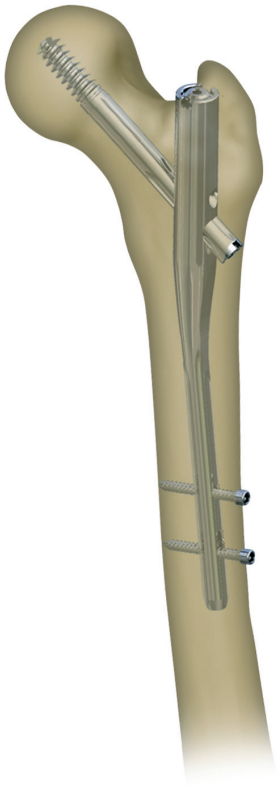
ChM®

Charfix Femoral Nail
ChFN system

INTRAMEDULLARY OSTEOSYNTHESIS OF FEMUR WITH ChFN TROCHANTERIC NAILS

- *IMPLANTS*
- *INSTRUMENT SET 40.5590.600*
- *SURGICAL TECHNIQUE*



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

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I. INTRODUCTION

Intramedullary Osteosyntesis of Femur with ***CHARFIX*** Femoral Nail consists of:

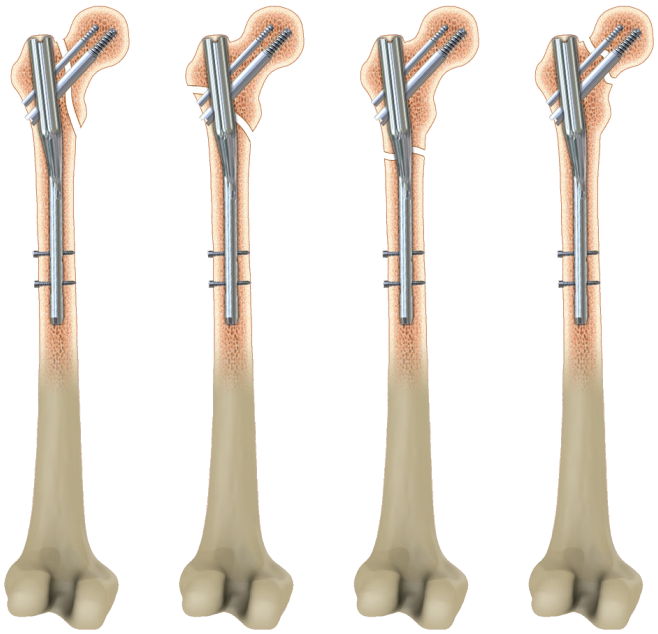
- implants *(intramedullary nails, locking screws, join screws, end caps)*,
- instrument sets for implants' insertion and removal,
- instructions for use

Intramedullary osteosynthesis of femur with ChFN nails allows for stable anastomosis of femur peritrochanteric fractures. Application of two join screws eliminates rotation of 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.

Application for usage:

- subtrochanteric fractures,
- intertrochanteric fractures,
- pertrochanteric fractures.



Examples of femur fractures treated with ChFN nail

Good result are obtained in case of:

- Pathological damages *(one-place)* as well as damage to ipsilateral intertrochanteric area,
- Pathological damages *(one-place)* as well as ipsilateral fractures of femoral shaft.

Also good results are obtained in case of:

- Multifragmental fractures of near-trochanter area,
- Basic fractures of femoral neck.

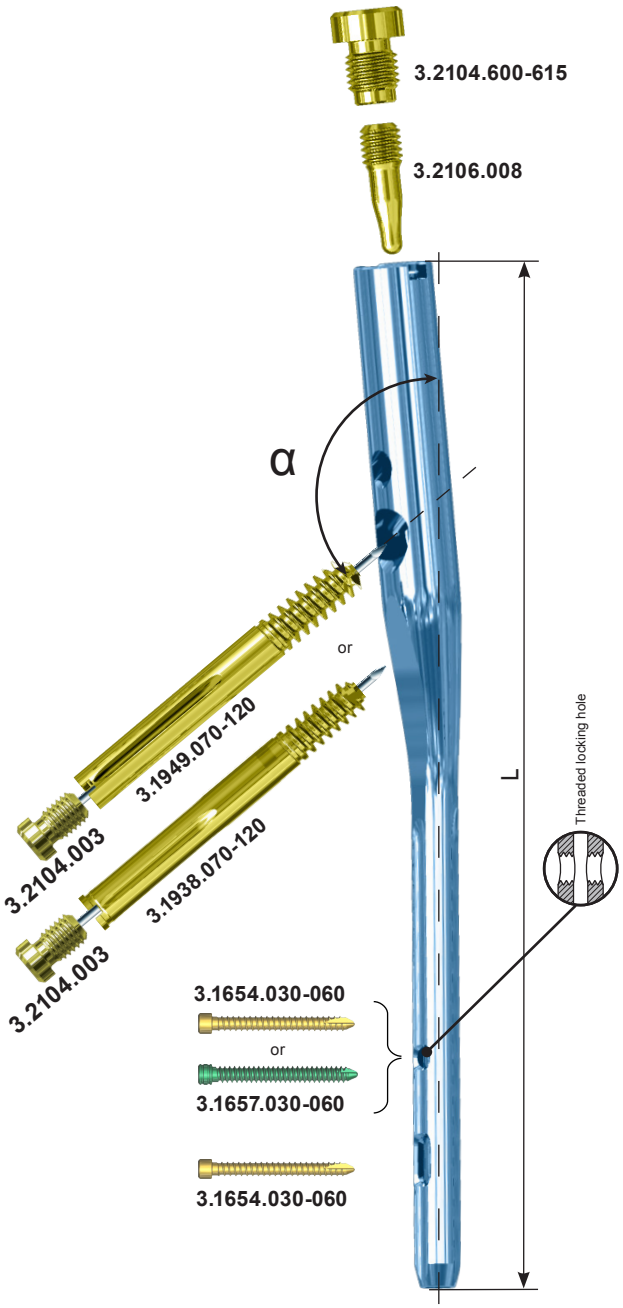
II. IMPLANTS

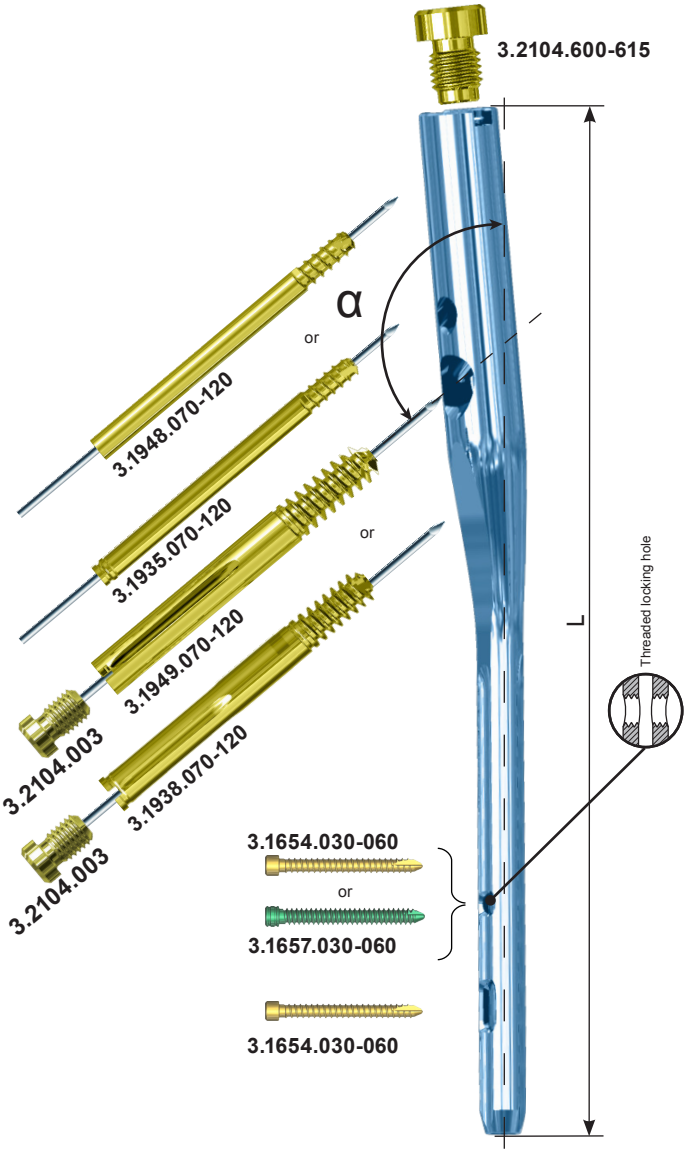
Implants consist of:

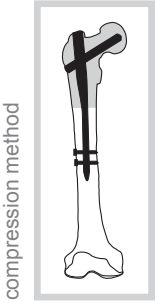
- solid and cannulated trochanteric nails 8÷19mm diameter graded by 1mm and length 200÷600mm graded by 5mm;
- distal screws 4.5,
- distal screws 5.0,
- end cap M8,
- end cap M12,
- join screw 11,
- join screw 6.5,
- compression screw *(locking option using one join screw)*.

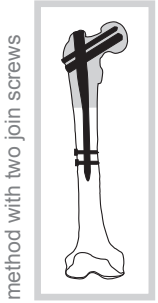
ChFN TROCHANTERIC NAIL

Charfix Femoral Nail
ChFN system
TITANIUM ALLOY Ti






compression method


method with two join screws

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ChFN TROCHANTERIC NAIL

L [mm]	Ø	α 125°	α 130°	α 135°
180 200	**10**	3.4864.180 3.4864.200	3.4876.180 3.4876.200	3.4888.180 3.4888.200
180 200	**11**	3.4865.180 3.4865.200	3.4877.180 3.4877.200	3.4889.180 3.4889.200
180 200	**12**	3.4866.180 3.4866.200	3.4878.180 3.4878.200	3.4890.180 3.4890.200

Suggested

available	
Ø [mm] pitch 1 mm	10÷12
L [mm] pitch 5 mm	180÷280

	Ø10	**Ø11**	**Ø12**
colours			

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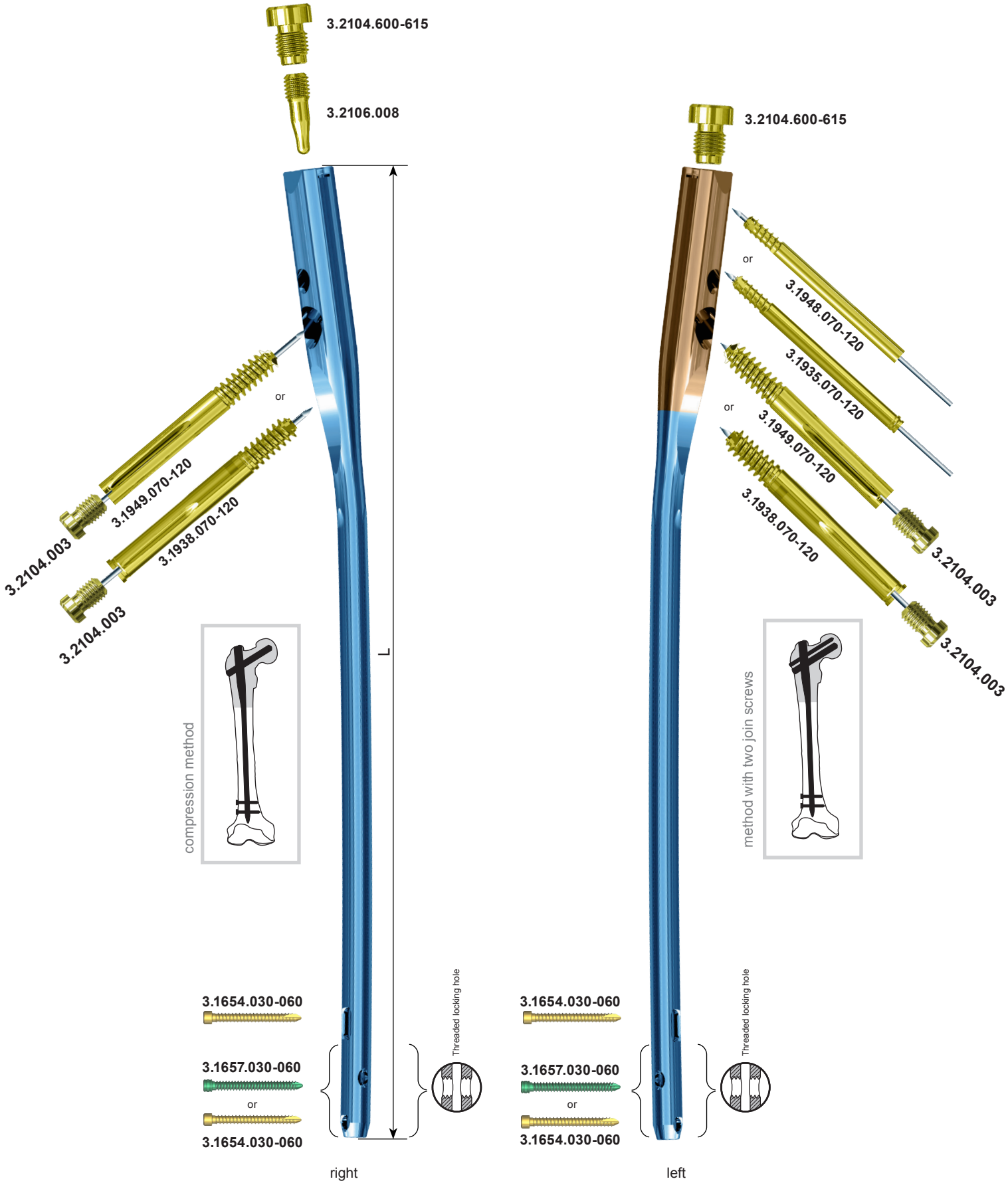
ChFN TROCHANTERIC NAIL LONG



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ChFN TROCHANTERIC NAIL LONG

L [mm]	Ø	α 125° left	α 125° right	α 130° left	α 130° right	α 135° left	α 135° right
340	10	3.4927.340	3.4926.340	3.4951.340	3.4950.340	3.4975.340	3.4974.340
360		3.4927.360	3.4926.360	3.4951.360	3.4950.360	3.4975.360	3.4974.360
380		3.4927.380	3.4926.380	3.4951.380	3.4950.380	3.4975.380	3.4974.380
400		3.4927.400	3.4926.400	3.4951.400	3.4950.400	3.4975.400	3.4974.400
420		3.4927.420	3.4926.420	3.4951.420	3.4950.420	3.4975.420	3.4974.420
340	11	3.4929.340	3.4928.340	3.4953.340	3.4952.340	3.4977.340	3.4976.340
360		3.4929.360	3.4928.360	3.4953.360	3.4952.360	3.4977.360	3.4976.360
380		3.4929.380	3.4928.380	3.4953.380	3.4952.380	3.4977.380	3.4976.380
400		3.4929.400	3.4928.400	3.4953.400	3.4952.400	3.4977.400	3.4976.400
420		3.4929.420	3.4928.420	3.4953.420	3.4952.420	3.4977.420	3.4976.420
340	12	3.4931.340	3.4930.340	3.4955.340	3.4954.340	3.4979.340	3.4978.340
360		3.4931.360	3.4930.360	3.4955.360	3.4954.360	3.4979.360	3.4978.360
380		3.4931.380	3.4930.380	3.4955.380	3.4954.380	3.4979.380	3.4978.380
400		3.4931.400	3.4930.400	3.4955.400	3.4954.400	3.4979.400	3.4978.400
420		3.4931.420	3.4930.420	3.4955.420	3.4954.420	3.4979.420	3.4978.420

Suggested

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

	Ø10	Ø11	Ø12
left			
right			
colours			

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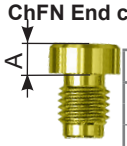
TITANIUM ALLOY Ti

LOCKING ELEMENTS

ChFN End cap M12x1.75

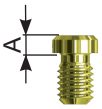


A	Catalogue no
0	3.2104.600
+5	3.2104.605
+10	3.2104.610
+15	3.2104.615

ChFN Compression screw M8x1.25

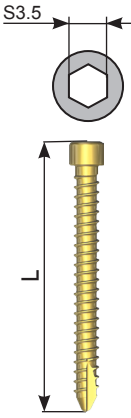
Catalogue no
3.2106.008

ChFN End cap M8x1.25



A	Catalogue no
+3	3.2104.003

CHARFIX Distal screw 4.5

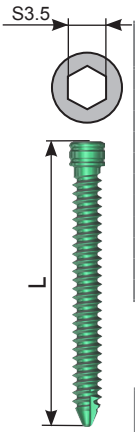


L [mm]	Catalogue no
30	3.1654.030
35	3.1654.035
40	3.1654.040
45	3.1654.045
50	3.1654.050
55	3.1654.055
60	3.1654.060
65	3.1654.065
70	3.1654.070
75	3.1654.075
80	3.1654.080

available

L [mm]	16 ÷ 100

CHARFIX Distal screw 5.0

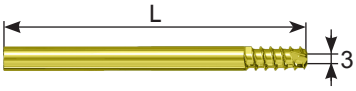


L [mm]	Catalogue no
30	3.1657.030
35	3.1657.035
40	3.1657.040
45	3.1657.045
50	3.1657.050
55	3.1657.055
60	3.1657.060
65	3.1657.065
70	3.1657.070
75	3.1657.075
80	3.1657.080

available

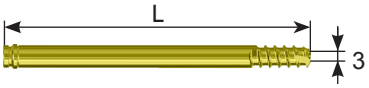
L [mm]	16 ÷ 100

ChFN Join cannulated trochanteric screw 6.5



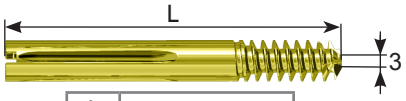
L [mm]	Catalogue no
70	3.1948.070
75	3.1948.075
80	3.1948.080
85	3.1948.085
90	3.1948.090
95	3.1948.095
100	3.1948.100
105	3.1948.105
110	3.1948.110
115	3.1948.115
120	3.1948.120

ChFN Join cannulated trochanteric screw with collar 6.5



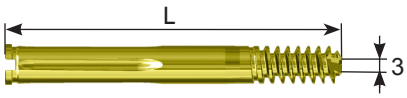
L [mm]	Catalogue no
70	3.1935.070
75	3.1935.075
80	3.1935.080
85	3.1935.085
90	3.1935.090
95	3.1935.095
100	3.1935.100
105	3.1935.105
110	3.1935.110
115	3.1935.115
120	3.1935.120

ChFN Join cannulated trochanteric screw 11



L [mm]	Catalogue no
70	3.1949.070
75	3.1949.075
80	3.1949.080
85	3.1949.085
90	3.1949.090
95	3.1949.095
100	3.1949.100
105	3.1949.105
110	3.1949.110
115	3.1949.115
120	3.1949.120

ChFN Join cannulated trochanteric screw with collar 11



L [mm]	Catalogue no
70	3.1938.070
75	3.1938.075
80	3.1938.080
85	3.1938.085
90	3.1938.090
95	3.1938.095
100	3.1938.100
105	3.1938.105
110	3.1938.110
115	3.1938.115
120	3.1938.120

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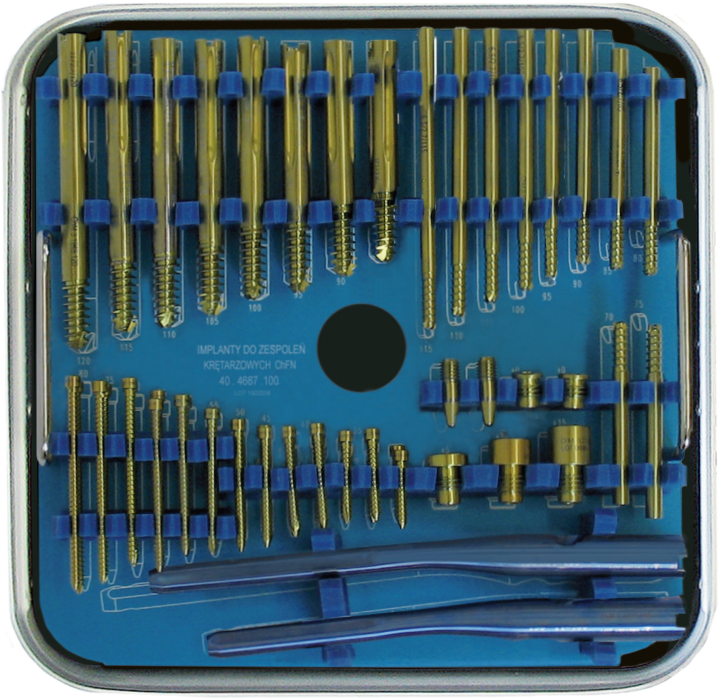
LOCKING ELEMENTS

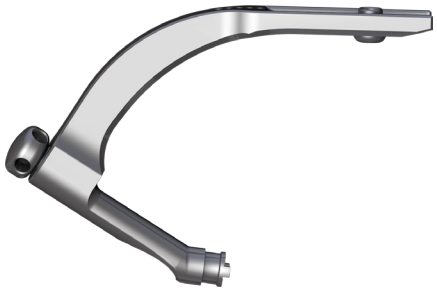
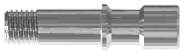


40.4687.200
Stand for ChFN trochanteric nails - set
(set with a box without implants)

III. INSTRUMENT SET

The fixation of the femoral fractures in trochanter area and removal of the implants after finished treatment is carried out with a single instrument set **[40.5590.600]**. All instruments are placed in the stand with a lid which facilitates storage and transport to the oparating suite.

The instrument set consists of the following instruments:

No.		Name	Catalogue no.	Pcs.
1		Proximal targeter B	40.5591.000	1
2		Targeter 120/130	40.5592.000	1
3		Targeter 125/135	40.5593.000	1
4		Distal targeter D	40.5546.000	1
5		Drill guide 14/12	40.5544.100	1
6		Protective guide 12/2.8	40.5545.100	1
7		Connecting screw M12x1.75 L-34	40.5547.000	1
8		Drill guide 9.0/7.0	40.5537.100	1
9		Protective guide 7.0/2.8	40.5538.100	1
10		Drill with scale 3.5/350	40.5339.001	2
11		Drill guide 7/3.5	40.5511.100	2
12		Protective guide 9/7	40.5510.100	2
13		Compression wrench	40.5532.300	1
14		Screwdriver S3.5	40.5525.000	1
15		Cannulated screwdriver S4	40.5524.000	1
16		Drill 6.5	40.5529.000	1
17		Gradual drill 11/6.5	40.5528.000	1
18		Screwdriver S10 with pilot	40.5521.000	1

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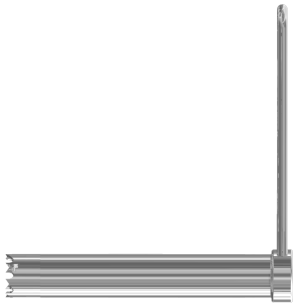
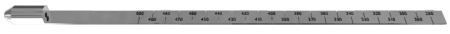
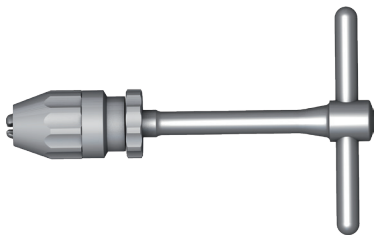
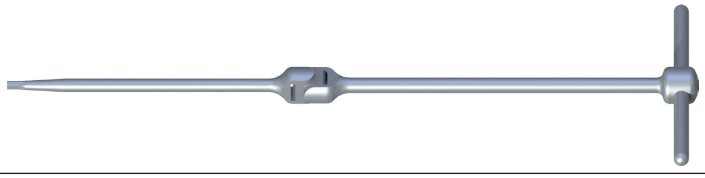
No.		Name	Catalogue no.	Pcs.
19		Mallet	40.3667.000	1
20		Wrench S10	40.5526.100	1
21		Impactor-extractor	40.5507.000	1
22		Curved awl 8.0	40.5523.000	1
23		Protective guide 20.0/17.0	40.4711.000	1
24		Guide 17/2.8	40.4712.100	1
25		Set block 9/4.5	40.5533.000	2
26		Cannulated drill 17.0	40.4715.000	1
27		Connector of extractor M12x1.75	40.4731.000	1
28		Trocar 2.8	40.5527.000	1
29		Trocar 6.5	40.5534.000	1
30		Screw length measure	40.5530.000	1
31		Cannulated screw length measure	40.4724.000	1
32		Nail length measure	40.4798.500	1
33		Teflon pipe guide	40.1348.000	1
34		Guide rod 3/580	40.3925.580	1
35		Guide rod 2.8/385	40.5531.000	4
36		Steinmann handle	40.0987.200	1
37		Wrench for self-aligning joint S4	40.5540.000	1

No.		Name	Catalogue no.	Pcs.
38		Stand	40.5599.600	1

Not included in the Instrument Set				
No.		**Name**	**Catalogue no.**	**Pcs.**
39		Screw position measure	40.5522.000	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 patient on the traction 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 is essential in order to not overlook the injuries in its proximal or distal part. It is especially important in cases of pathological subtrochanteric fractures. Special attention should be paid to concurrent neck fractures or proximal epiphysis multi-fragment 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 fixation may be difficult or even impossible to perform. In addition it should be checked whether alloplasty of hip or knee has ever been performed on the fractured limb before.
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 grater 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.

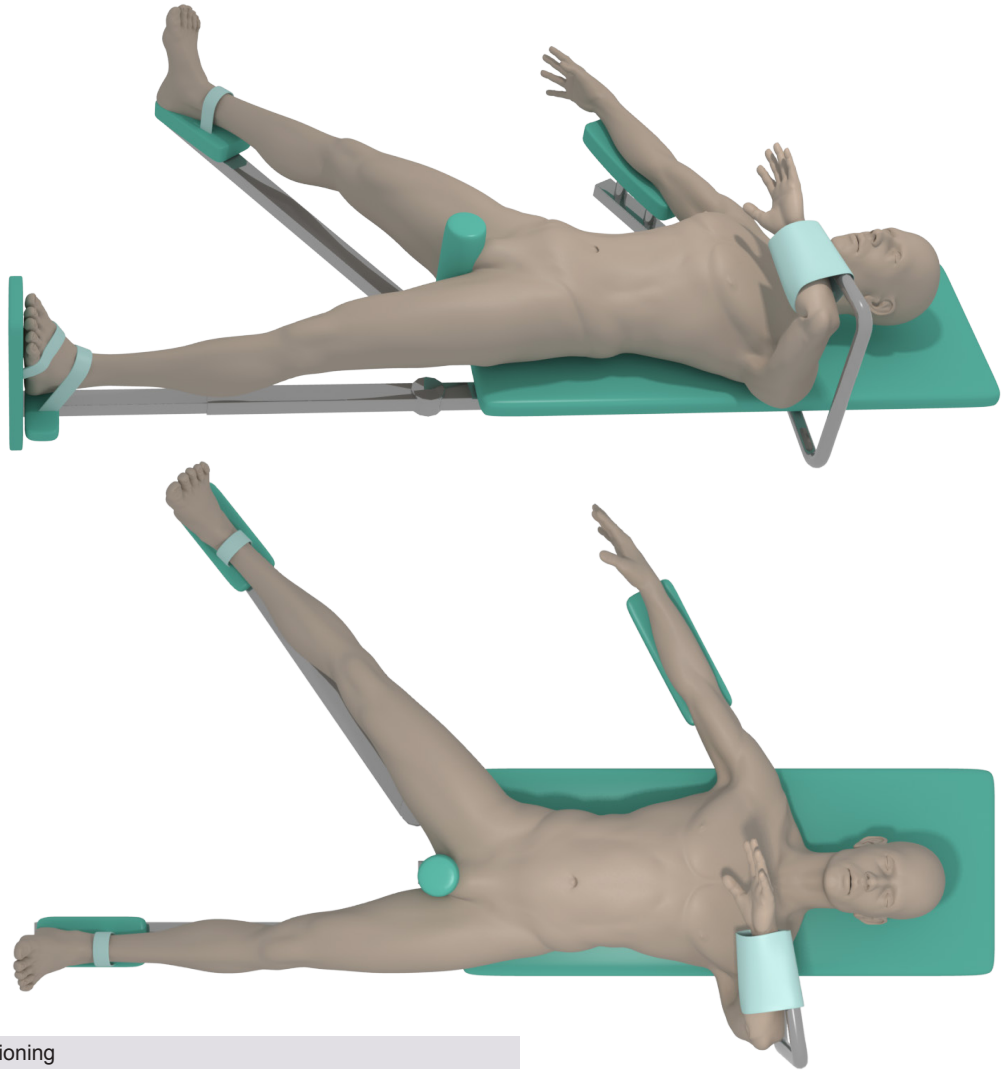
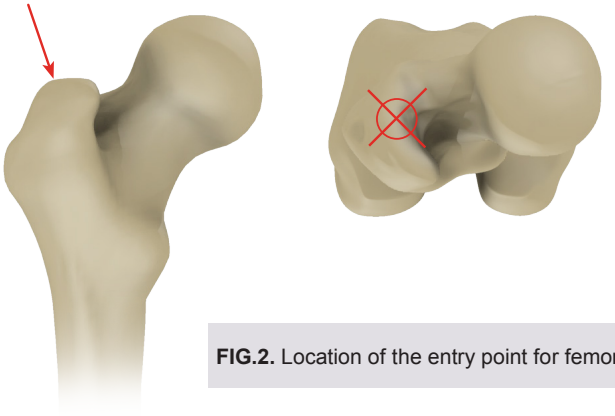


FIG.1. Patient positioning

Lateral surgical approach shall be applied starting the incision near the tip of greater trochanter in line with the femoral shaft axis for 8 cm. The incision should be longer in patients with overweight. Perform similar incision in fascia. Fibres of greater gluteal muscle are then split, thus providing approach to the tip of greater trochanter.



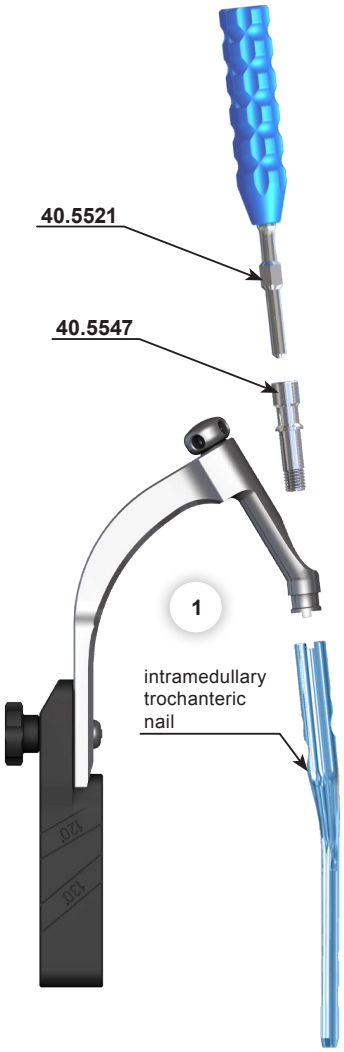
The trochanteric nail should be introduce in such a way that its axis is approximately in line with the medullary canal axis. This beneficially influences loads distribution that transmits mechanical loads in the case of patient who has already started to walk.

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

The following paragraphs describe most important steps during implantation of ChFN trochanteric nails; nevertheless it is not a detailed instruction of use. The surgeon decides about choosing the surgical technique and its application in each individual case.

On the basis of X-Rays of fractured femur and of the healthy one, the surgeon decides about the type of nail, its length, angle and diameter

IV.2. PREPARATION FOR IMPLANTATION OF SHORT TROCHANTERIC NAIL 120°,125°,130° OR 135°



1 Mount trochanteric nail to the Proximal targeter B **[40.5591]** using the Connecting Screw M12x1.75 L-34 **[40.5547]** and the Screwdriver S10 With Pilot **[40.5521]**.

Mount specified Targeter onto the Proximal targeter B depending on selected nail angle.

- for nail 120° and 130° use Targeter 120/130 **[40.5592.000]**,
- for nail 125° and 135° use Targeter 125/135 **[40.5593.000]**.

120°/130°
[40.5592.000]

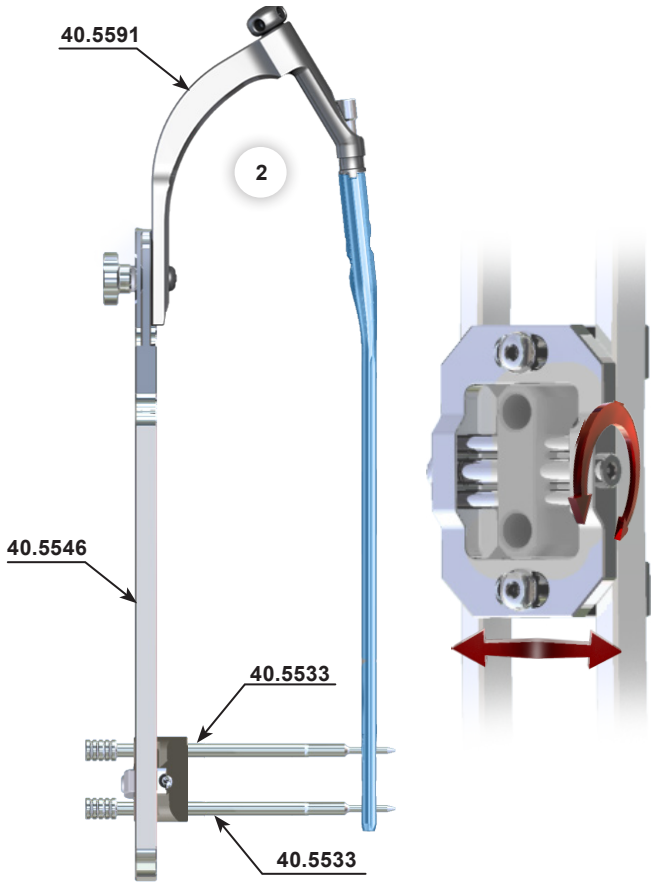
125°/135°
[40.5593.000]

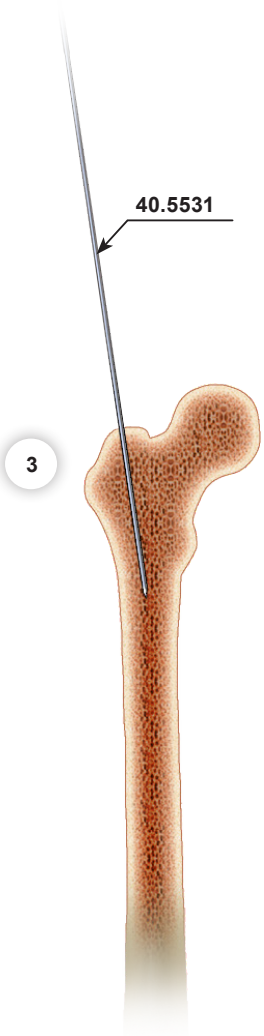
IV.3. POSITIONING OF TARGETER D SLIDER

2 In case of long nail implantation, mount the Distal Targeter D **[40.5546]** to the Proximal targeter B **[40.5591]**. Then set correct position of the targeter slider in relation to the nail locking holes in distal part using two Set Blocks 9/4.5 **[40.5533]**. Lock the position of slider using the Screwdriver S3.5 **[40.5525]**.

Check:
Correctly positioned and locked slider should allow easy insertion of the Set Blocks into the nail hole.

Remove the Set Blocks.
Dismount the Distal Targeter D from the Proximal targeter B.

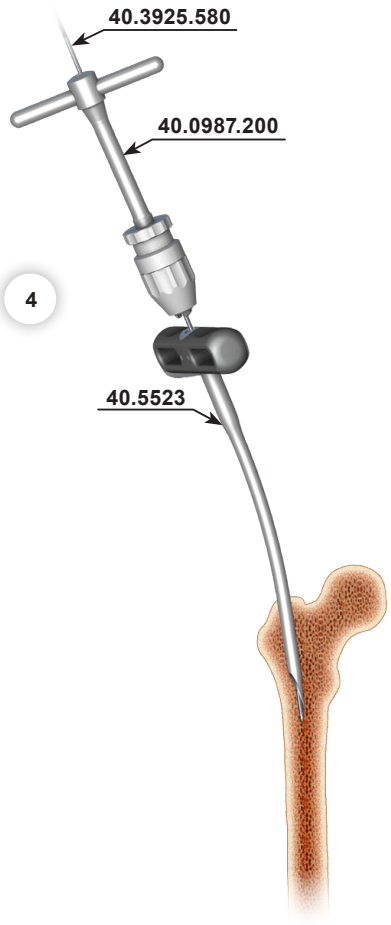




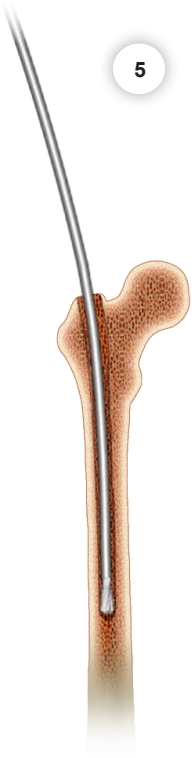
IV.4. OPENING AND PREPARING THE MEDULLARY CANAL FOR INSERTION OF TROCHANTERIC NAIL *(SHORT AND LONG)*

3 Make the skin incision near the tip of a grater trochanter.
Having localized the nail entry point, using the drive insert the Guide Rod 2.8/385 **[40.5531]** into the medullary canal. The rod should be inserted in the angle corresponding to the deviation angle of the nail shaft from the main axis *(about 6 degrees)*.
The process should be controlled with image intensifier.

4 Using Guide rod 2.8/385 **[40.5531]**, 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 2.8/385 **[40.5531]**.
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.
Open the medullary canal using Cannulated drill 17.0 **[40.4715]** inserted into Protective guide 20.0/17.0 **[40.4711]** via Guide rod 3.0/580 **[40.3925.580]**.
Slowly ream the medullary canal using cannullated drill until it rests on the protective guide.
Remove protective guide, cannullated drill.



5 In the case medullary canal is reamed, gradually increase the diameter of reamers with steps of 0.5 mm, until the diameter 1.5 to 2.0 mm wider than the diameter of the nail is reached, for the depth at least equal to the nail length *(but not lesser)*.
In both cases when the medullary canal was reamed or not, the proximal part of the canal should be reamed using 17 mm reamer to the depth of approx. 6 cm.
Remove flexible reamer.

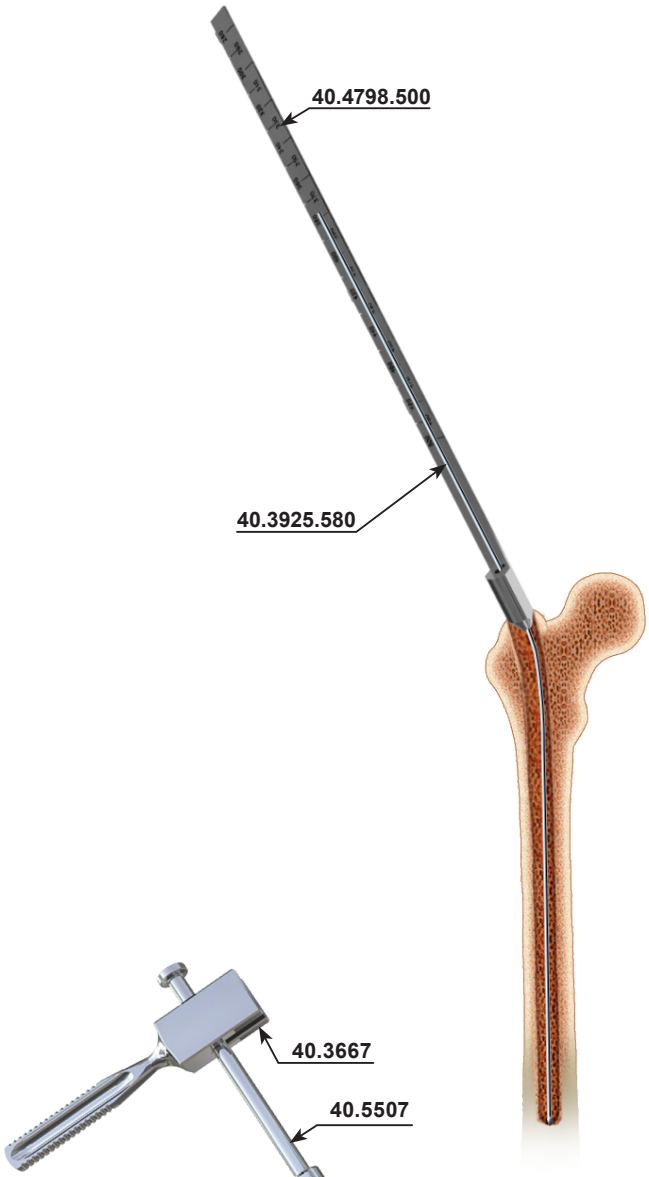


Should a different reamer guide than provided guide rod 3.0/580 **[40.3925.580]** be used, for nail length measuring, the reamer guide must be replaced
with the guide rod 3.0/580 **[40.3925.580]**.
Insert teflon pipe guide **[40.1348]** into the medullary canal via flexible reamer guide. Remove flexible reamer guide. Insert guide rod 3.0/580 **[40.3925.580]** *(guide for cannulated nail)* using Stainmann handle **[40.0987.200]** into the teflon pipe guide **[40.1348]** for the appropriate length.
Remove Stainmann handle and teflon pipe guide

The below step concerns long trochanteric nails

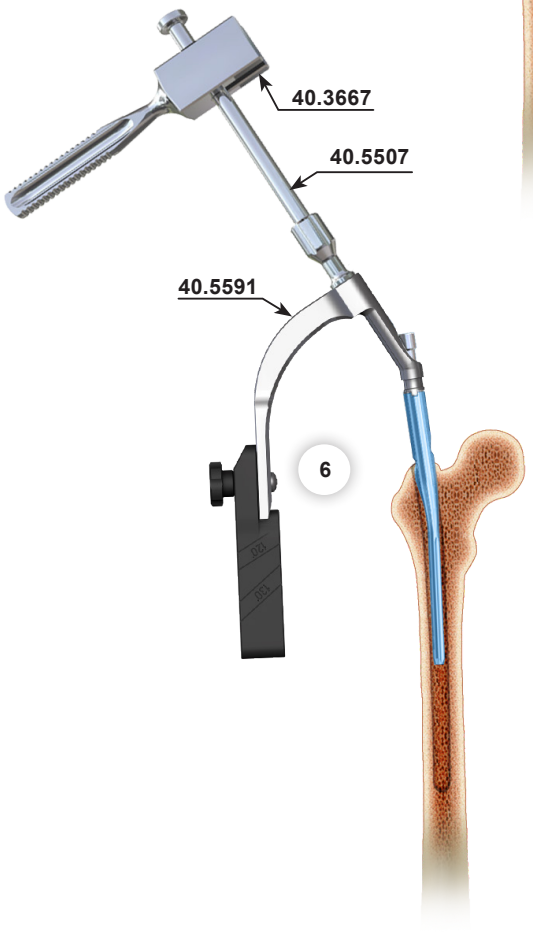
Insert nail length measure **[40.4798.500]** via guide rod. The beginning of the measure should be set in the place of depth insertion of the nail. Read
the length of the nail on a scale.

Remove nail length measure.
Remove guide rod if solid nail has been chosen.
Medullary canal has been prepared for nail insertion.



IV.5. NAIL INSERTION INTO MEDULLARY CANAL
(SHORT AND LONG NAILS)

6 Connect the Proximal targeter B **[40.5591]** with the Impactor-Extractor **[40.5507]** and using the Mallet **[40.3667]** insert the nail into the medullary canal.
Remove the Guide Rod.

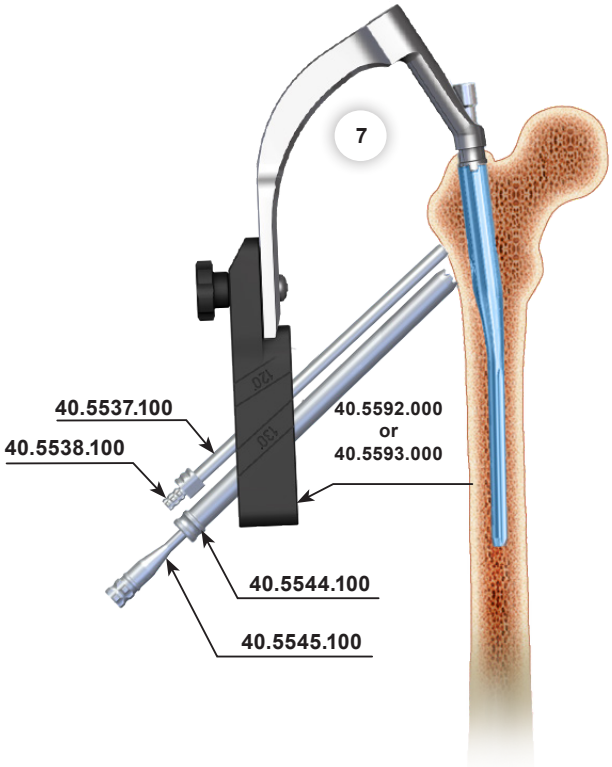


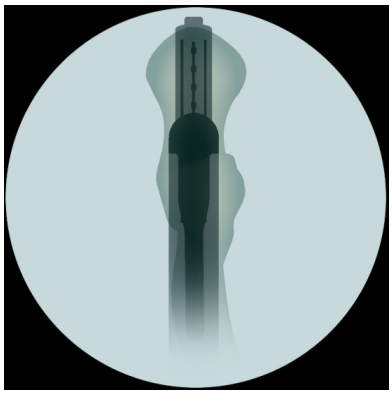
IV.6. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART

IV.6A. LOCKING THE TROCHANTERIC NAIL *(SHORT AND LONG)* IN THE PROXIMAL PART USING TWO JOIN SCREWS

NOTE:
Nail must be locked with two join screws.

7 Mount the Targeter **[40.5592.000]** or **[40.5593.000]** to the Proximal targeter B. Insert the Drill Guide 9.0/7.0 **[40.5537.100]** and the Protective Guide 7.0/2.8 **[40.5538.100]** into smaller hole of the Targeter. Insert the Drill Guide 14/12 **[40.5544.100]** and the Protective Guide 12/2.8 **[40.5545.100]** into bigger hole of the Targeter.



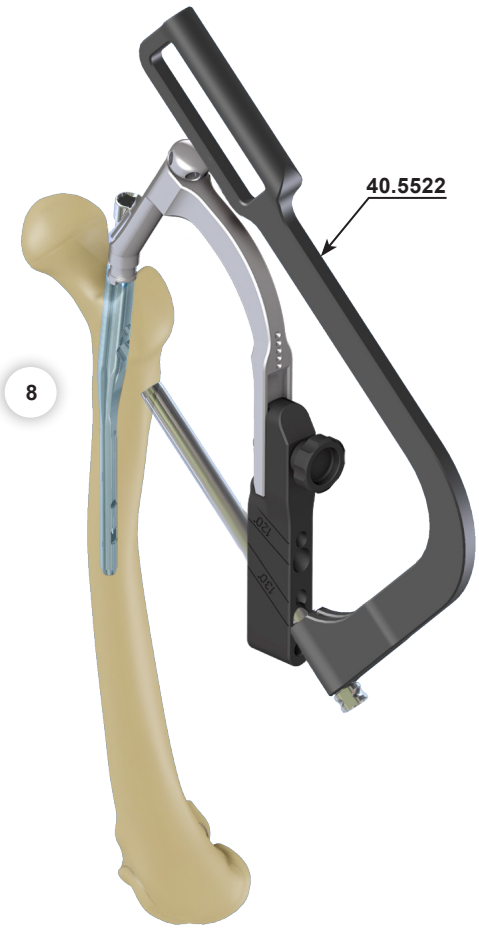


To perform the nail positioning in the lateral plane for the join screws insertion, the Screw position measure **[40.5522]** shall be set perpendicular to the plane of projection. Simultaneously set the Screw position measure in such way that two outer lines match with the hole edges that are seen in the X-Ray.

Rotate the nail with the Targeter and set the nail in such way to enable insertion of join screws according to the angle of anteversion of femur neck.

8 Correct nail placement needed for the insertion of the join screws can be verified by the Screw position measure **[40.5522]**. In such case, mount the Screw position measure **[40.5522]** onto the Drill Guide 14/12 **[40.5544.100]** and position the nail under the control of image intensifier in two projections *(AP and lateral)*.

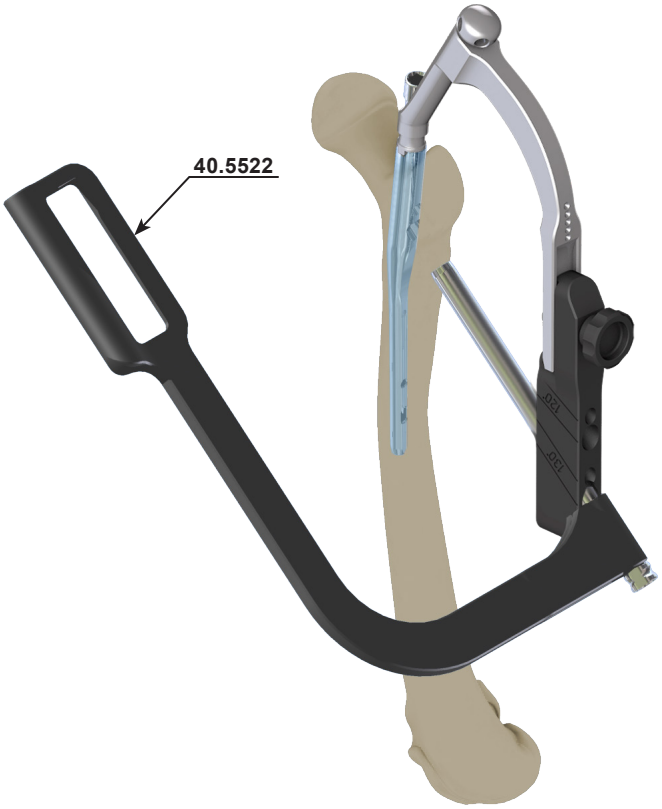
The Instrument Set does not include the Screw position measure [40.5522].



IMPLANT PLACED TOO HIGH

CORRECT PLACEMENT

IMPLANT PLACED TOO LOW

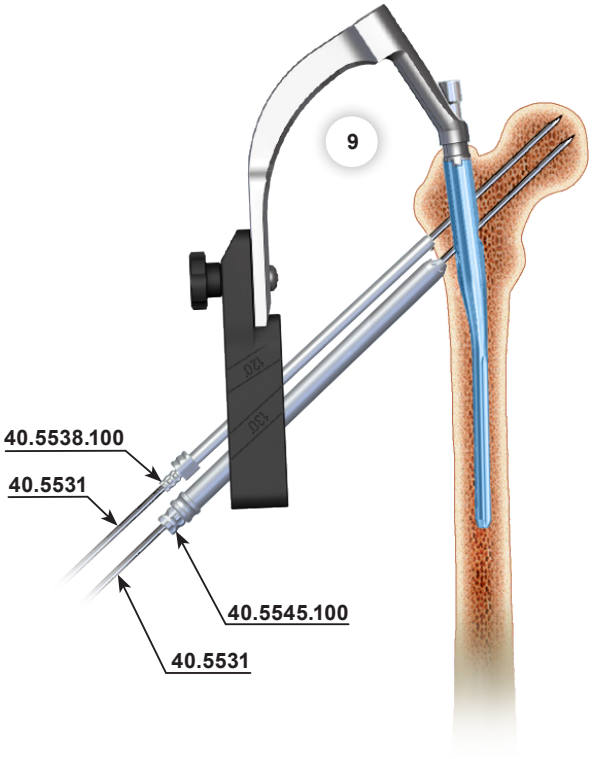


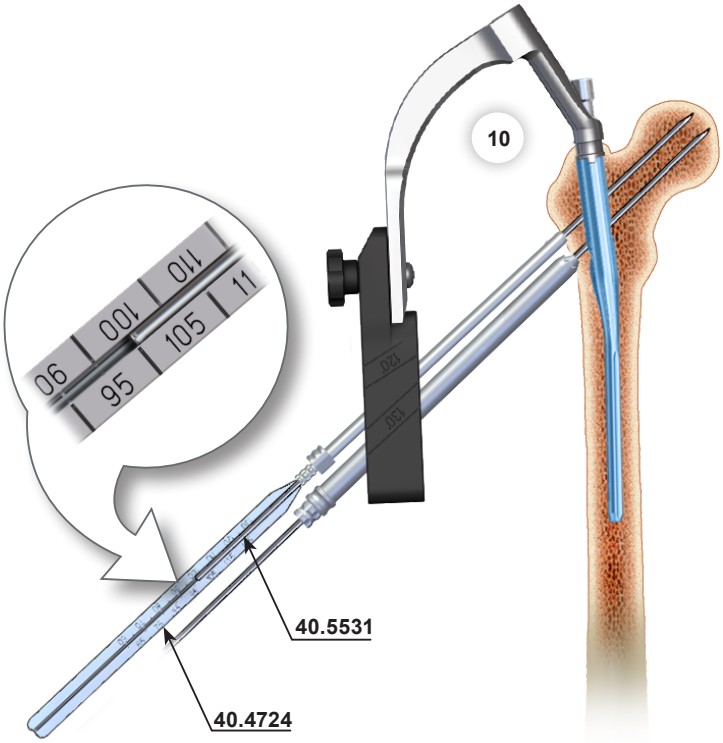
To perform the nail positioning in the AP plane in order to define the screw insertion place in relation to femur neck, rotate the Screw position measure **[40.5522]** on the Drill Guide and set perpendicular to the plane of projection. Simultaneously set the Screw position measure in such way that two outer lines match with the hole edges of intramedullary nail. Establish the depth of nail insertion to enable insertion of the Join Screws in the central part of femoral neck.

9 Connect the Guide Rod **[40.5531]** with electric drive and advance such system into the Protective Guide 7.0/2.8 **[40.5538.100]**.

Connect the Guide Rod **[40.5531]** with electric drive and advance such system into the Protective Guide 12/2.8 **[40.5545.100]**.

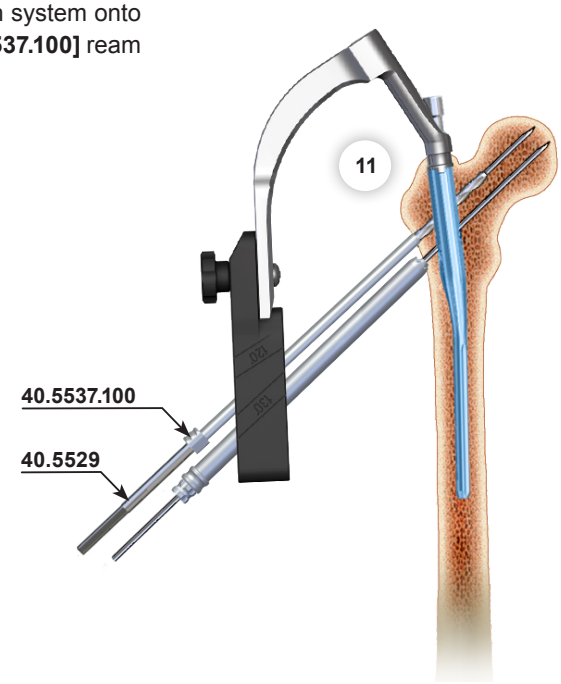
The Guide Rod [40.5531] shall be inserted into the femoral head at the distance to the cartilage 5-10mm.

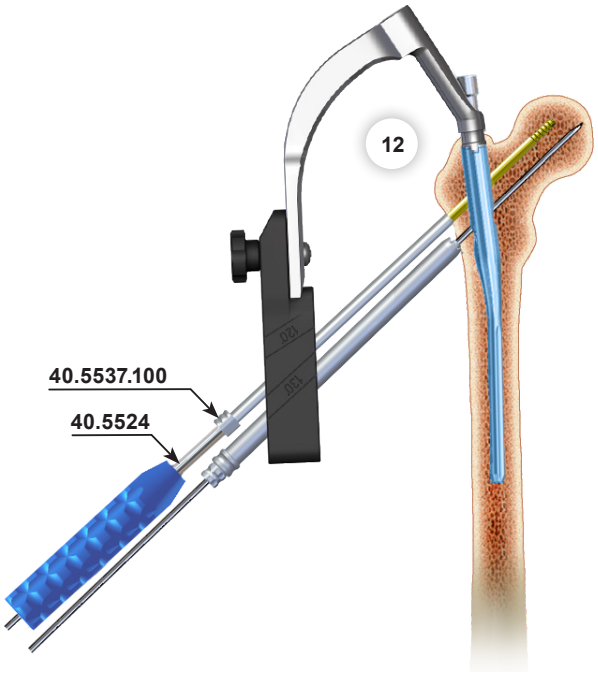




10 Insert the Cannulated Screw Length Measure **[40.4724]** via the Guide Rod 2.8/385 **[40.5531]** *(placed into the Protective Guide7.0/2.8 [40. 5538.100])* Read the length of the join screw on the scale indicated by end of the Guide Rod.
During the measurement the tip of the Cannulated Screw Length Measure should rest on the Protective Guide 7.0/2.8, and the Guide on cortex bone.
Remove the Screw Length Measure and the Protective Guide 7.0/2.8.
Leave the Guide Rod.

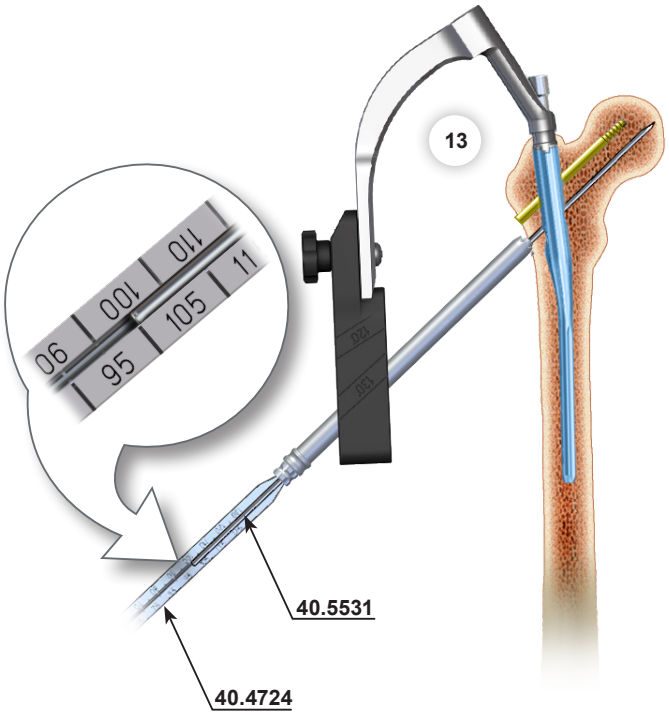
11 Connect the Drill 6.5 **[40.5529]** with the electric drive, and insert such system onto the Guide Rod 2.8/385 **[40.5531]** and via the Drill Guide 9.0/7.0 **[40.5537.100]** ream the hole in first cortex layer *(up to the inserted nail)*.
Remove the Drill.
Leave the Guide Rod.



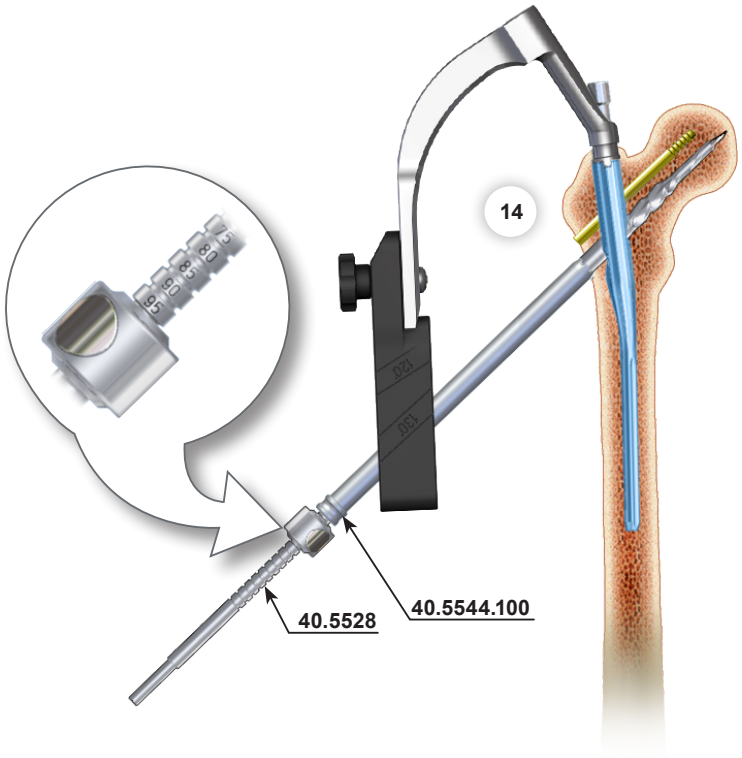


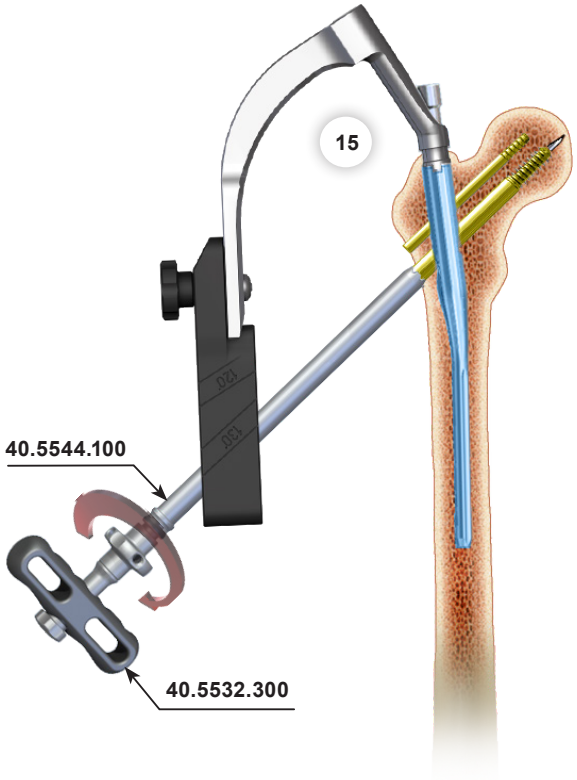
12 Insert the join cannulated screw 6.5, defined by the Cannulated Screw Length Measure **[40.4724]**, onto the Guide Rod 2.8/385 **[40.5531]**. Use the Cannulated Screwdriver S4 **[40.5524]** to advance the screw via the Guide Rod into the femur neck until the Screwdriver tip rests on the Drill Guide 9.0/7.0 **[40.5537.100]**.
Remove the Screwdriver, the Guide Rod and the Drill Guide 9.0/7.0.
Guide Rod 2.8/385 **[40.5531]** is single use instrument.

13 Onto the Guide Rod 2.8/385 **[40.5531]** insert the Cannulated Screw Length Measure **[40.4724]** until its tip rests on the Protective Guide 12/2.8 **[40.5545.100]**. Read the length of the join cannulated screw on measure scale, indicated by end of the Guide Rod.
When measuring, the end of the screw length measure should rest on the guide 12/2.8.
Remove the Cannulated Screw Length Measure and the Guide 12/2.8.
Leave the Guide Rod.



14 Use the adjusting bolt to set the depth of drilling *(corresponding to the Join Screw)* on the Gradual drill 11/6.5 **[40.5528]**. Connect the Gradual drill with electric drive, and advance such system onto the Guide Rod 2.8/385 **[40.5531]** until the bolt set rests on the Drill Guide 14/12 **[40.5544.100]**.
Remove the Gradual drill.
Leave the Guide Rod and the Drill Guide.

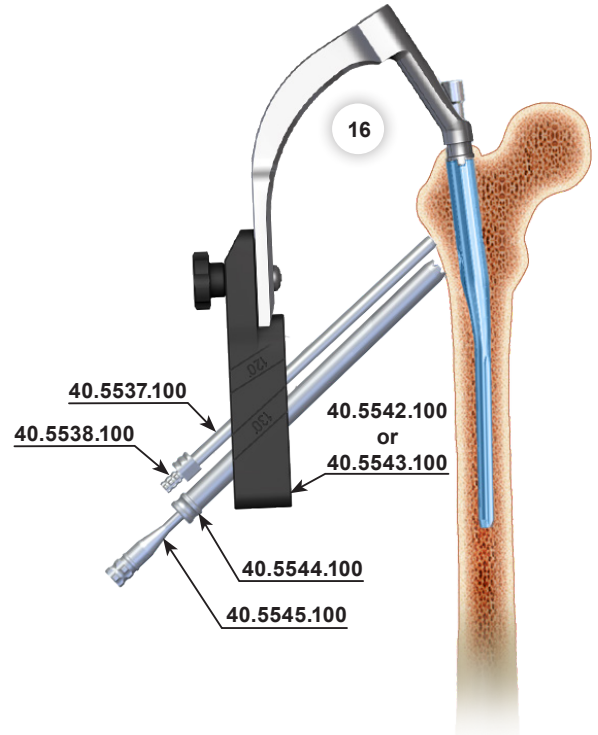


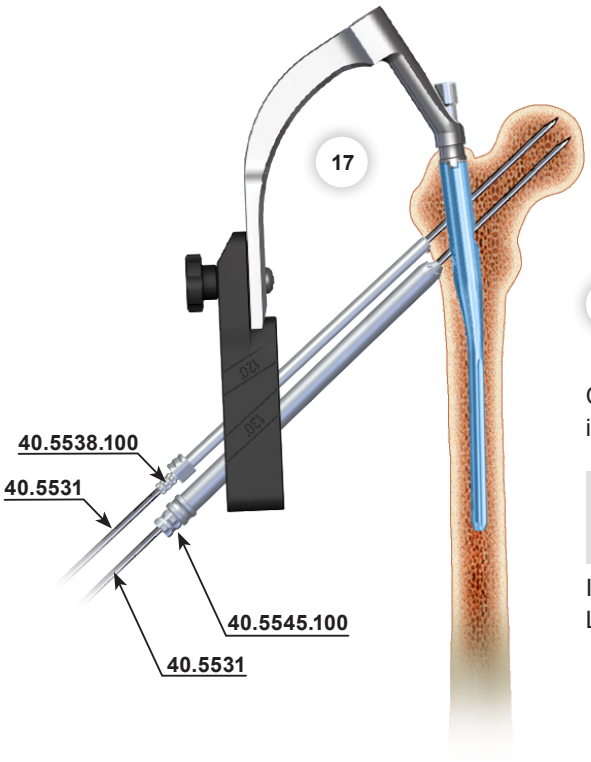


15 Mount the Join Screw *(previously determined by the Cannulated Screw Length Measure [40.4724])* onto the Compression Wrench **[40.5532.300]**. Move back the nut of the wrench until it rests on the sleeve of wrench. Insert the Join Screw onto Guide Rod 2.8/385 **[40.5531]**. Advance the Join Screw into femur neck using the Compression Wrench until the wrench nut rests on the Drill Guide 14/12 **[40.5544.100]**. If necessary, fracture compression should be made by the wrench nut.
Remove the Compression Wrench, Guide Rod and Drill Guide.
Guide Rod 2.8/385 **[40.5531]** is single use instrument.

IV.6B. LOCKING THE TROCHANTERIC NAIL IN THE PROXIMAL PART USING THE JOIN SCREWS WITH ANTIROTARY PROTECTION.

16 Mount previously chosen Targeter **[40.5592.000]** or **[40.5593.000]** on the Proximal targeter B. Insert the Drill Guide 9.0/7.0 **[40.5537.100]** and the Protective Guide 7.0/2.8 **[40.5538.100]** into smaller Targeter hole. Insert the Drill Guide 14/12 **[40.5544.100]** and the Drill Guide 12/2.8 **[40.5545.100]** into bigger Targeter hole.





17 Connect the Guide Rod **[40.5531]** with electric drive and advance such system into the Protective Guide 7.0/2.8 **[40.5538.100]**.

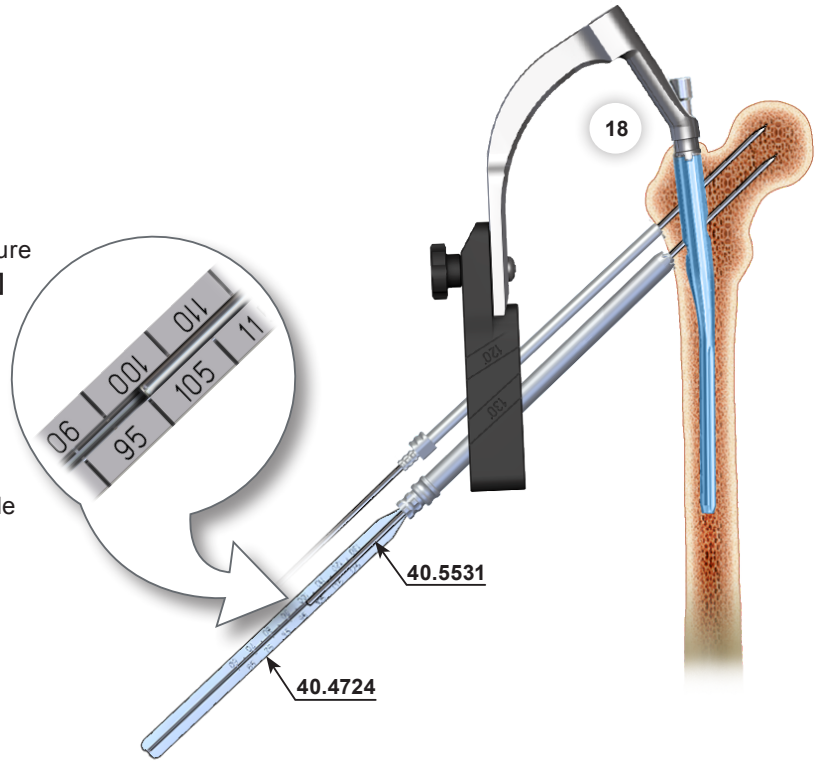
Connect the Guide Rod **[40.5531]** with electric drive and advance such system into the Protective Guide 12/2.8 **[40.5545.100]**.

The Guide Rod [40.5531] shall be inserted into the femoral head at the distance to the cartilage 5-10mm.

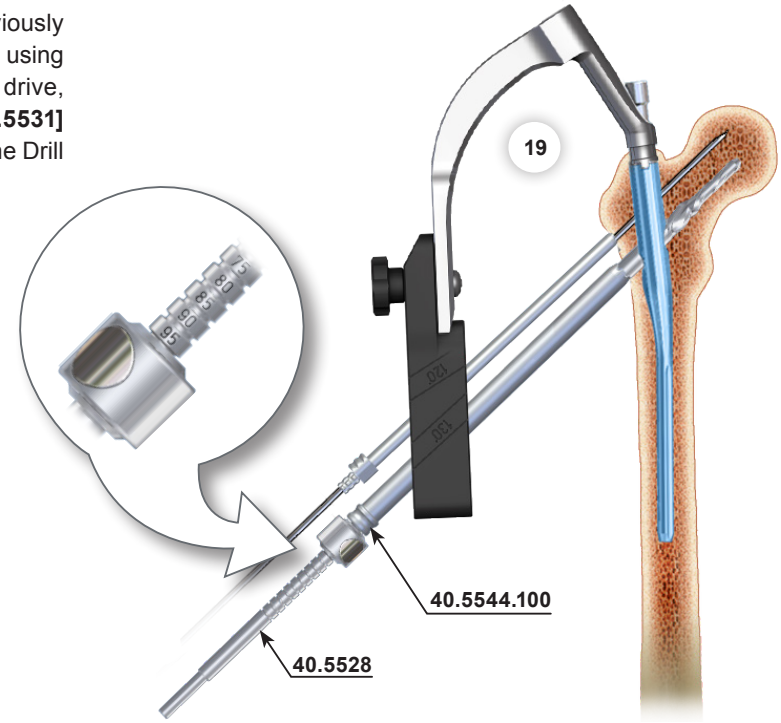
In case of inappropriate positioning of the Guide Rod, repeat the step. Leave the Guide Rod and Guides in the holes.

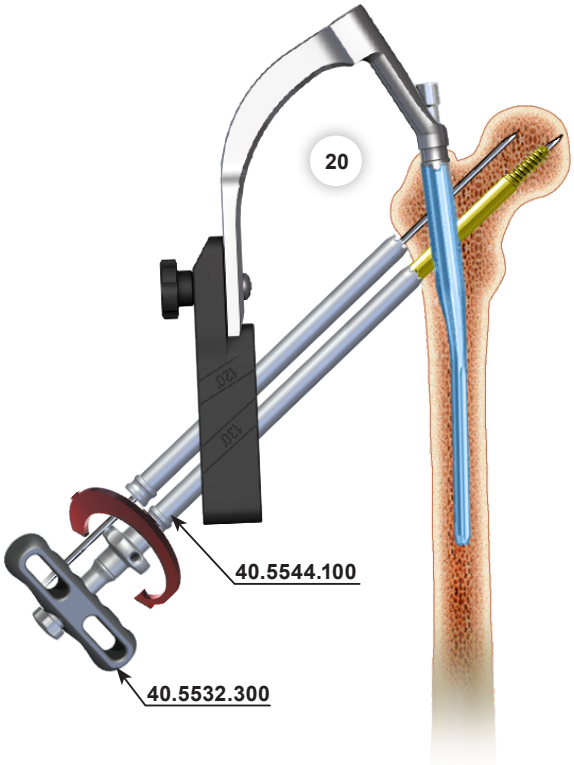
18 Insert the Cannulated Screw Length Measure **[40.4724]** onto the Guide Rod 2.8/385 **[40.5531]** *(placed into the Guide 12/2.8 **[40.5545.100]**)*. Read the length of the join cannulated screw on the scale. The tip of the Cannulated Screw Length Measure should rest on the Guide 12/2.8 during the measurement.

Remove the Cannulated Screw Length Measure, Guide 12/2.8 and Protective Guide 7,0/2,8 **[40.5538.100]**. Leave the Guide Rod.



19 Define the drilling depth coresponding to the previously chosen Join Screw on Gradual drill 11/6.5 **[40.5528]** using the adjusting bolt. Connect the drill 11/6.5 with electric drive, and insert such system onto the Guide Rod 2.8/385 **[40.5531]** and advance into the femur neck until the slider rests on the Drill Guide 14/12 **[40.5544.100]**.
Remove the Gradual drill 11/6.5.
Leave the Guide Rod and the Drill Guide.





20 Mount the Join Screw **[3.1949]** previously determined by the cannulated screw length measure **[40.4724]** onto the Compression Wrench **[40.5532.300]**. Screw the wrench nut until it rests on the wrench sleeve.
Insert the the join cannulated screw onto the Guide Rod 2.8/385 **[40.5531]**. Insert the screw into femur neck using the Compression Wrench leading via Guide Rod. Handle of the wrench should be set in the plane corresponding to the main axis of the femur. It allows for the correct placenment of the implant and facilitates insertion of the Compression Screw.
If necessary, the fracture compression should be made by the nut.
Remove upper inserted Guide Rod.

21 Compression screw **[3.2106.008]** should be inserted using wrench for self-aligning joint S4 **[40.5540]** through the hole in the Connecting Screw in the Targeter in such way to hit in 1 of 4 grooves in join screw.

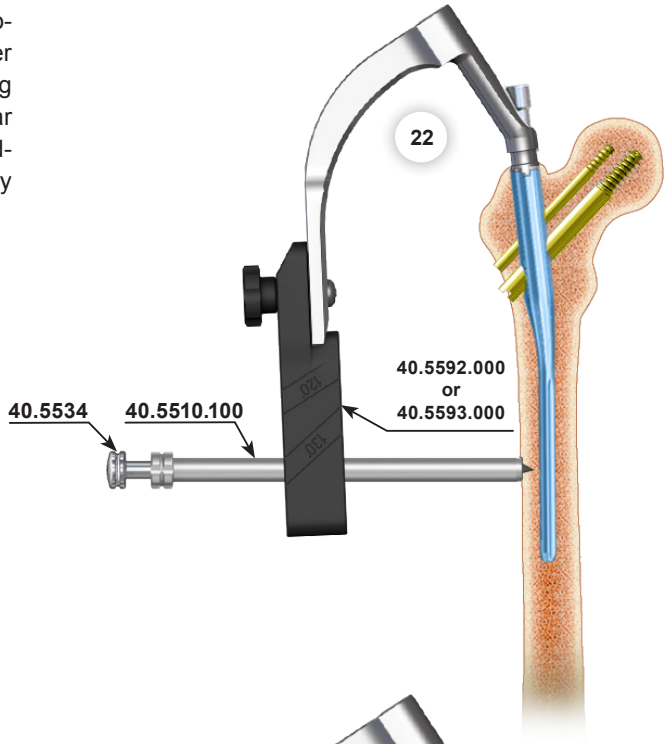
Join screw can be set in two positions:
• dynamic - compression screw is not tightened up and allows join screw for sliding inside the nail without possibility of turn. *(compression screw is maximal tightened up, and next loosened by ¼ turn)*
• static - after compression of locking elements, compression screw is maximal tightened up.

Remove the Compression Wrench, Guide Rod and Drill Guide.

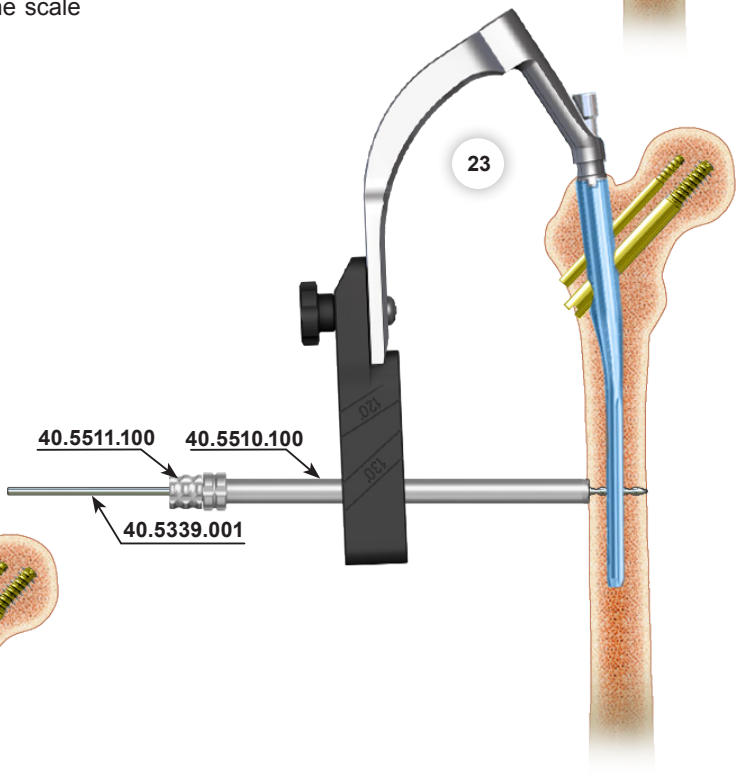
Secure the inner thread of the join screw against tissue overgrowth by insertion of end cap **[3.2104.003]** using screwdriver S3,5 **[40.5525]**.

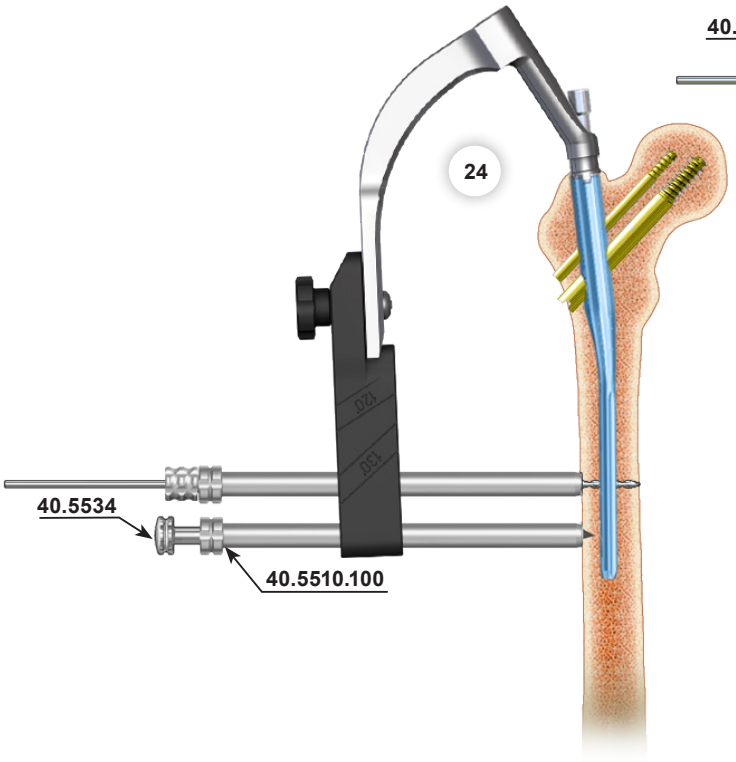
IV.7. LOCKING THE SHORT TROCHANTERIC NAIL IN DISTAL PART

22 Insert the Protective Guide 9.0/7.0 **[40.5510.100]** and the Trocar 6.5 **[40.5543.100]** into the proximal hole of the Targeter **[40.5592.000]** or **[40.5593.000]**. Mark the entry point for the locking screw, then make an incision of the soft tissues. Advance the Trocar until it reaches the cortex and mark the entry point for the drill. Advance the Protective Guide together with the Trocar in such a way that its end is placed as close to the bone as possible.
Remove the trocar.
Leave the Protective Guide 9.0/7.0 in the Targeter hole.



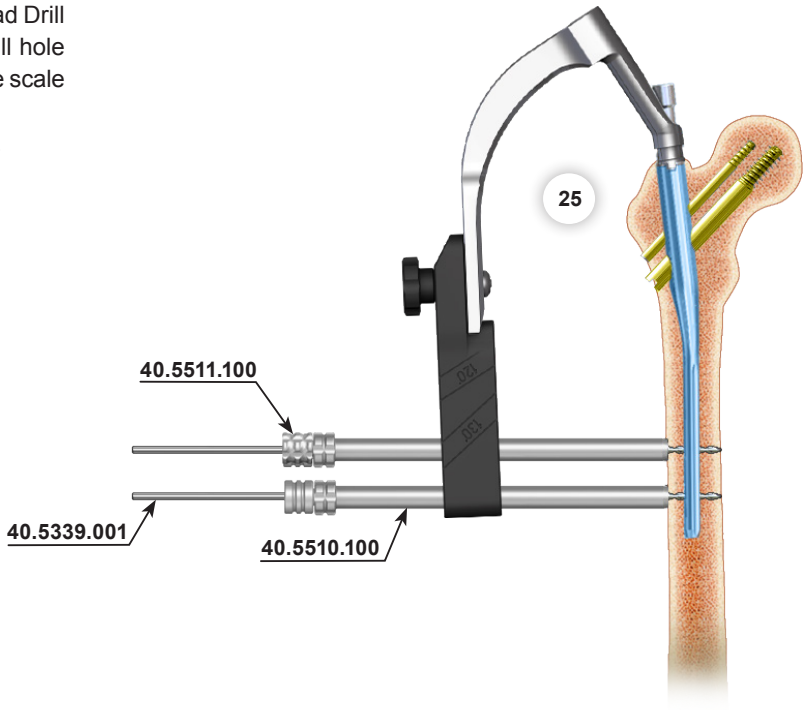
23 Insert the Drill Guide 7/3.5 **[40.5511.100]** into the Protective Guide 9.0/7.0 **[40.5510.100]**. Using electric drive, lead the Drill With Scale 3.5/350 **[40.5339.001]** into the Drill guide and throughout both cortex layers and the nail hole. The scale on the drill indicates the length of locking elements.
Drilling should be controlled with an image intensifier.
Remove electric drive.
Leave Drill, Drill Guide and Protective Guide.

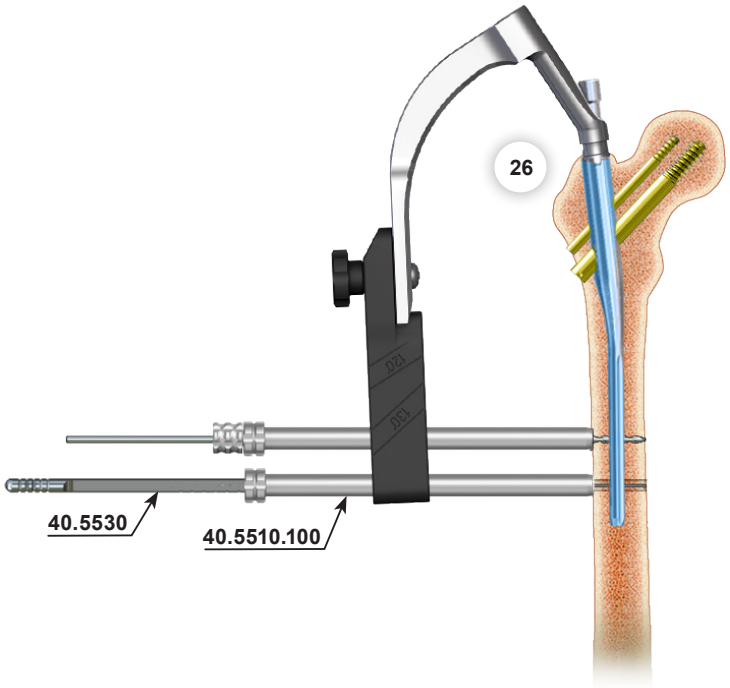




24 Insert the Protective Guide 9.0/7.0 **[40.5510.100]** and the Trocar 6.5 **[40.5534]** into the second *(distal)* hole of the targeter. Advance the Trocar until it reaches the cortex and mark the entry point for the drill. Advance the Protective Guide with the Trocar in such way that its end is placed as close to the bone as possible.
Remove the trocar.
Leave the Protective Guide 9.0/7.0 in the targeter hole.

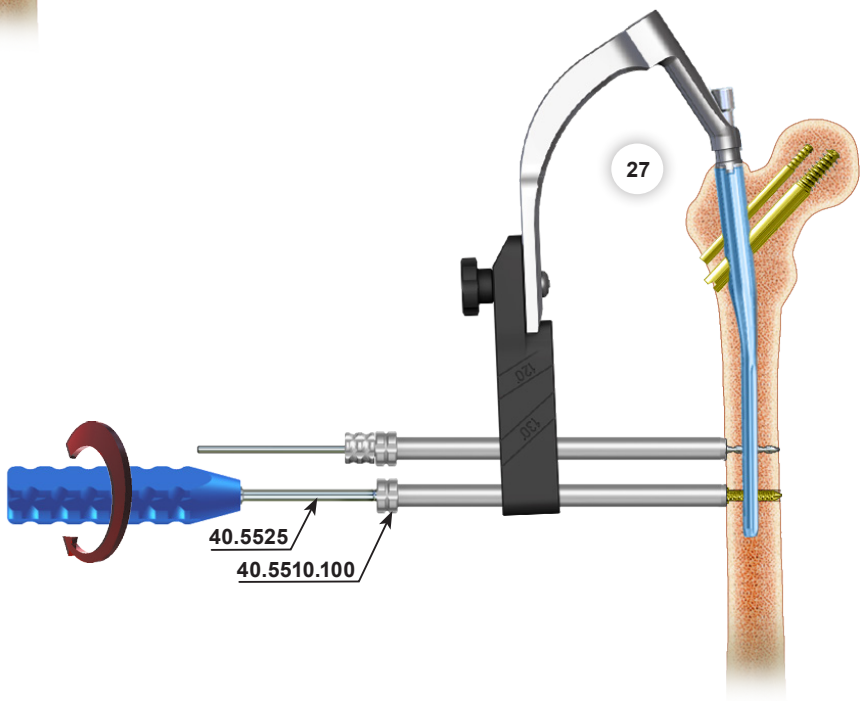
25 Insert Drill guide 7/3.5 **[40.5511.100]** into the Protective Guide 9.0/7.0 **[40.5510.100]**. Use electric drive to lead Drill With Scale 3.5/ 350 **[40.5339]** into the Drill guide, and drill hole in femur throughout both cortex layers and the nail hole. The scale of the drill indicates the length of locking elements.
Drilling process should be controlled with image intensifer.
Remove the Drill and the Drill guide.
Leave the Protective Guide 9.0/7.0.



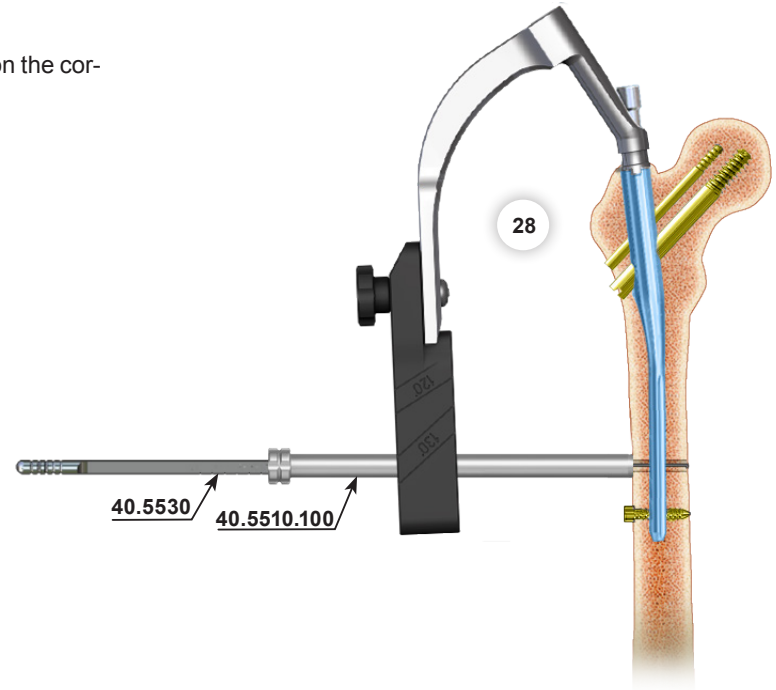


26 Insert into drilled hole the Screw Length Measure **[40.5530]** through the Protective Guide 9.0/7.0 **[40.5510.100]** until its hook reaches the exit hole.
Read the length of locking screw on the B-D scale.
During measurements the tip of Protective Guide 9.0/7.0 should rest on the cortex bone.
Remove the Screw Length Measure.
Leave the Protective Guide 9.0/7.0 in the Targeter hole.

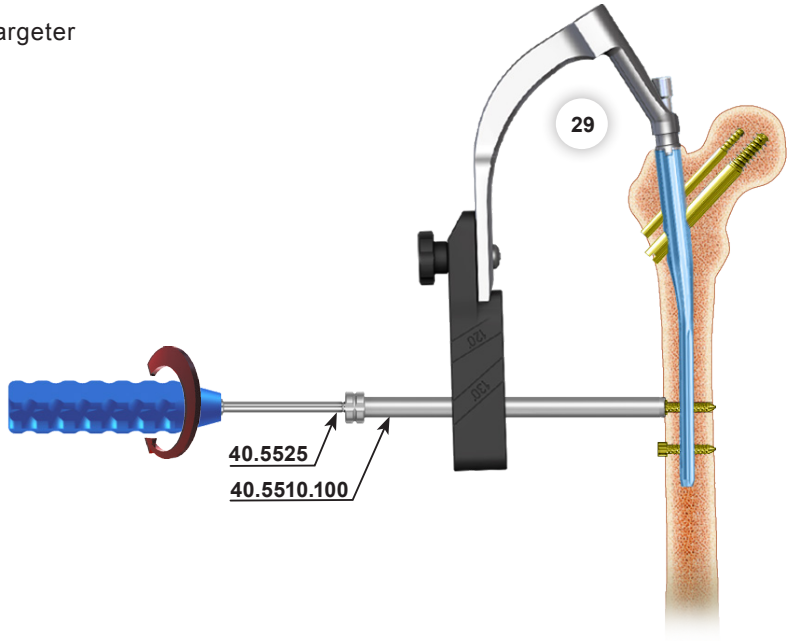
27 Insert the tip of the Screwdriver S3.5 **[40.5525]** into the hexagonal socket of selected locking screw. Then advance both into the Protective Guide 9.0/7.0 **[40.5510.100]**.
Insert the locking screw in the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft shall match the edge of protective guide)*.
Remove the Screwdriver and the Protective Guide 9.0/7.0.



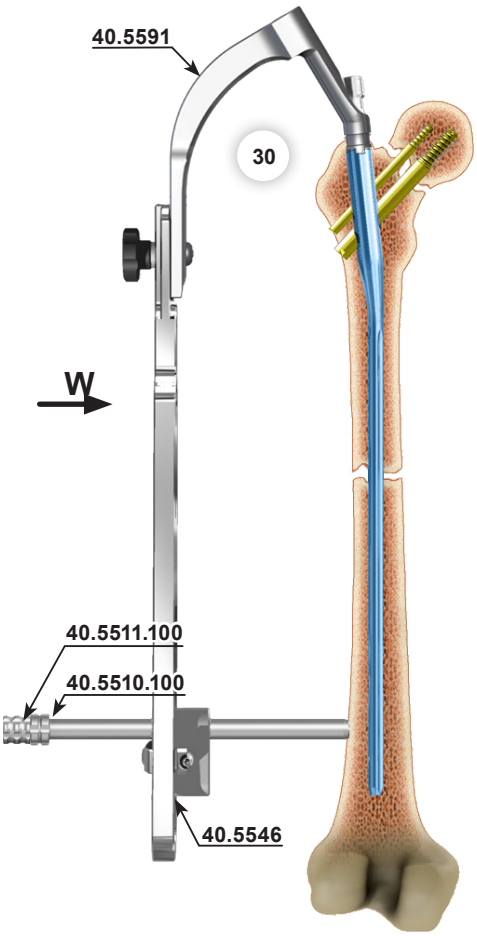
28 Remove the Drill With Scale 3.5/350 **[40.5339]** and the Drill guide 7/3.5 **[40.5511.100]** out of proximal hole in the targeter. Leave the Protective Guide 9.0/7.0 **[40.5510.100]** in targeter hole. Insert the Screw Length Measure **[40.5530]** into the drilled hole until its hook reaches the exit plain of the hole.
Read the length of the screw on the B-D scale.
During measurement the Protective Guide should rest on the cortex of bone.
Remove the Screw Length Measure.
Leave the Protective Guide in the hole of targeter.



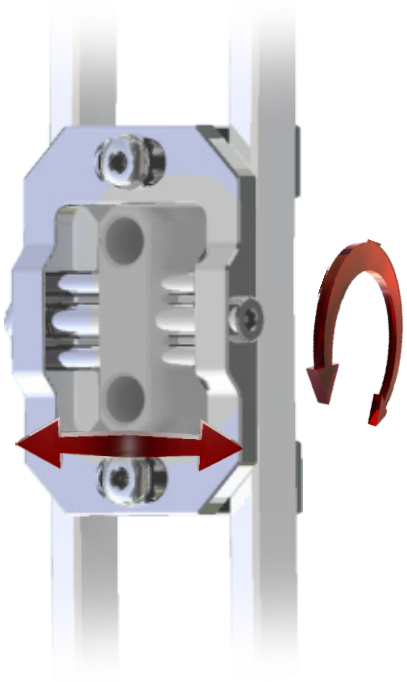
29 Insert the tip of the Screwdriver S3.5 **[40.5525]** into the hexagonal socket of selected locking screw. Then advance both into the Protective Guide 9.0/7.0 **[40.5510.100]**. Insert the locking screw into the prepared hole until the head of the screw reaches the cortex of the bone *(the groove on the screwdriver shaft shall match the edge of the protective guide)*.
Remove the Screwdriver, Protective Guide and Targeter **[40.5592.000]** or **[40.5593.000]**.

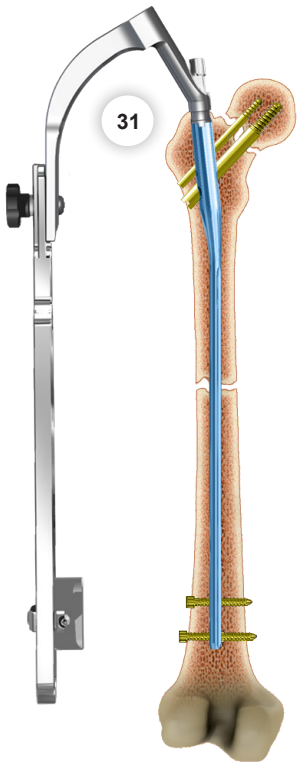


IV.8. LOCKING THE LONG TROCHANTERIC NAIL IN THE DISTAL PART



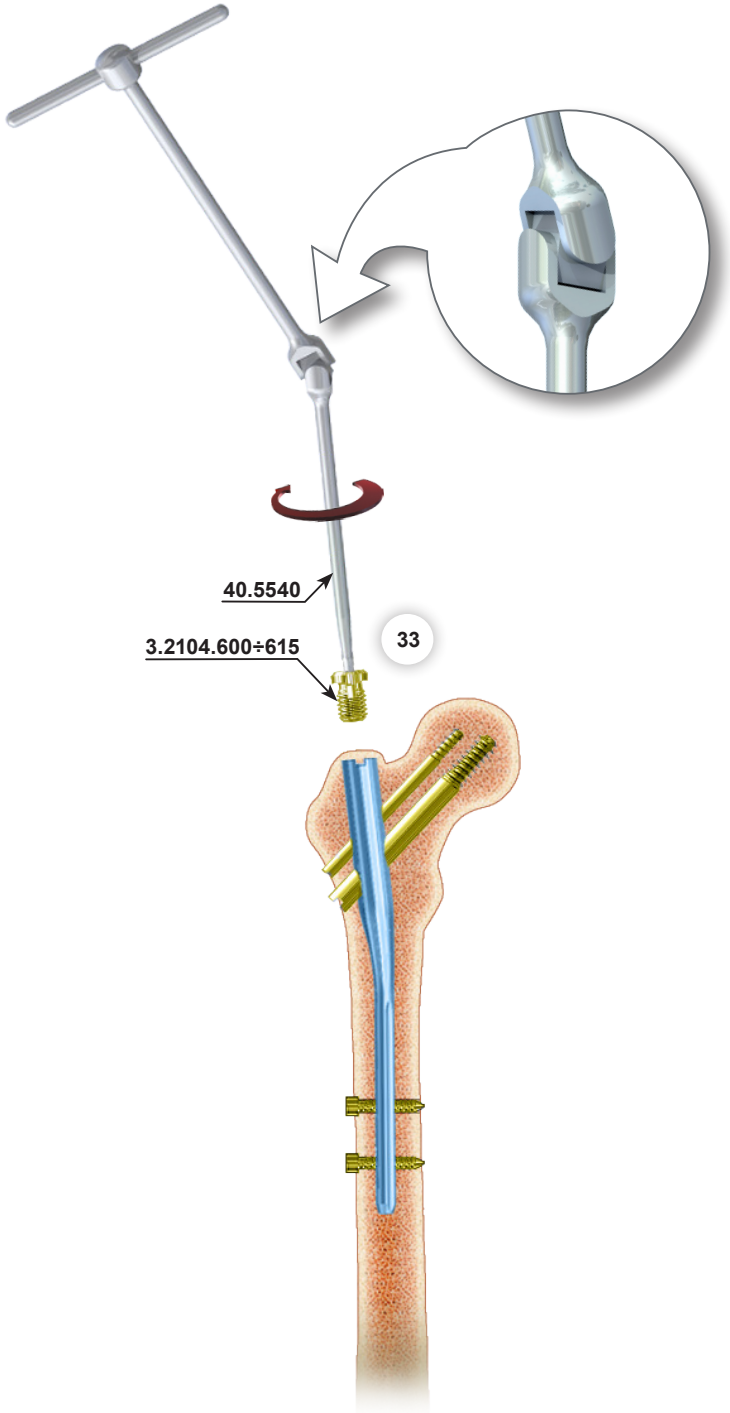
30 After locking the long trochanteric nail in proximal part and dismounting the Targeter; mount the Distal Targeter D **[40.5546]** onto the Proximal targeter B **[40.5591]**. Verify with the image intensifier the position of the holes in targeter slider and distal holes in trochanteric nail. The image intensifier should be positioned in such a way, that nail locking holes *(proximal or distal)* pictures on the screen are circles.
Insert the Protective Guide 9.0/7.0 **[40.5510.100]** and the Drill guide **[40.5511.100]** into the slider hole of Distal Targeter D.
Check with the X-Ray the position of the drill guide hole and the nail hole. The holes in the nail and drill guide must overlap. The circle image shall appear *(image close to circle is acceptable)* on the screen. If the image on the screen is not a circle settings of D Targeter must be corrected.
To do so, use the nub of the screw in the Distal Targeter D **[40.5546]** to move the slider *(turn the nub left or right)* until the circle appears on the screen *(image close to circle is acceptable)*.

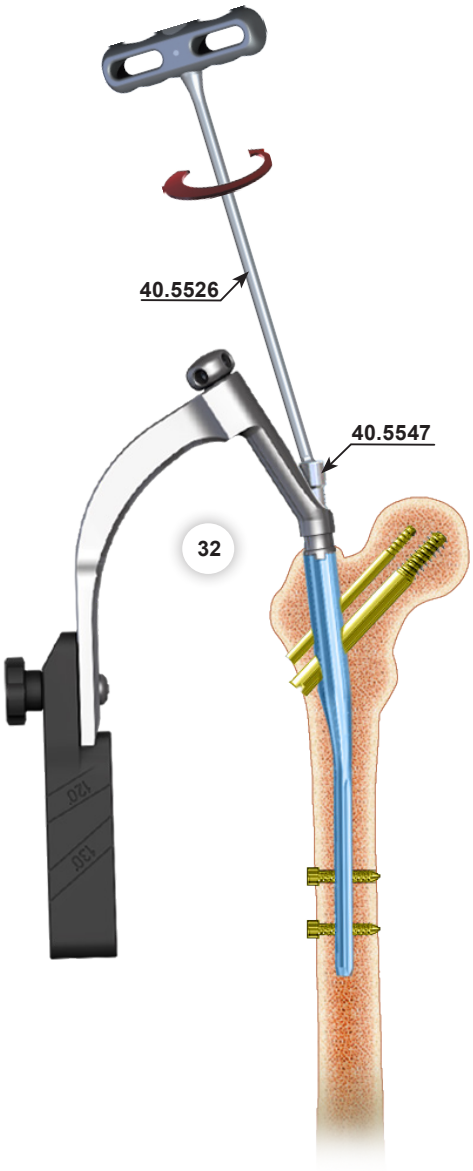




31 Remove the Drill guide 7/3.5 **[40.5511.100]** out of the protective guide 9.0/7.0 **[40.5511.100]**. Locking the nail by the screws shall proceed in accordance with steps 22-29 presented on page 28.

32 Remove the Connecting Screw M12x1,75 L-34 **[40.5547]** from the nail using the Wrench S10 **[40.5526]**. Dismount the Proximal targeter B **[40.5591]** from the nail locked in the medullary canal.

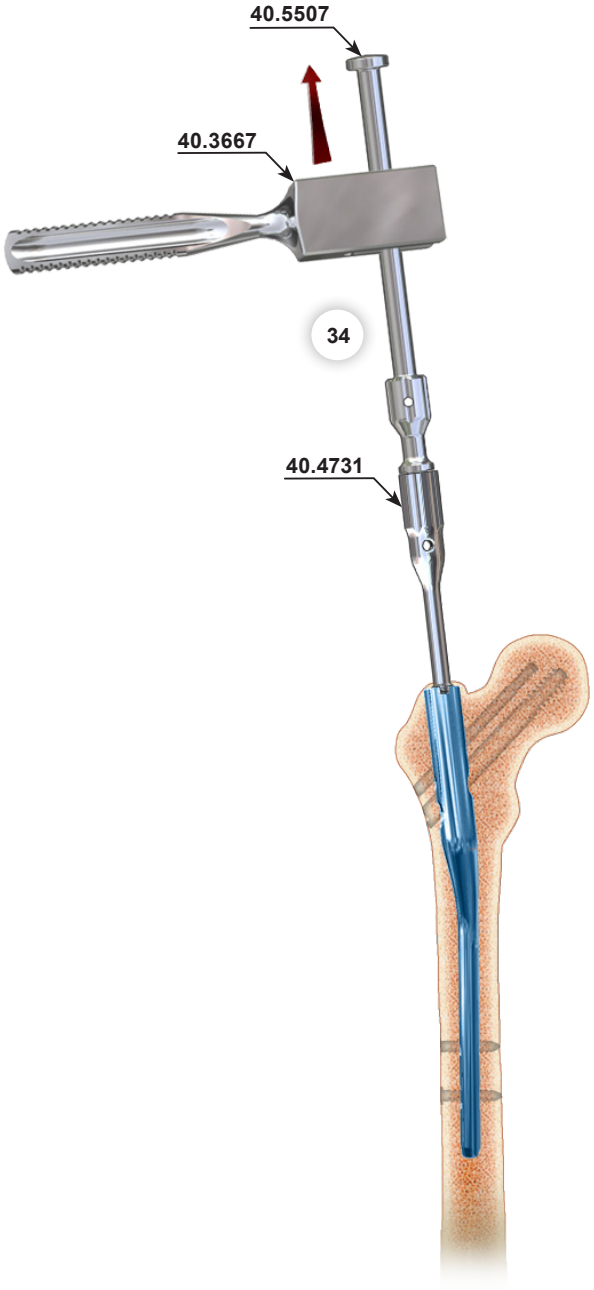




33 In order to secure the inner thread of the nail form bone ingrowth, insert the End Cap **[3.2104.600]** using the Wrench for self-aligning joint S4 **[40.5540]**.

IV.9. THE NAIL EXTRACTION *(LONG AND SHORT)*

34 Using the Wrench for self-aligning joint S4 **[40.5540]** remove the end cap, compression screw, join screw 6.5mm. Using the Screwdriver S3.5 **[40.5525]** remove all locking screws. Insert the Connector of extractor M12/1.75 **[40.4731]** into the threaded nail hole. Using Compression wrench **[40.5532.300]** remove join screw 11mm. Insert the Impactor-extractor **[40.5507]** onto the Connector of extractor and remove the nail from the medullary canal using the Mallet **[40.3667]**.



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

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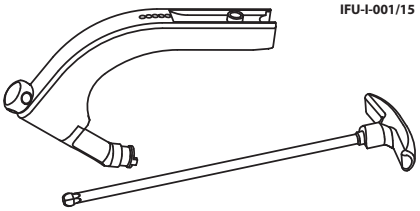

GB

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 $1/10^6$ ($SAL=10^{-6}$, 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**

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

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 • Řídte 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 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 • 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.
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

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland
tel. +48 85 713 13 20
fax +48 85 713 13 19
chm@chm.eu
www.chm.eu

CE 0197
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ISO 13485