

instruction

INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA

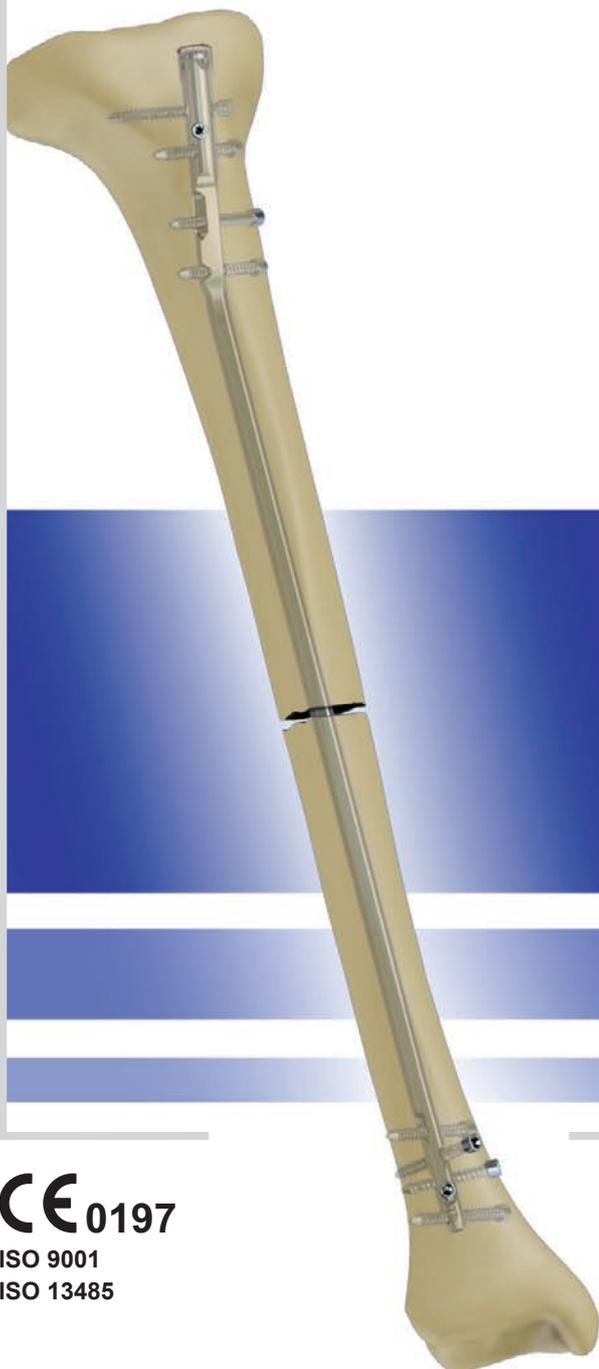
IMPLANTS ◦
INSTRUMENT SET ◦
SURGICAL TECHNIQUE ◦

CHARFIX *system*

25B

CE 0197
ISO 9001
ISO 13485

ChM®



I. INTRODUCTION	5
II. IMPLANTS OF COMPRESSIVE METHOD	8
III. IMPLANTS OF RECONSTRUCTIVE METHOD	9
IV. LOCKING ELEMENTS	10
V. INSTRUMENT SET	11
VI. SURGICAL TECHNIQUE	16
<i>VI.1. Introduction</i>	16
<i>VI.3. Preparation of intramedullary canal for nail insertion</i>	17
<i>VI.2. Opening the medullary canal</i>	17
<i>VI.4. Nail insertion</i>	19
<i>VI.5. Distal locking of intramedullary nail</i>	21
OPTION I: <i>With image intensifier control</i>	21
OPTION II: <i>Whitout x-ray control</i>	24
<i>a) setting nail holes by adjusting position of target D slider</i>	24
<i>b) setting nail holes using Kirschner wire, and setting position of target D slider</i>	30
<i>Insertion of instrument devices into slider holes of target D</i>	35
<i>VI.6. Proximal nail locking</i>	36
<i>VI.6.1. Dynamic method and dynamic method with compression (compressive)</i>	36
<i>VI.6.2. Static method</i>	38
<i>VI.7. Placing Compression screw or End cap</i>	40
VII. SURGICAL TECHNIQUE - RECONSTRUCTIVE METHOD	41
<i>VII.1. Proximal locking of the reconstructive intramedullary nail</i>	41
<i>VII.2. Placing end cap</i>	45
VIII. LOCKING OF INTRAMEDULLARY NAIL USING TARGET D AND TARGET B	46
<i>VIII.1. Distal locking of the nail using Target D [40.1344] – „freehand technique”</i>	46
<i>VIII.2. Proximal locking of the nail using Proximal Tibia Target B [40.5001]</i>	47
IX. NAIL EXTRACTION	48

I. INTRODUCTION

CHARFIX system - INTRAMEDULLARY OSTEOSYNTHESIS OF TIBIA consists of:

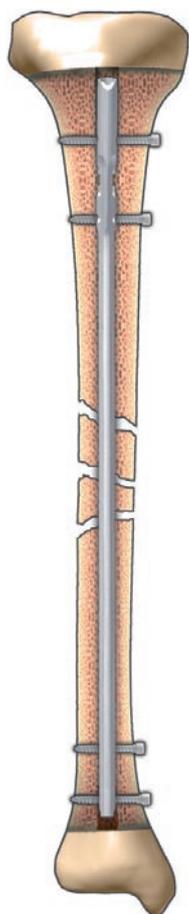
- implants (intramedullary nail, locking screws, end cap or compression screw),
- instrument set for implants insertion and extraction,
- instruction for use (surgical technique).

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

Indication:

- multi-fragmental fractures
- tibia and fibula fractures,
- fracures 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.

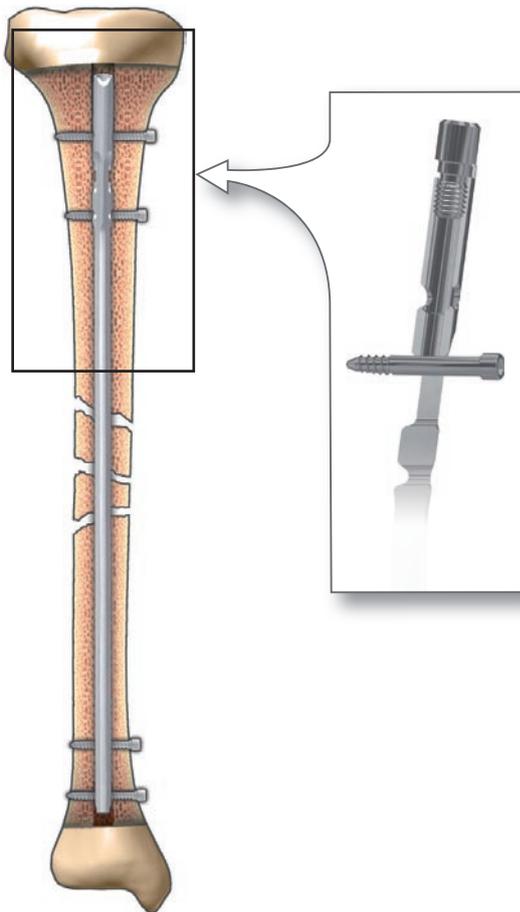
CHARFIX system provides following methods:



Static Method

Static fixation is used in multi-fragmental fractures with not-axial alignment.

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

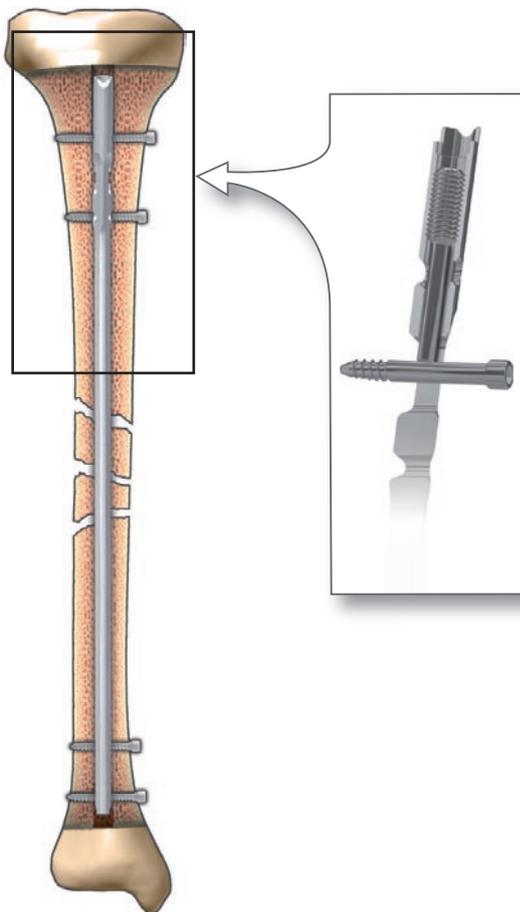


Dynamic Method

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

One 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 union and remodelling of bone.



Dynamic Method with Compression

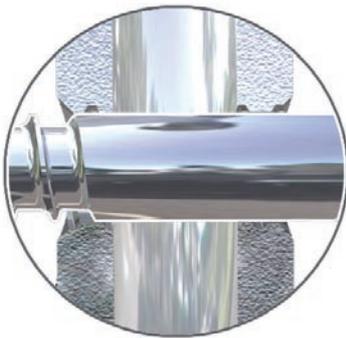
In the dynamic fixation with compression, the compressive screw is axially inserted to put pressure on screw locking the nail. Compressive fixation eliminates all micromovements of the treatment in its early stage.

Reconstructive Method

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

Threaded holes enable optional locking using:

- proximal screw $\varnothing 4,5$;



- locking distal screw $\varnothing 5,0$ which prevents angular displacement of bone fragments (using threaded hole).

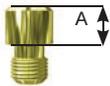


II. IMPLANTS OF COMPRESSIVE METHOD



Śruba zaślepiająca M8x1,25
End cap M8x1,25
Винт слепой M8x1,25

A	Nr katalogowy, Catalogue no., Каталожный №.	
	Stal, Steel, Сталь	TYTAN, Titanium, Титан
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
+20	1.2104.120	3.2104.120
+25	1.2104.125	3.2104.125
+30	1.2104.130	3.2104.130



Stal, Steel, Сталь
 1.2106.002
 Tytan, Titanium, Титан
 3.2106.002

Śruba kompresyjna M8x1,25
Compression screw M8x1,25
Винт компрессионный M8x1,25

dostępne available		
доступные		
Ø [mm] skok, pitch, шаг 1 mm	7 ÷ 19	7 ÷ 19
L [mm] skok, pitch, шаг 5 mm	190 ÷ 600	190 ÷ 600

Kolory Colors						
Ø7	Ø8	Ø9	Ø10	Ø11	Ø12	Ø13

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

Stal, Steel, Сталь
 1.1653.025 -075
 Tytan, Titanium, Титан
 3.1653.025 -075

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

Stal, Steel, Сталь
 1.1657.016 -100
 Tytan, Titanium, Титан
 3.1657.016 -100

lub or либо

Gwintowane otwory blokujące
 Threaded locking holes
 Блокирующие отверстие с
 нарезкой резьбы.

Ø	L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
9	270	1.2076.270	3.2076.270
	285	1.2076.285	3.2076.285
	300	1.2076.300	3.2076.300
	315	1.2076.315	3.2076.315
	330	1.2076.330	3.2076.330
	345	1.2076.345	3.2076.345
	360	1.2076.360	3.2076.360
	375	1.2076.375	3.2076.375
	390	1.2076.390	3.2076.390
	10	270	1.2077.270
285		1.2077.285	3.2077.285
300		1.2077.300	3.2077.300
315		1.2077.315	3.2077.315
330		1.2077.330	3.2077.330
345		1.2077.345	3.2077.345
360		1.2077.360	3.2077.360
375		1.2077.375	3.2077.375
390		1.2077.390	3.2077.390
11		270	1.2078.270
	285	1.2078.285	3.2078.285
	300	1.2078.300	3.2078.300
	315	1.2078.315	3.2078.315
	330	1.2078.330	3.2078.330
	345	1.2078.345	3.2078.345
	360	1.2078.360	3.2078.360
	375	1.2078.375	3.2078.375
	390	1.2078.390	3.2078.390
	12	270	1.2079.270
285		1.2079.285	3.2079.285
300		1.2079.300	3.2079.300
315		1.2079.315	3.2079.315
330		1.2079.330	3.2079.330
345		1.2079.345	3.2079.345
360		1.2079.360	3.2079.360
375		1.2079.375	3.2079.375
390		1.2079.390	3.2079.390

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

Stal, Steel, Сталь
 1.1653.025 -075
 Tytan, Titanium, Титан
 3.1653.025 -075

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

lub or либо

Stal, Steel, Сталь
 1.1654.016 -100
 Tytan, Titanium, Титан
 3.1654.016 -100

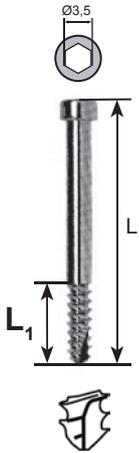
Stal, Steel, Сталь
 1.1657.016 -100
 Tytan, Titanium, Титан
 3.1657.016 -100

Gwintowane otwory blokujące
 Threaded locking holes
 Блокирующие отверстие с
 нарезкой резьбы.

Ø	L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
8	240	1.2063.240	3.2063.240
	255	1.2063.255	3.2063.255
	270	1.2063.270	3.2063.270
	285	1.2063.285	3.2063.285
	300	1.2063.300	3.2063.300
	315	1.2063.315	3.2063.315
	330	1.2063.330	3.2063.330
	345	1.2063.345	3.2063.345
	360	1.2063.360	3.2063.360
	375	1.2063.375	3.2063.375
	390	1.2063.390	3.2063.390
	405	1.2063.405	3.2063.405
9	240	1.2064.240	3.2064.240
	255	1.2064.255	3.2064.255
	270	1.2064.270	3.2064.270
	285	1.2064.285	3.2064.285
	300	1.2064.300	3.2064.300
	315	1.2064.315	3.2064.315
	330	1.2064.330	3.2064.330
	345	1.2064.345	3.2064.345
	360	1.2064.360	3.2064.360
	375	1.2064.375	3.2064.375
	390	1.2064.390	3.2064.390
	405	1.2064.405	3.2064.405
10	240	1.2065.240	3.2065.240
	255	1.2065.255	3.2065.255
	270	1.2065.270	3.2065.270
	285	1.2065.285	3.2065.285
	300	1.2065.300	3.2065.300
	315	1.2065.315	3.2065.315
	330	1.2065.330	3.2065.330
	345	1.2065.345	3.2065.345
	360	1.2065.360	3.2065.360
	375	1.2065.375	3.2065.375
	390	1.2065.390	3.2065.390
	405	1.2065.405	3.2065.405
420	1.2065.420	3.2065.420	

IV. LOCKING ELEMENTS

Wkręt blokujący trzonowy Ø4,5
Proximal screw Ø4.5
Блокирующий проксимальный Ø4,5



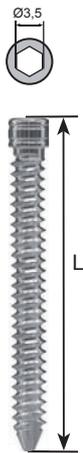
		Nr katalogowy, Catalogue no., Каталожный Но.	
L [mm]	L ₁ [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан
25	12	1.1653.025	3.1653.025
30	12	1.1653.030	3.1653.030
35	16	1.1653.035	3.1653.035
40	16	1.1653.040	3.1653.040
45	16	1.1653.045	3.1653.045
50	18	1.1653.050	3.1653.050
55	18	1.1653.055	3.1653.055
60	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

Wkręt blokujący Ø4,5
Distal screw Ø4.5
Блокирующий винт Ø4,5



		Nr katalogowy, Catalogue no., Каталожный Но.	
L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан	
16	1.1654.016	3.1654.016	
18	1.1654.018	3.1654.018	
20	1.1654.020	3.1654.020	
22	1.1654.022	3.1654.022	
24	1.1654.024	3.1654.024	
25	1.1654.025	3.1654.025	
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	
85	1.1654.085	3.1654.085	
90	1.1654.090	3.1654.090	
95	1.1654.095	3.1654.095	
100	1.1654.100	3.1654.100	

Wkręt blokujący Ø5,0
Distal screw Ø5.0
Блокирующий винт Ø5,0



		Nr katalogowy, Catalogue no., Каталожный Но.	
L [mm]	STAL, Steel, Сталь	TYTAN, Titanium, Титан	
16	1.1657.016	3.1657.016	
18	1.1657.018	3.1657.018	
20	1.1657.020	3.1657.020	
22	1.1657.022	3.1657.022	
24	1.1657.024	3.1657.024	
25	1.1657.025	3.1657.025	
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	
85	1.1657.085	3.1657.085	
90	1.1657.090	3.1657.090	
95	1.1657.095	3.1657.095	
100	1.1657.100	3.1657.100	

V. INSTRUMENT SET

Instrument set [40.5000] is used for tibia shaft fixation, and implant removal after finished treatment. All instruments are placed in a stand with a lid to enable sterilization and transport to the surgical suite.

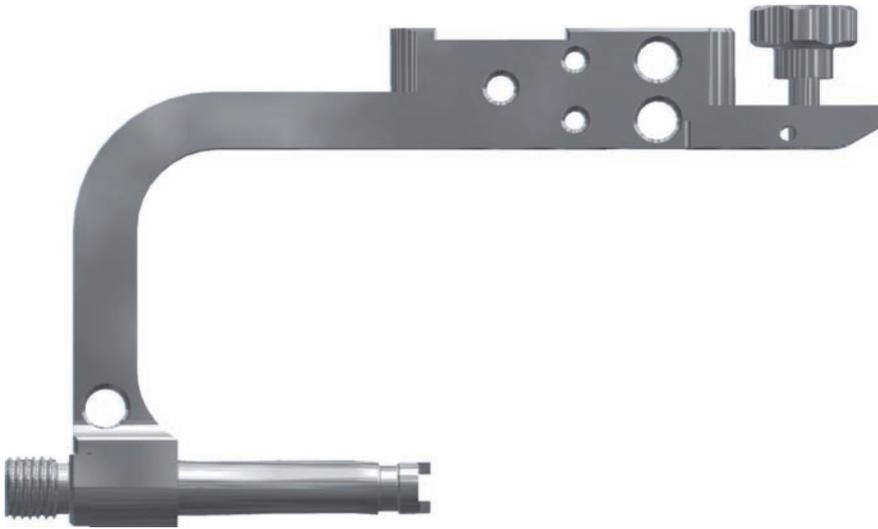
Instrument set consists of:

Lp.	Nr katalogowy Catalogue no. Каталожный №	Nazwa	Name	Название	Szt.
1	40.5001.100	Celownik B	Proximal tibia target B	Целенаправитель проксимальный большеберцовый	1
2	40.5002.000	Celownik D	Distal tibia target D	Целенаправитель дистальный большеберцовый	1
3	40.5003.000	Śruba łącząca M8	Connecting screw M8x1.25 spec.	Винт соединительный M8x1,25 спец.	1
4	40.5005.000	Drut prowadzący Ø2,5/500	Guide rod Ø2.5/500	Проволока направляющая Ø2,5/500	1
5	40.5009.000	Celownik rekonstrukcyjny piszczelowy	Tibial reconstruction target	Целенаправитель реконстр. для большеберцовой к.	1
6	40.5065.000	Wkładka celująca Ø9,0	Insertion target Ø9.0	Целенаправительный вкладыш Ø9,0	4
7	40.1344.000	Celownik D	Target D	Целенаправитель дистальный	1
8	40.1351.000	Uchwyt drutu prowadzącego	Handle guide rod	Держатель направляющей проволоки	1
9	40.1354.000	Trokar Ø7,0	Trocar short Ø7.0	Троакар короткий Ø7,0	1
10	40.1358.000	Prowadnica wiertła krótka Ø7/Ø3,5	Drill guide short Ø7/Ø3,5	Направитель сверла короткий Ø7] Ø3,5	1
11	40.1361.000	Klucz nasadowy S 11	Socket wrench S 11	Ключ торцовый S11	1
12	40.1364.000	Wiertło Ø3,5/150	Drill Ø3,5/150mm	Сверло Ø3,5/150	1
13	40.1374.000	Wzorzec długości wkrętów	Screw length measure	Измеритель длины винтов	1
14	40.5330.000	Wiertło ze skalą Ø3,5/250	Drill with scale Ø3,5/250	Сверло с измерительной шкалой Ø3,5/250	2
15	40.1387.000	Wiertło Ø4,5/250	Drill Ø4,5/250	Сверло Ø4,5/250	1
16	40.3614.000	Prowadnica ochronna Ø9/Ø6,5	Protective guide Ø9/Ø6,5	Направитель-протектор Ø9] Ø6,5	2
17	40.3615.000	Prowadnica wiertła Ø6,5/Ø3,5	Drill guide Ø6,5/Ø3,5	Направитель сверла Ø6,5/Ø3,5	2
18	40.3616.000	Ustawiak Ø9/Ø4,5	Set block Ø9/Ø4.5	Инструмент установочный Ø9/Ø4,5	2
19	40.3617.000	Trokar Ø6,5	Trocar Ø6,5	Троакар Ø6,5	1
20	40.3619.000	Śrubokręt sześciokątny S 3,5	Hexagonal Screwdriver 3.5	Отвертка S 3,5	1
21	40.3665.000	Wbijak - wybijak	Impactor-extractor	Импактор-экстрактор	1
22	40.3667.000	Pobijak	Mallet	Пробойник	1
23	40.3669.000	Łącznik M8/M16	Connector M8/M16	Соединитель M8/M16	1
24	40.3696.000	Prowadnica wiertła Ø6,5/Ø4,5	Drill guide Ø6,5/Ø4,5	Направитель сверла Ø6,5/Ø4,5	1
25	40.3700.000	Prowadnica rurkowa Ø8/400	Teflon pipe guide Ø8/400	Трубка-направитель Ø8/400	1
26	40.4799.000	Miarka długości gwoździ	Nail length measure	Измеритель длины стержня	1
27	40.4491.000	Statyw	Stand	Подставка	1

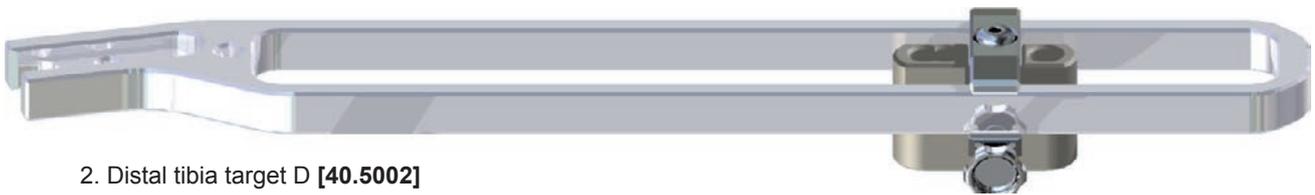
40.5000.100

To carry out the surgery some other basic devices are needed:

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



1. Proximal tibia target B [40.5001.100]



2. Distal tibia target D [40.5002]



3. Connecting screw M8x1.25 spec. [40.5003]

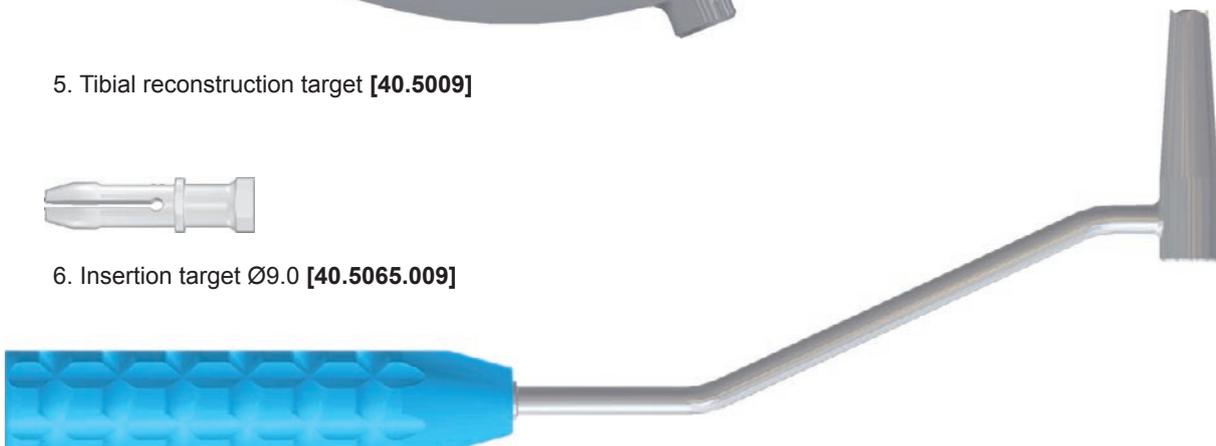
4. Guide rod $\text{Ø}2.5/500$ [40.5005]



5. Tibial reconstruction target [40.5009]



6. Insertion target $\text{Ø}9.0$ [40.5065.009]



7. Target D [40.1344]



8. Handle guide rod [40.1351]



9. Trocar short Ø7.0 [40.1354]



10. Drill guide short Ø7/Ø3.5 [40.1358]



11. Socket wrench S 11 [40.1361]



12. Drill Ø3.5/150mm [40.1364]



13. Screw length measure [40.1374]



14. the Dril With Scale Ø3.5/250 [40.5330]



15. Drill Ø4.5/250 [40.1387]



16. Protective guide Ø9/Ø6.5 [40.3614]



17. Drill guide Ø6.5/Ø3.5 [40.3615]



18. Set block Ø9/Ø4.5 [40.3616]



19. Trocar Ø6,5 [40.3617]



20. Hexagonal Screwdriver 3.5 [40.3619]



21. Impactor-extractor [40.3665]



22. Mallet [40.3667]



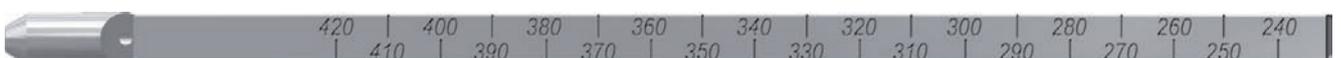
23. Connector M8/M16 [40.3669]



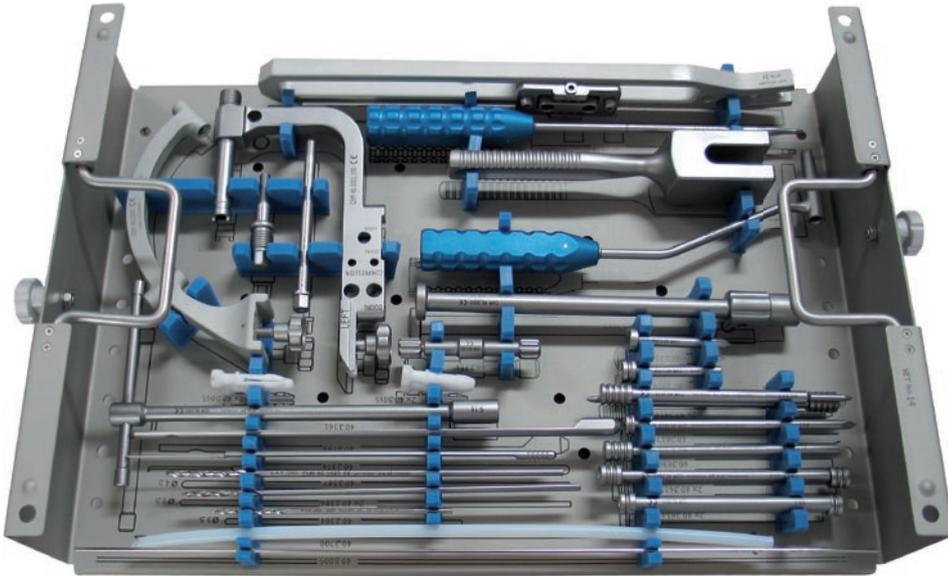
24. Drill guide Ø6.5/Ø4.5 [40.3696]



25. Teflon pipe guide Ø8/400 [40.3700]



26. Nail length measure [40.4799]



27. Stand [40.4491]

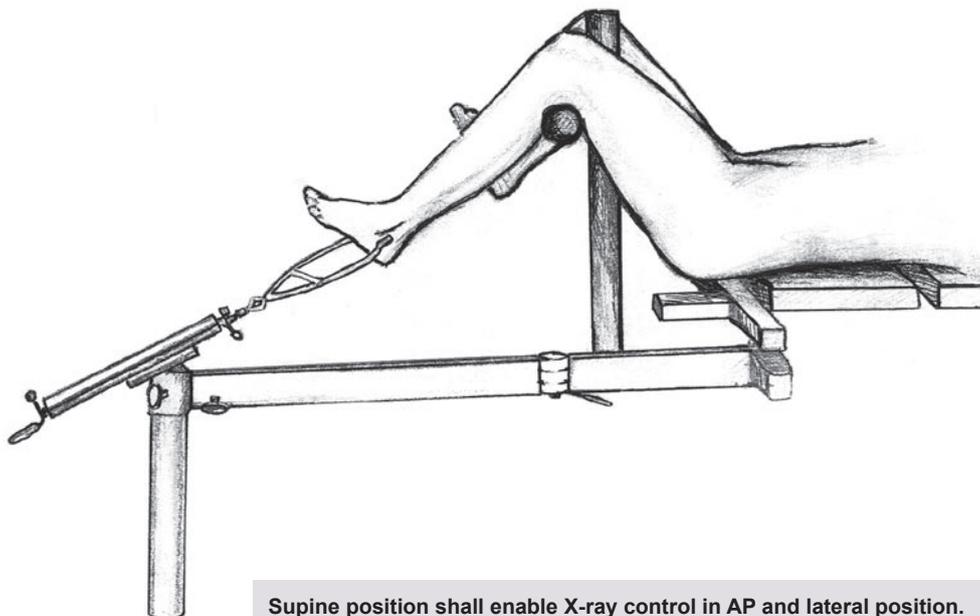
VI. SURGICAL TECHNIQUE

VI.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 a hip at an angle of 70-90°, inclined 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).



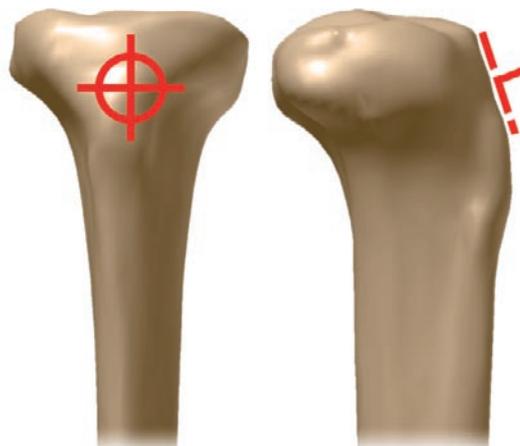
Surgical approach should be prepared by:

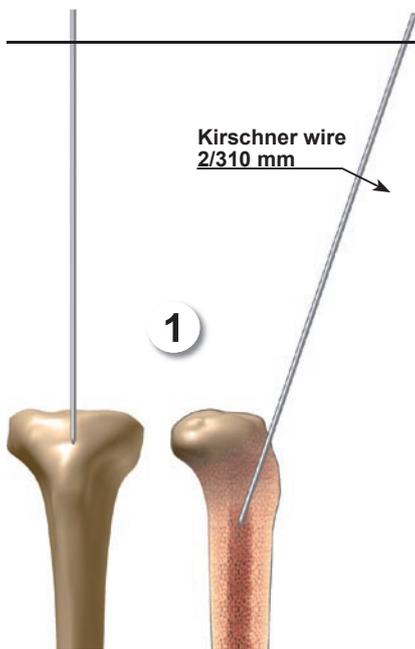
- longitudinal skin incision from the lower pole of patella to the point placed medially from tuberosity of tibia,
- longitudinal incision along medial edge of patella tendon and its aside move.

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.

After opening the medullary canal, gradual reaming should be performed. Intramedullary canal should be 1.5-2.0 mm wider than the diameter of tibia nail.

In case of reamed canal, the intramedullary canal should be wider 1.5-2 mm than the diameter of the nail. The proximal part of the canal shall be widened in depth of 5 cm for width diameter 11 mm.





VI.2. Opening the medullary canal

1 After preparing the surgical approach and locating insertion point for the nail (description: chapter IV.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).

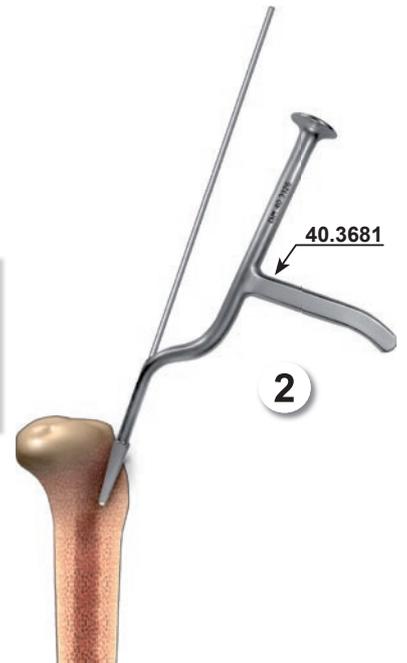
 The process should be controlled with image intensifier.

Kirschner wire acts as the guide for the cannulated awl.
Kirschner wire is single use instrument.

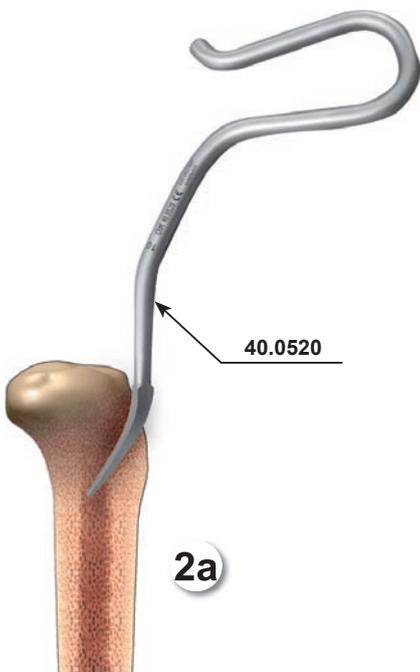
2 Open the intramedullary canal using the Cannulated Awl [40.3681] (not included in the Instrument set).

Remove the awl and Kirchner wire.

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



2a Widen the opened canal using the Curved Awl [40.0520] (not included in the Instrument set) to enable nail insertion.



VI.3. Preparation of intramedullary canal for nail insertion

Option I: Reamed canal

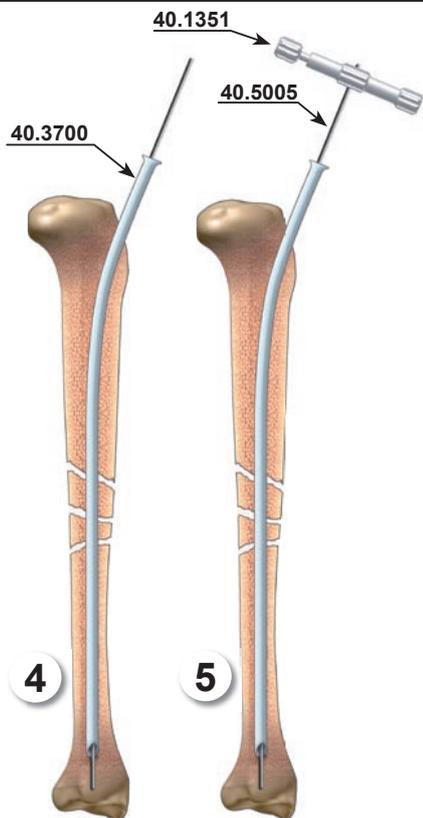
3 Insert the guide of the flexible reamer into the intramedullary canal (not included in the Instrument set) until its tip reaches the distal epiphysis of tibia, reducing the fracture at the same time.

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, for the depth at least equal to the nail length.

In case of using the nail Ø9 mm or smaller diameter, widen proximal part of intramedullary canal with reamer to the 11 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** Insert the Teflon Pipe Guide Ø8/400 [40.3700] via the flexible reamer guide into the intramedullary canal.

Remove the Flexible Reamer Guide.

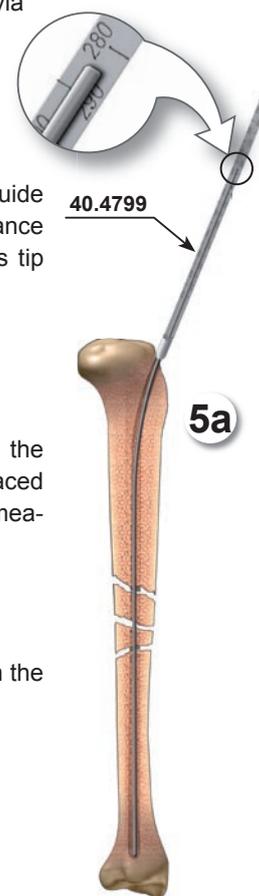
- 5** Mount the Handle Guide Rod [40.1351] on the Guide Rod (for cannulated nail) [40.5005] and advance into the Teflon Pipe Guide Ø8/400 [40.3700] until its tip reaches the distal epiphysis of tibia.

Remove the Handle Guide Rod.
Remove the Teflon Pipe Guide Ø8/400.

- 5a** Insert the Nail Length Measure [40.4799] via the guide rod. The tip of the measure should be placed in the demanded depth. Read the nail length on the measure.

Remove the measure from the guide rod.

In case of using solid nail, remove the guide rod from the intramedullary canal.



Option II: Unreamed canal

- 3** Mount the Handle Guide Rod [40.1351] on the Guide Rod [40.5005] and advance into intramedullary canal until its tip reaches the distal epiphysis of tibia, reducing the fracture at the same time.

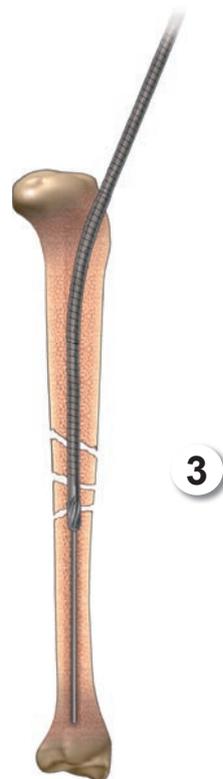
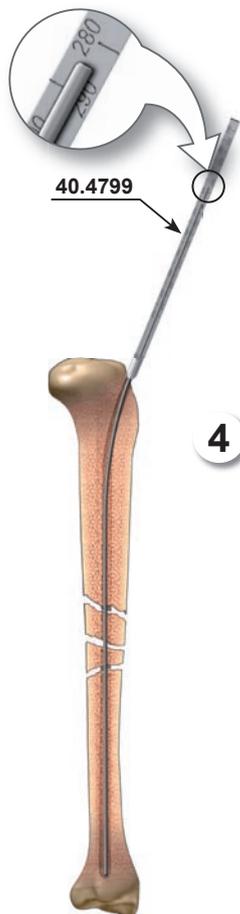
Remove the Handle Guide Rod from the Guide Rod.

Widen the proximal part of the intramedullary canal with flexible reamers on depth approx. 5 cm. In case of using the nail Ø9 mm or smaller diameter, widen proximal part of medullary canal to the 11 mm diameter; for nail Ø10 mm or larger – the diameter 1,5 to 2 mm wider then the diameter of the nail.

Remove the Flexible Reamer.
Leave the Guide Rod in medullary canal.

- 4** Insert the Nail Length Measure [40.4799] via the guide rod. The tip of the measuring gauge should be placed in demanded depth of nail insertion. Read the length of the nail on the measure. Remove the measure from the guide rod.

In case of solid nail, remove the guide rod from the medullary canal.
The medullary canal has been prepared for the nail insertion.



VI.4. Nail insertion



Note:
 The way of mounting the Proximal Tibia Target B [40.5001] with the Distal Tibia Target D [40.5002] and the position of the slider in distal part depends on the operated limb (left or right).
 It is recommended to place the target in such a 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 Tibia Target D should be inserted into socket of Proximal Tibia Target B from the right side and mounted using nut.
- the slider of Distal Tibia Target D in distal part should be arranged in such a way, that its adjusting and mounting elements are placed on the left side.

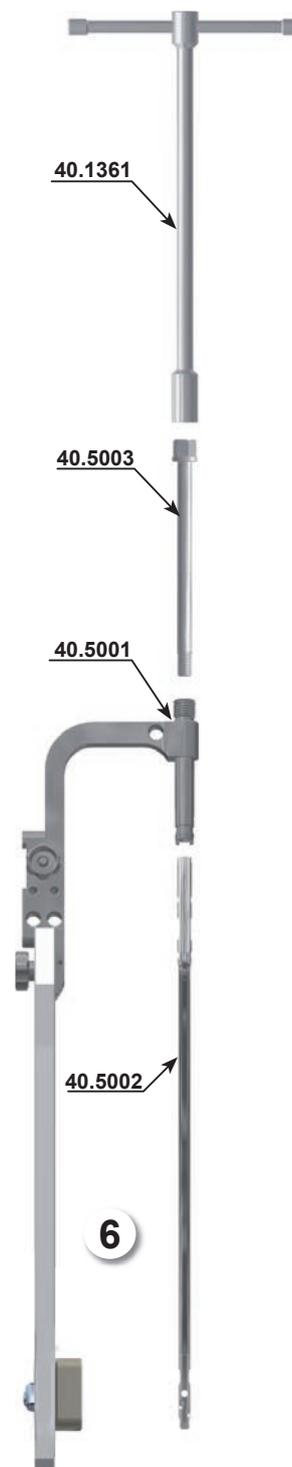
Left leg:

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

- 6 Using the Socket Wrench S 11 [40.1361] fix the intramedullary nail to the Proximal Tibia Target B [40.5001] with the Connecting Screw M8x1.25 spec [40.5003].



IMPORTANT!
 The accordance in direction of deflection of nail distal part and the distal tibia target D [40.5002] proves the mounting correctness.



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

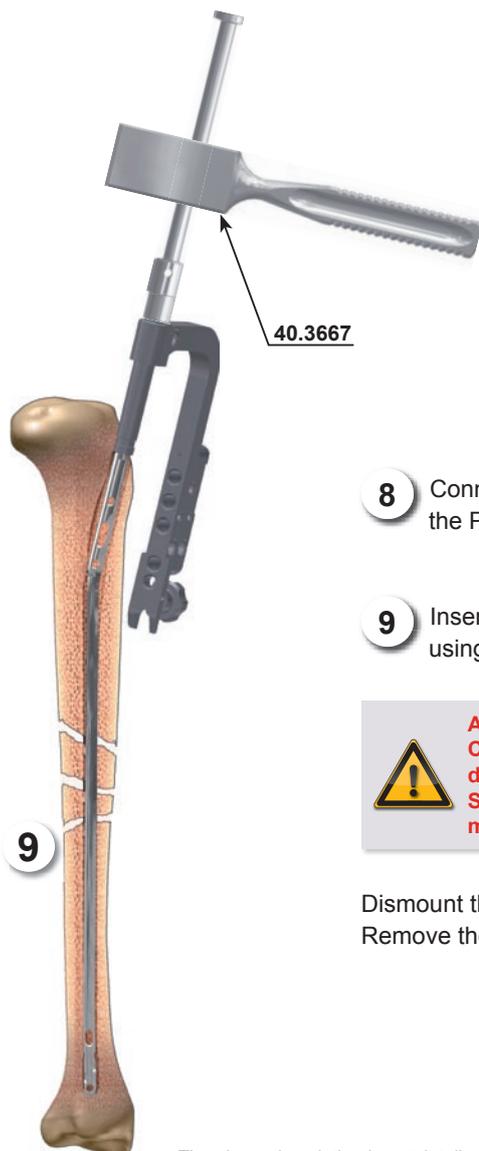
- 7** Setting of the Distal Tibia Target D [40.5002] to the nail. Using The Hexagonal Screwdriver 3.5 [40.3619] adjust the sliding element of target in the middle of the slider plate. With a pair of the Set Blocks Ø9/Ø4.5 [40.3616] place the slider of distal target in line with distal locking holes of intramedullary nail. Secure the slider of the distal target with two screws 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 the set blocks from the target.

Dismount the Distal Tibia Target D [40.5002] from the Proximal Tibia Target B [40.5001].



- 8** Connect the Impactor-Extractor [40.3665] with the Proximal Tibia Target B [40.5001].
- 9** Insert the nail into medullary canal at appropriate depth using the Mallet [40.3667].



Attention!

Cannulated nail should be inserted into the intramedullary canal via the Guide Rod [40.5005]. Solid nail should be inserted directly into the intramedullary canal (without use of guide rod).

Dismount the Impactor – Extractor [40.3665] from the guide. Remove the guide rod (when using cannulated nail).



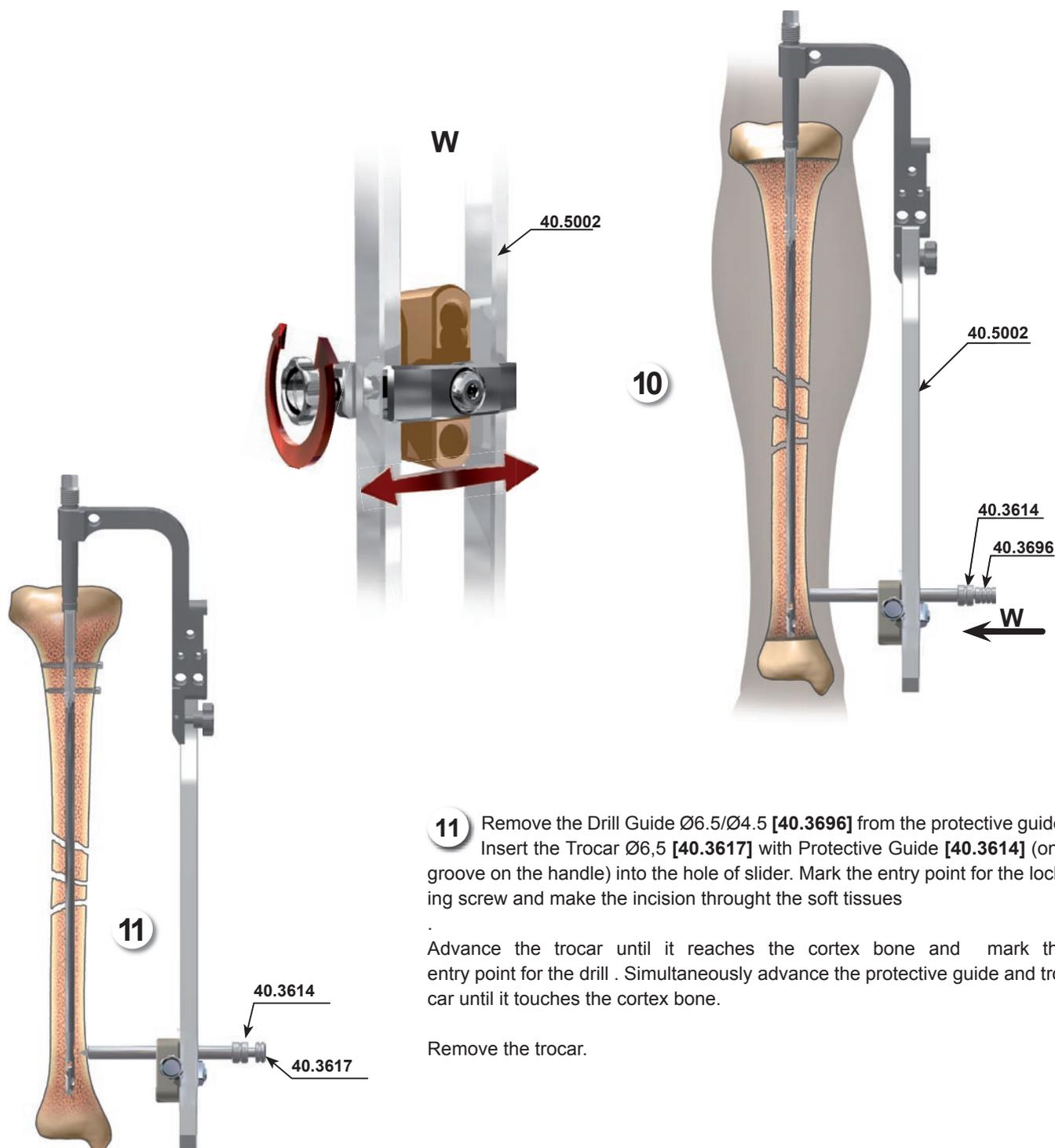
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

VI.5. Distal locking of intramedullary nail.

OPTION I: With image intensifier control

- 10** Verify the position of holes in the target slider and in the distal part of the nail using image intensifier.
- Mount the Distal Tibia Target D [40.5002] onto the proximal tibia target B.
 - Place image intensifier in such a way, that the image on display shows round shaped holes (proximal or distal) in the nail.
 - Insert the Protective Guide Ø9/Ø6.5 [40.3614] and the Drill Guide Ø6.5/Ø4.5 [40.3696] into appropriate hole of the target slider until the tip should rest on soft tissue of lower limb.
 - 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 target should be corrected in case when shape on the display is different from circle. Then using the the Hexagonal Screwdriver 3.5 [40.3619], shift target slider (by turning the screw to the left or to the right) to the position when circle shape will be shown on the display (shape similar to circle is accepted).

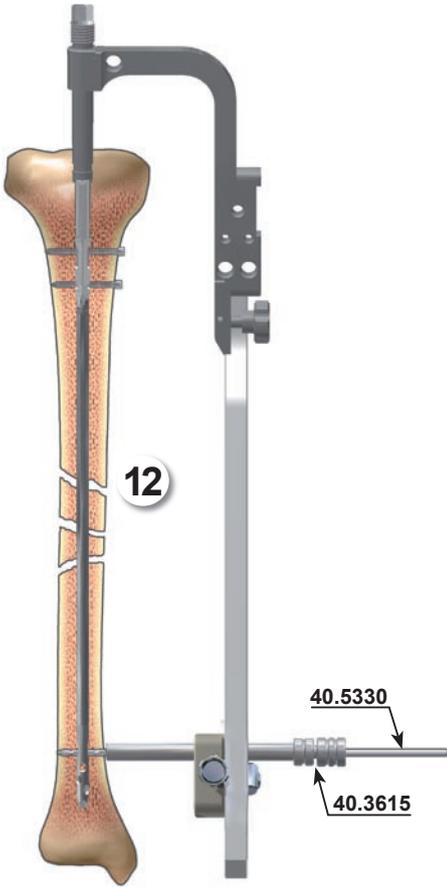


- 11** Remove the Drill Guide Ø6.5/Ø4.5 [40.3696] from the protective guide. Insert the Trocar Ø6,5 [40.3617] with Protective Guide [40.3614] (one groove on the handle) into the hole of slider. Mark the entry point for the locking screw and make the incision through the soft tissues

Advance the trocar until it reaches the cortex bone and mark the entry point for the drill . Simultaneously advance the protective guide and trocar 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.

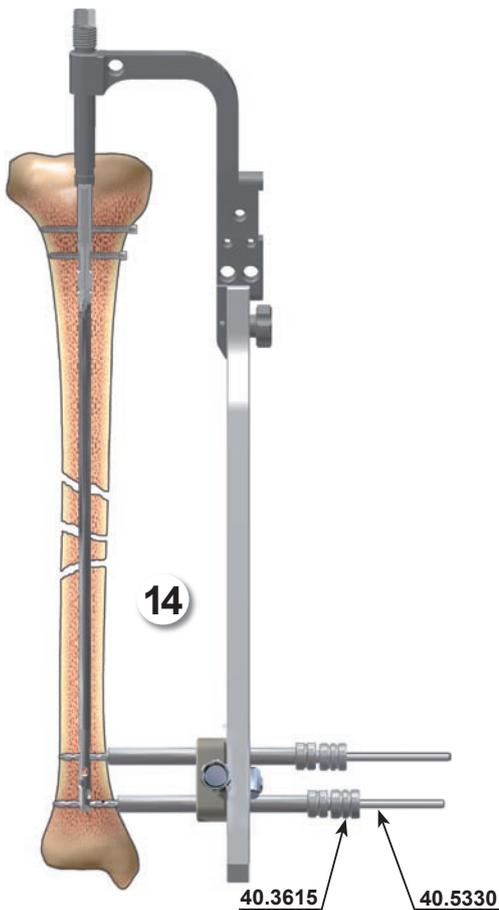


12 Insert the Drill Guide Ø6.5/Ø3.5 [40.3615] (with two grooves) into the protective guide left in the slider hole. Mount the Drill With Scale Ø3.5/250 [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia through both cortex layers and the nail hole. The scale on the drill shows the length locking element.



The drilling process should be controlled with image intensifier.

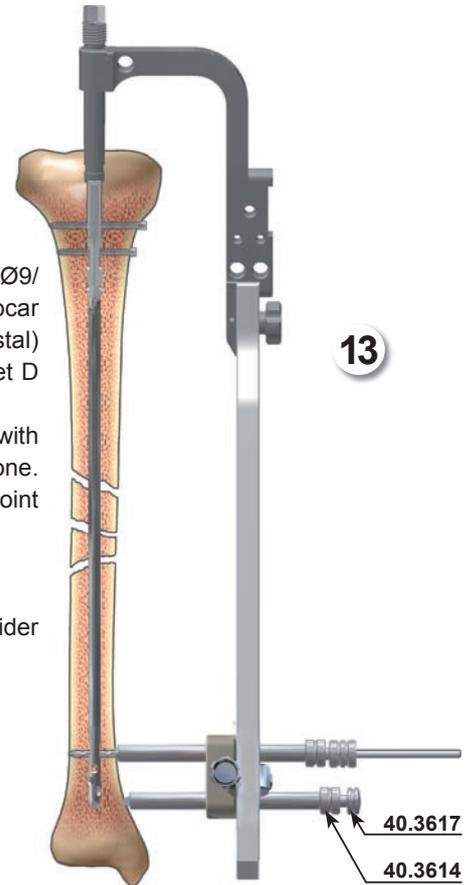
Dismount the Surgical Drive.
Leave the Drill in the reamed hole.



13 Insert the Protective Guide Ø9/Ø6.5 [40.3614] with the Trocar Ø6,5 [40.3617] into the second (distal) slider hole of the Distal Tibia Target D [40.5002].

Advance the protective guide with trocar until it reaches the cortex bone. Using the trocar mark the entry point for insertion the locking screw.

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



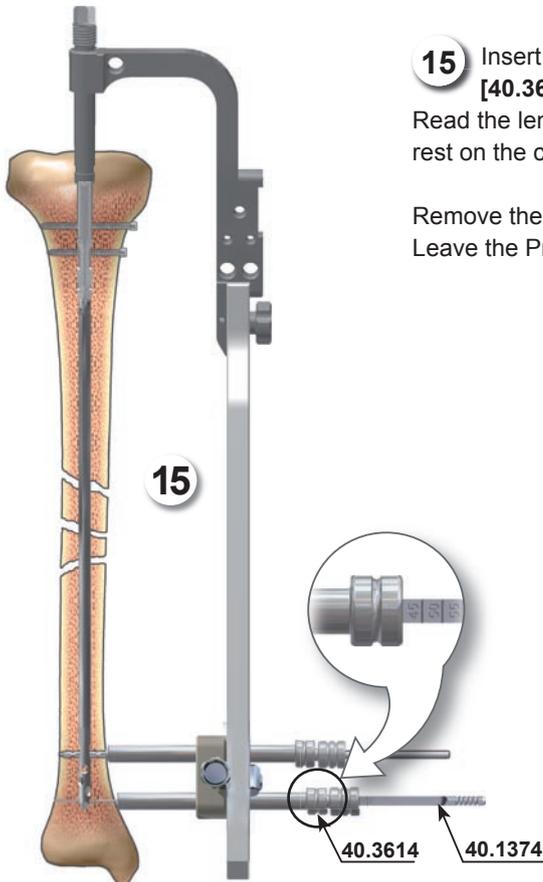
14 Insert the the Drill Guide Ø6.5/Ø3.5 [40.3615] into the Protective Guide Ø9/Ø6.5 [40.3614]. Mount the Drill With Scale Ø3.5/250 [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia through both cortex layers and the nail hole.



The drilling process should be controlled with image intensifier.

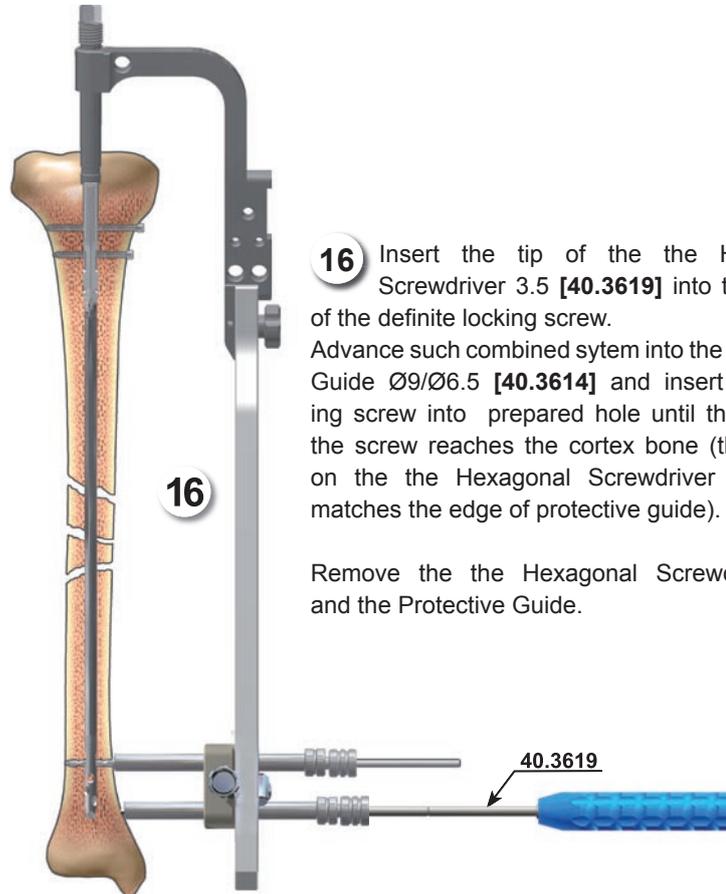
Remove the Drill and Drill Guide.
Leave the Protective Guide in the slider.

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



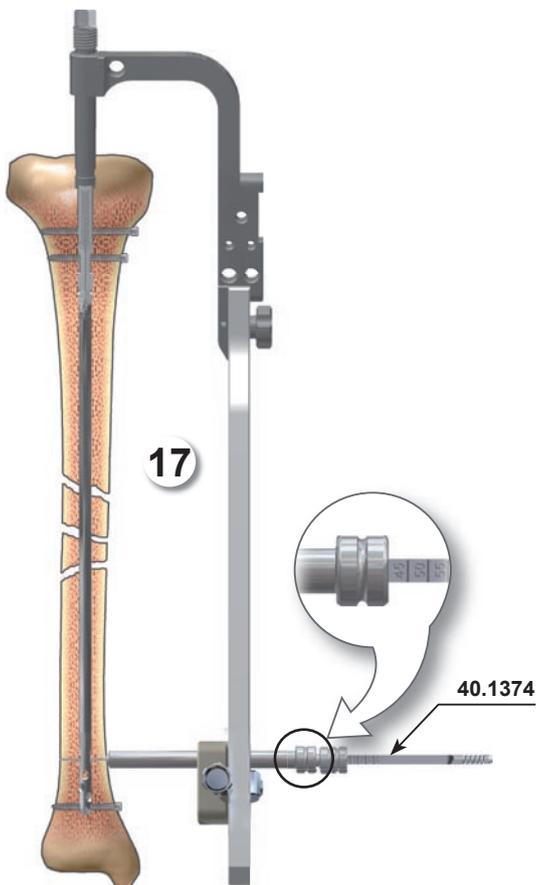
15 Insert the Screw Length Measure [40.1374] through the Protective Guide Ø9/Ø6.5 [40.3614] into the drilled hole until its hook reaches the „exit” plain of the hole. Read the length of the locking screw on the B-D scale. The tip of the protective guide should rest on the cortex during the measurement.

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



16 Insert the tip of the the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the definite locking screw. Advance such combined system into the Protective Guide Ø9/Ø6.5 [40.3614] and insert the locking screw into prepared hole until the head of the screw reaches the cortex bone (the groove on the the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

Remove the the Hexagonal Screwdriver 3.5 and the Protective Guide.



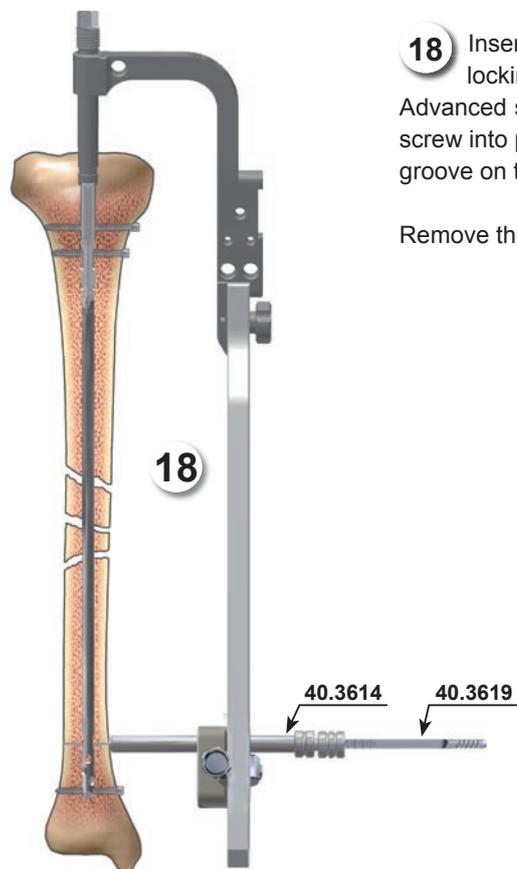
17 Remove the Drill With Scale Ø3.5/250 [40.5330] and the the Drill Guide Ø6.5/Ø3.5 [40.3615] from the proximal hole of slider. Leave the Protective Guide [40.3614] in the slider hole. Insert the Screw Length Measure [40.1374] through the protective guide [40.3614] into the drilled hole until its hook reaches “exit” 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 the Hexagonal Screwdriver 3.5 [40.3619] into socket of the definite locking screw.

Advanced 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 the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

Remove the the Hexagonal Screwdriver 3.5 and the Protective Guide.

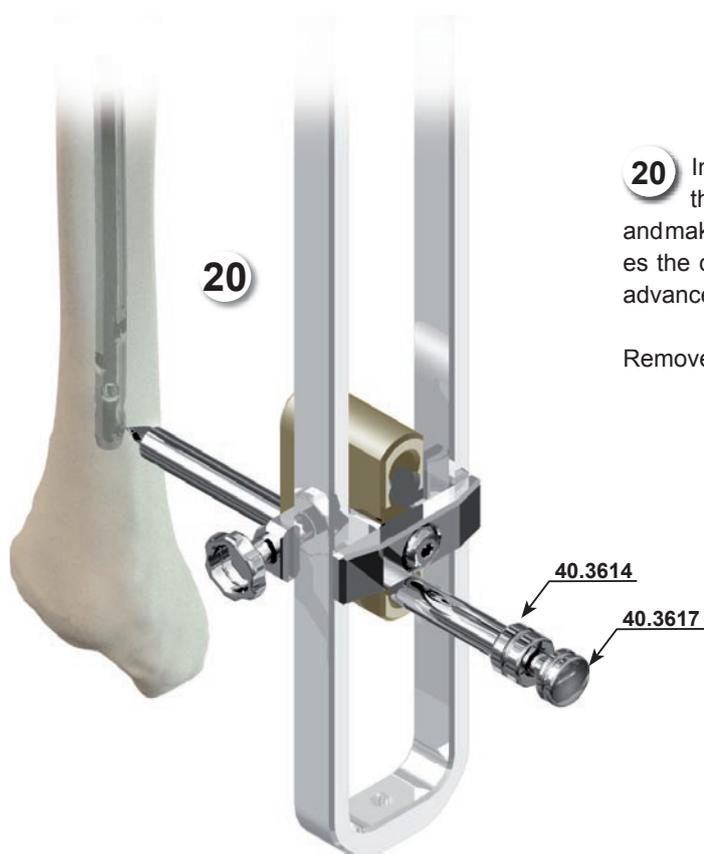
OPTION II: Whitout x-ray control

a) setting nail holes by adjusting position of target D slider

- 19** Mount the Distal Tibia Target D [40.5002] onto the proximal tibia target B



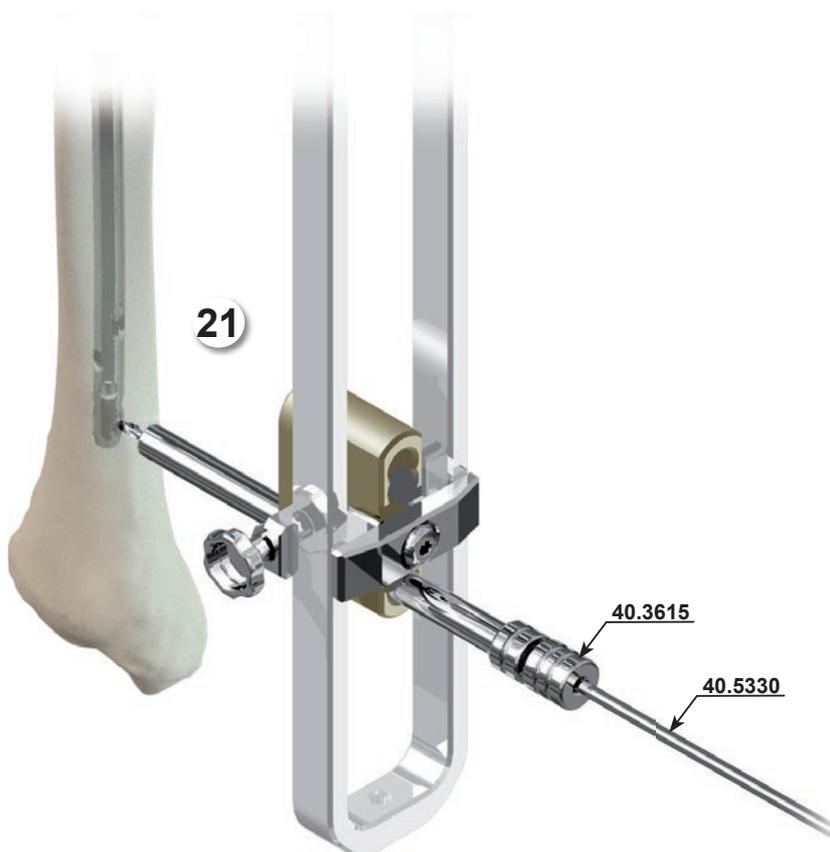
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.



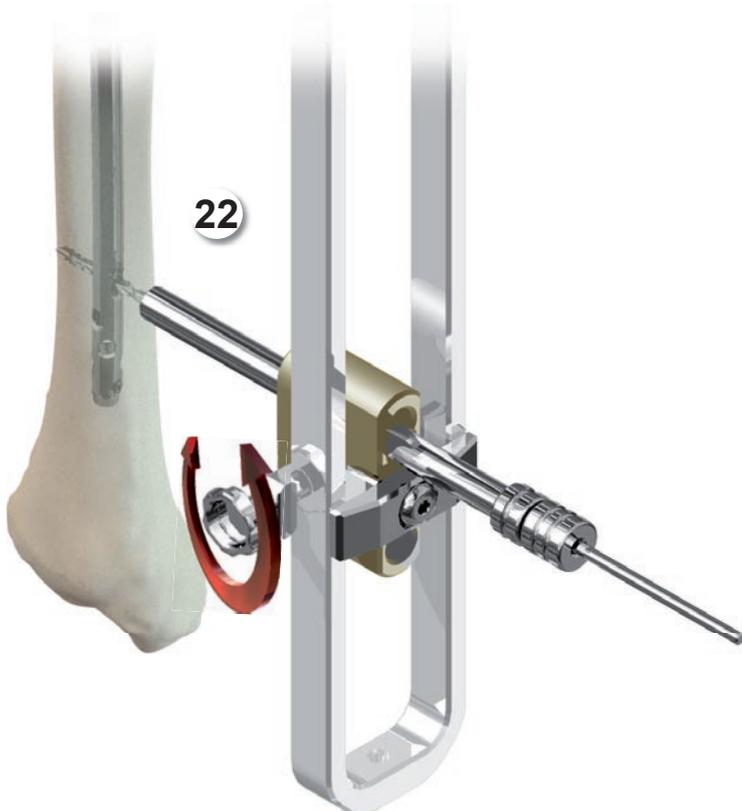
20 Insert the Trocar **[40.3617]** with the Protective Guide **[40.3614]** into the slider hole (preferred distal one). Mark on the skin the entry point and make the incision through the soft tissues. Advance the trocar until it reaches the cortex bone and mark the entry point for the drill. Simultaneously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

Remove the Trocar.

21 Insert the Drill Guide Ø3,5mm **[40.3615]** into the protective guide left the slider hole. The end of the drill guide should rest on the soft tissues. Mount the Drill Ø3,5/250 **[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** If the drill passes through the first corical layer but does not pass the nail hole:
- remove the drill to enable movements of the slider,
 - make one turn of the slider knob in the desired direction.
 - into the second hole of the Distal Tibia Target D [40.5002] insert the Protective Guide [40.3614] with the Trocar [40.3617] and advance until the protective guide rests on the cortex bone. Mark the entry point for the drill using the trocar.

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

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

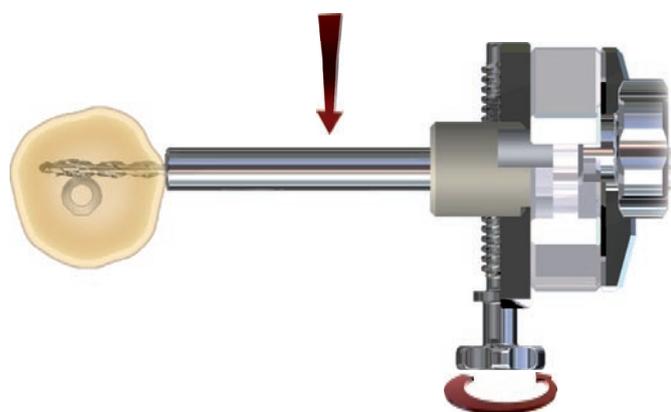
- 23** Correct placement of the drill can be controlled by the guide rod which is led through the connecting screw and oval shaped hole. The drill placed in the nail hole is a resistance to the guide rod.



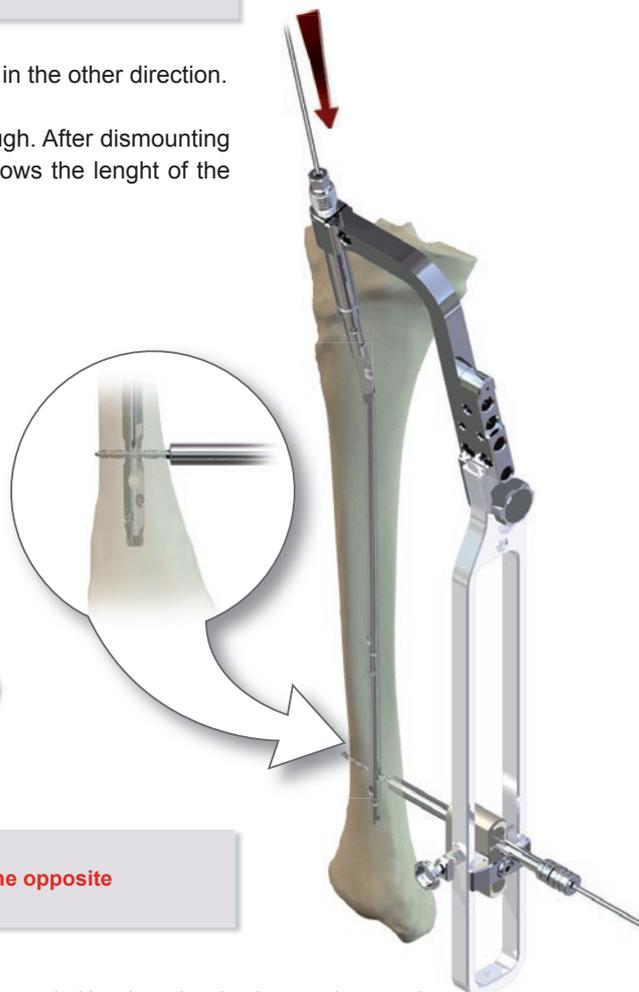
If one of the hole (distal or proximal) is located, locating another hole is not necessary.

If the drill does not pass the nail hole, locating the hole should be done in the other direction.

If the drill passes the hole, the other 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.

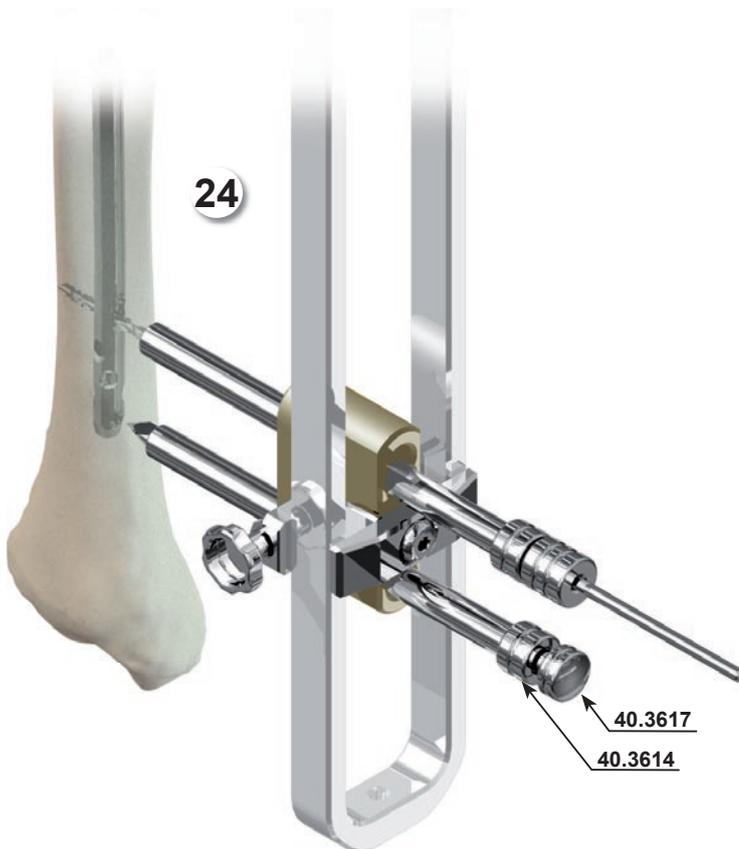


23



NOTE: Clockwise turn of the knob 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 Tibia Target D [40.5002]. Advance the protective guide with trocar until it reaches the cortex bone. Use the trocar to mark the entry point to insert the drill.

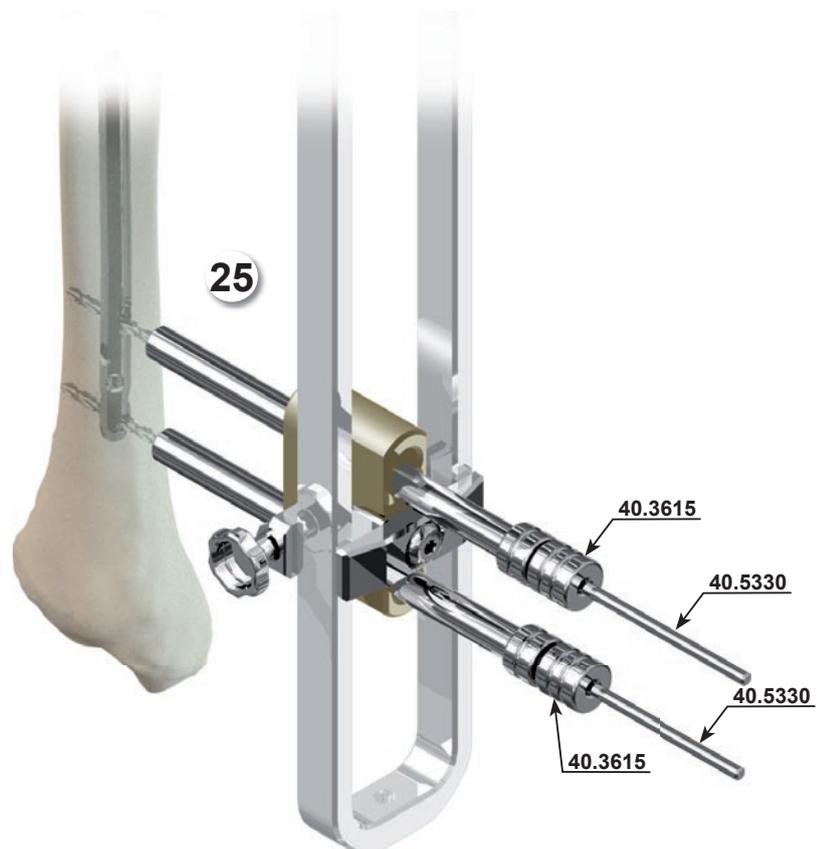
Remove the Trocar.
Leave the Protective Guide in the slider hole.

25 Insert the Drill Guide Ø3.5 [40.3615] into the Protective Guide [40.3614]. Mount the Drill With Scale Ø3.5/250 [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia through first cortex layer and the nail hole.

Verify if the drill is located in the hole using the rod. 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 shows the length of the locking elements.

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

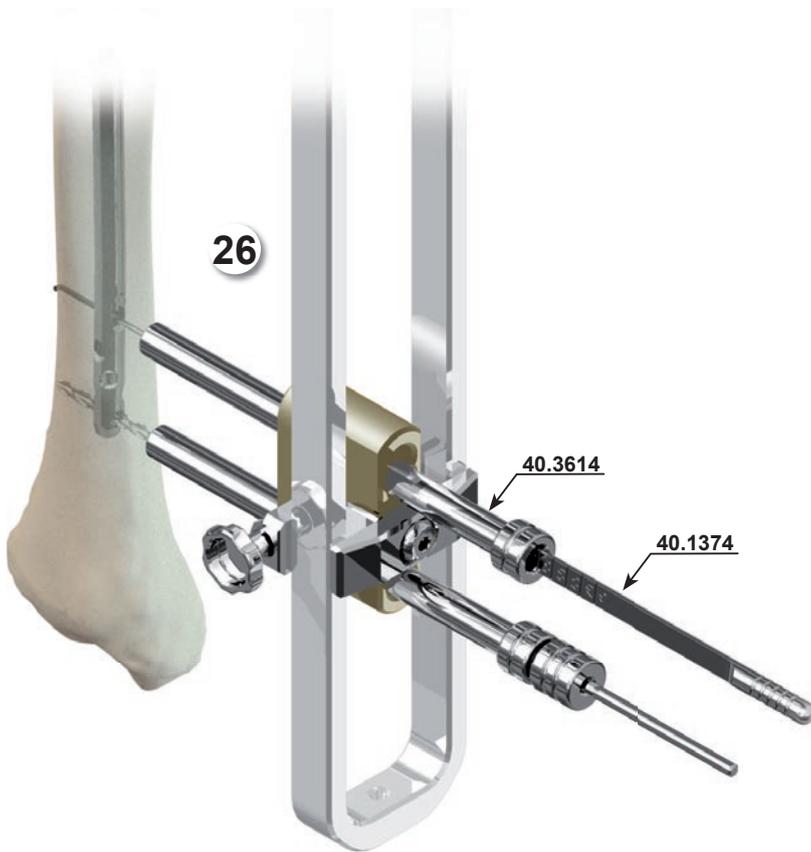


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

- 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.

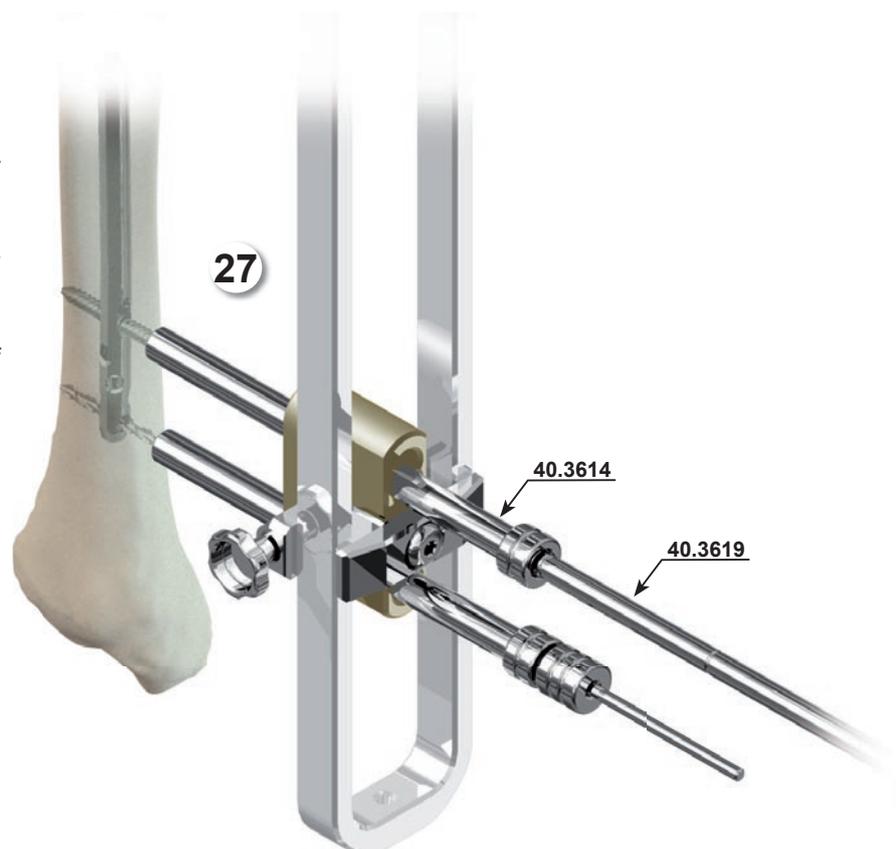
The tip of the protective guide should rest on the cortex during the measurement.

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

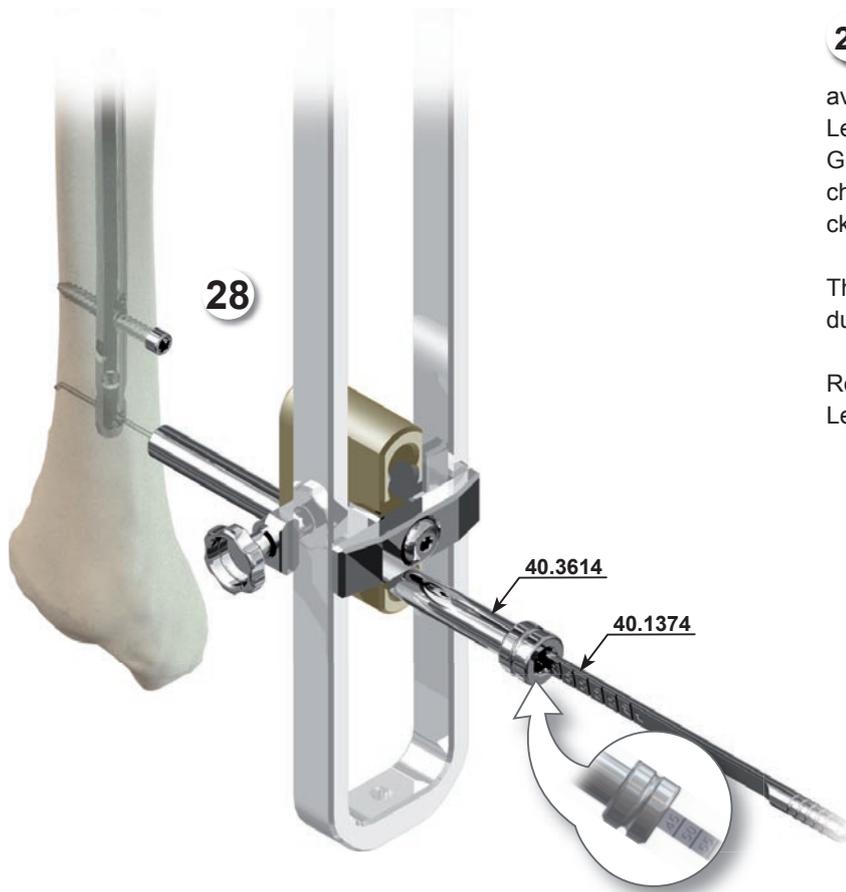


- 27** Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into socket of the definite locking screw. Then insert such combined system into the Protective Guide [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (the groove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



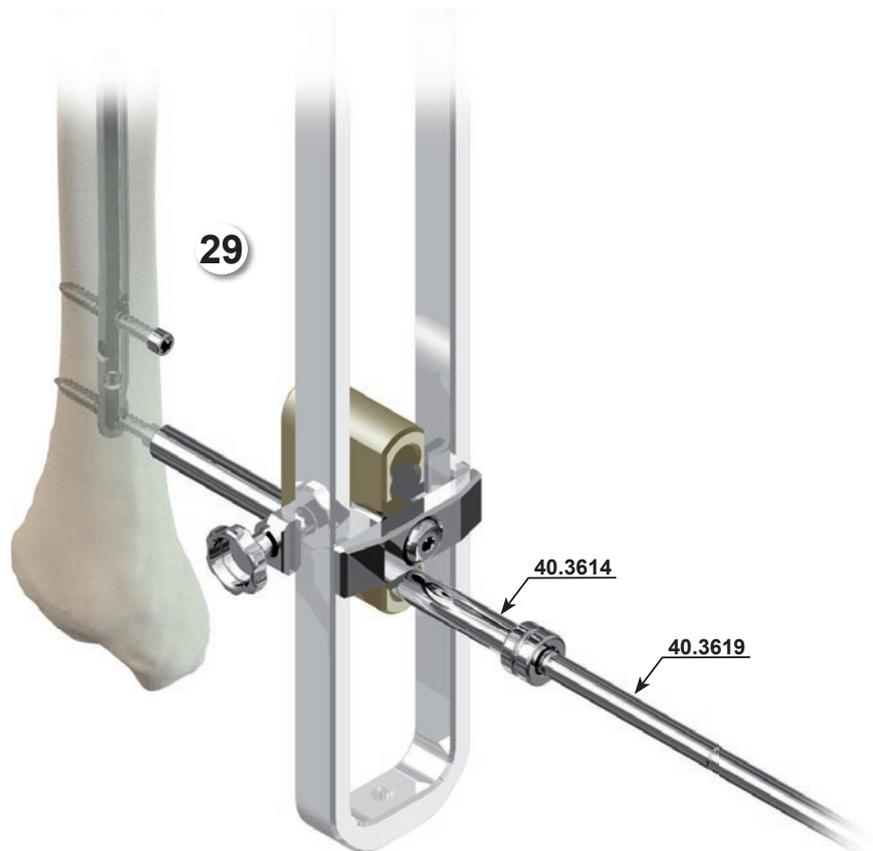
28 Remove the Drill With Scale [40.5330] and the Drill Guide [40.3615] from the slider hole but leave the Protective Guide [40.3614]. Insert the Screw Length Measure [40.1374] through the Protective Guide [40.3614] into the drilled hole until its hook reaches the „exit” plane of the hole. Read the length of 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 socket of the definite locking screw. Then insert 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 shaft 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.

b) setting nail holes using Kirschner wire, and setting position of target D slider

30 Mount the Distal Tibia Target D [40.5002] onto the proximal target B.



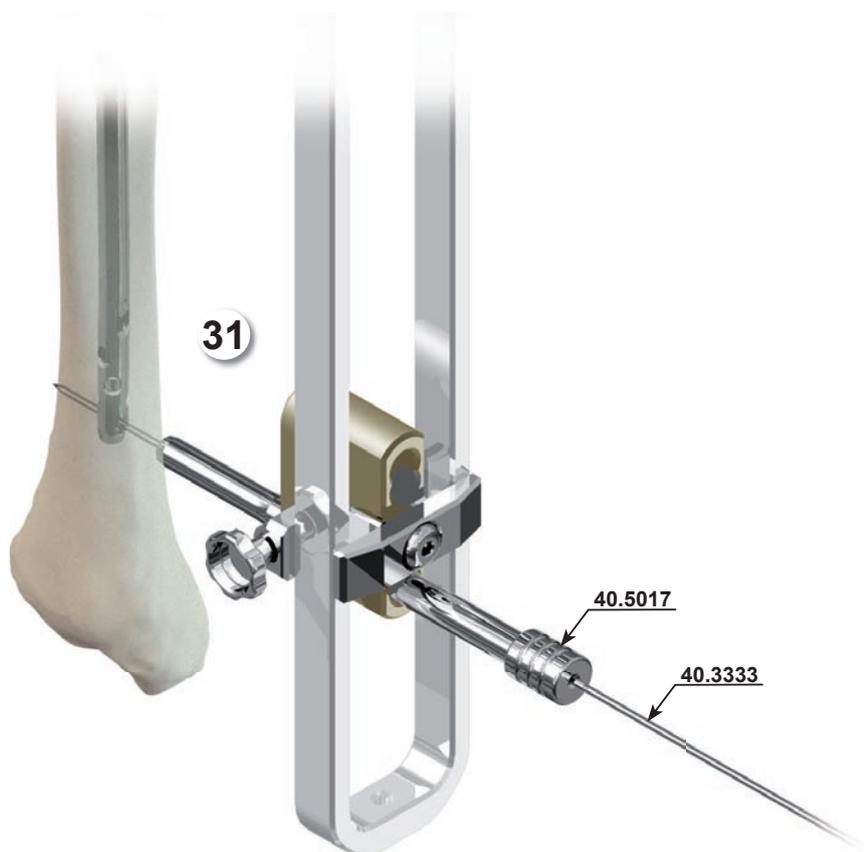
31 Insert the Guide 9/2,0 [40.5017] for Kirschner wire into one slider hole .

Mount Kirschner 2.0/380 [40.0333] wire on the surgical drive and advance it into the Guide 9/2,0 [40.5017] and drill through both cortex layers.

The tip of the Guide 9/2,0 [40.5017] should be thicken to the skin during Kirschner wire insertion.

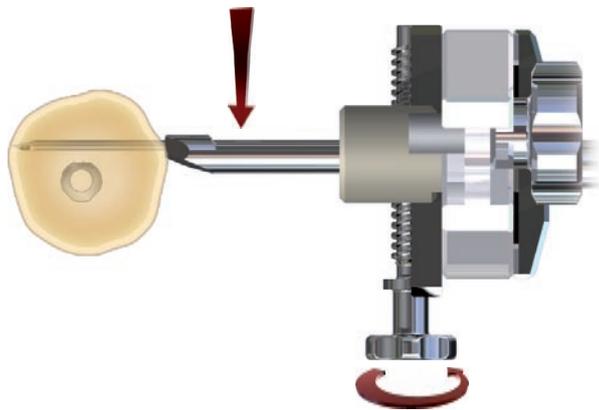
Dismount the surgical drive but leave Kirschner wire in the hole.

Leave Kirschner wire in the hole.

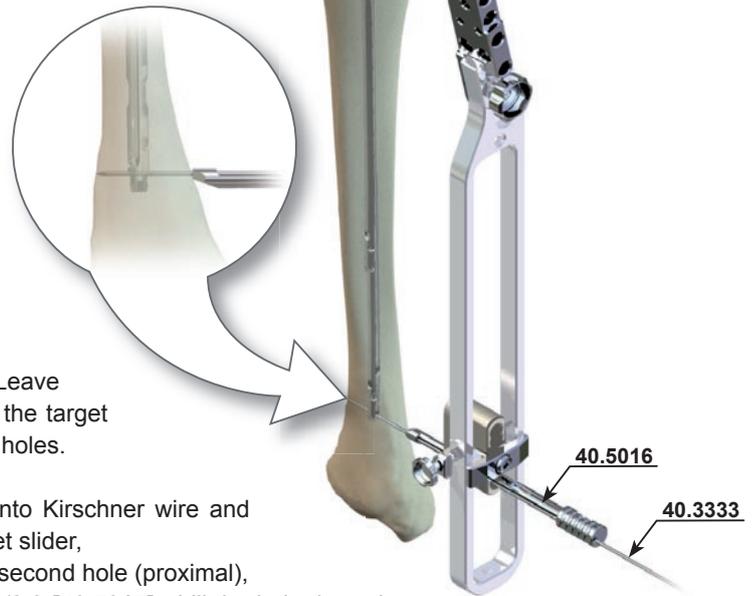


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

- 32** Verify if Kirschner wire is located in the hole using the Guide Rod [40.5005]. The tip of the guide rod should rest on Kirschner wire.

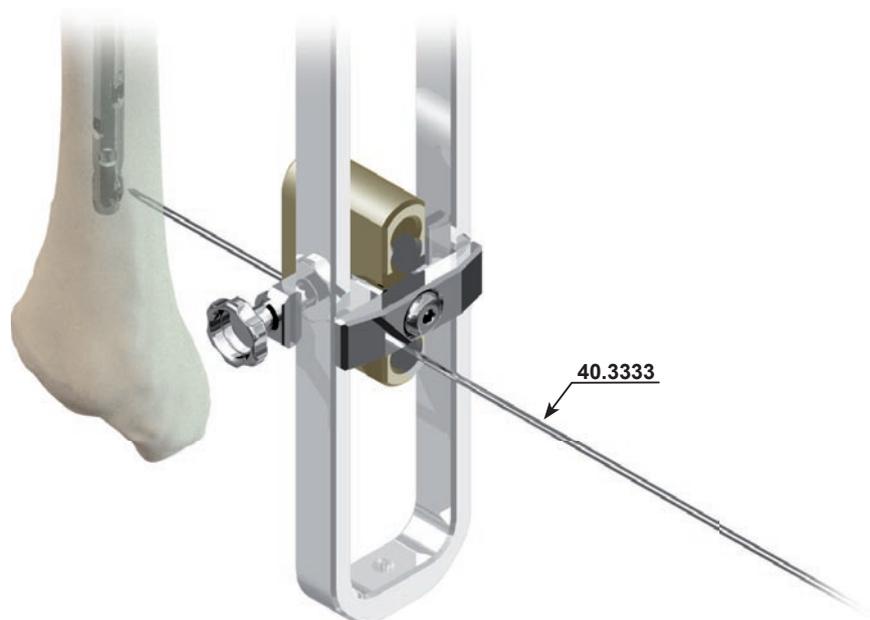


32

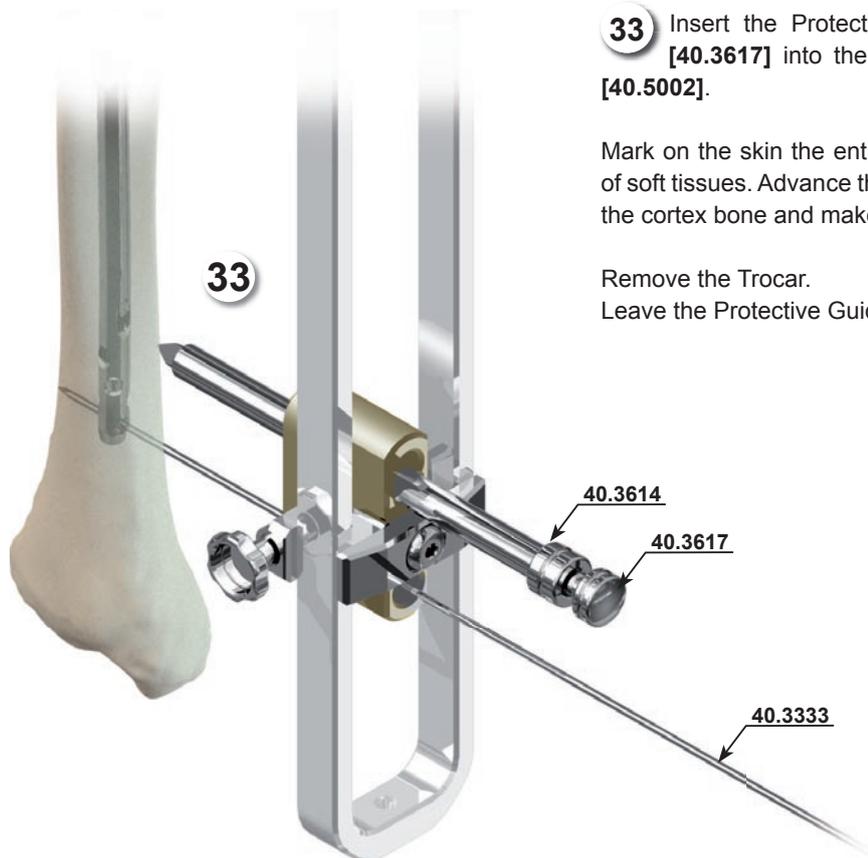


If Kirschner passes through the first corical layer of the bone but do not pass through the nail hole:

- remove the Guide 9/2.0 [40.5017] from the slider hole. Leave Kirschner wire 2.0/380 [40.3333]. It enables movements of the target slider in the perpendicular plane to the axis of main locking holes.
- make one turn of the slider knob in the desired direction.
- in the new slider position, insert the Sleeve [40.5016] onto Kirschner wire and advancing via Kirschner wire insert the sleeve into the target slider,
- insert the guide 9/2.0 [40.5017] for Kirschner wire into the second hole (proximal),
- inserting Kirschner wire 2.0/380 [40.3333] into the Guide 9/2.0 [40.5017], drill the hole through both cortex layers and the nail hole,
- through the hole of connective screw insert the guide rod until its tip rest on Kirschner wire,
- if Kirschner wire does not pass the nail hole, repeat the process.



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



33 Insert the Protective Guide Ø9/Ø6.5 [40.3614] with the Trocar [40.3617] into the second slider hole (proximal) of the Target D [40.5002].

Mark on the skin the entry point for locking screw and make the incision of soft tissues. Advance the protective guide with the trocar until it reaches the cortex bone and make the entry point for the drill.

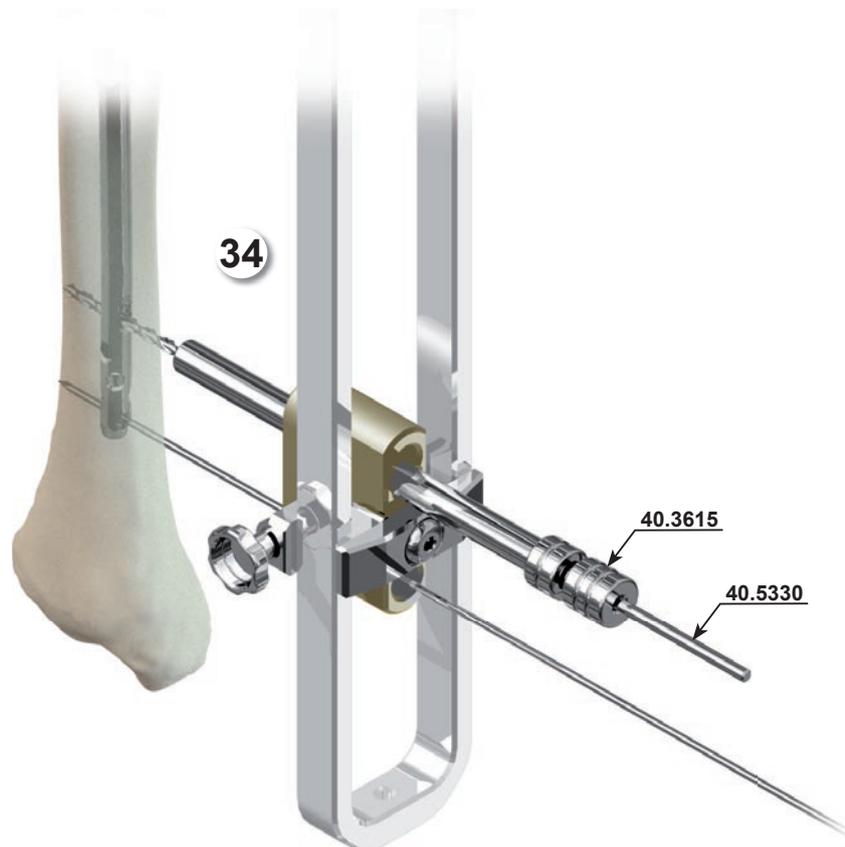
Remove the Trocar.

Leave the Protective Guide in the slider hole.

34 Insert the Drill Guide Ø3.5mm [40.3615] into the protective guide left in the slider hole. Mount the Drill With Scale Ø3.5/250 [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.

Dismount the surgical drive but leave the drill in the hole. Scale on the drill shows the length of the locking element.

Use the guide rod to verify the placement of the drill (the tip of the guide rod should rest on the drill).



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

35 Remove Kirschner wire [40.3333] and the guide 9/2,0 [40.5017].

Insert the Protective Guide Ø9/Ø6.5 [40.3614] into the slider hole, than insert the Drill Guide Ø6.5/Ø3.5 [40.3615] into the protective guide

Using the surgical drive, insert the Drill With Scale Ø3.5/250 [40.5330] into the drill guide until it passes both cortex layer and the nail hole.

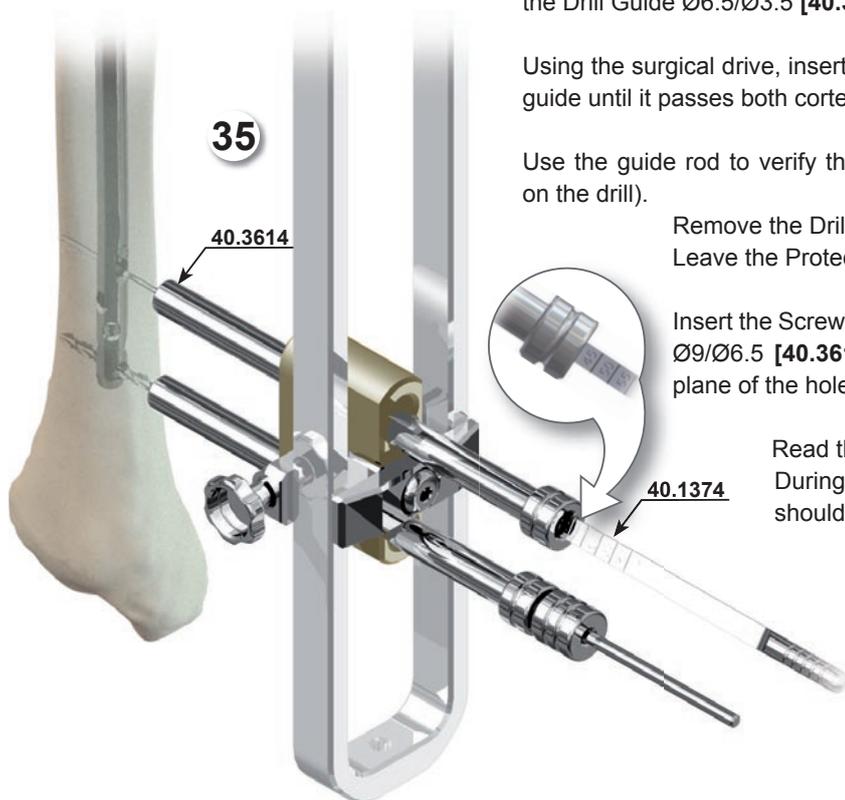
Use the guide rod to verify the position of the drill (the tip of the rod should rest on the drill).

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

Insert the Screw Length Measure [40.1374] into the Protective Guide Ø9/Ø6.5 [40.3614], until the tip of the measure reaches the „exit” plane of the hole.

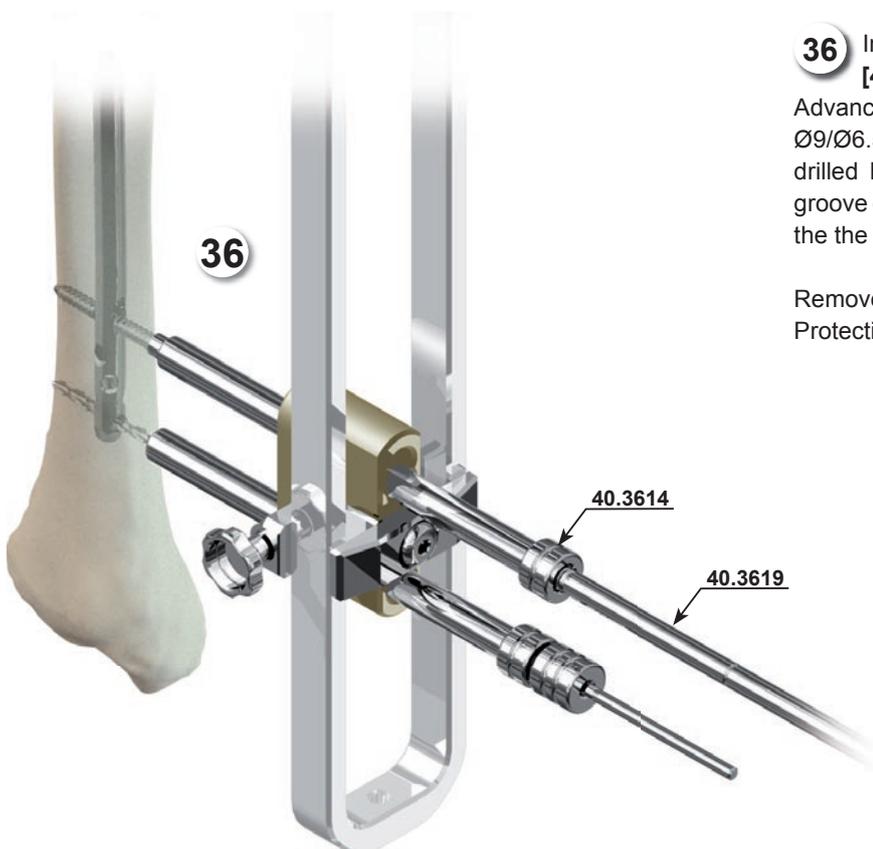
Read the length of the locking elements on the BD-B scale. During the measurement the tip of the protective guide should rest on the cortex bone.

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



36 Insert the tip of the the Hexagonal Screwdriver S3.5 [40.3619] into the socket of the locking screw. Advance such connected system into the Protective Guide Ø9/Ø6.5 [40.3614]. Insert the locking screw into the drilled hole until its head reaches the cortex layer (the groove of the the Hexagonal Screwdriver 3.5 shaft matches the the protective guide).

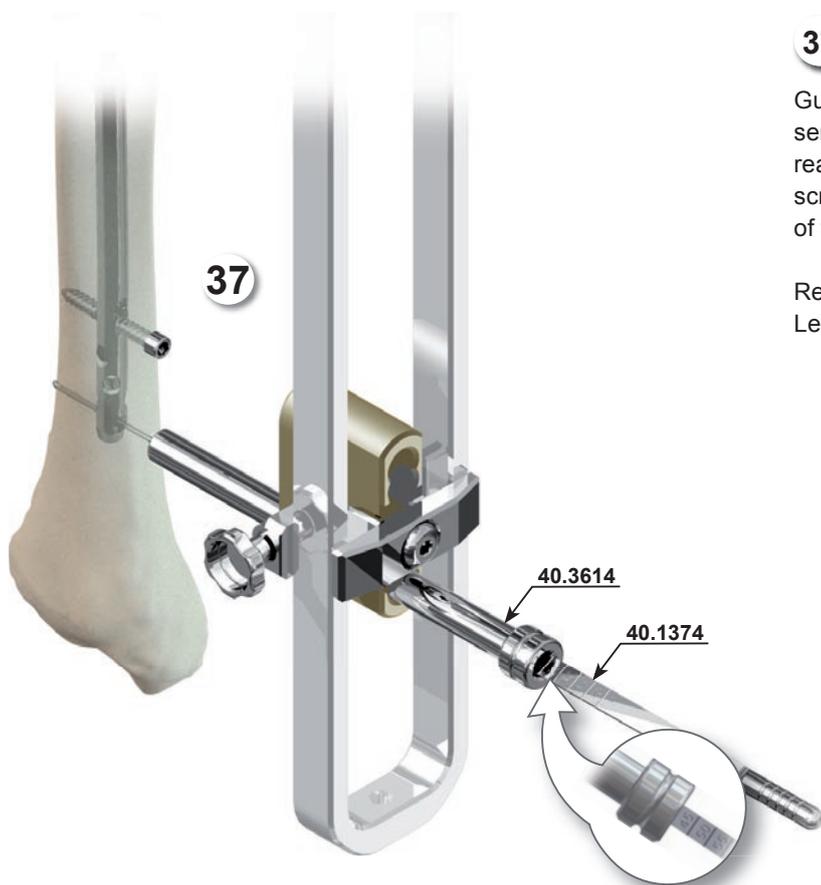
Remove the the Hexagonal Screwdriver 3.5 and the Protective Guide.



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

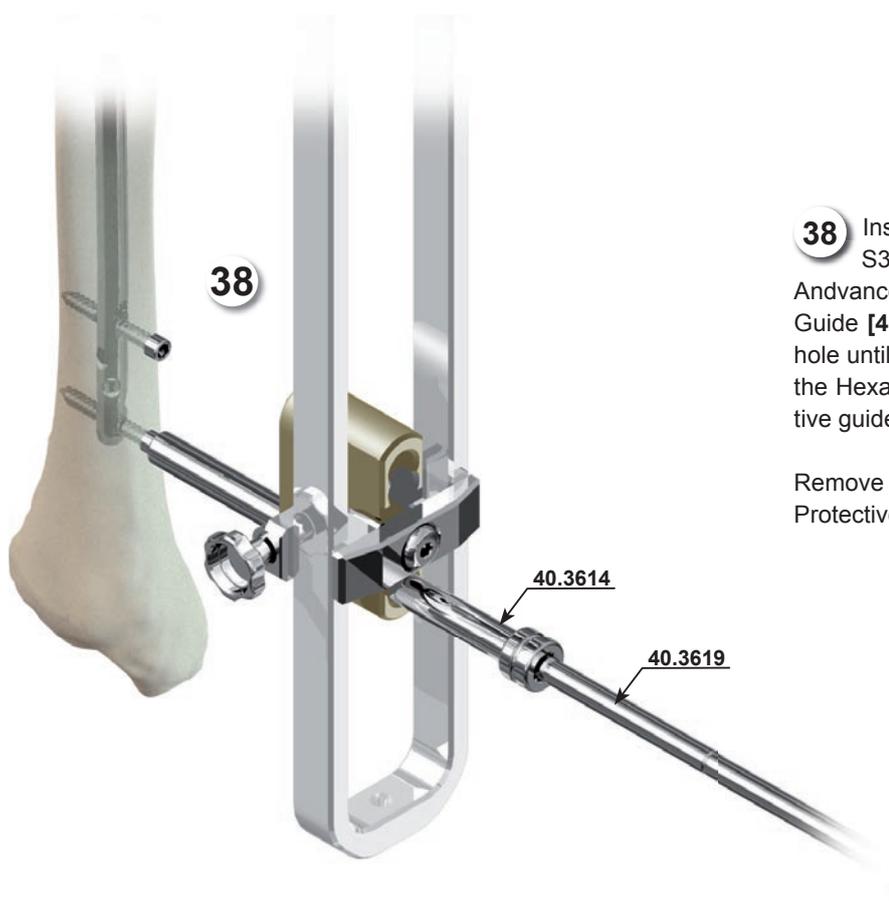
- 37** Remove the Drill With Scale Ø3.5/250 [40.5330] and the Drill Guide [40.3615] but leave the Protective Guide [40.3614]. Into the Protective Guide [40.3614] insert the Screw Length Measure [40.1374] until its tip reaches the „exit” plane. Read the length of the locking screw on the BD-B scale. During the measurement the tip of the guide should rest on cortex bone.

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



- 38** Insert the tip of the Hexagonal Screwdriver 3.5 S3.5 [40.3619] into the socket of the locking screw. Advance such connected system into the Protective Guide [40.3614]. Insert the locking screw into the drilled hole until its head reaches the cortex layer (the groove of the Hexagonal Screwdriver 3.5 shaft matches the 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.

Insertion of instrument devices into slider holes of target D.

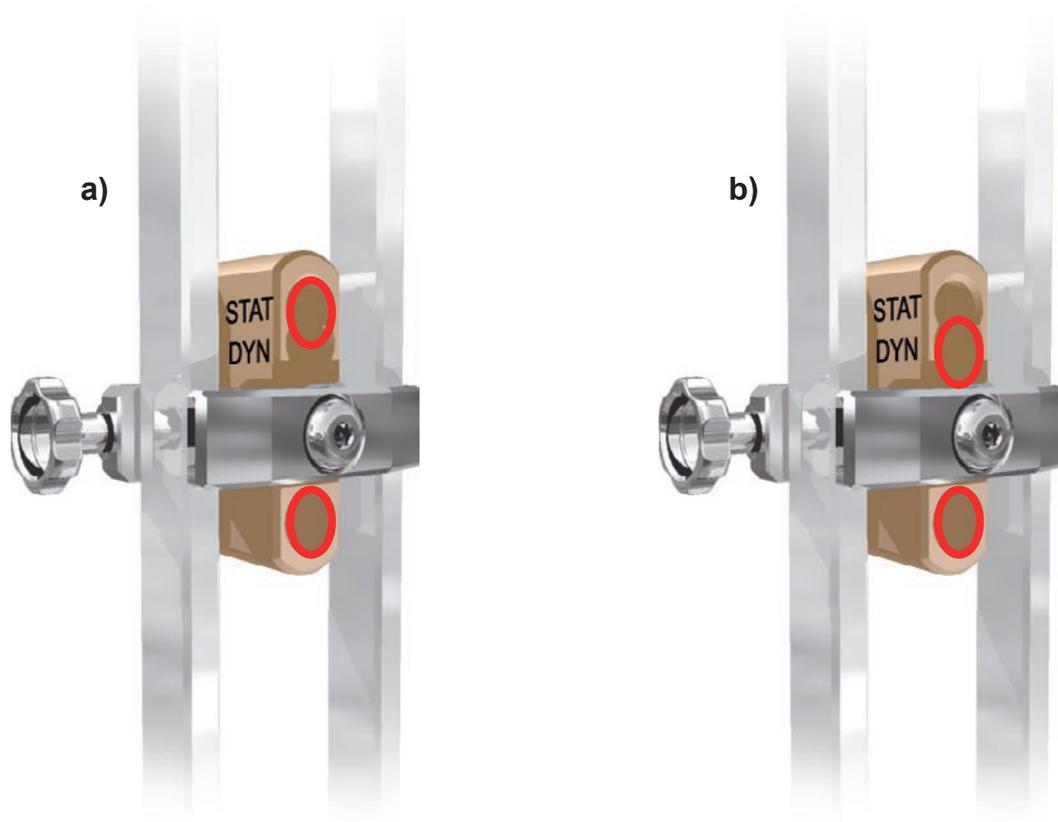
Insertion of the instrument devices into the slider hole of target D is possible and depends on the chosen method.

a) static method:

The instrument devices [40.5000.100] should be inserted into the distal slider hole and proximal part of the double hole named STAT.

b) dynamic and compressive method:

The instrument devices [40.5000.100] should be inserted into the distal slider hole and distal part of the double hole named DYN.



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

VI.6. Proximal nail locking

VI.6.1. Dynamic method and dynamic method with compression (compressive)



IMPORTANT!

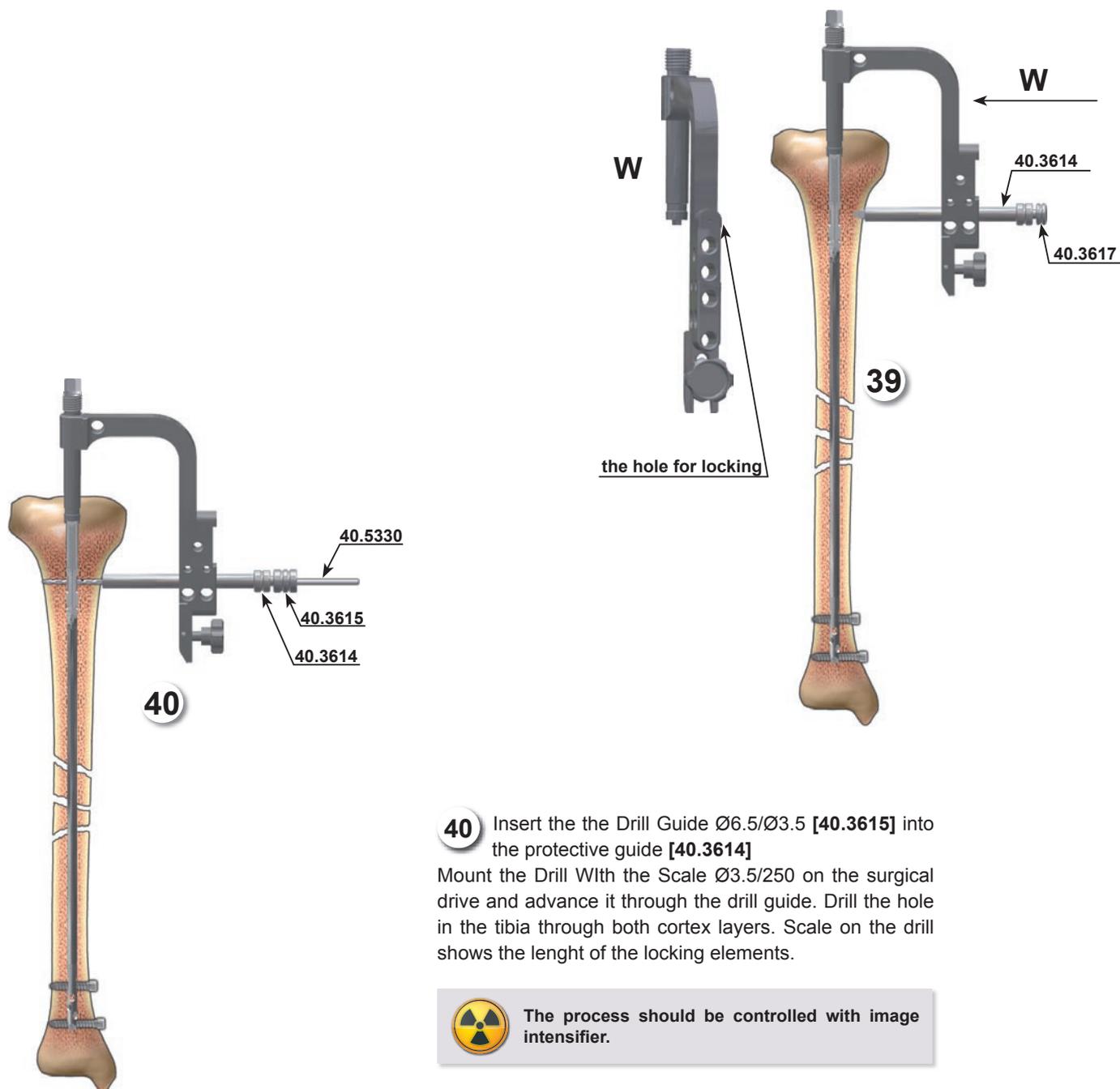
There are three holes in proximal part of the target for locking the nail.

The central hole of the target should be used in dynamic or compressive method for locking the nail in proximal part (correspondingly oval shaped hole in the intramedullary nail).

39 Insert the Protective Guide [40.3614] with the Trocar Ø6,5 [40.3617] into the hole (named: „compression”) in the proximal part of the target. Mark on the skin the entry point for locking screw and make adequate incision through soft tissues approx. 1,5 cm in length. 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 target.



40 Insert the the Drill Guide Ø6.5/Ø3.5 [40.3615] into the protective guide [40.3614]

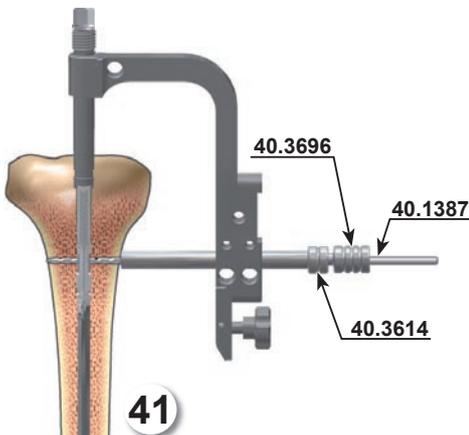
Mount the Drill With the Scale Ø3.5/250 on the surgical drive and advance it through the drill guide. Drill the hole in the tibia through both cortex layers. Scale on the drill shows the length of the locking elements.



The process should be controlled with image intensifier.

Remove the Drill and the Drill Guide.

Leave the Protective Guide in the slider hole.



41 Insert the Drill Guide Ø6.5/Ø4.5 [40.3696] into the protective guide [40.3614]. Insert the Drill Ø4.5/250 [40.1387] into the drill guide and widen the hole in first cortex layer.



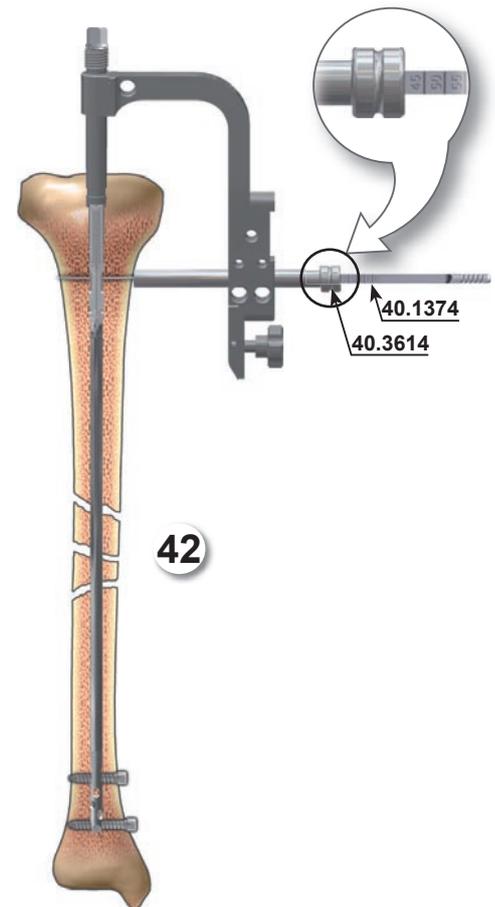
The widening process should be controlled with image intensifier.

Remove the Drill and the Drill Guide.
Leave the Protective guide in the target hole.

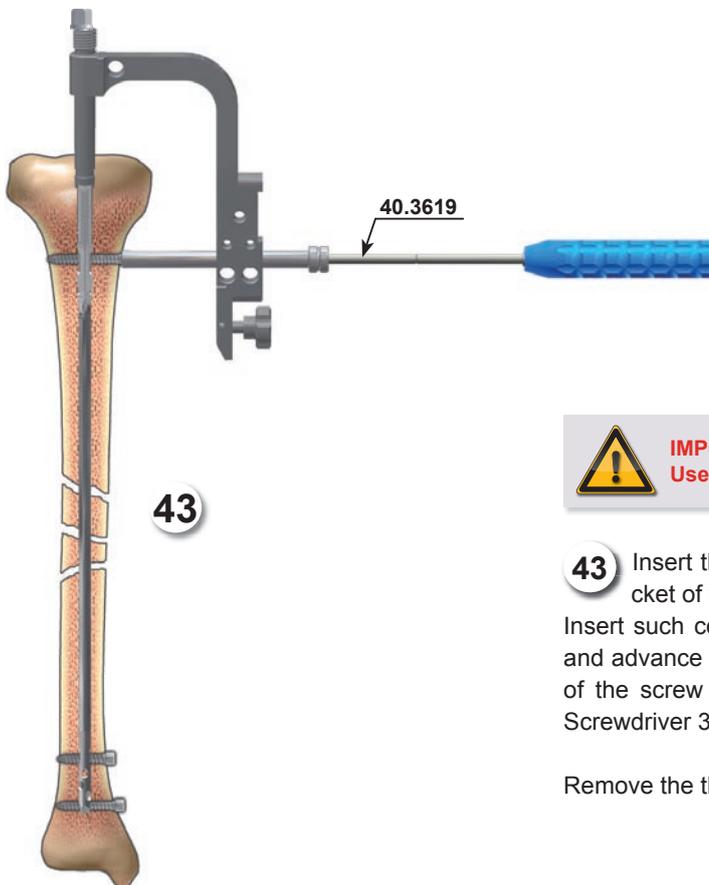
42 Insert the Screw Length Measure [40.1374] through the Protective Guide Ø9/Ø6.5 [40.3614] into the drilled hole until its hook reaches "exit" of the hole. Read the length of locking screw on the B-D scale.

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.



42



43



IMPORTANT!
Use the proximal screw to lock the nail.

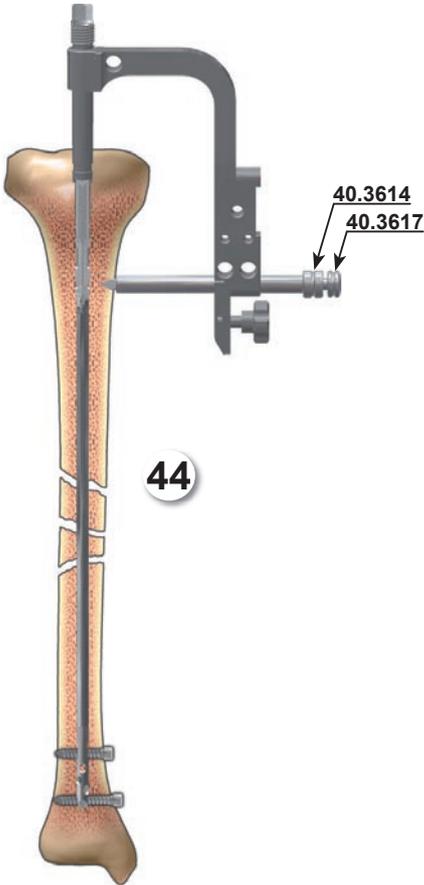
43 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the defined proximal screw. Insert such combined system into the Protective Guide Ø9/Ø6.5 [40.3614] and advance the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (the groove on the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

Remove the 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.

VI.6.2. Static method

It is recommended to lock a nail in proximal part using two screws.
The circular hole distally placed should be used in all cases of nail locking.



44 Insert the Protective Guide Ø9/Ø6.5 [40.3614] with the Trocar Ø6,5 [40.3617] into the distal hole in proximal part of Tibia Target B [40.5001].

Mark on the skin the entry point for the locking screw and make adequate incision through the soft tissues approx. 1,5 cm in length.

Insert the protective guide with the trocar until it reaches the cortex bone. Mark the point for drill insertion using the trocar.

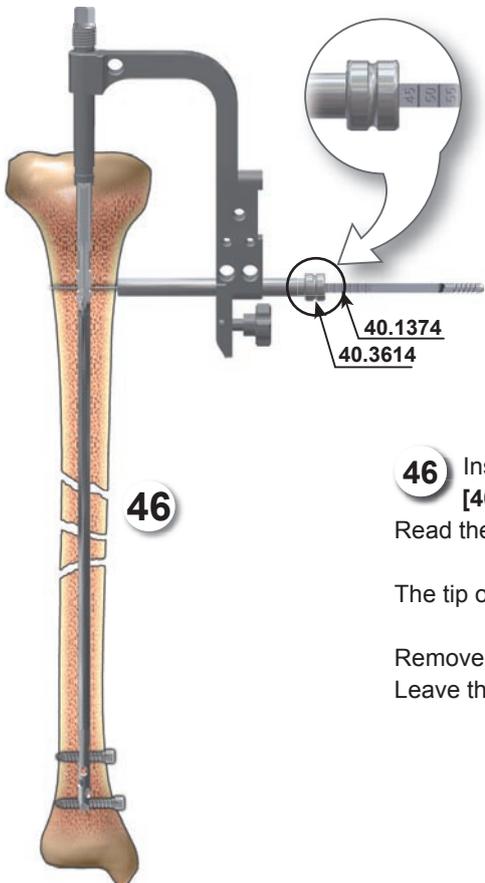
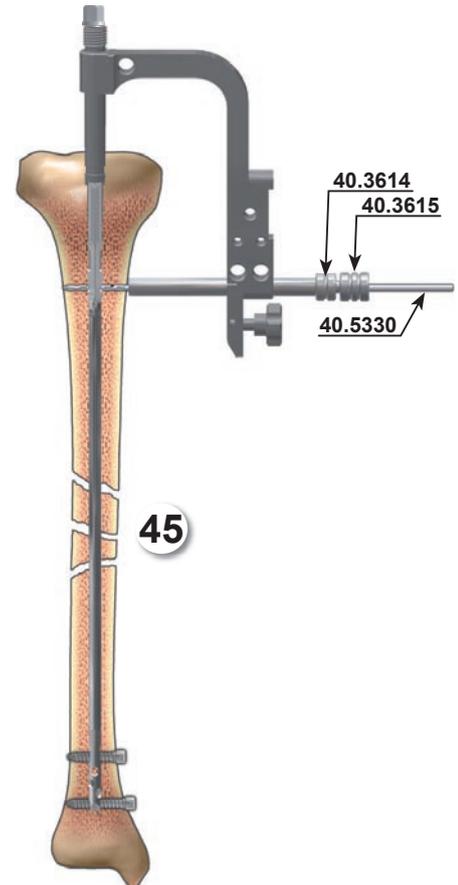
45 Insert the the Drill Guide Ø6.5/Ø3.5 [40.3615] into the protective guide.

Mount the Drill With Scale Ø3.5/250 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 shows 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 target.



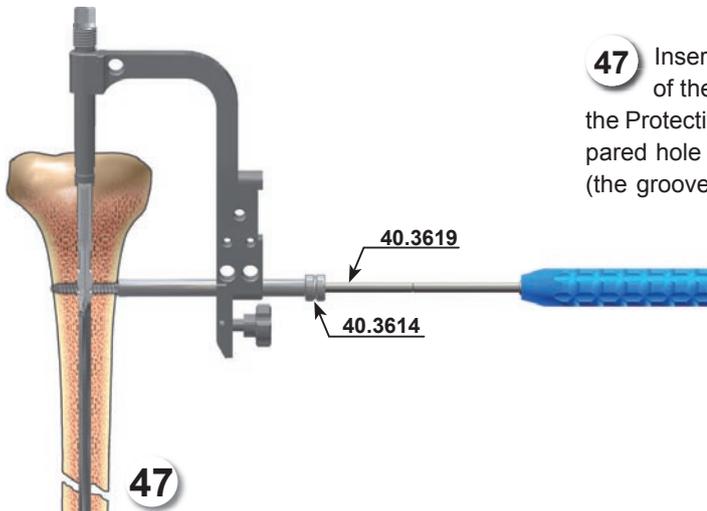
46 Insert the Screw Length Measure [40.1374] through the the Protective Guide Ø9/Ø6.5 [40.3614] into the drilled hole until its hook reaches "exit" of the hole.

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 target.

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

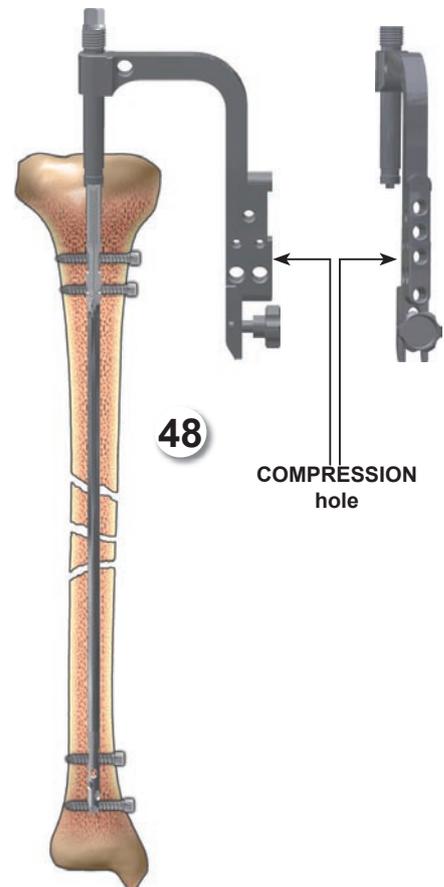


47 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the head of the definite locking screw and then advanced combined system into the Protective Guide Ø9/Ø6.5 [40.3614] and insert the locking screw into prepared hole in the bone until the head of the screw reaches the cortex bone (the groove on the the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

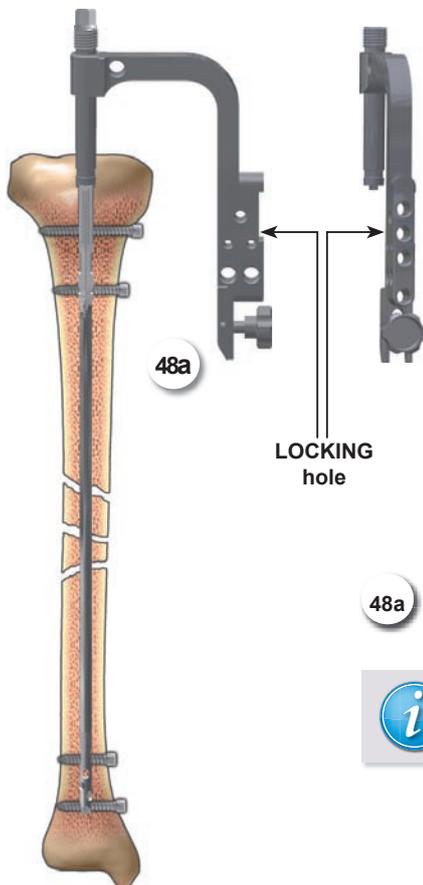
Remove the the Hexagonal Screwdriver 3.5 and the Protective Guide.

48 Using the second locking screw lock the nail in the proximal part, through the central hole (named COMPRESSION) of the target - (in the intramedullary nail use oval shaped hole)

i To lock the nail follow the steps from 20 to 24.



COMPRESSION hole



LOCKING hole

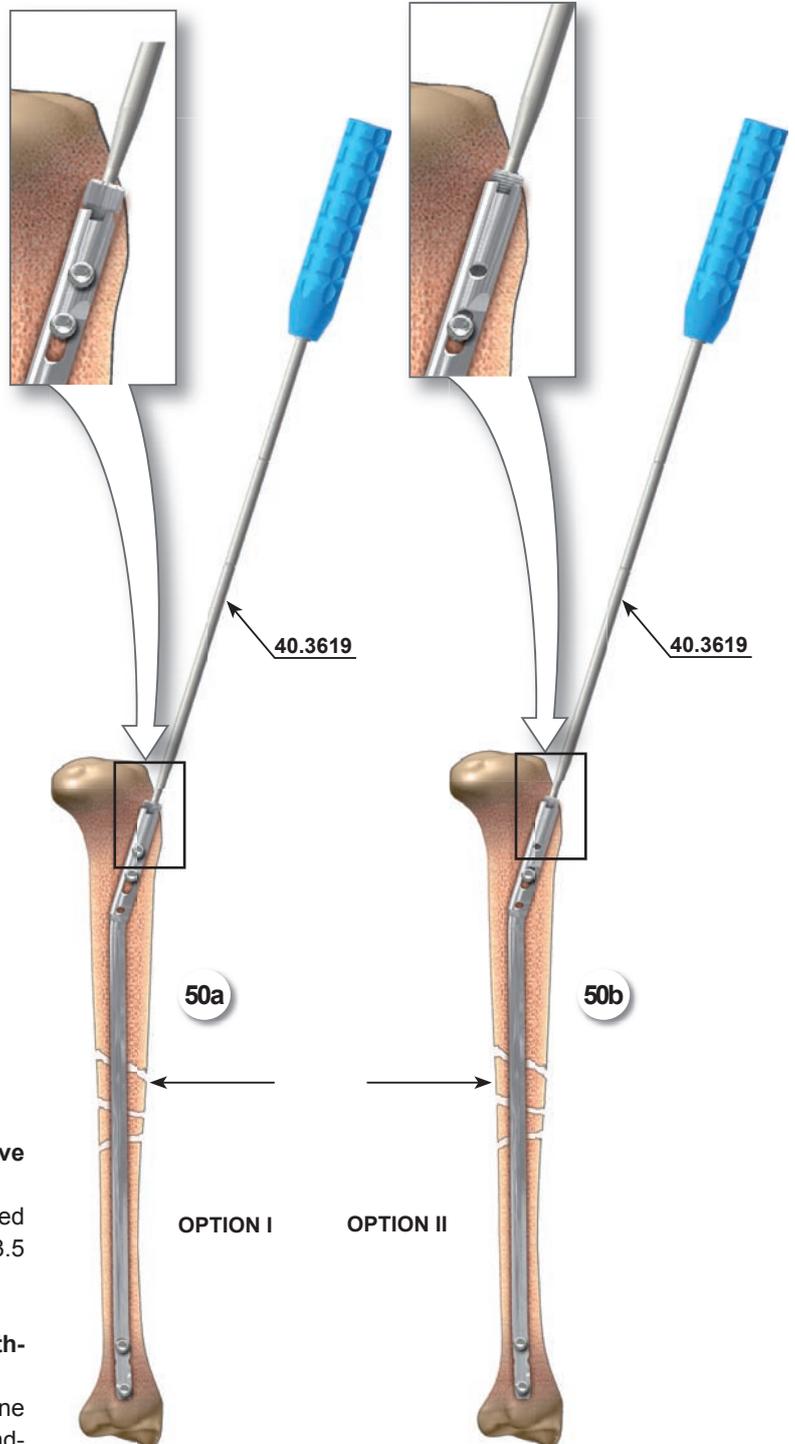
48a Using the second locking screw lock the nail in the proximal hole (named: LOCKING) of the target - (in the intramedullary nail use oval shaped hole).

i To lock the nail follow the steps from 25 to 28.

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

VI.7. Placing Compression screw or End cap

49 Using the Socket Wrench S 11 [40.1361] unscrew the Connecting Screw M8x1.25 spec. [40.5003] of the nail shaft. Dismount the Proximal Tibia Target B [40.5001] and the Distal Tibia Target D [40.5002] from the nail locked in the intramedullary canal.



50 Placing compression screw or end cap.

Option I: Placing compression screw (compressive method).

Insert the compression screw (implant) into the threaded nail hole shaft using the Hexagonal Screwdriver 3.5 [40.3619].

Option II: Placing end cap (dynamic and static method).

In order to secure the inner thread of the nail from bone overgrowth, insert in the end cap (implant) into the threaded nail hole shaft using the Hexagonal Screwdriver 3.5 [40.3619].

51 Operative technique using tibia reconstructive nail is very similar to implantation of standard tibia nail. Therefore in order to insert the nail into intramedullary canal and than to lock the nail in the distal part follow steps 1-19.

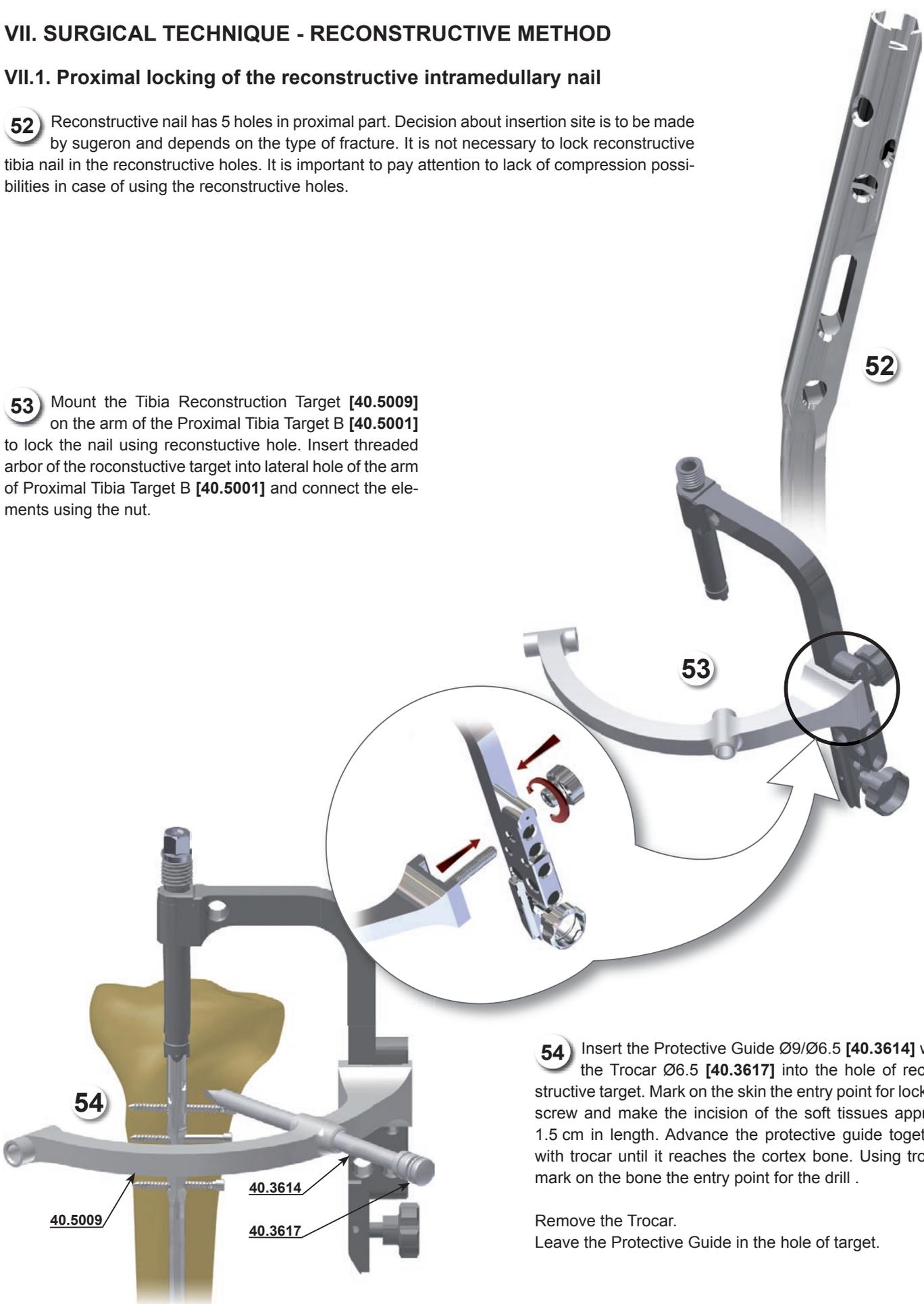
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

VII. SURGICAL TECHNIQUE - RECONSTRUCTIVE METHOD

VII.1. Proximal locking of the reconstructive intramedullary nail

52 Reconstructive nail has 5 holes in proximal part. Decision about insertion site is to be made by surgeon and depends on the type of fracture. It is not necessary to lock reconstructive tibia nail in the reconstructive holes. It is important to pay attention to lack of compression possibilities in case of using the reconstructive holes.

53 Mount the Tibia Reconstruction Target [40.5009] on the arm of the Proximal Tibia Target B [40.5001] to lock the nail using reconstructive hole. Insert threaded arbor of the reconstructive target into lateral hole of the arm of Proximal Tibia Target B [40.5001] and connect the elements using the nut.



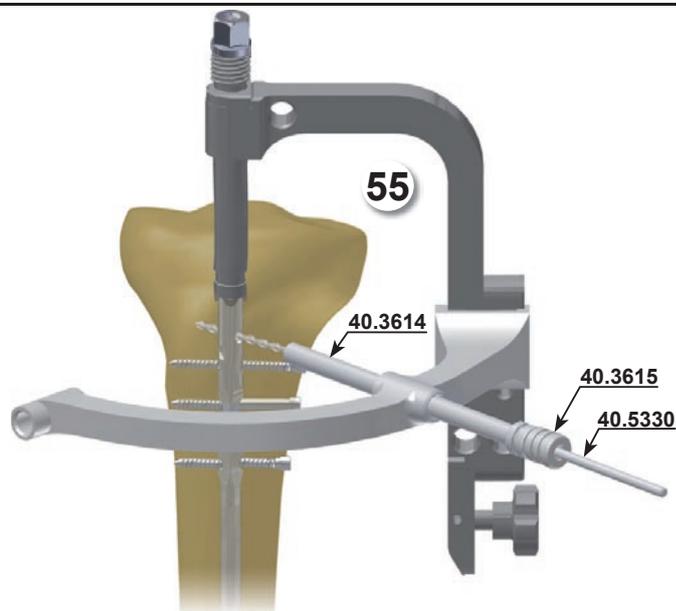
54 Insert the Protective Guide Ø9/Ø6.5 [40.3614] with the Trocar Ø6.5 [40.3617] into the hole of reconstructive target. Mark on the skin the entry point for locking screw and make the incision of the soft tissues approx. 1.5 cm in length. Advance the protective guide together with trocar until it reaches the cortex bone. Using trocar mark on the bone the entry point for the drill .

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

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

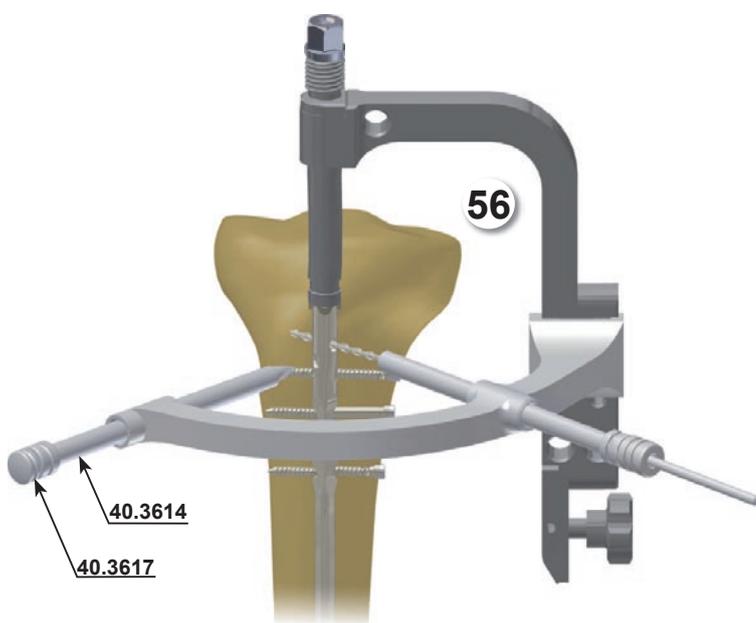
- 55** Insert the the Drill Guide $\text{\O}6.5/\text{\O}3.5$ [40.3615] into the Protective Guide $\text{\O}9/\text{\O}6.5$ [40.3614] left in the hole of target. Mount the Drill With Scale $\text{\O}3.5/250$ [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia to the proper depth. The scale on the drill shows the locking elements.

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



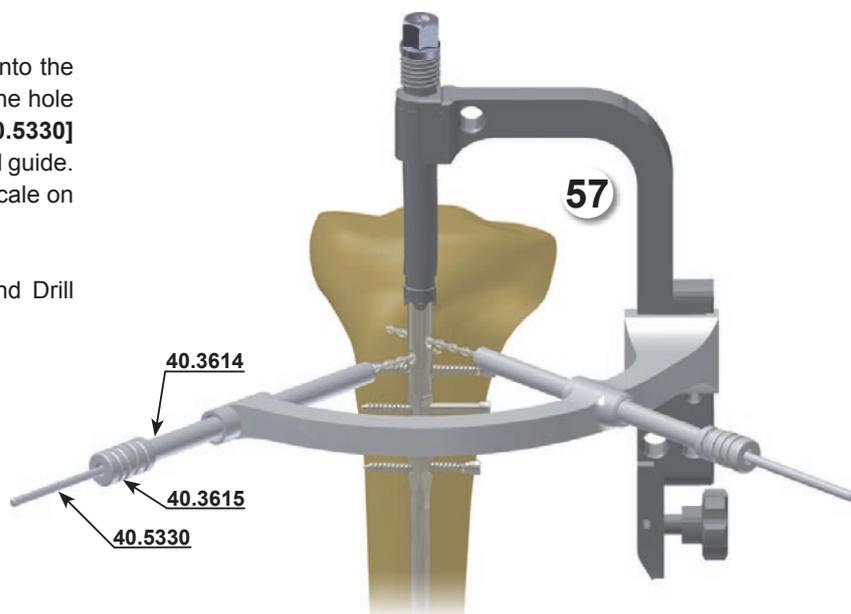
- 56** Insert the Protective Guide $\text{\O}9/\text{\O}6.5$ [40.3614] with the Trocar $\text{\O}6,5$ [40.3617] into second reconstructive hole of target. Mark on skin entry point for the locking screw and make incision of the soft tissues across the point on length approx. 1.5 cm. Advance the protective guide together with trocar until it reaches the cortex bone. Using trocar mark the entry point for the drill .

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

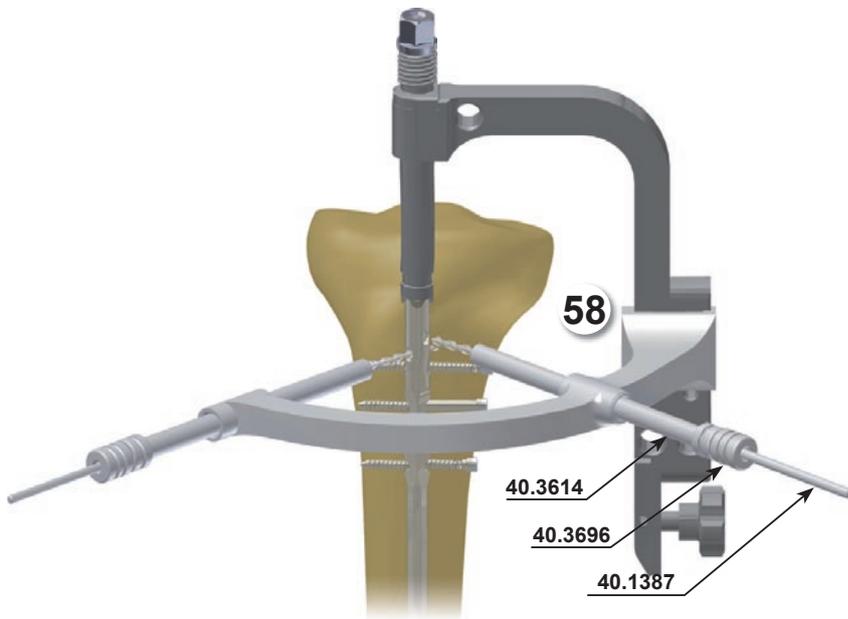


- 57** Insert the Drill Guide $\text{\O}6.5/\text{\O}3.5$ [40.3615] into the Protective Guide $\text{\O}9/\text{\O}6.5$ [40.3614] left in the hole of target. Mount the Dril With Scale $\text{\O}3.5/250$ [40.5330] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia to the proper depth. The scale on the drill shows the locking elements

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



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



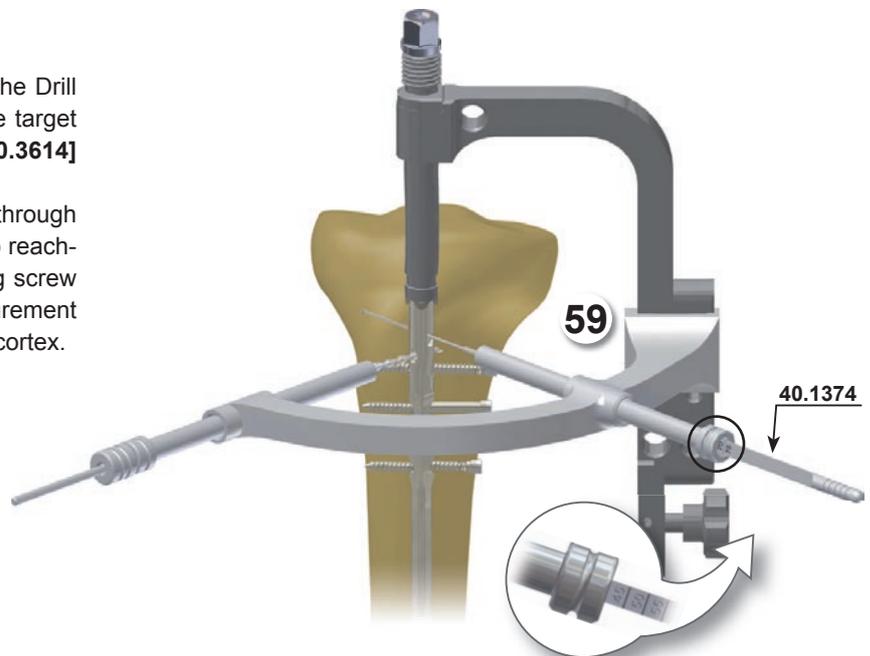
58 In case of nail locking using Proximal Screw 4.5 mm [1.1653.xxx] it is necessary to use the Drill Ø4.5/250 [40.1387] to ream the hole in first cortex (previously insert the Drill Guide Ø6.5/Ø4.5 [40.3696] into protective guide Ø9/Ø6.5 mm [40.3614]).

Remove drill and drill guide.

59 Remove the Drill Ø4,5/250 [40.1387] and the Drill Guide Ø6.5/Ø3.5 [40.3615] from one of the target hole. Leave the Protective Guide Ø9/Ø6.5 mm [40.3614] in target 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 measure scale B-D. During the measurement the end of the protective guide should rest on the cortex.

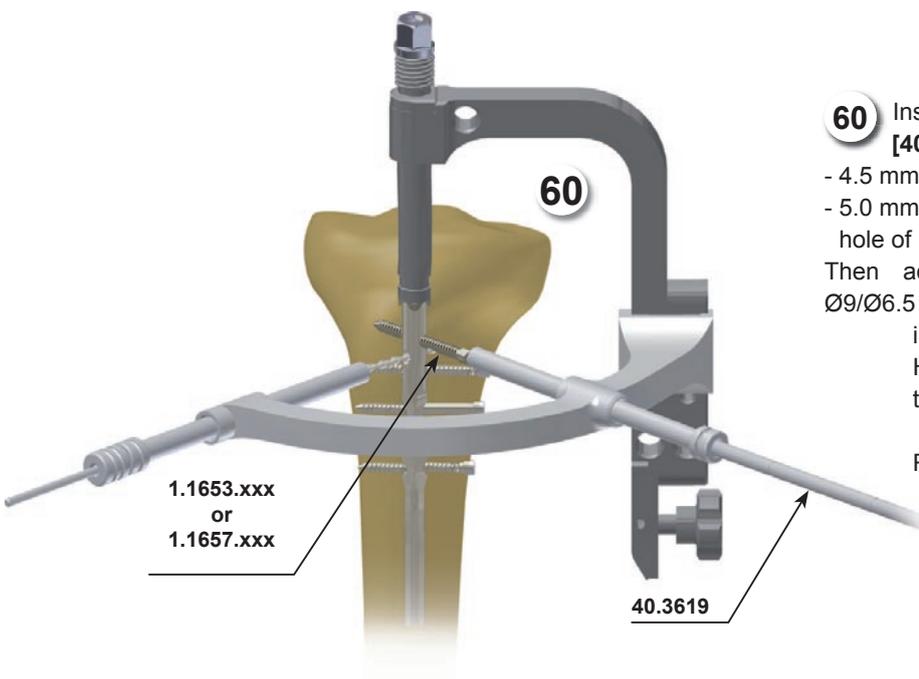
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of target.



60 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 case of standard locking,
- 5.0 mm [1.1657.xxx] in case of locking in threaded hole of nail.

Then advance both into the Protective Guide Ø9/Ø6.5 mm [40.3614]. Insert the locking screw in the prepared hole (until the groove on the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

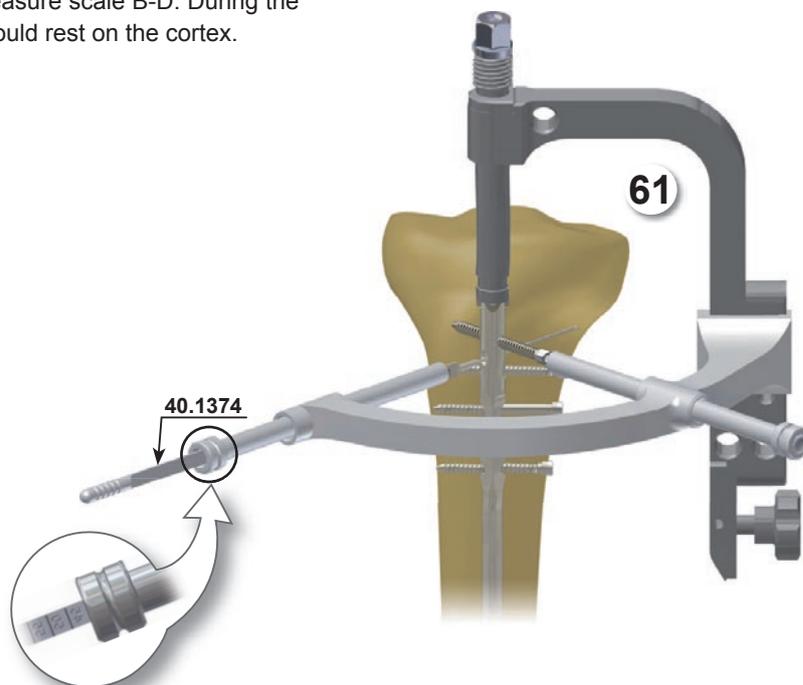
Remove the Hexagonal Screwdriver 3.5.
Leave the Protective Guide.



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

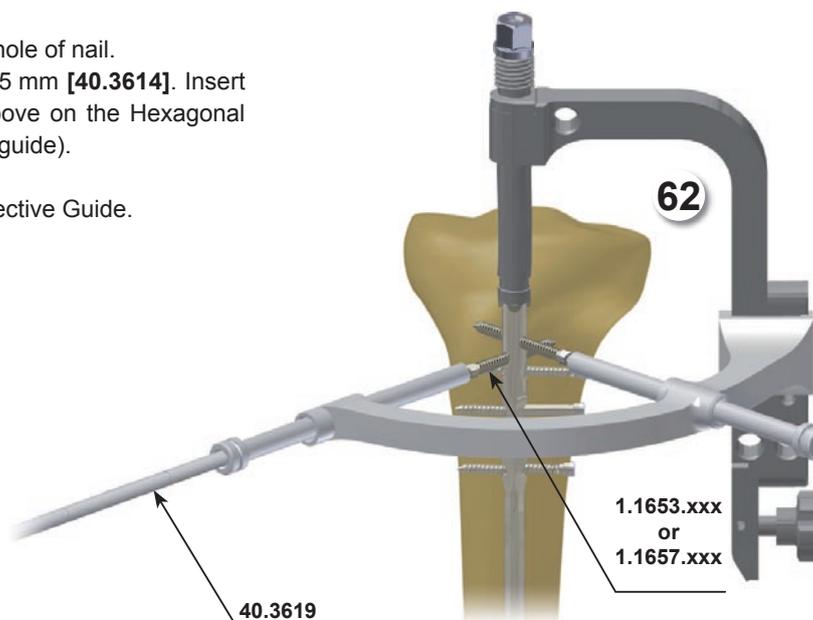
- 61** Remove the Drill With Scale Ø3.5/250 [40.5330] and the Drill Guide Ø6.5/Ø3.5 [40.3615] from the second hole of the reconstructive target. Leave the Protective Guide Ø9/Ø6.5 mm [40.3614] in target hole. Insert the Screw Length Measure [40.1374] through the protective guide into the drilled hole until its tip reaches the end of hole. Read the length of the locking screw on the measure scale B-D. 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 target.



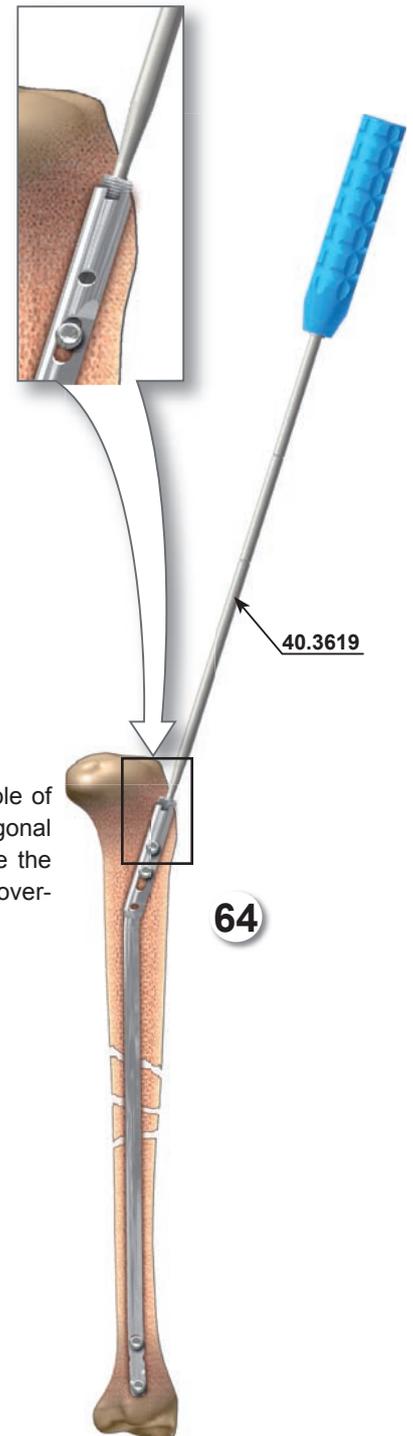
- 62** Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the locking screw:
- 4.5 mm [1.1653.xxx] in case of standard locking,
- 5.0 mm [1.1657.xxx] in case of locking in threaded hole of nail.
Then advance both into the Protective Guide Ø9/Ø6.5 mm [40.3614]. Insert the locking screw in the prepared hole (until the groove on the Hexagonal Screwdriver 3.5 shaft matches the edge of protective guide).

Remove the the Hexagonal Screwdriver 3.5 and Protective Guide.



VII.2. Placing end cap

- 63** Unscrew the Connecting Screw M8x1.25 spec. **[40.5003]** using the Socket Wrench S 11 **[40.1361]**. Dismount the Target D and Target B from the nail.



- 64** Insert the end cap into the hole of the nail shaft using the Hexagonal Screwdriver 3.5 **[40.3619]** to secure the inner thread of the nail from bone overgrowth.

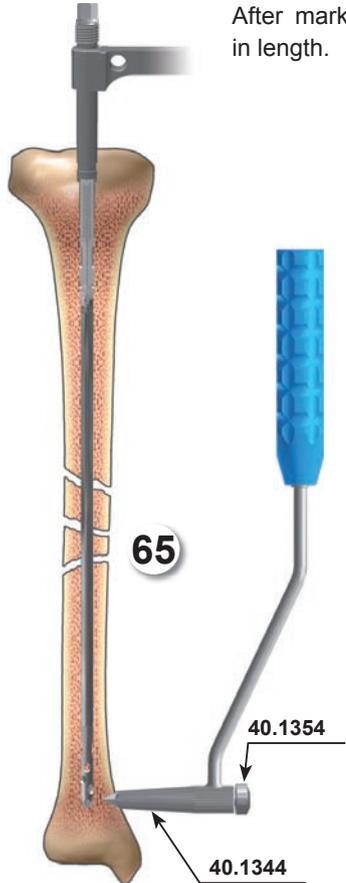
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

VIII. LOCKING OF INTRAMEDULLARY NAIL USING TARGET D AND TARGET B

VIII.1. Distal locking of the nail using Target 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.

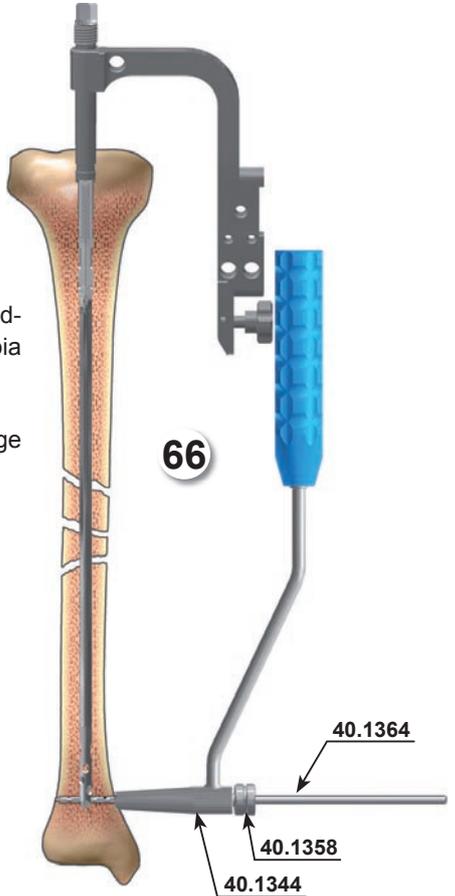


65 Using the image intensifier establish place of the target D in line with the nail hole. The centers of the holes in the target and the nail have to match. The teeth of the target have to be merged in the cortex. Insert the Short Trocar [40.1354] into the target hole, advance it until it reaches cortex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

Remove the Trocar.
Leave the Target D in place.

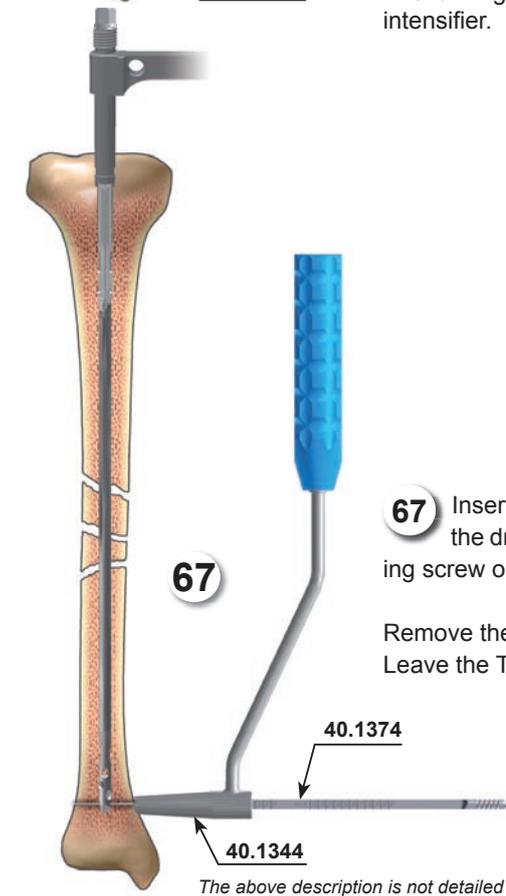
66 Insert the Drill Guide Short [40.1358] into the hole in Target D [40.1344]. Mount the Drill Ø3.5/150 mm [40.1364] on the surgical drive and advance it through the drill guide. Drill the hole in the tibia shaft through both cortex layers.

The drilling process should be controlled with image intensifier.

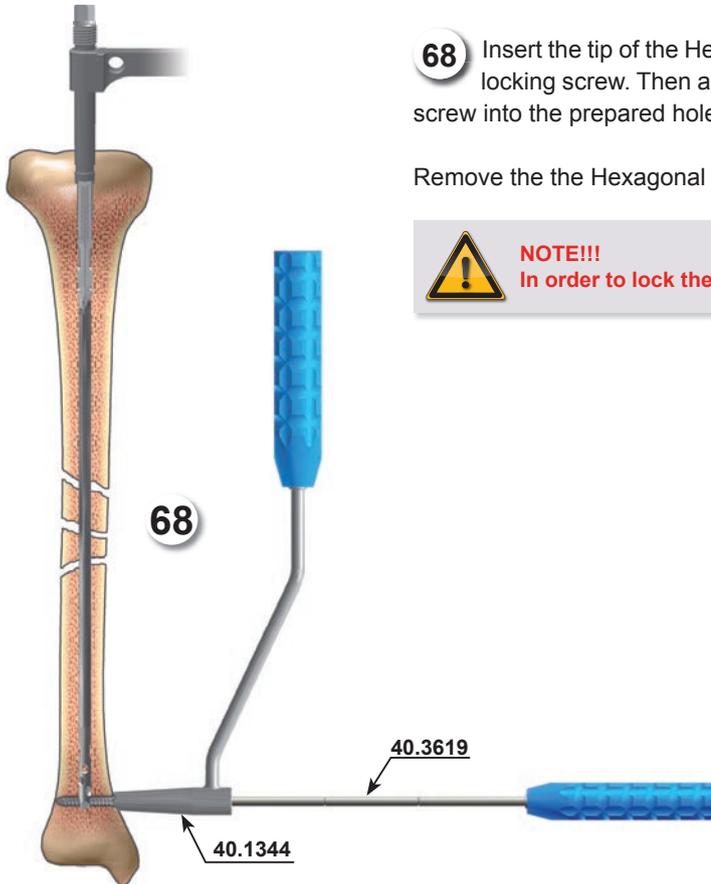


67 Insert the Screw Length Measure [40.1374] through the Target D hole [40.1344] into the drilled hole until its hook reaches the “exit” plain of the hole. Read the length of the locking screw on the gauge scale D.

Remove the Screw Length Gauge.
Leave the Target.



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



68 Insert the tip of the Hexagonal Screwdriver 3.5 [40.3619] into the socket of the selected locking screw. Then advance both into the hole in Target D [40.1344]. Insert the locking screw into the prepared hole until its head reaches the cortex of the bone.

Remove the the Hexagonal Screwdriver 3.5 and the target.



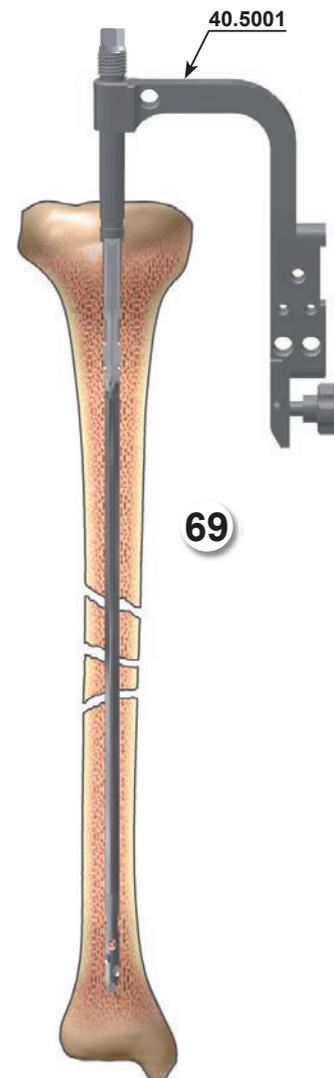
NOTE!!!
In order to lock the nail in the second distal hole follow the steps [32] to [35].

VIII.2. Proximal locking of the nail using Proximal Tibia Target B [40.5001]

69



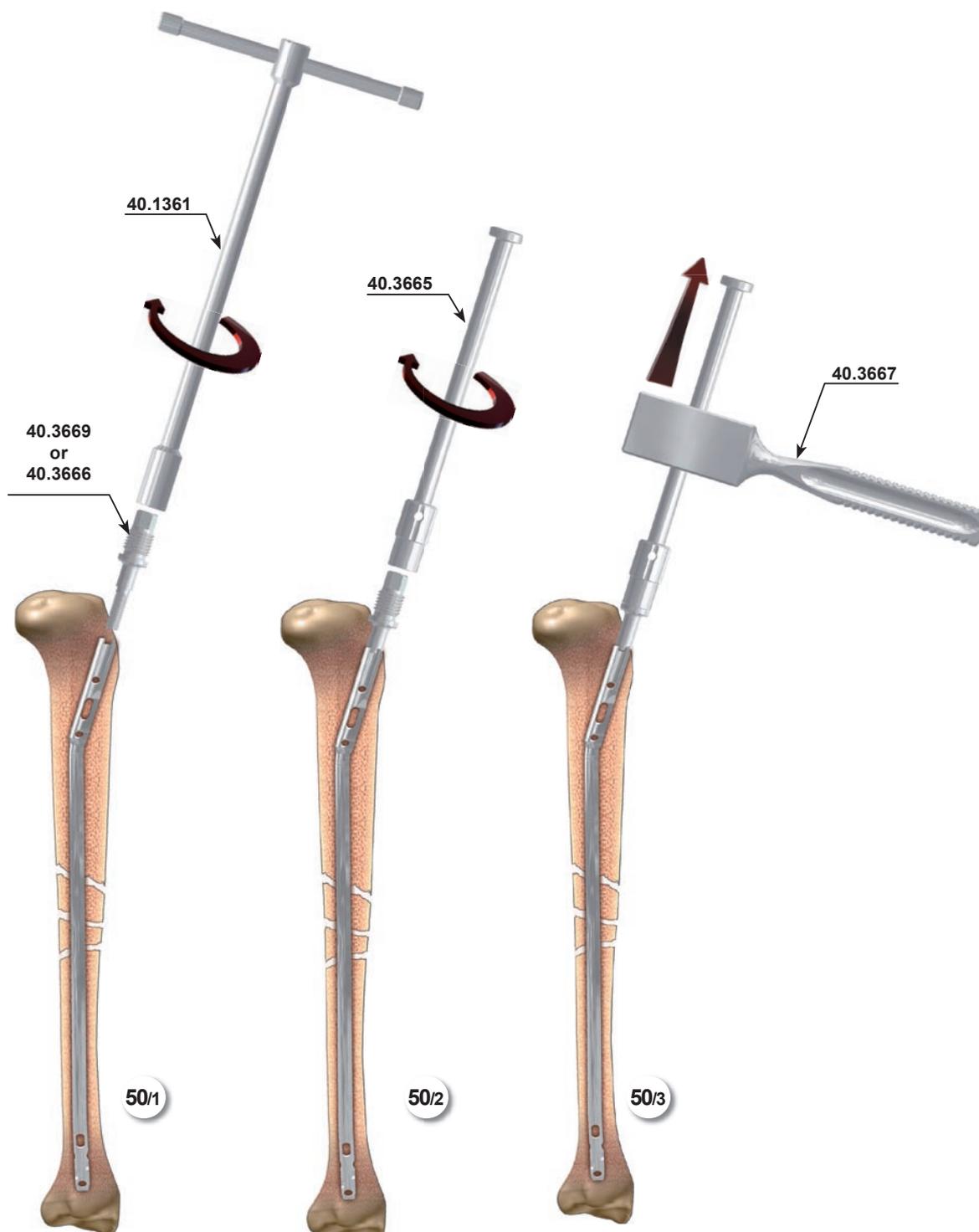
In order to carry out the proximal locking follow the steps [20] – [29a] chapter IV.6. „Proximal locking of the nail”.



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

IX. NAIL EXTRACTION

70 Use the Hexagonal Screwdriver 3.5 [40.3619] to remove the end cap or compression screw and all locking screws from the nail shaft. Using the Socket Wrench S 11 [40.1361] insert the Connector M8/M16 [40.3669] or [40.3666] into the threaded the nail hole. Using the Hexagonal Screwdriver 3.5 [40.3604] unscrew all locking screws. Attach the the Impactor-Extractor [40.3665] 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.



REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

ChM®

Instruments manufactured by ChM Ltd. are made of stainless 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 recommendations below.

1. Materials

Devices are produced of corrosion-resistant steels. The protective layer (passive layer) against corrosion is formed on the surface of the stainless 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 screwdriver, awl or wrench, 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 surface 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 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-disinfection with pH values from 4 to 9.5.



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

2. 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 sterilizers, recommendations of cleaning and disinfection agents, as well as recommendations for cleaning and sterilizing automatic machines shall be observed.



Read and follow the instructions and restrictions specified by the manufactures 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 detergent. It is recommended to use water solutions of cleaning-disinfection 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 disinfection properties) normally used for reusable medical devices (remember to prevent drying out 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, only the nylon brushes are recommended. Do not use brushes made of metal, bristles or damaging material as they can cause physical or chemical corrosion.
4. Next, thoroughly rinse the instrument under the warm running water, paying particular attention for carefully rinsing the slots. Use nylon brushes making multiple moves back and forth on the surface of the product. It is recommended to rinse in 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 such as anodized. During the rinsing manually remove the adherent remains.
5. Visually inspect the entire surface of the product to ensure that all contaminations 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-disinfection agents manufacturer.

3. Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds as residues after disinfection and sterilization processes, without structure damages (cracks, fractures, bending, peeling). Remember that sterilization is not 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 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 min. 134°C, pressure of 2 atm.



The above given parameters of sterilization are to be absolutely observed.

Validated sterilization methods are allowed. Durability and strength of instruments highly depend on their usage. Careful usage consistent with intended application of the product, prevents product damaging and prolongs its life.

ChM®

ChM Ltd.

Lewickie 3b
16-061 Juchnowiec K.
Poland

tel. +48 85 713-13-20
fax +48 85 713-13-19
e-mail: chm@chm.eu



- 4 Intramedullary osteosynthesis of humerus
- 7 Intramedullary osteosynthesis of fibula and forearm
- 6 Intermedullary osteosynthesis of femur by trochanteric nails
- 8 Dynamic Hip (DSB)/ Condylar (DSK) stabilizer
- 9 Spine stabilization CHARSPINE
- 15 Tibial and femoral angular set block
- 20 Radial Head Prosthesis KPS
- 22 Locking plates
- 23 Intramedullary osteosynthesis of femur (reversed method) 40.3660
- 24 Intramedullary osteosynthesis of femur 40.5060.000
- 25 Intramedullary osteosynthesis of tibia 40.5370.500
- 28 Intramedullary osteosynthesis of femur by trochanteric nail - ChFN
- 29 Cervical locking plate system
- 30 Proximal humeral plate
- 32 4.0 ChLP plates for distal part of radial bone
- 35 Spine stabilization [6mm]
- 36 ChLP screws removing
- 37 Stabilization of the pubic symphysis
- 38 Intramedullary tibia osteosynthesis with ChTN nails

SALES OFFICE

tel.: + 48 85 713-13-30 ÷ 38

fax: + 48 85 713-13-39