.028
30	3.5159.030
35	3.5159.035
40	3.5159.040
45	3.5159.045
50	3.5159.050
55	3.5159.055
60	3.5159.060
65	3.5159.065
70	3.5159.070
75	3.5159.075
80	3.5159.080
85	3.5159.085
90	3.5159.090

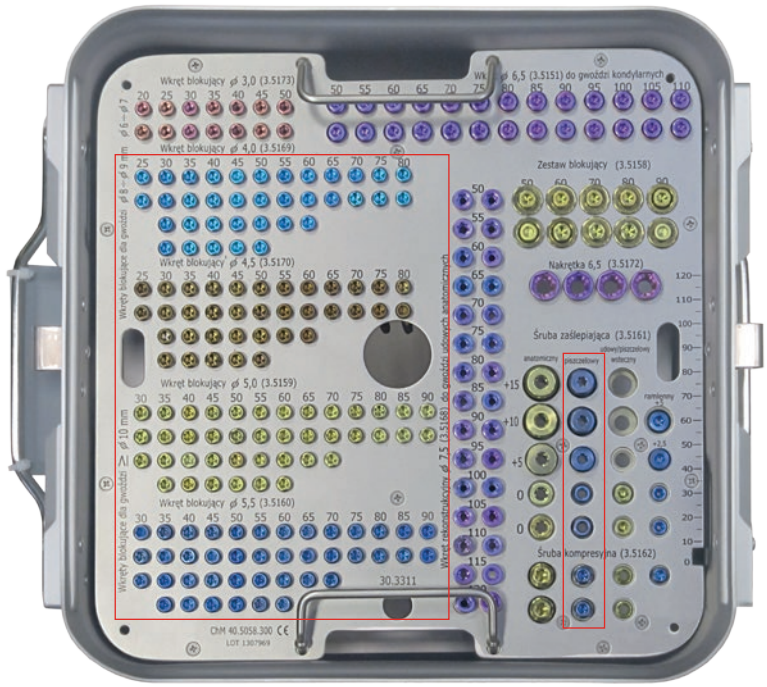
L [mm]	available
	16 ÷ 90

CHARFIX2 Distal screw Ø5.5



L [mm]	Catalogue no. Titanium
26	3.5160.026
28	3.5160.028
30	3.5160.030
35	3.5160.035
40	3.5160.040
45	3.5160.045
50	3.5160.050
55	3.5160.055
60	3.5160.060
65	3.5160.065
70	3.5160.070
75	3.5160.075
80	3.5160.080
85	3.5160.085
90	3.5160.090

L [mm]	available
	16 ÷ 90



40.5058.200
Stand for *CHARFIX2* nail locking elements
(set with a box without implants)

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

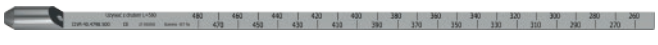
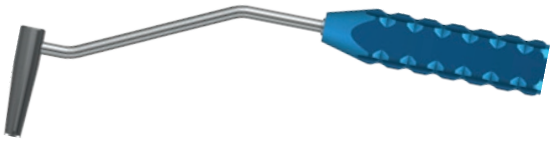
IV. INSTRUMENT SET

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 lid to enable sterilization and transportation to the operating suite.

Instrument set for tibial nails 40.5300.500

No.		Name	Catalogue no.	Pcs
1		Targeter arm B	40.5301.000	1
2		Targeter D	40.5302.100	1
3		Targeter B	40.5303.100	1
4		Wrench S8	40.5304.000	1
5		Connecting screw M8x1.25 L-89	40.5305.000	1
6		Connecting screw M8x1.25 L-22	40.5306.000	1
7		Reconstruction targeter	40.5307.100	1
8		Impactor-extractor	40.5308.000	1
9		Connector M8x1.25/M14	40.5309.000	1
10		Targeter arm B short	40.5312.000	1
11		Compression screw	40.5313.000	1
12		Mallet	40.3667.000	1
13		Set block 9/5.0	40.5509.100	2
14		Protective guide 9/7	40.5510.200	2

Instrument set for tibial nails 40.5300.500

No.		Name	Catalogue no.	Pcs
15		Drill guide 7/3.5	40.5511.200	2
16		Trocar 6.5	40.5534.100	1
17		Nail length measure	40.4798.500	1
18		Guide rod handle	40.1351.000	1
19		Teflon pipe guide 8/400	40.3700.000	1
20		Drill with scale 3.5/150	40.5343.002	1
21		Targeter D	40.1344.100	1
22		Drill guide short 7/3.5	40.1358.100	1
23		Trocar short 7	40.1354.100	1
24		Aiming insert 9.0	40.5065.009	2
25		Guide rod 2.5/580	40.3673.580	1
26		Screwdriver T25	40.5575.100	1
27		Drill with scale 3.5/350	40.5339.002	2
28		Screw length measure	40.5530.100	1
29		Hole depth measure	40.2665.000	1
30		Curved awl 8.0	40.5523.000	1
31		Stand for tibial nails	40.5319.500	1

In addition, to carry out the surgery some other devices *(the basic equipment of the orthopaedic surgical theater)* are needed, such as:

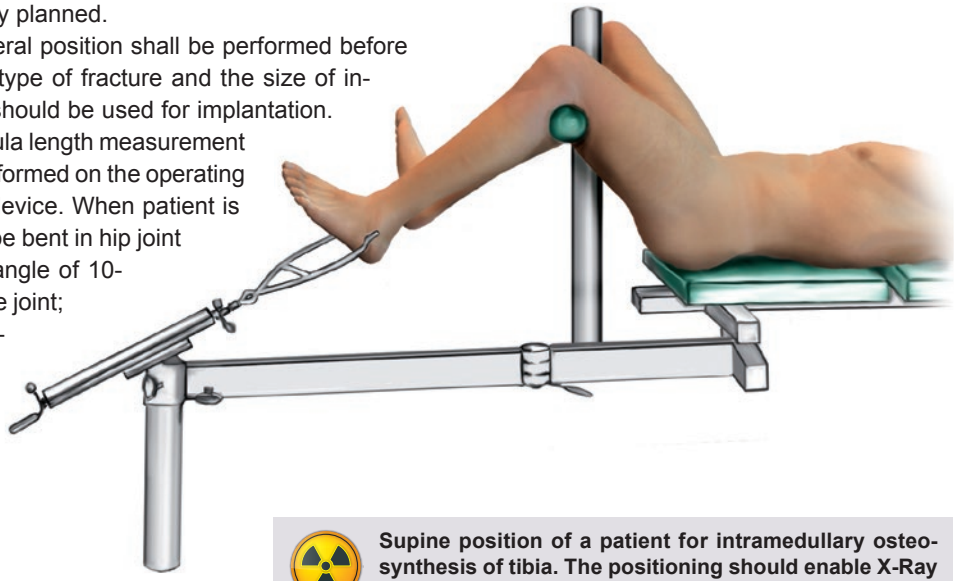
- electric drive,
- set of flexible intramedullary reamers *(8.0 ÷ 13.0 mm)* with guide and a handle,
- set of awls *(solid and cannulated)*,
- set of surgical drills,
- Kirschner wires,
- hammers,
- and others.

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, POLAND, tel. + 48 85 713 13 20, fax + 48 85 713 13 19, chm@chm.eu, www.chm.eu

V. SURGICAL TECHNIQUE

V.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)*.



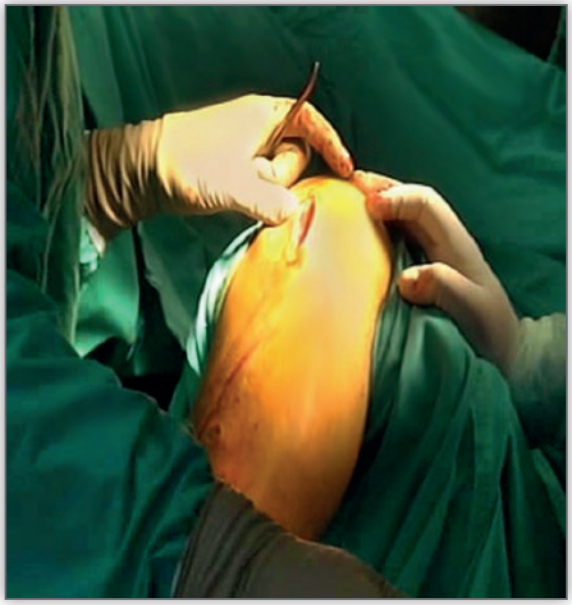
Supine position of a patient for intramedullary osteosynthesis of tibia. The positioning should enable X-Ray control in two planes *(AP and lateral)*.

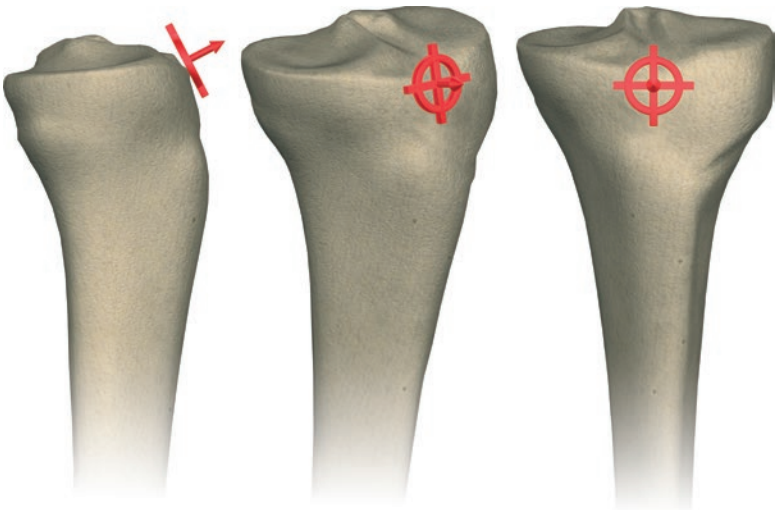
Surgical approach should be prepared by:
- longitudinal skin incision from the lower pole of patella to the point placed medially from tuberosity of tibia,
- incision along medial edge of patella tendon as well as its aside move.

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.

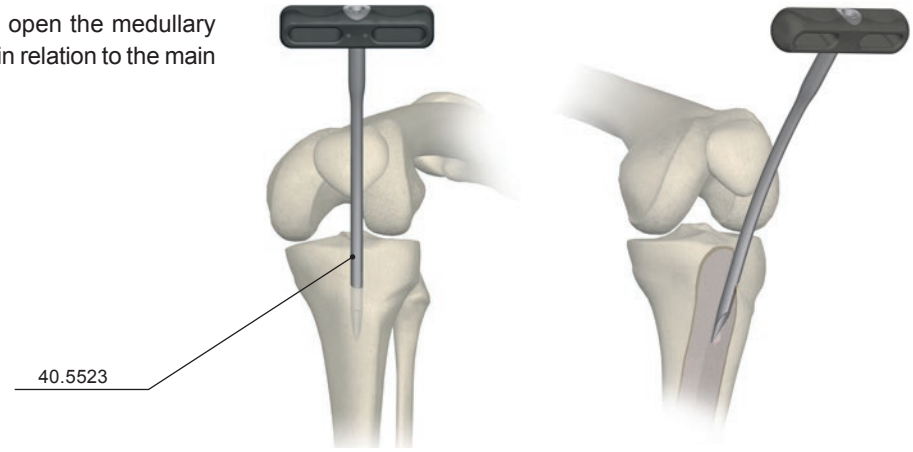




V.2. OPENING THE MEDULLARY CANAL

1 Use the Curved Awl 8,0 **[40.5523]** to open the medullary canal. Insert the awl at an angle of 10° in relation to the main axis of the medullary canal.

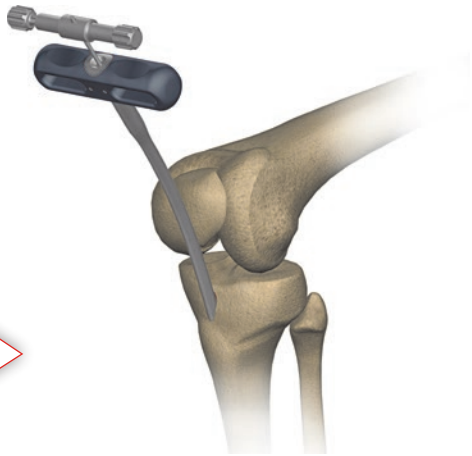
1

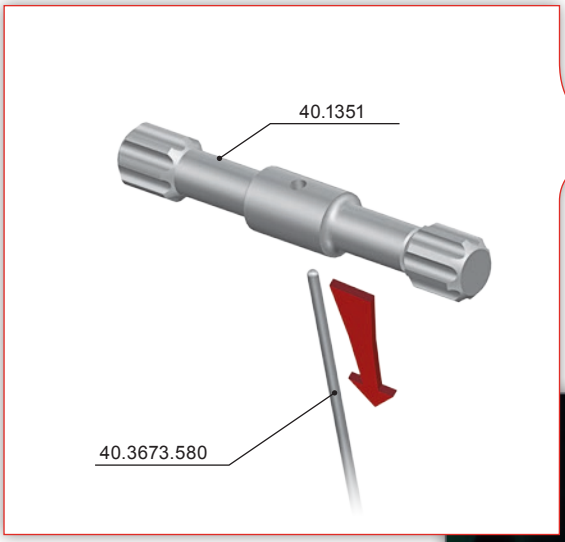


2 Mount the Guide rod handle **[40.1351]** onto the Guide Rod 2.5/580 **[40.3673.580]**. Advance both via the Curved Awl 8.0 **[40.5523]** into the hole until it reaches the distal epiphysis of tibia reducing the fracure at the same time.

Remove the Guide rod handle **[40.1351]** and the Curved Awl **[40.5523]**.

2





V.3. PREPARATION OF MEDULLARY CANAL FOR NAIL INSERTION

V.3.1. OPTION I: Reamed canal

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.

3

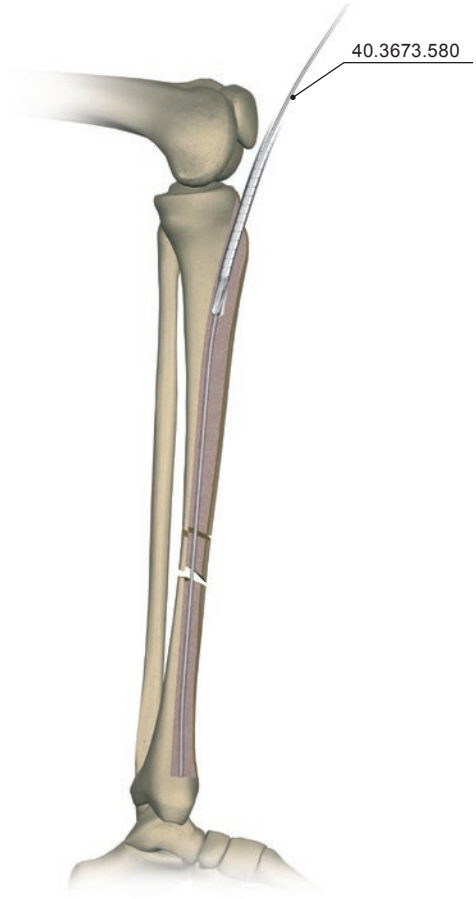
V.3.2. OPTION II: Unreamed canal

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.

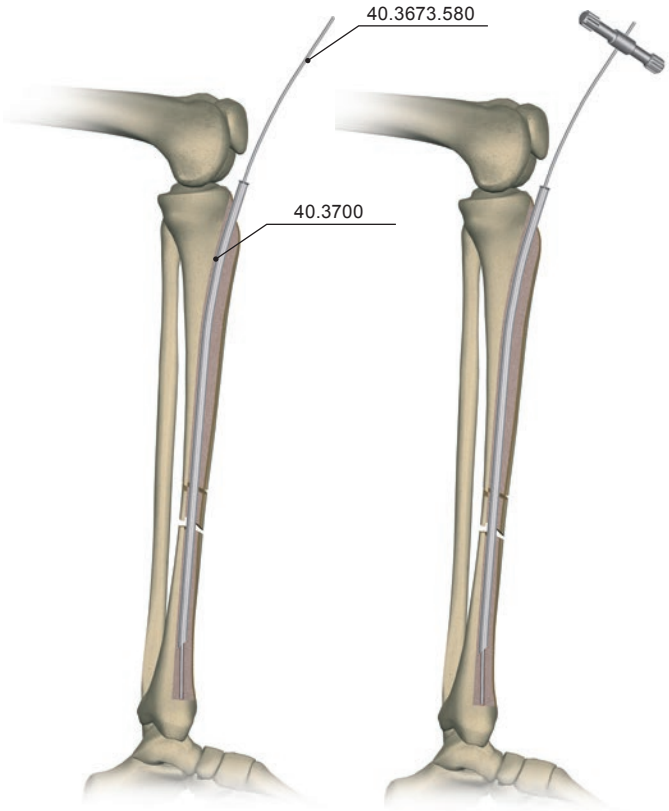
4



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.

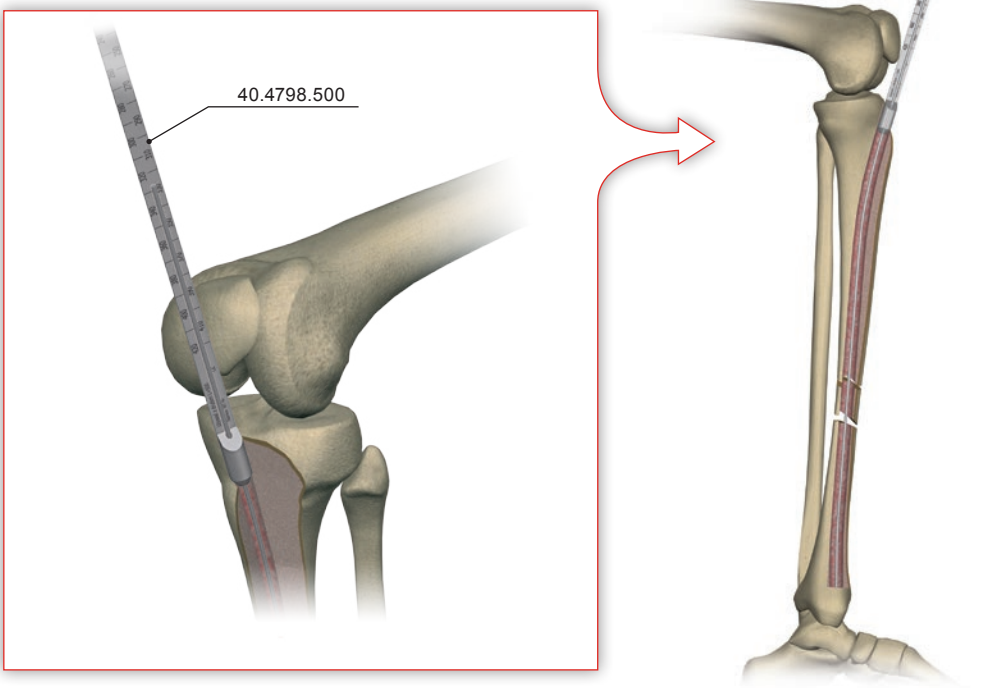
Remove the handle from the guide rod.
Remove the teflon pipe guide.

5



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.

6



V.4. 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.**

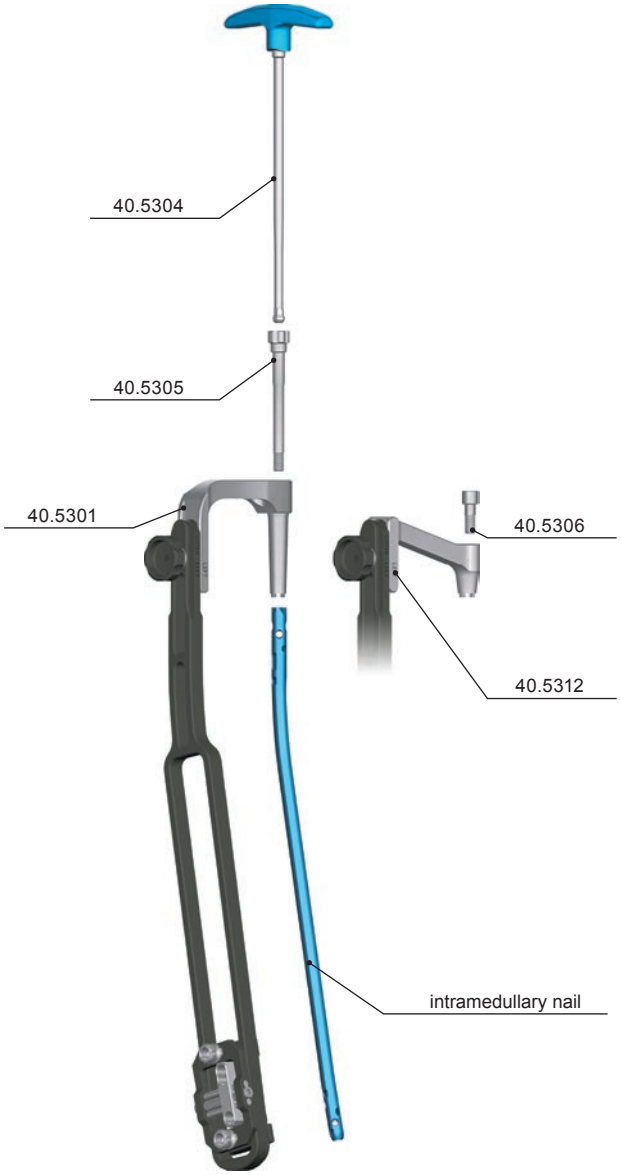
Right leg:
- connective part of the targeter D should be insertd into socket of the targeter arm B from the right side and mounted using cap,
- slider of the targeter D in distal part should be arranged in such a way, that fixing and mounting elements are placed on the left side.

Left leg:
- connective part of the targeter D should be insertd 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.

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 **[40.5575.100]** 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 **[40.5575.100]**.

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]**.

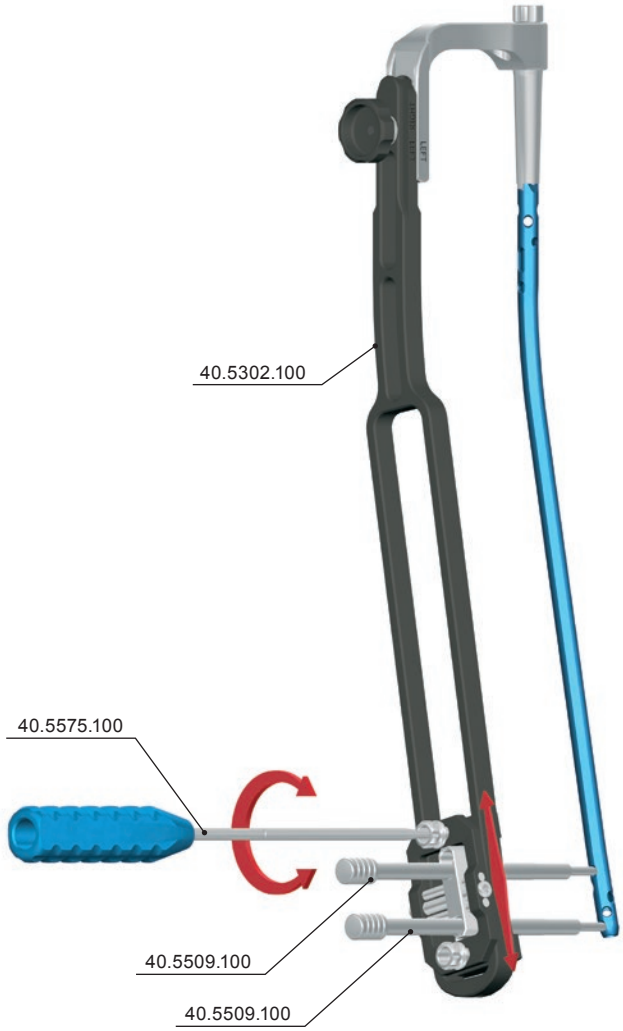
10 Attach the impactor-extractor **[40.5308]** to the targeter arm B **[40.5301]** or **[40.5312]**.

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

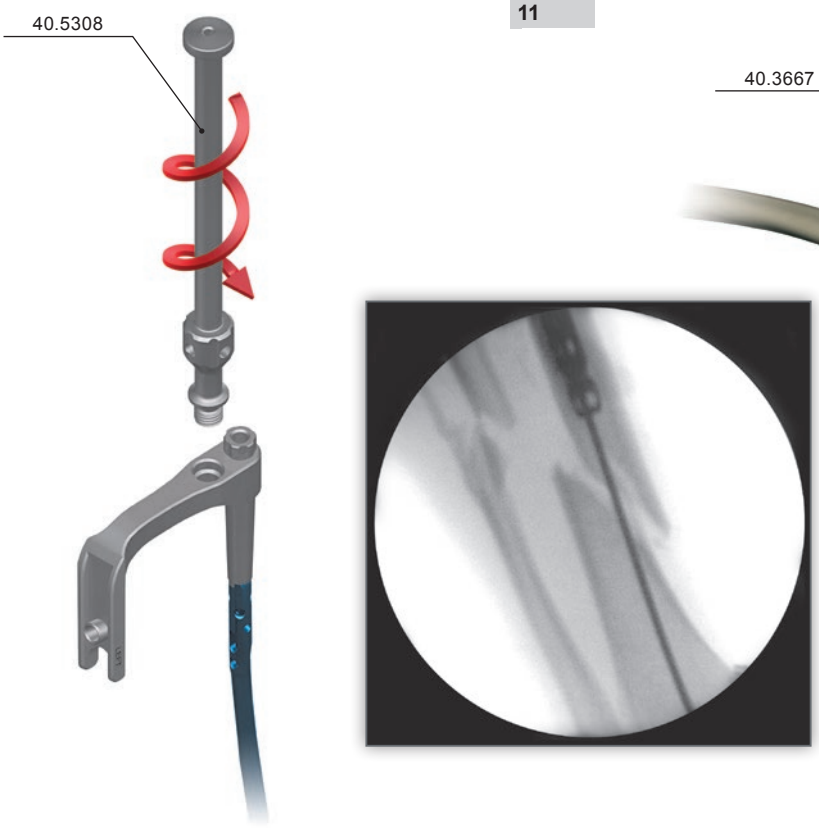
Cannulated nail should be inserted into the medullary canal via the guide rod 2.5/580 [40.3673.580]. Solid nail should be inserted directly into the medullary canal *(without the use of a guide rod)*.

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

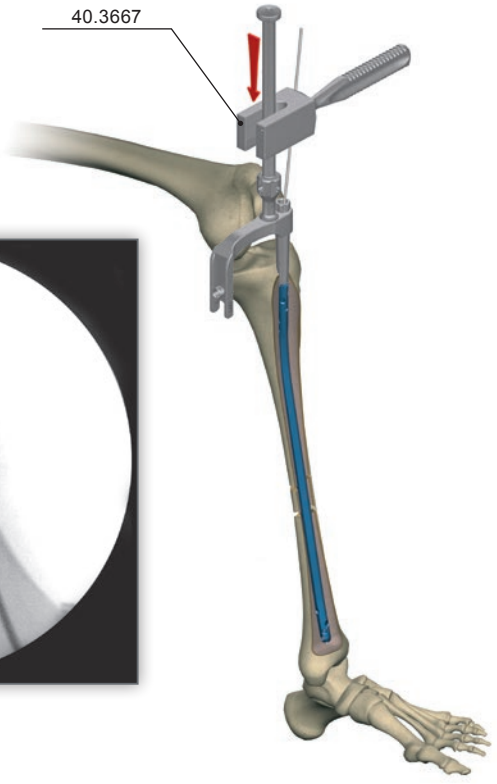
9



10



11



V.5. 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)*	

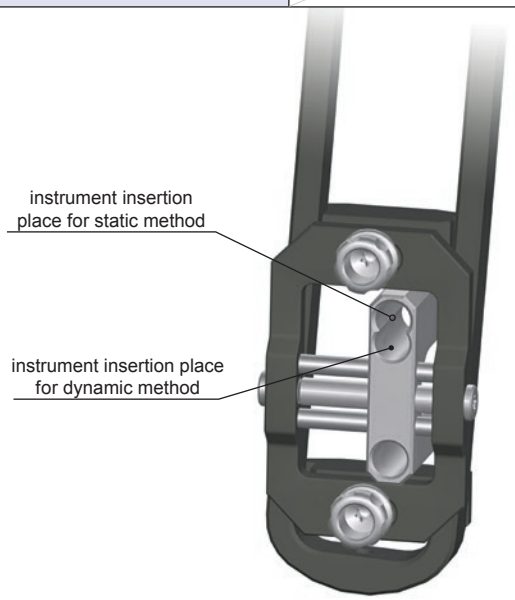
Depending on the method of bone fragments stabilization it is possible to insert the distal screws into the nail oval-shaped hole:

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.



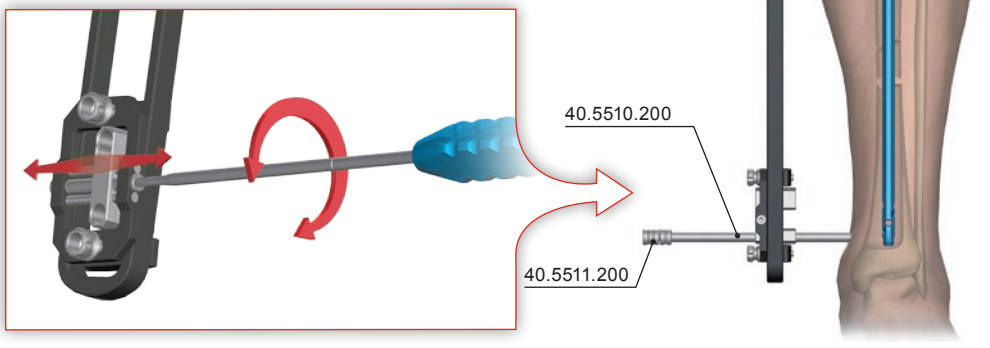
V.5.1. OPTION I: With X-Ray control

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 **[40.5575.100]** 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)*.

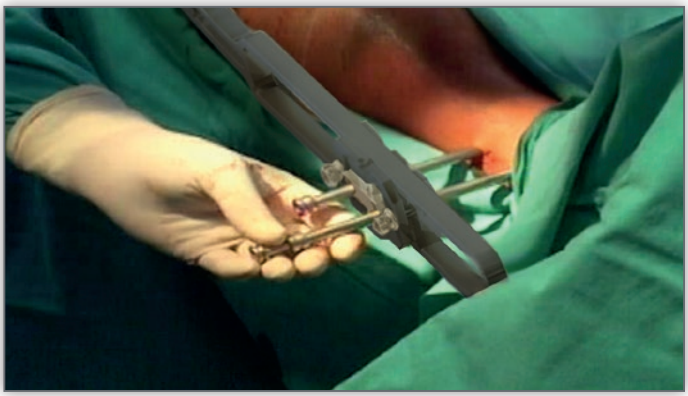
14



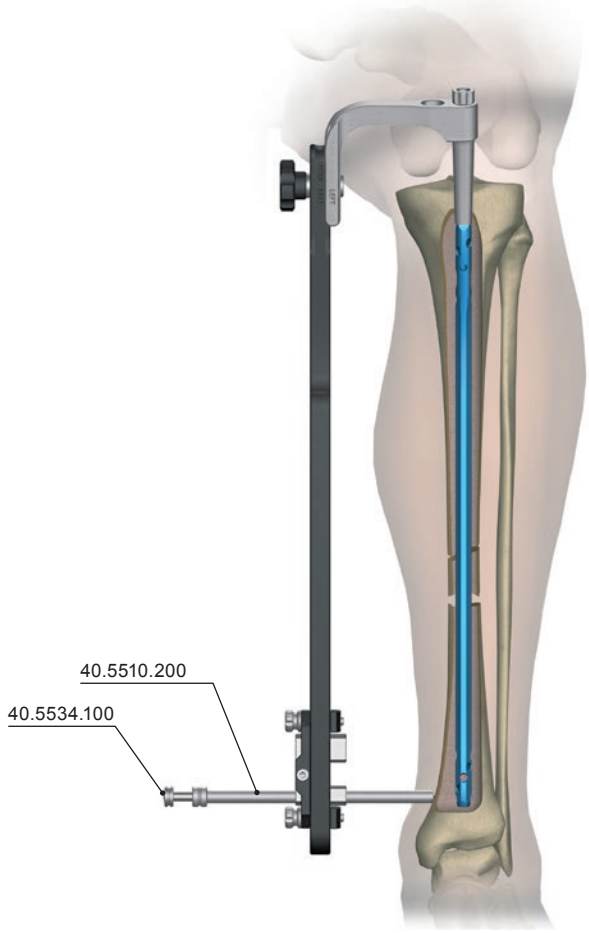
15 Remove the drill guide from the protective guide. Insert the protective guide 9/7 **[40.5510.200]** *(one groove on the handle)* together with the trocar 6.5 **[40.5534.100]** into one of the slider holes. Mark the entry point for the locking screws, then perform incision through the soft tissues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



15

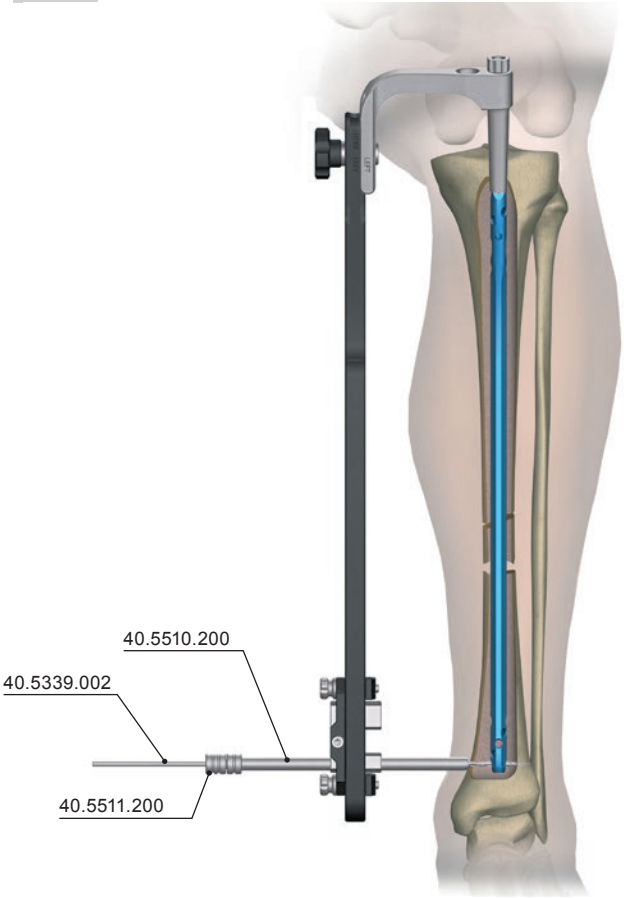


16 Insert the drill guide 7/3.5 **[40.5511.200]** into the left protective guide. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers and the nail hole. The scale on the drill indicates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

The drilling process should be controlled with image intensifier.

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

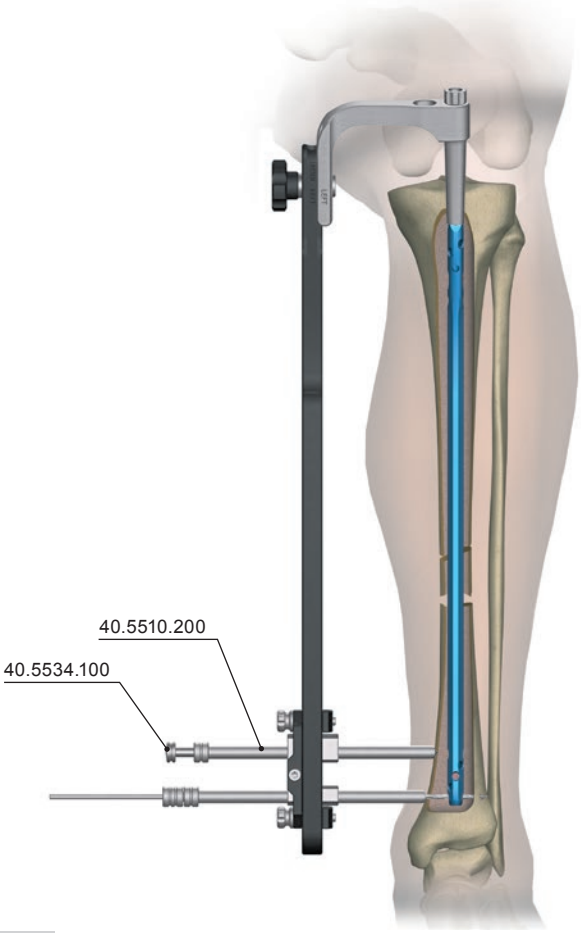
16



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.

17

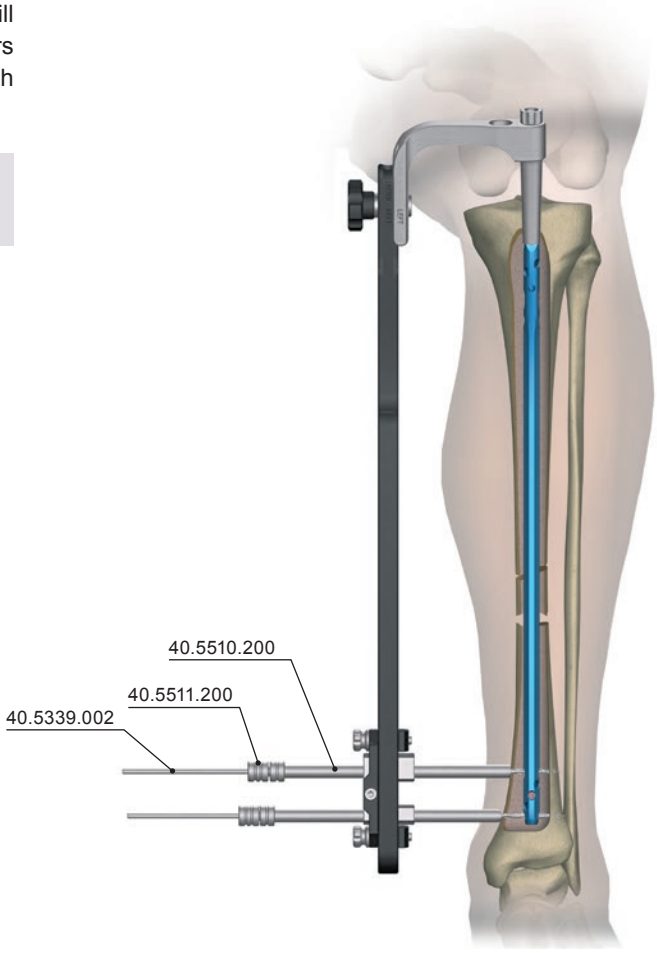


18 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]**. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers and the nail hole. The scale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

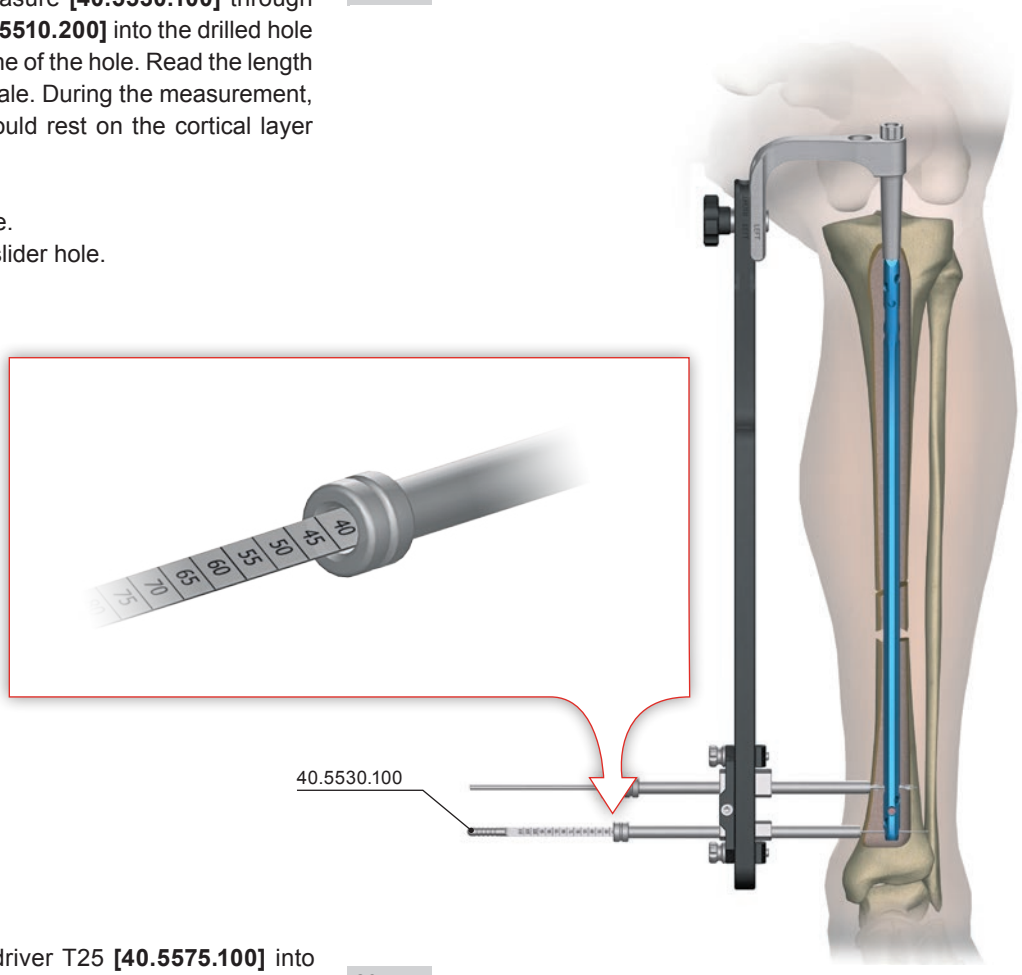
18



19 Insert the screw length measure **[40.5530.100]** 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.

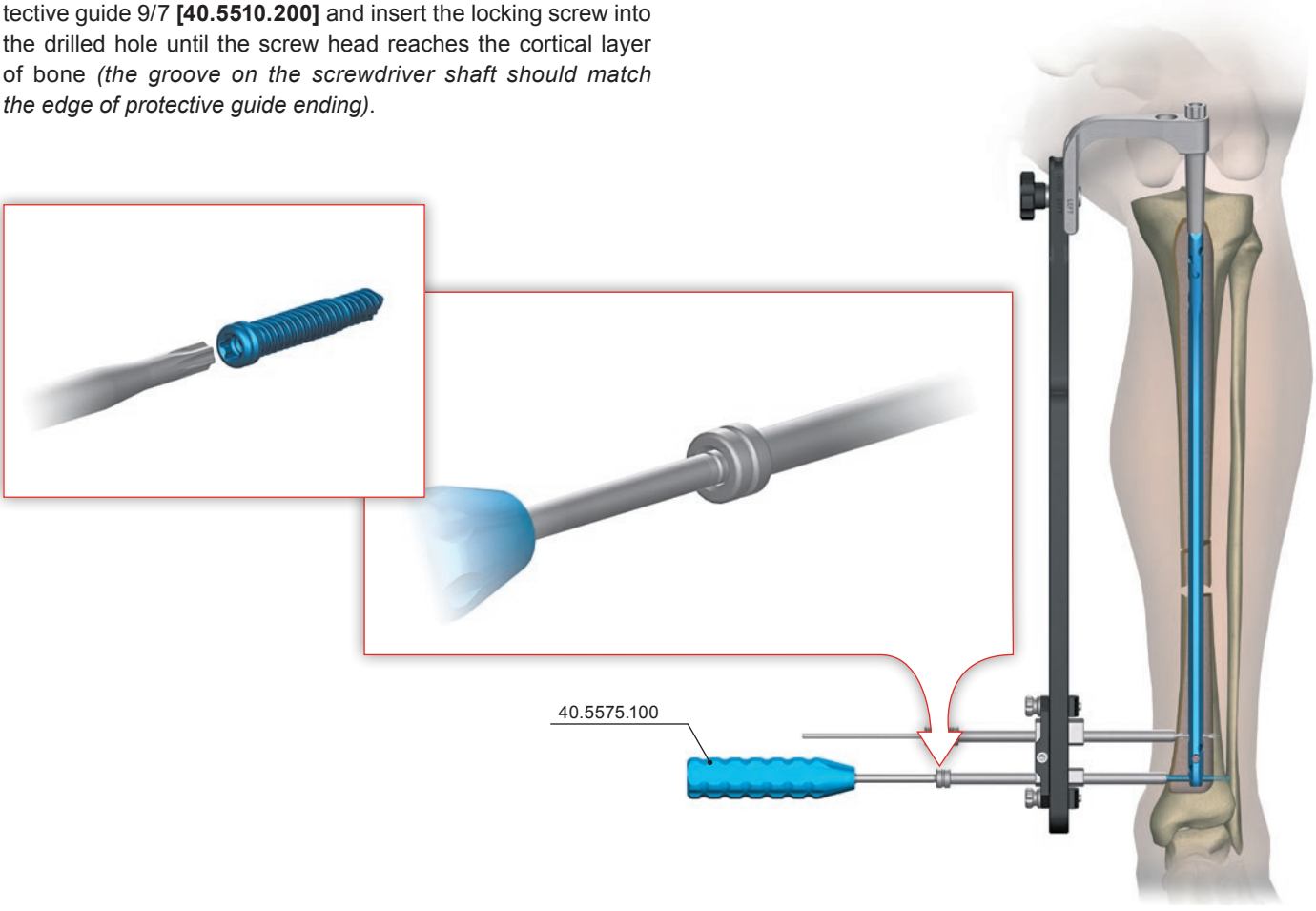
Remove the screw length measure.
Leave the protective guide in the slider hole.

19



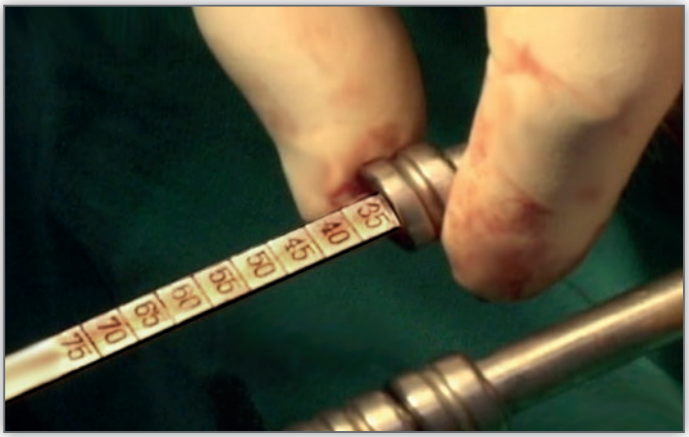
20 Insert the tip of the screwdriver T25 **[40.5575.100]** into the socket of a locking screw. Then insert them into the protective guide 9/7 **[40.5510.200]** and insert the locking screw into the drilled hole until the screw head reaches the cortical layer of bone *(the groove on the screwdriver shaft should match the edge of protective guide ending)*.

20

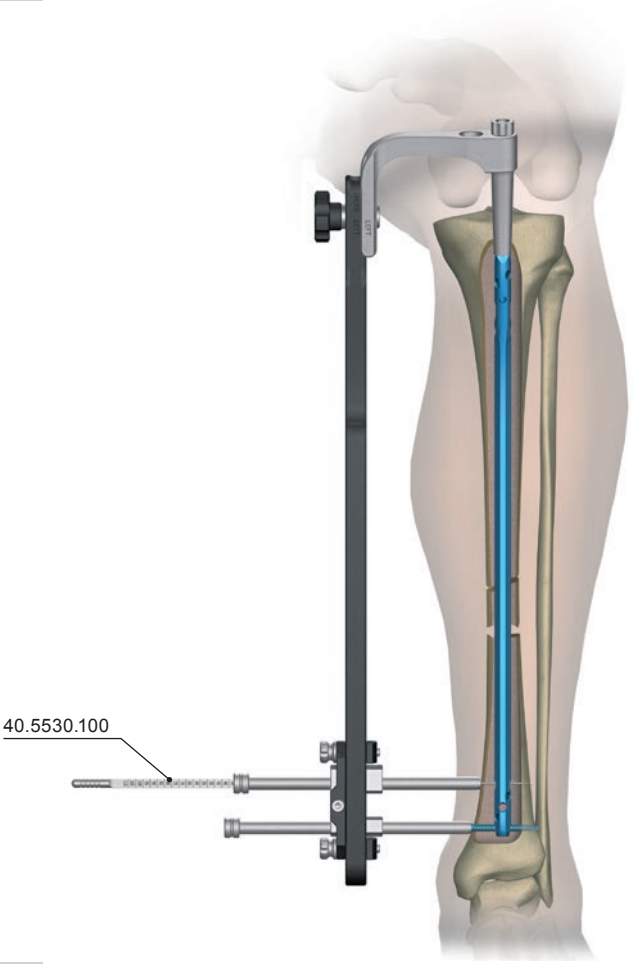


21 Remove the drill with scale 3.5/350 **[40.5339.002]** and drill guide 7/3.5 **[40.5511.200]** from the proximal hole in the slider. Leave the protective guide 9/7 **[40.5510.200]** in the slider hole. Insert the screw length measure **[40.5530.100]** through the protective guide into the drilled hole 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.



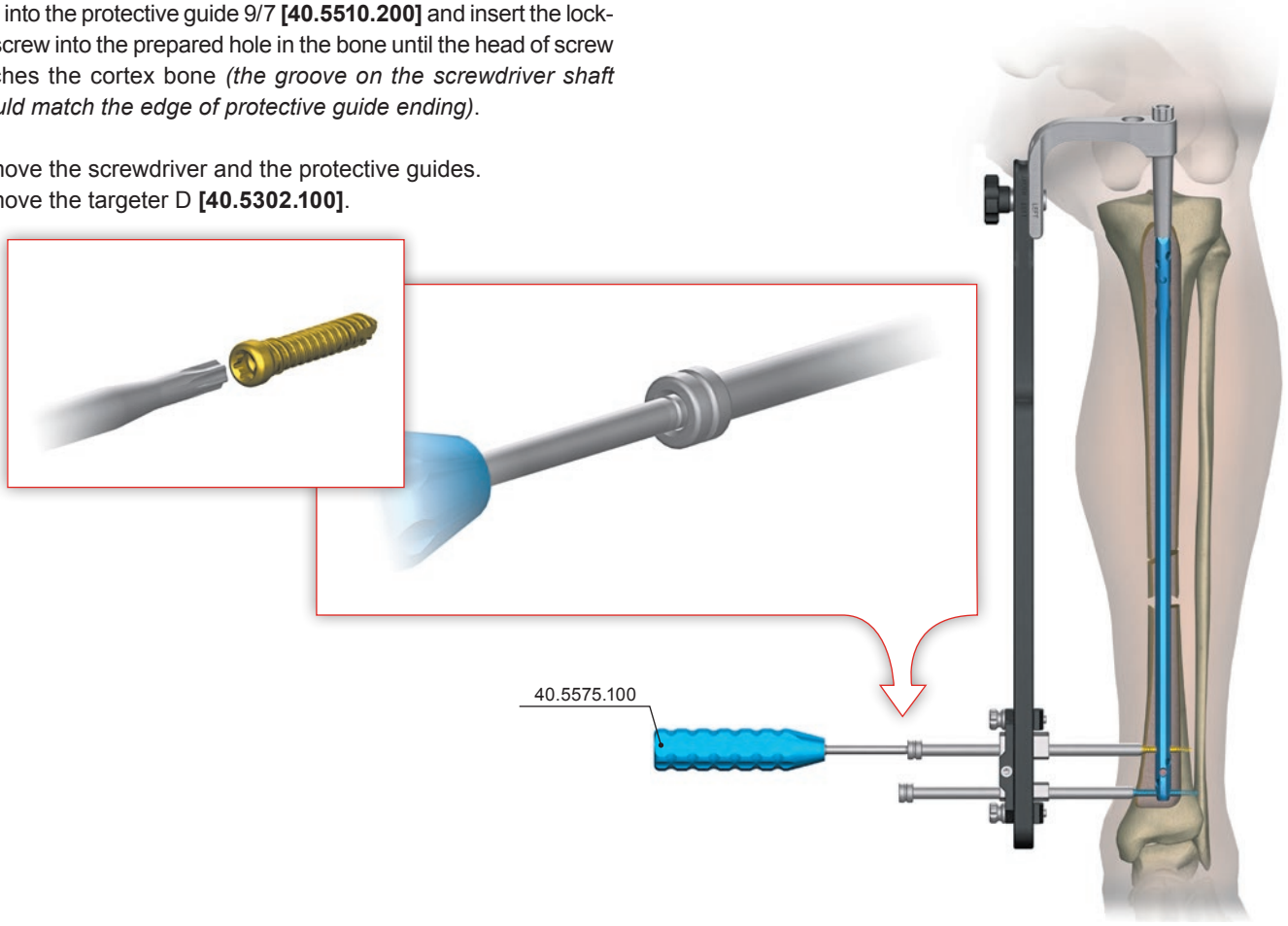
21



22 Insert the tip of a screwdriver T25 **[40.5575.100]** 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]**.

22

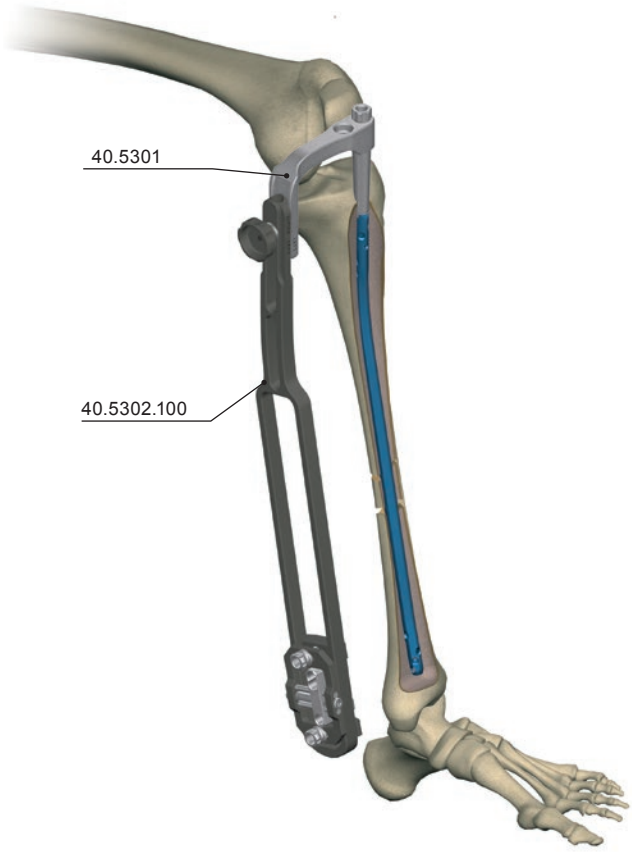


V.5.2. OPTION II: Without X-Ray control

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]**.

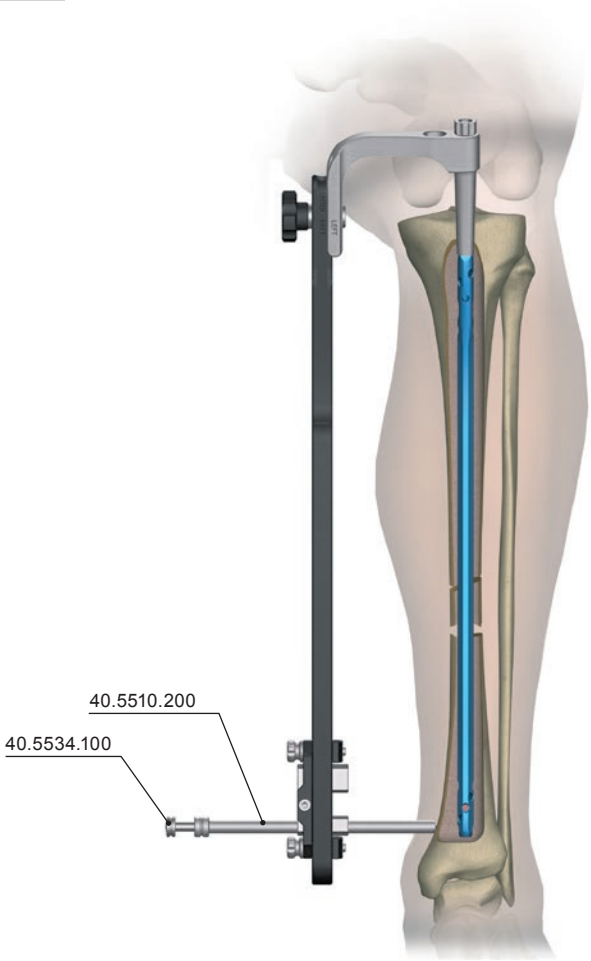
23



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.

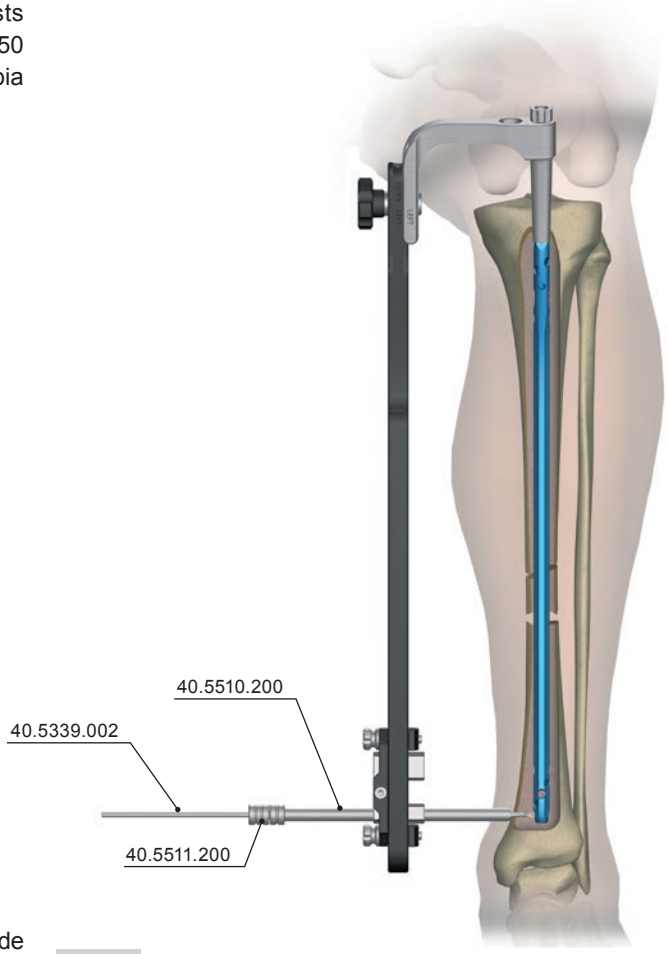
Remove the trocar.

24



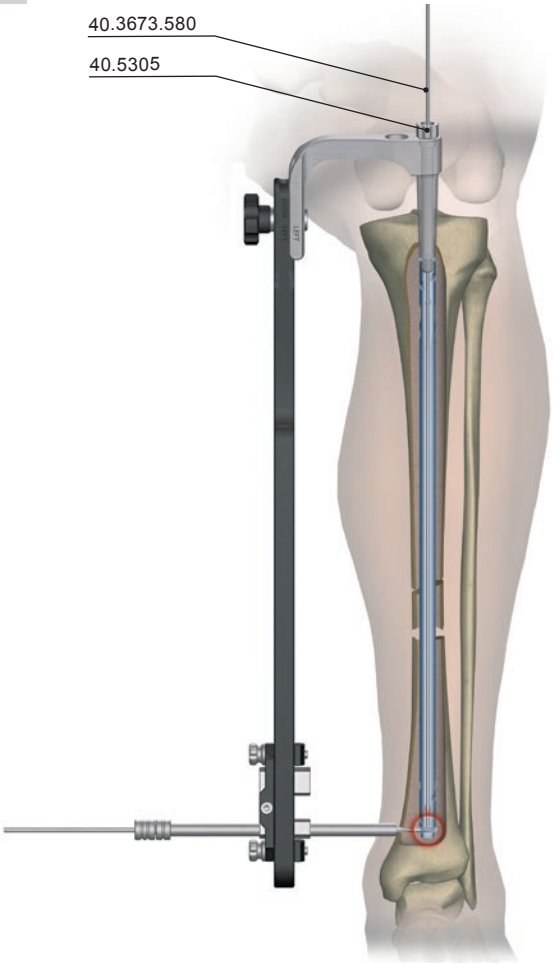
25 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]** until the drill guide end rests on the bone. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its first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

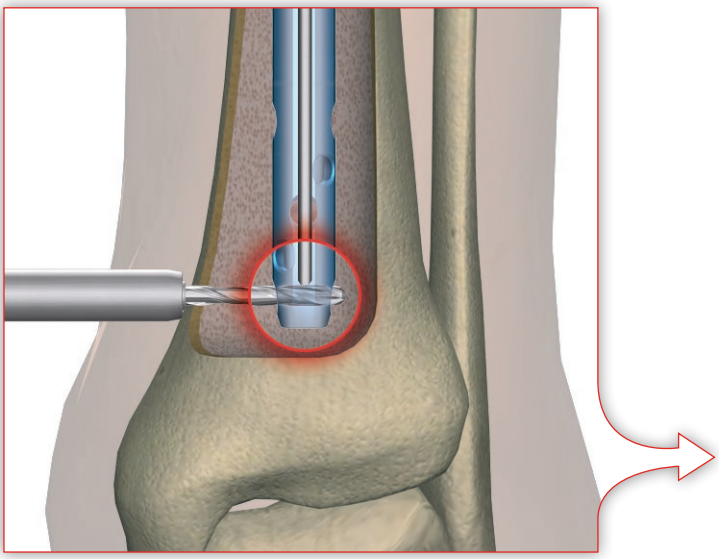
25



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.

26





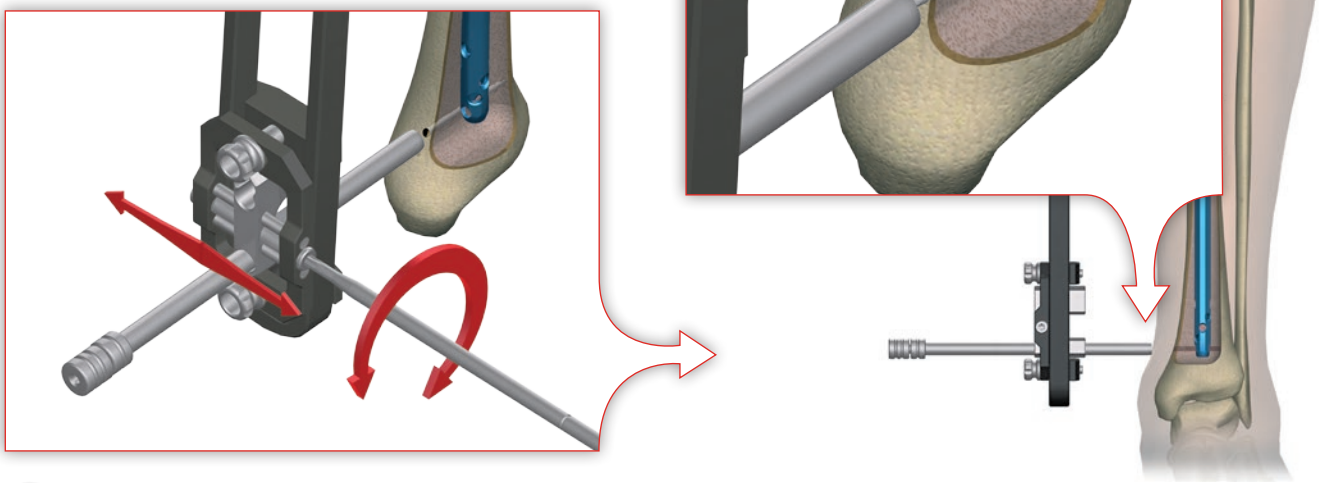
27 If the drill goes through the first cortical layer but misses the hole, then:

- 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.

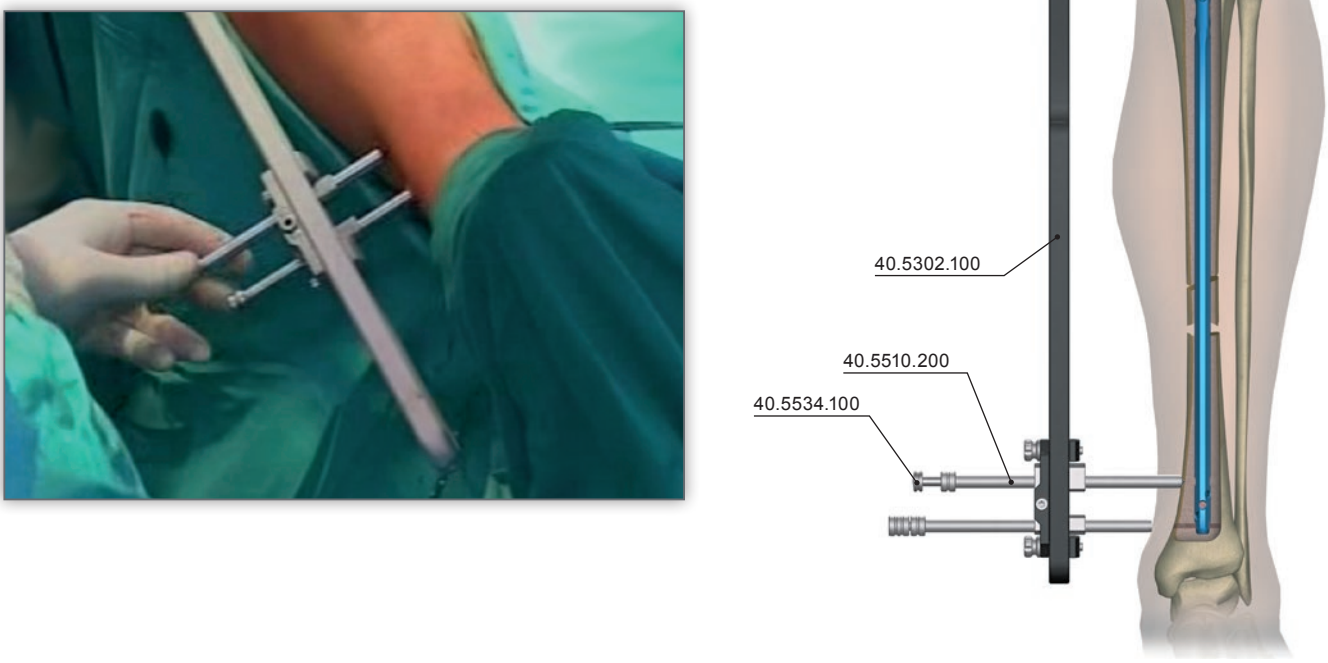
27



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.

28



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.

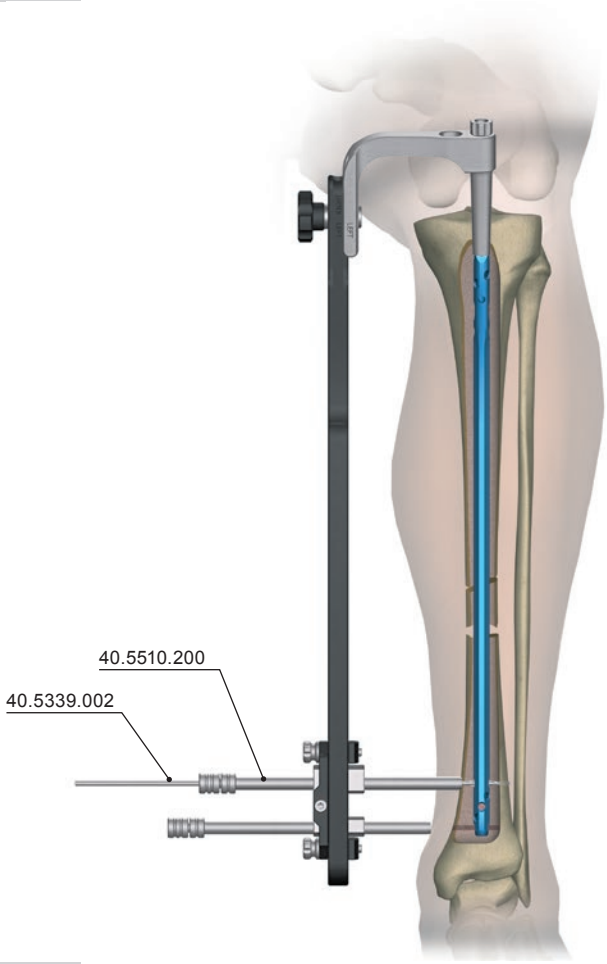
If the drill misses the nail hole then use the first hole in the targeter slider to find the hole.

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.

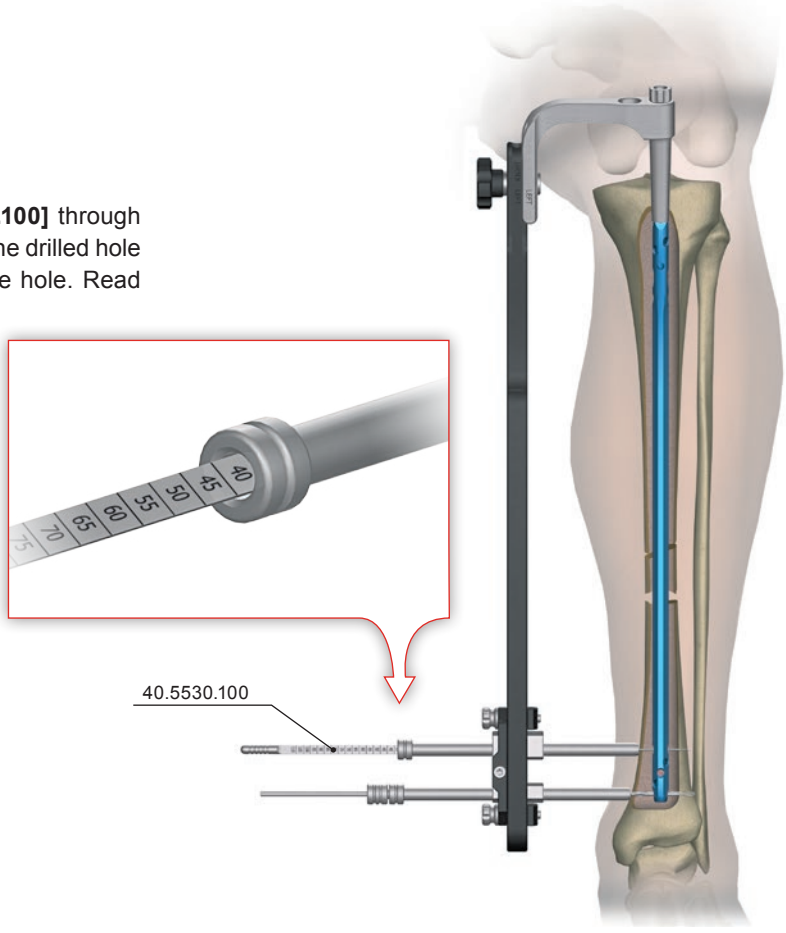
29



30

30 Insert the screw length measure **[40.5530.100]** 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.

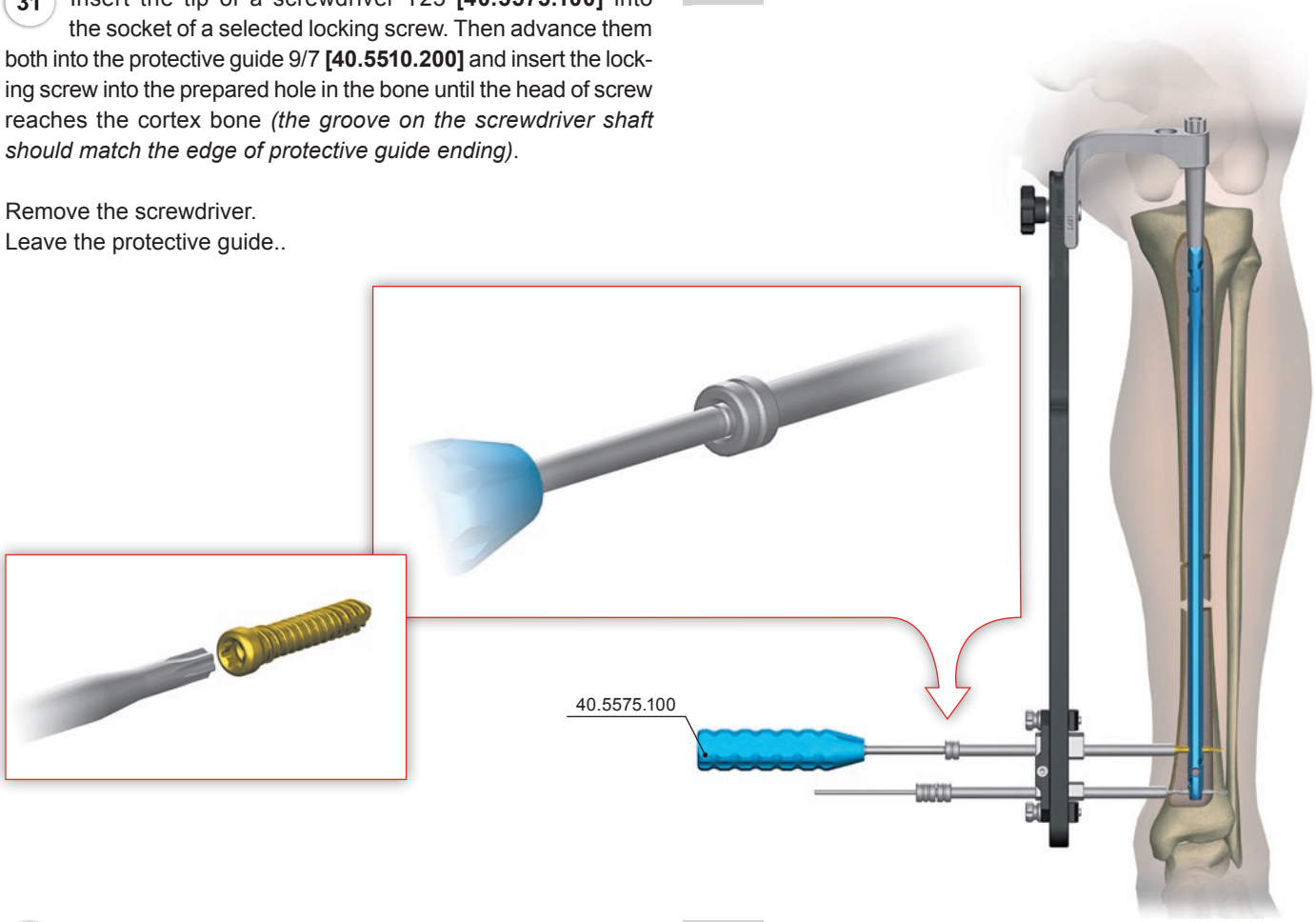
Remove the screw length measure.
Leave the protective guide in the slider hole.



31 Insert the tip of a screwdriver T25 **[40.5575.100]** 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..

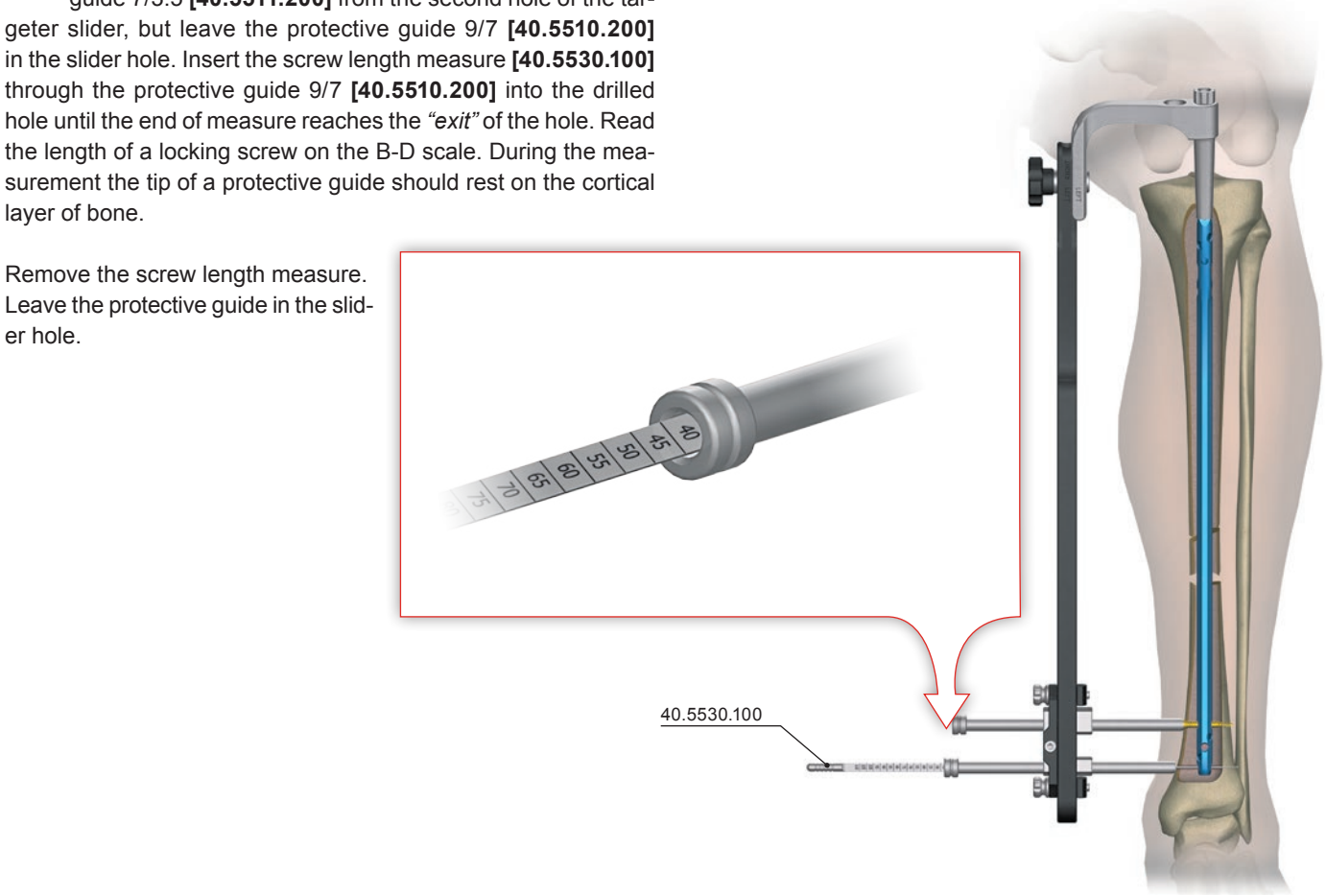
31



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 **[40.5530.100]** 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.

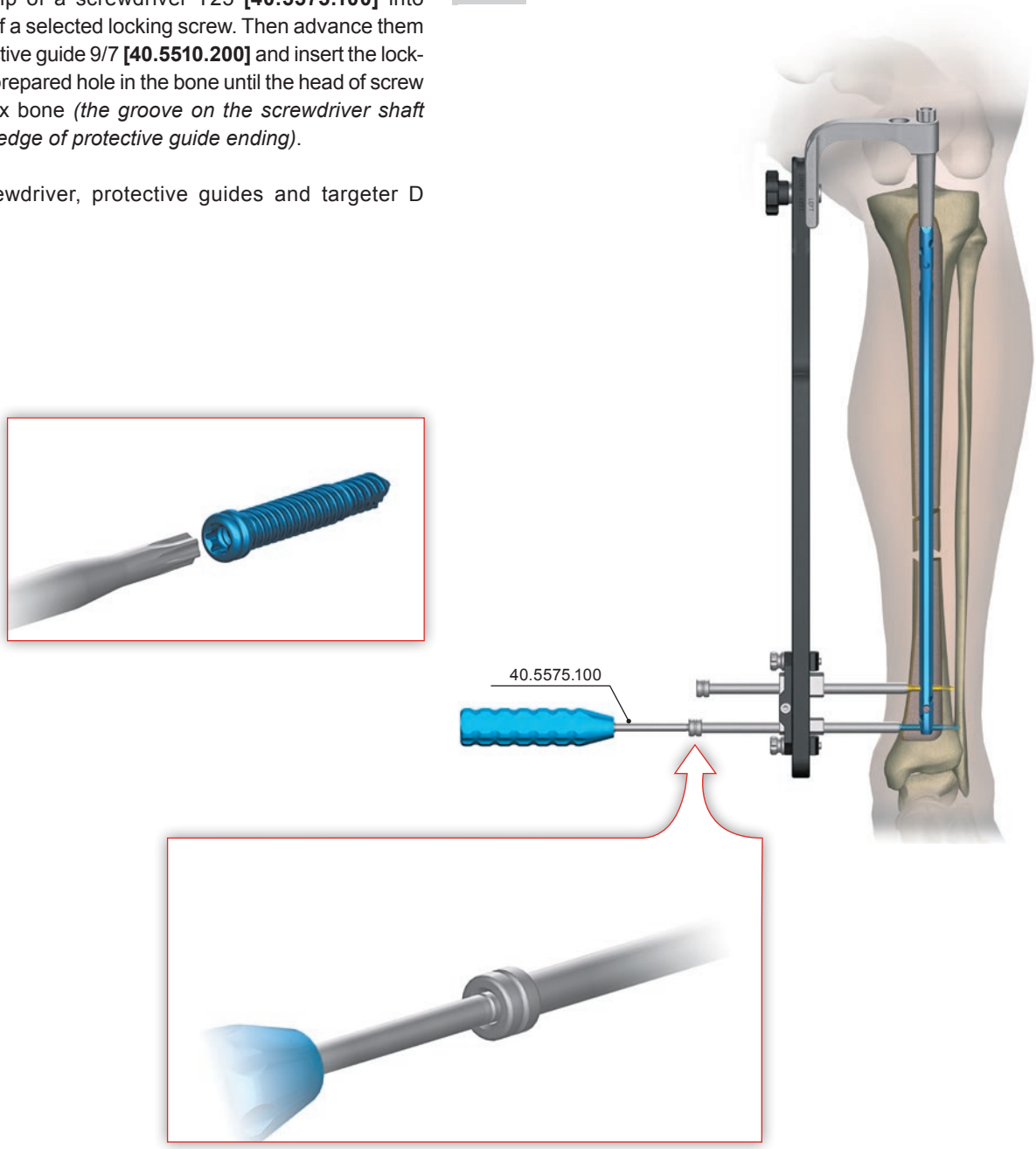
32



33 Insert the tip of a screwdriver T25 **[40.5575.100]** 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]**

33



	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)*	

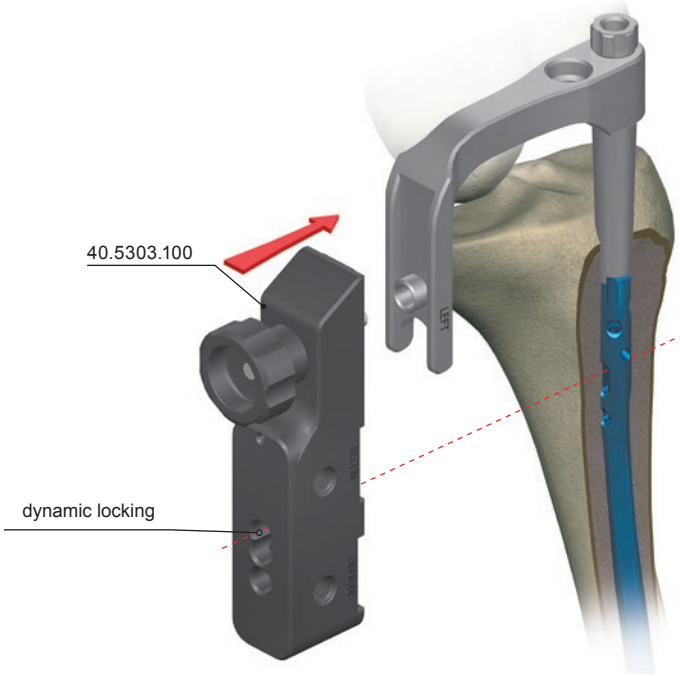
V.6. PROXIMAL LOCKING OF INTRAMEDULLARY NAIL

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.**

V.6.1. Dynamic fixation and dynamic fixation with compression *(compressive fixation)*

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

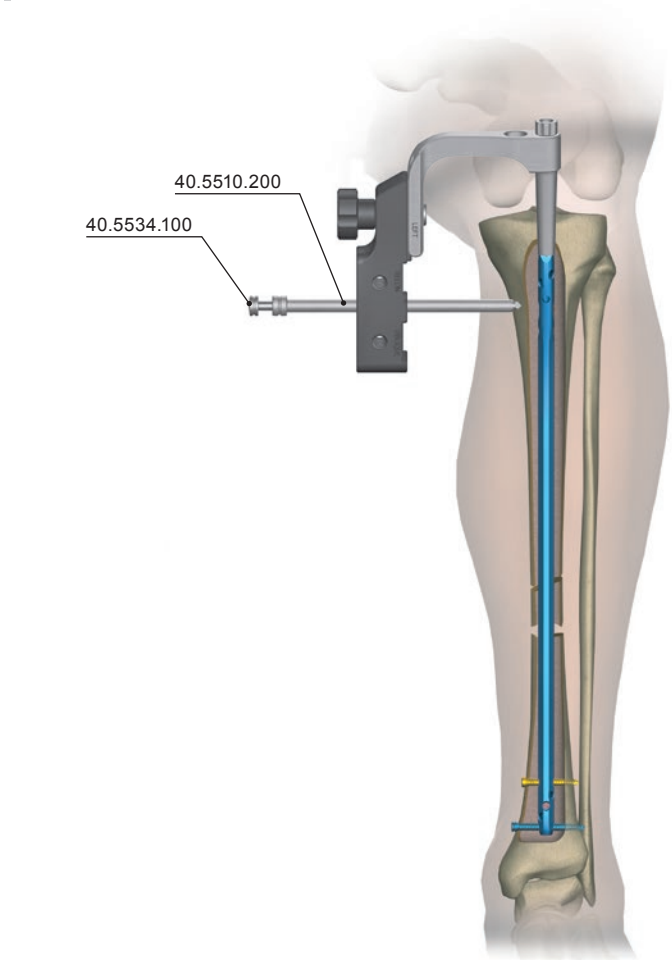
When the dynamic fixation or dynamic fixation with compression is used, the proximal locking of the nail should be performed through the proximal targeter hole *(the oval-shaped hole in the intramedullary nail)*.

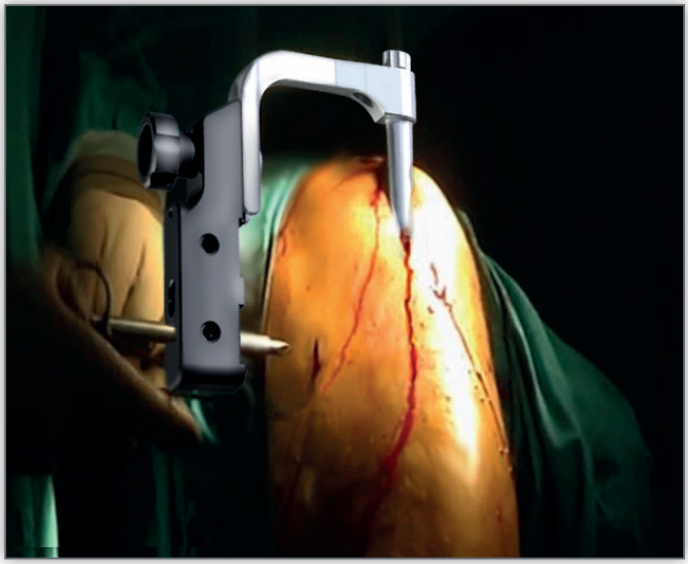


34 Insert the protective guide 9/7 **[40.5510.200]** together with the trocar 6.5 **[40.5534.100]** into the proximal part of the targeter. Mark the entry point for the locking screw, then perform incision through the soft tissues along the marked point with a length of about 1.5 cm. Advance the protective 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.

34

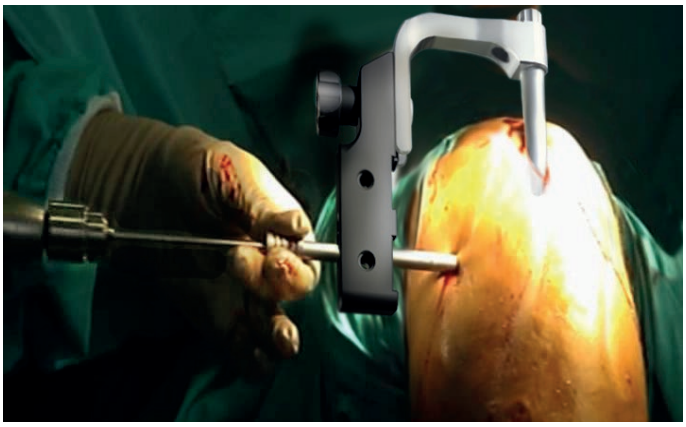




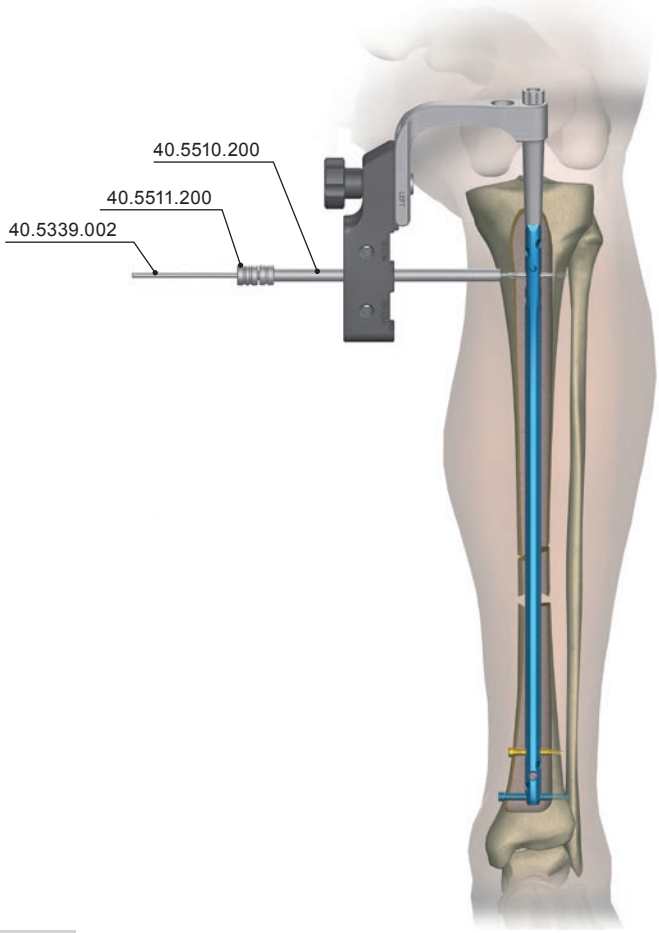
35 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]**. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates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



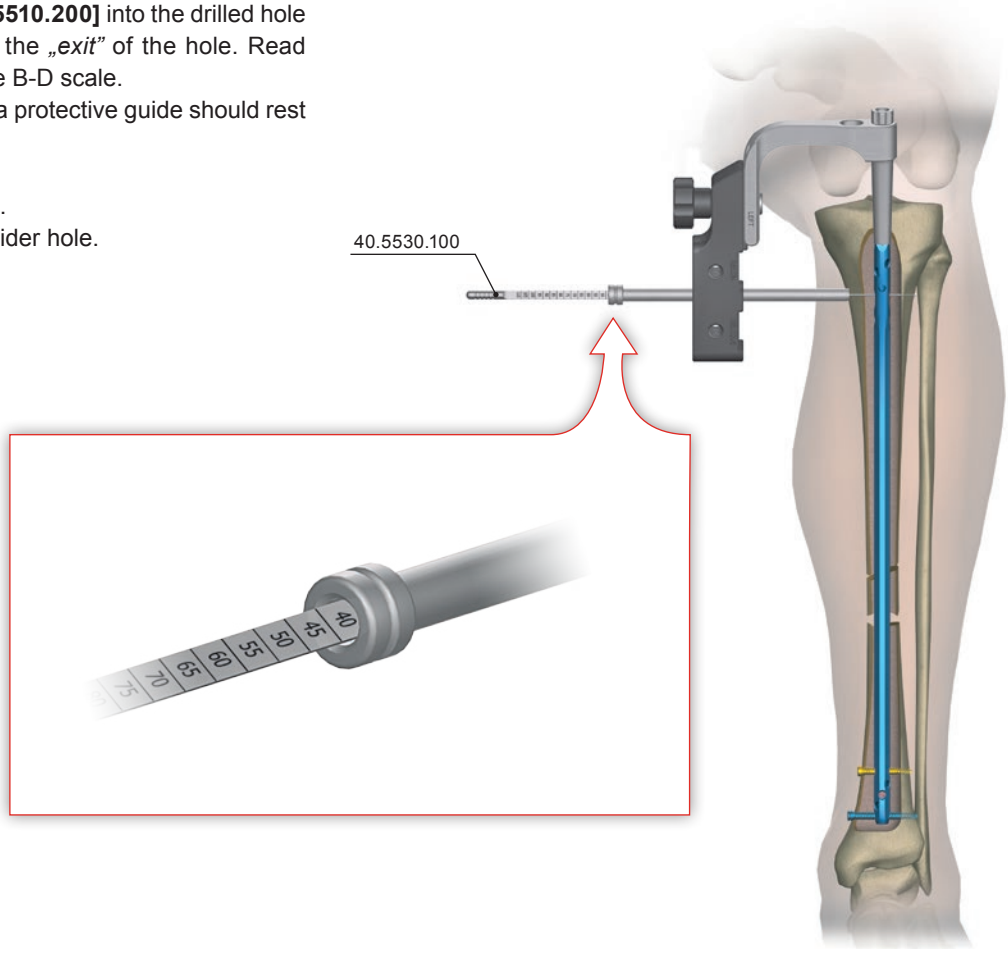
35



36 Insert the screw length measure **[40.5530.100]** 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.

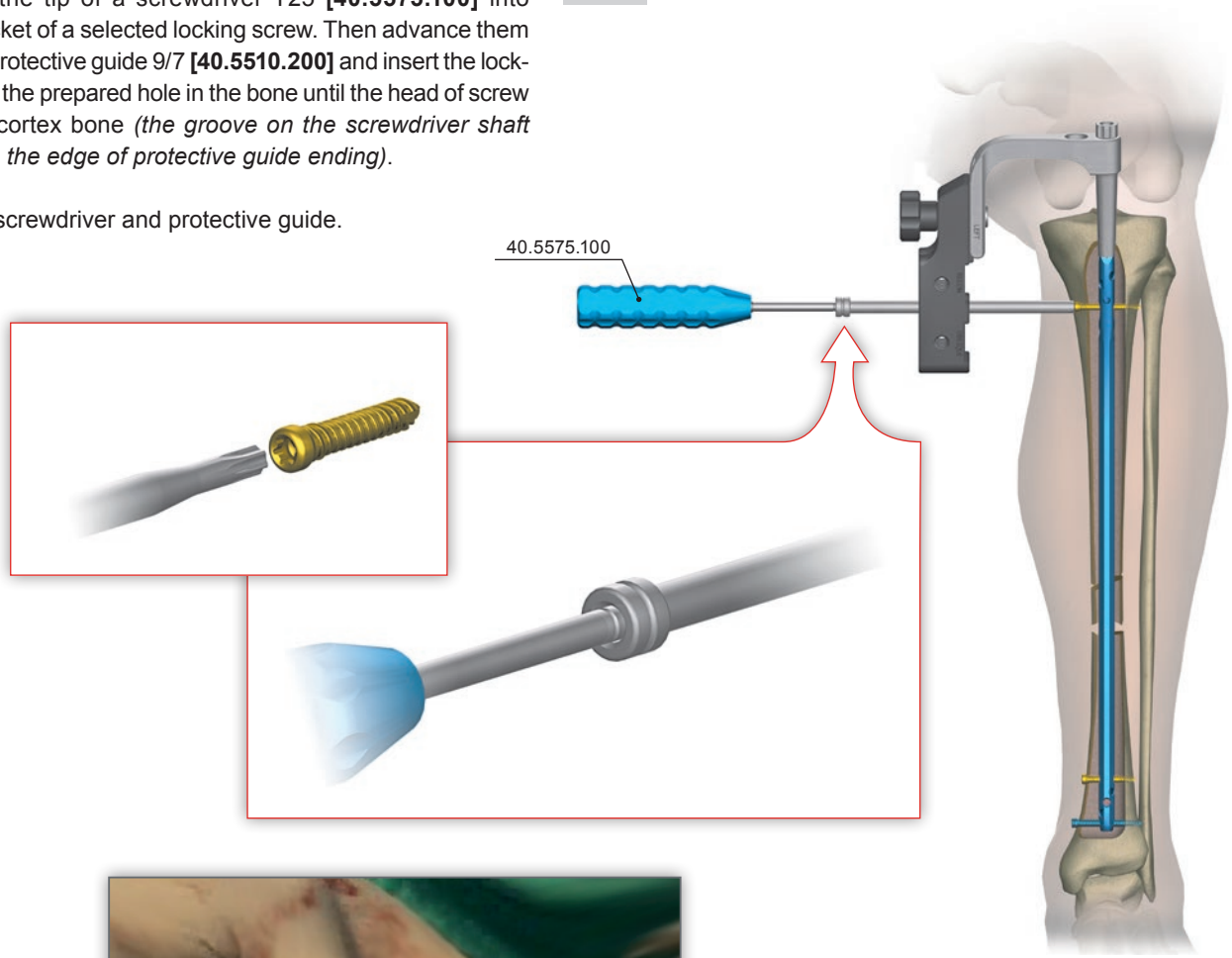
36

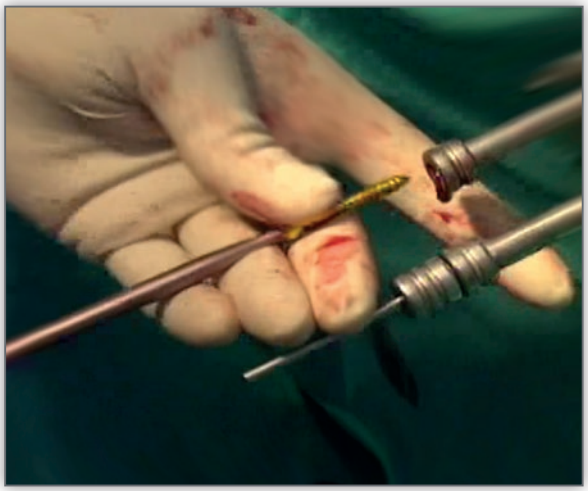


37 Insert the tip of a screwdriver T25 **[40.5575.100]** into the socket of a selected locking screw. Then advance them both into the protective guide 9/7 **[40.5510.200]** and insert the locking screw into the prepared hole in the bone until the head of screw reaches the cortex bone *(the groove on the screwdriver shaft should match the edge of protective guide ending)*.

Remove the screwdriver and protective guide.

37





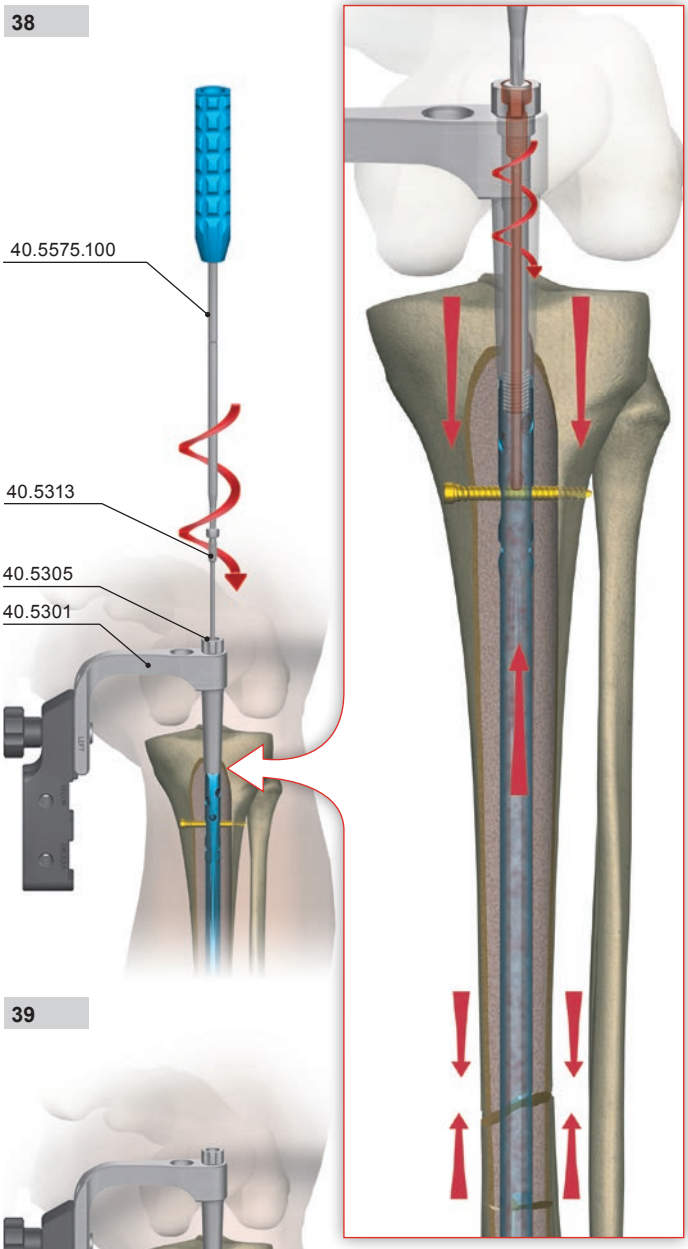
V.6.2. Intraoperative compression of fractures

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 **[40.5575.100]** to insert the compression screw **[40.5313]** *(screw it until the resistance is felt)* into the connecting screw **[40.5305]**, which is used to connect the targeter arm B **[40.5301]** with the intramedullary nail. Further screwing-in causes bone fragments compression by 1 mm at one screw turn.

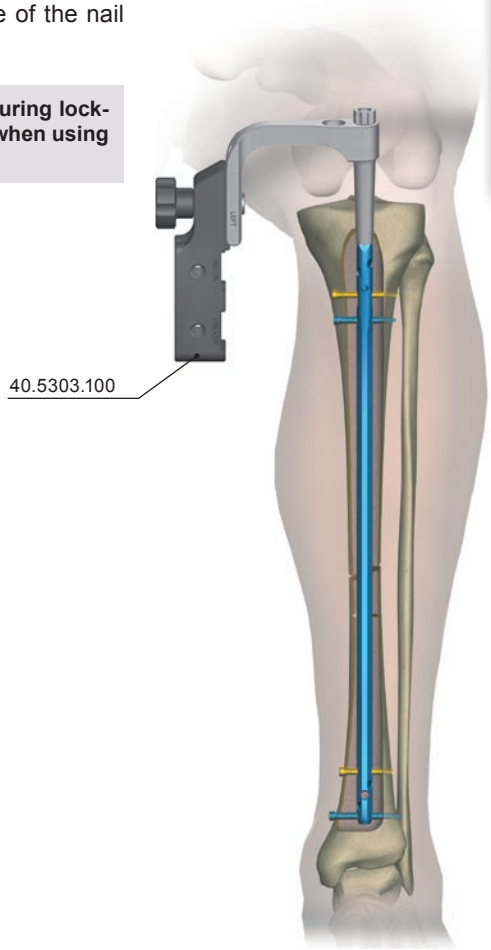
38



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]**.

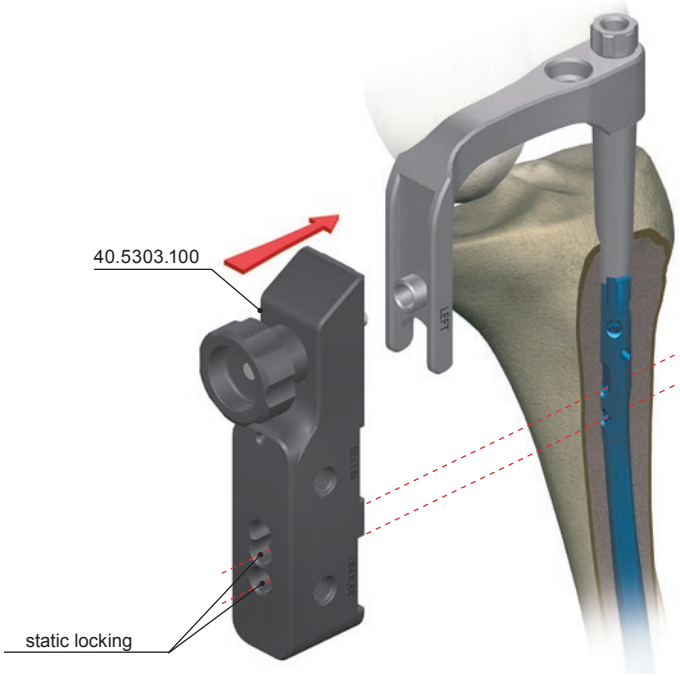
Remove the compression screw [40.5313] during locking in the reconstructive and oblique holes when using the reconstruction targeter [40.5307.100].

39



V.6.3. Static fixation

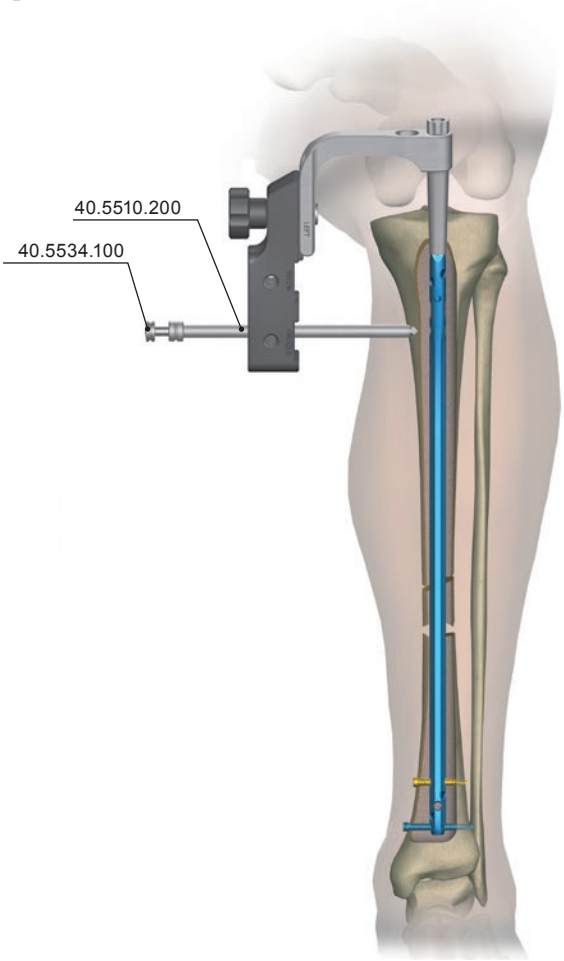
When using the static fixation, it is recommended to lock the nail in the proximal part with two screws. In each case of locking the nail the distally located round hole shall be used.



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 proximal part 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 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

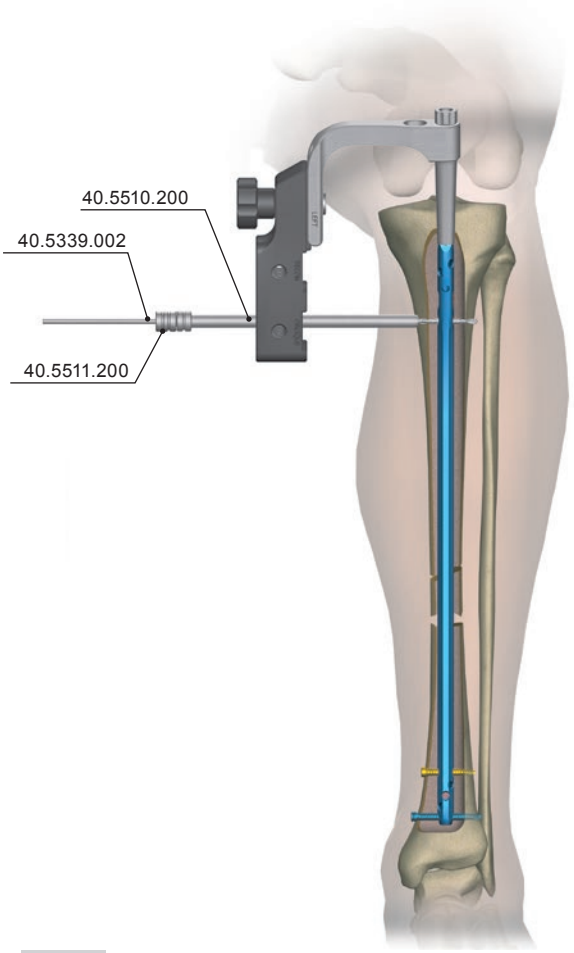


41 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]**. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates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

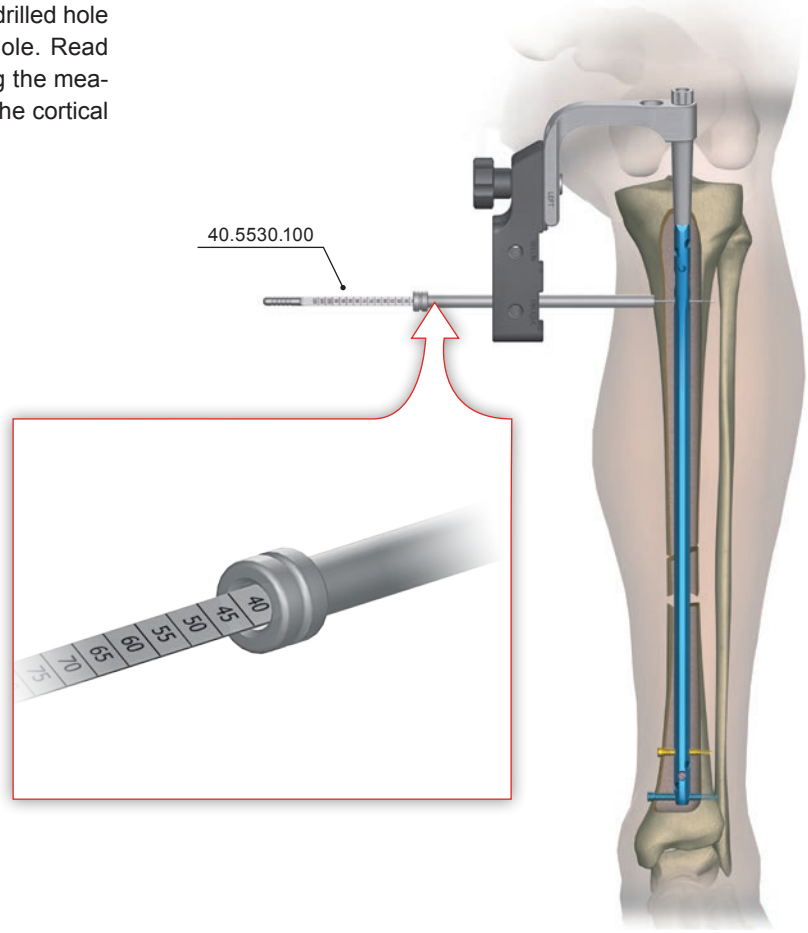
41



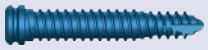
42 Insert the screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole until the end of measure reaches the *"exit"* of the hole. Read the length of a locking screw on the B-D scale. During the measurement the tip of a protective guide should rest on the cortical layer of bone.

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

42

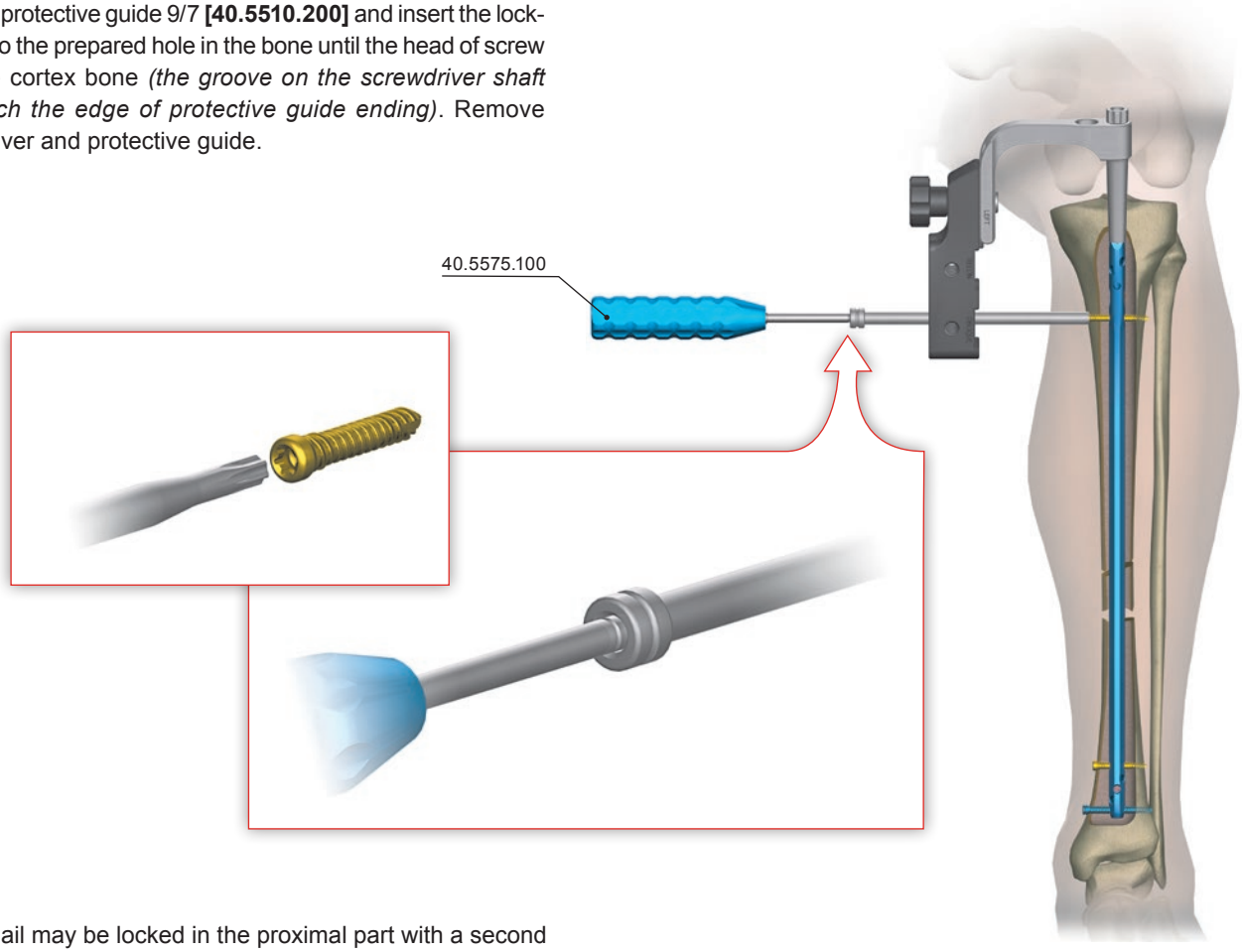


43 The following screws may be used to lock the nail:

	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 **[40.5575.100]** 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.

44

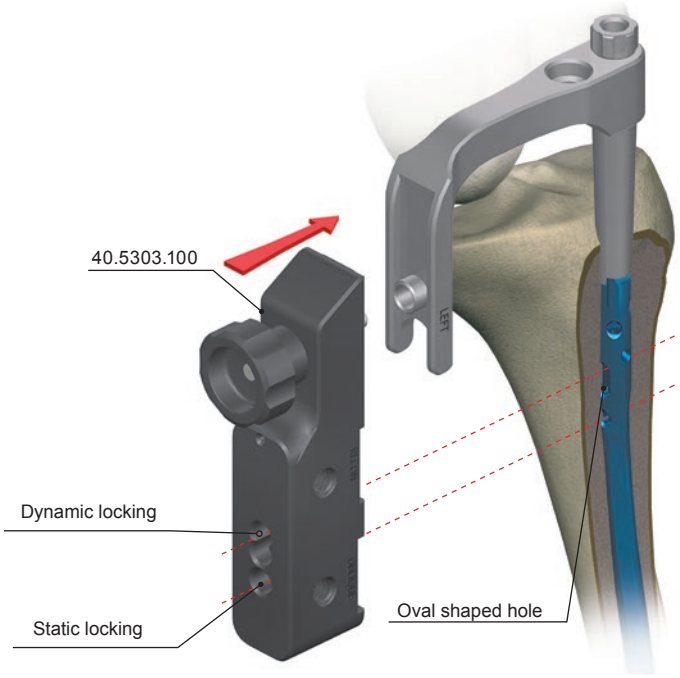


45 The nail may be locked in the proximal part with a second locking screw by using the central hole of the targeter B **[40.5303.100]**.

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

V.6.4. Static fixation with later dynamization

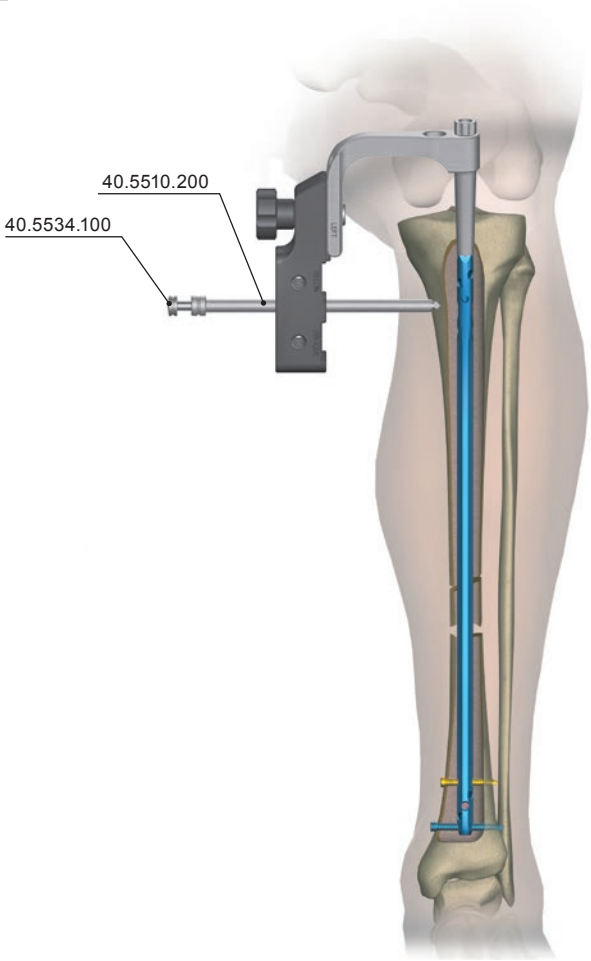
When using the static fixation, it is recommended to lock the nail in its proximal part with two screws - dynamically in the oval-shaped hole and statically in the round hole below the oval-shaped hole. The dynamization is obtained in the subsequent period by removing the locking screw from round hole.



46 Insert the protective guide 9/7 **[40.5510.200]** together with the trocar 6.5 **[40.5534.100]** into the proximal hole in the proximal part of the 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 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.

46

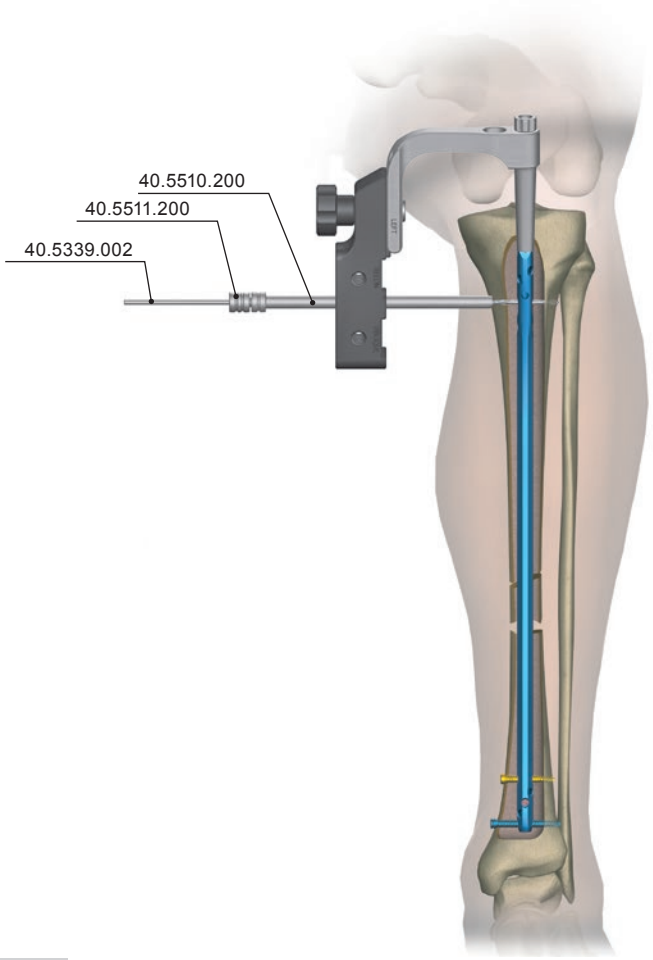


47 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]**. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates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

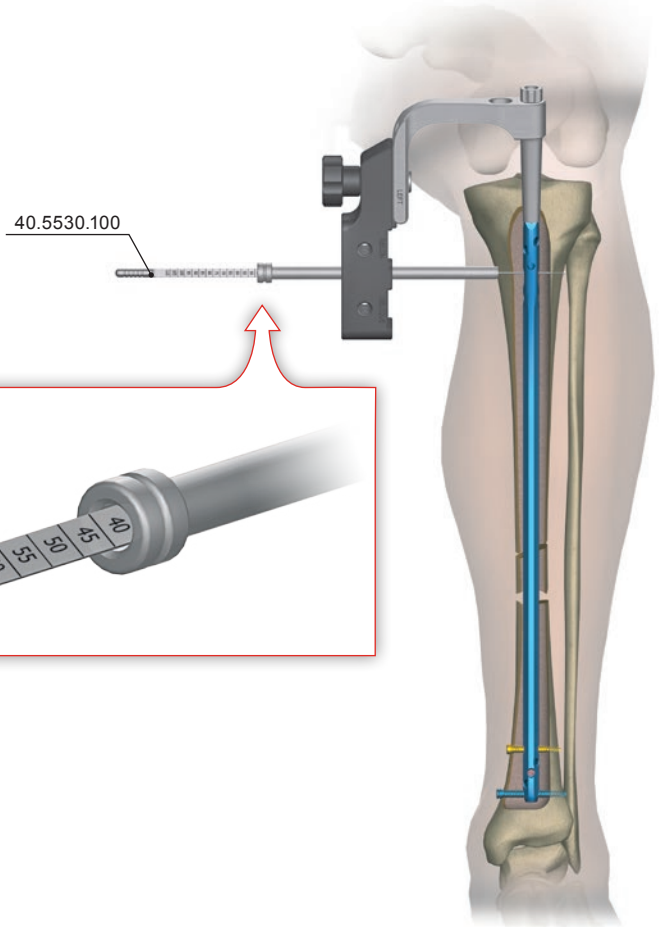
47

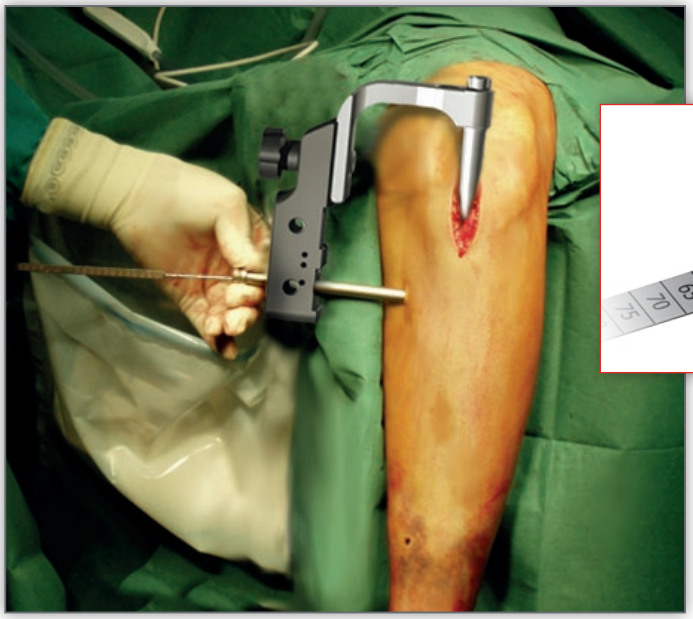


48 Insert the screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole until the end of measure reaches the *"exit"* of the hole. Read the length of a locking screw on the B-D scale.
During the measurement the tip of a protective guide should rest on the cortical layer of bone.

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

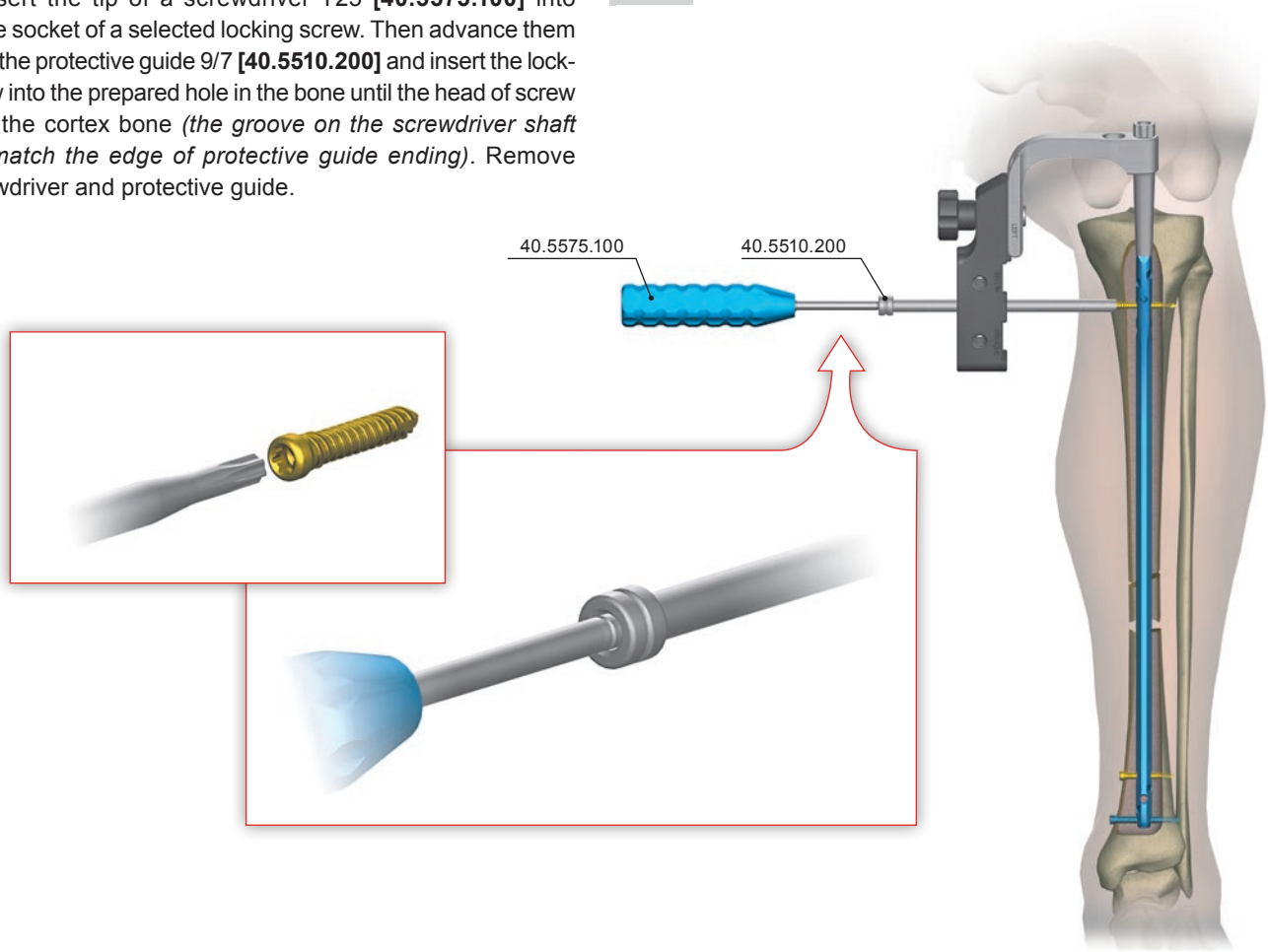
48





49 Insert the tip of a screwdriver T25 **[40.5575.100]** 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.

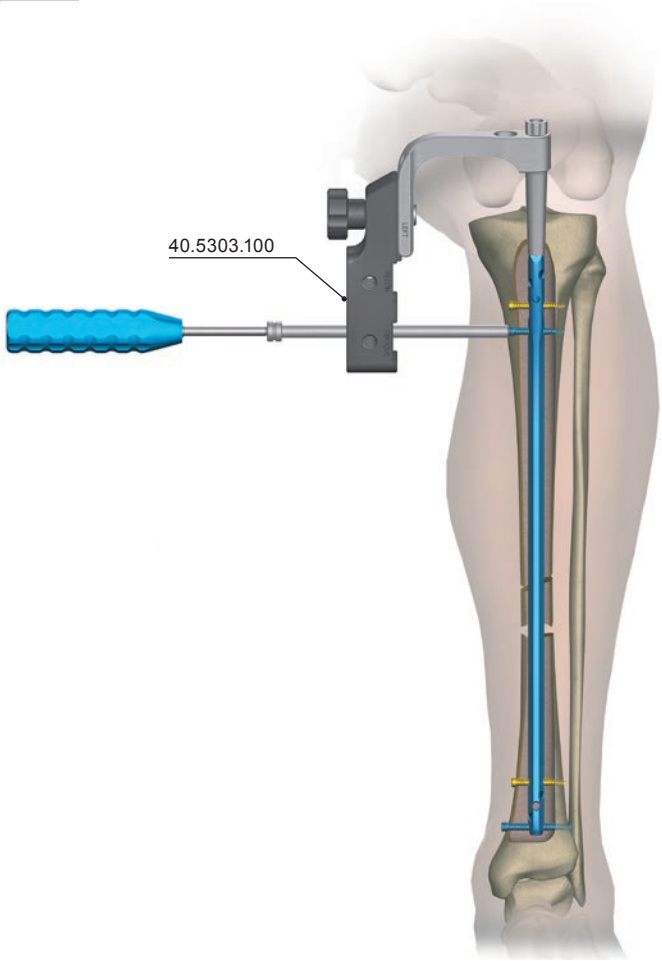
49

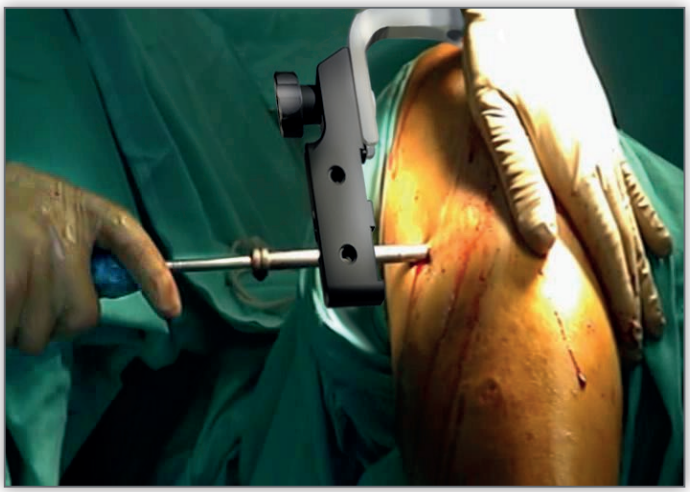


50 The nail may be locked in the proximal part with a second locking screw by using the distal hole of the targeter B **[40.5303.100]**.

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

50

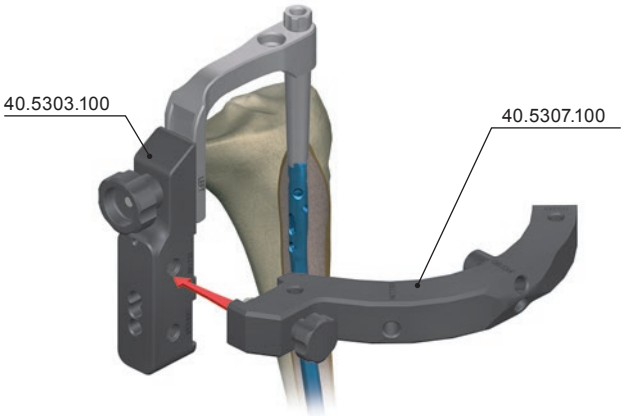




V.6.5. Reconstruction and oblique fixation

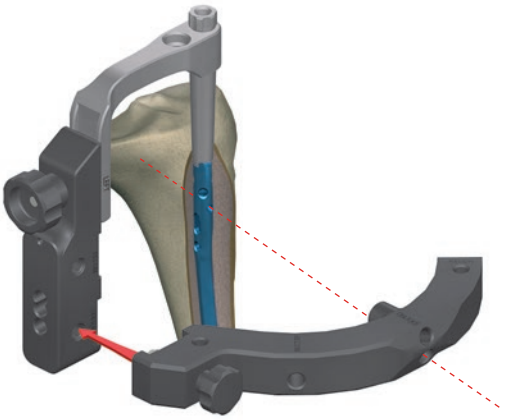
In order to lock the tibial nail in the reconstructive holes it is necessary to mount the reconstruction targeter **[40.5307.100]** onto the targeter B **[40.5303.100]**. The targeter B **[40.5303.100]** has two sockets for the reconstruction targeter.

51



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.

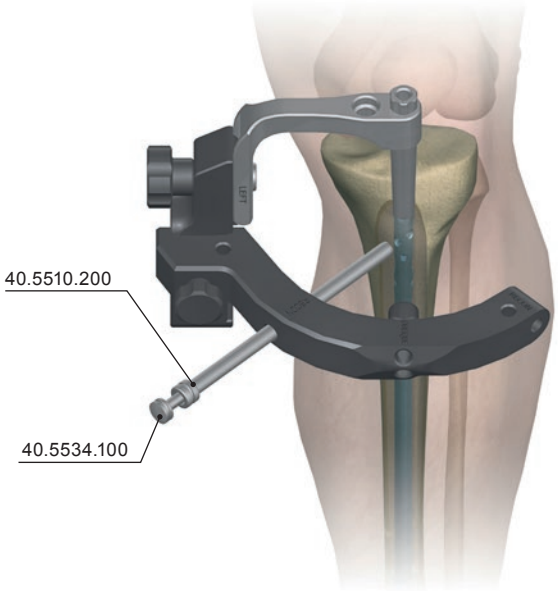
52



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.

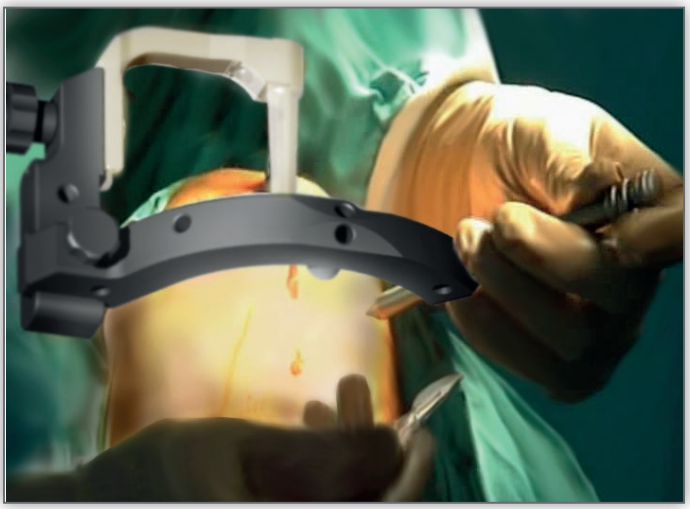
V.6.5.A. Reconstructive fixation

53



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 **[40.5307.100]**. 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 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.

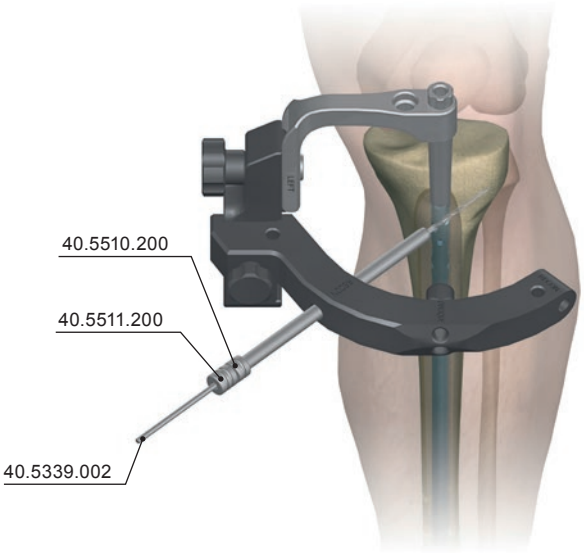


54 Insert the drill guide 7/3.5 **[40.5511.200]** into the protective guide 9/7 **[40.5510.200]**. Use the electric drive with a drill with scale 3.5/350 **[40.5339.002]** led via the drill guide to drill an opening in the tibia that goes through its both cortical layers. The scale on the drill indicates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

The drilling process should be controlled with image intensifier.

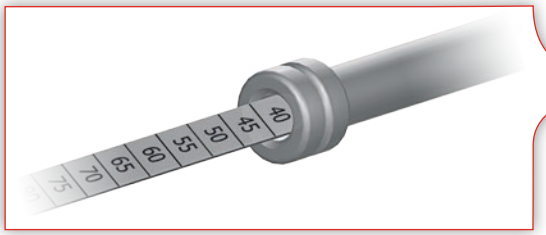
Remove the drill and drill guide.
Leave the protective guide in the targeter hole.

54

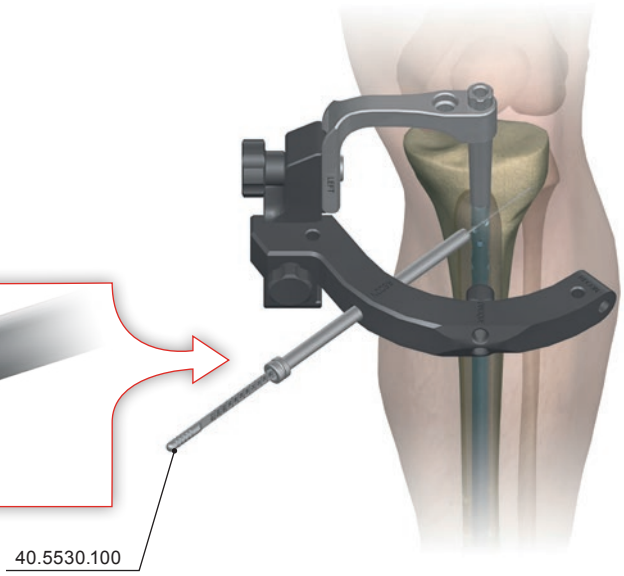


55 Insert the screw length measure **[40.5530.100]** through the protective guide 9/7 **[40.5510.200]** into the drilled hole until the end of measure reaches the *"exit"* of the hole. Read the length of a locking screw on the B-D scale.
During the measurement the tip of a protective guide should rest on the cortical layer of bone.

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



55



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

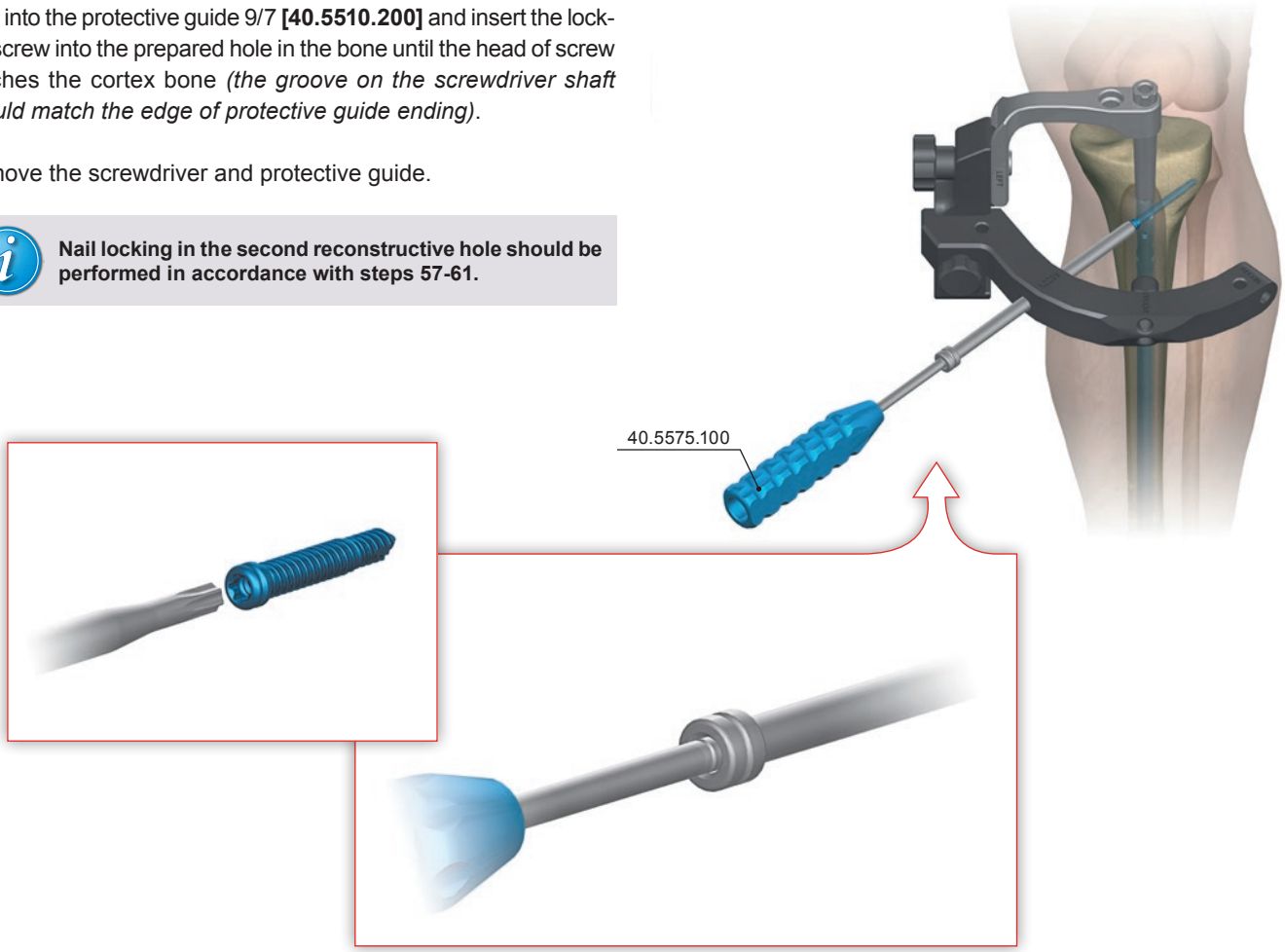
	Diameter of intramedullary nail			
	Ø8 and Ø9 mm		Ø10 mm and larger	
	Standard locking	Standard locking with angular stabilization	Standard locking	Standard locking with angular stabilization
Round hole	***CHARFIX2*** Distal screw 4.0 *(turquoise)*	***CHARFIX2*** Distal screw 4.5 *(brown)*	***CHARFIX2*** 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 **[40.5575.100]** 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.

57



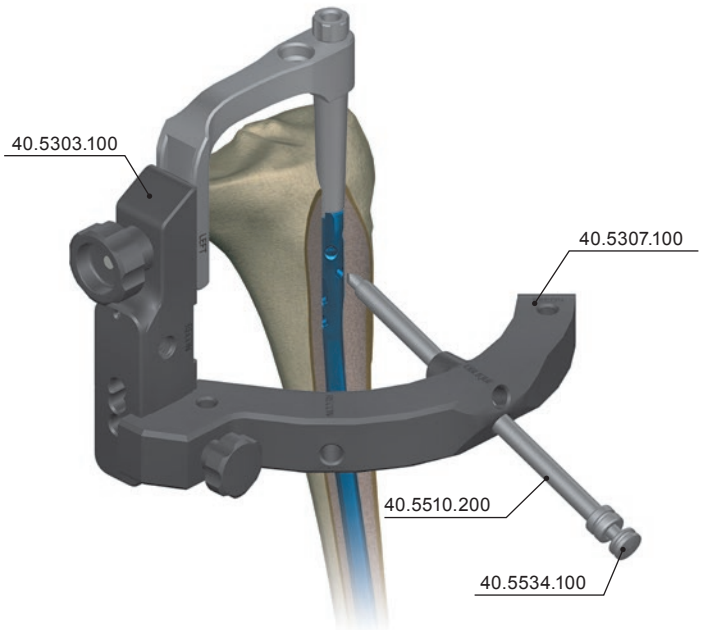
V.6.5.B. Oblique fixation

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 **[40.5307.100]** 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

58



V.7. PLACING COMPRESSION SCREW OR END CAP

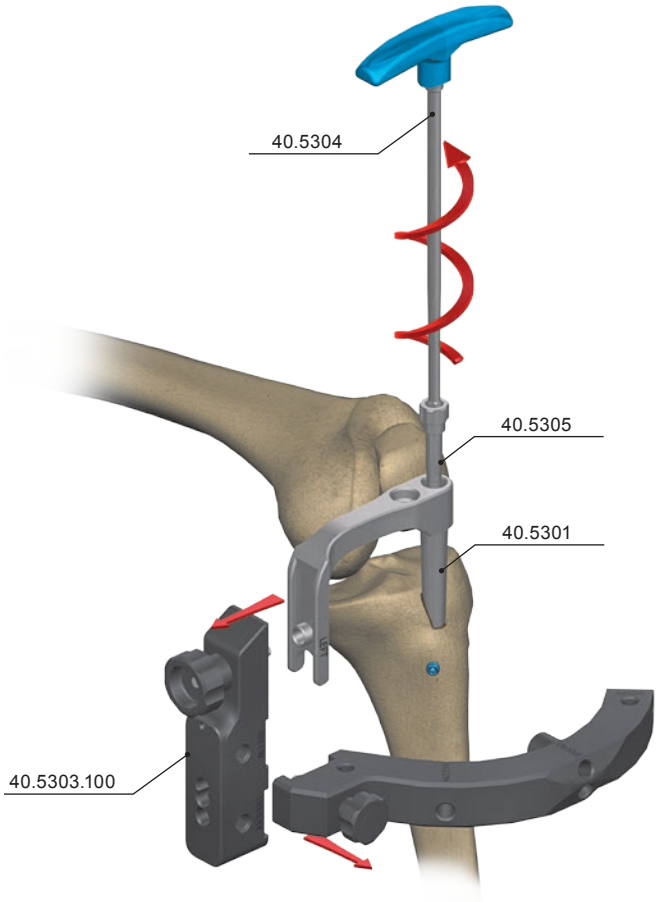
Use the wrench S8 **[40.5304]** to remove the connecting screw **[40.5305]** or **[40.5306]** from the intramedullary nail shaft. Detach the targeter arm **[40.5301]** with targeter B **[40.5303.100]** and targeter D **[40.5302.100]** from the nail locked in the medullary canal.

Insertion of the compression screw or end cap

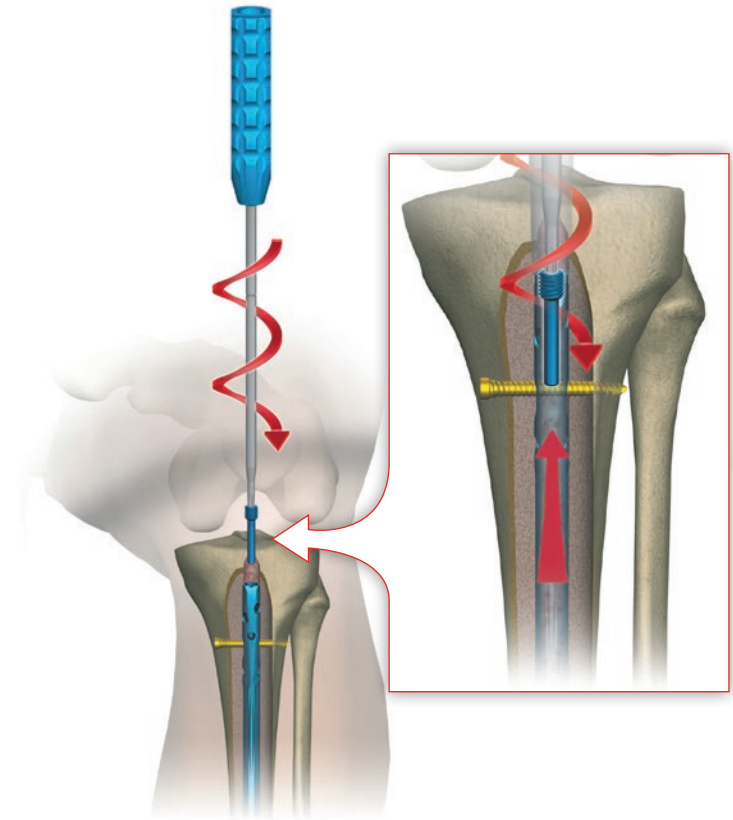
59 **OPTION I:** Insertion of the compression screw - for dynamic fixation with compression *(compressive fixation)*.
Use the screwdriver T25 **[40.5575.100]** to insert the compression screw *(implant)* into the threaded hole of the nail shaft.

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

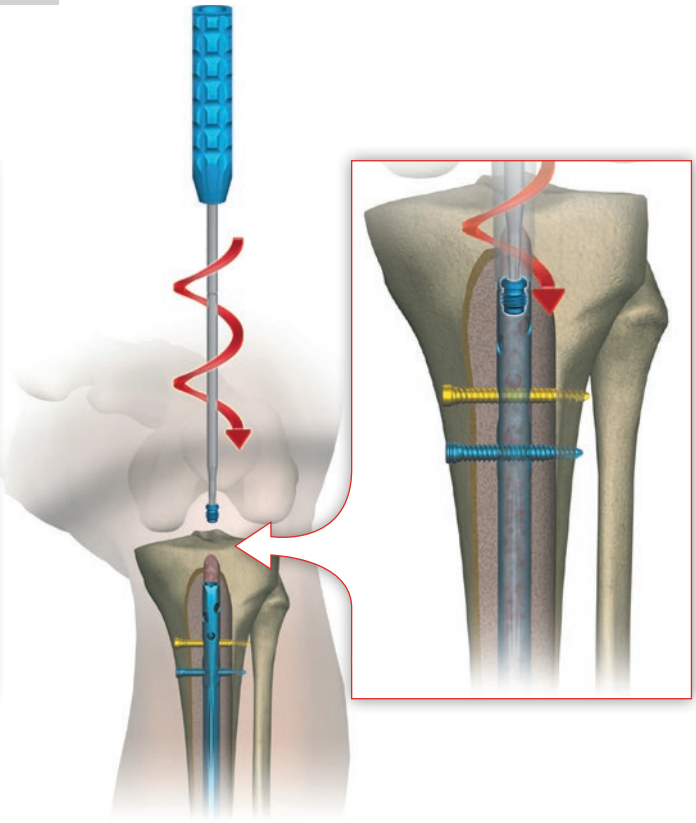
To secure the internal thread of the nail against the bone tissue ingrowth, use the screwdriver T25 to insert the end cap *(implant)* into the threaded hole of the nail shaft.



59



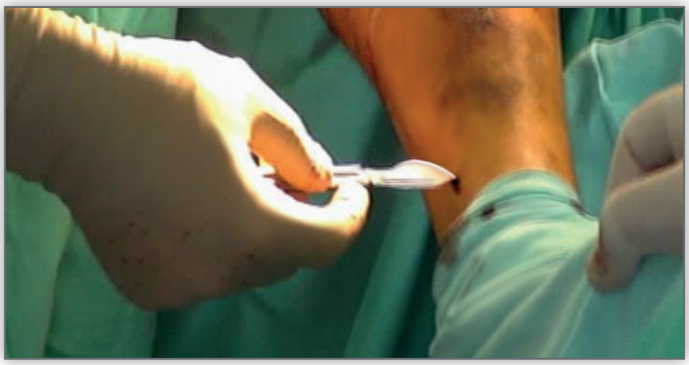
60



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

VI.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.

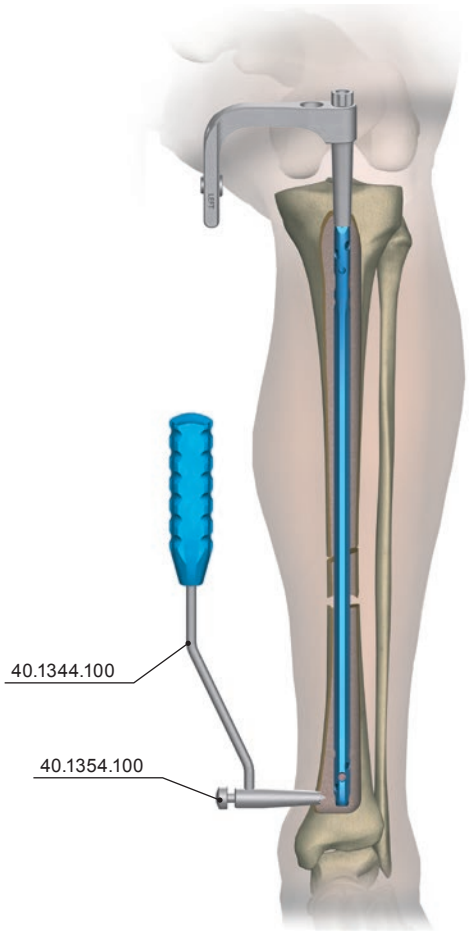
Remove the trocar.
Leave the targeter D in place.

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.

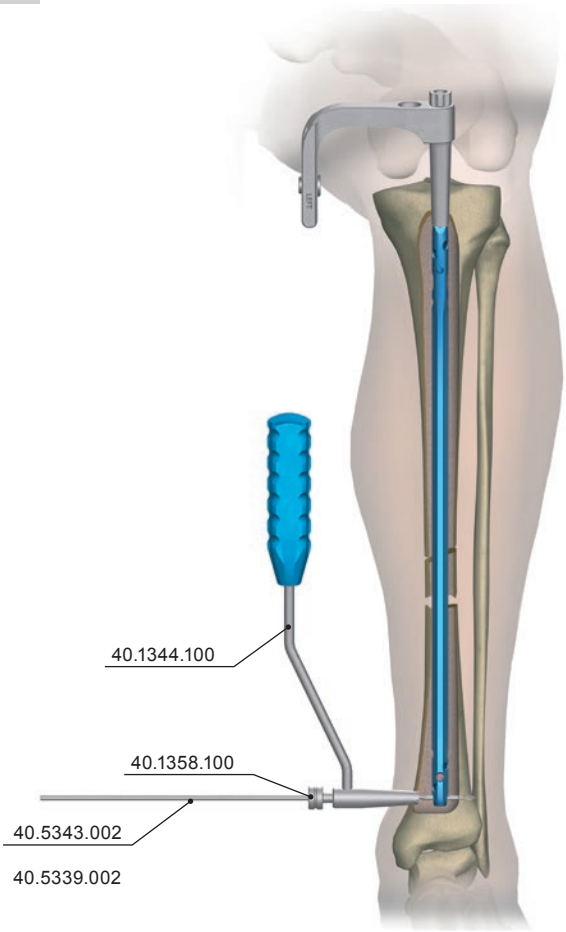
The drilling process should be controlled with image intensifier.

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

61



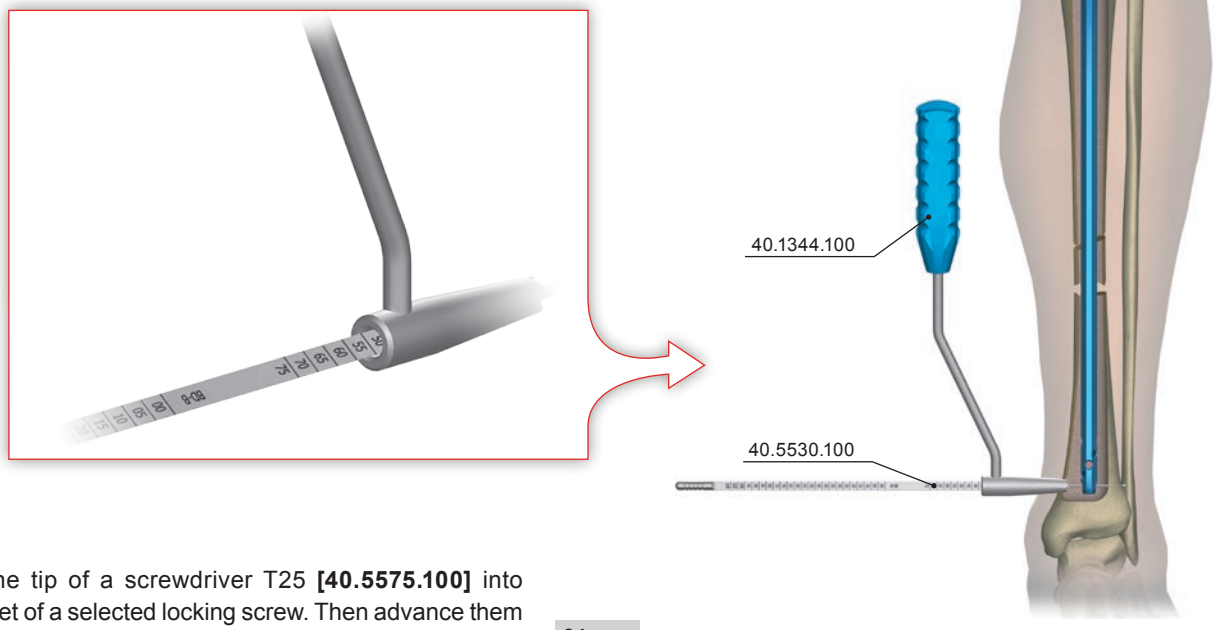
62



63 Insert the screw length measure **[40.5530.100]** 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.

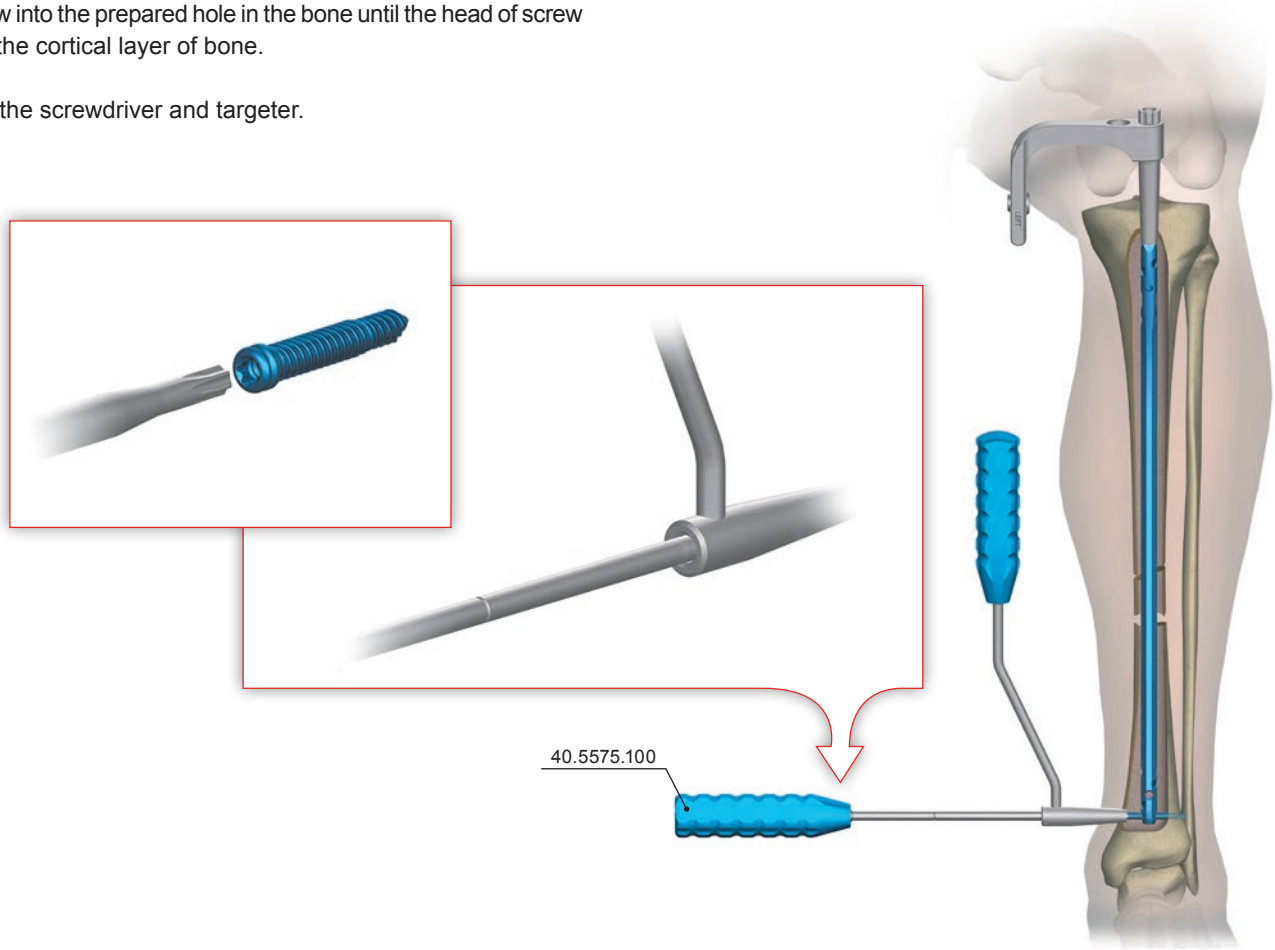
63



64 Insert the tip of a screwdriver T25 **[40.5575.100]** 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.

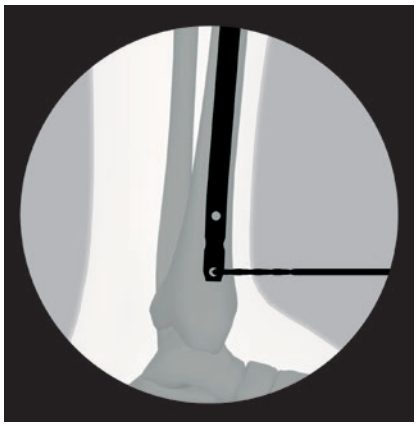
64

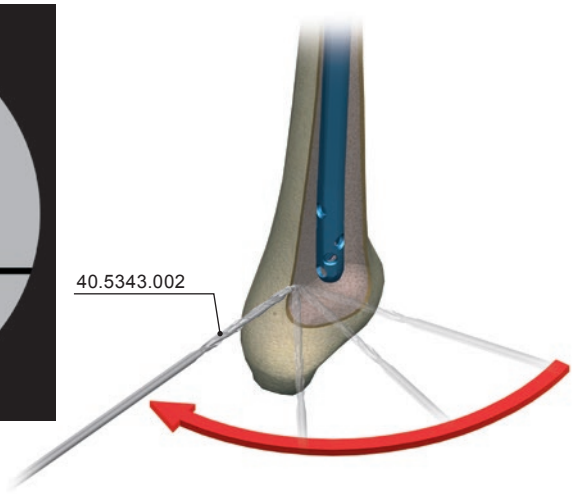


VI.2. FREEHAND TECHNIQUE LOCKING

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.



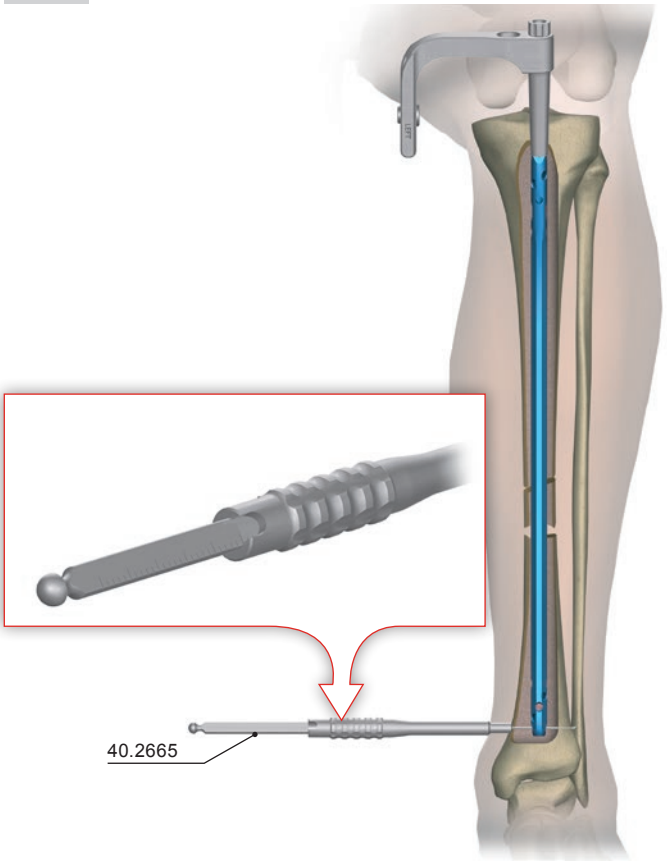


65 Use the drill with scale 3.5/150 **[40.5343.002]** to make a hole going through both cortical layers and the hole in the nail. Remove the drill.

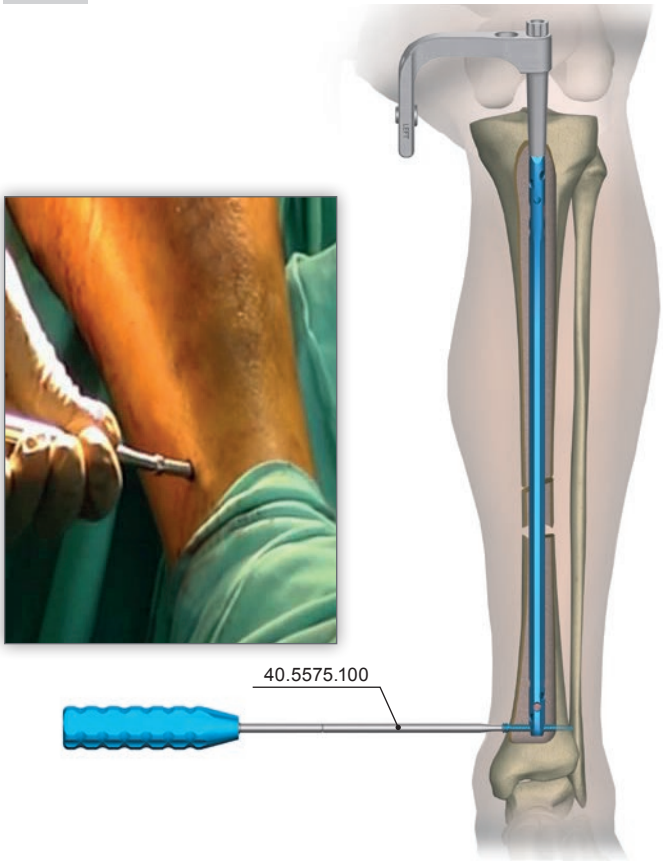
66 Insert the hole depth measure **[40.2665]** into the drilled hole until the end of measure reaches the *"exit"* of the hole. Read the length of a locking screw on the scale.

67 Insert the tip of a screwdriver T25 **[40.5575.100]** 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.

66



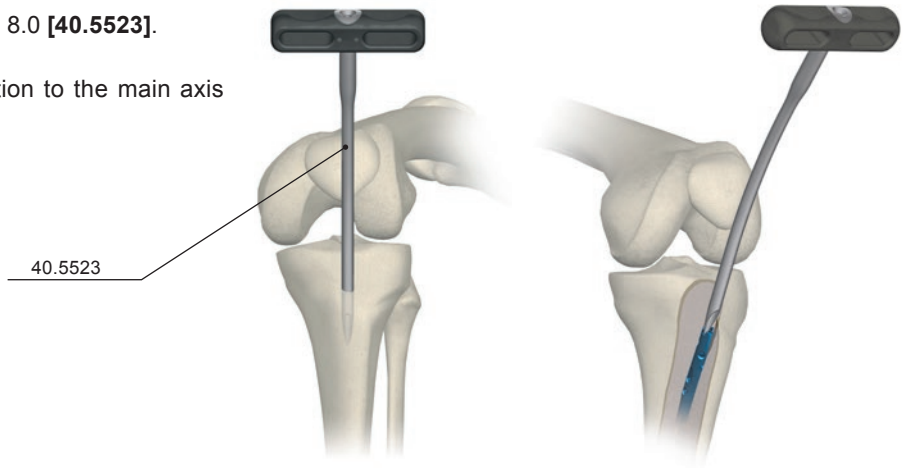
67



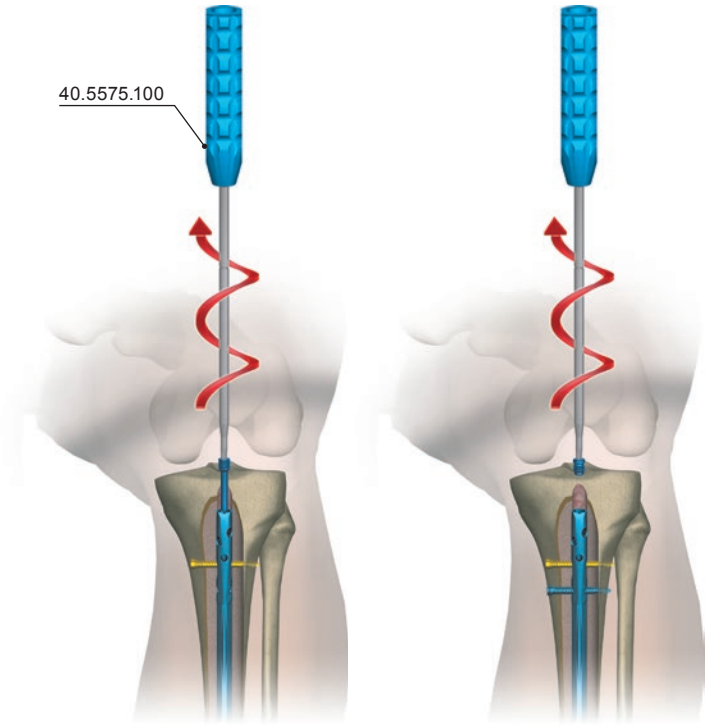
VII. NAIL EXTRACTION

68 Open the canal using the curved awl 8.0 **[40.5523]**.

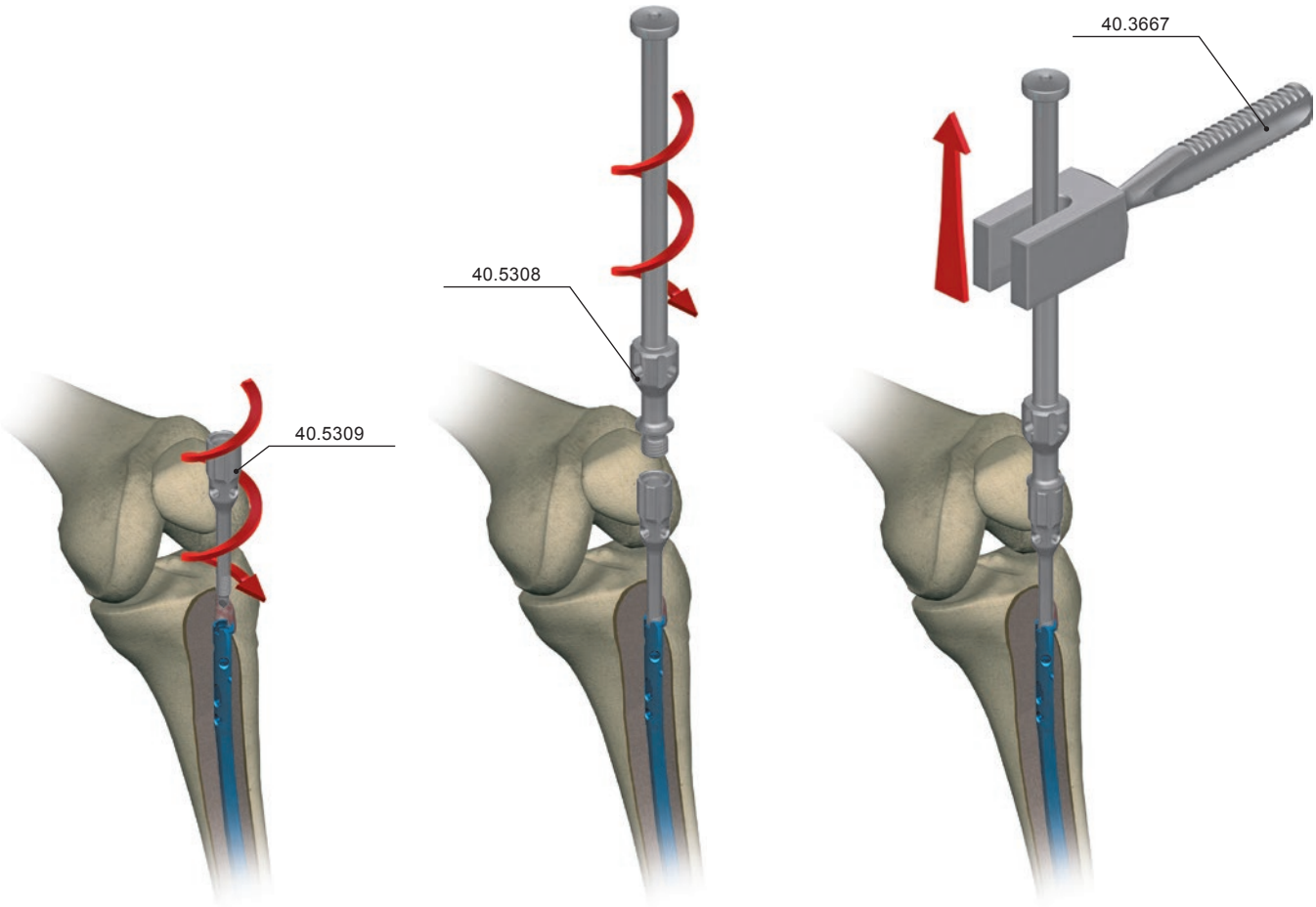
Insert the awl at the angle of 10° in relation to the main axis of the medullary canal.



69 Use the screwdriver T25 **[40.5575.100]** 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.



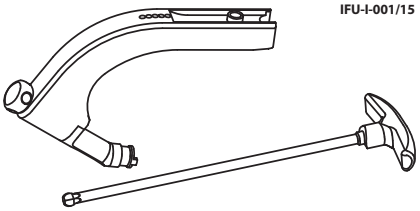
GB

ISO 9001/ ISO 13485

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/15



GB

INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and – in consequences – damage of the instrument.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction.

If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:

- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

ATTENTION! The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:

- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than $1/10^6$ ($SAL=10^{-6}$, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*.

   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

If this instructions appears unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available on the following website: **www.chm.eu**

IFU-I-001/15; Date of verification: December 2015

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

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при поврежденной упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řídte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH202	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 713 13 20
fax +48 85 713 13 19
chm@chm.eu
www.chm.eu

CE 0197
ISO 9001
ISO 13485