ST/24E

ChM®

CHARFIX system

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR

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

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SYMBOLS DESCRIPTION

Ti	Titanium or titanium alloy
St	Steel
L	Left
R	Right
L R	Available versions: left/right
Len	Length
	Torx drive
	Torx drive cannulated
	Hexagonal drive
	Hexagonal drive cannulated
	Cannulated
	Locking
	Diameter
	Inner diameter
	Recommended length range for a particular nail
	Angle
16 ÷ 90	Available lengths
Ster Non Ster	Available in sterile/ non- sterile condition

	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.

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The manufacturer reserves the right to introduce design changes.
Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

I. INTRODUCTION

CHARFIX system provides the following methods of intramedullary fixation:
- Reconstruction,
- Compression, dynamic, static,
- Retrograde *(condylar approach)*.

Each fixation method of **CHARFIX** system comes with:
- adequate selection of implants *(intramedullary nails, screws, locking screws)*,
- instrument sets for implants insertion and removal,
- instructions for use *(surgical technique)*.

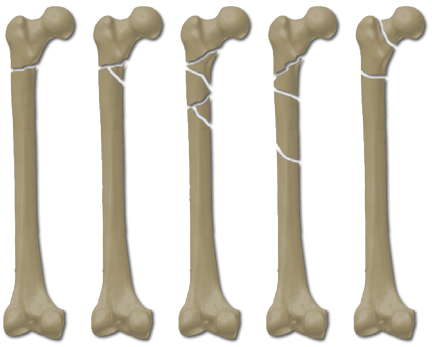
The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of Quality Management Systems and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

I.1. RECONSTRUCTION, PERTROCHANTERIC METHOD

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

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

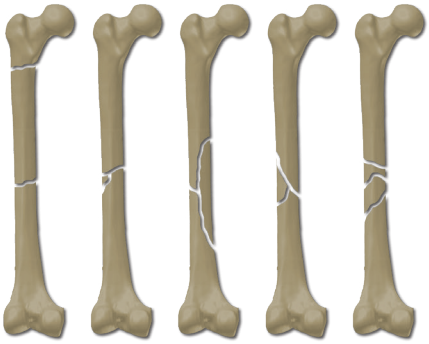
Position of the implants in femur:



Examples of fractures treated with this method:

To fix the femoral fracture fragments with pertrochanteric method use:
- right nail for fixation of the left femur fractures
- left nail for fixation of the right femur fractures

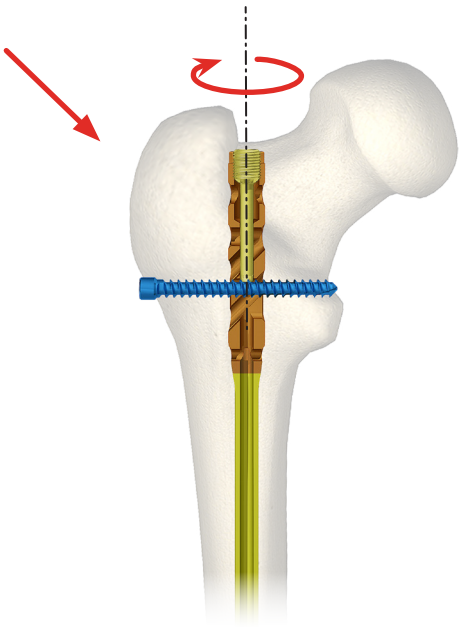
Position of implants in femur:



Examples of fractures treated with this method:

I.2. COMPRESSION, DYNAMIC AND STATIC METHOD

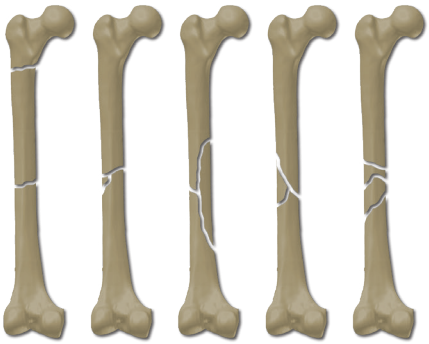
Compressive lockings are used in the intramedullary fixations of femoral shaft fractures, providing that fractures are not closer than 3cm from locking screw. Nail design allows treatment with the compression, dynamic and static method.



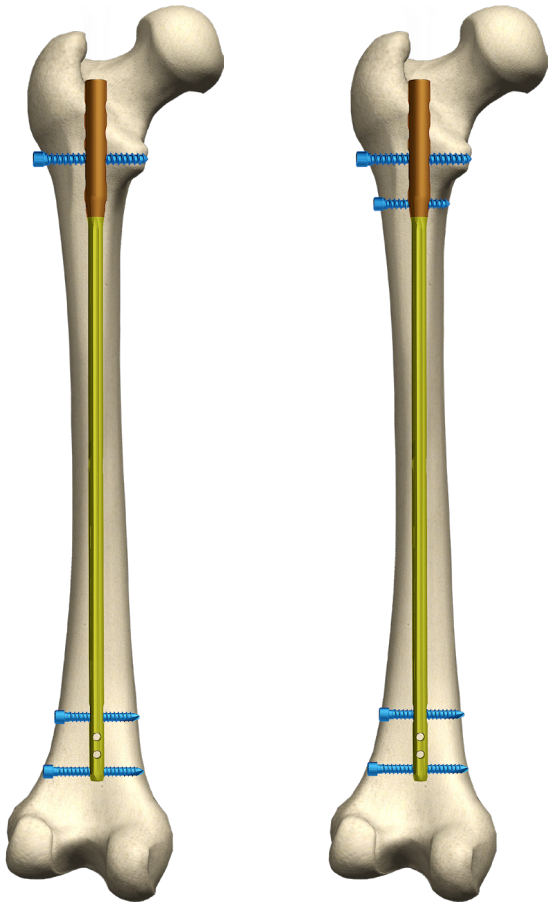
Compression method

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

Position of implants in femur



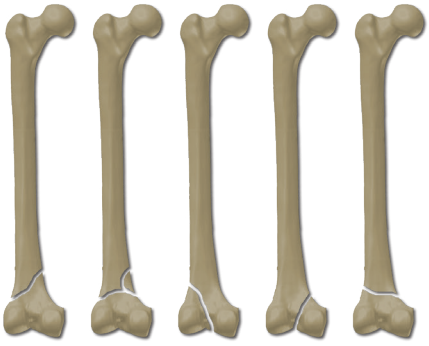
Examples of femoral shaft fractures treated with this method:



I.3. RETROGRADE *(CONDYLAR APPROACH)*

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

Position of the implant in femur:



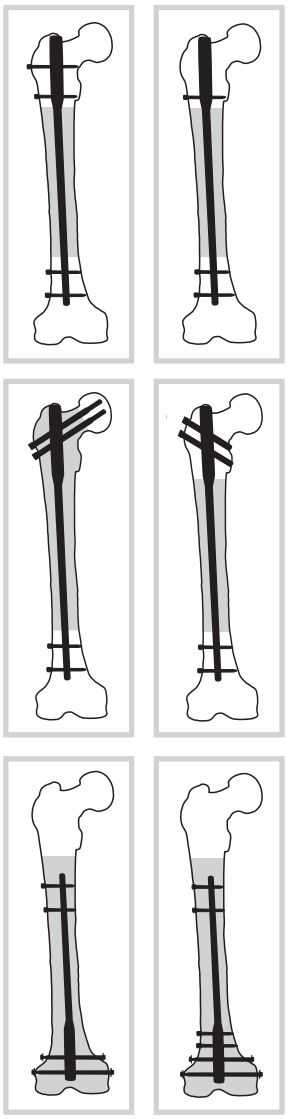
Examples of femoral shaft fractures treated with this method:

II. IMPLANTS

II.1. IMPLANTS OF RECONSTRUCTION, CONPRESSION AND RETROGRADE METHOD

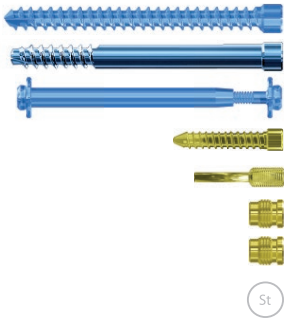
CHARFIX FEMORAL NAIL

CHARFIX system



	Len	L	R
9	200	3.2855.200	3.2854.200
	220	3.2855.220	3.2854.220
	240	3.2855.240	3.2854.240
	260	3.2855.260	3.2854.260
	280	3.2855.280	3.2854.280
	300	3.2855.300	3.2854.300
	320	3.2855.320	3.2854.320
	340	3.2855.340	3.2854.340
	360	3.2855.360	3.2854.360
	380	3.2855.380	3.2854.380
	400	3.2855.400	3.2854.400
	420	3.2855.420	3.2854.420
	440	3.2855.440	3.2854.440
	460	3.2855.460	3.2854.460
10	200	3.2857.200	3.2856.200
	220	3.2857.220	3.2856.220
	240	3.2857.240	3.2856.240
	260	3.2857.260	3.2856.260
	280	3.2857.280	3.2856.280
	300	3.2857.300	3.2856.300
	320	3.2857.320	3.2856.320
	340	3.2857.340	3.2856.340
	360	3.2857.360	3.2856.360
	380	3.2857.380	3.2856.380
	400	3.2857.400	3.2856.400
	420	3.2857.420	3.2856.420
	440	3.2857.440	3.2856.440
	460	3.2857.460	3.2856.460

St



	Ti				
3.1651.xxx	✓			6.5	40÷110
3.1652.xxx	✓		✓	6.5	60÷120
3.2109.xxx	✓			6.5	50÷90
3.1654.xxx	✓			4.5	30÷90
3.2106.007	✓				
3.2104.002	✓				
3.2104.3xx	✓		✓		0÷15

St

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CHARFIX FEMORAL NAIL

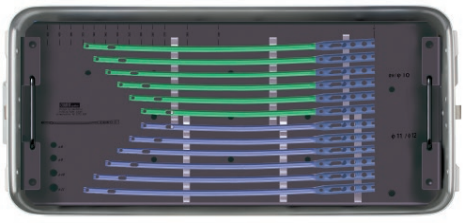
CHARFIX system

Ti

	Len	L	R
11	200	3.2859.200	3.2858.200
	220	3.2859.220	3.2858.220
	240	3.2859.240	3.2858.240
	260	3.2859.260	3.2858.260
	280	3.2859.280	3.2858.280
	300	3.2859.300	3.2858.300
	320	3.2859.320	3.2858.320
	340	3.2859.340	3.2858.340
	360	3.2859.360	3.2858.360
	380	3.2859.380	3.2858.380
	400	3.2859.400	3.2858.400
	420	3.2859.420	3.2858.420
	440	3.2859.440	3.2858.440
	460	3.2859.460	3.2858.460
12	200	3.2861.200	3.2860.200
	220	3.2861.220	3.2860.220
	240	3.2861.240	3.2860.240
	260	3.2861.260	3.2860.260
	280	3.2861.280	3.2860.280
	300	3.2861.300	3.2860.300
	320	3.2861.320	3.2860.320
	340	3.2861.340	3.2860.340
	360	3.2861.360	3.2860.360
	380	3.2861.380	3.2860.380
	400	3.2861.400	3.2860.400
	420	3.2861.420	3.2860.420
	440	3.2861.440	3.2860.440
	460	3.2861.460	3.2860.460

St

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



Stand for universal femoral nails (implants not included) 40.5753.000

LOCKING ELEMENTS

Ster
Non Ster

CHARFIX system

CHARFIX DISTAL SCREW 4.5

Ti

30	3.1654.030
35	3.1654.035
40	3.1654.040
45	3.1654.045
50	3.1654.050
55	3.1654.055
60	3.1654.060
65	3.1654.065
70	3.1654.070
75	3.1654.075
80	3.1654.080
85	3.1654.085
90	3.1654.090

16 ÷ 100

St

CHARFIX DISTAL SCREW 6.5

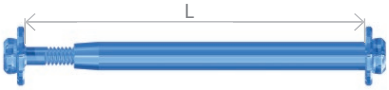
Ti

40	3.1651.040
45	3.1651.045
50	3.1651.050
55	3.1651.055
60	3.1651.060
65	3.1651.065
70	3.1651.070
75	3.1651.075
80	3.1651.080
85	3.1651.085
90	3.1651.090
100	3.1651.100
105	3.1651.105
110	3.1651.110

30 ÷ 110

St

CHARFIX LOCKING SET 6.5



Ti

L	Range	
50	50-65	3.2109.050
60	60-75	3.2109.060
70	70-85	3.2109.070
80	80-95	3.2109.080
90	90-105	3.2109.090

St

CHARFIX RECONSTRUCTION CANNULATED SCREW 6.5

Ti

L	L_1	
60	25	3.1652.060
65	25	3.1652.065
70	25	3.1652.070
75	25	3.1652.075
80	25	3.1652.080
85	25	3.1652.085
90	25	3.1652.090
95	32	3.1652.095
100	32	3.1652.100
105	32	3.1652.105
110	32	3.1652.110
115	32	3.1652.115
120	32	3.1652.120

St

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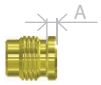
LOCKING ELEMENTS

CHARFIX system

Ster
Non Ster

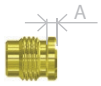
CHARFIX END CAP M10X1



A	
0	3.2104.300
+5	3.2104.305
+10	3.2104.310
+15	3.2104.315

St

CHARFIX END CAP M10x1



A	
2	3.2104.002

St

CHARFIX COMPRESSION SCREW M10X1

	3.2106.007

St

Stand for CHARFIX nail locking elements (set with a box without implants) 40.4686.200

III. INSTRUMENT SET

III.1. INTRODUCTION

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

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

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

	Name	Pcs.	Catalogue no.
	Targeter arm	1	40.5091.000
	Targeter 135	1	40.5097.000
	Distal targeter D	1	40.5093.000
	Connecting screw M10x1 L=55	1	40.5094.000
	Connecting screw M10x1 L=66	1	40.5095.000
	Compression screw	1	40.5096.000
	Nail length measure	1	40.5098.000
	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
	Set block 9/4.5	2	40.3616.000
	Trocar 6.5	1	40.3617.000
	Drill guide 6.5/4.5	1	40.3696.000
	Screw length measure	1	40.1374.000

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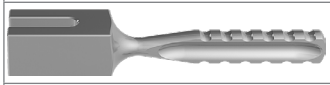
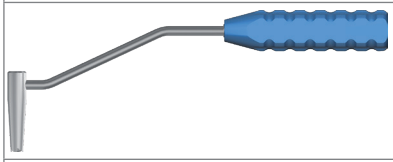
	Name	Pcs.	Catalogue no.
	Curved awl 8.0	1	40.5523.000
	Impactor-extractor	1	40.5507.000
	Mallet	1	40.3667.000
	Connector M10x1/M12	1	40.5071.000
	Wrench S10	1	40.5526.100
	Teflon pipe guide	1	40.1348.000
	Guide rod 3.0/580	1	40.3925.580
	Guide rod handle	1	40.1351.000
	Screwdriver S3.5	1	40.3604.000
	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 6.5/2/300	1	40.3674.000
	Cannulated screwdriver S5.0/2.2	1	40.3675.000
	Cannulated screw length measure	1	40.3676.000
	Aiming insert 9.0	2	40.5065.009
	Aiming insert 11.0	2	40.5065.011
	Screwdriver S3.5	1	40.5074.000
	Bolt guide	1	40.5075.000
	Drill 4.5/270	1	40.1387.001
	Targeter D	1	40.1344.000
	Drill guide short 7/3.5	1	40.1358.000
	Trocar short 7	1	40.1354.000
	Protective guide 11/9	1	40.3662.000

	Name	Pcs.	Catalogue no.
	Stand	1	40.5099.500

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IV. SURGICAL TECHNIQUE

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

IV.1.1. Introduction

Tightly fitting the medullary canal is not necessary if the locking nail is used. In case of placing the nail without reaming the canal the following diameters 8, 9, 10, 11 mm of the nail should be used. Nails with diameter 12, 13, 14 are used in the cases where reaming has to be done.
Please note, that the diameter of reamed canal has to be about 2mm wider than the diameter of the nail.
In every case, a hole is to be made in proximal part of the femur, 13 mm in diameter for the nails sizes 8, 9, 10, 11, 12, 13 mm or 14 mm in diameter for the nail 14 mm, and to 8 cm in depth.
It enables a free insertion of a thicker proximal part of the nail . Decision about possible reaming after verifying the shape of canal and type of fracture shall be made by the surgeon.

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

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

Placing patient on table with traction is integral part of the surgery.
Presented method of intramedullary osteosynthesis requires radiological examination.

Each surgical procedure must be carefully planned. X-Ray of the entire femur is essential as to make sure no injuries in its proximal or distal part are overlooked.
It is especially important in cases of nailing the pathological subtrochanteric fractures. Special attention is to be paid to concurrent femoral neck fractures or proximal epiphysis multi-fragmental fractures, and to the possibility of theirs occurrence during the procedure of nail insertion. During the operation secondary fractures of main fragments may occur.
In such cases the dynamic stabilization has to be replaced by a static one.
The condition of the hip joint is also very important. In advanced arthrosis or contracture fixation may be difficult or even impossible to perform.
In addition, it should be verify whether alloplasty of hip or knee has ever been performed on the fractured bone. The procedure has to be carried out on the operating table with traction with the patient placed supine or on the side. The side position enables the approach to the greater trochanter, which is especially important with overweight patients.
The supine position provides less favorable access to the grater trochanter, but makes all other stages of the operation considerably easier *(especially rotary corrections)*.

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

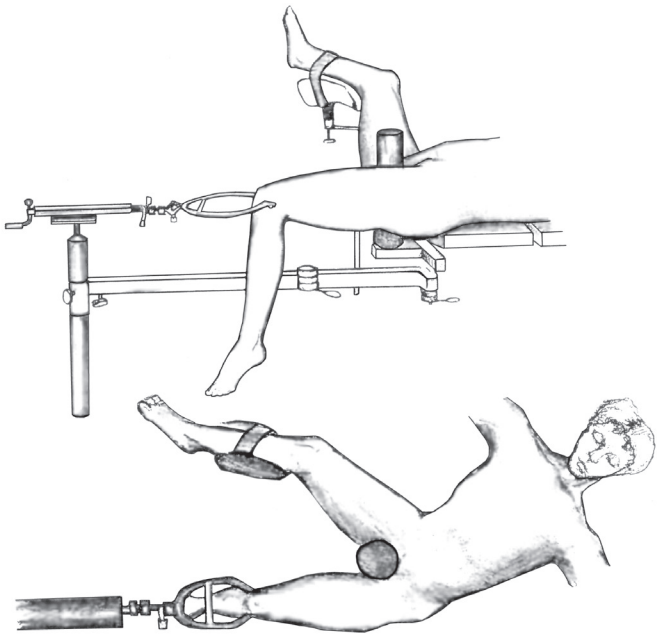
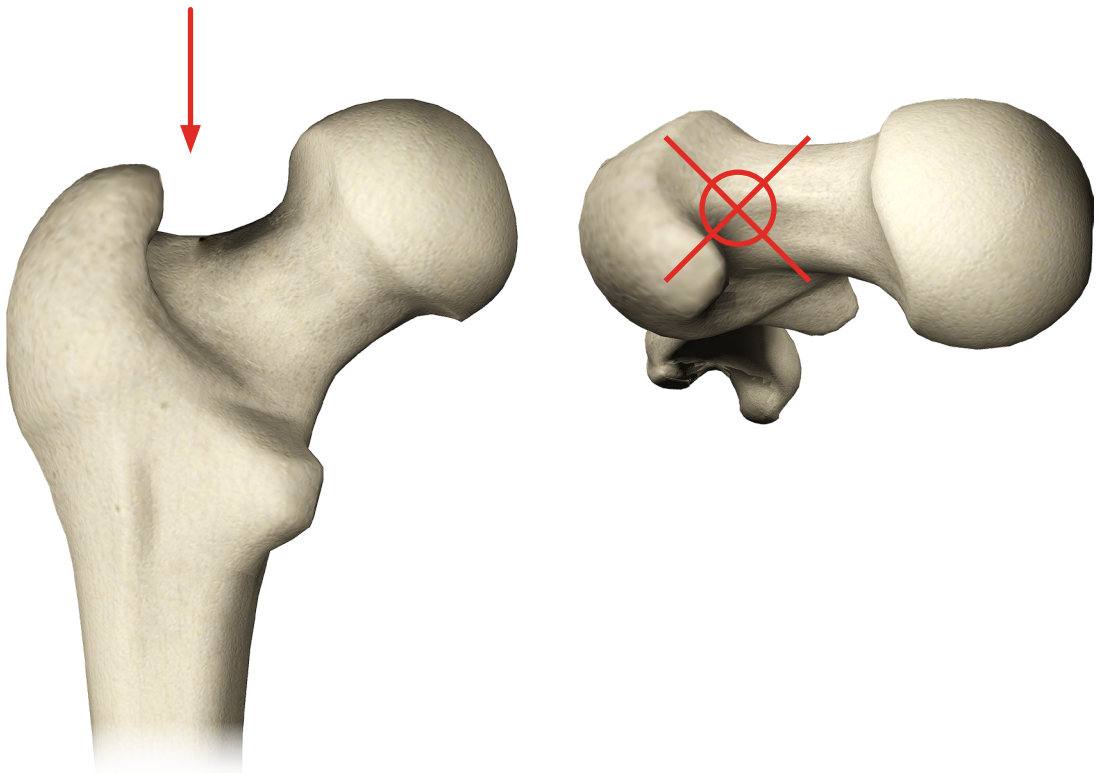


FIG. 1. Supine position for intramedullary osteosynthesis of femur.

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

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

FIG. 2 Entry point for femoral nail.



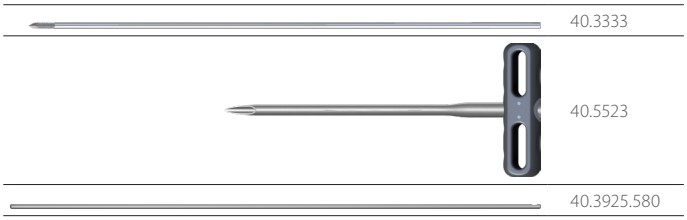
ATTENTION! The following paragraphs describe most important steps during insertion of intramedullary interlocking femoral nails nevertheless it is not a detailed instructions for use. The surgeon decides about choosing the surgical technique and its application in each individual case.

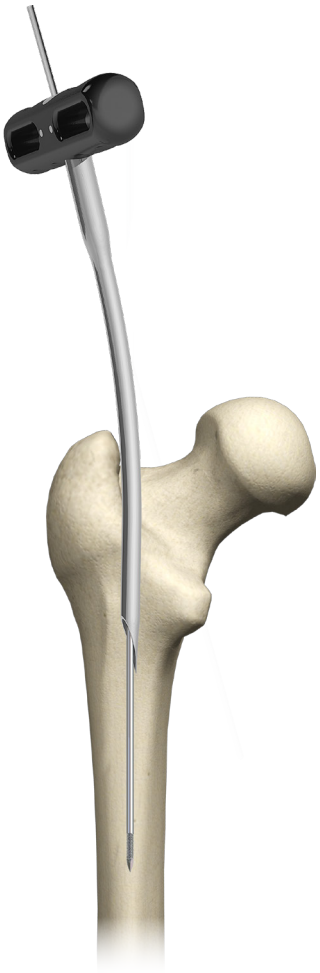
The physician uses images of both fractured and healthy femur to determine the length, type and diameter of the nail

.

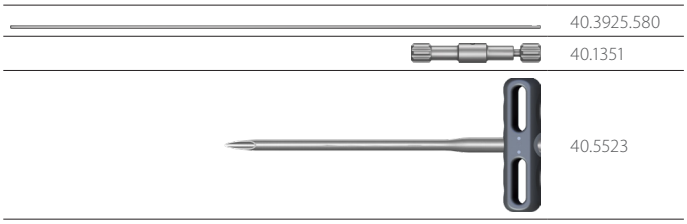
IV.1.2. Preparation of medullary canal and nail insertion.

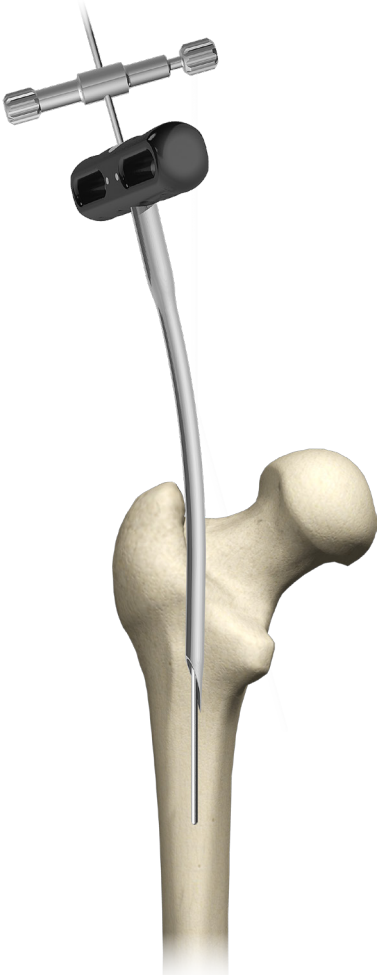
1 Using Kirschner wire 2.0/380 **[40.3333]**, insert into the medullary canal Curved awl 8.0 **[40.5523]** to the depth at which the Awl blade goes along the medullary canal, allowing proper insertion of Guide rod 3.0/580 **[40.3925.580]**.
Having opened the medullary canal, remove Kirschner wire 2.0/380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





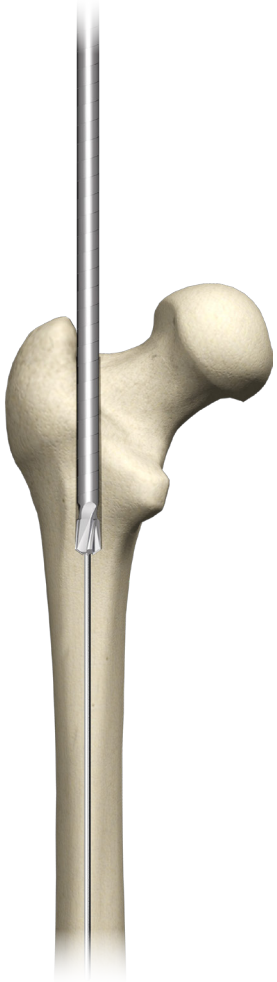
2 Mount Guide rod 3.0/580 **[40.3925.580]** to Guide rod handle **[40.1351]** and enter the guide into the medullary canal through Curved awl 8.0 **[40.5523]** cannulated hole to the depth required for the proper fixation of bone fragments. While guide rod insertion, control the fracture reduction and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





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

Remove the Flexible Reamer.



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

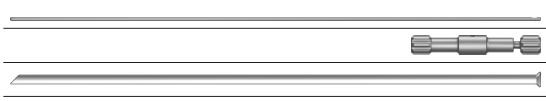
4 When using a guide wire which is not included in the instrument set provided, replace it with a guide wire **[40.3925.580]**. Insert the Teflon Pipe Guide **[40.1348]** onto the flexible reamer guide until it reaches the end of medullary canal in distal femur.

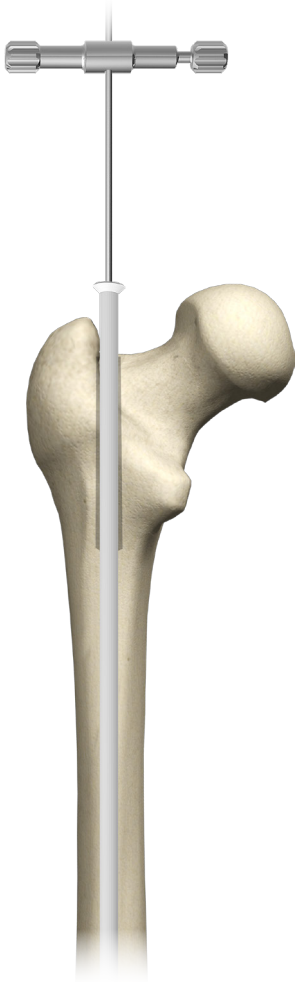
Remove the Flexible Reamer Guide.

	40.3925.580
	40.1348

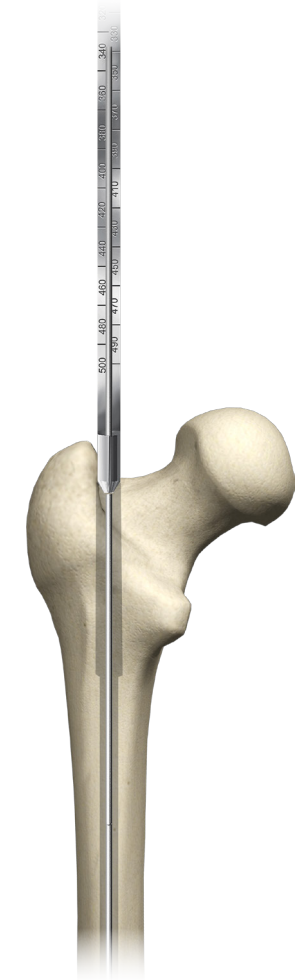
5 Mount the Guide rod handle **[40.1351]** on the Guide Rod 3.0/580 **[40.3925]** and advance into the Teflon Pipe Guide until its tip reaches the distal epiphysis.

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



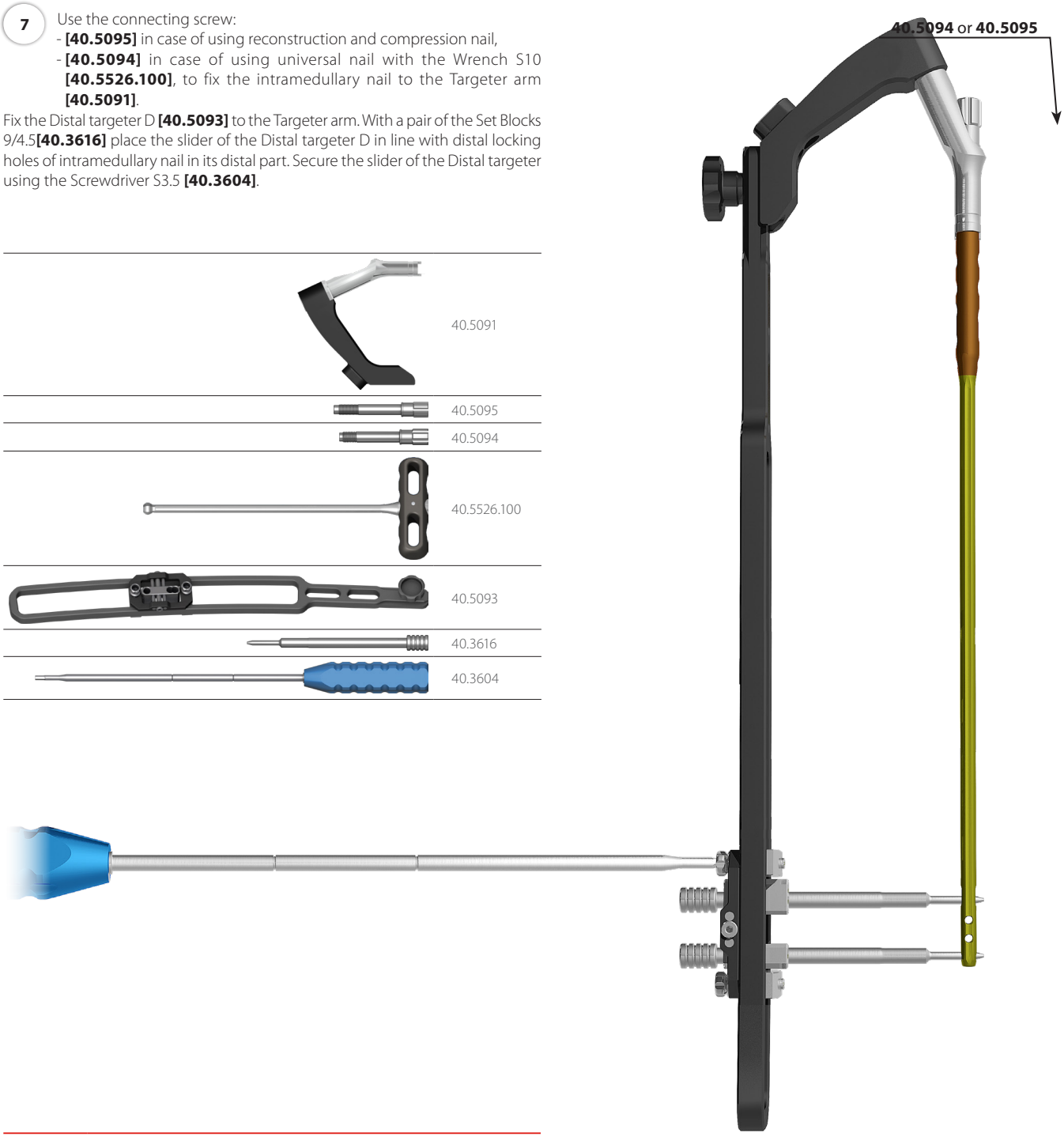


6 Insert the Nail Length Measure **[40.5098]** via the Guide Rod until it rests on the bone. Read the length on the nail measure to asses the length of intramedullary nail. Remove the Nail Length Measure from the Guide Rod. In case of using the solid nail, remove the Guide Rod. Medullary canal is ready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



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

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

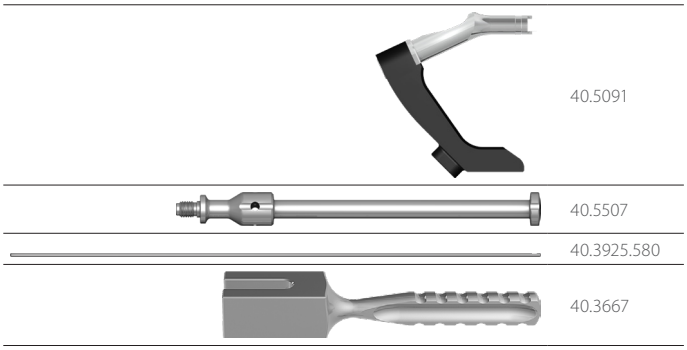


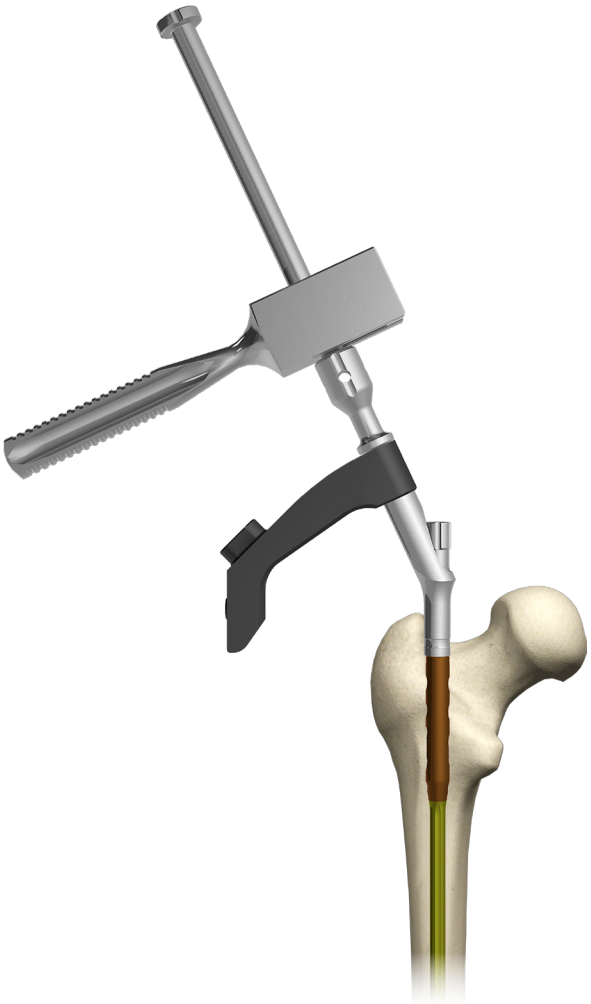
CHECK:
Properly set and secured slider of the Distal targeter D makes it possible to set the Set Blocks 9/4.5 into the holes of the nail easily.

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

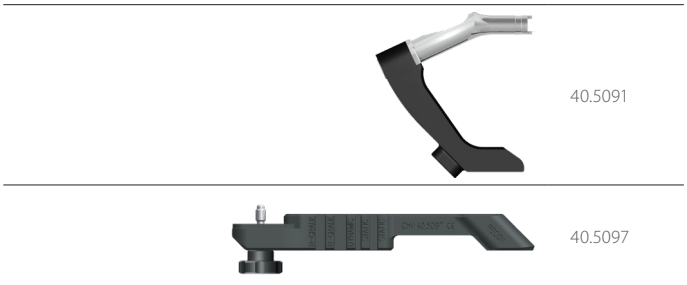
8 Mount the Impactor-Extractor **[40.5507]** on the Targeter arm **[40.5091]** with fixed nail. Insert the nail onto the Guide Rod 3.0/580 **[40.3925]** in medullary canal. Advance the nail by pushing and maneuvering it until it reaches adequate depth.

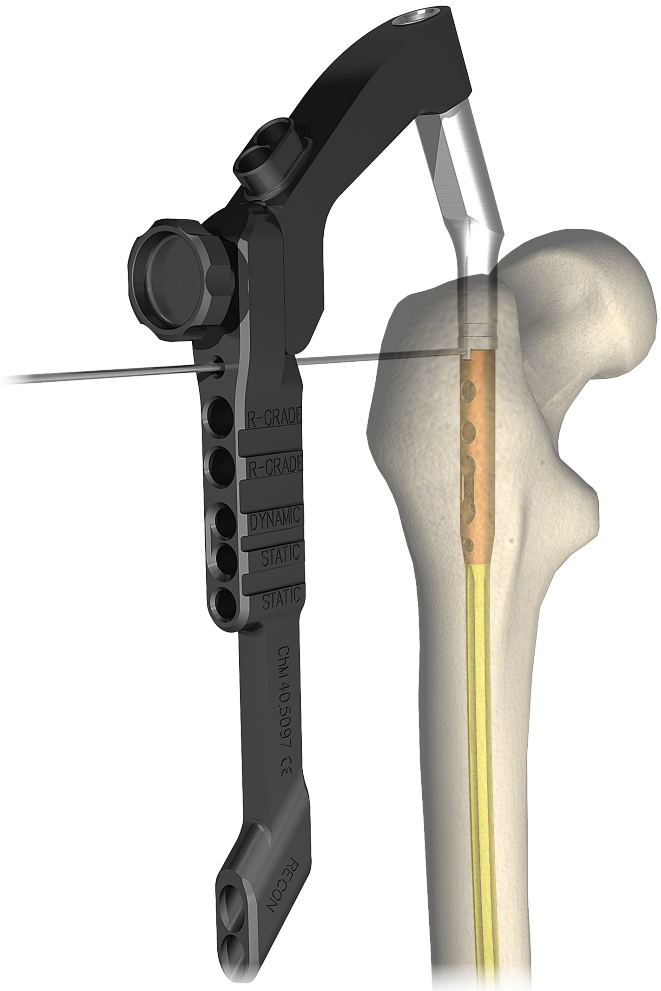
Remove the Guide Rod 3.0/580 [40.3925].
Dismount the Impactor-Extractor **[40.5507]** from the Targeter arm.





8a Mount the Targeter 135 **[40.5097]** on the Targeter arm **[40.5091]**.
Use Kirschner wire inserted in the hole of the Targeter 135 **[40.5097]** *(marked "0")* to verify correct placement of the nail. The end of the wire shows the beginning of the nail.





IV.2. RECONSTRUCTION METHOD

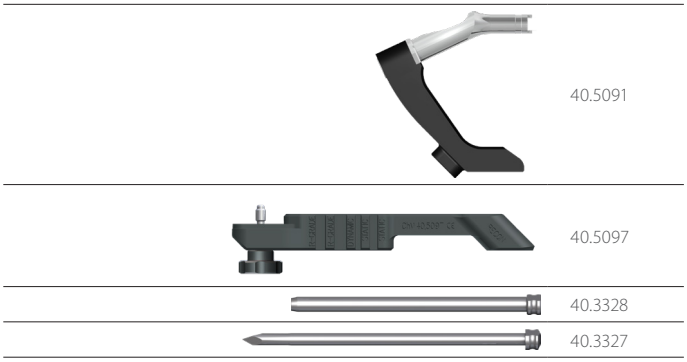
IV.2.1. Proximal locking of nail

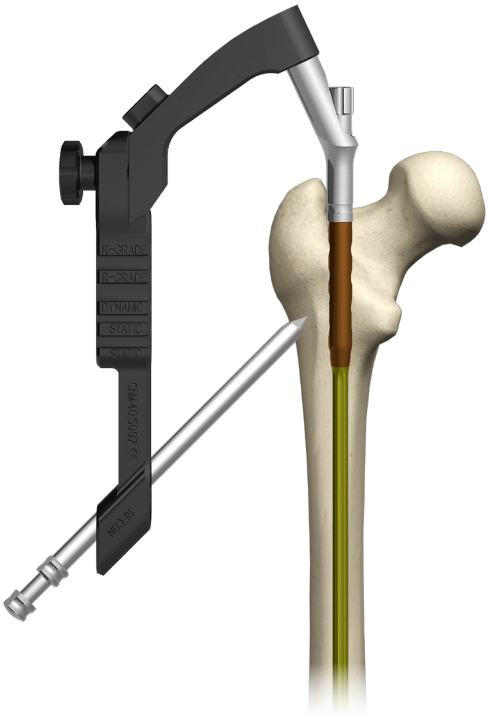
IV.2.1.A. OPTION I: Locking with reconstruction screws

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

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

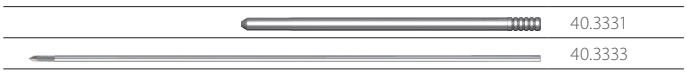
Remove the Trocar.
Leave the Protective Guide in the hole.

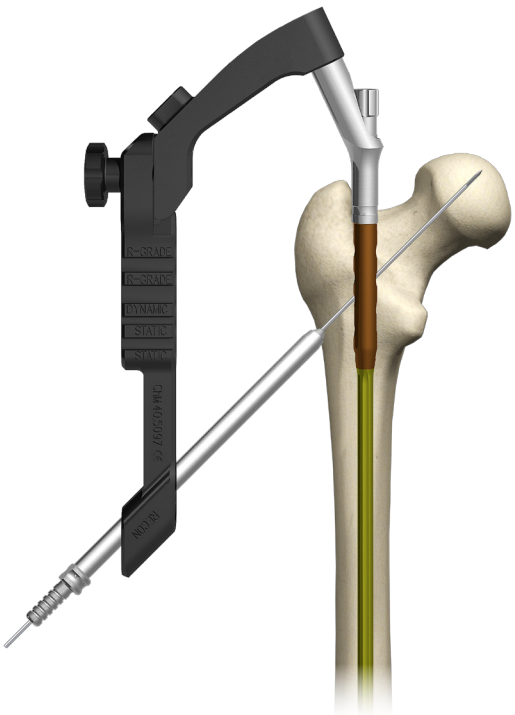




10 Insert Kirschner Guide **[40.3331]** into the Protective Guide. Mount Kirschner wire 2.0/380 **[40.3333]** on the surgical drive and place KW into the femoral neck but do not perforate the femoral head. The above steps should be controlled with X-Ray *(image in the drawing plane)*. Verify the position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

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





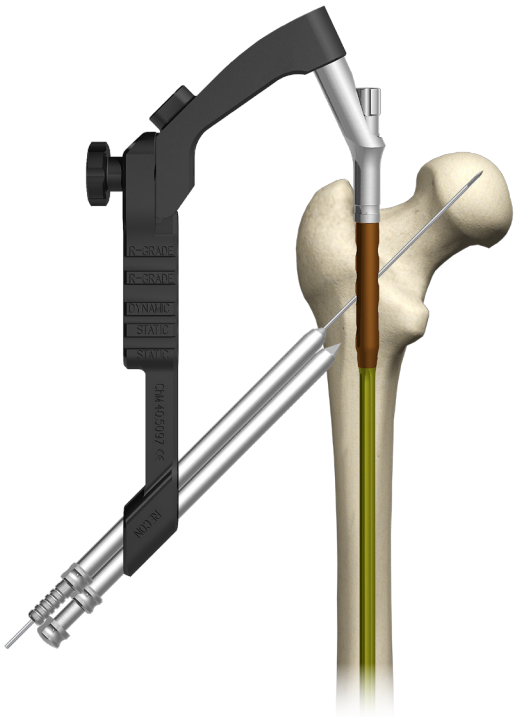
11 Insert the Protective Guide 11/9 **[40.3328]** with the Trocar 9 **[40.3327]** into the second hole in the Targeter 135 **[40.5097]**. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it touches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

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


40.5097


40.3328


40.3327



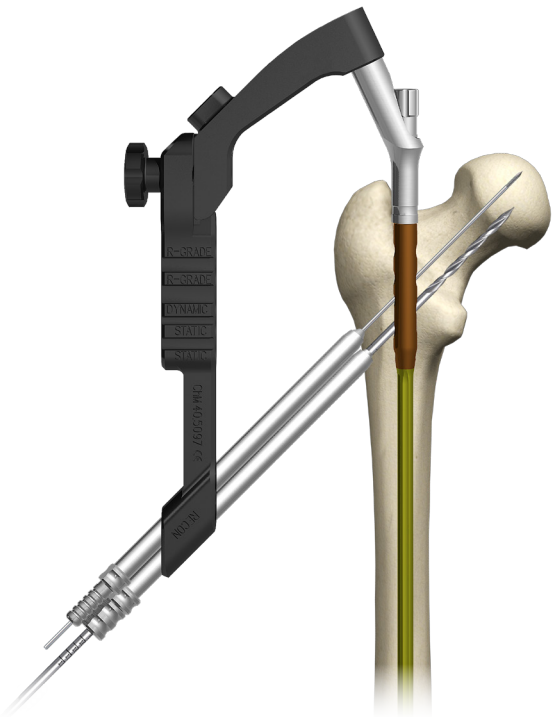
12 Insert the Drill Guide 9/4.5 **[40.3330]** *(with two grooves on the handle)* into the Protective Guide 11/9 **[40.3328]** into the second hole of the targeter. Mount the Drill With Scale 4.5/370 **[40.5333.001]** on the surgical drive and advance it through the drill guide.
Drill the hole in the femoral neck *(through the proximal hole in the nail)* until it reaches adequate depth, but do not perforate the head. The scale on the Drill shows length of the locking element. Control the drilling process with the X-Ray image intensifier.

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


40.3328


40.3330

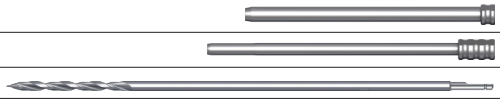

40.5333.001

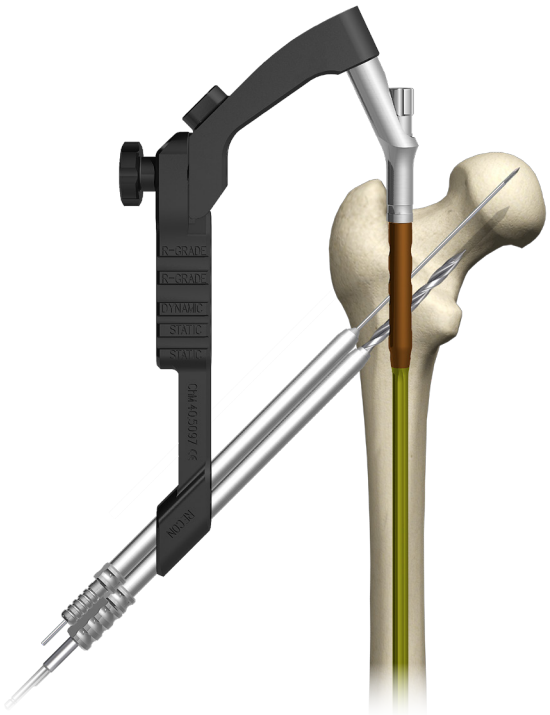


13 Insert the Drill Guide 9/6.5 **[40.3329]** *(with three grooves)* into the Protective Guide 11/9 **[40.3328]**. Mount the Drill 6.5/370 **[40.2068.371]** on the surgical drive and advance it through the drill guide. Ream the hole in the femoral neck for the depth lesser approx. 30mm than before drilled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

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

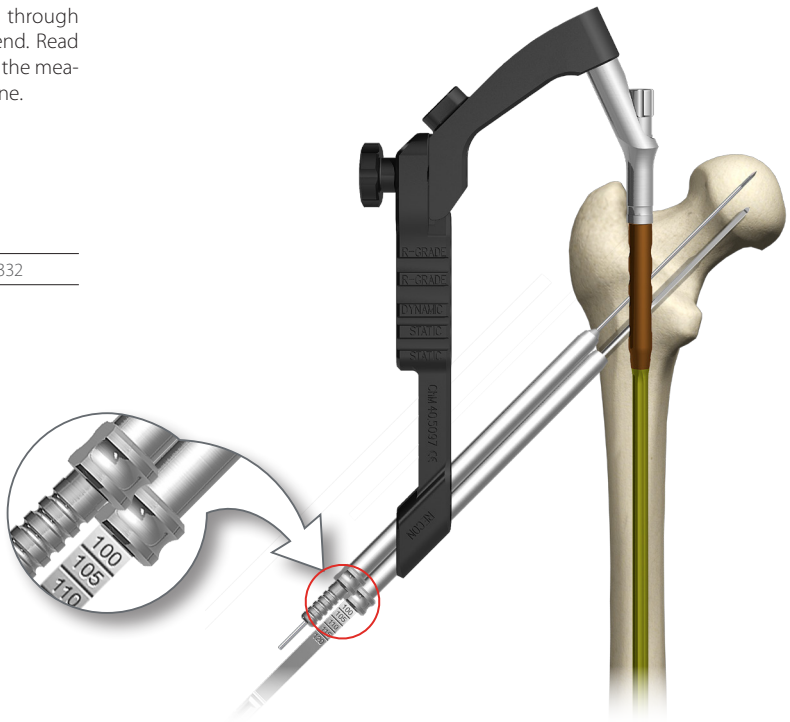
Remove the Drill and the Drill Guide.
Leave the Protective Guide in the hole of targeter.





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

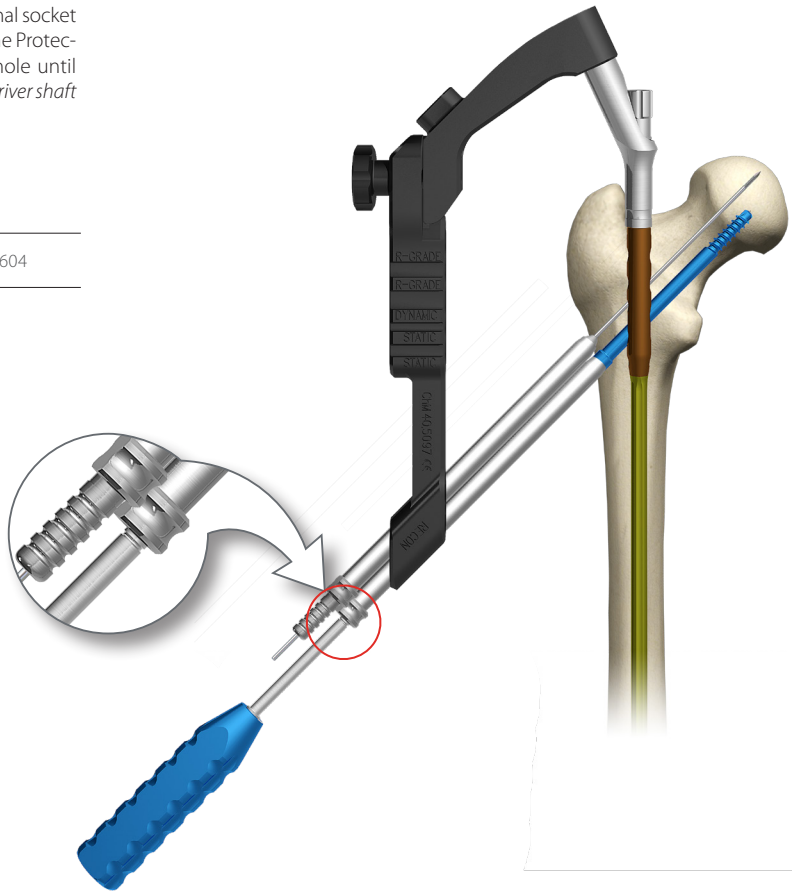
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of targeter.



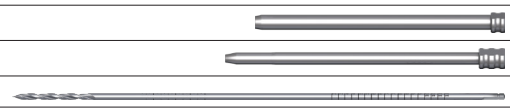
15 Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected reconstruction screw. Then advance both into the Protective Guide. Insert the reconstruction screw in the prepared hole until the head of the screw reaches the cortex bone *(the groove on the screwdriver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

Remove the Screwdriver.


40.3604

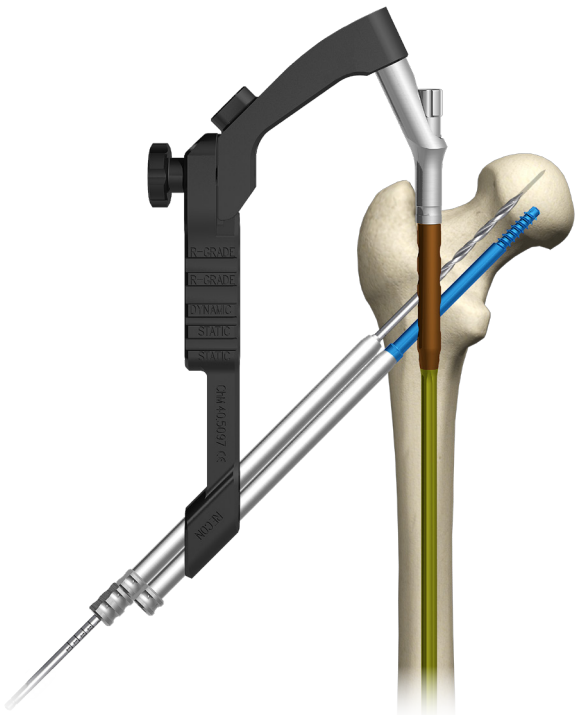


16 Remove Kirschner wire and Kirschner Guide from the Protective Guide 11/9 **[40.3328]**. Insert the Drill Guide 9/4.5 **[40.3330]** *(with two grooves on the handle)* into the Protective Guide 11/9 **[40.3328]** *(with one groove)* left in hole of the targeter. Mount the Drill With Scale 4.5/370 **[40.5333.001]**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


40.3328
40.3330
40.5333.001

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

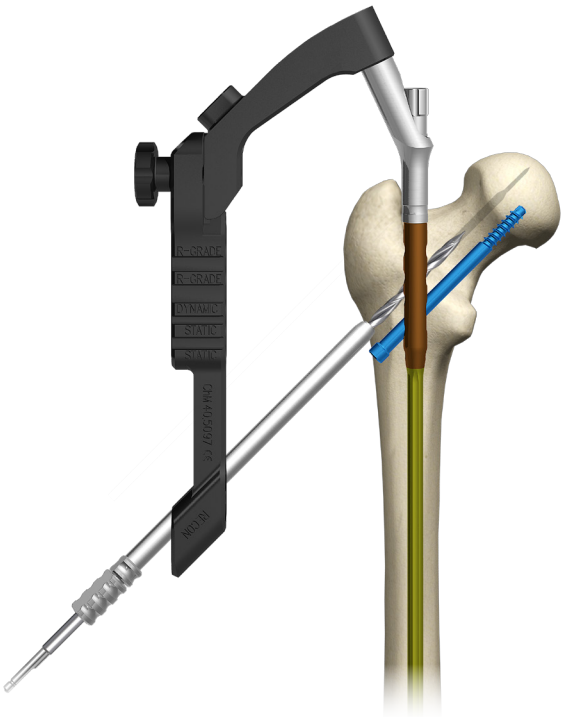
Remove the Drill and the Drill Guide.
Leave the Protective Guide in the hole of targeter.



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

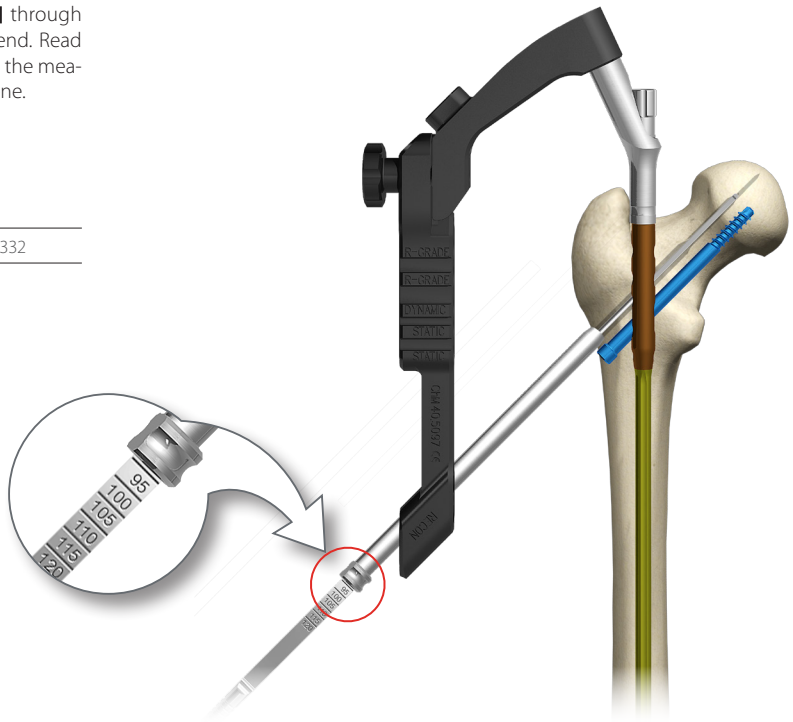
Control the drilling process with the X-Ray image intensifier.

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



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

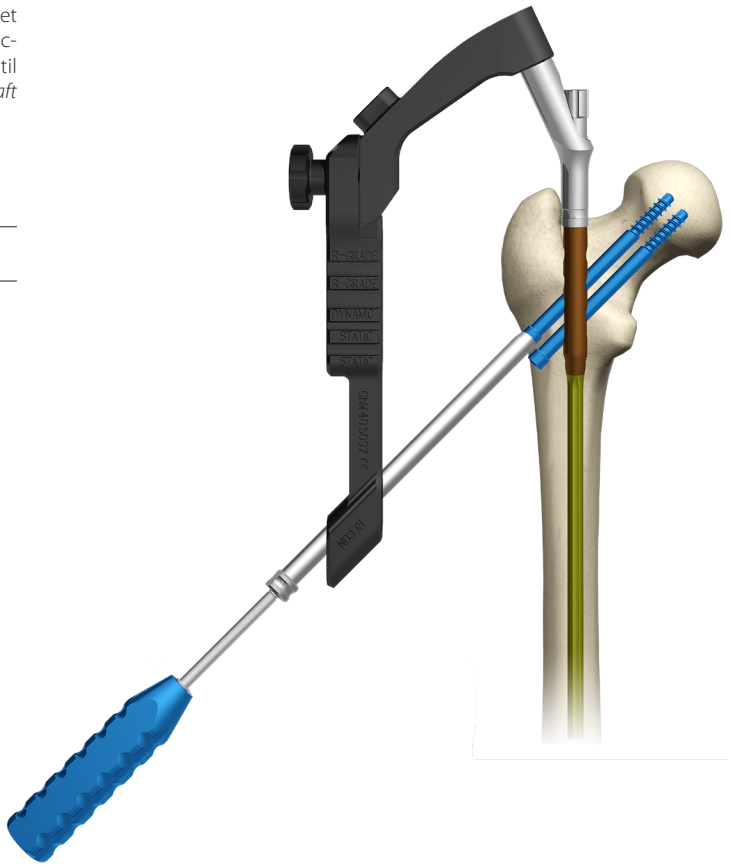
Remove the Screw Length Gauge.
Leave the Protective Guide in the hole of targeter.



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

Remove the Screwdriver S3.5 and Protective Guide.


40.3604



IV.2.1.A. OPTION II: Locking with reconstruction cannulated screws

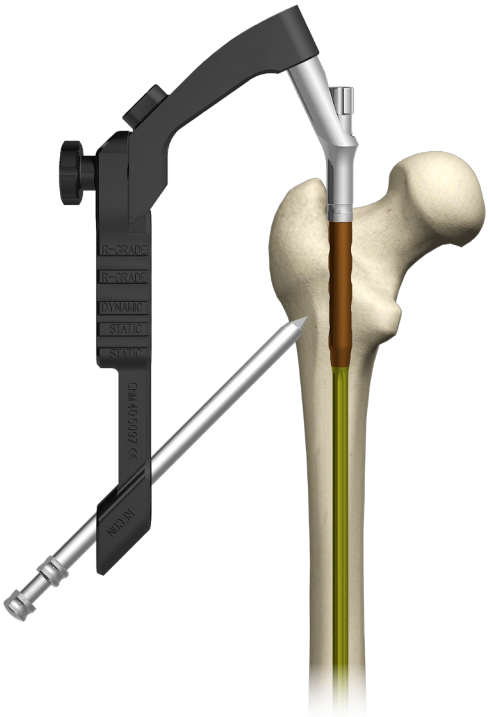
20 Insert the Protective Guide 11/9 **[40.3328]** with the Trocar 9 **[40.3327]** into the first proximal hole in the Targeter 135 **[40.5097]**. Mark the entry point for the trocar and make the adequate incision of the soft tissues. Advance the Trocar until it reaches the cortex bone and mark the entry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

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


40.5097


40.3328


40.3327



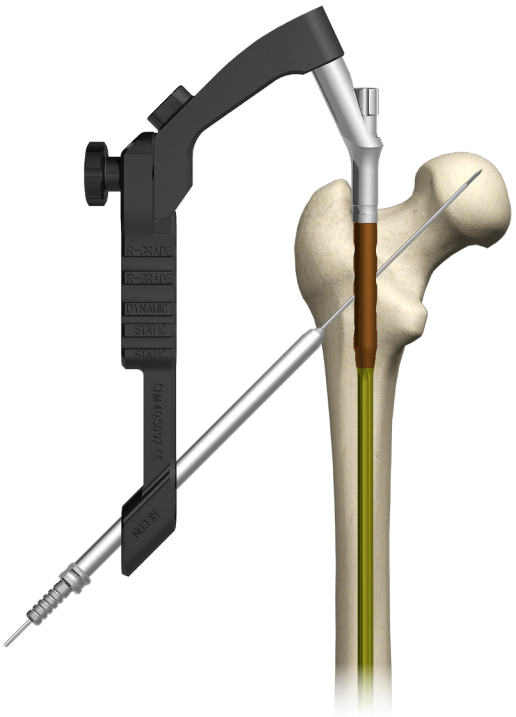
21 Insert Kirschner Guide **[40.3331]** and Kirschner Wire 2.0/380 **[40.3333]** into the Protective Guide 11/9 **[40.3328]**. Mount KW in the surgical drive and advance into the femoral neck but do not to perforate the femoral head. The above step should be controlled with X-Ray *(image in the drawing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

Remove Kirschner guide.
Leave Kirschner wire.


40.3328

40.3331

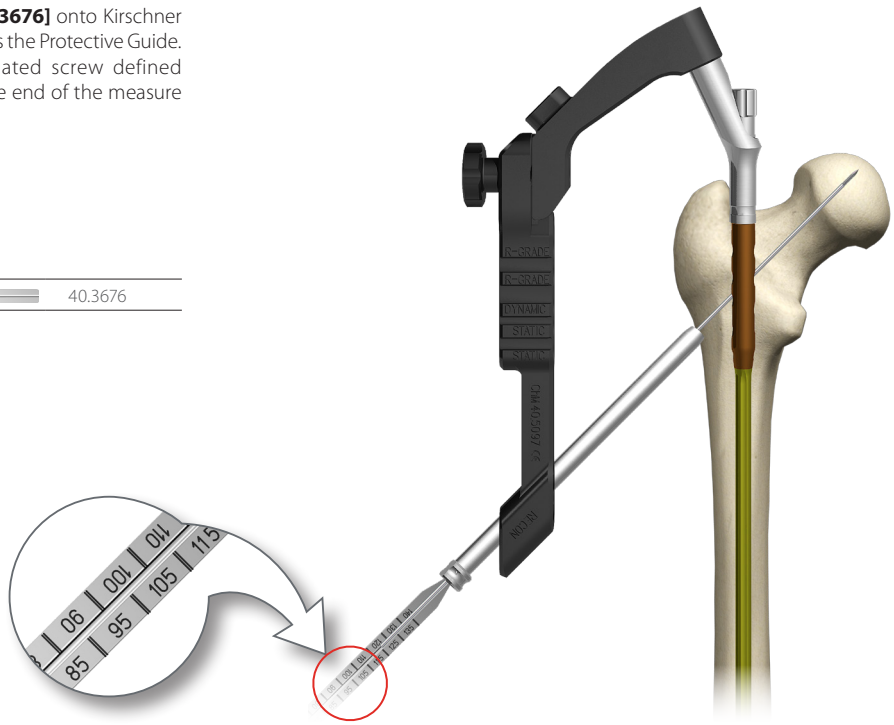
40.3333



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

Remove the Cannulated screw length measure.
Leave Kirschner wire.

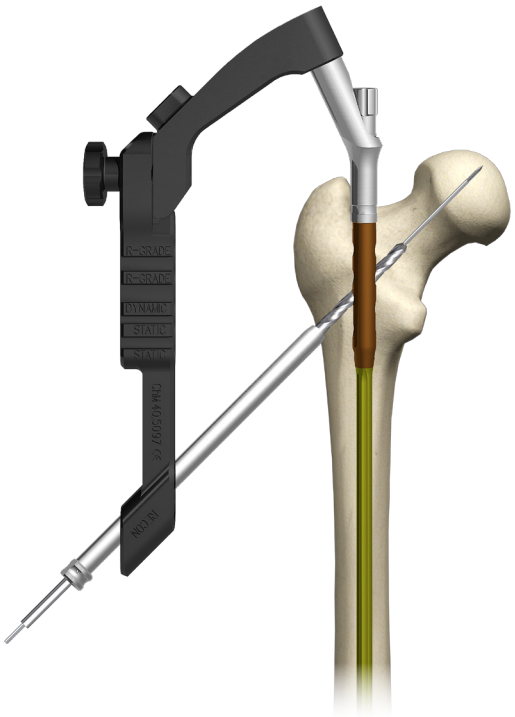
40.3676



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

Remove the Cannulated Drill.
Leave Kirschner Wire.


40.3674

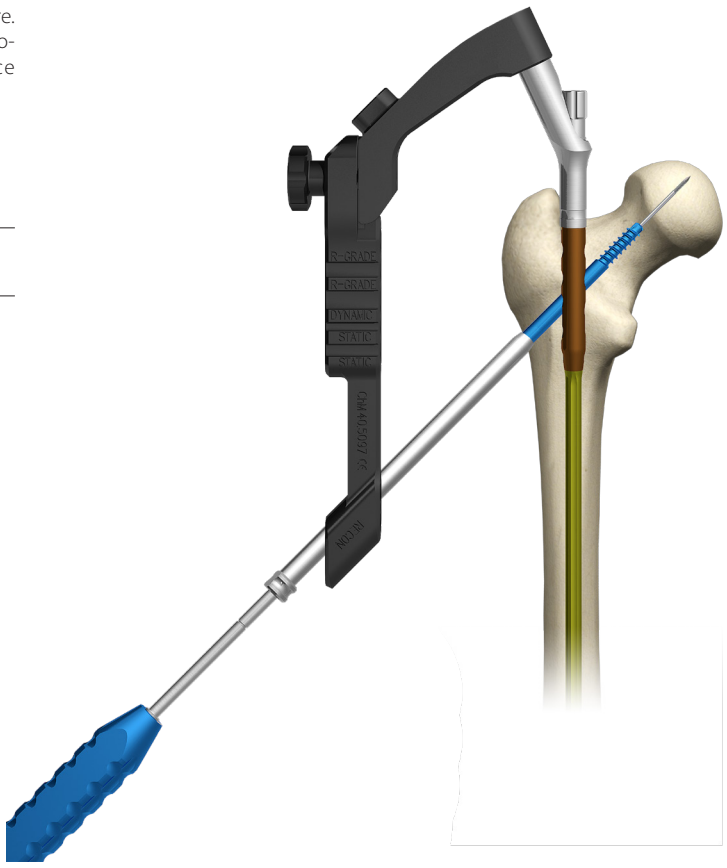


24 Insert the selected reconstruction cannulated screw onto Kirschner wire. Advance the Cannulated Screwdriver **[40.3675]** onto Kirschner wire going through the proximal hole of the nail and advance the reconstruction cannulated screw until its head reaches cortex bone.

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


40.3675

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



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

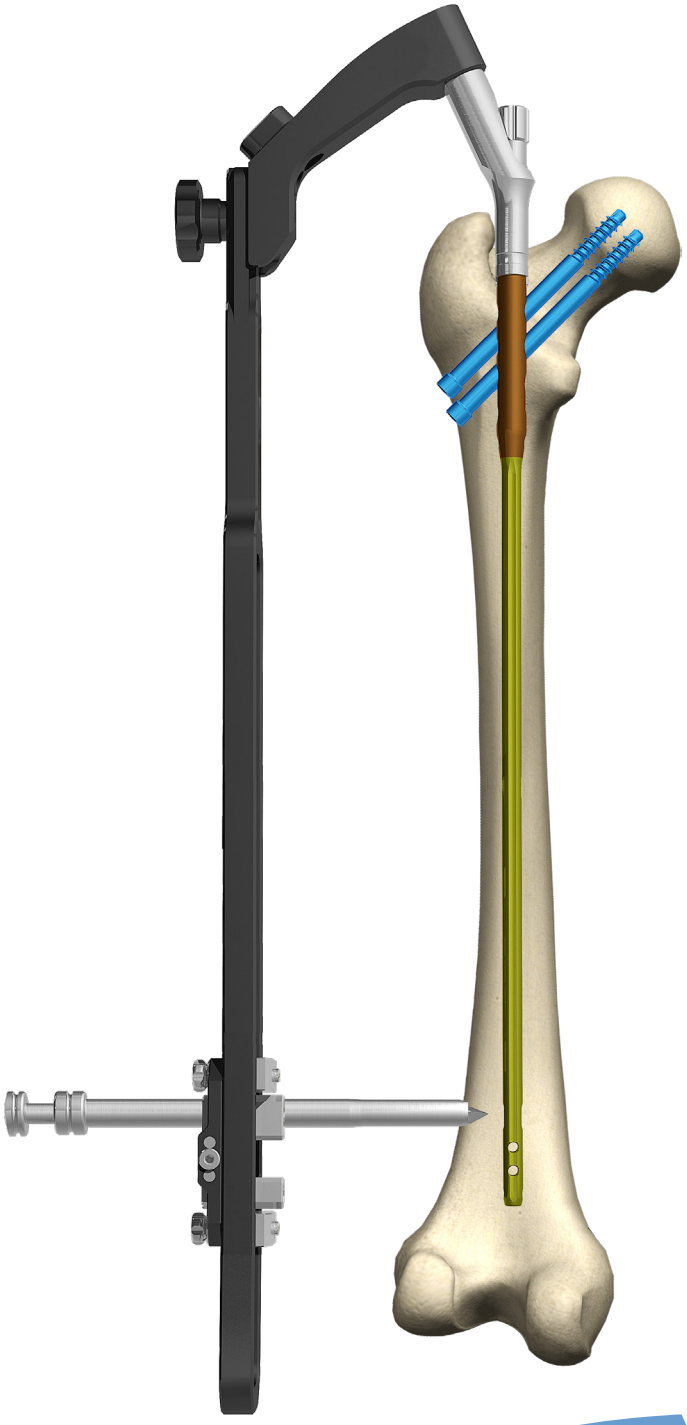
IV.2.2. Distal locking of the nail

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

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

40.5091

40.5093



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

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

40.3614

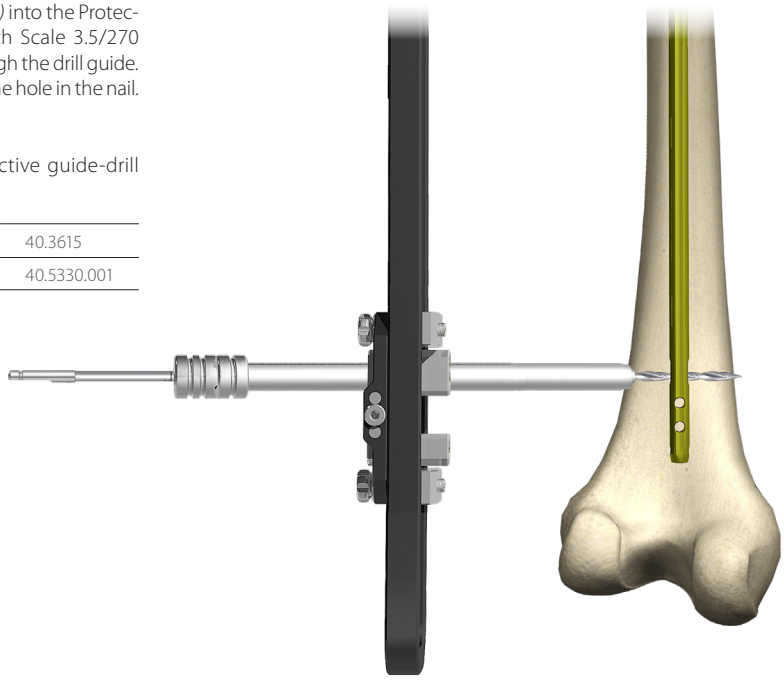
40.3617

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

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


40.3615

40.5330.001

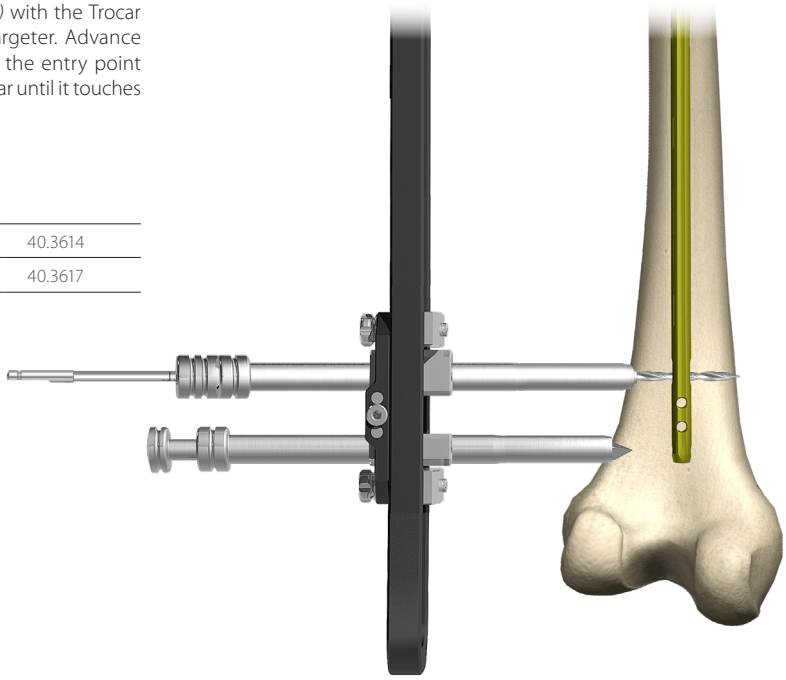


27 Insert the Protective Guide **[40.3614]** *(with one groove)* with the Trocar 6.5 **[40.3617]** into the second slider hole of distal targeter. Advance the Trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar until it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

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


40.3614


40.3617



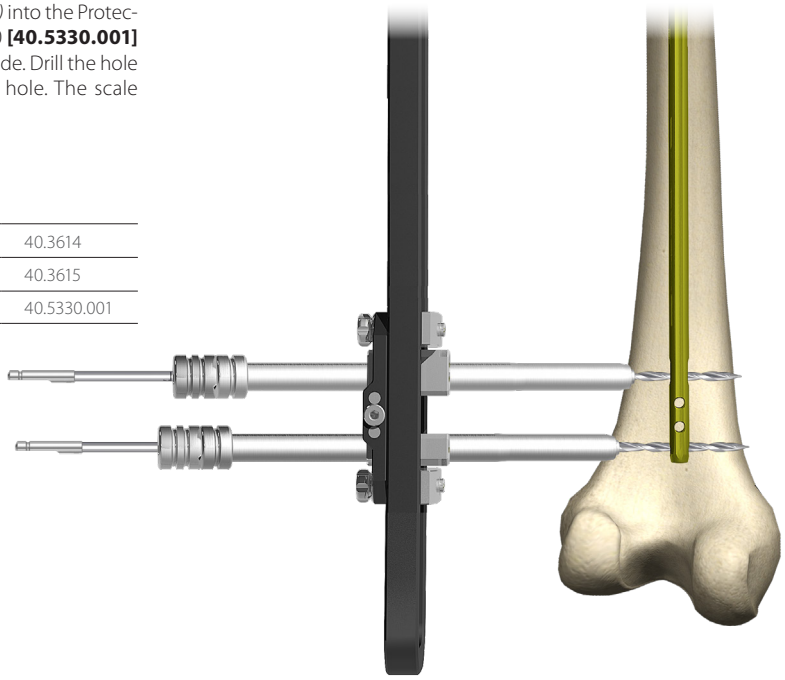
28 Insert the Drill Guide 6.5/3.5 **[40.3615]** *(with two grooves)* into the Protective Guide **[40.3614]**. Mount the Drill With Scale 3.5/270 **[40.5330.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femoral shaft through both cortex layers and the nail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

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


40.3614


40.3615

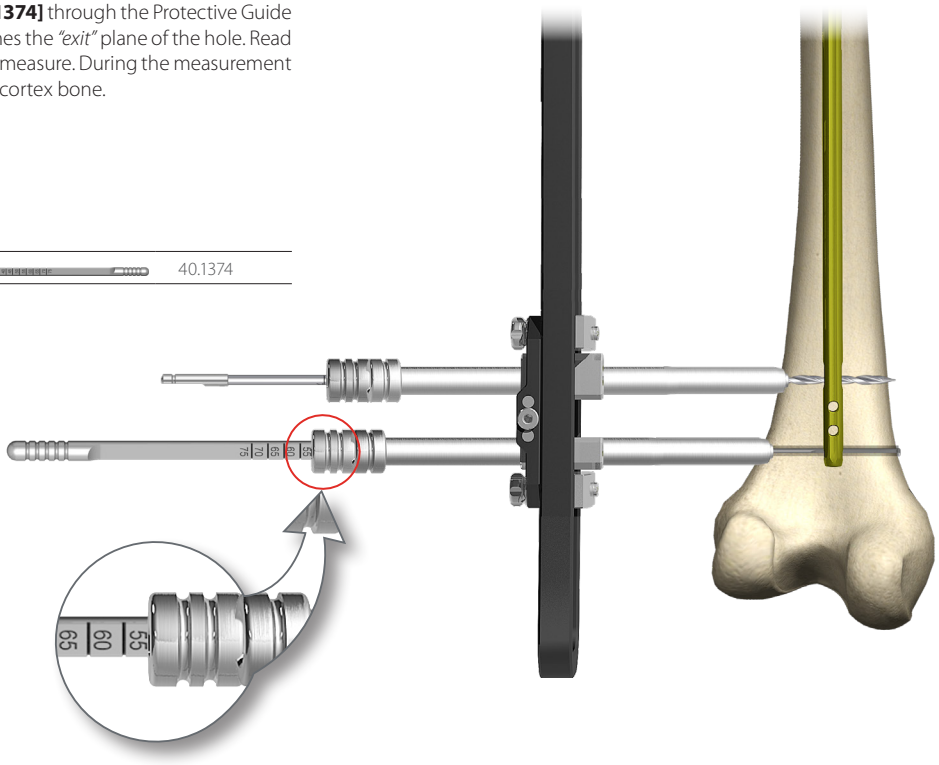

40.5330.001



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

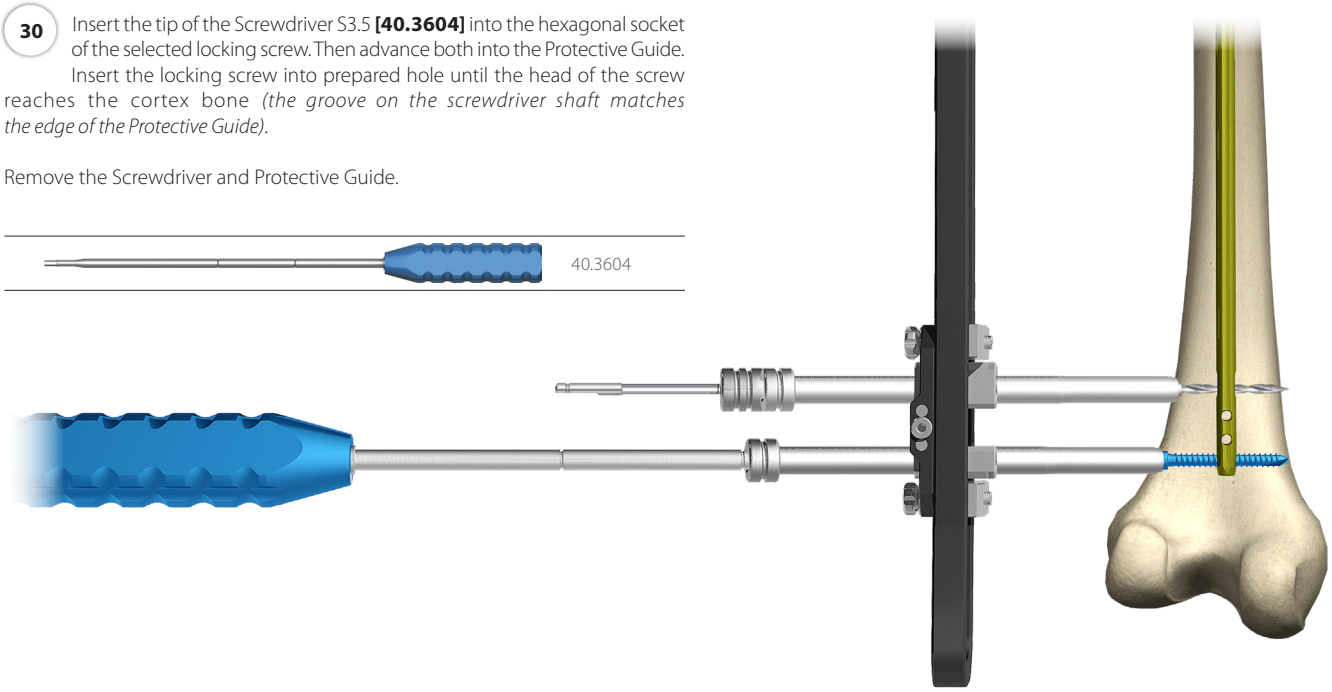
Remove the Screw Length Measure.
Leave the Protective Guide in place.


40.1374



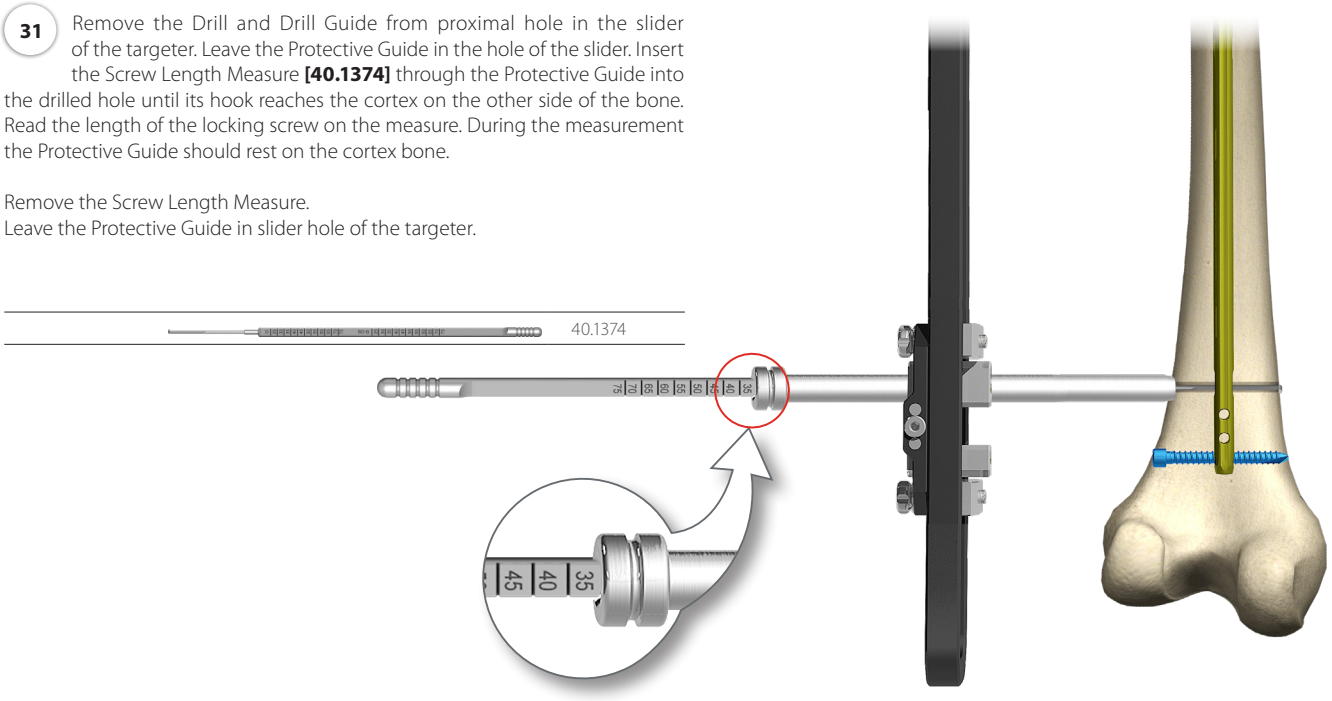
30 Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw into prepared hole until the head of the screw reaches the cortex bone *(the groove on the screwdriver shaft matches the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

Remove the Screwdriver and Protective Guide.



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

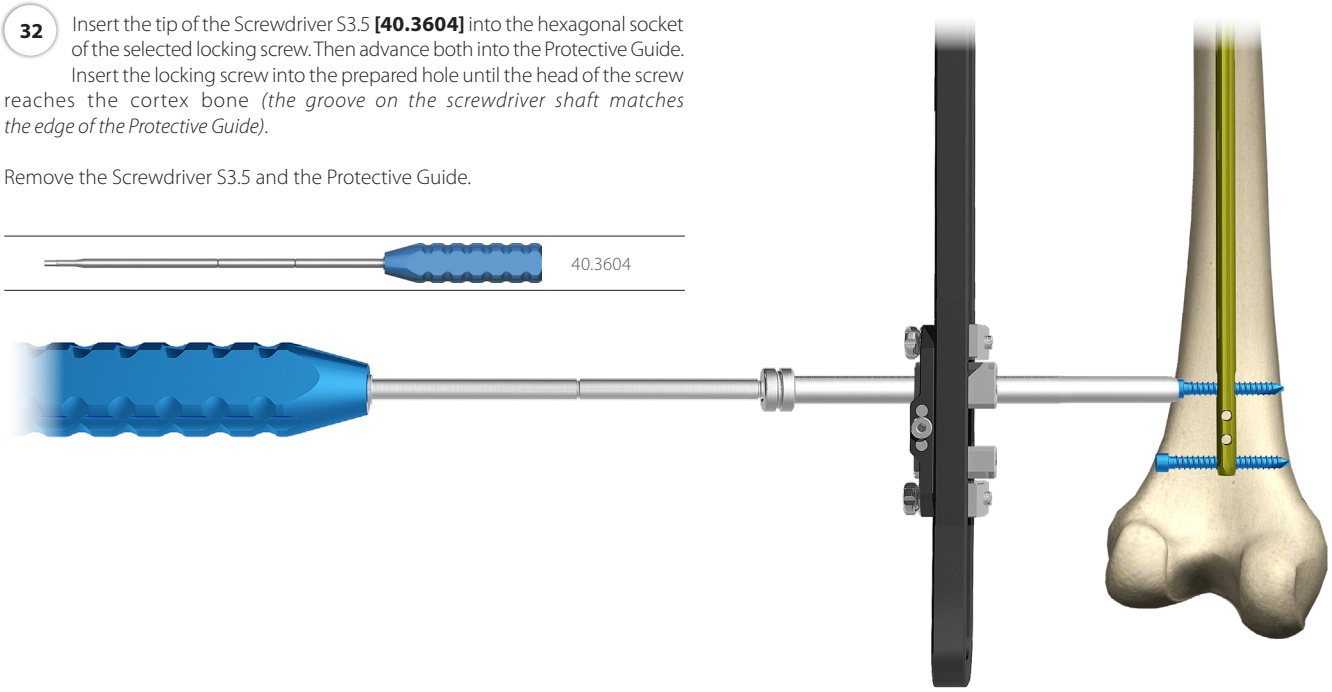
Remove the Screw Length Measure.
Leave the Protective Guide in slider hole of the targeter.



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

Remove the Screwdriver S3.5 and the Protective Guide.

40.3604



IV.2.3. Targeter removal, placing end cap

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

40.5526.100

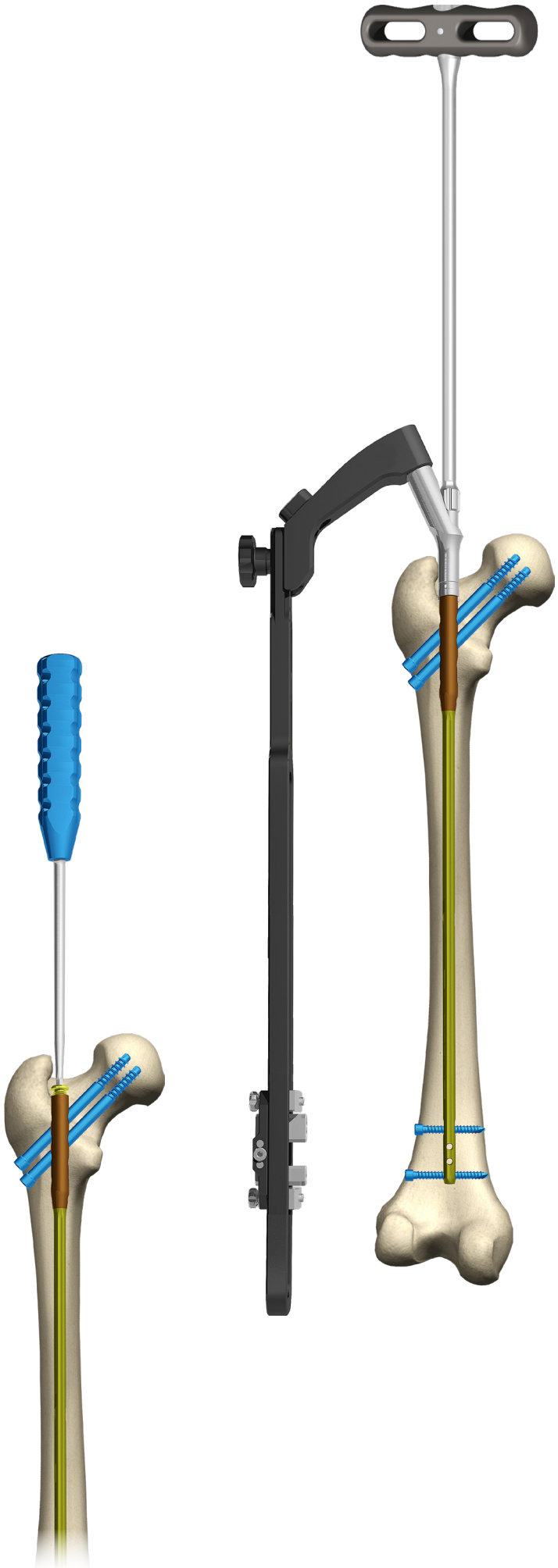
40.5094

40.5095

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

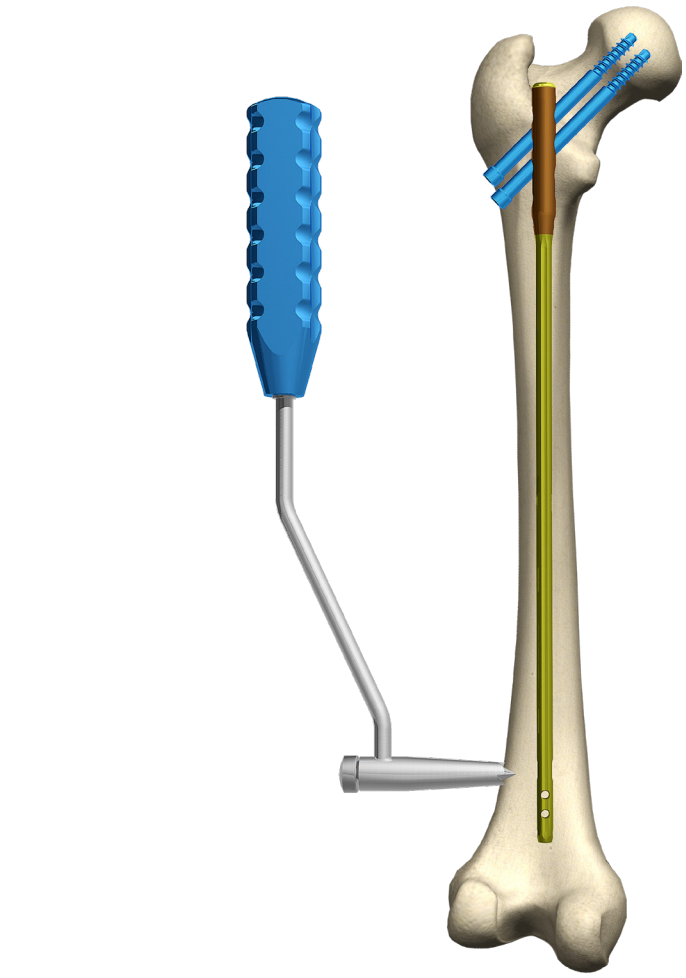
- the End Cap **[1.2104.3xx]** or **[3.2104.3xx]** in the case of using universal nail.
- the End Cap **[1.2104.4xx]** or **[3.2104.4xx]** in the case of using reconstruction nail.

40.3675



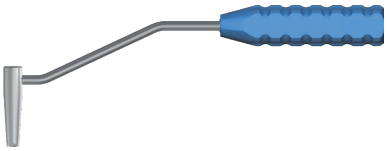
IV.2.4. Distal locking of the nail "freehand technique"

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



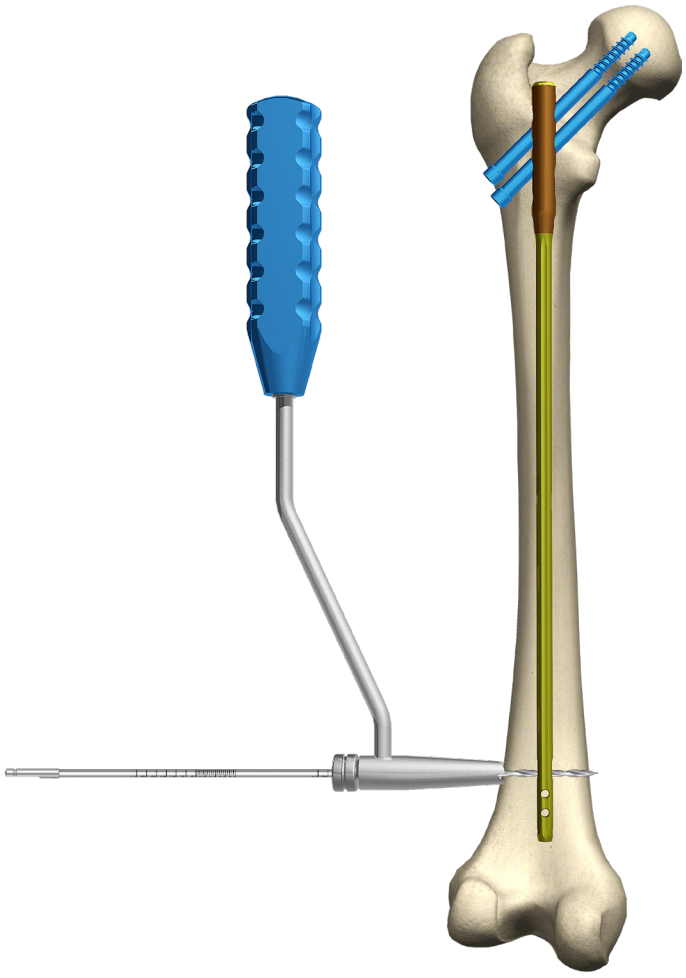
35 Using X-Ray place the Targeter D **[40.1344]** in the line with the nail hole. The centers of the holes in the targeter and nail have to match. The teeth of the Targeter D have to be merged in the cortex. Insert the Short Trocar 7 **[40.1354]** into the hole in targeter, then advance until it reaches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

Remove the Trocar.
Leave the Targeter D.



40.1344

40.1354



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

Remove the Drill and Drill Guide.
Leave the Targeter.

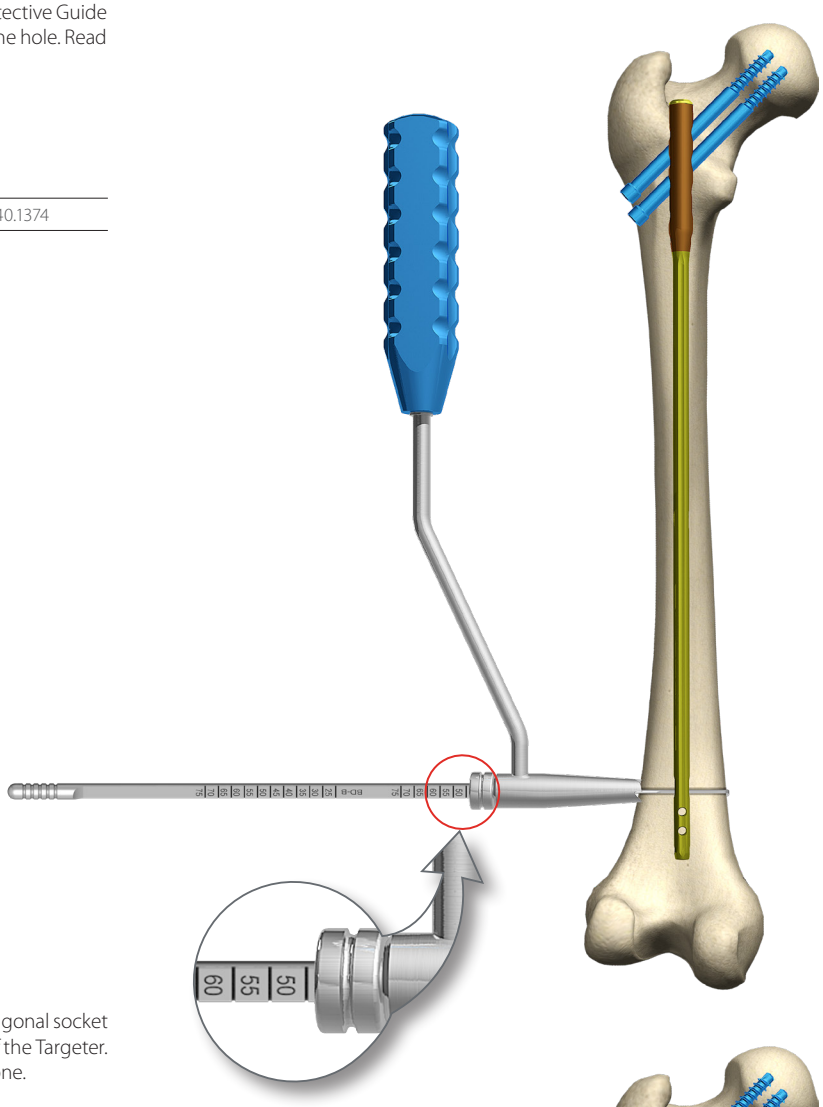
40.1358

40.5330.001

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

Remove the Screw Length Measure.
Leave the Targeter.

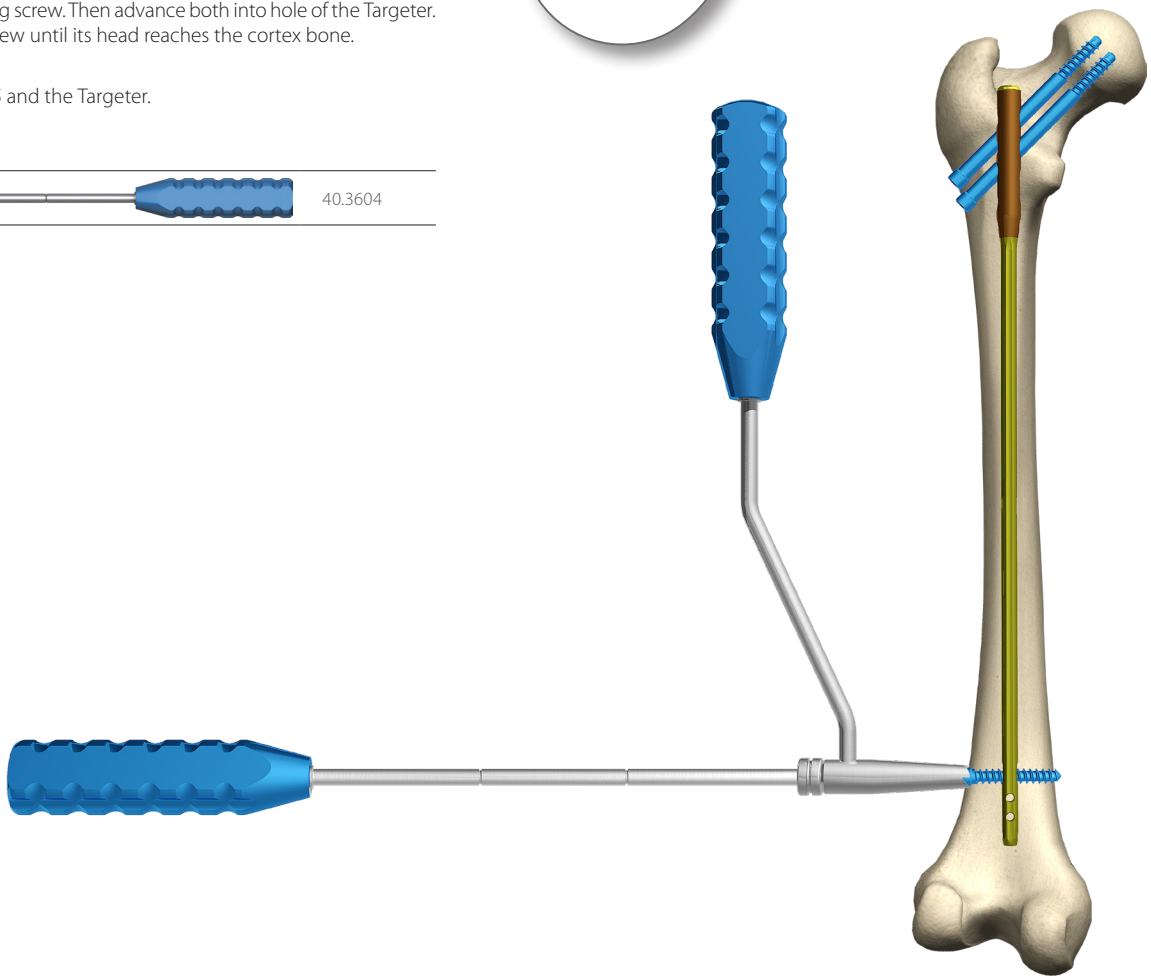
40.1374



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

Remove the Screwdriver S3.5 and the Targeter.

40.3604



IV.3. DYNAMIC AND COMPRESSION METHODS

IV.3.1. Distal locking of the nail

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

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

40.5091

40.5093

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

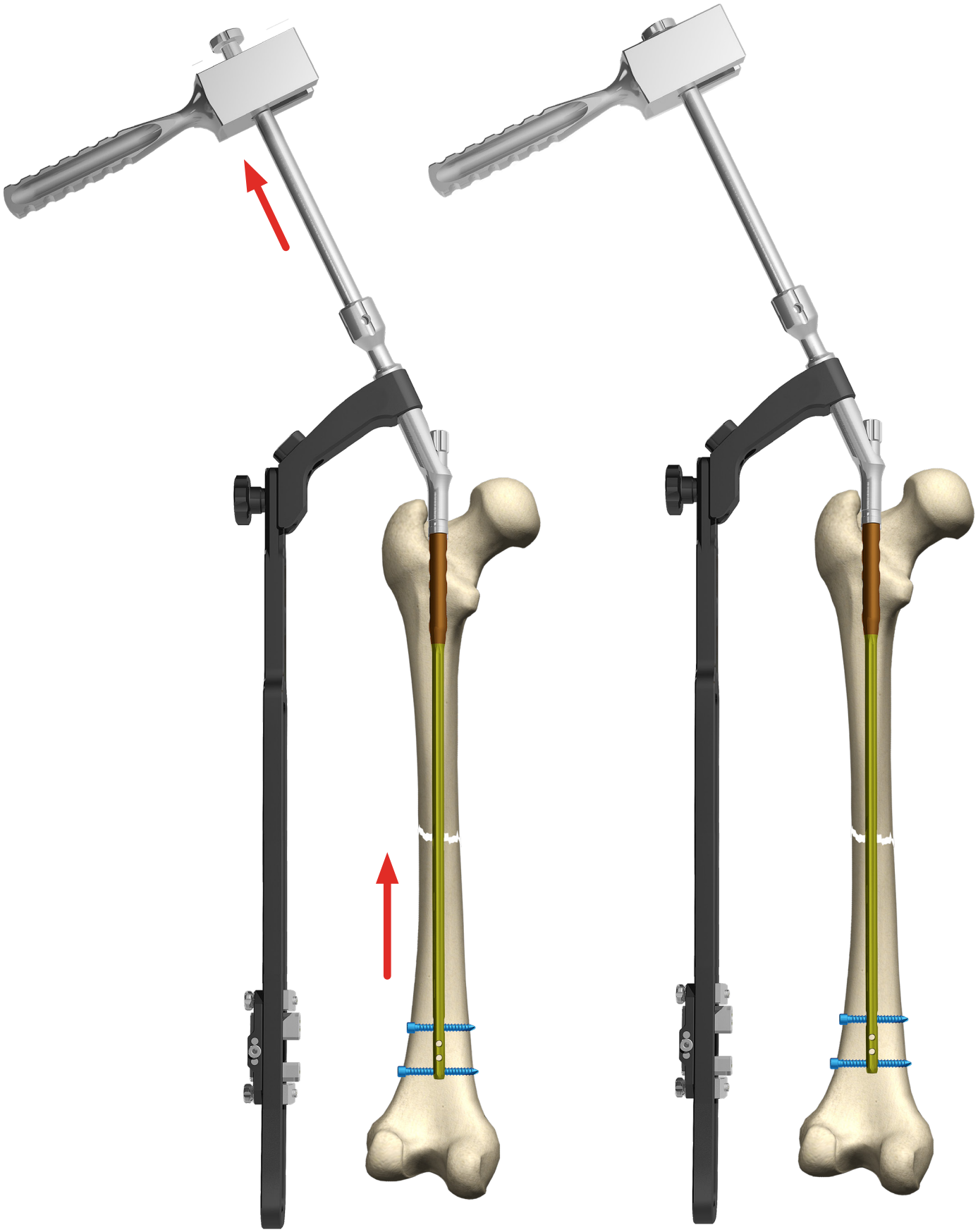
Remove the Trocar.
Leave the Protective Guide in the hole of targeters.

40.3614

40.3617

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

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



IV.3.2. Proximal locking of the nail

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

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

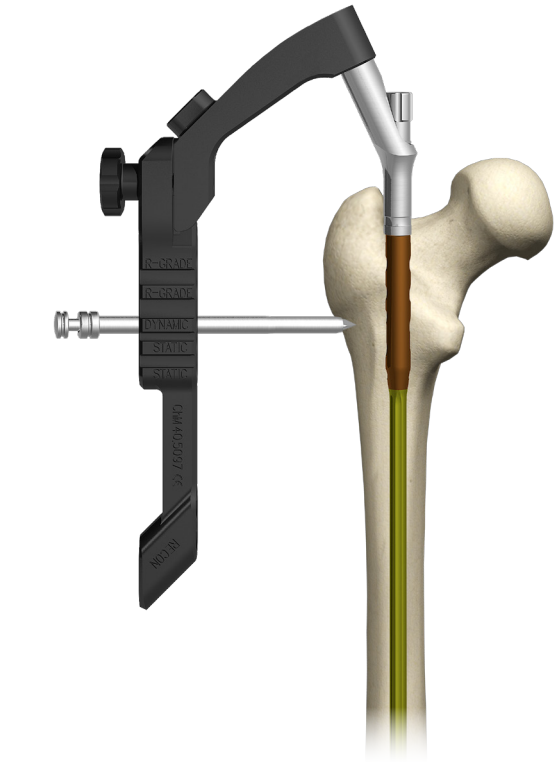
Remove the Trocar.
Leave the Protective Guide in the hole of targeter.


40.5091


40.5097


40.3614


40.3617

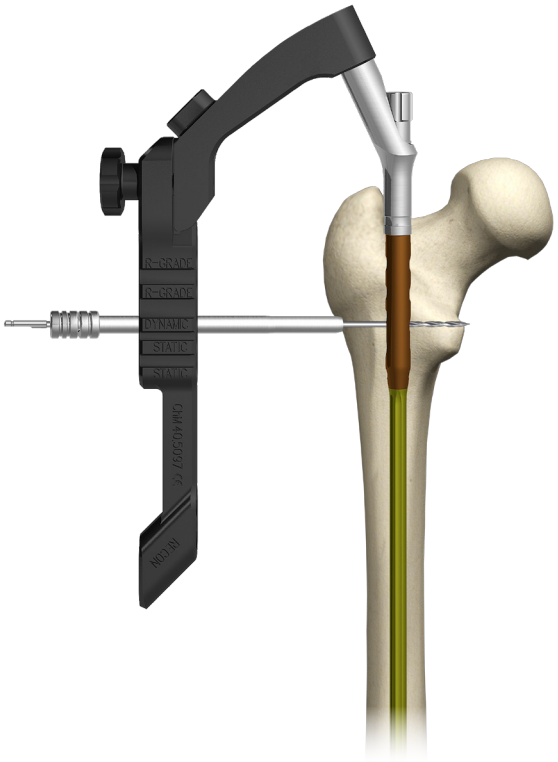


42 Insert the Drill Guide 6.5/3.5 **[40.3615]** *(with two grooves)* into the protective guide. Mount the Drill With Scale 3.5/270 **[40.5330.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through both cortex layers and the hole in the nail. The scale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

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


40.3615

40.5330.001



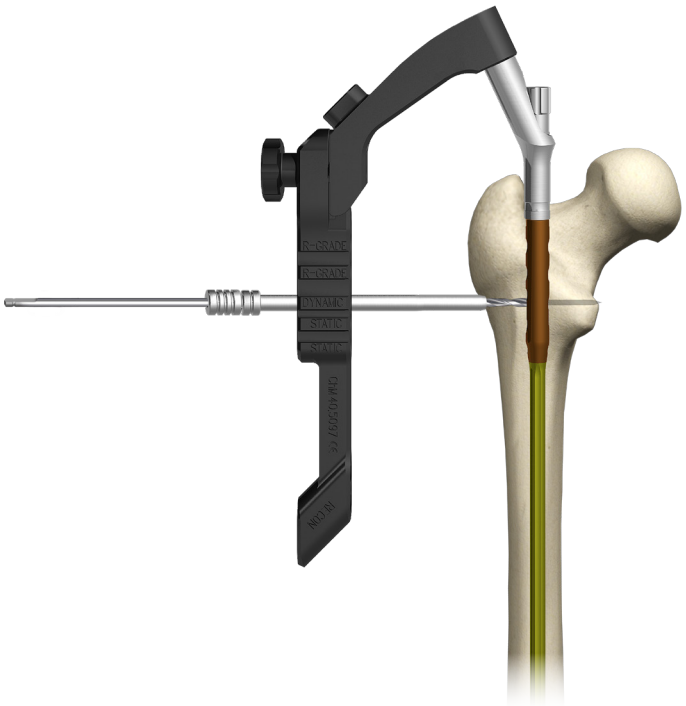
43 Insert the Drill Guide 6.5/4.5 **[40.3696]** into the Protective Guide 9/6.5 **[40.3614]**. Mount the Drill 3.5/270 on the surgical drive and advance it through the drill guide. Drill the hole in the femur through first cortex only up to the nail hole.

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


40.3614


40.3696

40.1387.001

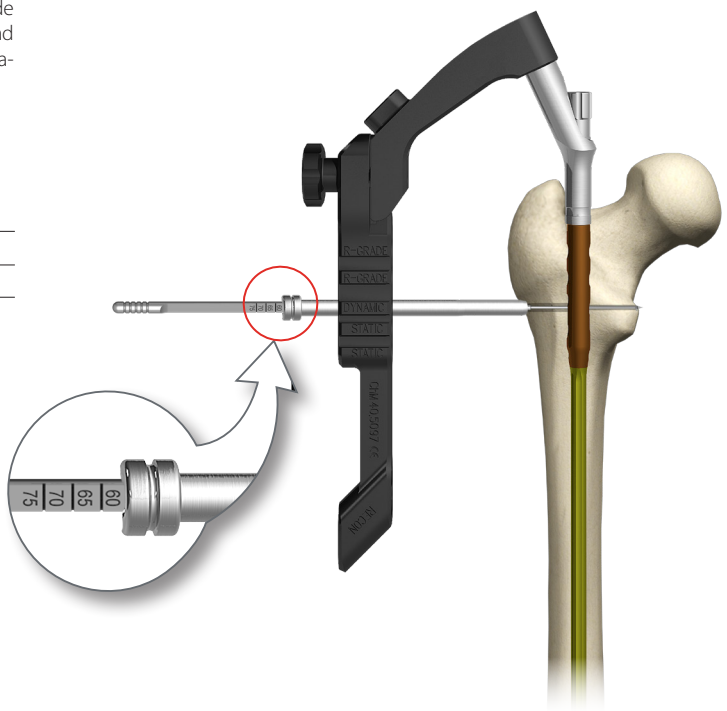


44 Insert the Screw Length Measure **[40.1374]** through the protective guide into the drilled hole until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the Measure scale B-D. During the measurement the end of the Protective Guide should rest on the cortex.

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

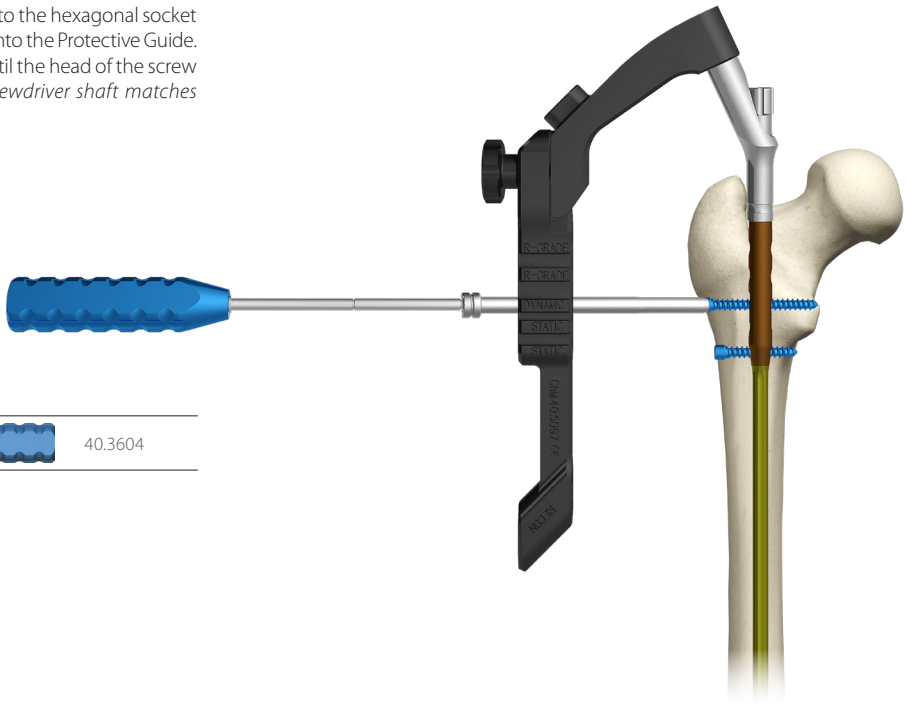

40.3614

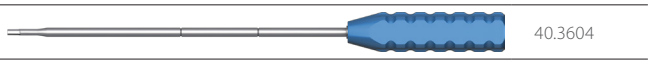
40.1374



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

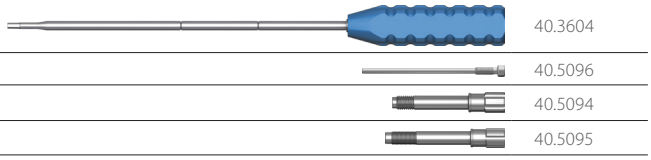
Remove the Screwdriver and Protective Guide.

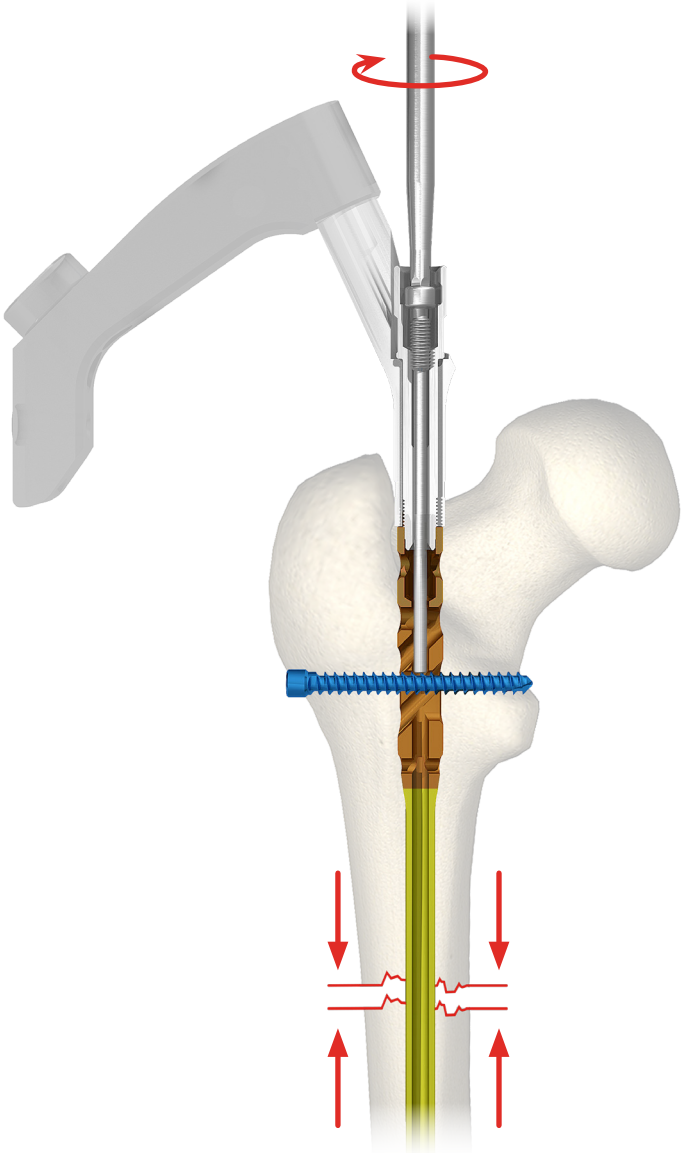



40.3604

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

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


40.3604
40.5096
40.5094
40.5095



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

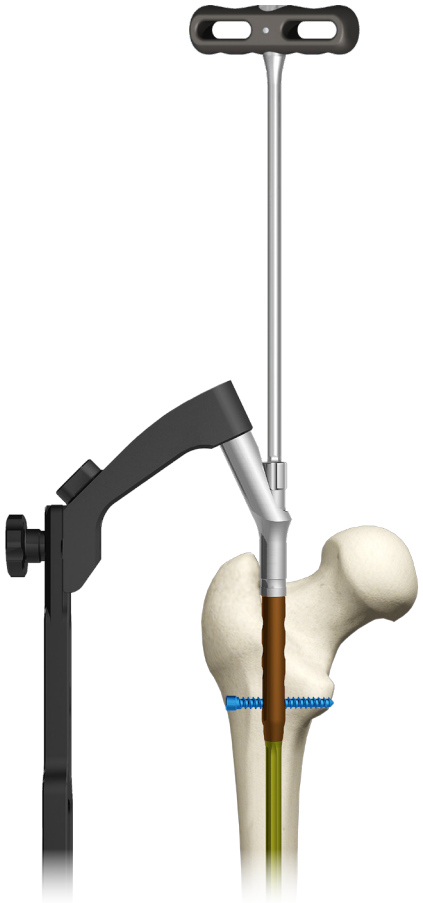
IV.3.3. Targeter removal

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

40.5526.100

40.5094

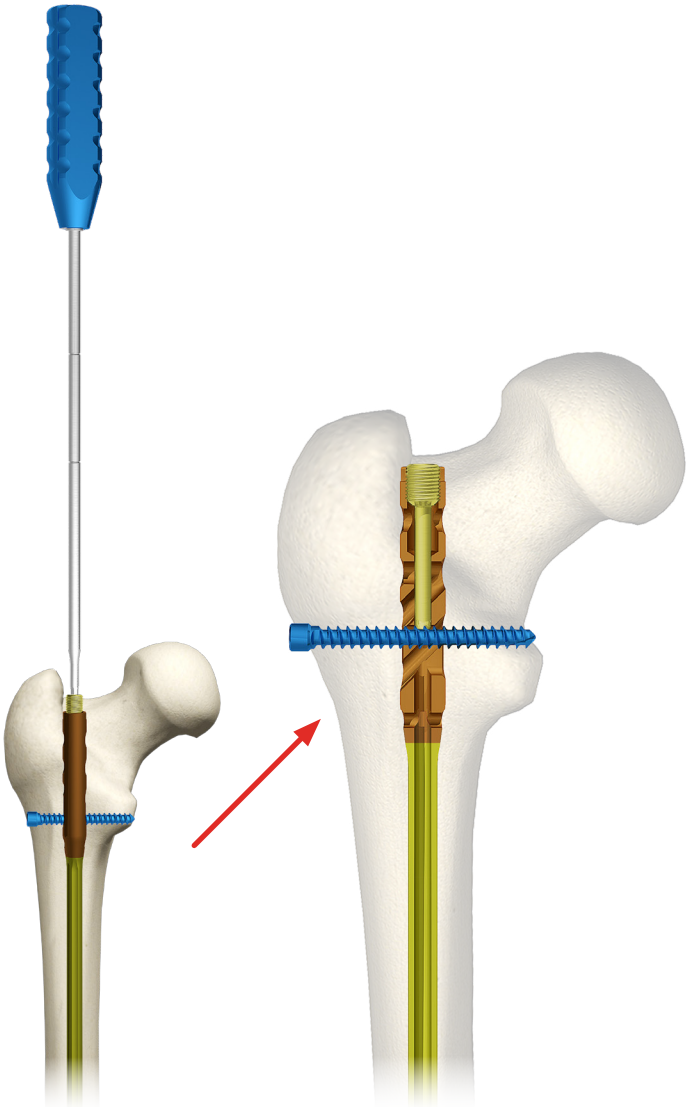
40.5095



IV.3.4. Placing Compression Screw

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

40.3604



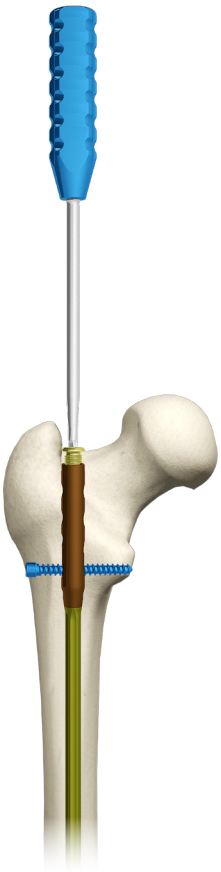
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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

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

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

40.3675



IV.4. STATIC METHOD

IV.4.1. Distal locking of the nail

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

1. Mount the Distal targeter D **[40.5093]** on the Targeter arm **[40.5091]** and secure it with a collar bolt *(provided with the targeter)*.

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

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

40.5091

40.5093

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

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

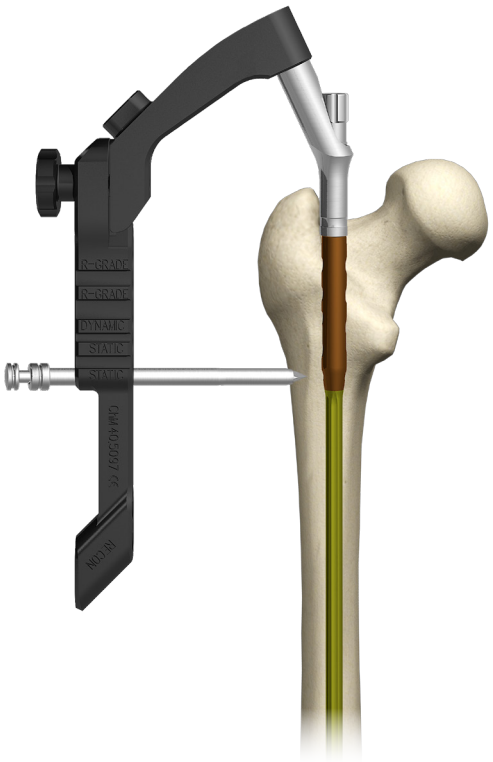
40.3614

40.3617

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

IV.4.2. Proximal locking of the nail

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



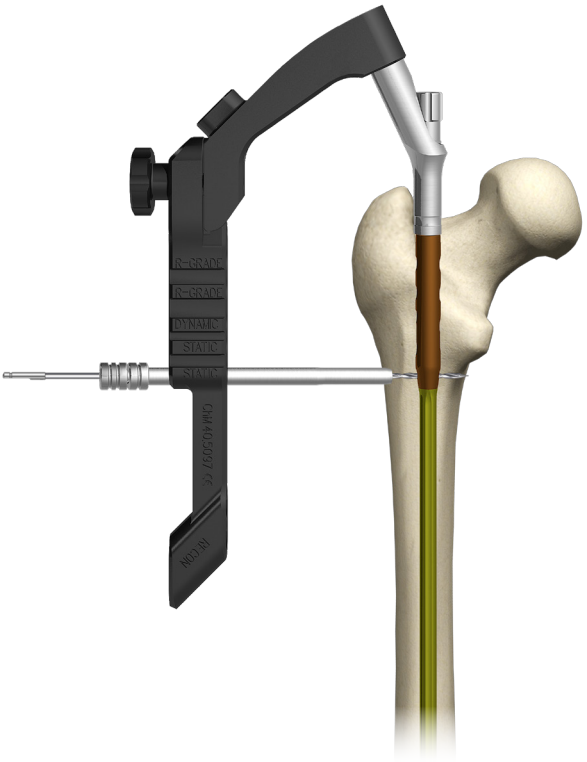
50 Insert the Protective Guide 9/6.5 **[40.3614]** *(with one grove on the handle)* with the Trocar 6.5 **[40.3617]** into the distal hole in Targeter 135. Mark the entry point for the locking screw on the skin and make adequate 1.5cm long incision through the soft tissues. Advance the trocar until it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

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


40.5097


40.3614


40.3617



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

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

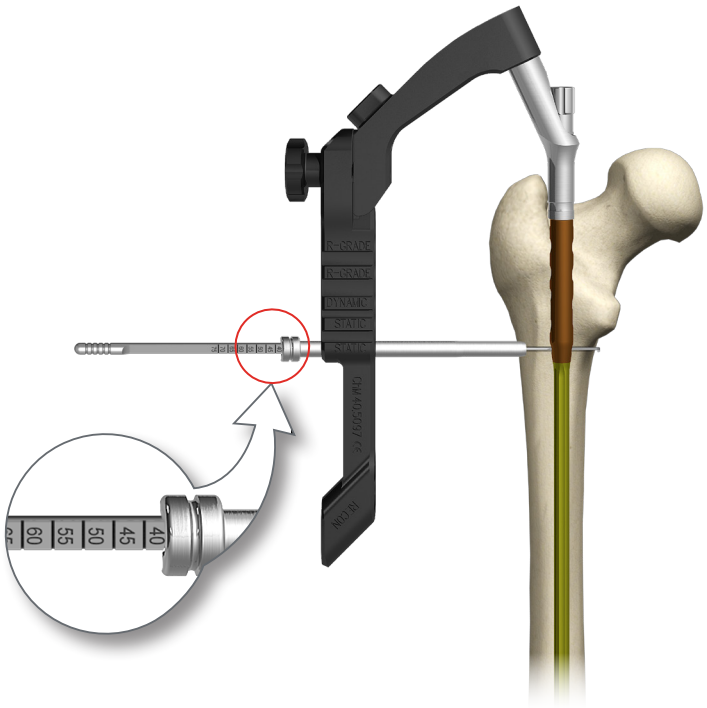

40.3614


40.3615

40.5330.001

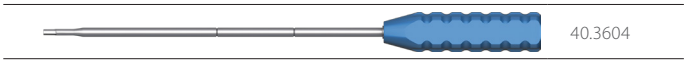
52 Insert the Screw Length Measure **[40.1374]** through the Protective Guide 9/6.5 **[40.3614]** into the drilled hole until its hook reaches the *"exit"* plane of the hole. Read the length of the locking screw on the gauge scale B-D. During the measurement the end of the Protective Guide should rest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

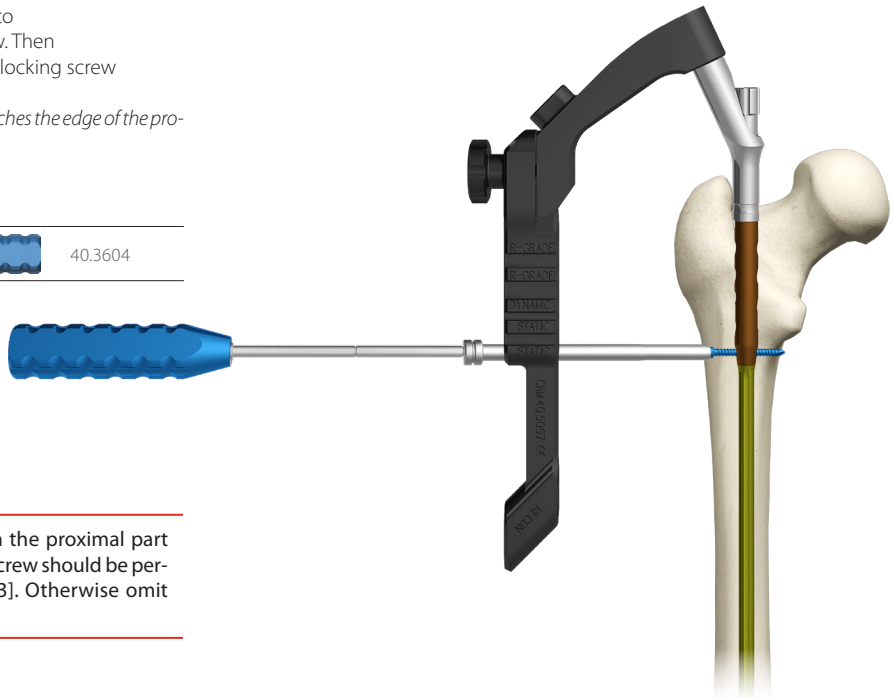
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of targeter.



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

Remove the Screwdriver and the Protective Guide.





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

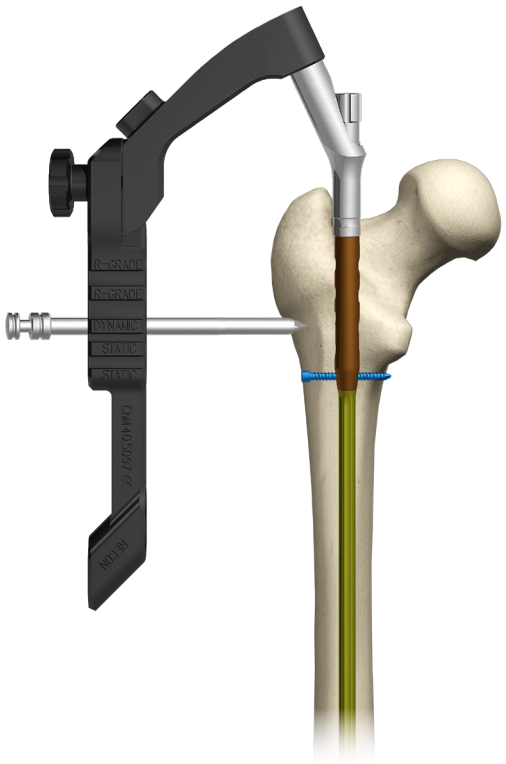
54 Insert the Protective Guide 9/6.5 **[40.3614]** *(with one grove on the handle)* with the Trocar 6.5 **[40.3617]** into the proximal hole of proximal targeter. Advance Trocar until it reaches cortex and mark the entry point for the drill. Advance the Protective Guide together with the trocar until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

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

40.5097

40.3614

40.3617

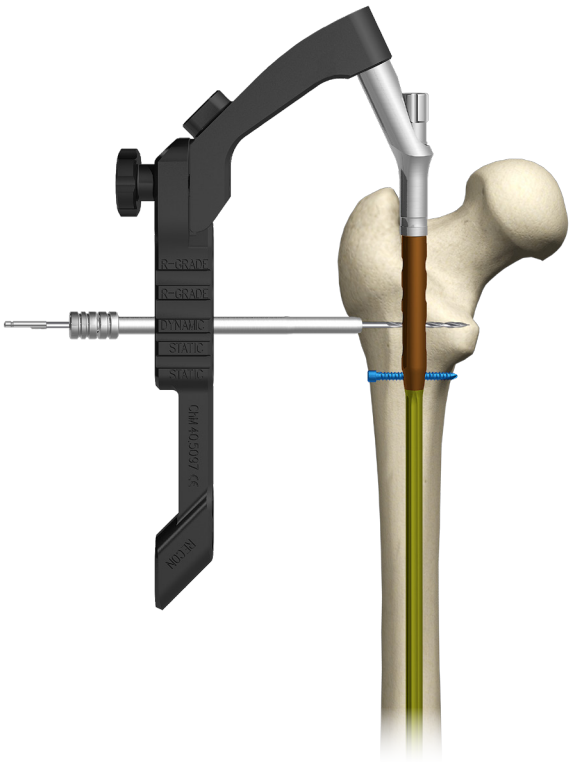


55 Insert the Drill Guide 6.5/3.5 **[40.3615]** *(with two grooves)* into the Protective Guide. Mount the Drill With Scale 3.5/270 **[40.5330.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through both cortex layers and the nail hole. The scale on the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

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

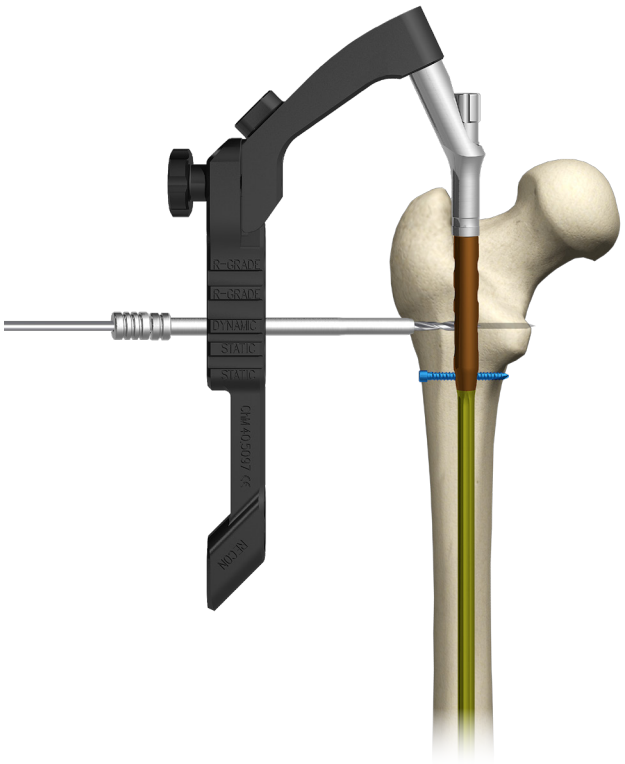
40.3615

40.5330.001



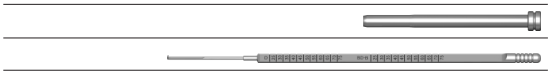
56 Insert the Drill Guide 6.5/4.5 **[40.3696]** into the Protective Guide. Mount the Drill 4.5/270 **[40.1387.001]** on the surgical drive and advance it through the Drill Guide. Drill the hole in the femur through first cortex up to the hole in the nail.

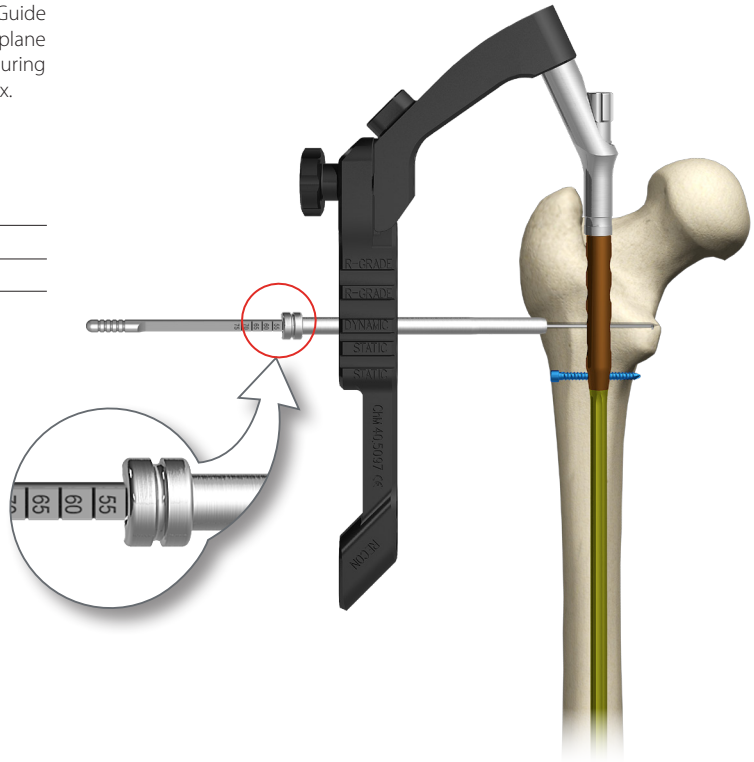
Remove the Drill and the Drill Guide.
Leave the Protective Guide in the hole of targeter.



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

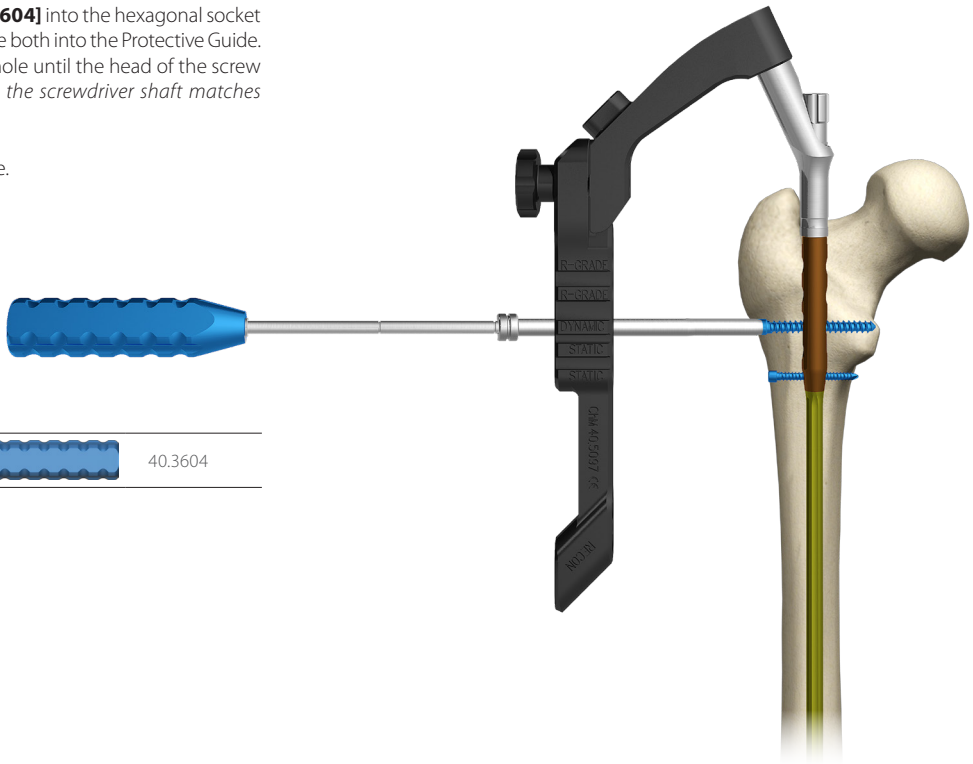
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of targeter.

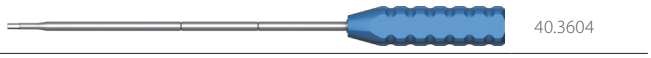




58 Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the selected locking screw. Then advance both into the Protective Guide. Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft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

Remove the Screwdriver and the Protective Guide.





40.3604

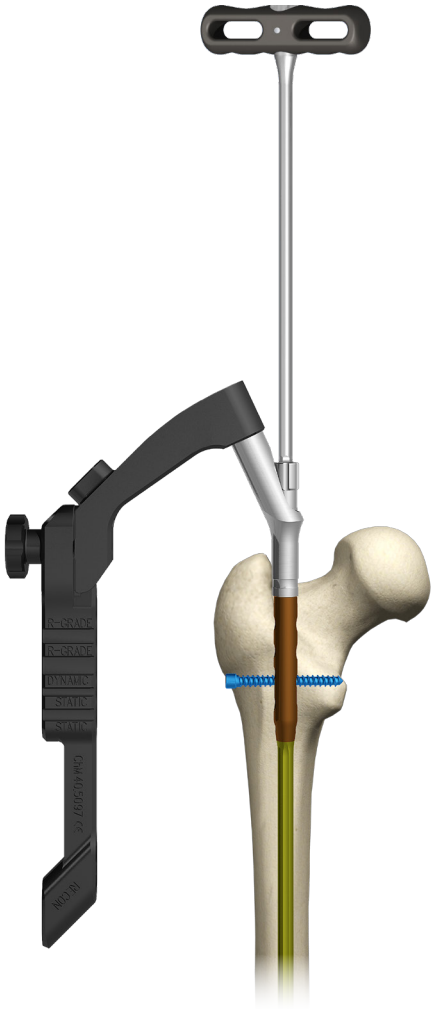
IV.4.3. Targeter removal, placing end cap

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

40.5526.100

40.5094

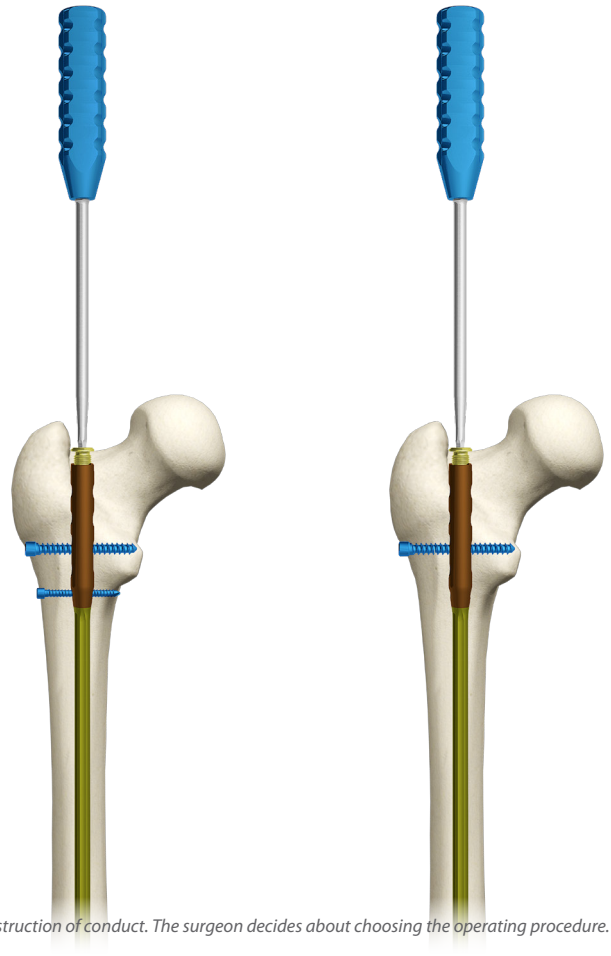
40.5095



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

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

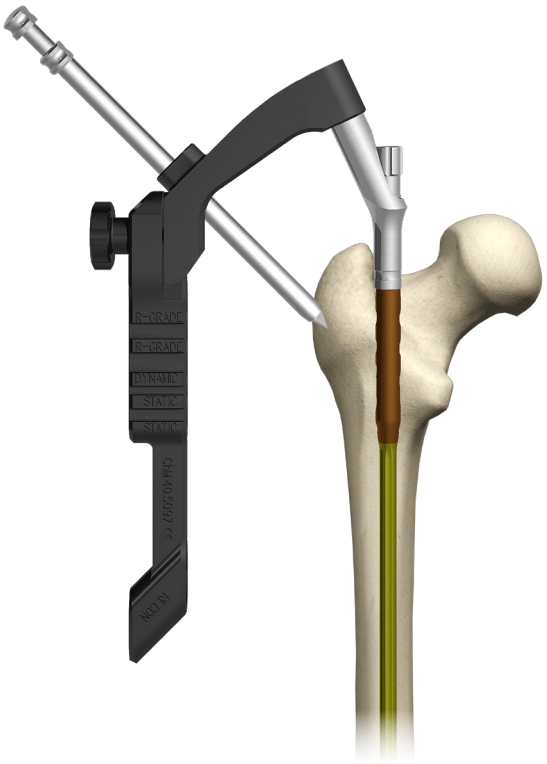
40.3675



IV.5. STATIC METHOD WITH USE OF RECONSTRUCTION NAIL

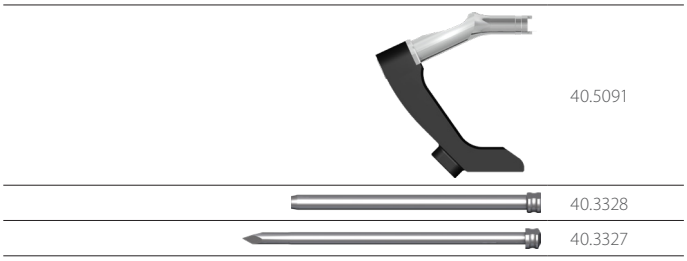
IV.5.1. Proximal locking of the nail

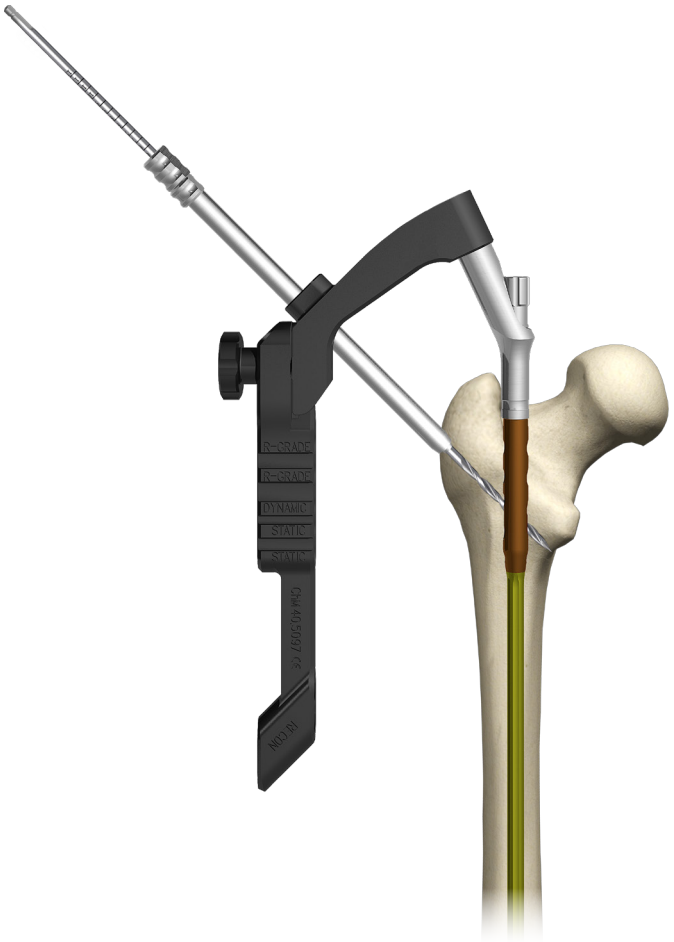
In the static method, the intramedullary reconstruction nails for fixation of femoral fragments may be used:
- right nail *(market RIGHT)* should be used for fixation of the left femur,
- left nail *(market LEFT)* should be used for fixation of the right femur.



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

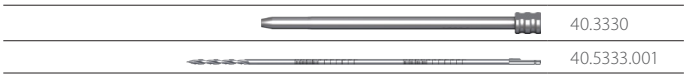
Remove the Trocar.
Leave the Protective Guide in the hole of targeter.





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

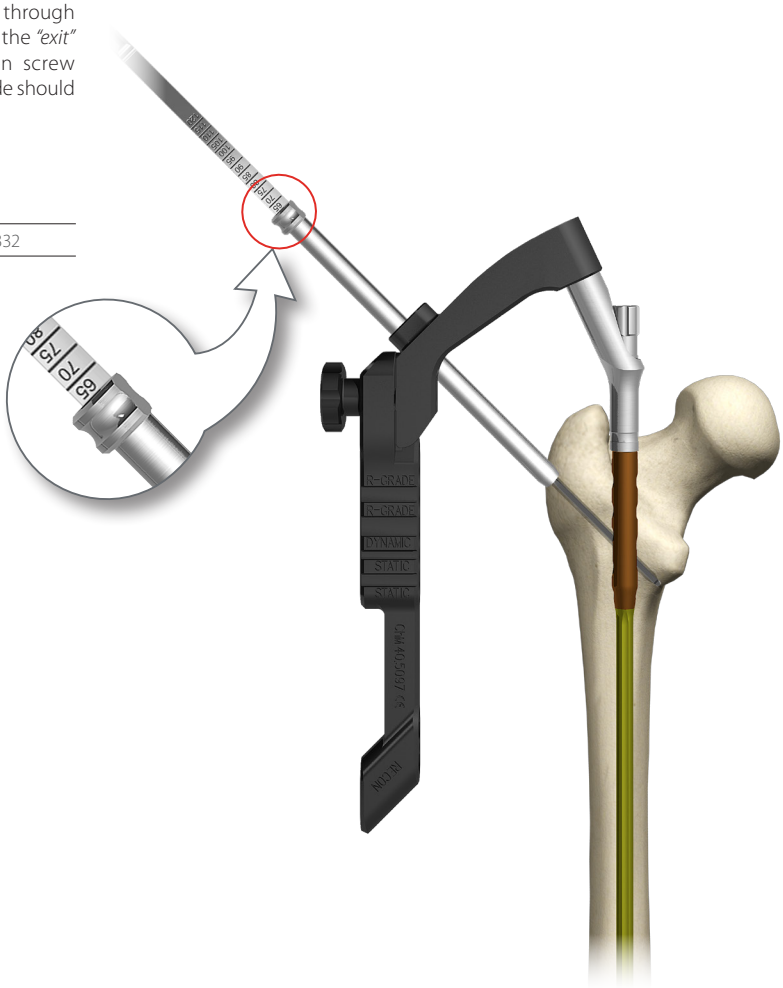
Remove the Drill and the Drill Guide.
Leave the Protective Guide in the hole of targeter.



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

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

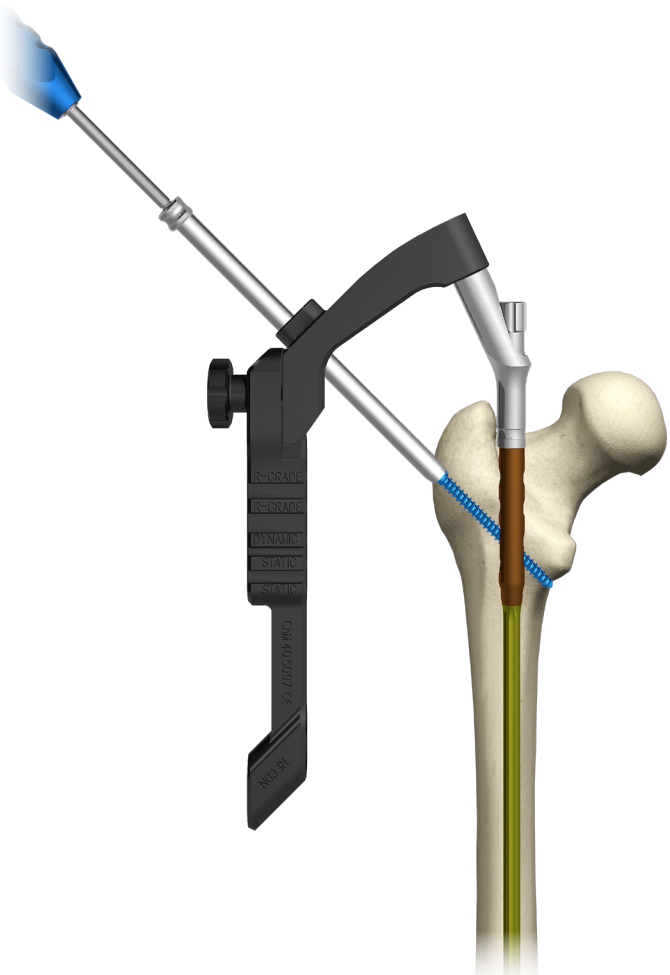
40.3332



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

Remove the Screwdriver S3.5 and Protective Guide.

40.3604



IV.5.2. Distal locking of the nail

Before distal locking of the nail do the following:

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

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

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


40.5091


40.5093

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

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


40.5093


40.3614


40.3617

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

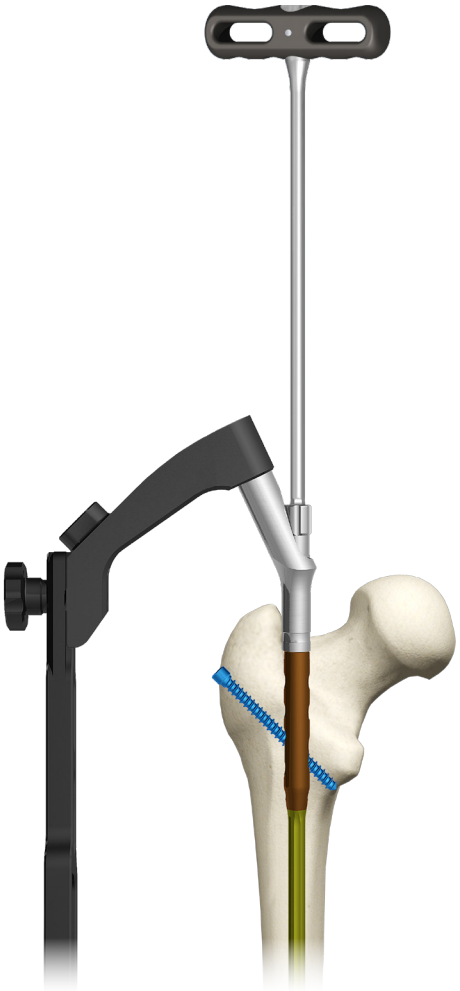
IV.5.3. Targeter removal, end cap placing

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


40.5526.100


40.5094

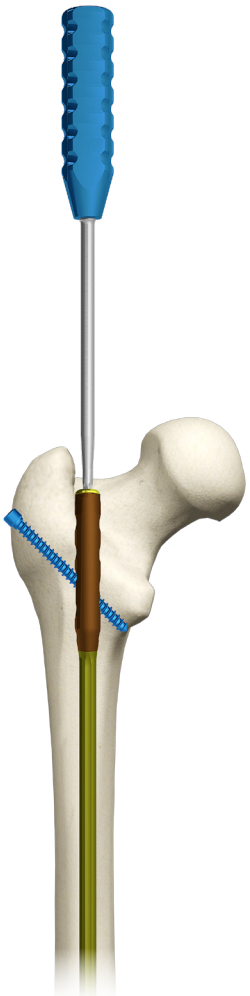

40.5095



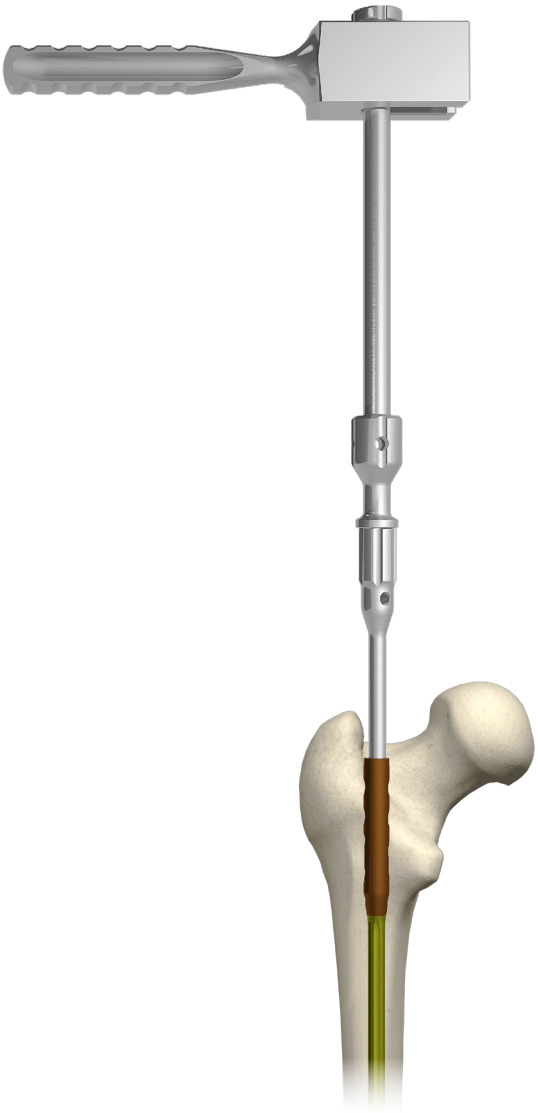
67 In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 **[40.3675]** insert:

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


40.3675



IV.6. NAIL EXTRACTION



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

40.3675


40.3604

40.5096


40.5071


40.5507


40.3667

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

IV.7.1. Implants for retrograde method

IV.7.2. Introduction

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

CHARFIX system provides the retrograde nails with diameters 10, 11 or 12mm and length between 160 and 440 mm. To lock the nail distally *(by the knee joint)* depending on the fracture type use:
- two locking screws 6.5mm,
- two locking sets.

There are five sizes of locking sets:
- 50, with range between 50 and 65 mm,
- 60, with range between 60 and 75 mm,
- 70, with range between 70 and 85 mm,
- 80, with range between 80 and 95 mm,
- 90, with range between 90 and 105 mm.

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

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

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

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

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

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

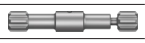
40.5523

Control the procedure with the X-Ray.

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

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

40.3925.580

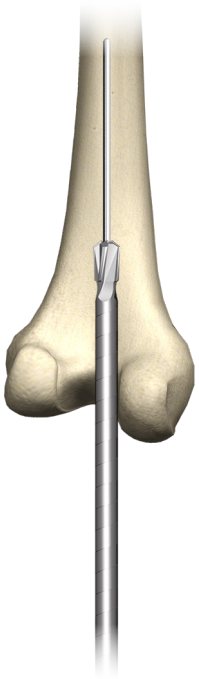


40.1351

40.5523

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

Remove the Flexible Reamer.

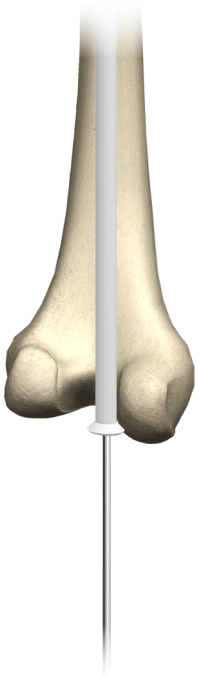


NOTE! Steps [4] and [5] are applicable only if the medullary canal has been reamed or if another not provided in the instrument set reamer guide has been used. Otherwise go directly to the step [6]. If the medullary canal is not reamed, the distal canal in step 3 should be reamed up to the diameter of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

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

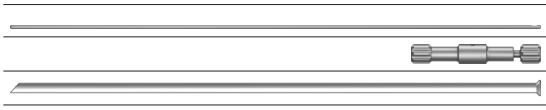
Remove the Reamer Guide.

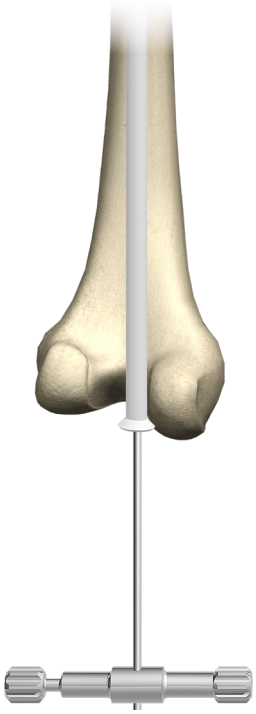

40.1348



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

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

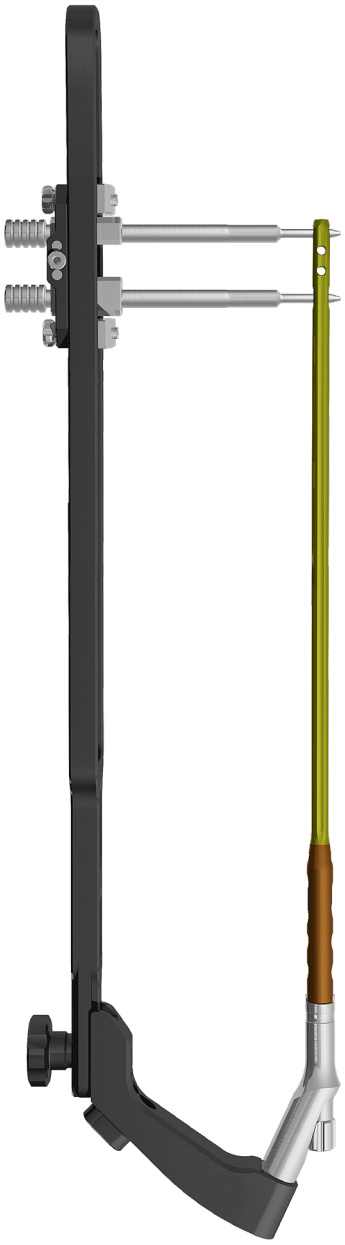




6 Insert the Nail Length Measure **[40.5098]** on the Guide Rod until it rests on bone. Read the lenght of the nail on the Nail Length Measure. Remove the Nail Length Measure from the guide rod. In case of using solid nail, remove the Guide Rod from medullary canal. Medullary canal is ready for nail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

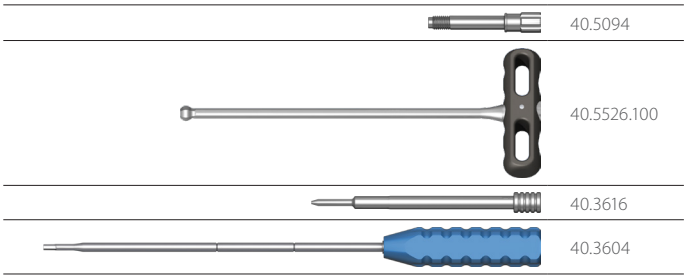
IV.7.3. Nail assembling to the targeter, nail insertion into the medullary canal

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



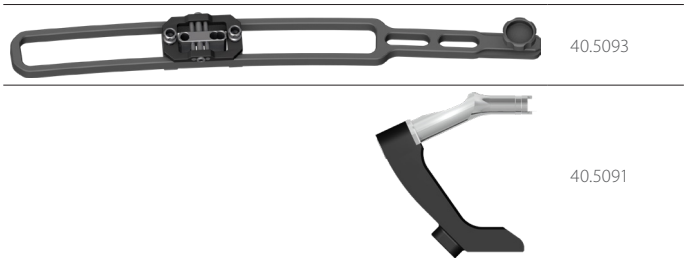
NOTE! When operating right limb the targeter should be connected so the RIGHT signs on both side shall be in line. In the case of left limb - the LEFT signs on both side shall be in line.

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



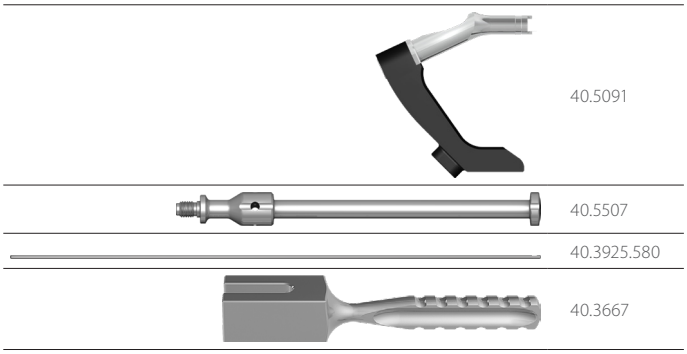
CHECK! Properly set and secured slider means that set blocks smoothly hit the holes in the nail.

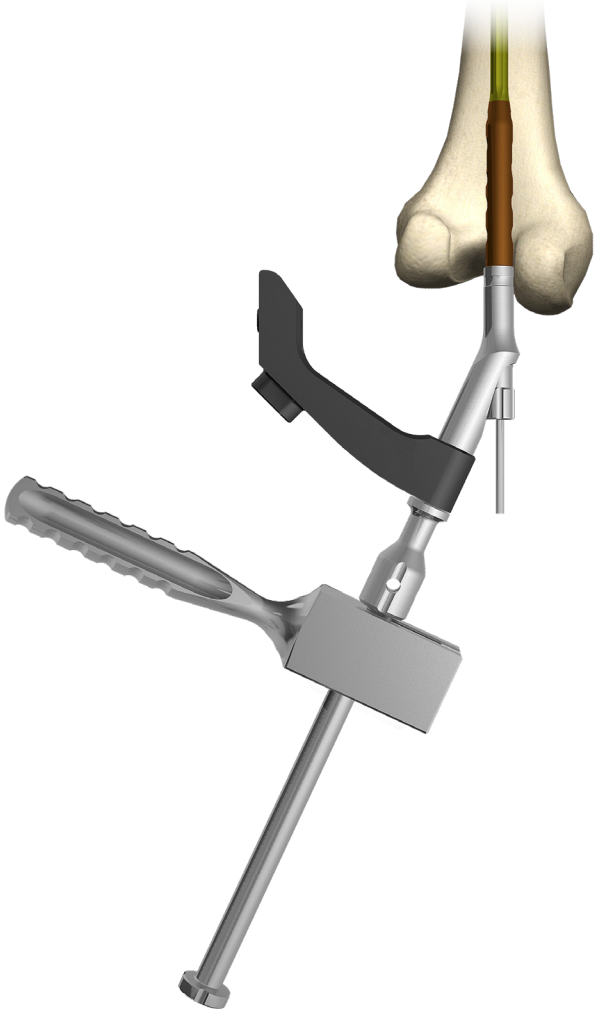
Remove the Set Blocks from Distal targeter.
Dismount Distal targeter from Targeter arm.



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

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

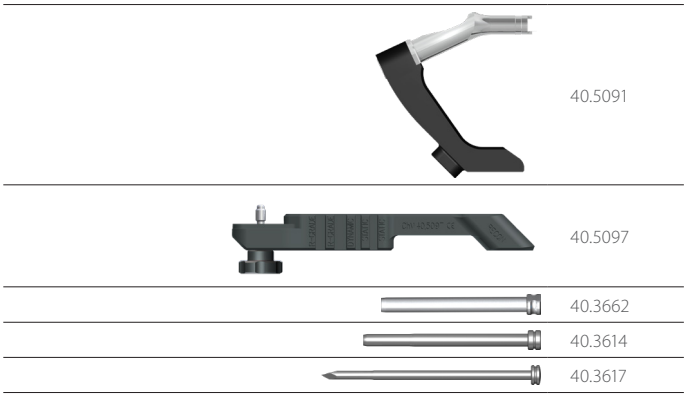


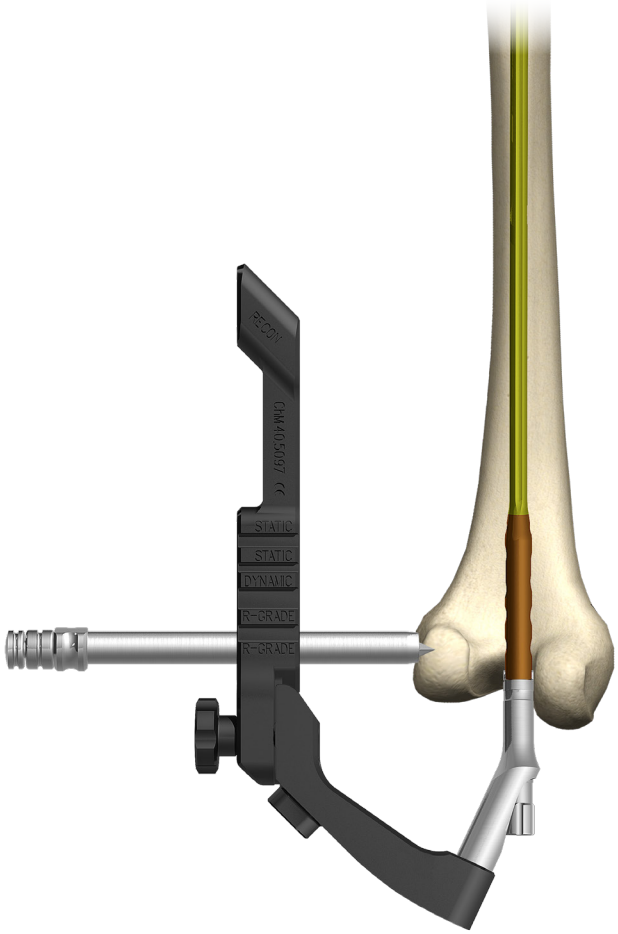


IV.7.4. Locking the nail in the condyral femur

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

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

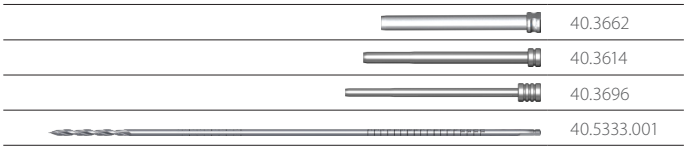


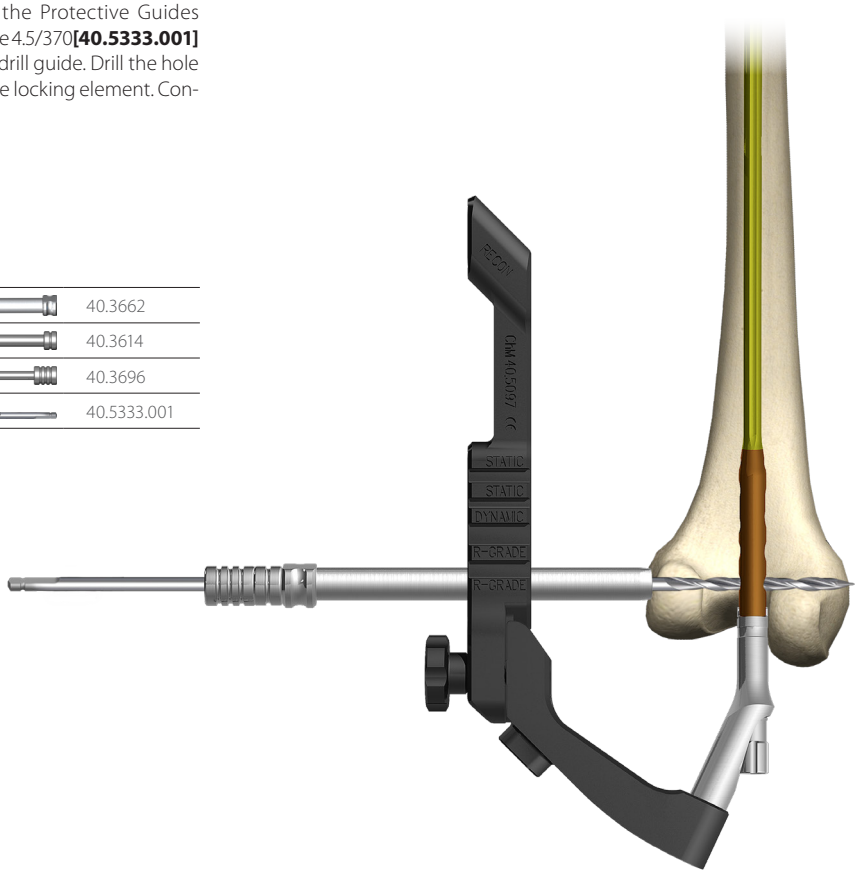


IV.7.4.A. OPTION I: Locking with screws

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

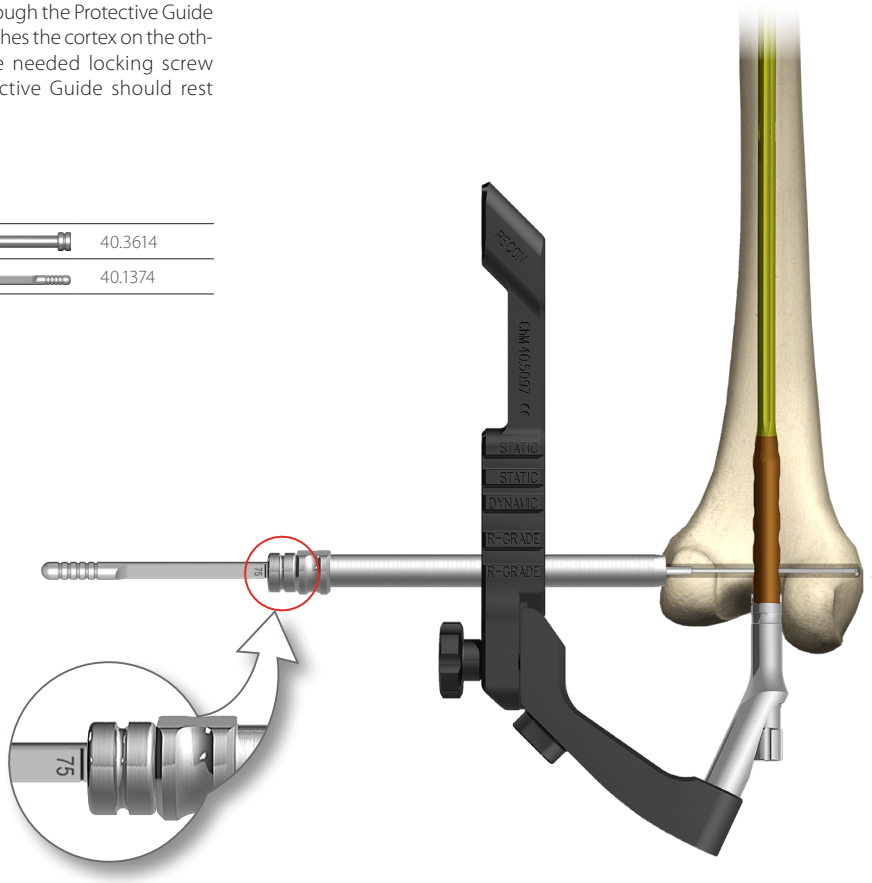
Remove the Drill and drill guide.
Leave the Protective Guide in the hole of the targeter.





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

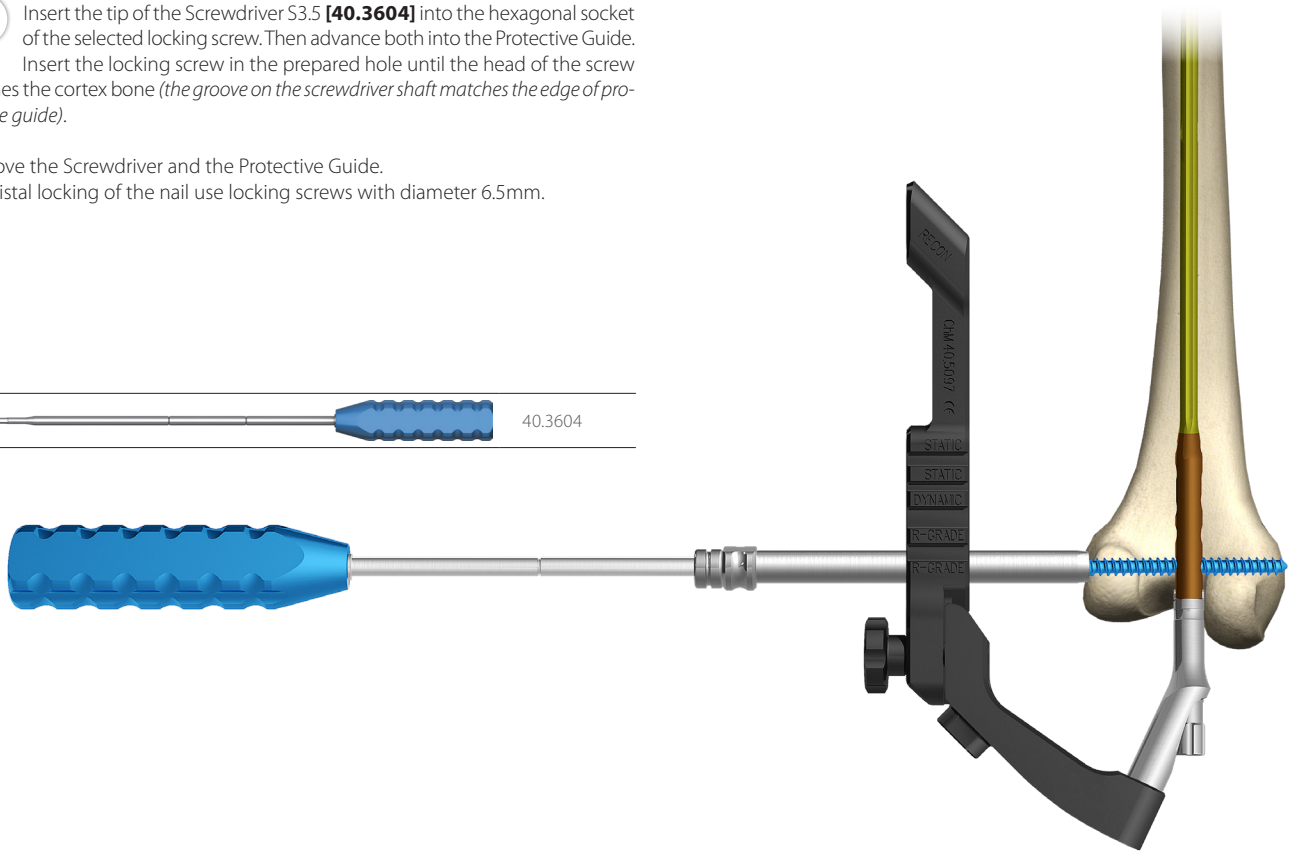
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of the targeter.



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

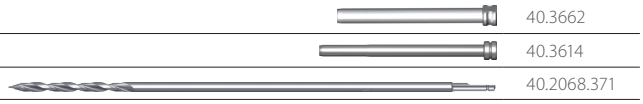
Remove the Screwdriver and the Protective Guide.
For distal locking of the nail use locking screws with diameter 6.5mm.

40.3604



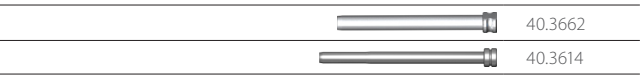
IV.7.4.A. OPTION II: Locking with locking set

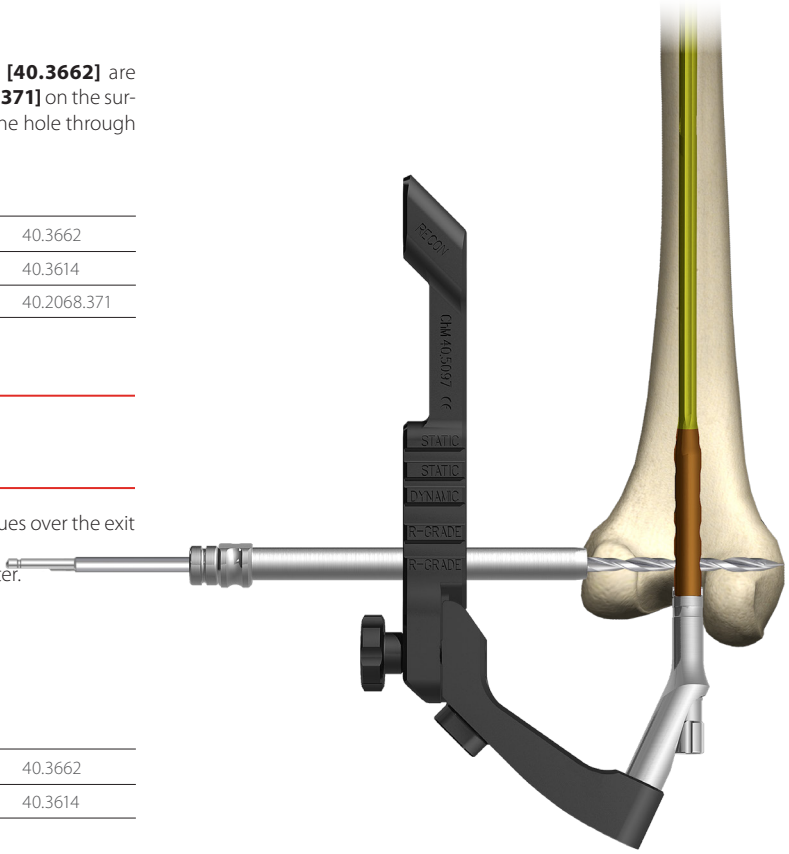
13 The Drill Guide **[40.3614]** and the Protective Guide **[40.3662]** are in the hole of targeter. Mount the Drill 6.5/370 **[40.2068.371]** on the surgical drive and advance it through the Drill Guide. Drill the hole through the bone.



Control drilling with X-Rays image intensifier.

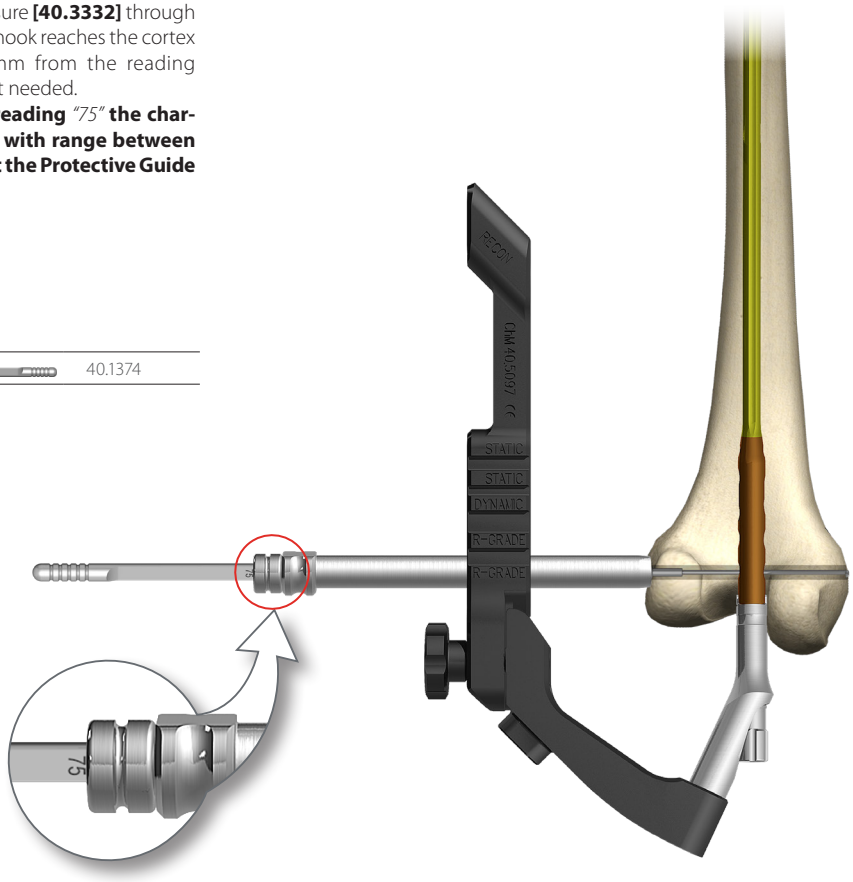
With help of X-Ray image intensifier make incision of the soft tissues over the exit point of the drill. Remove the Drill.
Leave the Protective Guides **[40.3662]** and **[40.3614]** on targeter.





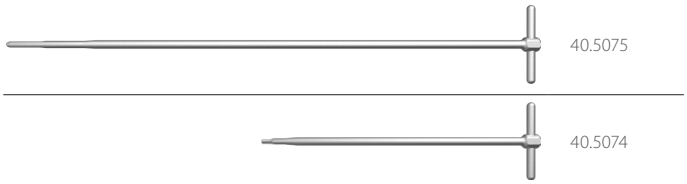
14 Insert the the Reconstruction Screw Length Measure **[40.3332]** through the Protective Guide into the drilled hole until its hook reaches the cortex on the other side of the bone. Deduct 10mm from the reading on the Measure, to get a characteristics of the locking set needed.
Select locking set with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

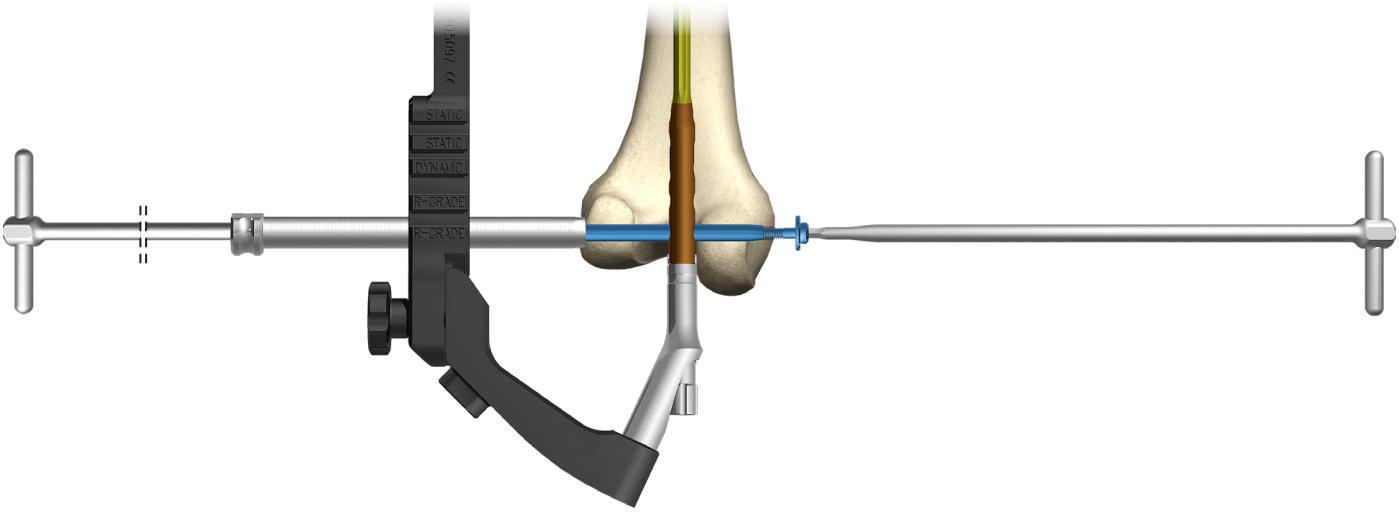
Remove the screw length measure.
Leave the protective guide in the hole of the targeter.



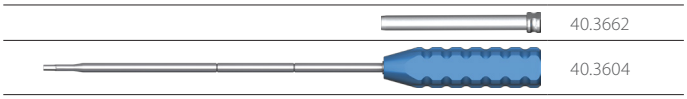
15 Insert the Bolt Guide **[40.5075]** into the protective guide. The pilot which is integral part of the the Bolt Guide **[40.5075]**, should be attached on the Bolt Guide. Advance the Bolt Guide through the drilled hole until its tip reaches the hole from the other side. Remove the pilot from the the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

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

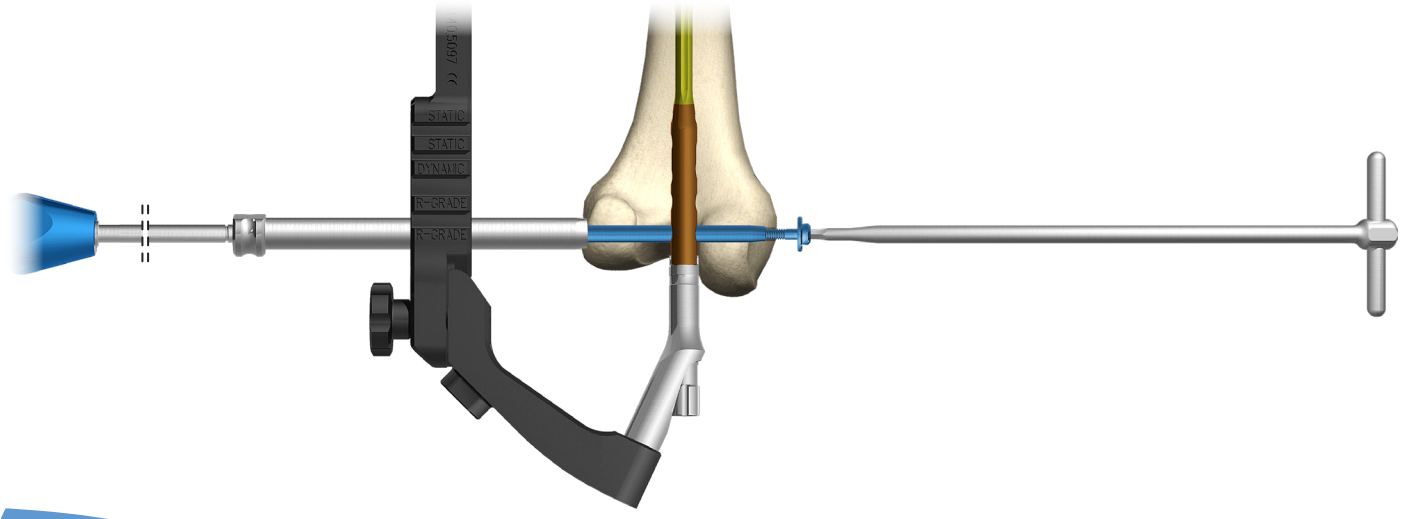




16 Leave the Protective Guide **[40.3662]** in the hole of the targeter. Insert the tip of the Screwdriver S3.5 **[40.3604]** into the hexagonal socket of the locking screw *(implant)* and advance both into the Protective Guide. Put the washer *(implant)* over the locking screw when it leaves the protective guide and enters the hole in the bone. Insert the locking screw in the threaded hole in the bolt *(hold the bolt with the screwdriver)*.
Two screwdrivers are used to secure the locking set *(locking screw, two washers, bolt)*. Remove the screwdrivers and protective guide.



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



IV.7.5. Proximal locking of the nail

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

1. Mount the Distal targeter D **[40.5093]** on the Targeter arm **[40.5091]** and secure it with a collar bolt *(included in distal targeter)*.

If properly installed, the signs RIGHT or LEFT on both target should comply *(be in one plane)***.**

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


40.5091


40.5093

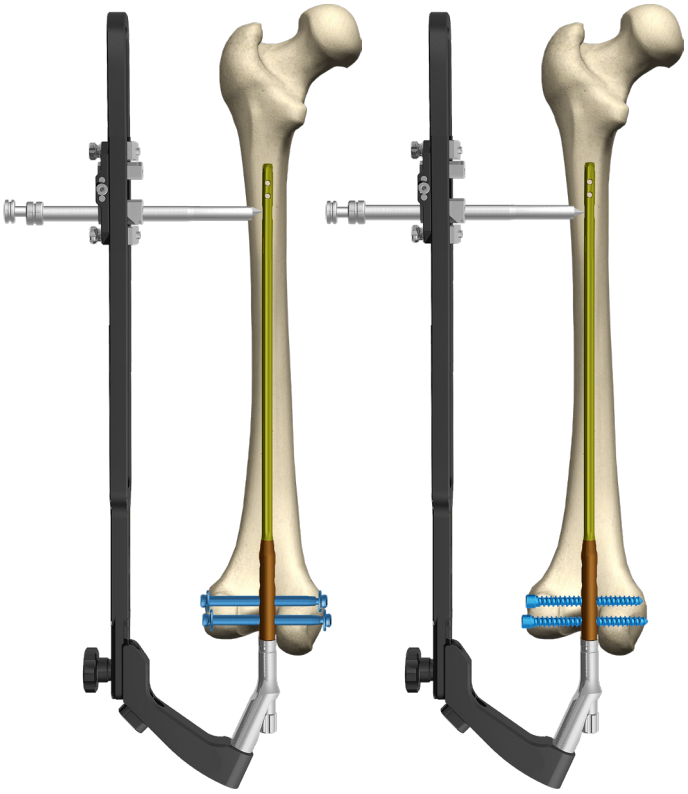
17 Insert the Protective Guide 9/6.5 **[40.3614]** with the Trocar 6.5 **[40.3617]** into the distal hole in the Distal targeter D **[40.5093]**. Mark the entry point for the Trocar, make an adequate incision of the soft tissues. Advance the trocar together with protective guide until it reaches the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

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


40.5093

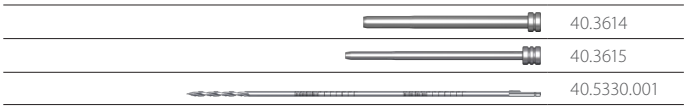

40.3614

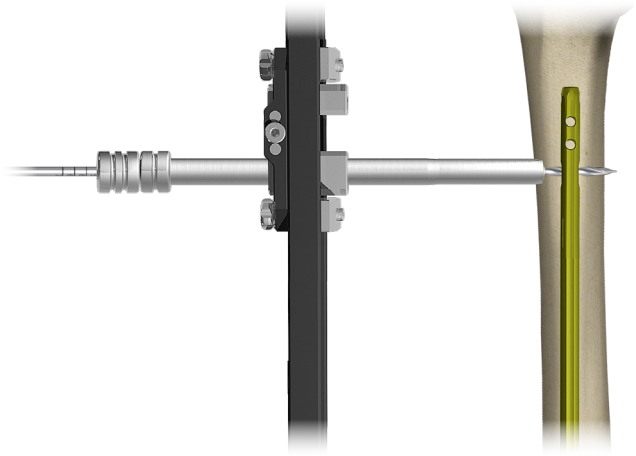

40.3617



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

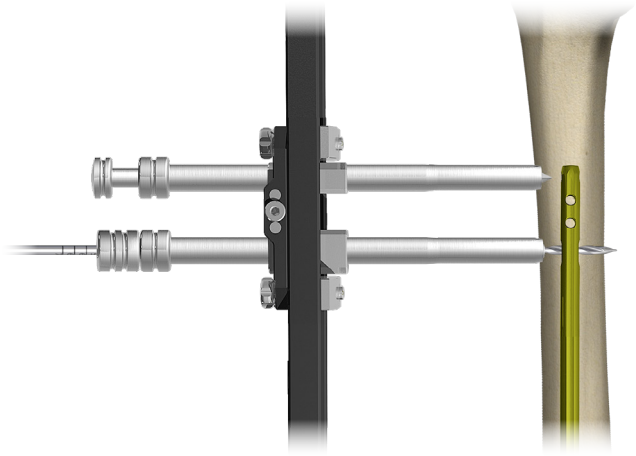
Disconnect the drive from the drill and leave in place system: the protective guide - drill guide - drill.





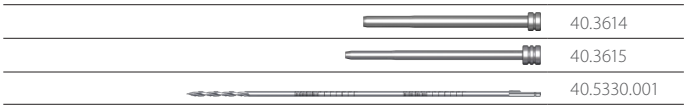
19 Insert the Protective Guide 9/6.5 **[40.3614]** *(with one groove)* with the Trocar 6.5 **[40.3617]** into the second hole in the slider of the targeter. Advance the trocar until it reaches the cortex bone and mark the entry point for the drill. Advance the Protective Guide together with the Trocar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

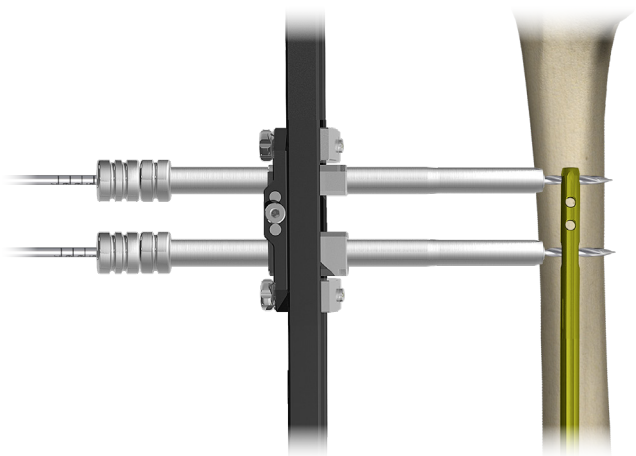
Remove the Trocar.
Leave the Protective Guide in the hole of the slider.



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

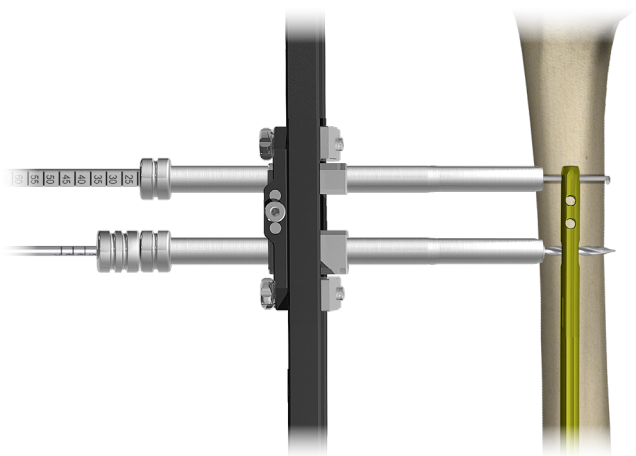
Remove the Drill and Drill Guide.
Leave the Protective Guide in the hole of the slider.





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

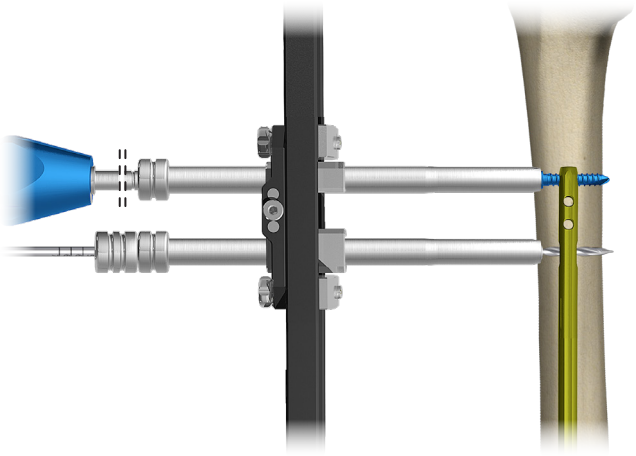
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of the targeter.



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

Remove the Screwdriver.
Leave the Protective Guide.

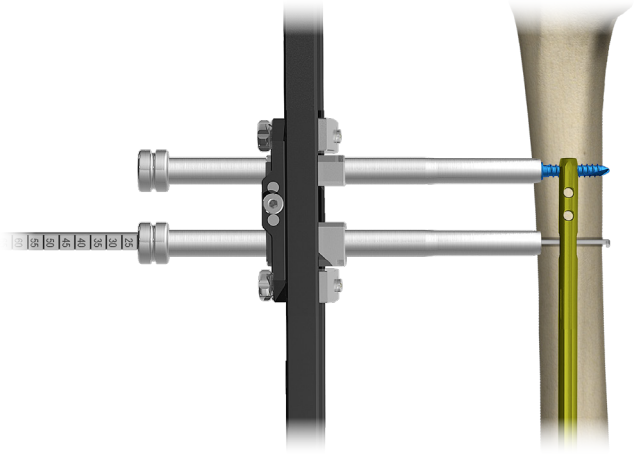

40.3604



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

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

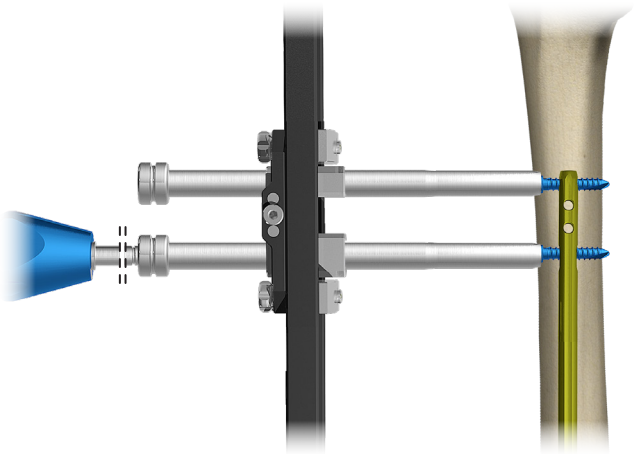
40.1374



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

Remove the Screwdriver and Protective Guide.


40.3604



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

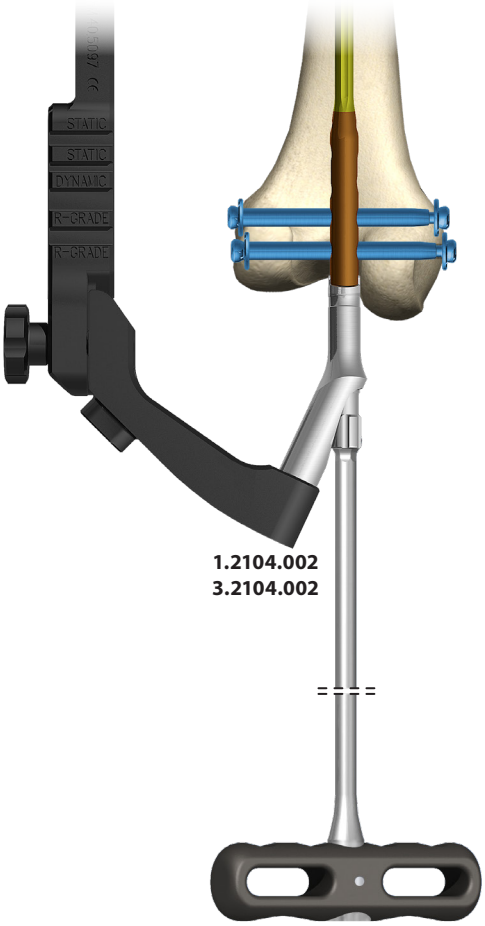
IV.7.6. Targeter removal and end cap placing

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

Dismount the targeter.

40.5526.100

40.5094

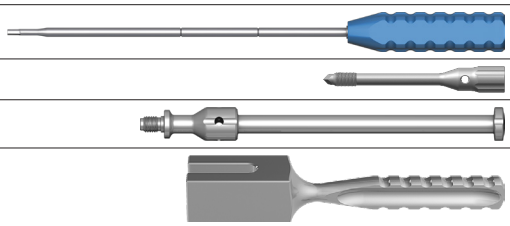


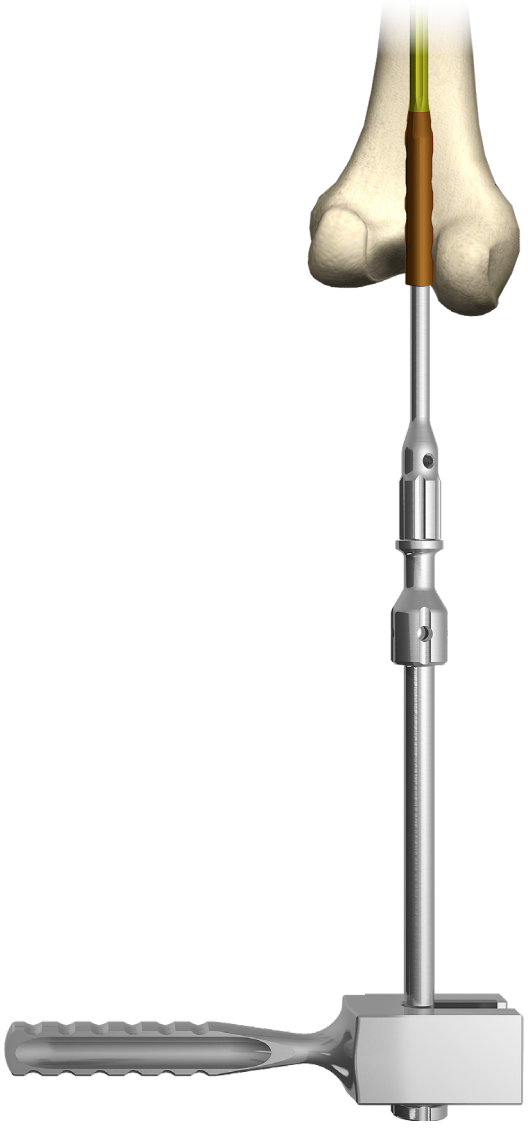
26 In order to secure the inner thread of the nail from bone ingrowth, using the Cannulated Screwdriver S5.0/2.2 **[40.3675]** insert the End Cap **[1.2104.002]** or **[3.2104.002]** *(implant)* inside the nail.

40.3604

IV.7.7. Nail extraction

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





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