

*instruction*

# INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA

IMPLANTS ◦

INSTRUMENT SET 40.5000.600 ◦

SURGICAL TECHNIQUE ◦

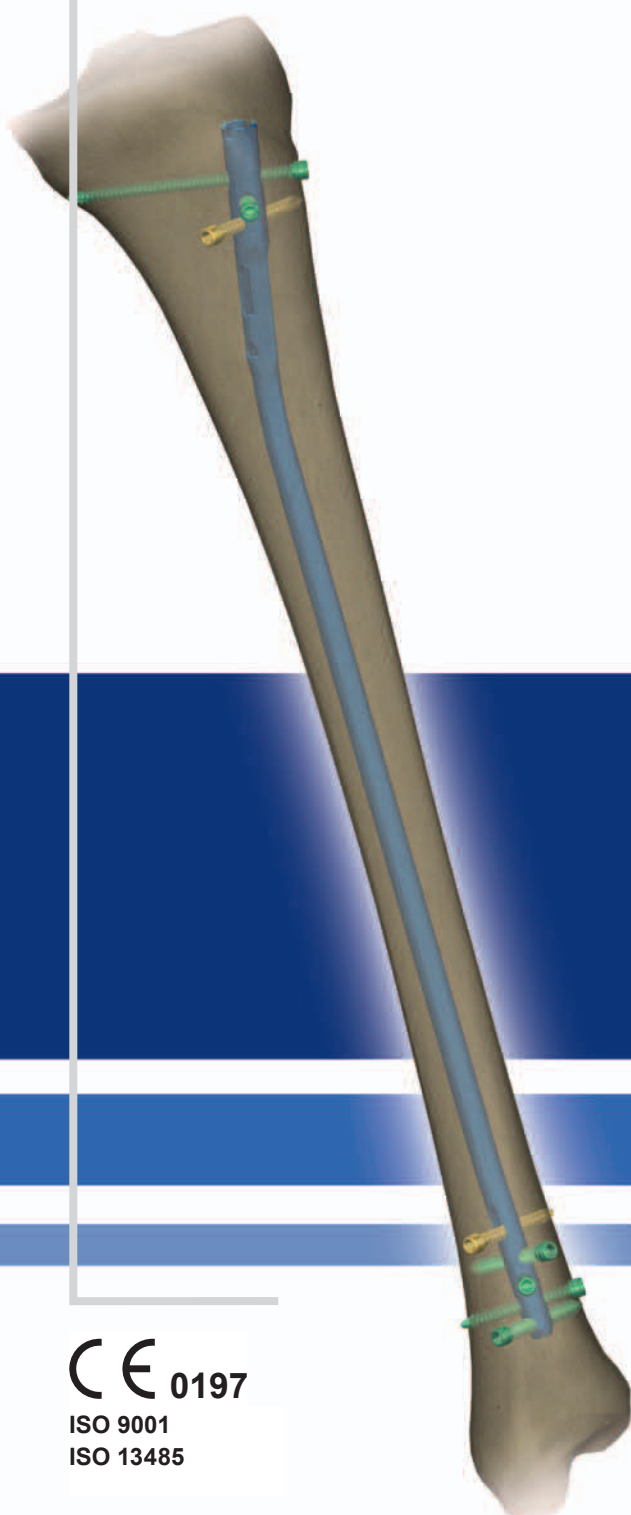
**CHARFIX** *system*

**25C**

CE 0197

ISO 9001  
ISO 13485

**ChM**®





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## I. INTRODUCTION

**CHARFIX<sub>system</sub>** - INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA consists of:

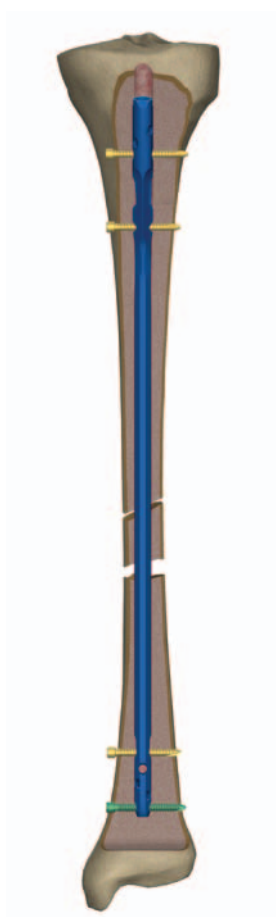
- implants (*intramedullary nail, locking screws, end cap or compression screw*),
- instrument set for implants insertion and extraction,
- instruction for use (*surgical technique*).

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

Indications:

- multi-fragmental fractures of the shaft of the tibia
- tibia and fibula fractures,
- fractures with knee ligaments injury,
- tibia fractures with compartment syndrome,
- open fractures I, II, IIIA degree by Gustillo-Anderson,
- pathological fractures,
- malunion of tibia shaft fractures treated with other methods.

**CHARFIX<sub>system</sub>** provides the following methods:



### Static Method

Static fixation is used in multi-fragmental fractures with bone fragments mal-alignment.

In the static fixation to lock the nail with the screws, two distal holes and two or all proximal holes should be used.

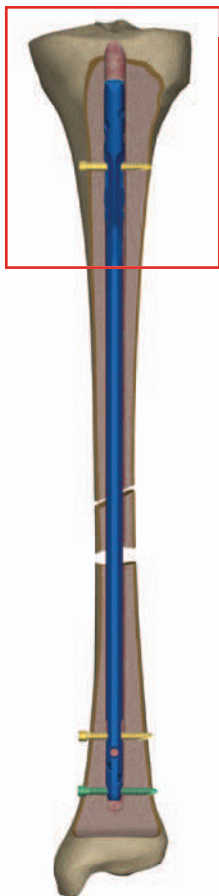
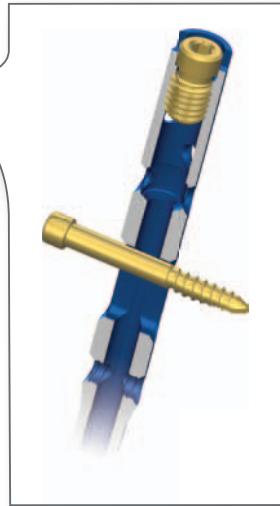


### Dynamic Method

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

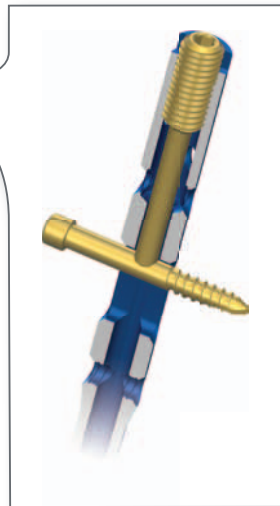
One oval shaped proximal and two distal holes of intramedullary nail should be used.

Dynamic fixation enables axial movements of bone fragments during the limb loading and stimulates creating bone scar and its reconstruction into the lamellar bone.



### Dynamic Method with Compression

In the dynamic fixation with compression, the compression screw is axially inserted to put pressure on screw locking the nail. Compressive fixation eliminates all micromovements in early stage of treatment.

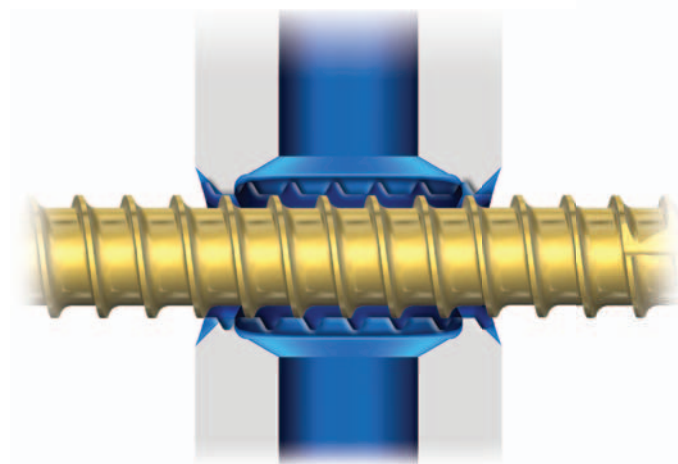


## Reconstruction Method

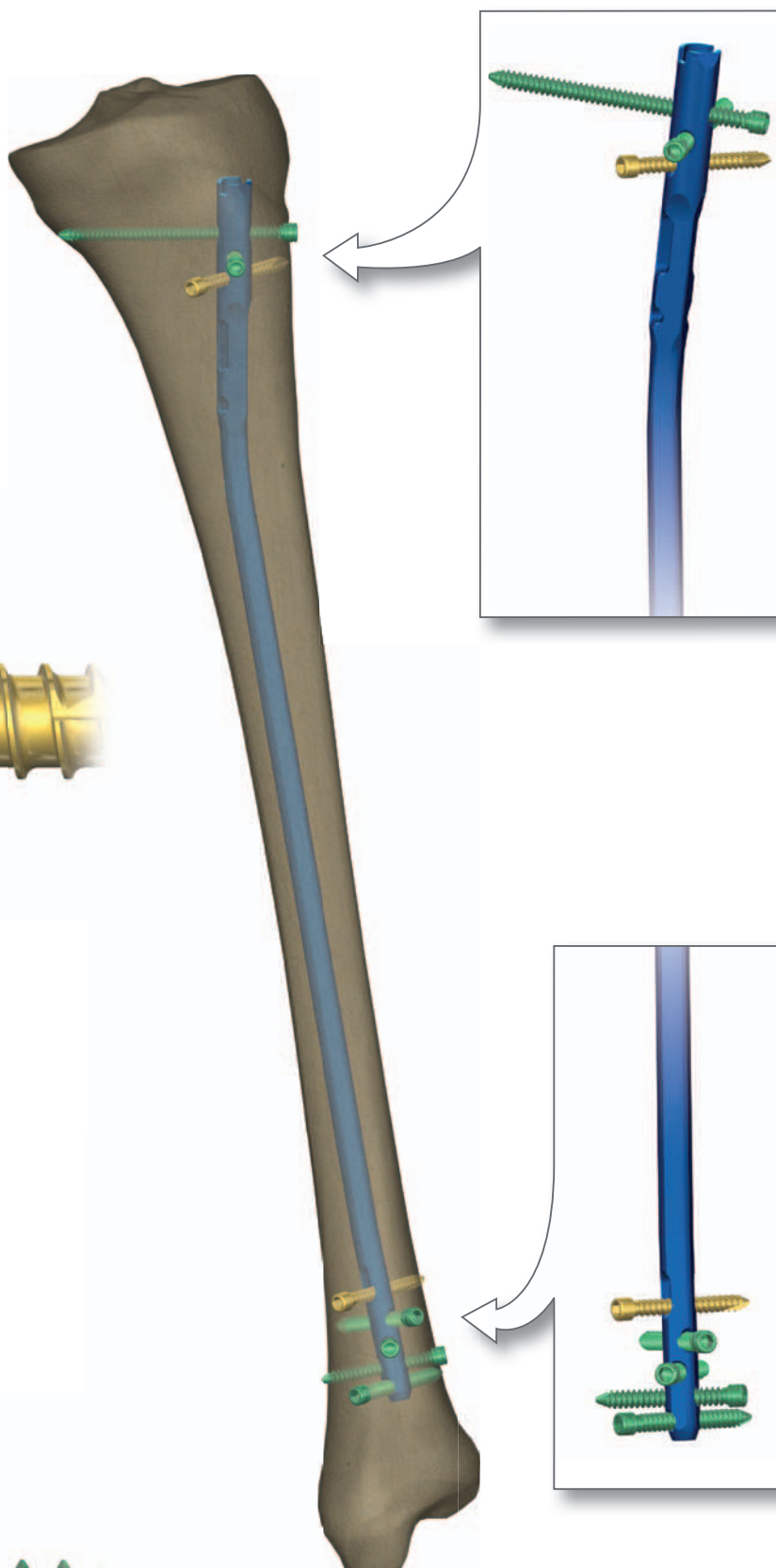
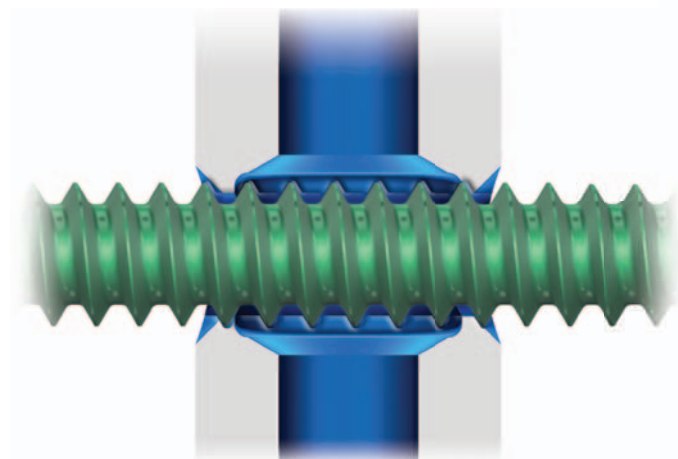
Threaded reconstructive holes in proximal part enable stable fixation of the tibial condyle.

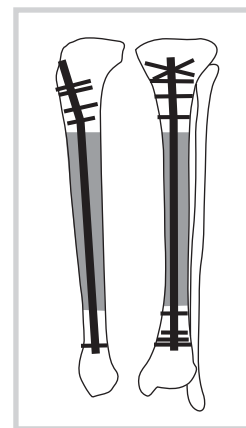
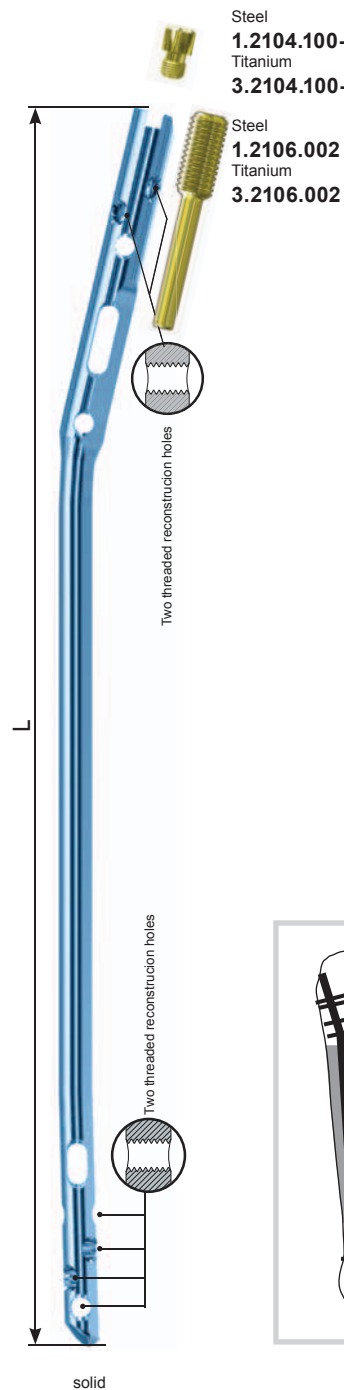
Threaded holes enable optional locking using:

- proximal screw 4.5;





- locking distal screw 5.0 which prevents angular displacement of bone fragments (*using threaded hole in the nail*).







			
L [mm]	Ø	Steel	Titanium
270	8	1.2623.270	3.2623.270
285		1.2623.285	3.2623.285
300		1.2623.300	3.2623.300
315		1.2623.315	3.2623.315
330		1.2623.330	3.2623.330
345		1.2623.345	3.2623.345
360		1.2623.360	3.2623.360
375		1.2623.375	3.2623.375
390		1.2623.390	3.2623.390
270	9	1.2624.270	3.2624.270
285		1.2624.285	3.2624.285
300		1.2624.300	3.2624.300
315		1.2624.315	3.2624.315
330		1.2624.330	3.2624.330
345		1.2624.345	3.2624.345
360		1.2624.360	3.2624.360
375		1.2624.375	3.2624.375
390		1.2624.390	3.2624.390
270	10	1.2625.270	3.2625.270
285		1.2625.285	3.2625.285
300		1.2625.300	3.2625.300
315		1.2625.315	3.2625.315
330		1.2625.330	3.2625.330
345		1.2625.345	3.2625.345
360		1.2625.360	3.2625.360
375		1.2625.375	3.2625.375
390		1.2625.390	3.2625.390
270	11	1.2626.270	3.2626.270
285		1.2626.285	3.2626.285
300		1.2626.300	3.2626.300
315		1.2626.315	3.2626.315
330		1.2626.330	3.2626.330
345		1.2626.345	3.2626.345
360		1.2626.360	3.2626.360
375		1.2626.375	3.2626.375
390		1.2626.390	3.2626.390
270	12	1.2627.270	3.2627.270
285		1.2627.285	3.2627.285
300		1.2627.300	3.2627.300
315		1.2627.315	3.2627.315
330		1.2627.330	3.2627.330
345		1.2627.345	3.2627.345
360		1.2627.360	3.2627.360
375		1.2627.375	3.2627.375
390		1.2627.390	3.2627.390

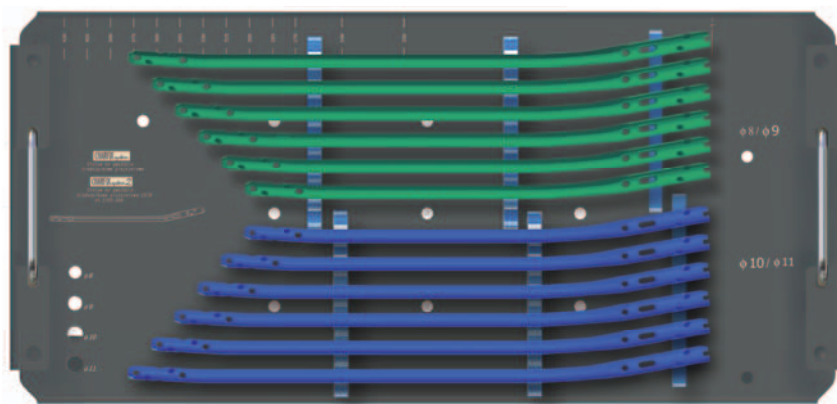
			
L [mm]	Ø	Steel	Titanium
270	8	1.2637.270	3.2637.270
285		1.2637.285	3.2637.285
300		1.2637.300	3.2637.300
315		1.2637.315	3.2637.315
330		1.2637.330	3.2637.330
345		1.2637.345	3.2637.345
360		1.2637.360	3.2637.360
375		1.2637.375	3.2637.375
390		1.2637.390	3.2637.390
270	9	1.2638.270	3.2638.270
285		1.2638.285	3.2638.285
300		1.2638.300	3.2638.300
315		1.2638.315	3.2638.315
330		1.2638.330	3.2638.330
345		1.2638.345	3.2638.345
360		1.2638.360	3.2638.360
375		1.2638.375	3.2638.375
390		1.2638.390	3.2638.390
270	10	1.2639.270	3.2639.270
285		1.2639.285	3.2639.285
300		1.2639.300	3.2639.300
315		1.2639.315	3.2639.315
330		1.2639.330	3.2639.330
345		1.2639.345	3.2639.345
360		1.2639.360	3.2639.360
375		1.2639.375	3.2639.375
390		1.2639.390	3.2639.390

available

Ø[mm] pitch 1 mm	7÷14	7÷14
L [mm] pitch 5 mm	210÷600	210÷600

Titanium

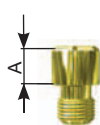
Ø8	Ø9	Ø10	Ø11	Ø12
				
colours				

**40.5750.000**

Stand for intramedullary tibial nails (implants not included)

## III. LOCKING ELEMENTS

### End cap M8x1.25

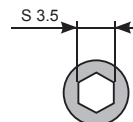


Catalogue no.		
A	Steel	Titanium
0	1.2104.100	3.2104.100
+5	1.2104.105	3.2104.105
+10	1.2104.110	3.2104.110
+15	1.2104.115	3.2104.115

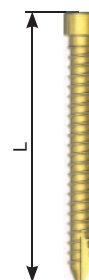


### Compression screw M8x1.25

Catalogue no.	
Steel	Titanium
1.2106.002	3.2106.002

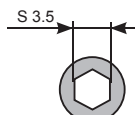


### Distal screw Ø4.5

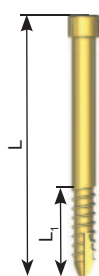


Catalogue no.		
L [mm]	Steel	Titanium
26	1.1654.026	3.1654.026
28	1.1654.028	3.1654.028
30	1.1654.030	3.1654.030
35	1.1654.035	3.1654.035
40	1.1654.040	3.1654.040
45	1.1654.045	3.1654.045
50	1.1654.050	3.1654.050
55	1.1654.055	3.1654.055
60	1.1654.060	3.1654.060
65	1.1654.065	3.1654.065
70	1.1654.070	3.1654.070
75	1.1654.075	3.1654.075
80	1.1654.080	3.1654.080

L [mm]	16 ÷ 100
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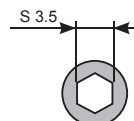


### Proximal screw Ø4.5

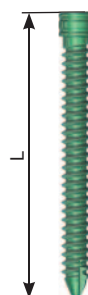


Catalogue no.			
L [mm]	L1 [mm]	Steel	Titanium
25	12	1.1653.025	3.1653.025
30	12	1.1653.030	3.1653.030
35	16	1.1653.035	3.1653.035
40	16	1.1653.040	3.1653.040
45	16	1.1653.045	3.1653.045
50	18	1.1653.050	3.1653.050
55	18	1.1653.055	3.1653.055
60	18	1.1653.060	3.1653.060
65	20	1.1653.065	3.1653.065
70	20	1.1653.070	3.1653.070
75	20	1.1653.075	3.1653.075
80	20	1.1653.080	3.1653.080

L [mm]	25 ÷ 90
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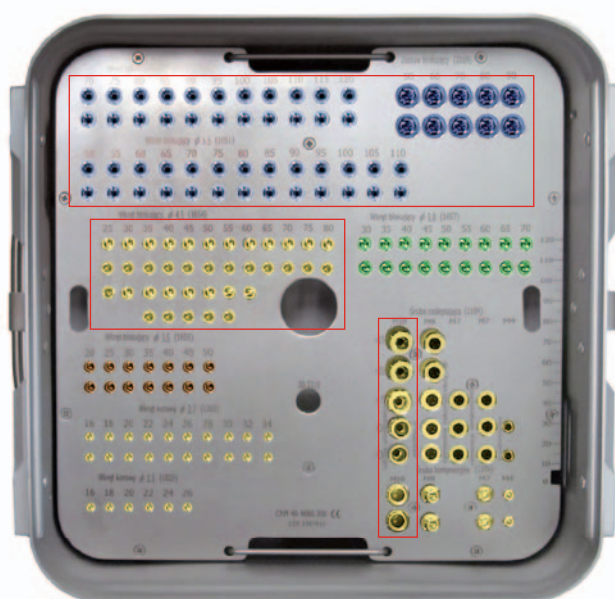


### Distal screw Ø5.0



Catalogue no.		
L [mm]	Steel	Titanium
26	1.1657.026	3.1657.026
28	1.1657.028	3.1657.028
30	1.1657.030	3.1657.030
35	1.1657.035	3.1657.035
40	1.1657.040	3.1657.040
45	1.1657.045	3.1657.045
50	1.1657.050	3.1657.050
55	1.1657.055	3.1657.055
60	1.1657.060	3.1657.060
65	1.1657.065	3.1657.065
70	1.1657.070	3.1657.070
75	1.1657.075	3.1657.075
80	1.1657.080	3.1657.080

L [mm]	16 ÷ 100
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**40.4686.200**  
Stand for nails' locking elements  
(set with a box without implants)

## IV. INSTRUMENT SET













Instrument set **[40.5000.600]** is used for tibia shaft fixation, and implant removal after finished treatment. All instruments are placed in a stand with a lid to facilitate sterilization and transportation to the surgical suite.

Instrument set consists of:

### 40.5000.600

No.		Name	Pcs	Catalogue No.
1		Targeter arm B	1	40.5301.000
2		Distal targeter D	1	40.5322.000
3		Targeter B	1	40.5373.000
4		Wrench S8	1	40.5304.000
5		Connecting screw M8x1.25 L-91	1	40.5325.000
6		Reconstruction targeter	1	40.5377.000
7		Impactor-extractor	1	40.5308.000
8		Connector M8x1.25/M14	1	40.5309.000
9		Compression screw	1	40.5324.000
10		Curved awl 8.0	1	40.5523.000
11		Mallet	1	40.3667.000
12		Protective guide 9/6.5	2	40.3614.000
13		Drill guide 6.5/3.5	2	40.3615.000
14		Set block 9/4.5	2	40.3616.000
15		Trocar 6.5	1	40.3617.000
16		Drill guide 6.5/4.5	1	40.3696.000
17		Screw length measure	1	40.1374.000
18		Hole depth measure	1	40.2665.000
19		Nail length measuring	1	40.4798.500

## INSTRUMENTS

No.		Name	Pcs	Catalogue No.
20		Targeter D	1	40.1344.000
21		Trocac short 7	1	40.1354.000
22		Drill guide short 7/3.5	1	40.1358.000
23		Guide rod handle	1	40.1351.000
24		Teflon pipe guide 8/400	1	40.3700.000
25		Aiming insert 9.0	2	40.5065.009
26		Guide rod 2.5/580	1	40.3673.580
27		Hexagonal screwdriver 3.5	1	40.3619.000
28		Drill with scale 3.5/250	2	40.5330.001
29		Drill 3.5/150	1	40.1364.001
30		Drill 4.5/250	1	40.1387.001
31		Stand	1	40.5379.500

To perform the surgery, some other basic devices each operating room should be equipped with are needed:

- electric drive,
  - set of flexible intramedullary reamers ( $\varnothing 8.0-13.0\text{ mm}$ ) with the drill guide and handle,
  - set of surgical drills,
  - Kirschner wires,
  - set of awls (*standard and cannulated*),
  - mallets
- and others.



There is additional place for the Targeter B-D [40.5372] and the Lateral targeter [40.5378] in the Instrument Stand. The devices may be used for osteosynthesis of the tibia using retrograde tibial nail.



**Additional devices are not included in the Instrument Set [40.5000.600].**

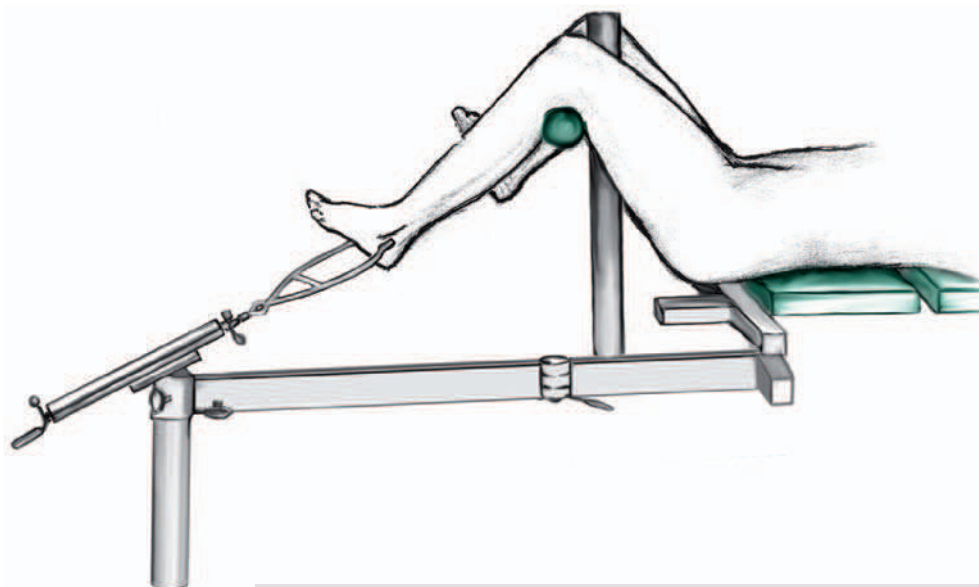
## V. SURGICAL TECHNIQUE

### 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 the type of fracture and the size of intramedullary nail (*length, diameter*). To define the length of the nail, measuring the length of the fibula can be helpful. The operation shall be performed on operating table equipped with traction and C-arm device.

When patient is placed supine, the operated limb should be bent in the hip at an angle of 70-90°, abducted at an angle of 10-20° and bent at 80-90° in the knee joint; the ankle joint should stay in neutral position (*foot perpendicular to tibia*).



Supine position shall enable X-Ray control in AP and lateral position.

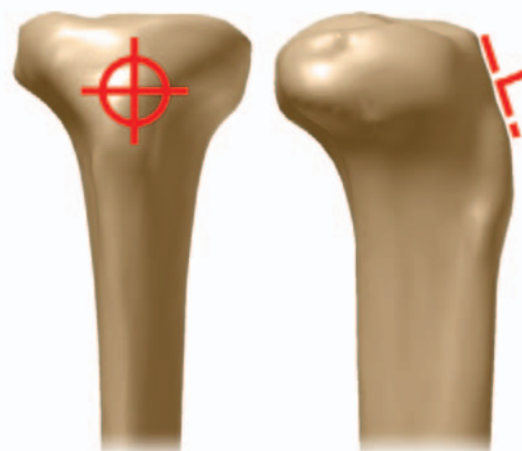
Surgical approach should be prepared by:

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

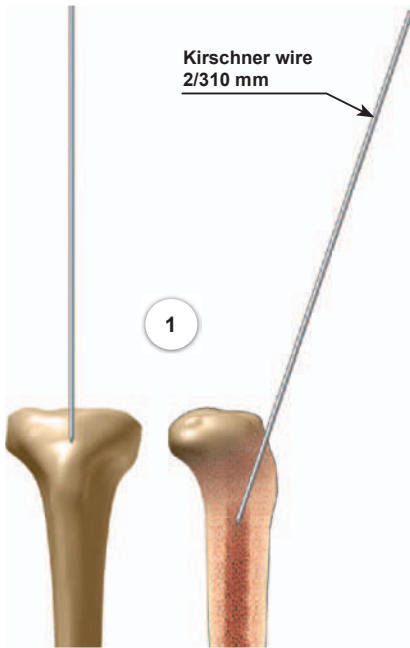
Insertion point is placed on extension of the line proceeding in the middle of medullary canal (*X-Ray in AP position*) and on the tuberosity edge of tibia and its front epiphysis edge.

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

In the case of reaming the canal, the intramedullary canal should be wider 1.5-2 mm then the diameter of the nail. The proximal part of the canal shall be widened for 12 mm at the depth of 5 cm.



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



## V.2. OPENING THE MEDULLARY CANAL

- 1 After preparing the surgical approach and locating insertion point for the nail (*description: chapter III.1. Introduction*), use the electrical drive to insert Kirschner wire (recommended 2/310 mm) into intramedullary canal at an angle appropriate to the deflection of the nail shaft to the main axis (13 degrees).



The process should be controlled with image intensifier.

Kirschner wire acts as the guide for the Curved Awl.  
Kirschner wire is a single use instrument.

- 2 Open the intramedullary canal leading the Curved Awl [40.5523] via Kirschner Wire.

Remove the Curved Awl and Kirschner Wire.



**Note:**  
It is recommended to open the intramedullary canal with technique described in step 1 and 2. However, the surgeon may use different technique depending on equipment of the surgical suite.



## V.3. PREPARATION OF INTRAMEDULLARY CANAL FOR NAIL INSERTION

### OPTION I: Reamed canal

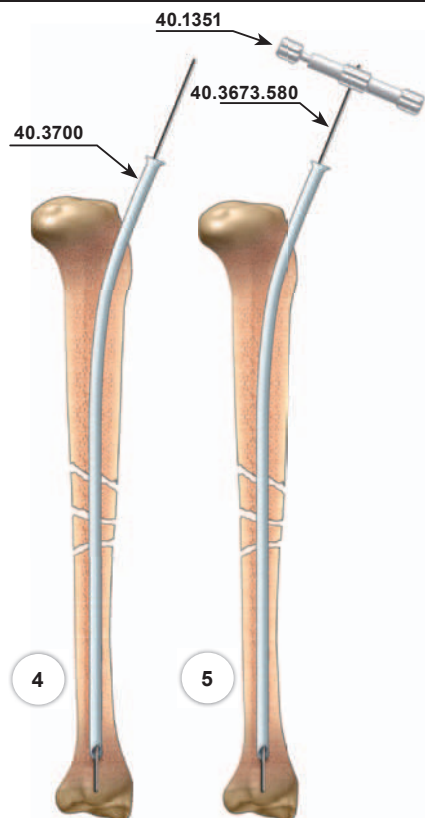
- 3 Insert the Guide Rod 2.5/580 [40.3673.580] into the medullary canal until its tip reaches the distal epiphysis of tibia, reducing the fracture at the same time.  
Gradually widen intramedullary canal using the flexible reamers with steps of 0.5 mm until it reaches the diameter 1.5 to 2 mm wider then the nail, to the depth at least equal to the nail length.  
In the case of using the nail 10 mm or smaller diameter, widen proximal part of intramedullary canal with reamer to the 12 mm diameter to the depth approx. 5 cm.

Remove the flexible reamer.  
Leave the flexible reamer guide in the medullar canal.



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





- 4 In the case of using other guide for the reamer then the Guide Rod, insert the Teflon Pipe Guide 8/400 [40.3700] into the medullary canal.

Remove the Reamer Guide.

- 5 Mount the Guide rod handle [40.1351] on the Guide Rod (for cannulated nail) [40.3673.580] and advance into the Teflon Pipe Guide 8/400 [40.3700] until its tip reaches the distal epiphysis of tibia.

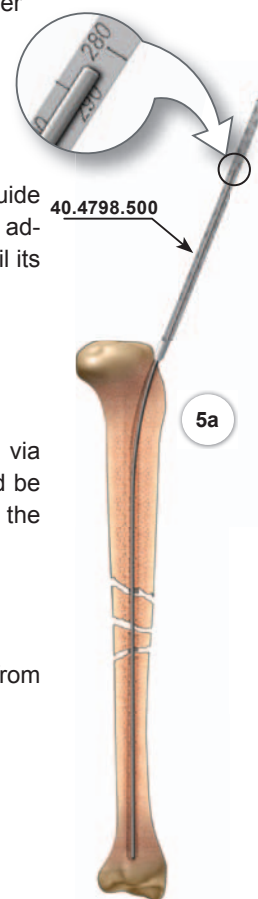
Remove the Guide rod handle.

Remove the Teflon Pipe Guide 8/400.

- 5a Insert the Nail Length Measure [40.4798.500] via the Guide Rod. The tip of the measure should be placed in the desired depth. Read the nail length on the measure.

Remove the Measure from the Guide Rod.

In the case of using solid nail, remove the Guide Rod from the intramedullary canal.



### OPTION II: Unreamed canal

- 3 Mount the Guide rod handle [40.1351] on the Guide Rod [40.3673.580] and advance into intramedullary canal until its tip reaches the distal epiphysis of tibia, reducing the fracture at the same time.

Remove the Guide rod handle from the Guide Rod.

Widen the proximal part of the intramedullary canal with flexible reamers to the depth approx. 5 cm. In the case of using the nail 10 mm or smaller diameter, widen proximal part of medullary canal to the 12 mm diameter; for nail 11 mm or larger – the diameter 1.5 to 2 mm wider than the diameter of the nail.

Remove the Flexible Reamer.

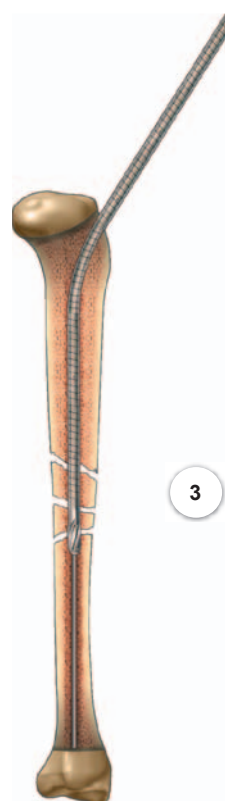
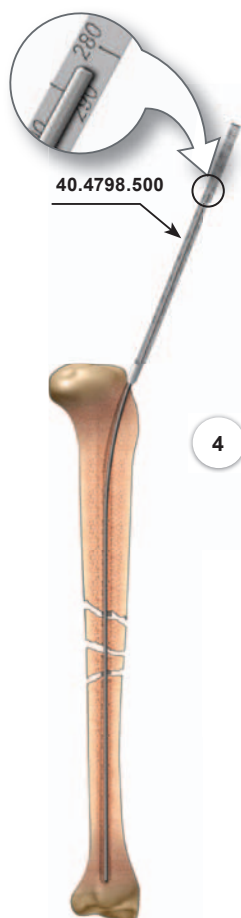
Leave the Guide Rod in medullary canal.

- 4 Insert the Nail Length Measure [40.4798.500] via the Guide Rod. The tip of the Measure should be placed in desired depth of nail insertion. Read the length of the nail on the measure.

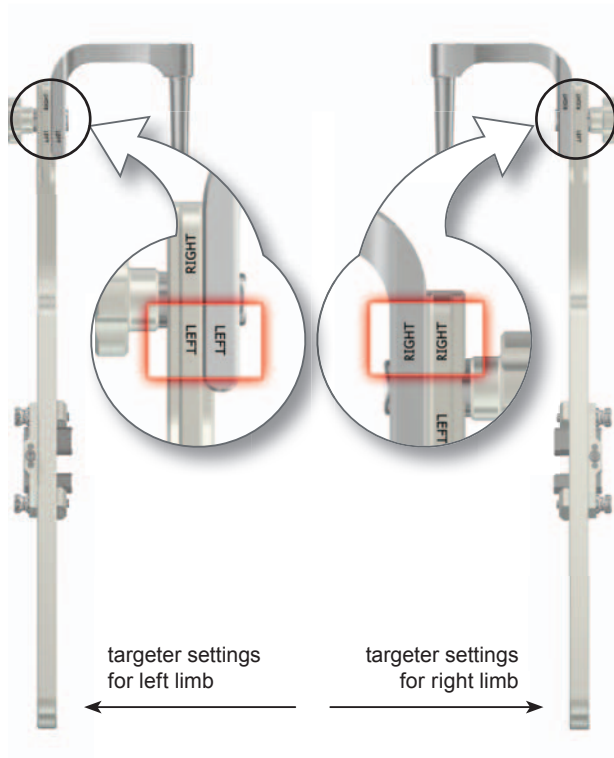
Remove the Nail Length Measure from the Guide Rod.

In the case of solid nail, remove the Guide Rod from the medullary canal.

The medullary canal is prepared for the nail insertion.



## V.4. NAIL INSERTION



### Note:

The way of mounting the Targeter arm B [40.5301] with the Distal targeter D [40.5322] and the position of the slider in distal part depends on the operated limb (left or right).

It is recommended to place the targeter in such way that its proximal part is directed to the operator and the distal bent part is directed upward.

### Then:

#### Right leg:

- connective part of the Distal targeter D should be inserted into socket of the Targeter arm from the right side and mounted using nut.
- the slider of the Distal targeter D in distal part should be arranged in such way, that its adjusting and mounting elements are placed on the left side.

#### Left leg:

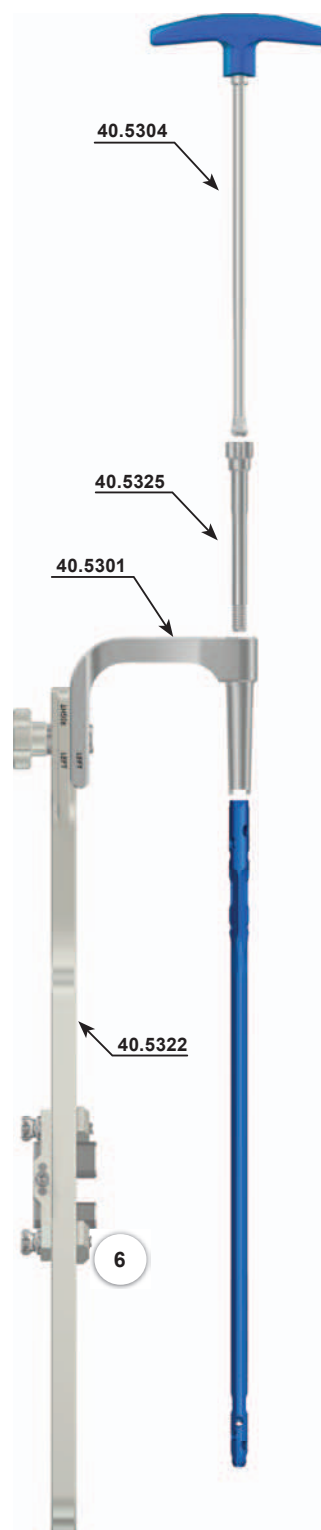
- connective part of Distal targeter D should be inserted into socket of the Targeter arm from left side and mounted using nut.
- slider of the Distal targeter D in distal part should be arranged in such a way, that its adjusting and mounting elements are placed on the right side.

- Using the Socket Wrench S8 [40.5304] fix the intramedullary nail to the Targeter arm B [40.5301] with the Connecting Screw M8x1.25 L-91 [40.5325].



### IMPORTANT!

The accordance in direction of deflection of the nail distal part and the Distal targeter D [40.5322] proves the mounting correctness.



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



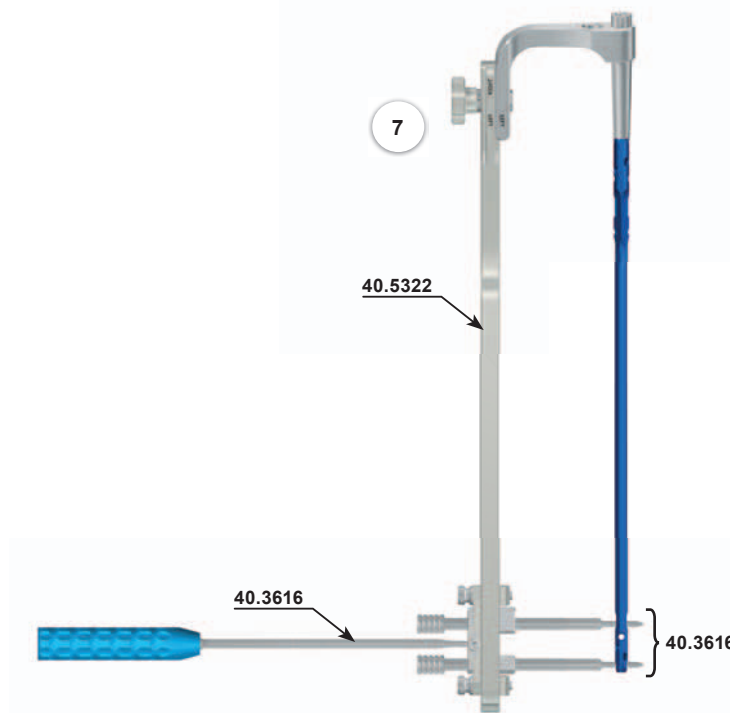
- 7 Setting the Distal targeter D [40.5322] to the nail. Using the Hexagonal Screwdriver 3.5 [40.3619] adjust the sliding element of the targeter in the middle of the slider plate. With a pair of two Set Blocks 9/4.5 [40.3616] place the slider of targeter in line with distal locking holes of the intramedullary nail. Secure the slider of targeter with screw using the Hexagonal Screwdriver 3.5 [40.3619].



**VERIFY:**

If the slider is properly set and secured, the set blocks should smoothly pass through the nail holes.

Remove set blocks from the targeter slider. Dismount the Distal targeter D [40.5322] from the Targeter arm B [40.5301].



- 8 Connect the Impactor-Extractor [40.5308] with the Targeter arm B [40.5301].
- 9 Insert the nail into medullary canal to the appropriate depth using the Mallet [40.3667].

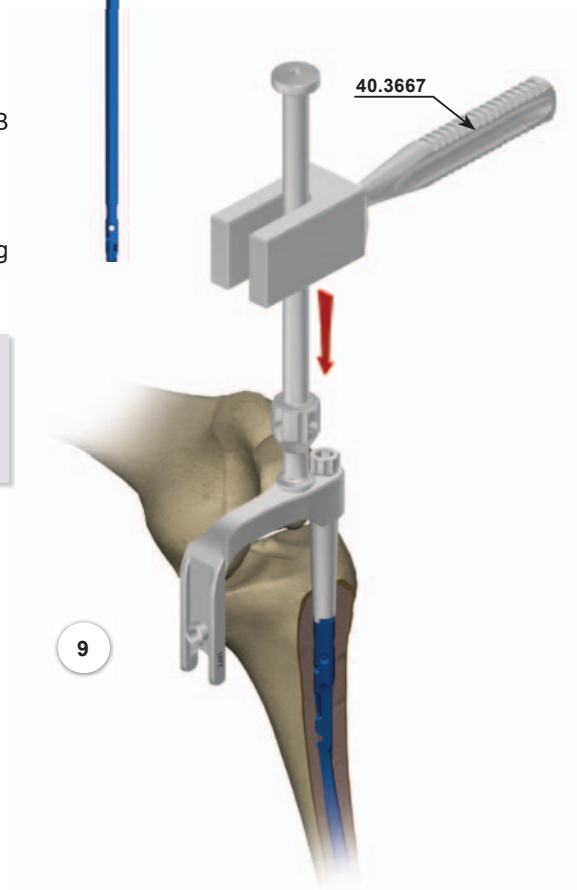


**Attention!**

Cannulated nail should be inserted into the medullary canal via the Guide Rod [40.3673.580].

Solid nail should be inserted directly into the medullary canal (without use of guide rod).

Dismount the Impactor – Extractor [40.5308] from the guide.  
Remove the Guide Rod (when cannulated nail was used).



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

## V.5. DISTAL LOCKING OF INTRAMEDULLARY NAIL.

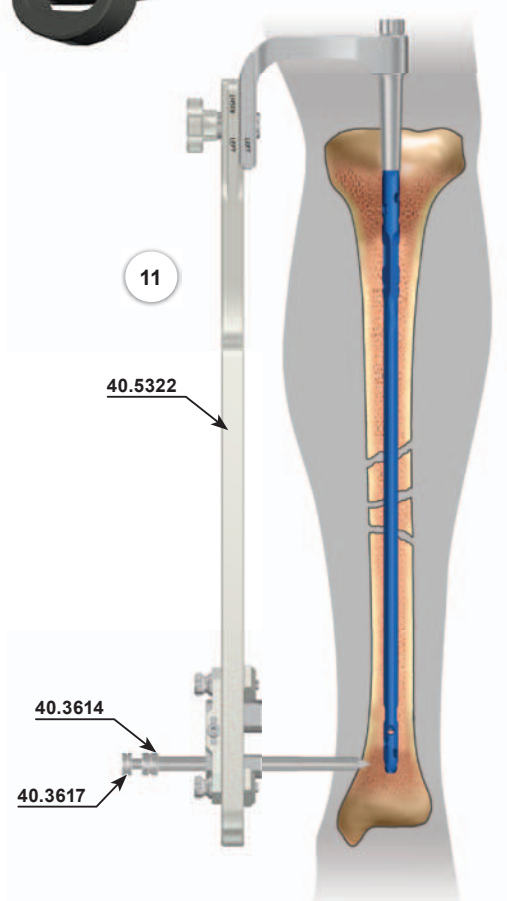
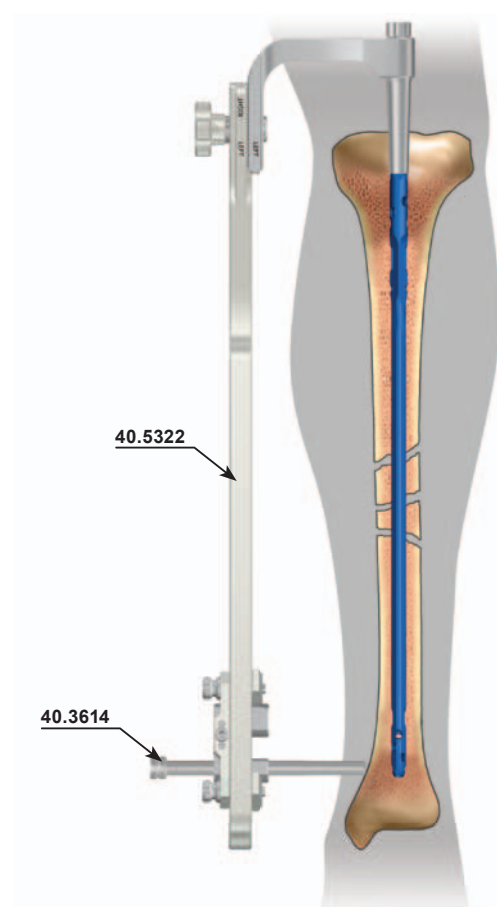
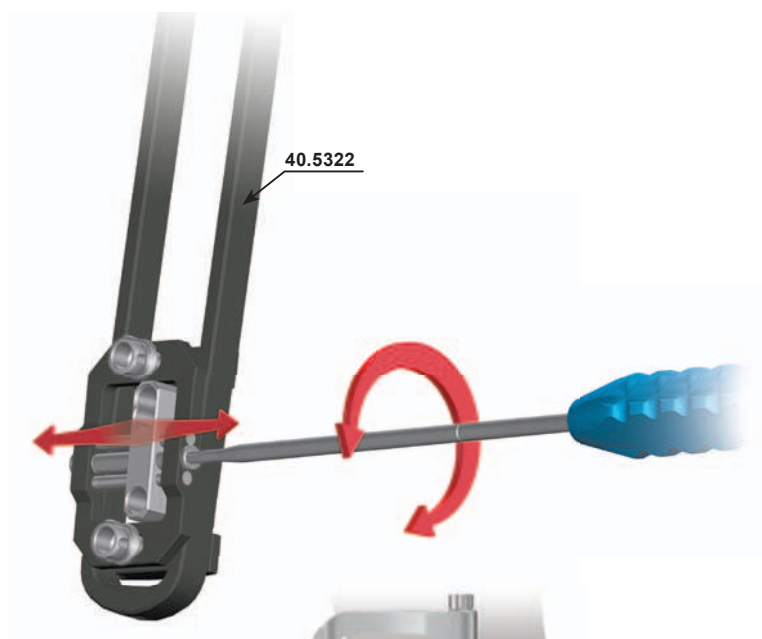
### V.5.1. **OPTION I: X-Ray control**

10 Verify the position of holes in the targeter slider and in the distal part of the nail using image intensifier.

- Mount the Distal targeter D [40.5322] onto the Targeter arm [40.5301].
- Place image intensifier in such way, that the image on display shows round shaped holes (*proximal or distal*) in the nail.
- Insert the Protective Guide [40.3614] into the appropriate hole of targeter slider until its tip reaches the soft tissue.
- Verify with X-Ray mutual position of the hole in the Drill Guide and the hole in the intramedullary nail.



The holes in the nail and the drill guide are to be congruent on the display – circle shape should be shown (*shape similar to circle is accepted*). The position of targeter should be corrected in the case shape on the display is different from circle. Then using the Hexagonal Screwdriver 3.5 [40.3619], shift targeter slider (by turning the screw to the left or to the right) to the position when circle shape are shown on the display (*shape similar to circle is accepted*).

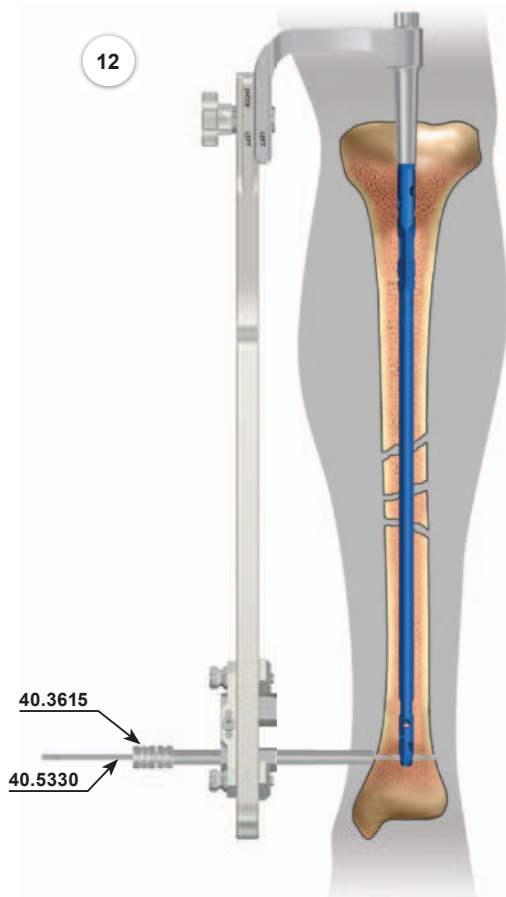


11 Insert the Protective Guide [40.3614] (*one groove on the handle*) with the Trocar 6.5 [40.3617] into the one hole of slider (*distal hole recommended*). Mark the entry point for the locking screw and make the incision through the soft tissues.

Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Simultaneously advance the Protective Guide until it touches the cortex bone.

Remove the Trocar.

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

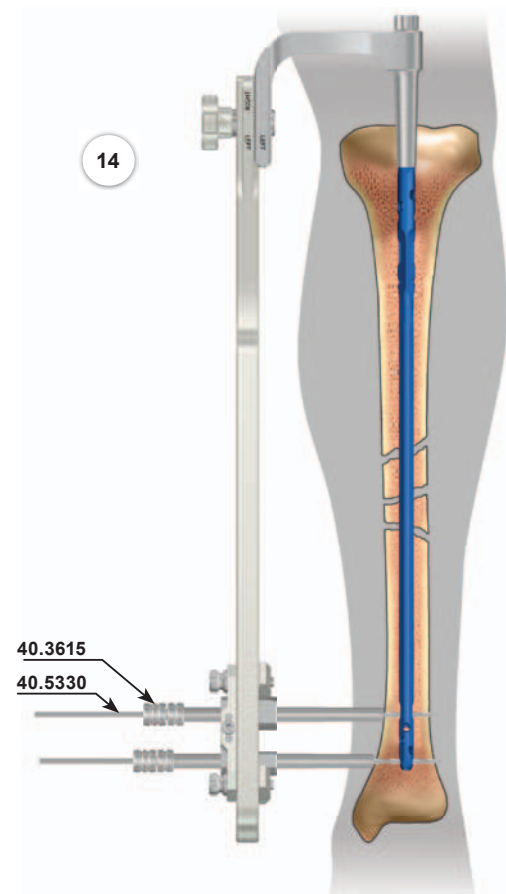


- 12 Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the Protective Guide left in the slider hole. Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia through both cortex layers and the nail hole. The scale on the Drill shows the length of locking element.



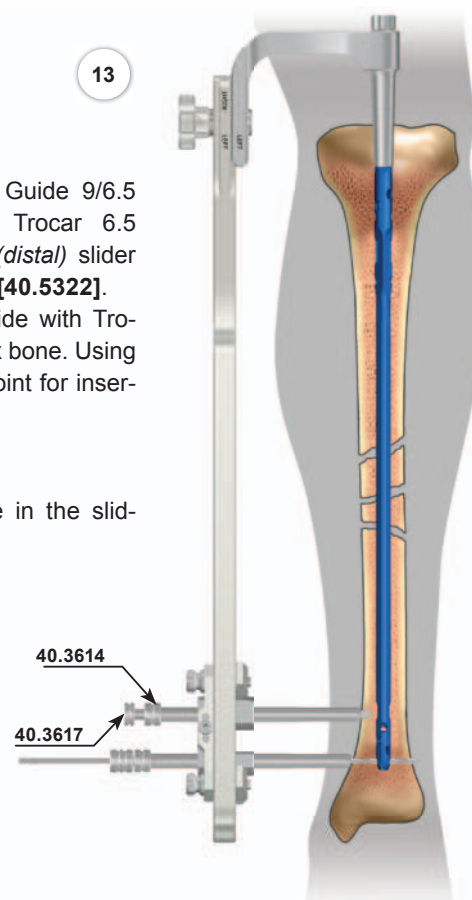
The drilling process should be controlled with image intensifier.

Dismount the Surgical Drive.  
Leave the Drill in the reamed hole.



- 13 Insert the Protective Guide 9/6.5 [40.3614] with the Trocar 6.5 [40.3617] into the second (distal) slider hole of the Distal targeter D [40.5322]. Advance the Protective Guide with Trocar until it reaches the cortex bone. Using the Trocar mark the entry point for insertion of locking screw.

Remove the Trocar.  
Leave the Protective Guide in the slider hole.



- 14 Insert the Drill Guide 6.5/3.5 [40.3615] into the Protective Guide 9/6.5 [40.3614]. Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia through both cortex layers and the nail hole. The scale on the drill indicates the length of locking elements.

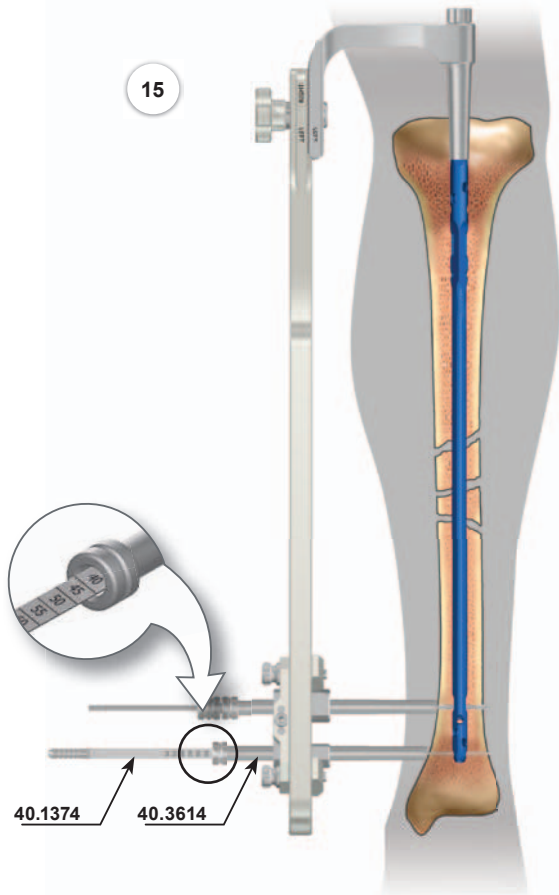


The drilling process should be controlled with image intensifier.

Remove the Drill and Drill Guide.  
Leave the Protective Guide in the slider.

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

15



- 15 Insert the Screw Length Measure **[40.1374]** through the Protective Guide 9/6.5 **[40.3614]** 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. The tip of the protective guide should rest on the cortex during the measurement.

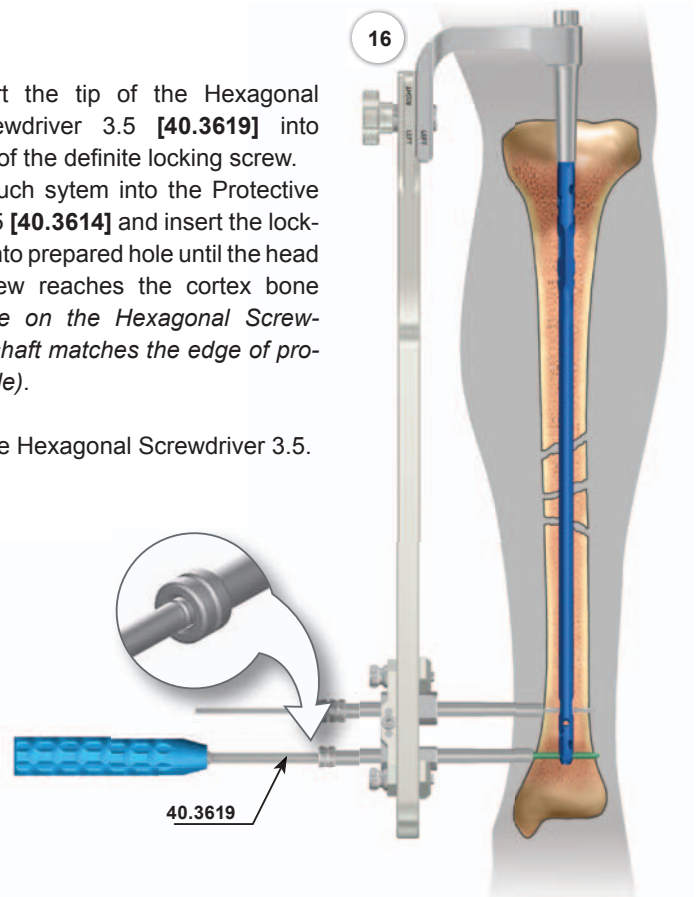
Remove the Screw Length Measure.

Leave the Protective Guide in the slider hole.

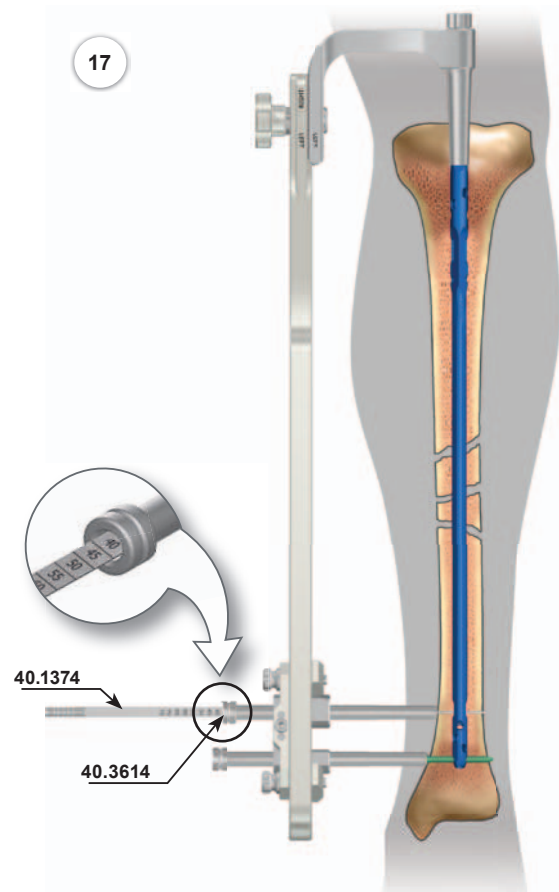
16

- 16 Insert the tip of the Hexagonal Screwdriver 3.5 **[40.3619]** into the socket of the definite locking screw. Advance such sytem into the Protective Guide 9/6.5 **[40.3614]** and insert the locking screw into prepared hole until the head of the screw reaches the cortex bone *(the groove on the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide)*.

Remove the Hexagonal Screwdriver 3.5.



17



- 17 Remove the Drill With Scale 3.5/250 **[40.5330]** and the Drill Guide 6.5/3.5 **[40.3615]** from the second hole of slider. Leave the Protective Guide **[40.3614]** in the slider hole. Insert the Screw Length Measure **[40.1374]** through the Protective Guide **[40.3614]** into the drilled hole until its hook reaches „exit” plane of the hole.

Read the length of locking screw on the B-D scale.

The tip of the Protective Guide should rest on the cortex during the measurement.

Remove the Screw Length Measure.

Leave the Protective Guide in the slider hole.

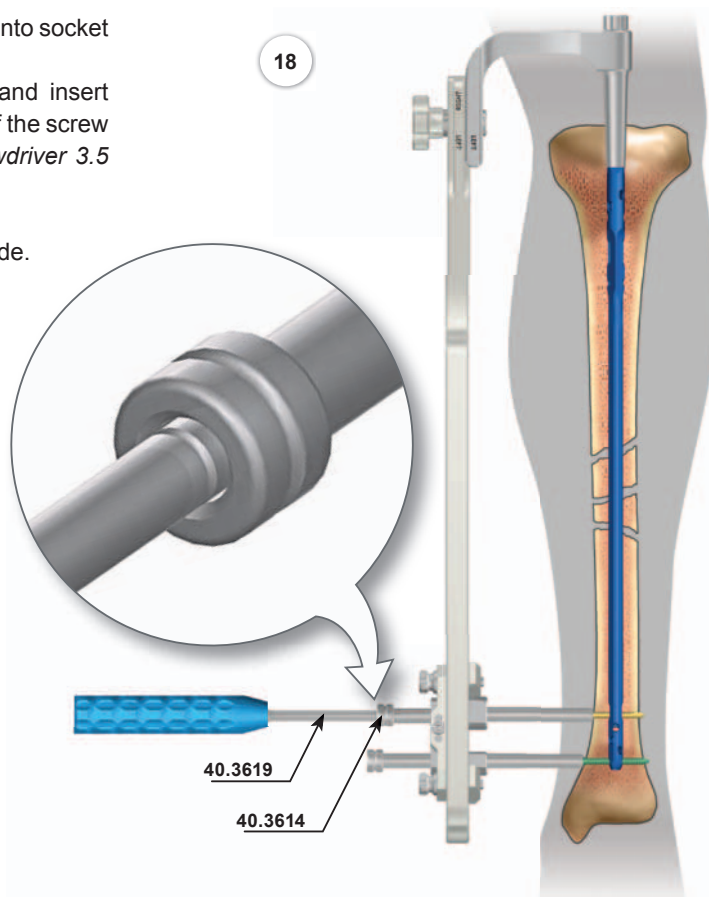
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*



- 18 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into socket of the definite locking screw.

Advanced such system into the Protective Guide [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (*the groove on the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide*).

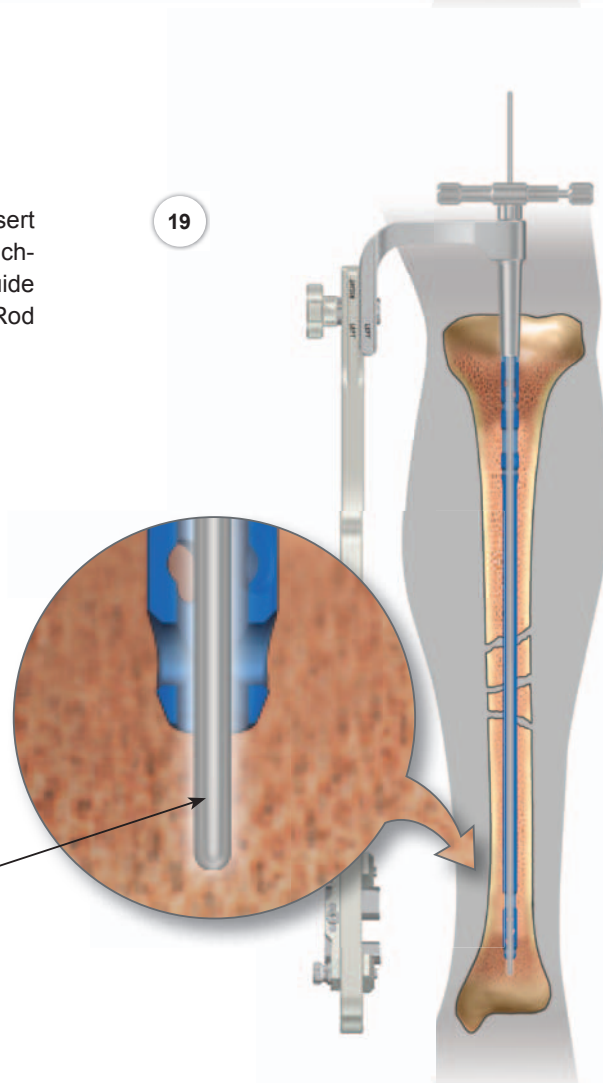
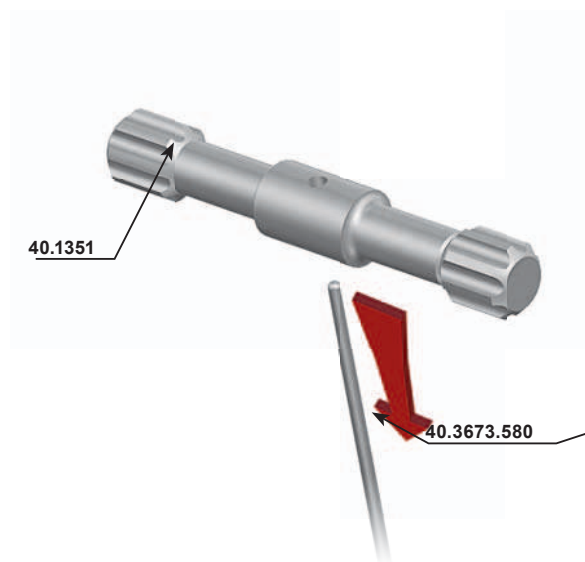
Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



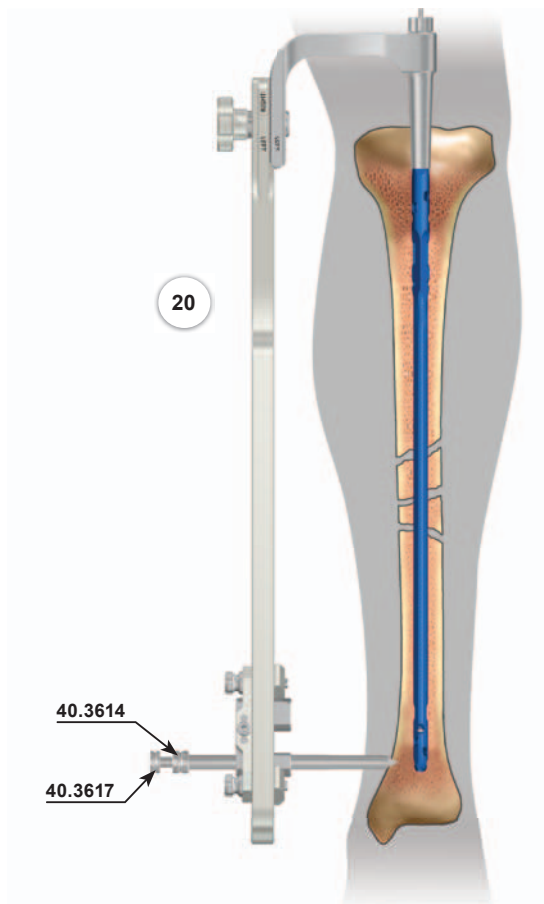
## V.5.2. OPTION II: Whitout X-Ray control

### Setting nail holes by adjusting position of targeter D slider

- 19 Mount the Distal targeter D [40.5322] onto the Targeter arm. Insert the Protective Rod into the nail via the Connecting Screw until it reaches the end of the nail. Mount the Guide rod handle [40.1351] onto the Guide Rod next to the head of the Connecting Screw. Then reverse the Guide Rod to the distance of 5-7 cm.



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

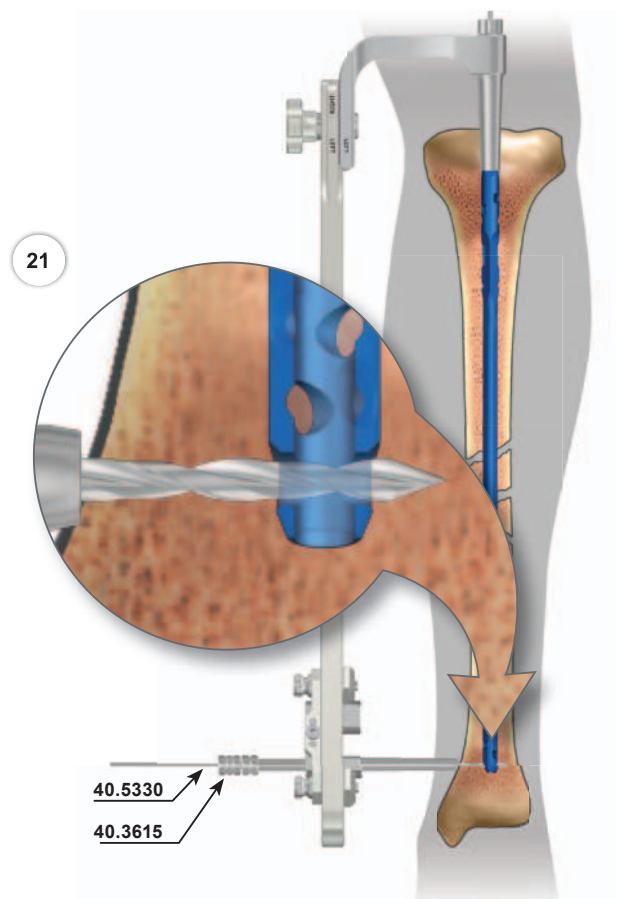


- 20 Insert the Protective Guide [40.3614] with the Trocar [40.3617] into the slider hole (*preferred distal one*). Mark on the skin the entry point and make the incision through the soft tissues. Advance the Protective Guide with the Trocar until it reaches the cortex bone and mark the entry point for the drill.

Remove the Trocar.

- 21 Insert the Drill Guide 3.5mm [40.3615] into the Protective Guide left in the slider hole. The end of the Drill Guide should rest on the soft tissues.

Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia through first cortex layers and the nail hole.



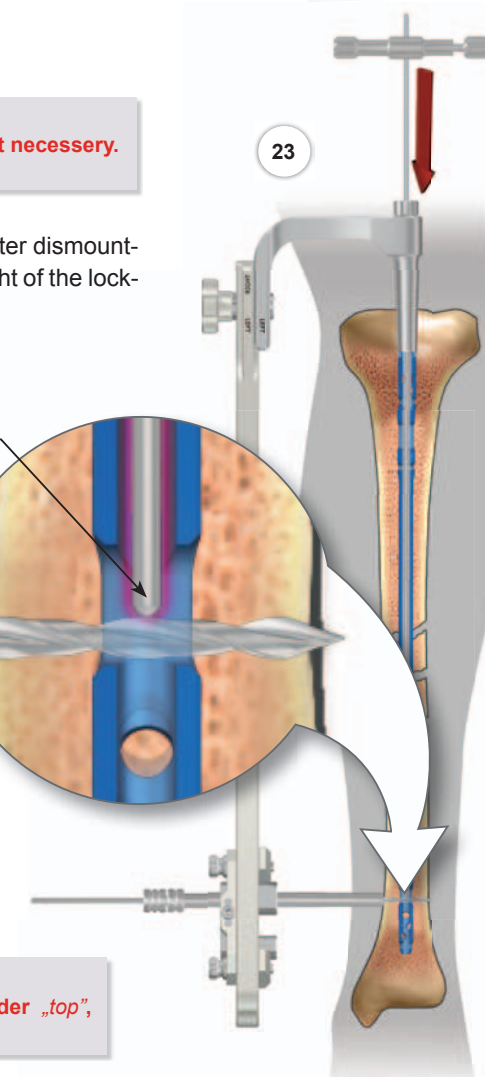
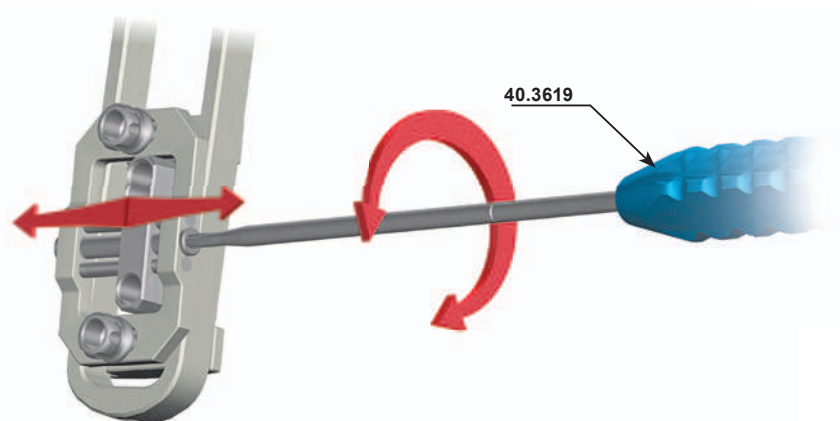
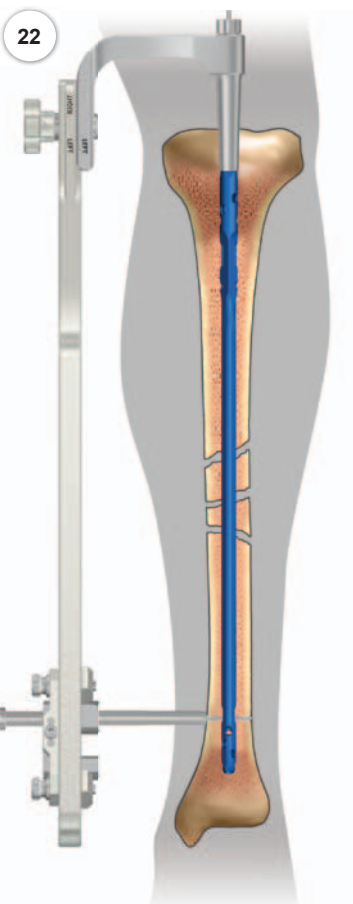
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

22 Use the Guide Rod [40.3673.580] to verify if the drill properly hit the nail hole. If the drill properly hits the nail hole, the Guide Rod rests on the drill but the Guide rod handle does not reach the Connecting Screw. If the Drill passes through the first cortical layer but does not pass the nail hole:

- withdraw the Drill to enable movements of the slider,
- into the second hole of the Distal targeter D [40.5322] insert the Protective Guide [40.3614] with the Trocar [40.3617] and advance until the Protective Guide rests on the cortex bone. Use the Trocar to mark the entry point for the drill.

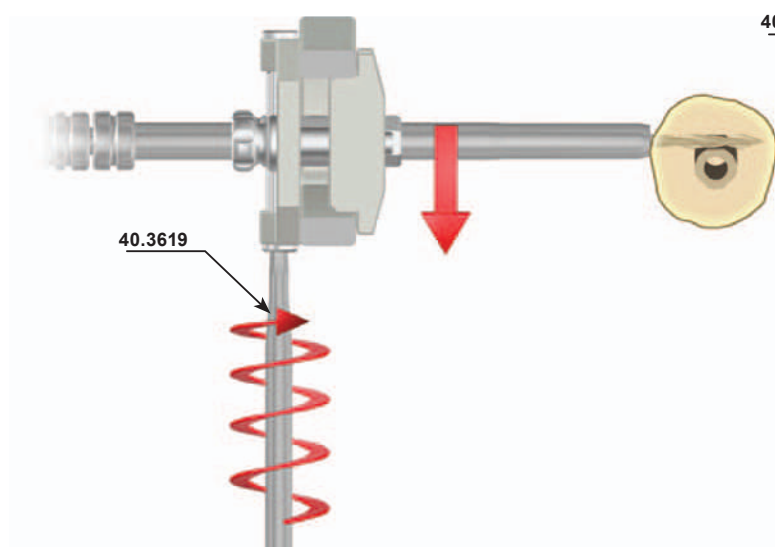
Remove the Trocar but leave the Protective Guide in the slider hole.

- Insert the Protective Drill 3.5 [40.3615] into Protective Guide [40.3614] until its tip rests on the soft tissues.
- Mount the Drill Guide [40.5330] on the surgical drive and drill hole through the first cortex layer and the nail hole.

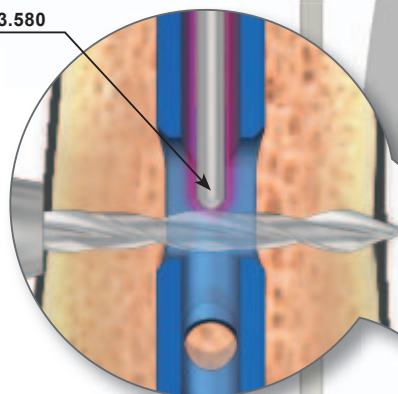


**If one of the holes (distal or proximal) is localized, locating another hole is not necessary.**

If the drill passes the nail hole, the second cortex layer should be drilled through. After dismantling the surgical drive, leave the drill in the hole. The scale on the drill shows the length of the locking elements.



40.3673.580



**NOTE:**  
Clockwise turn of Hexagonal Screwdriver S3.5 [40.3619] moves the slider „top”, the turn in the opposite direction moves it „down.”

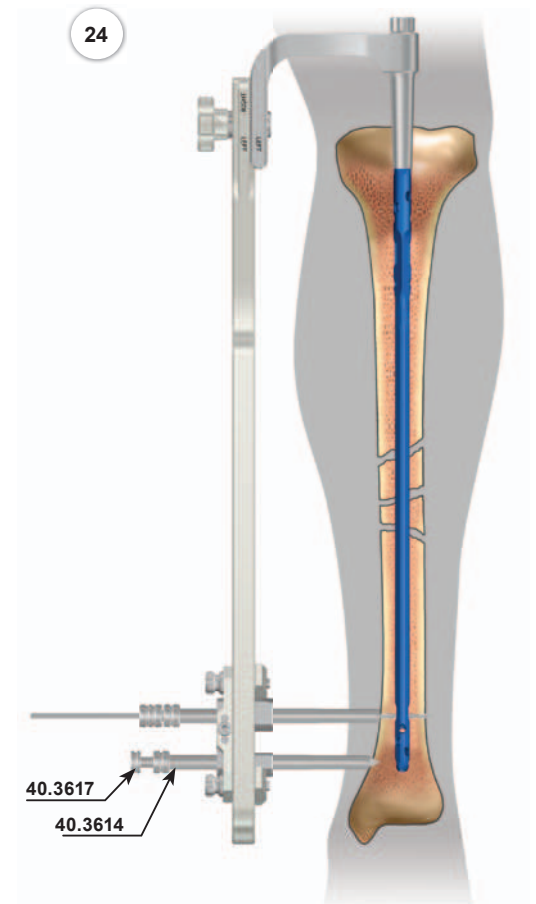
*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*

- 24 Insert the Protective Guide [40.3614] with the Trocar [40.3617] into the second (distal) slider hole of the Distal targeter D [40.5322].

Advance the Protective Guide with the Trocar until it rests on the cortex bone. Use the Trocar to mark the entry point to insert the Drill.

Remove the Trocar.

Leave the Protective Guide in the slider hole.



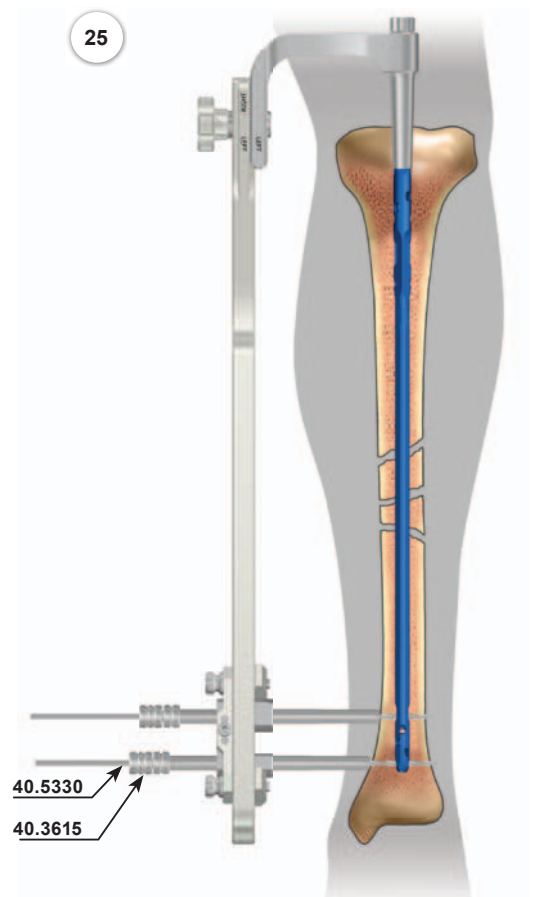
- 25 Insert the Drill Guide 3.5 [40.3615] into the Protective Guide [40.3614]. Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole in tibia through first cortex layer and the nail hole.

Verify if the drill is located in the hole using the rod. The tip of the Guide Rod should rest on the drill.

If the drill passes through the nail hole, drill it through the second cortex layer. The scale on the drill indicates the length of the locking elements.

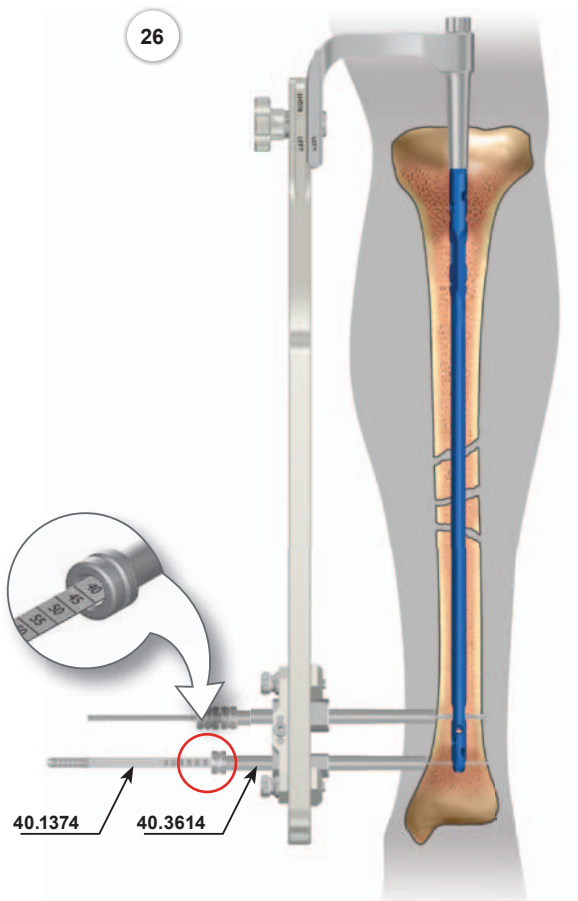
Remove the Drill and the Drill Guide.

Leave the Protective Guide in the slider hole.



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





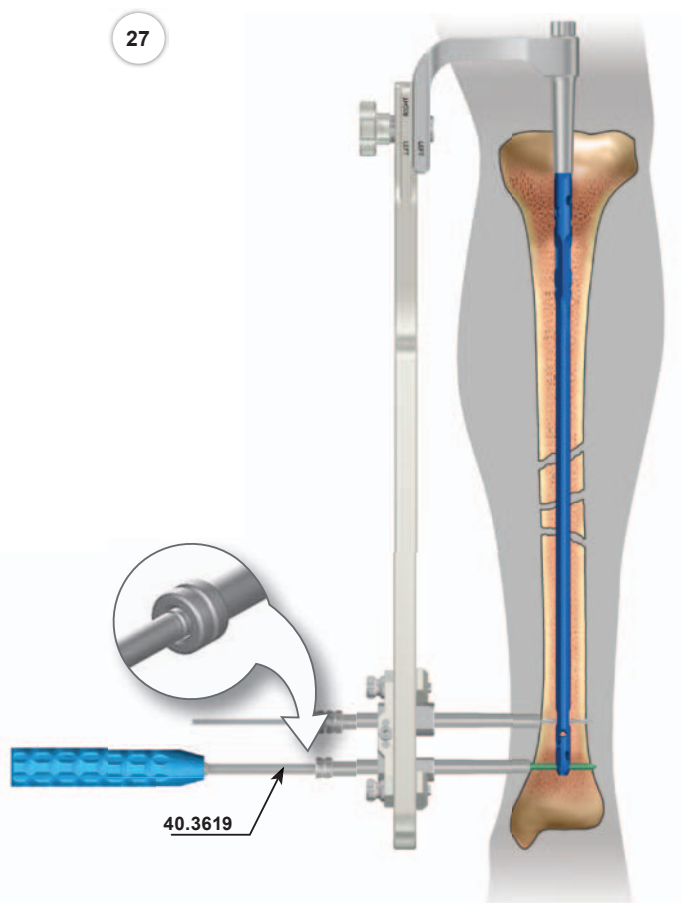
- 26** Insert the Screw Length Measure [40.1374] through the Protective Guide [40.3614] into the drilled hole until its hook reaches the „exit” plane of the hole. Read the length of the locking screw on the B-D scale.

The tip of the Protective Guide should rest on the cortex during the measurement.

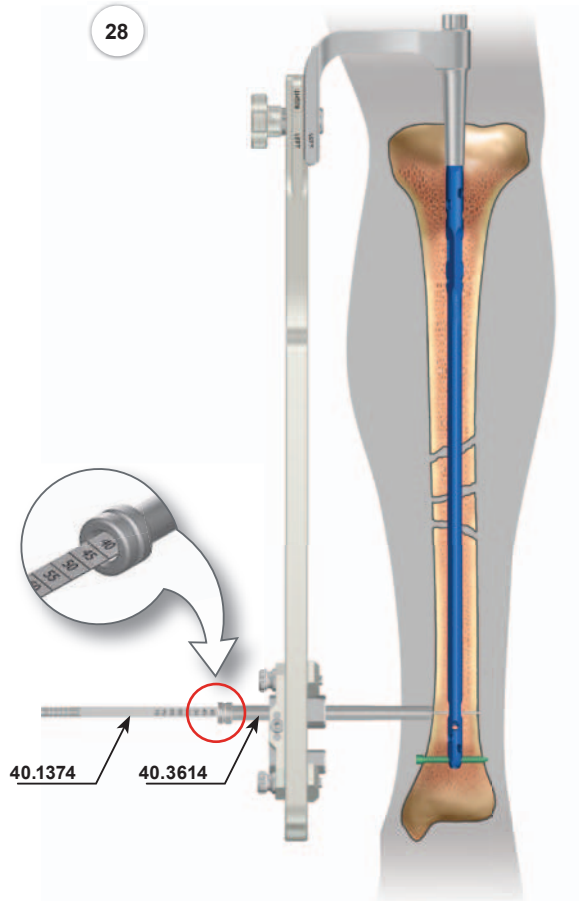
Remove the Screw Length Measure.  
Leave the Protective Guide in the slider hole.

- 27** Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into socket of the definite locking screw. Then advance such combined system into the Protective Guide [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (*the groove on the hexagonal screwdriver 3.5 matches the edge of protective guide*).

Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



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



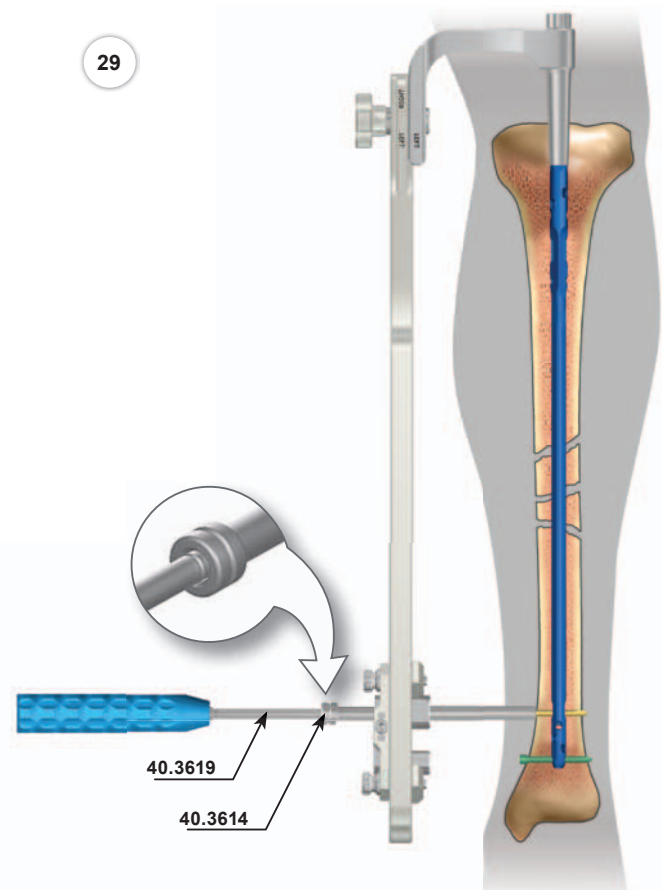
- 28 Remove the Drill With Scale 3.5/250 [40.5330] and the Drill Guide 6.5/3.5 [40.3615] from the slider hole but leave the Protective Guide 9/6.5 [40.3614]. Insert the Screw Length Measure [40.1374] through the Protective Guide 9/6.5 [40.3614] into the drilled hole until its hook reaches the „exit” plane of the hole. Read the length of locking screw on the B-D scale.

The tip of the Protective Guide should rest on the cortex during the measurement.

Remove the Screw Length Measure.  
Leave the Protective Guide in the slider hole.

- 29 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of definite locking screw. Then advance such combined system into the Protective Guide 9/6.5 [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (*the groove on the Hexagonal Screwdriver 3.5 matches the edge of Protective Guide*).

Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



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

**V.5.3. Insertion of instruments into slider holes of Distal targeter**

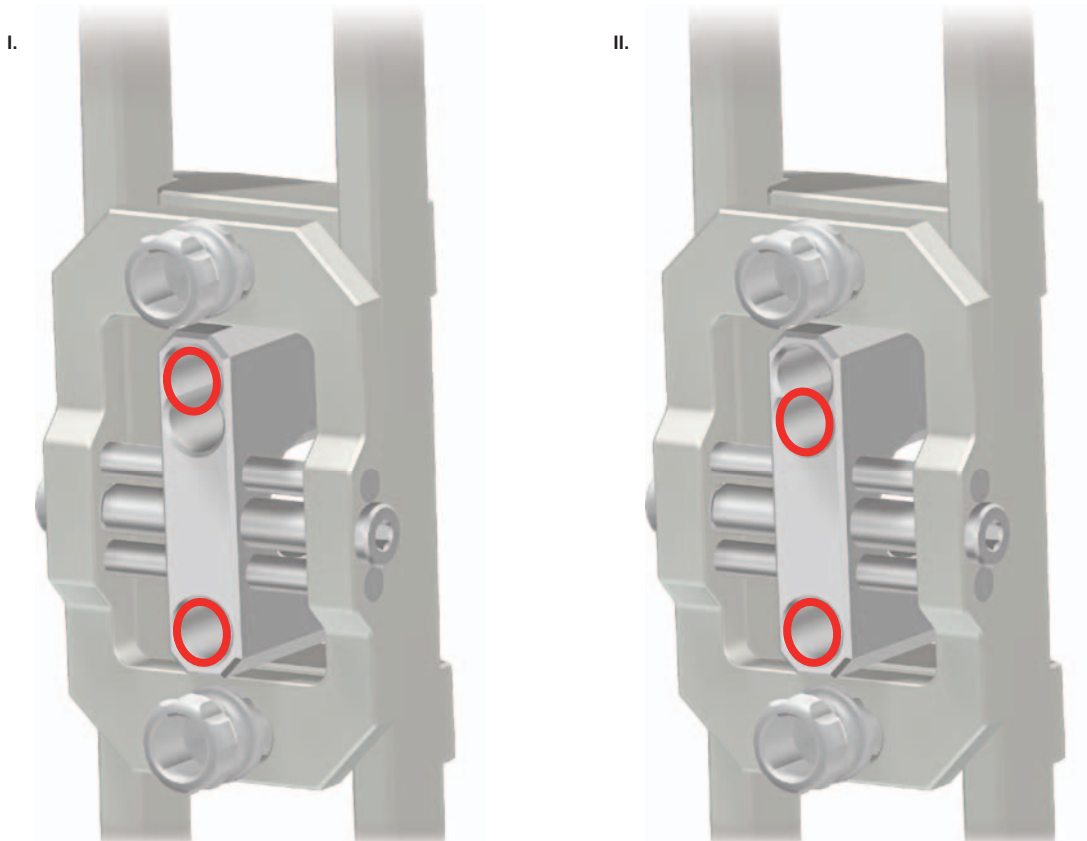
Insertion of the devices into the slider hole of the Distal targeter is possible and depends on the chosen method.

**I. static method:**

The instruments [40.5000.600] should be inserted into the distal slider hole and in proximal part of the double hole.

**II. dynamic and compressive method:**

The instruments [40.5000.600] should be inserted into the distal slider hole and in distal part of the double hole.



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

## V.6. PROXIMAL NAIL LOCKING

### V.6.1. Dynamic method and dynamic method with compression



#### IMPORTANT!

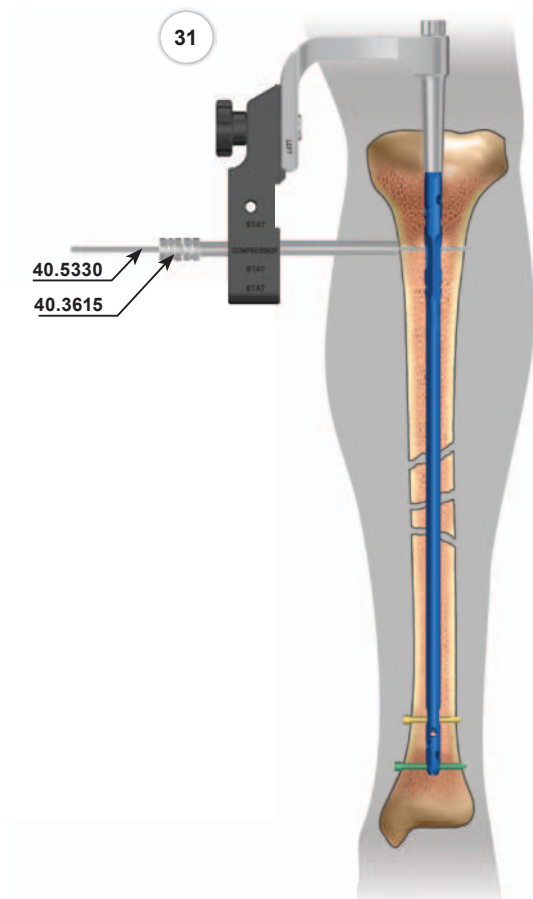
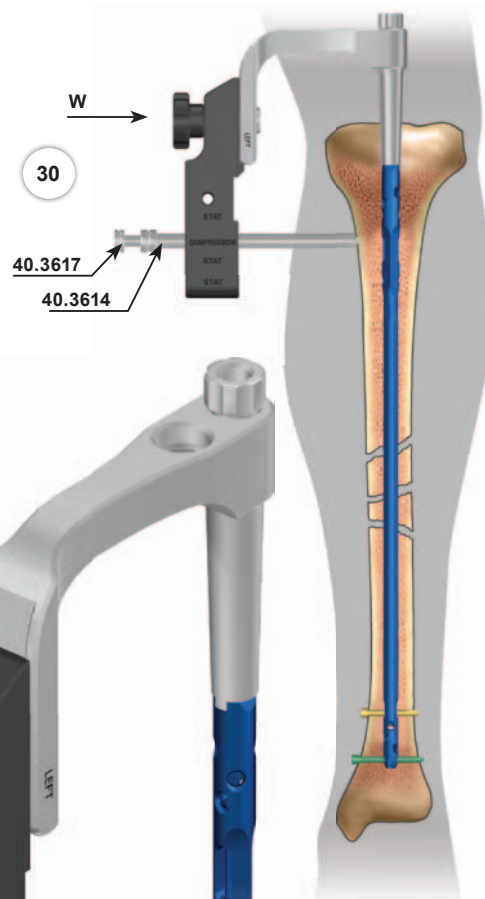
There are four holes in proximal part of the targeter for locking the nail.

The central hole of the targeter, marked **COMPRESSION**, should be used in dynamic or compression method for locking the nail in proximal part (correspondingly oval shaped hole in the intramedullary nail).

**30** Insert the Protective Guide [40.3614] with the Trocar 6.5 [40.3617] into the hole (marked: „compression”). Mark on the skin the entry point for locking screw and make adequate approx. 1.5 cm long incision through soft tissues. Insert the Protective Guide with the Trocar until it reaches the cortex bone. Mark the point for drill insertion using the Trocar.

Remove the Trocar.

Leave the Protective Guide in the hole of the targeter.



compression locking hole

**31** Insert the Drill Guide 6.5/3.5 [40.3615] into the Protective Guide 9/6.5 [40.3614]

Mount the Drill With the Scale 3.5/250 on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia through both cortex layers. Scale on the drill indicates the length of the locking elements.



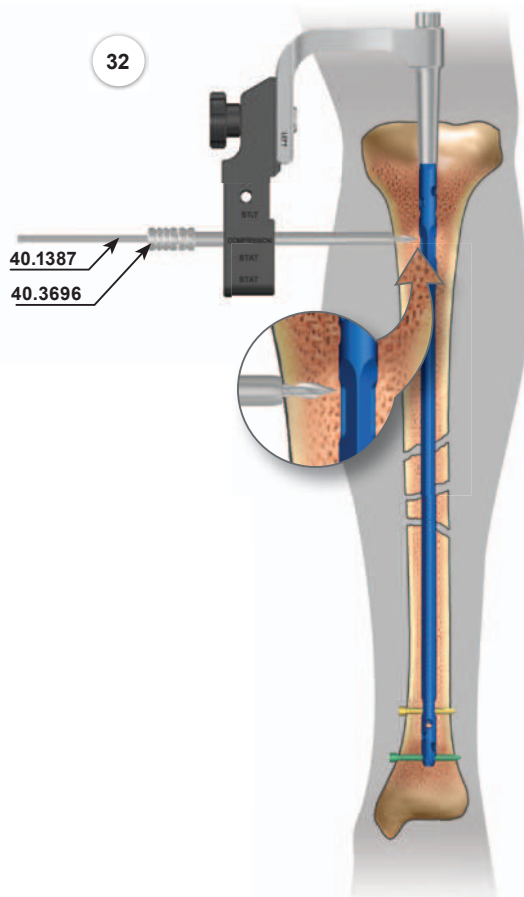
The process should be controlled with image intensifier.

Remove the Drill and the Drill Guide.

Leave the Protective Guide in the slider hole.

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

32



32

Insert the Drill Guide 6.5/4.5 [40.3696] into the Protective Guide 9/6.5 [40.3614]. Insert the Drill 4.5/250 [40.1387] into the Drill Guide and widen the hole in first cortex layer.

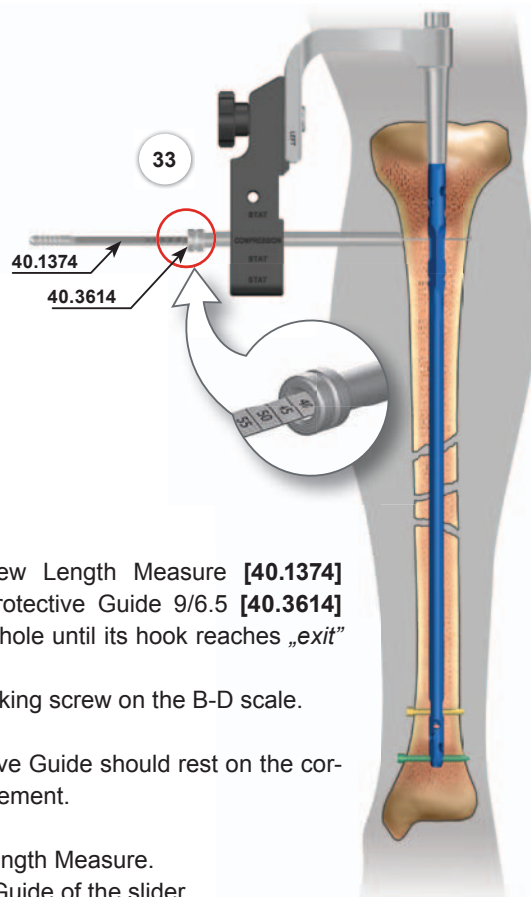


The widening process should be controlled with image intensifier.

Remove the Drill and the Drill Guide.

Leave the Protective Guide in the targeter hole.

33



33

Insert the Screw Length Measure [40.1374] through the Protective Guide 9/6.5 [40.3614] into the drilled hole until its hook reaches „exit” plane of the hole.

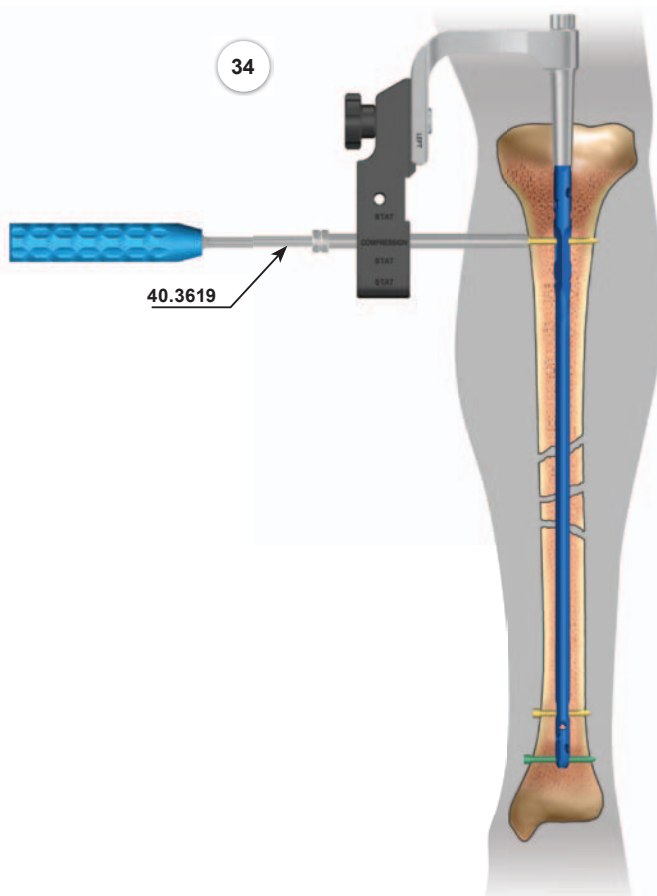
Read the length of locking screw on the B-D scale.

The tip of the Protective Guide should rest on the cortex during the measurement.

Remove the Screw Length Measure.

Leave the Protective Guide of the slider.

34



34

Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the defined proximal screw.

Advance such combined system into the Protective Guide 9/6.5 [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (*the groove on the Hexagonal Screwdriver 3.5 matches the edge of the Protective Guide*).

Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



**IMPORTANT!**

Use the proximal screw to lock the nail.

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



35

40.3617  
40.3614

## V.6.2. Static method

It is recommended to lock a nail in proximal part using two screws. One of round holes should be used in every case of nail locking.

35

Insert the Protective Guide 9/6.5 [40.3614] with the Trocar 6.5 [40.3617] into the hole of the Targeter B [40.5373].

Mark on the skin the entry point for the locking screw and make adequate 1.5 cm long incision through the soft tissues.

Insert the Protective Guide with the Trocar until it reaches the cortex bone. Mark the entry point for drill insertion using the Trocar.

36

40.3615  
40.5330

36

Insert the Drill Guide 6.5/3.5 [40.3615] into the Protective Guide.

Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia through both cortex layers. Scale on the Drill indicates the length of the locking elements.



The drilling process should be controlled with image intensifier.

Remove the Drill and the Drill Guide.

Leave the Protective Guide in the hole of the targeter.

37

40.1374  
40.3614

37

Insert the Screw Length Measure [40.1374] through the Protective Guide 9/6.5 [40.3614] into the drilled hole until its hook reaches „exit” plane of the hole.

Read the length of the locking screw on the B-D scale.

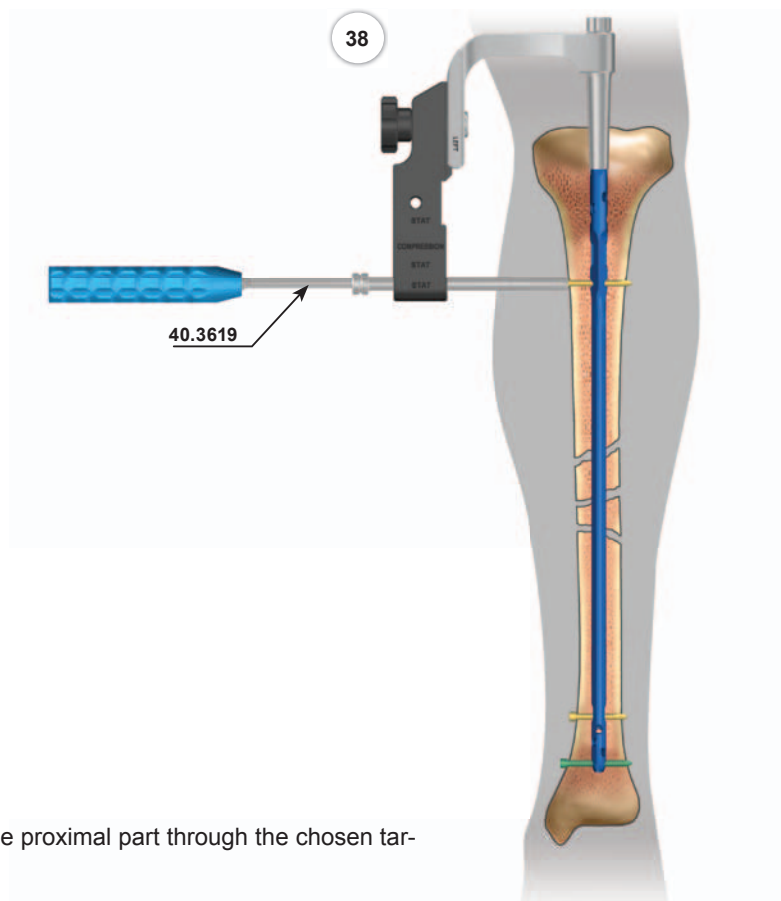
The tip of the Protective Guide should rest on the cortex during the measurement.

Remove the Screw Length Measure.

Leave the Protective Guide in the hole of the targeter.

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

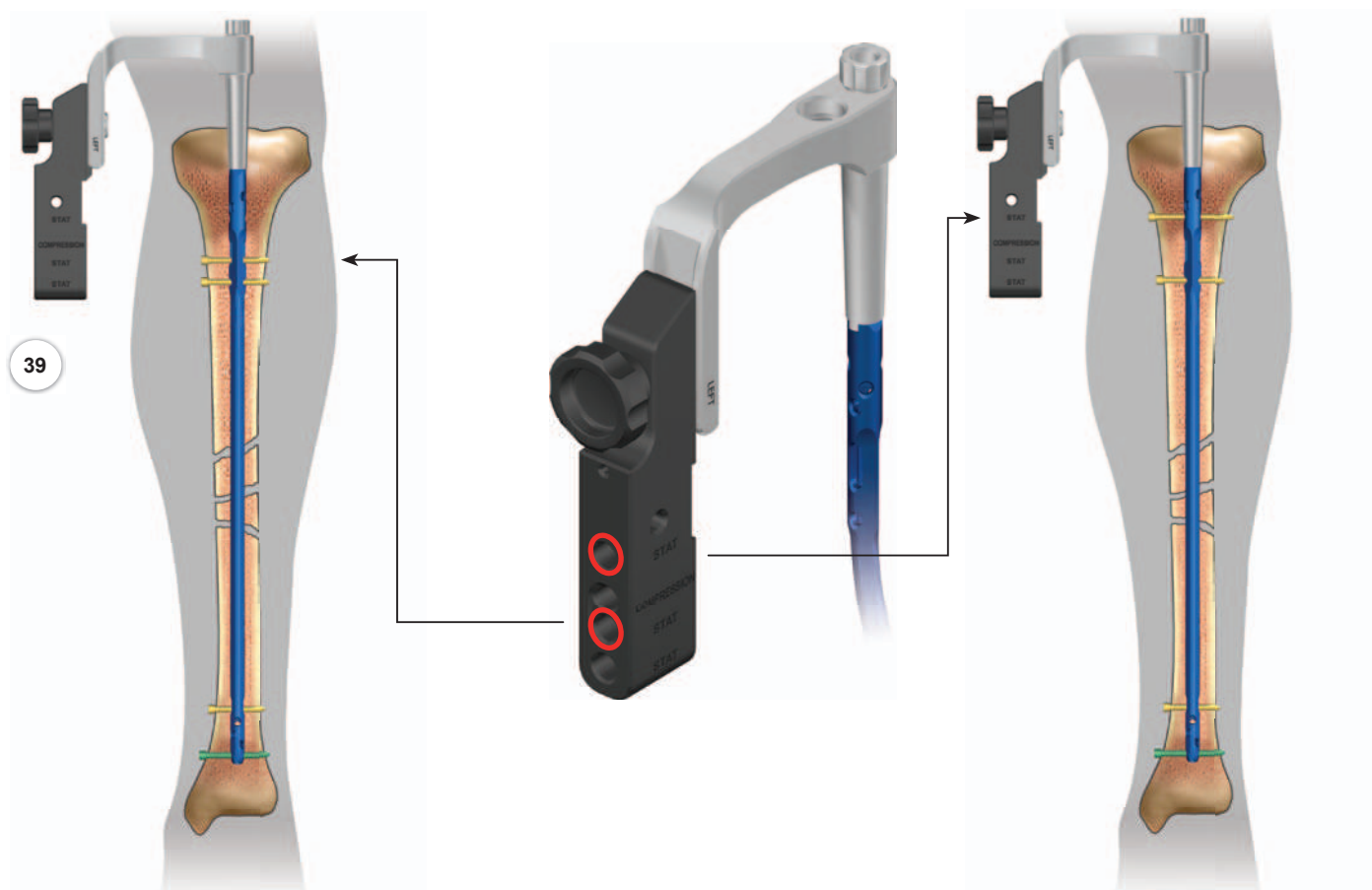
- 38 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the head of the definite locking screw and then advance such system into the Protective Guide 9/6.5 [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (*the groove on the Hexagonal Screwdriver 3.5 matches the edge of the Protective Guide*). Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



- 39 Use the second locking screw to lock the nail in the proximal part through the chosen target hole.



To lock the nail follow the steps from 35 to 38.



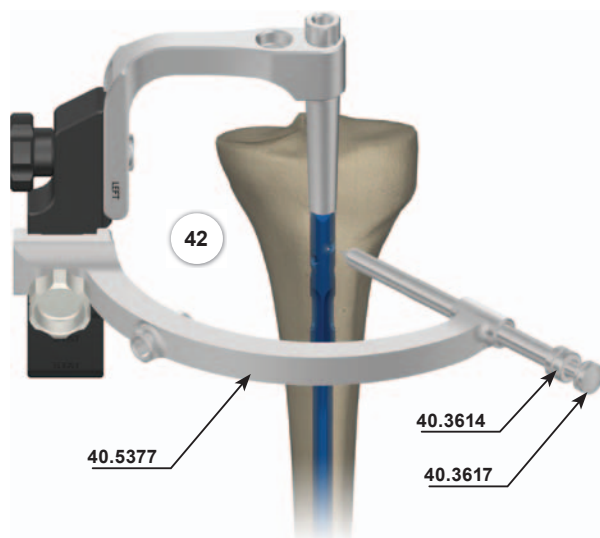
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

## VI. SURGICAL TECHNIQUE - RECONSTRUCTIVE METHOD

### VI.1. PROXIMAL LOCKING OF THE RECONSTRUCTION INTRAMEDULLARY NAIL

**40** Reconstruction nail has 5 holes in proximal part. Decision about insertion site and number of used screws is to be made by surgeon and depends on the type of fracture. It is not necessary to lock reconstruction tibial nail in the reconstruction holes. In such case, lock the nail as in the compression method. It is important to pay attention to lack of compression possibilities in the case of using the reconstruction holes. In the case of locking the reconstruction tibial nail in the proximal part follow steps [30]-[39].

**41** Mount the Reconstruction targeter **[40.5377]** on the Target B **[40.5373]** to lock the nail using reconstruction holes. Insert threaded arbor of the Reconstruction targeter into lateral hole of the Targeter arm B **[40.5301]** and connect both elements using the nut.

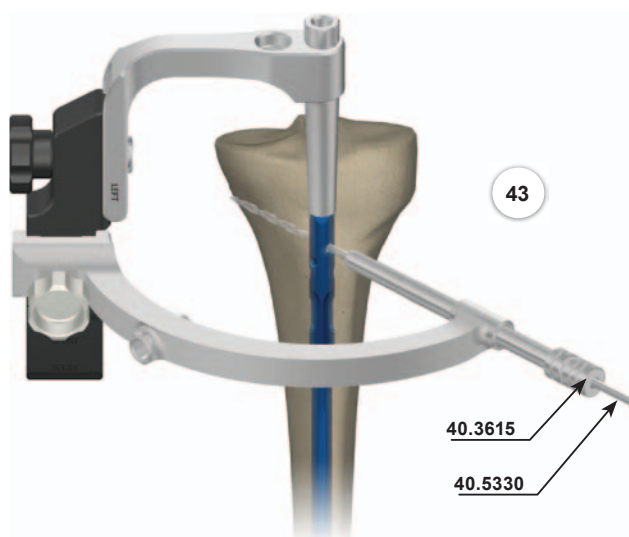


**42** Insert the Protective Guide 9/6.5 **[40.3614]** with the Trocar 6.5 **[40.3617]** into the hole of the Reconstruction targeter. Mark on the skin the entry point for locking screw and make 1.5 cm long incision of the soft tissues. Advance the Protective Guide together with the Trocar until it reaches the cortex bone. Use the Trocar to mark the entry point for the drill.

Remove the Trocar.  
Leave the Protective Guide in the hole of the targeter.

**43** Insert the Drill Guide 6.5/3.5 **[40.3615]** into the Protective Guide 9/6.5 **[40.3614]** left in the hole of the targeter. Mount the Drill With Scale 3.5/250 **[40.5330]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia to the appropriate depth. The scale on the Drill indicates the locking elements.

Leave the Protective Guide together with Drill and Drill Guide in the hole of the targeter.



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

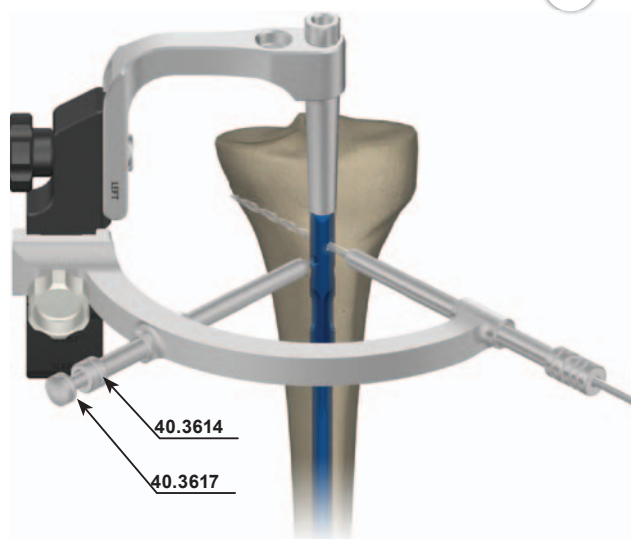


44

44 Insert the Protective Guide 9/6.5 [40.3614] with the Trocar 6.5 [40.3617] into second reconstruction hole of the targeter. Mark on skin entry point for the locking screw and 1.5 cm long incision of the soft tissues across the point. Advance the Protective Guide together with Trocar until it reaches the cortex bone. Use the Trocar to mark the entry point for the drill .

Remove the Trocar.

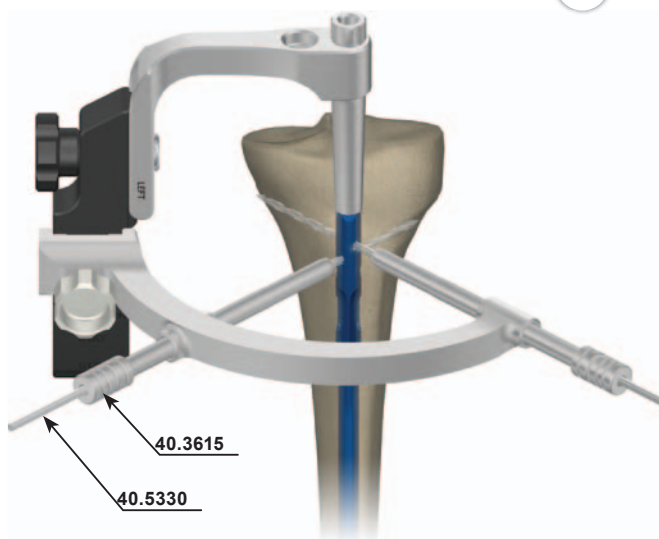
Leave the Protective Guide in the hole of the targeter.



45

45 Insert the Drill Guide 6.5/3.5 [40.3615] into the Protective Guide 9/6.5 [40.3614] left in the hole of the targeter. Mount the Drill With Scale 3.5/250 [40.5330] on the surgical drive and advance it through the Drill Guide. Drill the hole in the tibia to the appropriate depth. The scale on the drill indicates the locking elements

Leave the Protective Guide together with Drill and Drill Guide in the hole of the targeter.



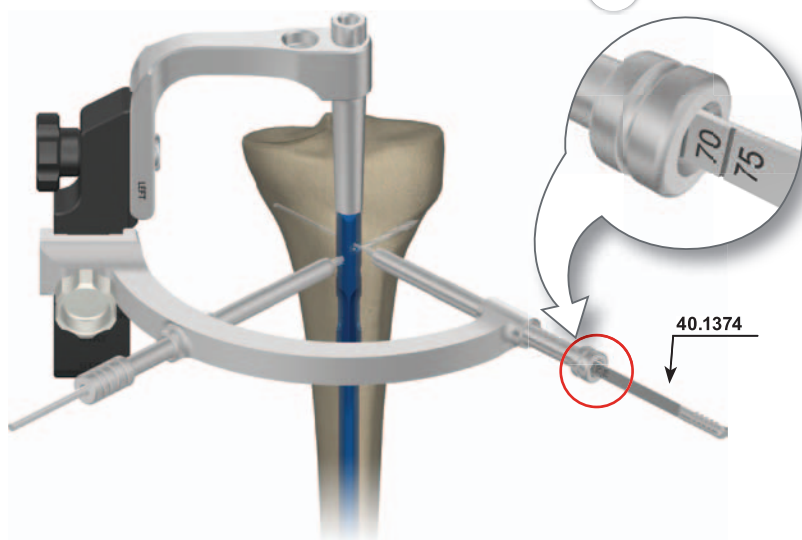
46

46 Remove the Drill With Scale [40.5330] and the Drill Guide 6.5/3.5 [40.3615] from one of the targeter holes. Leave the Protective Guide 9/6.5 mm [40.3614] in the targeter hole.

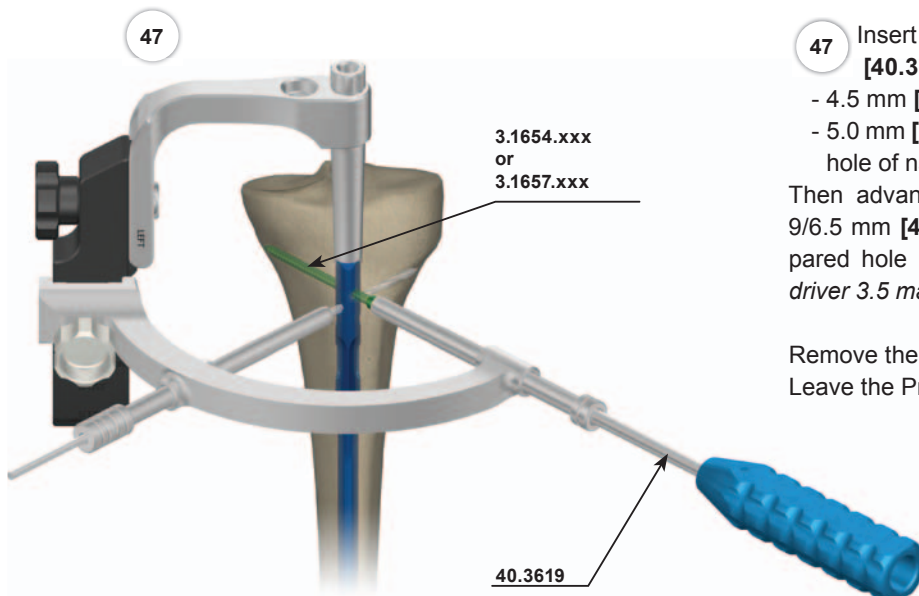
Insert the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its tip reaches the end of hole. Read the length of the locking screw on the B-D scale. During the measurement the end of the Protective Guide should rest on the cortex.

Remove the Screw Length Measure.

Leave the Protective Guide in the hole of the targeter.



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



- 47 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the locking screw:
- 4.5 mm [3.1654.xxx] in the case of standard locking,
  - 5.0 mm [3.1657.xxx] in the case of locking in threaded hole of nail.

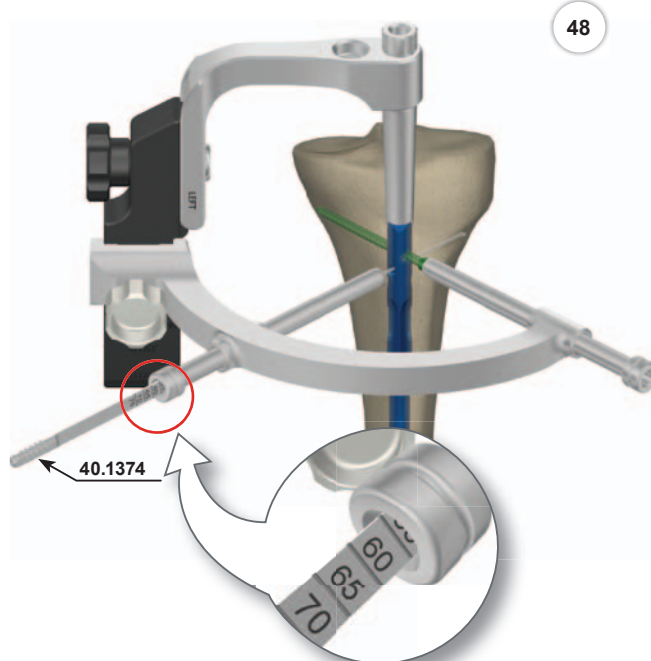
Then advance such system into the Protective Guide 9/6.5 mm [40.3614]. Insert the locking screw in the prepared hole (until the groove on the Hexagonal Screwdriver 3.5 matches the edge of the Protective Guide).

Remove the Hexagonal Screwdriver 3.5.  
Leave the Protective Guide.

- 48 Remove the Drill With Scale 3.5/250 [40.5330] and the Drill Guide 6.5/3.5 [40.3615] from the second hole of the reconstruction targeter. Leave the Protective Guide 9/6.5 mm [40.3614] in the targeter hole. Insert the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its tip reaches the end of hole.

Read the length of the locking screw on the B-D scale. During the measurement the end of the Protective Guide should rest on the cortex.

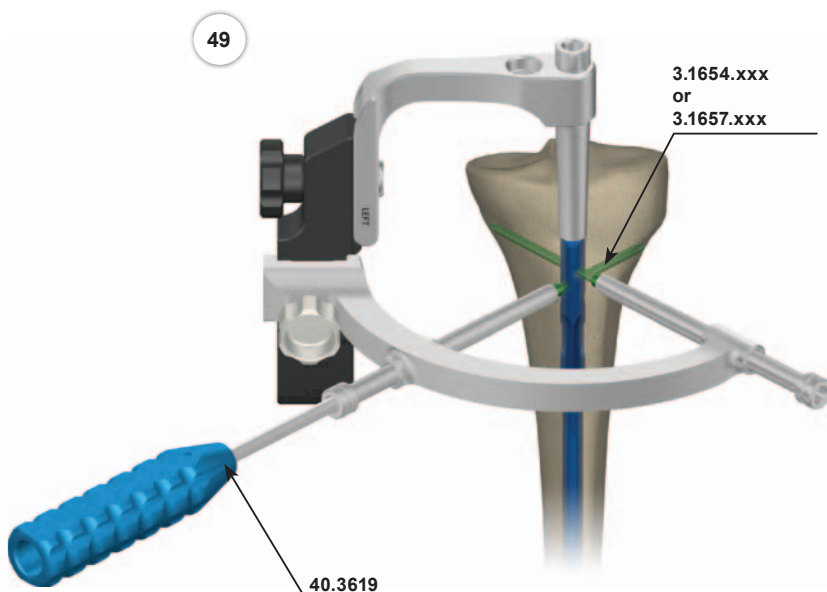
Remove the Screw Length Measure.  
Leave the Protective Guide in the hole of the targeter.



- 49 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the locking screw:
- 4.5 mm [1.1653.xxx] in the case of standard locking,
  - 5.0 mm [3.1657.xxx] in the case of locking in threaded hole of nail.

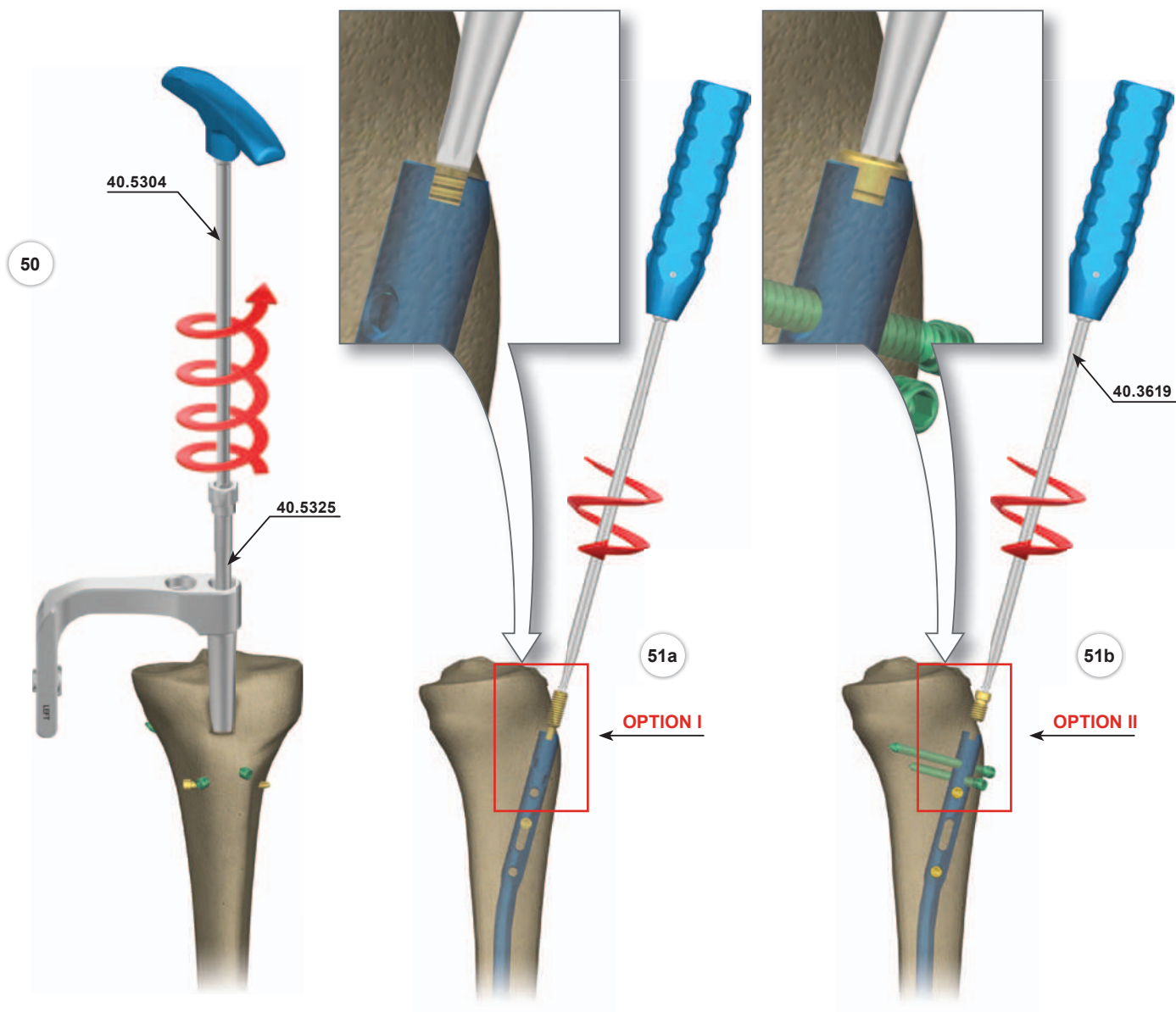
Then advance such system into the Protective Guide 9/6.5 mm [40.3614]. Insert the locking screw in the prepared hole (until the groove on the Hexagonal Screwdriver 3.5 matches the edge of protective guide).

Remove the Hexagonal Screwdriver 3.5 and the Protective Guide.



## VI.2. INSERTING COMPRESSION SCREW OR END CUP

- 50 Unscrew the Connecting screw M8x1.25 L-91 [40.5325] using the Socket Wrench S8 [40.5304].  
Dismount the the Targeter arm [40.5301] from the nail.



- 51 Insertion of Compression Screw or End Cap.

**OPTION I: Inserting the Compression Screw refers to dynamic method with compression.**

Use the Screwdriver [40.3619] to insert the Compression Screw (*implant*) into the threaded hole of the nail.

**OPTION II: Inserting the End Cap refers to dynamic and static methods.**

To secure the inner thread of the nail form bone ingrowth, insert the End Cap (*implant*) using the Screwdriver [40.3619].

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

### VII. LOCKING OF INTRAMEDULLARY NAIL USING TARGETER D [40.1344] AND TARGETER ARM B [40.5301]

#### VII.1. DISTAL LOCKING OF THE NAIL USING TARGETER D [40.1344] – „FREEHAND TECHNIQUE”

In this technique an image intensifier is used to verify the entry points for the Drill and to control the drilling processes. It is recommended to use angular attachment with the surgical drive while drilling the holes, so that surgeon's hands are not directly exposed to X-rays.

After marking the entry points on the skin, make incisions through the soft tissues, each about 1.5 cm in length.

- 52 Use the image intensifier to establish the place of the Targeter D [40.1344] in line with the nail hole.  
The centers of the holes in the targeter and the nail have to match. The teeth of the targeter have to be merged in the cortex. Insert the Short Trocar [40.1354] into the Targeter D hole, advance it until it reaches cortex and mark the entry point for the drill.

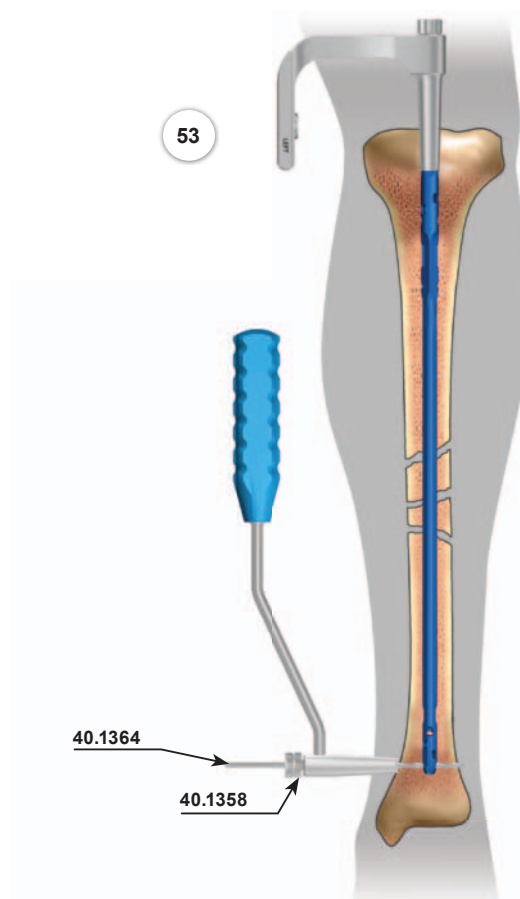
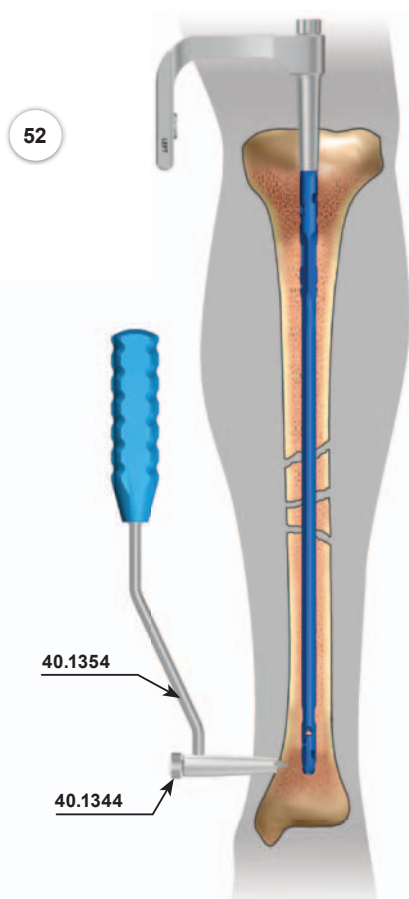
Remove the Trocar.

Leave the Targeter D in place.

- 53 Insert the Drill Guide Short 7/3.5 [40.1358] into the hole in Targeter D [40.1344]. Mount the Drill 3.5/150 mm [40.1364] or Drill 3.5/250 [40.5330] on the surgical drive and advance such system through the Drill Guide. Drill the hole through both cortex layers.



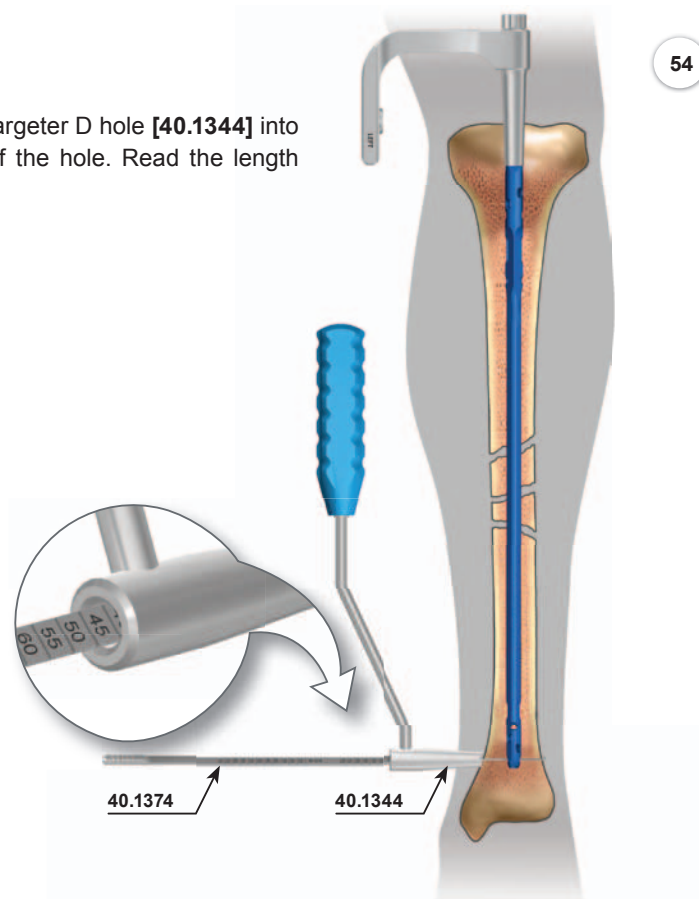
The drilling process should be controlled with image intensifier.



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

- 54 Insert the Screw Length Measure [40.1374] through the Targeter D hole [40.1344] into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the D scale.

Remove the Screw Length Measure.  
Leave the Targeter D.



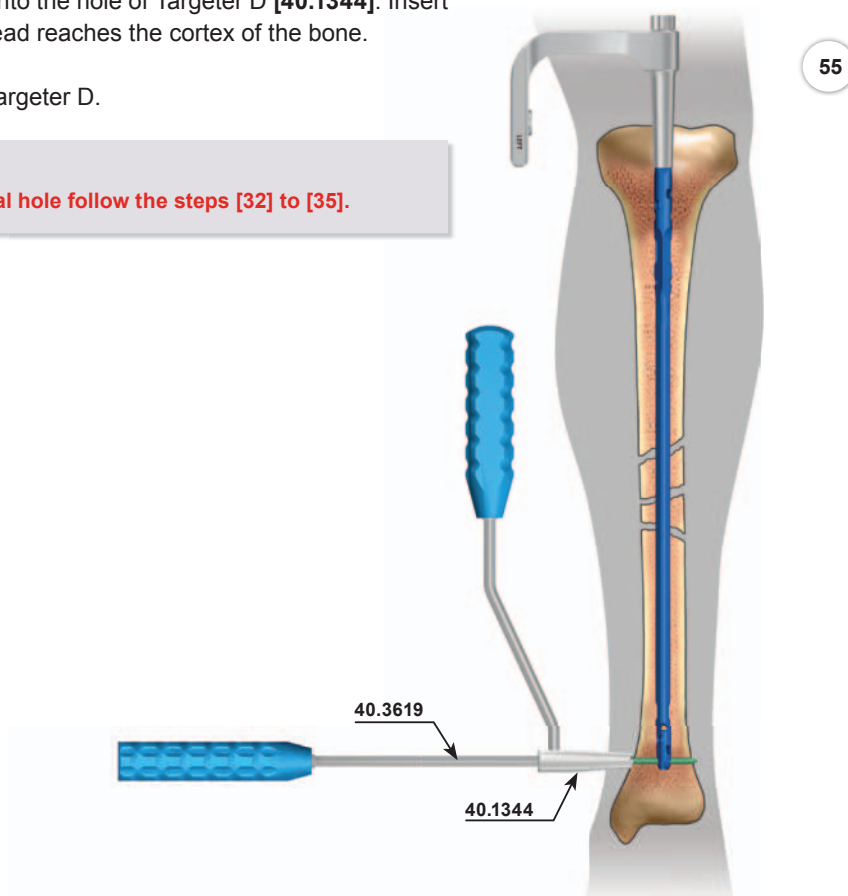
- 55 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the selected locking screw. Then advance such system into the hole of Targeter D [40.1344]. Insert the locking screw into the prepared hole until its head reaches the cortex of the bone.

Remove the Hexagonal Screwdriver 3.5 and the Targeter D.



**NOTE!!!**

In order to lock the nail in the second distal hole follow the steps [32] to [35].

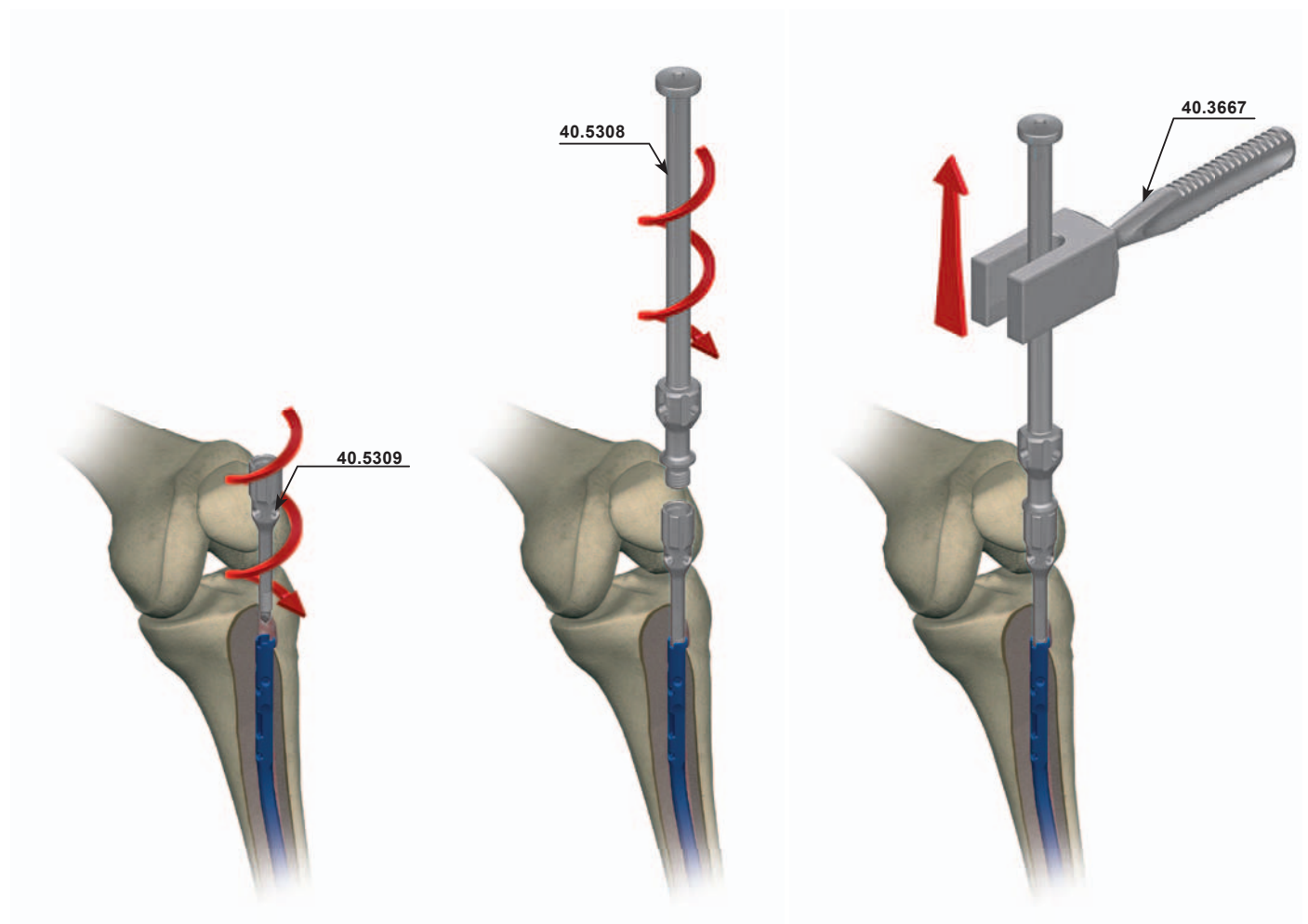
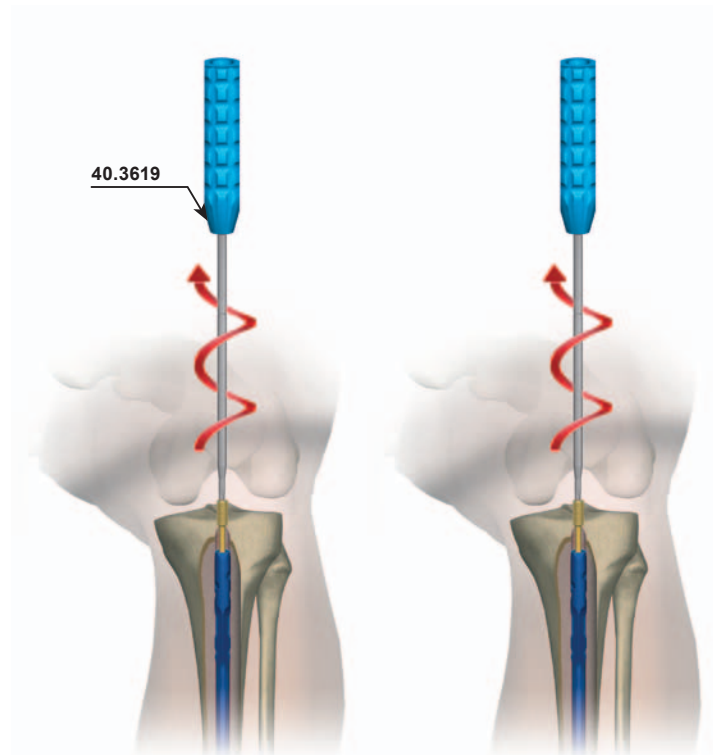


*The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.*



## VIII. NAIL EXTRACTION

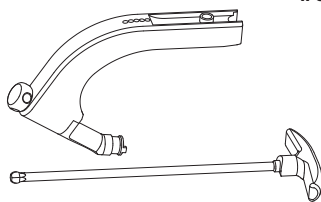
- 56 Use the Hexagonal Screwdriver 3.5 [40.3619] to remove the End Cap (or compression screw) and all locking screws.  
Insert the Connector M8x1.25 [40.5309] into the threaded nail hole.  
Attach the Impactor-Extractor [40.5308] to the Connector and using the Mallet [40.3667] remove the nail from the medullary canal.



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

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IFU-I-001/14



INSTRUCTIONS FOR USE

## REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS



Instruments manufactured by ChM Ltd. are made of steel, aluminium alloys and plastics according to ISO standards. Each medical instrument is exposed to occurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

## 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 stay 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 on the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: POM-C (*Polyoxymethylene Copolymer*), PEEK (*Polyetheretherketone*) and teflon (*PTFE*). 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 9.5.

• If the material of the device cannot be specified, please contact ChM Ltd. company representative.

## DISINFECTION AND CLEANING

Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quality of used detergent, the technique of cleaning (*manual/machine*), the correct rinsing and drying, the proper preparation of the instrument, the time, the temperature. Internal procedures of sterilization rooms, recommendations of cleaning and disinfecting agents, as well as recommendations for cleaning and sterilization in automatic machines shall be observed.

• Read and follow the instructions and restrictions specified by the manufacturers of the agents used for disinfection and cleaning procedures.

1. Before the first use, the product has to be thoroughly washed in the warm water with washing-disinfecting detergent. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use water solutions of cleaning-disinfecting agents with a neutral pH.

2. After use, for at least 10 minutes the product has to be immediately soaked in an aqueous disinfectant solution of enzyme detergent with a neutral pH (*with a disinfecting properties*) normally used for reusable medical devices (*remember to prevent drying out of any organic remains on the product surface*). Follow all the instructions specified by the producer of those enzyme detergents.

3. Carefully scrub/clean the surfaces and crevices of the product using a soft cloth without leaving threads, or brushes made of plastic, the nylon brushes are recommended. Do not use brushes made of metal, bristles or another damaging material as they can cause physical or chemical corrosion.

4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention to rinse the slots carefully. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse under demineralized water, in order to avoid water stains and corrosion caused by chlorides, found in the ordinary water, and to avoid forming the stains on the surface (*e.g. anodized one*). During the rinsing, manually remove the adherent remains.

5. Visually inspect the entire surface of the product to ensure that all contaminants are removed.

• If there are any residues of human tissue or any other contamination, repeat all stages of the cleaning process.

6. Then, the instrument has to undergo a process of machine washing in the washer-disinfector (*use washing-disinfecting agents recommended for reusable medical devices and instruments*).

• Procedure of washing with 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.

**ATTENTION!** The manufacturer does not recommend using any preservatives on surgi-

cal and orthopedic devices.

## 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, without structure damage (*cracks, fractures, bending, peeling*). Remember that sterilization is not a substitute for cleaning process!

• Devices manufactured out of plastics (PEEK, PTFE, POM-C) 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.

Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards. It is recommended to sterilize in steam sterilizers where sterilizing agent is water vapour. Recommended parameters of the sterilization method:

- temperature: 134°C,
- pressure: 2 atm. of pressure above atmospheric (*overpressure*),
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

Validated sterilization methods are allowed. 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.

If this instruction 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](http://www.chm.eu)

IFU-I-001/14; Date of verification: March 2014

SYMBOL TRANSLATION - OBJAŚNIENIA SYMBOLI - ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ  
EXPLICACIÓN DE LOS SÍMBOLOS - SYMBOLERKLÄRUNG - SYMBOLY PŘEKLADY

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