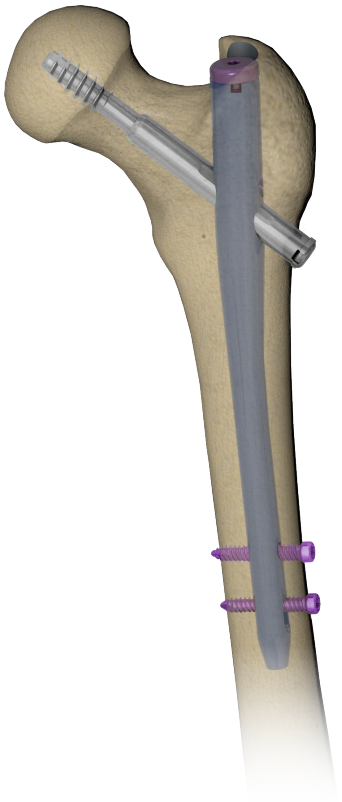
ChM®

Charfix Femoral Nail
ChFN system 2

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH TROCHANTERIC NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.6340.500*
- *INSTRUMENT SET 40.6340.510*
- *SURGICAL TECHNIQUE*



SYMBOLS DESCRIPTIONS	
	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceedings
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.

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I. INTRODUCTION

Intramedullary osteosynthesis of femur with Charfix Femoral Nail ChFN system 2 femoral nail consists of:

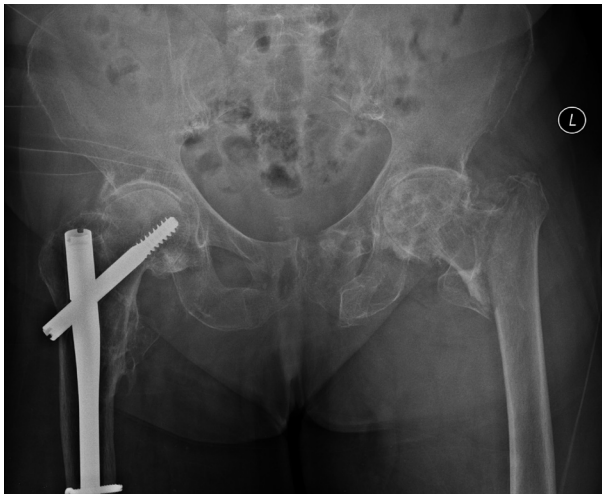
- implants *(intramedullary nail, distal screws, join screws, end caps)*,
- instrument set for implants insertion and removal,
- instructions for use *(surgical technique)*.

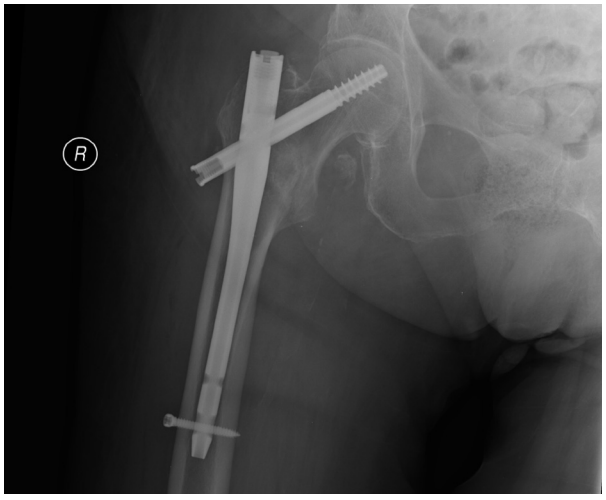
Intramedullary osteosynthesis of femur with trochanteric nails allows for stable reduction of femur pertrochanteric fractures. Application of two join screws eliminates rotation of the femur neck.

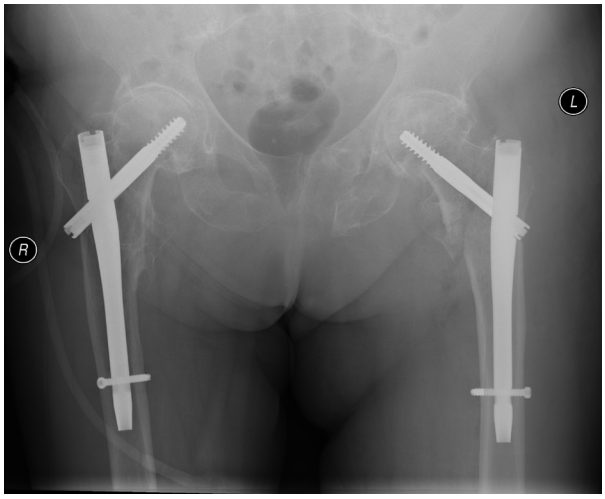
The presented range of implants is made of titanium and its alloys and implantable steel in accordance with ISO 5832 standard. Compliance with the requirements of Quality Management Systems ISO 9001, EN ISO 13485 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality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

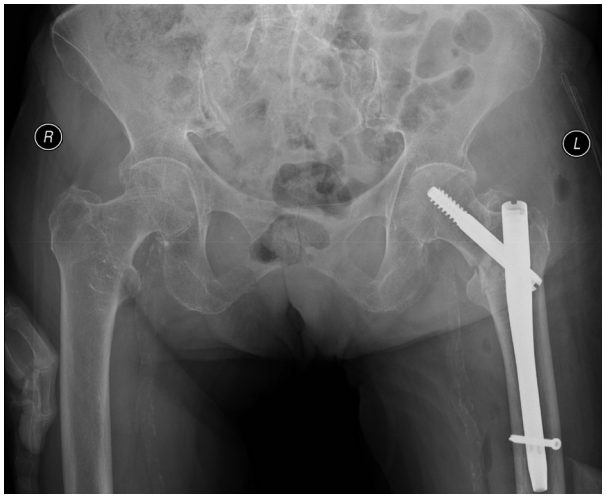
Indicated use:
- subtrochanteric fractures,
- intertrochanteric fractures,
- pertrochanteric fractures.

Examples of femur fractures treated with trochanteric nails.









Good results are also obtained in the case of:
- Pathological *(one-place)* and ipsilateral damage of intertrochanteric region,
- Pathological *(one-place)* and ipsilateral damage of femoral shaft.

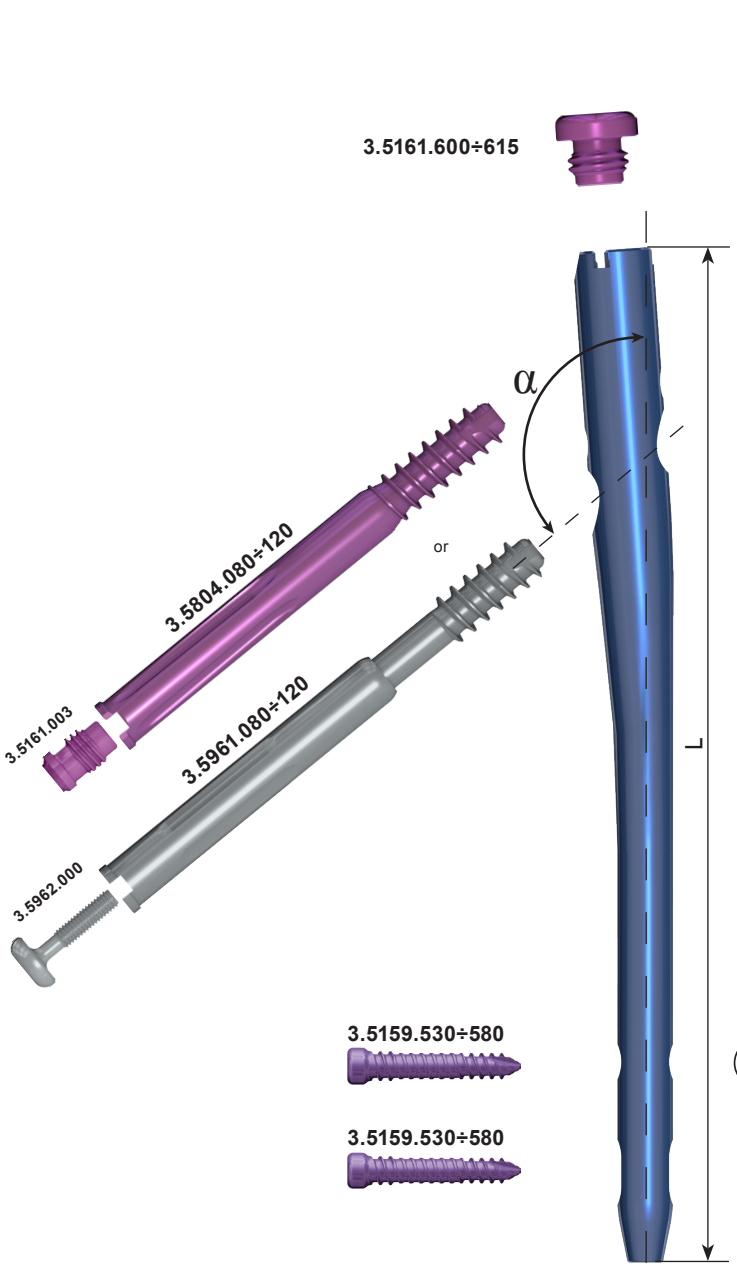
Trochanteric nails are also used in the case of:
- Multifragmentary fractures of trochanteric-subtrochanteric region,
- Basic fractures of the femur neck.

Charfix Femoral Nail
ChFN system 2

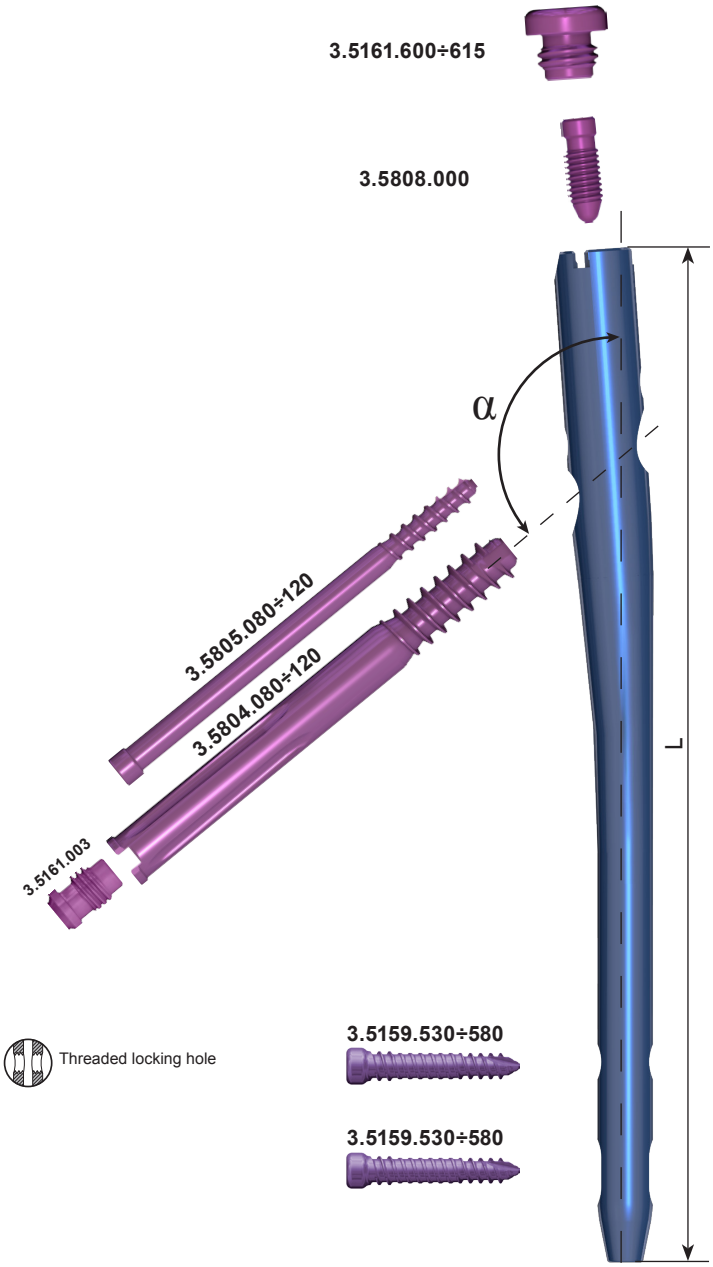
TITANIUM ALLOY Ti

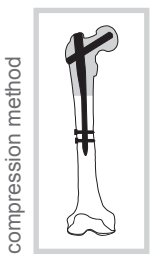
II. IMPLANTS

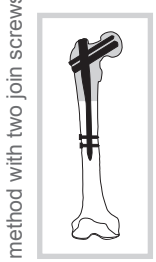
ChFN2 TROCHANTERIC NAIL



Threaded locking hole







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ChFN2 TROCHANTERIC NAIL

		Titanium		
L [mm]	ø	α 125°	α 130°	α 135°
180 200	10	3.5639.180 3.5639.200	3.5651.180 3.5651.200	3.5663.180 3.5663.200
180 200	11	3.5640.180 3.5640.200	3.5652.180 3.5652.200	3.5664.180 3.5664.200
180 200	12	3.5641.180 3.5641.200	3.5653.180 3.5653.200	3.5665.180 3.5665.200

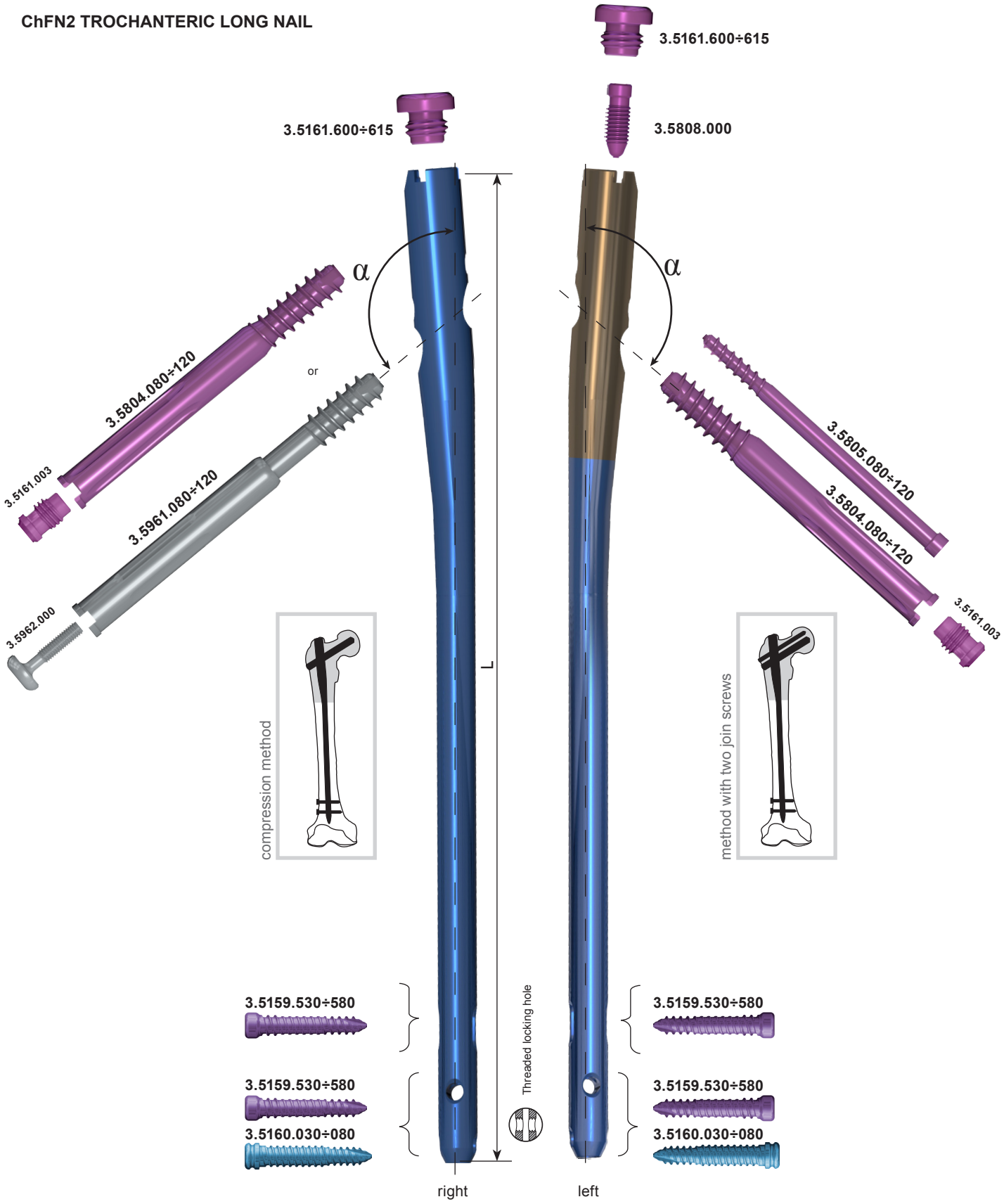
Recommended

available	
Ø [mm] pitch 1 mm	10÷12
L [mm] pitch 5 mm	170÷280

Titanium	Ø10	Ø11	Ø12
colours			

Charfix Femoral Nail
ChFN system 2
TITANIUM ALLOY Ti

ChFN2 TROCHANTERIC LONG NAIL



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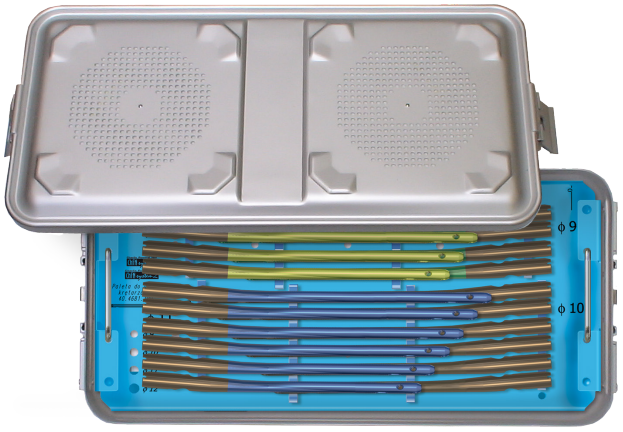
ChFN2 TROCHANTERIC LONG NAIL

L [mm]	Ø	Titanium α 125° left	Titanium α 125° right	Titanium α 130° left	Titanium α 130° right	Titanium α 135° left	Titanium α 135° right
340	10	3.5737.340	3.5738.340	3.5761.340	3.5762.340	3.5785.340	3.5786.340
360		3.5737.360	3.5738.360	3.5761.360	3.5762.360	3.5785.360	3.5786.360
380		3.5737.380	3.5738.380	3.5761.380	3.5762.380	3.5785.380	3.5786.380
400		3.5737.400	3.5738.400	3.5761.400	3.5762.400	3.5785.400	3.5786.400
420		3.5737.420	3.5738.420	3.5761.420	3.5762.420	3.5785.420	3.5786.420
340	11	3.5739.340	3.5740.340	3.5763.340	3.5764.340	3.5787.340	3.5788.340
360		3.5739.360	3.5740.360	3.5763.360	3.5764.360	3.5787.360	3.5788.360
380		3.5739.380	3.5740.380	3.5763.380	3.5764.380	3.5787.380	3.5788.380
400		3.5739.400	3.5740.400	3.5763.400	3.5764.400	3.5787.400	3.5788.400
420		3.5739.420	3.5740.420	3.5763.420	3.5764.420	3.5787.420	3.5788.420
340	12	3.5741.340	3.5742.340	3.5765.340	3.5766.340	3.5789.340	3.5790.340
360		3.5741.360	3.5742.360	3.5765.360	3.5766.360	3.5789.360	3.5790.360
380		3.5741.380	3.5742.380	3.5765.380	3.5766.380	3.5789.380	3.5790.380
400		3.5741.400	3.5742.400	3.5765.400	3.5766.400	3.5789.400	3.5790.400
420		3.5741.420	3.5742.420	3.5765.420	3.5766.420	3.5789.420	3.5790.420

Recommended

available	
Ø [mm] pitch 1 mm	10÷12
L [mm] pitch 5 mm	300÷480

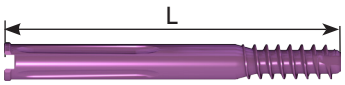


Titanium	Ø10	Ø11	Ø12
left			
right			
colours			

40.4681.100
Palette for trochanteric nails *(implants not included)*

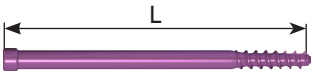
LOCKING ELEMENTS

ChFN2 Join screw 10.5



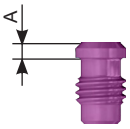
L [mm]	Catalogue no. Titanium
80	3.5804.080
85	3.5804.085
90	3.5804.090
95	3.5804.095
100	3.5804.100
105	3.5804.105
110	3.5804.110
115	3.5804.115
120	3.5804.120

ChFN2 Join screw 5.0



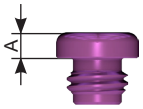
L [mm]	Catalogue no. Titanium
80	3.5805.080
85	3.5805.085
90	3.5805.090
95	3.5805.095
100	3.5805.100
105	3.5805.105
110	3.5805.110
115	3.5805.115
120	3.5805.120

CHARFIX2 End cap M8



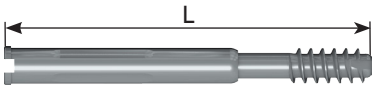
A	Catalogue no. Titanium
+3	3.5161.003

ChFN2 End cap M12x1.75



A	Catalogue no. Titanium
0	3.5161.600
+5	3.5161.605
+10	3.5161.610
+15	3.5161.615

ChFN2 Telescopic join screw 10.5



L [mm]	Catalogue no. Titanium
80	3.5961.080
85	3.5961.085
90	3.5961.090
95	3.5961.095
100	3.5961.100
105	3.5961.105
110	3.5961.110
115	3.5961.115
120	3.5961.120

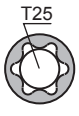
ChFN2 Compression screw

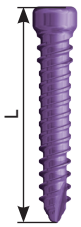
Catalogue no. Titanium
3.5962.000

ChFN2 Setting screw M6

Catalogue no. Titanium
3.5808.000

CHARFIX2 Distal screw 5.0

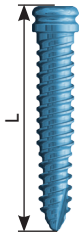




L [mm]	Catalogue no. Titanium
30	3.5159.530
35	3.5159.535
40	3.5159.540
45	3.5159.545
50	3.5159.550
55	3.5159.555
60	3.5159.560
65	3.5159.565
70	3.5159.570
75	3.5159.575
80	3.5159.580

L [mm]	available 16 ÷ 90

CHARFIX2 Distal screw 5.5



L [mm]	Catalogue no. Titanium
30	3.5160.030
35	3.5160.035
40	3.5160.040
45	3.5160.045
50	3.5160.050
55	3.5160.055
60	3.5160.060
65	3.5160.065
70	3.5160.070
75	3.5160.075
80	3.5160.080

L [mm]	available 16 ÷ 90

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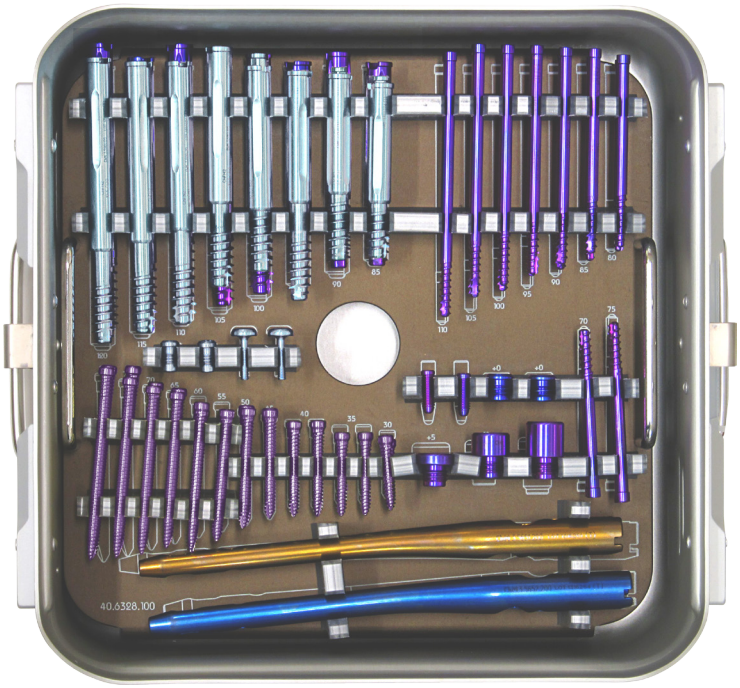
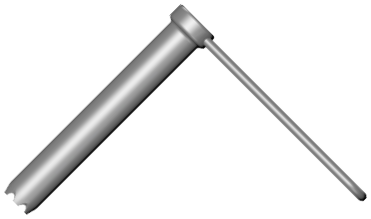
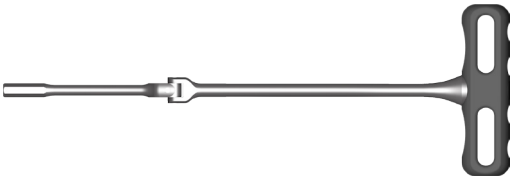
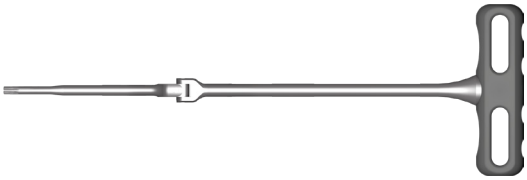
LOCKING ELEMENTS



40.6328.000
Stand for ChFN2 trochanteric nails
(set with a container without implants)

III. INSTRUMENT SET

INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS 40.6340.500				
No.		**Name**	**Catalogue No.**	**Pcs**
1		Targeter arm	**40.6341.000**	1
2		Targeter 120/130	**40.6342.000**	1
3		Targeter 125/135	**40.6343.000**	1
5		Connecting screw M12x1.75	**40.6305.000**	1
6		Drill guide 14/11.5	**40.6346.000**	1
7		Protective guide 11.5/3.2	**40.6347.000**	1
8		Drill guide 9.0/6.0	**40.6348.000**	1
9		Protective guide 6.0/3.2	**40.6349.000**	1
10		Trocar 3.2	**40.6350.000**	1
11		Gradual drill 10.5/7	**40.6351.000**	1
12		Drill 5.0	**40.6352.000**	1
13		Cannulated drill 16.0	**40.6313.000**	1
14		Protective guide 16.0	**40.6314.000**	1
15		Guide 16/3.2	**40.6315.000**	1
16		Guide rod 3.2/500	**40.6356.100**	4
17		Compression wrench	**40.6357.000**	1
18		Cannulated screw length measure	**40.6548.000**	1
19		Wrench for self-aligning joint S7	**40.6319.000**	1
20		Wrench for self-aligning joint T25	**40.6320.000**	1
21		Screwdriver T25 with holder	**40.6361.000**	1

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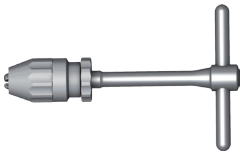
INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS 40.6340.500				
No.		**Name**	**Catalogue No.**	**Pcs**
22		Protective guide 12/10	**40.6353.000**	2
23		Drill guide 10/4	**40.6362.000**	2
24		Trocar 10	**40.6355.000**	1
25		Wrench S10	**40.5526.100**	1
26		Drill with scale 4.0	**40.5346.002**	2
27		Mallet	**40.3667.000**	1
28		Impactor-extractor	**40.5507.000**	1
29		Curved awl 8.0	**40.5523.000**	1
30		Guide 11.5/6	**40.6363.000**	1
31		Screw length measure	**40.6358.000**	1
32		Guide rod 3.0/580	**40.3925.580**	1
33		Steinmann handle	**40.0987.200**	1
34		Stand for instrument set for ChFN2 trochanteric nails	**40.6369.500**	1

INSTRUMENT SET FOR ChFN2 TROCHANTERIC NAILS - II 40.6340.510				
No.		**Name**	**Catalogue No.**	**Pcs**
1		Distal targeter D	**40.6344.000**	1
2		ChFN2 trial	**40.6360.000**	1
3		Set block 12/5.0/4.0	**40.6359.000**	2
4		Connector of extractor M12x1.75	**40.6345.000**	1
5		Nail length measure	**40.5098.000**	1
6		Teflon pipe guide	**40.1348.000**	1
7		Protective guide short	**40.5871.000**	1
8		Drill guide short 7/4.0	**40.6365.000**	1
9		Drill with scale 4.0/150	**40.5348.002**	1
10		Stand for instrument set for ChFN2 tro-chanteric nails - II	**40.6368.500**	1

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IV. SURGICAL TECHNIQUE

IV.1. INTRODUCTION

When the 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 will considerably facilitate fracture reduction and nail insertion. Positioning of the patient on the traction table is an integral part of the operating procedure.
Presented method of intramedullary osteosynthesis requires image intensifier control.

Each operating procedure must be carefully planned. X-Ray of the entire femur *(in AP and lateral position)* is essential in order to not overlook the injuries in its proximal or distal part. It is especially important in the cases of pathological subtrochanteric fractures. Special attention should be paid to concurrent neck fractures or proximal epiphysis multi-fragmental fractures, and the possibility of its occurrence during the procedure.
During the operation, secondary fractures of main fragments may occur. The condition of hip joint is also important.
In advanced arthrosis or contracture, nailing may be difficult or even impossible to perform. Always check whether alloplasty of hip or knee has ever been performed on the fractured limb.
The procedure has to be carried out on the operating table with traction with the patient placed supine or on the side. Side position facilitates the approach to the greater trochanter which is especially important with overweight patients. Supine position provides less favorable access to the greater trochanter but makes all other stages of the operation considerably easier *(especially rotary corrections)*.

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

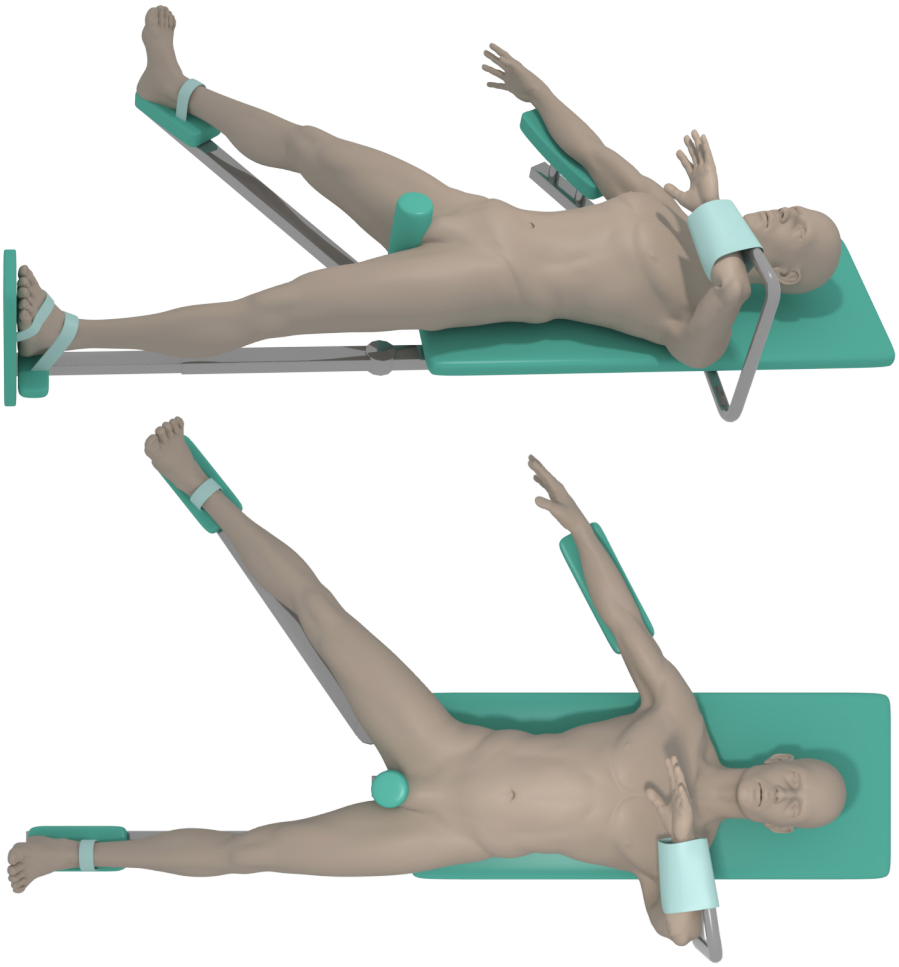


FIG.1. Patient positioning

Lateral surgical approach shall be applied starting the incision near the tip of the greater trochanter in line with the femoral shaft axis for 8 cm. The incision should be longer in obese patients. When the fascia is reached, cut it along the skin incision line. Next the dissection of gluteus maximus muscle fibres should be performed. Back from gluteus medius muscle, approach to trochanter major apex is enabled.

The trochanteric nail should be introduced in such a way that its axis is approximately in line with the bone shaft axis. This beneficially influences the load distribution forces that transmit mechanical loads in a patient who started to walk.

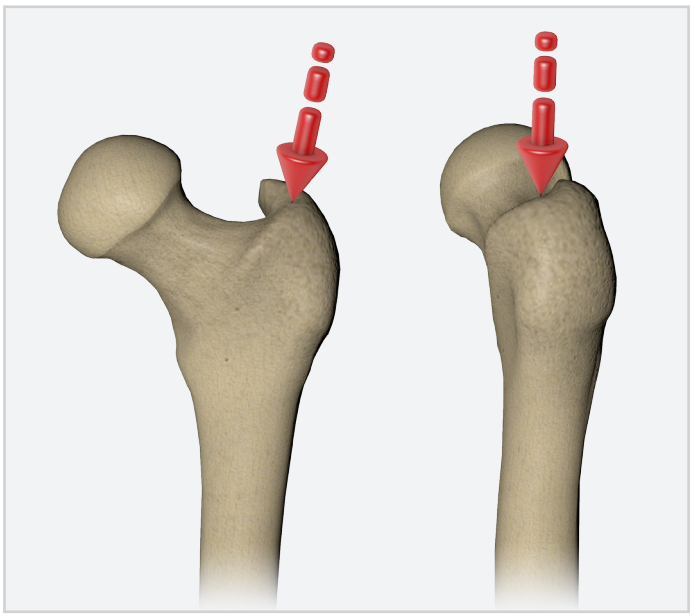


FIG. 2. Location of the entry point for trochanteric nail

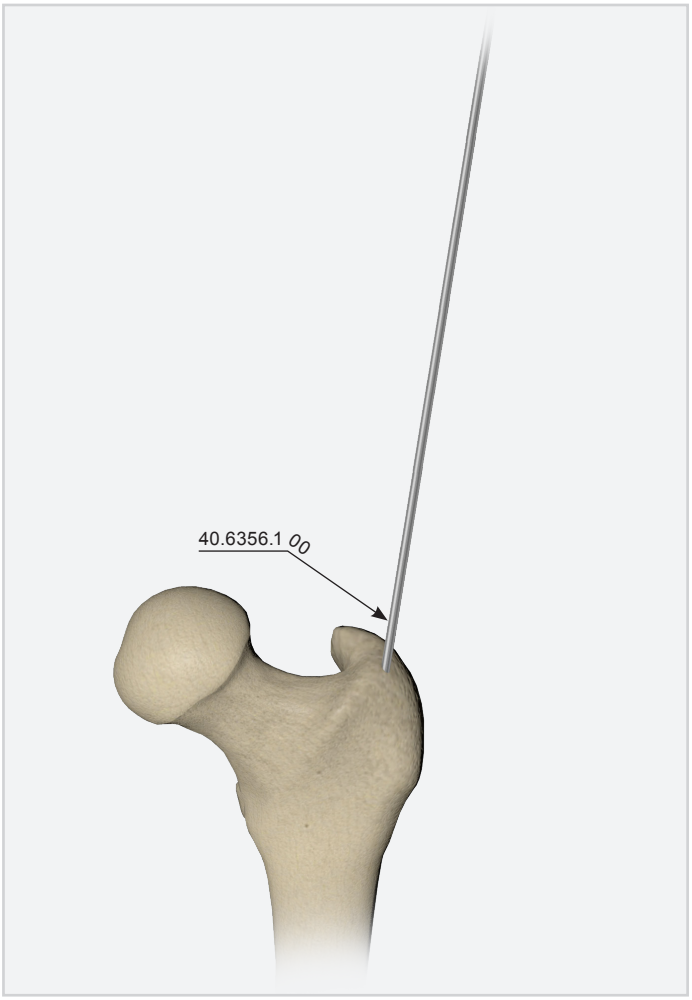
The following paragraphs describe the most important steps during the implantation of trochanteric nails. Nevertheless, it is not a detailed instruction of conduct. The surgeon decides about choosing the surgical technique and its application in each individual case. Based on the images of the fractured and healthy *(the other)* femur, using a trial, the surgeon decides on an angle, length and diameter of the nail.

IV.2. OPENING AND PREPARATION OF MEDULLARY CANAL FOR TROCHANTERIC NAIL INSERTION
(SHORT AND LONG NAILS)

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

Having located the entry point for the nail, using drive, insert the guide rod 3.2/500 **[40.6356.100]** into the medullary canal at an angle corresponding to the angle deviation of the nail shaft from the main axis *(about 4°)*.

The insertion process should be done under X-Ray with visual track control.

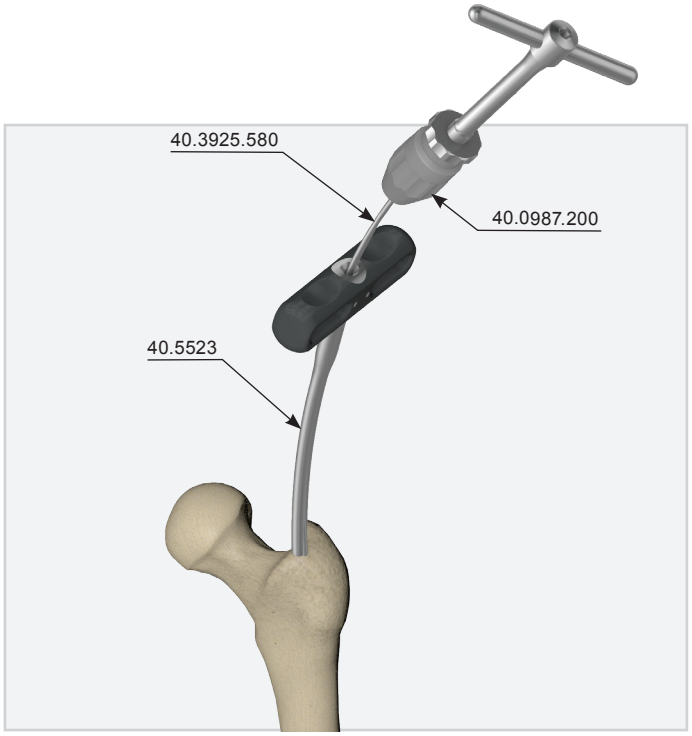


2 Using guide rod 3.2/500 **[40.6356.100]**, insert into the medullary canal curved awl 8.0 **[40.5523]** to the depth at which the awl blade goes along the medullary canal, allowing proper insertion of guide rod 3.0/580 **[40.3925.580]**.

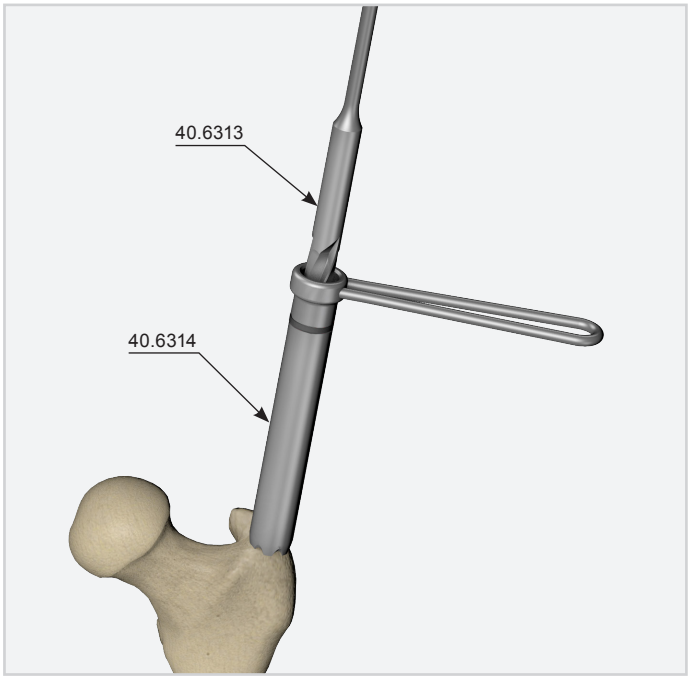
Having opened medullary canal, remove guide rod 3.2/500 **[40.6356.100]**.

Mount guide rod 3.0/580 **[40.3925.580]** to Steinmann handle **[40.0987.200]** 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.

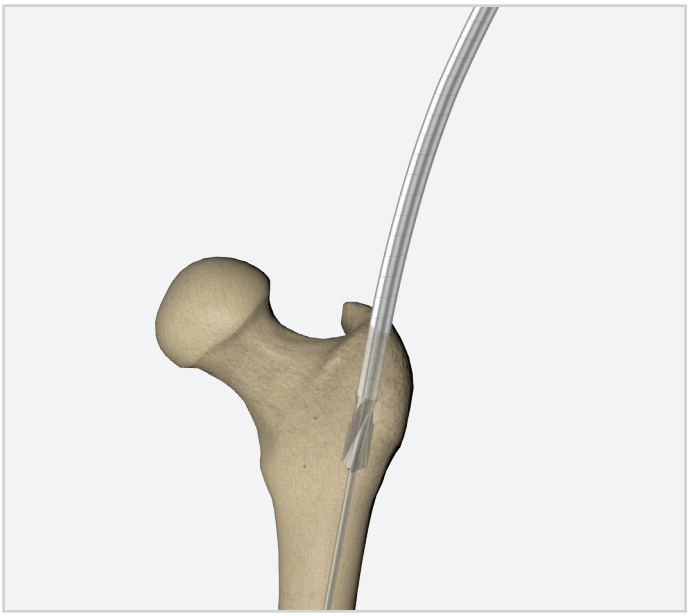
Remove Steinmann handle **[40.0987.200]** and curved awl 8.0 **[40.5523]**. Leave guide rod 3.0/580 **[40.3925.580]** in place.



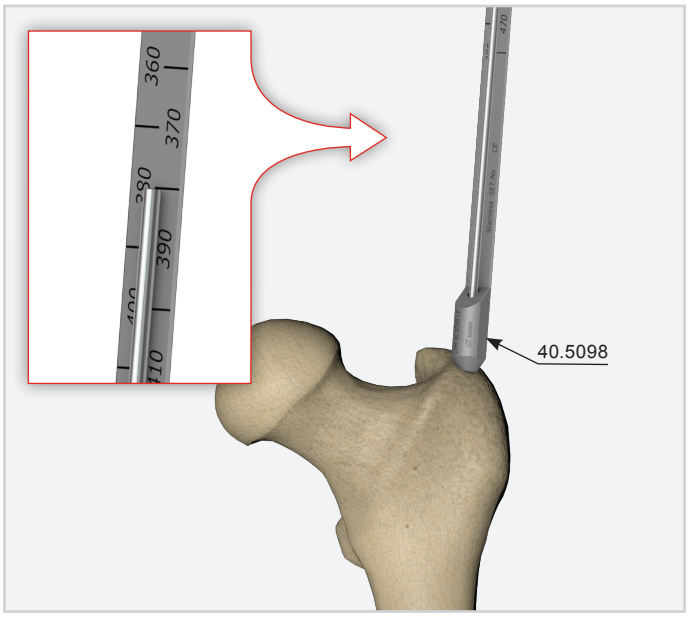
Lean protective guide 16.0 **[40.6314]** with guide 16/3.2 **[40.6315]** against the cortex. Remove the guide 16/3.2 **[40.6315]**.
Using the cannulated drill 16.0 **[40.6313]** led in the protective guide 16.0 **[40.6314]** on the guide rod 3.0/580 **[40.3925.580]** open the medullary canal. Slowly ream the medullary canal using the cannulated drill until it rests against the protective guide. Remove the cannulated drill and protective guide.



3 When reaming the medullary canal, the process should be performed gradually using reamers 0.5 mm thicker than the previous one until the diameter of the opening is 1.5 ÷ 2 mm greater than the diameter of the nail for a depth of not less than its length.
Whether the medullary canal is reamed or not, the proximal part of the medullary canal should be reamed to a diameter of 16 mm to a depth of about 6 cm.
Remove the reamer.



4 In the case of implantation of a long nail, measure its length. Insert a nail length measure **[40.5098]** via the guide rod until it rests on the bone. Read the length of the nail from the scale. Remove the measure. In the case of a solid nail, remove also the guide rod from the medullary canal. The medullary canal is ready for nail implantation.

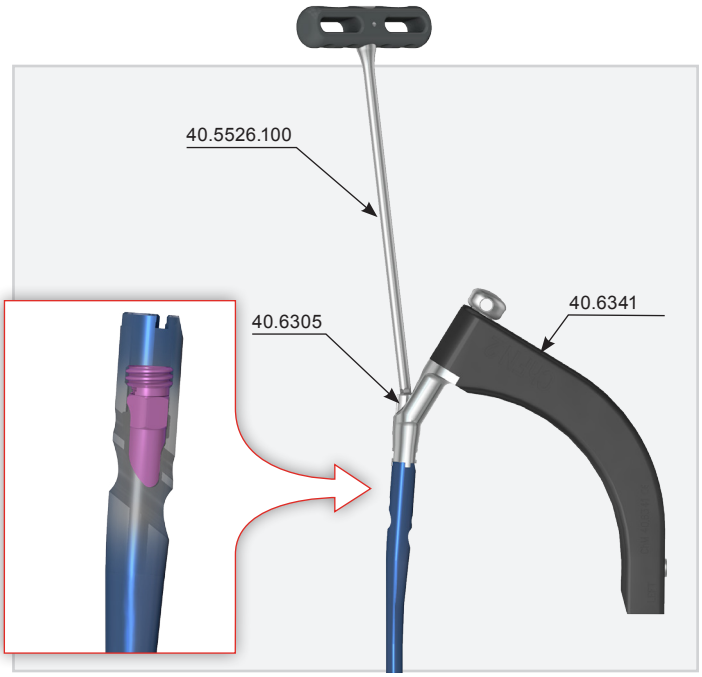


IV.3. NAIL-TARGETER CONNECTING, NAIL INSERTION

5

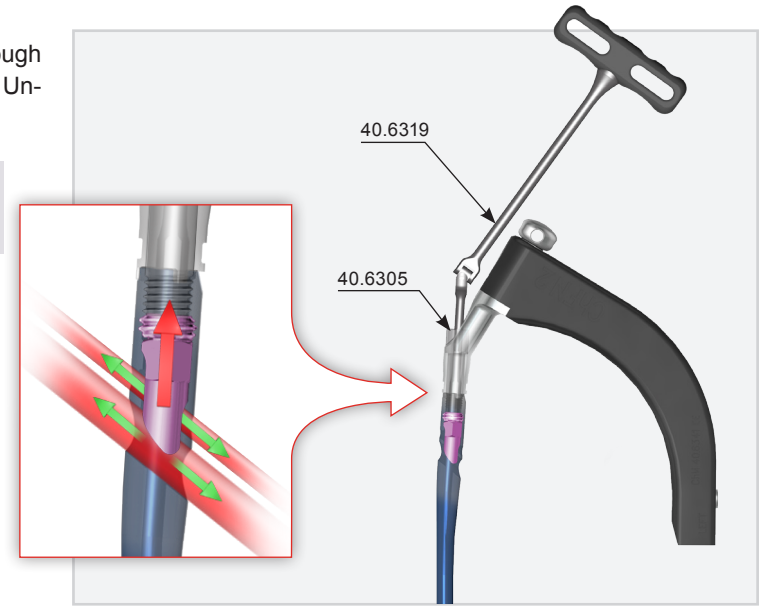
A fork screw has been inserted in the nail.

Mount the intramedullary nail to the targeter arm **[40.6341]** using connecting screw M12x1.75 **[40.6305]** and wrench S10 **[40.5526.100]**.
For a long nail, set the slider of the distal targeter acc. to point 6.



5a Insert wrench for self-aligning joint S7 **[40.6319]** through the hole in the connecting screw M12x1.75 **[40.6305]**. Unscrew the fork screw until it rests on the connecting screw.

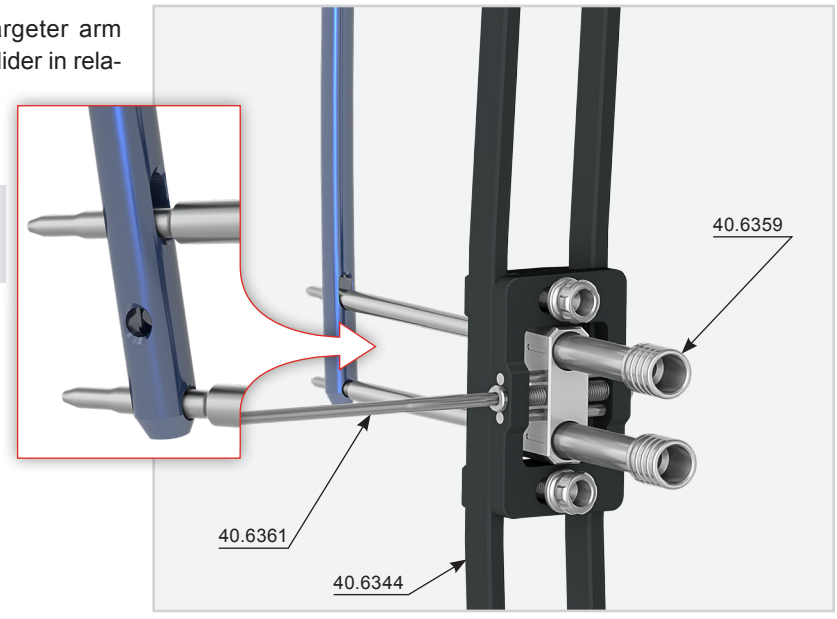
This step is necessary to avoid complications when preparing the hole for the join screw insertion.



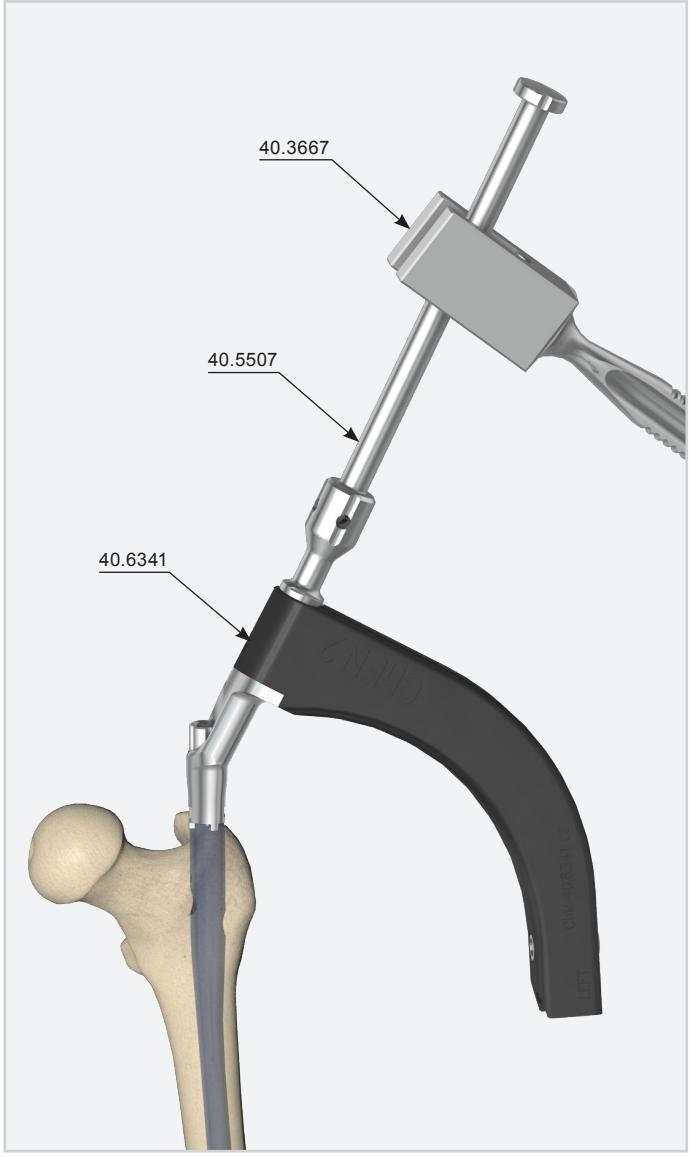
6 Attach distal targeter D **[40.6344]** to the targeter arm **[40.6341]** and set the correct position of the slider in relation to the locking holes of the nail in its distal part using two set blocks 9/5.0 **[40.6359]**. Lock the slider using the screwdriver T25 with holder **[40.6361]**.

CHECK! When targeter slider is properly set and locked, set blocks should easily go through the nail holes.

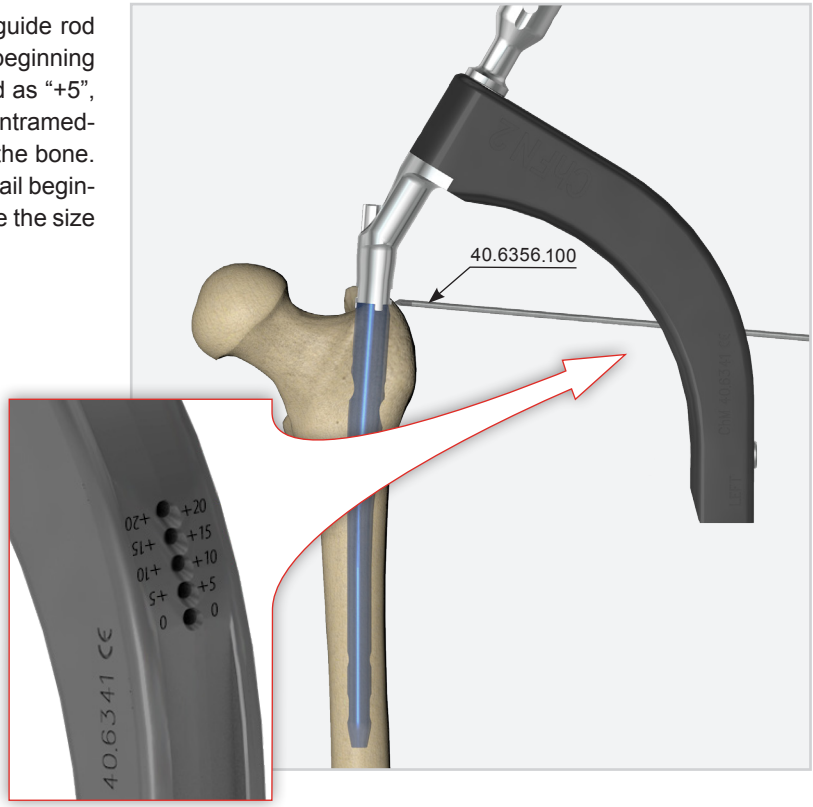
Remove set blocks from the targeter slider.
Disconnect the distal targeter D from the targeter arm.



7 Connect impactor-extractor **[40.5507]** to the targeter arm **[40.6341]** and using a mallet **[40.3667]** insert the nail into the medullary canal; remove the guide rod.



8 To determine the correct insertion depth use a guide rod 3.2/500 **[40.6356.100]**, which will indicate the beginning of the nail at the hole marked as “0”. The holes marked as “+5”, “+10”, “+15”, “+20” are used when the nail is so deep in intramedullary canal that the nail beginning does not flush with the bone. The holes are used to establish the depth at which the nail beginning is in relation to the bone beginning and to determine the size of end cap.

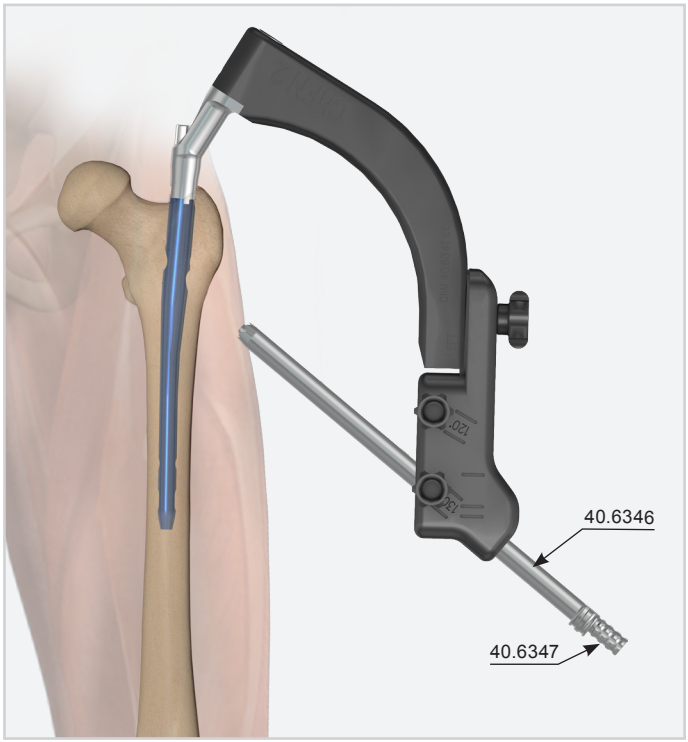


IV.4. PROXIMAL LOCKING OF THE TROCHANTERIC NAIL USING JOIN SCREWS

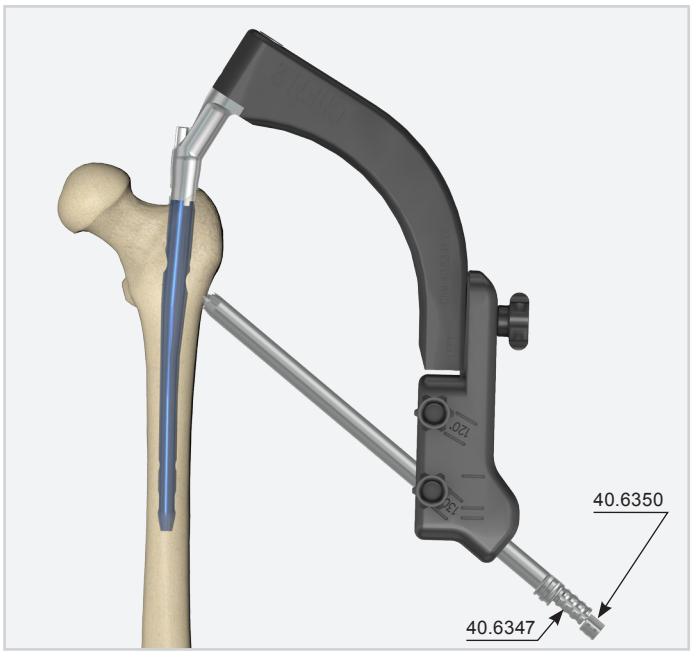
9 Attach chosen targeter 120/130 **[40.6342]** or targeter 125/135 **[40.6343]** to the targeter arm.

- for the nails 120° and 130° - targeter 120/130 **[40.6342]** shall be used,
- for the nails 125° and 135° - targeter 125/135 **[40.6343]** shall be used.

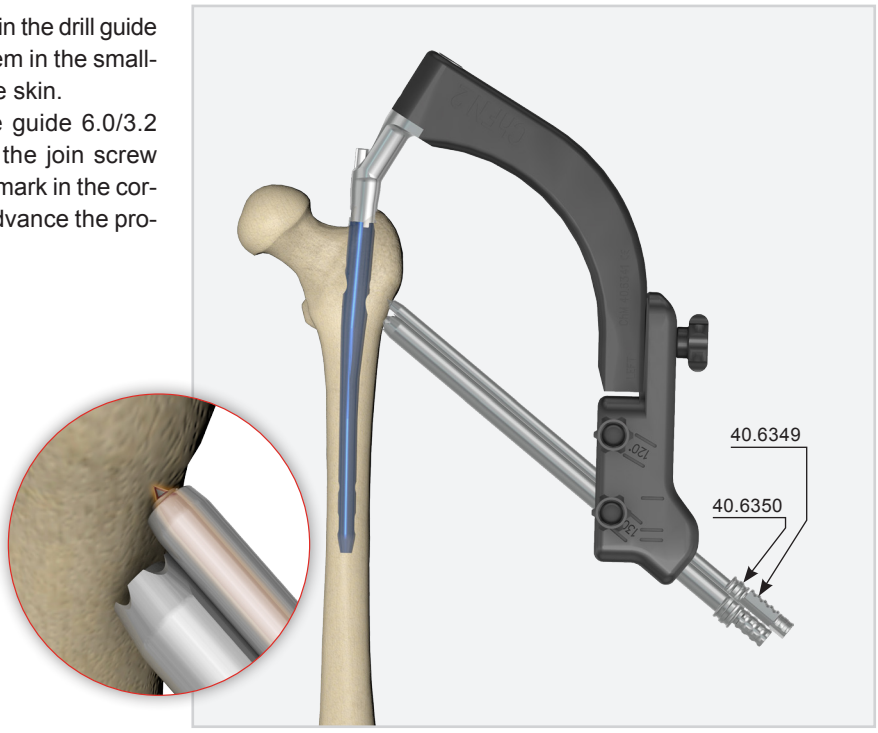
10 Insert protective guide 11.5/3.2 **[40.6347]** into the drill guide 14/11.5 **[40.6346]** and then insert this system into the larger hole of the targeter until it rests on the skin.



11 Insert the trocar 3.2 **[40.6350]** in the protective guide 11.5/3.2 **[40.6347]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.
Remove the trocar.
Leave protective guide in place.

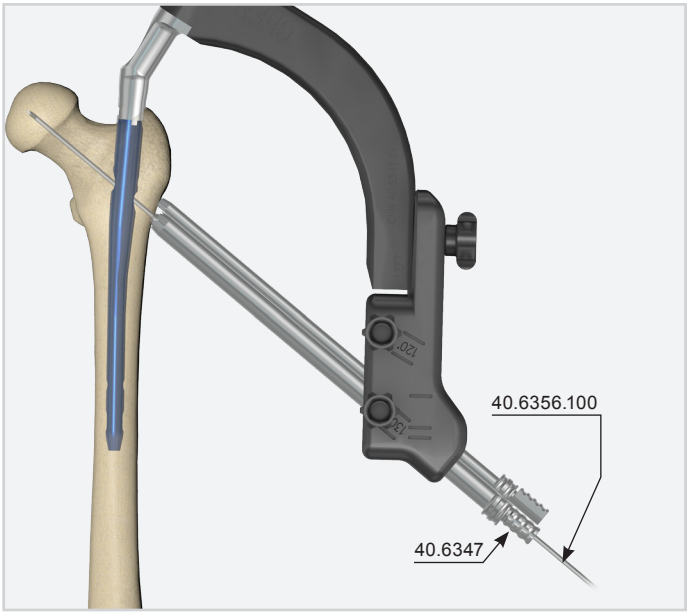


12 Insert the protective guide 6.0/3.2 **[40.6349]** in the drill guide 9.0/6.0 **[40.6348]** and then insert this system in the smaller hole of the proximal targeter until it rests on the skin.
Insert the trocar 3.2 **[40.6350]** in the protective guide 6.0/3.2 **[40.6349]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.
Remove the trocar.
Leave protective guide in place.

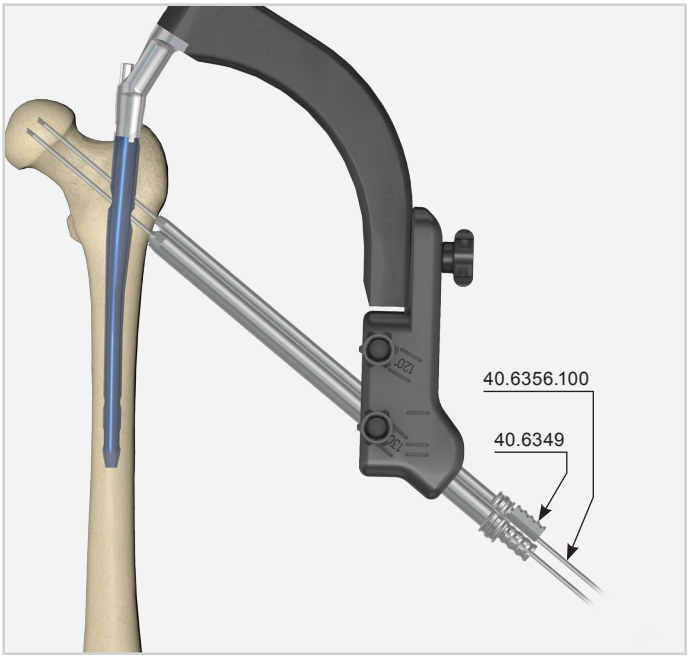


13 Connect the guide rod 3.2/500 **[40.6356.100]** with electric drive and advance such system into the protective guide 11.5/3.2 **[40.6347]**.

Insert the guide rod [40.6356.100] into the femoral head:
- at the depth of about 5 ÷ 10 mm from articular cartilage for join screw 10.5 and
- at the depth of about 15-20 mm for the join screw 5.0.

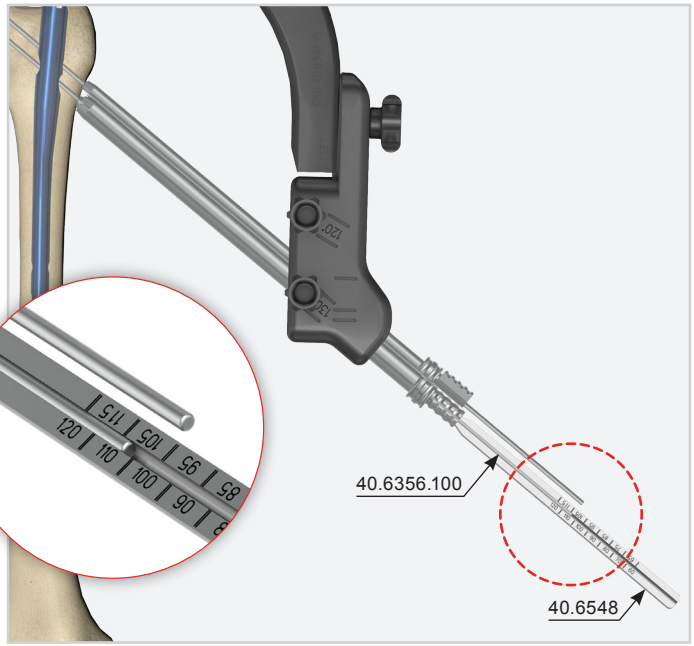


14 Connect the guide rod 3.2/500 **[40.6356.100]** with electric drive and advance such system into the protective guide 6.0/3.2 **[40.6349]**.



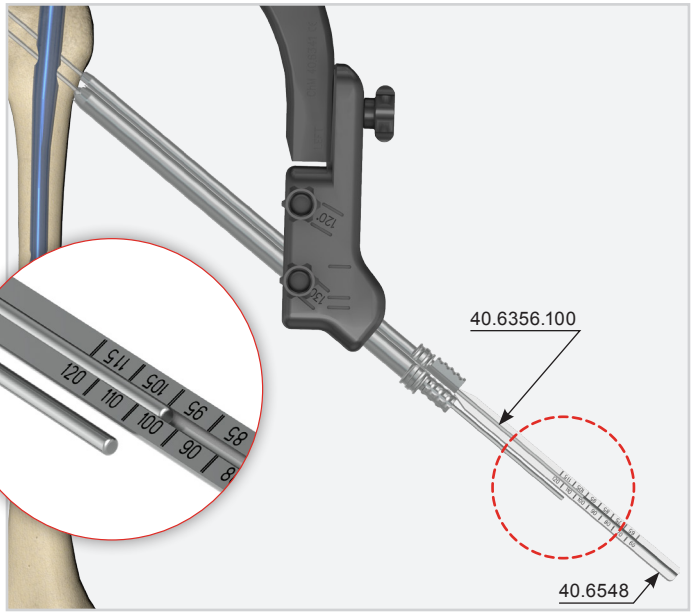
15 Insert the cannulated screw length measure **[40.6548]** via the guide rod **[40.6356.100]** *(placed into the protective guide 11.5/3.2 [40.6347])* until its end rests on the protective guide 11.5/3.2. Read the length of the join screw on the scale indicated by the end of the guide rod.
During the measurement, the tip of the cannulated screw length measure should rest on the protective guide 11.5/3.2, and the guide on cortex.

Remove the cannulated screw length measure and the protective guide 11.5/3.2.
Leave the guide rod in place.



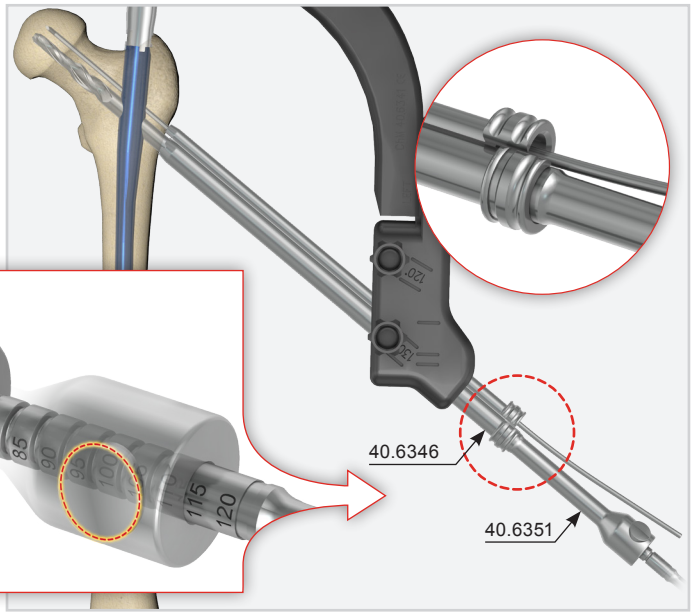
16 Insert the cannulated screw length measure **[40.6548]** via the guide rod **[40.6356.100]** *(placed into the protective guide 6.0/3.2 [40.6349])* until its end rests on the protective guide 6.0/3.2. Read the length of the join screw 5.0 on the scale indicated by the end of the guide rod.
During the measurement, the tip of the cannulated screw length measure should rest on the protective guide 6.0/3.2, and the guide on cortex.

Remove the cannulated screw length measure and the protective guide 6.0/3.2.
Leave the guide rod in place.

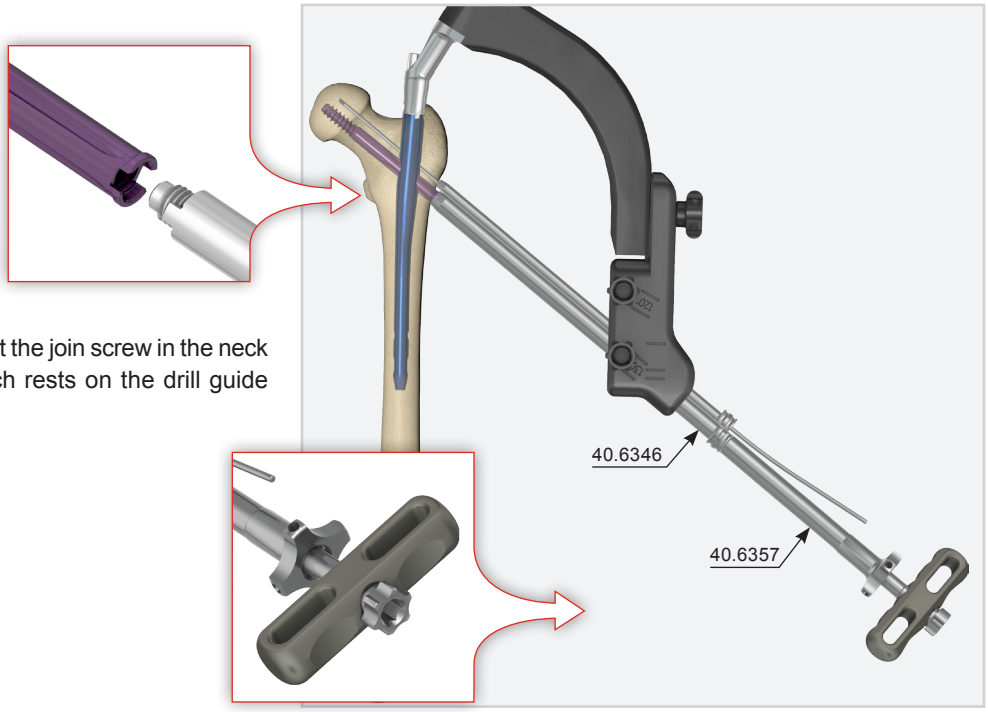


17 Set the drilling depth corresponding to the length of previously selected join screw on the gradual drill 10.5/7 **[40.6351]** using the setting latch. Mount the gradual drill in the drive and insert on the guide rod **[40.6356.100]** placed in the femoral neck. Drill a hole until the latch rests on drill guide 14/11.5 **[40.6346]**.

Remove the gradual drill.
Leave guide rod and drill guide in place.



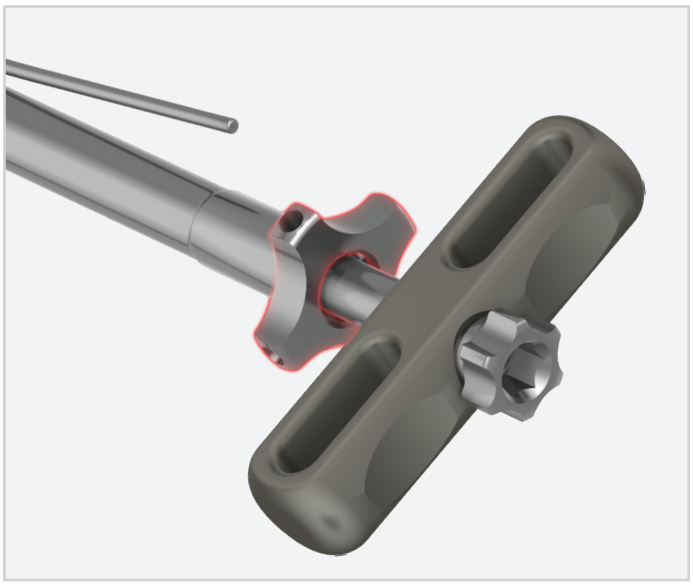
18 Set the nut of the compression wrench at “0” acc. to the scale. Attach the join screw 10.5 of the length earlier determined by the cannulated screws length measure **[40.6548]** to the compression wrench **[40.6357]**. Insert the join screw on the guide rod **[40.6356.100]**. Using the compression wrench that is led on the guide rod, insert the join screw in the neck of the femur until the nut of the wrench rests on the drill guide 14/11.5 **[40.6346]**.



19 If fracture compression is intended, do the following:

- unscrew the compression nut *(by the length of a distance between the fragments)*,
- insert the join screw at the desired depth,
- perform compression by turning the compression screw until it is on “0” position according to the scale.

Be careful during compression and do not tear the join screw out of the bone.

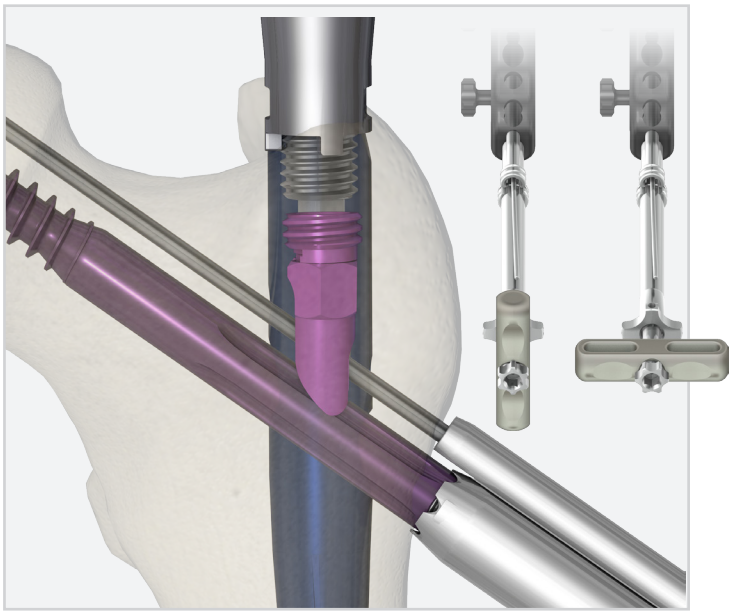


20 Set the combined join screw 10.5 with compression wrench so that the handle of the wrench is positioned parallel or perpendicular to the longitudinal axis of the nail. Insert the wrench for self-aligning joint S7 **[40.6319]** in the connecting screw located in the targeter arm. Tighten the fork screw located inside the nail. Join screw can be locked in two positions:

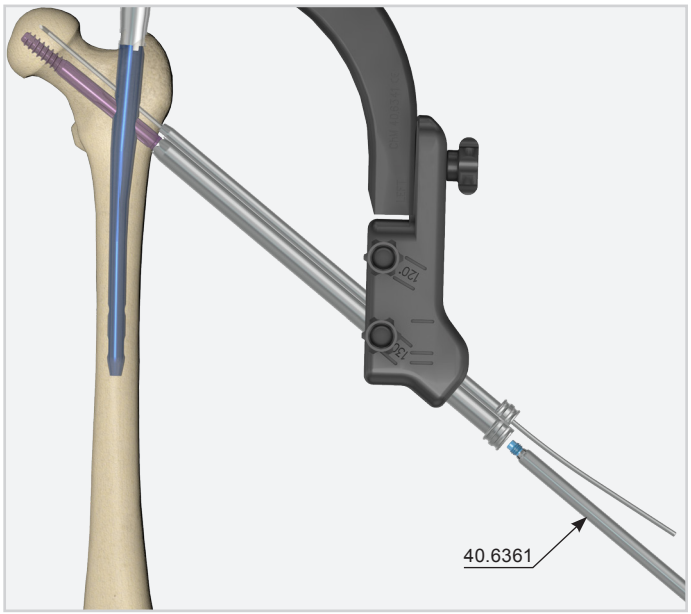
- dynamic - the fork screw is loose and allows the sliding of the screw inside the nail without the possibility of rotation *(tighten it up to the limit and then loosen by 1/4 turn)*,
- static - the fork screw is tightened up.

Remove the compression wrench, guide rod and protective guide.

Guide rod [40.6356.100] is a disposable device.



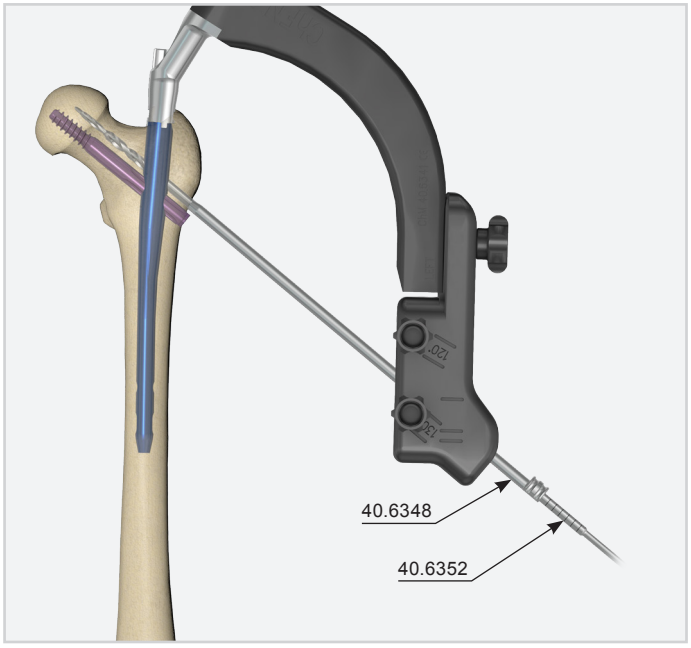
21 In order to protect the internal thread of the join screw against bone ingrowth, insert an end cap M8 *(implant)* into the threaded hole of the screw using a screwdriver T25 **[40.6361]**.



In the case of locking the nail using a single join screw 10.5, omit the steps 23-25.

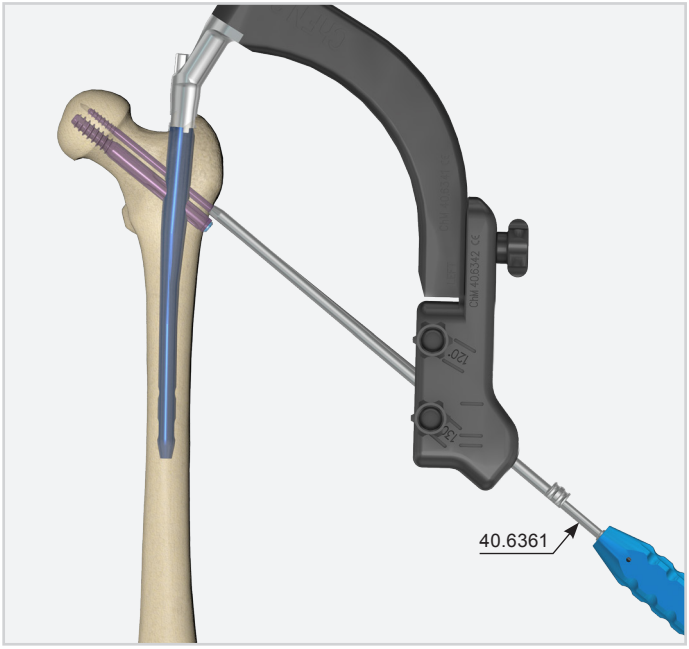
22 Remove the guide rod. Mount the drill 5.0 **[40.6352]** in the drive, insert it in the drill guide 9.0/6.0 **[40.6348]** and deepen the hole in the first cortical layer *(up to the intramedullary nail)*.

Remove the drill.

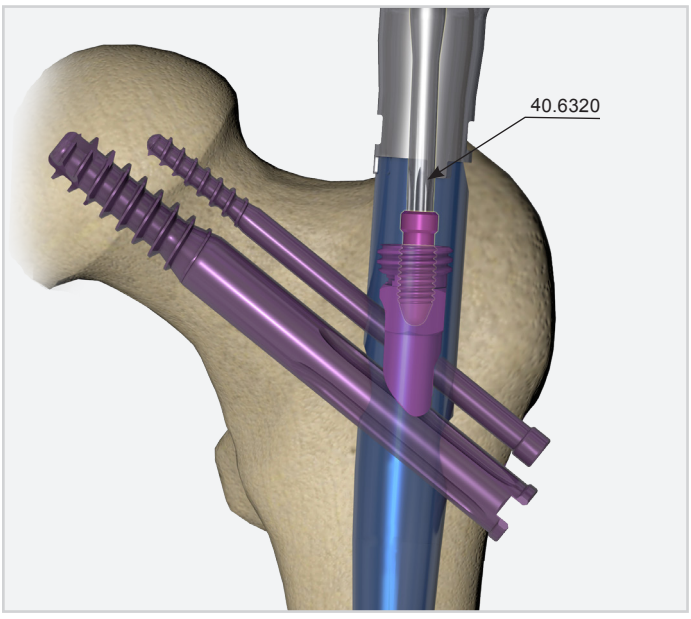


23 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of the specified join screw 5.0 and then into drill guide 9.0/6.0 **[40.6348]**. Insert the join screw 5.0 in the previously drilled hole until its head reaches the cortex *(the groove on the screwdriver shaft matches the end of the protective guide)*. Remove screwdriver T25 and protective guide.

CAUTION:
The holder of the screwdriver [40.6361] is not adapted to work in protective guide. The holder must be removed.



24 Join screw 5.0 locking:
Attach the setting screw *(implant)* to the wrench for self-aligning joint T25 **[40.6320]** by tightening the fixing nut. Insert the wrench for self-aligning joint T25 **[40.6320]** with the setting screw in the connecting screw located in the targeter arm. Tighten the setting screw until immobilization of join screw 5.0 occurs. Remove the wrench for self-aligning joint T25.

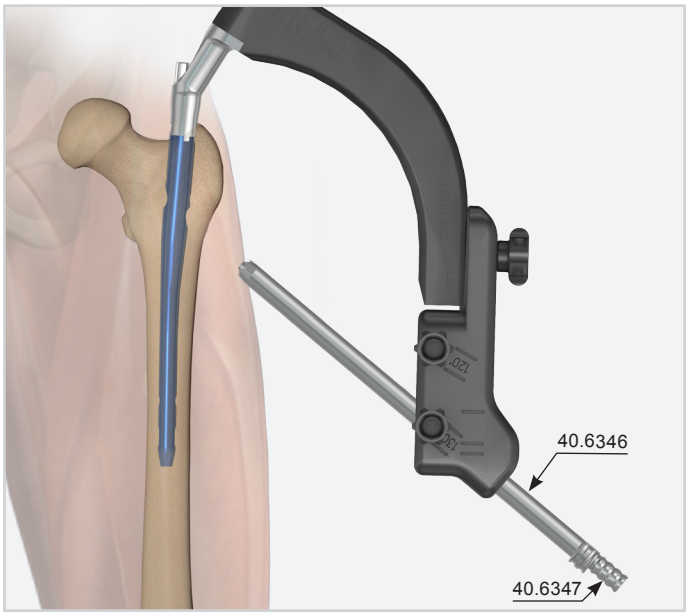


IV.5. PROXIMAL TROCHANTERIC NAIL LOCKING USING JOIN TELESCOPIC SCREW 10.5

25 Attach chosen targeter 120/130 **[40.6342]** or targeter 125/135 **[40.6343]** to the targeter arm.

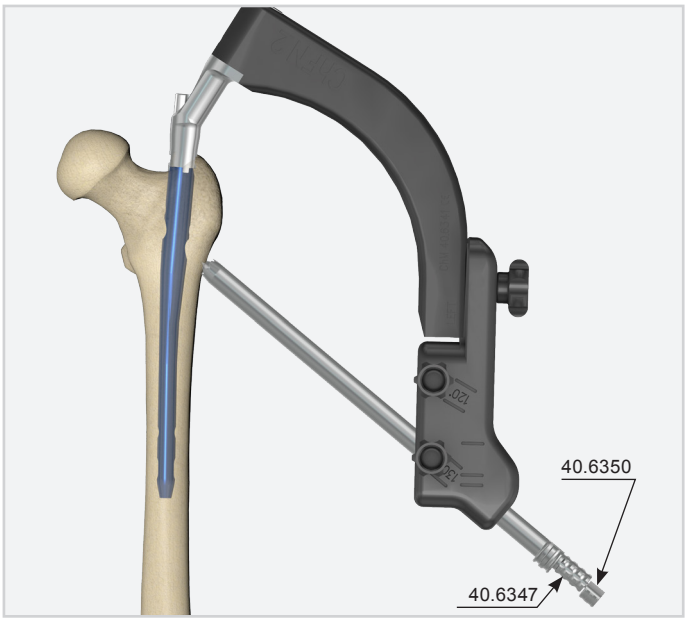
- for the nails 120° and 130° - targeter 120/130 **[40.6342]** shall be used,
- for the nails 125° and 135° - targeter 125/135 **[40.6343]** shall be used.

26 Insert protective guide 11.5/3.2 **[40.6347]** into the drill guide 14/11.5 **[40.6346]** and then insert this system into the larger hole of the targeter until it rests on the skin.



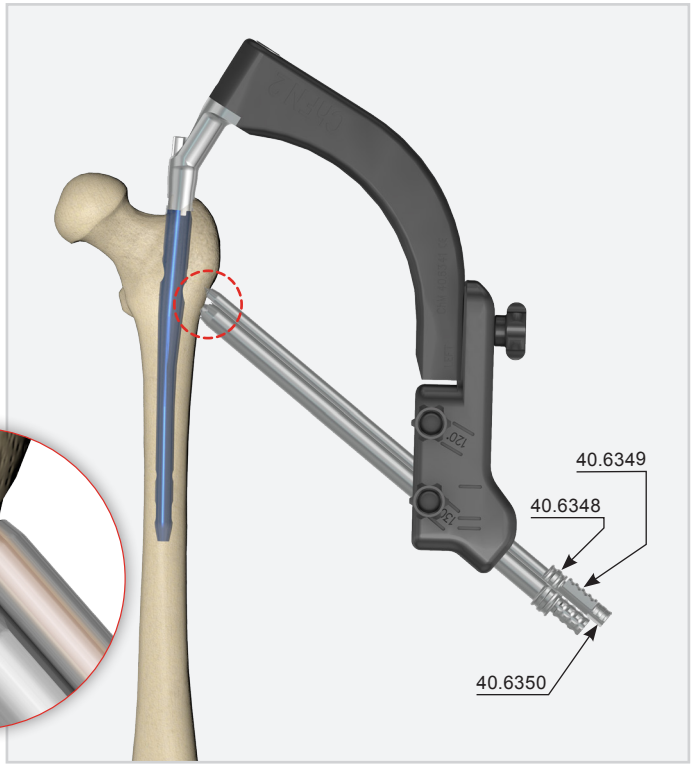
27 Insert the trocar 3.2 **[40.6350]** in the protective guide 11.5/3.2 **[40.6347]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

Remove the trocar.
Leave protective guide in place.



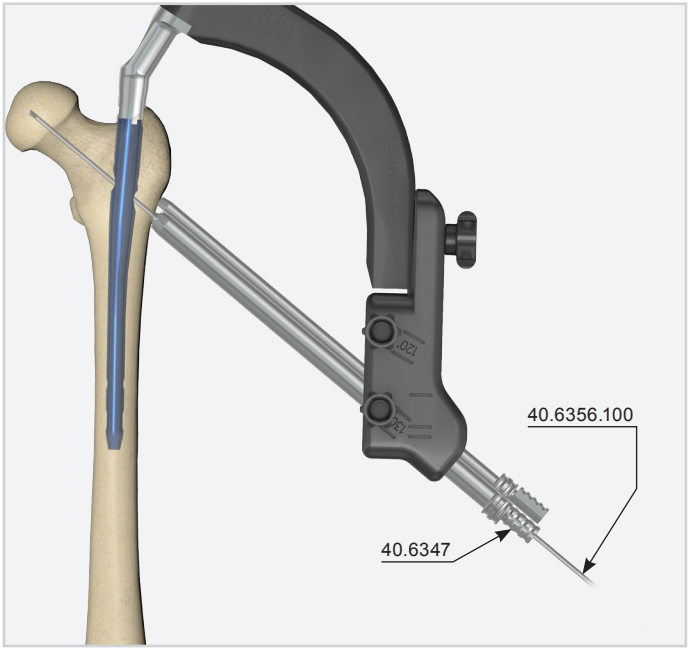
28 Insert the protective guide 6.0/3.2 **[40.6349]** in the drill guide 9.0/6.0 **[40.6348]** and then insert this system in the smaller hole of the chosen targeter.
Insert the trocar 3.2 **[40.6350]** in the protective guide 6.0/3.2 **[40.6349]**. Mark on the skin the entry point for the join screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

Remove the trocar.
Leave protective guide in place.



29 Connect the guide rod 3.2/500 **[40.6356.100]** with electric drive and advance such system into the protective guide 11.5/3.2 **[40.6347]**.

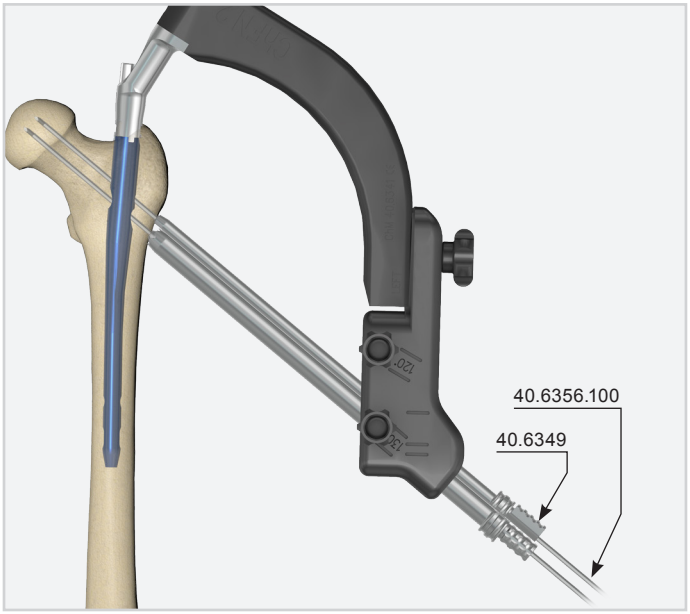
Insert the guide rod [40.6356.100] into the femoral head at the depth of about 5÷10 mm from articular cartilage for join telescopic screw 10.5 and at the depth of about 15-20 mm for the join screw 5.0.



30 Connect the guide rod 3.2/500 **[40.6356.100]** with electric drive and advance such system into the protective guide 6.0/3.2 **[40.6349]**.

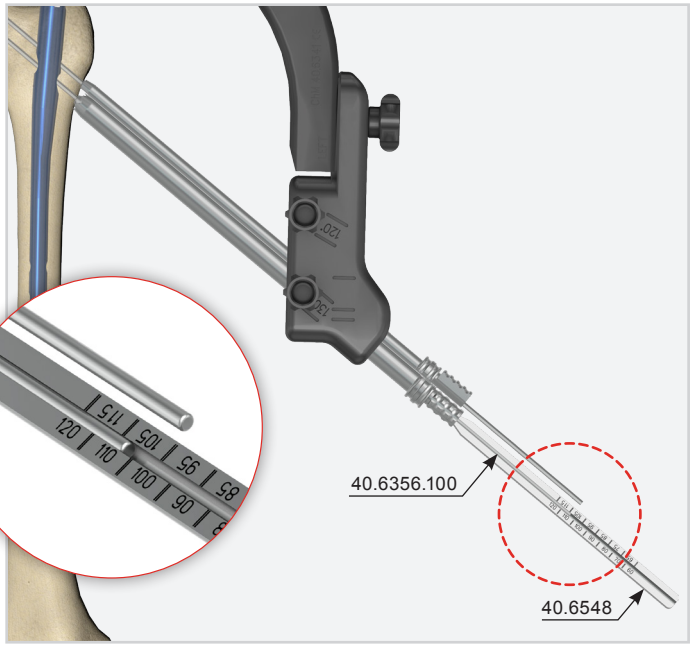
31 Insert the cannulated screw length measure **[40.6548]** via the guide rod **[40.6356.100]** *(placed into the protective guide 11.5/3.2 [40.6347])* until its end rests on the protective guide 11.5/3.2 **[40.6347]**. Read the length of the join telescopic screw on the scale indicated by the end of the guide rod.
During the measurement, the tip of the cannulated screw length measure should rest on the protective guide 11.5/3.2, and the guide on cortex.

Remove the cannulated screw length measure and the protective guide 11.5/3.2.
Leave the guide rod in place.



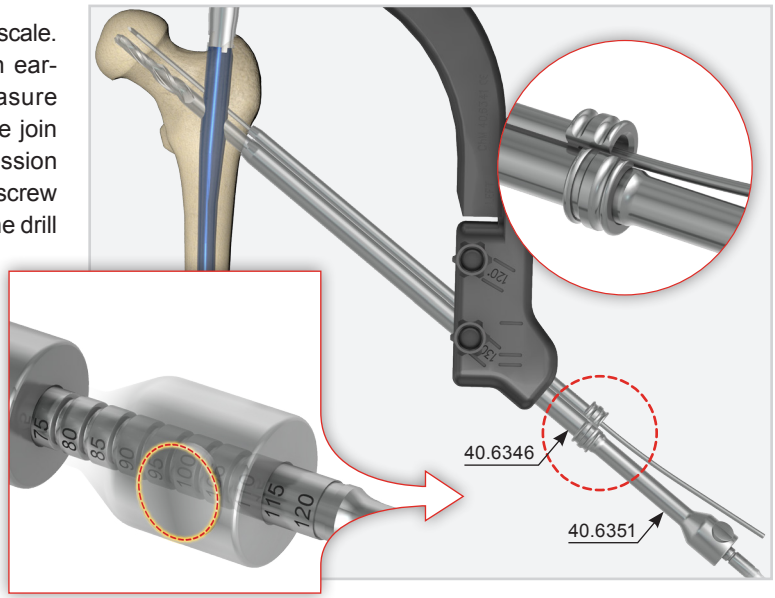
32 Set the drilling depth corresponding to the length of previously selected join screw on the gradual drill 10.5/7 **[40.6351]** using the setting latch. Mount the gradual drill in the drive and insert on the guide rod **[40.6356.100]** placed in the femoral neck. Drill a hole until the latch rests on drill guide 14/11.5 **[40.6346]**.

Remove the gradual drill.
Leave guide rod and drill guide in place.

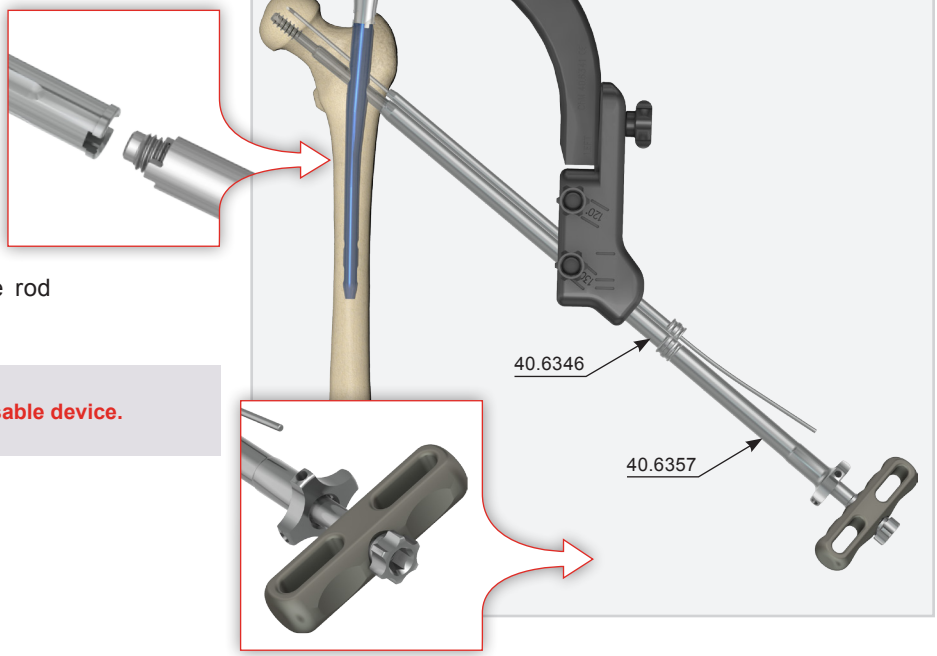


33 Set the nut of the compression wrench at "0" acc. to the scale. Attach the join telescopic screw 10.5 of the length earlier determined by the cannulated screws length measure **[40.6548]** to the compression wrench **[40.6357]**. Insert the join screw on the guide rod **[40.6356.100]**. Using the compression wrench that is led on the guide rod, insert the join telescopic screw in the neck of the femur until the nut of the wrench rests on the drill guide 14/11.5 **[40.6346]**.

Do not use the wrench for fracture compression. Compression may be performed using a compression screw *(implant)* after locking join telescopic screw.



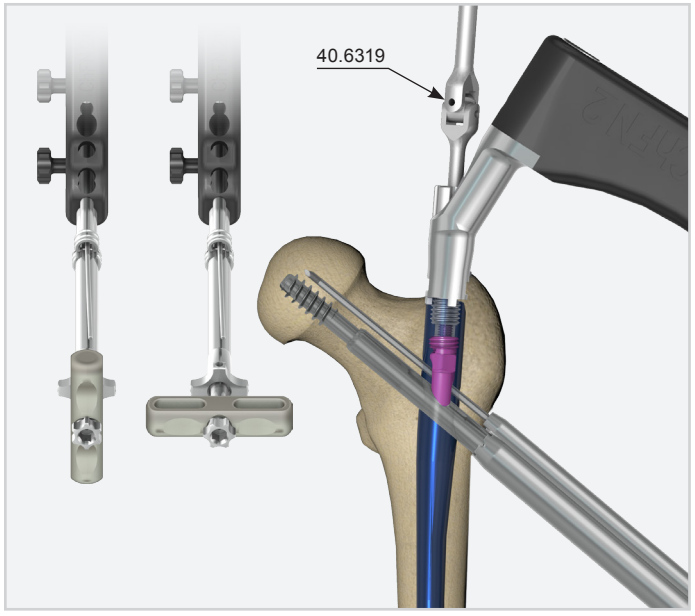
34 Set the combined join screw 10.5 with compression wrench so that the handle of the wrench is positioned parallel or perpendicular to the longitudinal axis of the nail. Insert the wrench for self-aligning joint S7 **[40.6319]** in the connecting screw located in the targeter arm. Tighten the fork screw located inside the nail. Remove the compression wrench, guide rod and protective guide.

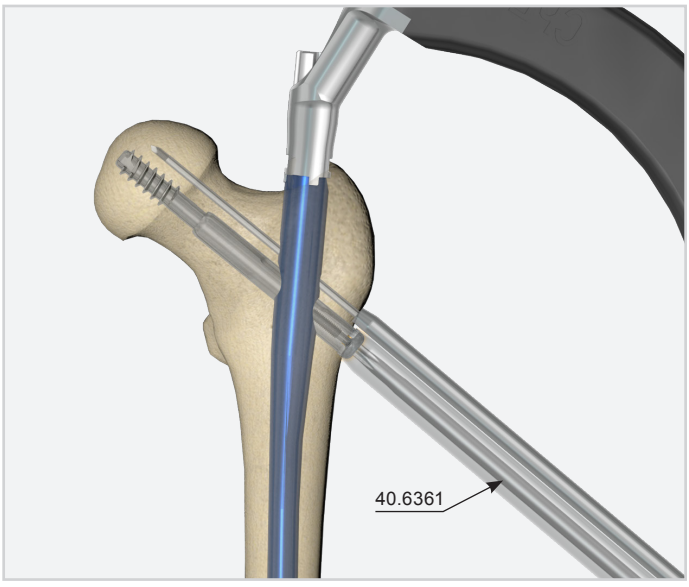


Guide rod [40.6356.100] is a disposable device.

35 If fracture compression is intended, do the following:

- insert the compression screw *(implant)* in the join telescopic screw using screwdriver T25 with holder,
- perform compression.



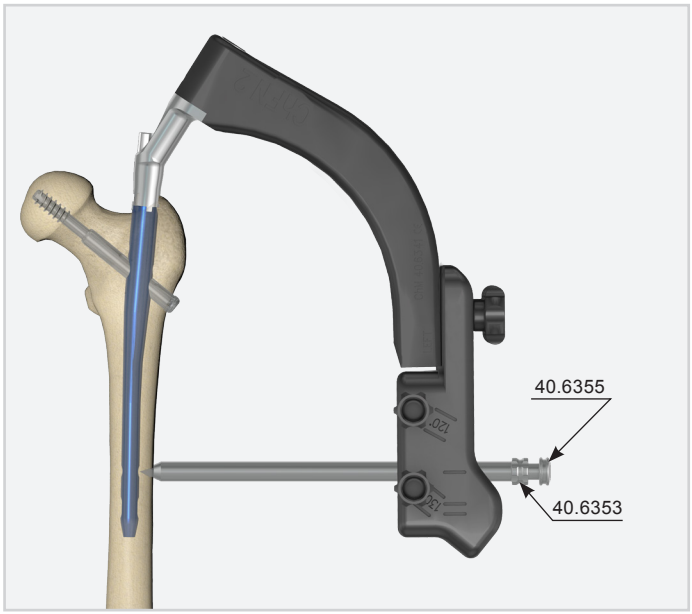


IV.6. DISTAL TROCHANTERIC NAIL *(SHORT)* LOCKING

Nails of the length of 170 or 180 can only be locked with one distal screw using the 12 mm proximal hole of the targeter [40.6342] or [40.6343].

36 Insert the trocar 10 **[40.6355]** in the protective guide 12/10 **[40.6353]** and insert this system in the proximal 12 mm hole of the targeter **[40.6342]** or **[40.6343]**. Mark on the skin the entry point for the distal screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

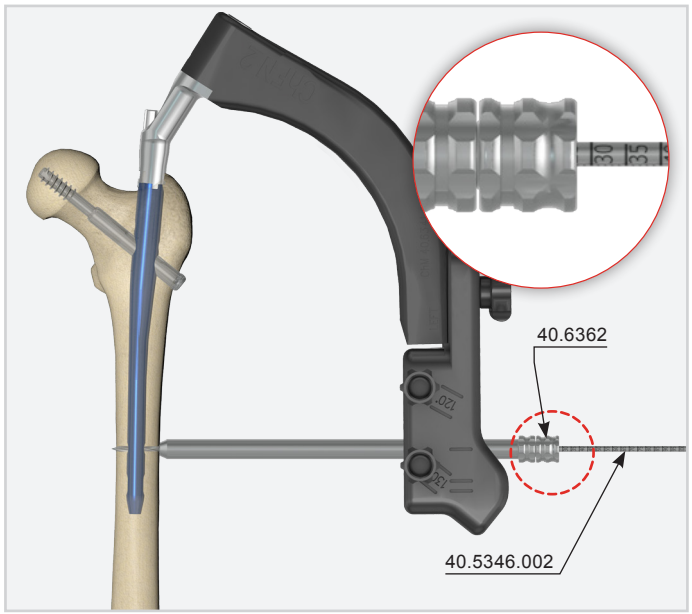
Remove the trocar.
Leave protective guide in place.



37 Insert the drill guide 10/4.0 **[40.6362]** in the protective guide 12/10 **[40.6353]**. Using a drive and a drill with scale 4.0 **[40.5346.002]** via the drill guide drill a hole in the femur extending through both layers of the cortex and the hole in the nail. The scale on the drill indicates the length of the locking element.

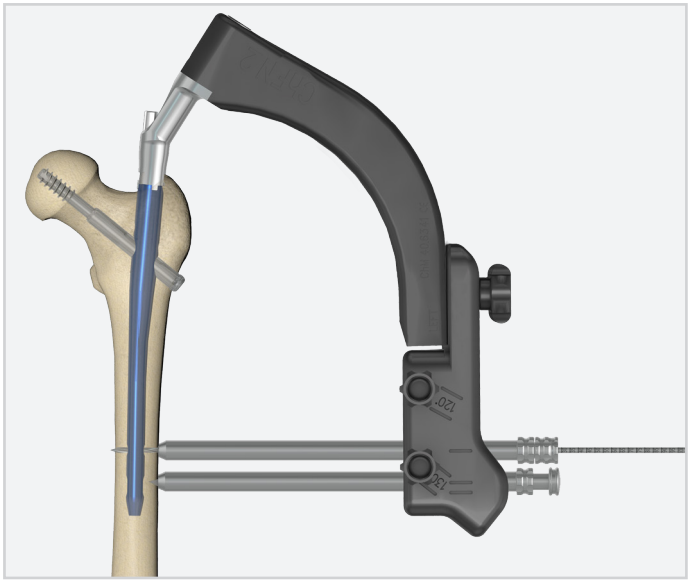
The drilling process should be done under X-Ray with visual track control

After disconnecting the drive, leave drill, drill guide and the protective guide in the hole.



38 Insert the trocar 10 **[40.6355]** in the protective guide 12/10 **[40.6353]** and then insert this system in the other *(distal)* hole of the proximal targeter. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

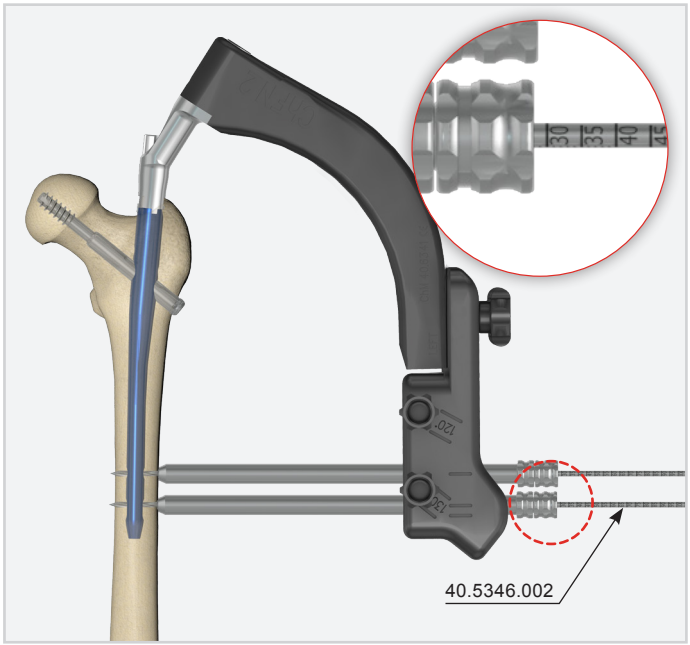
Remove the trocar.
Leave protective guide in place.



39 Insert the drill guide 10/4.0 **[40.6362]** in the protective guide 12/10 **[40.6353]**. Using a drive and a drill with scale 4.0 **[40.5346.002]** via the drill guide drill a hole in the femur extending through both layers of the cortex and the hole in the nail. The scale on the drill indicates the length of the locking element.

The drilling process should be done under X-Ray with visual track control.

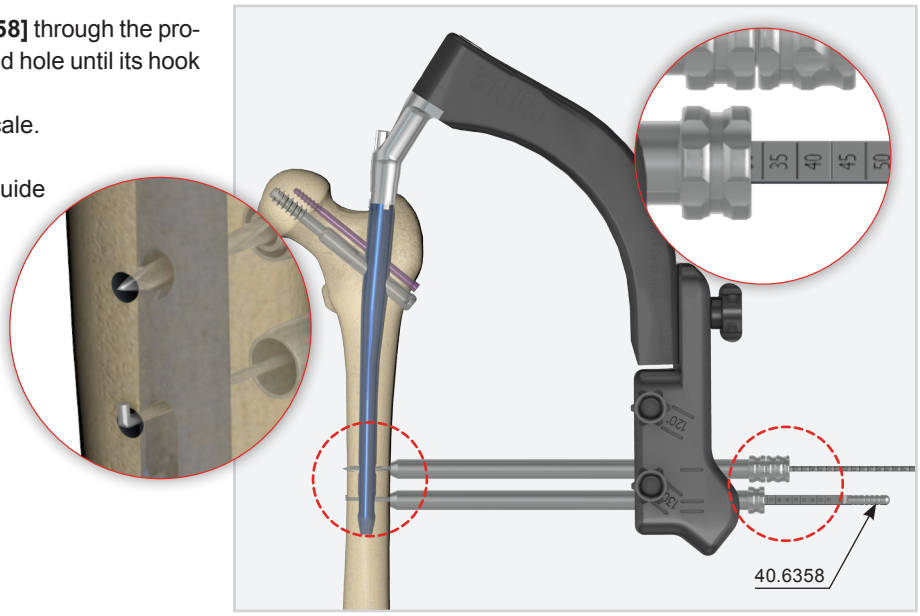
Remove drill and drill guide.
Leave protective guide in the proximal targeter hole.



40 Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole.
Read the length of distal screw on the B-D scale.

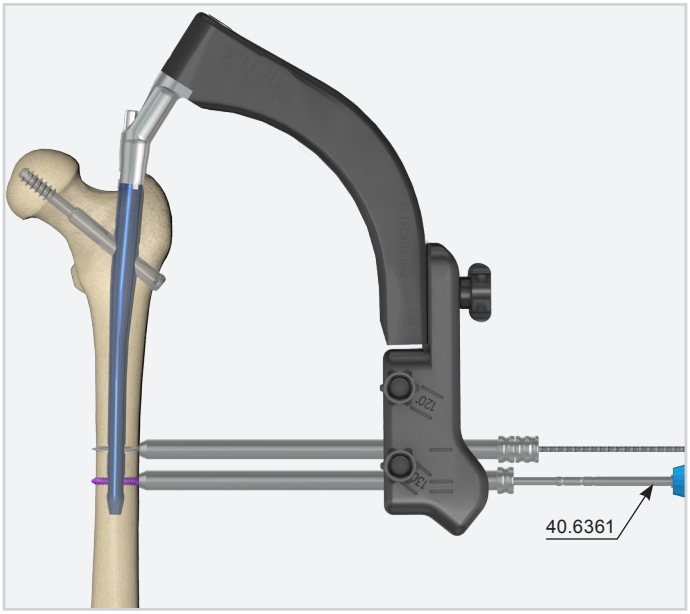
During measurements the tip of protective guide 12/10 should rest on the cortex bone.

Remove the screw length measure.
Leave the protective guide 12/10 in the proximal targeter hole.



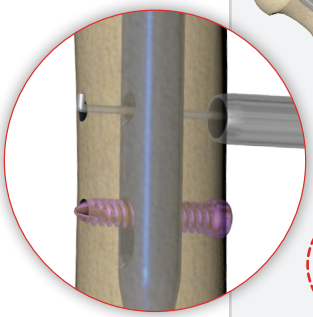
41 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft shall match the edge of protective guide)*.

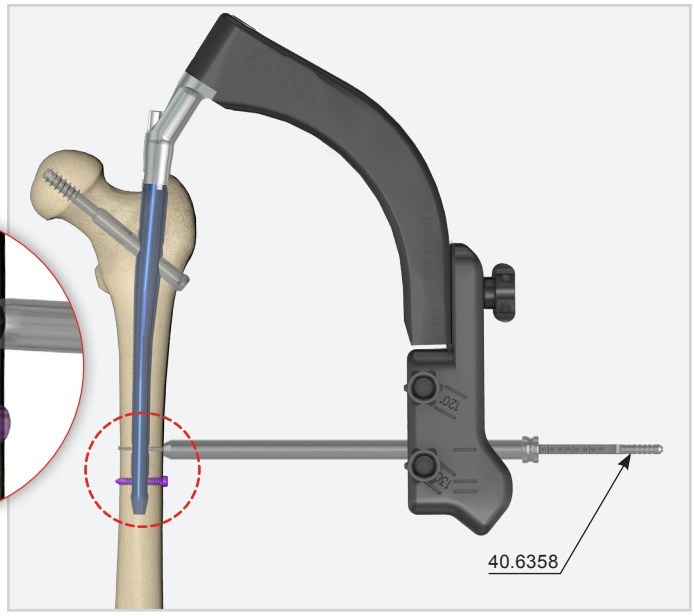
Remove the screwdriver and the protective guide 12/10.



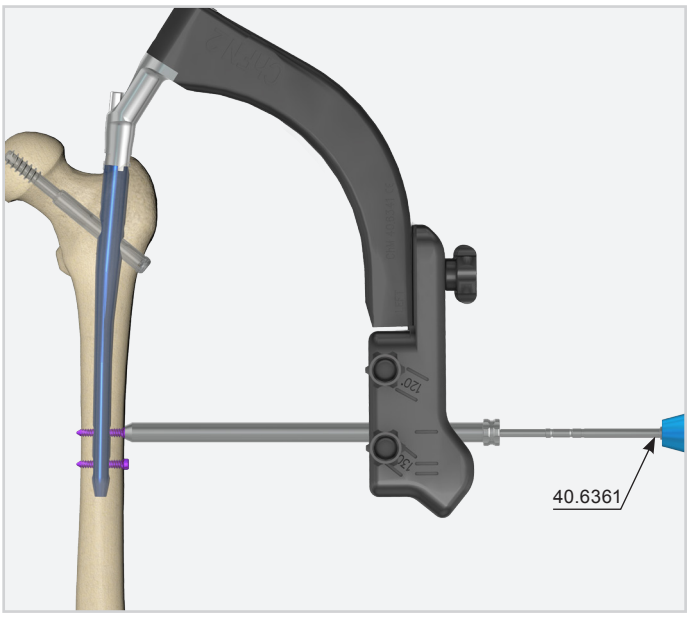
42 Remove drill with scale 4.0 **[40.5346.002]** and the drill guide 10/4.0 **[40.6362]** from the proximal hole of the targeter. Leave the protective guide 12/10 **[40.6353]** in the targeter hole. Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole. Read the length of distal screw on the B-D scale.

During measurements the tip of protective guide 12/10 should rest on the cortex of the femur.
Remove the screw length measure.
Leave the protective guide in the targeter hole.





43 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft shall match the edge of protective guide)*.
Remove the screwdriver, protective guide 12/10 and the targeter **[40.6342]** or **[40.6343]**

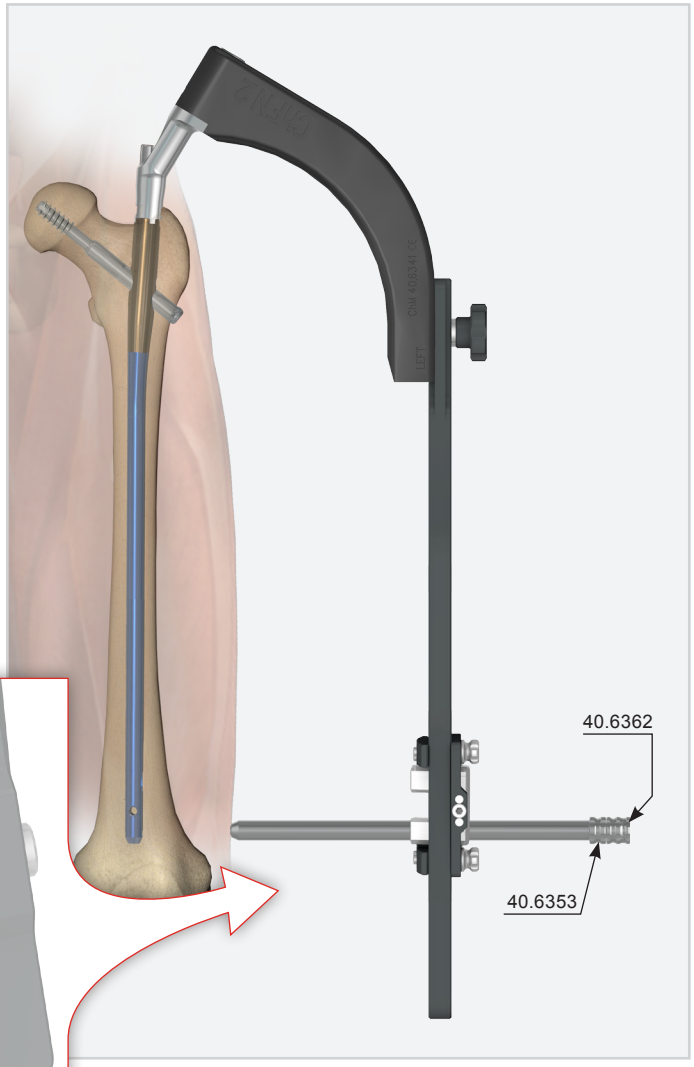


IV.7. DISTAL TROCHANTERIC NAIL *(LONG)* LOCKING

44 After locking the trochanteric nail long in its proximal part and disconnecting the chosen targeter, attach the distal targeter D **[40.6344]** to the targeter arm **[40.6341]**.

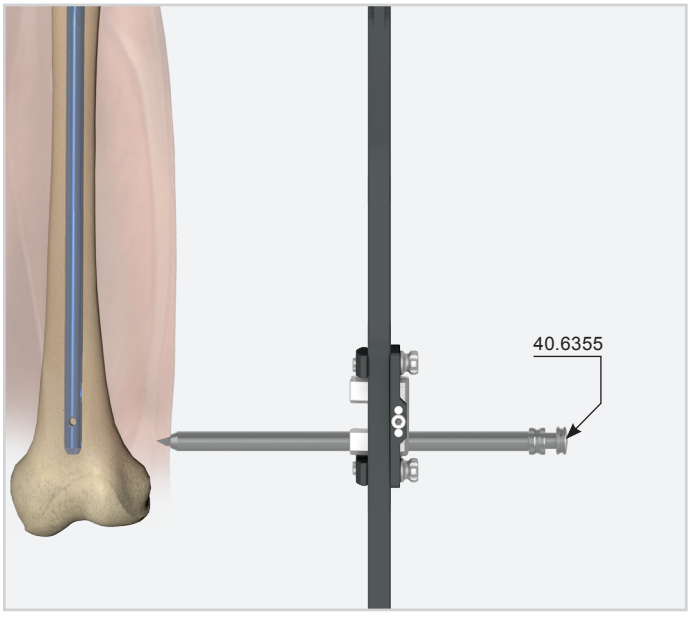
Verify, using X-Ray vision track, the mutual position of the holes in the targeter slider and holes in the distal trochanteric nail.

Set X-Ray vision track so that the image of the hole in the targeter *(proximal or distal)* seen on the screen is a circle. Insert the drill guide 10/4.0 **[40.6362]** in the protective guide 12/10 **[40.6353]** and then the system in the appropriate hole of the distal targeter D slider. The end of drill guide should rest on the soft tissues of the lower extremity. Verify using the X-Ray vision track the position of the drill guide hole and the nail hole. The holes must overlap. The circle image on the screen shall appear *(image close to the circle is acceptable)*. If the image on the screen is not a circle, settings of the distal targeter D must be corrected. To do so, use the knob of the setting screw of the distal targeter D slider **[40.6344]** to move the slider *(turn the knob left or right)* until the circle appears on the screen *(image close to circle is acceptable)*.



45 Remove the drill guide 10/4.0 **[40.6362]** from the protective guide 12/10 **[40.6353]** and insert trocar 10 **[40.6355]** there. Mark on the skin the entry point for the distal screw and perform soft tissue incision. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

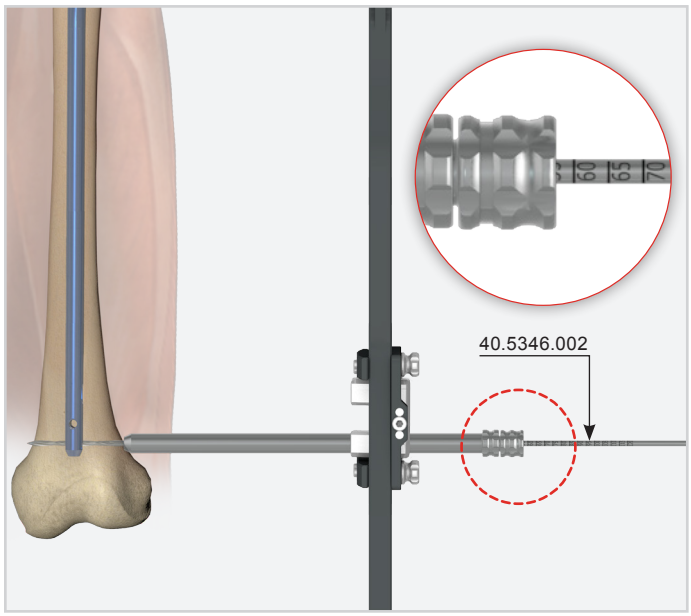
Remove the trocar.
Leave protective guide in place.



46 Insert the drill guide 10/4.0 **[40.6362]** in the protective guide 12/10 **[40.6353]**. Using a drive and a drill with scale 4.0 **[40.5346.002]** via the drill guide drill a hole in the femur extending through both layers of the cortex and the hole in the nail. The scale on the drill indicates the length of the locking element.

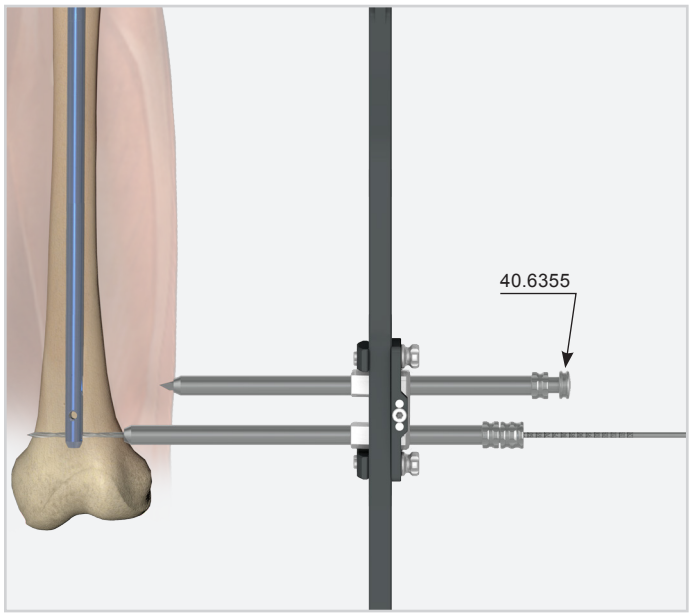
The drilling process should be done under X-Ray with visual track control.

After disconnecting the drive, leave drill, drill guide and the protective guide in the hole.



47 Insert the trocar 10 **[40.6355]** in the protective guide 12/10 **[40.6353]** and then the system in the other distal hole of the distal targeter D. Use the trocar to mark in the cortex the entry point for the drill. At the same time advance the protective guide as close to the bone as possible.

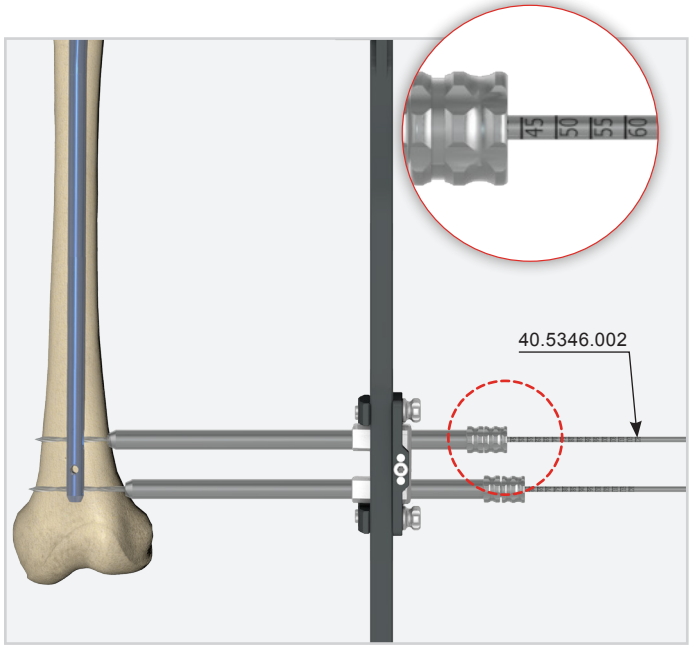
Remove the trocar.
Leave protective guide in place.



48 Insert the drill guide 10/4.0 **[40.6362]** in the protective guide 12/10 **[40.6353]**. Using a drive and a drill with scale 4.0 **[40.5346.002]** via the drill guide drill a hole in the femur extending through both layers of the cortex and the hole in the nail. The scale on the drill indicates the length of the locking element.

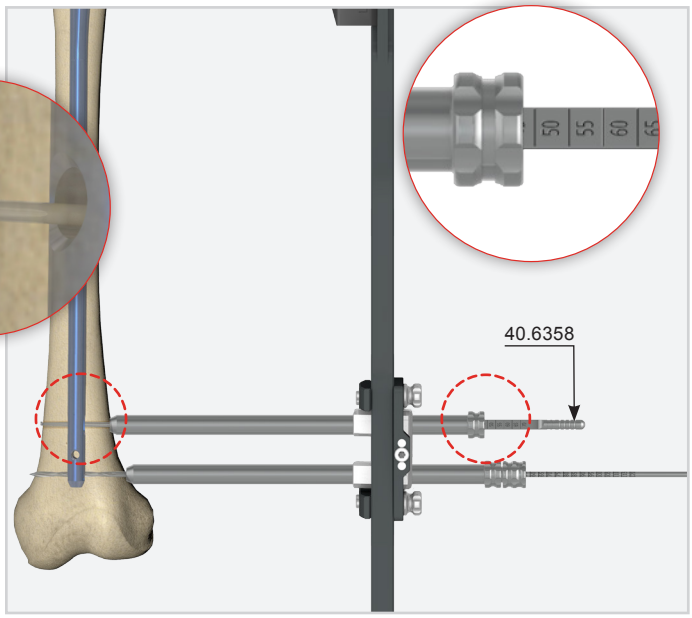
The drilling process should be done under X-Ray with visual track control.

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



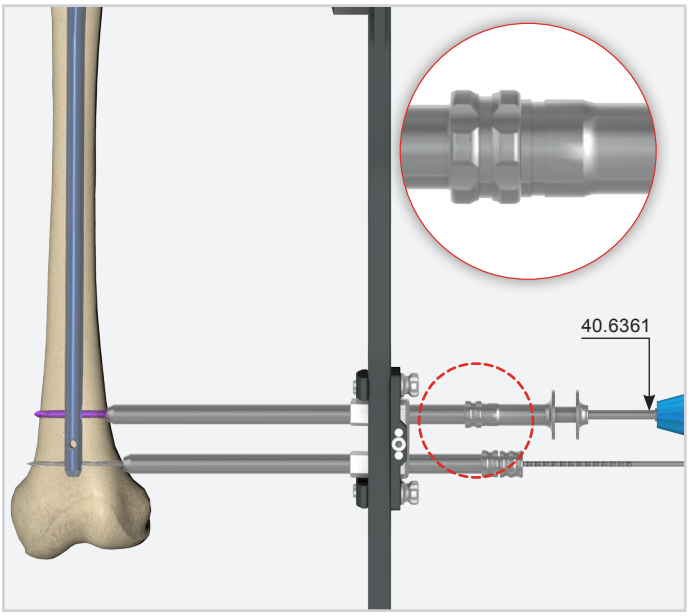
49 Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole.
Read the length of distal screw on the B-D scale.
During measurements the tip of protective guide 12/10 should rest on the cortex bone.

Remove the screw length measure.
Leave the protective guide 12/10 in the targeter hole.



50 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone.

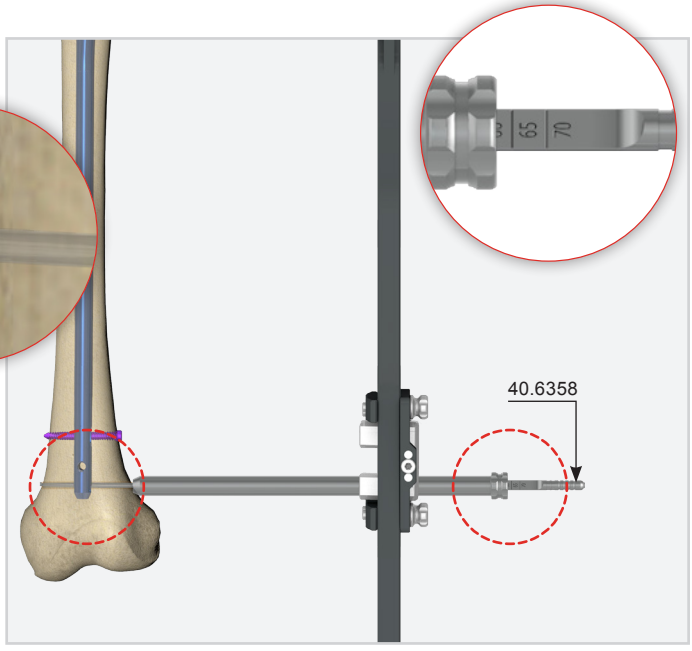
Remove the screwdriver and the protective guide 12/10.



51 Remove drill with scale 4.0 **[40.5346.002]** and the drill guide 10/4.0 **[40.6362]** from the distal hole of the targeter. Leave the protective guide 12/10 **[40.6353]** in the targeter hole. Insert the screw length measure **[40.6358]** through the protective guide 12/10 **[40.6353]** into drilled hole until its hook reaches the exit hole. Read the length of distal screw on the B-D scale.

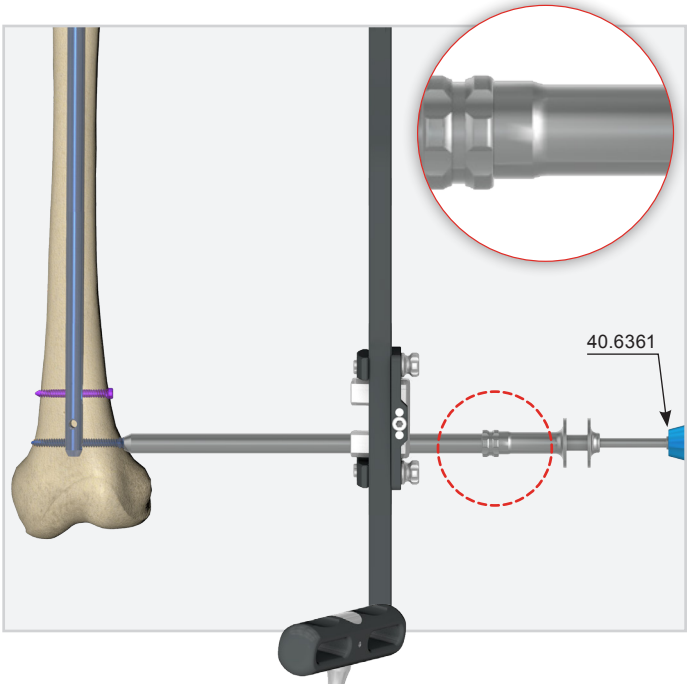
During measurements the tip of protective guide should rest on the cortex bone.

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

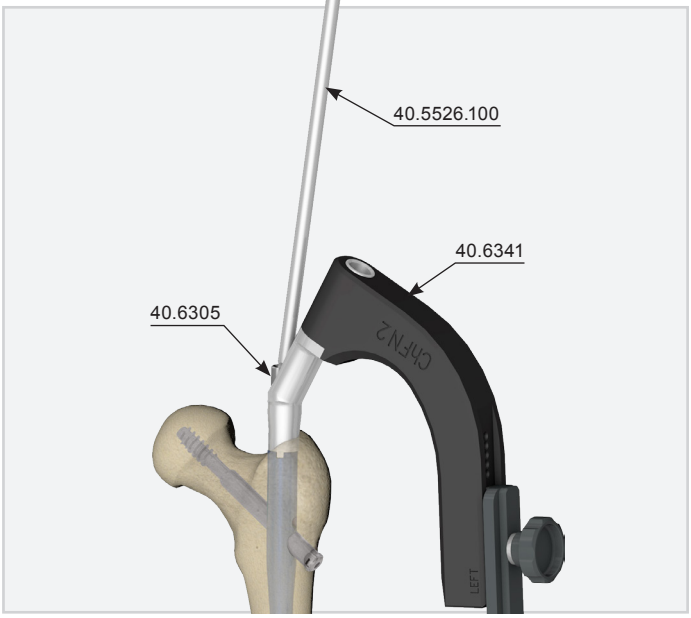


52 Insert the tip of the screwdriver T25 with holder **[40.6361]** into the socket of selected distal screw. Then advance both into the protective guide 12/10 **[40.6353]**.
Insert the distal screw in the prepared hole until the head of the screw reaches the cortex of the bone.

Remove the screwdriver, protective guide 12/10 and the distal targeter D.

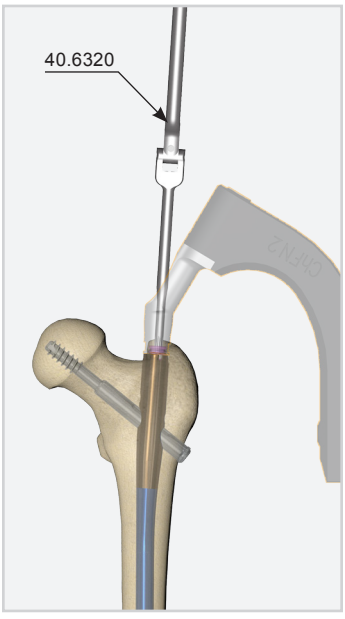


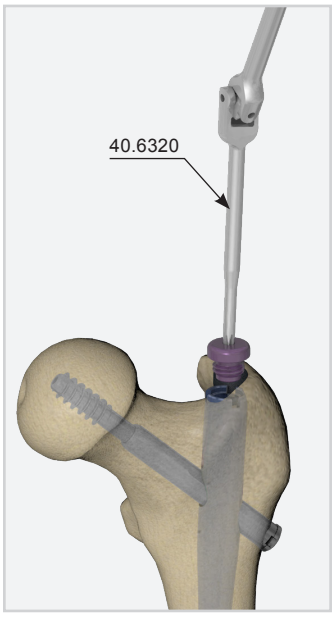
53 Using wrench S10 **[40.5526.100]**, remove the connecting screw **[40.6305]** from the trochanteric nail stem.



54 In order to protect the internal thread of the nail against bone ingrowth, insert an end cap *(implant)* into the threaded hole of the nail using the wrench for self-aligning joint T25 **[40.6320]**.

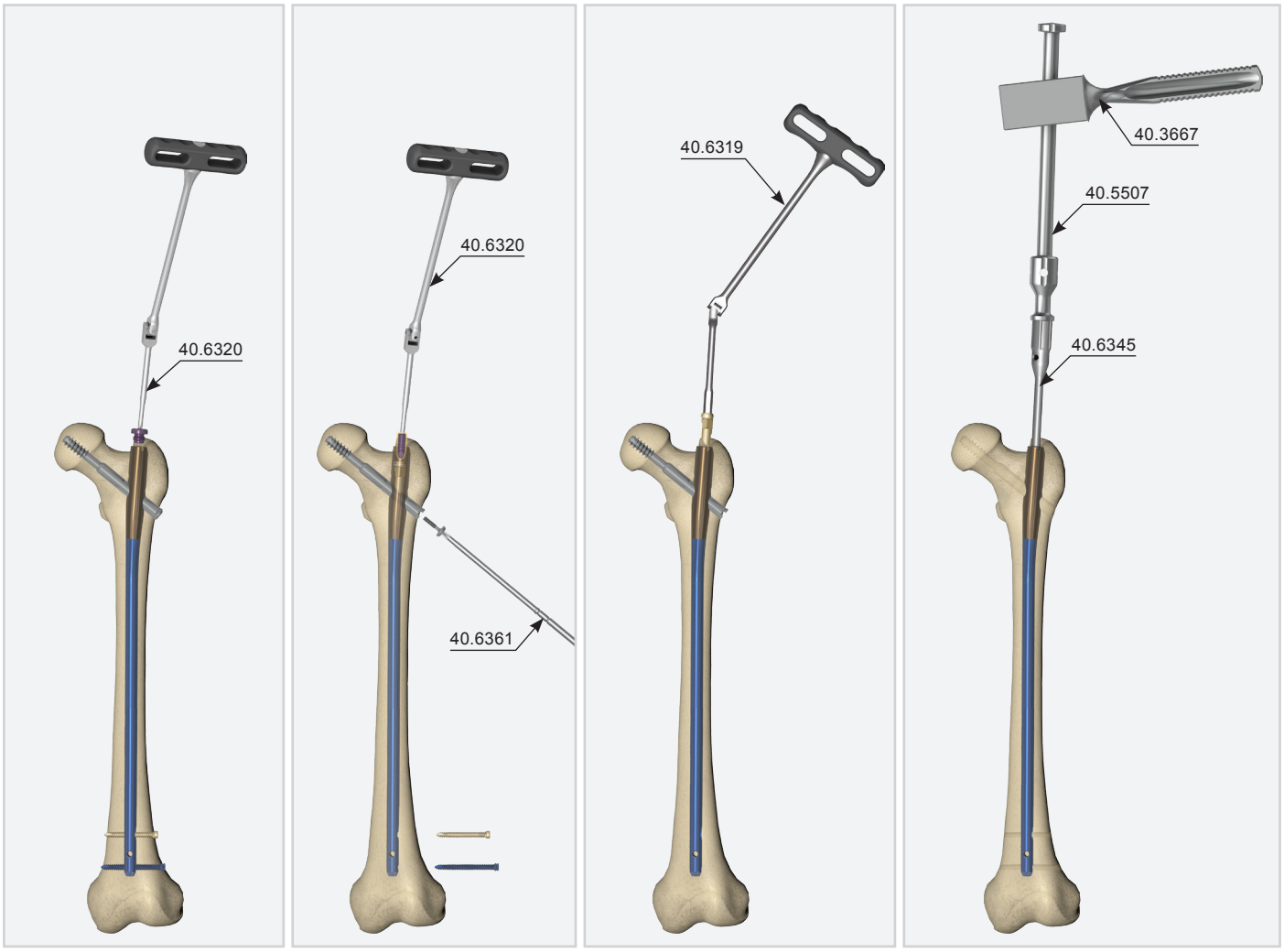
End cap „0”, „+5”, „+10” or „+15” [3.5161.600÷615] may be inserted via the targeter arm [40.6341] after removing the connecting screw.





IV.8. TROCHANTERIC NAIL REMOVAL *(SHORT AND LONG NAILS)*

55 Using wrench for self-aligning joint S7 **[40.6319]**, wrench for self-aligning joint T25 **[40.6320]** and screwdriver T25 with holder **[40.6361]**, remove end cap, fork screw and all the locking *(distal and join)* screws. Insert the connector of extractor M12x1.75 **[40.6345]** in the threaded hole of the nail shaft. Apply impactor-extractor **[40.5507]** to the connector and using the mallet **[40.3667]**, remove the nail from the medullary canal.



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ISO 9001/ ISO 13485

CE 0197

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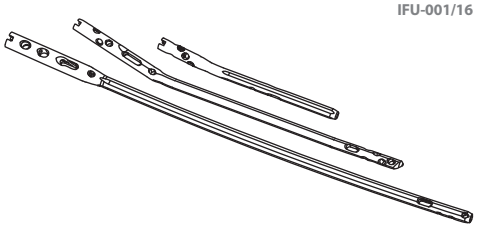
IFU-001/16



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INSTRUCTIONS FOR USE

Important product information for

INTERLOCKING NAIL SYSTEM

CHARFIX system | CHARFIX system 2

Charfix Femoral Nail ChFN system | Charfix Femoral Nail ChFN system 2

1 PURPOSE AND INDICATIONS

1. Bone nails of CHARFIX, CHARFIX2, ChFN, ChFN2 systems are intended for osteosynthesis of long bone fractures. There are the following indications for bone treatment: transverse and slightly oblique fractures, trochanteric zone fractures *(per-, inter-, sub-trochanteric)*, comminuted fractures, open fractures of I, II, IIIA degree Gustillo-Anderson, pathologic fractures, disturbance of union *(false joint)* after treatment using other methods, corrective osteotomies, neck base region fractures.
2. There are the following bone nail locking elements: locking screws, reconstruction screws, locking sets, setting screws, compression screw, join screws, end cap and nuts used to lock the above-mentioned systems used in the treatment of long bone fractures by means of intramedullary fixation method.
3. Stable osteosynthesis of bone fragments is obtained by locking the appropriate nail in the medullary canal with the use of locking elements suitable for the given nail and fixation method used.
4. Nails and telescopic sleeves are intended for fracture treatment in children and adolescents with congenital osteogenesis imperfecta.
5. **ChM** sp. z o.o. does not recommend any specific treatment method for a particular patient.

2 CONTRAINDICATIONS

1. Contraindications may be relative or absolute. The choice of particular device must be carefully weighed against patient's overall condition. Conditions listed below may preclude or reduce the chance of successful outcome:
   1) Infection local to the operative site.
   2) Signs of local inflammation.
   3) Fever or leukocytosis.
   4) Pregnancy.
   5) Neuromuscular disorders which can create unacceptable risk of fixation failure or complications in postoperative care.
   6) Any other condition which would preclude the potential benefit of implant insertion surgery and disturb the normal process of bone remodeling, e.g. the presence of tumours or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cells *(WBC)* count, or a marked left shift in the WBC differential count.
   7) Suspected or documented allergy or intolerance to implant materials. Surgeon shall find out if the patient develops allergic reaction to the material of the implant *(content of the implant material is presented in IMPLANT MATERIAL)*.
   8) Any case not needing a surgical intervention.
   9) Any case not described in the indications.
   10) Any patient unwilling to cooperate with postoperative instructions; mental illness, a condition of senility or substance abuse may cause the patient to ignore certain necessary limitations and precautions in the implant usage.
   11) Any case where the implant components selected for use would be too large or too small to achieve a successful result.
   12) Any case that requires the simultaneous use of elements from different systems that are made of different metals.
   13) Any case in which implant utilization would disturb physiological processes.
   14) Blood supply limitation in the operative site.
   15) Morbid obesity *(defined according to the WHO standards)*.
   16) Any case in which there is inadequate tissue coverage of the operative site.
   17) Shaft fractures with a fissure less than 5 cm from the nearest interlocking hole of the nail.
2. The above-mentioned list does not exhaust the topic of contraindications.

3 ADVERSE EFFECTS

1. The adverse effects may necessitate reoperation or revision. The surgeon should warn the patient about the possibility of adverse effects occurrence.
2. The undermentioned list does not exhaust the topic of adverse events. There is a risk of occurrence of adverse events with unknown aetiology which may be caused by many unpredictable factors.
3. Potential adverse events include but are not limited to:
   1) Implant damage *(fracture, deformation or detachment)*.
   2) Early or late loosening, or displacement of the implant from the initial place of insertion.
   3) Possibility of corrosion as a result of contact with other materials.
   4) Body reaction to implants as foreign bodies e.g. possibility of tumour metaplasia, autoimmune disease and/or scarring.
   5) Compression on the surrounding tissue or organs.
   6) Infection.
   7) Bone fractures or *"stress shielding"* phenomenon causing loss of bone above, below or at the operative site.
   8) Haemorrhage of blood vessels and /or hematomas.
   9) Pain.
   10) Inability to perform everyday activities.
   11) Mental condition changes.
   12) Death.
   13) Deep vein thrombosis, thrombophlebitis.
   14) Occurrence of respiratory complications, e.g.: pulmonary embolism, atelectasis, bronchitis, pneumonia, pulmonary infection, disturbed lung growth, respiratory acidosis, etc.
   15) Scar formation that could cause neurological impairment, or nerves compression and /or pain.
   16) Late bone fusion or no visible fusion mass and pseudoarthrosis.
   17) Loss of proper curvature and/or length of bone.

4 WARNINGS

1. The important medical information given in this document should be conveyed to the patient.
2. The selection of proper shape and size of the implant appropriate for a specific patient is crucial to achieving success of the surgery. The surgeon is responsible for this choice.
3. Preoperative and operating procedures, including knowledge of surgical techniques, and correct placement of implants are important and shall be considered by the surgeon in order to achieve success during operation.
4. No implant can withstand body loads without the biomechanical continuity of the bone.
5. During normal use all surgical implants are subjected to repeated stresses which can result in material fatigue and failure of the implant.
6. To avoid excessive stress on the implant which could lead to non-union or implant failure and associated clinical problems, the surgeon must inform the patient about the physical activity limitations during the treatment period.
7. If the patient is involved in an occupation or activity *(e.g.: substantial walking, running, lifting weights, muscles strain)* which may apply excessive stress on the implant, the surgeon must inform the patient that resultant forces can cause implant failure.
8. A successful result is not always achieved in every surgical case. This fact is especially true in the case where other patient's conditions may compromise the results.
9. The proper selection, compliance of the patient and observance of post-operative recommendations will greatly affect the results. The bone union is less likely to occur among patients who smoke. These patients should be informed about this fact and warned of this consequence.
10. Overweight may cause additional stresses and strains within implant which can lead to fatigue and deformation of the implant.
11. Patients who are overweight, malnourished and/or abusing alcohol or drugs, with weak muscles and low quality bones and/or with nerve palsy are not the best candidates for the procedure of surgical stabilization. These patients are not able or not ready to observe the post-operative recommendations and limitations.
12. The implants are intended as an aid to the healing process and are **NOT** intended to replace body structures or bear the body weight when the treatment process has not yet finished.
13. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
14. The surgeon must warn the patient that the device cannot and does not restore the function and efficiency of a healthy bone.
15. In the case of delayed union or non-union, the load or weight bearing may eventually cause the implant bending, loosening, disassembling or fatigue breakage.

5 PACKAGING AND STORAGE

1. Implants are single-use devices, provided sterile or non-sterile.
2. Implants not labeled as sterile are non-sterile.
3. Implant packaging must be intact at the time of receipt.
4. The unit package contains:
   1) sterile version - one piece of the product in a sterile condition. A double package made of Tyvek-foil or a single blister are typical packaging material.
   2) non-sterile version - one piece of the product. Clear plastic bags are a typical packaging material.
5. A sterility indicator is placed on the sterile package.
6. The packaging is equipped with the product label. The label *(as a primary label)* contains e.g.:
   1) Sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) STERILE sign - indicating a sterile device and the sterilization method used, e.g.: R or VH202 *(symbols are described in the footer of this Instructions For Use)*.
      f) Sterilization batch number, e.g.: S-XXXXXXX.
      g) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
      h) Expiration date and sterilization method.
   2) Non-sterile product
      a) Logo **ChM** and the address of the manufacturer.
      b) Name and size of the device and its catalogue number *(REF)*, e.g.: 3.XXXX.XXX.
      c) Production batch number *(LOT)*, e.g. XXXXXXX.
      d) Material of the implant *(see IMPLANT MATERIAL)*.
      e) NON-STERILE sign - indicates non-sterile product.
      f) Device pictogram and information symbols *(described in the footer of this Instructions For Use)*.
7. In addition to the device primary label, an auxiliary label with specific market requirements of a given area may be placed on the unit package *(e.g. legal requirements of the country in which the device will be distributed)*.
8. The package may contain: Instructions For Use and labels to be placed in a patient's medical record.
9. Depending on the size or type of the product, the following information may be marked on its surface: manufacturer's logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.
10. Implants should be stored in appropriate protective packages, in a clean, dry place with a moderate temperature and under conditions that provide protection from direct sunlight.

6 IMPLANT MATERIAL

1. Identification of the materials
   1) Depending on the material used, the following symbols may be marked on the device surface:
      a) Steel: symbol *(S)*.
      b) Titanium and titanium alloys: symbol *(T)*.
   2) The implants are made of:
      a) Implantable stainless steel.
      b) Implantable titanium alloy.
   3) Percent composition of elements in the implantable materials *(max. values)*:
      a) Titanium alloy according to ISO 5832-3/ASTM F136: | Al:6.75 | V:4.5 | Fe:0.3 | O:0.2 | C:0.08 | N:0.05 | H:0.015 | Ti:rest.
      b) Titanium alloy according to ISO 5832-11/ASTM F1295: | Al:6.5 | Nb:7.5 | Ta:0.5 | Fe:0.25 | O:0.2 | C:0.08 | N:0.05 | H:0.009 | Ti:rest.
      c) Steel according to ISO 5832-1/ASTM F138: | C:0.03 | Si:1.0 | Mn:2.0 | P:0.025 | S:0.01 | N:0.1 | Cr:19.0 | Mo:3.0 | Ni: 15.0 | Cu:0.5 | Fe:rest.
      d) Steel according to ISO 5832-9/ASTM F1586: | C:0.08 | Si:0.75 | Mn:4.25 | P:0.025 | S:0.01 | N:0.5 | Cr:22.0 | Mo:3.0 | Nb:0.8 | Ni: 11.0 | Cu:0.25 | Fe:rest.
   4) ATTENTION: Implantable titanium, titanium alloy and/or implantable cobalt alloy may be used together in the same construct. Never use titanium, titanium alloy and/or cobalt alloy with implantable stainless steel components in the same construct as it may lead to corrosion and reduction of mechanical strength of implants.
2. Magnetic Resonance compatibility
   1) **ChM**'s implants made completely from or containing elements made of implantable steel were not assessed for their safety and compatibility with magnetic resonance imaging procedures. The performance of MRI on these implants *(especially in the magnetic field with a significant induction)* may pose a potential risk of, i.a.:
      a) implant displacement or heating up,
      b) artifacts on MR images.
   2) Implants made of titanium, titanium alloys and cobalt alloys are conditionally compatible with magnetic resonance imaging.
   3) The patient can be scanned safely under the following conditions:
      a) static magnetic field of ≤ 3 Tesla,
      b) maximum magnetic field spatial gradient of ≤ 720 Gauss/cm,
      c) maximum MR system reported whole-body-averaged specific absorption rate *(SAR)* of 3W/kg for 15 minutes of scanning.
   4) CAUTION: the user should be absolutely familiar with the contraindications and warnings established by the manufacturer of the MRI scanner to be used for imaging procedure.
   5) MR imaging may be interfered with if the area of interest is in the exact same area or relatively close to the position of the implant.
   6) Do not perform MRI if there are doubts about the tissue integrity and the implant fixation or if the proper location of the implant is impossible to be established.

7 PRE-OPERATIVE RECOMMENDATIONS

1. Only patients that meet the criteria described in the PURPOSE AND INDICATIONS should be selected.
2. Patients' conditions and/or predispositions such as those addressed in the above-mentioned CONTRAINDICATIONS should be avoided.
3. Before deciding about implantation, the surgeon shall inform the patient about indications and contraindications of such procedure and possibility of complications occurrence after the operation. Patient shall be introduced to the purpose and manner of the procedure, and to functional and aesthetic effects of such treatment. Proper clinical diagnosis and accurate operation planning and performance are needed to achieve good final result of treatment.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation *(alloying elements of implant material are presented in IMPLANT MATERIAL)*.
5. The implantation shall be carried out by the surgeon familiar with adequate rules and operating techniques, and who has acquired practical skills of using **ChM** instrument set. The selection of surgical technique adequate for a specific patient remains surgeon's responsibility.
6. The operation procedure shall be carefully planned. The size of implant should be determined prior to the beginning of the surgery. An adequate inventory of implants with required sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. The surgeon should be familiar with all components of the implant system before use and should personally verify if all components and instruments are present before the surgery begins.
8. Do not use the implant if the original, sterile packaging is damaged. Sterility cannot be guaranteed if the packaging is not intact. The packaging shall be carefully checked prior to use.
9. Implants are delivered in protective packages. The package should be intact at the time of receipt.
10. Unless supplied sterile, all implants and instruments should be washed, disinfected and sterilized before use. Additional sterile components should be available in case of any unexpected need.
11. Before procedure begins, all implants should be carefully checked to ensure that there is no damage *(surface scratching, dents, signs of corrosion and shape deformations)*. Damaged implant cannot be inserted into the body.

8 RECOMMENDATIONS FOR IMPLANTS PROVIDED STERILE

1. Sterile implant - is delivered in sterile package, with the inscription: *"STERILE"*. Such product is sterile and the manufacturer is responsible for the process of sterilization. The sterilization is performed with the use of one of the following methods:
   1) gamma radiation, with a minimum dose of **25 kGy**,
   2) hydrogen peroxide vapour.
2. The symbol designating the sterilization method used is visible on the device label *(symbols are described in the footer of this Instructions For Use)*.
3. Prior to use of a sterile device the following rules apply:
   1) Check out the expiration date of sterilization. Do not use the device with an overstepped sterility date!
   2) Check out if the sterile package is not damaged. Do not use the device if the sterile package is damaged.
   3) Check out the colour of the sterility indicator on the sterile packaging which indicates that sterilization of the device was performed. Do not use the device if the sterility indicator colour is different than:
      a) red - for devices sterilized with gamma radiation,
      b) blue - for devices sterilized with hydrogen peroxide vapour.
4. CAUTION: products should be removed from their packages in accordance with aseptic rules.

9 RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE

1. Prior to use of a non-sterile device the following rules apply:
   1) The device must undergo washing, disinfection and sterilization procedures. It is recommended to use automated procedures for washing and disinfecting in the washer-disinfector.
   2) Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the technique of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the device, the time, the temperature and carefulness of the person conducting this process.
   3) Labels to be placed in patient's medical records *(delivered together with the implant)* must be protected against loss or damage during the implant washing and sterilization.
2. Preparation for washing
   1) After taking the device out from the original package, remove possible surface contamination *(resulting from e.g.: damage to unit package)* using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*. Do not use brushes made of metal, bristles or materials which could damage the implant.
3. Cleaning and disinfection process
   1) The chosen washing and disinfecting detergents must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of those detergents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.
4. Manual cleaning
   1) Apply washing detergent *(e.g. MEDICLEAN)* to implant surface and brush carefully. Suitable brushes must be used for holes cleaning.
   2) If applicable, ultrasonic cleaning may be performed. The ultrasonic bath must be prepared according to the manufacturer's instructions.
   3) Rinse thoroughly under running water. It is recommended to rinse with demineralized water.
   4) Visually inspect the entire surface of the device for damage and contaminants. Damaged implants must be removed.
   5) For contaminated implants, the cleaning process should be repeated.
5. Cleaning in the washer-disinfector
   1) The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*. CAUTION: The equipment used for washing/disinfection should meet the requirements of ISO 15883.
   2) Procedure of washing in the washer-disinfector shall be performed according to internal hospital

procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agent manufacturer. Disinfection should be carried out at temperature of 90°C *(soak in demineralized water)* for at least 10 minutes without the use of detergents.

6. Drying
   1) Drying of the device must be performed as a part of the washing/disinfection process.
7. Packaging
   1) The device supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1. The packaging procedure must be performed in controlled purity conditions. The device must be packed in such a way that during removal from the package, when used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.
8. Sterilization
   1) Washed, disinfected, and dried device shall undergo the sterilization process. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:
   a) temperature: 134°C,
   b) minimum exposure time: 7 min,
   c) minimum drying time: 20 min.
9. CAUTION:
   1) Sterilization must be effective and in accordance with requirements of the EN 556 standard to ensure the required level of guaranteed sterility SAL 10^{-6} *(where SAL stands for Sterility Assurance Level)*.
   2) Implant must not be sterilized in the package in which it was delivered.
   3) Validated sterilization methods used by sterilization facilities are allowed.
   4) The above-mentioned rules of cleaning and sterilization must be followed when dealing with any device intended for implantation.
   5) Surgical instrument set, which is used for device implantation, shall also be included into the cleaning and sterilization procedure.

10 RE-STERILIZATION

1. It is permitted to re-sterilize devices by end-user.
   1) ATTENTION: The user of the product bears all responsibility for re-sterilization. In such case the device shall be washed and sterilized in a way described in RECOMMENDATIONS FOR IMPLANTS PROVIDED NON-STERILE.

11 PRECAUTIONS

1. Implant is intended for single use only. After removing the implant from the patient's body, it must be secured against re-use, and then finally disposed of in accordance with current hospital procedures.
2. Under no circumstances is it allowed to reuse or reimplant once used device. Even if the removed implant appears to be undamaged, it may have small latent defects or internal stresses, which could lead to early failure, fatigue wear, and as a result to e.g.: an implant breakage.
3. Implant which had contact with tissues or body fluids of another patient cannot be re-implanted due to a potential risk of cross-infection caused by viruses, bacteria and prions.
4. Misuse of instruments or implants may cause injury to the patient or operative personnel.
5. Avoid damaging implant surface and deforming its shape during the implantation; the damaged implant cannot be implanted or left in the patient's body.
6. Insertion, removal and adjustment of implants must only be done with instruments specially designated for those implants, and manufactured by **ChM** sp. z o.o.
7. Use of **ChM**'s implants and instruments in combination with implants and instruments from other manufacturers may cause damage or failure of those implants or instruments and may lead to improper course of surgery and healing process.
8. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to prolonged use or excessive force are more susceptible to fractures, depending on care taken during surgery, number of procedures performed and attention paid. Instruments should be examined for wear or damage prior to surgery.
9. While inserting the screw, it is essential to correctly set the screwdriver in relation to the screw. Following the instructions given allows for reduction of the risk of mechanical damage to the screw, screwdriver, or bony hole:
   1) screwdriver should be set in the screw axis,
   2) apply proper axial pressure to ensure that the screwdriver goes as deep in the head of the bone screw as possible,
   3) the final phase of tightening shall be performed carefully.

12 POST-OPERATIVE RECOMMENDATIONS

1. It is essential to follow all of physician's postoperative directions and warnings.
2. It is essential to confirm proper position of the implant by roentgenographic examination.
3. In postoperative period, in treatment, the correctness of implant positioning and immobilization of union should be confirmed by roentgenographic examination.
4. The patient should be warned about the risk should he fail to follow the above-mentioned rules, or should he be unavailable for follow-up clinical examination.
5. The surgeon must instruct the patient to report any unusual changes of the operative site to his/her physician. If any change at the site has been detected, the patient should be closely monitored.
6. The patient should be informed about the type of implant material.
7. The patient should be warned to inform the medical staff about the inserted implants prior to any MRI procedure.
8. The patient should be advised not to smoke or consume alcohol excessively during the period of treatment.
9. If the patient is involved in an occupation or activity which may apply excessive stress on the implant *(e.g. substantial walking, running, lifting, or muscle strain)* the surgeon must advise the patient that resultant forces can cause implant failure.
10. The surgeon must instruct the patient regarding appropriate and restricted activities during consolidation and maturation of the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and further clinical problems. The implant may break or become damaged as a result of strenuous activity or trauma, and may need to be replaced in the future.
11. Failure to perform appropriate immobilization of bone when delayed or non-union occurs may lead to excessive fatigue stresses in the implant. Fatigue stresses may be a potential cause of implant becoming bent, loosened or fractured. If non-union of fracture or implant bending, loosening or fracture occurs, the patient should be immediately revised, and the implants should be removed before any serious injuries occur. The patient must be appropriately warned about these risks and closely monitored to ensure compliance during the treatment until the bone union is confirmed.
12. After locking the nail in the bone it is necessary to verify whether the locking screws have been inserted in the nail holes.

13 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER TREATMENT

1. When bone union is achieved, the implants serve no functional purpose and their removal is recommended. The possibility of another surgical procedure and associated risks must be analysed and discussed with the patient. The final decision on implant removal is up to the surgeon. In most patients, removal is indicated because the implants are not intended to transfer forces developed during normal activities.
2. If the device is not removed following completion of its intended use, one or more complications may occur, in particular:
   1) Corrosion, with localized tissue reaction or pain.
   2) Migration of the implant, possibly resulting in injury.
   3) Risk of additional injury from postoperative trauma.
   4) Bending, loosening, or breakage, which could make implant removal difficult or impossible.
   5) Pain, discomfort, or abnormal sensation due to the presence of the implant.
   6) Increased risk of infection.
   7) Bone loss due to the stress shielding.
   8) Potentially unknown and/or unexpected long term effects.
3. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
4. Implantable stainless steel implant shall be removed after period of not more than two years after its implantation.

If these instructions appear unclear, please contact the manufacturer, who shall provide all required explanations.

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

IFU-001/16; Date of verification: March 2016

SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при повреждённой упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Avvertenza
STERILE R	Sterilized using irradiation • Sterylizowany przez napromieniowanie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH202	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Material • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

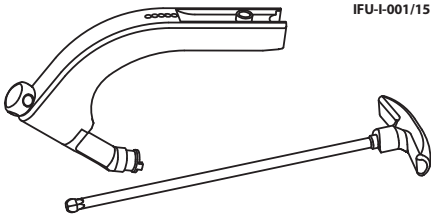
GB

ISO 9001/ ISO 13485

CE

Manufacturer: ChM sp. z o.o.
Lewickie 3b, 16-061 Juchnowiec K., Poland
tel.: +48 85 713-13-20 fax: +48 85 713-13-19
e-mail: chm@chm.eu www.chm.eu

IFU-I-001/15



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INSTRUCTIONS FOR USE
REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

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

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

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

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

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

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

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

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

MATERIALS

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

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

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

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

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

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

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

WARNINGS AND PRECAUTIONS

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

If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

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

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

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

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

Cleaning and disinfection process

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

CAUTION:

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

Manual cleaning

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

CAUTION:

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

Cleaning with washer-disinfector

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

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

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

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

Drying

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

Inspection

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

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

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

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

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

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

Packaging

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

Sterilization

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

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

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

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

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

STORAGE

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

CALIBRATION

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

   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

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

Updated INSTRUCTIONS FOR USE are available on the following website: **www.chm.eu**

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SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILIZE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при поврежденной упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le instruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromienianie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH2O2	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

Manufacturer: ChM sp. z o.o.
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CE 0197
ISO 9001
ISO 13485