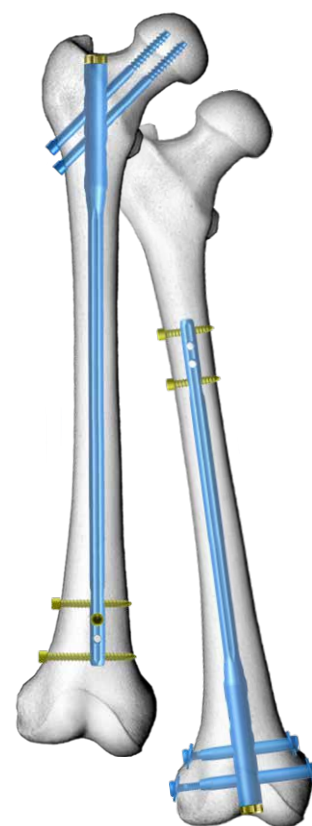


CHM[®]



















CHARFIX *system*








INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR

- *IMPLANTS*
- *INSTRUMENT SET 40.5090.700*
- *INSTRUMENT SET 40.5090.710*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTION

	Titanium or titanium alloy		Cannulated
	Steel		Locking
	Left		Diameter
	Right		Inner diameter
	Available versions: left/right		Recommended length range for a particular nail
	Length		Angle
	Torx drive		Available lengths
	Torx drive cannulated		Available in sterile/ non- sterile condition
	Hexagonal drive		
	Hexagonal drive cannulated		

	Caution - pay attention to a special procedure.
	Perform the activity under X-Ray control.
	Information about the next stages of a procedure.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

www.chm.eu

Document No ST/24G
 Date of issue 08.02.2021
 Review date P-001-28.02.2022

The manufacturer reserves the right to introduce design changes.

Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

I. INTRODUCTION	4
I.1. RECONSTRUCTION, PERTROCHANTERIC METHOD	5
I.2. COMPRESSION, DYNAMIC AND STATIC METHOD	7
I.3. RETROGRADE METHOD (<i>CONDYLAR APPROACH</i>)	9
II. IMPLANTS	10
II.1. IMPLANTS FOR RECONSTRUCTION METHOD	10
II.2. IMPLANTS FOR COMPRESSION METHOD	11
II.3. IMPLANTS FOR RETROGRADE METHOD	12
III. INSTRUMENT SET	16
III.1. INTRODUCTION	16
III.2. INSTRUMENT SET FOR RECONSTRUCTION, COMPRESSION AND STATIC METHOD [40.5090.700] AND [40.5090.710]	16
IV. SURGICAL TECHNIQUE	19
IV.1. METHODS: RECONSTRUCTION, COMPRESSION, DYNAMIC, STATIC	19
IV.1.1. Introduction	19
IV.1.2. Preparation of medullary canal and nail insertion.	21
IV.2. RECONSTRUCTION METHOD	27
IV.2.1. Proximal locking of the nail	27
IV.2.1.1. OPTION I: Locking with reconstruction screws	27
IV.2.1.2. OPTION II: Locking the nail with reconstruction cannulated screws	33
IV.2.2. Distal locking of the nail	36
IV.2.3. Targeter removal. End cap insertion	42
IV.2.4. Distal locking of the nail - "freehand technique" - Method I	43
IV.2.5. Distal locking of the nail - "freehand technique" - Method II	45
IV.3. DYNAMIC AND COMPRESSION METHODS	47
IV.3.1. Distal locking of the nail	47
IV.3.2. Proximal locking of the nail	48
IV.3.3. Targeter removal	51
IV.3.4. Compression screw insertion	52
IV.3.5. End cap insertion (<i>DYNAMIC method only</i>)	53
IV.4. STATIC METHOD	54
IV.4.1. Distal nail locking	54
IV.4.2. Proximal nail locking	55
IV.4.3. Targeter removal, End cap insertion	57
IV.5. STATIC METHOD WITH THE USE OF RECONSTRUCTION NAIL	58
IV.5.1. Proximal nail locking	58
IV.5.2. Distal nail locking	60
IV.5.3. Targeter removal, end cap insertion	61
IV.6. NAIL REMOVAL	62
IV.7. RETROGRADE METHOD (<i>CONDYLAR APPROACH</i>)	63
IV.7.1. Introduction	63
IV.7.2. Preparation and nail insertion	64
IV.7.3. Targeter installation and nail implantation	66
IV.7.4. Condylar locking of the nail	69
IV.7.4.1. OPTION I: Locking with a screw	69
IV.7.4.2. OPTION II: Locking with locking set (bolt - two washers - locking screw)	71
IV.7.5. Locking of the nail in the femoral shaft	73
IV.7.6. Targeter removal. End cap insertion	79
IV.7.7. Nail removal	80

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:

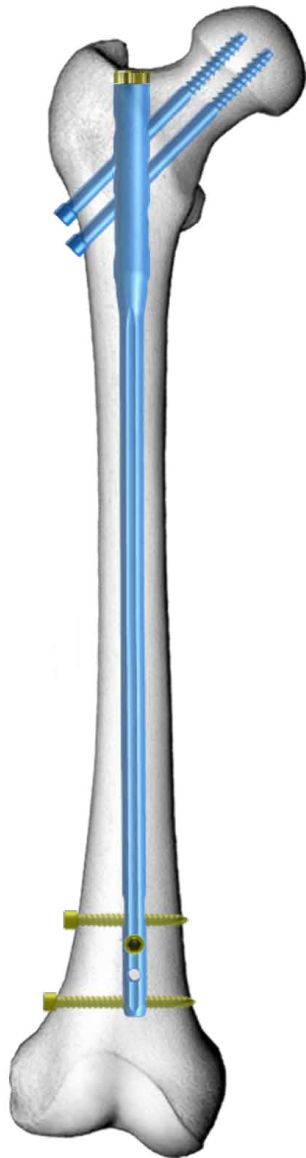
- adequate selection of implants (*intramedullary nails, screws, locking screws*),
- instrument sets for implants insertion and removal,
- instructions for use (*surgical technique*).

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

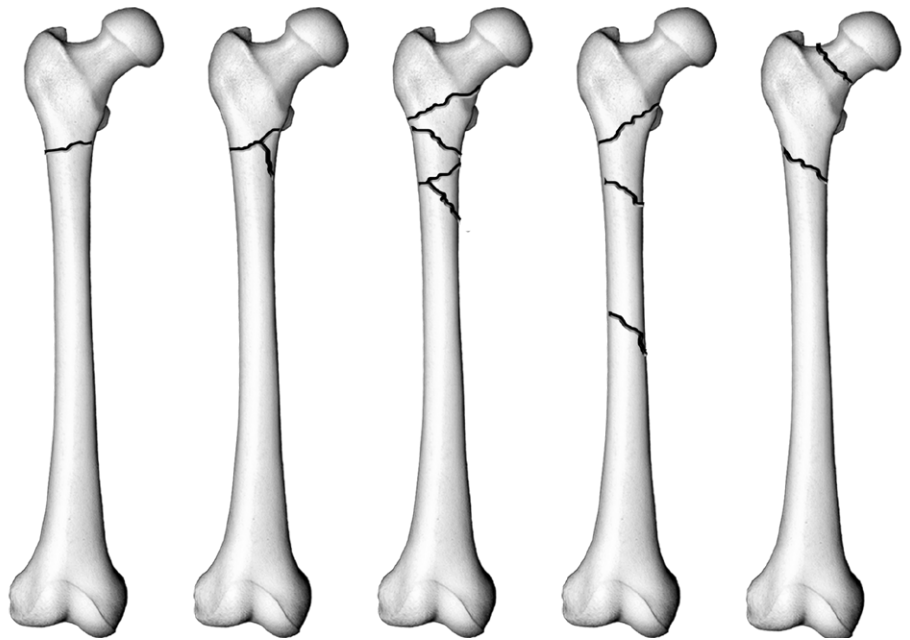
I.1. RECONSTRUCTION, PERTROCHANTERIC METHOD

Reconstruction nails are used for intramedullary fixation of proximal femur, neck and peritrochanteric fractures. Angular position of reconstruction screws ensures 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:



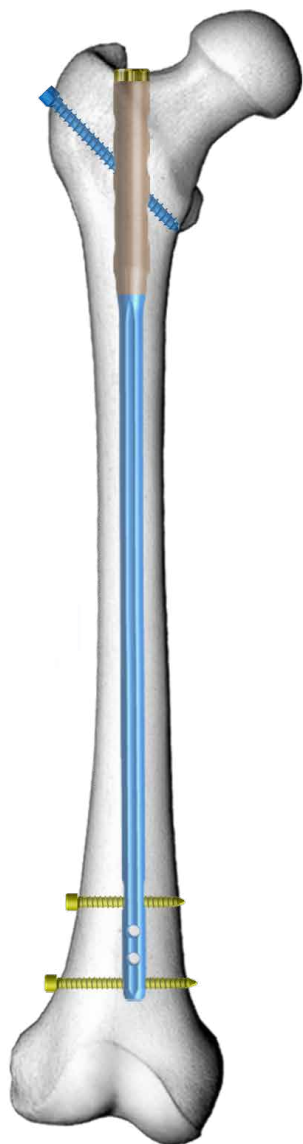
Examples of fractures treated with this method



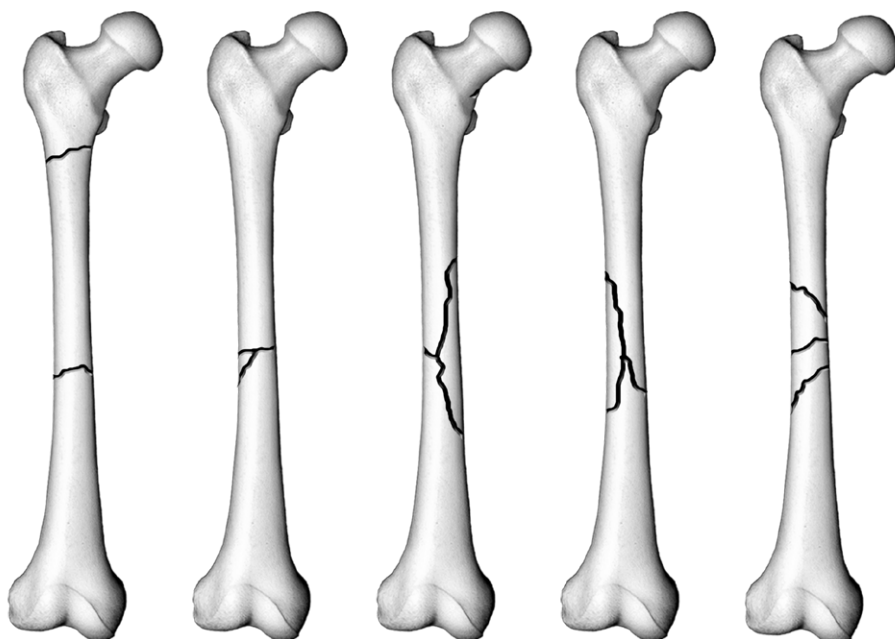
To fix the femoral fracture fragments with pertrochanteric method use:

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

Position of implants in femur:

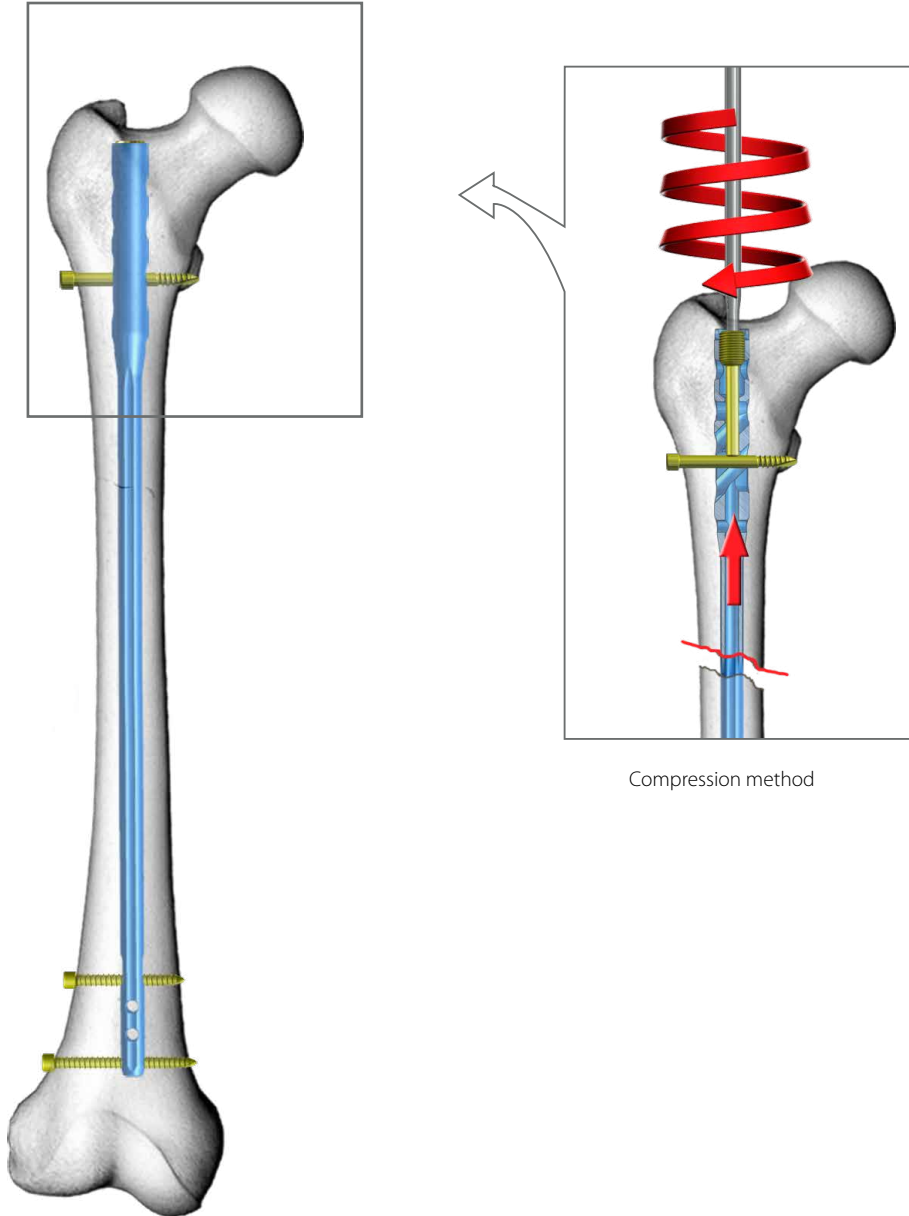


Examples of fractures treated with this method



I.2. COMPRESSION, DYNAMIC AND STATIC METHOD

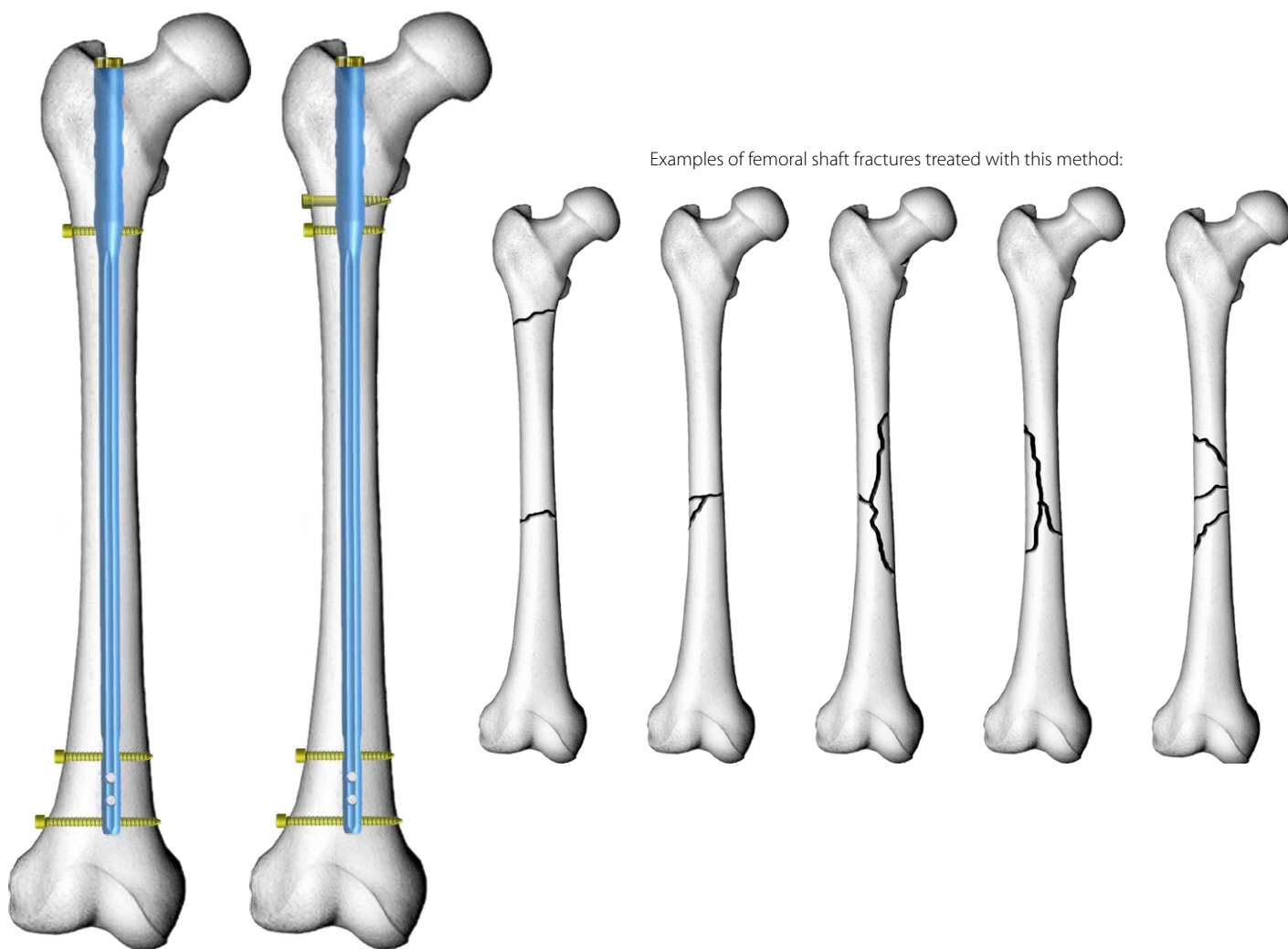
Compressive lockings are used in the intramedullary fixations of femoral shaft fractures, providing that fractures are not closer than 3cm from the locking screw. Nail design allows for treatment with the compression, dynamic and static method.



Static locking

Position of implants in femur:

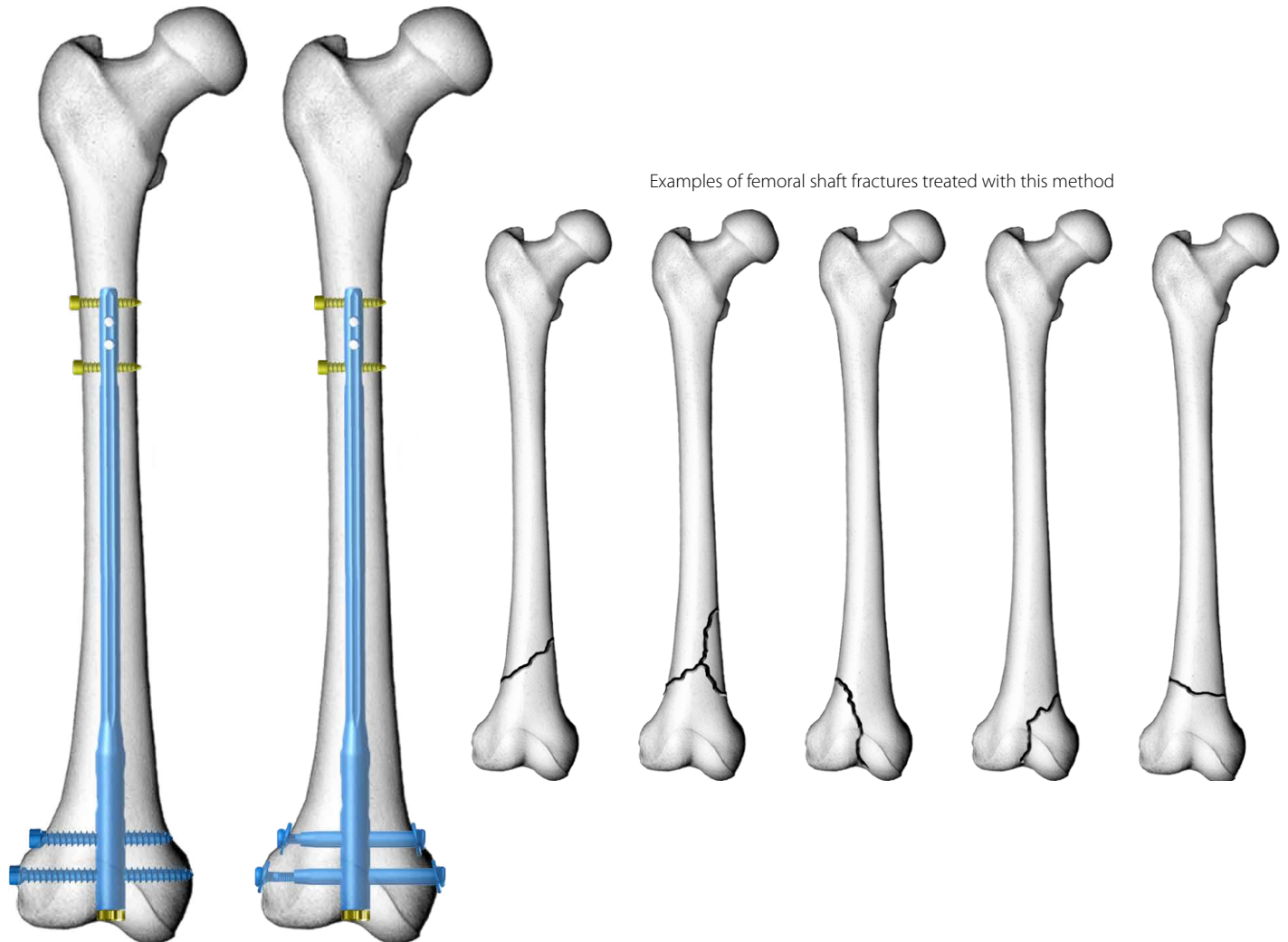
Static locking (if necessary, a shaft locking screw is used additionally to ensure better locking of bone fragments).



I.3. RETROGRADE METHOD (CONDYLAR APPROACH)

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

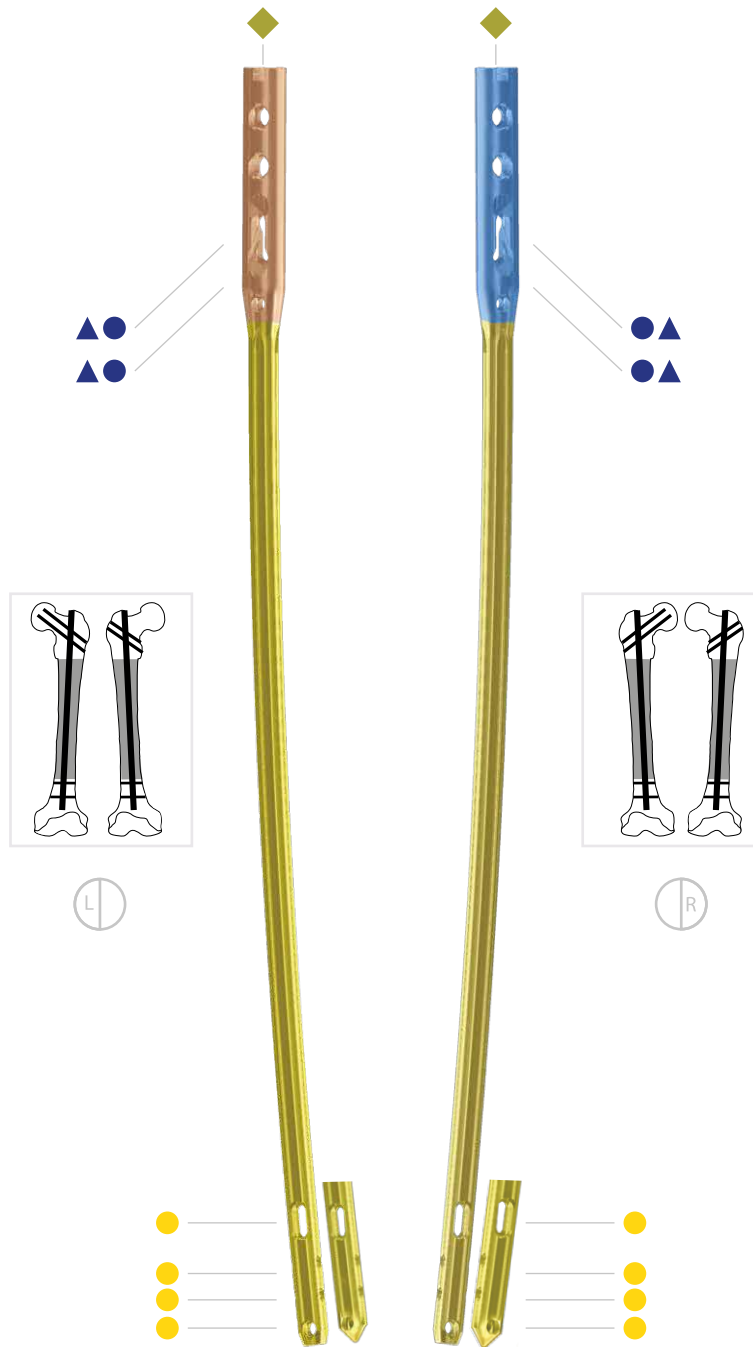
Position of the implant in femur:



II. IMPLANTS

II.1. IMPLANTS FOR RECONSTRUCTION METHOD

FEMORAL NAIL



	Ti	St					
	3.1651.xxx	1.1651.xxx	✓		6.5	50÷120	
	3.1652.xxx	1.1652.xxx	✓	✓	6.5	60÷120	
	3.1654.xxx	1.1654.xxx	✓		4.5	30÷90	
	3.2104.xxx	1.2104.xxx	✓	✓		0÷15	

available			
∅ [mm] pitch 1 mm	8÷15	8÷10	11÷15
L [mm] pitch 5 mm	160÷600	160÷600	160÷600

II.2. IMPLANTS FOR COMPRESSION METHOD

FEMORAL NAIL

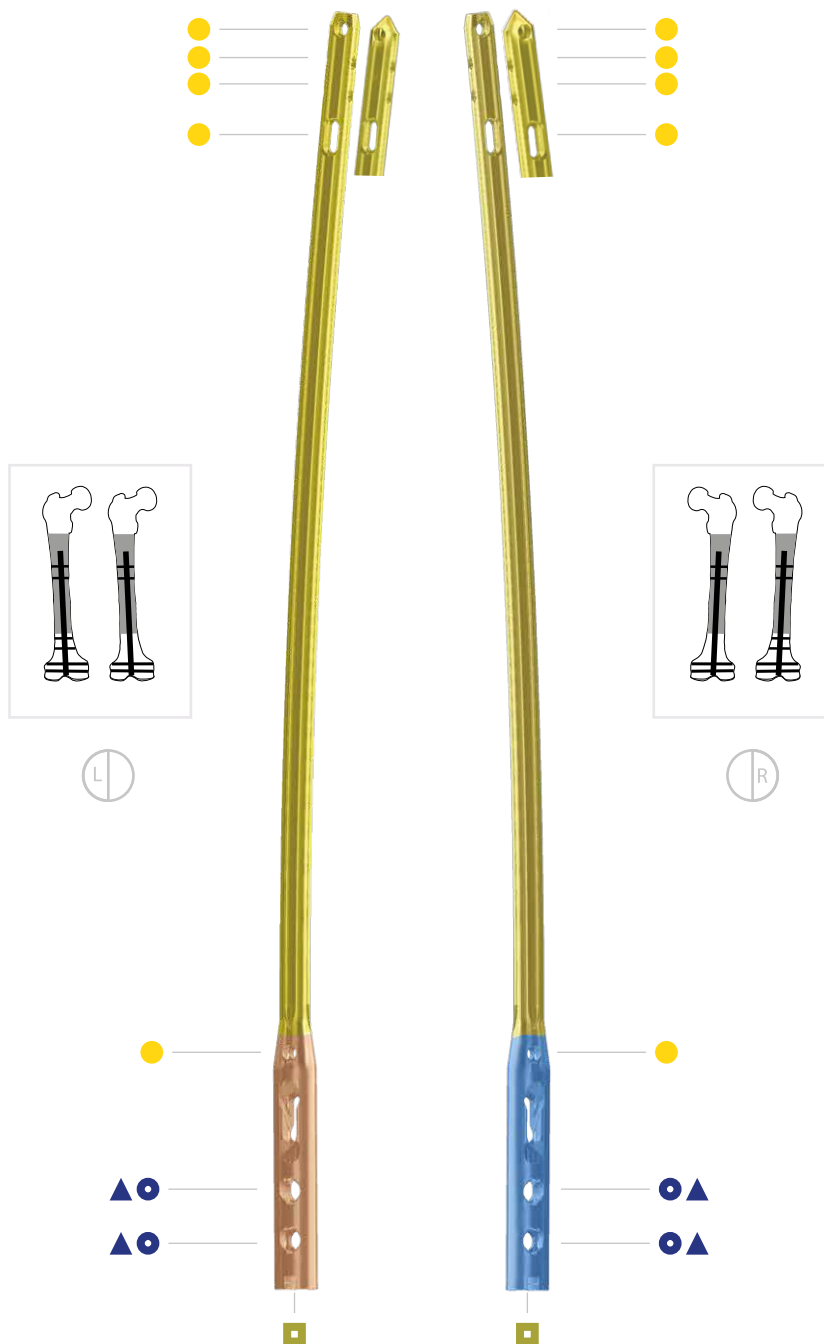


	Ti	St					
	3.1654.xxx	1.1654.xxx	✓		4.5	30÷90	●
	3.1653.xxx	1.1653.xxx	✓		4.5	30÷90	○
	3.2104.xxx	1.2104.xxx	✓	✓		0÷15	◆
	3.2106.007	1.2106.007	✓				◐

available			
∅ [mm] pitch 1 mm	8÷15	8÷10	11÷15
L [mm] pitch 5 mm	160÷600	160÷600	160÷600

II.3. IMPLANTS FOR RETROGRADE METHOD

FEMORAL NAIL



	Ti	St					
	3.1651.xxx	1.1651.xxx	✓		6.5	50÷120	
	3.2109.xxx	1.2109.xxx	✓		6.0	30÷90	
	3.1654.xxx	1.1654.xxx	✓		4.5	30÷90	
	3.2104.002	1.2104.002	✓			2	

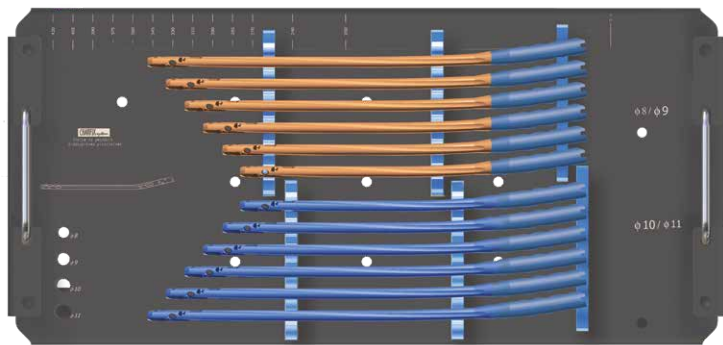
available			
∅ [mm] pitch 1 mm	8÷15	8÷10	11÷15
L [mm] pitch 5 mm	160÷600	160÷600	160÷600

FEMORAL NAIL

St					Ti						
Len	∅	L	R		Len	∅	L	R			
200		1.2855.200	1.2854.200	3.2855.200	3.2854.200	200		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	9	1.2855.340	1.2854.340	3.2855.340	3.2854.340	340	12	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		1.2855.400	1.2854.400	3.2855.400	3.2854.400	400		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		1.2857.320	1.2856.320	3.2857.320	3.2856.320	320		1.2863.320	1.2862.320	3.2863.320	3.2862.320
340	10	1.2857.340	1.2856.340	3.2857.340	3.2856.340	340	13	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
460		1.2857.460	1.2856.460	3.2857.460	3.2856.460	460		1.2863.460	1.2862.460	3.2863.460	3.2862.460
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
200		1.2859.200	1.2858.200	3.2859.200	3.2858.200	200		1.2865.200	1.2864.200	3.2865.200	3.2864.200
220		1.2859.220	1.2858.220	3.2859.220	3.2858.220	220		1.2865.220	1.2864.220	3.2865.220	3.2864.220
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	11	1.2859.340	1.2858.340	3.2859.340	3.2858.340	340	14	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		1.2859.400	1.2858.400	3.2859.400	3.2858.400	400		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

St					Ti				
Len	L	R	L	R	Len	L	R	L	R
200	1.2877.200	1.2876.200	3.2877.200	3.2876.200	200	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
260	1.2877.260	1.2876.260	3.2877.260	3.2876.260	260	1.2883.260	1.2882.260	3.2883.260	3.2882.260
280	1.2877.280	1.2876.280	3.2877.280	3.2876.280	280	1.2883.280	1.2882.280	3.2883.280	3.2882.280
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
340	1.2877.340	1.2876.340	3.2877.340	3.2876.340	340	1.2883.340	1.2882.340	3.2883.340	3.2882.340
360	1.2877.360	1.2876.360	3.2877.360	3.2876.360	360	1.2883.360	1.2882.360	3.2883.360	3.2882.360
380	1.2877.380	1.2876.380	3.2877.380	3.2876.380	380	1.2883.380	1.2882.380	3.2883.380	3.2882.380
400	1.2877.400	1.2876.400	3.2877.400	3.2876.400	400	1.2883.400	1.2882.400	3.2883.400	3.2882.400
420	1.2877.420	1.2876.420	3.2877.420	3.2876.420	420	1.2883.420	1.2882.420	3.2883.420	3.2882.420
440	1.2877.440	1.2876.440	3.2877.440	3.2876.440	440	1.2883.440	1.2882.440	3.2883.440	3.2882.440
460	1.2877.460	1.2876.460	3.2877.460	3.2876.460	460	1.2883.460	1.2882.460	3.2883.460	3.2882.460
480	1.2877.480	1.2876.480	3.2877.480	3.2876.480	480	1.2883.480	1.2882.480	3.2883.480	3.2882.480
200	1.2879.200	1.2878.200	3.2879.200	3.2878.200	200	1.2885.200	1.2884.200	3.2885.200	3.2884.200
220	1.2879.220	1.2878.220	3.2879.220	3.2878.220	220	1.2885.220	1.2884.220	3.2885.220	3.2884.220
240	1.2879.240	1.2878.240	3.2879.240	3.2878.240	240	1.2885.240	1.2884.240	3.2885.240	3.2884.240
260	1.2879.260	1.2878.260	3.2879.260	3.2878.260	260	1.2885.260	1.2884.260	3.2885.260	3.2884.260
280	1.2879.280	1.2878.280	3.2879.280	3.2878.280	280	1.2885.280	1.2884.280	3.2885.280	3.2884.280
300	1.2879.300	1.2878.300	3.2879.300	3.2878.300	300	1.2885.300	1.2884.300	3.2885.300	3.2884.300
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
360	1.2879.360	1.2878.360	3.2879.360	3.2878.360	360	1.2885.360	1.2884.360	3.2885.360	3.2884.360
380	1.2879.380	1.2878.380	3.2879.380	3.2878.380	380	1.2885.380	1.2884.380	3.2885.380	3.2884.380
400	1.2879.400	1.2878.400	3.2879.400	3.2878.400	400	1.2885.400	1.2884.400	3.2885.400	3.2884.400
420	1.2879.420	1.2878.420	3.2879.420	3.2878.420	420	1.2885.420	1.2884.420	3.2885.420	3.2884.420
440	1.2879.440	1.2878.440	3.2879.440	3.2878.440	440	1.2885.440	1.2884.440	3.2885.440	3.2884.440
460	1.2879.460	1.2878.460	3.2879.460	3.2878.460	460	1.2885.460	1.2884.460	3.2885.460	3.2884.460
480	1.2879.480	1.2878.480	3.2879.480	3.2878.480	480	1.2885.480	1.2884.480	3.2885.480	3.2884.480
200	1.2881.200	1.2880.200	3.2881.200	3.2880.200	200	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
240	1.2881.240	1.2880.240	3.2881.240	3.2880.240	240	1.2887.240	1.2886.240	3.2887.240	3.2886.240
260	1.2881.260	1.2880.260	3.2881.260	3.2880.260	260	1.2887.260	1.2886.260	3.2887.260	3.2886.260
280	1.2881.280	1.2880.280	3.2881.280	3.2880.280	280	1.2887.280	1.2886.280	3.2887.280	3.2886.280
300	1.2881.300	1.2880.300	3.2881.300	3.2880.300	300	1.2887.300	1.2886.300	3.2887.300	3.2886.300
320	1.2881.320	1.2880.320	3.2881.320	3.2880.320	320	1.2887.320	1.2886.320	3.2887.320	3.2886.320
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



40.5753.000
Stand for universal femoral nails (implants not included)

available



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

Ti	Ø8	Ø9	Ø10	Ø11	Ø12	Ø13
left	[Color swatches]					
right	[Color swatches]					
colours						



LOCKING ELEMENTS



A	St	Ti
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



A	St	Ti
2	1.2104.002	3.2104.002



COMPRESSION SCREW

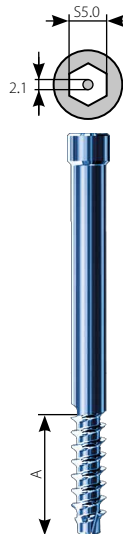
St	Ti
1.2106.007	3.2106.007

DISTAL SCREW 6.5



Len	St	Ti
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		
30 ÷ 110		

RECONSTRUCTION CANNULATED SCREW 6.5



Len	A	St	Ti
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

LOCKING SET 6.5

Len	Len	St	Ti
50	50-65	1.2109.050	3.2109.050
60	60-75	1.2109.060	3.2109.060
70	70-85	1.2109.070	3.2109.070
80	80-95	1.2109.080	3.2109.080
90	90-105	1.2109.090	3.2109.090

DISTAL SCREW 4.5



Len	St	Ti
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
available		
16 ÷ 100		

PROXIMAL SCREW 4.5



Len	A	St	Ti
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			
25 ÷ 90			



III. INSTRUMENT SET




















III.1. INTRODUCTION









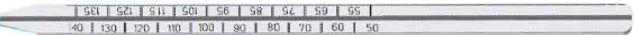



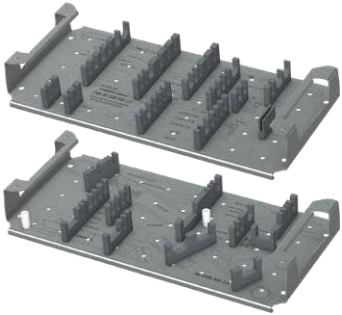

For the fixation of femoral fractures with reconstruction, compression, dynamic or static method, a single instrument set is used. Additionally, the flexible reamers with the following diameters and a drive are required:



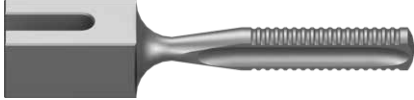




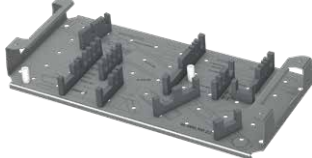
8 [40.3854], 8.5 [40.3855], 9 [40.3856], 9.5 [40.3857], 10 [40.3858], 10.5 [40.3859], 11 [40.3860], 11.5 [40.3861], 12 [40.3862], 12.5 [40.3863], 13 [40.3864], 13.5 [40.3865], 14 [40.3866], 14.5 [40.3867], 15 [40.3868]. The procedure should be performed on an X-Ray transparent operating table with a traction.

III.2. INSTRUMENT SET FOR RECONSTRUCTION, COMPRESSION AND STATIC METHOD [40.5090.700] AND [40.5090.710]

All instruments are placed on a stand with a lid to enable sterilization and transportation to the operating suite.

Instrument set for femoral nails 40.5090.700	Name	Pcs	Catalogue No.
	Targeter arm	1	40.5091.100
	Targeter 135	1	40.5097.000
	Connecting screw M10x1 L=55	1	40.5094.000
	Connecting screw M10x1 L=66	1	40.5095.000
	Trocar 9	1	40.3327.000
	Protective guide 11/9	2	40.3328.000
	Drill guide 9/6.5	1	40.3329.000
	Drill guide 9/4.5	1	40.3330.000
	Kirschner guide	1	40.3331.000
	Reconstruction screw length measure	1	40.3332.000
	Kirschner wire 2.0/380	4	40.3333.000
	Protective guide 9/6.5	2	40.3614.000
	Drill guide 6.5/3.5	2	40.3615.000
	Trocar 6.5	1	40.3617.000
	Screw length measure	1	40.1374.100
	Screw length measure protection	1	40.8552.000
	Connector M10x1/M12	1	40.5071.000
	Impactor-extractor	1	40.5507.000
	Cannulated drill 13/3.5	1	40.5415.000
	Protective guide 16/13	1	40.5416.000

Instrument set for femoral nails 40.5090.700	Name	Pcs	Catalogue No.
	Wrench S10	1	40.5526.200
	Guide rod 3.0/580	1	40.3925.580
	Screwdriver S 3.5	1	40.3604.100
	Drill with scale 4.5/370	1	40.5333.001
	Drill with scale 3.5/270	2	40.5330.001
	Drill 6.5/370	1	40.2068.371
	Cannulated drill 6.5/300	1	40.3674.000
	Cannulated screwdriver S 5.0/2.2	1	40.3675.100
	Cannulated screw length measure	1	40.3676.000
	Screwdriver S3,5	1	40.5074.000
	Bolt guide	1	40.5075.000
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand	1	40.5099.700
	Container with solid bottom 1/1 595x275x185mm	1	12.0750.103

Instrument set for femoral nails - II 40.5090.710	Name	Pcs	Catalogue No.
	Distal targeter D	1	40.5093.000
	Compression screw	1	40.5096.000
	Nail length measure	1	40.5098.000
	Protective guide 9/6.5	1	40.3614.000
	Drill guide 6.5/3.5	1	40.3615.000
	Set block 9/4.5	2	40.3616.000
	Drill with scale 3.5/270	1	40.5330.001
	Curved awl 8.0	1	40.5523.100
	Mallet	1	40.3667.000
	Guide rod handle	1	40.1351.000
	Aiming insert 9.0	2	40.5065.009
	Aiming insert 11.0	2	40.5065.011
	Angular set block	1	40.5004.500
	Drill guide short 7/3.5	1	40.1358.000
	Celownik D Targeter D	1	40.1344.200
	Perforated aluminum lid 1/1 595x275x15mm Gray	1	12.0750.200
	Stand	1	40.5229.000
	Container with solid bottom 1/1 595x275x86mm	1	12.0750.100

IV. SURGICAL TECHNIQUE

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

IV.1.1. Introduction

Tight fitting the medullary canal is not necessary if locking nail is used. Use nails with diameters 8, 9, 10, 11 mm for implantation in not reamed medullary canal. Nails with diameters 12, 13, 14 are used for cases where reaming has to be performed. Please note that the diameter of reamed canal has to be about 2mm wider than the diameter of the nail to be used.

In every case, a 13mm hole is to be made in the proximal part of femur for nails sized 8, 9, 10, 11, 12, 13 mm or a 14 mm hole for the 14mm nail, and to 8 cm in depth for both cases. It enables the insertion of proximal part, where the nail is made thicker. Decision about possible reaming after verifying the shape of the canal and type of fracture shall be made by a surgeon.

Canal reaming is not recommended for patients with chest injuries due to the risk of fat embolism.

It is recommended to apply strong traction for 2 up to 3 days to spread the fracture fragments, unless the patient can be treated at the day of femoral fracture. The use of traction will considerably facilitate the fracture reduction and nail insertion.

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

Presented method of intramedullary osteosynthesis requires intraoperative 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 for nailing of the pathological subtrochanteric fractures. Special attention must be paid to concurrent femoral neck fractures or proximal epiphysis comminuted fractures, and the possibility of their occurrence during the procedure of nail insertion. During the procedure, 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, nail fixation may be difficult or even impossible to perform. Make sure no alloplasty of hip or knee has ever been performed on the fractured bone before.

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*).

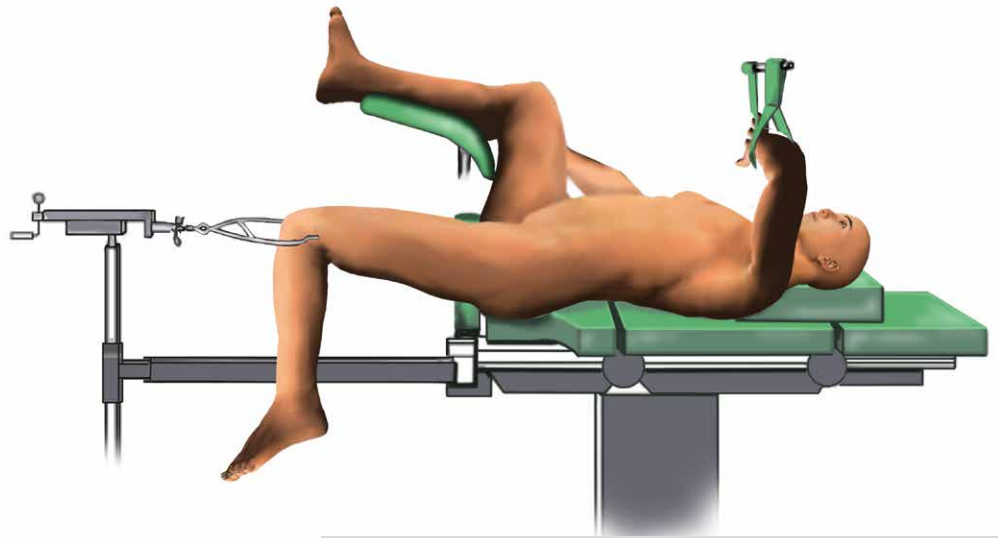


FIG. 1. Supine position for intramedullary osteosynthesis of femur.

In the presented method, the supine position is recommended with traction applied to the condyles of the operated 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 performed incision. Fibers of gluteus maximus muscle are then split.

An approach to the tip of the greater trochanter is achieved from gluteus medius muscle site. The entry point for the nail should be located in line with the axis of medullary canal. It can be found in the following way. If one finds the tip of the greater trochanter with their index finger, the entry point for the nail is located "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 their index finger (see Fig. 2).

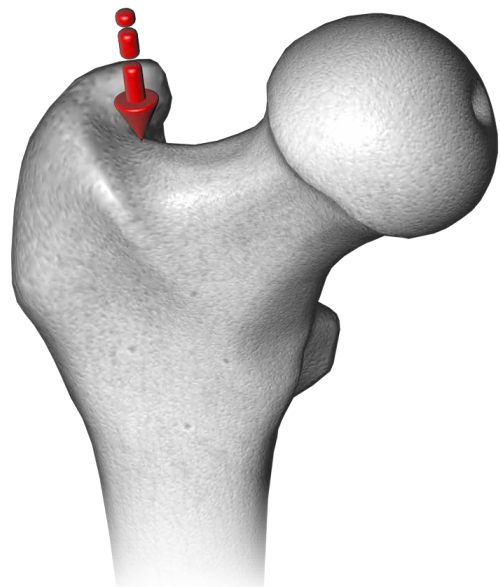


FIG. 2 Entry point for femoral nail.

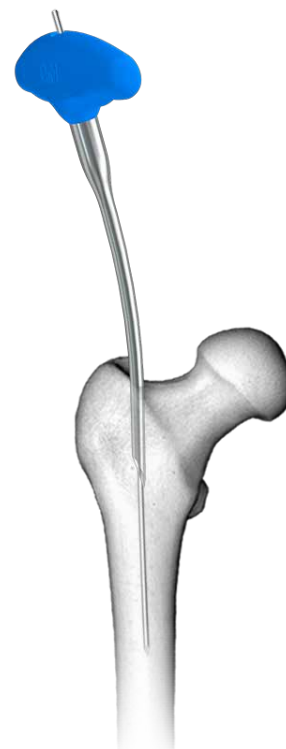
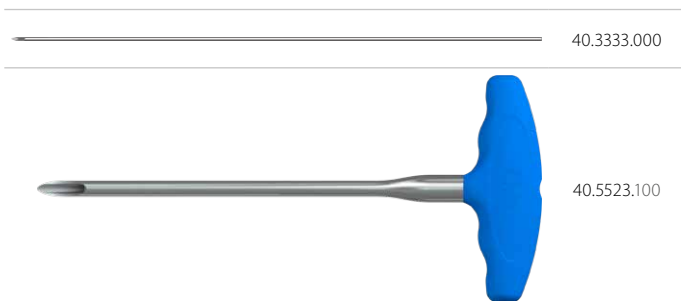


ATTENTION! The following paragraphs describe the most important steps during insertion of intramedullary interlocking femoral nails; nevertheless, it is not a detailed instructions for use. The surgeon decides about choosing the surgical technique and its application in each individual case.

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

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

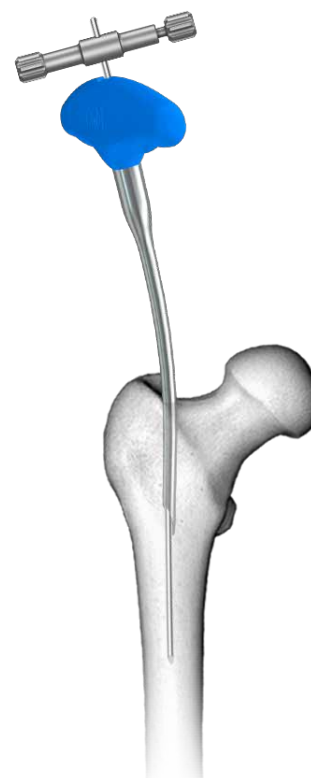
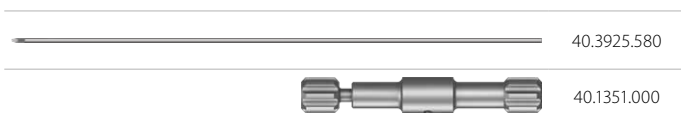
- 1 Use Kirschner wire 2.0/380 [40.3333.000] to insert the curved awl 8.0 [40.5523.100] into medullary canal to the depth at which the awl blade goes along the medullary canal, allowing proper insertion of the guide rod 3.0/580 [40.3925.580]. Having opened the medullary canal, remove Kirschner wire 2.0/380.



- 2 Mount the guide rod 3.0/580 [40.3925.580] to guide rod handle [40.1351.000] and enter the guide into the medullary canal through the curved awl 8.0 [40.5523.100] to the depth required for the proper fixation of bone fragments. While inserting the guide rod, control the fracture reduction and make sure the rod passes through all the bone fragments.

Remove guide rod handle and curved awl.

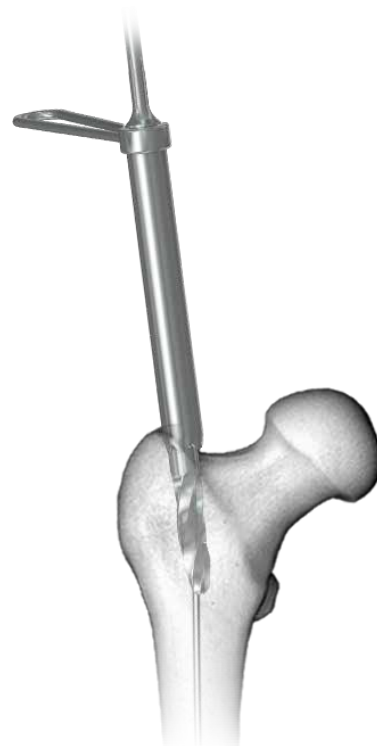
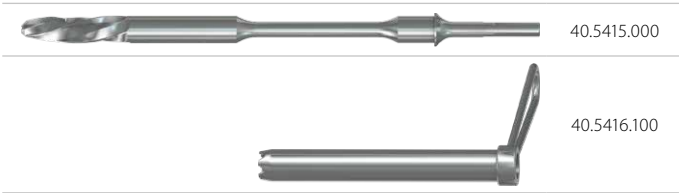
Leave guide rod in place.



- 3 The guide rod 3.0/580 [40.3925.580] is a guide for cannulated drill 13/3.5 [40.5415.000] placed in the protective guide 16/13 [40.5416.100].

Slowly ream the medullary canal with the cannulated drill until the drill collar rests against the protective guide.

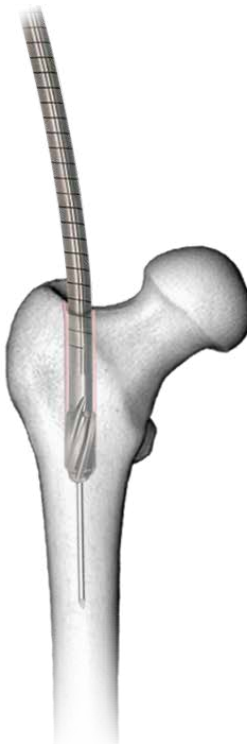
Remove the drill and protective guide.



- 4 For reamed medullary canal, 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.

In both cases, when the medullary canal was reamed or not, the canal should be reamed using 13 or 14 mm reamer to the depth of approx. 8 cm.

Remove the flexible reamer.



- 5 Insert the nail length measure [40.5098.000] via the guide rod 3.0/580 [40.3925.580] until it rests on the bone. Read the length of the nail to be used.

Remove the nail length measure from the guide rod.



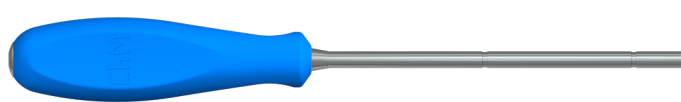
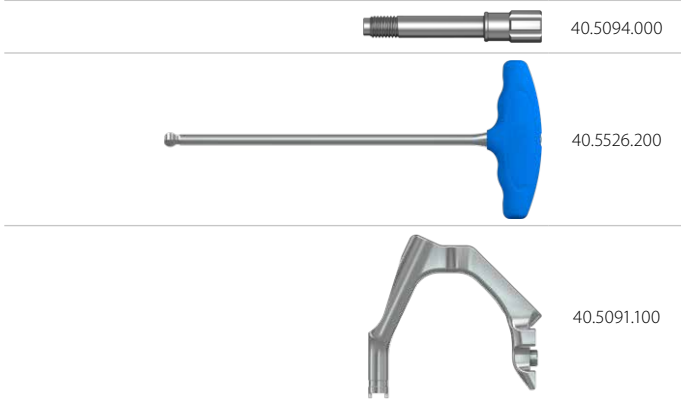
Remove the guide rod if solid nail is used.



Medullary canal is ready for nail insertion.



- 6 Use the connecting screw [40.5094.000] and wrench S10 [40.5526.200] to install the nail on the targeter arm [40.5091.100].

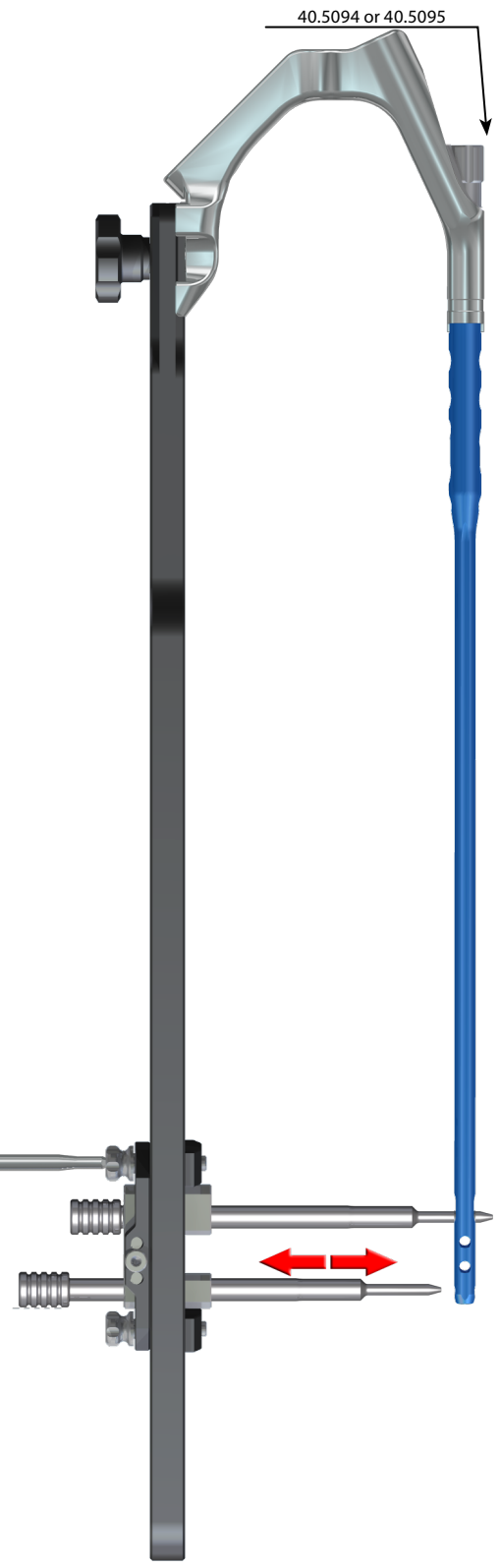
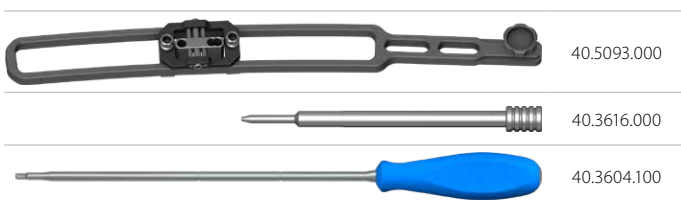


Attach the distal targeter D [40.5093] to the targeter arm.

Use a pair of set blocks 9/4.5 [40.3616.000] to set the slider of the distal targeter D in line with distal locking holes of the nail.

Use the screwdriver S3.5 [40.3604.100] to secure the slider.

! CHECK:
 Properly set and secured slider of the distal targeter D makes it possible for the set blocks 9/4.5 to pass through the holes of the nail easily.



7

I. Attach the angular set block [40.5004.500] to the targeter D so that it rests on the slider of the targeter. Screw up the locking nut in hole of angular set block.

II. Insert the pin to the locking nut. Use screwdriver S3.5 [40.3604.100] to loosen the screws locking the arms of the angular set block and set them so that the pin passes through the transverse hole of the nail. Lock back the arms of angular set block.



Firstly, tightening the locking screw in the body of the set block (1st step). Next, lock the arm with the pin (2nd step).

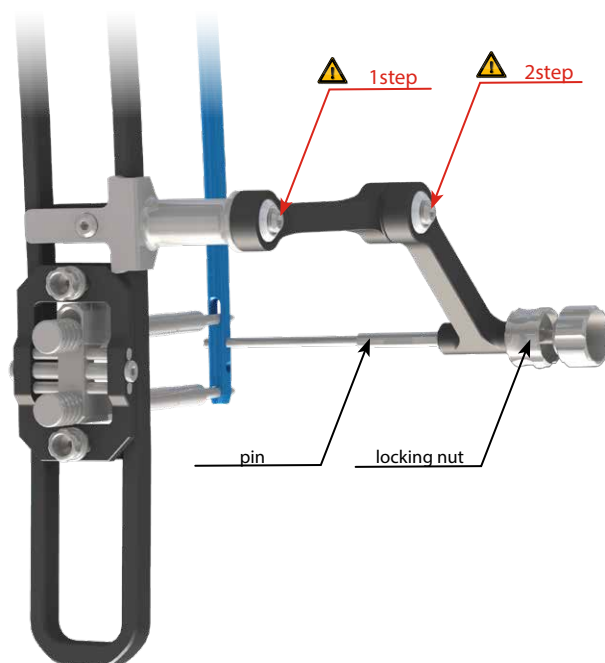
III. Remove the pin from the angular set block.



40.5004.500



40.3604.100

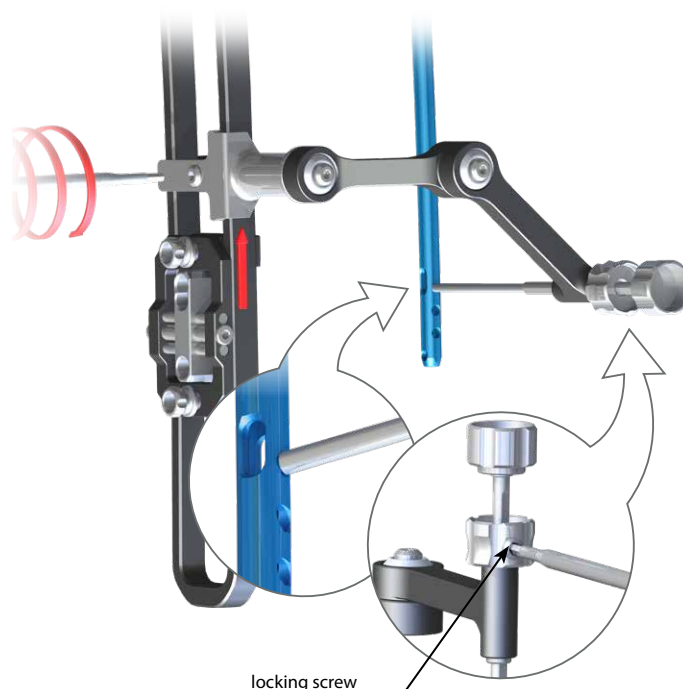


8

I. Loosen the screw mounting the angular set block to the targeter D, move it up 10-15 mm and lock back using screwdriver S3.5 [40.3604.100].

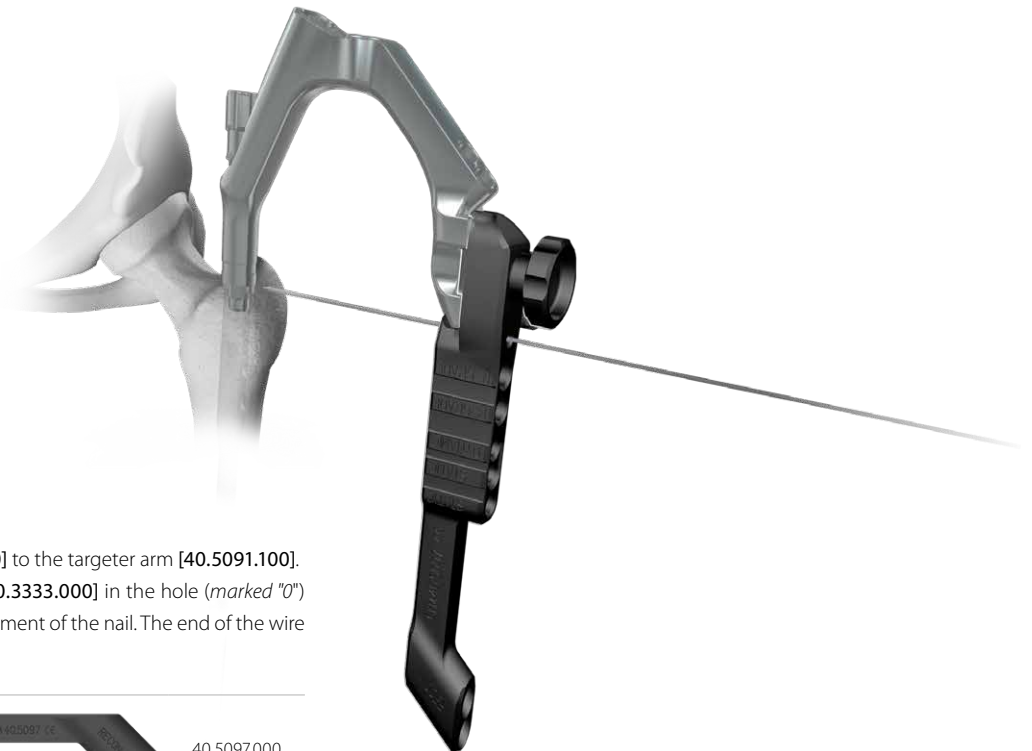
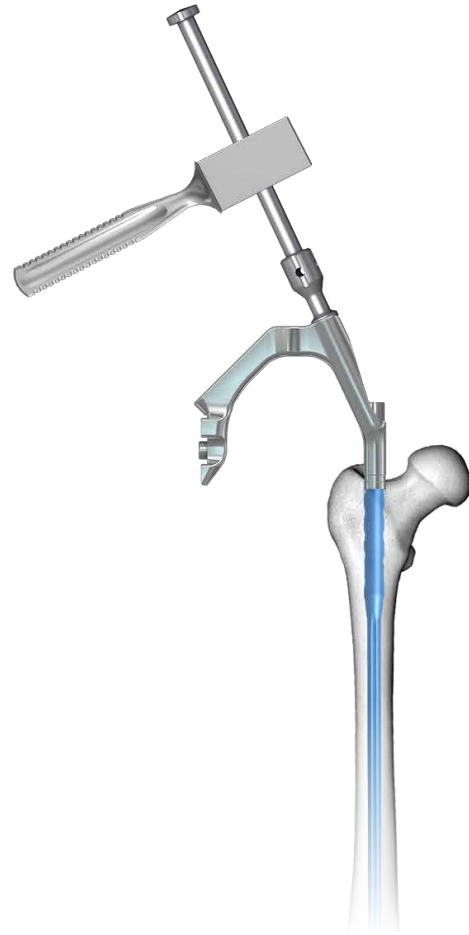
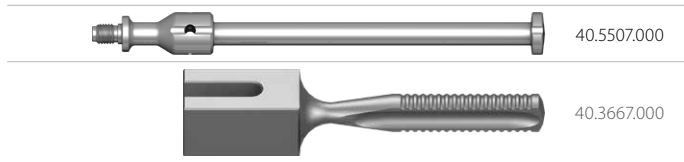
II. Insert the pin so that its end leans against the nail. Use screwdriver S3.5 [40.3604.100] to lock the pin.

III. Unscrew the locked pin-nut set from the angular set block. Dismount the distal targeter D from the targeter arm.

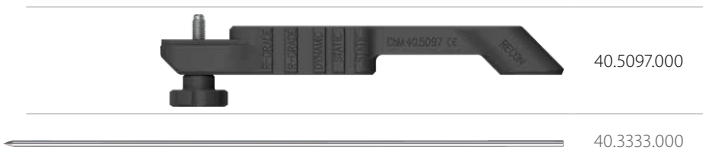


- 9 Install the impactor-extractor [40.5507.000] to the targeter arm [40.5091.100] with the nail attached. Insert the nail onto the guide rod [40.3925.580] and into medullary canal. Advance the nail until it reaches adequate depth.

Remove the guide rod, and impactor-extractor from the targeter arm.



- 10 Install the targeter 135 [40.5097.000] to the targeter arm [40.5091.100]. Insert Kirschner wire 2.0/380mm [40.3333.000] in the hole (marked "0") of the targeter 135 to verify the correct placement of the nail. The end of the wire shows the beginning of the nail.



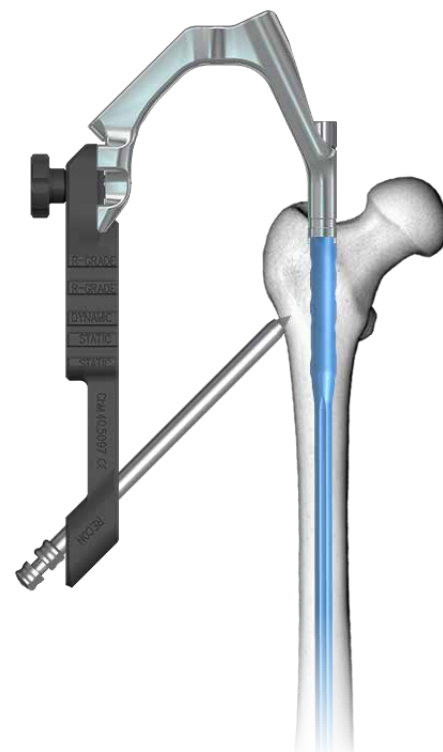
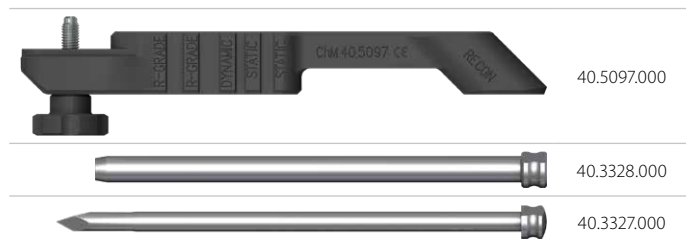
IV.2. RECONSTRUCTION METHOD

IV.2.1. Proximal locking of the nail

IV.2.1.1. **OPTION I:** Locking with reconstruction screws

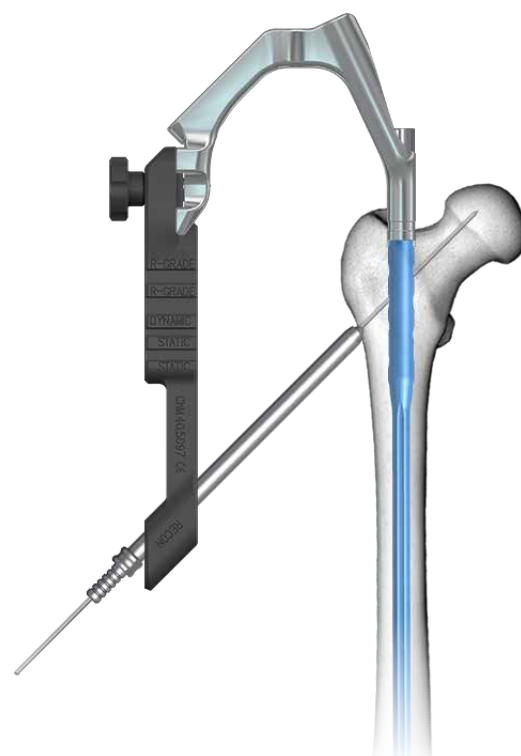
11 Attach the targeter 135 [40.5097.000] to the targeter arm [40.5091.100]. Insert the protective guide 11/9 [40.3328.000] with trocar 9 [40.3327.000] into the first proximal hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. Advance the trocar 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 place.



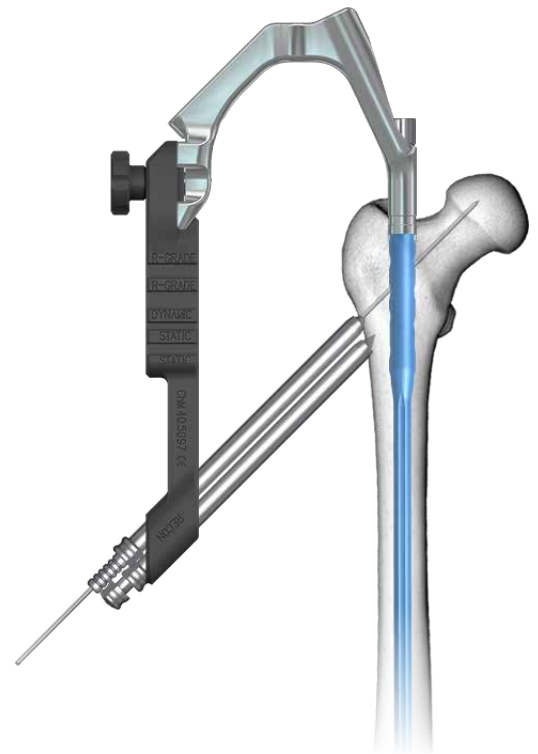
12 Insert the Kirschner guide [40.3331.000] into the protective guide. Install the Kirschner wire 2.0/380 [40.3333.000] to the surgical drive and place the wire in the femoral neck but do not perforate the femoral head. The above step should be controlled with X-Ray imaging (*drawing plane*). Verify the position of the wire in the lateral view. The wire should be in the middle of the neck; deviation is acceptable if allows for the screw insertion without damaging outer cortex of the neck. If the wire is mal-positioned, repeat the step.

Leave: Kirschner guide, protective guide and Kirschner wire in place.



- 13 Insert the protective guide 11/9 [40.3328.000] with trocar 9 [40.3327.000] into the other hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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 place.

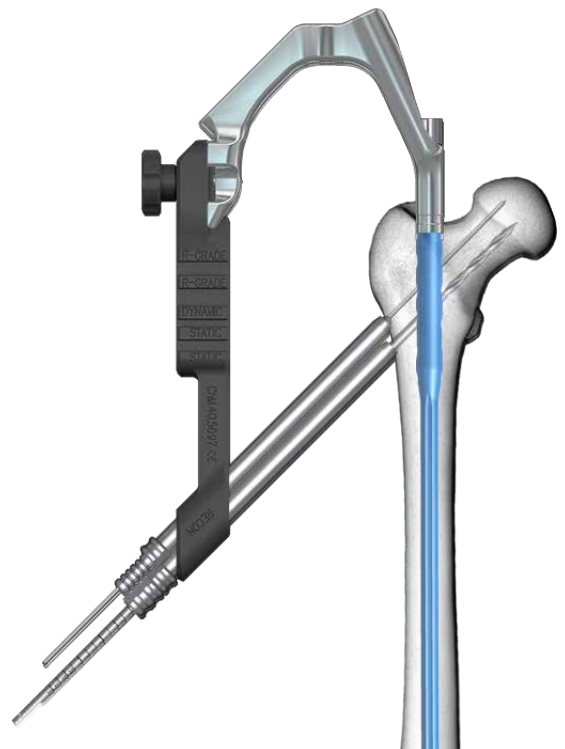


- 14 Insert the drill guide 9/4.5 [40.3330.000] (with two grooves on the handle) into the protective guide 11/9 [40.3328] placed in the second hole of the targeter. Mount the drill with scale 4.5/370 [40.5333.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femoral neck until it reaches adequate depth, but do not perforate the head. The scale on the drill indicates the length of the locking element.



Drill under X-Ray control.

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



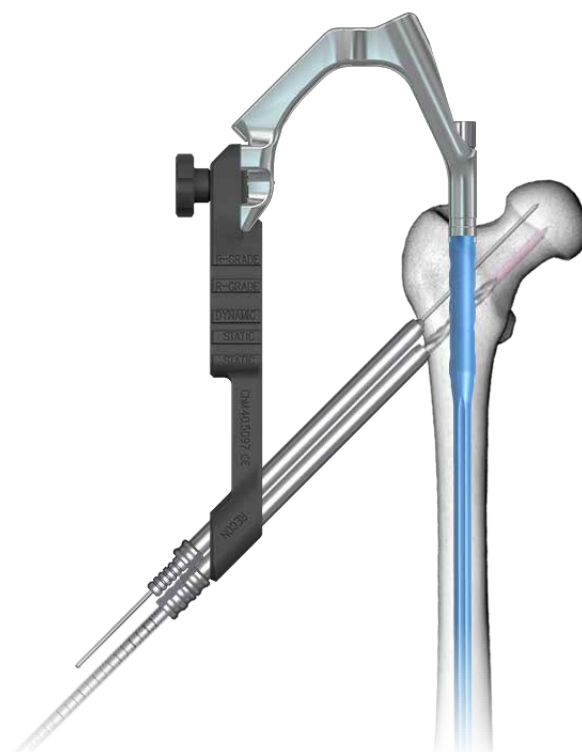
- 15 Insert the drill guide 9/6.5 [40.3329.000] (with three grooves) into the protective guide 11/9 [40.3328.000]. Mount the drill 6.5/370 [40.2068.371] to the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the depth approx. 30mm lesser than the hole drilled beforehand with 4.5 drill (due to the length of the thread of the reconstruction screw).



Ream under X-Ray control.

Remove the drill and drill guide.

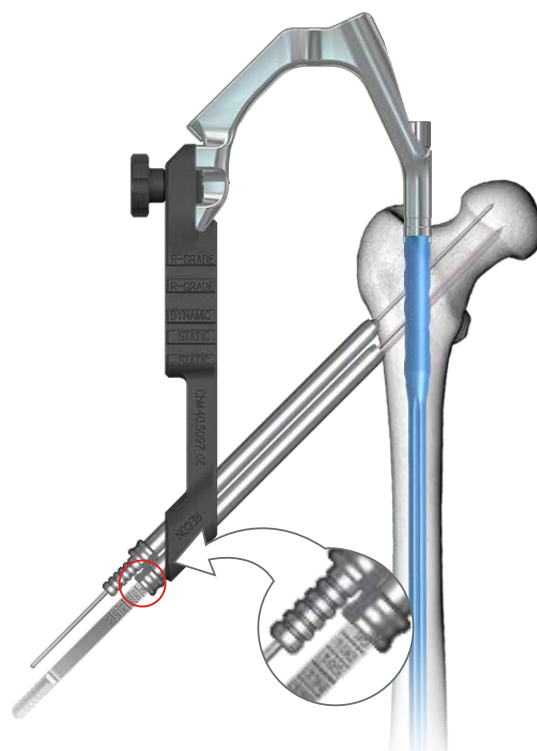
Leave the protective guide in the hole of targeter.



- 16 Insert the reconstruction screw length measure [40.3332.000] through the protective guide 11/9 [40.3328.000] into the drilled hole up until 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.

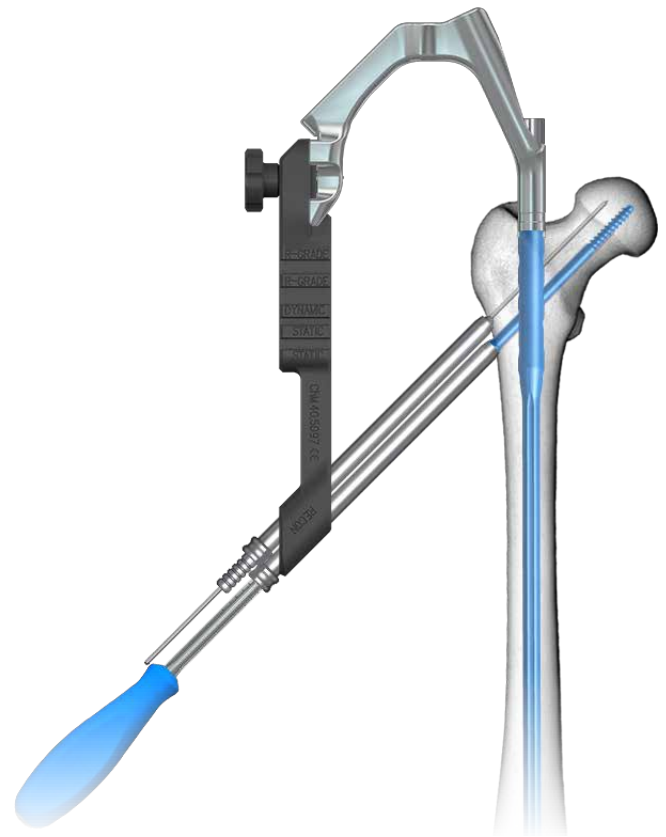
Remove the measure.

Leave the protective guide in the hole of targeter.



- 17 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of 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.

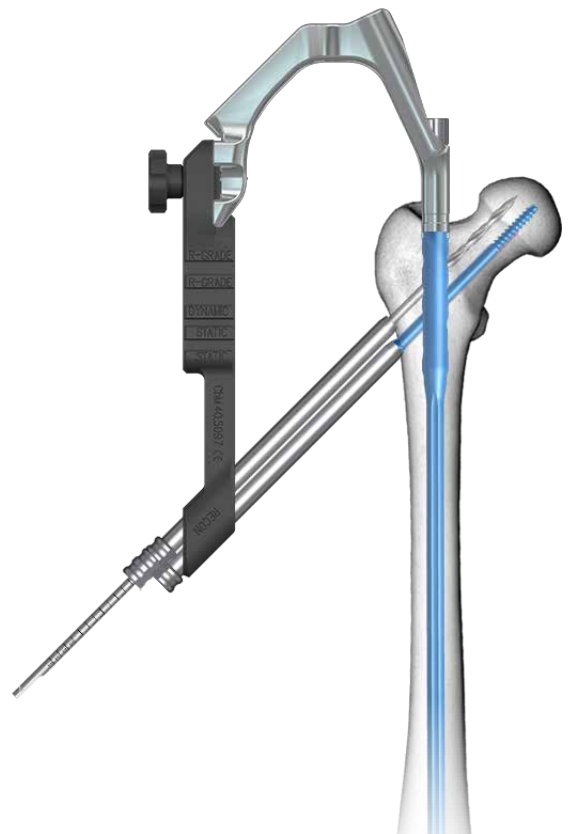


- 18 Remove the Kirschner wire and Kirschner guide from the protective guide 11/9 [40.3328.000] of the first targeter hole. Insert the drill guide 9/4.5 [40.3330.000] (with two grooves on the handle) into the protective guide 11/9 [40.3328.000] (with one groove) left in hole of the targeter. Mount the drill with scale 4.5/370 [40.5333.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femoral neck until it reaches adequate depth, but do not perforate the head. The scale on the drill indicates the length of the locking element.



Drill under X-Ray control.

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



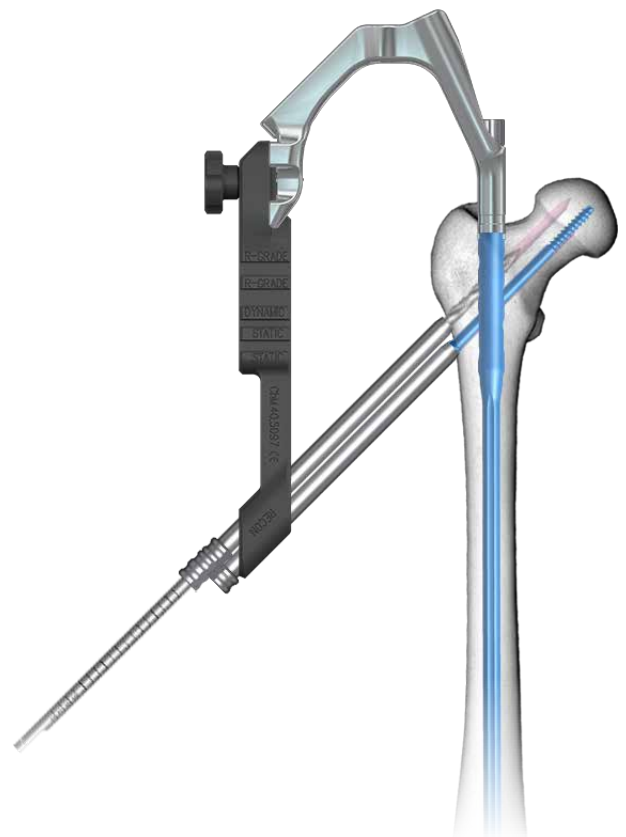
- 19 Insert the drill guide 9/6.5 [40.3329.000] (with three grooves) into the protective guide. Mount the drill 6.5/370 [40.2068.371] to the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the depth approx. 30mm lesser than the hole drilled beforehand with 4.5 drill (due to the length of the thread of the reconstruction screw).



Ream under X-Ray control.

Remove the drill and drill guide.

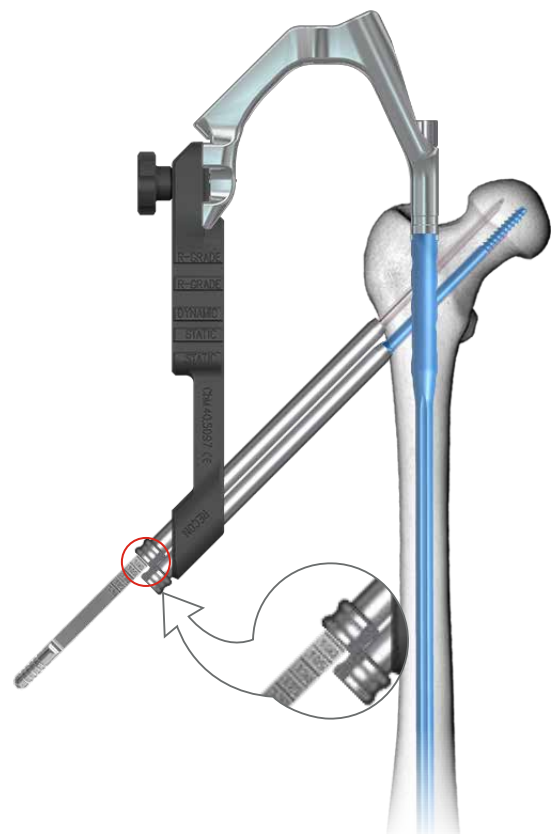
Leave the protective guide in the hole of targeter.



- 20 Insert the reconstruction screw length measure [40.3332.000] through the protective guide 11/9 [40.3328.000] into the drilled hole up until 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.

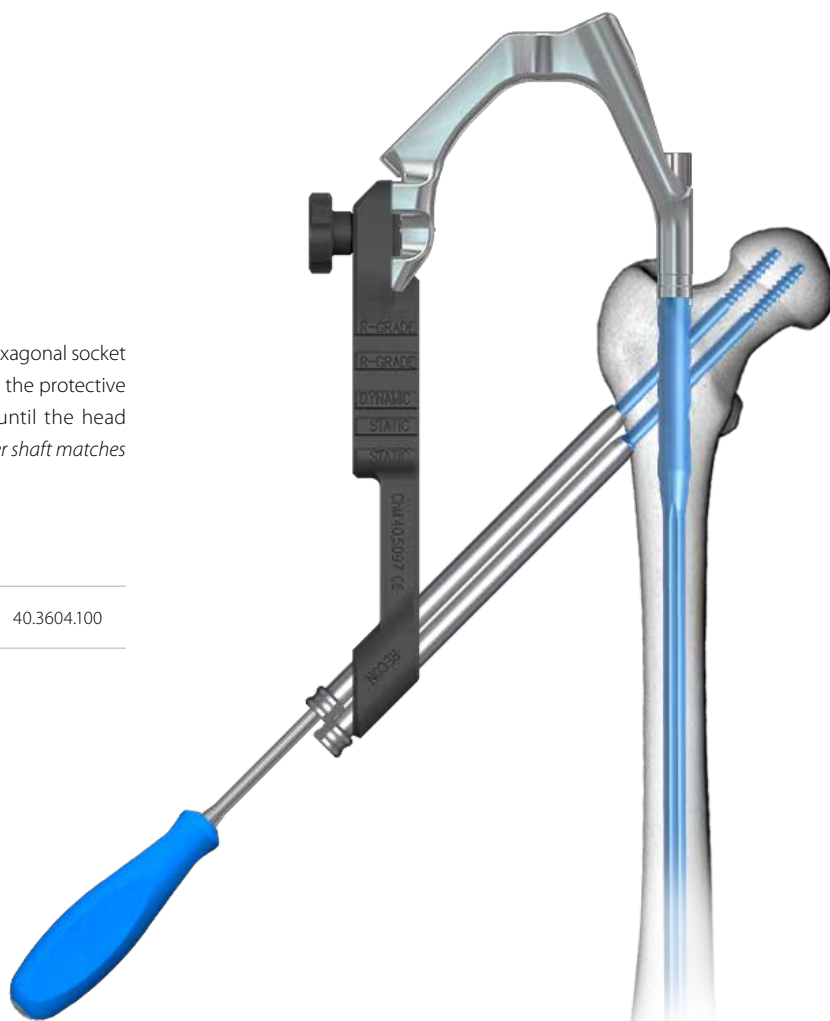
Remove the measure.

Leave the protective guide in the hole of targeter.



- 21 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of 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*).

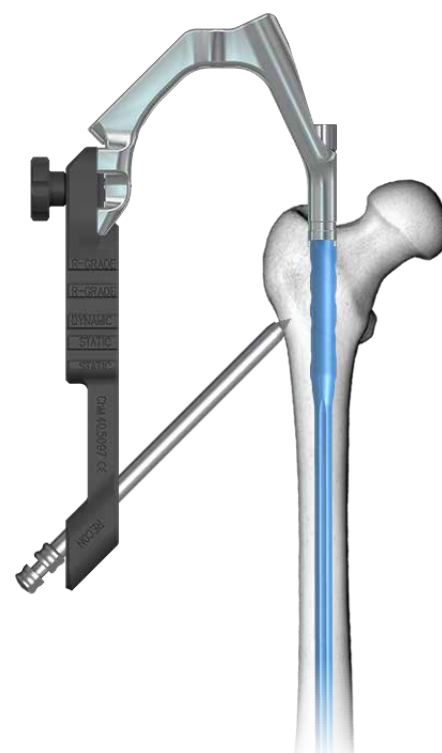
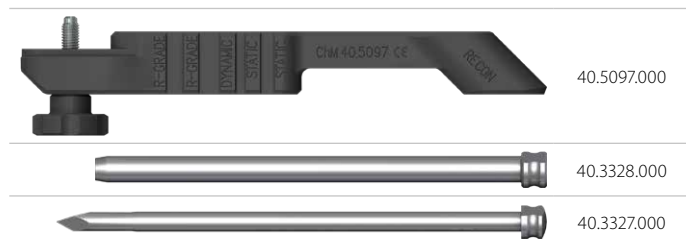
Remove the screwdriver and protective guide.



IV.2.1.2. **OPTION II: Locking the nail with reconstruction cannulated screws**

22 Insert the protective guide 11/9 [40.3328.000] with trocar 9 [40.3327.000] into the most proximal hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

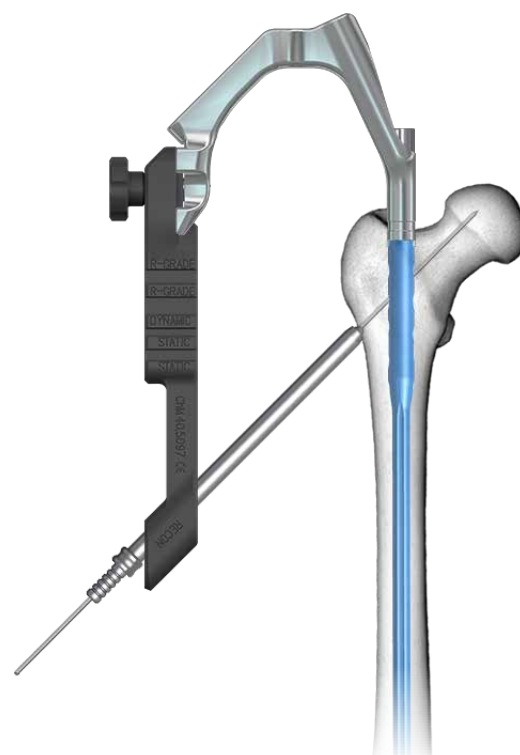
Remove the trocar.
Leave the protective guide in place.



23 Insert the Kirschner guide [40.3331.000] into the protective guide. Install the Kirschner wire 2.0/380 [40.3333.000] to the surgical drive and place the wire in the femoral neck but do not perforate the femoral head. The above step should be controlled with X-Ray imaging (*ap plane*).

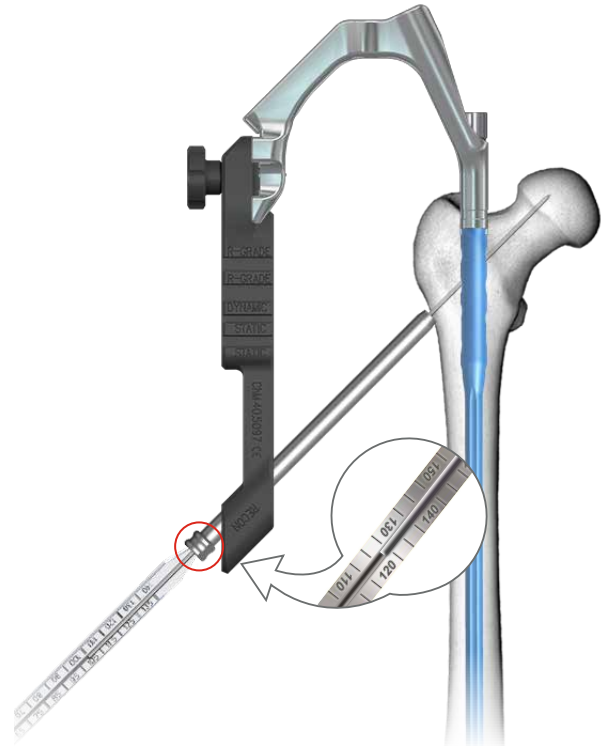
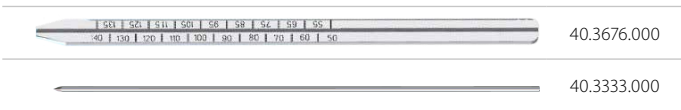
Verify the position of the wire in the lateral view. The wire should be in the middle of the neck; deviation is acceptable if allows for the screw insertion without damaging outer cortex of the neck. Use only Kirschner nails 2.0/380mm [40.3333.000] with a diameter of 2 mm and a length of 380 mm. If the wire is mal-positioned, repeat the step.

Remove the Kirschner guide
Leave the Kirschner wire in place.



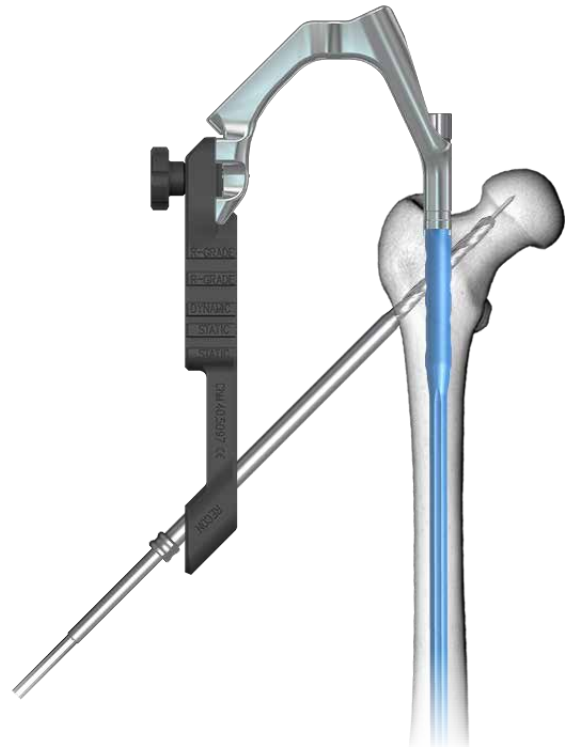
- 24 Insert the cannulated screw length measure [40.3676.000] onto Kirschner wire placed in the femoral neck, until the measure leans against the protective guide. Read the length of the reconstruction cannulated screw defined by the end of Kirschner wire. During the measurement the end of the measure should rest on the cortex bone.

Remove the measure.
Leave Kirschner wire in place.



- 25 Mount the cannulated drill 6.5/2/300 [40.3674.000] to the surgical drive and advance via the Kirschner wire 2.0/380mm [40.3333.000] installed in the femoral neck. Ream the hole through the first cortex (up to the nail placed in the medullary canal).

Remove the drill.
Leave the Kirschner wire in place.

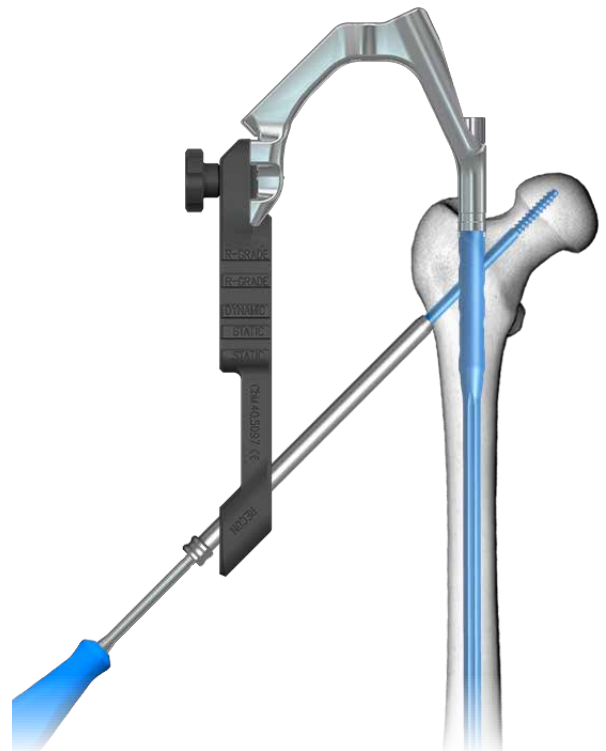


- 26 Use the cannulated screwdriver S5.0/2.2 [40.3675.100] to insert the selected reconstruction cannulated screw onto the Kirschner wire and then into the femoral neck, through the nail, up until the the cortex layer is reached.

Remove the screwdriver and Kirschner wire.
Kirschner wire is single use instrument.



CAUTION:
To insert the other reconstruction screw, repeat steps 22 to 26.



Verify the femoral neck fixation performing X-Ray imaging in two projections. Small overall dimensions of the targeter 135 additionally angled of antetorsion angle, allows for taking X-Ray images 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

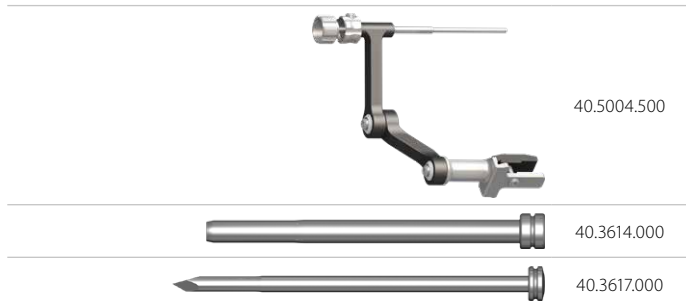
Prior to distal locking of the nail, do the following:

1. Install the distal targeter D [40.5093.000] with attached angular set block to the targeter arm [40.5091.100]. The angular set block should be distanced from the distal targeter slider. If properly installed, the signs RIGHT or LEFT on both targeters should comply.
2. Use X-Ray imaging to verify the position of holes in the nail and targeter - they need to be in line.



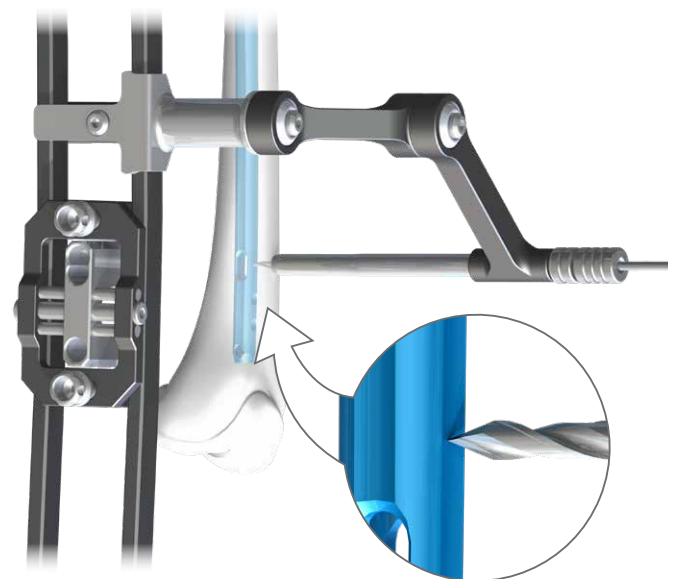
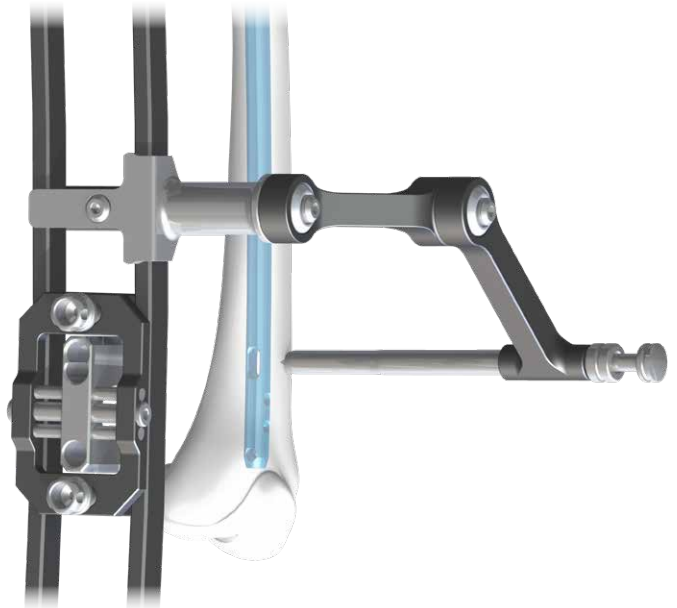
27 Insert the protective guide 9/6.5 [40.3614.000] with trocar 6.5 [40.3617.000] into the hole of angular set block [40.5004.500]. Mark on the skin the entry point for screws and make adequate soft tissues incision. Advance the trocar until it reaches the cortex bone and mark the entry point for the 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 place.

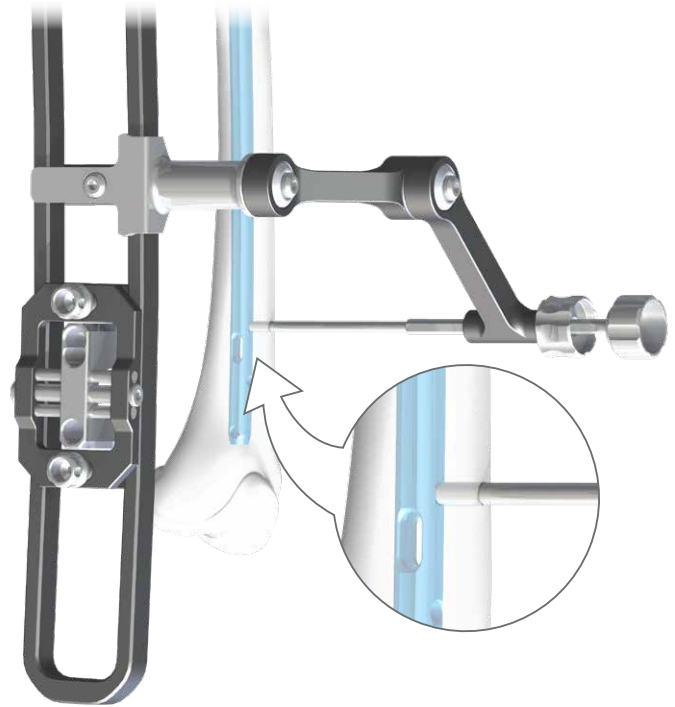
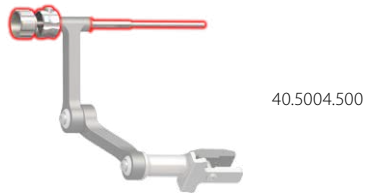


28 Insert the drill guide 6.5/3.5 [40.3615.000] into the protective guide 9/6.5 [40.3614.000]. Mount the drill 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill (*under image intensifier control*) the hole in the femur until the drill reaches the nail.

Remove: the drill, drill guide and protective guide.

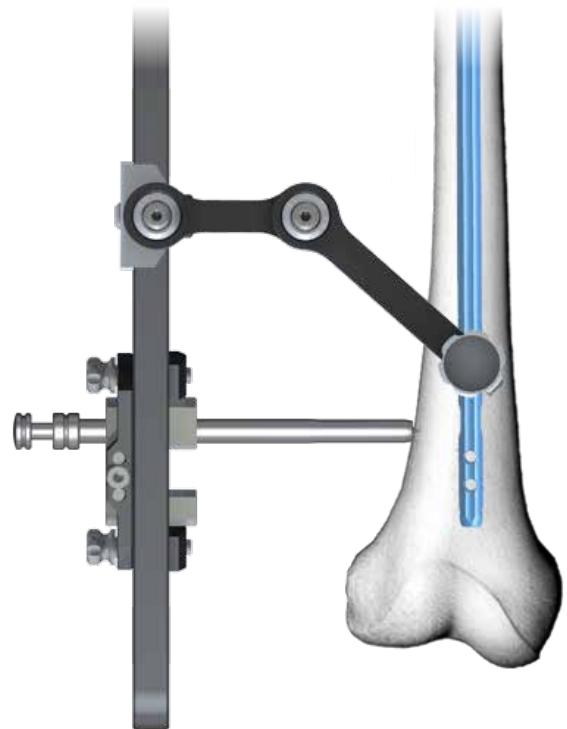


- 29 Insert and tighten up the pin and the nut in the hole of the angular set block [40.5004.500]. Afterwards, proceed with locking the dial from the slider of the distal targeter.



- 30 Insert the protective guide 9/6.5 [40.3614.000] (1 groove in the handle) with trocar 6.5 [40.3617.000] into the proximal hole of distal targeter D [40.5093.000]. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

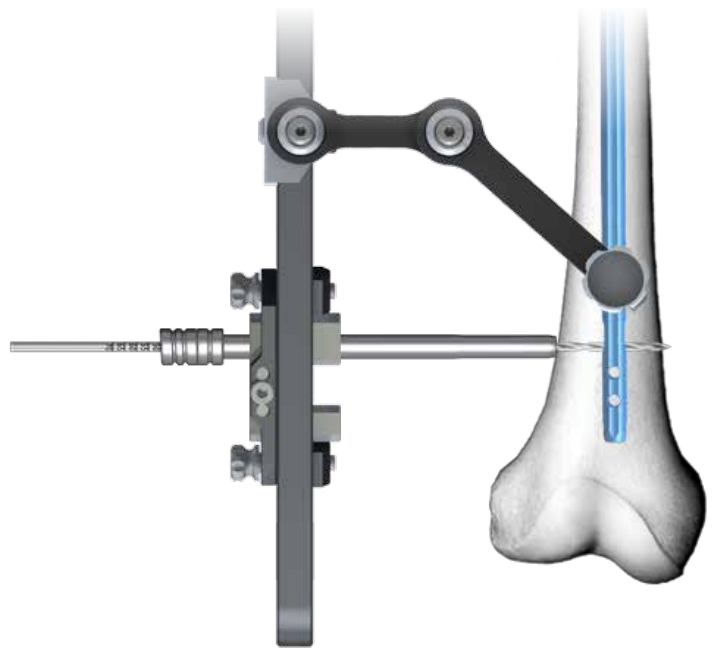
Remove the trocar.
Leave the protective guide in place.



- 31 Insert the drill guide 6.5/3.5 [40.3615.000] (2 grooves) into the protective guide 9/6.5 [40.3614.000]. Mount the drill 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole through its both cortex layers and the nail hole. The scale on the drill indicates the length of the locking element.

Remove the drive

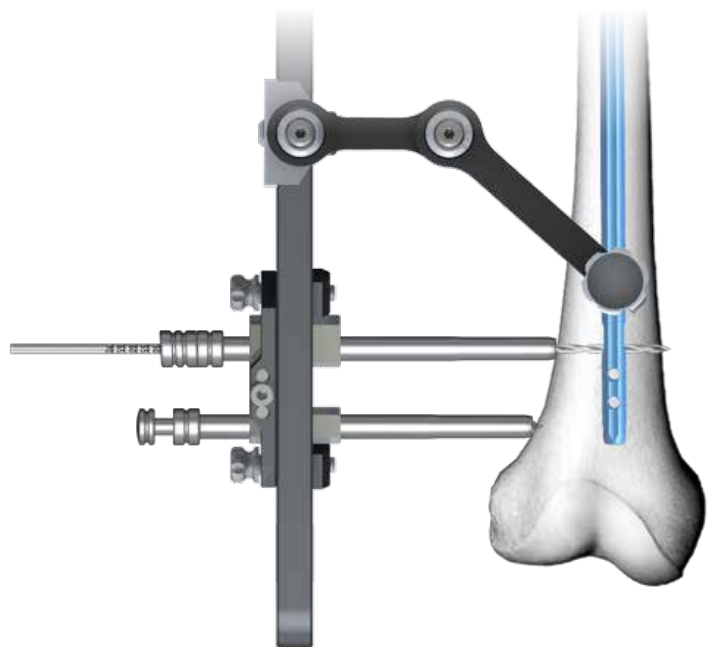
Leave the set: protective guide - drill guide - drill, in place.



- 32 Insert the protective guide [40.3614.100] (with one groove) with the trocar 6.5 [40.3617.000] into the other hole of the distal targeter. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

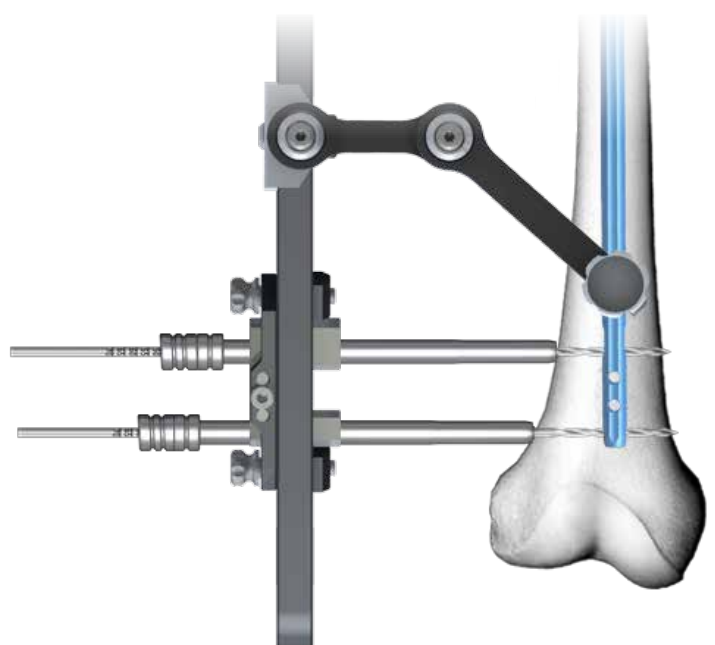
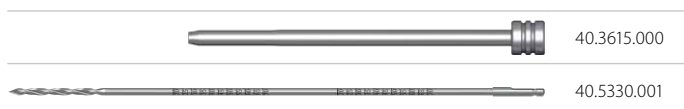
Leave the protective guide in place.



- 33 Insert the drill guide 6.5/3.5 [40.3615.000] (2 grooves) into the protective guide 9/6.5 [40.3614.000]. Mount the drill 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the nail. The scale on the drill indicates the length of the locking element.

Remove: the drill, drill guide.

Leave protective guide in place.

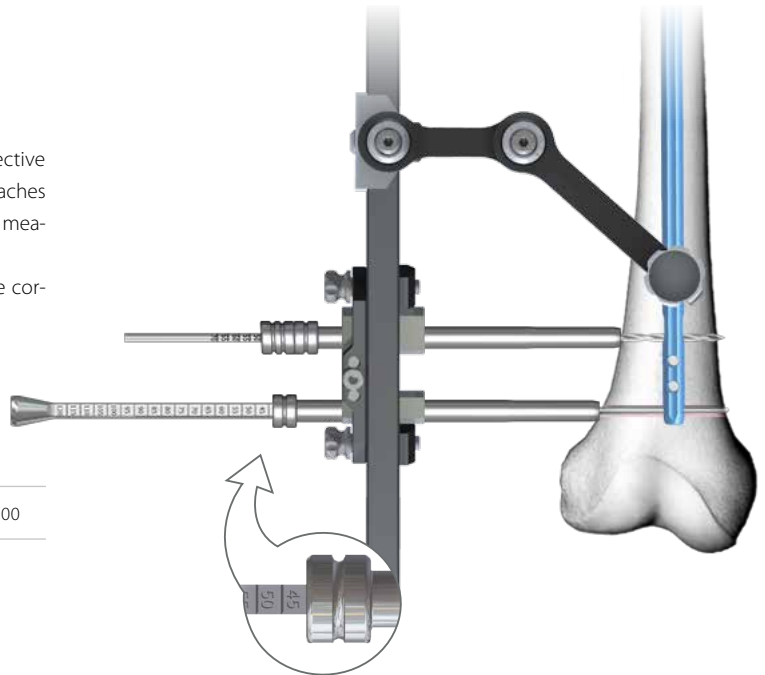


34 Insert the screw length measure [40.1374.100] through the protective guide 9/6.5 [40.3614.000] into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale.

During the measurement, the tip of protective guide should rest on the cortex bone.

Remove the measure.

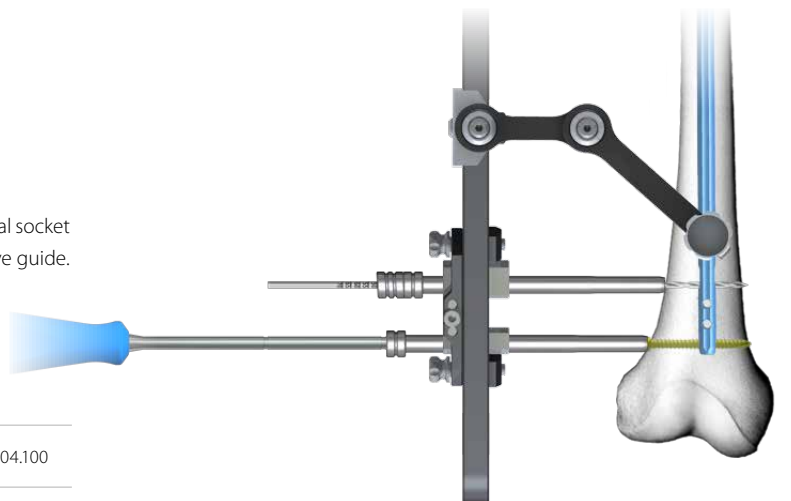
Leave the protective guide in place.



35 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide.

Insert the 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 protective guide.

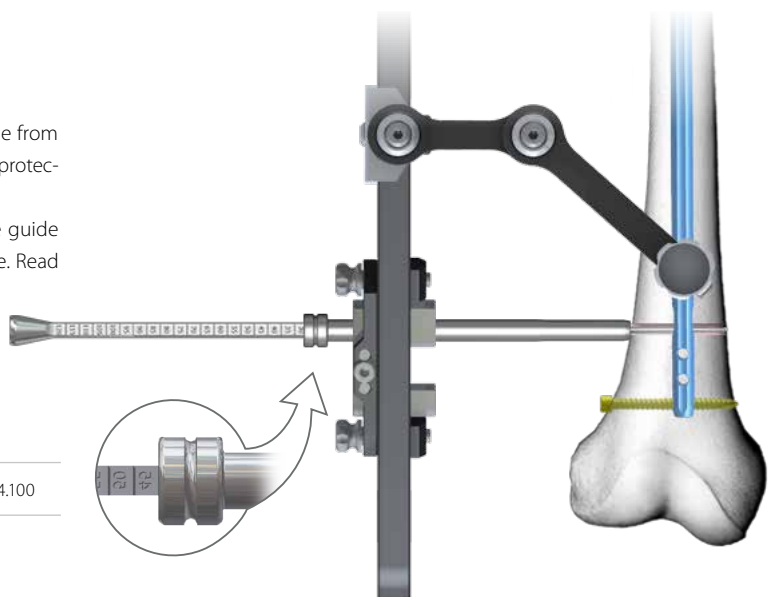


36 Remove the drill with scale 3.5/270 [40.5330.001] and drill guide from the proximal hole of the distal targeter D [40. 5093.000]. Leave the protective guide 9/6.5 [40.3614.000] in the hole of the targeter.

Insert the screw length measure [40.1374.100] through the protective guide into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale. During the measurement the protective guide should rest on the cortex bone.

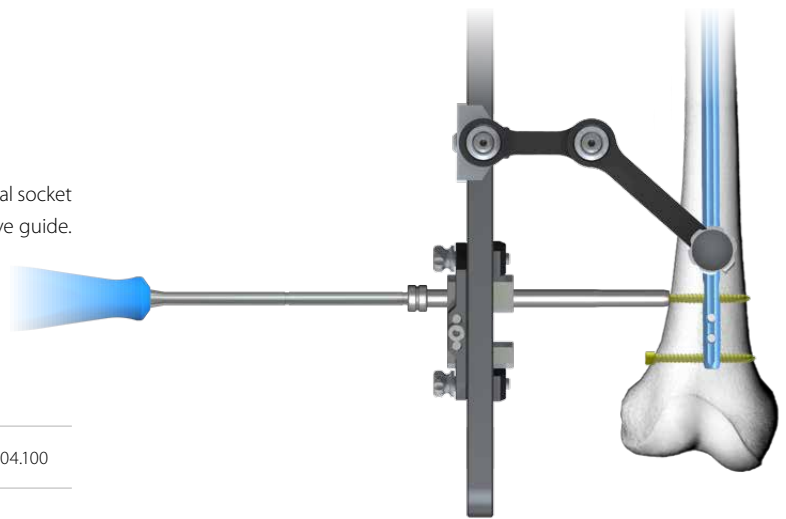
Remove the measure.

Leave the protective guide in the hole of the targeter.



- 37 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the 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 protective guide.



- 38 After locking the nail in its distal part, remove only one of protective guides used for locking in the AP plane and proceed to locking the nail in the other plane.

Remove the pin and nut from the angular set block.

Move the angular set block [40.5004.500] so that it leans against the slider of the distal targeter.

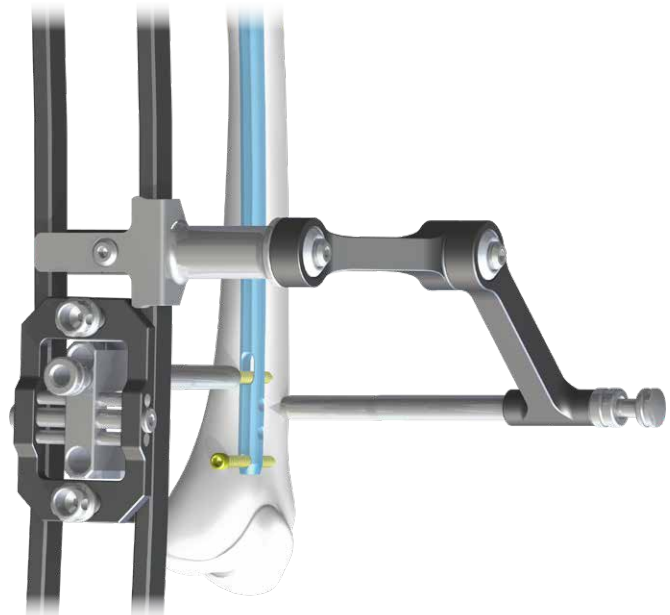
Lock the angular set block.



- 39 Insert the protective guide 9/6.5 [40.3614.000] with trocar 6.5 [40.3617.000] into the hole of angular set block [40.5004.500]. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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 place.



40 Insert the drill guide 6.5/3.5 [40.3615.000] into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill (*under image intensifier control*) the hole through both cortex layers of the bone and the nail hole.

Remove the drill.



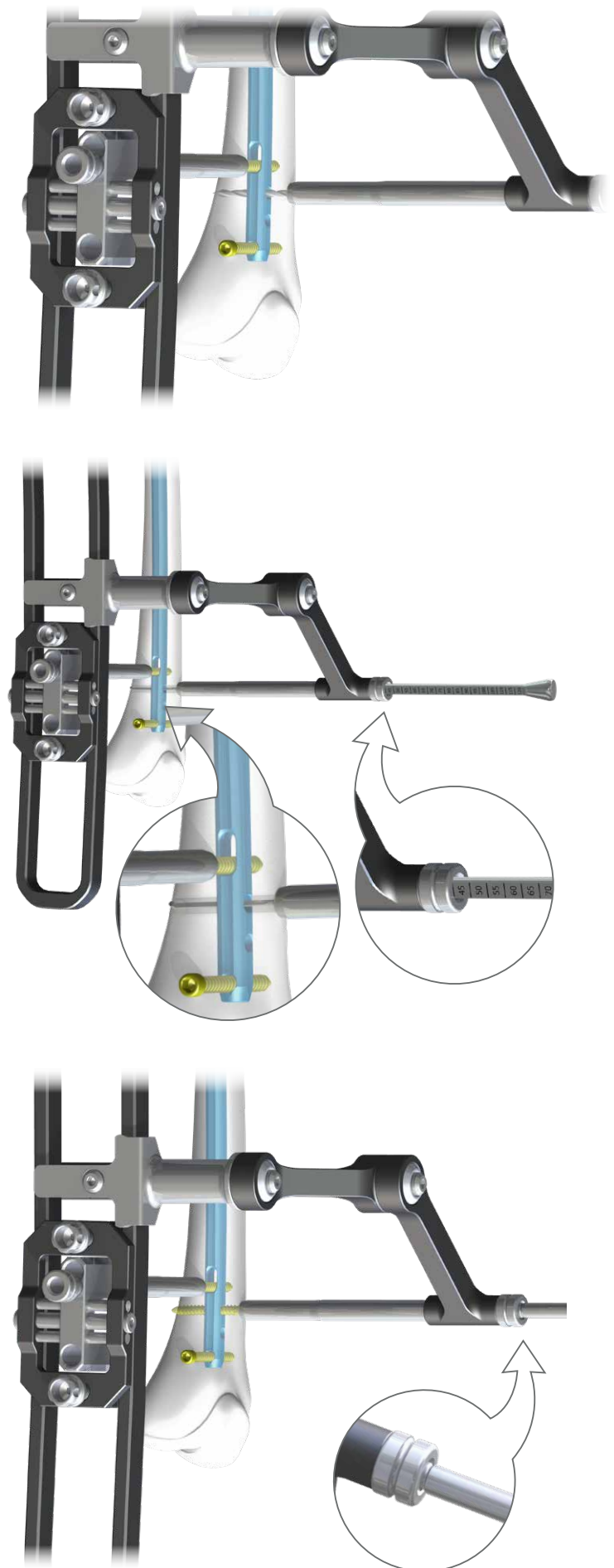
41 Insert the screw length measure [40.1374.100] through the protective guide 9/6.5 [40.3614.000] into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale. During the measurement the protective guide should rest on the cortex bone.

Remove the measure.



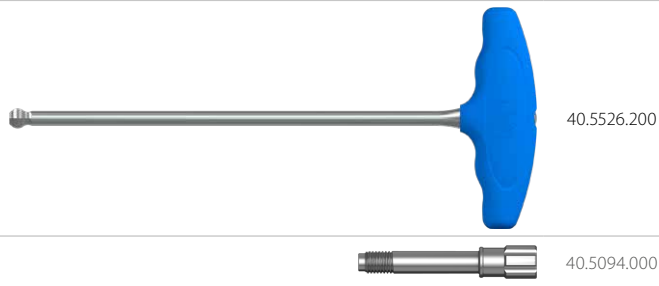
42 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the screw in the prepared hole until the head of the screw reaches the cortex bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the screwdriver and angular set block and proceed to proximal locking of the nail.



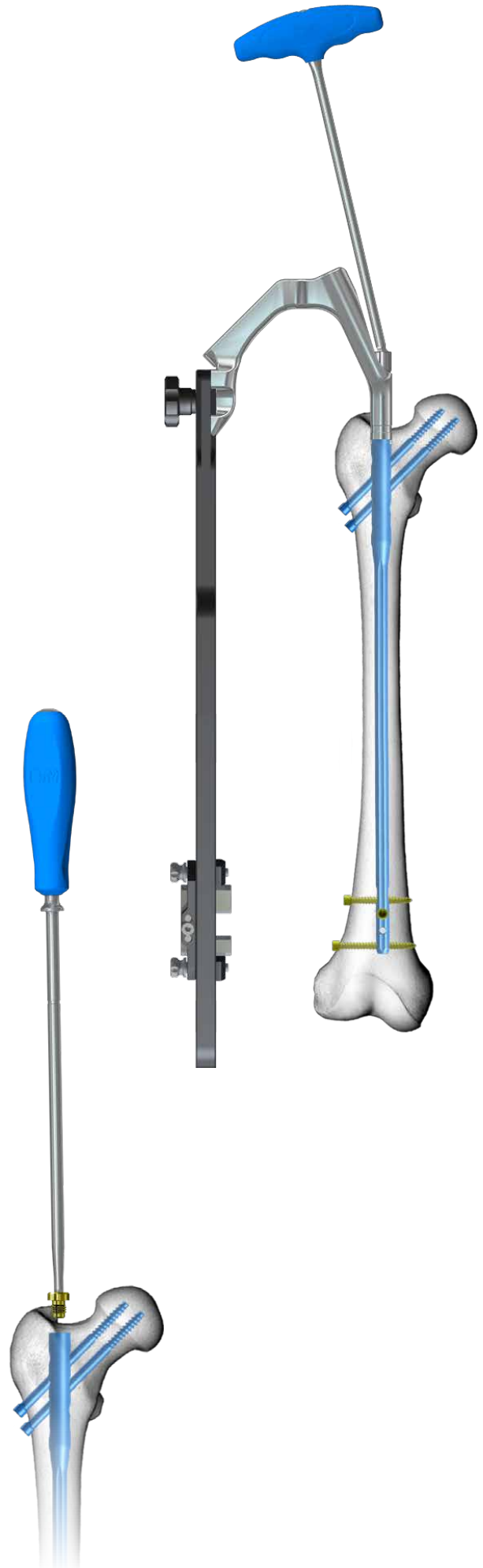
IV.2.3. Targeter removal. End cap insertion

43 Use the wrench S10 [40.5526.200] to remove the connecting screw [40.5094.000] and targeter arm [40.5091.100] from the nail locked in the medullary canal.



44 In order to secure the inner thread of the nail from bone ingrowth, use the cannulated screwdriver S5.0/2.2 [40.3675] to insert:

- the end cap [1.2104.3xx] or [3.2104.3xx] for an universal nail,
- the end cap [1.2104.4xx] or [3.2104.4xx] for a reconstruction nail.

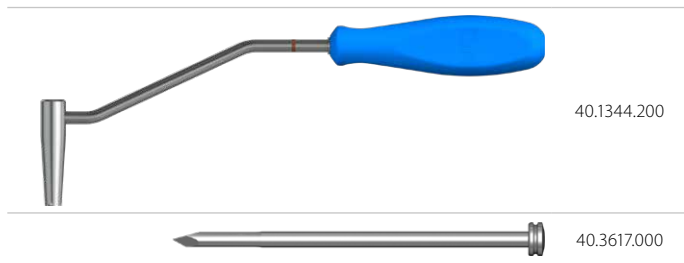


IV.2.4. Distal locking of the nail - "freehand technique" - Method I

With this technique, the X-Ray imaging is used to identify the entry points for the drills and to control the drilling process. It is recommended to use an angular attachment with the surgical drive while drilling, so that surgeon's hands are not directly exposed to radiation. 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.

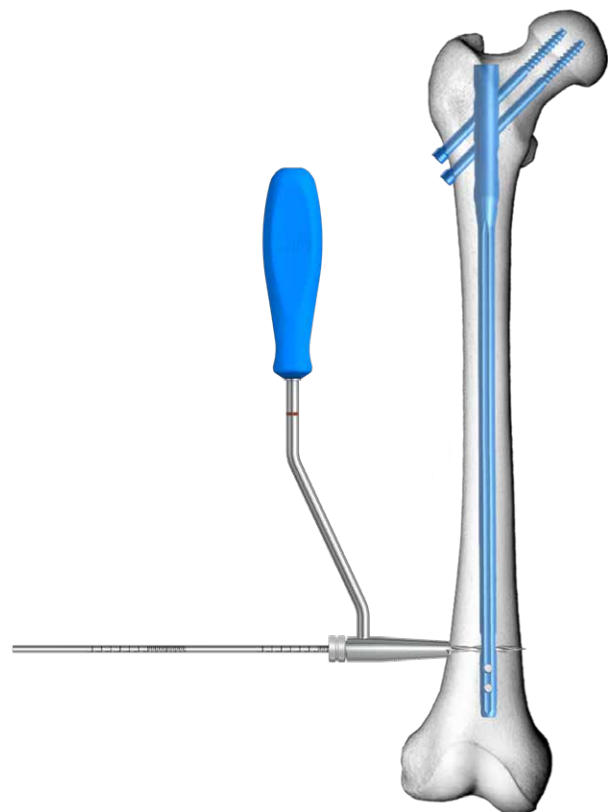
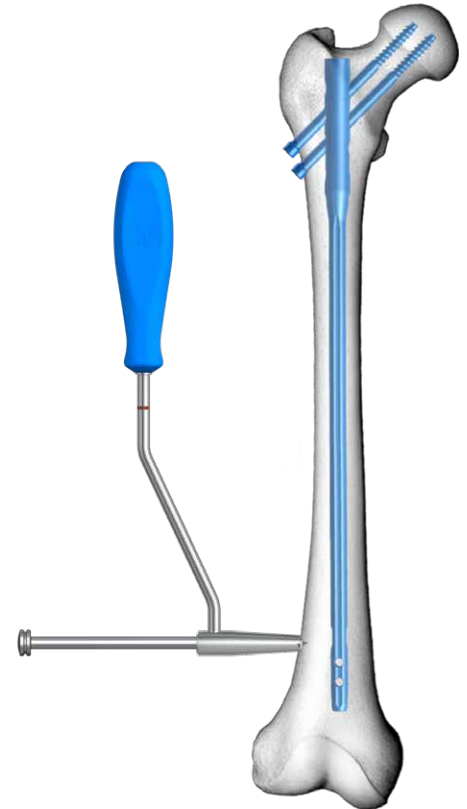
- 45 Use an X-Ray device to position the targeter D [40.1344.200] in the line with the nail hole. The holes in the targeter and nail have to match. Put the teeth of the targeter D in the cortex. Insert the trocar 6.5 [40.3617.000] into the targeter and mark the entry point for the drill.

Remove the trocar.
Leave the targeter D in place.



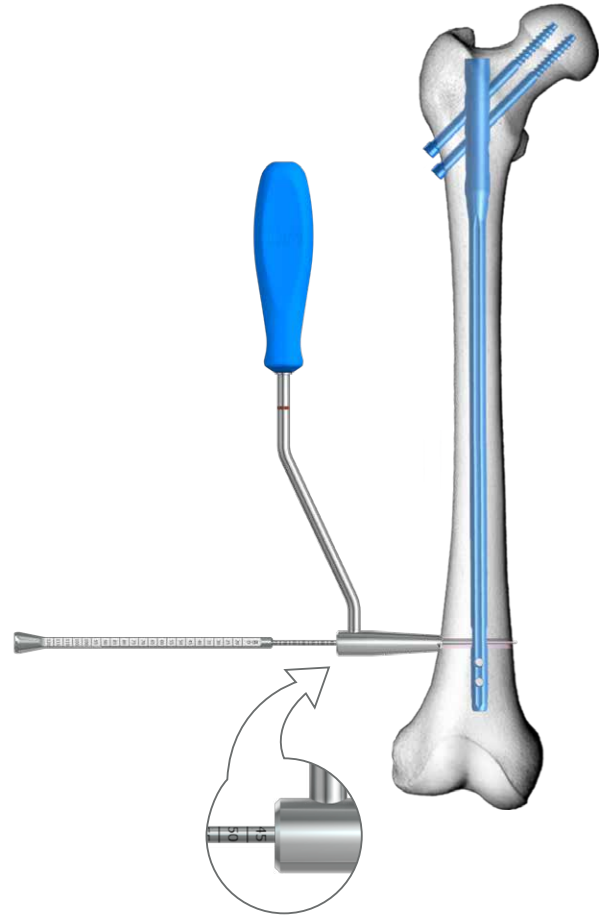
- 46 Insert the drill guide short 7/3.5 [40.1358] into the targeter hole. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole through both cortex layers and the nail hole. The scale on the drill indicates the length of the locking element.

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



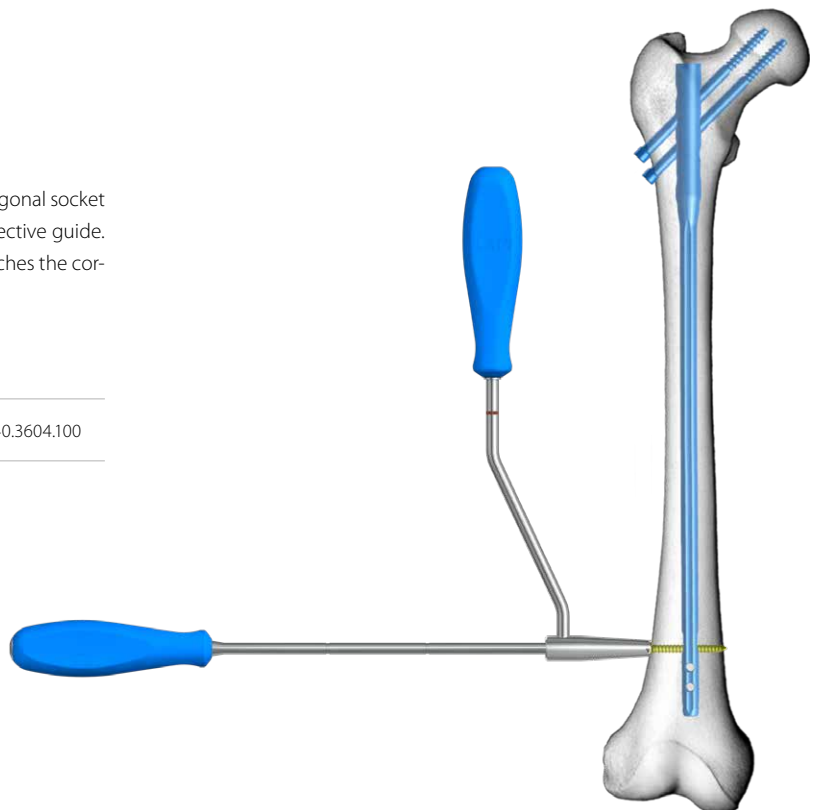
- 47 Insert the screw length measure [40.1374.100], through the targeter D [40.1344.200], into the drilled hole until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the scale.

Remove the measure.
Leave the targeter in place.



- 48 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the screw in the prepared hole until the head of the screw reaches the cortex bone.

Remove the screwdriver and targeter.



IV.2.5. Distal locking of the nail - "freehand technique" - Method II



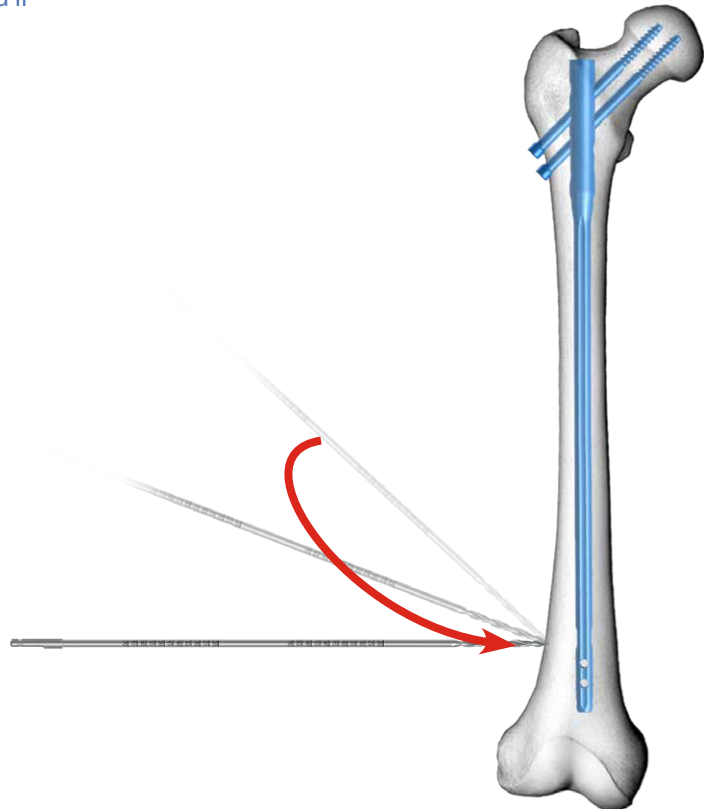
To determine the drilling holes and when drilling, radiological control should be used.

- 49 Position the X-Ray machine in such a way that the nail hole on the monitor screen is a circle.

Place the tip of the drill with scale 3.5/270 [40.5330.001] in the center of the nail hole visible on the screen.

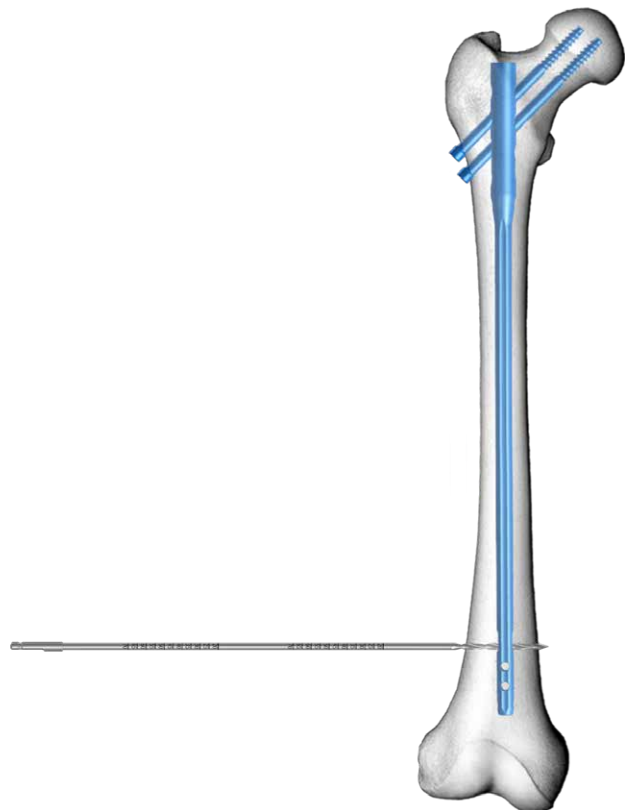
Mark the drilling points on the skin and make 1.5 cm long incisions of soft tissues through these points.

 40.5330.001



- 50 Set the tip of the drill with scale 3.5/270 [40.5330.001] in the center of the nail hole visible on the screen, again. Place the drill against the bone and drill a hole through the nail and both cortical layers of the bone.

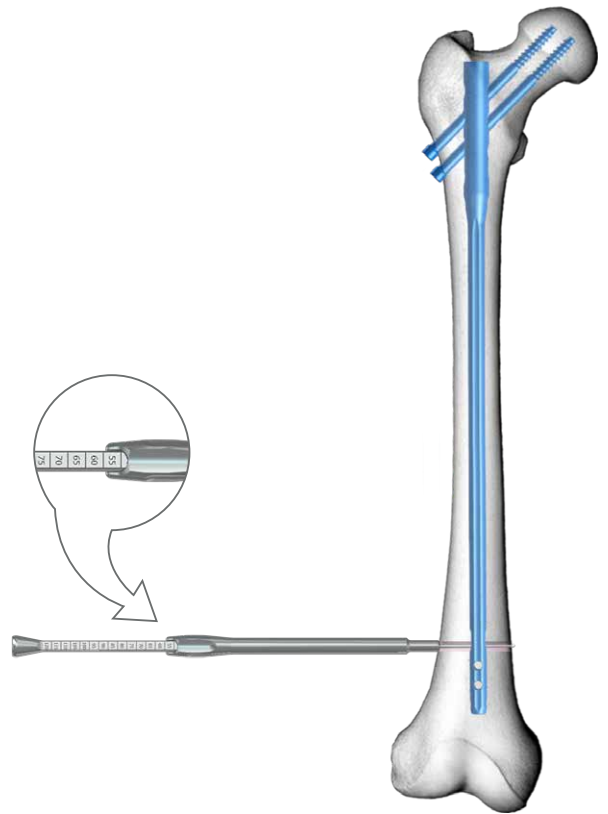
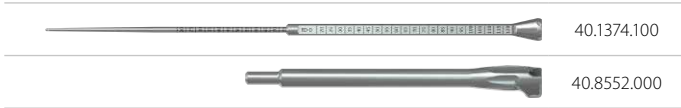
Remove the drill.



- 51 Insert the screw length measure [40.1374.100] with screw length measure protection [40.8552.000] applied, until the hook of the measuring tip rests on the outer surface of the second cortex.

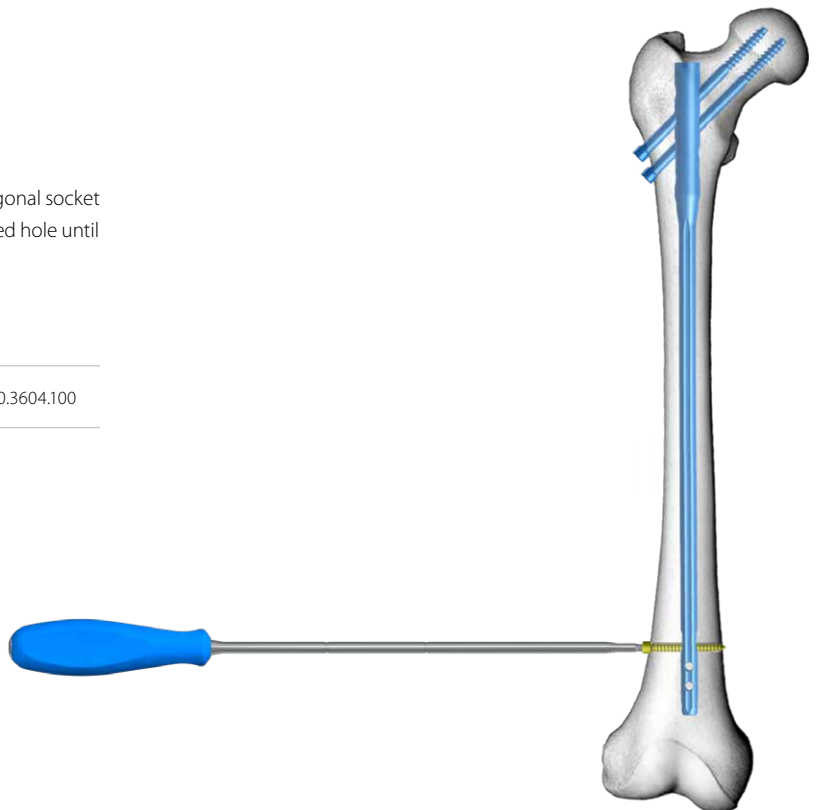
The screw length measure protection indicates the length of the locking screw on the scale.

Remove the measure.



- 52 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the prepared hole until the head of the screw reaches the cortex bone.

Remove the screwdriver.



IV.3. DYNAMIC AND COMPRESSION METHODS

IV.3.1. Distal locking of the nail

Prior to distal locking of the nail, do the following:

1. Mount the distal targeter D [40.5093.000] to the targeter arm [40.5091.100].

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

2. Use X-Ray imaging to verify the position of holes in the nail and targeter - they need to be in line.

- 53 Insert the protective guide 9/6.5 [40.3614.000] (1 groove) with trocar 6.5 [40.3617.000] into the proximal hole of distal targeter D [40.5093.000].

Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

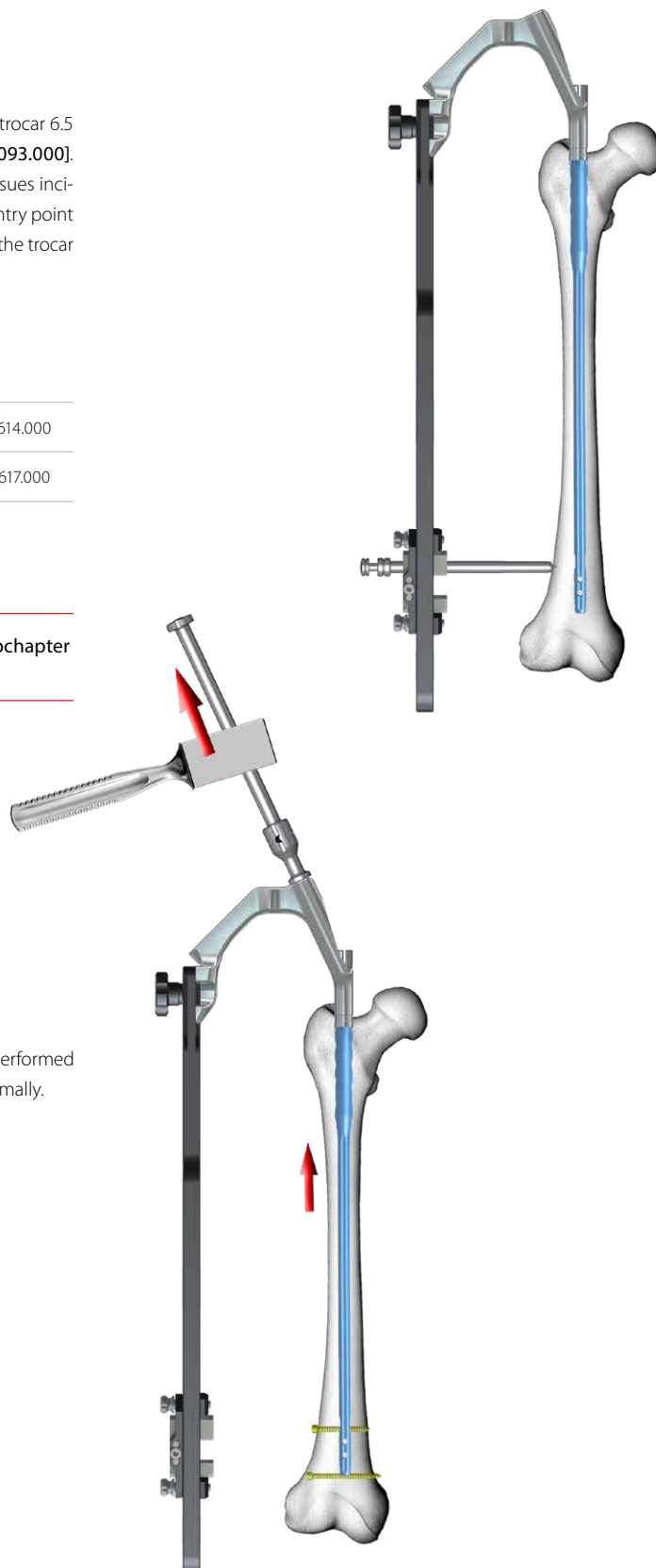
Remove the trocar.

Leave the protective guide in the hole.



CAUTION! For the rest of the procedure, follow the subchapter IV.2.2 of these instructions.

- 54 Reduction of fracture gap after distal locking of the nail may be performed by slightly knocking the nail up, and then locking the nail proximally.



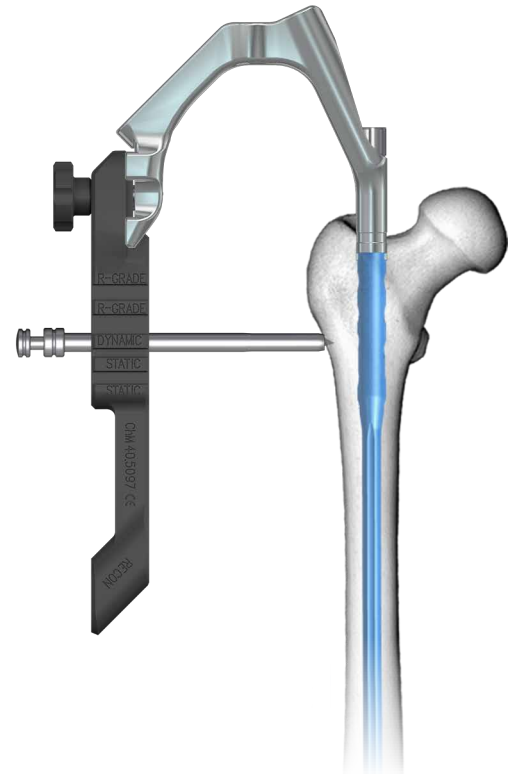
IV.3.2. Proximal locking of the nail



CAUTION! In compression and dynamic methods, insert the screw using DYNAMIC hole in the targeter 135 [40.5097.000].

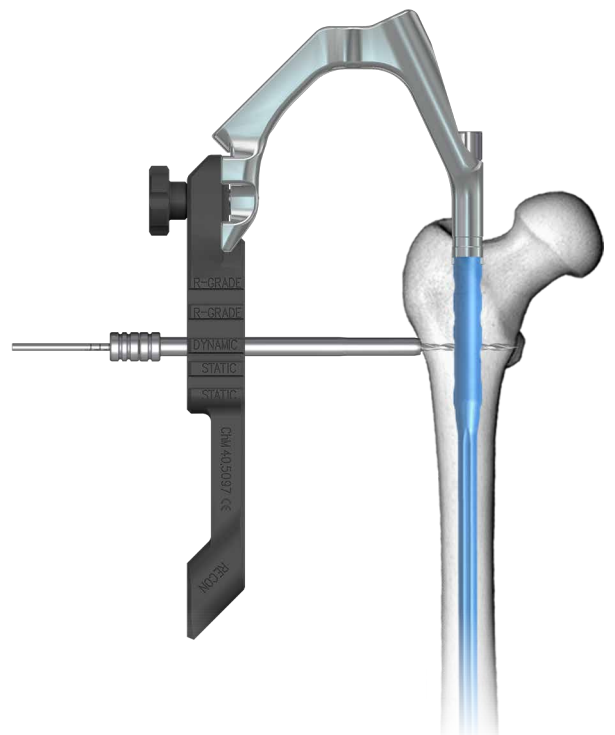
55 Attach the targeter 135 [40.5097.000] to the targeter arm [40.5091.100]. Insert the protective guide 9/6.5 [40.3614.000] (1 groove) with trocar 6.5 [40.3617.000] into the proximal hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. Advance 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.



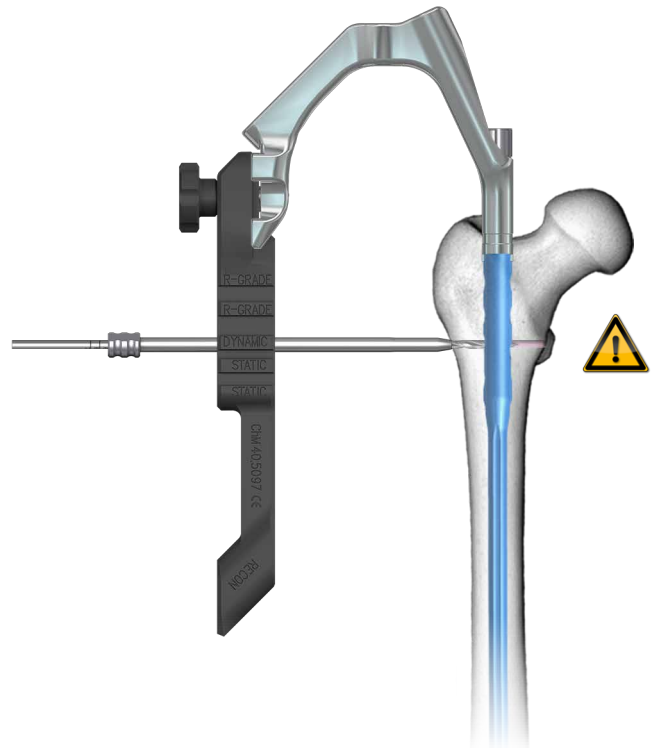
56 Insert the drill guide 6.5/3.5 [40.3615.000] (with two grooves on the handle) into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

Remove the drill, drill guide and protective guide.



- 57 Insert the drill guide 9/4.5 [40.3330.000] into the proximal hole of the targeter 135 [40.5097.000]. Mount the drill with scale 4.5/370 [40.5333.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur only through its first cortex up to the nail hole.

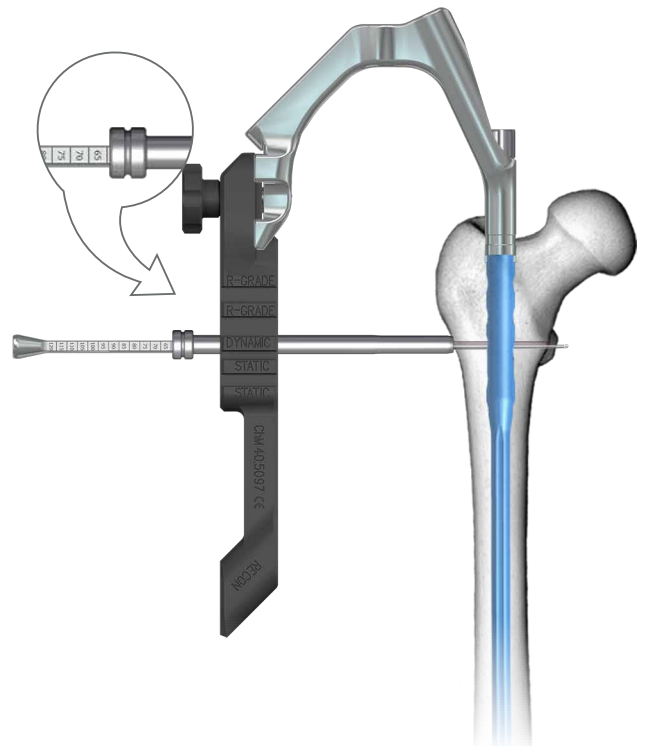
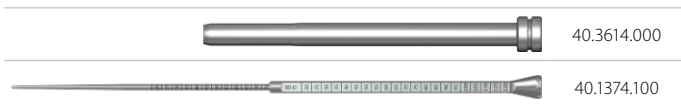
Remove the drill and drill guide.



- 58 Insert the protective guide 9/6.5 [40.3614.000] in the proximal hole of the targeter 135 [40.5097.000] and then the screw length measure [40.1374.100] through that guide into the drilled hole up until its end. Read the length of the screw on the B-D scale measure. During the measurement, the end of the protective guide should rest on the cortex bone.

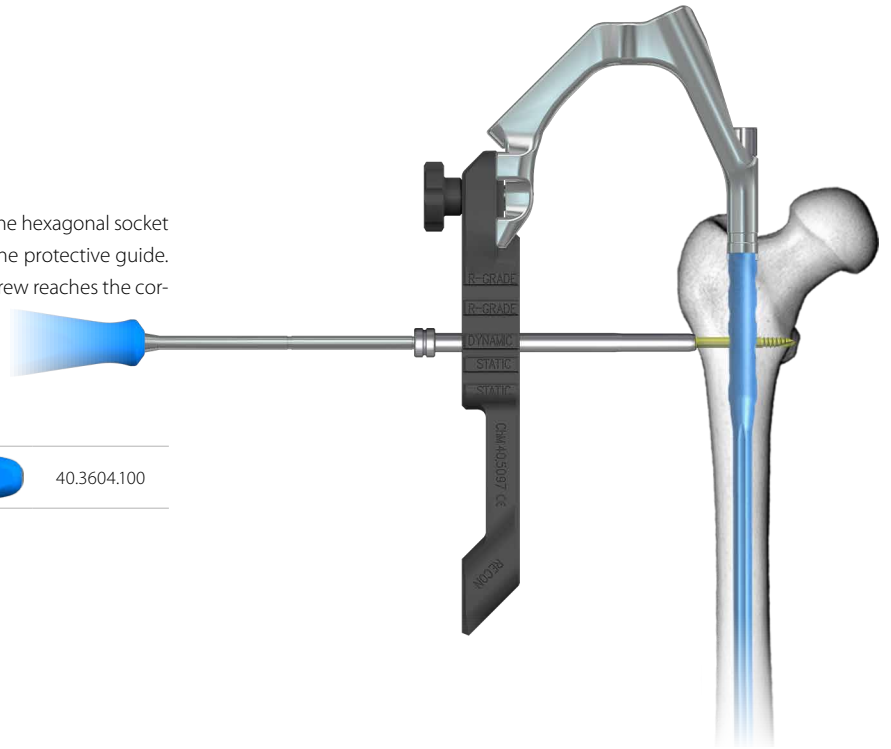
Remove the measure.

Leave the protective guide in the hole.

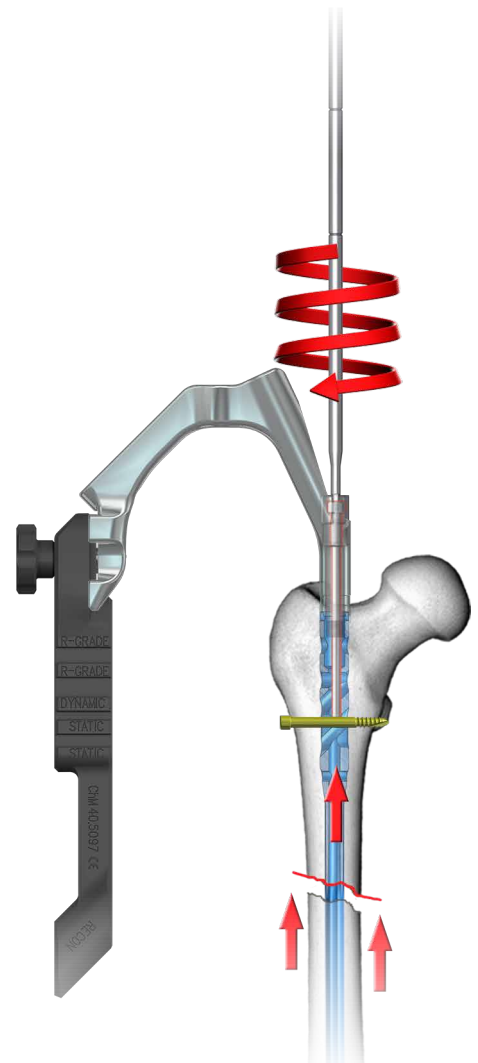


59 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the screw in the prepared hole until the head of the screw reaches the cortex bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver and protective guide.



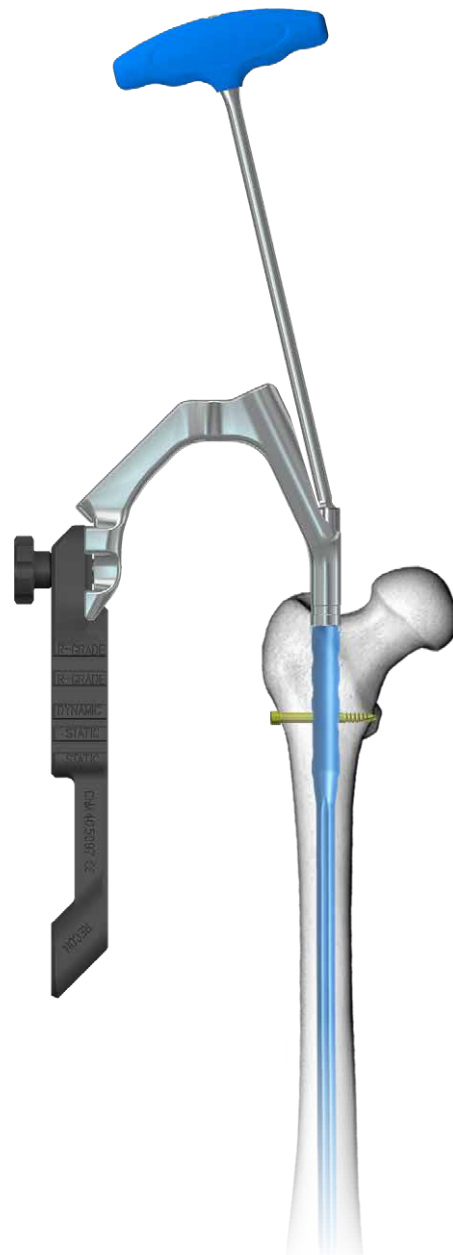
60a In order to make the intraoperative compression, use the screwdriver S3.5 [40.3604.100] to insert the compression screw [40.5096] into the connecting screw M10x1 that joins the intramedullary nail with the targeter arm. When front of the screw reaches the shaft of locking screw, further screwing in will cause the compression of bone fragments. The above steps should be controlled with X-Ray image intensifier to observe the change of interfragmental slot.



61b In order to maintain the bone fragments compression, lock the nail by using STATIC hole - repeat steps 66-69.

IV.3.3. Targeter removal

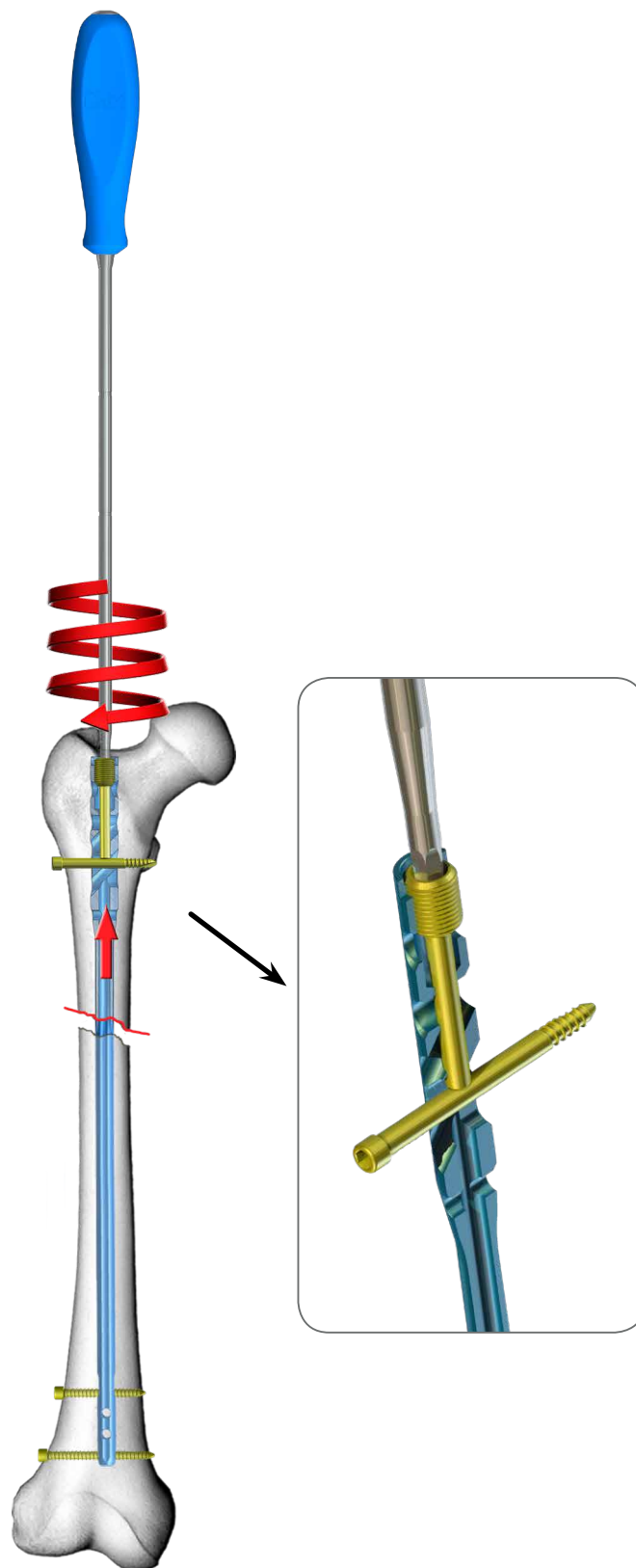
- 62 Use the wrench S10 [40.5526.200] to unscrew the connecting screw [40.5094.000] from the nail and remove the targeter from the nail locked in the medullary canal.



IV.3.4. Compression screw insertion

- 63 Use the screwdriver S3.5 [40.3604.100] to insert the compression screw in the threaded hole of the nail.

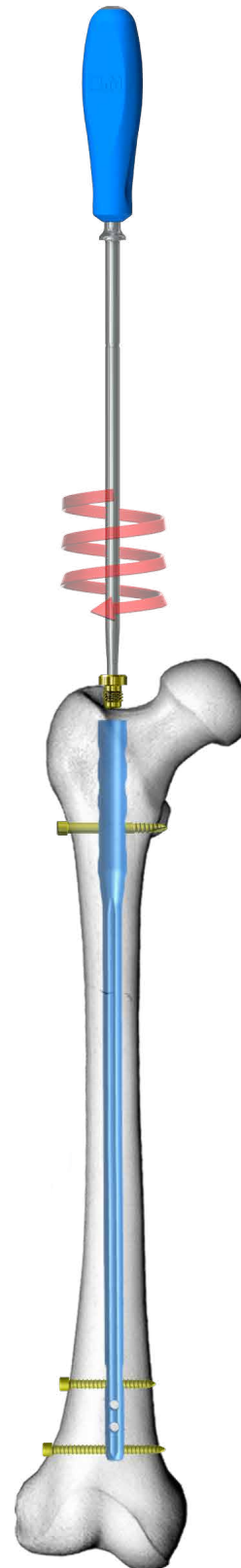
The surgeon decides about the level of compression.



IV.3.5. End cap insertion (*DYNAMIC method only*)

64 In order to secure the inner thread of the nail from bone ingrowth, use the cannulated screwdriver S5.0/2.2 [40.3675.100] to insert:

- the end cap [1.2104.3xx] or [3.2104.3xx] for an universal nail,
- the end cap [1.2104.4xx] or [3.2104.4xx] for a compression nail.



IV.4. STATIC METHOD

IV.4.1. Distal nail locking

Prior to distal locking of the nail, do the following:

1. Mount the distal targeter D [40.5093.000] to the targeter arm [40.5091.100].

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

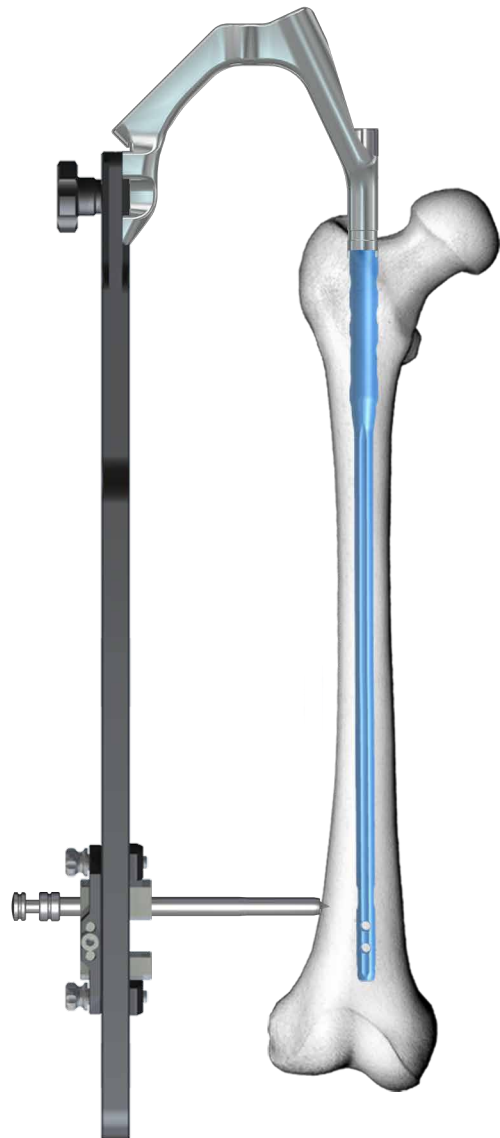
2. Use X-Ray imaging to verify the position of holes in the nail and targeter - they need to be in line.

65 Insert the protective guide 9/6.5 [40.3614.000] (1 groove) with trocar 6.5 [40.3617.000] into the proximal hole of distal targeter D [40.5093.000].

Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.



CAUTION! For the rest of the procedure, follow the subchapter IV.2.2 of these instructions.

IV.4.2. Proximal nail locking

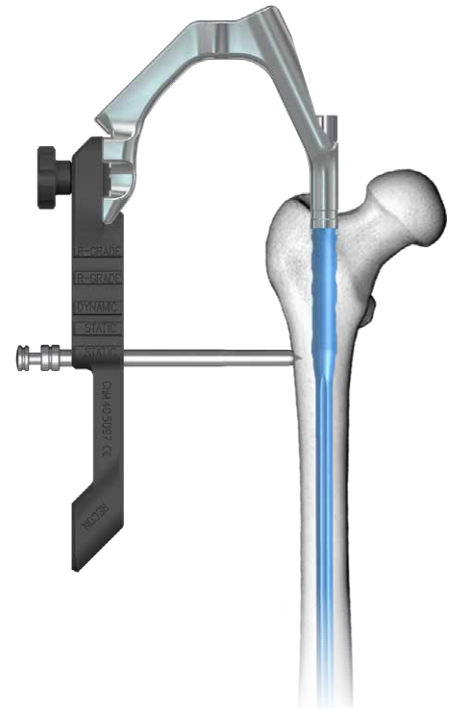
**CAUTION!**

In static method of femoral fracture fixation, for locking the nail, use distal hole of Targeter 135 [40.5097.000] marked as **STATIC**. The second hole (*proximal*) may be used for locking the nail with second locking screw.

- 66 Insert the protective guide 9/6.5 [40.3614.000] (1 groove) with trocar 6.5 [40.3617.000] into the distal hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

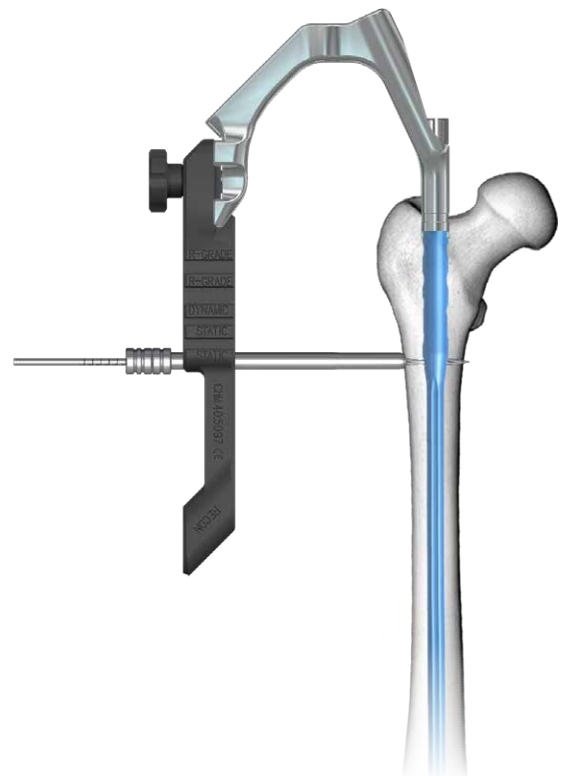
Leave the protective guide in the hole.



- 67 Insert the drill guide 6.5/3.5 [40.3615.000] (with two grooves on the handle) into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

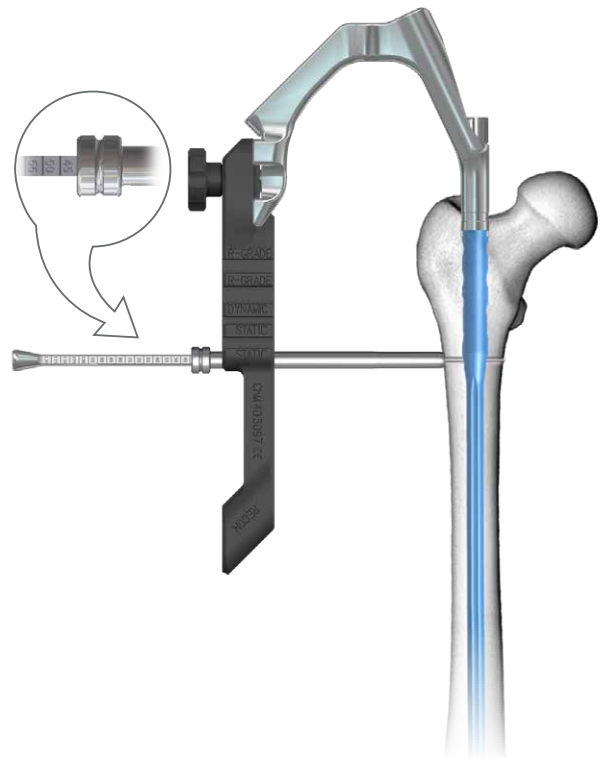
Remove the drill and drill guide.

Leave the protective guide in place.



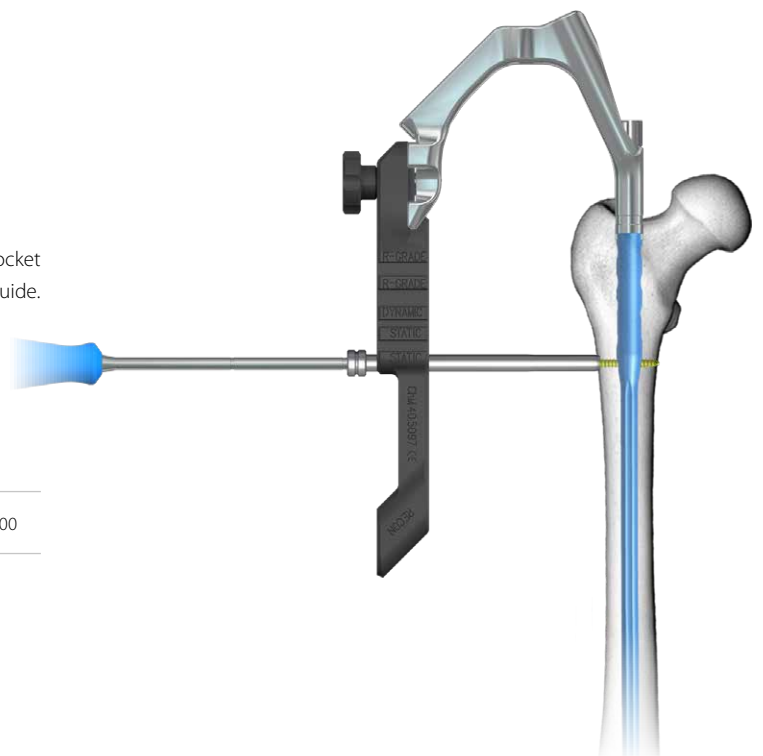
68 Use the protective guide 9/6.5 [40.3614.000] to insert the screw length measure [40.1374.100] into the drilled hole up until its end. Read the length of the screw on the B-D scale measure. During the measurement, the end of the protective guide should rest on the cortex bone.

Remove the measure.
Leave the protective guide in the hole.



69 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the 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 protective guide.

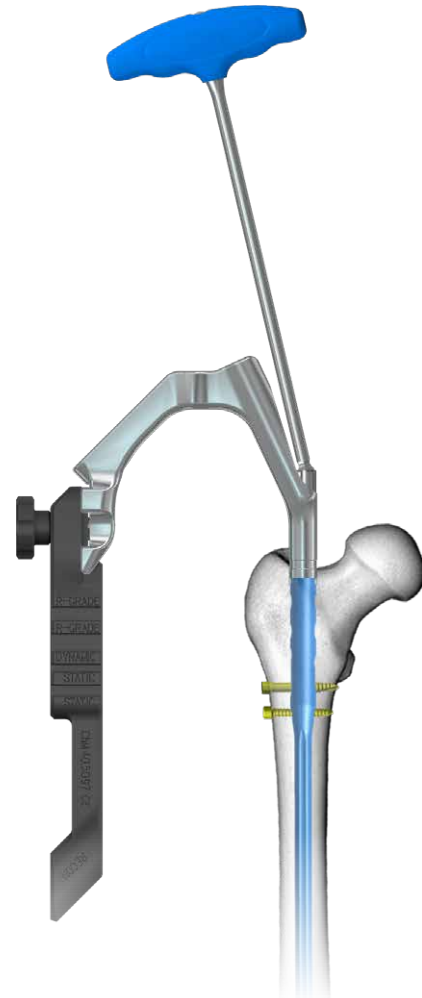


CAUTION!

If the surgeon decides to lock the nail in the proximal part with two screws, insertion of the other screw should be performed as presented in steps 66 to 69. Otherwise, omit these steps.

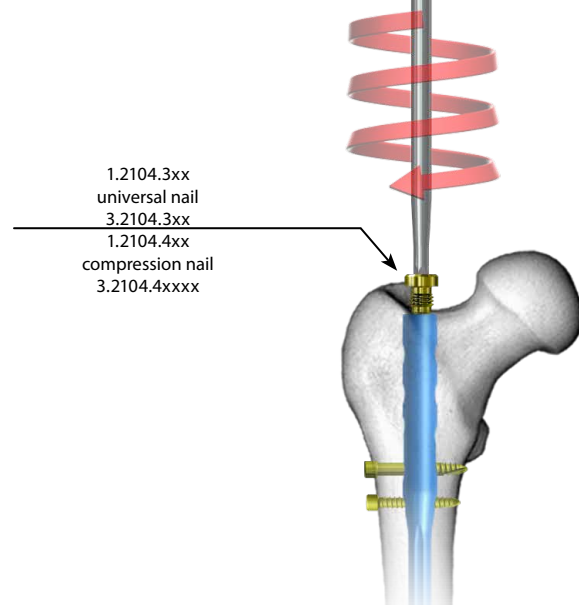
IV.4.3. Targeter removal, End cap insertion

70 Use the wrench S10 [40.5526.200] to unscrew the connecting screw [40.5094.000] from the nail and remove the targeter from the nail locked in the medullary canal.



71 In order to secure the inner thread of the nail from bone ingrowth, use the cannulated screwdriver S5.0/2.2 [40.3675.100] to insert:

- the end cap [1.2104.3xx] or [3.2104.3xx] for an universal nail,
- the end cap [1.2104.4xx] or [3.2104.4xxx] for a compression nail.



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

IV.5.1. Proximal nail locking

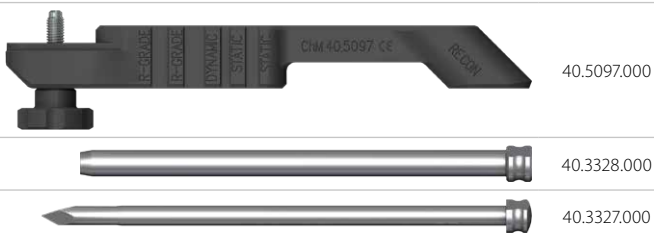
In the static method, the reconstruction nails may be used:

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

72 Insert the protective guide 11/9 [40.3328.000] (1 groove) with trocar 9 [40.3327.000] into the hole of proximal targeter. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

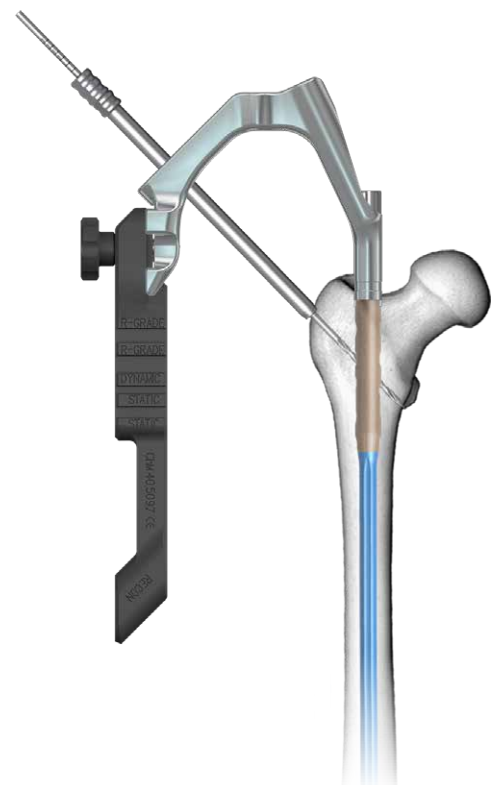
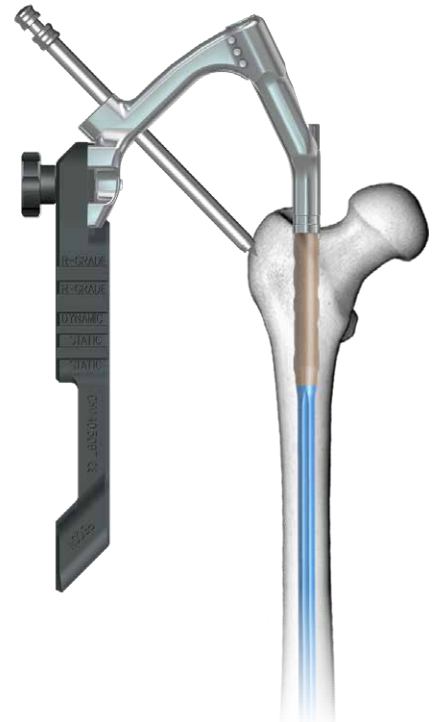
Leave the protective guide in the hole.



73 Insert the drill guide 9/4,5 [40.3330.000] (with two grooves on the handle) into the protective guide 11/9 [40.3328.000]. Mount the drill with scale 4.5/370 [40.5333.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the hole in the nail. The scale on the drill indicates the length of the locking element.

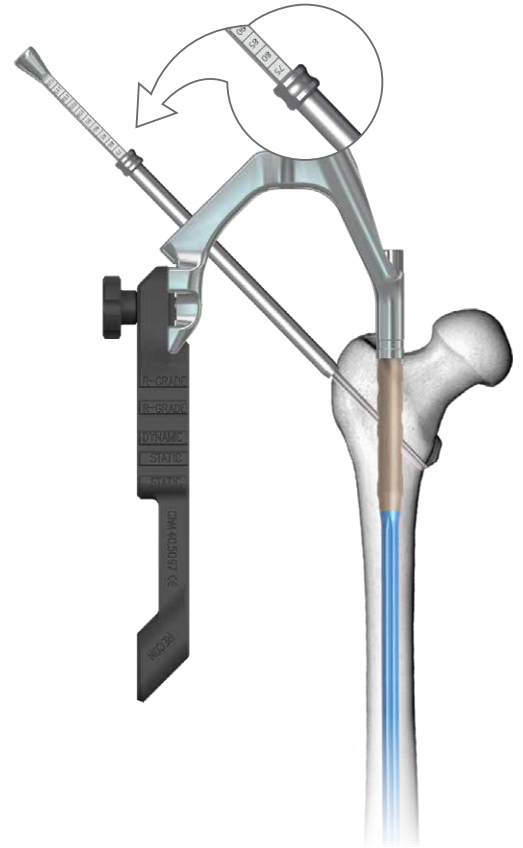
Remove the drill and drill guide.

Leave the protective guide in the hole.



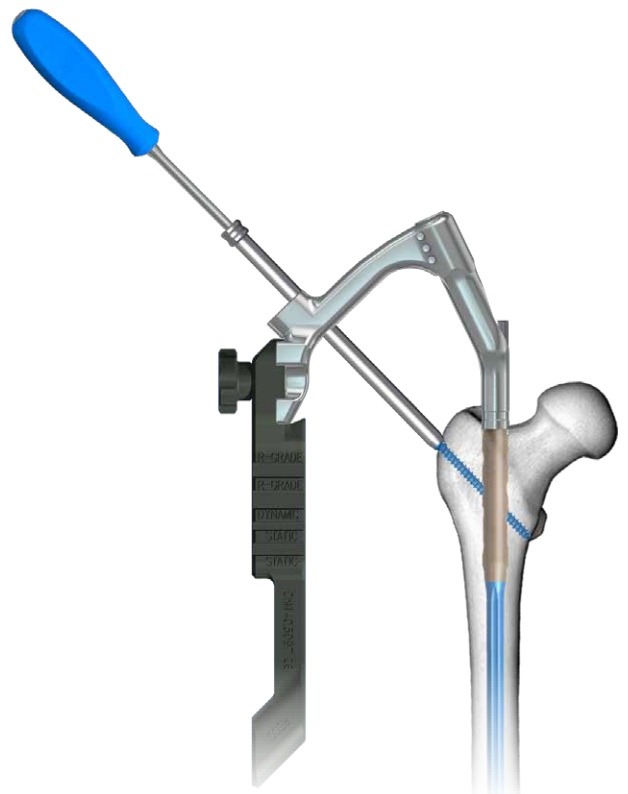
- 74 Insert the screw length measure [40.3332.000] through the protective guide 11/9 [40.3328.000] into the drilled hole up until its end. Read the length of the screw on the measure. During the measurement, the end of the protective guide should rest on the cortex bone.

Remove the measure.
Leave the protective guide in place.



- 75 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. For locking use the screw with 6.5mm diameter and length determined in a previous step. Then advance both into the protective guide. Insert the 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 protective guide.



IV.5.2. Distal nail locking

Prior to distal locking of the nail, do the following:

1. Mount the distal targeter D [40.5093.000] to the targeter arm [40.5091.100].
If properly installed, the signs RIGHT or LEFT on both targeters should comply.

2. Use X-Ray imaging to verify the position of holes in the nail and targeter - they need to be in line.

- 76 Insert the protective guide 9/6.5 [40.3614.000] (1 groove) with trocar 6.5 [40.3617.000] into the proximal hole of distal targeter D [40.5093.000]. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

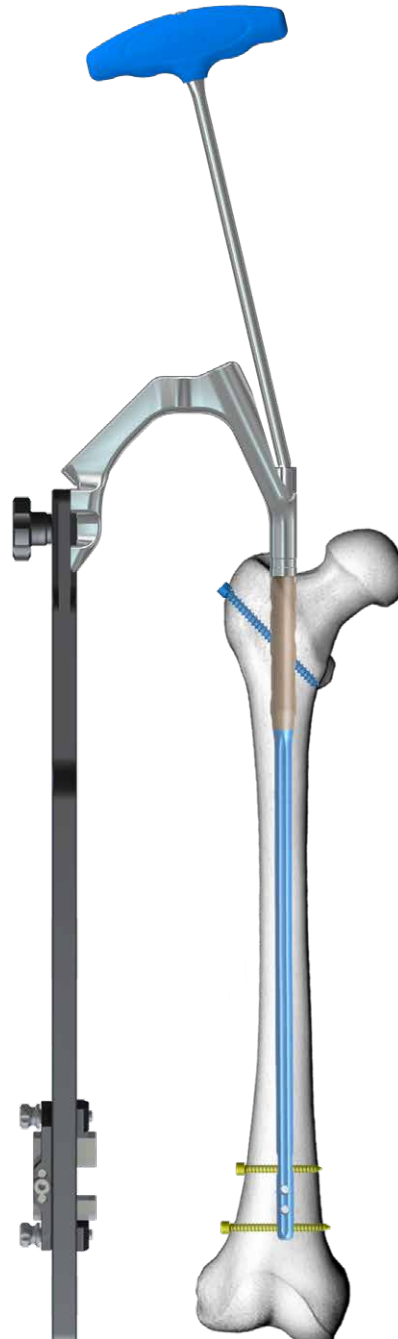
Remove the trocar.
Leave the protective guide in the hole.



CAUTION! For the rest of the procedure, follow the subchapter IV.2.2 of these instructions.

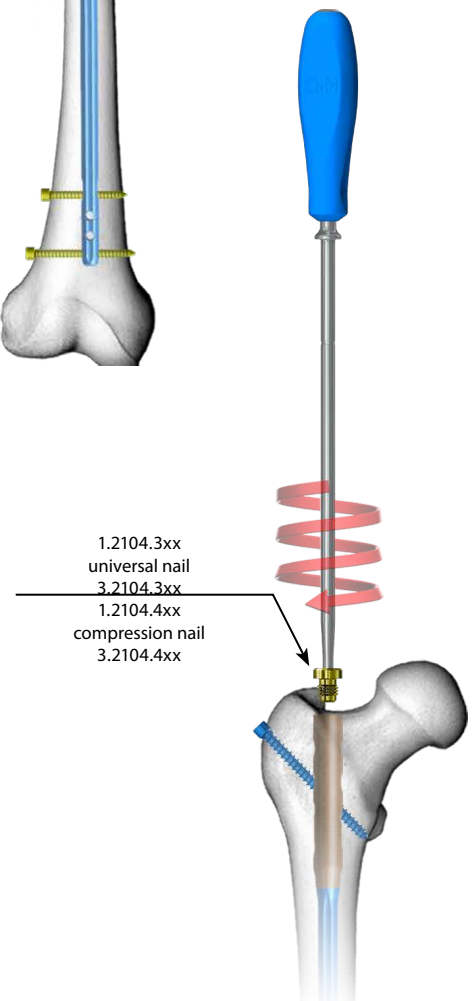
IV.5.3. Targeter removal, end cap insertion

77 Use the wrench S10 [40.5526.200] to unscrew the connecting screw [40.5094.000] from the nail and remove the targeter from the nail locked in the medullary canal.



78 In order to secure the inner thread of the nail from bone ingrowth, use the cannulated screwdriver S5.0/2.2 [40.3675.100] to insert:

- the end cap [1.2104.3xx] or [3.2104.3xx] for an universal nail,
- the end cap [1.2104.4xx] or [3.2104.4xx] for a compression nail.

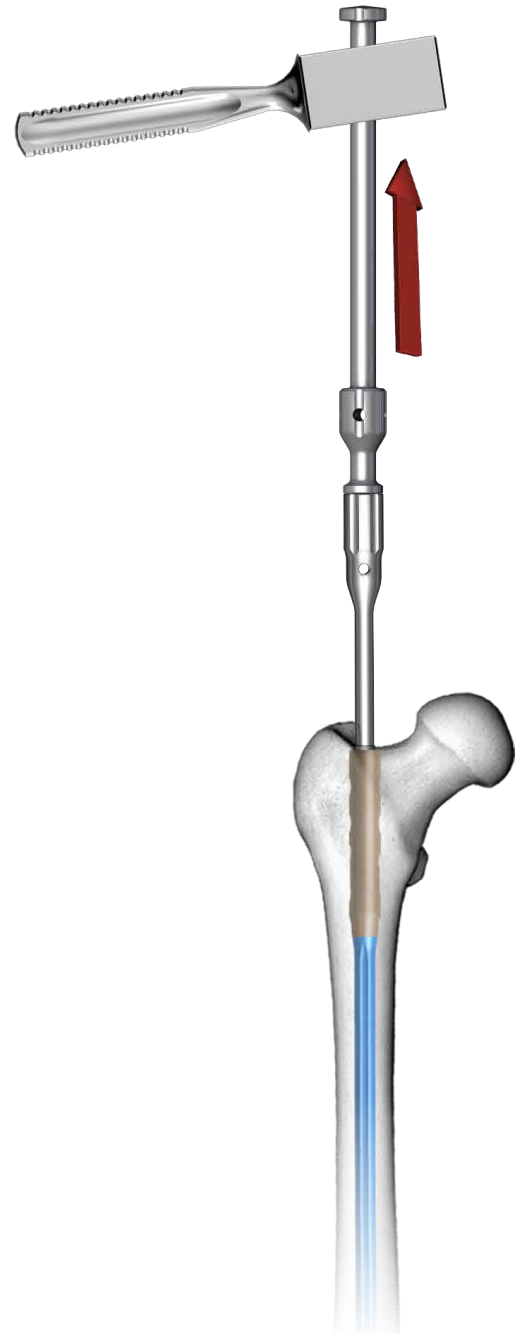
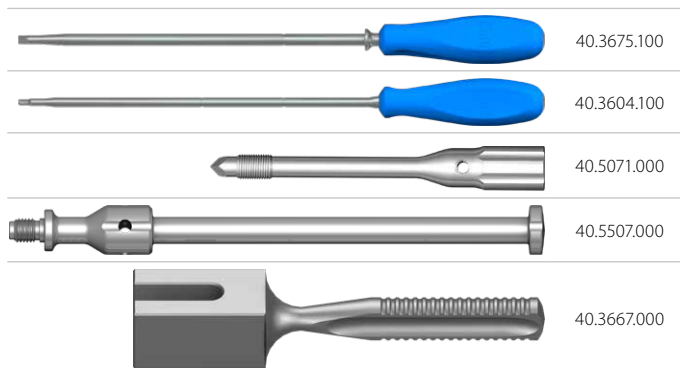


IV.6. NAIL REMOVAL

79 Use the cannulated screwdriver S5.0/2.2 [40.3675.100] to remove the end cap or screwdriver S3.5 [40.3604.100] to remove the compression screw from the nail.

Insert the connector [40.5071.000] into the threaded nail hole, then use the screwdriver S3.5 [40.3604.100] to remove all the locking screws.

Attach the impactor-extractor [40.5507.000] to the connector and, using the mallet [40.3667.000], extract the nail from the medullary canal.



IV.7. RETROGRADE METHOD (CONDYLAR APPROACH)

IV.7.1. Introduction

Retrograde nailing of the femur ensures fixation of fractures above the knee joint (*up to 20cm from the distal end of femur*) or comminuted fractures of condyle. The retrograde nailing may also be used for femurs with a hip prosthesis or another implant already implanted proximally.

CHARFIX system provides the retrograde nails with the following 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 or
- two locking sets.

There are five sizes of locking sets available:

- 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.

The locking set consists of: a bolt, two washers and a locking screw. Locking screws are used for locking the nail proximally.

Each surgical procedure has to be planned carefully. Prior to the procedure, adequate X-Ray images have to be taken in order to examine the fracture type and assess the dimensions of an implant (*diameter and length*) to be used.

The surgical procedure should be performed on a patient in supine position, with a tourniquet applied and the knee joint flexed at 90°.

Nailing may be performed with or without reaming of the medullary canal. In both cases the diameter of medullary canal ought to be bigger than the diameter of nail used; if the 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 its distal end is 12mm*).



The following paragraphs describe the most important steps during implantation of intramedullary interlocking femoral nails; nevertheless, these are not 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 image taken of fractured femur and of the healthy one, the surgeon decides about the length and diameter of the nail.

IV.7.2. Preparation and nail insertion

- 1 Make an incision over the middle of patellar ligament or more medially. Expose intercondylar region (*split the fibers of ligament or retract laterally*). Use the curved awl 8.0 [40.5523.100] to open the medullary canal to the depth of about 6 cm.

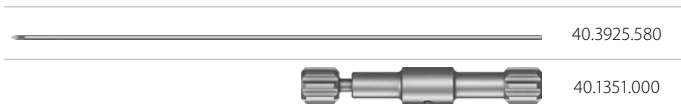


Control the procedure with the X-Ray imaging.



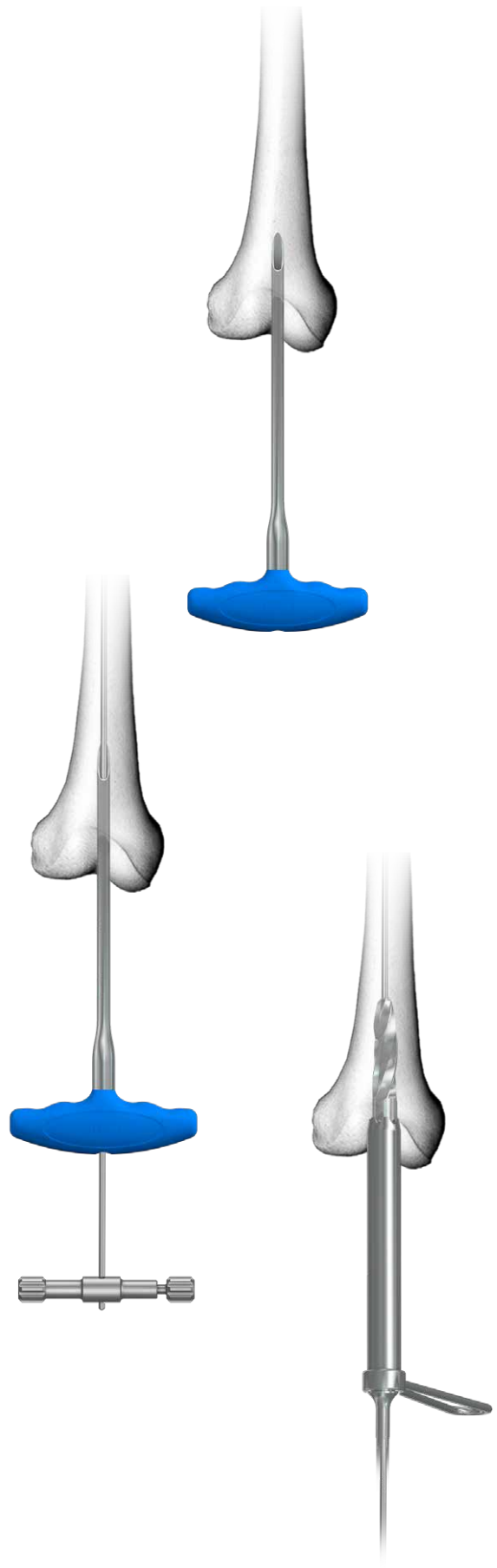
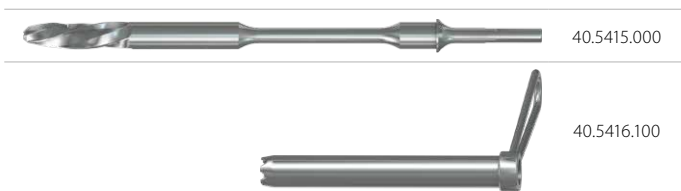
- 2 After opening the medullary canal, use the guide rod handle [40.1351.000] to insert the guide rod 3.0/580 [40.3925.580] up until an adequate depth is reached.

Remove the handle and awl.



- 3 The guide rod 3.0/580 [40.3925.580] is a guide for cannulated drill 13/3.5 [40.5415.000] placed in the protective guide 16/13 [40.5416.100]. Slowly ream the medullary canal with the cannulated drill until the drill collar rests against the protective guide.

Remove the drill and protective guide.



- 4 For reamed medullary canal, 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. In both cases, when the medullary canal was reamed or not, the canal should be reamed using 13 mm reamer to the depth of approx. 6 cm.



Remove the flexible reamer.



- 5 Insert the nail length measure [40.5098.000] via the guide rod 3.0/580 [40.3925.580] until it rests on the bone. Read the length of the nail to be used.

Remove the measure.

Remove the guide rod unless cannulated nail is used.

	40.3925.580
	40.5098.000



Medullary canal is ready for nail insertion.

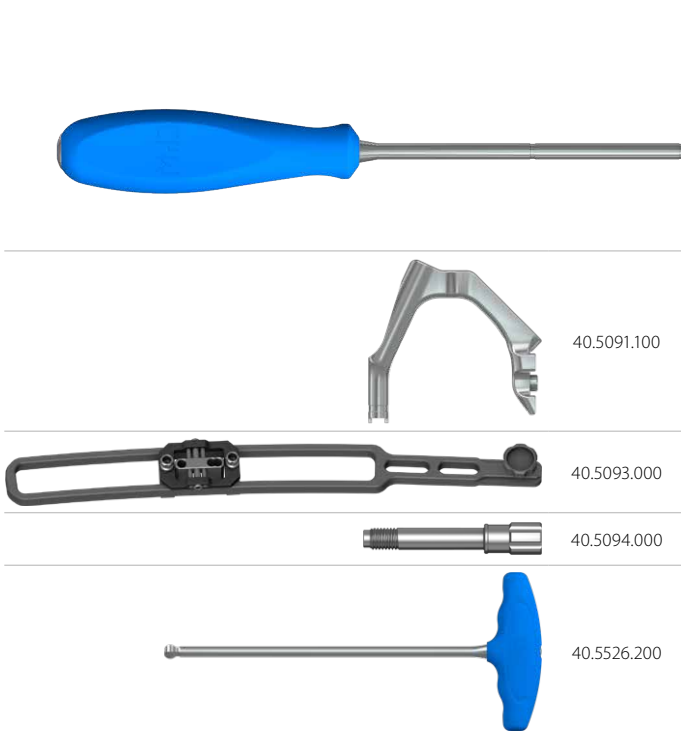
IV.7.3. Targeter installation and nail implantation

- 6 Mount the distal targeter D [40.5093.000] to the targeter arm [40.5091.100].



NOTE! For the right limb, the RIGHT markings on both targeters should be in line. For the left extremity - the LEFT signs need to match.

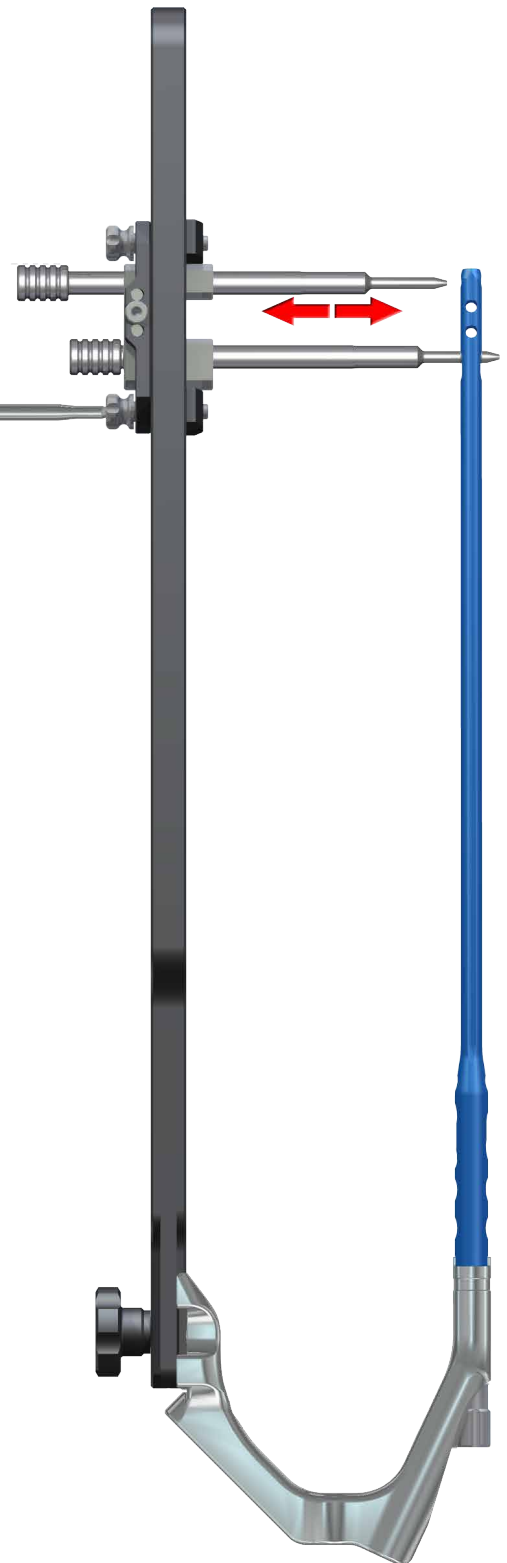
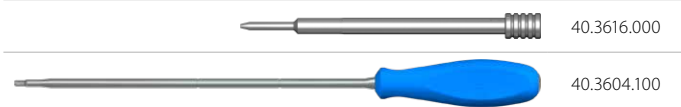
Use the connecting screw M10x1 L=55 [40.5094.000] and wrench S10[40.5526.200] to install the nail on the targeter arm [40.5091.100].



Use a pair of set blocks 9/4.5 [40.3616.000] to set the slider of the distal targeter D in line with distal locking holes of the nail. Use the screwdriver S3.5 [40.3604.100] to secure the slider.



CHECK: Properly set and secured slider of the distal targeter D makes it possible for the set blocks to pass through the holes of the nail easily.



8

I. Attach the angular set block [40.5004.500] to the targeter D so that it rests on the slider of the distal targeter D. Screw up the locking nut in hole of angular set block.

II. Insert the pin to the locking nut. Use screwdriver S3.5 [40.3604.100] to loosen the screws locking the arms of the angular set block and set them so that the pin passes through the transverse hole of the nail. Lock back the arms of angular set block.



Firstly, tightening the locking screw in the body of the set block (1st step). Next, lock the arm with the pin (2nd step).

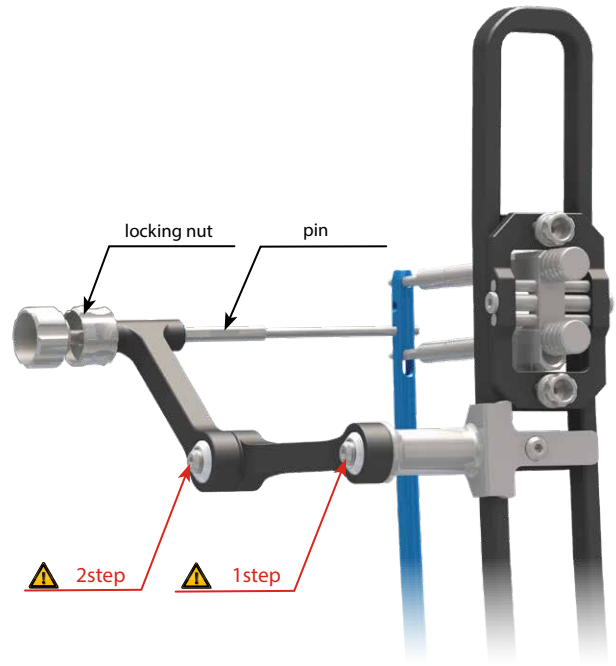
III. Remove the pin from the angular set block.



40.5004.500



40.3604.100

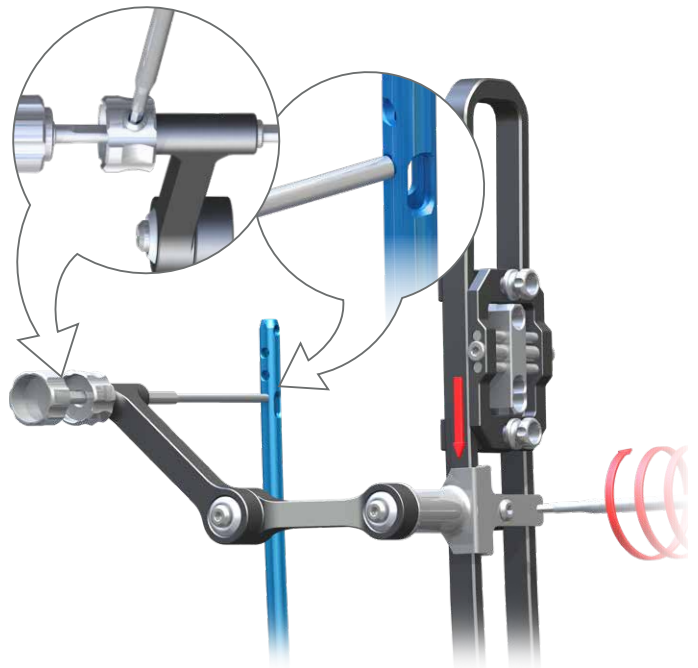


9

I. Loosen the screw mounting the angular set block to the targeter D, move it 10-15 mm and lock back using screwdriver S3.5 [40.3604.100].

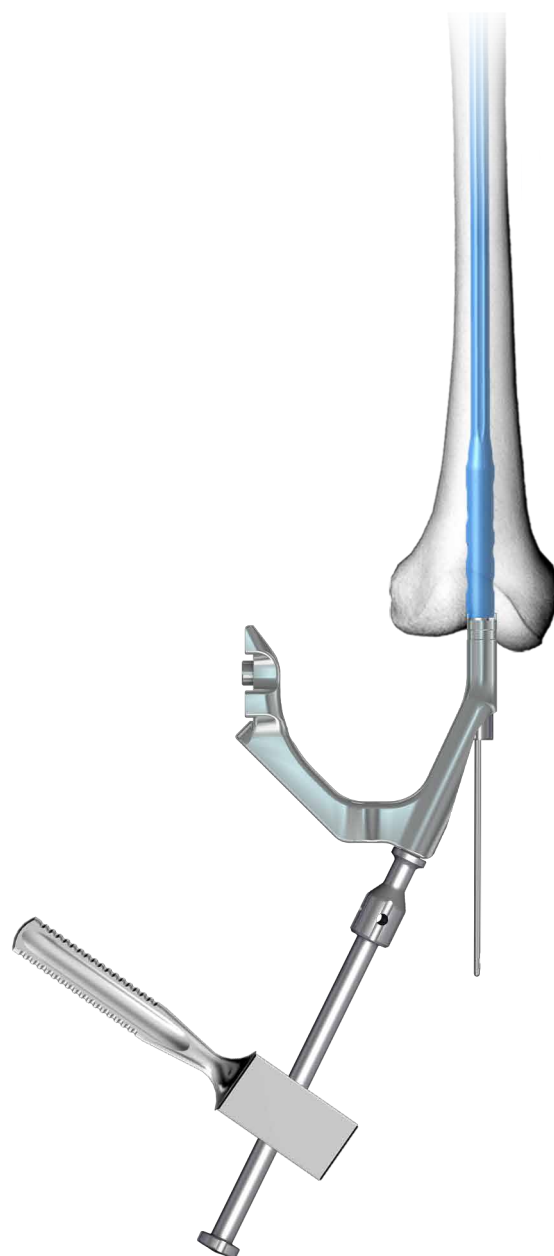
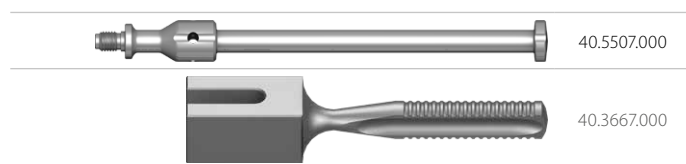
II. Insert the pin so that its end leans against the nail. Use screwdriver S3.5 [40.3604.100] to lock the pin.

III. Unscrew the locked pin-nut set from the angular set block. Dismount the distal targeter D from the targeter arm.



- 10 Install the impactor-extractor [40.5507.000] to the targeter arm [40.5091.100] with the nail attached. Insert the nail onto the guide rod 3.5/580 [40.3925.580] and into medullary canal. Advance the nail until it reaches adequate depth. Use mallet [40.3667.000], if need be.

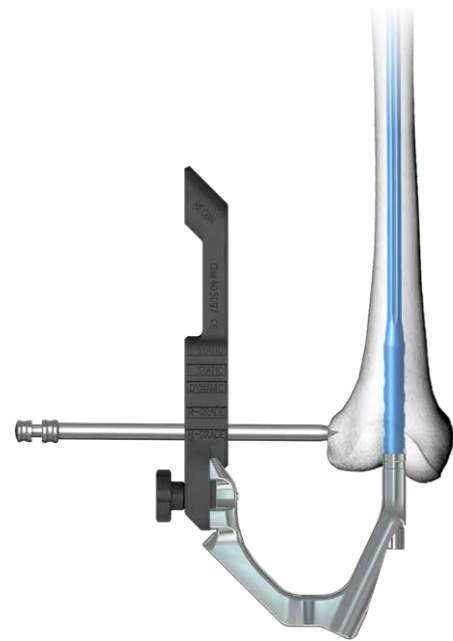
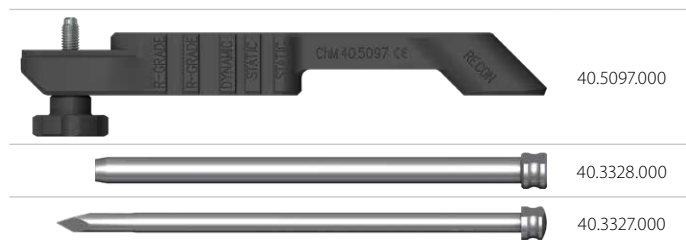
Remove the guide rod, and impactor-extractor from the targeter arm.



IV.7.4. Condylar locking of the nail

- 11 Attach the targeter 135 [40.5097.000] to the targeter arm [40.5091.100]. Insert the protective guide 11/9 [40.3328.000] with trocar 9 [40.3327.000] into the most distal hole of the targeter 135. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

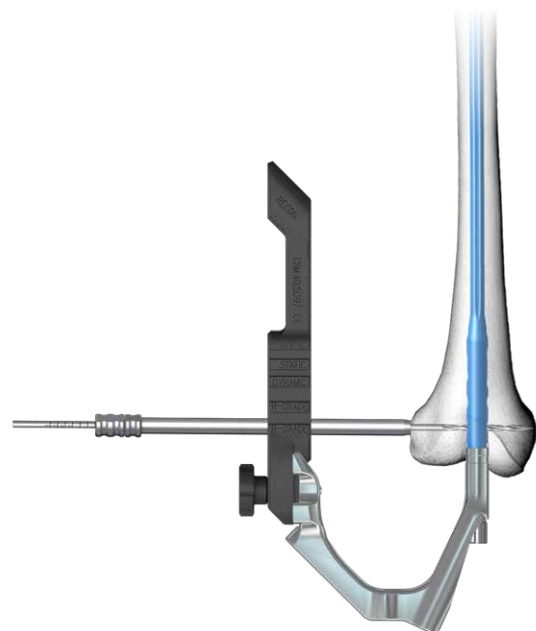
Remove the trocar.
Leave the protective guide in place.



IV.7.4.1. OPTION I: Locking with a screw

- 12 Insert the drill guide 9/4.5 [40.3330.000] into the protective guide 11/9 [40.3328]. Mount the drill with scale 4.5/370 [40.5333.001] to the surgical drive, advance it through the drill guide and drill a hole. The scale on the drill indicates the length of the locking element.

Drill under X-Ray control.
Remove the drill and drill guide.
Leave the protective guide in the hole of targeter.



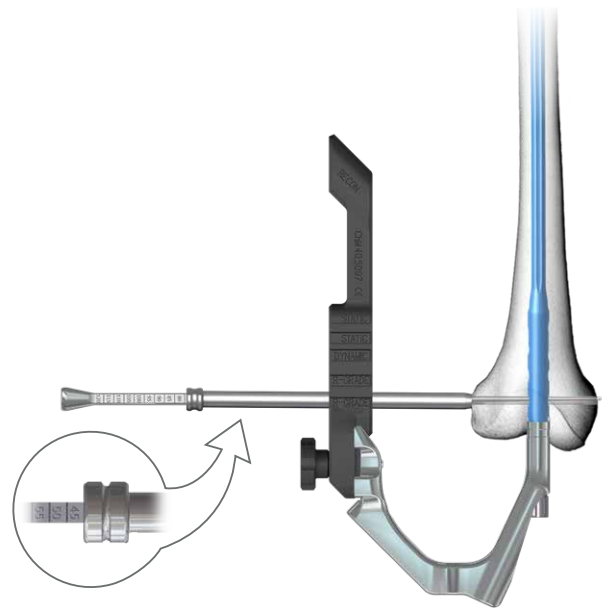
- 13 Insert the reconstruction screw length measure [40.3332.000] through the protective guide 11/9 [40.3328.000] into the drilled hole up until its end. Read the length of the reconstruction screw on the measure. During the measurement, the end of the protective guide should rest on the cortex bone.

Remove the measure.

Leave the protective guide in the hole of targeter.



40.1374.100



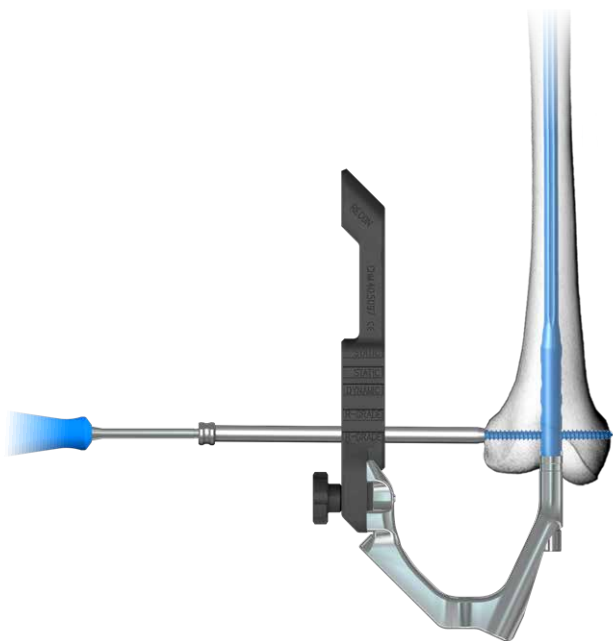
- 14 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected reconstruction screw. Then advance both into the protective guide. Insert the reconstruction screw in the prepared hole until the head of the screw reaches the cortex bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the screwdriver and protective guide.

Use 6.5mm screws for distal locking of the nail.



40.3604.100



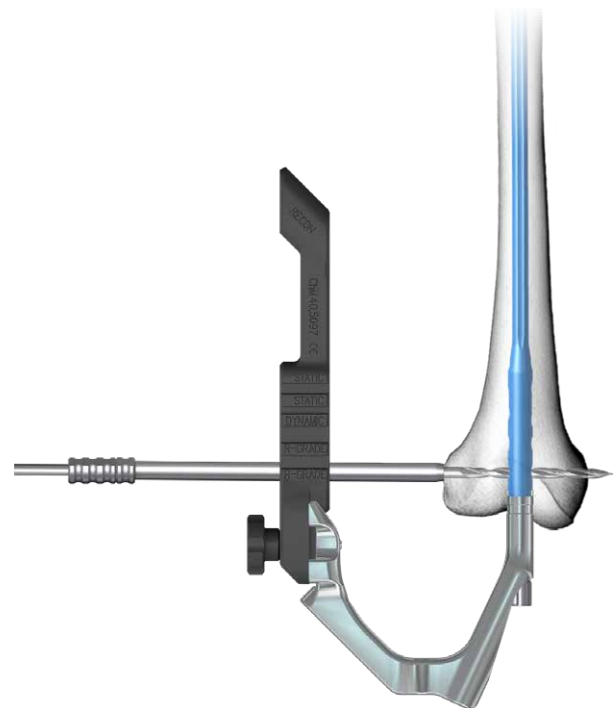
IV.7.4.2. **OPTION II: Locking with locking set (bolt - two washers - locking screw)**

15 The drill guide 9/6.5 [40.3629.000] and protective guide 11/9 [40.3328] are already in the hole of the targeter135. Mount the drill 6.5/370 [40.2068.371] to the surgical drive and perform a through hole.



Drilling and skin incision should be controlled with X-Rays image intensifier.

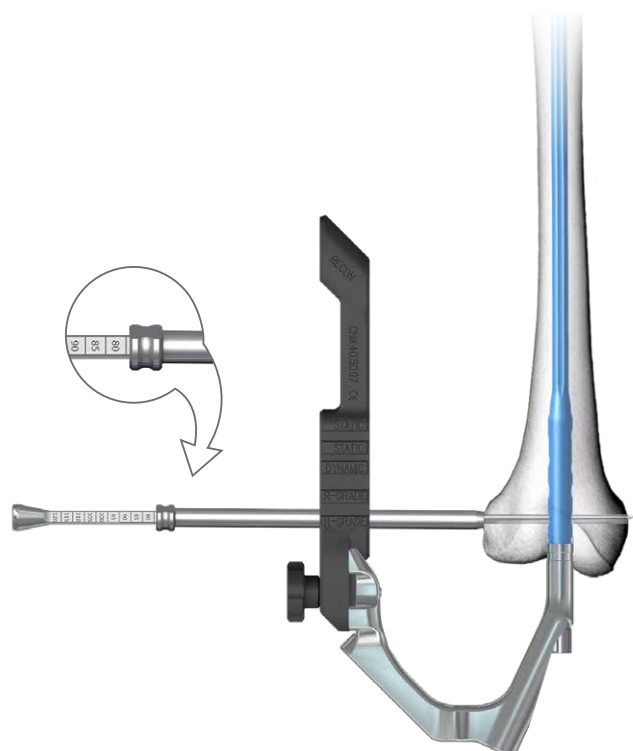
Remove the drill and drill guide.
Leave the protective guide 11/9 in place.



16 Insert the reconstruction screw length measure [40.3332.000] through the protective guide 11/9 [40.3328.000] into the drilled hole up until its end. Deduct 10mm from the reading scale, to get the dimensions of the locking set required.

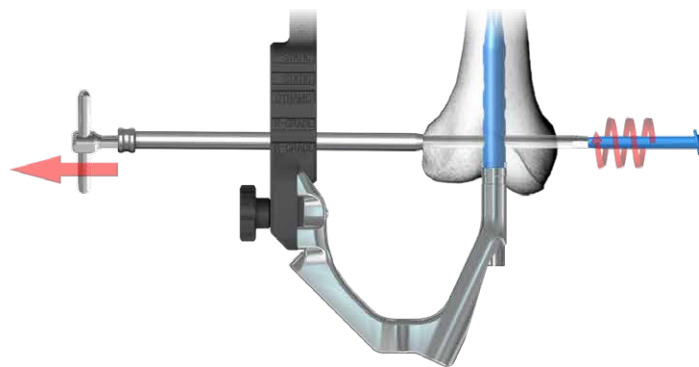
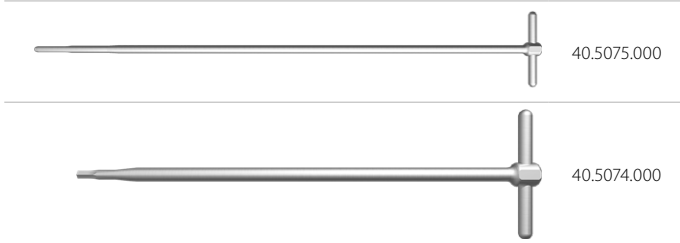
Select a locking set with adequate range, e.g. with "75" on the scale, the actual size is "65", therefore locking set 60 with a range between 60 and 75 mm should be used. During the measurement, the protective guide should rest on the cortex.

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



- 17 Insert the bolt guide [40.5075.000] into the protective guide 11/9 [40.3328.000]. The pilot which is integral part of the the bolt guide should be attached thereof. Advance the bolt guide through the drilled hole until its tip reaches the end of the hole. Remove the pilot. Put the bolt (*implant*) through the washer (*implant*) and screw it in onto the the bolt guide using the screwdriver S3.5 [40.5074.000]. Advance the bolt into the hole in the bone (*head of the bolt should rest on the cortex with the washer between them*).

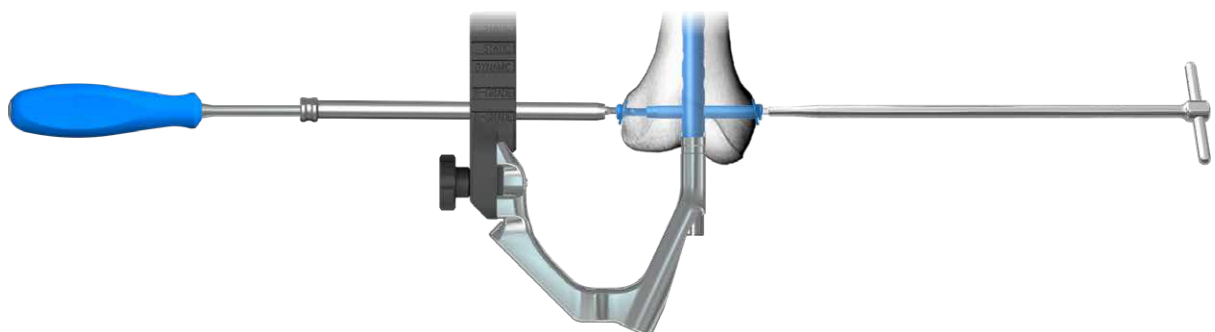
Remove the bolt guide.
Leave the protective guide in place.



- 18 Insert the tip of the screwdriver S3.5 [40.3604.100] 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 insert the locking screw in the threaded hole of 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.



CAUTION!
For distal locking of the nail, follow the steps 11 and 15-18.

IV.7.5. Locking of the nail in the femoral shaft

Prior to distal locking of the nail, do the following:

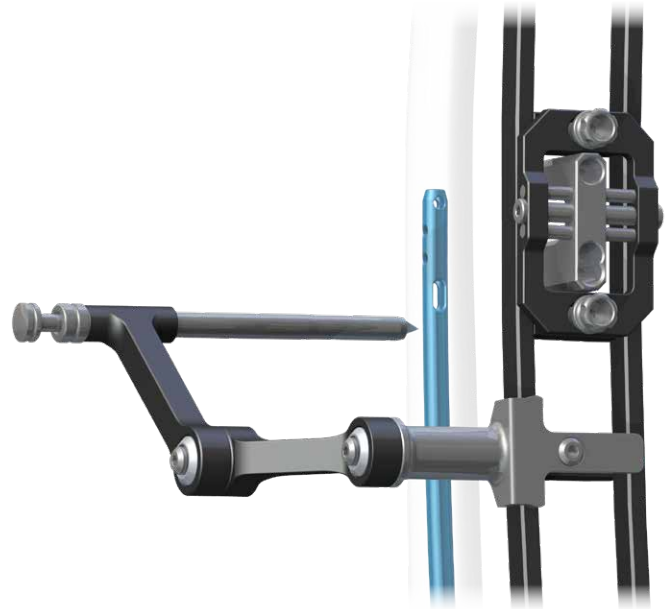
1. Install the distal targeter D [40.5093.000] with attached angular set block to the targeter arm [40.5091.100].
If properly installed, the signs RIGHT or LEFT on both targeters should comply.

2. Use X-Ray imaging to verify the position of holes in the nail and targeter - they need to be in line.

19 Insert the protective guide 9/6.5 [40.3614.000] with trocar 6.5 [40.3617.000] into the hole of angular set block [40.5004.500]. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

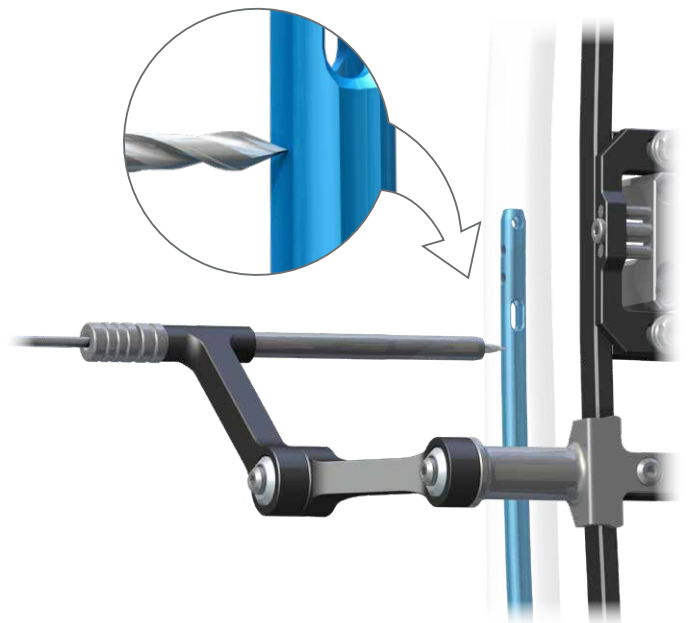
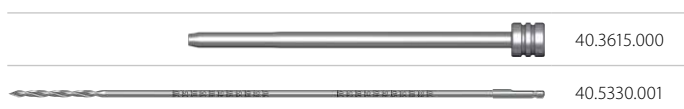
Remove the trocar.

Leave the protective guide in place.

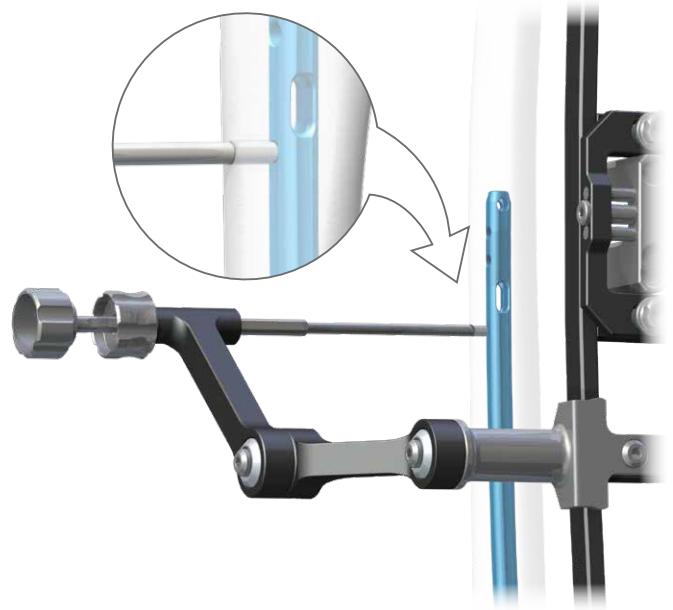


20 Insert the drill guide 6.5/3.5 [40.3615.000] into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill (*under image intensifier control*) the hole in the femur until the drill reaches the nail.

REMOVE: the drill, drill guide and protective guide.

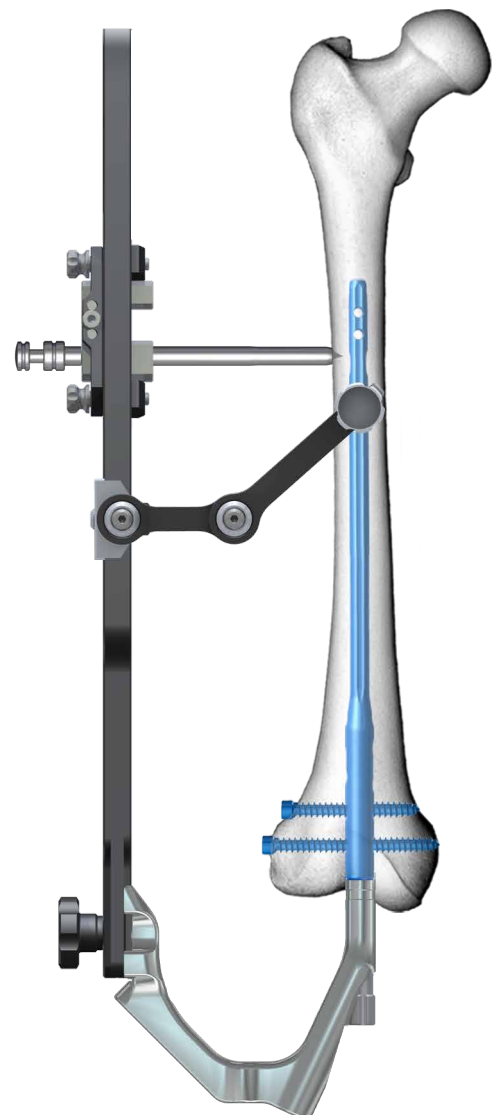


- 21 Insert and tighten up the pin and the nut in the hole of the angular set block [40.5004.500]. Afterwards, proceed with locking the nial from the slider of the distal targeter.



- 22 Insert the protective guide 9/6.5 [40.3614.000] with trocar 6.5 [40.3617.000] into the more distal hole of distal targeter D [40.5093.000]. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

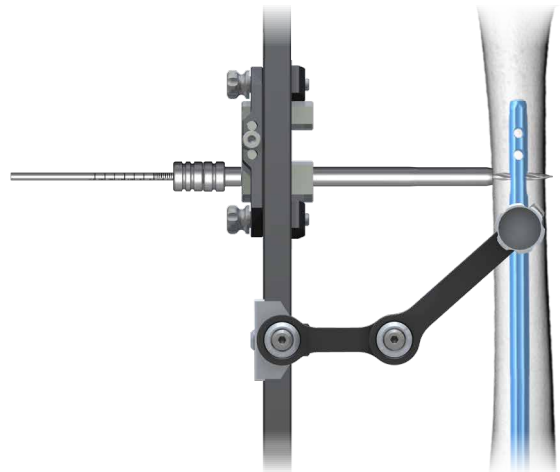
Remove the trocar.
Leave the protective guide in place.



- 23 Insert the drill guide 6.5/3.5 [40.3615.000] (2 grooves) into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole through its both cortex layers and the nail hole. The scale on the drill indicates the length of the locking element.

Remove the drive

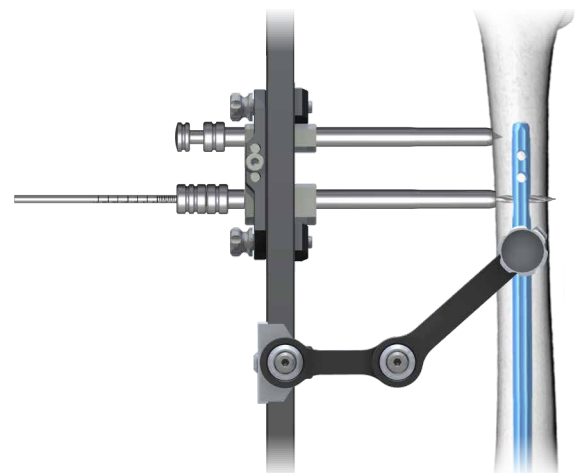
Leave the set: protective guide - drill guide - drill, in place.



- 24 Insert the protective guide 9/6.5 [40.3614.100] (with one groove) with the trocar 6.5 [40.3617.000] into the other hole of the distal targeter. Mark on the skin the entry point for screws and make adequate soft tissues incision. 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.

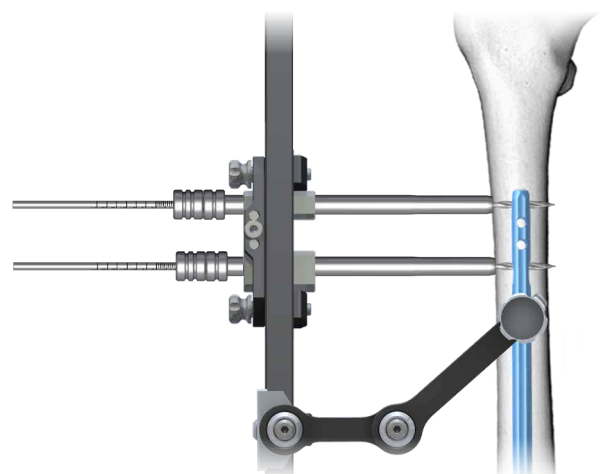
Leave the protective guide in place.



- 25 Insert the drill guide 6.5/3.5 [40.3615.000] (2 grooves) into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the nail. The scale on the drill indicates the length of the locking element.

Remove: the drill, drill guide.

Leave protective guide in place.



26 Insert the screw length measure [40.1374.100] through the protective guide 9/6.5 [40.3614.000] into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale. During the measurement, the tip of protective guide should rest on the cortex bone.

Remove the measure.
Leave the protective guide in place.



27 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the 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.
Leave the protective guide in place.



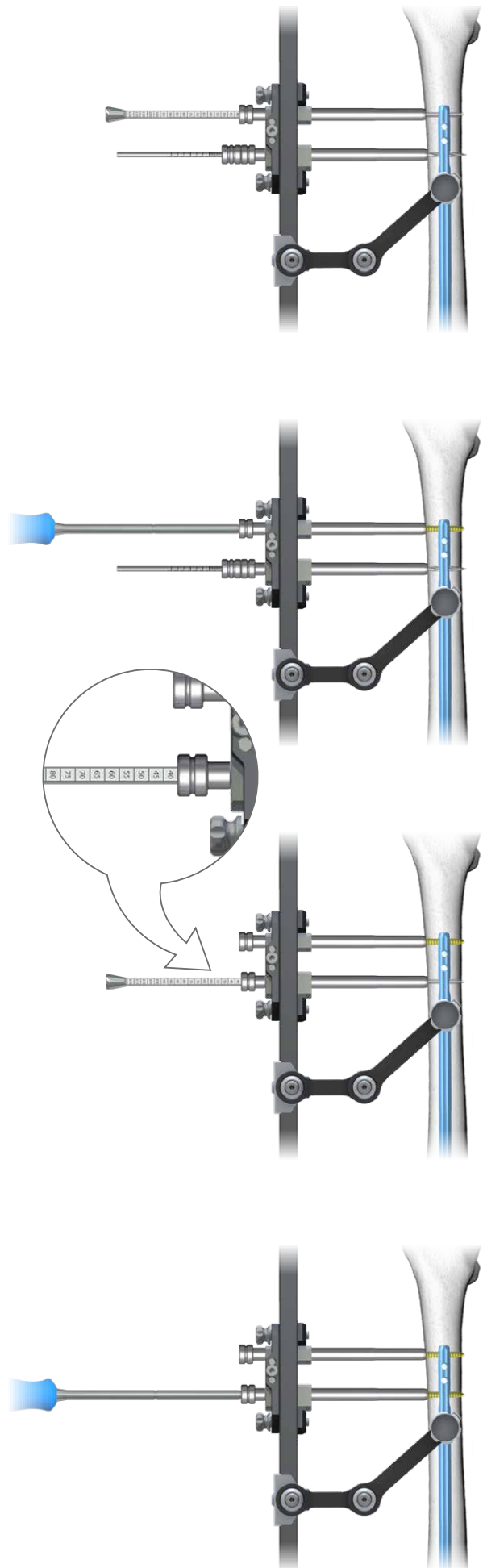
28 Remove the drill with scale 3.5/270 [40.5330.001] and drill guide from the more distal hole of the distal targeter D [40.5093.000]. Leave the protective guide 9/6.5 [40.3614.000] in the hole of the targeter. Insert the screw length measure [40.1374.100] through the protective guide into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale. During the measurement the protective guide should rest on the cortex bone.

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



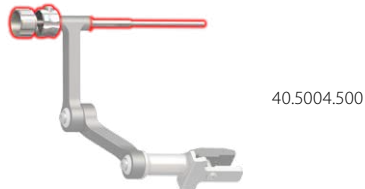
29 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the screw in the prepared hole until the head of the screw reaches the cortex bone (the groove on the screwdriver shaft matches the edge of protective guide).

Remove the screwdriver.



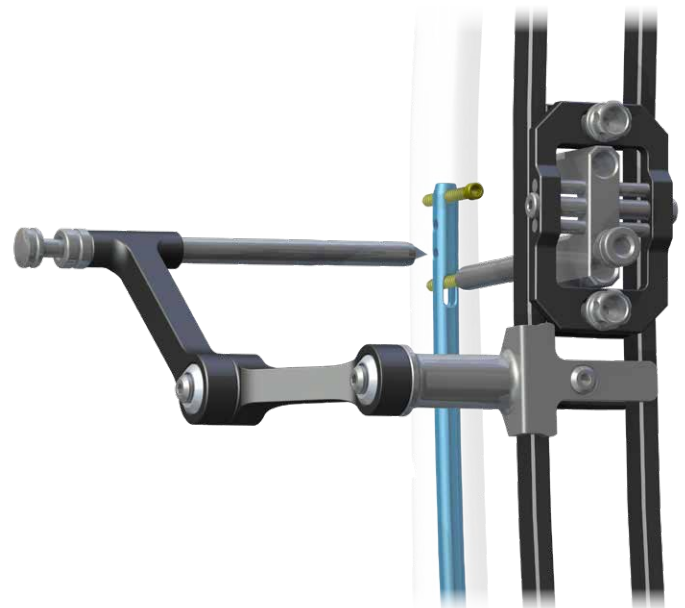
- 30 After locking the nail in its distal part, remove only one of protective guides used for locking in the AP plane and proceed to locking the nail in the other plane.

Remove the pin and nut from the angular set block. Move the angular set block [40.5004.500] so that it leans against the slider of the distal targeter. Lock the angular set block.



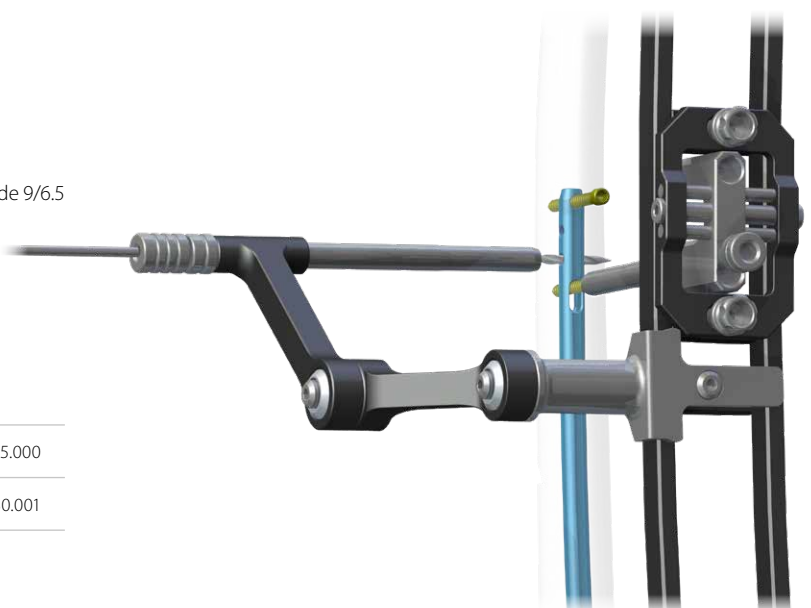
- 31 Insert the protective guide 9/6.5 [40.3614.000] with trocar 6.5 [40.3617.000] into the hole of angular set block [40.5004.500]. Mark on the skin the entry point for screws and make adequate soft tissues incision. Advance the trocar until it reaches the cortex bone and mark the entry point for the 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 place.



- 32 Insert the drill guide 6.5/3.5 [40.3615.000] into the protective guide 9/6.5 [40.3614.000]. Mount the drill with scale 3.5/270 [40.5330.001] to the surgical drive and advance it through the drill guide. Drill (*under image intensifier control*) the hole through both cortex layers of the bone and the nail hole.

Remove the drill.

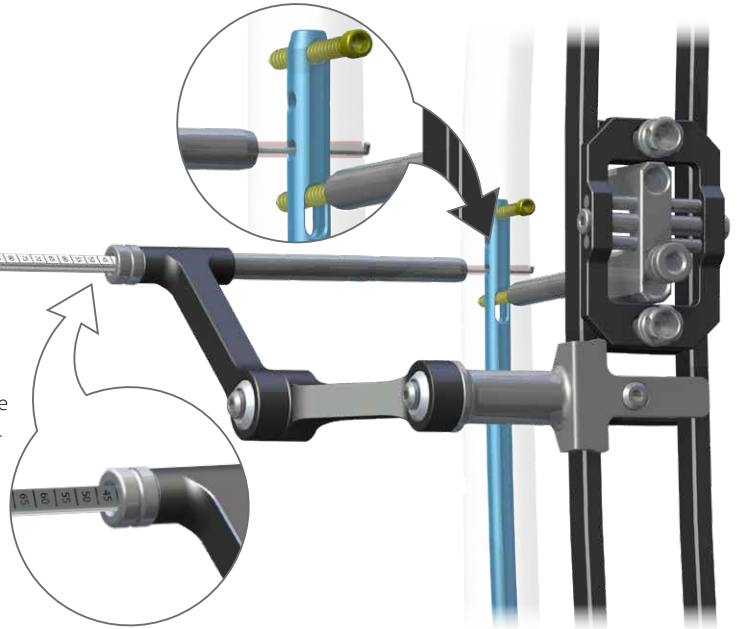


- 33 Insert the screw length measure [40.1374.100] through the protective guide 9/6.5 [40.3614.000] into the drilled hole up until its hook reaches the "exit" plane of the hole. Read the length of the locking screw on the B-D measure scale. During the measurement the protective guide should rest on the cortex bone.

Remove the measure.



40.1374.100

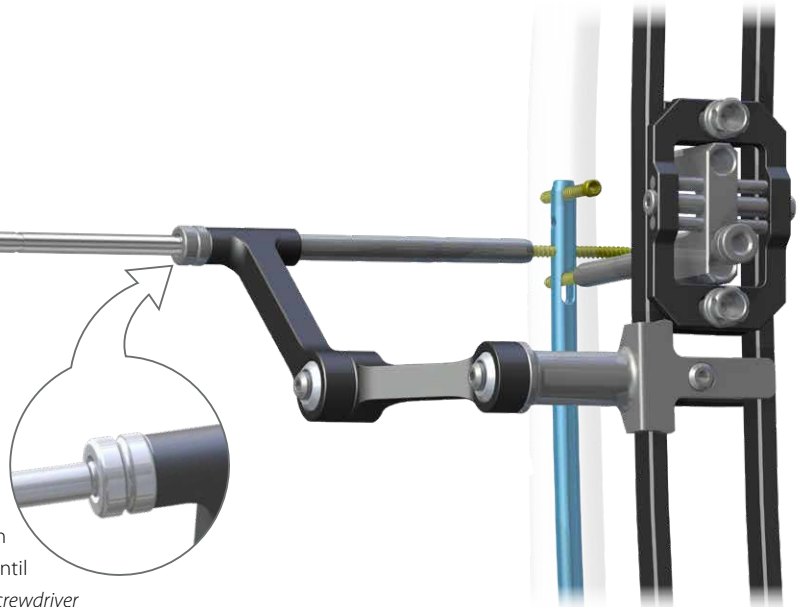


- 34 Insert the tip of screwdriver S3.5 [40.3604.100] into the hexagonal socket of selected locking screw. Then advance both into the protective guide. Insert the screw in the prepared hole until the head of the screw reaches the cortex bone (*the groove on the screwdriver shaft matches the edge of protective guide*).

Remove the screwdriver, protective guide and angular set block and proceed to proximal locking of the nail.



40.3604.100



CAUTION:

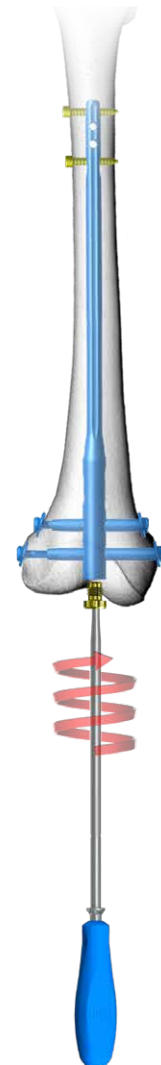
Locking of the nail in its proximal part may also be performed using "free hand" technique. If applicable, refer to the description of the reconstruction method - steps from 45 to 52 of these instructions.

IV.7.6. Targeter removal. End cap insertion

- 35 Use the wrench S10 [40.5526.200] to remove the connecting screw [40.5094.000] and targeter arm [40.5091.100] from the nail locked in the medullary canal.



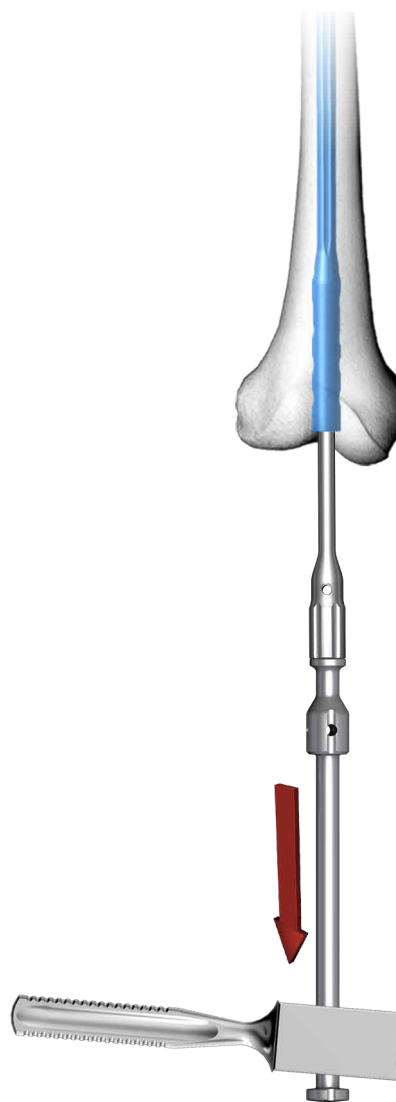
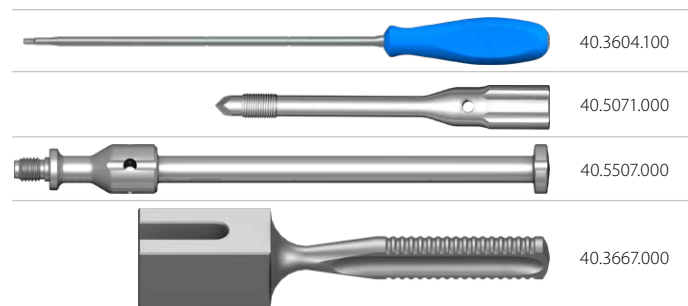
- 36 In order to secure the inner thread of the nail from bone ingrowth, use the cannulated screwdriver S3.5 [40.3604.100] to insert the end cap [1.2104.002] or [3.2104.002] into the nail.



IV.7.7. Nail removal

- 37 Use the screwdriver S3.5 [40.3604.100] to remove the end cap and all the locking screws (use 2 screwdrivers to remove the locking set).

Insert the connector M10x1/M12[40.5071.000] into the threaded nail hole. Attach the impactor-extractor [40.5507.000] to the connector and, using the mallet [40.3667.000], extract the nail from the medullary canal.



ChM sp. z o.o.

Lewickie 3b
16-061 Juchnowiec Kościelny
Polska

tel. +48 85 86 86 100

fax +48 85 86 86 101

chm@chm.eu

www.chm.eu



CE 0197