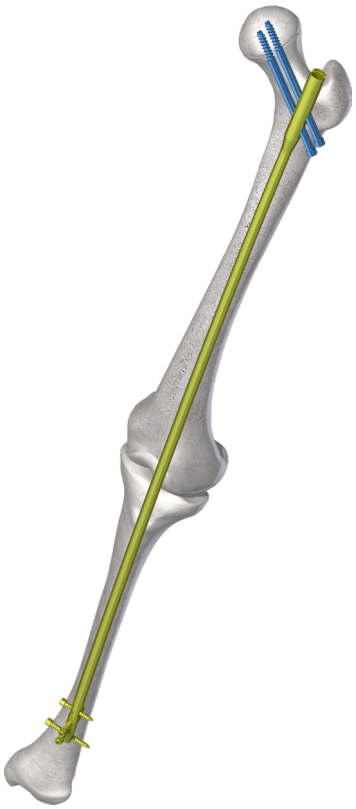
ST/26A

CHM®

CHARFIX system

UNIVERSAL FEMORO-TIBIAL NAIL

- *IMPLANTS*
- *INSTRUMENT SET*
  40.3320.xxx, 40.5060.xxx, 40.5090.xxx
- *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

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1. INTRODUCTION

Femoro-tibial nail is used to treat knee joint arthrodesis.

Intended use:

- failed knee arthroplasty
- post-infection state
- periprosthetic fractures
- post-traumatic state which does not allow for implantation of the knee prosthesis
- tumors in the knee joint area
- loss of or damage to the knee extensor
- neoplastic transformations
- knee arthrodesis.

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

2. IMPLANTS

TITANIUM

2.1. UNIVERSAL FEMORO-TIBIAL NAIL

	Len	L	R
10	600	3.5573.600	3.5572.600
	620	3.5573.605	3.5572.605
	640	3.5573.610	3.5572.610
	660	3.5573.615	3.5572.615
	680	3.5573.620	3.5572.620
	700	3.5573.625	3.5572.625
	720	3.5573.630	3.5572.630
	740	3.5573.635	3.5572.635
	760	3.5573.640	3.5572.640
	780	3.5573.645	3.5572.645
	800	3.5573.650	3.5572.650
11	600	3.5575.600	3.5574.600
	620	3.5575.605	3.5574.605
	640	3.5575.610	3.5574.610
	660	3.5575.615	3.5574.615
	680	3.5575.620	3.5574.620
	700	3.5575.625	3.5574.625
	720	3.5575.630	3.5574.630
	740	3.5575.635	3.5574.635
	760	3.5575.640	3.5574.640
	780	3.5575.645	3.5574.645
	800	3.5575.650	3.5574.650
12	600	3.5579.600	3.5576.600
	620	3.5579.605	3.5576.605
	640	3.5579.610	3.5576.610
	660	3.5579.615	3.5576.615
	680	3.5579.620	3.5576.620
	700	3.5579.625	3.5576.625
	720	3.5579.630	3.5576.630
	740	3.5579.635	3.5576.635
	760	3.5579.640	3.5576.640
	780	3.5579.645	3.5576.645
	800	3.5579.650	3.5576.650

	3.1652.xxx	✓		✓	6.5	60÷120
	3.1654.xxx	✓			4.5	30÷90
	3.2104.3xx	✓		✓		

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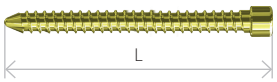
2.2. LOCKING ELEMENTS

TITANIUM

Ti Ster Non Ster

CHARFIX DISTAL SCREW 4.5



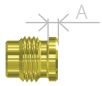
	Ti
30	3.1654.030
35	3.1654.035
40	3.1654.040
45	3.1654.045
50	3.1654.050
55	3.1654.055
60	3.1654.060
65	3.1654.065
70	3.1654.070
75	3.1654.075
80	3.1654.080
85	3.1654.085
90	3.1654.090

16 ÷ 100

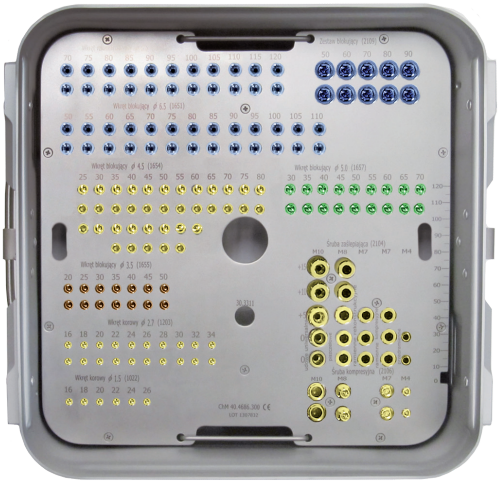
CHARFIX RECONSTRUCTION CANNULATED SCREW 6.5

L	L1	Ti
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

CHARFIX END CAP M10x1



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



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

3. INSTRUMENT SET

Use instrument set **40.3320**.xxx; **40.5060**.xxx; **40.5090**.xxx. to implant the femoro-tibial nail. This surgical technique is prepared with the use of instrument set **40.5090.500**.

In addition, to perform the procedure, use instruments that are the basic equipment of the operating theater for orthopedic procedures, such as:

- bone saws,
- drive,
- set of flexible intramedullary reamers of 8.0÷13.0 mm with guide and handle,
- awls, raspators, bone curettes,
- set of drill bits,
- Kirschner wires,
- mallets.

Instrument set 40.5090.500	**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 mm	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
	Curved awl 8.0	1	40.5523.000
	Impactor-extractor	1	40.5507.000

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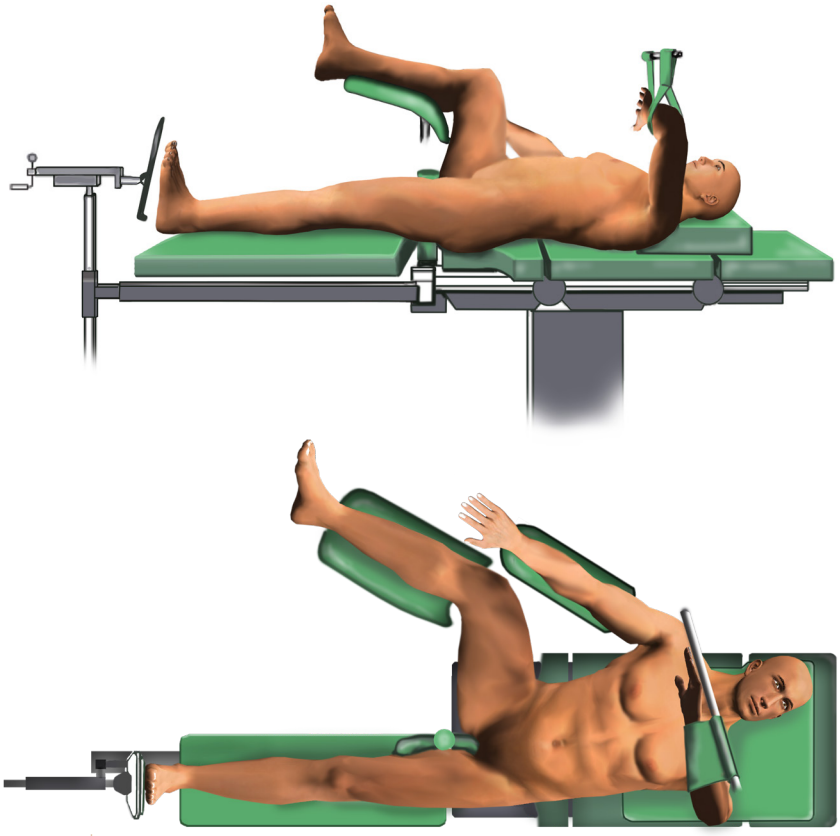
Instrument set 40.5090.500	**Name**	**Pcs.**	**Catalogue No.**
	Mallet	1	40.3667.000
	Connector M10x1/M12	1	40.5071.000
	Wrench S10	1	40.5526.100
	Teflon pipe guide	1	40.1348.000
	Guide rod 3.0/580	1	40.3925.580
	Guide rod handle	1	40.1351.000
	Screwdriver S 3.5	1	40.3604.000
	Drill with scale 4.5/370	1	40.5333.001
	Drill with scale 3.5/270	2	40.5330.001
	Drill 6.5/370	1	40.2068.371
	Cannulated drill 6.5/300	1	40.3674.000
	Cannulated screwdriver S 5.0/2.2	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
	Stand	1	40.5099.500

4. SURGICAL TECHNIQUE

4.1. PATIENT PREPARATION

Patient positioning

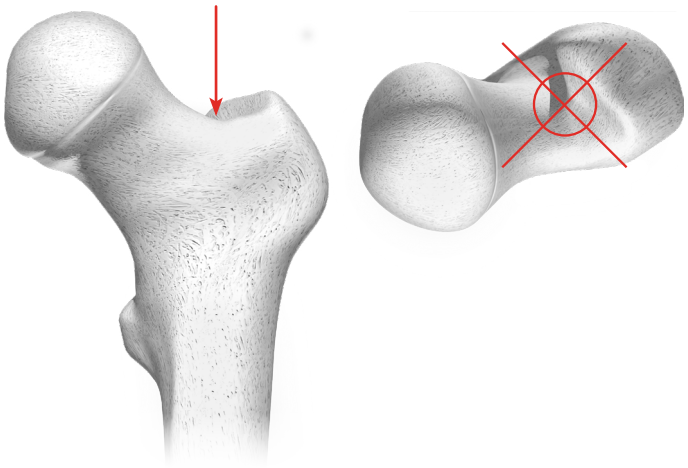
Place the patient supine on the operating table with applied orthopedic traction shoe. Surgery must be properly planned. It is necessary to take X-Ray images.



Surgical approach

Perform incision of soft tissues above the knee so that an easy access to the affected joint is provided.
In the case of presence of tumors in the knee area or prior prosthesis use, cut off the diseased joint ends using a bone saw.

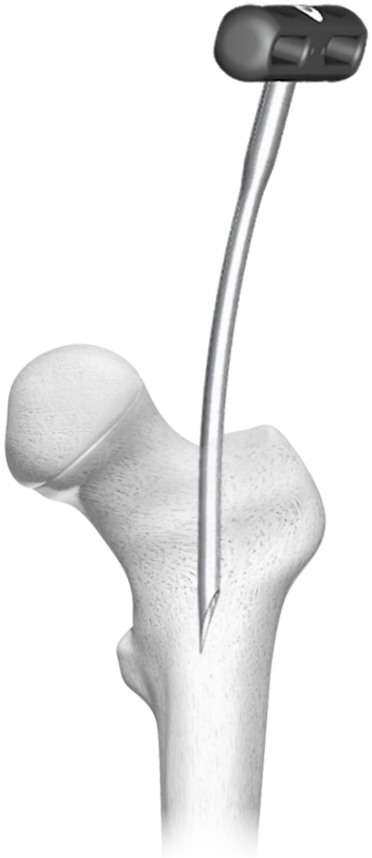
Perform a skin incision near the top of the greater trochanter.



Entry point for the nail.

4.2. OPENING OF THE MEDULLARY CANAL OF THE FEMUR

40.5523.000



1 Use curved awl 8.0 **[40.5523]** to open the medullary canal.

40.3925.580

40.1351.000

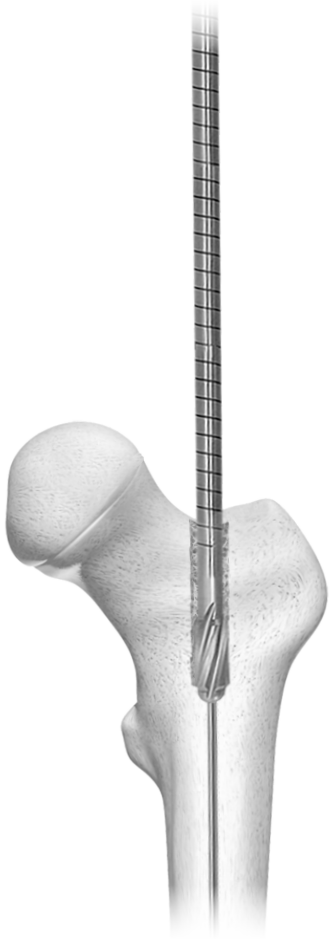
2 Having opened the medullary canal, insert (*under X-Ray control*) guide rod 3.0/580 **[40.3925.580]** using guide rod handle **[40.1351]** into the medullary canal at the depth until the tibia has been reached.

Remove guide rod handle **[40.1351]** and curved awl 8.0 **[40.5523]**.

4.3. REAMING MEDULLARY CANAL OF FEMUR

3 Using flexible reamers, gradually increase the diameter of the medullary canal with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the nail is reached. Ream the femur until the reamer enters the tibia.

Remove the flexible reamer and guide rod.



4.4. REAMING MEDULLARY CANAL OF TIBIA

	40.3925.580
	40.1351.000

4 Mount guide rod 3.0/580 **[40.3925.580]** to guide rod handle **[40.1351]** and enter the rod (*under X-Ray control*) into the medullary canal of the tibia until the desired depth is reached.

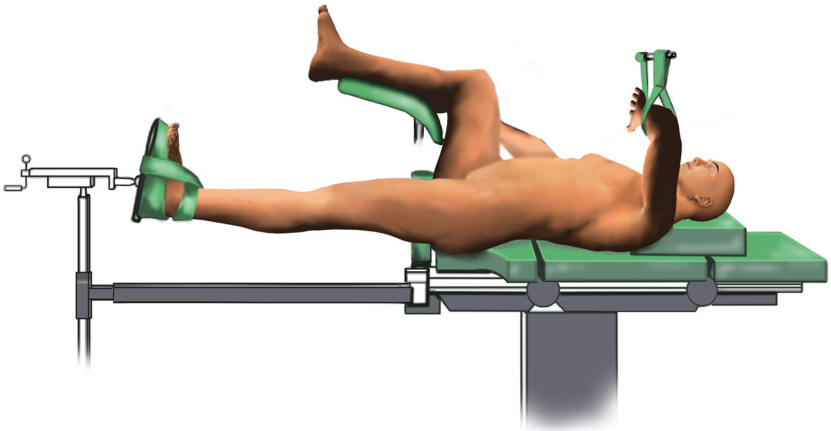
Remove guide rod handle **[40.1351]**..

5 Using flexible reamers, gradually increase the diameter of the medullary canal with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the nail is reached, for the depth equal to the tibia length.

Remove the flexible reamer and guide rod.

4.5. NAIL INSERTION

Prior to nail insertion, position the operated limb properly and place it in the orthopedic traction shoe.



40.5095.000

40.5091.000

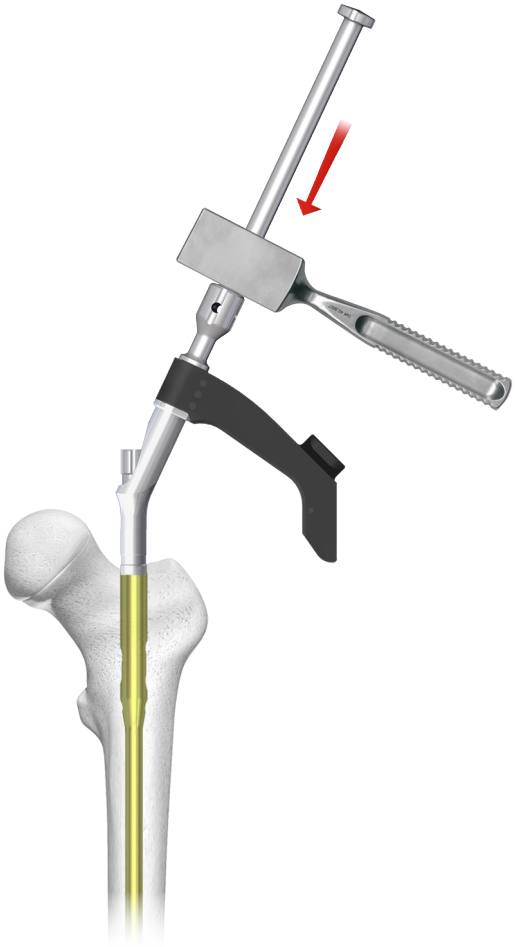
40.5526.100

6 Use the connecting screw M10x1 L=66 **[40.5095]** to fix the intramedullary nail to the targeter arm **[40.5091]**.


40.5507.000


40.3667.000

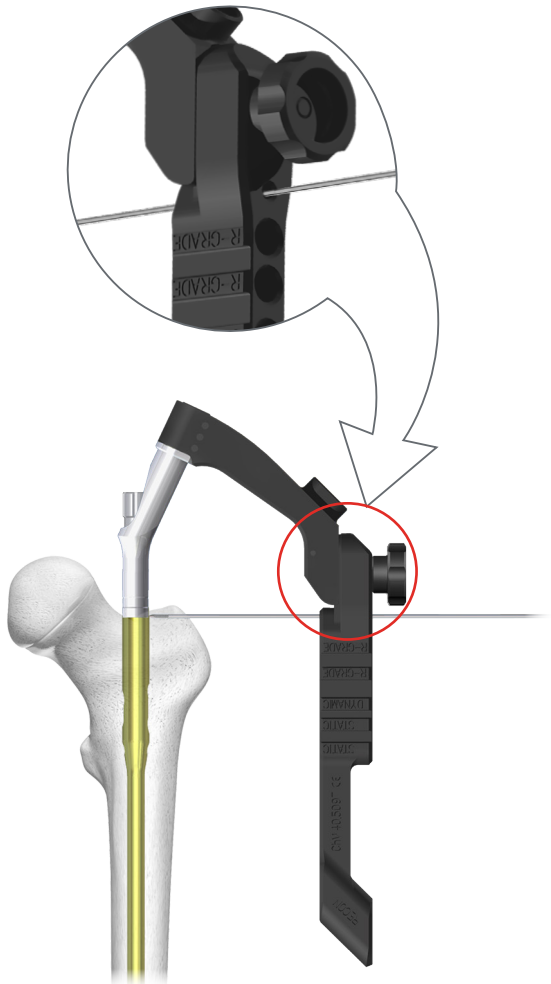
7 Mount the impactor-extractor **[40.5507]** to the targeter arm **[40.5091]** with fixed nail. Advance the nail, by pushing and maneuvering, into the medullary canal of the femur and tibia until the adequate depth is reached.



40.3333.000


40.5097.000

8 Mount the targeter 135 **[40.5097]** on the targeter arm **[40.5091]**. Insert Kirschner wire 2.0/380 in the hole (*marked "0"*) of the targeter 135 **[40.5097]** to verify correct placement of the nail in the medullary canal. The end of the wire shows the beginning of the nail.



4.6. RECONSTRUCTION METHOD

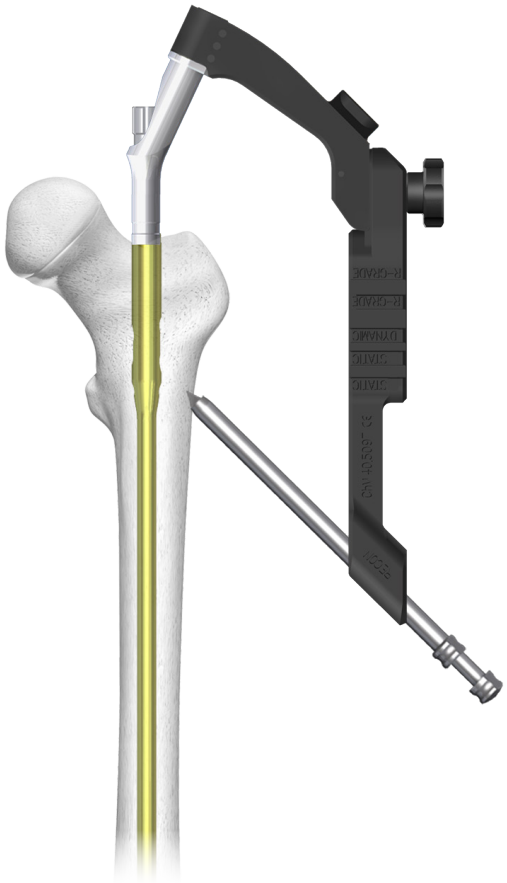
40.5097.000

40.3327.000

40.3328.000

9 Mount the targeter 135 **[40.5097]** to the targeter arm **[40.5091]**.
Insert the protective guide 11/9 **[40.3328]** with trocar 9 **[40.3327]** into the distal RECON hole of the targeter 135 **[40.5097]**. Mark on the skin the entry point for the screw and make adequate incision of soft tissues that passes through the marked place and the other screw insertion place. Advance the trocar until it reaches the cortex bone and mark the entry point for the drill.
Simultaneously, advance the protective guide together with trocar until its tip rests on the cortex bone.

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

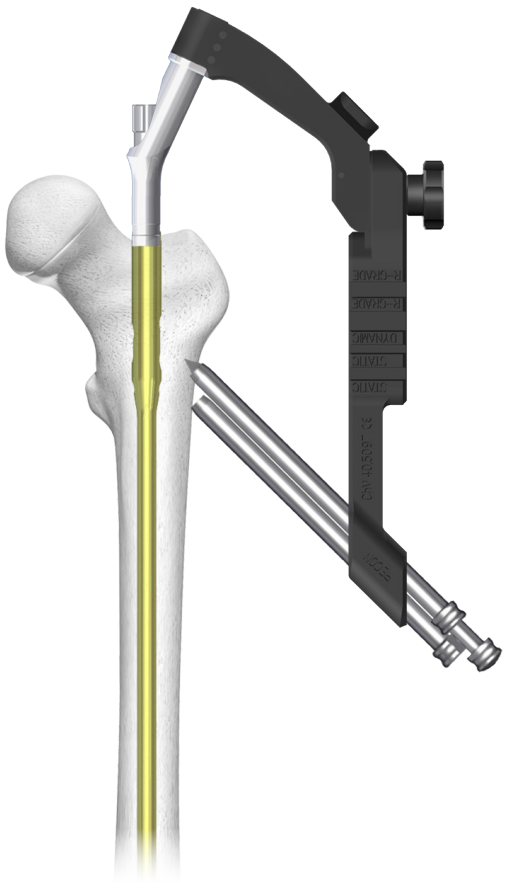


40.3327.000

40.3328.000

10 Insert the protective guide 11/9 **[40.3328]** with trocar 9 **[40.3327]** into the other RECON 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.



11 Insert Kirschner guide **[40.3331]** into the distally placed protective guide 11/9 **[40.3328]**. Mount Kirschner wire 2.0/380 **[40.3333]** to the surgical drive and place the wire into the femoral neck but do not perforate the femoral head. The above step should be controlled with X-Ray (*image in the drawing plane*). Verify the position of the wire in the other plane (*image in a plane perpendicular to the drawing plane*). The wire should be placed below the centre of the neck, so that the screw may be inserted near the bottom of the cortical layer without damaging the cortical wall of the neck. Use only new Kirschner wires 2.0/380 **[40.3333]** with diameter 2mm and length 380mm.
In the case of mis-positioning of the wire, repeat the step.

Remove Kirschner guide
Leave Kirschner wire in place.

12 Insert Kirschner guide **[40.3331]** into the other protective guide 11/9 **[40.3328]**. Mount Kirschner wire 2.0/380 **[40.3333]** to the surgical drive and place the wire into the femoral neck but do not perforate the femoral head. The above step should be controlled with X-Ray (*image in the drawing plane*). Verify the position of the wire in the other plane (*image in a plane perpendicular to the drawing plane*). Use only new Kirschner wires 2.0/380 **[40.3333]** with diameter 2mm and length 380mm.

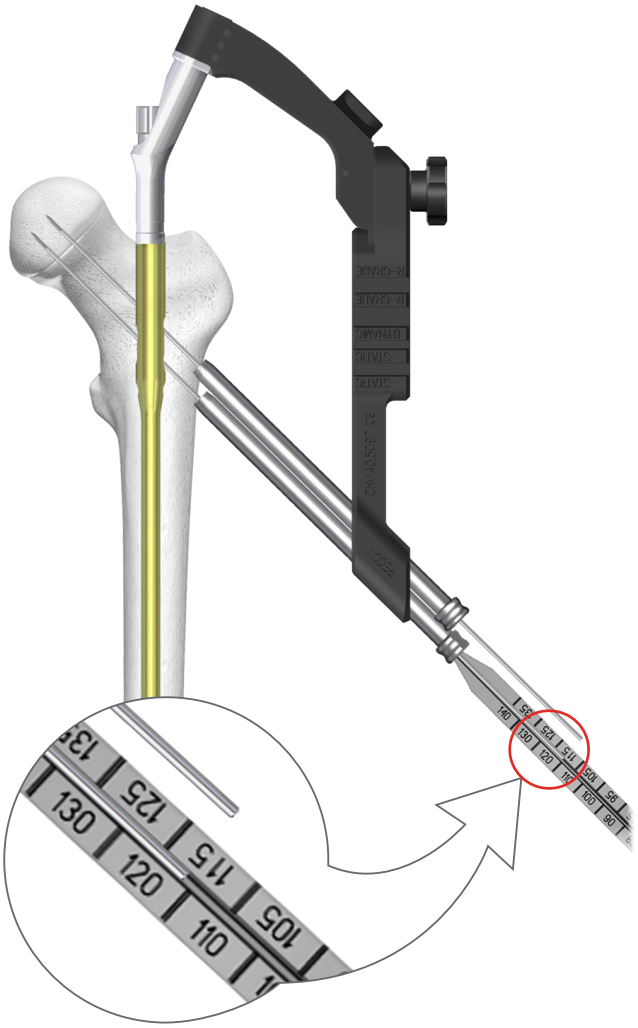
Remove Kirschner guide
Leave Kirschner wire in place.

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

40.3676.000

13 Insert cannulated screw length measure **[40.3676]** onto the Kirschner wire placed in the femoral neck until it rests on the protective guide. Read the length of the reconstruction cannulated screw on the measure scale indicated by the end of the Kirschner wire. During the measurement, the end of the cannulated screw length measure should be place against the protective guide.

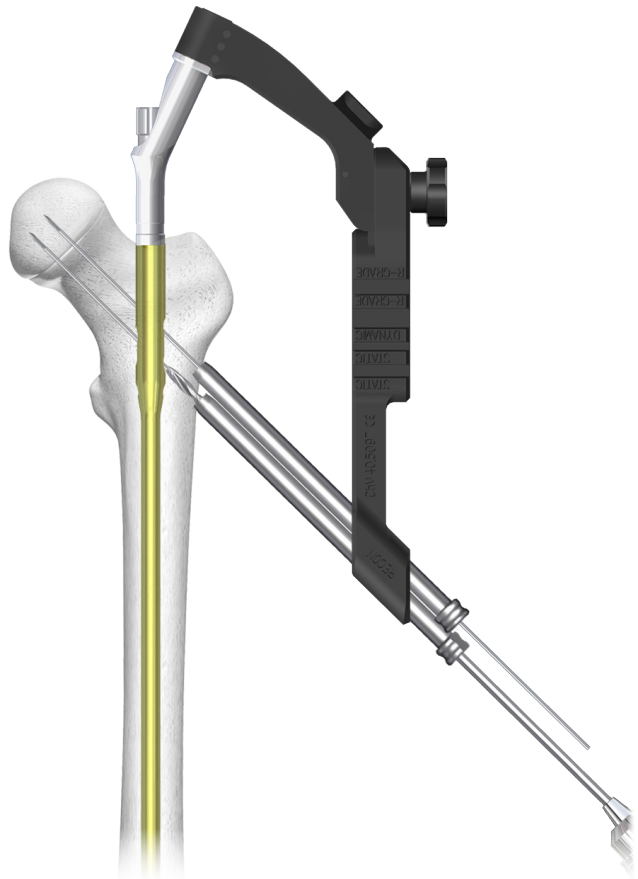
Remove cannulated screw length measure.
Leave Kirschner wire in place.



40.3674.000

14 Mount cannulated drill 6.5/2/300 **[40.3674]** to the drive then place it onto the Kirschner wire situated in the femoral neck and deepen the hole in the first cortical layer (*up to the nail*).

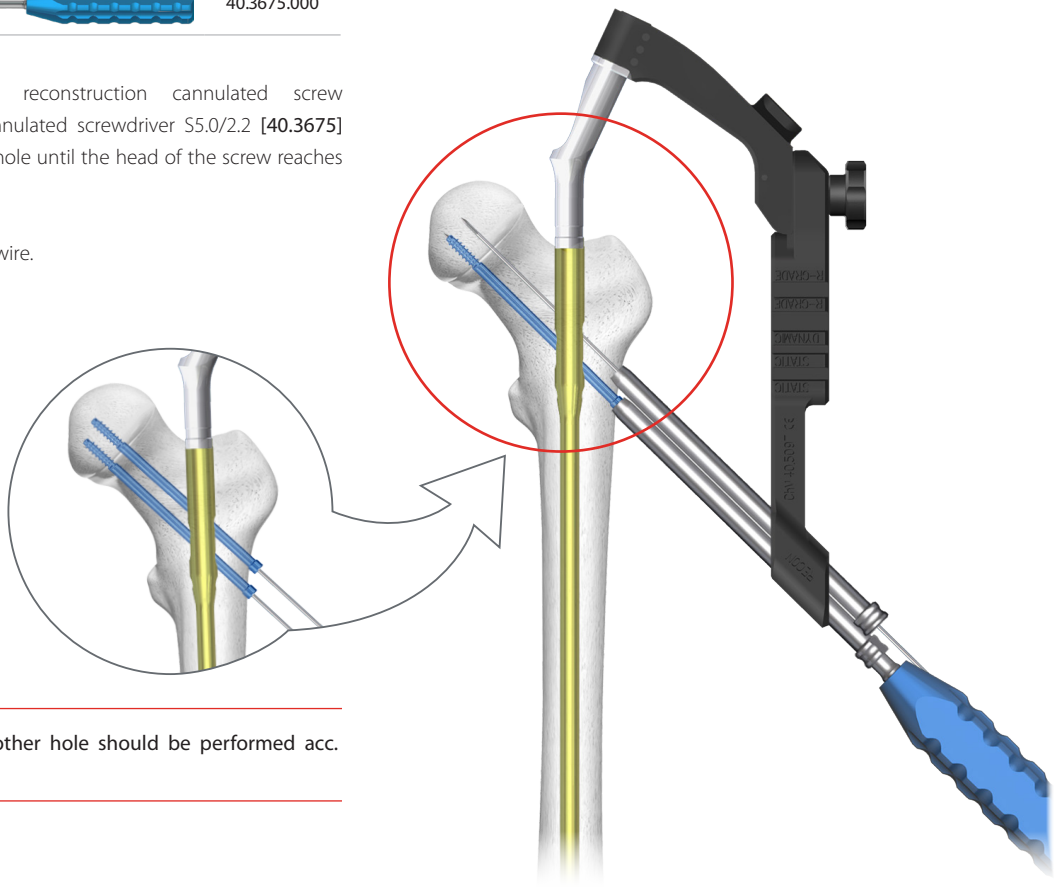
Remove the drill.
Leave Kirschner wire in place.



40.3675.000

15 Place the already defined reconstruction cannulated screw on the Kirschner wire. Use cannulated screwdriver S5.0/2.2 **[40.3675]** to advance the screw in the prepared hole until the head of the screw reaches the cortex bone.

Remove the screwdriver and Kirschner wire.
Kirschner wire is a single-use device.

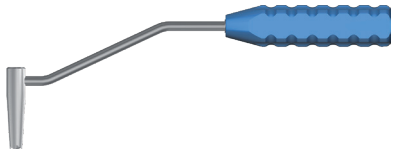


Locking the nail in the other hole should be performed acc. to points 10-15.

4.7. DISTAL LOCKING OF THE NAIL

Locking of the nail using "*freehand technique*" and targeter D **[40.1344]**.

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

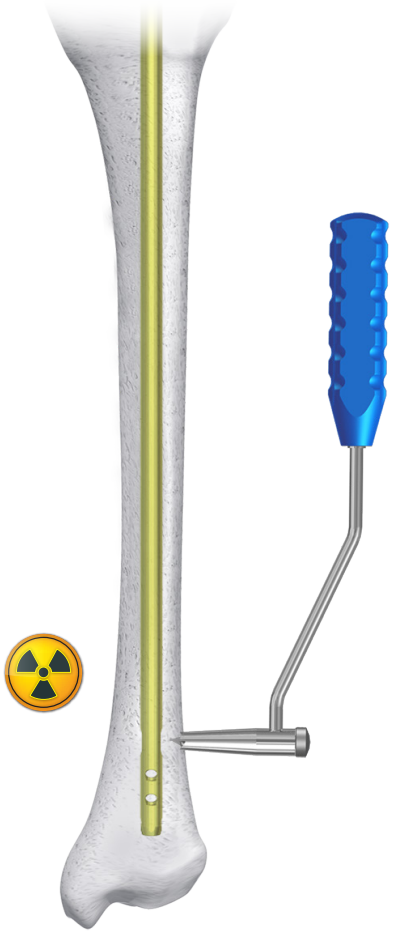


40.1344.000

40.1354.000

16 Using X-Ray device, 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 of the targeter and advance it until cortex is reached. Mark the entry point for the drill.

Remove the trocar.
Leave the targeter D in place.

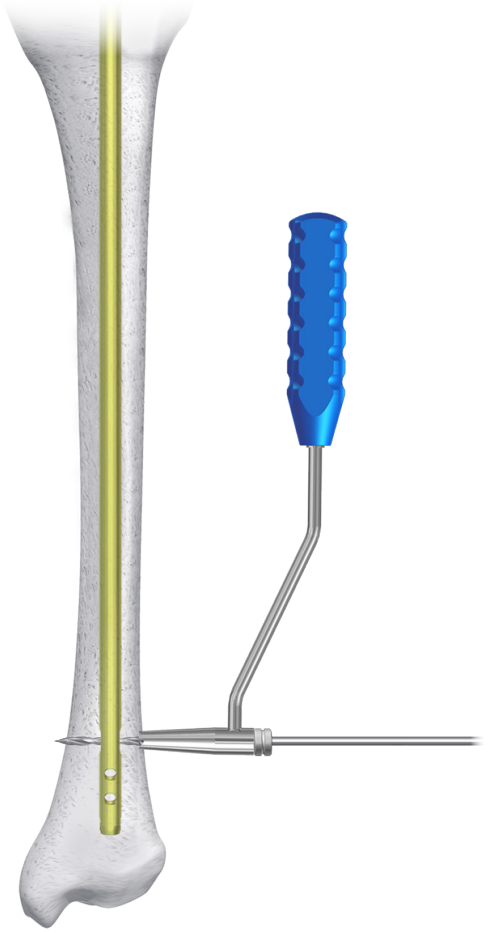



40.1358.000

40.5330.001

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

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

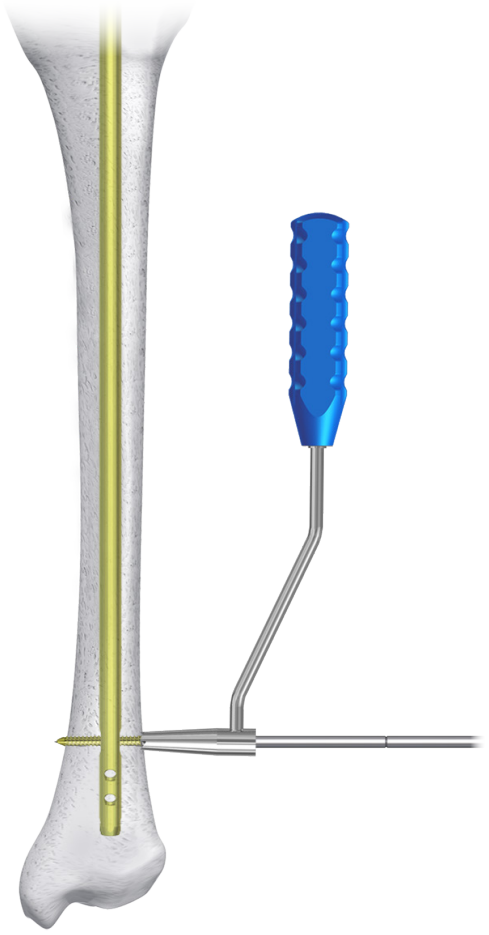



40.3604.000

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

Remove the screwdriver S3.5 and the targeter.

Locking the nail in the other holes should be performed acc. to points 16-18.



4.8. COMPRESSION METHODS

NOTE: Prior to this method, lock the nail distally first.

IMPORTANT: Use DYNAMIC hole of targeter 135 [40.5097] for screw insertion in compression method.

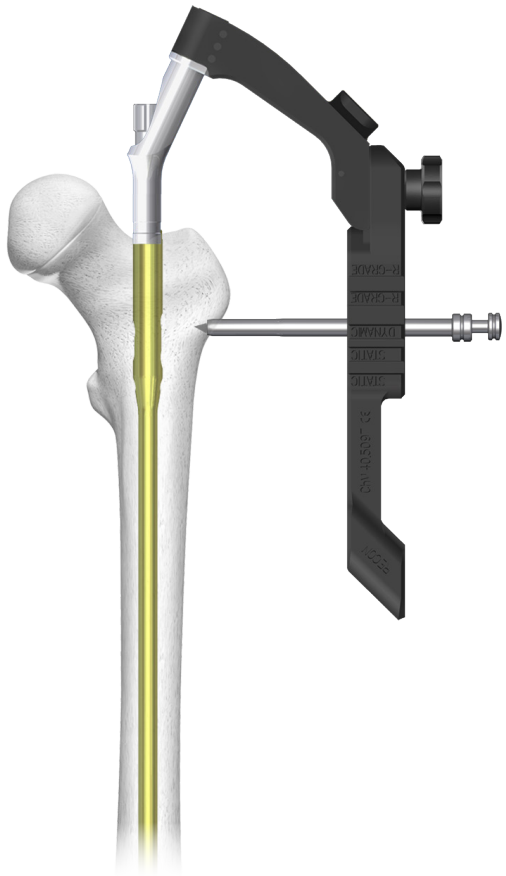
40.5097.000

40.3614.000

40.3617.000

19 Mount the targeter 135 **[40.5097]** on the targeter arm **[40.5091]**. Insert the protective guide 9/6.5 **[40.3614]** with trocar 6.5 **[40.3617]** into the proximal hole of the targeter 135 **[40.5097]**. Mark on the skin the entry point for the locking screw and make adequate incision through soft tissues about 1.5cm in length. Advance the trocar until it reaches the cortex and mark the drill entry point. Advance the protective guide together with trocar until it touches the cortex.

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

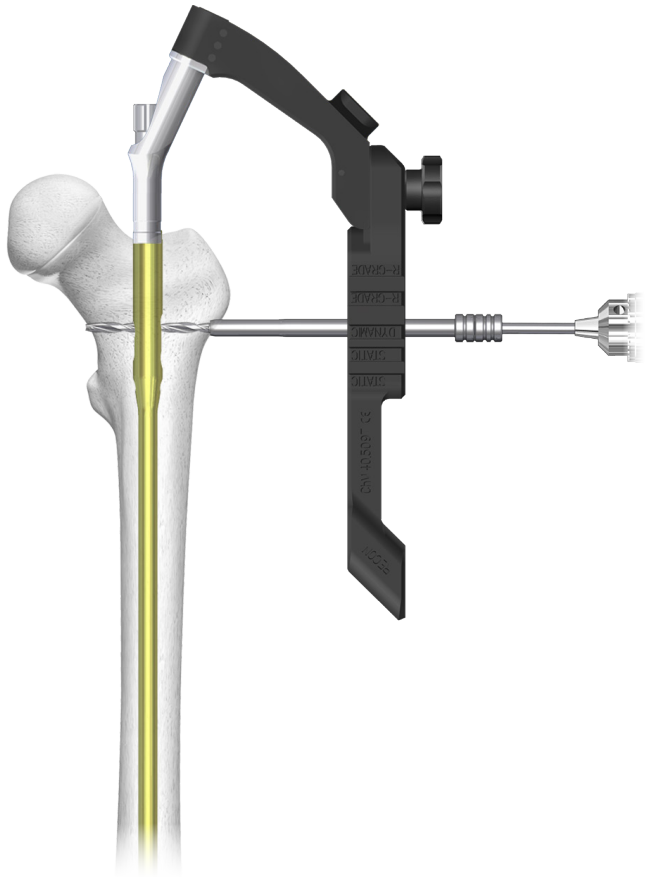


40.3615.000

40.5330.001

20 Insert the drill guide 6.5/3.5 **[40.3615]** into the protective guide. Mount the drill with scale 3.5/270 **[40.5330.001]** to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the hole in the nail. The scale on the drill shows the length of the locking element.

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

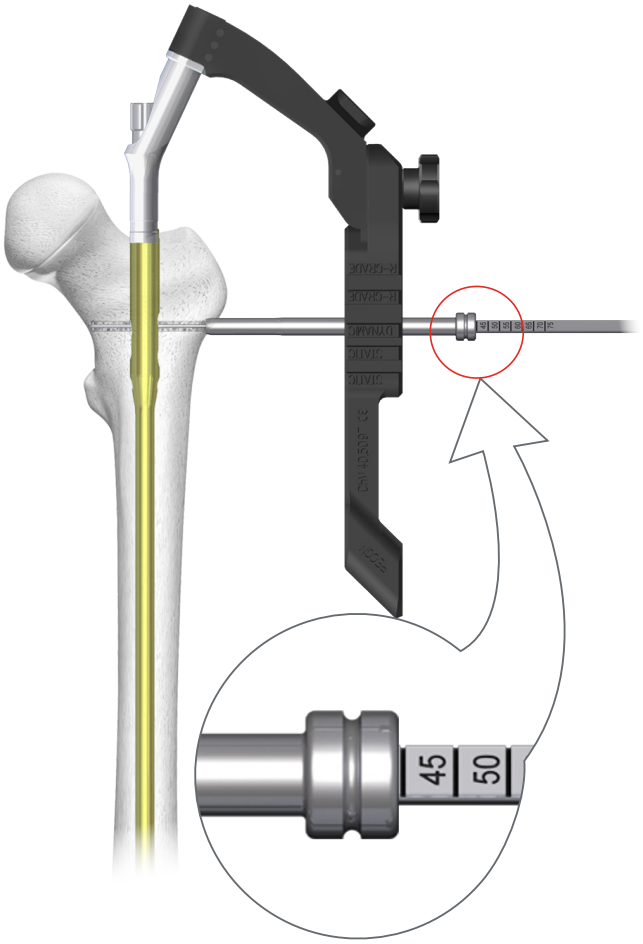


40.3614.000

40.1374.000

21 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.

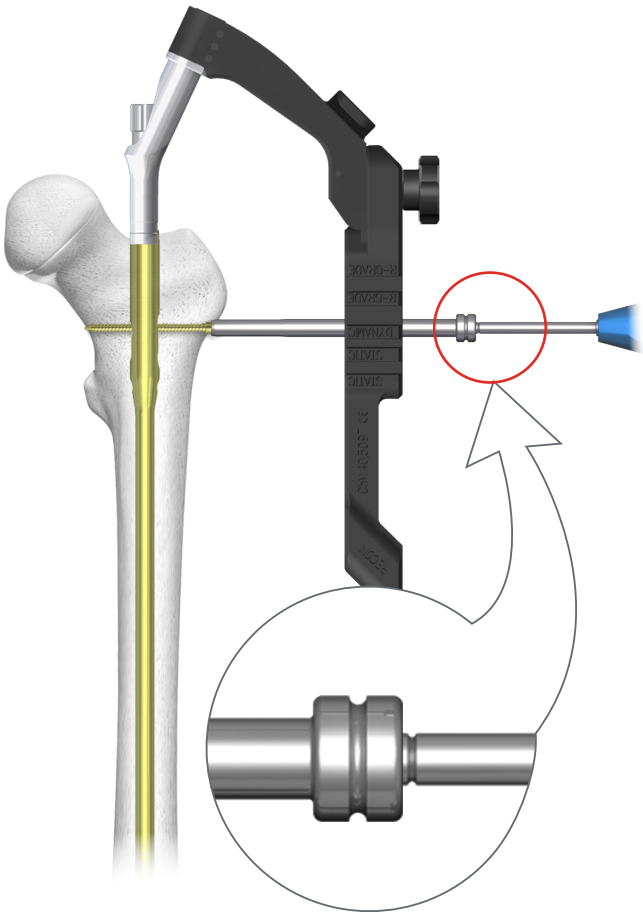
Remove the screw length measure.
Leave the protective guide in the hole of the targeter.



40.3604.000

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 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*).

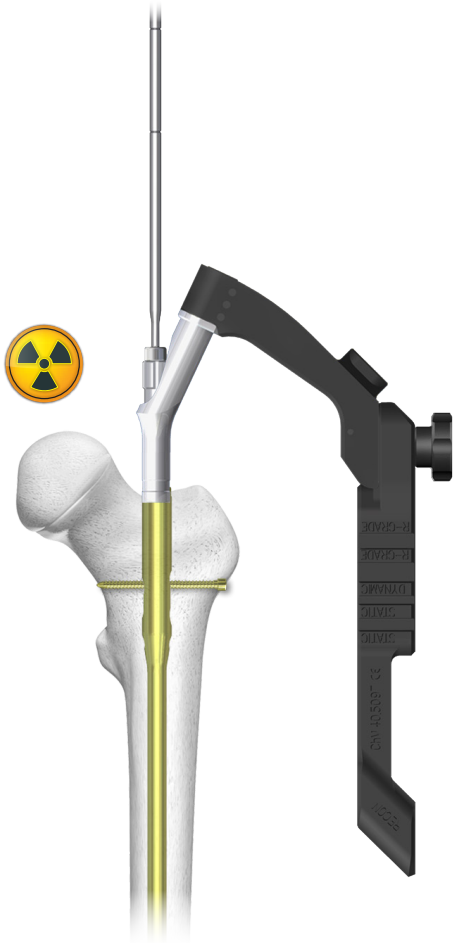
Remove the screwdriver and protective guide.



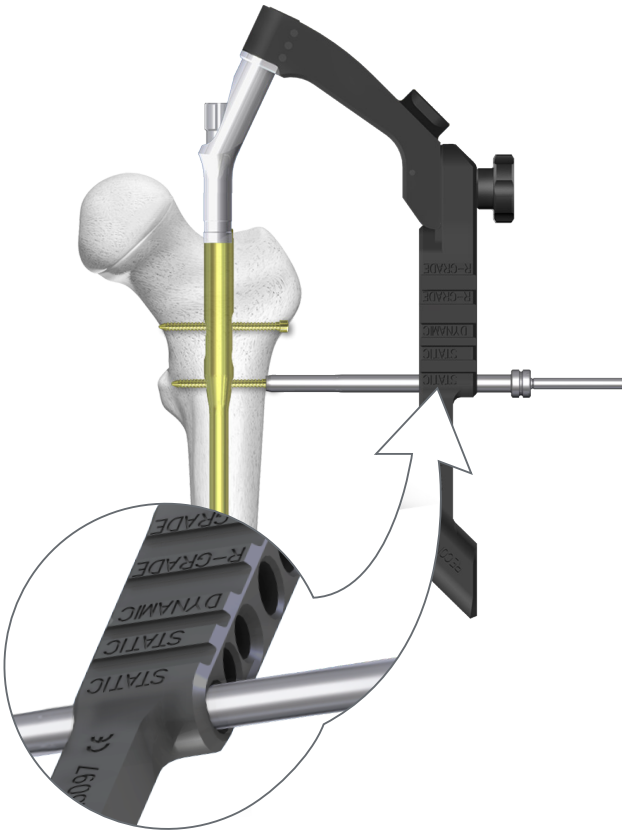
40.3604.000

40.5096.000

23 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 that connects the intramedullary nail with the targeter arm. When front of the screw reaches the shaft of locking screw, further screwing will cause the compression of femur and tibia.
The above steps should be controlled with X-Ray image intensifier.



24 In order to maintain the compression, lock the nail using the STATIC hole of targeter 135.



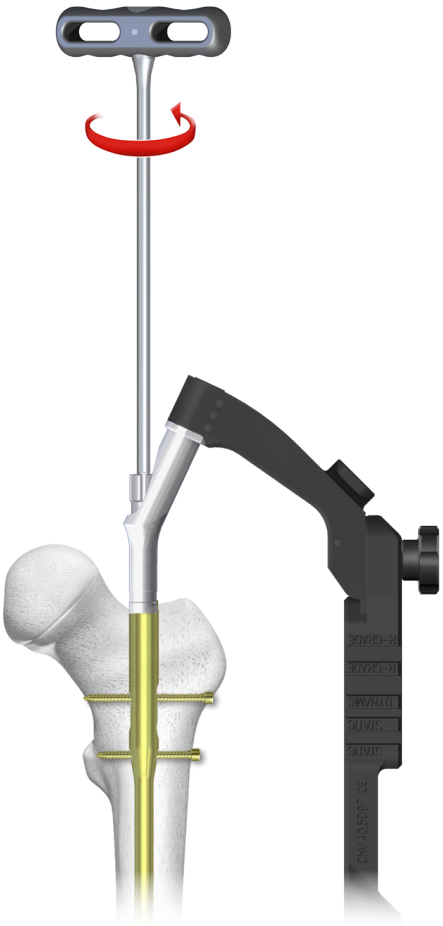
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

4.9. TARGETER REMOVAL, END CAP INSERTION

40.5526.100

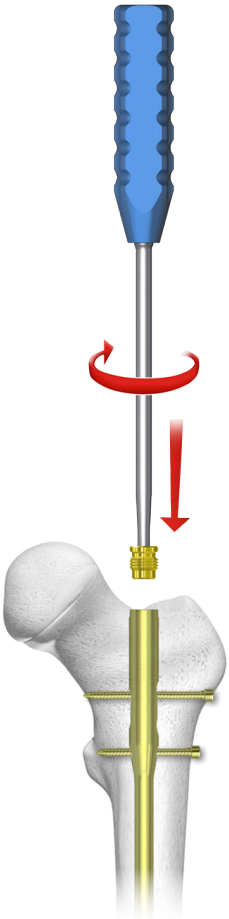
40.5095.000

25 Using the wrench S10 **[40.5526.100]** remove connecting screw **[40.5095]** from the nail and then remove the targeter from the nail locked in the medullary canal.



40.3675.000

26 In order to secure the inner thread of the nail from bone ingrowth, insert the end cap using the cannulated screwdriver S5.0/2.2 **[40.3675]**.



4.10. STATIC METHOD

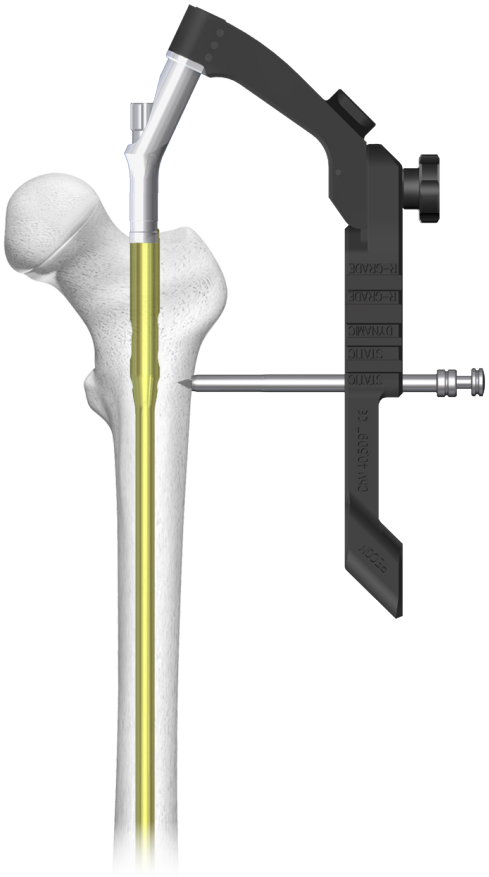

40.5097.000


40.3614.000


40.3617.000

27 Insert the protective guide 9/6.5 **[40.3614]** with trocar 6.5 **[40.3617]** into the distal hole of the targeter 135. Mark on the skin the entry point for the locking screw insertion and make adequate about 1.5cm long incision through the soft tissues. Advance the trocar until it reaches the cortex and mark the entry point for the drill. Advance protective guide together with trocar until it touches the cortex.

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

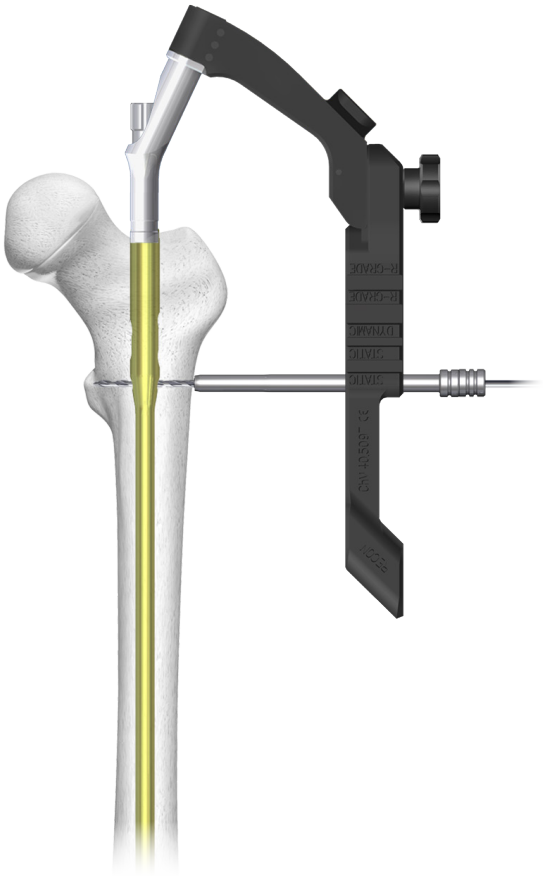



40.3615.000

40.5330.001

28 Insert the drill guide 6.5/3.5 **[40.3615]** into the protective guide 9/6.5 **[40.3614]**. Mount the drill with scale 3.5/270 **[40.5330.001]** to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the hole in the nail. The scale on the drill shows the length of the locking element.

Remove the drill and drill guide.



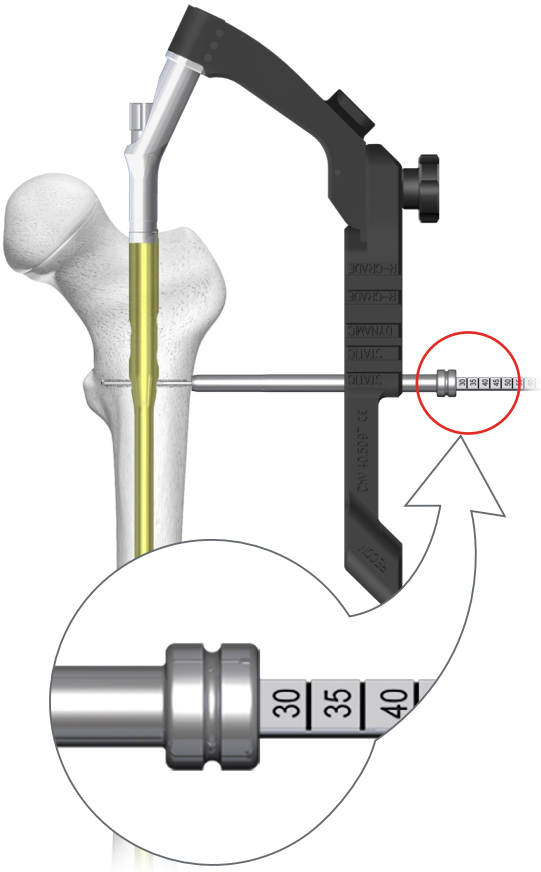
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.


40.3614.000

40.1374.000

29 Leave protective guide in the targeter hole. 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.

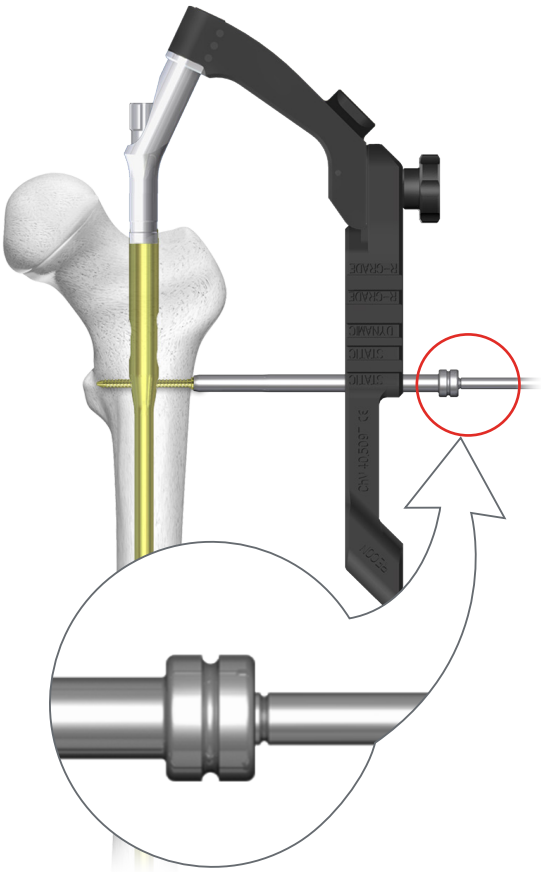
Remove the screw length measure.
Leave the protective guide in the hole of the targeter.




40.3604.000

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 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.

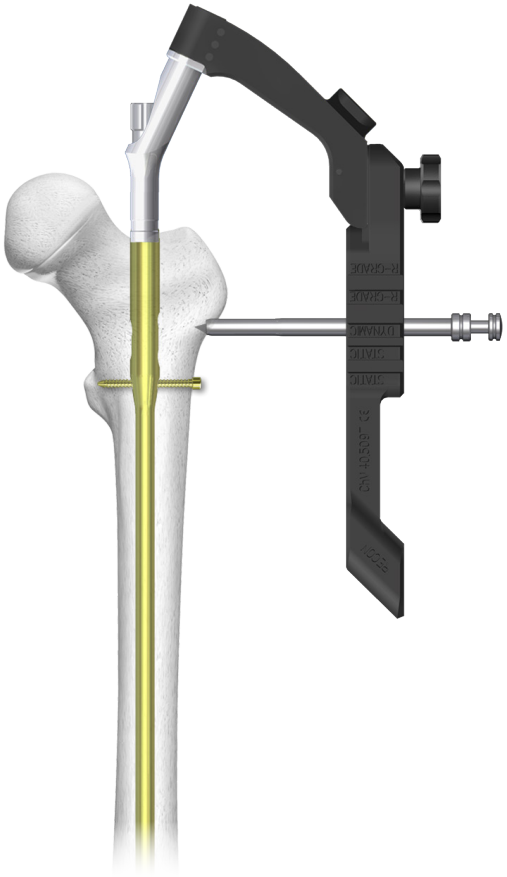



40.3614.000


40.3617.000

31 Insert the protective guide 9/6.5 **[40.3614]** with trocar 6.5 **[40.3617]** into the proximal hole of the targeter 135. Advance the trocar until it reaches the 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.

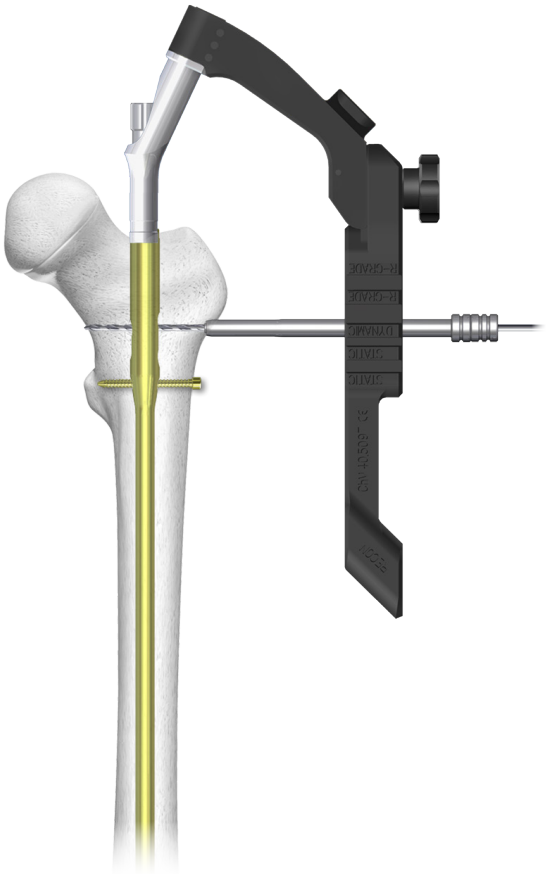



40.3615.000


40.5330.001

32 Insert the drill guide 6.5/3.5 **[40.3615]** into the protective guide. Mount the drill with scale 3.5/270 **[40.5330.001]** to the surgical drive and advance it through the drill guide. Drill the hole in the femur through its both cortex layers and the nail hole. The scale on the drill shows the length of the locking element.

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

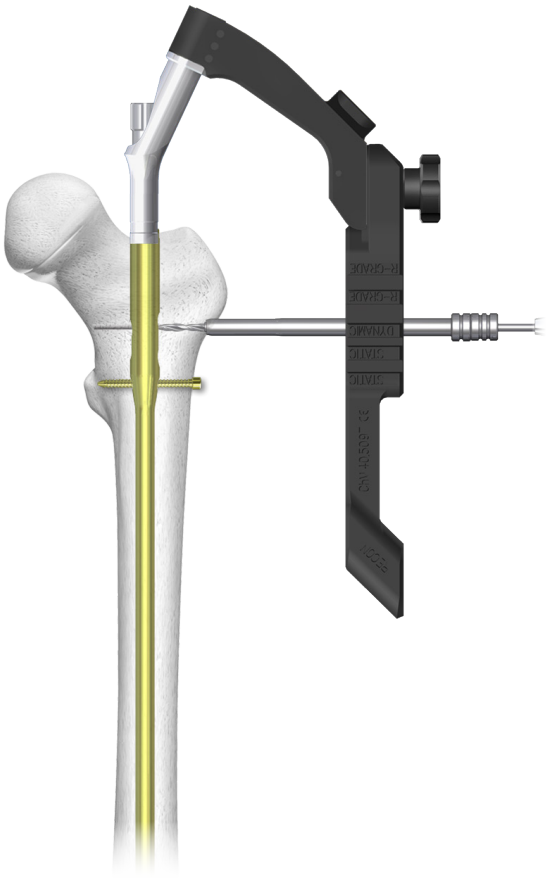



40.3696.000

40.5330.001

33 Insert the drill guide 6.5/4.5 **[40.3696]** into the protective guide.
Mount the drill 4.5/270 **[40.1387.001]** to the surgical drive and advance it through the drill guide. Drill the hole in the femur only through its first cortex up to the hole in the nail.

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

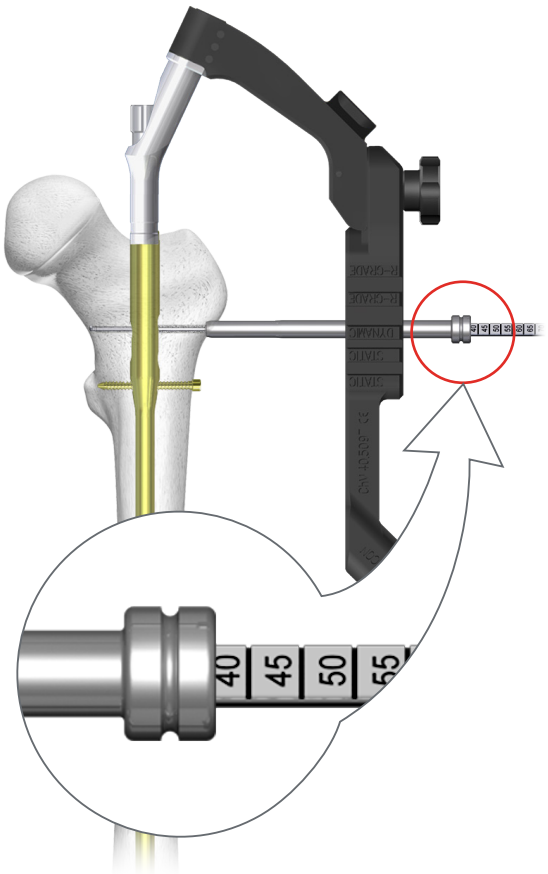



40.3614.000

40.1374.000

34 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.

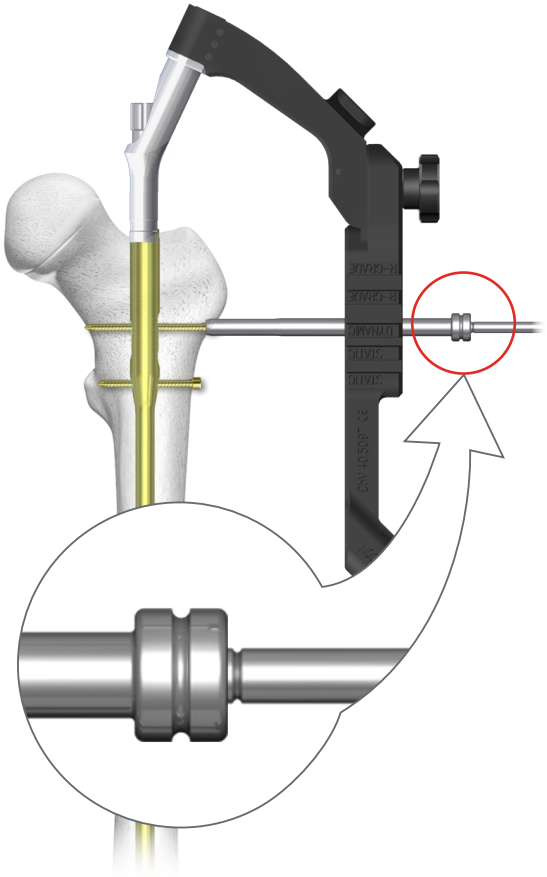
Remove the screw length measure.
Leave the protective guide in the hole of the targeter.



40.3604.000

35 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.

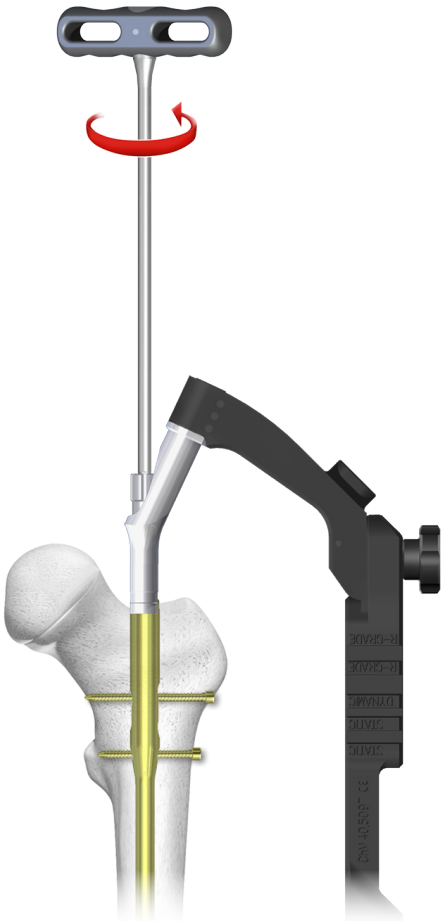


4.11. TARGETER REMOVAL, END CAP INSERTION

40.5526.100

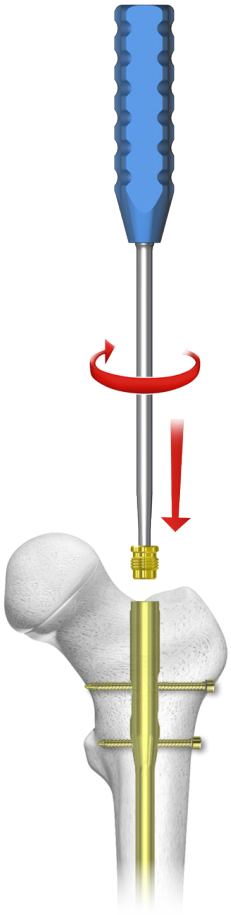
40.5095.000

36 Using the wrench S10 **[40.5526.100]** unscrew the connecting screw **[40.5095]** from the nail shaft and dismount the targeter from the nail locked in the medullary canal.

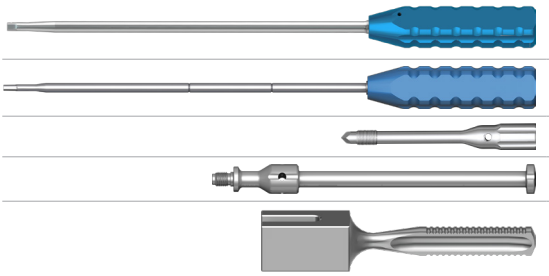



40.3675.000

37 In order to secure the inner thread of the nail from bone ingrowth, insert the end cap using the cannulated screwdriver S5.0/2.2 **[40.3675]**.

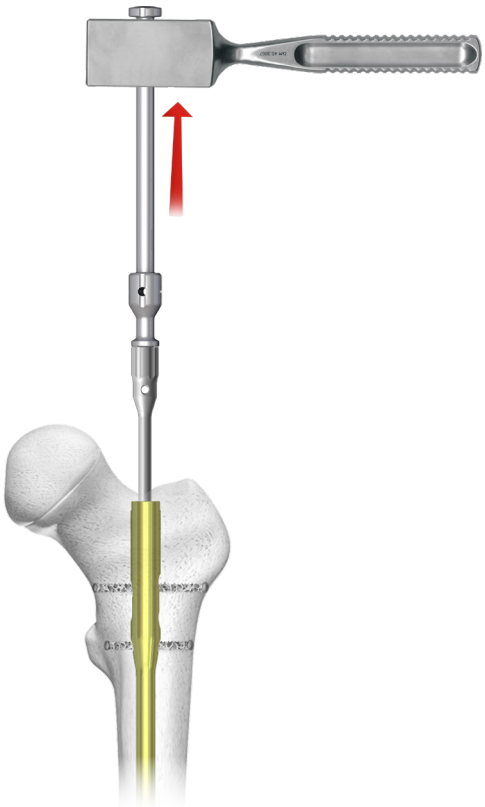


4.12. NAIL REMOVAL


40.3675.000
40.3604.000
40.5071.000
40.5507.000
40.3667.000

38 Use the cannulated screwdriver S5.0/2.2 **[40.3675]** to remove the end cap. Use screwdriver S3.5 **[40.3604]** to remove all the locking screws. Insert the connector M10x1/M12 **[40.5071]** into the threaded nail hole.
Attach the impactor-extractor **[40.5507]** to the connector and with the help of the mallet **[40.3667]** extract the nail from the medullary canal.

NOTE: **Prior to nail extraction, remove all locking elements.**



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