








**CHARFIX***system*

## INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR

- *IMPLANTS*
- *INSTRUMENT SET 40.5090.500*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Consult the Instructions For Use.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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Document No            ST/24E  
Date of issue            02.08.2010  
Review date              P-005-07.06.2016

*The manufacturer reserves the right to introduce design changes.*

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## I. INTRODUCTION

**CHARFIX** system provides the following methods of intramedullary fixation:

- Reconstruction,
- Compression, dynamic, static,
- Retrograde (*condylar approach*).

Each fixation method of **CHARFIX** system comes with:

- adequate selection of implants (*intramedullary nails, screws, locking screws*),
- instrument sets for implants insertion and removal,
- instructions for use (*surgical technique*).

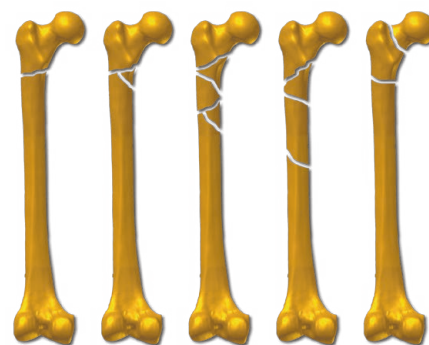
The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of Quality Management Systems ISO 9001, EN ISO 13485 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

### I.1. RECONSTRUCTION, PERTROCHANTERIC METHOD

Reconstruction nails are used for intramedullary fixation of proximal femur neck or trochanteric fractures.

Angular position of reconstruction screws gives anatomical position of the head and trochanteric region against the femoral shaft. The nail comes in two versions: right nail for right femur, left nail for left femur.

Position of the implants in femur:

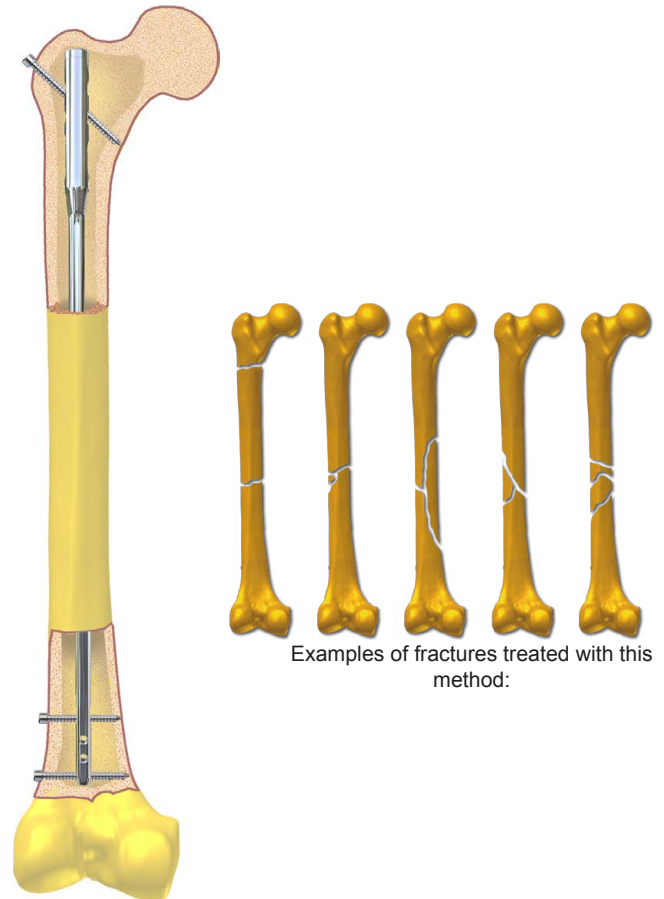


Examples of fractures treated with this method:

To fix the femoral fracture fragments with pertrochanteric method use:

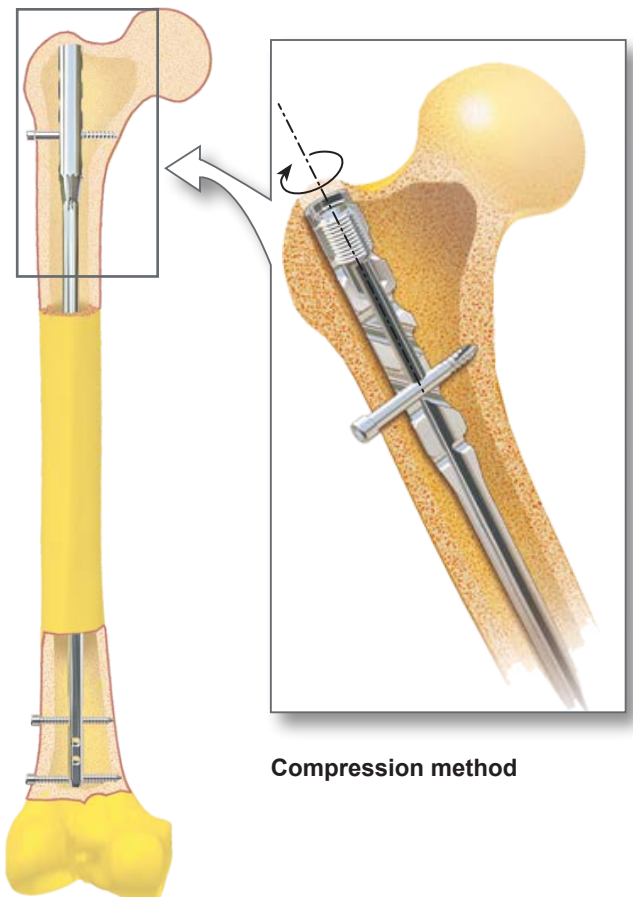
- right nail for fixation of the left femur fractures
- left nail for fixation of the right femur fractures

Position of implants in femur:



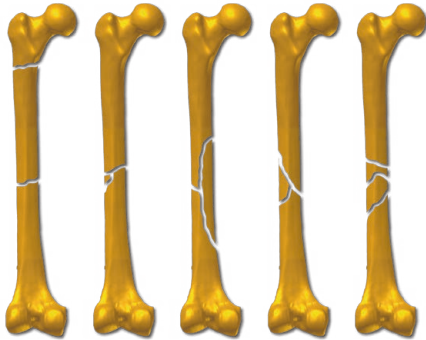
## I.2. COMPRESSION, DYNAMIC AND STATIC METHOD

**Compressive lockings** are used in the intramedullary fixations of femoral shaft fractures, providing that fractures are not closer than 3cm from locking screw. Nail design allows treatment with the compression, dynamic and static method.

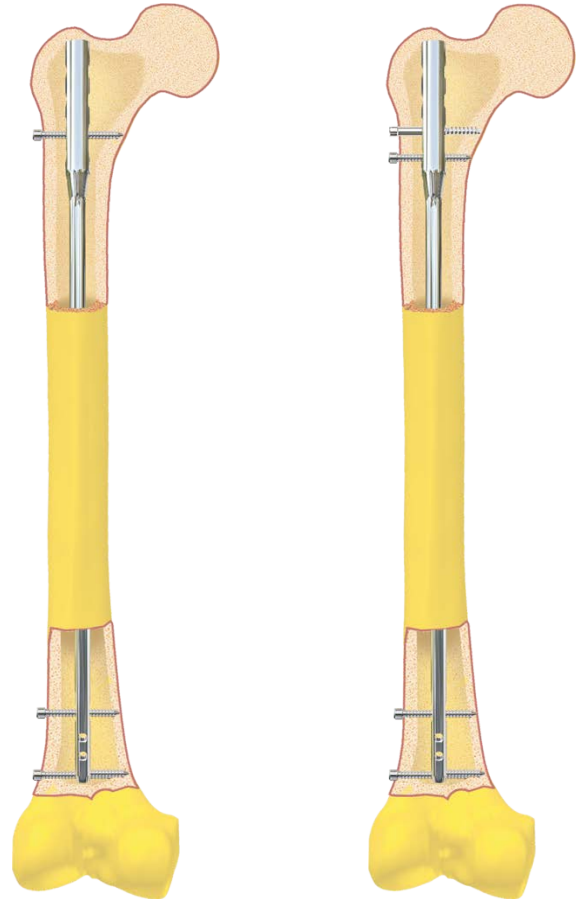


**In static locking**, when needed, the proximal screw can be used to provide better locking.

Position of implants in femur



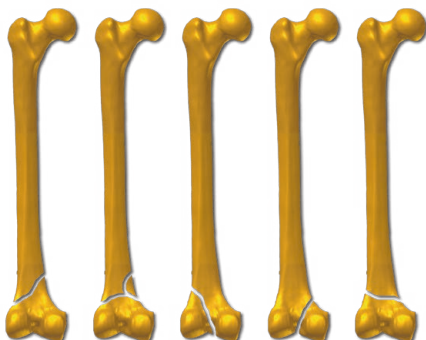
Examples of femoral shaft fractures treated with this method:



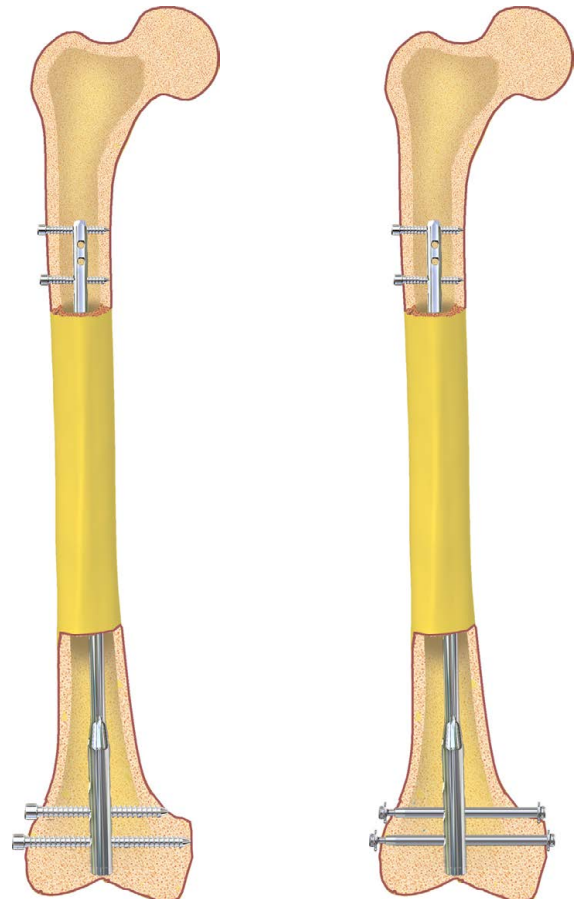
### I.3. RETROGRADE (CONDYLAR APPROACH)

Intramedullary nails with condylar approach enable fixation in the distal part of femur in the case any other method (*reconstruction, compression, dynamic, static*) cannot be used. The reversed method can be used if prosthesis or other implant is located in the femur proximal or in case of condyle multifragmental fracture

Position of the implant in femur:



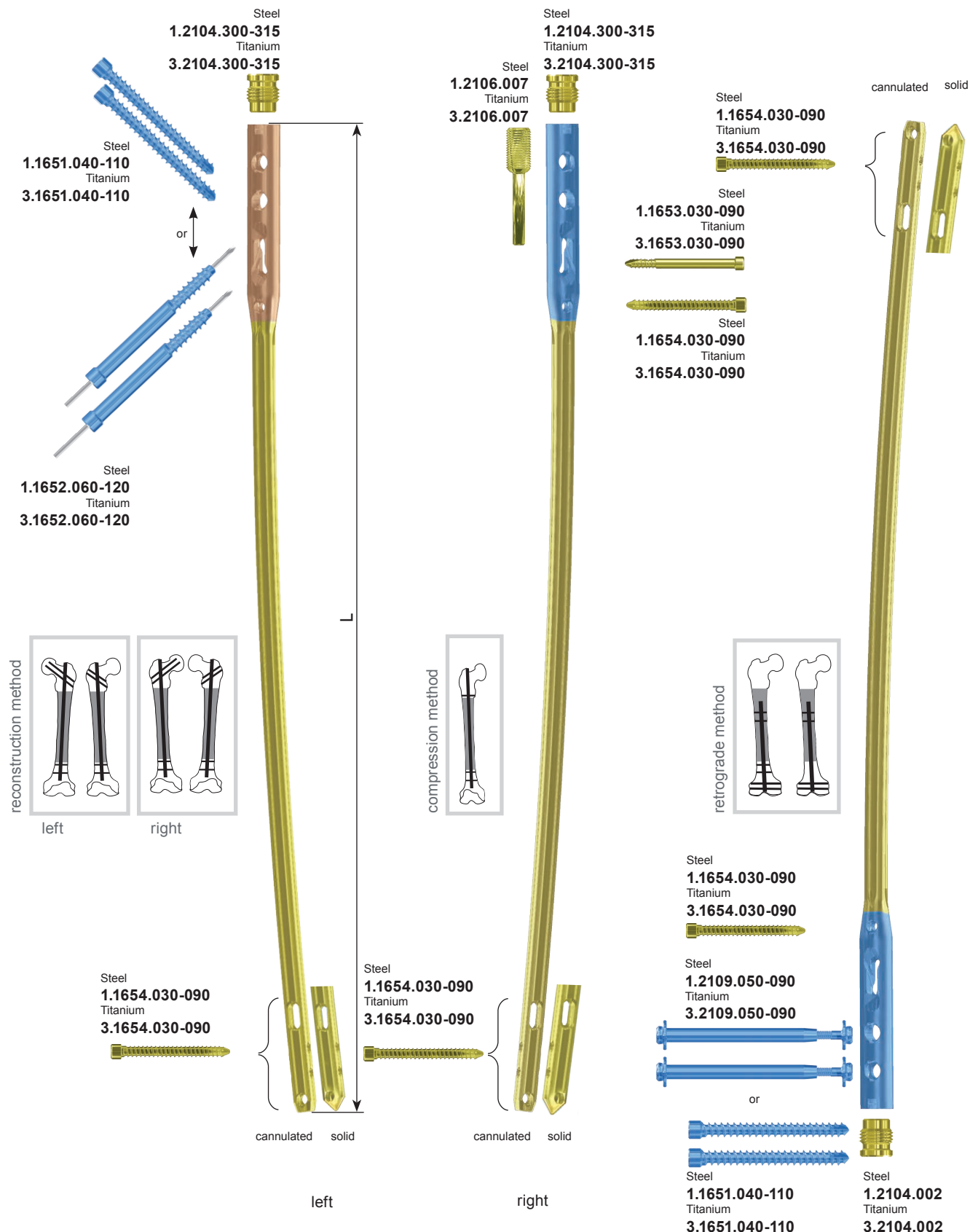
Examples of femoral shaft fractures treated with this method:



## II. IMPLANTS



### II.1. IMPLANTS OF RECONSTRUCTION, COMPRESSION AND RETROGRADE METHOD

#### FEMORAL NAIL





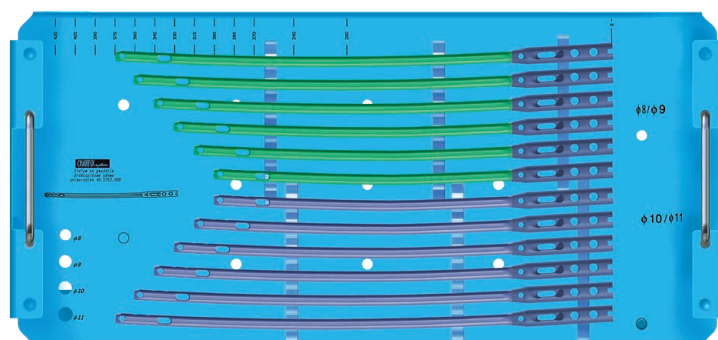
## FEMORAL NAIL

											
		Steel		Titanium				Steel		Titanium	
L [mm]	Ø	left	right	left	right	L [mm]	Ø	left	right	left	right
200	9	1.2855.200	1.2854.200	3.2855.200	3.2854.200	200	12	1.2861.200	1.2860.200	3.2861.200	3.2860.200
220		1.2855.220	1.2854.220	3.2855.220	3.2854.220	220		1.2861.220	1.2860.220	3.2861.220	3.2860.220
240		1.2855.240	1.2854.240	3.2855.240	3.2854.240	240		1.2861.240	1.2860.240	3.2861.240	3.2860.240
260		1.2855.260	1.2854.260	3.2855.260	3.2854.260	260		1.2861.260	1.2860.260	3.2861.260	3.2860.260
280		1.2855.280	1.2854.280	3.2855.280	3.2854.280	280		1.2861.280	1.2860.280	3.2861.280	3.2860.280
300		1.2855.300	1.2854.300	3.2855.300	3.2854.300	300		1.2861.300	1.2860.300	3.2861.300	3.2860.300
320		1.2855.320	1.2854.320	3.2855.320	3.2854.320	320		1.2861.320	1.2860.320	3.2861.320	3.2860.320
340		1.2855.340	1.2854.340	3.2855.340	3.2854.340	340		1.2861.340	1.2860.340	3.2861.340	3.2860.340
360		1.2855.360	1.2854.360	3.2855.360	3.2854.360	360		1.2861.360	1.2860.360	3.2861.360	3.2860.360
380		1.2855.380	1.2854.380	3.2855.380	3.2854.380	380		1.2861.380	1.2860.380	3.2861.380	3.2860.380
400	10	1.2855.400	1.2854.400	3.2855.400	3.2854.400	400	13	1.2861.400	1.2860.400	3.2861.400	3.2860.400
420		1.2855.420	1.2854.420	3.2855.420	3.2854.420	420		1.2861.420	1.2860.420	3.2861.420	3.2860.420
440		1.2855.440	1.2854.440	3.2855.440	3.2854.440	440		1.2861.440	1.2860.440	3.2861.440	3.2860.440
460		1.2855.460	1.2854.460	3.2855.460	3.2854.460	460		1.2861.460	1.2860.460	3.2861.460	3.2860.460
480		1.2855.480	1.2854.480	3.2855.480	3.2854.480	480		1.2861.480	1.2860.480	3.2861.480	3.2860.480
200		1.2857.200	1.2856.200	3.2857.200	3.2856.200	200		1.2863.200	1.2862.200	3.2863.200	3.2862.200
220		1.2857.220	1.2856.220	3.2857.220	3.2856.220	220		1.2863.220	1.2862.220	3.2863.220	3.2862.220
240		1.2857.240	1.2856.240	3.2857.240	3.2856.240	240		1.2863.240	1.2862.240	3.2863.240	3.2862.240
260		1.2857.260	1.2856.260	3.2857.260	3.2856.260	260		1.2863.260	1.2862.260	3.2863.260	3.2862.260
280		1.2857.280	1.2856.280	3.2857.280	3.2856.280	280		1.2863.280	1.2862.280	3.2863.280	3.2862.280
300		1.2857.300	1.2856.300	3.2857.300	3.2856.300	300		1.2863.300	1.2862.300	3.2863.300	3.2862.300
320	11	1.2857.320	1.2856.320	3.2857.320	3.2856.320	320	14	1.2863.320	1.2862.320	3.2863.320	3.2862.320
340		1.2857.340	1.2856.340	3.2857.340	3.2856.340	340		1.2863.340	1.2862.340	3.2863.340	3.2862.340
360		1.2857.360	1.2856.360	3.2857.360	3.2856.360	360		1.2863.360	1.2862.360	3.2863.360	3.2862.360
380		1.2857.380	1.2856.380	3.2857.380	3.2856.380	380		1.2863.380	1.2862.380	3.2863.380	3.2862.380
400		1.2857.400	1.2856.400	3.2857.400	3.2856.400	400		1.2863.400	1.2862.400	3.2863.400	3.2862.400
420		1.2857.420	1.2856.420	3.2857.420	3.2856.420	420		1.2863.420	1.2862.420	3.2863.420	3.2862.420
440		1.2857.440	1.2856.440	3.2857.440	3.2856.440	440		1.2863.440	1.2862.440	3.2863.440	3.2862.440
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480		1.2857.480	1.2856.480	3.2857.480	3.2856.480	480		1.2863.480	1.2862.480	3.2863.480	3.2862.480
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240		1.2859.240	1.2858.240	3.2859.240	3.2858.240	240		1.2865.240	1.2864.240	3.2865.240	3.2864.240
260		1.2859.260	1.2858.260	3.2859.260	3.2858.260	260		1.2865.260	1.2864.260	3.2865.260	3.2864.260
280		1.2859.280	1.2858.280	3.2859.280	3.2858.280	280		1.2865.280	1.2864.280	3.2865.280	3.2864.280
300		1.2859.300	1.2858.300	3.2859.300	3.2858.300	300		1.2865.300	1.2864.300	3.2865.300	3.2864.300
320		1.2859.320	1.2858.320	3.2859.320	3.2858.320	320		1.2865.320	1.2864.320	3.2865.320	3.2864.320
340		1.2859.340	1.2858.340	3.2859.340	3.2858.340	340		1.2865.340	1.2864.340	3.2865.340	3.2864.340
360		1.2859.360	1.2858.360	3.2859.360	3.2858.360	360		1.2865.360	1.2864.360	3.2865.360	3.2864.360
380		1.2859.380	1.2858.380	3.2859.380	3.2858.380	380		1.2865.380	1.2864.380	3.2865.380	3.2864.380
400	13	1.2859.400	1.2858.400	3.2859.400	3.2858.400	400	16	1.2865.400	1.2864.400	3.2865.400	3.2864.400
420		1.2859.420	1.2858.420	3.2859.420	3.2858.420	420		1.2865.420	1.2864.420	3.2865.420	3.2864.420
440		1.2859.440	1.2858.440	3.2859.440	3.2858.440	440		1.2865.440	1.2864.440	3.2865.440	3.2864.440
460		1.2859.460	1.2858.460	3.2859.460	3.2858.460	460		1.2865.460	1.2864.460	3.2865.460	3.2864.460
480		1.2859.480	1.2858.480	3.2859.480	3.2858.480	480		1.2865.480	1.2864.480	3.2865.480	3.2864.480



## FEMORAL NAIL

		Steel		Titanium				Steel		Titanium	
L [mm]	Ø	left	right	left	right	L [mm]	Ø	left	right	left	right
200	8	1.2877.200	1.2876.200	3.2877.200	3.2876.200	200	11	1.2883.200	1.2882.200	3.2883.200	3.2882.200
220		1.2877.220	1.2876.220	3.2877.220	3.2876.220	220		1.2883.220	1.2882.220	3.2883.220	3.2882.220
240		1.2877.240	1.2876.240	3.2877.240	3.2876.240	240		1.2883.240	1.2882.240	3.2883.240	3.2882.240
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300		1.2877.300	1.2876.300	3.2877.300	3.2876.300	300		1.2883.300	1.2882.300	3.2883.300	3.2882.300
320		1.2877.320	1.2876.320	3.2877.320	3.2876.320	320		1.2883.320	1.2882.320	3.2883.320	3.2882.320
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320		1.2879.320	1.2878.320	3.2879.320	3.2878.320	320		1.2885.320	1.2884.320	3.2885.320	3.2884.320
340		1.2879.340	1.2878.340	3.2879.340	3.2878.340	340		1.2885.340	1.2884.340	3.2885.340	3.2884.340
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200	10	1.2881.200	1.2880.200	3.2881.200	3.2880.200	200	13	1.2887.200	1.2886.200	3.2887.200	3.2886.200
220		1.2881.220	1.2880.220	3.2881.220	3.2880.220	220		1.2887.220	1.2886.220	3.2887.220	3.2886.220
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340		1.2881.340	1.2880.340	3.2881.340	3.2880.340	340		1.2887.340	1.2886.340	3.2887.340	3.2886.340
360		1.2881.360	1.2880.360	3.2881.360	3.2880.360	360		1.2887.360	1.2886.360	3.2887.360	3.2886.360
380		1.2881.380	1.2880.380	3.2881.380	3.2880.380	380		1.2887.380	1.2886.380	3.2887.380	3.2886.380
400		1.2881.400	1.2880.400	3.2881.400	3.2880.400	400		1.2887.400	1.2886.400	3.2887.400	3.2886.400
420		1.2881.420	1.2880.420	3.2881.420	3.2880.420	420		1.2887.420	1.2886.420	3.2887.420	3.2886.420
440		1.2881.440	1.2880.440	3.2881.440	3.2880.440	440		1.2887.440	1.2886.440	3.2887.440	3.2886.440
460		1.2881.460	1.2880.460	3.2881.460	3.2880.460	460		1.2887.460	1.2886.460	3.2887.460	3.2886.460
480		1.2881.480	1.2880.480	3.2881.480	3.2880.480	480		1.2887.480	1.2886.480	3.2887.480	3.2886.480



available

Ø[mm] pitch 1 mm	8×15	8×10	11×15
L [mm] pitch 5 mm	160÷600	160÷600	160÷600

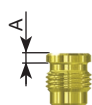
Titanium

	Ø8	Ø9	Ø10	Ø11	Ø12	Ø13
left						
right						
colours						

40.5753.000

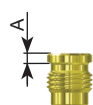
Stand for universal femoral nails (implants not included)

## LOCKING ELEMENTS



End cap M10x1

Catalogue no.		
A	Steel	Titanium
0	1.2104.300	3.2104.300
+5	1.2104.305	3.2104.305
+10	1.2104.310	3.2104.310
+15	1.2104.315	3.2104.315



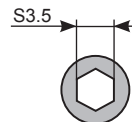
End cap M10x1

Catalogue no.		
A	Steel	Titanium
2	1.2104.002	3.2104.002



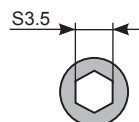
Compression screw

Catalogue no.	
Steel	Titanium
1.2106.007	3.2106.007



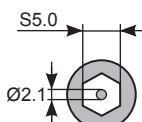
Distal screw Ø4.5

Catalogue no.		
L [mm]	Steel	Titanium
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



Proximal screw Ø4.5

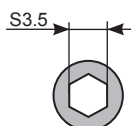
Catalogue no.			
L [mm]	L <sub>1</sub> [mm]	Steel	Titanium
30	12	1.1653.030	3.1653.030
35	16	1.1653.035	3.1653.035
40	16	1.1653.040	3.1653.040
45	16	1.1653.045	3.1653.045
50	18	1.1653.050	3.1653.050
55	18	1.1653.055	3.1653.055
60	18	1.1653.060	3.1653.060
65	20	1.1653.065	3.1653.065
70	20	1.1653.070	3.1653.070
75	20	1.1653.075	3.1653.075
80	22	1.1653.080	3.1653.080
85	22	1.1653.085	3.1653.085
90	22	1.1653.090	3.1653.090
available			
L [mm]	25 ÷ 90		



Reconstruction cannulated screw Ø6.5

Catalogue no.			
L [mm]	L <sub>1</sub> [mm]	Steel	Titanium
60	25	1.1652.060	3.1652.060
65	25	1.1652.065	3.1652.065
70	25	1.1652.070	3.1652.070
75	25	1.1652.075	3.1652.075
80	25	1.1652.080	3.1652.080
85	25	1.1652.085	3.1652.085
90	25	1.1652.090	3.1652.090
95	32	1.1652.095	3.1652.095
100	32	1.1652.100	3.1652.100
105	32	1.1652.105	3.1652.105
110	32	1.1652.110	3.1652.110
115	32	1.1652.115	3.1652.115
120	32	1.1652.120	3.1652.120

available	
L [mm]	16 ÷ 100



Distal screw Ø6.5

Catalogue no.		
L [mm]	Steel	Titanium
40	1.1651.040	3.1651.040
45	1.1651.045	3.1651.045
50	1.1651.050	3.1651.050
55	1.1651.055	3.1651.055
60	1.1651.060	3.1651.060
65	1.1651.065	3.1651.065
70	1.1651.070	3.1651.070
75	1.1651.075	3.1651.075
80	1.1651.080	3.1651.080
85	1.1651.085	3.1651.085
90	1.1651.090	3.1651.090
95	1.1651.095	3.1651.095
100	1.1651.100	3.1651.100
105	1.1651.105	3.1651.105
110	1.1651.110	3.1651.110

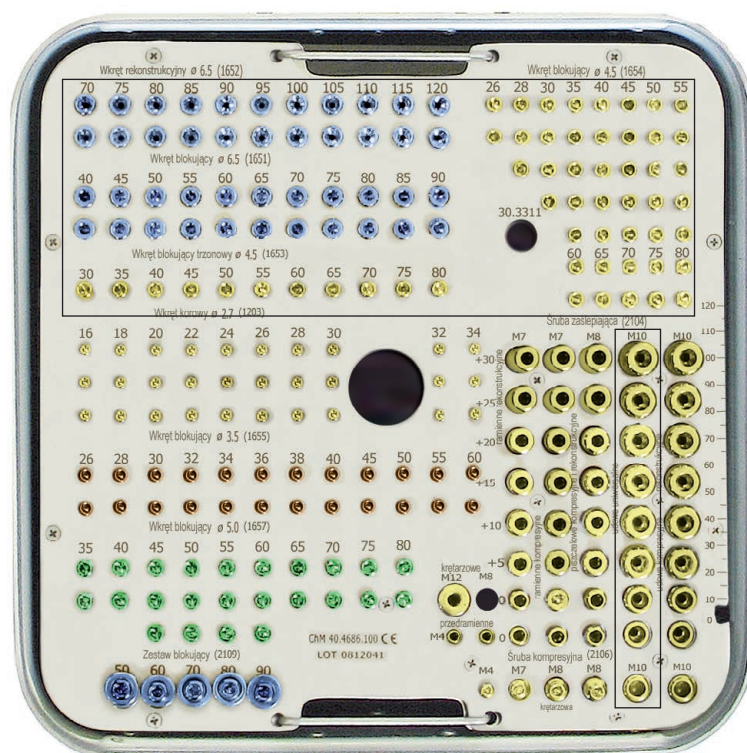
available	
L [mm]	30 ÷ 110

Locking set Ø6.5



Catalogue no.			
L [mm]	Range	Steel	Titanium
50	50-65[mm]	1.2109.050	3.2109.050
60	60-75[mm]	1.2109.060	3.2109.060
70	70-85[mm]	1.2109.070	3.2109.070
80	80-95[mm]	1.2109.080	3.2109.080
90	90-105[mm]	1.2109.090	3.2109.090

## LOCKING ELEMENTS

**40.4686.000**

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

### III. INSTRUMENT SET















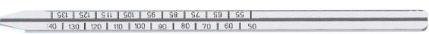









#### III.1. INTRODUCTION


Fixation of the femoral fractures with reconstruction, compression, dynamic or static method is carried out with single instrument set. When using the above mentioned methods, it is also required to have at your disposal a set of flexible intramedullary reamers in following diameters: 8 [40.3854], 8.5 [40.3855], 9 [40.3856], 9.5 [40.3857], 10 [40.3858], 10.5 [40.3859], 11 [40.3860], 11.5 [40.3861], 12 [40.3862], 12.5 [40.3863], 13 [40.3864], 13.5 [40.3865], 14 [40.3866], 14.5 [40.3867], 15 [40.3868] and surgical drive or handle for manual reaming. The operation is to be performed on operating table equipped with the X-Ray image intensifier.

#### III.2. INSTRUMENT SET FOR RECONSTRUCTION, COMPRESSION AND RETROGRADE METHOD [40.5090.500]

The set of instruments and devices are placed on a stand with a lid to enable sterilization and transportation to the operating suite.

No.		Name	Catalogue no.	Pcs.
1		Targeter arm	40.5091.000	1
2		Targeter 135	40.5097.000	1
3		Distal target D	40.5093.000	1
4		Connecting screw M10x1 L=55	40.5094.000	1
5		Connecting screw M10x1 L=66	40.5095.000	1
6		Compression screw	40.5096.000	1
7		Nail length measure	40.5098.000	1
8		Trocax 9	40.3327.000	1
9		Protective guide 11/9	40.3328.000	2
10		Drill guide 9/6.5	40.3329.000	1
11		Drill guide 9/4.5	40.3330.000	1
12		Kirschner guide	40.3331.000	1
13		Reconstruction screw length measure	40.3332.000	1
14		Kirschner wire 2.0/380	40.3333.000	4
15		Protective guide 9/6.5	40.3614.000	2
16		Drill guide 6.5/3.5	40.3615.000	2
17		Set block 9/4.5	40.3616.000	2
18		Trocax 6.5	40.3617.000	1
19		Drill guide 6.5/4.5	40.3696.000	1
20		Screw length measure	40.1374.000	1

No.		Name	Catalogue no.	Pcs.
21		Curved awl 8.0	40.5523.000	1
22		Impactor-extractor	40.5507.000	1
23		Mallet	40.3667.000	1
24		Connector	40.5071.000	1
25		Wrench S10	40.5526.100	1
26		Teflon pipe guide	40.1348.000	1
27		Guide rod 3.0/580	40.3925.580	1
28		Guide rod handle	40.1351.000	1
29		Screwdriver S 3.5	40.3604.000	1
30		Drill with scale 4.5/370	40.5333.001	1
31		Drill with scale 3.5/270	40.5330.001	2
32		Drill 6.5/370	40.2068.371	1
33		Cannulated drill 6.5/300	40.3674.000	1
34		Cannulated screwdriver S 5.0/2.2	40.3675.000	1
35		Cannulated screw length measure	40.3676.000	1
36		Aiming insert 9.0	40.5065.009	2
37		Aiming insert 11.0	40.5065.011	2
38		Screwdriver S3.5	40.5074.000	1
39		Bolt guide	40.5075.000	1
40		Drill 4.5/270	40.1387.001	1
41		Targeter D	40.1344.000	1
42		Drill guide short 7/3.5	40.1358.000	1
43		Trocar short 7	40.1354.000	1
44		Protective guide 11/9	40.3662.000	1

No.		Name	Catalogue no.	Pcs.
45		Stand	40.5099.500	1

## IV. SURGICAL TECHNIQUE

### IV.1. METHODS: RECONSTRUCTION, COMPRESSION, DYNAMIC, STATIC

#### IV.1.1. Introduction

Tightly fitting the medullary canal is not necessary if the locking nail is used. In case of placing the nail without reaming the canal the following diameters 8, 9, 10, 11 mm of the nail should be used. Nails with diameter 12, 13, 14 are used in the cases where reaming has to be done.

Please note, that the diameter of reamed canal has to be about 2mm wider than the diameter of the nail.

In every case, a hole is to be made in proximal part of the femur, 13 mm in diameter for the nails sizes 8, 9, 10, 11, 12, 13 mm or 14 mm in diameter for the nail 14 mm, and to 8 cm in depth.

It enables a free insertion of a thicker proximal part of the nail. Decision about possible reaming after verifying the shape of canal and type of fracture shall be made by the surgeon.

Reaming of medullary canal is not recommended for patients with chest injuries due to the risk of fat embolism.

When patient cannot be operated at the day of femoral fracture, it is recommended to apply strong traction for 2 to 3 days to spread the fragments. This considerably enables fracture reduction and nail insertion.

Placing patient on table with traction is integral part of the surgery.

Presented method of intramedullary osteosynthesis requires radiological examination.

Each surgical procedure must be carefully planned. X-Ray of the entire femur is essential as to make sure no injuries in its proximal or distal part are overlooked.

It is especially important in cases of nailing the pathological subtrochanteric fractures. Special attention is to be paid to concurrent femoral neck fractures or proximal epiphysis multi-fragmental fractures, and to the possibility of theirs occurrence during the procedure of nail insertion. During the operation secondary fractures of main fragments may occur.

In such cases the dynamic stabilization has to be replaced by a static one.

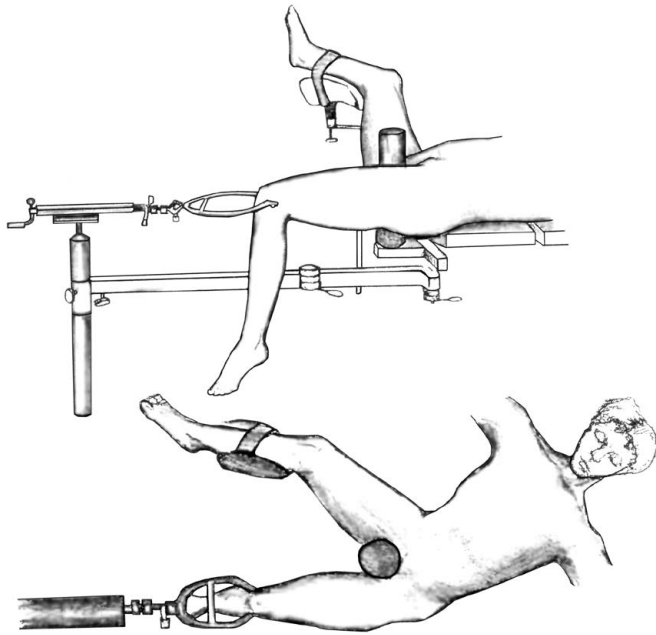
The condition of the hip joint is also very important. In advanced arthrosis or contracture fixation may be difficult or even impossible to perform.

In addition, it should be verify whether alloplasty of hip or knee has ever been performed on the fractured bone. The procedure has to be carried out on the operating table with traction with the patient placed supine or on the side. The side position enables the approach to the greater trochanter, which is especially important with overweight patients.

The supine position provides less favorable access to the greater trochanter, but makes all other stages of the operation considerably easier (*especially rotary corrections*).



In the presented method the supine position is recommended with traction applied behind the condyles of the operated femur.

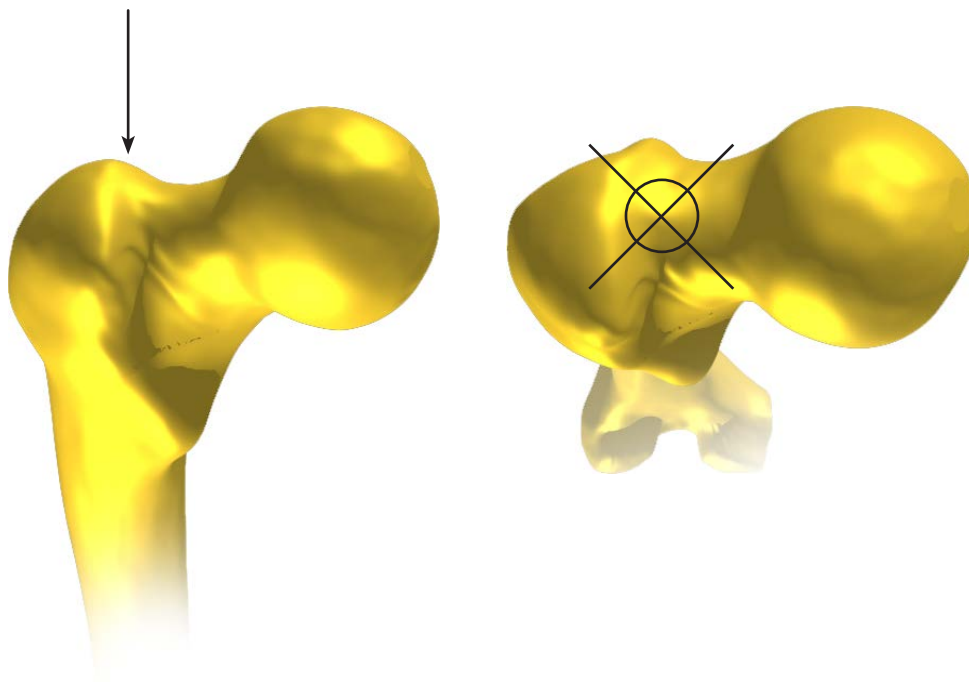


**FIG. 1.** Supine position for intramedullary osteosynthesis of femur.

Lateral surgical approach shall be applied, starting the incision near the tip of greater trochanter in line with the femoral shaft axis for 8cm. The incision should be longer for overweight patients. The fascia should be cut in the same direction as the incision. Fibers of greater gluteal muscle are then split, as to provide an approach to the tip of greater trochanter. The entry point for the nail should be located in line with the axis of medullary canal. It can be found in practice in the following way.

If one finds the tip of greater trochanter with his index finger, the entry point is “a little bit medially” (*in the direction to the base of the femoral neck*) and “slightly anteriorly”, in a place where one should feel small dale (*fossa piriformis*) with his index finger (see Fig. 2).

**FIG. 2** Entry point for femoral nail.

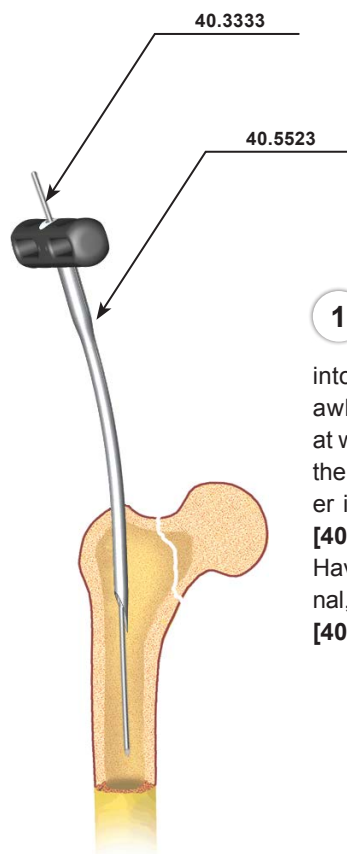




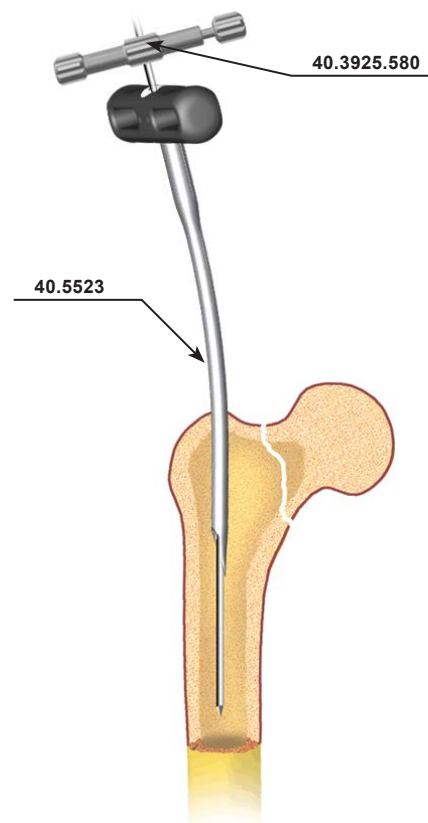
**ATTENTION!** The following paragraphs describe most important steps during insertion of intramedullary interlocking femoral nails nevertheless it is not a detailed instructions for use. The surgeon decides about choosing the surgical technique and its application in each individual case.

The physician uses images of both fractured and healthy femur to determine the length, type and diameter of the nail.

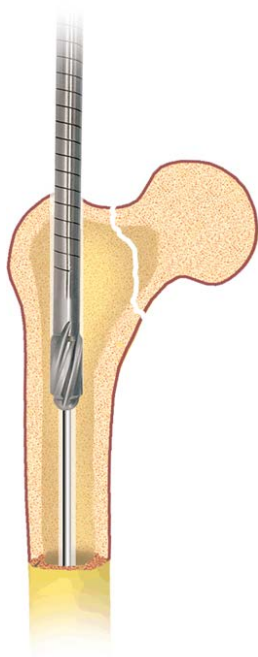
#### IV.1.2. Preparation of medullary canal and nail insertion.



- 1 Using Kirschner wire 2.0/380 [40.3333], insert into the medullary canal Curved awl 8.0 [40.5523] to the depth at which the Awl blade goes along the medullary canal, allowing proper insertion of Guide rod 3.0/580 [40.3925.580]. Having opened the medullary canal, remove Kirschner wire 2.0/380 [40.3333].



- 2 Mount Guide rod 3.0/580 [40.3925.580] to Guide rod handle [40.1351] and enter the guide into the medullary canal through Curved awl 8.0 [40.5523] cannulated hole to the depth required for the proper fixation of bone fragments. While guide rod insertion, control the fracture reduction and make sure the guide rod passes through all the bone fragments. Remove Guide rod handle [40.1351] and Curved awl 8.0 [40.5523]. Leave Guide rod 3.0/580 [40.3925.580] in place.



- 3 In case medullary canal is reamed, gradually increase the diameter with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the femoral nail is reached, for the depth at least equal to the nail length (*but not lesser*). In both cases when the medullary canal was reamed or not the canal should be reamed using 13 or 14 reamer to the depth of approx. 8 cm

Remove the Flexible Reamer.

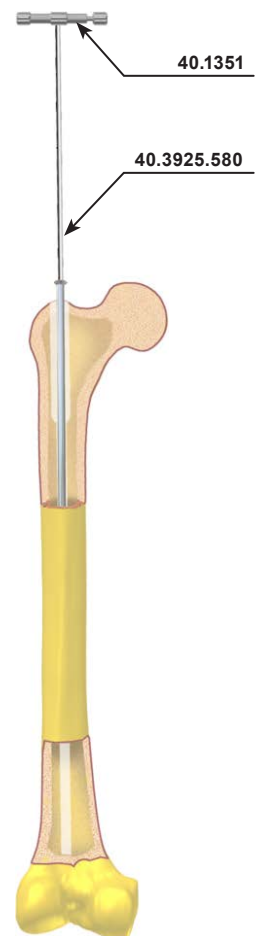


**NOTE!** Steps [4] and [5] are applicable only if the medullary canal has been reamed or if another reamer guide has been used. Otherwise go directly to the step [6].



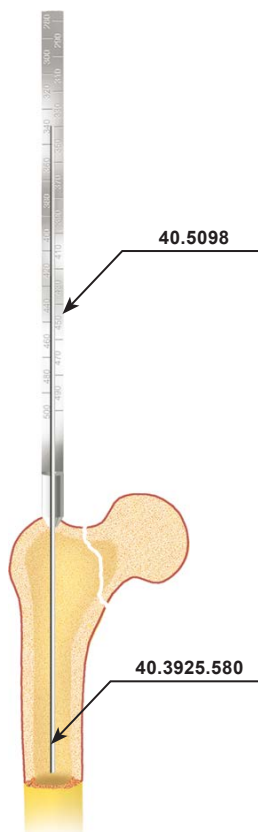
- 4** When using a guide wire which is not included in the instrument set provided, replace it with a guide wire [40.3925.580]. Insert the Teflon Pipe Guide [40.1348] onto the flexible reamer guide until it reaches the end of medullary canal in distal femur.

Remove the Flexible Reamer Guide.



- 5** Mount the Guide rod handle [40.1351] on the Guide Rod 3.0/580 [40.3925] and advance into the Teflon Pipe Guide until its tip reaches the distal epiphysis.

Remove the the Guide rod handle [40.1351].  
Remove the Teflon Pipe Guide [40.1348].



- 6** Insert the Nail Length Measure [40.5098] via the Guide Rod until it rests on the bone. Read the length on the nail measure to assess the length of intramedullary nail. Remove the Nail Length Measure from the Guide Rod. In case of using the solid nail, remove the Guide Rod. Medullary canal is ready for nail insertion.

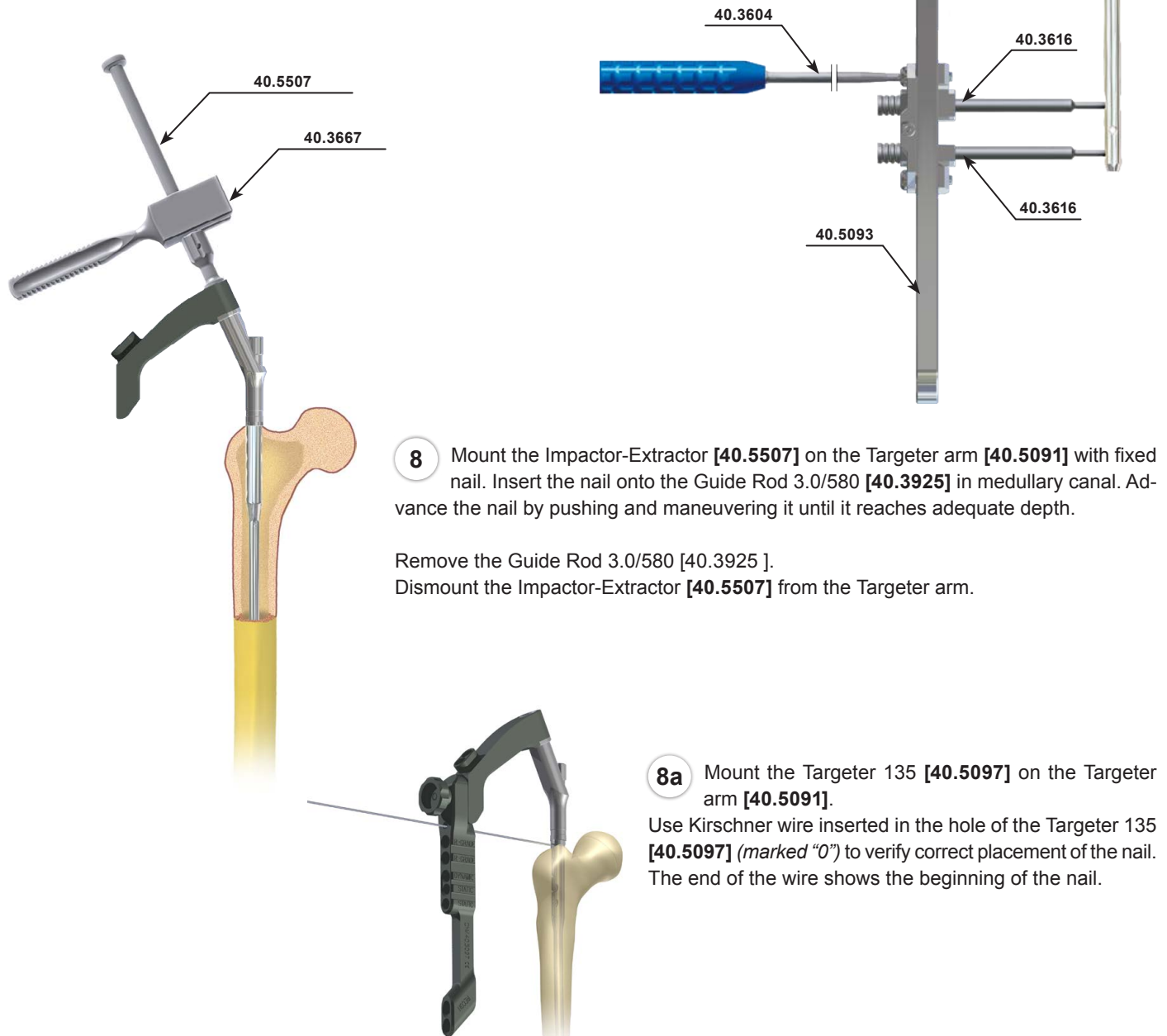
- 7 Use the connecting screw:
- [40.5095] in case of using reconstruction and compression nail,
  - [40.5094] in case of using universal nail with the Wrench S10 [40.5526.100], to fix the intramedullary nail to the Targeter arm [40.5091].

Fix the Distal targeter D [40.5093] to the Targeter arm. With a pair of the Set Blocks 9/4.5 [40.3616] place the slider of the Distal targeter D in line with distal locking holes of intramedullary nail in its distal part. Secure the slider of the Distal targeter using the Screwdriver S3.5 [40.3604].



**CHECK:**  
Properly set and secured slider of the Distal targeter D makes it possible to set the Set Blocks 9/4.5 into the holes of the nail easily.

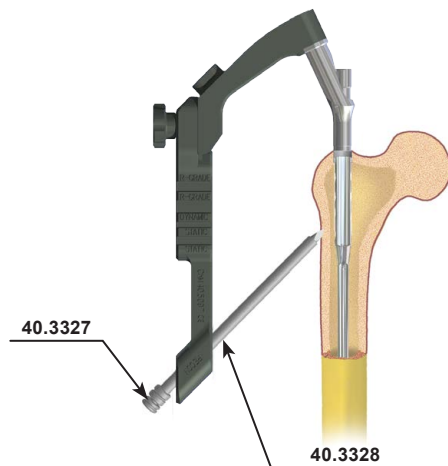
Remove the Set Blocks 9/4.5 from the targeter.  
Dismount the Distal targeter D [40.5093] off the Targeter arm [40.5091].



## IV.2. RECONSTRUCTION METHOD

### IV.2.1. Proximal locking of nail

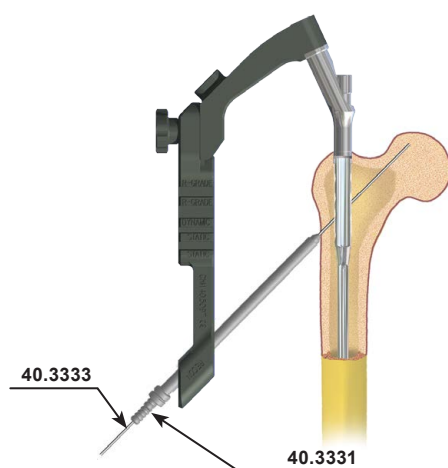
#### IV.2.1.A. **OPTION I: Locking with reconstruction screws**



- 9 Mount the Targeter 135 [40.5097] onto the Targeter arm [40.5091]. Insert the Protective Guide 11/9 [40.3328] with the Trocar 9 [40.3327] into the first proximal hole of the Targeter 135 [40.5097]. Mark on the skin the entry point for screws and make adequate incision of the soft tissues.

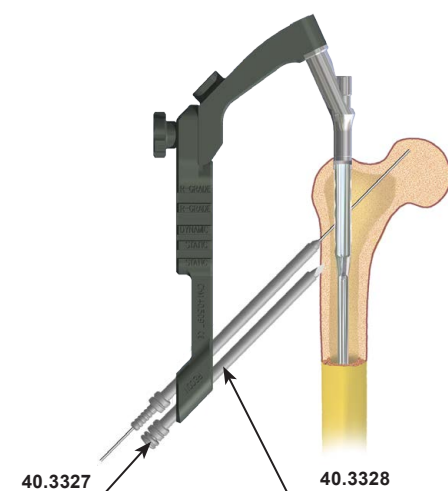
Advance the trocar until it reaches the cortex bone and mark the entry point for the drill. Simultaneously advance the Protective Guide together with the Trocar until its tip rests on the cortex bone.

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



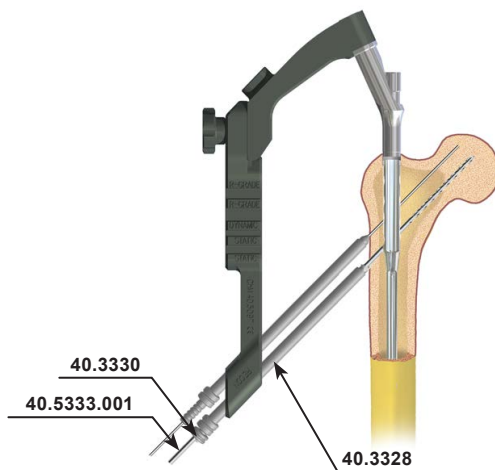
- 10 Insert Kirschner Guide [40.3331] into the Protective Guide. Mount Kirschner wire 2.0/380 [40.3333] on the surgical drive and place KW into the femoral neck but do not perforate the femoral head. The above steps should be controlled with X-Ray (*image in the drawing plane*). Verify the position of KW in the lateral view. The wire should be in the middle of the neck, deviation is acceptable if allows the screw insertion without damaging outer cortex of the neck. In case of mis-positioning of the wire, repeat the step.

Leave: Kirschner Guide, Protective Guide and Kirschner wire in place.



- 11 Insert the Protective Guide 11/9 [40.3328] with the Trocar 9 [40.3327] into the second hole in the Targeter 135 [40.5097]. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

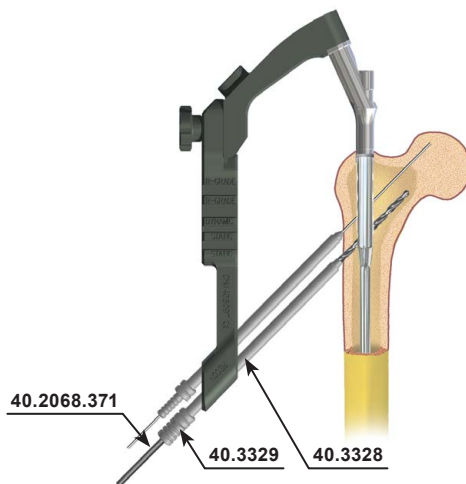
Remove the Trocar.  
Leave the Protective Guide in the hole.



- 12** Insert the Drill Guide 9/4.5 [40.3330] (with two grooves on the handle) into the Protective Guide 11/9 [40.3328] into the second hole of the targeter. Mount the Drill With Scale 4.5/370 [40.5333.001] on the surgical drive and advance it through the drill guide.

Drill the hole in the femoral neck (*through the proximal hole in the nail*) until it reaches adequate depth, but do not perforate the head. The scale on the Drill shows length of the locking element. Control the drilling process with the X-Ray image intensifier.

Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.

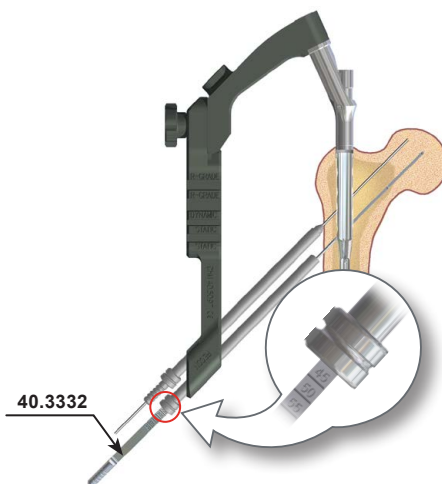


- 13** Insert the Drill Guide 9/6.5 [40.3329] (with three grooves) into the Protective Guide 11/9 [40.3328]. Mount the Drill 6.5/370 [40.2068.371] on the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the depth lesser approx. 30mm than before drilled hole with 4.5 drill (*due to the length of the thread of the reconstruction screw*).



Control the drilling process with the X-Ray image intensifier.

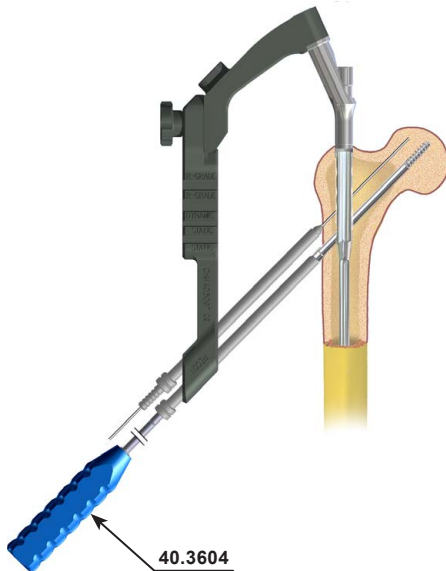
Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.



- 14** Insert the Reconstruction Screw Length Measure [40.3332] through the Protective Guide into the drilled hole until it reaches its end. Read the length of the reconstruction screw on the measure. During the measurement the end of the Protective Guide should rest on the cortex bone.

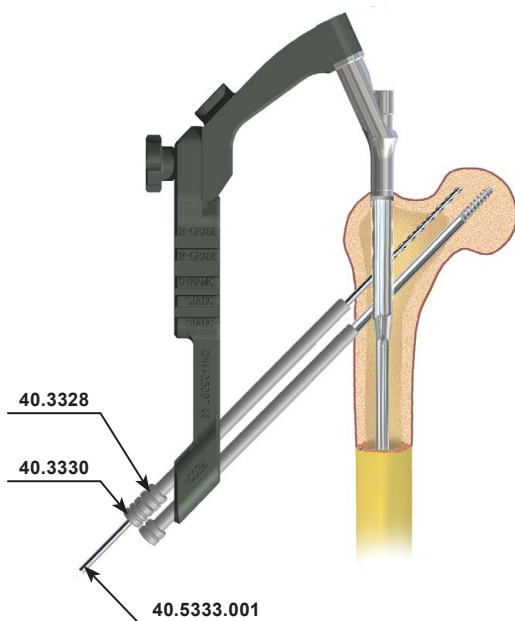
Remove the Screw Length Measure.  
Leave the Protective Guide in the hole of targeter.





- 15** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected reconstruction screw. Then advance both into the Protective Guide. Insert the reconstruction screw in the prepared hole until the head of the screw reaches the cortex bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the Screwdriver.

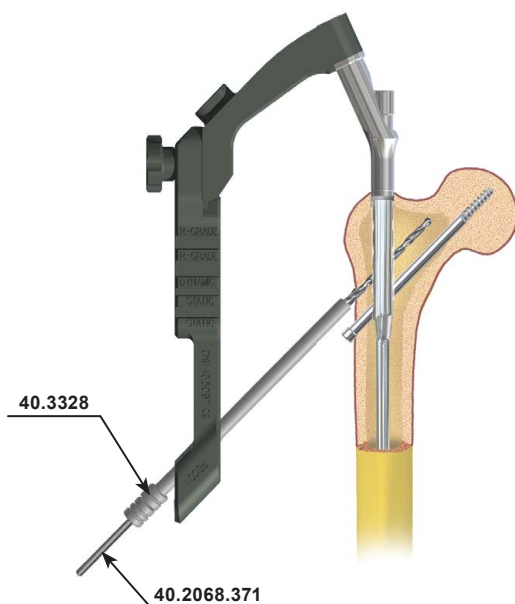


- 16** Remove Kirschner wire and Kirschner Guide from the Protective Guide 11/9 [40.3328]. Insert the Drill Guide 9/4.5 [40.3330] (*with two grooves on the handle*) into the Protective Guide 11/9 [40.3328] (*with one groove*) left in hole of the targeter. Mount the Drill With Scale 4.5/370 [40.5333.001] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral neck (*through the proximal hole in the nail*) until it reaches adequate depth, but do not perforate the head. The scale on the drill shows the length of the locking element.



Control the drilling process with the X-Ray image intensifier.

Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.



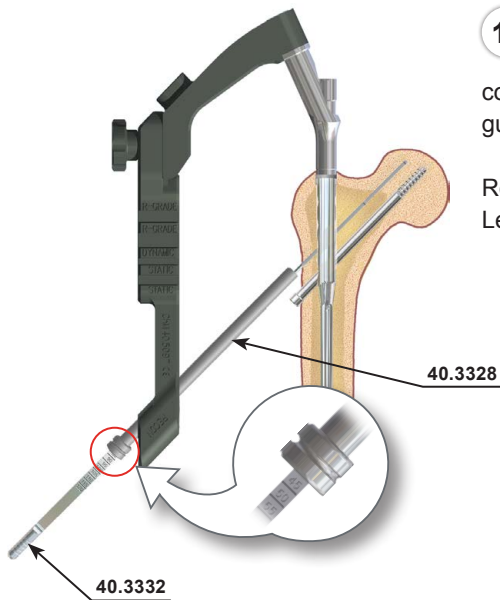
- 17** Insert the Drill Guide 9/6.5 [40.3329] (*with three grooves*) into the Protective Guide. Mount the Drill 6.5/370 [40.2068.371] on the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the lesser depth approx 30mm than before drilled hole with 4.5 drill (*due to the length of the thread on the reconstruction screw*).



Control the drilling process with the X-Ray image intensifier.

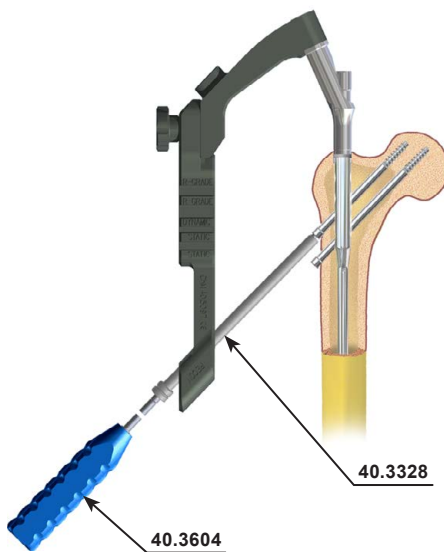
Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.





- 18** Insert the Reconstruction Screw Length Measure [40.3332] through the Protective Guide into the drilled hole until it reaches its end. Read the length of the reconstruction screw on the measure. During the measurement the end of the protective guide should rest on the cortex bone.

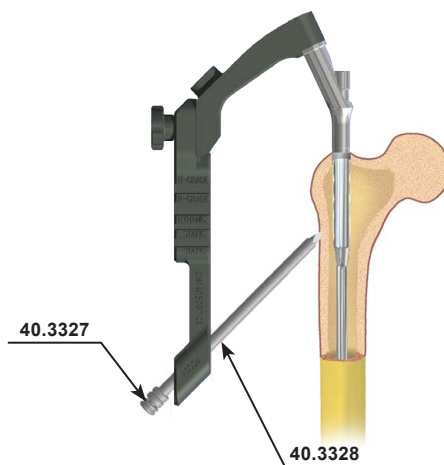
Remove the Screw Length Gauge.  
Leave the Protective Guide in the hole of targeter.



- 19** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected reconstruction screw. Then advance both into the Protective Guide. Insert the reconstruction screw in the prepared hole until the head of the screw reaches the cortex bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

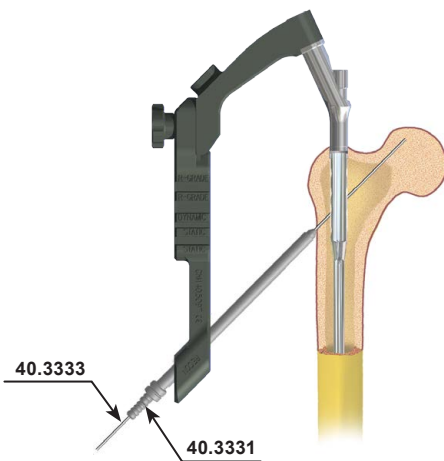
Remove the Screwdriver S3.5 and Protective Guide.

#### IV.2.1.B. **OPTION II:** Locking with reconstruction cannulated screws



- 20** Insert the Protective Guide 11/9 [40.3328] with the Trocar 9 [40.3327] into the first proximal hole in the Targeter 135 [40.5097]. Mark the entry point for the trocar and make the adequate incision of the soft tissues. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

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

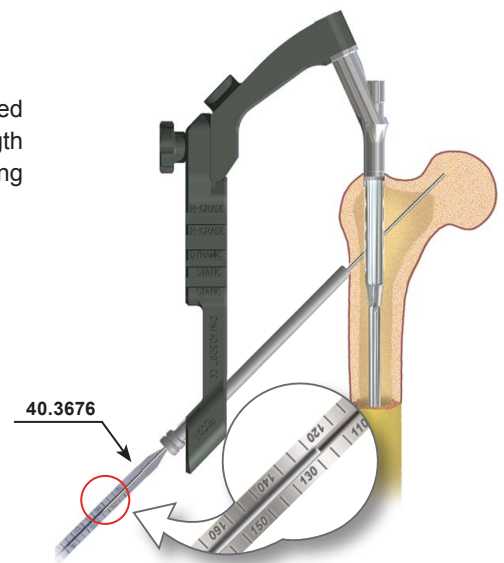


- 21** Insert Kirschner Guide **[40.3331]** and Kirschner Wire 2.0/380 **[40.3333]** into the Protective Guide 11/9 **[40.3328]**. Mount KW in the surgical drive and advance into the femoral neck but do not perforate the femoral head. The above step should be controlled with X-Ray (*image in the drawing plane*). Verify the position of KW in the lateral view. KW should be in the middle of the neck, deviation is acceptable if allows screw to be inserted without damaging outer cortex of the neck. Use Kirschner Wire 2.0/380 **[40.3333]**. In case of mis-positioning the wire, repeat this step.

Remove Kirschner guide.  
Leave Kirschner wire.

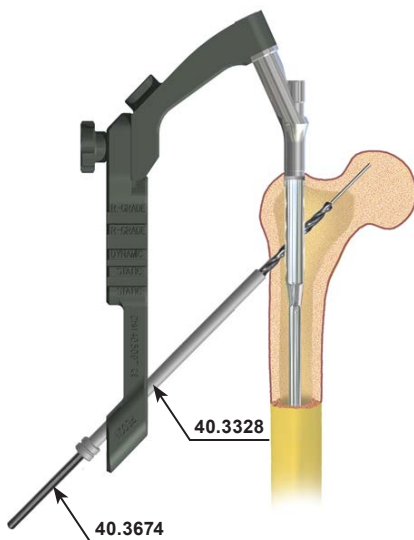
- 22** Insert the Cannulated screw length measure **[40.3676]** onto Kirschner wire drilled into the femoral neck until its tip touches the Protective Guide. Read the length of the reconstruction cannulated screw defined by the end of Kirschner wire. During the measurement the end of the measure should rest on the cortex bone.

Remove the Cannulated screw length measure.  
Leave Kirschner wire.



- 23** Mount the Cannulated Drill 6.5 **[40.3674]** on the surgical drive and advance via Kirschner wire mounted in the femoral neck. Drill the hole through the first cortex (up to the nail placed in medullary canal).

Remove the Cannulated Drill.  
Leave Kirschner Wire.

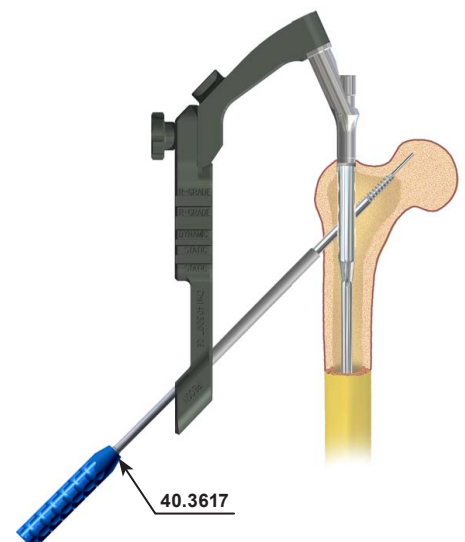


- 24** Insert the selected reconstruction cannulated screw onto Kirschner wire. Advance the Cannulated Screwdriver **[40.3675]** onto Kirschner wire going through the proximal hole of the nail and advance the reconstruction cannulated screw until its head reaches cortex bone.

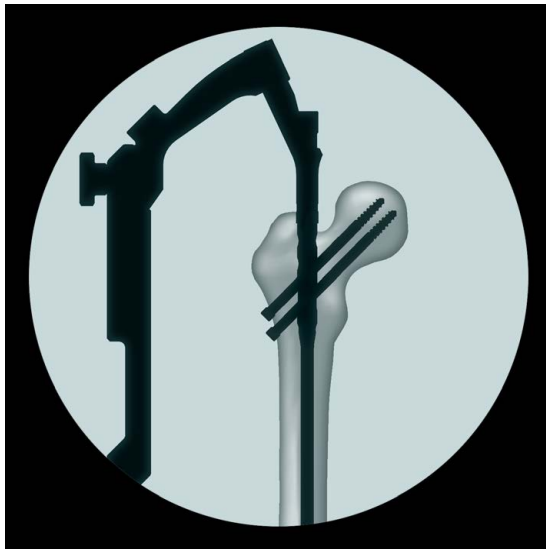
Remove the Screwdriver and Kirschner Wire.  
Kirschner wire is single use instrument.



**NOTE!** To insert second reconstruction screw into the second hole in targeter, repeat steps [21] to [24].



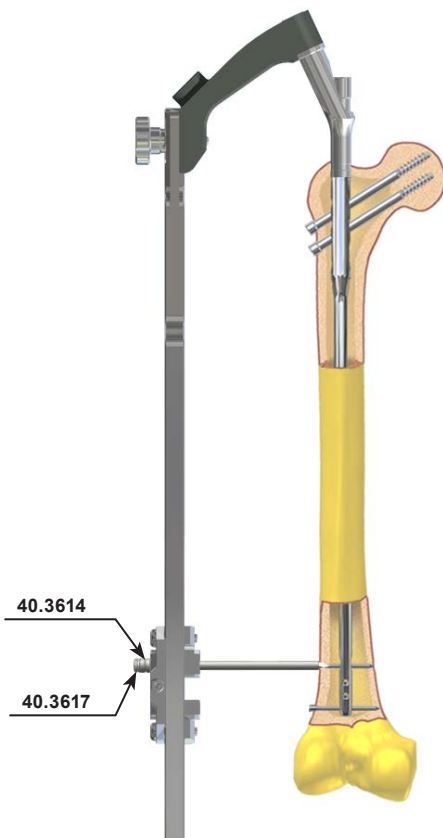
Correctness of femoral neck fixation should be verified by taking X-Ray in two projections. Small overall dimensions of the Targeter 135 which is additionally angled of antetorsion angle allows for taking X-Ray in lateral position (*C-arm is then positioned at small angle in relation to targeter position*). Nail with its locking elements both seen at radiological image can be helpful in confirming the correctness of locking.



#### IV.2.2. Distal locking of the nail

Before continuing steps connected with distal locking of the nail, do the following:

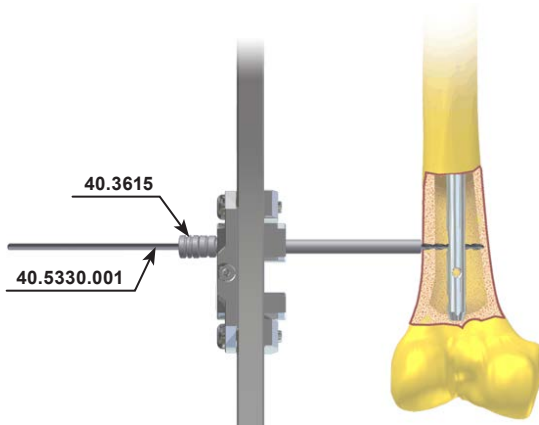
1. Mount the Distal targeter D [40.5093] on the Targeter arm [40.5091] and secure it with a locknut (*provided with the targeter*). If properly installed, the signs RIGHT or LEFT on both targeters should comply.
2. Verify with the X-Ray the position of holes in the nail and in the targeter slider. The centers of the holes in nail and targeter have to be in line.



- 25** Insert the Protective Guide 9/6.5 [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the proximal slider hole of distal targeter. Mark the entry point and make the adequate incision of the soft tissues. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

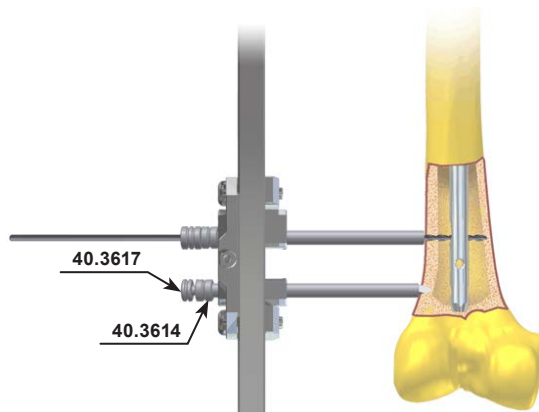
Remove the Trocar.

Leave the Protective Guide in the hole of the targeter.



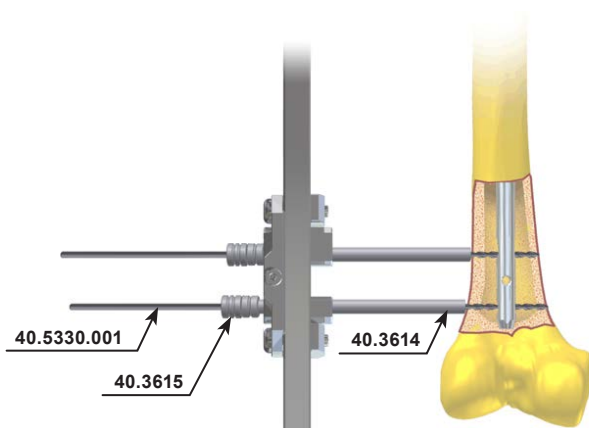
- 26** Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the Protective Guide left in the slider hole. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Disconnect the drive off the drill and leave in system: protective guide-drill guide-drill.



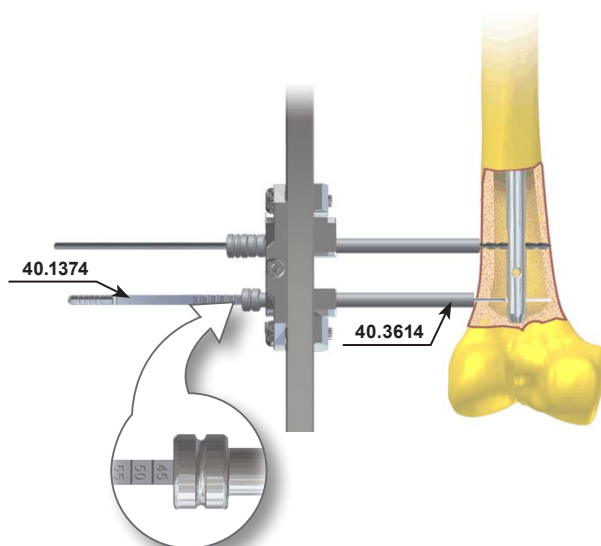
- 27** Insert the Protective Guide [40.3614] (with one groove) with the Trocar 6.5 [40.3617] into the second slider hole of distal targeter. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

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



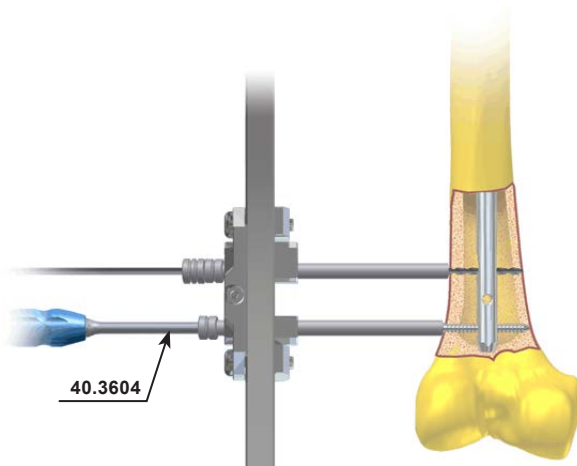
- 28** Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the Protective Guide [40.3614]. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the Drill Guide. Drill the hole in the femoral shaft through both cortex layers and the nail hole. The scale on the drill shows length of the locking element.

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



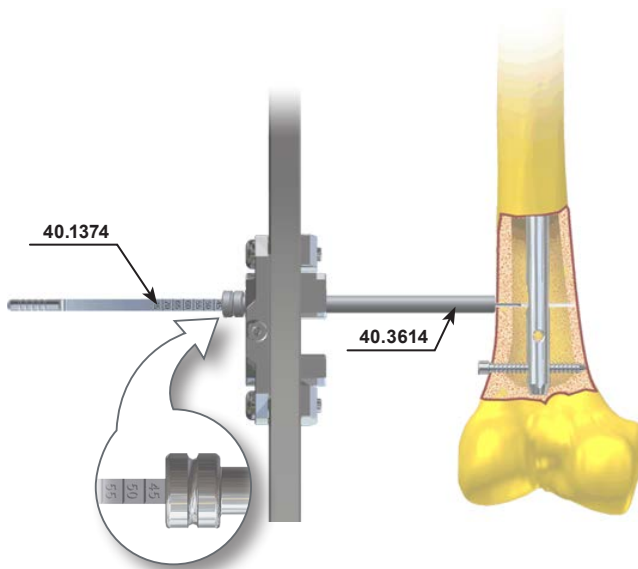
- 29** Insert the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the measure. During the measurement the tip of Protective Guide should rest on the cortex bone.

Remove the Screw Length Measure.  
Leave the Protective Guide in place.



- 30** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into prepared hole until the head of the screw reaches the cortex bone *(the groove on the screwdriver shaft matches the edge of the Protective Guide)*.

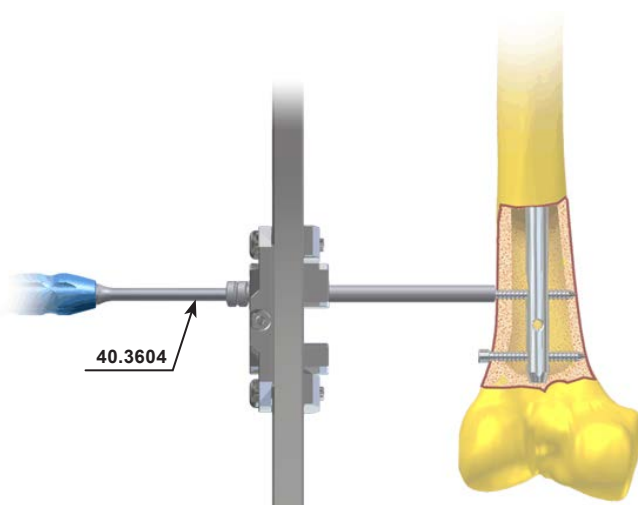
Remove the Screwdriver and Protective Guide.



- 31** Remove the Drill and Drill Guide from proximal hole in the slider of the targeter. Leave the Protective Guide in the hole of the slider. Insert the Screw Length Measure [40.1374] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the measure. During the measurement the Protective Guide should rest on the cortex bone.

Remove the Screw Length Measure.

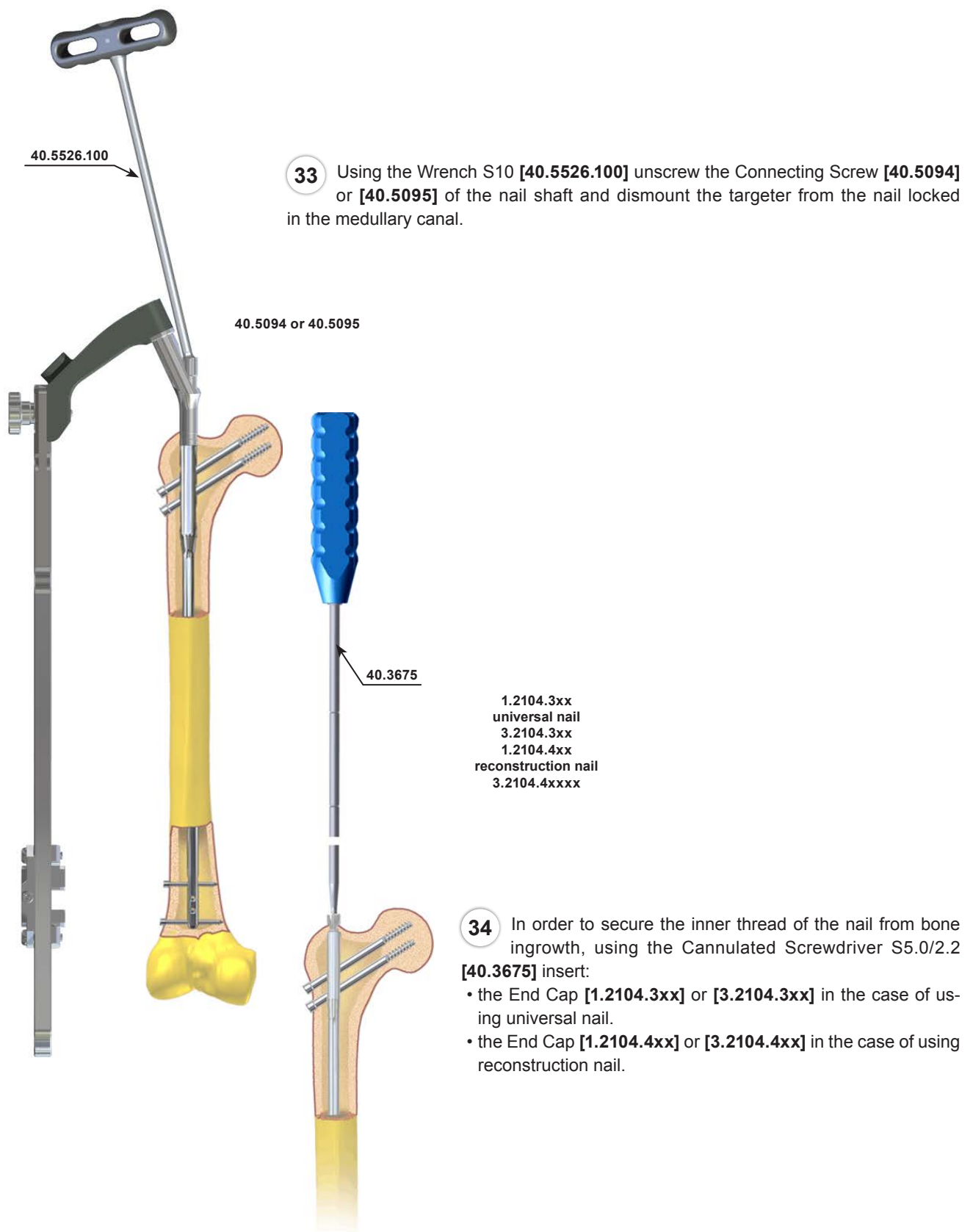
Leave the Protective Guide in slider hole of the targeter.



- 32** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into the prepared hole until the head of the screw reaches the cortex bone *(the groove on the screwdriver shaft matches the edge of the Protective Guide)*.

Remove the Screwdriver S3.5 and the Protective Guide.

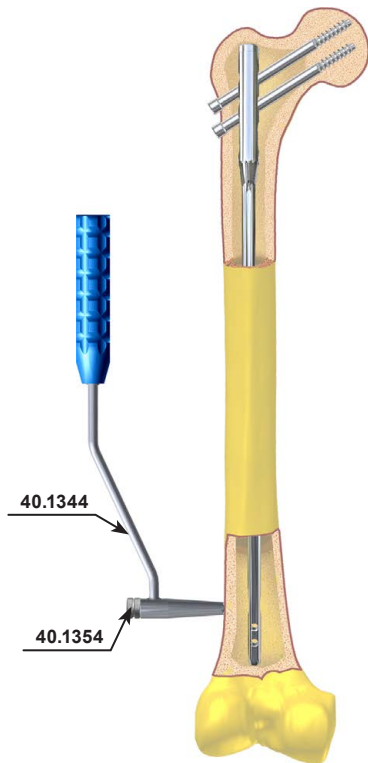
## IV.2.3. Targeter removal, placing end cap





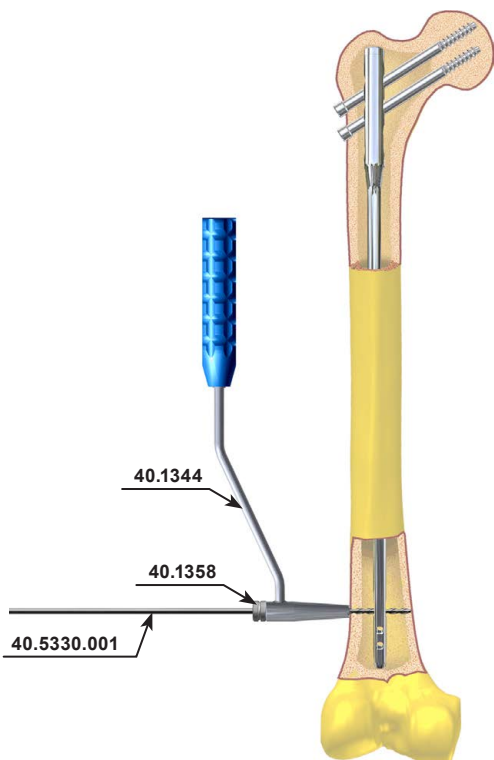
#### IV.2.4. Distal locking of the nail “freehand technique”

With this technique the X-Ray is used to identify the entry points for the drills and to control the drilling process. It is recommended to use angular attachment with the surgical drive while drilling, so that surgeon's hands are not directly exposed to X-Ray. After marking the entry points on the skin, incisions shall be made in the marked places through the soft tissues, each about 1.5cm in length.



- 35** Using X-Ray place the Targeter D [40.1344] in the line with the nail hole. The centers of the holes in the targeter and nail have to match. The teeth of the Targeter D have to be merged in the cortex. Insert the Short Trocar 7 [40.1354] into the hole in targeter, then advance until it reaches cortex and mark the entry point for the drill.

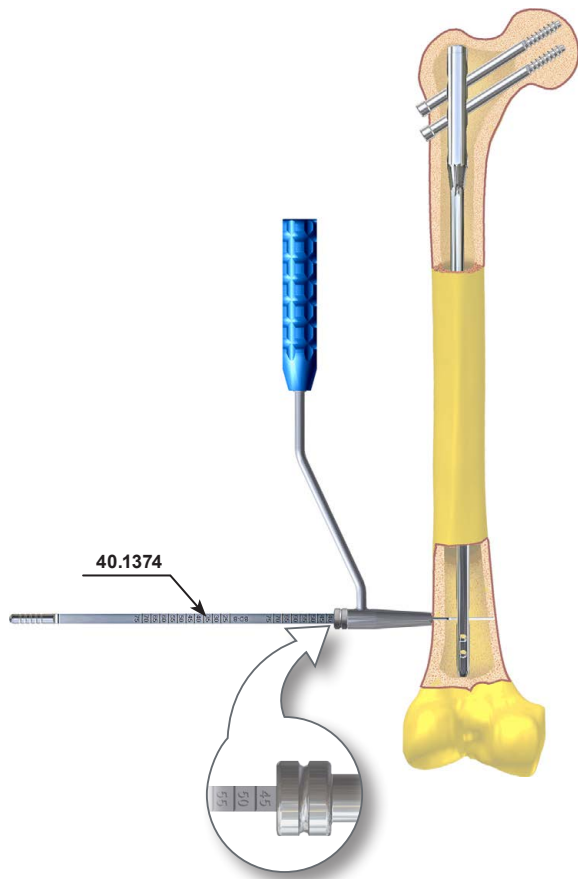
Remove the Trocar.  
Leave the Targeter D.



- 36** Insert the Drill Guide Short 7/3.5 [40.1358] into the targeter hole. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the nail hole. The scale on the drill shows length of the locking element.

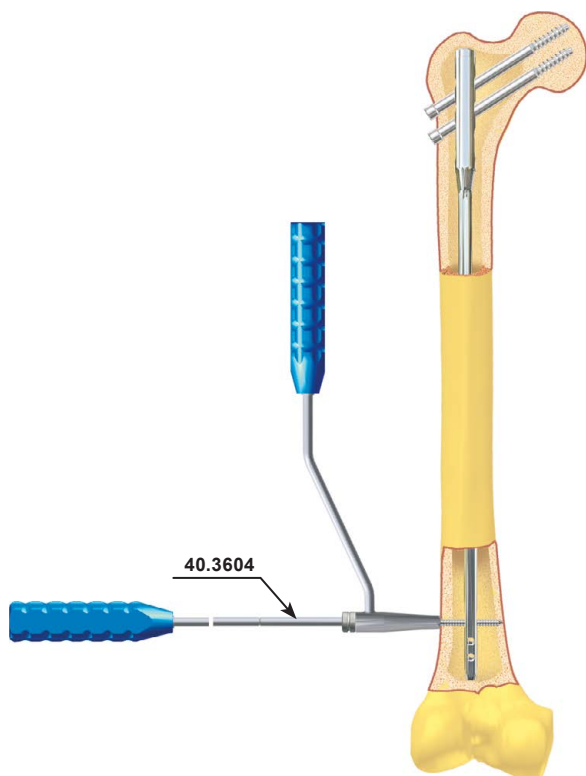
Remove the Drill and Drill Guide.  
Leave the Targeter.





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

Remove the Screw Length Measure.  
Leave the Targeter.



- 38** Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance both into hole of the Targeter. Insert the locking screw until its head reaches the cortex bone.

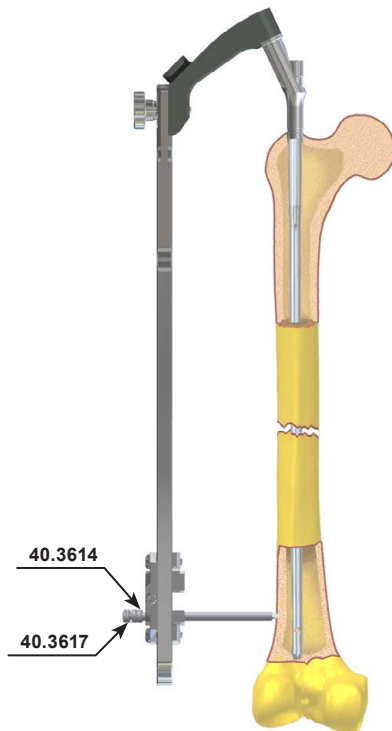
Remove the Screwdriver S3.5 and the Targeter.

### IV.3. DYNAMIC AND COMPRESSION METHODS

#### IV.3.1. Distal locking of the nail

Before starting the steps connected with distal locking of the nail, do the following:

1. Mount the Distal targeter D [40.5093] to the Targeter arm [40.5091] and secure it with a collar bolt. If properly installed, the signs RIGHT or LEFT on both targeters should comply.
2. Verify using X-Ray the position of nail holes and in distal targeters slider. The centers of the holes in nail and in distal targeters slider have to be in line.



- 39** Insert the Protective Guide [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the proximal hole in the distal targeters slider. Mark the entry point for the locking screw on the skin and make adequate incision through the soft tissues. Advance the Trocar until it reaches cortex and mark the drill entry point. Advance Protective Guide together with the Trocar until it touches the cortex bone.

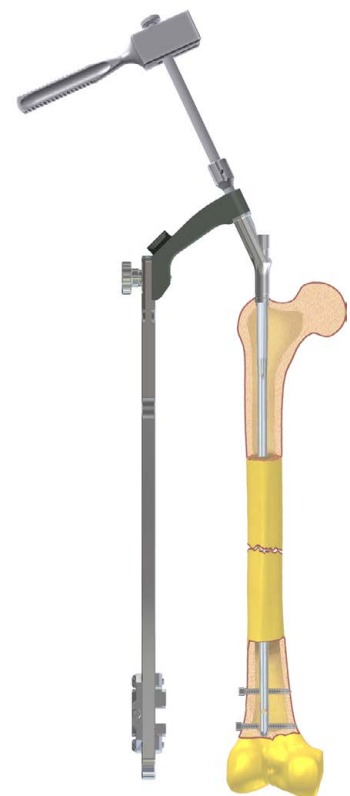
Remove the Trocar.

Leave the Protective Guide in the hole of targeters.



**NOTE!** For the rest of the procedure follow the steps [26] to [32].

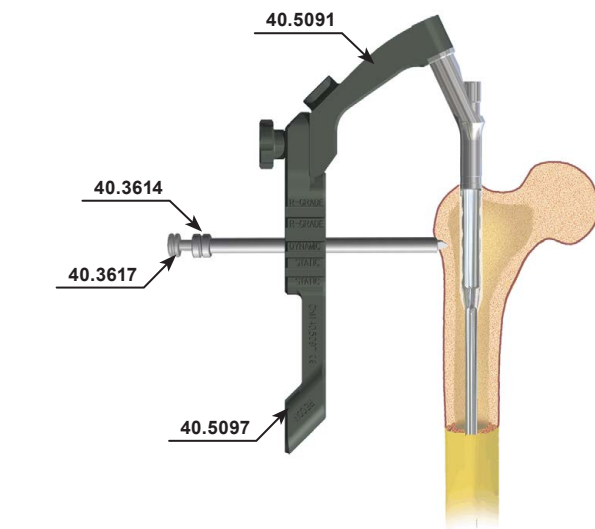
- 40** It is possible to make reduction of fracture after locking the nail in distal part by slightly knocking the nail up, and then locking the nail in proximal part.



## IV.3.2. Proximal locking of the nail



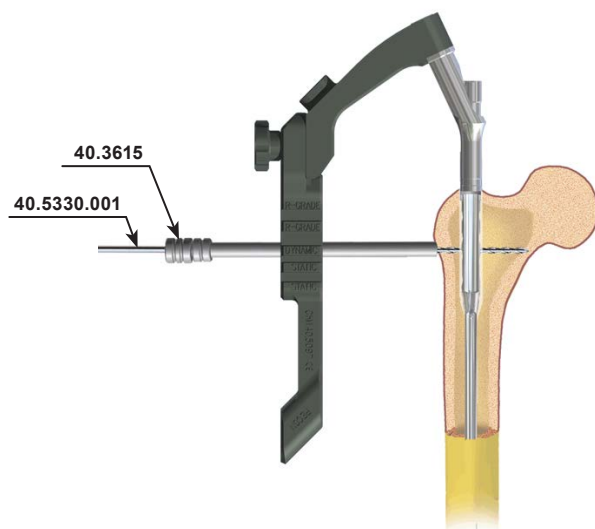
**NOTE!** In compression and dynamic methods insertion shall be done into the hole of the Targeter 135 [40.5097] marked DYNAMIC.



- 41** Mount the Targeter 135 [40.5097] on the Targeter arm [40.5091]. Insert the Protective Guide 9/6.5 [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the proximal hole in the Targeter 135 [40.5097]. Mark on the skin the entry point for the locking screw and make adequate incision through soft tissues 1.5cm in length. Advance the trocar until it reaches cortex and mark the drill entry point. Advance the Protective Guide together with the Trocar until it touches the cortex.

Remove the Trocar.

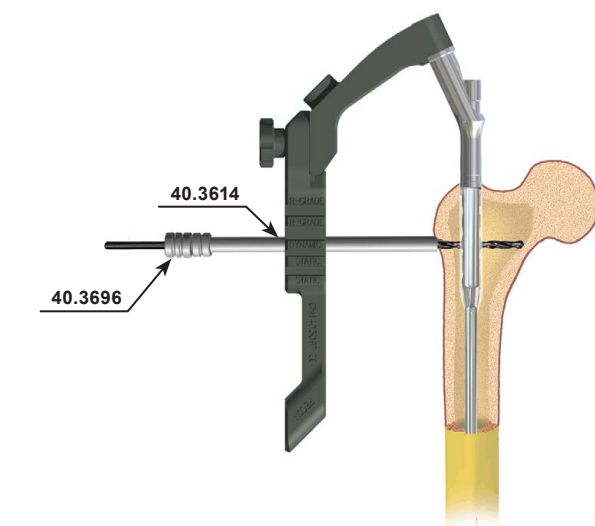
Leave the Protective Guide in the hole of targeter.



- 42** Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the protective guide. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Remove the Drill and Drill Guide.

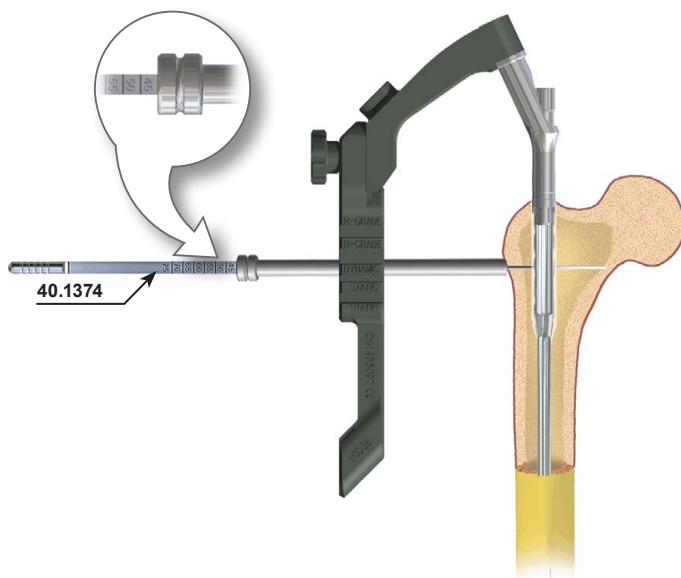
Leave the Protective Guide in the hole of targeter.



- 43** Insert the Drill Guide 6.5/4.5 [40.3696] into the Protective Guide 9/6.5 [40.3614]. Mount the Drill 3.5/270 on the surgical drive and advance it through the drill guide. Drill the hole in the femur through first cortex only up to the nail hole.

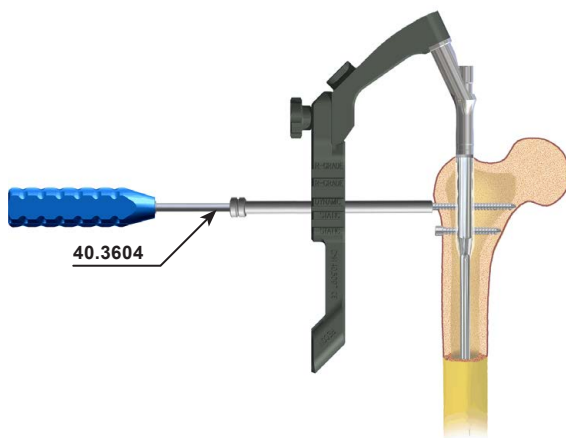
Remove the Drill and Drill Guide.

Leave the Protective Guide in the hole of targeter.



- 44** Insert the Screw Length Measure [40.1374] through the protective guide into the drilled hole until its hook reaches the "exit" plane of the 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 targeter.



- 45** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of the Protective Guide*).

Remove the Screwdriver and Protective Guide.



- 45a** In order to make the intraoperative compression, using the Screwdriver S3.5 [40.3604] insert the Compression Screw [40.5096] into the Connecting Screw M10x1 L=55 [40.5094] that connects intramedullary nail to the Targeter arm. If front of the screw reaches the shaft of locking screw, the following screw insertion will cause the compression of bone fragments.

The above steps should be controlled with X-Ray image intensifier to observe the interfragmental slot.

- 45b** In order to maintain the bone fragments compression, lock the screw by using hole STATIC placed further from DYNAMIC hole. Repeat steps 41-45.

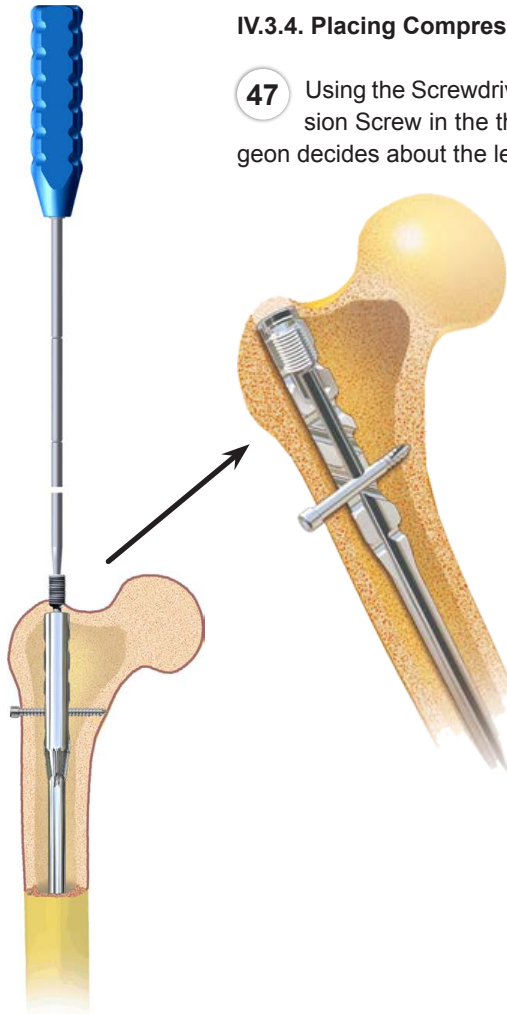
## IV.3.3. Targeter removal

- 46 Using the Wrench S10 [40.5526.100] unscrew the Connecting Screw [40.5094] or [40.5095] of the nail shaft and dismount the targeter from the nail locked in the medullary canal.



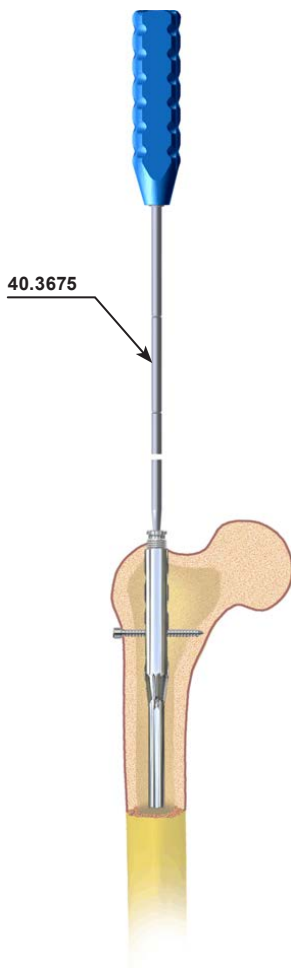
## IV.3.4. Placing Compression Screw

- 47 Using the Screwdriver S3.5 [40.3604] insert the Compression Screw in the threaded hole in the nail shaft. The surgeon decides about the level of compression.



## IV.3.5. Placing end cap (dynamic method only)

- 48 In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 [40.3675] insert:
- the End Cap [1.2104.3xx] or [3.2104.3xx] in the case of using universal nail,
  - the End Cap [1.2104.4xx] or [3.2104.4xx] in the case of using compression nail.



## IV.4. STATIC METHOD

### IV.4.1. Distal locking of the nail

Before starting with steps connected with distal locking of the nail, do the following:

1. Mount the Distal targeter D [40.5093] on the Targeter arm [40.5091] and secure it with a collar bolt (provided with the targeter).  
*If properly installed, the signs RIGHT or LEFT on both targeters should comply.*
2. Verify with the X-Ray the position of holes in nail and in targeter slider. The centers of the holes have to be in line.

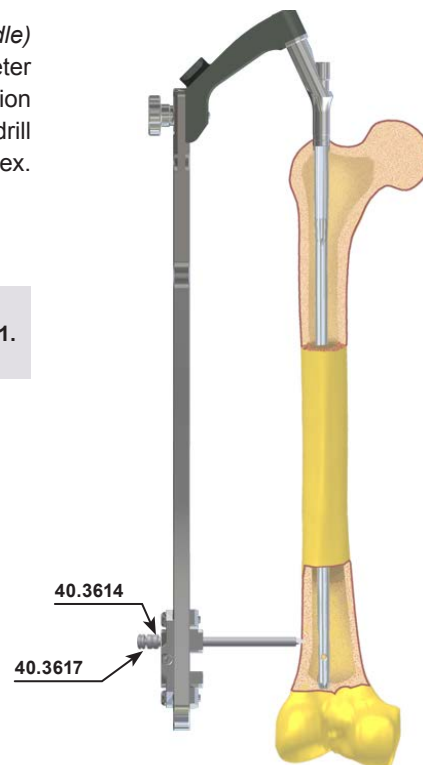
- 49** Insert the the Protective Guide 9/6.5 [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the proximal hole in the slider of distal targeter D. Mark the entry point for the locking screw on the skin and make adequate incision through the soft tissues. Advance Trocar until it reaches cortex bone and mark the drill entry point. Advance Protective Guide together with the Trocar until it touches the cortex.

Remove the Trocar.

Leave the Protective Guide in the hole of slider.



**NOTE!** For the rest of the procedure follow the steps [26] to [32] on page 30-31.



### IV.4.2. Proximal locking of the nail

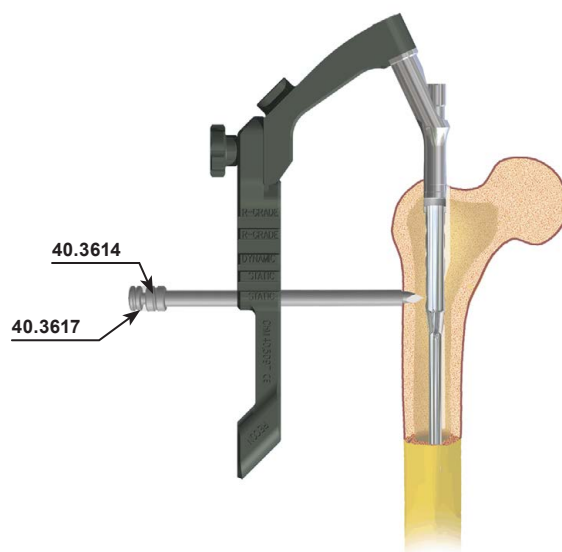


**NOTE!** In static method of femoral fixation to lock the intramedullary nail, distal hole in Targeter 135 [40.5097] marked **STATIC** shall be used. The second hole (proximal) may be used for locking with second locking screw.

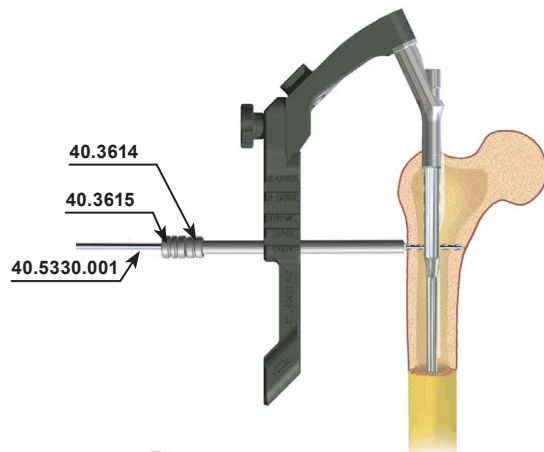
- 50** Insert the Protective Guide 9/6.5 [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the distal hole in Targeter 135. Mark the entry point for the locking screw on the skin and make adequate 1.5cm long incision through the soft tissues. Advance the trocar until it reaches cortex and mark the entry point for the drill. Advance Protective Guide together with the Trocar until it touches the cortex.

Remove the Trocar.

Leave the Protective Guide in the hole of targeter.

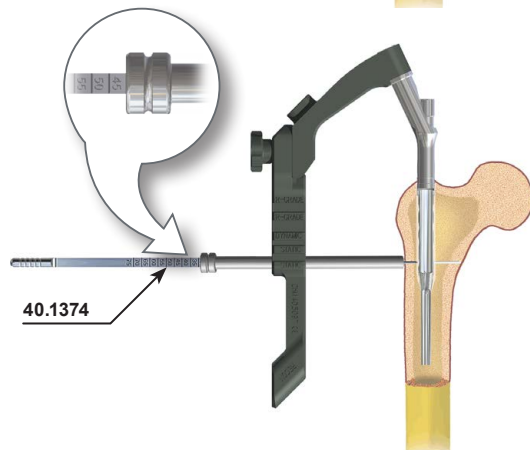






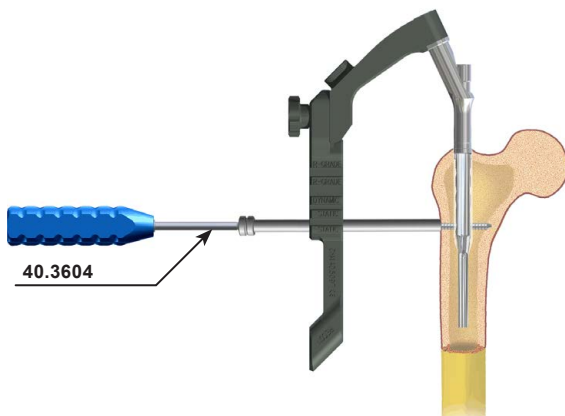
- 51** Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the Protective Guide 9/6.5 [40.3614]. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element.

Remove the Drill and Drill Guide.  
Leave the Protective Guide in the hole of targeter.



- 52** 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 gauge 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 targeter.

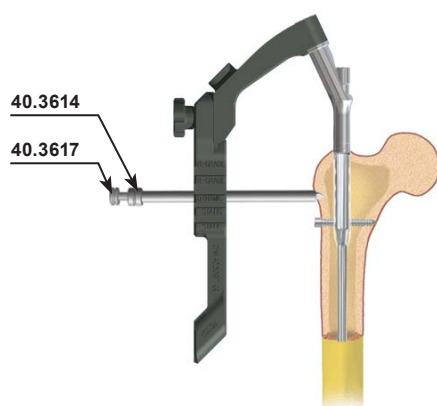


- 53** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of the protective Guide*)

Remove the Screwdriver and the Protective Guide.

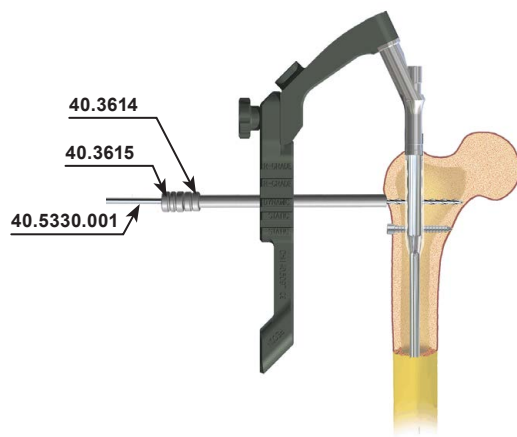


**NOTE!** If surgeon decides to lock the nail in the proximal part with two screws, insertion of second screw should be performed as shown in steps [50] to [53]. Otherwise omit these steps.



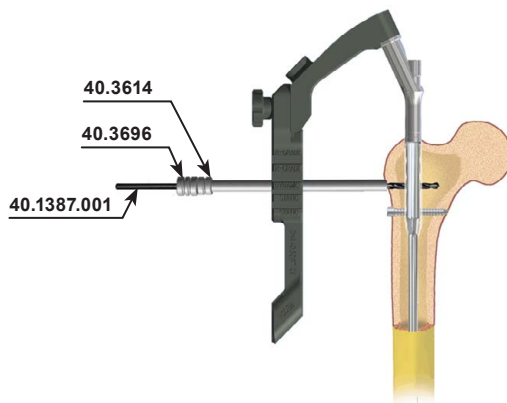
- 54** Insert the Protective Guide 9/6.5 [40.3614] (with one groove on the handle) with the Trocar 6.5 [40.3617] into the proximal hole of proximal targeter. Advance Trocar until it reaches cortex and mark the entry point for the drill. Advance the Protective Guide together with the trocar until it touches the bone.

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



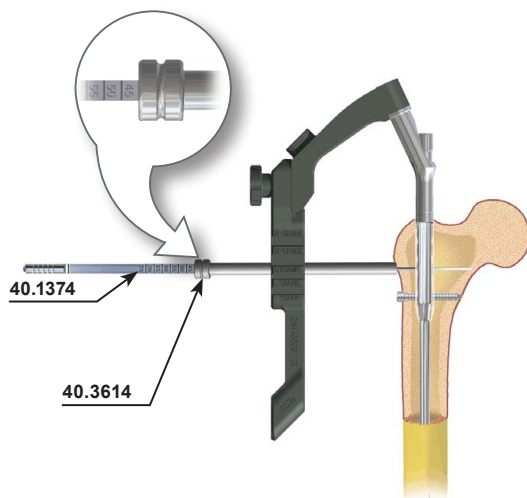
- 55** Insert the Drill Guide 6.5/3.5 **[40.3615]** (with two grooves) into the Protective Guide. Mount the Drill With Scale 3.5/270 **[40.5330.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through both cortex layers and the nail hole. The scale on the Drill shows length of the locking element.

Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.



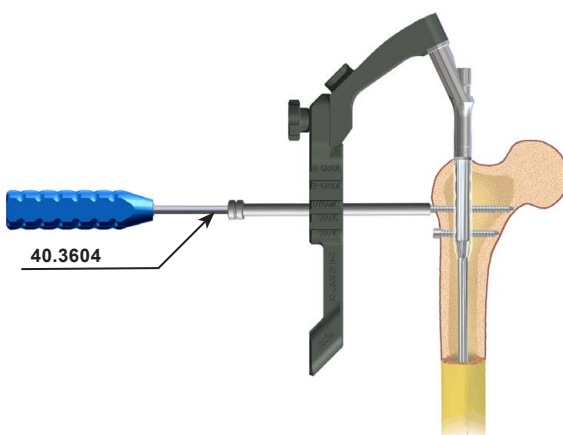
- 56** Insert the Drill Guide 6.5/4.5 **[40.3696]** into the Protective Guide. Mount the Drill 4.5/270 **[40.1387.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through first cortex up to the hole in the nail.

Remove the Drill and the Drill Guide.  
Leave the Protective Guide in the hole of targeter.



- 57** 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 scale B-D. During the measurement the end of the Protective Guide should rest on the cortex.

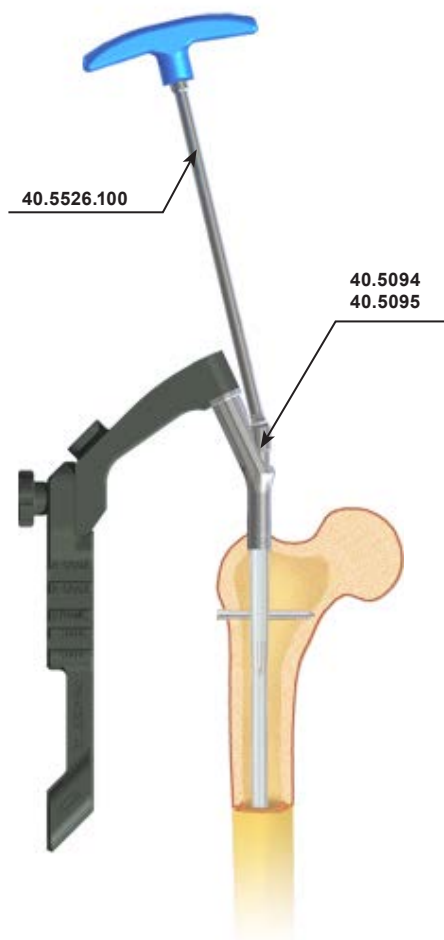
Remove the Screw Length Measure.  
Leave the Protective Guide in the hole of targeter.



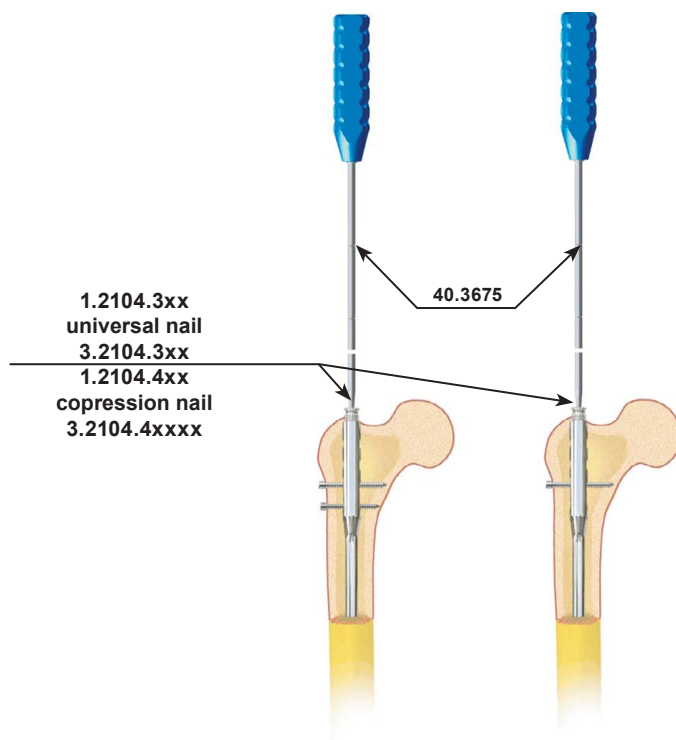
- 58** Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the Screwdriver and the Protective Guide.

## IV.4.3. Targeter removal, placing end cap



- 59** Using the Wrench S10 [40.5526.100] unscrew the Connecting Screw [40.5094] or [40.5095] from the nail shaft and dismount the Targeter from the nail locked in the medullary canal.



- 60** In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 [40.3675] insert:

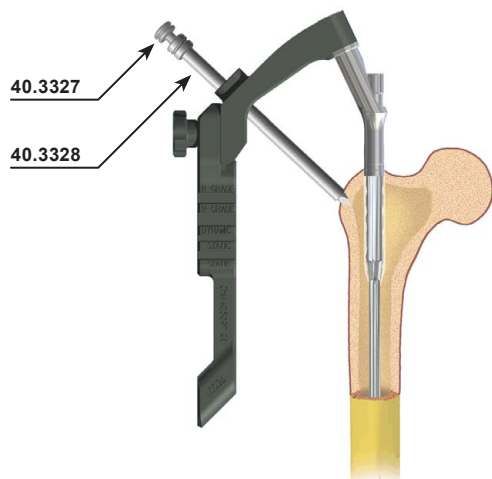
- the End Cap [1.2104.3xx] or [3.2104.3xx] in case of using the universal nail;
- the End Cap [1.2104.4xx] or [3.2104.4xx] in case of using the compression nail.

## IV.5. STATIC METHOD WITH USE OF RECONSTRUCTION NAIL

### IV.5.1. Proximal locking of the nail

In the static method, the intramedullary reconstruction nails for fixation of femoral fragments may be used:

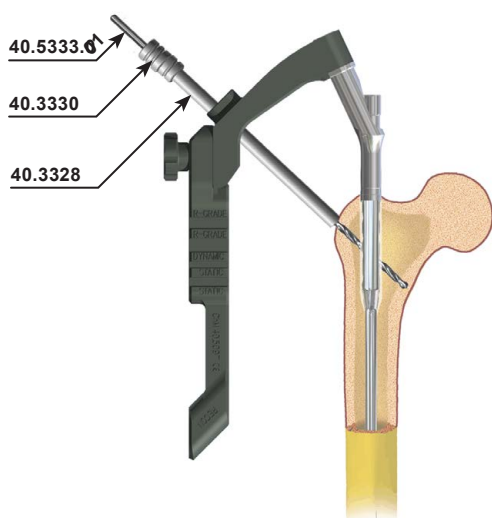
- right nail (*market RIGHT*) should be used for fixation of the left femur,
- left nail (*market LEFT*) should be used for fixation of the right femur.



- 61** Insert the Protective Guide [40.3328] (*with one groove on the handle*) with the Trocar Ø9 [40.3327] into the hole in the Targeter arm [40.5091]. Mark the entry point for the locking screw and make an adequate incision of the soft tissues. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

Remove the Trocar.

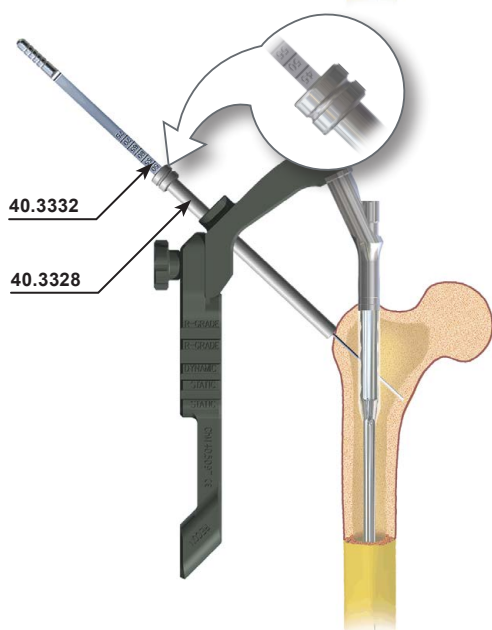
Leave the Protective Guide in the hole of targeter.



- 62** Insert the Drill Guide 9/4.5 [40.3330] (*with two grooves*) into the protective guide. Mount the Drill With Scale 4.5/370 [40.5333.001] on the surgical drive and advance it through the drill guide. Drill the hole in the femur through both cortex layers and the hole in the nail. The scale on the drill shows length of the locking element

Remove the Drill and the Drill Guide.

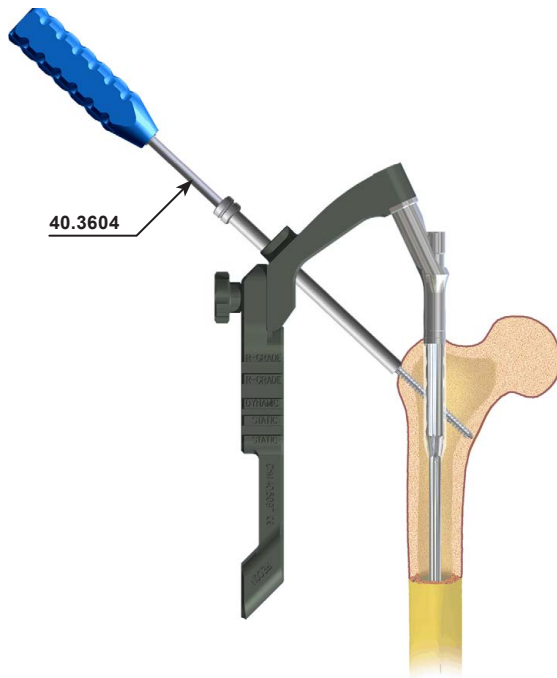
Leave the Protective Guide in the hole of targeter.



- 63** Insert the Reconstruction Screw Length Measure [40.3332] through the Protective Guide into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the reconstruction screw on the measure. During the measurement the end of the Protective Guide should rest on the cortex bone.

Remove the Screw Length Measure.

Leave the Protective Guide in the hole of targeter.



- 64** Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. For locking use the screw with 6.5mm diameter and length determined in previous step. Then advance both into the Protective Guide. Insert the reconstruction screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of Protective Guide*).

Remove the Screwdriver S3.5 and Protective Guide.

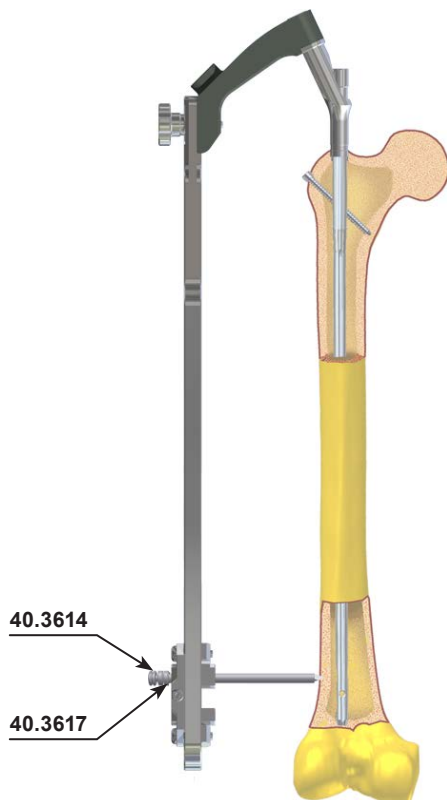
#### IV.5.2. Distal locking of the nail

Before distal locking of the nail do the following:

1. Mount distal targeter [40.3322] again on the arm of the proximal targeter [40.5061] and secure it with a locknut included in proximal targeter).

*If properly installed, the signs RIGHT or LEFT on both targeters should comply.*

2. Verify with the X-Ray image intensifier the position of holes in the nail and in targeter slider. The centers of the holes have to be in line.



- 65** Insert the Protective Guide 9/6.5 [40.3614] (*with one groove on the handle*) with the Trocar 6.5 [40.3617] into the proximal hole in the slider of distal targeter. Mark on the skin the entry point for the locking screw and make adequate incision through the soft tissues. Advance the Trocar until it reaches cortex and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the cortex.

Remove the Trocar.

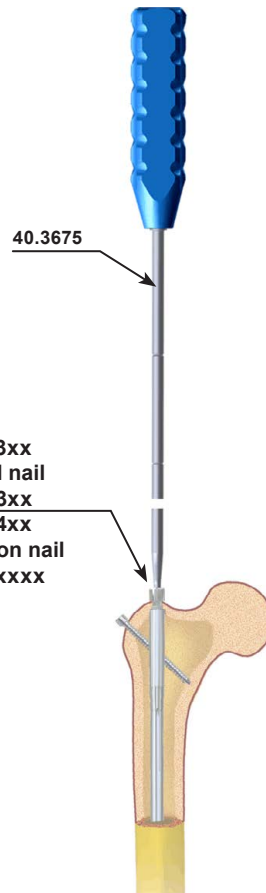
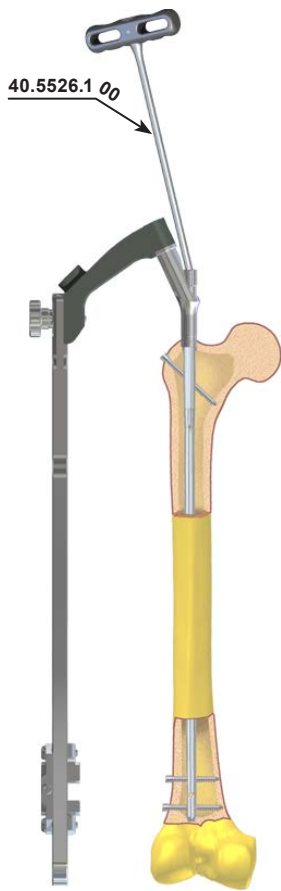
Leave the Protective Guide in the hole of slider of targeter.



**NOTE!** For the rest of the procedure follow the steps [26] to [32] on page 30 to 31.

## IV.5.3. Targeter removal, end cap placing

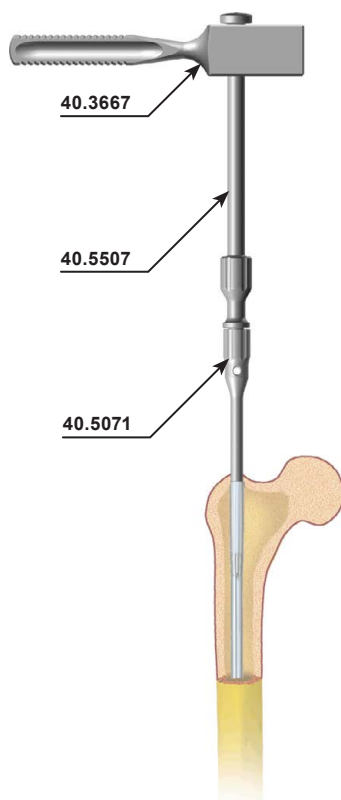
- 66** Using the Wrench S10 [40.3326] unscrew the Connecting Screw [40.5094] or [40.5095] of the nail shaft and dismount the targeter from the nail locked in the medullary canal.



- 67** In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 [40.3675] insert:

- the End Cap [1.2104.3xx] or [3.2104.3xx] in the case of using universal nail,
- the End Cap [1.2104.4xx] or [1.2104.4xx] in the case of using compression nail.

1.2104.3xx  
universal nail  
3.2104.3xx  
1.2104.4xx  
compression nail  
3.2104.4xxx







## IV.6. NAIL EXTRACTION





- 68** Use the Cannulated Screwdriver S5.0/2.2 [40.3675] to remove the End Cap or Screwdriver S3.5 [40.4604] to remove compression screw from the nail shaft. Insert the Connector [40.5071] into the threaded nail hole. Using the Screwdriver S3.5 [40.3604] unscrew all the locking screws. Attach the Impactor-Extractor [40.5070] to the connector and with help of the Mallet [40.3667] extract the nail from the medullary canal.











## IV.7. SURGICAL TECHNIQUE - RETROGRADE METHOD (CONDYLAR APPROACH)





## IV.7.1. Implants for retrograde method





			
Steel	Titanium	Steel	Titanium
1.1654.016-100	3.1654.016-100	1.1654.016-100	3.1654.016-100





			
Ø8+19	Ø8+10	Ø8+10	Ø11+19



			
1.1654.016-100	3.1654.016-100	1.1654.016-100	3.1654.016-100





			
Steel	Titanium	Steel	Titanium
1.1654.016-100	3.1654.016-100	1.1654.016-100	3.1654.016-100



			
1.2109.050-090	3.2109.050-090	1.2109.050-090	3.2109.050-090

			
Steel	Titanium	Steel	Titanium
1.1651.030-110	3.1651.030-110	1.1651.030-110	3.1651.030-110

			
Steel	Titanium	Steel	Titanium
1.2104.002	3.2104.002	1.2104.002	3.2104.002

available		
Ø[mm] pitch 1 mm	8 + 19	8 + 19
L [mm] other 6 mm	240 + 600	240 + 600

			
1.2104.002	3.2104.002	1.2104.002	3.2104.002

			
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1.2104.002	3.2104.002	1.2104.002	3.2104.002

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#### IV.7.2. Introduction

Retrograde nailing of the femur provides fixation in the cases of fractures above the knee joint (*up to 20cm from distal end of femur*) or multi-fragment fractures of condyle. The reverse nail may also be used when a hip prosthesis or other implant has been already implanted in proximal femur.

**CHARFIX** system provides the retrograde nails with diameters 10, 11 or 12mm and length between 160 and 440 mm. To lock the nail distally (*by the knee joint*) depending on the fracture type use:

- two locking screws 6.5mm,
- two locking sets.

There are five sizes of locking sets:

- 50, with range between 50 and 65 mm,
- 60, with range between 60 and 75 mm,
- 70, with range between 70 and 85 mm,
- 80, with range between 80 and 95 mm,
- 90, with range between 90 and 105 mm.

Locking set consists of: bolt, two washers and locking screw. Locking screws are used to lock the nail proximally. The nail features anatomical shape of the femur - its distal end is 5° angled.

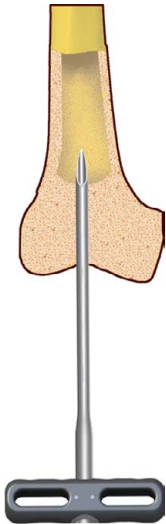
Each surgical procedure has to be planned. Before the operation adequate X-Ray images have to be taken in order to examine the type of fracture and assess the dimensions of implant (*diameter and length*). The operation should be performed on the patient in supine position, with tourniquet on and the knee joint bent 90°.

Nailing may be performed with or without reaming of medullary canal. In both cases the diameter of medullary canal ought to be bigger than the diameter of used nail; if canal is reamed its final diameter should be 1.5 to 2mm wider than the diameter of the nail. In both cases the canal has to be additionally reamed in distal part (*entry point*) with a 13.0 reamer at the distance of first 6cm (*diameter of the nail in distal end is 12mm*).



The following paragraphs describe most important steps during implantation of intramedullary interlocking femoral nails nevertheless it is not a detailed instructions for use. The surgeon decides about choosing the surgical technique and its application in each individual case.

On the basis of X-Ray of fractured femur and of the healthy one, the surgeon decides about the length and diameter of the nail.



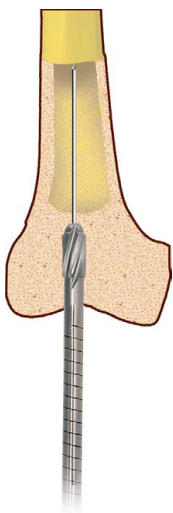
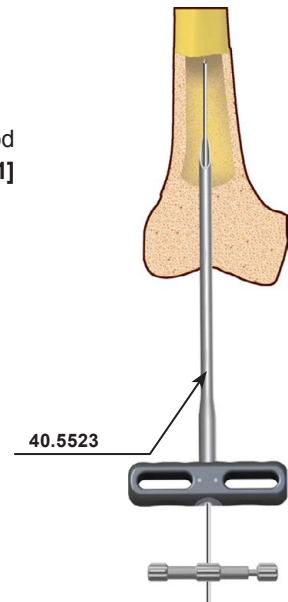
- 1 Make the incision over the middle of patellar ligament or more paracentrally. Expose intercondylar region (*split the fibers of ligament or move it laterally*). Use the Curved Awl 8.0 [40.5523] to open the medullary canal to depth of about 6 cm.



Control the procedure with the X-Ray.

- 2 After opening the medullary canal, insert the Guide Rod 3.0/580 [40.3925] with fixed the Guide rod handle [40.1351] until adequate depth is reached.

Remove the Curved Awl 8.0 [40.5523].  
Remove the Guide rod handle [40.1351].

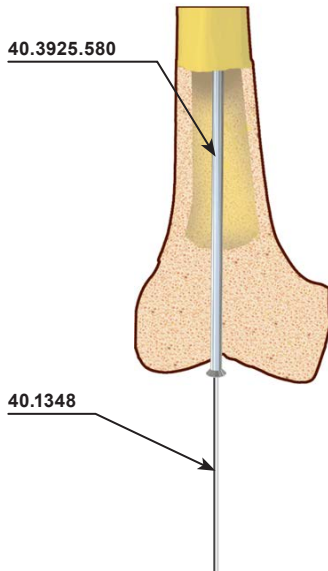


- 3 In case medullary canal is reamed, gradually increase the diameter of canal with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the femoral nail is reached, for the depth at least equal to the nail length (*but not lesser*). In both cases, when the medullary canal was reamed or not, the canal should be drilled using 13 reamer to the depth of approx. 6 cm

Remove the Flexible Reamer.



**NOTE!** Steps [4] and [5] are applicable only if the medullary canal has been reamed or if another not provided in the instrument set reamer guide has been used. Otherwise go directly to the step [6]. If the medullary canal is not reamed, the distal canal in step 3 should be reamed up to the diameter of 13mm to a depth of about 6 cm. Proceed directly to step 6, skipping steps 4 and 5.

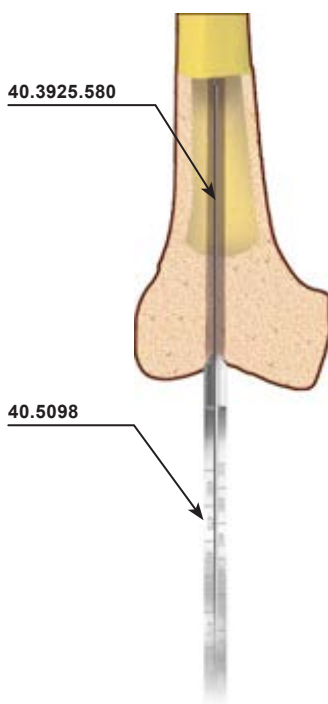
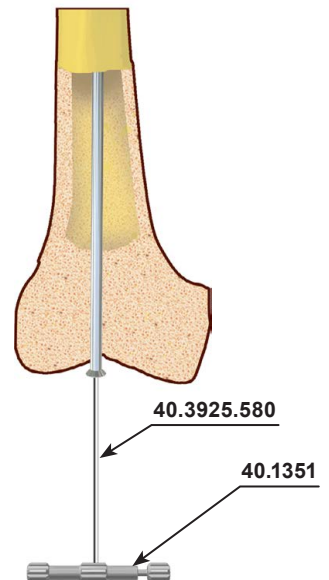


- 4** Insert the Teflon Pipe Guide [40.1348] onto the flexible reamer guide in the medullary canal.

Remove the Reamer Guide.

- 5** Mount the Guide rod handle [40.1351] on the Guide Rod [40.3925.580] and advance the rod into the Teflon Pipe Guide until its tip reaches the proximal epiphysis.

Remove the Guide rod handle [40.1351] from the Guide Rod.  
Remove the Teflon Pipe Guide [40.1348].



- 6** Insert the Nail Length Measure [40.5098] on the Guide Rod until it rests on bone. Read the length of the nail on the Nail Length Measure. Remove the Nail Length Measure from the guide rod. In case of using solid nail, remove the Guide Rod from medullary canal. Medullary canal is ready for nail insertion.

## IV.7.3. Nail assembling to the targeter, nail insertion into the medullary canal



- 7 Mount the Distal targeter D [40.5093] on the Targeter arm [40.5091] using collar bolt (included in distal targeter).



**NOTE!** When operating right limb the targeter should be connected so the RIGHT signs on both side shall be in line. In the case of left limb - the LEFT signs on both side shall be in line.

Use the Wrench S10 [40.3336] to mount the intramedullary nail on the targeter arm with the Connecting Screw M10x1 L=55 [40.5094]. With a pair of the Set Blocks 9/4.5 [40.3616] place the slider of distal targeter in line with distal locking holes of intramedullary nail. Secure the slider of the targeter using the Screwdriver S3.5 [40.3604].

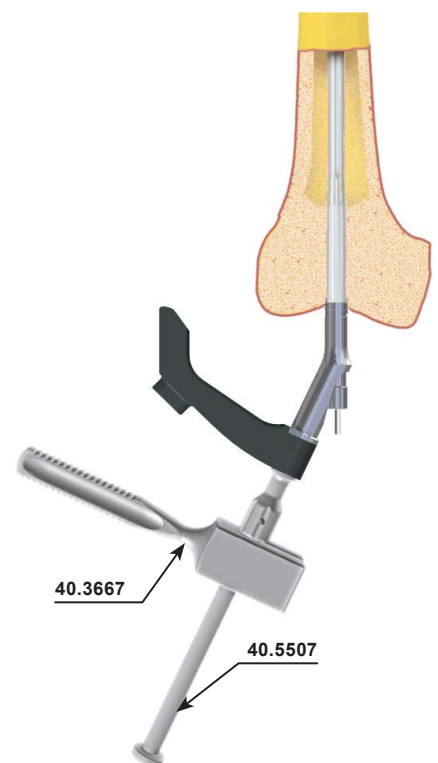


**CHECK!** Properly set and secured slider means that set blocks smoothly hit the holes in the nail.

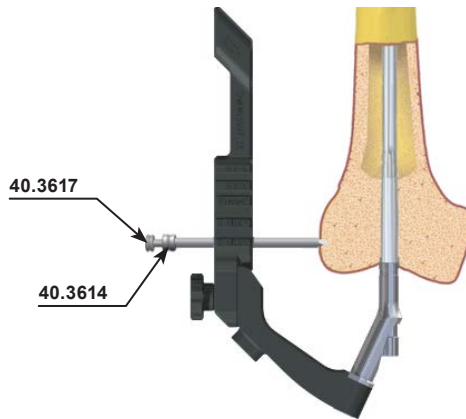
Remove the Set Blocks from Distal targeter.  
Dismount Distal targeter from Targeter arm.

- 8 On the Targeter arm [40.5091] with attached intramedullary nail insert the Impactor-Extractor [40.5507]. Insert the intramedullary nail into the medullary canal through the Guide Rod 3.0/580 [40.3925]. Advance the nail into the medullary canal until adequate depth is reached.

Remove the Guide Rod 3.0/580 [40.3925].  
Unscrew Impactor-Extractor [40.5507] off the targeter.



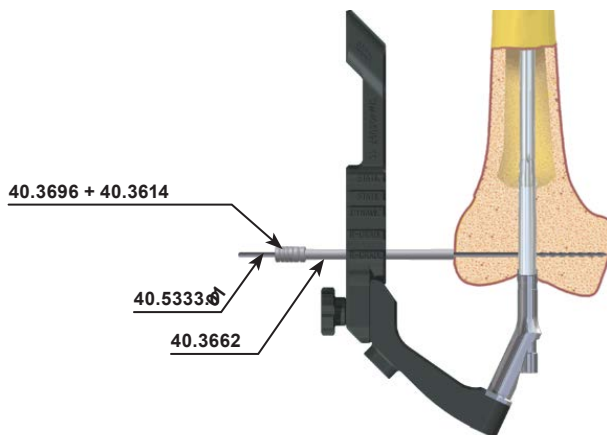
## IV.7.4. Locking the nail in the condylar femur



- 9 Insert the Targeter 135 [40.5097] on the Targeter arm [40.5091]. Insert the Protective Guides [40.3662] and [40.3614] and the Trocar 6.5 [40.3617] into targeter hole positioned in the most distal part. Mark the entry point for the trocar and make an adequate incision of the soft tissues. Advance the trocar with protective guides until they reach the cortex bone. Mark with the trocar the entry point for canal that is to be done for locking screws.

Remove the Trocar.

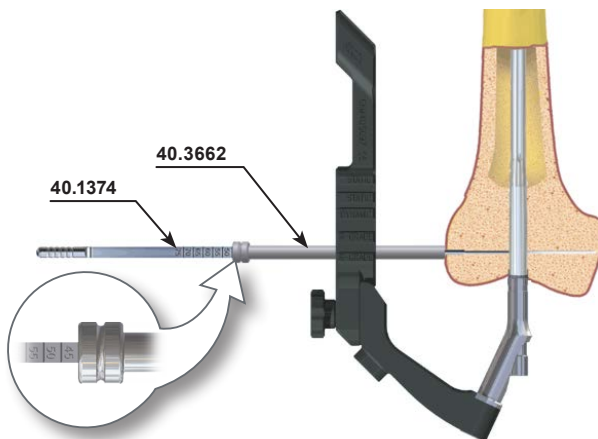
Leave the Protective Guides in the hole of the targeter.

IV.7.4.A. **OPTION I: Locking with screws**

- 10 Insert the Drill Guide 6.5/4.5 [40.3696] into the Protective Guides [40.3662] and [40.3614]. Mount the Drill With Scale 4.5/370 [40.5333.001] on the surgical drive and advance it through the drill guide. Drill the hole for locking screw. The scale on the drill shows length of the locking element. Control drilling process with X-Ray.

Remove the Drill and drill guide.

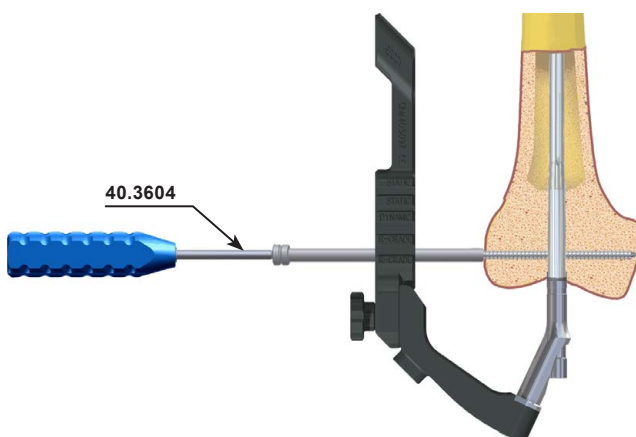
Leave the Protective Guide in the hole of the targeter.



- 11 Insert the Screw Length Measure [40.1374] through the Protective Guide [40.3662] into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the needed locking screw on the gauge. During the measurement the Protective Guide should rest on the cortex bone.

Remove the Screw Length Measure.

Leave the Protective Guide in the hole of the targeter.



- 12 Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw in the prepared hole until the head of the screw reaches the cortex bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the Screwdriver and the Protective Guide.

For distal locking of the nail use locking screws with diameter 6.5mm.



IV.7.4.B. **OPTION II: Locking with locking set**

- 13** The Drill Guide [40.3614] and the Protective Guide [40.3662] are in the hole of targeter. Mount the Drill 6.5/370 [40.2068.371] on the surgical drive and advance it through the Drill Guide. Drill the hole through the bone.



**Control drilling with X-Rays image intensifier.**

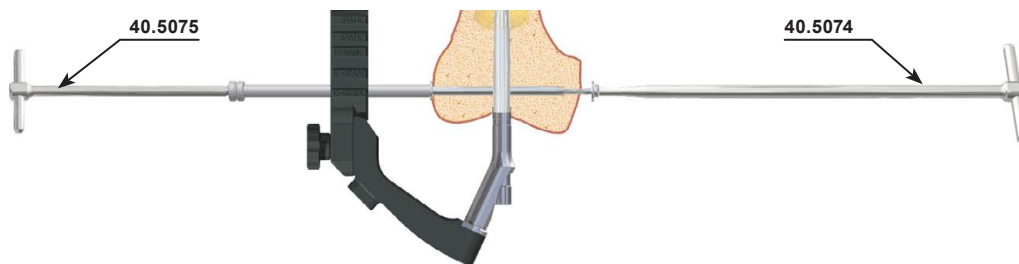
With help of X-Ray image intensifier make incision of the soft tissues over the exit point of the drill. Remove the Drill. Leave the Protective Guides [40.3662] and [40.3614] on targeter.

- 14** Insert the the Reconstruction Screw Length Measure [40.3332] through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Deduct 10mm from the reading on the Measure, to get a characteristics of the locking set needed.  
**Select locking set with adequate range, e.g. with reading "75" the characteristics amount to "65", therefore locking set 60 with range between 60 and 75 mm is adequate. During the measurement the Protective Guide should rest on the cortex bone.**

Remove the screw length measure.  
Leave the protective guide in the hole of the targeter.

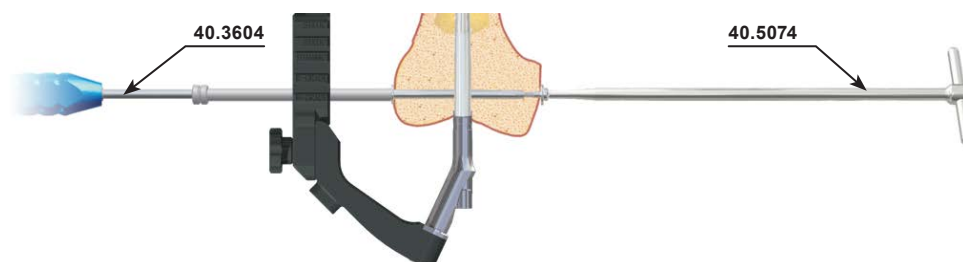
- 15** Insert the Bolt Guide [40.5075] into the protective guide. The pilot which is integral part of the the Bolt Guide [40.5075], should be attached on the Bolt Guide. Advance the Bolt Guide through the drilled hole until its tip reaches the hole from the other side. Remove the pilot from the the Bolt Guide. Put the bolt (*implant*) through the washer (*implant*) and screw it in onto the the Bolt Guide using the Screwdriver S3.5 [40.5074]. Advance the bolt into the hole in the bone (*head of the bolt should rest on the cortex with washer between*).

Unscrew the Bolt Guide from the bolt and remove it from the Protective Guide.



- 16** Leave the Protective Guide [40.3662] in the hole of the targeter. Insert the tip of the Screwdriver S3.5 [40.3604] into the hexagonal socket of the locking screw (*implant*) and advance both into the Protective Guide. Put the washer (*implant*) over the locking screw when it leaves the protective guide and enters the hole in the bone. Insert the locking screw in the threaded hole in the bolt (*hold the bolt with the screwdriver*).

Two screwdrivers are used to secure the locking set (*locking screw, two washers, bolt*).  
Remove the screwdrivers and protective guide.



**NOTE!** To lock second locking set for the other distal hole follow the steps [13] to [16].

#### IV.7.5. Proximal locking of the nail

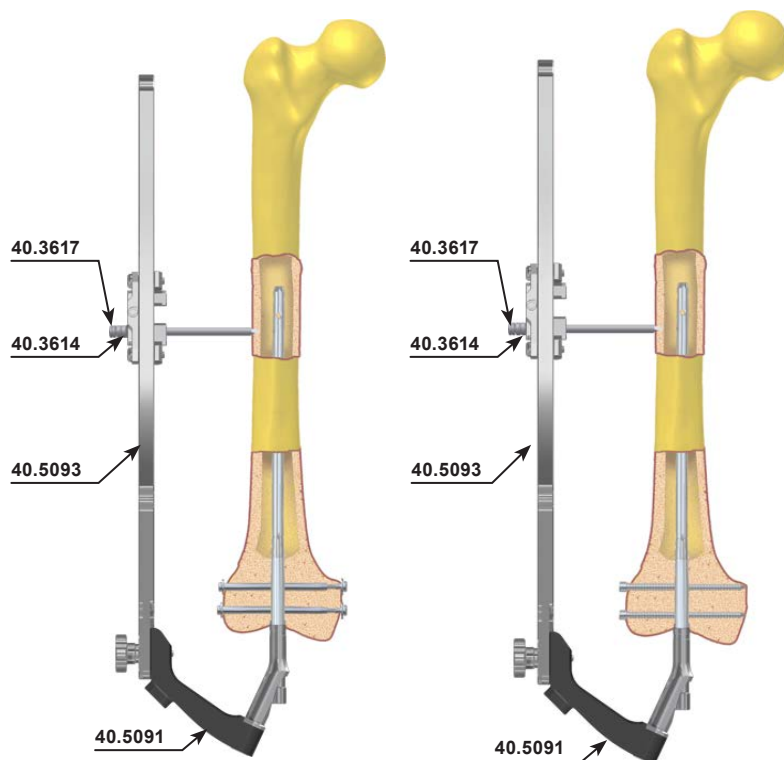
Before continuing with steps connected with distal locking of the nail, do the following:

1. Mount the Distal targeter D [40.5093] on the Targeter arm [40.5091] and secure it with a collar bolt (included in distal targeter).  
*If properly installed, the signs RIGHT or LEFT on both target should comply (be in one plane).*
2. Verify with the X-Ray image intensifier the position of holes in the nail and in the targeter slider. The centers of the holes have to be in line.

- 17** Insert the Protective Guide 9/6.5 [40.3614] with the Trocar 6.5 [40.3617] into the distal hole in the Distal targeter D [40.5093]. Mark the entry point for the Trocar, make an adequate incision of the soft tissues. Advance the trocar together with protective guide until it reaches the cortex bone. Using Trocar mark the entry point for locking screw.

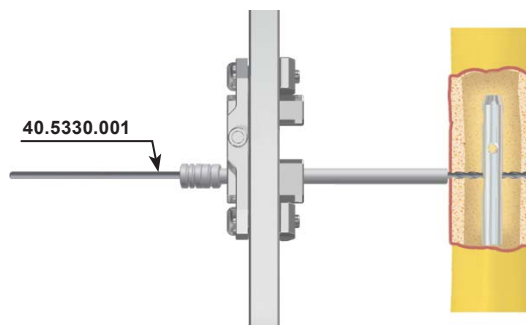
Remove the trocar.

Leave the Protective Guide in the hole of the targeter.



- 18** Insert the Drill Guide 6.5/3.5 [40.3615] (with two grooves) into the Protective Guide 9/6.5 [40.3614] left in the hole of the slider. Mount the Drill With Scale 3.5/270 [40.5330.001] on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through its both cortex layers and the nail hole. The scale on the drill shows the length of the locking element.

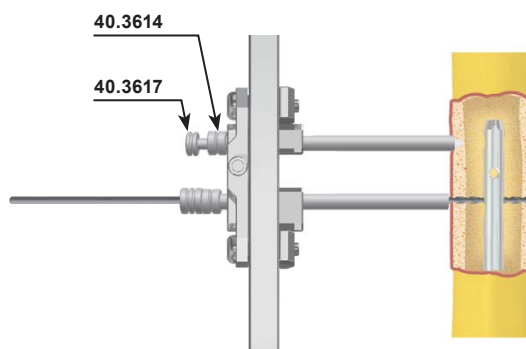
Disconnect the drive from the drill and leave in place system: the protective guide - drill guide - drill.

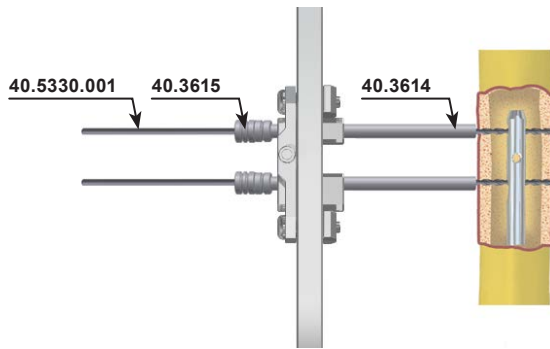


- 19** Insert the Protective Guide 9/6.5 [40.3614] (with one groove) with the Trocar 6.5 [40.3617] into the second hole in the slider of the targeter. Advance the trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches the bone.

Remove the Trocar.

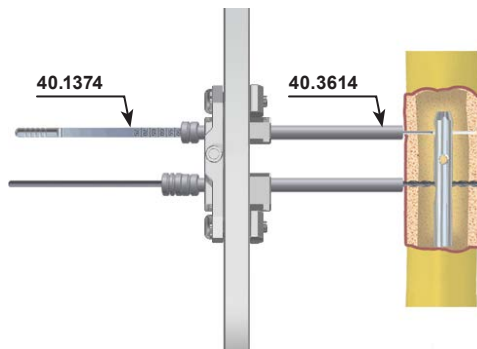
Leave the Protective Guide in the hole of the slider.





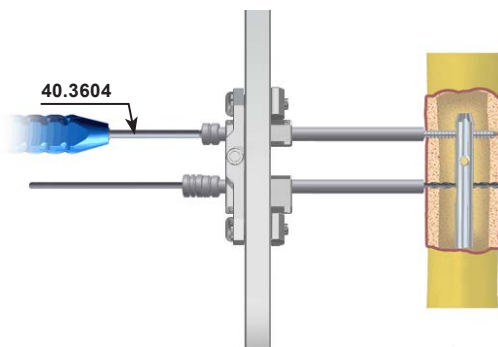
- 20** Insert the Drill Guide 6.5/3.5 **[40.3615]** (with two grooves) into the Protective Guide 9/6.5 **[40.3614]**. Mount the Drill With Scale 3.5/270 **[40.5330.001]** on the surgical drive and advance it through the drill guide. Drill the hole in the femoral shaft through both cortex layers and the nail hole. The scale on the drill shows length of the locking element.

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



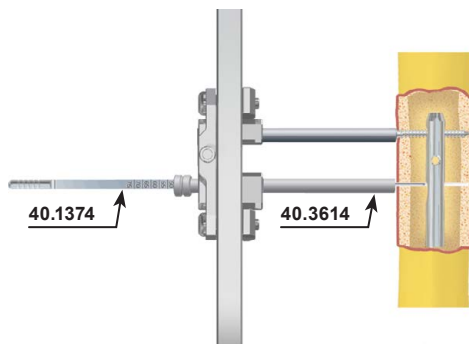
- 21** Insert the Screw Length Measure **[40.1374]** through the Protective Guide 9/6.5 **[40.3614]** into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the gauge B-D scale. During the measurement the Protective Guide should rest on the cortex bone.

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



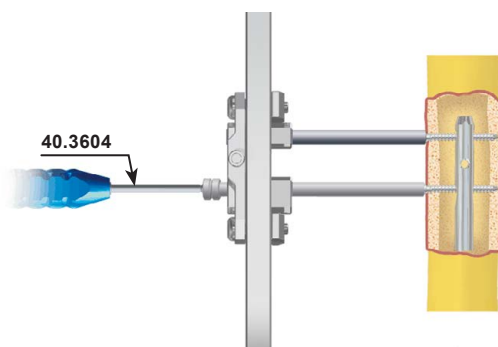
- 22** Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the Screwdriver.  
Leave the Protective Guide.



- 23** Remove the drill from distal hole in the targeter. Leave the Protective Guide in the hole of the slider. Insert the Screw Length Measure **[40.1374]** through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Read the length of the locking screw on the gauge B-D scale. During the measurement the Protective Guide should rest on the cortex bone.

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



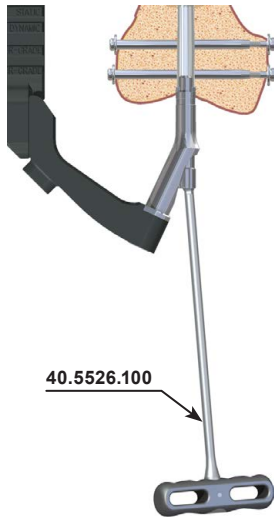
- 24** Insert the tip of the Screwdriver **[40.3619]** into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the Screwdriver and Protective Guide.



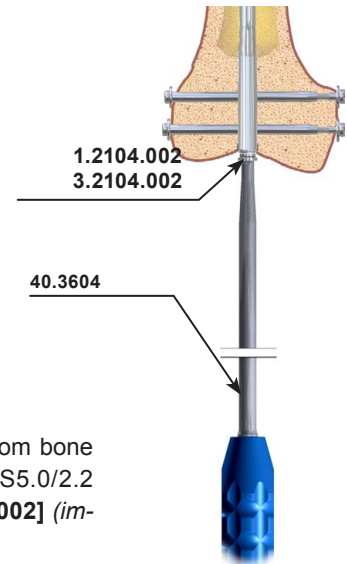
**NOTE!** Proximal locking of the nail may be also performed using freehand technique. The procedure is described within reconstruction method. Refer to steps [35] to [38].

#### IV.7.6. Targeter removal and end cap placing



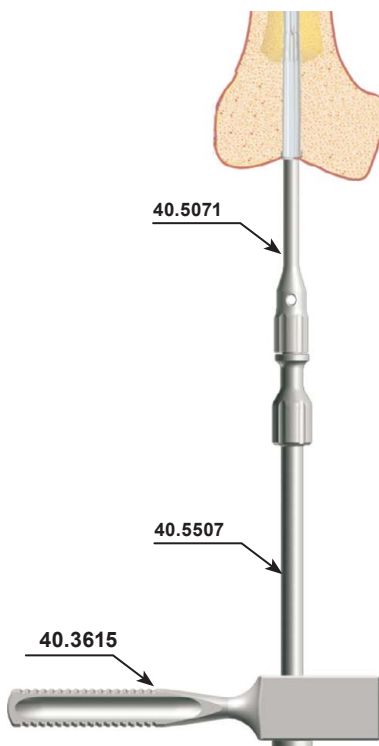
- 25** Using the Wrench S10 [40.5526.100] unscrew the Connecting Screw M10x1 L=55 [40.5094] out of the nail shaft and dismount the targeter from the nail locked in the medullary canal.

Dismount the targeter.



- 26** In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 [40.3675] insert the End Cap [1.2104.002] or [3.2104.002] (implant) inside the nail.

#### IV.7.7. Nail extraction



- 27** Use the Screwdriver S3.5 [40.3604] to remove the End Cap from the nail shaft. Using the Screwdriver S3.5 [40.3604] unscrew all the locking screws (use 2 screwdrivers to remove locking set). Using the wrench insert the Connector [40.5071] into the threaded hole in the nail. Attach the Impactor-Extractor [40.5507] to the connector and using the Mallet [40.3667] extract the nail from the medullary canal.



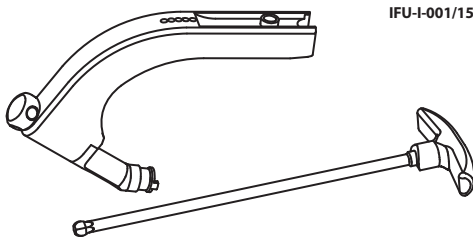


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ISO 9001/ ISO 13485



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IFU-I-001/15



## INSTRUCTIONS FOR USE REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

### DESCRIPTION AND INDICATIONS

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

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

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

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

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

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

The packaging is equipped with the product label. The label contains:

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

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

### MATERIALS

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

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

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

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

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

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

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

### WARNINGS AND PRECAUTIONS

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

### CLEANING, DISINFECTION AND STERILIZATION

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

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure (washer-disinfector) for cleaning and disinfecting.

ommended to use an automated procedure (washer-disinfector) for cleaning and disinfecting.

- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning (manual, ultrasound, with the use of washing/disinfecting machine), the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

#### Preparation for cleaning

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

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

#### Cleaning and disinfection process

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

#### CAUTION:

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

#### Manual cleaning

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

#### CAUTION:

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

#### Cleaning with washer-disinfector

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

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

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

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

#### Drying

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

#### Inspection

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

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

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
  - holes, cannulations,
  - places where soil may be pressed during use,
  - cutting edges should be checked for sharpness and damage,
  - special care should be taken to inspect the instruments for complete dryness prior to their storage.
- Functional checks should be performed where possible:
- mating devices should be checked for proper assembly,
  - all reusable orthopaedic and surgical instruments should be checked for straightness.

#### CAUTION:

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

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

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

#### Packaging

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

#### Sterilization

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

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

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

#### CAUTION:

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

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

### STORAGE

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

### CALIBRATION

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

To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.

- The calibration is conducted by the manufacturer – ChM sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

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

Updated INSTRUCTIONS FOR USE are available on the following website: [www.chm.eu](http://www.chm.eu)

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

#### SYMBOL TRANSLATION - OBJASŇENIA SYMBOLŮ - ПОВЕЩЕНИЕ ОБОЗНАЧЕНИЙ - EXPLICACIÓN DE LOS SÍMBOLOS - SYMBOLERKLÄRUNG - SYMBOLY PŘEKLADY - TRADUZIONE SIMBOLI

	Do not reuse - Nie używać повторно - Не использовать повторно - No reutilizar - Nicht wiederverwenden - Nepoužívejte opakovaně - Non riutilizzare
	Do not re-sterilize - Nie sterylizować ponownie - Не стерилизовать повторно - No reesterilizar - Nicht reesterilisieren - Nepoužívejte resterilizaci - Non ristilizzare
	Do not use if package is damaged - Nie używać jeśli opakowanie jest uszkodzone - Не использовать если упаковка повреждена - No utilizar si el empaque está dañado - Nicht verwenden falls Verpackung beschädigt ist - Nepoužívejte, pokud je obal poškozen - Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use - Zapřijte do instrukcí užívání - Обращаться к инструкциям по применению - Consult Instructions for use - Siehe die Gebrauchsanweisung - Riferite se navedem k použití - Consultare le istruzioni per l'uso
	Non-sterile - Niesterylizowany - Не стерильно - Non sterile - Unsteril - Nesterilni - Non sterile
	Caution - Ostrzeżenie - Осторожно - Advertencia - Vorsicht - Varoitus - Attenzione leggere il foglio illustrativo
	Sterilized using irradiation - Sterylizowany przez napromieniowanie - Радиационная стерилизация - Esterilizado mediante radiación - Sterilisiert durch Bestrahlung - Sterilizzato tramite radiazione
	Sterilized using hydrogen peroxide - Sterylizowany nadtlenkiem wodoru - Стерилизован перекисью водорода - Esterilizado con peróxido de hidrógeno - Sterilisiert mit Wasserstoffperoxid - Sterilizzato con ossigeno perossido - Sterilizzato mediante perossido di idrogeno
	Catalogue number - Numer katalogowy - Номер по каталогу - Número de catálogo - Katalognummer - Katalogové číslo - Numero di catalogo
	Batch code - Rod partií - Код партии - Código de lote - Chargennummer - Císlo šarže - Codice del lotto
	Material - Materiał - Материал - Material - Material - Materiale
	Quantity - Ilość - Количество - Cantidad - Menge - Množství - Quantita'
	Use by - Użyć do - Использовать до - Usar antes de - Verwenden bis - Použijte do - Da utilizzare entro il

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CE 0197  
ISO 9001  
ISO 13485